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# Africa, the Clinical Research Hub: Prospect and Challenges for Pharmaceutical and Biotechnology Companies

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## Abstract

**Background:** It is the right of all humans to have access to safe, quality, and effective medicines. Clinical trials are essential for the development of medicines for patient care and disease management. Africa has many of the best conditions for conducting clinical research. The continent remains underrepresented in clinical research for several reasons. With 25% of the world's burden of disease, only 2% of all clinical trials are conduted in Africa. Africa still lags significantly behind and continues to face challenges in building capacity for conducting sustainable clinical trials in the continent. Boosting R and D in Africa could be a better means of unlocking immense untapped value and improving public health responses to diseases.

**Objectives:** This article examines various government's efforts by way of policies and regulations aimed at making the clinical research space more attractive to sponsors in Africa. This paper will contribute to the body of knowledge by improving the emerging governance systems for health research in Africa through harmonized regulatory framework, research infrastructure development, and capacity building.

**Methods:** The study will adopt the doctrinal methodology which will be basically analytical, and comparative in nature. It employs case studies from selected jurisdictions where clinical research activities continue to rise.

**Results:** Africa has many of the best conditions for conducting clinical trials. The continent has a vast population of potential patients from diverse ethnic backgrounds, many of whom have never received any pharmaceutical treatment for their disease, and thus provides a source of potentially accurate research findings for pharmaceutical and biotechnology companies.

**Conclusion:** This paper provides three-way benefit to sponsors, Africa and patient. Africa offers the sponsor a diverse patient pool to conduct clinical trials. Ease of recruiting trial participants and the availability of health workers with clinical research experience. On the other hand, unlocking clinical research potential will improve inclusion of Africa in the global landscape; attract innovations, health care benefits, research infrastructure development, sharing of resources and capacity building. For patients, by participating in clinical research, patients would gain access to new and possibly effective treatments.

**Keywords:** Biomedical research; Public health; Medical law and bioethics; Pharmaceutical and biotechnology; Patent layering; Intellectual property rights

## Introduction

Africa is an emerging continent based on its size, demographics, and level of economic growth. Presently, the population of the African continent is made up of over 1.34 billion people and it is anticipated that this will rise to at least two billion people by 2038 and 2.5 billion by 2050 [1]. Making up over 17% of the global population, with a diverse population and bearing the greatest disease burden in the world (at around 25%), the African continent can provide many of the conditions optimal for carrying out clinical trials. Despite the clinical advantages of Africa with multiple disease burden, Africa contributes to less than 2% of the total number of clinical research globally [2]. The continent has a vast population of potentials patients from diverse ethnic backgrounds, many of whom have never received any pharmaceutical treatment for their disease, and thus provides a source of potentially accurate research findings. Unlocking clinical research potential will improve inclusion of Africa in the global landscape, attract innovations, health care benefits, research infrastructure development, sharing of resources and capacity building. Lack of prioritization and trust, exploitative research partnerships, limited capacity building and varied regulatory requirements have continued to pose a danger to the advancement of clinical trial in Africa. When there are resources that need to be invested in research, such research must aim at bringing something new and novel not necessarily repeating what has been published elsewhere or before the public domain without any added value. A good study should be researched and support claims by including references to other studies that support the study's findings [3]. A reliable study should also undergo peer review, which is a rigorous scrutiny by experts in the same field to determine its accuracy and relevance before it is published.

## Why Africa?

The term "Africa" is used to refer to a continent. The continent is made up of 68 countries, totalling a population of over 1.6 billion *i.e.,* 20% of the world. The countries in the continent, and more specifically those discussed in this article, are by no means a homogenous group, and important differences exist between them, including in terms of economic development and health research capacity and policies. There are, however, important similarities which make a group analysis possible, including but not limited to typically weaker regulatory capacities than they are in other parts of the world. The continent contributes little to the international effort of health knowledge production, hosting only 2% of the global registered trials.

Among the many weaknesses of clinical research in Africa is the cultural gap and lack of recognition for the need of developing a sustainable clinical research infrastructure. Very few countries have developed capacity for research. Lack of robust international standards and regulatory frameworks is a major hurdle [4]. The health systems are typically weak, health indices of many of these countries are poor, universal health coverage in many cases is still a faraway prospect, and most citizens may find it difficult to pay for medical treatments that become available. Furthermore, research funding and trained researchers may be in shorter supply than they may be in the developed countries. In addition, there is uncertain public confidence and poor awareness of the importance and the objective of clinical research.

However, the continent has a number of attractive features, such as population size and large pool of eligible patients, least trial saturated of all continent, diversity in genetic profile, lifestyle, and eating habits, and large medication-naive patient population. Some of these countries have been chosen as case studies because they have a relatively high capacity for research, that is, they are research-active and have had a longer experience of regulating research. This is the case in South Africa, which has been the site of some of the HIV drug trials. This is also the case with India. Nigeria on the other hand is firming up health governance policies.

