EARLY CAREER RESEARCH INVESTIGATORS' EXPERIENCE OF CLINICAL RESEARCH

By

WILMA PELSER

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DEDICATION

I dedicate this study to Avy Violari, the current Deputy Executive Director and Director: Paediatric clinical trials at the Perinatal HIV Research Unit, Soweto, from whom I have learned everything about clinical research and clinical trials.

DECLARATION

Student number: 05421926

I declare that early career investigators' experience of clinical research is my own work and that all sources that I have used or quoted have been indicated and acknowledged by means of complete references.

_____   _____

SIGNATURE   DATE

Mrs W Pelser

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Early career investigators' experience of clinical research

STUDENT NUMBER: 05421926
STUDENT: WILMA PELSER
DEGREE: MASTER OF ARTS IN NURSING SCIENCE
DEPARTMENT: HEALTH STUDIES, UNIVERSITY OF SOUTH AFRICA
SUPERVISOR: PROF J MARITZ

ABSTRACT

The clinical research enterprise is an industry in crisis due to the challenges investigators and sites experience to stay viable. Clinical researchers might therefore also become an "endangered species".

The purpose of this study was to gain an understanding of early career research investigators' experience of clinical research. A generic, exploratory, descriptive and contextual qualitative design was used. Fourteen participants were recruited and interviewed face-to-face from three different clinical research sites in the Gauteng. Data were analysed thematically and cyclically.

Findings indicated that early career investigators entered the clinical research "maze" for various reasons and levels of preparedness. As they explored the maze, early career investigators found their way into a labyrinth, all the while making discoveries about the clinical environment and their own desires. They finally reached a point where they needed to move beyond the centre of the labyrinth and ask 'Quo Vadis' (where are we going to)?

KEY CONCEPTS

Clinical research, Early career researcher/investigator, Experience, Investigator

ABSTRAK

Die kliniese navorsingsbedryf is 'n industrie in krises weens die uitdagings wat ondersoekers en navorsingsinstansies beleef om lewensvatbaar te bly. Kliniese navorsers mag daarom ook 'n 'bedreigde spesie' word.

Die doel van die studie was om die belewenis van vroeë beroepsnavorsingsondersoekers in kliniese navorsing te verstaan. 'n Generiese, verkennende, beskrywende en kontekstuele kwalitatiewe ontwerp is gebruik. Veertien deelnemers van drie verskillende kliniese navorsingsinstansies in Gauteng het deelgeneem aan een-tot-een onderhoude. Data is tematies en siklies geanaliseer.

Bevindinge het aangedui dat vroeë beroepsnavorsingsondersoekers die kliniese navorsingsdoolhof betree vir verskillende redes en vlakke van gereedheid. Soos wat hulle die doolhof verken het, het vroeë beroepsnavorsingsondersoekers hulle weg in die labirint gevind, terwyl hulle die kliniese omgewing en hul eie wense ontdek het. Hulle het uiteindelik 'n punt bereik waar hulle verby die middel van die labirint moes beweeg en hulself afvra: "Quo Vadis" (waarheen gaan ons)?

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ABBREVIATIONS

ASSAF	Academy of Science of South Africa
CAPRISA	Centre for the AIDS Programme of Research in South Africa
CPD	Continuing Professional Development
DCC	Dual-career couple
DoE	Department of Education
ESI	Early Stage Investigator
FDA	US Food and Drug Administration
GCP	E6 Good Clinical Practice
GP	General Practitioners
IPE	Inter-professional Education
NIH	National Institute of Health
HIV	Human Immunodeficiency Virus
HPCSA	Health Professions Council of South Africa
JTF	Joint Task Force for Clinical Trial Competency
MCC	Medicines Control Council
MEC	Member of the Executive Council
MRC	Medical Research Council
NHLS	National Health Laboratory Service
NHRS	National Health Research Summit Report
OCD	Obsessive-Compulsive Disorder
PAIDS	Paralyzed Academic Investigator's Disease Syndrome
PhD	Doctor of Philosophy
PHRU	Perinatal HIV Research Unit
PI	Principle Investigator
QC	Quality Control
SAHPRA	South African Health Products Regulatory Agency
SANCTR	South African National Clinical Trial Register
SCRS	Society for Clinical Research Sites
S-OJT	Structured on-the-job training
SOP	Standard Operational Procedure
TB	Tuberculosis
WHO	World Health Organisation
WMA	World Medical Association

WRHI   Wits Reproductive Health and HIV Institute

CHAPTER 1
ORIENTATION TO THE STUDY

1.1   INTRODUCTION

The clinical research enterprise is an industry in crisis due to the challenges investigators and sites experience to stay viable (Society for Clinical Research Sites [SCRS] White Paper 2014:1). Clinical researchers might therefore also become an "endangered species" (Armstrong, Decherney, Leppert, Rebar & Maddox 2009:665). The SCRS White Paper (2014:1) mentions that some investigators and sites enter the industry with little chance to succeed, and they often leave quickly after conducting only one study; in some instances, no studies at all. The crisis in the clinical research field has enormous negative societal costs, financial costs to the industry, and human cost of productive lives lost. It is thus deemed appropriate and necessary to further explore the experiences of early career research investigators of clinical research, within the South African context.

This first chapter of the study will present the background and significance of the study, the aims of the study, terms relevant to the study, and the research design. The chapter will conclude with the ethical considerations and measures of trustworthiness.

1.2   BACKGROUND

Clinical research sites can be viewed as a pyramid. The top section of the pyramid consists of 10% of clinical research sites and represents mature clinical research sites. Mature clinical research sites, according to the SCRS White Paper (2014:1), refer to sites contributing to the majority of participants for any given study; these sites conduct more than 10 studies each annually. The middle section, about 50% of clinical research sites, represents clinical research sites or investigators who perform four or less studies per year, often as an add-on to their other full-time commitments. The bottom of the pyramid represents 40% of clinical research sites, and consists of the new sites and naïve investigators who face a steep and difficult path to success.

In 2012, the number of active unique investigators filing a Statement of Investigator Form 1572 worldwide was 27,834 – very similar to the figures in 2004. Form 1572 is an

agreement signed by the Principal Investigator (PI) to provide specific information to the sponsor and to assure that he/she complies with US Food and Drug Administration (FDA) regulations related to the conduct of a clinical investigation of an investigational drug or biologic. Approximately 40% of investigators who filed a Statement of Investigator Form 1572 in 2012 did not re-file a Form 1572 in 2013. From 2000 to 2010 the proportion of novice clinical investigators increased: the increase was from 33% to 44% against 67% to 56% in experienced investigators. The turnover of investigators for the Africa region was 47%; this was based on the number of investigators who have not returned to conduct another clinical trial since initially submitting a Form 1572 in 2006 (Woodin 2013:1).

1.3   PROBLEM STATEMENT

There is an increasing trend for medical doctors to start a career path in research as clinical investigators, but subsequently leaving the field (Armstrong et al 2009:665). Many investigators from the lowest part of the pyramid start their research career full of inspiration and motivation. They believe they can make a difference but soon find that there are several barriers to overcome, such as little access to adequate resources and training regarding the principles of clinical research operations (SCRS White Paper 2014:1). In addition, these investigators often lack exposure to many core industry fundamentals such as effective recruitment and retention strategies, knowledge of regulatory obligations, and negotiation of fair budgets and contracts. The result is a 40% quitting rate after just one attempt at conducting clinical research (SCRS White Paper 2014:1).

Research conducted by Flood, Wallace, Bloch, Kublin and Bekker (2015:1) shed some light on factors influencing the attraction and retention of South African medical doctors to clinical research. Some of these factors, according to the findings from Flood et al's (2015:1) research included the need for medical training programmes, a more clearly defined career pathway, programmes coordinating and funding research, training and mentorship opportunities and lastly, access to academic resources such as courses and libraries.

Over the last two decades, several universities and other research organisations and institutions worldwide have recognised the lack of training and other skills needed for

clinical research (Armstrong et al 2009:664-666; Daye, Patel, Ahn & Nguyen 2015:883-887; Culican, Rupp & Margolis 2014:3219-3222). Brass, Akabas, Burnley, Engman, Wiley and Andersen (2010:701) remark that research careers require research training, which is not usually part of the medical school curriculum. The lack of research training has also been expressed by students, and Burgoyne, O'Flynn and Boylan (2010:7) have found that medical students are largely unaware of the research activities in their host institutions. Burgoyne and colleagues (2010:7) also found from their study that over one quarter of students had a negative orientation towards following a career incorporating medical research after completing their degree.

The ASSAF consensus report (Magosi, Dhai, Folb, Gevers, Hussey, Kirkman, Madela-Mntla, Moja, Moodley, Ncayiyana, Pick, Siegried & Volmink 2009:146-147) reported that South Africa is experiencing a declining size and increasing age of the active workforce in clinical research. Due to the ageing clinical research population, there was an increase in ageing publishing scientists in South Africa (authors over the age of 50 years) from 18% in 1990 to 48% in 2002. A second concern mentioned in the report is the absence of effective training programmes and suitable career paths for the clinical researchers in South Africa. It is clearly stated in the report that "there is no national plan for the education and training of clinical researchers in South Africa". The budget (2007-2010) given for clinical training at both undergraduate and postgraduate level did not specify *clinical research training*, and due to the high priority given to primary health care in the national public health system, most of the money was allocated to primary health care. This resulted in the weakening of academic hospitals and tertiary facilities in the public sector, with consequent withdrawal of any kind of support for research by provincial health administrators. Furthermore, there was a refusal of the National Health Laboratory Service (NHLS) to discount fees for research projects and the Medical Research Council (MRC) was under funded. All these factors lead to a massive disinvestment by the state in clinical research activity.

The 2011 National Health Research Summit Report (NHRS) (South Africa 2011:1) identified seven main priorities for action by the NHRS on problems identified, and included:

1. Inadequate funding of health research by the South African government.
2. Shortage of human resources for health resources.

3. Lack of health research facilities and infrastructure.
4. There are certain priority research fields or areas that need attention.
5. The regulatory system for registration of new medications and conduct of clinical trials is cumbersome – Medicines Control Council (MCC).
6. There is a virtual absence of national planning, coordination, and translation of research.
7. There is a lack of national mechanisms for monitoring and evaluating the performance of the health research system of South Africa.

The negative effect has a broader impact on science, technology, economy, culture, society, policy, organisation, environment, and training. Struggling sites and investigators lead to many studies being unable to keep to their study recruitment and completion timelines. It could also result in sub-standard data quality. Ultimately, it counterfeits the purpose of bringing much needed new therapies to patients (SCRS White Paper 2014:1). This is already evident in the decline in new drugs that were approved by the FDA from 157 between 1996 and 1999, to 76 between 2006 and 2009 (Roberts, Fishhoff, Sakowski & Fieldman 2012:266).

The decline in clinical researchers doing clinical research has led to increased laboratory research done by basic researchers causing a gulf between bedside treatment and bench research. This phenomenon is known as "the valley of death" – it is here where promising scientific discoveries hang for a while and eventually die (Roberts et al 2012:266). Dev, Kauf, Zekry, Patel, Heller, Schulman and McHutchison (2008:208) mention that there is "enormous potential in the biomedical sciences for translating new knowledge and technological capability into powerful tools for the prevention and treatment of diseases", but this potential is unlikely to be reached without the full support of all the components of the health sector.

Flood et al (2015:1) expressed their concern concerning the large scale of HIV vaccine and other prevention trials that were scheduled to start in South Africa during 2016 that would need a wide breadth of research capacity. Part of their concern was that there were several senior level South African HIV vaccine researchers with vast expertise, but the new and younger generation of researchers entering the field were lacking. They were, therefore, unable to train and mentor a new generation of investigators.

It was thus unclear what early career research investigators' experience was of clinical research at sites specialising in infectious diseases in Gauteng, and the possible influence on the viability of the clinical research enterprise. This research aimed to fill this gap.

1.4   AIM OF THE STUDY

The aim of this study was to understand early career research investigators' experience of clinical research at sites specialising in infectious diseases in Gauteng. In other words, the task of this research was to provide as clear a picture as possible about the experience of early career clinical research investigators.

1.4.1   Research objective

The objective of this research was to:

- explore and describe early career research investigators' experience of clinical research at sites specialising in infectious diseases in Gauteng.

1.4.2   Research question

The primary research question driving this research was:

- What are early career research investigators' experiences of clinical research at sites specialising in infectious diseases in Gauteng?

1.5   DEFINITION OF KEY CONCEPTS

1.5.1   Clinical research

Clinical research is research intended to test safety (not harmful or dangerous to human health), quality (ingredients are of good quality), effectiveness (working to diagnose, treat, prevent or cure a disease condition), and efficacy (better/best when compared with other treatment or medicine for a similar condition) of new and/or existing or old medicines, medical devices, and/or treatment options, using human participants (South

African Clinical Research Association 2016).

In this study, clinical research refers to research intended to test the safety, quality, effectiveness, and efficacy of mainly HIV and Tuberculosis (TB) preventative and curative treatments or medication, using human participants.

1.5.2   Early career researcher/investigator

According to the United Kingdom Research Council, there is no one single definition of an early career researcher/investigator. In most cases individual institutions define early career researchers according to their own set needs and criteria. The European Research Commission refer to early career researcher as "early stage" researchers and identify them as researchers in the first four years (full-time equivalent) of their research activity, including the period of research training (Early Career Researchers 2016).

In this study, early career refers to medical doctors who worked at clinical research sites for five years or less.

1.5.3   Experience

Hassenzahl, Wiklund-Engblom, Bengs, Hägglund and Diefenbach (2015:531) define experience as a complex and retrospectively created personal narrative based on feelings, thoughts, and actions remembered from a collection of moments.

In this study, the experience of an early career investigator refers to an early career investigator's thoughts and feelings around his/her day to day tasks within the clinical research setting.

1.5.4   Investigator

An investigator refers to a person responsible for the conduct of the clinical trial at a clinical trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principle investigator (ICH GCP E6 guidelines 2016:134).

In this study, an investigator refers to the medical doctor who is responsible for conducting a clinical trial at a clinical research site, and the terms 'investigator' and 'researcher' are used interchangeably.

1.6   RESEARCH DESIGN

A generic, exploratory, descriptive and contextual qualitative design was used (Percy, Kostere & Kostere 2015:76; Langdridge & Hagger-Johnson 2013:15). I focused on describing the qualities of the phenomenon to develop an understanding of the experiences of early career researchers. In using a qualitative design, I was able to recognise the subjective experience of participants and it afforded me an 'insider' perspective on the phenomenon (Langdridge & Hagger-Johnson 2013:15). A full discussion will follow in Chapter 2.

1.6.1   Population

The larger population from which sampling was done for this study consisted of approximately 50 medical doctors in careers as investigators in infectious diseases such as HIV and TB at three research sites. Participants were recruited from three different clinical research sites in the Gauteng area, and included the Perinatal HIV Research Unit (PHRU), the Wits Reproductive Health and HIV Institute (WRHI), and the Aurum Institute over a period of three months.

1.6.2   Sample and sampling strategy

The sampling for this study followed the quota purposive method for sampling (Robinson 2014:33). It was a non-probability method and therefore did not involve random selection of participants. Participants were selected with the purpose to learn about the phenomenon in mind.

1.6.3   Data collection

Face-to-face interviews were conducted with participants (Lapan, Quartaroli & Riemer 2012:69; Creswell 2014:239). I guided the interviews using open-ended questions to get a deeper understanding of the participants' experiences in the clinical research field

(Lichtman 2014:248). In addition, I compiled personal notes in the form of memos at the time of the interview to highlight certain points that I felt to be important (Creswell 2014:244; Lichtman 2014:263; 362-372).

The data collected were transcribed verbatim by a professional transcriber. I then analysed and coded the data myself. I used field and reflective notes to document personal experiences, reflections, and progress (Lichtman 2014:255). Multiple data sources made triangulation possible and assisted the process of understanding the phenomenon under study (Creswell 2014:251; Lichtman 2014:407; Miles, Huberman & Saldana 2014:299). A full discussion will follow in Chapter 2.

1.6.4   Data analysis

I made use of thematic and cyclic data analysis, a method used to identify, analyse and report patterns or themes within the data (Hanley, Lennie & West 2013:112). More information is provided in Chapter 2.

1.6.5   Measures of trustworthiness

Lincoln and Guba (in Polit & Beck 2017:584) suggested four criteria for developing the trustworthiness of a qualitative inquiry: credibility, dependability, confirmability, and transferability. This section will be discussed in detail in Chapter 2.

1.7   ETHICAL CONSIDERATIONS

Ethical clearance for this study was granted by the University of South Africa (UNISA) (HSHDC/544/2016, Annexure A) and the clinical research institutions – PHRU, Aurum, and WRHI (Annexure B).

Researchers and reviewers of research have an ethical responsibility to recognise and protect the rights and well-being of human research participants (Grove, Burns & Gray 2013:163). The Belmont Report, published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research in 1979 identified three ethical principles to guide the researcher: *respect* for persons – protecting the autonomy of subjects and treating them with courtesy and respect and

allowing for informed consent; *beneficence* – maximising benefits for the research project (good outcome) while minimising risks or harm to subjects; *justice* – subjects are treated fairly during the selection process, and risks and benefits are balanced through procedures that are reasonable, non-exploitative, carefully considered, and fairly administered (Informed consent background 2013; Lapan et al 2012:19). For this study, I adhered to the three ethical principles as discussed next.

1.7.1 Respect for persons

The participants were treated as autonomous persons who are capable of making their own decisions. No participant was coerced into participating in this study (Bordens & Abbott 2014:197). For the participants to be able to make this voluntary decision, they were fully informed about the nature of the study. Information included the purpose of the study, risks involved, confidentiality, participant's rights, and what were expected of them as participants. Information about the study was explained to the participants to enable them to make an informed decision whether or not to participate in the study. Participants, therefore, voluntarily chose to participate and were informed that should they wish to withdraw their participation during the study, they were at liberty to do so without penalty. Participants were given an informed consent form to read and they had the opportunity to ask questions about the study. They were given enough time to read and make a decision before signing the informed consent. Written confirmation of their agreement to participate was obtained on the informed consent document. Participants were given a copy of the signed informed consent form.

1.7.2 Beneficence/non-maleficence

There is always some possibility that even after careful consideration on the part of the researcher, the interaction with the participants may inadvertently harm them in some unintended way. As part of the ethical consideration to ensure that no harm befell the participants in this research, I made use of informed consent. Informed consent can be seen as the cornerstone of the conduct of ethical human subject research, and is based on the concept of autonomy and the principle of respect for persons (Lapan et al 2012:19).

During the approval process, the Departmental Higher Degrees Committee at UNISA assessed the potential for risk, such as physical, psychological, social, economic, or legal harm to participants (Creswell 2014:73). Information was only gathered from the participants after the informed consent process was completed. Data were only collected for the purpose of this study and participants were free to decide on the extent to which they wanted to give information. Participants were reassured that should they experience psychological discomfort, they might request that the interview be stopped. I demonstrated sensitivity when asking questions that might have caused discomfort to the participants by portraying empathy and carefully observing their reactions. I believe that the potential benefit of this study to the clinical research field outweighed the potential psychological, financial, or social harms. Results of the study were disseminated to the participants at the end of the study (Lapan et al 2012:23). All the date collected were kept confidential, and de-identification measures were applied to protect participants' privacy. Code numbers were used and a master list of the participants was kept. Consent forms and audio-recordings were locked in a safe place to maintain anonymity and confidentiality.

1.7.3 Justice

A qualitative research method was chosen to discover and understand how early investigators experience their clinical research career. Therefore, participants were selected for their usefulness as rich sources of information (Robinson 2014:33). Giving the participants the opportunity to express their experiences was a justice issue because the interviews contributed to the understanding of human experience, in this case, the experiences of early career investigators. I believe that the face-to-face interviews generated in-depth knowledge of a range of experiences that otherwise would have remained hidden or misunderstood. A small group of participants was selected according to the following inclusion criterion: early career investigators who had medical degrees and worked at clinical research sites for five years or less from each of the three sites specialising in infectious diseases in Gauteng. Participants were not excluded on the basis of gender, age, ethnicity, or disability (Lapan et al 2012:19). Appointments were kept as scheduled and changes were communicated to the participants. The format of the interview process as explained to the participants at the beginning of the interview session was adhered to. At the end of the interview session

participants were thanked for their time and for sharing their experiences that could contribute to improving the retention of investigators.

1.8   STRUCTURE OF THE DISSERTATION

Chapter 1 – Orientation to the study

In this chapter, an overview of the study is provided and the introduction and background to the research problem are covered. The aim of the study and research question is outlined. Concepts are defined, and a summary of the methodology is provided.

Chapter 2 – Research design and methods

Chapter 2 presents the in-depth design and methodology of the study.

Chapter 3 – Findings of the study

In this chapter, the findings of the study are presented.

Chapter 4 – Discussion of the findings of the study and literature control

In Chapter 4 the findings of the study are discussed and validated within related study findings.

Chapter 5 – Recommendations, limitations and conclusions of the study

The implications of the study, limitation of the study, suggestions for further studies, and final conclusions are discussed in this chapter.

1.9   SUMMARY

In this chapter, an orientation and introduction to the study was presented and the significance of the study was also described. The research objective was to explore and describe early career research investigators' experience of clinical research at sites specialising in infectious diseases in Gauteng. The research design, which included the population, sampling, data collection and analysis followed, and the chapter concluded with a discussion of the ethical considerations. In Chapter 2 the research design and methods are discussed

CHAPTER 2
RESEARCH DESIGN AND METHODS

2.1   INTRODUCTION

Being a person is the activity of meaning-making - Robert Kegan, Developmental Psychologist Harvard University (Patton 2015:3)

Chapter 2 focuses on the research design and methods of the study, elaborating on the design, population, sampling and data collection methods, followed by an overview of how data were managed and analysed. The chapter concludes by addressing trustworthiness measures in qualitative research.

2.2   THE RESEARCH 'ONION'

The act of research can be compared to peeling different layers of an onion (Saunders, Lewis & Thornhill 2016:162). The outer two layers of the research 'onion' could be observed as the research philosophy and approaches to theory development. Moving to the inside of the 'onion', the third, fourth, and fifth layers consist of methodological choices (for example, qualitative/quantitative), strategy (for example, experimental/ survey), and time horisons (for example, cross-sectional/longitudinal). These three layers can also be thought of as the process of research design. The sixth layer refers to data collection and analysis (Saunders et al 2016:162).

2.2.1   Research philosophy

Philosophy, the first layer of the research 'onion', refers to our own beliefs and assumptions. It colours all our decisions and will, therefore, have an influence on developing new knowledge during the research process (Polit & Beck 2017:9). Saunders et al (2016:124) note that making numerous types of assumptions is often an unconscious process during different stages of our research. Assumptions are made about human knowledge, known as epistemological assumptions, about realities encountered in research, known as ontological assumptions, as well as about the influence of one's own values on the research, known as axiological assumptions (Saunders et al 2016:124). Reflecting on one's own assumptions is essential for a

credible research philosophy that will support one's research design, methods, data collection techniques, and analysis procedures (Saunders et al 2016:125).
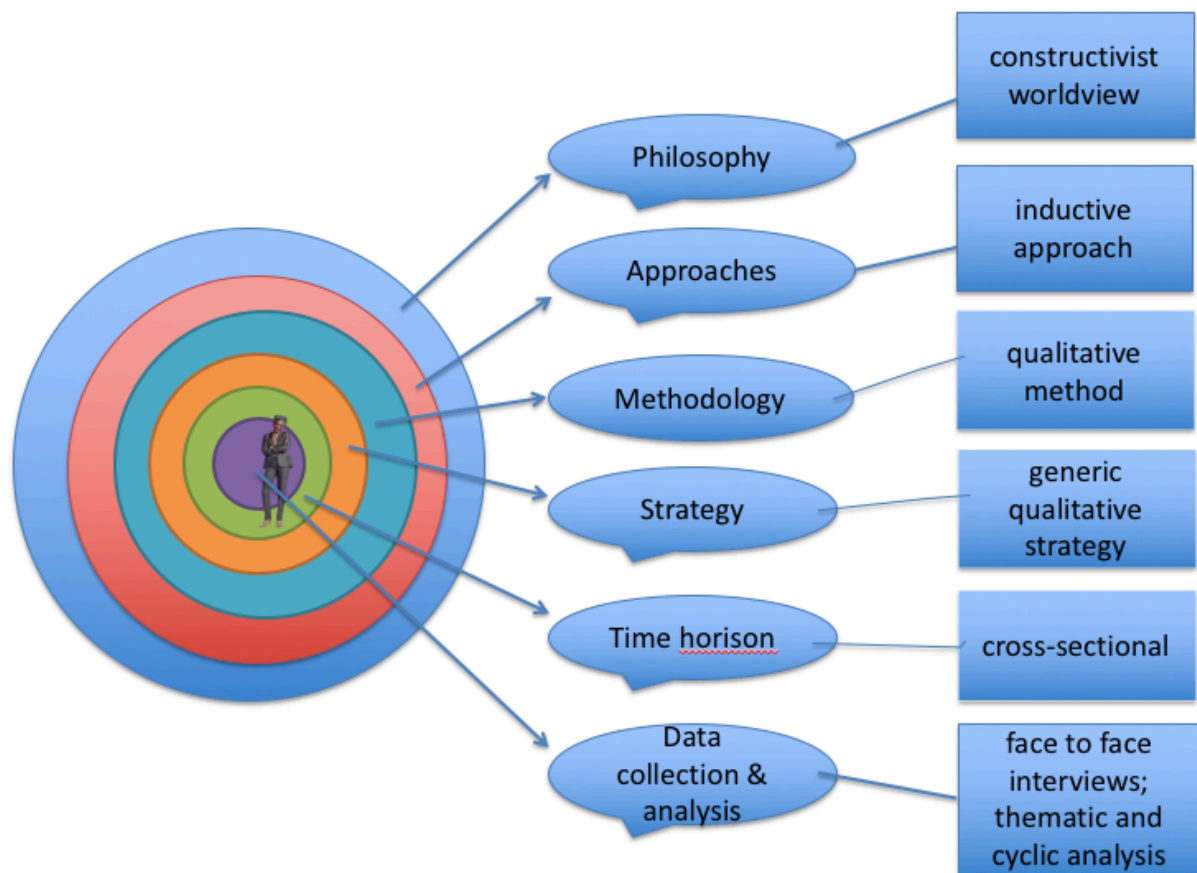
Figure 2.1: The research 'onion' (Saunders et al 2016:124)

Creswell (2013:35) refers to individual assumptions as the basis of philosophical 'worldviews' and it could be related to academic or work background, student advisors/mentors' preferences, and past research experiences. Creswell (2013:36) acknowledges that there is an ongoing debate about what worldviews and beliefs researchers bring to the research setting. Four of these worldviews often discussed in literature include post-positivism (determination, empirical observation and measurement, theory verification), constructivism (understanding, multiple participant meanings, social and historical construction, theory generation), transformative worldviews (political, power and justice oriented, collaborative, change-oriented) and pragmatism (consequences of actions, problem-centred, pluralistic, real-world practice oriented) (Creswell 2013:36). Creswell's description of the constructivist worldview resonated well with my beliefs and assumptions when I had to design my research project. These beliefs and assumptions included the notion that humans construct

meaning as they engage with the world they are interpreting; I used open-ended questions so that participants could share their views. They furthermore make sense of the world based on their historical and social perspectives: participants were able to share with me their previous experiences while comparing it with their current experiences. Lastly, participants generate meaning through interaction with a human community; I generated meaning from the data collected – an inductive process.

2.2.2   Theory development

The second layer we need to peel from our research 'onion' is the different approaches to theory development. Saunders et al (2016:152) describe three main approaches: deduction, in which instance a theory or hypothesis is developed and a research strategy is designed to test the hypothesis; induction, in which data are collected and a theory is developed as a result of the data analysis; and abduction, in which data are used to explore a phenomenon, themes are identified, and patterns are explained to generate a new theory or to modify an existing theory which is subsequently tested. The purpose of exploring and describing the experiences of early career investigators to better understand the nature of the problem was best done through an inductive approach whereby I approached the field without a hypothesis or explicit framework and data were collected and analysed inductively allowing information to emerge from the data.

2.2.3   Research design

The research design is a general plan or blueprint to be used to answer the research questions(s) (Saunders et al 2016:163). The research question(s) forms the basis for the objective(s) of the study. The research design provides an overall picture of the entire research project, touching almost all aspects of the research (Flick 2014:112; Kumar 2011:95). Saunders et al (2016:163) combine layers three (methodology), four (strategy), and five (time horisons) of the research 'onion' to focus on the process of research design.

2.2.3.1 Methodology

Continuing on the third layer of the research 'onion', namely methodology, we see that the choice of methodology for a study would be determined by the research question (Saunders et al 2016:162). Answering the question or solving the problem will be done in a systematic way or by following a research methodology. The methodology of a study forms the general research strategy or the science that outlines how the research should be carried out. It also includes, among others, the methods to be used during the research process (Rajasekar, Philominthan & Chinnathambi 2013:5). Methodology could also be defined as the procedures used by researchers to describe, explain, and predict phenomena, while research methods are the various procedures, schemes and algorithms used in research to help collect samples, data, and find an answer (Rajasekar et al 2013:5). The methodology, therefore, does not provide answers or solutions – it offers the theoretical ground for understanding which methods, set of methods, or best practice can be used in a specific setting (Rajasekar et al 2013:5).

Saunders et al (2016:165) advise that the first methodological choice is to decide which research design to follow. The authors (Saunders et al 2016:164) outline three research designs: quantitative, qualitative, or mixed methods. Creswell (2014:41) defines research designs as types of inquiry within quantitative, qualitative, and mixed method approaches that would lead to specific procedures involved in the research process (Creswell 2012:20). Quantitative study designs are specific, structured, and can be clearly defined and recognised, and is mostly concerned with numeric data (numbers). Qualitative study designs are less specific, precise, and well designed, and is mostly concerned with non-numeric data (words, images, video clips). A combination of both creates a mixed method study design (Saunders et al 2016:165; Kumar 2011:133). Considering my research question: 'What are early career research investigators' experience of clinical research at sites specialising in infectious diseases in Gauteng?', a qualitative research design was the best methodological choice. The justification for the chosen design follows.

a.   Qualitative design

For this study, I used a generic, exploratory, descriptive and contextual qualitative design (Percy et al 2015:76). The underlining philosophy of a qualitative research

design could be connected to an interpretive philosophy where the researcher needs to make sense of the subjective and socially constructed meanings that came forward during the research process (Saunders et al 2016:168). Trust, participation, access to meaning, and in-depth understanding are established through a natural setting or within a research context (Saunders et al 2016:168). Qualitative research puts the researcher in the world with material practices that make the world visible (Davies & Hughes 2014:9). The world becomes visible through a series of representations, recordings, field notes, interviews, conversations, photographs, and memos to the self (Davies & Hughes 2014:9).

Langdridge and Hagger-Johnson (2013:15) describe qualitative research methods as research that is interested in the quality(ies) of some phenomenon. It is concerned with text and meaning and rejects the idea that there is a simple relationship between our perception of the world and the world itself.

Qualitative research can also be defined by characteristics. Describing the characteristics of qualitative research gives a more comprehensive understanding of qualitative research. Some of these characteristics, according to Polit and Beck (2017:463), Creswell (2014:234), and Mack, Woodsong, MacQueen, Guest and Namey (2005:1), tend to apply across many different disciplines and can be applied to this study as well. It is flexible – as researcher, I was able to adjust to new information during the course of data collection; it is holistic – as researcher, I wanted to understand the whole; it is merging various data collection strategies, for example, there is intense involvement of the researcher – I was the key instrument for data collection; there is a process of building patterns, categories, and themes from the bottom up by organising the data into increasingly more abstract units of information – I used inductive data analysis; it is focusing on participants' meanings, not my meaning; it is reflective – I reflected on how my role in the study and how my personal background, cultures, and experiences could have influenced my interpretations; it is happening in a natural setting at the site where participants experience the problem under study – I conducted the interviews at the sites where the participants were employed at; it is a method of collecting evidence – I collected information(evidence) through interviews; it is producing findings that were not determined in advance – I worked from the information provided (interviews) to create themes (inductive method); it is producing findings that

are applicable beyond the immediate boundaries of the research – I was able to make recommendations to stakeholders from different clinical research fields.

The advantages of qualitative research are closely related to its characteristics. Polit and Beck (2017:485) describe qualitative research in terms of an emergent kind of design – a design that emerges while the study unfolds in the field, and that gives flexibility to the research. This ability allows qualitative research to be creative and intuitive while combining numerous rich data drawn from many sources to develop a holistic understanding of the phenomenon (Polit & Beck 2017:485). Another distinctive advantage is the fact that qualitative research analyses real cases in their time-based and local setting, taking people's expressions and activities in their local context into consideration (Flick 2014:22). Qualitative research, according to Flick (2014:22), thus have the ability to "design ways for social sciences, psychology and other fields to make concrete the tendencies to transform them into research programs and to maintain the necessary flexibility towards their objects and tasks".

Flick (2014:23) notes that qualitative research shows a variety of approaches, but there are common features among the different approaches. Different schools and trends are characterised by their research perspectives. Saunders et al (2016:168) refer to Basal and Corley (2011) who point out that despite methodological variations, qualitative research remains essential irrespective of the method used to demonstrate methodological precision and theoretical contribution. Qualitative research has developed over time and has a special relevance for contemporary research in many fields (Flick 2014:23).

b.   Exploratory, descriptive approach

The research question, as mentioned previously, is core to the choice of research design. According to Saunders et al (2016:174), research can be designed to fulfil either an exploratory, descriptive, explanatory, or evaluative purpose, or a combination of these.

b.i   Explorative qualitative research

In explorative qualitative research, the researcher wants to answer questions such as: a) what is the full complexity of the phenomenon, b) what is really going on, c) what is lying underneath the setup, d) how is the phenomenon experienced, and e) what is the process by which the phenomenon develops? (Polit & Beck 2017:15). An exploratory approach helped to answer these questions as it is designed to shed light on the various ways in which a phenomenon is expressed, and is able to get to the full nature of a sometimes little understood phenomenon (Polit & Beck 2017:15).

b.ii   Descriptive qualitative research

Descriptive research, according to Polit and Beck (2017:206), forms part of non-experimental studies and the purpose of descriptive studies is to observe, describe and to note what happens in a natural setting when something occurs. Grove et al (2013:66) point out that descriptive research provides an accurate picture or description of characteristics of a particular individual, group or situation. According to Saunders et al (2016:175), research questions and data collection questions will likely start with 'who', 'what', 'where', 'when', or 'how'. The descriptive study may form part of an explorative study or could be the forerunner to a piece of explanatory research (Saunders et al 2016:175).

This study was conducted with the purpose of exploring and describing the experiences of early career investigators to identify a particular need for information that can be addressed only through gaining the viewpoint of the people most affected (Grove et al 2013:66).

c.   Contextual

Qualitative studies are always contextual as the collected data are only valid in a specific context – the data are related to the research setting (Saunders et al 2016:362). Contextual data are able to give background information about the setting and the data collection process, and could include the following: the location or place where the interview took place; when it happened – date and time; the setting of the interview, such as the noise level, interruptions, and privacy; background information about the

participant, such as gender, title, job description; an immediate impression of how well or bad the interview went, for example, was there any resistance on the part of the participant or did he/she truly open up and reveal their thoughts and feelings (Saunders et al 2016:412). This study's data is valid in the specific context of early career investigators or medical doctors who worked at clinical research sites, specialising in infectious diseases in Gauteng, for five years or less.

2.2.3.2 Research strategy

Layer four of the research 'onion', the research strategy, forms the methodological link between the underlying philosophy of the study and the subsequent choice of methods to be used during data collection and analysis (Saunders et al 2016:177). The chosen strategy will help to answer the research question; it could be seen as a plan of action to achieve a goal. Both Saunders et al (2016:194) and Creswell (2013:236) mention the following strategies for qualitative studies: grounded theory and case study (to explore processes, activities and events), ethnography (to learn about broad cultural behaviours of individuals and groups), and narrative inquiry (studying individuals).

Percy et al (2015:76) claim that in some instances, for one reason or another, the most used or traditional approaches of qualitative research such as ethnography, case study, grounded theory, or phenomenology are not suitable for a study. In such instances, a generic qualitative inquiry strategy could be a better option. The generic qualitative inquiry approach is specifically suitable for answering questions with regard to people's attitudes, beliefs about a particular issue, or their experiences. Therefore, it made this a suitable approach to follow to investigate early career investigators' experience of clinical research (Percy et al 2015:76). During generic qualitative inquiry, participants give their subjective opinions, attitudes, or reflections on their experiences of things in the outer world; the external happenings (Percy et al 2015:78). In contrast to the phenomenology that follows a "go deep" approach, the researcher looks for information from a representative sample of people about the real-world happenings or about their experiences to get a broad range of opinions, ideas or reflections (Percy et al 2015:79). Polit and Beck (2017:479) refer to qualitative studies that do not have a formal name, due to the fact that they are not following a particular disciplinary or methodology, as 'descriptive qualitative studies'. Other researchers might refer to similar research simply as a qualitative study, or a naturalistic inquiry. They might also say that they have done

a content analysis of their qualitative data, meaning that they have done an analysis of themes and patterns that emerge in the narrative content (Polit & Beck 2017:479). Patton (2015:155) refers to qualitative methods such as in-depth interviewing, fieldwork observations, and document analysis within generic qualitative inquiry, that are used to answer what he calls "straightforward questions without framing the inquiry within an explicit theoretical, philosophical, epistemological or ontological tradition".

