The Immense Potential of Africa's Advantageous Landscape

Whilst not ordinarily making the shortlist for trials in the past, Africa is an emerging as a continent based on its size, demographics, level of economic growth, and desire to improve healthcare and life expectancy. Today, Africa represents over 1.34 billion people and it is expected to surpass two billion people by 2038 and 2.5 billion by 2050. Accounting for over 17% of the global population, representing a diverse population, and carrying the highest disease burden in the world at around 25%, the African continent offers many of the best conditions for conducting clinical trials. Importantly, several diseases – particularly those defined as neglected and tropical – are endemic to the developing world, which includes Africa. Despite all these advantages, Africa contributes to less than 2% of the number of clinical trials.

Africa Displays Incredible Amount of Genetic Diversity

The low representation of African countries in clinical trials is not unusual. Poor visibility of existing sites, limited infrastructure, cultural barriers, misunderstandings of requirements to work in the region, and unpredictable clinical trial regulatory timelines are some of the key issues hindering investments in this area and hence causing a burden to conducting clinical trials within Africa.

Africa's virtual absence from the clinical trials map poses a big problem. The continent displays an incredible amount of genetic diversity. If this diversity is not well represented in clinical trials, the trial findings cannot be generalised to large populations. Genetic analyses have clearly demonstrated that ethnic groups show variable results to various treatments, hence it is imperative to conduct clinical trials in Africa, as Africa suffers more than any other continent from diseases linked to poverty, and the interventions mainly used to cure or treat these diseases from which Africans suffer are designed elsewhere.

Cerba Research strongly believes that Africa offers an enormous opportunity for pharmaceutical, biotech companies and non-governmental organisations searching for low-cost study sites, low risk of litigation and a diverse participant population. The latter makes Africa an ideal location for research, as the diseases of affluence and poverty are prevalent. Moreover, the majority of patients to be potentially enrolled in clinical trials have not received any previous treatment for their diseases – either because it is not available, or they cannot afford it – facilitating patient recruitment.

Challenges of Running Clinical Trials in Africa: Are They Really Challenges Still?

Good clinical trial infrastructure in the region – There is continuous investment and growth in the scientific base in African countries, strongly encouraged by local authorities. There are centralised healthcare institutions, well qualified, highly motivated and experienced investigators and excellent clinical trial facilities, which are comparable to the best in class globally. From a laboratory perspective, a lot of the tests are done overseas in central labs, when there is in fact the capacity to have the central lab work done in some local countries. Ideally, central lab hubs strategically placed in Africa can help advance science and increase the knowledge pool around diseases.

Efficient regulatory and ethics committee processes – The regulatory approval processes in most African countries is no more complex than in Europe or the US. Faced with a sudden influx of clinical trials, many countries in Africa have been addressing the need to establish or evolve regulatory infrastructures. Some emerging markets are developing these for the first time, and many are adopting the US or European standards in a shift towards global alignment. For a product to be registered, it requires WHO approval, so one must do EMA registration of products. By now, each African country has a regulatory board, some more developed than others; for example, SAPHRA in South Africa, NAFDAC in Nigeria or TFDA in Tanzania.

ICH/GCP the only standard – African countries are adhering to or have already adopted the ICH/GCP guidelines in the process for regulatory and ethics committee approval. Clinical trials are conducted according to the required standard operating procedures to guide and train all the local staff, to ensure operations are carried out in compliance with ICH/GCP regulations, and to fulfil sponsor requests and requirements.

Faster participant recruitment – There is a large naïve population, with diseases of both the developed and developing world, which offers strong prospects for large and rapid participant recruitment.

Cost benefits – The majority of trials running in Africa are funded by NGOs/governments. Including investigator sites in Africa in general will help reduce the overall drug development timelines, with a higher number of participants in fewer sites. This accelerated participant recruitment allowing for fewer sites and less regulatory applications will equate to an overall lower cost for the study.

