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How clinical development can tackle Africa's unique health needs

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- **Commercially-led clinical development activity has been vastly neglected in Africa, a situation that must change considering the changing demographics and health profile of the continent.**
- **Clinical trials in Africa carry huge benefits including innovation in medicinal development, improved healthcare and patient outcomes, and subsequent benefits for Africa's development as a whole.**
- **Better regulation of medicines in Africa will improve medicinal quality and manufacturing capacity.**

While the second most populous continent with over 1.2 billion people, Africa has vast unmet patient needs. By 2050, the United Nations projects that 25% of all humanity will be African and that population will be older and more concentrated within urban settings. Although infectious diseases exact a terrible toll across many African countries, non-communicable illnesses are poised to become the leading causes of death in sub-Saharan Africa by 2030, diversifying Africa's disease burden.

The continent also has greater human genetic diversity than any other region globally, which means that the aetiology and epidemiology of Africa's health challenge present significant unknowns that can only be addressed through African population research and African clinical development.

Clinical development far-reaching benefits

Clinical development for diseases plays a direct role in improving treatment. For example, the benefits to patients of conducting clinical trials for sickle cell anaemia (SCA) in sub-Saharan Africa (SSA) extend beyond access to novel medications.

Over 1 million children are affected by SCA in this region and an estimated 60,000 children have ischemic strokes, a known complication. Over the last two decades and in many parts of the world, it has been standard practice to screen children for stroke risk each year. An ultrasound technique known as transcranial Doppler ultrasound (TCD) is used to treat children with elevated risk to prevent stroke more aggressively, greatly reducing morbidity in children with SCA.

This life-changing TCD screening was not available in the region until clinical research in SCA. As part of both academic- and industry-sponsored trials, TCD equipment and training allow TCD screening on a much wider scale than ever before. The technology and expertise for TCD screening are now finding their way into the standard of care in some countries in the region to the benefit of many children and families.

Although clinical research can improve treatment practices, in 2020/21, the proportion of clinical trials starting in Africa, out of the worldwide total, was a mere 3.9%, according to IQVIA analysis of the Citeline TrialTrove database. This percentage represents a doubling of African trial starts in the last decade but is still a small proportion of the global trial landscape and under-represents the potential for 16% of humanity, effectively ignoring many of the major unmet health burden challenges of the 21st century. So, what must change?

Maturing regulatory environment

Regulation of African medicines has been historically weak and fragmented and must be strengthened to encourage clinical development. With 54 countries, 32 of which have populations over 10 million people, harmonization of regulatory practice across Africa is essential to creating an attractive and sustainable research environment.

The COVID-19 pandemic accelerated regulatory collaboration. The African Vaccine Regulatory Forum (AVAREF), previously a platform coordinating clinical trials on vaccine candidates for Ebola, played a crucial role in facilitating clinical trials for COVID-19, such as the ANTICOV trial of repurposed COVID-19 treatments, by organizing a joint review of clinical trial authorization across regulators.

The African Union's African Medicines Regulatory Harmonisation (AMRH) aims to strengthen regulatory capacity and drive the adoption of shared practices and protocols across the continent. If successful, alongside benefits for clinical development, there could be enormous benefits for medicine manufacturing, quality and access.

Regulation has also strengthened because of individual country initiatives. For example, South Africa sees an improving speed of clinical trial approvals, being the first country for site start-up after the United States for one recent trial.