Each of these countries has developed policies for research ethics and put in place some governance structures. However, there is no gainsaying the fact that the physical and regulatory infrastructure in these countries could do with some improvement.

An analysis of the emerging domestic regulatory and governance regimes in these countries is necessary to understand the context for the local application of ethical principles; to provide information on these recent developments; and, as mentioned earlier, to proactively identify and draw attention to national systems and practices, and the potential issues, weaknesses, and problems that may arise in these new regimes. The analysis recognises differences in context and identifies how this affects research governance in each of the countries. More generally, there are also differences with regard to political governance, healthcare systems and priorities, and organisation of the legal system, which have potential effects on the governance of health research. For instance, while Nigeria runs a common law system, South Africa runs a hybrid system, comprising the civil and common-law system, yet legislation plays a key role, sometimes limiting the differences in the way law applies in the research governance system.

In African, there is a high burden of disease and high levels of poverty, including communicable diseases; non-communicable diseases; and health related social issues, such as violence and low levels of life expectancy. In these countries, health research is particularly important to finding ways of reducing that burden and, where possible, doing so by the least expensive means. Although many of the diseases in Africa require simple interventions that perhaps do not necessitate extensive health research, such as improved sanitation, adequate nutrition, and clean water, the high incidence of diseases such as HIV/AIDS and malaria means that continued health research remains crucial. Also, therapies that have already proven effective elsewhere may need to be tested specifically in Africa because of genetic and environmental differences.

Research undertaken in the past in many African countries into diseases such as malaria, yellow fever, sickle cell disease, and trypanosomiasis has contributed immensely to knowledge about the prevention and treatment of these diseases. Clinical trials conducted in Africa have contributed to public health knowledge and practice in both Africa and developed countries.

For instance, the HIV/AIDS epidemic with an estimated 36.7 million people infected worldwide in 2015 and most of these people living in sub-Saharan Africa, emphasises the high rate of the continent's disease burden and the need for more clinical research in the region. HIV/AIDS research has made it possible to discover the cause of the disease and interventions, such as antiretroviral drugs that have made the disease a manageable condition rather than a death sentence. Nigeria is rated first as country with the highest number of Sickle Cell Disease (SCD). The disease is considered by most African societies as a spiritual issue "ogbanje" and not medical. However, through clinical trials, Oxbryta (voxelotor) a hemoglobin S polymerization inhibitor indicated for the treatment of the disease in adults and children was discovered. It restores patient's red blood cells to a normal shape, thereby reducing damage to the body's tissues and to red cells. This means that SCD warriors in Africa have hope of being treated and recovery from the disease.

The development of new drugs may be targeted for the needs of developing countries or may simply be undertaken for the development of new interventions for diseases which may not necessarily be prevalent in Africa. The dependence on foreign sponsors creates its own problems, raising questions about the motives of such sponsors, research priorities and how responsive research projects are to the health needs of the population, who sets the agenda for research in Africa, and whether Africans benefit adequately from such research efforts.

Even with the resources provided by sponsors in the developed world, there is still a wide gap in the resources for, and therefore the level of health research conducted in Africa. The increase in research has been noted to be uneven between

countries and even between diseases. Although there appears to be in recent years, an increase in drug development in Africa, pharmaceutical and biotechnology companies have frequently ignored diseases that occur in these countries because investment in Research and Development (R and D) would yield only poor, if any, returns. Research findings in developed countries, where more resources are expended on research, may not be easily transferable to African countries for various reasons, including the facts that communicable diseases which are prevalent in Africa are not typically prevalent and thus are not the focus of research in the developed world, socio-cultural and economic circumstances differ, and interventions developed in the Western world do not always work as effectively in Africa.

Genetics, cost factors, and climate conditions may require different interventions to be developed for African countries. Despite the obvious need for health research in Africa, resources for undertaking such research are sadly lacking. Many African countries lack enough trained researchers, infrastructure, and general resources to allocate to health research. They often lack the political will to devote the resources available to them to health research. Where resources are allocated within national research policies, they are sometimes not expended and, in some cases, misapplied. There is a high level of dependence, therefore, on foreign sponsors in the developed world.

Although some increase in resources and in the volume of health research has been noted, the disequilibrium in resources devoted to health research in Africa persists. More research remains necessary to address public health needs, improve health outcomes, increase life expectancy, and promote human rights and economic development. Hopefully, the growing trend in health research in Africa will continue and will extend to African countries and to neglected diseases.

The emergence of public health problems such as COVID-19, Pneumonia, Ebola Virus Disease, Tuberculosis, and the Zika virus with an increased risk of the transmission which has posed challenges world over, and the consequent globalisation of diseases indicates that this would benefit not only Africa but the world. The need for more research in Africa should, however, be balanced with the necessity of adequate oversight in African countries. Finding this balance is likely to be tricky; a potential conflict of interest situation may arise between getting ready research funding or pharmaceutical R and D and tightening regulations.

