AN INCLUSIVE CLINICAL TRIAL RESEARCH EDUCATION PROGRAMME FOR INVESTIGATORS IN HEALTH SCIENCES

By

WILMA PELSER

Submitted in accordance with the requirements

for the degree of

DOCTOR OF PHILOSOPHY IN NURSING

in the subject of

HEALTH STUDIES

at the

UNIVERSITY OF SOUTH AFRICA

SUPERVISOR: PROF JEANETTE MARITZ

July 2023

Student number: 05421926

DECLARATION

Name: **Wilma Pelser**
Student number: **05421926**
Degree: **DOCTOR OF PHILOSOPHY IN NURSING**

AN INCLUSIVE CLINICAL TRIAL RESEARCH EDUCATION PROGRAMME FOR INVESTIGATORS IN HEALTH SCIENCES

I declare that the above thesis is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references.

I further declare that I submitted the thesis to originality-checking software and that it falls within the accepted requirements for originality.

I further declare that I have not previously submitted this work, or part of it, for examination at Unisa for another qualification or at any other higher education institution.

Welser

30 JUNE 2023

_____ _____

SIGNATURE DATE

DEDICATION

I dedicate this thesis to my loving family, who never questioned my ability to achieve anything. My wonderful husband Casper, my children, Yonanda, Pierre, Chris-Jan and Ankia, my grandchildren Simone and Milan, my mother Susan and my mother-in-law Gerrie. My dogs, Peanut, Pablo and Jack, who faithfully kept me company while I was writing.

ACKNOWLEDGEMENTS

I am in awe of the Almighty Father, who was the Wind beneath my wings.

I would like to express my gratitude to the numerous individuals who have played a crucial role in facilitating my PhD journey over the past five years. Their unwavering commitment, assistance, and mentorship have been indispensable.

First, I sincerely thank my supervisor, Professor Jeanette Maritz, who agreed to accompany me on this journey. Thank you, Prof Jeanette, for allowing me to learn from you, for having confidence in my ability to do this, and for your friendship, mentoring and unwavering support.

My editor, Leatitia Romero, calmly gave life to the thesis document with high precision.

Kennedy Otwombe helped me with interpreting the statistics.

I sincerely thank Linda van Rensburg and her team at Academic Advance (Wits Health Consortium) for all the administrative tasks that went into the set-up and logistics of organising the implementation of the inclusive clinical trial research education programme. I have been very privileged to have such a high-performing and friendly team surrounding me.

My mentors, Avy Violari, Glenda Gray and Neil Martinson, thank you for your input and guidance over the many years in clinical trial research.

Finally, I would like to thank all the participants who agreed to be part of my research for their time and effort.

AN INCLUSIVE CLINICAL TRIAL RESEARCH EDUCATION PROGRAMME FOR INVESTIGATORS IN HEALTH SCIENCES

STUDENT NUMBER:	**05421926**
STUDENT:	**Wilma Pelser**
DEGREE:	**DOCTOR OF PHILOSOPHY IN NURSING**
DEPARTMENT:	**HEALTH STUDIES, UNIVERSITY OF SOUTH AFRICA**
SUPERVISOR:	**Prof. Jeanette Maritz**

ABSTRACT

Upscaling the pool of clinical trial investigators is critical to address the evolving challenges of clinical trials and meet the increasing demand for skilled health professionals. By developing an inclusive clinical trial research education programme for investigators in health sciences, that includes nurses and other health professionals in South Africa, the study aimed to ensure a diverse and well-equipped workforce capable of navigating the complexities of modern clinical trials and contributing to advancements in healthcare.

A sequential exploratory qualitative-driven multiple-method quasi-experimental design was employed to achieve this objective, consisting of three projects. The Medical Research Council (MRC) framework was adopted to guide the process, acknowledging the dynamic nature of developing an education programme.

Project 1 explored and described stakeholders' perspectives of an inclusive clinical trial research education programme. Ten experienced clinical trial professionals were interviewed to develop and validate the programme.

Project 2 involved the programme's implementation with 28 investigators, including nurses, pharmacists, statisticians, and social workers, registering for participation. This phase was quantitative in nature.

Project 3 evaluated the clinical trial research education programme, encompassing both quantitative and qualitative segments. The 28 participants from Project 2 formed the basis of the quantitative evaluation. Pre- and post-questionnaires were used to assess changes in participants' self-perceived competency and knowledge of clinical trials after the intervention. Additionally, five participants were selected for qualitative evaluation through interviews.

Qualitative findings from the study indicated that participants' need for clinical trial education was met, while quantitative results supported these findings by demonstrating a significant improvement in participants' self-perceived competency and knowledge of clinical trials following the intervention.

The developed inclusive clinical trial research education programme provides explicit recommendations for various stakeholders, including nurses, educators, supervisors, and the clinical trial industry, to use the programme and ensure well-trained clinical trial professionals who can contribute to favourable patient outcomes.

In conclusion, upscaling the pool of clinical trial investigators through an inclusive education programme is essential for meeting the challenges of modern clinical trials and the growing demand for skilled health professionals. This study demonstrates the effectiveness of such a programme in enhancing participants' competencies and knowledge.

KEY CONCEPTS

Inclusive clinical trial research education programme; investigator; health professionals; clinical trial; intervention; nurses; self-perceived competency; clinical trial knowledge; stakeholders; curriculum.

TABLE OF CONTENTS

CHAPTER 2

LITERATURE REVIEW

CHAPTER 3

RESEARCH DESIGN AND METHODS

CHAPTER 4

PROJECT 1: RESEARCH DESIGN, DATA COLLECTION, DATA ANALYSIS AND FINDINGS OF THE FIRST SEGMENT AND SITUATION ANALYSIS (QUALITATIVE)

CHAPTER 5

PROJECT 1: DEVELOPMENT AND VALIDATION OF THE INCLUSIVE CLINICAL TRIAL RESEARCH EDUCATION PROGRAMME

CHAPTER 7

PROJECT 3: RESEARCH DESIGN, DATA COLLECTION, RESULTS AND EVALUATION OF INTERVENTION

CHAPTER 8

SUMMARY OF FINDINGS AND INTEGRATION, CONCLUSIONS, RECOMMENDATIONS, CONTRIBUTIONS AND LIMITATIONS

LIST OF TABLES

LIST OF FIGURES

SCHEMATIC DIAGRAMS

LIST OF ANNEXURES

ABBREVIATIONS

ACTG	AIDS Clinical Trials Group
ACRP	Association of Clinical Research Professionals
ART	Antiretroviral Therapy
CAPS	Capital Letters
CCF	Core Competency Framework
CICRP	Competency Index for Clinical Research Professionals
CQMP	Clinical Quality Management Plan
CIPD	Chartered Institute of Personnel and Development
CoAPCR	Consortium of Academic Programs in Clinical Research
COVID-19	Coronavirus Disease 2019
CTRM	Clinical Trial Research Manual
CTU	Clinical Trial Units
CRA	Clinical Trial Associate
CRAI	Clinical Research Assessment Inventory
CRF	Case Report Forms
CRO	Clinical Research Organisation
CTTI	Clinical Trials Transformation Initiative
DoH	Department of Health/Declaration of Helsinki
ECG	Electrocardiograph
ECRIN	European Clinical Research Infrastructure Network
EMA	European Medicines Agency
FDA	US Food and Drug Administration
GCP	E6 Good Clinical Practice
GSE	General self-efficacy
HIV	Human Immunodeficiency Virus
IB	Investigators Brochure
ICH	International Conference of Harmonisation
IRBs/ECs,	Institutional Review Board/Ethics Committee
NIH	National Institute of Health
HPCSA	Health Professions Council of South Africa
HREC	Health Research Ethics Council

ICF	Informed Consent Form
IP	Investigational Product
IoR	Investigator of Record
JTF	Joint Task Force for Clinical Trial Competency
LMS	learning management systems
MOODLE	Modular Object-Oriented Dynamic Learning Environment
MRC	Medical Research Council
MRCT	Multi-Regional Clinical Trial Center
MTA	Material Transfer Agreement
NIHR	National Institute for Health and Care Research
NHRS	National Health Research Summit Report
PhD	Doctor of Philosophy
PHRU	Perinatal HIV Research Unit
PI	Principal Investigator
QUAN	Quantitative
QUAL	Qualitative
QA	Quality Assessment
QC	Quality Control
RTES	Research Training Environment Scale
SA	South Africa
SAE	Serious Adverse Event
SAHPRA	South African Health Products Regulatory Agency
SANCTR	South African National Clinical Trial Register
SAS	Statistical Analysis System
SOCRA	The Society of Clinical Research Associates
SOP	Standard Operational Procedure
TDR	Global Competency Framework for Clinical Research
UK	United Kingdom
UNISA	University of South Africa
US	United States
WHC	Wits Health Consortium
WHO	World Health Organization
Wits RHI	Witwatersrand Reproductive Health and HIV Institute
WMA	World Medical Association

CHAPTER 1
ORIENTATION TO THE STUDY

1.1 INTRODUCTION

Trained clinical trial investigators play an indispensable role in ensuring the safety, integrity and success of clinical trials, ultimately advancing clinical knowledge and improving patient care. I will foreground the importance of upscaling the pool of clinical trial investigators to meet the evolving clinical trial challenges and address the increasing demand for well-trained and skilled health professionals. By developing an inclusive educational programme, such as a clinical trial research education programme for investigators in health sciences in South Africa (encompassing nurses and other health professionals), we can ensure a diverse and well-equipped workforce that can effectively navigate the complexities of modern clinical trials and contribute towards advancements in health care.

Chapter 1 provides an orientation to the study. It includes the background of the research, problem statement, research aim and objectives, research questions, pertinent concepts, data collection strategies, the research paradigm, and theoretical framework. The research design and methods, data analysis, the significance of the study, ethical considerations and chapter divisions are also outlined.

1.2 BACKGROUND INFORMATION REGARDING THE RESEARCH PROBLEM

The clinical research industry, nurses' role in clinical trials, upskilling clinical trial staff and the evolution of clinical trial education were considered as important background information to the research problem.

1.2.1 The clinical research industry

The clinical research industry has evolved significantly (Kremidas 2019:1; Palombini 2022:1). This is particularly true for clinical trials when the COVID-19 pandemic

created massive disruptions at the beginning of 2020 (van Dorn 2020:523). The clinical research industry had to rapidly adapt during the pandemic to expand data collection in real-world settings, using artificial intelligence and technology (National Academics of Sciences, Engineering and Medicine 2021:1). The increased use of technology, increased scale and complexity of clinical trials as part of the transformation process before the pandemic resulted in an update in the International Council for Harmonisation (ICH) E6 Guideline for Good Clinical Practice (GCP) in 2016 (May 2019:2). Following the COVID-19 pandemic, the ICH is busy rewriting the ICH E6 (R2) guidelines to incorporate new clinical trial technologies and accelerate regulatory approvals of new drug candidates (Mauri 2021:1).

However, it is a concern that the upskilling of clinical trial staff has not kept pace with new technologies and the increased demands of clinical trials, even during the COVID-19 pandemic (Woolfall, Roper, Humphreys, Lyttle, Messahel, Lee, Noblet, Lyer, Gamble, Hickey, Rainford & Appleton 2019:2; Mitchell, Ahmed, Breeman, Cotton, Constable, Ferry, Goodman, Hickey, Meakin, Mironov, Quann, Wakefield & McDonald 2020:7; National Academics of Sciences, Engineering and Medicine 2021:75). Current old-fashioned training approaches for clinical research professionals harm trial participants and jeopardise professionals' experience, setting them up for failure (Harper 2020:1). The outcome is poor performance, high turnover rates, and an increased risk of costly protocol deviations (Harper 2020:1), which is an alarming situation.

Sponsors typically choose medical doctors as clinical trial investigators, even though nurses (or other non-medical health professionals) could be as efficient in this role as medical doctors (Turner & Saunders 2000:129; NIHR 2018:1; Ceh 2022:2).

1.2.2 Nurses' role in clinical trials

There is a strong history of nurses being part of clinical research professionals working on clinical trials whose practice is guided by one or more aspects of GCP (Clinical Research Professionals 2023; Castro, Bevans, Miller-Davis, Cusack, Loscalzo, Matlock, Mayberry, Tondreau, Walsh & Hastings 2011:72). Showalter, Cline, Yungclas, La Frentz, Stafford and Maresch (2017:633) explain that clinical research

nursing is a speciality nursing field recognised by the American Nurses Association. Clinical research nurses are an essential component of the research team, although there has been no effort to provide infrastructure for their training. According to McCabe, Behrens, Browing, Vessey, and Williams (2019:24), clinical research nurses ensure the safety of participants in clinical trials by providing care that is in line with the trial's protocols. They achieve this by utilising their nursing experience and knowledge of baseline clinical practices.

Clinical trial nurses in Australia and Ireland reported that although they are involved in protocol development, ethics approval applications, recruitment and participant consent, administering treatment and evaluating protocols, they are undervalued. They also reported they do not receive formal education for their role and are seldom co-authors of research publications in which they are involved (Wilkes, Jackson, Miranda & Watson 2012:1; Hernon, Dalton & Dowling 2020:667). Clinical trials are the backbone of medicine, and nurses are the foundation of clinical trials. Nurses' clinical practice knowledge, combined with their expertise in the principle and practices of clinical research, play a critical role in the collaborative multidisciplinary team, making them excellent candidates for being investigators on a clinical trial (Sapega 2022:1).

A survey (NIHR 2018:1) in the United Kingdom (UK) found that despite the increase in trained clinical nurse specialists, very few take on the principal investigator (PI) role mainly because they lack confidence and self-efficacy in heading research projects. A contributing problem is that sponsors and clinical trial organisations, for a very long time, have failed to recognise that clinical trial coordinators, who are, in most instances, not medical doctors but nurses, are the brains behind clinical trials' success (Nkala-Dlamini, personal communication, 16 July 2019). Non-medical clinical trial members often get the impression they are not considered by the clinical trial industry (sponsors and organisations) to lead clinical trials.

Downhour (2018:3) mentioned that nurse practitioners (in some instances equal to primary healthcare nurses or midwives in South Africa) are gaining momentum as PIs in clinical research. In addition, Turner and Saunders (2000:1) argue that nurse practitioners are well-suited for the position due to their training in conducting physical examinations, making clinical assessments, diagnosing and treating diseases, and

prescribing medications, either autonomously or in cooperation with a physician. In support, Rosenzweig, Bender, and Brufsky (2005:293) found that nurses with doctoral degrees are well-suited to take on the role of Principal Investigator (PI) in pharmaceutical clinical trials.

1.2.3 Upskilling clinical trial staff

Globally, clinical trial education has received growing interest. Experts in the scientific community concur that clinical research has a crucial role in shaping the future of medicine and enhancing contemporary public healthcare. (Hight 2022:1; Silva, Kennedy, Koski, Sonstein & Stonier 2020:608; Skivington, Matthews, Simpson, Baird, Blazeby, Boyd, Craig, French, McIntoch, Petticrew, Rycroft-Malone & Moore 2021:2; Maybach, Sarfaty, Gould, Damle & Armstrong 2020:398). Simultaneously, the scientific community has highlighted various obstacles to the conduct of clinical research, with the shortage of proficient and expert clinical research personnel being cited as a prominent hurdle. (Hight 2022:1; Kao, Hamilton & Lin 2019:489; Silva, Stonier, Kerpel-Fronius & Dubois 2021:131; Sonstein et al. 2018:1). The lack of proper clinical trial education, combined with clinical trials' increased complexity, could result in a clinical trial workforce that feels inadequate and incapable of performing their daily tasks. Put differently, it could result in a lack of self-efficacy with consequent poor clinical trial outcomes (Pelser 2018:43; Anders 2018:15).

Moreover, the issue of enhancing the skills of clinical trial personnel is further complicated by ambiguous criteria about the qualifications and expertise necessary for individuals involved in clinical research. For example, ICH GCP (2016:19) stipulate that individuals working on a clinical trial should have the necessary education, training and experience to perform their daily tasks. Moreover, the latest version of the Declaration of Helsinki (DoH), dated October 2013, is also not shedding more light on the matter. Using almost similar wording, the DoH merely indicates that individuals who conduct medical research must have appropriate training and qualifications in clinical research (Sonstein, Brower, Gluck, Kolb, Aldinger, Jones & Bierer 2020:2).

To align with the guidance from the DoH (2013), several academic institutions, some clinical research organisations and the pharmaceutical industry are providing clinical

research certification programmes of a high standard. Nonetheless, formal regulations, policies or guidelines that outline the experiential or educational requirements and certification for clinical research are not mandated. Silva et al. (2020:615) added another problematic matter, namely the lack of harmonised standards of expectation for clinical research professionals. The completion of GCP training, recognised as the *gold standard* for the preparation of individuals to work on clinical trials, is insufficient to ensure high-quality conduct (Clinical Trials Transformation Initiative [CTTI] 2018:7; Mozersky, Antes, Baldwin, Jenkerson & DuBois 2020:167). Kremidas (2019:1) argues that employees entering the clinical research field deserve advanced, cutting-edge standards and certifications to ensure a good foundation for success.

1.2.4 Evolution of clinical trial education

In 2013, there was a substantial effort to establish a highly educated and skilled clinical research workforce. The Joint Task Force for Clinical Trial Competency (JTF) was established to amalgamate the diverse contributions of contract research organisations, clinical research sites, pharmaceutical corporations, professional groups, and academic institutions. (Sonstein, Brouwer, Gluck, Kolb, Aldinger, Bierer & Jones 2018:1; Sonstein et al. 2020:2). The outcome of the JTF's work was the alignment and harmonisation of numerous statements related to the core competencies of research professionals and clinical investigators into one high-level set of standards (Sonstein et al. 2018:1). Since the JTF's establishment in 2013, competencies for clinical investigators and research professionals have been formulated and validated in combination with clinical research stakeholders. In the process, eight broad domains of competence were identified: (1) Scientific concepts and research design; (2) Ethical and participant safety considerations; (3) Medicine development and regulations; (4) Clinical trial operations; (5) Study and site management; (6) Data management and informatics; (7) Leadership and professionalism; and (8) Communication and teamwork (Sonstein et al. 2014:3). The utilisation of these basic competencies by the JTF in the development of curriculums or job descriptions has the potential to have a significant worldwide influence by establishing a standardised framework and eliminating unnecessary duplication in training requirements. Moreover, these suggestions have the potential to establish

uniformity and official recognition of educational programmes, as well as a more precise delineation of career paths and assessments of success. (Sonstein et al. 2018:1).

Education and training for clinical trial investigators and research teams in South Africa are offered by professional organisations, universities and private organisations, including the African Clinical Research Organisation (ACRO), Clinical Research Education and Development (CREDE), Wits Health Consortium – Academic Advance, South African Clinical Research Association (SACRA), InGonoGo, Fundisa – African Academy of Medicines Development and Global Health Trials. However, these training opportunities are not reaching all investigators or clinical trial professionals working in clinical research in South Africa. At the beginning of the COVID-19 pandemic, most organisations had to move fast to provide a fully online basic GCP course. Previously (before COVID-19), the South African Health Products Regulatory Agency (SAHPRA) approved only online training for GCP refresher courses. At the same time, new research professionals had to do a face-to-face basic GCP training course at an approved organisation. Consequently, the online GCP course covered mainly the theory part of GCP, and several practical exercises previously included in the face-to-face GCP course fell away. Thus, the practical implementation of GCP is often not fully understood by research professionals, as it became evident during clinical trial data monitoring (Cohen 2022).

The need to adapt to a changing clinical research landscape and future disruptions, as seen during the COVID-19 pandemic, is evident. The changing landscape highlighted the need for adequately trained investigators and health professionals working on clinical trials (Saleh & Naik 2018:378; CTTI 2018:2; Coons 2021:1; Shiely, Foley, Stone, Cobbe, Browne, Murphy, Kelsey, Walsh-Crowley & Eustace 2021:3). Not fulfilling this need could have several negative consequences, as expressed by Kremidas (2019:1). Clinical trials play a crucial role in advancing innovation in the field of global healthcare. They include a broad spectrum of fields, including therapy, prevention, identification, screening, assistance, research on healthcare services, and fundamental scientific study. (Park, Grais, Taljaard, Nakimuli-Mpungu, Jehan, Nachega, Ford, Xavier, Kengne, Ashorn, Socias, Bhutta & Mills 2021:1). Participation

in clinical trials could also improve public health, as shown by numerous clinical trial results (Lesser, Anderson, Younossi & Overman 2022:1).

The primary purpose of clinical research is to benefit the public by promoting a healthier and longer life while the individual participant might benefit from the trial intervention (Anderson, Borfitz & Getz 2018:9). One of the core pillars of good public health practice is policies derived from high-quality scientific data, as demonstrated in clinical research (Curtis, Dember, Vazques, Murray, DeBar, DeBar, Staman, Septimus, Mor, Volandes, Wells, Huang, Green, Coronado, Meyers, Tuzzio, Hernandez & Sugarman 2019:432). The findings of the Children with HIV early Antiretroviral (CHER) randomised trial conducted in South Africa revealed that administering antiretroviral medication (ART) to HIV-infected newborns between the ages of 6 and 12 weeks resulted in a 76% reduction in overall mortality and a 75% decrease in HIV progression. The World Health Organisation (WHO) modified its guidelines to advocate for universal antiretroviral therapy (ART) beginning in newborns, regardless of their immunological or clinical disease stage, as a consequence. (Colebunders & Musilime 2013:1539; Cotton, Violari, Otwombe, Panchia, Dobbels, Rabie, Josipovic, Liberty, Lazarus, Innes, Rensburg, Pelser, Truter, Madhi, Handelsman, Jean-Philippe, Mcintyre, Gibb & Babiker 2013:1555; Violari, Cotton, Gibb, Babiker, Steyn, Madhi, Jean-Philippe, McIntyre & CHER Study Team 2008:22330). Therefore, well-trained clinical trial investigators, including nurses, are crucial in driving innovation in clinical trials, benefiting the health sector.

1.3 STATEMENT OF THE RESEARCH PROBLEM

The evidence provided in the background could suggest that clinical trial investigators might not be sufficiently trained or skilled to execute expected tasks during times of stability when conventional clinical trials are conducted, and during fragile times such as pandemics. Various academic institutions and research organisations, both nationally and internationally, have implemented programmes that offer young clinicians the chance to enhance their research skills by pursuing a PhD. This is in response to the demand for and significance of training and developing the abilities of research investigators. (Kramer, Veriava & Pettifor 2015:153; Verderame, Freedman Kozlowski & McCormack 2018:1; Daye, Patel, Ahn & Nguyen 2015:883-887; Culican,

Rupp & Margolis 2014:3219-3222). However, research educational programmes developed by universities and professional organisations are primarily advantageous for master's and doctoral students within the medical field and do not address the execution of a clinical trial. Research course content for pre- and postgraduate medical students primarily focuses on increasing methodology knowledge and biostatistics and might include tools to improve knowledge and skills in understanding and writing academic articles (Al-Tannir, Abu-Shaheen, AlSumaih, AlMukaibil, AlHarbi, Heena, Sallout, Mahha, Marran & AlFayyad 2018:1; Patil & Hasamnis 2018:1).

Nurses and other non-medical students experience similar difficulties. Nursing students study nursing theory and are introduced to nursing research. However, they are seldom informed or trained in clinical research (Downhour 2018:3). Research educational programmes are, for the most, not targeting clinical trial investigators per se to prepare and train them to conduct clinical trials during conventional or non-pandemic times. A different knowledge and skill set is needed to conduct a clinical trial (Kremidas 2019:1). Thus, during the COVID-19 pandemic, several organisations, including Wits Health Consortium (WHC) Johannesburg (online 2022), Stellenbosch University (online 2022), the University of Cape Town (online 2022), University of California San Francisco (online 2022) and the Global Health Training Centre (online 2022), developed online courses to train clinical trial staff on how to conduct a clinical trial during a pandemic. However, the course material still lacked an inclusive approach.

Thus, there is an urgent need to build health practitioners' (including nurses) capacity as investigators and create developmental opportunities in clinical research, particularly clinical trials in South Africa, incorporating advanced training and academic knowledge to advance public health.

1.4 RESEARCH AIM

This study aimed to develop and pilot an inclusive clinical trial research education programme for investigators in health sciences in South Africa.

1.5 RESEARCH OBJECTIVES

The study's objectives expanded over three consecutive projects. Guided by Morse and Niehaus (2016:149), I refer to 'projects' and 'segments.

Project 1

The first project had three segments with mainly an inductive drive (Creswell & Creswell 2022:23). The first project included a situation analysis, the development of the inclusive programme, and the programme's validation by stakeholders before implementation.

A Qualitative segment – situation analysis:

(i) Explore and describe stakeholders' (supervisors of investigators, departmental heads) perspectives of opportunities and challenges in supporting investigators.

(ii) Explore and describe stakeholders' perspectives of what an inclusive clinical trial research education programme should consist of.

B Development segment:

(i) Develop an inclusive clinical trial research education programme.

C Qualitative segment – programme validation:

(i) Validate the programme (by stakeholders) before implementation.

Project 2

The second project had a deductive drive (Creswell & Creswell 2022:23) with two segments.

A Quantitative segment:

(i) Measure investigators' self-perceived level of competency in clinical trial conduct.

(ii) Determine baseline levels of investigators' clinical trial knowledge.

(iii) Collect investigators' basic demographic characteristics.

B Implementation segment:

(i) Implement the inclusive clinical trial research education programme for investigators.

Project 3

The third project consisted of two segments and had a deductive drive for segment A and an inductive drive for segment B:

A Quantitative segment:

(ii) Measure investigators' self-perceived level of competency in clinical trial conduct.

(iii) Measure investigators' knowledge of clinical trial conduct following the inclusive clinical trial research education programme.

B Qualitative segment:

(i) Stakeholders' evaluation of the outcome of the intervention to refine the inclusive clinical trial research education programme.

1.6 RESEARCH QUESTIONS

Each segment under Projects 1, 2 and 3 had its own research question.

Project 1

A Qualitative segment – situation analysis:

(i) What are stakeholders' (supervisors of investigators, departmental heads) perspectives of the opportunities and challenges in supporting investigators?

(ii) What are stakeholders' perspectives of what an inclusive clinical trial research education programme should consist of?

B Development segment:

(i) What should an inclusive clinical trial research education programme for health sciences investigators consist of? (context)

C Qualitative segment – programme validation:

(i) What are specialist stakeholders' views of the inclusive clinical trial research education programme before implementation?

Project 2

A Quantitative segment:

(i) What are investigators' self-perceived levels of competency in clinical trial conduct?

(ii) What are the baseline levels of investigators' clinical trial knowledge?

(iii) What are the basic demographic characteristics of investigators?

B Implementation segment:

(i) How should the inclusive clinical trial research education programme's implementation process look?

Project 3

A Quantitative segment:

(i) What are investigators' self-perceived competency levels in clinical trial conduct following the inclusive clinical trial research education programme?

(ii) What are investigators' clinical trial knowledge levels following the inclusive clinical trial research education programme?

B Qualitative segment:

(i) What is the stakeholders' evaluation of the inclusive clinical trial research education programme? (A= participants and B= supervisors of investigators).

(ii) Findings from this evaluation were applied in refining and finalising the inclusive clinical trial research education programme.

1.7 DEFINITIONS AND KEY CONCEPTS

The following definitions and key concepts were employed in this thesis:

1.7.1 Clinical trial research

A clinical trial is a specific form of clinical research study focusing on the safety and efficacy of new treatments for human use. Clinical trials fall under the umbrella of clinical research (University of Virginia Online 2019:1). In this study, a clinical trial refers to a clinical study focusing on the safety and efficacy of new treatments for human use.

1.7.2 Clinical research professionals

These personnel may have specialised knowledge in nursing, pharmacology, medical technology, business administration, health record management, statistics, science,

education, or other related professions. Their professional activities are influenced by one or more components of the principles of Good Clinical Practice (GCP). (Clinical Research Professionals 2023).

In this study, clinical research professionals include nurses, doctors, pharmacists, statisticians, clinical research educators, social workers and medical assistants.

1.7.3 Health sciences

Health science is the combination of science (research, engineering, mathematics, and technology) and healthcare into a large group of disciplines (pharmacy, medical, nursing and occupational health) to deliver health care to humans and animals (All Allied Health Schools Online 2022:1).

In this study, health science refers to a large group of disciplines, including medicine, nursing, pharmacology, homoeopathy, dentistry, nutrition and clinical research. Practitioners in these fields utilise their foundational education as healthcare professionals to apply practical and clinical methods in order to enhance the well-being of living organisms.

1.7.4 Health professionals

According to the WHO (2022:1), 'health professionals' are individuals who preserve human health by utilising evidence-based medicine and demonstrating compassion. In addition, they engage in research as part of their responsibilities to enhance or create theories and operational approaches in order to progress healthcare. In this study, health professionals include medical and non-medical people.

1.7.5 Medical and non-medical professionals (staff)

A ‘medical professional’, defined by Davis (2021:1), is a person working in a vocation characterised by a specialised body of knowledge of medicine. As a practitioner of this occupation, individuals are required to adhere to a service-oriented code of ethics that prioritises patient care over personal interests. Healthcare Management Degree Guide

Online (2020:1) listed dieticians, nutritionists, radiologists, chiropractors, registered nurses, genetic counsellors, occupational therapists, physical therapists, biomedical engineers, medical and health services managers, physician assistants, pharmacists, advanced practice registered nurses and midwives as non-medical professionals who fulfil a supplementary/complementary role within the medical field.

In this study, medical staff refer to medical doctors, physicians and specialists. Non-medical staff refer mainly to registered nurses, midwives, pharmacists, medical and health services managers, dieticians, nutritionists, radiologists and physical therapists.

1.7.6 Investigator

An ‘investigator’, as defined by the ICH E6 GCP (2016:5) and SAGCP (2020:20) guidelines, is responsible for the implementation of a clinical trial; when the investigator becomes the leader of the clinical trial team, they will be called the PI. The PI is ultimately responsible for all aspects of the trial. The Principal Investigator (PI) is supported by a sub-investigator, who can be any qualified member of the clinical trial team appointed and overseen by the PI to carry out essential trial-related processes and make significant trial-related judgements. (ICH E6 GCP 2016:5; SAGCP 2020:20).

In this study, the term "investigator" includes both individuals with medical and non-medical backgrounds. (a medical doctor, registered nurse, social worker, pharmacist, data manager or other health professionals) who is either responsible for the conduct of a clinical trial as the PI or is part of the clinical trial team as sub-investigator. *Note that when I refer to investigators throughout the thesis, it includes nurses.*

1.7.7 Research education programme

In his work, Biesta (2020:91) delineated education into three distinct domains: qualification, which pertains to the transfer and acquisition of knowledge, skills, and dispositions; socialisation, which involves the replication of prevailing social structures, divisions, and inequalities; and subjectification, which concerns the process by which children and adolescents develop as individuals with agency and accountability.

According to the Project Management Institute Online (2022), a ‘programme’ could be defined as a collection of related projects. The related projects are overseen and synchronised to achieve advantages and governance that would otherwise be unattainable by managing them separately. An education programme would be a programme for providing education, as described by Biesta (2020:91).

In this study, an education programme refers to the inclusive programme that was developed to increase the clinical trial knowledge and skills of investigators in the health sciences. The education programme is referred to as the *inclusive clinical trial research education programme* throughout the study.

1.7.8 Stakeholders

Mertens and Wilson (2018:16) define ‘stakeholders’ as those with an entrusted interest in the programme, policy or product. In this study, stakeholders were (1) experienced clinical research investigators, such as leaders of clinical trial sites, leaders of different departments within a clinical trial site, or leaders within academic or pharmaceutical research fields; (2) participants in the inclusive clinical research programme because they were the intended beneficiaries of the programme; (3) the developer, administrator, presenter and programme manager (researcher) who took full responsibility for the inclusive clinical research programme.

1.7.9 Participant

A participant in a study is a person who voluntarily joins a research study to provide data that will help answer a research question (Clinical Research Glossary 2023). In this study, the inclusive clinical trial research education programme participants were the investigators who registered for the programme. In this study, the terms ‘participants’, ‘investigators’ and ‘student’ are used interchangeably.

1.7.10 Intervention

Participants in a research study might be asked to test something new to determine how well it works; the process is called an intervention (Clinical Research Glossary

2023). An intervention could be medication, devices, or ways to change behaviour, attitudes and knowledge.

In this study, the intervention is the inclusive clinical trial research education programme. This study used ‘intervention’ and ‘inclusive clinical trial research education programme’ (described under 1.7.7) interchangeably.

1.7.11 Inclusive

The aim of inclusive education is described by Salha and Albadawi (2021:97) as education provided to all students who experience the education that improves their learning relationships and prepares them for a quality life. Inclusive education gives new opportunities to students previously underrepresented in specific education (Salha & Albadawi 2021:97).

In this study, inclusive refers to an approach to include all health professionals, such as nurses, pharmacists, statisticians and social workers, who were previously underrepresented as investigators in clinical trial research.

1.8 OPERATIONAL DEFINITIONS

The operational definitions employed in this study included dependent variable (outcome variable), independent variable, pre-knowledge, post-knowledge and confidence.

1.8.1 Dependent variable (outcome variable)

In the quantitative segment of the first and third projects, the dependent variables were (1) investigators’ self-perceived competency in the fundamentals of the clinical trial process and life cycle, and (2) investigators’ level of knowledge of the fundamentals of the clinical trial process and life cycle. Investigators’ self-perceived level of competency in clinical trials was measured using an assessment questionnaire before and after their participation in the inclusive clinical trial research education programme. Investigators’ self-perceived competencies were their reported self-efficacy in task

performance (Katowa-Mukwato & Banda 2016:122; Gomez, Trespalacios, Hsu & Yang 2022:159). The assessment questionnaires used before and after the intervention were referred to as pre-and post-test questionnaires in section 1.10.5.2 under Data collection instruments.

The same questions covering the eight competency domains were part of the questionnaire before and after the inclusive clinical trial research education programme. Baseline levels of investigators' research knowledge were measured before the inclusive programme with a questionnaire focusing on eight competency domains. After the programme, the same questionnaire was given to participants to complete. Investigators' knowledge reflected what they knew or what they thought (or a *justified true belief*) about clinical trial research (Bolisani & Bratianu 2018:2).

1.8.2 Independent variable

The independent variable was the inclusive clinical trial research education programme intervention. The independent variable is one that can affect the dependent variable or the outcome (Leedy & Ormrod 2019:193). The inclusive clinical trial research education programme was evaluated or measured by comparing investigators' answers to the questionnaires related to their perceived competencies and knowledge of the clinical trial process and life cycle before the inclusive clinical trial research programme and those given after the programme. The outcome of the evaluation depended on how successful the intervention was; in other words, any change in the (1) participants' self-perceived competency in the fundamentals of the clinical trial process and life cycle, and (2) investigators' level of knowledge in the fundamentals of the clinical trial process and life cycle depends on the inclusive clinical research education programme (intervention).

1.8.3 Pre-knowledge

Pre-knowledge was any knowledge of the fundamentals of the clinical trial process, and life cycle a participant might have because of their education or experience.

1.8.4 Post-knowledge

Post-knowledge was any newly acquired knowledge the participant had after completing the inclusive clinical research education programme (intervention). This was determined by the pre-post-test questionnaires all participants completed and the interviews with selected participants.

1.8.5 Confidence

Confidence was determined when participants gave feedback during the interviews confirming that they felt more equipped and competent to handle their daily tasks successfully. They also reportedly understood what was expected of them regarding the eight competencies set out by the JTF.

1.9 THEORETICAL FOUNDATION OF THE STUDY

The foundation of a research study forms the fundamental elements that aid researchers in demonstrating the practical theoretical framework, research design, and technique that underpin their aims.

1.9.1 Research paradigm

Using a multiple-method design, I tend towards pragmatism as a paradigm for the current study (Brewer & Hunter 2006:54; Allemang, Sitter & Dimitropoulos 2022:39). There is no favourite ‘child’ in pragmatism. I needed to critically analyse what best good is served in a specific situation using specific knowledge (Allemang et al. 2022:39). Different ways of knowing are accepted by pragmatism. Hence, the formulation of the comprehensive clinical research programme necessitated thoughtful deliberation on the most appropriate form of knowledge that would be beneficial to the community of clinical research investigators. A full discussion of pragmatism, as a paradigm for this research, is presented in Chapter 3.

1.9.2 Theoretical framework

This study was first guided by Bandura's Social Cognitive Theory (1977) with specific reference to "self-efficacy" (people's beliefs about their competencies to produce results or successful outcomes) (Bandura 1977:1). Second, the eight competency domains set out by the JFT to marry investigators' theoretical knowledge and daily core activities within clinical trials were used (Sonstein et al. 2014:3; Sonstein et al. 2018:1). Third, the development process included an intervention phase to implement the inclusive clinical trial research education programme. I therefore found it appropriate to use the Medical Research Council (MRC) framework for developing, piloting, evaluating and reporting a complex intervention as part of my research approach (Bleijenberg, de Man-van Ginkel, Trappenburg, Ettema, Sino, Heim, Hafsteindottir, Richards & Schuurmans 2018:86). A full discussion of the different theoretical frameworks for this research is presented in Chapter 3.

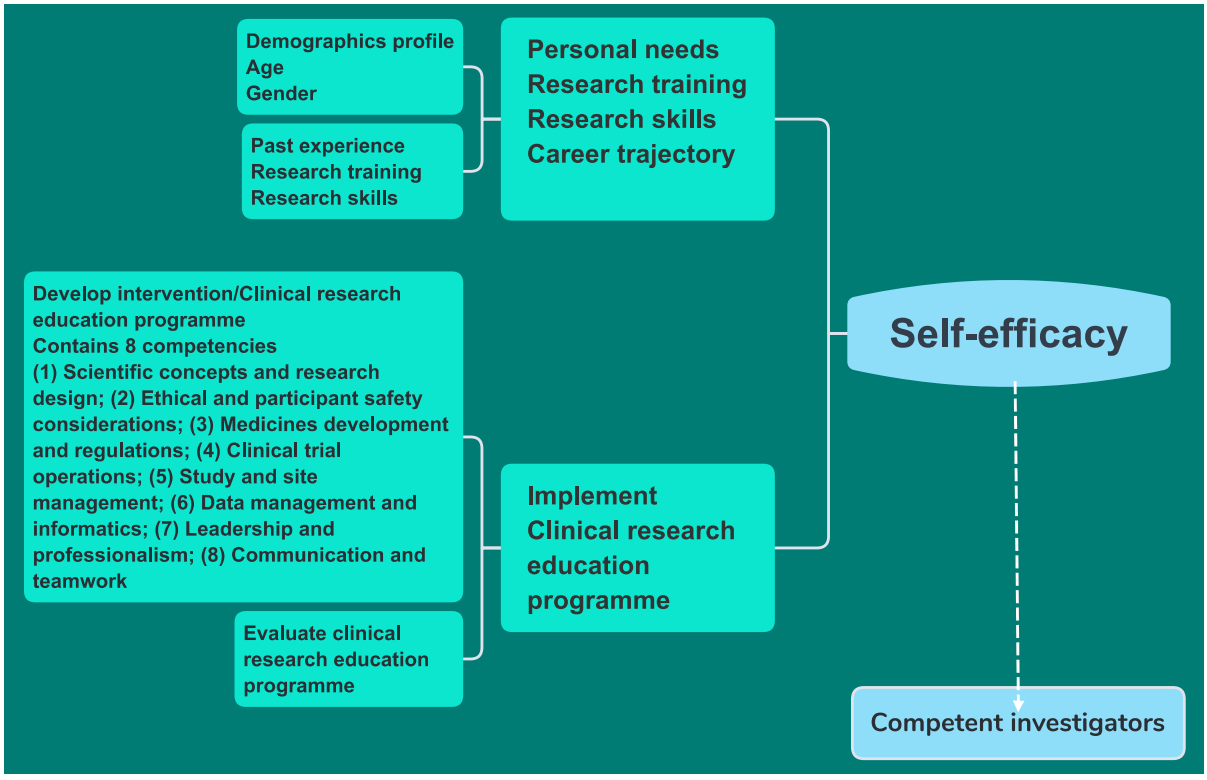


Figure 1.1: Summary of the theoretical framework

1.10 RESEARCH METHODOLOGY

This section offers a broad overview of the research methodology adhered to in this study. Details are described in full in Chapter 3.

The research methodology for the current study covers the research design, including the data collection and analysis methods. The research methodology explained what I did and how I did it, enabling the reader to evaluate the reliability and validity of my research.

1.10.1 Research design

I used a sequential qualitative-driven multiple-method design (Morse & Niehaus 2009:147) to (1) explore and describe stakeholders' perspectives of what an inclusive clinical trial research education programme should consist of; (2) develop an inclusive clinical trial research programme; and (3) evaluate the inclusive clinical trial research education programme. The research design that answered my research question was a multiple-method research programme promoted by Morse and Niehaus (2009:149). In a multiple-method research programme, one programmatic aim is reached by conducting a series of interrelated studies (Morse & Niehaus 2009:149). Each of these interrelated studies or projects is complete in itself with minimal overlap. However, each project validates and extends the previous, and the combined results (at the narrative) could therefore provide a more balanced and holistic understanding of the programmatic aim (Morse & Niehaus 2009:147; Morse & Chung 2003:8).

This research programme's quantitative segments used a pre-experimental one-group-pre-test-post-test design, also known as quasi-experimental (Leedy & Ormrod 2019:201). The one-group-pre-test-post-test quasi-experimental design was chosen since the research was conducted with a single group of investigators from academic, private or research-dedicated clinical research units/sites in South Africa, demonstrating a census sample. The 'one group' in this study consisted of 28 investigators who willingly enrolled in the comprehensive clinical trial research education programme. The one-group pre-test-post-test quasi-experimental design is a reliable method for assessing if there is a noticeable change in the dependent

variable after an intervention takes place (Leedy & Ormrod 2019:201; Appiah & Essiam 2022:87).

For the qualitative part of the research programme, in projects one and three, an explorative, descriptive and contextual qualitative design was used to understand stakeholders' viewpoints (Leedy & Ormrod 2019:230; Gray & Grove 2020:326) and get their feedback on the programme.

1.10.2 Research setting

The setting for the study was all provinces of South Africa. Dedicated clinical trial sites, universities, research organisations and the pharmaceutical industry employ medical and non-medical investigators to work on clinical trials conducted in both urban and rural regions of South Africa.

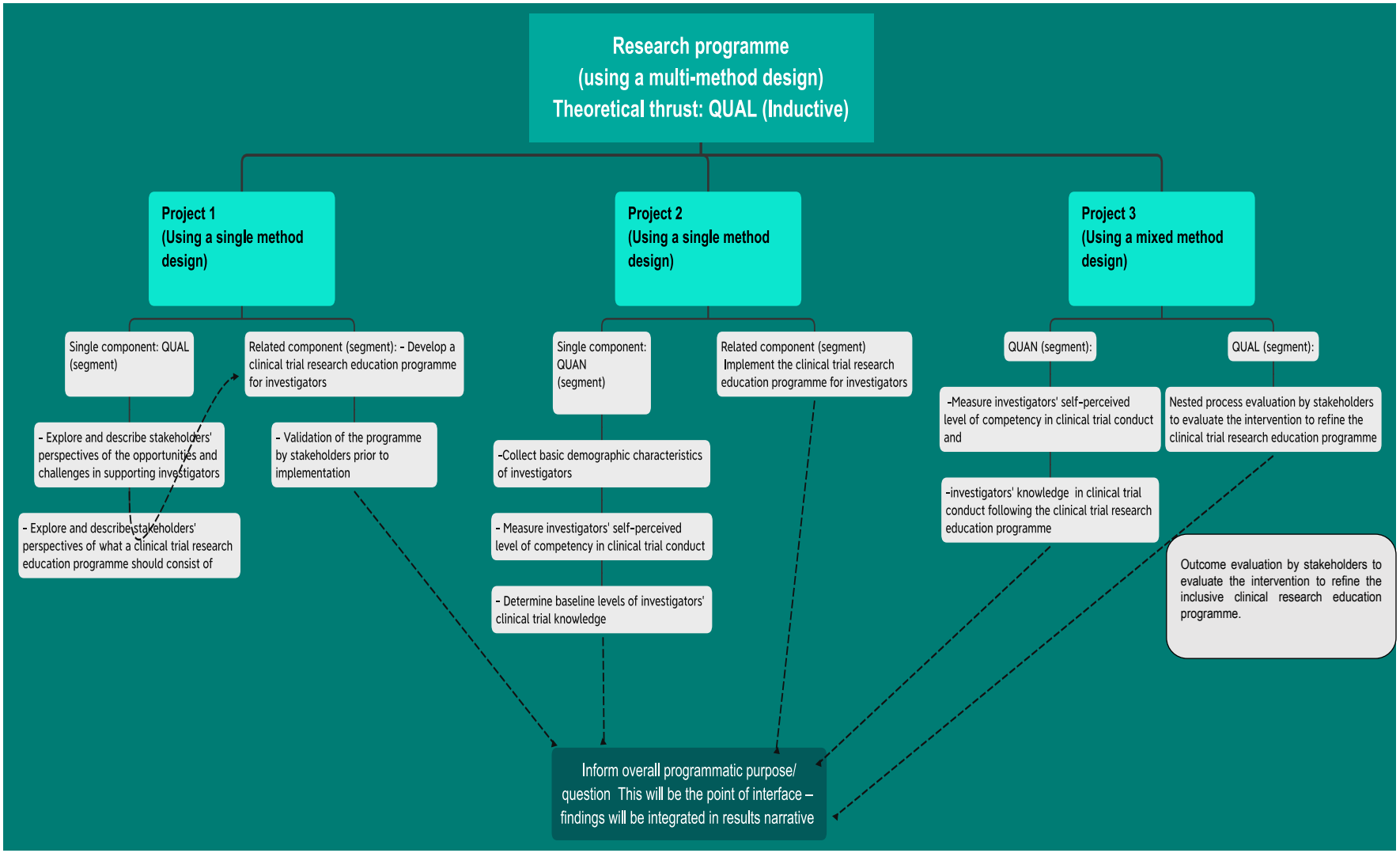


Figure 1.2: Summary of the research objectives and design

The selected venue was in Parktown, Gauteng, limiting the accessibility to candidates living and working in Gauteng or surrounding areas such as the North-West Province, Limpopo, Mpumalanga and the Free State.

1.10.3 Research population

There is no formal database for the registration of investigators; therefore, it is unclear how many investigators are employed to work on clinical trials at one point. Statistics from the Health Professions Council of South Africa (HPCSA) (2019) do not differentiate between doctors and investigators. Legally, every doctor is required to be registered with the HPCSA. Since 2005, it has been mandatory for all clinical studies to be registered on the South African National Clinical Trial Register (SANCTA). However, there is still no information available regarding the number of investigators assigned to a clinical trial at a particular site. The South African MRC stated in correspondence with Kredo on January 16th, 2018 that the number of investigators working on clinical trials in South Africa is unknown and no further demographic statistics are available. This is, however, a global problem. Getz (2021:13) commented that global databases, for example, ClinicalTrials.gov, lack data on individual clinical investigators, and CenterWatch (news.centerwatch.com) published an article titled “Number of global clinical PIs remains a mystery”. This same gap could potentially be identified by this study.

Only a few organisations in South Africa offer the mandated GCP course needed by any individual working on a clinical trial. Academic Advance, a division of WHC in Johannesburg, is one of the well-recognised GCP training providers. I approached Academic Advance to assist in promoting the inclusive clinical trial research programme through their extensive reach of clinical research professionals and clinical research sites. Academic Advance train approximately 400 people a year in basic GCP; about 124 of the 400 are medical and non-medical investigators (van Rensburg, personal communication, 4 February 2019); therefore, the population size (or population target) for this study is 124.

1.10.4 Sample and sampling method

Project 1’s qualitative segment sample (stakeholders): non-random purposeful sampling was used to select stakeholders for this pilot study (Mertens & Wilson

2018:408). Ten stakeholders were approached, including heads of organisations or departments, supervisors of investigators, principal investigators, and managers from the pharmaceutical industry. I identified stakeholders through Academic Advance. The WHC has a database of all stakeholders in South Africa.

Project 2 and 3's quantitative segments' sample (participants): the population was small, and all 28 candidates who were interested in the inclusive clinical trial research education programme were registered; thus, it was not necessary to select a sample.

Project 3's qualitative segment sample (participants/stakeholders):
This segment consisted of two groups: (1) five participants who completed the inclusive clinical trial education programme and (2) five experts who were also supervisors of participants who attended the inclusive clinical trial research education programme.

1.10.5 Data collection

Data refers to factual information, views, and statistics that are gathered and documented for the purpose of reference or analysis. (Saunders 2019:801).

1.10.5.1 Methods and techniques for data collection

Data collecting methods refer to the specific approaches or procedures selected by the researcher to gather data for analysis in their study. The data collection methods chosen by the researcher are linked to the research question, the philosophical underpinning, and the research approach (Kumar 2019:170).

Project 1: Interviews were conducted with ten stakeholders for qualitative data collection to get their perspectives on the opportunities and challenges in supporting investigators. Furthermore, stakeholders were asked for their suggestions on what an inclusive clinical trial education programme should consist of. Data were collected from April 2020 to June 2021. During data collection, I used reflective notes to bracket my preconceived notions (Polit & Beck 2022:522).

The stakeholders' validation of the inclusive clinical trial research programme occurred before implementation to establish if the proposed programme had fulfilled its purpose. Validation was done through a validation tool (questionnaire) completed by the same ten

stakeholders initially interviewed after reviewing the curriculum from 2 May to 13 June 2022.

Project 2: Data were collected from 1 to 17 August 2022 from 28 participants using developed questionnaires. Quantitative data collection for Project 2 included demographic information, such as age, length of previous research exposure, gender, and future career plans. After completing the demographic questionnaire, participants were asked about their self-perceived level of knowledge and competency in clinical trials (self-assessment). Thereafter, their knowledge of the eight competency domains of the clinical trial process and life cycle was determined using questionnaires (pre-test).

Project 3: Quantitative data collection for Project 3 repeated the same questionnaires used to determine participants' self-perceived level of knowledge and competencies, and their knowledge in the eight competency domains of the clinical trial process and life cycle of clinical trials (post-test). The two questionnaires described above contained approximately 100 items (combined), measuring participants' self-perceived level of knowledge and competency in clinical trials (self-assessment) and their knowledge of the eight competency domains of the clinical trial process and life cycle. The tests contained the same set of items, which were presented in a multiple-choice format. These items covered questions about GCP and the eight competency domains. Data collection was completed between 1 to 15 December 2022 with the same 28 participants.

Outcome evaluation, as part of the qualitative segment of my study, involved interviews with five stakeholders reviewing the inclusive clinical trial programme before and after implementation. These reviews were in the format of in-person face-to-face or online/mobile application interviews or an evaluation questionnaire from 1 December 2022 to 30 January 2023 (Mertens & Wilson 2018:219). For the quantitative segment, impact assessment and outcome evaluation were done through the pre-test-post-test questionnaires.

1.10.5.2 Data collection instruments

There were seven questionnaires in total for the study:

(i) Validation questionnaire for the stakeholders

(ii) Demographic questionnaire
(iii) Pre-test questionnaire to determine participants' self-perceived level of knowledge and competencies
(iv) Pre-test questionnaire to determine their knowledge of the eight competency domains of the clinical trial process and life cycle
(v) Post-test questionnaire to determine participants' self-perceived level of knowledge and competencies
(vi) Post-test questionnaire to determine their knowledge of the eight competency domains of the clinical trial process and life cycle
(vii) Inclusive clinical trial research education programme evaluation

There were two interview instrument guides with open-ended questions for the entire study:

(i) Interview instrument for stakeholders before the development of the inclusive clinical trial education programme
(ii) Interview instrument for the outcome evaluation with stakeholders after completion of the inclusive clinical trial education programme

1.11 DATA ANALYSIS

Data analysis is a systematic procedure that enables researchers to derive insights from raw data by extracting, organising, and attributing significance to it. (Creswell & Creswell 2020:215).

1.11.1 Data analysis for the qualitative segment of research

The first and third projects had qualitative segments. The data analysis process for these qualitative segments is briefly discussed, and a full description is available in Chapters 4 and 7.

- **The qualitative segment of the first and third projects:** I followed Saldaña's (2021:68) cyclical analytic coding process. This process consisted of first-cycle methods, second-cycle coding methods, and a cross method in-between (Saldaña 2021:68). The themes identified during the coding process were incorporated into the

development of the inclusive clinical research education programme. Analytical memos and reflective notes formed part of the data analysis process (Saldaña 2021:47).

1.11.2 Data analysis for quantitative statistical procedures

The data analysis procedure for the quantitative segment of Projects 2 and 3 is briefly discussed, and a full description is offered in Chapter 7.

- **Paired samples t-test:** A paired-sample t-test was used to compare the pre and post-test assessments for all the continuous score data. The assessments involved evaluating the overall scores for items followed by individual item comparisons (Fowler, Jarvis & Chevannes 2021:145; Bowers 2019:243).
- **Significance level and confidence intervals:** The alpha level was established at 0.05, and a confidence interval of 95% was used. By utilising a two-sided p-value of 0.05, I was able to either reject or accept the null hypothesis, which states that there was no change in assessment scores after the implementation and delivery of an inclusive clinical research education course for investigators, independent of the direction of the change. (Bowers 2019:243; Altman 1999:167).

All the statistical analyses involving the paired-sample t-test were conducted using SAS Enterprise 7.15 (SAS Institute Inc, Cary, NC, USA), assuming a 5% significance level.

Table 1.1: Summary of the research design, objectives, questions, data-gathering techniques and sampling methods

Segment and design	Objective	Question	Data-gathering technique	Population and size	Sampling and size
Project 1					
A: Qualitative segment	(i) Explore and describe stakeholders' perspectives of opportunities and challenges in supporting investigators. (ii) Explore and describe stakeholders' perspectives of what an inclusive clinical trial research education programme should consist of.	(i) What are stakeholders' perspectives of the opportunities and challenges in supporting investigators? (ii) What are stakeholders' perspectives of what an inclusive clinical trial research education programme should consist of?	Interviews (in-person, face-to-face and online/digital)	Experts from the clinical trial, academic and pharmaceutical fields.	Non-random purposeful sampling was used to select the stakeholders for this study. The ten stakeholders included heads of organisations or departments, supervisors of investigators, principal investigators, and managers from the pharmaceutical industry.
B: Development segment	(i) Develop an inclusive clinical trial education programme.	(i) What should an inclusive clinical trial research education programme for health sciences	The developed programme consisted of face-to-face lectures and online learning material.		

Segment and design	Objective	Question	Data-gathering technique	Population and size	Sampling and size
		investigators consist of?			
C: Qualitative segment	(i) Validation of the programme by stakeholders before implementation	(i) What are specialist stakeholders' views of the inclusive clinical trial research programme before implementation?	Validation tool Questionnaire	Experts from the clinical trial, academic and pharmaceutical fields.	The ten stakeholders included heads of organisations or departments, supervisors of investigators, principal investigators, and managers from the pharmaceutical industry.
Project 2					
A: Quantitative segment	(i) Measure investigators' self-perceived level of competency in clinical trial conduct. (ii) Determine baseline levels of investigators' clinical trial knowledge. (iii) Collect investigators' basic demographic characteristics.	(i) What are investigators' self-perceived levels of competency in clinical trial conduct? (ii) What are the baseline levels of investigators' clinical trial knowledge?	Pre-test assessment Questionnaires	The population size for the investigators completing the basic GCP course at Academic Advance was 124	Non-random purposeful sampling was used to select the participants for this study. 28 Research investigators employed at an academic, private or dedicated clinical trial unit in South Africa.

Segment and design	Objective	Question	Data-gathering technique	Population and size	Sampling and size
B: Implementation segment	(i) Implement the inclusive clinical trial research education programme for investigators.	(i) How should the inclusive clinical trial research programme's implementation process look?		124	28 Research investigators employed at an academic, private or dedicated clinical trial unit in South Africa.
Project 3					
A: Quantitative segment	(i) Measure investigators' perceived level of competency in clinical trial conduct. (ii) Measure investigators' knowledge of clinical trial conduct following the inclusive clinical trial research education programme.	(i) What are investigators' self-perceived competency levels in clinical trial conduct following the clinical trial research education programme? (ii) What are investigators' clinical trial knowledge levels following the inclusive clinical trial research education programme?	Post-test assessment Questionnaires	The population size for the investigators completing the basic GCP course at Academic Advance was 124	Non-random purposeful sampling was used to select the participants for this study. 28 Research investigators employed at an academic, private or dedicated clinical trial unit in South Africa.

Segment and design	Objective	Question	Data-gathering technique	Population and size	Sampling and size
B: Qualitative segment	(i) Stakeholders' evaluation of the outcome of the intervention to refine the inclusive clinical trial research education programme.	(i) What is the stakeholders' evaluation of the clinical trial research programme? (ii) Findings from this evaluation were applied in refining and finalising the inclusive clinical trial education programme.	Interviews (in-person, face-to-face and online/digital)	The 28 participants who had completed the programme and experts/supervisors from the clinical trial, academic and pharmaceutical fields.	The stakeholders consisted of two groups: (a) five participants who completed the inclusive clinical trial education programme and (b) five experts/supervisors from the clinical trial, academic and pharmaceutical fields.

1.12 MEASURES TO ENSURE TRUSTWORTHINESS, RELIABILITY AND VALIDITY

Trustworthiness relates to the extent to which the findings of a research study are true to the objectives of the study; in other words, it serves as a validation of the significance and genuineness of the research results. (Polit & Beck 2022:559).

1.12.1 Measures to ensure the trustworthiness of the qualitative segments of the study

Credibility, dependability, confirmability, and transferability measure the trustworthiness of the data, which can determine whether the qualitative findings are rigorous (Polit & Beck 2022:559). These measures are discussed exhaustively in Chapter 3.

1.12.2 Internal and external validity of the quantitative segment of the study

Ensuring the validity of this research meant that I (and others) could believe that the research results were trustworthy and meaningful (Creswell & Creswell 2022:223). A full description of internal and external validity measures is discussed in Chapter 3.

1.13 ETHICAL CONSIDERATION

Ethical considerations such as ethical approval of the study, respect for persons (informed consent), beneficence, justice and confidentiality are thoroughly discussed in Chapter 3.

1.14 SIGNIFICANCE OF THE STUDY

What sets this research study apart from existing education and training for investigators in South Africa is aligning the inclusive clinical trial education programme curriculum with all eight competencies proposed by the JTF. At the same time, the programme clarified what investigators' roles and those of other key players are, and prepared investigators with practical advice and skills around the inner workings of the clinical trial processes, equipping them for their daily tasks previously marked by trial and error. I specifically

highlighted the inclusion of nurses (and other non-clinical health professionals) as future investigators to build their capacity for leading clinical trial studies. The content of the inclusive clinical trial research programme was readily translated to practice during and after the intervention – it gave investigators the 'how-to'. This inclusive clinical trial research education intervention promoted self-efficacy, curtailing feelings of worthlessness and incompetence.

1.15 PROPOSED STUDY LAYOUT

The thesis is structured into eight chapters, as specified in Table 1.2. In line with the multiple-method design of this research, each study or project for this research is covered as a whole. According to Morse and Niehaus (2016:149), one project can include different studies. Each study addresses a different research question within the broad programmatic aim, and each study is thus methodologically complete. The thesis concludes with a final discussion on how the research contributes to the broader literature, recommendations, and a conclusion.

Table 1.2: Chapter layout

Chapter	Content
1	Orientation to the study
2	Literature review (1) Clinical trial education (2) Competency-based education (3) Self-efficacy (4) MRC framework
3	Research design and methods
4	Project 1 Research design, data collection, data analysis and findings (First segment: situation analysis - qualitative)
5	Project 1 Development and validation of the inclusive clinical trial research education programme (Second and third segments)
6	Project 2 Research design, data collection and implementation of the intervention
7	Project 3 Research design, data collection, results, and evaluation of intervention
8	Summary of integration of findings, conclusion, recommendation, contribution and limitations of the study

1.16 SUMMARY

This chapter provided an overview of the study's background, issue statement, aims, research questions, and methods. Additionally, it presented a preview of the content that will be covered in the subsequent seven chapters. This study developed and tested a much-needed inclusive clinical trial education programme to prepare investigators for the many challenges they will encounter in the evolving clinical trial industry and public health sector.

In Chapter 2, a review of the literature is discussed.

CHAPTER 2
LITERATURE REVIEW

2.1 INTRODUCTION

As mentioned in Chapter 1, an inclusive clinical trial research education programme for investigators in health sciences could provide a foundation for research education in South Africa. Such an education programme for investigators may promise free-from-harm training and modern teaching methods to produce well-equipped, knowledgeable, skilled, and confident clinical trial investigators.

This chapter critically reviews relevant literature to demonstrate how this study is located, considering the current body of knowledge and discourses. The different research questions of this study, as described in Chapter 1, guided the literature search to:

- Explore the currently available educational opportunities and challenges for clinical trial professionals (investigators) to equip them for their specific daily tasks as a member of the clinical trial team. In other words, what does clinical trial education look like, and what are the realities?
- As highlighted in the literature, those elements could potentially create a positive turn within clinical trial education. The evolving role of a competency framework for clinical trial professionals will be explored.
- Bandura's Social Cognitive Theory (1977) refers explicitly to "self-efficacy" and how it applies to clinical trial investigators' competencies. This necessitates a review of the definition of Bandura's Social Cognitive Theory and the theory's widespread use in education.
- The MRC framework for developing, piloting, evaluating and reporting a complex intervention.

The literature review will not cover the:

- barriers to the conduct of clinical research as barriers were not discussed and addressed in the study,

- theories and methods of learning, including adult learning methods, as these are covered in Chapter 5, and
- Bloom's Taxonomy, as some aspects of Bloom's Taxonomy is covered in Chapter 5.

The databases used for my literature search included Google Scholar, Science Direct, Pubmed, Ebscohost, ProQuest; Directory of Open Access Journals; Open Science Directory; BASE; CORE; Science.gov; Semantic Scholar and Google's electronic databases. Search terms included (clinical trial investigator training or training of clinical trial investigator); (research professionals and training); (future of clinical trials or clinical trial future); (current trends in clinical trials); (competency training); (competencies in clinical trials); (clinical researcher education); (self-efficacy) and (Bandura's self-efficacy theory). I only looked at articles published in English between 2018 and 2023. Literature from before 2018 was occasionally used for specialised reviews of clinical trial education in South Africa, middle- and low-income nations, and the United States of America. Relevant older articles were cited to highlight the historical significance of the topic.

2.2 CLINICAL TRIAL EDUCATION

Numerous publications emphasising the importance of clinical research professionals' training and education highlighted the lack of trained staff as a major hurdle to quality clinical research outcomes improving medical therapies (Magnin, Iversen, Calvo, Cecetkova, Dale, Demlova, Glasko, Keane, Kovacs, Levy-Marchal, Monteiro, Palmisano, Pella, Perez, Rascol, Schmid, Tay, von der Leyen & Ohmann 2019:2; Madeira, Santos, Kubiak, Demotes, & Monteiro 2019:1; Bechtel, Chuck, Forrest, Hildebrand, Panhuis, Pattee, Comc-Savic & Swezey 2020:1). However, what is available on clinical research education and training is not always clear and detailed.

2.2.1 Clinical trial education in European countries for clinical trial professionals

A survey by Magnin and colleagues (2019:2) investigated the clinical research training landscape in European countries. Their findings showed that 11 European countries had opportunities, to different extents, for academic training in clinical research. Table 2.1 summarises their findings.

Table 2.1: Summary of clinical training in European countries

Clinical research professional	Type of training	Number of European countries
Study nurses/coordinators	GCP basic and refresher training is provided by Clinical Trial Units (CTUs), private organisations and European Clinical Research Infrastructure Network (ECRIN)	Ten EU countries but mandated in one country.
	Standardised curriculum (did not mention training providers)	Only Germany
Principal investigators (PIs)	Mandatory clinical trial training by CTUs	Four EU countries
	Optional clinical trial training (did not mention training providers)	One country, although it is available in ten EU countries
	Standardised curriculum (did not mention training providers)	One country
	GCP basic and refresher training is provided by Clinical Trial Units (CTUs), private organisations and European Clinical Research Infrastructure Network (ECRIN)	Ten countries
Combination PI/coordinator	Standardised and non-standardised curriculums (did not mention training providers)	Available in seven countries and mandatory in one
	GCP basic and refresher training is provided by Clinical Trial Units (CTUs), private organisations and European Clinical Research Infrastructure Network (ECRIN)	Ten countries
Postgraduates	Clinical trial management, clinical trial evaluation, clinical research and translational medicine, medical biometry/biostatistics, and pharmaceutical medicine (did not mention training providers)	Mandatory for PhD students but is available for other students in some EU countries.

Four European countries had an overarching national strategy or roadmap for training in clinical research for future clinical trial professionals. Still, career options for clinical research are very limited in most European countries (Magnin et al. 2019:2). From Magnin et al.'s (2019:2) survey, it is clear that for most European countries, the basic standard

and requirement for entering the clinical research field is GCP training, and formal clinical research training is optional.

COVID-19's impact on Europe forced clinical trial teams to develop new methods of training for clinical research professionals (Mitchell, Ahmed, Breeman, Cotton, Constable, Ferry, Goodman, Hickey, Meakin, Mironov, Quann, Wakefield & McDonald 2020:5). Mitchell et al. (2020:5) admit that although the technology was previously available for training, it was seldom used because clinical trial teams preferred to keep to standard training methods. A positive result of the COVID-19 pandemic was that clinical trial teams were forced to implement remote training through video conferencing, short training videos and webinars. Training materials were provided on the trial website or a shared drive (Mitchell et al. 2020:5). New virtual methods of training reduced the cost of training and decreased footfall in health institutions (Mitchell et al. 2020:5). According to Mitchell et al. (2020:5), it is still to be seen if clinical trial teams will continue with virtual training after the pandemic.

2.2.2 Clinical trial education in the United States (US)

The investigation into clinical research training was not limited to European countries. However, literature on clinical research professionals' training before the pandemic in the US is sparse and not recent. Samuals, Ianni, Chung, Eakin, Martina, Murphy and Jones (2020:12) commented that the US supports clinical and translational research through numerous federal, industrial and academic organisations and other stakeholder groups. Canter and Lewis (2014:27) also investigated training opportunities in the US and found that 70% of participants felt underprepared for clinical research due to the lack of training opportunities. This view is consistent with the findings by Pelser (2018:83) in South Africa. Participants from Canter and Lewis's (2014:29) study also felt training methods did not align with their needs. Bechtel, Chuck, Forrest, Hilebrand, Panhuis, Pattee, Comc-Savic and Swezey (2020:3) mentioned that qualified and trained clinical research staff is essential to ensure participants' safety and data quality. However, clinical trial education and training are not equally important to medical and nursing education. According to Bechtel and colleagues (2020:11), they made several recommendations. Firstly, they suggested expanding the qualifications of clinical trial staff beyond just GCP training. Secondly, they emphasised the importance of identifying the specific learning needs of

each trial and site. Thirdly, they proposed adopting a targeted approach to qualifications. Lastly, they highlighted the need for improving educational offerings.

2.2.3 Clinical trial education in middle- and low-income countries

A systematic review and narrative synthesis were done on research capacity-building in middle- and low-income countries to increase research activity through educational and more comprehensive interventions (Ekeroma, Kenealy, Shulruf & Hill 2015:7). The intervention classifications that were identified include training workshops, postgraduate training, supportive collaborations, and environmental enhancers. A theoretical framework followed, linking these interventions to clinicians' successful research capacity-building (Ekeroma et al. 2015:7). Alfaar, Hassan, Bakry and Ezzat (2017:1) investigated the reasons for the gap in clinical research training from a medical student's perspective and found that clinical trial execution knowledge got the lowest score. In support of Alfaar et al.'s (2017:1) findings, a clinical trial education programme to show investigators the 'how-to', as promoted by this pilot study, is needed and relevant in 2023.

2.2.4 Clinical trial education in South Africa

Focusing on South Africa, literature and research on clinical research education are minimal and outdated. In October 2022, the South African Health Products Regulatory Agency (SAHPRA) revised its 2019 *Capacity-Building and Transformation in Clinical Research* document, stipulating the following essential points relating to clinical research professionals' training: (1) stakeholders should be encouraged to take part in the transformation of academic institutions to develop and include topics related to clinical research and regulatory sciences in their curriculum; (2) it is advisable to motivate healthcare and scientific graduates at the beginning of their careers to receive training and develop the essential skills required for conducting clinical research. (3) every clinical research facility should undertake formal and informal ongoing upskilling of clinical trial staff to acquire further competence. This includes guiding and supporting novice trial sites to improve the procedures required to conduct clinical trials.

As mentioned, South African-related information is quite dated, but research by Siegfried, Volmink and Dhansay (2010:1) is worth mentioning. Two key themes identified from their research included research methods training and statistical support. The research

conducted by Siegfried et al. (2010:1) revealed a clear necessity for a national programme to promote and improve the implementation of clinical research in the public sector. As a result, they raised the question of whether South Africa should establish a national clinical trial support unit. Looking at the future of clinical trials in South Africa in 2010, Burgess and Sulzer (2010:1) proposed the implementation of uniform training programmes and certification procedures, incorporating a central curriculum and dependable accreditation. In South Africa, clinical research is not considered a distinct field with structured training, apart from Good Clinical Practice (GCP). Assessment does not include evaluation of demonstrated skill and ability. Once again, the need for clinical research training was expressed by Burgess and Sulzer (2010:1) without any view of available clinical research education. There is no evidence in the literature that the South African clinical research community implemented Burgess and Sulzer's (2010:1) recommendations.

2.2.5 Capacity-building for clinical trial professionals' education

Discussions on clinical trial professionals' preparation have come a long way (Janowsky, Glick, Lash, Mitnick, Klein, Frederick, Goodwin, Hanin, Nemeroff & Robins 1986:1; Kelly & Randolph 1994:5; Reynolds, Martin, Brent, Ryan, Dahl, Pilkonis, Marcus & Kupfer 1998:190). Canter and Lewis (2014:1) mentioned that there is a lack of research on the preparation of clinical research professionals worldwide. According to Raffo and Crook (2019:1), the growth in the clinical trial industry has led to an increased demand for clinical trial professionals, and it is challenging to find competent, trained candidates while retaining high-performing staff. Most academic institutions have minimal content related to clinical research at undergraduate and postgraduate levels for different medical and health sciences professions, including nurses.

Most of the clinical research workforce is trained 'on the job' (Canter & Lewis 2014:25; Silva et al. 2015:133; Pelser 2018:80; Nanivadekar 2017:37). Similar to Europe, the US and other countries, including South Africa, clinical trial staff's training follow employment; in other words, they will receive on-the-job training (Canter & Lewis 2014:25). Specific training guidelines developed by either sites, institutions or sponsors are often followed to facilitate the training (Samuals et al. 2020:12). As mentioned, training often includes mentoring, academic programmes, medical school courses, training courses by professional organisations and societies, and graduate and undergraduate programmes

(Deeter, Hannah, Reyes, Mack, Stroo, Freel, Brouwer, Gaudaur, Doughty & Snyder 2020:15; Ng, Jones, Sivapragasam, Nath, Mak & Rosenblum 2019:664).

Wieland (2020:1) mentioned that it could take up to eight years for a research professional to be on a level where they can function autonomously, be self-directed and reliably contribute with little guidance and mistakes. It could take years to comprehend the complexity, good clinical practice, the ever-evolving regulations, and the entire life cycle of a clinical trial. As Tontonoz (2014:2) describes, you need “fire in the belly” to be committed to clinical research as a career. Moreover, this fire in the belly cannot be instilled; it is mainly nurtured and is one of educators’ most important jobs. After running his laboratory for 15 years, Tontonoz (2014:2) recognised that people largely come into clinical research and either get it or not.

Canter and Lewis (2014:25) and Ng et al. (2019:664) reported that little research had been conducted on training for clinical trial professionals. Publications on clinical research training are random and often relate to specific roles within the clinical research team. A study investigating study coordinator training found that clinical trial training consists mainly of self-study, lectures, small group discussions, and on-the-job training (Canter & Lewis 2014:1). Hastings, Fisher, and McCabe (2012:9) also noted the absence of formal assessment research that demonstrates the influence of nurses, in their roles as study coordinators and leaders in a research context, on specific outcomes related to quality, safety, or efficiency.

Investigations into research capacity-building also triggered some publications. Capacity-building expanded over the last two decades to include computer scientists and engineers to cope with the increased use of technology and data science in clinical trials (Inan, Tenaerts, Prindiville, Reynolds, Dizon, Cooper-Arnold, Turakhia, Pletcher, Preston, Krumholz, Marlin, Mandl, Klasnja, Spring, Iturriaga, Campo, Desvigne-Nickens, Rosenberg, Steinhubl & Califf 2020:4). Clinical trial team training should thus include digital technology education as teams need to know about cybersecurity and the privacy of participant data (Inan et al. 2020:4). Moreover, the need for capacity-building to recruit minority groups to clinical trials has been emphasised by clinical training staff and some defined training programmes have been developed (Niranjan, Durant, Wenzel, Cook, Fouad, Vickers, Konety, Rutland, Simoni & Martin 2019:33).

However, the most significant change to clinical trial training methods was brought forward by the COVID-19 pandemic (Pennell, Szczepanek, Spiegel & Ramalingam 2022:2). Training and skills development on technology and digital devices had to be upscaled. In addition, teams had to adapt to working remotely, and training on remote access to system records and shared drives had to be included (Pennell et al. 2022:2). Pennell et al. (2022:2) made an important observation that the downside of the new virtual method of training clinical teams is the loss of on-the-job training where an experienced staff member would mentor an inexperienced staff member side-by-side. The authors (Pennell et al. 2022:3) suggested the development of simplified, accessible training modules that could be shared with all sites to lessen the burden of creating new training programmes for each new clinical trial.

Training courses developed before the COVID-19 pandemic and staff's in-service training had to be adjusted to change the course structure and presentation from only face-to-face training to include virtual sessions (Berkness, Carrillo, Sperling, Petersen, Aisen, Flournoy, Snyder, Raman & Grill 2021:4; Jones, Lane, Shah, Carter, Lackey & Kolb 2021:1). There is thus a need to develop training courses that will satisfy the need for face-to-face training in combination with online training to build skills and share knowledge on specific competencies. The developed clinical research education programme in this pilot study used blended training to combine face-to-face and online training.

2.2.6 Clinical trial education – global stance

Currently, when browsing the internet, numerous national and international academic and non-academic institutions and organisations offer different online and face-to-face short courses related to clinical research to prepare a variety of professionals for the clinical research industry. Some of these include IQVIA, University of Columbia San Francisca, Harvard Medical School, PharmaTrain, IMARC, Association of Clinical Research Professionals (ACRP), Society for Clinical Research Administrators (SoCRA), WHC, Fundisa, IMPAACT Network, FHI 360, CITI program, London School of Hygiene and Tropical Medicine, National Institute of Health (NIH). These offered funding for principal investigators through academic medical centres and individual training rewards such as the K08 and K23 or K99 mechanisms.

The impression was created that the clinical research community have taken the *lack of clinical research training* message seriously. The result was the evolution of education and training in clinical research. A series of activities followed, including informal training through coaching, tutoring and short-term courses mainly provided by professional bodies. Formal training was offered through academic institutions with standards, competencies, traditional curriculum, national accreditation and certification, followed by international standards and certifications (Deeter et al. 2020:15). It is essential to mention that each organisation or academic institution have their own set of standards, competencies and curriculum; the process of harmonising all these different sets of standards and competencies is still in progress (Harper 2020:3).

However, as mentioned, little evidence shows the success and efficiency (or failure) of currently advertised clinical research training and education courses. Few attempts have been made to focus on developing and evaluating clinical research programmes, and even less effort has been made to evaluate the process involved (Samuels et al. 2019:12). The aspect of research knowledge and skills was investigated by Al-Tannir, Abu-Shaheen, AlSumaih, AlMukaibil, AlHarbi, Heena, Sallout, Mahha, Marran & AlFayyad (2018:1), who assessed research knowledge and skills among medical and Allied Health students through a pre-test-post-test questionnaire. The results showed a statistically significant difference in research knowledge after the students underwent a research training programme. Rees, Salto-Tellez, Lee, Oien, Verril, Freeman, Mirabile, West, Cheang, Rodriguez-Justo, Howlett, Moretti, Da Silva, Nacs, Hartridge-Lambert, Beecham, Traub, Katugampola, Blagden, Morden, Robinson, James, Jones, Craig, Sloan, Thomas, Elliott, Driskell and Hall (2019:100) proposes the establishment of training and accreditation criteria for pathologists involved in clinical trial activities, but, the effectiveness of the suggested courses is not addressed. Turning the attention back to South Africa, there is currently no evidence from the literature or web searches that available courses and training programmes for clinical research professionals in South Africa include the eight competency domains specified in the JTF competency framework. The practicality or the “how to do a clinical trial” does not appear either.

The root cause of the current state of clinical research training and unmet needs lies in the lack of clear training guidelines from authorities regulating clinical research. The Food and Drug Administration (FDA) guidelines recommend that clinical trial sponsors select investigators who are qualified by training and experience, but they do not elaborate on

the training content. According to the Canadian health guidelines, a competent investigator is defined as an individual who is a member in good standing of a professional medical or dentistry group, and according to the ICH (and SA) GCP guidelines, individuals participating in clinical trials should be qualified to do so by the necessary education, training, and experience in the performance of their specific tasks (Harper 2020: slide 9; SAGCP 2020).

