Akkreditierungsagentur
im Bereich Gesundheit und Soziales
Accreditation Agency in Health and Social Sciences

Assessment Report

for the Application of
Addis Ababa University, Ethiopia
for the Assessment of the Certification Course
“Clinical Trial Operations” (Advanced Certificate).

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Decision	**September 20, 2024**

Inhalt

1 Introduction

The Accreditation Agency in Health and Social Sciences (AHPGS) is an interdisciplinary and multi-professional organization. Its mission is to evaluate Bachelor and Master' programs in the fields of health and social sciences, as well as in related domains such as medicine or psychology. By conducting accreditation and recommendation procedures, the AHPGS contributes to the improvement of the overall quality of teaching and learning. However, the higher education institutions remain responsible for implementing the quality assurance recommendations made by the AHPGS. Since 2004, the AHPGS has been a member of the European Consortium for Accreditation (ECA). In 2006, the AHPGS also joined the European Association for Quality Assurance in Higher Education (ENQA) and became a member of the International Network for Quality Assurance Agencies in Higher Education (INQAAHE) in 2009. Since 2012, the AHPGS has been a member of the Network of Central and Eastern European Quality Assurance Agencies in Higher Education (CEENQA). Furthermore, the AHPGS has been listed in the European Quality Assurance Register (EQAR) since 2009. On top of that, since 2023, the World Federation of Medical Education (WFME) has recognized the AHPGS as an agency with recognition status for 10 years.

In carrying out accreditation procedures, the AHPGS follows the requirements of the Standards and Guidelines for Quality Assurance in the European Higher Education Area (ESG). In the present case, the decision regarding the accreditation of the certification course is carried out by the AHPGS Accreditation Commission based on the following accreditation criteria[1]:

1. Program aims and their implementation
2. Structure of the study program
3. Admission and Feasibility
4. Examination System and Transparency
5. Teaching Staff and Material Equipment
6. Quality Assurance

[1] Approved by the AHPGS Accreditation Commission

7. Gender equality and equal opportunities

I. The University's application

The AHPGS verifies the sufficiency of the documents submitted by the University, namely the Self-Evaluation Report and its corresponding annexes. These are to fulfil the assessment spheres as well as the AHPGS standards. With these information, the AHPGS produces a summary, which is to be approved by the University and subsequently made available for the expert group, together with all other documentation.

II. Written review

The main documents are reviewed by the expert group assigned by the accreditation commission of AHPGS. This is done in order to verify the compliance of the certification course with the applicable accreditation criteria. Consequently, the experts comprise a short summary regarding the course.

III. On-site visit (peer-review)

The experts carry out a site visit at the University. During this visit, discussions are held with members of the University, which include University and department administration, degree program management, teachers, and students. These discussions provide the expert group with details about the certification course beyond the written documents. The task of the experts during the site visit is to verify and evaluate the objectives of the program and its projected study results, its structure, staff, material resources, course of studies, methods of assessment (selection of students, assessment of achievements, students' support), as well as the program management (program administration, external assurance of study quality).

Following the site visit, the expert group evaluates the fulfilment of the criteria based on the results of the visit and the documents submitted by the HEI. This Assessment Report is based on the results of the visit, the written review of the certification course, and the documents submitted by the University. Finally, the

Assessment Report is made available to the University for the opportunity to issue a response opinion.

The Assessment Report as well as the University's response opinion – together with the provided documents – is submitted to the accreditation commission of the AHPGS.

IV. The AHPGS decision

The accreditation commission of the AHPGS examines the documentation made available in the process of application, namely the University's self-evaluation report, its annexes, the Assessment Report, as well as the University's response opinion. These documents lay basis for the decision of the Accreditation Commission of the AHPGS regarding the assessment of the certification course.

2 Information about the University

Addis Ababa University (AAU), established in 1950 as the University College of Addis Ababa, is the oldest and largest higher education and research institution in Ethiopia. It has graduated over 222,000 students. The University is led by a president and supported by four vice presidents and one executive director. AAU currently has 47,610 students and 8,709 staff members. It offers 83 undergraduate and 417 graduate programs across 10 colleges, 4 institutes, and 6 research institutes.