Governance of health research is necessary in African countries, alongside the need for increased research on neglected diseases. External help from developed countries and international organisations may be necessary to address issues of costs and gain increased understanding of regulatory and governance systems from countries which have had them for longer. Such external help recognises the fact that developed countries have an interest in disease eradication in Africa because many diseases do not respect geographic boundaries.

Some external assistance and collaboration from foreign countries has been forthcoming and is increasingly a key component of the steps that some African countries have taken in regard to the domestic governance of research. By some accounts, an estimated 19 million dollars was spent on ethics review between 2002 and 2012, targeted at establishing new ethics review committees and building research ethics capacity. The issue of costs does not negate the need for domestic governance systems.

## Literature Review

In addition, some of the critical health problems which African countries face require research, and such research would occur more safely within a regulated environment which takes into consideration the peculiarities of the African context with more vulnerable population. It would of course be naive to ignore or gloss over global inequalities and how these may affect the steps that African countries are willing to take to protect their citizens while encouraging that beneficial health research be undertaken.

This, in turn, may help create trust between researchers and research participants and the wider community, thus potentially making increased room for research that is more likely to be beneficial to the target population. This way, everyone stands to gain researchers, research participants, and the wider community. It may also create more bureaucratic structures to give a semblance of regulation more ethics review committees, more documents to file, to meet international and foreign sponsor requirements without necessarily protecting research participants effectively. Trust is particularly important factor to consider in the African context. This is because the erosion of trust affects not only the potential participation in health research but also participation by the general population in important and beneficial health programmes. The unanticipated costs of failure to ensure that governance structures are effective may be catastrophic to much-needed health research and may therefore exceed the costs of proper governance. Research governance does not therefore draw a strict dichotomy between increasing research and ensuring the protection of research participants. Indeed, the view is taken that better research protections will help to ensure the safety, and preserve the trust of research participants in Africa, which might, in turn, facilitate greatly needed health research in those countries.

### Consequences of lack of significant clinical trials on the continent

A major consequence of Africa's poor capacity to conduct clinical trials is that it prevents the availability of suitable medicines on the continent. Certain diseases are more prevalent in a particular ethnic group, and the genetic makeup of individuals influences their response to treatment. It is therefore often clinically inappropriate to extrapolate research findings from the Global North to the African population [5].

Therefore, limited clinical trials in Africa make it difficult for the continent to tackle its growing disease burden, especially non-communicable diseases which have been estimated by the World Health Organisation (WHO) to become the leading cause of diseases in Africa in the next decade.

## Benefits of conducting clinical trials in Africa

Clinical trials can potentially play an important role in helping to contribute to the development of a country's healthcare system in a number of ways including raising research standards, exposing physicians to new diagnosis and treatment modalities and bringing health improvements as well as badly needed investment.

It is also important, however, to note that despite the potential collateral benefits of clinical trials, the benefit of faster access to drugs may not always be relevant as a recent paper by Hay et al. reported that only 10.4% of drugs entering into phase 1 clinical trials are approved by the US food and drug association.

However, in order for Africa to increase its footprint in the clinical research space, the topic of corruption, whether actual or perceived, and its associated impact on data quality, patient safety and pharmaceutical engagement in the region needs to be further explored, understood and addressed. Whilst corruption represents just one of several challenges related to conducting trials in the region, it represents arguably one of the most significant and therefore needs to be addressed before other more practical topics can be discussed. The virtual absence of Africa from the clinical trials map presents a significant problem. As the continent presents an enormous amount of genetic diversity, if it is not well represented in clinical trials, the trial findings cannot be universal to large populations.

Genetic analyses have clearly shown that ethnic groups show variable results to different treatments, so it is vital to carry out clinical trials in Africa, as Africa endures diseases linked to poverty more than any other continent, and the interventions typically used to treat or cure the diseases of which Africans suffer are developed elsewhere.

Cerba research firmly believes that Africa provides a significant opportunity for pharmaceutical and biotechnology companies, as well as non-governmental organizations seeking out low-cost study sites, low risk of litigation and a diverse participant population. The latter makes Africa a prime location for research, as the diseases of affluence and poverty are widespread. Moreover, most of the potential patients for enrollment in clinical trials have not received any previous treatment for their diseases, either because they cannot afford it, or it is not available. It means that patient recruitment in this continent is easier.

With these clinical advantages, Africa ought to be a powerhouse of clinical research, as it is expected that clinical trials for medicines are conducted in the areas most affected by the diseases the medicines intend to treat. Unfortunately, this is not the case, as the successful conducting of clinical trials in Africa faces many challenges.

