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Development, implementation, and evaluation of an innovative clinical trial operations training program for Africa (ClinOps)

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Abstract

Background Africa's involvement in clinical trials remains very low. Although the crucial role of training initiatives in building clinical trial capacity in Africa has been documented, current efforts fall short as they lack alignment with local contexts. This study aimed to design, develop, implement, and evaluate an innovative clinical trial operations training program for Africa.

Methods We developed ClinOps, a novel 10-week clinical trial operations training program for study coordinators in Africa to enhance their expertise in four fundamental areas: designing, conducting, managing, and reporting clinical trials. To streamline the learning process, we used cloud-based applications that minimize the need for software installations while maximizing student engagement. VoiceThread facilitated interactive content that could be accessed offline. Moodle, an open-source learning management system, offered a platform for sharing learning tools, mentorship, and rubric-driven competency assessments, including quizzes, forums, tutorials, and group assignments. We utilized Zoom for live tutorials and mentoring as required. Effectiveness of the program was evaluated through quantitative pre- and post-surveys, qualitative end-course evaluations, and a comprehensive monitoring and evaluation framework. The pre- and post-surveys measured changes in trainees' confidence in clinical trial domains and leadership and coordination skills. End-course evaluations gathered feedback on the course content, organization, technology, and instructional methods. We used Wilcoxon rank test to analyze pre- and post-survey scores and thematic analysis to analyze the qualitative data.

Results In the initial cohort, 88 study coordinators from 19 countries participated, including 56 (64%) females, with 57 (65%) actively employed as study coordinators during the training, and 85 (97%) possessing prior experience in clinical trial roles. Among these, 71 (81%) successfully completed the course, with 69 (97%) also completing the post-course assessment. Post-training scores demonstrated substantial improvement compared to pre-training scores in each competency area, including in designing (pre-post training median score = 3.6 vs. 4.6, median difference = 1.0, 95% CI 0.8–1.1, $p < 0.001$), managing (pre-posttest median score = 3.4 vs. 4.2, median difference = 0.6, 95% CI 0.4–0.8, $p < 0.001$), conducting (pre-post training median score = 3.9 vs. 4.7, median difference = 0.9, 95% CI 0.6–1.0, $p < 0.001$), and reporting (pre-posttest median score = 3.0 vs. 4.5, median difference = 1.0, 95% CI 0.9–1.5, $p < 0.001$) clinical trials. The monitoring and evaluation data confirm the program's adherence to training best

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practices, including alignment with local priorities, country ownership, pedagogic innovation, institutional capacity building, sustainability, and ongoing partnerships. The end-course evaluation reflects participants' positive feedback on the program's structure, content, relevance to their current roles, and overall delivery methods.

Conclusion The ClinOps program, designed by experts from academia and product development partners, enhanced participants' clinical trial competencies. To effectively build clinical trials capacity on the continent, training programs should provide thorough competency development in designing, conducting, managing, and reporting trials.

Keywords Clinical trial, Training, ClinOps, Africa, Product development partners

Background

Clinical trials in Africa face significant challenges stemming from human resources, infrastructure, regulatory, and financial constraints [1, 2]. With a population of 1.5 billion, the continent boasts remarkable genetic and demographic diversity, presenting a unique opportunity to thoroughly evaluate the efficacy and safety of medical interventions across a wide spectrum of origins, age groups, genders, and socioeconomic strata. Despite this advantageous position, the successful initiation and operation of clinical trials in the continent remains challenging, as it necessitates navigating through a complex array of resources and operations [3–6]. Although the number of registered clinical trials in Africa has been steadily increasing, its overall contribution still stands at just 2% of the global total [7, 8].

Studies demonstrate that strengthening human resource capacity stands as a primary and critical measure in building the overall clinical trial capacity in Africa [9, 10]. By investing in research readiness training programs for clinical trial experts, countries can attract more clinical trials while enhancing the quality, efficiency, and integrity of clinical trial operations [11, 12]. Such training initiatives provide professionals with the necessary knowledge and skills to effectively design, conduct, and manage clinical trials. This encompasses a comprehensive understanding of regulatory requirements, ethical considerations, and adherence to international standards. Ongoing training fosters continuous professional development, enabling experts to remain informed of advancements in clinical trial methodologies, regulatory changes, industry standards, and emerging trends in clinical trial approaches. Professionals who undergo thorough training in clinical trials are better positioned to network and collaborate with pharmaceutical companies and individual experts in medicinal product development [13, 14]. This collaboration may not only mobilize resources and attract funding but also strengthens the reputation and competitiveness of a country within the global clinical research landscape. Overall, effective training for clinical trial experts plays a crucial role in advancing

medical science, improving patient care, and fostering innovation in healthcare.

Recognizing the critical need for high-quality clinical trial training programs, global stakeholders in clinical trials, including academia, industries, research institutions, and non-governmental organizations, have taken proactive steps to design and implement relevant education and training initiatives for Africa and other developing regions [15–22]. These programs are offered either free of charge or for a fee, with the goal of providing professionals with the requisite knowledge and skills to conduct clinical trials effectively. However, publications stemming from these initiatives demonstrate a predominant focus of the courses on broader aspects of clinical trials rather than actual practical skills tailored to local contexts. Trainees then confront the harsh reality that while the practical application of clinical trials appears feasible in theory, it frequently proves complex in real-world scenarios, resulting in a limited contribution of the training programs to the development of clinical trials capacity in Africa. To overcome these limitations, innovative clinical trial training programs are needed. These programs should integrate peer learning, real-life scenarios, and authentic case studies that would enhance the day-to-day efficiency of clinical trial professionals, enabling them to coordinate trials independently with minimal supervision.

Given these pressing demands for effective clinical trials training programs, we aimed to design, develop, implement, and evaluate a novel clinical trials operation training program for Africa. This manuscript outlines the innovative strategies we employed in creating and evaluating a clinical trial training program, showcasing the significant accomplishments achieved through the program.

