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THE POSSIBLE APPLICATION OF THE INTERNET OF THINGS
TO IMPROVE CLINICAL RESEARCH IN SOUTH AFRICA

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DEDICATION

I will like to dedicate this to:

God almighty, the giver of my life.

My wife, Princess Nthabiseng Yolanda (Temilade) Ademiluyi, your support is second to none. Thank you for the great effort to help me secure those difficult appointments and for your understanding. I love you.

My children: Prince Obasefade, the exceptionally great and amazing gentleman; Prince Ademipe, the awesome and excellent gentleman and Prince Adebobape, the outstanding and superb gentleman. Thank you all for your love and understanding and help. I love you all. You are LEGENDS!

ACKNOWLEDGEMENT

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ABSTRACT

Clinical trials are research studies that (amongst other things) explore whether a medical strategy, treatment, or device is safe and effective for humans. Clinical trials are conducted all over the world –including in South Africa- and they form the basis from which drugs and solutions to health problems are discovered. During clinical trials, human subjects are monitored and data is collected and analysed to reach conclusions that leads to possible solutions to the problem being examined. The internet of everything, commonly just referred to as the internet of Things provides opportunity to connect everything to the internet. This includes the people, devices and everything that may be needed in a clinical research. The prospect of using the Internet of Things in clinical trials conducted in South Africa seem to be highly beneficial and it is very worthwhile to know if the South African Clinical trial industry is ready for such a revolutionary approach.

The findings of this study strongly suggests that provided fears- such as fears of losing jobs to an efficient technology are allayed, most stakeholders in the clinical trial industry will be very happy to make use of the Internet of things while conducting clinical trials. Although there is a big room for improvement, the facilities and

infrastructures available in South Africa should be sufficient to start taking advantage of the Internet of things but it is not certain whether the legal framework in existence will be enough to cater for the use of the Internet of things.

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CHAPTER 1

INTRODUCTION

1.1 INTRODUCTION

This chapter gives general information relevant to the whole research. The discussion begins with a proper insight to the background of the research. The section after that then presented the problem statement before moving on to explain the objectives of this research. The scope of the research is then discussed followed by the assumptions and limitations of the research.

1.2 BACKGROUND

Clinical trial is the approach used by medical researchers to conduct experiments using real human beings to find solutions to medical problems of human beings and answer questions relating to preventing, diagnosing and treatment of human ailments or diseases. Prior to clinical trials, according to The Pennsylvania State University (2017:1),"clinicians attempted to answer such questions by generalizing from the experiences of individual patients to the population at large. Clinical judgment and reasoning were applied to reports of interesting cases. (But) The concepts of variability among individuals and its sources were not formally addressed". With clinical trials, it can be said that attention is paid to variability amongst individuals to a large extent and thus there is room for better and more effective interventions to be developed. Popularity and acceptance of clinical trials have gone through a lot of ups and downs mainly because the research is being conducted with human beings and many issues such as balancing the benefits derived or derivable from such studies with the level of risks to which participants are exposed and ethical issues that stem from the high potential for exploitation and maltreatment of especially vulnerable group of people such as disabled children, old people, prisoners, terminally ill people and many others in similar categories. However, due to improvement in policies, laws, process and understanding of the clinical trials, more and more clinical studies are being conducted per year. As of March 2017, there are over 230, 000 registered clinical studies being conducted worldwide with the majority of them being conducted in the USA. Figure 1 below shows the percentage of clinical studies being conducted per location and

figure 2 shows the number of registered studies over time between the year 2000 and 2017(the improvement is highly noticeable in less than 20 years!):
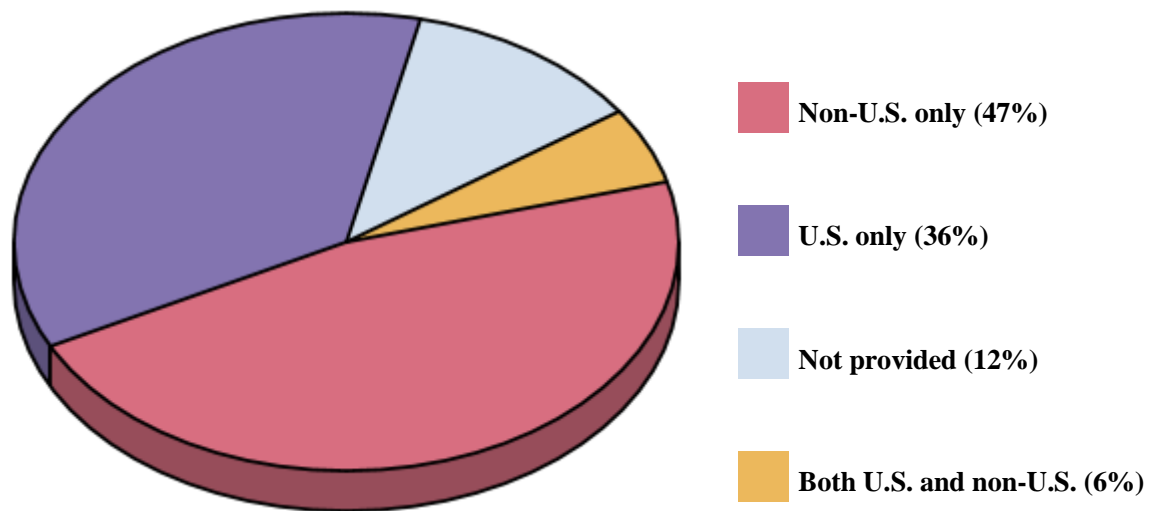
Figure 1: Percentage of Registered Studies by Location

(Adapted from clinicaltrials.gov, 2017:1)

Number of Registered Studies Over Time and Some Significant Events (as of March 19, 2017)

Source: https://ClinicalTrials.gov
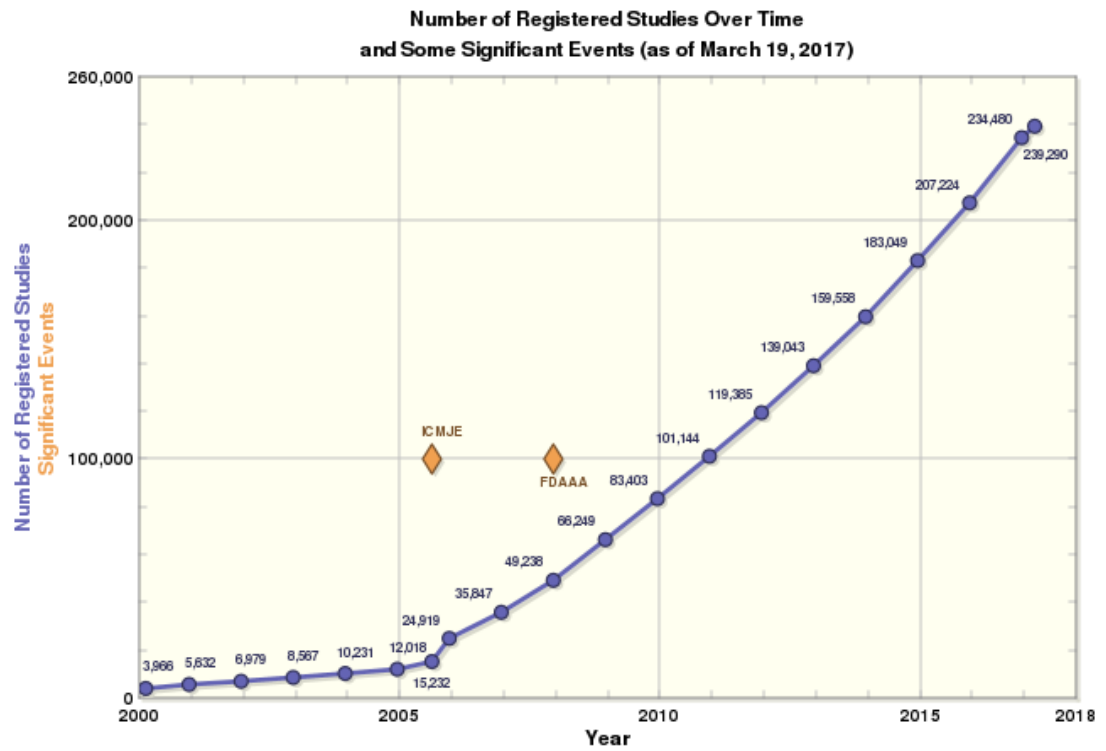
Figure 2: Number of registered studies over time

The number of registered studies in South Africa in 2012 as shown in Figure 3 is quite encouraging with companies such as Quintiles and Parexel taking the lead in the South African market.