Global expected standards in clinical research do not exist. Currently, there are no obligatory regulations, standards, or licencing criteria for certain employment positions in clinical research. Additionally, there are no accreditation requirements for academic programmes or established standards for internal or external training programmes. (Harper 2020:10; Brandenburg & Ward 2022:1). There are, therefore, no standards for entering the field; anyone from any academic or training background could apply for a position within clinical trials. The reality is thus that a clinical trial team will consist of individuals from various medical and non-medical backgrounds (Canter & Lewis 2014:1). Consequently, there are no job descriptions or standards to evaluate entry-level competencies.

The need for globally integrated efforts to strengthen health research capacity was emphasised by the WHO in 2013. Despite the rise in the availability and accessibility of sufficient training programmes, there is still a need for integration. Integration in clinical trials necessitates the cultivation of clinical research abilities among team members in various roles, such as the principal investigator, sub-investigator, clinical research coordinator, clinical research associate, data manager, study nurse, and pharmacist. In 2013, the Consortium of Academic Programmes in Clinical Research (CoAPCR) performed research to determine the range of learning requirements that should shape academic curriculums for clinical research. This research highlighted the importance of clinical research core competences. (Sonstein, Brower, Gluck, Kolb, Aldinger, Bierer & Thomas Jones 2018:1). Research professionals thus decided to move towards competency-based education to train a multi-professional clinical research workforce (Silva, Sonstein, Stonier, Dubois, Galdson, Thomas Jones, Criscuolo, Daemen, Kesslring, Klech & Klingmann 2015:131).

2.3 COMPETENCY-BASED EDUCATION

The process involved in competency-based learning originated centuries ago when apprentices learnt from master craftsmen. An apprentice learning to make a barrel would advance through different levels from novice to master. In the process, the apprentice needed to show mastery of each level before the tradesman would graduate from the apprenticeship to full craftsman status (Stafford 2019:243). Similarly, licensure programmes for doctors were part of the history of outcome-based approaches centuries ago (Nodine 2016:6; Nel, Burch, Adam, Ras, Mawela, Buch & Green-Thompson 2022:742). Vogel-Walcutt and Schatz (2019:262) argued that in the future labour market, skills and competencies will be highly valued. This will require an education system that focuses on developing and assessing competencies, both in early-life schooling and throughout a person's lifetime. This pilot study supports Vogel-Walcutt and Schatz's (2019:262) view and bases clinical research education on a competency framework to educate investigators.

2.3.1 Competence and competency

Searching the literature for definitions, theories, models and frameworks related to competence and competency is like losing sight of the forest amid the endless number of trees – it becomes increasingly complex and confusing. Various authors have different views and, therefore, different definitions, theories and models for competency-based education (White 1959; McClelland 1973; Klemp 1980; Boyatzis 1982; Hogg 1993; Parry 1996; Marrelli 1998; Dubois 1998; Hoffman 1999; Selby et al. 2000; Jackson & Schuler 2003; Spencer & Spencer 1993; Kramer 2004; Gartner Group; American Nurse Association; Lucia & Lepsinger 1999; People Soft in Sanghi 2016:335). Without a clear definition of 'competency', two main meanings have emerged over time, one referring to the outputs or results of training (learning), and the other relating to the inputs or underlying qualities required of a learner, teacher, the curriculum, and the time invested to achieve competent performance (Sanghi 2016:330; Stafford 2019:243).

As workplace expectations change due to an ever-evolving society, economy and work environment, a competent person will be highly valued (Beheshtifar 2013; Bell et al. 1997; Eraut 1998; McClelland 1998; Schroeter 2008; Pinapati 2011; Torr 2008 in Collazo 2016:47). Consequently, competency-based training for vocational and professional education programmes have gained popularity in developing a competent worker (Collazo 2016:48). However, there is no clear understanding of the meaning of the terms:

‘competence’, ‘competencies’, ‘competent’, and ‘competency’. The word ‘competence’ originates from *competentia* and ‘competent’ from *competens* in the Latin language (Guerrero & De Los Rios 2012:1291). The Latin meaning for ‘competence’ refers to a conflict between two people, while the word ‘competent’ could have several meanings in Latin: “to go hand in hand with someone or something, adequate for something; suited for something” (Guerrero & De Los Rios 2012:1291).

The multifaceted nature of the word ‘competent’ could cause confusion unless it is evaluated in the correct context. The term ‘competence’ has transcultural connections wherein the meanings of the word unite but differ in their specific definition (Guerrero & De Los Rios 2012:1291). Wright (in Collazo 2016:48) therefore urged organisations in 2005 to stipulate the meaning of the words ‘competent’ and ‘competence’. A few years later, in 2013, Mathelitsch (Collazo 2016:48) agreed with Wright and recommended that different standards and expectations within various cultures (South Africa vs America) and professions (health science vs engineering) require definitions of ‘competency’ to be made within context.

Vazirani (2010:121) calls the word ‘competence’ “fuzzy”, attributed to the combination of distinct concepts and uses of the term. The term 'competence' typically encompasses talent and the level of performance attained, whereas 'competency' pertains to the behaviour or conduct required to accomplish the performance. (Sanghi 2016:335). Definitions of ‘competency’ found in the literature include one from the training package Development Handbook for Units of competency that describes ‘competency’ as the capacity to carry out specific tasks and obligations to the level of performance required in the workplace (Guthrie 2009:18). Eraut (2003 in Guthrie 2009:18) as well as Mulder, Weigel and Collins (2007:67), similarly stated that ‘competency’ is the ability or capability to perform tasks and roles required to the expected standards by using knowledge, skills and attitudes integrated into the individual’s professional scope.

According to Spencer and Spencer (1993:9), 'competency' refers to the inherent traits of an individual that are directly linked to achieving high levels of performance in a job or situation, as judged by established standards. The plural of ‘competence’ and ‘competency’ also have two meanings. ‘Competences’ (the “what”) are the different skills and abilities that have been performed to a satisfactory level of performance; ‘competencies’ (the “how”) are the conduct and behaviour that lead to competent

performance (Sanghi 2016:335). Ultimately, the definition of ‘competency’ often depends on the lens through which the author or scientist is looking. Did they analyse the situation from a behaviourist perspective, emphasising quantifiable and applicable standards that define expected behaviour? Or did they analyse it from a cognitive, constructivist, and situational perspective, where transferability might be less likely due to the theory's emphasis on context and cultural differences? (Collazo 2016:49).

A widely held perspective is that competences are crucial in the development of competency, and competency is a prerequisite for attaining competence and being competent. (Moore, Cheng & Dainty 2002; Torr 2008 in Collazo 2016:49). Conversely, other researchers argue that competence is not the ultimate goal but merely a point on the road to mastery (Rosenberg 2012:10; Mukhtar & Gunderman 2017:1621). According to Rosenberg (2012:2), there are four stages of mastery. The starting point is being a *novice* who needs to be shown what to do before they can do the job. As a novice is shown what to do and become familiar with the task, they become competent and can do their job to basic standards. Once a *competent* worker gains more experience, they become *experienced* in the work, and they move beyond competent and can vary their performance based on unique situations. The last step or stage is reached when a person can create their learning through new knowledge, research, collaboration and problem-solving – they become an *expert or master* of the job and can teach others how to do the job.

The argument between the viewpoints mentioned above seems to be around the place of mastery. Is mastery the goal or end destination, or is mastery needed at different stages of learning for the person to become competent? The term ‘mastery’ is not often used as the end goal of competency-based learning but rather as part of becoming competent.

2.3.2 Competency-based education history

Competency-based education resulted from teacher education and training reform in the 1960s (Brown 1994:1). As part of Brown’s (1994:9) historical account of competency-based learning, he elevated five generations of the competency model. The first generation was integral to the Australian competency-based vocational education framework, which implemented scientific management principles to job positions. The

second generation, which emerged in the 1920s and 1930s, prioritised the development of mastery learning models. The third generation was based on the work of Skinner and therefore had a psychological and behavioural foundation and was primarily related to formative vocational education and training. Moving beyond vocational training to education formed the fourth generation and was brought forth by the teacher education movement in the US. This period (fourth generation) also represented the time when the word ‘competency’ started to be used in connection with instruction and learning.

The competency-based learning models that arose in the 1980s and 1990s were the fifth generation. (Brown 1994:10). During the fifth generation, Tuxworth (1994:109) commented that competency-based methods are particularly suitable for healthcare-related education, training and professional development. However, according to literature (Carraccio, Wolfsthal, Ferentz & Martin 2002:361), the use of competency-based models in medical education did not get off the ground as initially hoped. Carraccio et al. (2002) found that medical educators did not establish a clear connection between the curriculum and residency training and specific competencies. Instead, they primarily emphasised broad competence and learning objectives. Carraccio and colleagues (2002:361) also found a lack of proper assessment tools and methods to evaluate competencies, limiting the use of competency-based models.

The sixth generation, which occurred after the 1990s, was marked by significant technical progress that had a profound impact on education. The sixth generation of competency-based models includes online learning, advancements in learning analytics, adaptive technology, and direct assessment models. In this generation, students are supported, guided, or mentored instead of being taught. (Klein-Collins 2013:5). Due to technological and scientific advancements, the education system had to fast-track change and employment competencies were introduced to increase levels of skills and flexibility to satisfy a competitive economy (Ten Cate 2017:1). The process of fast-tracking change has been accelerated in recent years by the COVID-19 pandemic (Coons 2021:1).

In contrast with Carraccio and colleagues’ findings, the medical school in Cleveland, Ohio, recognised in the early 1950s that medical students would benefit if the content of medical training focused on clinical relevance combined with scientific matter. The medical school thus started the first outcome-based medical education programme. Several other medical schools followed, and according to Ten Cate (2017:2), medical

education and teacher education have consequently advocated for competency-based education since the 1960s, both from an academic and a professional vocation point. Numerous competency-based medical education programmes and competency frameworks were successfully developed over the years in response to the technological and scientific evolution and reaction to public demand for increased accountability for physicians (Ten Cate 2017:2).

2.3.3 Competency frameworks

The Chartered Institute of Personnel and Development (CIPD) (2022:1) describes a ‘competency framework’ as a model that sets out and defines each competency (knowledge, skills and attributes), such as the development of a protocol individuals need to perform their job in a clinical research organisation. The International Atomic Energy Agency (2022:3) has a broader definition and refers to a ‘competency framework’ as a structure that contains a broad description of performance excellence within an organisation. According to Englander, Cameron, Ballard, Dodge, Bull, and Aschenbrener (2013:1088), a 'medical competency framework' is a systematic and structured depiction of a collection of interconnected and purposeful competencies.

Competency frameworks within the medical field vary due to different descriptions of specific outcomes; therefore, countries have different frameworks for physician competencies (Englander et al. 2013:1088). Competency frameworks in the medical profession include the Outcome Project by the Accreditation Council for Graduate Medical Education, the American Board of Medical Specialties, the CanMEDS framework by the Royal College of Physicians and Surgeons of Canada, the Scottish Doctor Project in Scotland, and the Framework for Undergraduate Medical Education in the Netherlands. (Englander et al. 2013:1088). Other health professions, such as nursing, dentistry and pharmacology, have also developed and used competency frameworks (Englander et al. 2013:1088). Literature shows several competency frameworks for the nursing profession.

The College of Registered Nurses of Manitoba, Canada, has developed a competency framework for entry-level registered nurses. The new American Academy of Nurses' criteria on cultural competences are founded upon universal guidelines for cultural care. The American Hospital Association possesses fundamental governance skills, while the Massachusetts Nurse of the Future key competencies were formulated in 2016. In 2014,

the South African Nursing Council implemented a comprehensive competency framework for advanced nurse practitioners and nurse educators. Different disciplines within nursing also have their own competency frameworks; for example, global/public/community health, mental health, paediatric care, advanced nursing practice, nurse educator and midwifery (Sundean, White, Thompson & Prybil 2019:2).

Competency-based education has been adopted by the medication development industry. It consists of a workforce in support of the medicine development process and one that conducts clinical trials (Silva, Sonstein, Stonier, Dubois, Gladson, Jones, Criscuolo, Daemen, Kesselring, Klech & Klingmann 2015:132). However, each group within the medicine development industry has their own set of competencies even though the different groups work together for the same goal of improving public health. In 2003, the Consortium of Academic Programs in Clinical Research (CoAPCR) was formed by directors of academic clinical research degree-granting programmes to consolidate core competencies from the different institutions. The aim was to develop a curriculum tailored for the upcoming cohort of clinical research experts. (Hornung, Jones, Calvin-Naylor, Kerr, Sonstein, Hinkley & Ellingrod 2018:47).

Following the CoAPCR's initiative, in 2013 (ten years later - evidence of the slow progress in clinical research training) representatives from the pharmaceutical industry, clinical research organisations, academic institutions, clinical research sites, and professional societies met under the backing of the Alliance for Clinical Research Excellence (ACRES), the Multi-Regional Clinical Trial Centre at Harvard University (MRCT), PharmaTrain, the Model Agreements & Guidelines International (MAGI), and the Drug Information Association (DIA). The outcome of this meeting was the founding of the Joint Task Force for Clinical Trial Competency (JTF) (Silva et al. 2015:135).

The objective of the JTF was to consolidate and synchronise the various fundamental skills into a unified, top-tier collection of criteria to serve as a competency framework for all professionals operating in the global clinical research field. (Silva et al. 2015:135). The JTF defined 'competency' as a skill and 'core competency' as one needed to perform a task by similar professional groups and used as a basis for interprofessional education. Conversely, 'competence' is described by the JTF as the selection of skills spanning various domains or aspects of professional performance in a given context (Silva et al. 2015:135). They regard a competent professional as someone who has attained all the

required abilities in all domains at a particular stage of their education or practice. The Core Competency Framework (CCF) agreed on by the JTF has eight domains and 51 competencies. The eight domains are (1) Scientific concepts and research design; (2) Ethical and participant safety considerations; (3) Medicine development and regulations; (4) Clinical trial operations; (5) Study and site management; (6) Data management and informatics; (7) Leadership and professionalism; and (8) Communication and teamwork (Silva et al. 2015:136).

Although the JTF framework has become more widely adopted, literature on its use in training clinical research professionals is scarce. Saunders, Pimenta, Zuspan, Berent, Noelle, Hertzog, Jones, Kline, Kocher, Robinson, Thomas and Stanley (2017:1) conducted a needs assessment survey. Part of the survey was to determine the JTF competency domains' inclusion as part of clinical research coordinators' onboarding training and identify enablers and barriers to their inclusion. The results showed that not all the JTF competency domains were included in the onboarding training. Most clinical research coordinators felt their training was inadequate and they were not competent in all the domains, even after their training. The authors recommended that the JTF competency domains be included in higher education curriculums so that competencies are defined by levels of experience (fundamental, intermediate, and advanced) to assist in shaping targeted training and job descriptions (Saunders et al. 2017:2).

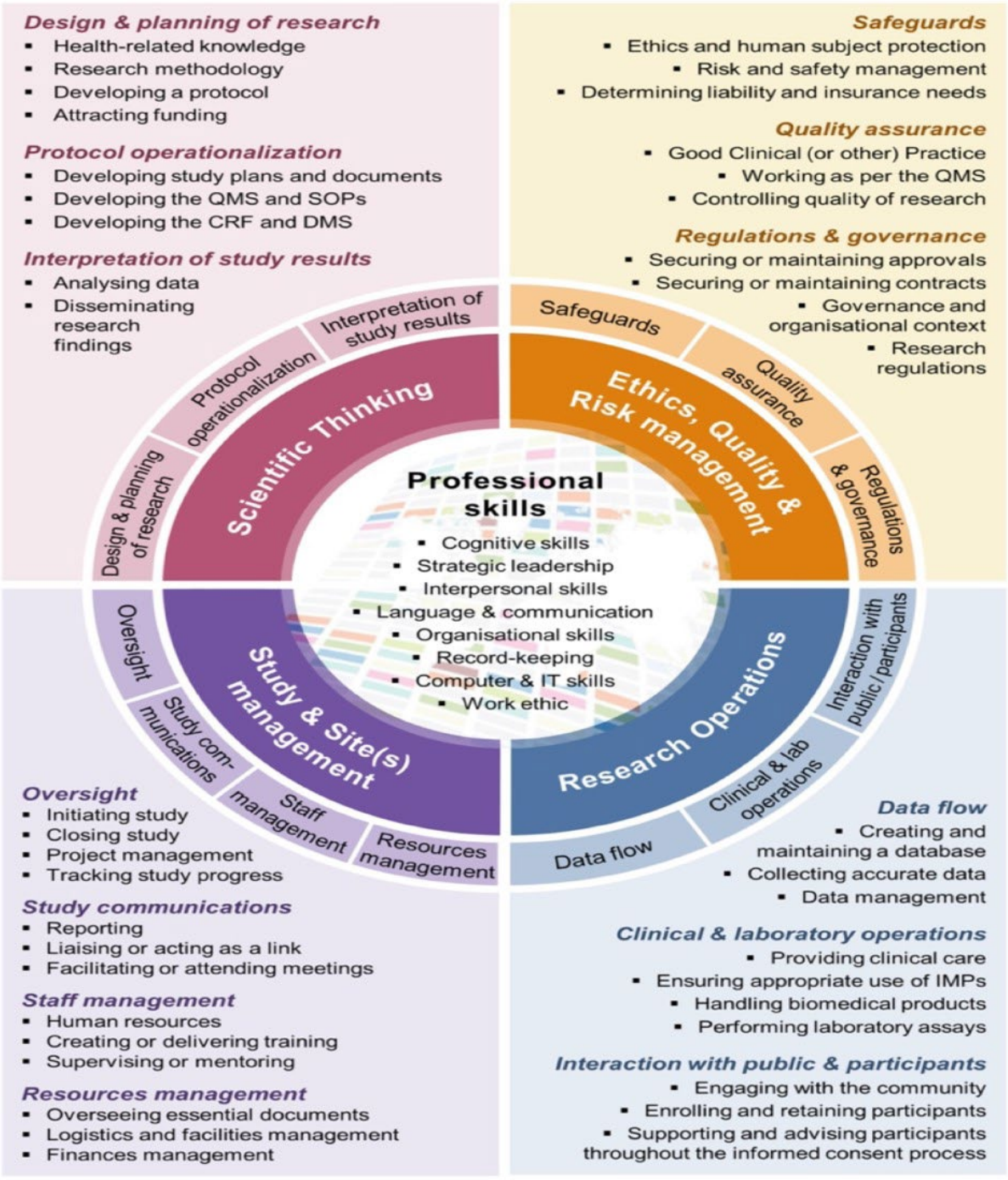
Another survey in 2016 included clinical research professionals from the US, Europe, Latin America, Asia and Australia. The survey aimed to determine participants' self-perceived competence and indicate the relevance of the JTF framework for their job roles (Saunders et al. 2017:2). The outcome of the survey showed that the items/topics within the different domains were globally relevant, but what was expected of staff in various roles differ between countries in terms of their competency requirements (Saunders et al. 2017:2). From the survey, it was also clear that there was a need to acknowledge increased levels of competence as a person moves from novice to experienced over time (Saunders et al. 2017:2). Based on these surveys and feedback from the research community, the JTF workforce revised the JTF framework (version 2.0) in 2017 and again in 2018 (version 3.0) to 'level' competencies and reflect increased levels of competence. Version 3.1 included competencies related to clinical project management and technology-based enhancements for the clinical research enterprise; it came out in 2020.

The JTF workforce commented that the levelled competency framework now guides the development of training programmes and specialised role descriptions. Moreover, it has the benefit that it could be adapted to site-specific practice cultures and provides direction internationally for clinical research sites (Sonstein et al. 2018:9). To assess an individual's competency, the JTF workforce used Bloom's Taxonomy to create specific examples of knowledge, skills and abilities for each competency, starting from novice to expert (Sonstein et al. 2018:9).

Schematic diagram 2.1: JTF competency domains for the clinical research professional

The JTF was not the only group to develop a globally applicable competency framework for clinical research professionals. Julé, Furtado, Boggs, Van Loggerenberg, Ewing, Vahedi, Launios and Lang (2017:2) further explored the harmonisation of competencies to include all activities needed for clinical trial implementation, regardless of which individual may perform them, to create the *Special Programme for Research and Training in Tropical Diseases (TDR) Global Competency Framework for Clinical Research*. Based on their definition of a 'competency' (required knowledge and skill to perform an activity, not the activity itself), Julé et al. (2017:3) distinguished three types of competencies. These included (1) theoretical or knowledge-based competency – best acquired through learning, (2) the practical execution of a task that requires task-based competency and is best learnt by doing, and (3) trait or skill-based competency that comes from experience, enabling a person to show appropriate behaviour in various situations.

Julé and colleagues (2017:2) aimed to adapt the existing framework to real-life data that could be used globally for different types of research, research settings, team sizes and disease types. They looked at competencies for different clinical research roles and recognised that underlying competencies are very similar and overlap, making it possible to develop a unifying framework. Therefore, the *TDR Global Competency Framework for Clinical Research* applies to all research roles and is in the format of an encompassing 'competency wheel' (Julé et al. 2017:3). The competency wheel consists of five categories with 50 competencies between the categories. The five categories include (1) professional skills, (2) ethics, quality, and risk management, (3) research operations, (4) study and site management, and (5) scientific thinking (Julé et al. 2017:4).



Schematic diagram 2.2: Competency wheel

Source: Julé and colleagues (2017:2)

Developing a competency framework for the clinical research professional workforce was significant in ensuring a well-trained workforce and safe, ethical, and high-quality clinical research. Moreover, the JTF framework and the TDR competency wheel both have advantages. Still, in light of the wide acceptance of the JTF framework globally (Sonstein & Jones 2018:2), I have chosen to use the eight competencies of the JTF framework as a basis for the development of the clinical trial education programme for this study.

As mentioned, the JTF was not the only or first group to develop a competency framework for clinical trial professionals. In the ten-year gap between 2003 (when the CoAPCR) and 2013 (when the JTF harmonised competencies for clinical research professionals), Mullikin, Bakken and Betz developed an assessment tool to measure clinical research self-efficacy among doctors receiving clinical research training in preparation to follow a clinical research career (Hornung et al. 2018:48). Initially, the Clinical Research Assessment Inventory (CRAI) tool consisted of 92 items from ten competency domains. However, it was shortened to 88 items and six competency domains (CRAI-12). Over time, the CRAI tool was adapted and used within different clinical research fields with different clinical research professionals. The University of Washington, for example, used a 76-item CRAI in a study to evaluate clinical research training programmes. After factor analysis, they reduced the 76 items to 69, and the overall results showed that the participants' self-efficacy had improved significantly after training. The CRAI tool has its roots in the self-efficacy theory (Hornung et al. 2018:48).

Hornung and colleagues (2018:48) took it a step further. They developed a competency index for clinical research professionals (CICRP) based on the CRAI tool to assess clinical research professionals' self-efficacy in implementing and managing clinical trials. Their survey asked participants to self-identify their role in the clinical research team and indicate their competency on each item in each domain. Participants were given the option to select from three choices: 'unfamiliar with the subject', 'knowing of the content but not requiring further information', or 'exposed to the content and knowledgeable enough to research what is essential for my work'. 'Competent' refers to the ability to understand and explain concepts, as well as solve basic problems by applying these concepts. On the other hand, 'mastery' implies the capability to apply knowledge to more intricate situations, integrate information, and provide solutions. (Hornung et al. 2018:48). The survey results showed role confusion due to job titles and roles varying across research sites and institutions. The authors recommended that the clinical research community clarify job titles and performance expectations as a first step in developing education and training programmes for the 21st-century clinical trial workforce (Hornung et al. 2018:51). Their recommendation urged sponsors and investigators to use the CICRP indices regardless of role ambiguity because they will still benefit from choosing individuals who are confident they can competently complete a task. Employers can be assured that those individuals who rate themselves as competent will be more likely to

succeed within the role offered to them than those who lack confidence in their ability to perform a task (Hornung et al. 2018:51).

Given their findings, Hornung et al. (2018:51) recommended that education training programme developers, including academic institutions, use the competency indices to determine early career and experienced individuals' educational needs (Hornung et al. 2018:51). According to Hornung et al. (2018:51), educators and trainers can benefit from the competency indices by using pre-and post-test evaluation instruments to measure their programme curriculums and other training activities' impact on students' self-confidence. Data from competency index evaluation instruments could play an essential role in guiding competency-based curriculum and training changes in preparation for a well-trained and skilled clinical research workforce that is urgently needed (Hornung et al. 2018:51).

One of the gaps in Hornung et al.'s (2018:51) study, and admitted by them, is that data were collected through self-selection and included participants from the US and Canada only. My pilot study aimed to fill the gap Hornung et al. (2018:51) identified and build investigators' self-efficacy in South Africa. The self-efficacy theory was thus used as the basis for developing competency domains for the CRAI tool and was successful in showing improvements in participants' self-efficacy after training (Hornung et al. 2018:48). The self-efficacy theory proved to be an essential foundation for future training programmes to facilitate change in participants.

2.4 SELF-EFFICACY

Bandura's (1977:3) work as the progenitor of Social Cognitive Theory has exerted a significant influence on various domains, including education, health sciences, social policy, and psychotherapy. Prior to the 1950s, psychologists held a strong belief that human behaviour could be most effectively understood by examining the influence of reinforcement and punishment mechanisms (Greene 2018:12). Following the 1950s, psychologists, particularly Bandura, began to adopt a more comprehensive and integrated approach to their thinking. Greene (2018:12) determined that behaviourism was insufficient in elucidating the reasons behind individuals' ability to proficiently engage in language and intricate decision-making. Bandura transitioned from the Social Learning Theory to the Social Cognitive Theory primarily to distinguish his conceptual framework

from the prevailing perspectives of psychologists during that period (Bandura 1977:14). During this period, it was acknowledged that an individual's cognitive processes have an impact on their behaviour both prior to and following an action. These thoughts surely aid an individual in comprehending their social surroundings and gaining insight into oneself and one's own requirements (Greene 2018:12). As a result, Social Cognitive Theory included three aspects of human experience: personal cognitions, behaviours, and the social context or environment (Greene 2018:12). The focus shifted from solely considering behaviour to incorporating the self as a cognitive system capable of premeditation and utilising self-reflection and language to comprehend and manage existence (Greene 2018:13). The Social Cognitive Theory is founded on four mechanisms for achieving goals: self-observation, self-evaluation, self-reaction, and self-efficacy. The concept of self-efficacy was introduced by Social Cognitive Theory, which primarily involves a cognitive process or cognition (Greene 2018:35).

2.4.1 Definition of 'self-efficacy'

Self-efficacy is rooted in the beliefs we have about our abilities. Numerous articles in the literature refer to Bandura's (1977:3) as the formal definition of 'self-efficacy', described as beliefs in one's capacity to plan and carry out the actions necessary to produce specified attainments. More simply, self-efficacy reflects how much confidence a person has that they can successfully engage in actions needed to learn or complete a specific task (Greene 2018:35). According to Greene (2018:38), self-evaluation is the act of assessing one's own ability to achieve a specific objective (future judgement) inside a certain setting (context-specific). For instance, what is the amount of certainty regarding my ability to successfully complete a statistics course as part of my PhD degree? Self-efficacy beliefs can manifest as either optimistic or pessimistic and can either facilitate or impede self-improvement (Nabavi & Bijandi 2012:15). Individuals' engagement in activities is influenced by their perceived ability and past achievements (Nabavi & Bijandi 2012:16).

Beliefs of incompetence and unworthiness are messages received within the social context in which individuals learn or perform a task (Greene 2018:40). To be successful, and for this study, investigators need to know that they are good at what they do. It breeds motivation and success, and people will have more positive energy for their work. Bandura (1982:122) suggests that individuals' performance and motivation are influenced

by their perception of their own effectiveness. The sentiment expressed by Mahatma Gandhi in his statement is that if one possesses the belief in their ability to accomplish something, they will ultimately develop the necessary skills and capabilities, even if they first lack them. (Wilson 2013:1). Bandura (2001:2) elaborated that through agentic action, humans develop strategies for adjusting adaptability to extraordinarily varied geographic, climatic, and social contexts. They work out how to get around obstacles in the physical and environmental world, redesign, and build surroundings to their preferences. People increase their chances in the fitness survival game with these creative strategies.

“I can because I believe I can” is a statement of perceived self-efficacy; it is what people believe about their ability to use their motivation, cognitive resources and actions to control a situation (Ozer & Bandura 1990:472). Perceived self-efficacy does not imply a person’s actual abilities to perform a task; rather, it implies a person’s self-perception of believing that they can do the task within certain circumstances (Maraghi, Mortazavi-Tabatabaei, Ahmady & Hosseini 2018:1). Part of the methodology for the pilot study included a pre-test and post-test questionnaire about participants’ self-perceived level of competency in clinical trial conduct. The results between the pre-test and post-test questionnaires have the potential to show if there was any improvement in individuals’ level of self-perceived competency after attending the inclusive clinical trial research education programme.

Bandura (1997:72) described that a person’s beliefs bring forth feelings, thinking, motivation and behaviour through cognitive, motivational, affective and selection processes. A threatening situation will give rise to anxiety if the person’s perceived self-efficacy fails to exercise control (Ozer & Bandura 1990:473). In the worst-case scenario, a person could visualise frightening images (cognitive) because they dwell on their inability to control a stressful situation to such a degree that it could impair their level of functioning (Ozer & Bandura 1990:473). In the best-case scenario, people will choose a social environment they think they can handle. Because of the social influences within that environment, personal development can occur by cultivating interests and competencies (Ozer & Bandura 1990:473). The aim of the developed clinical research education programme for this pilot study aligns with Ozer’s view to create an educational environment where investigators can handle the required tasks, enabling them to grow from novice to expert.

According to Bandura (1994:71), the development of self-efficacy stems from four primary sources, namely mastery of experiences or personal achievements, vicarious or visual learning (modelling others), social or verbal persuasion, and physiological (mood) or biological conditions (sensations from their body). Personal experience is considered the most efficient of the four sources because it is built on skills an individual has already mastered (Ashrafi-Rizi, Soleimanzade, Zahra & Behjat 2015:2). Personal experience therefore broadens Bandura's formal definition of 'self-efficacy' in the sense that a person's belief in their capacity to successfully complete a task is shaped by how successfully the person has completed the task in the past. Mastery of experiences can improve self-efficacy, increase the establishment of the desired behaviour, and might include overcoming challenges and difficulties (Bandura 1977:2). However, the decision to use the skills one already has depends on one's ability and beliefs about likely outcomes. According to Hansen (2012:12), self-perceptions about competency and ability are at the core of the interaction between learning and success.

Bandura also describes how the four primary sources mentioned above can be used to improve self-efficacy. These strategies are particularly crucial for instructing or educating students (Greene 2018:44), such as the students or participants included in this study. The first method includes the provision of successful experiences or challenging situations (with obstacles) where sustained effort is required for success. Students need ample opportunities to practice, enabling them to master a task or situation. During this process, students need to know they are instrumental in the success or mastery of the task (they did it!). At the same time, they need to be challenged to move from moderate to more complicated tasks to give them a sense of accomplishment that can strengthen their self-efficacy. Study participants (in this study) were challenged to develop a protocol in the pilot, and different scenarios were added to stretch their knowledge and skills.

The second method entails observing and modelling others. When students look at someone similar to them who had great success, they might be more motivated, and with some built-up self-efficacy, they might attempt the same task (Greene 2018:41). Observing others recovering from a setback might give them the courage to draw on support for self-efficacy. Having attained knowledge in conducting a clinical trial, participants from the pilot study could go back to their clinical trial work environment to observe and follow what experienced clinical trial investigators are doing.

The third method is to receive support and encouragement from others. Educators should develop and implement assessment tools like the CICRP to assess individual students' knowledge and self-efficacy. This can also be done by a self-assessment grading tool where students score their knowledge and self-efficacy, similar to the tool used in this study. At the same time, such an exercise could boost students' autonomy, giving them a sense of control over their learning experience. Along with the educator's feedback, a sense of control or autonomy will support self-efficacy (Greene 2018:45). Assessments will help students focus more on their progress and less on how they compare to others (Greene 2018:46).

The fourth method relates to relying on their bodies' observation to assess tension in stressful situations, followed by either altering the interpretation of the physical status or reducing the stress levels (Hansen 2012:12). Educators' calming persona and voice when students' anxiety threatens to immobilise them is critical. Convincing students to relax will lower their heart rate and breathing and move them to positive self-efficacy (Greene 2018:43). In a 1993 study by Bandura, he found that students and teachers experience individual feelings of self-efficacy and a teacher's sense of efficacy will determine the type of learning environment they will provide, while the student's characteristics will impact the teacher's beliefs (Hansen 2012:14).

Several researchers have explored Bandura's model. Studies conducted in Italy, Hungary and Poland on children's self-efficacy showed self-efficacy is multifaceted and generalisable as a model (Pastorelli, Caprara, Barbaranelli, Rola, Rozsa & Bandura 2001). Since then, meta-analyses combining numerous studies on domain-specific self-efficacy related to human adaptation have followed (Holden 1992:53; Holden, Moncher, Schinke & Barker 1990:1044; Multon, Brown & Lent 1991:30; Stajkovic & Luthans 1998 in Bandura 2001:14250). More studies related to self-efficacy, stretching over several fields such as medical education, health, homelessness, and the use of the internet, are found in the literature after the meta-analysis mentioned by Bandura in 2001 (Babenko & Oswald 2019; Yumashita & Okamura 2011; Maccio & Schuler 2012; Tsai 2019; Anders 2018:13).

Self-efficacy has also influenced the research field. Research self-efficacy refers to a person's belief that they can complete and carry out the steps and tasks required by the research process (Bishop & Bieschke 1998:182). Therefore, a person's interest in

research will be influenced by their research self-efficacy (Bieschke 2006:77). Several studies have examined the construct of research self-efficacy. Phillips and Russell (1994:628) found a positive relationship between research self-efficacy, the research environment and research productivity when studying these relationships among counselling psychology doctoral students.

The first study of research self-efficacy within the clinical research domain was conducted by Mulliken et al. (2007:376). As described in section 2.3.3, Mulliken and colleagues (2007:376) initially developed a 92-item CRAI and later modified it to 88 items. The CRAI is a reliable tool for assessing eight different areas of research self-efficacy in academic physicians. It provides valuable information about the connection between research self-efficacy and career advancement (Mulliken et al. 2007:376). Unrau and Beck (2004:167) examined the perceived deficiency in the focus on research training for students studying social work and speech-language pathology. The researchers assessed the self-efficacy of students who were doing both research and practice courses, as well as those who were only taking practice courses. The results indicated that the majority of students had experienced an increase in confidence. However, the students who were registered in research and practice courses achieved almost twice the ratings on the research self-efficacy scale (Unrau & Beck 2004:167). In Geisler's (1995) study, the correlation between research self-efficacy and the progress of counselling psychology students' dissertations was examined. The findings revealed a favourable association between research self-efficacy and dissertation progress. That study did not show that the research environment had any significant effect on the dissertation progress, but it did show that scientific interest had a positive influence (Geisler 1995).

The research environment plays a crucial role in influencing students' interest in research. Gelso (1979) and colleagues (1996) identified ten elements that can positively influence students' interest in research: faculty examples of appropriate behavior, strengthened student research, early involvement, disentangling of statistics and research, encouraging self-reflection for research ideas, teaching that experiments have flaws and are limited, emphasizing various investigative styles, merging science and clinical practice, and training focusing on how research is done in agencies. Literature thus supports the notion that there is a relationship between a student’s perception of the training environment and their interest in research opportunities (Bard, Bieschke, Herbert

& Eberz 2000:8; Bishop & Bieschke 1998:182; Kahn & Miller 2000:103; Phillips & Russell 1994:628).

A survey by Kahn (2001:344) determined that an effective research training environment could inspire a student to engage fully in research and act as an instigator for self-efficacy toward research. Mentoring, as an element of the research environment, was also found by Kahn (2001:344) and other authors (Jones & Straker 2006:165; Gelso 1979:7; Betz 2000:205; Kahn & Scott 1997:38; Royalty, Gelso, Mallinckrodt & Garrett 1986:9; Love, Bhaner, Jones & Nilsson 2007:319) as an essential contributor to the enhancement of research productivity. Lynch, Zhang and Korr (2009:193) investigated the impact of research training, institutional support and self-efficacy on social workers' research activities and found self-efficacy to be an essential factor. Contrary to previous findings (Fraser & Jensen 1993; Kirk 1999; Lindsey, Brass & Thomas 1995; Proctor 1990 in Lynch et al. 2009:194), research training did not significantly contribute to research activities when institutional support was controlled. According to Lynch et al. (2009:204), possible explanations could be that social workers' self-confidence in research is demonstrated when they are in the actual research process, or they have already transformed their research training into research self-efficacy.

Bieschke (2006:77) mentioned that a person's interest in research would be influenced by their research self-efficacy. Lent, Brown and Hackett (1994:79) also claim that besides research self-efficacy, personal efforts (including investigative interest, social interest, gender, and age), environmental involvement (including research training environment and year of study), and research outcomes influence a person's interest in research. Two stand-out studies from the literature that examined the interest in research construct are those by Royalty et al. (1986:9) and Shivy, Worthington, Birtel-Wallis and Hogan (2003:297). Royalty et al. (1986:9) surveyed doctoral students' research attitudes, interest in research, and research training environment, using a four-item researcher-developed scale and the Research Training Environment Scale (RTES). Their results showed that facility modelling and highly impactful programmes positively affected the participants' research attitudes. Shivy and colleagues' (2003:297) participants were also doctoral students. They used the Research Training Environment Revised Scale (RTES-R) and the Self-Efficacy in Research Measure to determine participants' perceptions of the research environment and their level of self-efficacy. Ranking the highest

interpersonal aspects of the Research Training Environment (RTE) indicated the research environment as the most important aspect influencing research interest.

2.4.2 Self-efficacy, agency and competencies

Self-efficacy, introduced by Bandura, has been studied and integrated in various theories and models of competence as mentioned in section 2.4.1 (Hornung, Thomas, Jones, Calvin-Naylor, Kerr, Sonstein, Hinkley & Ellengrod 2018:51; Anders 2018:14; Robinson et al. 2013:2). It enhances competence and primarily pertains to the cognitive aspect of competence or perceived competence. Recent research has focused on 'trait-like' aspects of self-efficacy, which refer to an individual's perception of their overall capability to successfully perform in various achievement scenarios (Rama & Sarada 2017:33). Ruyle et al. (2018:270) advocate for competency-based personalized education systems, drawing on the foundational work of Bloom, Bramante and Colby, Guskey, Hattie, and Bandura, as the optimal path for educational progress. Bandura's research on self-efficacy has a significant impact on schooling and posits that confidence in one's ability to exert control over actions and circumstances is a fundamental aspect of personal agency (Bandura 2001:14250).

The concept of self-efficacy has been researched over subsequent decades and has contributed to a shift from ‘one size fits all’ to a more personalised experience for students by focusing on individual needs when instructing students (Martin 2011; Martin 2012; Martin & Liem 2011; Pintrich 2003; Schenck 2011; Schenk 2012 in Ruyle et al. 2018:270). The importance of self-efficacy to vocational competence has been widely studied (Komarudin, Sutadji & Suhartadi 2019:166; Rama & Sarada 2017:33; Saks 1995:211; Martocchio & Baldwin 1997:1; Stajkovic & Luthans 1998:240). Researchers have concluded that self-efficacy helps students to excel, contributes to work readiness and the choice of employment or a career, instils interest in work, determines work attitudes, and contributes to training efficiency and job performance and effectiveness. In 2015, the concept of self-efficacy was redefined by Ferguson (Gomez & Ferguson 2020:272 in Ruyle et al. 2018:271) as ‘learner agency’, meaning the ability and tendency to take deliberate initiative – the antithesis of helplessness. According to Ferguson (in Ruyle et al. 2018:271), developing learners’ agency could equal the skills we measure with standardised testing as an outcome of schooling.

In Bandura's view (2001:1), an agent (person) will act intentionally to make something happen through their actions. He distinguishes between four core characteristics of human agency: intentionality, forethought, self-reflectiveness, and self-reactiveness. Intentionality refers to a proactive commitment to bringing about a future course of action; the intention is grounded in self-motivators that will ensure the move will probably happen. Forethought forms part of a person's plans for the future by setting goals and selecting specific actions that will most likely produce desired outcomes. These goals could be extended or short-term. The person will also try to predict any future problems, rewards and costs related to their selection of actions. Self-reflectiveness will include metacognitive capabilities to evaluate one's motives and values while reflecting on one's life. It is a cognitive process in which individuals analyse and evaluate their own ideas, emotions, behaviours, and motivations, with the ability to modify their intentional perspective. Self-reactiveness is the process of self-regulating motivation, affect and action by self-monitoring one's patterns of behaviour, measuring oneself against personally set goals and standards and taking self-directed corrective actions. This process integrates thought and action.

In light of the evidence that self-efficacy plays a vital role in the drive for competence, it makes sense to build investigators' self-efficacy in skills necessary to conduct clinical research. Giving novice investigators a feeling of "I can do it" can build their confidence (self-efficacy) to become good and even excellent in completing specific tasks. All investigators deserve the opportunity to receive the necessary training to equip them for the increasing challenges of clinical research in a constantly changing environment.

More training opportunities, such as this pilot study, might improve the chance that more new graduates will pursue clinical research as a career path (Sebastian, Robinson, Dumeny, Dyson, Fantone, McCormack & May 2019:1). In line with Ferguson's learner agency concept and Bandura's characteristics of human agency, new graduates or novice investigators might purposefully choose a clinical research training programme to obtain the necessary skills and knowledge for clinical research. Despite challenges, they will succeed through intentionality, forethought, self-reflectiveness and self-reactiveness. As mentioned in section 2.4.1, competence, autonomy, and relatedness must be satisfied to ensure ongoing psychological well-being. Clinical research professionals have a personal need to master challenging tasks thrown at them during their day-to-day duties. It is thus important to them to satisfy the need for competence.

In support of building self-efficacy and giving the 'how-to' to investigators, I developed an intervention in the form of an inclusive clinical trial research education programme, incorporating the eight competency domains of the JTF framework.

2.5 THE MRC FRAMEWORK

To assist me in developing the inclusive clinical trial research education programme, I adopted the MRC's framework for complex interventions. The MRC framework is often used in health and social care services; for example, when a new surgical procedure is needed or redesigning a healthcare programme (Skivington et al. 2021:1; Yan, Chan, Chow, Xiao & Li 2023:1).

The MRC developed the framework in 2000 to assist researchers in developing, evaluating and implementing complex experimental and non-experimental interventions inside and outside health services (Craig, Dieppe, Macintyre, Michie, Nazareth & Petticrew 2008:4; Skivington et al. 2021:1). The framework was revised in 2006 and 2021. What makes an intervention complex? Skivington et al. (2021:1) propose that the complexity of an intervention can be determined by various factors, such as the number of elements involved, the range of behaviours targeted, the expertise and skills required by those involved in delivering and receiving the intervention, the number of groups, settings, or levels targeted, and the potential for flexibility in the intervention or its components. Looking at this thesis's different projects (with two or more segments under each project), the developer and presenter of the inclusive clinical trial research education programme's expertise, participants' entry educational level, the eight competency domains, and the factor of self-efficacy, then this study is regarded by the MRC as a complex intervention (MRC 2019:3).

The MRC framework should not only be used as a determination of the effectiveness of the intervention, but it should also include the intervention's acceptability, implementability, cost-effectiveness, transferability and scalability in real-world conditions (Skivington 2021:2). Hence, comprehensive complex intervention research should encompass the creation, identification, and assessment of interventions that target the entire system, as well as the evaluation of how these interventions have resulted in systemic transformation. Guidance from the MRC framework is provided through different

phases that harness quantitative and qualitative investigation methodologies to evaluate the complex intervention. Nevertheless, as stated by Skivington et al. (2021:1), these phases may not always occur in a certain order, as they can be tailored to suit the unique requirements of the research. The benefit of following these phases is that it sets out objectives in each step that needs to be reached before moving to the next phase (Skivington et al. 2021:1). As an international and systematic framework, the MRC framework's application in this study can improve the effectiveness of the complex intervention, namely the inclusive clinical trial research education programme (Yan et al. 2023:2).

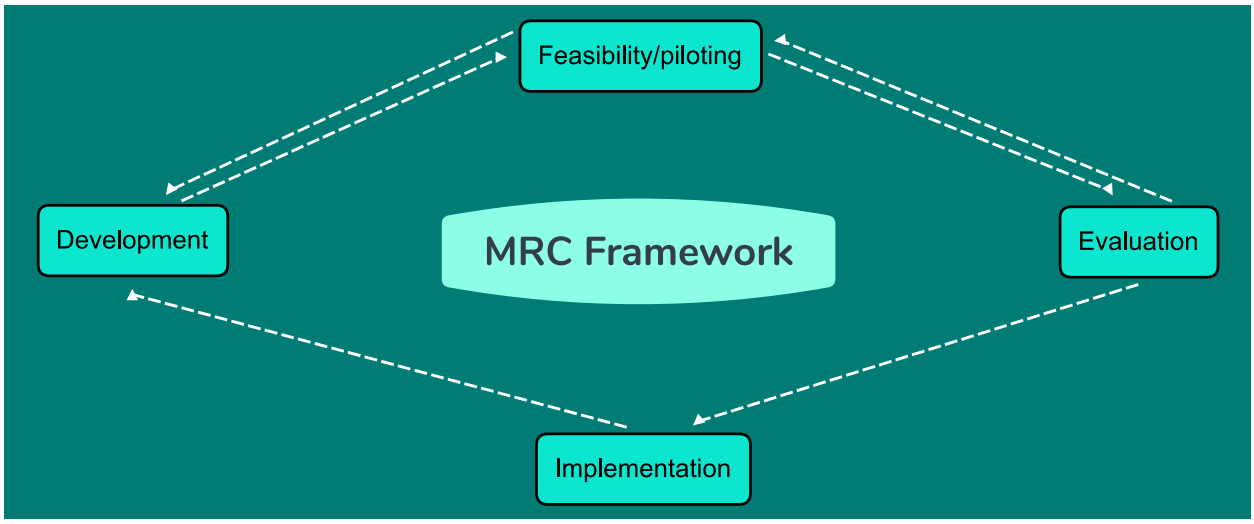


Figure 2.1: Key elements of the MRC framework's development and evaluation process

Source: Craig et al. (2008:8)

2.6 SUMMARY

Self-efficacy and clinical trial research investigators' career paths can significantly be improved through appropriate and needed education and training programmes. The need for well-trained, efficient clinical trial research staff was expressed throughout the literature. According to the reviewed literature, several factors affect clinical trial research investigators' education and training. These include the lack of clear training guidelines from authorities regulating clinical research, the lack of global expected standards in clinical research, and the lack of education and training courses besides GCP.

An evolution started in 2013 to improve the situation by harmonising clinical trial professionals' standards, competencies and curriculums. Competency-based education and training were identified as the way to train clinical trial and research professionals. The concept of self-efficacy was thus adopted to form the basis for future training programmes. Training and education for clinical trial research professionals were fast-tracked during the COVID-19 pandemic. Several courses and programmes were developed and became available online to assist clinical trial staff in coping with the new way of conducting clinical trial research. However, these were emergency measures, and it is still to be seen if clinical trial research will maintain the new approach. Basic principles of implementation of clinical trial research remain intact, and therefore, clinical trial research professionals need to be trained to become competent in the eight competency domains identified by the JTF.

The extensive literature review revealed a significant need for investigators' clinical trial research education in the health sciences to equip them with essential knowledge, skills and self-efficacy. The right strategy and curriculum can promote this population's self-efficacy and competence and fill the gap of well-trained clinical trial research professionals. The MRC framework could be used to develop, evaluate, pilot, and implement a study as a strategy for implementing complex interventions. Creating an environment that fosters clinical trial research knowledge and skills may address concerns of investigator loss, setting standards and promoting needed treatments for public health. The literature review demonstrated that research education programmes could increase research knowledge, productivity and student satisfaction. The reported study aspired to be the first in South Africa to use the JTF framework, which is hands-on and practical, setting out a standard curriculum for training new investigators in health sciences.

The study's overall research approach and methodology are discussed in Chapter 3.

CHAPTER 3
RESEARCH DESIGN AND METHODS

3.1 INTRODUCTION

Chapter 3 discusses the overall research design and methods employed in this study. The outline of Chapter 3, and how it fits into the study, is indicated in Table 3.1.

Table 3.1: Chapter 3: Research progress

Chapter	Content
1	Orientation to the study
2	Literature review (1) Clinical trial education (2) Competency-based education (3) Self-efficacy (4) MRC framework
3	Research design and methods
4	Project 1 Research design, data collection, data analysis and results (First segment: situation analysis – qualitative)
5	Project 1 Development and validation of the clinical trial research education programme (Second and third segments)
6	Project 2 Research design, data collection and implementation of the intervention
7	Project 3 Research design, data collection, results, and evaluation of intervention
8	Summary of integration of findings, conclusion, recommendation, contribution and limitations of the study

3.2 RESEARCH PARADIGM

When we recognise our beliefs, we can use logic to form arguments, with practices that will follow. As soon as these practices take root, we no longer think about them, but take them for granted. However, in academic research, we must think about the origin of our thinking because there might be alternative answers to our questions. The same question asked by two researchers may be approached differently by each researcher. Depending on their beliefs of ontology and epistemology, each will set up their study according to

their view of the evidence, analysis, and the purpose of their research (Potter 1996:35). Researchers will also align their paradigm with the most popular epistemological views in a given field (Brown & Dueñas 2020:545; Sauders 2019:143).

I believe that we live in an ever-changing world, and reality is created by our acts and is based on human experience that drives problem-solving (Allemang, Sitter & Dimitropoulos 2022:39). I acknowledge that my belief system, rooted in my social, educational, and cultural upbringing, influenced the design of this research study. I believe that I am biased as a researcher and that my assumptions led me to undertake this study (Brown & Dueñas 2020:545; Saunders 2019:129). The assumptions underlying this study are based on the following factors: (1) Clinical research investigators who enter the field lack sufficient preparation and require enhanced knowledge of clinical trial research operations; (2) Investigators' actual knowledge of clinical trial research may differ from their perceived competency in this area; (3) Existing medical/health education curriculums lack the necessary components to adequately train students in conducting clinical trials, as they do not cover the essential knowledge and skills required for clinical trial research. (4) Past job experiences do not adequately prepare investigators for conducting clinical trials. (5) Implementing a well-structured clinical trial research education curriculum will enhance investigators' understanding and self-assessed proficiency in clinical trial research subjects.

Research is a journey researchers and scientists undertake to gain new knowledge. It is undertaken systematically, it is well-planned, and it takes time to gather data and analyse and synthesise various phenomena before any meaningful knowledge is added to existing literature (Kumar 2019:2; Leedy & Ormrod 2019:2). Researchers might start by asking what is it that we value? (axiology), what is available to know? (ontology), what can we do, and how can we know about it? (epistemology), what can we do to attain that knowledge? (methodology), are there procedures we can use to acquire it? (methods) and lastly, what kind of data can we collect? (sources) (Grix 2002:180; Brown & Dueñas 2020:546; Saunders 2019:133). A researcher’s quest for axiology, ontology, epistemology, methodology and methods forms roadblocks during the research journey and is viewed through the lens of a philosophical paradigm (DeCarlo 2018:144).

The pragmatic paradigm has elements of the positivist, interpretivist, and critical paradigms (Ragab & Arisha 2017:2). The pragmatist paradigm provided the study with

the necessary practical methods to *develop an inclusive clinical trial research education programme for investigators in the health sciences.* Since pragmatism offers an alternative epistemological paradigm between positivism and constructivism, it is viable to implement more than one philosophy within a single research project (Ragab & Arisha 2017:2). The philosophy promotes the application of both quantitative and qualitative methods, as each on their own is not the best way to address a research problem. Revisiting the definition of 'multiple-method research' using more than one method or more than one worldview, the pragmatist paradigm was the best approach for the current study (Tashakkori & Teddie 2010:3).

Pragmatism enabled my active engagement with study participants throughout the study. The study's primary objectives were to use information from stakeholders to develop the pilot clinical research programme and use feedback from stakeholders and participants to evaluate the outcome of the course. The lived experience of both stakeholders and participants was captured through quantitative and/or qualitative methods (Allemang et al. 2022:39). In other words, the real-world problem of investigator experience concerning clinical research education was investigated through pragmatism. Part of the active engagement included researcher involvement and subjectivity. My involvement was evident throughout the study and entailed stakeholder and participant interviews, developing and facilitating the clinical research programme, and drawing conclusions based on participants' responses (Saunders 2019:151).

In pragmatism, there is an inherent connection between experience and knowledge (Allemang et al. 2022:41). The emphasis is on action, the consequences of actions, and what it means. The participatory aspect of the clinical research programme, through Modular Object-Oriented Dynamic Learning Environment (Moodle) and in-class discussions, facilitated knowledge gain. Participants could implement new knowledge and practice skills in their jobs during the clinical research programme. Pragmatism also recognises the influence of the social, physical and phycological worlds and considers all cultures, genders, languages, institutions, and subjective thoughts. Stakeholders and participants in the current study were thus a diverse group with varied cultures, languages and genders, and they were from different institutions. They offered various experiences and knowledge to address the research questions (Allemang et al. 2022:41). Pragmatism worked here within the particular time, place, and local context of delivering the education programme.

Previous knowledge and experience do not guarantee or predict future outcomes of actions; therefore, investigators cannot rely on their previous job experience as doctors, nurses, pharmacists, or laboratory technicians. Our previous experiences are riddled with assumptions, coloured by our history, social and cultural context. An inquiry is thus required to determine what is needed to facilitate future behaviours and actions. The inquiry process employs a systematic approach that entails meticulous and contemplative decision-making prior to taking action. (Allemang et al. 2022:41).

3.3 THEORETICAL FRAMEWORK

This study was first guided by Bandura's Social Cognitive Theory, with specific reference to self-efficacy (people's beliefs about their competencies to produce results or successful outcomes) (Bandura 1977:1). According to Bandura (1994:160), a person's self-efficacy is shaped by the messages they receive within the social context in which they learn or perform a task. Anders (2018:15) explains that self-efficacy is connected to capabilities for self-direction and motivation. Experience and past mastery influence a task's self-efficacy (Greene 2018:40). Within this social context, how a person is treated according to age and gender could also influence their self-efficacy. When an experience reveals a lack of self-efficacy, this lack needs to be addressed, and, in most instances, this will happen through education (Greene 2018:40). Clinical research investigators frequently communicate emotions of inadequacy and worthlessness, including low self-efficacy. (Pelser 2018:43). Feelings of unpreparedness and uselessness were especially true during the COVID-19 pandemic when clinical research professionals had to make a massive shift in managing clinical trials (Shiely et al. 2021:1; Audisio, Lia, Robinson, Rahouma, Soletti, Cancelli, Auraria, Shadow, Tam, Vervoort, Farkouth, Bhatt, Frames & Gaudino 2022:8). Therefore, clinical research investigators' self-efficacy needs to be developed by applying knowledge and skills using authentic learning tasks and support structures that could be provided by a formal clinical trial education programme (Anders 2018:18).

Second, this study used the eight competency domains set out by the JFT to marry investigators' theoretical knowledge and daily core activities within clinical trials (Sonstein et al. 2014:3; Sonstein et al. 2018:1). The eight primary areas of expertise include (1) Scientific principles and experimental design; (2) Ethical considerations and ensuring

participant safety; (3) Development of medicines and adherence to regulations; (4) Efficient management of clinical trials; (5) Effective oversight of studies and research sites; (6) Skillful handling of data and utilisation of informatics; (7) Demonstrating leadership and professionalism; and (8) Excelling in communication and teamwork. (Sonstein et al. 2018:3). Curriculum development for clinical trial research educational programmes in South Africa must be rooted in competency frameworks to fill the current gap in investigators' formal training. Addressing the main competency domains through a clinical research education programme holds the possibility of increased self-efficacy. Clinical research investigators will feel not only competent but also become competent in successfully handling their daily core tasks.

Third, the development process included an intervention phase for implementing the clinical trial research education programme. The MRC created a framework to assist researchers in developing, evaluating and implementing experimental, non-experimental and complex interventions inside and outside the health service (Skivington et al. 2021:2). An intervention targeting health professionals, such as clinical research investigators in this study, is regarded by the MRC as a complex intervention (NIHR 2021:1). Guidance is provided in the form of different sequential phases of investigation to evaluate the complex intervention (Skivington et al. 2021:3). Figure 3.1 summarises the theoretical framework, while Figure 3.2 summarises key elements of the MRC framework's development and evaluation process.

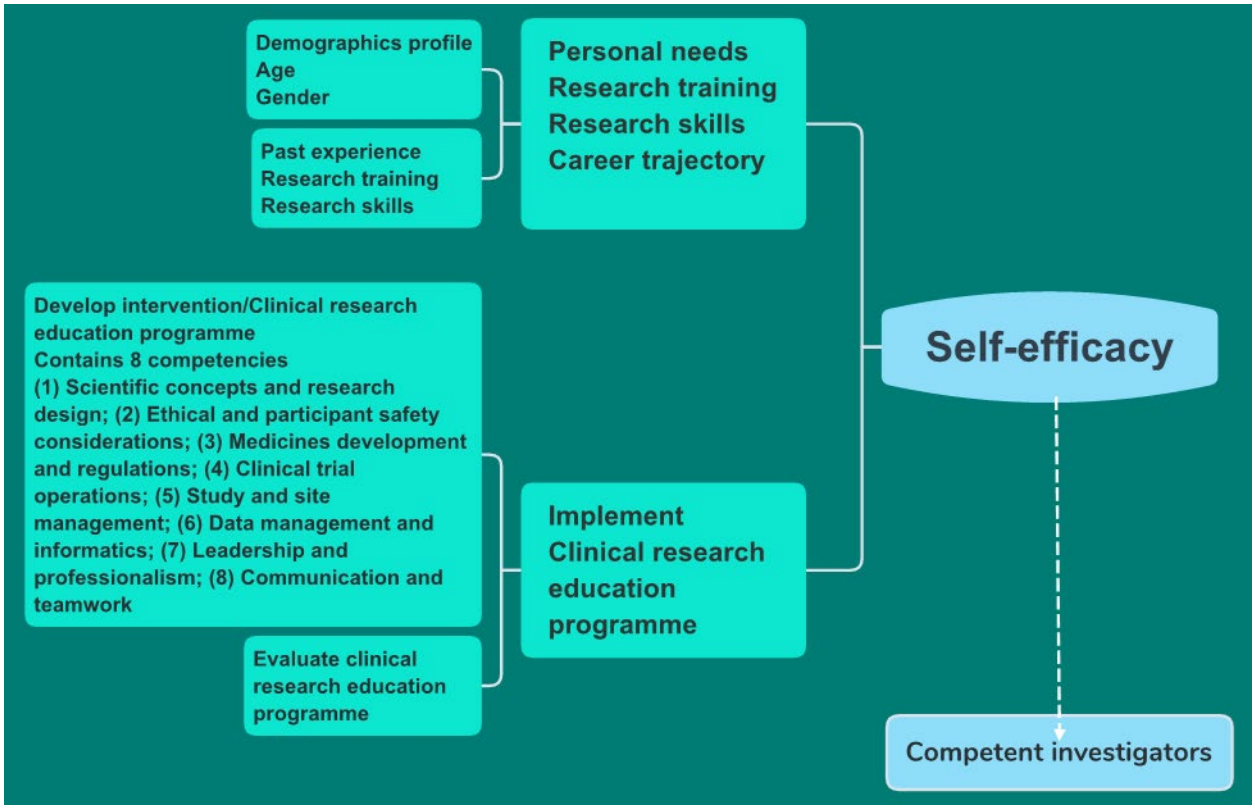


Figure 3.1: Summary of the theoretical framework

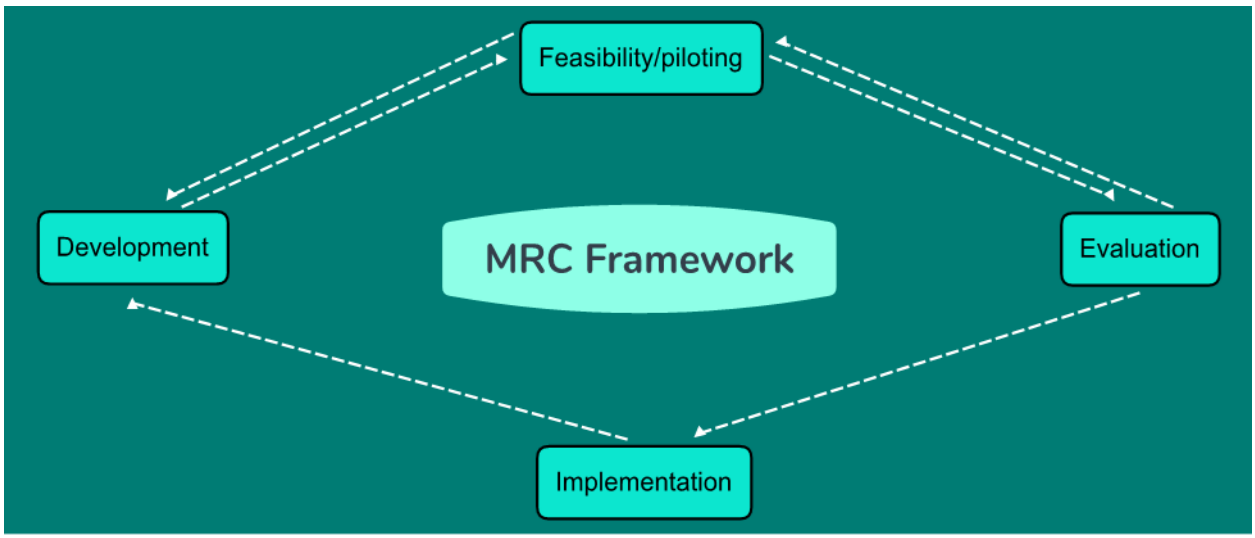


Figure 3.2: Key elements of the MRC framework's development and evaluation process

Source: Craig et al. (2008:8)

3.4 RESEARCH DESIGN

The study used a sequential exploratory qualitative-driven multiple-method design (Morse & Niehaus 2009:147) first to explore and describe stakeholders' perspectives of what a clinical trial research education programme should consist of to develop and validate the research programme; second, to implement the developed programme; and third, to evaluate the clinical trial research education programme. Considering the dynamic nature of an education programme's development, the MRC framework was adopted to guide the process.

Although a part of this study evaluated the education programme, the aim of the study was not programme evaluation but development. Therefore, it did not fall neatly within the 'process evaluation of complex interventions' described by the MRC. The MRC considers an intervention complex when it contains numerous interacting components. How you handle these interacting components will depend on the kind of evaluation you want to do. An example of a complex intervention will be a randomised clinical trial to test a drug's efficacy and safety. Alternative research designs for developing a clinical trial research education programme were sought, and mixed-method and multiple-method designs were identified.

Researching mixed-method designs illuminated several definitions of 'mixed-method research', varying in focus or orientation due to various schools of thought. A definition, inclusive of diverse viewpoints, was given by Schoonenboom and Johnson (2017:108). They described the core characteristics of mixed-method research as a combination of at least one qualitative and one quantitative element to understand and validate the topic under investigation more broadly and deeper. It is important to mention that data integration is a characteristic of mixed-method data analysis (Creswell & Creswell 2022:233).

Morse and Niehaus (2016:13) described a multiple-method research programme as a research design where the theoretical thrust of the programme drives a series of complete and related qualitative and/or quantitative research projects. Vivek and Nanthagopan (2021:203) summarised the multiple method is applied in many contexts, but is limited to one objective. A characteristic of the multiple-method design is that all projects are complete, as described by Morse and Niehaus (2016:13).

The complexity of developing a clinical trial research education programme meant it did not neatly fit into a mixed-method design. The alternative was a multiple-method design where a series of qualitative and/or quantitative interrelated projects are conducted over time to address one programmatic aim, namely the inclusive clinical trial research education programme.

3.4.1 MRC framework

With the MRC's guidance, several elements were applied to this study. The MRC framework formed the outline or road map of the research project, and the multiple-method design formed the path of the research project. It meant that this study adhered to the fundamental tenets of the MRC framework for creating and assessing complex interventions. It was used to identify causal constructions and contextual variables that might be related to outcome variations. Rather than the MRC's stated goal of establishing credibility and standards of execution (Moore, Audrey, Barker, Bond, Bonell, Hardeman, Moore, O'Cathain, Tinati & Baird 2015:3; Evans, Spiby & Morrell 2020:777), it acted as a guide for the steps involved in outcome evaluation.

I adapted and used the elements in the following way: Phase one, the development stage, included a thorough literature review to identify the relevant existing information (situational analysis) related to clinical trial professionals' clinical research education to identify intervention objectives. In phase one, I considered the intervention's desired outcome and included the study of underlying theories and possible frameworks for the education programme and interviews with stakeholders. During phase one, I also developed the education programme and the evaluation tools (pre-test and post-test questionnaires). Phase two of the study included piloting the pre-test and post-test questionnaires to refine the questions. An evaluation stage followed to determine if the developed education programme included feedback from the stakeholders and all the required competencies according to the JTF framework. The third, or implementation, phase focused on the implementation of the clinical trial education programme, and the fourth phase was the evaluation of the efficiency of the programme and the publication of results (Craig, Nuffield, Macintyre, Michie, Nazareth & Petticrew 2008:8; Skivington et al. 2021:1). Since this was a pilot study, the piloting stage in the sequence adapted from the MRC framework included only the piloting of the questionnaires.

As mentioned, this pilot study tested the methodology and procedures for implementing a final intervention trial (Bell, Whitehead & Julius 2018:153). Thus, a well-designed pilot study was essential to demonstrate the feasibility and efficacy of the clinical trial research education programme. The same rigorous methodology planned for the main study was followed for the pilot study. Figure 3.3 summarises the phases adapted from the original MRC framework.

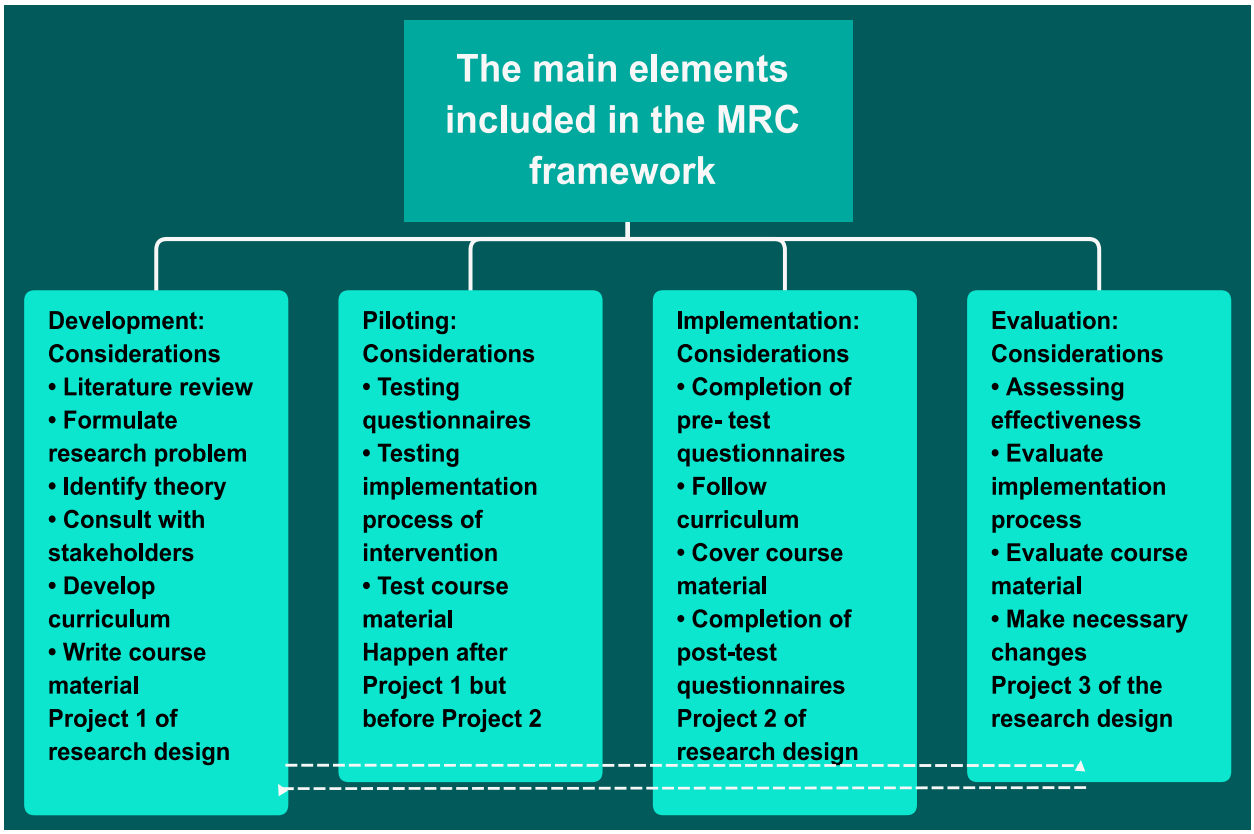


Figure 3.3: Phases adapted from the original MRC framework

Source: Craig et al. (2008:8)

3.4.2 Multiple-method research design

Anguera, Blanco-Villasenor, Losada, Sánchez-Algarra and Onwuegbuzie (2018:5) mentioned that multimethod studies preceded mixed-method studies and were referred to in 1959 by Campbell and Fisker (Anguera et al. 2018:5). Because researchers used different terminology, Kerlinger was the first author in 1973 to attempt to distinguish between multimethod and mixed-method research on the grounds of the methodology used in each (Anguera et al. 2018:5). Authors also have their preference when referring to multiple-method research. Terminology could include ‘multiple method’, ‘multimethod’

and ‘multi method’ (Anguera et al. 2018:8). I support Morse in using the term ‘multiple method’, since I used her guidance in designing a multiple-method research programme.

In a multiple-method research programme, one programmatic aim is reached by conducting a series of interrelated studies (Morse & Niehaus 2009:147). Each of these interrelated studies or projects is complete in itself with minimal overlap. However, each project validates and extends the previous, and therefore, the combined results could provide a more balanced and holistic understanding of the programmatic aim (Morse & Niehaus 2009:147; Morse & Chung 2003:8; Brewer & Hunter 2006:65). Each project could have its theoretical drive using a single method design or a mixed-method design (Morse & Niehaus 2009:149). Anguera et al. (2018:9) described a multimethod study is conducted when there is a shared overall research question, incorporating a sequence of complementary methodologies selected according to a given criterion, for example, internal control.

Morse’s description of the multiple-method design was the method of choice for developing a clinical trial research education programme, where one project dictated the direction and nature of the next project. While validating and extending the previous project, when pieced together, the results will give an understanding of the concept or overall aim of the programme (Morse & Chung 2003:5). Morse’s viewpoint is also supported by Brewer and Hunter (2006:66). The set of research studies chosen may include qualitative and/or quantitative and/or mixed-method studies (Morse & Niehaus 2016:148). It is important to note that each study can be written up and published separately because it is complete in itself.

Morse (2003:190) identifies three primary principles to be followed when designing a multiple-method programme, namely (1) a theoretical drive needs to be identified for the research project; (2) an overt awareness of the dominance of each project needs to be developed; and (3) methodological integrity needs to be respected.

According to Morse (2003:196), the multiple method is often used by researchers who want to either discover (inductive) or test (deductive) a research programme or clusters of research projects on the same topic. The programme might consist of two or more interrelated studies but will be driven by one major problem or question (Morse 2003:199). If the programme’s theoretical drive is either inductive or deductive, projects conducted

simultaneously or sequentially within the umbrella of the main project might be inductive (discover) or deductive (confirm) depending on the researcher's needs; however, the programme's major theoretical drive will not change.

The first project of the multiple-method programme, indicating the theoretical thrust, is written in CAPS; for example, it was QUAL for this study. The distinguishing factor is that each project is complete but still falls under the same theoretical thrust, and I therefore list subsequent projects in caps but in small font. For example, the second project was listed as QUAN for this study. It used a single method, while Project 3 was listed as QUAN → qual because it was a mixed-method project. The listing of Project 3 was put in square brackets, and the complete listing of this study was: QUAL→QUAN→[QUAN→qual] (Morse & Niehaus 2016:147).

A project's dominant component forms the study's backbone and is called the core component. In contrast, the method introduced to expand the core component is referred to as the supplemental component (Morse & Niehaus 2016:23). The core and the supplemental component need to be synchronised, and this is done in the narrative of the study, where an account is given of how each project contributed to the overall aim of the programme. According to Morse (2003:200; 2006:67), the triangulated results of each project will inform the research problem. Brewer and Hunter (2006:65) also agreed with Morse that the validity of the measurements is tested by triangulation. The triangulation process followed in this study showed each project's contribution to the overall research programme (DeCuir-Gunby & Schutz 2017:119).

3.4.3 Benefits and disadvantages of using multiple-method research

Choosing a mixed method or multiple-method design has the benefit of overcoming the limitations of a single method and gaining from the strengths of combined methods (Morse 2017:17; Brewer & Hunter 2006:4). A multiple-method design prompts a robust investigation with richer and more reliable research results (Yawson 2016:267). According to Yawson (2016:268), multiple-method research also has the benefit of being multidisciplinary, interdisciplinary and transdisciplinary. This study's educational and health sciences concepts thus addressed the research question and aim. The combination of the results from the multiple sources of data (gathered from the three projects) resulted in better insight into what a clinical trial research education programme

should contain (Yawson 2016:273). Multiple and mixed-method designs also enable researchers to publish multiple articles from a single study (which was my intention) or a multiple research programme (Creswell & Clark 2018:13; Morse & Niehaus 2016:147).

Greene, Caracelli and Graham (1989:255) describe a five-element typology to explain why researchers will mix qualitative and quantitative approaches. The five-element typology includes triangulation, complementarity, development, initiation, and expansion (Greene et al. 1989:255). Onwuegbuzie and Hitchcock (2019:220) similarly affirm that the typology applies to multiple and mixed-method research.

In Project 1 of the study, I used the development element, where the results from the individual interviews with stakeholders helped inform the clinical trial research education curriculum. In Project 3 I used triangulation, where I compared the findings from my interviews with participants and the questionnaires completed by stakeholders with the results of the post-test questionnaires. In the narrative (conclusion) of the study, the elements of complementarity and triangulation were used. The expansion element was also used for the overall research programme to expand the breadth and range of this study.

Project 3 used a mixed-method design within the multiple-method research programme. Therefore, the limitations of a single method overcame the strengths of the combined methods (Creswell & Creswell 2022:32). For example, in this study, the interviews from the qualitative segment of Project 3 gave voice to participants, sharing their personal experiences of the clinical trial research education programme. In contrast, the quantitative segment of Project 3 minimised personal bias and promoted the interpretation of the programme to determine its efficacy. Different tools were thus used to evaluate the outcome of the intervention (the clinical trial research education programme) to give a better conclusion of its efficacy. The practicality of the mixed-method design within the multiple-method programme allowed me to use the data from the pre-test and post-test quantitative questionnaires to answer research objectives. I also used the qualitative approach (part of Project 3) to validate the clinical trial research education programme. Using these different tools increased my skillsets to become proficient in using multiple methods of research (Creswell & Creswell 2022:23).

On the opposing side, using more than one study to answer a research question or fulfil the research aim, for example, two or more complete methods, took more time, required more resources, and required more skills (Morse & Niehaus 2016:13; Schoonenboom & Johnson 2017:110). Although these barriers applied to this study, I preferred the chosen approach because it allowed me to understand and assess the content and efficacy of the clinical trial research education programme. It also allowed me to master different skills. For example, the development of the pre-test and post-test questionnaires, the use of computer and digital technology to conduct online interviews, and the development of blended training to present the programme.

3.5 STRUCTURE OF THE MULTIPLE-METHOD RESEARCH EDUCATION PROGRAMME

This multiple-method research programme was divided into three projects.

Project 1

Project 1 had a qualitative segment for the situational analysis, followed by a development segment and another qualitative segment for programme validation.

A. The first qualitative segment entailed once-off (cross-sectional) interviews with stakeholders to get their perspectives on opportunities and challenges in supporting investigators. Furthermore, stakeholders were asked for their suggestions for what a clinical trial education programme should consist of.

B. The second segment was the development of a clinical trial research education programme for investigators. I considered the feedback I received from interviews with stakeholders. First, the competency framework of Sonstein et al. (2018:1) was used as a structural framework for developing the curriculum and pre-test-post-test questionnaires for the clinical trial education programme. Second, Bloom's Taxonomy was incorporated to steer the education programme's implementation. Learning objectives were formulated in *behavioural* terms to enable participants to *do* as a result of the directives. Furthermore, these learning objectives required a higher level of cognitive skills, expanding the variety of tasks and contexts to be mastered by investigators (Adams 2015:153; Hornung, Jones, Calvin-Naylor, Kerr, Sonstein, Hinkley & Ellingrod 2018:48; Calvin-Naylor, Jones, Wardak, Blackwell,

Davis, Divecha, Ellerbeck, Kieburtz, Koziel, Luzuriaga, Radovich, Rubinstein, Selker, Tenaerts, Unsworth, Wilson, Wright, Barohn & Shanley 2017:19).

C. The third segment (qualitative) was the stakeholders' validation of the clinical trial research education programme before implementation to establish if the proposed programme had fulfilled its purpose. A validation tool (questionnaire) was completed by the same ten stakeholders initially interviewed after reviewing the curriculum.

