## Pharma's Global Footprint in Africa

#### Thanyani Nathaniel Ramuthaga, Med.Sci. & Pr.Sci.Nat.

Clinical Operations Portfolio Leader (COPL) PDG, SA & SSA, Geo Lead – SA & Africa, Co-Active Coach Roche Products (Pty) Ltd



## Agenda



- Introduction
- Impactful Clinical Research Activities in Africa
- Future Investment Plans: Pipeline Strategy for Research in Africa
- Why Choose Africa for Clinical Research?
- Africa's Role in Meeting Pharma Expectations: Strategies for Growth
  - Addressing how Africa can Effectively Meet and Exceed Pharmaceutical Industry Expectations

#### Introduction

- Africa is the 2nd largest continent in the world
  - Population of 1.4 billion = 18% of the total world's population
  - 25 % World's Disease Burden
- Yet, only accounts for:
  - < 2 % of genomic data in Medical Innovation
  - < 3 % of Clinical Trials Data Contribution
- Africa as a continent remains a major marketplace for medicines and medical devices<sup>1</sup>



#### Introduction

- Africa's contribution to Medical Innovations in the last 60 years:
  - **The World's First Human-to-Human Heart Transplant** Operation in 1967: <u>Prof Chris Barnard</u>
  - The First Cure of Deafness in the World using 3D-Printed Bones for Reconstructive Middle Ear Implants at the University of Pretoria and Steve Biko Academic Hospital: <u>Led by Prof</u> <u>Tshifularo</u>
  - COVID-19 Omicron Sub-Variant XBB. 1.5, First detected in South Africa by the <u>Network for Genomics Surveillance team</u> <u>at Stellenbosch University</u> from a sample collected late in December 2022
  - **Biomedical Smart Jacket** that can diagnose Pneumonia 4x faster than a doctor, and also more accurate. It analyzes the chest and sends the info via Bluetooth to Smartphone App: <u>Ugandan Inventor Brian Turyabagye</u>



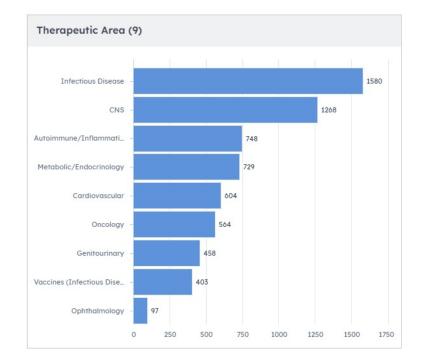


#### Introduction

- Africa's contribution to Medical Innovations in the last 60 years:
  - Koniku Kore the world's first device that fuses live neurons from mice stem cells into a silicon chip. The device can be used to detect explosives & cancer cells: <u>Nigerian Inventor</u>, <u>Osh Agabi</u>
  - The potentially life-saving Cardiopad, Revolutionizing Rural Healthcare – a touch-screen heart monitoring device that records, and then sends heart activity to a National Healthcare Center for Evaluation; the brainchild of 2<u>6-year-old engineer</u> <u>Arthur Zang, from Cameroon</u>
  - Usalama, the Panic Button App sends a distress signal with the shake of a phone. The App works by connecting people with emergency service providers, and sends their exact location when they shake their phone 3x. It also alerts a next of kin and every other Usalama users within 200m: <u>3</u> students from Kenya - Marvin Makau, Edwin Inganji and Kenneth Gachukia



#### **Impactful Clinical Research Activities in Africa**



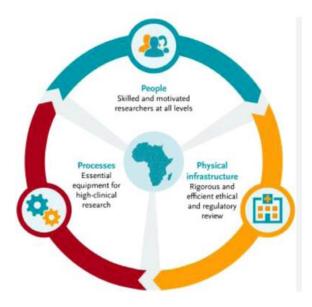
#### No. of CT in the 9 TAs across the African Region: Jan 2010 to Jan 2023

- Above & beyond participants receiving IMP
  - How have they benefited the disease area landscape in the participating country?
  - Has the data generated impacted the treatment policy/practice in the region?
  - Has the infrastructure of the participating centres been positively impacted?
  - Has it improved collaboration between the relevant stakeholders to advance healthcare in the region and DA?
    - Networks for Centres of Excellence & Knowledge Exchange
  - Has it improved patient access to advanced treatment regimens in the region/ participating countries?
- Are there quantifiable changes brought by the country's participation in CT at a local, national and/or regional level?