Total number of registered clinical trials in South Africa
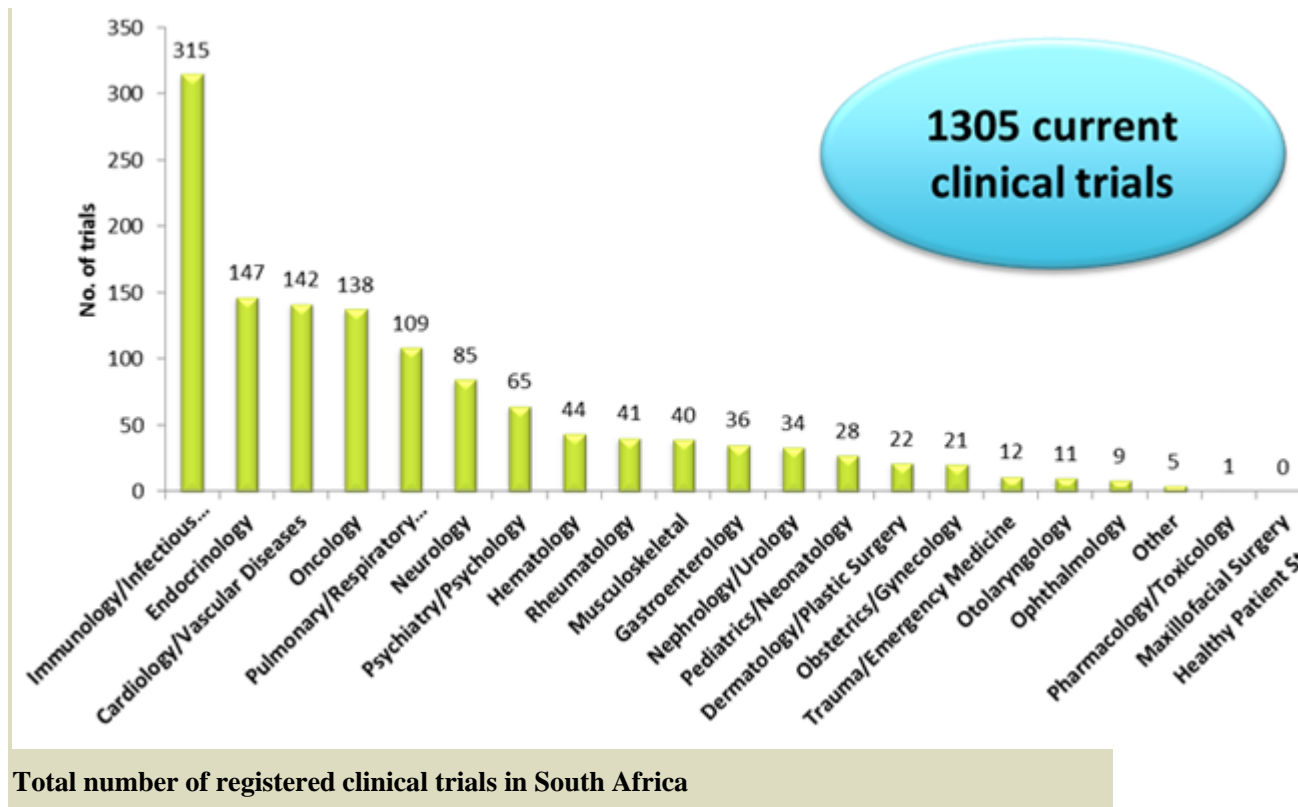
Figure 3: Registered clinical trials in South Africa in 2012

Available statistics on the global market worth of the clinical trial industry is a little bit discrepant. While Fassbender (2017: 1) put that the value at $27 billion as at 2014 and projected that the value will increase to more than 45 billion by the year 2020, Pharmsource (2017:1) believes the amount to be spent on clinical trials could reach a whopping $72 billion by the year 2020. Whichever way one looks at it, a conclusion can be drawn that clinical trial industry is a thriving and growing industry. In South Africa, about R2 billion was spent on health related research and development activities and about R800million of this amount was spent on clinical trials (Kahn & Gastrow, 2008: 1)

At the core of this thesis is an investigation of how The INTERNET OF THINGS (IoT) may be used to improve clinical trials in South Africa thus it is equally important to understand the industry of Internet of Everything alongside that of clinical trials. The advent of the internet was well lauded by many people who believed that it was the best thing to have ever happened to humanity and hitherto, we are still reaping the benefits offered by the internet in almost all ramifications of life, be it business or personal. The promises of Internet of everything (referred to as Internet of Things in this study) on the other hand are overwhelming and the expected benefits surpass all

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we have ever thought of. In 2011, Evans (2011:1) predicted that about 50 billion things would be connected to the internet by the year 2020. Though this figure is now fast turning out to be quite unrealistic, the general agreement is still that a lot of things will soon be connected to the internet (Nordrum, 2016:1). According to Postscapes (2016:1) "The Global Internet of Things (IoT) market reached USD 598.2 Billion in 2015 and the market is expected to reach USD 724.2 Billion by 2023. Further, the market is projected to register a CAGR of 13.2% during the forecast period 2016-2023 globally". Figure 4 below shows a projected increase in the revenue opportunity of the Internet of Things from$132 billion in 2014 to $313 billion in 2018.

Worldwide Internet of Things Revenue Opportunity

2018								
Banking	Manufacturing	Retail	Healthcare	Transportation	Utilities	Government	Other	
$154 B	$913 B	$326 B	$313 B	$325 B	$201 B	$570 B	$1.79 T	$4.59T

2014								
Banking	Manufacturing	Retail	Healthcare	Transportation	Utilities	Government	Other	
$92 B	$472 B	$160 B	$132 B	$156 B	$100 B	$301 B	$877 B	$2.29T

IDC, Internet of Things Spending Guide by Vertical Market, 2014
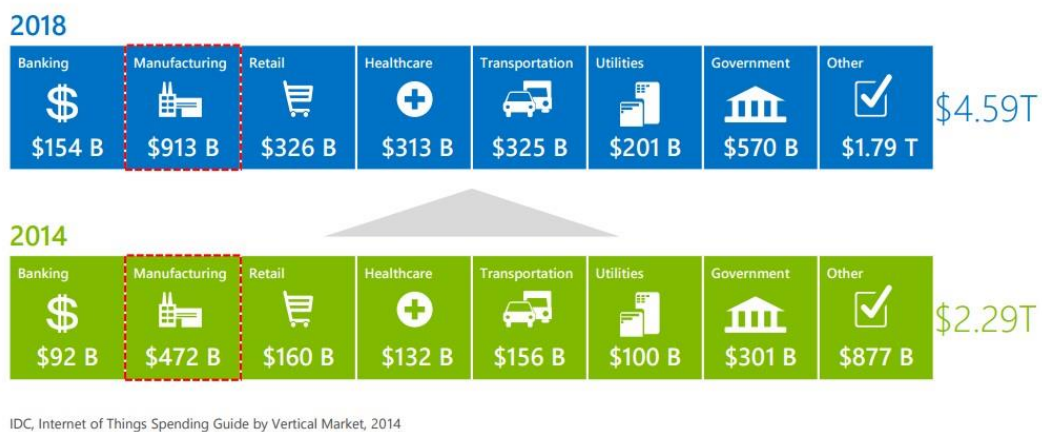
Figure 4: Worldwide internet of things revenue opportunity
(Adapted from Columbus 2015:1)

1.3   PROBLEM STATEMENT

The usefulness of Internet of Things today cannot be over emphasized, the application cuts across all spheres of life and several industries including but not limited to education, manufacturing, retail, finance and even healthcare. Clinical research deals with researches -conducted all over the world including in South Africa- that use of human subjects to find solutions to medical or health problems. One however wonders the extent to which the promising internet of Things have been applied to clinical research particularly in South Africa and it will be very worthwhile to find out the reason for slow adoption of application of the Internet of Things to clinical researches

and also possibly see how the application of Internet of Things to such clinical researches conducted in South Africa can be encouraged.

1.4   RESEARCH OBJECTIVES

PRINCIPAL OBJECTIVE

The aim of this research is to determine the level or extent to which THE INTERNET OF THINGS (IoT) is presently being used or applied and the possibility of applying the Internet of Things while conducting clinical trials in South Africa.

SUBPROBLEMS

While looking at the extent to which IoT is presently being used, sub problems include the following:

- To understand the reason behind slow adoption of IoT in clinical trials, why is IoT not used if it is not used?
- To understand if South African Clinical research industry is really ready for IoT application
- To investigate what needs to be done in order for South African clinical research industry to start applying IoT while conducting the clinical trials

IMPORTANCE OF THE RESEARCH

- **Relevance to the clinical trial industry**
    ◦ It will help to understand how to make clinical trials easier through application of IoT
    ◦ Will provide better understanding of link between clinical trials and IoT
    ◦ Monitoring study participants can be done better
    ◦ It can provide vital insight leading to reduction in clinical trial costs
    ◦ Add to the already existing body of knowledge relating to the use of IoT in clinical research
- **Relevance to researcher**
    ◦ Acquire more knowledge
    ◦ Help to lay foundation for further studies on clinical research and IoT

1.5 SCOPE

The research only investigated the application of IoT to clinical trials in South Africa and not focused elsewhere. In the process of doing this, opinions of stakeholders were sampled, recorded and analysed but no attempt was made to implement any actual application of Internet of Things (IoT) to clinical trials.

1.6 ASSUMPTION AND LIMITATIONS OF THE RESEARCH

While the findings of this research could be said to be applicable throughout South Africa,-since the samples are drawn from the major stakeholders in clinical research in South Africa-such application should be done very carefully bearing in mind the nature of the methodology used (focused group). It was assumed that there was no difference between clinical research stakeholders in different parts of South Africa as the research was mainly based on stakeholder resident in the Free State province of South Africa concerning the way they do their jobs and how they feel about IoT and application of IoT to clinical research.

The findings of this research is not expected to be applied outside South Africa in any way unless the political, economic and technological conditions of such country is highly comparable to what obtains in South Africa.

Also strong attention is drawn to the fact that the focus group method was used and that only stakeholders in the Free state of South Africa participated but for the purpose of this research, location does not really matter since many of the participants- though based in the Free state- do sometimes have to carry out their assignments even outside the Free State.

1.7 SUMMARY

The internet is everywhere and everyone is taking advantage of the benefits of the internet to effect improvement wherever possible. The chapter has given a general background of the research. The main objective of research is to get a feel of the general opinion of stake holders in clinical trials in South Africa about the use of the internet of Things. The research is limited to South Africa and no actual implementation was done but a sampling of opinion on possibility of using the Internet of Things to improve clinical trials.