A traditional strategy as described by Saunders et al (2016:178) and Creswell (2013:236) was not followed. The current study did not fall neatly within a particular established methodology. Therefore, a generic qualitative strategy was chosen because it draws on the strengths of established methodologies while maintaining flexibility. Another reason was that few studies had been conducted on the topic of the current research study (Kahlke 2014:46).

2.2.3.3 Time horisons

Choosing a time horison constitutes layer number five. A study could be a once off "snapshot" of the phenomenon under study, or it could be a series of snapshots representing events over a given time period (Saunders et al 2016:200). Polit and Beck (2017:464; 2010:277) refer to qualitative studies with one data collection point as cross-sectional, and those with multiple data collection points as longitudinal. Longitudinal collection points assist researchers to observe the evolution of a phenomenon. I chose a cross-sectional time horison to do once off interviews with early career investigators because it is a relatively inexpensive way to collect a great deal of information in a short period of time.

2.3   RESEARCH METHODS

2.3.1   Research setting

The real-world, naturalistic setting for this study consisted of three different clinical research sites that are conducting research in infectious diseases in Gauteng, one of the nine provinces in South Africa. Early career investigators with less than five years of experience in clinical research were selected from each site. The sites chosen were the Perinatal HIV Research Unit in Soweto, the Aurum Institute in Parktown, and the Wits

Reproductive Health and HIV Institute in Hillbrow. All three sites are well established research institutes and well known nationally and internationally for their high standard of research work in infectious diseases, including HIV and TB mainly.

2.3.2 Selection of participants

It is necessary to locate 'excellent' participants to obtain excellent data – Janice Morse (Patton 2015:264)

2.3.2.1 Sampling criteria

Bordens and Abbott (2014:159) define a sample as a small subgroup from the larger population. It can be seen that the population will "give" the researcher the sample and in return it will "take" conclusions from the results obtained that might apply to the entire population. I chose a purposeful or purposive, non-random sampling strategy as I believed such a strategy would give me the answers to my research question. Patton (2015:264) describe purposeful sampling as a strategy of "selecting information-rich cases to study, cases that by their nature and substance will illuminate the inquiry question being investigated". I purposefully and strategically selected participants with variation on scopes of interest, including diverse perspectives, viewpoints and backgrounds, to incorporate enrichments of and challenges to emerging themes (Polit & Beck 2017:493; Leedy & Ormrod 2014:158; Davies & Hughes 2014:172). I also took an emerging approach where I chose two possible participants to approach for participation, and according to the information I received from them, I chose the third and fourth participants to confirm, modify, challenge or enrich my understanding (Polit & Beck 2017:491).

I selected a small sample according to the following inclusion criterion: early career investigators with medical degrees who worked at clinical research sites for five years or less. I chose fourteen (14) investigators for the sample group from the three sites specialising in infectious diseases in Gauteng. A list of possible participants at each site was provided by the different human resources departments. They were then personally (face-to-face or telephonic) invited to take part in the study and those who willingly agreed were included in the study. A total of six participants were selected from the possible list of twelve (12) candidates at PHRU, and four were selected from each of the possible lists of seven (7) and eight (8) candidates at Aurum and WRHI. Using a

small group gave an explanatory depth to the explored experiences of each participant (Davies & Hughes 2014:180).

2.4   THE RESEARCHER AS INSTRUMENT

I personally interviewed all 14 participants who agreed and consented willingly to participate in this qualitative study. According to Polit and Beck (2017:506), the researcher as instrument is a way of using the "self" to collect rich descriptions of human experiences and to develop relationships in intensive interviews with a small number of people.

I made a deliberate attempt to "be like" the participants I interviewed without losing distance through being sensitive to the way they dress, their modes of speech, customs, and schedules (Polit & Beck 2017:507). Through "being like" them I wanted to show them that I tried to understand their actions, decisions, and behaviour from their perspective. Having been part of clinical research teams in the past, I had to guard against personal bias and prevent my previous experiences with early career investigators from influencing data collection and analysis. I then relied on reflexivity by making use of a reflective diary in which I reflected critically on myself and on analysing and making note of personal values that could affect data collection (Polit & Beck 2017:508). I made use of field and reflective notes in which my personal experiences, reflections, and progress were documented while in the field. I attempted to be supportive and engaging to show my willingness to understand the participants' responses without getting too emotionally involved, giving them advice or disclosing my own thoughts, beliefs and feelings (Leedy & Ormrod 2014:159; Polit & Beck 2017:508). In using the "self" to collect rich information, I made use of bracketing and intuiting (Polit & Beck 2017:471).

2.4.1   Bracketing

Before I could start describing and interpreting participants' experiences related to early career clinical research, it was important to bring my own assumptions and prejudices about the phenomenon into awareness. The process of creating a distance from previously held assumptions and beliefs in qualitative research is known as "bracketing" (Simon 2011:41). Bracketing is also seen as a means of demonstrating the validity of the data collection and analysis process (Chan, Fung & Chien 2013:2). A "bracketing

interview" was used to explore my subjectivity, assumptions, and vested interests in undertaking this research, and to consider how these may impact on my interviews with participants. The bracketing interview was conducted by a colleague who was knowledgeable about reflexivity and about the study phenomenon (Polit & Beck 2017:563; Tufford & Newman 2010:80). The bracketing interview enabled me to perform a thematic analysis on the transcript, and by making my reflective practice transparent, I believe that I have lent rigor and credibility to the research. It was not an easy and painless experience, but it was one of liberation and transformation. I learned that I could not entirely separate myself from the research; I can only hope to see what was said by participants with fresh eyes (Polit & Beck 2017:471). The process of bracketing brought me closer to my participants and I was able to approach them with "emphatic openness" (Polit & Beck 2017:471).

As a novice qualitative researcher, I was further assisted by my supervisor during debriefing interviews and coaching conversations before and during data collection to bracket out the world and any prejudice as far as possible in an attempt to confront the data in a clear and uncontaminated form (Maritz & Jooste 2011:972; Polit & Beck 2017:471). I also had to bracket out my personal past knowledge and theoretical knowledge so that I could pay full attention to the phenomenon which currently appeared on my conscious mind (Chan et al 2013:4). This was achieved through attempting to withhold all knowledge and past experiences which would contaminate the studied phenomenon by keeping and using a reflective journal. During the course of the study (time period I was conducting the interviews), I kept a reflective journal that served as a strategy to facilitate reflexivity where my experiences, opinions, thoughts, and feelings were made visible and acknowledged (Polit & Beck 2017:471; Tufford & Newman 2010:86). By becoming aware of my personal biases, I was more likely to be able to pursue essential issues as stated by the early career investigators rather than leading them to issues that I deemed relevant (Chan et al 2013:3).

2.4.2   Intuiting

Smith (2012:1) quoted psychologist Frances Vaughan who refers to intuition as "intuition allows you to see and to sense possibilities that are inherent in a situation but have not yet been realised". Smith (2012:4) furthermore refers to intuition as "the space in-between theory and practice, that is, where the connection between therapist and

client takes place, a meeting of the minds". Although the word "intuition" stems from the Latin term *in-tuir*, meaning "looking, regarding or knowing from within", the meaning or definition has changed over time and could include words such as insight, knowing of the third kind, practical wisdom, creative cognition, perceptual knowing, a gut feeling, following a feeling (Einstein), and evenly suspended attention (Sigmund Freud) (Smith 2012:9). I attempted to use intuition to get a sense of the experiences of early career investigators by remaining open to the lived meaning of each description they gave (Polit & Beck 2017:472). I made a conscious effort to apply deep listening skills to myself and to my participants. I tried to quiet myself by listening deeply to my own internal processes and to external information from the participants and the environment to make sense of their experiences. This process helped me to move from the *what* of understanding to the *how* (Smith 2012:12).

2.4.3   Facilitative communication techniques

Obtaining rapport and a general feeling of closeness and trust is a critical element of gaining rich information from participants. During the interview process, I strived to show compassion and interest by not only listening intensively, but also through body language (maintaining eye contact, smiling sometimes leaning forward) and neutral encouragements such as "go on", "tell me more about…", "what do you mean…?" (Leedy & Ormrod 2014:159; Davies & Hughes 2014:186). At the same time I was cautious not to show any surprise, disagreement, or disapproval of what a participant was telling me through my own words or body language. The interviews were conducted in English as both parties were comfortable with the language. I refrained from putting words in the participants' mouths, and I gave participants the chance and time to choose their own way of expressing their thoughts, accepting the fact that there would be inconsistencies in their recollections, attitudes and logic at times (Leedy & Ormrod 2014:159).

Although I had semi-structured questions, I allowed the interviews to run a natural course without trying to keep all the questions in a specific order (Davies & Hughes 2014:186). When necessary, I provided the participants with emotional support, showing them that I understand, and by having a positive attitude. To ensure that my questions were understood I gave participants the opportunity to ask questions to clarify

any misunderstandings. In the event I needed to confirm that I understood the meaning of what they shared with me, I reflected on their feelings and answers.

2.5   DATA COLLECTION

The centre, or sixth layer, of our research 'onion' deals with data collection and data analysis (discussed under 2.6). In peeling the different layers of the research 'onion' it has become evident that every stage of the research design process is interconnected with the other and, therefore, the choice of data collection and analysis methods were determined by the research question and objective.

My choice of a data collection method was driven by my research question. I made use of a one-point-in-time face-to-face interviews with early career investigators. In other words, I made use of the "self" as instrument to collect data. The purpose of interviewing, according to Patton (2015:426), is to "allow us to enter into the person's perspective". I believed that the perspectives of my participants were meaningful and knowable. To overcome bias and to arrive at an accurate representation of reality or participants' perspectives of the phenomenon, I included field and reflective notes, as well as analytic memos in my data collection (Polit & Beck 2017:563, 747; Creswell 2014:251; Lichtman 2014:407; Miles et al 2014:299). I prepared a written open-ended question guide to use as data collection tool during the semi-structured interviews with my participants (Polit & Beck 2017:510). Participants were encouraged to reconstruct their experiences as early career investigators (Seidman 2013:495). The advantage of exploratory qualitative research is the fact that open-ended questions and probing can be used to give participants the opportunity to respond in their own words without coercing them to respond in a set way. By using open-ended questions, I was able to get meaningful explanations from the participants with regard to their experiences as early career investigators. Probing gave me the opportunity to go back to initial participant responses and I was able to ask them why or how, and they could elaborate on the issue.

2.5.1   Qualitative interviews

Qualitative interviews, according to Saunders et al (2016:388), is about "asking purposeful questions and carefully listening to the answers to be able to explore these further". During the process of gathering valid and reliable data relevant to my research

question, I had intensive dialogues with 14 early career investigators (Annexure D outline the open-ended questions asked during these interviews). The average duration of an interview was 43 minutes with a total number of 602 interview hours. These intensive dialogues required my thoughtful presence in the quest to understand the meaning of the experiences as it is lived by the participants (Seidman 2013:385). While listening, I tried to put their behaviour in context in an attempt to understand their actions, and at the same time I bracketed my perspectives and biases with regard to what they were saying (Seidman 2013:593). In the process of listening, I concentrated on three levels of listening. First, I listened to what participants were saying to make sure I understand what they mean (part of bracketing) and that nothing has been left out. Secondly, I listened with my intuition or inner voice and made use of probing to get more information when I sensed that there were more to tell. Thirdly, I listened by being sensitive to the whole process of interviewing. I kept to the timeframe and tried to cover all the questions in the guide and gave participants a break if they needed one (Seidman 2013:1765). Every word used by participants in these interviews is a "microcosm of their consciousness" according to Seidman (2013:351).

Appointments were made with the participants at a time and place that were convenient and comfortable for them, outside their working hours, and included lunch times and after-hours. Participants were advised to choose a time and location that would provide the opportunity for an in-depth conversation. I interviewed participants and at the same time recorded the interviews with a high-quality digital voice recorder after they gave their permission willingly. Ethical issues were considered during these interviews in that participants were informed about the nature and purpose of the study as it appeared on the consent form and on the participant information leaflet. They were reminded that they could withdraw from the study at any stage during the interview.

2.5.2   Field notes

Field notes are data that may contain both conceptualisation and analytical remarks (Saunders et al 2016:361; Polit & Beck 2017:522). It is a way of writing everything you encounter in the course of interviewing, what you hear, see, experience and think about. I preferred to maintain eye contact with my participants during the interviews and, as a result, I wrote most of my field notes after the interviews; it made me feel better connected to them. I did, however, make notes of things the participants said that

I wanted to "investigate" further by asking probing questions. My field notes contained a report of approximately three pages (per participant) of the interview, the actual discussion and communication, and it included aspects like emotions, gestures, uncertainty, as well as enthusiasm portrayed during the interview by the participants. My own feelings and perceptions were also noted. Field notes helped me with the process of finding meaning and understanding of early career investigators' experiences. This was also used as a triangulation measure as well as a back-up measurement (Patton 2015:473).

2.5.3   Reflective notes

Reflection is considered by Patton (2015:473) as a time of quality control to assure that the data collected will be useful. It was vital for me to write reflective notes as soon as possible after each interview, while the information and situation were still fresh in my mind because, as noted by Patton (2015:474), this is the beginning of analysis and insights could already start emerging here. I was then able to follow-up on these emerging ideas and interpretations in following-up interviews and reviews of collected data. Part of my reflections included my personal experiences, reflections, and progress while doing interviews (Polit & Beck 2017:522). Challenges encountered during the study were also recorded, including any improvements that I felt needed to be implemented. Using the reflective notes, I was able to make the necessary changes to my pre-planned data collection tool. After my first interview with a male participant, I got a sense that maybe males and females have different experiences of clinical research and I started probing around the male/female experience factor. Some participants I interviewed early in my study felt strongly that it is necessary to first specialise before entering clinical research, I therefore added the specialisation factor to my probing. Reflecting on my own personal background, culture and experiences, setting aside all preconceived ideas and assumptions, assisted me in shaping the meaning I assigned to the data (Creswell 2014:186; Maritz & Jooste 2011:973). Therefore, I used these reflective notes in an effort to bracket (Polit & Beck 2017:522; Maritz & Jooste 2011:972).

2.5.4   Debriefing interviews

Being a novice qualitative researcher, the reassurance that I could debrief with my supervisor, felt like a safety (catching) net (Maritz & Jooste 2011:978). I knew I could

discuss my uncertainties, lack of knowledge with regards to qualitative research, feelings of discomfort and worry with my supervisor during these sessions. These debriefing interviews opened me up for self-awareness, transformation and methodological awareness (Maritz & Jooste 2011:979). It also gave me the ability to act and react more quickly to research challenges, resulting in improved confidence. The debriefing interviews served as self-correcting measures during the research process, as they illuminated challenges emerging during the research process and allowed for appropriate adjustments to be made (Maritz & Jooste 2011:982).

2.6   DATA ANALYSIS

Data analysis is the process of extracting, organising, and giving meaning to raw data – in other words, it is a process to help make good sense of data (Miles et al 2014:277). I followed a cyclical analytic process as endorsed by Saldana, consisting of first cycle methods, a cross method in-between, and second cycle coding methods (Saldana 2016:68). Saldana (2016:68) views the nature of coding as a continuous process of recoding – comparing data to data, data to code, code to code, code to category, category to category, category back to data. My research question: 'What are early career research investigators' experience of clinical research at sites specialising in infectious diseases in Gauteng?', as well as my lack of qualitative research experience, determined my choice of first, cross, and second cycle coding methods. These coding methods are discussed in more detail under Section 2.6.3. A similar way of data analysis is described by Saunders et al (2016:579) as "thematic analysis". An independent co-coder was not used – this was in accord with Lichtman (2014:340) who states that: "as the researcher, you are the best equipped to make sense of the data. Using others to verify your interpretations assumes that there are right concepts to find or that some findings are better than others. You should be closer to your data than anyone else". My supervisor monitored the analysis.

2.6.1   Organising the data

Data collected from individual interviews with audio-recording, followed by verbatim transcriptions, field notes and personal notes/memos were found to be very lengthy and needed appropriate organising and preparation for analysis. An essential aspect of organising the data were to find a suitable anonymising method to code the data of

different participants (Saunders et al 2016:575). I created a paper file as well as a computer file for each participant, containing all the data collected (including reflective notes and analytic memos) for each participant. Each file was identified by a code number for future retrieval. Paper files were kept in a locked cabinet in my locked office, and computer files were protected with a pin code.

2.6.2   Transcribing the data

Audio-recorded data were transcribed or reproduced verbatim as a word-processed account (rewritten word for word). Due to the time-consuming process of transcribing audio-recorded interviews, I involved a professional transcriber following an agreement as to how data should be transcribed to include the tone in which it was said and the participant's non-verbal communication. It was also discussed how confidentiality would be maintained. I checked the accuracy of the transcribed data with the transcriber through continuous telephonic and email communication.

2.6.3   Coding the data

A code in qualitative research can be described as a word or short phrase representing a collective portion, or a portion of the most striking information of language-based data. It could also bring strong images, memories or feelings to mind (Saldana 2016:4). Saldana (2016:4) used Charmaz's description of coding. Charmaz sees coding as the "critical link" between data collection and their explanation of meaning. Saldana (2016:4) compares the title of a book, film or poem with a code. The same way the title represents and captures a book, film or poem, so does a code represent and capture the main content and real meaning of data collected. Saunders et al (2016:567), on the other hand, compare codes with pieces of a puzzle; the pieces of data and the relationships between the pieces help to bring a clear picture to us of what we think the data are telling us. Codes are generated by the researcher to symbolise or translate data and thus gives meaning to each individual datum that could be used later for pattern detection, categorisation, theory building, and other analytic processes (Saldana 2016:4). The process of condensing the raw data starts with coding, as described, and continues with grouping these coded data into analytic categories (Saunders et al 2016:584).

A pattern is when a word/phrase or action appears more than twice to form a repetitive or consistent occurrence in the data. Patterns will demonstrate human habits and would, therefore, confirm our descriptions of people's routines, rituals, rules, roles and relationships. If we can discern these trends we can solidify our observations into concrete examples/illustrations of meaning (Saldana 2016:5).

Themes, similar to codes and categories, give meaning and identity to patterned experience through capturing and merging the construction of the experience into a meaningful whole (Saldana 2016:199). Thus, a theme will tell us more about what is happening with our participants in relation to the phenomenon we are studying. It will show us a clear picture of the puzzle we started with.

First cycle methods, according to Saldana (2016:68), are "those processes that happen during the initial coding of data". To reveal the meaning of data from the interviews I conducted with participants, I choose In-Vivo (words or short phrases from the participant's own language), Initial (breaking down data into separate parts, closely studying them, comparing for similarities and differences) and Process (using "-ing" words to connote action in the data or general conceptual action) coding methods for my first cycle coding as suggested by Saldana (2016:71). Before starting with the second cycle methods, I used a cross method by which I took all the codes written in the margin of the transcript, cut it into separate pieces of paper, piled them together into appropriate categories, stapled them, and labelled them with a category name as well as their source (Saunders et al 2016:584; Saldana 2016:230). During second cycle coding, I took these piles of coded categories and recoded them. During this process, I looked for more accurate words or phrases, I merged some codes that were conceptually similar, I considered infrequent codes, and I dropped some codes that were marginal or redundant. Reorganising and condensing codes in second cycle coding produced a "main dish" with broader categories and themes (Saldana 2016:234). In second cycle coding, I made use of what Saldana (2016:235) called "Focused Coding" (searched for recurrent or significant Initial Codes to develop categories and themes).

Practically, I took a hard copy of the interview transcripts to read. The hard copy consisted of the script covering two thirds of the page from the left side, leaving a one third space on the right side of the page without script. During my first reading I

highlighted words and or phrases that caught my immediate attention. The second time around I decided which of the highlighted words/phrases I wanted to code. I coded the selected words/phrases by giving it a superscript number in the text. Next to the data, on the right side of the page, I linked the superscript numbers with the data excerpt. Table 2.1 is an example of the hard copy transcribed interview with codes.

Table 2.1:   Example of hard copy transcribed interview with codes

I was very <mark>unhappy</mark>[1] during the first few months as investigator. I was <mark>not sure where my "medical" responsibilities start and where my "research" responsibilities start.</mark>[2] Everyone else was so busy, I <mark>felt useless</mark>[3] and was not sure <mark>who to ask guidance</mark>[4] from.	1 "unhappy" (In-vivo coding 2 confusing roles (process coding) 3 "felt useless" (In-vivo coding) 4 mentoring (process coding)

I repeated the process until I was satisfied that I coded all the data I felt should have been coded. Before cutting the codes from the script, I made a copy of the hard copy with the codes. I used a different colour paper for each interview transcription. I cut out each code (coloured paper one), placed it on a clean table, and when all the codes were on the table I started organising them into groups with similar meanings. I had several groups after sorting the codes. Picking up each group I recoded them. During this process, I looked for more accurate words or phrases, I merged some codes, I considered infrequent codes and I dropped some codes that were marginal or redundant. Keeping my research question in mind, I asked myself certain questions while I was doing the recoding in my search for patterns to create a list of themes. I wanted to know what were the key concepts in these codes, what patterns were evident in the coded data, which codes appeared to be related, what was the essence of each apparent theme, how might themes be associated with each other, how well did the initial thematic map represent the relationships between themes, which themes needed to be refined, discarded or newly introduced, and how may the themes be modified to represent my data better? (Saunders et al 2016:585). The end result of this process of coding, recoding, categorising and re-categorising was a set of four themes, representing the meaning of the data, answering the research question "What are early career research investigators' experience of clinical research at sites specialising in infectious diseases in Gauteng?"

2.6.4   Analytic memos

Analytic memos are conversations we have with ourselves about our data. It is a process of thinking, writing, thinking more and writing more about the participants and/or phenomenon (Saldana 2016:44). Analytic memoing gave me the opportunity to reflect on and write about my code choices and their operational definitions, about emergent patterns, categories and themes (Saldana 2016:47). In the process of writing and reflecting I was able to make some links, connections and overlaps among the codes, patterns, categories and themes. Saldana (2016:54) suggests that analytic memos should be coded and categorised as well, not only as an organisational act but as an important analytic act that outlines the basic components of a write-up. I, therefore, used my reflective notes mainly to reflect on my own personal emotions, relationships, values, attitudes and beliefs with regard to the phenomenon and the analytic memos for reflecting on the participants' routines, rituals, rules, roles and relationships (Saldana 2016:47).

2.7   MEASURES OF TRUSTWORTHINESS

Many attempts and efforts have been made to define what is meant by "high-quality" research in a qualitative inquiry, and although it is considered as important, there is still a lack of consensus (Polit & Beck 2017:557; Okeke & van Wyk 2016:218). According to Saunders et al (2016:209), the result is that "researchers from different research traditions have developed different criteria to judge and ensure the quality of research". In this regard, I lean more towards the five criteria suggested by Lincoln and Guba (Saunders et al 2016:209; Polit & Beck 2017:559) for developing the trustworthiness of a qualitative enquiry, namely: dependability (for reliability), credibility (for internal validity), transferability (for external validity), confirmability (for objectivity), and authenticity criteria (alternative to validity), opposed to the "mainstream" terms. My reason is that Lincoln and Guba's (Polit & Beck 2017:559) criteria for developing the trustworthiness of a qualitative inquiry represent parallels to the positivists' criteria of internal validity, reliability objectivity, and external validity. Whittemore and colleagues, and Morse and colleagues (in Polit & Beck 2017:557) favour the mainstream terms, namely validity and rigor, as they argue that it could be applied to all research. Another group of qualitative researchers argue that there should be a generic set of standards or specific standards for different types of study (Polit & Beck 2017:558).

2.7.1 Credibility

Credibility can be compared to internal validity that is used in the natural sciences and quantitative research in the social sciences to judge quality (Saunders el al 2016:202) and is related to the confidence in the truth of the data and the interpretations of the data (Polit & Beck 2017:559). To enhance data quality, through prolonged engagement I practiced intensive listening and concentration during individual face-to-face interviews with participants. I allocated enough time for each interview and over a period of 62 days I conducted 14 interviews. The total time of the recorded interviews was 602 minutes. After each interview, I spent time reflecting, writing reflective notes, analytic memos, and discussions with my supervisor. Analytic memos and reflective notes assisted in revealing my preconceived expectations about what the research would or should reveal and formed part of the reflexivity process. Throughout the study, as part of my external checks, I checked my data analysis and interpretations with my supervisor. My data analysis system were developed with the purpose to produce the best possible explanation of the phenomenon being studied, namely: early career investigators' experience in clinical research. Findings were analysed against a body of similar work discussed in the literature review which helped to ensure this study had created trustworthy data (Polit & Beck 2017:557).

Four kinds of person: zeal without knowledge; knowledge without zeal; neither knowledge nor zeal; both zeal and knowledge – Pascal, Pensees. Four kinds of qualitative triangulations: interviews with observations; interviews with documents; observations with documents; and interviews from multiple sources with observations of diverse events and documents of many kinds – Halcolm, Qualitative Pensees (Patton 2015:662)

2.7.2 Dependability

Dependability relates to reliability (in quantitative research) and the question to be answered here is: If we repeat the same study with the same participants within the same context, would we find the same results? To enhance the dependability of the study, I audited my research by checking the accuracy of the transcriptions and the relationship between the research question and the data (Creswell 2014:203). Furthermore, I followed Saldana's cyclical analytic process, consisting of first cycle

methods, a cross method in-between, and second cycle coding methods – comparing data to data, data to code, code to code, code to category, category to category, category back to data. To prevent different interpretations of the data (Lichtman 2014:34), I preferred not to make use of an outside researcher to do an inquiry audit or external audit (I believed I was the best equipped to make sense of the data). Instead, I made use of the following to further enhance dependability: I provided a justification for the study and the readers can judge the quality of my argument independently; I justified my choice for using a qualitative inquiry; I attempted to do the study under the most natural conditions possible; I treated participants ethically; and the methodology chosen for the research was thoroughly described and followed throughout the study (Williams 2011:4).

2.7.3   Confirmability

Confirmability refers to objectivity (in quantitative research), meaning that there is potential for similarity between two or more independent people's data in relation to accuracy, relevance or meaning (Polit & Beck 2017:559). I ensured that the full research project was reviewed by my supervisor who is an expert in qualitative research with qualifications in advanced research methodology. Reflective notes and analytic memos were shared with my supervisor who gave objective feedback for further reflection. These records also formed part of the chain of evidence and were kept safely and could be made available if necessary.

2.7.4   Transferability

Transferability is the parallel criterion to external validity or generalisability and refers to the possibility of transferring findings and interpretations to other settings or groups (Saunders et al 2016:206; Polit & Beck 2017:560). I provided a full thick description of the research question, design, findings and interpretations to enable the reader or other investigators to judge the transferability of the research to another setting in which they are interested (Saunders et al 2016:206; Polit & Beck 2017:560). I chose a purposive, non-random sampling strategy as I believed such a strategy would give me the answers to my research question and the possibility to "take" my conclusions from the results I have obtained to apply them to the entire population (Patton 2015:264).

The trouble with generalization is that they don't apply to particulars – Lincoln and Guba (Patton 2015:710)

2.7.5   Authenticity criteria

Authenticity criteria are not seen as parallel criteria but as a criterion that is designed for the nature of interpretivist research (Saunders et al 2016:206). Authenticity is seen in a research report when it expresses the feeling or tone of participants' lives as they are lived (Polit & Beck 2017:560). In other words, it promotes fairness and faithfulness by representing all views in the research; it raises awareness, generates learning, and can bring about change (Saunders et al 2016:206). I audio-recorded participants' interviews with their permission. This data were transcribed verbatim to include some sense of the mood, feeling, experience, language, and context of their lives (Polit & Beck 2017:560). I empowered participants by asking them open-ended questions, giving them the opportunity to share freely and to reflect on their experience in clinical research. I hoped that their participation would make them rethink their position as early career investigators and that it would motivate them to stay within clinical research. During my literature review I looked at a wide variety of viewpoints with regards to barriers clinical research investigators experience to get a general concept of the experience of clinical research investigators. I planned to share my findings and recommendations with each participant's clinical research institution. Furthermore, I planned to write articles to be published in medical scientific journals.

2.8   SUMMARY

In this chapter all the research design components, which included the research method, data collection, data analysis and measures of trustworthiness were discussed. The results of the experiences of early career investigators in clinical research are discussed in Chapter 3.

CHAPTER 3

FINDINGS OF THE STUDY

> *Classification is Ariadne's clue through the labyrinth of nature* – George Sand (1869)
> Nouvelles Lettres d'un Voyageur (Patton 2015:553)

3.1   INTRODUCTION

The task of this research was to provide as clear a picture as possible about the experience of early career clinical research investigators. First, I offer a description of the demographics of the participants. Thereafter, I present the findings with verbatim quotes in *italics*.

3.2   DESCRIPTION OF THE DEMOGRAPHICS OF THE PARTICIPANTS

Table 3.1 summarises the biographical data of the early career investigators who participated in the study. Data were collected during February to April 2017 from participants working at the PHRU, Aurum Institute, and Wits RHI in Gauteng. The study comprised of 14 early career investigators. Four (4) participants were male and ten participants were female. At the time of the interviews, three participants had less than one years' experience, four participants had one to two years' experience, two participants had two to three years' experiences, three participants had three to four years' experience, and two participants had four to five years' experience as investigators in clinical research. Considering the racial breakdown, five different racial groups were represented: three Black participants, three White participants, one Coloured participant, five Indian participants, one Asian participant, and one Malaysian participant. Their age breakdown was as follows: five participants were between the ages of 25-30, three were between the ages of 30-35, four were between the ages of 35-40, and two were older than 40.

Table 3.1: Participant's demographic profile

VARIABLE	PARTICIPANTS
Gender	Male = 4
	Female = 10
Years' experience	0-1 year = 3
	1-2 years = 4
	2-3 years = 2
	3-4 years = 3
	4-5 years = 2
Age breakdown	25-30 = 5
	30-35 = 3
	35-40 = 4
	40 and above = 2
Racial breakdown	Black = 3
	White = 3
	Coloured = 1
	Indian = 5
	Asian = 1
	Malaysian = 1

Accurate statistics with regard to the total number of investigators working in infectious diseases is difficult to obtain. Statistics from the Health Professions Council of South Africa (HPCSA) (HPCSA 2017) do not indicate how many of the doctors registered with the council are working as investigators in clinical research. By law, all doctors should be registered with the HPCSA. From 2005, all clinical trials had to be registered on the South African National Clinical Trial Register (SANCTR) (SANCTR 2005). Currently, there are about 200 clinical trials registered related to infectious diseases. All clinical trials have a principle investigator and two sub-investigators on average. It could, therefore, be estimated that there are approximately 600 investigators in South Africa working in infectious diseases' clinical research. Correspondence with Kredo (16 January 2018) from the South African MRC confirmed the fact that it is not known how many investigators are working in infectious disease on clinical trials in South Africa or any other demographic detail. This could potentially be a gap identified by this study.

3.3   DESCRIPTION OF THE FINDINGS

> *A vast underground palace, hundreds of rock-carved rooms linked by a spider's web of passages: a labyrinth, a maze …* (Mcleish 1983:143)

Four main themes emerged from the analysis. Early career investigators' experience of clinical research seemed to have followed a course or process. I will be using two metaphors to explain aspects of their experience namely that of a maze and the labyrinth.

It is essential to have some understanding of the meaning of both a labyrinth and a maze when using the metaphors. Over centuries the two entities were often understood as synonyms in writings and references (Ullyatt 2010:74). Searching for clarity in dictionaries of different languages does not bring any clear separation of the two constructs.

In asking the question: is there a difference between the words *maze* and *labyrinth*?, the editor, giving the definition in the Dictionary by Merriam-Webster, (Dictionary by Merriam-Webster online 1996, sv "maze, labyrinth"), responded that there is not much difference as both words refer to a confusing network of passages, channels, or something that is profoundly complicated and confusing. However, according to the editor, in origin the two words are quite different: "*Maze* is presumed to come from an unrecorded Old English word *masian* ("to confuse"), whereas *labyrinth* has a more classical pedigree. Ancient Greek legends tell of King Minos of Crete, who had the inventor Daedalus create a labyrinth beneath his palace in which was housed the Minotaur, a fearsome monster with the head of a bull and body of a man. The Minotaur was said to have been slain by the Greek hero Theseus, who then managed to find his way out of the labyrinth with the aid of a ball of thread that had been given to him by Ariadne, the daughter of Minos".

Findings indicated that early career investigators entered the clinical research 'maze' for various reasons and levels of preparedness. As they explored the maze, early career investigators found their way into a labyrinth all the while making discoveries about the clinical environment and their own desires. They finally reached a point where they

needed to move beyond the centre of the labyrinth and ask 'Quo Vadis' (where are we going to)?

What follows are the themes, categories, and codes as they emerged from the data analysis. Direct quotes are provided in *italics*. Participants were provided with pseudonyms in order to protect their identity. Table 3.2 offers a summary of these themes, categories, and codes. Table 3.3 provides a summary of the participants' pseudonyms and codes.

Figure 3.1: Representation of the clinical maze

Table 3.2: Themes, categories and codes

THEME	CATEGORY	CODE
3.3.1 Entering the maze of clinical research	3.3.1.1 Motivation to enter and interest in the research field	a. Pre-existing desire
		b. Personality type
		c. Stepping-stone
	3.3.1.2 Readiness related to knowledge, skills and experience of clinical research	a. Challenges experienced
3.3.2 Exploring the maze to find a way into the labyrinth	3.3.2.1 Supportive environment	a. Shadowing
		b. Mentoring
		c. On-the-job training
		d. Courses and training programmes

THEME	CATEGORY	CODE
		e. Exposure to experienced and skilled investigators
		f. Teamwork
3.3.3 Discoveries while walking the labyrinth	3.3.3.1 The nature of clinical research	a. Mundane work
		b. It is a process and it takes time/no instant gratification
	3.3.3.2 Personal desires, growth and exposure	a. Increased responsibility, authority and leadership
		b. Skills
3.3.4 Moving beyond the centre - Quo Vadis?	3.3.4.1 Unclear career trajectory	a. Promotion structure unclear
		b. Stagnation
		c. Transferability of knowledge/niche industry

Table 3.3: A summary of the participants' pseudonyms and codes

Participant code	Pseudonym
310124	Allie
310207	Sarah
410303	Reba
520413	Tammy
220514	Jacky
210615	Arthur
310715	Robin
310804	Jeff
320912	Joslyn
321012	Donald
231119	Samantha
231225	Veronica
231325	Vernon

Participant code	Pseudonym
331424	Meagan

3.3.1 Entering the maze of clinical research

Early career investigators' journey of clinical research started at the point of entering the maze. Their reaction to the maze was influenced by their motivation to enter clinical research, their interest in clinical research, as well as their previous knowledge and experience of clinical research. Each of these aspects will now be discussed in more depth.

3.3.1.1 Motivation to enter and interest in the research field

It would appear that early career investigators had different reasons for initially entering the research field. In some way, it would seem to be connected to their framework of reference (what they knew or had experienced before) regarding research. This included their pre-existing desire, personality type, and the notion to use clinical research as a stepping-stone in their career.

a.   Pre-existing desire

Desire refers to a (sometimes strong) feeling of wanting something (Dictionary by Merriam-Webster online 1996, vs "desire"). Pre-existing desires to enter the clinical research field were expressed by some participants. Arthur, Allie, Vernon and Reba indicated that they were sensitised by friends, colleagues, or previous experience, and developed an aspiration and curiosity that prompted them to enter the clinical research field to find out more and to experience for themselves what clinical research is all about.

> "*Back in the days at medical school there were some students that were involved in CAPRISA. I mean, I was...it was…I always thought it would be interesting to see what…what it's like actually collecting the data. We read these journals but nobody understands what kind of...goes into the research on the ground*" Arthur.

"Dr Silo, he's a team leader, I did a presentation and he said that I'm very good at researching things…and I should go...go into research. So…so, from then, it stuck with me and I always wanted to do it" Allie.

"I've always wanted to know how to get involved in research…to begin with, so a friend of mine told me about the post in clinical trials at this site and I applied for it, got an interview and got the job" Vernon.

"I wanted to see the clinical aspect of things - its real life. What get involved, what about the patients, what about the ethics, what is the process involved in getting - a big trial going and...big sponsors. That's what I wanted to know" Reba.

b.   Personality type

A person's personality is what distinguishes him or her as an individual and could be seen as the totality of that individual's behavioural and emotional characteristics (Dictionary by Merriam-Webster online 1996, vs "personality"). Personality played a role in making a decision to discover what clinical research holds for them. Sarah, Jeff, Arthur, Robin and Samantha felt strongly that the nature of clinical research suited their personality and they believed they had made the right choice in following a career in clinical research. Specific aspects, such as a perceived structured and controlled environment (of clinical research) was an attractive option, possibly as opposed to the unpredictable nature of a hospital setting, or in the case of Sarah, the casualty department of a hospital. Sarah also referred to herself as an academic person. Jeff and Arthur both labelled themselves as obsessive-compulsive (OCD), which also reflected their need for control. Robin highlighted the *analytical tendency* of his personality. Meagan knew that she gets bored quickly and that boredom could be a stumbling block for her to continue with clinical research.

