Competitiveness of the South African Pharmaceutical Clinical Research Industry

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By

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PLAGIARISM DECLARATION

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ABSTRACT

Purpose: This exploratory study examined the global competitiveness of the South African pharmaceutical clinical research industry using Porter’s Diamond with a comparison of South Africa to other emerging markets like China and India.

Research Methodology and Design: The study followed an inductive research approach to identify the factors that affect the competitiveness of the South African pharmaceutical clinical research industry. A non-probability sample of managers working in both public and private clinical research companies in South Africa was used. The primary data collection instrument was an online survey sent via e-mail to these managers. The research questions were developed based on the literature review. The results were captured electronically using an appropriate online survey tool. Following collection of the data through the survey, the data was analysed and coding was applied. The emerging constructs were grouped together, to form propositions that complied with Porter’s Diamond Model.

Findings: The study identified 8 propositions which contained the factors that affect the pharmaceutical clinical research industry competitiveness which were the following: the regulatory environment hinders pharmaceutical clinical research in South Africa, factor conditions are a problem within the pharmaceutical clinical research industry, demand conditions within the South African pharmaceutical clinical research industry are poorly developed, firm rivalry is poorly developed in the South African pharmaceutical clinical research industry, there is no deficiency in related and supporting sectors for the South African pharmaceutical clinical research industry, the single most important factor that affects clinical research in South Africa is the MCC (regulatory authority), South Africa’s competitiveness can be improved by improving MCC approval timelines, establishment of a patient database, and by focusing on skills development and training and South Africa compares well with other emerging markets (like China and India) in the pharmaceutical clinical research industry.

Significance: Exploratory data that identifies factors that affect industry competitiveness, has been provided by this study. This data could help improve industry competitiveness resulting in an increase in the number of clinical research conducted with resultant financial and health benefits.
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1 Introduction

The discovery and development of better, safer and newer medicines has resulted in tremendous improvement of patient lives. Life expectancy for cancer patients has increased by approximately 3 years since 1980 and 83% of those gains are attributable to new treatments, which include medicines (Sun et al., 2008). In a different study of cancer patients, medicines were found to account for 50% to 60% of increases in survival rates since 1975 (Lichtenberg, 2004). The management of cardiovascular disease has also realized significant benefits as a result of drug development. The American Heart Association published a statistics update in 2010, where it was reported that death rates for cardiovascular disease fell an impressive 28% between 1997 and 2007 (Roger et al., 2010). The scourge of HIV and AIDS confronts patients and national health departments worldwide and medicines have played a major role in this important disease area. Since the approval of the first antiretroviral treatment in 1995, the United States AIDS death rate has dropped by more than 75% (www.cdc.gov/nchs/data/hus/hus09.pdf). However, the spectre of HIV and AIDS is particularly disparaging in South Africa. The South African National HIV survey of 2008 estimates that 16.9% of South Africans between the ages of 15 and 49 are infected with HIV, comprising mainly of black patients. In spite of the South African government’s antiretroviral (ARV) treatment programme, the South African government reported in February 2010 that an estimated 5,7 million South Africans were infected with HIV and that only 900 000 of these were receiving treatment through the government’s ARV programme. However, indications are that an ever-increasing number of eligible HIV patients are accessing ARV treatment resulting in markedly improved quality of life and survival rates. Nicol and Kashuba, 2010 have published that “innovations in antiretroviral (ARV) treatment strategies have resulted in treated HIV-infected patients having life expectancies similar to those of uninfected individuals”. Anti-retroviral drugs also present a pharmacologic opportunity for the prevention of HIV transmission with impressive results. According to Fowler et al., 2007, “prevention of mother-to-child transmission (PMTCT) of human immunodeficiency virus (HIV) in the United States and Europe has been a tremendous success, such that transmission rates of less than 2% have been achieved”. Fitzgerald et al., 2010 reported that the rate of HIV transmission in South Africa is higher than reported in high-income countries for PMCT. They reported an HIV transmission rate of 5.1%. However, “without any preventative
measure the overall rate of the mother-to-child transmission (MTCT) of HIV in breastfeeding women could be 25-45%” (Taha, 2011).

Therefore, medicines have a demonstrable value in the lives of patients suffering from various medical conditions and the use of medicines results in better outcomes. However, the discovery and development of new medicines is a complex, difficult, risky, time-consuming and expensive process costing $1.3 billion on average per new medicine developed (DiMasi and Grabowski, 2007). It also takes an average of 10 to 15 years to develop a new medicine (Dickson and Gagnon, 2004) and only one or two of every 10,000 substances synthesised (on average) in laboratories, will successfully pass all the stages to become marketable medicines (DiMasi et al, 2003). Figure 1 below graphically presents the drug discovery, research and development process that each new medicine has to navigate prior to obtaining regulatory approval. The medicine can only be made available to patients once regulatory approval (by the Food and Drug Administration (FDA) in the United States and the Medicines Control Council (MCC) in South Africa) in a country has been obtained.


Figure 1: Drug discovery and development process
The clinical research portion of drug development is represented by phases I to III in the graphic above. As illustrated, clinical research consumes the longest time of the drug development process (approximately 6 years) and this works out to be 50 to 60% of the total period of drug development. The clinical research portion also consumes the largest budget (especially phase III). The major global sponsors of clinical research are the United States, the European Union and Japan. The United States spent 67.4 billion dollars in research and development in 2010 (PhRMA report, 2011), whilst the European Union spent 27 billion euros in research and development in 2010 (EFPIA report, 2011) and Japan spent 1193700 million yen in research and development in 2009 (EFPIA report, 2011). South Africa is not a significant sponsor of pharmaceutical research and development. South African pharmaceutical companies spent R500 million rand in research and development in 2009 (Deloitte report, 2010). As such, most of the clinical research activity in South Africa is sponsored by international pharmaceutical companies based in the United States, Europe and Japan. The South African Department of Trade and Industry conducted a survey in 2000, which revealed that South Africa is currently awarded 0.6% of the world’s clinical research contracts from international research companies and clinical research organization (CROs), and has the capacity to conduct 2.5% of the current global work (Baird and Van Niekerk, 2004). This continues to occur in present day South Africa despite “rapid growth in the market and research environment in emerging economies such as Brazil, China and India, leading to a migration of economic and research activities outside of Europe to these fast-growing markets. In 2010 the Brazilian and Chinese markets grew by more than 20% (20, 1% and 21, 9% respectively) compared with an average market growth of 1.8% for the five major European markets and 3.3% for the US market” (EFPIA report, 2011). Varawalla, 2006 published that “there are three key clinical development regions in Asia, namely India, China, and South East Asia. The similarities between the regions are the attractions of rapid patient recruitment driven by large patient populations with diseases of both the developed and developing world and fewer competitor trials as compared to North America and Europe. In addition, there could be a substantial potential for cost savings as well as the opportunity to penetrate some of the fastest growing pharmaceutical markets in the world”. Similarly, South Africa offers clinical research sponsors an accommodating environment for cost-effective, high-quality clinical research because the country possesses modern health care facilities, well-trained medical professionals, large populations of treatment-naïve subjects, and a favourable exchange rate (Scholtz and Pretorius, 2005). Nevertheless, South Africa remains
1.1 Research area and problem

In this exploratory study, the global competitiveness of the South African pharmaceutical clinical research industry was examined using Porter’s Diamond as a model, with particular focus and comparison of South Africa to other emerging economies whose performance far surpasses that of South Africa.

South Africa offers clinical research sponsors an accommodating environment for cost-effective, high-quality clinical studies as the country possesses modern health care facilities, well-trained medical professionals, large populations of treatment-naïve subjects and a favourable exchange rate (Scholtz and Pretorius, 2005). Nevertheless, South Africa is currently awarded 0.6% of the world’s clinical research contracts from international research companies and clinical research organization (CROs), although it has the capacity to conduct 2.5% of the current global work (Baird and Van Niekerk, 2004). In contrast, “rapid growth in the market and research environment in emerging economies such as Brazil, China and India, led to a migration of economic and research activities outside of Europe and the United States to these fast-growing markets. In 2010 the Brazilian and Chinese markets grew by more than 20% (20, 1% and 21, 9% respectively) compared with an average market growth of 1.8% for the five major European markets and 3.3% for the US market” (EFPIA report, 2011).

“Reasons cited for this shift include the ability to reduce operational costs while recruiting a large number of patients in a timely manner; the establishment of contract research organizations focused on global clinical trials; the rapid pace of growth of market size, research capacity and regulatory authority in emerging regions; and the harmonization of guidelines for clinical practice and research” (Thiers et al, 2008). South Africa matches and even outperforms other emerging countries in a number of these key competitive areas. For example, in China the regulatory authority (a key variable in clinical research) is in its infancy and is less sophisticated – the State Drug Administration (SDA) of China was established in 1998 and in 2003 was transformed to the State Food and Drug Administration of China (SFDA) by Acts passed in 2001 and 2002 (Chin and Bairu, 2011). Additionally, regulatory approval timelines in China range from 4 to 20 months with a mean of 8 months and a median of 7 months (Chin and Bairu, 2011). In contrast, South Africa’s regulatory authority, the Medicines Control Council MCC) within the Department of Health, has been in
existence since 1965 and was formed following the passing of the Medicines and Related Substances Control Act (Act 101 of 1965) (Baird and Van Niekerk, 2004). The MCC is an experienced, internationally recognised regulatory authority such that it was designated a category A country by the Indian regulatory authority (the DCGI). Category A countries include the United States (US), the United Kingdom (UK), Switzerland, Australia, Canada, Germany, South Africa and Japan. The regulatory authorities of these countries are deemed to be more sophisticated regulatory environments than that of India (Chin and Bairu, 2011). South Africa remains less competitive than Brazil, China and India in spite of its superior regulatory authority, sophisticated healthcare facilities and highly trained medical staff. South Africa possesses a large, clinical research naïve, patient population. Optimal conduct of clinical research in a country has a number of benefits. According to Thiers et al, 2008 “potential benefits include diffusion of medical knowledge and effective medical practice, and greater patient access to high quality medical care”. Additional benefits include increased investment in innovation, contribution to the economy, employment and skills development and, most importantly, patient access to medical treatments and investigations that would otherwise be inaccessible, particularly in resource-constrained settings like South Africa. For example, the United States spent 67.4 billion dollars in research and development in 2010 (PhRMA report, 2011), whilst the European Union spent 27 billion euros in research and development in 2010 (EFPIA report, 2011) and Japan spent 1193700 million yen in research and development in 2009 (JPMA report, 2010). The clinical research portion of this spending was spent globally in all countries that conducted clinical research. Therefore, clinical research acted as a source of foreign direct investment in South Africa and other countries involved in global clinical research. Clinical research is a highly skills intensive process and requires the involvement of doctors, nurses, technicians and other scientists. It contributes to skills development and retention of key staff members in health institutions. There was a total of 78,950 people employed in the research and development industry in 2009 in the United States (PhRMA report, 2011). By being uncompetitive, South Africa is missing out on the optimal realisation of the benefits that accrue to a country that conducts global pharmaceutical clinical research. Why does South Africa continue to be less competitive compared to other emerging market economies? This qualitative study helped to elicit the factors that affect South Africa’s global competitiveness of its pharmaceutical clinical research industry.
1.2 Research question and scope

The research examined the factors that affect the global competitiveness of South Africa’s pharmaceutical clinical research industry. The study utilised Porter’s Diamond as a model or framework to conduct this industry analysis with a particular focus and comparison of South Africa to other emerging economies whose performance far surpasses that of South Africa.

Primary research question:

- What are the factors that influence the competitiveness of the South African pharmaceutical clinical research industry?

Secondary research questions:

- How does South Africa compare with other emerging economies like India and China on competitiveness?
- What actions can be taken to enhance the competitiveness of the South African pharmaceutical clinical research industry?

