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CASE STUDY

REVISED The ASCEND Project (2020-2023): Strengthening clinical trial ethics review and pharmacovigilance capacity in Tanzania mainland and Zanzibar

[version 2; peer review: 1 approved, 1 approved with reservations]

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Abstract

Background

Clinical trials and related health research in sub-Saharan Africa continue to expand in volume and complexity, increasing the need for strong and responsive research ethics oversight, regulatory reviews, and pharmacovigilance systems. The ASCEND project was implemented in Tanzania Mainland and Zanzibar from November 2020 to December 2023 to support these functions through capacity development and system-strengthening activities. Objective To describe the implementation approach and documented outputs of the ASCEND project as a case study focusing on operational processes that may inform similar initiatives. Approach We compiled and synthesized project documentation produced during implementation, including training materials, activity reports, system development records, and consortium deliverables. We summarized implementation components and verified output counts across records. Outputs The project developed and delivered training packages for clinical trial protocol review and Good Clinical Practice

Open Peer Review

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inspection and trained 30 clinical trial protocol reviewers or assessors and 25 inspectors, including on-the-job inspection exposure for Zanzibar Food and Drug Authority staff. Assessors' mean test scores rose from 61 to 80 out of 100. Nineteen early- and mid-career researchers and 50 trainers from institutional ethics committees were trained on research ethics and clinical trial-related topics. Digital tools from an earlier project were operationalized or upgraded to support ethics review workflows and safety reporting, including an online serious adverse event reporting module and linked electronic submission and review workflows. A Pharmacovigilance Community Engagement Model was developed and applied to sensitization activities in both settings. Networking forums were convened to support interactions among researchers, institutional review boards, and regulators.

Conclusion

This case study documents the implementation of a multicomponent capacity development initiative that combines training, digital tools, community engagement, and stakeholder networking. The experience highlights practical considerations for similar programs, including institutional ownership, integration of electronic tools into routine workflows, and early planning for sustainability within existing structures.

Plain language summary

Clinical trials help identify better medicines and vaccines, but they must be reviewed and monitored to protect participants. This includes an ethics review, checks that trials follow good practice, and pharmacovigilance, meaning the monitoring and reporting of side effects and other safety problems from medicines and vaccines. The ASCEND project supported these functions in Tanzania Mainland and Zanzibar between 2020 and 2023 by training ethics reviewers and regulators, improving online systems for submitting and reviewing trial documents, strengthening systems for reporting serious side effects during trials, and working with communities to increase awareness of safety reporting. This study summarizes what was implemented and the outputs achieved based on routine project records. This experience highlights the practical steps that other countries or institutions can adapt to, for example, working through existing institutions, training trainers to extend skills, and integrating digital tools into routine workflows.

Keywords

clinical research ethics, pharmacovigilance, capacity building, Tanzania, Zanzibar, EDCTP



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REVISED **Amendments from Version 1**

In response to the reviewers' comments, we have revised the manuscript to distinguish more clearly between project outputs and demonstrated capacity gains. Table 1 has been expanded to show, for each project component, the documented output, early adoption indicators, outcomes not measured, and proposed future evaluation metrics. The Results now report measured learning outcomes for the clinical trial protocol assessor cohort, drawn from a published training needs assessment and pre- and post-training evaluation, together with early system use indicators, including serious adverse event reports submitted through the online module and clinical trial protocols processed in Zanzibar. A new paragraph summarises user and stakeholder feedback recorded in project documentation, including a REIMS user survey, user acceptance testing and stakeholder forums, and the Methods have been corrected to describe these feedback mechanisms accurately.

We have added an account of project governance and institutional roles, clarified post-grant sustainability arrangements for the electronic systems and training resources, and revised the Discussion to separate transferable elements of the approach from context-specific enabling conditions. The limitations now state that review turnaround times and learning outcomes for other training cohorts were not assessed, and recommend that future projects define such indicators at baseline.

We have clarified that the electronic ethics review and adverse drug reaction reporting systems and the ethics curriculum were first developed under the earlier SMERT project, corrected the name of the Pharmacovigilance Community Engagement Model, clarified the community sensitisation figures and the accreditation of the bioethics course, and defined all abbreviations on first use. The Abstract and plain language summary have been revised accordingly.

The Data Availability statement now specifies the availability of each project material. The Pharmacovigilance Community Engagement Model is openly available on Zenodo and is cited as Extended data. Two new references have been added.

Any further responses from the reviewers can be found at the end of the article

Introduction

The increasing number and complexity of health research conducted in sub-Saharan Africa continue to drive the demand for robust research ethics oversight, efficient and consistent regulatory review, and functional pharmacovigilance systems.[1] Public health emergencies, outbreaks, and evolving technologies have increased the need for regulatory bodies and ethics committees to adapt their processes while maintaining the protection of participants and quality standards in clinical trials.[2]

Despite bearing approximately 25% of the global disease burden, Africa accounts for only 0.02% of the clinical trials registered globally, even though the region represents approximately 15% of the world's population.[3] Recent analyses highlight persistent under-representation: the 2024 Access to Medicine Index found that only 27.5% of late-stage research and development projects from 20 leading pharmaceutical companies included one or more African countries, and just 16 of 80 candidate medicines targeting priority diseases were tested in African settings.[4] Common challenges facing clinical trial regulatory authorities and ethics committees in the region include limited funding, staffing constraints, infrastructure gaps, and shortages of specialized expertise. These constraints may contribute to delays in protocol review, reduce the frequency and quality of inspection and monitoring, and limit the capacity to manage safety reporting and data governance as the volume of clinical research increases.[2]

Several continental and regional initiatives support harmonization and shared learning in clinical trial oversight. The African Vaccine Regulatory Forum (AVAREF) facilitates joint reviews, capacity building, and emergency preparedness,[5] while the African Medicines Agency (AMA) is being established to coordinate regulatory harmonization across the continent.[6] The African Medicines Regulatory Harmonization (AMRH) initiative, led by the African Union Development Agency (AUDA-NEPAD), has advanced progress toward the African Medicines Agency (AMA), with milestones such as the 2025 Memorandum of Understanding among World Health Organization (WHO) Maturity Level 3 National Regulatory Authorities to foster collaboration and reliance.[7–9] In Tanzania, strengthening ethics and regulatory systems has been supported through partnerships among regulatory bodies, universities, and research institutions, including capacity development initiatives funded by the European and Developing Countries Clinical Trials Partnership (EDCTP).[10]

The ASCEND project "*Moving Tanzania's Clinical Research Ethics and Medicines Regulatory Capacity to the Next Level*" was implemented to enhance clinical trial oversight and pharmacovigilance capabilities in the Tanzania Mainland and Zanzibar. The project combined training, the operationalization, upgrading, and linkage of digital systems, community engagement in safety reporting, guideline domestication, and networking among researchers and regulators.

