THE CLINICAL TRIALS INDUSTRY IN KENYA

Realities, Risks and Challenges
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GLOSSARY OF TERMS AND DEFINITIONS

**ARV:** Antiretroviral drugs. HIV is treated with antiretrovirals (ARVs), which work against the HIV infection by slowing down the spread of the virus in the body.

**AMREF:** African Medical and Research Foundation

**CDC:** Centers for Disease Control and Prevention

**DoH:** Declaration of Helsinki. The World Medical Association (WMA) developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

**EC:** Ethics Committee: A committee consisting of healthcare professionals and non-medical members, whose responsibility is to protect the rights, safety and wellbeing of human subjects involved in a clinical trial and to provide public assurance of that protection.

**FDA:** Food and Drug Administration (US)

**KAIS:** Kenya AIDS Indication Survey

**KEMRI:** Kenya Medical Research Institute

**KeNAAM:** The Kenya Alliance of NGOs Against Malaria

**KMA:** Kenya Medical Association

**MNC:** Multinational Corporation (including pharmaceutical companies)

**MTRH:** Moi Teaching and Referral Hospital

**Nuremberg Code:** A set of research ethics principles for human experimentation set as a result of the Subsequent Nuremberg Trials at the end of the Second World War.

**NCST:** National Council for Science and Technology

**NHIF:** National Health Insurance Fund

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**PHASE I trial:** A Phase I clinical trial is the first step in testing a new investigational medication (or new use of a marketed drug) in humans. Phase I studies are mainly concerned with evaluating a drug’s safety profile, including the safe dosage range.

**PHASE II trial:** Phase II clinical trials involve volunteers who have the disease or condition to be treated. These trials help physicians and researchers to learn more about the safety of the new drug treatment and how well the drug treats the targeted disease or condition.
**PHASE III trial:** Phase III clinical trials involve greater numbers of patients and are undertaken for the purpose of determining whether the medicine confers clinical benefit in the disease for which effectiveness was demonstrated in Phase II clinical trials. They also determine the nature and likelihood of any side effects.

**PPBK:** Pharmacy and Poisons Board of Kenya

**PRI:** Public Research Institutions

**TI:** Transparency International

**UNESCO:** The United Nations Educational, Scientific and Cultural Organization

**UNICEF:** The United Nations Children's Fund

**UHC:** Universal Health Coverage. Defined as ensuring that all people can use the promotive, preventive, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.

**WHO:** World Health Organisation
Clinical trials are increasingly taking place on the African continent. To date limited information about this trend is publicly available. This is the second report of Wemos in a series of two reports on clinical trials in Africa. The previous report, on clinical trials in South Africa, was published in July 2013. Wemos has been investigating the situation of clinical trial participants for the last seven years. We have already published reports on clinical trials in India, Russia, Poland, China, the United States (US) and Latin America. The reports form the basis for Wemos’ ongoing advocacy for the rights of clinical trial participants at a global level.

This research report aims to provide a clearer picture of the current situation of clinical research in Kenya. The country experiences a rapid economic growth and is increasingly becoming an international business destination. This contrasts sharply with the country’s high rates of poverty, a high burden of disease and a weak public healthcare system. These are elements, as we know from previous studies, that lead to vulnerable clinical trial participants. Wemos is concerned that Kenyans could be exposed to ethical violations if a closely monitored system of checks and balances is insufficiently in place.

It is our hope that this report will raise more awareness about the potential risks faced by vulnerable people from Kenya’s low-income communities taking part in clinical trials. People who, until now, remained hidden amongst the shadows and bureaucracy of the lucrative clinical research industry. Their right to knowledge and protection can no longer be ignored.

_Wemos, January 2014_
METHODOLOGY

This report is the culmination of three months (October–December 2013) of desk and field research in various locations across Kenya. The report is largely based on interviews with a number of Kenyan experts from the field of clinical research, ethics, healthcare and the media, all of whom have had involvement with the country’s clinical trial sector in recent years. The field research was primarily done over a three-week period in Kenya where interviews and information were gathered both in the capital Nairobi and in areas around the western port city of Kisumu where the majority of Kenya’s clinical trials are taking place.

The government’s Kenya Medical Research Institute (KEMRI) and the US-based Centers for Disease Control and Prevention (CDC) are two of the leading organisations approving, overseeing and conducting clinical trials in Kenya, but many other organisations, including all the major international pharmaceutical companies are gaining a foothold in Kenya. A number of employees from KEMRI were very generous with their time and were happy to contribute their thoughts, recommendations and concerns to this report. However, various authorities from other key organisations, including the CDC, the public Kenyatta National Hospital, and Kenya’s National Human Rights Commission on Human Rights (KNCHR), refused to answer our queries or grant us interviews. Therefore, as highlighted in this report, a number of important questions still remain unanswered. With this report we hope to encourage activists and the Kenyan media to ask further questions about pressing issues such as the safe and ethical recruitment of patients, the monitoring of clinical trial and post-trial access to healthcare.

Gathering initial information and getting an overview of the current situation in Kenya was immediately challenging. Due to a lack of time, resources and senior editorial endorsement, very few of the dynamic Kenyan media have investigated the clinical trials industry in any great detail. Difficulties in tracking down the trial patients and the bureaucratic and complex nature of the public information on websites and opaque databases provided by the key government agencies such as KEMRI and the Pharmacy and Poisons Board of Kenya (PPBK) have proved a deterrent to any meaningful investigation. Through websites such as ClinicalTrials.gov, it is relatively easy to get an overview of how many trials, testing for what kinds of diseases, are going on in Kenya. But finding out exactly who the trial sponsors are and where (and how) they are recruiting the patients, still remains difficult.

Throughout the course of the research, Wemos worked closely with a number of Kenyan journalists who had covered this issue in the past and who, through their networks, were able to access both senior health experts and grassroots activists with their fingers on the pulse of this growing, yet shadowy sector. In the slums of the western city of Kisumu, a local health activist, brought to our attention through a local radio journalist, was able to introduce our researcher to a middle-aged man and a young woman both of whom, for diverse reasons, had signed up for clinical trials. Through our face-to-face discussions with them, and a first hand look at their poverty-stricken and difficult environments, we were able to get an initial sense of the types of people being targeted for clinical research and the ethical violations and harm they could potentially be exposed to if strict monitoring procedures are not in place and/or maintained.
The information compiled in this report derives from background research, clearly indicated sources and direct interviews with people who are either quoted or paraphrased. The names of the two clinical trial patients have been changed to protect their identity, but they were fully aware of the nature of this research and gave their consent to take part. One of the patients also provided us with a copy of his signed consent form, which, along with his testimony and once translated from the local language, provided a useful insight into the current system of recruitment. A copy of this form is attached for reference (see Annex I). Despite some difficulties in terms of accessing information about clinical trials in Kenya, an investigative journalist, on behalf of Wemos, has endeavoured to source, verify and cross-check all the information presented to her, either in the form of written literature or verbal accounts. Please contact Wemos with any comments.
INTRODUCTION

International pharmaceutical companies are increasingly outsourcing drug trials to African countries. In this report we take a deep dive into the clinical trial landscape of one of these countries: namely Kenya. Kenya is a country of extremes. On the one hand, Kenya is well known for its beautiful landscape, pure wildlife, natural resources, and an expanding middle class. On the other hand, this country is also characterized by chronic poverty, corruption, and a high burden of diseases. Infectious diseases such as tuberculosis (TB) and HIV/AIDS are a major public health risk to the people. At the same time, the burden of non-communicable diseases (NCDs) is rising rapidly in Kenya, which presents an enormous challenge to the Kenyan healthcare system. In particular since the Kenyan public health sector is struggling heavily to deliver equitable access to quality and affordable healthcare. Today, many Kenyan people simply have no access to effective medicines or special treatments they may need.

It is against this background of poverty, limited access to healthcare, and the high prevalence rate of illnesses that an increasing number of clinical trials are taking place in Kenya. As Kenya quickly becomes one of the most popular testing grounds of Africa, different actors raise concerns that, due to insufficient public awareness, lack of monitoring by competent authorities, and lack of scrutiny by Non-Governmental Organisations (NGOs), and the Kenyan media, exploitation of trial participants could be going unchecked. This report sheds light on the serious risks and challenges involved when carrying out clinical trials in Kenya.

In the first chapter (1), we invite you to the east coast of Africa, to Kenya. We provide you an insight into the context of this country in which numerous clinical trials are taking place. Observations and interviews with medical professionals and health activists illustrate Kenya’s poignant poverty, as well as its increasing wealth, the country’s development issues, the current challenges in Kenya’s health and healthcare system, and its rapidly developing infrastructure. These are key factors that fuel the interest of pharmaceutical companies to expand their testing area to countries such as Kenya. In the second chapter (2), we set out the key reasons why East Africa and Kenya have become popular as clinical testing sites. Furthermore, we highlight the growing interest of the Kenyan government to become an important emerging player in the international pharmaceutical arena. Although the presence of pharmaceutical companies in Kenya is on the rise, the majority of clinical trials are still mainly managed through Public Research Institutions (PRIs). Therefore, at the end of this second chapter, we describe the three leading PRIs in Kenya.

In the next chapter, the third chapter (3), we explore the human side of the clinical trial industry in Kenya. We provide a description of the Kenyan clinical trials participants, address the motivation of clinical trial participants to take part in a trial, and elaborate on the short- and long-term benefits of a trial to both the participants and the country. In doing so, we pay special attention to the ethical questions that arise when clinical trials are carried out involving poverty-stricken people who are in an urgent need for healthcare.
Conversations with clinical trial researchers and Kenyan journalists, and testimonies from trial participants depict the potential for exploitation and risks for the participant, such as lack of compensation in case of injury, limited or no post-trial access to healthcare, and lack of informed consent. To prevent ethical malpractice, it is key that authorities involved have well-organized, effective and credible approval, registration, and monitoring policies in place. In the fourth chapter (4), we set out the different bodies, inter alia ethics committees, that are involved in the process of giving the green light of approval in Kenya. In addition, concerns, as well as positive developments, regarding the approval and monitoring process, patient consent, and compensation, expressed by clinical trial experts and journalists, are discussed. Hence, this chapter provides a good understanding of the ethical challenges and (public health) risks within the Kenyan clinical trial landscape. Chapter five (5) describes the lack of access to up-to-date information and basic public data about clinical trials and the limited public awareness about the fast expanding clinical trials industry in Kenya. In the final chapter (6), we look at the controversial issue of post-trial access to treatment; a long-term benefit for the trial participants. We address the question whether trial participants are granted access to healthcare and previously unaffordable medical treatments after participating in a trial. Finally, a brief conclusion is presented, summarizing the main outcomes of the report and the most striking issues regarding the clinical trial landscape in Kenya.
CHAPTER ONE:
‘Karibu Sana’ - Welcome to Kenya

Since gaining independence from Great Britain in 1963, the Republic of Kenya has steadily developed an international reputation as an attractive destination for tourists, the business community, and most recently the international humanitarian aid industry. With its tropical climate, beach resorts and abundance of unique wildlife, adventurous tourists continue to flock to Kenya, contributing significantly to the country’s profitable tourism industry.

Strategically located along the east coast of Africa and with good transport connections to the neighbouring countries of Ethiopia, Uganda, Tanzania, Sudan and Somalia, Kenya has become an important and practical hub for international business, trade and diplomacy. Over seventy different ethnic groups make up the country. The five largest Kikuyu, Luo, Luhya, Kamba and Kalenjin account for around seventy per cent. The predominant religion in Kenya is Christianity, which is practised by about four-fifths of the population. Other faiths practised in Kenya are Baha’i, Hinduism, Islam, and traditional African religions. In terms of size, Kenya is about 580,000 square kilometres, which is roughly comparable to the size of France.

With a fast growing population of almost forty million¹, Kenya has one of highest population growth rates in Africa. According to the United Nations (UN), Kenya’s population has almost doubled in the past 25 years², and is expected to continue to grow by three per cent annually. The capital Nairobi is currently home to around three million people and the urban population in other major cities such as Mombasa and Kisumu is rapidly expanding. Kenya’s overall urban population is currently estimated to be at around ten million. According to UNICEF, 75-80 per cent of Kenya’s population lives in the rural areas and largely relies on agricultural activities as a source of livelihood.

According to Kenya’s Treasury, the country’s market-based economy is now the largest in East Africa, currently valued at around $37 billion and forecast to grow as much as six per cent in 2013. Major investment in infrastructure, a large pool of English speaking professionals, high rates of computer literacy and relative political stability have been important factors underlying Kenya’s business appeal and significant economic growth over recent years. The government, currently headed by President Uhuru Kenyatta³, is generally perceived as investment friendly and has pushed through several regulatory reforms to simplify and encourage both foreign and local investment. The discovery of natural resources, notably oil and gas, combined with an expanding middle class, has led to further optimism that Kenya will continue to enjoy economic prosperity and international appeal.

The UN Office in Nairobi is the UN Headquarters for Africa and many major UN agencies, including the headquarters of the United Nations Environmental Organisation (UNEP), have a sizeable presence in the country’s capital. Alongside the many thousands of expatriate humanitarian workers is a sizeable diplomatic and foreign business community whose presence in Nairobi has sparked a lucrative boom in expensive shopping malls, coffee shops and private schools.

³ Uhuru Muigai Kenyatta (born 26 October 1961) is the fourth and the current President of Kenya. He has been in office since 9 April 2013.
Parallel worlds

But beyond the upbeat boardrooms, trendy coffee shops and luxurious safari lodges, another side of Kenya exists in parallel to the world displayed in the tourist brochures. In 2013, an estimated 1.4 million tourists are predicted to come to Kenya on vacation. But many of these visitors would probably be shocked to learn that around fifty per cent of Kenya’s population (over twenty million people) survives on less than one dollar a day, the price of two bottles of Coca Cola. Kenya’s economy may be booming, but it would seem that not everyone in Kenya is enjoying a slice of the national prosperity pie.

Kenya is still amongst the world’s poorest countries, ranking 145 out of 187 countries on the 2013 UNDP Human Development Index. Nearly half of the country’s forty million people live below the poverty line and are unable to meet their daily nutritional requirements. Chronic poverty in Kenya is caused and exacerbated by various factors, amongst them drought, food insecurity and lack of access to clean water - the UN has categorised Kenya as a chronically water-scare country, with statistics showing that an estimated seventeen million people in Kenya lack access to safe drinking water. Corruption is also widely cited as a key factor hindering humanitarian development in the country and a scourge, which undermines public services and the development of key infrastructure. According to Transparency International, the global corruption barometer, Kenya is currently ranked as the fourth most corrupt country in the world, only ahead of Sierra Leone, Liberia and Yemen.

Wealth and poverty live side by side in Kenya. Air conditioned 4x4s, high gated houses and the comfort of western style malls and restaurants enable those with financial security to go about their business without ever having to interact with the poverty around them. Just five kilometres from Nairobi city centre and a ten minute walk from Nairobi’s ‘Prestige Plaza’ shopping mall is the over-crowded Kibera slum, the biggest slum in Africa and one of the biggest urban slums in the world. A few hours spent here, walking in the hot muddy squalor and raw sewage of over a million people, is enough to make even the most optimistic person highly sceptical of the government’s claim of progress and commitment to social welfare.