The ClinOps advanced certificate is an online course offered by the College of Health Sciences (CHS) at AAU, which includes the Schools of Medicine, Pharmacy, Public Health, and Allied Health Sciences, as well as Tikur Anbessa Specialized Hospital. The CHS was established in 2009, consolidating various health institutions.

AAU's research facilities include several specialized institutes, such as the Institute of Biotechnology and the Institute of Ethiopian Studies. AAU continues to develop its academic and research capabilities, establishing partnerships with over 200 international and local institutions in 2022.

The ClinOps course hosted under CDT-Africa, part of the regional Center of Excellence established in 2014 and recognized in 2017 under the World Bank's ACE II initiative, has seen a completion rate of 86.5% over its two cohorts. The center offers a Master study program “Clinical Trials” and a PhD program “Translational Medicine”, along with various short courses in clinical research and related fields. The center has also gained international accreditation for its Master study program “Clinical Trials” from the Accreditation Agency in Health and Social Sciences (AHPGS).

AAU's CDT-Africa center is notable for its work in drug, vaccine, and diagnostic development, and for its comprehensive training programs in translational medicine. The center's efforts attract significant partnerships and funding, contributing to advancements in medical research and education in Africa.

3 Overview

3.1 Procedure-related documents

The Self-Evaluation Report for assessment of the above-mentioned certification course (hereinafter the SER) of the Addis Ababa University (hereinafter the University) was submitted to the Accreditation Agency in Health and Social Science (AHPGS) in electronic format on April 01, 2024. The decision regarding the assessment of the certification course is carried out by the Accreditation Commission of the AHPGS. The contract between the Addis Ababa University and the AHPGS was signed on February 09, 2024.

On May 17, 2024 the AHPGS forwarded the open questions and explanatory notes (hereinafter OQ) pertaining to the application for assessment for certification course to the University. On May 31, 2024 the University submitted the answers to the open questions and explanatory notes (hereinafter AOQ) to the AHPGS in electronic format.

The application documentation submitted by the Addis Ababa University follows the outline recommended by the AHPGS. Along with the application request towards assessment of the advanced certificate program "Clinical Trial Operations", the following additional documents can be found in the application package (the documents submitted by the University are numbered in the following order for easier referencing):

Specific documents for the Certification Course "Clinical Trial Operations"

Annex	Description
1	Module Description
2	Curriculum Vitae for Instructors
3	Teaching Matrix
4	Brochure SC Training
5	Assessment in the Clinical Trials Operation Training Course
6	M & E Report
7	Final AAU Senate Legislation
8	AAU Strategic Plan
9	AAU Gender Policy
10	AAU Guidelines for Program Design, Approval and Review
11	AAU Students Discipline Rules and Regulations

12	Evaluation Templates

The application, the open questions (OQ) and the answer to the open questions (AOQ) as well as the additional documents build the basis for the present summary. The layout bears no significance, as it solely reflects the agreed standard between the AHPGS and the University.

3.2 Structural data of the certification course

University	Addis Ababa University
Faculty/Department	College of Health Sciences / Center for Innovative Drug Development and Therapeutic Trials for Africa
Cooperation partner	- Product Development Partners (FIND, Medicines for Malaria Ventures, TB Alliance, IAVI, PATH), - Special Program for Research and Training in Tropical Diseases (TDR).
Title of the Certification Course	„Clinical Trial Operations“
Degree awarded	Advanced Certificate
Form of studies	Distance Learning/Online-Study
Organisational structure	Monday to Friday from 8:00 am to 5:00 pm
Language of Studies	English
Period of education	Ten weeks
Credit Points (CP) according to the European Credit Transfer System (ECTS)	Not applicable
Hours/CP	Not applicable
Workload	Total: 100-120 hours Contact hours: 20 hours Individual work: 60-80 hours Practice: 20 hours
Launch date of the certification course	Fall 2021
Time of admission	No fix time of admission
Number of available places on the program	90

Number of enrolled students by now	0 No students enrolled right now.
Particular enrollment conditions	The applicants are required to have: - experience in roles of study coordinator, investigator, co-investigator, study manager or assistant, or aspire to take a clinical study role. Priority consideration is given to applicants from: - sites with limited clinical trial capacity, - sites planning to initiate a trial.
Tuition fees	4,500 USD[2]

Chart 1: Structural data of the certification course

4 Expert Report

The virtual site visit was carried out on June 25, 2024, according to the previously agreed schedule (and following the site visit in 2023 with the same expert group). Representatives from the head office of AHPGS accompanied the expert group.