CHAPTER 2
LITERATURE REVIEW

2.1 INTRODUCTION

This chapter provides a review of concepts and theories that form the basis of the research conducted. Since the whole research was about the use of Internet of Things and its possible application to clinical trials, this chapter attempted a description of the concept of Internet of Things, a description of clinical trials and clinical trials with the South African perspective. The chapter gives an insight into the various stages of clinical trials and the factors that engender motivation and barrier for people to participate in clinical trials. Finally, the possible links between clinical trials and the Internet of things are duly explored

2.2 OVERVIEW OF INTERNET OF EVERYTHING (IOE)

2.2.1 What is the Internet of Everything?

While it is generally acceptable to define the Internet as the world-wide network of all networks where all the computer devices may be interconnected to one another, the limitation of the internet lies with the very connection of computer devices together. However, the world has evolved to such a level where things or objects not traditionally seen as a computer device may function in ways similar to computer device, example include a door that can be operated like a computer device to open and close automatically or as designed by a computer program. The Internet of Everything is a network which connects everything, everything in this regard include people, process, data and things. The people refer to human beings who interact with the other components of the network in many ways such as people-to-people (P2P) or machine-to-people (M2P). The people may also be at the helm of producing or using data, people may be involved with process receiving the right process or sending the right process to follow to other people or machines in the network. Process is a procedure (to put it lightly) of doing something. The Internet of Everything has the necessary processes connected to people, machines and data. The data is simply the data generated or necessary for the task at hand while things refer to every other things

such as machines, animals and other non-living things that we interact with on daily basis like cars and so on (Ali, 2015:15-17)

2.2.2 How is the Internet of Everything different from the Internet and the Internet of Things?

The internet is a worldwide network of networks which include computer devices, the Internet of Things is an extension of the internet in that it is an internet but other things that are not computers are also connected and the Internet of Everything is even a further extension of the Internet of Things. While Internet of Everything connects everything which include people, data, process and things to the internet, the Internet of Things connects just things (objects) to the Internet, these are objects such as cars, fridges, doors or any of the things that are traditionally not computers. Though one may naturally think the communication type possible with internet of things will be machine-to-machine but the internet of things goes beyond machines and that is why it is also called the internet of Objects (Ali, 2015:15-17) Internet of everything can in any way be seen as a massive improvement on Internet of Things as described above, Internet of things is a single technology transition but internet of everything is made up of multiple transition of technologies. Internet of Things is embedded in Internet of Everything (Cisco, 213:1).

It is very important to mention that people loosely use the term Internet of Things (IoT) and Internet of Everything (IoE) interchangeably. More often than not, when they talk about IoT they actually mean IoE but for the purpose of this report, IoT and IoE will be treated as different based on the distinction explained above. However, from now onward in this report, only the term Internet of Things (IoT) will be used but the definition attached to the term IoT is the definition given for IoE. In other words, the researcher has decided to go with the popular usage where people use the Internet of Things but actually are referring to the Internet of Everything. So the rest of the thesis will only mention Internet of Things (IoT) and every time that is mentioned, we actually mean the Internet of Everything which is a connection of people, data, process and things to the internet.

2.3 CLINICAL TRIALS

2.3.1 What are clinical trials

According to National Heart, Lungs and Blood Institute, "Clinical trials are research studies that explore whether a medical strategy, treatment, or device is safe and effective for humans. These studies also may show which medical approaches work best for certain illnesses or groups of people. Clinical trials produce the best data available for health care decision making."(U.S National Library of Medicine 2008:1). Clinical trials can also be described as special kinds of experiments where the objects of the study are subjected to pre-determined manipulations aimed at achieving a predictable expected result (Hansson, 2014:42). The objects of study in clinical trials are human beings, usually patients that volunteer to take part in the study, this makes clinical trials a lot more delicate kind of experiment where a lot of caution need to be exercised. Clinical trials are experiments where the manipulations done are treatments and the expected outcome is such that the ailment is cured or the patients get better. The experiment performed via clinical trials must be very repeatable in order for the trial to be seen as successful, this is because the aim of the trial is probably to find cure or treatment for a medical condition. It will therefore be futile if the same results could not be achieved with similar objects under the same condition. For example, if we have two patients with diabetes of the same age, and weight and other conditions are similar, administering a certain medication is expected to produce the same kind of effect or else such medication cannot be relied on in actual practice of treating the disease. (Hansson, 2014:42-43). It is also important to add that clinical trials are "action-guiding" experiments as against being epistemic experiments. Action guiding experiments are experiments that satisfy the following two criteria (Hansson, 2014:42-42): "(1) the outcome sought after should be aligned towards reaching some desired goals of human action."

"(2) The interventions studied should be potential candidates for being performed in a non-experimental setting in order to achieve that goal."

The underlining spur to conduct action guiding experiment is the actual need to find solution to the problem and the experiment is not academic in nature (Schiaffonati: 17)

2.3.2 Stages of clinical trials

Clinical trials are conducted in different stages based on the aim and objectives of such trials. These stages are called phases and we have phase I, phase II, phase III and phase IV. In Phase I, a small group of people is used to test a new treatment to see things such as how it works, the range of dose to use depending on patients, possible side effects, the actual effectiveness of such drug or treatment and if it is safe for human use. Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects (U.S National Library of Medicine 2008:1). In Phase II, the researcher now proceed to test the treatment on a larger group of people, the aim here is to confirm that the treatment is effective and to establish if it will still be safe for use(U.S National Library of Medicine 2008:1). In Phase III, the treatment is now given to large groups of people and this time the aim is to be sure that the treatment is effective, to concentrate a bit more on the side effects and determine the actual cause and parameters around those side effects and to compare the treatment compare to other treatments that are used for the same medical condition. Lastly in phase III, all necessary information needed in order to use the treatment safely are collected (U.S National Library of Medicine 2008:1). The last stage is Phase IV, which can be said to be a post marketing stage. In phase IV, researchers conduct the research after the treatment have been marketed and used by people generally. The purpose is to establish the effect of the treatment on various populations of people. For instance, some side effects hitherto not discovered may now surface (some of these may be due to long-term usage of the treatment) (U.S National Library of Medicine 2008:1).

2.3.3 Barriers and motivation for participating in clinical trials

2.3.3.1 Barriers to participation in clinical trials

The very sensitive nature of clinical trials may be the very reason why people are reluctant to take part in them. Some of the main reasons for shying away include fear and lack of trust in the research or the researchers. Fear may be ascribed to lack of knowledge, wrong beliefs about the safety of the procedures used in conducting clinical trials and also the inconvenience, discomfort or pains anticipated by the participants. In a study conducted by Owens, Jackson, Thomas, Friedman, and Hébert,

(2013:4), it was discovered that African Americans are less receptive to participation in clinical research than their white counterparts. Apart from the reasons already mentioned, other reasons stated by the participants include lack of health insurance to fall back on if something goes wrong as a result of participation in such trials and lack of time for the commitment required for participation in clinical trials. It may not be wrong to believe the same reasons mentioned here are applicable to South Africans as well.

2.3.3.2 Motivators for participation in clinical trials

Having talked about the barriers to participation in clinical trials, it is equally important to mention if there is any, the factors that can motive people to participate in clinical trials. According to Owens, Jackson, Thomas, Friedman, and Hébert, (2013:4), factors motivating people to participate in clinical trials include "money, assurance of safety while participating in the clinical trial, education regarding clinical trial procedures, the potential for the research to benefit someone in their family or community, encouragement from peers, and free healthcare".

2.4 THE LINK BETWEEN INTERNET OF THINGS AND CLINICAL TRIALS

If it is believed that the Internet of Things (IoT) will bring revolutions to organizations across industries such as Education, manufacturing, transport, retail and other industries, then the same can be said of the health industry. If the traditional Internet of Things is half as powerful as it is claimed to be, then one can only start to imagine the level of advancement that Internet of Everything (IoE) brings!

In health generally, benefits of the use of the Internet of things or the Internet of Everything cannot be overlooked in anyway. Lot of interesting changes are envisaged: the number of cell phone users is expected be more than 5 billion by 2019; 100 billion devices are expected to be connected by 2025 and an impact of more than 11 trillion is anticipated on the world economy (Rose, Eldridge & Chapin, 2015:1: Iqbal, 2016:1). One may be right to say Health industry stands to gain a lot (maybe more than the other industries) with the advent and application of IoT for the use of IoT is estimated to "be worth $117 million by 2020"(Iqbal, 2016:1).

Clinical trials are very complex research to conduct for many reasons such as the fact that the objects of the experiments are human beings who may actually be sick or having a medical problem to which solution is sought. Some of the studies include

many patients who are not close to one another or to the researchers, processes need to be followed and data need to be generated, collected and analyzed. The benefit brought by IoT in clinical trials include remote monitoring and remote gathering of data. These can be done by using wearables and the mobile phones (mHealth) among other available technologies. MHealth is simply administering medical care through the use of mobile phones while wearables are devices that the user can wear. These devices have embedded sensors that assists in gathering necessary data on regular basis (Iqbal, 2016:1).

2.5 SUMMARY

This chapter looked at various underlying theories and concepts that motivated the research. Clinical trials are studies conducted using human subjects with the aim of finding solutions to health issues. The Internet of everything, commonly called the internet of things connects everything to the internet and thus promises a great benefit when applied in health sector.

CHAPTER 3
RESEARCH METHODOLOGY

3.1 INTRODUCTION

As mentioned earlier, the main aim of this research was to see the extent to which Internet of things is applied to clinical trials and to get a view of the reasons behind the reluctance in the use of the Internet Of Things while carrying out clinical trials in South Africa and to see if there is a possibility of encouraging the use of Internet of Things in Clinical trials conducted in South Africa. The researcher use qualitative method while carrying out this research.

