

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



AFRICA  
REGULATORY  
CONFERENCE  
**2025**

4-PART SERIES



# STREAMLINING REGULATORY AND ETHICS APPROVALS

25 November 2025

13H00 – 15H00 CET & SAST



# SPEAKERS



**Caxton Murira**  
Science for Africa  
Foundation



**Lada Leyens**  
Takeda, on behalf of  
IFPMA



**Adriaan Kruger**  
nuvoteQ  
Foundation



**Marina Lazaridis**  
nuvoteQ Foundation





# **Research capacity activities in clinical trials**

**IFPMA REGULATORY CONFERENCE WEBINAR SERIES**

**25<sup>TH</sup> NOVEMBER 2025**

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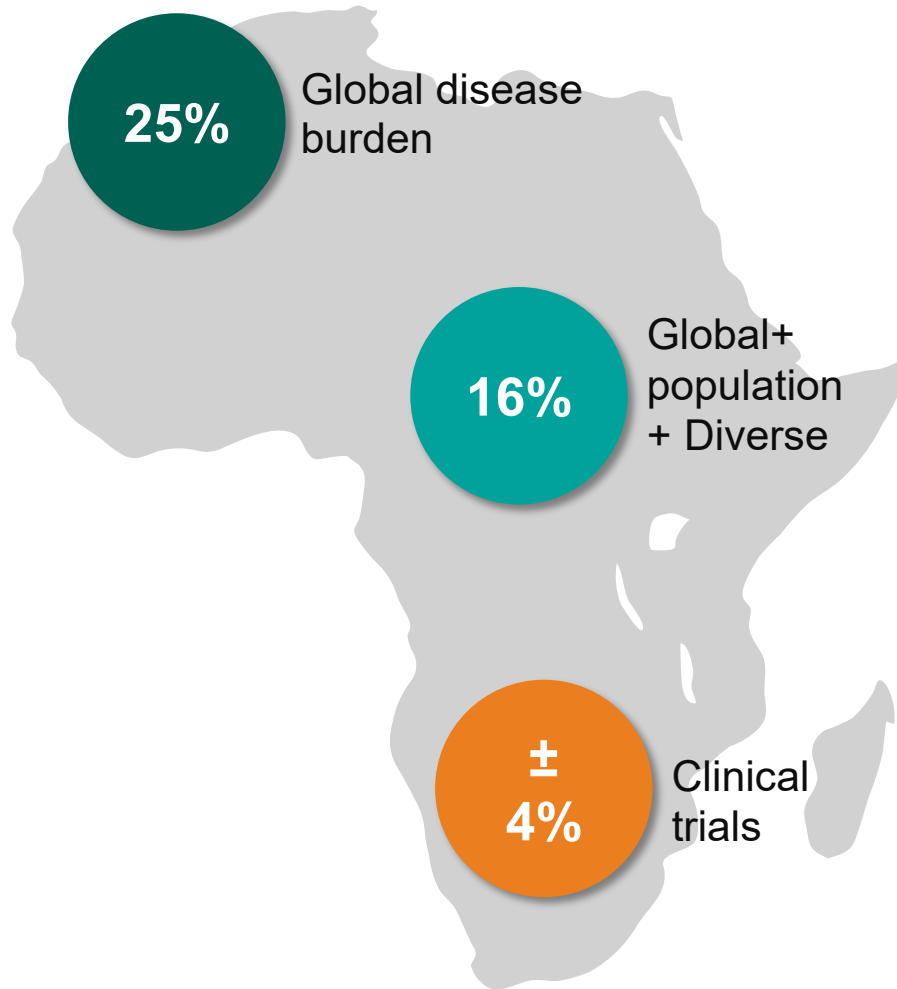
**PRESENTED BY: CAXTON MURIRA**