Project 2

Project 2 focused on implementing the clinical trial research education programme and consisted of the following:

A. The quantitative segment in which (i) basic demographic characteristics were collected from investigators, (ii) investigators' self-perceived level of competency in clinical trials was measured, and (iii) baseline levels of investigators' research knowledge were measured.

B. The implementation of the education programme.

Project 3

Project 3 was an evaluation of the programme and consisted of a quantitative and a qualitative segment.

A. The quantitative segment (i) measured investigators' self-perceived level of competency in clinical trials following the educational programme, and (ii) investigators' levels of clinical trial knowledge. As mentioned earlier, the same group of investigators who participated in Project 1 was asked to participate in Project 3.

B. An outcome evaluation was done in the qualitative segment of the project. Two groups took part in evaluating the education programme: (i) five participants who completed the clinical trial education programme, and (ii) five supervisors of participants who attended the education programme. The programme was assessed for effectiveness and outcome.

3.5.1 Data collection

Data collection methods are the techniques researchers choose to collect data for analysis in their study (Kumar 2019:170).

3.5.1.1 Data collection methods

The data collection methods I chose were linked to the research question, the philosophical underpinning, and the research approach I had decided on (Kumar 2019:170). A detailed description of the data collection process is offered in each chapter as I report on the project.

Project 1: Interviews were conducted with stakeholders to collect qualitative data on stakeholders' perspectives of the opportunities and challenges in supporting investigators (Seidman 2019:85). Furthermore, stakeholders were asked for suggestions for what a clinical trial education programme should consist of. Data were collected from April 2020 to June 2021.

The stakeholders' validation of the clinical trial research education programme occurred before implementation to establish if the proposed programme had fulfilled its purpose. Validation was done through a validation tool (questionnaire) completed by the same ten stakeholders initially interviewed after reviewing the curriculum from 2 May to 13 June 2022.

Project 2: Quantitative data collection for Project 2 included basic demographic information such as participants' age, length of previous research exposure, gender, and future career plans. After completing the demographic questionnaire, participants were asked about their self-perceived knowledge and competency in clinical trials (self-assessment). Then their knowledge of the eight competency domains of the clinical trial process and life cycle was determined, both through questionnaires (pre-test) (Polit & Beck 2022:266). Data were collected from 1 to 17 August 2022.

Project 3: Quantitative data were collected for Project 3 using the same questionnaires used to determine participants' self-perceived level of knowledge and competencies and their knowledge of the eight competency domains of the clinical trial process and life cycle (post-test). Data collection was completed between 1 and 15 December 2022.

Outcome evaluation (Samuels et al. 2019:3), as part of the qualitative segment of my study, involved interviews with stakeholders reviewing the clinical trial programme before

and after implementation. Interviews were scheduled from 1 December 2022 to 30 January 2023 (Mertens & Wilson 2018:219). For the quantitative segment, an impact assessment and outcome evaluation were done through the pre-test-post-test questionnaires.

3.5.1.2 Data collection instruments

There were seven questionnaires and two interview instrument guides with open-ended questions for the study.

The full methodology is discussed with the report on each project in Chapters 4 and 7.

3.6 DATA ANALYSIS

Data are analysed to give meaning to raw data by extracting and organising the collected data (Creswell & Creswell 2020:215).

3.6.1 Data analysis for the qualitative segment of the research

The qualitative segment of the first and third projects: I followed Saldaña's (2021:68) cyclical analytic coding process. The themes identified during the coding process were incorporated into the development of the clinical trial research education programme. Analytical memos and reflective notes formed part of the data analysis process (Saldaña 2021:47).

3.6.2 Data analysis for quantitative statistical procedures

A paired-sample t-test was employed to analyse and compare the continuous score data from both the pre-test and post-test evaluations (Fowler, Jarvis & Chevannes 2021:145; Bowers 2019:243). The alpha level, denoted as 0.05, was chosen as the significance threshold, along with a confidence range of 95%. By utilising a two-sided p-value of 0.05, I was able to either reject or accept the null hypothesis, which states that there was no change in assessment scores after the implementation and delivery of a clinical research education course for investigators, independent of the direction of the change. (Bowers 2019:243; Altman1999:167).

All the statistical analyses involving the paired-sample t-test were conducted using SAS Enterprise 7.15 (SAS Institute Inc, Cary, NC, USA), assuming a 5% significance level. Categorical variables such as age, gender, role in clinical trials, years of experience, and race were presented in frequencies and percentages for the demographic assessment. Details on the quantitative and qualitative data analysis strategies are fully described in Chapters 4 and 7.

3.7 MEASURES TO ENSURE TRUSTWORTHINESS, VALIDITY AND RELIABILITY

Trustworthiness is the confirmation of the value and authenticity of the research findings; it is the extent to which the findings are true to the objectives of the study (Polit & Beck 2022:559).

3.7.1 Measures to ensure the trustworthiness of the qualitative segment of the study

The strategies that were employed to establish the study's trustworthiness, as suggested by Lincoln and Guba (1985 in Polit & Beck 2022:559; Amin, Ezzat, Norgaard, Cavaco, Witry, Hillman, Cernasev & Desselle 2020:1472), included credibility, dependability, confirmability, transferability, and authenticity.

3.7.1.1 Credibility

Credibility, akin to internal validity in quantitative research, refers to the assertion of having trust in the accuracy and interpretations of the data (Polit & Beck 2022:559). In order to improve the quality of the data, I actively engaged in extensive face-to-face interviews with participants, where I attentively listened and focused. After each interview, I spent time reflecting and writing reflective notes and analytic memos. Therefore, I bracketed these reflective notes (Polit & Beck 2022:522). After the interviews, I wrote field notes to inspect my expectations and values to remind me of my role in the inquest. Reflecting and field notes were also used as triangulation and backup measurements (Leedy & Ormrod 2019:256). I checked in with my supervisor throughout the study and as part of my internal checks. Furthermore, I analysed my findings alongside related

debated work from the literature review, ensuring that this study had created trustworthy data (Polit & Beck 2022:557).

Confirmation was attained through triangulation of the credibility of collected data, research analysis and interpretation. Triangulation refers to exploring an event from two or more viewpoints or methodological approaches to know and understand it (Flick, mentioned in Santos, Ribeiro, de Queiroga, de Silva & Ferreira 2020:657). Similarly, Saunders (2019:218) views triangulation as using multiple data sources and data collection methods to confirm the credibility of collected data, research analyses and interpretations. In other words, triangulation rules out the possibility that a study's results depend on the characteristics of a single measure or measurement method (Chian & Green 2018:2).

The qualitative segment of Project 1 (interviews with stakeholders) was used to assist in developing the clinical trial research education programme. The developed programme was implemented as part of Project 2, characterised by a deductive approach. In the third project, there was a merging of quantitative and qualitative results (results of questionnaires with themes of interviews with participants and stakeholder questionnaires). Survey findings were used to expand the interview findings in Project 3. The findings from interviews were also used to support the findings from the pre-post-tests. Therefore, the results from the thematic analysis of Project 1's interviews were discussed, followed by an explanation of how it was incorporated into the programme's development. Then, the results from Project 3's interviews were discussed according to the analysed themes, and these results were merged with the results from the questionnaires (quantitative core component). I used the narrative approach in this study's conclusion, limitation, and recommendation section. In the narrative, I discussed each project's contribution to inform the research programmatic question.

3.7.1.2 Dependability

According to Mertens and Wilson (2018:344), dependability (similar to reliability in quantitative research) is concerned with the process of inquiry or inquest. It determines if the research process was followed logically and traceably, and if the researcher or inquirer documented it. In response to Mertens and Wilsons' (2018:344) claims related to dependability, I audited my transcriptions to verify the correctness and association

between the research question and the data (DeCarlo 2018:4670). In addition, I followed a logical data analysis strategy using Saldaña's cyclical analytic process (Saldaña 2021:68).

I believe I am the best equipped to get behind the meaning of the data and, at the same time, prevent diverse interpretations and understandings of the data (Keene 2021:1); I thus preferred not to use an external researcher to do an inquiry audit. Instead, to improve dependability, I treated participants according to ethical principles. Furthermore, I made use of the following: I provided a complete rationalisation for the research, and any reader can assess the quality of my reasoning independently; I explained my preference for making use of a qualitative inquiry; I made an effort to execute the study within a typical clinical research environment; and the methodology I chose was well described and followed throughout the research (Forero, Nahidi, De Costa, Mohsin, Fitzgerald, Gibson, McCarthy & Aboagye-Sarfo 2018:3).

3.7.1.3 Confirmability

Confirmability (similar to objectivity in quantitative research) means that there is confirmation that the data and findings (interpretations) of the inquiry are accurate; it is not attributed to the researcher's imagination (DeCarlo 2018:4670). My supervisor reviewed my interpretations and research to assist in evaluating my neutral position. My supervisor has qualifications in advanced research methodology and is an expert in qualitative research. In the end, all records mentioned formed part of the chain of evidence. Confidentiality measures were also applied to all records and will be available if necessary.

3.7.1.4 Transferability

Transferability (similar to external validity in quantitative research), often referred to as generalisability, opens up the possibility of transferring findings/results and interpretations/explanations on a case-by-case basis to other backgrounds or collections (Polit & Beck 2022:560; Saunders 2019:217). To accomplish the transferability of my findings, I provided a complete clarification of the research question followed by a dense description of the design, results and explanations of the research. This enables any reader to draw conclusions about this study's generalisability or transferability (Polit &

Beck 2022:560; Saunders 2019:217; Mertens & Wilson 2018:270). I believe my chosen sampling strategy – a purposive, non-random sampling strategy – provided the answers to my research questions. These answers allowed me to apply the conclusions from each project in a final main study (Creswell & Creswell 2022:224).

3.7.1.5 Authenticity

Authenticity per se is not regarded as a parallel criterion but as a criterion intended for the interpretive research type (Saunders 2019:217). By representing all views in the research, authenticity promotes impartiality and believability (Polit & Beck 2022:560). I used open-ended questions to empower participants, allowing them to communicate and spontaneously share what positive impact the clinical trial research education programme had on them. The final closure of my research entailed sharing my findings and recommendations with participants and their respective clinical research institutions and writing articles for publication in scientific journals.

3.7.2 Internal and external validity of the study

Ensuring the validity of this research meant that I (and others) could believe the research results were trustworthy and meaningful (Creswell & Clark 2018:217).

3.7.2.1 Internal validity

Internal validity relates to how well the study was conducted and how accurately the findings represent the studied group (Leedy & Ormrod 2019:195). I aimed to control extraneous variables and eliminate alternative explanations for my results. To protect the internal validity by excluding some cause-and-effect scenarios, I recruited investigators who were new to the clinical trial field and who did not have (in most instances) any or much previous training in the field. To reduce history, maturation, confounding and statistical regression, I ran the clinical trial programme over eight weeks at a venue outside the investigators' institutions (Leedy & Ormrod 2019:195; Mertens & Wilson 2018:290). Another strategy to improve the internal validity entailed incorporating stakeholder feedback when I developed the programme. I used a quasi-experimental study design with rigorous procedures to ensure maximum control over variables

compared to true experimental studies to come to my conclusions (Polit & Beck 2022:261).

3.7.2.2 External validity

External validity speaks to the applicability of the findings in the real world (Creswell & Clark 2018:217). I aimed to find ways to ensure the study can be applied to practical situations in the world at large. External validity was improved by stating the inclusion and exclusion criteria clearly. The venue's location also contributed to external validity; the participants were removed from their familiar, daily clinical trial environment, and there were no interruptions. Although the external validity might be weak, the research was highly valuable to the clinical trial field. To further improve the external validity, I invited clinical and non-clinical investigators in South Africa.

3.7.2.3 Validity and reliability of data-gathering instrument

Both questionnaires for measuring investigators' self-perceived level of competency and knowledge of clinical trials (pre-and post-test) were based on the guidelines set out by the JTF, focusing on the eight competency domains for clinical trial professionals. These questions are related to ICH GCP guidelines. I did an intensive literature review on the design of questionnaires and looked at several questionnaires used in previous educational programmes (Saunders 2019:502-557; Woodin 2019:615). I also conducted a pilot test on both questionnaires to confirm that the questions made sense and were understood as I intended (Saunders 2019:540).

3.8 ETHICAL CONSIDERATIONS

Ethical considerations are part of every aspect of life. They could have adverse consequences for individuals, organisations and public health if improperly handled or unethical behaviour occurs (Saunders 2019:232). Therefore, a researcher should consider the ethical principles of research conduct throughout their research. Permission to conduct this study was sought from the University of South Africa (UNISA). Approval was received from the Research Ethics Committee of the Department of Health Studies at UNISA (HSHDC/943/2019 see Annexure A) for the research proposal. At the beginning of the COVID-19 pandemic, additional approval was obtained from the ethics committee

to conduct stakeholder interviews virtually (online) and telephonically (HSHDC/943/2019 AMENDED 2020 – Annexure B).
The rights and safety of research participants should always be protected. The Declaration of Helsinki forms the most notable code of ethics, and both ICH and SA GCP guidelines are rooted in its principles (SA GCP 2020:9).

Interviews with stakeholders asked me to consider the three basic ethical principles of the Belmont Report, which also form the basis for The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research Guidelines, formulated in 1979 (Seidman 2019:62).

3.8.1 Respect for persons

Respect for persons pertains to an individual's self-governance and the imperative to safeguard those whose ability to self-govern is diminished due to their vulnerable circumstances. (Seidman 2019:62). Respect for persons require that research participants must be treated with dignity and their well-being and safety must be recognised as the most critical concern during any research involving human participants (South Africa 2015:14). Therefore, the safety and interests of research participants should always outweigh the interest of science and the community. At the same time, the researcher's interest should also be considered, including the researcher's safety, authorship, and intellectual property interest.

Respect for persons also includes their right to privacy and confidentiality of their person and personal data. Extending the in-person face-to-face interviews in the current study to include online and mobile application interviews for participants (stakeholders) had the potential to hold a threat to the confidentiality and privacy of the conversations. I had no control over the location from which participants conducted interviews or over the way internet platforms retain information. However, I established a 'safe' online environment by choosing an online platform that promised confidentiality of data; I created an interview ID login where I gave the participant permission to enter the interview meeting after they typed in a password. On agreeing to do the online interview, I recommended the potential participant seek out a space where they had some privacy and could engage in uninterrupted conversation; it could even have been outside the building, for example, on a patio. They could also use headphones or earphones to stay focused on the interview.

3.8.2 Beneficence and non-maleficence

The equivalent of beneficence is ‘do no harm’ and forms part of the Hippocratic Oath (Nation Institute of Health 2002:1). It also includes the nature and scope of risks and benefits that must be assessed systematically throughout the research. It meant that I had to ensure the benefits for participants outweighed the risks for them to be in the study at all stages (Seidman 2019:62). This study was a medium-risk study and had the potential to pose psychological harm to participants (quantitative phase of Project 3). Determining participants’ perceived level of knowledge and skills and putting their knowledge to the test could cause feelings of depression, altered self-concepts, increased anxiety, decreased confidence, embarrassment and frustration (Labott, Johnson, Fendrich & Feeny 2013:53). It might have been difficult for some participants to receive information about themselves that is unpleasant and inconvenient, even if it is meant to be positive and to lead to improvement of the self.

3.8.3 Justice

Research must involve fair procedures and outcomes in selecting participants and being fair to all participants. In contrast to the Tuskegee research, once a positive benefit has been discovered, it must be shared with all participants (Seidman 2019:62). Participants chose to participate in the research voluntarily, and they all received the same intervention.

3.8.4 Informed consent

Respecting individuals necessitates that participants willingly and fully informedly join a research study. Information about the research is captured in an informed consent document, also called a participant information leaflet/form (Seidman 2019:62). I respected participants’ autonomy by providing them with written and verbal information about all aspects of the study. I confirmed that they understood the information given to them by asking questions; for example, I asked: ‘What did you understand by *confidentiality* when I explained it to you?’ I allowed the participant to ask questions and responded with answers. I gave the participant enough time to consider if they would like

to participate in the research; in other words, the participant could make an informed decision without coercion. The participant then signed the informed consent form.

3.9 SUMMARY

The research paradigm of pragmatism, Bandura's Social Cognitive Theory and the JTF and MRC theoretical frameworks underpinning the chosen multiple-method research design were discussed in this chapter. The research design and structure of the multiple-method research education programme followed. The study's three projects with related segments, including data collection and analysis strategies, were also touched on in this chapter. Further, measures to ensure trustworthiness, authenticity and ethical considerations were discussed.

Chapter 4 presents a situation analysis as part of the first project of the study.

CHAPTER 4
PROJECT 1: RESEARCH DESIGN, DATA COLLECTION, DATA ANALYSIS AND FINDINGS OF THE FIRST SEGMENT AND SITUATION ANALYSIS (QUALITATIVE)

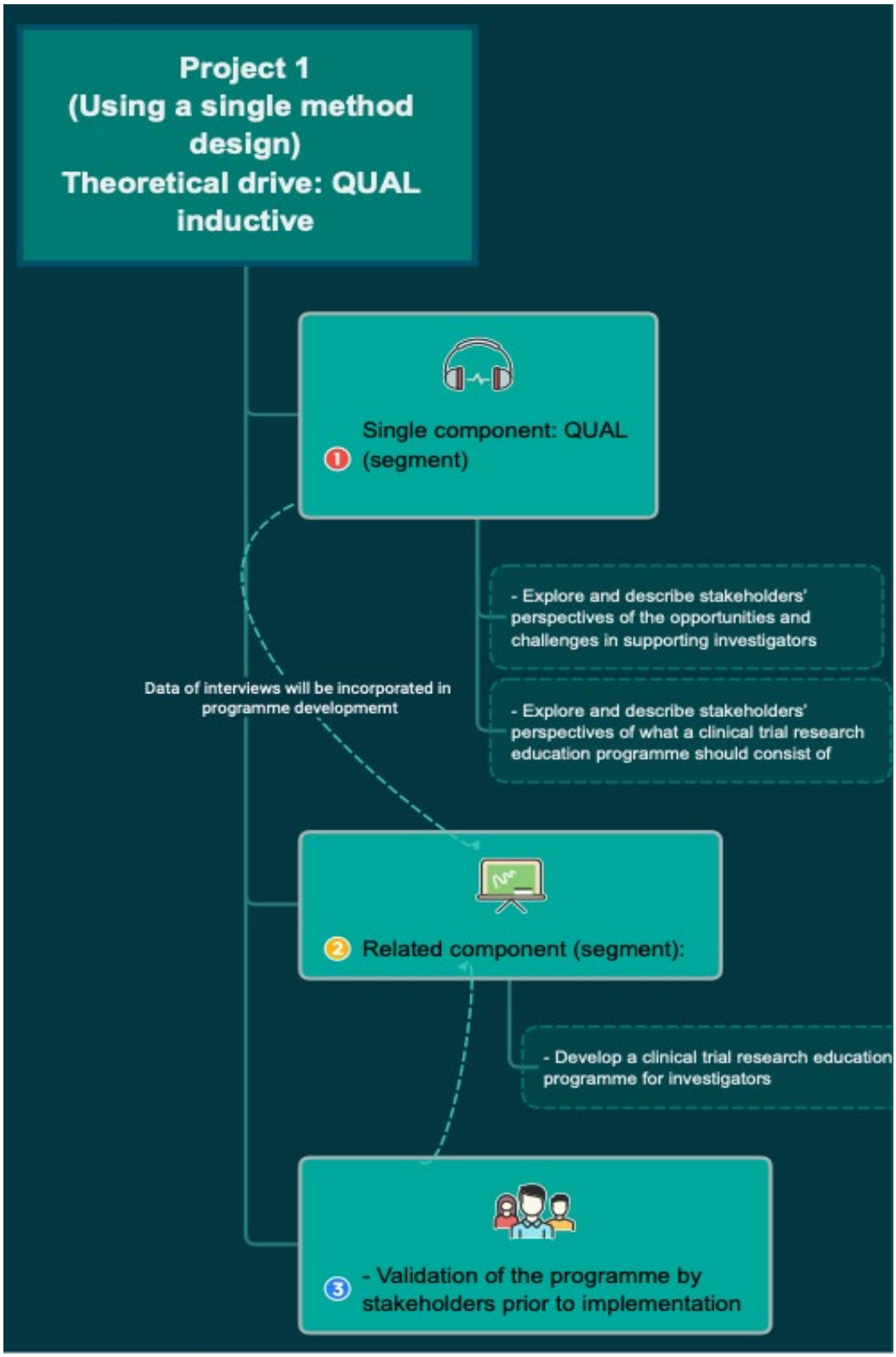
4.1 INTRODUCTION

The first project of the study aimed to develop a clinical trial research education programme with input from stakeholders. The first segment of Project 1 explored and described stakeholders' perspectives of available opportunities and challenges in supporting investigators and their perspectives of what a clinical trial research education programme should include. Chapter 4 discusses the research design, data analysis and interpretation of the interview results with stakeholders, forming the first segment of Project 1 of the study. The first segment represents the situation analysis or developmental phase of the MRC framework and is qualitative (see Table 4.1). Diagram 4.1 summarises the flow of Project 1.

Table 4.1: Chapter 4: Research progress

Chapter	Content
1	Orientation to the study
2	Literature review (1) Clinical trial education (2) Competency-based education (3) Self-efficacy (4) MRC framework
3	Research design and methods
4	Project 1 Research design, data collection, data analysis and findings (First segment: situation analysis - qualitative)
5	Project 1 Development and validation of the clinical trial research education programme (Second and third segments)
6	Project 2 Research design, data collection and implementation of the intervention
7	Project 3 Research design, data collection, results, and evaluation of intervention

Chapter	Content
8	Summary of integration of findings, conclusion, recommendation, contribution and limitations of the study



Schematic diagram 4.1: Flow of Project 1

4.2 RESEARCH DESIGN

Segment one of Project 1 used an inductive approach and a qualitative design (Creswell & Creswell 2022:191). An inductive approach uses qualitative methods to form the theoretical drive of a project to 'think up' from the data to concepts or themes (Morse 2017:5). Segment one expanded current knowledge about perceived opportunities and challenges in supporting investigators and offered perspectives of what a clinical trial research education programme should consist of.

4.2.1 Exploratory approach

The research questions – what are stakeholders' (supervisors of investigators, departmental heads) perspectives of the opportunities and challenges in supporting investigators, and what are stakeholders' perspectives of what a clinical trial research education programme should consist of – are vital to the choice of research design. As per Saunders (2019:186), research can be structured to serve an exploratory, descriptive, explanatory, evaluative objective, or a mix thereof. An exploratory approach was followed in the current segment of the study.

An exploratory approach aspires to clarify understanding of an issue that is not clear or where the precise nature of the phenomenon is not evident (Saunders 2019:186). Exploratory research could include a literature search, interviews with experts in the field, and in-depth interviews with participants (Saunders 2019:187). I explored two issues: (i) stakeholders' perspectives of the opportunities and challenges in supporting investigators and (ii) stakeholders' perspectives of what a clinical trial research education programme should consist of through personal face-to-face and online semi-structured interviews. The explorative approach assisted me in answering these questions as it shed light on the stakeholders' perspectives (Polit & Beck 2022:17).

4.3 POPULATION

The target population can be described as the group of individuals from which the researcher wants to draw conclusions. For this study, the group size was 124 and included PIs, sub-investigators, study coordinators, clinical research associates and clinical research consultants from the clinical trial, academic and pharmaceutical fields

(Cohen, Manion & Morrison 2018:202). However, for segment one of Project 1, the supervisors of the group of 124 formed the population. On average, a PI or supervisor might oversee five investigators at a site (Koen, personal communication 2020; Martinson, personal communication 2020; Gouws, personal communication 2020); therefore, the population size for segment one was 25 supervisors.

4.3.1 Sample

A sample can be described as a subset of the group of individuals selected to participate in a study (Cohen et al. 2018:202). A subset makes it manageable for a researcher to investigate a phenomenon identified in a population (Polit & Beck 2022:243). Non-random purposeful sampling was used to select the stakeholders for this study. Cohen and colleagues (2018:224) describe purposeful sampling as one of the methods that could be selected for a multiple-method research design. These authors (Cohen et al. 2018:224) believe the objectives of the study and the selected strategy's potential should be considered when selecting a purposeful sampling approach. With limited resources and information-rich research material, purposeful sampling was deemed the best strategy for this project.

Considering that this study was conducted to complete a PhD, the intended sample size was required during the proposal phase, and I decided on a sample size of ten. My decision was based on the following findings and recommendations: saturation is difficult to prove; choosing experts in the chosen topic and using multiple methods in one study could reduce the sample size (Mason 2010:2; Kindsiko & Poltimae 2019:10). In a study by Guest et al. (Mason 2010:5), findings reflected that studies with high levels of homogeneity among the population lean to smaller sample sizing (as low as six) to provide enough information and derive meaningful themes and functional interpretations (Mason 2010:5; Kindsiko & Poltimae 2019:15). Ten experts (stakeholders) were invited to participate in the study, including PIs, sub-investigators, study coordinators, clinical research associates and consultants. Ten participants, all experts in the field of clinical trials, were not only a manageable number, but with a sample size of ten, I was able to address the questions: 'What are stakeholders' perspectives of the opportunities and challenges in supporting investigators', and 'what are stakeholders' perspectives of what a clinical trial research education programme should consist of?'

4.3.2 Eligibility (inclusion and exclusion criteria)

Eligibility criteria increase the possibility of producing the necessary information/results by selecting a group with similar characteristics or excluding participants most unlikely to provide the necessary information/results (van Eijk, Westeneng, Nikolakopoulus, Verhagen, van Es. Marinus, Eijkemans & van den Berg 2019:451).

Inclusion criteria

- Participants must have a minimum of ten years' experience in clinical research to ensure extensive knowledge and skills about the full clinical trial cycle, different types of clinical research and sponsors.
- Participants must currently work in clinical research.

Exclusion criterion

- Stakeholders who have been out of the clinical research field for over three years.

4.4 DATA COLLECTION

According to Morse (2020:5), researchers should select excellent participants to obtain excellent data. Data were collected from April 2020 to June 2021 from participants from the Perinatal HIV Research Unit (PHRU) in Johannesburg, Wits Reproductive and Health Institute (Wits RHI) Johannesburg, and local and international clinical research organisations. The initially planned time frame for interviews was between March and June 2020. However, due to the COVID-19 lockdown regulations in South Africa and my then-new work commitments related to COVID-19 regulations, the time frame was extended to June 2021.

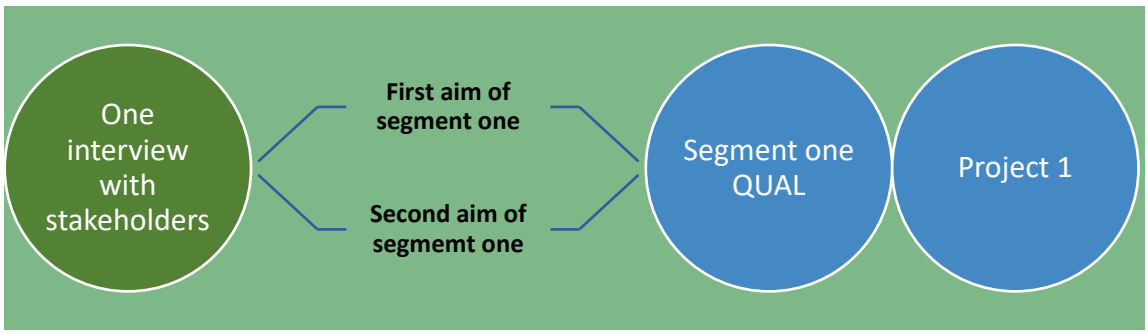
4.4.1 Recruitment of participants

Stakeholders: On receiving a list of stakeholders from WHC, I emailed the stakeholders to explain the pilot study's purpose and their vital role in developing an effective and efficient clinical trial research education programme for new investigators. I requested that they reply to the email if they were interested in being interviewed. I also followed up with telephone calls when needed. I responded to those stakeholders who agreed to be interviewed to set up a date, time and venue that suited them.

4.4.2 Data collection method

Data were collected through interviews. In the Old French culture, the word ‘interview’ meant “to see one another” (Etymology Dictionary 2021). Since then, interviews have become increasingly important because it is a way for individuals to make sense of their lives and be understood by others (Seidman 2019:85; Dale & Abbott 2019:440). In the same way, I used interviews to make sense of essential information to include in a clinical trial research education programme. I used semi-structured interviews led by an interview guide containing open-ended questions and applicable probes (Polit & Beck 2022:510). The interview with the first participant served to pilot the open-ended interview guide, and the participant’s responses showed that the open-ended questions were adequate to collect the necessary information. Probes included in the interview guide were used during interviews with the rest of the participants when it seemed more information was needed (see Annexure D).

Interviews took approximately 25–35 minutes and explored participants’ experience when they entered the clinical trial field and if it was an experience they wished for new investigators, coordinators or other health professionals entering clinical trials. Furthermore, participants were asked about the ideal preparation for new investigators and their suggestions for health professionals who want to enter the clinical research field (see Annexure D). An exploration of the first aim, namely stakeholders’ perspectives of the opportunities and challenges in supporting investigators, and the second aim, namely stakeholders’ perspectives of what a clinical trial research education programme should consist of (see diagram 4.2), was covered in one interview with each participant. However, open-ended interview questions on the first aim of segment one were analysed separately from those addressing the second aim of segment one. Participants informed me upfront that they did not have much time, and in most instances, they could share their experiences and ideas about preparing new investigators in less than half an hour.



Schematic diagram 4.2: Summary of the data collection method

According to Saunders (2019:434-458), qualitative interviews are about asking the right questions and practising good listening skills to explore the answers further. The interview process required my thoughtful presence to understand what was needed to support investigators and what needed to form part of a clinical trial research education programme (Seidman 2019:121). At the same time, I used bracketing to bracket my perspectives and biases about what participants were saying by focusing on three levels of listening (Seidman 2019:85). First, I listened for understanding (part of bracketing) and to ensure nothing had been left out. Second, I listened with intuition; when I sensed more to tell, I used probing. Third, I listened by being sensitive to the whole interviewing process without being judgemental. I aimed to capture the participant's experience as a single entity in and of itself. Seidman (2019:85) described participants' words as a small-scale universe, presenting their consciousness. However, while listening to the participants, I was aware of my assumptions that they must have had little or no clinical research education when they entered the clinical trial field, and they would have seen new investigators with similar experiences making errors.

While planning for each interview, I would reflect on my expectations of what I would like participants to say or my ideas of how a clinical trial research education programme should look. Meditating and writing reflective notes helped me set aside my background, culture and experience to hear what the participants wanted to tell me. By disregarding any preconceived notions and assumptions, I was able to effectively determine the significance I attributed to the evidence. (Leedy & Ormrod 2019:276). Therefore, I bracketed these reflective notes (Polit & Beck 2022:522). After the interviews, I wrote field notes to inspect my expectations and values to remind me of my role in the inquest. Writing these field notes made me feel more connected to the participants. Additionally, I made a point of identifying statements made by the participants that I wished to further

scrutinise through the use of probing inquiries. Reflecting and field notes were also used as triangulation and backup measurements (Leedy & Ormrod 2019:256).

4.4.3 Influence of COVID-19 on data collection

Data collection strategies can set boundaries for the study by specifying a selected number of participants, using unstructured or semi-structured observations and interviews, incorporating notes, and visual and recording material to collect information (Creswell & Creswell 2020:210). The COVID-19 pandemic contributed to a shift in some of these boundaries. In the education system, the previous classroom model had to be supported and, in some instances, replaced by the online and blended model to create a "new normal" (Jackson 2018:139). New competencies had to be learnt by teachers and students, including technology (Jackson 2018:139). Similarly, the way we conduct research had to move from face-to-face interviews to technology-based systems. Technology provides a cost-effective and convenient solution when traditional face-to-face interviews cannot occur (Gray, Wong-Wylie, Rempel & Cook 2020:1292). The use of technology was explicitly applicable during the strict COVID-19 lockdown regulations that were put in place in South Africa. Technology made a connection with research participants accessible with a flexible timeframe for interviews (Gray et al. 2020:1297). However, disadvantages that had to be considered were the increased cost of software and annual fees, uninterrupted internet service, distractions, and lack of privacy (Gray et al. 2020:1297). I had to secure unlimited internet access and upgrade to paid Zoom sessions. There were also distractions on the participant's side sometimes, and they could not focus entirely on the interview. Breaks in internet connection were also experienced.

At the onset of the COVID-19 lockdown regulation in South Africa, I had conducted only four face-to-face interviews with stakeholders. After an amended informed consent (see Annexure J) to include interviews via technology was approved, stakeholders were invited to participate in the study by email. I contacted the WHC, which owned an extensive database of investigators, to provide me with the email addresses of identified stakeholders. For international stakeholders, I made use of LinkedIn to retrieve contact details. When potential stakeholders responded to my email invitation and agreed to participate, I forwarded them the informed consent to read and invited them to email me with any questions. I confirmed their preferred choice for the interview via email; between

a face-to-face interview at a location of their choice, a face-to-face online interview via the internet on the computer or cell phone, or just a telephonic interview. Irrespective of their choice, the interview was recorded with a high-quality digital voice recorder after the stakeholders gave their permission willingly by signing the informed consent form.

Ethical issues were taken into account during these interviews. Participants were provided with information regarding the nature and objective of the study through the consent form and the participant information brochure. The participants were informed of their option to discontinue their participation in the study at any point throughout the interview. They were also given another chance to ask questions before we started the interview. I cautiously kept within the timeframe promised in the informed consent form while covering all the questions in the guide and, where necessary, I gave participants a break to get some water, tea, or coffee, or take a 'body break' (Seidman 2019:101).

4.5 DATA ANALYSIS

Data analysis is a systematic procedure that enables researchers to derive valuable insights from raw data by extracting, organising, and attributing significance to it. (Creswell & Creswell 2022:221). During the first segment of Project 1, interview questions aimed to explore stakeholders' perspectives of what is essential to include in a clinical trial research education programme. Recommendations from stakeholders were adhered to during the development of the research education programme. My data analysis process started with organising the data, followed by transcribing and coding the data.

4.5.1 Organising the data

I anticipated the data collected from individual interviews with audio recordings, followed by verbatim transcriptions and personal notes/memos, would be lengthy. Therefore, a thorough preparation for analysis was needed. Appropriate organising was essential, which included a suitable anonymising method to code different participants' data (Saunders 2019:644). I generated both a physical paper and a digital computer file for each participant, encompassing all the gathered data. A unique alphanumeric code assigned to participant files for future retrieval. The physical documents were stored in a secure cabinet within my closed office, while the digital data were safeguarded with a personal identification number (PIN) code. As mentioned, I separated open-ended

questions related to the first aim of segment one from open-ended questions asked for the second aim of segment one and analysed them separately.

4.5.2 Transcribing the data

Audio-recorded data were transcribed verbatim, giving a word-for-word replication of the interview (Seidman 2019:124). I involved a professional transcriber for the time-consuming process of transcribing. A confidentiality agreement (refer to Annexure P) was established with the transcriber, outlining the specific guidelines for transcribing data, including the accurate representation of tone and non-verbal communication exhibited by the participants. The transcriber ensured the precision of the transcribed data by maintaining ongoing telephonic and email communication. (Seidman 2019:124).

4.5.3 Coding the data

I opted for manual coding as it was the process I used during my master's study, and was therefore familiar to me. Manual coding was also an affordable option; although it was more time-consuming, I saved some time by not learning new coding software. I followed a cyclical analytic coding process as proposed by Saldaña, made up of a first-cycle method, a cross method in-between, and a second-cycle coding method (Saldaña 2021:68).

According to Saldaña (2021:68), coding is seen as an ongoing process of recoding, which involves comparing data to data, data to code, code to code, code to category, category to category, and category back to data. My research questions: 'What are stakeholders' (supervisors of investigators, departmental heads) perspectives of the opportunities and challenges in supporting investigators', and What are stakeholders' perspectives of what a clinical trial research education programme should consist of', determined my choice of first, cross, and second-cycle coding methods. Saunders' (2019:651) thematic analysis strategy described a similar way for data analysis. I chose not to bring in an independent co-coder since I believe I am the best equipped to get behind the meaning of the data and, at the same time, prevent diverse interpretations and understandings of the data (Keene 2021:1). Researchers should trust their interpretations without needing others, thinking that others might bring different or better concepts to the analysis (Keene 2021:1). My supervisor monitored the analysis process.

A code represents and captures the main content and real meaning of data collected during qualitative research (Saldaña 2021:4). Therefore, coding forms that critical connection between the collected data and the explanation of the meaning of that data (2021:4). A code is a word or short phrase that represents a significant amount or specific information within language-based data. Additionally, it has the potential to evoke vivid mental images, recollections, or emotions. (Saldaña 2021:4). Another code comparison comes from Saunders (2019:653), who compares codes with puzzle pieces. The data elements and their interconnections enable a clear understanding of the insights conveyed by the data. Researchers employ codes to represent or convert data, so assigning significance to each individual piece of information that can be subsequently utilised for identifying patterns, categorising, constructing theories, and other analytical procedures. (Saldaña 2021:4). Raw data are condensed by coding and grouping coded data into analytic categories (Saunders 2019:656).

Patterns are recurring or regular occurrences in data that are characterised by the repetition of words, phrases, or activities appearing more than twice. Human habits are exemplified by patterns and serve to validate our descriptions of people's routines, rituals, rules, roles, and connections. We have the ability to transform our observations into tangible instances that exemplify meaning. (Saldaña 2021:5).

Themes encompass and integrate the development of the experience, drawing from codes and categories, to form a coherent and significant entirety (Saldaña 2021:199). Therefore, a theme will provide us with further insights into the participants' experiences with our study topic. The puzzle we started with will form a clear picture.

Commencing with the initial stage of data coding, I employed In-Vivo, initial, and process coding methods to extract the significance from the interview data. In-Vivo coding involved using words or short phrases from the participant's language. Initial coding entailed breaking down the data into distinct parts and closely examining them, while also comparing them for similarities and differences. Process coding involved using "ing" words to indicate action within the data or general conceptual action. These coding methods were utilised to uncover the underlying meaning in the interview data (Saldaña 2021:71). Prior to commencing the second-cycle approach, I employed a cross method wherein I extracted all the codes inscribed in the margin of the transcript, fragmented

them into individual pieces of paper, organised them into relevant categories, affixed them together with staples, and affixed labels indicating the category name and their respective source (Saunders 2019:653; Saldaña 2021:230). The second phase of coding involved the process of reevaluating and reclassifying the previously categorised data. I conducted a thorough search for more precise terminology, consolidated comparable ideas, took into account less commonly used codes, and eliminated some codes that were of little importance or duplicated others. Through the process of reorganising and consolidating codes during the second-cycle phase, I created a comprehensive "main dish" that encompasses more extensive categories and topics (Saldaña 2021:234). Saldaña (2021:235) refers to the process of searching for recurring or noteworthy initial codes to construct categories and themes during second-cycle coding as "focused coding."

Table 4.2: Example of hard copy of a transcribed interview accompanied with codes.

I had significant dissatisfaction[1] in the initial months of my tenure as an investigator. I was uncertain about the delineation of my "medical" and "research" obligations[2] Amidst everyone's busyness, I experienced a sense of uselessness[3] and found myself uncertain about seeking help[4] from anyone.	1 "dissatisfaction" (coding conducted in a live setting, in-vivo) 2 ambiguous obligations (process coding) 3 "experienced a sense of uselessness " (In-vivo coding) 4 mentoring (coding process)

4.5.4 Analytic memos

Analytic memos refer to internal dialogues that researchers engage in to discuss and reflect upon their collected data. Recording memoranda enhances our cognitive processes and facilitates deeper analysis of our subjects and/or the research phenomenon (Saldaña 2021:44). Memoing refers to the act of composing contemplative notes, while analytic memoing specifically involves reflecting on and documenting my coding decisions and their practical explanations, as well as identifying emerging patterns, categories, and themes (Saldaña 2021:47). I contemplated the interrelationships, associations, and intersections between the codes, patterns, categories, and themes. According to Saldaña (2021:54), it is recommended to

categorise and categorise analytic memoranda not only for organisational purposes, but also as an essential analytical step that identifies the fundamental elements of a written analysis. Hence, I employed reflective notes to contemplate my feelings, relationships, values, attitudes, and views about the phenomena. Additionally, I utilised analytic memos to ponder over the participants' routines, rituals, rules, roles, and relationships (Saldaña 2021:47).

4.6 RESEARCH FINDINGS

The first and second aims' findings of Project 1's first segment are discussed separately; findings of the interviews with stakeholders are part of the development stage of the MRC framework. First, I offer a description of the participants' demographics (stakeholders). Table 4.3 summarises the biographical data of the stakeholders who participated in segment one of Project 1.

4.6.1 Description of the participants' demographics

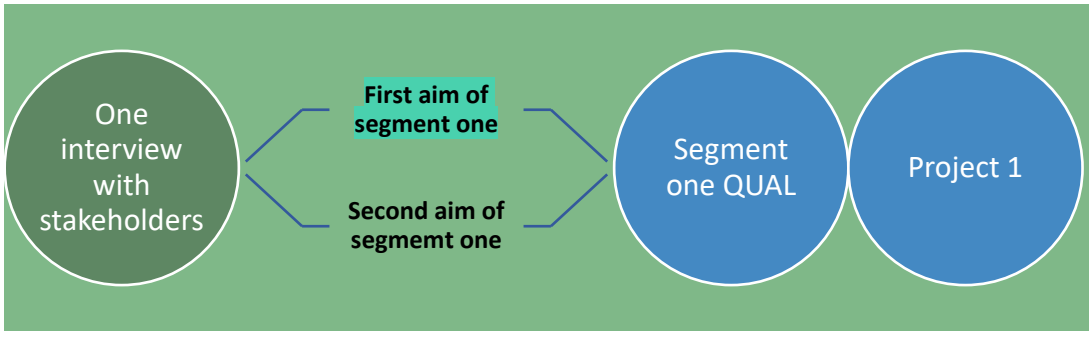
The Qual segment of Project 1 comprised ten female stakeholders (also called participants). Experienced male clinical researchers who were approached were not interested in participating in this study. Experienced male clinical researchers at the sites where the experienced female researchers worked were in the minority; for example, at Wits RHI, five senior researchers and departmental directors were female. At the time of the interviews, three participants had between 10 and 15 years of experience, three participants had between 16 and 19 years of experience, and four participants had more than 20 years of experience as investigators in clinical research. Regarding the racial breakdown, four racial groups were represented: one Black participant, five White participants, three Indian participants, and one Zambian participant. Their age breakdown was as follows: four participants were between the ages of 40 and 45, two were between 45 and 50, one was between the ages of 50 and 55, and three were older than 55.

Table 4.3: Participants' demographic profile

VARIABLE	PARTICIPANTS
Gender	Male = 0 Female = 10
Years' experience	10–15 years = 3 16–19 years = 3 20+ years = 4
Age breakdown	40–45 = 4 45–50 = 2 50–55 = 1 55+ = 3
Racial breakdown	Black = 1 White = 5 Indian = 3 Zambian = 1
Role in clinical research	Principal investigator = 4 Sub-investigator = 1 Study coordinator = 2 Clinical research associate = 1 Clinical research consultants = 2

4.6.2 Project 1: Segment one (QUAL) - Description of the findings of the first aim

Table 4.4 summarises the participant identification and pseudonym log as a reference for the direct quotes provided under themes, categories, and codes. Diagram 4.3 shows the layout of the data collection process.



Schematic diagram 4.3: Layout of the data collection process

Table 4.4: Participant identification log

Number	Pseudonym
P001	Veronica
P002	Ann
P003	Louise
P004	Brenda
P005	Charlene
P006	Reba
P007	Daphne
P008	Ada
P009	Vivien
P010	Verena

Stakeholders' perspectives of the opportunities and challenges new investigators experienced varied from subjective views, mentioning their personal experience, to more objective views, mentioning what they have observed. Stakeholders tended to focus only on the challenges new investigators experienced while opportunities were overlooked, although most of the challenges could be turned into opportunities for the new investigator and the stakeholder. During my reflective notes, I commented that some stakeholders were very cynical about new investigators' attitudes. Most stakeholders did not mention a positive experience with new investigators or reported they were hopeful for the future of clinical trials because of the new cadre of investigators. Table 4.5 summarises the themes, categories, and codes that emerged from the data analysis.

Table 4.5: Summary of themes, categories, and codes: *first aim* of segment one of Project 1

THEME	CATEGORY	CODE
1. Motivation to enter and interest in clinical research	1.1 Convenient option	1.1.1 Indecision about the future
	1.2 Lack of commitment, motivation and passion	1.2.1 Not prepared to put in the hours 1.2.2 No interest
2. Readiness related to knowledge, skills, experience and	2.1 Lack of knowledge about clinical trials	2.1.1 Underprepared for the role
	2.2 Lack of training and mentoring	2.2.1 No previous training or guidance

THEME	CATEGORY	CODE
confidence upon entering clinical research	2.3 Previous experience	2.3.1 No previous experience with clinical trials 2.3.2 Lack of Confidence
	2.4 Inexperienced investigators make errors	2.4.1 Terrible chart noting 2.4.2 Making mistakes
3. The nature of clinical research	3.1 The concept and scope of clinical research	3.1.1 Raising money is hard 3.1.2 Lack of funding 3.1.3 It is time-consuming 3.1.4 Long-term dedication 3.1.5 Overwhelming experience 3.1.6 The way forward Unclear career trajectory

4.6.2.1 Themes, categories, and codes

The findings reflected three main themes, namely (1) new investigators' motivation to enter and their interest in clinical research; (2) new investigators' readiness related to knowledge, skills, experience and confidence upon entering clinical research; and (3) the nature of clinical research. These main themes, with the related categories and codes, will now be discussed along with verbatim quotes. Direct quotes are provided in *italics*.

a) Motivation to enter and interest in clinical research

Stakeholders thought investigators seldom entered the clinical research field to further scientific knowledge and bring about the necessary relief of suffering. Instead, they do so to satisfy their own needs. For some new investigators, clinical research was a convenient option; for unknown reasons, others just lacked passion and commitment.

a.i) Convenient option

Veronica related the convenience factor to female investigators wanting to start a family; therefore, clinical trials have become an excellent option.

> *"They want to have a baby, so they do not want nights"* [Veronica]

Veronica also mentioned that investigators often choose a clinical trial job because they are unsure about a future career. Brenda agreed with her. Clinical trials seem to be a good option, but it might also be a generational phenomenon.

> *"They do not know what they should do in life, and they try this out because it seems glamorous. We see that maybe six months to eighteen months, the young doctors can't cope… it seems to be a generational issue"* [Veronica]

> *"We certainly hear a lot that many doctors that may be foreign trained graduates but they come to the US and they have a year or so before they can get their license so they pick up a job in clinical trials. These people come and go and they don't stay and see it as a lifelong profession"* [Brenda]

In an article, *Women in medical schools* (2021), the American Medical Association reported that during the 2019-2020 intake of students to medical schools, more than 53.5% were women. Consequently, over time, more female investigators entered the clinical research field. Davis, Meagher, Pomeroy, Lowe, Rubenstein, Wu, Curtis and Jackson (2022:1) mentioned that women are disproportionally overrepresented in clinical research and will therefore feel the long-term burden of COVID-19 on their careers more significantly. According to the regulatory office at one of the larger clinical trial sites in Johannesburg, the ratio of male to female clinical investigators is 1:5 (Gous, personal communication, 10 March 2022).

According to a study by Pelser (2018:80), some novice investigators did not initially choose to conduct clinical trial research. The dearth of registrar positions was one of the main reasons these investigators frequently could not find the position they desired. Academic institutions' employment advertisements make clear that there is a significant lack of registrar positions. There are just a few registrar positions open at many institutions.

Clinical research seemed to be the ideal option at that point in their lives for female investigators who sought to balance a career and a family. (Pelser 2018:80; D'Arrietta, Vangaveti, Crowe & Malau-Aduli 2022:185). Krastef (2019:1) mentioned that statistically, 70–75% of clinical research staff are women; however, men still dominate managerial

positions. The reasons were that women are more empathetic and more inclined to sacrifice their time for their children. Peterson Gloor, Okimoto, and King (2022:623) highlighted the fact that, for the majority of women, their training and early career stage align with their phase of childbearing. Both phases are influenced by the passage of time, one being the duration of employment and the other being the natural ageing process. Women face limited opportunities to alter their work schedules, and their educational programmes or professional paths often fail to meet their desire to balance career and family responsibilities (Peterson Gloor et al. 2022:634).

a.ii) Lack of commitment, motivation and passion

Several stakeholders mentioned the lack of commitment among new investigators as a challenge mentors have to deal with when working alongside new investigators.

> *"It is not always that easy to get people involved, and they, you know, sorry if I sound cynical, everyone wants to be in this, very exciting, but they are not necessarily prepared to put in the hours around it, you know"* [Ada]

> *"I think a lot of people are theoretically interested in science and research, but they are not when it comes down to do it"* [Charlene]

> *"Level of commitment and motives of people, maybe they are too young, from a maturity point of view. They are not yet at the stage to make a commitment to doing research"* [Veronica]

In addition to not being committed, some stakeholders believed new investigators also lack motivation and passion, which often go hand in hand.

> *"I think you can pretty quickly detect the motivation, which makes a difference in how much oversight, training and everything else you have to build into, for example, monitoring processes. If someone is just a dabbler, you know you face more considerable challenges than someone who believes that it's the core and the essence of their work. That was my work and I would say 50% of them had the same passion and the other 50% were much more ad-hoc about it"* [Brenda]

"It is something when you start working with new people, you can very soon see this person is clinical research orientated or this person isn't" [Louise]

"The data, they are a bit removed from it, whether it is from choice or whether it is because they don't like it. They did not necessarily care to understand it" [Ann]

The Oxford English Online Dictionary (1992 vs "motivation") describes 'motivation' as the reason you want to do something, and 'passion' as a strong emotion. D'Arrietta et al. (2022:185) mentioned that motivation to undertake research is a key factor in medical research but can be limited by barriers such as cost. Other factors could also play a role. D'Arrietta et al.'s (2022:186) study confirms Pelser's findings that personal characteristics, referring to abilities, previous experience, goals, self-concepts, beliefs and expectations, contribute to investigators' motivation or lack of motivation for clinical research. Furthermore, environmental influences through the community, socialisation, and the cultural milieu could also become barriers to motivation (D'Arrietta et al. 2022:186).

b) Readiness related to knowledge, skills, experience and confidence upon entering clinical research

Most stakeholders referred to their own experiences because they could relate to young investigators' unpreparedness when starting a career in clinical trials. Stakeholders mentioned that new investigators' ability to cope during their first few months depends on their knowledge, skills, and experience upon entering the clinical research field.

b.i) Lack of knowledge about clinical trials

Most stakeholders commented on new investigators' lack of knowledge about clinical trials.

"Whereas the private guys, when they first start in research, actually start like brand new. So they pretty much are brand new, and the good thing is that you can teach them you know, properly without the history and the baggage of all the bad habits…but it takes them longer I think to pick things up than the academic guys" [Reba]

"*…then I would go to these new investigators and say, won't you help me and often they didn't had a clue about the line items and how to do a budget …they didn't know anything that was needed"* [Verena]

"They find it challenging…they don't have the understanding of how. They have frustration and then you would need to explain things to them" [Ann]

"So the presumption that because you are clever and you became a doctor or an entry level provider that you would automatically know how research works, I don't think that's so simple. I meant, it's a whole new area that you need to spend time learning and you need to. Right so I think a lot of people sort of go into trials without the foundational preparation of how research is designed or implemented" [Charlene]

Readiness is the state of being fully prepared or feeling prepared for a specific activity or situation (Oxford English Living Dictionaries online 1992, versus "readiness"). A lack of knowledge, skills and competence has been highlighted by D'Arrietta et al. (2022:186) to be barriers to health professionals' engagement in clinical research. The value that health professionals put on research is a stimulus for motivation or amotivation to engage in clinical research, as it directly affects the relevance of the barriers. Contributors to the research journey are part of research training and mentoring programmes, and they support an organisational research culture (D'Arrietta et al. 2022:185).

Pelser's (2018:83) participants exhibited a deficiency in knowledge, abilities, and experience, rendering them susceptible to numerous obstacles. This was particularly evident when they entered the clinical trial domain with simply GCP training.

b.ii) Lack of training and mentoring

Stakeholders also mentioned that new investigators' lack of training and mentoring is challenging.

"So its so hard because I also like learnt by trial and error. Its not like I got taught how to run it; its like here's a trial and you have to run it" [Vivien]

"So I got a lot of personalised mentoring and training from somebody who recognised transferable competencies, but I know a lot of people don't have that" [Brenda]

"Yah and I think that's helpful to know because I think many of us weren't actually taught anything. No, you kind of figure it out as you go along but I think its very helpful information, you know and I'm sure something that people would enjoy knowing about" [Ada]

The development of a well-trained clinical trial research workforce has become more evident during the COVID-19 pandemic, and barriers such as a lack of and/or inadequate training and mentoring need to be addressed (Knapke, Henkerson, Tsao, Freel, Fritter, Helm, Jester, Kolb, Mendell, Pretty & Jones 2022:1). Adequate training and mentoring programmes need to replace outdated and fragmented patterns of pedagogy with new technologies, keeping in mind that clinical research professionals are part of a socio-technical ecosystem (power structure, values, communication, rewards, behavioural styles, equipment, capability, and flexibility) (Knapke et al. 2022:5).

According to a White Paper from ACTG (2020:1), the future of clinical trials will include decentralised and hybrid trials, and increased use of technology will impact nearly every role. Existing roles will expand, and technology training needs to be standard practice and written into each site manual and delegation log.

Ughasoro, Musa, Yakubu, Adefuye, Folahanni, Isah, Onyemocho, Chukwu, Chukwudi, Dadi Mamud, Effa, Egharevba, Etokidem, Mbachu, Njokanma, Ogunfowokan, Ohihoin, Onwuamah, Orunmuyi, Salako, Yusuf, Okubadejo, Anepo-Okopi, Ezechi and Salako (2022:215) claim mentoring investigators is not without challenges. Hence, it is imperative to employ methodical strategies for identifying and executing suitable remedies in order to overcome obstacles, including a deficiency in comprehending the mentorship procedure, a scarcity of mentoring capabilities, a prevailing culture of self-centeredness and individuality, and a dearth of formal associations. However, mentoring does have the potential to foster healthy growth and develop a well-trained clinical research workforce.

b.iii) Previous experience

Investigators' tertiary training and work experience often do not prepare them for clinical trials. Stakeholders mentioned that medical school training and previous work experience were inadequate preparation for investigators.

> *"Their medical school training does not give them any experience in how to run a clinical trial"* [Daphne]

> *"I think the new investigators sometimes are relatively junior; they have not managed teams; they come from an environment where they were supervised"* [Verena]

> *"New investigators are completely green. The investigators that have probably worked for longer in a public setting compared to investigators that are much younger when they come in, more green, like they haven't had that much experience in the public sector before doing clinical trials are more amenable to accepting the rules"* [Ann]

A few stakeholders regarded confidence and emotional intelligence as necessary to become skilled leaders. One stakeholder felt strongly that new investigators should be led to self-reflection – they should think about their skills and abilities and where they want to apply them. According to Passmore, Edwards, Sorkness, Esmond and Brasier (2020:4), training programmes have the potential to improve self-confidence and communication skills.

> *"Get more confidence"* [Ann]

> *"Self-reflection"* [Veronica]

> *"Emotional intelligence"* [Verena]

Veronica believed inexperienced investigators need to build their confidence:

"I'd start the day with giving them a sense of confidence in their medicine and I think that is what that six months in a research environment without doing research is meant for" [Veronica]

Underpreparedness is the state of being insufficiently prepared for a given scenario (Merriam-Webster Dictionary online 1996, vs "underprepared"). The insufficient training of medical practitioners in clinical research has led to a situation, as expressed by Duke University's Matthew Roe and the FDA, a phenomenon known as the "one-and-done" situation, where investigators conduct only one study and then discontinue their involvement (Adair 2021:1).

Bastek (2022:1) mentioned that it is hard for potential candidates to learn about clinical research because the US Bureau of Labour Statistics does not recognise it as a primary career path, and there are very few dedicated educational pathways in the field. The same could be said of South Africa. Therefore, new investigators enter the research field without previous clinical research experience. Working in a health or medical field might give investigators specific health and/or disease knowledge, and they might become experts in their field, but previous health or disease knowledge will not equip them for a clinical trial. Several organisations like ACRP and academic institutions have started offering training programmes in an attempt to overcome strict educational and career requirements for job seekers who have not previously worked in clinical research; however, the industry needs to be open to receiving curious, passionate candidates from different backgrounds (Bastek 2022:1). Once they have joined the industry, they need opportunities to grow in knowledge and skills, such as the current study's training programme.

b.iv) Inexperienced investigators make errors

Due to previous experience that most likely did not include knowledge about clinical trials or training and mentoring, new investigators' work was full of errors.

"Their chart notes were sometimes terrible" [Verena]

"They learn more when they make mistakes. They don't see the need for it, they focus mainly on the clinical aspects of it and then if they make mistakes then

there's repercussions, then they start oops maybe I should have done it correctly" [Ann]

"The big one is the medical notes of patients. They can't just write short notes; scanty notes, you have to remember, if you haven't written it down, it never happened. They need to be very clear" [Reba]

The US FDA's routine and "for cause" inspections revealed a failure rate of 36% over the past five years. The FDA has found failures in these inspections include failure to follow the investigational plan (protocol) (51%), inadequate and inaccurate records (33%), inadequate drug accountability (7%), failure to obtain and/or document subject consent (5%), and inadequate informed consent forms (4%). Inadequate and inaccurate records are the second-most prevalent failures in the FDA findings and focus specifically on record-keeping; an example of this failure is a missing or incomplete subject record. Investigators are part of the clinical trial professionals guilty of causing inadequate and inaccurate records (Top 5 Trial site 2022:1; Rizvi 2019:6).

The FDA's findings reflect those of the Clinical Research Associates (CRAs) who monitor clinical trials' site files. Frequent errors are observed in clinical trial documents at clinical trial sites during monitoring visits (Jung, Kang & Kim 2021:3).

c) The nature of clinical research

The nature of clinical trials is often characterised as overwhelming for investigators entering the clinical trial field. Time-consuming, budget-restricted clinical trials worsen the situation, and investigators do not see a clear career path.

c.i) The concept and scope of clinical research

Understanding the concept and scope of clinical research will illuminate the nature of clinical trials. Financial management forms part of the scope of a clinical trial. How to manage a budget is not the only concern of an investigator, but also obtaining grants and funding for clinical research.

"*I will say the thing I primarily do um is to initiate a trial and the thing about the investigator role is that raising money is so much harder than a doctor…you're working like a dog to put in an application"* [Charlene]

Lack of funding and long-term dedication were inherent challenges of clinical trials. Moreover, stakeholders mentioned that being an investigator was an overwhelming experience for some new investigators. Investigators often cannot see the bigger picture on entering the clinical trial arena, and therefore, their career paths within clinical trials are blurred.

"Early investigators are not compelled to think of research as a career. There is no stated down path about what research as investigator was going to be like and what I should be doing and accomplish" [Veronica]

"I think the other thing that is always surprising is that how long it takes to get a study from ideas to publication" [Charlene]

"Sometimes they go on the GCP training, they come back and they are so overwhelmed. But what came to my mind now based on own experience, when you have an inexperienced investigator that I have worked with, a course like this will be relevant and hopefully help them to know for the future as well if they are going to stay in clinical trials because they often say they just got thrown into the deep end and maybe we can keep more of them. If they have a better basis because there is not such an enthusiasm for a lot of these people to stay, they come and go, the turnover is a lot for new investigators, it's a struggle to retain them" [Verena]

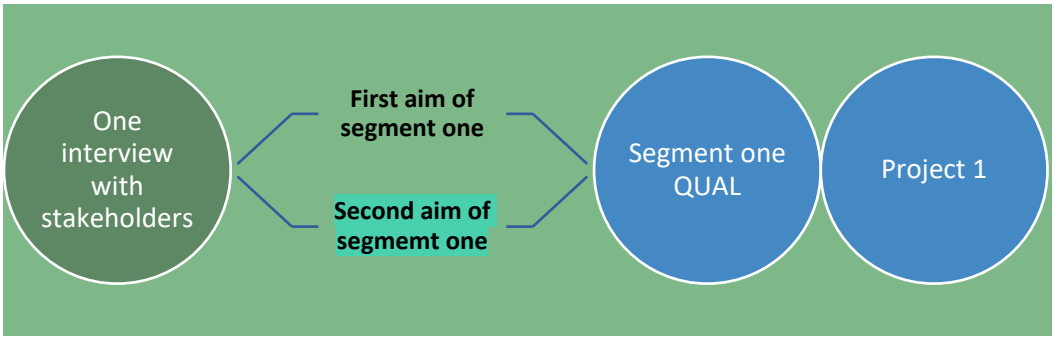
Before the COVID-19 pandemic, clinical trials took years to complete and escalated exorbitant costs with limited generalisability (Gaba & Bhat 2020:673). Although more innovative methods for sponsoring clinical trials became available during the COVID-19 pandemic vaccine studies, funds for other areas of medical research have remained tight (Sathian, Asim, Banerjee, Pizarro, Roy, van Teijlingen, Borges do Nascimento & Alhamad 2020:882).

In addition to being green and trying to find their place in a clinical trial team, investigators need to navigate their way through burdened administrative tasks, cumbersome paperwork, complex protocols, new technology, setbacks from the pandemic and lack of mentoring and support by senior staff and the sponsor (Georg, Evers & Flanagan 2022:1). The literature provides much information on the barriers clinical investigators need to overcome, especially in developing countries (Khoja, Kazim & Ali 2019:294; Alemayehu, Mitchell & Nikles 2018:1; Rouse 2022:1).

Findings from the first aim of the QUAL segment of Project 1 were considered while developing the inclusive clinical trial research education programme. Investigators' lack of clinical trial research was addressed, irrespective of their previous research experience. The Moodle platform created an opportunity to incorporate some motivational and inspiring articles and videos. Assignments aimed to build participants' self-confidence, knowledge, and skills, and they were given time to reflect.

4.6.3 Description of the findings of the *second aim* of segment one (QUAL) Project 1

Table 4.6 summarise the themes, categories, and codes as they emerged from the data analysis. Diagram 4.4 shows the layout of the data collection process.



Schematic diagram 4.4: Layout of the data collection process

Stakeholders' perspectives of what a clinical trial research education programme should consist of varied. Some stakeholders thought new investigators should know everything about clinical research. In contrast, other stakeholders felt some topics should be covered by only mentioning the topics.

Most stakeholders mentioned specific training topics important to them. However, Veronica commented that what kind of training and education new investigators require is a topic that is still unanswered by her:

> *"That's been a question that has been going through our minds for many years. And we still don't have an answer. I don't have a good answer for you"* [Veronica]

Verena commented, likely from her own experience, that clinical trial education is a case of on-the-job learning, and some investigators have the fire in the belly while others just never "get it":

> *"But I think it is on the job learning. They can go on courses and you can give them the foundation and then they need to be keen to learn and try new things you know. Some people are really keen and other people just hate clinical trials"* [Verena]

Brenda commented that it is not necessary for investigators to know all topics in detail, but they should have a perspective of the bigger picture of what clinical trials are about:

> *"I think just the whole, big picture; that's what so great about the competency framework; is the depth and detail that you have to know about; you don't have to know about data informatics or regulatory science, but you need to understand how all the pieces fit together so that you can be effective in your role…it was such a great resource to have the joint taskforce framework, it make things so much easier because we can start translating that as we have into different role"* [Brenda]

Conversely, Daphne, Vivian and Verena felt that investigators should know everything about clinical trials:

> *"Everything, I'd like to say everything. Their medical school training does not give them any experience on how to run a clinical trial. Just to understand clinical trials, time management, in the sense that you have a start-up period, recruitment period."* [Daphne]

> *"I think for me it's useful to understand everything about being an investigator"* [Vivian]

"So that like a big jigsaw puzzle is a clinical trial with a lot of pieces and if you are an investigator of a site and you are waiting to become the PI one day and you are managing a team, I think you need to know everything from A to Z of that clinical trial" [Verena]

Table 4.6: Summary of themes, categories, and codes, aim two, segment one Project 1 (QUAL)

THEME	CATEGORY	CODE
1. Clinical trial management	1.1 Regulatory	1.1.1 The regulatory process of how to make an application to ethics, and SAHPRA 1.1.2 Little understanding of regulatory
	1.2 Financial management	1.2.1 Budgeting 1.2.2 Grants 1.2.3 Feasibility
2. The clinical trial process and study operations	2.1 Data management	2.2.1 Data flow 2.2.2 Dealing with data 2.2.3 Dealing with data queries 2.2.4 Design study documents 2.2.5 Essential documents for the study
	2.2 Protocol	2.3.1 Protocol design and implementation
	2.3 Quality management	2.4.1 QA and QC 2.4.2 Monitoring 2.4.3 Audits 2.4.4 Inspections
	2.4 Investigational Product Management	2.5.1 Investigational product handling and storage
3 Role as sub-investigator	3.1 Ownership/Accountability	3.1.1 Take more ownership
	3.2 Responsibility	3.2.1 Oversight 3.2.2 Management 3.2.3 Leadership 3.2.4 Communication 3.2.5 Teamwork

THEME	CATEGORY	CODE
		3.2.5 Professionalism 3.2.6 Workplace interaction
	3.3 Participant safety	3.3.1 Reporting AEs 3.3.2 Reporting SAEs 3.3.3 Confidentiality

4.6.3.1 Themes, categories, and codes

The findings revealed three themes, namely (1) clinical trial management; (2) the clinical trial process and study operations; and (3) the role of the sub-investigator. These main themes, with related categories and codes, will now be discussed along with verbatim quotes. Direct quotes are provided in *italics.*

a) Clinical trial management

Stakeholders mentioned a few topics related to clinical trial management. Several stakeholders agreed that the regulatory aspect, which includes the application process to regulatory authorities and maintaining the site investigator files, is an important training point. Some stakeholders felt there was not enough transparency around the financial aspects of a clinical trial.

a.i) Regulatory

A full application to conduct a clinical trial must be prepared and sent to the ethics committee and, where applicable, SAHPRA. Most stakeholders believed new investigators should receive the necessary information outlining the application process. Stakeholders also suggested that new investigators should know where to find all the essential documents and how to maintain the files (regulatory files) containing all the essential documents.

> *"So regulation was big, seriously. I feel, and they, need a separate whole day training session on regulations"* [Ann]

> *"They also have very little understanding of regulatory"* [Veronica]

"They have no clue about the amount of documents that are required to get to the Ethics committee and to our regulator, to SAHPRA. I think definitely that to be included in the course that they know about regulatory. I mean sometimes these new investigators didn't know about a trial master file or what the investigator site file is and they actually need to know about all of these documents" [Verena]

The ethical conduct of a clinical trial entails much more than getting informed consent from a participant. An investigator needs to know how to apply the principles of the Declaration of Helsinki, GCP and country-specific guidelines (SA GCP 2020). Therefore, before any clinical trial can start, it will be reviewed and approved by an independent ethics committee and, where applicable, SAHPRA. The ethics committee and SAHPRA will provide continuous oversight during the trial's conduct.

a.ii) Financial management

Some stakeholders in the current study believed new investigators should only be briefly introduced to the financial aspects of a clinical trial, while others felt new investigators should know from the start how to manage the study budget and apply for grants and funding.

"As a PI, the biggest thing that you do is run a budget, how the money and cost reimbursement work that was very hard to understand that you don't have upfront money and like your sustainability of your site is based on your site performance" [Vivian]

"So having to learn about application writing, about grants writing and putting the understanding that if you don't go out to earn money…ya. I think it is important for them to have an understanding of the financial principles of running a study" [Veronica]

"They need to learn about budgets and applying for grants" [Charlene]

Findings from a study initiated by Lee, Lensing, Botello-Harbaum, Medina and Zozus (2020:3) showed that investigators had a perceived competency of less than 60% in site management, including financial management of the site. Much has been written on the

importance of clinical research and randomised controlled trials, but very little has been said about managing these clinical trials. Failure to manage clinical trials with a structured, practical, business-like approach can result in failing some clinical trials, wasting billions of rands (Farrell, Kenyon & Shakur 2010:1).

According to the JTF framework (2019:3), clinical trial management encompasses content required at the site level to run a study, including site and study operations. The JTF framework outlines the essential skills required for clinical trial management, which include: submitting all necessary regulatory documents, such as informed consent forms and recruitment materials, to an independent regulatory board (IRB) or ethics committee; understanding the fundamental principles of project management and applying them to clinical research projects; familiarising oneself with the applicable guidelines in their country regarding informed consent, drug development and approval, IRBs/ECs, conflict of interest, investigator responsibilities, and sponsor responsibilities; and comprehending the role of IRBs in approving protocols, evaluating risk, and determining exemptions.

Moreover, it is essential for investigators to possess a fundamental comprehension of the medication development and approval procedure and acknowledge the necessity of obtaining approval from the FDA in order to market investigational goods in the United States. It is necessary for them to oversee the maintenance of the investigation product (IP) tracking log, case report forms (CRFs), and have a thorough understanding of the investigator brochure (IB) or device instructions. To perform a study at a location using a new possible protocol, investigators must have a clear understanding of the study-related requirements, including the availability of a specific study population. They must organise study visits and requisite labs using the correct requisition and account numbers for the study and be able to track and reconcile those documents. Investigators must clearly state any factors that could jeopardise a key performance metric and propose measures to minimise the likelihood of such occurrences. Additionally, they need to specify the specific documents and methods utilised for tracking recruitments and retaining participants. The investigator understands the importance of seeking further guidance to confirm the presence of a materials-transfer agreement before shipping samples from the freezer to another investigator for a lab-based research endeavour.

Stakeholders only mentioned some of these competencies; in fact, very few, as outlined by the JTF framework. It could be that stakeholders themselves did not have a clear

picture or understanding of the clinical trial management process, or it could be that they highlighted those essential competencies, or in their mind, they have categorised it somewhere else within the clinical trial process.

b) The clinical trial process and study operations

Study operations form the "how to run a clinical trial daily". Most clinical research professionals, such as investigators and clinical research coordinators, gradually transition to managers of their respective studies. Although the operational side of a clinical trial could include several aspects, most stakeholders were concerned about managing the data of a clinical trial, the importance of essential documents, quality management of data, and the handling of the IP.

Stakeholders explicitly described what is expected of and what competencies investigators should develop to run a clinical trial.

b.i) Data management

Data integrity is one of the pillars of GCP, and although acknowledged by investigators, they do not always understand the full scope of data management. Investigators often focus only on the part they fulfil and do not have a complete picture of data management. Knowing how to create and complete different essential documents was regarded by most stakeholders as a requirement for new investigators:

> *"ICF design and document design. Data management, source documentation"* [Daphne]

> *"I think also per study to be aware of what needs to be documented specifically so you know whether you have to make a note on the source notes, I suppose be very careful how you complete the source notes. So making sure that all the checks are checked and that you haven't left stuff out"* [Ada]

> *"Maybe how to develop other documents, logs and trackers and things like that for the study and often they don't know that; they don't know from the beginning how*

to develop these documents that will be needed in a clinical trial, to develop CRFs and source documentation" [Verena]

Reliable data information will support the results of a clinical trial. It will make it believable to the scientific community (Houston, Probst, Yu & Martin 2018:72). Participant data, captured on source documentation, are transcribed to case report forms to answer all the questions that originated from the study protocol. Essential documents for a clinical trial reflect the processes followed during the clinical trial and the quality of the data produced (SA GCP 2020:51). Essential documents will therefore provide an audit trail for monitoring and auditing a clinical trial.

b.ii) Protocol

Most stakeholders underlined the importance of understanding, knowing, and following the study-specific protocol. Some participants felt new investigators do not need to be able to write a protocol at the start of their career, but they should gradually develop the skill. However, new investigators need to know the layout or design of a protocol and execute the study accordingly.

"Foundational preparation of how research is designed and implemented" [Charlene]

"Need to know how to read and use the protocol, what is important and what is not" [Vivien]

"They need to know how to develop a study design and write a protocol" [Daphne]

b.iii) Quality management

Oversight of the quality of a clinical trial is essential for protecting the safety of trial participants and ensuring data integrity (Vohora & Singh 2018:129). Stakeholders agreed that investigators should know how to ensure quality data:

"I guess the overarching concept of what quality is; is all of the quality by design, quality aspects. How do you build quality into your entire process and not rely on monitoring?" [Brenda]

"We have become arrogant especially at site level at how good we are, but in fact we are not particularly in terms of quality. Investigators should learn to work with the CRA (monitor) and not just see the CRA as mini auditor coming to find things wrong" [Reba]

"You need to go into their details and I think sometimes the investigators ask the basic questions as if they are working in a primary health care clinic. They did not go into more depth about what we need. We write a lot and document a lot, it is important all the documentation. The QC and sometimes they also don't have a good idea of developing CRFs and what information is required in a clinical database" [Verena]

The sponsor of a clinical trial is ultimately responsible for developing a quality management plan and system with input from the trial site. The quality management plan and the system should describe trial procedures, training, quality control (QC), quality assessment (QA) procedures, and retention strategies (Vohora & Singh 2018:129).

b.iv) Investigational product management

According to most stakeholders, new investigators must know about the investigational product:

"You know sometimes I find investigators know nothing about accountability of the IP, the leave it all up to the pharmacist. Need to know about drug accountability and randomisation and blinding" [Verena]

"Understanding of how the IP is meant to be maintained" [Reba]

"For the IP they probably don't have to go into too many detail, just explaining the whole process, maybe the chain of custody" [Ada]

Lee et al.'s (2020:3) findings showed that although investigators are comfortable (80%) with assessing and reporting adverse events, they are much less confident (57.1%) in describing how the investigational product is stored, dispensed, and controlled. The JTF framework (2019:3) defines clinical study operations as the activities involved in managing a study, including identifying and reporting adverse events, conducting post-market surveillance, ensuring drug safety, and managing investigational items. Examples encompass: discerning the study protocol methods to mitigate selection bias in a clinical study, hence ensuring the credibility and validity of the outcomes; Effectively communicating one's role responsibilities and defining the boundaries of one's role in carrying out clinical study activities; explaining the principles outlined in the Declaration of Helsinki and their integration into clinical protocols and application in human subject research to uphold ethical and quality standards. Analysing the disparities in legislation and recommendations between the United States and Europe regarding the development and marketing of experimental medical medicines. The tasks involved include finding and implementing a standard operating procedure (SOP) for receiving, storing, and using investigational products in a clinical study at the research site. This includes correctly classifying adverse events based on sample cases, such as AE, SAE, Serious and Unexpected AE, Adverse Drug Reaction, etc. Additionally, accurately describing the measures in place to protect human research subjects and their privacy according to global, national, and local regulations and guidelines. Participating in local quality assurance audits of clinical studies to prepare for a monitoring visit by a Clinical Research Organisation (CRO). Assisting in the preparation for clinical study audits and understanding the roles of the team during an audit. Lastly, identifying safety issues, developing risk mitigation strategies, and creating action plans for diabetic patients who need to fast for an extended study visit.

It seems stakeholders were more informed about the clinical trial and site operations described by the JTF framework. They also mentioned that new investigators should understand the full clinical trial process involved, from consulting with a participant to data management. Stakeholders mentioned that the investigators should have good protocol knowledge, know how to develop an SOP, know how to do QC, know how to handle the monitor, auditors and inspectors, and know how to manage the IP and develop study documentation. The aspects of participant safety and the management of AEs and SAEs were mentioned under the investigators' role. It could be that stakeholders had their classification of where competencies fit into the clinical trial process, and it did not

specifically correlate with the JTF framework classification of competencies. It could also be that because stakeholders are very involved in the operational side of clinical trials, it was easier for them to mention several operational aspects that should be taken up in the training programme.

c) Role as sub-investigator

Stakeholders considered knowledge about investigators' roles and responsibilities to be a vital contributor to the success of a clinical trial:

> *"What am I getting into…understand that is a big deal. For them to understand the different roles more where they are going to be doing the other roles as well. The overlapping of different roles. So a broad understanding of their responsibility I think for all the roles"* [Reba]

> *"Take ownership of the everything of the study"* [Louise]

> *"If they are working on an investigator driven clinical trial they need to know do their how to lead their staff, hire the correct people for the job, delegate the staff correctly"* [Verena]

Many different skills are necessary to run a clinical trial. Therefore, a clinical trial team consists of experts and might include a PI, sub-investigators, study coordinators, study nurses, counsellors, data managers, and pharmacists (NIH-NCI 2022). The clinical trial team works towards a common research goal, and individuals understanding their roles and those of other team members will contribute to reaching the research goal (Sampat 2022:1).

c.i) Ownership/Accountability

According to SA GCP (2020:20) guidelines, the investigator assumes responsibility for the proper conduct of the clinical trial and will therefore be held accountable. Investigators should take ownership of their study to execute their responsibility. Very few stakeholders touched on ownership and accountability:

"Well I find personally that if investigators would take more ownership of everything of the study, they would be more proactive" [Ann]

"I think it is really really important for them to understand their liability and their responsibility because a lot of time they think they can delegate and lose accountability, whereas they need to be accountability; simple things, they take a lot of short cut; we never take shortcuts. They really need to understand well in terms of their responsibility" [Reba]

c.ii) Responsibility

Stakeholders mentioned they are not skilled in the softer skill domains:

"Training on how to manage staff" [Daphne]

"We learnt…it's the softer skill domain; it's the professionalism and leadership, teamwork, and communication. How do I ensure appropriate oversight and delegation of my team? How do I ensure they receive the proper training? How do I lead them and help them priories or address issues?" [Brenda]

Different aspects of communication skills were mentioned by stakeholders and varied from communication with the media to participants and the community:

"Staff management, HR management. Presentation skills and media training. Sponsor requirements and rules. A communication plan. Learn to respect the community" [Daphne]

"The investigator must have the right mindset of how not only to deal with the staff but also with the participants" [Verena]

Sonstein and Jones (2018:14) described some skills investigators should have under leadership and professionalism. Skills include managing clinical trial teams, setting strategic planning goals, training and mentoring staff, and communication skills. Stakeholders agreed with Sonstein and Jones (2018:14). According to the competency domains Sonstein and Jones (2018:17) described, investigators should be able to

communicate effectively what the clinical trial was about and the relevance of the findings. Results are often disseminated to the scientific and non-scientific community through articles for publication.

