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

GCTF
Global clinical trials forum
WHO Managed Network

AFRICA REGULATORY CONFERENCE 2025

SPEAKERS

Caxton Murira
Science for Africa Foundation

Lada Leyens
Takeda, on behalf of IFPMA

Adriaan Kruger
nuvoteQ Foundation

Marina Lazaridis
nuvoteQ Foundation

AFRICA REGULATORY CONFERENCE 2025

Research capacity activities in clinical trials

IFPMA REGULATORY CONFERENCE WEBINAR SERIES

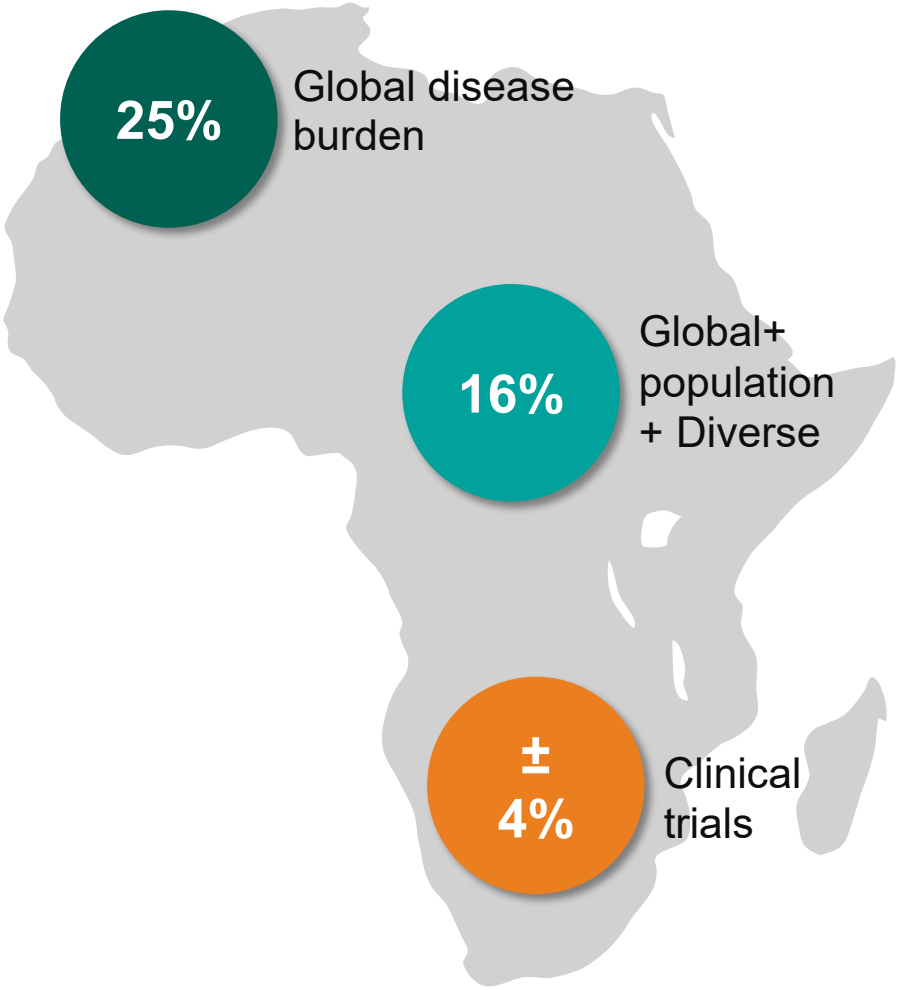
25TH NOVEMBER 2025

PRESENTED BY: CAXTON MURIRA

PROGRAMME MANAGER: CRTC

SCIENCE FOR AFRICA FOUNDATION

Challenges in the Clinical Trials Ecosystem



Mismatch in R&D pipeline driven by global market and industry strategies, not local burden

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

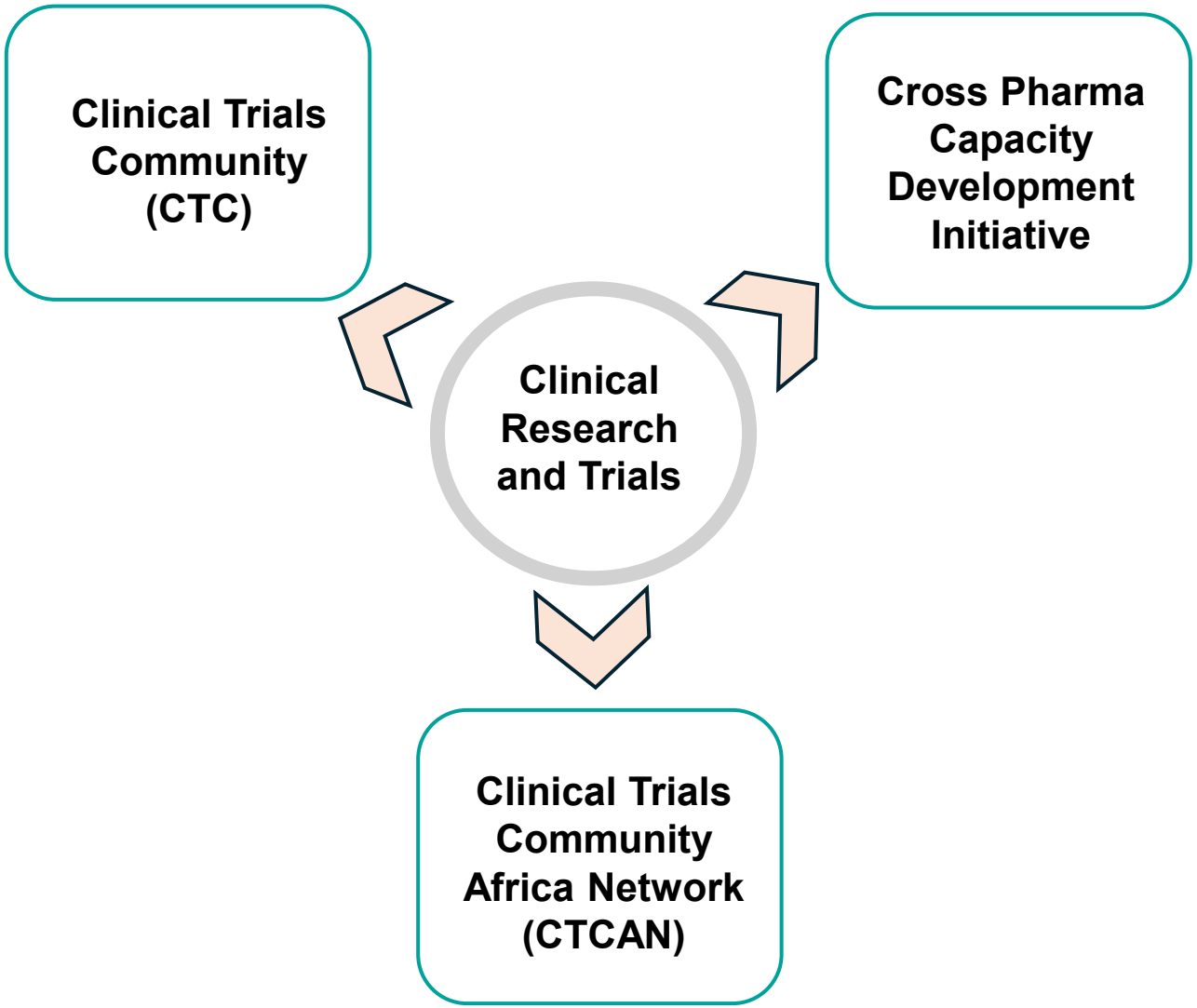
Disease area imbalance - Neglect of NCDs, despite rising dual burden

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

Equity & Inclusion gaps in patient populations

Complex, time-consuming and unharmonized **regulatory processes**

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.