## The issues and challenges of running clinical trials in Africa

**Good clinical trial infrastructure in the region:** There is ongoing investment and growth in the scientific base across the African continent, which is actively encouraged by local authorities. There are centralized healthcare institutions, highly motivated, well-qualified and experienced investigators and superb clinical trial facilities, which can be held up against the best in class all over the world.

From a laboratory perspective, most of the tests are conducted overseas in central labs, when there is, in fact, the capacity to have the central lab work done in some of the local countries. Preferably, central lab hubs placed strategically across Africa can help science progress and boost the knowledge pool around diseases. Recent reports reveal that only 7 medical laboratories in Nigeria have achieved international regulatory standard, out of 5,349. Inadequate capacity building due to insufficient training of research personnel to carry out clinical trials that meet global standards.

**Efficient regulatory and ethics committee processes:** Regulatory barriers caused by inconsistent ethical guidelines across the continent and operational barriers regarding study initiation, study population and cultural factors, hence poor legislative protection for participants in trials. The processes for regulatory approval in the majority of African countries are no more complex than in Europe or the US. Several countries in Africa have been addressing the need to establish or evolve regulatory infrastructures when faced with a sudden influx of clinical trials.

For the first time, several emerging markets are developing these new regulations while many are adopting the US or European standards in a shift towards global alignment. For a product to be registered, it necessitates approval from the WHO; thus, EMA registration of products is key. As such, each African country has a regulatory board, some more advanced than others, including SAPHRA in South Africa, and NAFDAC in Nigeria.

**ICH/GCP the only standard:** To prevent unethical practices in clinical research, the World Medical Association (WMA) through the declaration of Helsinki has established since 1964 guidelines for medical researchers to balance the need to generate medical knowledge with the need to protect the health and interests of research participants. In 1978, following the infamous Tuskegee syphilis study, the national commission for the protection of human subjects of biomedical and behavioral research of the United States has stated moral principles and guidelines for the protection of human subjects summarized in the belmont report.

African countries are following or have already incorporated the ICH/GCP guidelines in the approval process for the regulatory and ethics committee.

Clinical trials are being performed in line with the requisite standard operating procedures to guide and train all staff locally, making sure operations are conducted in compliance with ICH/GCP regulations and to meet sponsor requests and requirements.

**Faster participant recruitment:** There is a large naive population with diseases of both the developed and developing

world, which presents a significant opportunity for rapid, large scale participant recruitment.

**Cost benefits:** Most trials running in Africa are being funded by NGOs/governments and partly pharmaceutical sponsors. Including general investigator sites in Africa will help reduce the drug development timelines overall, with an increased number of participants across fewer sites. This expedited participant recruitment means fewer sites and regulatory applications are needed equating to a reduction in the cost of the study.

As challenging as it may seem, Africa offers a unique profile that is of interest to NGOs and governmental organizations and should be of equal interest to a number of pharmaceutical and biotech companies. Shifting requirements, larger sample sizes in clinical trials and the need for participant diversity in parallel with enhanced clinical research environments in African countries are resulting in a sizeable growth in clinical research across the region.

**There is more than TB, sickle cell disease, malaria, and HIV:** Until recently, clinical research has mainly focused on infectious diseases, specifically HIV/AIDS, TB, sickle cell disease and malaria, as significant numbers of the population are considerably affected by these diseases. There is little emphasis on oncology or other lifestyle/metabolic diseases, although there is a rapid increase in the prevalence of these illnesses.

Accordingly, cooperative clinical trial groups, sponsored by the national cancer institute, have started to work in the Africa region, demonstrating a great interest in bringing cancer therapies to Africa. Alongside oncology, such as cervical cancer, other emerging topics are metabolic and other lifestyle diseases such as maternal and infant health, diabetes, ischemic heart diseases and strokes and lower respiratory infections.

**COVID-19 as an eye-opener:** The African Academy of Sciences (AAS) recently launched the first carnation of the Clinical Trials Community (CTC) online platform to boost the visibility of African clinical trial sites and investigators with the possibility of contributing to COVID-19 clinical trials, with a final objective of promoting the progression of intra-African collaboration around clinical trials. As previously indicated, only a small percentage of clinical trials are conducted in Africa: COVID-19 has revealed why this necessitates immediate change.

While there are vast movements across the industry to invest in COVID-19 vaccines, the outcomes of such COVID-19 studies will be limited to the patient population exposed to the trial. In the end, these vaccines may not be relevant for people in African countries, unless the studies are carried out locally.

This is because responses to vaccines or drugs are part of a complicated process and can be dependent on, among other things, human genetics as different people respond to different drugs and vaccines in different ways. It is vital and urgent that more countries on the African continent become involved in the clinical trials so that the acquired data can be representative of the entire continent.

Time is of the essence and the standard approach of developing site or country specific protocols will not work. Instead, African governments must look at ways to reconcile the response towards COVID-19 across the continent. It is as important today as ever before that African countries work together.