Methods

Course design and development

The study employed a pre- and post-intervention design with a focus on instructional design. The ClinOps program, a novel training program in clinical trial operations, was designed collaboratively by a team of several academic and product development partners, including

the Faculty of Capacity Development (FCD), Foundation for Innovative New Diagnostics (FIND), MMV Medicines for Malaria Venture (MMV), International AIDS Vaccine Initiative (IAVI), Program for Appropriate Technology in Health (PATH), and the Special Programme for Research and Training in Tropical Diseases (TDR), among others. The design and development of the program were guided by the WHO-TDR monitoring and evaluation report of the study coordinators course, which identified a persistent need for enhanced training in clinical research operations among product development partners [23]. Accordingly, the team opted to tailor the program for individuals already engaged in research, recognizing their potential to quickly apply and transfer the newly acquired skills. Aligned with the WHO/TDR Global Competency Framework for Clinical Research [24], the program aimed to develop specific competencies essential for the effective management of clinical trials. The main goal was to equip study coordinators with the skills needed for trial management and operational support at their sites.

The program followed the ‘CHAOS’ framework (Fig. 1), an acronym that, despite its name, underscores the structured and deliberate nature of participants’ learning journeys. This framework is based on the Relationship of Inquiry framework [25] akin to the Community of Inquiry framework [26], but adapted for a one-to-one

learning environment. The course integrates cognitive, constructivist and humanistic learning theories to develop learners’ skills, attitudes, behaviors, and confidence, enabling them to evolve as professionals and derive positive changes within their institutions. By employing constructivist teaching methodologies, the program intended to substantially enhance participants’ skills. This approach was grounded in Lev Vygotsky’s sociocultural theory of cognitive development [27–29], which emphasizes the impact of culture and social environment on how individuals perceive and understand reality.

The training program utilized innovative multimedia components (Fig. 2), including VoiceThread, Moodle Learning Management System, offline-accessible downloadable content, and Zoom to deliver the course effectively. Led by such technologies, the course was specifically designed to be accessible to participants worldwide via an online learning platform. This approach aimed to provide training to individuals who might not have access to similar programs in urban areas, ensuring they could acquire the necessary skills to become proficient trial study coordinators.

Course content

The program was a ten-week course covering key aspects of clinical trials, consisting of ten weekly lessons (Fig. 3).

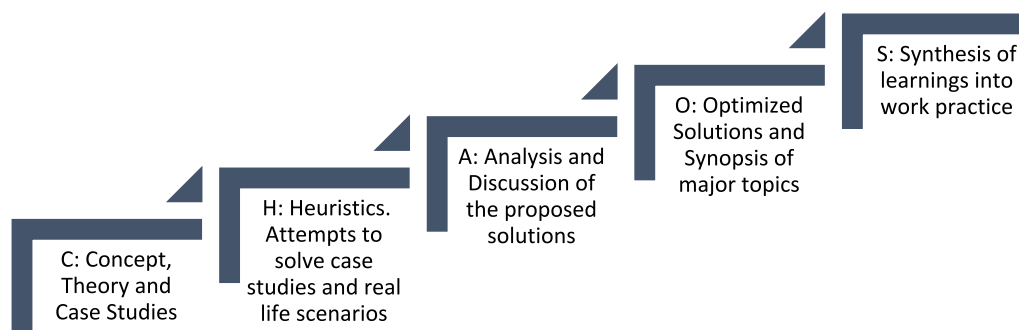


Fig. 1 CHAOS framework for the design of ClinOps training program. The course’s framework with the acronym ‘CHAOS’: Concept, Heuristics, Analysis and Discussion, Optimized Solutions and Synopsis, Synthesis

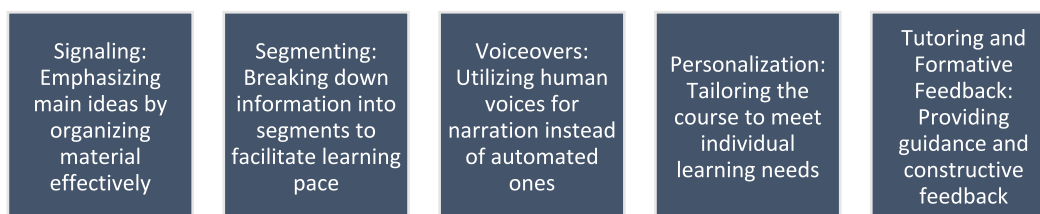


Fig. 2 Innovative multimedia learning components ClinOps. Core multi-media learning elements leveraged to the course: signaling, segmenting: voiceovers, personalization, tutoring and formative feedback