#### **Impactful Clinical Research Activities in Africa**

Across Clinical Trials Value Chain

- Logistics Services e.g. IMP Depots
- Laboratory Services
  - E.g. BARC Biobanking being used?
- Patient Management Services
  - Mobile Nursing
  - Travel & Reimbursement Services
  - Recruitment Services etc
- Ethics Committees Capacity e.g. eSystems / Inspections
- Regulatory Processes & Policies
- Publication of Manuscripts
  - African based Researchers as first Author
- Active Locally-Based Community & Public Engagement e.g. PAGs
- What kind of impact are the research activities having on the above?



#### Impactful Clinical Research Activities in Africa

Refers to activities which will enrich & positively impact the local communities, well beyond the task of generating expected study data

- How did the research activity impact
  - The facilities
  - Patient population
  - Local communities
  - Research Communities
  - Local Treatment Policy or Disease Management Approaches
  - Patient Support / Advocacy Groups

#### ? What is the ultimate societal value brought about?

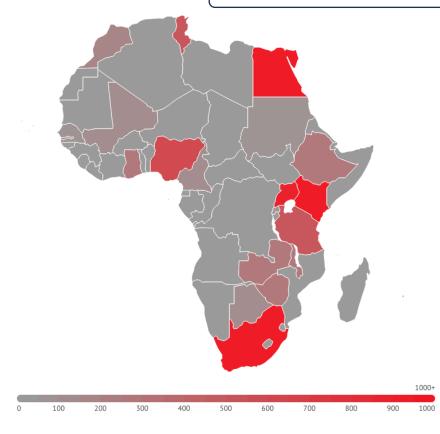
? Are the study objectives addressing pressing health concerns?

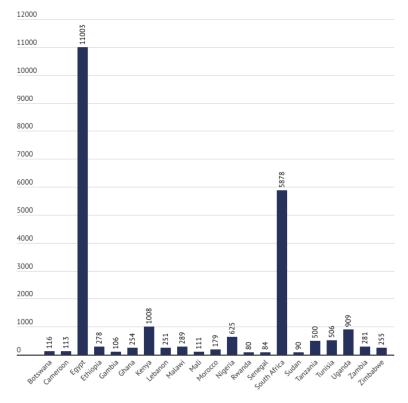




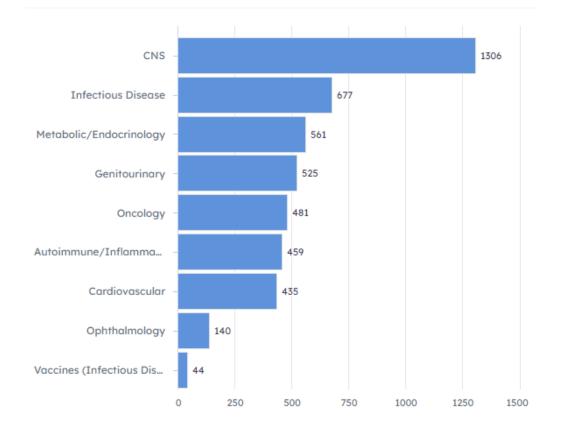
- Collaborate in Coordinating Local/Regional Disease Databases/Registries
  - Close the Gap on Fragmented Databases
    - It downplays ability to access the target patient population
    - Limits the estimate of actual disease burden
    - Misalignment of site selection vs patient sources
    - Have our suitability to participate questioned
    - Complicated Patient Journey
  - Enable estimation of Disease
    Prevalence/Incidence at a Country vs High
    Burden Areas

#### Total Number of Studies between 2003 & 2021 (Top 20)

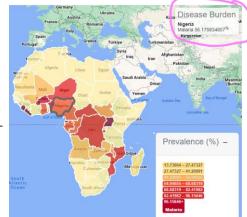




#### TAs of Studies between 2003 & 2021 (Top 9) in Egypt



- Establish Platforms to enable sharing & making African CT landscape more visible
  - E.g. Clinical Trials Community Platform for Africa
    - By Africans to Highlight the Strengths, Capability & Opportunities in Africa
    - Where to find sites with experience in target DA
    - Areas with Disease Burden in TAs of choice
    - Possible sites with experience in different TAs and CT Phases
  - E.g. ClinRegs Portal
    - Actively review on an ongoing basis to ensure our regulatory landscape is actively updated, kept current and accurate



