

**WHITE PAPER**

## **ADVANCING CLINICAL TRIALS IN AFRICA: OPPORTUNITIES & CHALLENGES**

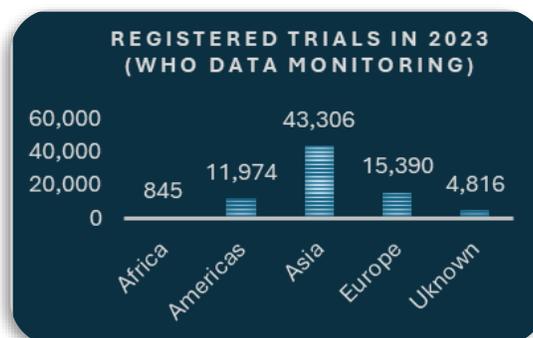


## Executive Summary

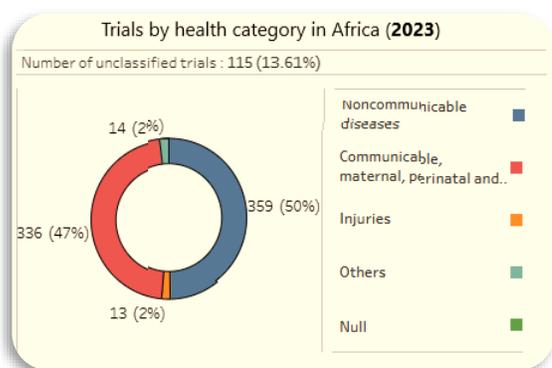
The African continent is emerging as a promising frontier for clinical trials due to its diverse patient populations, growing healthcare infrastructure, and favorable regulatory reforms. Africa's unique healthcare landscape presents both opportunities and challenges for pharmaceutical companies and Contract Research Organizations (CROs) seeking to expand into the region. This white paper delves into the clinical trials ecosystem in Africa, with an emphasis on regulatory environments, operational challenges, key therapeutic areas, patient recruitment strategies, and evolving trends in clinical trial management. By leveraging Africa's unique landscape, pharmaceutical companies and CROs can tap into the promising market while addressing global healthcare needs.

### 1. Introduction

Africa, home to over 1.5 billion people, is projected to reach 2.5 billion by 2050 and 4 billion by 2100. The continent is increasingly recognized for its potential in clinical trials, thanks to its unique population dynamics, unparalleled genetic diversity and a substantial disease burden, making it a potentially attractive destination for pharmaceutical research.



Source: WHO data Monitoring



Source: WHO data Monitoring

Historically, clinical trials in Africa have been concentrated on infectious diseases like malaria, HIV, and tuberculosis, but there is increasing interest in non-communicable diseases such as cardiovascular diseases, diabetes, cancer, endocrine, blood, and immune disorders<sup>1</sup>.

This paper provide insights into the benefits of conducting clinical trials in Africa, highlighting market opportunities and strategies to address challenges such as infrastructure limitations, regulatory complexities, patient engagement, and ethical and operational considerations in low-resource settings.

<sup>1</sup> "Number of Clinical Trials by Year, Location, Disease, Phase, Age and Sex of Trial Participants."

## 2. Strategic Benefits of Conducting Clinical Trials in Africa

- **Diverse Patient Populations:** Africa's genetic diversity provides pharmaceutical companies with the opportunity to study drug effects across varied genotypes, which is essential for understanding drug efficacy and safety on a global scale<sup>2</sup>.
- **High Disease Burden:** Many African countries face high rates of infectious diseases and non-communicable diseases are on the rise, making the continent an ideal location for trials in these therapeutic areas<sup>3</sup>.
- **Cost-Effectiveness:** Clinical trials in Africa are typically more cost-effective compared to Europe or North America due to lower operational costs, such as site fees, patient recruitment, and labor costs<sup>4</sup>.

- **Improving Expertise and Infrastructure:**
- ✓ **Expertise Beyond Infections:** African researchers and healthcare professionals are gaining significant expertise in conducting clinical trials focused on non-communicable diseases, including cancer, diabetes, and cardiovascular conditions. For instance, south Africa has been a hub for advanced oncology trials, and Kenya has made notable contributions to global diabetes research<sup>5</sup>.



- ✓ **Improved Healthcare Infrastructure:** Significant investments in hospitals, clinics, and diagnostic facilities have enhanced Africa's capacity to manage complex trials. Institutions such as Uganda's Infectious Diseases Institute - Makerere University and Nigerian Institute of Medical Research (NIMR) now conduct trials involving innovative treatments and cutting-edge medical technologies<sup>6 7</sup>.

<sup>2</sup> "Africa: The New Superpower in Clinical Trials."

<sup>3</sup> MS, "Why Conduct Clinical Research in Africa."

<sup>4</sup> "Africa: An Advantageous Landscape for Conducting Clinical Trials."

<sup>5</sup> Toto et al., "Conducting Clinical Trials in Sub-Saharan Africa."

<sup>6</sup> "How Scaling up Clinical Research in Africa Can Benefit Society and the Economy."

<sup>7</sup> "How Rwanda Is Managing to Contain the Marburg Virus Outbreak."