A qualitative synthesis of the lessons learned from the ASCEND project was published previously by the consortium.[10] The present manuscript differs by presenting an implementation-focused case study that documents the components delivered, approaches used, and project period outputs. This manuscript is presented as a case study to support transparency and practical learning in capacity development for research ethics and clinical trial oversight.

Program description

Overview of implementation approach

The ASCEND project implemented a multi-component capacity development approach that combined targeted training, operationalization, upgrading, and linkage of digital systems, community engagement in pharmacovigilance, guideline domestication, and networking among key stakeholders (Figure 1). Implementation activities were coordinated by partner institutions in Tanzania Mainland and Zanzibar, with roles aligned with institutional mandates for research ethics oversight, clinical trial regulation, and pharmacovigilance.

The figure illustrates the multi-component implementation approach of the ASCEND project, including training, digital systems development, community engagement for pharmacovigilance, guideline domestication, and stakeholder networking across Tanzania Mainland and Zanzibar.

The project was coordinated by the Tanzania Medicines and Medical Devices Authority (TMDA) and overseen by a steering committee chaired by the TMDA Director General, comprising one member from each partner institution, with a secretariat based at TMDA. Implementation was organized in seven work packages led according to institutional mandate. TMDA led the assessment of capacity needs and the domestication of AVAREF guidance, pharmacovigilance community engagement, networking, and project management. The National Institute for Medical Research (NIMR) led the electronic systems for ethics and pharmacovigilance. The Muhimbili University of Health and Allied Sciences (MUHAS), with the Kilimanjaro Clinical Research Institute (KCRI), led training, and the Zanzibar Health Research Institute (ZAHRI), with the Zanzibar Food and Drug Authority (ZFDA), led capacity building in Zanzibar. The University of St Andrews supported networking and doctoral supervision. Within this structure, regulatory approval of clinical trials is the mandate of TMDA in Tanzania Mainland and ZFDA in Zanzibar, while ethics review is overseen by NIMR, through the National Health Research Ethics Committee (NatHREC), and by ZAHRI, respectively.

ASCEND built on the earlier EDCTP-funded Streamlining Health Research Ethics and Medicines Regulation in Tanzania (SMERT) project, under which an electronic research ethics review system, an adverse drug reaction reporting

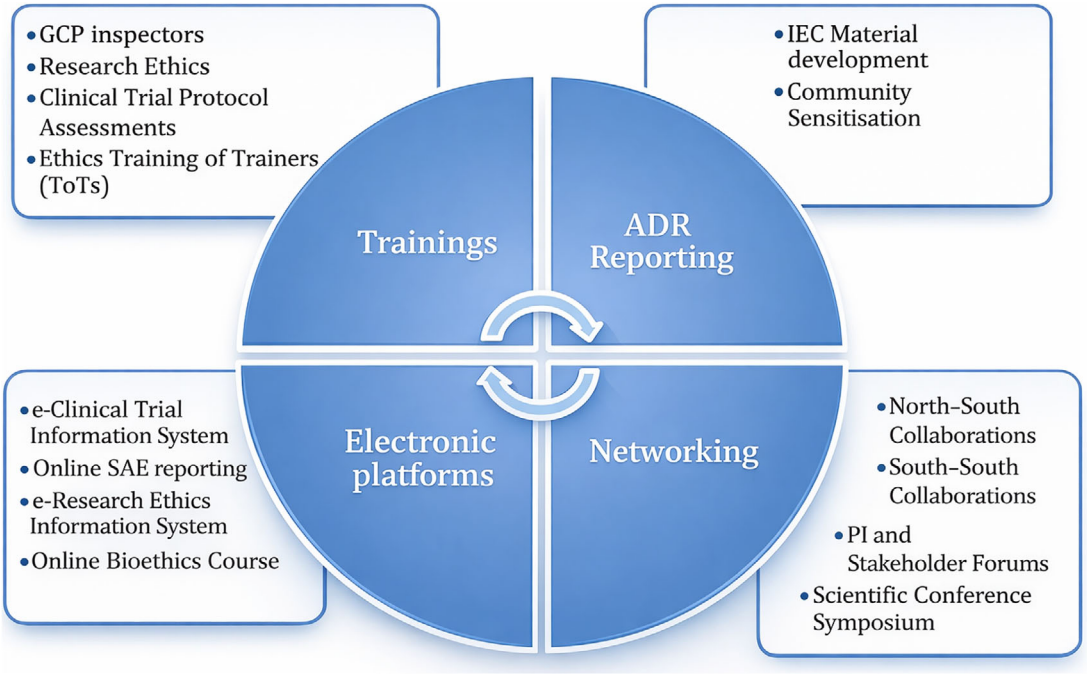

Figure 1. Core components of the ASCEND Project capacity-building interventions.

system, and a bioethics curriculum had been developed. ASCEND operationalized, upgraded, and customized these resources and extended their use to Zanzibar.

No primary qualitative data, such as interviews, focus group discussions, or direct observations, were collected for the purposes of this study. We conducted a document-based case study using routine ASCEND project documentation generated by the implementing institutions during the project period. Documents reviewed included approved training curricula and materials, participant registers and attendance lists, training and mentorship reports, records of guideline domestication, including adopted guidance documents, assessment templates, and inspection checklists, consortium deliverables and reports submitted to EDCTP2, steering committee minutes, the end-term evaluation report, stakeholder forum reports, and digital system documentation such as system linkage and user acceptance testing reports, a system user manual, a user survey report, and records of system use where available. We included only documents produced between November 2020 and December 2023 that were directly related to ASCEND implementation. Documentation completeness was assessed by confirming that each major implementation component and planned deliverable had corresponding records. Where records were incomplete, we reported outputs conservatively. Output counts were verified by triangulating figures across at least two sources where possible and prioritizing signed registers, institutional logs, and the most contemporaneous implementation records. Where discrepancies were identified, they were reconciled using the most complete and contemporaneous records, with consultation with the relevant implementing institution when needed.

Training package development and delivery

Training activities were designed to strengthen competencies in clinical trial protocol assessment, Good Clinical Practice inspection, and research ethics review. A structured curriculum development process was used, including drafting of training content, review by subject matter experts, and validation steps to ensure relevance to national processes, alignment with international standards, and AVAREF guidance. The clinical trial assessment and Good Clinical Practice (GCP) inspection courses were designed from a training needs assessment of clinical trial assessors and ethics reviewers conducted in 2021[14] and were accredited by MUHAS as 70-hour (7-credit) short courses. Delivery combined classroom-based sessions, hands-on practice, mentorship, and a train-the-trainer approach for institutional ethics committees.