**PROGRAMME MANAGER: CRTC**

**SCIENCE FOR AFRICA FOUNDATION**

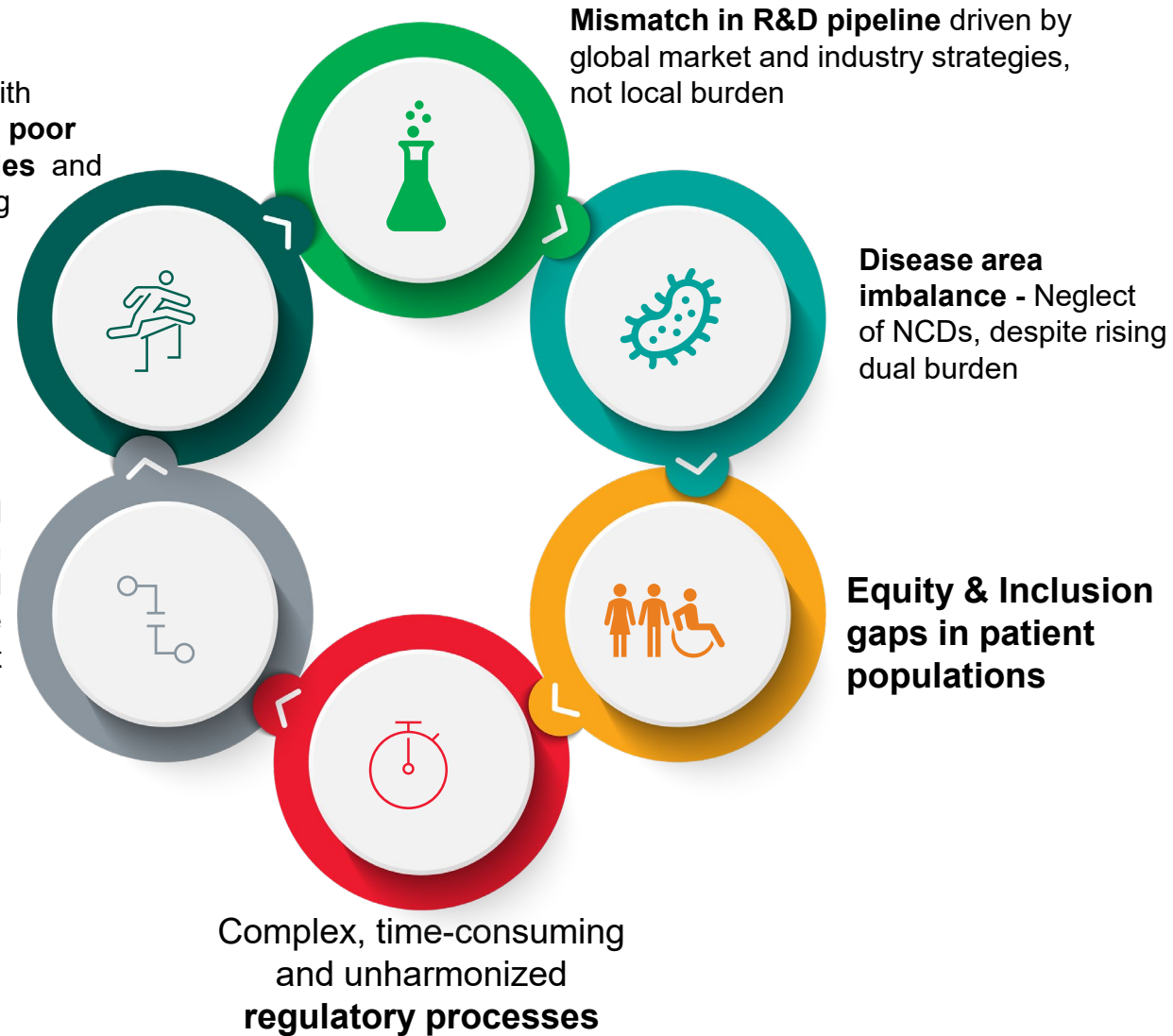


# Challenges in the Clinical Trials Ecosystem

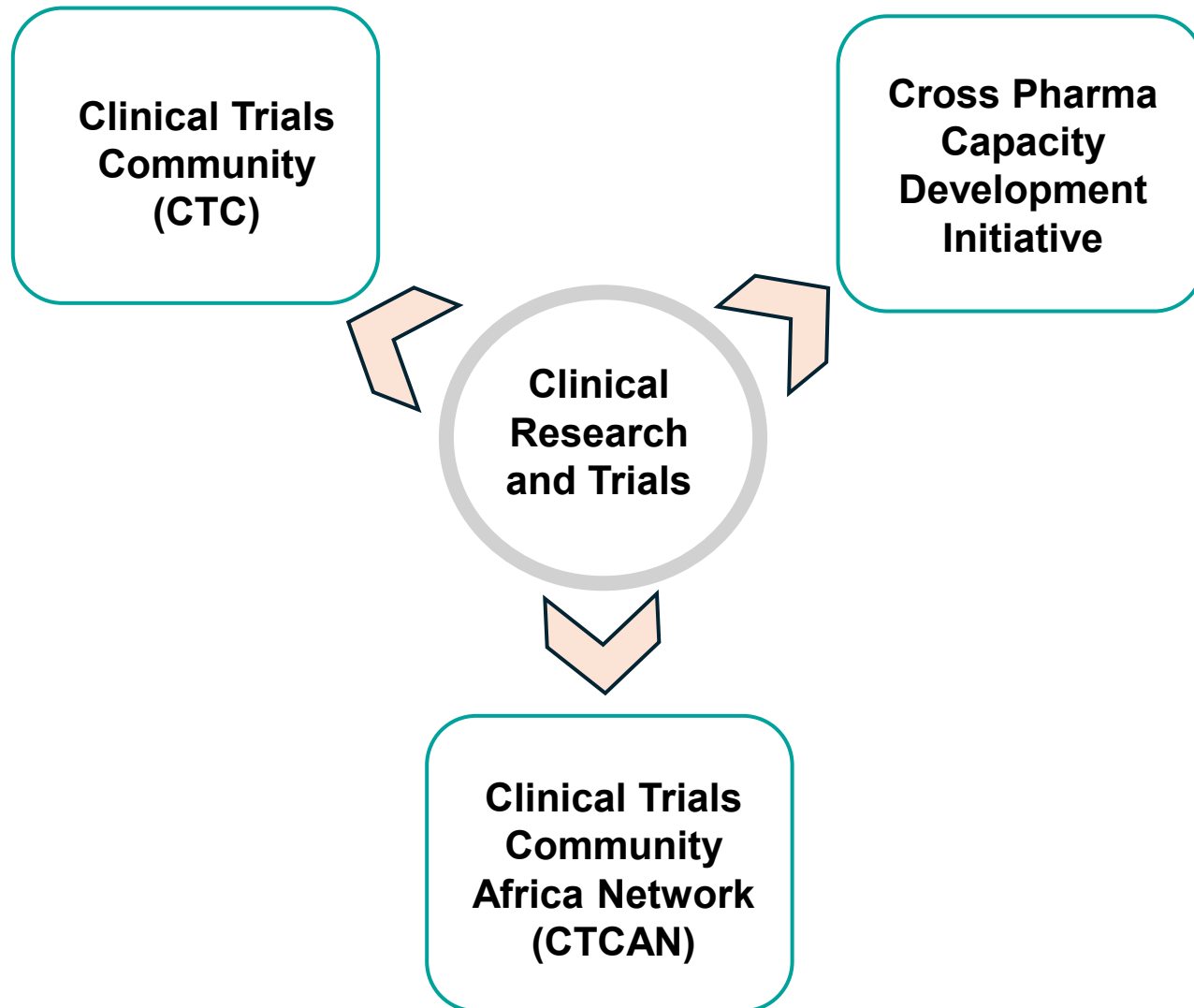


Competition with “established” sites, **poor visibility of capacities** and biased funding

Widely **fragmented clinical research capacity and practices** across the continent



# Our approach and initiatives



Enhance visibility of **capacity** in clinical research and strengthening gaps

Foster **trust** between researchers, regulators, sponsors, funders and the community

**Increase investments** in ethical clinical trials in Africa

Support creation of a **sustainable** clinical trials ecosystem in Africa.

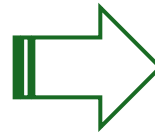
# Progress made and outlook

## Landscape:

- **3,500 +** Clinical Trial Centres Mapped
- Regulators from **55** countries Mapped
- **196** Research Ethics Committees (RECs) mapped
- **100 +** Networks mapped
- **Disease burden data:** GBD (IHME) and Country level data
- **Operational:** Mapped CROs, Logistics Companies, Labs, Sponsors etc