The expert group met on June 24, 2024 for preliminary talks prior to the site visit. They discussed the submitted application documents and the results of the written evaluation as well as questions that had been raised prior. Furthermore, they prepared the plan of the site visit at the University.

During the virtual site visit, experts conducted discussions with the University management, representatives of the CDT-Africa, the chair, vice chair and the teaching staff of the Certification Course "Clinical Trial Operations" as well as with alumni. Furthermore, the experts were provided with a video of the premises and labs of the University.

The Assessment Report is structured in compliance with the "Standards and Guidelines for Quality Assurance in the European Higher Education Area" (ESG), established by the European Association for Quality Assurance in Higher Education (ENQA). The certification course will be described and analyzed in a comprehensive manner below. The documents submitted by the University, the experts' feedback to the documents, the observations made during the site visit, the results of discussions with the representatives of the University, CDT-Africa and

[2] Upon discussion with course partners, the fee is reduced to 2,000 USD for the next round of the course scheduled for September 2024.

the staff as well as alumni serve as the foundation for the statements made in the Assessment Report.

4.1 Program aims and their implementation

Summary

The ClinOps course is designed to support Study Coordinators (SCs) in conducting high-quality, regulatory-compliant clinical trials. Its aim is to equip SCs with the necessary knowledge, skills, and competencies to effectively plan, conduct, manage, and monitor clinical trials in accordance with regulatory requirements, ethical principles, and best practices. The course covers essential topics such as study design and protocol development, bioethics, good clinical practice (GCP), data management, regulatory affairs, safety monitoring, and practical management skills, with a focus on enhancing the quality, efficiency, and ethical conduct of clinical trials in Low and Middle-Income Countries (LMICs).

The learning objectives of the course include (SER 3.1.1):

- Gaining a comprehensive understanding of the entire clinical trial process.
- Preparing research sites for trial start-up with an understanding of project management, trial design, and protocol development.
- Conducting GCP-compliant clinical trials with effective patient recruitment and retention, data management, data monitoring, pharmacovigilance, and safety reporting.
- Designing and maintaining a clinical trial's quality system through SOPs, risk management, audits, inspections, and quality control measures.
- Identifying and addressing challenges in site management, including capacity development, staff retention, community engagement, and grant management.
- Developing people management skills for effective collaboration with internal and external partners.
- Efficiently closing out clinical trials, managing post-trial responsibilities, and timely reporting of results.

The ClinOps advanced certificate program prepares trainees to manage all aspects of clinical trials at a site, ensuring they are proficient in site preparation, GCP-compliant trial execution, and quality system management throughout the

trial lifecycle. Trainees will also be capable of addressing site management challenges, developing effective people management skills, and efficiently closing out trials while handling post-trial responsibilities. Additionally, they will gain a thorough understanding of research methods, clinical trial fundamentals, and the regulatory and legal frameworks governing clinical trials. For the qualification to engage in a skilled occupation, the course provides study coordinators and clinical research professionals with the necessary skills and knowledge to conduct high-quality, regulatory-compliant clinical trials. Regarding social responsibility, the course emphasizes ethical conduct, patient well-being, data integrity, and community engagement. Participants are trained to prioritize ethical considerations, patient welfare, and contribute to research that benefits society. In terms of personality development, the program builds essential skills such as ethics, critical thinking, and problem-solving, which are crucial for personal and career growth (SER 3.1.2).

The course equips graduates with the skills and knowledge to pursue careers in diverse settings, including pharmaceutical industries, regulatory agencies, contract research organizations (CROs), hospitals, academia, and other research centers. Potential career opportunities for graduates include roles such as Clinical Research Coordinator (CRC), Clinical Trial Assistant, Clinical Research Associate (CRA), Clinical Trial Manager, and Data Coordinator/Manager. Graduates may work in project management, monitoring, or data coordination within CROs, and in clinical research departments of pharmaceutical or biotech companies, managing trials or patient recruitment (SER 3.2.1).