1.3 Research assumptions

It is assumed that the researcher’s perspective and assumptions had an influence on the conduct of the research, the interpretation of findings and the theory that emerged from the research. Although there is significant research published on the South African pharmaceutical clinical research industry – there were 195 articles describing randomised trials in the local flagship South African Medical Journal between 1976 and 1987, and 92 between 1988 and 1997 (Pienaar et al, 2003) - none specifically examine industry competitiveness. To overcome this, research from other markets including the US, Europe and Asia, was reviewed with inferences made to South African conditions. This had the potential to weaken the research as the South African pharmaceutical clinical research industry has its own needs and its regulatory landscape has unique elements compared to the other emerging markets although an emphasis was placed on accessing research on emerging economies as opposed to developed economies.
1.4 Research ethics

The research was conducted in compliance with the UCT/GSB research guidelines. The research had no potential harmful consequences for participants. The challenges related to the openness and transparency of participants in the sharing of information and views. Participants were not coerced to participate and the research was on a voluntary basis. Those participants that elected to participate were not coerced to divulge sensitive information.
2 Literature review

2.1 Discussion

Introduction

The literature review and supporting theory are utilised to focus the discussion on the pharmaceutical clinical research industry in South Africa and globally, highlighting the key success attributes required based on the global success of pharmaceutical clinical research-focused countries with a particular emphasis and comparison of South Africa to emerging economy countries. A literature assessment of competitiveness from a country perspective was examined and Porter’s Diamond model was used to measure competitiveness. The outcome of the literature review is summarised followed by a conclusion section.

Introduction to pharmaceutical clinical research

The advent of the modern pharmaceutical industry in Europe in the late 19th century revolutionised the science and art of the discovery and development of medicinal preparations. Prior to this, discovery and development of medicinal preparations was almost an exclusive domain of public research institutions and virtually all-major discoveries originated in academic laboratories. With the emergence of the first pharmaceutical companies in Europe and then in the United States, this status quo was radically changed, as most of medicinal innovations were generated by these pharmaceutical companies (Figure 2).

![Figure 2. Provenance of Medicinal Innovations (as percentage of total)](image)

Originating from these humble beginnings, this trend has intensified, making the research-based pharmaceutical industry almost an exclusive source of new medicines. A substantial, critical element of the drug development process is the conduct of pharmaceutical clinical research.

Clinical research is defined as “any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy” (www.ich.org). Any discussion on clinical research that does not delve into the ethical aspects would be inadequate. A succinct history of ethics in clinical research is provided by Blustein, 2007 when he published that “the history of biomedical research involving human subjects is filled with instances of ethically questionable or blatantly unethical research. The most gruesome of these were carried out by the Japanese in Manchuria in the 1930s and 1940s and by German physicians in Nazi concentration camps in World War II. The pseudoscientific medical experiments of the Nazi doctors were showcased at the so-called Doctors Trial at Nuremberg, Germany, beginning in 1946. With the aid of documentary evidence and witness testimony, prosecutors exposed the cruel and inhumane procedures to which concentration camp prisoners had been subjected in the name of medical research. Twenty-three of these so-called physicians were put on trial: 16 were convicted of war crimes, and seven were sentenced to death. The judges at the trial enunciated a set of principles called the Nuremberg Code in an effort to clarify the basis of the tribunal’s condemnation of the Nazi experiments. The Nuremberg Code, a milestone in protecting the rights of research subjects, makes explicit the ethical requirements for acceptable research and imposes extremely stringent ethical constraints on how research is to be conducted. In unambiguous and unqualified language, the Nuremberg Code begins by noting the critical importance of the voluntary consent of the subject: the voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and
enlightened decision. There were also ethical abuses of human-subjects research in the United States in the aftermath of the war, although these cannot be compared in intent or outcome with the horrific and barbaric practices of the Nazi doctors. Many researchers here thought the Nuremberg Code applied only to “barbarians” and not to “civilized physician-investigators” such as themselves, so human-subjects research was not as strongly influenced by the principles of the Nuremberg Code as it ought to have been. Among the best known of these abuses was the research conducted at the Jewish Chronic Disease Hospital, in which foreign cancer cells were injected into the skin of 22 debilitated residents without informing them of the nature of the injections; the Willowbrook hepatitis studies, in which institutionalized children were intentionally injected with hepatitis in the search for an effective vaccine; and, perhaps most infamous of all, the Tuskegee syphilis study, which actually began in 1932 and continued for 40 years. In this study, to determine the effects of untreated syphilis, itinerant black farm workers from Alabama were lied to about their condition and were not given standard therapy for their disease. It was not until 1997 that President William Clinton apologized on behalf of the United States to a handful of survivors and their relatives” (Blustein, 2007). As a result of this history, the World Medical Association met in Helsinki, Finland in 1964 and published the Declaration of Helsinki “as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data” (http://www.wma.net/en/30publications/10policies/b3/17c.pdf). This was followed by a proliferation of laws, regulations and guidelines by member countries, which governed how clinical research, should be conducted in each country and these differed from country to country. However, the pharmaceutical industry was already globalised to address the various medical conditions in each country. There was a realisation by different countries that drug development was expensive and time consuming and the difference, from country to country, in laws, regulations and guidelines resulted in duplication of clinical research activities. In the 1980’s, the European community pioneered the harmonisation of regulatory requirements and achieved success. Trilateral discussions between Europe, the United States and Japan on the possibility of harmonisation followed but it was the WHO Conference of Drug Regulatory Authorities (ICDRA), in Paris, in 1989 that a concrete plan of action emerged. The birth of the International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use (ICH) occurred in Brussels in August 1990 where representatives from Europe, the United States and Japan met. Guidelines called Good
Clinical Practice (GCP) were published by ICH in order to harmonise the conduct of clinical research in the 3 regions. The World Health Organisation and several other countries later came on board and adopted the guidelines now called ICH/GCP (www.ich.org).

“ICH/GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible” (http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf). ICH/GCP outlines the responsibilities of each of the parties involved in clinical research and the requirements for conducting research in human beings. All global clinical research is conducted according to ICH/GCP and compliance with ICH/GCP means that each clinical trial must meet all of the following requirements:

- Review and approval of the research by an accredited independent ethics committee,
- Review and approval of the research by a competent regulatory authority
- A trial should be conducted in compliance with the protocol that has received prior independent ethics committee (IEC) approval/favourable opinion
- The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society
- Freely given informed consent should be obtained from every subject prior to clinical trial participation

Clinical research in South Africa

South Africa has a proud and distinguished history of medical research. Early achievements include Max Theiller’s 1951 Nobel Prize for his work on yellow fever and the first heart transplant by Christiaan Barnard in 1967 (Chin and Bairu, 2011). Clinical research started to expand globally in the 1960s and South Africa attracted a number of clinical research projects because of the strong research ethos in universities and the presence of a high number of international key opinion leaders based in universities (Chin and Bairu, 2011). The industry has now matured into a well-regulated, flourishing sector.

South Africa’s healthcare system and infrastructure informs the conduct of clinical research. Healthcare is provided through a dual public/private system (Pelzer K, 2009). The public
healthcare system provides free and low-cost essential healthcare to more than 41.5 million people (out of 50 million people in South Africa), mostly from the lower income sector. The country is served by a range of primary to advanced tertiary healthcare facilities, with between 20 and >300 facilities in each of the 52 districts (Day C et al, 2010). **Figure 3** summarises South Africa’s public health facilities.

![Figure 3: Structure and Size of South Africa’s Public Healthcare Infrastructure (adapted from Day C et al, 2010. District Health Barometer 2008/2009. Health Systems Trust)](image)

There are 11,237 general practitioners and 8,097 medical specialists and equivalent to 23 and 17 per 100,000 patients respectively ([http://www.medpages.co.za](http://www.medpages.co.za)). Approximately 40% of these medical professionals work in the public sector (Mooney G and McIntyre D, 2008). Therefore, 40% of the medical professionals in the country look after 84% of the population, resulting in an overworked staff population. As a result clinical research is limited to academic centres since there is no capacity to conduct clinical research elsewhere in the system. The private healthcare system provides a standard of medical care comparable to advanced western countries. Patients access private healthcare mainly through medical insurance provided by 124 registered medical insurance companies that currently cover only 16% of the population ([http://www.medicalschemes.com/Content.aspx?1](http://www.medicalschemes.com/Content.aspx?1)). Providers generally do not cover clinical research specific treatment and diagnostic costs. It is
estimated that 60% of the country’s health expenditure rests in the private sector (Mooney G and McIntyre D, 2008). The country has 4 major private hospital and clinic groups, whose 149 hospitals contain 28,226 beds including many high-care, cardiology, stroke, renal, spinal, psychiatric, rehabilitation and other specialised units. The majority of research-experienced doctors can be found in the private sector.

South Africa’s total burden of disease per capita has been estimated to be four times higher than that of developed countries and almost double that of some developing countries (ECONEX report, 2009). According to Chin and Bairu, 2011, “the most comprehensive prevalence data available is from Statistics South Africa, which collates the causes of death captured on death certificates. The top ranking group of causes of death in 2007 was a group of infectious and parasitic diseases which accounted for a quarter of all deaths (25.4%), predominantly attributable to overt or underlying HIV and/or TB, followed by diseases of the respiratory and cardiovascular system, which together accounted for another quarter of the deaths (27.5%). Next highest are unnatural causes (mostly accidents and violence)”. Figure 4 shows the percentage distribution of causes of deaths by groups classified according to International Classification of Diseases (ICD10) codes.

**Figure 4:** Statistics SA, 2009. Leading causes of death in South Africa in 2007.
South Africa’s disease burden informs the therapeutic areas in which clinical research is conducted, namely infectious diseases (especially HIV/AIDS and TB), oncology, respiratory diseases (mainly asthma and chronic obstructive pulmonary disease (COPD)), type 2 diabetes and other endocrinology conditions mainly sponsored by multi-national pharmaceutical companies (www.clinicaltrials.gov). There is tremendous potential for the conduct of a lot more clinical research in the public sector but this is limited by lack of capacity and resource (physical and human) constraints.

The Medicines Control Council (MCC) is the regulatory authority that approves and oversees the conduct of clinical research in South Africa. It was established following the passing of the Medicines and Related Substances Control Act (Act 101 of 1965). Each clinical trial must first gain MCC approval prior to its commencement. The MCC resides within the Department of Health and is headed by a Registrar. The MCC has 11 technical committees and one of these is the Clinical Trials Committee (CTC), which is responsible for the review and approval of clinical trial applications. Due to funding limitations and a finite national pool of reviewer expertise, CTC members and evaluators are contracted per review or task resulting in a bottleneck and a delay in approval of applications. The average MCC approval period of a clinical trial is 3 months and can sometimes be longer (Matsebula T et al 2005). Additionally, the MCC has a set number of submission dates of around 6 per year – no applications are accepted outside of these set dates. This also limits the number of clinical trials that can be conducted in South Africa. A fee of R320 is required to accompany each submission (www.mccza.com), which is very low compared to the ethics submission fee, which is approximately R10 000 per submission. As a result of all these constraints, the Medicines and Related Substances Amendment Act, No. 72 of 2008 (National Gazette No. 30985) decreed that within the next 2 to 5 years, the MCC will be replaced by a new para-statal regulatory authority, the South African Health Products Regulatory Authority (SAHPRA), functioning on behalf of government but outside its infrastructure. SAHPRA is earmarked to appoint expert reviewers as full-time permanent staff, a development welcomed by industry as likely to accelerate regulatory processes and create an agency consultation mechanism. SAHPRA is also expected to formalise the regulation of medical devices and complementary medicines.

Chin and Bairu, 2011 published that “the first Human Research Ethics Committee (EC) was established in October 1966 at Johannesburg’s University of the Witwatersrand; many other
universities soon followed suit with ECs that govern research conducted at the institution and its affiliated hospitals. In 1979, South Africa’s Medical Research Council issued research ethics guidelines. Properly constituted ECs were established by the South African Medical Association in 1992 and another independent organization in 1995 to oversee trial sites in the private sector. The Bill of Rights, contained within the 1996 Constitution of the Republic of South Africa, explicitly entrenched the principle of informed consent in research”. Twenty South African ECs have for many years been registered with the Office for Human Research Protection (OHRP) of the Department of Health and Human Services of the United States (http://www.hhs.gov/ohrp). The National Research Ethics Council (NHREC) was created as a statutory body responsible for establishing guidelines and setting norms and standards for ethical review of health research in South Africa under the National Health Act No 61 of 2003 (http://www.doh.gov.za/nhrec/index.php). Its mandate includes the audit of ECs, though implementation of this process has been slow. In 2004, the DOH issued Research Ethics Guidelines establishing mechanisms for the ethical review of human research protocols (http://www.doh.gov.za/docs/factsheets/guidelines/ethics). All ethics committees review clinical trial applications, at least on a monthly basis resulting in rapid approvals compared to the MCC.