"…one of my friends was working here and there was a position open…and I didn't wanna work in casualty so I was like okay, I'll come. I…one, liked the sort of structure of it that everything is quite controlled…um, so that's…that…that sort of suits my personality quite a lot. I'm quite an academic person. I wasn't really sure exactly what I was getting myself into when I…worked as a medical officer

in research the first time around…and then I went to do my specialisation…in psychiatry" Sarah.

"I think it's more suited to my personality as well…where I have a bit of OCD, you would say. The first thing, I think, is all about personality. That's one of the main things…if you don't like this kind of work, you never going to last in it" Jeff.

"I think I have a bit of an OCD personality…to some extent for certain things. So, I think it was the team, basically, around me and also just sort of my OCD type" Arthur.

"If you are an analytical person…and especially if you…love public health, you would enjoy the research" Robin.

"I might get a bit bored. I...don't know yet" Meagan

c. Stepping-stone

Stepping stones denote something that helps one to advance or achieve something (Dictionary by Merriam-Webster online 1996, vs "stepping-stone"). Making a choice to use clinical research as a stepping-stone rang true for some participants. The scarcity and availability of registrar posts for newly qualified doctors "forced" some of these newly qualified doctors to follow other avenues during the time they waited to be chosen for specialisation. Jeff thought that it would be a temporary job until he has decided what to do with his career. Since Jeff started in clinical research, he saw several of his friends also biding time in clinical research. Joslyn and Meagan also heard about doctors who were just using it as a stepping-stone in their career path. Veronica could not get a registrar post when she qualified as a doctor because she did not have South African citizenship at that time, and Samantha made a choice to go into clinical research after she qualified as a doctor and realised that the dream she had to become a consultant at the age of thirty would not materialise because of the scarcity in registrar posts. Meagan did not mention that she chose clinical trials as a stepping-stone, but she decided on clinical trials because it suited her lifestyle at that stage.

"…in fact...I thought this was gonna be...be a temporary thing...for a year and then I'll probably end up, uh, you know either working in...as a GP or trying to specialise in something else" Jeff.

"I've had since I started here...a lot of friends come and go...and most of them were here for, like, a year or two...and yeah they...it's almost if they feel like it's just a stepping stone to something...else...instead of being a permanent sort of job...and I think that the main attitude that people...to research...with. It's like, o, no…I'm gonna be here for a year or so and then...find what's my next thing to do" Jeff.

"I heard at conferences some people see this as a temporary kind of…stepping stone. They don't know what to do with their life so they see it as an easy job and that is not the kind of thing that you need in clinical trials…because it takes so much effort just to get someone...passed by ethics" Joslyn.

"I think...what I've seen are, people use trials as a sort of...an interim step. So...either they wait for a reg post because job are getting frozen in government...so then they sort of, in the meantime, do trials. I don't know how you would get around that" Meagan.

"I love internal medicine…because I'm not a South African, I never managed to get a reg post, I got permanent residency only last year but then I had a baby, having a baby and work is not easy so I decided to make strategic choice" Veronica.

"For most of us it was a dream or goal in university to be a consultant at the age of thirty...but when you finish community service and you realise there are no jobs, not as a registrar for a few years. So it's either you wait in government to get an internship, that could take a long time to eventually become a consultant and end up having children while you are doing calls and work terrible hours or you take a job where you have a better lifestyle" Samantha.

"Look, I have a young family so...as a working mom...who is...really enjoys the flexi hours because I do work a pos...which I think trials kind of enable you to do

that...it's really great. So there is not as much stress associated. At this stage it's ideal. I might get a bit bored. I...don't know yet" Meagan.

3.3.1.2 Readiness related to knowledge, skills and experience of clinical research

Readiness refers to a state of being or feeling prepared for a task (Oxford English Living Dictionaries online 1992, vs "readiness"). A lack of exposure, limited knowledge of clinical research and insufficient interpersonal or soft skills among young doctors are often the reality of the situation. Not knowing where they were going in the maze, participants in the current study encountered a number of challenges.

a.   Challenges experienced

Most participants felt strongly that they entered clinical research completely underprepared; it was like entering the field as a blank slate, making it extremely hard to cope, and resulting in high levels of frustration.

Being underprepared refers to a situation where a person is inadequately prepared for that situation (Dictionary by Merriam-Webster online 1996, vs "underprepared"). The lack of preparation of medical doctors for clinical research during their training, created a situation, as expressed by Samantha and Veronica, where they did not realise that clinical research was an option as a career. For those who got a job in clinical research by "accident" it was not what they expected and they felt completely underprepared. Jacky felt that she was not qualified by training to do clinical research and was surprised to be employed as sub-investigator. Sarah compared it to being asked to do something, like mathematics, without being taught how to do it. Tammy and Jeff felt they were not made ready or prepared for the modus operandi in clinical research, and they had to learn how to follow different processes such as writing clinical notes and following a protocol.

> *"I actually didn't know that was an option…because no-one actually teaches us about research…you know, and I spoke to a lot of my friends who studied at different universities…and none of them got experience in...research. At university no-one tells you...you can actually do research...only find out when you're done with community service, if you knew before then...you had an*

interest...you could've probably looked into doing...the things beforehand…and I only stumbled across when I...was looking for a job...that there was actually research posts. Otherwise, I would never have thought about it" Samantha.

"We just hear about the studies. Actually, we hate reading…journals because it seems like extra work on top of what you doing. So, coming into it, our expectations were...I think what lots of people, were like I never thought you'd go into research because we have an idea that we don't see patients in research 'cause we think research calls lab work or experiments so most students think that's what research is about" Veronica.

"Cause I remember I was like I'm not even qualified. I don't have a masters in public health or three years of experience in...research. So, it was quite a big shock...for me to be accepted and...and not know anything at all" Jacky.

"Well, just a little bit more of, like, oh, what am I supposed to be doing? How do I do this? Like literally - I feel like… you know, I've been asked to do maths and…no-one's ever taught me maths...before" Sarah.

"Also, the way how to write clinical notes for clinical trials, it's totally different. It's totally different, I had to learn how to do things" Tammy.

"No, definitely not…it was absolutely new for me. I'd never come across anything...like research before. So, it was a big difference, a big change, following protocols and SOPs" Jeff.

Being underprepared and starting with a clean slate goes hand-in-hand, but they are not referring to the same concept. As mentioned, being underprepared means that undergraduate medical students are not sufficiently prepared (Oxford English Living dictionaries online 1992, vs "underprepared") or they are inadequately prepared (Dictionary by Merriam-Webster online 1996, vs "underprepared") to fulfil tasks in clinical research. Starting with a clean slate means that newly qualified doctors are entering clinical research without any existing restraints or commitments. They are starting clinical research without any past experience that might influence them in carrying out their current new tasks (Cambridge Dictionary online 1995, vs "clean

slate"). In the current study, both concepts were applicable to some participants; they were underprepared and felt they started clinical research with a clean slate. It is not clear if those participants who only mentioned that they started clinical research with a clean slate actually meant that they were underprepared. It is a point for further investigation.

The fact that early career investigators cannot rely on their existing knowledge, experience and skills, free them from restraints holding them back to make a completely new start in clinical trials. Early career investigators started clinical research with a clean record and as Joslyn mentioned, it was almost like starting with a "blank slate" and he could fill the "blank" with information on clinical research. Participants had different expressions for relating their experience with having no knowledge and being open to learn about clinical research. Reba said she did not "know" research because she did not have basic knowledge about research. Jacky felt that discussions at work were going over her head because she did not understand the clinical research language. Arthur saw himself as "fresh", while Robin admitted that she was open to learn about clinical research and she also knew about a colleague who had started "fresh".

> *"Um, I guess I had no expectations of…of what a…cause I had…I had no preconceived notions of...what it was gonna be because I had no exposure to it. So I kind of came, almost like a blank slate. I was a blank slate and they could teach me about…clinical trials"* Joslyn.

> *"You're coming in, you're a specialist...you should know everything...but you don't know research"* Reba.

> *"I know the first four months, everything was just...just you know, going past my face and I was like...I don't understand what they saying"* Jacky.

> *"I mean, I was, you know, fresh"* Arthur.

> *"I was actually opened for…I'm like, I want to...I want to come back but I'm also more willing now to learn things in terms of, um the application, the protocol, you know, not just implementing and not just...seeing participants"* Robin.

"An ex-colleague...who was...I think one of the things with him, he started out fresh and, for him, um, one of the...one of the things that he said was he wished that he...the PI had actually given more guidance...from the go" Robin.

Unable to cope with the situation, Allie made the choice to resign from clinical research. After a few months, she realised that it was what she wanted to do and she returned to clinical research. The change in environment, for most early career investigators from a hospital to a clinical research site, held various new expectations and responsibilities. Sarah found the transition very hard. For Jacky, some of these expectations and responsibilities were overwhelming; it caused her tremendous stress when she was expected to "know" everything. Joslyn struggled to cope with all the paperwork and interpersonal conflict. In other words, participants struggled to face and deal with responsibilities, difficult situations, and problems in a successful or adequate manner (Dictionary.com 2018 vs "cope").

"It was very challenging at first because I was placed on multiple studies…so I found it extremely difficult to cope. So then I did eventually end up leaving" Allie.

"To be honest, it was a very nice kind of transition from… what I had been doing but, in some ways, it was also quite hard…cause I was used to that kind of fast placed sort of, you know, emergencies, do everything yourself…have no supervision" Sarah.

"So I'll make a few mistakes, with investigators, they were expected to know everything...and that was also a little bit overwhelming where I found, it's not just a nurse who's asking me something, the study coordinator, the lab would ask me things, and I'd be like I'm not sure? Is it okay? like, I felt scared. Do I... should I know this, uh, off by heart? So it's always a bit scary when they ask and you're expected to just know the answer. Very stressed out" Jacky.

"There's a lot more paperwork, that was a bit of a struggle 'cause I'm not use to paperwork. Another challenge I found is the interpersonal conflict. Different personalities you know, which is the one thing I didn't really expect" Joslyn.

Other challenges participants encountered were the frustration and restlessness they felt while waiting to be approved to work on studies, the frustration of not being sure what was expected of them, and the challenge of being in an environment that was completely different from what they previously experienced in a hospital set-up. Jacky, Jeff and Vernon found they were wasting time while waiting to work on clinical trials and it was something they were not prepared for. It was also in contrast to the environment they were used to where previously they had made an immediate difference and where time was crucial and never enough. The difference in processes, procedures and methods were significant challenges for Jeff, Tammy, Donald and Samantha. They had to get used to performing their daily duties in a different way. Some of these challenges where frustrating, according to Reba, Veronica, Donald and Meagan (frustration is the sense of dissatisfaction, an irritation arising from unresolved problems, unfulfilled needs or the inability to change or achieve something [Dictionary by Merriam-Webster online 1996, vs "frustration]). Frustration was expressed by Reba because she felt she did not know if she was coming or going. Consulting my field notes, I found that I reflected on how Reba's body language and tone of voice also expressed her feelings of frustration and anger. Veronica and Meagan had frustration around the paperwork, and Donald was frustrated by all the rules and boundaries he had to follow and abide by. Samantha expressed her frustration by wondering who will benefit from all her hard work, but her biggest challenge was the fact that she was the only doctor (early career investigator) at the site and needed to run several clinical trials. Once again, my field notes described Samantha's whole demeaner of frustration and even some hopelessness in the tone of her voice. Challenges and frustration in some instances were running hand-in-hand in the current study.

> "But I think in the early stages, while I was still sort of waiting to actually work on some of the studies...I was getting a bit restless and I even discussed this with my mom. I'm like I don't...really know what I'm doing...here, I don't feel like I'm doing anything. I'm wasting time. I'm always sitting at a computer and reading all the time" Jacky.

> "...and just the process involved and the attention to detail that, you need to have, there was a big challenge...to get used to initially and then, the other thing would be ethics approvals as well, those takes ages. So you sit with a study wanting to get going and...it just doesn't start" Jeff.

"The next challenge when I started is to wait for approvals to work on the studies, it was something I didn't know about – the waiting period...everywhere else that we've been employed so far…day one, you start working" Vernon.

"Also the way how to write clinical notes for clinical trials, it's totally different. It's totally different, I had to learn how to do things" Tammy.

"The challenge for me would be, research itself, like I was saying earlier, it very detail-orientated…so the challenge would be that" Donald.

"So the first challenge was learning about the documentation, the documentation is very different from what you would write in government. The second thing, especially in this site…for me, was that I'm the only doctor here…and we now have six studies...and it's very stressful. That, for me, was the biggest challenge because how do you then...stay here knowing you're the only person? and they got more and more studies but there's very little help. And if there is no help that comes soon, I don't know how long I can do this…for. I'm not saying I'm lazy...or anything. I'm doing a lot here...and I'm not going to do more if I'm not going to be recognised...for it, I think that's fair. If you have only one clinician...you should support the person...and do everything you can...to prevent them from leaving...but I don't feel that's happening. I feel like I'm just being told to do more...but no one is helping" Samantha.

"…its frustration if I don't know whether I'm coming or going. I don't know what's expected of me. Then by the end of the first year, you really frustrated...thinking should I stay or...should I leave? So people do love research...and it is just that, because we don't know what we doing...that we get frustrated...then leave" Reba.

"To change from being mostly clinical to now having to fill papers and photocopying, it was quite frustrating...at the beginning" Veronica.

"If you are not comfortable with working according to rules and working according to boundaries or in...doing things just specifically...every time, every day, a

certain way, then you might get frustrated, ja, then you can be very frustrating. There was initial frustration for me, I would say" Donald.

"Okay, I think you are initially very overwhelmed by…al the paperwork…and there are still processes that are not horribly clear…so that does get a bit frustrating" Meagan.

"…but being here and just doing research and not knowing how it's...helping isn't very nice...because...you think, I'm doing all this work but...who is it benefiting?" Samantha

"but also a little bit like, oh well, I don't really have any kind of say as such cause I kind of have to just follow this...process. and then having to do all the QCs was really awful. So...yes, it drove me up the wall. I mean, ...and again, you don't have the bigger picture…of like, you know, the...data and what its gonna do if you don't do that...it, like...you just find it...frustrating. I was here for 18 months before I went to specialise" Sarah.

3.3.2   Exploring the maze to find a way into the labyrinth

The metaphor of the labyrinth with its difficult, winding passages and mythic Minotaur, half human, half beast, encapsulates the experiences of early career investigators moving from the maze they experienced when they started their journey to finding their way in clinical research. During this process, they looked to find a way through the maze to reach the daylight and for a point where they knew their experience of the maze had ended (Dockendorf 1980:144). Some of these ways included a supportive environment with shadowing, mentoring, on-the-job training, courses and training programmes, exposure to experienced and skilled investigators, and teamwork. Hearing and listening to the participants' experience of the first part of their journey, left me with an impression of hardship and extreme challenges. As participants started sharing their experience with exploring the maze to find a way into the labyrinth, I could sense a change in the way they felt. It seems that the different support systems gave them a more positive attitude towards their experience.

3.3.2.1 Supportive environment

Hahn (2013:4964) gives a description of the "Paralyzed Academic Investigator's Disease Syndrome" or PAIDS, described initially by Dr Joseph Goldstein, in which someone does not receive the necessary support to move beyond a first observation to create a career. Support needed and identified by the early career investigators in the current study included shadowing, mentoring, on-the-job training, courses and training programmes, exposure to experienced and skilled investigators, and teamwork.

a.   Shadowing

McDonald (2005:4) describes shadowing as a process or research technique in which a person (or researcher) will closely follow a member of an organisation over an extended period of time. Veronica, Reba, Joslyn, Meagan, Arthur and Jeff found that a good way of learning how to do clinical research was to shadow experienced staff. Shadowing was done mainly by observing how experienced investigators were doing clinical research. Joslyn said she felt like a student who was following her principle investigator to the clinic, doing nothing but observing. Meagan mentioned that although shadowing could become boring, it can be supported by online courses. Listening to Meagan it seemed that the boring part could initiate the benefit of exploring some additional knowledge. From her experience, Reba advised shadowing should be part of a training programme for new investigators.

> *"I think what helped me most was sitting in with the doctors…who were seeing patients and seeing how they were filling the forms and randomising the patients…I think observing is the best way of learning"* Veronica.

> *"The other option would be to shadow…while waiting…but to shadow the ones that are already involved in clinical trials and who knows their stuff. Shadow in the morning and maybe the programme can be in the afternoon for the training or teaching"* Reba.

> *"The first few months…I wasn't doing anything. So I was following the PI to the clinic. Almost like being a student again. So I actually had a good amount of time*

where I got to learn and I got to just observe what...he does...and how they do it....and so they helped me" Joslyn.

"I think shadowing other clinical doctors gets quite boring after a while. So...I don't think you need to...do lots of that. So I think there's some good e-learning courses. So things like that...go through the doctors' course or...just actually just up, not wasting...that time...but at least...updating your knowledge...on HIV or whatever...trial you're involved in" Meagan.

"Most of the staff had been here for a while…and were able to show me what…needs to be done. So that was a big help. Learning from everyone and seeing how things are done" Jeff.

b.   Mentoring

"Mentoring is to support and encourage people to manage their own learning in order that they may maximise their potential, develop their skills, improve their performance and become the person they want to be" (Parsloe 2018:1). Jeff, Vernon, Robin and Joslyn indicated that mentoring, specifically from their supervisors, meant a great deal to them and without that support they might not have made it. Jeff appreciated the good relationship he had with his boss and the fact that he could approach him at any time with questions. For Vernon it was important that he received guidance from someone who went through the same process and knows how it is in the beginning. However, it seemed that mentoring was not always part of a supervisor's training methods; Robin had to ask her PI to mentor her. Joslyn felt strongly that a mentor should be an experienced person.

"… and obviously, my boss. I mean…he was the biggest support…through the whole process. So he basically showed me everything. I mean, we had this relationship where I could just go up to him and ask him, like how do you do this? That's what got me through the first year" Jeff.

"I would have been lost if I was here without that support, so having had someone there to kind of...just help you through the beginning stages...'cause I suspect that with...time, your...experience just gets much easier. That's been

really helpful to have someone who knows...who's been there and...can kind of guide you…through the problems you're likely...to encounter" Vernon.

"I did ask...to be involved. I actually told...I told my PI I want her to sort of mentor me...that's what I said to her, that I want to you to...so she's been doing that" Robin.

"My experience has been very good, I've had a lot of support, if you speak to a sub-investigator who was alone in the clinic somewhere they might give you...a complete different story. Even if they are alone at a site, send an experience investigator to help them for the first...two weeks or first three weeks. Ease them into it. They could observe what you're doing. So I think slowly...introduce someone slowly...not just start" Joslyn.

c.   On-the-job training

Jacobs and Bu-Rahmah (2012:75) describe structured on-the-job training (S-OJT) as a planned "process of having experienced employees train novice employees on units of work in the actual work setting". The experience of being trained on the job was found to be the best kind of support for Allie, Tammy and Robin. It gave them the opportunity to ask questions and to practise what they had been taught. Jacky mentioned that without the practical part to back-up her reading, her reading felt empty. Joslyn made her experience very practical by using a mock file to practice with before she saw her first research participants.

"I think the best way to learn something is to…learn it on the job" Allie.

"It is to listen, listen and listen. I listen to other people's experiences and how they overcome that experiences. And you can ask questions if…you are not sure…I don't understand…so interaction…and practical work, practicing and practicing and while you are practising you need support" Tammy.

"The QC person can also help with one-on-one corrective action-...to say this is how it should be done. Yes, you've been to GCP but a lot of the stuff, until you've

actually doing the practical, does not get...answered...um, until you are here and then that...helps you" Robin.

"Because I started in the middle, you sort of...doing a lot of self…reading on your own…and, as much as somebody can explain it, without actually doing it, it…feels very empty. It feels like empty reading." Jacky.

"Also what helped me, I asked for a mock file for one of the studies...so I could kind of go through it before I actually...saw the patient...so I knew what to expect" Joslyn.

d.   Courses and training programmes

As expected, most participants valued courses and any kind of training as very supportive and beneficial during the first few months. They commented that it gave them some basic understanding of clinical trials and it guided them on how to do things the correct way. A training programme is typically associated with a long-term training activity which includes a series of courses, and it is usually flexible in time and cost (Business Dictionary online 2008, vs "training programme"). Sarah felt it was important to have further training beyond medical training and therefore valued the Good Clinical Practice (GCP) course she had to do. Tammy agreed that it helped to get a good understanding of what clinical trials are about. Joslyn was privileged to have the opportunity to attend training courses as she needed. Jacky mentioned that she even received training at conferences she attended, and Samantha learned more about the bigger picture by attending available training.

"So I think…you do need further training from your medical training. In my specialisation, I had to do an Mmed, so masters in medicine…and so I had to do a whole research project. So I learnt a lot of skills…from just doing that and that was part of my degree" Sarah.

"…you first sort of go on the GCP course and you've…like, properly get onto the research and then, once you on it, then it takes a while to kind of learn the whole process and stuff" Sarah.

"When I came here they send me for training…which helped me to understand what is a clinical trial and how to do things in a correct way. GCP training, which really give me...what? Overall view...of clinical trials...which really really helps me..." Tammy.

"The other thing was the trainings that we do. I was send on GCP but whatever training I requested, I was sent for" Joslyn.

"but just working alongside with them, going for the training. We actually go for training at conferences" Jacky.

"It was very nice, I had the opportunity to go for training…when I went to that training, it actually helped you see all the data collected from the different points...and formulated into one thing. It shows you what the outcome was. It's encouraging to know you make a difference" Samantha.

e. Exposure to experienced and skilled investigators

Exposure to experienced and skilled staff and mentoring are related but different concepts. Experienced and skilled staff are staff who are wise and skilful in clinical research because they have mastered clinical trials through their own process of personally observing, encountering or undergoing the experience of doing clinical trials over a period of time (Business Dictionary online 2008, vs "experienced and skilled"). It would include the totality of the cognitions given by perception; all that is perceived, understood and remembered by a person doing clinical trials (dictionary.com 2018, vs "experienced, skilled staff"). On the other hand, mentoring means that a person (mentee or junior) is assigned to receive counselling, advice, guidance or teaching from a wise and trusted counsellor, teacher, or senior and more experienced individual (mentor). The mentor is responsible for providing support to and feedback on the mentee (Business Dictionary online 2008, vs "mentoring").

Several participants agreed that a nurturing environment in the "neonatal" phase of their career as investigators helped them, especially because the nurturing environment was created by experienced and skilled staff, willing to give the necessary support. Vernon appreciated experienced staff who informed him of possible challenges he might

encounter and their suggestions on how to circumnavigate it. Arthur's supervisor had a lot of practical knowledge that he shared with Arthur. Assistance from her PI meant a lot to Tammy, and Robin was shown the ropes by another doctor and her PI. Robin emphasised that guidance from an experienced sub-investigator and the PI is vital in the beginning when you have only the theory of the GCP course and you still need the practical experience. Samantha was fortunate to receive training from an experienced sub-investigator before the sub-investigator resigned. Staff with different kinds of research experience contributed to Vernon's experience of support and he was therefore able to become knowledgeable about different areas of clinical research.

> *"There's a lot of experienced staff here and they know the things new investigators would have challenges with, so they do their best to…come inform you of the challenges that you're likely to…face, the obstacles you're likely to encounter...and to suggest or put forward suggestions of how you can circumnavigate those or make it work through them and...there's a lot of support from the staff. I quite appreciate that and the experience from all the sub-investigators"* Vernon.

> *"I was very lucky to have a very good supervisor. He did quite a lot of research, so he had a lot of practical knowledge*" Arthur.

> *"So I always have support from him (PI). At any time he can support me because it's...it's a very little bit daunting, things because I know that we can't make mistakes...at all. So he assists me and the team…"* Tammy.

> *"What helped me a lot was that…that the doctor then...she was open to showing me what needs to be done, um, also the PI was you know, so I think maybe that...few...a month or...two, you just need someone to actually hold your hand to...guide you through the process...and understanding sort of the systems, understanding sort of, um why...the reporting lines...understanding the organogram..."* Robin.

> *"So its...either the PI or another sub-investigator who is experienced...to actually guide you through some things"* Robin.

"When I came there was another doctor with experience and she teached me and then she resigned" Samantha.

"People who have been involved in research like this…for the past two years…are very good with clinical information and with…things that are relevant to this study…but people who are involved in research in general (clinical trials and observational studies) for many many years have got, skills and other...they aid your learning...in other aspects...not clinical information, per se, but with a lot of the technical details and with, discussions with pharmacy and the laboratory and other things like that ...and raising concerns in that regard...and the study group and that you plan and...other things. So each person whose research experienced...contributes in...in their own-...respectable...ways" Vernon.

f. Teamwork

An uncomplicated way to describe teamwork is to call it the willingness of a group of people to work together to achieve a common aim (Dictionary.com online 2018, vs "teamwork"). To make the description of teamwork more complicated, it could also be seen as a group of people working together cohesively towards a common goal, creating a positive working atmosphere and supporting each other to combine individual strengths to enhance team performance (Dictionary by Merriam-Webster online 1996, vs "teamwork"). A team assisting in the need for support were of great value to many participants at the clinical research sites. The support participants received from different team members varied from basic procedures such as completing documents, to more complicated clinical trial procedures. Veronica was assisted in learning all the different documents to be used, while Tammy got answers from the team when she could not find it in the protocol. Arthur felt the team directed him on his way and Meagan experienced the support of team members who pulled their weight within the team and who knew their roles and responsibilities within the team. Arthur and Joslyn felt it was worthwhile to partner with all team members, including the study coordinator, study nurses, and the quality control officer because they were the members who knew the detail of how certain things should happen during a clinical trial.

"...so there was a good team around that...that helped to kinda just, you know, point me in the right directions...and stuff" Arthur*.*

"To change from being mostly clinical to now having to fill papers and photocopying, it was quite frustrating...at the beginning but everyone has been really helpful the whole team" Veronica.

"We have a really nice team. So the…things are really important for…an I don't mind working hard…but I like having a good team…that everyone pulls their weight...this is a very good team. There's a lot of support, there's also just…seems to be, like everyone's got a allocated role which is...quite nice" Meagan.

"Our study coordinator have been...invaluable. They know so much...and little things, you know, maybe the investigators would think that I know...but they, the study coordinator, would guide me. So everyone, actually helped me...along the way. it was everyone even the nursing staff in the clinic" Joslyn.

"if I can't remember and have a patient with a problem. Everything is not always in the book or protocol then I have to ask the team for example how to complete a form for a patient visit" Tammy.

"Partner quite closely with the QC officers...and the nursing staff that are already on the...study. Don't be afraid to ask anything 'cause...they know the answers. Um, I think that's where you get a lot of support. If the PI is busy there always somebody...who knows. Don't underestimate anybody because of their...their ranking or whatever. Don't think that you are better than a QA officer. You're not" Arthur.

3.3.3   Discoveries while walking the labyrinth

The processes and structure for early career investigators to do clinical trials were developed over time and through their "lived experiences" of doing clinical research. The processes were invariably rethought, reshaped, and recreated as early career investigators travelled through the passageways of the labyrinth (Dockendorf 1980:143).

3.3.3.1 The nature of clinical research

Finding a description of what is meant by the "nature" of clinical research in the literature is not easy. There are numerous definitions of what clinical research is. The NIH National Institute Dictionary of Cancer Terms define clinical research as the study of people or the data of people or samples of tissue from people, to help understand health and diseases. Clinical research aims to find new and better ways to detect, diagnose, treat and prevent disease (NIH 2014). A clinical trial is a type of clinical research designed to answer specific questions about possible new treatments or new ways of using existing treatments. Clinical trials are conducted to determine if the new drugs and treatments are safe and effective (NIH 2014).

While walking the labyrinth, especially during the implementation phase of clinical trials, participants in the current study discovered that the nature of clinical research (for them) was related to mundane work, and it was a long process without instant gratification. Participants also found their need for growth in responsibility, authority and leadership, and the need for more exposure to build good clinical trial skills.

a.   Mundane work

Mundane work could be described as work that is dull, and lacking excitement and interest (Oxford English Living Dictionaries online 1992, vs "mundane"). Tammy, Samantha and Meagan feared that they might become bored in future with clinical research because there is not a lot of stimulation in clinical research. A large part of clinical trial work involves meticulous paperwork and seeing participants for scheduled trial visits. It is the same routine over and over, day after day. Donald plainly said it is mundane, rote work, nothing exciting to stimulate the brain. I noted in my field notes that Donald was very adamant about the nature of clinical research work.

> "*So here's not that hands-on action. It's more paperwork, you must concentrate on that and you must be very thorough. So you need to love it, otherwise you will get bored and leave"* Tammy*.*

> "*…on a regular basis, you're often faced with fairly mundane and...fairly rote...work. There's nothing exciting about asking the same questions, you are*

asking the same questions over and over again. It's very rote, because the work itself...the questions are so...the thing...the whole process is so rote...and so mundane, it feels like forever..." Donald.

"...And you're stuck here for the whole day and see participants and you have no other stimulation and if you don't stimulate your brain you're going to get bored...in your job" Samantha*.*

"At this stage its ideal. I might get a bit bored. I...don't know yet. So I think, for me, but this is my personality…'cause I…I do get bored seeing patients. I need something a bit more…stimulating" Meagan.

b.   It is a process and it takes time/no instant gratification

The nature of the process of clinical research had an unmistakable effect on some participants. The 'process' of clinical research can be seen as certain actions or steps participants had to take in order to get to the end of their clinical research study and there were no instant or quick pleasures or rewards during this process (Oxford English Living Dictionaries online 1992, vs "instant gratification"). Samantha felt discouraged by the fact that she might not be part of writing up and publishing the results of the studies she had worked on. Arthur commented on the fact that there is not the same kind of motivation in clinical research as in a hospital situation where he would treat a patient and see the patient recover in a short period of time. According to Arthur, you can motivate yourself by keeping in mind that you are doing it for future generations. Donald and Joslyn mentioned that in clinical research you do not get an immediate sense of fulfilment; there is no instant gratification. Sarah said it is a process, a long road, full of hard work and you could become unmotivated when you decide to do clinical research. Tammy pointed out that young people want to see quick results and that is not possible in clinical trials.

"What's discouraging is knowing you're just doing this and then someone else is formulating a study but you don't know the real results until it is published often then by someone else" Samantha.

"So, you know, motivation-wise...you know, when you go the hospital and you treat a patient and they get better...you know, there's a...little bit of motivation...that comes...with that but not so much here. So there's a bigger...sort of long-term reward, but nothing sort of instantly" Arthur.

"…here is not a lot of...necessarily a lot of personal...sense of achievement because you're not gonna be the person that's going to analyse those results. You're kinda at the bottom of the spectrum...saying I got…I done...now see what you can do with this, so you try to keep that big picture mind...but that...the results are gonna come back to you months down the line...if not years...once you're already started a new project and a new project and a new project. So that immediate sense of fulfilment isn't there all the time, isn't a regular feature" Donald.

"…and I really...I do get satisfaction. Not immediately because we don't see...results...but satisfaction in terms of I know...I'm giving better patient care" Joslyn.

"…And ja, I think it's just, patients with a transition and also…that mind shift that need to happen...that what you're doing now is for the benefit of future generations...you might not see a reward immediately. Don't be too hard on yourself. Just take it...take it easy, take it slow and...try and figure things out" Arthur.

"It's a really satisfying process…because it's a long-term thing. So there's no instant gratification…from doing research…you know, it was a lot of hard work and…you know it…at some point, you felt quite unmotivated by the whole thing, you were like, oh, do I have to look at this thing again? But...but...which I think is part of the process...when the results come in...you were like, oh, my word, that thing that I thought was gonna...be the case is actually there" Sarah.

"It's a long road. In the beginning I thought, well, you just go into research and you become a researcher…like you could just become a researcher…and publish something. So…it obvious isn't, and…you have to learn all those steps

because it helps you to do it better, and...ja, so I think that it's just that it's a learning process and it...it is quite a long road" Sarah*.*

"Young people also want to see quick results and that is not possible in clinical trials" Tammy*.*

3.3.3.2 Personal desires, growth and exposure

While walking the labyrinth, early career investigators became aware of their own desires related to their personal and work environments. They discovered their need for growth and a desire to develop skills to become excellent in clinical research.

a.   Increased responsibility, authority and leadership

Responsibility, authority and leadership meant that participants would be held accountable for procedures within their power, control or management (Dictionary.com online 2018, vs "responsibility, authority"). They would have the power or right to give orders, make decisions, and enforce obedience (Oxford English Living Dictionary online vs "leadership"), and they would be able to develop the art of motivating colleagues to work towards achieving the goals of the clinical research study (Dictionary.com online 2018, vs "leadership"). Participants expressed the need to increase, and in some instances, to develop their current responsibility, authority and leadership.

Donald felt that the clinical research environment is not one in which there is a lot of growth opportunities and unless it fits in with your lifestyle and your choice, it could become very frustrating. Allie was working towards a title that would hopefully give her more authority to initiate change in the research unit. Allie was also excited by the opportunity to start writing a protocol and articles; she felt she was finally being exposed to things that really interest her. Writing proposals and articles helped Sarah to be part of the bigger picture and to steer research. For Arthur's growth it was important that his seniors and boss gained trust in him to give him more responsibilities, especially some responsibilities to coordinate aspects of a new study. The responsibilities that were given to Jeff motivated him to do even better. Jeff was allowed to work with the sponsor, giving him the feeling that it was his study. He was of the opinion that some of his colleagues left clinical trials because they were not given the opportunity to do their own

thing and they felt they were micromanaged. Meagan wanted to be challenged by being more involved in the clinical research process, for example, writing standard operating procedures (SOPs), instead of just seeing patients and doing a lot of administrative work.

"So the environment itself is not necessarily a big growth one...because it's becoming more challenging...for organisations…and if they can't have that opportunity to learn more and grow more...at some point they're gonna get frustrated, unless...of course, it fits in with...their lifestyle and they've made that decision, okay...this is not my personality but it fits in with my...lifestyle and I'm not looking for career growth...then it's fine" Donald.

"So I think, um, I unofficially, I have taken on a leadership role but, um, in terms of …sometimes you would like a title…you know, but…a…a title sometimes allows you to do things and to effect changes that you wouldn't be able to do. I think I have to work to...and, hopefully...I will...uh, people will recognise it and then award me with that title or that authority, and I think will assist me in effecting more changes" Allie.

"Um, first of all, the workload was manageable…I was allowed to get into other aspects of research…was allowed to start writing protocols and things that I was actually interested in, it was great doing that…the experience, than just mundane clinical work. I get very excited with publications…enjoyed writing as well" Allie.

"Writing proposals and...research and articles...do something a bit different from what your sort of day-to-day job as a doctor is...in our country, it feels like you can kind of do even more...for more people. So now that you're involved in the bigger picture... you kind of get to direct that bigger picture towards...this a problem. So, going away and coming back made it probably a little bit easier to...take the next step in research" Sarah.

"You sort of have to get, um, input from those above you to sort of invest in you…to teach you things…and then also trust you enough to give you...you know, responsibilities and that kind of stuff. So maybe when there's a new study...they'll say, okay, in addition to doing this, we'll let you coordinate

these...and these and...these sections or whatever so that you can kinda grow and get used to the ...the feel. It has to be a top-down thing, unfortunately" Arthur.

"Well, for me, one of the main things that made me stay was also that, um, I was allowed to interact with the sponsors, and you know, basically, I was running the study. There was no interference, so I felt almost as if, it was my study...and I felt responsible for it. So with the people that have left, I know they were not given that kind of responsibility. It was basically they were always...always someone looking over them, always telling them what to do and I think might have been a big thing that put pressure on them to leave. And another thing is that, like I said, maybe it wasn't just...it wasn't them having the mind-set to stay...and push through it. But I think the big factor is that the more responsibility you have...the more you'd want to...do your best...and then you'd try to excel in it" Jeff.

"So it's just to be more involved in the process itself. So developing the SOPs…or even the write-up or…so, in the actually trial...administration...I think that will make it a bit more challenging...so be involved in the process...which I think some of your senior researchers...would be...probably are. That could be why they stay. Otherwise, literally, all you doing is just...you just doing a lot of administration, seeing patients. It's not...always the most challenging" Meagan.

b. Skills

Boulet (2015) described skills as the ability to apply knowledge (information acquired through sensory input: reading, watching, listening and touching) to specific situations, and skills are developed through practice. The lack of skills and the need to gain skills through practice was verbalised by participants. Although Reba trained as a specialist (paediatrician), she did not know how to do research. She depended on her colleagues to show her the 'how' of clinical research. Reba felt that the waiting period to get Ethics and MCC approval could have been used to build the necessary skills she needed to be an investigator. Robin felt it was good to learn more skills, extending the boundaries of implementing the protocol and seeing participants, to prepare her for future responsibilities. According to Robin, it is necessary to verbalise one's learning needs. Exposure to new procedures and information such as writing, presenting and media

interaction, and being able to learn these skills, are some of the learning needs Veronica had. Jeff felt that his biggest stepping-stone in growth would be to learn how to write grants. Samantha would like to get back some experience for all her hard work at the research site. It is very similar for Vernon, who wanted as much experience in clinical (trials) research as possible.