## Partnerships:

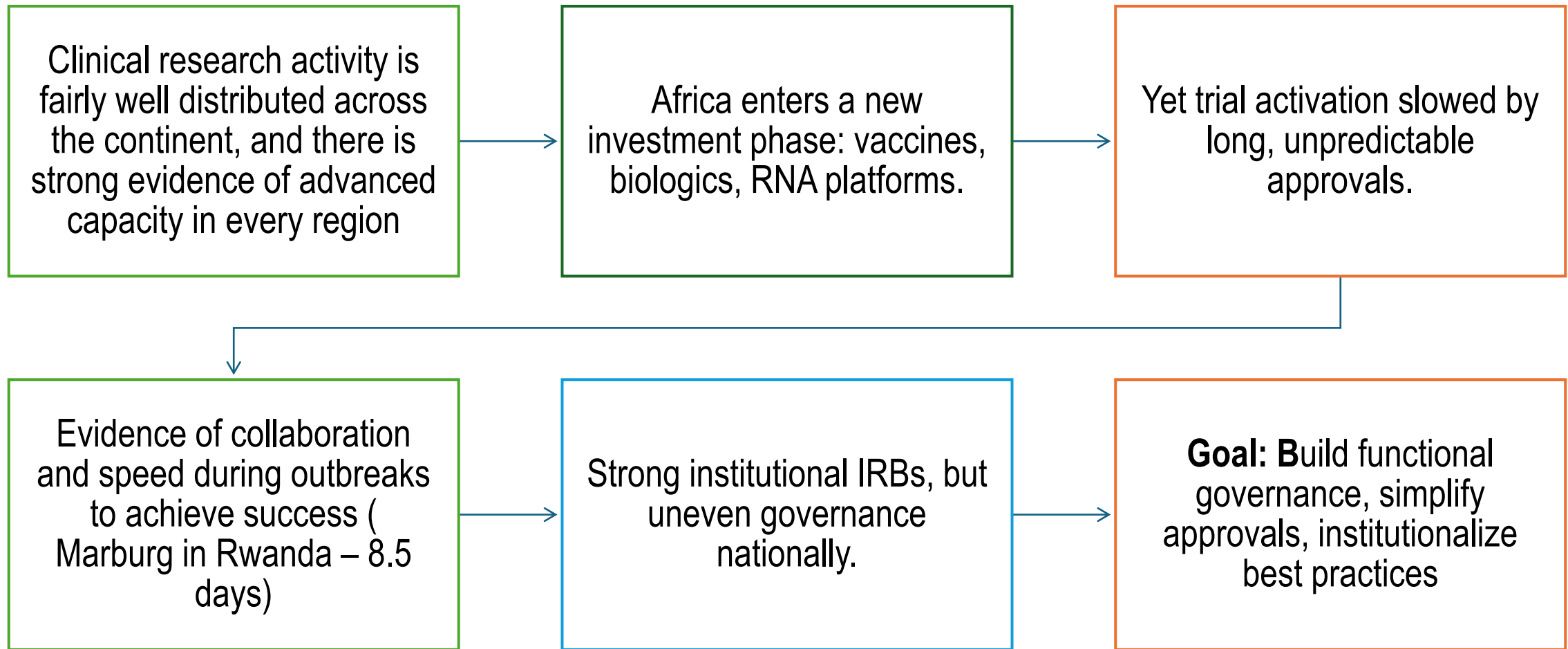
- Partnerships with research institutions and the research community ( Networks, sites,
- Partnerships with country, regional / continental partners and funders
- Partnership with Sponsors and Industry players



## Leveraging available capacity to draw solutions:

- **Continued Cocreation:** What are researchers willing to lead and how can this be facilitated?
- **Standardization:** Clinical research capacity mapping, disease burden data, regulatory and ethical requirements, Operational guidelines ( templates, Sops), promoting centralised and digital platforms
- **Capacity Strengthening activities** - Funding for CTUs, Regulatory capacity strengthening ( Research Ethics Committees)
- **Training initiatives** – fellowships, training for researchers, regulators

# Africa's clinical research paradox





# ML3: A huge milestone, but not a finish line.....

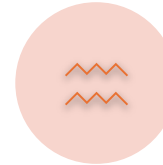
- Eight African NRAs now at WHO ML3.
- ML3 status signifies a stable, well-functioning, and integrated regulatory system
- ML3 MoU (2025) enables regulatory reliance. ( Reliance mechanism MoU)
  - Cooperation, Shared assessments, inspections, QC results for faster decisions.
- MoU ≠ operational practice and duplication that existed will still persists if no deliberate activities towards implementation ( Who leads / who supports / who finances / how can the best practices be streamlined and incentivized)
- Ethics harmonization as an urgency – funding, operational challenges, capacity, governance, standardized ethics SOPs, templates, and governance tools,
- Alignment to the newly launched African Medicines Agency (AMA) and other existing mechanisms such as AVAREF's joint review mechanism has been helping to cut through red tape for multi-country trials.



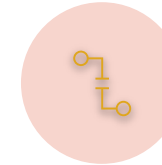
# CR/CT Networks as accelerators of harmonization

- **Central to unlocking norms and standards** especially regarding research ethics and supporting regulatory harmonization
- Networks enable continent-wide 'trial-ready corridors', joint training and offer continent-wide evidence for policy change
- **Shared infrastructure:** QC labs, CTUs, data systems.
- Networks will **leapfrog standardization** Ethics Norms Across Multiple IRBs eg shared templates, common consent approaches, aligned data-sharing and coherent frameworks for sensitive research (maternal, neonatal, genomic, AI-driven diagnostics)

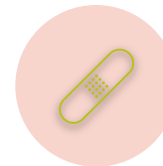
## Bottlenecks



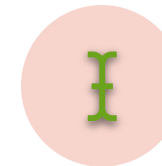
**Sustainability -**  
Fragmented funding ,  
projects end, networks  
collapse.



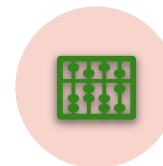
**Governance** – lack of  
unified oversight, weak  
network implementation  
plans, politics.