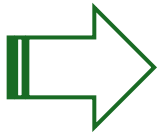
Progress made and outlook

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:

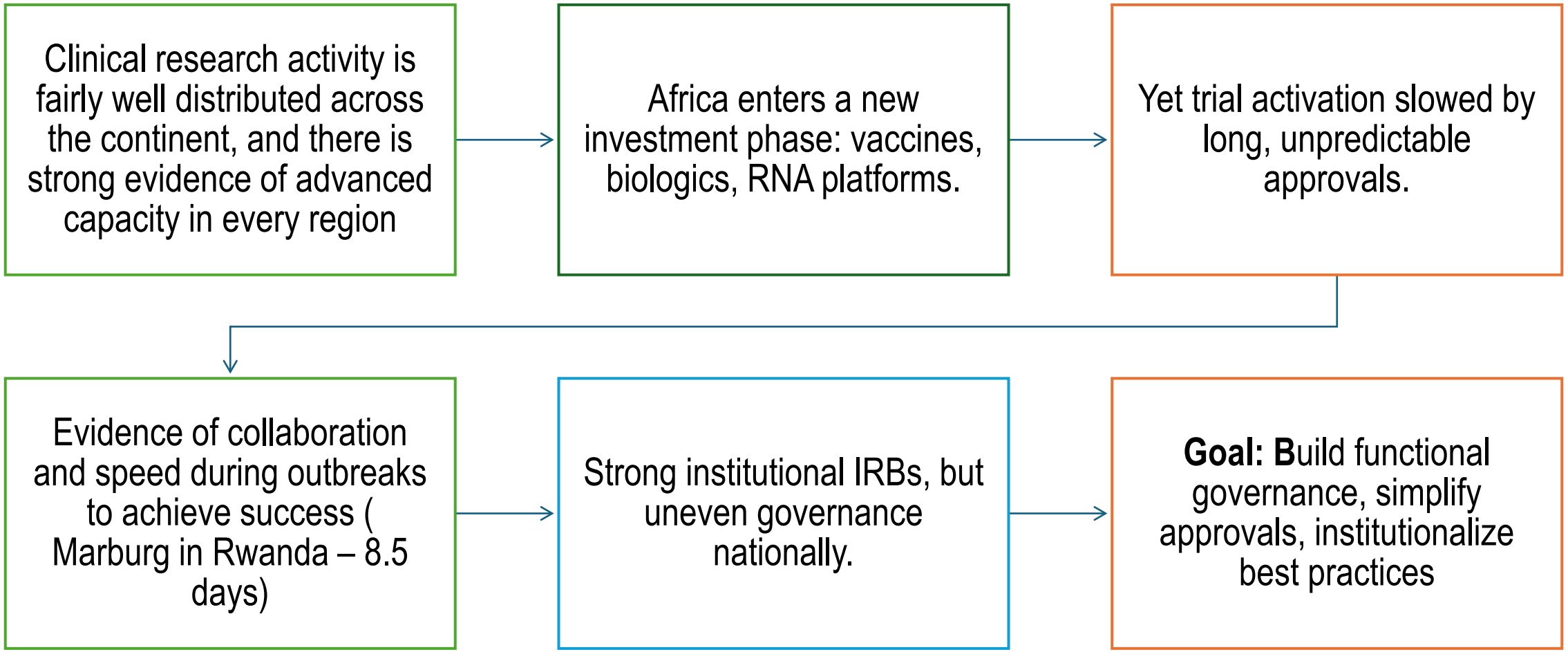
- Partnerships with research institutions and the research community (Networks, sites,
- Partnerships with country, regional / continental partners and funders
- Partnership with Sponsors and Industry players



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 Commitees)
- **Training initiatives** – fellowships, training for researchers, regulators

Africa's clinical research paradox



ML3: A huge milestone, but not a finish line……

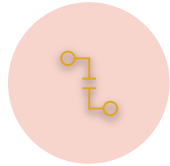
- Eight African NRAs now at WHO ML3.
- ML3 status signifies a stable, well-functioning, and integrated regulatory system
- ML3 MoU (2025) enables regulatory reliance. (Reliance mechanism MoU)
  - Cooperation, Shared assessments, inspections, QC results for faster decisions.
- MoU ≠ operational practice 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

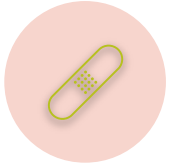
- **Central to unlocking norms and standards** especially regarding research ethics and supporting regulatory harmonization
- Networks enable continent-wide ‘trial-ready corridors’, joint training and offer continent-wide evidence for policy change
- **Shared infrastructure**: QC labs, CTUs, data systems.
- 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

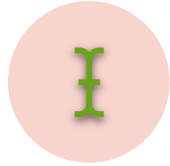
Sustainability - Fragmented funding , projects end, networks collapse.



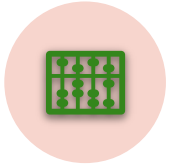
Governance – lack of unified oversight, weak network implementation plans, politics.



Ethics lagging behind regulation.



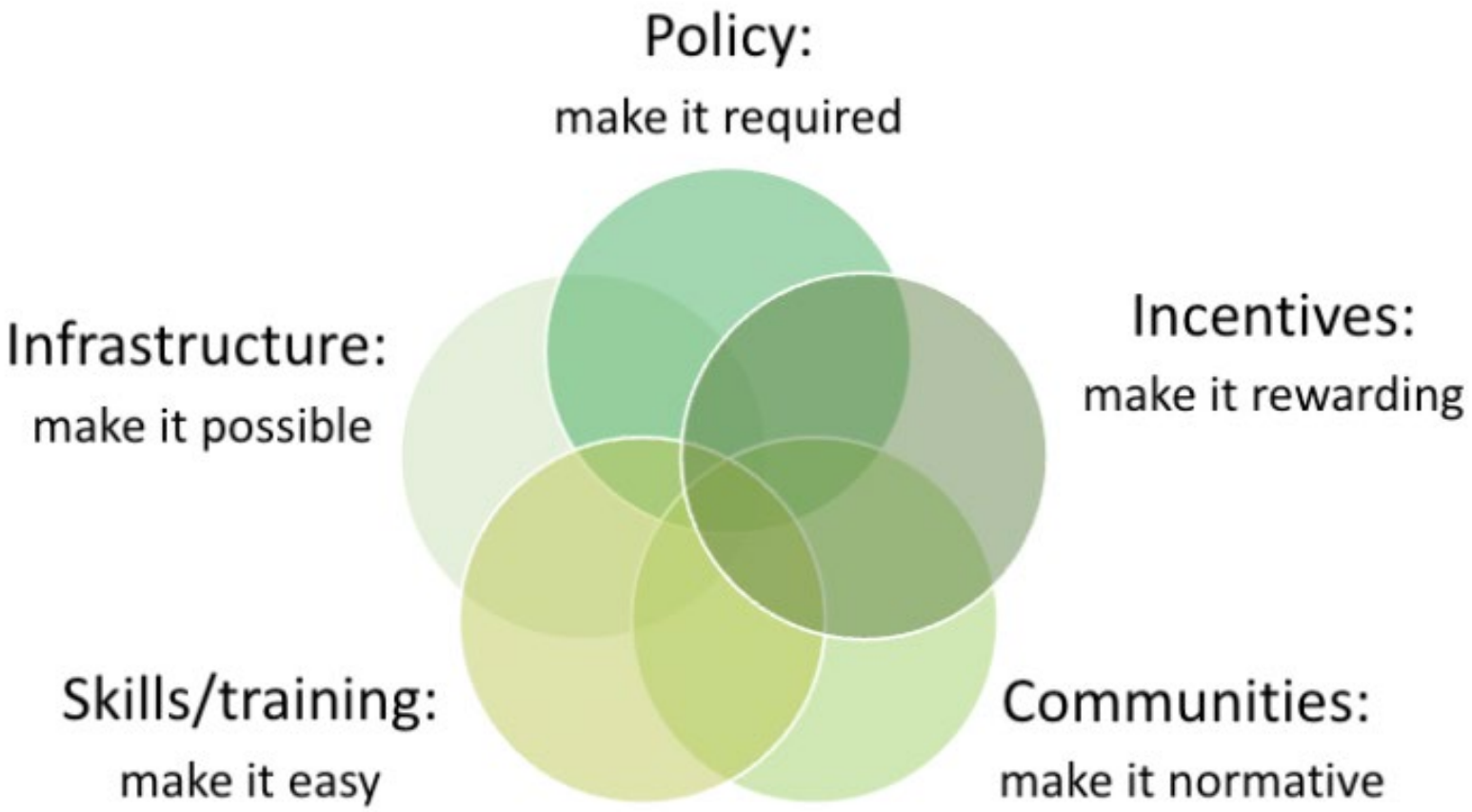
Duplicated reviews – sovereignty concerns override reliance.



