# UNIVERSITY OF THE WESTERN CAPE

## Faculty of Community and Health Sciences

Exploring the perceptions of health professionals regarding participation in clinical trials in Gauteng Province, South Africa

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A mini-thesis submitted in partial fulfilment of the requirements for the degree of Master of Public Health at the School of Public Health, University of the Western Cape

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## KEYWORDS

Clinical trials

Participation

Willingness

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Covid-19

Perception

Health care professionals

Medical intervention

Influencers

Hindrances

# DECLARATION

I declare that this thesis titled *"Exploring the perceptions of health professionals regarding participation in clinical trials in Gauteng Province, South Africa"* is my own work. None of the sources I used or quoted in this essay have ever been submitted, in whole or in part, for a degree or examination at another university, and all references to them have been properly cited.

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Signed:

# ABSTRACT

**Background:** Clinical trials are defined as research studies in which people volunteer to test new treatments, interventions or devices to prevent, detect, treat or manage different medical conditions. They are important in drug development; however, recruitment is a challenge often faced by researchers. Recent studies have suggested that there should be more effort to increase awareness of clinical trials, which may in turn increase willingness to enrol and participate in trials amongst all sectors of society. Currently, there is little known about the perceptions of health professionals, particularly from low- and middle-income countries (LMICs) regarding clinical trials.

**Aims and Objectives:** The aim of this study was to explore the perceptions and willingness of health professionals in Gauteng Province, South Africa on participating in clinical trials.

**Methodology:** The study was an exploratory qualitative study using semi-structured interviews in English. Fifteen health care professionals from different backgrounds and geographical locations within Gauteng Province were purposively selected. In order to derive themes from the data, interviews were recorded, transcribed, and thematically coded. All study subjects gave informed consent, and the University of the Western Cape Bio-Medical Research Ethics Committee granted ethical approval.

**Results:** All participants claimed to have some prior knowledge of clinical trials, however the Covid-19 outbreak greatly increased their awareness. The majority of participants participated in the Sisonke clinical trial, with influencing factors for enrolling including personal benefit and altruism. Other influencing factors for participating in clinical trials were monetary incentives and free amenities. The main inhibiting factors for participation were the fear of developing severe side effects and time-constraints. Due to increased awareness most of the participants in this study were willing to participate in future clinical trials. This study found that religious and cultural beliefs did not have an influence on decisions to participate in clinical trials.

**Conclusion:** In this study, health professionals admitted that the Covid-19 pandemic had considerably boosted their knowledge of clinical trials and motivation to take part in them in the future. Altruism and personal benefit were the main influencers of participation and fear of side effects was the main inhibitor.

**Recommendations:** Further research should be carried out to understand the awareness, perceptions and willingness of other sections of the population to participate in clinical trials, including those who are not employed. It is recommended that more resources should be invested by educational establishments, research organisations, drug companies and the government to increase awareness of clinical trials amongst the general population.

# GLOSSARY OF ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| FDA | The Food and Drug Administration |
| HIV | Human Immunodeficiency Virus |
| LMICs | Low- and Middle-Income Countries |
| NDoH | National Department of Health |
| SAHPRA | South African Health Products Regulatory Authority |
| USA | The United States of America |
| WHO | World Health Organization |

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Furthermore, I want to thank my mother, without whom it would not have been possible to accomplish this. I am also grateful for the support I have received from the rest of my family and friends.

# DEDICATION

This thesis is a tribute to everyone who has helped me succeed in my academic career. I appreciate your assistance in ensuring that I accomplished my goal.

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# CHAPTER ONE: INTRODUCTION

## 1.1 Background

Clinical trials are defined as research studies in which people volunteer to test new treatments, interventions, or devices to prevent, detect, treat, or manage different medical conditions (WHO, 2019). Clinical trials are vital as they enable researchers to determine whether the proposed interventions are effective and safe for human use. Clinical trials also permit the testing and monitoring of a new intervention on a large population to ensure that any improvement as a result of the intervention helps most of the population and is not just a random effect for one person (Australian Clinical Trials, 2015).

Africa as a continent offers attractive conditions for conducting clinical trials since it has a diverse population of potential patients that may not have been exposed to any pharmaceutical drugs, thus resulting in the ease of recruiting trial participants (Toto et al., 2020). Also, many diseases are widespread in low- and middle-income countries (LMICs), which predominate on the continent (Patra, 2018), making it a good area for conducting trials. In addition to this, clinical trials conducted in LMICs assist in building both the research and health care capacity. Some studies have shown that clinical trials also assist in strengthening health systems and in providing sufficient evidence to improve future health crises responses. (Toto et al., 2020). However, even though Africa has the appropriate conditions for conducting clinical trials, it still lags in terms of the numbers of clinical trials currently being conducted across the continent. According to the most recent data, there were 26 006 clinical trials being conducted in the East Asian region, the European region had 77 473 clinical trials being conducted, and Africa had just 7 192 active trials, which is only 2.5% of the global total (Patra, 2018). According to an article by Toto (2020:2) "only 20–30% of global clinical trials are conducted in LMICs and less than 10% in sub-Saharan Africa". These statistics show that there is a great opportunity for more trials to be conducted in Africa, especially Sub-Saharan Africa.

In South Africa, clinical trials are overseen by the National Department of Health (NDoH). The NDoH keeps a public register of all the clinical trials that have been conducted and currently active studies (Department of Health, 2015). The register provides the general public with information on the purpose of the trial, the inclusion criteria, the location of the clinical trials and contact details. Additionally, the Clinical Trial Unit of the South African Health Products Regulatory Authority (SAHPRA), which provides the legislative framework for the review of clinical studies and recommends authorisation of the conduct of those trials, provides additional

information (South African Health Products Regulatory Authority, 2020). According to the Pan-African Clinical Trials Registry, there were 890 active clinical trials in South Africa as of 2020 (Pan African Clinical Trials Registry, 2020).

Participation in clinical trials may be influenced by a range of factors such as the payment of gratuities and food provisions (Owen-Smith, 2016). Other participants revealed that they chose to participate in clinical trials to obtain better health care treatment (Mfutso-Bengo et al., 2008). Despite these influencing factors, several studies in various locations in Africa including South Africa have found that participants are wary of participating in clinical trials due to a lack of knowledge (Malan and Moodley, 2016)

Recently, the coronavirus (Covid-19) pandemic has turned our lives upside down, with millions of people infected and thousands of deaths around the globe. To combat the disease, there have been over 1000 studies aimed at addressing various aspects of Covid-19 registered on the American website ClinicalTrials.gov (Bauchner and Fontanarosa, 2020). These include clinical trials for therapeutic agents, vaccines, and devices such as tests. However, for these trials to be successful they need to meet participant recruitment targets.

The lack of an effective vaccine for Covid-19 in South Africa prompted the government to take the unusual step of introducing a vaccine roll-out in the form of a clinical trial which was titled Sisonke. The main aim of this trial was to assess the effectiveness of Ad26.COV2.S vaccine on severe Covid, hospitalizations and deaths in health care workers as compared with the general unvaccinated population in South Africa (Wits Health Consortium (Pty) Ltd et al., 2021). The trial also monitored the rate of vaccine uptake and hesitancy amongst health care workers (Wits Health Consortium (Pty) Ltd et al., 2021). Thus, the Sisonke trial was the most usual way that health care workers in the country accessed Covid-19 vaccines.

Since clinical trials play an important role in new treatments and interventions, it is imperative that the views and perceptions of the trial participants are explored. Several studies on clinical trial participant perceptions have been conducted but there is a lack of data from settings in South Africa or the African continent.

### 1.2 Problem statement

Clinical trials are the backbone of drug and medical intervention development, providing important information on the safety and effectiveness of new medical interventions (Frenck, 2018). Despite the vital role that clinical trials play in the health sector, willingness of people

to participate in clinical trials seems to be lacking. Some researchers found that the general reasons that hinder people from participating in clinical trials include lack of trust, fear of being made a guinea pig and lack of awareness regarding clinical trials (Roberson, 1994). However, research shows that there are a variety of reasons that influence people to participate in clinical trials, include receiving incentives such as money, fuel, and food (Owen-Smith et al., 2016). Research has also shown that people are more willing to participate if their participation would help save a family member's life (Chu, 2015). Other studies showed that people in lower income countries were more inclined to participate in trials in pursuit of better health care (Mfutso-Bengo et al., 2008). Most of the studies on willingness to participate in clinical trials have been carried out in high income countries and amongst the general population thus, there is limited information about the willingness of healthcare professionals in South Africa to participate in clinical trials, hence the reason for conducting this study.

### 1.3 Research setting

The study was conducted in Gauteng, which is an urban province of South Africa. The province is home to the capital city of Pretoria and the city of Johannesburg. Johannesburg is the economic hub of the country, thus making Gauteng the most populated province in South Africa with 15.5 million people which translates to 26,0% of the country's population (Statistics South Africa, 2020). According to a 2017 report published by the Gauteng Department of Health there are 6548 clinical professionals and 5773 allied health professionals currently employed in both the public and private health sectors (Department of Health, Province of Gauteng, 2017). Public health care facilities in the province amount to 554, this number is inclusive of clinics, district hospitals and regional hospitals amongst others (Health Systems Trust, 2020). Figures on health care facilities in the private sector are, however, not readily available.

The study participants, health professionals, were selected from three different privately-owned medical facilities in the two main metropolitan cities of Johannesburg or Pretoria. The medical facilities included a multi-disciplinary medical centre, a clinical research organisation and a retail pharmacy. The medical centre was located in the city of Pretoria. In addition to doctors, the medical centre also has dieticians, dentists, radiologists, and a pharmacy. The privately-owned clinical research organisation is located in the central business district of Johannesburg and health professionals that can be found at this facility include doctors, nurses, pharmacists, and clinical trial assistants amongst others. The retail pharmacy was located in a small shopping

centre in Johannesburg. The pharmacy was managed by 3 pharmacists that were assisted by 4 pharmacist assistants.

### 1.4 Aim of the study

To explore the perceptions of health professionals in Gauteng Province on participating in clinical trials.

### 1.5 Objectives

- To explore the awareness of clinical trials amongst health care professionals.
- To explore reasons that act as influencers to participate in clinical trials.
- To explore reasons that act as hindrances to participate in clinical trials.
- To explore cultural or religious reasons that affect the willingness to participate in clinical trials.
- To explore the influence of Covid-19 on the awareness of clinical trials.
- To explore the influence of Covid-19 on the willingness to participate in clinical trials.

### 1.6 Thesis structure

There are six chapters in this thesis. In Chapter one, the study's context, purpose, and goals are all described. An overview of the literature on the views and attitudes of healthcare professionals towards their participation in clinical trials is presented in chapter two. The study's conception, methods of execution, and data analysis are covered in Chapter three, also included are rigor and moral issues. The study's findings are presented in Chapter four. The findings are discussed in detail in Chapter five. Chapter six summarizes the study's findings and offers suggestions for further research as well as recommendations based on the findings.

# CHAPTER TWO: LITERATURE REVIEW

## 2.1 Introduction

This section provides an overview of published literature on the study topic of clinical trial awareness and participation. This chapter starts by defining and describing the importance of clinical trials. It then explores the concept of clinical trial awareness amongst health care professionals and other people in general. Thereafter, it discusses the reasons and factors that have either influenced or inhibited people from participating in clinical trials. It concludes by discussing the influence of the Covid-19 pandemic on the awareness and willingness of people to participate in a clinical trial.

## 2.2 Definition and importance of clinical trials

According to the World Health Organization, clinical trials are defined as a type of research that studies new tests and treatments and evaluates their effects on human health outcomes (World Health Organization, n.d.). Clinical trial studies are the backbone of developing new drugs and other medical interventions. The history of clinical trials dates to as early 1946 with the first randomised controlled of trial of streptomycin (Bhatt, 2010). There are other claims, however, that the origin of clinical trials goes as far back as biblical times (Bhatt, 2010).



There are four phases of clinical trials, and, in all phases, human participants are required to monitor any adverse events associated with the new medical intervention or treatment as well as to evaluate the efficacy of the said treatment or intervention. (World Health Organization, n.d.). Phase I trials are the first step when an investigational agent is studied in a small number of either healthy or diseased human volunteers, the purpose of this phase is to determine the safest dosage range (Umscheid, Margolis and Grossman, 2011). Phase II trials are conducted at a larger scale than phase I with a small number of volunteers who have the disease of interest, this aim of this phase is to determine the safety, pharmacokinetics, and pharmacodynamics of the test drug (Umscheid, Margolis and Grossman, 2011). Phase III trials are conducted on an even larger scale and usually have a more diverse target population, to establish and confirm efficacy of the test drug. As well as comparing the new treatment alternatives to the standard of care, this phase helps in identifying and assessing the occurrence of common adverse effects. (Umscheid, Margolis and Grossman, 2011). Phase IV trials are studies carried out to evaluate a drug's efficacy and safety following registration by the pharmaceutical regulatory authority

of any country; the Food and Drug Administration (FDA) in the United States of America (USA) is one such example (Suvarna, 2010).

In addition to the different phases, clinical trials can also be classified into two categories, namely interventional and observational. Interventional studies, also known as experimental study designs, are often prospective and are specifically designed to investigate the direct effects of therapy or preventive measures on disease (Cancer Research UK, 2014). Participants in these trials are randomly assigned to various treatment groups and this allows the study team to compare the findings. A randomized controlled trial is the most common and effective interventional study design; however, there are additional interventional study designs, such as pre-post study designs, non-randomized controlled trials, and quasi-experiments (Thiese, 2014).

Observational studies, often known as epidemiological studies, are ones in which the researcher does not influence study participants, instead choosing to observe natural relationships between different variables and results (Thiese, 2014). An ecological study is the most basic type of observational study. The comparisons made by this study's methodology involve groups of individuals who are typically categorized according to their geographic location or chronological associations. Ecological studies determine one exposure level for each unique group and can give a general idea of the prevalence of disease within a population. Other examples of observational studies are cross-sectional, case-control studies, retrospective and prospective cohort studies (Thiese, 2014).