**Ethics lagging behind  
regulation.**



**Duplicated reviews** –  
sovereignty concerns  
override reliance.

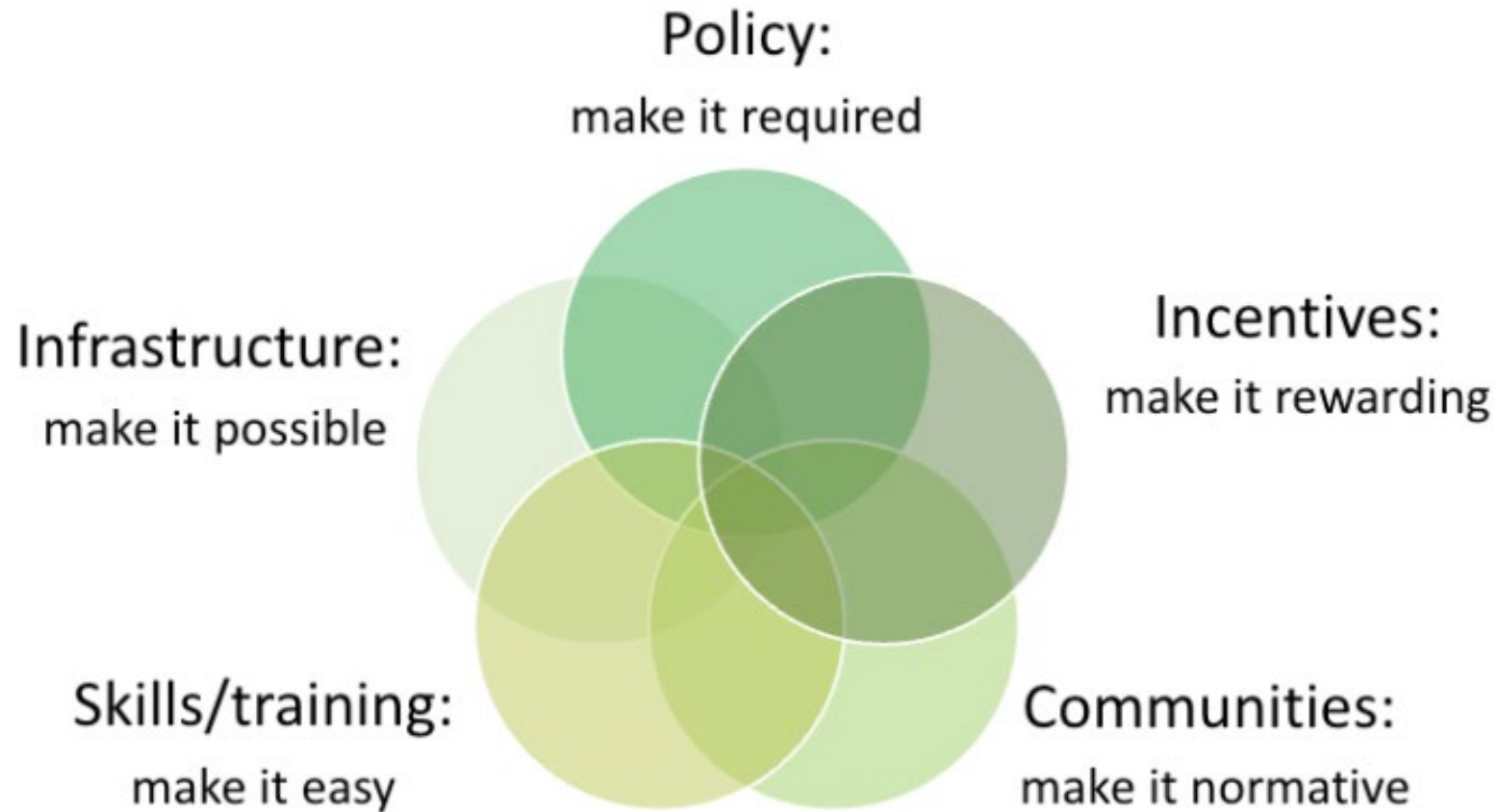


**Siloed initiatives** –  
everyone builds their  
own network.



**Digital gaps** – systems  
don't talk to each other  
(data, tools, systems)

# Approaches towards the change needed.



Adapted by from Brian Nosek, [Strategy for Culture Change](#) (2019)

# CALL TO ACTION: Accelerating Africa's Clinical Trials Ecosystem

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**Build / sustain trial-ready networks** – Invest in multi-country sites that share infrastructure, data systems, and governance. (eg CTCAN approach, hub and spoke model)

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**Make reliance real** – Move beyond MoUs. Use shared assessments and eliminate duplicated reviews, embrace digital technology and AI where possible

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**Harmonise ethics** – Standardise SOPs, templates, and strengthen EC/IRB capacity. Ethics must move at the speed of science.

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**Reduce friction everywhere** – Build trust, align processes, simplify pathways, and cut delays across the entire trial lifecycle.

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**Ecosystem approach** – Move towards addressing challenges as an interconnected piece and not in siloed approaches

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Building on existing platforms and already existing work = **Avoiding duplication** aligned with country, regional and continental agenda's ( **AMA, Africa CDC, AUDA NEPAD, AVAREF**)







# Considerations on the Use of Reliance in Clinical Trials Review

Key factors influencing collaborative trial assessments

Lada Leyens (Takeda) on behalf of IFPMA

Supported by a great group of experts from different pharmaceutical and biotech companies

November 2025





# Introduction

## Transformation of Clinical Trials

Global clinical trials are evolving with multiregional designs and rapid scientific progress shaping the landscape.

## Regulatory Fragmentation Challenges

Country-specific regulatory requirements cause delays and reduce attractiveness for clinical research globally.

## Regulatory Reliance Benefits

Leveraging trusted NRAs assessments reduces duplication, speeds approvals, and fosters collaboration.

## Necessity of Reliance Principles

Applying reliance principles enhances efficiency, safety, and harmonization in clinical trial reviews.



# What is Regulatory Reliance?



## Definition of Regulatory Reliance

The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision (WHO definition).

## Benefits of Reliance

Adopting reliance reduces redundant reviews, shortens approval timelines, and enhances global research collaboration.

## Impact on Multiregional Trials

Reliance supports harmonization in multiregional trials, improving efficiency and timely patient access to therapies.





# Scope of Reliance in Clinical Trials

## Key Elements of Reliance

Reliance applies to scientific rationale, study design, risk-benefit assessments, IMP quality, ethics, and data integrity in trials.

## Methodological and IMP Assessment

Clinical Trial Protocols and IMP quality documents use standardized formats enabling effective reliance in clinical trial reviews.

## Ethical Review Considerations

Ethical reviews require selective reliance due to cultural and legal differences, with local ethics committees maintaining authority.

# Options to facilitate good quality regulatory decision – reliance in focus

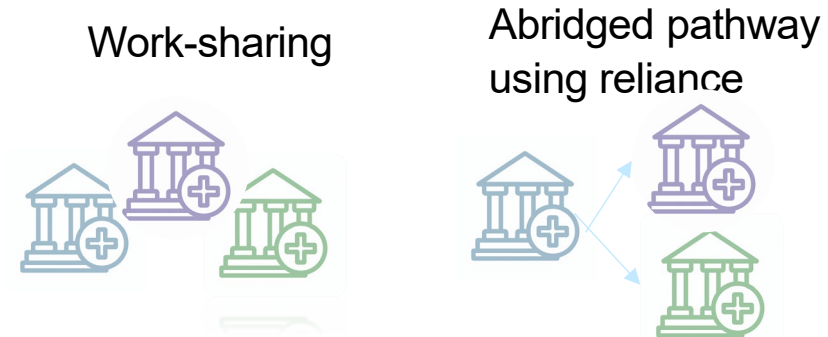
## Independent decisions

Based on its own reviews and/or inspections



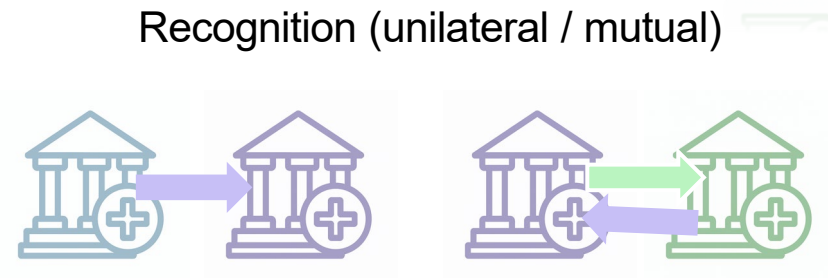
## Leveraging regulatory work

Performed by other competent and trusted authorities to increase resource efficiency and speed up timelines



## Unilateral or mutual recognition

Based on agreements or treaties or equivalent



Building trust between NRAs, increasing reliance and efficiency





# WHO Good Reliance Practices

## Annex 10

### Good reliance practices in the regulation of medical products: high level principles and considerations

#### Background

WHO supports reliance on the work of other regulators as a general principle in order to make the best use of available resources and expertise. This principle allows leveraging the output of others whenever possible while placing a greater focus at national level on value-added regulatory activities that cannot be undertaken by other authorities, such as, but not limited to: vigilance, market surveillance, and oversight of local manufacturing and distribution. Reliance

The act whereby the regulatory authority in one jurisdiction **takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution**, or to any other authoritative information in reaching its own decision.