Digital systems for ethics review and safety reporting

Digital tools were operationalized, upgraded, or customized to support consistent workflows for ethics review and safety reporting, building on the systems developed under the SMERT project. Implementation included requirement definition with end users, tailoring of system modules, user testing, and integration into institutional workflows. Requirement definition and testing involved information and communication technology (ICT) and technical staff from the participating institutions representing ethics review, pharmacovigilance, and regulatory functions. User feedback informed system refinement: a user survey of the Research Ethics Information Management System (REIMS), conducted by NIMR in June 2021, identified priorities for the system upgrade, and the linkage between the ZFDA and ZAHRI systems underwent structured user acceptance testing against predefined test cases, with sign-off by both institutions, before going live in December 2023.

End-user training was conducted to support adoption, including for serious adverse event reporting and clinical trial application submission and review processes.

Community engagement for pharmacovigilance

Community engagement drew on a community engagement model in pharmacovigilance and was implemented through district and regional sensitization activities. The Pharmacovigilance Community Engagement Model (PCEM), developed by TMDA with partner experts in July 2023 and subsequently issued as a TMDA guideline, is a structured approach that identifies priority community stakeholder groups, selects appropriate communication channels, and links sensitization activities to clear reporting pathways for suspected adverse drug reactions and adverse events following immunization. The model was applied using multiple approaches during community sensitization activities, with the aim of increasing awareness and reducing fear related to reporting. The model was piloted in Dar es Salaam and Dodoma regions and was also applied in Unguja and Pemba, where it was adapted to reach health sciences students, community pharmacists, and the general public through radio and television. The full PCEM document is openly available (Extended data).[15]

Engagement aimed to increase public understanding of rights and responsibilities in research participation and to promote the reporting of adverse drug reactions and adverse events following immunization. Multiple communication channels were used to reach the community members and relevant local stakeholders.

Capacity strengthening in Zanzibar
A dedicated set of activities supported capacity strengthening for the Zanzibar Health Research Institute and Zanzibar Food and Drug Authority, including train-the-trainer courses, facilitated access to online ethics training resources, implementation of electronic systems for ethics review and serious adverse event reporting, and mentorship linkages with mainland institutions. This approach aimed to support both skill acquisition and institutionalization of processes.

Domestication of AVAREF guidance
The project supported the domestication of AVAREF guidance to harmonize ethical and regulatory review processes for clinical trials conducted in Tanzania Mainland and Zanzibar. Implementation included orientation for selected principal investigators and review and alignment of relevant guidelines, assessment templates, and inspection checklists within participating institutions.

Networking and stakeholder engagement
Networking activities convened forums for institutional review boards, national ethics committees, clinical trials and pharmacovigilance committees. Forums supported dialogue between researchers and regulators, promoted a shared understanding of requirements, and identified coordination improvements that could be implemented within existing mandates.

Ethics
Ethics clearance was obtained from ZAHRI under reference number ZAHREC/03/APRIL/2021/05. For the Tanzania Mainland, ethics clearance was obtained from NIMR under the reference number NIMR/HQ/R.8 a/vol. IX/3666.

This manuscript is a case study based on project documentation and does not report additional human participant data collection or post-project follow-up beyond the activities implemented during the ASCEND project period.

Results
Training outputs for protocol review, inspection, and ethics capacity development
Training materials for clinical trial protocol assessment and Good Clinical Practice inspection were developed and used to deliver capacity development activities for regulators and ethics reviewers. Thirty clinical trial protocol reviewers or assessors and 25 Good Clinical Practice inspectors were trained on international standards and AVAREF guidance. Three Zanzibar Food and Drug Authority inspectors received on-the-job exposure by participating in inspections at five clinical trial sites on Tanzania Mainland. The clinical trial assessment course was designed from a training needs assessment in which 90 of 128 targeted clinical trial assessors and ethics reviewers (70.3%) responded; the proportions rating themselves proficient were 20.0% for clinical, 8.4% for quality, and 10.7% for statistical assessment, and more than 90% reported a critical need for training in each area. Pre- and post-training tests of the assessor cohort showed that mean scores increased from 61 to 80 out of 100 (mean difference 18.96; 95% confidence interval 13.15–24.76; $p < 0.0005$).[14] Learning outcomes were not assessed for the GCP inspector cohort.

Nineteen early- and mid-career researchers were trained in research ethics and clinical trial-related guidelines, application processes, and compliance. Fifty trainers drawn from institutional ethics committees were trained on research bioethics and clinical trial topics to support dissemination within institutional review structures in Tanzania Mainland and Zanzibar. A 40-hour (4-credit) bioethics short course was digitized and accredited by the Medical Council of Tanganyika for 20 continuing professional development (CPD) points.

Digital systems outputs
An online serious adverse event reporting module was operationalized within the national medicines regulatory authority online pharmacovigilance reporting system. Thirty-nine users, including scientists and research administrators, were trained to use this module. By August 2023, 112 serious adverse event reports had been submitted through the module. Zanzibar institutions customized and adopted electronic systems developed by sister institutions in Tanzania Mainland. These figures reflect the users reached during the project period for initial system operationalization and rollout, and do not represent full coverage of all potential end users nationally.

Community pharmacovigilance engagement outputs
The Pharmacovigilance Community Engagement Model was developed for use in Tanzania Mainland and Zanzibar. Sensitization activities using the model reached at least 718 people (218 in Tanzania Mainland and 500 in Zanzibar), as recorded in the project final report, focusing on adverse drug reaction reporting and adverse events following immunization reporting.

Table 1. Project components, documented outputs, early adoption indicators, outcomes not measured, and proposed future evaluation metrics, ASCEND Project (2020–2023). This table summarises, for each component of the ASCEND project implemented in Tanzania Mainland and Zanzibar between November 2020 and December 2023, the capacity gap addressed, the documented outputs, early adoption indicators, outcomes that were not measured within the project, and proposed metrics for future evaluation.