Although a tracer study has not been conducted, most trainees have been working as study coordinators, investigators, monitors, research nurses, or in other roles within research institutions across Africa. It is anticipated that graduates will continue in similar or related clinical research careers. In the post-course assessment for the 2021 cohort, 85.5% of graduates reported that the course is relevant to their current work in coordinating clinical trials. Additionally, a community of practice platform has been developed as part of the course, allowing previous participants to exchange ideas on real-world challenges (SER 3.2.2).

Judgement

As the University states, the "Clinical Trials Operations" course was initiated due to the need identified by product development partners across various African

sites, highlighting the necessity for study coordinators to enhance their knowledge and skills to effectively support the execution of clinical trials. The development of the course followed a competency framework to ensure that the skills taught would be relevant and applicable. The development of the program began in 2017 with extensive discussions among curriculum development teams, product development partners, and other stakeholders to identify the necessary competencies for study coordinators. This collaborative approach ensured that the course content was relevant and comprehensive.

As the University states, the program's ambition includes engaging entire institutions rather than just individuals, with efforts to link with the African clinical trial community (CTC), a platform hosted in South Africa already underway. Additionally, there is a task force dedicated to expanding the clinical trial basis and establishing 250 clinical research centers in hospitals and health centers throughout Africa.

The experts inquire about the motivations for participants to join the course, which include:

1. The advanced nature of the course, which fills a gap between basic clinical trial knowledge and practical application.
2. The opportunity to become part of a professional network post-completion.
3. The potential for high-performing students to continue their studies within the Master study program at CDT-Africa.

From the experts' point of view, the course effectively prepares study coordinators to manage clinical trials, enhancing their capacity and efficiency. The program is well-aligned with the needs of clinical trial operations in resource-limited settings, contributing to the professional growth of the participants and the overall quality of clinical research.

Decision

From the experts' point of view, the requirements of this criterion are fulfilled.

4.2 Structure of the certification course

Summary

The program comprises ten modules, out of which all are obligatory. There are no elective modules. Each module is delivered weekly for ten weeks. All modules have to be completed within ten weeks. There is no semester offered as a period for exchange programs, as it is an online short course (SER 4.1.1).

All modules are program specific. There are no lessons provided from or in collaboration with other study programs (SER 4.1.2).

The list of modules offered:

Nr.	**Title**
1	Introduction to Clinical Trial Operations
2	Data Management and Biostatistics
3	Study Design and Protocol Development
4	Project and Financial Management
5	Conducting a Trial - Part 1
6	Conducting a Trial – Part 2
7	Closing Out and Reporting a Trial
8	Working with External Partners
9	Quality Systems, Audits and Inspections
10	Pharmacovigilance

Table 02: Module Overview

The module description/catalogue covers the following aspects: module number, level/semester, credit hours, language of course, learning outcomes, content, and examination.

The ClinOps advanced certificate program comprises ten modules delivered via interactive recorded presentations, live and asynchronous tutorials, discussion forums, and personalized mentoring. The following essential knowledge is included in the program:

- Study design and protocol development.
- Bioethics.
- Good clinical practice (GCP).
- Data management.
- Regulatory affairs.
- Safety monitoring.
- Practical management skills.

The University highlights the following special features offered by the program:

- Real-time application: The study coordinators actively work with their study teams to evaluate the current processes and implement improvements during and following the completion of the course. Each student is seen as an individual with a preferred learning style.
- Wide range of expertise and experience: self-directed learning prioritized.
- Addressing the specific challenges encountered in resource-limited settings: engagement of the students in dialogue about real-world situations encountered in challenging geographic, cultural, and political settings.

The first lesson is about the phases of clinical trial, ethical considerations, and informed consent. The applicability of the guidelines of the International Council for Harmonization (ICH) in Good Clinical Practice (GCP) is also an important theme. The second lesson deals with the various steps involved in data management process as well as with the site responsibilities in due process as well as important aspects of biostatistics very relevant to the role of study coordination. In the third lesson, the students learn about clinical trials design and protocol, outlining the different types of designs that can be employed to evaluate the effectiveness of health interventions. Protocol deviation and amendments are also treated under lesson three. The fourth lesson includes concepts of project and financial management in the context of clinical trials. Lessons five and six give an overview of the main clinical trial processes and requirements, including the application of key GCP tenets, essential document management, etc. Lesson seven teaches key regulatory aspects that need to be considered during trial close-out and strategies to avoid delays in trial close-out. Lesson eight delves into working with collaborators and elements important for smooth collaboration including metrics and deadlines as well as management of intellectual property rights. Lesson nine is about quality aspects in clinical trials including Standard Operating Procedures (SOPs) as well as audit and inspection The last lessons describes the safety aspects in clinical trials.