### 2.3 Awareness of clinical trials

As stated above, clinical trials are important for determining if a new therapy is effective (Willison et al., 2019), however, clinical trials at times face difficulties in reaching the proposed enrolment figures due to lack of awareness. Awareness refers to the cognitive ability of a person to discern, decipher and judge a given phenomenon (Reinhardt et al., 2021). General awareness of clinical trials has varied in prior studies. A study in Canada listed lack of awareness regarding clinical trials as a possible reason for low participation numbers (Willison et al., 2019). In the same study, 43% of the respondents expressed that they were either not very informed or not at all informed about clinical trials (Willison et al., 2019). A Polish study conducted in the year 2019, showed that 67% of the surveyed population had never heard of

clinical trials until they were approached to take part in one by their physicians (Bartoszkiewicz, 2021). The same study concluded that most patients who participate in clinical trials do not have a full understanding of the process or concept of clinical trials but rather they only know the essential parts.

A study conducted in Scotland concluded that increased awareness of clinical trials did not necessarily increase willingness of the respondents to participate (Mackenzie et al., 2010). This, however, contradicted the data obtained from an article by Ellis et al. (2001) which suggested that participants with a greater awareness of clinical trials were more willing to consider participation. Not being fully aware about clinical trials was not only limited to non-health care professionals as physicians also expressed that they had little to no awareness of clinical trials even though they were more willing to participate (Powell et al., 2008). A similar sentiment was shared by university pharmacy students in India. The study had 102 participants and they scored below the average scale of 30-40% when asked if they had basic concepts of clinical trials (Meena et al., 2010).

A study conducted in America concluded that general clinical trial awareness is increasing in the United States, particularly in populations that are underrepresented such as African American/Black and Hispanic populations. Despite the increase in awareness, the article suggested that these populations remain underrepresented due to lower education levels, lower income levels and lack of Internet-use (Leiter et al., 2015). These factors and other reasons for non-participation are discussed further in the section below.



### 2.4 Reasons for not participating in clinical trials

The factors that discourage people from taking part in clinical trials typically outweigh those that encourage them. According to an article by Owen-Smith (2016), the main barriers to participation were (1) Lack of trust because the participants questioned the researcher's motives and expressed that clinical trial participation was not beneficial; (2) Lack of awareness as they did not want to participate in activities that they are unaware of; (3) Some people reported having psychosocial or emotional issues and being afraid of the potential repercussions of taking part in research trials. Another study confirmed these findings, citing mistrust in the process of obtaining informed permission and concern about side effects from the drug or treatment as the key reasons (Chu, 2015). The same study concluded that eagerness to participate in a clinical trial and awareness were significantly correlated. (Chu, 2015).

A 1994 study in Buffalo, New York, looked at how various ethnic groups felt about taking part in clinical trials (Roberson, 1994). The findings of this study revealed that around a third of the participants (29%) of African American descent cited mistrust, a lack of knowledge, and a fear of being treated as test subjects as their top reasons for avoiding clinical trials (Roberson, 1994). The other ethnic groups that participated in the study were Hispanics and Native Americans (71%) they also shared similar sentiments of mistrust and lack of information as key issues for not participating in clinical trials (Roberson, 1994). Some of the other reasons that were listed as hindrances for clinical trial participation included cultural factors such as religion, moral values, folk/traditional medicines, and beliefs (Roberson, 1994). In a related study carried out in Glasgow, the participants stated that they would not take part in a clinical trial because of their i) reluctance to be used as test subjects, ii) lack of information about clinical trials, and iii) fear of the potential negative effects of the test medication or gadget. (Bevan et al., 1993).

A study from South Africa focused on exploring attitudes of people towards HIV cure research found that participants were unwilling to enrol in trials due to not having a full understanding of the impact of participating. They also revealed that they were fearful that their involvement in the trial would negatively impact them socially and psychologically (Moodley, 2016). Another hindrance to participation in the trial, as stated by the participants, was that HIV cure research had no guarantee for developing a cure; thus, they deemed it unnecessary to participate (Moodley, 2016).



Time constraints, a lack of staff and training, concern for patients, worries about the impact on the doctor-patient relationship, loss of professional autonomy, problems with the consent procedure, a lack of rewards and recognition, and an insufficiently interesting question were found to be the top barriers, according to a systematic review of the studies on clinical trial participation from a researcher perspective (Alemayehu, Mitchell and Nikles, 2018).

### 2.5 Reasons for participating in clinical trials

Although there are numerous reasons given why people may not want to engage in clinical trials, research has shown that there are various factors that can influence clinical trial participation. These factors varied depending on the settings and demographics. According to research, incentives and altruistic motives like saving other people's lives were the most common motivations for taking part in clinical trials. Transgender people in San Francisco, California, were the subjects of a study that found that they would agree to take part in clinical

studies provided they were offered incentives like food and money, as well as having their travel expenses to and from the study site paid for (Owen-Smith et al., 2016). In terms of humanitarian causes, a study looking at the factors influencing clinical trial participation among South Koreans found that 45% of participants thought that participating in clinical trials was beneficial and that 48.6% of participants said they would participate in a clinical trial to save a family member. (Chu, 2015). In addition, patients in a hospital in Glasgow, Scotland, in the United Kingdom, were found to be prepared to take part in a clinical trial to both aid others and increase their own chances of receiving treatment, according to a 1992 study (Bevan et al., 1993).

In 2016, 15 people participated in a small study in South Africa at an HIV research centre in the Western Cape Province. The study participants indicated that they would be open to taking part in a research trial to find a cure for HIV if they were assured of a successful outcome in the form of a cure (Moodley, 2016). Another study examined the participation of different racial groups in clinical trials. The results showed that participants were more receptive to taking part in a trial if the research site was in a favourable setting, such as if there was free parking available or if the site allowed weekend participation. (Roberson, 1994). These studies and others support the idea that people are willing to participate in clinical trials if it is beneficial to either them or family members.



As seen above, most respondents in the studies had similar views, but they mainly resided in high income countries thus, their influences may have been different from respondents that reside in LMICs. According to a study conducted in Malawi, people agreed to take part in clinical trials in order to receive better medical care (Mfutso-Bengo et al., 2008). These participants complained that the local government hospitals were overcrowded and lacked drugs thus, they agreed to take part in clinical trials in hopes that they would be treated better (Mfutso-Bengo et al., 2008).

Another study conducted in Zimbabwe which is regarded as a LMIC (Cain, 2015), investigated the voluntariness in participating in clinical trials amongst a group of 766 people. According to the study's findings, the need for tuberculosis diagnosis and treatment, the severity of their condition's need for assistance, the advice given by a doctor or nurse, the potential for receiving better care or follow-up treatment, and the availability of free and easily accessible treatment were the most frequently mentioned reasons for participating (Mutenherwa, 2012). The opinions of these respondents may have been influenced by the fact that there is poor service

delivery in both Malawi and Zimbabwe, thus they may not have considered the negative side effects of participating in comparison to participants in affluent areas but rather concentrated on promotion of their health.

According to other studies, individuals were open to taking part in clinical trials in order to learn more or satisfy their curiosity. An illustration of this would be the findings of the San Francisco study, where a number of the participants stated that they would be happy to take part in clinical studies to keep up with advancements in science pertaining to transgender health (Owen-Smith, 2016).

### 2.6 The Covid-19 pandemic and its influence

The World Health Organization recognized SARS-CoV-2 as a novel kind of coronavirus in early 2020 following an epidemic in China in December 2019. (WebMD, 2021). According to the WHO, a coronavirus illness (Covid-19) is an infectious condition that can infect your nose, sinuses, or upper throat (World Health Organization, 2022). The outbreak was deemed a Public Health Emergency of International Concern by the World Health Organization on January 30, 2020, and a pandemic on March 11, 2020 (World Health Organization, 2022). The highest risk factors for serious complications and death were advanced age, male gender, and the existence of comorbidities. (Abdelhafiz et al., 2021). The Covid-19 pandemic resulted in overburdened health care systems in all countries, high and low-income alike (Edoka et al., 2021). Countries were working hard to stop the spread of the virus by treating patients, tracking contacts, limiting travel, placing residents in quarantine, and banning public gatherings including sporting events, concerts, and schools (Abdelhafiz et al., 2021).

More quickly than ever, researchers from all over the world worked to create vaccinations that can halt the spread of COVID-19. There were 2,636 trials exploring treatments for Covid-19 in the world as of April 8, 2022 (Mikulic, 2022). Numerous articles suggested that the pandemic may have increased the levels of awareness of clinical trials amongst the general public. One of the speakers at a webinar conducted in 2020 stated that, “The Covid-19 pandemic and the effort to develop treatments and vaccines have brought awareness of clinical trials into the public view like never before” (WCG, 2020). According to a news report from United States of America news due to the pandemic, Covid-19 vaccines were fast-tracked, treatments were authorized, and the role clinical trials played in all these advancements was propelled to the limelight (Brennan, 2021). The report went on to state that newscasts about

clinical trials, newly emerging data and enrolment needs were aired nightly (Brennan, 2021). According to another article, this pandemic received unprecedented media coverage in nations like Egypt, Saudi Arabia, and Jordan. The same article suggested that clinical trials testing new antiviral vaccines or treatments received media attention, which raised public awareness of clinical trials (Abdelhafiz et al., 2021).

### 2.7 Sisonke clinical trial

Prior to the Covid-19 pandemic, South Africa had built up considerable expertise in conducting clinical trials in HIV and Tuberculosis, this experience enabled the country to conduct several Covid-19 vaccine trials (Preiser and Fish, 2022). In early 2021, South Africa found itself without a licenced and available SARS-CoV-2 vaccine. The South African government had previously procured the ChAdOx1 nCoV-19 vaccine, but it did not protect against infection with the beta (B.1.351) variant of concern (Preiser and Fish, 2022). The ENSEMBLE trial had however shown that a single dose of the Ad26.COV2.S vaccine was effective (Sadoff et al., 2021). The results of the ENSEMBLE trial provided a rational for the country to make the single dose Ad26.COV2.S vaccine available to health-care workers, as part of the Sisonke study (Sadoff et al., 2021).

The Sisonke study was a collaboration between the National Department of Health, South African Medical Research Council, Desmond Tutu Health Foundation, CAPRISA, Janssen and Johnson & Johnson (Sisonke, 2021). The Sisonke study wasn't a typical clinical trial; rather, it served as a tool that allowed the government to make a vaccine for Covid-19 accessible to health care workers while the licensing procedure was underway (Sisonke, 2021). The South African government made the decision to continue forward with this initiative because it would have been unethical to withhold a vaccine that was known to be safe and effective, particularly for health care workers who were at a higher risk of contracting the virus (Sisonke, 2021).

The definition of health-care worker used for this study was broad, and it included both patient-facing and non-patient facing health-care workers, support staff, community health workers as well as funeral parlour workers (McQuoid-Mason, 2022). The Sisonke study recruited a total of 477 102 health care workers (Preiser and Fish, 2022). The study was divided into three phases. In the first phase, Sisonke, health care professionals and other high-risk communities received a single dose of the Ad26.COV2.S vaccine by injection. Participants in the initial Sisonke trial received a second Ad26.COV.2 dose through Sisonke2, a Sisonke follow-up trial,

which was perfectly timed to evaluate its efficacy against the omicron variant (Sisonke, 2021). The third phase, dubbed SHERPA, is still in progress, with individuals receiving a single dose of heterologous mRNA-1273 (Moderna) boost vaccination (Preiser and Fish, 2022).

## 2.8 Conclusion

In conclusion, the majority studies found that people expressed lack of knowledge as one of the key issues that discouraged them from participating in clinical trials. Fear of harm from the investigational drug or treatment method was also an important factor that acted as barrier to participation in clinical trials. It is also evident that in general people are willing to participate in a clinical trial if they are assured and if they know that the experimental drug would be beneficial to them as in the case of the HIV cure study from South Africa (Moodley, 2016) and the South Korean study (Chu, 2015). It is however worth noting that reasons to participate in clinical trials may differ between LMICs and developed countries. Studies showed that the Covid-19 pandemic had overwhelmed health systems in both low- and high-income countries, and, in an effort to find a cure, numerous clinical trials were started. The pandemic made headline news on most news stations which may have resulted in an increased awareness of clinical trials amongst health-care workers and the general population.

# CHAPTER THREE: METHODOLOGY

## 3.1 Introduction

The research techniques and processes used in the study are described in this chapter. It outlines the study's methodology, equipment, and steps. Additionally, it describes the study population and the process used to choose the participants. It also discusses the procedures used to gather and analyse the data. The steps used to ensure data quality and ethical considerations are also highlighted.

## 3.2 Study design

The study was an exploratory qualitative study, which was aimed at obtaining a deeper understanding of how, and what, health care professionals know about clinical trials and how they felt about participating in one. According to Langen and Ntlaletse, (2009), explorative studies are undertaken when investigating either a new phenomenon or one in which little information is known. Thus, this design was appropriate as it helped to describe a phenomenon and to explore factors that influence and interact with participation in clinical trials. The purpose of this design, according to one author, is to investigate circumstances in which the intervention under study has no obvious, discrete set of outcomes (Baxter and Jack, 2015). The flexibility of qualitative research methodologies allowed for the identification of novel discoveries that might not have been expressly mentioned in the research topic by using an interview guide with open-ended questions and appropriate probing questions (Willoughby, 2019).

## 3.3 Study population

The study population consisted of health care professionals that reside and work in the Gauteng province in South Africa, from different health professional backgrounds such as, but not limited to, doctors, pharmacists, dentists, radiographers, and clinical trial assistants. The health care professionals were from three different institutions - a privately-owned clinical trials research centre, a privately-owned medical centre, and a privately-owned pharmacy. The participants included in the study had at least one year working experience post university, however, the time spent at their current job was not included in the selection criteria. Participants with experience in clinical trials and those without experience were included.