Although they were many studies conducted into the application of the Internet of Things to healthcare (Bui & Zorzi, 2011; Islam et al 2015), it is very hard to come across one conducted with specific consideration of the South African perspective. Hence this research attempted to fill the gap and pave way for more of such studies in South Africa.

The following sections deal with the paradigm, the research strategy and methodology used in this research.

3.2 PARADIGM AND METHODOLOGY

For a very long time, positivist paradigm has dominated the studies conducted in healthcare (Burns and Grove, 2001). The positivist paradigm is the backbone of quantitative research and it is of the view that human behaviours could be studied as reality that can be seen as observable, objective-as against being subjective- and that these behaviours can be quantified. This means that human behaviours could be seen as "ordered, rational, and logical" and that obtained data could be collected and analysed in a strict controlled manner (Reiners, 2012: 1).

However this study wanted to allow for the subjective views of the stakeholders in clinical trial industry in South Africa to be taken into consideration. The possibility of multiple -not absolute- truths which emanates from the constructivist paradigm is employed. Constructivism form basis for qualitative research where participants are seen in a more naturalistic view (Labonte, & Robertson 1996:434) where human realities are constructed based on previous experience and prone to different interpretations as perceived by different people. An example is a temperature of 15

degrees Celsius which is perceived as warm by somebody from Finland and the same temperature is perceived as cold by someone from Nigeria. In line with the objectives of this research, which is to gain an understanding from stakeholders of clinical trials in South Africa about the application of Internet of Things to clinical trials conducted, the researcher deemed it highly appropriate to use a qualitative approach.

3.3 METHODS

The Focus group method was used in conducting this research. Focus group is a research method based on the qualitative approach, it can be described as "a type of in-depth interview accomplished in a group, whose meetings present characteristics defined with respect to the proposal, size, composition, and interview procedures. The focus or object of analysis is the interaction inside the group. The participants influence each other through their answers to the ideas and contributions during the discussion. The moderator stimulates discussion with comments or subjects. The fundamental data produced by this technique are the transcripts of the group discussions and the moderator's reflections and annotations" (Freitas, Oliveira Jenkins and Popjoy, 1998:2). Prior to the use of focus group, qualitative studies used participants observations and interviews but focus group method serves as a combination of these two previous methods with benefits such as saving time and saving costs(Morgan, 1996:8-10). According to Nagle and Williams (2013:1-12), an effective focus group research consists of a process of 5 stages. These are briefly described below:

STAGE 1- STUDY PURPOSE

This is the stage where the purpose of the research is defined, it is very important to get this stage very right as it will hugely affect all other stages that follow. A focus group can be for exploration, program development, systematic research or evaluation (Nagle & Williams 2013:3). In this study, the purpose was for exploration. The researcher only wanted to find out from the participants about their views on the application of Internet of Things to clinical trials.

STAGE 2-METHODOLOLY

The methodology stage of focus group has two aspects; conceptualisation and logistics (Nagle & Williams 2013:3) Conceptualisation involves the definition of population and sampling. These are further discussed in details in the sampling section below. The methodology stage is also the stage where the questions are developed and the logistics planned. For this research, the following questions were developed and used for the focus group:

1. TO WHAT EXTENT DO YOU THINK IOT IS APPLIED TIN CLINICAL TRIALS CONDUCTED IN SOUTH AFRICA?
2. HOW DO YOU THINK IOT CAN IMPROVE CLINICAL TRIALS IN SOUTH AFRICA
3. WHY DO YOU THINK THERE HAS BEEN SLOW ADOPTION OR INCORPORATION OF IoT IN CLINICAL TRIALS IN SA?
4. IF IT WAS ONLY UP TO YOU, WOULD YOU USED IoT IN YOUR REASEARCH RIGHT NOW, WHY?
5. WHY WOULD YOU SAY SOUTH AFRICAN CLINICAL RESEARCH INDUSTRY IS READY OR NOT READY FOR INCORPORATION OF IoT IN THE TRIALS TO BE CONDUCTED FROM NOW?(DO WE HAVE WHAT IT TAKES?)
6. WHAT DO YOU THINK NEEDS TO BE DONE FOR CLINICAL TRIALS IN SOUTH AFRICA TO TAKE PROPER ADVANTAGE OF IoT

It should be noted that all of the above questions are open ended questions, close-ended questions will completely defeat the purpose of any focus group interaction. In addition to defining the population and sample and developing the appropriate questions, the methodology stage is also the stage where logistics are planned. Nagle and Williams (2013:4) suggested that the following tasks-with the suggested time frame may be needed in order to conduct an effective focus group:

"Develop the Study Purpose	6-8 Weeks
Identify the Participants	6-8 Weeks
Develop Participant Contact List	6-8 Weeks
Select the Facilitator	4-5 Weeks

Question Development	4-5 Weeks
Develop the Script	4-5 Weeks
Pilot test questions and script. Revise as necessary	4 Weeks
Obtain IRB Approval	dependent on institution
Identify and reserve focus group site	4 Weeks
Invite Participants	3-4 Weeks
Verify Invitation to Participants by Phone	2 Weeks
If there are multiple facilitators,	
Conduct a training on the script to promote study reliability	2 Weeks
Finalize Room Arrangements	1 Week
Reminder Call to Participants	2 Days
Organize all Needed Materials	2 Days"

(Nagle and Williams 2013:4)

STAGE 3 FACILITATION

The third stage is facilitation. This is a very important stage as facilitation can make or mar a focus group. Proper facilitation involve knowing when to pause, probe, use non-verbal communication, take different personalities of the participants into consideration and properly forming and enforcing rules that govern the activities of the focus group (Nagle and Williams 2013:6-8).

In this particular study, owing to the fact that the researcher was working alone, a member of the group has been asked to assist with facilitation thereby giving the researcher ample opportunity to take notes and to observe non-verbal communication during the course of the focus group activities. It also came with an advantage of members of the focus group owning the focus group and it enhanced a much freer participation. The volunteering member was briefed before the focus group and the researcher only had to come in if the discussion seem to be veering off the main focus.

STAGE 4 ANALYSIS

This is the stage where all the focus group discussion are brought together into "manageable form" that can be used to write a report (Nagle and Williams 2013:6-8). This stage sets the pace for the next stage which is report writing. It is in this

stage that each question is looked at and the responses to the questions are organised in such a way to make it easy to write a meaningful report.

STAGE 5 REPORT

This is the stage where the actual report of the whole focus group discussions is written (Nagle and Williams 2013:6-8). Factors which must be considered while writing the report include the following (Nagle and Williams 2013:6-8):

The Audience: It is very important to know the audience for which the report is intended, that will also help in shaping the style and the language of the report. Or this study, the audience include all the stake holders in clinical research and those that can benefit from clinical research (including the Government)

The style of writing: the style should be decided based on the audience and other factors, the researcher should consider either writing in the narrative style of bullet points. Bullet-point style is much more suitable where the audience will not have much time to read and will like to just get to the points but details may be missed. The narrative style on the other hand is more detailed but time consuming. In this study, the report has been written in the narrative style.

Sequence of report: The report could either be written according to theme or according to the questions. In this study, the report has been written on a question by question sequence

Participant Information: It is very important to include the participants' information in the report. The report in this thesis include details such as the number of people that participated, number of women, the number of men, and the different capacities (such as clinical researcher, project manager) in which they participated.

Use of quotes from focus groups: one of the best way to write a very effective report from focus group activities is by using quotes directly taken from participants of the focus group discussions.

Summary: the last step to take in writing report is to give a summary of "how the focus group results align with the focus group purpose" (Nagle and Williams 2013:6-8)

3.4 SAMPLING

Because focus group method is used, probability sampling or random sampling are automatically excluded as they do not go in line with the focus group method. While the researcher tried to make sure that the composition of each focus group was balanced (by having mixed stake holders), it should be noted that striking such balance was so difficult since the study actually used convenience sampling- which proved to be more appropriate and more practicable in this study. The population, from which the samples are drawn, in this case includes stakeholders in clinical research in South Africa, these include clinical Site Study Coordinators, Study Nurses, and Laboratory Clinical Technologists

 Laboratory Technicians, Administrative Assistants, Data Administrators, study project managers and Recruitment Officers. Sampling is done from staff of three major clinical research companies in Bloemfontein South Africa. Three focus groups were conducted for this study and each focus group consisted of between 8 to 13 participants. The subjects were selected based on availability and willingness to participate in the focus group activities.

3.5 DATA

3.5.1 Data collection

Since the focus group method is used, data is collected in all focus group discussions through audio recording and by note takings done by the researcher. Some important no-verbal data are collected through observation of body language and recorded in the notes taken by the researcher.

3.5.2 Data validity and reliability

Reliability is a very important factor in any study, it is the extent to which a measurement taken is consistent, precise and reproducible.   (Flom, 2017:1;

Professional Testing Inc, 2006: 1) When the focus group method is used, attention should be paid to reliability because of the fact that human beings are most unlikely to respond in the same way to a particular question. Even the same people may respond to a particular question in slightly different manners if asked at different times thus big chances are that another focus group consisting of similar but different people may not necessarily give similar answers to the same question. Flom (2017:1) is of the opinion that reliability can be improved if "the moderator is highly trained and Questions are relatively specific" In line with Flom (2017:1) as quoted above, the researcher, while conducting this study, took every caution to stick to the questions as written down in order to foster reliability.