"My responsibilities went up as a specialist but I found that I got very frustrated...by the fact that I depend on my colleagues to…teach me research. You're coming in, you're a specialist...you should know everything...but you don't know research and so I just...I also felt like I...like, there's a waiting process...you wait to get approval for things...yes, you do general stuff, but that waiting process can be used to prepare a person to be a investigator. If you use the time to prepare...a person, sort of, by the time they become sub-investigators...they already know...what it is all about" Reba*.*

"…but I'm also more willing now to learn things in terms of, um the application, the protocol, you know, not just implementing and not just...seeing participants...but also the ethics submissions and...so that's actually what I'm doing now as...I'm exposed more to seeing the submissions. So I think before, it was sort more just up to the PI. So, in a sense, I've gotten a bit more responsibility with some of the...studies here. So, in that sense, I'm not PI but I...sort of have some of that roles which maybe will prepare me for something...like that in the future. At the end of the day you are making a contribution like the participants. It requires you to be accurate. Ask to be able to learn more...have patience...Let them know what your needs are and what you want to know" Robin*.*

"So, it's not something that...but ja, writing, presenting...and media interaction cause...that are the two areas...that I would like to also be mentored in...or get exposure to...to say. I would also like to know how do you become a PI? What do I still need to learn or what other qualifications do I need? Also more about grant applications, I think we need to be exposed to those things…to understand the financial aspects of it" Veronica.

"…the next plan is to start writing grants and…some publications. I think that's my main focus…at the moment to get some publications out…and sort of build up a nice CV and, we see from there, I don't have many other plans for now. Writing grants is a big challenge because that's actually a big stepping stone then also because you will grow...in writing those big grants" Jeff.

"So it makes you a bit worried that you spend so much time of what you have back from it...and that's what I took from her story...if I am going to be here for a certain amount of time...I want to walk away having learnt a lesson...or learnt something important. Even if I don't publish or anything like that, it's just learning something that you can take forward...as an experience" Samantha.

"So, in clinical trials. This is where I have started so I'd like to get as much experience as I can…in clinical trials. As time goes by I'll pick up interests here and there…and see…where it go…I like to notice trends, I like to ask questions…and how trends came about and its definitely related to clinical medicine but it could be anything, it doesn't have to be clinical trials. I can see myself writing a protocol to solve a problem" Vernon.

3.3.4   Moving beyond the centre - Quo Vadis?

Early career investigators have examined uncertainties, problems, tensions and confusions within the labyrinth passages in search of the centre of the maze. It was a process of continuous struggling with the messiness of the maze, of discovering the secrets of the labyrinth to unwind the "thread of spider's web of passages to find their way" (McLeish 1983:143). However, getting to the centre of the maze did not give early career investigators the comfort of knowing that they had discovered all the secrets of the labyrinth. There was another secret to unlock: *where do we go from here*? Their career trajectory was unclear to them.

3.3.4.1 Unclear career trajectory

A career trajectory refers to the career path an employee will follow to grow in an organisation and would include the various positions he/she would move to, one by one, as they grow within the organisation (MBASKOOL online 2011). For the participants in

the current study, the unclear career trajectory revolved around three pertinent issues: (1) the unclear promotion structure, (2) stagnation, and (3) the transferability of knowledge (clinical research is a niche industry).

a.   Promotion structure unclear

Moving from one position to the other in an organisation as part of growth within the organisation, normally implicated that the employee had received a raise in position or rank (Dictionary by Merriam-Webster online 1996 vs "promotion"). Such movement was important for some participants, however, they had concerns about how and when this movement would happen. Donald was not quite sure about the direction of his career growth in clinical research and mentioned that the career trajectory (the movement) was not set out. Anxiety was present when Reba asked what the future held and what the next step would be for her in clinical research. There was uncertainly expressed by Sarah on what she needed to do to progress from junior level to senior level. Arthur was really concerned about the fact that his peers who chose to follow the "specialist" road could be far better off than he was. For Veronica and Meagan, the salary structure was important and they were not sure if better salaries were in the pipeline but it was definitely something that should be part of the promotional structure.

> *"If you are looking for a path in terms of career growth…you know, the only other option would be for you to start in clinical research as a sub-investigator, then PI and then maybe go to a pharmaceutical work, I guess…or opportunities at private-led. I don't think you gonna...the career trajectory is not set out"* Donald.

> *"…And the other thing for me is, what is the future for me as a...If I continue with this, what's the next step? Where am I going to go...Will you ever become a PI, or you know, what does it mean being a PI? What are the benefits? Does it mean I'll see...less patients, do admin? What are the responsibilities of a PI? How far can you go with research? When do you become a professor? Will I get the opportunity to public or be an co-author on an article? Will I be able to do a sub-study or to present a poster at a research day?"* Reba.

> *"Um, ja, I think it was just, not…not sort of understanding...how I could progress... what I needed to do in order to...go from a junior level to more senior*

level. Um, I must say, I also felt like if you didn't…hadn't specialised, like, if you didn't have a specialisation behind you...it was gonna be very difficult for you to go up anyway…cause I feel like, if you don't have that, it's very...hard for you to move up...up the ranks" Sarah.

"…Because of the way things have been structured…those who are ahead of us are very experienced…and so, in terms...of progression...there's not much you can do to progress now. It's, I mean, it's either you're a sub-investigator or a…a principle investigator and...and that gap, um, you know...I'm not sure sort of how...what period of time you'd have to work as sub-investigator...to get to the stage where you can be given your own study to handle. I...I know there's nothing really in between those two...titles...but, if there was somewhere whereby, you know, you could see that, okay I'm actually getting better...at this, I'm progressing... you know. I mean, even with...clinical medicine, even if you stay in the same job for...a period of time, you go from being a medical officer, grade one...to being a grade two medical officer. So there's, like, there's a...a promotion type...setup, ye, which is not so much the case here, as far as I know. I think it is the inability to progress. I think that will still get me. I'm watching some of my friends becoming, you know…from medical officer…becoming registrars and working towards becoming consultants and all of that and, in terms of my career progression...sort of what is the pathway for me...here. So you know, if...if there wasn't...that kind of movement, I...think maybe I would...I'd get irritable with it. And then, I think, even from there, once you become a PI, then I think the things that separate PIs from each other...is the amount of studies that you get...and the amount of work that you do. So that's also another...long-term kind of thing...you don't know how long. So you still have to build credibility...even as a PI. With the consultant ones, you're a consultant that means a certain pay cut or...pay increase or whatever, it means a certain role that you play" Arthur.

"Better salary, that's for sure. Cause we took a nock with our...salary. It's less than the public sector" Veronica.

"The pays not wonderful. To be honest it's not great" Meagan.

b. Stagnation

Stagnation is when growth or development stops or is very slow (Cambridge Dictionary online 1995 sv "stagnation"). Due to the nature of clinical research an investigator might end up stagnant. According to Donald, you might become stuck in a PI position for ten years, for example. Meagan, Samantha and Donald felt that clinical research is not very challenging, that it is repetitive, prescriptive work without the opportunity to be creative. Sarah confirmed that she did not have a say in how things should be done, she just followed the process, leaving little room for stimulation. There should be a love relationship with clinical research because there is not a lot of hands-on action. Without the love for clinical research, there will be only boredom, according to Tammy. Samantha shared the experience of a colleague who left clinical research because she repeatedly had to train new staff who did not stay long and had to be replaced.

"I think one has to realise that you can only do a certain amount...because the nature of clinical research or research in general...is such for a reason. You might end up stagnant. You might end up being a PI for ten years. So you have to ask yourself, going in, what is it you want from the job? If you want a job where you like a comfort zone...and you like knowing that you going to ask same questions...every day you're at a stage in your career...and your life where you want stability...then it's more likely but...if you're looking for...if you don't know,...if you want to go into your day not knowing what your day is going to be like, which some people do, this is not the career for you" Donald.

"Otherwise, literally, all you doing is just...you just doing a lot of administration, seeing patients. It's not...always the most challenging…look, I have a young family so...as a working mom...who is...really enjoys the flexi hours because I do work a pos-...which I think trials kind of enable you to do that...it's really great. So there is not as much stress associated. So I don't take stress home. At this stage it's ideal. I might get a bit bored" Meagan.

"When you come into research you need to understand that it's not what you think, it's what the protocol says. So it take away most of your clinical thinking...actually and it leaves you little room to do this or that..." Samantha.

"It was this very sort of narrowly focused on this person in front of you...and then making sure you do the checklist of…things that need to be done - um, so...so it wasn't, I think as stimulating as it is now...so you just...have to follow what they...what they've thought of...but also a little bit like, oh well, I don't really have any kind of say as such - cause I kind of have to just follow this...process. and then having to do all the QCs was really awful. So...yes, it drove me up the wall" Sarah.

"Only come to clinical trials if you love it because some people find it boring… like young people just…graduated and…so they…they want to be in action. So here's not that hands-on action. Its more paperwork, you must concentrate on that and you must be very thorough. So you need to love it, otherwise you will get bored and leave" Tammy.

"So it makes you a bit worried that you spend so much time of what you have back from it...m not saying I'm lazy...or anything. I'm doing a lot here...and I'm not going to do more if I'm not going to be recognised...for it, I think that's fair. Everyone is doing it for a reason...and you have your own reasons...even though some people may not want to admit...their reasons. And I think that's also what triggered it because...for her (colleague who resigned), she did say, every time that she would train someone...a few months later, they would leave...and then she'd have to start all over again...and that must be frustrating...for you because you want help but then your help leaves and you start all over again and the new people can't start immediately, they first have to wait for approval that could take a few months" Samantha.

"I'm more kind of ideas, concepts and things like that...while this is more...everything's set out, everything's already done…prescribed for you per protocol and SOP. So there's not a lot of trying to, you know, come up with solutions or ideas, so that takes a bit of adjustment in terms of my personality. Then again, you really have to enjoy the process of research...which it...itself is not a very...its not a linear thing. It's a iterative process sometimes and its very....it can be frustrating. It's very structured...you must love structure. You must enjoy it, you must be-...it must be your warm blanket. Otherwise you're in

trouble. I've been here for a while, you get settled in. You do adjust...to it" Donald.

"When you become a PI, especially when you're not young but relatively…in the middle of your career…there isn't necessarily a lot of room for growth. Every protocol is pretty much the same…and you don't necessarily get a lot of opportunities to learn new things" Donald.

c.   Transferability of knowledge/niche industry

A niche is defined as a position a person holds within a submarket of a market that is particularly well suited to the person (Castiglioni, Aagaard & Spencer 2013:137). For some participants, clinical research was associated with a niche industry and realisation of such an association created some concern.

For Samantha, it was important for a person to know what he/she wants out of life and his/her work. If a person chooses clinical research for the sake of a better lifestyle, his/her career might take a side step because research experience does not count as anything clinical. Donald referred to clinical research as a niche industry and according to him an investigator cannot take his/her knowledge to another industry, for example, a medical insurance company, and think it will be acknowledged there. Following a clinical research career could be a disadvantage for a doctor. According to Tammy, the following could happen: depending on the clinical research field you might see mostly healthy and not so sick participants, making it difficult to return to medicine as a general practitioner; a doctor cannot continue with clinical trials after retirement age, while a doctor who is a general practitioner can continue with his/her practice up to a high age; if a doctor started off with clinical research as a career, changing much later in life might turn out to be problematic.

"It's nice hours because there's no calls, so in that sense, if you want a better life...you should do it but also bear in mind that, if you're going to do research, your career on the other hand also takes a side step because they don't really count your research experience as anything clinical. So there's two ways about it. You need to know what you want to do in the future...and in your personal life because, especially as a female, as you get older, it's more difficult to go into

certain types of work...and if you're going to do research, you need to know that you are going to forfeit one of...one or the other. So it's a gamble that your making, you either want better working hours...or you gonna stick to the bad working hours to advance your career" Samantha.

"One more, transferability, I think of knowledge is also a thing. When you're in clinical research you can't necessarily take this information and go to another industry. Like where can I go and say...let's say to a GP practice...even within health orient...health industry...Ii can't go to, let's say medical insurance company and say...well, I've done four years of being a PI...doesn't that help you here? It doesn't. I've done four...years of being a PI, doesn't that help you with being a medical advisor for pharmaceuticals, uh, maybe, but I think they mostly looking for people with specialist knowledge, not so much...so much clinical trial...experience. I can't take this and go to Discovery, medical insurance or a non-health related company, hospital or whatever kind of company. Whatever information or...or experience or knowledge that I've gained here...I can't transfer that...anywhere else. So it's almost like you get in here, if you're not happy...you're kind of a little bit stuck. If you move out you have to start there from scratch. What your learn here it's...it's a niche industry. Another thing is if a PI wants to leave, it is a three months' notice and that poses a problem if you wanna get some job...somewhere else. What do I put on my CV in terms of skills? Working in teams and project management is a bit transferrable. What you have done here doesn't qualifies you for moving into other industries. So the fact it's a niche industry...is partly one of the things that makes you have to think twice" Donald.

"If you compare with other specialities the...income...is not comparable. You can work as a surgeon specialist till seventy/eighty...ninety if you still...perform, but, at clinical trial, there's...I think some limitations...for your career. You can't start after clinical trials when you are seventy with a new career and you can't go back to clinical work or become a specialist. So that is...that is why I think the young people are not...keen to do this clinical trial, because they don't really see a good future for them. In clinical trials the road ends but with your own practice the road ends when you say it ends. Uncertainty is also there in clinical trials, because, if you say, we don't need you...you...your career end where should you go? if you

are about forty years and...you do only clinical trials. It could also be a disadvantage that depending on the clinical trials you do you mostly see people who are not very sick" Tammy.

3.4   SUMMARY

Starting their career, early career clinical investigators did not expect to enter a maze. They expected to travel a linear path with little interaction or problems, leaving them with a feeling of satisfaction that they had accomplished their tasks as investigators. However, as difficulties emerged, they started realising there were complexities and intricacies associated with their jobs as investigators and they found themselves in the midst of a maze. By confronting these difficulties, they were able to navigate their way and make sense of the labyrinth. In Chapter 4 I will discuss the findings of the study.

CHAPTER 4

DISCUSSION OF THE FINDINGS OF THE STUDY AND LITERATURE CONTROL

Simply observing and interviewing do not ensure that the research is qualitative; the qualitative researcher must also interpret the beliefs and behaviour of participants – Valerie J. Janesick (Patton 2015:570)

4.1 INTRODUCTION

In Chapter 3, I provided as clear as possible a description, supported with verbatim quotes, on the experiences of early career investigators in clinical research. In Chapter 4 I will discuss the findings of the study in more detail. The discussion in Chapter 4 will enrich the understanding and meaning of early career investigators' experience and it will relate the findings to literature.

A young man travelling through a new country heard that a great Mulla, a Sufi guru with unequalled insight into the mysteries of the world, was also traveling in that region. The young man was determined to become his disciple. He found his way to the wise man and said, "I wish to place my education in your hands that I might learn to interpret what I see as I travel through the world." After six months of traveling from village to village with the great teacher, the young man was confused and disheartened. He decided to reveal his frustration to the Mulla. "For six months I have observed the services you provide to the people along our route. In one village you tell the hungry that they must work harder in their fields. In another village you tell the hungry to give up their preoccupation with food. In yet another village you tell the people to pray for a richer harvest. In each village the problem is the same, but always your message is different. I can find no pattern of Truth in your teachings." The Mulla looked piercingly at the young man. "Truth? When you came here you did not tell me you wanted to learn Truth. Truth is like the Buddha. When met on the road it should be killed. If there were only one Truth to be applied to all villages, there would be no need of Mullahs to travel from village to village. When you first came to me you said you wanted to 'learn how to interpret' what you see as you travel through the world. Your confusion is simple. To interpret and to state the Truth are two quite different things." Having finished his story

Halcolm smiled at the attentive youth. "Go, my children. Seek what you will, do what you must." – Halcolm's Evaluation Parables. (Patton 2015:652)

4.2   ENTERING THE MAZE OF CLINICAL RESEARCH

It seemed that entering clinical research had a vast impact on early career investigators in the current study, to such an extent that some of them reported that they left clinical research after a very short time, only to return.
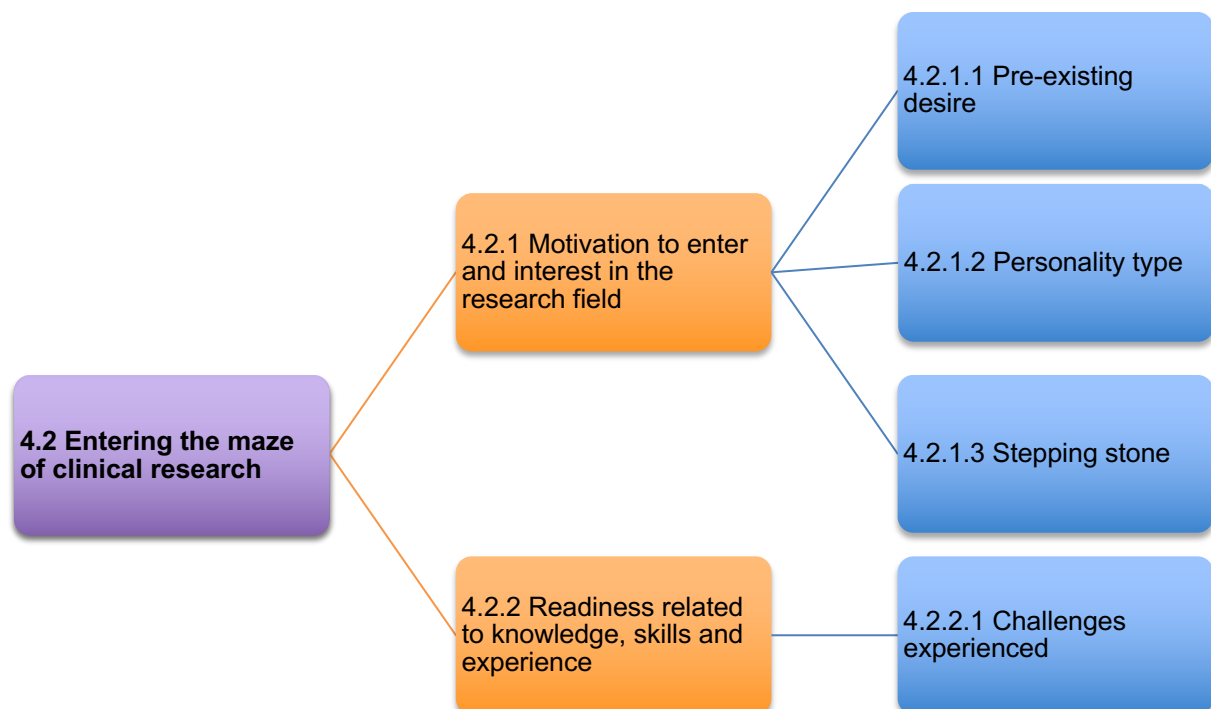
Figure 4.1: The experience of entering the maze of clinical research

4.2.1   Motivation to enter and interest in the research field

We learned from Chapter 3 that some of the reasons why early career investigators entered clinical research could relate to their frame of reference regarding research. What they knew and had experienced before could have led to a pre-existing desire to enter the clinical research field or the notion to use it as a stepping-stone in their career. Some just felt that it suited their personality, and that was enough reason for them to enter clinical research.

4.2.1.1 Pre-existing desire

In line with the findings of this study, Flood et al (2015:2) similarly found that even a small prod/nudge could light some spark in a doctor to consider a career in research. However, it would still remain the individual's choice to investigate clinical research as the majority of young doctors are unaware of clinical research, or that it could be a viable career. Flood et al (2015:2) also mentioned that some doctors they interviewed reported that they were motivated to enter the clinical research field because they were made aware of the need for HIV preventative methods by the medical community.

Burgoyne et al (2010:8) found in their study that undergraduate medical students who consider a career in clinical research are those who had been made aware of research during their course work. Their finding was confirmed by the experiences of Arthur who heard about the CAPRISA trial when he was a medical student, and Allie who was told by her team leader that she should think about research as a career.

Early exposure to research could increase a physician's interest in pursuing a research career according to Jain, the president of the American Society for Clinical Investigation (Jain 2015:3308). Although early exposure played a role in motivating for a career in clinical research in the current study, other factors, such as personality, were also highlighted.

4.2.1.2 Personality type

Who we are, our personalities/identities developed along a continuum; in other words, it is a process of becoming who we are (Giordano 2016:4; Maritz & Prinsloo 2015:697). Seeing personality as a process of becoming has the benefit of integrating the person and the situation (Giordano 2016:4). Individual personality should be understood within its contextual framework, and it therefore reflects the ecology of personal experiencing (Giordano 2016:4). Part of the process is the development of amiable relationships with others and the environment, and representing a personality that functions on the highest level (Giordano 2016:4). Personality as process is seen as superior to personality as structure in the sense that, according to Giordano (2016:4), it is "tapping into the complexities of individual personality variation as it unfolds in situ". In the current study the relationship between participants and their environment, meaning the

clinical research field, have been explored. According to their individual experiences, Sarah, Jeff, Arthur, Robin and Samantha relayed how their personalities harmonised with others and the clinical research environment.

A study by Alkhelil (2016:139) on the relationship between personality and career choices, found that research roles had been chosen by people who ranked high on openness (to experience, analyse problems, being broadminded and curious) and extraversion (a tendency to be sociable). This is in line with Robin's claim of being an analytical person.

Kemboi, Kindiki and Misigo (2016:102) used the John Holland Personality Theory of Career Choice to determine the relationship between personality and the career choices of undergraduate students at the Moi University, Kenia. Holland's theory advocates that people seek environments that are aligned with their personality and would participate in activities that develop their abilities (Kemboi et al 2016:102; Hampson 2012:315). According to Holland, people have a combination of six personalities: realistic, investigative, artistic, social, enterprising, and conventional (Nauta 2010:11). Kemboi et al (2016:107) also found that there was a significant relationship between undergraduate students' personality and career choice. Many students were not in courses that were in line with their personality, and these students potentially did not develop in interest values and the ability to make a success of their future career.

Rubio, Primack, Switzer, Bryce, Seltzer and Kapoor (2011:1571) developed a comprehensive career success model with the purpose to address and evaluate the personal factors, organisational factors, and their interplay that contribute to career success. As part of the personal elements of success they included demographics, the psychosocial milieu, education, and personality. Personality was an essential component to the model based on previous studies in the literature that indicated that personality factors are important individual determinants of career success (Rubio et al 2011:1571). In Rubio et al's (Rubio et al 2011:1571) model they included motivation, creativity, passion, interest, leadership, self-efficacy, and professionalism as personality qualities. Yin, Gabrilove, Jackson, Sweeney, Fair and Toto (2015:861) noted that some of these characteristics could be improved through institutional interventions such as mentor training, training, and leadership programmes. Evidence from the literature and

the current study indicate that personality should be considered as a factor when investigating strategies for retaining early career investigators.

Robinson, Schwartz, DiMeglio, Ahluwalia and Gabrilove (2016:570) expanded on Rubio et al's model and explained it in terms of extrinsic or intrinsic success. Extrinsic success could include personal finance, grant funding, publications, leadership positions and promotion in academic ranks, while intrinsic success is more subjective and personal and could include career and life satisfaction. Robinson et al (2016:588) tested Rubio et al's model in a study they did to examine the personal and organisational factors that influence early career investigators to become independent investigators. Robinson et al (2016:588) found that their findings aligned with the building blocks in the Rubio model of physician-scientist career success. In another approach by Rubio, Robinson, Gilliam, Primack, Switzer and Kapoor (2014:441) to determine factors leading to a productive career, they found that investigators use one of three approaches to research: a linear, a holistic, or a technical approach. It is therefore crucial for the mentor and the institution to understand the different approaches to be able to support the early career investigators according to their personality. Rubio et al's (2014:441) study showed that early career investigators with a holistic personality have abilities such as the willingness to stretch beyond usual levels of comfort.

Taking the findings of Kemboi et al's (2016:102) study into consideration, as well as studies done using the five factor dimensions model of John and McCrae (Alhelil 2016:139; Facets of the Big Five 2012; Komarraju, Karau, Schmeck & Avdic, 2011:472), it is not surprising that some participants in the current study indicated that they believed they made the right choice. Entering clinical research suited their personality; especially those participants who indicated that they are OCD and prefer to work within boundaries. Reviewing my reflective notes, I discovered that I reflected on the fact that certain personality types could be drawn to clinical research, for example, those with OCD or a meticulous, perfectionistic kind of personality. There could, however, be other factors besides early exposure to research that could motivate doctors to enter clinical research, and findings from the current study showed that a third motivation for some participants was the fact that they could use clinical research as a stepping-stone along their career path.

4.2.1.3 Stepping-stone

The reality of a shortage in registrar posts is evident in jobs advertised by academic institutions. Many institutions have a limited number of positions available for registrars. In a memo written by Dr Mzukwa (2017) on behalf of the KwaZulu-Natal Coastal Branch of the South African Medical Association to the Member of the Executive Council (MEC) of Health Dr Dhlomo, Dr Mzukwa notified the MEC of the concerns of doctors in KwaZulu-Natal. One of their concerns was that the registrar posts which were abolished were never replaced with commensurate service medical posts.

Registrar posts to train more specialists have been restrained due to available funding and the high cost of training specialists. Roughly R3.1 million is needed to train a specialist for four years, and R2 million is required to train a specialist for two years, having a direct impact on newly qualified doctors' choices of a career (Identifying the… 2015:23). The shortage could also be justified by the increased demand for posts by medical graduates wanting to specialise (du Plessis & Andronikou 2007:18). According to Dr Nicolas Crisp (cited in Identifying the… 2015:23), the root cause of the problem for the shortage of specialists is the fact that there are not enough general practitioners (GPs) to serve the population of South Africa where the real burden of disease is. Also, because of consumer and specialist pressure, general clinicians increasingly doubt their ability and pass patients on to specialists. Thus, we are not using specialist as they should be used, namely as consultants and not the first port of call. The shortage of doctors and specialists have become a global problem according to the World Health Organisation (Identifying the… 2015:23).

Veronica, Samantha and Meagan expressed secondary motives for choosing clinical research. They had a professional and a family life to balance and choosing clinical research at that stage of their lives seemed to be the best choice to balance a lifestyle that included raising children. Veronica, Samantha and Meagan's needs were confirmed in Lambert, Smith and Goldacre's (2015:3) findings from a survey they did on how to make a clinical academic career more attractive. Lambert et al (2015:3) found that women wanted more flexible working hours, more part-time posts, and more career guidance to be able to balance their work-life situation. Maritz (2015:4) noted similar challenges among women in academia, and refer to Wolfinger, Mason and Goulden (in Maritz 2015:4) who described an additional trajectory consisting of part-time teaching

positions. These positions are normally filled by women with children, and Wolfinger et al (in Maritz 2015:4) refer to this additional trajectory as the "mommy track". Clinical research was therefore a good alternative for Veronica, Samantha and Meagan, since they wanted to follow the "mommy track".

Kelly and Randolph (1994:287) pointed out that for most women their training and early career life phase coincide with their childbearing phase. Both phases are subjected to the ticking of the time clock, one the tenure and one the biological clock. Women do not have a lot of options to change the ticking of the time clock and most of the time their training programmes or their careers (surgery) do not accommodate their need to pursue a career and a family life at the same time (Kelly & Randolph 1994:287).

Cochran, Elder, Crandall, Brasel, Hauschild and Neumayer (2013:661) found that childbearing was a perceived influence for female senior residents and early career faculty members in academic surgery who viewed childbearing as a career barrier. Likewise, Ogdie, Shah, Makris, Jiang, Nelson, Kim, Angeles-Han, Castelino, Golding, Kalenberg and Barg's (2015:1191) study showed that gender was a barrier in pursuing a career in research and that woman found it difficult to continue a career in research while they have to care for young children without the opportunity to work flexible hours, or to have time off to have children, or to return part-time. Participants in Ogdie et al's (2015:1191) study felt that the environment/institution was unsupportive in contrast with Veronica, Samantha and Meagan in the current study, who chose clinical research because they were given the opportunity to work flexible or better hours in comparison with other institutions in the medical field. Themes identified in Borges, Grover, Navarro, Raque-Bogdan and Elton's (2013:156) study included work-life balance, destiny, intellectual stimulation, mentors, choosing academic medicine by default, research and teaching among reasons for female physicians to choose academic medicine as a career path. Findings from Borges et al's (2013:156) study was in agreement with Veronica, Samantha and Meagan's experience.

Challenges experienced by female investigators, brought forward by the literature, included issues related to work-life balance such as scheduled meetings that interfered with previously planned child care responsibilities, the absence of on-site or emergency child care, the lack of lactation facilities at sites, and a lack of clear career development and promotion paths for women in part-time positions (Rubio et al 2011:1571).

A literature search on newly qualified doctors' career choices and the choice of clinical research as a "stepping-stone" to bide time did not show any research results and can be considered as a unique finding and a topic for further investigation. From the responses in the current study, it was clear that clinical research was a "stepping-stone" for some participants and there was knowledge about other newly qualified doctors who also used it as a "stepping-stone".

A second major reaction to entering the clinical research maze, was the early career investigators' inability to cope with their new environment because of their lack of previous knowledge, skills and experience in clinical research.

4.2.2 Readiness related to knowledge, skills and experience

Responses from participants in the current study exposed their knowledge, skills and experience of clinical research and, unfortunately, it was not a favourable or encouraging picture of early career investigators' readiness for clinical research. Their reality of a lack of necessary knowledge, skills and experience made them vulnerable for all kinds of challenges, especially on entering the maze of clinical research. The challenges experienced by early career investigators in the current study are portrayed in the following paragraphs.

4.2.2.1 Challenges experienced

Similar to the findings of this study, Burgoyne et al (2010:7) found that undergraduate students have a narrow definition of research and what it entails, and most medical students are largely unaware of the research activities in their own institution. Findings of the current study confirmed Burgoyne et al's (2010:7) research. Flood et al (2015:2) reported that in their study participants had similar feelings, believing there is little exposure to research in medical training and that most young doctors completing their training are not aware of the possibility of choosing research as a career.

The need for younger investigators to enter the clinical research field is undermined by the fact that they are not receiving the necessary training and experience in doing research as undergraduates. Rahman, Majumder, Shaban, Rahman, Ahmed,

Abdulrahman and D'Souza (2011:85) mentioned that there has been significant discussion regarding the decline in medical graduates choosing careers as clinical scientist. It was emphasised that all physicians should receive education and training in the fundamentals of research, including the development of a 'student-focused teaching-learning and research culture'. Introducing medical students to research can influence their choice of clinical speciality or interest in research (Bierer & Chen 2010 cited in Rahman et al 2011:90).

In an attempt to address the lack of research knowledge and skills, several academic institutions globally, including South Africa, have started with programmes to provide opportunities for young clinicians to develop research skills through enrolling for a PhD (Kramer, Veriava & Pettifor 2015:153). These programmes look promising and it is hoped that they will lead to the training of a pool of clinician scientist, including African based clinical scientists (Kramer et al 2015:154). Some participants in the current study who left clinical research for specialisation, and who then returned after specialisation, mentioned that they have benefited from the research knowledge gained during their post-graduation studies.

Developing skills and resources through capacity building to create a culture of research is necessary according to Ethiopian authors Franzen, Chandler, Enquselassie, Siribaddana, Atashili, Angus and Lang (2013:5). Researchers in Ethiopia were reluctant to take on their own research because of a lack of knowledge and skills. Even experienced investigators who conducted foreign-led studies did not feel confident to initiate their own research. Investigators in Ethiopia believed the operational difficulties and the lack of mentors and role models to support them made investigator-driven research almost impossible. This belief had a negative influence on early career investigators in Ethiopia (Franzen et al 2013:5).

Being underprepared, however, was only part of the challenges experienced by early career investigators in the current study. Some participants associated their under-preparedness with the feeling of starting clinical research with a clean slate. The lack of knowledge and experience made it challenging for some participants to cope in the maze, yet it also opened up some participants to admit that because they lack knowledge, they are starting clinical research with a clean slate and are therefore open to learn.

Barriers and challenges faced by early career investigators, with some solutions, are discussed by Flood et al (2015:2), but there is no mentioning of how their participants experienced the clinical research environment. Participants in Flood et al's (2015:2) study expressed the need for the development of a programme to provide an opportunity for young investigators to experience the full range of activities and to develop the practical skills needed to be successful investigators. The literature is silent about the experiences (daily struggles) of early career investigators associated with the barriers mentioned in the literature. From the literature, it is not clear if early career investigators experienced frustration due to the process of waiting for ethics and country specific regulatory approvals, if they had challenges with understanding the research language, the documentation processes, with sticking to rules and boundaries, or the fact that they did not know what were expected of them, as participants experienced in the current study.

Ogdie et al (2015:1191) mentioned that second to funding, clinical workload, administrative duties, the lack of institutional research infrastructure and support, were reported as barriers by young investigators. According to Ogdie et al (2015:1191), the resolve to these barriers included better funding, protected research time, good mentors, institutional support, and building the personal skills of young investigators. With the hard work, resilience, initiative, persistence, and passion of the young investigators it could lead to a successful career in clinical research (Ogdie et al 2015:1191). Samantha's experience confirmed the pressure of the clinical workload and she was fearful of what would happen if she did not get the necessary support in time. Samantha was willing to work hard, but she expressed her need for institutional support and recognition.

The effect of workload pressure was captured by Robinson et al's (2016:577) study where burnout was reported because the rewards of working hard often led to being assigned even more research-related responsibilities. One of Robinson et al's (2016:577) participants remarked that he was not sure if the work's effect on his home life was worth the reward and the effort of persisting. Another of Robinson et al's junior participants experienced an unusual amount of autonomy without guidance and support from adequate senior investigators. Although he enjoyed the freedom, the lack of direction and mentorship prevented formal socialisation into academic norms, which hindered his progress (Robinson et al 2016:577). Samantha's experience in the current

study was similar; she was also at risk for burnout. She was given too much autonomy from the start and although she said she was not lazy, a lot was expected from her as the only doctor, and she was not receiving the necessary support and guidance. Samantha was also wondering who would benefit from all her effort.

Results from Robinson et al's (2016:577) study showed that the majority of participants had an issue with balancing their personal life and professional work. Coping mechanisms were learned from colleagues and mentors enabling them to allocate appropriate time to their different roles. Some participants learned to have a long-term approach to balance personal life and work instead of finding balance on a daily basis (Robinson et al 2016:577). However, there were those participants who rejected the expectation of work-life balance, and who accepted that creating any balance, at times, would be extremely challenging. The importance of work-life balance was also mentioned by several participants in the current study and in contrast with Robinson et al's (2016:577) study, participants mentioned that clinical research was providing them with good work-life balance.

Hahn (2013:4964) mentioned that early career investigators need to move beyond a first observation to create a career. What would it mean for early career investigators to move out of the maze into the labyrinth?

4.3   EXPLORING THE MAZE TO FIND A WAY INTO THE LABYRINTH

At this stage of their journey, early career investigators are on the lookout for 'coping mechanisms' to support and guide them through all the challenges encountered in the first phase of the journey. This 'second phase' of their journey is defined by a supportive environment, consisting of different actions required from them as well as from the clinical research environment or institution they work at.
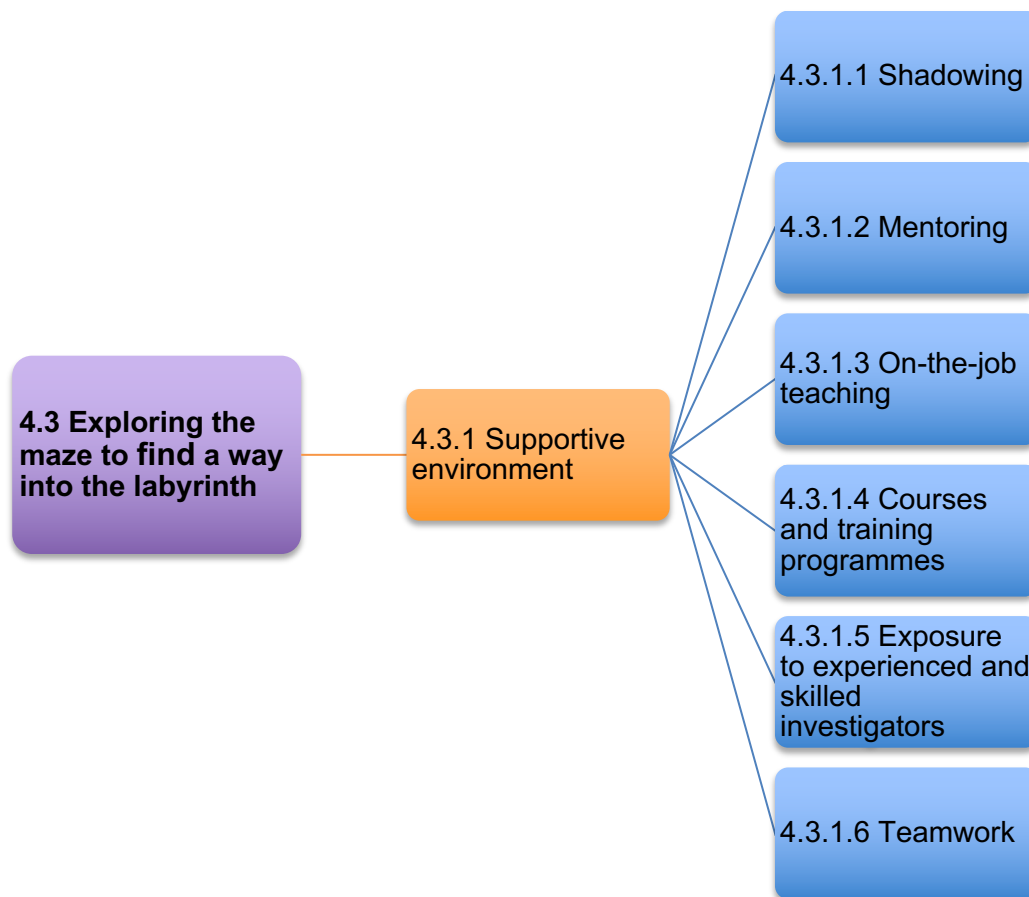
Figure 4.2: Exploring the maze to find a way into the labyrinth

4.3.1   Supportive environment

With the necessary support described by early career investigators in the current study, it is possible for early career investigators to move successfully into the labyrinth to create a career in clinical research.