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

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

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

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

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

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

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

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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.

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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

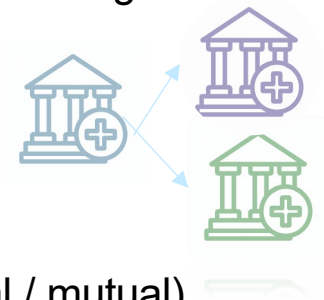
Unilateral or mutual recognition

Based on agreements or treaties or equivalent

Standard process

Work-sharing

Abridged pathway using reliance



Recognition (unilateral / mutual)

Building trust between NRAs, increasing reliance and efficiency

Source: adapted from presentation by Dr Samvel Azatyan, 08 – 12 May 2023 on WHO guidelines on Good Reliance Practices: applicability and prospects for implementation

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Key Principles for Effective Reliance

Patient Safety and Trust

Reliance mechanisms must prioritize patient safety and build trust through demonstrated reference agency competence and transparency.

Minimize Duplication and Standards

Effective reliance upholds international data standards and minimizes duplication to enhance efficiency and consistency.

Respect Sovereignty and Legal Alignment

Mechanisms must respect national sovereignty and align with local legal frameworks for ethical and lawful operation .

Clear Communication and Accountability

Transparent communication of scope and documented decisions creates predictability and accountability in reliance.

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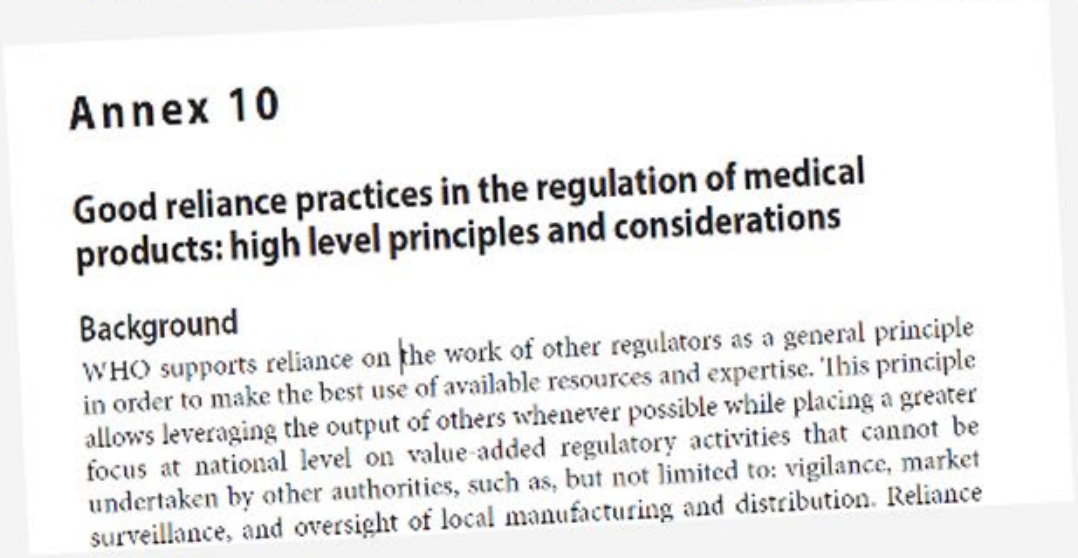
WHO Good Reliance Practices



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

World Health Organization

Source: presentation by Dr Samvel Azatyan, 08 – 12 May 2023 on WHO guidelines on Good Reliance Practices: applicability and prospects for implementation

Implementation Considerations

International Standards Alignment

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

Formal Agreements for Information Exchange

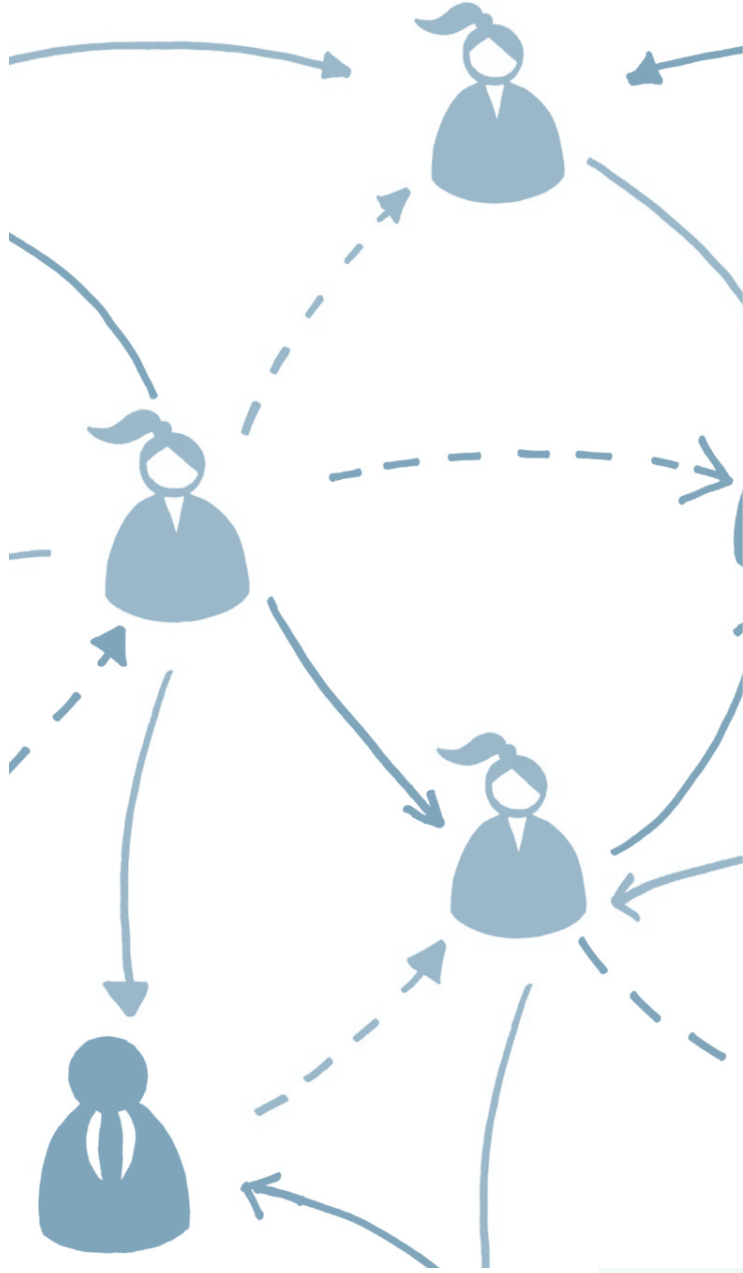
Establish MRAs or MoUs to secure and formalize information sharing among regulatory authorities.

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.

Marketing Authorisation Application **Implemented successfully**	**UK MHRA** **Clinical Trial reliance pathway**
Formal process: Mexico, Tunisia, Taiwan, Brazil, Philippines **Informal process in other National Agencies**	**EU Clinical Trial Regulation AVAREF** **Multi-national trial review (work-sharing)**

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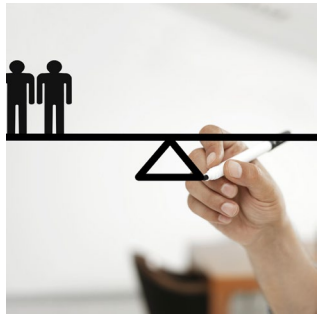
Challenges and Ethical Considerations



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.