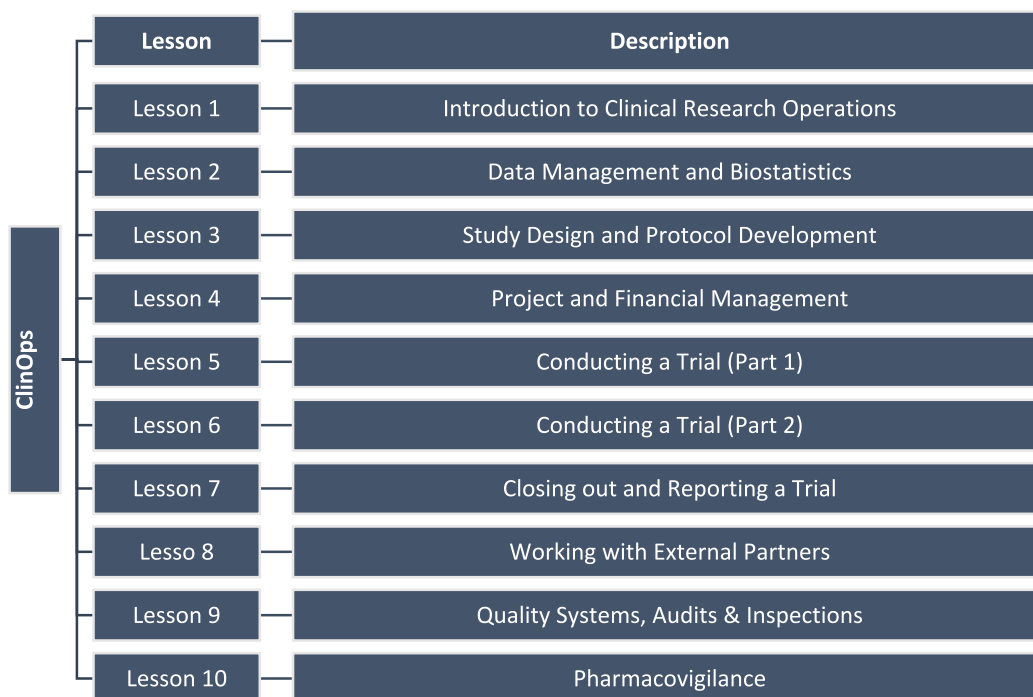


Fig. 3 ClinOps training program's ten lessons. Ten weekly lessons of the Clinops program: introduction to clinical research operations, data management and biostatistics, study design and protocol development, project and financial management, conducting a trial 1, conducting a trial 2, closing out and reporting a trial, working with external partners, quality systems, audits& inspections, pharmacovigilance

While each lesson is scheduled to last one week, some learners may not complete a lesson within the allotted time frame. Therefore, building social presence is crucial to provide positive support, helping learners form an emotional connection to the course. This not only motivates them to relate the skills being taught to their current professional practice but also encourages them to continue the course while balancing family and work commitments. Each lesson, began with introductory activities and progressed through problem-based learning. Depending on their background, participants spend 8–12 h per week on the course. They were given three-weeks after the course ended to finalize their assessment if not already completed during the course. Each learner had a mentor throughout for interaction, reflective practice, and formative assessments. The program's reference materials were freely available under Creative Commons licenses. Core components, including On-Demand Content and tasks, were openly accessible and could be modified under a CC BY SA license. This allowed users to share, copy, redistribute, and adapt the materials, including commercial ventures.

Participant competency was assessed through forum discussions, live tutorials, quizzes, and group assignments, using pre-defined assessment rubrics that clearly outline specific components and expectations for each

participant. Participants must achieve a minimum score of 70% in each assessment criterion as well as an overall score of 70% to receive the certificate. Most assessments were completed during the course, with a three-week period afterward for final submission. The program team designed the course with careful input from all stakeholders, ensuring it addressed the specific needs of clinical trial stakeholders in LMICs and common trial challenges. Insights were gathered from product development partners, contract research entities, and former TDR fellows.

Learning outcomes

Upon successful completion of the course, participants were expected to exhibit competency in four fundamental areas of clinical trial operations: designing, conducting, managing, and reporting clinical trials (Fig. 4). Two top-performing participants were offered the opportunity to join a two-year MSc program in Clinical Trials at CDT Africa, Addis Ababa University in Ethiopia.

Setting and participants

This training program targeted African study coordinators or aspiring to work in this field. Applications were open continent-wide and evaluated based on merit. Selection criteria included prior experience as a study coordinator, investigator, co-investigator, study manager,

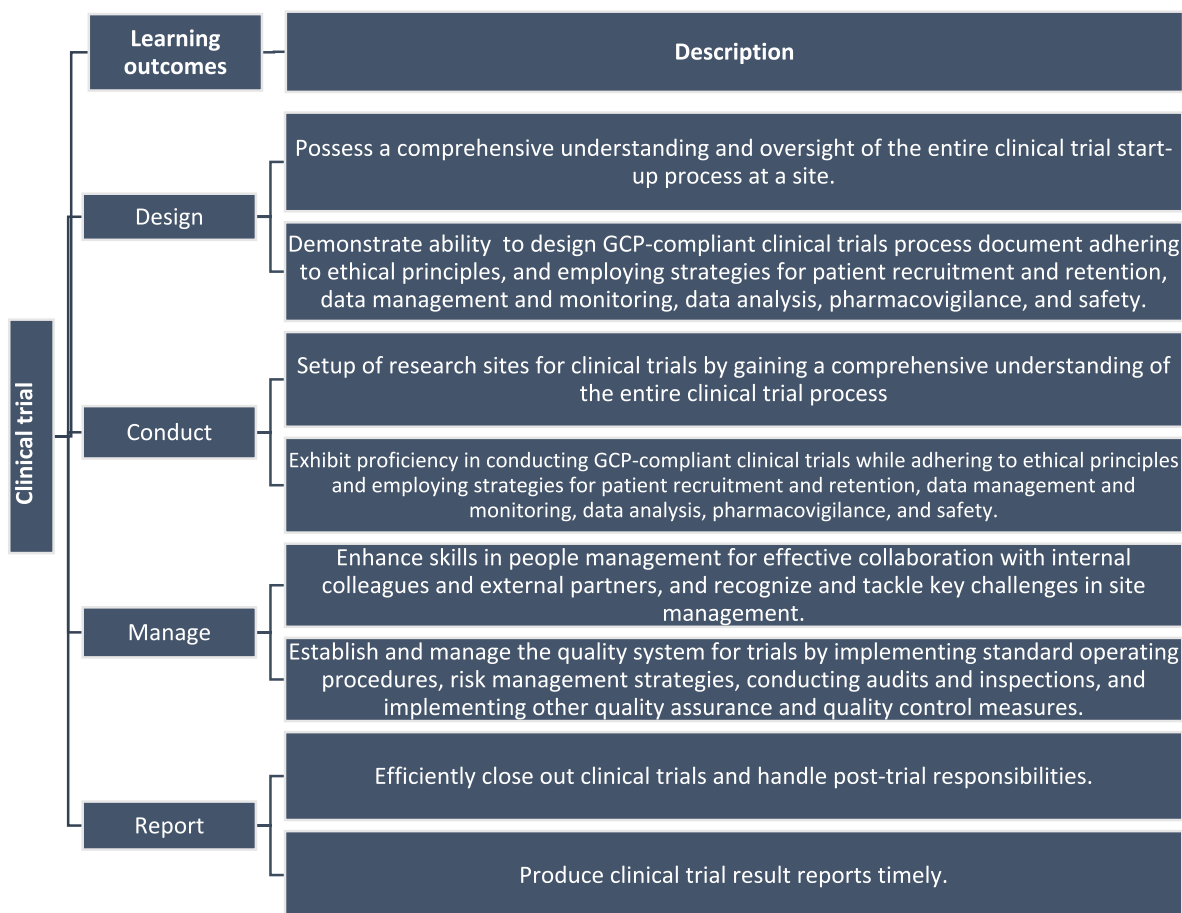


Fig. 4 Intended learning outcomes of the ClinOps training program

or assistant, and ideally, academic qualifications in medicine, nursing, pharmacy, biomedical sciences, statistics, or related subjects. Applicants had to submit a letter of motivation, of 400–500 words, detailing benefit of the course to themselves and their institutions, along with a curriculum vitae outlining their academic and professional achievements. They also needed to include a signed letter of endorsement (LOE) from their line manager or authorized supervisor.