Each country's epidemic preparedness kit should contain funds dedicated to clinical trials in the event of an epidemic or pandemic. This would require governments on the African continent to assess their role and level of investment in the broad area of clinical research.

This will influence the quality and quantity of clinical trials in the face of the persistent global challenge of emerging and re-emerging infectious diseases, as well as a steady increase in non-communicable diseases.

Moreover, clinical trial centres and clinical research institutions on the continent should be motivated to improve their visibility in the global space. This will make them easy to identify in times of crisis and promote both South-South and North-South collaborations.

## Discussion

### Steps to improve Africa's inclusivity in clinical research

**The development of a set of uniform, pan African guidelines:** These guidelines can be developed by the African union, similar to what has been done by the European union, which created ethical guidelines for all its member states. This will provide legislative protection for participants and increase participants' retention in trials. NAFDAC in Nigeria, SAHPRA in South Africa, and a few African countries have stepped up in recent years on clinical trial guidelines, but it needs to be African wide.

**The establishment of clinical trials research hubs across Africa:** There is a need for the strengthening of current research sites in Africa and the establishment of new ones with the capacity for sustainable research. This will provide reliable sites, having the required infrastructure, staffing, and systems to effectively conduct clinical trials. Such capacity can be developed by the establishment of clinical trial hubs across Africa through the collaboration of partners in the industry and academia.

**Capacity-building through training of African researchers** by conducting a variety of training programmes, and the provision of grants to early career investigators [6]. A few scientists on the continent are making very encouraging steps in this direction, but the urgency of this requires that it be scaled up with the necessary funding and technical support.

Although Africa still lags behind in conducting clinical trials, the COVID-19 pandemic has led to a building up of momentum in the continent's research and development space. We believe that through strategic partnerships and collaborations across the continent, Africa can build capacity to sustainably conduct clinical trials that tackle its growing disease burden.

## The impact of Africa's health governance systems on clinical research

The developments in global health, digital technology, and persistent health systems challenges, coupled with global commitments like attainment of universal health coverage, have elevated the role of health research in Africa. However, there is a need to strengthen health research governance and create a conducive environment that can promote ethics and research integrity and increase public trust in research, as well as the inclusion of Africa in clinical research landscape.

## What are the governance mechanisms currently employed in African countries to attract clinical research?

While some aspects of research governance have received attention, others have only begun to receive attention, such as the legal frameworks. What is the contribution of law to health research governance in Africa? Professional regulatory bodies, often unctioning under the shadow of law, could also play an important role in health research governance. What is their place in the current health research governance matrix? Other institutions potentially involved in research governance such as non-governmental organisations and civil society bodies have not received much attention in current literature. Evidence from other areas of health indicates that these organisations are a powerful force in the health space in many African countries. What is their place, if any, in current health research governance structure? What role could they or ought they to play? Can research participants ind a voice through civil society organisations as has happened in some developed countries? What challenges do African countries face in regulating research? [7]

**African Medicines Regulatory Harmonization (AMRH:** Initiation of the African Medicines Regulatory Harmonization (AMRH) initiative in 2009 was a hallmark step in the process of continent-wide harmonization. Implemented within the African Union (AU) Pharmaceutical Marketing Plan of Africa (PMPA) and supported by a number of international organizations, its objective is to ensure African people have access to essential medical products and devices.

**AU model law:** Endorsed by the African heads of state and government at the AU summit in January 2016, the AU model law on medicinal products legislation provides a framework for good medicine regulation at a national level and is intended as guidance for AU Member States to address the gaps and inconsistencies in regulatory legislation and enable harmonization.

It outlines key unctions and standards that should be used by each country's NMRA:

- Registration and authorization of all medical products.
- Licensing for manufacturing and distribution of health technologies.
- Monitoring and analyzing the quality and safety of health technologies.
- Inspections of manufacturing facilities.
- Review and authorization of clinical trials.
- Establishment of administrative appeals committees.

**AUDA-NEPAD:** In 2018, the NEPAD planning and coordination agency was re-established as the AUDA-NEPAD with additional programs centered around human capital development, science, technology and innovation, and regional integration. It was tasked with integrating research and innovation within the "Africa health strategy 2016-2030,"2 which recognizes the interdependency of public health initiatives and equitable access to new medicines.

The Africa health strategy was adopted in line with the AU Agenda 2063 and the United Nation Sustainable Development Goals (SDG) 5, 6 and prioritizes investment in research and innovation to address the challenges across the African continent. To achieve this end, the Health Research and Innovation Strategy for Africa (HRISA) were developed to provide guidance for member states and prioritize the following:

- Establishing functional national and institutional ethics and regulatory committees that provide timely and efficient review.
- Strengthening and harmonizing national and regional regulatory systems.
- Adopting a regional approach to strengthen health research oversight.

