Advancing the clinical research ecosystem in Africa: inclusive, innovative and impact-driven approaches

AFRICA REGULATORY CONFERENCE 2025

4-PART SERIES

INNOVATIVE CLINICAL TRIAL DESIGNS AND DIGITAL TECHNOLOGIES

21 October 2025

13H00 – 16H00 CET & SAST

GCTF
Global clinical trials forum
WHO Managed Network

AFRICA REGULATORY CONFERENCE 2025

SESSION 1:

STRENGTHENING THE CLINICAL RESEARCH ECOSYSTEM

SPEAKERS

Romina Mariano
Africa Clinical Research Network

Kwasi Nyarko
AdVAncIng Clinical TRials Excellence in Africa

Adriaan Kruger
nuvoteQ Foundation

AFRICA REGULATORY CONFERENCE 2025

ACRN AFRICA CLINICAL RESEARCH NETWORK

ACRN | IFPMA

Innovative clinical trial designs and digital technologies

21 OCTOBER 2025

Africa Clinical Research Network

ACRN is an Africa led clinical research network that drives clinical research excellence by connecting researchers to opportunities, enhancing research capacity in existing facilities, implementing high-quality trials and research, building trust in research from communities and key stakeholders while leveraging technology for a robust digital infrastructure.

ACRN aims to raise Africa's share of global clinical trials from 3% today to 15% within the next decade (China grew from ~1% in 2009 to ~22% today). This requires true partnership—across global health, industry, and African institutions. By expanding beyond traditional global health into all therapeutic areas, we will meet Africa's health needs, advance global health priorities, and deliver for industry through faster start-up, higher quality, and diverse, inclusive trials.

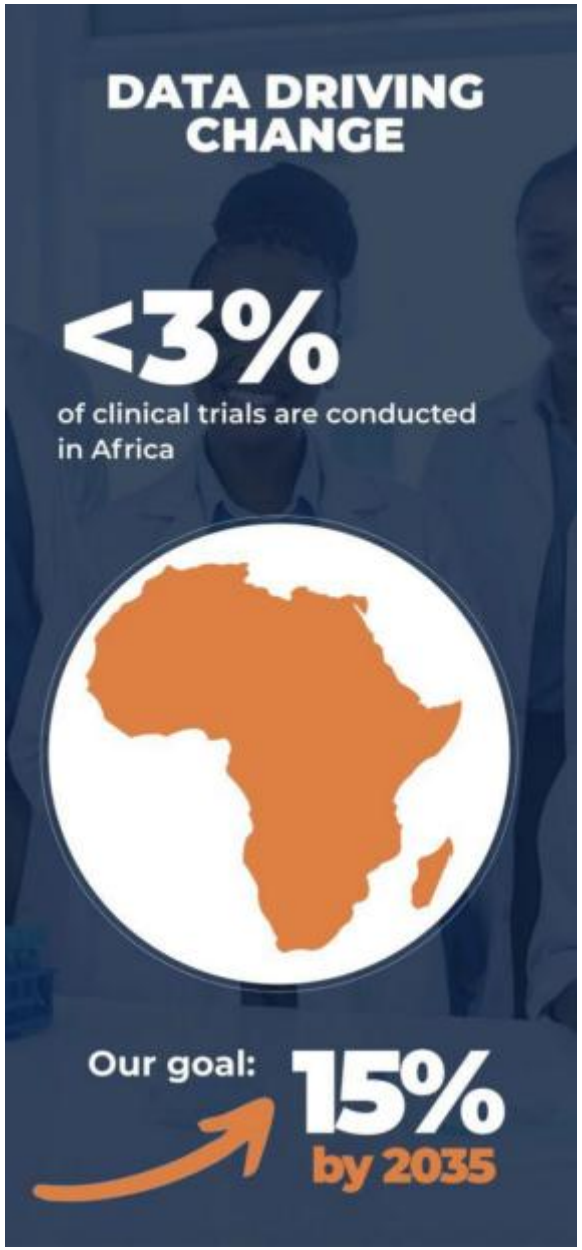
ACRN's Mission & Vision

Driving Innovation and Quality in Africa's Clinical Research Landscape

- **Mission:** Enable Africa-led, globally competitive clinical research by building a sustainable network of trial-ready sites.
- **Vision:** Increase Africa's share of global trials from ~3% today to 15% by 2035.

Approach:

1. Standardize trial quality across sites
2. Accelerate study start-up and recruitment
3. Build long-term capacity and sustainability



Why Clinical Trials Cannot Ignore Africa

Africa is not optional — it's essential to solving today's trial bottlenecks and meeting sponsor demand

Enrollment Crisis in Established Markets

- In oncology, >70% of U.S. trials fail to meet enrollment targets on time (JCO, 2021).
- Trial saturation: many patients in US/EU already cycled through multiple studies, limiting naïve populations.
- Average per-patient trial costs >$20K in the US vs. far lower in Africa.

Africa's Untapped Potential

- 18% of world's population, 25% of global disease burden, <3% of trials.
- Fastest projected growth in oncology, diabetes, cardiovascular disease, inflammation.
- 80% of global sickle cell cases, yet insufficient trials in Africa — highlighting missed opportunities in high-value pipelines.

Strategic Imperatives for CROs

- Sponsors increasingly mandate diverse enrollment (FDA/EMA).
- Early movers in Africa will gain competitive advantage with pharma and biotech clients.
- Building African capability now = positioning for the next decade of growth markets and global health pipelines.

Sponsors that invest in Africa today can solve immediate global trial bottlenecks, win new sponsor trust, and secure long-term growth

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Learning from Global Challenges: Building Differently in Africa

What's Broken Elsewhere (US/Global Industry Pain Points)

- **Site Concentration:** Over-reliance on a small cluster of academic/urban sites; most patients never see trial opportunities where they get care.
- **Insufficient Diversity:** African Americans = ~13% of US population but only ~5% of trial participants. Latinos = ~19% of US population but <10% of trial participants.
- **Limited Data on Patients:** Weak visibility on where patients are, their care pathways, and their genetic makeup → trials designed without sufficient real-world representativeness. Data available e.g., EHRs, fragmented access, not linked to genetic data
- **Delayed Start-Up:** Feasibility, site activation, and recruitment readiness.
- **Contracting Delays:** Complex, protracted negotiations across fragmented legal and compliance systems.
- **Fragmented Requirements:** Each sponsor/site/IRB has slightly different standards → inefficiency and duplication.
- **Digital Fragmentation:** Multiple uncoordinated, costly platforms at the site level; burdensome for staff; poor interoperability.
- **Investigator/Staff Burden:** Heavy admin workload, burnout, high turnover → loss of continuity and quality.
- **Community Trust Gap:** Historical mistrust and lack of proactive engagement hinder recruitment and retention.

How Africa Can Build Differently

Distributed Site Network
Accessing patients where they seek care

Embedded Diversity
Better representation, relevance, and safety

Integrated Digital Backbone
Trial efficiency and AI input

Streamlined Start-Up
Harmonized SOPs, centralized contracting, and regulatory intelligence → reduced timelines.

Trusted Community Partnerships
Longstanding relationships with patients, providers, and governments → higher retention and adherence.

Epidemiology & Genomics
Better trial design and faster recruitment

Unified Requirements
Standardized templates and common processes across the network → sponsor efficiency.

Sustainable Workforce
Training pipelines, secondees, and regional capacity-building to reduce staff turnover.

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Building to Deliver on Research Priorities

A strategic platform aligned to sponsor pipelines, delivery needs, and commitment to equity in trials

Site Expansion Focus

- Growing a trial-ready network inclusive of ML3 countries and high-burden non-ML3 regions
- Structured onboarding process with transparent criteria, due diligence, and tiered readiness

Flexible contracting

- Platform enables ACRN to serve as SMO, trial execution partner, or sponsor delegate
- Modular service model aligned to sponsor structure and trial complexity

Community Trust infrastructure

- Embedding community engagement strategies aligned with Good Participatory Practice (GPP)
- Social-behavioral research informs culturally tailored recruitment and retention strategies

Therapeutic Alignment

- Focus on global health, maternal-child health and non-communicable diseases
- Network includes sites with clinical and operational capability to execute across these areas

Digital Enablement

- Integrated digital stack for trial execution, including Oracle CTMS, eSource, and real-time tracking
- AI-enhanced workflows for project oversight, site performance, and risk monitoring

ACRN's Service Offering

One Network. One Entry Point. Scalable, Credible, Africa-Led Delivery.

Site Management Organization (SMO)
Enabling trial-ready sites across Africa

Modular Trial Execution Services
Flexible trial execution from Start to Finish

Policy & Regulatory Advocacy Platform
Driving harmonization and catalyzing regulatory consistency

Community Engagement Solutions
Building trust, retention and trial literacy

Real World Evidence & Research
Cohorts + Biomarkers + Genomics → Faster recruitment, smarter trial design, stronger regulatory evidence.

Clinical research is not just science — it's a development strategy. Every trial run improves the standard of care.

Workforce Development

A modular, multi-tiered workforce development platform

Core Competencies
Virtual + in-person training on courses which include GCP,EDC, monitoring, and regulatory topics among others

Internal Training Curriculum & Materials
Develop a comprehensive program that includes project management, quality assurance, foundational research skills, and specialized modules for early-phase trials

Role-Specific Training for Staff
Role-specific training opportunities with career path trajectories and development

Site-Based Training at Affiliate & Specialized Centers
Provide hands-on training for local teams, emphasizing study execution, compliance, and consistent data management

Study-Specific Training Materials
Customize protocols, SOPs, and checklists for upcoming trials, ensuring clarity on sponsor duties, regulatory steps, and data reporting

Embedded Fellowships
On-the-job training for early-career professionals, with mentorship and performance tracking

Site-Based Capacity Uplift
Support for full site teams via accreditation, SOP libraries, and system integration

Executive Upskilling
Training for site leads in finance, contracting, and digital systems

Integrate Digital Learning & Evaluation Platform
Deploy an online system for self-paced modules, performance tracking, and continuous professional development.