As challenging as it may seem, **Africa presents a unique profile** that interests NGOs and governmental organisations and should be equally interesting for many pharmaceutical and biotech companies. Changing requirements, the need for participant diversity and larger sample sizes in clinical trials in parallel with improved clinical research environments in African countries are resulting in a notable growth in clinical research in the region.

There's More than TB and HIV

Until now, the focus on clinical research has primarily been on infectious diseases, particularly HIV/AIDS, TB, and malaria, as large numbers of the population are greatly affected by these diseases. There is not much focus on oncology or other lifestyle/metabolic diseases, although the prevalence of these is rapidly increasing. As such, cooperative clinical trial groups, sponsored by the National Cancer Institute, have already begun working in the Africa region, showing a large interest in bringing cancer therapies to Africa. Next to oncology, such as cervical cancer, other emerging topics are metabolic and other lifestyle diseases such as diabetes, maternal and infant health, ischemic heart diseases and strokes, and lower respiratory infections.

COVID-19 as the Big Revealer

Recently, the African Academy of Sciences (AAS) has launched the first iteration of the Clinical Trials Community (CTC) online platform in an attempt to increase the visibility of African clinical trial sites and investigators with the potential to participate in COVID-19 clinical trials, with an end goal of promoting the enhancement of intra-African collaboration around clinical trials.

As already indicated, few clinical trials are done in Africa: COVID-19 shows why this urgently needs to change. While there are massive movements within the industry to invest in COVID-19 vaccines, the outcomes of these COVID-19 studies will only be limited to the patient population included. These vaccines in the end might not be relevant for people in African countries, unless the studies are conducted locally. This is because responses to drugs or vaccines are complicated and can be influenced by, among other things, human genetics: different people will respond differently to different drugs and vaccines. More countries on the African continent must urgently get involved in clinical trials so that the data collected can be representative of the whole continent.

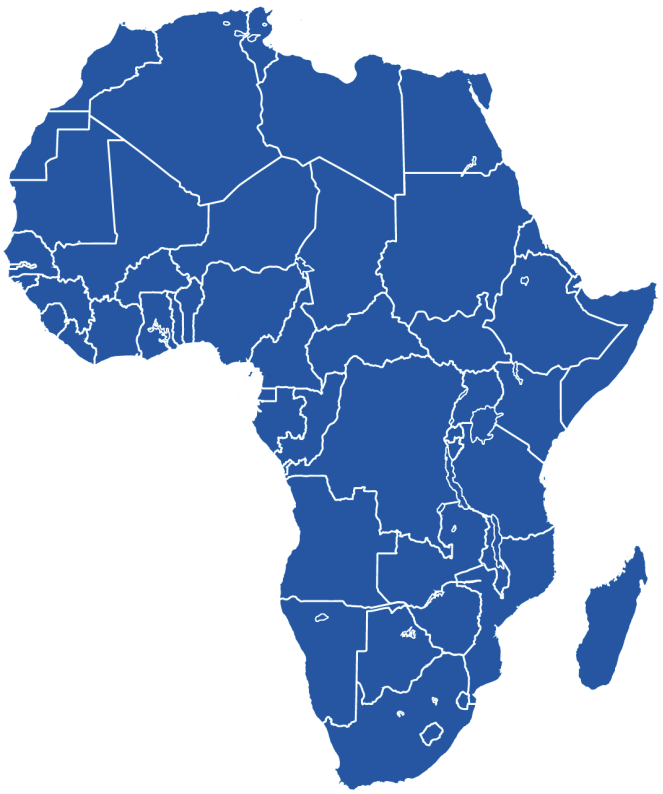
Time is of the essence. The usual approach, of developing site- or country-specific protocols, won't work. Instead, African governments need to look at ways to harmonise the response towards COVID-19 across the continent. Now, more than ever, African countries need to work together. Every country's epidemic preparedness kit should contain funds set aside for clinical trials during epidemics or pandemics. This would require governments on the continent to evaluate their role and level of investment in the general area of clinical trials. This will augment the quality and quantity of clinical trials in the face of the constant challenge of emerging and re-emerging infectious diseases, as well as a steady rise in non-communicable diseases. On top of this, clinical trial centres and clinical research institutions on the continent should

strive to increase their visibility in the global space. This will make them easy to find in times of crisis and enhance both south-south and north-south collaborations.