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4 Rose Ogola, WFP Public Information Officer in Kenya, finds out what she can buy for a dollar at a food market in the Kibera slum, in Nairobi. See http://www.wfp.org/videos/dollar-day-kenya
5 The Human Development Index is a composite statistic of life expectancy, education, and income indices used to rank countries into four tiers of human development.
Healthcare challenges

Equitable access to quality and affordable healthcare is one of the most critical challenges facing Kenya today. It is widely accepted that Kenya still faces enormous healthcare challenges, most notably amongst the poorest and most vulnerable sectors of society. The average life expectancy in Kenya is an average 58 years\(^6\), which is comparable to many of its East African neighbours, but seemingly paradoxical if one considers Kenya’s advancements in modern technology, business and infrastructure outlined above.

A high incidence of disease and a lack of access to affordable and quality healthcare are issues of alarming and often life-threatening concern for many Kenyans. According to the Ministry of Health, Kenya’s under-five mortality rate in urban slums, such as Kibera, is around 151 per 1,000 live births, a disease easily treated in developed countries, is tragically one of the leading causes of these deaths. “Urban slum areas have become notorious for sewer farming, placing unsuspecting consumers at great risk for diseases such as cholera, amoeba, typhoid and even cancer,” told Patrick Mutua, a public health expert with the Ministry of Health, to the Inter Press Service in August 2013.

Malaria and Tuberculosis - TB

Malaria and TB have long been a public health problem in Kenya and great efforts have been made by many medical and charitable institutions to prevent and better treat those affected by these and other infectious diseases. According to the United States Agency for International Development (USAID), 77 per cent of Kenya’s population lives in areas where malaria is transmitted and an estimated 6,000 pregnant women suffer from malaria-associated anaemia every year. According to USAID, malaria is also responsible for thirty per cent of out-patient visits. “Although the rate of malaria has been going down, there is still a high burden of the disease in Kenya,” confirms Elizabeth Mwai from the Kenya Alliance of NGOs Against Malaria (KeNaam)\(^7\). “We estimate that around 16,000 under-fives are dying every year, but cases do not always get reported. The wider issue here is the weakness and vulnerability of the population. If you are already malnourished or dehydrated, the impact of malaria will be more severe,” she added.

TB also remains a major cause of illness and death worldwide, especially in Africa and Asia, and continues to be a significant public health challenge in Kenya. In 2011, the Kenyan government reported more than 106,083 new TB cases alongside 4,000 TB-related deaths. Kenya currently ranks thirteenth on the list of 22 high-burden TB countries in the world and has the fifth highest burden in Africa. The Kenyan authorities and health experts have openly admitted that funding for TB is lacking in the country. “The resources that are available cannot cope with the burden of the disease as it is today. It is important to remember there are other health concerns competing for the little resources available,” explained Joseph Sitienei, Director of the National Leprosy and TB Control Programme, to IRIN news in February 2012.

HIV/AIDS

Alongside TB and malaria, HIV/AIDS (Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrom\(^8\)) also remains a major killer in Kenya, with the country being home to the fourth largest HIV-positive population in the world, after South Africa, Nigeria and India. Accurate figures are hard to obtain, but, according to a report from Kenya’s AIDS Indicator Survey (KAIS) published in 2013,

\(^{6}\) According to the latest data of the World Health Organisation published in April 2011.

\(^{7}\) The Kenya NGOs Alliance Against Malaria (KeNaAM) is a network of Kenyan civil society organisations (CSOs) working to eradicate malaria in Kenya. KeNaAM was formed in 2001, established a secretariat in 2003, and was legally registered in 2006.

\(^{8}\) AIDS is the final stage of the HIV infection. People at this stage of HIV disease have badly damaged immune systems, which put them at risk of acquiring infections, other diseases and ailments.
close to 1.2 million Kenyans are currently living with the HIV virus. The KAIS report also revealed that Kenyan women have an overall HIV prevalence of 6.9 per cent, compared to men’s prevalence of 4.4 per cent. Despite politically charged disputes over statistics, the Kenyan government has declared HIV/AIDS a national disaster. Notably, TB is the leading cause of illness and death among people living with HIV/AIDS across Africa. In low-income countries, such as Kenya, many people infected with HIV contract TB as the first sign of AIDS. Delays in diagnosis and a lack of access to effective treatment can significantly undermine their already weakened state of health.

Noncommunicable Diseases - NCDs
Whilst infectious illnesses such as HIV/AIDS and TB still remain the common and most immediate public health risk to Kenyans, recent research from the World Health Organisation (WHO) also suggests that many African countries, including Kenya, will soon experience a surge in demand for treatment of NCDs, such as cardiovascular and respiratory disorders as well as cancer and diabetes. In the 2010 Global Status Report on NCDs, the WHO estimated that “by 2020 the biggest increases in NCD deaths will occur in Africa”. These concerns are echoed by recent government figures, which, according to Kenya’s Ministry of Public Health and Sanitation, show that the leading causes of deaths due to NCDs include cardiovascular diseases (thirteen per cent), cancers (seven per cent) and diabetes (four per cent).

The reasons behind the rise in NCDs in Kenya are numerous and difficult to accurately pinpoint. However, many health experts have pointed to an increase in the more affluent middle class and a subsequent change in diet and lifestyle. As the official external broadcast institution of the US, the Voice of America, pointed out in a 2011 media report, “The unhealthy habits that come along with economic development, including smoking, drinking and eating fast food, are taking their toll on the health of Kenyans, who are suffering from increasing rates of high blood pressure.” Many Kenyan health professionals, such as veteran Dr Patrick Orege, a senior researcher at KEMRI in Kisumu, and a former director of the National Aids Control Council (NACC), have been observing these trends for over a decade and agree that rapid economic development and more sedentary lifestyles could be having a major impact on public health. “The western diet binge in recent years could be taking its toll and created a higher incidence of so-called western illnesses,” he notes. But it’s not just the affluent at risk from the rise of NCDs. So called ‘western diseases’ are also increasingly prevalent amongst Kenya’s lower socio-economic classes, where poor diet, increased tobacco intake and alcohol consumption contribute to cases of hypertension, asthma and chronic lung diseases. And with limited access to screening and treatment, the impact of NCDs amongst Kenya’s poorer communities could become extremely serious in the long term.

Cancer – the new killer
A rapid increase in the rate of cancer, notably breast, cervical and prostate cancer, has provoked grave concern amongst the health authorities in Kenya over the past decade. Cancer is now the third highest cause of morbidity in Kenya after infectious and cardiovascular diseases. There are an estimated 28,000 new cases of cancer each year, resulting in 20,000 deaths and around sixty per cent of Kenyans affected by cancer are younger than seventy years. According to some medical doctors, Kenya’s public health system has so far not been able to develop and adapt to the new realities of cancer in the country, with resources and oncology expertise in dangerously short supply.

One oncologist at the government run Kenyatta National Hospital in Nairobi said there are currently very few qualified oncologists to meet the needs of Kenya’s population of around forty million and that all the latest technology and treatments were located exclusively in the capital. According to an analysis by pharmaceutical giant Astra Zeneca, “Kenya has only eight trained oncologists, five trained oncologist nurses, and five breast surgeons, and they are all based in Nairobi. This makes it virtually impossible for the majority of women across the country to get the early diagnosis and treatment needed to improve the chances of survival. Today, of the 10,500 women that are diagnosed, eighty per cent have already progressed to untreatable, late stage breast cancer”

A long road to Universal Health Coverage - UHC
This lack of basic resources, medical personnel and access to healthcare facilities is a major factor in Kenya's overall public healthcare challenge, and ultimately the country’s mortality rate. Despite the commitment and provisions under Chapter Four, Article 43 (1) of Kenya’s new Constitution, promulgated in August 2010, which states that “every person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care”, Universal Health Coverage (UHC) is long from becoming a reality in Kenya.

According to the Global Health Policy Centre, by the late 1980s, Kenya had more than quadrupled the number of health facilities serving its growing population. However, the economic downturn and the intensification of the HIV/AIDS pandemic in the 1990s exacerbated a number of health challenges for Kenya. At present, the government reports that there are now more than 5,000 health facilities in Kenya of which the government oversees 41 per cent, NGOs run fifteen per cent, and the private sector operates 43 per cent. As noted earlier, the capital Nairobi is home to the country’s largest and best-equipped government-run facilities, notably the Kenyatta National Hospital and the Moi Referral and Teaching Hospital (MRTH). A large number of private hospitals and health clinics are available, notably the Aga Khan hospital in Nairobi, which claims to lead the way in the ‘cutting edge’ private healthcare.

The difference between the public and private health facilities in Nairobi is unsurprisingly vast and disconcerting. A morning spent at Kenyatta National Hospital’s casualty and cancer treatment waiting rooms revealed rows and rows of tired patients, some swaddled in blankets after a night sleeping on the grass outside (many coming from rural areas cannot afford somewhere to stay), and several patients were being pushed on stretchers by members of their own families. The dedicated 6,000 Kenyatta National Hospital employees do what they can in a gloomy, shabby environment, which is characterised by poverty and exhaustion. The hospital itself, an ugly building constructed in the 1960s, look down on bald lawns and rows of ATM’s, banks and money transfer offices, all an intimidating reminder that all medical costs need to be paid for.

In contrast, the private Aga Khan University hospital is a modern red brick building, nestled quietly amongst manicured lawns and rippling fountains and offers much more attractive working and pay conditions for Kenya’s limited pool of medical professionals, some of whom start with a monthly government salary of KES30,000 (€250) per month. The lack of incentive to stay in public service is reflected in WHO figures that suggest only around 1,000, out of a total 45,000, physicians now work in Kenya’s public sector. According to Kenya Medical Practitioners Pharmacists and Dentist Union (KMPPDU), eighty per cent of the doctors quit government service after about three years.
“We have created a parallel health system. One for the rich and a public system for everyone else,” says Kizito Lubano, Head of Planning, Monitoring and Evaluation at KEMRI, who created a public outcry with an op-ed entitled ‘African Healthcare Systems, what went wrong?’ in 2012. “When African heads of state or governments die in their countries, they do not die in hospital,” his article states. “No doctor or hospital at home is good enough for them; these are for the ordinary citizens.”

According to the Africa Health Dialogue, in Kenya, as in many Sub-Saharan countries, four factors come to play in restricting access to healthcare for poor people: (a) where public health facilities lack essential equipment, drugs, supplies and commodities; (b) where people have to travel long distances to reach health facilities, especially where public transport is scarce and costly; (c) when fees charged for services are unaffordable, and even if there is official exemption (e.g. for pregnant women and children under five) or waiver of fees, people still end up paying on top for drugs and transport (out-of-pocket expenditure); and (d) where people lack confidence in the services provided at local public health facilities and decide not to utilise them (e.g. poor quality services or negative provider attitudes).

The limited availability of trained medical staff and healthcare facilities is a major factor in illness diagnosis and treatment rates in Kenya, particularly in rural areas. “It’s very hard for people living hand to mouth in the rural areas to access medical care,” says KEMRI’s Lubano. “Travelling takes time out of their day and from their farming activities or businesses. Transport is costly and uncomfortable for those who are ill, so sometimes they improvise and travel to get medical help on donkeys, bicycles or even being pushed in wheelbarrows.”

Besides the lack of geographical and physical access to healthcare facilities, the cost of doctor consultations and treatment is prohibitive and simply out of reach for many Kenyans who are not protected with any kind of health insurance. “It can cost anywhere between KES20 and KES2,000 (between €1 and €20) just to see a doctor before any treatment,” explains Lubano. “Then medicines and treatment can go up to KES10,000 or around €85. So for many people who don’t have any kind of health insurance, they delay seeing a doctor until it is far too late and then they are forced to pay for healthcare out of their own pockets. This can be catastrophic with people selling their possessions and women even selling their bodies to meet the costs.”

Moreover, there is a growing concern that the prohibitive expense of even the most basic medicines is forcing people to turn to cheaper and often dangerous alternatives. About 100,000 deaths a year in Africa are linked to the counterfeit drug trade, according to the WHO. The proliferation of bogus medication and pharmaceuticals in Kenya has caused many unnecessary deaths, disabilities and injuries to patients, but also greatly contributes to the high cost of public healthcare, said Kenya Medical Association (KMA) Chairman Elly Nyaim. Indeed, data from the PPBK reveals that an estimated thirty per cent of drugs sold in Kenya last year were fake or counterfeit, accounting for an annual loss of more than ten billion shillings ($117 million). “We are spending millions in correcting resistance to diseases such as malaria and TB because patients unknowingly take the (counterfeit) drugs, which have less or no medicinal value to cure them,” Nyaim said in a media interview recently.
Health insurance for all

The issue of health insurance still continues to provoke debate in Kenya and little progress seems to have been made with regard to the provision of equal, accessible and sufficient health insurance for all. For Kenyans that do have regular employment or a consistent income, a monthly contribution of around KES320 (just less than €3) will provide a degree of coverage under the National Hospital Insurance Fund (NHIF). The NHIF, established by an Act of Parliament in 1966, is mandated to provide health insurance to Kenyans over the age of eighteen. The NHIF requires compulsory membership for all salaried employees with contributions automatically deducted through the payroll. Contributions are calculated on a graduated scale based on income, with a majority contributing between KES30 to KES320 per month. According to the most recent figures from The United Nations Industrial Development Organization (UNIDO), 1.6 million Kenyans (9.5 million, when dependants are included) are currently covered by the NHIF.

However, as veteran Kenyan investigative journalist Douglas Okwatch clarifies, “Even if you are covered by the NHIF, this will only cover the cost of your hospital bed. It wouldn’t cover the costs of consultations or medication. Many people also take out a private healthcare policy so everything is covered - you are in serious trouble if you only have the NHIF to rely on. You cannot access healthcare in Kenya without having to pay something, making it a very unfair system.” The status of the NHIF is continually under review as public pressure to ensure access to health for the poor continues to mount. The Kenyan government recently announced the creation of the Household Insurance Subsidy Programme (Hisp), which will enable the provision of a comprehensive in- and outpatient healthcare service package for the very poor and several thousand households across the country to access ‘free-to-patient’ healthcare services. The success of this new initiative will be monitored with cautious optimism.

The March 2013 elections and the inauguration of new President Uhuru Kenyatta have generated renewed debate and brought new hope for a better-resourced and fairer public healthcare system in Kenya. The leading political parties in their manifestos all vowed to ensure Kenya achieved free primary healthcare (as it happened in the education sector with free schooling program in 2003) and expressed commitment to the long-standing government commitment to transform Kenya into a middle-income nation by 2030. This commitment to change and progress should be welcomed and encouraged. But not everyone is optimistic. KMA’s chairman, Dr Abdi Mohamed, noted that while it is possible to offer free healthcare, the East African nation may not achieve it in the next decade. “This is not because there is no will, but health provision is bigger than offering free primary education due to the numbers involved,” he says frankly. “While in education you are dealing with about ten million people, in healthcare, you have to cater for the entire population of forty million people.”

