TRACE
Trial Regulation And Clinical Ethics Optimization

TRACE Project Quarterly Newsletter

December 2025

AFRICA'S NEXT CHAPTER IN ETHICS SYSTEMS OPTIMIZATION

Foreword

The Trial Regulation and Clinical Ethics System Optimization (TRACE) Project is a multi-country initiative launched in 2025 to strengthen clinical trial oversight and ethics systems across Africa. Implemented in Nigeria, Rwanda, Tanzania, and Zimbabwe with expansion to Kenya underway, TRACE aims to improve transparency, predictability, and overall efficiency in clinical trial governance. The project focuses on harmonizing review processes, advancing digital oversight systems, strengthening communication and change-management, developing sustainable financing models, and building institutional and professional capacity.

Across the continent, clinical trial regulatory and ethics systems face persistent challenges: fragmentation of processes, duplication of reviews, limited digital infrastructure, and uneven capacity among regulatory and ethics authorities. These gaps can lead to delayed approvals, reduced confidence among sponsors and researchers, and slower access to lifesaving innovations for African populations. Strengthening these systems is therefore essential to ensure high-quality, ethical, and efficient clinical research that meets both national and global standards.

TRACE is delivered through strong partnerships with AVAREF, the MRCT Center, CIIC-HIN, together with each country's National Ethics Committees and National Regulatory Authorities; the institutions legally responsible for approving and overseeing clinical trials. Working directly with these authorities ensures local leadership, national ownership, and sustainable system improvements. Participating agencies include NHREC and NAFDAC (Nigeria), RNEC and Rwanda FDA (Rwanda), NIMR and TMDA (Tanzania), and MCAZ and MRCZ (Zimbabwe). Supported by the Gates Foundation and coordinated by Garnet Partners, TRACE operates through a Steering Committee, a Core Project Team, and five technical sub-teams covering harmonization, capacity building, communication, digitalization, and financing models. The project aligns with the African Medicines Agency (AMA) framework and World Health Assembly Resolution 75.8 towards accelerated and harmonized continental regulatory environment that reduces duplication, improves review quality, and accelerates access to safe and effective health products across Africa.

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WHO: World Health Organization
AVAREF: African Vaccine Regulatory Forum
The MRCT Center: The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard.
NHREC: National Health Research Ethics Committee (Nigeria).
NAFDAC: National Agency for Food and Drug Administration and Control (Nigeria).
NIMR: National Institute for Medical Research (Tanzania).
TMDA: Tanzania Medicines and Medical Devices Authority.
MCAZ: Medicines Control Authority of Zimbabwe.
MRCZ: Medical Research Council of Zimbabwe.
CIIC-HIN: Center for Impact, Innovation and Capacity Building for Health Information Systems and Nutrition (Rwanda).
RNEC: Rwanda National Research Ethics Committee.
Rwanda FDA: Rwanda Food and Drugs Authority

RWANDA: TRACE HOSTS COUNTRY SCOPING TO STRENGTHEN ETHICS OVERSIGHT

TRACE PROJECT SCOPING MISSION IN RWANDA

The TRACE project scoping mission was held in Kigali on 13 December 2024 at Hôtel des Mille Collines, marking a key step toward strengthening Rwanda's clinical trial regulatory and ethics systems. The meeting brought together representatives from The Gates Foundation, Ministry of Health and RBC, Rwanda FDA, RNEC, NCSA, Garnet Partners, CIIC-HIN, Institutional Review Boards (IRBs), selected district hospitals, academic partners and stakeholders that each play a crucial role in Rwanda's clinical trial oversight, ethical review, regulatory decision-making, and research implementation.

The meeting participants emphasized the need for a coordinated national approach to strengthen ethics oversight through mentorship, training, and evidence-based tools. Dr. David Mukanga from the Gates Foundation outlined the objectives of the scoping mission, including the importance of improved transparency, efficiency, and predictability in ethics review through capacity bulding, fincancial suitainability communication, digital enhancement managed by the National ethics committees.

Rwanda FDA's representative, Dr. Alphonse Ndayambaje presented ongoing progress toward streamlined clinical trial approvals through the national digital portal (IRIMS), while RNEC leadership highlighted Rwanda's achievement of accelerating ethics reviews timelines and the country's commitment to aligning with continental and international best practices. Following the mission, stakeholders endorsed the development of a national country plan which was subsequently submitted in March, 2025.

ADVANCING COORDINATION AND NEXT STEPS

KIGALI - JULY 29-31, 2025

In July 2025, the TRACE Core Team met in Kigali. The three-day in-person meeting delivered a unified roadmap for strengthening clinical trial oversight through harmonized ethics and regulatory systems, enhanced digital transformation, and sustainable financing models.

Key outcomes of this meeting were:

- Agreement on next steps for a registration, accreditation and certification framework for Institutional Review boards (IRBs).
- Progress on a harmonized training curriculum for NECs, coordinated by MRCT.
- Alignment on digital transformation priorities, including user requirements and next steps for enhancing national platforms.
- Building communication and change management across the selected countries.