The population group most easily accessible to the researcher for the purposes of the mini-thesis was private sector health practitioners, hence they were chosen for this study. The

opportunity to include this group was deemed valuable because private sector health practitioners are typically less likely to be included in research studies.

### 3.4 Study sample and Sampling strategy

The study sample consisted of 15 health care professionals from different backgrounds and settings that worked and lived in the Gauteng province. The sample was heterogenous and included male and female adults over 18 years and with no upper age limit, with and without clinical trials experience and people from all ethnicities were welcome to participate. Participants that worked in the clinical trial industry were included in this study s this population was accessible to the researcher.

The sampling strategy used in this study was purposive sampling. This strategy enabled the researcher to focus on a particular population which was able to answer the research questions in a sufficient manner (Taherdoost, 2017). The researcher approached the owners/managers of the establishments, once approval was obtained, the researcher was provided with a list of possible participants. The list contained professions, ages and sex and email contact details. The researcher then used this list to purposively select candidates representing different professions, ages, and sex. The researcher sent an email invitation to participate in the study along with the consent form and study information sheet to those who were carefully chosen as suitable subjects. The consent form was signed by those who expressed an interest in taking part. Other willing individuals took the place of those who declined to participate in the study.

### 3.5 Data collection

Between September 2021 and October 2021, in-depth interviews were used to gather study data. Interviews are excellent for recording participants' perspectives, perceptions, or stories concerning attitudes toward and responses to certain circumstances or phenomena (Paradis et al., 2016). In an effort to comply with Covid-19 protocols that applied during the data collection period all the interviews were conducted virtually using the Zoom video conferencing application using a semi-structured interview guide (Appendix A). Participants were requested to have their Zoom video function on during the entire interview. One of the advantages of this application as a data collection tool is that it is convenient, simple and user friendly (Archibald et al., 2019). Since all the participants are health care professionals, they were able to afford and access the internet needed for the Zoom interview. All the interviews were conducted in English and took place after working hours or over the weekend at a time conducive to the participant. The researcher observed the participants' non-verbal cues during the interviews and made note of these findings. The interviews were videotaped with the participants' permission using the video-enabled Zoom application. The recordings of the data from each interview were afterwards safely kept on the researcher's computer, and the transcripts were transcribed verbatim.

### 3.6 Data analysis



The qualitative methodology allows for concurrent analysis of data during the data collection stage (Corbin and Strauss, 1994). Thus, the data in this study was analysed concurrently with data collection. This approach was appropriate for the study as it made it easier for the researcher to follow up on emerging themes. The explorative study design usually yields a large quantity of raw data, which is not suitable to present in a report, thus, it is important to categorise the different themes (Ryan, 2006). The data was manually analysed using the thematic analysis approach (Pope et al., 2000). This process involves five main steps which are familiarisation, identifying a thematic framework, indexing/categorising information, charting and mapping and interpretation of data (Pope et al., 2000).

**Step 1: Familiarisation**

Following each interview, a word document was created by verbatim transcribing the video recordings. To become acquainted with the data and identify key ideas and recurring themes, the researcher then reviewed and reread the interview notes and transcripts multiple times.

(Robson, Colin, McCartan, 2016). All the data was put into an excel spreadsheet to make it easier for the researcher to analyse.

**Step 2: Identifying a thematic framework**

This process entails identifying all the crucial concerns, ideas, and themes that may be used to analyse and cite the data (Pope, Ziebland and Mays, 2000). The related concepts and actions in the transcripts and other notes served as the basis for the creation of data codes.

**Step 3: Indexing/categorising information**

The researcher arranged the coded data into themes and these themes were put into different worksheets on the Excel document. Similar or related themes were put on the same worksheet and the same colour codes were applied. Emerging themes were shared with the supervisor, and this determined whether the themes were sound and also establish if they convincingly satisfy the research objectives.

**Step 4: Charting**

This step of data analysis involved identifying patterns within the different codes and rearranging the data to fit into the appropriate group/theme.

**Step 5: Mapping and interpretation**

This step made sense out of the various categories, codes and the connections or relationships between them, as well as general discoveries about the research topic. To make them easier to understand, topics were divided into sub-themes. This process also gave the researcher the chance to summarize the information and deliver it in thesis form.



### 3.7 Rigour

Rigour is defined as the trustworthiness of qualitative research and is said to exist when findings of a qualitative study represent validity (Cypress, 2017). According to Cresswell and Miller (2000), qualitative studies are judged by credibility, confirmability, and transferability. Due to the small size of the study, the extent of transferability was limited.

#### 3.7.1 Credibility

Credibility refers to how well the data collected accurately reflects the phenomenon's multiple realities (Sikolia et al., 2013). In this study credibility was achieved by data triangulation, member checking and reflexivity.

The researcher ensured that data triangulation was achieved by collecting data from healthcare professionals in different fields with varying qualifications, this also increased the trustworthiness. The data was collected from a mix of doctors, pharmacists, dentists, radiologists, dieticians, lab technicians and clinical trial associates.

Member checking was achieved by the researcher providing a summary of the participants responses after each interview. Participants were able to verify that their comments had been correctly interpreted and recorded by doing so. (Robson & McCartan, 2016).

The researcher also informed the participants of their right to refuse to participate in the study to ensure that the data collection sessions only involved those that were willing to take part. Self-awareness is required for reflexivity, which means actively participating in the research process (Haynes, 2012), thus, to achieve this, the researcher clearly stated her belief in clinical trials participation as well as the fact that she is currently employed in the same industry, and this was included in the final write-up of the mini-thesis. The researcher kept a research journal in which she documented her personal experience of each interview. This ensured that she could identify her perspective and not let it influence the research itself.

### 3.7.2 Confirmability



Confirmability is the neutrality, or the degree findings are consistent and could be repeated (Polit & Beck, 2014). The researcher ensured as far as possible, that the perceptions and attitudes of the participants were accurately represented and were not her own. Participants were encouraged to be honest, and the researcher explained to them prior to each interview that there were no right answers to the questions.

## 3.8 Ethical considerations

Before commencing with the study, ethical clearance was obtained from the University of the Western Cape's Biomedical Research Ethics Committee (BM21/5/14) (Appendix D) and permission was also obtained from the relevant gatekeepers or authorities at the selected institutions. To ensure that the study is ethical, the three principles of human research ethics were applied. These principles are autonomy, beneficence, and justice (Vanclay, Baines and Taylor, 2013).

### 3.8.1 Autonomy

To ensure the participants' autonomy, participation in the study was voluntary. Written informed consent was obtained from each participant prior to being interviewed and permission to video record the interviews was also sought from the participants. The participants were asked to send a scanned copy of the Informed Consent form. All participants were informed about the purpose and procedure of the study, their right to refuse and/or withdraw at any time without any adverse consequences (Appendix B and C).

### 3.8.2 Beneficence

To uphold the principle of beneficence, the researcher informed
the participants that confidentiality of the information collected will be always maintained, and no personal information will be published. In addition to this, the recorded data will always be stored in a locked cabinet at my place of residence and will only be taken out for purposes of fulfilling the requirements of the study. Data stored on electronic devices such as a laptop will be password protected and only accessible to the researcher. The data will be stored for a period of five years.

### 3.8.3 Justice



To ensure the principle of justice, the researcher ensured that the English language used throughout the study was easily understandable.

Although the study's actual participants may not directly benefit from it, the information gathered could be utilized to guide future research focused at examining and/or enhancing clinical trial participation. The results obtained from this research study will be summarised in an article and will be available to the participants upon request.

# CHAPTER FOUR: RESULTS

## 4.1 Introduction

This research study aimed to understand the perceptions of health care professionals in the Gauteng Province in South Africa regarding participation in clinical trials. Additionally, it was a way to see if the Covid-19 pandemic influenced people's awareness of and desire to take part in clinical trials. A total of fifteen participants were interviewed, comprising eight females and seven males, with the majority aged between 18-40 years old. Nine of the participants worked in the city of Johannesburg and seven in the city of Pretoria. The participants worked in different sectors within the health profession. They included medical doctors, pharmacists, dentists, dieticians, radiographers and a lab technician. All the participants had bachelor's degrees in their chosen professions and two participants had a master's degree, one was Master of Public Health, and the other was a Master of Pharmacy. All the participants worked in privately owned companies with almost half of them working at a clinical research organisation, several worked at an upmarket medical practice and one participant worked at a retail pharmacy. The majority of the participants had worked in their current position for less than five years. Table 1 depicts the key characteristics of the study participants.

**Table 1: Participant demographics**

| Participant Number | Profession | Gender | Age in years | Highest Education level | Time in position | Workplace | Location |
|---|---|---|---|---|---|---|---|
| 1 | Pharmacist | F | 35 | MPH | 5 years | Clinical Research Organisation | Johannesburg |
| 2 | Medical Doctor | M | 52 | MBChB | 2 years | | |
| 3 | Pharmacist | F | 33 | MPharm | 1.5 years | | |
| 4 | Pharmacist | F | 29 | BPharm | 4 years | | |
| 7 | Clinical Trial Assistant | M | 28 | BSc Hons | 7 months | | |
| 10 | Lab Technician | F | 27 | BSc Hons | 3 years | | |
| 11 | Medical Doctor | M | 43 | MBChB | 7 years | Medical practice | Centurion (Pretoria) |
| 12 | Medical Doctor (Intern) | F | 27 | MBChB | 4 years | | |
| 15 | Radiographer (Intern) | F | 24 | BRad | 6 months | | |
| 16 | Radiographer | F | 38 | BRad | 2 years | | |
| 19 | Dietician | M | 29 | BMedSc Hons | 1 year | | |
| 20 | Dietician | F | 28 | BMedSc Hons | 2,5 years | | |
| 22 | Oral Hygienist | M | 29 | BOHSc | 1,5 years | | |
| 23 | Dentist | M | 33 | BDS | 4 years | | |
| 26 | Pharmacist | M | 31 | BPharm | 3,5 years | Private Retail Pharmacy | Johannesburg |

The study yielded seven themes that highlighted health professionals' perceptions of clinical trial participation. The themes included their awareness of clinical trials and information about factors that would either influence or inhibit participants from participating in a clinical trial, as well as the influence of the recent Covid-19 pandemic on clinical trial participation. Table 2 displays the major themes and related sub-themes that were derived from the data.

**Table 2: Study themes and sub-themes**

| Themes | Sub-themes |
|---|---|
| **1.Awareness of clinical trials** | 1.1 Prior knowledge<br>1.2 Sources of information and reliability<br>1.3 Increase awareness of clinical trials |
| **2.Value of clinical trials** | 2.1 Development of new treatments<br>2.2 Ethical appropriateness |
| **3.Clinical trial experience** | 3.1 Previous experience in clinical trials<br>3.2 Covid-19 Sisonke clinical trial<br>3.3 Positive experiences about clinical trials<br>3.4 Negative experiences about clinical trials |
| **4.Influencers for clinical trial participation** | 4.1 Benefit to myself or loved ones<br>4.2 Benefit to society<br>4.3 Clinical trial participation incentives<br>4.4 Monetary influence |
| **5.Inhibitors for clinical trial participation** | 5.1 Side effects/death<br>5.2 Fear of the Unknown<br>5.3 Unknown impact on fertility<br>5.4 Time consuming |
| **6.Religious and cultural factors** | |
| **7. Covid 19 awareness and its influence** | 7.1 Impact on awareness of clinical trials<br>7.2 Covid-19 awareness impact on participation |



These themes and sub-themes are further described as follows:

### 4.2 Awareness of clinical trials

All the participants interviewed in this study had heard the term 'clinical trials' before and all understood the concept of clinical trials. The participants mentioned several different sources that they use to obtain information about clinical trials, and they expressed their thoughts on how reliable they thought these sources of information were.

#### 4.2.1 Prior knowledge

All the participants had some prior knowledge of clinical trials. The majority of participants who were asked to define a clinical trial correctly responded that it was a means to determine whether a new drug was both safe and efficacious for use in humans. Some of the participants expressed that they had obtained their knowledge of clinical trials from their studies at university, which wasn't surprising as all were health professionals.

*"I know that clinical trials are studies that are done to test if new drugs or medical devices are effective and safe for use…. I learnt this from my studies at university"* (Female, Dietician).

The views of the dietician were supported by a medical doctor who also expressed that they learnt about clinical trials at university.

*"…Yeah, I learnt about clinical trials in either my second or third year at med school."* (Male, Medical Doctor).



Though most participants stated they learnt about clinical trials at university, a few others expressed that they had knowledge of clinical trials because they are employed within the medical sector.

"*I might be a bit biased though because I already work in the field. But I know that clinical trials started a while back and they help us to see if new medicines are effective and safe to use in different populations."* (Male, Clinical Trial Assistant).

A female pharmacist also stated that she knew about clinical trials due to the fact that she is currently employed in that sector.

*"…if I didn't work in clinical trials, I most probably would have known less information."* (Female, Pharmacist)

### 4.2.2 Sources of information and reliability

When participants were asked about where they could find reliable information about specific clinical trials, including the type of trial, the duration of the trial and the drug being investigated, most mentioned the internet, although several participants cautioned on the reliability of information from all internet sites.

*"I would say the Internet ey. A quick google search can reveal the different studies/ trials that are being conducted. The internet lies a lot, so one needs to be careful of what the information they are getting. The best would be to visit company websites that are verifiable and known by many."* (Female, Lab Technician)

A dietician shared similar sentiments and stated that the though the internet is not the most reliable source of information, it is quick and convenient.