As the political and public debates continue, the harsh reality of inequality and poverty remain clearly visible in Kenya in 2013. As Erik Okioma, a community health activist and coordinator of the Kenya branch of the AIDS Candlelight Memorial in Kisumu, says frankly: “In Kenya, if you don’t have money and you get seriously ill, you will die.”

It is in this context and against this background of mass poverty and inequality that an increasing number of clinical trials are taking place in Kenya.
CHAPTER TWO: 
Clinical research in Africa: “A ripe opportunity?”

Over the past decade there has been a growing trend for the Multinational (Pharmaceutical) Companies, typically referred to as MNCs, to outsource clinical trials to countries beyond their own borders.

Until around 1995, most clinical trials were conducted in Europe, the US and Japan. However, many more clinical trials are now being carried out in ‘new markets’ in low-income countries. According to a report published in The Guardian newspaper in July 2011, in 2008 there were three times as many low-income countries participating in clinical trials registered with the US Food and Drug Administration (FDA) than there were in the entire period between 1948 and 2000. And this trend is showing no sign of slowing down.

The reasons why MNCs choose to outsource their clinical research to countries other than their own are numerous and open to debate. One attractive reason is the lower operating costs and the opportunity to circumvent the high fees, which can come with trials in high-income countries such as the US. “Developing nations are boon for cost reduction as the labor costs required for clinical trials are up to fifty to sixty percent cheaper here,” states the 2013 review article on the outsourcing of clinical trials in the journal Drug Designing. Further reasons for the burgeoning of clinical trials in low-income countries are, according to Sue Miles, who published an article on the globalisation of clinical trials in the Journal for Clinical Studies in 2013, “the potential to shorten timelines, the wide pool of potential (treatment-) naïve participants, and cost benefits.”

With the rapid expansion and globalisation of the clinical trials industry, medical experts, activists and journalists have started to scrutinise this new reality and question the ethics, safety and sustainability of such outsourcing practices. Concerns that a lack of quality monitoring and oversight could lead to improper practice and the exploitation of vulnerable people continue to fuel the global clinical trials debate. As a 2009 article in the United Kingdom’s (UK’s) Guardian pointed out, “(in low-income countries) it is quicker to recruit volunteers, cheaper to conduct and monitor trials and, it is feared, easier to get past ethical rules.” (For the full article see the reference section.)

Over the past decade, emerging ‘global giants’ such as India, China and Russia have become the destination of choice for many MNCs looking to outsource their clinical research. But new markets continue to appear on the radar and other countries have started to open their doors and offer their people and resources for clinical trials.

Growing clinical trials industry in Kenya
The vast and diverse continent of Africa is one continent attracting the increasing attention of the global pharmaceutical industry. According to Cutting Edge Information (CEI) website: “Africa presents a unique profile that interests many life science companies. Of all emerging locations or regions, Africa has arguably the least access to quality care, ensuring a steady stream of dedicated patients to fill trial enrolments.”

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2 S. Miles. 2013. Clinical Trial Logistics and the Globalisation of Clinical Trials. In: Journal for Clinical Studies Vol 5 No. 3.
3 Treatment-naïve patients are patients who are much less likely to have been previously exposed to treatment.
4 CEI: A US based pharmaceutical and biotech industry source for business research.
According to a 2013 report by IMS Health\textsuperscript{15}, entitled ‘Africa: A Ripe Opportunity: Understanding the pharmaceutical market opportunity and developing sustainable business models in Africa’, (see full report in the reference section), pharmaceutical spending on the continent is expected to reach $30 billion in 2016, up from about $18 billion now. By 2020, the market could represent a $45 billion opportunity for drug makers, spurred in part by robust economic growth and demographic changes. "The pharmaceutical business is growing and it will grow. It’s the next big thing in Africa," one South African pharmacist told CNN in reaction to the publication of the 2013 IMS report. "We have a lot of potential in Africa," he added.

Africa’s fast-growing population, high rates of infectious diseases, increasing wealth, a rising middle class (and consequent demand for drugs to treat chronic diseases) are key factors playing into the global market analyses. “Most multinationals have Africa in the sights of their expanding global footprint. It is a continent ripe with potential,” double states the IMS report. Kenya is fast becoming one of the most popular destinations in Africa for clinical trials. Accurate and updated information is hard to access, with traditional global information sites such as ClinicalTrials.gov, only revealing limited information. Industry watchers estimate that hundreds of trials for both vaccines and drugs are currently underway in the country, largely focusing on infectious diseases, but increasingly for NCDs as highlighted earlier. The increase in NCDs are from a commercial perspective the most interesting development for pharmaceutical industry as most of their blockbuster drugs are treatments for NCDs\textsuperscript{16}. The Kenyan government, historically seen as business friendly, is jumping at the opportunity to take part and has big ambitions for the country to become a global player in clinical research. Kenya’s Public Health Minister Beth Mugo recently outlined Kenya’s grand ambitions in a speech saying, “The government hopes to follow in the footsteps of other developing countries such as India that have managed to become pharmaceutical and health sectors of excellence. Through sustainable research, Kenya could leapfrog other nations and become a regional hub for East and Central Africa.”

\textsuperscript{15} IMS Health is a company that provides information, services and technology for the healthcare industry. It is the largest vendor of US physician prescribing data.

Due to its high burden of tropical and infectious diseases, Kenya, like many other African countries, has long been of interest to medical researchers in search of cures for the world’s most deadly and non-western diseases such as malaria, rift valley fever and chikunguya. In the late 1970s and 1980s, with the rise of HIV, numerous foreign research organisations, universities and charities set up operations in Kenya and continue to play an active role in medical research and clinical studies across the country. But in the past decade, these small-scale and arguably humanitarian-driven research projects have also been joined by the big, profit-driven international players from the MNC sector.

“Kenya is now a mix of all kinds of infectious and non-infectious diseases; we have an intersection of everything,” explains KEMRI’s Kizito Lubano. “We also have highly skilled, English speaking manpower, which puts us up there with South Africa as clinical trial leader.” Kenya now hosts a number of multinational pharmaceutical companies including Glaxo Smith Kline (GSK), Astra Zeneca, Pfizer, Sanofi Pasteur, Ely Lilly, Novartis, Bayer and Boehringer Ingelheim.

A recent analysis, undertaken by the healthcare unit at Frost & Sullivan Africa in October 2013, showed that within the Kenyan pharmaceutical market, GSK is regarded as the market share leader with approximately twelve per cent market share. And 41 per cent of all anti-infectives sold in pharmacy were licensed to GSK. “GSK’s dominance in the overall market is largely attributable to its success in the anti-infectives market segment, a therapeutic segment which accounts for approximately 42 per cent of all revenues generated in the Kenyan prescription market segment,” states Frost & Sullivan healthcare team leader Ryan Lobban. The Frost & Sullivan Africa report also showed that Kenya’s cardiovascular market is the most dominant and fastest growing prescription market segment in Africa. The market was valued at approximately $36 million in 2012 and is expected to grow at 15.4 per cent between 2012 and 2019. The Kenyan diabetes market was valued at approximately $33.1 million in 2012 and is expected to grow 13.5 per cent between 2012 and 2019.

Despite the growing MNC presence, the majority of trials in Kenya are still largely managed through PRIs such as the CDC, the Walter Reed Project (WRP), the Wellcome Trust and a number of Universities (largely from the US) with the help of donor funding and in close cooperation with KEMRI or other such government-mandated clinical research agencies. Phase I, II and III trials (see glossary for detailed explanation) are taking place in various locations across the country, notably in western Kenya where burdens of HIV and malaria are the highest. However, the extent to which these international PRIs and western universities are working with, or even on behalf of the MNCs, is not easy to ascertain and public information regarding their relationships is not readily available. (These, and other research challenges, will be outlined in chapter five.)

**Raison d’être Kenyan PRIs**

According to official information from these three leading PRIs noted above, their raison d’être and their activities can be defined as follows:

- The CDC is the national public health institute of the US. The CDC is a federal agency under the Department of Health and Human Services and is headquartered in Atlanta, unincorporated DeKalb County, Georgia, in Greater Atlanta. In Kenya, the CDC is addressing the region’s toughest health problems at their source, directly working with vulnerable families and communities in local hospitals, clinics, and laboratories.
The WRP is the local name for the US Military HIV Research Program activities executed in Kenya. All WRP activities in Kenya are conducted under the US Army Medical Research Unit–Kenya (USAMRU-K), which is on the campus of KEMRI in Nairobi.

The KEMRI-Wellcome Trust was formally established in 1989 as a partnership between KEMRI, Oxford University and the Wellcome Trust. It conducts basic, epidemiological, and clinical research in parallel, with results feeding into local and international health policy and aims to expand the country’s capacity to conduct multidisciplinary research that is strong, sustainable and internationally competitive.

In summary, as the global demand for clinical trials continues to grow, Kenya is clearly keen to play an active role in the international pharmaceutical arena. Through collaboration with MNCs and research institutions, such as those listed above, Kenya is now considered to be an important emerging player in the global clinical trials industry. But, as the business opportunities continue to flourish in Kenya, questions surrounding the nature of patient recruitment and the potential for violations of the rights of clinical trial participants, need further exploration.
CHAPTER THREE:  
“I consent” The human face of clinical trial participants

As outlined in the two previous chapters, Kenya’s high burden of infectious and tropical diseases, coupled with its rapidly developing infrastructure, human resources and approval procedures (see next chapter), have made the country an attractive destination for the undertaking of clinical trials.

Multinational Pharmaceutical Companies, PRIs, notably the CDC, western Universities and NGOs, have all been looking to East Africa as a prime location for clinical studies for well over a twenty years. Logic does of course dictate that the best place to test drugs for specific diseases would be in a country with a high prevalence, which is why the majority of clinical trials in Kenya continue to focus on HIV/AIDS and malaria, two of the country’s biggest killers. “If you take for example malaria, if it doesn’t exist in your country, it’s not easy to study it. As a tropical disease you will only study it in the tropics where you find the mosquitoes,” says Ambrose Rachier, Head of KEMRI’s ethics committee.

Yet logic and practicalities aside, it is also important for both the pharmaceutical industry and the government decision makers to consider the bigger and longer-term picture of the clinical trials industry in Kenya. Who is taking part in these clinical trials and why? What is the long-term benefit of a trial to both the trial participant and to the country as whole?

As mentioned earlier, like in so many other low-income countries, the majority of the Kenyans struggle to afford and/or access quality healthcare. The prohibitive cost of treatment and the lack of physical access to health services combined with poor sanitation, poor diet and a vast array of tropical diseases is a deadly combination. Therefore, for organisations looking to recruit sick patients for their pioneering drug trials, logic again would dictate that there is no shortage of potential trial participants across Kenya. Few people would argue that medical research and the search for cures for debilitating and deadly diseases are not necessary or beneficial. And if taking part in a study enables poverty-stricken people to access much-needed treatment without any cost, some would describe the collaboration between participant and trial sponsor as ‘win-win’ situation. In theory, and on a superficial level, this argument does seem plausible. But if we probe a little deeper into the ways in which Kenyans are being located, recruited and treated during the clinical trial process, important ethical questions arise.

Unlike in countries, such as China and India, where clinical trial opportunities are widely posted in public spaces such as newspapers and university campuses, the trial recruitment process in Kenya is still largely done discreetly through local healthcare facilities and community outreach workers. For example, once a study is approved by KEMRI (or other mandated institutions with ethics committees) through the official channels, KEMRI will send a team of ‘data handlers’ to approach a health clinic in the targeted area and identify patients on file with the specific disease or ailment needed for the trial. Alternatively, recruiting agencies such as KEMRI will identify local community representatives, some of whom may have initially be in trials themselves, to serve as a link with other potential participants in the area.
“Most participants in clinical trials are recruited through our field workers,” explains Rachier. “These are what we call ‘fishers of men’ - people you send out to look for the specifications that you have because there is an inclusion and exclusion criteria depending on the nature of the research.”

Whilst the location of patients may be a reasonably straightforward and a necessary procedure, the process of recruiting them and getting their official consent to participate in a trial is, as in many countries, one fraught with potential risks and ethical violations. Despite KEMRI’s assertion that all their data handlers and recruiters are trained in ethics and consent, an anonymous official from the organisation claimed that because vast majority of trial participants are being drawn from poor rural areas, their motivations for taking part could be through desperation or a lack of a better alternative.

“Many poor people are taking part in trials because it’s the only way they can access healthcare and get a better chance for their kids,” said the official on condition of anonymity. Kenyan journalist Catherine Karongo, who flagged the issue of ethics and clinical trials in 2011 (see chapter five), is also sceptical about the way in which patients are signed up for trials. “These people have nothing and will die anyway, so they see no harm in doing a trial. People come to Kenya to do trials because it’s easy to get people because of poverty.”

According to former Director of Medical Services, Dr James Nyikal, quoted in Kenya’s National Guidelines for Research and Development of HIV/AIDS Vaccines: “People have the right to make their own informed decisions as to whether they want to participate in any research. They must, therefore, be informed about the background of the study, what benefits and risks are involved, how long the study will go on, and they must be able to comprehend the information given.”

But according to the anonymous KEMRI official, a full and comprehensive understanding of the consent procedure is undermined by “A lack of education, not just literacy, but the ability to analyse and interpret the meaning of the consent to form is lacking, so it’s questionable if they fully understand the consent form.” However a Principal Investigator from KEMRI disagrees with his colleague: “It is patronizing to assume that the common man does not understand anything. In fact, they ask us questions.”

KEMRI’s Kizito Lubano explains that the idea of individual consent, as understood in western societies, differed greatly in rural, traditional communities. “Consent is not like in the west. In many areas of Kenya it’s a communal process. They (potential trial participants) will ask advice from their neighbour or a teacher, so by the time they sign a form they will have many influences around them.”

He also suggested that time pressures are sometimes put on by sponsors. The rewriters are in a hurry to get as many people signed up as possible. This could undermine the informed consent procedure.

The questions around the motivations of people to agree to offer their bodies for clinical research have been explored in a variety of country contexts. In Kenya’s case, aside from the clear lack of alternative to affordable treatment and healthcare, the issue of payment is also one which merits further exploration. Officials from KEMRI and patients themselves interviewed for this report all denied that people are ‘paid’ to take part in trials and that the only compensation they received, was a daily stipend for travel and time lost or taken away from livelihoods. A number of officials made it clear that paying people to take part should be avoided at all costs. “We look at any compensation that is supposed to be given (to the participants) because when it is very attractive then we are dealing with the principle of inducement - that the people may not be acting in a voluntary manner; they may be coming in for money,” said Rachier adding that it is a requirement that participants in a
study be compensated for their travel and meals. “The ethics committee is very vigilant to ensure that researchers are not escaping from the north to try and exploit an area that is thought to have easier prey,” Mr Rachier assured. For a research proposal to be approved in Kenya, it has to go through scientific clearance, peer review, the researchers must be competent, and there must be consent from participants without inducement.”

**Unanswered questions about Phase I trials on ‘healthy volunteers’**

Whilst the assertion that clinical trial participants are reimbursed but ‘never paid’ for their participation is widely held and substantiated in the case of Phase II and III trials, the claim does not quite ring true in the case of Phase I trials. In the case of patients already suffering with a disease, the opportunity to access free healthcare is a strong motivating factor in Kenya’s clinical trials industry. But Phase I trials, designed to test for safety on healthy patients who volunteer their bodies, the alleged lack of financial incentive does generate cynicism.