*Summary of clinical research in India*

India has 16% of the global population and 20% of the global disease burden and infectious and tropical diseases are widely prevalent. In addition, non-communicable diseases like cardiovascular disease; cancer and diabetes have prevalence similar to that found in developed countries (Chin and Bairu, 2011). Healthcare is one of India’s largest sectors and was valued at US$34 billion in 2007 (PWC report, 2007). India has a mixture of private and state-subsidised healthcare totalling 15000 hospitals and two-thirds of these hospitals were in the public sector (Chin and Bairu, 2011). 80% of the healthcare spending was in the private sector (PWC report, 2007) and public hospitals suffer from physical, medical equipment and human resource constraints with a significant lack of capacity (Chin and Bairu, 2011). Private companies are thought to provide 60% of all outpatient healthcare and 40% of all in-patient healthcare and an increasing number of patients is covered by health insurance. There is a large number of highly skilled medical professionals in India.
India is a recent entrant to the global clinical research market and has been participating for less than 10 years (Chin and Bairu, 2011). It is one of the fastest growing clinical research destinations with a growth rate two and a half times higher than the rest of the global market (Kearney A, 2009). India offers savings of up to 40% of clinical research costs compared to North America and Western Europe (Chin and Bairu, 2011). Clinical research is conducted according to GCP and other international regulations. Regulatory approvals take 45 days on average and ethics approvals take up to 60 days although approval is occasionally granted in 30 days (Chin and Bairu, 2011).

**Summary of clinical research in China**

China is the most populous country in the world with a population of 1.33474 million in 2009 (Chinese Health Statistical Digest, 2010). China has seen rapid economic growth driven by low labour costs amongst others. In 2008, China’s GDP was US $ 4,326,200 million (International Statistics, 2009). The Ministry of Health oversees all healthcare in China and spends 4.96% of the Chinese GDP on Healthcare (Briefing of the Nation’s Health, 2009). In 2009, there were 1.62 doctors and 2.96 hospital beds per 1000 population with a total of 20,291 hospitals (Briefing of the Nation’s Health, 2009). There is a large rural population in China but China’s medical insurance called the New Cooperative Medical System (NCMS) was introduced in 2003 and covers 94% of the population (Briefing of the Nation’s Health, 2009). In 2009, the main causes of death in China were malignant neoplasms, cerebrovascular disease, heart disease and diseases of the respiratory system (Chinese Health Statistical Digest, 2009). The Chinese regulatory authority – the State Drug Administration (SDA) of China was established in 1998 and in 2003 was transformed to the State Food and Drug Administration of China (SFDA) by Acts passed in 2001 and 2002 (Chin and Bairu, 2011). Regulatory approval timelines in China range from 4 to 20 months with a mean of 8 months and a median of 7 months, which is long by international standards (Chin and Bairu, 2011). All global clinical trials are conducted according to GCP. Most ethics committees are attached to the research institutions although there are a few central ethics committees. There is confusion as to how the ethics approval works in China and a draft guideline is currently under review to clarify the situation (Hung J et al, 2009). Patient recruitment methods fall short of international standards and need to be improved. Recruitment materials are rarely submitted for ethics review and do not specify that the patients would be participating in clinical research. Phrases such as “free treatment” and “high re-imbursement for
participation” are used deliberately to attract patient attention (Chin and Bairu, 2011). This is in direct contravention of GCP/ICH guidelines. China offers savings of up to 50% of clinical research costs compared to North America and Western Europe (Chin and Bairu, 2011).

**Competitiveness**

In microeconomics, the term competitiveness refers to the ability of firms to compete in the domestic or global market (Kong, 2001). A wide range of indicators such as market shares, profit and growth, dividends and investment are used to assess the competitiveness of firms. Firms that offer products and services that are adapted to the needs of target customers and market them faster and more efficiently than their competitors, are in a better position to create a sustainable competitive advantage (Calantone et al., 1995). Competitive advantage is increasingly derived from knowledge, technological skills and experience when creating new products and services (Tidd, Bessant, and Pavitt (1997). The world competitiveness report outlines how nations manage their economic future. The IMD World Competitiveness Yearbook defines business competitiveness as follows “competitiveness of nations looks at how nations create and maintain an environment which sustains the competitiveness of their enterprises” (Garelli, 2003). The competitiveness cube model can be used to determine the competitiveness of a nation. It has four dimensions and each dimension is described below. The priority, to develop people who are able to operate the modern infrastructure and who are leaders of future development, is highlighted (Garelli, 2003).

![Figure 5: The Competitiveness Cube (Garelli, 2003)](attachment:image)
Attractiveness versus aggressiveness

These measure the different ways that nations use to manage their relationships with the world business community (Garelli, 2003). Aggressiveness refers to the way a nation interacts on the world market and whether it focuses on exports and foreign direct investment (FDI). Attractiveness comprises incentives and job creation. Companies should focus on both of these in order to compete in the global market.

Proximity versus globality

These are concerned with measures of openness of trade (barriers), trade agreements, regional integration, privatisation and deregulation (Garelli, 2003). The economy of proximity provides value added close to the end user. It is protectionist and expensive, whereas globality looks at operational efficiency.

Assets versus processes

The national competitive environment is managed by competing more heavily either on assets or on processes (Garelli, 2003). Some nations are rich in assets and are endowed with land, people, and natural resources but are not necessarily competitive (as is the case in many African countries) whilst others have poor resources and tend to focus on transformation processes and beneficiation (Garelli, 2003).

Individual risk taking versus social cohesiveness

The last dimension that determines the competitiveness environment of a country is the distinction between a system that promotes individual risk and one that preserves social cohesiveness (Garelli, 2003).
**Porter’s Diamond of Competitiveness Model**

In 1990, Porter published that, over and above its competitive strength or core competence micro-economically; the competitiveness of a firm also depends on the interaction of its capabilities with its external environment. Porter developed the “Diamond of National Competitiveness” in 1990, which shows the relationship between four sets of factors or attributes which together influence the success of a nation’s firms (Porter, 1990).

![Figure 6: Porter’s Diamond of Competitiveness Model (Porter 1990)](image)

**Factor conditions**

According to Porter's Diamond Model, factors of production are the basic sources of competition. Factors are *human resources* (skilled labour pool and cost of personnel), *infrastructure* (the type, quality and user costs of infrastructure available including aspects that affect the quality of life and attractiveness of a nation as a place to live and work), *capital resources* (refers to the amount and cost of capital available to finance the industry and raw material required to compete in a given industry) and *knowledge resources* (the nation’s stock of scientific, technical and market knowledge). The South African surveys by (Donninger, 2006) and (Mulder and Henschel, 2003) identified skills shortages. Porter states “to support competitive advantage, a factor must be highly specialised to an industry’s particular needs” (Porter, 1990).
Demand conditions

Porter, states that home demand conditions for the industry’s product or service are critical to competition and success. Three broad attributes are described as being significant: composition of home demand buyers’ needs, the size and pattern of growth of home demand and the mechanism by which a country’s domestic preferences are transmitted to foreign markets (Porter, 1990). Porter further states that “nations give competitive advantage in industries where the home demand gives their companies a clearer or earlier picture of emerging buyer needs, and where demanding buyers’ pressure companies to innovate faster and achieve more sophisticated competitive advantages than foreign rivals.”

Related and supporting industries

According to Porter, “the presence of competitive supplier industries in a nation creates advantages in downstream industries in several ways” enabling rapid, early preferential access to the most cost-effective inputs (Porter, 1990).

Firm rivalry

Porter defines firm rivalry as “the conditions, which govern how companies are created, organised and managed, as well as the nature of the domestic rivalry”. National advantage results from a good match between these choices and sources of competitive advantage in a particular industry (Porter, 1990).

The role of government

According to Porter, “the real role of government in a nation’s competitive advantage is in influencing the four determinants” (factor conditions, demand conditions, related and supporting industries and firm rivalry). Government can influence each of the four determinants either positively or negatively. Factor conditions are affected through subsidies, policies towards the capital market and policies towards education (Porter, 1990). Governments are also major buyers of many products in a nation and can provide incentives to develop innovative products (Porter, 1990). Government can shape the circumstances of related and supporting industries in other ways, such as control of advertising media or regulation of supporting services (Porter, 1990). Government policies also influence firm strategy, structure and rivalry through such instruments as capital market regulations, tax
policy and antitrust laws (Porter, 1990). Porter states “national prosperity is created, not inherent. It does not grow out of a country’s natural endowments, its labour pool, its interest rates or its currency value as classical economics insists” (Porter, 1990). “A nation’s competitiveness depends on the capacity of its industry to innovate and upgrade. Companies gain advantage against the world’s best competitors because of pressure and challenge. They benefit from having strong domestic rivals, aggressive home-based suppliers, and demanding local customers.” Porter suggests that pressures and challenges force companies to become innovative through this mechanism, and that the companies either become globally competitive or cease to exist. Porter’s Diamond Model addresses the four attributes, which were identified as playing a critical role in competitiveness.

**Literature review conclusion**

Drug discovery and development is a risky, lengthy and expensive process for global pharmaceutical sponsors. Most of the time and costs are consumed by clinical research. The major global pharmaceutical sponsors, which include the US, the EU and Japan, are increasingly out-sourcing clinical research to emerging countries like South Africa, India and China, in a bid to cut costs and shorten the timelines. South Africa, like India and China, has excess capacity, highly skilled staff and a large patient population for the conduct of clinical research. However, South Africa has a more developed regulatory environment for the conduct of clinical research although India and China have lower costs. The competitiveness cube outlines the theoretical attributes that determine a country’s competitiveness. Porter’s Diamond of National Competitiveness describes 4 attributes that affect the competitiveness of a country.
3 Research Methodology

3.1 Research approach and strategy

Methodology refers to the philosophical basis on which research is founded (White, 2002). The nature of the research question determines the research methodology. The objective of this research is to evaluate the competitiveness of the South African pharmaceutical research industry and in so doing identify the strengths, weaknesses and identify factors that could enhance the competitiveness of this industry in South Africa. Therefore, the inductive research approach is the most appropriate for this research. According to Bryman and Bell (2007), this approach results in theory being the output of the research by the process of drawing generalisable inferences from observations. Cooper and Schindler (1998) state “to induce is to draw a conclusion from one or more particular facts or pieces of evidence. The conclusion explains the facts and the facts support the conclusion”. This is in contrast to the deductive approach, where the researcher deduces a hypothesis based on available theory and subjects it to empirical scrutiny (Bryman and Bell, 2007).

Limited research has been conducted on this particular topic although thorough research exists on the broader pharmaceutical clinical research industry in South Africa. Hence, the need for exploratory research to learn about this specific problem. According to Kumar (2000) “exploratory research assists to identify problems, to define the problem more precisely or to investigate the possibility of new alternative courses of action”, (Kumar, 2000). Exploration is useful when the problems that will be encountered in the research study are not entirely clear (Cooper & Schindler, 1998). Exploratory research allows the use of current knowledge as a basis to collect and analyse new data that enables the researcher to refine the research question. According to Cooper and Schindler (1998), exploration typically begins with a search of published data. In this research study, published information on the factors that affect the global competitiveness of South Africa’s pharmaceutical clinical research industry was reviewed. The study utilised Porter’s Diamond as a model or framework to conduct this industry analysis with a particular focus and comparison of South Africa to other emerging economy countries. The qualitative research strategy, commonly associated with the inductive research approach, was used. Qualitative research studies are typically used to enable a researcher to gain new insights about a particular phenomenon and to develop theories about that phenomenon (Peshkin, 1988). Leedy and Ormond (2005) state that by studying those phenomena in all of their complexity, data is continuously being
collected and analysed. This contrasts with quantitative research, which “emphasises quantification in the collection and analysis of data and entails a deductive approach to the relationship between theory and research, in which the accent is placed on testing of theories.” (Bell and Bryman, 2007). The qualitative research was primarily interpretive, to understand the factors that affect the global competitiveness of South Africa’s pharmaceutical clinical research industry. Theory was developed from reflecting on the research findings.