Component (capacity gap addressed)	Documented output	Early adoption indicator	Not measured within the project	Proposed future metric
Clinical trial protocol assessment training (limited protocol review capacity)	Accredited 70-hour (7-credit) course; 30 assessors trained	Mean test score increased from 61 to 80 out of 100 after training[14]	Application of skills in routine reviews; review quality	Follow-up assessment of review quality and consistency
GCP inspection training (limited inspection capacity)	Accredited 70-hour (7-credit) course; 25 inspectors trained; three ZFDA inspectors joined inspections at five trial sites	ZFDA inspectors participated in TMDA-led inspections	Learning outcomes; inspection quality	Pre- and post-training tests; review of inspection reports; number of inspections led
Ethics training of trainers (limited ethics review capacity in institutional committees)	50 trainers from institutional ethics committees trained	Not documented	Learning outcomes; onward training delivered	Number of onward trainings and trainees; pre- and post-training tests
Early- and mid-career researcher training (limited awareness of clinical trial requirements)	19 researchers trained	Not documented	Learning outcomes; quality of applications submitted	Proportion of applications complete at first submission
Digitized bioethics course (limited access to ethics training)	40-hour (4-credit) course accredited for 20 CPD points	Course available on the KCMC University online platform	Enrolment and completion	Enrolment, completion, and assessment scores
Serious adverse event reporting module (paper-based safety reporting)	Module operationalized; 39 users trained	112 reports submitted by August 2023	Completeness and timeliness of reports	Proportion of reports complete and submitted within required timelines
Electronic submission systems and linkages (fragmented ethics and regulatory workflows)	NIMR-TMDA linkage operational (October 2023); ZAHRI and ZFDA systems operationalized and linked (December 2023)	Two protocols processed through the Zanzibar system; user acceptance testing passed	Review turnaround times; user uptake	Time to acknowledgement and time to decision from system records
Pharmacovigilance Community Engagement Model (limited community awareness of safety reporting)	Model developed and issued as a TMDA guideline; at least 718 people sensitized	Model applied in Dar es Salaam, Dodoma, Unguja, and Pemba	Change in community awareness and reporting	Community adverse event reports before and after sensitization; awareness surveys
AVAREF domestication (limited harmonization of review processes)	Guidance documents, assessment templates, and inspection checklists adopted by TMDA and ZFDA	Documents in use at TMDA and ZFDA at project close	Consistency of reviews with adopted guidance	Audit of completed reviews against adopted templates
Networking (limited dialogue among researchers, ethics committees, and regulators)	Two stakeholder forums, one principal investigator forum, and a scientific symposium; study visits to Uppsala and St Andrews	Recommendations recorded at forums	Implementation of forum recommendations	Tracking of recommendations implemented

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Networking outputs

The project convened two stakeholder forums and one principal investigator forum and organized a scientific symposium during the NIMR Annual Joint Scientific Conference 2022, chaired by the Chief Medical Officer from the Ministry of Health. Consortium visits to the Uppsala Monitoring Centre and Uppsala University supported exposure to pharmacovigilance system operations and contributed to networking activities.

Table 1 summarises, for each project component, the capacity gap addressed, the documented outputs, early adoption indicators, outcomes not measured, and proposed metrics for future evaluation.

Early adoption indicators were available for selected digital systems at project close. In Zanzibar, operationalization of the ZAHRI and ZFDA systems enabled receipt, review, and approval processes, and by project close, the system had been used to receive two protocols for review leading to approval. In addition, electronic submission workflows were linked between NIMR and TMDA, and between ZAHRI and ZFDA, establishing an operational pathway for digital submission and review intended to strengthen routine regulatory processes. Sustainability-linked adoption was also supported through the institutionalization of training resources, including accreditation of the Bioethics CPD course and availability of the online course on the KCMC University online learning platform in Moshi, Tanzania.

User and stakeholder feedback recorded in project documentation

Project documentation recorded feedback from system users and stakeholders. In the REIMS user survey (June 2021; 19 respondents), most users were satisfied with ease of use (89.5%), first-time registration (84.2%), and form submission (84.2%), whereas satisfaction was lower for responding to reviewer comments (63.2%) and tracking application progress (55.6%). Users requested progress tracking, automated alerts when reviewer comments were posted, the ability to save draft applications, and linkage with other institutional review boards. Similar requests were raised at the principal investigator forum in July 2022, where participants also proposed a shorter version of the national research ethics guidelines and delegation of some reviews to NIMR research centers. Participants at a forum for regional and district medical officers in December 2023 reported unclear roles for regional health authorities in clinical trial oversight and the absence of formal communication channels with NIMR and TMDA. During community sensitization, participants cited fear of reporting, medicine information available mainly in English, and limited feedback after reporting as barriers to adverse event reporting.

Discussion

This case study documents the implementation of a multi-component capacity development initiative for research ethics oversight, clinical trial regulation, and pharmacovigilance in Tanzania Mainland and Zanzibar. The project combined training, digital tools, community engagement, and structured forums for engagement between the researchers and regulators.

Operational achievements included the delivery of training packages and trainer cohorts within institutional ethics committees, implementation of electronic workflows for ethics review and safety reporting, and development of a community engagement model for pharmacovigilance. These outputs reflect institutional ownership by anchoring activities within mandated institutions and using the internal technical capacity for system development and maintenance.[10]

Implementation considerations included sustainability planning for staff turnover, continued demand for refresher training, and routine budgeting for stakeholder engagement forums.[11] The adoption of digital tools depends on user onboarding, clarity of roles, and maintaining data confidentiality through appropriate hosting, access control, and governance arrangements.[10] Recent pharmacovigilance capacity-building efforts in East Africa, such as the PROFORMA project (focused on Ethiopia, Kenya, Rwanda, and Tanzania) have similarly emphasized short-term training, cascade models, and integration with national systems to achieve sustainable knowledge development and post-marketing surveillance.[9] Likewise, the PAVIA project (2018-2023) demonstrated that blended e-learning and collaborative "triangle" models (linking regulators, public health programs, and research institutions) can lead to significant increases in adverse event reporting and knowledge gains in Tanzania and other countries, highlighting the value of structured, multi-stakeholder approaches, like those in ASCEND.[8]

After the grant ended, the electronic systems remained hosted on institutional servers and maintained by in-house ICT staff, with operating costs met through institutional budgets and the fees paid for ethical clearance and regulatory review. The accredited courses remain available through MUHAS and the KCMC University online platform as continuing professional development offerings, and the PCEM has been issued as a TMDA guideline. A lesson from ASCEND is that sustainability arrangements, including hosting, user support, and refresher training, and the indicators needed to monitor them, are best agreed at the design stage rather than at project close.

Implementation occurred in a context with established institutional mandates for clinical trial oversight and ethics review in both Tanzania Mainland and Zanzibar, which enabled the rapid integration of training and digital tools into existing workflows. An enabling factor was the presence and active role of the TMDA-MUHAS Regional Centre of Regulatory Excellence (RCORE) as a platform for developing and delivering training packages for assessors and inspectors, supporting institutionalization beyond single workshops.