This strategy envisions an Africa where African-led research and innovation drives health and wellbeing.

**Africa Medicine Agency (AMA):** Along the same lines of strengthening capabilities within African countries, the AMA was established with the vision of ensuring all Africans have access to quality-assured, safe, efficacious and affordable medical products that meet internationally recognized standards, for priority diseases or conditions. Building on the experiences of the REC MRHs, including those of the EAC and SADC, the AMA:

Provides a single approach to product review and approvals across the continent based on the AU model law.

- Improves regulatory harmonization and reliance.
- Increases efficiency and effectiveness by pooling expertise and capacities and strengthening existing networks.

Although adopted in February 2019, in order for the AMA to go into effect, 15 countries had to sign and ratify the AMA treaty. In June 2019, Rwanda was the first member state to sign the treaty, 11 and as of October 5, 2021, 15 countries had ratified the treaty, thereby formalizing the institution12 as the second specialized health agency of the AU following the Africa Centers for Disease Control (CDC).

One year after it was ratified, as of October 11, 2022, a total of 23 countries have ratified, 11 countries have signed but not ratified and 21 countries have yet to sign the treaty.

With each country that joins the AMA, every other member state benefits from additional research experience, investigators and resources; their populations gain greater access to affordable, quality medicines; and sponsoring institutions can conduct research within a harmonized framework and a greater population.

**The CVCT initiative:** Since clinical research regulations should be incorporated in national regulations, issued by national experts, and voted by national parliaments, national initiatives and potential multi-national efforts must be initiated and driven by local governments. However, given the global framework of clinical research, national regulations should inevitably converge and ideally be harmonized with the body of international regulations. Because national governments are making progress at different but very slow pace, with differing levels of priorities, we believe that bottom-up initiatives, helped by pertinent stakeholders, such as investigators, industry R and D experts, patient organisations and other health care professionals' must coalesce in an overarching effort to help health authorities in the region scaling up and harmonizing their national regulations.

The Cardio Vascular Clinical Trialists Middle East, Mediterranean and Africa (CVCT-MEMA) organisation, affiliated to the CVCT global initiative, offers such an international multi-stakeholder platform capable of a bottom-up initiative of working towards the much-needed reform and harmonisation of the regulatory framework and towards a sustainable capacity building in the region.

In September 2018, CVCT MEMA held a regulatory summit for 2 days in Cairo, Egypt to discuss the clinical research community's ideas and challenges as well as the recommendations going forward on a regional level. Indeed, cardiovascular disease is one of the medical areas where practice is most driven by robust clinical evidence, stemming from well-designed clinical trials. It was intended that the experience accumulated by international and local experts in this area may serve as a case study and a starting point, which may be applied to other disease areas.

**H3 Africa initiative:** H3 Africa empowers African researchers to be competitive in genomic sciences, establishes and nurtures effective collaborations among African researchers on the African continent, and generates unique data that could be used to improve both African and global health.

There is currently a global effort to apply genomic science and associated technologies to further the understanding of health and disease in diverse populations. These efforts work to identify individuals and populations who are at risk for developing specific diseases, and to better understand underlying genetic and environmental contributions to that risk. Given the large amount of genetic diversity on the African continent, there exists an enormous opportunity to utilize such approaches to benefit African populations and to inform global health.

This initiative further highlights the potential benefits of research and emphasises the need for understanding and enforcing ethics in health research. Several factors, both global and local, have had a significant impact on the adoption of domestic governance research governance frameworks. The combination of the increase in externally funded research, greater cognizance of research scandals, increased awareness of the need to protect research participants, more bioethics expertise and capacity, and the drive towards the use of clinical trials registries has resulted in more formalised governance frameworks within some African countries, including through legislation, strengthening of drug regulatory authorities, and ethics review mechanisms. In this regard, a number of African countries have developed instruments for guiding and regulating health research involving humans. These instruments form the basis of governance of research in these countries, and this seems to be an appropriate time, therefore, to consider the governance of health research in Africa.

## The impact of patents and intellectual property laws on clinical research in Africa

Intellectual property refers to any creative invention of the mind that is developed and produced through a distinct idea or process, and then used in commerce. Patent rights are a form of intellectual property, along with trademarks and copyrights, and are the standard means of encouraging innovation and fostering scientific pursuits in any industry.

Yet patents provide the patent holder with a limited monopoly power for a minimum of 20 years that excludes others from unauthorized capitalization on the uniqueness of the invention by means of making, selling, or using the patented product or technology. Thus, patents provide patent holders with incentives to invest in R and D and facilitate the returns on investment by prohibiting competitors from "free-riding" on the patented invention.