According to Bryman and Bell (2007), the qualitative research strategy has epistemological and ontological considerations. Its epistemological orientation will be of interpretivism, which “rejects the practices and norms of the natural scientific model and of positivism in particular in the emphasis on the ways in which individuals interpret their social world” (Bryman and Bell, 2007). The ontological orientation will be of constructionism, implying that social phenomena and categories are not only produced through social interaction but that they are constantly changing. The research must take into consideration that the sample population may not be aware of social phenomena, which can influence their behaviour and interpretations.

3.2 Research design, data collection methods and research instruments
According to Bryman and Bell (2007) “a research design provides a framework for the collection and analysis of data. The choice of research design reflects decisions about the priority being given to a range of dimensions of the research process.” For the purposes of this research, the dimensions considered include the expression of causal connections between variables and understanding the behaviour and the meaning of that behaviour in its specific social context. Bryman and Bell (2007) further state that there are five different types of research designs, namely experimental design, cross-sectional, longitudinal design, case study design and comparative design. The cross-sectional design was utilized for the research as it can be applied to a qualitative research strategy (Bryman and Bell, 2007) and took the form of an online survey. Surveys are useful in cross-sectional, industry research, such as that being proposed for this research. However, Bryman and Bell (2007) state that surveys are more relevant in the context of quantitative research.

A research method is defined as a technique for collecting data. The data collection method was based on formal, primary, data collection. A non-probability sample of managers working in both public and private clinical research companies in South Africa was used. The
primary data collection instrument was an online survey sent via e-mail to managers working in public and private clinical research companies in South Africa. The research questions were developed based on the literature review. A request for completion of the survey was sent via e-mail and followed by a telephone call, enclosing an outline of the nature and purpose of the research, the sponsors of the research and how the findings may be useful to the respondents’ organisation. The results were captured electronically using an appropriate online survey tool.

### 3.3 Sampling

The most appropriate sampling technique for the proposed research was the non-probability sampling framework, as some units in the population were more likely to be selected than others. Specifically, convenience sampling, a sample that is available by virtue of its accessibility, was utilised. For the purposes of homogeneity, managers in pharmaceutical clinical research companies in South Africa were selected. However, Bryman and Bell (2007) argue that convenience sampling may be disadvantageous due to the belief that issues of representativeness are less important in qualitative research as the objective is to generate in-depth analysis.

The sample size was determined by considerations of accessibility, time and the number of clinical research companies in South Africa. According to Bryman and Bell (2007), the larger the sample size, the less the sample error.

### 3.4 Research criteria

Bryman and Bell (2007) state that reliability, replication and validity must be considered when evaluating business and management research. Reliability is concerned with the question of whether the results of the study are repeatable while replication is concerned with the ease of replication of the study. Validity is concerned with the integrity of the conclusions that are generated from research. However, there is considerable discussion among researchers of the relevance of applying reliability and validity to qualitative research. LeCompte and Goetz (1982) define reliability in relation to qualitative research as external reliability or the degree to which a study can be replicated, and internal reliability or the consistency of observations between two or more observers. These authors further define validity as internal validity or the degree to which a match exists between the researcher’s observations and the theoretical ideas they develop, and external validity or the degree to
which findings can be generalized across social settings. Internal validity tends to be the strength of qualitative research while external validity is usually weak due to the generally small samples in such research.

3.5 Data analysis methods

Following collection of the data, the researcher performed an analysis of the completed surveys and applied coding. Cooper and Schindler (1998) state that coding is the assigning of numbers or symbols to responses so they can be arranged in categories or classes. Bryman and Bell (2007) state that coding is the starting point for the majority of qualitative data. The authors quote Lofland and Lofland (1995) in listing some considerations in coding qualitative data. These include:

a. Of what general category is the item of data an instance?
b. What does the item of data represent?
c. What is the item of data about?
d. Of what topics is the item of data an instance?
e. What question about a topic does the item of data suggest?
f. What sort of answer to a question about a topic does the item of data imply?

In preparing to code, Bryman and Bell suggest the researcher consider the following steps:

a. Code as soon as possible
b. Read through the initial sets of responses.
c. Repeat the above process
d. Review the codes
e. Consider more general theoretical ideas in relation to the codes and data
f. Keep coding in perspective

Cooper and Schindler claim that four rules guide the establishment of coding categories:

a. The categories should be appropriate to the research problem
b. The categories should be exhaustive
c. The categories must be mutually exclusive
d. The categories must be derived from one classification principle
3.6 Limitations of the study

According to Bryman and Bell (2007), qualitative research has a number of limitations, which include:

- Too subjective – findings are reliant on researcher’s unsystematic impressions about what is significant
- Difficult to replicate – it is thus hard to refute or confirm a research finding
- Problems of generalisation – the samples of qualitative research are generally small and non-representative
- Lack of transparency – it is difficult to decipher what the researcher actually did and how they arrived at the conclusion

Aaker (2001) argues that non-probability sampling has the danger of introducing bias as specific categories of the population are chosen.

4 Research Propositions

Following collection of the data through the survey, the data was analysed and coding was applied. The emerging constructs were grouped to form propositions that complied with Porter’s Diamond Model. This section identifies the propositions and research questions that were answered in the research study. The propositions are only stated without explanation here, but follow the literature from the preceding sections. The literature review indicated that Porter’s Diamond model is a good tool for assessing national competitiveness as it is able to assess an industry within a country. The diamond describes four broad attributes which together, when optimal, can lead to an industry becoming competitive. This research assessed the state of the industry in terms of the four broad attributes. The research addressed the following eight propositions:

**Proposition 1:**

The regulatory environment hinders pharmaceutical clinical research in South Africa.

**Proposition 2:**

Factor conditions are a problem within the pharmaceutical clinical research industry in South Africa.
Proposition 3:
Demand conditions within the South African pharmaceutical clinical research industry are poorly developed.

Proposition 4:
Firm rivalry is poorly developed in the South African pharmaceutical clinical research industry.

Proposition 5:
There is no deficiency in related and supporting sectors for the South African pharmaceutical clinical research industry.

Proposition 6:
The single most important factor that affects pharmaceutical clinical research in South Africa is the MCC (Medicines Control Council – regulatory authority).

Proposition 7:
South Africa’s competitiveness can be improved by improving MCC approval timelines, establishment of a patient database and by focussing on skills development and training.

Proposition 8:
South Africa compares well with other emerging markets (like China and India) in the clinical research industry.
5 Research Findings
This section describes the findings from the data collected through the research. This section reports only on the findings without any analysis.

5.1 Overview of the data analysis process
The results of the application of the Porter’s Diamond Model framework to the data set are described in this section. The focus in this section is not to interpret the data but to outline in detail the key findings of the process used for framework analysis. Insight and analysis of the research findings will be provided in the next section. This section begins with the presentation of the stakeholder profiles of the respondents. Thereafter, the results are presented under the research propositions as outlined above, namely:

Proposition 1
- Regulatory authority hinders pharmaceutical clinical research in South Africa.
- Government policy, in general, enables pharmaceutical clinical research in South Africa.

Proposition 2
- Recruitment of skilled workers is difficult in South Africa.
- The general infrastructure for the conduct of clinical research in South Africa is sufficient.

Proposition 3
- The general South African public does not understand clinical research.
- Customers are based overseas and there is a lack of local entrepreneurial culture.

Proposition 4
- There is no local competition.
- The focus is on competing internationally for clinical research projects.
Proposition 5

- A strong network of local clinical research organisations exists.
- The local clinical research industry is fragmented.
- It is easy to source equipment and clinical research services locally.

Proposition 6

- The single most important factor affecting pharmaceutical clinical research in South Africa is the Medicines Control Council of the Department of Health (MCC).
- The MCC has unduly long approval timelines and this reduces the competitiveness of the South African pharmaceutical research industry.
- The single most important factor that affects the competitiveness of the South African pharmaceutical clinical research industry is patient recruitment into clinical trials.
- The single most important factor that affects the competitiveness of the South African pharmaceutical clinical research industry is a lack of doctors experienced in the conduct of clinical research.

Proposition 7

- South Africa’s competitiveness in the pharmaceutical clinical research industry can be improved by:
  - Improving MCC approval timelines.
  - Establishing a national patient database.
  - Providing skills development and training

Proposition 8

- South Africa compares favourably to other emerging markets (like China and India) in the pharmaceutical clinical research industry.
5.2 Descriptive statistics
A total of 40 managers and senior executives were approached and requested to complete the online survey. Contact was made via e-mail and telephone calls. In addition, a brief presentation and requests for completion of the online survey was made to an audience of 200 pharmaceutical clinical research stakeholders, at the quarterly meeting of the South African Clinical Research Association (SACRA).
Ten senior employees of the Medicines Control Council (MCC) were also contacted by e-mail and requested to complete the online survey. A follow-up telephone call was also made. 37 managers and senior executives in the South African pharmaceutical clinical research industry completed the survey. None of the senior employees of the Medicines Control Council (MCC) completed the survey. This translates to a 74% response rate. However, 30 responses (60%) had been received at the time of the data analysis. The additional 7 responses (14%) received later did not alter the results of the survey.

5.2.1 Sector analysis
The sample included senior and experienced stakeholders in the industry who have diverse roles and knowledge of the local clinical research industry. The most senior respondent was a local university professor and non-executive chairman, Asia-Pacific Management Board of a transnational clinical research corporation. The most junior respondent was a pharmaceutical company clinical research associate with 6 months experience in this position. The sample selection attempted to obtain views of a diverse group of industry stakeholders. This included investigator sites, pharmaceutical companies with local headquarters, pharmaceutical companies with headquarters based overseas, clinical research organisations with local headquarters, clinical research organisations with headquarters based overseas, representatives of the government’s Medicines Control Council (MCC) and other sectors which included dedicated research centres, clinical research laboratories, site management organisations and pharmaceutical trade organisations.

The respondents are a broad representation of the industry in South Africa. Having such an equitably distributed sample is important because the research focuses on an overview of the competitiveness of the South African pharmaceutical clinical research industry as a whole. This wide distribution of the respondents ensures that a representative perspective of the industry is presented.
5.2.2 Respondents experience (years in the pharmaceutical clinical research industry)

35% of respondents had experience between 1 – 3 years in their current management position although they did not specify the total number of years experience in the pharmaceutical clinical research industry. 27% of the respondents had more than 10 years experience in the industry and 24% had experience ranging between 3 – 5 years. 14% of the respondents had experience ranging between 5 and 10 years.

Figure 7: Respondents experience (years) in the pharmaceutical clinical research industry
5.2.3 Seniority

2.7% of the respondents were non-executive chairman of the board. Another 2.7% were chief executive officers (CEO). 27% of the respondents were company directors and 30% were senior managers. The majority of the respondents (37.6%) were managers of varying experience in this particular position.

Figure 8: Seniority of respondents
5.3 Analysis of findings

5.3.1 Proposition 1: The regulatory environment hinders pharmaceutical clinical research in South Africa

The online survey contained questions geared at assessing the impact of the South African regulatory authority – the Medicines Control Council (MCC) on the competitiveness of the local industry. The MCC approves each clinical research project conducted in South Africa and as such plays an important oversight role in the conduct of pharmaceutical clinical research. The questions assessed whether the MCC enables or hinders clinical research in South Africa. Specifically, the following question was posed:

- In your opinion, does the regulatory authority enable or hinder clinical research in South Africa?

Respondents were further asked to substantiate their response to the abovementioned question.