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Conclusion and Benefits

Streamlined Research Process

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

Improved Recruitment and Access

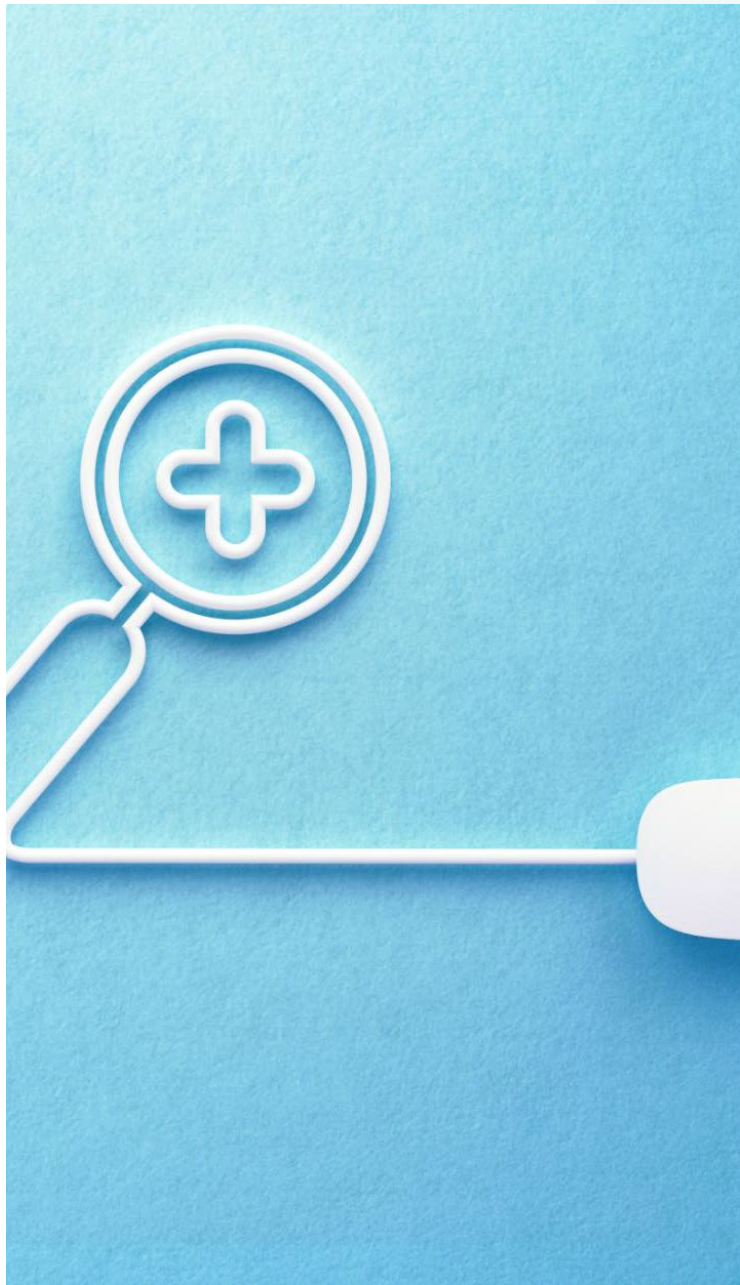
These practices improve multi-national recruitment timelines and enhance patient access to innovative therapies worldwide.

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.



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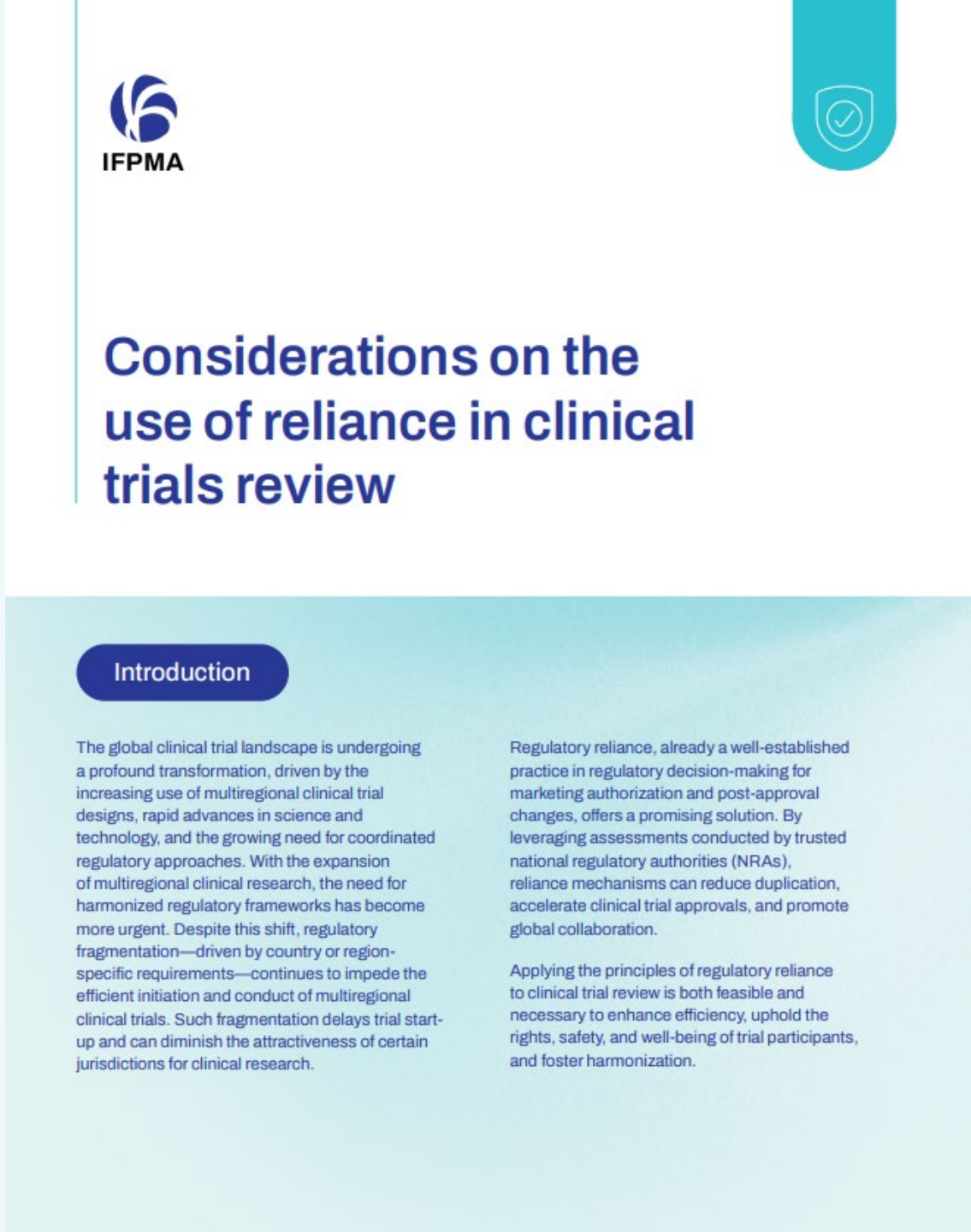
IFPMA position paper