The countries reaffirmed their commitment to TRACE's goals, emphasizing peer learning, proactive communication, and engagement with continental efforts such as AVAREF and the objectives of the African Medicines Agency (AMA). As the project advances, TRACE enters a critical implementation phase focused on capacity building, digital transformation, and the strengthening of sustainable and harmonized ethics and regulatory governance systems in participating countries.

TRACE Core Team members: Participating Countries, The MRCT Center, Garnet Partners,
CIIC-HIN, AVAREF and Gates Foundation

IRIMS: Integrated Regulatory Information Management System

NCSA: National Cyber Security Authority

RBC: Rwanda Biomedical Centre

NIGERIA: STRENGTHENING OVERSIGHT THROUGH THE TRACE MISSION

ABUJA – MAY 5, 2025

Left to Right - Dr. Collins Mitambo (Garnet Partners), Prof. Barbara Bierer (The MRCT Center), Dr. Iziaq Adekunle Salako (Minister of State for Health), Dr. Lolade Adeyemi (Special Advisor to the Minister of State on Research and Innovation)

NIGERIA STEPS UP ETHICS OVERSIGHT WITH TRACE PROJECT VISIT

Nigeria has reaffirmed its commitment to ethical and transparent clinical research through the TRACE mission held in Abuja. The mission brought together the TRACE team and the NHREC as well as Institutional and local committees to strengthen clinical trial oversight. Stakeholders explored the potential measures to improve coordination and financial sustainability, including proposed ethics application fees across different research categories to fund review operations. Stakeholders also discussed the use of WHO Ethics Committee Benchmarking tools to support continuous quality improvement and strengthening ethics governance over time. The Honourable Minister of State for Health and Social Welfare, Dr. Iziaq Adekunle Salako endorsed the initiative, emphasizing the need for credible and ethical research.

ADVANCING DIGITAL ETHICS AND RESEARCH GOVERNANCE

Nigeria is embracing a new era of digital innovation in clinical research oversight through the collaborative efforts of the TRACE Project. In partnership with NHREC, the TRACE mission team supported the capacity building of the ethics committee members for using the platform (NHREC E-Portal system), designed to digitize ethics review processes and streamline research protocol submissions.

The successful rollout of the NHREC E-Portal and subsequent training of ethics reviewers have demonstrated Nigeria's commitment to advancing digital ethics systems. These reforms not only enhance the efficiency of research oversight but also contribute to TRACE's wider mission of empowering African countries to build resilient, transparent, and harmonized research ethics frameworks that uphold global standards.

More than 60 ethics committee members were trained on the newly developed NHREC E-Portal system for digital protocol submission and review processes, marking a major step toward efficient and standardized ethics processes nationwide.

TANZANIA: DRIVING EFFICIENCY THROUGH ETHICS AND REGULATORY SYNERGY

DAR ES SALAAM - JANUARY 28, 2025

Marcellina Kisanko Mhando (NIMR), Dr. Collins Mitambo (Garnet Partners), Ms Dina Ngaka (NIMR), Dr Obadia Bishoge (NIMR)

STRENGTHENING CLINICAL RESEARCH GOVERNANCE - INSIGHTS FROM THE TRACE SCOPING MISSION

A scoping mission in Tanzania has provided critical insights into the country's national ethics systems, paving the way for stronger regulatory oversight and collaboration in clinical trials. Held from the 21 to 24 January 2025, the mission engaged key institutions including the NIMR and the TMDA. The meeting aimed to assess Tanzania's ethics framework, identify gaps, and explore opportunities, which focuses on transparency, predictability, and efficiency in clinical trial oversight.

Despite these advances, challenges remain, including limited resources and training for ethics committee members, delays in review processes, and the need to strengthen digital systems.

Recommendations from the scoping mission included the development of a joint project plan by NIMR and TMDA, appointing focal persons, and enhancing the National Research Ethics Information Management System (NREIMS) to manage amendments and serious adverse events. Officials emphasized that improving coordination between NIMR and TMDA will enhance efficiency, reduce delays, and ensure compliance with international research ethics standards.

ZIMBABWE: MODERNISING MEDICAL RESEARCH FRAMEWORK AMID DIGITAL TRANSFORMATION

HARARE – JUNE 19 , 2025

Dr. Collins Mitambo (Garnet Partners) with The MRCT Center, MRCZ and MCAZ Teams

Zimbabwe is modernizing its medical research governance and accelerating digital ethics review systems after decades under outdated regulations. The MRCZ, established in 1974 under the Rhodesian Government Notice 225, has operated under a legal framework that has remained unchanged for over 50 years. In response to the growing complexity of health research driven by HIV, TB, and emerging health challenges the Ministry of Health and Child Care, in collaboration with MRCZ, initiated consultations to draft a new Medical Research Bill to modernize oversight and promote innovation.