Further, the impact of government policy, in general, (as an element of the regulatory environment) on the local clinical research industry was assessed by asking the following question:

- Does government policy, in general:
  - Enable clinical research in South Africa
  - Hinder clinical research in South Africa

The responses to the different questions will be discussed separately below followed by an overall analysis in respect to this proposition statement.

5.3.1.1 Regulatory environment

The respondents’ responses to whether the MCC enables or hinders clinical research in South Africa were collated and summarised. Figure 9 presents a mind map of the key words or phrases used by the different respondents. The key words or phrases were then analysed to determine the relevant emerging constructs. Table 1 and Figure 10 present the frequency count per construct. Figure 10 demonstrates that the commonest response was the construct: the regulatory authority hinders clinical research in South Africa (frequency = 25). A
minority of the respondents were of the opinion that the regulatory authority enables clinical research in South Africa (frequency = 5).

Figure 9: Mindmap of strategy success for the regulatory environment:
Table 1: Rank order of the different constructs: regulatory authority

<table>
<thead>
<tr>
<th>RANK ORDER</th>
<th>CONSTRUCT</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Regulatory authority hinders clinical research in South Africa</td>
<td>25</td>
</tr>
<tr>
<td>2</td>
<td>Regulatory authority enables clinical research in South Africa</td>
<td>5</td>
</tr>
</tbody>
</table>

Figure 10: Frequency graph of the different constructs arising from the regulatory environment sub-proposition:
A respondent sector analysis of the two constructs (Table 2 and Figure 11) shows that the majority of investigator sites, local pharmaceutical companies, global pharmaceutical companies, local and global clinical research organisations and other stakeholders were of the opinion that the regulatory authority (MCC) hinders clinical research in South Africa. Regretably, no response was received from the MCC itself. This could have been a useful self-assessment gauge of how the MCC thinks they are performing.

Table 2: Sector analysis of the different constructs: regulatory authority

<table>
<thead>
<tr>
<th>SECTOR ANALYSIS</th>
<th>CONSTRUCT</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator site</td>
<td>Regulatory authority enables clinical research in South Africa</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Regulatory authority hinders clinical research in South Africa</td>
<td>5</td>
</tr>
<tr>
<td>Pharmaceutical Company (Local)</td>
<td>Regulatory authority enables clinical research in South Africa</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Regulatory authority hinders clinical research in South Africa</td>
<td>4</td>
</tr>
<tr>
<td>Pharmaceutical Company (Global)</td>
<td>Regulatory authority enables clinical research in South Africa</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Regulatory authority hinders clinical research in South Africa</td>
<td>4</td>
</tr>
<tr>
<td>CRO (Local)</td>
<td>Regulatory authority enables clinical research</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Regulatory authority hinders clinical research</td>
<td>3</td>
</tr>
<tr>
<td>CRO (Global)</td>
<td>Regulatory authority enables clinical research</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Regulatory authority hinders clinical research</td>
<td>7</td>
</tr>
<tr>
<td>Government</td>
<td>There was no response to the survey request from the MCC representing the government.</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>Regulatory authority enables clinical research in South Africa</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Regulatory authority hinders clinical research in South Africa</td>
<td>1</td>
</tr>
</tbody>
</table>
Figure 11: Frequency graph of the regulatory environment per sector analysis
5.3.1.2 Government policy

The opinions of the respondents with regard to the impact of government policy in general, were solicited in the online survey by posing the following question:

- Does government policy, in general:
  - Enable clinical research in South Africa?
  - Hinder clinical research in South Africa?

Figure 12 represents the mind map of the key words or phrases used by the respondents.

![Mind map of strategy success: government policy](image-url)
These key words or phrases were further analysed to demonstrate the relevant emerging constructs. Table 3 and Figure 13 present the frequency count per construct.

As per Table 3 and Figure 13 below, the commonest response to the question of whether government policy enables/hinders clinical research in South Africa, was the construct: government policy, in general, enables clinical research in South Africa (frequency = 23). A minority of the respondents were of the opinion that government policy hinders clinical research in South Africa (frequency = 7).

Table 3: Rank order of the different constructs: government policy

<table>
<thead>
<tr>
<th>RANK ORDER</th>
<th>CONSTRUCT</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Government policy enables clinical research in South Africa</td>
<td>23</td>
</tr>
<tr>
<td>2</td>
<td>Government policy hinders clinical research in South Africa</td>
<td>7</td>
</tr>
</tbody>
</table>
Figure 13: Frequency graph of the different constructs arising from government policy

A sector analysis of the respondents different constructs (Table 4 and figure 14) revealed that investigator sites were equally divided on this question (frequency = 3). The majority of local pharmaceutical company respondents felt that government policy is enabling (frequency = 3). One respondent in this sector felt that the government policy was a hindrance. Global pharmaceutical respondents were marginally disposed towards the construct: government policy enables clinical research (frequency = 3). Two respondents in this sector felt that government policy was a hinderance. All of the local contract research respondents felt that government policy is enabling (frequency = 3).

An overwhelming majority of global contract research organisations felt that government policy is enabling (frequency = 6). A single respondent in this sector was of the opinion that government policy hinders clinical research in South Africa. No response was received from
government representatives. All the other remaining respondents were of the opinion that government policy enables clinical research in South Africa.

Table 4: A sector analysis of the different constructs: government policy

<table>
<thead>
<tr>
<th>SECTOR ANALYSIS</th>
<th>CONSTRUCT</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator site</td>
<td>Government policy enables research</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Government policy hinders research</td>
<td>3</td>
</tr>
<tr>
<td>Pharmaceutical Company (Local)</td>
<td>Government policy enables research</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Government policy hinders research</td>
<td>1</td>
</tr>
<tr>
<td>Pharmaceutical Company (Global)</td>
<td>Government policy enables research</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Government policy hinders research</td>
<td>2</td>
</tr>
<tr>
<td>CRO (Local)</td>
<td>Government policy enables research</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Government policy hinders research</td>
<td>0</td>
</tr>
<tr>
<td>CRO (Global)</td>
<td>Government policy enables research</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Government policy hinders research</td>
<td>1</td>
</tr>
<tr>
<td>Government</td>
<td>There was no response from the government representatives.</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>Government policy enables clinical research</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Government policy hinders clinical research</td>
<td>0</td>
</tr>
</tbody>
</table>
Figure 14: Frequency graph of government policy per sector analysis
5.3.1.3 Summary of proposition 1 findings

The major construct of the 2 discussion points are summarised in the table below:

Table 5: Summary of proposition 1 main findings

<table>
<thead>
<tr>
<th>Sub-proposition</th>
<th>Main construct that emerged</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory environment</td>
<td>The MCC (regulatory authority) hinders pharmaceutical clinical research in South Africa by delaying regulatory approval of clinical research applications</td>
</tr>
<tr>
<td>Government policy</td>
<td>Government policy enables pharmaceutical clinical research in South Africa</td>
</tr>
</tbody>
</table>

Discussion points around proposition 1 gave mixed responses. There was overwhelming consensus that the MCC hinders clinical research in South Africa. At the same time, the majority of respondents were of the opinion that government policy in general, enables clinical research in South Africa.

5.3.2 Proposition 2: Factor conditions are a problem within the pharmaceutical clinical research industry.

In order to address this proposition, issues relating to the recruitment of skilled workers and the general infrastructure in South Africa, were examined.

The online survey questions related to this proposition were aimed at assessing the ease of recruitment of skilled workers in the local clinical research industry. Additionally, opinions regarding the adequacy of the general infrastructure for the conduct of clinical research in South Africa, were solicited. Specifically, the following questions were asked and the respondents were given the specified options – they had to select one option:

- Recruitment of skilled workers is:
  - Easy
  - Difficult
  - Other
The general infrastructure for clinical research is:

- Severely lacking
- Inadequate
- Sufficient
- Excellent

The responses to the above questions will be discussed separately followed by an overall analysis in respect to this proposition statement.

5.3.2.1 Recruitment of skilled workers

The online survey tool collated the individual responses to whether the respondents thought it was easy or difficult to recruit skilled workers in the South African pharmaceutical clinical research industry. Table 6 and Figure 15 below present the frequency count per construct. The commonest response was the construct: recruitment of skilled workers is difficult (frequency = 21). A minority of respondents were of the opinion that recruitment of skilled workers is easy (frequency = 5). Four respondents selected the “other” category and their response was that there are different levels of skilled workers in the industry resulting in some being easy and others difficult to recruit.

Table 6: Rank order of the different constructs: recruitment of skilled workers

<table>
<thead>
<tr>
<th>RANK ORDER</th>
<th>CONSTRUCT</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Recruitment of skilled workers is difficult</td>
<td>21</td>
</tr>
<tr>
<td>2</td>
<td>Recruitment of skilled workers is easy</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>Other</td>
<td>4</td>
</tr>
</tbody>
</table>
Figure 15: Frequency graph of the different constructs arising from recruitment of skilled workers

5.3.2.2 General infrastructure for clinical research

Respondents’ answers to whether the general infrastructure for clinical research is severely lacking, inadequate, sufficient or excellent were collated by the online survey tool. These were grouped further and presented in Table 7 and Figure 16 below, which show the frequency count per construct. The most common response was that the general infrastructure in South Africa is sufficient for the conduct of clinical research (frequency = 20). The second most common response was that the general infrastructure in South Africa is inadequate (frequency = 8). This was followed by those who felt that the general
infrastructure is excellent (frequency = 2). No respondents were of the opinion that the general infrastructure is severely lacking (frequency = 0)

Table 7: Rank order of the different constructs: general infrastructure for clinical research

<table>
<thead>
<tr>
<th>RANK ORDER</th>
<th>CONSTRUCT</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>General infrastructure is sufficient</td>
<td>20</td>
</tr>
<tr>
<td>2</td>
<td>General infrastructure is inadequate</td>
<td>8</td>
</tr>
<tr>
<td>3</td>
<td>General infrastructure is excellent</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>General infrastructure is severely lacking</td>
<td>0</td>
</tr>
</tbody>
</table>

Figure 16: Frequency graph of the different constructs arising from the general infrastructure for clinical research

Figure 16: Frequency graph of the different constructs arising from the general infrastructure for clinical research
5.3.2.3 Summary of proposition 2 findings

The major constructs of the 2 discussion points are summarised in the table below:

Table 8: Summary of proposition 2 main findings

<table>
<thead>
<tr>
<th>Sub-proposition</th>
<th>Main construct that emerged</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment of skilled workers</td>
<td>Recruitment of skilled workers is difficult.</td>
</tr>
<tr>
<td>General infrastructure for clinical research</td>
<td>General infrastructure, for the conduct of pharmaceutical clinical research, is sufficient.</td>
</tr>
</tbody>
</table>

5.3.3 Proposition 3: Demand conditions within the South African pharmaceutical clinical research industry are poorly developed.

In order to assess this proposition, issues related to local customers were examined. Specifically the following questions were asked in the online survey:

- What is the proportion or percentage of locally funded versus globally funded studies?
- Do you think that the general public understands clinical research?

The results of the two different questions are discussed separately and then summarised overall with respect to the proposition statement.

5.3.3.1 Proportion/percentage of locally funded studies vs globally funded studies

The individual respondents’ responses to this question are summarised here-under. The raw data is contained in the attached survey report (on page 5). They show that the majority of the respondents were of the opinion that less than 10% of clinical research is locally funded (frequency = 13). This was followed by respondents who felt that between 10 and 50% of
clinical research is locally funded (frequency = 7). One respondent was of the opinion that 100% of clinical research is locally funded. The rest of the respondents did not know the proportion/percentage of locally funded versus globally funded studies (frequency = 9).

5.3.3.2 Understanding of clinical research by the general public

The respondents were asked whether they thought the general public understands clinical research. The responses were collated and summarised. Figure 17 presents a mind map of the key words and phrases of the different respondents. The key words and phrases were analysed to determine the relevant emerging constructs. Table 9 and Figure 18 present the frequency count per construct. These graphics both demonstrate that the commonest response was the construct: the general public does not understand clinical research (frequency = 25). A small proportion of the respondents felt that the general public understands clinical research (frequency = 5).