- ✓ **Partnership and Collaboration:** These collaborations involve NGOs, private companies, universities, and healthcare facilities. Examples of such partnerships include the partnership among the Kenyan Medical Research Institute (KEMRI), the Wellcome Trust, and the University of Oxford as well as initiatives for oncology Clinical Trials in Africa<sup>8</sup> and collaborations between HIV care centers and cancer centers<sup>9</sup>.



- **Enhancing Regulatory Harmonization and Efficiency:** The African regulatory landscape has made notable advancements in recent years to improve efficiency and harmonization through regional initiatives such as the East African Community (EAC) Medicines Regulatory Harmonization (MRH), and the African Medicines Agency (AMA)<sup>10</sup>. Moreover, individual countries have made significant investments in strengthening their regulatory systems. As a result, in 2024, three additional countries achieved WHO Maturity Level 3, bringing the total to eight—up from just two in 2021<sup>11</sup>. For instance, Rwanda signed mutual recognition agreements with Tanzania and Ghana allowing products and clinical trials registered in one country to be fast-tracked for approval in the other with minimal additional processes as well as sharing data on Drug Safety<sup>12 13</sup>.

These leading efforts aim to harmonize regulations, foster collaboration, and reduce approval timelines across the continent, ultimately improving access to quality medicines.

<sup>8</sup> Ezeani et al., “SWOT Analysis of Oncology Clinical Trials in Africa.”

<sup>9</sup> Solarin et al., “Partnerships and Collaborations.”

<sup>10</sup> “The African Medicines Agency: Building a New Gold Standard in Regulatory Excellence.”

<sup>11</sup> “Statement from Africa CDC on Rwanda and Senegal National Regulatory Authorities Achieving WHO Maturity Level 3”; “Senegal and Rwanda Achieve WHO Maturity Level 3 in Medicines Regulation.”

<sup>12</sup> “RBC: Rwanda FDA and Ghana FDA Sign a Memorandum of Understanding.”

<sup>13</sup> “COOPERATION IN THE REGULATION OF MEDICAL PRODUCTS.”

### 3. Key Therapeutic Areas

- **Infectious Diseases:** Africa continues to bear a significant burden of infectious diseases beyond malaria, tuberculosis, and HIV/AIDS. Additionally, the growing threat of antimicrobial resistance further underscores the region's importance as a key location for testing and developing treatments and vaccines to address these health threats.
- **Non-Communicable Diseases (NCDs):** NCDs have become the leading cause of mortality in sub-Saharan Africa, accounting for 37% of deaths in 2019, up from 24% in 2000<sup>14</sup>. In 2021, there were 24 million people living with diabetes in the region. This number is projected to increase by 129%, reaching 55 million by 2045<sup>15</sup>. Additionally, by 2030, nearly half of women in Africa are expected to be obese or overweight, reflecting a significant increase over recent decades<sup>16</sup>. Moreover, cancer rates are also projected to increase significantly, with breast and cervical cancers being particularly prevalent among women<sup>17</sup>.
- **Maternal and Child Health:** Africa faces significant challenges in maternal and child health, making it a critical area for research. Clinical trials focused on improving maternal health, reducing neonatal mortality, and addressing childhood diseases offer immense potential for healthcare advancements on the continent.



### 4. Effective Strategies for Patient Recruitment

- **Treatment-Naïve Populations:** Africa provides access to large treatment-naïve populations, particularly in rural areas. Many patients have not previously received standard-of-care treatments for common conditions, making them ideal candidates for new interventions and subsequently enabling rapid patient recruitment.
- **Community Engagement and Trust-Building:** Successful clinical trials in Africa require culturally sensitive recruitment strategies. Engaging local communities, collaborating with local healthcare providers, and building trust through transparency and ethical practices are crucial for effective patient recruitment.
- **Technology-Driven Recruitment:** As mobile penetration increases across Africa, digital tools such as mobile health platforms, text messaging, and telemedicine are valuable resources for recruiting and retaining patients as well as obtaining informed consent.

<sup>14</sup> “Deaths from Noncommunicable Diseases on the Rise in Africa | WHO | Regional Office for Africa.”

<sup>15</sup> “Noncommunicable Diseases | WHO | Regional Office for Africa.”

<sup>16</sup> Lay and correspondent, “Nearly Half of Women in Africa Will Be Obese or Overweight by 2030 – Study.”

<sup>17</sup> “Deaths from Noncommunicable Diseases on the Rise in Africa | WHO | Regional Office for Africa.”