Adopted by WHO Expert Committee on Specification for Pharmaceutical Products in October 2020, published in March 2021

<https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations>

- Importance of **international cooperation** to ensure the safety, quality and efficacy/performance of locally used medical products
- **Make best use of available resources and expertise**, avoid duplication and concentrate regulatory efforts and resources where most needed



# Implementation Considerations

## International Standards Alignment

Promote convergence with international standards like ICH and WHO guidelines for regulatory harmonization.

## Formal Agreements for Information Exchange

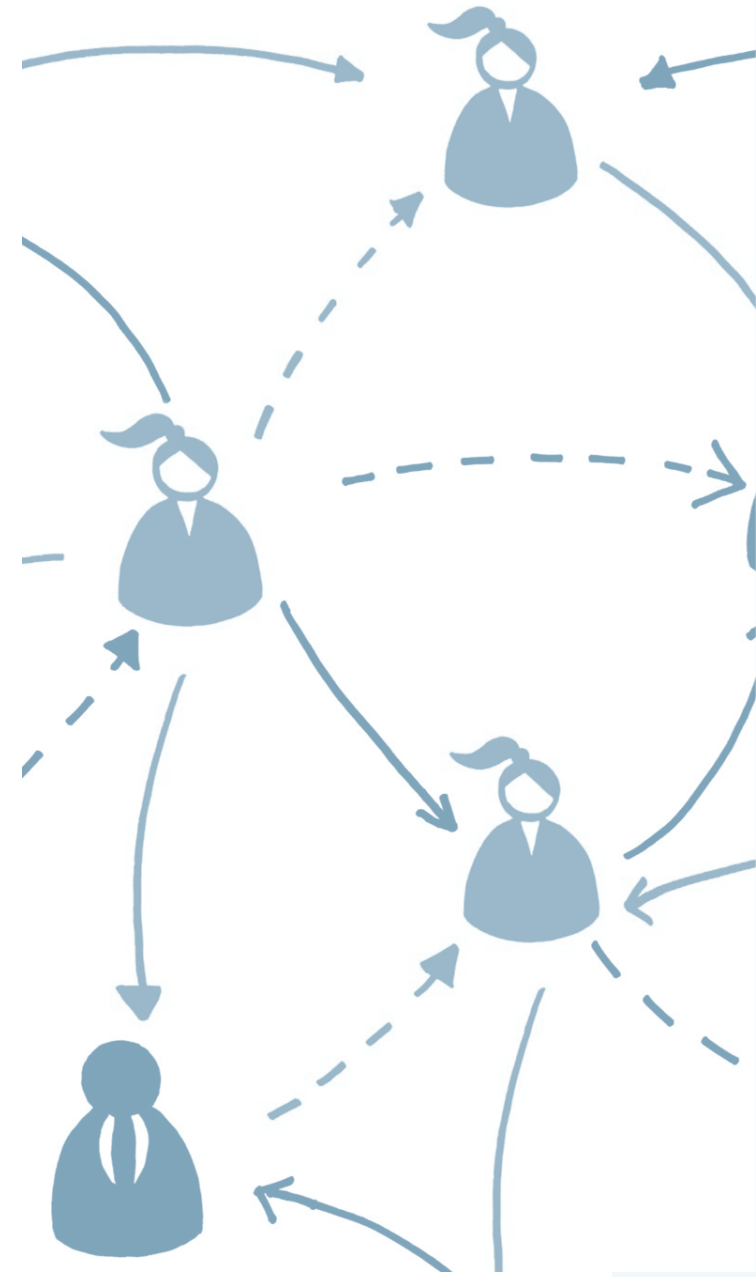
Establish MRAs or MoUs to secure and formalize information sharing among regulatory authorities.

## Centralized Assessment Platforms

Develop secure digital platforms to share regulatory assessments and facilitate collaboration across agencies.

## Training and Capacity Building

Invest in training for NRAs, ethics committees, and trial staff to ensure consistent application of reliance principles.



# Additional Steps for Successful Implementation

## Pilot Testing Reliance Models

Piloting reliance models helps identify challenges and refine implementation processes for success.

## Stakeholder Engagement

Engaging various stakeholders including NRAs, sponsors, and patient groups promotes transparency and collaboration.

