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Transforming Healthcare Research in Africa

Managing Diversity in Clinical Trials

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ICR Clinical Allsorts Forum, 06 September, 2019

Agenda

- Diversity in Clinical Trials
- Why Africa?
- eMQT Background
- Clinical Trials Landscape in Africa
- Sickle Cell Disease Clinical Trials

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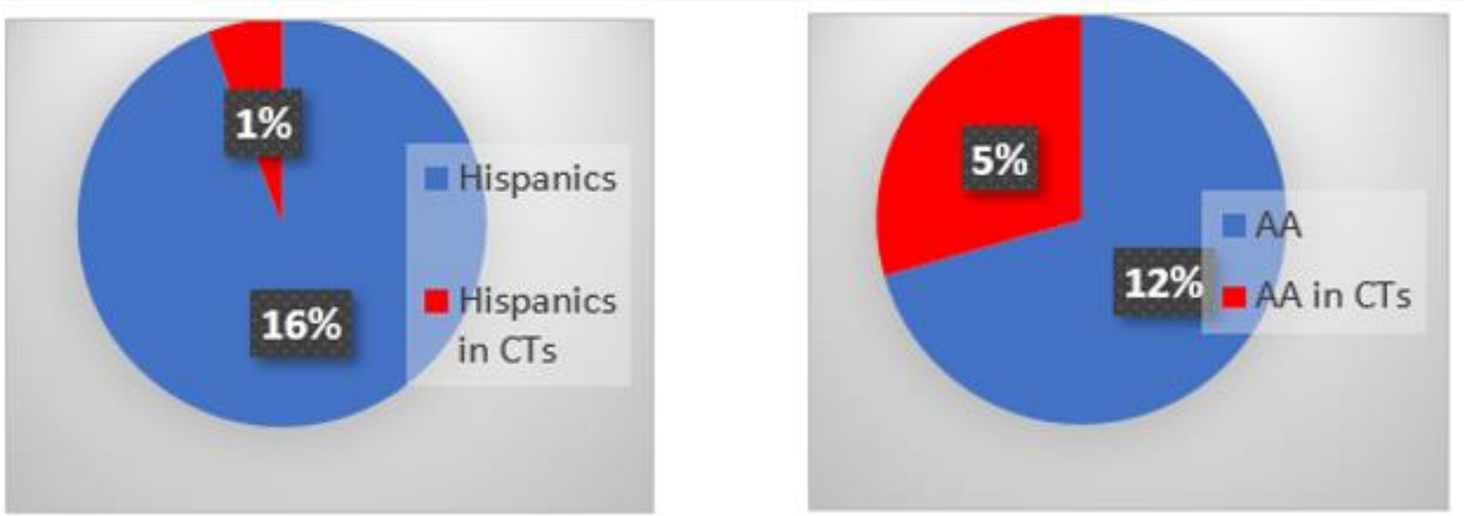
DIVERSITY

Although the people of African descent make up 17% of the world's population (over 1 billion), Black People are underrepresented in clinical trials globally reported as less than 3% by the Genome-Wide Association Studies (GWAS).



Amezcua L, Lund BT, Weiner LP, Islam T. Multiple sclerosis in Hispanics: a study of clinical disease expression. Mult Scler 2011;17:1010–1016

Diversity in clinical trials defines good science and better medicine.

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Barriers to Diverse Participation in the US - Reported by the FDA

- Mistrust and distrust of the medical system due to historical abuses
- Lack of access
- Lack of awareness
- Inadequate recruitment efforts
- Lack of minority Physicians and PIs
- Misaligned cultures, values and beliefs
- Perceptions that minorities do not want to participate
- Enrolment criteria
- Privacy concerns

FDA: Diversity in Clinical Trials is Essential

"Patients enrolled in a trial should be representative of the types of patients who are likely to use the medical product if it is approved or cleared by the FDA".

"And experience has shown that there can be important differences in how people of diverse groups respond to medical products".

"Information on those differences can then be included in the product labelling to help doctors and patients make treatment decisions".

"The bottom line? Researchers should test medical products in all groups of people to help ensure medical products are safe and effective in everyone who will use them".

"And the FDA offers guidance for researchers as appropriate, including recent recommendations to industry and agency staff on how race and ethnicity data should be collected".

https://www.fda.gov/consumers/consumer-updates/fda-encourages-more-participation-diversity-clinical-trials

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FDA Office of Minority Health and Health Equity (OMHE)

Mission: To promote and protect health of diverse populations through research and communication that addresses health disparities.