According to a senior medical doctor working and managing trials at KEMRI, the institution is currently preparing to carry out Phase I trials at its headquarters in Nairobi. The investigator confirmed, as we walked along the empty corridors of the forty-bed research facility that: “We (KEMRI) are currently recruiting healthy volunteers, between the ages of eighteen and forty to test the safety of (unapproved) drugs,” he explained stressing again that these participants were simply being reimbursed and not paid. Given that some of those volunteers were being ‘brought in on buses’ from remote regions and sometimes staying up to 22 days in the KEMRI facility, one would however question their motivation for doing so. As they are healthy volunteers, and therefore not in need of healthcare, it seems questionable that they would come for free. In response to this observation, the investigator replied: “There is no benefit to them, but they are happy to contribute to the research, Africans have a strong sense of solidarity and want to help others,” he added saying he was developing good face-to-face relationships with other MNCs including GSK, Eli Lilly, Sanofi and Pfizer.

When questioned about the danger and serious risks associated with Phase I trials, he assured us that if a volunteer would get sick “as a result of the Phase I trial at KEMRI”, the patients would qualify for free healthcare at Kenyatta National Hospital and would be monitored for a period of ninety days after the trial. However, no one from KEMRI was later available to confirm or elaborate on this claim and tracking down any of the patients involved in the Phase I trials proved extremely difficult.

Strangely, a different senior official at KEMRI, also working on the trial approvals, denied all knowledge of Phase I trials were even taking place on the KEMRI premises in either Nairobi or Kisumu. Subsequent follow-up questions to other officials about the Phase I trials taking place at KEMRI headquarters were then left unanswered, and it is still not clear which companies and which drugs are involved. This lack of transparency and availability of complete information is a worrying issue, which will be addressed in more depth in chapter five.

**Clinical trials in Kisumu, the ‘human laboratory’ of Kenya.**

Aside from the on-site research going on in Nairobi, KEMRI has a large office in Kisumu, a port city in western Kenya in the province of Nyanza. The Kisumu region has become a hub for clinical trials due to the very high burden of HIV and malaria. A large number of research organisations are based there, including the CDC, which works in partnership with KEMRI.
Kisumu has been described as an ‘open laboratory’ by the media, with the 2003 report by Okwatch stating: “Just because the kind of infectious diseases such as malaria, HIV/AIDS, diarrhoea and anaemia that CDC and KEMRI have been understood to be interested in are widespread in many other parts of the country, it has only been a matter of conjecture as to why, for close to two decades now, researchers maintained such a keen interest only in Rarieda and some parts of Kisumu.” In the same vein, an anonymous official at KEMRI also cynically questioned why the region, after all these years of clinical research and influx of medical personnel still has the highest disease burden in the country.

Given the debates and unanswered questions about the Nyanza region, we decided to travel to the main regional city of Kisumu to track down and hopefully interview some trial participants themselves and get a clearer picture of what motivated them to participate.

**TESTIMONIES:**

Clinical trial participants in the Manyatta Slums, Kisumu City Western Kenya

Manyatta is the second largest informal settlement in Kisumu. About a twenty minute drive from the bustling port city of Kisumu, the Manyatta estate is an area characterised by poverty, disease and violent crime. The “Taking It Global” youth network vividly paints a portrait of daily life for the many thousands of Manyatta’s residents stating: “A walk through the narrow, filthy gangways in the Manyatta slums leaves one asking whether there are proper policy frameworks in the Kenyan nation to take care of people living under such poor and unhygienic conditions.” The high burden of illness and disease, notably HIV/AIDS, has made the Manyatta estate a key target area for medical researchers looking for possible recruits into clinical trials. The nearby Nyanza Provincial General Hospital and research institutes such as KEMRI, CDC and Walter Reed are very active in the area and often work together to recruit participants. Below are the personal testimonies of two Manyatta residents who took part in a clinical research.

- **Suzanne, 34, housewife and part-time juice seller**

  **Trial subject in: Kisumu Breastfeeding Study (KiBS): A clinical trial of maternal antiretroviral therapy for reduction of Mother-to-Child HIV transmission through breastfeeding.**

  Life for a young women like Suzanne, a 34-year-old housewife, is hard in the Manyatta slum. Money is scarce and basic essentials like clean water, toilets and electricity are in short supply. When she is not taking care of her two young children, Suzanne supplements her husband’s meagre income by selling plastic packets of fruit juice and eggs from her two chickens to local residents.

  Suzanne was diagnosed with the HIV virus during a routine check-up at the start of her second pregnancy in 2006. Like many women in Kenya, Suzanne had never previously been tested for the virus until adulthood. Despite the high rates of HIV/AIDS in the Kisumu region, the flourishing sex industry and the young age at which girls begin sexual activity, the stigma and fear surrounding HIV still creates a culture of denial and many people avoid any behaviour that could arouse public suspicion, including going to a clinic for testing.

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18 TakingItGlobal is a global network of young people learning about, engaging with, and working towards tackling global challenges. See [http://www.tigweb.org/about/](http://www.tigweb.org/about/)
Once Suzanne had come to terms with her diagnosis, she was then confronted by the possibility that her new baby could also contract HIV from her. Luckily her first child, a son, had tested negative for the virus, but doctors warned her that she may not be so fortunate with her second child. During a medical consultation, Suzanne was told about a special programme called the Kisumu Breastfeeding Study (KiBS), which was being run across the region by KEMRI and the CDC.

During this study\(^{19}\), in which Suzanne agreed to participate, HIV-infected pregnant women took three antiretrovirals (ARVs) (Zidovudine, Lamivudine and either Nevirapine or Nelfinavir) Infants received a single dose at birth. The purpose of the study was to investigate whether this triple antiretroviral regimen that was “designed to maximally suppress viral load in late pregnancy and the first six months of lactation was a safe, well tolerated and effective PMTCT (preventing mother-to-child transmission) intervention.”\(^{20}\) 522 women were enrolled in the study of which 310 women were initiated on Nevirapine and 212 women received Nelfinavir. The mothers were asked to exclusively breastfeed till five and a half months with rapid weaning over two weeks and cessation of breastfeeding at six months when ARVs are discontinued.

“We didn’t know yet if my baby would test positive like me, so the doctor said doing this study could save mine and the baby’s life,” recalls Suzanne. “The doctor told me that the study was trying to find a way to protect my baby from contracting HIV/AIDS through use of the Nevirapine drug,” Suzanne remembers. Once the trial began, Suzanne was prescribed a regular dose of Nevirapine free of charge, her first ever experience of an ARV treatment.

\(^{19}\) A Study of Zidovudine/Lamivudine and Either Nevirapine or Nelfinavir for Reduction of mother-to-child HIV Transmission During Breastfeeding (KiBS). Available at http://clinicaltrials.gov/ct2/show/NCT00146380, last consulted on 7.01.2013.

“The doctor assured me that Nevirapine was safe for both myself, and my baby and he did not mention the existence of any side effects due to Nevirapine intake,” she continues. “But he told me that I should alert them as soon as possible, if I experienced any side effects.”

“I signed a form to agree that I would only breastfeed the baby for the first six months,” she continues. “They were very strict about the rules. We had to follow the instructions or the doctors said we would have to leave the study.” When asked if she was concerned about breastfeeding, as she was HIV positive, she said: “I do not have any concerns about breastfeeding my baby due to HIV-positive status. The positive impacts of breastfeeding for my baby were explained to me and I was convinced it was the right thing to do.”

As directed, Suzanne followed the instructions of the researchers for six months. She took oral doses of Nevirapine whilst nourishing her baby exclusively with breast milk. “We went for check-ups at the clinic on a regular basis and they always gave me money for the bus fare,” says Suzanne. “They also said that if I got sick with malaria or anything else, my healthcare costs would be free for two years because I had taken part in the trial and I would get priority treatment.”

Six months later, the breastfeeding trial was completed and Suzanne’s new baby fortunately tested negative for the HIV virus. “I am so grateful that because of the study my baby was protected,” says Suzanne when asked if she minded that now the study had ended, she no longer qualifies for free healthcare.

“I was aware that the free healthcare services would be stopped after the trial. The CDC team informed me well in advance. But it is not fair. Since the need is still great, I know a number of people who are not happy with the decision to end the trial,” she says adding that even though other types of ARV drugs are available free of charge in Kenya, many women on the study are reluctant to go and seek them out without the protection and anonymity provided by the KiBS trial. “Joining the public facility programme means everyone will know of our HIV/AIDS status, which is not yet public knowledge. Some relatives, enemies and friends could stigmatize HIV-positive persons,” she worries.

Luckily for Suzanne, her story had a happy ending. Her baby did not contract the HIV virus. But for some of the other mothers taking part in the KiBS programme, the outcome was reportedly not so positive.

“Some women and children who were part of the trial died before the end of the trial period,” says Suzanne. “I learnt of their deaths from the group members and regular meetings.”

The Kisumu Breastfeeding Study (KiBS): Post-trial analysis

The KiBS study illustrates dilemmas that clinical trials on diseases such as HIV/AIDS pose to health systems in resource limited settings.

First of all, transmission of the HIV virus through breastfeeding accounts for 25-40 per cent of all cases in which a child becomes infected as a result of mother-to-child transmission. Because of this risk, HIV-positive mothers, notably in high-income countries, have historically been encouraged to...
exclusively formula-feed, not breast-feed, their babies. However, the risk of HIV transmission through breastfeeding must be balanced against the benefits of breast milk’s protective properties, which are often lifesaving in resource poor communities that are characterized by shortage of safe water and lack of consistent availability of replacement milk and food. Therefore, the WHO recommends that HIV-infected mothers should breastfeed exclusively unless replacement feeding is acceptable, feasible, affordable, sustainable and safe. Obviously these criteria are exclusively met in high income settings. Hence, the importance of studying a drug regimen that potentially reduces the risk of mother-to-child transmission more effectively than the current treatments is evident.

The second dilemma relates to the safety of the drugs that are used. In 2005, the FDA issued a safety warning regarding the use of Nevirapine, especially for women and even more so if these women have a high CD4 count. This group has a high risk of liver toxicity and the FDA notes that cases have been reported where this toxicity has been fatal. However, the FDA also points out the different benefits of Nevirapine such as the chemical stability in environmental conditions and the fact that other ARVs have other serious side effects. Furthermore, the FDA emphasizes that the seriousness of the underlying disease must be considered as part of the risk benefit analysis when treating HIV-infected patients. As a result of this safety warning, the KiBS trial was halted for six months and the regimen for women with a high CD4 count changed from Nevirapine into Nelfinavir to limit chances of liver toxicity. This issue had already been tackled in 2005, before Suzanne entered the KiBS trial.

The third dilemma relates to the moment when mothers stop breastfeeding their infants. The KiBS trial followed the WHO guidelines of 1996, which advised rapid weaning before six months. However, as a result of this rapid weaning, numerous infants of HIV-infected mothers experienced high rates of diarrhoea. Twelve infant deaths were attributed to diarrhoea as a result of early weaning.

To address this problem, mothers in the KiBS study were given safe water storage vessels, hygiene education and bleach for household water treatment. In 2006, the WHO recommendations have been modified to suggest that women continue breastfeeding beyond six months if replacement feeding is not acceptable, feasible, affordable, safe and sustainable. Nevertheless, in the information on the study that is publicly available, nothing indicates that this change in WHO recommendations resulted in an advice to participating mothers to extend breastfeeding beyond six months.

### Awareness of adverse effects and informed consent

The Declaration of Helsinki states: “In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study.” However, as mentioned before, in the case of Suzanne it seems that she was not informed about the possible side effects of Nevirapine nor was she informed of the risk of HIV transmission as a result of breastfeeding.

### Post-trial access to healthcare

The fact that Suzanne’s access to free healthcare was taken away after the two-year trial period is problematic in a country where most people have no access to healthcare. In addition, although

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23 Ibidem, 22.
ARVs are available free of charge in Kenya, the withdrawal of free and direct doses of Nevirapine, did have a negative impact on the mothers taking part in the study. As Suzanne pointed out, many women simply stopped seeking treatment once the study was over, many too ashamed to admit their HIV status in public. On the other hand, as part of the trial Suzanne and her family benefitted from access to clean drinking water and education regarding hygiene and HIV prevention. Suzanne says: “Through the programme I have learnt so much. I know how to protect my loved ones from contracting HIV. I have known how to handle this situation and I am contented.” It seems that the trial sponsors such as the CDC took a lot of effort to provide the trial participants with meaningful benefits. Sadly, this is not common practice. Numerous\textsuperscript{25, 26, 27} cases have been documented where post-trial treatment benefits were not provided.

- **EDWIN: 47, Plastic goods repair and salesman**

**Trial subject in TB study: Pharmacokinetic and pharmacodynamics studies of efficacy, tolerability and safety of higher dosage Rifapentine for treatment of TB.**

For 47-year old Edwin, life has always been a struggle and the strain shows clearly on his face. Edwin has spent his entire life living in this area of the impoverished Manyatta estate, just outside Kisumu. His one-room mud hut opens out onto a muddy dirt path where chickens, pigs and goats drink from putrid pools of stagnant water. Malaria and water-borne diseases are rife here and it isn’t hard to see why. Yet even amid the dirt and the squalor, it seems that small pockets of beauty can still prevail. Edwin has potted a few young banana plants and neatly lined them up in clean white plastic tubs at the entrance to his house. “A small garden,” he says with a smile.

Plastic is Edwin’s trade. For the past twenty years, he has earned his living by patching up used water canisters and other plastic items, and re-selling them around the slum for a minimal profit. Depressed and beaten down by a difficult life, Edwin also drinks heavily, the local ‘brew’ is potent (and allegedly contains formaldehyde), and he spends a lot of time in the slums crowded and smoky bars.

In 2012, Edwin started to feel unwell and lethargic. It was when he began coughing up blood that he was forced to use his mother’s life savings for a doctor’s consultation and then a chest x-ray in the local government hospital. Unsurprisingly, Edwin had contracted TB, a disease which still kills many in Kenya every year and spreads quickly in crowded places.

It was during a follow-up visit to the same local hospital a week later that Edwin was called out of the queue by a doctor and asked to come through to a separate room to meet a team of medical researchers, whom he believes were from the CDC. “They called me from the line and then they said that they knew I had TB and that I should think about trying a treatment. They said if I wanted to get better without paying anything, I should take the medication, so I just agreed,” he says. “The other option was to pay five shillings for every hospital visit, and I couldn’t afford it, so it was my only choice.”

Edwin was asked to sign a consent form, written in the local language of Luo, which he did in the presence of a doctor. However, as our interview with Edwin unfolded, it became clear that, almost a year since the study had finished, Edwin was still not aware that he had taken part in a clinical trial. “They just said it was a free treatment that would cure me and that some of my blood samples would go to Atlanta in America,” he recounts, saying that even though he had been warned about the potential side effects, he just assumed the drug was free and safe for him to take. His mother Esther, listening intently, also appears to not fully understand that her son signed up for a clinical trial.