4.3.1.1 Shadowing

During the period of shadowing the early career investigator has the opportunity to ask questions. This enables him/her to obtain a rich and comprehensive knowledge base for what is expected in future when it is his/her turn to do the job (McDonald 2005:5).

In 2010, as part of its global health agenda, the World Health Organisation added Inter-professional Education (IPE) to the agenda, considering it as an indispensable component of all health professionals' education (Riva, Lam, Stanford, Moore, Endicott & Krawchenko 2010:3). IPE is described by the Centre for the Advancement of Inter-

professional Education as: "Inter-professional Education occurs when two or more professions learn with, from and about each other to improve collaboration and the quality of care" (Riva et al 2010:3).

As part of IPE, Riva et al (2010:3) looked at shadowing experiences in multidisciplinary clinical settings in Ontario, Canada. Riva et al (2010:3) recommended that educational institutions should not define specific objectives for the shadowing; instead, institutions should follow an adult learning approach. The institution can contribute by describing the main learning outcomes to ensure learner participation in reaching goals. For instance, identifying profession-specific terminology, benefits and challenges of team-building, and inter-professional communication (Riva et al 2010:3). Giving the learner opportunities to gain insight into different approaches to patient assessment, professional-specific terminology, and to establish their own team-building expertise is of great value to both the learner and the institution, and form part of effective IPE (Riva et al 2010:3).

Clinical observation or shadowing is a requirement at various educational institutions and according to the Indiana University of Bloomington it is strongly recommended if it is not already a requirement of an institution. According to the Health Professions and Prelaw Centre of the Indiana University of Bloomington (Indiana University 2017), shadowing means "watching", in other words, it is clinical observation of a healthcare professional providing care in a research setting. The purpose of clinical observation experiences is to get a good understanding of the day-to-day responsibilities of a given health career, such as a clinical researcher, in a given health care setting (Indiana University 2017). Clinical observation/shadowing assists with the facilitation of clinical skills and ways of communicating with research participants and stakeholders.

In the current study, Arthur and Jeff mentioned that they were not only shadowing experienced investigators, they were also shadowing other experienced staff, for example, the study coordinators, the quality control staff, and regulatory staff. Reba mentioned shadowing those staff who are already involved in clinical trials and who know their stuff. My field notes, in fact, indicated that Reba felt very strongly about the importance of shadowing. Reba went further to explain that shadowing should occur during the morning and the afternoons should be covered by formal training sessions for early career investigators. Examples from the current study showed that IPE

occurred in the same institution between colleagues with different levels of experience but also between colleagues of different professions. Arthur experienced the value of gaining rich and comprehensive information by asking questions while shadowing.

As Meagan mentioned, shadowing could get boring on its own but if combined with other methods of support, such as mentoring, it can result in even better learning and skill-gaining outcomes.

4.3.1.2 Mentoring

Not only are physicians in research declining and becoming an "endangered species", the role models are also decreasing and as Cheung (2017:3569) rightly claimed: "how can we expect young people to want to become physician-scientists?" On their long journey through their medical studies young people often do not have any meaningful contact with role models. Cheung (2017:3569) emphasised that the research community cannot sit and accept the reports on declining funds for research and the decreasing numbers of young physicians going into research. They need to fix the problems with practical and actionable solutions. Cheung's (2017:3569) first suggestion as a solution is to assist and support young investigators at the beginning of their careers when they move from training, which implies dependence, to independence as a scientist. According to Cheung (2017:3570), this period is also called the "neonatal care" period and this vulnerable period can be supported with the necessary funds and mentoring, including strong commitment from advisors to help young investigators to independence.

The literature describes the benefits of mentoring quite extensively. Rubio et al (2011:1571) refer to a meta-analysis of results of mentoring studies that revealed some of the benefits of effective mentoring. These include increased job satisfaction, greater self-esteem, increased organisational commitment, higher perception of promotion opportunities, decreased work stress, and lower levels of work-family conflict. Mentoring is seen as an activity with a positive outcome on the physician-scientists' career trajectory and leads to higher research productivity, increased professional socialisation and networking, and increased satisfaction with salaries and promotions (Rubio et al 2011:1571). Specific benefits as outlined by the literature have not been mentioned by participants in the current study, although it could be assumed that mentoring had a

positive outcome for participants because they mentioned that they would not have survived if it was not for their supervisors' guidance and support.

In recent years there has been a shift in the traditional mentoring model to include interdisciplinary and peer mentoring (Yin et al 2015:861). Mentoring competencies, mentoring outcome metrics, and best practices for developing effective mentor-mentee relations are defined in the literature, and Yin et al (2015:861) mentioned that mentoring should support the mentees' career functions as well as psychosocial personal functions. Yin et al (2015:861) refer to a survey that was conducted which showed that mentees were of the opinion that their mentors were effective in supporting them on different levels of career functioning. However, they felt that mentors were less effective in promoting psychosocial personal functions. Their mentors were not only modelling professional and ethical behaviour, they were also sharing knowledge and skills, advising them about publishing their work, and serving as role models and advocates (Yin et al 2015:861). Psychosocial personal functions that were neglected by mentors included assistance with professional networking, advising on negotiating for resources, preparing for career progression, and particularly how to find a work-life balance (Yin et al 2015:861). It seems that there is a need for the upscaling of mentors' abilities in psychosocial personal functions to better assist mentees in this critical area. The sharing of knowledge and skills by mentors were the main competencies of mentors mentioned by participants in the current study. It is not clear if the "support" mentioned by participants included psychosocial personal functions as well.

Results from a study conducted by Shea, Stern, Koltman, Clayton, O'Hara, Feldman, Griendling, Moss, Straus and Jagsi (2011:779) showed that junior researchers had a need for an academic mentor to provide guidance on promotion, career milestones, local politics, clinical work, and work-life balance, as well as for a scientific mentor to provide guidance on research. However, a participant from Robinson et al's (2016:577) study reported that she, as clinical and translational investigator, had the need for five different mentors. Robinson et al (2016:577) described the five types of mentors as: (1) a scientific (content) mentor to provide discipline-specific training and scientific guidance; (2) a career mentor to provide career development strategies and choices; (3) a confidante or "vent mentor" in whom the trainee can confide when having professional issues or when in need of an emotional outlet; (4) an impartial politically removed mentor that could be a senior faculty member from another department; and

(5) a peer mentor role model that could be someone the mentee aspires to be like but with whom he/she is not professionally connected. Participants in the current study did not elaborate on the kind of support they had received during mentoring, and this could be seen as a gap in the current study. Early career investigators in the current study felt that mentoring helped them to survive the first year but there was not much further detail offered by participants, except mentioning that the mentors showed them what to do, they guided them, they were able to ask questions of the mentor, and the mentors had experience to share. Referring back to the objectives of shadowing, it might connect well to the recommendation that learners must determine their own goals according to their needs. In the current study, these needs have not been explored.

Ambati and Cahoon (2014:1853) had a good expression when saying that trainees should engage fully in basic research, clinical trials, outcome research or technology development in a "dance" with mentors who can model successful, fulfilling and contented careers. It seemed that Jeff, in the current study, was able to work out such a dance with his mentor.

Qualitative interviews conducted by the MRC (Oldfield et al 2015:14) as part of a survey to bring research careers into focus, asked participants what in particular would have been useful with regards to guidance and support or training; 50% said mentoring and 47% said advice, support or guidance from professionals in the field of interest. Some of the participants mentioned that the lack of mentoring or powerful senior backers early in their careers might have slowed their career progression (Oldfield et al 2015:14). In asking the question: "What will help to make it easier for new investigators to find their feet in clinical research?", several participants in the current study referred to mentoring. One participant mentioned that she asked her supervisor to mentor her. Most participants in the current study did not explain their own experience with mentoring, and it is not clear if they received mentoring or if there was a lack of mentoring – a point for more exploration.

Following on shadowing and mentoring, OJT was experienced as part of a supportive environment by some participants in the current study.

4.3.1.3 On-the-job training

As mentioned in Chapter 3, Jacobs and Bu-Rahmah (2012:75) describe structured S-OJT as a planned "process of having experienced employees train novice employees on units of work in the actual work setting". Jacobs and Bu-Rahmah (2012:76) also mentioned that unstructured on-the-job training (OJT), classroom training and blended versions of training does not have the same effectiveness as S-OJT. In the current study, participants did not distinguish between S-OJT and unstructured OJT, and it is not clear which one they received, although they were able to testify to the benefits of on-the-job training. In a case study conducted by Jacobs and Bu-Rahmah (2012:83), newly hired employees expressed their appreciation for the S-OJT programme because they felt the employer cared about them and how they adapt to their new environment. Furthermore, mentors in the setting could build on the S-OJT programme to assist the new employees more effectively and it may lead to newly hired employees learning new skills quicker (Jacobs & Bu-Rahmah 2012:83).

A study conducted in the Netherlands on different perspectives on the modernisation of post-medical training due to the pressure of societal needs noted that there had been a shift from the old, implicit model of medical training of learning by doing and role modelling, to a more explicit approach of encoded knowledge and maintaining standards in practice (Wallenburg, van Exel, Stolk, Scheele, de Bont & Meurs 2010:1082). Wallenburg et al's (2010:1089) study showed that the demand for change was not only external, there was also a need from the younger generation of doctors for a more balanced life between the private sphere and work, as well as formalisation of the old master-mate relationship. With time, the social status and authority of medical professions have been influenced by the empowerment of patients, leading to a more balanced relationship between medical doctors and patients. Wallenburg et al (2010:1089) mentioned that medical work has become more like a "normal" job instead of a way of life. Results from the current study revealed that participants and research institutions in Gauteng were still believing in and following the old school of training which included OJT or learning by doing.

In another study by Pagon, Banutai and Bizjak (2011:45) on the effect of openness to experience by managers receiving OJT, they found that managers only benefited from OJT if they were open to the experience. It seemed that some participants in the current

study were open to the experience of OJT because they mentioned that they benefited from it. The findings of Pagon et al (2011:45) could be linked to a statement made by Lader, Cannon, Ohman, Newby, Sulmasy, Barst, Fair, Flather, Freedman, Frye, Hand, Jesse, Van de Werf and Costa (2004:2672) in which they said that the lack of trial experience could be overcome by early career investigators having a willingness to "learn by doing".

4.3.1.4 Courses and training programmes

Recommendations from Patel et al (2015:883) to preserve the pipeline of successful physician-scientists include the rekindling of the physician-scientist workforce through restructuring of their training and better support at their transition period from dependant to independent researchers.

GCP, having its origin in the Declaration of Helsinki (World Medical Association 2013), forms an international guideline for clinical researchers to follow when designing, conducting and reporting clinical trials involving human participants. GCP, globally implemented according to the International Conference on Harmonisaton Guidelines for Good Clinical Practice (ICH GCP), has been traditionally regarded as a 'gold' standard (Silva, Sonstein, Stonier, Dubois, Gladson, Jones, Criscuolo, Kesselring, Klech & Klingmann 2015:131). In South Africa, the basic GCP course is a face-to-face, normally one-and-a-half-day course, followed by an open book post-test. Participants in the current study were in possession of a GCP certificate. According to Silva et al (2015:131), such GCP courses lack applicability to complex clinical, safety and bioethical issues beyond GCP.

ICH GCP is quite vague with regards to requirements and experience of people involved in clinical research. In most countries, anyone with a medical license can get approval to be a PI. However, the latest version of the Declaration of Helsinki, dated October 2013, stipulated that "medical research must be conducted by individuals with appropriate training and qualifications in clinical research". Various institutions and organisations offer excellent certification programmes, but there are no formal regulations that define the educational or experiential requirements, and personnel certification is not mandated. There is also no harmonisation of standards for investigators or clinical trial staff qualifications (Silva et al 2015:131).

The United States FDA requires investigators and clinical trial staff to be qualified by training and experience before they can work with participants partaking in clinical trials. The FDA published a recommendation on risk-based monitoring and required training. Training of clinical trial staff is regarded by the FDA as being of utmost importance to ensure the validity and quality of the data collected. Over time it became evident that GCP is not enough; education and training need to expand beyond basic GCP courses (Silva et al 2015:137).

The need for the development of a comprehensively educated and trained clinical research workforce became a priority and in 2013, in an effort to combine different contributions of pharmaceutical companies, contract research organisations, academic institutions, clinical research sites and professional societies, the Joint Task Force for Clinical Trial Competency (JTF) was established (Sonstein, Seltzer, Li, Silva, Jones & Daemen 2014):2. Competencies for clinical research staff were formulated and validated by clinical research stakeholders. The purpose of the JTF was to align and harmonise the many statements relating to core competency for clinical research professionals into a single, high-level set of standards (Sonstein et al 2014:2). The JTF recommends that these core competencies should be used globally for curricula or job descriptions to standardise and eliminate redundancy in training requirements, for standarisation and accreditation of educational programmes, and for better definition of career tracks and performance evaluations (Sonstein et al 2014:3).

Silva et al (2015:135) believe that competency-based education (see Figure 4.3) will enable clinical research staff to apply their knowledge to the full process from laboratory research to the bedside of participants to close the existing gaps and prepare the experts for future scientific development. Competencies can be applied as the 'currency' to align and harmonise the desired learning outcomes for effective performance irrespective if formal, informal, in-formal education, vocational training or continuing professional development (CPD) were used as educational method. The same principles applicable to competency-based profiles of key roles in clinical research could be applied to inter-professional learning and teamwork for improved performance (Silva et al 2015:136).

Literature emphasise the importance and urgent need for improved education of investigators in clinical research. The need to conclude and harmonise competencies is

necessary to safeguard the future of knowledgeable and skilled clinical research investigators.

Figure 4.3: Competency Domains for the Clinical Research Professional according to Silva et al (2015:136) and Sonstein et al (2014:3)

The relevance of discussing the development of training programmes for early career investigators, and the importance thereof, becomes clearer in light of the findings of the current study. Apart from mentioning GCP training that is normally a requirement of most clinical research sponsor companies, participants in the current study did not mention specific courses or training programmes that they have attended by name. Jacky did say she benefited from training provided by sponsor companies at conferences. Participants also did not mention any training courses that were developed and offered by their own institutions. It is unknown if training courses are available at research institutions. Therefore, it is not clear what the competency requirements and standards for training are at the different institutions. Overall, early career investigators in the current study did not really describe the training programmes they received. However, participants said that they received training from experienced and skilled clinical research staff at their research sites.

4.3.1.5 Exposure to experienced and skilled investigators

Nurturing by a mentor through actions, attitude and approach towards scientific discovery can set the ideal environment for young investigators as experienced by Tontonoz (2014:2818). As president of the American Society for Clinical Investigation, Tontonoz (2014:2818) told the audience in his presidential address that the most critical thing that academic physicians can do is to lead by example. He himself had two outstanding scientific mentors namely Bruce Spiegelman and Ron Evans, and he was specifically invigorated by the passion Spiegelman had for science. Witnessing Spiegelman get excited over even small discoveries was inspiring and it continuously inspired him to be committed to research as a career. He commented that according to his experience of working in a research laboratory for 15 years, people who enter the research field either get it, or not. According to his mentor Spiegelman, you cannot instil the "fire in the belly", you mostly nurture it (Tontonoz 2014:2818). Jeff, in the current study, testified that his boss inspired him. Recommendations to revitalise clinical research in South Africa include a nurturing environment and a system of support. Institutions should focus on creating such environments to encourage young researchers to choose research as a career (Academy of Science of South Africa 2009:154).

Robinson et al (2016:574) point out that participants in their study mentioned four institutional resources cardinal to their success as investigators: (1) a strong community of investigators, (2) good research infrastructure (facilities) with logistical support, (3) a good pool of study participants from the relevant patient populations, and (4) the ability to delegate. Participants in the current study felt that they were exposed to experienced investigators who were very willing to transfer their knowledge to the new investigators. As a result, the process of learning from experienced staff was described with phrases and words like: "experienced staff do their best to inform you; supervisor had a lot of practical knowledge"; "he (PI) assists me; she was open to showing me what needs to be done"; "the PI or another sub-investigator who is experienced actually guide you through some things"; "another doctor with experience and she taught me"; "so each person whose research experienced contributes in their own respectable ways". These participants did not refer to mentoring or being mentored by a senior staff member. As part of the mentoring process there is usually an agreement between two people; the mentor agrees to be the mentor and the mentee agrees to be mentored by the mentor.

The mentor and mentee then decide how the mentoring process will look. This mentoring relationship can develop spontaneously or informally over time. Learning from experienced and skilled staff, as mentioned in the current study, typically takes on a more informal way of training and there is generally no agreement between two people (Mbuagbaw & Thabane 2013:17).

McHugh and Lake (2010:276) define experience as "both time in practice and self-reflection that allows preconceived notions and expectations to be confirmed, refined or disconfirmed in real circumstances". Participants in the current study had the opportunity to acquire experience in real circumstances from experienced and skilled staff. Apprenticeship (overlapping qualities of mentorship), where an aspiring doctor would apprentice with a senior experienced physician, has been part of medical education for centuries (Pfund, House, Asquith, Spencer, Silet & Sorkness 2012:vii). In some instances, the apprentice might receive quality education and in other instances the senior physician might be indifferent to the needs of the apprentice. We see that in the current study Robin had to request her supervisor to mentor her. It is not clear from the information given by Robin if the supervisor was indifferent to her needs, if the supervisor did not acknowledge the important impact of mentoring or if the supervisor lacked mentoring skills. Similar to apprenticeship, scientific research has relied on transference of critical knowledge, skills and attitudes from experienced investigators to early career investigators (Pfund et al 2012:vii). In the early days, research mentoring was explicitly articulated and until recently there was an implicit assumption that mentorship came naturally (Pfund et al 2012:vii). It is only over the past few years that there has been a growing interest in the theory and practice of mentoring (Pfund et al 2012:vii).

Participants in the present study mentioned that, above and beyond experienced and skilled investigators, they were also able to rely on the support of a good team.

4.3.1.6 Teamwork

The importance of having the support of the right research team, both locally and internationally have been emphasised by participants in Robinson et al's (2016:574) study. Robinson et al's (2016:574) participants felt that it contributed to increased productivity and created an enjoyable research career experience. Hulley, Cummings,

Browner, Grady and Newman (2013:19) mention that investigators who enjoy teamwork will develop rewarding relationships with all stakeholders at their site and in the research field. Meagan, in the current study, experienced the reward of being part of a nice team and therefore did not mind working hard.

In a module written by Salas (2015:4) for the World Health Organisation (WHO) on being an effective team player, she describes the nature of teams according to six categories namely: (1) teams that draw from a single professional group; (2) multi-professional teams; (3) teams that work closely together in one place; (4) teams that are geographically distributed; (5) teams with constant membership; and (6) teams with constantly changing membership. The module was written for the training of medical students and newly qualified doctors. The WHO refers to Salas's definition of teams as a "distinguishable set of two or more people who interact dynamically, interdependently and adaptively towards a common and valued goal/objective/mission, who have been each assigned specific roles or functions to perform, and who have a limited lifespan of membership". The current study had participants from multi-professional teams (doctors, nurses, study coordinators, QC and regulatory officers), working in the same department/in one place, and where there was a constant change in team membership (Salas 2015:4).

A survey conducted in Japan among physicians not only showed the need for greater knowledge of clinical research but also a need for more administrative assistance from the team in the production of study documents (Sumi, Murayama & Yokode 2009:7). In another survey by Cascade, Nixon and Sears (2014:7) to better understand sources of investigator burden in clinical trial operations and to determine the value of potentially supportive solutions, showed that the most burdensome activity for young investigators was completing contractual and regulatory documents. To assist investigators with such burdensome administrative tasks most dedicated clinical trial sites, including the sites chosen for this study (as mentioned by participants), have staff, as part of the team and site, allocated to help with contractual documents, regulatory issues, and any other essential documents for clinical trials.

Strong, Paramasivan, Mills, Wilson, Donovan and Blazeby (2016;6) found in a study they conducted on the role of teamwork in recruiting participants for a clinical trial, that working as part of a team over a period of time with the same team members lead to

increased efficiency of the team. It was also imperative that team members were taken up in the team from the beginning of a project to ensure team members perceive that they participated in influencing the design and that they have engaged in the study. Participants in the current study did not mention having the opportunity to be part of a clinical trial from the planning phase, through the start-up and implementation, to the end of a clinical trial. It is unclear what their experience might have been should they have had the opportunity to be part of a clinical trial from the start-up till close-out phase. However, their experience of team support was believed to have contributed to a more efficient adaption period.

An article by Hutton (2017:1) on behalf of the Australian Institute of Business highlighted some benefits of teamwork, and one of the most important benefits is the fact that it brings people together from different backgrounds and levels of experience. Teamwork, therefore, serves as an opportunity for professional development and learning. This learning could occur during a meeting, or even just by listening to others and then using the knowledge to build skills. According to Nordmeyer (in Hutton 2017:1), "individual team members serve as educational resources to other employees in a team environment". This was proven in the current study by participants articulating that they partnered with the study coordinator, nursing staff and QC officer to learn from them. Knowledge gained from other team members could lead to increased confidence, consequently leading to better attitudes and increased job satisfaction. Support from the team gives a sense of belonging in a workplace, and a strong team environment would count as a great support mechanism for new staff members as confirmed by Arthur, Veronica and Meagan in the current study (Hutton 2017:1). Team members who help each other and who rely on each other build trust within the team and during challenging times they can support each other for the success of the project. When new staff members can rely on the guidance of more experienced team members, they can focus on what they need to learn for that specific project. As soon as a member feels he or she needs to handle a challenge individually without team support, they could become overwhelmed (as experienced by participants in the current study) and make irrational decisions. Thus, there are benefits to working as part of a team for the person as well as for the organisation. It could make life much easier for a team member and they can develop professionally (Hutton 2017:1).

There were also benefits for early career investigators as they found their way through the labyrinth and were able to discover for themselves what it was like to be part of clinical research.

4.4   DISCOVERIES WHILE WALKING THE LABYRINTH

Travelling through the passages of the labyrinth brought some positive and negative experiences for early career investigators. They had to decide if these discoveries were to their benefit or to their disadvantage, and it was these decisions that played a role in their commitment to stay within clinical trials or not.

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                                              │ 4.4.1.1 Mundane     │
                                              │ work                │
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                    │ of clinical      │      ┌─────────────────────┐
                    │ research         │      │ 4.4.1.2 It is a     │
                    └──────────────────┘      │ process and it takes│
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│ 4.4 Discoveries  │                          │ gratification       │
│ while walking the│                          └─────────────────────┘
│ labyrinth        │
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                                              │ 4.4.2.1 Increased   │
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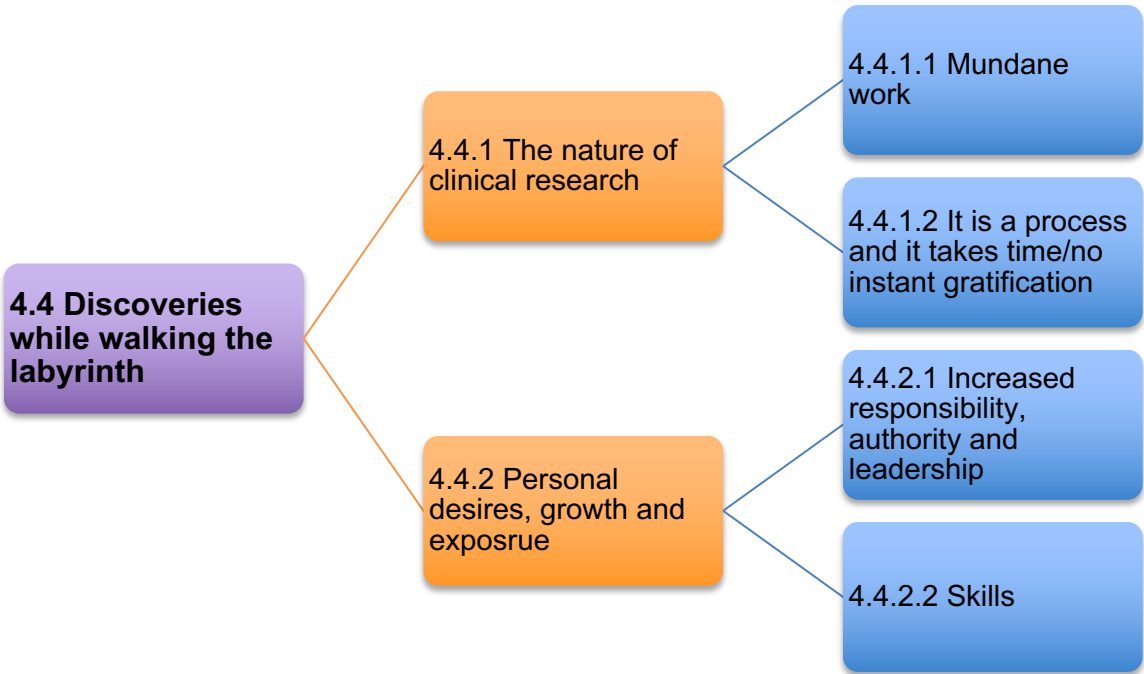
Figure 4.4: Discoveries while walking the labyrinth

4.4.1   The nature of clinical research

The discovery that the nature of clinical research is not very exciting on a day-to-day basis and that it relates to mundane work without instant gratification was acceptable for some participants, mostly because it suited their personality. For others, it was a warning sign of boredom and stagnation.

4.4.1.1 Mundane work

Iber, Riley and Murray (2012:22) mentioned that personal/professional motivation to enter clinical research needs to be considered in light of the reality that clinical research work is, at times, a mundane, repetitive chore that must be attended to every day of the year, as confirmed by Donald in the current study. In an article written by Newman (2012:737) on the eight common misconceptions about HIV vaccines, he commented that HIV vaccine development faces enormous challenges and that these challenges can only be overcome by dealing with the mundane challenges of implementation. On another note, Wallace (2005:4) claims that most graduate seniors do not know what "day in, day out" really means because normally nobody at a commencement speech talks about it. Wallace (2005:4) informs the graduate seniors that a great deal of adult "day in, day out" life involves boredom, routine, and petty frustration.

Already in 1998, Farrell (1998:1236) wrote about the lack of information about the day-to-day and strategic management of clinical trials. According to Farrell (1998:1236), at that stage (1998) there was no clearly defined operational models or any code of practice for managing a randomised controlled trial. The result was that clinical trials often failed because of the lack of practical business-like approach to get the job done. Farrell (1998:1236) suggested that the trial team needs to nurture clinicians by helping with the boring mundane aspects of a clinical trial.

In 2017 Lawton, White, Rankin, Elliott, Taylor, Cooper, Heller and Hallowell (2017:2) commented in an article on staff experience of closing out a clinical trial, that research on clinical trials has previously focused predominantly on patients' understanding and experiences of clinical research. Over time, the value of staff perspectives had been recognised and staff were included in studies on clinical research to show how staff's attitudes and understandings can influence, for example, recruitment of participants, delivery of trial interventions, and trial outcomes. Lawton et al (2017:2) chose to explore staff experiences of closing out a clinical trial from November 2011 to June 2015, since it was under-researched like most trial work. The perspectives of early career investigators with regards to the nature of clinical research work, such as the fact that it is mundane and boring, is therefore critical because there is little written on the day-to-day experiences of early career investigators.

Clinical research is not only mundane and boring for some early career investigators in the current study, it is also a process that takes time and investigators should not expect instant gratification.

4.4.1.2 It is a process and it takes time/no instant gratification

Woodcock (cited in Institute Of Medicine (IOM) 2010:5) mentioned that many young scientists and clinicians find clinical research unattractive because of the long and challenging process of seeing a clinical trial through from the beginning to the end. According to Woodcock (cited in IOM 2010:5), successful clinical investigators are characterised by tenaciousness, persistence, as well as exceptional motivation to complete the clinical trial process. The lengthy process does not only include administrative burdens in applying for clinical trials at local authorities; there might also be institutional bottlenecks preventing trials from starting or from efficient implementation, such as the lack of qualified, experienced staff (Institute of Medicine (US) 2010).

Forstmeier, Drobetz and Maercker (2011:121) defined the delay of gratification as "the voluntary postponement of an immediate reward for a later but larger one". According to them, having to choose between an immediate reward and a greater reward that may require the investment of time and effort is a recurrent challenge in life. As Donald, Joslyn and Arthur in the current study mentioned, they might only see the results of the studies they have worked on in a few years' time, but in the end, it would be worthwhile on a personal and community level. Reflecting on their comment, did they display characteristics of tenaciousness, persistence and exceptional motivation to complete the clinical trial process that might ultimately make them successful clinical investigators?.

Wilmer and Chein (2016:1607), backed up by popular media, refer to today's youth as the "BNow Generation and BGeneration (for BConnected and BIntroducing)". Similar to the BGeneration, today's young adults, also known as "Generation C" or the Millennials, have grown up with technology and possess an especially strong need for instant gratification (Wilmer & Chein 2016:1607; Nielson 2012:1; Au-Yong-Oliviera, Goncalves, Martins & Branco 2018:954). Millennials are the first generation to grow up with, as Ritter (2018:1) called it "instant gratification" technology of digital media. According to

Wilmer and Chein (2016:1607), technology could offer a gratifying escape from ongoing monotonous tasks and therefore engagement with e-devices may occupy basic reward-related processes. Wilmer and Chein (2016:1607) also mentioned that studies on the relationship between technology habits and delays of gratification are still quite limited. However, current findings indicated that technology behaviours could be understood in terms of frequently researched decision-making processes and therefore encourage the conclusion that personality variables related to both impulsivity and reward processing are relevant factors in mobile technology use. In the current study, the majority of participants were between the ages 20-35 and could be considered as young adults, and although the use of e-devices was not part of the current study, it could be assumed that the comments of Wilmer and Chein (2016:1607) would also be applicable to the early career investigators in the current study. Branch (2011:19) mentioned that behavioural issues are extraordinarily complex and promising translational relevance to any relationship between phenomena could put a person at high risk of making promises that could be broken.

Taubenfeld (2017:1) commented that new graduates (such as the majority of early career investigators), often in their first job, tend to expect fast feedback and they will get disappointed should they be passed over for an increase and promotions, and even the lack of positive reinforcement will discourage them. If their expectations are not fulfilled, they may feel frustrated and may start looking for another job. Rightfully, Taubenfeld (2017:1) mentioned that in certain fields (such as clinical research), accomplishments take time and the Millennials (or Generation Y – those born between 1984 and 2004 and is now in their 20s and 30s) have to learn to be patient to finally receive the pat on the back or the reward. For those who cannot learn the ability to delay gratification, who prefer the thrill of instant gratification, they will encounter serious problems on an individual and community-based level (Taubenfeld 2017:1). For some of the participants in the current study, the issue of instant gratification was something they had to deal with in their new environment where clinical trials could be a very long process from the planning to the end phase.

As mentioned, times are changing and although numerous studies have been conducted around the Millennials, the corporate world, including the clinical research world, has been slow to adapt (Rius 2015:1). Moving away from the traditionally valued job security and benefits, Millennials are more focused on employability and it is the

Millennials who are replacing the older generation of investigators (Rius 2015:1). Looking always outward to see how their current jobs can be leveraged within their overall career, Millennials often consider their current job as one step on a more significant career path (Rius 2015:1), like using their job as a stepping-stone as mentioned by some participants in the current study. This is a significant phenomenon that institutions and employers should keep in mind when hiring and retaining employees in today's work environment. It requires a new way of managing employees. Employers have to adapt to adjusting employees' incentives, benefits and culture to better match the emerging workforce (Rius 2015:1). Results from the current study might, therefore, be a good reflection of the fact that most of the early career investigators (participants) were in the bracket of being Millennials, and it might be true for other clinical research institutions as well.

4.4.2   Personal desires, growth and exposure

Moving through the labyrinth, participants also discovered their need for growth in responsibility, authority and leadership, and the need for more exposure to build good clinical trial skills.

4.4.2.1 Increased responsibility, authority and leadership

Increased responsibility and the ability to make your own decisions are important for employees as shown in a research survey by Grant, Fried and Juillerat (2010:417). Bank tellers were dissatisfied with their jobs; they felt they were treated like "glorified clerks", they could not make their own decisions, and were micromanaged. A soon as their jobs were redesigned, giving them added responsibility, autonomy and a broader range of skills, their job satisfaction increased, their performance increased, and they were more committed to the organisation. Responses from participants in the current study is in line with Grant et al's (2010:417) findings. Immediately after Allie, Sarah, Jeff and Arthur were given more responsibility, they expressed their satisfaction and how it motivated them. They had a desire for increased responsibility, authority and leadership. It was also apparent from Jeff's response that early career investigators who were not so fortunate to be given responsibilities, had left clinical research.

Besides mentoring, leadership training could empower early career investigators to increase emotional intelligence, negotiation and conflict management skills, teamwork, influence, coping, managing time and relations, and political acumen according to findings from Yin et al (2015:861). Yin et al (2015:861) confirmed that their findings are supported by early empirical data from formal institutional leadership development programmes for physicians and clinical investigators of both genders.

Robinson et al (2016:574) pointed out that having autonomy over multiple areas was crucial for career success and a feeling of satisfaction. Participants from Robinson et al's (2016:574) study indicated that autonomy is an enabler to ownership of one's work, to having a choice to decide what to work on, or having the ability to decline projects that would not be beneficial for a person's career. On a daily basis autonomy enables a person to organise his/her work schedule and environment to fulfil his/her needs and to increase productivity (Robinson et al 2016:574). Allie and Meagan could not agree more with the participants in Robinson et al's (206:574) study. Developing ownership of one's work includes building the necessary skills to do the work with excellence and confidence.

4.4.2.2 Skills

The MRC survey (Oldfield et al 2015:17) reported that most (91%) of their participants wanted the opportunity to publish to progress their research career. Siegfried, Volmink and Dhansay (2010:521) mentioned that training specialists at universities in South Africa mainly focus on accruing clinical experience and skills, and lack a research focus; with the result that many doctors interested in clinical research emigrate to develop these skills elsewhere. Findings of the current study confirmed the first part of Siegfried, Volmink and Dhansay's (2010:521) statement. In the current study participants stated specific clinical research skills such as writing protocols, grants, articles for publishing, preparing applications for approval, and any other clinical research procedures they see necessary to acquire. Participants did not mention a need for clinical experience and skills, and it could be assumed that they received those during their training or in their previous jobs as doctors.

However, participants did not use the word "skills" in particular when they referred to their learning needs, but to be able to "learn" how to write a grant you need to develop

skills in how to write a grant; knowledge alone is not enough. Boulet (2015:1) describes skills as the ability to apply knowledge (information acquired through sensory input: reading, watching, listening and touching) to specific situations – skills are developed through practice. It is therefore important that participants from the current study get the opportunity to practice or to perform certain actions, such as writing a protocol or grant, in order to improve their performance at the task until they master it.

The survey conducted in Japan (Sumi et al 2009:7) found that less than 20% of participants had specific training in clinical research, and most of them indicated a need to acquire concepts and skills regarding clinical research. Thus, there is a need to develop skills related to the operational side of clinical trials to establish good practice (Sumi et al 2009:7). Referring once more to the SCRS White Paper (2014:1), the author drew our attention to the fact that although young investigators are eager to do clinical trials, they often have little access to adequate resources and training. They lack exposure to core operational principles and fundamentals such as effective participant recruitment and retention techniques, regulatory processes, budgets, and quality assurance of data. Reba was in agreement with this statement and felt strongly that she should have been better prepared for different aspects of clinical trials during the period she was awaiting Ethics and MCC approvals.

Ogdie et al (2015:1191) point out that some participants in their study reported a fear of failure due to a lack of confidence in abilities or skills. Participants also felt that institutions lack the necessary infrastructure and the knowledge about what early career investigators' needs are.

Skills required by early career investigators need to be provided by skilled mentors. A study by Shea et al (2011:779) showed that there is a need for additional support of mentoring in academic medicine, and that mentors for early career investigators need a skill set that is above the usual requirements in the course of medical training or research.

However, acquiring all the knowledge and skills necessary through increased responsibility, authority and leadership do not seem to be the only answer to retain early career investigators in clinical research.