Only one stakeholder believed new investigators should know how to write for publication. Most participants felt that how to write for publication should be a complete module to train more established investigators.

> *"Writing skills for publications"* [Daphne]

Investigators should also communicate through meetings, according to Verena:

> *"So also train the new investigators to have meetings and also emphasise to them that they are the ones ultimately that need to retrain the team if necessary. So I think it is very important that they have those leadership skills; that they learn how to lead their team and get everyone working together on the protocol"* [Verena]

However, all said, the investigators' responsibilities include the full clinical trial cycle, as explained by Louise:

> "*I think it would be very good if they can see exactly how a patient is done from the informed consent, the physicals, everything and how is Adverse Events reported, how it is captured, how is the medication dispensed, if they can attend the briefing after the monitor been to the site, budgeting, grant writing, feasibility"* [Louise]

c.iii) Participant safety

The SA GCP (2020:28) guidelines outline the investigator's responsibilities regarding the safety of participants in a clinical trial. These guidelines stress the importance of reporting all safety-related issues to the sponsor and regulatory authorities.

Due to the weight that protecting the safety of trial participants carries, all stakeholders recommended that investigators receive a thorough education on all aspects of participant safety:

"How you manage the clinical team, the results process and then the result dissemination process. Short course on EAEs and SAE reporting. Selecting people to work on the team Respect the community. SAHPRA guidelines, who can be an investigator. Any training on audits and inspections" [Daphne]

"Sponsors have different requirements for EAE and SAE reporting, so I think clear guidance per study for each" [Ada]

"The other thing for me, very important is safety reporting. You could give them some guidance on what they need to put in the safety report, in the six monthly safety report" [Verena]

Understanding the foundational science behind a clinical trial, developing a protocol, and following a protocol will enable any investigator to conduct a clinical trial successfully. However, scientific thinking needs to be supported by professional skills (Calvin-Naylor, Jones, Wartak, Blackwell, Davis, Divecha, Ellerbeck, Kieburtz, Koziel, Luzuriaga, Maddox, Needler, Murphy, Pemberton, Radovich, Rubinstein, Selker, Tenaerts, Unsworth, Wilson, Wright, Barohn & Shanley 2018:22). Professionalism is the ability to apply the principles of leadership in managing a clinical trial team. Investigators should be able to follow ethical codes and professional guidelines during a trial. The ability to work within a multidisciplinary and interprofessional team will guarantee the success of the clinical trial and ensure good communication. Communication skills can create a positive relationship with participants and improve participant care and, ultimately, the quality of health services (Mata, de Azevedo, Braga, de Medeiros, de Oliveira Segundo, Bezerra, Pimenta, Nicolás & Piuvezam 2021:1).

Domain 8 of the JTF framework (2019:4) focuses on communication and collaboration. It includes all aspects of communication within the site and between the site, sponsor, CRO, and regulators. It also emphasises the importance of understanding teamwork skills required for performing a clinical trial. Examples include: determining adverse events that meet the specific criteria to be classified as 'serious'; comprehending the reporting obligations for various types of adverse events; explaining the role of an investigator as outlined in FDA 1572 and the transfer of responsibilities from sponsor to a CRO; understanding the rationale behind the inclusion and exclusion criteria for women capable of bearing children in a clinical study; comprehending the professional roles and clinical

practice domains of all individuals in the clinical study team; identifying and acknowledging each team member and their specific roles and responsibilities; and recognising the importance of effective communication within the clinical study team for the study's success.

The interviewed stakeholders, in most cases, did not receive formal training in clinical trial research. They mainly had to learn on the job with some support from senior staff and the sponsor. They were, therefore, unfamiliar with the JTF competency framework.

Findings from the second aim of the QUAL segment Project 1, namely to understand stakeholders' perspectives of what a clinical trial research education programme should consist of, were incorporated during the clinical trial research education programme's development.

4.7 SUMMARY

Chapter 4 described the data collection and analysis processes and findings of the first segment of Project 1. Segment one represented the situation analysis and was qualitative in nature. Interviews with stakeholders were described, and the themes that emerged from second-cycle coding during the first segment of Project 1 were incorporated during the developmental phase of the inclusive clinical trial research education programme. Chapter 4 formed part of the MRC framework's development phase. The next chapter discusses the development and validation of the inclusive clinical trial research education programme.

CHAPTER 5
PROJECT 1: DEVELOPMENT AND VALIDATION OF THE INCLUSIVE CLINICAL TRIAL RESEARCH EDUCATION PROGRAMME

5.1 INTRODUCTION

This chapter discusses the second and third segments of Project 1, namely developing and validating the inclusive clinical trial research education programme before implementation (see Table 5.1). I first discuss the programme's development, followed by teaching approaches and methods, the delivery format, the programme description, the programme curriculum, and stakeholders' validation of the education programme. The research questions, 'What should an inclusive clinical trial research education programme for investigators in health sciences consist of' (context), and 'What are specialist stakeholders' views of the clinical trial research programme before implementation' are addressed.

Table 5.1: Chapter 5: Research progress

Chapter	Content
1	Orientation to the study
2	Literature review (1) Clinical trial education (2) Competency-based education (3) Self-efficacy (4) MRC framework
3	Research design and methods
4	Project 1 Research design, data collection, data analysis and results (First segment: situation analysis - qualitative)
5	Project 1 Development and validation of the inclusive clinical trial research education programme (Second and third segments)
6	Project 2 Research design, data collection and implementation of the intervention
7	Project 3 Research design, data collection, results, and evaluation of intervention
8	Summary of integration of findings, conclusion, recommendation, contribution and limitations of the study

5.2 DEVELOPMENT OF A CLINICAL TRIAL RESEARCH EDUCATION PROGRAMME

Oerman, de Gagne and Phillips (2018:309) emphasise that curriculum development is rooted in an educational philosophy that assists in answering value-laden questions and choices related to the purpose of education, the role of the clinical trial research students, the role of the teacher, and the teaching and learning process. As a developer and teacher of the inclusive clinical trial research education programme, I first had to note my philosophy of education before selecting a programme philosophy.

5.2.1 Personal philosophy

My philosophy of education is that all clinical trial research students are unique, and my moral obligation is to enter into a partnership with my clinical trial research students while I hold each student to the highest expectations. I strive to create an environment that offers a supervised exploration and integration of classroom clinical scenarios and subject knowledge. The most significant learning occurs in meaningful, realistic, practical and relevant situations (Cox 2023:1). An environment must be created where clinical trial research students can use their knowledge and skills; the best way is through small groups or one-on-one teaching in the relevant setting. However, I firmly believe the student must assume substantial responsibility and actively approach learning.

I strive to be non-judgemental, enthusiastic, flexible, open-minded, consistent, diligent, and warm, and I have a positive attitude while interacting with clinical trial research students. At the same time, I believe in-class sessions should provide a safe community where they can speak their minds. Learning is a lifelong process, and I believe I can learn from my clinical trial research students, colleagues and the community, and that my philosophy might change over time as I grow as an educator and human.

The developed education programme strives to incorporate practical learning experiences (through assignments) with students' knowledge based on self-reading and in-classroom sessions. The curriculum for the programme reflects the collaboration between me, the educator, and the clinical trial research students to replace a lack of knowledge around clinical trial research with the necessary knowledge, skills, competency and self-efficacy. This includes the development of a curriculum with well-

reasoned and specific objectives and outcomes for each stage of training and regular fair assessments.

> “Tell me, and I will forget, show me, and I may not remember. Involve me, and I will understand” Native American saying

5.2.2 Programme philosophy

I embrace the constructivist approach to teaching and learning and base my programme philosophy on the constructivist learning theory. Constructivists see clinical trial research students as active participants in the learning journey. Knowledge is therefore constructed based on the clinical trial research students’ experience (Kurt 2021:1). Another essential aspect is the fact that the clinical trial research students will reflect on their experience and incorporate new ideas with their prior knowledge (Kurt 2021:1). The current study’s curriculum required that clinical trial research students take part in classroom and small group discussions, and complete pre-reading material and assignments to develop as intrinsically motivated and independent clinical trial research students. The developed curriculum enabled clinical trial research students to acquire a range of processes and skills, including information retrieval, critical analysis, evaluation, synthesis, reflection, interpretation, inquiry, and knowledge generation in the context of clinical trial research. In line with constructivism, classroom sessions were interactive, promoting the dialogical exchange of ideas among clinical trial research students and between me as a teacher and the students. I facilitated the process according to the curriculum. In-classroom sessions were supported by curriculum material on the Moodle online platform that clinical trial research students could access and interact with.

5.2.3 Theoretical framework

Based on my philosophy of education, this programme is rooted in the principles of the situated learning theory, the andragogy and adult learning theory, single and double-loop learning theory, self-directed learning, and self-regulated learning theory.

5.2.3.1 Situated learning theory

According to situated learning advocates, competency results from cognitive learning processes and occurs because of students' social interaction with their environment, including both human and non-human interactions (Collazo 2016:34). This was especially true in the post-COVID-19 period. The correct balance needed to be struck between, on the one hand, in-person teaching and, on the other hand, technology-driven teaching approaches. This balance was an important aspect that had to be considered during the development of the clinical trial research education programme.

5.2.3.2 Andragogy and adult learning theory

Investigators are viewed as adult clinical trial research students who approach learning as critical thinking and learn best when the subject of instruction encourages confidence. Bechtel, Chuck, Forrest, Hildebrand, Panhuis, Pattee, Comic-Savic and Swezey (2020:1) recommend that educational programmes for clinical research investigators should be developed with adult clinical trial research students in mind. In line with Knowles's (Mukhalalatsi & Taylor 2019) beliefs, Betchel, Chuck, Forrest, Hildebrand, Panhuis, Pattee, Comic-Savic and Swezey (2020:2) suggested that adults need to be ready to learn, they need to know why they must learn specific learning material, they need to learn by doing (experientially), they need training in role-specific skills to apply elements (for example, GCP), they need hands-on application of GCP principles, and they need to move from being motivated extrinsically to intrinsically and from novice to expert. Adults will therefore value training strategies such as contextual analyses, role-playing, simulations, and self-assessments within the role as co-facilitator of their education.

Knowles's ideas on adult learning were evident while developing a mock clinical trial for the clinical research education programme. Participants could select a topic for developing a mock clinical trial and build on topics covered in the classroom each week, providing a scaffolding learning experience. Consequently, new information is added each week, providing participants with information to complete each mock clinical trial segment. Keeping to the features of blended learning, student involvement and peer communication play a significant role in completing the mock clinical trial.

5.2.3.3 Single and double-loop learning theory

The programme incorporates single- and double-looped learning as promoted by traditional scholars of contemporary learning theories related to competency learning and development (Collazo 2016:37). In single-loop learning, the person will follow the rules to ensure things are done correctly, and discovering that things are not going according to plan, they will make changes to mitigate the situation. In double-loop learning, the person will go a step further by changing the rules to change the underlying or root cause of the problem; this process requires self-awareness, honesty and taking responsibility for actions (Smith 2013:1). Action or practice forms an essential component of becoming competent as an investigator. Such a theory is ideal for the new investigator who needs to move from novice to expert. The clinical research education programme allowed new investigators to measure themselves against the competency statement (outcome) using an interval scale (not knowing; knows; know-how; shows how; does). The investigator could make corrections or changes until complete competence or excellence had been reached.

5.2.3.4 Self-directed learning and self-regulated learning theory

Self-directed learning and self-regulated learning are often synonymous. According to Jossberger et al. (in Saks & Leijen 2014:198), self-directed learning may include self-regulated learning but not the other way around. Students have a degree of control in both kinds of learning; however, in self-directed learning, the student directs and defines the learning task, while the teacher will define the student's task in self-regulated learning. Bandura's self-efficacy notion forms part of the personal capabilities and qualities needed for self-directed learning. Other qualities include self-assessment, resourcefulness, planning skills, learning skills, and motivation to learn (Lombardozzi 2021:10). Reaching complete competence or excellence in each of the eight competency domains of clinical research requires self-directed and self-regulated learning from an investigator. The current education programme provides a combination of self-directed learning and self-regulated learning opportunities.

Derived from the theories above, it is clear that adult clinical trial research students need course or programme content combining aspects of seeing, researching and doing. Content in the current study was conveyed through text, such as pre-readings and course manuals, technology, Moodle, and activities, such as small group discussions and assignments.

5.3 CURRICULUM DEVELOPMENT PROCESS

Curriculum development is a systematic process with logical steps and considerations of what, who, how, when and where (Button 2020:5). I now discuss the following steps taken during the development of the educational curriculum: the identification of the need (what), the target audience (who), the intended outcome and objectives (what clinical trial research students will be able to do), the relevant content (what), the methods used to accomplish the intended outcomes (how), and the evaluation strategy for the intended outcome (does it work) (Kotze 2021:195).

5.3.1 Identification of the need (what)

Clinical trial research investigators in health sciences lack the necessary knowledge and skills for clinical trial research. Therefore, the **learning goal** for this study was to provide investigators with the knowledge and skills to develop competency in clinical trial conduct through the clinical trial research education programme.

5.3.2 The target audience (who)

The target audience for this study was medical and non-medical health professionals working as investigators or who aspired to become investigators in clinical trial research.

5.3.3 The intended objectives and outcome (what clinical trial research students will be able to do)

In line with adult learning needs and requirements, clear objectives and outcomes were formulated for the education programme (El-Amin 2020:54).

Programme objectives for this study:

The objectives of the programme are as follows:

- Clinical trial research students develop the ability to understand and use scientific concepts and terminology in clinical research protocol development and effectively comprehend these terminologies in existing research protocols.

- Clinical trial research students demonstrate a clear understanding of ethical and participant safety considerations.
- Clinical trial research students gain valuable insight into investigating product development and the regulatory requirements for the approval of clinical research.
- Clinical trial research students learn key issues in the operations of a clinical trial and the responsibilities related to conducting clinical research with human participants.
- Clinical trial research students gain knowledge about study and site management.
- Clinical trial research students gain the ability to develop study-related essential documents.
- Clinical trial research students understand data accuracy and integrity when completing or using any essential documents.
- Clinical trial research students learn about monitoring, auditing and inspection visits from the sponsor and the different authorities.
- Clinical trial research students gain insight into the role of each study (team) member and how tasks could be delegated to accomplish daily study activities.
- Clinical trial research students become familiar with various communication methods and tools to facilitate efficient teamwork.

Programme outcome - on completion of the educational intervention, clinical trial research students should have:

• The capacity to identify potential compliance concerns (Domain 1-6)

• Comprehension of safety terminology and regulations regarding safety and risk reporting (Domain 3)

• Proficiency in comprehending the staff training and educational prerequisites, as well as the capability to accurately execute assigned responsibilities (Domains 1 & 3)

• Capacity to communicate proficiently using various techniques and addressing obstacles to guarantee proper supervision and adherence of personnel to trial procedures (Domain 4)

• A comprehension of the procedure for evaluating the practicality and amount of labour required for a task (Domains 1 & 2)

• The capacity to assess the causality and severity of adverse events in the absence of a Principal Investigator (Domain 2)

• Proficiency in understanding safety reporting schedules and procedures, and the capability to adhere to all safety reporting obligations (Domain 3)

• The capacity to assess and modify participant treatment/medical care in the event of a principal investigator's absence (Domain 4)
• Proficiency in comprehending and effectively executing informed consent (Domain 1)

5.3.4 Learning outcomes for each of the eight domains

Learning outcomes for all the sessions covering the eight domains are described starting at session 0, which acted as a background and reflection session.

5.3.4.1 Session 0

On completion of session 0, the clinical trial research students should have:
1. background information on past and present clinical research investigator training and clinical trials; and
2. an understanding of own reasons for being a clinical research investigator.

5.3.4.2 Session 1 Domain 1

On completion of session 1, the clinical trial research students should have:
1. acquired knowledge and skills in the development of a protocol for a clinical trial; and
2. developed the ability to understand and use scientific concepts and terminology in clinical research protocol development and comprehend these terminologies in existing research protocols effectively.

5.3.4.3 Session 2 Domain 2

On completion of session 2, the clinical trial research students should be able to:
1. describe the various methods by which safety issues are identified and managed;
2. understand different types of adverse events, adverse event management and reporting;
3. understand a) the importance of protecting the safety of the participant, b) reviewing, assessing and managing participant laboratory test results;
4. complete a serious adverse event form for submission; and
5. comprehend the necessity of obtaining informed permission from individuals participating in research and the fundamental principles and contents of the essential

documents that safeguard the rights and well-being of human participants in clinical research.

5.3.4.4 Session 3 Domain 3

On completion of session 3, the clinical trial research students should be able to:

1. supervise the coordination of a protocol amendment for approval by the regulatory authorities;
2. understand the application process for ethical/regulatory approvals;
3. understand other relevant approvals, for example, DoH and SANCTR;
4. manage contracts and sponsor agreements, transfer agreements;
5. develop a clinical trial budget;
6. understand the grant application process; and
7. identify, verify and maintain essential documents for the site investigator files.

5.3.4.5 Session 4 Domain 4

On completion of session 4, the clinical trial research students should be able to:

1. determine if a new clinical trial will be feasible to conduct at their site;
2. enumerate the primary regulations and guidance materials pertaining to the duties of a clinical investigator.
3. determine the fundamental components of investigator accountability as outlined in the International Council for Harmonisation (ICH) and the South African Good Clinical Practice (GCP) guidelines.
4. explain the requirements for investigator supervision in a clinical trial;
5. assess the resource needs for conducting and supervising the trial in terms of finances and staff workload by utilising a trial budget and evaluating staff capabilities.
6. have methods and formulas to project recruitment targets for a clinical trial;
7. develop strategies for recruitment and retention at their site; and
8. have knowledge of delegating and overseeing the management of the IP.

5.3.4.6 Session 5 Domain 5

On completion of session 5, the clinical trial research students should be able to:

1. determine and improve clinic flow;

2. design an overall operational plan for the clinical trial using a Gantt chart (project management);
3. track the clinical trial's progress using tracking tools or software, and measure these against planned objectives and targets;
4. fully understands the clinical trial process;
5. screen and enrol participants in a clinical trial;
6. understand the application of inclusion and exclusion criteria and evaluate participant eligibility criteria to ensure safe and appropriate inclusion of participants;
7. randomise participants in the trial;
8. monitor enrolment progress to ensure timely and complete enrolment through an evaluation of progress reports, team discussions, etc;
9. perform study visits with participants, guaranteeing their well-being and security;
10. conduct, record and review clinical assessments according to the protocol, sponsor regulatory and GCP requirements;
11. attend study initiation and close-out visits to demonstrate supervision in accordance with sponsor/CRA/institutional protocols;
12. prepare and manage monitoring visits from the sponsor, including how to respond to and resolve findings from the monitor; and
13. prepare for audits and inspections (for sponsor, FDA, SAHPRA and EMA audits/inspections).

5.3.4.7 Session 6 Domain 6

On completion of session 6, the clinical trial research students should be able to:

1. describe the role that data management and statistical reviews serve in clinical trials;
2. describe the normal flow of data throughout a clinical trial;
3. develop a clinical quality management plan for their study;
4. plan and translate the quality management plan into pragmatic SOPs;
5. ensure data integrity by overseeing data collection, correction (cleaning) and reporting procedures throughout the trial;
6. contribute to the enhancement of quality management systems for the study by applying them to data processes, including monitoring safety data and verifying database requirements;
7. apply knowledge to review and address monitors' findings according to GCP/protocol guidelines on time to ensure data integrity; and

8. possess expertise in computer programmes and understand the significance of information technology in the process of gathering, recording, and overseeing clinical trials.

5.3.4.8 Session 7 Domain 7

On completion of session 7, the clinical trial research students should be able to:

1. explain the fundamental concepts and methods of leadership, management, and mentorship, and implement them in the workplace;
2. establish and execute protocols to prevent or address ethical and professional conflicts that may arise during the execution of clinical research;
3. assess the staff's credentials based on their training, education, and experience to determine the suitable allocation of study-related responsibilities;
4. ensure all staff are adequately trained to perform delegated tasks;
5. identify team member expertise to solve complex clinical trial issues;
6. describe the impact of cultural diversity and the necessity for cultural competency in the planning and execution of clinical research;
7. oversee tasks that were delegated to staff to ensure accuracy, completeness and consistency; and
8. effectively manage many tasks and prioritise conflicting deadlines, requirements, and requests from colleagues and stakeholders.

5.3.4.9 Session 8 Domain 8

On completion of session 8, the clinical trial research students should be able to:

1. comprehend the significance of collaboration in the execution of trials and acquire the skills to effectively function in a diverse and interdisciplinary team;
2. develop a communication plan for their clinical trial to circulate information among trial staff and to key stakeholders (including dissemination of results);

3. ensure consistent and efficient contact with team members during the trial using several communication methods such as team meetings, email, shared drives, voice communication, and WhatsApp;

4. comprehend distinct and fluctuating reporting prerequisites for heterogeneous entities; and

5. elucidate the components of a conventional scientific publication.

5.3.5 The relevant content (what)

A competency-based curriculum was chosen to support students in developing knowledge and skills related to clinical trial research. Clinical trial research students' learning styles were supported so they could master the competency domains, such as the execution of a clinical trial (Kotze 2021:192).

The eight competency domains used as a framework for curriculum building are illustrated in the schematic diagram.

Schematic diagram 5.1: Competency domains for the clinical research professionals

The clinical trial research education programme curriculum included the following topics:

1. Scientific Concepts and Research Design. *Encompasses understanding of scientific principles pertaining to the development and evaluation of clinical trials* (Competency domain 1)
2. Ethical and Participant Safety Considerations. *This encompasses the provision of medical treatment to patients, the implementation of measures to protect human subjects, and the assurance of safety during the execution of a clinical trial.* (Competency domain 2)

3. Product Development and Regulation. *Encompasses understanding of the process and regulations involved in the development of experimental products.* (Competency domain 3)
4. Clinical Trial Operations. *Includes the management of several aspects of study, such as detection and reporting of adverse events, post-market surveillance, pharmacovigilance, and the handling of experimental product.* (Competency domain 4)
5. Study and Site Management. *This includes the necessary content at the site level to manage a study, including financial and human elements. Encompasses activities related to the running of the site and the study, excluding regulatory and Good Clinical Practise (GCP) aspects.* (Competency domain 5)
6. Data Management and Informatics. *The term "data management" refers to the process of acquiring and handling data in a clinical study. This includes activities such as collecting source data, entering data, addressing queries, ensuring quality control, making corrections, and establishing a finalised database.* (Competency domain 6)
7. Professionalism and Leadership. *Encompasses the fundamental ideas and practical application of leadership and professionalism in the field of clinical research.* (Competency domain 7)
8. Communication and Teamwork. *Encompasses all aspects of communication occurring within the site and between the site, sponsor, CRO, and regulators. Comprehension of the essential teamwork qualities required for performing a clinical researc..* (Competency domain 8)

5.3.6 The teaching approach and methods used to accomplish the intended outcomes (how)

I decided to use a blended-learning approach to promote an environment of collaboration between myself as a facilitator and the clinical trial research students, and among clinical trial research students through social interaction (Setiawan, Putra, Sujalwo & Cahyo 2020:53; Jackson 2018:146; Westerlaken et al. 2019:7).

5.3.6.1 Blended learning

Blended learning, described by Janse van Rensburg and Oguttu (2022:285) as a techno-pedagogical innovation, holds the advantage of educators creating a deepened learning experience by selecting the right combination of classroom and online approaches. I strived to overcome the weaknesses of traditional and digital learning by combining various learning approaches, delivery methods, teaching models and learning styles to bring unity between face-to-face and digital learning (Sabah 2020:875; Setiawan 2020:33; Sandanayake 2019:1). The blended-learning curriculum for the current study therefore consists of in-class, face-to-face sessions and online course work. It includes pre-reading, assignments, quizzes, videos, and classroom lectures with PowerPoint presentations or group work. The different media methods create a dialogue between me, the educator, and the clinical trial research students (Setiawan 2020:33; Sandanayake 2019:1). Studies by Stanford, Tennessee, Moratuwa and Auckland Universities (Mirmoghtadaie, Kohan & Rasouli 2020:206; Sandanayake 2019:14; Jowsey et al. 2020:9) found that students preferred blended-learning mechanisms over traditional approaches, that clinical trial research students were supported in active learning, that study material was more purposefully and effectively conveyed, and that blended learning was, therefore, a more effective educational method.

5.3.6.2 Features of blended learning

Online and classroom social interaction through small group activities increased motivation and collaborative learning, and were used throughout the current education programme (Westerlaken et al. 2019:5). Active learning required my full involvement and authentic, stimulating learning material to make the teaching practice effective (Jowsey et al. 2020:2). Crucial to this study (the development of a clinical trial education programme) are the findings mentioned by Suwannaphisit, Anusitviwat, Tuntarattanapong and Chuaychoosakoon's (2021:1) comparison study between traditional and blended learning. The authors found blended learning has the potential to improve clinical competencies and could be cost-effective when used frequently for multiple target groups after initial development (Suwannaphisit et al. 2021:1; Sandanayake 2019:1); another important feature of this study. Selecting the delivery format is an intentional process on the educator's side to ensure an enabling blended-learning environment that could include a learning management system (LMS), media tools, synchronous and asynchronous tools, and multimedia courseware (Koneru 2019:50; Jackson 2018:140).

5.3.7 Delivery method (format)

The delivery format selected for the inclusive clinical trial research education programme combined online and classroom sessions.

5.3.7.1 Online format

The online coursework was done through Moodle, one of the most widely used LMSs in the academic and business world. The attraction of using Moodle for this study lies in its flexibility, easy-to-use interface and modular nature (Saxena & Parekh 2019:137; Jackson 2018:141; Quansah & Essay 2021:419). The LMS could be regarded as the course hub or centre where the course is administered and managed, resources are developed and integrated, and communication and discussion happen (Koneru 2019:50). The attraction to using the Moodle platform for this study was a free, open-source virtual learning environment that made marrying traditional and digital training easier (Saxena & Parekh 2019:137; Jackson 2018:141; Sabah 2020:3; Quansah & Essay 2021:419). I could access and upload course material such as video and audio clips, PowerPoint slides, assignments, evaluations, quizzes and topics for discussion groups (Koneru 2019:50; Sandanayake 2019:4; Quansah & Essay 2021:419).

5.3.7.2 Features of Moodle

Small or large groups of students of all ages can use Moodle anytime and anywhere through a digital connection (Saxena & Parekh 2019:137; Sabah 2020:3; Quansah & Essay 2021:419). Engagement provides opportunities for students to participate in group and peer discussions or even initiate talking points with the educator and/or co-clinical trial research students (Sabah 2020:3; Quansah & Essay 2021:419). The educator can choose between a range of unique learning methods such as gamification, mobile learning, flipped classroom, distance education (essential for this study), and competency-based education to enable a blended approach (Saxena & Parekh 2019:137; Quansah & Essay 2021:419). Moodle also provided the educator with the means to add readable material to the course module in the form of a text and/or web page, a link to anything on the web, a label that displays any text or image, and a view of the course directories (Jackson 2018:142). Moodle's interactive capability enables real-

time feedback to students; it can track and record clinical trial research students' progress, it has several testing and assessment tools, and it can include assignments, journals, lessons, quizzes, forums, chats, Wiki's and glossaries (Jackson 2018:141; Quansah & Essay 2021:419). Data integrity is secured and maintained through a sign-in feature, providing controlled access to Moodle (Jackson 2018:145).

Sabah (2020:13) reported that the continuous use of blended learning using Moodle had a significant positive effect on students' self-efficacy, perceived usefulness, and perceived behavioural control. Another study by Luo, Cheng, Wang, Zhang, Zhu, Yang and Liu (2017:1), on blended learning and the use of Moodle in medical statistics, found that it had a positive effect on students' knowledge, attitudes and practices related to e-learning and learning outcomes. Moreover, blended learning using the Moodle platform is a good option for the implementation of other curriculums. Quansah and Essay (2021:427) determined that students found the introduction of Moodle in their learning useful for theory; however, clinical trial research students preferred the hybrid teaching mode for practical aspects of the teaching.

5.3.7.3 Classroom sessions

Clinical trial research students attended in-class lecture sessions every eight weeks. The classroom sessions and the education programme's implementation are discussed in Chapter 6.

Table 5.2 summarises the assessment schedule for the clinical trial research education programme. The assessment schedule was uploaded to the Moodle platform to inform students about the topic of each module, the programme work, and assignments expected from them, the due date of the assignments, and the learning outcome of each module.

Table 5.2: Assessment schedule

Week	Session	Topic	Programme work	Due	Learning outcome
1	**0**	Pre-assessments	Connect with Moodle to retrieve pre-reading work.	Must be completed prior to the beginning of session 1	On completion of session 0, the clinical trial research students should have: 1. background information on past

Week	Session	Topic	Programme work	Due	Learning outcome
					and present clinical research investigator training and clinical trials; and 2. an understanding of own reasons for being a clinical research investigator.
1	**1**	Domain I – Scientific Concepts and Research Design	Read Module 1 of the Clinical Trial Research Manual (CTRM) Read compulsory pre-reading on Moodle Complete assignment 1 after in-class session 1 and before in-class session 2 After the group has decided who will write different elements of the protocol, instructions for completing the assignment will be given during the in-class session. Assignment 1 instructions: Please complete your section of the protocol as decided during the in-class session. When completed, please upload it on Moodle.	In-class discussion Determine the topic and title for a mock clinical trial. Divide elements of the protocol to be written between delegates.	On completion of session 1, the clinical trial research students should have: 1. acquired knowledge and skills in the development of a protocol for a clinical trial; and 2. developed the ability to understand and use scientific concepts and terminology in clinical research protocol development and comprehend these terminologies in existing research protocols effectively.

Week	Session	Topic	Programme work	Due	Learning outcome
2	**2**	Domain II – Ethical and Participant Safety Considerations	Read Module 2 of CTRM (handed out at session 2) Complete assignment 2 after in-class session 2 and before in-class session 3	In-class discussion Assess, manage, and review participant laboratory values, test results and alerts.	On completion of session 2, the clinical trial research students should be able to: 1. describe the various methods by which safety issues are identified and managed; 2 understand different types of adverse events, adverse event management and reporting;
			Assignment 2 ➢ Use the SAHPRA template (included in the SAHPRA guideline from pre-reading) and complete SAE for mock protocol. ➢ Use the WHC ICF template and develop an ICF for a mock protocol.	Identify an adverse event for a participant in the mock protocol. Discuss management and reporting of the AE. Complete Serious Adverse Event Form Key elements of the ICF. Importance of the ICF process.	3. understand a) the importance of protecting the safety of the participant, b) reviewing, assessing and managing participant laboratory test results; 4. complete a serious adverse event form for submission; and 5. comprehend the necessity of obtaining informed permission from individuals participating in research and the fundamental principles and contents of the essential documents that safeguard the rights and well-being of human participants in clinical research.

Week	Session	Topic	Programme work	Due	Learning outcome
3	**3**	Domain III – Product Development and Regulation	Read Module 3 of CTRM (handed out at session 3) Complete assignment 3 ➢ Assignment 3: amendment application for the mock protocol to SAHPRA ➢ Develop a budget for your mock clinical trial	In-class discussion Identify institutional and regulatory requirements for approval of mock amendment (e.g. Ethics and SAHPRA) Determine items to include when drawing up a budget for their mock clinical trial. Identify essential documents that must be ready in the die Investigator site file for their mock clinical trial.	On completion of session 3, the clinical trial research students should be able to: 1. supervise the coordination of a protocol amendment for approval by the regulatory authorities; 2. understand the application process for ethical/regulatory approvals; 3. understand other relevant approvals, for example, DoH and SANCTR; 4. manage contracts and sponsor agreements, transfer agreements; 5. develop a clinical trial budget; 6. understand the grant application process; and 7. identify, verify and maintain essential documents for the site investigator files.
4	**4**	Domain IV – Clinical Trial Operations (GCP)	Read Module 4 of CTRM Complete assignment 4 ➢ Please complete the feasibility checklist for your mock clinical trial –	In-class discussion Determine the feasibility of the mock clinical trial. Discuss key elements of investigator responsibility	On completion of session 4, the clinical trial research students should be able to: 1. determine if a new clinical trial will be feasible to conduct at their site; 2. enumerate the primary regulations

Week	Session	Topic	Programme work	Due	Learning outcome
			the checklist is available with assignment instructions. Please upload it to Moodle.	(ICH & SA GCP) and the expectations for investigator oversight of a clinical trial. Set up a research team for the mock clinical trial. Predict target recruitment numbers. Develop ethical recruitment and retention strategies for mock protocol. Develop source documentation for screening, randomisation and follow-up visits.	and guidance materials pertaining to the duties of a clinical investigator. 3. determine the fundamental components of investigator accountability as outlined in the International Council for Harmonisation (ICH) and the South African Good Clinical Practice (GCP) guidelines. 4. explain the requirements for investigator supervision in a clinical trial; 5. assess the resource needs for conducting and supervising the trial in terms of finances and staff workload by utilising a trial budget and evaluating staff capabilities. 6. have methods and formulas to project recruitment targets for a clinical trial; 7. develop strategies for recruitment and retention at their site; and 8. have knowledge of delegating and overseeing the

Week	Session	Topic	Programme work	Due	Learning outcome
					management of the IP.
5	**5**	Domain V - Study and Site Management	Read Module 5 of CTRM Complete assignment 5 ➢ Please develop and complete a study start-up tracking tool or timeline using the Gantt chart, an Excel spreadsheet, or any other project management tool. Please lists all the study-specific start-up activities along with the responsible staff. More extensive projects should be broken down into minor activities with timelines for each activity. ➢ Please upload it to Moodle.	In-class discussion Determine clinic flow for the mock clinical trial.	On completion of session 5, the clinical trial research students should be able to: 1. determine and improve clinic flow; 2. design an overall operational plan for the clinical trial using a Gantt chart (project management); 3. track the clinical trial's progress using tracking tools or software, and measure these against planned objectives and targets; 4. fully understands the clinical trial process; 5. screen and enrol participants in a clinical trial; 6. understand the application of inclusion and exclusion criteria and evaluate participant eligibility criteria to ensure safe and appropriate inclusion of participants; 7. randomise participants in the trial; 8. monitor enrolment progress to ensure timely and complete enrolment through an evaluation of progress

Week	Session	Topic	Programme work	Due	Learning outcome
					reports, team discussions, etc; 9. conduct study visits with participants, ensuring their care and safety; 10. conduct, record and review clinical assessments according to the protocol, sponsor regulatory and GCP requirements; 11. participate in study initiation and close-out visits to demonstrate oversight following sponsor/CRA/institutional procedures; 12. prepare and manage monitoring visits from the sponsor, including how to respond to and resolve findings from the monitor; and 13. prepare for audits and inspections (for sponsor, FDA, SAHPRA AND EMA audits/inspections)
6	**6**	Domain VI – Data Management & Informatics	Read Module 6 of CTRM Complete assignment 6 ➢ **Please develop a Clinical Quality Management Plan (CQMP)**	In-class discussion Show timely performance and supervision of query resolution Develop a Clinical Quality management plan for your	On completion of session 6, the clinical trial research students should be able to: 1. describe the role that data management and statistical reviews serve in clinical trials; 2. describe the typical flow of data throughout a clinical trial;

Week	Session	Topic	Programme work	Due	Learning outcome
			for your mock clinical trial. ➢ Please develop and include the tools you will use for QA and QC described in the CQMP. ➢ Please upload it to Moodle.	mock clinical trial Meet with an external monitor to review monitor findings during the mock clinical trial to maximise trial performance	3. develop a clinical quality management plan for their study; 4. plan and translate the quality management plan into pragmatic SOPs; 5. ensure data integrity by overseeing data collection, correction (cleaning) and reporting procedures throughout the trial; 6. contribute to quality management systems for the study as they apply to data processes, such as monitoring of safety data and checking database requirements; 7. apply knowledge to review and address monitors' findings according to GCP/protocol guidelines on time to ensure data integrity; and 8. have knowledge of computer programs and the importance of information technology in data collection, capture and the management of clinical trials.
7	**7**	Domain VII – Professionalism & Leadership	Read Module 7 of CTRM	In-class discussion	On completion of session 7, the clinical trial research

Week	Session	Topic	Programme work	Due	Learning outcome
			Complete assignment 7 ➢ Please finalise your protocol, ICF, feasibility study, budget, team, projections for screening and enrolment, recruitment and retention strategies, source documentation and CRFs and the CQMP you have developed for your mock clinical trial for your group. ➢ Please delegate a member or members of the team to present your clinical trial. Use the planning you have done on the Gantt chart (or project management tool) to prepare the study. ➢ Present your mock clinical trial during session 8.	Delegate study-related roles and responsibilities as appropriate for your mock clinical trial team members. Identify team member expertise to solve complex clinical trial issues Discuss how the team accommodate cultural diversity within the team (workforce) and the cultural diversity of participants Good time management Good self-management	students should be able to: 1. explain the fundamental concepts and methods of leadership, management, and mentorship, and implement them in the workplace; 2. establish and execute protocols to prevent or address ethical and professional conflicts that may arise during the execution of clinical research; 3. assess the staff's credentials based on their training, education, and experience to determine the suitable allocation of study-related responsibilities; 4. ensure all staff are adequately trained to perform delegated tasks; 5. identify team member expertise to solve complex clinical trial issues; 6. describe the effect of cultural diversity and the need for cultural competency in the design and conduct of clinical research;

Week	Session	Topic	Programme work	Due	Learning outcome
					7. oversee tasks that were delegated to staff to ensure accuracy, completeness and consistency; and 8. multitask and prioritise competing deadlines, needs and demands from colleagues and stakeholders.
8	**8**	Domain VIII – Communication & Teamwork	Read Module 8 of CTRM Complete assignment 8 ➢ Please complete post-assessment knowledge and self-assessment questionnaires. ➢ Please follow the link that will be emailed to complete the self-assessment questionnaire. ➢ The post-assessment knowledge questionnaire could be accessed on Moodle for completion. ➢ Please complete both questionnaires	In-class discussion Develop a communication plan for your mock clinical trial Discuss the relationship and appropriate communication between the sponsor, CRO, and clinical research site	On completion of session 8, the clinical trial research students should be able to: 1. comprehend the significance of collaboration in the execution of trials and acquire the skills to effectively function in a diverse and interdisciplinary team; 2. develop a communication plan for their clinical trial to circulate information among trial staff and to key stakeholders (including dissemination of results); 3. ensure consistent and efficient contact with team members during the trial using several communication methods such as team meetings, email, shared drives, voice

Week	Session	Topic	Programme work	Due	Learning outcome
			for the last assignment to receive your certificate.		communication, and WhatsApp; 4. comprehend distinct and fluctuating reporting prerequisites for heterogeneous entities; and 5. elucidate the components of a conventional scientific publication.

Evaluation strategy for the intended outcome (does it work?)

The programme was evaluated by stakeholders, consisting of selected participants and supervisors of participants who completed the education programme. A full description will be given in Chapter 7.

5.4 STAKEHOLDER VALIDATION OF THE CLINICAL RESEARCH TRIAL EDUCATION PROGRAMME

On completing the development of the curriculum outline for the education programme, this outline was sent to the same ten stakeholders who were previously interviewed (described in Chapter 4) to validate the programme.

Stakeholders also received a validation instrument. The purpose of the validation instrument was to establish whether the developed clinical trial research education programme included the information and opportunities stakeholders suggested during the interviews to learn about clinical research.

Stakeholders were asked to give their answers to the following questions briefly. They could give a basic “yes” or “no”, but if they wanted, they could also elaborate:

1. Will the programme offer a satisfactory educational experience?
2. Will the programme prepare new clinical research investigators for the opportunities available in clinical research upon completion?

3. Does the course guarantee that the new clinical research investigator's entire experience is characterised by logical and intellectual coherence in relation to specific outcomes?
4. Is the programme balanced, taking into account the eight competency domains outlined in the JTF framework, which include: 1) Scientific concepts and research design; 2) Ethical and participant safety considerations; 3) Medicine development and regulations; 4) Clinical trial operations; 5) Study and site management; 6) Data management and informatics; 7) Leadership and professionalism; and 8) Communication and teamwork?
5. Is the programme designed to treat new clinical research investigators equally, regardless of gender, age, ethnicity, disability, sexual orientation, or religion?
6. Do the programme learning outcomes include the development of employability and career management skills?
7. Additional comments or recommendations.

5.4.1 Feedback and analysis of validation instrument

Stakeholders had three weeks to review the curriculum and respond to the validation instrument. Stakeholders received email reminders once a week to complete the validation questionnaire. Two stakeholders responded, indicating they would not have the time to review the curriculum. Five stakeholders responded with answers on the validation tool. Three stakeholders did not respond. Table 5.3 summarises the stakeholders' feedback.

Table 5.3: Feedback from stakeholders

Question	Yes	No	Other (comments)
1. Will the programme offer a satisfactory educational experience?	5	0	The curriculum is comprehensive.
2. Will the programme prepare new clinical research investigators for the opportunities available in clinical research upon completion?	5	0	Although the content needs to include investigators who will do non-PI studies. The clinical research manual will be a good reference for the future.

Question	Yes	No	Other (comments)
3. Does the course guarantee that the new clinical research investigator's entire experience is characterised by logical and intellectual coherence in relation to specific outcomes?	5	0	To include a list of abbreviations.
4. Is the programme balanced, taking into account the eight competency domains outlined in the JTF framework, which include: 1) Scientific concepts and research design; 2) Ethical and participant safety considerations; 3) Medicine development and regulations; 4) Clinical trial operations; 5) Study and site management; 6) Data management and informatics; 7) Leadership and professionalism; and 8) Communication and teamwork?	5	0	There should be an outline of the various local and international guidelines they should comply with.
5. Is the programme designed to treat new clinical research investigators equally, regardless of gender, age, ethnicity, disability, sexual orientation, or religion?	5	0	It seems so. The programme design does not display any biases toward the mentioned groups. The conduct of the trainer will be a test of this. Should include this in the survey.
6. Do the programme learning outcomes include the development of employability and career management skills?	5	0	However, clinical trial research students may not be assured of jobs at the end of the training as additional internships may be required. It is not clear what aspects of career management. The trainer must emphasise the importance of practising skills learnt. Experience in the field will also be necessary
7. Additional comments or recommendations			Explain how the post-test will be structured.

Question	Yes	No	Other (comments)
			Are there any references for the course? Will clinical trial research students be expected to do additional research? Do you have any mark breakdowns for tests, assignments, and presentations? Investigator oversight and accountability (despite delegation) need to be explained. Examples of ethical violations and litigation in Africa and Africa can be used to illustrate this. The investigator is responsible for training site staff and not relying on CRO/sponsor, especially during amendment implementation—awareness of recruitment commitments to sponsors. There is no indication of how long the course is in days. Is each session a day long? Does the in-class portion of the course restrict clinical trial research students to the Johannesburg location? Can clinical trial research students join remotely? How will the mock clinical trial be selected? It may be necessary to identify the audience. If the investigators are working on pharma-sponsored trials vs academic trials, epidemiology studies vs non-drug studies vs device studies – the audience should drive the type of mock used so that it is relevant. The adverse event section seems to focus on IP-related adverse events. Device-related adverse events should be taken into account. Session 4 should include Re-consent, and role-play should include different scenarios, e.g. assent. Session 7 should include understanding site staff qualification requirements for specific roles, e.g. what are nurses qualified to do? Who can do ECG or lung

Question	Yes	No	Other (comments)
			function? The output seems to indicate that this will be done. SAHPRA is adamant about capacity-building. Investigators need to implement this in their team construction. It was unclear if progress reports, MTA, export permits and language translation are covered. Recommend that the completion of the FDA 1572 and IoR forms are emphasised. Suggest the development of ICFs with regard to risk categories.

5.4.2 Addressing comments, suggestions and recommendations from stakeholders

Although only five stakeholders responded, they offered insightful and positive feedback. All five stakeholders agreed that the programme would provide a good learning experience, will prepare new clinical research investigators for the opportunities potentially available in clinical research upon completion of the programme, that the programme is balanced with regards to the eight competency domains for investigators, that there are clearly defined programme outcomes, and that all trainees will be treated equally.

Each suggestion and recommendation were evaluated against the curriculum content to ensure the information was included. Table 5.4 shows the stakeholders' suggestions and comments and the evaluation outcome. When stakeholders responded with a question, I returned an answer.

Table 5.4: Suggestions/comments from stakeholders and outcome of evaluation against the curriculum

Suggestions/comments from stakeholders	The outcome of evaluation against curriculum
The curriculum is comprehensive	Was noted.
Although the content needs to include investigators who will do non-PI studies.	Yes, the content included investigators who will do non-PI studies.

Suggestions/comments from stakeholders	The outcome of evaluation against curriculum
The clinical research manual will be a good reference for the future.	Yes, the manual was written to use as a future reference manual.
To include a list of abbreviations	A list of abbreviations was included at the beginning of the manual.
There should be an outline of the various guidelines that they should comply with, both locally and internationally	A list of national and international guidelines was included in the manual.
The programme design does not display any biases toward the mentioned groups. The conduct of the trainer will be a test of this. Should include this in the survey.	Was included in the in-depth interviews with five trainees to ask about their experience with the inclusion of different groups.
However, clinical trial research students may not be assured of jobs at the end of the training as additional internships may be required.	This comment was noted. The future vision is to develop the course to register it as a skills course that will require practical hours.
It is not clear what aspects of career management.	Career management was included in a discussion during sessions 7 & 8 as part of leadership and management (domains 7 & 8).
The trainer must emphasise the importance of practising skills learnt.	The trainer noted this.
Explain how the post-test will be structured.	**Pre-knowledge** will be any knowledge with regard to the fundamentals of the clinical trial process and life cycle a participant might have because of their education or experience. Pre-test the questionnaire to determine participants' self-perceived level of knowledge and competencies. Pre-test the questionnaire to determine their level of knowledge in the eight competency domains of the clinical trial process and life cycle of clinical trials. **Post-knowledge** will be any newly acquired knowledge the participant has after the clinical research education programme (intervention). This will be determined by the pre-post-test questionnaires completed by all participants and the interviews with selected participants. Post-test the questionnaire to determine participants' self-perceived level of knowledge and competencies.

Suggestions/comments from stakeholders	The outcome of evaluation against curriculum
	Post-test the questionnaire to determine their level of knowledge in the eight competency domains of the clinical trial process and life cycle of clinical trials.
Are there any references for the course?	Yes, there are.
Will clinical trial research students be expected to do additional research?	No, it was not part of the initial planning of the course, but it is a good suggestion that I will keep in mind for future planning.
Do you have any mark breakdowns for tests, assignments, and presentations?	There is no breakdown for tests, assignments and presentations, but this will change when it becomes a skills qualification course.
Investigator oversight and accountability (despite delegation) need to be explained. Examples of ethical violations and litigation in South Africa and Africa can be used to illustrate this. The investigator is responsible for training site staff and not relying on CRO/sponsor, especially during amendment implementation. Awareness of recruitment commitments to sponsors. There is no indication of how long the course is in days. Is each session a day long? The in-class portion of the course restricts clinical trial research students to the Johannesburg location. Can clinical trial research students join remotely?	Investigator oversight and accountability were included and will be emphasised by the trainer. Examples of ethical violations and litigation in South Africa and Africa were included. The manual highlighted the investigator's responsibility to train site staff and not rely on CRO/sponsors. Awareness of recruitment commitments to sponsors will be covered during the face-to-face session. The course will run over eight days, with one session in the morning and one in the afternoon for eight weeks (twice a week) – the duration will appear on the agenda when the course is advertised and on the curriculum. The course will be presented in Cape Town and Durban as well.
How will the mock clinical trial be selected? It may be necessary to identify the audience. If the investigators are working on pharma-sponsored trials vs academic trials vs, epidemiology studies vs non-drug studies vs device studies – the audience should drive the type of mock used so that it is relevant.	The trainees will select the mock clinical trial on the first day of their face-to-face training.
The adverse-event section seems to focus on IP-related adverse events. Device-related adverse events should be taken into account.	Yes, all types of AEs will be discussed.

Suggestions/comments from stakeholders	The outcome of evaluation against curriculum
Session 4 should include Re-consent, and role-play should include different scenarios, e.g. assent.	Yes, section 4 will include re-consent and role-play with different scenarios.
Session 7 should include understanding site staff qualification requirements for specific roles, e.g. what are nurses qualified to do? Who can do ECG or lung function? The output seems to indicate that this will be done. SAHPRA is adamant about capacity-building. Investigators need to implement this in their team construction. It was unclear if progress reports, MTA, export permits and language translation are covered.	Yes, an understanding of site staff qualification requirements for specific roles was included in section 7. Capacity-building will be highlighted during the face-to-face training session. Yes, progress reports, MTAs, export permits and language translation were covered in the manual.
Recommend that the completion of the FDA 1572 and IoR forms are emphasised. Suggest the development of ICFs with regard to risk categories.	The FDA 1572 and IoR forms were included in the manual, as well as the development of ICFs regarding risk categories.
Experience in the field will also be necessary	The trainer noted this.

5.5 SUMMARY

Based on a thorough literature review on clinical research investigator training, including adult and current learning approaches, and findings from the interviews with stakeholders, I developed an inclusive clinical trial research education programme for investigators working in human sciences. The inclusive clinical trial research education programme was an intervention to determine if a change had occurred in investigators' knowledge of and competency in clinical trial conduct after completing the clinical trial research education programme.

This chapter answered the questions, *what should an inclusive clinical trial research education programme for investigators in health sciences consist of*? (context), and *what are specialist stakeholders' views of the clinical trial research education programme before implementation*? It became clear that the COVID-19 pandemic significantly influenced the education system. Educators and researchers had to adapt to previously known but infrequently used alternative education and research methods, such as blended learning and LMSs, like Moodle. In Chapter 6, the developed clinical trial

research education programme's implementation, which included the stakeholders' views, will be discussed.

CHAPTER 6
PROJECT 2: RESEARCH DESIGN, DATA COLLECTION AND IMPLEMENTATION OF THE INTERVENTION

6.1 INTRODUCTION

Chapter 6 discusses the research design, data collection and implementation of the inclusive clinical trial research education programme (intervention) (see Table 6.1). Project 2 represents the quantitative part of the multiple-method research design.

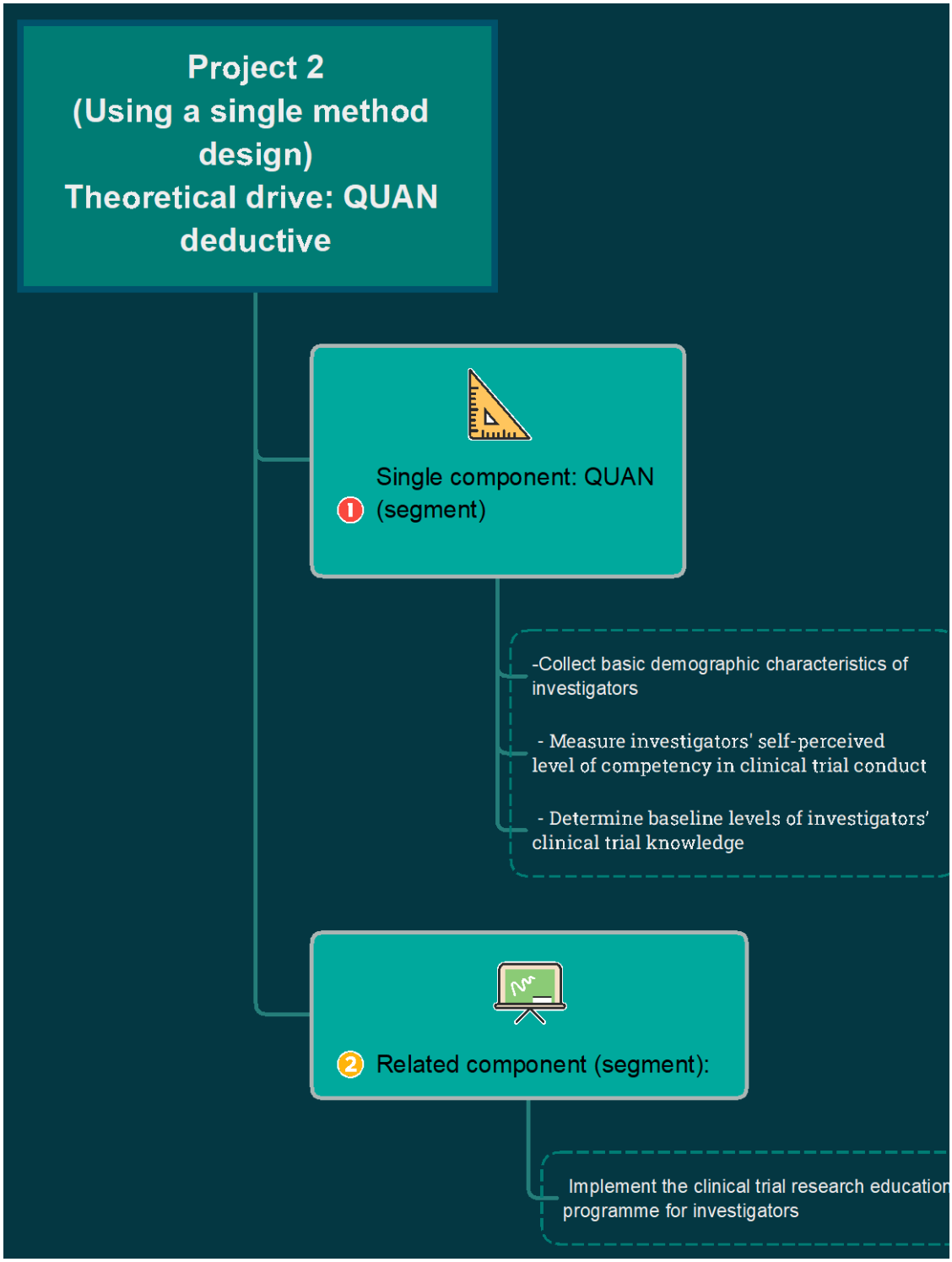
Table 6.1: Chapter 6: Research progress

Chapter	Content
1	Orientation to the study
2	Literature review (1) Clinical trial education (2) Competency-based education (3) Self-efficacy (4) MRC framework
3	Research design and methods
4	Project 1 Research design, data collection, data analysis and results (First segment: situation analysis - qualitative)
5	Project 1 Development and validation of the inclusive clinical trial research education programme (Second and Third segments)
6	Project 2 Research design, data collection and implementation of the intervention
7	Project 3 Research design, data collection, results, and evaluation of intervention
8	Summary of integration of findings, conclusion, recommendation, contribution and limitations of the study

6.2 RESEARCH DESIGN

Project 2 of the multiple-method study was descriptive and evaluative, and the research design was quantitative. The second phase, namely Project 2 of the study, comprised the:

- quantitative segment in which (a) basic demographic characteristics of investigators were collected, (b) investigators' self-perceived level of competency in clinical trials were measured, (c) baseline levels of investigators' research knowledge were measured; and
- implementation of the education programme.



Schematic diagram 6.1: Showing the flow of Project 2 of the study

6.2.1 Deductive approach

The second project had a deductive drive. I reached out to the population (investigators) in which the phenomenon (lack of clinical trial research education) was expected to be found, made use of questionnaires to investigate the phenomenon, and defined the phenomenon carefully (Saunders 2019:150; Creswell 2022:16). Pre-and-post-questionnaires were administered to establish the extent of investigators' knowledge and skills gained as a result of the intervention. Deductive logic moves from general to particular information or from premises to conclusions and is mainly applied when using quantitative studies (Palys & Atchison 2021:1263).

6.2.2 Descriptive

Descriptive data were collected to clearly understand investigators' knowledge and skills in clinical trial research (Saunders 2019:175). Descriptive data were based on an ordinal measurement scale that obtained data from the questionnaires.

6.2.3 Population

The target population can be described as the collection of individuals the researcher wants to study and draw conclusions from (Tan, Machin, Tan & Campbell 2018:252). For Project 2 of the study, individuals were selected from the clinical trial, academic and pharmaceutical fields. Individuals included clinical research professionals, such as principal investigators, sub-investigators, study coordinators, clinical research associates, consultants, research nurses, pharmacists, and statisticians who were interested and registered for the education programme (Cohen, Manion & Morrison 2018:202). These clinical research professionals, who were not investigators at the time of the programme's registration, could have been prospective investigators. A total of 28 candidates registered for the inclusive clinical trial research education programme (investigators, participants, clinical trial research students, and candidates were used interchangeably, as applicable).

6.2.4 Sampling method and sample size

The population was small, and all 28 candidates interested in the inclusive clinical trial research education programme were registered; thus, a sample selection was unnecessary (Otvombe 2019; Bell, Whitehead & Julious 2018:154).

6.2.5 Inclusion and exclusion criteria

Table 6.2 illustrates the inclusion and exclusion criteria for determining the eligibility of investigators who wanted to register for the clinical trial research education programme.

Table 6.2: Inclusion and exclusion criteria for investigators

	Inclusion criteria	Exclusion criteria
Investigators	a) Investigators who had worked in the clinical trial field who completed a basic GCP course	Investigators without a GCP certificate

6.2.6 Recruitment of participants

I approached Academic Advance to advertise the clinical trial research education programme. They have a comprehensive database of all clinical research units in South Africa. Participants were asked to respond to me for application and acceptance to the eight-week educational programme. The investigators who responded and agreed to participate formed a single group representing a census sample. A central venue in Johannesburg was chosen to accommodate a minimum of 12 participants.

I contacted investigators who informed WHC that they were interested in the pilot study through the email addresses they provided. I explained the study's purpose and inclusion/exclusion criteria. Interested investigators had a choice to participate in the pilot study; they could still register for the education programme without being a participant in the pilot study. When they decided to register for the clinical trial research education programme as a participant in the pilot study, they were asked to sign a consent form (see Annexure K) on registration at the venue where the programme was presented. Participants who registered online were emailed the informed consent form; some signed it electronically, and others brought the signed form to the venue on the first day of the course.

6.2.7 Data-gathering technique

I had to develop appropriate data collection instruments to ensure a valid outcome of the intervention or inclusive clinical trial research education programme (Mertens & Wilson 2019:336). Quantitative data collection is based on numerical data. To measure if there was any difference in the clinical trial research students' knowledge and skills, I had to develop instruments that measured their baseline knowledge and skills, and instruments that measured their knowledge and skills after the intervention (Polit & Beck 2022:2048). In addition, quantitative data collection for Project 2 included basic demographic information, such as age, previous research exposure, gender, and future career plans. Demographic information was identified as a data variable, and the collection of demographic information was needed to determine if the collected data were representative of the total population (Saunders 2019:445). After completing the demographic questionnaire, participants were asked about their self-perceived level of competency in clinical trials (self-assessment), after which their knowledge of the eight competency domains of the clinical trial process and life cycle was determined, both through questionnaires (pre-test). Their self-perceived level of competency in clinical trials (self-assessment) and knowledge were considered part of behaviour and event variables (Saunders 2019:445).

There were three questionnaires in total for Project 2 of the study:

- Demographic questionnaire
- Pre-test questionnaire to determine participants' self-perceived level of competency
- Pre-test questionnaire to determine their knowledge in the eight competency domains of the clinical trial process and life cycle

Using questionnaires as a research tool does have some advantages and disadvantages, as described by Lambert (2019:1); Siripipatthanakul (2020:1); Polit and Beck (2022:266); Pozzo, Borgobello and Pierella (2019:2).

6.2.7.1 Advantages of questionnaires

Questionnaires provide a relatively fast or quick way of gathering information (speed and practicality). The current study used self-administered questionnaires that saved time

because there was no involvement from myself or an interviewer. At the same time, it allowed the clinical trial research students to complete the questionnaire in their own time at their own pace (respondent comfort). Anonymity and confidentiality were maintained during the completion process as the clinical trial research students did not have to identify themselves by name. A link was sent to each participant to give them access to the questionnaires. Bias was limited as well, as an interviewer was not required.

Using a questionnaire is inexpensive and cost-efficient. Questionnaires were made available online for completion by clinical trial research students. There was no cost involved for travelling or time. Standardisation and comparability were also possible, and the same questionnaires could be used after the pilot study. The questionnaires were a way of obtaining accurate information about the population sample. The questionnaires facilitated numerical data and established a range of views about the clinical trial research students' competencies (Likert rating scale). They also provided statistical means of analysis to present findings using figures, tables and percentages.

6.2.7.2 Disadvantages of questionnaires

The interpretation of questions could be a barrier, especially with a multi-cultural sample using different home languages, such as in the current study; however, the questionnaires were piloted to identify and correct any questions that could cause misunderstanding. Questionnaire fatigue was another reality for the current study as two questionnaires were to be completed before and after the clinical trial research education programme, consisting of approximately 100 questions in total. In addition, a demographic questionnaire also had to be completed. Unfortunately, the number of questions was necessary as all eight competency domains had to be covered to determine the clinical trial research students' level of knowledge and skills and their perceived level of knowledge and skills.

Some questions were in the form of a scenario, and clinical trial research students had to choose the correct answer(s). These questions create the possibility of participants not reading the questions thoroughly or entirely and then offering inaccurate answers that could have impacted data validity; however, I did try to make questions as short and direct as possible. As mentioned, the questionnaires were pre-tested on a diverse group of clinical research professionals to limit the effects of the disadvantages.

6.2.7.3 Development of the questionnaire

A thorough literature review and guidance from distinguished authors of articles and books written on the topic assisted me in developing the questionnaires needed for Project 2.

First instrument: Demographic assessment tool (questionnaire)

The assessment tool captures the participants' demographic data and individual participant characteristics such as gender, age, years of experience in clinical trials, race, role in clinical research, specific education/training in clinical trials, type of education/training received, duration of education/training in clinical trials, mandatory or elective education/training in clinical trials, and future career plans. Components of the demographic questionnaire were compiled according to key factors believed to affect clinical research investigators' research literacy. The demographic questionnaire was the first to be completed by participants after registering for the programme (see Annexure L).

Second instrument: Pre-assessment of self-perceived competency in clinical trial research questionnaire

The self-assessed level of competency in clinical trials questionnaire was developed to capture data related to investigators' self-perceived competency in the eight competency domains, taking into account the eight competency domains outlined in the JTF framework, which include: 1) Scientific concepts and research design; 2) Ethical and participant safety considerations; 3) Medicine development and regulations; 4) Clinical trial operations; 5) Study and site management; 6) Data management and informatics; 7) Leadership and professionalism; and 8) Communication and teamwork? (Sonstein et al. 2018:3). The self-perceived competency questionnaire was created using Miller's clinical assessment paradigm, specifically designed to evaluate clinical abilities, competence, and performance.

Miller's framework is structured like a pyramid, beginning with knowledge as the foundation. This refers to the learner's understanding of a particular topic or skill. Above knowledge is the competency level, which indicates the learner's ability to apply their information and perform a task. Progressing to the next level of the pyramid occurs when

the learner reaches a sufficient level of familiarity to effectively demonstrate the skill or provide an explanation to others. The last step, or tip of the pyramid, involves the learner's skill performance. When this level is reached, the learner demonstrates the ability to perform the skill successfully (Miller 1990:2; Witheridge, Ferns & Scott-Smith 2019:191). The instrument contained 40 items (see Annexure L). Registered clinical trial research students were asked to complete the self-perceived competency questionnaire before the level of knowledge questionnaire so that they would not first read through the clinical trial knowledge application and conceptual items to estimate their competency throughout the self-perceived questionnaire.

Third instrument: Pre-assessment of clinical trial research knowledge questionnaire

The knowledge of clinical trial research instrument was developed to capture the investigators' baseline knowledge of the eight competency domains (see Annexure L). The 75 multiple-choice items selected for inclusion were based on the eight competency domains. Scenarios were created for each item, followed by multiple-choice options. The scenarios were based on the most essential clinical trial concepts within each competency domain, considering GCP guidance documents, previous studies on competency-based frameworks, and guidance documents from the ACRP certified course for investigators (ACRP 2019). Clinical trial research students had to apply their knowledge of clinical trial research when answering each item. The pre-assessment knowledge instrument was reviewed, revised and refined after pre-testing (piloting) by eight clinical research professionals with similar qualifications and experiences as the intended group of investigators who registered for the programme.

6.2.8 Validity

Creswell and Creswell (2020:175) describe three traditional forms of validity: (i) content validity – meaning, do the items measure the content they were intended to measure?; (ii) predictive or concurrent validity – meaning, do the scores predict a criterion measure, and do the results connect with other results?; and (iii) construct validity – in other words, do the items measure hypothetical constructs or concepts, are they useful? When deciding to use questionnaires, it is important to know if the instrument will measure what it should (Polit & Beck 2022:340). The validity of the questionnaire is not tested but

instead supported by the accumulation of evidence, according to Polit and Beck (2022:340).

Using existing instruments (questionnaires) has the benefit of describing the established validity of the scores obtained from past or previous use of the instrument (Creswell & Creswell 2020:175). The validity of the questionnaires used in the current study was not established. However, I developed them from examples of validated instruments available in the literature, GCP and ACRP guidelines. I successfully covered content validity using key concept questions under all eight competency domain areas.

6.2.9 Reliability

Reliability provides the researcher with information about the instrument's consistency or repeatability in measuring the same attribute (Creswell & Creswell 2020:175). In most instances, peoples' attitudes, aptitudes, personality traits, personal values and cognitive styles are relatively stable, although they can change to some degree over time. Therefore, a researcher should be able to get the exact measures from an instrument tested on the same group of people on two successive occasions. This procedure is also known as test-retest reliability. Another reliability strategy is the inter-rater-reliability, where other people can make the same judgement you, as a researcher, would make about a particular construct (Palys & Atchison 2021:2311). The current study's questionnaires were pre-tested to establish their reliability and stability (Polit & Beck 2022:336).

6.2.10 Pre-testing the questionnaires

The questionnaires were pre-tested after approval from the scientific review committee and the Research Ethics Committee of the Department of Health Studies at UNISA was received. A group of eight clinical trial professionals, including research coordinators, nurses, pharmacists and investigators who were not from the sample for the current study, were purposefully selected to test the pre-and-post-assessment questionnaires. The eight clinical trial professionals attended a clinical research coordinators course. After being informed about the reason for pre-testing the questionnaires, all eight clinical trial professionals volunteered to test the pre-and-post-assessment questionnaires.

The respondents did not have any recommendations for content changes to the questionnaires. According to the respondents, they understood all the questions; however, most expressed concern about the length and number of items in each questionnaire. After deliberation with experienced clinical trial colleagues, I decided to keep the questionnaires as is for the pilot study to ensure all eight competency domains are well represented. This was necessary to ensure a realistic indication of investigators' self-perceived competency level and clinical trial knowledge (Lambert 2019:8).

6.2.11 Data gathering

The questionnaire on participants' characteristics and the pre-test questionnaires were administered before the onset of the clinical trial research programme. The post-test questionnaires were administered after the programme. The pre-test and post-test questionnaires were two separate documents. Participants were emailed questionnaires via an email link, which they had to open. Each participant completed the questionnaire at their own convenience online. Full instructions on completing each questionnaire were given to participants, and my contact details were available should any participant need further explanation. Participants received a study identification number. The page with the basic identifying information and the informed consent that they signed were kept separately from the questionnaires. The questionnaires only showed the study identification number.

I acknowledged that the instrument was lengthy due to measuring all eight competencies. I managed participants' fatigue in the following manner: I oriented participants before administrating the survey regarding the time needed; they could pace their own time for the completion of each question; and they did not need to complete it in one session.

6.3 IMPLEMENTATION OF INTERVENTION

I facilitated all the in-class clinical research education sessions outlined in the curriculum. Guest speakers were invited to share their expertise on selected topics, including developing a clinical trial budget, ethics and the SAHPRA application process, the importance of statistical methods in clinical trials, participant safety, and data management. The first in-class session started on 17 August 2022 and ended on 11

November 2022. Figure 6.1 is an illustration of the first slide used for the introduction of the inclusive clinical trial research education programme.

Figure 6.1: Illustration of the first slide used for the introduction of the inclusive clinical trial research education programme

6.3.1 Delivery format and learning environment

The course content was delivered through a blended-learning approach, combining face-to-face and online experiences for the clinical trial research students. Many learning methods and materials promoted the clinical trial research students' relevant information and skills development. Interactive learning formed part of the experience to facilitate learning.

The curriculum's development considered differences in clinical trial research students' learning styles to ensure a rich learning experience. PowerPoint presentations provided a visual representation of the content of the course. The course manual gave detailed course content with additional information. Pictures, graphs and flowcharts broadened the visual learning experience and clearly illustrated certain concepts. Videos provide illustrative examples for the application of translations to practical situations. Interactive discussions offered various learner-specific modalities of information delivery, catering to visual, auditory, and tactile learners. (Armstrong 2005:680; Quansah & Essay 2021:420).

6.3.2 Curriculum intervention description

The intervention's implementation is described as the last step in developing and evaluating a complex intervention, according to the MRC framework (Skivington et al. 2021:1). Skivington and colleagues (2021:7) explained an evaluation of the implementation's outcome should be considered part of the last step, alongside an evaluation of the implementation strategy and contextual factors that advanced or hindered the success or impacted the intervention. The inclusive clinical trial research education programme intervention was delivered over eight weeks and consisted of eight sessions.

6.3.2.1 Session 0: Pre-assessments

Session 0 started after confirming that the clinical trial research student agreed (or did not agree) to be part of the research and had read, understood and signed the informed consent form. Clinical trial research students received access to the Moodle platform after registering for the programme. They familiarised themselves with Moodle through a short introduction session. Clinical trial research students were guided to some pre-reading work and the first assignment they needed to complete before session one. Pre-reading content included articles and information on clinical research investigator training and clinical trials. The pre-assignment reflected their current experience as clinical research investigators.

6.3.2.2 Session one: In-class

Session one started with an explanation of the pre-test questionnaire, and clinical trial research students who had not completed the questionnaires were asked to complete these before the next session, followed by an overview of the eight-week programme. A PowerPoint presentation shared knowledge on the development of a protocol. The group was divided into three smaller groups that decided on a topic for a mock clinical trial for their group. Small group discussions on the protocol's elements were extended on the Moodle platform. Members in each small group decided who would write which sections

of the protocol. Assignment one included completing the protocol development for the mock clinical trial.

6.3.2.3 Session two: In-class

Clinical trial research students were instructed on the wide range of safety and risk concerns that participants may encounter throughout a clinical study, as well as strategies to minimise these difficulties. Students learnt how to identify the expected and unexpected effects of the IP, how to evaluate the causality and severity of AEs in relation to the IP to facilitate an understanding of product safety, continuous monitoring for AEs through all participant interactions, and adjust participant treatment/medical care in relation to the adverse event (e.g., stop IP, retest or treat participant) to ensure participant safety. The importance of timely safety reporting and the management of risks throughout the clinical trial were covered during a PowerPoint presentation. Clinical trial research students participated in an interactive session where they identified safety issues in research and the obligation to report such findings.

During session two, the class decided on an adverse event (AE) a participant had developed; they also had to decide if it was an SAE. Assignment two entailed completing an SAE case report form and the reporting lines.

Clinical trial research students had to discuss the elements that should be part of the informed consent, and by role-play, they had to demonstrate the informed consent, screening and enrolment processes. Follow-up visits were discussed, including the prescription and oversight of the investigational product. The clinical trial research students had to use the WHC ICF template and develop an ICF for their mock protocol as part of assignment two.

6.3.2.4 Session three: In-class

The relevant submissions for approval (Ethics, SAHPRA, SANCTA, DoH) were discussed. Clinical trial research students received an overview and demonstration of the investigator site files (also called master trial files or regulatory files) and how to maintain these. During the class session, the clinical trial research students decided on a topic for preparing an addendum to the protocol they had developed. As part of assignment three,

each clinical trial research student had to download and complete the correct application forms for ethics committees and SAHPRA. The role of the investigator's brochure and the investigation product was covered in a PowerPoint presentation. Another PowerPoint presentation shared information on a clinical trial budget – developing a clinical trial budget was part of assignment three.

6.3.2.5 Session four: In-class

A quick review of the pre-reading assignment for session four was conducted. The assignment focused on important regulations and guidance documents pertaining to the duties of a clinical investigator, as well as the essential components of investigator responsibility according to ICH and SA GCP. Additionally, the assignment covered the anticipated level of oversight that investigators should exercise during a clinical trial.

In session four, after PowerPoint presentations and discussions, clinical trial research students had to determine the feasibility of the mock clinical trial, set up a research team, develop ethical recruitment and retention strategies, and predict target recruitment numbers for the mock protocol. During session four, clinical trial research students also learnt how to develop source documentation for screening, randomisation and follow-up visits for a study. Data accuracy and integrity, as well as data storage, were covered.
Part of assignment four was the development of source documentation for their mock clinical trial.

6.3.2.6 Session five: In-class

Session five started with the Lean Six Sigma Principles, demonstrating the importance of good clinic flow. Clinical trial research students had to determine if they might encounter clinic flow challenges in the mock clinical trial and what solutions they would implement.

At the end of session five, clinical trial research students had to decide on a project management tool (Gantt chart) to keep track of the study preparation phase. The tool was completed as an assignment for session six.

During session five, the importance of inclusion and exclusion criteria was stressed as part of the screening and enrolment process. How to prepare and manage monitoring

visits from the sponsor, including how to respond to and resolve all the monitoring findings, were covered. Audits and inspections from the sponsors, the FDA, SAHPRA and EMA were also discussed.

During the session, clinical trial research students also had to meet with an external monitor to review the monitor's findings during the mock clinical trial to maximise trial performance.

6.3.2.7 Session six: In-class

In session six, clinical trial research students received the necessary knowledge to develop a CQMP for their mock protocol. They were also informed about data management and the statistical review's important role in clinical trials. Their assignment for session six was to complete the CQMP.

6.3.2.8 Session seven: In-class

Session seven gave background information on each team member's role within the clinical trial team, and the students had to reflect on their role as investigators and how it fits within the team. Clinical trial research students had to identify tasks they would be responsible for and how they would relate to tasks completed by other team members.

The clinical trial research students had to delegate tasks and responsibilities according to the team members' roles as selected for their mock protocol. Students also had to discuss how they would accommodate cultural diversity within the team and the cultural diversity of participants.

Clinical trial research students had to identify time- and self-management tools they could use to complete their study-related duties with minimal supervision. For assignment seven, students had to complete a time- and self-management tool they had decided on.

6.3.2.9 Session eight: In-class

The discussion revolved around the significance of collaboration in trial management and the strategies for efficiently operating within a diverse and interdisciplinary team. During

session eight, clinical trial research students had to develop a communication plan for their mock clinical trial after receiving the necessary information on the different forms of communication that could be used when sharing information with stakeholders.

Clinical trial research students had to finalise their protocol, ICF, feasibility study, budget, projections for screening and enrolment, recruitment and retention strategies, source documentation and CRFs and CQMP that they developed for their mock clinical trial for their group. Each small group had to delegate a member or members of the team to present their mock clinical trial. They had to use the planning they had done on the Gantt chart (or project management tool) to prepare the study. Each team was allowed to present their mock clinical trial to the class.

Assignment eight entailed the completion of the post-test questionnaire.

6.4 PROGRAMME RESOURCES

Programme resources were available for participants registered for the inclusive clinical trial research education programme, starting with the programme location, followed by a textbook, the Moodle platform, additional readings and presentations.

6.4.1 Programme location

In-class sessions were presented in a training venue at WHC in Parktown, Johannesburg. The in-class sessions were supported by educational information provided on the Moodle platform.

6.4.2 Textbook

Clinical trial research students were provided with a CTRM I developed. The manual contained detailed information about all the topics covered during the in-class and Moodle sessions.

6.4.3 Moodle platform

Course sessions on the Moodle platform followed the same index as the in-class sessions, and clinical trial research students had to complete the related course session on the Moodle platform before attending the session with the same session number.

6.4.4 Additional readings

Additional readings were taken from peer-reviewed journals and placed on the Moodle platform as pre-reading before each in-class session.

6.4.5 Presentations

PowerPoint presentations were prepared for each in-class session according to the specific topics. Information shared during the presentations was captured in the manual provided at the beginning of the course.

6.5 PROGRAMME ACTIVITIES

Pre-readings, presentations, quizzes, assessments, discussions, assignments and programme policies formed part of the programme activities and were available on the Moodle platform while discussions also occurred during in class sessions.

6.5.1 Pre-readings

Before each in-class session, clinical trial research students had to read the related articles and information provided on the Moodle platform.