*"I think google. We can find anything we want on google nowadays. It's a quick way of getting information. That's where I would go first if I wanted info about anything. I don't think it's the most reliable but it's the most convenient. Government websites would most probably have information that's true"* (Male, Dietician)

Other sources of information that the participants mentioned were, doctor's offices, medical school, pharmaceutical and research companies, radio, television, and medical journals.



*"There are a few reliable sources ey. Sometimes research organisations do drives at malls and shopping centres to tell people about the different trials that they have. They also sometimes publicize on the radio and in newspapers. Sometimes the doctors' rooms also have information pamphlets that people can read. But I think the internet is the easiest and fastest way to get information."* (Female, Pharmacist)

One participant expressed that in addition to these sources they also received information about clinical trials through word of mouth from a family member that worked in the industry.

*"I know about clinical trials through a family member that works in the industry, he always tells me about the new developments that are happening in the industry. I also learnt a few things back in school [university]. But I think the internet has more readily available information. It may not be the most trustworthy information, but it's the most accessible. It's not the most reliable source because anyone can just post stuff there. I think the best would be to get information from people or companies that are actually involved in the industry."* (Female, Radiographer)

### 4.2.3 Increase awareness of clinical trials

Although several sources of information about clinical trials was mentioned, it was suggested by most participants that more work should be done to increase awareness of clinical trials, such as advertising on the different media platforms as well as increasing the content taught as part of health professions education.

*"You know, to be straight with you. I can't say I've heard it or seen it in print media. I can't say I've heard it on the radio. I also don't think I would know anything about clinical trial information sources if I didn't work in the field. Something definitely needs to be done to increase awareness of clinical trials, maybe there should be more media coverage of the different trials that are being conducted in the city. I think in that way a lot more people would be willing to participate."* (Female, Pharmacist)

Another participant shared similar views and suggested that the South African Health Products Regulatory Authority (SAHPRA) should start advertising more information about clinical trials.

*"Google. for most of the things you can find via Google If you're a day-to-day person. Otherwise, if you're a health care professional, sometimes you learn through doing extra stuff like CPDs. Maybe SAHPRA can come start advertising more info about Clinical Trials on different social platforms.* (Male, Medical Doctor)



## 4.3 Value of clinical trials

Participants had different views regarding the value of clinical trials in society. Some participants' opinions on the value and importance of clinical trials were based on personal perspectives, that is, benefit to themselves and their loved ones whilst others were concerned about the benefit of clinical trials in society. Despite the majority of the participants having a positive outlook about clinical trials, some of the participants questioned the appropriateness of clinical trials.

### 4.3.1 Development of new treatments

When questioned on the reasons why clinical trials are important, most of the respondents said that clinical trials are important because they assist in the development of new and safer drugs. According to the World Health Organization, clinical trials can be defined as a type of research

that studies new tests and treatments and evaluates their effects on human health outcomes (World Health Organization, n.d.).

One participant placed a high value on clinical trials and stated that if we did not have clinical trials, we would not have any safe medication.

*"If we didn't have them, we wouldn't have any safe medication."* (Female, Dietician)

Some of the participants stated that clinical trials provided more treatment options for illnesses that are difficult to treat. A common example was cancer, most of the participants expressed that cancer is a disease that can be terminal and difficult to treat, thus they think clinical trials will help in finding a cure or new drugs that will help to manage symptoms.

*"They help to decrease mortality and to give people the opportunity to choose an alternative treatment. It also helps increase the treatment options available for the different diseases."* (Female, Radiographer).

A few other participants stated that they were important because new illnesses keep emerging thus new medication is needed.

"*I think that they are very important because we always need more effective drugs especially considering that we are always getting new diseases."* (Female, Pharmacist)

These sentiments were shared by another female pharmacist that stated that the world is progressing thus more effective drugs were needed.

*"The world is progressing, and new and more effective drugs are needed*." (Female Pharmacist)

In addition, a male dentist expressed that the health sector needed to keep up with new diseases.

*"But I think clinical trials are really important… They help us to find new drugs that we need to manage illnesses. It is even more important because we keep getting new illnesses & the health sector needs to keep up."* (Male, Dentist).

Some participants' perspectives were focused on the benefit of clinical trials to society, and expressed those clinical trials assisted in improving health systems.

*"Clinical trials are important in society because they help to improve the health system…"* (Female, Radiographer).

Another participant shared these same sentiments and stated that clinical trials were essential to society.

*"They are essential to society because they help us to ensure that we develop drugs that are safe and effective for humans."* (Female, Lab Technician)

### 4.3.2 Ethical appropriateness

Two participants raised concerns about clinical trials and suggested that they should not be conducted in human subjects citing safety and ethical appropriateness concerns. One participant expressed that they felt that people in lower income areas were unfairly targeted for clinical trials as they earned less and were more likely to sign up to a trial if they were promised food or money as compensation for their participation. They suggested that to mitigate this situation more trials should be conducted in affluent areas.

*"However, I feel like in South Africa they tend to only take place in high density or mostly underprivileged communities which happen to be predominantly black people. The people in these areas are quick to sign up because they are hungry and need money, so I feel like the big pharma companies are taking advantage of the poor. I think it would be fairer if they were also conducted in rich affluent areas."* (Female, Pharmacist)

An oral hygienist questioned the significance of clinical trials and stated that human life is worth protecting and, in their opinion, it nullifies the need for clinical trials. They also expressed that the advancement of technology should allow for scientists to test new drugs on robots that mimic humans.

*"Clinical trials are important in society, I guess. I am not totally convinced though about their importance. They apparently help us in getting safer medicines, but I think that technology has advanced so greatly, so instead of testing out a new drug on humans, why don't they build a robot that mimics the human body and then test the drug there. Surely these scientists can find better ways of drug testing instead of using humans. I strongly feel that human life is worth protecting so we should not experiment and cause unnecessary harm"* (Male, Oral Hygienist)

### 4.4 Clinical trial experience

Participants were asked about their experiences of clinical trials. Prior to the Covid-19 pandemic only two participants had participated in clinical trials and both were trials for dermatological products. Understandably, the majority of the participants took part in the Sisonke Covid-19 clinical trial, with most stating that they participated because it was the way for health professionals to get early access to the Covid-19 vaccine.

#### 4.4.1 Previous experience in clinical trials

Both the participants who had previously participated in a clinical trial prior to Covid-19 did so whilst they were in university and both participants stated that the trial, they participated in was for dermatological products. It is noteworthy that both participants expressed that money was a strong influencing factor as they were students not earning any money at the time. One participant stated that they were not concerned about the side effects of the cream that was being tested because money and food were more important to them at the time.

"*I have participated in two trials before. The first one was in varsity, and it was for an eczema cream, about 10 years ago. I didn't have any eczema, but I was willing to participate because of the extra money that I could make, we also got free lunch every time we went to the clinic for a refill of the cream and a check-up. The other reason why I didn't mind participating in that trial was because it was for a cream. At that point, I didn't think I could get any bad side effects from a cream."* (Male, Dentist)

In addition to receiving money for participating in the clinical trial, a male medical doctor stated that he had acne when he was younger and so he thought that joining an acne clinical trial may benefit him directly.

"*Yes actually. I have participated in a few trials. When I was a student I participated in a skin trial, there was cosmetic company that was testing out a new formulation for male skin to help with acne.... I was motivated to participate because I had acne and also, they were giving me money, and as a broke student I really needed the money."* (Male, Medical Doctor)

#### 4.4.2 Covid-19 Sisonke clinical trial

The majority of the participants stated that they had participated in the Covid-19 Sisonke trial and when questioned why they participated they expressed that they had no choice, some went as far as stating that there were forced to participate by the companies they work for.

"*Sisonke trial was the first trial I have ever participated in and I only participated in it because we were forced to get our jabs at work. If it wasn't for that I personally wouldn't have participated."* (Female, Lab Technician)

Love for family and close friends was a motivation for some of the participants as they said that participating in the Sisonke trial would protect their loved ones.

*"Yes, I did in the Sisonke trial, and I only participated because we are in a pandemic and that was the only way I could get the vaccine and I needed to get vaccinated because I live with my elderly parents."* (Female, Pharmacist)

Similar sentiments were shared by a female intern radiographer:

*"But because it was a pandemic, I had no choice. I needed to protect my family."* (Female, Intern Radiographer)

A small number of participants did not partake in the Sisonke trial, with the reasons for not participating including pregnancy, anxiety, and lack of time.

*"No, I have never participated in a clinical trial. I would have joined Sisonke, but I couldn't because at the time it happened, I was pregnant with my second baby."* (Female, Pharmacist)

Interestingly, a young clinical trial assistant expressed that they would not want to subject themselves to the anxiety that comes with participating in a trial, and so due to this anxiety they decided to not participate in the Sisonke Clinical trial.

*"I have never participated in a clinical trial, and I don't think I would ever want to participate in a trial. Despite the fact that I know everything that happens when conducting a trial, I don't want to subject myself to all that anxiety of not knowing what's being injected in my body. I didn't participate in Sisonke because of this anxiety that I have."* (Male, Clinical Trials Assistant)

### 4.4.3 Positive experiences about clinical trials

Since majority of the participants had only ever participated in the Covid-19 Sisonke clinical trial, most opinions of participating in clinical trials were based on that one trial. In general, participants said that registration to join the Sisonke Covid-19 trial was fairly easy.

*"…and the registration was quick."* (Female, Lab Technician)

Another participant enjoyed the fact that the registration was done online, thus making the process easier.

*"I liked the fact that registration was fairly easy because we had to do everything online. When the day of my vaccination came, I was quickly assisted at the vaccination facility."* (Female, Radiographer).

These sentiments were shared by an intern medical doctor who also stated that registration was easy.

*"My experience was good, the registration process was fairly easy"* (Female, Medical Intern)

Other participants were impressed that they only had to remain at the research site for a short time.

*"I was vaccinated within 2 hours and the registration was quick."* (Female, Lab Technician)

*"I went to the closest vaccine centre. once I arrived there, I was quickly assisted and vaccinated. it took less than an hour."* (Female, Medical Intern)

In addition to the easy registration and spending a short time at the vaccination facility, several participants stated that they felt that everything was transparent, and their questions were sufficiently answered.



*"I also participated in the Sisonke trial for Covid vaccines very recently in both instances I felt that everything was transparent, and all my questions were answered sufficiently by the investigators."* (Male, Medical Doctor).

The doctors' sentiments were shared by another participant that stated that the doctors explained every step to her, and they also gave her a detailed description of the side effects that she could expect.

*"The doctors there explained every step and they told us what side effects to expect."* (Female, Dietician)

### 4.4.4 Negative experiences about clinical trials

A few participants shared negative sentiments on their experience of clinical trial participation. The most common negative sentiment was a lack of, or insufficient information provided by the vaccinators. A female intern felt that she should have been provided more in-depth information about the side effects to be expected. In addition, she also expressed dissatisfaction at the lack of monitoring post the vaccination.

*"I don't think we were given adequate information as I would have preferred. The doctors at the vaccination site only gave us surface information of the side effects to expect. They also didn't really monitor us afterwards; we were left to just walk out soon after."* (Female, Intern Medical Doctor)

These sentiments were shared by a female lab technician who complained that the post vaccination time was less than fifteen minutes as stated in the protocol.

*"We weren't given enough information though, it was just a case of get your jab and go. We didn't even get observed for 15 minutes post vac as stated in the protocol."* (Female, Lab Technician)

A female radiographer complained that she had to resort to searching the internet for side effects of the Covid-19 vaccine and said that the government should have done a better job of providing more information. The same participant experienced mild symptoms.



*"We literally sat for five minutes afterwards, and they let us go without really explaining the expected side effects. I had to google all this information afterwards. The government could have really done better in this regard. I did suffer a few side effects such as a constant headache, an extremely painful arm and some mild rash on the injection site."* (Female, Radiographer)

The radiographer's sentiments were shared by a female pharmacist, who stated that she didn't appreciate the lack of information. She also experienced a tension headache that lasted for a month post taking the vaccine.

*"Side effects experienced, tension headache for a month, fatigue. I didn't like the fact that we weren't given enough information about the vaccine though."* (Female, pharmacist)

A male dentist that had participated in a previous trial whilst attending university stated that the Sisonke trial was the opposite of the experience, he had at his first clinical trial experience.

*"The Sisonke trial was absolutely the opposite of this. There was no to little communication. After the jab, I only received a text telling me to log my side effects on the website, I haven't been contacted since that text message. I also didn't get any side effects from the J&J jab. I participated in Sisonke so that I could receive the Covid vaccine. That was the only way I could receive the vaccine that would potentially save my life."* (Male, Dentist)

### 4.5 Influencers for clinical trial participation

The most common influencers participants mentioned for participating in a clinical trial were benefit either for themselves or their family and loved ones, whilst a few also said that they would participate if their participation would benefit society as a whole. Some participants reported that they appreciated incentives such as money, free health care and amenities like Wi-Fi and parking.

#### 4.5.1 Benefit to myself or loved ones

Most of the people interviewed stated that they were willing to join a clinical trial if it would benefit themselves or their loved ones by improving the quality of life, especially if they were suffering from a rare or serious disease. In fact, responsibility to their love ones came across as a strong motivational factor for participating in clinical trials.

*"I am willing to participate in a clinical trial if I know that the trial will benefit me or directly benefit my family and friends. If it's a cancer trial and I have the cancer, I would be quick to sign up. If the drug promises to improve my quality of life, then I will be the 1st one to sign up."* (Female, pharmacist)

A young mother of 33 years said that motherhood had changed her perspective and she would now be willing to participate in a clinical trial if it would benefit her children. She also stated that she does not live her life for herself anymore but lives her life for her children.