Implementation and course transfer

FCD, guided by PDPs, WHO TDR, and two former TDR fellows, developed the course framework, using decades of training materials. They set up the learning management system for course delivery and appointed fourteen subject matter experts from LMICs, who are skilled in conducting high-quality clinical studies in resource-constrained settings. The team delivered three course iterations in Africa, Asia and Latin America. A call for Expressions of Interest led to the selection of CDT-Africa, Addis Ababa University, as the preferred partner

in Africa. The program's administration, including technical, methodological, and administrative aspects, was transferred to CDT-Africa. FCD conducted a gap analysis of CDT-Africa's capabilities and established a collaboration based on a maturity model informed by the capability approach [19]. Nine months later, CDT-Africa began delivering the course. FCD trained CDT-Africa faculty in online teaching, updated the course content to meet local needs, and provided ongoing technical and academic support to ensure effective course delivery.

Evaluation

The program evaluation consisted of three main components: quantitative pre- and post-surveys assessment, end-course qualitative survey, and a monitoring and evaluation framework.

Quantitative pre- and post-training assessment

This assessment utilized a closed-ended online survey (Supplementary material) administered to trainees before and after their clinical trial operations training.

It measured confidence in areas such as clinical trial phases, regulations, ethics, data management, informed consent, project and financial management, internal and external team management, investigational product management, investigational site files (ISF), safety reporting, and patient recruitment and retention. Participants rated their confidence on a five-point scale ranging from “1” (Not Confident) to “5” (Extremely Confident).

The pre- and post-course questions are grouped into four themes: designing, managing, conducting, and reporting on a clinical trial. Participants related their confidence in each theme by answering related questions. The clinical trial design theme comprises eight questions on SOPs, protocol development, randomization, blinding, regulations, trial phases, informed consent, and approvals. The trial management theme covers five areas: project management, financial management, internal and external team management, and site file management. The conducting a trial theme has seven questions on trial coordination, ethics, recruitment and retention, safety reporting, standards of implementation, monitoring findings, and investigational products. The reporting trial results theme includes two questions on trial closure and result reporting.

End-course qualitative survey

After the training, participants evaluated the course on content, organization, technology, and instruction. Open-ended questions gathered feedback on the course's benefits, practical applications, dissemination strategies, and suggestions for improvement. Responses were summarized into key thematic areas.

Monitoring and evaluation

The monitoring and evaluation used Cancedda et al.'s framework [30], which focuses on best practices for training initiatives of health professionals in LMICs: alignment with local priorities, country ownership, competency-based training and pedagogic innovation, institutional capacity building, sustainability strategy, and the establishment of long-lasting partnerships with international stakeholders. Data were continuously collected from participants and instructors via the online platform, documenting challenges encountered during course attendance (participants) or delivery (instructors), which were regularly monitored and reviewed by the study team. This information, along with qualitative surveys, pre- and post-surveys, and program team feedback, were analyzed to provide a comprehensive evaluation.

Statistical analysis

We employed the Wilcoxon rank test using SPSS [31] to assess and compare participants' scores before and after

the course, analyzing confidence changes across various domains. We employed Bootstrap method to calculate the medians and confidence intervals. Due to demand-driven sampling and non-normal score distributions, non-parametric Wilcoxon tests were applied to the five-point scale responses. Descriptive statistics were computed for sociodemographic variables and components of clinical trial competencies, and the results were presented in percentages, medians, and interquartile ranges (IQR). Pre- and post-surveys score differences were analyzed for confidence in conducting, managing, designing, and reporting clinical trials as the dependent variables using data from the five-point scale (ranging from “1” for “Not Confident” to “5” for “Extremely Confident”).

Qualitative data from participants were analyzed thematically. The study team reviewed and coded open-ended survey responses to identify and refine major themes through iterative discussions. Initial coding was conducted by DAE and study staff, with a second researcher independently coding a subset of interviews, and the research team reviewed and revised the coding through group discussions to resolve discrepancies and ensure validity. The themes provided insights into the benefits and challenges of the clinical trial course.

Results

Participants characteristics

In the initial cohort of the course, 88 study coordinators, 56 (64%) females, hailing from 19 countries across Africa, mainly from Uganda (19.3%), Ethiopia (11.4%), South Africa (10.2%), and Kenya (9.1%), were enrolled and completed the pre-course assessment questionnaire. Regarding their clinical trials experience, 85 (97%) of the participants had prior experience in clinical trial roles, serving as study coordinators, co-investigators, or research assistants (Table 1). Moreover, 57 (65%) were actively employed as study coordinators during the training period. Out of the total number of participants, 17 (19%) withdrew from the course for various personal reasons, while 71 (81%) completed the course, with 69 (97%) of them also finishing the post-course assessment.