A copy of the consent form (for a copy of the form, see Annex I) revealed that Edwin had been enrolled on a test for CDC/KEMRI for the drug Rifapentine, which is made by the French MNC Sanofi Aventis. Approved in 2009, the 2012 trial in Kisumu entitled: ‘Pharmacokinetic and pharmacodynamics studies of efficacy, tolerability and safety of higher dosage of Rifapentine for treatment of tuberculosis’, was essentially testing the effect of higher dosages in a bid to cure TB more quickly.

“I was taking the drug for six months. They told me that I had to eat well to be strong, so every day, the researcher brought me a parcel of bread, boiled eggs, milk and ground nuts,” he recalls. “The neighbours thought it was strange and accused me of being HIV positive, which I am not.” “They also gave me three hundred shillings for transport, but I preferred to keep the money and walk there, even though I felt quite weak”.

A few weeks after the trial had finished, Edwin started to notice some unusual symptoms, “I started to sweat a lot at night, my joints were hurting and my eyes started watering,” he remembers. “Then slowly my eyesight started to get worse and now, six months later, I really have trouble seeing far away, which is affecting my work.”

“I never had any kind of problems before, so I think it’s the medication,” he says gaunt and with sunken cheeks. “I am cured of the TB now and I signed the form, so I don’t want to cause any trouble,”
he replies to our observation that problems with eyesight are listed as an adverse effect on the consent form. “I haven’t had any visits from the doctors in over ten months, so I couldn’t tell anyone. At one point, they asked me to become a tracer and find other people in the slum with TB, but I said: ‘No’. They have not cared about me, so why should I?” We also point out to Edwin that, according to the consent form, the hospital should treat any symptoms relating to the trial. “Please, I don’t want to cause any trouble,” he stresses. “They will say my eyes are damaged because I go to smoky places,” he says while his eyes are watering as he looks puzzled as we study the consent form, which seemingly means nothing to him.

Clinical study of the tolerability and safety of higher dosage Rifapentine – Post-trial analysis

Meeting Edwin is his cramped mud hut and hearing this story was disturbing. It is a clear example of how recruitment into drug trials can be unethical if not monitored correctly or carried out in line with the recommendations outlined in the Declaration of Helsinki. One of the core principles of the Declaration of Helsinki is that, “Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.” However, in Edwin’s case it is clear there were a number of failings, which will be discussed below.

The drug

Rifapentine, marketed under the brand name Priftin by Sanofi-Aventis, is an antibiotic drug used in the treatment of TB. Rifapentine was approved by the FDA in June 1998. However, despite the safety of the drug being proven, further studies were needed to examine impact of higher doses (more than the established 600mg) in humans on recovery times. The trial, in which Edwin was a participant, aimed, according to the title on the consent form, to establish efficacy, tolerability, and safety of higher dosage of Rifapentine for TB.

According to the consent form, similar trials were taking place at multiple sites at global level. In Kisumu, fifty people participated in the trial. The trial appears to have been a collaboration between KEMRI, CDC and the Nyanza Provincial General Hospital, where Edwin was initially diagnosed with TB. Edwin said he was told that all his blood samples would be sent away to Atlanta in the US, where the headquarters of CDC is located.

Informed consent?

Edwin’s case does raise a number of important ethical questions. First of all, when he was approached by the researchers in the hospital and asked to sign a form, was he fully aware of what he was signing? From his own testimony, it is clear that he did not fully read, nor fully understand the concept of a drug trial (despite the consent form clearly stating the drug is ‘still under research’), and, as he says, the researchers made it clear that he really had no other choice if he wanted to be treated.

The consent forms (one for the trial and one for the consent to store samples) was extensive, over ten pages long, and written in the local language of Luo. The only exception was the title at the top of the consent form to store samples (Title: Pharmacokinetic and Pharmacodynamic studies of efficacy, tolerability and safety of higher dosage Rifapentine for treatment of TB), which was written in English. Edwin does not understand English and, even for a native speaker, the terminology used here is extremely complicated to understand. According to the translated version of the consent form, the words ‘study’ and ‘research’ are used a number of times throughout the form. But perhaps
the title in English and the many pages of information confused Edwin as it became clear from discussions with him that he did not realise he had participated in a clinical trial. For him, the primary concern was to be cured of TB in the cheapest way possible. And now he has recovered from the illness, thanks to the drug trial, he is reluctant to look back and question it any further.

**Motivation to participate**

With the prospect of further medical bills, the opportunity to be treated for without cost, free food deliveries and a KES500 reimbursement fee, was an understandably tantalizing prospect for Edwin. It is also concerning to note that the fact Edwin did not use the money he was given for transport fees (choosing instead to save the money by walking to the hospital) was not more closely monitored. In his weakened condition, walking anywhere could have been very harmful to his health and, as an admitted alcoholic, there was a high probability that the money Edwin received was simply spent on alcohol and tobacco. It is the responsibility of the trial investigators to ensure participants have a clear understanding of the rules and procedures they need to follow for their own health and for the validity of the trial.

**Adverse effects**

Given Edwin's limited understanding of the consent form and purpose of the trial, it is likely that Edwin did not pay attention to the health risks associated with the trial. According to the consent form, participants in the trial could experience fever, chills and body aches – of all which Edwin later reported. As stated on the consent form, Edwin was also supposedly given the choice to participate in one of four categories of studies all involving Rifapentine in combination with three other approved TB drugs Isoniazid (INH), Pyrazinamide (PZA) and Ethambutol. It is unclear which combination he signed up for, but it is important to note that, according to the consent form, Ethambotal, which was administered alongside the Rifapentine in all four categories, “can cause loss of eyesight. The visual impairment may be temporary or permanent. We’ll test your eyes before commencing the research and twice a month for the initial two months of the research.” Also stated on the consent form is the warning that, “consuming alcohol while on TB treatment might affect your heart. Ideally, alcohol should be avoided during the TB treatment.”

Given that Edwin has a self-admitted drink problem, which may have affected the condition of his liver, and is visibly underweight, one should ask why he was even considered for a clinical trial in the first instance. The consent form and various other information sources regarding Rifapentine do clearly highlight the risks associated with alcohol and other pre-existing health conditions. According to a description of Rifapentine on Drugs Information Online: “The presence of other medical problems may affect the use of Rifapentine. Make sure you tell your doctor if you have any other medical problems, especially: Alcohol abuse (or history of) or liver disease - There may be an increased chance of side effects affecting the liver in patients with a history of alcohol abuse or liver disease.”

According to Edwin, no health checks, including on his eyesight, were made before or after the trial finished. This not only presented a risk to the participant but also to the general public, as the data collected from a trial could be deemed questionable if the subject failed to meet the basic health criteria and may even have been consuming alcohol as the trial was in progress. It is virtually impos-
sible to prove any problems with eyesight that are a direct result of the trial. Edwin claims that before taking part in the trial, he had never had any such ailments, but, as he says himself, as a heavy drinker and someone that works with smoke and chemicals, it would be easy for the medical researcher to absolve themselves of any responsibility.

Fear of authority

Research by Wemos into clinical trials in various countries has shown that the authority and instructions of medical professionals in low-income countries often goes unchallenged by patients. Fear of authority, hierarchical doctor-patient relationship and the lack of empowerment within poor communities have all been shown as reasons behind the lack of any questioning of clinical trial procedures. These factors combined with a desperate need to access medical treatment could undermine the credibility of genuine informed consent and the ability of trial patients to challenge decisions and procedures.

For men like Edwin, poor, unemployed and with little education, professionals in suits often represent something unquestionable and intimidating. Deference to authority, combined with little awareness of their rights and/or other alternatives, often means that trial participants in low-income countries are vulnerable to exploitation and lack the courage or awareness of their rights when it comes to challenging decisions and following up on issues relating to adverse effects and compensation entitlements.

The fact that Edwin is simply too scared to go back to the researchers and pursue his case, despite his failing eyesight, is probably caused by the underlying fear of authority amongst some poor communities. As he implies himself, once he put his signature on the form, he believes that he waived all rights to any kind of complaint or compensation. These kind of perceptions can only be changed through clearer communication at the recruitment, consent and follow-up stage. Given that no one from the research team have ever followed up with Edwin since the trial ended ten months ago, it is likely that they themselves are unaware of the adverse effects, which, as noted before, is detrimental to both the patients and the credibility of their research process and ultimate data analysis.

28 Call for ethical trials in developing countries. Available at http://www.fairdrugs.org/uploads/files/Call_for_Ethical_Clinical_Trials_in_Developing_Countries.pdf
CHAPTER FOUR: Getting the green light-approving a clinical trial in Kenya

As the number of clinical trials, largely commissioned by external institutions, has increased over the past decade, the Kenyan authorities have attempted to formulate and implement the necessary registration and approval systems in a bid to keep on top of the growing wave of research proposals. The current government systems in place appear to be working to a certain extent and, according to a number of officials, healthcare professionals and journalists, significant efforts are being made to create a professional, credible and effective clinical trial approval process.

Navigating one's way through the process and roles of the various, and often uncoordinated, approval agencies can still be a challenge to the most patient of bureaucrats.

Various Kenyan government agencies often appear to overlap and the extent of their authority remains unclear. But in simple ‘textbook’ terms, once a sponsor has decided Kenya is the most suitable destination for an upcoming trial, the organisation has to firstly, by law, seek formal approval and a research permit from the NCST. The NCST, empowered under the Science and Technology Act (1979), is a nebulous agency, responsible for coordinating all research work in Kenya and advising the government on research-related and scientific matters. According to the official information on the NCST website, the agency is also responsible for “assessing technical and ethical aspects of proposals submitted for clearance and authorisation”, and processing applications for research permits, which must be made to the NCST at least one month before the date the applicant intends to start conducting the research.

Effort to strengthen research structures

In 2010, a study into the Kenyan landscape for review and approval of clinical trials took place. A study report was written based on interviews with key actors (governmental and non-governmental) involved in clinical trials in Kenya30. However, the report was never officially published. The report highlights several gaps in the ethical review process. First of all, it recommends that the role of the National Council of Science and Technology (NCST) should be clarified vis-à-vis research stakeholders. Furthermore, the report advises the NCST to clearly outline situations that would lead to termination of studies. The report also concludes that ethical harmonization is needed as the current system could lead to investigators seeking approval from the least strict ethics committee. Next to that, there appeared to be no national level body to coordinate the harmonization of processes in the various ethics committees and to verify compliance with ethical standards. Furthermore, the report underlines the absence of concrete ethical guidance, which leads to many ethics committees focusing on the scientific basis of the proposal whilst ethical aspects are given less scrutiny.

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Yet, despite the stated official mandate and authority of the NCST, more detailed investigations and queries into the process reveal that a number of medical research institutions, all with ethics committees appointed by the NCST, actually are more active and influential when it comes to giving the final green light of the approval process.

“Actually no single body has the final authority,” says Ambrose Rachier, Chair of the ethics committee at KEMRI, Kenya’s leading research institute, which, mandated by the Ministry of Health, is the authority to approve and authorise clinical trials in Kenya. “The NCST is the umbrella organization, which appoints and works with the ethics committees at institutions involved in research on human subjects,” he clarifies citing KEMRI, Kenyatta National Hospital, Aga Khan, MRNH and African Medical and Research Foundation (AMREF) as the key players in Kenya’s clinical trials. “KEMRI is the main gatekeeper for reviewing and approving clinical trials,” Kizito Lubano says adding, “While researchers can seek final approval from the NCST, certain mandated institutions also have final approval power themselves.”

**Kenya Medical Research Institute (KEMRI)**

KEMRI, established in 1979, is the most recognised and high profile clinical research institution in the country and seemingly the organisation of choice for many MNCs looking to conduct clinical trials in Kenya. The importance and prestige of the organisation is clearly reflected by the explanatory text on the official website, which states: “Since its inception, KEMRI has developed a critical mass of scientists and technical personnel, to enable it mount a competitive research infrastructure to rank as a leading centre of excellence in health research both in Africa as well as globally.”

As should be standard practice in any clinical trial process, the ultimate decision to authorise a study lies with an ethics committee. This standard operating procedure also applies in Kenya where, by law, any research of a biomedical nature to be conducted on humans in Kenya requires mandatory ethical clearance.

As outlined earlier, a number of Kenya’s leading medical institutions have been authorised, through the NCST, to approve and carry out clinical trials with sponsors or PRIs on both their premises and at various sites across the country. KEMRI, MRTH, Kenyatta National Hospital, and Aga Khan Hospital all have ethics clearance committees that review all research proposals involving biomedical research on human beings. Due to time constraints and difficulties in accessing officials without official clearance from the Ministry of Health (see chapter five), the main bulk of the information regarding the approval process came from officials at KEMRI who were very open to sharing information about their ways of working.

According to the KEMRI website, the role of the institution’s ethics committee can be described as follows: “KEMRI has an Ethical Review Committee which reviews all research project proposals that involve human subjects. The Committee is accepted by the Ministry of Health as a National Ethical Review Committee and is multi-sectoral and multidisciplinary with most of the representation from outside the Institute, thereby maintaining its independence from any institutional influence. The Director of the Centre for Clinical Research serves as Secretary to the Committee. Any project proposal which requires ethical clearance will only be cleared for implementation by the Scientific Steering Committee when it has also been duly cleared by the Ethical Review Committee.”
The current chair of KEMRI’s ethics committee is Ambrose Rachier, a dynamic lawyer, with 32 years’ experience in Kenya’s clinical trials industry. “We (KEMRI) review at least thirty new applications for studies every month, out of which 25 are clinical,” he explains pointing to a desk piled high with paper files at his law firm in central Nairobi. “Our ethics committee is very diverse, we have a lawyer, a scientist, a vet, a priest, a clinician, a geneticist, a psychiatrist, and a community representative,” he explains adding that the positions on the KEMRI ethics committee are not paid. “People on our ethics committee are passionate about ethics and are interested in this subject; they are not doing it for any kind of financial gain. They get paid around forty euros per sitting as a kind of stipend,” he explains.

Positive developments.

Despite being publicly outspoken in the media about the various ethical challenges and risks within Kenya’s clinical trials industry, Rachier is also keen to stress the positive developments he has witnessed in over ten years at the Chair of KEMRI’s ethics committee. “If you think that in the 1960s there were no ethics committees at all and everything was approved by the government, then it’s clear that the capacity and independence of the ethics committees has greatly improved,” he states confirming that the number of clinical trials proposals has steadily increased in the past decade. “We now have clearer ethical guidelines and principles and there is a much greater awareness of the Declaration of Helsinki, the Nuremberg Code and other international norms and standards.” “The fact that more and more trials are coming from overseas countries, such as the US, has meant that we are subject to greater scrutiny and higher standards, so we have had to adapt to that. In particular the US requires strict compliance and expects order, so this has changed things in the country.”