Vision: To create a world where health equity is a reality for all.

Tactical tools and resources (translated, written, online and videos): Outreach, education, site selection and SMEs

BE A #CLINICALTRAILSCHAMPION

https://www.fda.gov/about-fda/office-commissioner/office-minority-health-and-health-equity

Why Africa?

2013 - 2020, emerging market economies forecasted growth 3X faster than developed economies

Home to 1.2 billion (Population by 2020 population projected to over 2BN)

By 2050, @ 42 million people p/a = doubled to 2.4 billion, according to the UN

3.5 million more people per month

80 additional people per minute

Africa alone will contribute 54% of world population re-fill an empty London five times a year

Strategic Market for pharma: Most Populous country with large cultural diversity

Nigeria will add more people to the world's population by 2050 than any other country

One of the most challenging but dynamic African countries

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Why Now?

The ‘Rising Billion’: People in Africa are expected to reach 3-5 billion by 2020 representing half of the world’s population. The rising GDP and consumer power offers an attractive therapeutic market.

The population offers drug naïve patients in multiple disease areas that are accessible through careful planning and engagement.

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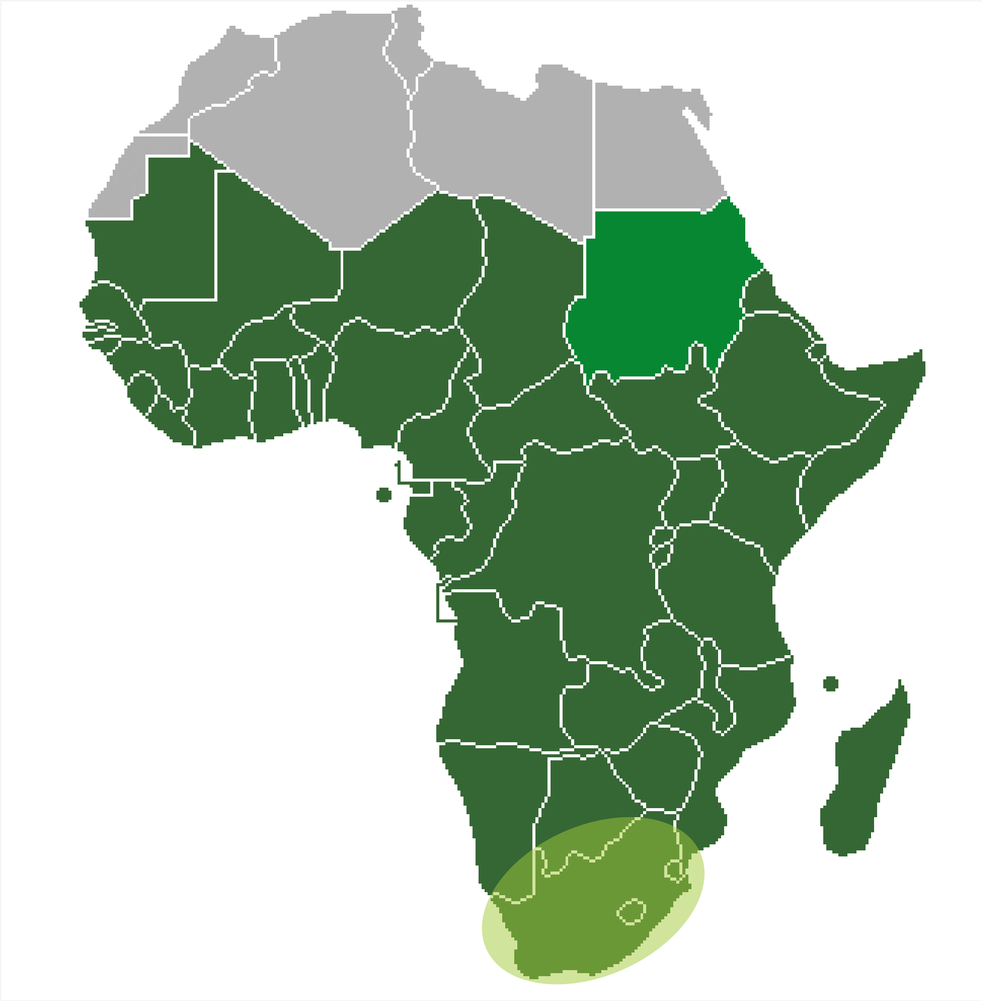
Why Sub Saharan Africa?