6.5.2 Presentations

Most in-class sessions had a PowerPoint presentation, and the clinical trial research students' pre-reading assignment was expected to lay a foundation for the information covered during the in-class presentations. A few in-class sessions included hands-on components, where students had to work on scenarios related to the mock protocol agreed on during the first session.

6.5.3 Quizzes

Some sessions on the Moodle platform included short (5–10 questions) quizzes.

6.5.4 Assessments

Prior to session one, clinical trial research students were mandated to do a baseline evaluation (pre-test) to evaluate their existing understanding of clinical research. Additionally, one week after finishing the course, students were expected to complete a comprehensive assessment (post-test) that encompassed all the material covered in sessions one through eight. A second questionnaire on self-perceived competencies in clinical research was completed in pre- and post-course sessions. Five clinical trial research students were non-randomly selected for an in-depth interview with me to evaluate the clinical trial research education programme.

6.5.5 Discussions

Clinical trial research students were required to engage in class and online discussions. The small groups planned the mock protocol and related scenarios during in-class discussions. These discussions enriched the clinical trial research students' learning experience.

6.5.6 Assignments

Clinical trial research students received an assignment during each in-class session and had time to start it in class during the discussion sessions and complete it at home before the next in-class session. Some students continued the discussions outside the class during their own time.

6.5.7 Programme policies

Instructor feedback/communication: I occasionally left messages and reminders for clinical trial research students on the Moodle platform.

Clinical trial research student feedback/communication: students were invited to contact me by email or cell phone when the need arose to clarify any course material or other course-related questions.

6.6 SUMMARY

This chapter discussed the pre-test questionnaires as data collection instruments of the quantitative deductive theoretical drive of Project 2. A full description of the intervention's implementation, namely the clinical trial research education programme, was given. A total of 28 participants registered and completed the education programme. In Chapter 7, the implementation of the post-test questionnaires and stakeholders' evaluation of the programme's outcome are discussed.

CHAPTER 7
PROJECT 3: RESEARCH DESIGN, DATA COLLECTION, RESULTS AND EVALUATION OF INTERVENTION

7.1 INTRODUCTION

Chapter 7 discusses Project 3, representing the mixed-method part of the multiple-method research design. The research design, data analysis process and interpretation of the results from the intervention or implementation of the inclusive clinical trial research education programme are discussed as part of the first segment of Project 3. The outcome evaluation by stakeholders to refine the inclusive clinical trial research education programme is discussed as part of the second segment of Project 3 (see Table 7.1).

Table 7.1: Chapter 7: Research progress

Chapter	Content
1	Orientation to the study
2	Literature review (1) Clinical trial education (2) Competency-based education (3) Self-efficacy (4) MRC framework
3	Research design and methods
4	Project 1 Research design, data collection, data analysis and results (First segment: situation analysis - qualitative)
5	Project 1 Development and validation of the inclusive clinical trial research education programme (Second and Third segments)
6	Project 2 Research design, data collection and implementation of the intervention
7	Project 3 Research design, data collection, results, and evaluation of intervention
8	Summary of integration of findings, conclusion, recommendation, contribution and limitations of the study

7.2 RESEARCH DESIGN

A mixed-method design with a QUAN deductive theoretical drive was used for the study's third phase or Project 3. Quantitative methods, followed by qualitative methods, were used to test the programme's effectiveness.

Project 3 consisted of (a) a quantitative segment in which (i) investigators' self-perceived levels of competency in clinical trial conduct following the inclusive clinical trial research education programme were measured, and (ii) investigators' clinical trial knowledge following the inclusive clinical trial research education programme were measured; (b) a qualitative segment in which stakeholders (participants and supervisors of participants) evaluated the programme.

The study did not focus on programme evaluation but on the development of such a programme. However, it was essential to evaluate the programme to apply the findings in refining and finalising the programme. Project 3 of the study aimed to assess the programme's effectiveness by focusing on an outcome evaluation. Mertens and Wilson (2019:103) describe product, outcome or impact evaluation as assessing a programme's effect on or reach to the target audience. Outcome evaluations focus on short-term results, while impact evaluations focus on long-term results (Mertens & Wilson 2019:265). Outcome/impact evaluation can show if a project is achieving its goal, it can motivate more funding, and is useful for a project's revision, expansion, or replication (Mertens & Wilson 2019:265). Because this was a pilot study, the focus was on short-term results for revision purposes to conclude the final education programme. This last phase of the study correlates with the fourth phase of the MRC framework, evaluating the programme's efficiency and publishing results (Skivington et al. 2021:1).

An important aspect of the education programme's evaluation was the selection of stakeholders who would be part of the evaluation process. Stakeholders are seen as individuals who have a stake in the programme, either as funders, administrators, service providers or receivers (Mertens & Wilson 2019:209). In this study, evaluators were the receivers of the service (the education programme); in other words, the participants and supervisors. In a sense, the supervisors could be regarded as funders because they had

to authorise the participants' registration in the programme; the supervisors did not attend the programme.

7.2.1 Internal validity

The evaluator needs to know if the intervention, rather than some other variables, has caused a change in the dependent variables. To confidently say that results occur because participants experienced the intervention, the evaluator needs to control the effect of variables other than the intervention (Mertens & Wilson 2019:290). Participants' random assignment to two groups was not possible for this study; therefore, a quasi-experimental single-group design was used, and internal validity was controlled by using the same test for both pre- and post-testing.

7.2.2 External validity

The evaluator also needs to know if the sample was representative of the population from which the sample was derived, and whether the same results would be obtained when another group of people from the same population are chosen (external validity) (Mertens & Wilson 2019:290). External validity in this study was controlled by the fact that most participants were reasonably new to clinical trials. Participants were from different clinical trial research settings, and there was a representation of different cultures. Figure 7.1 summarises the flow of Project 3.

7.2.3 Population

The total population for the study was 124. As explained in Chapter 1, Academic Advance train approximately 400 people a year in basic GCP; about 124 of the 400 are medical and non-medical investigators (van Rensburg, personal communication, 4 February 2019). However, for Project 3 segment A, the population comprised participants who completed the clinical trial research education programme. For segment B, the population included all the clinical trial research education programme participants and the supervisors of the 28 participants who completed the education programme.

7.2.4 Sampling method and sample size

For segment A, the small population became the sample as all 28 participants who completed the inclusive clinical trial research education programme agreed to participate. Non-random purposeful sampling was used to select the stakeholders for the qualitative segment (segment B) of Project 3. The sample consisted of two groups: (a) five participants who completed the clinical trial research education programme and (b) five stakeholders who supervised participants who completed the programme.

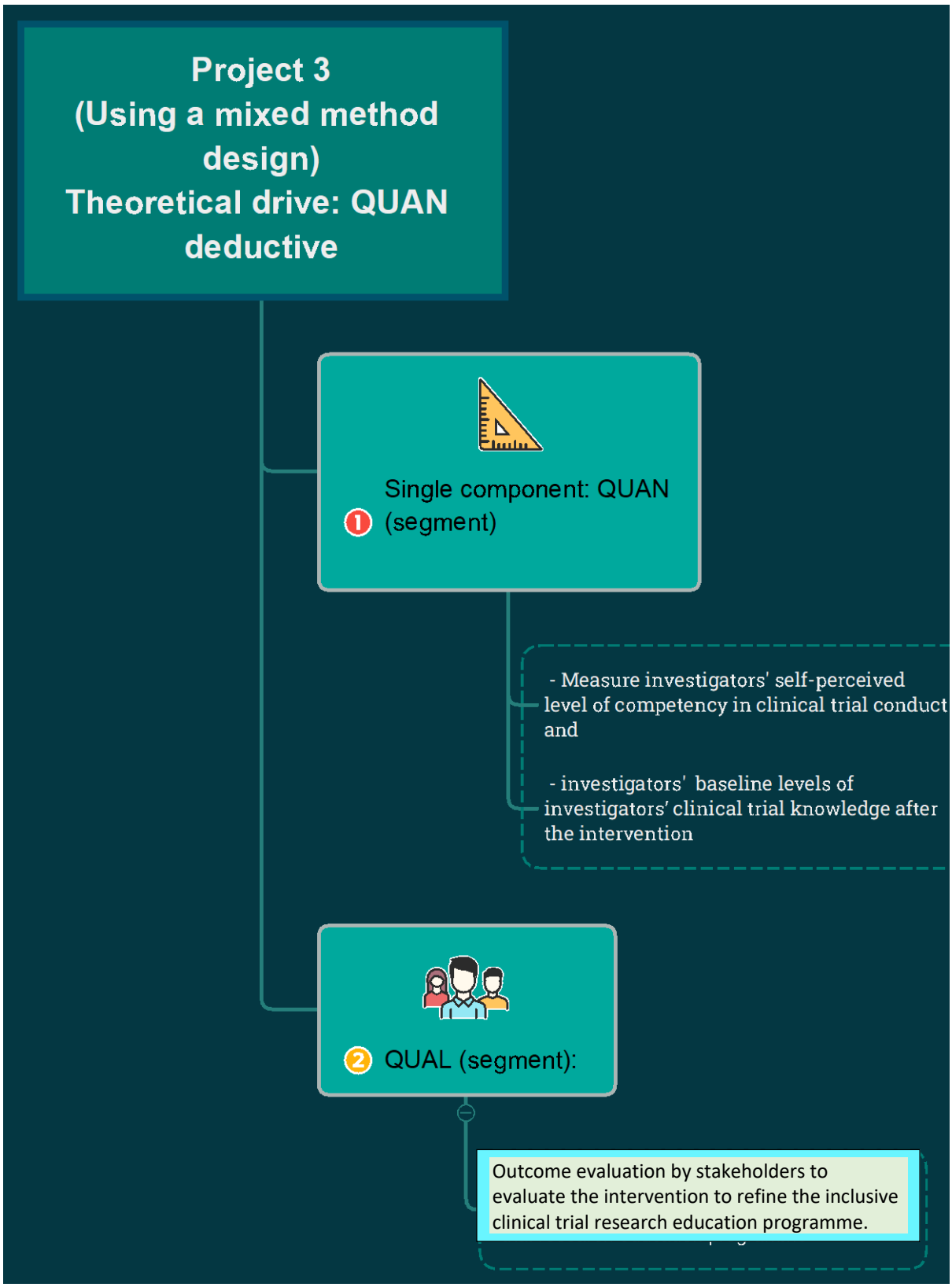


Figure 7.1: Flow chart of Project 3

7.2.5 Data-gathering technique

Pre- and post-tests were used for the outcome evaluation's quantitative data collection phase (segment A). The qualitative data collection phase (segment B) of the outcome evaluation used two instruments, namely semi-structured interviews with open-ended questions, and an outcome evaluation questionnaire with close-ended questions, including a comment section.

Segment A: To collect data for segment A of Project 3, the same questionnaires used to determine participants' self-perceived level of competency and their knowledge of the eight competency domains of the clinical trial process and life cycle were repeated from the pre-assessment phase of Project 2. The two questionnaires contained approximately 100 items (combined), measuring participants' self-perceived level of competency in clinical trials (self-assessment) and their knowledge of the eight competency domains of the clinical trial process and its life cycle. Items included on both tests were identical and were presented in a multiple-choice format covering the GCP and the eight competency domains.

There were two questionnaires for segment A of Project 3:

- Post-test questionnaire to determine participants' self-perceived level of competency
- Post-test questionnaire to determine their knowledge in the eight competency domains of the clinical trial process and life cycle

7.2.5.1 Advantages of questionnaires

The post-test questionnaires provided an instrument to measure if there were changes from baseline self-perceived competency and clinical trial research knowledge. The questionnaires provided numerical data and established a range of views about the students' competencies (Likert rating scale). Furthermore, the questionnaires provided statistical means of analysis to present findings using figures, tables and percentages.

7.2.5.2 Disadvantages of questionnaires

Questionnaire fatigue was a reality for the current study as two questionnaires consisting of approximately 100 questions were completed. Unfortunately, the number of questions was necessary as all eight competency domains had to be covered to determine students' knowledge levels and perceived skills.

Detailed information on the advantages and disadvantages of questionnaires was provided in Chapter 6.

7.2.5.3 Development of the questionnaires

(i) Post-assessment of self-perceived competency in the clinical trial research questionnaire (fourth assessment instrument of the study)

Participants' self-assessment of their competency in clinical trial research post-assessment (see Annexure M) was used to assess changes from baseline self-perceived competency in the eight competency domains. The items used in the pre-assessment were repeated in the post-assessment instrument in the same order and format. The post-assessment of self-perceived competency was completed after completing the clinical trial research education programme.

(ii) Post-assessment of clinical trial research knowledge questionnaire (fifth assessment instrument of the study)

Investigators completed the level of knowledge in the clinical trial research segment after completing the eight-week education programme and the post-self-assessment questionnaire (see Annexure M). The post-assessment knowledge instrument included identical questions to the pre-assessment knowledge instrument in order to measure any modifications in the practical use of information within the specified competency areas and overall knowledge.

Segment B: Qualitative data were collected from two stakeholder groups (participants and supervisors of participants) for segment B of Project 3.

a) **Participants:** Five non-randomly selected participants who attended the eight-week programme were interviewed, and open-ended questions were used as data collection instruments.

Data collection instrument for participants after the clinical trial research education programme intervention

Open-ended questions:

1. What was your motivation for registering for the clinical trial research education programme?
2. What were your expectations of the clinical trial research education programme, and why those specific expectations?
3. Can you describe your experience as a participant in the clinical trial research education programme?
4. Did the programme fulfil your expectations? If yes, describe why, and if not, describe why not.
5. Did the programme make a difference in how you did your tasks and took up your responsibilities after your return to the clinical trial site? If yes, can you describe what kind of difference did you experience? If not, do you have an explanation for why not?
6. What suggestions do you have with regard to the programme? It could include any aspect, for example, the content, the length, the presenter, etc.
7. What are your suggestions for health professionals wanting to enter clinical research?

Probing and follow-up questions were employed in accordance with the responses. As an illustration:

• Provide me with additional information.
• Could you please clarify your statement?
• Additionally...
• Could you provide a more comprehensive explanation?
• Let's discuss that more extensively.
• I have been informed by you that ... What is your rationale for experiencing those emotions?
• That is intriguing. Kindly provide me with supplementary details or an illustrative example.
• What significance does that hold for you?

b) **Supervisors of participants:** The programme evaluation assessment instrument was compiled based on the clinical trial research education curriculum that was

developed and implemented. Different outcome evaluation instruments and guidance manuals were reviewed in the literature (Samuels, Ianni, Chung, Eakin, Martina, Murphy & Jones 2019:3; Semyonov-Tal & Lewin-Epstein 2021:2; Siripipatthanakul 2020:3; Programme Evaluation Guide 2012:1). In addition to closed-ended items, supervisors were asked to comment on their choice of answers or make suggestions to improve the education programme.

Table 7.2: Data collection instrument for stakeholders after the clinical trial research education programme intervention

Inclusive Clinical Trial Research Education Programme Evaluation Form (Stakeholders/supervisors)				
Please mark each with an "X", either yes or no for each question. Please feel free to comment on your choice of answer.				
Q #	Question	Yes	No	Comment
1	Did you have an opportunity to review the content of the clinical trial education programme that your staff attended?			
2	Did knowledge about clinical trial research increase among your staff after completing the clinical trial education programme?			
3	Did the competency levels of the staff increase in the following domains:			
	(1) Scientific concepts and research design;			
	(2) Ethical and participant safety considerations;			
	(3) Medicines development and regulations;			
	(4) Clinical trial operations;			
	(5) Study and site management;			
	(6) Data management and informatics;			
	(7) Leadership and professionalism;			
	(8) Communication and teamwork			
4	Are staff implementing the knowledge acquired by the education programme in their daily work?			
5	Do you have any recommendations to offer for future programme implementers? (please expand in comments if yes)			

7.2.5.4 Pre-testing the questionnaires

For segment A: The self-assessment of competency in clinical trial research and level of knowledge in clinical trial research post-assessment questionnaires were tested with the same group of volunteers from the pre-assessment questionnaires.

For segment B: Participant interviews – the open-ended questions were tested with one participant who was not included in the sample, and after transcribing the interview, it was clear the participant's answers were very broad. Following on, I made sure to probe participants to give examples of where they benefited from the course material.

Stakeholder/supervisor questionnaire – the questionnaire for the supervisors was tested by a supervisor who was not included in the non-randomly selected stakeholders. The supervisor wanted to know if it would be a problem if the answer to the first question, "*Did you have an opportunity to review the content of the clinical trial education programme that your staff attended?*" was 'No'. It was a valid question, and I decided to attach the inclusive clinical trial research education programme's outline to the email I sent to the stakeholders with the questionnaire.

7.2.6 Data gathering

For segment A: On completion of the eight modules of the clinical trial research education programme, the 28 participants received access to the post-test questionnaires to determine their self-perceived level of competency and knowledge of the eight competency domains of the clinical trial process and life cycle. Participants received a link via email to access the questionnaires and had two weeks to complete both questionnaires.

For segment B: Participants and stakeholders (supervisors of participants who attended the programme) were asked to evaluate the clinical trial research education programme. Five participants were selected non-randomly for individual face-to-face interviews. The participants were from different clinical trial settings with varied research experiences. Open-ended questions were asked to gain a deeper understanding and explore their experiences during the educational intervention. The interviews were audio recorded with a digital recorder with their permission. During the interviews, I compiled field notes of my observations and reflections.

Five supervisors of participants were also selected non-randomly and were emailed a questionnaire with the request to give feedback within three weeks. Each supervisor would be responsible for approximately five investigators/participants at their site. Supervisors received email reminders once a week to complete the evaluation form.

7.2.7 Ethical considerations

All ethical considerations concerning freedom from exploitation, human dignity, anonymity and justice (described in Chapter 6) were adhered to during Project 3 of the study.

7.3 DATA ANALYSIS

The data analysis results for the quantitative segment of Project 3 are described next, followed by the qualitative data analysis findings.

7.3.1 Segment A

Segment A had a deductive drive and was quantitative.

7.3.1.1 Analysis 1: Baseline/pre-assessment data analysis

Before the clinical trial research education programme's implementation, participants who registered received a link by email with the request to complete the three assessments, including the (1) demographic assessment tool, (2) self-assessed level of knowledge and competency in clinical trial research, and (3) level of knowledge in clinical trial research. Collected data were entered into an Excel spreadsheet. Data on participants' knowledge of clinical trial research were captured on a spreadsheet provided by the Moodle software platform. The Moodle software provided the total score (percentage) each participant achieved on completion of the baseline or pre-assessment of knowledge of clinical trial research. Preliminary data analysis was not done at baseline but after the post-assessments.

a) Descriptive statistics for demographic assessment

Table 7.3 summarises participants' demographic characteristics. Categorical variables such as age, gender, role in clinical trials, years of experience, and race were presented in frequencies and percentages. The study's sample consisted of all 28 participants who registered for the clinical trial research education programme, as all 28 participants consented to participate.

The average age was 36.6 years, and 89% of the sample was female. In addition, 64% (n=18) of the sample were working as investigators on clinical trials, and 36% (n=10) were non-investigators (for example, clinical trial managers, laboratory managers, statisticians, and study nurses) working on clinical trials. Of the sample, 39.29% (n=11) had 0–1 year clinical trial research experience, 7.14% (n=2) had >1 but less than 2 years of experience, and 53.57% (n=15) had more than 2 years of experience. Racial representation was equal between White and Indian participants (28.57%; n=8), 39.19% (n=11) of participants were Black, and 3.57% (n=1) were Coloured (see Table 7.3).

Prior clinical research education and training: The findings from the preliminary demographic survey revealed that 50% (n=14) of the participants had prior exposure to specialised education or training in clinical trial research or research-related subjects prior to enrolling in the clinical trial research education programme. Approximately 21.43% (n=3) of individuals received specialised education or training in clinical research or research-related subjects during their medical school curriculum. Additionally, 42.86% (n=6) obtained specific education or training in clinical research or research-related topics from an external source after completing medical school. Furthermore, 35.71% (n=5) received specific education or training in clinical research or research-related subjects through another residency training programme. The majority of participants (71.43%; n=10) indicated that the clinical research training they got was compulsory, whereas the remaining participants (28.57%; n=4) stated that the training was optional.

The clinical research education lasted from less than one week for 28.57% (n=4) of participants, more than one week but less than one month for 21.43% (n=3) of participants, three months but less than six months for 7.14% (n=1) of participants, six months but less than one year for 28.57% (n=4) of participants, and up to two years for 14.29% (n=2) of participants.

The clinical research education programmes attended previously by participants primarily covered a range of research topics, including fundamental research concepts and terminology such as randomisation, blinding, and psychometric principles. Additionally, the programmes focused on research study design and sampling methods, encompassing descriptive, cohort, quantitative and qualitative approaches, as well as intervention studies, pharmaceutical studies, and experimental designs. Basic regulatory requirements, such as protocol development, adverse event reporting and documentation, and the involvement of regulatory agencies and institutional review boards (such as SAHPRA), were also addressed. The programmes also emphasised research ethics, privacy, responsible study conduct, informed consent, investigator responsibilities, and conflicts of interest. A small number of participants indicated that they had received limited education on topics such as contracts, budgets, research-related billing, and research career development, including mentor selection, grant acquisition, scientific writing, presentation, and publication (refer to Table 7.3).

Figure 7.2 shows that participants with previous research education had a slight advantage over those without.

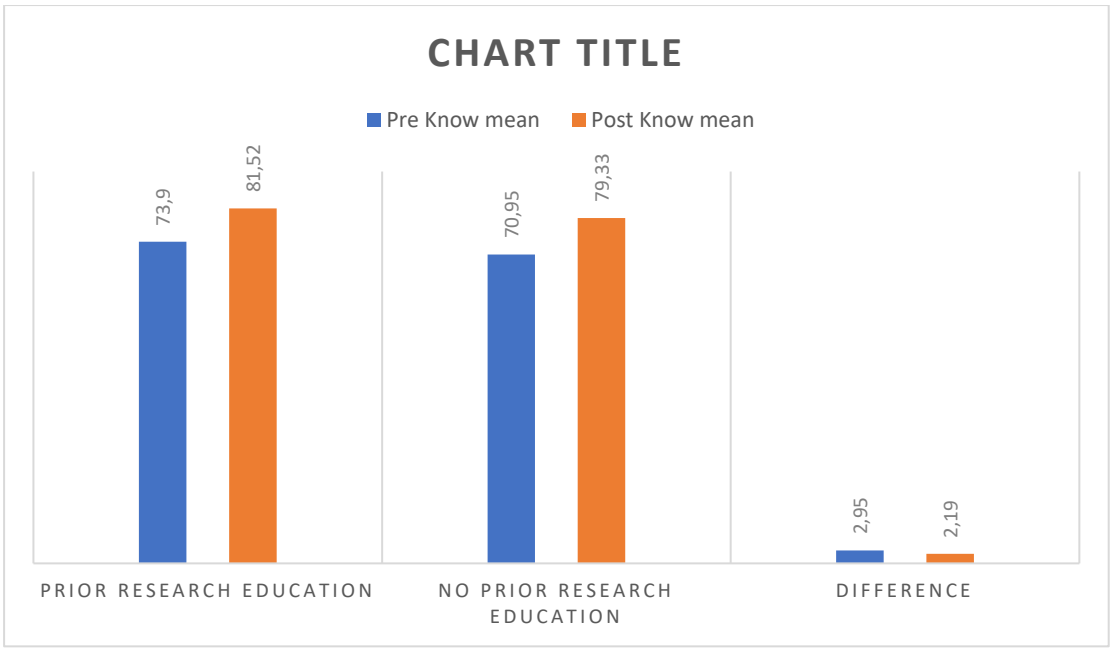


Figure 7.2: Participants' previous research education

Future career plans: Of the 28 participants who responded to the item asking about their future career plans, a greater proportion indicated their plan to extend their clinical research knowledge and skills through courses, training and working at highly

experienced sites (n=15, 53.57%), followed by a plan to engage in publication writing and publishing (n=11, 39.29%). In line with previous study findings (Pelser 2018:80), 38.57% (n=8) of the sample reported using clinical trials as a stepping-stone in their career journey. Only one participant was content with being a PI, eight participants wanted to become a PI, while four were content being sub-investigators with no intention of becoming PIs. Lesser options chosen were those who saw themselves in the academic field or planned to open their own clinical research facility. In addition, 14.29% (n=4) reported they had not decided whether to make clinical research part of their future career plans (see Table 7.3).

Table 7.3: Characteristics of participants

Characteristics of participants			
Variable	**Category level**	n	%
Gender	Female	25	89.29
	Male	3	10.71
Years of experience in clinical trials	0-1	11	39.29
	1-2	2	7.14
	2+	15	53.57
Age breakdown	25-30	3	10.71
	30-35	10	35.71
	35+	15	53.57
Racial breakdown	Black	11	39.19
	White	8	28.57
	Indian	8	28.57
	Coloured	1	3.57
Role in clinical research	Principal investigator	2	7.14
	Sub-investigator (included nurses)	16	57.14
	Other clinical research professionals (including nurses)	10	35.71
Specific education/training for clinical trials	Yes	14	50
	No	14	50

Kind of education/training received (N14 who answered yes)	Acquired specialised education or training in clinical research or research-related subjects as part of my medical school curriculum	3	21.43
	Acquired specialised education or training in clinical research or research-related subjects as part of my medical school curriculum	0	0
	Obtained specialised study or training in clinical research or research-related subjects from an external entity following completion of medical school	6	42.86
	Obtained specialised study or training in clinical research or research-related subjects through an internship or fellowship following completion of medical school.	0	0
	Obtained specialised education or training in clinical research or research-related subjects through a different residency training plan.	5	35.71
	Other	0	0
Mandatory or elective (N14)	Specialised education or training in clinical research or research-related subjects was required.	10	71.43

	The education or training in clinical research or research-related issues was optional.	4	28.57
Duration of the research training received (N14)	Within a week or less	4	28.57
	Between 7 and 30 days	3	21.43
	Between one and three months	0	0
	Exactly 3 months to less than 6 months	1	7.14
	Exactly 6 months to less than 1 year	4	28.57
	Exactly 1 year to less than 2 years	2	14.29
Received specific education or training in clinical research or research-related courses in the following topics (N14). Participants could choose more than one option.	Foundational research principles and vocabulary (randomization, blinding, psychometric principles)	10	71.43
	Research study design and sampling (descriptive, cohorts, quantitative and qualitative, intervention studies, pharmaceutical studies, experimental designs)	8	57.14
	Research ethics, privacy, and appropriate research conduct (informed consent, investigator obligations, conflicts of interest)	5	35.71
	Essential regulatory prerequisites include the formulation of protocols, reporting and documenting	6	42.86

	adverse events, dealing with regulatory bodies, obtaining approval from Institutional Review Boards, and complying with the South African Health Products Regulatory Authority (SAHPRA).		
	Research contracts, research budgets, and research-related billing are all components of the research process.	3	21.43
	Investigate the process of advancing one's career in research, including selecting a mentor, acquiring financing, mastering scientific writing, delivering presentations, and publishing findings.	2	14.29
Future career plans (N28). Participants could <u>choose more than one option.</u>	Not decided at this time whether or not I plan to make clinical research part of my future career plans.	4	14.29
	Use clinical research as a stepping-stone in my career journey.	8	38.57
	Plan to extend clinical research knowledge and skills through courses, training programmes and working at highly recommended clinical research facilities, even if it means moving to a foreign country for a while.	15	53.57
	Plan to be a competent sub-investigator but not interested in becoming a principal investigator.	4	14.29

	Plan to move fast from being a sub-investigator to becoming a principal investigator.	8	28.57
	Plan to open own clinical research facility.	5	17.86
	Plan to work at an academic institution to advance clinical research knowledge and skills.	6	21.43
	Plan to work as an investigator in clinical research and teach at an academic institution.	3	10.71
	Plan to engage in publication writing and publishing.	11	39.29
	Other: = I am a Co-PI who intends to continue to lead the current research unit where I am employed.	1	3.57

Baseline/pre-assessment results of participant level of knowledge

After collecting completed self-perceived competency pre-assessments, participants were asked to complete the pre-assessment of the clinical trial research knowledge questionnaire. All 28 participants completed this assessment. The knowledge assessment comprised 75 items representing the eight JTF competency domains. Different clinical trial scenarios were described, and participants were instructed to select the most appropriate response for each item. Each item on the test was weighted evenly, making each worth 1.33%, providing a possible score range of 0 to 100. The median clinical trial research knowledge grade at baseline was 72.43% (range = 49.33-85.33%). Figure 7.4 and Table 7.4 represent the different ranges in which participants' knowledge grades fell at baseline.

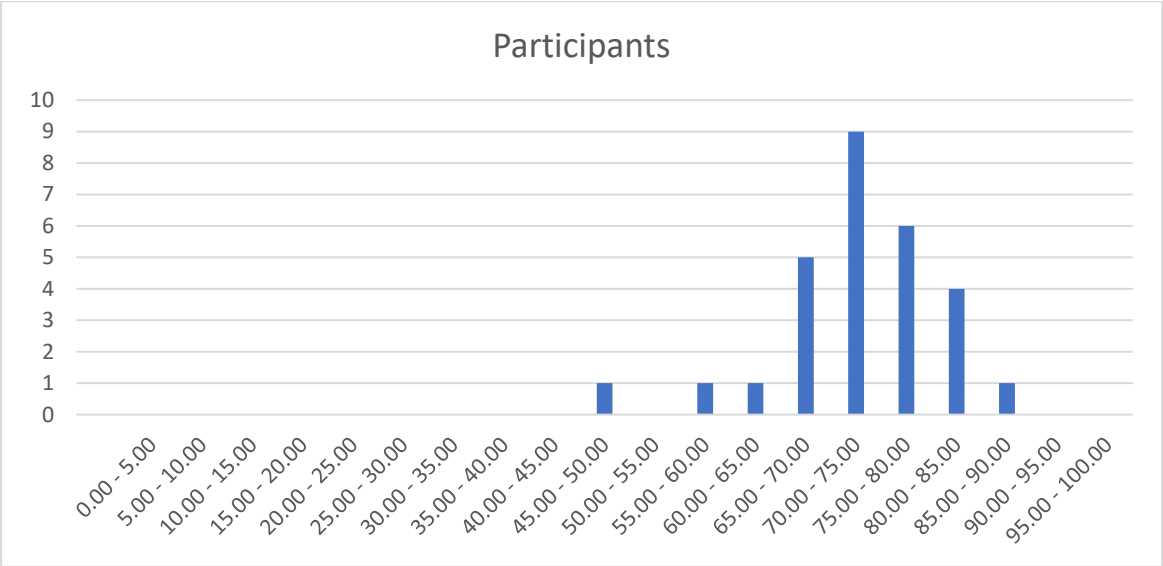


Figure 7.4: Range of participant level of knowledge scores at baseline

Table 7.4: Range of participants' level of knowledge scores at baseline

Range	Participants (n=28)
0.00 - 5.00	0
5.00 - 10.00	0
10.00 - 15.00	0
15.00 - 20.00	0
20.00 - 25.00	0
25.00 - 30.00	0
30.00 - 35.00	0
35.00 - 40.00	0
40.00 - 45.00	0
45.00 - 50.00	1
50.00 - 55.00	0
55.00 - 60.00	1
60.00 - 65.00	1
65.00 - 70.00	5
70.00 - 75.00	9
75.00 - 80.00	6
80.00 - 85.00	4
85.00 - 90.00	1
90.00 - 95.00	0
95.0 - 100.00	0

7.3.1.2 Analysis 2: Post-assessment and comparison

a) Descriptive statistics for the level of knowledge in clinical trial research post-assessment

After collecting the completed self-perceived competency post-assessments, participants were asked to complete the post-assessment of clinical trial research knowledge questionnaire. Except for one participant who attained an equal score for the pre- and post-test questionnaire, 27 out of 28 participants demonstrated an increase in score. The lowest score for the pre-test was 49.33%, the highest score was 85.33%, the lowest score for the post-test was 69.33%, and the highest was 89.33%.

Figure 7.5 and Table 7.5 represent the different ranges in which participants' knowledge grades fell post-assessment.

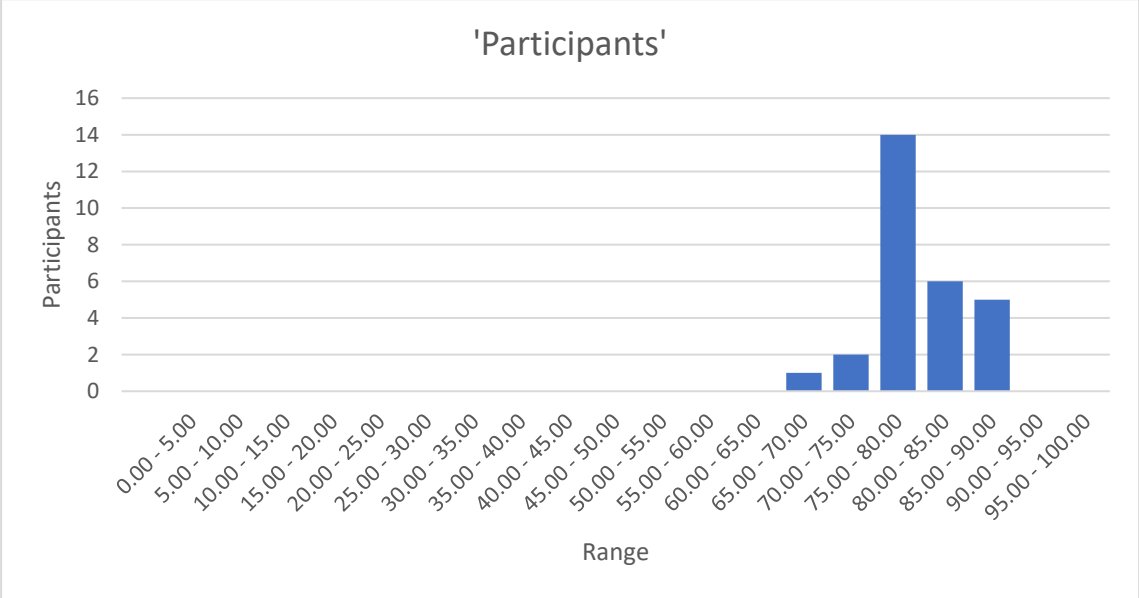


Figure 7.5: Range of participant level of knowledge scores at post-assessment

Table 7.5: Range of participant level of knowledge scores at post-assessment

Range	Participants (n=28)
0.00 - 5.00	0
5.00 - 10.00	0
10.00 - 15.00	0
15.00 - 20.00	0
20.00 - 25.00	0

Range	Participants (n=28)
25.00 - 30.00	0
30.00 - 35.00	0
35.00 - 40.00	0
40.00 - 45.00	0
45.00 - 50.00	0
50.00 - 55.00	0
55.00 - 60.00	0
60.00 - 65.00	0
65.00 - 70.00	1
70.00 - 75.00	2
75.00 - 80.00	14
80.00 - 85.00	6
85.00 - 90.00	5
90.00 - 95.00	0
95.00 - 100.00	0

b) Inferential statistics comparing the pre and post-test assessment levels of knowledge in clinical trial research.

Paired-sample t-test: A paired-sample t-test was used to compare the pre- and post-test assessments for all the continuous score data. The assessment involved determining the difference between the pre- and post-test values with a negative outcome, suggesting that the post-test value was greater. The difference between the pre- and post-test measures was then subjected to a student t-test evaluation to test the null hypothesis that the true mean difference is zero. These findings were assessed using t-statistics and p-values, with p-values < 0.05 suggesting a statistically significant difference between the data collected between the two time points. The assessments involved evaluating the overall scores for items followed by individual item comparisons (Fowler, Jarvis & Chevannes 2021:145; Bowers 2019:243).

Significance level and confidence intervals: The alpha level was established at 0.05, and a confidence interval of 95% was used. The utilisation of a two-sided p-value of 0.05 enabled me to either reject or accept the null hypothesis, which states that there was no change in assessment scores after the implementation and delivery of a clinical trial

research education programme for investigators, regardless of the direction of the change (Bowers 2019:243; Altman 1999:167). A 99% confidence interval provides stronger evidence in research findings, indicating results with a probability value of $p<0.01$ rather than $p<0.05$. The research findings were further validated by the inclusion of this significance level. However, in the present investigation, 99% confidence intervals were not utilised due to the small sample size resulting from a limited number of investigators working at research sites in South Africa during the eight-week teaching session. Therefore, utilising a 95% confidence interval was more practical and enabled me to identify outcomes that were marginally less significant. (Fowler et al. 2021:83; Altman 1999:167).

All the statistical analyses involving the paired-sample t-test were conducted using SAS Enterprise 7.15 (SAS Institute Inc, Cary, NC, USA), assuming a 5% significance level.

Results: Pre- and post-assessment of participants' knowledge of clinical trial research

In the overall comparison of the pre- and post-test grades, the post-test grades were statistically significantly higher (-8 (-10.6,-5.41) [$p<0.0001$]), suggesting a higher grade score post-test (see Table 7.6).

Table 7.6: Level of knowledge pre- and-post-score

Variable	Difference	Mean (95% CI)	Standard deviation	Test statistic	p-value
Overall (Pre & Post-Test Grade Scores)	pre-test - post-test grade	-8.00 (-10.6, -5.41)	6.69	-6.33	<.0001

Figure 7.6 shows the pre-test and post-test grade comparison for each of the 28 participants.

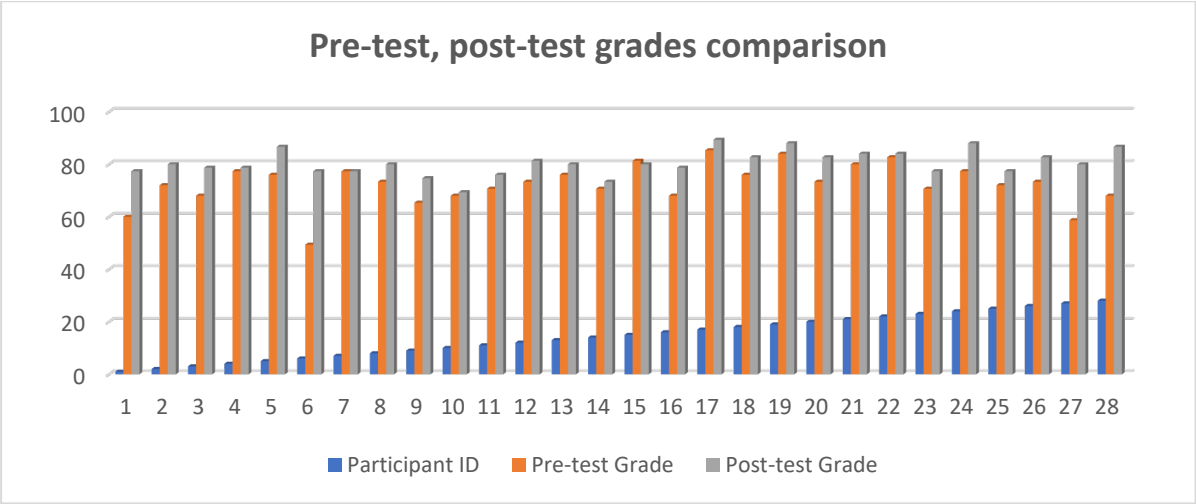


Figure 7.6: Pre-test and post-test grade comparison of participants

c) Individual domains of clinical trial research knowledge

The pre- and post-knowledge scores were compared across all eight domains. Each of the eight knowledge assessment domains was assessed independently with paired-sample t-tests to determine any significant changes from the baseline involving specific curriculum content. While all the domain scores showed that the post-knowledge domain scores were higher, not all were statistically significantly different. Domains 1 (-1.05 (-2.00,-0.09); p=0.0333), 3 (-1.66 (-3.14,-0.19); p=0.0287), 4 (-2.19 (-3.13,-1.24); p<0.0001) and 8 (-0.76 (-1.31,-0.21); p=0.0087) had statistically significant post-knowledge scores compared with the pre-test domain score measures (Table 7.7).

Table 7.7: Pre and post-knowledge scores compared across all eight domains

Variable	Difference	Mean (95% CI)	Standard deviation	Test statistic	p-value
Pre-Post Knowledge Domain Scores					
Domain 1	pre_scores_dom1 - post_scores_dom1	-1.05 (-2.00, -0.09)	2.46	-2.24	0.0333
Domain 2	pre_scores_dom2 - post_scores_dom2	-1.28 (-2.59, 0.02)	3.37	-2.02	0.0539
Domain 3	pre_scores_dom3 - post_scores_dom3	-1.66 (-3.14, -0.19)	3.81	-2.31	0.0287

Variable	Difference	Mean (95% CI)	Standard deviation	Test statistic	p-value
Domain 4	pre_scores_dom4 - post_scores_dom4	-2.19 (-3.13, -1.24)	2.43	-4.75	<.0001
Domain 5	pre_scores_dom5 - post_scores_dom5	-0.28 (-0.95, 0.38)	1.71	-0.88	0.3860
Domain 6	pre_scores_dom6 - post_scores_dom6	-0.52 (-1.19, 0.14)	1.71	-1.62	0.1177
Domain 7	pre_scores_dom7 - post_scores_dom7	-0.19 (-0.55, 0.17)	0.94	-1.07	0.2933
Domain 8	pre_scores_dom8 - post_scores_dom8	-0.76 (-1.31, -0.21)	1.42	-2.83	0.0087

Tables 7.8 and 7.9 show each domain's pre-test and post-test mean percentages, and Table 7.10 compares the pre- and post-mean of each domain. Figures 7.7 and 7.8 show the pre-test and post-test mean percentages of each domain, and Figure 7.9 compares the pre- and post-mean for each domain.

Table 7.8: Pre-assessment mean for each domain

	D1	D2	D3	D4	D5	D6	D7	D8
Pre	73.80%	75.54%	71.61%	67.38%	82.85%	67.85%	84.82%	70.71%

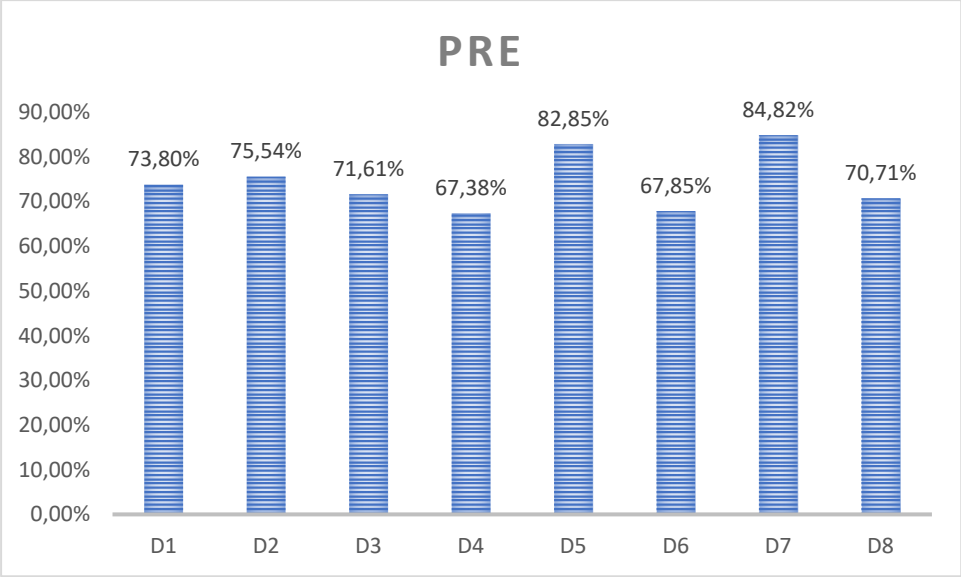


Figure 7.7: Pre-assessment mean for each domain

Table 7.9: Post-assessment mean for each domain

	D1	D2	D3	D4	D5	D6	D7	D8
Post	82.14%	82.41%	80.03%	78.33%	87.14%	75.71%	89.28%	82.14%

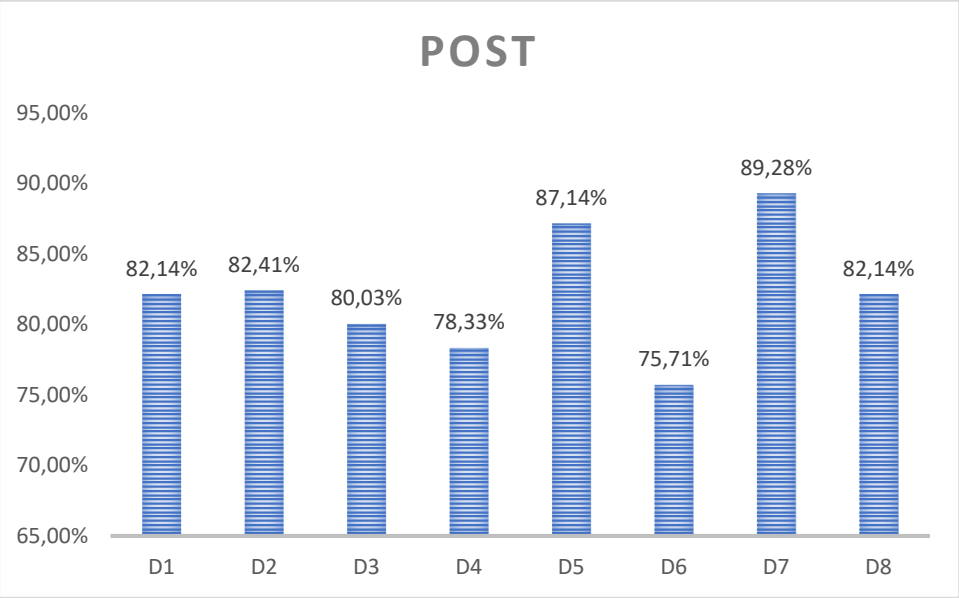


Figure 7.8: Post-assessment mean for each domain

Table 7.10: Comparison pre- and post-mean for each domain

	D1	D2	D3	D4	D5	D6	D7	D8
Pre	73.80%	75.54%	71.61%	67.38%	82.85%	67.85%	84.82%	70.71%
Post	82.14%	82.41%	80.03%	78.33%	87.14%	75.71%	89.28%	82.14%
Difference	8.34%	6.87%	8.42%	10.95%	4.29%	7.86%	4.46%	11.43%

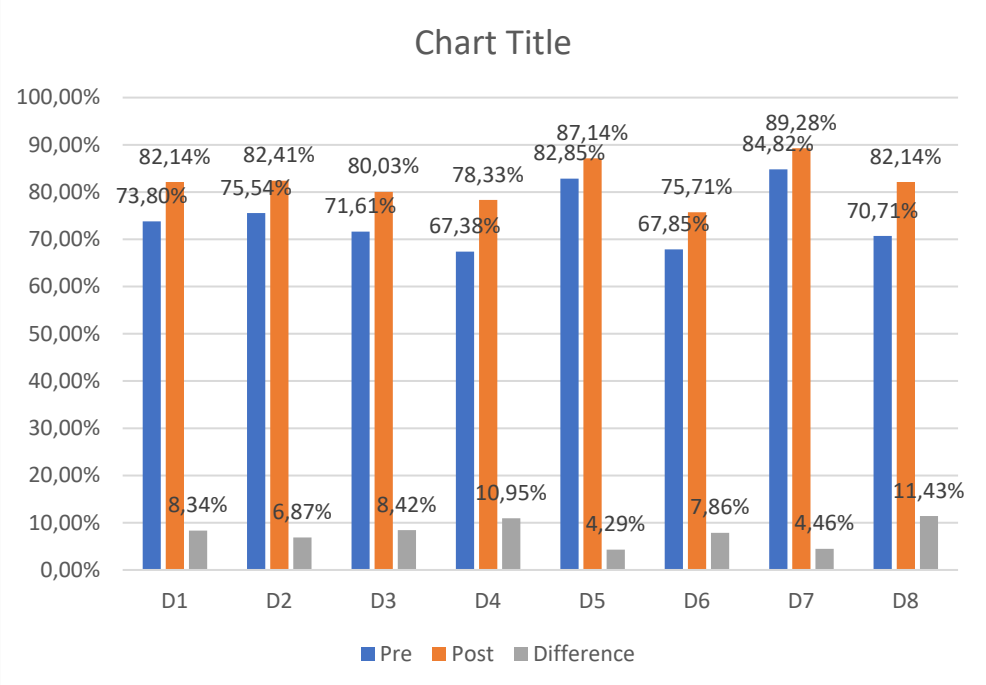


Figure 7.9: Comparison pre- and post-mean for each domain

d) Differences in the level of knowledge and self-perceived competency

At baseline, the participants' overall mean for perceived competency coding was 111.286, whereas the perceived competency coding at the post-test level was 150.714, representing a mean difference of 39.4 higher post-test scores. At baseline, the pre-test grade mean percentage was 72.43, whereas, at the post-test grading, it was 80.43, representing a mean difference of 8.0 higher percentage grade scores at the post-testing level. For the knowledge domains, the mean pre and post-test knowledge domain scores were: 8.7875 and 9.8325 in domain 1, representing a difference of 1.05; 12.9675 and 14.25 in domain 2, representing a difference of 1.2825; 18.0975 and 19.76 in domain 3, representing a difference of 1.6625; 13.4425 and 15.6275 in domain 4, representing a difference of 2.19; 5.51 and 5.795 in domain 5, representing a difference of 2.8; 4.5125 and 5.035 in domain 6, representing a difference of 0.52; 4.56 and 4.75 in domain 7, representing a difference of 0.19; and 4.7025 and 4.4625 in domain 8, representing a difference of 0.76. The decreasing disparity indicates that, although both measures rose, the real and perceived scores became more closely aligned after the implementation of the clinical trial research education curriculum. This may arise from the participants' recognition of their limited proficiency in research, or it could be attributed to other influencing variables.

e) Inferential statistics for self-perceived competency assessment

Participants' self-perceived competency in clinical trial research was assessed using a tool based on Miller's framework, designed to assess clinical skills, competence, and performance. The questionnaire assessed clinical competence by capturing investigators' self-rated competency level on each item, from "not knowing" to "does" (Miller 1990:2; Witheridge, Ferns & Scott-Smith 2019:191).

For this research study, the self-assessed level of competency in clinical trial research (questionnaire) was developed to capture investigators' beliefs about their knowledge and abilities in the eight JTF competency domains. The self-perceived competency assessment contained 40 items, enveloping all eight JTF competency domains. Participants were asked to rate themselves on each item using an ordinal scale indicating whether the participant do "*Not know*: no knowledge, no exposure, never heard of the

topic before" (Score of 1); "*Knows:* real-life knowledge, little exposure/know about this/have heard about this from others, courses or reading but do not how to do it" (Score of 2); "*Know how*: investigation, usage and comprehension of knowledge, received training/read about this/was told about this, therefore I know how to do this, but have never done it nor can I show or explain how to do it" (Score of 3); "*Show how:* application and practical demonstration in a simulated situation – I can show how to do this during a simulation or explain how to do this when asked, but have never done it in real-life situations" (Score of 4); "*Does:* performance in real-life situation – I have done this in real-life situations and therefore feel capable of doing it" (Score of 5). At baseline, the most common response to the presented items were "not know"; "knows" and "know how".

Although all 28 participants were asked to complete all assessment questionnaires, four participants did not complete the pre- or baseline self-perceived level of competency assessment, which indicated a response rate of 89%. The reason was that they thought they should complete only one of the pre-assessment questionnaires and did not realise the difference between them.

Results of the pre- and post-self-perceived assessment

A paired-sample t-test was used to compare the pre- and post-test assessments. The assessments involved evaluating the overall scores for items and individual item comparisons. All statistical analyses involving the paired-sample t-test were conducted using SAS Enterprise 7.15 (SAS Institute Inc, Cary, NC, USA), assuming a 5% significance level. In the pre-perceived and post-perceived competency coding items, the post-evaluation scores were significantly higher than the pre-evaluation scores; the difference between the overall means was -39 (-55.1, -23.8) [$p<0.0001$]. All the individual item measures of pre- and post-perceived competency showed that the post-perceived values were consistently higher than the pre-perceived values (Table 7.11).

Table 7.11: Pre- and post-test measures of the level of competency coding

Pre and post-test measures of competency coding					
Variable	**Difference**	**Mean (95% CI)**	**Standard Deviation**	**Test statistic**	**p-value**
Overall score	pre-score - post-score	-39.4 (-55.1, -23.8)	34.44	-5.25	<.0001

Pre and post-test measures of competency coding					
Correctly define clinical trial-related terminology	b - b1	-0.67 (-1.17, -0.16)	1.11	-2.75	0.0123
Manage a participant with adverse events according to the protocol (including grading of the adverse event)	c - c1	-0.52 (-1.07, 0.03)	1.21	-1.99	0.0610
Identify potential conflicts of interest in clinical research	d - d1	-0.71 (-1.26, -0.17)	1.19	-2.75	0.0123
Identify the required components of research informed consent documentation	e - e1	-1.00 (-1.58, -0.42)	1.26	-3.62	0.0017
Follow the appropriate processes for reporting clinical trial-related adverse events	f - f1	-0.95 (-1.54, -0.37)	1.28	-3.40	0.0028
Follow the proper procedures for conducting a clinical trial at your institution or workplace	g - g1	-1.10 (-1.70, -0.49)	1.34	-3.75	0.0013
Identify the basic elements of a clinical trial protocol	h - h1	-0.90 (-1.36, -0.45)	1.00	-4.17	0.0005
Determine when a clinical trial should be closed through the IRB	i - i1	-0.67 (-1.19, -0.14)	1.15	-2.65	0.0155
Follow the appropriate processes for adding study staff to a clinical trial	j - j1	-0.81 (-1.46, -0.16)	1.44	-2.58	0.0177
Follow the appropriate processes for removing study staff from a clinical trial	k - k1	-1.10 (-1.72, -0.47)	1.37	-3.65	0.0016
Correctly define who the sponsors and the stakeholders are for a clinical trial	l - l1	-1.19 (-1.88, -0.51)	1.50	-3.63	0.0017
Identify the essential documents that should be part of the regulatory or	m - m1	-1.00 (-1.64, -0.36)	1.41	-3.24	0.0041

Pre and post-test measures of competency coding					
investigator site files during the lifecycle of the clinical trial (before, during, and after)					
Develop a manual of procedures (MOP) to ensure smooth running and successful completion of the clinical trial	n - n1	-1.14 (-1.63, -0.66)	1.06	-4.93	<.0001
Correctly describe the different roles and responsibilities of each team member on the clinical trial	o - o1	-0.71 (-1.36, -0.07)	1.42	-2.31	0.0319
Analyse a proposed protocol to determine if the clinical trial will be suitable for your site (feasibility study)	p - p1	-1.29 (-1.79, -0.78)	1.10	-5.35	<.0001
Complete an application for approval for the clinical trial to the regulatory authorities (IRB/SAHPRA)	q - q1	-1.57 (-2.10, -1.04)	1.16	-6.18	<.0001
Set up a clinical trial team for a new study	r - r1	-1.33 (-2.01, -0.65)	1.49	-4.09	0.0006
Prepare site files for a new clinical trial	s - s1	-1.20 (-1.92, -0.48)	1.54	-3.48	0.0025
Prepare source documentation for a clinical trial	t - t1	-0.60 (-1.21, 0.01)	1.31	-2.04	0.0553
Set up a data management system programme to capture all relevant participants and trial information	u - u1	-1.33 (-1.93, -0.73)	1.32	-4.64	0.0002
Negotiate the budget or funding for a clinical trial with the sponsor	v - v1	-1.05 (-1.73, -0.37)	1.50	-3.20	0.0045

Pre and post-test measures of competency coding					
Describe the different regulatory authorities in South Africa (IRB/SAHPRA/NHREC/SA National Clinical Trails Register)	w - w1	-0.95 (-1.50, -0.40)	1.20	-3.63	0.0017
Complete progress reports to sponsors and regulatory authorities (IRB/SAHPRA)	x - x1	-1.52 (-2.06, -0.99)	1.17	-5.98	<.0001
Apply for an export permit for biological samples	y - y1	-1.05 (-1.65, -0.45)	1.32	-3.63	0.0017
Prepare a material transfer agreement (MTA)	z - z1	-0.81 (-1.30, -0.32)	1.08	-3.44	0.0026
Review and evaluate informed consent before presenting it to the IRB for approval	aa - aa1	-0.85 (-1.42, -0.28)	1.23	-3.10	0.0059
Review and evaluate an assent form for paediatric studies before presenting it to the IRB for approval	ab - ab1	-1.10 (-1.67, -0.52)	1.26	-3.98	0.0007
Plan for participant recruitment for the clinical trial)	ac - ac1	-0.95 (-1.55, -0.35)	1.32	-3.30	0.0036
Plan for participant retention for the clinical trial	ad - ad1	-1.14 (-1.79, -0.49)	1.42	-3.68	0.0015
Project participant recruitment to successfully complete recruitment during the recruitment period allowed for the clinical trial	ae - ae1	-1.43 (-2.03, -0.83)	1.33	-4.94	<.0001
Make use of a Gantt chart to track trial startup timelines as well as trial progress (project management)	af - af1	-1.67 (-2.28, -1.05)	1.35	-5.64	<.0001
Prepare for a site initiation visit	ag - ag1	-1.24 (-1.86, -0.61)	1.37	-4.13	0.0005

Pre and post-test measures of competency coding					
Screen a participant according to the inclusion and exclusion criteria of the protocol to determine if the participant is eligible for the clinical trial	ah - ah1	-0.81 (-1.46, -0.16)	1.44	-2.58	0.0177
Randomise or enrol a participant in a clinical trial	ai - ai1	-0.60 (-1.07, -0.13)	0.99	-2.70	0.0143
Evaluate clinic flow and make the necessary changes for improvement	aj - aj1	-0.62 (-1.24, -0.00)	1.36	-2.09	0.0499
Complete source documentation for a participant	ak - ak1	-0.67 (-1.17, -0.16)	1.11	-2.75	0.0123
Develop a CQMP	al - al1	-0.57 (-1.28, 0.14)	1.57	-1.67	0.1104
Prepare for trial end and trial close-out	am - am1	-0.76 (-1.51, -0.02)	1.64	-2.13	0.0459
Prepare for an audit or inspection from the sponsor or the FDA/EMEA/SAHPRA	an - an1	-0.95 (-1.55, -0.35)	1.32	-3.30	0.0036
Prepare dissemination of trial results	ao - ao1	-1.05 (-1.67, -0.43)	1.36	-3.53	0.0021

7.3.2 Segment B

Segment B had an inductive drive and was qualitative.

7.3.2.1 Data Analysis

According to Leedy and Ormrod (2019:344), analysing qualitative data is about finding meaning within the data. My data analysis process once again started with me organising the data, followed by data transcription and coding.

a) Organising the data

The individual interviews with audio recordings, followed by verbatim transcriptions and personal notes/memos, were not as long as those conducted during Project 1 of the study. However, thorough preparation for analysis was still needed. A suitable anonymising method was used to code the data of different participants (Saunders 2019:644). I generated both a physical paper and a digital computer file for each participant, encompassing all the gathered data. A unique alphanumeric code assigned to participant files for future retrieval. The physical documents were stored in a secure cabinet within my secured office, while the digital files were safeguarded by a password.

b) Transcribing the data

Audio-recorded data were transcribed verbatim, giving a word-for-word replication of the interview (Seidman 2019:124). I involved the same professional transcriber who did the transcriptions for the interviews from Project 1 to transcribe the audio-recorded interviews of Project 3. An accord was reached about the transcription of data, encompassing the manner in which it was spoken, and the non-verbal cues exhibited by the participants. The transcriber ensured the precision of the transcribed data by maintaining ongoing communication via telephone and email (Seidman 2019:124).

c) Coding the data

The same cyclical analytic manual coding process used in Project 1, namely Saldaña's cyclical analytic coding method, was used in Project 3. Data were compared with data, followed by comparing data to code, code to code, code to category, category to category, and category back to data (Saldaña 2019:651). My research question: "What are stakeholders' evaluations of the clinical trial research programme?" and the inclusion of these findings in refining and finalising the clinical trial research education programme determined my choice of first, cross, and second-cycle coding methods. The full process of cycle coding, the meaning of codes, categories and themes, as described in Chapter 3, was followed.

d) Analytic memos

I wrote some memos to help me think and write more about the participants and the feedback they gave me (Saldaña 2021:44). I used these reflective notes to reflect on my

emotions and attitudes regarding participants' feedback on the inclusive clinical trial research education programme (Saldaña 2021:47).

7.3.2.2 Findings of the QUAL segment Project 3, interviews with stakeholders (participants and supervisors of participants)

The QUAL segment of Project 3 aimed to understand the outcome of the clinical trial research education programme. First, participants who completed the inclusive clinical trial research education programme were asked about their experience with the programme. Second, the supervisors of the participants who attended the training programme were asked to give feedback on any change or increases in staff's clinical trial knowledge and competency levels in the eight JTF domains after they attended the training programme.

a) Description of the demographics of the participants

First, I describe the demographics of the interviewed participants (see Table 7.12). Data were collected after completing the eight-week inclusive clinical trial research education programme from 8 December 2022 to 20 January 2023. Five participants who attended the programme were approached for an interview. Participants were purposefully selected for their experience or lack of experience in clinical trial research and the field of clinical trial research. Two participants had less than one year's experience. The other three with more than a year of experience were from different research fields; one did preventative clinical trial research at a dedicated clinical trial site, one was a physician at a provincial hospital and tried to do clinical trials in her department as part of her routine work, and one was working at a laboratory processing samples from clinical trial participants. They were all relatively young (under 40), and only one participant was older than 40. Regarding their racial background, four were White, and one was Indian. At the time of the interviews, there was one PI, three sub-investigators, and one laboratory manager (other).

Table 7.12: Description of the participants' demographics

VARIABLE	PARTICIPANTS (n5)
Gender	Male = 1 Female = 4

VARIABLE	PARTICIPANTS (n5)
Experience	0-1 year = 2 >1 years = 3
Age breakdown	30-35 = 3 36-40 = 1 40+ = 1
Racial breakdown	Black = 0 White = 4 Indian = 1
Role in clinical research	Principal investigator = 1 Sub-investigator = 3 Other = 1

b) Description of the findings of the first aim of the QUAL segment Project 3: Participants' evaluation of the clinical trial research education programme

Participants' evaluation of the inclusive clinical trial research education programme was subjective, and they described their lived experiences while attending the education programme. During my reflective notes, I commented that the participants seemed at ease and spoke with some confidence about what they had learnt. Participants were eager to share their experiences. Table 7.13 shows the participant codes and pseudonyms used during the interviews to protect participants' identities.

Table 7.13: Participant codes and pseudonym log

Participant code	Pseudonym
310124	Arthur
310207	Meagan
410303	Reba
520413	Tammy
220514	Jacky

Table 7.14 summarises the themes, categories, and codes that emerged from the data analysis process.

Table 7.14: Summary of themes, categories, and codes QUAL segment project

THEME	CATEGORY	CODE
1. Expression of knowledge and guidance needed	1.1 Wanted to expand knowledge and expertise about clinical trials	To learn everything
	1.2 Because of previous mistakes made due to learning by trial and error	Learn by making mistakes
	1.3 There is a gap in the training of new investigators	1.3.1 Gets thrown into the deep end. 1.3.2 Identify a gap in the training of new investigators
2. Knowledge and guidance needs were addressed	2.1 Learnt a great deal	Learnt a lot
	2.2 Networking with others	Work in a team
	2.3 Clinical trial operations and management	2.3.1 Writing the protocol, registering protocol with SAHPRA, make amendments 2.3.2 Startup of a study, a budget and feasibility study 2.3.3The Gantt chart, managing projects and managing what needs to be done, staff management
3. Future vision	3.1 Additional information	More guidance, specifically concerning medical devices, needed
	3.2 Another format of the course	Long and intense
	3.3 A course for new investigators	Helpful course. Recommended for new or any experienced investigator

7.3.2.3 Themes, categories, and codes

The findings reflected three main themes, namely (1) expression of knowledge and guidance needed; (2) knowledge and guidance needs were addressed; and (3) future vision. These three main themes, with the related categories and codes, will now be discussed along with verbatim quotes. Direct quotes are provided in *italics*.

a) Expression of knowledge and guidance needed

Participants had different explanations of the clinical trial research knowledge and guidance they needed, which varied from personal experience to an objective view of clinical trial research.

a.i) Wanted to expand knowledge and expertise about clinical trials

Participants who were relatively new to clinical trials particularly needed to know more about clinical trial research. One participant mentioned that he was brand new to clinical trial research and wanted to know more:

> *"So I am brand new, so very interested in learning whatever I can"* [Arthur]

Another participant mentioned:

> *"I have been in clinical trial research for one year, so I wanted to get more of an oversight of the different domains. I just wanted to learn more, to get more insight into everything that goes into the startup and all the administrative things that goes into a clinical trial"* [Tammy]

A more experienced participant shared:

> *"There are many things that I was aware of but did not know how it occurred. Things that happened in the background, but I was never involved in them"* [Jacky]

Insufficient preparation was identified as one of the issues faced by early career investigators, according to a study conducted by Pelser (2018:84). According to Pelser

(2018:84), certain participants linked their lack of preparation to the sensation of commencing clinical research with a blank slate. Insufficient knowledge and expertise posed difficulties for certain participants in navigating the complex landscape of clinical trials. Nevertheless, it also enabled certain individuals to acknowledge that their lack of expertise prompted them to approach clinical research with a fresh perspective, making them receptive to acquiring new knowledge (Pelser 2018:84). In the present investigation, a similar sentiment was expressed.

a.ii) Because of previous mistakes made due to learning by trial and error

For two participants, learning from trial and error was a reality, and this motivated them to register for the training programme:

> *"I think the easiest way to explain it is like making mistakes. I don't have the experience to know that I am making mistakes. I realised after completing the study that I needed regulatory approval. I was very worried. I got a fright from that, it was all done in good faith. So that's why I did it because I was afraid and it made me more afraid"* [Reba]

> *"Because I do not have the experience, I learnt by trial and error"* [Jacky]

Their experience was similar to what Weeks-Rowe (2020:1) describes as the "trial-by-fire" method of learning clinical trial research that does not allow a controlled learning environment. Since no formal training programme exists, it forces the new employee to complete haphazard, inconsistent onboarding training. Trial-by-fire training widens the gap between angst and confidence, while a well-planned training programme helps transform anxiety into accomplishment with each lesson learnt. According to Weeks-Rowe (2020:1), trial and fire introduces errors into the learning process with a lack of direction and, in the end, could lead to increased staff turnover because employees are unable to flourish in an ineffective training environment. Using error as a learning opportunity is only valid at the end of a study when the purpose is to ensure that the subsequent study does not suffer the same mistakes. When new employees learn only by trial and error, it can impact raw confidence and create preventable quality and data issues (Weeks-Rowe 2020:1).

The current issue lies in the high rate of staff turnover at clinical trial locations. Bastek (2022:1) reported a 10% rise in active clinical trials compared to 2021. However, sites, sponsors, and CROs are facing a shortage of personnel to cope with this expansion. Several study sites experienced a surge in their turnover rates, with an increase of up to 50%. Because clinical trials are not recognised as a primary career path, there are few dedicated educational pathways into the career field. Therefore, it is difficult for prospective employees to learn about clinical trials. If sites are looking for experienced or educated staff, they have a tiny pool of candidates, making hiring more challenging.

a.iii) There is a gap in the training of new investigators

The gap in new investigators' training was mentioned by one of the participants:

> *"I think there is definitely a gap in the training of new investigators because you get into research not knowing really what it entails, and everyone is just thrown into the deep end"* [Tammy]

Two other participants referred to a lack of preparation to become a PI:

> *"Even as a sub-investigator, no one is preparing you to become a PI and I think this course also helps you to see where should you get some knowledge and skills in so if you get to the point being a PI then you should be able to do all these things"* [Reba]

> *"I work here already for many years and have not had any formal training in how to be a PI, how to be an investigator, so I thought this will give me extra background"* [Jacky]

The Clinical Trials Transformation Initiative (CTTI) aims to tackle the requirement for a more streamlined and productive method of finding competent clinical investigators. It highlights that relying just on GCP training is insufficient (Bechtel et al. 2020:105918). Saleh and colleagues (2020:1) mentioned that other than mentorship, new clinicians have few formal training opportunities to learn about clinical investigator competencies. The gap in training could also be because clinical trials are not recognised as a primary career path, as mentioned in the previous section.

b) Knowledge and guidance needs were addressed

Participants agreed that the inclusive clinical trial research education programme did address their need for knowledge and guidance, and it will possibly do the same for future investigators.

b.i) Learnt a great deal

Most participants mentioned that they had learnt a "lot":

> *"I learnt a lot and I learnt things about components that I didn't know existed. So very positive"* [Arthur]
>
> *"Yes, like I said, I learnt a lot; definitely did"* [Meagan]
>
> *"I certainly know a lot more now than before"* [Reba]
>
> *"…we learnt a lot from it and it was overall a good experience"* [Tammy]
>
> *"It was very good and I enjoyed it…I didn't think I would…I thought the work would be excessive but I learnt from it"* [Jacky]

Participants attending the clinical investigator training programme provided by the University of Alabama at Birmingham gave similar positive feedback that they had a rich experience. They learnt about budgets and practical aspects of conducting research, and claimed panel discussions were very enlightening, as was the group-based peer learning (Saleh et al. 2020:5).

b.ii) Networking with others

Working with others in a team throughout the eight weeks to prepare a presentation for the last training session meant a great deal to some participants:

> *"and it was also nice to work in a team because it makes it more real cause you do work in a team if you are putting a protocol together and all the aspects of*

research you are working in a team so it was good that we also worked in teams" [Tammy]

"…and I think again networking with people is helpful" [Reba]

"I was surprised that it was more interactive. There was a lot of learning space from you know colleagues which otherwise you don't really get. I really enjoyed that and it was very different from any expectations I had. People already in clinical trial for a few years could give valuable information about their experience. I feel there are multiple people in the room that you can draw from and create a better idea of what you do in situations" [Arthur]

"The group discussion which you allowed were good. Because we could hear from different people what they do and get a few good tips. That was very nice, and also to meet other people who struggle with the same things" [Jacky]

Investigators need to look for networking opportunities, mainly organised clinical research networks that can potentially strengthen and improve high-quality clinical trials (Nemeh, Buchbinder, Hawley, Nelson, Waterkeyn & Reid 2022:81). Other opportunities could be within their institution or across institutions among their peers, as was evident in the current study.

b.iii) Clinical trial operations and management

Although the first participants interviewed offered a very broad view of what they had learnt, it was still clear what stood out for them. The last participants interviewed had more specific examples of what they had learnt.

"Then also about the protocol, it is completely different when you write it. Doing the informed consent was good to…, if you have to put it together yourself you have to pay attention to all of the sections that need to be in the consent form. Okay we went through everything; how to apply or to register your protocol with SAHPRA and to make amendments. And then I also didn't know much about the startup of a study. So, everything about the study budget and the feasibility studies so that was also a good learning point. The Gantt chart; managing projects and

managing what needs to be done. Yah also the staff management was good" [Tammy]

"I got the big things and if I do it and do it again. So yes, I will definitely implement a lot more. You do feel more confident, but I don't want to leave it here" [Reba]

"To develop the protocol. I liked the regulatory files and what goes into them. The Gantt chart was nice. Management of staff helped a lot" [Jacky]

One participant took the aspect of adult learning very seriously when he realised that he could not rely on his restricted knowledge:

"But the Gantt chart is one example where – listen to the lecture and open the Gantt chart and oh my goodness what am I doing here? How does this work? So, I think, but then you go and then you watch a YouTube video; you google more about it. You research and then you come up with something that makes sense to you and hopefully you submit it and it made sense" [Arthur]

Clinical trial operations encompass the extensive array of tasks involved in carrying out a clinical trial, spanning from the initiation of a study to its conclusion (Smith, Siegel & Kennedy 2020:1). The activities conducted throughout the clinical trial adhere to an established protocol and comply with Good Clinical Practice (GCP) and International Council for Harmonisation (ICH) criteria, ensuring ethical behaviour. The operations of clinical trials encompass many procedures aimed at ensuring the safety of participants, adherence to the research protocol, high-quality data collection, timely completion of the study, exchange of data, and prompt publication and dissemination of results (Smith, Siegel & Kennedy 2020:1). Participants in the present study indicated that they acquired a greater understanding of various activities.

c) Future vision

Participants were not shy to offer some recommendations to be incorporated into future clinical trial research programmes. More experienced investigators had more specific

needs and recommendations, while new investigators generally recommended the course to all new investigators.

c.i) Additional information

Some of the more specific recommendations included:

> *"It would be nice if there were a little more guidance specifically with regards to medical devices. I think we need somebody who is an expert in how to do that kind of studies as well"* [Meagan]

> *"I think I might have learned more if I had done the whole protocol myself. I know it is a huge task but I think at the end of it I would have perhaps get in a little bit more because basically I was responsible only for my sections"* [Arthur]

> *"I think you should do a follow-up course"* [Reba]

> *"To develop the protocol. I unfortunately was only involved in the introduction and only the things I know. I didn't delve into the statistics and analysis and those sort of things because I am very afraid of stats"* [Jacky]

c.ii) Another format of the course

More than one participant referred to the programme or course format, and although they did not have some good suggestions for improvement, their comments were important for future considerations.

> *"Yes, I do think that it is a bit long; you know it is quite a time commitment, but I do understand that as well because there is a lot of material to cover and I think it is a bit intense that there are so many assignments to do"* [Meagan]

> *"I found it long and I did find and I don't know if just because I am new or it's a busy time of the year but I found the work load with a normal job, busy and we had a few deviations and things like that. Some of the time, if felt like I wanted to spend*

more time going through the weekly materials that were posted online; doing the assignments but I just couldn't find the time" [Arthur]

"I would recommend to my friend, but she can't take time off from work because she is already in trouble for that. Condense the work in different days and do more in a day and give them time to go over the work. Then they don't need to take off a day every week and travel from far away" [Jacky]

Being a pilot study, the programme format had to be tested, and from participants and my experience as a presenter, changes should be considered for the format of the final education programme. Other tested possibilities would be lunch-hour lectures or discussion groups over eight weeks (McGee 2013:34), or four 4-hour sessions over one month (Saleh et al. 2020:1).

None of the participants mentioned their experience with the blended format of the course; if they had found it acceptable, likeable, easy, hard to work with or challenging to learn Moodle. The online learning and meeting practices during the COVID-19 pandemic potentially made them comfortable with the blended format. García-Camacha Gutiérrez, Pozuelo-Campos, García-Camacha Gutiérrez and Jiménez-Alcázar (2022:922) looked at face-to-face and online teaching methods that coexisted in the same academic course with the same student group and found, in contrast, that students scored face-to-face training higher than online training. The researchers attributed the findings to the fact that the teaching methodologies used for the online modality had to be improvised due to the sudden onset of the COVID-19 pandemic. What the future will hold for the different teaching methodologies is still to be seen.

c.iii) A course for new investigators

Participants agreed that new investigators would benefit from the inclusive clinical trial research education programme and that they would recommend the programme.

"So it helped and would definitely recommend it for new or any experienced investigator" [Tammy]

"I would definitely like to include people like new scientists who don't have the experience. So especially for someone who is just starting up this course is definitely very helpful" [Meagan]

"I think every level should do this course because I think you should know what other people have to do" [Reba]

"Yes, definitely, I would recommend it to my friend" [Jacky]

Samuels, Ianni, Chung, Eakin, Martina, Murphy and Jones (2019:4) agreed that effective training programmes are essential to developing the clinical trial workforce. The incorporation of competency frameworks will ensure alignment between training offerings and professional standards, and training programme developers are motivated to make use of competency frameworks (Samuels et al. 2019:4; Bocchino, Butler & Harper 2020:2). Bocchino et al. (2020:1) suggested that further investigation is needed to thoroughly clarify the connection between expressed clinical research skills, real-world job performance, and the means of evaluating both in order to provide benefits for employers and researchers. Furthermore, clinical trial education should not be an "add-on" but recognised as part of an individual's professional identity. Thus, clinical trial education should be moved "upstream" in the development of health professionals (Bocchino et al. 2020:1).

7.3.2.4 Description of the findings of the second aim of the QUAL segment Project 3: Supervisors' evaluation of the inclusive clinical trial research education programme

The evaluation instrument was emailed to five stakeholders/participant supervisors. One supervisor would oversee a few participants at the same site. Stakeholders/supervisors had three weeks to evaluate the outcome of the clinical trial research education programme. Reminder emails were sent every week. Two stakeholders responded. One stakeholder promised to respond but never did; two did not. Table 7.15 summarises the feedback from the stakeholders.

Table 7.15: Feedback from stakeholders/supervisors

Inclusive Clinical Trial Research Education Programme Evaluation Form (Stakeholders/supervisors)				
Please mark each with an "X", either yes or no for each question. Please feel free to comment on your choice of answer.				
Q #	Question	Yes	No	Comment
1	Did you have an opportunity to review the content of the clinical trial education programme that your staff attended?		2	
2	Did knowledge about clinical trial research increase among your staff after completing the clinical trial education programme?	2		The content was good and applicable, and fill in gaps
3	Did competency levels of the staff increase in the following domains:			I REPORT THE THINGS THAT WERE SPONTANEOUSLY COMMUNICATED TO ME
	(1) Scientific concepts and research design;	2		
	(2) Ethical and participant safety considerations;	2		
	(3) Medicines development and regulations;	1		Not sure
	(4) Clinical trial operations;	2		
	(5) Study and site management;	2		Staff responsibilities, finance, trial budgets etc
	(6) Data management and informatics;	1		Not sure
	(7) Leadership and professionalism;	1	1	
	(8) Communication and teamwork	2		
4	Are staff implementing the knowledge acquired by the education programme in their daily work?	2		Yes, I think so
5	Do you have any recommendations to offer for future program implementers? (please expand in comments if yes)			DO SITE VISITS, INCLUDING REVIEW OF TRIAL DOCUMENTS. Practical detail AUDIT V MONITOR Drafting HREC communications
				This was a very useful course, which improved the team's ability to work, ensure

				compliance with required standards and build a network of colleagues to whom we could reach out with specific queries or guidance on our studies.