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



IFPMA Webinar 4: Streamlining regulatory and ethics approvals

A digital platform for Clinical Trial Approval

Adriaan Kruger & Marina Lazaridis
25 November 2025

nuvoteQ foundation

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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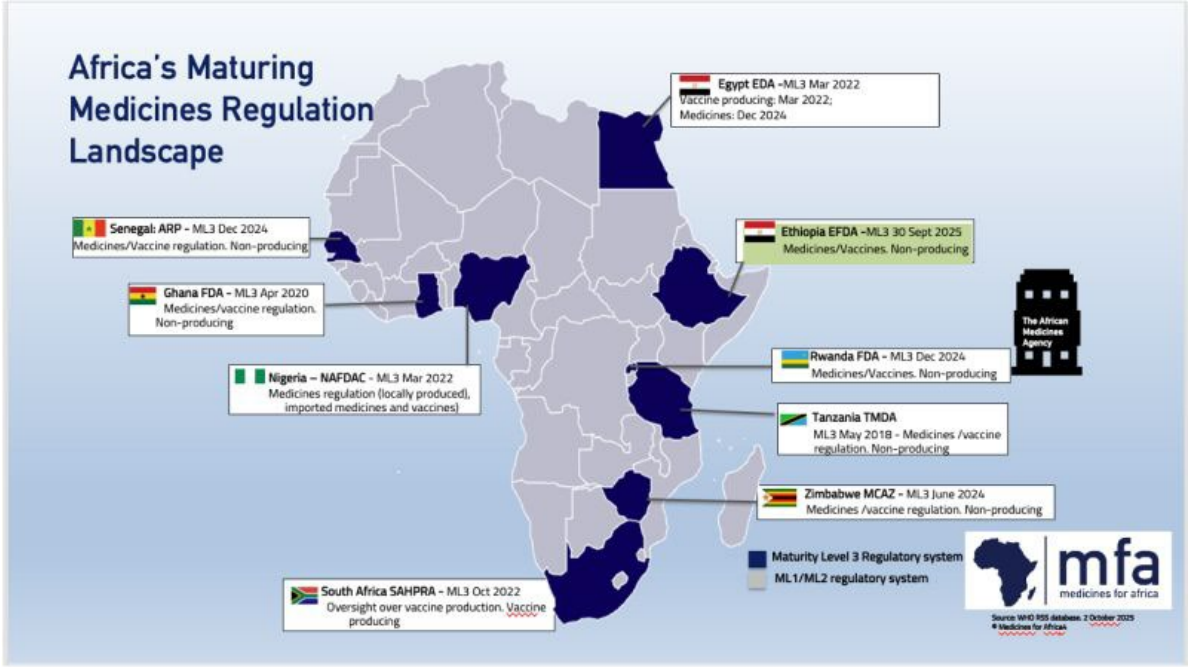
SAHPRA

South African
Health Products
Regulatory Authority

ENGAGEMENT PORTAL

nuvoteQ foundation

Portal Roadmap



Phase 1 | Nov 2023 – Sep 2025

- Health Product Applications (Orthodox & Biological)
- Compassionate Use Medication (S21)
- Clinical Trial Applications

Phase 2 | Oct 2025 – Sep 2027

- Additional HPA (Devices, Veterinary & Complimentary)
- Licensing
- Inspections
- Pharmacovigilance
- Section 36
- Other

Go-Live: 01 APRIL 2025

745+ Organisations

4600+ Monthly Users

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LIVE DEMO:

Clinical Trial Application
(CTA) Module

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CTA Module

ADDITIONAL FEATURES

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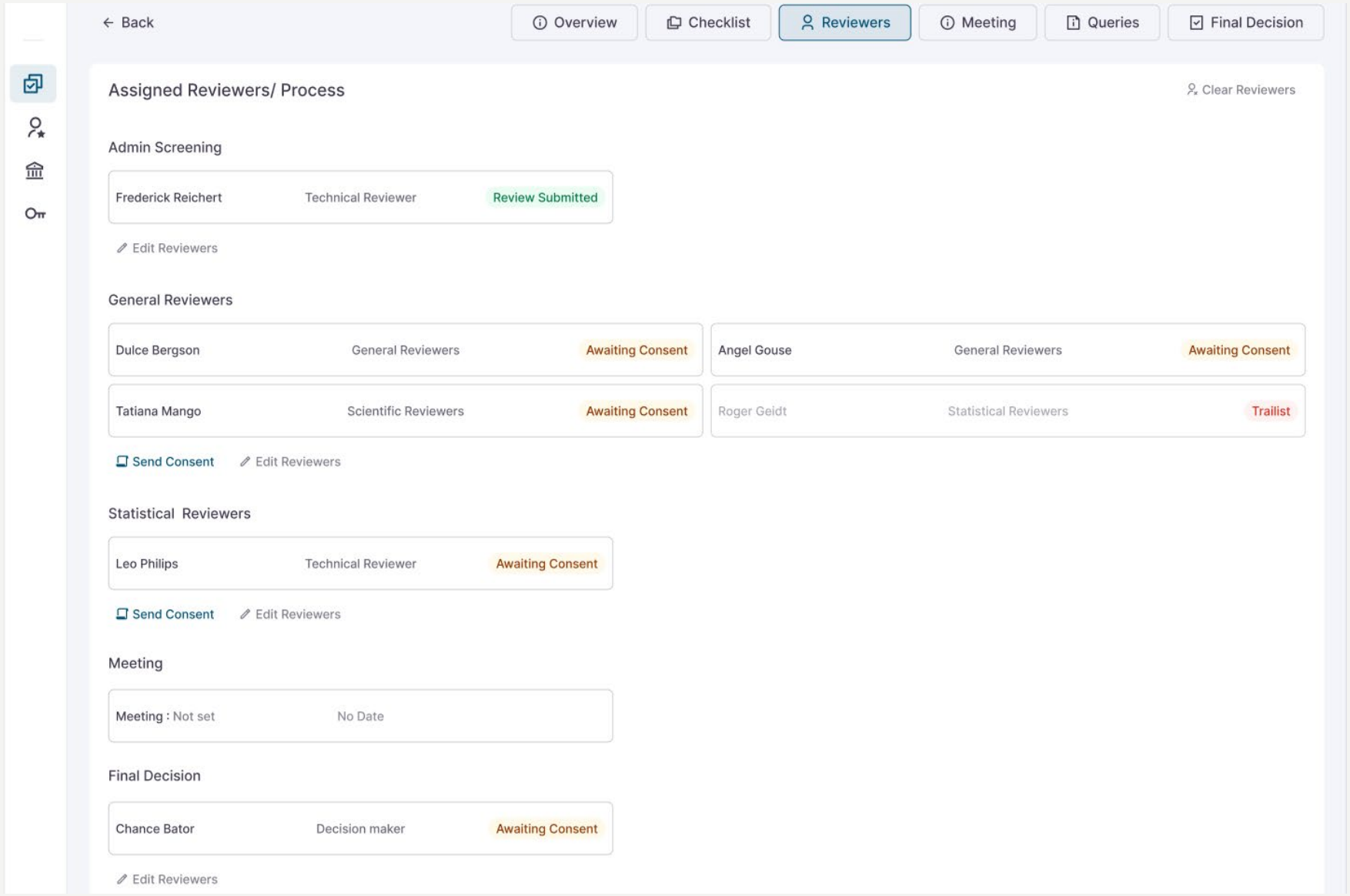

Workflow management has been incorporated for coordinators to easily manage reviewers and reviewing structure of each application if needed.