*"Before I had children, I would have been quick to sign up for a clinical trial especially if it meant getting a few extra bucks and intensive healthcare. But now I think I would only participate if it was a trial that would help find a cure for a chronic disease that either I or my kids would have been diagnosed with. I would also participate only if it was a trial that would help keep me safe from a deadly disease like in the case of Covid-19 and the Sisonke trial. I feel this way because I don't want to put my health in unnecessary danger, I don't live for myself anymore, so I need to make sure that I keep healthy for my kids."* (Female, pharmacist)

A female radiographer also felt the same as the pharmacist and stated that she would participate in future trials if either herself or her child were suffering from a serious illness such as cancer and was guaranteed a to receive the investigational drug instead of the placebo drug.

*"I would only participate in a trial if I or my child had a very rare disease or a serious disease such as cancer & I would only participate if I was guaranteed that I would get the real drug and not placebo."* (Female, Radiographer)

Another participant also stated that they would be willing to participate in a clinical trial if they suffered from a disease such as cancer and the trial drug promised to improve their quality of life.

*"I am willing to participate in a clinical trial if I know that the trial will benefit me or directly benefit my family and friends. If it's a cancer trial and I have the cancer, I would be quick to sign up. If the drug promises to improve my quality of life, then I will be the 1st one to sign up."* (Female, Pharmacist)

However, one participant had strong views and expressed that they would only participate in a clinical trial if they were 'on the verge of death', and they were guaranteed a cure.

*"I honestly don't think I would participate in another trial ey. I only participated in Sisonke because I had no choice. I don't like taking risks with my health. But I may be persuaded to participate if I had an extremely rare disease, and I was on the verge of death. So, I would participate if there was a guarantee that I would get cured and not necessarily suffer extreme side effects. I don't have any other factors that would encourage me to participate in a trial ey. with me it's either a Life-or-death situation."* (Female, Lab Technician)



### 4.5.2 Benefit to society

Some respondents stated that they would be willing to participate if their participation would benefit society, especially if there is a pandemic like the recent Covid-19 pandemic.

*"I would only participate if it was to the betterment of society like in the case of Covid-19, "emphasis on Only". There are no other incentives I would want to encourage me to participate in a trial."* (Female, Pharmacist)

Similarly, a male dietician also expressed that they would be willing to participate in a clinical trial if their participation would assist the world in dealing with a pandemic.

*"My influencing factors would be like in the case of Covid where my participation would assist the world in dealing with a pandemic, Then I would participate. I would also participate if my participation would help my family members e.g., if they have a rare debilitating disease with no current cure."* (Male, Dietician)

### 4.5.3 Clinical trial participation incentives

The participants were questioned on the incentives for enrolling in a clinical trial and the responses were varied. Some of the participants stated that they would want to receive good healthcare and/or easy access to doctors.

*"...But if I had to participate, I would appreciate if the research facility gave me good healthcare including free medication for at least two years after the study is complete. I would also want to be treated well at the facility, to be treated as human and not another number/statistic."* (Female, Radiographer)

A female dietician shared the same sentiments and stated that she would want the doctors to keep in contact with her.

*"If I was to participate in a trial, I would want the doctors to always keep in contact so that I don't develop severe side effects from the study drug."* (Female Dietician)

A male pharmacist expressed that he would want to be kept abreast with updates of the progress of the drug and disease.



*"I would expect to receive good healthcare throughout the duration of the trial. I would also want to be kept up-to-date with the progress of the drug and my disease."* (Male, Pharmacist)

Some participants wanted to receive incentives such as a comfortable and convenient research centre location with good parking. Similarly, a female medical doctor intern stated that, in addition to free healthcare, she would appreciate a clean environment with safe parking.

*"In the event that I do end up participating in the trial I would expect the place to have good safe parking, nice clean, comfortable seating environment. I would also appreciate some nice refreshments such as drinks, tea, cold water etc... I also would like continued free health care throughout the duration of the trial."* (Female, Medical Doctor, Intern)

Another participant expressed that in addition to all the other incentives that have been mentioned above, they would want to receive quality food and refreshments as well as free Wi-Fi and safe parking.

*"But in the case that I did participate in a trial I would want to be cared for medically, I mean free health care. I would also want to take part in a trial that doesn't take up too much time from me. I would also appreciate receiving nice quality food whilst I am getting the trial treatment, I also appreciate comfort, So the treatment place should have comfortable chairs, free fast WIFI, free refreshments, free safe parking."* (Male, Oral Hygienist).

### 4.5.4 Monetary influence

A few of the participants interviewed expressed that they would appreciate receiving money as compensation for their participation, however, they all stated that receiving money wasn't the primary reason that would influence their agreeing to participate at this stage in their lives. On the other hand, a male participant who had participated in a previous trial as a student explained that when he was younger, money and food were a big motivating factor to participate in clinical trials. His perceptions have, however, changed since he has more responsibilities and earns a regular salary.

*"...I also enjoyed the fact that we were given free food and some money, at that point in my life, having extra money was important to me. But now as an older person with more responsibilities in life, what's more important for me when participating in a trial is information and having frequent checks by the doctors. the money is an added incentive, but it wouldn't be my biggest influencer. Actually, money isn't an influencer anymore for me."* (Male, Dentist)



Another participant stated that they did not care for any other incentives

*"...I really don't care for any other incentives such as money."* (Female, Radiographer)

A female participant expressed that they are not concerned about money at present but that participating in a clinical trial could be an option if they fell on hard times and didn't have a regular income.

*"I am currently not too concerned about money but if I was in a desperate position, I would also participate for the monetary gains."* (Female, Dietician)

### 4.6 Inhibitors for clinical trial participation

The most common factors that inhibited participants from participating in a clinical trial were that they were scared of the possible side effects they may experience as a result of the drug or vaccine. A few participants expressed that they preferred being in control and 'in the know' about everything that happens in their lives, so they were not willing to participate in a clinical trial due to fear of the unknown. Two participants were unwilling to participate in a clinical trial because they were concerned about the unknown impact on their fertility. A few other participants reported that they wouldn't want to participate in a trial due to the amount of time they would be required to sacrifice in order to satisfy the clinical trial requirements.

#### 4.6.1 Side effects/death

The most common factor that would inhibit the participants from joining a clinical trial was fear of severe side effects or possible death, both during the trial or later in life. One participant stated that they had an auto-immune disease, and they also worked in an environment where they are constantly exposed to radio-waves, so they are already at risk of contracting diseases such as cancer. In their opinion, joining a clinical trial would further increase the risk of experiencing a health crisis.

*"I am scared of the side effects of drugs, I have an autoimmune disease that I was born with, so I must be very careful of the drugs/medication I take. Since these drugs under investigation are still new and unknown, I wouldn't want to risk getting side effects that may end up resulting in a serious health crisis episode for me. I also work with radio waves daily, so I'm already at a risk of contracting cancer due to my job, so I wouldn't want to intentionally add unnecessary risk to my body"* (Female, radiographer)

Another participant feared that being given a new drug may result in them contracting a new disease.

*'I fear that I would subject myself to a drug that may adversely affect me in the future. Maybe that new drug may end up causing me to have a disease that I didn't have all along. It may even cause death.'* (Male, Clinical Trials Assistant).

### 4.6.2 Fear of the unknown

Some of the participants stated that fear of the unknown was the main reason they would not opt to participate in a clinical trial. A young pharmacist felt that participating in a clinical trial was reckless due to the fact that the side effects are unknown.

*"The fact that the side effects from study or experimental drug are unknown makes me not want to join a trial, I feel like I would be acting recklessly by participating."* (Female, Pharmacist)

Another female pharmacist stated that they had a morbid fear of the unknown. They attributed this fear to a personality trait where they want to be in control.

*"I have a morbid fear of the unknown, I like being in control and I want to know exactly what's happening to me. So, the fact that the effect of the new medication under investigation is still unknown makes me not want to participate in a trial."* (Female, Pharmacist)

### 4.6.3 Unknown impact on fertility

Two participants expressed their desire to have children in the future and felt that a new experimental drug may negatively impact their fertility. It is noteworthy to note that both these participants were still young in age with one being 27 years old and the other being 29 years old.



A female Lab technician stated that she wanted a long future with the possibility of having children.

*"I am too scared of the unknown. Clinical trials present too many unknown factors that I personally do not want to deal with. Factors such as side effects, impact on fertility, impact on future health. I am still young, and I want a long future with a possibility of having kids."*

Interestingly enough, the sentiments on fertility were shared by a male oral hygienist that stated that they would not appreciate it if the trial affected their reproductive system.

*"I wouldn't participate in the trial if it would result in me having irreversible effects in my body. I would especially hate it if the trial affects my fertility or anything to do with my reproductive system and the kids I want to have in the future."*

### 4.6.4 Time consuming

Another common reason that inhibited the participants from participating was the amount of personal time they would need to take off to satisfy the requirements of a clinical trial. A

medical doctor intern stated that she would prefer a study that only asked for an hour of her time every month.

*"Another inhibiting factor for me would be time, if the study is going to demand too much time from me then I wouldn't sign up. too much time for me would be a visit that lasts over 2 hours on a weekly basis. I would preferably like something that only asks for an hour every month."* (Female, Medical Doctor Intern)

A female radiographer who had earlier expressed that her main inhibiting factor was her auto-immune disease, further went on to say that another inhibiting factor was the fact that clinical trials were time consuming.

*"…The other thing I don't like about clinical trials is that they are time consuming, and visits occur very often, these days' time is money, so I honestly don't have time to waste."*

A male pharmacist shared the same sentiments and stated that they enjoy having the freedom to choose what they do with their spare time.

*"I am also not a fan of spending too much time at a hospital or medical practise so that they can do the tests. I like being able to decide what to do with my own free time."* (Male, Pharmacist)

A female pharmacist that was quoted earlier when she stated that she feared the unknown side effects also stated that she doesn't have time to go to all the visits because she has a full-time job.

*"Trials are also time consuming because sometimes clinic visits for the participant can last a whole day and as a person that works fulltime, I wouldn't have enough time to go to all the visits."* (Female, Pharmacist)

### 4.7 Religious and cultural factors

The majority of the participants interviewed for this study said that they did not have any cultural or religious factors that would hinder them from participating in a clinical trial.

*"I am Christian, and I don't think there's anything in the Bible that stops me from getting into a trial."* (Female, Dietician)

A few participants agreed with the sentiments stated above, however, they did express that they would not be willing to participate in a clinical trial that was not based in science and is associated with spiritualistic practises.

*"I also wouldn't participate in any trial that's not scientific based and is somehow involved with spiritualistic rituals."* (Female, Pharmacist)

One participant stated that due to her religious beliefs she would not participate in a clinical trial that involved blood. She is not willing to either give her blood or receive blood in any form.

"*The only religious factor I have is that I wouldn't want to participate in any trial that involves blood or any blood by-products."* (Female, Radiographer)

### 4.8 Covid 19 awareness and influence

Responses for the influence of the Covid-19 pandemic on the awareness and willingness of participants to take part in clinical trials were mixed. A few said that the pandemic did not impact their knowledge of clinical trials as they had prior knowledge of clinical trials either because of where they work or because they learnt about clinical trials at university. However, the majority of participants interviewed agreed that the pandemic had highlighted clinical trials, especially for people that are not in the medical field. The majority of the participants interviewed in this study stated that the pandemic had influenced them to participate in future trials, although a few were remained unwilling to participate. Most participants also stated that they were willing to participate in future trials if certain conditions were met, conditions such as adequate provision of information and free health care.



#### 4.8.1 Impact on awareness of clinical trials

Before the Covid-19 outbreak, most of the participants claimed to have some familiarity with clinical studies. However, one participant said that though they had prior knowledge about clinical trials, the pandemic enhanced their knowledge.

*"I only knew the definition of clinical trials that I learnt from one of the modules at school. So yes, Covid has really made me know more about clinical trials."* (Male, Clinical Trial Assistant).

A female lab technician quoted earlier, said that the media coverage around the pandemic made her more aware of clinical trials. She also stated that when the Covid-19 vaccine rollout which was called Sisonke started, her knowledge of trials increased further.

*"Prior to Covid I really didn't have any information about Clinical trials. The pandemic really highlighted what clinical trials were and it became worse when Sisonke came about. It was all over and, on the TV, /Radio so I then got to learn more about Clinical Trials"* (Female, Lab Technician)

Another participant stated that they previously only had skeleton information about clinical trials but due to the pandemic they now have an in-depth understanding.

"*I wouldn't have known much about clinical research to the level I do now. Back then I knew in summary that it's done, but now I mean, I know in a greater detail."* (Male, Dietician).

### 4.8.2 Covid-19 awareness impact on participation

Some of the participants reported that although their knowledge and understanding of clinical trials had increased due to the pandemic, they were willing to participate in future trials but stated that certain conditions had to be met before they agree to participate. These conditions included having their questions answered by means of open communication. These included questions such the purpose of the clinical trial and what side effects to expect.



*"I would say that Covid did influence my participation to a certain extent. I will participate in a future clinical trial, but I will obviously still have questions such as, what is the purpose of the clinical trials? What side effects are there? So, though I am willing to participate I will still need my fears to be satisfied. Also, if the trial is going to benefit my health, then I am more than willing to participate & I would want open communication whilst the trial is going on."* (Male, Medical Doctor).

A few other participants stated they are now willing to participant in clinical trials because they have a better understanding about clinical trials.

*"I would say yes. If it wasn't for the Covid pandemic, I most probably wouldn't have participated in Sisonke, but I am willing to participate in future trials. I now know more information."* (Female, Pharmacist).

Prior to Covid-19 one participant stated that they would have rather died before agreeing to enrol in a clinical trial, however, they have since changed their mind since the pandemic started.

*"Before Covid, I would never have agreed to participate in a trial. I would have rather died. I am now willing to participate in a trial in a case of life and death."* (Female, Intern Radiographer)

A general theme that was common amongst a few participants were that they were willing to participate in future trials if it was their only option to survive life and was absolutely necessary.

*"…but going further, I will only participate in a trial if it's absolutely necessary."* (Female, Radiographer)

Another participant stated that they are willing to participant if the clinical trial would help either themselves or their family.