Joined-up Engagement

Cerba Research, part of Cerba Healthcare Group, has been focusing on central lab activities for the past 37 years. It has established a portfolio of customers based in Europe and the USA who need to expand to the Africa region to be able to easily enrol participants into both interventional and non-interventional studies. Cerba Research can draw on the support of the Cerba HealthCare and Lancet networks, who have joined forces to become the medical, biological and diagnostic leaders in Africa. With over 11,000 collaborators who share the same goal of providing patients, physicians, pharmaceutical and biotech companies with the best healthcare service, Cerba and Lancet ensure that patients, irrespective of their geographical location, benefit from proximity, quality and innovative biology. This joint venture follows a successful collaboration between the two diagnostic leaders and creates a network with coverage in over 23 African countries. The establishment of this joint venture and the increased resources within the group in Africa, make this the ideal opportunity for Cerba Research to also expand its activity across the African continent and become the global leader in central laboratory services in Africa.

Even before the establishment of CerbaLancet, partnering with Lancet Laboratories, Cerba Research (formerly BARC) has been able to set up and manage clinical trials in Africa for two decades. With a local team based in Johannesburg, BARC South Africa has conducted over 250 trials in a wide range of therapeutic areas. Working closely together with the US department of Health (NIH), NGOs, CROs and pharmaceutical companies, we have localised expertise which allows us to expand and execute trials in the entire Africa region, taking BARC South Africa as an example. This expansion can be seen in the rest of Africa as the laboratory infrastructure improves and acts as a catalyst for conducting clinical trials in the entire Africa region.



Biobanking in Johannesburg, South Africa

BARC South Africa has a **certified Sample Repository (Biobank) in Johannesburg, South Africa**. The biobanking facility in Johannesburg was launched in October 2009 and has been designed to store over seven million clinical samples (6.4 million samples at -80°C; a dedicated ambient storage area and 760,000 samples in the liquid nitrogen vapour phase) and is integrated into the central laboratory services. Storage conditions available include: Ambient (20°C to 30°C), refrigerated (2°C to 8°C), frozen (-20°C, -80°C and -196°C). There are currently approximately 3.2 million clinical trial samples in storage at -80°C, and 500,000 PBMC samples in the vapour phase of liquid nitrogen. The BARC South Africa biobank is involved in research looking at long-term storage preservation of mycobacteria in various media with the ACTG as part of the TB Quality Assurance Advisory Group. Continual internal auditing is done by the quality assurance officer on all work performed by staff to check for integrity of sample processing, storage and on source data recording, with ongoing training and development of all staff as needed. All samples are quality assured 100% on entry and prior to ship-out from the facility. Furthermore, robust methods have been developed for receipt of samples into the biobanking unit, sample processing and storage within the Biobanking unit and for sample distribution from the Biobanking unit. These methods include: pre-notification steps, shipment approvals, capturing of shipments and quality control into the laboratory management system, sample issues reported on a specimen discrepancy report (SDR), management of permits (import and export), rapid and accurate retrieval of samples. All shipping performed is done to IATA standards. The biobank therefore has the ability to disseminate frozen specimens to destinations worldwide for further research and development in accordance to international guidelines and recommendations. A system known as Citect Scada (FDA approved) is set up to ensure real-time continual monitoring of the temperature, equipment's electronic processing systems, liquid detection monitors, acceptable oxygen levels and related equipment failures within the facility. All are electronically documented with SMS notification via two independent service providers to the standby staff in case of error.

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Sofie joined Cerba Research six years ago and holds a PhD in Science, biotechnology. She combines her contracts and proposals experience with her scientific background to function as the Cerba Research head of business operations & marketing.

Carole Wallis

Carole has a PhD in molecular medicine and medical biochemistry and serves as a virologist on several different NIH protocols. Carole currently holds the position of medical director of Cerba Research (Barc) South Africa.