Table 9: Rank order of the different constructs related to general public understanding of clinical research

<table>
<thead>
<tr>
<th>RANK ORDER</th>
<th>CONSTRUCT</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The general public does not understand clinical research</td>
<td>25</td>
</tr>
<tr>
<td>2</td>
<td>The general public understands clinical research</td>
<td>5</td>
</tr>
</tbody>
</table>
Figure 17: Mind map of strategy success related to general public understanding of clinical research
A respondent sector analysis of the two constructs (Table 10 and Figure 19) revealed that the majority of the respondents in all sectors were of the opinion that the general public does not understand clinical research. Unfortunately, no response was received from government officials.
Table 10: Sector analysis of the different constructs arising from general public understanding of clinical research

<table>
<thead>
<tr>
<th>SECTOR ANALYSIS</th>
<th>CONSTRUCT</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator sites</td>
<td>General public understands clinical research</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>General public does not understand clinical research</td>
<td>5</td>
</tr>
<tr>
<td>Pharmaceutical</td>
<td>General public understands clinical research</td>
<td>1</td>
</tr>
<tr>
<td>Company (Local)</td>
<td>General public does not understand clinical research</td>
<td>3</td>
</tr>
<tr>
<td>Pharmaceutical</td>
<td>General public understands clinical research</td>
<td>2</td>
</tr>
<tr>
<td>Company (Global)</td>
<td>General public does not understand clinical research</td>
<td>3</td>
</tr>
<tr>
<td>CRO (Local)</td>
<td>General public understands clinical research</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>General public does not understand clinical research</td>
<td>4</td>
</tr>
<tr>
<td>CRO (Global)</td>
<td>General public understands clinical research</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>General public does not understand clinical research</td>
<td>6</td>
</tr>
<tr>
<td>Government</td>
<td>There was no response from the governments MCC representing the Deptart of Health</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>General public understands clinical research</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>General public does not understand clinical research</td>
<td>5</td>
</tr>
</tbody>
</table>
Figure 19: Frequency graph of the general public’s understanding of clinical research per sector.
5.3.3.3 Summary of proposition 3 findings

The major construct of the two discussion points are summarised below.

Table 11: Summary of proposition 3 findings

<table>
<thead>
<tr>
<th>SUB - PROPOSITION</th>
<th>MAIN CONSTRUCT THAT EMERGED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion /percentage of locally versus globally funded studies</td>
<td>The majority of clinical research is funded by global companies as opposed to local organisations</td>
</tr>
<tr>
<td>Understanding of clinical research by the general public</td>
<td>The general public does not understand clinical research</td>
</tr>
</tbody>
</table>

All the discussion points around proposition 3 gave a negative response. This shows that the majority of the respondents are of the opinion that demand conditions with the South African pharmaceutical clinical research industry, are poorly developed.

5.3.4 Proposition 4: Firm rivalry is poorly developed in the South African pharmaceutical clinical research industry

In order to assess the above proposition, issues related to competitor focus were examined. Specifically the following question was asked in the online survey:

- In the South African clinical research industry:
  - Local competition exists for clinical research
  - The focus is on competing internationally for studies

Respondents were requested to select one of two options in this question.

The pie chart below demonstrates that the most common response was that the focus is on competing internationally for studies (60%). The second construct that the local competition exists for clinical research had a response rate of 40%. This means that the majority of respondents in all sectors felt that South Africa has less local versus international competition.
The discussion points around proposition 4 gave a negative response in respect of rivalry attributes of Porter’s diamond model. This means that the majority of the respondents are of the opinion that firm rivalry is poorly developed in the South African pharmaceutical clinical research industry.

![Figure 20: Respondents’ response regarding local vs international focus for competition](image)

5.3.5 Proposition 5: There is no deficiency in related and supporting sectors for the South African pharmaceutical clinical research industry.

Issues related to networking, sourcing of equipment and supporting services were examined in order to assess the above proposition. Specifically the following questions were asked in the online survey:

- In your opinion:
  - The local clinical research industry is fragmented
  - A strong network with other organisations exist

Respondents were requested to select one option.
• Is it:
  - Easy to source equipment and clinical research services in South Africa?
  - Difficult to source equipment and clinical research services in South Africa?

Respondents were requested to select one option from the two.

The results of the respondents’ responses are discussed separately below followed by an overall analysis in respect to the proposition statement.

5.3.5.1 Sourcing of equipment and related clinical research services

The online survey tool collated the individual responses to whether it was easy or difficult to source equipment and clinical research services in South Africa. The pie chart below presents the results to this question.

![Pie chart showing 63% easy to source and 37% difficult](chart.png)

Figure 21: Sourcing of equipment and related clinical research services

63% of all the respondents were of the opinion that it is easy to source equipment and clinical research services whilst 37% of respondents felt that it was difficult to source equipment and clinical research services in South Africa.
5.3.5.2 Networking
The results of the respondents’ answers to whether the local clinical research industry is fragmented or whether a strong network with other organisations exists, are presented in the pie chart below. Respondents were equally divided in their views on this question.

![Pie chart showing 50% of respondents believe the clinical research industry is fragmented and 50% believe there is a strong network with other organisations.](image)

Figure 22: Networks in the South African clinical research industry

5.3.5.3 Summary of proposition 5 findings
The major outcomes of the above discussion points are summarised in Table 12 below.

<table>
<thead>
<tr>
<th>SUB - PROPOSITION</th>
<th>MAIN CONSTRUCT THAT EMERGED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sourcing of equipment and clinical research services in South Africa</td>
<td>It is easy to source equipment and clinical research services</td>
</tr>
<tr>
<td>Networking</td>
<td>It is not clear whether the local clinical research is fragmented or if a strong network with other organisations exists</td>
</tr>
</tbody>
</table>

5.3.6 Proposition 6: The single most important factor that affects clinical research in South Africa is the MCC (regulatory authority)
This issue was examined by asking the respondents what they thought is the single most important factor that affects clinical research in South Africa. This question was posed
through the online survey. The respondents’ responses were summarised. Figure 23 presents a mind map of the key words or phrases used by the different respondents.

Figure 23: Mindmap of strategy success related to the single most important factor that affects clinical research in South Africa

These key words or phrases were analysed to determine the relevant emerging constructs. Table 13 and Figure 24 present the frequency count per construct. They show that the commonest response was the construct: MCC approval timelines are the single most important factor affecting clinical research in South Africa (frequency = 17).
The second most common construct that emerged was that lack of doctors experienced in clinical research is the single most important factor affecting clinical research in South Africa (frequency 6). 5 respondents felt that recruitment of patients into clinical trials is the single most important factor whilst one respondent thought it was cost.

Table 13: Rank order of the different constructs related to the single most important factor affecting clinical research in South Africa

<table>
<thead>
<tr>
<th>RANK ORDER</th>
<th>CONSTRUCT</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>MCC Approval Timelines</td>
<td>17</td>
</tr>
<tr>
<td>2</td>
<td>Lack of doctors experienced in clinical research</td>
<td>6</td>
</tr>
<tr>
<td>3</td>
<td>Patient recruitment</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>Cost</td>
<td>1</td>
</tr>
</tbody>
</table>
Figure 24: Frequency graph of the different constructs arising from the single most important factor affecting clinical research in South Africa

A respondent sector analysis of the 4 emerging constructs showed that investigator sites, global pharmaceutical companies, local and global contract research organisations were of the opinion that the MCC approval timelines is the single most important factor affecting clinical research in South Africa. Whereas, local pharmaceutical companies felt that both the MCC approval timelines and patient recruitment were equally important factors affecting clinical research in South Africa. However, other stakeholders in the industry were of the opinion that shortage of doctors experienced in the conduct of clinical research was the single most important factor affecting clinical research in South Africa.
Table 14: Sector analysis of the different constructs arising from the single most important factor affecting clinical research in South Africa

<table>
<thead>
<tr>
<th>SECTOR ANALYSIS</th>
<th>CONSTRUCT</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator site</td>
<td>MCC approval timelines</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Shortage of doctors</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Patient recruitment</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Cost</td>
<td>1</td>
</tr>
<tr>
<td>Pharmaceutical</td>
<td>MCC approval timelines</td>
<td>2</td>
</tr>
<tr>
<td>Company (Local)</td>
<td>Shortage of doctors</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Patient recruitment</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Cost</td>
<td>0</td>
</tr>
<tr>
<td>Pharmaceutical</td>
<td>MCC approval timelines</td>
<td>4</td>
</tr>
<tr>
<td>Company (Global)</td>
<td>Shortage of doctors</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Patient recruitment</td>
<td>1</td>
</tr>
<tr>
<td>CRO (Local)</td>
<td>MCC approval timelines</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Shortage of doctors</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Patient recruitment</td>
<td>0</td>
</tr>
<tr>
<td>CRO (Global)</td>
<td>MCC approval timelines</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Shortage of doctors</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Patient recruitment</td>
<td>1</td>
</tr>
<tr>
<td>Government</td>
<td>There was no response from the MCC representing the Department of Health</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>MCC approval timelines</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Shortage of doctors</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Patient recruitment</td>
<td>0</td>
</tr>
</tbody>
</table>
Figure 25: Frequency graph of the different constructs arising from the single most important factor affecting clinical research per sector analysis.
5.3.6.1 Summary of proposition 6 findings

The major constructs of proposition 6 discussion points are summarised in the table below.

Table 15: Summary of proposition 6 findings

<table>
<thead>
<tr>
<th>SUB - PROPOSITION</th>
<th>MAIN CONSTRUCT THAT EMERGED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single most important factor affecting clinical research in South Africa</td>
<td>MCC approval timelines</td>
</tr>
<tr>
<td></td>
<td>Shortage of doctors experienced in clinical research</td>
</tr>
<tr>
<td></td>
<td>Patient recruitment</td>
</tr>
<tr>
<td></td>
<td>Cost</td>
</tr>
</tbody>
</table>

5.3.7 Proposition 7: South Africa’s competitiveness can be improved by improving MCC approval timelines, establishment of a patient database, and by focussing on skills development and training

Proposition 7 was examined by asking the respondents how they thought South Africa’s competitiveness could be improved.

The respondents’ responses were collated and summarised. Figure 26 presents a mind map of the key words or phrases used by the different respondents. These key words or phrases were analysed to determine the relevant emerging constructs.
Figure 26: Mind map of strategy success related to how South Africa’s competitiveness can be improved
Table 16 and Figure 27 present the frequency count per construct. They show that the most common response was the construct: improve MCC approval timelines (frequency= 20). The second most common response was the construct: establish a patient database (frequency = 7) and the least common response was: focus on skills development and training (frequency = 3).

Table 16: Rank order of the different constructs related to how South Africa’s competitiveness can be improved

<table>
<thead>
<tr>
<th>RANK ORDER</th>
<th>CONSTRUCT</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Improve MCC Approval Timelines</td>
<td>20</td>
</tr>
<tr>
<td>2</td>
<td>Establish a patient database</td>
<td>7</td>
</tr>
<tr>
<td>3</td>
<td>Skills development and Training</td>
<td>3</td>
</tr>
</tbody>
</table>
Figure 27: Frequency graph of the different constructs arising from how South Africa’s competitiveness can be improved

A respondent sector analysis of the 3 emerging constructs demonstrated that all sectors were of the opinion that South Africa’s competitiveness would be improved if MCC timelines were improved (Table 17 and Figure 28 below).
Table 17: Sector analysis of the different constructs related to the improvement of South Africa’s competitiveness

<table>
<thead>
<tr>
<th>SECTOR ANALYSIS</th>
<th>CONSTRUCT</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator site</td>
<td>Improve MCC Approval Timelines</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Establish a patient database</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Skills development and Training</td>
<td>1</td>
</tr>
<tr>
<td>Pharmaceutical</td>
<td>Improve MCC Approval Timelines</td>
<td>2</td>
</tr>
<tr>
<td>Company (Local)</td>
<td>Establish a patient database</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Skills development and training</td>
<td>0</td>
</tr>
<tr>
<td>Pharmaceutica</td>
<td>Improve MCC Approval Timelines</td>
<td>5</td>
</tr>
<tr>
<td>Company (Global)</td>
<td>Establish a patient database</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Skills development and training</td>
<td>2</td>
</tr>
<tr>
<td>CRO (Local)</td>
<td>Improve MCC Approval Timelines</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Establish a patient database</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Skills development and training</td>
<td>0</td>
</tr>
<tr>
<td>CRO (Global)</td>
<td>Improve MCC Approval Timelines</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Establish a patient database</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Skills development and training</td>
<td>0</td>
</tr>
<tr>
<td>Government:</td>
<td>There was no response from the MCC representing the Department of Health in the government.</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>Improve MCC Approval Timelines</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Establish a patient database</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Skills development and training</td>
<td>0</td>
</tr>
</tbody>
</table>
Figure 28: Frequency graph of the different constructs arising from how South Africa’s competitiveness can be improved
5.3.7.1 Summary of proposition 7 findings

The major constructs of proposition 7 discussion points are summarised in the table below.