- Patient Populations
- Minimal Exposure to Modern Medicine
- Enthusiasm
- Clinical Talent
  - Some trained in Western World
  - Highly Educated
  - ICH GCP Aware
- Technology Enabled Innovation

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Africa - Why Not?

Volatile Uncertain Complex Ambiguous

INFRASTRUCTURE

Lack of infrastructure (logistics etc.)

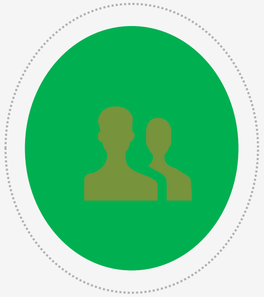
Well equipped hospitals , linked community hospitals, willingness to build, sample/drug import/export

EXPERIENCE

Insufficient experience

Excess of well educated talent

Eager to learn



CULTURE

Impact of culture

Recognizing, understanding and respecting differences in culture enables and supports ease of doing business

ETHICS & REGS

uncertain regulatory environment?

Current tightening of local import rules for non-regulated medicines; Empower Regulators via CT process

DATA PROTECTION

Data protection and Confidentiality

Awareness and understanding of the importance of confidentiality of patient information

Delivering through **leadership + direction + developing & nurturing talent + training =** delivering sustainable operations & compliance excellence

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Diversity improves outcomes for all

We are the bridge between the pharmaceutical industry and Africa, utilizing research qualified healthcare experts and technology innovation to provide access to patients and high quality evidence-based patient data.

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Our Objectives

01 Increase Diversity

Increasing diversity representation in industry trials across regions under-served in Africa and Caribbean to participate in clinical trials.

02 Best Practice

Transfer best practices across mature and emerging regions that conduct clinical trials.

03 Change Public Opinion

Deliver engagement and advocacy to drive consistency and alignment to allow benefits of clinical trials to be available to all.

04 Knowledge Sharing

Educate on quality standards through training and sharing of procedures and guidelines for conducting high quality, Good Clinical Practice compliant, ethical global trials; create clinical trials **Centers of Excellence** in both hospitals and clinics.

05 Provide Capacity Building

Provide capacity building to support the use of technology enabled processes for the conduct of global clinical trials and delivery of high quality data.

Value Proposition

Excellence

Excellence in delivering standard quality data.

Legitimacy

Legitimacy to demonstrate the highest standards of compliance and adherence to all laws and regulations governing clinical trials.

Sustainability

Sustainability to generate and support projects that can create long lasting income for local communities.

Credibility

Credibility to become a trusted collaborator to all core stakeholders.

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Core Stakeholders

THIRD PARTY PROVIDERS (LABS, IMAGING ETC)

CLINICAL RESEARCH MANAGEMENT TEAM (CRO)

AFFILIATED SOCIETIES AND ASSOCIATIONS

HEALTHCARE PROVIDERS

PATIENT ADVOCACY & REGULATORY BODIES

SPONSOR(S) INCLUDING PHARMA AND ACADEMIA

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Services to Clinical Trial Stakeholders

Regulators

Patients

Healthcare Professionals

Pharmaceutical Industry

Technology Innovators

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Our Network

Capabilities & Reach

Pan-Africa Reach
Access to over 60 sites across more than 15 countries

Diverse Therapeutic Capabilities
From local endemic disease to global illnesses

Clinical Trial Experience
Including investigator initiated to international supported studies (PIs and Sub-Is are Professors), Accredited Laboratories and Trusted Supply Chain

Understanding of Regulatory Terrain
Awareness of current status in regulatory climate of change