Both stakeholders who responded did not review the content of the clinical trial research education programme that their staff attended, although it was forwarded to them with the evaluation form. Still, both stakeholders agreed that their staffs' knowledge about clinical trial research increased after completing the education programme. One stakeholder was unsure if staff's competency levels increased in domain 3, 'medicines development and regulations' and domain 6, 'data management and informatics'. In contrast, the other stakeholder felt that competency levels did not increase in domain 7, 'leadership and professionalism for staff who attended the programme'. Stakeholders agreed that competency levels in domain 1 'scientific concepts and research design'; domain 2 'ethical and participant safety considerations'; domain 4 'clinical trial operations', and domain 8 'communication and teamwork' increased. Stakeholders also felt that staff were implementing the knowledge they acquired during the education programme in their daily work.

A few comments were made by the two stakeholders who responded. One stakeholder highlighted that he was only sharing the details spontaneously reported to him. Stakeholders felt the content was good and applicable and filled knowledge gaps regarding staff responsibilities, finance and trial budgets. Another comment was that it was a very useful course, which improved the team's ability to work as a team, ensure compliance with required standards, and build a network of colleagues to whom they could reach out with specific queries or guidance on their studies. One stakeholder commented that the presenter should conduct site visits, and review trial documents to include a practical detail audit versus monitoring and guidance on the draft of HREC communication.

7.4 SUMMARY

This chapter discussed the mixed method part of the multiple-method research design. The intervention results were presented with tables and figures to show the significance of the quantitative section. Results of the participants' self-perceived level of competency

and knowledge in the eight clinical trial process and life cycle domains showed a significant change pre- to post-intervention. Themes with quotations reflected the qualitative section of the results. Participants and supervisors of participants agreed on the positive outcome of the inclusive clinical trial research education programme.

A summary of the findings' integration, conclusions, recommendations, contributions and limitations of the study are discussed in Chapter 8.

CHAPTER 8
SUMMARY OF FINDINGS AND INTEGRATION, CONCLUSIONS, RECOMMENDATIONS, CONTRIBUTIONS AND LIMITATIONS

8.1 INTRODUCTION

Chapter 8, as represented in Table 8.1, includes a concise and comprehensive overview of the research outcomes, conclusions, relevant suggestions, contributions, and constraints of the study.

Table 8.1: Chapter 8: Research progress

Chapter	Content
1	Orientation to the study
2	Literature review (1) Clinical trial education (2) Competency-based education (3) Self-efficacy (4) MRC framework
3	Research design and methods
4	Project 1 Research design, data collection, data analysis and results (First segment: situation analysis - qualitative)
5	Project 1 Development and validation of the inclusive clinical trial research education programme (Second and third segments)
6	Project 2 Research design, data collection and implementation of the intervention
7	Project 3 Research design, data collection, results, and evaluation of intervention
8	Summary of integration of findings, conclusion, recommendation, contribution and limitations of the study

8.2 SUMMARY AND INTEGRATION OF FINDINGS

This study aimed to develop and pilot an inclusive clinical trial research education programme for investigators, including but not limited to nurses in health sciences in South Africa. Selecting pragmatism as a paradigm, I integrated the JTF and MRC frameworks. I incorporated basic principles of contemporary learning theories related to

competency learning to develop an education curriculum that promotes clinical trial competency and self-efficacy as advocated by Bandura's Social Cognitive Theory (Bandura 1977).

I used a sequential qualitative-driven multiple-method design (Morse & Niehaus 2009:147), where one programmatic aim was reached by conducting a series of interrelated studies (Morse & Niehaus 2009:149). As described in Chapter 1, each of these interrelated projects is complete in itself, with minimal overlap. However, each project validates and extends the previous, and the combined results with the narrative, as shown in this chapter, provide a more balanced and holistic understanding of the programmatic aim (Morse & Niehaus 2009:147; Morse & Chung 2003:8).

The objectives of this study expanded over three projects (Morse & Niehaus 2016:149) and were achieved as follows:

Project 1

The first project had three segments and included a situation analysis (segment one), the development of the programme (segment two), and stakeholders' validation of the programme before its implementation (segment three).

Segment One, Project 1 – situation analysis

In segment one, I explored stakeholders' perspectives of opportunities and challenges in supporting investigators. Furthermore, I explored stakeholders' perspectives of what an inclusive clinical trial research education programme should consist of.

Several themes related to new investigators' motivation, readiness, and the nature of clinical research were explored. Stakeholders mentioned that new investigators often choose clinical trial research as a convenient career option or as a stepping-stone while awaiting other opportunities. However, they highlighted a lack of commitment, passion, and motivation among new investigators. Another challenge was insufficient knowledge, skills, and experience in clinical trial research among new investigators, resulting from a lack of training and mentoring during their education. The overwhelming nature of clinical trials and the absence of a clear career path were also mentioned as hurdles. Stakeholders emphasised the need for a clinical trial research education programme that covers topics such as clinical trial management, the clinical trial process and study

operations, and the role of the sub-investigator. Additionally, they stressed the importance of developing soft skills and prioritising participant safety. The qualitative findings, along with relevant frameworks and learning theories, were used to inform the development of the clinical trial research education programme.

Segment Two, Project 1 – Development of the educational programme

The findings from segment one was used to meet the objective of segment two: the development of the clinical trial research education programme. The programme's development is described in Chapter 5. My application of various learning theories based on my educational philosophy was briefly discussed and included the *situated learning theory, andragogy and adult learning theory, single and double-loop learning, self-directed learning,* and *self-regulated learning* (Collazo 2016:37).

This section followed a discussion on teaching approaches and methods focusing on blended learning. The combination of online instructional resources and in-person teacher-facilitated activities used in blended learning made it the preferred choice to embed theory and develop skills simultaneously over time (University of the Free State 2019; Mirmoghtadaie, Kohan & Rasouli 2020:49).

My decision to use Moodle as a delivery format for the education programme was discussed. The Moodle platform's attraction for this study was linked to it being a free, open-source virtual learning environment that made marrying traditional and digital training easier (Saxena & Parekh 2019:137; Jackson 2018:141; Sabah 2019:3; Quansah & Essay 2021:419).

Chapter 5 included an outlay of the programme's curriculum. The clinical research education programme was an intervention to determine if a change had occurred in investigators' knowledge of clinical trials and the competency they perceived to have in clinical trial conduct after completing the education programme.

Segment Three, Project 1 – Programme validation

The third segment was the stakeholders' validation of the clinical trial research education programme before implementation to establish if the proposed programme had fulfilled its purpose. Validation was qualitative and done through a validation tool (questionnaire) completed by the same ten stakeholders initially interviewed after reviewing the

curriculum. The purpose of the validation instrument was to establish whether the developed clinical research education programme included the information and opportunities suggested during the interviews with the stakeholders. Each suggestion and recommendation were evaluated against the curriculum content to ensure the information was included. Stakeholders who responded had insightful and positive feedback and felt that the programme had the potential to lay an excellent clinical trial research education foundation.

Project 2

The second project had a deductive drive with two segments. The first segment was quantitative and aimed to measure investigators' self-perceived level of competency in clinical trial conduct, to determine baseline levels of investigators' clinical trial knowledge, and collect basic demographic information from investigators. Participants completed two pre-test questionnaires. The questionnaires' development was discussed in Chapter 6.

Results of investigators' self-perceived level of competency in clinical trial conduct and the baseline levels of their clinical trial knowledge were not analysed at this point. Analysis was done during Project 3 after completing the same two questionnaires, re-named post-test questionnaires.

The second segment of Project 2 entailed implementing the clinical trial research education programme, which was fully described in Chapter 6. The intervention's implementation is described as the last step in developing and evaluating a complex intervention, according to the MRC framework (Skivington et al. 2021:1). Skivington and colleagues (2021:7) explained that an evaluation of the implementation's outcome should be considered part of the last step, alongside an evaluation of the implementation strategy and contextual factors that advanced or hindered the intervention's success or impact. The inclusive clinical trial research education programme intervention was delivered over eight weeks (from October to December 2022) and consisted of eight sessions.

Project 3

A mixed-method design with a QUAN deductive theoretical drive was used for the study's third phase or Project 3. Quantitative methods followed by qualitative methods were used to test the programme's effectiveness. For the quantitative segment, the investigators' self-perceived level of competency in clinical trial conduct was measured, and

investigators' knowledge of clinical trial conduct following the inclusive clinical trial research education programme was determined.

The pre-test and post-test quasi-experimental approach was employed to evaluate the effect of the education intervention. This was done by evaluating the pre-test and post-test questionnaire scores to measure the difference between the participants' perceived level of competency and knowledge of clinical trial conduct before and after the intervention.

An analysis of Project 3's quantitative data was discussed in Chapter 7. In the overall comparison of the pre- and post-test grades, the post-test grades were statistically significantly higher (-8 (-10.6,-5.41) [p<0.0001]), suggesting a higher grade score post-test. The pre- and post-knowledge scores were compared across all eight domains. While all the domain scores showed post-knowledge domain scores were higher, not all were statistically significantly different. Domains 1 (-1.05 (-2.00,-0.09); p=0.0333), 3 (-1.66 (-3.14,-0.19); p=0.0287), 4 (-2.19 (-3.13,-1.24); p<0.0001) and 8 (-0.76 (-1.31,-0.21); p=0.0087) had statistically significant post-knowledge scores compared with the pre-test domain score measures.

In the pre-perceived and post-perceived competency coding items, the post-evaluation scores were significantly higher than the pre-evaluation scores; the difference between the overall means was -39 (-55.1, -23.8) [p<0.0001]. All the individual item measures of pre- and post-perceived competency showed that the post-perceived values were consistently higher than the pre-perceived values.

Data analysis for the qualitative segment of Project 3, referring to the participants of the education programme, reflected the following thoughts:

Participants had different reasons for their expression of the clinical trial research knowledge and guidance they needed, which varied from personal experience to an objective view of clinical trial research. Most participants also wanted to expand their knowledge and expertise about clinical trials because of previous errors they made due to learning by trial and error. Participants felt a gap in the training of new investigators.

Participants agreed that the inclusive clinical trial research education programme did address their need for knowledge and guidance, and that it will possibly do the same for future investigators. Participants agreed that they had learnt much and explicitly referred to clinical operations and management. They enjoyed networking with others and offered recommendations for other course formats; they agreed that they would recommend the course to all investigators.

Participants were not shy to make some recommendations to be incorporated into future clinical trial research programmes. More experienced investigators had more specific needs and recommendations, while new investigators generally recommended the course to all new investigators.

An analysis of the last qualitative segment of Project 3, referring to stakeholders' evaluation of the outcome of the intervention to refine the clinical trial research education programme, showed a positive outcome. Stakeholders felt that staff were implementing the knowledge acquired from the education programme in their daily work.

Qualitative and quantitative analyses were measured to evaluate the effectiveness of the clinical trial research education programme, and the outcome of the results was used to refine the intervention. The positive feedback from participants during the qualitative (interview) analysis strengthened the quantitative evidence that showed a significant improvement in their clinical trial knowledge. Therefore, qualitative and quantitative data enhanced the effectiveness and quality of the intervention, a crucial finding of the study.

8.3 CONCLUSIONS

The changing landscape of clinical trial research highlighted the need for adequately trained investigators, including nurse investigators and other health professionals working on clinical trials (Saleh & Naik 2018:378). However, a concern was expressed that the upskilling of clinical trial staff did not keep pace with new technology and the increased demands of clinical trials, even during the COVID-19 pandemic (Woolfall et al. 2019:2). In response, this study was exclusively designed to develop an inclusive clinical trial research education programme. The education programme aimed to equip investigators, including but not limited to nurses in health sciences, with the necessary knowledge and skills to make them competent in the eight competency domains set out by the JTF

framework for clinical trials. The MRC framework's application was an additional strength of the study.

The purpose of the study was successfully achieved over eight weeks and produced an extensive and comprehensive curriculum to train and educate investigators working in health sciences. Further, implementing the blended training format made it an advanced and competitive education programme. The multiple-method design, incorporating qualitative and quantitative approaches, enhanced the validity of the findings. The nature of the multiple-method design required more time, resources, and skills. However, I preferred the chosen approach because it allowed me to master different skills; for example, the development of the pre-test and post-test questionnaires, the use of computer and digital technology to do online interviews, and the development of blended training to present the programme (Morse & Niehaus 2016:13; Schoonenboom & Johnson 2017:110).

I included several nurses and non-clinical health professionals in the study. I believe it opened the door for more nurses to register for the programme in future to build their capacity for leading clinical trial research as investigators. The content of the inclusive clinical trial research programme was readily translated to practice during and after the intervention – it gave investigators the 'how-to'. The study's findings convinced me that the education intervention had promoted self-efficacy, curtailing feelings of worthlessness and incompetence among investigators.

8.4 RECOMMENDATIONS

Recommendations were made concerning future inclusive clinical trial research education programmes. These include recommendations for clinical trial research nurses, educators, supervisors, the clinical trial research industry, and further research.

8.4.1 Recommendations for clinical trial research nurses

As mentioned in Chapter 1, nurses often form the backbone of clinical trial conduct. However, very few become PIs or sub-investigators. A lack of confidence or self-efficacy often prevents nurses from mentioning their availability to become investigators to stakeholders (Nkala, personal communication, 16 Jul 2019). Nurses should enrol in

educational courses and programmes, such as the current programme, to equip them with the knowledge and skills they might lack to become investigators in a clinical trial. Furthermore, nurses should seek opportunities to prove to stakeholders, such as pharmaceutical companies and clinical trial networks, that they are as capable as doctors to become excellent investigators. Therefore, nurses must take the lead and initiate the process to path the way for more nurses to become investigators; they should not wait on stakeholders to approach them.

8.4.2 Recommendations for clinical trial research educators

The findings from the inclusive clinical trial research education programme illustrated that the programme has the potential to improve investigators' clinical trial knowledge and skills. Therefore, the knowledge gained should be used to promote educational programmes for investigators, including nurses. Clinical trial research educators should be motivated to develop or improve their current programmes to reach as many investigators as possible because there will be value in this undertaking. Furthermore, nursing and medical education curriculums should incorporate clinical trial research education in their programmes. The education material developed for this study could be used during curriculum development, and nurses and other health science students should be introduced to clinical trial research.

The current study showed that new and more experienced investigators benefited from the education programme. However, it might be more beneficial to introduce an advanced education programme for experienced investigators. Clinical trial research professionals gain increased competency as they progress in their careers and will consequently need a higher level of competency in the different domains. The JTF framework provides an application for the competencies across a wide range of roles by defining the competencies as fundamental, skilled and advanced levels (Sonstein et al. 2018:3).

The lowest research knowledge scores were obtained in domains (2) Ethical and participant safety considerations, (5) Study and site management, (6) Data management and informatics, and (7) Leadership and professionalism. Building on this knowledge, it might be beneficial for clinical trial research educators (and investigators) to implement a more intensive curriculum around each domain to prepare investigators for specific areas of clinical trial research.

8.4.3 Recommendations for clinical trial research supervisors

Clinical trial research supervisors can build on the content of the clinical trial research education programme by using the JTF framework to improve staff training and adapt it to help define workforce development. The latest JTF framework clarifies terminology and can assist in refining the organisation and description of certain competencies to include all types of clinical research (Sonstein et al. 2018:2). Furthermore, the JTF framework can be used to restructure job titles and profiles and to address job predictability and professional advancement. Supervisors can use the current education programme as a foundation to improve the knowledge and skills of all clinical trial professionals at their sites by sending staff to attend the programme. However, it will be advisable that supervisors complete a clinical trial education programme before embarking on such a plan to support professionals in attaining their competencies.

8.4.4 Recommendations for the clinical trial research industry

Furthermore, the clinical trial programme intervention highlighted the need for collaborative, engaging approaches among the various stakeholders whose participation and expertise are crucial for the success of any clinical trial. Stakeholders within the pharmaceutical industry, contract research organisations, academic medical centres, clinical research sites and professional societies should be approached by clinical trial research educators to see how such a programme could become mandatory for all investigators in South Africa.

8.4.5 Recommendations for further research

Further research with a larger group of investigators is needed. In addition, the current study only measured participants' knowledge and self-perceived competencies gained from the education programme. Therefore, a recommendation for future studies is to validate the effectiveness of the programme's content and process.

There is a need to evaluate competency frameworks' implementation. Batt (2022:153) reported that after the completion of a literature review, it revealed that out of the total number of competency frameworks reviewed, only 66 (35%) included plans or recommendations for evaluating outcomes after applying the framework. Furthermore,

only seven (4%) of these frameworks actually conducted an evaluation and published the results. Understanding the relationship between the development processes, outcomes, and the use of the competency frameworks in the current study can inform future revisions and improvements, not only of the education programme but also of the competency frameworks. Evaluating the processes and outcome of implementing these frameworks could confirm that the frameworks were implemented as intended.

8.5 CONTRIBUTION OF THE STUDY

Despite being a pilot study, the clinical trial research education curriculum equipped investigators with the necessary skills to begin careers in clinical research and develop novel approaches to improve the efficiency of clinical trial sites. The pilot programme established a systematic framework for performing clinical trials in a consistent manner. It will prepare investigators for the numerous challenges they will likely encounter in preparing and conducting a clinical trial.

The participants (investigators) in this research gained educational advantages from the study by acquiring a higher level of expertise in the eight competency domains of the clinical trial procedure and life cycle. The potential impact of this clinical trial education programme extends to both society and the research community, offering numerous benefits. As far as I know, there is currently no research curriculum designed for both medical and non-medical investigators that includes all eight JTF competency areas, which provide practical knowledge and skills. This implemented educational programme has the potential to establish the foundation for obligatory and officially recognised clinical trial education. In addition, the provision of comprehensive education and training to investigators in the field of clinical trials plays a crucial role in enhancing patient care, thereby benefiting society. Put simply, it supports public health by facilitating the application of research findings to clinical practice. This is achieved by improving the training experience of researchers and fostering greater interest in occupations related to clinical research among both medical and non-medical health workers. Furthermore, this study, along with the developed extensive clinical trial research education programme, has the ability to offer useful insights for present and future education and policy advancement.

8.6 LIMITATIONS OF THE STUDY

The main constraint of this study was the restricted number of investigators participating in clinical trials (employed as investigators). The restriction applied to the finite number of non-medical researchers accessing the domain of clinical research. This limited the pool of potential participants for the sample size, but there have been successful research studies published on the creation and execution of educational programmes for medical residents (Chung, Kwan, Wagner, Braund, Hanmore, Hall, McEwan, Dalgarno & Dagnone 2022:1; Day, Miles, Ginsburg & Melvin 2020:1). Despite the reduced sample size, the greater confidence range allowed for the detection of any significant differences between pre- and post-testing, assuming they were present. One additional constraint arose from the absence of a control group, which was a result of the research design and the geographical location of the clinical trial programme. Despite being promoted to research investigators around South Africa, the programme was only held in Johannesburg, which posed logistical and cost obstacles for investigators to participate. Therefore, these findings may not be applicable to a wider population.

8.7 DISSEMINATION OF RESULTS

Appropriate outlets will be identified for disseminating the study findings, such as poster and oral presentations targeting national and worldwide audiences in the field of clinical trial research. The findings of the research will be converted into written form and submitted to reputable academic publications for dissemination. Other avenues for dissemination to a larger population, such as ‘the Conversation’, will also be used.

8.8 CONCLUDING REMARKS

It is hoped that the inclusive clinical trial research education programme will lead to a diverse and well-prepared workforce capable of successfully navigating the intricate challenges presented by modern clinical trials. By equipping healthcare professionals with the necessary knowledge and skills, we can make significant contributions to advancements in healthcare and, ultimately, improve patient outcomes. The importance of fostering collaboration and ensuring a comprehensive understanding of clinical trial research cannot be overstated. Therefore, investing in inclusive educational programmes is a vital step towards achieving these goals.

As for the future, your task is not to foresee it but to enable it!

Antoine de Saint Exupery (1900-1944)

LIST OF REFERENCES

ACRP see The Association of Clinical Research Professionals.

Adair, T. 2021. *How to Motivate and Retain Clinical Research Staff*. The Society of Clinical Research Associates. Available at: https://www.socra.org. (accessed 20 May 2020).

Adams, N.E. 2015. Bloom's taxonomy of cognitive learning objectives. *Journal of Medical Library Association,* 103(3):152-3. doi: 10.3163/1536-5050.103.3.010. PMID: 26213509; PMCID: PMC4511057. (accessed 15 February 2022).

Maybach, E., Sarfaty, M., Gould, R., Damle, N. & Armstrong, F. 2020. A call to action by Health Professionals, in *Health of People, Health of Planet and Our Responsibility,* edited by Al-Delaimy, W.K., Ramanathan, V. & Sánchez Sorondo, M. SpringerOpen. DOI: 10.1007/978-3-030-31125-4

Alemayehu, C., Mitchell, G. & Nikles, J. 2018. Barriers for conducting clinical trials in developing countries- a systematic review. *International Journal for Equity in Health,* 17(1):37. doi: 10.1186/s12939-018-0748-6. Available at: https://www.ncbi.nlm.nih.gov/pubmed/29566721. (accessed 20 June 2019).

Alfaar, A.S., Hassan, W.M., Bakry, M.S. & Ezzat, S. 2017. Clinical Research Recession: Training Needs Perception Among Medical Students. *Journal of Cancer Education,* 32(4):728-733. Available at: https://link.springer.com/article/10.1007/s13187-016-0995-4. (accessed 20 June 2019).

All Allied Health Schools Online. 2022. *Health Science.* 2022. Available at: https://www.allalliedhealthschools.com (accessed 20 November 2022)

Allemang, B., Sitter, K. & Dimitropoulos, G. 2022. Pragmatism as a paradigm for patient-oriented research. *Health Expectations: An International Journal of Public Participation in Health Care and Health Policy,* 25(1):38-47. Available at: https://onlinelibrary.wiley.com/doi/abs/10.1 111/hex.13384. (accessed 12 April 2023).

Altman, D.G. 1999. Statistics in the medical literature: 3. *Statistics in Medicine,* 18(4):487-490. doi: 10.1002/(SICI)1097-0258(19990228)18:4<487::AID-SIM106>3.0. CO;2-J. Available at: https://api.istex.fr/ark:/67375/WNG-8LSRLWWJ-C/fulltext.pdf. (accessed 12 April 2023).

Al-Tannir, M., Abu-Shaheen, A., AlSumaih, S., AlMukaibil, N.F., AlHarbi, R., Heena, H., Sallout, L., Mahha, A., Marran, N.M. & AlFayyad, I. 2018. Research Knowledge and

Skills Among Medical and Allied Health Students Attending a Summer Research Course: A Pretest and Posttest Analysis. *Cureus,* 10(8):e3132. doi: 10.7759/cureus.3132. PMID: 30345191; PMCID: PMC6183895. (accessed 15 May 2019).

Amin, M.E.K., Nørgaard, L.S., Cavaco, A.M., Witry, M.J., Hillman, L., Cernasev, A. & Desselle, S.P. 2020. Establishing trustworthiness and authenticity in qualitative pharmacy research. *Research in Social and Administrative Pharmacy,* 16(10):1472-1482. doi: 10.1016/j.sapharm.2020.02.005. Available at: https://www.sciencedirect.com/science/article/pii/S1551741119309155[ID: 273422]. (accessed 12 April 2023).

Anders, A.D. 2018. Networked learning with professionals boosts students' self-efficacy for social networking and professional development. *Computers and Education,* 127:13-29. Available at: https://dx.doi.org/10.1016/j.compedu.2018.08.009. (accessed 11 November 2022).

Anderson, A., Borfitz, D. & Getz, K. 2018. Global Public Attitudes About Clinical Research and Patient Experiences With Clinical Trials. *Journal of American Medical Association Network Open,* 1(6):e182969. Available at: http://dx.doi.org/10.1001/jamanetworkopen.2018.2969. (accessed 12 April 2019).

Anguera, M.T., Blanco-Villaseñor, A., Losada, J.L., Sánchez-Algarra, P. & Onwuegbuzie, A.J. 2018. Revisiting the difference between mixed methods and multimethods: Is it all in the name? *Quality & Quantity,* 52(6):2757-2770. Available at: https://link.springer.com/article /10.1007/s11135-018-0700-2. (accessed 12 April 2019).

Appiah, S. & Essiam, C. 2022. Effect of computer-assisted instruction on students' performance in selected cell division topics: A Quasi-experimental study at Adisadel College, Ghana. *KAD International, Ghana,* 9(2):86-91. Available at: http://kadint.net/our-journal.html. (accessed 14 April 2023).

Armstrong, E.P.R. 2005. How can physicians' learning styles dive educational planning. *Academic Medicine,* 80(7):680-684.

Ashrafi-Rizi, H., Najafi, N.S.S., Kazempour, Z. & Taheri, B. 2015. Research self-efficacy among students of Isfahan University of Medical Sciences. *Journal of Education and Health Promotion,* 4(26):1-6. doi: 10.4103/2277-9531.154117. Available at: https://www.ncbi.nlm.nih.gov/pubmed/25883996. (accessed 08 January 2020).

Audisio, K., Lia, H., Robinson, N.B., Rahouma, M., Soletti, J., Giovanni, Cancelli, G., Olaria, R.P., Chadow, D., Tam, D.Y., Vervoort, D., Farkouh, M.E., Bhatt, D.L., Fremes, S.E. & Gaudino, M. 2022. Impact of the COVID-19 Pandemic on Non-COVID-19 Clinical Trials. *Journal of Cardiovascular Development and Disease,* 9(1):19. doi: 10.3390/jcdd9010019. Available at: https://www.ncbi.nlm.nih.gov/pubmed/35050229. (accessed 12 January 2023).

Babenko, O. & Oswald, A. 2019. The roles of basic psychological needs, self-compassion, and self-efficacy in the development of mastery goals among medical students. *Medical Teacher,* 41(4):478-481. Available at: https://www.tandfonline.com/ doi/abs/10.1080/0142159X.2018.1442564. (accessed 05 June 2019).

Bandura, A. 1977. *Social Learning Theory*. New York: General Learning Press.

Bandura, A. 2001. Social cognitive theory: An agentic perspective. *Annual Review of Psychology,* 52(1):1-26. doi: 10.1146/annurev.psych.52.1.1. Available at: https://www.ncbi.nlm.nih.gov/pubmed/11148297. (accessed 05 June 2019).

Bandura, A. 1997. *Self-efficacy.* BF637.S38. 1st print edition. New York: W.H. Freeman and Company.

Bandura, A. 1982. Self-efficacy mechanism in human agency. *The American Psychologist,* 37(2):122-147. doi: 10.1037/0003-066X.37.2.122. Available at: https://search.proquest.com/docview/1289828547. (accessed 05 June 2019).

Bandura, A. 1994. Self-efficacy. In V. S. Ramachaudran (Ed.), *Encyclopedia of human behavior* (4):71-81. New York: Academic Press. (Reprinted in H. Friedman [Ed.], Encyclopedia of mental health. San Diego: Academic Press, 1998).

Bard, C.C., Bieschke, K.J., Herbert, J.T. & Eberz, A.B. 2000. Predicting Research Interest Among Rehabilitation Counseling Students and Faculty. *Rehabilitation Counseling Bulletin,* 44(1):48-55. Available at: https://journals.sagepub.com/doi/full/10.1177/003435520004400107. (accessed 13 October 2022).

Bastek, A. 2022. Career Advancement in Clinical Trials: How developing new skills can prevent turnover. *MedCity News*. Available at: https://www.medcitynews.com. (accessed 14 January 2023).

Batt, A.M. 2022. Do we preach what we practice? The development of competency frameworks in healthcare professions. Doctor of Philosophy at Monash University.

Bechtel, J., Chuck, T., Forrest, A., Hildebrand, C., Panhuis, J., Pattee, S.R., Comic-Savic, S. & Swezey, T. 2020. Improving the quality conduct and efficiency of clinical trials with training: Recommendations for preparedness and qualification of investigators and delegates. *Contemporary Clinical Trials,* 89:105918. Available at: https://dx.doi.org/10.1016/j.cct.2019.105918. (accessed 15 May 2022).

Beheshtifar, M.E.Z. 2013. Interpersonal Conflict: A Substantial Factor to Organizational Failure. *The International Journal of Academic Research in Business and Social Sciences,* 03:400-407. Available at: https://www.semantic scholar.org. (accessed 14 June 2019).

Bell, M.L., Whitehead, A.L. & Julious, S.A. 2018. Guidance for using pilot studies to inform the design of intervention trials with continuous outcomes. *Clinical Epidemiology,* 18(10):153-157. doi: 10.2147/CLEP.S146397. PMID: 29403314; PMCID: PMC5779280. (accessed 15 February 2022).

Berkness, T., Carrillo, M.C., Sperling, R., Petersen, R., Aisen, P., Flournoy, C., Snyder, H., Raman, R. & Grill, J.D. 2021. The Institute on Methods and Protocols for Advancement of Clinical Trials in ADRD (IMPACT-AD): A Novel Clinical Trials Training Program. *Journal of Prevention of Alzheimer's Disease*, 8(3):286-291. doi: 10.14283/jpad.2021.12. PMID: 34101785; PMCID: PMC8019089. (accessed 12 June 2022).

Betz, N.E. 2000. Self-Efficacy Theory as a Basis for Career Assessment. *Journal of Career Assessment,* 8(3):205-222. doi: 10.1177/106907270000800301. Available at: https://journals.sagepub.com/doi/full/10.1177/10690727000080 0301. (accessed 14 June 2019).

Bieschke, K.J. 2006. Research Self-Efficacy Beliefs and Research Outcome Expectations: Implications for Developing Scientifically Minded Psychologists. *Journal of Career Assessment,* 14(1):77-91. Available at: https://journals.sagepub.com/doi/full /10.1177/1069072705281366. (accessed 14 June 2019).

Biesta, G. 2020. Risking Ourselves in Education: Qualification, Socialization, and Subjectification Revisited. *Educational Theory,* 70(1):89-104. Available at: https://onlinelibrary.wiley.com/doi /abs/10.1111/edth.12411. (accessed 17 June 2022).

Bishop, R.M. & Bieschke, K.J. 1998. Applying Social Cognitive Theory to Interest in Research Among Counseling Psychology Doctoral Students. *Journal of Counseling Psychology,* 45(2):182-188. doi: 10.1037/0022-0167.45.2.182. Available

at: http://eric.ed.gov/ERICWebPortal/detail?accno=EJ573201. (accessed 12 February 2023).

Bleijenberg, N., de Man-van Ginkel, J.M., Trappenburg, J.C.A., Ettema, R.G.A., Sino, C.G., Heim, N., Hafsteindóttir, T.B., Richards, D.A. & Schuurmans, M.J. 2018. Increasing value and reducing waste by optimizing the development of complex interventions: Enriching the development phase of the Medical Research Council (MRC) Framework. *International Journal of Nursing Studies,* 79:86-93. doi: https://doi.org/10.1016/j.ijnurstu.2017.12.001. Available at: https://www.sciencedirect.com/science/article/pii/S0020748917302754[ID: 271 253]. (accessed 12 February 2023).

Bocchino, J.M., Butler, J. & Harper, B. 2020. A perspective on the current state of Clinical Research Education. *Clinical Researcher, June 2020.* Available at: https://acrpnet.org. (accessed 18 April 2022).

Bolisani, E. & Bratianu, C. 2018. Emergent Knowledge Strategies: Strategic Thinking in Knowledge Management. *Knowledge Management and Organizational Learning.* Cham: Springer International Publishing.

Bowers, D. 2019. *Medical Statistics from Scratch.* Fourth edition. Newark: Wiley. Available at: https://www.perlego.com/book/1148697/medical-statistics-from-scratch-an-introduction-for-health-professionals-pdf. (accessed 11 March 2023).

Boyatzis, R.E. 1982. *The competent manager.* HD31B683 1982. New York [u.a.]: Wiley.

Brandenburg, C. & Ward, E.C. 2022. “There hasn’t been a career structure to step into”: a qualitative study on perceptions of allied health clinician researcher careers. *Health Research Policy and Systems,* 20(1):6. doi: 10.1186/s12961-021-00801-2. Available at: https://www.ncbi.nlm.nih.gov/pubmed/35000610. (accessed 11 February 2023).

Brewer, J. & Hunter, A. 2006. *Foundations of multi-method research.* London: SAGE.

Brown, M. 1994. An introduction to the discourse on competency-based training (CBT), in *Competency based education and training,* edited by Burk, J.W. (ed.),*:* 1-17. London, UK: Falmer Press. Available from: https://www.researchgate.net/publication/ 317797610_Implementing_Competency-Based_Education (accessed 07 February 2023).

Brown, M.E.L. & Dueñas, A.N. 2020. A Medical Science Educator’s Guide to Selecting a Research Paradigm: Building a Basis for Better Research. *Medical Science Educator,* 30(1):545-553. Available

at: https://link.springer.com/article/10.1007/s40670-019-00898-9. (accessed 07 February 2023).

Burgess, L.J. & Sulzer, N.U. 2010. Clinical trials in South Africa: Need for capacity building and training. *South African Medical Journal,* 100(7):402. doi: 10.7196/SAMJ.4013. Available at: https://www.ncbi.nlm.nih.gov/pubmed/20822581. (accessed 12 June 2019).

Button, L. 2020. *Curriculum development: a journey.* Creative Commons Attribution-Share Alike 4.0 International License.

Calvin-Naylor, N.A., Jones, C.T., Wartak, M.M., Blackwell, K., Davis, J.M., Divecha, R., Ellerbeck, E.F., Kieburtz, K., Koziel, M.J., Luzuriaga, K., Maddox, J., Needler, N.A., Murphy, S., Pemberton, K., Radovich, C., Rubinstein, E.P., Selker, H.P., Tenaerts, P., Unsworth, K., Wilson, K., Wright, J.E., Barohn, R. & Shanley, T.P. 2017. Education and training of clinical and translational study investigators and research coordinators: A competency-based approach. *Journal of Clinical and Translational Science,* 1(1):16-25. doi: 10.1017/cts.2016.2. Available at: https://www.ncbi.nlm.nih.gov/pubmed/28480054. (accessed 12 April 2022).

Canter, C.M. & Lewis, K.O. 2014. Training Clinical Trial Teams Current Training Practices and Educational Needs of Clinical Research Personnel. *Clinical Researcher*, 14(1):25-30. Available at: https://www.acrpnet.org (accessed 15 October 2022).

Carraccio, C., Wolfsthal, S.D., Englander, R., Ferentz, K. & Martin, C. 2002. Shifting Paradigms: From Flexner to Competencies. *Academic Medicine,* 77(5):361-367. doi: 10.1097/00001888-200205000-00003. Available at: http://eric.ed.gov/ERICWebPortal/detail?accno=EJ649098. (accessed 18 March 2020).

Castro, K., Bevans, M., Miller-Davis, C., Cusack, G., Loscalzo, F., Matlock, A.M., Mayberry, H., Tondreau, L., Walsh, D. & Hastings, C. 2011. Validating the Clinical Research Nursing Domain of Practice. *Oncology Nursing Forum,* 38(2): E72-E80. doi: 10.1188/11.ONF.E72-E80. Available at: https://www.ncbi.nlm.nih.gov/pubmed/21356644. (accessed 29 July 2019).

Ceh, S.E. 2022. The clinical research investigator: clarifying the misconceptions. *Clinical Researcher,* 36(1):6-17. Available at: https://acrpnet.org. (accessed 28 July 2019).

Chian, M.M. & Green, J.L. 2018. Triangulation, in *The Sage Encyclopedia of Educational Research, Measurement, and Evaluation.* London: SAGE: 1717-1720. Available at: DOI: 10.4135/9781506326139.n711. (accessed 08 March 2023).

Chung, A.D., Kwan, B.Y.M., Wagner, N., Braund, H., Hanmore, T., Hall, A.K., McEwan, L., Dalgarno, N. & Dagnone, J.D. 2022. An adaptation-focused evaluation of

Canada's first competency-based medical education implementation in radiology. *European Journal of Radiology,* 147:110109. doi: 10.1016/j.ejrad.2021.110109. Available at: https://dx.doi.org/10.1016/j.ejrad.2021.110109. (accessed 12 January 2023).

Clinical and non-clinical job. 2022. The University of Adelaide. Available at: https://www.adelaide.edu.au (accessed 15 May 2022)

Clinical Research Coordinator Handbook. Fifth edition. 2019. Beaverton: Ringgold, Inc.

Clinical Research Glossary. 2023. The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard. Available at: https://mrctcenter.org (accessed 20 April 2023).

Clinical research professionals. 2023. The Society of Clinical Research Associates. Available at: https://socra.org (accessed 20 April 2023).

Clinical Trials Transformation Initiative (CTTI) Online. *Recommendations: Identifying Qualified Investigators and Their Delegates to Conduct Sponsored Clinical Trials.* 2018. Available at: https://www.ctti-clinicaltrial.org. (accessed 20 May 2022)

Clinical vs Non-clinical roles in Healthcare. The University of Adelaide. Available at: https://online.adelaide.edu.au (accessed 1 Jan 2023).

Cohen, S. 2022. Correspondence. Clinical trial monitoring. 15 July, Johannesburg.

Cohen, L., Manion, L. & Morrison, K. 2018. *Research methods in education.* Eighth edition. London; New York: Routledge.

Colebunders, R. & Musiime, V. 2013. Does the CHER trial open up new therapeutic perspectives? *The Lancet (British Edition),* 382(9904):1539-1540. Available at: https://www.clinicalkey.es/p laycontent/1-s2.0-S0140673613617171. (accessed 08 February 2023).

Collazo, S. 2016. Nursing professional development educator competency learning and development. Thesis for PhD. Capella University. ProQuest Dissertations Publishing.

Coons, S. 2021. The role of structural racism in lack of clinical trial diversity. *Relias Media.* Available at: https://www.reliasmedia.com/ articles/148111-the-role-of-structural-racism-in-lack-of-clinical-trial-diversity. (accessed 12 April 2023).

Cotton, M.F., Violari, A., Otwombe, K., Panchia, R., Dobbels, E., Rabie, H., Josipovic, D., Liberty, A., Lazarus, E., Innes, S., Rensburg, A.J., Pelser, W., Truter, H., Madhi, S.A., Handelsman, E., Jean-Philippe, P., Mcintyre, J.A., Gibb, D.M. & Babiker, A.G. 2013. Early limited antiretroviral therapy is superior to deferred therapy in HIV-infected South African infants: results from the CHER (Children with HIV Early

antiRetroviral) Randomized Trial. *Lancet (London, England)*, 382(9904):1555–1563. https://doi.org/10.1016/S0140-6736(13)61409-9. (accessed 15 February 2023).

Cox, J. 2023. 4 Teaching Philosophy Statement Examples. *ThoughtCo part of Dotdash Meredith publishing.* Available at: https://www.thoughtco.com/teaching-philosophy-examples-2081517. (accessed 5 April 2023).

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I. & Petticrew, M. 2008. Developing and evaluating complex interventions: the new Medical Research Council guidance. *British Medical Journal,* 337(7676):979-983. doi: 10.1136/bmj.a1655. Available at: http://dx.doi.org/10.1136/bmj.a1655. (accessed 07 February 2020).

Creswell, J.W. & Creswell, J.D. 2020. *Research Design.* Fifth edition. Los Angeles: SAGE.

Creswell, J.W. 2022. *A concise introduction to mixed methods research.* Second edition. Los Angeles; London; New Delhi; Singapore; Washington DC; Melbourne: SAGE.

Creswell, J.W. & Creswell, J.D. 2022. *Research Design.* Sixth edition. Los Angeles; London; New Delhi; Singapore; Washington DC; Melbourne: SAGE

Creswell, J.W. & Clark, V.L.P. 2018. *Designing and conducting mixed methods research.* Third edition. Los Angeles; London; New Delhi; Singapore; Washington DC; Melbourne: SAGE.

Culican, S.M., Rupp, J.D. & Margolis, T.P. 2014. Retaining clinician-scientists: nature versus nurture. *Investigative Ophthalmology & Visual Science,* 55(5):3219-3222. doi: 10.1167/iovs.14-14605. Available at: https://www.ncbi.nlm.nih.gov/pubmed/24867910. (accessed 12 April 2023).

Curtis, L.H., Dember, L.M., Vazquez, M.A., Murray, D., DeBar, L., Staman, K.L., Septimus, E., Mor, V., Volandes, A., Wells, B.L., Huang, S.S., Green, B.B., Coronado, G., Meyers, C.M., Tuzzio, L., Hernandez, A.F. & Sugarman, J. 2019. Addressing guideline and policy changes during pragmatic clinical trials. *Clinical Trials (London, England),* 16(4):431-437. Available at: https://journals.sagepub.com/doi/full/10.1177/1740774519845682. (accessed 25 July 2019).

Dale, J. & Abbott, S. 2019. *Qual-online – the essential guide: what every research should know about conducting and moderating interviews via the web*. Paramount Market Publishing.

Da Silva Santos, K., Ribeiro, M.C., De Queiroga, D.E.U., Da Silva, I.A.P. & Ferreira, S.M.S. 2020. The use of multiple triangulations as a validation strategy in a qualitative study. *Ciência & Saude Coletiva,* 25(2):655-664. doi: 10.1590/1413-81232020252.12302018. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32022205. (accessed 23 April 2023).

D'Arrietta, L.M., Vangaveti, V.N., Crowe, M.J. & Malau-Aduli, B.S. 2022. Rethinking Health Professionals' Motivation to Do Research: A Systematic Review. *Journal of Multidisciplinary Healthcare,* 15:185-216. doi: 10.2147/JMDH.S337172. Available at: https://www.ncbi.nlm.nih.gov/pubmed/35115782. (accessed 12 April 2023).

Davis, C.P. 2021. *Medical professional*. Available at: https://www.medicinenet.com (accessed 25 October 2022)

Davis, P.B., Meagher, E.A., Pomeroy, C., Lowe, J., William L, Rubenstein, A.H., Wu, J.Y., Curtis, A.B. & Jackson, R.D. 2022. Pandemic-related barriers to the success of women in research: a framework for action. *Nature Medicine,* 28(3):436–438 doi: 10.1038/s41591-022-01692-8. Available at: https://www.ncbi.nlm.nih.gov/pubmed/35177858. (accessed 13 February 2023).

Day, L.B, Miles, A., Ginsburg, S. & Melvin, L. 2020. Resident Perceptions of Assessment and Feedback in Competency-Based Medical Education: A Focus Group Study of One Internal Medicine Residency Program. *Academic Medicine,* 95(11): 1712-1717. doi: 10.1097/ACM.0000000000003315. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32195692. (accessed 22 October 2022).

Daye, D., Patel, C.B., Ahn, J. & Nguyen, F.T. 2015. Challenges and opportunities for reinvigorating the physician-scientist pipeline. *The Journal of Clinical Investigation,* 125(3):883-887. doi: 10.1172/JCI80933. Available at: https://www.ncbi.nlm.nih.gov/pubmed/25689260. (accessed 17 March 2020).

DeCarlo, M. 2018. Scientific Inquiry in Social Work. *Open Social Work Education*. Independent publisher. Available at: https://open.umn.edu/opentextbooks/textbooks/591. (accessed 17 March 2020).

DeCuir-Gunby, J.T. & Schutz, P.A. 2017. *Developing a mixed methods proposal.* Mixed Methods Research Series. First edition. Thousand Oaks: SAGE.

Deeter, C., Hannah, D., Reyes, C., Mack, M.E., Stroo, M., Freel, S.A., Brouwer, R.J.N., Gaudaur, H.E., Doughty, A.L. & Snyder, D.C. 2020. Professional Development for Clinical Research Professionals: Implementation of a Competency-Based Assessment Model. *The Journal of Research Administration,* 51(2):15-40. Available at: https://search.proquest.com/docview/2519040589. (accessed 16 March 2020).

DoH see World Medical Association Declaration of Helsinki. 2013.

Downhour, M. 2018. Consider a Role in Clinical Trials Research as an Evolution of Your Nursing Career. *Oncology Nursing Society*. Available at: https://www.voice.ons.org. (accessed on 12 June 2019).

Ekeroma, A., Kenealy, T., Shulruf, B. & Hill, A.G. 2015. Educational and Wider Interventions that Increase Research Activity and Capacity of Clinicians in Low to Middle Income Countries: A Systematic. Review and Narrative Synthesis. *Journal of Research and Development,* 3(120):1-8. doi: 10.4172/jrd.1000120.

El-Amin, A. 2020. Andragogy. A Theory in Practice in Higher Education. *Journal of Research in Higher Education,* 4(2):54-69. Available at: https://www.researchgate.net. (accessed on 15 February 2023).

Englander, R., Cameron, T., Ballard, A.J., Dodge, J., Bull, J. & Aschenbrener, C.A. 2013. Toward a Common Taxonomy of Competency Domains for the Health Professions and Competencies for Physicians. *Academic Medicine,* 88(8):1088-1094. doi: 10.1097/ACM.0b013e31829a3b2b. Available at: https://www.ncbi.nlm.nih.gov/pubmed/23807109. (accessed 17 March 2020).

Eraut, M. 2003. National vocational qualifications in England: Description and analysis of an alternative qualification system, in *Zertifizierung non-formell und informell erworbener beruflicher Kompetenzen* edited by Straka, G. Münster, Germany: Waxmann.

Eraut, M. 1998. Concepts of competence. *Journal of Interprofessional Care,* 12(2):127-139. Available at: https://www.tandf online.com/doi/abs/10.3109/13561829809014100. (accessed 17 March 2020).

Etymology Dictionary Online. 2021. Sv *"interview".* Available at: https://www.etymonline.com. (accessed 20 January 2022).

Evans, K., Spiby, H. & Morrell, C.J. 2020. Developing a complex intervention to support pregnant women with mild to moderate anxiety: application of the Medical Research Council framework. *Biomed Central Pregnancy and Childbirth,* 20(1):777-789. doi: 10.1186/s12884-020-03469-8. Available at: https://www.ncbi.nlm. nih.gov/pubmed/33317463. (accessed 24 September 2022).

Farrell, B., Kenyon, S. & Shakur, H. 2010. Managing clinical trials. *Trials,* 11(1):78-84. doi: 10.1186/1745-6215-11-78. Available at: https://www.ncbi.nlm.nih. gov/pubmed/20626885. (accessed 12 April 2023).

Forero, R., Nahidi, S., De Costa, J., Mohsin, M., Fitzgerald, G., Gibson, N., McCarthy, S. & Aboagye-Sarfo, P. 2018. Application of four-dimension criteria to assess rigour of

qualitative research in emergency medicine. *Biomed Central Health Services Research*, 18(1):120-125. doi: 10.1186/s12913-018-2915-2. PMID: 29454350; PMCID: PMC5816375. (accessed 15 February 2022).

Flick, U. (ed). 2004. Triangulation in Qualitative Research, in a *Companion to Qualitative Research,* edited by Flick, U., von Kardorff, E., & Steinke, I. Los Angeles; London; New Delhi; Singapore; Washington DC; Melbourne: SAGE.

Fowler, J., Jarvis, P. & Chevannes, M. 2021. *Practical statistics for nursing and health care.* Second edition. Hoboken, NJ: Wiley Blackwell.

Fraser, M. & Jensen, J. 1993. Research training in social work: The continuum is not a continuum. *Journal of Social Work Education,* 29:46-62. Available at: https://www.proquest.com. (accessed 20 November 2020).

Gaba, P. & Bhatt, D.L. 2020. The COVID-19 pandemic: a catalyst to improve clinical trials. *Nature Reviews Cardiology,* 17(11):673-675. doi: 10.1038/s41569-020-00439-7. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32873977. (accessed 02 September 2022).

García-Camacha Gutiérrez, I., Pozuelo-Campos, S., García-Camacha Gutiérrez, A. & Jiménez-Alcázar, A. 2022. Face-to-Face or Online Learning in Applied Statistics in Health Sciences? Failed Experiment or Opportunity after COVID-19? *Education Sciences,* 12(12):922-934. doi: 10.3390/educsci12120922. Available at: https://search.proquest.com/docview/2756682930. (accessed 09 February 2023).

Geisler, C.C. 1995. *Scientist-practitioner interests, research self-efficacy, perceptions of the research training environment and their relationship to dissertation progress.* Michigan State University. Department of Counseling, Educational Psychology and Special Education.

Gelso, C.J. 1979. Research in Counseling: Methodological and Professional Issues. *Counseling Psychologist,* 8(3):7-14. Available at: http://eric.ed.gov/ERICWebPortal/detail?accno=EJ236172. (accessed 12 June 2019).

Gelso, C.J., Mallinckrodt, B. & Judge, A.B. 1996. Research Training Environment, Attitudes toward Research, and Research Self-Efficacy. *The Counseling Psychologist,* 24(2):304-322. Available at: https://journals.sagepub.com/doi/full/10.1177/0011000096242010. (accessed 09 April 2020).

Georg, K.C., Oldfield, C., Evers, J. & Flanagan, J. 2022. *The Clinical Trial Challenge: To Win Patients, Win Over Physicians*. Available at: https://www.bain.com. (accessed 12 April 2023).

Getz, K. 2021. Tracking change in the global investigative site landscape. *Applied Clinical Trials,* 30(12):13.

Gomez, F.C., Trespalacios, J., Hsu, Y. & Yang, D. 2022. Exploring Teachers' Technology Integration Self-Efficacy through the 2017 ISTE Standards. *TechTrends,* 66(2):159-171. Available at: https://link.springer.com/article/10.1007/s11528-021-00639-z. (accessed 12 April 2023).

Gomez, R. & Ferguson, M. 2020. Improving self-efficacy for hearing aid self-management: the early delivery of a multimedia-based education programme in first-time hearing aid users. *International Journal of Audiology,* 59(4): 272-281. Available at: https://www.tandfonline.com/doi/abs/10.1080/14992027.2019.1677953. (accessed 22 October 2022).

Gous, H. 2020. Correspondence: investigator supervisors. 20 March.

Gray, J.R. & Grove, S.K. 2020. *Burns and Grove's The Practice of Nursing Research - E-Book: Appraisal, Synthesis, and Generation of Evidence.* Elsevier. Available at: https://www.vlebooks.com/vleweb/product/openreader?id=none&isbn=9780323779258. (accessed 14 February 2023).

Gray, L.P., Wong-Wylie, G., Rempel, G.R., & Cook, K. 2020. Expanding Qualitative Research Interviewing Strategies: Zoom Video Communications. *The Qualitative Report*, 25(5):1292-1301. DOI:10.46743/2160-3715/2020.4212. Available at: https://www.semanticscholar.org. (accessed 20 February 2022).

Greene, B.A. 2018. *Self-Efficacy and Future Goals in Education.* Ed Psych Insights. First edition. London: Routledge. Available at: https://www.taylorfrancis.com/books/9781315523019. (accessed 15 March 2020).

Greene, J.C., Caracelli, V.J. & Graham, W.F. 1989. Toward a Conceptual Framework for Mixed-Method Evaluation Designs. *Educational Evaluation and Policy Analysis,* 11(3):255-274. Available at: https://journals.sagepub.com/doi/full/10.3102/01623737011003255. (accessed 22 February 2023).

Grix, J. 2002. Introducing Students to the Generic Terminology of Social Research. *Politics,* 22(3):175-186. Available at: https://doi.org/10.1111/1467-9256.00173 (accessed 12 March 2020).

Guerrero, D. & De los Ríos, I. 2012. Professional Competences: a Classification of International Models. *Procedia - Social and Behavioral Sciences,* 46:1290-1296. doi: 10.1016/j.sbspro.2012.05.290. Available at: https://www.sciencedirect.com/science/article/pii/S187704281201419X[ID: 277811] (accessed 12 April 2020).

Guthrie, H. 2009. *Competence and competency-based training: what the literature says.* National Centre for Vocational Education Research. Available at: http://vuir.vu.edu.au/22082/ (accessed 12 April 2020).

Hansen, M.A. 2012. Children's Perceptions Of Competence And Self-Concept. A Thesis Presented to The Faculty Humboldt State University In Partial Fulfilment of the Requirements for the Degree Master of Arts in Education.

Harper, B. 2020. Competency-Based Career Advancement. *Association of Clinical Research Professionals.* Available at: https://acrpnet.org. (accessed 07 November 2020).

Harper, B. 2020. Clinical trial workforce struggle in the absence of clear career paths. *The Association of Clinical Research Professionals.* Available at: https://acrpnet.org/2020/02/19/clinical-trial-workforce-struggles-in-absence-of-clear-career-paths-professional-standards/. (accessed 17 March 2023).

Harper, B. 2020. A Perspective on the Current State of Clinical Research Education and Training. *Clinical Researcher,* 34(9):8-20. Available at: https://acrpnet.org. (accessed 07 November 2020).

Hastings, C.E., Fisher, C.A. & McCabe, M.A. 2012. Clinical research nursing: A critical resource in the national research enterprise. *Nursing Outlook,* 60(3): 149-156. Available at: https://dx.doi.org/10.1016/j.outlook.2011.10.003. (accessed 14 May 2020).

Health Professions Council of South Africa. 2019. *Doctors and investigators statistics*. Available at: https://www.hpcsa.ac.za. (accessed 12 April 2019)

Healthcare Management Degree Guide Online. 2022. *Medical professional*. Available at: https://www.healthcare-management-degree.net (accessed 20 November 2022)

Hernon, O., Dalton, R. & Dowling, M. 2020. Clinical research nurses' expectations and realities of their role: A qualitative evidence synthesis. *Journal of Clinical Nursing,* 29(5-6):667-683. Available at: https://onlinelibrary.wiley.com/doi/abs/10.1111/jocn.15128. (accessed 12 April 2023).

Hight, T.N. 2022. A clinical research career could be your best path to follow in medicine. *Clinical Researcher, December 2022*, 36(6):65-67. Available at: https://acrpnet.org. (accessed 12 April 2023).

Hogg, B.A. 1993. European Managerial Competences. *European Business Review,* 93(2):21-26. doi: 10.1108/EUM0000000001914. Available at: https://www.emerald.com/insight/content/doi/10.1108/EUM0000000001914/full/html. (accessed 12 November 2020).

Holden, G. 1992. The Relationship of Self-Efficacy Appraisals to Subsequent Health Related Outcomes. *Social Work in Health Care,* 16(1):53-93. Available at: https://www.tandfonline.com/doi/ abs/10.1300/J010v16n01_05. (accessed 14 May 2020).

Holden, G., Moncher, M.S., Schinke, S.P. & Barker, K.M. 1990. Self-Efficacy of Children and Adolescents: A Meta-Analysis. *Psychological Reports,* 66(3):1044-1046. Available at: https://journals.sagepub. com/doi/full/10.2466/pr0.1990.66.3.1044. (accessed 03 April 2020).

Hornung, C.A., Jones, C.T., Calvin-Naylor, N.A., Kerr, J., Sonstein, S.A., Hinkley, T. & Ellingrod, V.L. 2018. Competency indices to assess the knowledge, skills and abilities of clinical research professionals. *International Journal of Clinical Trials,* 5(1):46-53. Available at: doi: 10.18203/2349-3259.ijct20180130. (accessed 15 February 2020).

Houston, L., Probst, Y., Yu, P. & Martin, A. 2018. Exploring Data Quality Management within Clinical Trials. *Applied Clinical Informatics,* 9(1):72-77. Available at: http://dx.doi.org/10.1055/s-0037-1621702. (accessed 16 August 2020).

HPCSA see Health Professions Council of South Africa.

Hughes, A., Galbraith, D. & White, D. 2011. Perceived Competence: A Common Core for Self-Efficacy and Self-Concept? *Journal of Personality Assessment,* 93(3):278-289. Available at: https://www.tandfonline.com/doi/abs/10.1080/00223891.2011.559390. (accessed 06 April 2020).

ICH E6 GCP see International Council of Harmonisation. 2016.

ICH GCP see International Council of Harmonisation. 2016.

Inan, O.T., Tenaerts, P., Prindiville, S.A., Reynolds, H.R., Dizon, D.S., Cooper-Arnold, K., Turakhia, M., Pletcher, M.J., Preston, K.L., Krumholz, H.M., Marlin, B.M., Mandl, K.D., Klasnja, P., Spring, B., Iturriaga, E., Campo, R., Desvigne-Nickens, P., Rosenberg, Y., Steinhubl, S.R. & Califf, R.M. 2020. Digitizing clinical trials. *NPJ: Nature Portfolio Digital Medicine,* 3(1):101-105. doi: 10.1038/s41746-020-0302-y.

Available at: https://www.ncbi.nlm.nih.gov/pubmed/33594216. (accessed 24 November 2022).

International Council of Harmonisation. 2016. *International Council for Harmonisation (ICH) E6 Guideline for Good Clinical Practice (GCP) 2016*. Available at: https://www.ich.org. (accessed 11 May 2019).

Jackson, E.A. 2018. Moodle Platform: A Case of Flexible Corporate Learning in the Financial Sector (Chapter 9) in Sierra Leone, in *Trends in E-learning*, edited by Sinecen, M. E-book ISBN 978-1-83881-532-5. Available at: doi:10.5772/intechopen.75617 (accessed 15 September 2022).

Jackson, S.E. & Schuler, R.S. 2003. *Managing human resources through strategic partnerships.* Eighth edition. Mason, Ohio: Thomson/South-Western.

Janowsky, D.S., Glick, I.D., Lash, L., Mitnick, L., Klein, D.F., Goodwin, F.K., Hanin, I., Nemeroff, C. & Robins, L. 1986. Psychobiology and psychopharmacology: issues in clinical research training. *Journal of Clinical Psychopharmacology,* 6(1):1-7. doi: 10.1097/00004714-198602000-00002. Available at: https://www.ncbi.nlm.nih.gov/pubmed/3950064. (accessed 11 May 2020).

Janse van Rensburg, E.D. & Oguttu, J.W. 2022. Blended teaching and learning: Exploring the concept, barriers to implementation and designing of learning resources. *South African Journal of Higher Education,* 36(6):285-298. doi: 10.20853/36-6-4595. Available at: http://www.scielo.org.za/scielo.php? script=sci_arttext&pid=S1753-59132022000600016&lng=en&tlng=en. (accessed 21 January 2023).

Jones, M. & Straker, K. 2006. What informs mentors' practice when working with trainees and newly qualified teachers? An investigation into mentors' professional knowledge base. *Journal of Education for Teaching: JET,* 32(2):165-184. Available at: https://www.tandf online.com/doi/abs/10.1080/02607470600655227. (accessed 15 March 2023).

Jones, C.T., Lane, A., Shah, A., Carter, K., Lackey, R. & Kolb, R. 2021. The Un-meeting approach to stimulate collaborative adult learning: an application for clinical research professionals. *Journal of Clinical Translational Science,* 5(1):e162-e167. doi: 10.1017/cts.2021.821. PMID: 34527301; PMCID: PMC8427545. (accessed 11 February 2022).

Jowsey, T., Foster, G., Cooper-Ioelu, P. & Jacobs, S. 2020. Blended learning via distance in pre-registration nursing education: A scoping review. *Nurse Education in Practice*, 44:102775. doi: 10.1016/j.nepr.2020.102775. Epub 2020 Mar 25. PMID: 32247200; PMCID: PMC7195119. (accessed 15 February 2022).

JTF competency framework, *Version 3.1*. 2019. The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard. Available at: https://mrctcenter.org. (accessed 20 February 2019)

Julé, A., Furtado, T., Boggs, L., van Loggerenberg, F., Ewing, V., Vahedi, M., Launois, P. & Lang, T. 2017. Developing a globally applicable evidence-informed competency framework to support capacity strengthening in clinical research. *British Medical Journal Global Health,* 2:e000229. Available at: https://doi.org/10.1136/bmjgh-2016-000229. (accessed 13 June 2019).

Jung, S., Kang, J.W. & Kim, T. 2021. Monitoring in clinical trials of complementary and alternative medicine. *Integrative Medicine Research,* 10(2):100666. Available at: https://dx.doi.org/10.1016/j.im r.2020.100666. (accessed 15 February 2023).

Kahn, J.H. 2001. Predicting the Scholarly Activity of Counseling Psychology Students. *Journal of Counseling Psychology,* 48(3):344-354. doi: 10.1037/0022-0167.48.3.344. Available at: https://search.proquest.com/docview/614357753. (accessed 12 May 2020).

Kahn, J.H. & Miller, S.A. 2000. Measuring Global Perceptions of the Research Training Environment Using a Short Form of the RTES-R. *Measurement and Evaluation in Counseling and Development,* 33(2):103-119. Available at: https://www.tandfonline.com /doi/abs/10.1080/07481756.2000.12069001. (accessed 25 November 2022).

Kahn, J.H. & Scott, N.A. 1997. Predictors of Research Productivity and Science-Related Career Goals among Counseling Psychology Doctoral Students. *The Counseling Psychologist,* 25(1):38-67. Available at: https://journals.sagepub.com/doi/full/10.1177/0011000097251005. (accessed 13 February 2023).

Kao, C., Hamilton, B., Lin, Y. & Hu, W. 2019. Ward-Based Nurses' Knowledge and Attitudes Toward Clinical Trials: A Survey Study in Taiwan. *Journal of Nursing Scholarship,* 51(4):489-496. Available at: https://onlinelibrary.wiley.com/doi/abs/10.1111/jnu.12484. (accessed 25 February 2023).

Katowa-Mukwato, P. & Banda, S. 2016. Self-perceived versus objectively measured competence in performing clinical practical procedures by final year medical students. *International Journal of Medical Education,* 7:122-129. doi: 10.5116/ijme.5709.2a7e. Available at: https://www.ncbi.nlm.nih.gov/pubmed /27132255. (accessed 27 February 2020).

Keene, D. 2021. 'Spotlight on Qualitative methods: Do I need multiple coders', *The Interdisciplinary Association for Population Health Science (IAPHS).* Available at: https://iaphs.org (accessed 16 March 2023).

Kelly, W.N. & Randolph, M.A. 1994. *Careers in Clinical Research: Obstacles and Opportunities.* Washington: National Academies Press. ISBN: 0-309-58547-3. Available at: http://www.nap.edu/catalog/2142.html**.** (accessed 13 February 2020).

Khoja, A., Kazim, F. & Ali, N.A. 2019. Barriers to Conducting Clinical Trials in Developing Countries. *The Ochsner Journal,* 19(4):294-295. doi: 10.31486/toj.19.0068. Available at: https://www.ncbi.nlm.nih.gov/pubmed /31903050. (accessed 11 April 2020).

Kindsiko, E. & Poltimäe, H. 2019. The Poor and Embarrassing Cousin to the Gentrified Quantitative Academics: What Determines the Sample Size in Qualitative Interview-Based Organization Studies? *Forum: Qualitative Social Research,* 20(3):1-25. Available at: doi: 10.17169/fqs-20.3.3200. (accessed 16 May 2020).

Kirk, S. A. 1999. Good intentions are not enough: Practice guidelines for social work. *Research on Social Work Practice, 9*(3):302–310. https://doi.org/10. 1177/104973159900900303 (accessed 20 April 2020).

Klein-Collins, R. 2013. *Sharpening Our Focus on Learning: The Rise of Competency-Based Approaches to Degree Completion*. National Institute for Learning Outcome Assessment. Available at: https://via.library.depaul.edu/snl-cbe/34. (accessed 22 April 2020).

Klemp G.O. Jr. 1980. *The Assessment of Occupational Competence. Final Report: I. Introduction and Overview.* Available at: http://eric.ed.gov/ERICWebPortal /detail?accno=ED192164 (accessed 22 April 2020).

Knapke, J.M., Jenkerson, M., Tsao, P., Freel, S., Fritter, J., Helm, S.L., Jester, P., Kolb, H.R., Mendell, A., Petty, M. & Jones, C.T. 2022. Academic medical center clinical research professional workforce: Part 2 – Issues in staff onboarding and professional development. *Journal of Clinical and Translational Science,* 6(1): e81-e88. doi: 10.1017/cts.2022.412. Available at: https://search.proquest.com/ docview/2689435152. (accessed 03 March 2023).

Koen, A. 2020. Correspondence: investigator supervisors. 20 March.

Komarudin, K., Sutadji, E. & Suhartadi, S. 2019. Contribution of Teaching Factory Learning Strategy Implementation, Mastery of Basic Knowledge, and Self Efficacy to the Vocational Competence and Its Impact to Student Work Readiness. *International Journal of Novel Research in Education and Learning,* 5(1):1-7. doi:

10.2991/icovet-17.2017.36. Available at https://www.noveltyjournals.com. (accessed 14 April 2020).

Koneru, I. 2019. *The impact of technology-enabled learning implementation at Rajiv Gandhi University of Knowledge Technologies*. Commonwealth of Learning. Available at: https://www.researchgate.net/publication/366055982_The_Impact_of_Blended_Learning_at_the_Fiji_National_University (accessed 20 February 2023).

Kotze, W. 2021. *Nurse educators guide to management.* Fourth edition. Johannesburg: van Sheik.

Kramer, B. 2004. *Teaching and Evaluating Design Competencies in the 21st Century*. Best Berkeley Edu. Available at: http://best.berkeley.edu (accessed 14 April 2020).

Kramer, B., Veriava, Y. & Pettifor, J.M. 2015. Rising to the challenge: Training the next generation of clinician scientists for South Africa. *African Journal of Health Professions Education,* 7(2):153-154. doi: 10.7196/AJHPE.671. Available at: https://explore.openaire.eu/search/publication?articleId=dedup_wf_001::0e9c934a53b97aab74a11e82a28fcb45. (accessed 14 June 2019).

Krastef, S. 2019. *'Statistically 70-75% of clinical research staff are women, but it looks that still clinical trials are dominated by males?'.* Linkedin. Available at: https://linkedin.com (accessed 02 April 2023).

Kredo. 2018. Correspondence: Number of investigators. 16th January.

Kremidas, J. 2019. ACRP calls on industry to raise bar in clinical trial performance. *Clinical Researcher,* 33(6):4-5. Available at: https://www.acrpnet.org (accessed 18 March 2020).

Kumar, R. 2019. *Research methodology:: A Step-by-Step Guide for Beginners.* Fifth edition. Los Angeles; London; New Delhi; Singapore; Washington DC; Melbourne: SAGE. Available at: http://bvbr.bib-bvb.de:8991/F?func=service&doc_library=BVB01&local_base=BVB01&doc_number=030391358&sequence=000002&line_number=0001&func_code=DB_RECORDS&service_type=MEDIA. (accessed 16 April 2020).

Kurt, S. 2021. 'Constructivist Learning Theory', *Educational Technology*. Educational Technology. Available at: https://educationalthechnology.net/constructivist-learning-theory (accessed 13 March 2023)

Labott, S.M., Johnson, T.P., Fendrich, M. & Feeny, N.C. 2013. Emotional Risks to Respondents in Survey Research. *Journal of Empirical Research on Human*

Research Ethics, 8(4):53-66. Available at: https://www.jstor.org/stable/10.1525/jer.2013.8.4.53. (accessed 14 April 2020).

Lambert, M. 2019. *Practical Research Methods in Education.* Taylor and Francis.

Lee, J.Y., Lensing, S.V., Botello-Harbaum, M.T., Medina, R. & Zozus, M. 2020. Assessing clinical investigators' perceptions of relevance and competency of clinical trials skills: An international AIDS Malignancy Consortium (AMC) study. *Journal of Clinical and Translational Science,* 5(1):e28-e34. doi: 10.1017/cts.2020.520. Available at: https://www.ncbi.nlm.nih.gov/pubm ed/33948251. (accessed 22 April 2022).

Leedy, P.D. & Ormrod, J.E. 2019. *Practical Research: Planning and Design.* Twelfth Edition. Pearson.

Lent, R.W., Brown, S.D. & Hackett, G. 1994. Toward a Unifying Social Cognitive Theory of Career and Academic Interest, Choice, and Performance. *Journal of Vocational Behavior,* 45(1):79-122. Available at: https://dx.doi.org/10.1006/jvbe.1994.1027. (accessed 16 April 2020).

Lesser, N., Anderson, D., Younossi, A & Overman J. 2022. Broadening clinical trial participation to improve health equity. *Deloitte Insights,* Available at: http://www2.deloitte.com. (accessed 04 April 2023).

Lindsey, D.H., Brass, DJ. & Thomas, J.B. 1995. Efficacy-performance spirals: A multilevel perspective. *Academy of Management Review*, 20(3):645-678.

Lombardozzi, C. 2021. *Create Ideal Conditions for Self-Directed Learning: As they embark on their learning journeys, employees will need a support crew to prevent them from running adrift*. Association for Talent Development. Available at: https://www.td.org (accessed 20 March 2023).

Love, K.M., Bahner, A.D., Jones, L.N. & Nilsson, J.E. 2007. An Investigation of Early Research Experience and Research Self-Efficacy. *Professional Psychology, Research and Practice,* 38(3):314-320. doi: 10.1037/0735-7028.38.3.314. Available at: http://psycnet.apa.org/journals/pro/38/3/314. (accessed 16 April 2020).

Lucia, A.D. & Lepsinger, R. 1999. *The art and science of competency models.* San Francisco, Calif: Jossey-Bass.

Luo, L., Cheng, X., Wang, S., Zhang, J., Zhu, W., Yang, J. & Liu, P. 2017. Blended learning with Moodle in medical statistics: an assessment of knowledge, attitudes and practices relating to e-learning. *BioMed Central Medical Education,* 17(1):170-177. doi: 10.1186/s12909-017-1009-x. PMID: 28927383; PMCID: PMC5606039. (accessed 16 February 2022).

Lynch, M.T., Zhang, L. & Korr, W.S. 2009. Research Training, Institutional Support, and Self-Efficacy: Their Impact on Research Activity of Social Workers. *Advances in Social Work,* 10(2): 193-210. doi: 10.18060/219. Available at: https://search.proquest.com/docview/61398336. (accessed 14 February 2020).

Maccio, E.M. & Schuler, J.T. 2012. Substance Use, Self-Esteem, and Self-Efficacy Among Homeless and Runaway Youth in New Orleans. *Child & Adolescent Social Work Journal,* 29(2):123-136. Available at: https://link.springer.com/article/10.1007/s10560-011-0249-6. (accessed 02 March 2020).

Madeira, C., Santos, F., Kubiak, C., Demotes, J. & Monteiro, E.C. 2019. Transparency and accuracy in funding investigator-initiated clinical trials: a systematic search in clinical trials databases. *British Medical Journal Open,* 9(5): e023394. Available at: http://dx.doi.org/10.1136/bmjopen-2018-023394. (accessed 08 April 2020).

Magnin, A., Iversen, V.C., Calvo, G., Čečetková, B., Dale, O., Demlova, R., Blasko, G., Keane, F., Kovacs, G.L., Levy-Marchal, C., Monteiro, E.C., Palmisano, L., Pella, D., Portolés Pérez, A., Rascol, O., Schmid, C., Tay, F., von der Leyen, H. & Ohmann, C. 2019. European survey on national training activities in clinical research. *Trials,* 20(1):616. doi: 10.1186/s13063-019-3702-z. Available at: https://www.ncbi.nlm.nih.gov/pubmed/31665085. (accessed 10 March 2020).

Maraghi, M., Mortazavi-Tabatabaei, S.A., Ahmady, S. & Hosseini, M. 2018. The relation of educational self-efficacy and motivation among Medical Education students. *Journal of Advances in Medical Education*. 1(2):1-5 Available at: http://jamed.ir/article-1-31-en.html. (accessed 12 April 2020).

Marrelli, A.F. 1998. An introduction to competency analysis and modeling. *Performance Improvement (International Society for Performance Improvement),* 37(5):8-17. doi: 10.1002/pfi.4140370505. Available at: https://api.istex.fr/ark:/67375/WNG-JRVQFZZX-X/fulltext.pdf. (accessed 04 March 2020).

Martinson, N. 2020. Correspondence: investigator supervisors. 20 March.

Martocchio, J. & Baldwin, T. 1997. The Evolution of Strategic Organizational Training: New Objectives and Research Agenda*. Research in Personnel and Human Resources Management*, 15:1-46.

Mason, M. 2010. Sample size and saturation in PhD studies using qualitative interviews. *Forum, Qualitative Social Research,* 11(3):19-11. Available at: http://www.fachportal-paedagogik.de/fis_bildung/suche/fis_set.html?FId=927386. (accessed 15 May 2020).

Mata, Á.N.d.S., de Azevedo, K.P.M., Braga, L.P., de Medeiros, G.C.B.S., de Oliveira Segundo, V.H., Bezerra, I.N.M., Pimenta, I.D.S.F., Nicolás, I.M. & Piuvezam, G. 2021. Training in communication skills for self-efficacy of health professionals: a systematic review. *Human Resources for Health,* 19(1):30-39. doi: 10.1186/s12960-021-00574-3. Available at: https://www.ncbi.nlm.nih.gov /pubmed/33676515. (accessed 13 April 2020).

Mauri, K. 2021. Clinical Trial evolution: the drive to update ICH E6. *Applied clinical trials*. Available at: https://appliedclinicaltrialsonline.com (accessed 12 February 2022).

May, M. 2019. Twenty-five ways clinical trials have changed in the last 25 years. *Nature medicine,* 1:2-5. Available at: https://search.proquest.com/doc view/2165098981. (accessed 13 February 2022).

McCabe, M., Behrens, L., Browning, S., Vessey, J. & Williams, M.J. 2019. CE: Original Research: The Clinical Research Nurse: Exploring Self-Perceptions About the Value of the Role. *The American Journal of Nursing,* 119(8):24-32. doi: 10.1097/01.NAJ.0000577324.10524.c9. Available at: https://www.ncbi.nlm. nih.gov/pubmed/31361266. (accessed 04 April 2023).

McClelland, D.C. 1973. *Testing for Competence Rather Than for "Intelligence*". *American Psychologist, 28*(1):1–14. Available at: https://doi.org/10.1037/h0034092. (accessed 17 April 2020).

McClelland, D.C. 1998. Identifying Competencies with Behavioral-Event Interviews. *Psychological Science,* 9(5):331-339. doi: 10.1111/1467-9280.00065. Available at: https://www.jstor.org/stable/40063317. (accessed 17 April 2020).

McGee, J. 2013. Educating Future Clinical Research Investigators: An 8-Week Clinical Research Education Course for Neurology Residents. Thesis for PhD. A.T. Still University.

Merriam-Webster Dictionary Online. 1996. Sv *"underprepared".* Available at: https://www.merriam-webster.com (accessed 20 May 2020).

Mertens, D.M. & Wilson, A.T. 2018. *Program Evaluation Theory and Practice,* Second Edition: A Comprehensive Guide. The Guilford Press.

Miller, G.E. 1990. The assessment of clinical skills/competence/performance. *Academic Medicine,* 65(9):s63-s67. doi: 10.1097/00001888-199009000-00045. Available at: https://www.ncbi.nlm.nih.gov/pubmed/2400509. (accessed 16 April 2020).

Mirmoghtadaie, Z., Kohan, N. & Rasouli, D. 2020. Determination and Comparison of the Factors Related to Effective Blended Learning in Medical Sciences from the Viewpoints of Instructors and Learners. *Advances in Medical Education Practice*,

11:205-214. doi: 10.2147/AMEP.S239216. PMID: 32214865; PMCID: PMC7083639. (accessed 16 February 2022).

Mitchell, E.J., Ahmed, K., Breeman, S., Cotton, S., Constable, L., Ferry, G., Goodman, K., Hickey, H., Meakin, G., Mironov, K., Quann, N., Wakefield, N. & McDonald, A. 2020. It is unprecedented: trial management during the COVID-19 pandemic and beyond. *Trials,* 21(1):784-789. doi: 10.1186/s13063-020-04711-6. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32917258. (accessed 16 March 2022).

Moore, D.R., Cheng, M. & Dainty, A.R.J. 2002. Competence, competency and competencies: performance assessment in organisations. *Work Study,* 51(6):314-319. Available at: https://www.emerald.com/insight/content/doi/10.1108/00438020210441876/full/html. (accessed 16 April 2021).

Moore, G.F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., Moore, L., O'Cathain, A., Tinati, T., Wight, D. & Baird, J. 2015. Process evaluation of complex interventions: Medical Research Council guidance. *British Medical Journal Clinical Research,* 350(h1258):1-7. Available at: https://doi.org/10.1136/bmj.h1258. (accessed 16 April 2021).

Morse, J.M. 2003. Principles of mixed methods and multi-method research design. In C. Teddlie, & A. Tashakkori (Eds.), *Handbook of mixed methods in social and behavioral research*:189-208. Thousand Oaks, CA: SAGE.

Morse, J. 2020. The Changing Face of Qualitative Inquiry. *International Journal of Qualitative Methods,* 19:1609-4069. Available at: https://journals.sagepub.com/doi/full/10.1177/1609406920909938. (accessed 20 April 2021).

Morse, J.M. 2017. *Analyzing and conceptualizing the theoretical foundations of nursing.* First edition. Springer Publishing Company.

Morse, J.M. & Chung, S.E. 2003. Toward Holism: The Significance of Methodological Pluralism. *International Journal of Qualitative Methods,* 2(3):13-20. Available at: https://journals.sagepub.com/ doi/full/10.1177/160940690300200302. (accessed 20 July 2019).