## 5. Overcoming Challenges: Strategies for Success

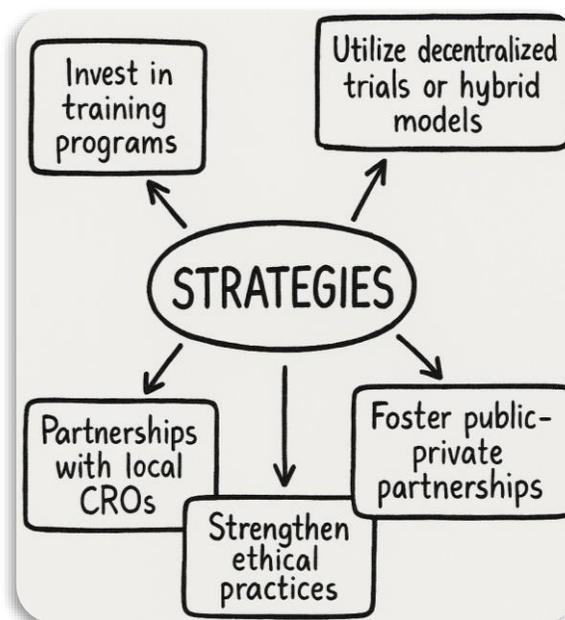
### Challenges

- **Regulatory Complexity:** Although progresses have been made, Africa’s regulatory environment remains fragmented, with different processes, timelines, and requirements across countries.
- **Infrastructure Gaps:** Some countries face challenges related to infrastructure, such as limited access to state-of-the-art laboratories and healthcare facilities and trained clinical personnel.
- **Ethical Considerations:** Conducting trials in low-resource settings requires stringent ethical oversight to ensure that local populations are adequately informed and protected.
- **Logistics and Supply Chain:** The logistics of clinical trials, including transportation of biological samples and investigational products, can be complex in rural and underserved regions.



### Strategies to Overcome Challenges

- Utilize decentralized trials or hybrid models and collaborate with local health care providers improve efficiency in trial execution and product distribution.
- Invest in training programs to increase local expertise in clinical research.
- Foster public-private partnerships to enhance clinical research infrastructure and improve regulations that align with scientific advancements.
- Strengthen ethical practices and implement community engagement programs to ensure informed participation and protection of local populations.
- Partnerships with local CROs to help international sponsors navigate the complexities of Africa’s regulatory and healthcare systems while benefiting from local expertise and established relationships with trial sites.



*"Turning Obstacles into Opportunities for Clinical Research Excellence in Africa."*

## 6. Why Choose THESYL as a Partner

THESYL is uniquely positioned to support clinical trials in Africa by addressing key challenges and leveraging emerging opportunities to offer tailored solutions. Our strengths include:



**Advanced Digital Solutions:** Technologies (EDC, ePRO, CTMS, eCRF, eConsent, etc.) are utilized to simplify patient recruitment and trial management, addressing infrastructure challenges and ensuring seamless trial execution.

**Collaboration with Private Clinics:** We partner with and engage private clinics, a resource often underutilized in Africa. This expands site availability, provides advanced infrastructure, and offers access to diverse patient populations.

**Focus on NCDs:** THESYL addresses Africa's growing NCDs burden by emphasizing research on cardiovascular diseases, diabetes, cancer, and endocrine, blood, and immune disorders rather than solely focusing on infectious diseases.

**Training the Next Generation:** To foster a skilled workforce for future trials, THESYL provides hands-on Clinical Research training for students, graduates, and clinical research staff.

**Regulatory Expertise:** With deep knowledge of Africa's regulatory landscape, we streamline approvals while maintaining the highest quality standards and compliance.

**Ethical and Community-Centric Approach:** We prioritize ethical practices and culturally sensitive recruitment, building trust with local communities to ensure successful patient enrollment and retention.

**Strategic Approach:** The company's forward-thinking approach reflects the integration of local expertise with global standards ensuring successful execution of clinical trials across all phases (Phase I–IV) and various therapeutic areas.

**Strategic Partnerships:** By partnering with multinational biopharma companies and global CROs, we help them navigate the local landscape with confidence and provide access to a broader range of sites.

## 7. Closing Reflection

Africa's clinical trial landscape is evolving rapidly, presenting new opportunities for pharmaceutical companies and CROs. The continent's diverse patient populations, high disease burden, increasing prevalence of non-communicable diseases (NCDs), improving regulatory environment, expanding infrastructure, and growing skilled scientific workforce make it an attractive destination for global clinical research. By understanding the nuances of the regulatory landscape, adopting technological solutions, forging local partnerships, and addressing logistical challenges, companies can leverage Africa's potential to bring new treatments to patients.

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*"Inclusive & Diverse Trials: Advancing Science, Delivering Better Outcomes for All"*

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### Evolving trends in clinical trial management

Clinical trial management is evolving with new technologies and regulatory shifts. Key trends include:

- **Decentralized Trials (DCTs):** The shift from traditional site-based trials to decentralized or hybrid models is improving accessibility and convenience for participants.
- **AI & Machine Learning:** Analyze vast amounts of medical data and prior trial outcomes to optimize study design and enable more precise recruitment, enhancing overall trial efficiency.
- **Real-World Data (RWD):** Supports regulatory decisions and post-market surveillance.
- **Risk-Based Monitoring (RBM):** Focusing on critical data and risks for enhanced efficiency and costs reduction.
- **Patient-Centric Trials:** Digital engagement improves retention.
- **Sustainability:** Remote and paperless processes reduce environmental impact.
- **Collaboration & Outsourcing:** Growing reliance on CROs and external partners for specialized expertise in regulatory affairs, pharmacovigilance, and data analytics.

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