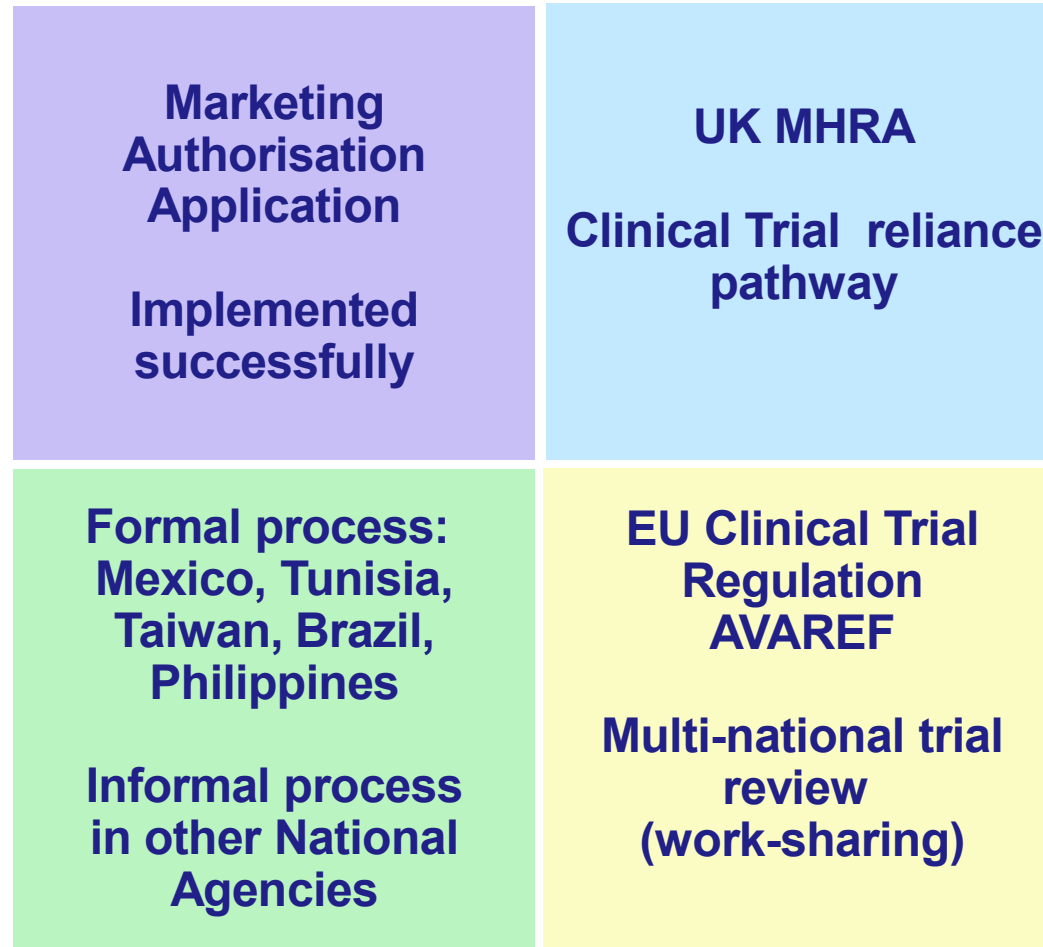
## Quality Assurance & Monitoring

Embedding continuous process quality assurance with regular monitoring and performance indicators ensures effective reliance practices.

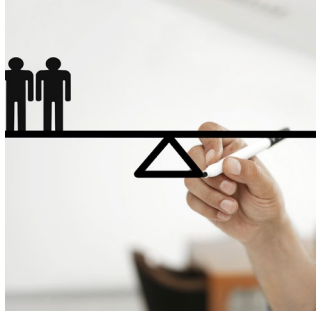


# Some examples

Applying reliance to clinical trial review will increase the impact and bring efficiency and learning to the CT regulatory ecosystem.



# Challenges and Ethical Considerations



## Importance of Local Review

Local ethical reviews ensure informed consent and data protection reflect cultural and legal contexts accurately.



## Selective Reliance Application

Reliance should focus on globally consistent ethical principles while respecting local authority for specific evaluations.



## Balancing Protection and Sovereignty

Balancing participant protection with respect for national sovereignty is essential for ethical research practices.



# Conclusion and Benefits

## Streamlined Research Process

Reliance and converging review processes speed approvals and reduce costs in clinical research globally.

## Improved Recruitment and Access

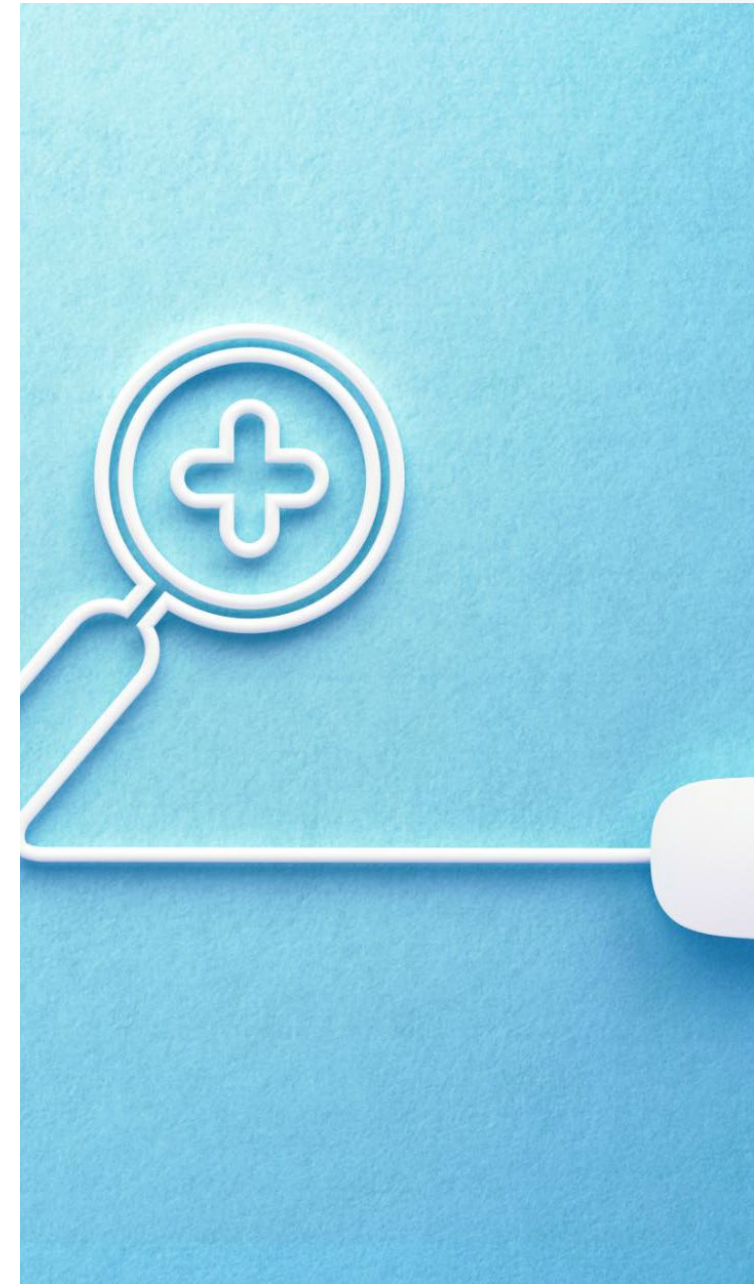
These practices improve multi-national recruitment timelines and enhance patient access to innovative therapies worldwide.

## Global Collaboration between Regulators and Ethics

Reliance fosters collaboration among regulators and ethic committees, ensuring an efficient and ethical clinical trial ecosystem.

## Safety and Quality Standards

These approaches uphold high safety and quality standards, ensuring equitable patient care worldwide.





# IFPMA position paper



Scan the QR code for the Position Paper:  
**Considerations on the use of reliance in  
clinical trials review**



## Considerations on the use of reliance in clinical trials review

### Introduction

The global clinical trial landscape is undergoing a profound transformation, driven by the increasing use of multiregional clinical trial designs, rapid advances in science and technology, and the growing need for coordinated regulatory approaches. With the expansion of multiregional clinical research, the need for harmonized regulatory frameworks has become more urgent. Despite this shift, regulatory fragmentation—driven by country or region-specific requirements—continues to impede the efficient initiation and conduct of multiregional clinical trials. Such fragmentation delays trial start-up and can diminish the attractiveness of certain jurisdictions for clinical research.

Regulatory reliance, already a well-established practice in regulatory decision-making for marketing authorization and post-approval changes, offers a promising solution. By leveraging assessments conducted by trusted national regulatory authorities (NRAs), reliance mechanisms can reduce duplication, accelerate clinical trial approvals, and promote global collaboration.

Applying the principles of regulatory reliance to clinical trial review is both feasible and necessary to enhance efficiency, uphold the rights, safety, and well-being of trial participants, and foster harmonization.