Findings from pre- and post-survey evaluations

The Wilcoxon Signed-Ranks test and the Bootstrap method revealed significant post-survey improvements in participants' confidence scores across the four fundamental areas of competence for clinical trials. For designing clinical trials, post-training scores (median = 4.6) significantly exceeded pre-training scores (median = 3.6) (median of differences = 1.0, $p < 0.001$). Similarly, in managing clinical trials, post-training scores (median = 4.2) surpassed pre-training scores (median = 3.4) (median difference = 0.6,

Table 1 Characteristics of participants enrolled in the clinical trial operations training program (ClinOps)

Characteristics	Status	Number (%)
Gender	Male	32 (36.4%)
	Female	56 (63.6%)
Completed the course	Yes	71 (81%)
	No	17 (19%)
Prior experience in clinical trials	Yes	85 (97%)
	No	3 (3%)
Role as study coordinator	Yes	57 (65%)
	No	31 (35%)
Experience as study coordinator	0–2 years	53 (60.2%)
	3–5 years	24 (27.3%)
	> 5 years	11 (12.5%)
Educational status	MD or PhD and above	36 (41%)
	Masters	29 (33%)
	Bachelor	18 (20%)
	Other	5 (6%)

$p < 0.001$). In conducting clinical trials, post-training scores (median = 4.7) were notably higher than pre-training scores (median = 3.9) (median difference = 0.6, $p < 0.001$). Also in reporting clinical trials, post-training scores (median = 4.5) were notably higher than pre-training scores (median = 3.0) (median difference = 1.0, $p < 0.001$) (Table 2).

The components of competency within each dimension of clinical trial competency, along with their pre- and post-course median scores and interquartile ranges, are summarized in Table 3.

Findings from end-course qualitative survey

Participants' responses to the four open-ended questions are summarized as described below.

The most beneficial aspects of the course

The responses to this question are summarized in four themes:

Course design and content

Participants expressed appreciation for various aspects of the training design. They found the distribution of course content over time to be appropriate and accessible, with resources related to clinical trials readily available without restrictions. The shared documents and templates used were directly applicable to clinical trial practices, enhancing the realism of the training. Reading materials, checklists, and risk management plans were particularly lauded for their practicality. VoiceThreads explanations, questions, and discussions were deemed helpful. Moreover, the availability of study materials and direct communication with tutors, coupled with flexible timing, enabled participants to progress at their own pace without sacrificing quality. The flexibility to undertake the training at their convenience was highly valued. Additionally, collaborative activities such as risk management group work and tutorial sessions provided opportunities for active participation and clarification of doubts. Discussions with foreign partners, group forums, and exposure to new methods like Moodle were cited as beneficial experiences. The learning platform's accessibility from anywhere and at any time was commended, as was the ability to listen to recordings offline and meet deadlines.

In design context, participants noted that the course comprehensively addressed nearly all essential aspects of a clinical trial. They found the study materials to be abundant, offering detailed information on clinical trials along with supplementary readings and references.

Trainers' competency

In general, trainers were regarded as highly knowledgeable about the course, drawing from significant lived experience in clinical trials. This expertise greatly enriched the learning experience for trainees. Additionally, the tutors were recognized for their subject matter expertise, injecting vitality into the course content beyond what textbooks could offer. They were noted for their approachability and accessibility, with their lectures skillfully presenting course material. The availability and effective communication of trainers during virtual training sessions were consistently commended. Coordinators

Table 2 Difference in the score of the participants in the measures of the four dimensions of competence (conduct, manage, design & report) in clinical trials before and after the training

Dimension of clinical trial competency	Pre-course median score	Post-course median score	Median of differences (95% CI)	P-value
Conduct CT	3.9	4.7	0.9 (0.6, 1.0)	< 0.001
Manage CT	3.4	4.2	0.6 (0.4, 0.8)	< 0.001
Design CT	3.6	4.6	1.0 (0.8, 1.1)	< 0.001
Report CT	3.0	4.5	1.0 (0.9, 1.5)	< 0.001

Post post-training, pre pre-training, CT Clinical trial, significance at $p < 0.05$

Table 3 Pre- and post-course median scores and interquartile ranges in each dimension of clinical trial competency

Dimension of clinical trial competency	Components of the competency	Pre-course median score (IQR)	Post-course Median score (IQR)	Pre-post course Median change (IQR)
Design CT	SOP design	4 (2, 4)	5 (4, 5)	1 (0, 2)
	SOP implement	4 (4, 5)	5 (4, 5)	1 (0, 1)
	Protocol design	3 (2, 4)	4 (3, 4)	1 (0, 2)
	Protocol implements	4 (3, 5)	5 (4, 5)	1 (0, 1)
	Randomization	3 (2, 4)	4 (4, 5)	1 (0, 2)
	Blinding	3 (2, 4)	4 (4, 5)	1 (0, 2)
	Regulations	4 (3, 4)	5 (4, 5)	1 (0, 1)
	Trial phases	4 (3, 5)	5 (4, 5)	1 (0, 1)
	Informed consent	4 (4, 5)	5 (5, 5)	1 (0, 1)
	Approvals	4 (3, 5)	5 (4, 5)	1 (0, 1)
Manage CT	Project management	3 (2, 4)	4 (4, 5)	1 (0, 2)
	Financial management	3 (3, 4)	4 (4, 4)	1 (1, 2)
	Internal team management	3 (3, 4)	5 (4, 5)	1 (1, 2)
	External team management	3 (2, 4)	4 (4, 5)	1 (1, 2)
	Site file management	4 (3, 5)	5 (4, 5)	1 (0, 1)
Conduct CT	Trial coordination	4 (3, 4)	5 (4, 5)	1 (0, 1)
	Ethics	4 (4, 5)	5 (5, 5)	1 (0, 1)
	Recruitment	4 (3, 4)	5 (4, 5)	1 (0, 1)
	Retention	4 (3, 4)	5 (4, 5)	1 (0, 1)
	Safety	4 (3, 4)	5 (4, 5)	1 (0, 1)
	Implementation standards	4 (3, 4)	5 (4, 5)	1 (0, 1)
	Manage monitoring findings	4 (3, 4)	5 (4, 5)	1 (0, 2)
	Investigational products	4 (3, 4)	4 (4, 5)	1 (0, 2)
Report CT	Trial closure	3 (2, 4)	4 (4, 5)	1 (0, 2)
	Report trials findings	4 (3, 4)	4 (4, 5)	1 (0, 2)

CT Clinical Trial, IQR Interquartile range

were also lauded for their deep understanding of the subject matter, enabling them to provide insightful examples.