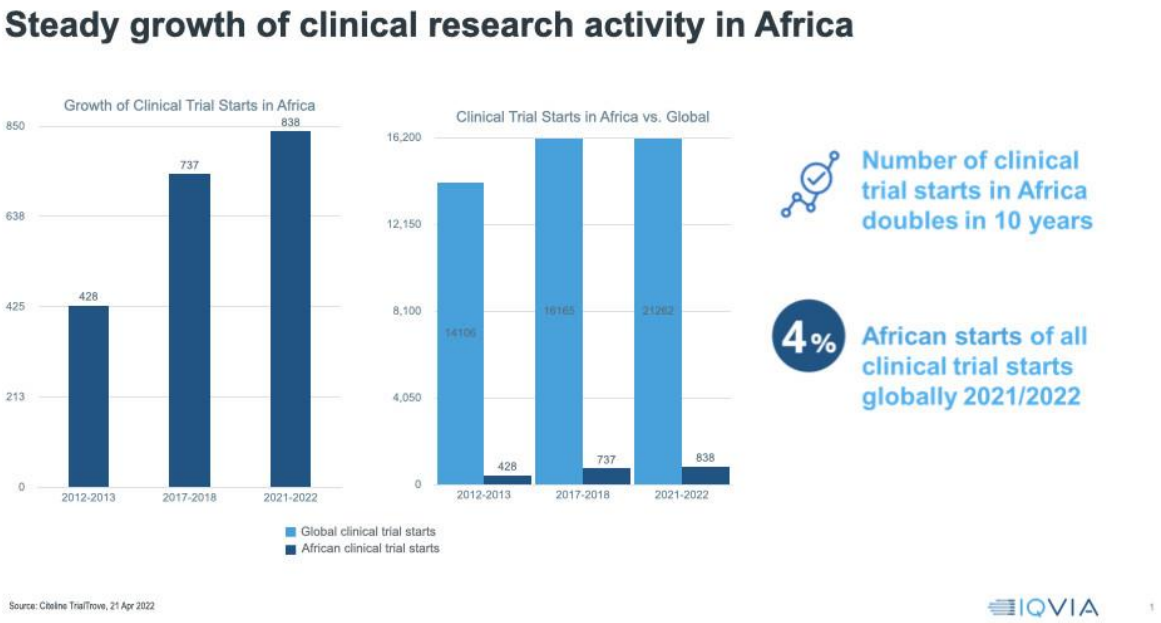

Figure 1: Steady growth of clinical development activity in Africa. Image: Citeline TrialTrove 21 April 2022

More choice of trial sites

IQVIA analysis of Citeline TrialTrove data has further found that the number of clinical trial investigator sites in Africa now stands at over 1,400, with 11 countries possessing 20 sites or more. Commercial sponsors, however, account for only 35% of African clinical trial starts – the number of mature investigator sites and research infrastructure must continue to grow to attract more commercial trial activity.

Important drivers in countries with significant and growing numbers of sites include:

- The increasing willingness of healthcare professionals and facilities they work in to be involved in academic and commercial research.
- Ongoing innovation and investment in medical infrastructure, as with the SCA example, and a growing supply of clinicians who are high-quality investigators.

For commercial pharmaceutical enterprises, another attractive facet of the current African clinical development environment is the relative absence of competing trials. African trial activity largely focuses on later-stage Phase III and IV trials, testing efficacy compared to existing treatments and long-term outcomes across large patient groups rather than the basic

safety tests of earlier-stage trials. In addition, an uncrowded field for sites and patients is helpful with large groups of patients to recruit.

The African clinical trials environment is still a work in progress with continued improvement needed on:

- Availability of diagnostic and other equipment across investigator sites and within local healthcare systems.
- Health system infrastructure strengthening to support the identification and referral of trial candidates and patient follow up, where effective community engagement and partnership are critical for recruitment and long-term study results.
- Mature, reliable and secure supply chains for trials to ensure delivery of medicines and supplies and ongoing medical care.

New phase of clinical development in Africa

Africa's growing activity around infectious disease clinical trials will likely continue, e.g. clinical trials for Mosquirix, the world's first malaria vaccine. While Africa increasingly hosts non-communicable disease clinical trials, there must be a balance given the ongoing risks from communicable threats. Growth in the level and variety of clinical development activities have multiple benefits to meeting Africa's rapidly evolving healthcare needs.

Clinical development and regulatory strengthening and harmonization are symbiotic, progress in one encouraging development in the other. Strengthened regulators would improve medicine quality and are crucial to developing African medicines' manufacturing capacity.

Growing African clinical trial activity benefits healthcare professionals by developing their skills and experience with new treatments and equipment. Finally, and most importantly, it benefits African patients by bringing medical innovation into Africa faster, opening opportunities to develop medicines to fit better the African continent's unique and highly diverse populations.

Accessed at: https://www.weforum.org/agenda/2022/05/how-clinical-development-can-meet-africas-unique-health-needs/

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