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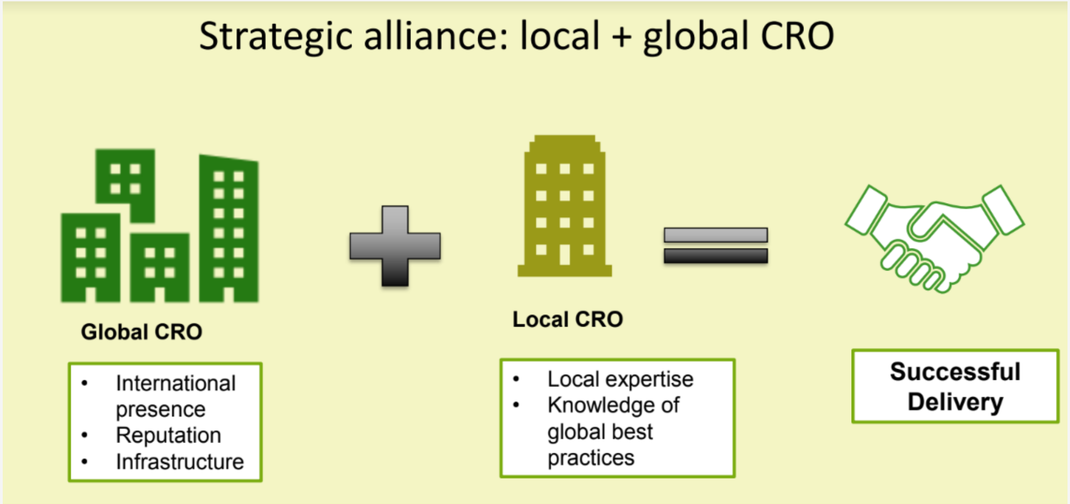
Reminder of Challenges in Africa

- Lack of local representation
- Inadequate knowledge of:
  - local healthcare practices
  - regulatory requirements
- Complex ethical set-up
- Poor connections with investigators
- Poor awareness of subtle challenges
  - Language
  - Culture
- Infrastructure: internet, electricity, transportation