# IFPMA Webinar 4: Streamlining regulatory and ethics approvals

A digital platform for Clinical Trial Approval

Adriaan Kruger & Marina Lazaridis  
25 November 2025

# Our Commitment

## 01 PROTECTING PUBLIC HEALTH INNOVATIONS

We safeguard Intellectual Property (IP) and ensure these advancements remain available for the greater good.

## 02 BUILDING SELF-SUFFICIENCY

We foster long-term sustainability for our initiatives through diversified funding models.

## OUR IMPACT

By safeguarding and empowering public health innovations, the nuvoteQ Foundation is building a healthier future for all. We invite you to explore our website to learn more about our initiatives, governance structure, and how you can get involved.



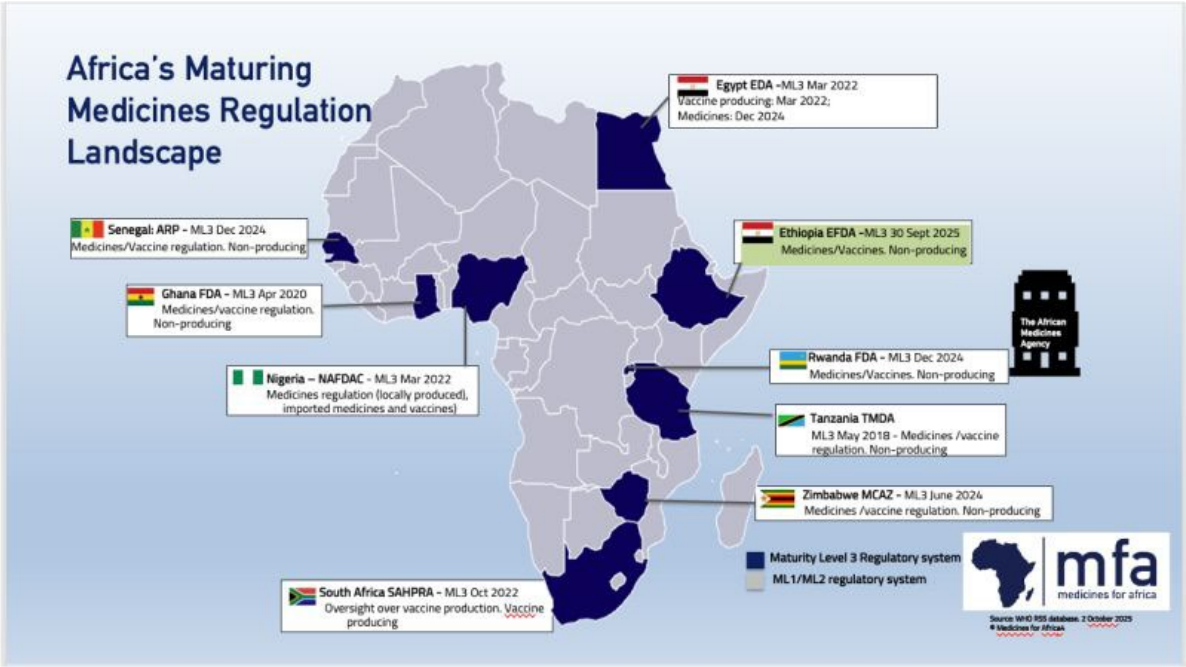
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# ENGAGEMENT PORTAL



# Portal Roadmap

Phase 1 | Nov 2023 – Sep 2025



Phase 2 | Oct 2025 – Sep 2027

Go-Live: 01 APRIL 2025

745+ Organisations  
4600+ Monthly Users



**LIVE DEMO:**

Clinical Trial Application  
(CTA) Module



## CTA Module

ADDITIONAL FEATURES



← Back

Overview

Checklist

Reviewers

Meeting

Queries

Final Decision

Assigned Reviewers/ Process

Clear Reviewers

Admin Screening

Frederick Reichert

Technical Reviewer

Review Submitted

Edit Reviewers

General Reviewers

Dulce Bergson

General Reviewers

Awaiting Consent

Angel Gouse

General Reviewers

Awaiting Consent

Tatiana Mango

Scientific Reviewers

Awaiting Consent

Roger Geldt

Statistical Reviewers

Trailist

Send Consent

Edit Reviewers

Statistical Reviewers

Leo Philips

Technical Reviewer

Awaiting Consent

Send Consent

Edit Reviewers

Meeting

Meeting : Not set

No Date

Final Decision

Chance Bator

Decision maker

Awaiting Consent

Edit Reviewers

**Reviewer question sets for different groups can be set here and status of reviews can be tracked.**

SAHPRA

South African Health Products Regulatory Authority

Reviewer

My Reviews

My Drafts Reviews

My Calendar

<<

To Do

Completed

Pending Response

All

Search Application Id

CREATED DATE	APPLICATION ID	APPLICATION TYPE	STATUS (FILTER)	ACTION
14 Apr 2023 8:43 PM	#caceacajbgdh	Clinical Trial Application: New Application	Awaiting Review	<div>Review</div>

Showing 1 application

<Phase II Oncology Study>

Application ID: APP-2024-001

Trial Title

Phase III Randomized Controlled Trial of Novel Antiviral Therapy for Hepatitis C

Protocol Number/ID

HCV-2025-001

Sponsor Name

MediPharm Solutions Ltd.

Principal Investigator(s)

<Dr. Sarah Nkosi>

Study Site(s)

Groote Schuur Hospital (Cape Town, South Africa)

Cancel

Decline

Accept

External reviewer users registered on the portal receive a conflict and consent of review declaration when assigned to each application.

SA

>>

Back

Part 1: Administrative Details

20%

Study Title

Input title

Protocol No

Version

Date

Input Protocol No

Input Version

Input Date

Phase of Trial

Select Trial

Protocol Document

Upload Protocol Document

Sponsors/Funders - Please specify exact roles

Specify Sponsor/Funder

Select Role/Input Role

Contact Person(s) to answer queries/outcome about the unregistered medicine

Input Full name

Input Telephone Number

Input Cellular Phone Number

Enter Email address

Reviewer Questions

SAHPRA Reference number

Study Title

Protocol No

Phase of trial

Sponsor(s)/Funder(s) – Please specify exact roles

Applicant

National Principal Investigators

Regional Monitor

Return

Next Section

Reviewer Questions

SAHPRA Reference number

Study Title

Protocol No

Phase of trial

Sponsor(s)/Funder(s) – Please specify exact roles

Applicant

National Principal Investigators

Study Title

Study title must be clear; identify the IP; include the disease area, target population, objectives; allow for ease of traceability on SANCTR.

✓

✗

Comment

Phase of trial

Is the phase acceptable? See also preclinical/clinical data and study objectives

✓

✗

Comment

Sponsor(s)/Funder(s) – Please specify exact roles

Is there a differentiate between a Sponsor and funder? Are their responsibilities described.

✓

✗

Comment

Applicant

Applicant and alternative contact should be SA-based.