Table 18: Summary of proposition 7 findings

<table>
<thead>
<tr>
<th>SUB - PROPOSITION</th>
<th>MAIN CONSTRUCT THAT EMERGED</th>
</tr>
</thead>
<tbody>
<tr>
<td>How can South Africa’s competitiveness be improved</td>
<td>Improving MCC approval Timelines</td>
</tr>
<tr>
<td></td>
<td>Establishment of a patient database</td>
</tr>
<tr>
<td></td>
<td>Focus on skills development and training</td>
</tr>
</tbody>
</table>

5.3.8 Proposition 8: South Africa compares well with other emerging markets (like China and India) in the clinical research industry

One of this research study’s objectives was to explore the competitiveness of the South African pharmaceutical clinical research industry compared to other key emerging markets like India and China.

The issue was examined by questioning respondents and soliciting their perception of how South Africa fares. Specifically, the following question was asked:

- How does South Africa compare to other emerging markets (like China and India) in the clinical research industry:
  - Poor performance
  - On an equal footing
  - Better performance

Respondents were requested to select 1 of the 3 responses above. Their answers were collated and summarised. The pie chart below (figure 29) presents the results to this question. 47% of all the respondents felt that South Africa’s competitiveness was as good as other emerging markets like China and India. 33% of respondents thought that South Africa
was performing better that other emerging market whilst 20% were of the opinion that South Africa performs poorly compared to other emerging markets.

![Chart showing respondents perception of South Africa’s performance compared to other emerging markets](chart.png)

Figure 29: respondents perception of South Africa’s performance compared to other emerging markets (like China and India)

5.3.8.1. **Summary of proposition 8 findings**

The major outcome of proposition 8 discussion points is summarised in the table below.

<table>
<thead>
<tr>
<th>SUB - PROPOSITION</th>
<th>MAIN CONSTRUCT THAT EMERGED</th>
</tr>
</thead>
<tbody>
<tr>
<td>South Africa’s competitiveness compared to other emerging markets</td>
<td>South Africa’s performance is as good or better than other emerging markets like China</td>
</tr>
</tbody>
</table>
6 Research Discussion

6.1 Introduction

In this section, interpretation of the findings highlighted in the previous section, is provided. The results applied to Porter’s Diamond framework are analysed and the strengths and weaknesses of the South African pharmaceutical clinical research industry are identified and addressed. The analysis is presented under the same headings (propositions) as the previous section - each proposition and research question is discussed separately.

6.2 Demographic data

Three sets of demographic variables were considered important for obtaining a good assessment of the South African pharmaceutical clinical research industry.

The first demographic variable was sector analysis. The key stakeholders were identified as investigator sites, local and global pharmaceutical companies, local and global contract research organizations, government and others (which included clinical research laboratories, industry trade organisations and dedicated clinical research units). A broadly representative sample of these groups of role-players was obtained and was considered important in view of the fact that the study focused on the competitiveness of an industry. The second demographic variable that was considered was years involved in their current role or a total in the clinical research industry. This variable is used to confirm validity and reliability of the data collected. According to the results, the majority of the respondents have been involved in the industry for a considerable number of years, with 27% with more than 10 years experience. All sectors were represented by experienced managers and executives.

The third demographic variable was seniority. This demographic variable was collected to ensure that the respondents were suitably experienced and able to provide a holistic appraisal of the industry. There was a chairman of the board, a CEO, 37% were directors and 30% of the respondents were senior managers. A disadvantage for this study was that not all levels of employment in the industry were considered.

6.3 Proposition 1: The regulatory environment hinders pharmaceutical clinical research in South Africa.

Each clinical trial has to be approved by the regulatory authority prior to its execution (the MCC). Therefore, the MCC plays a crucial role in the conduct of clinical research in South Africa. Additionally, general government policy contributes to whether an enabling
environment exists for the competitive conduct of clinical research in South Africa. Each of these variables were assessed independently.

6.3.1 Regulatory authority
Main Construct: The MCC hinders pharmaceutical clinical research in South Africa by delaying regulatory approval of clinical research applications

The overwhelming response from respondents was that the MCC is a major hindrance to the competitiveness of the pharmaceutical clinical research industry. The following are some of the quotations from the respondents’ comments:

“Delays in approval have cost clinical research stakeholders a lot of money”

“Delays in approval puts South Africa in the backline for conducting global clinical research”

“Delays in approval results in delayed start resulting in restricted patient recruitment”

“Long regulatory approval timelines makes it difficult for SA to compete”

6.3.2 Government policy
Main Construct: Government policy enables pharmaceutical clinical research in South Africa

In contrast to the above, a large majority of the respondents were of the opinion that government policy, in general, enables clinical research in South Africa, substantiated by the following:

“There is a tax incentive”

“The D T I has great support for the research industry”

“We have suitable laws and guidelines in place”

“There is a lot of support from government especially for locally funded research”

“High standards of ethics and protection of patients”
6.3.3 Summary of Proposition 1 findings

The slow MCC approval timelines have been identified as a significant factor that is negatively affecting the competitiveness of pharmaceutical clinical research in South Africa. If these were improved, competitiveness would be greatly enhanced.

Although the MCC is situated within the government (Department of Health), this did not prevent the respondents in recognizing that government policy in general was a factor that was positively affecting the competitiveness of the industry.

6.4 Proposition 2: Factor conditions are a problem within the pharmaceutical clinical research industry

Porter (1990) states that nations succeed in industries in which they are good at factor creation. Factor conditions include skills and physical infrastructure levels within a particular industry. The results indicated that this attribute of the Porter Diamond model was weak in South Africa’s pharmaceutical clinical research industry.

6.4.1 Skills

*Main Construct: recruitment of skilled workers within the industry is difficult.*

The majority of the respondents were of the opinion that it is difficult to recruit skilled workers in the industry. Because pharmaceutical clinical research is in the service industry, it relies upon skilled workers for the conduct of its business. Difficulty in recruiting skilled staff is a factor that negatively affects the competitiveness of South Africa’s pharmaceutical clinical research industry.

6.4.2 General infrastructure for clinical research

*Main construct: general infrastructure for the conduct of pharmaceutical clinical research is sufficient*

The most frequently cited response was that the general infrastructure is sufficient. Pharmaceutical clinical research requires transport of samples, medication and other clinical research supplies from the suppliers to the service providers. Often, the suppliers are based abroad whilst the service providers are in South Africa. Therefore, sufficient general infrastructure is a factor that positively affects the competitiveness of pharmaceutical clinical research in South Africa.
6.4.3 Summary of Proposition 2 findings
Workers skilled in all levels of pharmaceutical clinical research are required in order for South Africa to optimize its competitiveness in this industry. However, South Africa possesses an infrastructure that is generally regarded as being sufficient. Although the impact of the sufficient general infrastructure is positive, the difficulty in recruiting skilled workers results in factor conditions being problematic for this industry in South Africa.

6.5 Proposition 3: Demand conditions within the South African pharmaceutical clinical research industry are poorly developed.
As discussed previously, Porter, 1990 states that nations succeed in industries where they are particularly good at demand conditions. Demand conditions include:

- The needs of the local consumer of pharmaceutical clinical research
- The size and pattern of growth opportunities in the market for pharmaceutical clinical research
- The mechanism through which a nation’s domestic preference for pharmaceutical clinical research can be transferred to foreign markets.

The survey results show that this attribute of the Porter Diamond model is weak in South Africa’s pharmaceutical clinical research industry. The proportion/percentage of locally versus globally funded studies and the understanding of clinical research by the general public, were the two variables used to assess this attribute and both were found to be weak within the industry in South Africa.

6.5.1 Proportion/percentage of locally funded vs globally funded studies
*Main construct: The majority of clinical research is funded by global companies as opposed to local organizations*

The majority of the respondents were of the opinion that less than 10% of pharmaceutical clinical research is funded locally. Most of the pharmaceutical clinical research is globally funded. This means that the clinical research agenda is driven by global companies as opposed to local needs and this weakens the local industry competitiveness.
6.5.2 Understanding of clinical research by the general public

*Main construct: The general public does not understand clinical research*

Human subjects are critical in the conduct of clinical research. It is important that the general public has an accurate understanding of clinical research in a country, so that potential participants are comfortable with participating in these studies. Misunderstanding has a negative effect on the competitiveness of this industry in South Africa. Respondent comments included:

“*News headlines from trials gone wrong influences the public’s perception that trials are unsafe and exploitative*”

“There is a general misinformation and misconception with regards to clinical research”

“General public still perceives clinical research as a dark and sinister world of science fiction in laboratories

“Health literacy, in general, in South Africa is not good. Clinical research is a complex concept”

“Majority of the population are not well educated to understand scientific terminology “

6.5.3 Summary of Proposition 3 findings

The majority of clinical research is funded by global companies, driven by their own scientific and commercial agendas. Very little clinical research is funded locally. Additionally, the South African general public has a poor understanding of clinical research. All these factors have a negative effect on the competitiveness of clinical research in South Africa.

6.6 Proposition 4: Firm rivalry is poorly developed in the South African pharmaceutical clinical research industry

*Main construct: Local competition is weak, the focus is on international competitors*

The most frequent response by the respondents was that the focus is on competing internationally for studies. This means that the majority of respondents are of the opinion that firm rivalry is poorly developed in the South African pharmaceutical clinical research
industry. Poor local firm rivalry has a negative effect on the competitiveness of the industry in South Africa.

6.6.1 Summary of Proposition 4 findings
The findings support the proposition that firm rivalry is poorly developed in the South African pharmaceutical clinical research industry. Poor local firm rivalry has a negative effect on the competitiveness of the industry in South Africa.

6.7 Proposition 5: There is no deficiency in related and supporting sectors for the South African pharmaceutical clinical research industry.

The pharmaceutical clinical research industry is a highly specialised industry requiring highly specialized equipment and supporting clinical research services like laboratories, data management and monitoring. This proposition explores whether supporting industries for pharmaceutical clinical research exist in South Africa and whether networks exist within the local industry.

6.7.1 Sourcing of equipment and related clinical research services

Main construct: It is easy to source equipment and clinical research services in South Africa
Most respondents were of the opinion that it is easy to source equipment and clinical research services in South Africa. This is a factor that encourages the conduct of clinical research and exerts a positive influence on the competitiveness of the local industry.

6.7.2 Networking

Main construct: it is not clear whether the local clinical research industry is fragmented or if a strong network with other organizations exists

Respondents were equally divided in their responses to questions regarding this proposition. It is, therefore, difficult to assess the impact of this factor on the competitiveness of the local industry.

6.7.3 Summary of Proposition 5 findings
The study found that although it is easy to source equipment and other supporting clinical research services, it is unclear whether the local industry is fragmented or if a strong network with other local organisations exists.
Overall the findings from the respondents show that there is no deficiency in related and supporting sectors for the South African pharmaceutical clinical research industry. This factor has a positive impact on the competitiveness of the local industry.