Strategic Country Footprint for Scalable Trial Execution

Where regulatory strengthening, market potential and trial infrastructure converge

>65% of all trials in Africa over last 5 years took place in these countries ♦
Presence of regional logistics hubs (e.g., Nairobi, Johannesburg) ♦
Population reach of >600 million

Feasibility & Infrastructure
Presence of trial-ready hospitals, IRBs, specialists and experienced investigators

Regulatory Accessibility
Clear pathways, improving timelines and NRA status as ML3 (preferred), ML2 (Kenya)

Market Potential
High disease burden in priority therapeutic areas (ID, oncology, NCDs, vaccines).

Sponsor Momentum
Existing industry trial activity or partner interest

Government Alignment
MOUs, political will and policy environments that support clinical research

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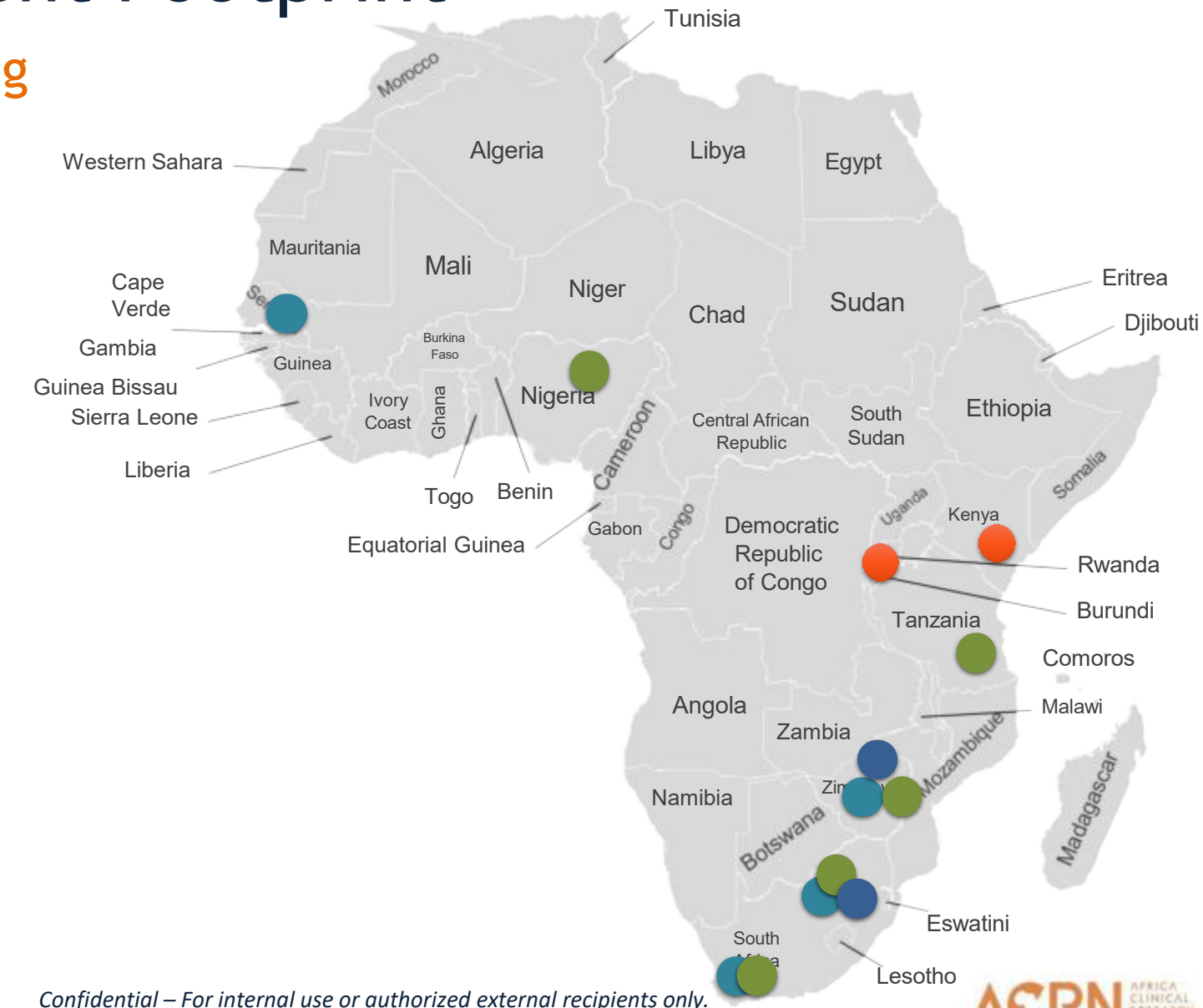
ACRN Network: Current Footprint

Sites partnered MOUs or working on ACRN 2025 trial pipeline

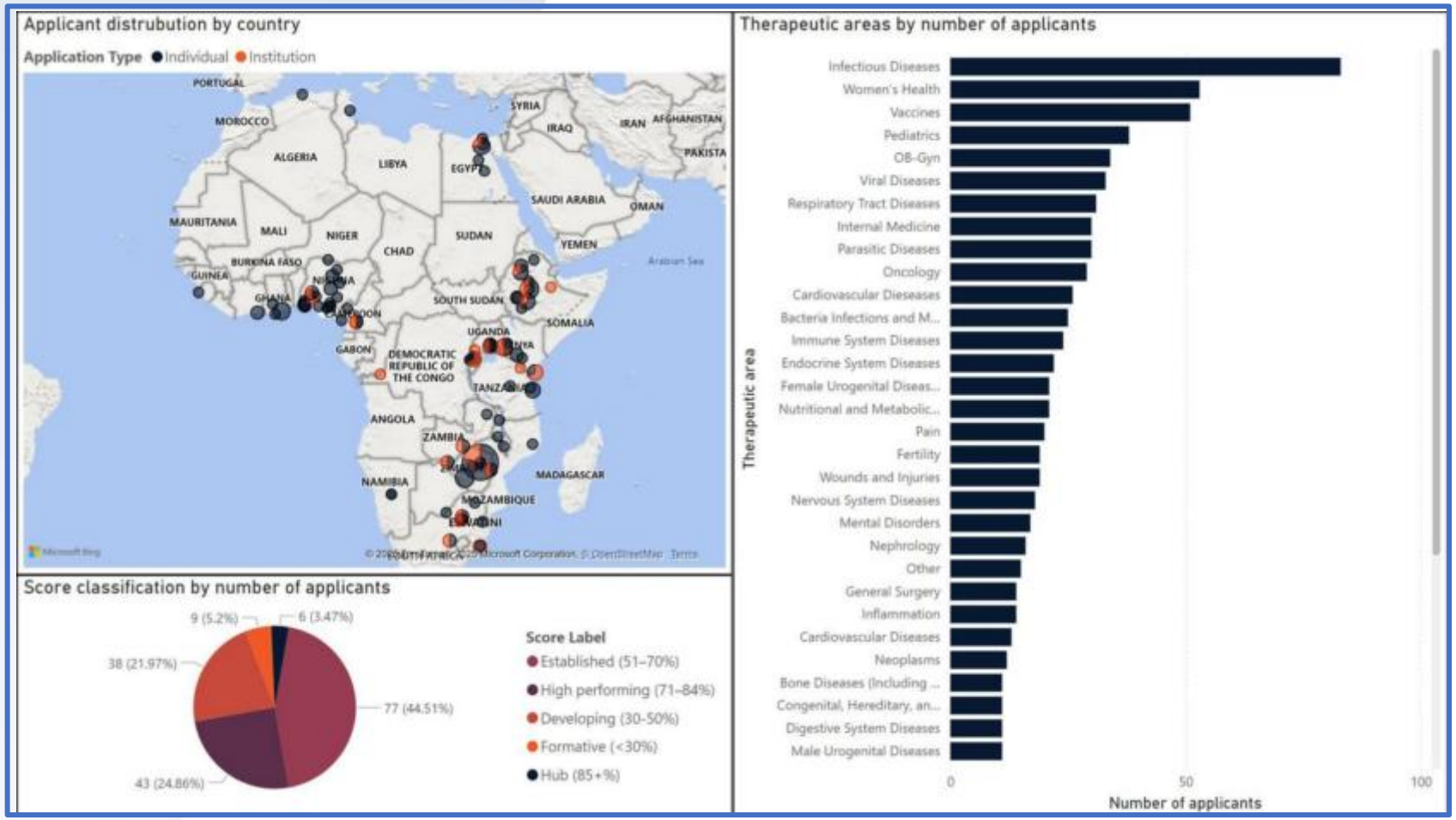
Geographic Footprint

- **High-performing partner hubs**
- **Integrated ACRN units**
  With full-time research staff (IDRL, Mutala, Clinresco)
- **Specialty partners**
  PK/PD, pharmacogenomics, field epidemiology research
- **Hospital-based partner sites**
  Selected for specific studies



ACRN EOI-Driven Network Expansion

Building a Site and Investigator network enabling shift from opportunistic partnership to strategic network expansion



317+ submissions, with **83% meeting ACRN eligibility requirements**

- 74% from individual researchers
- 26% from institutions

Key Highlights:

- 36% applicants identified as high-performing or potential hub sites
- 84% of applicants reported clinical research experience, including:
  - All phases of clinical trials
  - A wide range of therapeutic areas
  - Diverse patient demographics
- 81% have experience with regulatory infrastructure,

Top Performing Countries:

- Nigeria
- Kenya
- Zimbabwe
- Ethiopia
- South Africa
- Egypt

Community Trust & Retention

Build trust before trials begin — ensuring higher recruitment and stronger retention

Trust & Retention Mechanisms

1 Structured Community Engagement

- Dedicated Community Engagement Managers in-country
- Grassroots partnerships with local health promoters & networks

2 Evidence-Based Recruitment

- Socio-behavioral research to surface motivations, barriers, facilitators
- Tailored messaging strategies rooted in cultural context

3 Trust & Retention Mechanisms

- Community Advisory Boards representing community voice
- Retention support frameworks for long-duration studies
- Transparent feedback and participant-first approach

Outcomes for Trials

Improved recruitment speed, reduced screen failures

Higher participant retention over multi-month trials

Stronger community acceptance → reduced risk of trial disruption

→ Faster recruitment | Higher retention | Ethical, equitable research

Regulatory and Policy Intelligence

Accelerating trial start-up and strengthening regulatory alignment across Africa

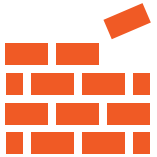
What it Supports

- End-to-end trial submissions (ethics + NRA)
- Import permits and MTA coordination
- Site-level regulatory readiness reviews
- Version control and submission archive (in build-out)

What we Track

- Mapped 8 countries: SN GH NG KE TZ RW ZW ZA
- Ethics & NRA timelines, import/export rules, and required documents
- Real-time policy and regulation updates (e.g., ML3–ML4 transitions)
- Harmonization initiatives via AVAREF and regional authorities

What we are Building

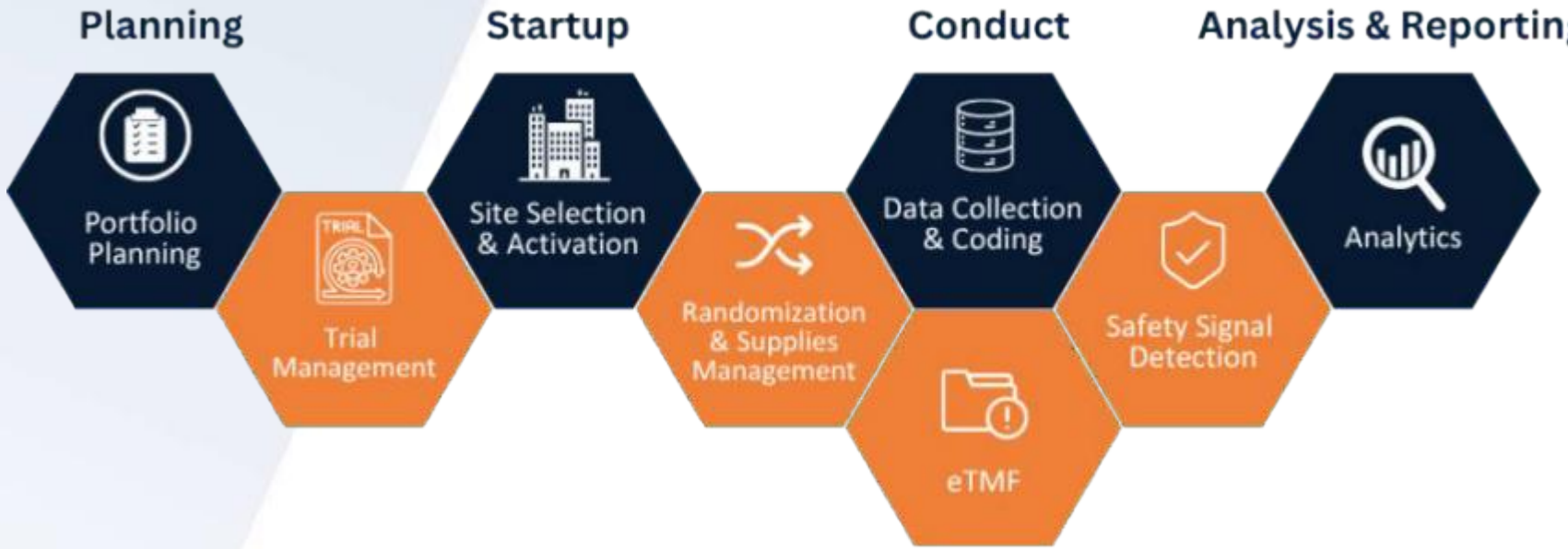


- Regulatory dashboard + intelligence system
- Shared submission templates and SOP library
- Embedded regulatory officers across countries
- Site training on evolving regulatory expectations
- Strategic engagement with ministries and ethics bodies

Engineering the Trial Ecosystem of Tomorrow

Technology is not an add-on—it is the backbone of ACRN's operating model

From inception, ACRN has been designed as a digitally enabled, data-driven clinical research ecosystem that meets the expectations of tomorrow's trials today



Digital-First by Design: Embedding technology into every layer of trial planning, execution, and oversight—from feasibility to closeout.

Interoperable and Scalable: Committed to systems integration and open architecture to ensure seamless collaboration across sites. Aim to support advocacy for systems integration with regulators, and sites.

AI-Ready and Cloud-Based: Investing in future-proof infrastructure that supports AI-enabled epidemiology, digital monitoring, and decentralized trial models.

In partnership with the Ellison Institute of Technology and Oracle

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ACRN Digital Operating System for Trials

Leveraging technology to streamline clinical trials workflows

Digitally enabled site, investigator and country selection

Pharmacovigilance

Digital Dashboards and analytics

AI-enabled feasibility

Protocol and other key document Automation

Logistics & Cost monitoring

Document Tracking
Performance tracking

Automated visit scheduling
Remote & Risk Based Monitoring

Multifaceted Digital Stack to Support Clinical Trials

In partnership with Ellison Institute of Technology & Oracle

Building Africa's Predictive Trial Readiness Engine

OCR, EHR, and synthetic cohort modeling to power site selection and recruitment

From fragmented records to predictive trial readiness

AI Layer

OCR/ICR +NLP for diagnosis, treatment, and outcome extraction

Source Data

Semi-structured PDFs, handwritten charts, basic EMRs

Analytics

Cohort simulation, prevalence mapping, site selection dashboards

Designed with modularity to plug in external AI/ML tools and pipelines

Data Storage

Local cloud hosting

Data extraction tools

AI-enabled ICR/OCR

Synthetic cohort modeling

Build data science team in collaboration with partners

Partners

Practices and hospital groups, EIT, Data infrastructure, AI-OCR/ICR

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Triangulating Expertise to make Africa Trial Ready

Technology is driving a rethink in how trials are done, let's work together to ensure Africa is not only ready but leads the transformation

01 ACRN

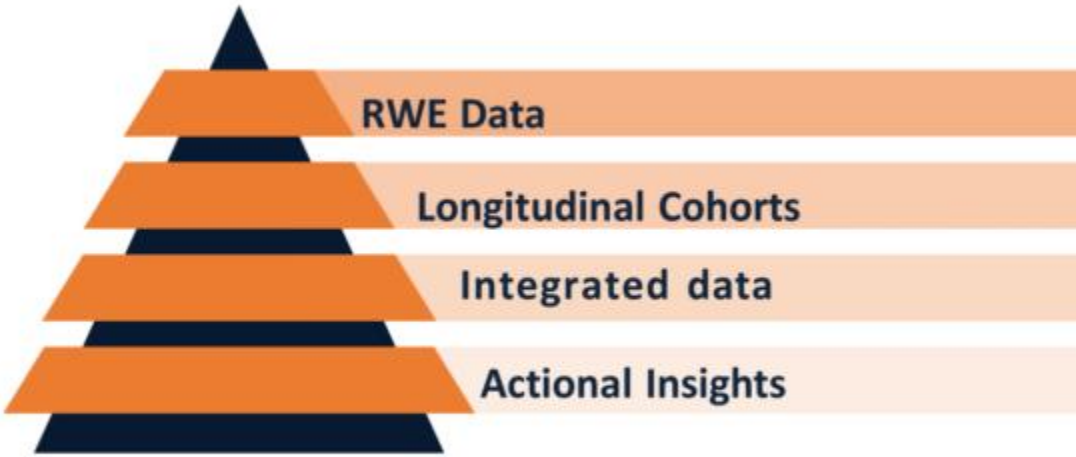
- Partnerships with physicians & hospital groups
- Data governance & policy frameworks
- Clinical care integration
- Sequencing capabilities
- Regional expertise & implementation
- Stakeholder partnerships and trust

02 Industry, Global Health Funders, & Governments

- Subject area expertise
- Longitudinal cohort support
- Establishing Biomarker sub-datasets
- Omics integration: genomics, proteomics

Digital Technology 03

- Optical reading & data extraction
- EHR integration & data structuring
- Data analytics & data science
- Data hosting & security
- Hardware & localization



