

SCALING UP CAPACITY TO SUPPORT CONDUCT OF CLINICAL TRIALS IN THE EAST AFRICAN COMMUNITY (SCALE-IT)



Prof. Pauline Byakika

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Remarks From the PI

“It gives me great pleasure to welcome you to the second issue of the SCALE-IT Newsletter. This edition comes at an important moment in the life of the project as we reflect on the progress made, celebrate the milestones achieved, and prepare for the successful close-out of the initiative.

Since its inception, SCALE-IT has been driven by a clear vision: to strengthen systems, and build capacity for the conduct of clinical trials in the East African Region. Over the course of implementation, we have had the privilege of working alongside dedicated partners, institutions, research regulators and researchers whose commitment has been central to our achievements.

I am proud to note that the project has made significant contributions in areas of training in Emerging and Complex Study Designs, Clinical Trial Monitoring and Personal Effectiveness and Leadership skills. Through these efforts, SCALE-IT has not only delivered on its planned outputs but has also laid foundations that will continue to benefit institutions, and communities beyond the formal project period. This newsletter highlights some of the progress registered since our last issue, shares stories of change

from the field, and outlines the final activities. I encourage you to read through and celebrate with us the collective efforts that have made this journey meaningful.

As we approach project closure, our focus is on ensuring documentation of lessons learned and dissemination of achievements, as we look to the future for additional support to strengthen and ensure sustainability of the gains made. Closure is not the end of impact; rather, it marks the beginning of a new phase where the knowledge, tools, partnerships, and strengthened systems developed through SCALE-IT continue to serve the people and institutions for whom they were intended.

On behalf of the project leadership team, I extend sincere appreciation to EDCTP3 Joint Undertaking who funded this work (EDCTP3, Grant ID: 101103332) implementing partners, participating institutions, communities, and every member of the SCALE-IT team. Your support, trust, and dedication have been invaluable.

As we move towards the final chapter of SCALE-IT, we do so with pride in what has been accomplished and optimism about the lasting legacy of this work.

Thank you for walking this journey with us. ”

Introductory remarks



Dear Readers,
With this final issue of the SCALE-IT Newsletter, I warmly invite you to reflect on the journey we have undertaken to strengthen research ethics and regulatory capacity across the East African Community (EAC). What began

as a shared ambition has grown into a regionally connected effort, bringing together partner institutions, regulatory authorities, ethics committees, and a broad network of research stakeholders working in close collaboration.

This edition provides a closing reflection on the collective effort and progress that have defined the SCALE-IT project over the past years. In this final edition, we highlight key milestones achieved during the recent phase of implementation, including the completion of training programmes across

all six EAC partner states, meaningful consortium engagements, and dissemination of project outputs at regional and international platforms. Together, these activities reflect not only progress against planned objectives, but also the strengthening of systems, relationships, and capacity that will continue beyond the life of the project.

We close this chapter with appreciation for all partners and contributors who have been part of the SCALE-IT journey, and we hope this edition provides a meaningful snapshot of the impact we have created together.

We invite you to read on and reflect on the progress, partnerships, and legacy of SCALE-IT.

Belinda Twesigye
Project Assistant, SCALE-IT

About the SCALE-IT Project

Clinical research in East Africa has grown rapidly in recent years, particularly in response to emerging and re-emerging diseases such as HIV, Ebola, and COVID-19. While this growth brings exciting opportunities for scientific discovery, it also highlights the need for stronger systems to ensure that research is conducted ethically, safely, and effectively.

The SCALE-IT project aims to strengthen the capacity of professionals including REC members, NRRA personnel, researchers, clinical trial monitors, research administrators involved in clinical research across the region.

The project is implemented through a regional consortium of partners from across the East African Community, including: Infectious Diseases Institute (IDI), Makerere University, Uganda; Uganda National Drug Authority (NDA); Uganda National Council for Science and Technology (UNCST); Kenya Medical Research

Institute (KEMRI); Ministry of Health, Rwanda; National Institute for Medical Research (NIMR); University of Burundi; Bahr El Ghazal University, South Sudan; East African Health Research Commission (EAHRC), and Mbarara University of Science & Technology (MUST)—the coordinating body for health research within the region and EPICENTRE, France. SCALE-IT is a project funded by the Global Health EDCTP3 Joint Undertaking (EDCTP3, Grant ID: 101103332) and hosted at the Infectious Diseases Institute (IDI) in Uganda.



Program Updates

Tanzania: Training Successfully Conducted at NIMR, Dar es Salaam

A week-long physical training was successfully conducted at the National Institute for Medical Research (NIMR), Dar es Salaam, from 21st to 25th October 2024. The training brought together 85 participants, including NIMR personnel, Research Ethics Committee (REC) members, clinical trial monitors, and researchers.