6.8 Proposition 6: The single most important factor that affects clinical research in South Africa is the MCC (regulatory authority)

Main construct: The single most important factor affecting clinical research in South Africa

This exploratory study solicited the respondents’ opinions regarding the single most important factor affecting pharmaceutical clinical research in South Africa. The overwhelming response was that delayed MCC approval timelines is the single important factor. Lack of doctors with experience in clinical research was a distant second followed by challenges in recruiting patients into clinical trials. A single respondent thought that high cost was the single most important factor. Unfortunately, MCC representatives did not respond to the request for completion of the survey. It would have been telling to see what the MCC regards as the single most important factor. The following are comments postulated by some of the respondents regarding this construct:

“South Africa is most of the time the last country to receive regulatory approval”

“Improvement in MCC approval timelines will result in increased business”

“Regulatory timelines are to variable and too long”

6.8.1 MCC Approval timelines

The majority of the respondents consistently identified delayed, variable and unpredictable MCC approval timelines as the major factor that is negatively affecting the competitiveness of the local pharmaceutical clinical research industry. Some of the causes identified by the survey included the outdated structure of the MCC, reliance on part-time (mainly academic) reviewers who are grossly underpaid and poor administrative systems within the MCC.

6.8.2 Shortage of doctors experienced in the conduct of clinical research

The vast majority of clinical trials are conducted in the private sector where there are fewer patients (as a percentage of the whole population) compared to the public sector. The public sector has the patients but lacks the focus and capacity to conduct commercial clinical trials. As a result, a small number of doctors are experienced in the conduct of clinical research and those are based in the private sector. Additionally, a very small number of doctors from historically disadvantaged groups have the experience required for conducting clinical trials.
20% of the respondents identified this construct as the single most important factor affecting clinical research in South Africa. The following are some of the comments registered by the respondents:

“Not enough doctors experienced in conducting clinical research”

“We cannot provide enough experienced sites to complete with Eastern Europe and Asia”

6.8.3 Patient recruitment
16.75% of respondents identified challenges with recruiting patients into clinical trials as the single most important factor affecting clinical research in South Africa. This is likely to be due to the fact that private sector clinical research facilities (who perform the majority of clinical trials) struggle to gain access to public sector patients who are in the majority in South Africa. Some of the respondents comments about this construct included:

“Recruitment of patients is a major factor”

“Lack of interest by patients due to misinformation”

6.8.4 Cost
3.33% of respondents were of the opinion that the higher costs (compared to other emerging markets) of conducting clinical research in South Africa is the single most important factor affecting clinical research in South Africa.

6.8.5 Summary of Proposition 6 findings
An overwhelming majority of respondents identified MCC approval timelines as the single most important factor negatively affecting the competitiveness of the South African pharmaceutical clinical research in South Africa. This was followed by shortage of doctors experienced in clinical research, challenges with recruiting patients into clinical trials and relatively higher costs.
6.9 Proposition 7: South Africa’s competitiveness can be improved by improving MCC approval timelines, establishment of a patient database, and by focusing on skills development and training

This exploratory study solicited suggestions from the respondents as to how the local industry competitiveness could be improved. There were 3 main constructs that emerged under this proposition. Respondents were of the opinion that industry competitiveness could be improved by improving MCC approval timelines, establishing a patient database from which patients could be recruited into clinical trials and by focusing on skills development and training, particularly of historically disadvantaged population groups in order to expand the skills base.

6.9.1 Improve MCC approval timelines

66.7% of respondents felt that improving MCC approval timelines would greatly improve the local industry competitiveness. Some of the suggestions included:

“Restructure or privatise the regulatory authority (MCC)”

“A 28 day clinical trial application turn around”

6.9.2 Establish a patient database

23.3% of respondents thought that the establishment of a patient database would positively affect the competitiveness of the South African pharmaceutical clinical research industry. Suggestions included:

“Set up a database of patient information which can be reviewed for potential patients”

“Better access to patient data which must be kept on a central database”

6.9.3 Skills development and training

10% of respondents were of the opinion that focusing on skills development and training would positively affect the competitiveness of the local industry. Suggestions included:

“Training of previously disadvantaged doctors to widen experience and expand access”

“Offer further education programmes in clinical research in tertiary institutions”
6.8 Summary of the main research findings using Porter’s Diamond model and highlighting deficiencies

<table>
<thead>
<tr>
<th>Proposition</th>
<th>Competitiveness level</th>
<th>Major Deficiencies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory environment</td>
<td>Below average</td>
<td>Regulatory authority hinders pharmaceutical clinical research in South Africa.</td>
</tr>
<tr>
<td>Factor conditions</td>
<td>Average</td>
<td>Recruitment of skilled workers is difficult in South Africa.</td>
</tr>
<tr>
<td>Demand conditions</td>
<td>Below average</td>
<td>The general South African public does not understand clinical research. Customers are based overseas and there is a lack of local entrepreneurial culture.</td>
</tr>
<tr>
<td>Firm rivalry</td>
<td>Below average</td>
<td>There is no local competition. The focus is on competing internationally for clinical research projects</td>
</tr>
<tr>
<td>Supporting industries</td>
<td>Above average</td>
<td>It is not clear whether a strong network of local clinical research organisations exists or if the local clinical research industry is fragmented.</td>
</tr>
<tr>
<td>Proposition</td>
<td>Competitiveness level</td>
<td>Major Deficiencies</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>-----------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Single most important factor</td>
<td>Below average</td>
<td>The MCC has unduly long approval timelines and this reduces the competitiveness of the South African pharmaceutical research industry. A lack of doctors experienced in the conduct of clinical research. Challenges with patient recruitment into clinical trials</td>
</tr>
<tr>
<td>How can competitiveness be improved?</td>
<td>Average</td>
<td>Improving MCC approval timelines. Establishing a national patient database. Providing skills development and training</td>
</tr>
<tr>
<td>How does South Africa compare with other emerging markets?</td>
<td>Above average</td>
<td>There are no deficiencies identified – south Africa compares favourably</td>
</tr>
</tbody>
</table>

Table 20: Summary of the main research findings using Porter’s Diamond model and highlighting deficiencies
7 Recommendations

Porter’s Diamond model was used to identify the factors that affect competitiveness of the South African pharmaceutical clinical research industry. The main constructs that emerged were presented as propositions amounting to 8 propositions in total. The recommendations will also be presented under each proposition here-under.

7.1 Proposition 1: Recommendations related to the regulatory environment

The South African regulatory authority has been identified as the principal factor affecting clinical research in South Africa. It hinders the pharmaceutical clinical research industry due to its long and unpredictable approval timelines. The inefficiencies are mainly due to a chaotic administrative process and an outdated review process utilising part-time, mainly academic reviewers. The reviewers are grossly underpaid and conduct the reviews in their spare time. Therefore, a drastic change in the structure and function of the authority is required in order to enhance the competitiveness of the clinical research industry. The government has, for years, been bombarded by complaints from the industry about these approval timelines. A legislative process aimed at modernising the MCC was initiated in 2008 (Medicines and Related Substances Amendment Act, No. 72 of 2008: National Gazette No. 30985). At the time, the process was planned to take 2 years before a new body with dedicated review staff and a streamlined administrative process could be implemented. This process was delayed by the then Minister of Health’s insistence that she have the last word as far as approvals are concerned and wanted powers to veto any approval. Industry and the parliamentary standing committee had an issue with this and the bill had to be returned to parliament. The bill was due to be debated in the 2011 parliamentary session but no feedback has been received so far. It is, therefore, recommended that this legislative process be speeded up in order to facilitate the speedy introduction of a new regulatory body.

7.2 Proposition 2: Recommendations related to factor conditions

Recruitment of skilled workers was identified as being difficult in South Africa. This was found to be due to shortage of skilled individuals. There is no quick solution for this finding as it requires training. However, a large pool of doctors and other health professionals already exists in South Africa. It is recommended that these doctors and health professionals be made
aware of the benefits of clinical research as discussed previously. Those doctors who are interested should be trained by industry in issues pertinent to clinical research. The industry association (South African Clinical Research Association) has already started a campaign to encourage doctors to be trained in Good Clinical Practice, however this initiative needs to be accelerated and expanded to all provinces in South Africa.

7.3 Proposition 3: Recommendations related to demand conditions
The general South African public was found not understand clinical research. This was thought to be due to misinformation by the media. An extensive public education effort is, therefore, recommended. Recently, there have been positive media reports about clinical trials. This was due to important advances in the treatment and prevention of serious illnesses like HIV/AIDS. However, a more concerted effort is required and this will be costly. The suggested driver for this process is the South African Clinical Research Association (SACRA) as it can leverage the different stakeholders and the media.

Under this proposition, clinical research customers were found to be based, mainly, overseas. The clinical trials that are sponsored by these companies are largely driven by the health needs of their own countries although the MCC is careful not to approve clinical research with products that will not be marketed in South Africa in future. The fact that customers are based overseas weakens South Africa’s own clinical research agenda and negatively impacts competitiveness. It is recommended that the local pharmaceutical industry be strengthened with support from government.

7.4 Proposition 4: Recommendations related to firm rivalry
Because there is little local competition, the focus is on competing internationally for clinical research projects. This proposition speaks to minimal local pharmaceutical activity identified above. Once the local pharmaceutical industry as a whole is invigorated, then local competition would increase.

7.5 Proposition 5: Recommendation related to supporting sectors
It was not clear from the research whether a strong network of local clinical research organisations exists or if the local clinical research industry is fragmented. It is recommended that local networking activities be strengthened. The recommended go-to stakeholder for promoting networking activities is the South African Clinical Research Association.
(SACRA). Established companies and experienced individuals are already active in this organisation but it is recommended that new roleplayers (like black doctors) be encouraged to participate. Mailshots should be sent to potential participants, highlighting the benefits of participating in SACRA activities.
The local industry is encouraged to maintain the high quality standards of its equipment and clinical research services.

7.6 Proposition 6: Recommendations related to the single most important factor affecting the local industry competitiveness

The study identified 3 factors under this proposition which are:

1. the Medicines Control Council of the Department of Health (MCC) has unduly long approval timelines and this reduces the competitiveness of the South African pharmaceutical research industry. As it discussed above, it is recommended that the structure and function of the MCC be modernised

2. challenges related to patient recruitment into clinical trials. An extensive public education initiative, as recommended above, will help inform the general public about clinical research and possibly improve the number of patient participants

3. a shortage of doctors experienced in the conduct of clinical research (especially those from historically disadvantaged backgrounds) was also identified as a key factor. The recommendation here is for awareness campaigns targeting these doctors followed by practical training in clinical research.

7.7 Proposition 7: How South Africa’s competitiveness could be improved

The following factors were identified by this study as recommendations for improving South Africa’s competitiveness in the pharmaceutical clinical research industry:

a. Improve MCC approval timelines.

b. Establish a national patient database.

c. Provide skills development and training
7.8 Proposition 8: South Africa compares well with other emerging markets

This study found that South Africa compares favourably to other emerging markets (like China and India) in the pharmaceutical clinical research industry. However, competitiveness would be greatly enhanced if the factors, that negatively impact the competitiveness of the local industry, could be urgently addressed as discussed in preceding sections.

8 Future Research

This exploratory study is intended to serve as a basis for more extensive research on this topic in future. Future research should focus on:

- A quantitative study of the sector using Porter’s Diamond model.
- A quantitative study to assess the financial impact of poor competitiveness
- Participants at all levels of the pharmaceutical clinical research industry.
- A more detailed study of the particular skills in short supply
- A study to describe the structure and function of the new, proposed, modernized regulatory authority

9 Conclusion

South Africa has a long and proud history of involvement in ethical, scientifically sound pharmaceutical clinical research. South Africa boasts a mature regulatory environment, experienced medical professionals of international standing, a world class general infrastructure, availability of high quality equipment and supporting clinical research services and (most importantly) a large pool of patients that are clinical trial naïve.

However, several deficiencies were identified and highlighted using Porter’s Diamond model of national industry competitiveness. These deficiencies included long and unpredictable regulatory approval timelines, poor capacity within the public sector, challenges with recruiting patients into clinical trials, shortage of doctors experienced in the conduct of clinical research (particularly those from historically disadvantaged backgrounds).

These deficiencies are amenable to a solution but this will require a concerted effort and collaboration amongst the industry stakeholders in collaboration with the government.
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