Practicality

Participants expressed appreciation for the practicality of the course in relation to their clinical trials. They found the content to be directly relevant to their everyday work duties and activities. The course was deemed practical, offering real-life experiences and insights into handling and managing clinical trials. Regarding its practicality, one participant articulated:

It was timely on my part, as I am considering a new career path into research monitoring and CRO management. It encompassed project management, research skills, etc. Further to that, it has helped a lot in my day-to-day execution of study coordination roles at the facility especially on the risk assessment and prioritization (PM52).

The satisfaction with the entire approach, encompassing content, trainers, and methodology, is aptly captured in the following quote from another participant:

The best thing about this course for me was the easy accessibility to study materials and availability of experts in the field to explain them further during tutorials and in comment sections on Voice threads" (YN70).

Another participant stated:

The best thing about the course was the discussion forums where we had to discuss the topics. This part enables me to express my thoughts and understanding about the topics under discussion. It also afforded me the opportunity to know what my colleagues' thoughts were on issues being discussed. lastly, it allows me to see how diverse people's views are regarding a given matter.

As a concluding remark, the overall evaluation of the training can be encapsulated most effectively with the following quote from one of the participants:

The best thing about this course was that not only content was good but also moderators and other participants were committed to sharing experiences, and much more. Being a part of this course was a great opportunity for me and I would love to get another chance if there is another opportunity (PAB34).

Application in participants' current roles

Participants' responses for this section are organized into three themes: improved understanding, improved practice, and improved skill of project management.

Improved understanding

Participants highlighted that the training facilitated their acquisition of techniques in clinical trials, leading to revisions and enhancements of their existing documents and manuals. Moreover, it aided in refining their ability to teach clinical research methods, particularly focusing on clinical trials. Specifically, participants cited increased knowledge in operations, conducting, and reporting clinical trials, as well as in preparing Investigator ISF. Overall, these improvements contributed to enhancing confidence in their clinical trial-related roles.

Improved clinical practice

Several participants noted that the training facilitated improvements in their daily clinical trial responsibilities. It provided valuable input for coordinating ongoing studies and proved particularly beneficial for those in roles such as clinical coordinator, allowing them to integrate performance indicators into their work and assisting in the development of SOPs. This enabled them to prepare comprehensive checklists, including quality management checklists, prior to clinical trials, enhancing performance monitoring through key performance indicators. Additionally, the training. Participants highlighted an increase in their adherence to clinical trial procedures and improvement in team management.

Improved project management skills

Several participants found the training beneficial for enhancing quality management, data management, and regulatory activities within their clinical trial work. They noted that the training aided in improving documentation practices and streamlining work processes and scheduling. Moreover, participants mentioned that the training equipped them with skills in financial management and risk management, including identifying and

implementing mitigating measures for potential risks. Additionally, they learned how to effectively close out a project. Other skills gained included improved preparation for audits and inspections, as well as fostering and maintaining positive relationships with both internal and external partners.

Dissemination of course contents within their institutions

This question reveals two distinct themes, which are identified and presented as follows:

To teach, mentor or share experience

Some participants utilized the course to instruct clinical research methods and ethics to resident students, while others employed it to mentor doctors and junior colleagues in coordinating clinical trials. They provided guidance to staff on maintaining quality standards in clinical trial conduct and shared their course experiences with their team members. Furthermore, they shared course documents with individuals engaged in similar practices and distributed modules and templates to colleagues. Participants also indicated using the course material as a training tool for other members. Additionally, some organized their own capacity-building training sessions, which included retraining lab staff, onboarding new personnel, and instructing fellow workers involved in trials they coordinated.

Practical support

In addition to teaching and training, participants also emphasized providing direct support in practice. For instance, they assisted their sites in reporting, updating, and distributing data, as well as re-evaluating their site key performance indicators. Some participants actively worked to combat fraud, fabrication, and falsification that could compromise the quality of data collection.

Potential modifications to the course to better meet their needs

The responses to this question are categorized into three themes:

Proceed as it is

Some participants expressed their appreciation for the training and conveyed a desire for it to continue without any changes. They indicated that they had no suggestions for improvement. For instance, three participants specifically mentioned that they believe the training is already perfect and should remain unchanged.

Satisfaction expression

Rather than providing specific suggestions for improving the training as requested, most participants chose to

express their satisfaction by congratulating and offering praise such as: informative, well-organized, perfect for current position, effective, simply perfect, meticulously planned, superb content, immediately relevant, comprehensive material, highly engaging, well-crafted, tailored to needs, and so forth.

Specific improvement suggestions

Although many respondents expressed satisfaction without specific comments and praised the training's quality, there were also constructive suggestions for enhancement. In this section, these suggestions are categorized into four areas.

Several participants suggested extending the duration of the course from 10 weeks to 14 weeks to allow for more in-depth discussions of the course material. They recommended extending the one-hour tutorial sessions to provide attendees with additional time for exchanging views. Additionally, some participants found the timing of the live tutorials challenging as they occurred during working hours, highlighting the need for greater time flexibility. There was a consensus on the need to allocate more time to live classes. Participants proposed allocating two weeks for submission of group work and extending the duration of each lesson to two weeks to accommodate these changes.

Participants recommended improving coordination of group projects and enhancing participant interaction, potentially through open forum discussions. One participant identified group work as a significant challenge within an otherwise excellent course. The approach to team activities, particularly regarding the risk management plan, was perceived as lacking smoothness. It was suggested that senior management should oversee group work, and if feasible, teams should be organized by country to facilitate communication. Measures should be implemented for non-responsive participants during group assignments, with coordinators working closely with team leads to clarify requirements. One participant proposed that group meetings should be financially supported by the institution offering the course.

Another suggestion pertained to accessibility, particularly concerning VoiceThreads. One participant noted difficulty accessing VoiceThreads via phone and recommended improvement in this area. Participants found it challenging to complete VoiceThreads before live tutorials and suggested making presentations readily available for download in PowerPoint format. Furthermore, they recommended incorporating more interactive virtual sessions with colleagues through platforms like Zoom or Microsoft Teams. Additionally, there was a suggestion for a smartphone interface to enhance accessibility.