Participants were trained on emerging and complex study designs, clinical trials monitoring, and Personal Effectiveness and Leadership Skills. The physical training was followed by four weeks of self-paced online learning, concluding with virtual sessions and certification for participants who successfully completed the programme.



Figure 1: Participants and facilitators during the SCALE-IT capacity building training at NIMR, Dar es Salaam, Tanzania.

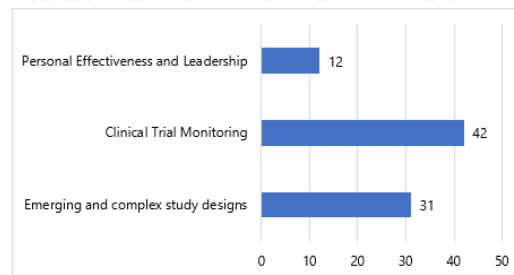


Figure 2: Number of participants that attended the trainings.

Participant evaluations indicated a high level of satisfaction with both the training content and overall organisation of the workshop. The sessions on research study designs in clinical trial monitoring and randomised controlled trials emerged as the most preferred among participants, reflecting the growing interest in practical and complex clinical research methodologies. Participants also expressed strong interest in more frequent refresher trainings, with the majority recommending quarterly sessions to support continuous learning and skills development.

South Sudan: Training Successfully Conducted at the University of Juba, South Sudan

A week-long physical training from 28th October to 1st November 2024 was successfully held at the University of Juba, South Sudan, bringing together 73 participants, including NIMR personnel, Research Ethics Committee (REC) members, and researchers.

Participants were trained on emerging and complex study designs, clinical trials monitoring, and Personal Effectiveness and Leadership Skills. The physical training was followed by four weeks of self-paced online learning, concluding with virtual sessions and certification for participants who successfully completed the programme.



Figure 3: Participants and facilitators during the SCALE-IT capacity building training held at University of Juba, South Sudan

Participant evaluations reflected high levels of satisfaction with both the training content and overall organisation of the workshop, particularly the training venue and facilitation approach. Among the sessions delivered, protocol interpretation emerged as the most preferred topic, followed by statistical principles, research study designs, and randomised controlled trials, highlighting participants' strong interest in practical aspects of clinical research review and oversight. Most participants recommended that refresher trainings be conducted annually to support continued knowledge enhancement and skills development.

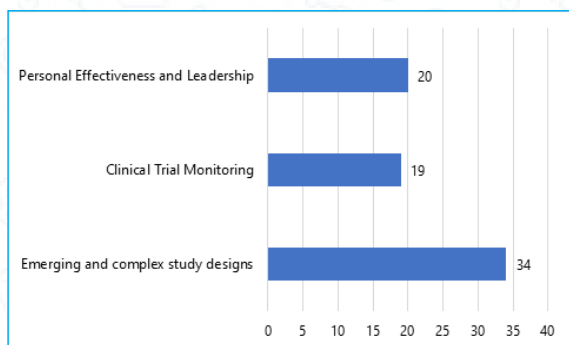


Figure 4: Number of participants that attended the training

Progress meeting with Co-Investigators

Following the successful completion of trainings across the six partner states, members of the SCALE-IT consortium came together for a progress meeting to reflect on the journey thus far and explore the next steps for the project.

The meeting provided an opportunity for partners to celebrate the achievements made in delivering the regional trainings and to share ideas on how the impact of the programme can be expanded. Plans were made to conduct additional training in Southwestern and Eastern Uganda, guided by a needs assessment survey.

Training in South Western and Eastern Uganda

Under the SCALE-IT project, a cross-sectional assessment of 46 Research Ethics Committee (REC) members in South-Western Uganda identified critical gaps in reviewing protocols involving emerging and complex study designs, & vulnerable populations.

Findings from the survey informed, targeted capacity-building training which were delivered to 69 REC members across South Western and Eastern Uganda. These were held at Mbarara University of Science and Technology (27th–31st October) and Mbale Clinical Research Institute (17th–19th November).

The trainings resulted in a measurable improvement in participant knowledge and competencies, with mean assessment scores increasing from 62.7% at pre-test to 82.1% at post-test.

This demonstrates strengthened capacity for high-

quality, timely ethical review of complex research protocols, ultimately supporting more robust research oversight and participant protection.



Figure 5: Participants and facilitators during the training on complex and emerging study designs held at MUST



Figure 6: (L) Provia, IDI delivering a session during the training. (R) Participants and facilitators during the training on complex and emerging study designs held at MCRI, Mbale

Participants appreciated the use of context-relevant examples and interactive discussions, noting that these strengthened their understanding of the ethical and methodological considerations in emerging study designs and research involving vulnerable populations.