*"I will only participate if it will help either me or my kids, and maybe my parents."* (Female, Pharmacist)

Whilst majority of the participants interviewed in this study stated that the pandemic had influenced them to participate in future trials, a few other participants were not willing to participate.

For instance, one participant stated that they still would not participate in a clinical trial

*"I don't think the pandemic changed anything. I just don't have time nor am I really interested in participating..."* (Male, Pharmacist)



One other participant reported that they only participated in the Sisonke clinical trial because that was the only way they could obtain the Covid-19 vaccine and protect their loved ones, but they are not willing to participate in future trials.

*"No, I don't think Covid has done anything to influence me to participate in trials. It kind of influenced my participation in Sisonke, but we are in a pandemic, I needed to do whatever I can to protect me and my family."* (Male, Oral Hygienist)

### 4.9 Conclusion

The findings demonstrate the variations in participants' perceptions and experiences regarding clinical trials. Although most participants were familiar with the concept of clinical trials, the depth and willingness to participate varied. The study also showed that Covid-19 typically had a favourable impact on the awareness and desire of participants to take part in subsequent clinical studies. However, some participants remained sceptical and said they were unwilling

to participate in clinical trials due to ethical concerns such as the unknown effects of the investigational drugs on fertility. Others were unwilling to participate in clinical trials due to fear of the unknown and fear of side effects and ultimately death. The participants stated that monetary incentives were not influential when it came to whether they would participate in clinical trials or not.

# CHAPTER FIVE: DISCUSSION

## 5.1 Introduction

This chapter discusses the results of this study which explored the perceptions of health care professionals in the Gauteng province of South Africa regarding participation in clinical trials. As health professionals, all the participants had received a tertiary education and most of them were less than 40 years of age. The respondents were asked about their own perceptions regarding participating in clinical trials, as well as their experiences and willingness to participate in current and future clinical trials. Thereafter, the researcher explored their opinions regarding the influence of the Covid-19 pandemic on their willingness to participate.

## 5.2 Awareness and value of clinical trials

Awareness refers to the cognitive ability of a person to discern, decipher and judge a given phenomenon (Reinhardt et al., 2021). The concept of clinical trials was a relatively familiar concept amongst the respondents and the majority were able to provide a definition as well as explain the importance of a clinical trial.

However, it is important to highlight that this study discovered that the Covid-19 pandemic significantly impacted health professionals' awareness, perceptions, and willingness to take part in clinical studies in this environment. Due to the Sisonke clinical study, which was implemented by the government in an effort to safeguard frontline workers from the SARS-CoV-2 virus, these findings may be enhanced in the instance of South Africa.

The healthcare workers in this study demonstrated a broad understanding that vaccination against the SARS-CoV-2 virus was important on an individual and population level. These finding is in line with a recent study conducted in South Africa that found that health care workers had a good understanding of the importance of protecting themselves against Covid-19 since they were a high-risk group (Adeniyi et al., 2021).

When investigating the participants' attitudes towards the value of clinical trials, it was noted that majority placed high value on the importance of clinical trials in the development of new medication and treatments for the benefit of society and they believed that clinical trials ultimately save lives. This result is comparable to the results of a study conducted across sixty-eight countries which suggested that 84.5% of the respondents regarded clinical trials to be very important to the discovery and development of new medicines (Anderson, Borfitz and Getz, 2018).

Despite having some knowledge about clinical trials, several of the respondents said they would like more in-depth information to help them make informed decisions about participating in specific clinical trials. This may be due to the fact that all the participants were health care professionals and were well educated as they all had, at least, a university degree. Some studies conducted previously suggested that knowledge of clinical trials was associated with higher education (Ahram et al., 2020 and Brown and Moyer, 2010). Another factor contributing to the high levels of awareness is the Covid-19 pandemic's unparalleled media attention, as well as news stories about clinical trials launched to test novel antiviral vaccinations or therapies (Abdelhafiz et al., 2021). This has increased public knowledge of clinical trials.

Several sources of information about clinical trials were mentioned by participants in this study. The internet and social media were the most popular followed by other platforms such as doctor's offices, medical school, pharmaceutical and research companies, radio, television, and medical journals. These findings are consistent with earlier studies that discovered the internet to be the primary source of health-related information (Abdelhafiz et al., 2021). Another study revealed that social media and the internet have been utilized to promote and communicate ideas to specific target audiences. (Akhu-Zaheya et al., 2013). The study's participants said that the general population should be informed about the use of the internet and social media because, while they offer rapid and simple access to information, they can also be a source of misinformation.



### 5.3 Influencing factors in clinical trials participation

Prior to the Covid-19 pandemic and the Sisonke trial, only two study participants had previously participated in clinical trials and both trials were for dermatological products. The main influencing factor for participating in clinical trials was money. It is noteworthy though that both participants said that they participated in these trials when they were still young students, and they had no other source of income. However, this study showed that monetary incentives were not an important influencer for clinical trial participation. This outcome is comparable to that of a study conducted amongst health care workers in Jordan (Abdelhafiz et al., 2021).

As stated earlier the Covid-19 pandemic and the unique situation with the Sisonke trial greatly influenced the participation in clinical trials for participants in this study. The decision to participate in clinical trials was influenced by a number of variables. Respondents who said

they would take part in clinical trials to safeguard their families and communities and restore them to pre-Covid 19 conditions did so for a variety of reasons, with altruism and personal benefit appearing to be the two main motivators. In the context of this study, personal benefit can be identified as better health care, being cured from ailments, and receiving better medical attention. Altruism can be described as performing actions that will benefit others regardless of the harm on self (Locock and Smith, 2010).

A previous study suggested that people are initially predisposed toward participation to help others but that personal benefit features as an important secondary factor (Locock and Smith, 2010). However, in this study the results showed that majority of the participants were equally driven by personal considerations and helping others. Though participation in this study was greatly influenced by the pandemic, the results showed that the influencing factors were not materially different from results in other studies that were not conducted during a pandemic (Locock and Smith, 2010).

According to research conducted in South Asia, altruism and a sense of social responsibility were the most frequent justifications given for enrolling in clinical trials (Hussain-Gambles, Atkin and Leese, 2006). Similarly, other studies found that people were interested in participation in clinical trials only if their participation was of benefit to either themselves or to family members and their communities at large (Chu et al., 2015; Bevan et al., 1993). It was noted that participants in this study were willing to participate in future trials. The reasons for wanting to participate in future trials were the same as the ones discussed above - personal gain and altruism.

Despite having strong personal and altruistic reasons for participating in Covid clinical trials, the majority of the study participants felt forced by the pandemic to participate in the Sisonke study. They stated that the Sisonke study was the only option for them to receive the vaccine and they would have preferred to receive the vaccine on their own terms. A South African study reported that there were significant levels (41%) of Covid-19 vaccine hesitancy amongst health care workers, however, the majority received the vaccine in order to protect their loved ones and they also regarded regard vaccination as a collective effort to control the Covid-19 pandemic (Wiysonge et al., 2022).

Other factors that the participants regarded as influencers for clinical trial participation were free amenities such as free food and parking and monetary incentives. Studies conducted in Ireland and Jordan conducted amongst people that were employed showed that factors such as

money and free food were not strong influencers, but rather, people were more concerned with improving their health (Walsh and Sheridan, 2016; Abdelhafiz et al., 2021). Monetary incentives were important for students and those with a low income. The two participants in this study that had previously participated in a trial as students stated that money was the main motivating factor for participation. Participants in studies conducted in LMICs such as Zimbabwe and Malawi stated that incentives such as money and free health care were motivating factors for participating in clinical trials (Cain, 2015; Mutenherwa, 2012). With these factors in mind, some of the participants in this study questioned the ethical appropriateness of clinical trials in LMICs, especially those in which money is used to compensate participants.

### 5.4 Factors inhibiting health care workers from participating clinical trials

Although most of the participants in this study were willing to participate in clinical trials, they mentioned various reasons that would inhibit them from participating, with concern about drug side effects the most common deterrent. The majority of the participants stated that they were fearful of side effects that may develop after taking an experimental drug. Some of the participants stated that they were only willing to participate in a clinical trial if there was a 'guarantee' that they would not develop long term side effects. This response was in line with other studies. For example, a Danish study noted that fear of adverse effects from treatments in clinical trials was the most common reason for not participating (Madsen, Holm, and Riis, 2007) and in an American study concern of health risk was the main reason for lack of participation (Bevan et al., 1993). In this study, most participants showed concern regarding the safety of the Covid-19 vaccines provided to them as part of the Sisonke trial. A South African study addressing vaccine hesitancy showed similar results and concluded that fear of side effects could be linked to the vaccine hesitancy that was observed during the Covid-19 pandemic (Adeniyi et al., 2021).

Some participants interestingly stated that, though they were scared of side effects, fear of the unknown was their most notable inhibiting factor. This was consistent with previous studies where fear of the unknown and fear of being a medical "guinea pig" were major reasons to decline participation in a clinical trial, especially in the case of cancer patients (Bevan et al., 1993; Quinn et al., 2012). In addition to fear of the unknown, a few participants were concerned about the effect of experimental drug on their fertility.

Another inhibiting factor identified by this study was the time obligations of being a clinical trial participant. This response was similar to that found in a study conducted in Ireland which concluded that time commitment was an inhibitor. The same study concluded that time costs were cumulative, and they included the inconvenience of trial related requirements and visits, travel, following specific drug regimens and at times it also meant that a daily diary log needed to be completed (Walsh and Sheridan, 2016).

### 5.5 Limitations

The limitations of the study included the small number of study participants thus, the information obtained may not have reached saturation. This was due to the scope and constraints of the mini thesis. Also, due to the small scale of the study, it did not take into consideration the differences in awareness levels and willingness to participate from the different sexes.

The study did not include any participants that worked in a public/government setting thus data from this study did not fully reflect the actual perceptions of all health care workers in the province.

A significant number of the participants in this study already worked in the clinical trial industry thus the data obtained may have been skewed and may not have provided a true reflection of health care worker's perceptions. Their experience in the field undoubtedly increased their knowledge of clinical trials and may also have influenced their willingness or unwillingness to participate in future trials.

Due to the limiting nature of a mini-thesis, thematic analysis was the only method used to analyse the data, and according to Kiger and Varpio (2020:8) "a particular disadvantage with thematic analysis is that it is more prone to inconsistent or improper use of terminology as compared to other methods with more well-defined and less flexible frameworks". This could result in data that does not accurately represent the true perceptions of the population being investigated.

# CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

## 6.1 Conclusion

This study found that participants already had a high level of awareness of clinical trials, and they regarded them to be important in the development of new medications. All the participants had prior knowledge of clinical trials from their time in university, but their awareness was substantially influenced by the recent Covid-19 pandemic and the media attention that resulted from it. There appeared to be little difference in the levels of knowledge between participants that worked in a clinical trial company and those that worked in other sectors. Participants acknowledged that their background as health professionals greatly influenced their awareness and suggested that other people without medical knowledge would not have the same level awareness.

Study participants stated that increased efforts should be made to raise public knowledge of clinical trials. The most common suggestion was to increase advertising of clinical trials on the different social media platforms. Some participants also suggested that more educational material should be provided at health facilities such as doctor's rooms and clinic waiting areas.

Most of the participants had participated in the Sisonke clinical trial, thus their responses to the questions they were asked were mainly based on that experience. Although they had agreed to participate in the Sisonke trial, some participants felt that they were 'forced' to participate due to the Covid-19 situation that was present at that time.

The study found that the main motivators for participating in clinical trials were personal gain and altruism. In this study personal gain referred to a collective of benefits i.e., protection/cure against diseases, free health care and easy access to medical professionals. In addition to personal gain and altruism, other less important motivators were monetary benefits, and free amenities. It was noted that monetary benefits were not high on the list of motivators of participants involved in this study as they were all gainfully employed on a full-time basis.

The study found that the main inhibitors for clinical trial participation were the fear of developing severe side effects or death, fear of the unknown and time constraints. The participants expressed that they would not want to develop any side effects that would adversely affect them now or in the future. They also stated that due to work and family commitments, they may not have enough free time to participate in a clinical trial. Religion and culture did not seem to influence participants' decisions to participate in clinical trials.

Participants said they were willing to participate in future clinical trials if they were provided with sufficient information regarding the study drug and if they were 'guaranteed' that they would not develop severe side effects.

## 6.2 Recommendations

The results of this study prompted the following recommendations regarding participation of health care workers in clinical trials.

Since this study was conducted with a small sample size and was restricted to the Gauteng province, expanding this study to other provinces, and using a bigger sample size would be beneficial to have a better understanding of the experiences of health care workers when participating in clinical trials. Further research will be required to understand and comprehend the knowledge and willingness of people who work in other professions, as well as in other provinces in South Africa, as this study was specifically focused on health care employees in the Gauteng province.

It would also be advantageous for future research to include participants who work in the public health sector as this study was conducted entirely with health care workers from the private sector. By including these participants, researchers will gain a better understanding of health care workers' attitudes toward clinical trial participation. This study showed that the Covid-19 pandemic had a pronounced influence on the clinical trial participation of health care workers, thus, further studies may need to be conducted to further explore this phenomenon.

Though the participants in this study had some form of prior knowledge about clinical trials, it was greatly enhanced by the pandemic, thus, it is recommended that medical schools and training institutions for other health professionals should include clinical trials in their curricula. Professional bodies could also include clinical trials content as part of Continuing Professional Development (CPD) requirements.

More work should be done to increase awareness of clinical trials in the general population. This could be done by advertising clinical trials on social media platforms, radio and television stations, as well as putting up posters with clinical trial information at health care centres.

# REFERENCE LIST

Abdelhafiz, A.S., Abd ElHafeez, S., Khalil, M.A., Shahrouri, M., Alosaim, B., Salem, R.O., Alorabi, M., Abdelgawad, F. and Ahram, M. (2021). Factors Influencing Participation in COVID-19 Clinical Trials: A Multi-National Study. *Frontiers in Medicine*, 8. doi:10.3389/fmed.2021.608959.