Patent holders receive exclusive market rights on their inventions, however, only in exchange of disclosing the patented process or invention, which would encourage the public use and reproduction of the invention/process once the duration of the patent expires. This is especially important in the pharmaceutical industry, where knowledge of technology use and adaptation are crucial in disseminating generic versions of pharmaceutical products for the wider public health use. As Condon points out those private patent rights in the pharmaceutical field do not benefit just the owners of patents. They also serve the interests of the public, by promoting the development of new pharmaceuticals; of governments, by advancing public health objectives; and of generic competitors, by providing them with a source of technological information and research data, new products, and new commercial opportunities.

Protection of intellectual property rights is important to any industry which is knowledge driven and which entails a considerable investment in knowledge that is limited to the public. The pharmaceutical industry is one such industry, where patent rights and protection are of utmost importance. Thus, the pharmaceutical industry's willingness to invest in a market and bring its technology there is a function of how adequate a protection that market provides of Intellectual Property Rights (IPRs).

It is further exacerbated by the fact that inadequate IP protection in many African countries provides a disincentive for pharmaceutical companies to develop drugs for diseases prevalent in the developing world, such as AIDS, tuberculosis, malaria, and COVID-19. Since the pharmaceutical industry is propelled by innovation, it is therefore highly dependent on

patent protection to sustain its research, market share and profits. It is a costly and risky industry due to the high cost of chemical compound development, bio-research and clinical trials.

In 2000, the Pharmaceutical Research and Manufacturers Association (PhRMA) estimated that the average cost of developing a single drug is $500 US million and only a small portion of the researched chemical compounds ever reaches the market. Furthermore, again according to the pharmaceutical industry, only 30% of new drugs that reach the market are profitable.

Thus, the industry follows market incentives very closely for its research and development activities, and the weak patent protection environments in many developing countries create weak investment incentives for pharmaceutical firms to develop drugs of particular concern to those countries. Instead, about 90% of the over $65 US billion invested annually in health R and D by pharmaceutical companies and Western governments is not focused on the treatment of tropical problems and diseases plaguing the African region. Rather, it is focused on problems faced by the 10% of the global population living in the developed world, such as baldness, obesity, and depression.

Furthermore, of the 1233 new drugs that have entered the global market between 1975 and 1997, only 13 pharmaceutical products were targeted specifically at tropical infectious diseases, such as malaria. In 2000, the World Bank also addressed the issue of the stark global disproportions in health research. It made public a report by the global forum on health research, which also concluded that less than 10% of global health research was ascribed to the 90% of the world's health problems, mainly found in African countries.

## The place of medical law, ethics and bioethics in clinical research

Laws are societal rules or regulations that are prudent or obligatory to observe. Failure to observe the law is punishable by the state. Laws are designed to protect the welfare and safety of society. Ethics is a set of moral standards or a code for behaviour to govern an individual's interactions within the society. These concepts are different yet related. There are many reasons that make medical law, ethics, and bioethics important for healthcare professionals. Medical law, ethics, and bioethics have become central to our understanding of these issues and are important tools for the analysis and resolution of problems, real or imagined. It is necessary to comply with medical laws and to examine one's actions considering both laws and ethics. It is important to learn more from the bioethical issues that participant face. Some of these bioethical issues are informed consent, standard of care, ethics review and governance, regulatory challenges, bureaucracy, lack of timely approvals of regulatory submissions across board, impacts on trust and confidence of research participants, impacts on researchers and clinical research organisations.

## South Africa

In South Africa, the single country hosting the largest number of trials in the region, a comprehensive set of good clinical practice was made available back in 2006. June 1, 2017, the South African Health Products Regulatory Authority (SAHPRA) was established as the regulatory authority overseeing medicines and clinical research. Constant progress is being made, year on year, toward an attractive international grade clinical trials legislation.

For instance, informed consent is a constitutional requirement. There is sophisticated research infrastructure, substantial government support for health research and evidence based medicine in South Africa abound, an effective institutions like medical research council, national health research council established by the national health act, R and D based multinational pharmaceutical sector makes significant contribution to the South African economy, between 2016 and 2015, IPASA estimates that 2.95 billion Rand would have been spent on clinical research by biopharma for new treatments into unmet needs. South Africa has more clinical trials than most African countries, national health research strategy, research priorities for South Africa 2021-2024, South Africa has a large number of CROs more than other African countries, an Innovative Pharmaceutical Association South Africa (IPASA).

Defines health research broadly (including any research which contributes to knowledge of the biological, clinical, psychological, or social processes in human beings; improved methods for the provision of health services; development of new pharmaceutical, medicines, related substances, health technology, informed consent, mandatory ethics review, research involving children, ICH Harmonised Tripartite Guideline - Guideline for good clinical practice, NHREC guideline for management of complaints revised, payment of trial participants in South Africa: Ethical considerations for research ethics committees, South African Health Products Regulatory Authority (SAHPRA), is South Africa's drug regulatory authority. SAHPRA was constituted as an independent entity that reports to the national minister of health through its board. Clinical trials are thus required by law to obtain approval from both the SAHPRA and the HREC, and to adhere to the Regulations. South African Health Products Regulatory Authority (SAHPRA) is the regulatory authority overseeing medicines and clinical research, as well as medical devices and radiation safety. Operationalised in 2017 and replaced the Medicines Control Council (MCC) to address delays in approvals department of health, 2020. South African good clinical practice: Clinical trial guidelines.