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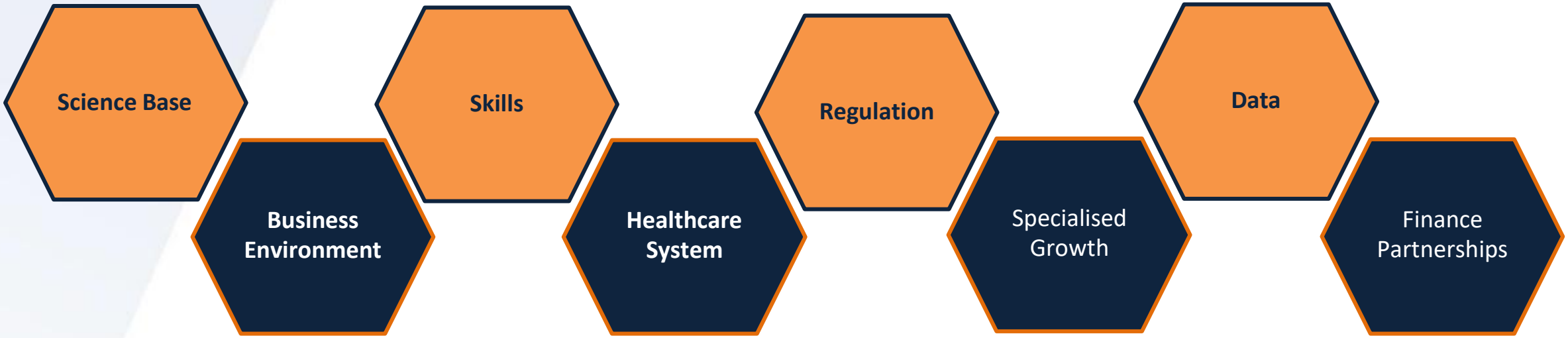
Building a Life Sciences Ecosystem

From Individual Trials to a Sustainable Research Economy

Life Science Value Chain

Critical Enablers



Let's Build Boldly Together

Be Bold.

Think beyond traditional models. This is an opportunity to co-create with purpose.

Be collaborative.

This is not about what ACRN can do alone but what we can build together.

Be imaginative.

Africa's future in life sciences needs new thinking, new models, and a shared ambition.

Partner with ACRN.

We want to be shape Africa's growth story. This not a short-term story but one with a long-term vision for transformation.

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Ending disease in Africa

Innovation in Africa clinical trials and ongoing continental updates

AVAREF - Advancing Clinical Trials Excellence in Africa

World Health Organization
African Region

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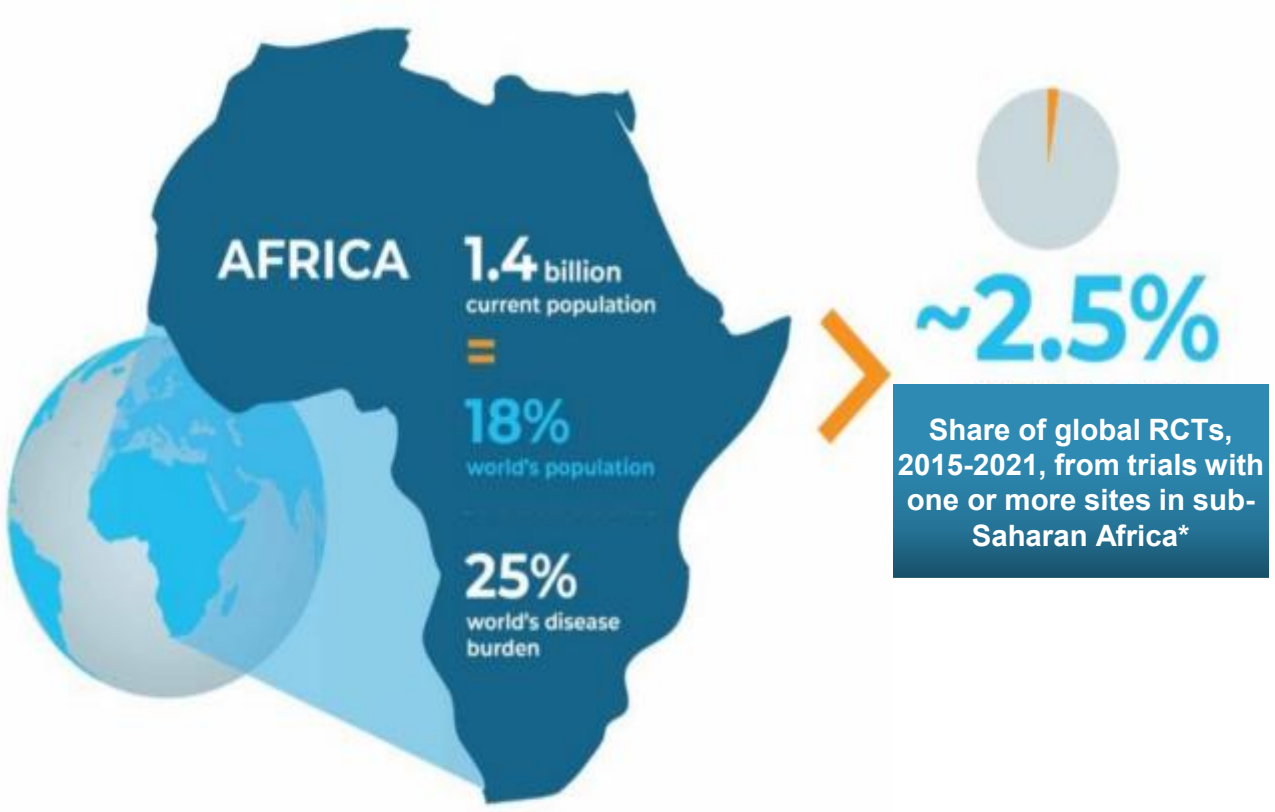
OUTLINE

- Introduction and Context
- State of clinical trial ecosystem
- Clinical Trials, and Indictors for Innovation
- Innovations in Clinical Trials Capacity Strengthening
- Clinical Trials Oversight in era of African Medicines Agency
- Considerations & Conclusions

Clinical Trials in Africa



- 30 million <5 years suffer from vaccine-preventable diseases (VPDs) annually in Africa.
- Continent Produces less than 1% of its vaccines
- Deficit in African generated data for most medicines
- Majority of Genetic Diversity in the world exists within Africa
- Emerging Environment initiatives such as African Medicines Regulatory Harmonization (AMRH)/African Medicines Agency (AMA), Continental Free Trade Zone
- The global clinical trials market size was valued at USD 74.8 billion in 2023 and is expected to expand at a compound annual growth rate (CAGR) of 5.8% from 2024 to 2030.

Africa – An Attractive Venue for Clinical Trials

- Second-largest and second-most populous continent after Asia population 1.5 billion people, about 20% of the world's population.
- Youngest population with a median age of about 19 years.
- At least 3000 distinct nations with the greatest genetic diversity
- Africa Continental Free Trade Zone – a single marketplace with a population of 1.4 billion estimated to be 2.5 billion by 2050
- African Medicines Agency, a continental regulatory agency, will tremendously influence the future of clinical trials in Africa

Benefits of Clinical Trials

- Increased access to novel(innovative) therapies and/or medicines not yet authorized
- Access to new research treatments for rare conditions
- Availability of data to support the safe use of the product in the population for registered products.
- Increased opportunities for innovation …. Newer indications for use
- Decreased cost of medicines (?)
- Enriched ecosystem for clinical research and innovation
- Access to leading experts and facilities

AVAREF & African Medicines Agency (AMA)

- AVAREF, Advancing Clinical Trials Excellence in Africa, is the Technical Coordinating Committee for Clinical Trials under the African Medicines Agency (AMA).
- AVAREF Continues to support continent wide joint clinical trials application submission and review
- AVAREF will support the setting up of the clinical trial unit of AMA and its operationalization
- The expected respective continuing roles of WHO-AFRO/EMRO/HQ and AMA to be guided based on mutual agreement between WHO and AMA.
    - *Stage I: Set-up of Clinical Trial Unit of AMA*
    - *Stage II: An Operational and functioning AMA Clinical Trial Unit – The Continental Clinical Trial Enterprise, a collaboration between WHO (AFRO/EMRO/HQ and AMA).*
- Distinct role of AVAREF in clinical trial excellence in Africa such as capacity building for member states, contributing to a thriving clinical trial ecosystem, leveraging and pivoting of network in support of regulatory, ethics, and other functions along the innovation life cycle expected to continue.

Gaps in Africa's Regulatory Ecosystem

Limited Clinical Trial Activity

- Low numbers of clinical trials (limited phase I, few First In Africa [FIA] studies, complex trial designs)
- African clinical research represents <2% of global trials despite high disease burden and diverse populations

Human Resource Capacity Gaps

- Shortage of experienced evaluators and ethics reviewers in NRAs and NECs
- Lack of structured training and mentorship pathways
- Language and capacity disparities in Francophone and Lusophone countries

Fragmented and Inefficient Regulatory Processes

- Fragmented and inconsistent regulatory review pathways
- Absence of centralized digital systems, now being addressed by AVAREF's upcoming e-CTA platform
- Overreliance on lengthy national processes without harmonized regional models

Weak Collaboration and Regional Alignment

- Limited implementation of reliance and joint review mechanisms
- Fragmented engagement between NRAs, NECs, and global regulatory partners
- Donor and technical partner fragmentation hinders coordination
- Lack of alignment with continental institutions like AMA, AUDA-NEPAD

These gaps hinder Africa's ability to lead in clinical research, underscoring the urgent need for harmonized systems, skilled reviewers, and coordinated action

Root Cause(s) - Top Challenges & Problems (NRA Reviewers)

- Collectively identified as the top irritants
  - Timelines and lengthy procedures stood out as the number one issue
  - Fragmented systems & poor coordination
  - Lack of harmonized guidelines / clear SOPs
  - Limited resources and expertise as a major contributors

WHAT IS INNOVATION ?