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

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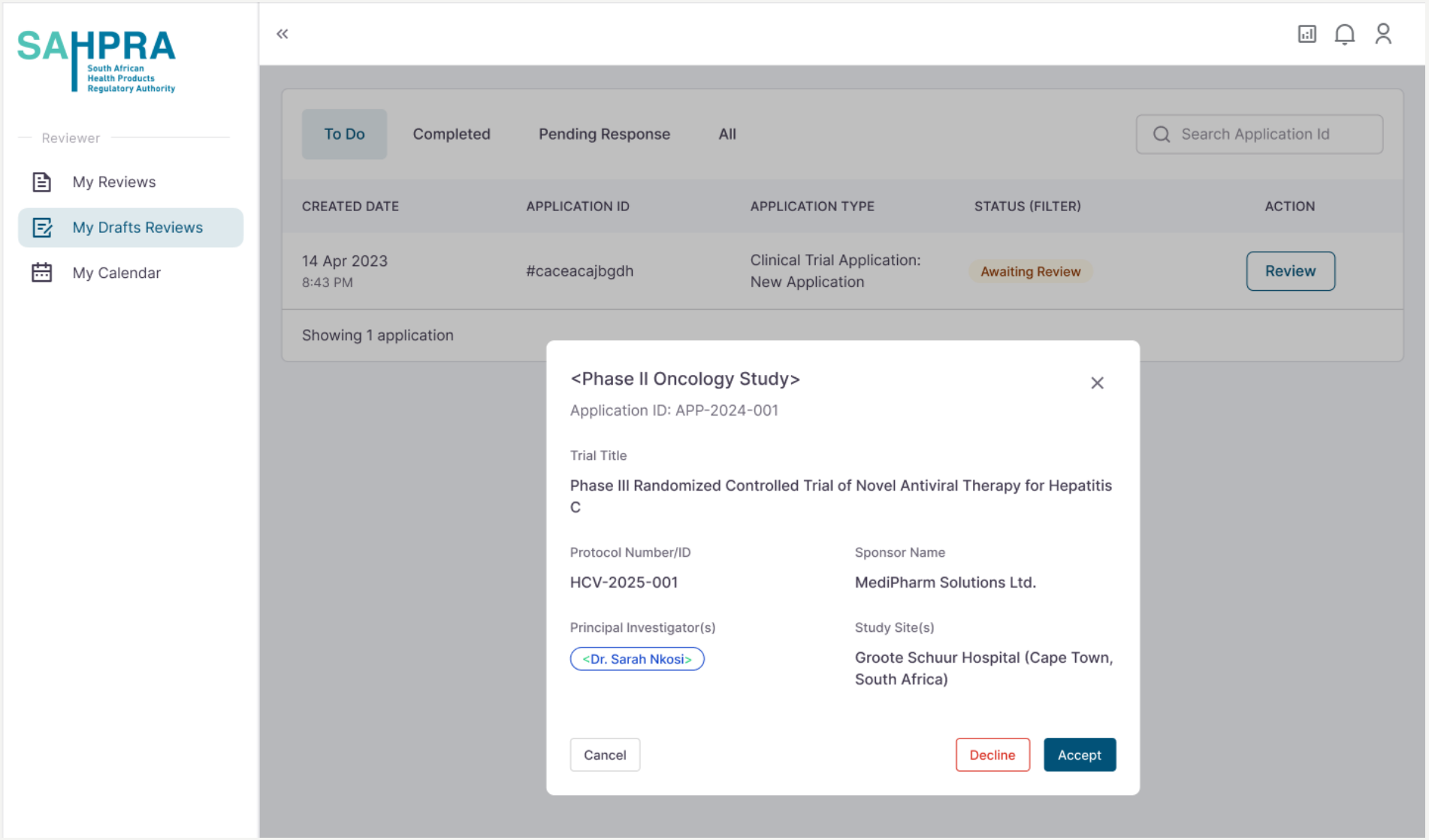

External reviewer users registered on the portal receive a conflict and consent of review declaration when assigned to each application.

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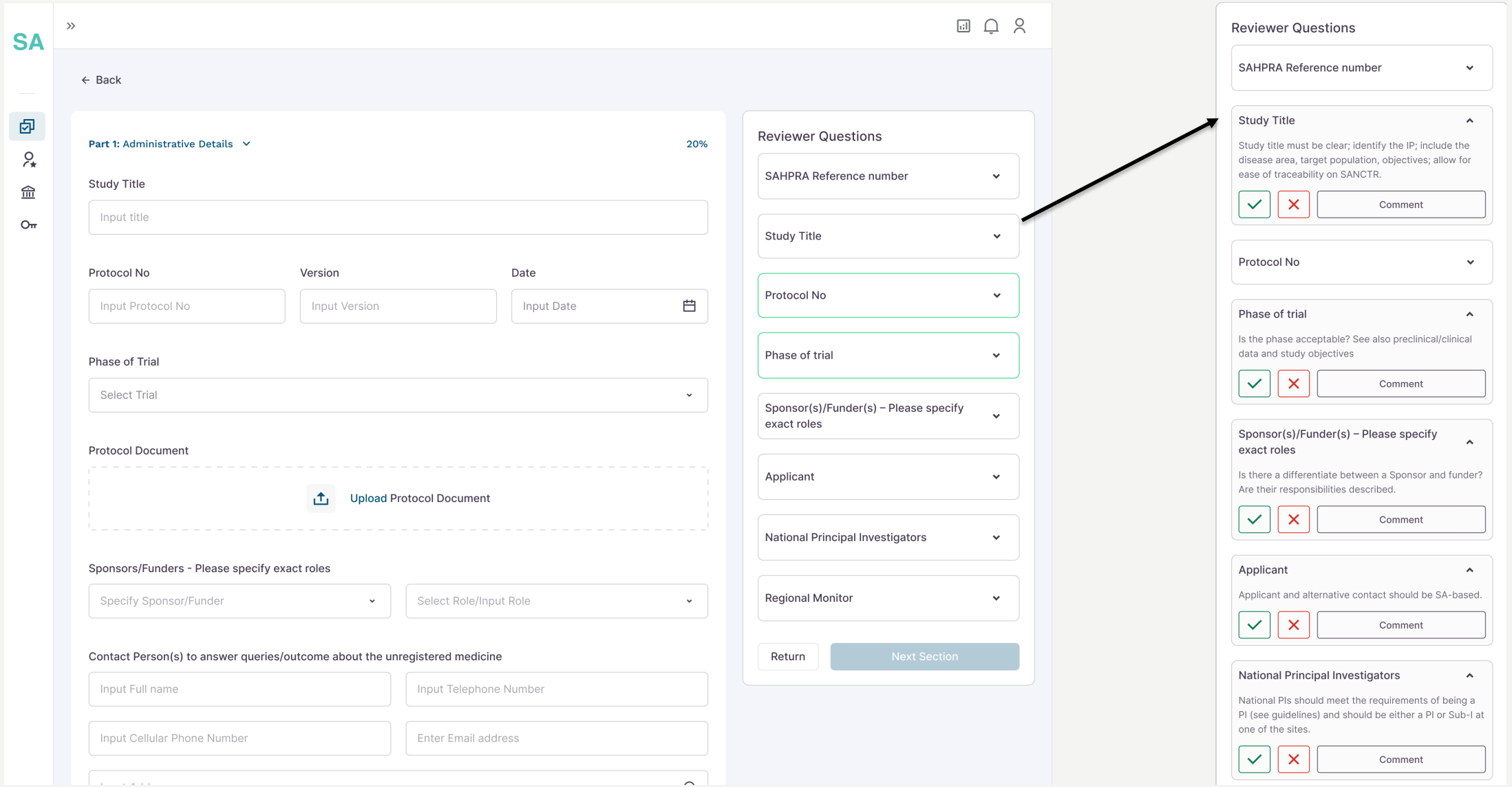
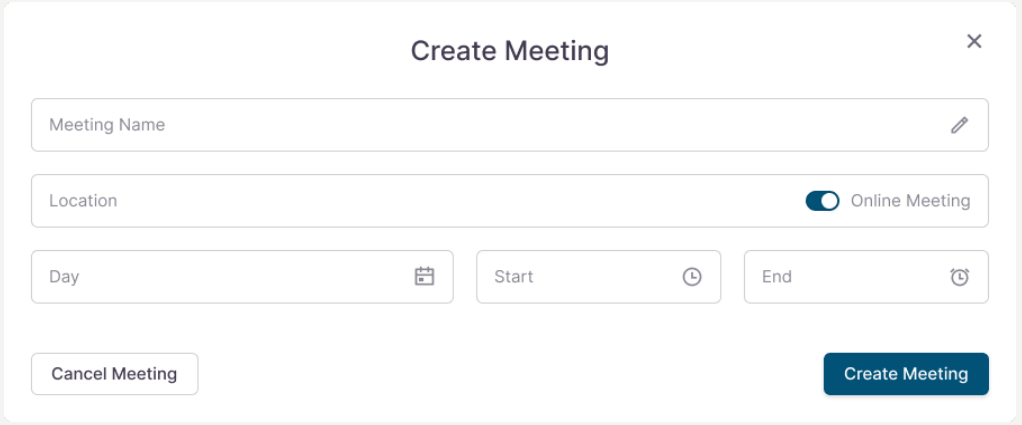
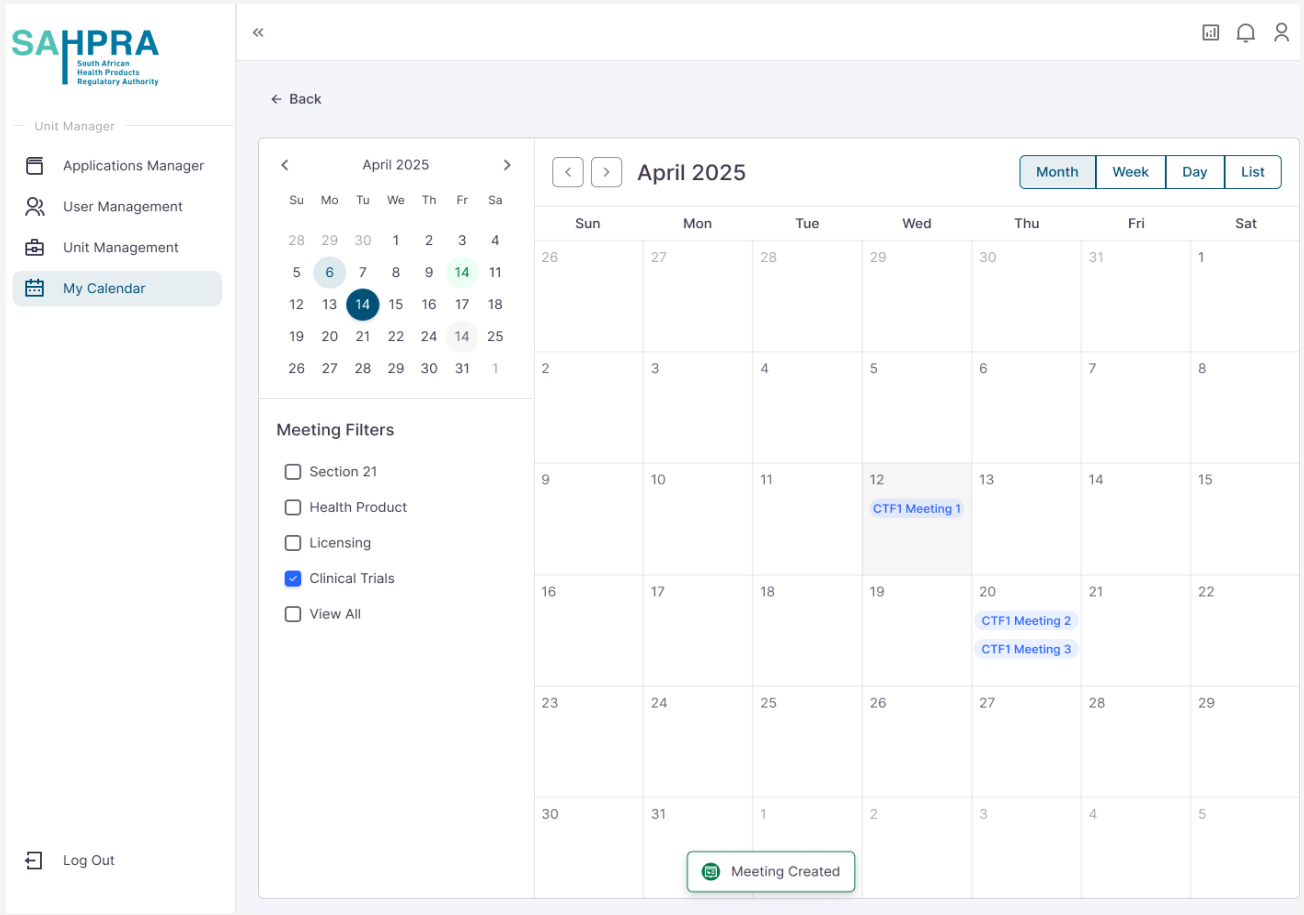