Rachier also stresses that he and his team often take a tough line with sponsors who fail to provide adequate information or sufficient protocols and safeguards in their trial proposals. “We amend their proposals and force them to adapt,” he stresses playing down any accusations that MNCs or western research agencies bully or pressure the national approval authorities. “Of course, we need to remember that pharmaceutical people are usually no scientists or medical professionals. They are business people looking for a profit,” he stresses. “Pharmaceutical companies can come under a lot of pressure because huge amounts of money are involved and there is always a risk they could take shortcuts or put pressure on us to do things quickly and get favourable results.” “We need to change this mind set and make sure they behave rationally and ethically when working in Kenya.” However the pressure that a pharmaceutical company is under to have a trial approved quickly is immense as was described in a Mc Kinsey report (Cure for CTs). This report clarified that taking a single month off a trial by improving recruitment could generate an additional $40 million in sales. Recent reports show that ethics committees are indeed under a lot of pressure by pharmaceutical industry to rapidly approve a trial proposal.30

In theory and in line with the law, all clinical trial applications should contain at the very least a full proposal, namely; adverse reactions - minor, moderate, major, ethical questions, and justification of the relevance and benefit to the host country. But as in many countries, such as Kenya, where corruption is rife and oversight potentially lax, there are concerns that pharmaceutical companies could exploit the situation to circumvent the necessary procedures and regulations. “They (sponsors) think they can get away with anything because it’s Africa,” warns Dr Patrick Orege from KEMRI’s

division in Kisumu. “I often send proposals back because they are not acceptable. Just this week, I returned a proposal submitted by a major US company as the provisions in it were too vague and they did not sufficiently detail how they were planning to recruit two hundred plus people for a trial,” he adds without revealing further information due to confidentiality.

Funding challenges and lack of independent monitoring

Others express concern about the level of influence MNCs and PRIs, such as the CDC, have on the research priorities of KEMRI. A large proportion of the organisation’s funding comes from external foreign sources such as universities and PRIs, (one estimate is around six-sevenths of the final total of the KES100 million budget), which according to one anonymous senior source at KEMRI is extremely detrimental to the independence of the organisation. “We are over-reliant on external funding,” said the source on condition of anonymity. “If our funding and priorities come from outside, this makes our research ‘demand driven’ by others. Research should be scientific and not driven by demand. There could be a risk of people being bought off.”

Despite the general optimism and confidence of experienced officials such as Rachier that the ethical review process is continuing to improve, questions and concerns still remain about the monitoring process. “Our oversight, monitoring and follow-up of clinical trials is still too ad hoc,” admits Rachier. “We sign off on so many trials that we don’t always have the capacity to monitor efficiently. We really do need an independent monitoring body to make sure this is done,” he asserts, echoing the concerns highlighted in the case of Edwin in Kisumu who has never once received a follow-up despite the adverse impact of a TB trial on his health (see previous chapter).

“After you approve a research, nothing stops a dishonest researcher from designing a different consent form and administering to participants. We usually do random checks on researchers to curb this,” he told Catherine Karongo in her 2011 news report for Capital FM. A reliance on courageous staff or concerned ‘whistle-blowers’ to report back evidence of ethical malpractice during clinical trials is, according to Rachier, a clear consequence of a lack of effective monitoring systems. Sporadic spot checks by KEMRI researchers are not always enough to identify problem areas, as illustrated in the following anecdotes, related by Rachier.

Reliance on whistle-blowers

In October 2011, a whistle-blower based in the port city of Kisumu alerted KEMRI headquarters in Nairobi that a clinical trial for malaria, being undertaken by a leading US PRI, had aroused suspicions. Further investigations revealed that the chemical being tested had been injected into the blood of live cattle to study the toxic effect on mosquitoes once they had bitten the animal. According to the trial protocol, all cows used in the study would be slaughtered so as to prevent any contamination of meat and milk. But according to the whistle-blower, and as a consequence of lax monitoring by the investigating team, the cows were simply being returned back to their owners in the village. “The public health risk there is obvious,” says Rachier explaining that the research institute in question, following the tip off from the whistle-blower, admitted their error and the trial was stopped immediately.

A week earlier, another study sponsored by a leading international donor, was suspended in the same region after a local staff member reported ethical concerns about the consent procedure.
The study, behaviour/observational study on HIV, involved monitoring the sexual activity of high-
school age adolescents and taking samples of blood and urine. An investigating team from KEMRI
was deployed to the trial site and discovered the consent for the participants had been granted by
the head teacher only and not by the parents, a clear ethical violation. “These are invasive procedu-
res and need parental consent,” said Rachier. Moreover, he continued, it turns out that the applica-
tion for the study, which was also being conducted in partnership with two leading US Universities,
had been submitted to the ethics committee several months earlier. “They had actually applied to
us for urgent approval due to a funding deadline,” explains Rachier. “I sent the proposal back as it
needed more clarification, and they never came back to me. I was suspicious and then I heard they
have gone ahead with the trial anyway!”

Challenges in registering and monitoring data

It is not just the lack of capacity in monitoring and ethical oversight that concerns many of Kenya’s
clinical trial experts. Inaccurate or ineffective logging of trial data and a failure to report unfavourable
outcomes were also issues of concern that came up in a number of interviews.

“Investigators don’t always report failure or adverse effects to the sponsor,” says a KEMRI official
without being named. “Sometimes people exaggerate success or fail to report bad results because
of their pride. This can affect the accuracy of the data. All problems should be reported, so we can
learn from them.” The official also expressed his concern that once a trial was completed, hardly
any follow-up checks were done on the participants. “Twenty years after a trial, how do we know
about the long-term effects of a trial,” he questions echoing the same sentiment of journalist
Catherine Karongo. “KEMRI can’t even tell you where the patients are,” she says. “Once the drug is
approved, they have the profits, and they don’t care what happens to them. You can’t even find
them again.”

Unlike in a country such as India, where CROs play a key and recognised role, this side of the indus-
try does not yet seem to be established to the same extent in Kenya. In a large number of cases,
once the green light has been issued for a trial, KEMRI and the sponsor provide the research team
and principal investigators themselves and therefore keep the process ‘in house’ without any need
for an outsourcing agency such as a CRO. The Standard Health Editor Peter Orengo has long sus-
ppected that doctors, mainly those working in private practices, are being approached by trial spon-
sors to carry out trials, possibly without official approval. “Contracting here is big business and doc-
tors can get approached individually by companies for incentives,” he says. “Sometimes a company
will approach a doctor and pay them to use a certain new drug on patients and report the results.
Usually the patients are not told it’s a trial. Sometimes the doctors don’t know themselves either,” he
adds without elaborating whether this is based on facts or purely speculation. “A doctor can double
his salary doing that kind of thing. The data is then sent back to the sponsor and out of the country
before KEMRI even knows about it.” When presented with these allegations, Rachier was keen to
downplay any speculation, but did not rule it out altogether. “There could be trials going on that we
don’t know about and have been done without approval and ethical clearance,” he conceded, refer-
ring to the HIV-consent case in the high school (see above) as an example of how sponsors are able
to find ways to circumvent the official approval process.

The suspicions and concerns of journalists such as Peter Orengo and the lack of information to sup-
port their allegations, reflect a wider problem in Kenya - the limited ability of journalists to investiga-
CHAPTER FIVE:
A matter of public interest? Investigating the clinical trials industry in Kenya

How much information is out there?
Before arriving in Kenya to undertake this field research, a significant amount of time was spent locating any existing public information about Kenya’s clinical trials industry. Given the expansion of the sector in Kenya and its lucrative economic potential (as outlined in the IMS report cited earlier), one would assume that the Kenyan media, NGOs, activists and health professionals would be taking an active interest in the reporting and scrutiny of this burgeoning national and transnational industry. However, this assumption proved erroneous and in hindsight rather naïve. In fact, efforts to get even a general understanding of the country’s clinical trials industry from open-source information such as internet search engines proved quite challenging.

Clinical trials and the scrutiny of Kenyan media
Aside from the administrative, technical and specialist information available on the public websites managed by the official healthcare and/or government agencies (see chapter four), a generic google search for the most recent media articles on clinical trials did not reveal an abundance of useful leads. Perhaps the most significant (and most recent) media article about Kenya’s clinical trials industry was published back in March 2011, when Capital FM journalist, Catherine Karongo, published a piece entitled ‘Kenya’s guinea pigs short changed’. In this article Karongo quotes Mr Ambrose Rachier, the Chair of KEMRI’s ethics committee, as saying that from the over three hundred trials going on in the country, the chances of Kenyans benefitting from them are ‘close to nil’. The article is scant on detail and any meaningful analysis, but the quotes from Rachier are thought-provoking. Such frank observations from an official in senior position within the country’s trial industry do generate further questions, which, in 2013, still seem to have gone unanswered or at the very least unexplored by the national media. “I actually wrote that report off the back of a press conference about trials given by the Health Ministry,” says Karongo conceding that the story had simply been presented to her rather than revealed through any personal investigation. “People are not really interested in this issue, so it’s a hard sell to editors,” she explains. “I would have liked to track down some trial patients to continue with this story, but there was no money or time for it.”

“There is a lack of resources and specialism amongst our reporters,” agrees Douglas Okwatch, a senior investigative journalist who, back in 2003, broke one of the major clinical trials stories in recent times. Okwatch and his team from The East African Standard, ran a major expose entitled ‘The human guinea pigs of Rarieda’, referring to a region in the western Nyanza province where, the report claimed, KEMRI and the CDC were recruiting local people, some unknowingly, as human guinea pigs. “Something not quite right regarding research protocol and ethics is happening in Kisumu, Siaya and Bondo Districts,” the report stated as claiming that, for over twenty years, many people with infectious diseases, including HIV/AIDS, had never been told the full scope of the research. The KMA’s Human Rights Committee Chairman, Dr Mohammed Said, responded to the expose, clearly stating for the record that it was totally unethical for researchers to use humans as guinea pigs without their consent.

As a result of Okwatch’s damning report, the KMA launched an immediate investigation. However, a further internet search about this story reveals little follow-up. It would seem that the outcome of the promised ‘investigation’ was never followed up in any detail by the media, and as Okwatch himself says, big news stories are easily forgotten once the media move onto new stories. “The media often don’t do enough follow-up on big stories, largely due to time. So often nothing really changes, even not after something big is exposed,” he says. The fact that the next article dealing with the ethical question of clinical trials only appears almost a decade later in 2011, clearly demonstrates this lack of media interest and scrutiny of the issue.

Difficulties in accessing accurate and updated information are widely cited by Kenyan journalists as a deterrent for digging into the clinical trial issue in any depth. “It is very difficult to access information about these trials and people do tend to get misled due to the lack of public information,” worries Karongo. “It’s very hard to get accurate and up-to-date data about clinical research,” agrees Peter Orengo, the well-respected health editor of The Standard. “We tend to read about the clinical trials done in Kenya once the data has been published in journals outside of the country!” Orengo, who reported on the publication of the 2006 SOMO report about clinical trials in Kenya (but again with very little analysis or follow-up), also says that the big money and political aspects of trials make the subject hard to investigate. “People are very silent about clinical trials; my friends in the healthcare industry tell me to stay away from it. It’s big money and people are afraid to lose their jobs. There are so many stories we can’t write because we get blocked,” he says adding, “I have heard unconfirmed rumours about people dying in clinical trials, but it’s never been investigated and it can be covered up or autopsies can be easily faked.”

The lack of time and money to commit to investigations is compounded by the lack of simple and transparent information about what is actually going on. Unlike in other countries with a strong civil society and advocacy sector, such as India and Brazil, there are very few independent organisations focusing on ethics and the protection of human rights in Kenya. Due to the pressing immediate needs of the population, the vast majority of healthcare activism in the country is centred on treatment, care and general patient welfare. Therefore, human rights groups and specialist watchdog agencies have yet to emerge in the humanitarian space. Even the specialist healthcare NGOs, approached during the researching of this report, generally said that they had little information about clinical trials - other than that they knew were taking place. Conversations with a number of health activists also suggested that the desire to find cures for so many diseases in Kenya could only be considered a good thing and any further questioning about the ethical aspects of clinical trials had not really been considered. This lack of a ‘go-to’ organisation for information about clinical trials is also a reason why the media are either unaware or unable to investigate the issue easily.

**Information sources and clinical trial databases**

Initial efforts by the author to gather some basic public data about the nature and number of clinical trials ongoing in Kenya were challenging for a number of reasons. Aside from the general media search on clinical trials, the most obvious place to start was the international portal ClinicalTrials.gov and CenterWatch. ClinicalTrials.gov, an online global registry and results database of public and private trials, did throw up some interesting background information. The data showed that in November 2013, 250 trials were registered in Kenya, the vast majority for HIV, malaria and infectious diseases. In some cases, the PRI or a university would be listed alongside the site locations, but it
proved difficult to find any information about the name of any pharmaceutical sponsor. Also problematic for the lay person seeking out basic information, is the description of the trials; titles such as computerized counselling, empiric therapy, and intermittent screening are very technical terms and would require further reading and research for a complete understanding of the trial.

Research on CenterWatch, a registry and analysis portal for clinical trials information for both clinical research professionals and patients, also revealed information about the trials currently recruiting patients and details about the types of diseases being tested. But as with ClinicalTrials.gov, the information was limited, notably with regard to the international sponsors and did not provide simple and accessible information for a busy journalist or non-specialist researcher.

Given the complex and limited results generated by the international portals, the next logical step was to try and access basic trial data from national registries and databases. However, discussions with journalists and health professionals, including researchers at KEMRI, revealed that a single ‘go-to’ accurate (and regularly updated) portal for clinical trial information does not yet exist in Kenya. A number of people referred our data search to the PPBK, the national drug regulatory and registration authority. However, in order to access any information, we were required to register - and to do that, we had to testify that we were working in the pharmaceutical sector. If not, we would be subject to a follow-up based on the warning: “This system and related equipment are subject to monitoring. Information regarding users may be obtained and disclosed to authorised personnel, including law enforcement authorities, for official purposes.” A second, more intensive search through the PPBK site revealed the existence of a second site dealing specifically with the monitoring and reporting of adverse drug reactions and poor-quality human medicines. The National Pharmaco-vigilance Centre also provides some basic information about the category of clinical trials taking place in Kenya, the locations, the types of drugs and in some cases the name of the Principal Investigator. But there is limited information about the sponsor or the research institution available. Moreover, the website seemed to be often out of action and at times would not load at all.

Similarly, the KEMRI website provides a lot of useful information about the institution and their mandate, but is less user friendly when it comes to detailing the specifics about clinical trials and their sponsors. There is no obvious section pointing to a database or registry of clinical trials and a number of the links are broken or peppered with incomprehensible acronyms and bureaucratic explanations. Initial efforts to navigate through the KEMRI website in search for information about clinical trials were therefore not immediately encouraging. Such cumbersome, complicated and time-consuming research processes are likely to deter journalists who are often stretched for time and up against deadlines, from taking time to investigate the clinical trials issue in any significant detail.
In addition to the challenges in accessing basic data about the industry, persuading people to talk about the issue proved difficult, especially when it came to government agencies and doctors. Senior officials from institutions such as Kenyatta National Hospital refused to grant us an interview (or even an anonymous background briefing) without proof we had been granted official permission from the Ministry of Health. A number of doctors and PhD students, who were initially interested in contributing, backed out from the research without any reason. KNHRC, despite their stated mandate to protect the rights of the people, repeatedly cancelled our engagements and then eventually stopped returning our calls. KEMRI officials on the other hand were very open to granting access to this research and expressed no requirement for official permission from the Ministry of Health.