Validity deals with determining whether or not the study actually measures what it is supposed to measure. A data is valid if it is a measure of what it is intended to measure. (Flom, 2017:1; Professional Testing Inc, 2006: 1) For example, if one wants to see how good a set of Finish students are in mathematics and a mathematics test is set up in English language without considering whether the students understands English language to the extent of taking a mathematics set up in English language, the data from such a test may not be seen as valid. Focus group is said to have a strong validity (Flom, 2017:1) since the moderator is present at the time of focus group discussions and the moderator ensures that participants are actually talking about what they should be talking about.

3.5.3 Data Analysis

Analysing data is very much as important as generating or collecting the data. It is through the analysis of the collected data that meaningful conclusions can be drawn. In this study, the generated data found in the notes and the recorded audio was reviewed at the end of each focus group discussions. These reviews provided an insight into the key issues derived from the voiced out opinions of the participants and non-verbal information observed by the researcher.

3.6 SUMMARY

This chapter looked in depth at the research methodology used in conducting this research. As against the positivist paradigm, the constructivist paradigm-which allows for multiple truths- was used and the actual method of focus group was used in line with the qualitative nature of this study. There are 5 stages involved in a focus group study; these are study purpose, methodology, facilitation analysis and the report stages. Data for this was sampled from a population that include various stakeholders in the clinical research industry in a convenient manner based on the availability of the research participants.

CHAPTER 4

RESULTS

4.1 INTRODUCTION

One of the most important aspects of conducting a study is being able to come up with the result of such a study. In this section, the result is presented and analysed and some conclusions are then drawn from the analysed result. Also the ethical consideration taken are discussed in this section.

4.2 RESULTS AND ANALYSIS

4.2.1 Participant composition

Three (3) focus group discussions were conducted altogether in this research. The first group was made up of 8 participants, the second group was made up of thirteen (13) participants and the third was made up of ten (10) participants. This brings the total number of participants to thirty one (31) and out of the 31 total participants, 39% (n= 12) were male while about 61% (n= 61) were females. The exact composition of the three groups are as shown in the table below:

Table 1: Participants composition

PARTICIPANT TYPE	GROUP 1	GROUP2	GROUP 3	TOTAL
Study coordinators	2	1	2	5
Recruitment Officers	3	2	3	8
Laboratory personnel	0	1	1	2
Study Nurses	0	6	3	9
Study Project managers	1	1	1	2
Database Administrators	1	2	0	2

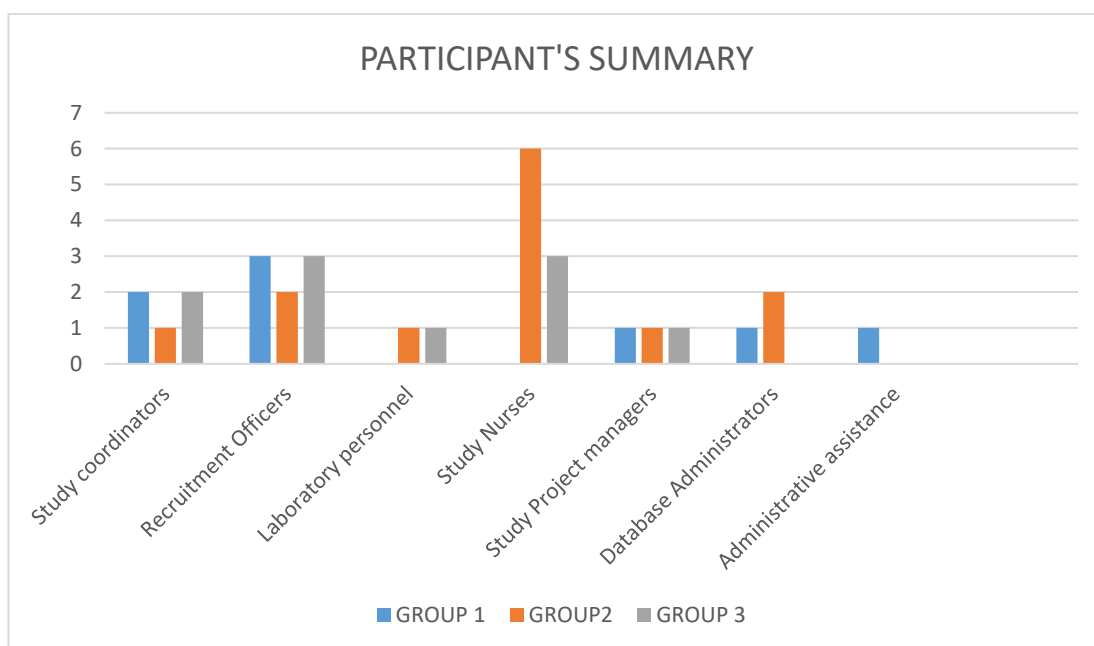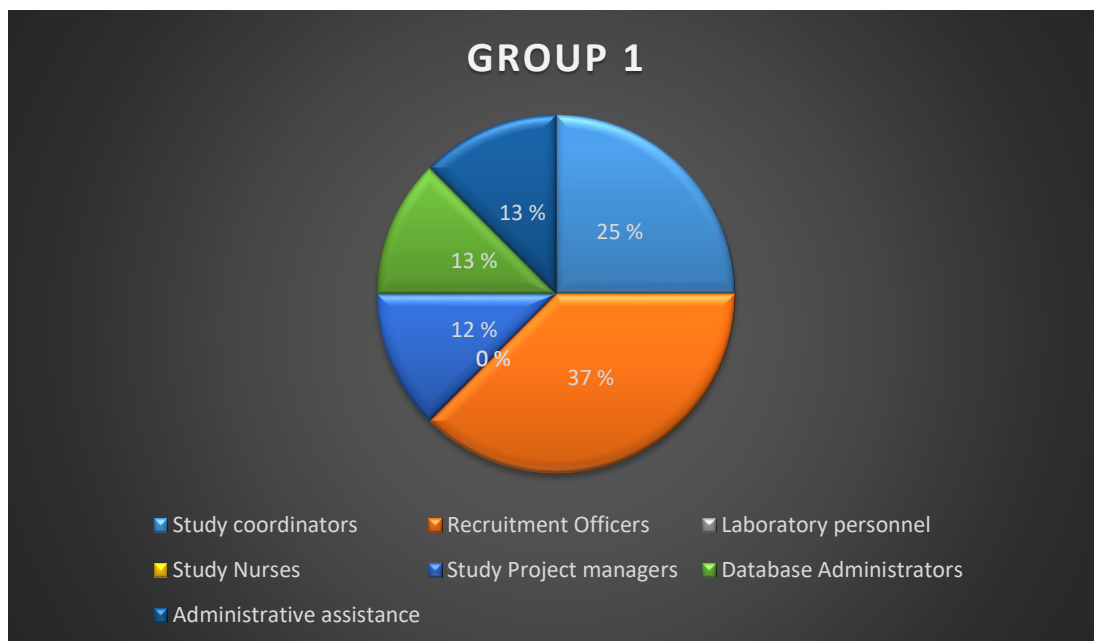| Administrative assistance	1	0	0	1
TOTAL	8	13	10	31

Figure 5: Participant's summary
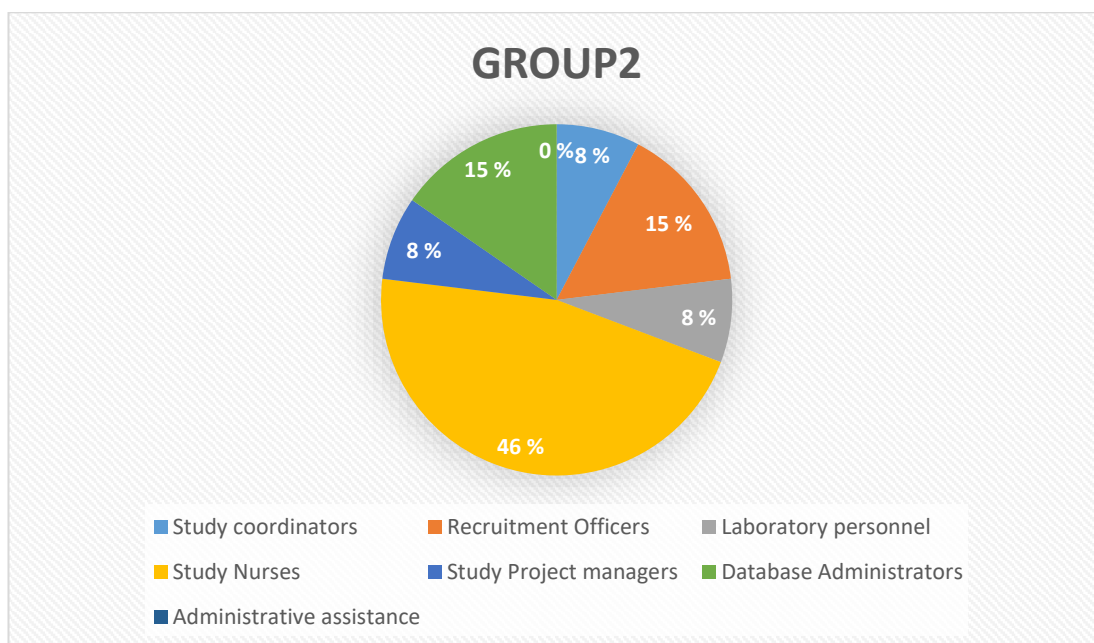
Figure 6: Group 1 summary
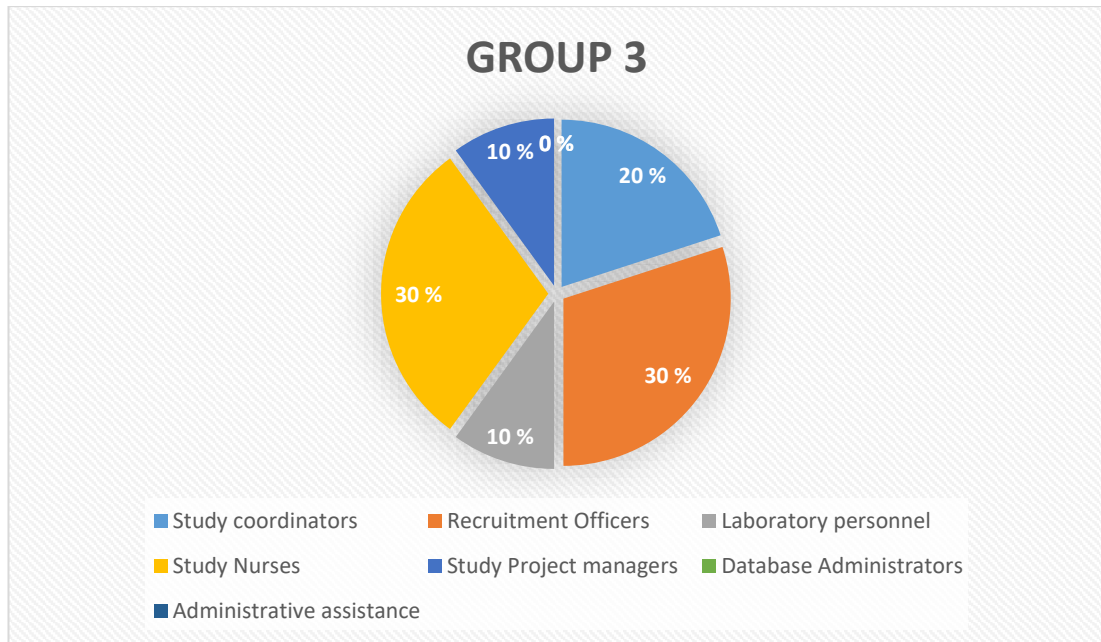