- New creation(s)
- Improved products, services, processes, business models
- Creativity
- Application
- Value creation
- Novelty
- Usefulness
- Impact

The Call for Innovation

- The current ecosystem
  - Adaptive designs, prohibitive costs for traditional designs
  - Vaccines for diseases such as iNTS, Streptococus pyrogenes vaccines, Mpox vaccines, Ebola vaccines, biological products such as Snakebite antiserum, etc. which require surrogate markers, use of Challenge Human Infection Models (CHIM), combination vaccines
- Unrealized potential of the African Region
  - Limited phase 1,2 data and at times phase III data. Critical importance of phase IV and/or effectiveness data.
  - Goal originally announced by IQVIA of 10% by 2035 as a rallying call
- Perceived and real challenges within the ecosystem
  - Vaccine hesitancy …. New technologies in medicines; effectiveness of medicines.
- The desires and aspirations of a continent
  - African Medicines Agency operationalization
  - Local manufacturing of vaccines, medicines, and other health technologies

AVAREF Clinical Trials Reliance Oversight Pilot Project

- **Designed to address commonly anticipated challenges** (Irritants) experienced by Product Developers, NRAs, NECs, & AVAREF Secretariat
  - Predictability and Consistency
    - Data/Information Requirements for regulatory and/or ethics approval
    - Timelines for regulatory decision making
    - Streamlined Processes and/or Procedures
  - High Quality Scientific Advice and Regulatory Decisions
- **Designed to Reinforce Capacity** for NRAs, NECs, Ecosystem
  - Regulatory Strengthening, Harmonization, and Excellence
  - Pandemic Preparedness
  - Reviewer Development Programs
  - Access to wide range of expertise within the network
  - Access to Expert Specialist Support

Regional Representation for the Reliance Network

16 Member Countries designated for the Clinical Trial Pilot project based on:

- **Maturity levels**
- **Number of Clinical Trials**
- **Involved in AU3S**
- **Regional and linguistic representation**

Role of Reliance Network – *Leveraging the potential of the network*

- **Pooled capacity of 48 NRA reviewers, 16 NEC reviewers, etc** within the network as a valuable resource for excellence in high quality, timely, and harmonized CTA reviews.
- Leveraging the **strong networks** of regulators, ethics committees, researchers, clinical trial centers, and manufacturers of medicines, vaccines, and other health products.
  - The basis for an ecosystem approach to a thriving sector
- AVAREF NRA **focal points as anchors** for the network of networks

- AVAREF to operate as **a network of networks** pivoting on clinical trials as the gateway to access to innovative, affordable, safe, efficacious medicines of assured quality.

ECOSYSTEM & LIFE CYCLE APPROACH OF AVAREF CT PILOT PROJECT

- Integrated implementation
  - Real life simulations through AVAREF Secretariat
  - Matrix based capacity strengthening and training
  - Emergency Preparedness and Response (Focal Points?)
  - Ecosystem Pivot Technical Working Groups
  - Special Expertise
    - Non-clinical
    - Clinical
    - Quality
    - Biostatistics
  - Product Development and New Product Introductions (Focal points)
- Streamlining and Harmonization
  - Regulatory Working Group (Focal Points)
  - Ethics Working Group
  - Digital Working Group (Selected WG Members)

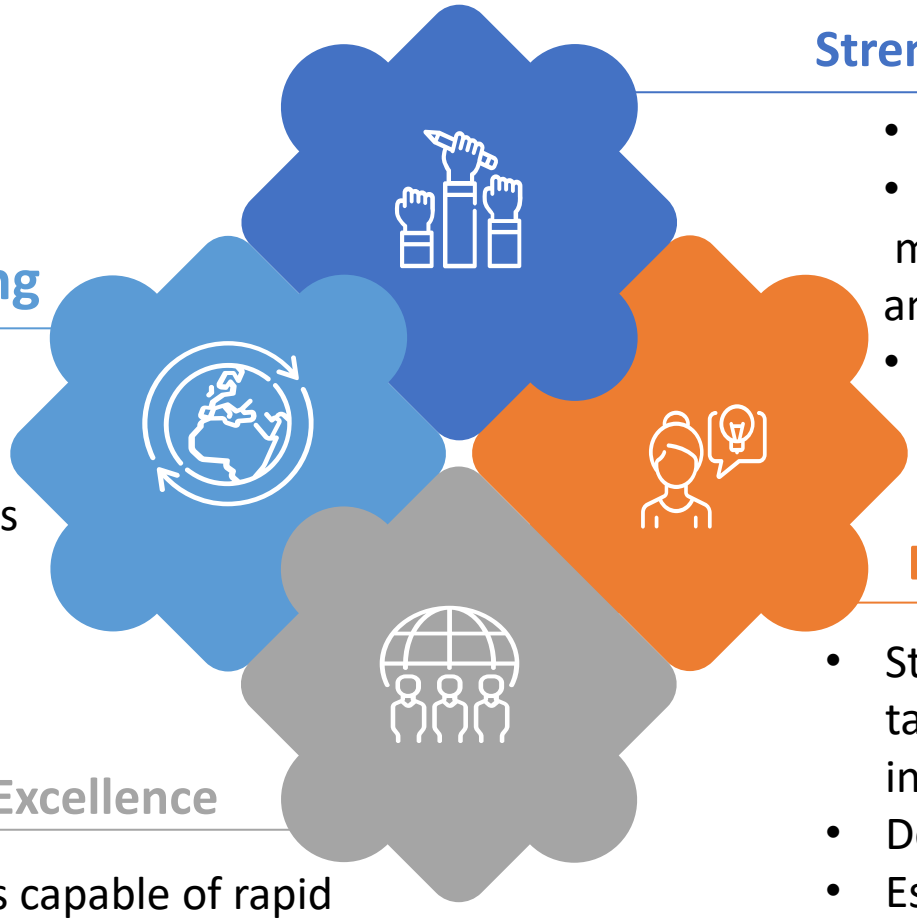
AVAREF CT DIGITAL PLATFORM

- A secure, collaborative platform enabling review and/or evaluation of Clinical Trial Applications (CTAs)
  Supported by Gates Foundation and CEPI
- Key Features
  - Multi-location **collaboration**: Reviewers access, share, and work in real time on CTA dossiers
  - **Structured expertise matrix**: Review teams organized by domain – Clinical, Non-clinical, Quality, and Biostatistics
  - **Review 'rooms'**: Dedicated spaces for discussion, deliberation, and decision-making
  - Integrated **submission management**: Streamlined handling of CTA dossiers from submission to conclusion
  - Supported by an NRA nominated **Digital Working Group**: Ensures national engagement and alignment.
- Expected Impact
  - Improved efficiency, transparency, and consistency in reviews
  - Enhanced data access and sharing
  - Strengthened collaboration and capacity across AVAREF Member States

Key Components of the Clinical Trials Pilot Project

Harmonization and Streamlining

- Align regulatory and ethics regulation and review process according international standards
- Develop a central platform for multi-country joint review.



Strengthening Specialized Reviewers

- In dept trainings programs
- Activities include modular training, mentorship, joint reviews participation, and certification based on performance
- AVAREF tools enrichment

Emergency preparedness

- Strengthen scientific knowledge in targeted disease areas, new vaccine introduction and complex intervention
- Develop emergency recommendations
- Establish advanced regulatory standards

Clinical Trial Unit Network of Excellence

- Build a network of trial-ready sites capable of rapid deployment
- Aligned with WHO CTU maturity framework

AVAREF – Role in Regulatory and Ethics Reviews

AVAREF Reboot

Leveraging the AVAREF Platform

- The AVAREF Network established in 2006 is being leveraged for the implementation of the 16-member state reliance network for regulatory and ethics decision making.
- The AVAREF Clinical Trial Pilot Network would be utilized to strengthen the technical capacity of the reviewers and establish harmonized processes for excellence and effectiveness.
- The 16 member countries would be pivoted as the foundation for the establishment of the network of networks for enrichment of the ecosystem for results.
- ----------

"An African population with timely access to safe and efficacious innovative medical products of assured quality."

What We Will Do

- **Network for Research and Development**
  Platform for Researchers and Investigators, Research Institutions, Government establishments.

- **Network for Clinical Trial Sites**
  Research Centres of excellence involved in clinical trials.

- **Network of Bio/Pharma Manufacturers**
  Platform for manufacturers and/or NRAs involved in the manufacturing of medicines, vaccines, and health products

- **Network of Safety Monitoring for New Introductions**
  Oversight across the full product development cycle — from design to post-market

Ethics Capacity Building Network

- AVAREF has since 2016 worked with NECs in member states, provided capacity building although the rate of advancement of the Ethics community is not as advanced as the NRAs.
- WHO has recently developed a GBT Assessment tool for NECs for which AVAREF has started the training of NECs for its use.
- Need to support member states on use of GBT tools
- Need to develop training for Francophone members on use of GBT tool
- Need to establish a working group for the development of a harmonized guidelines for the ethical review of CTAs – based on recently developed AVAREF checklist

Clinical Trial Unit Network

It is important that world class clinical trial sites become available in Africa for a thriving clinical trial ecosystem.

The AVAREF network, specifically the 16 member reliance network could be leveraged for supporting clinical trial sites.

- Access to dedicated world class clinical trial sites, especially within teaching health care establishments such as medical schools or university hospitals would support a network of CT sites for the continent.
- A proposal for identification of at least 1 clinical trial unit (site) with each of the 16 countries in the network to be supported, if not already at international standards, would facilitate bringing clinical trials into Africa.
- The WHO Clinical Trial Maturity Framework could be used to support these sites and the network, which could be promoted to national and international sponsors for clinical trials and support the goal of increasing the clinical trials on the continent to 10% of global activity by 2035.