Simple, public information about clinical trials is not easily accessible and there is little public awareness about this burgeoning industry. It is also unclear whether information is being kept secret on purpose or whether people have simply never thought to ask the pertinent questions. Whatever the reasons, it is hoped that this report will serve as a good basis upon which to initiate further investigations.

Legal developments

In July 2011, one development that has raised the hopes of investigative journalists was the decision made by President Mwai Kibaki to launch the Kenya Open Data Initiative. This initiative had a stated aim of making key government data freely available to the public through a single online portal. As of November 2011, there were close to 390 datasets that have been uploaded to the site, with a plan currently in place to upload more data over the next years. Though this move is welcomed, a quick search reveals that any information about clinical trials is so far limited to audits and public expenditure data. It should also be noted that in September 2013, the Kenya Parliament passed a draconian new media law that, critics say, amounts to a gag order on Kenya’s media. Under the new legislation, journalists could incur heavy fines as high as KES20 million (more than $200,000) on journalists and news organizations deemed to be ‘irresponsible’ in their reporting - a short-hand for stories that disrespect public institutions, including cabinet ministers as well as the national army and police. It is possible that this new legislation could further hinder Kenya’s investigative journalists.
CHAPTER SIX:
“How have you left us?”
Post-trial access to treatment

Alongside the critical ethical issues surrounding patient consent, compensation and protection, the long-term question about the overall benefit of a clinical trial has steadily become a pertinent one in various low-income countries. Whilst it is generally agreed and understood that clinical trials are a necessary and important part of medical advances, this should never serve as an excuse to overlook the sometimes difficult ethical questions. The immediate risks of patient harm or exploitation are starting to become a little more known by the general public thanks to media investigations and the occasional expose of an unethical clinical trial. But the longer-term ethical question about who should and does benefit from participation in a clinical trial is somewhat less explored and to a degree unresolved.

The question of benefits, notably a patients right to access the trial drug once its approved, continue to colour debates surrounding the clinical trials in low-income countries countries. In 2004, the World Medical Association clarified one of its ethical guidelines to physicians on biomedical research to ensure that those people taking part in research would continue to have access to proven beneficial treatment following the research study. In paragraph thirty of The Declaration of Helsinki, regarded as the world’s most widely recognised source of ethical guidance on biomedical research on humans (see glossary), the new provision states that “At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.” “Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review.”

In line with global research standards, details and provision surrounding post-trial access should be contained in any study protocol submitted for approval in Kenya, but as Ambrose Rachier from KEMRI notes in an interview with Capital FM in 2011 “What happens most often is that when the product comes into the country it is unaffordable and therefore those who had participated (in the study) do not get the benefit despite taking the risk.” “And the ethics committee and participants are powerless at that time; we have no bargaining power,” he continued, adding “This is a policy issue that is handled at governmental level. (...) If vaccine studies are done in Kenya, for instance, the country should get the final vaccines at an affordable price after successful research.”

Following in the footsteps of India, where activists have revealed gross violations in post-trial access to treatment, a number of prominent Kenyans have started to speak out about the potential for unfair and prohibitive costs of drugs tested in Kenya on Kenyans. In 2009, Public Health Minister Beth Mugo became embroiled in a bitter battle with a vaccine manufacturer who had refused to subsidise the cost of a pneumonia vaccine despite the research having been done on Kenyan children. Government statistics indicate that at least 30,000 children die annually from pneumonia in the country, making it the second largest killer disease in children, after malaria. “Kenyan children cannot be guinea pigs just to be used to develop the medicine and after that we cannot access it. There are areas that we have to put our foot down because we also have a right to those vaccines,” a furious Mrs Mugo...
told the media at the time. Her persistence paid off when in 2011 the PCv10 vaccine, previously only available in private hospitals, was provided to children free of charge in all public health facilities at national level.

Ms Mugo may also have inspired other companies. GSK and Pfizer have both committed to provide up to three hundred million doses each of their pneumococcal vaccines, with ninety per cent cost reduction in low-income countries over the next ten years. Whilst advocacy organisations have welcomed this as a positive development, it should not detract from the importance of addressing the deeper issues of poverty and social determinants of ill health in Kenya. The ‘quick fix’ provision of accessible medication should be accompanied by robust policy making and serious investment in healthcare provision and basic development infrastructure in the country.

Other developments in Africa’s battle to ensure greater access to healthcare came in 2012, when Pfizer announced the drop in the cost of cancer medication by sixty per cent in a fresh drive to combat escalating prevalence of the disease in Africa. Similarly in 2011, GSK, which has a significant presence in Kenya, followed through on a pledge to reduce the cost of its medicines in low-income countries and directed its Kenya unit to reduce prices on essential drugs by fifty per cent.

“People like good-quality medicine, but are not able to afford it,” Kenya’s GSK Director Musunga told Bloomberg at the time. “We cannot afford to focus only on the high-income social groups.”

However, as the probing author of the article noted, the move was “not a purely altruistic one”. “Improving patient access to medicines can boost the volume of sales, and in emerging markets, higher volumes may make up for the lower prices,” Musunga told Capital Business adding that, after cutting the price of its leading antibiotic by forty per cent, GSK saw a sixty per cent increases in volume, thus compensating for the price change.
As debates surrounding the controversial issue of post-trial access to treatment continue, these moves by the world’s leading MNCs are a positive step and should be welcomed. However, doctors and health activists in Kenya remain concerned that many life-saving drugs, tested on patients in low-income countries, still remain out of the reach of many once the trial is completed. David Makumi from Kenya Cancer Care is particularly concerned about the affordability of leading cancer drugs such as Herceptin and Avastin (both produced by Swiss company Roche) as cancer rates continue to climb in the country. “The price of (branded) cancer drugs remains very high and just not affordable. Cancer is the next big thing in Kenya and these middle-class prices are not justifiable,” he says adding “Cancer patients often have no other choice to turn to shady generic drugs, which can be dangerous.” Makumi also strongly believes that if the number of multinational clinical trials for cancer drugs increases in Kenya, strict conditions conceding post-trial access must be included in the proposal. “If more trials do start up, we need to make sure that we have a rigorous policy in place and that we can manage the trials on our own terms. It is not fair or ethical to withdraw treatment from a patient after a trial.”

Another concern expressed by Makumi and several others is the long-term benefit of a clinical trial to the wider population of Kenya, including the ailing healthcare service. “I have heard of (pharma) companies coming to our public hospitals to do clinical trials and offering the staff laptops, modern registration cards and other fancy things, and then simply taking everything away once the study is finished,” he said declining to name the specific company involved. Journalist Peter Orengo also asks a similar question. “Why do they come to Kenya for a clinical trial,” he asks rhetorically. “If these big companies like GSK built a hospital or a school, Kenya would benefit, but millions of dollars leave the country once the trial is finished.”

“People in Kenya do not benefit from the clinical trials,” agrees an anonymous official from KEMRI. “For every KES100 invested in a trial, only about five per cent comes back to Kenyans. This does not translate into benefit.”

As KEMRI’s Dr Orege notes. “I don’t see an ethical problem if people don’t benefit from trials,” he says. “Trials are for the benefit of science, the price issue should not prevent trials from going on. One step at a time. Let’s make the science work first. We can deal with the issue of access and affordability later.”

But for community outreach activists like Erick Okiama, himself HIV positive and a strong, personal supporter of medical research, protection and the welfare of the patients must come first. “We have very often seen situations of desperation and a lack of alternative,” he says. “In our community, we have a saying, “koro iweyowa made”, which in the local Luo language poignantly translates as, “We had hoped for your support, but now how have you left us?”
CONCLUDING REMARKS

Transition
Kenya has long been a country of interest for external parties. From the British colonial period through to the current era of investment from emerging superpowers such as India and China, this strategically located country will continue to grow as a hub for international business and trade. Whilst infectious diseases such as HIV/AIDS and TB still remain the most immediate public health risk, Kenya will soon experience a surge in demand for treatment of NCDs. This transition will change the clinical trials landscape, which has historically been dominated by PRIs. The increase in NCDs will lead to an increase of NCD-related clinical trials in Kenya. The development and marketing of NCDs is the core of the business model of the pharmaceutical industry. Therefore, the multinational pharmaceutical industry is steadily gaining ground and seizing new research and market opportunities in Kenya.

Vulnerability
Other reasons why MNCs are increasingly interested in clinical trial opportunities in countries such as Kenya have been well documented in this report. The practicalities of an English speaking country with established transport, medical and communications infrastructure are an obvious business asset. However, the general levels of poverty and the lack of access to quality healthcare for millions of Kenyans is a disturbing reality and a factor that must be considered by any entity looking to carry out clinical research in the country. This report has revealed examples of Kenyan’s signing up for clinical trials without having a clear understanding of why they have been enrolled. The opportunity to access free healthcare throughout the course of the trial, and in some cases free food, is a questionable incentive in a country where twenty million people live below the poverty line. For them participation in a clinical trial is the only option to get access to healthcare. Moreover, the lack of follow-up with the trial patients, limited (or zero) post-trial access to healthcare, and the inability of patients to complain if things go wrong, still remain serious issues of ethical concern.

Regulatory framework
According to officials and experts interviewed, significant efforts are being made to create a professional, credible and effective clinical trial process. Several of the officials interviewed in the report demonstrated expertise and commitment to protect the rights of clinical trial participants. However, the report also highlights a number of concerns on the part of the Kenyan regulatory framework. One of the concerns that was highlighted by a Kenyan official was the lack of capacity to monitor clinical trials, which may result, as was illustrated in the report, in health problems of clinical trial participants remaining unknown to the researchers. Another concern described in the report is the absence of concrete ethical guidance that leads to many ethics committees giving more attention to scientific review and less on ethical aspects. This is particularly concerning knowing the vulnerable position of the clinical trial participant. Given the growing international interest in the Kenyan market, the case load is likely to increase, placing yet more pressure on approval bodies. This development renders the harmonization of ethical review and the verification that ethics committees have integrated ethical standards in their approval procedure essential. The creation of an independent monitoring agency, as suggested by a senior KEMRI official, to ensure the recruitment and general process of a clinical trial is safe, ethical and free from the risk of malpractice or corruption, would be an extremely important step forward.
Transparency

This report has also highlighted how little the general public in Kenya know about the flourishing clinical trials industry in their country. With diseases such as malaria, TB and HIV claiming thousands of lives every year, the search for a cure is fully supported by all, including Wemos. But the way in which trials patients are recruited and monitored has thus far been subject to very little scrutiny by the Kenyan media, largely due to time and resource constraints. Given that clinical trials will continue to flourish and form an important part of the Kenyan business market, it is critical that the media, notably health and investigate journalists, work with the government and institutions such as KEMRI to ensure that a system of checks and balances are in place and that a transparent flow of information is established. The famous Watergate quote “follow the money” could be equally applied in this context and it is the hope of Wemos that this report will spark the interest of senior editors and journalists to explore this issue further. Equally, it is our hope that activists and advocacy groups, both in Kenya and in the international community, will start to mobilise and take more of a specialised interest in the issue of clinical trials. Whilst we all share the belief that the cure for diseases is the ultimate achievement, the protection and fair treatment of vulnerable people should also be an equally important goal.
THANK YOU LIST

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- Mr Douglas Okwatch, investigative journalist.
- Peter Orengo, Health Editor for The Standard Newspaper.
- Dr Joep van Oosterhout, Medical and Research Director Dignitas.

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KEY REFERENCE LIST


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Reports


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The Kenya National AIDS and STI Control program (NASCOP) under the Ministry of Health (MO) disseminated preliminary results of the Kenya AIDS Indicator Survey (KAIS) 2012 on September 10, 2013.

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Websites
AIDS Candlelight Memorial. See http://www.candlelightmemorial.org/

Africa Health Dialogue. See http://africahealth.wordpress.com/


Global Policy Health Centre. See http://csis.org/program/global-health-policy-center
CSIS’ Global Health Policy Center (GHPC) is a leading policy research institution focused on building bipartisan awareness about global health and its importance to US national security.

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National Treasury of Kenya. See www.treasury.go.ke

Media sources


ANNEX I:
Informed consent form Rifapentine

Fleisch – Kincaid 7.3:

INFORMATION ON CONSENTING TO THE RESEARCH

Research on Rifapentine, a drug used on the first stage of tuberculosis (TB) treatment

Version 2.2, 14th July 2011

FOREWORD

You are requested to be part of this research because your doctor suspects that you have TB. The Kenya Medical Research Institute (KEMRI), Kisumu Branch and Centers for Disease Control and Prevention (CDC), Atlanta have partnered in this research.

WHY IS THIS RESEARCH NECESSARY?

TB treatment involves four kinds of drugs; Isoniazid (INH), Rifampin, Pyrazinamide (PZA) and Ethambutol. In this research, we want to investigate the effect of Rifapentine in the first two months of TB treatment. The side effects of these drugs are also under investigation.

All drugs used in this research have been approved by the department of the American Food and Drug Administration (FDA). The approved dose of Rifapentine is 600mg (10ml depending on the patient’s body weight) given once or twice a week as the approved TB treatment. About 250 patients were given the approved Rifapentine dose five times a week for eight weeks during the initial stages of this research. TB experts checked the results periodically and there were no side effects found.

In this research, we will use the highest dose of Rifapentine given daily for eight weeks as one of the treatments of TB. The dosage depends on the patient’s weight and the type of treatment he is on. Giving a daily dose of above 600mg is not recommended by FDA because Rifapentine is still a drug under research.

WHERE IS THIS RESEARCH DONE?

It is being done at Nyanza Provincial General Hospital and at KEMRI/CDC Research Center situated next to it.

HOW MANY PEOPLE WILL BE INVOLVED?

About 250 people will be part of this research globally. In the research center at Kisumu, fifty people will take part. It will involve adults over eighteen years of age.

HOW LONG WILL ONE BE PART OF THIS RESEARCH?

You will be involved in this research for the whole period of your TB treatment. Your treatment will take six to nine months. The length of your treatment will depend on how severe your TB is and how you will respond to the drugs.

You will not be part of this research:

• If your first sputum test shows no evidence of TB
• If one has TB but has become drug resistant

CONTENTS OF THIS RESEARCH

If you consent to be part of this research, these are the procedures and what is expected of this as a TB patient.

Levels of involvement

• You will be asked questions to determine your understanding of the different levels of involvement in the research. This will take approximately fifteen minutes on a day you agree upon in the first two months of the research.

Before commencement of research medication, you will be tested in the following areas:

• A blood test checking on the condition of your heart, kidneys and your blood count. We’ll take a blood sample of approximately 10ml, which is equivalent to two teaspoonfuls. This will be taken from a vein.
• An HIV test (Human Immunodeficiency Virus) from 1ml of blood using a rapid results AIDS kit. This is a compulsory test for everyone with TB and has been selected for this research. This test is not necessary if one already knows their HIV status or had tested negative within the past three months and has a chit confirming this.

• A pregnancy test will be necessary for all female adults who are still in their reproductive years. It must be confirmed that one is not pregnant to be qualified to be part of this research.

• A chest x-ray.

• 10ml or two spoonfuls of blood from a vein. This will be stored in a cooler. It will not have any identification tag. This blood may be tested for any drugs concerned in this research. It will be used in future researches to increase our knowledge on TB how to treat it. No test on human behaviour will be done.