Project Outputs and Knowledge Translation

Publications

We have made progress with project communication and visibility outputs that demonstrate the extent of our work to different stakeholders in the EAC.

Thus far, we have drafted 6 manuscripts from the work completed, 4 have been submitted for peer review in prestigious journals, 1 has been accepted for publication and 2 are under co-author review

Published

Amperize et al. *BMC Medical Ethics* (2026) 27:70
<https://doi.org/10.1186/s12910-026-01418-2>

BMC Medical Ethics

RESEARCH

Open Access

Strengthening research regulatory capacity in the East African community: a multi-country training program on emerging and complex study designs



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1. The SCALE-IT consortium recently published a paper in BMC Medical Ethics titled: "Strengthening research regulatory capacity in the East African Community: a multi-country training

program on emerging and complex study designs." The publication highlights the project's work in delivering a blended training programme across six EAC countries, demonstrating significant improvements in participants' knowledge and capacity to review and oversee clinical research with complex and emerging study designs. Read the full article here.

Manuscripts Under peer review

1. "Strengthening Capacity for Clinical Trial Monitoring in the East African Community: A Multi-Country Training Programme" submitted to BMC Medical education, April 2026
2. Strengthening Leadership and Personal Effectiveness Among Research Regulatory and Ethics Committee Professionals in the East African Community: A Multi-Country Training Programme" submitted to Discover Health Systems, February 2026
3. "Research Regulation for Clinical Trials in the East African Community: A desk review" submitted to Journal of Empirical Research on Human Research Ethics, January 2026

Manuscripts under co-author review

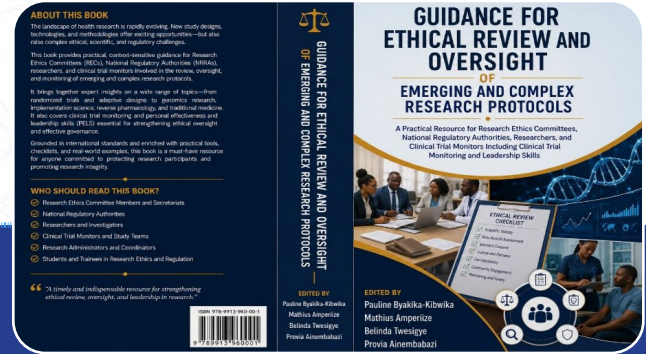
1. Building capacity of research ethics committee members in South-Western and Eastern Uganda: a needs assessment and targeted training on emerging and complex study designs and vulnerable populations.
2. Strengthening communication among research administrators: a needs assessment and targeted peer group intervention at the Infectious Diseases Institute, Kampala, Uganda



The SCALE-IT Capacity-Building Handbook

The project is currently developing a book that will serve as a refresher resource for Research Ethics Committee (REC) and National Regulatory Authority (NRA) members. It will cover key areas including the review of emerging and complex study designs, clinical trial monitoring, and personal effectiveness and leadership skills.

The book will be published in both print and digital formats to ensure broad accessibility and visibility among stakeholders.



12th EDCTP Forum

The SCALE-IT project was proudly represented at the Twelfth EDCTP Forum on **15–20 June 2025**, at the Kigali Convention Centre in Kigali where Prof. Pauline Byakika-Kibwika and Provia Ainembabazi showcased the project's work on strengthening capacity for clinical trials in East Africa.

During the session, the two demonstrated what a strong and effective mentor–mentee relationship should look like in practice. Prof. Pauline Byakika-Kibwika introduced Ms Provia Ainembabazi as her mentee, provided an overview of the presentation, and then handed over to her to lead the session.

Participants warmly applauded the mentorship pair and commended the approach as a model of best practice in mentorship, reflecting the SCALE-IT

project's commitment not only to research capacity strengthening, but also to leadership development and succession building.

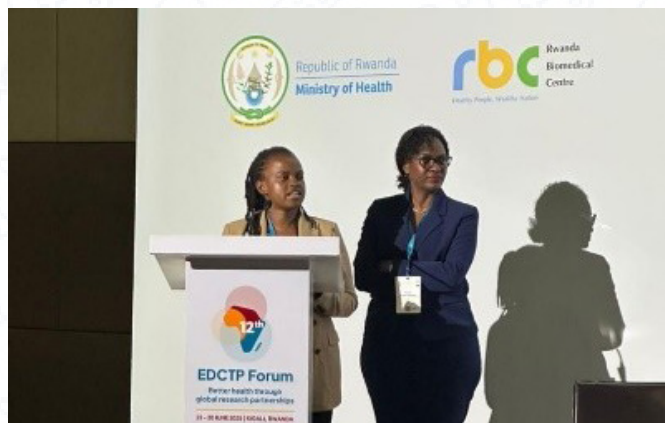
The team shared insights from the project's training programmes and regional collaboration efforts, highlighting the importance of building strong systems for ethical review and clinical trial oversight across the region.