Adeniyi, O.V., Stead, D., Singata-Madliki, M., Batting, J., Wright, M., Jelliman, E., Abrahams, S. and Parrish, A. (2021). Acceptance of COVID-19 Vaccine among the Healthcare Workers in the Eastern Cape, South Africa: A Cross Sectional Study. *Vaccines*, 9(6), p.666. doi:10.3390/vaccines9060666.

Ahram, M., Farkouh, A., Haddad, M., Kalaji, Z. and Yanis, A. (2020). Knowledge of, attitudes to and participation in clinical trials in Jordan: a population-based survey. *Eastern Mediterranean Health Journal*, 26(5), pp.539–546. doi:10.26719/2020.26.5.539.

Akhu-Zaheya, L.M., Jagbir, M.T., Othman, A. and Ahram, M. (2013). Media use for seeking health/cancer-related information: Findings from knowledge, attitudes and practices towards cancer prevention and care survey in Jordan. *International Journal of Nursing Practice*, 20(6), pp.608–615. doi:10.1111/ijn.12196.

Alemayehu, C., Mitchell, G. and Nikles, J. (2018). Barriers for conducting clinical trials in developing countries- a systematic review. *International Journal for Equity in Health*, [online] 17(1). doi:10.1186/s12939-018-0748-6.

Anderson, A., Borfitz, D. and Getz, K. (2018). Global Public Attitudes About Clinical Research and Patient Experiences with Clinical Trials. *JAMA Network Open*, [online] 1(6), p.e182969. doi:10.1001/jamanetworkopen.2018.2969.

Archibald, M.M., Ambagtsheer, R.C., Casey, M.G. and Lawless, M. (2019). Using Zoom Videoconferencing for Qualitative Data Collection: Perceptions and Experiences of Researchers and Participants. *International Journal of Qualitative Methods*, [online] 18, p.6. doi:10.1177/1609406919874596.

Bartoszkiewicz, M. (2021). Assessment of knowledge and awareness about clinical trials of patients participating in cancer trials. *Polish Annals of Medicine*, p.4.

doi:10.29089/2020.20.00145.

Bauchner, H. and Fontanarosa, P.B. (2020). Randomized Clinical Trials and COVID-19. *JAMA*, [online] pp.2262–2263. doi:10.1001/jama.2020.8115.

Baxter, P. and Jack, S. (2015). Qualitative Case Study Methodology: Study Design and Implementation for Novice Researchers. *The Qualitative Report*, [online] 13(4), p.548. doi:10.46743/2160-3715/2008.1573.

Bevan, E., Chee, L., McGhee, S. and McInnes, G. (1993). Patients' attitudes to participation in clinical trials. *British Journal of Clinical Pharmacology*, [online] 35(2), p.207. doi:10.1111/j.1365-2125.1993.tb05687.x.

Brennan, C. (2021). COVID-19 Has Proved the Importance of Clinical Trials. Help Us Make Them Better. *U.S News*. [online] 21 May. Available at: https://www.usnews.com/news/health-news/articles/2021-05-20/covid-19-highlighted-clinical-trials-and-how-to-make-them-better [Accessed 9 Apr. 2022].

Brown, M. and Moyer, A. (2010). Predictors of awareness of clinical trials and feelings about the use of medical information for research in a nationally representative US sample. *Ethnicity & Health*, 15(3), pp.223–236. doi:10.1080/13557851003624281.

Cain, G. (2015). *The Downtown Review The Downtown Review Bad Governance in Zimbabwe and Its Negative Consequences Bad Governance in Zimbabwe and Its Negative Consequences*. pp.5–6.

Cancer Research UK (2014). *Types of clinical trials*. [online] Cancer Research UK. Available at: https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are/types-of-clinical-trials [Accessed 31 Oct. 2022].

Chatio, S., Baiden, F., Achana, F.S., Oduro, A. and Akazili, J. (2016). Knowledge and Perceptions about Clinical Trials and the Use of Biomedical Samples: Findings from a Qualitative Study in Rural Northern Ghana. *PLOS ONE*, [online] 11(4), p.e0152854. doi:10.1371/journal.pone.0152854.

Chu, S.H., Kim, E.J., Jeong, S.H. and Park, G.L. (2015). Factors associated with willingness

to participate in clinical trials: a nationwide survey study. *BMC Public Health*, [online] 15(1). doi:10.1186/s12889-014-1339-0.

Clarke, J.F., van Rumste, M.M.E., Farquhar, C.M., Johnson, N.P., Mol, B.W.J. and Herbison, P. (2010). Measuring outcomes in fertility trials: can we rely on clinical pregnancy rates? *Fertility and Sterility*, 94(5), pp.1647–1651. doi:10.1016/j.fertnstert.2009.11.018.

Corbin, J. and Strauss, A. (1994). Grounded theory methodology: An overview. *Handbook of qualitative research*, pp.273–285.

Creswell, J.W. and Miller, D.L. (2000). Determining Validity in Qualitative Inquiry. *Theory Into Practice*, [online] 39(3), pp.124–130. doi:10.1207/s15430421tip3903_2.

Cypress, B.S. (2017). Rigor or Reliability and Validity in Qualitative Research. *Dimensions of Critical Care Nursing*, [online] 36(4), p.254. doi:10.1097/dcc.0000000000000253.

Department of Health, Province of Gauteng (2017). Annual Report. [online] p.3. Available at: https://provincialgovernment.co.za/department_annual/534/2017-gauteng-health-annual-report.pdf [Accessed 21 Apr. 2021].

Edoka, I., Fraser, H., Jamieson, L., Meyer-Rath, G. and Mdewa, W. (2021). Inpatient Care Costs of COVID-19 in South Africa's Public Healthcare System. *International Journal of Health Policy and Management*, p.1. doi:10.34172/ijhpm.2021.24.

Ellis, P.M., Butow, P.N., Tattersall, M.H.N., Dunn, S.M. and Houssami, N. (2001). Randomized Clinical Trials in Oncology: Understanding and Attitudes Predict Willingness to Participate. *Journal of Clinical Oncology*, 19(15), pp.3554–3561. doi:10.1200/jco.2001.19.15.3554.

Frenck, R. (2018). *Top 6 Reasons Why Clinical Trials Are Important*. [online] Cincinnati Children's Blog. Available at: https://blog.cincinnatichildrens.org/research-and-discoveries/top-6-reasons-why-clinical-trials-are-important.

Haynes, K. (2012). Reflexivity in Qualitative Research. [online] p.1. Available at: https://www.researchgate.net/publication/286352842_Reflexivity_in_qualitative_research [Accessed 15 Mar. 2021].

Health Systems Trust (2020). *South African Health Review, Chapter 20: Health and Related*

*Indicators*. [online] www.hst.org.za. Available at: https://www.hst.org.za/publications/South%20African%20Health%20Reviews/SAHR_Chapter%2020_17122020_Final.pdf [Accessed 22 Apr. 2021].

Hussain-Gambles, M., Atkin, K. and Leese, B. (2006). South Asian participation in clinical trials: The views of lay people and health professionals. *Health Policy*, 77(2), pp.149–165. doi:10.1016/j.healthpol.2005.07.022.

Irani, E. (2018). The Use of Videoconferencing for Qualitative Interviewing: Opportunities, Challenges, and Considerations. *Clinical Nursing Research*, [online] 28(1), pp.3–8. doi:10.1177/1054773818803170.

Joshi, V., and Kulkarni, A.A. (2012). Public awareness of clinical trials: A qualitative pilot study in Pune. *Perspectives in Clinical Research*, [online] 3(4), pp.125–132. doi:10.4103/2229-3485.103593.

Kiger, M.E. and Varpio, L. (2020). Thematic analysis of qualitative data: AMEE Guide No. 131. *Medical Teacher*, [online] p.8. doi:10.1080/0142159x.2020.1755030.

Langen, D. and Ntlaletse, A. (2009). Nurses' opinion of pain in patients who suffer from dementia. [online] Available at: http://hdl.handle.net/10500/1796 [Accessed 21 Mar. 2021].

Leiter, A., Diefenbach, M.A., Doucette, J., Oh, W.K. and Galsky, M.D. (2015). Clinical trial awareness: Changes over time and sociodemographic disparities. *Clinical Trials: Journal of the Society for Clinical Trials*, 12(3), pp.215–223. doi:10.1177/1740774515571917.

Locock, L. and Smith, L. (2010). Personal benefit, or benefiting others? Deciding whether to take part in clinical trials. *Clinical Trials: Journal of the Society for Clinical Trials*, 8(1), pp.85–93. doi:10.1177/1740774510392257.

Mackenzie, I.S., Wei, L., Rutherford, D., Findlay, E.A., Saywood, W., Campbell, M.K. and MacDonald, T.M. (2010). Promoting public awareness of randomised clinical trials using the media: the 'Get Randomised' campaign. *British Journal of Clinical Pharmacology*, [online] 69(2), pp.128–135. doi:10.1111/j.1365-2125.2009.03561.x.

Madsen, S.M., Holm, S. and Riis, P. (2007). Attitudes towards clinical research among cancer trial participants and non-participants: an interview study using a Grounded Theory approach.

*Journal of Medical Ethics*, 33(4), pp.234–240. doi:10.1136/jme.2005.015255.

Malan, T. and Moodley, K. (2016). Phase 3 Oncology Clinical Trials in South Africa: Experimentation or Therapeutic Misconception? *Journal of Empirical Research on Human Research Ethics: An International Journal*, [online] 11(1), pp.47–56. Available at: https://www.jstor.org/stable/90012115 [Accessed 12 May 2022].

McQuoid-Mason, D.J. (2022). COVID-19 vaccine hesitancy and missed vaccine roll- out targets: The case for using general practitioners. *South African Medical Journal*, 112(3), pp.214–215. doi:10.7196/samj.2022.v112i3.16379.

Meena, K., Amberkar, M.B., Rajakannan, T. and Mohan, L. (2010). Awareness of clinical trials among university pharmacy students - a questionnaire survey. *Journal of Clinical and Diagnostic Research*, [online] 4(5), pp.3064–3074. Available at: https://www.scopus.com/record/display.uri?eid=2-s2.0-78549240190&origin=inward&txGid=e2fbd124d467fecdf071df4eb1266269# [Accessed 2 Apr. 2021].

Mfutso-Bengo, J., Ndebele, P., Jumbe, V., Mkunthi, M., Masiye, F., Molyneux, S. and Molyneux, M. (2008). Why do individuals agree to enrol in clinical trials? A qualitative study of health research participation in Blantyre, Malawi. *Malawi Medical Journal: The Journal of Medical Association of Malawi*, [online] 20(2), p.40. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3345665/ [Accessed 29 Mar. 2021].

Mikulic, M. (2022). *COVID-19 clinical drug trials by study type*. [online] Statista. Available at: https://www.statista.com/statistics/1119086/coronavirus-drug-trials-by-type-worldwide/ [Accessed 17 Apr. 2022].

Mutenherwa, F. (2012). *Voluntariness in Clinical Trials 1 Running head: VOLUNTARINESS IN CLINICAL TRIALS A Case Study to Assess Participants' Perceptions on Voluntariness and Motivations for Participating in a Clinical Trial in Zimbabwe*. pp.46–47.

Novitzke, J.M. (2008). The significance of clinical trials. *Journal of vascular and interventional neurology*, [online] 1(1), p.31. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3317309/ [Accessed 25 Feb. 2021].

Owen-Smith, A.A., Woodyatt, C., Sineath, R.C., Hunkeler, E.M., Barnwell, L.T., Graham, A.,

Stephenson, R. and Goodman, M. (2016). Perceptions of Barriers to and Facilitators of Participation in Health Research Among Transgender People. *Transgender Health*, [online] 1(1), pp.187–196. doi:10.1089/trgh.2016.0023.

Pan African Clinical Trials Registry (2012). *Map*. [online] Samrc.ac.za. Available at: https://pactr.samrc.ac.za/GIS_Viewer.aspx [Accessed 21 Mar. 2021].

Paradis, E., O'Brien, B., Nimmon, L., Bandiera, G. and Martimianakis, M.A. (Tina) (2016). Design: Selection of Data Collection Methods. *Journal of Graduate Medical Education*, [online] 8(2), pp.263–264. doi:10.4300/jgme-d-16-00098.1.

Pope, C., Ziebland, S. and Mays, N. (2000). Analysing qualitative data. *BMJ: British Medical Journal*, [online] 320(7227), pp.114–116. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1117368/.

Powell, J.H., Fleming, Y., Walker-McGill, C.L. and Lenoir, M. (2008). The Project IMPACT Experience to Date: Increasing Minority Participation and Awareness of Clinical Trials. *Journal of the National Medical Association*, [online] 100(2), pp.178–187. doi:10.1016/S0027-9684(15)31206-2.

Preiser, W. and Fish, T. (2022). Sisonke: Reaching Several Goals Together. *The Lancet*, [online] 399(10330), pp.1095–1097. doi:10.1016/S0140-6736(22)00482-2.

Quinn, G.P., Koskan, A., Wells, K.J., Gonzalez, L.E., Meade, C.D., Pozo, C.L.P. and Jacobsen, P.B. (2012). Cancer Patients' Fears Related to Clinical Trial Participation: A Qualitative Study. *Journal of Cancer Education*, [online] 27(2), pp.257–262. doi:10.1007/s13187-012-0310-y.

Reinhardt, W., Mletzko, C., Sloep, P. and Drachsler, H. (2021). *(PDF) Understanding the Meaning of Awareness in Research Networks*. [online] ResearchGate. Available at: https://www.researchgate.net/publication/230640624_Understanding_the_Meaning_of_Awareness_in_Research_Networks [Accessed 7 Apr. 2022].