The project also benefitted from the deliberate linkage of electronic submission systems between Mainland and Zanzibar institutions, supporting integration into routine processes rather than standalone project tools.

The resource requirements for similar initiatives include dedicated technical personnel for system development and maintenance, training design and delivery capacity, and coordination time across institutions. Implementation required adaptation to risks, including system compatibility, COVID-19-related disruptions, and the time required for institutional approval of system linkages, addressed by reviewing existing systems before linkage, involving IT experts, and using hybrid or virtual meeting modalities, where needed.

Transferability to other settings is more likely when enabling conditions are present, including clear institutional mandates for ethics and regulatory functions, willingness to align with regional harmonization mechanisms such as AVAREF, and availability of technical teams able to support the development and maintenance of electronic systems.[5,12] Differences in the legal frameworks, staffing patterns, and resource availability should be considered when adopting this approach. Elements likely to be transferable include designing training from a formal needs assessment and accrediting it within existing institutions, linking ethics and regulatory submission systems so that each body can view the other's decisions, and using a structured community engagement model with defined stakeholder groups and reporting pathways. The adaptation of the model in Zanzibar, where it was extended to health sciences students, community pharmacists, and mass media, illustrates this flexibility. Other enabling conditions were specific to the Tanzanian context, including the parallel regulatory and ethics mandates in Tanzania Mainland and Zanzibar, the electronic systems already developed under the SMERT project, and the established TMDA-MUHAS RCORE. These developments underscore the importance of building national projects to advance regional reliance and sustainability in pharmacovigilance and clinical trial oversight.[13]

This manuscript is limited to project documentation and project period outputs, and does not evaluate post-project outcomes, long-term effectiveness, or downstream impacts on review timelines or inspection performance. Learning outcomes were measured only for the clinical trial protocol assessor cohort; they were not assessed for the GCP inspector, ethics trainer, and researcher cohorts, and no follow-up assessment of the application of skills was undertaken. The REIMS user survey preceded the system upgrade, and no follow-up survey was conducted. Review turnaround times were not assessed as part of this project. The project's monitoring framework was designed to track deliverable completion rather than regulatory performance indicators, and the electronic linkages between ethics and regulatory systems became operational only in the final quarter of implementation (October and December 2023), leaving no period within the project for before-and-after comparison. Stakeholders at the final project forum reported that approval delays had reduced but persisted; this perception was not verified against system data. Future capacity-building projects should define performance indicators, such as time to acknowledgement and time to decision, at baseline and plan for their extraction from electronic systems, and future work could build on this documentation through formal evaluation designs that measure sustained system performance and use of pharmacovigilance reporting over time.[13]

Conclusion

The ASCEND project implemented a coordinated set of activities to support research ethics oversight, clinical trial regulations, and pharmacovigilance in Tanzania Mainland and Zanzibar from 2020 to 2023. Documented outputs include trained reviewer and inspector cohorts, with measured knowledge gains among protocol assessors, operational electronic systems for ethics and safety reporting workflows, a Pharmacovigilance Community Engagement Model issued as a national guideline, and structured forums that supported interactions between researchers and regulators.

By documenting the implementation approaches and outputs, this case study provides practical information that may assist institutions in planning similar capacity development initiatives. The conclusions are limited to activities and outputs achieved within the project period and do not include post-project follow-ups.

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Data availability

Underlying data

The data underlying this article consist of internal ASCEND project documentation, including activity and deliverable reports, steering committee minutes, system reports, and training registers, held by the participating regulatory, ethics, and academic institutions in Tanzania Mainland and Zanzibar. Training registers and attendance lists contain personal data and cannot be shared. Activity and deliverable reports, the end-term evaluation report, and the REIMS user survey report are available on reasonable request to the corresponding author, subject to approval by the relevant institution. No additional human participant data were collected for this case study.

Extended data

Zenodo: Pharmacovigilance Community Engagement Model to Advance the Reporting of Adverse Events in Tanzania (TMDA/DMC/CTP/G/013). Tanzania Medicines and Medical Devices Authority, First Edition, 2023. https://doi.org/10.5281/zenodo.22975959. The document is openly accessible. Copyright is retained by TMDA, and reuse is subject to the terms stated on the Zenodo record.

Other project materials

The training needs assessment questionnaire and the pre- and post-training test for the clinical trial assessment course are available as supplementary files to the published training study.[14] The digitized bioethics course is available on the KCMC University online learning platform (https://eboard.kcmuco.ac.tz). The accredited curricula for the clinical trial assessment and GCP inspection courses, held by MUHAS, and the domesticated AVAREF guidance documents, assessment templates, and inspection checklists, held by TMDA and ZFDA, are available on reasonable request, subject to institutional approval.

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Open Peer Review

Current Peer Review Status: ? ✓

Version 2

Reviewer Report 09 October 2026

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✓ **Gabriela Lenarczyk**
University of Copenhagen, Copenhagen, Denmark

Thank you for the careful revision and detailed response. The revised manuscript adequately addresses my earlier reservations. In particular, the distinction between documented outputs and demonstrated outcomes is clearer, the governance and sustainability arrangements are better explained, and the revised materials availability statement improves the article's practical usefulness.

My only additional note is that the authors may wish to double-check the 0.02% figure in the introduction against the 2.0% reported for sub-Saharan Africa in reference 14.

Within the scope of expertise stated in my original report, I am happy to approve the revised manuscript.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: I reviewed this manuscript from the perspective of health law, pharmaceutical regulation, research governance, data governance, ethics-related aspects of biomedical research oversight, and institutional capacity-building.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 03 June 2026

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Gabriela Lenarczyk
University of Copenhagen, Copenhagen, Denmark

General assessment

I reviewed this manuscript from the perspective of health law, pharmaceutical regulation, research governance, data governance, ethics-related aspects of biomedical research oversight, and institutional capacity-building. I do not have specialist expertise in pharmacovigilance practice, pharmacoepidemiology, or implementation science, and I have not assessed the manuscript from those specialist perspectives.

The manuscript provides a useful and timely implementation-focused case study of the ASCEND project in Tanzania Mainland and Zanzibar. Its main contribution is descriptive and practical: it documents how a multi-component capacity-building project was operationalised across research ethics oversight, clinical trial regulation, digital workflow development, pharmacovigilance-related reporting, community engagement, and researcher-regulator networking. This type of implementation account is valuable because capacity-building projects are often described at a high policy level without sufficient attention to institutional roles, operational processes, and the practical conditions needed for replication.