WE KNOW WHAT YOU'VE GOT AND WE NEED AN OVERSEAS-TRAINED DOCTOR TO BLAME IT ON



- Promoting Networks and Long-Term Sustainable Partnerships, across the African Region
  - Lessons Sharing
  - African-led Plans & Strategies
  - Awareness: Research & Development Course(s) in Mainstream Sci & Med Curricula
    - Including training in scientific-writing skills and translating research results into policy
  - Proper Coordination for Harmonisation of Strategies
    - Avoid Duplication of Effort & Optimize Resource Utilisation

- Improve & Strengthen Research and Regulatory Framework
  - Clear, Comprehensive regulatory Processes and Competitive Timelines
  - Continuous Engagement of Science & Health Researchers, Policy Makers and Regulators
- Grant Funding Partnerships with Government / Philanthropic Orgs to Build & Strengthen Research Infrastructure and Promote and Support Scientific Thought Leadership from the continent



Africa offers unique ways to identify and develop new therapies: Untapped Opportunity

Pathogenic Profile

Local CRO Footprint



Diverse Population: 1.4b+







Global

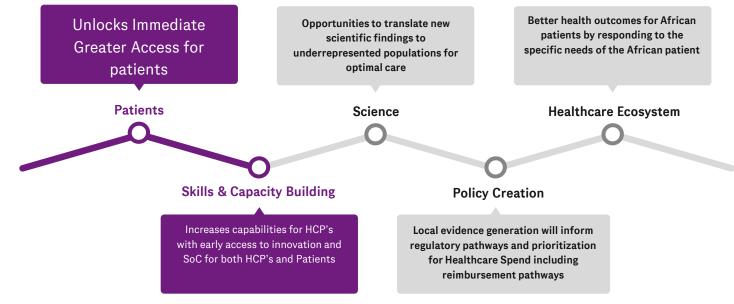
Footprint

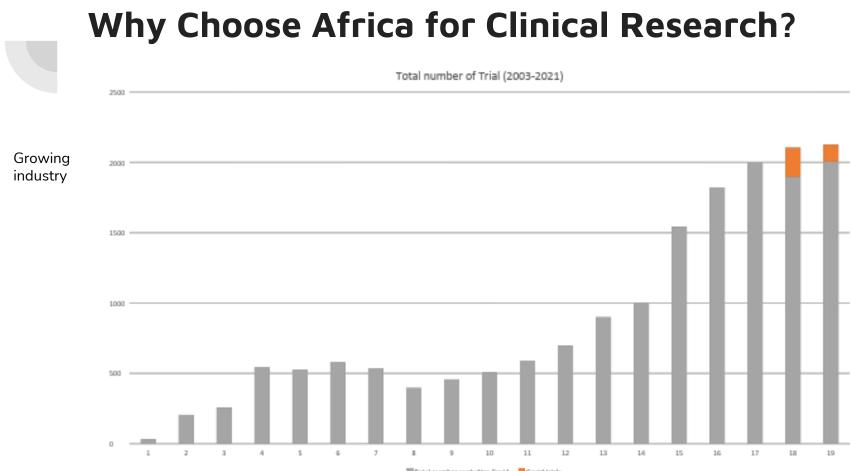
CRO





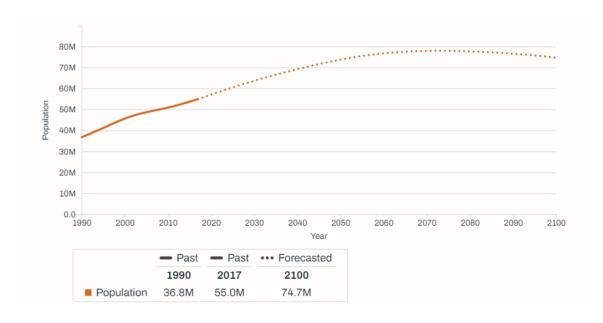
More clinical research will increase local evidence generation that will lead to:



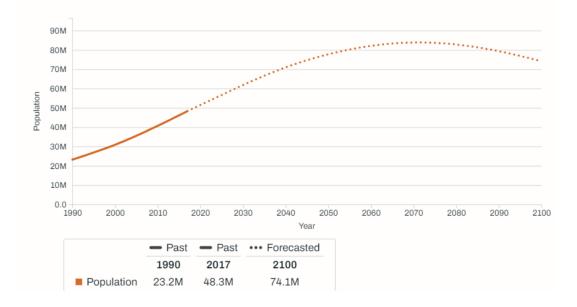


Total number excluding Covid Covid trials

E.g. South Africa



E.g. Kenya



First Ph. I global Oncology trial active in Kenya - (First-inhuman trial)

(+)