Research and Development Network

Research and development (R&D) is the gateway to innovation with clinical trials as a good indicator for medical products. Without an approach that recognizes this, a focus on only the regulatory and ethics approval for clinical trials would be short sighted.

After 18 years of regulatory capacity building and harmonization, it is important for the AVAREF platform to pivot to supporting R&D while deepening harmonization of regulatory and ethics processes.

An opportunity for a network for researchers involved in development of innovative medicines, especially vaccines for use in Africa.

The AVAREF Secretariat will develop a strategy for R&D including research prioritization for development of innovative medicines.

The network for R&D should be connected with clinical researchers and clinical trial centres

Vaccine Regulatory and Manufacturers Network

AVAREF will leverage its experience in regulatory and ethics capacity building to launch a regulatory preparedness platform for vaccine (biopharmaceuticals) manufacturers and regulators.

- This platform will provide:
  - Regulators an opportunity to harmonize frameworks for authorization of vaccines, including their manufacturing
  - A forum for manufacturers to discuss regulatory issues such as clinical trials, and good X practices relevant for vaccine manufacturing

Conclusions

- AVAREF Secretariat is working with member states in advancing excellence in clinical trials by contributing to innovative solutions that are:
  - Pragmatic
  - Based on real life solutions for real challenges:
  - Adaptable
  - Sustainable
- AVAREF Secretariat is supporting member states in
  - Strengthening the continental workforce
  - Supporting a thriving ecosystem to support the realization of African clinical trials, reaching 10% of global activity by 2025.

THANK YOU

REDEFINING PATIENT CENTRICITY THROUGH CTC AFRICA'S GEO-MAPPING TECHNOLOGY

ADRIAAN KRUGER

CO-FOUNDER

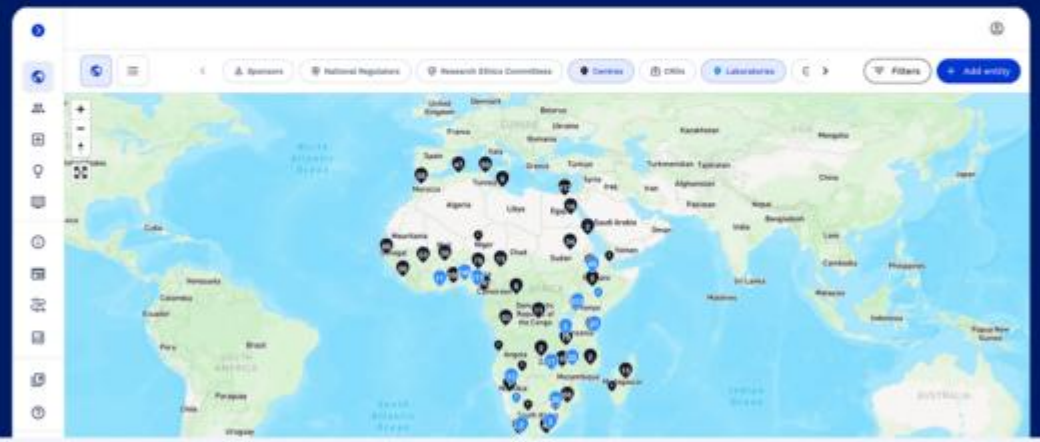
nuvoteq

nuvoteQ foundation

sciqenix

Clinical Trials Community

Africa conducts only 3% of global clinical trials, despite having 18% of the world's population and bearing 25% of its disease burden.



34,000+
Clinical Trials

3,500+
Total Centres

1,800+
Community Members

Our Data Story

Building trusted data, together.

The strength of the Clinical Trials Community lies in the data we build collectively. Every centre profiled, every trial registered, and every update suggested contributes to a comprehensive and trusted picture of Africa's clinical research landscape.

Through automated aggregation, AI verification, and transparent data practices, we ensure accuracy—but it is the active participation of our community that makes the data meaningful. By contributing your knowledge and insights, you help create a living resource that belongs to all of us.

Data Collection

Updated regularly

Automated aggregation from 5+ major clinical trial registries worldwide, including ClinicalTrials.gov, PACTR, and ISRCTN.

AI Verification

LLM + Embeddings

Advanced machine learning models detect duplicates, interpret free-text fields, and ensure data consistency across sources.

Trial Linking

Smart matching

High-confidence algorithms create bidirectional connections between trials and research centres for comprehensive relationship mapping.

Transparency

Known caveats

Complete openness about platform limitations, data dependencies, and ongoing efforts to improve accuracy and coverage.

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What the Platform Offers

A central resource for research across Africa

Whether you're planning a study, selecting a centre, or building partnerships, the CTC platform offers a trusted view of Africa's clinical trial ecosystem.

1. Search verified clinical trial centres
2. View linked studies, investigators, CROs, and labs
3. Access regulatory and ethics information by country
4. Discover trial-to-centre connections
5. Download data in structured formats (CSV, PDF, API)

How It Works

We don't just collect data — we curate it, intelligently

The CTC platform brings together information from multiple sources — then applies intelligent automation and community validation to ensure accuracy, structure, and discoverability.

- Data Collection
- Processing & Automation
- Verification
- Trial linking

Where the Data Comes From

We use a multi-source, semi-automated approach to give you a clear picture of Africa's clinical research activity.

Sources include:

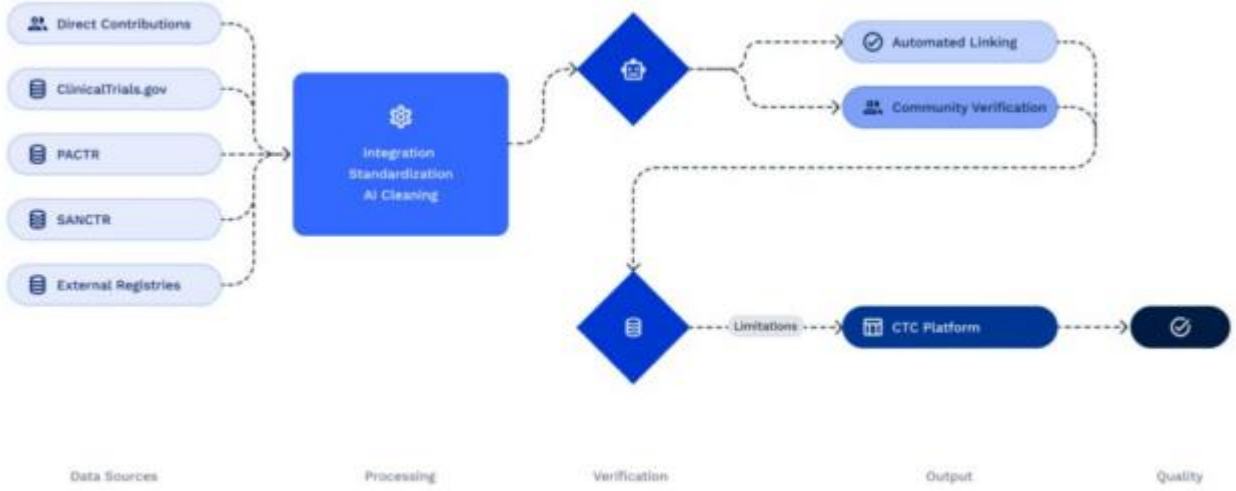
- Direct updates from trial centres, investigators, and sponsors
- Global and African registries such as:
  - ClinicalTrials.gov
  - PACTR
  - SANCTR
  - ISRCTN
  - IMPACT Global Health

Data is refreshed through APIs, scrapers, and contributor uploads.

From Fragmented to Findable

Across Africa, hundreds of capable trial centres and investigators are already doing world-class research. But too often, their efforts go unseen, their data is hard to access, and opportunities for collaboration are lost.

The CTC platform brings it all together — making clinical research data across the continent more searchable, discoverable, and connected than ever before.