Overall, I consider the manuscript to have academic and practical merit. However, I recommend revisions before the article can serve as a reference for other institutions or jurisdictions. My reservations concern the need to distinguish more clearly between outputs and **demonstrated capacity gains;** to strengthen the account of institutional governance and **sustainability**; and to improve the **availability** or description of non-sensitive project materials.

1. **Distinguish more explicitly between implementation outputs and demonstrated capacity gains**

The manuscript is appropriately framed as an implementation-focused case study based on project documentation. However, several parts of the manuscript could more clearly distinguish between activities delivered, outputs achieved, early adoption indicators, and longer-term outcomes that were not measured.

For example, the reported training of reviewers, inspectors, researchers, and trainers is an important output, but attendance or completion does not by itself demonstrate improved reviewer competence, inspection quality, institutional performance, or sustained behavioural change. Similarly, the establishment of digital workflows and reporting modules is an important system-strengthening output, but it does not by itself show whether review timelines, acknowledgement times, decision times, safety-reporting completeness, or user compliance improved over time.

I do not think the authors need to retrospectively produce a full outcome evaluation if the

necessary data were not collected. However, I recommend adding a table that separates:
- project component;
- documented output;
- available early adoption indicator;
- outcome or performance indicator not measured;
- proposed future evaluation metric.

This would strengthen the manuscript while remaining faithful to the available evidence.

2. **Strengthen the institutional governance account**

The manuscript would benefit from a more explicit account of institutional roles and responsibilities across the participating bodies, especially TMDA, NIMR, ZFDA, ZAHRI, training institutions, and technical partners. The current manuscript describes institutional ownership and the use of mandated institutions, but the governance architecture remains somewhat implicit.

3. **Clarify sustainability arrangements for digital systems and training resources**

The discussion refers to institutional ownership, technical capacity, and sustainability planning. These points are important, but they need more detail. Digital systems often fail not necessarily at launch but rather after the project period, when hosting, server costs, software maintenance, user support, access management, and refresher training become routine institutional responsibilities.

Could the authors clarify whether specific post-grant arrangements exist for aspects such as server hosting/technical maintenence/user support/system updates etc.?

If formal budget lines or commitments exist, the manuscript should say so. If they do not exist, or if the authors cannot confirm them, this should be stated transparently as a limitation and as a lesson for future capacity-building projects.

4. **Improve the materials and data availability statement**

The current data availability statement is understandable as regards internal records containing personal data, institutional records, training registers, and confidential implementation documents. However, the statement is too broad if it prevents access to non-sensitive project materials that would help others learn from or adapt the project.
I recommend that the authors distinguish between confidential or personal-data-containing records that cannot be shared; internal institutional documents that may be available on reasonable request; non-sensitive materials that could be shared publicly; materials that could be shared in redacted or template form.

In particular, the authors should consider depositing or otherwise making available non-sensitive materials such as curriculum outlines/ training agendas/generic user guidance for digital workflows/blank feedback forms or evaluation templates.

If any of these materials cannot be shared, the authors should provide artifact-specific reasons.

As a last note, as a reader, I would like to understand better what made the ASCEND approach

transferable and what was specific to Tanzania Mainland and Zanzibar.

On a smaller note, the authors should ensure that all abbreviations are defined on first use.

Is the background of the case's history and progression described in sufficient detail?
Yes

Is the work clearly and accurately presented and does it cite the current literature?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Not applicable

Are all the source data underlying the results available to ensure full reproducibility?
No

Are the conclusions drawn adequately supported by the results?
Yes

Is the case presented with sufficient detail to be useful for teaching or other practitioners?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: I reviewed this manuscript from the perspective of health law, pharmaceutical regulation, research governance, data governance, ethics-related aspects of biomedical research oversight, and institutional capacity-building.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 26 Sep 2026

Ndekya Oriyo

We thank the reviewer for a thoughtful review from the perspectives of health law, research governance and institutional capacity-building. The recommendations have substantially improved the manuscript's value as a reference for other institutions. We respond to each point below.

Comment 1: Distinguishing implementation outputs from demonstrated capacity gains We agree and have adopted the reviewer's suggested structure. Table 1 has been expanded to show, for each project component:

- the documented output;
- available early adoption indicators;

- outcomes or performance indicators not measured;
- a proposed future evaluation metric.

The table covers the protocol assessor, GCP inspector, ethics trainer and researcher training; the digitised bioethics course; the serious adverse event reporting module; the electronic submission systems and linkages; the Pharmacovigilance Community Engagement Model and community sensitisation; AVAREF domestication; and networking. Where measured evidence exists, the table cites it: the published pre- and post-training assessment for the protocol assessor cohort (reference 14), and system use indicators. Where it does not, the table says so. This includes learning outcomes for the other training cohorts and review turnaround times, which were outside the scope of the project's monitoring framework. **Changes:** Table 1; Results; Discussion (limitations).

Comment 2: Institutional governance We have added an explicit account of governance and roles. TMDA coordinated the project. A steering committee chaired by TMDA's Director General, with one member from each partner institution and a TMDA secretariat, oversaw implementation. Work packages were led according to institutional mandate:

- TMDA led capacity needs assessment and AVAREF domestication, pharmacovigilance community engagement, networking and project management;
- NIMR led the electronic systems for ethics and pharmacovigilance;
- MUHAS, with KCRI, led training;
- ZAHRI, with ZFDA, led Zanzibar capacity building;
- the University of St Andrews supported networking and doctoral supervision.

The account also sets out the division of mandates between the regulators (TMDA and ZFDA) and the ethics bodies (NIMR and ZAHRI) in Tanzania Mainland and Zanzibar. **Changes:** Program description (overview of implementation approach).

Comment 3: Sustainability of digital systems and training resources We have clarified the post-grant arrangements. The electronic systems are hosted on institutional servers and maintained by in-house ICT staff, with operating costs met through institutional budgets and the fees paid for ethical clearance and regulatory review. The accredited courses remain available through MUHAS and the KCMC University platform. The Pharmacovigilance Community Engagement Model has been institutionalised as a TMDA guideline. We have also added a lesson for future projects. Sustainability arrangements, including hosting, user support and refresher training, and the indicators needed to monitor them, should be agreed at the design stage rather than at project close. **Changes:** Discussion (sustainability and lessons).