After completing the program, the students should have acquired the following skills (SER 4.1.3):

- Knowledge of trial design methodologies and principles, including protocol development and adherence to regulatory requirements.
- Ability to conduct trials in compliance with the GCP guidelines, ensuring ethical conduct and patient safety.

- Ability to effectively recruit and retain participants in clinical trials, ensuring sufficient enrollment and minimal dropout rates.
- Skills in managing clinical trials data, ensuring the accuracy, integrity, and confidentiality.
- Understanding pharmacovigilance principles, adverse event reporting requirements, and ensuring participant safety throughout the trial.
- Designing and maintaining quality systems for clinical trials, including SOPs, risk management, and quality control/assurance processes.
- Knowledge of audit and inspection processes, preparing for audits, and effectively addressing findings to maintain the compliance.
- Strategies for developing and maintaining a site capacity, retaining research staff, and fostering community engagement to support ongoing research activities.
- Understanding project management principles and applying them to clinical trial planning and execution.
- Developing interpersonal skills to effectively collaborate with colleagues and external partners involved in clinical trial management.
- Efficiently closing out clinical trials, fulfilling post-trial responsibilities, and timely reporting of trial results to relevant stakeholders.
- Problem-solving and critical thinking.

There is no internship period offered in this short online course (SER 4.1.4).

The teaching methods used in the program are the following (SER 4.1.5):

- Interactive recorded presentations using VoiceThreads.
- Live and asynchronous tutorials.
- Collaborative learning through questions and answers.
- Discussion forums.
- Individual assignment.
- Practical group assignment (development of a risk management plan).

Since ClinOps is an online program, all the courses are delivered virtually. VoiceThreads is used for uploading PowerPoints and recorded explanations from the tutors. The students have the opportunity to interact with the tutors by putting questions or comments on the slides of the presentations. The program also

uses a Learning Management System (LMS), especially Moodle, where links, resources, task, forum discussions, and other assignments are uploaded. Moreover, Zoom is used for at least one-hour live tutorials (SER 4.1.6).

Research is not integrated in the program (SER 4.1.7).

The content of the course is designed to meet international standards. It was developed with training tools and resources made available from The Global Health Network, TDR Regional Training Centers, the University of Siena, and other similar institutions. Until now, the course has been delivered two times, always in collaboration with the following organizations who have participated in the design, delivery, and improvement: Faculty of Capacity Development (FCD), FIND, Medicines for Malaria Ventures (MMV), IAVI, PATH, Special Program for Research and Training in Tropical Diseases (TDR), and TB Alliance. The contents of the course are all prepared, instructed and delivered in the English language. There are no options for mobility (SER 4.1.8).

In addition to the experience of the tutors and rich learning experience in the resources shared in each lesson, ClinOps is designed to encourage sharing of experience and network building among the trainees, through forum discussions, postings in VoiceThreads, live tutorial discussions, and group assignment.

Judgement

The ClinOps training course has a course-based structure and a course-related examination system. As the University states, there are currently no specific plans to offer online exchange opportunities with other universities or institutions within this program. However, it is noted that there are ongoing exchanges within the Center more broadly, and Clinical Trials are cooperating on this front.