4.5   MOVING BEYOND THE CENTRE - QUO VADIS?

A great deal of uncertainty was expressed by participants in the current study around participants' career destination. They were not sure what the centre of the labyrinth looks like, and if they would recognise it when they have arrived. They were not sure what kind of road signs would be available to guide them to the centre of the labyrinth. It was like a "mystery fog" hanging in the passages of the labyrinth, obscuring their view of the centre. And then, their biggest concern was, "and what then?" Where will the road take them after they have reached the centre of the labyrinth?
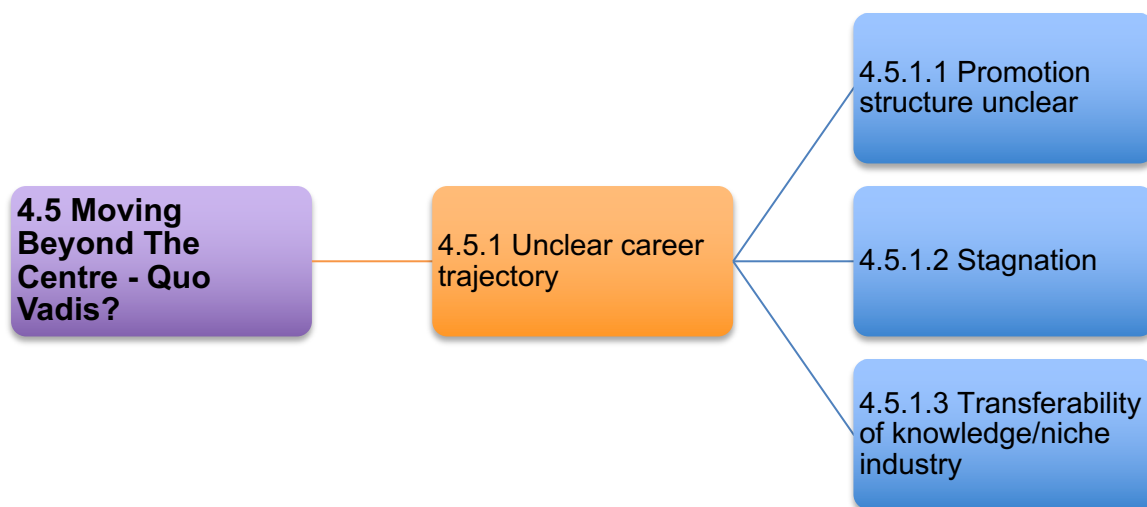
Figure 4.5: Moving beyond the centre – Quo Vadis?

4.5.1   Unclear career trajectory

4.5.1.1 Promotion structure unclear

A report published by the European Science Foundation (Education…2015:15) on investigator-driven clinical trials, reported that two of the reasons for the shortage of qualified researchers were a lack of job security and uncertain future prospects, and the absence of a clear, well-defined and predictable career path for clinical investigators. It also mentioned that choosing research does not bring a competitive salary and may even be a disadvantage at several stages of the career of a clinical investigator. Furthermore, it mentioned that researchers are more and more constrained by

regulations, guidelines, and the increasing demand for efficacy, leaving them with less freedom for imaginative and innovative research.

Armstrong et al (2009:664) found that early career investigators leave the research field due to a lack of career security as a result of the difficulty in finding and maintaining research funding. Others leave because of a lack of adequate training and mentoring, a problem mentioned earlier in this chapter. Insufficient financial reimbursement was also mentioned by Dev et al (2008:208) as a reason for the lack of attracting investigators to clinical research. According to them (Dev et al 2008:208), previous studies have shown that financial incentives are among the most important attractions to motivate doctors to get involved in research. In the current study, Veronica and Meagan commented that the salary for early career investigators was not a motivator for them to do clinical research.

Investigators' compensation in clinical trials has been a contentious issue with different opinions from academic researchers, clinical trialists, and the pharmaceutical industry. In most instances, the clinical trialists are of the opinion that the study budgets are inadequate considering the potential safety risks and many 'hidden costs' involved (Burgess & Sulzer 2010:249).

A junior academic commented that the lack of research career options forces students to migrate for work or to exclude research as a career possibility. According to the junior academic, plans should be made to secure jobs and to establish a career path in research for students to motivate them to stay or to return to their own country (Franzen et al 2013:8). Franzen et al's (2013:8) study reported that researchers felt they get little recognition for research and that promotion is often achievable without doing research. Participants from their study also mentioned strong salary and workload hindrances (Franzen et al 2013:8).

Salto-Tellez, Oh and Lee (2007:880) supported a mind-set shift; measuring success does not only depend on the ability to generate large incomes, it also includes what kind of life style you have, your scientific output, promotion, and a comfortable income. Looking at developing a higher degree research programme for doctors in Singapore, the following questions were asked by the clinical/surgical/diagnostic specialist community: "what is the incentive for our young graduates to follow this programme?;

will they be disadvantaged when their peers take positions of responsibility earlier, develop their clinical skills faster and better, and have access to jobs in the private sector more readily? what is the attraction in the long-term?" (Salto-Tellez et al 2007:879). Results from Robinson et al's (2016:574) study show that participants lacked confidence and/or clarity about their future career paths. There was a lack of a "steering wheel" according to one of Robinson et al's (2016:574) participants, and it was echoed by other participants in the study: "what is the end game,...where to take it?" These findings were specifically true for investigators in their mid-career phase where they felt little guidance was given on the steps necessary to continue to be successful (Robinson et al 2016:574). The same sentiments were echoed by Reba, Sarah and Arthur in the current study. Arthur felt that his friends, who are consultants, are way ahead of him in terms of clinical skills and salary. He admitted on the other hand that he enjoys working on clinical trials and it currently suited his life-style but he is afraid that the inability to progress might still catch up with him.

Receiving recognition and rewards are often correlated with success as seen in the MRC (Oldfield et al 2015:19) study; 96 % of participants who responded that it is easy for them to pursue a research career received recognition and reward. According to the survey, these rewards and recognition encompass a wide range of things such as awards and funding; salary; promotion or promotion prospects; acknowledgement and praise from employers, peers, others in the field; and internal reward or job satisfaction. Salto-Tellez et al (2007:880) agreed with the concept of reward and recognition and felt that careers in academic teaching and research must be rewarded to attract and retain good and enquiring clinicians. As mentioned in 4.4.2.a increased responsibility for Allie, Arthur and Jeff was like a reward for them and it motivated them to stay in clinical trials. Unfortunately, receiving rewards and promotions in clinical research is not always a sign of a clear career trajectory; it might bring job satisfaction for the moment, but what is next in line? From my own experience, the period before promotion is often characterised by a period of stagnation.

4.5.1.2 Stagnation

There could be multiple reasons for career stagnation according to Abele, Volmer and Spurk (2012:107). These reasons could be subjective or within the person, for example, self-efficacy issues, goal issues, and dual-career issues. On the other hand, it could be

objective, meaning it could originate from the organisation or the labour market situation, for example, discrimination, lack of socialisation, "dead-end-jobs", and economic meltdowns (Abele et al 2012:107). Any of these examples, or a combination of these, could have a negative impact on a person's quality of life and could become a dilemma if a person is not able to cope with it (Abele et al 2012:107). Stagnation due to dual-career issues has increased over the last four decades. Women's education and workforce participation increased, and a new partnership has evolved in cases where the women had a partner, a family, and other social bonds (Abele et al 2012:107). In instances where the women had a partner, partnership was called the "dual-career couple" (DCC) partnership, and can be defined as couples wherein both partners, with or without children, work full-time and have high career aspirations. Core values within the DCC partnership are high job commitment, respect and interest in the partner's career, and gender and value equality. Reasons mentioned by Abele et al (2012:107) were true for some participants in the current study who struggled with goals (pertaining to the future) and dual-career issues. In most instances, the female participants in this study mentioned the choice they had to make regarding a more balanced work-life situation that would include time to raise a family. Participants in the current study did not elaborate on their partners' job or role within the relationship, and it is unclear how they experienced the "dual-career couple" partnership.

Research conducted by Valcour and Tolbert (cited in Abele et al 2012:107) has shown that the traditional gender roles still exist even in DCCs, but that there is often a detrimental effect on women's career success as they more often give priority to their partner's career. Ethical principles relevant to the dual-career issue might relate to employees who experience a conflict because they feel torn between the fulfilment of both their work and non-work roles, and organisations might fear financial losses in instances where employees might devote too much time and effort to non-work areas. In the end, employees are responsible to organisations and organisations are responsible to employees, and together they need to look at strategies to integrate both life domains. Quality of life strategies could include offering flexible work hours (as some of the institutions in the current study are offering), telecommuting jobs, and dual-career hiring.

The well-being of employees depends on creating a work-life balance and need to be organised within an ethical environment by granting balance, autonomy, and justice. An

interesting result from the current study is that some early career investigators, Donald and Meagan for example, chose to be in a "stagnant" situation because it suited their lifestyle. They wanted a better, more balanced lifestyle which was possible with clinical research, especially for women in dual-career situations. They chose clinical research because they had the choice to work more flexible hours with less stress.

4.5.1.3 Transferability of knowledge/niche industry

A niche is defined as a position a person holds within a submarket of a market that is particularly well suited to the person (Castiglioni et al 2013:137). A clinical investigator (niche position), therefore, works in clinical research (niche) that is a submarket of healthcare. An ideal niche will support a person's personal interests and passions, contributing at the same time to recognition and institutional, field, and community expansion (Castiglioni et al 2013:137). Participants in the current study felt that although this might be true within the clinical research field, it is not true in relationship to clinical medicine. Participant felt that they will not be accredited for their clinical research knowledge and experience when they apply for a job in clinical medicine. Transferability of knowledge is not a given for doctors working in clinical research.

Clinical research represents a strong growth potential and ample opportunities. At the same time, it is a field not well known, especially to young medical graduates. As a result, fewer medical graduates would enter the clinical research field, presenting an ideal opportunity for trained and qualified professionals, with far less competition (Clinical Research… 2018:1). Occupation of a niche position, such as that of a clinical investigator, means that a person would focus all his/her attention to acquire the necessary knowledge and skills to make a success of becoming and being a clinical investigator (Castiglioni et al 2013:137). As Samantha mentioned in the current study, your career will take a "side step" when you choose to focus on clinical trials. This process of focusing on your interest and building on your strengths can take from three to five years, and the guidance of a mentor for early career investigators could be very insightful (Castiglioni et al 2013:137). The process of building on your strengths to advance a career in clinical research was an issue that troubled Arthur in the current study because it was a process that was unclear to him in terms of how it should happen and how long it should or could take.

Fiorillo, Volpe and Bhugra (2016:147) cautioned that you can outgrow your niche career and that you need to make provision for such an occurrence. You need to be open for change in your current career. At the same time, it is important to concentrate on additional professional development, for example, enhancing skills related to teaching, curriculum development, and leadership (Castiglioni et al 2013:137). To echo Donald's words in the current study "you have to think twice" before you choose clinical research and strive to better your situation through additional knowledge and skills as mentioned by Meagan.

4.6 SUMMARY

Initially, early career investigators experienced many recurrent obstacles as they struggled to live with the messiness, the complexities, and with what often appeared to be a lack of direction as they entered and tried to find their way in clinical research. They held onto and followed the thread that led them downward into the intricate corridors of knowledge. With time, they started to understand the maze. They began to understand what the labyrinth is all about as they continue the lifelong pathways of self-inquiring, gaining knowledge and skills. As early career investigators, they are still in the process of discovering all the secrets of the labyrinth and continue to unwind the "thread of spider's silk" (McLeish 1983:143) to find their way to the centre. It is important that we nurture our early career investigators through this whole process. In Chapter 5 I will broadly give recommendations on possible ways of "nurturing" that might enhance the attraction and retention of early career investigators within clinical research.

CHAPTER 5

RECOMMENDATIONS, LIMITATIONS, AND CONCLUSIONS OF THE STUDY

Certainty is false closure. Ambiguity is honest closure. Staying open eschews closure. Enough is enough yields pragmatic closure. Closure is hard. Not closing is harder. Close…for now – Halcolm's Benedictions (Patton 2015:633)

5.1 INTRODUCTION

Despite several universities and other research organisations and institutions worldwide admitting over the last two decades that there is a lack of training and skills shortages for clinical research (Armstrong et al 2009:664-666; Daye et al 2015:883-887; Culican et al 2014:3219-3222), the number of new clinical investigators have not increased. Several suggestions were made by the 2011 NHRS (South Africa 2011:1) to address the problem without any significant change in the numbers of new clinical investigators. It was therefore unclear what early career research investigators' experience was of clinical research and the possible influence on the viability of the clinical research enterprise.

In the previous chapter, I deliberated the findings that emerged from the analysed data related to the experiences of early career investigators in clinical research. Themes, categories and codes that emerged were discussed and complimented with the literature control. The purpose of this chapter is to determine whether the research aim, as stated in Chapter 1, has been achieved. Conclusions regarding the experiences of early career investigators, which answers the first objective in Chapter 1, are captured in this chapter. Furthermore, the summary, general conclusion of the study, recommendations, suggestions for further research, as well as the limitations of the study are presented in this chapter.

5.2 SUMMARY OF THE STUDY

5.2.1 Research objective

The objective of this research was to:

- explore and describe early career research investigators' experience of clinical research at sites specialising in infectious diseases in Gauteng

5.2.2 Research question

The primary research question driving this research was:

- What are early career research investigators' experience of clinical research at sites specialising in infectious diseases in Gauteng?

5.2.3 Research methodology

I approached the design of the study the same way you would peel different layers of an onion. I used a generic qualitative strategy, participants were purposefully selected, and data were analysed thematically. Information were collected through face-to-face interviews with 14 early career investigators from three research sites in Gauteng. I included information from my own reflective journal and field notes. All the participants in the study had less than 5 years experience as early career investigators.

I followed a cyclical analytic process as endorsed by Saldana, consisting of first cycle methods, a cross method in-between, and second cycle coding methods (Saldana 2016:68) to analyse all data. Ethical issues were taken into consideration and measures to ensure trustworthiness were adhered to. Four main themes emerged from the analysed data and they are discussed in the following section.

5.3 SUMMARY OF RESEARCH FINDINGS

This section contains the summary of the research findings that led to answering the research question. I used two metaphors to explain aspects of participants' experience, namely that of a maze and the labyrinth.

> *All perception of truth is the detection of an analogy* – Henry D Thoreau. (Patton 2015:606)

5.3.1 Entering the maze of clinical research

Early career investigators had different reasons for initially entering the research field. This included their pre-existing desire, personality, and the notion to use clinical research as a stepping-stone in their career. Despite the different reasons for entering clinical research, most participants' initial reaction to entering the clinical research maze was their inability to cope with their new environment because of their previous knowledge, skills and experience of clinical research.

Several barriers and frustrations were reported, however, literature is silent on the daily frustrations reported by participants in the current study. The study showed that even a small prod/nudge could light some spark in a doctor to consider a career in research, however, the majority of young doctors are unaware of clinical research or that it could be a viable career.

5.3.2 Exploring the maze to find a way into the labyrinth

Most participants felt they had a supportive environment although it was clear that the support system was not formally structured or well organised at all the sites. As part of the supportive environment participants mentioned that they were not only shadowing experienced investigators, they were also shadowing other experienced team members. Beyond experienced and skilled investigators, participants reported that they were also able to rely on the support of a good team.

Early career investigators in the current study felt that mentoring helped them tremendously to survive the first year. Participants did not elaborate on the kind of

support they received during mentoring. Most participants did not explain their own experience with mentoring, and it is not clear if they received mentoring or if there was a lack of mentoring. Results from the current study showed that participants and research institutions in Gauteng were still following the old school of thought in which training is the only support intervention and includes OJT or learning by doing.

Apart from mentioning GCP training that is usually a requirement of most clinical research sponsor companies, participants in the current study did not refer to specific courses or training programmes that they have attended by name. Participants also did not mention any training courses that were developed and provided by their own institutions. It is therefore not clear what the competency requirements and standards for training are at the different institutions.

5.3.3   Discoveries while walking the labyrinth

Several participants confirmed the reality that clinical research is at times a mundane, repetitive chore that must be attended to every day of the year. Clinical research is not only mundane and boring for some early career investigators in the current study, it is also a process that takes time and investigators could not expect instant gratification. Instant gratification could also be related to some personal desires, growth, and exposure of early career investigators, where they felt specific needs had to be addressed to become fully equipped for the job. Participants had a desire for increased responsibility, authority and leadership. Furthermore, participants mentioned wanting to acquire specific clinical research skills such as writing protocols, grants, articles for publishing, preparing applications for approval, and any other clinical research procedures.

Results from the current study showed that more than half of the participants (early career investigators), fell in the bracket of being Millennials, those between 18-35 years of age. In the current study, 8 out of the 14 participants were Millennials and I presume that it might be a good reflection of the representation of Millennials at other clinical research institutions as well. This is a point for further exploration.

On discovering the nature of research, some participants accepted it because, as mentioned, it suited some personalities. Yet, others would ask: Quo Vadis?

5.3.4   Moving beyond the centre - Quo Vadis?

Participants were not entirely sure about the direction of career growth in clinical research and mentioned that the career trajectory was not set out. There was anxiety about what the future held and what the next step would be in clinical research. Participants felt that due to the nature of clinical research an investigator might end up stagnant. An interesting result from the current study is that some early career investigators chose to be in a "stagnant" situation because it aligned with their lifestyles.

Participants referred to clinical research as a niche industry and they believed an investigator could not take his/her knowledge to another health-related field (or healthcare industry). The Business Dictionary defines the health industry (also called the **medical** industry or health economy) as: "an aggregation and integration of sectors within the economic system that provides goods and services to treat patients with curative, preventive, rehabilitative, and palliative care" (Business Dictionary online 2008, vs "healthcare industry"). Thus, for some, following a clinical research career could be a disadvantage, making it difficult to return to medicine as a general practitioner.

5.4   RECOMMENDATIONS

The results from this study indicated an urgent need to reinvigorate the clinical research workforce and to address the challenges facing clinical research investigators, with an emphasis on early career investigators' challenges. Some vital recommendations are necessary to preserve the pipeline of successful early career investigators. Based on my findings and the existing literature, I provide the following recommendations:

5.4.1   Recommendations for formalised academic training in the principles of clinical research in South Africa

In the absence of a national plan for the education and training of clinical researchers in South Africa, it is of utmost importance that the government initiates, funds, and supports such a plan. Some of the funds currently provided via the Department of Education (DoE) for clinical training at both undergraduate and postgraduate levels could, for example, be redirected for clinical research training (Academy of Science of South Africa 2009:147).

In support of a national plan for the education and training of clinical researchers, I suggest that academics, academic institutions, the government, national medical research institutions, societies and networks, such as the MRC in South Africa, form partnerships and collaborate to develop clinical research training programmes. The goal of these programmes should be to provide practicing or new doctors with the tools and research credentials to facilitate collaborations with investigators involved in large clinical trials (Armstrong et al 2009:664; MRC Annual Report 2012/2013; Brass et al 2010:700).

Besides an initiative for a national education and training plan, medical schools in South Africa, as well as the South African government, need to intensify their efforts to ignite a spark of interest for clinical research among medical students and newly qualified doctors, to pursue a career in research. Suggested recruitment strategies could include the promotion of a formal training programme, as well as good benefits for those choosing a career in clinical research such as substantial financial compensation, medical aid, aftercare for babies and young children, flexible working hours, and a supportive work environment (Roberts et al 2012:269).

The suggested formal training programme could include clinical research investigator training programmes to provide comprehensive support, particularly for early career investigators. The success of these programmes would depend on how well they are advertised within the clinical research community. Medical schools, registrar programmes, hospitals, conferences, workshops, social media and medical journals could play a role in promoting such programmes (Flood et al 2015:5).

Not only should clinical research in South Africa be recognised as a speciality with formalised training (other than GCP), expertise and competence should be assessed and proven. To be able to achieve that, clinical research training programmes and certification processes should be developed and standardised, with a core curriculum and accreditation (Burges & Sulzer 2010:402).

Without the necessary and much needed funding for the planned educational and training plan, it will be very difficult to develop and sustain training programmes. Formal clinical research training programmes would need funding (for example from government, pharmaceutical industry, corporate, donor) or a reasonable debt-

repayment programme should be available for doctors who consider entering such a programme (Roberts et al 2012:269).

When developing formal clinical research training programmes, medical school department chairs, division chiefs, fellowship directors and South African government officials should be better educated about the needs of early career investigators, especially from institutions without strong research enterprises (Ogdie et al 2015:1191). Clinical research training programmes should make provision to address the needs of early career investigators.

5.4.2 Recommendations for stakeholders in the training and education of clinical research investigators

The training and skills development of early career investigators demand the contribution of a diverse set of stakeholders and include a process of increasing levels of participation in diverse communities of practice (Maritz, Visagie & Johnson 2013:155). This process needs to start at the level of medical doctors' undergraduate and graduate education at academic institutions and should be followed through at clinical research institutions.

5.4.2.1 Stakeholder group one: Recommendations for medical schools or institutions (curriculum matters) to spark interest in (clinical) research

Given the current low priority of clinical research, it is recommended that all medical schools include a substantive introductory research experience as part of undergraduate medical education (Daye et al 2015:886). Medical schools should, therefore, embed research in the mission and vision of the medical school and raise student awareness of research and create a research environment (Rahman et al 2011:91).

Fostering a supportive undergraduate research environment is vital for kindling an interest in clinical research and medical schools and clinical research sites should incentivise and mandate the inclusion of undergraduate medical researchers where appropriate (Burgoyne et al 2010:5212). Opportunities should be made available for all

medical students to undertake undergraduate research inquiry within and outside the curriculum (Rahman et al 2011:91).

Research could be boosted by medical schools and institutions through career guidance for medical students to enhance self-awareness and self-understanding to empower them to make the correct choice of specialisation. Career planning and guidance should take aspects of personality into consideration, and there should be a system to follow up on medical students in their initial selection (of speciality), and also to check on their subsequent performance in the field of their choice (Kemboi et al 2016:108). Research career options should be mapped out to give a better understanding of the options available and should promote recognition for alternative and non-traditional career choices such as clinical research (Oldfield et al 2015:3).

Furthermore, on the level of graduate medical education, including clinical residencies and fellowships, intensive research training would better position doctors for ultimate success and will allow individuals to focus their research training and investigations in their area of clinical speciality, and to move more seamlessly from training to independence (Daye et al 2015:886; Culican et al 2014:3219). This can be done by offering a parallel degree to the medical student, such as an Honours degree and subsequently a PhD degree, in line with their medical degree. Parallel research degrees, as offered, for example, at the University of Cape Town (UCT) to medical students, are a proven route to train and produce cadres of young clinician-scientists (Katz, Futter & Mayosi 2014:113). Creating an environment to encourage and foster clinical research knowledge and skills could enrich and deepen the research experience in residency and fellowship (McGee 2013:14). Unfortunately, as described by Culican et al (2014:3219), the opposite happens because in most instances residents are told that they should focus on clinical medicine and not be distracted by science.

To facilitate the recommendations for doctors not interested in doing a master's degree or PhD degree, a training programme should be developed to support trainees in the form of formal instruction in non-research skills required for success, including grant writing, contract negotiation, research lab management, and mentorship for "budding" doctors (Daye et al 2015:886).

5.4.2.2 Stakeholder group two: Recommendations for clinical research institutions to enhance early career investigators' learning and skills building in the clinical research environment

Clinical research institutions have a crucial role to play in early career investigators' adaption from a dependent to an independent role. A well-developed orientation and training programme for early career investigators could be the first step on the side of clinical research institutions to lay the correct foundation. Considering the feedback from participants, a good time to implement such a training programme would be during the waiting period for Ethics and The South African Health Products Regulatory Agency (SAHPRA) approvals. Such a training programme should cover the full clinical trial process, from preparing for a clinical research study, the implementation of the clinical research, and the close-out of the study. Expanding on the training programme to include basic job description, roles and responsibility training, could assist early career investigators to find their own place in the clinical research team.

Given the numerous challenges and duties early career investigators have to adapt to in their new environment, orientation and training programmes should aim to give early career investigators the support they need to cope. In my opinion, preparing and supporting newly qualified doctors to transition from a hospital setting to a clinical research setting are of utmost importance to facilitate a successful career in clinical research and to retain early career investigators.

In support of a training programme and based on the needs mentioned by early career investigators, clinical research institutions should provide the necessary institutional research infrastructure and additional support, such as a well-qualified multidisciplinary team to handle the workload, and to assist with administrative duties, grant writing and budgets (Ogdie et al 2015:1191; Bagai & Udell 2015:1839).

Clinical supervision through mentoring and coaching for early career investigators should be viewed and promoted as an essential part of the orientation programme at clinical research institutions. The value of professional mentoring and coaching to improve the skills, performance and development of early career investigators should be recognised. Coaching (professional and self-coaching) has the potential to enhance the continued development of clinical supervision by providing clarity of purpose and

enabling early career investigators and supervisors to discover their untapped potential (Driscoll & Cooper 2005:18).

When developing and planning mentoring and coaching programmes for early career investigators, the following should be considered: programmes should be holistic in nature, should be based within an appreciative framework, should have a realistic outcome-based approach, should address goal setting and leadership development, and it should enhance open communication and discussions within the clinical research setting between mentor and mentee (Maritz & Jooste 2011:178). Consideration should be given to online mentoring and coaching programmes in conjunction with face-to-face formal and informal mentoring and coaching programmes (Boninger, Troen, Green, Borkan, Lance-Jones, Humphrey, Gruppuso, Kant, McGee, Willochell, Schor, Kanter & Levine 2010:429; Maritz et al 2013:89).

Essential awareness should be nurtured by mentors, coaches and supervisors by assisting early career investigators to be attentive to the complicated, challenging and wondrous moments that define their lives within clinical research (Treadway & Chatterjee 2011:1192). Early career investigators should therefore have the opportunity for "reflective time" with either a mentor, coach or supervisor for professional and emotional growth. Creating such a "safe space" for reflection and discussion, could empower early career investigators immensely. Allowing both positive (publishing, policy changes) and negative experiences (mundane work, expanding authority) to be used to reinforce values and behaviours conducive to the development of good clinical practice while still having compassion for participants, could be liberating for early career investigators (Treadway & Chatterjee 2011:1192).

Given the importance of mentorship, established and experienced clinical research investigators should be open to mentoring early career investigators and they should be well informed on the topics of effective mentorship, grant writing, navigating funding sources, administration, clinical trial work, teaching strategies, achieving work-life balance, and the tenure and promotion process (Nottingham, Mazerolle & Barett 2017:375). Also, they should show early career investigators the practical side of GCP.

Skills development planned by clinical research institutions for early career investigators should include coping mechanisms to be able to cope with the numerous challenges of

entering clinical research. Building technical competence, without which coping is difficult and sometimes even impossible in clinical research, should be part of skills development (Franzen et al 2013:8).

A well planned and implemented reward and recognition structure for early career investigators at clinical research institutions is likely to encourage early career investigators to stay within clinical research. There should be better compensation for early career investigators but financial recognition could also include promotion, and grants for attending conferences, while nonfinancial incentives could include formal institutional recognition, awards, news in the institution's newsletter or local media, and co-authorship (Rahman et al 2011:89; Ogdie et al 2015:1191). Early career investigators should not at any time feel that they need to stay within research or accept a lower paid position than they feel they deserve (Oldfield et al 2015:15). Salaries for early career investigators should compare well between different clinical research institutions (Flood et al 2015:5).

Job security and stability should be a given and clinical research institutions should provide early career investigators full-time positions and long-term sustainable jobs instead of short term contracts with limited funding (Oldfield et al 2015:15; Heggeness, Carter-Johnson, Schaffer & Rockey 2016:17). This is specifically important for early career investigators who would like to stay in clinical research without the option to become a PI, and who do not wish to lead people but who excel in their chosen field or who have particular technical skills (Oldfield et al 2015:15). Advanced opportunities and positions could be created with opportunities for independent research (Flood et al 2015:5).

To accommodate the desire expressed by women in the current study to balance work and their personal life, clinical research institutions should negotiate more flexible working opportunities to support women to balance the demands of family life and a career in clinical research. Where necessary, the option should also be given to men (Oldfield et al 2015:23).

The mundane nature of clinical research, as mentioned by participants, should be addressed by clinical research institutions through internal initiatives by senior experienced investigators (Ogdie et al 2015:1191). There could be monthly or more

frequent meetings where literature/articles are presented for discussion, early career investigators' interests could be discussed, case studies could be discussed, there could be an annual research day with posters and presenters from the site, an internal library with books and journals could be established, as well as networking with other institutions on a quarterly basis. Mentors and coaches could facilitate the process of coping with mundane work and how to substitute instant gratification with patience, and how to identify and recognise short term satisfaction (for example the gratitude voiced by a participant). Workshops could be organised on grant, protocol and article writing, as well as project and team management. Early career investigators in the current study expressed their motivation to be given the opportunity to publish as they gain experience, skills and confidence in the clinical research setting (Oldfield et al 2015:15).

Organisational support could also be demonstrated through organisational sosialisation that have the aim of helping newcomers to adjust and advancing the career of newcomers. Abele et al (2012:107) mentioned that a lack of social organisational socialisation tactics could be a main factor for career stagnation. One of the key methods for the success of organisational socialisation is mentoring. Unfortunately, it seems that a "rising star/high flyer/genius" would attract a mentor's eye above the mediocre learner who does not catch the mentor's eye, leading to a positive feedback process of higher objective and subjective success within his/her career (Abele et al 2012:107). It is normally those who do not catch the mentor's eye who may eventually experience career stagnation. When planning any strategies for career intervention, the needs and rights of employees should be respected (Abele et al 2012:107). An approach of "same size fits all" should not be used. The employees' rights for balance, respect, responsibility, autonomy, participation, justice, and voice should be respected at all times in the phases of career progress and stagnation (Abele et al 2012:107).

It is important for institutions to overcome career stagnation with strategies that are relevant for the institutions and new employees (early career investigators) because it is not only ethical, it is also essential for the survival and effectiveness of the organisation (Abele et al 2012:107). Institutions or industries, such as clinical research, that could be seen as a "niche" industry, should pay extra attention to prevent or alleviate stagnation to retain employees. Although some participants in the current study chose stagnation to secure a better work-life balance, other participants saw it as a drawback.

Approaches to overcome possible stagnation should be considered by clinical research institutions to prevent investigators being stuck in a position for several years. Diversification of jobs could be considered, such as combining the investigator job with that of quality assurance or grant writing. Opportunities for creativity should be considered and could directly relate to the investigator's daily work, such as recruitment and retaining of participants.

As part of the mentoring process, early career investigators need to learn how to be flexible with participant management without violating protocol, for example, by listening and hearing what their participants are telling them and what their real needs are (Fauci 2016). I suggest that mentors guide early career investigators to see the "bigger picture" instead of only following the structure, protocol, and ticking boxes on the checklist. Early career investigators should be led to insight into what clinical research really entails and what kind of career it could be.

As part of the training programme, clinical research institutions should prepare early career investigators to receive increased responsibility and authority. To assist the institutions with this task, additional internal and/or external courses could be incorporated covering staff, project and quality management, and leadership.

The lack of career trajectory needs to be address as a priority and I suggest that it should be addressed by individual clinical research institutions, in agreement with the clinical research community. A more standardised, objective and clearly defined career development pathway for early career investigators with clear expectations and incentives should be developed (Flood et al 2015:5). There should be set milestones and guidance for promotion. For example, it should spell out what an early career or junior investigator is, when a junior will become a senior investigator, when a senior investigator can become a PI, and what opportunities there are beyond a PI, or options if an investigator do not want to become a PI (Ogdie et al 2015:1191).

To address the transferability of knowledge, I recommend that clinical research institutions and medical institutions providing patient care should work together. What have been learned from clinical research should be practiced at the bedside of patients, and a collaboration programme should be worked out between the research institution and the medical institution to undertake this task. Working with doctors in the medical

institution will enable (early career) investigators to keep up with the medical field while they are doing research at dedicated clinical research institutions, making it easier for them should they wish to return to other areas within the medical field. Culican et al (2014:3219) and Ambati and Cahoon (2014:1853) promote a system where a balance can be established between clinical responsibilities and research demands that would lead to a lifelong attitude of maintaining balance.

5.4.2.3 Stakeholder group three: Recommendations for early career investigators for learning successfully

In the current study, the early career investigators are the most important stakeholders and, as such, they need to know that the final responsibility for their own professional and personal growth depend on them. They should initiate their own training programmes and goals to become successful investigators. They need to be proactive in looking for mentors, coaches and guidance (Oldfield et al 2015:23). Self-motivation, perseverance, and a personal passion to make a difference instead of money might be the key to "stick it out" in clinical research (Rosenberg 2014:4).

Promising early career investigators should recognise the benefits of mentorship. They need to realise that they should play an active role in the mentorship relationship, that they need to look for collaboration, and set clear expectations for the mentorship relationship (Nottingham et al 2017:375). Early career investigators should not only seek mentors within their current institution, they should also look externally for guidance and support. Developing external relationships will support early career investigators' research pursuits and tenure process at their respective institutions (Nottingham et al 2017:375).

Peer mentoring is an option that early career investigators can consider to support them with an additional benefit of the satisfaction they might get in helping another early career investigator to build new skills to cope with their challenges (Maritz et al 2013:165). In the end, being open to learn should be one of the qualities early career investigators show while working with their mentors and the clinical research team.

A last recommendation on my list for early career investigators would be to form their own national society to initiate their own training, development, and growth through

conferences, workshops, manuals, online courses, blogs and newsletter. This initiative could be sponsored by the pharmaceutical industry, for example (Bagai & Udell 2015:1840).

5.4.2.4 Stakeholder group four: Recommendations for improving the supportive learning environment in both theoretical and clinical research institutions

The focus for improving the current supportive learning environment for early career investigators need to be adjusted to target what really would have an impact. Medical educators should, therefore, focus on the integration of specific research skills training within all aspects of the undergraduate medical curriculum, so that these skills are perceived by undergraduates to be relevant to the routine practice of all doctors, and not just those working at dedicated clinical research sites (Burgoyne et al 2010:5212).

Furthermore, educators of undergraduate medical students should take into consideration that previous educational background, research experience, culture and gender could influence research skills training needs and research motivation (Burgoyne et al 2010:5212).

Another important task for educators would be to clarify misconceptions that undergraduates might have about clinical research. For instance, the idea that clinical research is totally divorced from patient contact or patient relevance, and only involve laboratory work. As an undergraduate responded, "I might like research but I much prefer working with people" (Burgoyne et al 2010:5212).

Considering the clinical research team's important role, staff at clinical research institutions should receive formal training in supervising early career investigators. Early career investigators should know they have a right to research supervision. Highly motivated and research-enabled early career investigators must be mentored by highly motivated clinical research staff (Burgoyne et al 2010:5212). Through mentoring, early career investigators learn their roles and responsibilities, and mentors need to realise that they become the role models for early career investigators (Nottingham et al 2017:375).

In addition to previous recommendations on mentoring and coaching, I agree with Maritz et al (2013:165) that mentoring and coaching programmes initiated by clinical research institutions should become part of the organisational and research culture to reach its full potential and to ensure sustainability. Clinical research institutions should provide additional resources and ongoing support for effective mentoring to enhance the mentoring relationships between mentors and mentees (Nottingham et al 2017:375). To take it outside the clinical research institution, a network of skilled mentors who can lead the development of early career investigators should be developed and supported by the South African government, academic institutions, the pharmaceutical industry, and clinical research institutions (Academy of Science of South Africa 2009:153).

For mentors in clinical research it is suggested that they should be positive about the future of research. Training programmes should provide early career investigators with the time to acquire skills on how to conduct research. The current, more experienced generation of researchers, should reinvest in guiding and supporting early career investigators to prevent the loss of an entire generation in clinical research (Hahn 2013:4964; Bagai & Udell 2015:1840).

Change is inevitable and we need to take into consideration that people change with the times. Therefore, medical schools and clinical research institutions need to take the needs of Millennials into consideration. This might involve changing the organisational culture of an institution. Thus, the organisational culture needs to change from an old setting of "my paycheck, my satisfaction, my boss, my annual review, my weaknesses, my job" to a new setting of "my purpose, my development, my coach, my ongoing conversations, my strengths, my life" (Clifton 2016:3). To accommodate the Millennial generation, institutions need to consider that Millennials fundamentally think about their role as a stepping-stone and a growth opportunity. They want to feel deeply committed to their role and want to work for a manager who will invest in their development and growth, and they want to be part of an institution with a great management culture (Clifton 2016:3).

I suggest that different avenues should be investigated to support early career investigators. An avenue to consider could include investing in continued support for career development workshops, webinars, seminars, annual meetings, collaboration

between institutions and networking opportunities for early career investigators (Ogdie et al 2015:1191). Part of this initiative would be the improvement of partnership and collaboration between the pharmaceutical industry and clinical research institutions so that research sites will remain sustainable and can perform high-quality research. This partnership should include proper, efficient, and formal training of early career investigators to prepare them for the specific clinical trials they are assigned to, and to train them on the financial management of clinical trials (SCRS White Paper 2014:4; Roberts et al 2012:269; Bagai et al 2015:1840).

A final recommendation is that support from different stakeholders such as the SCRS (an international organisation) and research networks (for example the Microbicide Network) should be considered by clinical research sites to provide mentorship, partnership, and collaboration to elevate their performance (SCRS White Paper 2014:4).

5.5   IMPLICATIONS OF THE STUDY

This study could contribute towards influencing the attraction and retention of medical doctors into clinical research in South Africa through an increased understanding of the resources and support needed to ensure their success. Better insight into the experiences of early career investigators in clinical research may assist academic and clinical research institutions to better prepare, equip, and support early career investigators. This study might elicit information to use as basis for developing different training, development and support programmes for early career investigators, as well as for the clinical research "industry" as such.

5.6   LIMITATIONS OF THE STUDY

As with any research, there are limitations to the current study. The sample size was small; the findings were primarily applicable to clinical research institutions involved with infectious diseases in Gauteng, South Africa. This may decrease the generalisability of the findings. It is possible that due to being loyal to their institutions or the fear that they might be identified, despite the removal of identifiers, some participants may have responded in general without mentioning any "risky" experiences. However, most participants were aware of the importance of the topic and the value the results could

hold for future early career investigators. It is therefore believed that there was openness and honesty during the interviews.