Figure 7: Group 2 summary

Figure 8: Group 3 summary

The focus groups lasted between 45 to 85 minutes. The first few minutes were used for introduction and a brief overview of the background and purposes of the focus group. It is interesting to note that the participants in all 3 focus groups held preferred to allow taping of the proceedings of the focus groups after introductions have been made. The researcher on each occasion arranged with one of the participants to co-facilitate the focus group in order to give more room for proper record taking and for free and fair participation. The co facilitator then proceeded to open discussion on a question by question basis while the researcher recorded and help to smoothen discussions where necessary

4.2.2 Results and General observations

From the focus group discussions and questions, six different themes could be identifies these include

1. Present usage of IOT in clinical trial in South Africa
2. Possible benefits of using IOT in clinical trials in South Africa
3. Causes of slow adoption of IOT in clinical trials conducted in South Africa
4. Willingness of stakeholders in using IOT while conducting clinical trials
5. Readiness of South African clinical research industry in using IOT in clinical trials to be conducted
6. Actions to be taken

In line with Bree and Gallagher (2016:2813-2818), the researcher used Microsoft Excel to process and analyse the data obtained from the focus group discussions. The data is processed based on the themes and the questions asked. Afters series of processing and reduction, the researcher came up with the summary on the following table:

Table 2: Obtained data summary

S/N	THEME/QUESTION	SOME SELECTED COMMENTS FROM WHICH KEY POINTS ARE DERIVED	KEY POINTS
1	THEME 1: PRESENT USAGE OF IOT IN CLINICAL TRIAL IN SOUTH AFRICA QUESTION: TO WHAT EXTENT DO YOU THINK IOT IS APPLIED TIN CLINICAL TRIALS CONDUCTED IN SOUTH AFRICA?	NO, WE ARE NOT USING IT; NONE THAT I KNOW OF; NOT AT ALL NOT YET; NOT USED IN ANY WAY; WE HAVE NEVER SEEN IT BEEN USED	NOT USED IN SOUTH AFRICA AT THE MOMENT

2	THEME 2: POSSIBLE BENEFITS OF USING IOT QUESTION: HOW DO YOU THINK IOT CAN IMPROVE CLINICAL TRIALS IN SOUTH AFRICA	IT'S NOT GONNA WORK BECAUSE OUR SUBJECTS' INFORMATION ARE NOT ALLOWED TO GO OUT; HOW WILL THE DOCTOR GET HOLD OF THE VITALS THAT ARE RECORDED? SO I THINK IT MAY AFFECT CONFIDENTIALITY NEGATIVELY BECAUSE EVERYTHING IS LEFT HERE IN THE OFFICE SO IT WILL SAVE TIME IT WILL SAVE MONEY IT WILL HELP TO IMPROVE PARTICIPATION (SOME SUBJECTS MAY FORGET APPOINTMENT)	IMMEDIATE FEEDBACK ON SUBJECTS' PROGRESS USE TIME WELL ENCOURAGE COMPLIANCE REDUCE STIGMA ISSUES WILL INCREASE CONFIDENTIALITY IF WELL ORGANISED SAVE MONEY INCRESE DIGNITY INCREASE CONFIDENTIALITY IMPROVED PATIENT/SUBJECT MANAGEMENT

		IT WILL ENCOURAGE PEOPLE	
		IT WILL HELP WILL ERODING STIGMA PROBLEM	
3	THEME 3: CAUSES OF SLOW ADOPTION OF IOT

QUESTION: WHY DO YOU THINK THERE HAS BEEN SLOW ADOPTION OR INCORPORATION OF IOT IN CLINICAL TRIALS IN SA? | NONE OF THE SPONSORS HAVE CAME UP WITH SUCH DEVICE;

LACK OF RESOURCES;

LACK OF INFORMATION;

COMPLETELY UNKNOWN IN SOUTH AFRICA

THE GOVERNMENT DON'T HAVE BUDGET FOR IT;

GOVERNMENT WOULD RATHER USE THE MONEY | LACK OF EDUCATION (SUBJECT AND PROFESSIONAL) NOT YET INTRODUCED BY SPONSORS FEAR OF BREACH IN CONFIDENTIALITY

FEAR OF LOSS OF JOBS BY PROFESSIONALS

LACK OF READINESS ON THE PART OF THE GOVERNMENT

FEAR OF THE UNKNOWN BY SUBJECTS |

		TO PROVIDE MEDICINES	AVAILABILITY OF FUNDS TO IMPLEMENT
			LAW AND LEGISLATIONS AVAILABILITY OF COLLABORATING INFRASTRUCTURE AND DEVICES
4	THEME 4: WILLINGNESS OF STAKEHOLDERS IN USING IOT QUESTION: IF IT WAS ONLY UP TO YOU, WOULD YOU USED IOT IN YOUR REASEARCH RIGHT NOW, WHY?	YES, IT WILL HELP ME A LOT NO, WHAT IF I END UP WITHOUT A JOB I WILL USE IT, IT WILL GIVE US MORE TIME TO DO OTHER THINGS IT WILL HELP WITH NON-COMPLIANT PATIENTS IT WILL ALLOW US TO HELP PATIENTS BETTER	WILL USE IT AS LONG AS THERE ARE NO RISKS WILLING TO USE IT IF IT DOES NOT LEAD TO LOSS OF JOBS WILLING TO USE IT BECAUSE OF THE BENEFITS OF SAVING TIME, MONEY AND CONVENIENCE
5	THEME 5: READINESS OF SOUTH AFRICAN	YES, WE ARE READY;	PEOPLE ARE GENERALLY NOT READY

	CLINICAL RESEARCH INDUSTRY QUESTION: WHY WOULD YOU SAY SOUTH AFRICAN CLINICAL RESEARCH INDUSTRY IS READY OR NOT READY FOR INCORPORATION OF IOT IN THE TRIALS TO BE CONDUCTED FROM NOW?(DO WE HAVE WHAT IT TAKES?)	WE ARE READY BUT WE STILL NEED TO FOLOLOW SOME PROCESS WE ARE NOT READY BECAUSE WE DO NOT HAVE EVERYTHING WE NEED WE HAVE WHAT IT TAKES TO AT LEAST START WE ARE NOT READY BECAUSE THE PEOPLE DO NOT KNOW ABOUT IT YET	PROFRESSIONALS ARE WILLING TO TRY IT OUT SPONSORS ARE NOT READY GOVERNMENT IS NOT READY
6	THEME 6: ACTIONS TO BE TAKEN QUESTION:WHAT DO YOU THINK NEEDS TO BE DONE FOR CLINICAL TRIALS IN SOUTH AFRICA TO TAKE PROPER ADVANTAGE OF IOE	WE SHOULD EDUCATE THEM SO THEY CAN UNDERSTAND EXPLAIN THE BENEFITS TO SUBJECTS	EDUCATE THE PEOPLE INVOLVE THE GOVERNMENT INVOLVE THE SPONSORS

		THE GOVERNMENT NEEDS TO TAKE INTEREST THE SPONSORS MUST BE WILLING TO PROMOTE IT	

Results

The following are deductible, based on the theme, from the focus groups conducted:

Present usage of The Internet of Things

The clinical trial industry in South Africa is not in any way presently making use of the internet of things in carrying out studies

Possible benefits

The stakeholders generally agreed that the use of internet of things will be very beneficial if applied to the conduct of clinical studies in South Africa. The possible benefits cuts across all stake holders from recruiters to study nurses, project managers, Study coordinators, laboratory personnel, database administrators all the way to Administrative assistance. Everybody is of the view that the internet of things will make a positive difference in terms of time saving, cost saving, effort saving, improving confidentiality, higher level of accuracy of lab results, easy updates of databases, easier filing and general administration, increasing level of interest to participate in studies and improvement in the quality of studies conducted.