Findings from the monitoring and evaluation

The monitoring and evaluation data have been summarized in alignment with the six best practices outlined in the Framework and Best Practices for Training Initiatives of Health Professionals in Low-income Countries (Table 4).

Discussion

This study aimed to design, develop, implement, and evaluate an innovative clinical trials operation training program for Africa. In its first cohort, the program enrolled 88 participants from 19 countries. There were significant improvements in participants' post-training scores compared to their pre-training scores across the four essential domains of clinical trials competence: designing, conducting, managing, and reporting clinical trials. Development and implementation of the program demonstrated efficiency across the six best practices for health professional training programs for low-income countries: alignment with local priorities, country ownership, competency-based training and pedagogic innovation, institutional capacity building, sustainability strategy, and the establishment of long-lasting partnerships with international stakeholders. The program's innovative approach, incorporating offline-accessible downloadable content, Moodle LMS, VoiceThread interactive sessions, and multidirectional competency assessment strategies, garnered high satisfaction among participants. Engaging academic and product development partners like FCD, FIND, IAVI, MMV, PATH, TB Alliance and TDR in the program team nurtured long-lasting partnerships. Previous studies on training initiatives for health professionals in Africa have shown the potential to improve competency and performance [32–34], yet there is limited information on competency in clinical trial capacity.

The program's success in enhancing participants' proficiency in clinical trials was notably marked by a significant improvement. This achievement can be largely credited to the effective utilization of innovative teaching strategies, including offline-accessible downloadable content, Moodle LMS, VoiceThread interactive sessions, multidirectional competency assessment strategies, and the TDR Core Competency Framework. Previous studies conducted in Africa suggest that incorporating multiple strategies into training programs has the potential to engage both trainees and trainers, fostering active participation [35–37]. The approach followed in the program addresses a common weakness found in many online courses, which are typically designed for individuals to complete independently, often leading to feelings of isolation and loneliness. Utilizing Moodle as the learning

Table 4 Summary of monitoring and evaluation findings based on the six outlined best practices in the Framework and Best Practices for Training Initiatives of Health Professionals in low-income countries

Anticipated best practices	Findings
Alignment with local priorities	<ul style="list-style-type: none"> - Participants quickly applied their new knowledge, effectively supporting their local institutions' objectives. - Participants exchanged personal insights and problem-solving approaches, with the learning activities tailored to address authentic challenges encountered in their fields.
Country ownership	<ul style="list-style-type: none"> - Transfer of the program to Addis Ababa University from FCD facilitated country ownership
Pedagogic innovation	<ul style="list-style-type: none"> - Downloadable content with offline access enabled participants to work offline, uploading their work to forums upon reconnecting. - Moodle LMS provided convenient access for participants to course materials, interactions, and submissions. - VoiceThread enhanced dynamic teaching, enabling interactive sessions and real-time addressing of academic challenges. - Zoom tutorials generally satisfactory, minor audio/connection issues reported. - Assessment strategies included forum participation, quizzes, and group assignments, promoting active participation and engagement. - Course leaders' proactive follow-up boosted participant confidence, ensuring continued engagement.
Institutional capacity building	<ul style="list-style-type: none"> - Training local faculty on the design and management of the course as part of knowledge transfer component enhanced local capacity. - Utilization of local institution-hosted digital course delivery and management platforms enhanced capacity managing training locally.
Sustainability strategy	<ul style="list-style-type: none"> - The local partner institution becomes a sustainable clinical trial training hub for Africa
Long-lasting partnerships	<ul style="list-style-type: none"> - Involving academic and product development partners in the program team, such as FCD, FIND, IAVI, MMV, PATH, TB Alliance, and TDR, fostered enduring partnerships. - The program cultivated formal and informal partnerships among participants, likely persisting post-course. - Top students invited to join a two-year MSc in Clinical Trials program at CDT-Africa Addis Ababa University.

FDC Faculty of Capacity Development, *FIND* Foundation for Innovative New Diagnostics, *MMV* Medicines for Malaria Venture, *IAVI* International AIDS Vaccine Initiative, *PATH* Program for Appropriate Technology in Health, *TDR* Training in Tropical Diseases, *CDT-Africa* Center for Innovative Drug Development and Therapeutic Trials for Africa

management system, where participants access course materials, upload their work, and interact with peers and faculty, facilitated convenient access to course resources. Incorporating VoiceThread into the teaching-learning process enabled dynamic lesson presentations, facilitating flipped classrooms and fostering interactive sessions. Participants were able to add comments or questions to any part of the presentation, allowing instructors to address academic challenges or misconceptions in real-time. The use of Zoom for live tutorials has generally been satisfactory, with few participants reporting issues with audio speed or connection. This is in support of previous studies that demonstrated the effectiveness of the Zoom teaching and learning method in educating and training health professionals and enhancing their readiness for real-life roles [38, 39]. This technology has become important for training during the COVID-19 pandemic, which restricts access to in-person classroom sessions. When issues arise in the use of Zoom, they are often attributed to participants relying on slow, local WiFi. To optimize connection quality for all, participant mics and cameras were typically switched off during tutorials, with participants typing comments or questions to the class instead. The recordings of the live tutorials were also made available immediately after the session. Each tutorial included at least one faculty member tasked

with monitoring and engaging with the chat, bringing key points to the presenter's attention as needed.

Participants from various countries initially expressed concerns about potential disruptions to their participation in the program due to poor internet connectivity. However, the implementation of innovative teaching and learning platforms in this course helped alleviate these anticipated challenges. By utilizing downloadable content, including a "downloads folder" in each lesson for participants to access all materials at once, individuals were able to work offline and subsequently upload their work to discussion forums upon connecting to the internet. While participants were encouraged to post on forums, and no time limits were imposed, offering maximum flexibility for those encountering internet or utility-related issues. Although proficiency in English was required for all participants, it was not the native language for some. Initially, a few lacked confidence to engage publicly on forums. However, through a positive learning environment and continuous support, their language confidence and verbal skills improved. The tutors clarified that participants didn't need fluent English proficiency. It was more important to communicate effectively, even if it meant making grammatical or spelling errors, rather than refraining from asking questions or sharing experiences.