Morse, J.M. & & Niehaus, L. 2016. *Mixed Method Design. Developing Qualitative Inquiry*. First Edition. Routledge: Taylor and Francis, London and New York.

Morse, J.M. & Niehaus, L. 2009. *Mixed method design.* Walnut Creek, Calif: Left Coast Press. Available at: http://bvbr.bib-bvb.de:8991/F?func=service&doc_library=BVB01&local_base=BVB01&doc_number=018814548&sequence=00

0002&line_number=0001&func_code=DB_RECORDS&service_type=MEDIA. (accessed 20 July 2019).

Mozersky, J.T., Antes, A.L., Baldwin, K., Jenkerson, M. & DuBois, J.M. 2020. How do clinical research coordinators learn Good Clinical Practice? A mixed-methods study of factors that predict uptake of knowledge. *Clinical Trials (London, England),* 17(2):166-175. Available at: https://journals.sagepub.com/doi/full/10.1177/1740774519893301. (accessed 08 April 2021).

MRC Framework. 2019. United Kingdom Research and Innovation. Available at: https://www.ukri.org . (accessed 20 February 2019)

Mukhalalati, B.A. & Taylor, A. 2019. *Adult Learning Theories in Context: A Quick Guide for Healthcare Professional Educators.* Los Angeles; London; New Delhi; Singapore; Washington DC; Melbourne: SAGE.

Mukhtar, M. & Gunderman, R.B. 2017. The Sixth Stage: Mastery. *Academic Radiology,* 24(12):1621-1623. Available at: https://dx.doi.org/10.1016/j.acra.2017.07.006. (accessed 17 March 2021).

Mulder, M., Weigel, T. & Collins, K. 2007. The concept of competence in the development of vocational education and training in selected EU member states: a critical analysis. *Journal of Vocational Education & Training,* 59(1):67-88. Available at: https://www.tandfonline.com/ doi/abs/10.1080/13636820601145630. (accessed 14 March 2021).

Mullikin, E.A., Bakken, L.L. & Betz, N.E. 2007. Assessing Research Self-Efficacy in Physician-Scientists: The Clinical Research Appraisal Inventory. *Journal of Career Assessment,* 15(3):367-387. Available at: https://journals.sagepub.com/doi/full/10.1177/1069072707301232. (accessed 08 February 2021).

Multon, K.D., Brown, S.D. & Lent, R.W. 1991. Relation of Self-Efficacy Beliefs to Academic Outcomes. *Journal of Counseling Psychology,* 38(1):30-38. doi: 10.1037/0022-0167.38.1.30. Available at: http://eric.ed.gov/ERICWeb Portal/detail?accno=EJ426706. (accessed 08 February 2021).

Nabavi, R.T. & Bijandi, M.S. 2012. Bandura's Social Learning Theory & Social Cognitive Learning Theory. *Journal of Personality and Social Psychology* 1(589):1-22. Available at: https://www.researchgate.net. (accessed 20 February 2021).

Nanivadekar, A. 2017. Clinical research: A personal perspective. *Perspectives in Clinical Research,* 8(1):37-40. doi: 10.4103/2229-3485.198547. Available

at: http://www.picronline.org/article.asp?issn=2229-3485;year=2017;volume=8; issue=1;spage=37;epage=40;aulast=Nanivadekar;type=0 (accessed 20 May 2019).

National Academies of Sciences, Engineering and Medicine. 2022. Available at: https://www.nationalacedemies.org (accessed 20 November 2022).

Nation Institute of Health. 2002. Greek Medicine - The Hippocratic Oath. Available at https://www.nlm.nih.gov › hmd › greek › greek_oath. (accessed 20 May 2023).

National Institute for Health Research (NIHR) Publishes New Framework on Complex Interventions to Improve Health. 2021. Targeted News Service, Oct 2. ProQuest. Available at: https://search.proquest.com/docview/2578363629. (accessed 15 May 2022).

National Institute For Health Research (NIHR). 2018. Available at: https://www.nihr.ac.uk (accessed 11 May 2022).

National Institute of Health – National Cancer Institute. 2022. *Clinical trial team*. Available at: https://www.nih.gov. (accessed 13 March 2022).

Nel, D., Burch, V., Adam, S., Ras, T., Mawela, D., Buch, E. & Green-Thompson, I. 2022. The introduction of competency-based medical education for postgraduate training in South Africa. *SAMJ. South African Medical Journal,* 112(9):742-743. Available at: https://doi.org/10.7196/SAMJ.2022.v112i9.16717. (accessed 20 May 2023).

Nemeh, F., Buchbinder, R., Hawley, C.M., Nelson, M.R., Waterkeyn, J.G. & Reid, C.M. 2022. Activities supporting the growth of Clinical Trial Networks in Australia. *Current Controlled Trials in Cardiovascular Medicine,* 23(1):81-87. doi: 10.1186/s13063-021-05974-3. Available at: https://www.ncbi.nlm.nih.gov /pubmed/35090533. (accessed 11 June 2019).

Ng, E., Jones, A.A., Sivapragasam, M., Nath, S., Mak, L.E. & Rosenblum, N.D. 2019. The Integration of Clinical and Research Training: How and Why MD–PhD Programs Work. *Academic Medicine,* 94(5):664-670. doi: 10.1097/ACM.0000000000002467. Available at: https://www.ncbi.nlm.nih. gov/pubmed/30256250. (accessed 20 June 2019).

NIH-NCI see National Institute of Health – National Cancer Institute

NIHR see National Institute For Health Research.

Niranjan, S.J., Durant, R.W., Wenzel, J.A., Cook, E.D., Fouad, M.N., Vickers, S.M., Konety, B.R., Rutland, S.B., Simoni, Z.R. & Martin, M.Y. 2019. Training Needs of Clinical and Research Professionals to Optimize Minority Recruitment and Retention in Cancer Clinical Trials. *Journal of Cancer Education,* 34(1):26-34.

Available at: https://link.springer.com/article/ 10.1007/s13187-017-1261-0. (accessed 22 February 2023).

Nkala-Dlamini, B. 2019. Registered nurse being a Principal Investigator. 16 July.

Nodine, T.R. 2016. How did we get here? A brief history of competency-based higher education in the United States. *The Journal of Competency-Based Education,* 1(1):5-11. Available at: https://onlinelibrary. wiley.com/doi/abs/10.1002/cbe2.1004. (accessed 22 March 2021).

Oermann, M.H., De Gagne, J.C. & Phillips, B.C. 2018. *Teaching in Nursing and Role of the Educator.* Second Edition: *The Complete Guide to Best Practice in Teaching, Evaluation, and Curriculum Development.* New York, NY: Springer Publishing Company. Available at: http://0-search.ebscohost.com. oasis.unisa.ac.za/login.aspx?direct=true&db=nlebk&AN=1568464&site=ehost-live&scope=site (accessed 15 April 2023).

Onwuegbuzie, A.J. & Hitchcock, J.H. 2019. Using Mathematical Formulae as Proof for Integrating Mixed Methods Research and Multiple Methods Research Approaches: A Call for Multi-Mixed Methods and Meta-Methods in a Mixed Research 2.0 Era. *International Journal of Multiple Research Approaches,* 11(3):213-234. Available at: doi: 10.29034/ijmra.v11n3editorial2. (accessed 20 June 2019).

Otwombe, K. 2023. Correspondence: Sample and population. 28 February.

Oxford English Dictionary Online. 1992. Sv *"readiness"*. Available at: http://www.oed.com/viewdictionaryentry/Entry/ (accessed 20 May 2020).

Oxford University Press Online. 2022. *Motivation verses passion.* Available at: https://www.oxford.co.za (accessed 13 December 2022).

Ozer, E.M. & Bandura, A. 1990. Mechanisms governing empowerment effects: A self-efficacy analysis. *Journal of Personality and Social Psychology,* 58(3):472–486. Available at: https://doi.org/10.1037/0022-3514.58.3.472. (accessed 09 February 2021).

Palombini, M. 2022. Trusting Digital Health Technologies: Why Global Standards are a must. *Clinical Leader*. Available at: https://www.clincalleader.com. (accessed 21 January 2022).

Palys, T. & Atchison, C. 2021. *Research Methods in the Social and Health Sciences Making Research Decisions.* London: SAGE. Kindle Edition.

Park, J.J.H., Grais, R.F., Taljaard, M., Nakimuli-Mpungu, E., Jehan, F., Nachega, J.B., Ford, N., Xavier, D., Kengne, A.P., Ashorn, P., Socias, M.E., Bhutta, Z.A. & Mills, E.J. 2021. Urgently seeking efficiency and sustainability of clinical trials in global

health. *The Lancet Global Health,* 9(5):e681-e690. Available at: https://dx.doi.org/10.1016/S2214-109X(20)30539-8. (accessed 20 January 2022).

Parry, S.B. 1996. The quest for competencies. *Training Magazine,* 33(7):48-56.

Passmore, S.R., Farrar Edwards, D., Sorkness, C.A., Esmond, S. & Brasier, A.R. 2020. Training needs of investigators and research team members to improve inclusivity in clinical and translational research participation. *Journal of Clinical and Translational Science,* 5(1):e57-e64. doi: 10.1017/cts.2020.554. Available at: https://www.ncbi.nlm.nih.gov/pubmed/33948278. (accessed 25 January 2021).

Pastorelli, C., Caprara, G.V., Barbaranelli, C., Rola, J., Rozsa, S. & Bandura, A. 2001. The Structure of Children's Perceived Self-Efficacy. *European Journal of Psychological Assessment: Official Organ of the European Association of Psychological Assessment,* 17(2):87-97. doi: 10.1027//1015-5759.17.2.87. Available at: https://search.proquest.com/docview/614358033. (accessed 08 April 2021).

Patil, S.S. & Hasamnis, A.A. 2018. The Role and Scope of Research in Undergraduate Medical Curriculum. *Journal of Clinical and Diagnostic Research,* 12(10): LI01-LI02. doi: 10.7860/JCDR/2018/36808.12135. Available at: https://explore.openaire.eu/search/publication?articleId=doajarticles::4efc8e44b3190828b6872992fc73044c. (accessed 20 May 2019).

Pelser, W. 2018. *Early career research investigators' experience of clinical research.* Available at: http://hdl.handle.net/10500/25325 (accessed 20 May 2019).

Pennell, N., Szczepanek, C., Spigel, D. & Ramalingam, S.S. 2022. Impact of Workforce Challenges and Funds Flow on Cancer Clinical Trial Development and Conduct. *American Society of Clinical Oncology educational book. American Society of Clinical Oncology. Annual Meeting*, 42:1–10. Available at: https://doi.org/10.1200/EDBK_360253 (accessed 02 April 2023).

Peterson-Gloor, J.L., Okimoto, T.G. & King, E.B. 2022. “Maybe baby?” The employment risk of potential parenthood. *Journal of Applied Social Psychology,* 52(8):623-642. Available at: https://onlinelibrary.wiley.com/doi/abs/10.1111/jasp.12799. (accessed 27 January 2022).

Phillips, J.C. & Russell, R.K. 1994. Research Self-Efficacy, the Research Training Environment, and Research Productivity among Graduate Students in Counseling Psychology. *The Counseling Psychologist,* 22(4):628-641. Available

at: https://journals.sagepub.com/ doi/full/10.1177/0011000094224008. (accessed 11 March 2020).

Pinapati, A.K. 2011. Competency management as a tool of talent management a study in Indian it organizations. *Journal of Economic Development, Management, IT, Finance and Marketing*, 5(1):44-56. Available at: https://www.semanticsholar.org. (accessed 20 February 2020).

Polit, D.F. & Beck, C.T. 2022. *Essentials of nursing research.* Tenth edition, international edition. Philadelphia: Wolters Kluwer.

Polit, D.F. & Beck, C.T. 2017. *Nursing research: generating and assessing evidence for nursing practice.* Tenth edition. Philadelphia: Wolters Kluwer.

Potter, J. 1996. *Representing Reality: Discourse, Rhetoric And Social Construction.* Proquest. Available at: https://search.proquest.com/ docview/60038001. (accessed 23 May 2020).

Pozzo, M.I., Borgobello, A. & Pierella, A.M. 2019. Using questionnaires in research on universities: analysis of experiences from a situated perspective. *Reire : Revista D'Innovació i Recerca En Educacio,* 12(2):1-16. doi: 10.1344/reire2019.12.227010. Proquest. Available at: https://search.proquest.com/docview/2317884519. (accessed 13 April 2020).

Programme evaluation guide. 2012. Centers for Disease Control and Prevention. Available at: https://cdc.gov (accessed 12 November 2022).

Project Management Institute Online. 2022. *Programme*. Available at: https://www.pmi.org (accessed: 02 Jan 2023).

Quansah, R. & Essay, C. 2021. The Use of Learning Management System (LMS) Moodle in the midst of Covid-19 Pandemic: Students' perspective. *Journal of Educational Technology and Online Learning,* 4(3):418-431. doi: 10.31681/jetol.934730. (accessed 16 February 2022)

Ragab, M.A. & Arisha, A. 2017. Research Methodology in Business: A Starter's Guide. *Management and Organizational Studies,* 5(1):1-23. doi: 10.5430/mos.v5n1p1. (accessed 13 June 2019).

Rama, L. & Sarada, S. 2017. Role of self-esteem and self-efficacy on competence - A conceptual framework. *IOSR Journal of Humanities and Social Science,* 22(2):33-39. doi: 10.9790/0837-2202053339. (accessed 15 April 2020).

Rees, G., Salto-Tellez, M., Lee, J.L., Oien, K., Verrill, C., Freeman, A., Mirabile, I., West, N.P., Cheang, M., Rodriguez-Justo, M., Howlett, E., Moretti, L., Da Silva, M., NACS, W., Hartridge-Lambert, S., Beecham, J.M., Traub, S., Katugampola, S., Blagden,

S., Morden, J., Robinson, M., James, J., Jones, L.J., Craig, C., Sloan, P., Thomas, G.J., Elliott, P., Driskell, O.J. & Hall, A. 2019. Training and accreditation standards for pathologists undertaking clinical trial work. *Journal of Pathology: Clinical Research,* 5(2):100-107. Available at: https://onlinelibrary.wiley.com/doi/abs/10.1002/cjp2.124. (accessed 19 April 2021).

Reynolds, 3., C F, Martin, C., Brent, D., Ryan, N., Dahl, R.E., Pilkonis, P., Marcus, M.D. & Kupfer, D.J. 1998. Postdoctoral clinical-research training in psychiatry: a model for teaching grant writing and other research survival skills and for increasing clarity of mentoring expectations. *Academic Psychiatry,* 22(3):190-196. doi: 10.1007/BF03341923. Available at: https://www.ncbi.nlm. nih.gov/pubmed/19617924. (accessed 02 April 2023).

Rizvi, S. 2019. *Common FDA Audit Findings: How do you find them before the FDA does?* Baltimore: Johns Hopkins University.

Robinson, A.L., Strahan, E., Girz, L., Wilson, A. & Boachie, A. 2013. 'I Know I Can Help You': Parental Self-efficacy Predicts Adolescent Outcomes in Family-based Therapy for Eating Disorders. *European Eating Disorders Review,* 21(2):108-114. doi: 10.1002/erv.2180. Available at: https://api.istex.fr/ark:/67375/WNG-RB2XTTCD-3/fulltext.pdf. (accessed 20 April 2020).

Raffo, R. & Crook, T. 2019. Good Management Practice Hiring, Upskilling, and Retaining Quality Talent for Clinical Trials. *Clinical Researcher,* 33(9):1-24. Available at: https://www.acrpnet.org. (accessed 22 January 2023).

Rosenberg, M. 2012. Beyond competence: It's the journey to mastery that counts. *Learning Solutions Magazine*. Available at: www.learningsolutionsmag.com/articles/930/beyond-competence-its-the-journey-to-mastery-that-counts. (accessed 20 April 2020).

Rosenzweig, M.Q., Bender, C.M. & Brufsky, A.M. 2005. The nurse as principal investigator in a pharmaceutically sponsored drug trial: considerations and challenges. *Oncology Nursing Forum,* 32(2):293-299. doi: 10.1188/05.ONF.293-299. Available at: https://www.ncbi.nlm.nih.gov/ pubmed/15759067. (accessed 25 May 2019).

Rouse, J. 2022. *3 Barriers Preventing Clinical Trial Innovation*. Pro-ficiency. Available at: https://www.pro-ficiency.com. (accessed 20 January 2023).

Royalty, G.M., Gelso, C.J., Mallinckrodt, B. & Garrett, K.D. 1986. The Environment and the Student in Counseling Psychology. *The Counseling Psychologist,* 14(1):9-30. Available at: https://journals.sage pub.com/doi/full/10.1177/0011000086141002. (accessed 14 April 2020).

Ruyle, M., O'Neill, T.W., Iberlin, J.M., Evans, M.D. & Midles, R. 2018. *Leading the Evolution.* Bloomington, Indiana: Marzano Research Lab.

Sabah, N.M. 2020. Motivation factors and barriers to the continuous use of blended learning approach using Moodle: students' perceptions and individual differences. *Behaviour & Information Technology,* 39(8):875-898. Available at: https://www.tandfonline.com /doi/abs/10.1080/0144929X.2019.1623323. (accessed 15 April 2022).

SAGCP see South Africa. Department of Health. 2020.

SAHPRA see South African Health Products Regulatory Authority. 2019.

Saks, A.M. 1995. Longitudinal Field Investigation of the Moderating and Mediating Effects of Self-Efficacy on the Relationship Between Training and Newcomer Adjustment. *Journal of Applied Psychology,* 80(2):211-225. Available at: http://psycnet.apa.org/journals/apl/80/2/211. (accessed 28 January 2020).

Saks, K. & Leijen, Ä 2014. Distinguishing Self-directed and Self-regulated Learning and Measuring them in the E-learning Context. *Procedia - Social and Behavioral Sciences,* 112:190-198. Available at: https://dx.doi.org/10.1016/j.sbspro.2014.01.1155. (accessed 13 February 2022).

Saldaña, J. 2021. *The coding manual for qualitative researchers.* Fourth edition. Los Angeles; London; New Delhi; Singapore; Washington DC; Melbourne: SAGE

Saleh, M. & Naik, G. 2018. So You Want to Be a Principal Investigator. *Journal of Oncology Practice,* 14(6):e384-e392. doi: 10.1200/JOP.18.00011. Available at: https://www.ncbi.nlm.nih.gov/pubmed/29750578. (accessed 08 March 2022).

Saleh, M., Naik, G., Jester, P., Joiner, C., Westfall, E., Kimberlin, D.W., Willig, J., Redden, D., Southworth, J. & Dransfield, M.T. 2020. Clinical Investigator Training Program (CITP) – A practical and pragmatic approach to conveying clinical investigator competencies and training to busy clinicians. *Contemporary Clinical Trials Communications,* 19(100589):1-6. Available at: https://dx.doi.org/10.1016/j.conctc.2020.100589. (accessed 15 April 2021).

Salha, M.O. & Albadawi, B. 2021. Lead inclusive education in higher education: challenges and opportunities. *Multicultural Education,* 7(11):1-5. DOI:

10.5287/zenodo.5644262. Available at: https://www.research gate.net/publication/356760271 (accessed 17 May 2023).

Sampat, K. 2022. 'Who's Who in Clinical Research – A Complete Guide'. *Clinical Trial Podcast* Available at: https://clinicaltrialpodcast.com clinical-research (accessed 08 January 2023)

Samuels, E., Ianni, P.A., Chung, H., Eakin, B., Martina, C., Murphy, S.L. & Jones, C. 2019. *Guidelines for Evaluating Clinical Research Training using Competency Assessments.* MedEdPublish. Available at: https://doi.org/10.15694/mep.2019.000202.1 (accessed 16 August 2022).

Sandanayake, T.C. 2019. Promoting open educational resources-based blended learning. *International Journal of Educational Technology in Higher Education,* 16(1):1-16. Available at: https://link.springer.com/article/10.1186/s41239-019-0133-6. (accessed 04 June 2022).

Sanghi, S. 2016. *The handbook of competency mapping.* Third edition. Los Angeles: SAGE. Available at: http://www.gbv.de/dms/zbw/863073999.pdf. (accessed 08 April 2020).

Sapega, S. 2022. 'Clinical Research Nurses: Making Research Happen', *Penn Medicine News*. Available at: https:www.penmedicine.org (accessed 11 January 2023)

Sathian, B., Asim, M., Banerjee, I., Pizarro, A.B., Roy, B., van Teijlingen, E.R., do Nascimento, I.J.B. & Alhamad, H.K. 2020. Impact of COVID-19 on clinical trials and clinical research: A systematic review. *Nepal Journal of Epidemiology,* 10(3):878-887. doi: 10.3126/nje.v10i3.31622. Available at: https://search.proquest.com/docview/2450012176. (accessed 12 February 2022).

Saunders, M. 2019. *Research methods for business students.* Eighth edition. Harlow, England: Pearson.

Saunders, J., Pimenta, K., Zuspan, S.J., Berent, R., Herzog, N., Jones, C., Kline, J., Kocher, K., Robinson, V., Thomas, B. & Stanley, R. 2017. Inclusion of the Joint Task Force Competency Domains in onboarding programs for clinical research coordinators: Variations, enabler and barriers. *Clinical Researcher,* 31(6):1-24. Available at: https://www.acrpnet.org. (accessed 21 May 2020).

Saxena, P. & Parekh, A. 2019. Moodle: a tool for self-directed learning in first year medical students. *International Journal of Medical Science and Education,* 6(1):131-135. doi: pISSN- 2348 4438 | eISSN-2349- 3208. (accessed 08 January 2022).

Schoonenboom, J. & Johnson, R.B. 2017. How to Construct a Mixed Methods Research Design. *Köln Z Soziol,* 69 (2):107–131. Available at: https://doi.org/10.1007/s11577-017-0454-1. (accessed 20 April 2021).

Schroeter, K. 2008. Competence Literature Review. CCI. *Scientific Research Publishing.* Available at: https://scirp.org (accessed 14 April 2020).

Sebastian, M., Robinson, M.A., Dumeny, L., Dyson, K.A., Fantone, J.C., McCormack, W.T. & Stratford May, W. 2019. Training methods that improve MD–PhD student self-efficacy for clinical research skills. *Journal of Clinical and Translational Science,* 3(6):316-324. doi: 10.1017/cts.2019.419. Available at: https://www.ncbi.nlm.nih.gov/pubmed/31827905. (accessed 11 March 2022).

Setiawan, A., Putra, D. R., Sujalwo, S., & Cahyo, A. N. 2020. Development of Moodle-based Learning Media using Blended Learning Methods in Graphic Design Subject. *IJID International Journal on Informatics for Development,* 8(2):52–54. Available at: https://doi.org/10.14421/ijid.2019.08201. (accessed 13 February 2022).

Seidman, I. 2019. *Interviewing As Qualitative Research: A Guide for Researchers in Education and the Social Sciences.* New York, NY: Teachers College Press. Available at: http://0-search.ebscohost.com.oasis.unisa.ac.za/login.aspx?direct=true&db=nlebk&AN=2168597&site=ehost-live&scope=site (accessed 22 April 2022).

Selby, S. C., Roos, I. & Wright, L. 2000. Investigation of the application of frontline management training in the community services and health industry: a progress report. Paper presented at the Victorian Community Services and Health Industry Training Board Conference, Melbourne, 22 June. *Fundamentals and New Directions in Sample Preparation.* Elsevier.

Semyonov-Tal, K. & Lewin-Epstein, N. 2021. The importance of combining open-ended and closed-ended questions when conducting patient satisfaction surveys in hospitals. *Health Policy OPEN,* 2(100033):1-6 Available at: https://dx.doi.org/10.1016/j.hp open.2021.100033. (accessed 12 January 2022).

Setiawan, D. 2022. EFL students' pedagogy for social constructivism in speaking blended mode activities: a case study. *Journal of English Education Program (JEEP),* 9(1):33-42. doi: 10.25157/(jeep).v9i1.7571. (accessed 08 January 2022).

Shiely, F., Foley, J., Stone, A., Cobbe, E., Browne, S., Murphy, E., Kelsey, M., Walsh-Crowley, J. & Eustace, J.A. 2021. Managing clinical trials during COVID-19: experience from a clinical research facility. *Current Controlled Trials in Cardiovascular Medicine,* 22(1):62-69. doi: 10.1186/s13063-020-05004-8.

Available at: https://www.ncbi.nlm.nih.gov/pubmed/33461595. (accessed 08 January 2022).

Shivy, V.A., Worthington, E.L., Wallis, A.B. & Hogan, C. 2003. Doctoral Research Training Environments (RTEs): Implications for the Teaching of Psychology. *Teaching of Psychology,* 30(4):297-302. Available at: https://journals.sagepub.com/ doi/full/10.1207/S15328023TOP3004_03. (accessed 13 February 2022).

Shore, C., Gee, A.W. & Wizemann, T. 2021. *Envisioning a Transformed Clinical Trials Enterprise for 2030.* National Academies of Sciences, Engineering, and Medicine, Division, Policy, Forum on Drug Discovery, Development, and Translation. Washington, D.C: National Academies Press.

Showalter, B.L., Cline, D., Yungclas, J., Frentz, K., Stafford, S.R. & Maresh, K.J. 2017. Clinical Research Nursing: Development of a Residency Program. *Clinical Journal of Oncology Nursing,* 21(5):633-636. doi: 10.1188/17.CJON.633-636. Available at: https://www.ncbi.nlm.nih.gov/pubmed/28945726. (accessed 13 February 2022).

SIegfried, N., Volmink, J. & Dhansay, A. 2010. Does South Africa need a national clinical trials support unit? *South African Medical Journal,* 100(8):521-524. doi: 10.7196/SAMJ.3958. Available at: https://www.ncbi.nlm.nih. gov/pubmed/20822621. (accessed 13 April 2019).

Silva, H., Kennedy, L., Koski, G., Sonstein, S. & Stonier, P. 2020. Overcoming inefficiencies in clinical research by fostering a systems approach and core competencies for biomedical professionals involved in medicines development. *Gaceta Médica De Carácas,* 128(4):607-618. doi: 10.47307/GMC.2020.128.4.15. (accessed 13 April 2019).

Silva, H., Sonstein, S., Stonier, P., Dubois, D., Gladson, B., Jones, C.T., Criscuolo, D., Daemen, E., Kesselring, G.L.F., Klech, H. & Klingmann, I. 2015. Alignment of Competencies to Address Inefficiencies in Medicines Development and Clinical Research: Need for Inter-Professional Education. *Pharmaceutical Medicine,* 29(3):131-140. Available at: https://link.springer.com/article/10.1007/s40290-015-0097-3. (accessed 13 April 2019).

Silva, H., Stonier, P., Kerpel-Fronius, S. & Dubois, D. 2021. Editorial: Grand Challenges in Pharmaceutical Medicine: Competencies and Ethics in Medicines Development. *Frontiers in Pharmacology,* 12(666406):1-5. doi:

10.3389/fphar.2021.666406. Available at: https://search.proquest.com/doc view/2535109503. (accessed 20 April 2021).

Siripipatthanakul, S. 2020. *Advantages and disadvantages of a quantitative survey study.* Academia. Available at: https://www.academia.edu. (accessed 07 January 2022).

Skivington, K., Matthews, L., Simpson, S.A., Craig, P., Baird, J., Blazeby, J.M., Boyd, K.A., Craig, N., French, D.P., McIntosh, E., Petticrew, M., Rycroft-Malone, J., White, M. & Moore, L. 2021. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *British Medical Journal Online,* 374:n2061-2066. Available at: http://dx.doi.org/ 10.1136/bmj.n2061. (accessed 21 May 2022).

Smith, L., Siegel, G. & Kennedy, A. 2020. Assessing the Operational Complexity of a Clinical Trial: The Experience of the National Institute of Mental Health. *Clinical Researcher,* 34(3):1-24. Available at: https://acrpnet.org. (accessed 20 April 2021).

Smith, M.K. 2013. 'Chris Argyris: theories of action, double-loop learning and organizational learning', *The encyclopaedia of Informal Education*. Available at: http://infed.org/mobi/chris-argyris-theories-of-action-double-loop-learning-and-organizational-learning/. (accessed 15 February 2022).

Sonstein, S.A., Namenek Brower, R.J., Gluck, W., Kolb, H.R., Aldinger, C., Bierer, B.E. & Jones, C.T. 2020. Levelling the Joint Task Force Core Competencies for Clinical Research Professionals. *Therapeutic innovation & regulatory science*, 54(1):1–20. Available at: https://doi.org/10.1007/s43441-019-00024-2.
(accessed 20 May 2021).

South Africa. Department of Health. 2015. *Ethics in Health Research: Principles, Processes and Structures.* Second edition. Pretoria, South Africa.

South Africa. Department of Health. 2020. *South African Good Clinical Practice: Clinical Trial Guidelines 2020.* Third edition. Pretoria South Africa

South African Health Products Regulatory Authority (SAHPRA). 2019. *Capacity building and Transformation in Clinical Research.* Available at: https://www.sahpra.org.za. (accessed 20 May 2022)

Spencer, L.M. & Spencer, S.M. 1993. *Competence at work: models for superior performance.* New York: John Wiley & Sons.

Stafford, M.C. 2019. Curriculum Evaluation and Transformation: Policies, Perspectives and Challenges. *Asia Pacific Journal on Curriculum Studies,* 2(1): 19-27. doi: 10.53420/apjcs.2019.3. (accessed 15 August 2022).

Stajkovic, A.D. & Luthans, F. 1998. Self-Efficacy and Work-Related Performance. *Psychological Bulletin,* 124(2):240-261. doi: 10.1037/0033-2909.124.2.240. Available at: https://search.proquest.com/docview /1791735386. (accessed 11 March 2020).

Stellenbosch University Online. 2022. *Clinical trial on line courses.* Available at: https://www.sun.ac.za (accessed 15 May 2022)

Sundean, L.J., White, K.R., Thompson, L.S. & Prybil, L.D. 2019. Governance education for nurses: Preparing nurses for the future. *Journal of Professional Nursing,* 35(5):346-352. Available at: https://dx.doi.org/10.1016/j.profnurs.2019.04.001. (accessed 20 April 2021).

Suwannaphisit, S., Anusitviwat, C., Tuntarattanapong, P. & Chuaychoosakoon, C. 2021. Comparing the effectiveness of blended learning and traditional learning in an orthopedics course. *Annals of Medicine and Surgery,* 72(103037):1-4. Available at: https://dx.doi.org/10.101 6/j.amsu.2021.103037. (accessed 22 February 2022).

Tan, S.H., Machin, D., Tan, S.B. & Campbell, M.J. 2018. *Sample Sizes for Clinical, Laboratory and Epidemiology Studies.* John Wiley & Sons, Ltd. Available at: https://library.biblioboard.com/viewer/0d8cde92-6d7e-41b8-bcc1-c0dc615f39db. (accessed 20 April 2021).

Tashakkori, A. & Teddlie, C. 2010. *Sage handbook of mixed methods in social & behavioral research.* Second edition. London; Washington DC: SAGE.

Ten Cate, O. 2017. Competency-based postgraduate medical education: past, present and future. *GMS Journal for Medical Education,* 34(5):69-74. doi: 10.3205/zma001146. Available at: https://www.ncbi.nlm.nih.gov/pubmed/ 29226237. (accessed 14 March 2020).

The Association of Clinical Research Professionals (ACRP). 2020. *White Paper: The Impact of Increased Technology Use on the Clinical Research Workforce*. Available at: https://www.acrpnet.org. (accessed 21 May 2022).

The Chartered Institute of Personnel and Development (CIPD). 2022. Available at: https://www.cipd.co.uk (accessed 15 May 2022).

The International Atomic Energy Agency. 2022. *Competency frameworks.* Available at: International Atomic Energy Agency | Atoms for Peace and Development https://www.iaea.org . (accessed 11 January 2023).

Tontonoz, P. 2014. American Society for Clinical Investigation Presidential Address. Leading by example: pastors, mentors, physician-scientists, and the ASCI. *The*

Journal of Clinical Investigation, 124(7):2816-2825. Available at: https://www.ncbi .nlm.nih.gov/pubmed/24983420. (accessed 07 January 2020).

'Top 5 Trial Site FDA Audit Failures and how to avoid them'. 2022. Florence. Available at: https://florence.com (accessed 07 February 2023).

Torr, A. 2008. 'A complex view of professional competence'*, presented at 17th National Vocational Education and Training Research Conference, NCVER, Adelaide.* Available at: https://www.ncver.edu.au (accessed 6 February 2023).

Tsai, C. 2019. Improving students' understanding of basic programming concepts through visual programming language: The role of self-efficacy. *Computers in Human Behavior,* 95:224-232. doi: 10.1016/j.chb.2018.11.038. Available at: https://www.sciencedirect.com/science/article/pii/S0747563218305739[ID: 271 802]. (accessed 09 March 2020).

Turner, B.S. & Saunder, C. 2000. The role of nurse practitioners as principal investigators for clinical studies. *Research Practitioner,* 1(4):129-133.

Tuxworth, E. 1994. Competence-based education and training: Background and origins, in *Competency Based Education and Training* edited by Burk, J.W. London, UK: Falmer Press:109-123.

Ughasoro, M., Musa, A., Yakubu, A., Adefuye, B., Folahanmi, A., Isah, A., Onyemocho, A., Chukwu, E., Chukwudi, C., Dadi Mamud, J., Effa, E., Egharevba, H., Etokidem, A., Mbachu, A., Njokanma, A., Ogunfowokan, A., Ohihoin, N., Onwuamah, C., Orunmuyi, T., Salako, A., Yusuf, A., Okubadejo, N., Anepo-Okopi, J., Ezechi, O. & Salako, B. 2022. Barriers and solutions to effective mentorship in health research and training institutions in Nigeria: Mentors, mentees, and organizational perspectives. *Nigerian Journal of Clinical Practice,* 25(3):215-225. doi: 10.4103/njcp.njcp_154_20. Available at: http://www.njcponline.com/article.asp?issn=1119-3077;year=2022;volume =25;issue=3;spage=215;epage=225;aulast=Ughasoro;type=0. (accessed 07 January 2023).

University of California San Francisco Online. 2022. *Clinical trial online course*. Available at: https://www.ucsf.edu (accessed 15 May 2022)

University of Cape Town Online. 2022. *Clinical trial online training.* Available at: https://www.uct.ac.za (accessed 15 May 2022)

University of the Free State. *Online courses and blended learning.* Available at: https://www.ufs.ac.za/southcampus/south-campus-home/South-Campus-Formal-Programmes/homepage (Accessed 20 June 2022).

University of Virginia Online. 2019. *Clinical trials.* Available at: https://www.virginia.edu (accessed 15 May 2022)

Unrau, Y.A. & Beck, A.R. 2004. Increasing Research Self-Efficacy among Students in Professional Academic Programs. *Innovative Higher Education,* 28(3):187-204. doi: 10.1023/B:IHIE.0000015107.51904.95. Available at: http://eric.ed.gov /ERICWebPortal/detail?accno=EJ771440. (accessed 11 February 2020).

van Dorn, A. 2020. COVID-19 and readjusting clinical trials. *The Lancet,* 396(10250): 523-524. Available at: https://dx.doi.org/ 10.1016/S0140-6736(20)31787-6. (accessed 19 April 2022).

Van Eijk, R.P.A., Westeneng, H.J., Nikolakopoulos, S., Verhagen, I.E., Van Es, M.A., Eijkemans, M.J.C. & Van Den Berg, L.H. 2019. Refining eligibility criteria for amyotrophic lateral sclerosis clinical trials. *Neurology,* 92(5):e451-e460. doi: 10.1212/WNL.0000000000006855. Available at: https://www.narcis.nl/publica tion/RecordID/oai:dspace.library.uu.nl:1874%2F388334. (accessed 23 January 2020).

van Rensburg, L. 2019. Correspondence: Number of investigators. 04 February.

Vazirani, N. 2010. Competencies and Competency Model-A Brief overview of its Development and Application. *SIES Journal of Management,* 7(1):121. Available at: https://search.proquest.com/docview/853607980. (accessed 20 January 2020).

Verderame, M.F., Freedman, V.H., Kozlowski, L.M. & McCormack, W.T. 2018. Competency-based assessment for the training of PhD students and early-career scientists. *eLife,* 7: e34801. Available at: https://doi.org/10.7554/eLife.34801. (accessed 20 January 2020).

Violari, A., Cotton, M.F., Gibb, D.M., Babiker, A.G., Steyn, J., Madhi, S.A., Jean-Philippe, P., McIntyre, J.A. & CHER Study Team 2008. Early Antiretroviral Therapy and Mortality among HIV-Infected Infants. *The New England Journal of Medicine,* 359(21):2233-2244. doi: 10.1056/NEJMoa0800971. Available at: http://content.nejm.org/cgi/content/abstract/359/21/2233. (accessed 14 April 2023).

Vivek, R. & Nanthagopan, Y. 2021. Review and Comparison of Multi-Method and Mixed Method Application in Research Studies. *European Journal of Management Issues,* 29(4):200-208. doi: 10.15421/192119. Available at: https://doaj.org/article/8f755fb6758e43149d22b0e723cd8e00. (accessed 22 February 2022).

Vogel-Walcutt, J.J. & Schatz, S. 2019. *Modernizing Learning.* Washington, D. C: United States Government Printing Office.

Vohora, D. & Singh, G. 2018. *Pharmaceutical medicine and translational clinical research*. London: Academic Press Elsevier.

Weeks-Rowe, E. 2020. Is your site's CRC training methodical or Trial by Fire. *Clinical Researcher,* 34(6):46-50. Available at: https://www.acrp.org. (accessed 20 April 2021).

Westerlaken, M., Christiaans-Dingelhoff, I., Filius, R.M., de Vries, B., de Bruijne, M. & van Dam, M. 2019. Blended learning for postgraduates; an interactive experience. *Biomed Central Medical Education,* 19(1):289-295. doi: 10.1186/s12909-019-1717-5. Available at: https://www.narcis.nl/publication/RecordID/oai:dspace.library.uu.nl:1874%2F388222. (accessed 20 April 2021).

White, R.W. 1959. Motivation reconsidered: The concept of competence. *Psychological Review,* 66(5):297–333. Available at: https://doi.org/10.1037/h0040934. (accessed 19 April 2020).

WHO see World Health Organisation

Wieland, A. 2020. 'Regulatory Science & Clinical Research: Where Do We Stand (And Where Are We Going)?' *Clinical Leader*. Guest column 14 July 2020. Available at: https://clinicalleader.com (accessed 19 February 2020).

Wilkes, L., Jackson, D., Miranda, C. & Watson, R. 2012. The role of clinical trial nurses: an Australian perspective. *Collegian*, 19(4):239-246. doi: 10.1016/j.colegn.2012.02.005. PMID: 23362610. (accessed 20 February 2020).

Wilson, C.B. 2013. *Optimism about medicine's future*. World Medical Association. Available at: https://www.wma.net. (accessed 15 May 2020).

Witheridge, A., Ferns, G. & Scott-Smith, W. 2019. Revisiting Miller's pyramid in medical education: the gap between traditional assessment and diagnostic reasoning. *International Journal of Medical Education,* 10:191-192. doi: 10.5116/ijme.5d9b.0c37. Available at: https://www.ncbi.nlm.nih.gov/pubmed/31655795. (accessed 22 April 2020).

Wits Health Consortium Online. 2022. *Clinical trial online courses.* Available at: https://www.witshealth.co.za (accessed 15 May 2022)

Women in medical schools: dig into latest record-breaking numbers. 2021. States News Service, Sep 29, 2021. American Medical Association. at: https://www.ama-assn.org (accessed 20 February 2023).

Woodin, K. 2019. The CRC's Guide to Coordinating Clinical Research, *PR Newswire.* Fourth edition. Washington: CentreWatch.

Woolfall, K., Roper, L., Humphreys, A., Lyttle, M.D., Messahel, S., Lee, E., Noblet, J., Iyer, A., Gamble, C., Hickey, H., Rainford, N. & Appleton, R. 2019. Enhancing practitioners' confidence in recruitment and consent in the EcLiPSE trial: a mixed-method evaluation of site training – a Paediatric Emergency Research in the United Kingdom and Ireland (PERUKI) study. *Trials,* 20(1):181-188. doi: 10.1186/s13063-019-3273-z. Available at: https://www.ncbi.nlm.nih.gov/pubm ed/30898169. (accessed 19 February 2020).

World Health Organisation (WHO). 2022. *Health Professionals*. Available at: https://www.who.int (accessed 15 May 2022)

World Health Organisation (WHO). 2022. *Health professions networks.* Available at: https://www.who,int/teams/health-professions-networks (Accessed: 01 January 2023)

World Medical Association Declaration of Helsinki (DoH): Ethical Principles for Medical Research Involving Human Subjects. 2013. *The Journal of the American Medical Association.* 310(20):2191-2194. doi:10.1001/jama.2013.281053 (accessed 20 May 2020).

Yan, T., Chan, C.W.H., Chow, K.M., Xiao, J. & Li, M. 2023. Development of an evidence-based, theory-driven, and culturally appropriate character strengths-based intervention for breast cancer patients, following the Medical Research Council Framework. *Supportive Care in Cancer,* 31(1):45-51. Available at: https://link.springer.com/article/10.1007/s00520-022-07538-w. (accessed 20 April 2023).

Yawson, R.M. 2016. The importance of multimethods and mixed methods research in understanding complexity in leadership. *International Journal of Complexity in Leadership and Management,* 3(4):261-277. Available at: https://www.inderscienceonline.com/doi/10.1504/IJCLM.2016. 087122. (accessed 19 February 2020).

Yumashita, M. & Okamura, H. 2011. Association between efficacy of self-management to prevent recurrences of depression and actual episodes of recurrence: A preliminary study. *International Journal of Psychological Studies.* 3(2):217-226. Available at: doi:10.5539/ijps.v3n2p217. (accessed 17 February 2020).

ANNEXURE A: Research Ethics Committee Approval

UNISA university of south africa

RESEARCH ETHICS COMMITTEE: DEPARTMENT OF HEALTH STUDIES

REC-012714-039 (NHERC)

18 December 2019

Dear Wilma Pelser

HSHDC/943/2019

Student: Wilma Pelser

Student No: 5421926

Supervisor: Prof JE Maritz

Qualification: Dcur

Decision: Approval

Name: Wilma Pelser

Proposal: A Clinical Trial Research Education Programme for Investigators in Health Sciences

Qualification: PhD

Risk Level: Medium risk

Thank you for the application for research ethics approval from the Research Ethics Committee: Department of Health Studies, for the above mentioned research. Final approval is granted from 18 December 2019 to 18 December 2024.

The application was reviewed in compliance with the Unisa Policy on Research Ethics by the Research Ethics Committee: Department of Health Studies on 12/12/2019.

The proposed research may now commence with the proviso that:

1) *The researcher/s will ensure that the research project adheres to the values and principles expressed in the UNISA Policy on Research Ethics.*

2) *Any adverse circumstance arising in the undertaking of the research project that is relevant to the ethicality of the study, as well as changes in the methodology, should be communicated in writing to the Research Ethics Review Committee, Department*

University of South Africa
Preller Street, Muckleneuk Ridge, City of Tshwane
PO Box 392, UNISA 0003 South Africa
Telephone: +27 12 429 3111 Facsimile: +27 12 429 4150
www.unisa.ac.za

ANNEXURE B: Research Ethics Committee: Amended 2020 registration

UNISA university of south africa

UNISA HEALTH STUDIES HIGHER DEGREES ETHICS REVIEW COMMITTEE

Date 29 April 2020

Dear Wilma Pelser

Decision: Ethics Approval from 29 April 2020 to 29 April 2023

NHREC Registration # : REC-012714-039

ERC Reference # : **HSHDC/943/2019 AMENDED 2020**

Name : Wilma Pelser

Student #: 5421926

Staff #:

Researcher(s): Name Wilma Pelser
Address 165 Bodenstein Street, Krugersdorp North, 1739
E-mail address wilma@wilmapelser.co.za , telephone # 074 887 2034

Supervisor (s): Name Prof JE Maritz
E-mail address maritje@unisa.ac.za , telephone # 082 788 8703

Working title of research:

A Clinical Trial Research Education Programme for Investigators in Health Sciences

Qualification: PhD

Thank you for the application for research ethics clearance by the Unisa Health Studies Higher Degrees Ethics Review Committee for the above mentioned research. Ethics approval is granted for three (3) years.

*The **medium** **risk application** was **expedited** by a Sub-committee of URERC on 28 April 2020 in compliance with the Unisa Policy on Research Ethics and the Standard Operating Procedure on Research Ethics Risk Assessment. The decision will be tabled at the next Committee meeting on 5 May 2020 for ratification.*

University of South Africa
Preller Street, Muckleneuk Ridge, City of Tshwane
PO Box 392 UNISA 0003 South Africa
Telephone: +27 12 429 3111 Facsimile: +27 12 429 4150
www.unisa.ac.za

ANNEXURE C: Gatekeeper email/letter

Gatekeeper E-mail/Letter
16 August 2019

Wits Health Consortium
Parktown, Johannesburg

To whom it may concern

My name is Wilma Pelser and I'm currently beginning a research project titled: "A Clinical Trial Research Education Programme for Investigators in Health Sciences" for my PhD at the University of South Africa (UNISA).

Subject to approval by UNISA Ethics committee this study will be using questionnaires and a clinical trial research education programme as intervention, to assess the viability of such an education programme for clinical trial research investigators. The purpose of this study is therefore to develop a clinical trial research education programme for investigators in health sciences in South Africa.

Knowing that you have an extensive database with contact details for all clinical trial institutions/sites, I'm writing to ask if you would kindly send out an advertisement to all heads of clinical trial research institutions/sites and investigators working at clinical trial research sites, to invite them to participate in the research programme. Potential participants responding to the advertisement can be referred to me and I will contact them personally to register them for the research programme. Furthermore, I would like to ask your permission to utilise your training venue at Wits Health Consortium for a period of two consecutive weeks at a time convenient for your organisation. There will not be any other burden on you or your staff.

The responses and findings obtained from the surveys are treated with utmost confidentiality. The results will be documented in a study paper that will be accessible to all participants upon its completion.
If feasible, kindly send an email to wilma@wilmapelser.co.za to verify your willingness to promote this educational programme and grant me permission to utilise your training facility.
Yours sincerely

Wilma Pelser

Note:

A face-to-face meeting was set up with a representative at Academic Advance, a division of Wits Health Consortium to discuss the proposal and my request. Verbal agreement was given on the 21st Aug 2019.

PARTICIPANTS NEEDED FOR

A CLINICAL TRIAL RESEARCH EDUCATION PROGRAMME FOR INVESTIGATORS IN HEALTH SCIENCES

We are looking for volunteers to take part in a study to develop a clinical trial research education programme for investigators. As part of capacity building we invite medical (doctors) and non-medical (pharmacists, nurses, social workers) investigators to participate in this clinical trial research education programme.
The curriculum will be aligned with globally defined competencies for investigators. In preparation for their daily tasks, the programme will furthermore clarify investigators' role and those of other key players.

As a participant in this study, you will be required to fill out questionnaires before and after the inclusive clinical trial research education training. These questionnaires will serve as pre-and-post-tests.. Basic demographic information will be collected in a separate questionnaire. You might randomly be selected to be interviewed about your experience related to the inclusive clinical trial research education programme.

Your participation is **entirely voluntary** and would take up approximately eight hours per day (Monday to Friday) of your time over two consecutive weeks. Participation in this programme will give you the "know-how" and you will be able to translate theory to practice, increasing your confidence and self-efficacy in clinical trials. The inclusive clinical trial research education programme could in future provide a framework for a consistent approach to all aspects of conducting clinical trials and could prepare investigators for the numerous challenges they are likely going to encounter in the preparation and conduct of a clinical trial.

To learn more about this study, or to participate in this study,
please contact:

Principal Investigator:
Wilma Pelser
Tel: 0748872034 or email: wilma@wilmapelser.co.za

This study is supervised by Prof Jeanette Maritz (UNISA)

This study has been reviewed by the UNISA Research Ethics Board.

ANNEXURE D: Data collection instrument for stakeholders before development of an inclusive clinical trial research education programme

Open-ended questions:

1. What were your experience as investigator when you entered the clinical trial field?
2. Elaborate according to your experience if it is an experience you wish for new investigators entering clinical trial.
3. In your mind, what would the ideal preparation look like for new investigators?
4. What recommendations can you provide to medical doctors aspiring to enter the clinical research field?

Probing and follow-up questions were employed in accordance with the responses. As an illustration:

• Provide me with additional information.
• Could you please clarify your statement?
• Additionally...
• Could you provide a more comprehensive explanation?
• Let's discuss that more extensively.
• I have been informed by you that ... What is your rationale for experiencing those emotions?
• That is intriguing. Kindly provide me with supplementary details or an illustration.
• What significance does that hold for you?

ANNEXURE E: Template for conducting a debriefing interview

1. Reflect upon your research interviews and assess the level of ease with which you engaged with your participants.
2. Which discoveries were unexpected to you?
a. Which discoveries elicited a negative response from you?
b. What factors do you believe contributed to your adverse reaction to these findings?
c. Which findings elicited a positive response from you?
d. What factors do you believe contributed to your favourable response to these findings?
3. During the interviews, were there any ethical difficulties that you encountered? If so, what types of issues were they?
a. How did you address the ethical dilemma(s)?
b. In your perspective, what was the influence of the ethical issue/s on the participants and/or the integrity of the interviews?
c. Throughout the interview, did you perceive any instances when the interviewee was offering responses that were socially or politically acceptable, but did not accurately represent the actual situation? If your answer is affirmative, what was your response?
d. What unanticipated challenges or ethical quandaries did you confront during your study? How did you address these challenges or ethical quandaries?
4. To what extent do you perceive any changes in your personal identity as a result of conducting the interviews?
5. In the future, how will you modify your interview process based on the insights gained from previous interviews?
6. How would you describe your experience in completing these questions?

ANNEXURE F: Data collection instrument for stakeholders after implementation of an inclusive clinical trial research education programme

Data Collection instrument for stakeholders after implementation of an inclusive clinical trial research education programme

Open-ended questions:

1. Can you elaborate on your experience observing new investigators after they have attended the clinical trial research programme?
2. What are your thoughts about the clinical trial research programme?
3. What suggestions do you have with regards to the clinical trial research programme? It could pertain to the content, to the logistics, anything that comes to mind.

Probing and follow-up questions were employed in accordance with the responses. As an illustration:

• Provide me with additional information.
• Could you please clarify your statement?
• Additionally...
• Could you provide a more comprehensive explanation?
• Let's discuss that more extensively.
• I have been informed by you that ... What is your rationale for experiencing those emotions?
• That is intriguing. Kindly provide me with supplementary details or an illustrative example.
• What significance does that hold for you?

ANNEXURE G: Data collection instrument for participants after the inclusive clinical trial research education programme intervention

Open-ended questions:

1. What was your motivation for registering for the inclusive clinical trial research education programme?
2. What was your expectations of the inclusive clinical trial research education programme, and why those specific expectations?
3. Can you describe your experience as participant of the inclusive clinical trial research education programme?
4. Did the programme fulfil your expectations, if yes, describe why and if not, describe why not?
5. Did the programme make a difference in how you did your tasks and take up your responsibilities after your return to the clinical trial site? If yes, can you describe what kind of difference did you experience? If no, do you have an explanation for why not?
6. What suggestions do you have with regards to the programme, it could include any aspect for example the content, the length, the presenter, etc.
7. What recommendations can you provide to health professionals aspiring to enter the clinical research field?

Probing questions were employed in accordance with the responses. As an illustration:

• Provide me with additional information.
• Could you please clarify your statement?
• Additionally...
• Could you provide a more comprehensive explanation?
• Let's discuss that more extensively.
• I have been informed by you that ... What is your rationale for experiencing those emotions?
• That is intriguing. Kindly provide me with supplementary details or an illustrative example.
• What significance does that hold for you?

ANNEXURE H: ICF for participants used before COVID-19 Lockdown period

Informed Consent Form

Principal Investigator: Ms W Pelser, Doctoral Degree in Nursing Science student, University of South Africa, (05421926)

Dear Potential Participant

My name is Wilma Pelser, I am the principal investigator, and I would like to invite you to take part in a research study titled: “An inclusive clinical trial research education programme for investigators in health sciences”. The study seeks investigators who have worked either at private or dedicated clinical research sites or academic institutions in South Africa, for less than one year.

Prior to making a decision on your participation in the study, I would like to elucidate the study's objective, the potential hazards and advantages, the anticipated responsibilities for you, and the obligations you can expect from me. Feel free to inquire about any concepts or topics that you find unclear or wish to gain further knowledge about.

Your participation is voluntary

This consent form contains details regarding the study that will be communicated to you. Upon comprehending the study and providing your consent to participate, you will be requested to affix your signature. You will be provided with a duplicate of this form for your retention.

Prior to acquainting yourself with the study, it is imperative that you are aware of the following:

• Your involvement is optional. Participation in the study is voluntary.

• You have the option to decline participation or withdraw from the study at any moment without facing any consequences.

Objective of the study

The objective of this study is to create a comprehensive educational programme for clinical trial researchers in South Africa.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) guidelines lack specificity when it comes to outlining the necessary qualifications and expertise of those engaged in clinical research. Approval to be principal investigator is typically granted to those holding a medical licence in most countries. The most recent edition of the Declaration of Helsinki, published in October 2013, specified that "medical research should only be carried out by individuals who possess the necessary expertise and qualifications in clinical research." While numerous schools and organisations provide exceptional certification

programmes, there is still a lack of legal legislation specifying the necessary educational or experiential prerequisites. Additionally, there is no requirement for people certification. Furthermore, there is a lack of standardisation regarding the qualifications of clinical investigators and trial workers. Completion of GCP training, recognised as the “gold standard” for preparation of individuals to work on clinical trials, is insufficient to ensure the quality conduct of a clinical trial. Employees entering the clinical research field deserve “the best” standardised and certified training to ensure a good foundation for success. Taking into consideration the increase in clinical trial protocol complexity, the highly regulated process of development and consequent licensing of new drugs and devices and the regulations and guidelines required to manage clinical trial activity, the need for adequately trained investigators is evident.

Founded on the findings of this study, the introduction of an inclusive clinical trial research education programme might be a positive step in the direction to better prepare, equip and support investigators in South Africa and to narrow the existing gap in formal training for investigators.

Procedure

If you choose to participate in the study, I will gather data from you through the use of questionnaires. Before commencing with the inclusive clinical trial research education programme, you will be asked to complete a demographic and descriptive questionnaire as well as a pre-test questionnaire. The pre-test questionnaire will consist of two parts, the first part will ask questions to determine your self-assessed level of knowledge and competency in clinical trials (pre-assessment), the second part will ask questions to determine your level of knowledge in the topics significant to the clinical trial process and life cycle of a clinical trial (pre-assessment). The demographic and pre-test surveys will require a time commitment of around 45-60 minutes for completion. The inclusive clinical trial research education programme will be presented over a period of two weeks from 08:30-16:00 during weekdays. After the educational training intervention, you will be asked to complete the same set of questionnaires to again, firstly to determine your self-assessed level of knowledge and competency in clinical trials (post-assessment), and secondly to determine your level of knowledge in the topics significant to the clinical trial process and life cycle of a clinical trial (post-assessment). The post-test questionnaires will take approximately 30 -45 minutes to complete. Following the educational intervention, three participants will be chosen at random to undergo a one-hour individual interview conducted in person. If you are chosen, I will employ open-ended inquiries during the interview to acquire a more profound comprehension and delve into your encounters throughout the educational intervention. The interview will be digitally recorded in audio format, contingent upon your approval. Throughout the conversation, I will document my observations and reflections by compiling field notes.

Risks

The research proposed could have the potential for psychological harm. It is hard to receive information about yourself that is unpleasant and inconvenient even if it is meant to be positive and could lead to improvement of the self. In extreme situations psychological harm can lead to social harm. You might

experience some physical discomfort due to the fact that you will be sitting in a classroom set-up for two consecutive weeks. There are no other foreseeable risks.

Should there be any minor discomforts or negative feelings emerging during answering the questions from any of the questionnaires, I will address their concerns, and if you so desire, you have the option to cease participation and withdraw from the study. Arranging a referral to a counsellor can be based on the specific emotions you may be experiencing. There will be no compensation provided for participation in this study.

Benefits

Your participation in this study will not only provide me, as the researcher, with a better understanding of your experiences during the educational intervention, but it will also help me determine if the inclusive clinical trial research education programme that I have developed has achieved its intended goals. Specifically, I am interested in assessing whether the programme has addressed the need for more formal training of investigators and whether it has been effective. The findings of this study may serve as the basis for support systems and programmes aimed at assisting investigators in South Africa in their pursuit of a successful career in clinical trial research.

Reimbursement and costs

You will not receive any reimbursement for your participation in the study neither will there be any costs to you for attending the inclusive clinical trial research education programme.

Confidentiality

Utmost effort will be exerted to uphold your confidentially throughout and following the study. Your responses will be maintained with utmost confidentiality, unless there is a legal or ethical obligation to disclose them. Your identity will remain anonymous, and no reference of your name will be made in the research report or when the study results are published. In order to protect secrecy, you will be assigned a numerical identifier. The data will be securely stored in a designated, lockable filing cabinet. The information you supplied will not be associated with your personal data or any other identifiable information.

The findings of this investigation can be included into a thesis or published in a scientific journal. Your identity will not be disclosed in any of these materials. None of the participants in this study will be referred to by their names in any presentation or publication. Both electronic and physical copies will be eliminated after a period of five (5) years, as well as when the findings have been made public.
You are entitled to be informed about the findings of this study. I will communicate with you using your preferred contact information in order to provide you with the results.

Questions

If you have any inquiries or difficulties, please don't hesitate to reach out to Ms. W Pelser at 074 8872034 or the alternative office number at work, 011 6604342. The operating hours are from 07:00 to 16:00 on Monday to Thursday, and from 07:00 to 13:00 on Friday. Alternatively, you can contact Prof J Maritz at maritje@unisa.ac.za. If you have any concerns regarding the research methodology, you may reach out to the Ethics Chair of the Department of Health Studies at HSREC@unisa.ac.za.

Signatures

I (first name & surname) _____ consent to participate in the study: “An inclusive clinical trial research education programme for investigators” to be conducted by Ms Wilma Pelser. I acknowledge and provide my approval that in the event of being chosen for an interview through a random selection process, the interview may be recorded using digital means. I acknowledge that my involvement in this study is optional and that I possess the autonomy to terminate the interview or the completion of any questionnaires at my discretion. I possess the ability to decline providing a response to any inquiry. I will not receive any compensation for participating in the interview. I understand that the study's findings will be disseminated as a research paper, however it is important to note that no individuals' names will be included in any publications.

I have received a detailed explanation and discussion of the topics of the study, which includes the information provided in this consent form. I have been granted permission to inquire and my inquiries have been addressed. I have been provided with Ms. Pelser's personal contact information (0748872034/ 011 6604342) if I may want to get in touch with her. I have received confirmation that the signed consent form will be securely stored and kept separate from the data I provided in the questionnaires. If I am chosen for an interview, the interview itself, as well as any audio recordings, transcriptions, observations, and field notes, will not include any identifying information about me.

Signature research participant Print Name Date

I, _____, have conferred on the aforementioned items with the participant. I believe that the participant comprehends the risks, benefits, and duties associated with participating in this study.

Signature Researcher Print Name Date

ANNEXURE I: ICF for senior investigators, principal investigators, heads of institutions or departments, supervisors or mentors of new investigators used before COVID-19 Lockdown period

Informed consent Form

Principal Investigator: Ms W Pelser, Doctoral Degree in Nursing Science student, University of South Africa, (05421926)

Dear Potential Participant

My name is Wilma Pelser, I am the principal investigator, and I would like to invite you to take part in a research study titled: "An inclusive clinical trial research education programme for investigators in health sciences". The study invites senior investigators, principal investigators, heads of institutions or departments, supervisors, or mentors of new investigators, who have worked either at private or dedicated clinical research sites or academic institutions in South Africa for more than five (5) years.
Prior to deciding on your participation in the study, I would like to elucidate the study's objective, the potential hazards and advantages, the anticipated responsibilities for you, and the obligations you can expect from me. Feel free to inquire about any concepts or topics that you find unclear or wish to gain further knowledge about.

Your participation is voluntary.
This consent form contains details regarding the study that will be communicated to you. Upon comprehending the study and providing your consent to participate, you will be requested to affix your signature. You will be provided with a duplicate of this form for your retention.
Prior to acquainting yourself with the study, it is imperative that you are aware of the following:
• Your involvement is optional. Participation in the study is voluntary.
• You have the option to decline participation or withdraw from the study at any moment without facing any consequences.

Objective of the study
The objective of this study is to create a comprehensive educational programme for clinical trial researchers in South Africa.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) guidelines lack specificity when it comes to outlining the necessary qualifications and expertise of those engaged in clinical research. Approval to be principal investigator is typically granted to those holding a medical licence in most countries. The most recent

edition of the Declaration of Helsinki, published in October 2013, specified that "medical research should only be carried out by individuals who possess the necessary expertise and qualifications in clinical research." While numerous schools and organisations provide exceptional certification programmes, there is still a lack of legal legislation specifying the necessary educational or experiential prerequisites. Additionally, there is no requirement for people certification. Furthermore, there is a lack of standardisation regarding the qualifications of clinical investigators and trial workers. Completion of GCP training, recognised as the “gold standard” for preparation of individuals to work on clinical trials, is insufficient to ensure the quality conduct of a clinical trial. Employees entering the clinical research field deserve “the best” standardised and certified training to ensure a good foundation for success. Taking into consideration the increase in clinical trial protocol complexity, the highly regulated process of development and consequent licensing of new drugs and devices and the regulations and guidelines required to manage clinical trial activity, the need for adequately trained investigators is evident.

Founded on the findings of this study, the introduction of an inclusive clinical trial research education programme might be a positive step in the direction to better prepare, equip and support investigators in South Africa and to narrow the existing gap in formal training for investigators.

Procedure

If you choose to participate in the study, I will gather data from you through a personal, in-person interview. Your participation might be asked for before the development of the clinical trial research programme and/or after participants (new investigators) have completed the programme. Each interview will take up approximately 30-60 minutes of your time and will be arrange at a venue and time that will be convenient for you. For interviews before the clinical trial research programme, To enhance my comprehension and delve into your encounters with fresh investigators, as well as to obtain your insights on the ideal structure of a clinical trial research plan, I will employ open-ended inquiries during the interview. During post-program interviews, I will employ open-ended questions to ascertain your perception of the encounter with new investigators following their completion of the programme. The interview will be digitally recorded in audio format, contingent upon your approval. Throughout the conversation, I will document my observations and reflections by compiling field notes.

Risks

Participating in this study does not pose any immediate hazards to you. If you have any slight discomfort while answering the questions, I will address them. If you would like, we can stop the interview.

Benefits

Your participation in this study could assist me, as a researcher, in gaining a more profound comprehension of your encounters with new investigators. Additionally, it could aid in the development of an effective and comprehensive clinical trial research programme. Furthermore, it would help determine if the inclusive clinical trial research education programme that I have created has successfully addressed the requirement for more formal investigator training and if it has been effective.

The findings of this study could serve as the basis for support systems and initiatives aimed at aiding researchers in South Africa in achieving a prosperous career in clinical trial research.

Reimbursement and costs

You will not receive any reimbursement for your participation in the study neither will there be any costs to you.

Confidentiality

Utmost effort will be exerted to uphold your confidentially throughout and following the study. Your responses will be maintained with utmost confidentiality, unless there is a legal or ethical obligation to disclose them. Your identity will remain anonymous, and no reference of your name will be made in the research report or when the study results are published. In order to protect secrecy, you will be assigned a numerical identifier. The data will be securely stored in a designated, lockable filing cabinet. The information you supplied will not be associated with your personal data or any other identifiable information.

The findings of this investigation can be included into a thesis or published in a scientific journal. Your identity will not be disclosed in any of these materials. None of the participants in this study will be referred to by their names in any presentation or publication. Both electronic and physical copies will be eliminated after a period of five (5) years, as well as when the findings have been made public.
You are entitled to be informed about the findings of this study. I will communicate with you using your preferred contact information in order to provide you with the results.

Questions

If you have any inquiries or difficulties, please don't hesitate to reach out to Ms. W Pelser at 074 8872034 or the alternative office number at work, 011 6604342. The operating hours are from 07:00 to 16:00 on Monday to Thursday, and from 07:00 to 13:00 on Friday. Alternatively, you can contact Prof J Maritz at maritje@unisa.ac.za. If you have any concerns regarding the research methodology, you may reach out to the Ethics Chair of the Department of Health Studies at HSREC@unisa.ac.za.

Signatures

I (first name & surname) _____ consent to participate in the study: “An inclusive clinical trial research education programme for investigators” to be conducted by Ms Wilma Pelser I acknowledge and provide agreement for an interview that may be recorded in a digital format. I acknowledge that my involvement in this study is optional and that I possess the autonomy to terminate the interview at my discretion. I have the ability to decline answering any particular question. I will not receive any compensation for participating in the interview. I understand

that the study's findings will be disseminated as a research paper, however it is important to note that no individuals' names will be included in any publications.

I have received a detailed explanation and discussion of the topics of the study, which includes the information provided in this consent form. I have been granted permission to inquire and my inquiries have been addressed. I have been provided with Ms. Pelser's personal contact information (0748872034/ 011 6604342) in the event that I may want to get in touch with her. I have received confirmation that the signed consent form will be securely stored and kept separate from the data I provided in the questionnaires. In the event that I am chosen for an interview, the interview itself, as well as any audio recordings, transcriptions, observations, and field notes, will not include any identifying information about me.

Signature research participant Print Name Date

I, _____, have conferred on the aforementioned items with the participant. I believe that the participant comprehends the risks, benefits, and duties associated with participating in this study.

Signature Researcher Print Name Date

ANNEXURE J: ICF for senior investigators, principal investigators, heads of institutions or departments, supervisors or mentors of new investigators used during and after COVID-19 Lockdown period

Informed consent Form

Principal Investigator: Ms W Pelser, Doctoral Degree in Nursing Science student, University of South Africa, (05421926)

Dear Potential Participant

My name is Wilma Pelser, I am the principal investigator, and I would like to invite you to take part in a research study titled: “An inclusive clinical trial research education programme for investigators in health sciences”. The study invites senior investigators, principal investigators, heads of institutions or departments, supervisors or mentors of new investigators, who have worked either at private or dedicated clinical research sites or academic institutions in South Africa for more than five (5) years.
Prior to making a decision on your participation in the study, I would like to elucidate the study's objective, the potential hazards and advantages, the anticipated responsibilities for you, and the obligations you can expect from me. Feel free to inquire about any concepts or topics that you find unclear or wish to gain further knowledge about.

Your participation is voluntary

This consent form contains details regarding the study that will be communicated to you. Upon comprehending the study and providing your consent to participate, you will be requested to affix your signature. You will be provided with a duplicate of this form for your retention.
Prior to acquainting yourself with the study, it is imperative that you are aware of the following:

• Your involvement is optional. Participation in the study is voluntary.

• You have the option to decline participation or withdraw from the study at any moment without facing any consequences.

Objective of the study

The objective of this study is to create a comprehensive educational programme for clinical trial researchers in South Africa.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) guidelines lack specificity when it comes to outlining the necessary qualifications and expertise of those engaged in clinical research. Approval to be principal investigator is typically granted to those holding a medical licence in most countries. The most recent

edition of the Declaration of Helsinki, published in October 2013, specified that "medical research should only be carried out by individuals who possess the necessary expertise and qualifications in clinical research." While numerous schools and organisations provide exceptional certification programmes, there is still a lack of legal legislation specifying the necessary educational or experiential prerequisites. Additionally, there is no requirement for people certification. Furthermore, there is a lack of standardisation regarding the qualifications of clinical investigators and trial workers. Completion of GCP training, recognised as the “gold standard” for preparation of individuals to work on clinical trials, is insufficient to ensure the quality conduct of a clinical trial. Employees entering the clinical research field deserve “the best” standardised and certified training to ensure a good foundation for success. Taking into consideration the increase in clinical trial protocol complexity, the highly regulated process of development and consequent licensing of new drugs and devices and the regulations and guidelines required to manage clinical trial activity, the need for adequately trained investigators is evident.

Founded on the findings of this study, the introduction of an inclusive clinical trial research education programme might be a positive step in the direction to better prepare, equip and support investigators in South Africa and to narrow the existing gap in formal training for investigators.

Procedure

If you want to participate in the study, I will gather data from you through either an in-person, face-to-face interview or an online interview. Your participation might be asked for before the development of the clinical trial research programme and/or after participants (new investigators) have completed the programme. Each interview will take up approximately 30-60 minutes of your time and will be arrange according to your preference, first your choice of either an in person or online interview, then, with regards to a venue if an in person face-to-face interview have been chosen, then date and time. During the interviews prior to the clinical trial research programme, I will employ open-ended questions to obtain a more profound comprehension and delve into your encounters with new investigators. Additionally, I will seek your recommendations regarding the ideal structure of a clinical trial research programme. During post-program interviews, I will employ open-ended questions to ascertain your perspective on the experience of new investigators after they have finished the programme. Upon your agreement, the interview will be recorded utilising both a digital recorder and an internet platform recorder, capturing both auditory and visual content if applicable. Throughout the conversation, I will document my observations and reflections by compiling field notes. Prior to commencing the online interview, I kindly request that you sign this informed consent form and return it to me by email.

Risks

Participating in this study poses no immediate hazards to you. The discussion of privacy and confidentiality risks is included inside the section labelled "confidentiality". If you have any minor pain while answering the questions, I will address them promptly. If you would prefer, we can end the interview.

Benefits

Your participation in this study may not directly benefit you as an individual, but it would greatly assist me as a researcher in gaining a deeper understanding of your experiences with new investigators. Additionally, it would help me in developing an efficient and comprehensive clinical trial research programme. Furthermore, it would enable me to determine if the inclusive clinical trial research education programme that I have developed has achieved the desired results, such as addressing the need for more formal training of investigators and assessing its effectiveness. The findings of this study could serve as the basis for support systems and initiatives aimed at aiding researchers in South Africa in achieving a prosperous career in clinical trial research.

Reimbursement and costs

You will not receive any reimbursement for your participation in the study neither will there be any costs to you.

Confidentiality

Utmost efforts will be exerted to uphold your confidentiality throughout and following the study. Your responses will be maintained with utmost confidentiality, unless there is a legal or ethical obligation to disclose them. Your identity will remain anonymous, and no reference of your name will be made in the research report or when publishing the study results. In order to protect secrecy, you will be assigned a numerical identifier. The data will be securely held in a highly protected facility, namely a lockable filing cabinet. The information you supplied will not be associated with your personal data or any other identifiable information.

Choosing an online interview, might hold a threat to the privacy of our conversations, I recommend that you seek out a space where you have some privacy and where you can have an uninterrupted conversation, it could even be outside your building for example on a patio. You can also use headphones or earphones to stay focused on the interview. For confidentiality I will establish a “safe” online environment by choosing an online platform that promises confidentiality of data, I will create an interview ID login where I will give you permission to enter the interview meeting after you have typed in a password.

The results of this study can be incorporated into a dissertation or disseminated in a scholarly periodical. Your identity will remain confidential in all of these products. All participants in this study will remain anonymous in any presentation or publication, with no mention of their names. Both electronic and physical copies will be eliminated within a span of five (5) years, following the release of the findings.

You are entitled to be informed about the findings of this study. I will communicate with you using the contact information you have provided, in order to share the results with you.

Questions

If you have any inquiries or difficulties, please don't hesitate to reach out to Ms. W Pelser at 074 8872034 or the alternative office number at work, 011 6604342. Operating hours are from 07:00 to 16:00 on Monday to Thursday, and from 07:00 to 13:00 on Friday. For any inquiries, please contact Prof J Maritz at maritje@unisa.ac.za.

The study has received approval from the Health Studied Ethics Committee (HSREC) HSHDC/943/2019, which is a department of the Department of Health. If you have any concerns regarding the research methodology, you may reach out to the Ethics Chair of the Department of Health Studies at HSREC@unisa.ac.za.

Signatures

I (first name & surname) _____ consent to participate in the study: “An inclusive clinical trial research education programme for investigators” to be conducted by Ms Wilma Pelser. I acknowledge and provide agreement for an interview that may be recorded in a digital format. I acknowledge that my involvement in this study is optional and that I possess the autonomy to terminate the interview at my discretion. I have the ability to decline answering any particular question. I will not receive any compensation for participating in the interview. I understand that the study's results will be disseminated as a research paper, but it will not include any personal identifiers in any publications.

I have been provided with a detailed explanation and discussion of the study's contents, which includes the information contained in this permission form. I have been granted permission to pose inquiries and my inquiries have been responded to. I have been provided with Ms. Pelser's personal contact information (0748872034/ 011 6604342) in the event that I may want to get in touch with her. I have received confirmation that the signed consent form will be securely stored and kept separate from the information I provided in the questionnaires. In the event that I am chosen for an interview, the interview process and all related recordings, transcriptions, observations, and field notes will not include any identifying information about me.

Signature research participant Print Name Date

I, _____, have deliberated upon the aforementioned aspects with the participant. I believe that the participant comprehends the risks, benefits, and responsibilities associated with participating in this study.

Signature Researcher Print Name Date

ANNEXURE K: ICF for participants used during and after COVID-19 Lockdown period

Informed Consent Form

Principal Investigator: Ms W Pelser, Doctoral Degree in Nursing Science student, University of South Africa, (05421926)

Dear Potential Participant

My name is Wilma Pelser, I am the principal investigator, and I would like to invite you to take part in a research study titled: “An inclusive clinical trial research education programme for investigators in health sciences”. The study invites investigators who have worked either at private or dedicated clinical research sites or academic institutions in South Africa, for less than one year.

Prior to making a decision on your participation in the study, I would like to elucidate the study's objective, the potential hazards and advantages, the anticipated responsibilities for you, and the obligations you can expect from me. Feel free to inquire about any concepts or topics that you find unclear or wish to gain further knowledge about.

Your participation is voluntary

This consent form contains details regarding the study that will be communicated to you. Upon comprehending the study and providing your consent to participate, you will be requested to affix your signature. You will be provided with a duplicate of this form for your retention.

Prior to acquainting yourself with the study, it is imperative that you are aware of the following:

• Your involvement is optional. Participation in the study is voluntary.

• You have the option to decline participation or withdraw from the study at any moment without facing any consequences.

Objective of the study

The objective of this study is to create a comprehensive educational programme for clinical trial researchers in South Africa.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) guidelines lack specificity when it comes to outlining the necessary qualifications and expertise of those engaged in clinical research. Approval to be principal investigator is typically granted to those holding a medical licence in most countries. The most recent edition of the Declaration of Helsinki, published in October 2013, specified that "medical research should only be carried out by individuals who possess the necessary expertise and qualifications in clinical research." While numerous schools and organisations provide exceptional certification

programmes, there is still a lack of legal legislation specifying the necessary educational or experiential prerequisites. Additionally, there is no requirement for people certification. Furthermore, there is a lack of standardisation regarding the qualifications of clinical investigators and trial workers. Completion of GCP training, recognised as the "gold standard" for preparation of individuals to work on clinical trials, is insufficient to ensure the quality conduct of a clinical trial. Employees entering the clinical research field deserve "the best" standardised and certified training to ensure a good foundation for success. Taking into consideration the increase in clinical trial protocol complexity, the highly regulated process of development and consequent licensing of new drugs and devices and the regulations and guidelines required to manage clinical trial activity, the need for adequately trained investigators is evident.

Founded on the findings of this study, the introduction of an inclusive clinical trial research education programme might be a positive step in the direction to better prepare, equip and support investigators in South Africa and to narrow the existing gap in formal training for investigators.

Procedure

If you choose to participate in the study, I will gather data from you through the use of questionnaires. Before commencing with the inclusive clinical trial research education programme, you will be asked to complete a demographic and descriptive questionnaire as well as a pre-test questionnaire. The pre-test questionnaire will consist of two parts, the first part will ask questions to determine your self-assessed level of knowledge and competency in clinical trials (pre-assessment), the second part will ask questions to determine your level of knowledge in the topics significant to the clinical trial process and life cycle of a clinical trial (pre-assessment). The demographic and pre-test questions will require around 45-60 minutes for completion. The inclusive clinical trial research education programme will make use of blended training that will include both internet communication technology and classroom work. The classroom lectures will be presented over a period of eight weeks from 08:30-13:00 during weekdays. After the educational training intervention, you will be asked to complete the same set of questionnaires to again, firstly to determine your self-assessed level of knowledge and competency in clinical trials (post-assessment), and secondly to determine your level of knowledge in the topics significant to the clinical trial process and life cycle of a clinical trial (post-assessment). The post-test questionnaires will take approximately 30 -45 minutes to complete. Following the educational intervention, three participants will be chosen at random to participate in either an in-person or online interview, each lasting approximately one hour. If you are chosen, I will employ open-ended inquiries during the interview to acquire a more profound comprehension and delve into your encounters throughout the educational intervention. Your interview will be documented using a digital recorder, which will capture both audio and video (where applicable), with your permission. Throughout the conversation, I will document my observations and reflections by compiling field notes.

Risks

The research proposed could have the potential for psychological harm. It is hard to receive information about yourself that is unpleasant and inconvenient even if it is meant to be positive and could lead to

improvement of the self. In extreme situations psychological harm can lead to social harm. You might experience some physical discomfort because you will be sitting in a classroom set-up for two consecutive weeks. There are no other foreseeable risks.