In addition, they participated in a high-level panel discussion on "How do we build strong networks for disease surveillance, epidemic response, and clinical research?". The discussion emphasized the critical role of cross-border collaboration and coordinated regional approaches in strengthening epidemic preparedness and response.



Figure 7: SCALE-IT team participating in a high-level panel discussion on strengthening regional collaboration for epidemic response and clinical research

Figure 8: Prof. Pauline Byakika-Kibwika and Provia Ainembabazi presenting SCALE-IT at the Global Health EDCTP3 Forum 2025, Kigali.



SCALE-IT PROJECT SCALING UP CAPACITY TO SUPPORT CONDUCT OF CLINICAL TRIALS IN THE EAST AFRICAN COMMUNITY (SCALE-IT).

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Presented at the 12th EDCTP Forum
17 June 2025

The Administrator's Peer Group

An important outcome of the Personal Effectiveness and Leadership Skills training has been the institutionalisation of the Administrators' Peer Group (APG) at the Infectious Diseases Institute. The APG is now an operational platform that promotes peer learning, knowledge sharing, and continuous professional development among research administrators. It brings together administrators through monthly engagements and virtual platforms, including WhatsApp, email, and Microsoft Teams, creating a sustained space for collaboration, problem-solving, and strengthening research administration practice within the institute.

Meet the Project Team



Prof. Pauline Byakika Kibwika, Vice Chancellor, Mbarara University of Science and Technology (MUST) & SCALE-IT Project Scientific Lead. Responsible for scientific governance and leadership of the SCALE-IT project.



Mathius Amperize, SCALE-IT Project Officer, Infectious Diseases Institute (IDI). Supports the coordination, implementation, and monitoring of project activities.



Belinda Twesigye, SCALE-IT Project Assistant, Infectious Diseases Institute (IDI). Handles project administrative functions.



Ainembabazi Provia, Clinical Trials Manager & SCALE-IT Project Co-Investigator, Infectious Diseases Institute (IDI). Coordinates Clinical Trials Unit activities.



Dr. Barbara Castelnovo, Senior Research Scientist; Research Ethics Committee Secretary & SCALE-IT Project Co-Investigator, Infectious Diseases Institute (IDI).



Dr. Vincent Mutabazi, Co-Investigator & SCALE-IT Project Focal Person, Ministry of Health, Rwanda program.



Linda Namara, SCALE-IT eLearning Team Specialist, Infectious Diseases Institute (IDI). Designs and delivers digital training solutions.



Dr. Stephen Okoboi, Ag. Head of Research Department & SCALE-IT Project Co-Investigator, Infectious Diseases Institute. Oversees regulatory, ethical, and monitoring frameworks.



Soazic Gardais, Clinical Research Associate, Epicentre, France & SCALE-IT Project Co-Investigator



Walter Arinaitwe, former Deputy Head of Training at the Infectious Diseases Institute (IDI) and Co-Investigator of the SCALE-IT Project. Assisted in development of e-learning modules and organisation of blended learning.



Dr. Steve Wandiga, Kenya Medical Research Institute, Centre for Global Health Research; SCALE-IT Project Co-Investigator & Focal Person IT Training Programme, Kenya.



Kidole Jeremiah, National Institute for Medical Research, Tanzania & SCALE-IT Co-Investigator & Focal Person, SCALE-IT Training Programme, Tanzania.



Dr. Ndagire Byomire Helen, Director of Product Safety, National Drug Authority (NDA) & Co-Investigator, SCALE-IT Project, Uganda.



Dr. Novat Twungubumwe, Deputy Executive Secretary, East African Health Research Commission (EAHRC) & Co-Investigator and Focal Person for EAC partner state National Research Regulatory Authorities (NRRAs).



Beth Mutumba, Science Officer, Uganda National Council for Science and Technology (UNCST), SCALE-IT Project Co-Investigator & Focal Person, UNCST.



Dr. Lina Sara Mathew, Bahr El Ghazal University, South Sudan & SCALE-IT Project Co-Investigator & Focal Person, IT Training Programme, South Sudan.



Dr. Ramadhan Nyandwi, University of Burundi, Faculty of Medicine & SCALE-IT Co-Investigator & Focal Person. Training programme, Burundi.



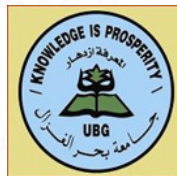
Dr. Hellen Opolot, Assistant Executive Secretary & Head of Directorate of Research Management & Quality Assurance, UNCST & SCALE-IT Co-Investigator, IT Training Programme.



Kenneth Mulindwa, SCALE-IT Project Communication Officer, Infectious Diseases Institute



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Pictorial



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