5.7   SUGGESTIONS FOR FURTHER STUDIES

Experiences and needs shared were mostly participants' own experiences and needs, and a broader impression from different clinical research fields is needed to get a more balanced perspective of the experience of early career investigators across South Africa. Thus, it is recommended that similar studies be extended to other clinical research institutions, for example, those involved in cancer, diabetic, cholesterol, and vaccine research across South Africa to compare findings from different medical fields and clinical research institutions. Participants in the current study were from dedicated clinical research institutions, they were not also working in clinical medicine (hospitals, clinics). It is recommended that participants from dedicated research institutions and participants from the clinical medical field who are involved in doing research should be included in future studies.

5.8   FINAL CONCLUSION

Enough had been said about the clinical investigator as an "endangered species" over the last decades, and it is important to start seeing the reverse of this situation. I hope that recommendations from this study have shown that "imagination fatigue" could be overcome to achieve the goal of increasing the number of clinical research investigators (Cheung 2017:3569). The recommendations made created a basis for stakeholders to pave the path for increasing and retaining the numbers of early career investigators. The need for practical and actionable solutions have been addressed through recommendations to both the academic education system and the clinical research institutions for medical doctors and, therefore, clinical research investigators.

It is, however, a bold step that needs to be taken by the diverse group of stakeholders (medical schools, clinical research institutions, pharmaceutical industry, professional societies, government, research organisations and networks, investigators) to drive this initiative as one man to achieve this critical goal. Stakeholders should consider the sustainability of such an initiative in terms of leadership, funding, effective strategies and policies, outcome goals, characteristics of candidates, resources and support.

5.9   PERSONAL REFLECTIONS AND LEARNING

As reader you might speculate about the relevance of this study to nursing science and practice as the research focus is solely on clinical investigators and clinical research. During the twenty (20) years I have spent in clinical research I have seen several early career investigators coming and going. Some of these early career investigators stayed for a few months and very few stayed longer than two years. Only those who had the "fire in the belly" for research stayed and the question "why?" always lingered at the back of my mind. The constant turnover undoubtedly had an effect on the rest of the clinical research team, including the nurses. Nurses had to adapt to new investigators every few months and it was the nurses who had to retrain these new investigators within their new working environment. Nurses were the "stable element" within the multi-disciplinary research team. With time the nurses got desponded, would get a negative attitude towards clinical research and leave. By addressing the root cause, namely the high turnover of early career investigators, nurses might start enjoying clinical research again. The findings of this study could be used to address some of the reasons why early career investigators leave clinical research soon after starting and would therefore have a ripple effect to the rest of the clinical research team, including the nurses.

Throughout this research project, I was aware of my own position within the context of the research setting. For some of the participants I was a colleague and I was not always sure if it influenced their responses to me. For others, I was a stranger and I was not sure if they trusted me enough to be honest with me. At the same time, I was aware of the fact that although I have nearly 20 years of experience in clinical research, they were medical doctors and I was, by training, a nurse. I had to deal with my own insecurities to display confidence during the interviews and to conceal my insecurities.

Despite these insecurities, I found most participants very open, forward, and accepting of me. At least five participants used the interview as a reflective opportunity. Two of them were very negative and upset about their experience and, I gave them the opportunity to talk about it and I listened. Afterwards, I felt bad that I was not able to do something immediately to improve their circumstances. The other three participants were more positive and while they were reflecting, they were able to suggest solutions for what they identified as problems during the interview. I felt good after those interviews because it felt as if I had helped someone by just listening.

Writing reflective notes after each interview guided me from one interview to the next. I started to get more comfortable with the interviews and with prompting to get some responses. Here the assistance and guidance of my supervisor came in very helpful.

Before I started the interviews, I had my own perspective of what I thought early career investigators' experience of clinical research are. But, experiencing and listening to what early career investigators had to say, gave me a real insider perspective and I felt humble to have been part of the process. I hope that I will be able to initiate some change for early career investigators to make their experience of clinical research so rewarding that they would like to stay within clinical research.

My experience of the data analysis resonates with Dockendorf (1980:5) who commented that the process felt like a sort of spiral:

"I'm winding around in a sort of circle that includes many possibilities where I have many questions. I have some thoughts, some beliefs based on informal observations, but I also have a few worries that perhaps that I won't find what I'm looking for, or that I might discover, instead, things that will make me question what I have been doing. And I suppose that is the risk, the challenge, that investigating questions brings – you might find something unexpected on the way, maybe you're not looking at the thing you thought it was all along".

Starting the process of data analysis was a daunting experience. It felt like looking through the glass window of a "haunted" house before entering it, filled with the fear of what was to come, seeing a maze of passageways, wondering how I would ever know which one to take and if I would ever find my way back again.

Halcolm: "What did you learn in your readings today?" Student: "I learned that the journey of a thousand miles begins with the first step." Halcolm: "A yes, the importance of beginnings." Student: "Yes, I am puzzled. Yesterday I read that there are a thousand beginnings for every ending." Halcolm: "Ah, yes, the importance of seeing a thing through to the end!" Student: "But which is more important? To begin or to end?" Halcolm: "Two great deceptions are asserted by the world's self-congratulators…that the hardest and most important step is the first.." Student: "…and the most resplendent

step is the last!" Halcolm: "While every journey must have a first and last step, what ultimately determines the nature and enduring value of the journey…are the steps in-between! Each step has its own value and importance. Be present for the whole journey." Student repeating as he goes along: "Be present for the journey" – Halcolm (Patton 2015:734)

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ANNEXURE A

Approval from the Research and Ethics Committee, Department of Health studies

UNISA | university of south africa

RESEARCH ETHICS COMMITTEE: DEPARTMENT OF HEALTH STUDIES
REC-012714-039 (NHERC)

5 October 2016

Dear Mrs W Pelser

| **Decision: Ethics Approval** |

HSHDC/544/2016

Mrs W Pelser

Student: 0542-192-6

Supervisor: Prof JE Maritz
Qualification: PhD
Joint Supervisor: -

Name: Mrs W Pelser

Proposal: Early career research investigators' experience of clinical research.

Qualification: MPCHS94

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 for the duration of the research period as indicated in your application.

The application was reviewed in compliance with the Unisa Policy on Research Ethics by the Research Ethics Committee: Department of Health Studies on 5 October 2016.

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 of Health Studies. An amended application could be requested if there are substantial changes from the existing proposal, especially if those changes affect any of the study-related risks for the research participants.*

> 3) The researcher will ensure that the research project adheres to any applicable national legislation, professional codes of conduct, institutional guidelines and scientific standards relevant to the specific field of study.
>
> 4) [Stipulate any reporting requirements if applicable].
>
> Note:
>
> The reference numbers [top middle and right corner of this communiqué] should be clearly indicated on all forms of communication [e.g. Webmail, E-mail messages, letters] with the intended research participants, as well as with the Research Ethics Committee: Department of Health Studies.

Kind regards,

Prof L Roets

Prof MM Moleki

CHAIRPERSON   ACADEMIC CHAIRPERSON

roetsl@unisa.ac.za   molekmm@unisa.ac.za

Approval template 2014

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

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APPROVAL HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

R14/49 Ms Wilma Pelser

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M1611146

NAME:
(Principal Investigator)
Ms Wilma Pelser

DEPARTMENT:
Nursing Education
Perinatal HIV Research Unit
Aurum Institute
Wits Reproductive Health and HIV Institute

PROJECT TITLE:
Early Career Research Investigators' Experience
of Clinical Research

DATE CONSIDERED:
Adhoc

DECISION:
Approved unconditionally

CONDITIONS:
No data may be collected from Wits sites
until site approvals have been provided to the
HREC (Medical) Administrators.

SUPERVISOR:
Prof Jeanette Maritz

APPROVED BY:
Prof P Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL:
20/12/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 301, Third floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in November and will therefore be due in the month of November each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

_____   _____
Principal Investigator Signature   Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

ANNEXURE B

Permission to Conduct Research

6 February 2017
HREC (MEDICAL)
University of the Witwatersrand
Johannesburg

Dear Prof P Cleaton-Jones

Re: Clearance Certificate No. M1611146.
**   R14/49 Ms Wilma Pelser**
**   Project title:** Early Career Research Investigators' Experience of Clinical Research
This letter serves to confirm that approval has been granted to Ms Wilma Pelser to collect data
from the Perinatal HIV Research Unit as part of her Master's degree in Nursing Science at the
University of South Africa.
Yours Sincerely
Dr XXXX
DIRECTOR PHRU

Permission to conduct research (Aurum Institute)

PERMISSION FORM AURUM

THE AURUM
INSTITUTE
NPC

7 February 2017

HREC (MEDICAL)

University of the Witwatersrand

Johannesburg

Dear Prof P Cleaton-Jones

Re: Clearance Certificate No. M1611146.

      R14/49 Ms Wilma Pelser

      Project title: Early Career Research Investigators' Experience of Clinical Research

This letter serves to confirm that approval has been granted to Ms Wilma Pelser to collect data from the Aurum Institute Clinical Research sites at Klerksdorp, Rustenburg and Tembisa as part of her Masters' degree at the University of South Africa.
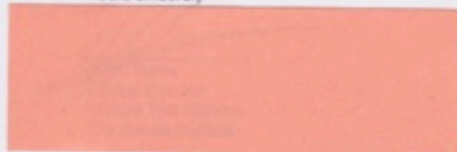
Yours sincerely

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Permission to conduct research (WHRI)

PERMISSIONS FROM WHRI

RE: Request to review Wilma Pelser's Protocol

To: Wilma Pelser <wilma@wilmapelser.co.za>
Cc:

Dear Wilma

Apologies for the delay in getting back to you. I discussed your study with Prof XXX who has given approval for you to interview staff.
We suggest that you contact XXX cc'd here our HR manager who can then provide you with the information that you request. We propose that an email with the details of your study is sent to those staff and that they then respond to you.
Good luck with data collection.
XXXX

ANNEXURE C

Informed Consent

Informed Consent

Principal Investigator: Ms W Pelser, Master of Arts in Nursing Science student, University of South Africa, (05421926)

You are invited to participate in a research study titled: Early career research investigators' experience of clinical research. The study invites medical doctors who have worked at clinical research sites, specialising in infectious diseases in Gauteng, for five years or less.

Before you decide whether to take part in the study, I would like to explain the purpose of the study, the risks and benefits, what is expected of you and what you can expect of me. Please ask questions about anything you do not understand or want to learn more about.

Your participation is voluntary

This consent form provides information about the study that will be discussed with you. Once you understand the study and if you agree to take part, you will be asked to sign your name. You will be offered a copy of this form to keep.

Before you learn about the study, it is important that you know the following:

- Your participation is voluntary. You do not have to take part in the study if you do not want to.
- You may decide not to take part in the study, or to leave the study at any time without penalty.

Purpose of the study

The purpose of this study is to understand the experiences of early career investigators in clinical research at sites specialising in infectious diseases in Gauteng. Based on the findings of the study, methods to better prepare, equip and support early career investigators could follow.

Procedure

If you decide to take part in the study, I will collect data from you by means of a face-to-face individual interview that will take about an hour of your time. Open ended questions will be used during the interview to gain a deeper understanding and explore your experiences and challenges as early career investigator. The interview will be audio-tape recorded with a digital recorder and with your permission. I will also ask you to provide naïve sketches in the form of short stories, notes or sketches of your experiences. During the interview I will compile field notes of my observations and reflections.

Risks

There are no direct risks to you by taking part in this study. During the interview, questions will be asked about your experiences as an early career investigator. Should there be any minor discomforts in answering the questions, I shall attend to them and if you do prefer we can discontinue the interview. No remuneration will be paid for participating in this study.

Benefits

Although as an individual you might not benefit directly from being interviewed, your participation might help me as the researcher to gain a deeper understanding of your experiences being an early career investigator. The results of this study may lead to the development of support systems and programmes to assist early career investigators toward a successful career in clinical research.

Confidentiality

Every attempt will be made to maintain your confidentiality during and after the study. Your answers will be kept under strict confidence, except in cases where professional code of ethics or legislation requires reporting. Your name will not be recorded anywhere and no name will be mentioned in the research report nor during publication of the study results. As part of maintaining confidentiality, you will be identified by a number. The information will be kept in a secure area (i.e., locked filing cabinet). Your name and any other identifying information will not be attached to the information you gave.

The results of this study may be included as part of a thesis or published in a scientific journal. Your name will not be mentioned in any of these documents. No participant in this study will be identified by name in either a presentation or publication. Electronic and hard copies will be destroyed after publication of the findings.

You have the right to learn about the results of this study.

Questions

Should you have any question or problems feel free to contact **Ms W Pelser at 074 8872034 and alternative office number at work 011 6604342 Monday to Thursday 07h00-16h00 and Friday 07h00-13h00 only or Prof J Maritz** at maritje@unisa.ac.za

Should you have concerns about the way in which the research has been conducted, you may contact Professor L Roets, Ethics Chair of the Department of Health Studies at roetsl@unisa.ac.za.

Signatures

I (First name) ---------------------------- (Surname) ------------------------------(day) consent to participate in the study: "Early career research investigators' experience of clinical research" to be conducted by Ms Wilma Pelser. I understand and give consent that the interview may be digitally recorded. I am aware that participation in this study is voluntary and that I have the right to stop the interview at my free will. I can also refuse to answer any specific question. I will not be remunerated for being interviewed. I am aware that the study's findings will be published as a research report but that no names will be mentioned in any publications.

The contents of the study have been explained to and discussed with me (including the information contained in this consent form). I have been allowed to ask questions and my questions were answered. I have been supplied with Ms Pelser's personal contact details (0748872034/ 011 6604342) in case I might wish to contact her. I have been re-assured that the signed consent form will be stored and locked separately from the information I gave during the interview and that the tape-recording, transcription, observation and field notes will not contain any name to identify me.

_____   _____   _____
Signature of research participant   Printed name   Date

I, _____, have discussed the above points with the participant. It is my belief that the participant understands the risk, benefits and obligations involved in participating in this study.

_____   _____ _____
Signature of the Researcher   Printed name   Date

ANNEXURE D

Data Collection Instrument

Open-ended questions:

1. Why did you choose to do clinical research?
2. To what extent were you [not] prepared for the clinical research field?
3. Tell me about your experience as an early career clinical research investigator.
4. What excites you about being a clinical research investigator?
5. What scares you about being a clinical research investigator?
6. What suggestions do you have for medical doctors who want to enter the clinical research field?

Probing and follow up questions will be asked based on the responses. For example:

- Tell me more…
- What do you mean?
- What else…
  Please explain more fully?
- Let's talk about that in more detail.
- I have heard that you say …. Why do you think you feel that way?
- That's interesting. Give me some additional information/an example.
- What does that mean to you?

ANNEXURE E

Debriefing Interview Template

1. Think about **your research interviews**, how comfortable were you interacting with your participants?

2. What **findings** surprised you?

a. **What findings gave you a negative reaction?**

b. **Why do you think you reacted negatively to this/these findings?**

c. **What findings gave you a positive reaction?**

d. **Why do you think you reacted positively to this/these findings?**

3. What types of **ethical** issues did you encounter during the interviews, if any?

a. **How did you handle the ethical issue/s?**

b. **In your opinion, how did the ethical issue/s impact on the participants and/or the integrity of the interviews?**

c. **During the interview, did you feel at any time that the interviewee was providing socially acceptable or politically acceptable answers that did not reflect the true state of affairs? If yes, how did you respond?**

d. What **unexpected issues or dilemmas** did you encounter during your study? How did you handle these issues or dilemmas?

e. In what ways, if any, do **you** feel **you** are a different person now that you have conducted the interviews?

4. In future, how will you conduct interviews based on what you have learned during the interviews?

5. What has it been like for you to complete these questions?

Interview Transcript

I   Okay, so you can just sign.

P   And you put your [CROSSTALK] –

I   Ja, I put my stuff there so you can just sign here and put today's date.

P   Okay, so you don't want the name again?

I   No, no, no.

P   Okay, [INDISTINCT]. Okay.

I   Okay, so…and then I use my phone as a backup –

P   To record [CROSSTALK].

I   …because I'm so scared that –

P   Yes.

I   …I might –

P   [CROSSTALK].

I   …you know, press the wrong thing or whatever. As you say, anything might happen. Thanks. Do you want a copy?

P   Um, yes, please.

I   Okay. I'll make you a copy and then I'll get you a copy. So, before we start, um, I know a little bit about you but what happened between…I've seen you last ye…ye…um –

P   Ja, twenty –

I   How many –

P   …twenty thirteen/twenty fourteen.

I   Ja.

[CROSSTALK]

I   How is it going with the marriage and the –

P   It's going well.

I   Ja, ja, ja.

P   It's going well. XX kids.

I   Ja.

P   And…ja.

I   And how old is the smallest one now?

P   He's XXX.

I   Shee, okay.

P   So now I've got XX kids. Ja, no, it's going well so far.

I   Ja.

P   Um, so, ja, was in research, went to private practice, and actually decided I actually miss research. So I'm back.

I   Okay. Okay, so how long have you been in the private practice then?

P   Um, late twenty fourteen to –

I   Ja?

P   …last year. So –

I   Ja.

P   …just about…almost two years.

I   Was it when you left here?

P   Yes.

I   Okay.

P   In that time that I left here –

I   Ja.

P   …and then I –

I   Ja.

P	…went and then I just came back here.
I	Ja.
P	Yes, yes.
I	So…okay, so now I'm then going to divide into sections sort of.
P	Yes.
I	So your first experience and your second experience.
P	Okay.
I	So your first experience, how did you get into research for that first time?
P	Um, I actually got into research sort of by accident.
I	Mm hm.
P	I wasn't actually looking for research.
I	Mm hm.
P	I was looking just to work in an HIV clinic as my…that was where my interest lied [sic] –
I	Oh, okay.
P	…um –
I	So HIV were [sic] your interest?
P	Yes, that's where my interest lied [sic] and then I was actually in Cape Town at the time –
I	Ja.
P	…um, and then I found the XXXX on the website –
I	Ja.
P	…saw there was a post and applied. So flew up to Johannesburg for an interview –
I	Okay.
P	…and Dr XXXX [SP] was –
I	Ja, ja.
P	Can…can I mention name?
I	Ja, ja, ja, you can –
P	[CROSSTALK].
I	…going to take out the names.
P	Okay. So he was the PI at the time.
I	Ja.
P	He took me around to the clinic and I actually remember, um…'cause he offered me the position and I started working, um, but I wasn't GC…I hadn't had GCP –
I	Mm hm.
P	…yet at…or anything of that at that stage and I actually remember asking guy the one day what am I doing here? Like, what is this? Like, okay, um, this is not what I expected but okay. And, uh, started [CROSSTALK] –
I	So you had to relocate?
P	Yes, I actually relocated from Cape Town, um, in March that year.
I	Okay.
P	Yes, I relocated. Um, and then I started sort of getting to know how things run in –
I	Mm.
P	…uh, research, you know, reading the protocols and things and I actually started developing a love for it because I actually feel that I do have a love for public health in –
I	Mm hm.
P	…in general and I just feel like this is just how we should be sort of doing medicine in general –
I	Mm.
P	…having that accountability –
I	Mm, mm.

P	…um, sort of saying this is [sic] the steps that need to be followed. So a patient has this problem –
I	Ja, ja.
P	…this is how you should…what should be done in –
I	Ja.
P	…those events and, if this doesn't work, do that. So I think, because I've worked in government setting before and, um, also in the military…okay, so military's a bit…a little bit better –
I	Oh, ja, ja.
P	…but, um –
I	More [sic] stricter than government.
P	…a bit, yes.
I	Ja.
P	So a lot of the times, like, in government, there's no-one sort of checking your files or –
I	Ja, ja.
P	…saying, by the way, you gave patient this –
I	Ja.
P	…why did you give this?
I	Ja.
P	You know. So you go on what you know –
I	Ja.
P	…but, in terms of that accountability –
I	Ja.
P	…that QC process –
I	Ja.
P	…and…so that is what I actually started loving about –
I	Ja.
P	…research.
I	Ja.
P	Ja.
I	So…so you…you…you said earlier that it wasn't what you expected. What…what did you expect or how…how can I say? How –
P	I think –
I	…and what did you get here and…?
P	Well, I think I was just expecting normal clinic visits, yes –
I	Ja.
P	…I was seeing patients…'cause at that time I was actually doing prevention more than HIV treatment which –
I	Yes, yes, yes.
P	…is what I had thought to be.
I	Ja, ja.
P	So the…it…it…that's why I'm saying it helped me to see the other side and –
I	Ja.
P	…because it actually helped me to see there's more to medicine –
I	Ja.
P	…'cause I was just used to treatment and –
I	Ja.
P	…then, being in prevention, I was like, oh, you can actually…there's a bigger role to play –
I	Mm.
P	…in terms of preventing things –
I	Mm.

P	…um, and also sort of…because a lot of the patients then, it was [sic] young adults, it was [sic] –
I	Mm.
P	…female patients that we were seeing. Um, looking at sort of the social circumstances, looking at what sort of leads people to get to that –
I	Mm.
P	…point.
I	Mm, mm, mm.
P	So it was nice to be a part of that –
I	Ja.
P	…sort of prevention studies and –
I	So it actually open [sic] you up for another side of the –
P	Yes.
I	…of the…also HIV related but –
P	HIV related, yes –
I	…but another side.
P	…but now the prevention side of it –
I	Ja.
P	…and also another side of medicine 'cause it's not…um, I've never sort of been…when I was at med school, I've never actually been told that, by the way, there's this stream of research that you can actually go into.
I	Mm, mm.
P	So it was, like, oh, this is nice. You…I mean, you know public health, you know –
I	Mm.
P	…but I never knew what was going on behind the scenes –
I	Mm.
P	…or also just in terms of protocol implementation, policy making within government, how they –
I	Ja.
P	…came to decide that these are the drugs we gonna be using.
I	Mm.
P	So it was very nice to see that –
I	Ja.
P	…and to get to see the big…the other side.
I	Ja, ja.
P	Ja.
I	And then what would you say…when you came back the second time, wha…wha…did…was it easier and wh…why was it easier, if it was?
P	I think it was a little bit easier but it was also different.
I	Okay.
P	Because I've worked on HIV prevention –
I	Mm hm.
P	…before, I'm now currently in treatment side.
I	Mm.
P	So, um, actually there was [sic] positions open for prevention –
I	Mm.
P	…but I actually…I was glad I took this position because I think –
I	Ja, ja.
P	…going in…into prevention –
I	Mm.
P	…it wasn't necessarily gonna grow me –
I	Mm hm.

P	…'cause I've learnt most things there.
I	Ja.
P	So, coming into treatments, I got to learn different things and, um…so I was actually opened for…I'm like I want to…I want to come back but I'm also more willing now to learn more things in terms of, um, the applications, the protocol, you know, not just implementing and not just –
I	Ja.
P	…seeing participants –
I	Ja.
P	…but also the ethics submissions and…coming back.
I	Mm.
P	So that's actually what I'm doing now and as…I'm…I'm exposed more to seeing the submissions –
I	Mm.
P	…getting feedback from ethics. So I think, before, um, it was sort more just up to the PI and everything –
I	Mm, [CROSSTALK].
P	…and I would just get the feedback –
I	Ja, ja.
P	…from them –
I	Ja.
P	…not…and, at this site, where I'm currently at, it's…you kind of part of making sure the submissions are getting in –
I	Okay.
P	…getting the feedback to say is it back? And making sure it's get…gets implemented. So a lot of things now it's also making…so I've just spoken to the team. I'm like, guys, we need to do timelines. So when things do come back and 'til when we actually implement because when the monitors do come –
I	Mm.
P	…we…it's easy to say, no, but we didn't do that from this time.
I	Mm.
P	So, at least if we have that timeline in place –
I	Ja.
P	…we can say, no, from this time, it was being done like this –
I	Ja.
P	…and going forward, this is how things –
I	Ja.
P	So I think before has actually prepared me for now.
I	Ja.
P	So in terms of –
I	Ja.
P	…I think I know a bit more –
I	Ja.
P	…because of the experience I had –
I	Ja.
P	…but I'm still open to learning more.
I	Ja.
P	So, even, like, your things like your MTAs –
I	Mm.
P	…and stuff like that –
I	Mm.
P	…I was never really exposed to –

I	Mm.
P	You'd hear about it but it wasn't really your problem, so to say.
I	Ja, ja.
P	So, in a sense, I've gotten a bit more responsibility with some of the –
I	Mm.
P	…studies here. So, in that sense, I'm not PI but I –
I	Mm.
P	…sort of have some of that [sic] roles which maybe will prepare me for something –
I	Mm.
P	…like that in the future.
I	Mm.
P	Ja.
I	So, when you decided, okay, no, maybe you must come back to research –
P	Ja.
I	…what…what were the things that –
P	That sort of –
I	…made –
P	…made me –
I	Ja.
P	…want to come back?
I	Ja.
P	Um, I actually…well, what I also enjoyed was because…I think it was because I was in a GP practice. So –
I	Mm hm.
P	…you kind of get exposed to…you don't know what's in the [INDISTINCT] basically.
I	Mm.
P	So it can be a [INDISTINCT] call and –
I	Ja.
P	…whereas, okay, I'm doing HIV, I know, yes, you will still see that adverse –
I	Yes.
P	…events and everything but –
I	Ja.
P	…you know your main focus is HIV and knowing everything about HIV.
I	Ja.
P	So, in a way, you kind of feel like a specialist but not a specialist.
I	Ja.
P	So, if that makes sense.
I	Ja.
P	So, you know, this is what we focusing on this is…so it…it makes it a little bit easier –
I	Mm.
P	…but, um, also I had actually done another HIV course in the time that I was there –
I	Oh, okay.
P	…and part of the course requirement was, um…it wasn't a research component –
I	Mm, mm.
P	…but they wanted us to look at our current site and to see what it is that we can improve, look at the QC process, look at things like that –
I	Mm hm.
P	…and I think that is also what triggered me 'cause, um, one of the things that we…um, I actually spoke to my colleague and I said to him…'cause we were seeing patients with –
I	Mm, mm.
P	…HIV, um, at the clinic –
I	Ja.

P	…as well but we weren't necessarily doing things like your adverse event reportings [sic] and stuff –
I	Mm.
P	…and grading them and so forth –
I	Ja.
P	…and, I mean, I managed to actually speak…speak to the…the board who deals with that and to get the forms and everything else –
I	Mm.
P	…and just to look at, um, our results follow-up and to look at the timelines for those. So I was able to implement that –
I	Oh.
P	…at the site –
I	Ja.
P	…to see…to make sure that we do nothing. Maybe that's why I ended up coming back, partly, to research. I…I ca…I think I missed it.
I	Ja.
P	So, when I left, I wanted a bit more clinical –
I	Mm, mm.
P	…and then…and that's the other thing. Treatment actually gives me the bo…the balance of both worlds.
I	Yes, yes, yes.
P	Ja –
I	It does.
P	…as opposed to –
I	It does.
P	…just prevention –
I	Ja.
P	…they generally healthy –
I	Ja.
P	…whereas the –
I	Ja.
P	…treatment site, you actually seeing –
I	Ja.
P	…you know, it's HIV as a chronic disease –
I	Ja.
P	…you doing the research but you also getting the clinical aspect.
I	Ja.
P	So I'm –
I	Ja.
P	…getting both. The best of both –
I	Ja.
P	…worlds.
I	So that's nice.
P	Ja.
I	Ja, ja. And your biggest challenges when you came back?
P	Um, what would I say the biggest challenges are? Um, I think I still had…because I still had to get an idea of how treatment –
I	Mm.
P	…works and…so some things were…were different compared to, um –
I	Prevention.
P	…prevention side, um, but I've learnt and I think, um, on our…on our team, we had…people are very busy.

I	Mm.
P	It's like…it's been –
I	Ja, ja, ja.
P	…busy. Um, when I…I remember when I joined, the nurse had just resigned.
I	Ja.
P	So it…there wasn't really that much of time –
I	Ja.
P	…to sort of get orientated, so to say.
I	Okay.
P	Um, and one of the other things which, um, I had…initially, when I got here, I felt like I didn't have enough sort of interaction with the PI –
I	Mm.
P	…um, but that has fortunately changed because –
I	Ja.
P	…we've…we've actually, like, asked can we have sort of management meetings –
I	Mm.
P	…and not just the big meeting.
I	Mm, mm.
P	Sort of we've had that management meeting where we can just touch base and discuss certain things before we have. So that has also been one of the things –
I	Mm hm.
P	…that…which I was able to sort of bring along with –
I	Ja.
P	…which we used to have in the prevention side.
I	Mm.
P	So that was one of the challenges initially. Sort of also, um, for me, it's…you have the protocol but sometimes what I find is people have different interpretations. So we –
I	Mm.
P	…can all read the protocol.
I	Mm.
P	So…so, initially, for me, I really sort of wanted the PI just…I –
I	Ja, ja, ja.
P	…needed to just –
I	Yes, yes.
P	…you know, uh, as in –
I	Ja.
P	…this is…this is…is this how you –
I	Ja.
P	…want things done?
I	Ja.
P	So…'cause that's how I'm used to working –
I	Ja.
P	…with the PI and saying, okay, so this is…yes, we see this –
I	Mm.
P	…are we all on the same page?
I	Ja.
P	So at least that now, um, I have spoken to the PI –
I	Mm.
P	…and that has improved.
I	Mm.
P	So that's quite nice.
I	Ja.

P	Because having that, um…like I said, the one team will interpret something this way.
I	Yes, yes.
P	So you can…then you end up going with the team because you don't wanna be, like, okay, I…I –
I	Ja, ja, ja.
P	…see it this way.
I	Ja.
P	So, ja, it's just that dynamic. Um, but I think what, um…one of the other things was…just in general was, um…so I've also spoken to my PI about to say I would like to have that, um…I'm not just seeing participants, I'm not just doing –
I	Mm.
P	…[INDISTINCT] reports, I want to know more about the running of the study –
I	Ja.
P	…in terms of…so now we've actually started doing, like…helping with the, um…the surveys, the feasibility studies.
I	Okay.
P	So those are before studies actually come to site –
I	Mm.
P	…we can get that access to say…to help answer those questions –
I	Mm.
P	…and then, from there, we will see is the site gonna be –
I	Mm.
P	…improved or not based on those things.
I	Mm.
P	So that's also nice. Those are all the things I have not been exposed to before which we are now doing and then we help give input on those.
I	So did you had [sic] to ask to be involved in that?
P	I did ask, ja.
I	Ja.
P	I did ask –
I	Ja.
P	…to be involved –
I	Ja.
P	…in that, um. I didn't ask, like, specifically for surveys but I just –
I	Ja.
P	…asked –
I	Ja, but –
P	Yes, I…I was –
I	…more in the –
P	Yes, to say –
I	…uh, running and the management [CROSSTALK].
P	I actually told…I told my PI I want her to sort of mentor me –
I	Yes, yes, yes.
P	…that's what I said to her, that I want you to…so she's been doing that.
I	Yes.
P	Um… I'm just acknowledging that she's –
I	Ja.
P	…doing that. So, even with the one study having closed down –
I	Mm.
P	…she called us in…so not only myself but also the other doctor –
I	Mm, mm.

P	…to say so, when the site closed out, having to sign off, having to close off delegation logs and –
I	Mm.
P	…and all of that.
I	Mm. Okay.
P	Yes.
I	And do you, uh, s…let's take feasibility as…that feasibility study that you have to do.
P	Ja.
I	So do…where do you get your, uh, information from and who's mentoring you into that –
P	So –
I	…process of what to say?
P	So we work then with the site, um, coordinator.
I	Okay.
P	So she will also help.
I	Okay.
P	A lot of the data, she will then –
I	Okay.
P	…obviously have.
I	Okay.
P	So, some of this, she might complete but then she'll send to us now as the doctors –
I	Okay.
P	…and then we will also add input and the –
I	Ja.
P	…the PI still signs off on the final –
I	Ja, ja.
P	…but sometimes the PI will also come down.
I	Mm.
P	Um, once we now have done the final, we actually go through it together now –
I	Mm, mm.
P	…to see, okay, this is what we have said, do we need to adjust numbers? Do we need to…um, where do we get this from? So –
I	Mm, mm.
P	…that is what's happening. So this…wo…working with the site coordinator plus the PI and then –
I	Mm, mm.
P	…and then –
I	Ja.
P	…so I was…I think, before, it was just the two of them generally –
I	Ja.
P	…completing, a site coordinator –
I	Ja.
P	…and the PI, and then they would submit and…so now that has –
I	Ja.
P	…also changed.
I	Ja. So there's now more involvement from –
P	Yes.
I	…the investigators' side as well.
P	Yes.
I	Ja.
P	Ja.
I	And…and…and, uh, what is the benefit you see from there?

P	Well, the benefit for me as…like, um…like, before, I mean, I would put some…maybe I'd put in, like, a number.
I	Mm.
P	So, I mean, the PI would say, okay, maybe we should rather bring the number down so that we can –
I	Mm, mm.
P	…um, as much as we want to show that we can –
I	Mm.
P	…get those numbers –
I	Ja.
P	…it's better to go a bit under.
I	Ja.
P	…so that we…it's better to go –
I	Yes.
P	…to…to meet target and go over targets.
I	Ja.
P	So those are the kind [sic] of things and then we'd also look at, okay, we need to look at staff complement –
I	Mm.
P	…we'd look at other factors –
I	Mm.
P	…to influence as much as we would say we want to do this –
I	Mm.
P	…but then…so, also, um, because some of the drugs we get from…are from DOH –
I	Mm.
P	…but then some of the things…so, because we have it –
I	Mm.
P	…maybe I would say, yes, by then, she might say, no, it's not…because it's not via –
I	Mm.
P	…um, it's not a study job. Actually, we don't have availability to it –
I	Ja.
P	…because it's government so we should say no. So those are the things that you learn.
I	Mm.
P	So I'm like, okay, so the next one, um, I think I'll better…be better equipped to answer –
I	Ja, ja.
P	…the next one –
I	Ja.
P	…because of –
I	Ja.
P	…ja –
I	Okay.
P	…having to go through that process.
I	Well…well, to me, it sounds, for me, a big benefit would be is it prepare [sic] you to be a PI.
P	That as well also.
I	Ja.
P	Ja.
I	Because, often, it happen [sic] that you bec…uh, they become a PI but they haven't got all these –
P	Yes.
I	…skills that they've developed –
P	Yes.

I	…with the time because nobody –
P	Because I think it happens you…you just so busy focused on seeing patients –
I	Yes.
P	…it's clinic –
I	Yes.
P	…and-and. So, as I'm saying, I…I've told them actually, when I came, and I said to her this is what I want –
I	Ja.
P	…I don't want to just –
I	Ja, ja.
P	…I need to learn more –
I	Ja.
P	…I need to get more.
I	Ja.
P	So I think it's been to the benefit of –
I	Yes.
P	…both me and the other doctor –
I	Ja.
P	…because now she's doing that to –
I	Ja.
P	…both of us. So…so we get that exposure.
I	Ja. That's very good.
P	Ja. So it's also nice, like I said now, the communication's better, there's more access to her –
I	Mm, mm.
P	…in terms of, um, discussions. So we still discuss the patients, we do –
I	Yes.
P	…all of that, but we also get to have a hand in these things.
I	Mm, ja. Okay. And…so, at this stage, what would make you leave?
P	What would make me –
I	What is still a frustration for you or…?
P	What would me leave –
I	Ja.
P	…in terms of research or just the company?
I	In…in everything. In research, company, whatever.
P	Mm.
I	Ja.
P	I wouldn't leave research, not yet.
I	Ja.
P	I still enjoy it.
I	Ja.
P	Um, although, I must say, I have…also, another thing I've learnt about myself is I enjoy monitoring –
I	Oh, okay.
P	…QCing files. I enjoy QCing files and I think sometimes it can seem like I'm a bit critical because I –
I	Ja.
P	…tend to pick things up –
I	Ja.
P	…and…so that's the other thing. So maybe that…it's one with the…it…you either, like, go –
I	Ja.

P	…that route –
I	Ja, ja.
P	or a PI route but –
I	Ja.
P	…um, if the opportunity arises.
I	Ja.
P	Um, I think things like, uh, bonuses –
I	Mm.
P	…thirteenth cheques –
I	Mm, mm.
P	…those are the things –
I	Ja, ja.
P	…that probably would make me leave.
I	Ja.
P	Um, but, just in general, um, I don't see myself leaving right now –
I	Ja.
P	…but, um, I think sometimes, you know, team dynamics –
I	Mm.
P	…in terms of, um, like I said, you see something –
I	Ja.
P	…a different way and –
I	Ja.
P	…and you feel like, okay, are we doing the thing correctly or –
I	Ja.
P	…not. Are we implementing the protocol because –
I	Ja.
P	…so, in that sense, you really need the –
I	Mm.
P	…PI. So I think that is still one area –
I	Mm.
P	…to work on –
I	Ja.
P	…in terms of when we start up a –
I	Mm.
P	…study or that initial, um, having sort of let's all be on the same page –
I	Mm.
P	…that's the only thing I would say –
I	Ja.
P	…is maybe have a complaint about –
I	Ja.
P	…that I can say. Um, so just in terms of that, um, but I don't…I'm enjoying research.
I	Mm.
P	Ja.
I	Mm. Okay, and…and sort of the same topic is that…i…uh, in a [sic] ideal situation –
P	Ja.
I	…what would you say what would be very helpful for…for…for new researchers, for new investigators? If it was a [sic] ideal situation, what would have helped them to find their feet in the research?
P	Um, what would help? Okay, I'll…I'll say from my…when I started out.
I	Mm, mm. Ja.
P	What helped me a lot was that the…the doctor then, Dr XXX [SP], she –
I	Mm, mm.