All reviewers receive a full view of the application and custom reviewer question set to guide the review process. Evaluators can direct queries to internal members or applicants and use tools like drag-and-drop for files and response formatting.





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.

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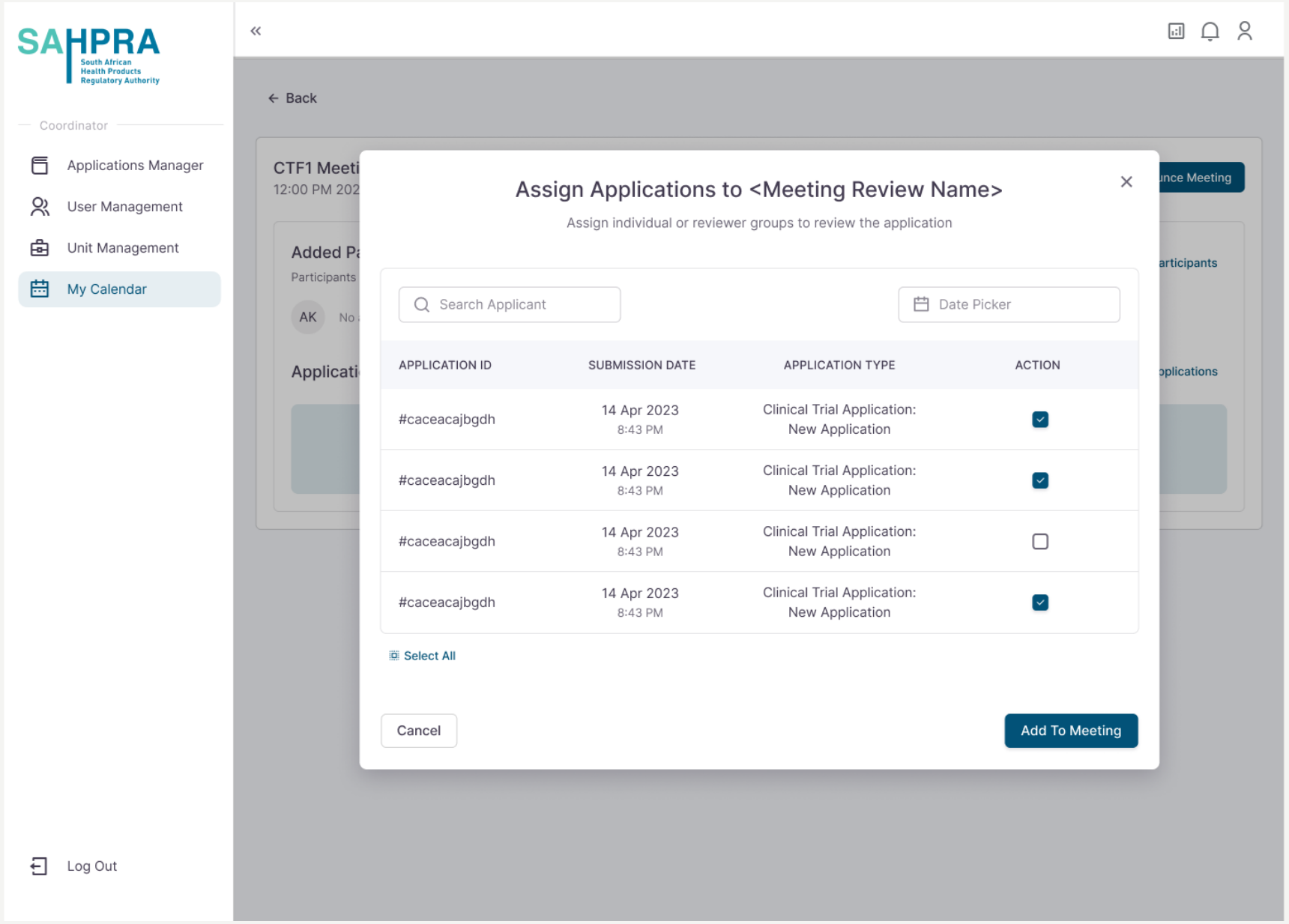

All evaluators involved in the review cycle are automatically included in the meeting, with the option to add or remove members