Regarding lecture sessions, the program employs a mix of asynchronous lessons and live tutorials. Materials are provided for students to read, with questions and discussions facilitated through a VoiceThread. The VoiceThread platform is highlighted as particularly helpful for student interaction, providing protected time for answers and fostering commitment from tutors. Discussions on this platform are noted to be very fruitful, as many students already have experience in clinical trial areas. Furthermore, live tutorials are conducted for one hour each week, offering a platform for real-time interaction and support. The experts also inquired about how practical transfer is guaranteed. As the University explains, each lesson addresses common problems encountered during clinical trials, providing

students with practical scenarios to tackle. After each lesson, students are tasked with developing a risk-management plan for various areas, working in groups to select and conduct protocols on-site. Live tutorials play a crucial role in evaluating student needs and addressing problems, with discussions and questions collected and shared via Moodle for ongoing reference. The experts appreciate the practical transfer. However, the experts recommend to make the risk-management-plan more visible in the module descriptions. Additionally, the experts miss the topic of "Logistics" in the module descriptions and inquire with the university why this subject is not addressed. The University explains that it is covered in the module "Clinical Trials Phase I and II." The experts recommend making this clear in the module descriptions as well.

From the experts' point of view, the combination and succession of the courses are consistent with the specified qualification objectives (described earlier). It is assured that students receive the support and guidance they need for the organization and accomplishment of assignments and the learning process in general.

In the experts' opinion, the structure of the curriculum seems to make the workload manageable.

Decision

From the experts' point of view, the requirements of this criterion are fulfilled.

4.3 Admission and Feasibility

Summary

The University does not have specific regulations for short courses. The admission and enrollment requirements for the ClinOps advanced certificate program were developed by CDT-Africa in collaboration with Product Development Partners (PDPs) including PATH, FIND, International AIDS Vaccine Initiative (IAVI), Malaria Medicines Venture (MMV), and TB Alliance.

Key requirements include prior experience working as a study coordinator, investigator, co-investigator, study manager or assistant in clinical trials (any disease area) or with a desire to become one, with priority given to applicants from sites with limited trial capacity and those initiating a trial soon. An academic qualification in fields like nursing, medicine, pharmacy, biomedical sciences, statistics or related subjects is preferred. For non-native English speakers, proof of

English proficiency may be required as the course is conducted entirely in English. The admission process involves sending the course brochure to partners, posting on the CDT-Africa website, receiving applications, screening based on the criteria, and final selection of participants. The course's effectiveness is measured by the degree to which participants can apply their learning, so those not currently in relevant roles may not benefit as much from the course (SER 5.1.2).

The admission procedure involves several steps:

- The course brochure is distributed to different partners and posted on the CDT-Africa website.
- Interested applicants express their interest through an online form.
- Admission procedures are communicated to applicants via email.
- Applicants submit their Curriculum Vitae, a motivation letter, proof of identity, and an endorsement from a senior manager in their organization for review.

In 2023, the application process was streamlined using an online application form to enhance efficiency. For the first cohort in 2021, PDPs conducted the assessments with two representatives evaluating each applicant. Due to time constraints, CDT-Africa handled the selection process in 2023 and then shared the results with the PDPs for approval. All applicants are informed of their admission status through email (SER 5.1.1).

Students needing clinical care and treatment can access available services. Although support is inconsistent, the University collaborates with various non-governmental organizations and development partners to assist students with disabilities in completing their studies (SER 5.1.2).

When students need to discuss issues, the ClinOps program leader and director are available. The program leader serves as the immediate contact and liaison between instructors and students. Seven of the course instructors also act as a mentor for the group assignments in drafting risk management plan and providing guidance. Being an online course, students can email their concerns at any time. For the 2023 cohort, a "How to's" section was added in Moodle to address frequently asked questions gathered from the 2021/22 cohort (SER 5.2.1).

Judgement

The admission policies and procedures along with the requirements are properly documented. However, the experts recommend to make the admission procedures publicly available on the website, as it is currently only communicated to applicants via email. The experts determine the admission procedures and requirements to be appropriate, as they correspond to the standards of the certification course. The experts confirm that the University takes good measures to guarantee the feasibility of the course. The organization of the education process ensures the successful implementation of the ClinOps Training.

The experts inquire whether there are already interested students for the next batch in the ClinOps course. As the University states, brochures have been sent to various networks, including pharmaceutical companies, whenever a course is conducted. This initiative has garnered significant interest, with 258 participants expressing their intent to join from over 20 countries. Among these, 24 are from Ethiopia, while the rest come from a diverse range of other nations.