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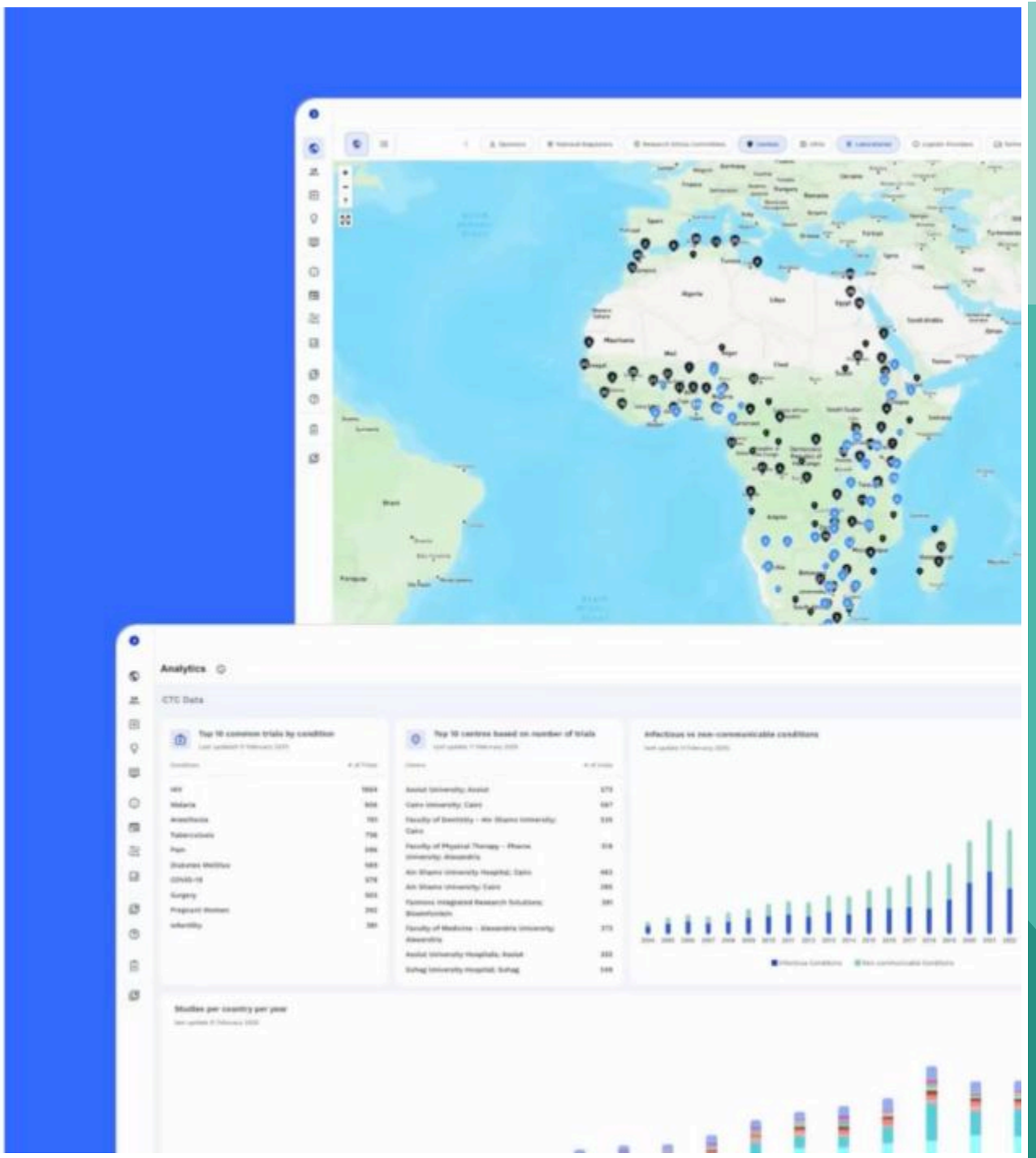
Clinical Trials Community

CTC Africa: Boosting clinical trial investment in Africa

- Easy SSO Access
- Comprehensive Trial Data
- Interactive Map
- Disease Burden Maps
- Funding Data Maps
- Real-Time Analytics
- Resource Library
- Networks
- Clinical Trial Preparedness

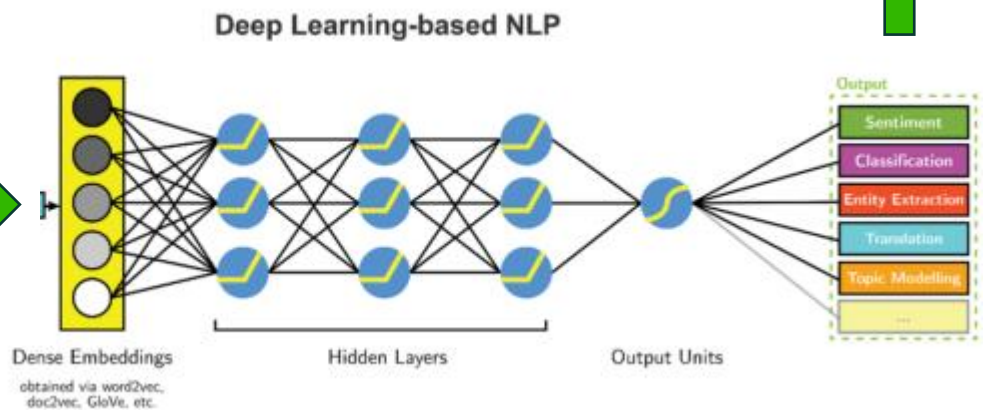
CLINICAL TRIALS COMMUNITY



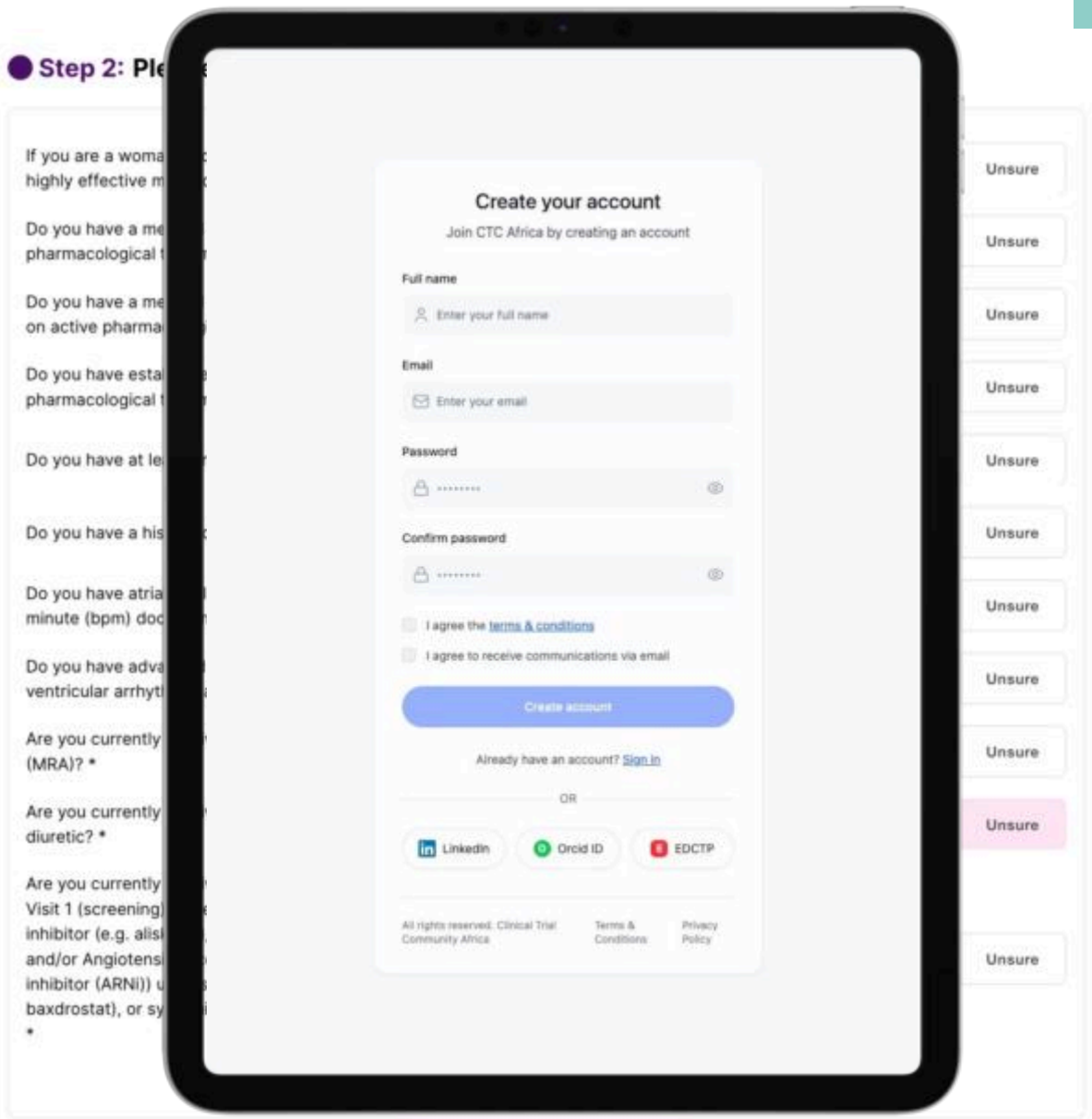
REDEFINING PATIENT CENTRICITY

Eligibility Criteria

ClinicalTrials.gov PACTR ICTRP



TrialScreen™



[Reference: https://shen.ai/]

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SESSION 2:

CASE STUDIES

SETTING THE SCENE

Vasee Moorthy
World Health Organization

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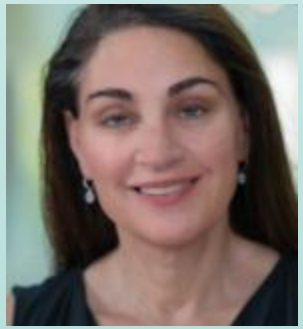
SPEAKERS

Ana Martin
Global Clinical Development Director, GSK

Amanda Oliver
Head of Clinical Development, GSK



Kimberly Smith
Senior Program Director, Regulatory, Roche

Kit Valentine
Senior Regulatory Program Director, Roche

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Global Regulatory Franchise Head Oncology, Roche

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AN OBSERVATIONAL PILOT STUDY OF AN ACTIVE SURVEILLANCE TOOL TO ENHANCE PHARMACOVIGILANCE IN BRAZIL

ANA MARTIN
AMANDA OLIVER

Oct 2025 / CLR-011280

ACTIVE SURVEILLANCE: SETA TECHNOLOGY

- An increasing number of medicines are being developed to address diseases that are prevalent only, or mainly, in low- and middle-income countries. However, these countries' health surveillance systems (including pharmacovigilance (PV)) have not kept pace with such innovations and need strengthening.
- New approaches are required to effectively monitor the introduction of new medicines and health technologies in low-resource and geographically challenging settings, without the need for repeat visits to a pharmacy or health facility.
- The Seta technology was developed to improve active surveillance of adverse events (AEs) or pregnancy in low- and middle-income countries and geographically challenging areas
- The study aimed to determine whether Seta facilitated reporting of AEs and pregnancies of patients enrolled in the T********** Roll-out STudy (TRuST) to the Brazilian National Health Surveillance Agency (ANVISA) and assess the sustainability of the technology

Pereira, D.B. *et al. Malar J* **24**, 71 (2025). https://doi.org/10.1186/s12936-025-05295-9

ACTIVE SURVEILLANCE: SETA TECHNOLOGY

- Seta is a new technology, designed for GSK by the digital communication company medDigital (medDigital Ltd, London, UK), to facilitate active surveillance.
- Seta technology is a bespoke, internet-based application that was designed to integrate a patient-facing website that provides information about a study with an administrative portal.
- Seta technology uses an application programming interface to connect with the WhatsApp Business Platform to send messages to and receive messages from patients using the WhatsApp mobile application on compatible Android or iOS devices.