The routine information collected throughout the various stages of course development, implementation, and evaluation, as part of the program's monitoring and evaluation framework, have documented various opportunities, challenges, and prospects associated with the ClinOps program. The study findings indicated that participants encountered various technical and personal challenges while taking part in the training, including family commitments, health issues, and internet disruptions. Those who faced these challenges early on often experience difficulties and ultimately withdrew from the course. Similarly, prior studies conducted in Africa indicate the need for a comprehensive support to participants, including resources, mentorship, and ongoing program monitoring to ensure successful training outcomes and impacts [19, 40–42]. Some challenges reported by participants during this course stemmed from personal issues. Health and family reasons, such as malaria or dengue fever, led some to lag on some specific courses. Other challenges included government internet shutdowns, bereavement, divorce, and pregnancy-related issues. Many faced obstacles but persevered to complete the course, despite these challenges. Issues were addressed through mentor and instructor discussions. The initial three weeks were crucial; participants falling behind during this period tended to withdraw. Vigilance during this period and proactive engagement helped resolve issues. This suggests that incorporating one-on-one mentorship was vital for fostering social presence, offering positive support, and building an emotional connection between students and course instructors, which helped students persist in the course despite personal challenges. Weekly mentor engagement and peer support fostered success within a positive learning environment. Participants appreciated the course leaders' proactive approach of following up through one-to-one emails and, if necessary, Zoom calls when engagement was lacking. This practice instilled confidence and encouraged continued participation.

In this study, participants were primarily problem-oriented in their approach to learning, seeking to apply new knowledge immediately in their professional roles. This aligns with the goals of their institutions, which prioritized tangible, immediate benefits stemming from the course. This sense of urgency was heightened by the expectation for participants to rapidly acquire the skills necessary to support ongoing projects and future capacity-building initiatives. Consequently, the learning activities were designed within the context of real-world challenges, encouraging participants to share their own experiences and problem-solving strategies. Initially, the teamwork aspect of the course assessment posed challenges for most groups, particularly

in navigating effective remote collaboration across different time zones. It was frustrating when some team members did not fully engage. However, considering time zone differences during team formation helped minimize these issues. With approximately twelve participants and one faculty mentor per team, each group had a private shared space on the Learning Management System for project discussions and file sharing. This setup fostered friendships and trust among team members, facilitating their working dynamics and fostering informal networks that may persist beyond the course.

The transfer of the ClinOps training program from a high-income to a lower-middle-income country—specifically from FDC to Addis Ababa University—spanning administrative, technical, and online teaching functions through knowledge transfer training for local faculty and research staff facilitated the alignment of the program with local priorities. The transfer of the program to Addis Ababa University CDT-Africa, facilitated by FCD and PDPs, fostered country ownership and positioned the local partner institution as a sustainable hub for clinical trials training in Africa. The local institution gained capacity to sustain and develop new programs, serving as a regional asset for LMIC capacity building. The approach in which the in-country Program Leader received guidance on establishing a learning management system and adapting the online pedagogy to meet the ongoing capacity-building needs of Ethiopia and the broader region was a significant leadership milestone that contributed to long-term sustainability of the program. This aligns with prior studies on clinical research courses conducted elsewhere that underscore the importance of training local experts in clinical research as a sustainable approach to mitigating research gaps in LMICs [43–47]. By updating the course content and delivering it through a local institution, the program strategically positioned itself to address regional capacity development needs in clinical research focusing on locally relevant clinical trial issues.

The project seeks to track and document the long-term impact of the course by conducting regular surveys with graduates. These surveys will evaluate how effectively graduates are applying the knowledge and skills gained during the course in the field of medical product development. By collecting feedback over time, the project aims to assess the lasting value of the course in real-world settings, identifying both successes and areas for improvement in preparing participants for future challenges in the industry. As the course enrolls additional cohorts, it will evolve into a sustainable African program, providing more comprehensive insights and data.

Conclusion

The ClinOps program, a clinical trial operations training initiative for Africa led by experts from academia and product development partners, significantly enhanced participants' competency in clinical trials. The program effectively followed the six best practices for health professional training programs for low-income countries, alignment with local priorities, country ownership, pedagogic innovation, institutional capacity building, sustainability, and long-lasting partnerships. Transferring the program to a local institution promoted country ownership and established the institution as a sustainable clinical trial training hub for Africa. Participants in the post-course qualitative evaluation expressed appreciation for the beneficial aspects of the course, its relevance to their current roles, and the dissemination of course content within their institutions. They also provided suggestions for potential modifications to better meet their needs, supporting beneficial aspects of the course and suggesting strategies for improvement. To enhance clinical trials capacity in Africa effectively, training initiatives should provide comprehensive competency in designing, conducting, managing, and reporting trials tailored to local contexts. Exploring the monitoring and evaluation aspects further could be an area for future research.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12909-025-06733-7>.

Supplementary Material 1.

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Authors' contributions

Study design and conception: DAE, AF, JW, TM, PN, AC, BO, AN, SW, HD, JL, RH, RB, MV, EM. Funding acquisition: DAE, AF, JW, EM. Study implementation and data analysis: DAE, AF, JW, TM, PN, AC, BO, AN, SW, HD, JL, RH, RB, MV, EM. Draft the Manuscript: DAE, TM. Reviewed and revised the manuscript: DAE, AF, JW, TM, PN, AC, BO, AN, SW, HD, JL, RH, SB, RB, BS, MV, EM. All authors read and approved the final manuscript for publication.

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Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

Scientific and Ethics Review Committee of the Center for Innovative Drug Development and Therapeutic Trials for Africa approved the study. Informed

consent was obtained from the course participants for both the pre- and post-course survey and the qualitative part. The study adhered to the Declaration of Helsinki.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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