P	…she was open to showing me what needs to be done, um, and also the PI was also…you know, if there was [sic] corrections that were done, they told me so.
I	Mm, mm.
P	In a nice way, they told me that, by the way, don't do things like that.
I	Okay.
P	So I think maybe for that –
I	Mm.
P	…few…a month or –
I	Mm.
P	…two, you just need someone to actually hold your hand to –
I	Ja.
P	…guide you through the process –
I	Okay.
P	…because, um, in terms of GCP, maybe writing the date correctly and…so it's…it's [sic] might be minor things –
I	Mm.
P	…but it's [sic] could be big things in research.
I	Mm.
P	So actually having someone, um, hold your hand and take you through the process and understanding sort of the systems, understanding sort of, um, wi…the reporting lines –
I	Mm, mm.
P	…understanding the organogram –
I	Ja.
P	…that's also a big thing. Um, 'cause I…other thing, when I started here though, because everyone was just so busy –
I	Mm, mm.
P	…there wasn't sort of a welcome pack –
I	Mm.
P	…in terms of, okay, bec…and we have multiple studies.
I	Mm.
P	So you'll find that, on the one study, things must be done this way –
I	Mm.
P	…and another study is done this way –
I	Mm.
P	…and…so that, um, you kind of get thrown in at the –
I	Ja, ja.
P	…deep end –
I	Ja, ja.
P	…and it's, like, you need to start work and you've already got GCP, so you must just start working and I remember I actually said to the site coordinator the one day and I said to her you guys should ideally have a welcome pack.
I	Ja.
P	Just, uh, for this study –
I	Mm.
P	…these are what is [sic] required or this is the system we working on.
I	Mm, mm.
P	For this study, it's this.
I	Mm.
P	And…'cause, for myself, what I can actually do is track those things.
I	Ja.
P	So, when you get into research, when you do the trainings, I mean, I will write down…so that's also another thing.

I	Yes, yes.
P	When you get in…okay, I've read this SOP today, data done –
I	Mm.
P	…because you'll find that the logs are being…you…will…will only arrive later.
I	Mm, mm.
P	At least you can say on the logs –
I	Ja, ja.
P	…by the way, I did these trainings –

[CROSSTALK]

P	So it's just, I think, someone…you need to be orientated –
I	Mm.
P	Um, it's also nice if your PI can do it. Um, I'm saying for my, um –
I	Mm.
P	…[INDISTINCT] my ex-colleague –
I	Ja.
P	…who was…I think one of the things with him, he started out fresh and, for him, um, one of the ques…one of the things that he said was he wished that he…the PI had actually given more guidance –
I	Mm.
P	…from the go.
I	Mm.
P	So if…when I even arrived –
I	Ja.
P	…I was able to still teach him –
I	Mm, mm.
P	…things although he'd been –
I	Ja, ja.
P	…here for almost a year.
I	Ja, that's what I want to try find out, you know.
P	Yes.
I	For new investigators, what would be the ideal to help them? Ja, ja.
P	So, either it's –
I	That's what you saying now.
P	So it's…either it's the PI or another sub-investigator who is experienced –
I	Ja.
P	…to actually guide you through some things.
I	Ja.
P	So whether it's documenting on a chart note –
I	Mm.
P	…whether it's corrections in terms of –
I	Mm.
P	…saying, no, this box wasn't ticked so you can document here, if it's like a week or two later –
I	Ja.
P	…not ticked in error.
I	Mm.
P	You don't just go and tick that box.
I	Ja.
P	So it's those little things which you actually have to…learning how to do the source documents –
I	Mm.
P	…SOP updates. So, ideally, have the PI or someone who's experienced –

I	Mm, mm.
P	…actually hold that person's hand –
I	Mm.
P	…for a bit, um, and not make them feel like, oh, you a –
I	Idiot.
P	Yes, you know, like, for not knowing these things. So I think, in myself, I was fortunate that I had –
I	Ja.
P	…that.
I	Ja.
P	People sort of helped me along the way.
I	Mm.
P	So, like I said, when I came through now, um, when we had the other…I could also advise him on certain things which I knew and he even said but no-one has told me that yet and I'm not sure if that is the reason why he ended up –
I	Mm.
P	…leaving but, um…so –
I	So what could have been done instead of you but nobody have [sic] told me that? How could that have been prevented that [sic] sentences –
P	That –
I	…from him?
P	Um, I think what…not only the PI or, like, the –
I	Yes, not only that.
P	…sub-investigator –
I	Ja.
P	…but the QC –
I	What else?
P	…person –
I	Ja.
P	…also –
I	Ja.
P	…like, when the files go via QC.
I	Ja.
P	So having, um, someone…the QC in terms of feedback from –
I	Mm, mm.
P	…QC, whether it's a one-on-one corrective action to say –
I	Mm.
P	…this is how things should be done or whether if it's maybe common findings in the team –
I	Ja.
P	…to do it as a global correction –
I	Mm, mm.
P	…as…so…especially if we have the QC person. That is…that's…I found to be –
I	Mm, mm.
P	…quite helpful –
I	Mm.
P	…um, 'cause I still make mistakes and –
I	Yes.
P	…things and then, having the QC person come –
I	Ja.
P	…to me to say…also to do…to do things standard.
I	Mm.

P	So you do this this way and then someone else is doing it –
I	Ja.
P	…that way. So just say, guys, listen, let's sit. How are we gonna complete this sentence –
I	Mm.
P	…going forward? And we all are on the same page. So, having the QC person, having the P…the PI –
I	Mm.
P	…the sub-PI, that involvement, and holding the person's hand, just…just for that few [sic] month or two because –
I	Ja.
P	…you do get into the hang of things, you do –
I	Ja.
P	…um, get a better understanding. Yes, you've been to GCP but a lot of the stuff, until you've [sic] actually doing the practical, does not get –
I	No.
P	…answered –
I	Mm-mm.
P	…um, until you are here and then that –
I	Mm, mm.
P	…helps you 'cause –
I	Ja.
P	…even…I mean, we've done the GCP and saying what documents must be done –
I	Mm, mm.
P	…before this study starts?
I	Ja.
P	Once the study starts, after the study starts –
I	Ja.
P	…but in…in the actual practical world –
I	Ja.
P	…it doesn't always get done.
I	Mm.
P	So I think that would…would be a big…um, also to understand how the systems work. So also understanding just the flow of the clinics or the flow of so this is what we do on –
I	Mm.
P	…these kind [sic] of days, that also helps a lot.
I	Ja.
P	So say from clinic and then…to understand also timelines.
I	Mm.
P	So, um, that reporting timeline to say you expected to have…give a weekly report. So those are also things which I've learnt along the way. Um, so, initially it wasn't said to me that, by the way, our PI wants a weekly report from you on your study. I found that out by the way. So, oh, and then where's the template? So you don't know that there's a share drive that has –
I	Mm, mm, mm.
P	…all these things on that you must just use this template. So, ideally, that orientation must happen from the –
I	Mm, mm, mm.
P	…go to say, um…so I…when I came, I asked.
I	Mm.
P	I asked for, um, expectations from my PI and I also asked the organogram in terms of who –

I	Ja.
P	…I'm reporting to, who is on what level with me, and stuff.
I	Mm.
P	So I asked for those things but most people coming in won't know –
I	No.
P	…tho…those things. So I think –
I	They won't know what to ask for.
P	Yes.
I	Mm.
P	So it's im…that's also important just to –
I	Mm.
P	…when…when they do come in, remind them what is expected –
I	Ja.
P	…of them, sort of what is priority –
I	Mm.
P	…because you can also come in and, because you the new doctor, you could have someone…uh, maybe the nurse telling you, no, you must do one, two, three, you know, um, but, meanwhile, that is not priority and it's not what your PI wants you to do.
I	Mm.
P	So it's important to understand, okay, I'm reporting to my PI and what is…what does my PI want?
I	Mm.
P	So those things are priority –
I	Mm.
P	…and then everything else, yes, you can help with QC –
I	Mm, mm.
P	…yes, you can help with the nurse, with the emergency trolley, but those are not your –
I	Mm.
P	…priorities. Your –
I	Ja, ja.
P	…priorities are…so it's important to know those things.
I	Mm.
P	So I think, coming in, um, being orientated, being under…understanding who you are reporting to and what that person's expectations of you…are of you –
I	Mm, mm.
P	…um, and just being orientated in terms of your reporting, when you report –
I	Mm.
P	…so do you…what do…what must be done by when? I think so.
I	Mm.
P	Those are important and knowing that, you know, I must check my e-mails, I need to respond by a certain time, I need to…so knowing the deadlines. I think those are –
I	Ja.
P	…important, um, 'cause if you don't know and –
I	Mm.
P	…you, like, ag, that…that e-mail's not important.
I	Ja.
P	So someone needs to maybe telling you, listen, if you see e-mails from whoever –
I	Ja.
P	…those are important.
I	Ja.
P	So [INDISTINCT] the orientation, it's, um…it's not just sort of here's the whole –
I	No, no.

P   …package. It's…it's really getting to…getting into it.
I   Ja. I like the idea that you say there should be a welcoming pack. So maybe that –
P   Yes.
I   …welcoming pack could include a lot of things.
P   Yes, it can –
I   It can include the different studies, how to…how each one work [sic] –
P   Yes.
I   …plus that [sic] extras [sic] things are…there's a who…there's a –
P   Yes. Share –
I   …share drive –
P   …drive, yes.
I   …on the share drive, you will –
P   Yes.
I   …find X, Y, and Z, and –
P   Yes, so then –
I   …all those things could be –
P   Yes.
I   …part of that…I like the idea –
P   Yeah.
I   …of that.
P   And then that orientation, I think, is…that's what I would've liked –
I   Ja, ja.
P   …coming in but –
I   Ja.
P   As I'm saying, you…you do find your feet eventually –
I   Ja.
P   …and you get the hang of things.
I   And it should be something that's written down –
P   Yes.
I   …so that, if there is a crisis that there's no-one to orientate –
P   Yes.
I   …that new person, that you can say, listen –
P   Yes.
I   …here's the binder –
P   Yes –
I   …you will –
P   …look through –
I   …find…ja, work through –
P   Yes.
I   …it, you will find a lot of information here –
P   Yes, yes.
I   …and then –
P   Yes.
I   …in a week [sic] time, when –
[CROSSTALK]
P   …ideally –
I   Ja.
P   …ideally you should maybe have a week or two just to read, to ask your questions.
I   Ja.
P   I think that should also be important, having someone who you can go to, because you don't want it to interrupt everyone.
I   Mm.

P	So either they tell you, listen, you can come to me at this time every day –
I	Mm, mm.
P	…and we can sit and –
I	Mm.
P	…answer all questions because, otherwise, you just go and you disturbing people and people are, like, irritated because you asking a hundred and one questions when you just joined and you don't understand –
I	Ja.
P	…and you don't know.
I	Mm.
P	So, yes, also having who's the…maybe your go-to person –
I	Ja.
P	…that, when you just start out, who must I go to if I have questions and then –
I	Mm hm.
P	…if they can't, they can tell you let me pass you over –
I	Ja.
P	…to someone else but…so you don't bug everyone –
I	Ja.
P	…and…of the staff and also get this one give [sic] you this information, that one give [sic] you the –
I	Ja.
P	…different information. So I think just that…that's very important –
I	Mm.
P	…helping, um, new sub-investigators –
I	Mm.
P	…to just find their feet –
I	Ja.
P	…and then, going forward, once they have there, to do…to help to grow them, so to speak, to send them on relevant courses –
I	Mm hm.
P	…and, um, sometimes maybe giving them that guidance to say, okay, um, I think, uh, XXXX is good, we do have the appraisals –
I	Mm.
P	…we do speak about, okay, maybe in…what are the plans for next year –
I	Mm hm.
P	…in terms of courses? Um, but I think sometimes we also need maybe a bit of guidance to say, listen, yes, you wanna do this course but how is that gonna help you –
I	Mm.
P	…in the future? What are you gonna do with –
I	Mm.
P	…this course? So, if your aim is to be principle investigator, you should be looking at X, Y, and Z –
I	Mm.
P	…rather than –
I	Ja.
P	So maybe that bit of guidance as well –
I	Mm.
P	…is also helpful.
I	Ja.
P	But, um, the appraisals do help –
I	Mm.
P	…although they can be somewhat nerve-wracking.

I	Ja.
P	They can be nerve-wracking although I feel, with the appraisals, it should be, um…ideally…and it shouldn't just be in the appraisal season. Again –
I	Ja, ja.
P	It should again be when you are starting out –
I	Mm.
P	…or also you should be told what the expectations are –
I	Mm.
P	…of you –
I	Ja.
P	…and, ideally, if you having your appraisal, if you have met all those expectations –
I	Mm, mm.
P	…what percent of increase you can be expecting –
I	Ja.
P	…because, if you saying –
I	Ja.
P	…okay, you didn't meet everything so you're gonna get five percent but, if you met everything, you're gonna get ten percent. That should be how –
I	Ja.
P	…appraisals –
I	Ja.
P	…should actually be run. If it's –
I	It…it's supposed to be like that.
P	If it's a, um…a…if it's a performance –
I	Ja, ja.
P	…appraisal then –
I	Ja.
P	…that is…but I don't think that's how it's run here. So –
I	No.
P	So that is –
I	But they…I…I know –
P	…ideal.
I	…initially, they wanted to run it like that but it never materialised to run like that.
P	You must tell them. You must tell them. Yes.
I	Ja.
P	So I think that's also just good in terms of meeting targets –
I	Ja.
P	…and knowing the expectations –
I	Mm.
P	…of…of you and, if things change, um –
I	Mm.
P	…knowing if things change, to be…to kept…to be kept in the loop –
I	Ja.
P	…is also important.
I	And what the…what other growth, uh, opportunities would you say should there be…should be part of it?
P	Um…um, I think…I'm not sure now but I know, in the past there was, you know, publishing –
I	Mm, ja, ja.
P	…and –
I	Ja.
P	…I remember, at the time, I didn't actually get the time –

I	Ja.
P	…to go 'cause I [INDISTINCT] and we couldn't come to class –
I	Ja, ja.
P	…and…but it's like something I would be interested in –
I	Ja.
P	…now to –
I	Ja.
P	…actually s…whether it's an abstract or just the poster just to get that –
I	Mm.
P	…um, to get that –
I	Mm.
P	…experience would also be good.
I	Ja.
P	So it is something that I've also talked to my PI ab…ab…PI about.
I	Ja.
P	We haven't had anything –
I	Mm.
P	…as yet but it would be something, whether, uh, co-author or –
I	Ja.
P	…what, I would like to be a part of –
I	Ja.
P	…to…in terms of writing, um, and also knowing sort of…'cause I think that's my other challenge.
I	Mm hm.
P	I never know how much, um…I don't know, with writing, how…what the channels are that I have go through –
I	Okay.
P	…in terms of saying do we need approval –
I	Ja.
P	…to write? Can I write about the –
I	Mm.
P	…study?
I	Mm.
P	Because this is not –
I	Mm.
P	…nothing is –
I	Ja.
P	…confirmed yet.
I	Ja.
P	So those are things I don't know –
I	Ja.
P	…yet and that's –
I	Mm.
P	…something I still would like to learn –
I	Ja.
P	…about in terms of how does one go about –
I	Ja.
P	…writing? What can you actually write about?
I	Ja.
P	Because –
I	And the sponsor, where does the sponsor come in?
P	Yes, because now I've gotten –

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I	Ja.
P	…this information but –
I	Ja.
P	…nothing is…it's still a study, it's –
I	Ja.
P	…nothing has been confirmed. So can I just say randomly, oh, I've noticed that, by the way –
I	Mm, mm.
P	…there are these ten pa…participants who, um, December period is…the STI rate has gone up –
I	Ja.
P	…by the way, for that [INDISTINCT].
I	Ja.
P	So I think that is an area that I would still like to…to grow in.
I	Ja.
P	Ja. For…mostly for writing and then –
I	Ja.
P	…um, I guess networking. I think… I mean, there are opportunities for travel and so forth.
I	Mm.
P	So it's not something that…but, ja, writing, presenting –
I	Ja.
P	…and, um, media interaction 'cause it's almost like –
I	Mm.
P	…what do you say?
I	Ja.
P	It's, like, [INDISTINCT] know how much can you –
I	Ja.
P	…say? And, you know…so I think those are the two key areas –
I	Mm.
P	…that I would like to also be mentored in –
I	Mm.
P	…or get more exposure to –
I	Ja.
P	…to say…
I	Okay. Ja. And for new medical doctors that think of research, uh, going into research, what would you tell them? What…what should they consider when they –
P	When…when they wanna come into research?
I	Ja.
P	Um, I think, especially if you an…an analytical person –
I	Mm hm.
P	…uh, um, you would enjoy the research and someone who likes things done a certain way –
I	Mm, mm.
P	…I think you would definitely enjoy research, um, and especially if you…if you love public health, I would say come into research.
I	Mm.
P	Um, I don't know for people who's [sic] left. I don't know if…initially, when I left, was because I was missing clinical a bit.
I	Ja.
P	So I guess it depends in which, um…what you researching –
I	Ja, ja, ja.

P	…in which field you are but, um, I would say…I'd say give it…give it…give it a go.
I	Mm.
P	Um, it's definitely opened my eyes to just, I think…going forward, to making sure that we are held accountable –
I	Ja.
P	…as doctors sort of, um…like I said, having to know this is how things must be done, are you doing it?
I	Ja.
P	Following up participants. Um, I know, outside in government, you can, you know, get…it gets busy, you get swapped –
I	Mm.
P	…but, um, I think, if you going from here to that, you would –
I	Mm hm.
P	…make sure that the…you know, right things are done, that you order stock on time, that you –
I	Mm.
P	…there's that drug accountability, there's…what's happening. It will make you question things. Say, like, a patient adherence.
I	Mm hm.
P	So you brought only back so many tablets, what happened? So it…it just…it just opens up your mind –
I	Mm.
P	…to looking at, uh, patients, I think, more holistically.
I	Mm.
P	But the main thing for me is making sure that you actually take accountability –
I	Ja, ja.
P	…of…of what you're doing and knowing that you have to answer to someone because –
I	Ja.
P	…I think a lot of the time…I mean, you'll hear stories outside and –
I	Mm.
P	…patients will be like, no, they just gave me a Panado and said just go. And you like that doesn't make sense.
I	No.
P	Ja. So I think, um…I think it's good, even if it was something that they would wanna do after the –
I	Ja.
P	…comserve. Um, they might come and not leave because –
I	Mm.
P	…you know, they might enjoy it or –
I	Ja.
P	…I know some people have gone on to actually be registrars in public health after this or, um, myself, I'm just telling you [INDISTINCT]. I would…like, I would…I would love to do –
I	Ja.
P	…my masters' in –
I	Ja.
P	…public health.
I	Ja.
P	Um, so that's another thing I would like to do.
I	Ja.
P	Um, so that…and maybe eventually be a part of policy making –
I	Ja.

P   …and so forth. So that's, ja –

I   Ja.

P   …in the future. So it's nice that, um, currently, um…'cause I think the one study has just…that…okay, I wasn't…I came after it was done –

I   Mm, mm, mm.

P   …but I'm just saying that that study now –

I   Ja.

P   …they possibly gonna, um, approve the…the TRUVADA with the [INDISTINCT] and [INDISTINCT] the…the decreased dose.

I   Ja, ja.

P   So it's nice to be a part of that, to know that you've had a hand in –

I   Change policy or what –

P   Ja.

I   …or…or…or set the policy or…what's the word?

P   Yes.

I   Ja.

P   So you've had a hand in –

I   Ja.

P   …government making a change –

I   Ja.

P   …and –

I   Ja.

P   …bringing about –

I   Ja.

P   …now a better regiment for participants –

I   Ja.

P   …or patients outside. So –

I   No, it's very rewarding.

P   Ja.

I   Ja.

P   So to know that you were part of that.

I   Ja. Okay.

P   Ja. So, hopefully –

I   And…and what…ja, so, as you say, you would say to them, if they like to be analytically orientated, then it's good –

P   Yes. And, if they wanna be part of something bigger –

I   Ja, ja.

P   …yes, come into research.

I   Ja.

P   Especially, like, if, you know, at the end of the day –

I   Ja.

P   …you…you make a contribution. Just like the participants are making a contribution –

I   Mm.

P   …so are you, at the end of the day.

I   Ja.

P   So it's…it requires you to be, um, like, ac…accurate, you know –

I   Mm.

P   …giving the correct data and all of that.

I   Ja.

P   So –

I   And do you think it would help if you have a speciality…if you have specialised in a direction? Like…like you said –

P	Um –
I	…in public health. Say you had done your masters' in public health.
P	Ja. Um, not necessarily –
I	Ja.
P	…in research.
I	Ja.
P	Maybe for if you were doing paeds, yes –
I	Mm.
P	…as a paediatrician –
I	Okay, ja.
P	…yes.
I	As a paediatrician, okay.
P	Um, for…for in HIV, maybe –
I	Ja.
P	…if I do my diploma in HIV –
I	Ja.
P	…management, it would help.
I	Ja.
P	Um, so I'm not sure if maybe having my masters' –
I	Ja.
P	…I might not necessarily be just maybe a PI. I might be working, say, there in Pretoria –
I	Mm.
P	…some…a company that helps oversee as opposed –
I	Mm.
P	…to being –
I	Okay.
P	…actually in research.
I	Ja.
P	So –
I	Ja.
P	…i…if…so then that would actually be a stepping stone.
I	Ja.
P	So the masters' does help, it…it helps –
I	Ja.
P	…if you do have your masters' –
I	Mm.
P	…but you wouldn't necessarily be a [INDISTINCT].
I	No, no, no.
P	Ja.
I	Ja.
P	So you'd actually… So it…it could help if you have a speciality –
I	Mm.
P	…I suppose.
I	Ja. But, as you say, it depends on –
P	On what –
I	Ja.
P	…your –
I	…ja, which field –
P	…interest is.
I	Ja.
P	Ja. So –
I	Ja.

P	…what your interest is but I think –
I	Ja.
P	…um, I don't think it…it's…it's…I don't think it's essential.
I	Ja.
P	Ja, I don't think it is essential.
I	Mm. Okay. Anything else you want to add?
P	No, I don't have…have I answered all your questions?
I	Ja, ja. So, as I said, it's open ended so I just –
P	Ja.

[CROSSTALK]

P	…from there.
I	…what…what –
P	Ja.
I	…your experience but is [sic] there any other experiences that you –
P	Um, want to add?
I	…want to add?
P	Mm. Um. Not so much but I just think…like I said, I enjoy the research, I enjoy –
I	Ja.
P	…the…having the protocol and…and also the team dynamic.
I	Ja.
P	It…it's good that you work in a team and…and I think it's also important that people just understand their roles and I think from where…like, the organogram is also –
I	Ja.
P	…important to know who you report to and also sort of who others are reporting –
I	Ja.
P	…to so that you don't sort of I'm telling you to do whatever –
I	Ja.
P	…but I'm not even your manager –
I	Ja.
P	…but I'm gonna tell you what to do.
I	Ja.
P	So I think that is important. And also just, um, working together as a team.
I	Mm.
P	It's nice to…to understand sort of that everyone's role is important –
I	Ja.
P	…in the team that –
I	Mm.
P	…like, I'm doing my job but, if there's no QC and –
I	Ja.
P	…you know, that's essential.
I	Mm.
P	If I don't have the nurse to do…put it that 'cause that's essential.
I	Ja.
P	That administrator checking contact details, whatever. So it's just understanding that we –
I	Ja.
P	…are all part –
I	Mm.
P	…of a bigger team and, um, we only as strong as our weakest link –
I	No, absolutely.
P	…at the end of the day. Ja, so, [CROSSTALK] –
I	You were mentioning about networking earlier. Wha…wha –

P	Um.
I	…what kind of networking –
P	Networking –
I	…were you thinking?
P	I think sometimes, um, we should maybe be exposed to…maybe like where the PI will maybe go and meet the people –
I	Ja.
P	…from government or –
I	Oh.
P	…yes, we do get to meet with our CAB [SP] –
I	Ja.
P	…members, you know –
I	Mm.
P	…the committee guys [INDISTINCT], we do meet with them –
I	Mm.
P	…but also [INDISTINCT] to…'cause as long as they can feel like people up there or –
I	Mm.
P	…your twelfth floor or your –
I	Ja, ja, ja.
P	…EXCOs –
I	Ja.
P	…they are, like, up there –
I	Ja.
P	…and you here and you, like…you feel like a little person.
I	Ja.
P	So sometimes it's good to sort of level the playing field, so to speak –
I	Mm.
P	…so that you…you open to speaking –
I	Mm.
P	…to them and maybe also getting to not only speak to your PI but other PIs –
I	Mm.
P	…and getting ideas –
I	Mm.
P	…from them or just maybe how they got to be there –
I	Mm.
P	…getting that experience. I think that's the other thing. We don't actually get to know –
I	No.
P	…or I haven't thought of it before but as to how did our PIs get to become PIs and that is another thing that we also need to find out or to learn –
I	Mm.
P	…about.
I	Mm.
P	It would be nice to know so what did you have to do or are you…do you…are you qualified if you've done –
I	Mm, mm.
P	…X amount of studies? Is that –
I	Mm, ja.
P	…are you –
I	What made you –
P	…auto –
I	…qualified?

P	Yes. Is it automatically then, okay, now I'm qualified to be…or what would be, um…what would I need to still know –
I	Ja.
P	…to get to that point and how does one even approach…I mean, who do I have to approach if I wanna get a study?
I	Mm.
P	Like, those are other things that I –
I	Ja.
P	…would –
I	Ja, ja.
P	…like to know. So –
I	Ja.
P	…I hear there's this whatever so how do I go about? How do I –
I	Ja.
P	…make myself available to say I'm interested? I mean, the other thing is, um, the financial side –
I	Mm.
P	…the grants and –
I	Ja.
P	…the grant applications and things.
I	Ja.
P	So I think, um, as sub-PI, we just need…we need to be exposed –
I	Yes.
P	…to all those things –
I	Ja.
P	…to understand the financial aspects of it –
I	Mm.
P	…um, the money, who…how it [INDISTINCT] goes. I mean, I know about the petty cash –
I	Ja.
P	…I know about the transport –
I	Yes.
P	…money –
I	Yes, yes.
P	…I know about that, but I don't know in terms of grant application, I don't know, um…so money has now come from the sponsor, what is the allocation?
I	Ja.
P	How does it…you know, how do we now feed back to the sponsor to say this is what we've done with the money and what's happened at the end of the day? So those are other things, actually –
I	Ja.
P	…thinking about it, I don't know.
I	Ja.
P	So those are also important –
I	Ja.
P	…and, like I said, speaking to other network, um…maybe now and again sitting in on these management –
I	Yes.
P	…meetings –
I	Ja.
P	…just to sit in.
I	Ja, ja, ja.

P	Not to say anything –
I	Ja, ja.
P	…just to sit in and –
I	To observe.
P	…just to observe –
I	Ja.
P	…and to see. I mean, I don't know. Maybe there's things that are private that's –
I	Ja.
P	…being discussed in there but just to be, um…to see –
I	Ja, how it –
P	…more or less or there's a financial –
I	Ja.
P	…meeting or…ja, these meetings to see what's happening –
I	Mm.
P	…or what's being discussed and not…those are…those are…so it doesn't just seem like it's up there –
I	Ja, ja.
P	…and out of your reach –
I	Ja.
P	…and, you know, way beyond –
I	Ja.
P	Ja.
I	So that's internal networking.
P	Internal networking and then also, like –
I	Ja?
P	…I think if…um, going outside to…or, if the sponsors do come, I think that does happen. We do –
I	Mm, mm.
P	…introduced to…when people…when visitors do come, the sponsors do…we do get introduced –
I	Mm, mm.
P	…in that sense, um, but sometimes it will be good if, um, they sort of, um…maybe other PIs.
I	Mm.
P	Not necessarily just, oh, by the way, this is a roundtable –
I	Ja.
P	…this is –
I	Ja, ja.
P	…our sub-PI, but saying, no, speak to this person, this whatever.
I	Mm.
P	Because sometimes it feels like you…you can't…you…you won't discuss, say, protocol –
I	Mm.
P	…or different sites maybe, um, challenges at different sites. You only maybe speak on the conference calls –
I	Ja.
P	…whatever –
I	Ja.
P	…as opposed to just getting to know people –
I	Ja.
P	…and –
I	Ja.

P	…saying, hey, how does your site do one, two, three?
I	Ja, ja.
P	Not for the sake of saying our site doesn't –
I	No, no.
P	…know how but just getting to know people and getting to also know what –
I	Ja.
P	…people are doing out there –
I	Ja.
P	…what are their experiences –
I	Mm.
P	…and what you can learn from them –
I	Ja.
P	…maybe what courses they've done. Um, so even, like, maybe in the –
I	Mm.
P	…government type meetings –
I	Ja.
P	…getting to know people in the DOH. Who are the relevant people to speak to?
I	Mm.
P	Like people for these approvals –
I	Ja.
P	…that we wait for, forever –
I	Ja.
P	…like, who must we be speaking to –
I	Ja.
P	…if things don't get approved?
I	Ja.
P	Who is the correct…the contact persons? So those are things I still –
I	Mm.
P	…don't know in terms of –
I	Mm.
P	…so, um, I think the site coordinator knows. So I need to speak to her [CROSSTALK].
I	Ja, ja.
P	So, now and again, maybe saying the doctor –
I	Yes, yes.
P	…needs to phone and –
I	Yes.
P	…and follow this up –
I	Ja.
P	…and make it sort of…maybe just give us some tasks –
I	Ja.
P	…which are a little bit beyond our scope –
I	Ja.
P	…to say, okay, I'm giving you this, follow this up.
I	Ja.
P	So, um, like I said, um, my PI, she's also great. We've had a third-line application –
I	Mm.
P	…now. So, in that sense, she's…she's sort of, um, allowed me to do it.
I	Ja.
P	So she will do the final but then –
I	Ja.
P	…I'll do the submission. So she'll tweak whatever she needs to.
I	Ja.

P	So those are nice but sometimes I think to just set those tasks –
I	Ja.
P	…that you know what? You need to follow this up. We haven't gotten approval yet. I want you to –
I	Ja.
P	…find out what's happening and…or ask so what do you think –
I	Ja.
P	…we should be doing? Maybe just to challenge us a bit out of our –
I	Yes.
P	…sub-PI zone.
I	Ja. Ja. And, as part of this –
P	Ja.
I	…application, we also want DOH, uh…uh, um, approval.
P	Yes.
I	So, go –
P	Yes.
I	…online and apply, da-da-da. Ja.
P	Yes. So those kind [sic] of things.
I	Ja, ja.
P	I mean, yes, you can maybe, um –
I	Ja.
P	…shadow and make sure that I've done –
I	Ja.
P	…the correct things because –
I	Ja.
P	…I mean, it's still your name at the end of the day –
I	Ja.
P	…as the PI –
I	Ja.
P	…but, ja, having that…'cause I think it…it…it's nice to know that –
I	Mm, mm.
P	…you know what?
I	Mm.
P	I am doing something different.
I	Ja.
P	So, like, even doing this third-line –
I	Ja.
P	…i…it…it was nice for me –
I	Ja.
P	…'cause it was the first one to have done. So it…it's nice that I could get that –
I	Mm, mm.
P	…exposure and that –
I	Mm.
P	…experience of it.
I	And would you say a lot of these things came because you asked for it? But, say for instance, it was –
P	I think I –
I	…somebody that's [sic] were very –
P	I think because I asked –
I	…uh, insecure and –
P	Or they just think that this is my…I must just –
I	Yes.

P	…have patience –
I	Yes, yes, yes.
P	…I must just do. Um, I think, because I asked for it.
I	Ja.
P	Ja. I think because I asked for it –
I	Ja.
P	…I think I made my PI a bit more –
I	Ja.
P	…aware that –
I	Ja.
P	…this is what I want. So I think, if I hadn't asked, I –
I	It would have been –
P	'Cause, like I said, initially, I was hardly having contact with her and now I've actually pushed to –
I	Ja.
P	…have more –
I	Ja.
P	…contact with her as well. So, ja, I think –
I	Ja.
P	…if, initially…um, because, um, I'm not…I think most PIs, they're…you know, the site coordinator –
I	Mm, mm.
P	…will tell them what's happening.
I	Yes, yes.
P	We have a meeting –
I	Ja.
P	…and then she'll feed back.
I	Ja, ja.
P	So I think because I've pushed –
I	Ja.
I	…for it and said, um, I'm not used to this.
I	Ja.
P	I –
I	Ja.
P	…um, I need to know what my –
I	Yes.
P	…PI wants and I…I need to know.
I	Ja.
P	Ja. I think that was probably a large part of who I am.
I	Ja.
P	So I think it's a…an unconscious thing –
I	Mm.
P	…[INDISTINCT] the side of the PIs, it's not something that they…you know, like, ugh, I don't want to sh…I don't want to teach them.
I	Mm, mm.
P	I think just an unconscious thing but –
I	Mm, mm.
P	…once you make them aware –
I	Mm.
P	…I think that will definitely put in that –
I	Ja.
P	…effort to say, okay –

I	Ja.
P	…um, whether it is, uh, maybe we should, um, say, by force, that you, you know…maybe they should –
I	Ja.
P	…also be getting targets to say that you should've showed [sic] a sub…um, a sub-I –
I	Ja.
P	…one, two, and three by –
I	Ja, ja.
P	You must appraisal. You didn't show me one, two, and three –
I	Ja.
P	…by, you know…like a feedback to say –
I	Ja, ja.
P	…um, I still don't know how to do one, two, and three.
I	Ja.
P	You haven't shown me. So I don't know what's gonna happen but you must get me five percent more bonus.
I	Ja.
P	I don't know.
I	Ja.
P	Something like that but, um, I think –
I	And the sub can go to that conference and you can't go.
P	Ja, and I will tell…give you feedback when I come back.
I	Ja.
P	See how you do. Ja, something like that but, um, I'm…maybe, uh, have a little…a programme –
I	Ja.
P	…I don't know, um, going where…just to make them more aware –
I	Ja.
P	…that, you know, as much as it seems like, okay –
I	Ja.
P	…the sub…sub-I has got everything –
I	Mm.
P	…under control but maybe just [CROSSTALK] –
I	Ja, as you say –
P	…to extend –
I	Ja.
P	…them a bit to –
I	If there was a little programme –
P	Ja.
I	…it would have forced them to follow that little programme but –
P	Yes.
I	…as you say, if there isn't, they would just carry on –
P	Ja.
I	…with their own stuff. Ja.
P	Or…I guess because not everyone's gonna know to ask to say –
I	No.
P	…listen, I want –
I	No, no.
P	…to know more because some –
I	Ja.
P	…not everyone's the same. Some people might just –
I	Ja.

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P	…be happy that I'm doing my job –
I	Ja.
P	…and I'm getting paid –
I	Ja.
P	…at the end of the month –
I	And they go –
P	…my…my reports are in, everything's done –
I	Ja.
P	…and that's it but –
I	Ja.
P	…um, I…I guess now and again it's good to ask what is the long-term plan –
I	Ja.
P	…to ask –
I	Ja.
P	…where do you –
I	Ja.
P	…wanna go? 'Cause, if this is what –
I	Ja.
P	…all you wanna do, then that's okay –
I	Ja.
P	…but, if you like to do more, you need to know more. So –
I	Mm. Ja, good. Thanks very much.
P	It's a pleasure. Thank you –
I	Thanks for your time –
P	You got me thinking.
[CROSSTALK]	
I	…learn from you.
P	I've also learnt now for myself now [CROSSTALK] –
I	Ja.
P	…I must go –
I	Ja. But you know what? You…we don't take the time to –
P	Ja.
I	…reflect on stuff.
P	Yes, I think that was…it was a good –
I	Ja.
P	…reflection session for me –
I	Yes, yes, yes.
P	…as well –
I	Yes, yes.
P	…just to actually…like I said, that was…that was…like, I'd forgotten about grants application –
I	Ja.
P	…and –
I	Ja.
P	…just networking and saying –
I	Ja.
P	…sit in on those meetings –
I	Ja.
P	…and…ja.
I	Ja.
P	It was good.
I	And it is like it i…i…if you don't ask to be part of the next budget –

P   Yes.
I   …you won't learn –
P   You won't learn.
I   …because they not going to think of –
P   Ja, I mean –
I   …maybe I should ask so-and-so to come.
P   Because they've got…I mean, they've got their own –
I   Ja.
P   …things on their –
I   Yes, yes.
P   …mind.
I   Yes.
P   You know, they've also got their –
I   Ja.
P   …plans, they've also got, um –
I   Ja.
P   …things that they've got –
I   Ja.
P   …targets they've gotta meet and stuff. So, unless you actually ask.
I   Ja.
P   So I must ask [INDISTINCT].
I   Tell them.
P   Yes.
I   [CROSSTALK].
P   Thank you so much.
I   Thanks.
P   I appreciate it.
--- END OF AUDIO ---