DIGITAL ETHICS REVIEW SYSTEM UNDER THE TRACE PROJECT: A GAME-CHANGER

In parallel with legislative reforms, the TRACE Zimbabwe initiative is spearheading the development of a digital ethics review system to streamline clinical trial approvals. The proposed platform will integrate workflows between MRCZ and the MCAZ to replace fragmented, manual processes and will include:

- End-to-end review tracking for clinical trials.
- Reduced reliance on proprietary code and costly external consultants.
- Enhanced transparency through governance and cost-sharing models.

NEXT STEPS:

The roadmap includes finalizing the Bill, accelerating digitalization, and conducting capacity-building sessions for ethics committees. Stakeholder engagement will continue to ensure alignment with global best practices and Zimbabwe's national priorities. As Prof. Tendayi Kureya of MRCZ noted during the TRACE update, "Modernizing our systems and legal frameworks is not just a compliance issue; it is about enabling ethical, efficient, and innovative research that benefits our communities."

TRACE PROJECT BENCHMARKS DIGITAL ETHICS PLATFORM

KAMPALA - JULY 24 - 26, 2025

Dr. Collins Mitambo (Garnet Partners) with Ms Robin Alwato and Mr. Collins Mwesigwa (UNCST)

TRACE DIGITAL BENCHMARKING EFFORTS

TRACE concluded a three-day benchmarking visit to the Uganda National Council for Science and Technology (UNCST), aimed at learning from their pioneering experience in digital ethics and clinical trial oversight. Held from 24-26 July 2025, the mission was led by Mr. Collins Mwesigwa from UNCST and Dr. Collins Mitambo representing TRACE. The discussions focused on how Uganda's digital platform, first introduced in 2020, has transformed the management of clinical trial and research ethics submissions.

During the visit, UNCST shared insights on the functionality, workflow, and technical architecture of its digital system, as well as challenges and lessons learned during implementation. The TRACE team observed a live demonstration of the NRIMS platform, which enables online submissions, tracks application progress, and facilitates communication between regulators, ethics committees, and researchers. Integrated with the National Drug Authority (NDA), the system allows for joint reviews, reducing duplication and improving efficiency. According to UNCST, the platform has significantly reduced paperwork, shortened turnaround times, and strengthened accountability.

Researchers and regulators praised the platform's user-friendly design and its ability to streamline workflows, though challenges remain. Limited integration of online payment systems, occasional server downtime, and the ongoing need for user training were identified as areas for continued improvement. Despite these hurdles, the platform's sustainability is ensured by strong government ownership, internal technical capacity, and phased upgrades supported by national budget allocations and plans to integrate into broader e-government infrastructure.

LESSONS AND FUTURE DIRECTIONS

The TRACE delegation commended UNCST for its leadership and expressed interest in exploring regional interoperability by aligning Uganda's experience with initiatives such as AVAREF. The lessons learned from Uganda's successful rollout will guide TRACE in designing similar systems across its partner countries.

NRIMS: National Research Information Management System

KENYA: TRACE PROJECT EXPLORES EXPANSION INTO KENYA

NAIROBI – JULY 10-12, 2025

Dr. Christabel Khaemba, Gabriel Leshan, Dr. Muthoni Kangai, Dr. Rosemary Njogu, Kibet Kisorio, Dr. Tuitai Lydia, Peter Kwena, Dr. Collins Mitambo

EXPANDING TRACE INTO KENYA

The TRACE Project is set to expand into Kenya, following initial consultations with national stakeholders on integrating the country into the initiative to strengthen clinical trial oversight and ethics systems. In July 2025, a meeting was convened in Nairobi at the Pharmacy and Poisons Board (PPB), where TRACE representatives engaged with senior officials from Kenya's regulatory and ethics bodies to discuss goals, collaborative strategies, and future actions. Key Kenyan institutions set to be engaged include the National Ethics Committee, PPB, National Commission for Science, Technology and Innovation (NACOSTI), 2 IRBs and county-level authorities. As Kenya is being considered for formal inclusion in the project, to ensure clarity and coordination, a virtual stakeholders' meeting was planned to introduce the project and outline project roles.

The outcomes of the meeting were to develop detailed work packages and a costed concept note with key institutions as stated above for alignment with the overall TRACE project.

STRENGTHENING OVERSIGHT AND FUTURE COLLABORATION

The meeting underscored Kenya's commitment to reviewing legal and regulatory frameworks to reduce duplication and align with global best practices, building digital platforms to manage ethics and regulatory submissions, and enhancing capacity development through partnerships with The MRCT Center and AVAREF. Stakeholders agreed that community engagement and benefit sharing must remain central to research implementation. Kenya will begin with a national needs assessment to map current ethics systems and identify priorities, followed by WHO Ethics Committee Benchmarking exercises to guide future collaboration. With Kenya's inclusion, TRACE will extend its reach across East Africa further advancing efforts toward a harmonized, efficient, and digitalized clinical trial ethics ecosystem.

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