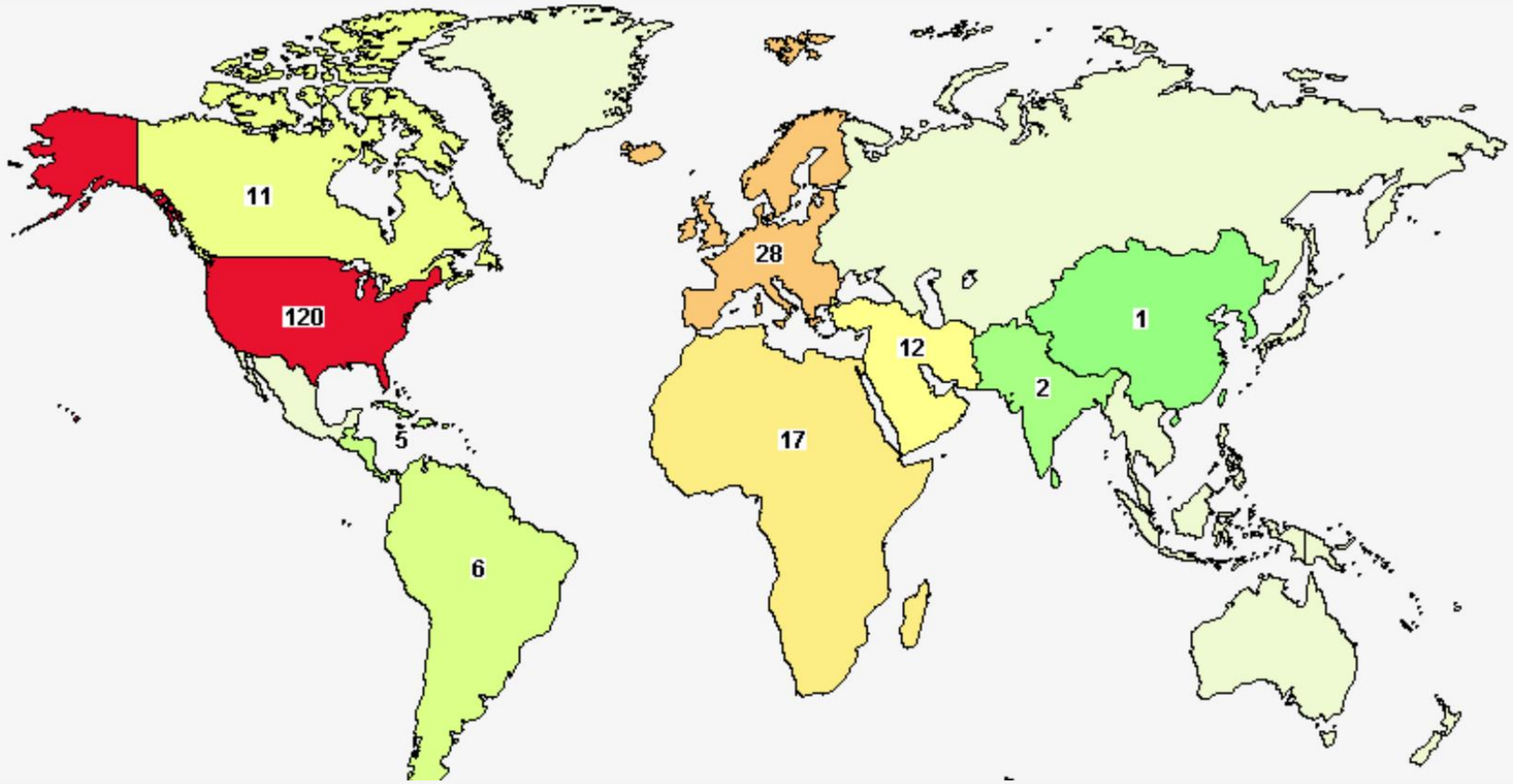
Clinical Trials Numbers

NIGERIA 129 TRIALS	180M POPULATION
POLAND 5,444 TRIALS	37M POPULATION
CHINA 11,583 TRIALS	1.378M POPULATION
UNITED STATES 110,201 TRIALS	321M POPULATION

UNTAPPED POTENTIAL & OPPORTUNITY

https://clinicaltrials.gov/

Active Global Sickle Cell Trials
ClinicalTrials.gov



- 166 active interventional trials
- 17 trials in Africa
  - Egypt
  - Tunisia
  - Nigeria
  - Cameroon
  - Democratic Republic of Congo
  - Kenya
  - Uganda
  - Angola
  - South Africa
  - Ghana
  - Tanzania

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NIGERIA

- Globally, about 312,000 neonates are born with the SCD annually and more than two-thirds (75%) of these occur in Africa
- Nigeria is the country with the highest burden of SCA in the world
- Population of 200 million people
- More than 25% of Nigerians are healthy carriers of SCD
- 150,000 babies with SCD are born in Nigeria every year
- Strategic Market

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5924488/

https://www.omicsonline.org/open-access/what-factors-influence-the-age-at-diagnosis-of-sickle-cell-anemia-in-enugu-nigeria-2155-9864.1000231.php?aid=33170

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KENYA

- Kenya has one of the heaviest burdens
- Kenya – 46 million people with 1.6 million new births each year
- New-born screening potentiality in Kenya -1.3 million
- Estimates show 20% or more Kenyans carry the gene for SCD
- It is estimated that 1 in 5 Kenyans carry the gene for SCD
- Kenya has a big demand for a reliable, affordable and fast method to diagnose SCD
- Strategic Market

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6261323/

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Visit to Africa

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SIV in Africa - Republic of Congo

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Confidence to Include African Sites into Sickle Cell Disease Clinical Trials

- Study teams want quick start-up, high patient numbers and quality data. To give study teams the confidence that Africa can deliver all three, we will DE-RISK:
  - PRESSURE TESTING ASSUMPTIONS: By initiating survey of selected study teams to identified perceived risks and concerns
  - REGULATORY AND ETHICS TIMELIMES: By aligning with country requirements at early stages of planning
  - RISK MANAGEMENT: Using a risk management matrix to assess, mitigate and control perceived risks
  - TRAINING: Site assessment, full training requirements and close engagement with site staff throughout.
  - DATA QUALITY: Following industry standards on data handling, privacy and confidentiality (according to ICH GCP and local laws and guidelines)
  - STUDY BUDGETS: Building standard site budgets up front and showing transparency of payments

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THE IDEAL - What we all want

ACCESS TO PATIENTS
Access to high patient population/ numbers (including access to drug naïve patients)

DATA INTEGRITY & CREDIBILITY = QUALITY
Meeting our scientific, GCP and regulatory needs through reliable quality data

TECHNOLOGY
Technology enabled innovation as a catalyst

TIME
Faster Time to Go/No Go decision + Reducing Time to Market

GOOD QUALITY + DIVERSE DATA ENABLING GOOD DECISIONS

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Meet Our Team

Our team come with solid experience and background in the pharmaceutical and Healthcare sector

Adama Ibrahim, EMBA

Founder and Chair

Shalom Lloyd, MBA

Chief Strategy Officer

Dr Tina Barton, PhD & MBA

Chief Operating Officer

David Lloyd

Chief Financial Officer

Nancy Meyerson-Hess

Chief Quality Assurance and Compliance Officer

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Questions

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