If you have any slight discomfort or bad emotions while taking the questionnaires, I will address them. If you choose, you have the option to stop participating in the study. Arrangements for a referral to a counsellor might be made based on the specific emotions you may be experiencing. There will be no compensation provided for participation in this study.

Benefits

Your participation in this study could assist me, as the researcher, in gaining a comprehensive understanding of your experiences during the educational intervention. Additionally, it will help me determine the effectiveness of the inclusive clinical trial research education programme that I have developed, as well as whether it has successfully addressed the need for more formal training of investigators. The findings of this study could serve as the basis for support systems and initiatives aimed at aiding researchers in South Africa in achieving a prosperous career in clinical trial research.

Reimbursement and costs

You will not receive any reimbursement for your participation in the study neither will there be any costs to you for attending the inclusive clinical trial research education programme.

Confidentiality

Utmost efforts will be used to uphold the privacy of your information throughout and following the study. Your responses will be maintained with utmost confidentiality, unless there is a legal or ethical obligation to disclose them. Your identity will remain anonymous, and no reference of your name will be made in the research report or when the study results are published. In order to protect secrecy, you will be assigned a numerical identifier. The data will be securely held in a highly protected facility, namely a lockable filing cabinet. The information you supplied will not be associated with your personal data or any other identifiable information.

The results of this study can be incorporated into a dissertation or disseminated in a scholarly periodical. Your identity will remain confidential in all of these products. All participants in this study will remain anonymous in any presentation or publication, with no mention of their names. Both electronic and physical copies will be eliminated within a span of five (5) years, following the release of the findings.

You are entitled to be informed about the findings of this study. I will communicate with you using the contact information you have provided to share the results with you.

Questions

If you have any inquiries or difficulties, please don't hesitate to reach out to Ms. W Pelser at 074 8872034 or the alternative office number at work, 011 6604342. The operating hours are from 07:00 to 16:00 from Monday to Thursday, and from 07:00 to 13:00 on Fridays. Alternatively, you can contact Prof J Maritz at maritje@unisa.ac.za.

The study has received approval from the Health Studied Ethics Committee (HSREC) HSHDC/943/2019, which is a department of the Department of Health. If you have any concerns regarding the research methodology, you may reach out to the Ethics Chair of the Department of Health Studies at HSREC@unisa.ac.za.

Signatures

I (first name & surname) _____ consent to participate in the study: “An inclusive clinical trial research education programme for investigators” to be conducted by Ms Wilma Pelser. I acknowledge and provide my approval that in the event of being chosen at random for an interview, the interview may be recorded via digital means. I acknowledge that my involvement in this study is optional and that I possess the autonomy to terminate the interview or the completion of any questionnaires at my discretion. I have the ability to decline answering any particular question. I will not receive any compensation for participating in the interview. I understand that the study's findings will be disseminated as a research paper, however it is important to note that no individuals' names will be included in any publications.

I have received a thorough explanation and discussion of the study's contents, including the information provided in this permission form. I have been granted permission to inquire and my inquiries have been responded to. I have been provided with Ms. Pelser's personal contact information (0748872034/ 011 6604342) in the event that I desire to communicate with her. I have received confirmation that the signed consent form will be securely stored and kept separate from the data I provided in the questionnaires. In the event that I am chosen for an interview, the interview itself, as well as any audio recordings, transcriptions, observations, and field notes, will not include any identifying information about me.

Signature research participant Print Name Date

I, _____, have deliberated on the aforementioned aspects with the participant. I am certain that the participant comprehends the risks, benefits, and responsibilities associated with participating in this study.

Signature Researcher Print Name Date

ANNEXURE L: Demographic and pre-questionnaires/pre-test/pre-assessment

Conceptual Questionnaire
Framework of Competence

Developed by:
Wilma Pelser

Updated: October 2019

Basic identifying information

Please complete your details below:

Name:
Signature:
Date:
To be completed by investigator:
Assigned assessment ID:

List of abbreviations

ABPI	Association of the British Pharmaceutical Industry
CQMP	Clinical Quality Management Plan
CRA	Clinical Research Associate
CRF	Case Report Form
CTM	Clinical Trial Management System
DMS	Data Management System
DSMB	Data Safety Monitoring Board
DSMP	Data and Safety Monitoring Plan
EMA	European Medicines Agency
ERB	Ethical Review Board
FDA	Food and Drug Administration
FH	Familial Hypercholesterolemia
GCP	Good Clinical Practice
HIV	Human Immunodeficiency Virus
HR	Human Resources
ICF	Informed Consent Form
IEC	Independent Ethics Committee
IP	Investigational Product
IRB	Institutional Review Board
MIMS	Monthly Index of Medical Specialities
MTA	Material Transfer Agreement
QMS	Quality Management System
PG	Pharmacogenetic
PI	Principal Investigator
SA	South Africa
SAHPRA	South African Health and Product Regulatory Agency
SOP	Standard Operating Procedures
TB	Tuberculosis

Glossary of terms

Clinical trials verses clinical research:

Clinical research encompasses all facets of scientific inquiry that involve human participants and facilitate the conversion of fundamental laboratory research into novel therapies and knowledge that can be advantageous to humans. Clinical trials are a subset of clinical research. Clinical trials are a specific form of clinical research that investigates the safety and effectiveness of new treatments intended for human use.

Clinical trials verses clinical studies:

Clinical trials are occasionally known as clinical studies. Clinical trials strictly pertain to clinical studies that involve medications and other interventions with the objective of decelerating or halting a disease. However, both phrases are sometimes used interchangeably.

Institutional review board:

An institutional review board (IRB), alternatively referred to as an independent ethics committee (IEC), ethical review board (ERB), or research ethics board (REB), is a committee that assesses the ethical aspects of research by scrutinising the planned research procedures to guarantee their adherence to ethical standards.

Investigator driven or initiated clinical trials:

Investigator-initiated clinical trials refer to clinical studies that are initiated and overseen by researchers who are not affiliated with pharmaceutical companies. These researchers can be individual investigators, institutions, collaborative study groups, or cooperative groupings. In such cases, the researcher assumes the legal and regulatory obligations of the trial sponsor in overseeing and administering the study, as stipulated by all relevant laws and regulations.

Investigational product:

An investigational product refers to a pharmaceutical form of either an active ingredient or a placebo. It is used in a clinical trial as a reference or for testing purposes. This includes a product that has been granted marketing authorization but is being used in a different way than what has been approved, or for an unapproved indication. It can also be used to gather additional information about an approved use.

Observational and interventional studies:

The two primary categories of clinical investigations are observational and interventional. An interventional study is a type of clinical trial that focuses on examining the effectiveness of a treatment strategy. The drug development pipeline mostly encompasses clinical studies.

Assigned assessment ID:_____

Demographic & Descriptive information

Please respond to the following questions by placing a "X" in the box next to the correct answer. Please enter only one "X" for each question, UNLESS otherwise specified.

1. Please select you gender

☐Female
☐Male
☐Other

2. 2. Kindly specify your age:

3. How long have you been working in clinical research?

_____ Years_____ Months

4. Have you had any specialised education or training in the field of clinical research or areas relevant to research? Please provide details exclusively about the education and/or training you received subsequent to obtaining your undergraduate degree. This encompasses all education and training received at medical school, including any additional sources, as well as any subsequent education and training beyond medical school.

   .☐ Yes
   ☐ No (please continue to question 9)

5. If you responded affirmatively to Question 4, kindly provide the relevant origin of the research-oriented education you obtained.

   ☐I have obtained specialised education or training in clinical research or research-related subjects as part of my medical school curriculum.

   ☐ Although I did not acquire clinical research or research-related education or training during my time in medical school, I obtained it from an alternative source.

   ☐ I got specific education or training in clinical research or research-related areas following medical school from an outside source.

   ☐ I obtained specialised education or training in clinical research or research-related subjects through an internship or fellowship following my completion of medical school.

   ☐ I have obtained specialised education or training in clinical research or research-related subjects during another residency training programme.

   ☐ Other: (Please provide other details)

   _____

_____

6. If you responded affirmatively to Question 4, please choose the appropriate option below.

☐ The education or training I got in clinical research or research-related areas was compulsory.

☐ The education or training I received in clinical research or research-related issues was optional.

7. If you responded affirmatively to Question 4, kindly choose the suitable option to accurately characterise the length of the research training you got.

☐ Less than 1 week

☐ Between 1 week and 1 month

☐ Between 1 month and 3 months

☐ 3 months to under 6 months

☐ 6 months to under 1 year

☐ 1 year to under 2 years

8. If you responded affirmatively to Question 4, kindly choose the suitable response(s) to accurately complete the following statement, which pertains to the subjects of specific research education or training you have undergone. Please indicate all the topics on which you have received education or training. You have the option to choose several responses for this question if necessary.☐ I received specific education or training in clinical research or research - related courses in the following topics:

☐Fundamental research concepts and terminology such as randomization, blinding, and psychometric principles.

☐ Investigate the design and sample methods used in research studies, including descriptive, cohort, quantitative and qualitative approaches, as well as intervention studies, pharmacological studies, and experimental designs.

☐ Investigate the ethical considerations, privacy concerns, and responsible practices in conducting studies (such as obtaining informed permission, fulfilling investigator responsibilities, managing conflicts of interest, etc.)

☐ Fundamental regulatory prerequisites (creation of protocols, reporting and documentation of adverse events, regulatory bodies, Institutional Review Boards, SAHPRA)

☐ Investigate contracts, budgets, and invoices connected to research activities.

☐ Conduct research on several aspects of career growth, including selecting mentors, acquiring financing, improving scientific writing skills, enhancing presentation abilities, and increasing publication opportunities.

☐ Other: (Please provide other details) _____

9. Please indicate the statements that most accurately depict your intended professional aspirations. You are allowed to choose multiple statements.
   ☐ I have not decided at this time whether or not I plan to make clinical research part of my future career plans

   ☐ At this stage I use clinical research as a stepping-stone in my career journey

   ☐ I plan to extend my clinical research knowledge and skills through courses, training programmes and working at highly recommended clinical research facilities even if it means that I have to move to a foreign country for a while

   ☐ I plan to be a competent sub-investigator but I am not interested in becoming a principal investigator

   ☐ I plan to move fast from being a sub-investigator to becoming a principal investigator

   ☐ I plan to open my own clinical research facility

   ☐ I plan to work at an academic institution to advance clinical research knowledge and skills

   ☐ I plan to work as an investigator in clinical research but also teach at an academic institution

   ☐ I plan to publish

   ☐ Other: (Please describe)

   _____

_____

_____

Pre-Course Self-Assessment

Please indicate your level of knowledge or competency for each of the following assertions by inserting an X in the corresponding box that best reflects your expertise with the given ideas.

		1 Not knowing	2 Knows	3 Know How	4 Show How	5 Does
1	Correctly define clinical trial-related terminology					
2	Manage a participant with adverse events according to the protocol (include grading of the adverse event)					
3	Determine possible conflicts of interest in clinical research.					
4	Determine the essential elements of study informed consent paperwork.					
5	Adhere to the prescribed procedures for documenting adverse events associated with clinical trials.					
6	Follow the specified protocols for recording negative occurrences linked to clinical studies.					
7	The fundamental components of a clinical trial protocol can be identified.					
8	Ascertain the appropriate time to terminate a clinical experiment by means of the Institutional Review Board (IRB).					
9	Adhere to the prescribed procedures for incorporating study personnel into a clinical trial.					
10	Adhere to the prescribed procedures for eliminating study personnel from a research trial					

		1 Not knowing	2 Knows	3 Know How	4 Show How	5 Does
11	Correctly define who the sponsors and who the stakeholders are for a clinical trial					
12	Identify the essential documents that should be part of the regulatory or investigator file during the lifecycle of the clinical trial (before, during, after)					
13	Develop a manual of procedures (MOP) to ensure smooth running and successful completion of the clinical trial					
14	Correctly describe the different roles and responsibilities of each team member on the clinical trial					
15	Analyse a proposed protocol to determine if the clinical trial will be suitable for your site (feasibility study)					
16	Complete an application for approval for the clinical trial to the regulatory authorities (IRB/SAHPRA)					
17	Set up a clinical trial team for a new study					
18	Prepare site files for a new clinical trial					
19	Prepare source documentation for a clinical trial					
20	Set up a data management system programme to capture all relevant participant and trial information					

		1 Not knowing	2 Knows	3 Know How	4 Show How	5 Does
21	Negotiate the budget or funding for a clinical trial with the sponsor					
22	Describe the different regulatory authorities in South Africa (IRB/SAHPRA/NHREC/SA National Clinical Trails Register)					
23	Complete progress reports to sponsors and regulatory authorities (IRB/SAHPRA)					
24	Apply for an export permit for biological samples					
25	Prepare a material transfer agreement (MTA)					
26	Review and evaluate an informed consent before presenting it to the IRB for approval					
27	Review and evaluate an assent form for paediatric studies before presenting it to the IRB for approval					
28	Plan for participant recruitment for the clinical trial					
29	Plan for participant retention for the clinical trial					
30	Project participant recruitment to successfully complete recruitment during the recruitment period allowed for the clinical trial					

		1 Not knowing	2 Knows	3 Know How	4 Show How	5 Does
31	Make use of a Gantt chart to track trial start-up timelines as well as trial progress (project management)					
32	Prepare for a site initiation visit					
33	Screen a participant according to the inclusion and exclusion criteria of the protocol to determine if the participant is eligible for the clinical trial					
34	Randomise or enrol a participant on a clinical trial					
35	Evaluate clinic flow and make the necessary changes for improvement					
36	Complete source documentation for a participant					
37	Develop a clinical quality management plan (CQMP)					
38	Prepare for trial end and trial close-out					
39	Prepare for an audit or inspection from the sponsor or the FDA/EMEA/SAHPRA					
40	Prepare dissemination of trial results					

Pre-Course Marked Assessment

For each of the following assessment items, please select the most appropriate answer, and mark this on the answer sheet.
There are **8** sections to complete.

Section 1: Scientific Concepts and Research Design

The following questions are related to the Design and Planning of a clinical trial and cover:

- Health related knowledge
- Research Methodology
- Developing a protocol
- Attracting funding

1. You are employed at a clinical research unit and the principal investigator is busy developing an investigator driven/initiated study that will treat children between the ages of one and 14years with a TB preventative investigational product. Having worked in a paediatric ward for five years the PI asked you to write the section of the protocol that will describe the management of children who might contract TB while on the study despite the preventative treatment. Your immediate reaction is:
    a. I don't know anything about protocol writing but because I have extensive experience with children I will give it a good try
    b. Working with children might come easily but I have treated very few children with TB. I first need to familiarise myself with TB in children before I can write the section
    c. I need to find a mentor who can guide me through the process
    d. I have written a protocol during my post graduate studies and I feel confident that this will be easy
    e. I know children, I know TB, how difficult can it be?

2. One of the studies you are employed to work on is a Phase II clinical trial with a new investigational product (IP) for diabetes. One of the primary purposes of the Phase II study is to:
    a. Demonstrate long-term safety and efficacy
    b. Gather information on additional indications for the IP
    c. Demonstrate efficacy within the established safe dose range
    d. Familiarise physicians with the drug

3. The title of the protocol can give you important information about the clinical trial but will not include:
    a. The name of the principal investigator
    b. The purpose of the research
    c. The scope of the research
    d. The method and design used to study the problem
    e. The kind of participants that will be included

4. When writing the protocol, which of the following will you NOT include:
    a. A description of the objectives and purpose of the study
    b. The inclusions and exclusion criteria for study participants
    c. The design of the study
    d. The amount of the grant per participant
    e. The investigator’s responsibilities

5. Your PI is interested in doing a sub-study as part of a main clinical trial and asked you to look for possible funding for the sub-study. Which one of the following points is not crucial for what you need to do?
    a. Have an understanding of major funding bodies, and that application requirements vary from one to another

b. Have previous experience in writing a grant
c. Understand the component parts of a grant application process
d. Plan costings and resources for a grant application
e. Independently write or contribute to grant application
f. Seek to address funders' interests by developing original grants

The following questions are related to the interpretation of study results and cover:

- Analysing data
- Disseminating research findings

6. Data analysis of the clinical trial will be done according to the data analysis plan described in the protocol and in most cases would involve a statistician:
    a. True
    b. False

7. The most suitable option for disseminating the results of your clinical trial to your participants is:
    a. Scientific Publication
    b. Presenting at a conference
    c. Calling participants back to your site for a dissemination meeting/event
    d. Written report
    e. Social media

The following questions are related to protocol deviation/violation identification

8. A modification to a research study protocol that occurs without prior approval and is unintentional or accidental, but does not pose an increased risk or significantly affect the rights, safety, welfare of research subjects, or the integrity of the data, is commonly known as:
    a. Protocol contention
    b. Protocol violation
    c. Protocol deficiency
    d. Protocol variance
    e. Protocol deviation

9. An unapproved modification to a research study protocol that has the potential to pose a higher risk to the rights, safety, or welfare of research subjects, or to compromise the integrity of the data, is commonly known as:
    f. Protocol contention
    g. Protocol violation
    h. Protocol deficiency
    i. Protocol variance
    j. Protocol deviation

Section 2. Ethical and Participant Safety considerations

The following questions are related to Safeguards for participant protection and cover:

- Ethics and human subject protection
- Risk and safety management
- Determining liability and insurance needs
- Planning recruitment strategies
- Planning retention strategies

1. What is an essential element of the research participant consent?
    a. The participant will be given a consent form that has been signed by the researcher.
    b. The participant will only receive the study results during the exit visit.
    c. Participation in the research study is voluntary only if a placebo is administered.
    d. The patient must continue to participate in the study until data from the final visit has been collected.

3. In your new clinical research, it is necessary to collect blood samples from study participants when they have not eaten and before they take their daily prescriptions. The possible research volunteer has a scheduled clinic appointment at 9am on Tuesday. When contacting the patient on Monday, inform them about the research study and schedule a review of the informed consent form during their clinic visit on Tuesday morning. However, refrain from
    a. Discuss the inclusion and exclusion criteria with them on the phone
    b. Tell them to remind you to mention the research study during their visit
    c. Ask them to withhold their morning medications for the research study blood draw
    d. Tell them they may bring someone to the visit with them if they wish

4. A research participant in your randomised, controlled clinical trial of a new investigational oral medication for multiple sclerosis has suffered a seizure. This participant has no history of seizures. According to the investigator brochure, seizures are a side effect of this medication. You should:
    a. Record the seizure in the research participant's source document
    b. Record the seizure in the research participant's source document and immediately report the seizure to the Ethics committee and SAHPRA by calling or emailing them
    c. Record the seizure in the research participant's source document and then report it to the sponsor by completing the CRF and to Ethics and SAHPRA on the 6 monthly progress report
    d. Not record or report the seizure as it is a common side effect of this medication

5. Potential reasons to discontinue a participant in a clinical trial are:
    a. The participant is not compliant with study procedures
    b. The participant has intolerable medical events or serious adverse events during treatment
    c. Pregnancy
    d. A and B above
    e. A, B and C above

6. Tracking results from samples taken from participants is very important for the following reasons:
    a. Sponsor would like to see that you have seen the result within a timeous manner
    b. Lab results reflect the safety and well-being of the participant while taking the IP
    c. Lab results outside the normal ranges need to be described in terms of clinically significant or not
    d. All of the above
    e. B and C

7. You are conducting a clinical trial that requires pharmacogenetic (PG) samples to be drawn. There is a delay with the ethics approval of these informed consent forms (ICF); however, the sponsor confirmed that the rest of the study can commence without this approval. You understand that your patients will not be able to take another day off work in order to come back for the PG samples once this ICF is approved. You thus instruct your study coordinator to draw the required sample from all participants and, if the participants later decide not to sign the consent form, you will instruct the laboratory to destroy the blood sample.
    Your instruction to the study coordinator was justifiable
    a. True
    b. False

8. In South Africa a participant who suffered a trial related injury will be compensated according to:
    a. ABPI guidelines
    b. FDA compensation guidelines
    c. Participant private insurance

d. Medical aid of participant

9. The following is Not important for your recruitment plan:
    a. Training of recruiters
    b. Ethics approval for using flyers
    c. An incentive for participants to come to your site
    d. A pre-screening log

10. Retention of participants is closely linked to satisfaction therefore you need to be very sensitive around:
    a. Consent signing
    b. Treating participants with respect
    c. Attention to factors such as transportation
    d. Conversations in the reception/waiting area
    e. All of the above
    f. A, B and C

The following questions are related to Clinical and Laboratory Operations and cover:

- Clinical care
- Participant privacy and confidentiality
- Performing laboratory assays

11. Doing a physical examination on your participant as part of the procedures for a study visit, you pick up a heart murmur. What decision will you make:
    a. Ask the participant to come back in two weeks' time
    b. Refer the participant to a cardiologist, before consulting your protocol
    c. Report it as an adverse event and leave it there
    d. Report it to the PI
    e. Consult your protocol, then refer participant according to the participant management section in protocol

12. In preparation for an investigator initiated/driven trial you are asked by the PI to liaise with the laboratory manager to draft laboratory requisition forms for the different visits. You will start the process by consulting:
    a. With the study coordinator
    b. The flow chart or schedule of events within the protocol
    c. The laboratory manual
    d. Previous used laboratory requisition forms
    e. SOP on laboratory procedures

13. Safeguarding the confidentiality of your participant entails an individual exercising authority over the scope, timing, and conditions of disclosing one's physical, behavioural, and intellectual self to others
    a. True
    b. False

14. Confidentiality is the process of protecting an individual's privacy.
    a. True
    b. False

Section 3. Clinical Trial Operations

The following questions are related to Trial Oversight and cover:

- Initiating study
- Closing study
- Tracking study progress

1. Clinical trial or study initiation meetings typically take place either:
   a. At least two months before to the commencement of the study.
   b. Once the site has obtained all necessary research supplies (including investigational product), approvals, and is prepared to begin enrolling participants.
   c. Once the first two participants have been registered
   d. Prior to the investigator meeting
   e. At the sponsor's office

2. When preparing a budged for your clinical trial, what should you consider:
   a. The effort of the coordinator and PI
   b. The overhead of your organisation
   c. The procedures, such as sample analysis that will be done by another department
   d. All of the above
   e. None of the above

3. One of the most difficult aspects of conducting clinical trials is:
   f. Following the protocol
   g. Finding a good study coordinator
   h. Recruiting sufficient participants
   i. Working with the pharmacy
   j. Obtaining a grant large enough to cover the study

The following questions are related to Protocol Operationalisation and cover:

- Developing study plans and documents
- Developing the quality management system (QMS)
- And standard operating procedures (SOPs)
- Developing case report form(s) (CRF) and data management systems (DMS)

4. During your basic GCP course you have learnt that a source document is any document where:
   a. Lab values are shown
   b. Ethics authorisation was received
   c. Data are first recorded
   d. A participant's name is shown
   e. Sponsor access to the document is not allowed

5. You have been asked to be part of a sub-committee to develop a data and safety monitoring plan (DSMP). Which of the following will you NOT consider:
   a. Participant safety
   b. Data integrity
   c. Participant privacy
   d. Key quality indicators
   e. Product accountability

6. Quality Assurance and Quality Control activities are outlined within your clinical quality management plan (CQMP). Some of the basic elements of a CQMP include:
   a. Responsibilities (who, when)
   b. Key indicators
   c. Quality management activities

d. Tools
e. All of the above
f. A and C

7. The SOPs you have been given to read during your first week at your site are essential for:
    a. Standardising processes
    b. Ensuring that regulatory requirements are met
    c. Training new personnel
    d. Managing workload
    e. All the above

8. After a Data and Safety Monitoring Board (DSMB) meeting it is not necessary to:
    a. Notify Ethics and SAHPRA about the DSMB meeting
    b. Notify participants about the outcome of the meeting
    c. Retrain staff on reporting of adverse events

The following questions are related to Quality Assurance and cover:

- Good clinical practice
- Working as per quality management system
- Controlling quality of research (monitoring)

9. GCP, or Good Clinical Practice, is an internationally recognised set of standards that ensures the proper design, execution, monitoring, and reporting of clinical trials. It serves to guarantee quality and protect the participants involved in the research. "GCP" is an acronym that stands for:
    a. General Clinical Procedures
    b. Efficient Coordination Practice
    c. Ethical Clinical Practice
    d. General Coordination Procedures

9. Quality control as part of quality management involves:
    a. Ongoing daily activities – “checking” of data. Is typically 100%
    b. Is ongoing and concurrent
    c. All of the above
    d. None of above

10. There are two main reasons that a sponsor might audit a clinical trial site. They are:
    a. The IRB has requested a sponsor audit
    b. To ensure that the site is complying with the regulations and protocol
    c. There is evidence that the site is out of compliance and the sponsor want to verify whether or not this is true
    d. A and B above
    e. B and C above

11. Which of the following is NOT one of the purposes of an FDA study-related or investigator-related inspection
    a. To determine the validity of the data
    b. To determine the integrity of the data
    c. To determine that the IP was properly manufactured
    d. To assess adherence to regulations and guidelines
    e. To determine that the rights and safety of participants were properly protected

12. The following documents are not subject to inspection during an FDA or EMA inspection:

a. Contracts
b. Budgets
c. Signed informed consent forms
d. All of the above
e. A and B

13. In preparation for a visit from the monitor or clinical research associate (CRA) you will not review:
    a. Your budget
    b. Investigator site files
    c. Drug accountability logs
    d. Recruitment rates
    e. Signed Informed consent forms

The following questions are related to Regulations and governance and cover:

- Securing or maintaining approvals
- Securing or maintaining contracts
- Governance and organisational context
- Research regulations

14. As investigator you must obtain IRB (Ethics and SAPHRA when necessary) approval of the clinical protocol (trial) and the consent form:
    a. Before the study has been completed
    b. Before enrolling any participants in the study
    c. Before receiving any grant or sponsor money for the study
    d. Within one month of starting the study
    e. Before the first participant has completed the study

15. You plan to use advertisements in local newspapers to recruit participants for your study. The advertisement:
    a. Must be submitted to the IRB and approved before it can be used
    b. Can be used as long as the IRB has approved a similar ad in the past
    c. Must be submitted to the IRB for information, but is not approved
    d. Must come from the sponsor, since the sponsor pays for it
    e. Must be submitted before the study can start

16. Dr Jensen is concerned that she is not meeting her recruitment target and decides to post an advert on the research unit's Facebook page looking for interested participants:

Do you have diabetes? If so, you may be eligible to participate in a clinical trial for a promising new drug for the treatment of diabetes. By participating in this trial, you will receive the following benefits:

- *Free medication*
- *Free medical examinations by a qualified doctor*
- *Free laboratory investigations*
- *Free refreshments at all visits*
- *Reimbursement of travel cost to and from the hospital*

Will your IRB approve Dr Jensen's ad?

    a. Yes
    b. No

17. Which statement is NOT relevant to the material transfer agreement (MTA):

a. Need to be signed by the PI of the clinical trial
b. Need to use the MTA template provided by SAHPRA
c. The MTA is a legal document
d. The MTA in not part of the application and can be forwarded to the IRB and SAHPRA during the conduct of the study
e. The MTA need to include the whole chain of custody

18. The staff member who is the "points" person to ensure smooth conduct and implementation of the protocol is:
    a. Sub-investigator
    b. Principal investigator
    c. Study coordinator
    d. Data manager
    e. Human Resources (HR) officer

Section 4: Study and Site Management

The following questions are related to:

- Study feasibility
- Project management

1. Some of the questions an investigator should ask when assessing protocol feasibility at their site include all the following **except**:
    a. Will the sponsor pay at least 30% of the grant in advance?
    b. Have we worked with this sponsor before and was the partnership successful?
    c. Is the number of participants to be enrolled realistic?
    d. Is the study scientifically sound?
    e. Is the Ethics committee apt to have problems with any aspects of this protocol?

2. As investigator you may have to juggle a number of people working on different tasks during a clinical trial project. Scheduling tools could be used very efficiently and include:
    a. Action Plans
    b. Gap Analysis
    c. Gantt Charts
    d. To-do-lists
    e. All of the above

3. Specialising before entering clinical research will benefit an investigator.
    a. True
    b. False

4. Project management involve the distinction between what is important and what is urgent. Urgent activities demand immediate attention and are usually associated with achieving someone else's goals.
    a. True
    b. False

5. The use of a clinical trial management system (CTM) to manage your project have numerous benefits. What is normally not included in a CTM:
    a. Recruitment and retention reports of participants
    b. Screening/enrolment reports
    c. Deadline and milestone reports
    d. Tracking study staff members

6. Clinic flow or participant visit flow is closely linked to retention. Improving the flow of work and eliminating waste ensures that the clinical site runs smoothly. One of the following wastes are NOT a common waste preventing the delivery of an efficient service:
    a. Overproduction
    b. Waiting
    c. Retraining
    d. Rework
    e. Transportation

The following questions are related to Interaction with public and study participants and cover:

- Engaging with the community
- Enrolling and retaining participants
- Supporting and advising throughout informed consent process

7. Working on a HIV preventative study you find it hard to recruit young women from the community. On investigating the problem, you discover that the partners of the young women are against the preventative treatment. What are your options:
    a. Tell the sponsor you are unable to recruit the required number of participants
    b. Send more recruiters into the community
    c. Invite the partners of the young women to the site to inform them about the trial
    d. Engage the community through the community advisory board to correct any misconceptions and to provide research training
    e. All of the above
    f. C and D

8. Peter (17 years old) has Familial Hypercholesterolemia (FH) and is eligible to participate in an FH clinical trial. He has been living with his aunt for the past 5 years because his mother passed away and his father is working overseas, with little contact with his son. The custody relationship is not formal or documented. Will Peter be able to be included in the trial?
    a. Yes
    b. No

9. Jane Cooke's parents have been contacted to come to the trial unit to discuss possible participation for Jane (7) on a clinical trial. Jane's parents are very interested but would like to know more about the trial and have agreed to the appointment. Her mother accompanies her to the trial unit. After hearing about the clinical trial, Jane decides that she does not want to participate even though her parents both give their informed consent. What is the way forward?
    a. Include Jane without her assent because her parents agreed, and she is a minor
    b. Exclude Jane because she did not give her assent to be part of the trial

The following questions are related to Staff Management and cover:

- Human Resources
- Creating or delivering training
- Supervising or mentoring

10. During recruitment of suitable staff, you can establish the foundation of an effective psychological contract by asking questions like these:
    a. What do you expect from me as your manager/supervisor/leader?
    b. What role do you see for yourself relative to the rest of your team?
    c. How does our organisation's culture fit with your values?
    d. Where do you see yourself within 10 years?
    e. All of the above

f. A, B and C

11. As investigator you do not need to be involved in staff training except for your own development and growth.
    a. True
    b. False

12. The Principal Investigator (PI) of a clinical trial must thoroughly examine the study protocol and determine the specific research responsibilities that will be delegated to each member of the research crew, taking into account their particular abilities, training, and education. This is commonly known as:
    a. Task assignment
    b. Delegation of authority
    c. Staff assignments
    d. Delegation of staff

The following questions are related to Resources Management and cover:

- Overseeing essential documents
- Logistics and facilities management
- Finances management

13. You have been asked to write a SOP on maintaining, storing and archiving of essential documents. Which of the following points will you NOT consider:
    a. Maintain security of documentation by controlling access
    b. Protect it physically from fire, water, and pests
    c. Protect is from participants
    d. Have it readily available for inspections or audits
    e. Update important documents as required

14. Looking at participants blood pressure measurements for the last week you noticed that all the measurements have increased with 10mmHg for the systolic and diastolic pressure. You suspect it could be due to:
    a. Blood pressure machine not being calibrated as required
    b. Participants being upset about something related to the trial
    c. Participants being from the same violent neighbourhood
    d. A new staff member who is not familiar with working the blood pressure machine

15. Reviewing the latest telephone bill for your department you noticed that the study nurse assigned to complete only case report forms has an amount of R800 for her part of the bill. The best way to address the problem will be to:
    a. Immediately have a conversation with the study nurse to find out what happened
    b. Get other staff members' opinion
    c. Send the study nurse to the HR for disciplinary action
    d. Remove the telephone from the study nurse's desk
    e. Subtract the R800 from the study nurse's salary without prior notice or conversation with her

Section 5. Investigational Product/Device Development and Regulation

The following questions are related to the Investigational Product and cover:

- Ensuring appropriate use of investigational products (IPs)
- Handling biomedical products
- Performing laboratory assays

1. In clinical trials where a pharmacy is used to store and distribute the study medicine to participants, the study drug is commonly referred to as "IP". What is the full form of "IP"?
    a. Investigational pharmaceuticals
    b. Inactive product
    c. Inactive pharmaceuticals
    d. Investigational product

2. A participant enrolled on the cancer trial you are involved in developed hypertension and you decide to prescribe medication to control the hypertension. Deciding which medication to prescribe you need to:
    a. Consult the protocol to see if there are any guidance on prohibited medication
    b. Consult your colleagues to determine what to prescribe
    c. Consult the MIMS
    d. Prescribe medication that you know previously worked well with hypertension patients

3. The clinical trial site where you are working consists of a main site and two satellite sites. One of the satellite sites do not have their own pharmacy and to overcome the problem you decide to ask the pharmacist in the main pharmacy to pack a container with all the IP, send the driver with the container to the satellite site to handover to the study-coordinator for dispensing to the participants. Will this be an acceptable solution:
    a. Yes
    b. No

4. Training of participants how to use the IP is the sole responsibility of the pharmacist who will be dispensing the IP
    a. True
    b. False

5. Drug adherence of participants could be done through
    a. Blood sample testing
    b. Counting remaining tablets that participant brought back at each visit
    c. Hair sample testing
    d. Saliva sample testing
    e. All of the above

Section 6. Data Management and informatics

The following questions are related to Data Flow and cover:

- Creating and maintaining a database
- Collecting accurate data
- Data management

1. Creating, maintaining and managing the data management system will assist you with:
    a. Planning and performing the trial
    b. Give you a reporting function
    c. Make participant demographic information easily available
    d. Track deadlines and milestones
    e. All of the above

2. As investigator you can rely on the study coordinator to complete the case report forms for a serious adverse event and to send it off to the sponsor within 24 hours.
    a. True
    b. False

3. You can respond to data queries when you have time as long as it gets done at some stage during the clinical trial.
    a. True
    b. False

4. Your data manager asked you to review the clinical data management plan (CDMP). One of the following will not be a heading within the CDMP:
    a. Database development
    b. CRF workflow
    c. Monitor access
    d. Data cleaning
    e. Database lock

5. Version control of essential documents is important for the following reason:
    a. The sponsor needs to approve the latest version
    b. It leaves an audit trail for auditors
    c. It looks professional
    d. It is prescribed by the SOP on essential documents

Section 7. Leadership and Professionalism

The following questions are related to:

- Strategic leadership
- Interpersonal skills
- Work ethic

1. "Leaders are people who do the right things; managers are people who do things right" Do you think as investigator:
    a. You are a leader?
    b. You are a manager?
    c. You are both?

2. Dealing with employee issues which of the following is not important:
    a. It is important to have up to date knowledge of the Labour Relations Act, basic company policies such as the Leave policy and procedures such as the Disciplinary Code
    b. Having monthly meetings with individual employees before their 6 monthly performance appraisal
    c. Keeping a list of all previous unacceptable performance issues to discuss them at the 6 monthly performance appraisals
    d. Keeping your criticism free of non-work-related matters when you have to address a performance or behavioural issue with an employee

3. When delegating tasks to team members on your study you need to keep the following in mind:
    a. The task needs to be within the person's scope of practice
    b. The team member had the necessary training to perform the task
    c. You need to complete the delegation log according to tasks delegated to specific team members
    d. All of the above
    e. Only c

4. You have been asked to serve as a scientific committee member on the Ethics committee that is affiliated to your clinical research institution. Attending your second meeting of the Ethics committee, you noticed that the breast cancer trial is on the agenda and you will be an investigator on the study. Which of the following statements is true given this scenario?

a. You keep quiet about the fact that you will be an investigator on the breast cancer trial
b. You pretend to feel ill and asked to be excused just before the item will be discussed
c. At the start of the meeting you declare your conflict of interest
d. You tell the person sitting to your left about your dilemma without telling the rest of the meeting

Section 8. Communication and Teamwork

The following questions are related to Study Communications and cover:

- Reporting
- Liaising or acting as a link
- Facilitating or attending meetings

1. Communication with team members and stakeholders will at times happen through reports. Select the option most unlikely to be in a report format:
   a. Data-fax report
   b. Data-clarification report
   c. Milestone reports
   d. Community communication
   e. Participant communication

2. Regular communication, interaction and liaison with stakeholders is important for the successful execution and completion of the trial. Who would you consider NOT a typical primary stakeholder:
   a. Trial participants
   b. Regulatory authorities and IRB
   c. Government officials
   d. South African Revenue Service
   e. Community Advisory Board

3. The purpose of a “stand-up” (10 minute) meeting is to report within a team:
   a. What they did yesterday
   b. What they plan to do today
   c. Brain storming an issue
   d. A and B
   e. B and C

4. Your strategic communication plan should summarise brief plans for the following:
   a. How your study will deal with controversy
   b. Dissemination of trial results
   c. Monitoring and evaluation of communication activities
   d. Approaches for communicating with stakeholders throughout the trial
   e. All of the above
   f. A, B and C

5. When planning communication with your community from which you are recruiting participants, the following are crucial:
   a. Your message should be culturally respectful and meaningful
   b. Who will be the best person to deliver the message
   c. What will be the best channel to use for delivering the message
   d. All of the above

Answer sheet

Section 1	A	B	C	D	E	F
1						
2						

3						
4						
5						
6						
7						
8						
9						
Section 2	**A**	**B**	**C**	**D**	**E**	**F**
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
Section 3	**A**	**B**	**C**	**D**	**E**	**F**
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
Section 4	**A**	**B**	**C**	**D**	**E**	**F**
1						
2						
3						
4						
5						
6						
7						
Section 4 cont.	**A**	**B**	**C**	**D**	**E**	**F**
8						
9						
10						
11						
12						
13						
14						

15						
Section 5	**A**	**B**	**C**	**D**	**E**	**F**
1						
2						
3						
4						
5						
Section 6	**A**	**B**	**C**	**D**	**E**	**F**
1						
2						
3						
4						
5						
Section 7	**A**	**B**	**C**	**D**	**E**	**F**
1						
2						
3						
4						
Section 8	**A**	**B**	**C**	**D**	**E**	**F**
1						
2						
3						
4						
5						

Section 1		/9	
Section 2		/13	
Section 3		/19	
Section 4		/15	
Section 5		/5	
Section 6		/5	
Section 7		/4	
Section 8		/5	
Total		**/75**	**%**

ANNEXURE M: Post-programme questionnaire/post-test/post-assessment

Assigned assessment ID:_____

Post-Course Self-Assessment

Please indicate your level of knowledge or competency for each of the following assertions by inserting an X in the corresponding box that best reflects your expertise with the given ideas.

		1 Not knowing	2 Knows	3 Know How	4 Show How	5 Does
1	Correctly define clinical trial-related terminology					
2	Manage a participant with adverse events according to the protocol (include grading of the adverse event)					
3	Determine possible conflicts of interest in clinical research.					
4	Enumerate the essential elements of study informed consent documents.					
5	Adhere to the prescribed procedures for reporting adverse events associated with clinical trials.					
6	Adhere to the appropriate protocols when carrying out a clinical trial at your institution or company.					
7	The fundamental components of a clinical trial protocol can be identified.					
8	Ascertain the appropriate time to terminate a clinical experiment via the Institutional Review Board (IRB).					
9	Adhere to the proper procedures for including study personnel into a clinical trial.					
10	Adhere to the prescribed procedures for eliminating study personnel from a clinical trial.					

		1 Not knowing	2 Knows	3 Know How	4 Show How	5 Does
11	Correctly define who the sponsors and who the stakeholders are for a clinical trial					
12	Identify the essential documents that should be part of the regulatory or investigator file during the lifecycle of the clinical trial (before, during, after)					
13	Develop a manual of procedures (MOP) to ensure smooth running and successful completion of the clinical trial					
14	Correctly describe the different roles and responsibilities of each team member on the clinical trial					
15	Analyse a proposed protocol to determine if the clinical trial will be suitable for your site (feasibility study)					
16	Complete an application for approval for the clinical trial to the regulatory authorities (IRB/SAHPRA)					
17	Set up a clinical trial team for a new study					
18	Prepare site files for a new clinical trial					
19	Prepare source documentation for a clinical trial					
20	Set up a data management system programme to capture all relevant participant and trial information					

		1 Not knowing	2 Knows	3 Know How	4 Show How	5 Does
21	Negotiate the budget or funding for a clinical trial with the sponsor					
22	Describe the different regulatory authorities in South Africa (IRB/SAHPRA/NHREC/SA National Clinical Trails Register)					
23	Complete progress reports to sponsors and regulatory authorities (IRB/SAHPRA)					
24	Apply for an export permit for biological samples					
25	Prepare a material transfer agreement (MTA)					
26	Review and evaluate an informed consent before presenting it to the IRB for approval					
27	Review and evaluate an assent form for paediatric studies before presenting it to the IRB for approval					
28	Plan for participant recruitment for the clinical trial					
29	Plan for participant retention for the clinical trial					
30	Project participant recruitment to successfully complete recruitment during the recruitment period allowed for the clinical trial					

		1 Not knowing	2 Knows	3 Know How	4 Show How	5 Does
31	Make use of a Gantt chart to track trial start-up timelines as well as trial progress (project management)					
32	Prepare for a site initiation visit					
33	Screen a participant according to the inclusion and exclusion criteria of the protocol to determine if the participant is eligible for the clinical trial					
34	Randomise or enrol a participant on a clinical trial					
35	Evaluate clinic flow and make the necessary changes for improvement					
36	Complete source documentation for a participant					
37	Develop a clinical quality management plan (CQMP)					
38	Prepare for trial end and trial close-out					
39	Prepare for an audit or inspection from the sponsor or the FDA/EMEA/SAHPRA					
40	Prepare dissemination of trial results					

Post-Course Marked Assessment

For each of the following assessment items, please select the most appropriate answer, and mark this on the answer sheet.
There are **8** sections to complete.

Section 1: Scientific Concepts and Research Design

The following questions are related to the Design and Planning of a clinical trial and cover:

- Health related knowledge
- Research Methodology
- Developing a protocol
- Attracting funding

1. You are employed at a clinical research unit and the principal investigator is busy developing an investigator driven/initiated study that will treat children between the ages of one and 14years with a TB preventative investigational product. Having worked in a paediatric ward for five years the PI asked you to write the section of the protocol that will describe the management of children who might contract TB while on the study despite the preventative treatment. Your immediate reaction is:
    a. I don't know anything about protocol writing but because I have extensive experience with children I will give it a good try
    b. Working with children might come easily but I have treated very few children with TB. I first need to familiarise myself with TB in children before I can write the section
    c. I need to find a mentor who can guide me through the process
    d. I have written a protocol during my post graduate studies and I feel confident that this will be easy
    e. I know children, I know TB, how difficult can it be?

2. One of the studies you are employed to work on is a Phase II clinical trial with a new investigational product (IP) for diabetes. One of the primary purposes of the Phase II study is to:
    a. Demonstrate long-term safety and efficacy
    b. Gather information on additional indications for the IP
    c. Demonstrate efficacy within the established safe dose range
    d. Familiarise physicians with the drug

3. The title of the protocol can give you important information about the clinical trial but will not include:
    a. The name of the principal investigator
    b. The purpose of the research
    c. The scope of the research
    d. The method and design used to study the problem
    e. The kind of participants that will be included

4. When writing the protocol, which of the following will you NOT include:
    a. A description of the objectives and purpose of the study
    b. The inclusions and exclusion criteria for study participants
    c. The design of the study
    d. The amount of the grant per participant
    e. The investigator’s responsibilities

5. Your PI is interested in doing a sub-study as part of a main clinical trial and asked you to look for possible funding for the sub-study. Which one of the following points is not crucial for what you need to do?
    a. Have an understanding of major funding bodies, and that application requirements vary from one to another

b. Have previous experience in writing a grant
c. Understand the component parts of a grant application process
d. Plan costings and resources for a grant application
e. Independently write or contribute to grant application
f. Seek to address funders' interests by developing original grants

The following questions are related to the interpretation of study results and cover:

- Analysing data
- Disseminating research findings

6. Data analysis of the clinical trial will be done according to the data analysis plan described in the protocol and in most cases would involve a statistician:
    a. True
    b. False

7. The most suitable option for disseminating the results of your clinical trial to your participants is:
    a. Scientific Publication
    b. Presenting at a conference
    c. Calling participants back to your site for a dissemination meeting/event
    d. Written report
    e. Social media

The following questions are related to protocol deviation/violation identification

8. A modification to a research study protocol that occurs without prior approval and is unintentional or accidental, but does not pose an increased risk or significantly affect the rights, safety, welfare of research subjects, or the integrity of the data, is commonly known as:
    a. Protocol contention
    b. Protocol violation
    c. Protocol deficiency
    d. Protocol variance
    e. Protocol deviation

9. An unapproved modification to a research study protocol that has the potential to pose a higher risk to the rights, safety, or welfare of research subjects, or to compromise the integrity of the data, is commonly known as:
    f. Protocol contention
    g. Protocol violation
    h. Protocol deficiency
    i. Protocol variance
    j. Protocol deviation

Section 2. Ethical and Participant Safety considerations

The following questions are related to Safeguards for participant protection and cover:

- Ethics and human subject protection
- Risk and safety management
- Determining liability and insurance needs
- Planning recruitment strategies
- Planning retention strategies

1. What is an essential element of the research participant consent?

a. The participant will be given a consent form that has been signed by the researcher.
b. The participant will only receive the study results during the exit visit.
c. Participation in the research study is voluntary only if a placebo is administered.
d. The patient must continue to participate in the study until data from the final visit has been collected.

1. In your new clinical research, it is necessary to collect blood samples from study participants when they have not eaten and before they take their daily prescriptions. The possible research volunteer has a scheduled clinic appointment at 9am on Tuesday. When contacting the patient on Monday, inform them about the research study and schedule a review of the informed consent form during their clinic visit on Tuesday morning. However, refrain from
    a. Discuss the inclusion and exclusion criteria with them on the phone
    b. Tell them to remind you to mention the research study during their visit
    c. Ask them to withhold their morning medications for the research study blood draw
    d. Tell them they may bring someone to the visit with them if they wish

2. A research participant in your randomised, controlled clinical trial of a new investigational oral medication for multiple sclerosis has suffered a seizure. This participant has no history of seizures. According to the investigator brochure, seizures are a side effect of this medication. You should:
    a. Record the seizure in the research participant's source document
    b. Record the seizure in the research participant's source document and immediately report the seizure to the Ethics committee and SAHPRA by calling or emailing them
    c. Record the seizure in the research participant's source document and then report it to the sponsor by completing the CRF and to Ethics and SAHPRA on the 6 monthly progress report
    d. Not record or report the seizure as it is a common side effect of this medication

3. Potential reasons to discontinue a participant in a clinical trial are:
    a. The participant is not compliant with study procedures
    b. The participant has intolerable medical events or serious adverse events during treatment
    c. Pregnancy
    d. A and B above
    e. A, B and B above

4. Tracking results from samples taken from participants is very important for the following reasons:
    a. Sponsor would like to see that you have seen the result within a timeous manner
    b. Lab results reflect the safety and well-being of the participant while taking the IP
    c. Lab results outside the normal ranges need to be described in terms of clinically significant or not
    d. All of the above
    e. B and C

5. You are conducting a clinical trial that requires pharmacogenetic (PG) samples to be drawn. There is a delay with the ethics approval of these informed consent forms (ICF); however, the sponsor confirmed that the rest of the study can commence without this approval. You understand that your patients will not be able to take another day off work in order to come back for the PG samples once this ICF is approved. You thus instruct your study coordinator to draw the required sample from all participants and, if the participants later decide not to sign the consent form, you will instruct the laboratory to destroy the blood sample.
Your instruction to the study coordinator was justifiable
    a. True
    b. False

6. In South Africa a participant who suffered a trial related injury will be compensated according to:
    a. ABPI guidelines
    b. FDA compensation guidelines
    c. Participant private insurance
    d. Medical aid of participant

7. The following is Not important for your recruitment plan:
    a. Training of recruiters
    b. Ethics approval for using flyers
    c. An incentive for participants to come to your site
    d. A pre-screening log

8. Retention of participants is closely linked to satisfaction therefore you need to be very sensitive around:
    a. Consent signing
    b. Treating participants with respect
    c. Attention to factors such as transportation
    d. Conversations in the reception/waiting area
    e. All of the above
    f. A, B and C

The following questions are related to Clinical and Laboratory Operations and cover:

- Clinical care
- Participant privacy and confidentiality
- Performing laboratory assays

9. Doing a physical examination on your participant as part of the procedures for a study visit, you pick up a heart murmur. What decision will you make:
    a. Ask the participant to come back in two weeks' time
    b. Refer the participant to a cardiologist, before consulting your protocol
    c. Report it as an adverse event and leave it there
    d. Report it to the PI
    e. Consult your protocol, then refer participant according to the participant management section in protocol

10. In preparation for an investigator initiated/driven trial you are asked by the PI to liaise with the laboratory manager to draft laboratory requisition forms for the different visits. You will start the process by consulting:
    a. With the study coordinator
    b. The flow chart or schedule of events within the protocol
    c. The laboratory manual
    d. Previous used laboratory requisition forms
    e. SOP on laboratory procedures

11. Safeguarding the confidentiality of your participant entails an individual exercising authority over the scope, timing, and conditions of disclosing one's physical, behavioural, and intellectual self to others.
    a. True
    b. False

12. Confidentiality is the process of protecting an individual's privacy.
    a. True
    b. False

Section 3. Clinical Trial Operations

The following questions are related to Trial Oversight and cover:

- Initiating study
- Closing study
- Tracking study progress

1. Clinical trial or study initiation meetings typically take place either:
   a. At least two months before to the commencement of the study.
   b. Once the site has obtained all necessary research supplies (including investigational product), approvals, and is prepared to begin enrolling participants.
   c. Once the first two participants have been registered
   d. Prior to the investigator meeting
   e. At the sponsor's office

2. The most common reason for a clinical trial to be closed at a site is:
   a. The clinical trial is complete
   b. The IP was found to be ineffective
   c. There were safety problems with the IP
   d. Lack of enrolment
   e. Falsification of data

3. One of the most difficult aspects of conducting clinical trials is:
   a. Following the protocol
   b. Finding a good study coordinator
   c. Recruiting sufficient participants
   d. Working with the pharmacy
   e. Obtaining a grant large enough to cover the study

The following questions are related to Protocol Operationalisation and cover:

- Developing study plans and documents
- Developing the quality management system (QMS)
- And standard operating procedures (SOPs)
- Developing case report form(s) (CRF) and data management systems (DMS)

4. During your basic GCP course you have learnt that a source document is any document where:
   a. Lab values are shown
   b. Ethics authorisation was received
   c. Data are first recorded
   d. A participant's name is shown
   e. Sponsor access to the document is not allowed

5. You have been asked to be part of a sub-committee to develop a data and safety monitoring plan (DSMP). Which of the following will you NOT consider:
   a. Participant safety
   b. Data integrity
   c. Participant privacy

d. Key quality indicators
e. Product accountability

6. Quality Assurance and Quality Control activities are outlined within your clinical quality management plan (CQMP). Some of the basic elements of a CQMP include:
    a. Responsibilities (who, when)
    b. Key indicators
    c. Quality management activities
    d. Tools
    e. All of the above
    f. A and C

7. The SOPs you have been given to read during your first week at your site are essential for:
    a. Standardising processes
    b. Ensuring that regulatory requirements are met
    c. Training new personnel
    d. Managing workload
    e. All the above

8. After a Data and Safety Monitoring Board (DSMB) meeting it is not necessary to:
    a. Notify Ethics and SAHPRA about the DSMB meeting
    b. Notify participants about the outcome of the meeting
    c. Retrain staff on reporting of adverse events

The following questions are related to Quality Assurance and cover:

- Good clinical practice
- Working as per quality management system
- Controlling quality of research (monitoring)

9. GCP, or Good Clinical Practice, is an internationally recognised set of standards that ensures the proper design, execution, monitoring, and reporting of clinical trials. It serves to guarantee quality and protect the participants involved in the research. "GCP" is an acronym that stands for:
    a. General Clinical Procedures
    b. Efficient Coordination Practice
    c. Ethical Clinical Practice
    d. General Coordination Procedures

9. Quality control as part of quality management involves:
    a. Ongoing daily activities – “checking” of data. Is typically 100%
    b. Is ongoing and concurrent
    c. All of the above
    d. None of above

10. There are two main reasons that a sponsor might audit a clinical trial site. They are:
    a. The IRB has requested a sponsor audit
    b. To ensure that the site is complying with the regulations and protocol
    c. There is evidence that the site is out of compliance and the sponsor want to verify whether or not this is true
    d. A and B above
    e. B and C above

11. Which of the following is NOT one of the purposes of an FDA study-related or investigator-related inspection
    a. To determine the validity of the data
    b. To determine the integrity of the data
    c. To determine that the IP was properly manufactured
    d. To assess adherence to regulations and guidelines
    e. To determine that the rights and safety of participants were properly protected

12. The following documents are not subject to inspection during an FDA or EMA inspection:
    a. Contracts
    b. Budgets
    c. Signed informed consent forms
    d. All of the above
    e. A and B

13. In preparation for a visit from the monitor or clinical research associate (CRA) you will not review:
    a. Your budget
    b. Investigator site files
    c. Drug accountability logs
    d. Recruitment rates
    e. Signed Informed consent forms

The following questions are related to Regulations and governance and cover:

- Securing or maintaining approvals
- Securing or maintaining contracts
- Governance and organisational context
- Research regulations

14. As investigator you must obtain IRB (Ethics and SAPHRA when necessary) approval of the clinical protocol (trial) and the consent form:
    a. Before the study has been completed
    b. Before enrolling any participants in the study
    c. Before receiving any grant or sponsor money for the study
    d. Within one month of starting the study
    e. Before the first participant has completed the study

15. You plan to use advertisements in local newspapers to recruit participants for your study. The advertisement:
    a. Must be submitted to the IRB and approved before it can be used
    b. Can be used as long as the IRB has approved a similar ad in the past
    c. Must be submitted to the IRB for information, but is not approved
    d. Must come from the sponsor, since the sponsor pays for it
    e. Must be submitted before the study can start

16. Dr Jensen is concerned that she is not meeting her recruitment target and decides to post an advert on the research unit's Facebook page looking for interested participants:

Do you have diabetes? If so, you may be eligible to participate in a clinical trial for a promising new drug for the treatment of diabetes. By participating in this trial, you will receive the following benefits:

- *Free medication*
- *Free medical examinations by a qualified doctor*
- *Free laboratory investigations*
- *Free refreshments at all visits*

- *Reimbursement of travel cost to and from the hospital*

Will your IRB approve Dr Jensen's ad?

a. Yes
b. No

17. Which statement is NOT relevant to the material transfer agreement (MTA):
    a. Need to be signed by the PI of the clinical trial
    b. Need to use the MTA template provided by SAHPRA
    c. The MTA is a legal document
    d. The MTA in not part of the application and can be forwarded to the IRB and SAHPRA during the conduct of the study
    e. The MTA need to include the whole chain of custody

18. The staff member who is the "points" person to ensure smooth conduct and implementation of the protocol is:
    a. Sub-investigator
    b. Principal investigator
    c. Study coordinator
    d. Data manager
    e. Human Resources (HR) officer

Section 4: Study and Site Management

The following questions are related to:

- Study feasibility
- Project management

1. Some of the questions an investigator should ask when assessing protocol feasibility at their site include all the following **except**:
    a. Will the sponsor pay at least 30% of the grant in advance?
    b. Have we worked with this sponsor before and was the partnership successful?
    c. Is the number of participants to be enrolled realistic?
    d. Is the study scientifically sound?
    e. Is the Ethics committee apt to have problems with any aspects of this protocol?

2. As investigator you may have to juggle a number of people working on different tasks during a clinical trial project. Scheduling tools could be used very efficiently and include:
    a. Action Plans
    b. Gap Analysis
    c. Gantt Charts
    d. To-do-lists
    e. All of the above

3. Specialising before entering clinical research will benefit an investigator.
    a. True
    b. False

4. Project management involve the distinction between what is important and what is urgent. Urgent activities demand immediate attention and are usually associated with achieving someone else's goals.
    a. True
    b. False

5. The use of a clinical trial management system (CTM) to manage your project have numerous benefits. What is normally not included in a CTM:
    a. Recruitment and retention reports of participants
    b. Screening/enrolment reports
    c. Deadline and milestone reports
    d. Tracking study staff members

6. Clinic flow or participant visit flow is closely linked to retention. Improving the flow of work and eliminating waste ensures that the clinical site runs smoothly. One of the following wastes are NOT a common waste preventing the delivery of an efficient service:
    a. Overproduction
    b. Waiting
    c. Retraining
    d. Rework
    e. Transportation

The following questions are related to Interaction with public and study participants and cover:

- Engaging with the community
- Enrolling and retaining participants
- Supporting and advising throughout informed consent process

7. Working on a HIV preventative study you find it hard to recruit young women from the community. On investigating the problem, you discover that the partners of the young women are against the preventative treatment. What are your options:
    a. Tell the sponsor you are unable to recruit the required number of participants
    b. Send more recruiters into the community
    c. Invite the partners of the young women to the site to inform them about the trial
    d. Engage the community through the community advisory board to correct any misconceptions and to provide research training
    e. All of the above
    f. C and D

8. Peter (17 years old) has Familial Hypercholesterolemia (FH) and is eligible to participate in an FH clinical trial. He has been living with his aunt for the past 5 years because his mother passed away and his father is working overseas, with little contact with his son. The custody relationship is not formal or documented. Will Peter be able to be included in the trial?
    a. Yes
    b. No

9. Jane Cooke's parents have been contacted to come to the trial unit to discuss possible participation for Jane (7) on a clinical trial. Jane's parents are very interested but would like to know more about the trial and have agreed to the appointment. Her mother accompanies her to the trial unit. After hearing about the clinical trial, Jane decides that she does not want to participate even though her parents both give their informed consent. What is the way forward?
    a. Include Jane without her assent because her parents agreed, and she is a minor
    b. Exclude Jane because she did not give her assent to be part of the trial

The following questions are related to Staff Management and cover:

- Human Resources
- Creating or delivering training
- Supervising or mentoring

10. During recruitment of suitable staff, you can establish the foundation of an effective psychological contract by asking questions like these:
    a. What do you expect from me as your manager/supervisor/leader?
    b. What role do you see for yourself relative to the rest of your team?
    c. How does our organisation's culture fit with your values?
    d. Where do you see yourself within 10 years?
    e. All of the above
    f. A, B and C

11. As investigator you do not need to be involved in staff training except for your own development and growth.
    a. True
    b. False

12. The Principal Investigator (PI) of a clinical trial must thoroughly examine the study protocol and determine the specific research responsibilities that will be delegated to each member of the research crew, taking into account their particular abilities, training, and education. This is commonly known as:
    a. Task assignment
    b. Delegation of authority
    c. Staff assignments
    d. Delegation of staff

The following questions are related to Resources Management and cover:

- Overseeing essential documents
- Logistics and facilities management
- Finances management

13. You have been asked to write a SOP on maintaining, storing and archiving of essential documents. Which of the following points will you NOT consider:
    a. Maintain security of documentation by controlling access
    b. Protect it physically from fire, water, and pests
    c. Protect is from participants
    d. Have it readily available for inspections or audits
    e. Update important documents as required

14. Looking at participants blood pressure measurements for the last week you noticed that all the measurements have increased with 10mmHg for the systolic and diastolic pressure. You suspect it could be due to:
    a. Blood pressure machine not being calibrated as required
    b. Participants being upset about something related to the trial
    c. Participants being from the same violent neighbourhood
    d. A new staff member who is not familiar with working the blood pressure machine

15. Reviewing the latest telephone bill for your department you noticed that the study nurse assigned to complete only case report forms has an amount of R800 for her part of the bill. The best way to address the problem will be to:
    a. Immediately have a conversation with the study nurse to find out what happened
    b. Get other staff members' opinion
    c. Send the study nurse to the HR for disciplinary action
    d. Remove the telephone from the study nurse's desk
    e. Subtract the R800 from the study nurse's salary without prior notice or conversation with her

Section 5. Investigational Product/Device Development and Regulation

The following questions are related to the Investigational Product and cover:

- Ensuring appropriate use of investigational products (IPs)
- Handling biomedical products
- Performing laboratory assays

1. In clinical trials where a pharmacy is used to store and distribute the study medicine to participants, the study drug is commonly referred to as "IP". What is the full form of "IP"?
   a. Investigational pharmaceuticals
   b. Inactive product
   c. Inactive pharmaceuticals
   d. Investigational product

2. A participant enrolled on the cancer trial you are involved in developed hypertension and you decide to prescribe medication to control the hypertension. Deciding which medication to prescribe you need to:
   1. Consult the protocol to see if there are any guidance on prohibited medication
   2. Consult your colleagues to determine what to prescribe
   3. Consult the MIMS
   4. Prescribe medication that you know previously worked well with hypertension patients

3. The clinical trial site where you are working consists of a main site and two satellite sites. One of the satellite sites do not have their own pharmacy and to overcome the problem you decide to ask the pharmacist in the main pharmacy to pack a container with all the IP, send the driver with the container to the satellite site to handover to the study-coordinator for dispensing to the participants. Will this be an acceptable solution:
   1. Yes
   2. No

4. Training of participants how to use the IP is the sole responsibility of the pharmacist who will be dispensing the IP
   1. True
   2. False

5. Drug adherence of participants could be done through
   a. Blood sample testing
   b. Counting remaining tablets that participant brought back at each visit
   c. Hair sample testing
   d. Saliva sample testing
   e. All of the above

Section 6. Data Management and informatics

The following questions are related to Data Flow and cover:

- Creating and maintaining a database
- Collecting accurate data
- Data management

1. Creating, maintaining and managing the data management system will assist you with:
   a. Planning and performing the trial
   b. Give you a reporting function
   c. Make participant demographic information easily available
   d. Track deadlines and milestones

e. All of the above

2. As investigator you can rely on the study coordinator to complete the case report forms for a serious adverse event and to send it off to the sponsor within 24 hours.
    a. True
    b. False

3. You can respond to data queries when you have time as long as it gets done at some stage during the clinical trial.
    a. True
    b. False

4. Your data manager asked you to review the clinical data management plan (CDMP). One of the following will not be a heading within the CDMP:
    a. Database development
    b. CRF workflow
    c. Monitor access
    d. Data cleaning
    e. Database lock

5. Version control of essential documents is important for the following reason:
    a. The sponsor needs to approve the latest version
    b. It leaves an audit trail for auditors
    c. It looks professional
    d. It is prescribed by the SOP on essential documents

Section 7. Leadership and Professionalism

The following questions are related to:

- Strategic leadership
- Interpersonal skills
- Work ethic

1. "Leaders are people who do the right things; managers are people who do things right" Do you think as investigator:
    a. You are a leader?
    b. You are a manager?
    c. You are both?

2. Dealing with employee issues which of the following is not important:
    a. It is important to have up to date knowledge of the Labour Relations Act, basic company policies such as the Leave policy and procedures such as the Disciplinary Code
    b. Having monthly meetings with individual employees before their 6 monthly performance appraisals
    c. Keeping a list of all previous unacceptable performance issues to discuss them at the 6 monthly performance appraisals
    d. Keeping your criticism free of non-work-related matters when you have to address a performance or behavioural issue with an employee

3. When delegating tasks to team members on your study you need to keep the following in mind:
    a. The task needs to be within the person's scope of practice
    b. The team member had the necessary training to perform the task
    c. You need to complete the delegation log according to tasks delegated to specific team members
    d. All of the above

e. Only c

4. You have been asked to serve as a scientific committee member on the Ethics committee that is affiliated to your clinical research institution. Attending your second meeting of the Ethics committee, you noticed that the breast cancer trial is on the agenda and you will be an investigator on the study. Which of the following statements is true given this scenario?
    a. You keep quiet about the fact that you will be an investigator on the breast cancer trial
    b. You pretend to feel ill and asked to be excused just before the item will be discussed
    c. At the start of the meeting you declare your conflict of interest
    d. You tell the person sitting to your left about your dilemma without telling the rest of the meeting

Section 8. Communication and Teamwork

The following questions are related to Study Communications and cover:

- Reporting
- Liaising or acting as a link
- Facilitating or attending meetings

1. Communication with team members and stakeholders will at times happen through reports. Select the option most unlikely to be in a report format:
    a. Data-fax report
    b. Data-clarification report
    c. Milestone reports
    d. Community communication
    e. Participant communication

2. Regular communication, interaction and liaison with stakeholders is important for the successful execution and completion of the trial. Who would you consider NOT a typical primary stakeholder:
    a. Trial participants
    b. Regulatory authorities and IRB
    c. Government officials
    d. South African Revenue Service
    e. Community Advisory Board

3. The purpose of a “stand-up” (10 minute) meeting is to report within a team:
    a. What they did yesterday
    b. What they plan to do today
    c. Brain storming an issue
    d. A and B
    e. B and C

4. Your strategic communication plan should summarise brief plans for the following:
    a. How your study will deal with controversy
    b. Dissemination of trial results
    c. Monitoring and evaluation of communication activities
    d. Approaches for communicating with stakeholders throughout the trial
    e. All of the above
    f. A, B and C

5. When planning communication with your community from which you are recruiting participants, the following are crucial:
    a. Your message should be culturally respectful and meaningful
    b. Who will be the best person to deliver the message
    c. What will be the best channel to use for delivering the message

d. All of the above

Answer sheet

Section 1	A	B	C	D	E	F
1						
2						
3						
4						
5						
6						
7						
8						
9						
Section 2	**A**	**B**	**C**	**D**	**E**	**F**
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
Section 3	**A**	**B**	**C**	**D**	**E**	**F**
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
Section 4	**A**	**B**	**C**	**D**	**E**	**F**
1						
2						
3						
4						
5						
6						
7						

Section 4 cont.	A	B	C	D	E	F
8						
9						
10						
11						
12						
13						
14						
15						
Section 5	**A**	**B**	**C**	**D**	**E**	**F**
1						
2						
3						
4						
5						
Section 6	**A**	**B**	**C**	**D**	**E**	**F**
1						
2						
3						
4						
5						
Section 7	**A**	**B**	**C**	**D**	**E**	**F**
1						
2						
3						
4						
Section 8	**A**	**B**	**C**	**D**	**E**	**F**
1						
2						
3						
4						
5						

Section 1		/9	
Section 2		/13	
Section 3		/19	
Section 4		/15	
Section 5		/5	
Section 6		/5	
Section 7		/4	
Section 8		/5	
Total		**/75**	**%**

ANNEXURE N: Validation instrument for the validation of the clinical research education programme by stakeholders

The purpose of this validation instrument is to establish whether the developed clinical research education programme includes the necessary information and opportunities to learn about clinical research.

Briefly give your answers to the following questions. A basic “yes” or “no” is acceptable, but feel free to elaborate on your yes or no:

8. Will the programme provide a good learning experience?

   _____

   _____

   _____

9. Will the programme prepare new clinical research investigators for the opportunities potentially available in clinical research on completion of the programme?

   _____

   _____

   _____

10. Is the programme designed to ensure that the overall experience of the new clinical research investigator has logic and an intellectual integrity that are related to clearly defined outcomes?

    _____

    _____

    _____

11. Is the programme balanced, for examples in relation to the eight competency domains developed by the Joint Task Force Framework, namely, 1) Scientific Concepts and research design; 2) Ethical and Participant Safety Considerations; 3) Medicines Development and Regulations; 4) Clinical Trials Operations; 5) Study and Site Management; 6) Data Management and Informatics; 7) Leadership and Professionalism; 8) Communication and Teamwork?

    _____

    _____

    _____

12. Is the programme designed so that new clinical research investigators are treated equally, regardless of gender, age, ethnicity, disability, sexual orientation, or religion?

    _____

    _____

    _____

13. Do programme learning outcomes feature employability and career management skills development?

_____
_____
_____

Additional comments or recommendations:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

ANNEXURE O: Confidentiality agreement - statistician

CONFIDENTIALITY AGREEMENT

This agreement dated 20 January 2023, by and between Kennedy Otwombe (statistician) and Wilma Pelser (UNISA student 05421926).

Whereas, Kennedy Otwombe (statistician) and Wilma Pelser, for their mutual benefit and pursuant to a working relationship which has been established, anticipate that Wilma Pelser may disclose or deliver to Recipient documents, information, drawings, data, sketches, plans programs, specifications, techniques, processes, and other materials, both written and oral, of a secret, confidential or proprietary nature, including without limitation any and all information relating to marketing, finance, invention, research, design or development of information in any jurisdiction, and any amendments or supplements thereto; and

WHEREAS **Wilma Pelser** desires to assure that the confidentiality of any Proprietary Information is maintained.

NOW, THEREFORE, in consideration of the foregoing premises, and the mutual covenants contained herein, **Wilma Pelser** and Recipient hereby agree as follows:

1. Recipient shall disclose Proprietary Information received under this Agreement to person within its organization only if such persons (i) have a need to know and (ii) are bound in writing to protect the confidentiality of such Proprietary Information.

2. Title to all property received by Recipient from **Wilma Pelser** including all Proprietary Information, shall always remain the sole property of **Wilma Pelser** and this Agreement shall not be construed to grant to Recipient any patents, licenses or similar rights to such property and Proprietary Information disclosed to Recipient hereunder.

3. Recipient shall, upon request of **Wilma Pelser** return to **Wilma Pelser** all documents, drawings and other tangible materials, including all Proprietary Information and all manifestation thereof, delivered to Recipient, and all copies and reproductions thereof.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

Wilma Pelser

Wpelser

Signature

Printed Name
Kennedy Otwombe,

Title Associate Professor

ANNEXURE P: Confidentiality agreement - transcriber

CONFIDENTIALITY AGREEMENT

This agreement dated 20 January 2020, by and between Sarah Cohen (transcriber) and Wilma Pelser (UNISA student 05421926).

Whereas, Sarah Cohen (transcriber) and Wilma Pelser, for their mutual benefit and pursuant to a working relationship which has been established, anticipate that Wilma Pelser may disclose or deliver to Recipient documents, information, drawings, data, sketches, plans programs, specifications, techniques, processes, and other materials, both written and oral, of a secret, confidential or proprietary nature, including without limitation any and all information relating to marketing, finance, invention, research, design or development of information in any jurisdiction, and any amendments or supplements thereto; and

WHEREAS **Wilma Pelser** desires to assure that the confidentiality of any Proprietary Information is maintained.

NOW, THEREFORE, in consideration of the foregoing premises, and the mutual covenants contained herein, **Wilma Pelser** and Recipient hereby agree as follows:

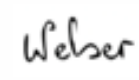
1. Recipient shall disclose Proprietary Information received under this Agreement to person within its organization only if such persons (i) have a need to know and (ii) are bound in writing to protect the confidentiality of such Proprietary Information.

2. Title to all property received by Recipient from **Wilma Pelser** including all Proprietary Information, shall always remain the sole property of **Wilma Pelser** and this Agreement shall not be construed to grant to Recipient any patents, licenses or similar rights to such property and Proprietary Information disclosed to Recipient hereunder.

3. Recipient shall, upon request of **Wilma Pelser** return to **Wilma Pelser** all documents, drawings and other tangible materials, including all Proprietary Information and all manifestation thereof, delivered to Recipient, and all copies and reproductions thereof.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

Wilma Pelser



Signature Sarah Cohen Digitally signed by Sarah Cohen Date: 2023.05.17 06:38:09 +02'00'

_Sarah Cohen_____ Consultant_____

Printed Name Title

ANNEXURE Q: Professional copy editor and proofreader

Between the lines editing

Leatitia Romero
Professional Copy Editor and Proofreader
(BA HONS)

Cell: 083 236 4536
leatitiaromero@gmail.com
www.betweenthelinesediting.co.za

26 June 2023

To whom it may concern:

I hereby confirm that I edited the thesis entitled: "AN INCLUSIVE CLINICAL TRIAL RESEARCH EDUCATION PROGRAMME FOR INVESTIGATORS IN HEALTH SCIENCES". Any amendments introduced by the author hereafter are not covered by this confirmation. Participants' verbatim quotes were not edited. The author ultimately decided whether to accept or decline any recommendations I made, and it remains the author's responsibility at all times to confirm the accuracy and originality of the completed work. The author is responsible for ensuring the accuracy of the references and its consistency based on the department's style guidelines.

Leatitia Romero

Affiliations

PEG: Professional Editors Group (ROM001) – Accredited Text Editor
SATI: South African Translators' Institute (1003002)
REASA: Research Ethics Committee Association of Southern Africa (104)

ANNEXURE R: Turnitin receipt

turnitin

Digital Receipt

This receipt acknowledges that Turnitin received your paper. Below you will find the receipt information regarding your submission.

The first page of your submissions is displayed below.

Submission author:	Wilma Pelser
Assignment title:	Complete dissertaion/thesis FINAL
Submission title:	An inclusive clinical trial research education programme for ...
File name:	Thesis_final.docx
File size:	3.67M
Page count:	226
Word count:	64,513
Character count:	378,428
Submission date:	26-Jun-2023 09:54AM (UTC+0200)
Submission ID:	2122850225

CHAPTER 1
ORIENTATION TO THE STUDY

1.1 INTRODUCTION

Trained clinical trial investigators play an indispensable role in ensuring the safety, integrity and success of clinical trials, ultimately advancing clinical knowledge and improving patient care. I will foreground the importance of upscaling the pool of clinical trial investigators to meet the evolving clinical trial challenges and address the increasing demand for well-trained and skilled health professionals. By developing an inclusive educational programme, such as a clinical trial research education programme for investigators in health sciences in South Africa, which encompasses nurses and other health professionals, we can ensure a diverse and well-equipped workforce that can effectively navigate the complexities of modern clinical trials and contribute towards advancements in health care.

Chapter 1 provides an orientation to the study. It includes the background of the research, problem statement, research aim and objectives, research questions, clarification of pertinent concepts, data collection strategies, research paradigm, and theoretical framework. The research design and methods, data analysis, the significance of the study, ethical considerations and chapter divisions are also outlined.

1.2 BACKGROUND INFORMATION ABOUT THE RESEARCH PROBLEM
1.2.1 The clinical research industry

The clinical research industry has evolved significantly (Kremidas 2019:1; Palombini 2022:1). This is particularly true for clinical trials when the COVID-19 pandemic created massive disruptions at the beginning of 2020 (van Dorn 2020:523). The clinical research industry had to rapidly adapt during the pandemic to expand data collection in real-world settings, using artificial intelligence and technology (National Academics of Sciences, Engineering and Medicine 2021:1). The increased use of technology, increased scale and complexity of clinical trials as part of the transformation process before the pandemic resulted in an update in the International Council for Harmonisation (ICH) E6 Guideline for Good Clinical Practice (GCP) in 2016 (May 2019:2). Following the COVID-19 pandemic, the ICH is busy rewriting the ICH E6 (R2) guidelines to incorporate new clinical

1

turnitin

Digital Receipt

This receipt acknowledges that Turnitin received your paper. Below you will find the receipt information regarding your submission.

The first page of your submissions is displayed below.

Submission author:	Wilma Pelser
Assignment title:	Chapter 5 FINAL
Submission title:	05421926 W Pelser Doctoral Thesis Final 2 Dec 2023
File name:	05421926_W_Pelser_Doctoral_Thesis_Final_2_Dec_2023.docx
File size:	5.58M
Page count:	383
Word count:	100,252
Character count:	599,860
Submission date:	13-Dec-2023 02:03PM (UTC+0200)
Submission ID:	2257795078

AN INCLUSIVE CLINICAL TRIAL RESEARCH EDUCATION PROGRAMME FOR INVESTIGATORS IN HEALTH SCIENCES

By

WILMA PELSER

Submitted in accordance with the requirements

for the degree of

DOCTOR OF PHILOSOPHY IN NURSING

in the subject of

HEALTH STUDIES

at the

UNIVERSITY OF SOUTH AFRICA

SUPERVISOR: PROF JEANETTE MARITZ

July 2023

An inclusive clinical trial research education programme for investigators in health sciences

ORIGINALITY REPORT

14%	12%	6%	3%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	hdl.handle.net Internet Source	3%
2	acrpnet.org Internet Source	1%
3	mrctcenter.org Internet Source	1%
4	uir.unisa.ac.za Internet Source	1%
5	apps.who.int Internet Source	<1%
6	stars.library.ucf.edu Internet Source	<1%
7	diamondportal.org Internet Source	<1%
8	www.ncbi.nlm.nih.gov Internet Source	<1%

05421926 W Pelser Doctoral Thesis Final 2 Dec 2023

ORIGINALITY REPORT

25%	21%	15%	11%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	hdl.handle.net Internet Source	3%
2	McGee, Jeanie. "Educating Future Clinical Research Investigators: An 8-Week Clinical Research Education Course for Neurology Residents.", Proquest, 2014. Publication	2%
3	uir.unisa.ac.za Internet Source	1%
4	www.brainscape.com Internet Source	1%
5	repository.up.ac.za Internet Source	<1%
6	acrpnet.org Internet Source	<1%
7	apps.who.int Internet Source	<1%
8	www.tandfonline.com Internet Source	<1%