✓

✗

Comment

National Principal Investigators

National PIs should meet the requirements of being a PI (see guidelines) and should be either a PI or Sub-I at one of the sites.

✓

✗

Comment

**All reviewers receive a full view of the application and custom reviewer question set to guide the review process. Evaluators can direct queries to internal members or applicants and use tools like drag-and-drop for files and response formatting.**

Create Meeting

×

Meeting Name

✎

Location

Online Meeting

Day

📅

Start

🕒

End

🕒

Cancel Meeting

Create Meeting

SAHPRA

South African Health Products Regulatory Authority

Unit Manager

Applications Manager

User Management

Unit Management

My Calendar

Log Out

←

April 2025

→

28

29

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Meeting Filters

☐

Section 21

☐

Health Product

☐

Licensing

☒

Clinical Trials

☐

View All

←

April 2025

→

Month

Week

Day

List

Sun	Mon	Tue	Wed	Thu	Fri	Sat
26	27	28	29	30	31	1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31	1	2	3	4	5

Meeting Created

A review meeting can be created for the scheduled final review of applications. Applications can be added on the application itself or via the meeting interface

Once the meeting is scheduled and the attendees are added it will show in their personal calendar view.



## Assign Applications to <Meeting Review Name>

Assign individual or reviewer groups to review the application

🔍 Search Applicant

📅 Date Picker

APPLICATION ID	SUBMISSION DATE	APPLICATION TYPE	ACTION
#caceacajbgdh	14 Apr 2023 8:43 PM	Clinical Trial Application: New Application	<input checked="" type="checkbox"/>
#caceacajbgdh	14 Apr 2023 8:43 PM	Clinical Trial Application: New Application	<input checked="" type="checkbox"/>
#caceacajbgdh	14 Apr 2023 8:43 PM	Clinical Trial Application: New Application	<input type="checkbox"/>
#caceacajbgdh	14 Apr 2023 8:43 PM	Clinical Trial Application: New Application	<input checked="" type="checkbox"/>

📌 Select All

Cancel

Add To Meeting

**All evaluators involved in the review cycle are automatically included in the meeting, with the option to add or remove members**

**Applications can be added to the meeting by date filtering or application number.**

## CTF1 Meeting 1- Clinical Trials Application

12:00 PM 2025-04-12

📄 Announce Meeting

### Added Participants

Participants will be added automatically

🔗 Invite Participants

AK Botha Saars Coordinator	AK Susan Welsh's Meeting Creator	AK John Snow Reviewer	AK Jason Dow Reviewer	AK Haylie Schleifer Reviewer
AK Alfredo Gouse Reviewer	AK Martin Madsen Reviewer	AK Anika Bator Reviewer	AK Terry Septimus Reviewer	AK Ryan Torff Reviewer

### Applications to review

📄 Assign Applications

#### CTF1 Applications

#0102030 CTF1 Application 4 Comments Review	#044334 CTF1 Application 2 Comments View	#01023434 CTF1 Application 4 Comments View	#0105345 CTF1 Application 4 Comments View
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#### CTF2 Applications

#0102030 CTF1 Application 4 Comments View	#044334 CTF1 Application 2 Comments View	#01023434 CTF1 Application 4 Comments View	#0105345 CTF1 Application 4 Comments View
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📄 Applications Added

The meeting overview tracks applications due for decision-making.

During the meeting, all evaluators' queries are visible for discussion, and the meeting administrator can add final comments.

SA

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Back

Application Summary

Review Summary

The clinical trial review of the application highlights its innovative approach to patient care. The study involved 200 participants over six months, assessing the app's effectiveness in managing chronic conditions. Results showed a 30% improvement in patient adherence to treatment plans and a significant reduction in hospital visits. Feedback from users indicated high satisfaction rates, with many appreciating the app's user-friendly interface and personalized features. Overall, the trial suggests that the application could play a crucial role in enhancing health outcomes.

Reviewers Recommendation

AK

John White (Technical Screener)

21 Jul | 08:20-10:30

Approved

AJ

Susan Walinsky (Admin Screener)

21 Jul | 08:20-10:30

Approved

SJ

Kruger Jeff (Reviewer)

21 Jul | 08:20-10:30

Rejected

Internal Comments

The details on the HPCSA certificate do not correspond with the applicant's details.

<Reviewer Name> 21 Jul | 08:20-10:30

Application seems to have alot of issues.

<Kruger Jeff> 21 Jul | 08:20-10:30

Application Timeline

Sent Back to Applicant ("issue")

21 Jul | 08:20-10:30

AK

John White ("screener 1")

The details on the HPCSA certificate do not correspond with the applicant's details.

View Query

Set Final Decision of Application

Select what is the final decision of the application <number>

Select the Decision

Approved

Application meets all the requirements

Approved with Minor Amendment

Requires small adjustments

Approved with Major Amendment

Needs significant changes

Conditionally Approved

Pending additional requirements

Rejected

Does not meet standards

Select reason for decision


Select Reason

Cancel

Submit Final Decision

The administrator can issue a final decision with notes for the applicant during the meeting.

Based on predefined decisions for the application type, the application progresses to the next scheduled stage.

nuvoteQ  
foundation

**LIVE DEMO:**

**AI ASSISTED CTA REVIEW**



Legacy Review Tool

Submit a new application for legacy review processing

+ Add New

🔍 Search applications...

Applications:

All

Processing

Finished

APPLICATION ID

CREATED DATE

ATTACHED FILE

ACTION

#caceacajbgdh

25 Nov 2025  
10:10 AM

caceacajbgdh.zip  
12.5 MB

👁️ View Report

#caceacajbgdh

18 Dec 2024  
2:15 PM

caceacajbgdh.zip  
12.5 MB

👁️ View Report

#caceacajbgfw

15 Dec 2024  
9:32 AM

caceacajbgfw.zip  
8.3 MB

👁️ View Report

#cdceacajhgah

12 Dec 2024  
4:57 PM

cdceacajhgah.zip  
15.7 MB

👁️ View Report

#bfceacajmnl

10 Dec 2024  
11:15 AM

bfceacajmnl.zip  
22.1 MB

👁️ View Report

#ggceacajklop

08 Dec 2024  
3:42 PM

ggceacajklop.zip  
7.9 MB

👁️ View Report

#rrceacajpqrs

05 Dec 2024  
1:28 PM

rrceacajpqrs.zip  
19.3 MB

Processing

#ttceacajuvwx

03 Dec 2024  
10:55 AM

ttceacajuvwx.zip  
14.2 MB

👁️ View Report

Showing 8 applications





Thank you

## Contact Us



Contact us

[hello@nuvoteq.foundation](mailto:hello@nuvoteq.foundation)



Website

[www.nuvoteq.foundation](http://www.nuvoteq.foundation)



Address

47 Hazelwood Rd, Hazelwood,  
Pretoria, 0081