Slow adoption

Lack of education (subject and professional)

The general opinion is that there is lack of awareness of the Internet of things and its uses amongst the stakeholders in the clinical trial industry in South Africa. Many of the participants involved in the focus groups did not know much about the Internet of Things by the time they were approached by the researcher. Those who knew about it knew very little and they did not think the Internet of Things could be useful in the health sector or in the clinical research industry at all. This is the same situation with both professional and the subjects that participate in actual clinical trials, nobody seems to know much about the Internet of Things! Thus, lack of awareness is one of the major factor contributing to the slow adoption or incorporation of the use of the Internet of Things in conducted clinical trials in South Africa.

Not yet introduced by sponsors

The importance of sponsors in clinical trials cannot be over emphasised. Sponsors initiate clinical trials and practically make them happen many times fund the clinical trials (Chan, Tetzlaff, Gøtzsche, Altman, Mann, Berlin, Dickersin, Hróbjartsson, Schulz, Parulekar & Krleža-Jerić). So one can understand that the drive to use the Internet of things in South Africa may not pick up until sponsors are deeply interested

Fear of breach in confidentiality

Some of the participants of the focus group think the use of Internet of things may lead to breach in confidentiality and may give room for tampering with the integrity of the data collected since data will have to pass through the internet.

Fear of loss of jobs by professionals

Another identified reason that may contribute to slow adoption is the perceived fear of loss of job or loss of relevance by professionals. Some are of the view that using the internet of Things may mean that they will not have much to do again and may lead to loss of jobs or relevance. For example, a participant mentioned that if monitoring the subjects' vital signs are done automatically through a wearable or through an implant, then it will mean she will not have much work to do and the employers may see no use for her anymore.

Lack of readiness on the part of the government

Another factor identified is the readiness on the part of the government in especially in terms of funding. Participants believe that the government will have to invest into the idea in order to be able to fully take advantage of the Internet of Things.

Fear of the unknown by subjects

Participants in the focus group are mostly of the strong view that the subject used in clinical trials may have a real hard time accepting the use of the Internet of Things since they are not used to it. Some may be wary for fear of the unknown damage that it may pose to their health and that of their family members. It may be very difficult to persuade them to use wearables and it may be almost impossible at this stage to convince them to use things an ingestible or implants.

Availability of funds to implement

As mentioned before, incorporation of the Internet of Things into clinical research will need an additional funding to implement, wearable, ingestible, implants and devices necessary to take full advantage of the Internet of Things. If the sponsors are not fully involved and the funders are not ready to invest extra money to make this happen, then the adoption of the Internet of Things in clinical research in South Africa will just have to wait.

Law and legislations

Clinical trials make use of human subjects and things can easily get complicated on the side of law concerning what is right and what is acceptable. Majority of the participants are of the opinion that existing laws may need to be modified or new laws may have to be put in place in order to take full advantage of the Internet of Things in clinical trials.

Availability of collaborating infrastructure and devices

Another hindrance mentioned is the availability of infrastructure that will be needed in order to take full advantage of the Internet of things in clinical research in South Africa. While many participants agree that there are necessary infrastructure in place,

most of them believe the infrastructure will need to be improved if clinical trials are to take full advantage of the Internet of things.

Willingness of participants to use IOT

Almost all of the participants expressed a high level of willingness to try out the use of Internet of Things if it were up to them. The researcher discovered that those who showed hesitations both by saying it and through body language are only being careful because of fear of the unknown and mostly fear of loss of job or relevance. A participant in one of the focus groups was unequivocal about it, she specifically mentioned fear of loss of her job.

Readiness of the clinical research industry

Many, with the exception of few believe that the clinical research industry in South Africa is actually ready to incorporate the use of Internet of Things to clinical research conducted. Their views is that lack of readiness is most probably on the side of the Government in terms of legislation that will permit the express use of IOT and availability of infrastructure such as accessibility of the internet in rural areas in South Africa. This needs to be seriously considered if the use of Internet of Things is to yield maximum benefits.

Although more people now have access to the internet in South Africa, Access to the internet may still pose a little hindrance. Statistics SA (2017:5) puts the number at 6 out of ten. This means "(59,3%)- of South African households- had at least one member who used the Internet either at home, their places of work or study, or at Internet cafés. Using any means, more than two-thirds of households in Gauteng (72,2%) and Western Cape (68,5%) had access to the Internet while only just over one-third of households in Limpopo (42,4%) had access to the Internet" (Statistics SA 2017:5). See the figure below:
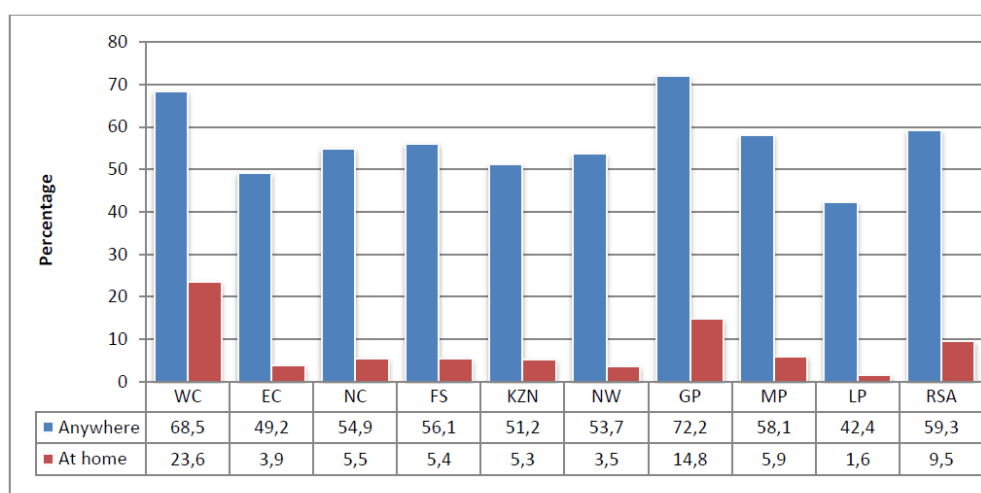
Figure 9: Percentage of households with access to the Internet at home

Figure 9 reflects the percentage of households with access to the Internet at home, or for which at least one member has access to or used the Internet by province, 2016 (adapted from Statistics SA. 2017:50)

Action to be taken

Educate stakeholders: All participants agreed that there is need for proper education of all the stakeholders in order to encourage acceptance of the use of IOT. Subjects need to know it is not risky and will not affect them negatively, professionals need to know that it will not lead to loss of jobs and all involved need to see the benefits.

Increase willingness on the part of study sponsors: While it is very important to educate the stakeholders about the potential benefits of the use of the Internet of Things in clinical trials, all will be a futile effort if the sponsors- who actually pay for studies- are not so interested in using IOT. All of the participants work according to the protocols set by the sponsors so it does not matter how much they are willing to use the IOT, if the sponsors are not willing, then IOT will not be used. So a way must be found to increase the interests of sponsors and funders in making use of the Internet of Things in clinical studies conducted in South Africa.

Government buy-in: The government need to be not only convinced that IOT should be used, they also need to take active participation to ensure that all necessary infrastructure is put in place and that all required legislations are attended to.

Although it is possible to start enjoying the benefits of the Internet of Things in clinical research in South Africa right now based on the available infrastructure, the government will need to make improvement and need to put the proper legislation in place before the full advantage can be taken.

General observations

The participants are very careful and cautious, they all requested that the proceedings of the focus groups should only be tapped after introductions have been conducted.

The researcher had to go through a whole lot of bottleneck in order to get permission from the companies to allow their workers to participate in the study. The researcher found out that most companies are wary and were very concerned that the researcher may be trying to change their protocols.

4.3 ETHICS

Ethics is a very important factor in research generally but there is even a bigger emphasis on ethics in clinical research because aside from the general ethics to be adhered to, good clinical practice (GCP) (National Institute for Health Research, 2008:1) must be strictly followed. Throughout the conduct of this research, good ethical practices have been used as the back bone of any action taken. Confidentiality and anonymity were given special consideration and no harm came to any participant or nature as a result of this research.

4.4 CONCLUSIONS

While it is clear that the stakeholders in clinical research in South Africa are not using the Internet of Things for now, there seem to be excitement and expectation of the possibility of using it in the very near future. Professional are very hopeful that the Internet of Things will bring about much needed improvements in the manner in which clinical trials are conducted and the quality of the process and the results. However, a lot still needs to be considered before such level is attained, the people need to be educated, the Government need to be carried along and the sponsors need to be deeply involved. There is much need for future research to be conducted in this regard to follow up on this research.

4.5 SUMMARY

Data obtained from any study need to be analysed in order to come up with results and probably draw conclusions and make recommendations. The data obtained from the focus groups were broken down based on the questions and 6 themes were derived. These themes include present usage of IoT in clinical trial in South Africa, possible benefits of using IoT in clinical trials in South Africa, causes of slow adoption of IoT in clinical trials conducted in South Africa, willingness of stakeholders in using IoT while conducting clinical trials and Readiness of South African clinical research industry in using IoT in clinical trials to be conducted. Final result lead to conclusion that the Internet of Things is not yet used but the participants are much willing to try it out provided it does not lead to loss of jobs and that the sponsors and the government do their parts.