Roberson, N.L. (1994). Clinical trial participation: Viewpoints from racial/ethnic groups. *Cancer*, [online] 74(S9), pp.2687–2691. doi:10.1002/1097-0142(19941101)74:9+<2687::aid-cncr2820741817>3.0.co;2-b.

Ryan, A. (2006). *Methodology: Analysing Qualitative Data and Writing up Your Findings*.

[online] Available at: http://mural.maynoothuniversity.ie/871/1/methodology.pdf [Accessed 10 Mar. 2021].

Sadoff, J., Gray, G., Vandebosch, A., Cárdenas, V., Shukarev, G., Grinsztejn, B., Goepfert, P.A., Truyers, C., Fennema, H., Spiessens, B., Offergeld, K., Scheper, G., Taylor, K.L., Robb, M.L., Treanor, J., Barouch, D.H., Stoddard, J., Ryser, M.F., Marovich, M.A. and Neuzil, K.M. (2021). Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19. *New England Journal of Medicine*, 384(23). doi:10.1056/nejmoa2101544.

Sikolia, D., Biros, D., Mason, M., Weiser, M., and Weiser (2013). *Association for Information Systems AIS Electronic Library (AISeL) Trustworthiness of Grounded Theory Methodology Research in Information Systems Recommended Citation*. p.16.

Sisonke (2021). *Sisonke - Protecting Healthcare Workers*. [online] Samrc.ac.za. Available at: https://sisonkestudy.samrc.ac.za/indexsisonke.html# [Accessed 30 Oct. 2022].

South African Health Products Regulatory Authority (2020). *Annual Report 2019/20*. [online] SAHPRA, p.47. Available at: https://www.sahpra.org.za/wp-content/uploads/2020/12/SAHPRA-ANNUAL-REPORT-2020-web.pdf [Accessed 18 Mar. 2021].

Suvarna, V. (2010). Phase IV of Drug Development. Perspectives in clinical research, [online] 1(2), pp.57–60. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3148611/. [Accessed 26 Oct. 2022].

Statistics South Africa (2020). *2020 Mid-year population estimates | Statistics South Africa*. [online] Department: Statistics South Africa. Available at: http://www.statssa.gov.za/?p=13453 [Accessed 22 Apr. 2021].

Taherdoost, H. (2017). Performance Management View project Development of an Adoption Model to Assess User Technology Acceptance View project Hamed Taherdoost Hamta Group. *International Journal of Academic Research in Management (IJARM)*, [online] 5(2), pp.173–197. doi:10.2139/ssrn.3205035.

Thiese, M.S. (2014). Observational and interventional study design types; an overview. Biochemia Medica, [online] 24(2), pp.199–210. doi:10.11613/bm.2014.022.

Toto, N., Douglas, E., Gmeiner, M., Barrett, L.K., Lindblad, R., Makhaza, L., Nedi, W., Phulusa, J., Quinnan, G.V., Sawyer, L.A., Thole, H., Van Voorhis, W.C. and Iroh Tam, P.-Y. (2020). Conducting clinical trials in sub-Saharan Africa: challenges and lessons learned from the Malawi Cryptosporidium study. *Trials*, [online] 21(1), p.2. doi:10.1186/s13063-020-04620-8.

Umscheid, C.A., Margolis, D.J. and Grossman, C.E. (2011). Key Concepts of Clinical Trials: A Narrative Review. *Postgraduate Medicine*, [online] 123(5), pp.194–204. doi:10.3810/pgm.2011.09.2475.

Vanclay, F., Baines, J.T. and Taylor, C.N. (2013). Principles for ethical research involving humans: ethical professional practice in impact assessment Part I. *Impact Assessment and Project Appraisal*, [online] 31(4), pp.243–253. doi:10.1080/14615517.2013.850307.

Walsh, E. and Sheridan, A. (2016). Factors affecting patient participation in clinical trials in Ireland: A narrative review. *Contemporary Clinical Trials Communications*, 3(3), pp.23–31. doi:10.1016/j.conctc.2016.01.002.

WCG (2020). *Public Awareness of Clinical Research and The Path to Diversity in Clinical Trials*. [online] Available at: https://www.clinicalleader.com/doc/public-awareness-of-clinical-research-and-the-path-to-diversity-in-clinical-trials-0001 [Accessed 6 Apr. 2021].

WebMD (2021). *Coronavirus and COVID-19: What You Should Know*. [online] WebMD. Available at: https://www.webmd.com/lung/coronavirus [Accessed 9 Apr. 2022].

Willison, D.J., Richards, D.P., Orth, A., Harris, H. and Marlin, S. (2019). Survey of Awareness and Perceptions of Canadians on the Benefits and Risks of Clinical Trials. *Therapeutic Innovation & Regulatory Science*, [online] 53(5), pp.669–677. doi:10.1177/2168479018805433.

Willoughby, J.-A. (2019). Acceptability of collectors of medicine parcels for noncommunicable disease patients from a primary health care facility in the Western Cape. pp.17–19.

Wits Health Consortium (Pty) Ltd, National Department of Health of South Africa, National Institute for Communicable Diseases, South Africa, KwaZulu-Natal Research Innovation and Sequencing Platform - KRISP, Fred Hutchinson Cancer Center, Hutchinson Center Research

Institute of South Africa (HCRISA), Janssen Vaccines & Prevention B.V., Bio Analytical Research Corporation, Dis-Chem Pharmacy, BioVac, Biocair, Right to Care and Clinical Laboratory Services (2021). *Open-label, Single-arm Phase 3B Implementation Study to Monitor the Effectiveness of the Single-dose Ad26.COV2.S COVID-19 Vaccine Among Health Care Workers in South Africa (VAC31518COV3012)*. [online] clinicaltrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT04838795 [Accessed 7 Jul. 2022].

Wiysonge, C.S., Alobwede, S.M., de Marie C Katoto, P., Kidzeru, E.B., Lumngwena, E.N., Cooper, S., Goliath, R., Jackson, A. and Shey, M.S. (2022). COVID-19 vaccine acceptance and hesitancy among healthcare workers in South Africa. *Expert Review of Vaccines*, 21(4), pp.1–11. doi:10.1080/14760584.2022.2023355.

World Health Organization (2022). *Coronavirus disease (COVID-19)*. [online] World Health Organization. Available at: https://www.who.int/health-topics/coronavirus#tab=tab_1 [Accessed 9 Apr. 2022].

World Health Organization (n.d.). *Clinical trials*. [online] www.who.int. Available at: https://www.who.int/health-topics/clinical-trials/#tab=tab_1 [Accessed 21 Mar. 2021].

# APPENDIX A

## INTERVIEW GUIDE

| Main theme | Sub-questions/ triggers (Example questions to ask) |
|---|---|
| Social-demographic Information | • Ask about information e.g.: Age, sex, professional, type of workplace and geographical area they work in and reside. |
| Tell me a bit about yourself (Ask them to describe their career and their place of employment) | • What job do you do and what made you choose that career path?<br>• How long have you worked in this job?<br>• What is your highest level of education? |
| How aware are you about clinical trials? (Ask them to describe how aware they are about clinical trials, their opinions on the importance of clinical trials, and their general opinions of participating in a trial) | • Please describe clinical trials as per your knowledge<br>• How important do you think clinical trials are in society?<br>• Where do you think information about clinical trials can be found?<br>• If you have participated in a clinical trial before, how was your experience?<br>• Please describe the type of people you think should participate in clinical trials. |
| Influencers of participation (Ask them to describe what will make them participate) | • If you were asked to participate in clinical trials, what would influence you to join?<br>• Please describe the positive expectations you have about participating in clinical trials. |
| Inhibitors of participating (Ask them to describe inhibitors of participating in clinical trials) | • If you were asked to participate in a clinical trial, please describe factors that would inhibit you from participating.<br>• Please describe any negative expectations you have about participating in clinical trials. |

| | |
|---|---|
| | • Please describe any incentives that would make you change your mind about participating in clinical trials |
| Cultural and religious reasons | • Please describe ways in which your culture/religion would either influence you or hinder you from participating.<br>❖ **If the person says they are not willing to participate due to cultural reasons, ask the question below:**<br>• Would there be any incentives or benefits from participating in clinical trials that would influence you to participate in a clinical trial despite your cultural/religious background? |
| Covid-19 and its influence<br>(Ask them if Covid-19 has influenced their perception and willingness to participate) | • In what ways do you think that Covid-19 has influenced your awareness of clinical trials?<br>• Would your increased awareness make you more or less likely to participate in a trial? |

# APPENDIX B

**UNIVERSITY OF THE WESTERN CAPE**
Private Bag X 17, Bellville 7535, South Africa
***Tel: +27 21 959 2809 Fax: 27 21 959 2872***
**E-mail: soph-comm@uwc.ac.za**

**INFORMATION SHEET**

**Project Title: Exploring the perceptions of health professionals regarding participation in clinical trials in Gauteng Province, South Africa**

**What is this study about?**

This is a research project being conducted by Nyasha Mhandire. The research is being conducted for a mini thesis as part of the Master of Public Health at the University of the Western Cape. We are inviting you to participate in this research project because you are a health care professional that fits the description of the study sample required for this study. The purpose of this research project is to understand how health care professionals feel about participating in clinical trials and it also seeks to explore the impact of the COVID-19 pandemic on awareness of clinical trials. It is hoped that with your participation, a better understanding will be gained of the reasons why health care professionals participate in clinical trials. Results from this research may inform future guidelines on clinical trials participation.

**What will I be asked to do if I agree to participate?**

You will be asked to sign an informed consent form to show that you have agreed to participate. By signing the consent form, you indicate that you understand what you have read and agree to take part in the research. You will be given a copy of the Participant Information Sheet and Consent Form for your records. The research will be conducted in the form of interviews which will be conducted at a time convenient to you either after work hours or over the weekend. Due to Covid-19 restrictions, the interviews will be conducted over the Zoom video and conferencing application. Only one interview will be required per participant, and the interview will range from 30-60 minutes. In addition to the interview, you might be contacted to provide

further clarification if necessary. The interview will be video recorded using the video conferencing application called Zoom.

**Would my participation in this study be kept confidential?**

The researchers undertake to protect your identity and the nature of your contribution. To ensure your anonymity, your name will not be included in any of the collected data, and a code will be developed using an identification key. I shall keep all records of your participation, including a signed informed consent form which I will need from you should you agree to participate in this research study, on password-protected devices and any hard copies will be always locked away.

**What are the risks of this research?**

There may be some risks from participating in this study; all human interactions and talking about self or others carry some number of risks. We will nevertheless minimise such risks and act promptly to assist you if you experience any discomfort, psychological or otherwise, during the process of your participation in this study. Where necessary, an appropriate referral will be made to the closest medical facility, or the participant will be encouraged to engage with their employee wellness agents.



**What are the benefits of this research?**

This research is not designed to help you personally, but the results may help the investigator learn more about the reasons why health care professionals choose to either participate or not participate in clinical trials. We hope that, in the future, other people might benefit from this study through improved understanding of the implications of participating in clinical trials.

**Do I have to be in this research, and may I stop participating at any time?**

Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalised or lose any benefits to which you otherwise qualify. You may also choose to not answer any questions that are asked in the study. If there is anything you choose not to discuss, please feel free to say so.

**What if I have questions?**

This research is being conducted by Nyasha Mhandire a Master of Public Health student at the School of Public Health, University of the Western Cape. If you have any questions about the research study itself, please contact:

Nyasha Mhandire (Student number: 3908564)
Telephone Number: 083 632 6006
Email address: 3908564@myuwc.ac.za

Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

Prof Uta Lehmann
Director, School of Public Health
University of the Western Cape
Private Bag X17
Bellville, 7535
soph-comm@uwc.ac.za

Prof Anthea Rhoda
Dean, Faculty of Community and Health Sciences
University of the Western Cape
Private Bag X17
Bellville, 7535
Chs-deansoffice@uwc.ac.za



This research has been approved by the University of the Western Cape's Biomedical Research Ethics Committee.

Biomedical Research Ethics Committee
University of the Western Cape
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e-mail: research-ethics@uwc.ac.za

# APPENDIX C

**UNIVERSITY OF THE WESTERN CAPE**
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**E-mail: soph-comm@uwc.ac.za**

**CONSENT FORM**

**Title of Research Project: Exploring the perceptions of health professionals regarding participation in clinical trials in Gauteng Province, South Africa**

The study has been described to me in a language that I understand. My questions about the study have been answered. I understand what my participation will involve, and I agree to participate of my own choice and free will. I understand that my identity will not be disclosed to anyone. I understand that I may withdraw from the study at any time without giving a reason and without fear of negative consequences or loss of benefits.

___ I agree to be audiotaped and videotaped during my participation in this study.

___ I do not agree to be audiotaped and videotaped during my participation in this study.



**Participant's name……..**

**Participant's signature…….**

**Date……**

# APPENDIX D

UNIVERSITY of the WESTERN CAPE

60 YEARS of hope, action & knowledge

4 August 2021

Ms N Mhandire
School of Public Health
**Faculty of Community and Health Sciences**

| | |
|---|---|
| **Ethics Reference Number:** | BM21/5/14 |
| **Project Title:** | Exploring the perceptions of health professionals regarding participation in clinical trials in Gauteng Province, South Africa. |
| **Approval Period:** | 04 August 2021 – 04 August 2024 |

I hereby certify that the Biomedical Science Research Ethics Committee of the University of the Western Cape approved the scientific methodology and ethics of the above mentioned research project.

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

**Please remember to submit a progress report annually by 30 November for the duration of the project.**

*Permission to conduct the study must be submitted to BMREC for record-keeping.*

The Committee must be informed of any serious adverse event and/or termination of the study.

*Ms Patricia Josias*
*Research Ethics Committee Officer*
*University of the Western Cape*

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*NHREC Registration Number: BMREC-130416-050*

FROM HOPE TO ACTION THROUGH KNOWLEDGE.