On the medical part of this research:
• You will be considered for four different treatment categories of eight weeks of TB treatment. The category of treatment will depend on your choice. You can choose any of the four categories of TB treatment.

These are the four different treatment categories

• Approved TB dose: INH, rifampin, PZA, Ethambutol – these are taken on a daily basis.

  OR

• 10mg of Rifapentine (depending on the weight of the patient) plus the approved TB dose of INH, PZA with Ethambol, which must be taken on a daily basis.

  OR

• 15mg of Rifapentine (depending on the weight if the patient) plus the approved TB drugs of INH, PZA with Ethambutol, which must be taken on a daily basis.

  OR

• 20mg of Rifepentine (depending on the weight of the patient) plus the approved TB drugs of INH, PZA and Ethambutol, which must be taken on a daily basis.

• All the participants of this research will be given Vitamin B6, which is taken with the full dose of TB drugs. Vitamin B6 reduces the incidence of numbness on the arm and legs after using INH, which is one of the approved TB drugs.

• The health worker will give you the drug doses to be taken between Monday - Friday. The researcher will discuss on the procedure for taking drugs over the weekends.

Research Visitation

For the eight weeks you will be taking the research drugs, you will be seeing a nurse or the researcher or the doctor. The visitation will take place in week two, four, six, and eight after being on medication. Each visit will take approximately thirty minutes.

• If you are HIV positive, on one of the visits, your CD4 count will be tested. For this test, 10ml or two spoonfuls of blood sample will be required from your vein.

• On one of the visits, two spoonfuls of blood sample would be required to check for any trace of the drug Rifapentine in your blood.

On all visitations, the following will be done:

• Checkup of the blood to check the condition of your heart, kidneys and your blood count. Blood samples of 10ml or two spoonfuls from a vein will be required.

• A sputum test will be required for testing TB.

The eight-week visitation will involve the following:

• Two sputum samples for testing TB.

• Two spoonfuls of blood sample will be kept in a cooler. There will be no identification tags. The blood will be tested for any traces of the research drugs. The sample can also be used in other future researches to increase knowledge on TB and its treatment. There is no test on human behaviour in this research.

Other drugs given in the course of the research:
• During the research period you are not expected to use any other drugs for two months preceding the TB treatment. These include drugs for HIV/AIDS.

• The TB drugs have to be taken exclusively. You should inform the research doctor of all the drugs you could be taking. You should inform the doctor before using any drug while on TB treatment. These include over-the-counter drugs like antacids, paracetamols, vitamins and other drugs.
• You should take TB drugs four hours before and eight hours after using antacids, drugs for treating diarrhoea, iron drugs and zinc because they could negate the effect of the TB drugs.

**Visitation schedule as you get to the last dosage of the TB drugs**

• When you are on your last dosage of the research drugs of eight weeks, on subsequent visits, you’ll be given the approved TB treatment from your hospital and doctor. Subsequent visits will continue until you get drugs for six to nine months.

• Visitation according to the research schedule:
  
  You will meet research workers or the research doctor once a month while on treatment for TB. Each visits will take twenty minutes.

  • During these visits, a blood test will be done to determine the state of your heart and kidneys and your blood count. A blood sample of 10ml or two spoonfuls will be harvested from your vein.

  • A sputum test will be done in each research visitation unless advised otherwise.

If you move your residence from the research area during the visitation period, we will continue our visits in your new residence. The visits will be planned to take into account your new residence. We’ll send the doctor to visit you there. We’ll request your doctor or your new clinic to allow us to observe your medical documents or file at that clinic. Dr Lena Matata will still supervise the research even in your new residence.

**WHAT SIDE EFFECTS SHOULD BE EXPECTED?**

All drugs in this research have side effects, though many people who use these particular drugs don’t tend to be affected.

**Side effects from Rifapentine**

• Rifapentine can change the colour of your tears, sweat, saliva, feaces and urine yellow while you are on it. The lenses of eyes can also change colour due to the change of colour of your tears.

• Other common side effects (one to five per cent): Running stomach, nausea, vomiting, accelerated heartbeats, dizzy spells, rashes, headaches, bloody sputum, anaemia, pus, blood or protein in the urine.

• Rare but serious side effects (less than one per cent): Hepatitis, which might turn your eyes yellow, loss of appetite, nausea, pain on the left side of your stomach, insufficient blood platelets making one prone to bleeding.

• Side effects like fever, high temperature, chills, headache, dizzy spells and aching bones.

**The approved TB drugs like INH, PZA and Ethambutol also have side effects**

Common side effects (five to ten per cent)

• Running stomach, loss of appetite, nausea, vomiting and diarrhoea

• Joint pains

• Itchiness and light rashes

Serious side effects, which are not so common (below one per cent)

• Hepatitis – side effects depend on high dosage of Rifapentine.

• Ethambutol can cause loss of eyesight. The visual impairment may be temporary or permanent. We’ll test your eyes before commencing the research and twice a month for the initial two months of the research.

• INH can cause memory loss.

• INH can cause numbness on the arm and legs. Vitamin B6 reduces the chances of that.

There can also be other side effects that have not yet manifested.

Consuming alcohol while on TB treatment might affect your heart. Ideally, alcohol should be avoided during the TB treatment.

If you get any side effects make sure you get in touch with the Research Supervisor or doctor immediately or tell the TB Ambassador who does DOTS. If you do that, you will be tested and directed on what to do. Your research drugs can be stopped and your doctor can decide on the best treatment for your strain of TB.

If you get side effects, fever and other serious symptoms, a blood sample of 20ml or four spoonfuls can be taken, while you have the side effects and again after 10-35 days. This is to find out why you have these side effects.

• Your heart, kidneys and blood count will be tested.

• 10ml or two spoonfuls of blood will be taken and kept in a cooler. This cooler shouldn’t have any identification tag on it. This blood will be tested for the reason for the side effects.
SIDE EFFECTS OF THE HIV TEST
You will be given the result of your HIV test shortly after the test. You will be told the result, whether you are HIV-positive or negative. You will also get special counseling after the test. The results of any HIV-positive person will be sent to a medical worker who deals with both HIV/AIDS and TB. This medical worker is stationed at the Nyanza Provincial General Hospital. We shall keep the HIV-positive results secret, as directed by the laws of Kenya.

SIDE EFFECTS OF GIVING A BLOOD SAMPLE
There are some negligible side effects of giving a blood sample. These are like: a little pain from the needle prick, rashes, bleeding, light headedness, which is very rare, infection on the jabbed spot on the vein.

WOMEN-RELATED ISSUES
We are not sure about the side effects of Rifapentine on pregnant women or on breastfeeding babies. You will not be allowed to be part of this research if:
• You are pregnant, or
• You are planning to be pregnant during the research period, or
• You are breastfeeding a baby.

Rifampin and Rifapentine might negate the effects of family planning drugs, injections and IUDs, and other methods of family planning. While on the drugs of this research, you must find other family planning methods like the diaphragm or cervical cap, condom, sponge or intrauterine device without hormones. It's better to use these family planning methods rather than family planning pills, injections and IUD or hormonal pills. Abstinence is a recommended method you can use to prevent pregnancies during the research period.

If you get pregnant in the course of the research, make sure you let the research worker know, together with the nurse or doctor as soon as you can. The research treatment would be stopped. Your doctor would decide on the best alternative treatment.

BENEFITS OF THE RESEARCH
There are no outward benefits of being part of this research. Your participation will help in finding out if Rifapentine can fortify TB treatment.

ANONYMITY
We will use your medical file to get what we need for this research. We will not use your name on any discussion or documentation of this research. The names will not be sent to the CDC. The people in charge of the research at FDA, CDC and supervisors or researchers might have access to your medical history. We will keep your medical details a secret, as demanded by law.

PAYMENT AND REIMBURSEMENT AS A PARTICIPANT IN THIS RESEARCH
You will not be expected to pay anything for being part of this research. You will not pay for any drugs or tests done in this research. You will be reimbursed the transport costs incurred (to the tune of KES500), when travel to the center is necessary.

IN CASE OF INJURY, DAMAGES OR HARM
If you get injured or harmed in the course of this research, you will be treated by the research nurses and doctors in partnership with medical staff at New Nyanza General Hospital (NNPGH). KEMRI/CDC will not reimburse any damage/accident that would result from being part of this research. Your signature and consent to being part of this research does not nullify any of your rights. If you think its causing you any harm, please get in touch with the Secretary of the KEMRI NERC on telephone number (020) 2722541 or 0722205901, fax (254) (020) 2720030, P.O.Box 54840-00200, Nairobi, Kenya on the issue of your rights and how you can be helped.

RIGHT OF REFUSAL AND DISCONTINUATION FROM THE RESEARCH
Being in this research is your own choice and decision. If you decide not to be part of it, your daily dosage of medication won’t be affected. If you choose to be part of it, you can discontinue without your daily dosage medication being affected. Even if you leave the research, you’ll still be under treatment for TB. If any new discovery comes up that might necessitate you leaving the research, we’ll let you know as soon as possible. We might be forced to stop research medication if:
• You have serious side effects.
• If the research doctor decides that it is in your best interest to be discontinued from research medication.
• If you are not responding to the research drugs.
• You don’t follow instructions on medication, or
• When the research is completed.

Even if you stop using the research drugs, we will continue with the visitations for a period of six months.

If you choose to remain part of the research, you can choose to give blood for further research. You must let the nurse or doctor of the research know that you don’t want your test kits to be preserved for further research. In that case, every preserved test kit will be destroyed.

ANY OTHER TREATMENT

If you are not part of this research, you will be given approved TB drugs. The approved drugs by the government for adults suffering from TB; is the initial two months on Rifampin and INH, PZA and Ethambutol taken every day, followed by four months of taking Rifampin and INH. The best part of these drugs is that they have known side effects (as explained on page four and five), and that they are available at government hospitals throughout the country in Kenya.

CONTACT PERSONS

When:
• You have any query on the research, get in touch with Janet Agaya, TBTC Study Coordinator, KEMRI/CDC on phone number 0700553578 or 057-2022902/59/02, fax (254) (020) 2720030, P.O. Box 54840-00200, Nairobi Kenya.
• If you think you can have problems with this research, get in touch with Dr Lena Matata, TBTC Study principal investigator, KEMRI/CDC on phone number 070011139 or 057-2022902/59/02

CONSENT FORM

A signature or thumb print at the end of this form shows my consent to being part of this research. I consent to the preservation of my blood for future research and investigation, to be sent to the CDC laboratories in Atlanta. I have not consented to any human behavioural test. I was given chance to ask questions. All my queries were answered. I am in this research by choice. I am informed that, after choosing to be part of this research, I can stop being any part of it any time I choose. I can give a blood sample for storage any time. I have been informed that I will get another form to sign.

Name of Volunteer (print)…………………………………………………………………..............………………
Volunteer’s sign/thumb print………………………………………..............  Date………………………………

Thumb print here (right thumb)  

Name of Witness (print)…………………………………………………………………………………...…..........
Sign of Witness………………………………………………………….... Date……………………...……...

Name of Researcher (print)………………………………………………………………………………..............
Sign of Researcher………………………………………………………………………………..............
Sign of Research Supervisor…………………………………………......... Date…………………….……....
MATERIAL CONSENT FORM
TBTC Sparse PK-29X
Luo Edition – Informed Consent

Subject Consent to store study samples and shipment of samples in TBTC Study PK – 29X

STUDY TITLE: “PHARMACOKINETIC & PHARMACODYNAMIC STUDIES OF EFFICACY, TOLERABILITY & SAFETY OF HIGHER DOSAGE RIFAPENTINE FOR TREATMENT OF TUBERCULOSIS.”

FOREWORD
We request you to be a volunteer in this Pharmacokinetic (PK) research that tests the amount of TB drugs in your blood. We request you to volunteer since you have been on treatment for TB as a research patient of TB Trials Consortium (TBTC) Study 29X.

We have made it clear to you that in this research, we will take samples three times in ten hours. Now, we want to let you know how this blood will be preserved in our medical laboratory at KEMRI/CDC, Kisumu, before being shipped to another medical laboratory.

Volunteering without intimidation
You are free to consent if your test kit will be kept back or sent to other medical laboratories. Your consent or refusal will determine whether you are a volunteer or not. To be a volunteer of this research, you must consent if your test kit will be kept back or can be sent to other medical laboratories.

PRESERVATION OF SAMPLES AT KEMRI/CDC
Right after taking a blood sample, the bottle with the sample will be kept in its carrier, which will have a cooler full of ice. This will regulate the temperature of the blood, as it is taken to the medical laboratory at KEMRI/CDC from New Nyanza General Hospital.

At the TB medical laboratory, the sample will be placed into special bottles, in which the blood will be turned into ice.

Once the research is over, all samples of the volunteers, which are turned into ice, will be taken from the fridge and transferred into suitcases to be sent to the University of Florida research center in America and there, the amount of Rifapentine in the blood will be tested. Some of the other items that will need to be tested will be sent to the University of Texas, San Antonio to check the percentage of the medication in your blood.

TO CONSENT OR NOT?
Even after making this clear to you, it’s your choice whether your test samples are preserved or not. You should not be forced to give your test samples for preservation if you are not willing. Even if you consent to the preservation of your test samples and its shipment, you can always change your mind at any time. We will let you know of any new discovery in this research that could change your mind.

Anonymity: Your test sample will be given a research number without your name

The supervisor of the research, together with the other researcher, may visit the medical laboratories to observe where the samples are stored, and to check if they are stored in the approved manner of the research. These research documents detailing how the test kits are kept, can be investigated by a committee concerned with the ethics and rights of the volunteers in this research (Ethical Review Committee- ERC and IRB).

Contact Persons
In case of any query on this research now, you are free to ask these persons. Even if you have questions after this, if you’d like to give a report of any distress from the treatment from this research, or if you have suffered damages from this research, you should contact the following persons:
If you have any query on your rights as a volunteer in this research, you can contact the department of KEMRI Ethical Review Committee, which investigates human rights issues (Institutional Review Board) by calling (020) 2722541 or 0722205901.

We will give you one copy of this signed form to take home.

**Signs of consent as a volunteer**

- Your signature on the form.
- You have had the chance to discuss the research, ask questions, and have been given satisfactory answers to your questions.
- You have given your consent to be part of the research, and that your test kit should be preserved and sent out for other tests.
- Even after the consent on your test kit, you can still discontinue your involvement any time.
- You have consented to be part of this research.
- You have been given a chance to ask questions.
- You are satisfied with the answers to your questions.
- Even as you consent to be part of this research, you can discontinue any time you choose.
- You have consented to the preservation of your blood samples at the TB Testing Center at KEMRI/CDC, Kisumu.
- You have consented to your blood sample being transferred to the Research Laboratory at the University of Florida, America and to the one at San Antonio, Texas.
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This publication is an initiative from the Medicines project of Wemos. The research has been conducted by an independent investigative journalist. Wemos has done everything it can to verify the quality and integrity of the research.

Wemos would like to thank all who contributed to this report, notably the investigative journalist and the interviewees.

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Design: www.ingerdesign.nl
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