Comment 4: Materials and data availability We agree that the original statement was too broad and have revised it along the lines the reviewer proposed. It now distinguishes:

- materials that are publicly available: the Pharmacovigilance Community Engagement Model, deposited openly on Zenodo (https://doi.org/10.5281/zenodo.22975959; reference 15), with copyright retained by TMDA and reuse subject to the terms stated on the record; the training needs assessment questionnaire and pre/post test published as supplementary files; and the online bioethics course;
- materials available on reasonable request, subject to institutional approval: the

accredited course curricula, domesticated AVAREF guidance documents and templates, and project reports;
- records that cannot be shared because they contain personal data: attendance registers and training records.

A reason is given for each restriction.
Changes: Data Availability; Extended data; Program description (community engagement for pharmacovigilance); References (new reference to the Zenodo deposit).

Comment 5: Transferability We have revised the Discussion to separate the transferable elements of the approach from those specific to the Tanzanian context.
Likely to transfer:
- designing training from a formal needs assessment and accrediting it within existing institutions;
- linking ethics and regulatory submission systems so that each body can see the other's decision;
- using a structured community engagement model with defined stakeholder groups and reporting pathways.

The adaptation of the community engagement model in Zanzibar, where it was extended to health sciences students, community pharmacists and mass media, shows that it can be adapted to a different audience. **Context-specific enabling conditions:**
- the dual institutional mandates in Tanzania Mainland and Zanzibar;
- existing electronic systems from the earlier SMERT project;
- an established regional centre of regulatory excellence at MUHAS and TMDA.

Changes: Discussion (transferability).

Comment 6: Abbreviations All abbreviations are now defined on first use. Additional revisions During revision we also:
- clarified the origin of the electronic systems and ethics curriculum in the earlier SMERT project;
- corrected the name of the Pharmacovigilance Community Engagement Model;
- clarified the community sensitisation figures;
- specified the accreditation of the bioethics course.

Competing Interests: No competing interests were disclosed.

Reviewer Report 27 February 2026

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basile chretien
Nagoya University, Graduate School of Medicine, Nagoya, Japan

General Assessment
This manuscript offers a welcome and necessary window into the "black box" of capacity building. Too often in global health, we see large grants and ambitious initiatives in Sub-Saharan Africa without ever seeing a detailed account of how the resources were translated into on-the-ground implementation. The authors should be commended for taking the time to document the administrative and operational outputs of the ASCEND project. However, as I read through the case study, I found myself left with a significant lingering question regarding the actual success of the intervention. While the paper does an excellent job of cataloging inputs, such as funding and curriculum development, and outputs, like the number of trainees and systems launched, it stops short of evaluating the outcomes. In the modern landscape of medical education and health systems strengthening, the field is moving away from simply counting "heads in a room" to measuring competence, behavioral change, and system efficiency.
Currently, the draft reads somewhat like a grant report listing deliverables to prove a contract was fulfilled. For a scientific case study, I would expect a deeper layer of analysis. We know that you trained 30 reviewers, but we do not know if their review quality improved. We know that you built a system, but it is unclear if it is reducing the backlog of applications. Without this level of assessment, it is difficult for the reader to judge the true value and replicability of the project. I have outlined these major concerns below, alongside specific recommendations to improve the openness of the data and some minor corrections to ensure the terminology used is precise.

1. The "Black Box" of Efficacy: Moving Beyond Headcounts
My primary reservation with the article is the lack of assessment data regarding the training and systems. The Results section lists the number of participants, such as 30 protocol reviewers and 25 inspectors, but attendance is a poor proxy for capacity built. Stating that reviewers were trained tells us about reach, not efficacy. I strongly suggest the authors include any available data regarding learning outcomes, such as pre- and post-test scores, participant satisfaction surveys, or even qualitative feedback from the "facilitated debriefing sessions" mentioned in the methods. Similarly, regarding the new digital workflows, it would be valuable to see early data on efficiency, such as the average time to acknowledgement or time to decision before and after the system was introduced. If quantitative data is unavailable, please explicitly discuss why in the limitations section and perhaps reflect on how future projects could build in these metrics from the start.

2. Data Availability and Open Science: Unlocking the Tools
The current Data Availability statement notes that underlying data, including internal documentation, are not publicly available due to institutional confidentiality. While I understand that registers containing names cannot be shared, Open Research Europe has a strong open data policy, and this restriction limits the utility of your case study. You describe developing valuable tools—specifically the Community Pharmacovigilance Engagement Model (PCEM) and the training curricula—but the reader cannot see them. I strongly recommend that the authors deposit non-sensitive project materials in a repository like Zenodo and link them in the paper. This should include the framework or field guide for the PCEM, the agendas or curriculum outlines for the ethics and GCP courses, and blank templates of the standard operating procedures or checklists developed. Sharing these tools would significantly increase the academic merit of this paper, allowing other regions to replicate your success rather than just reading about it.

3. Methodology Clarification
You state that no primary qualitative data were collected for the purposes of this study. Please clarify if the project documentation itself contained qualitative feedback. For instance, did the facilitated debriefing sessions generate minutes or reports that you reviewed? If so, a brief summary of the themes of user feedback regarding the digital tools would add valuable nuance to the operational success described, such as whether users found a specific interface difficult or appreciated a particular feature.

4. Precision in the Plain Language Summary
In the plain language summary, you state that clinical trials help identify better medicines and vaccines. This phrasing is a bit too narrow, as clinical trials are also essential for medical devices, diagnostics, and non-pharmaceutical interventions like surgery or behavioral therapy. I suggest broadening this to "health interventions" or explicitly adding devices and diagnostics, as these are increasingly relevant in the region. Furthermore, the summary distinguishes between an ethics review, checks that trials follow good practice, and pharmacovigilance in a way that is slightly muddy. "Good Clinical Practice" (GCP) is a broad standard that encompasses ethics, data integrity, and safety; it is not separate from checks that trials follow good practice. I would suggest rephrasing this to clarify that GCP ensures the rights, safety, and well-being of subjects and the credibility of data, while pharmacovigilance is the specific science of detecting adverse effects.

5. Contextualizing Regional Challenges
In the Introduction, you list common challenges facing regulatory authorities, including limited funding, staffing constraints, infrastructure gaps, and shortages of specialized expertise. While perhaps less acute in Tanzania specifically compared to some neighbors, political instability is a major documented barrier to consistent regulatory oversight across the wider Sub-Saharan African region. It often leads to high staff turnover in ministries and shifting health priorities. I suggest adding this to the list of regional challenges to provide a more complete picture of the environment in which these projects operate.

6. Sustainability Details
The discussion mentions institutional ownership and routine budgeting. It would be beneficial to clarify if a specific budget line or financial commitment has been secured by the national authorities (TMDA, ZFDA, NIMR, ZAHRI) to maintain the electronic systems, specifically regarding server hosting and IT support, post-grant. This is often the failure point for such interventions, and confirmation of this detail would strengthen the manuscript.