CHAPTER 5

CONCLUSIONS

The findings of this study strongly indicates that in South Africa at the moment, the people involved in clinical studies are not making use of the Internet of Things to help in anyway while conducting clinical trials. It is however believed that the Internet of Things, if used, promises to bring a whole lot of benefits such as saving cost, saving time, improving confidentiality and increased level of accuracy of lab results, easier maintenance of databases, easier filing and general administration, increasing level of interest to participate in studies and improvement in the quality of studies conducted.

It is noteworthy to say that despite all the attainable benefits of the Internet of Things, it is important to be prepared and put things in place in order to properly leverage these benefits and a lot of such preparations still need to be done in South Africa. For example, stakeholders in clinical research industry still need to be educated about these benefits, fears need to be allayed in terms of suspected negative effects on jobs, and health of the people. Participants need to know that the risk, if any exists, is minimal. Professionals need to be assured that they will not have to lose their jobs due to the adoption of the Internet of things in clinical trials.

This study also found that there is a high need to secure a strong buy-in from the government in order to take full advantage of the Internet of things. Infrastructures need to be in place and proper legislation must be promulgated or improvement to existing legislation must be made and all these are impossible if the government is not interested. In addition, the research findings indicates that it is highly imperative to also get the sponsors and the funders of clinical research in South Africa interested in using the Internet of Things. Once the sponsors and funders are interested, the use of Internet of Things will feature in the protocols of clinical trials and once this is in the protocols, then the Internet of things will have to be used as studies are done according to protocols provided by sponsors and or funders.

As a follow up to this research, further studies need to be conducted where a piloted clinical trial will make use of the Internet of Things, The piloted study will combine the traditional methods used for clinical trials now with the mild introduction of the

use of the Internet of things. Such a study should consider use of wearables and implants to monitor subjects and obtain important data such as vital signs while using the traditional methods to do all other things. Once several of such studies have been conducted with incremental use of the Internet of things in subsequent studies, it will gradually reach a level where the Internet of things is fully leveraged in clinical trials.

The overarching summary is that the Internet of Things promises to bring great improvements to clinical studies conducted in South Africa but like every good and beneficial things, focused steps need to be taken in order to make the benefits a reality, such steps include educating the stakeholders, getting the Government interested and getting the sponsors and funders interested.

REFERENCES

Ali, M., (2015). "Internet of Things, Everything and Nano-Things." [Online] (https://www.researchgate.net/publication/279501993_Internet_of_Things_Everything_and_Nano-Things)(Accessed on 20/02/2017)

Bree, R.T. and Gallagher, G., (2016). "Using Microsoft Excel to code and thematically analyse qualitative data: a simple, cost-effective approach." AISHE-J: The All Ireland Journal of Teaching and Learning in Higher Education, 8(2).

Bui, N. and Zorzi, M., (2011) October. Health care applications: a solution based on the internet of things. In *Proceedings of the 4th International Symposium on Applied Sciences in Biomedical and Communication Technologies* (p. 131). ACM.

Burns, N. and Grove, S.K., 2001. Introduction to qualitative research. *The practice of nursing research. Conduct, critique and utilization* pp.67-68.

Chan, A.W., Tetzlaff, J.M., Gøtzsche, P.C., Altman, D.G., Mann, H., Berlin, J.A., Dickersin, K., Hróbjartsson, A., Schulz, K.F., Parulekar, W.R. and Krleža-Jerić, K., 2013,. "SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials" Bmj, 346, p.e7586. [Online] (http://www.bmj.com/content/346/bmj.e7586.full)(accessed on 25/01/2018)

Cisco 2013. "African American Men's and Women's Perceptions of Clinical Trials Research: Focusing on Prostate Cancer among a High-Risk Population in the South`."[Online] (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3818250/)(accessed on 20/02/2017)

Cisco, 2013. "THE INTERNET OF THINGS Cisco IoE Value Index Study." [Online] (http://internetofeverything.cisco.com/sites/default/files/docs/en/IoE-value-index_FAQs.pdf)(accessed on 20/02/2017)

Clinicaltrials.gov, 2017. "Trends, Charts, and Maps." [Online] (https://clinicaltrials.gov/ct2/resources/trends)(accessed on 11/03/2017)

Columbus, L., 2015. "Roundup of internet of things forecasts and market estimates, 2015" [Online] (https://www.forbes.com/sites/louiscolumbus/2015/12/27/roundup-of-internet-of-things-forecasts-and-market-estimates-2015/#5393ead74b93) (accessed on 10/03/2017)

Evans, D., 2011. The internet of things: How the next evolution of the internet is changing everything. CISCO white paper, 1(2011), pp.1-11.

Fassbender, M. 2016. "CRO market to reach $45.2bn by 2022." [Online] (http://www.outsourcing-pharma.com/Clinical-Development/CRO-market-to-reach-45.2bn-by-2022)(accessed on 10/03/2017)

Flom, P., 2017. "Validity & Reliability of Focus Groups." [Online] (https://bizfluent.com/facts-6778649-validity-reliability-focus-groups.html)(accessed on 05/01/2018)

Freitas, H., Oliveira, M., Jenkins, M. and Popjoy, O., 1998. The Focus Group, a qualitative research method. *Journal of Education*, *1*(1), pp.1-22.

Hansson, S.O., 2014. Why and for what are clinical trials the gold standard?. Scandinavian journal of public health, 42(13 suppl), pp.41-48.

Iatros (2016) "Welcome", [online] http://www.iatros-sa.com/ (accessed on 10 October, 2016)

Iqbal, S., 2016. "Clinical trials and IoT: How mHealth, wearables and the Internet of Things will create the clinical trials of the future." [Online] (http://www.clinicaltrialpartnershipsblog.com/2016/09/clinical-trials-and-IoT-how-mhealth.html)(accessed on 20/02/2017)

Islam, S.R., Kwak, D., Kabir, M.H., Hossain, M. and Kwak, K.S., 2015. The internet of things for health care: a comprehensive survey. *IEEE Access*, *3*, pp.678-708.

Kahn, M. and Gastrow, M., 2008. Pharmacologically active: clinical trials and the pharmaceutical industry: original article. South African Medical Journal, 98(2), pp.114-116.

Labonte, R. and Robertson, A., 1996. Delivering the goods, showing our stuff: The case for a constructivist paradigm for health promotion research and practice. *Health education quarterly*, *23*(4), pp.431-447.

Morgan, D.L., 1996. Focus groups as qualitative research (Vol. 16). Sage publications.

National Heart, Lung and Blood institute, 2015. "What Are Clinical Trials?" [Online] (https://www.nlm.nih.gov/services/ctphases.html (accessed on 10/02/2017)

Nordrum, A. 2016. "Popular Internet of Things forecast of 50 billion devices by 2020 is outdated" [online] (http://spectrum.ieee.org/tech-talk/telecom/internet/popular-internet-of-things-forecast-of-50-billion-devices-by-2020-is-outdated) (Accessed on 10/03/2017)

Owens, O.L., Jackson, D.D., Thomas, T.L., Friedman, D.B. and Hébert, J.R., 2013. African American men's and women's perceptions of clinical trials research: focusing on prostate cancer among a high-risk population in the South. Journal of health care for the poor and underserved, 24(4).

Parexel (2016) "Bloemfontein", [online] https://www.parexel.com/solutions/clinical-research/early-phase-services/strategic-locations/bloemfontein/facility#sthash.ehKbEfRq.dpuf(accessed on 10 October, 2016)

PharmSource, 2017. "Market intelligence." [Online] (http://www.pharmsource.com/market/how-big-is-the-market-for/#ClinicalResearchTotal)(accessed on 11/03/2017)

Postscapes, 2016. "IOT market Forcast." [Online] (https://www.postscapes.com/internet-of-things-market-size/)(Accessed on 10/03/2017)

Professional Testing Inc, 2006. "How do you Determine if a Test has Validity, Reliability, Fairness, and Legal Defensibility?" [Online] (http://www.proftesting.com/test_topics/pdfs/test_quality.pdf)(accessed on 05/01/2018)

Quintiles (2016) "South Africa", [online] http://www.quintiles.com/locations/south-africa#sthash.aFAu1Nby.dpuf(accessed on 10 October, 2016)

Reiners GM (2012) Understanding the Differences between Husserl's (Descriptive) and Heidegger's (Interpretive) Phenomenological Research. J Nurs Care 1:119. doi:10.4172/2167-1168.1000119

Rose, K., Eldridge, S. and Chapin, L., 2015. The internet of things: An overview. The Internet Society (ISOC), pp.1-50.

Statistics SA. (2017). "General Household Survey 2016." [Online] (https://www.datafirst.uct.ac.za/dataportal/index.php/catalog/621 (accessed on 03/01/2018)

The Pennsylvania State University, 2017. "Design and Analysis of Clinical Trials - What Are Clinical Trials?" [Online] (https://onlinecourses.science.psu.edu/stat509/node/2) (accessed on 17/02/2017)

U.S National Library of Medicine, 2008. "FAQ ClinicalTrials.gov - Clinical Trial Phases." [Online] (https://www.nhlbi.nih.gov/studies/clinicaltrials)(accessed on 10/02/2017)

National Institute for Health Research, 2008. "Good Clinical Practice (GCP)" [Online] (https://www.nihr.ac.uk/our-faculty/clinical-research-staff/learning-and-development/national-directory/good-clinical-practice/)(accessed on 21/01/2018)

Chan, A.W., Tetzlaff, J.M., Gøtzsche, P.C., Altman, D.G., Mann, H., Berlin, J.A., Dickersin, K., Hróbjartsson, A., Schulz, K.F., Parulekar, W.R. and Krleža-Jerić, K., 2013. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. Bmj, 346, p.e7586.