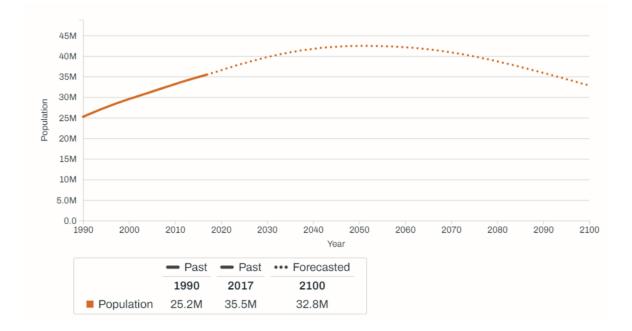
Data generated from some of the recent trials run in Kenya were published/shared in journals and congresses by Kenyan Investigators as 1st Authors

Growth & Expansion of Interventional global clinical trials in East, Central, and West Africa - some of the 1st TAs in the last 3 years

(+)

#### Scaled up Pharma R&D activities

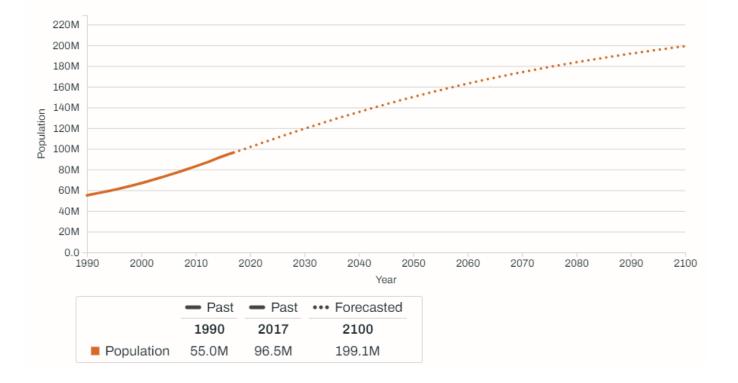
E.g. Morocco



E.g. MagHub: Morocco, Algeria & Tunisia - Value & Impact









#### E.g. Egypt Stories

#### **Patient Centredness**

"Our resilience and belief is that the Egyptian patients are in need of innovative medicines which reflects as the success factors of our stories!!

Member of the Pharma Group, Egypt

#### **Ecosystem Shaping**

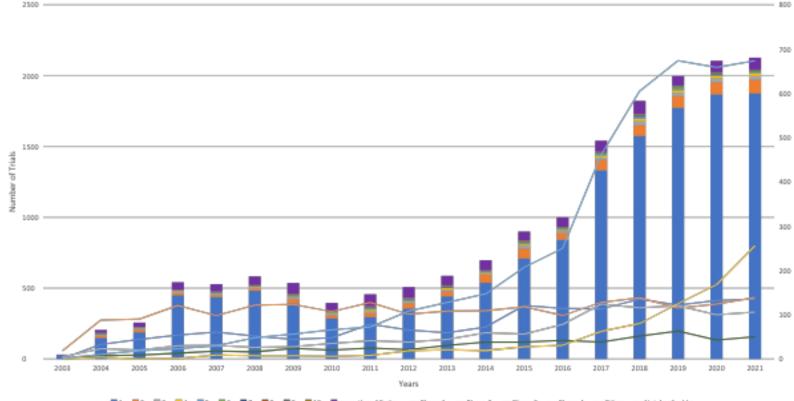
As one voice, The pharmagroup in Egypt developed a comprehensive report that provides an in-depth analysis of the intricate socio-economic factors related to Clinical Trials and presents an overview of the current clinical research ecosystem as well as offering strategic suggestions to enhance the clinical research landscape in Egypt CT Framework

#### **Quality Enhancement**

Recent site/study inspections by Egyptian Drug Authority returned minor findings only

Number of Trials per year vs number of Sites (2003-2021)

800



more than 10 sites - Phase 1 - Phase 2 - Phase 3 - Phase 4 - Other - Not Applicable

## Africa's Role in Meeting Pharma Expectations: Strategies for Growth

- Mapping Regional Cooperation: Africa-Centric Approach
- Collaborations
  - Networks
  - Partnerships
    - Academics, Scientists, Researchers
- Capacity Development & Sustainability Strategies
- Agile yet Robust Regulatory & Ethical Review Processes
- Policy Framework
- Investment in Expanding Infrastructure
- Patient Engagement
- Scientific Publications write own stories
- Sustainable access solutions
- Outcomes based data reflecting actual burden of disease
- Creation of value based healthcare systems informed by local data

# What have we done so far?