Final Recommendation
The description of the project is solid, but the manuscript needs to go deeper than a list of completed tasks. By adding even, a small amount of data on efficacy, sharing the actual tools developed, and refining the definitions in the introduction, this could become a much more impactful reference paper for the field.

Is the background of the case's history and progression described in sufficient detail?
Yes

Is the work clearly and accurately presented and does it cite the current literature?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Not applicable

Are all the source data underlying the results available to ensure full reproducibility?
No

Are the conclusions drawn adequately supported by the results?
Yes

Is the case presented with sufficient detail to be useful for teaching or other practitioners?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Pharmacoepidemiology & Pharmacovigilance & Medical Education

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 26 Sep 2026

Ndekya Oriyo

We thank the reviewer for a careful and constructive assessment. We respond to each point below.

Comment 1: Moving beyond headcounts to assess efficacy
We have strengthened the manuscript in three ways.
First, we now report measured learning outcomes for the clinical trial protocol assessor cohort. The 70-hour (7-credit) course was designed from a training needs assessment of 90 clinical trial assessors and ethics reviewers. That assessment found low self-rated proficiency in clinical (20.0%), quality (8.4%) and statistical (10.7%) assessment. Pre- and post-training tests showed mean scores rising from 61 to 80 (mean difference 18.96; 95% CI 13.15–24.76; $p < 0.0005$). These results have since been published in full (reference 14; Mwamwitwa et al., 2026), and we summarise them in the Results.
Second, we have added early adoption indicators for the digital systems. By August 2023, 112 serious adverse event reports had been submitted through the online reporting module. By project close, the Zanzibar system had received and processed two clinical trial protocols. The ZFDA–ZAHRI system linkage passed structured user acceptance testing in November 2023.
Third, as suggested, we now state explicitly what was not measured. Review turnaround times were not part of the project's monitoring framework, which tracked deliverable completion. In addition, the electronic linkages between ethics and regulatory systems became operational only in the final quarter of implementation, leaving no period within the project for before-and-after comparison. Learning outcomes were also not measured for the GCP inspector, ethics trainer and researcher cohorts. We have added these points to

the limitations, with a recommendation that future projects define performance indicators such as time to acknowledgement and time to decision at baseline, and plan to extract them from electronic systems.
Changes: Results (training and digital systems outputs); Table 1, expanded to separate outputs, early adoption indicators, outcomes not measured and proposed future metrics; Discussion (limitations).

Comment 2: Data availability and sharing of tools
We agree, and we have revised the Data Availability statement to set out, item by item, what is available and on what terms:
• The Pharmacovigilance Community Engagement Model is openly available on Zenodo (https://doi.org/10.5281/zenodo.22975959). The model is now cited in the main text and listed in the references (reference 15).
• The training needs assessment questionnaire and the pre/post training test are publicly available as supplementary files to the published training study (reference 14).
• The digitised bioethics course is available on the KCMC University online learning platform.
• The accredited curricula for the clinical trial assessment and GCP inspection courses, the domesticated AVAREF guidance documents and templates, and the project's activity and deliverable reports are held by the implementing institutions and are available on reasonable request, subject to institutional approval.
• Attendance registers and training records contain personal data and cannot be shared.
Changes: Data Availability; Extended data; Program description (community engagement for pharmacovigilance); References (new reference to the Zenodo deposit).

Comment 3: Qualitative feedback in project documentation
We thank the reviewer for this question, which led us to re-examine the documentation. The records contain user and stakeholder feedback, and we have added it to the manuscript. We have also corrected the Methods so that the feedback mechanisms described match those documented:
• REIMS user survey. An anonymous online survey of REIMS users, conducted by the National Institute for Medical Research (NIMR) in June 2021 (19 respondents), informed the REIMS upgrade under ASCEND. Users reported high satisfaction with ease of use (89.5%) and the form submission process (84.2%), and lower satisfaction with tracking application progress (55.6%) and responding to reviewer comments (63.2%). They requested progress tracking, automatic alerts and the ability to save draft applications.
• User acceptance testing. Testing of the ZFDA-ZAHRI system linkage used predefined test cases with sign-off by both institutions.
• Stakeholder forums and community sessions. The principal investigators' forum (July 2022), the regional and district medical officers' forum (December 2023), and the community sensitisation sessions recorded further themes. These included:
– requests for application tracking and automated notifications;
– a need for clearer roles and communication channels between regulators and regional health authorities;
– fear of reporting adverse events;
– medicine information available mainly in English;
– limited feedback to people who submit reports.

We report these as themes recorded in project documents. No additional primary data were collected for this case study.
Changes: Methods (program description, digital systems); Results (new paragraph on user and stakeholder feedback).

Comment 4: Precision in the plain language summary
We have revised the plain language summary. It now refers to health interventions, including medicines, vaccines, medical devices and diagnostics, and distinguishes Good Clinical Practice from pharmacovigilance. Good Clinical Practice is described as the international standard that protects the rights, safety and well-being of trial participants and ensures that trial data are credible. Pharmacovigilance is described as the science of detecting, assessing and preventing harmful effects of medicines and vaccines.
Changes: Plain language summary.

Comment 5: Political instability as a regional challenge
We thank the reviewer for this point. We agree that political instability is a documented barrier to consistent regulatory oversight in parts of the region. As this case study describes implementation in Tanzania Mainland and Zanzibar, where the project operated within stable institutional and governance structures, we have not added it to the list of challenges, to avoid implying it applied to this setting.

Comment 6: Sustainability and financial commitment
We have clarified the post-grant arrangements. The participating institutions are public bodies with statutory mandates for clinical trial regulation, ethics review and pharmacovigilance. The electronic systems are hosted on institutional servers and maintained by in-house ICT staff, with operating costs met through institutional budgets and the fees paid for ethical clearance and regulatory review. The accredited courses remain available through MUHAS and the KCMC University platform as continuing professional development offerings. TMDA issued the Pharmacovigilance Community Engagement Model as an official guideline.
Changes: Discussion (sustainability).

Additional revisions
During revision we also:
- clarified that the electronic ethics review and adverse drug reaction reporting systems, and the ethics curriculum, were first developed under the earlier SMERT project and operationalised, upgraded and customised under ASCEND;
- corrected the name of the Pharmacovigilance Community Engagement Model;
- clarified the community sensitisation figures;
- specified the accreditation of the bioethics course;
- defined all abbreviations on first use.

Competing Interests: No competing interests were disclosed.