Domestic patent laws in South Africa have traditionally provided developers with considerable patent protection, whereas India has dismissed the notion of patents on pharmaceutical products, maintaining that patent protection is unjustifiable in matters of public health.

Faster approval times improvement over MCC, Electronic Document Management System (EDMS) has been piloted. A systematic, structured approach to decision making is in place. Clarity in roles and responsibilities of assessors and committee members. A basic record trail of decisions made is available and

decisions are re-evaluated in the event of new information becoming available.

The National Health Research Database (NHRD) serves as a repository of health related research which has been and is currently being conducted in South Africa (now run by national health research database). A useful tool for monitoring and managing health research for both the national health research committee, and the 9 Provincial Health Research Committees (PHRCs). Facilitates the best use of limited research resources. Assists researchers to collaborate through sharing of research information. Reduces duplication in research efforts. Assists the health research committees in setting health research priorities, for the research committees and the country. Provides a checklist of criteria that must be fulfilled in order to conduct research in public sector health facilities. Increases transparency regarding ethical considerations in health research.

### Lessons learnt from South Africa

There is clear-cut identification of health research priorities, clear legal and regulatory framework, availability of key documents, coordination-the GCP is compulsory for clinical trials conduct in South Africa; however legal requirements under the national health act supersede the requirements of the GCP in the event of a conflict.

Department of health ethics ensures that research is design, plan, manage and conduct their clinical trials in accordance with the ethical principles and values that underpin their practical application to clinical trials. Implementation of research governance tools–clinical trials registry, health research database. Deliberate attention to approval times and processes while taking care not to jeopardise quality. Government funding and private sector engagement is relatively higher in South Africa compared to other Africa countries.

### India

India is a developing country with burgeoning population like Africa. India has a rich historical experience of regulating clinical research. A common motivation for foreign companies doing research in India is relatively lower cost in as compared to comparable research elsewhere. India was a single nation with a large, diverse population. Just like in Africa, many potential research participants in India had not previously had medical treatment, and clinical trials get better data from such people. India also has a well trained workforce and many research sites which met international good clinical practice standards. India's national health system provides a lot of care in large urban hospitals. This centralization is also favorable to conducting research.

When researchers conduct trials in multiple countries, collecting patient-reported outcomes is useful. However, to make sense of any such reports from India, then researchers have to adapt the instructions for local Indian culture. A 2011 evaluation found that a sample of clinical trials in India complied with the consolidated standards of reporting trials. To make India more compliant with international standards the government amended the drugs and cosmetics rules, 1945 in 2005 and 2008. In 2019 the government enacted the new drugs and clinical trials rules 2019. These rules provided more guidance for how the ethics committee of a clinical trial should oversee it.

At the end of 2010, India was conducting 7% of phase III and 3% of phase II trials globally. In 2019 India was hosting about 1% of the world's clinical trials.

Also, India agreed to comply with the TRIPS Agreement in 2005. The agreement changed the way India recognizes intellectual property and changed the research environment in way that enabled foreign companies to conduct clinical trials in India. Foreign contract research organizations were able to conduct clinical trials in India from this point.

## Conclusion

It is time for pharmaceutical and biotechnology companies to consider Africa as a clinical trials destination. Even though African countries are usually under-represented in clinical research due to a lack of commercial viability and trained researchers, the continent is gradually emerging as an important destination for clinical research.

Just like in India and South Africa that has an established infrastructure, standard ethics review committee, favourable legal and regulatory systems, diverse ethnic population, large disease burden with low cost of conducting clinical research, other African countries possess these features in varying degree. There is the need for other African countries to learn from South Africa and India by creating the enabling environment for research to attract sponsors to the continent. This can be done through investing in infrastructure and capacity building.

More collaborative effort from governments, pharmaceuticals and biotechnology companies, universities, research institutes, the private sector, funders, sponsors, and other stakeholders is essential to achieving sustainable capacity-building and inclusion of Africa in clinical research.

Harmonized regulatory framework will go a long way in making conduct of clinical research in the continent seamless and cheaper. Legal and regulatory frameworks in the continent should focus on ensuring that clinical research is potentially beneficial, mitigates the risks that exist in the process, facilitate the research environment, protect the safety, dignity, and well-being of research participants, maintaining trust between the research community and the society.

Pharmaceutical and biotechnology companies are encourage to consider Africa as a veritable clinical research destination by prioritizing public health above economic benefits. They should explore the opportunities on the continent and take advantage of its peculiarities to find healthcare solutions.

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