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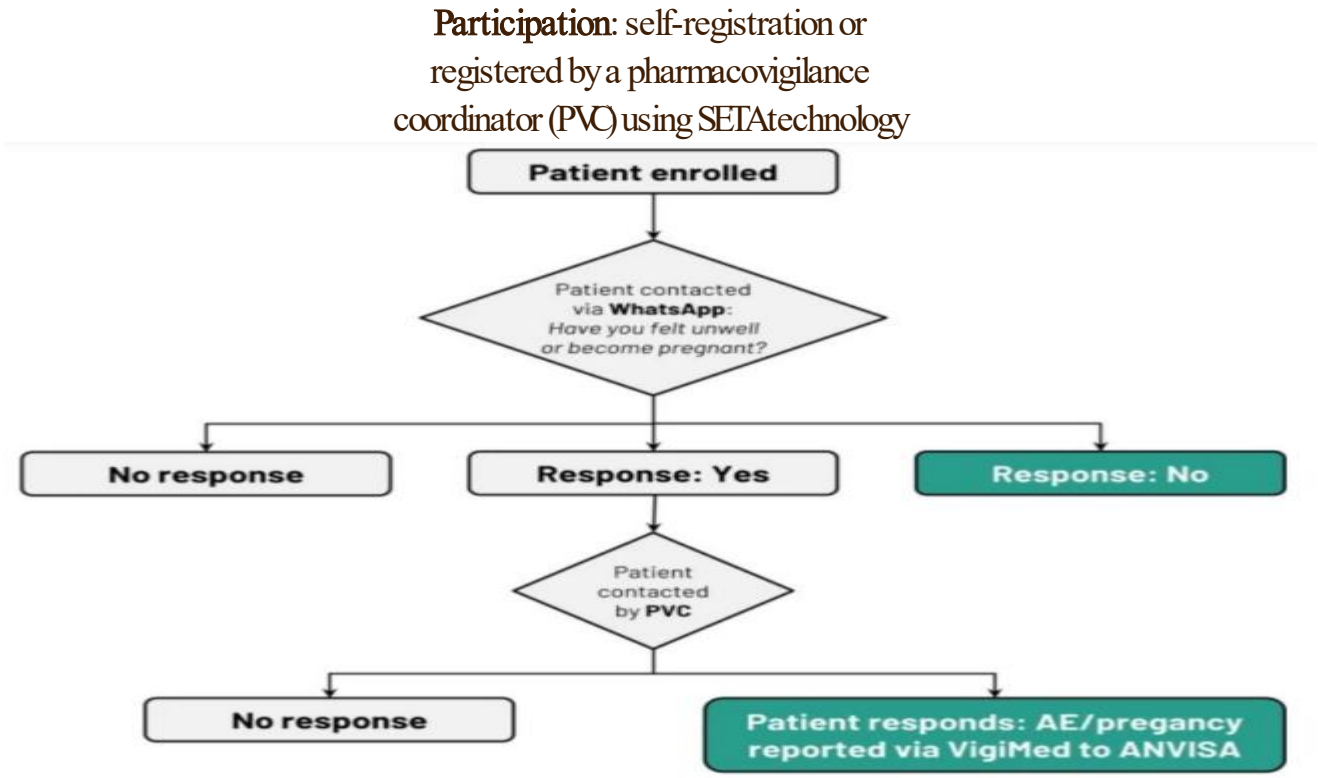
Pereira, D.B. *et al. Malar J* **24**, 71 (2025). https://doi.org/10.1186/s12936-025-05295-9

METHODOLOGY:

Inclusion criteria:

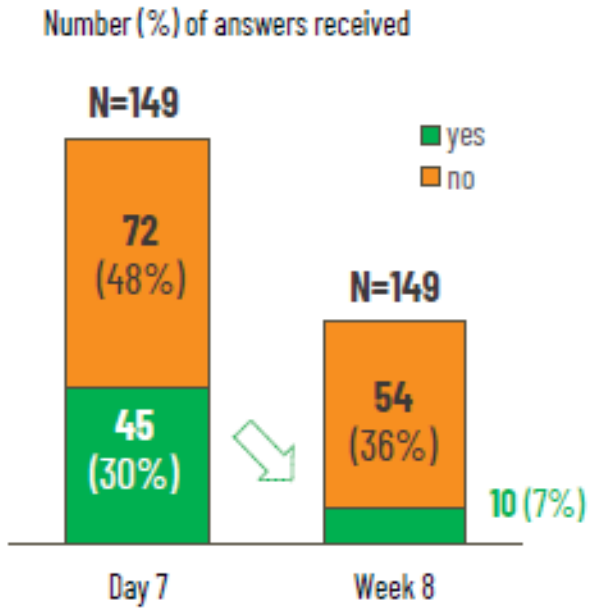
- 18+ yoa, *P. vivax* malaria patients participating in the T********* Roll-out STudy (TRuST NCT05096702) in Brazil's Amazon remote regions of Manaus and Porto Velho.
- Having a smart phone and WhatsApp, being familiar with the use of WhatsApp.



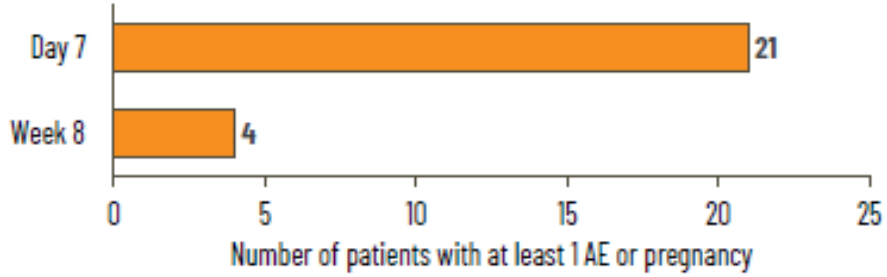
RESULTS:

- Recruitment period: 27 July 2022 to 31 August 2022
- 149 participants included in the analysis from Amazon remote areas, 50 from Manaus and 99 from Porto Velho
- **Day 7**: 117 (79%) responded to WhatsApp messages, 45 (30%) responded yes (i.e. experienced an AE or became pregnant)
- **Week 8**: 64 (55%) of those 117 that responded in Day 7 said yes, 10 (9%) of who indicated they had experienced an AE or become pregnant
- Overall, **25 (45%) AEs or pregnancies were reported to ANVISA** after successful contact with the participants

At Day 7, 45 patients (30%) responded "Yes" to a potential AE or pregnancy compared with 10 (7%) at Week 8"



Reports of at least one AE or pregnancy to ANVISA were more numerous at Day 7, compared to Week 8



Pereira, D.B. *et al. Malar J* **24**, 71 (2025). https://doi.org/10.1186/s12936-025-05295-9
Figures reproduced from Batista Pereira, D *et al* A pilot observational study of an active surveillance tool to enhance pharmacovigilance in Brazil. ASTMH, 18-22 October 2023, Chicago, IL, USA

DISCUSSION

- Most participants (117/149, 79%) enrolled in this study who responded on Day 7 were able to digitally communicate whether they had experienced an AE or a pregnancy.
- In addition, the study showed that Seta enabled PVCs to follow up AEs and pregnancies relayed via WhatsApp by participants, allowing these events to be reported to ANVISA, unlikely to have been reported otherwise.
- The sustainability of Seta over time could not be determined with this pilot study due to the small sample size, the low response rate in Week 8 of the study, and the large number of participants that were lost to follow up.
- However, as T ********** was given as a single-dose treatment, the participants may have lost interest in the study over time.

Image: Malaria parasite (sporozoite)

Pereira, D.B. *et al. Malar J* **24**, 71 (2025). https://doi.org/10.1186/s12936-025-05295-9

CONCLUSION

- This observational pilot study provides insights into how digital reporting tools such as Seta can enhance pharmacovigilance in remote areas and build upon existing signal detection methodologies on a larger scale. To widen access further, message patients with no or limited access to a smartphone by SMS instead of WhatsApp.
- Twenty-five AEs or pregnancies were reported to ANVISA that were unlikely to have been reported otherwise.
- This study was in line with the initiative introduced by the Brazilian National Health Surveillance Agency (ANVISA) in 2018 to improve the national PV system and comply with international PV standards

Pereira, D.B., Lacerda, M.V.G., Bilkhu, P. *et al.* An observational pilot study of an active surveillance tool to enhance pharmacovigilance in Brazil. *Malar J* **24**, 71 (2025). https://doi.org/10.1186/s12936-025-05295-9

Image: Hospital room with beds and nets

THANK YOU

Ana Martin, Global Clinical Development Director, GSK
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COI: I am employed by the GSK group of companies and own GSK shares

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COI: I am employed by the GSK group of companies and own GSK shares

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