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

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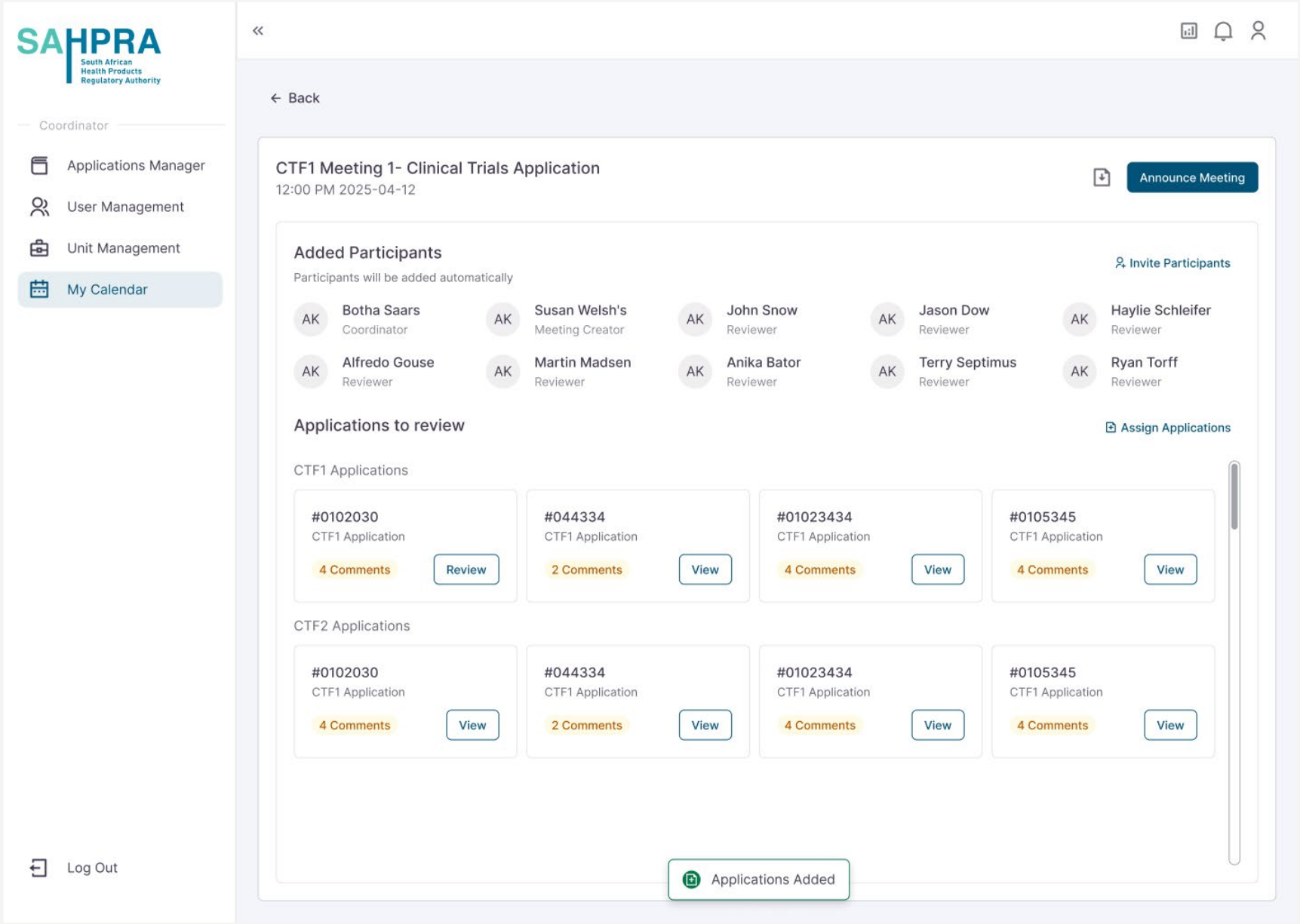

The meeting overview tracks applications due for decision-making.

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

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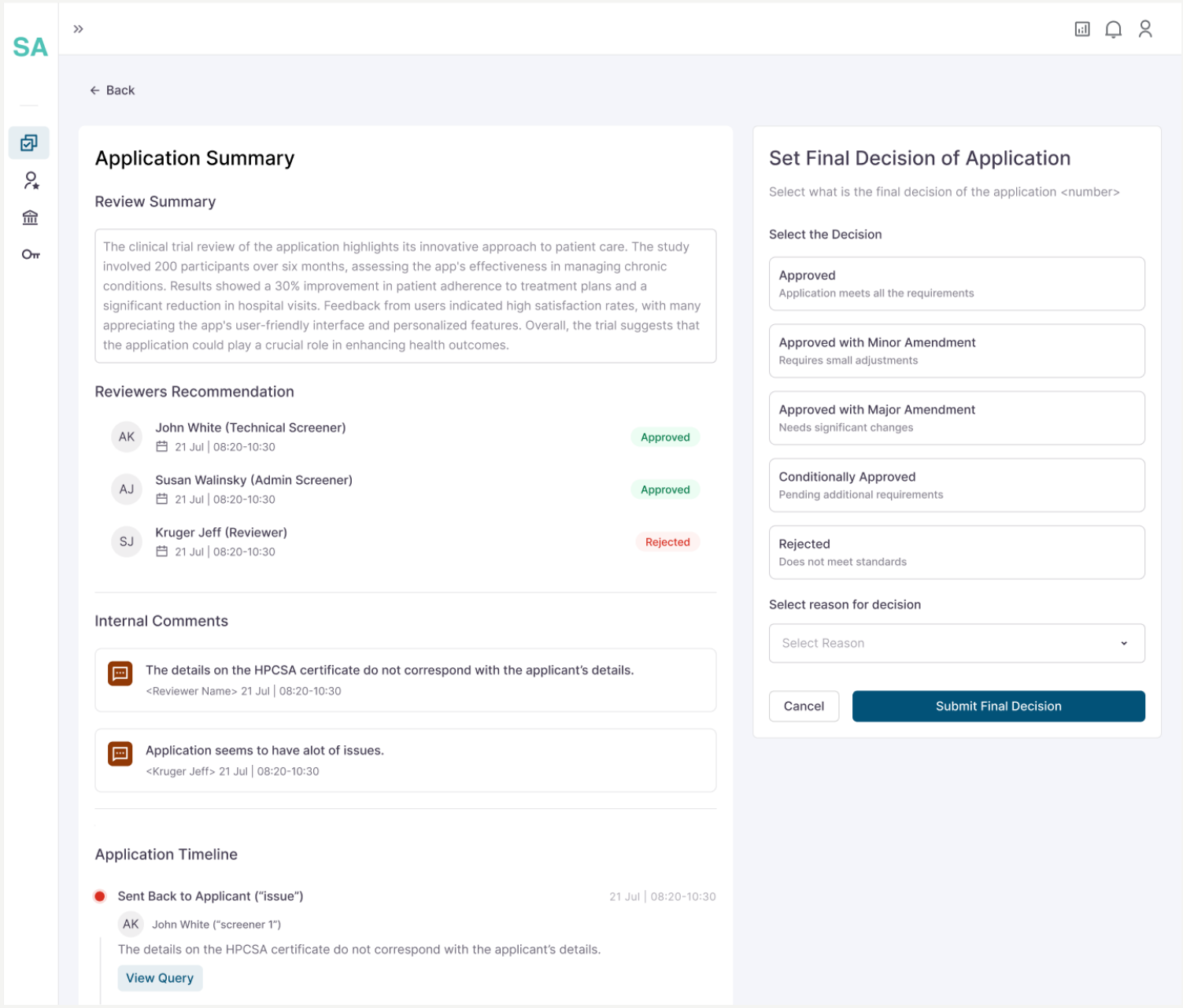

The administrator can issue a final decision with notes for the applicant during the meeting.

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

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LIVE DEMO:

AI ASSISTED CTA REVIEW

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SAHPRA
South African Health Products Regulatory Authority

System Admin

- Legacy Reviewer
- AI Reviewer

Log Out

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
#bfceacajmnal	10 Dec 2024 11:15 AM	bfceacajmnal.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

nuvoteQ foundation

Thank you

Contact Us

Contact us

hello@nuvoteq.foundation

Website

www.nuvoteq.foundation

Address

47 Hazelwood Rd, Hazelwood,
Pretoria, 0081