As the University states, there is strong support for students enrolled in the program. During the round of talks, it became obvious that the teaching staff follows an "open-door-policy". The department allocates dedicated time to supervise and support students, ensuring they receive the necessary guidance. The program schedule is communicated a year in advance, allowing staff to prepare thoroughly and commit their time effectively. During the course week, the VoiceThread platform is actively used to facilitate interactions and provide ongoing support. The experts find the support services at the University to be exemplary and conducive to the health and success of the student body.

Decision

From the experts' point of view, the requirements of this criterion are fulfilled.

4.4 Examination system and transparency

Summary

The assessment of the ClinOps course includes both group work and individual assessments. Detailed information on the assessments can be found in the assessment section on Moodle. Active participation in forum groups, live tutorials, and VoiceThreads is also considered. Individual assessments account for 50% of

the overall course grade. These assessments are based on students' participation in forum discussions, VoiceThreads, live tutorials, and performance on multiple-choice questions (MCQs). Each lesson, except for lesson nine, includes MCQs.

The program's brochure contains detailed key information about the certification course including learning objectives, structure, course descriptions, admission requirements, fees, application process, assessment, contact information for inquiries, and any special features or opportunities offered by the program. The brochure is emailed to previous students, PDPs, CDT-Africa partners, and individuals interested in similar topics whenever there is an intake. A webinar was hosted to introduce the course to different partners by sharing experiences from the 2021 cohort. An open-access version of the 2021/22 course is available for those who want to understand the proposed course better, as mentioned in the brochure.

The course brochure outlines the admission requirements. For the selection of the first cohort trainees in 2021, PDPs conducted assessments with two representatives evaluating each student. In 2023, the selection process was handled internally and then shared with PDPs for approval due to time constraints. All applicants are informed of their admission status via email. The assessment method and certification requirements are communicated to students during the induction session and are also available in Moodle (SER 6.2.1).

Judgement

Group work, also contributing 50% to the overall grade, involves developing a Risk Management Plan (RMP) for clinical trial sites. Students are divided into seven groups, each tasked with creating an RMP for a selected clinical trial protocol being implemented in the clinical trial sites where the trainees are affiliated to. Contributions may be made via Moodle forums or outside Moodle and participation confirmed by a group leader, with assigned tutors assisting in the development. Drafts for each section of the RMP are due weekly, with the final version of the collated weekly assignments due three weeks after the last lesson. The final RMP is assessed using rubrics that evaluate risk identification, analysis, mitigation, documentation, and mechanics. The pass mark is set at 70%. Students can complete the MCQs and participate in discussions at any time before the Moodle closure in week 13. However, group assignments must be submitted weekly starting from week five to incorporate tutor feedback into the RMP. The

compiled weekly assignments are submitted for final assessment by a different tutor. From the experts' point of view, the examination serves to determine whether the envisaged qualification objectives have been achieved. These examinations are focused on students' knowledge and competences.

From the experts' point of view, the relevant information concerning the study program, the process of education as well as the admission requirements are documented and shared with interested applicants. As also stated above, the experts recommend to also publish this information on the website.

Decision

From the experts' point of view, the requirements of this criterion are fulfilled.

4.5 Teaching staff and material equipment

Summary

During the two cohort courses, a total of ten facilitators were involved in coordinating the courses, delivering lectures, and tutoring students. Each cohort had nine facilitators, who dedicated approximately 20 hours per week to coordinate and deliver lectures. Additionally, eight out of the ten tutors served as instructors for group assignments, spending 2 hours per week assisting students in developing Risk Management Plans (RMPs) and reviewing them.

In total, eight faculty members and two adjunct faculty members were involved in lecturing, tutoring, and assessing students. The ClinOps course is primarily taught by four (44%) professors and five (56%) associate professors, resulting in a faculty/student ratio of 1:9 (SER 7.1).

The teaching staff for the ClinOps course is selected based on the Addis Ababa University Senate Legislation. Academic staff are required to demonstrate competence and expertise in their respective disciplines and to stay updated with new developments in their fields. Nominations for employment follow specific procedures outlined in the legislation, with approval by the Senate or relevant authorities.

Instructors for the ClinOps program are appointed based on their qualifications and expertise, following the University's senate legislation. Course schedules are shared with students and instructors to ensure transparency regarding course delivery. Staff development opportunities are provided based on the University's

legislation, allowing staff to enhance their skills and competencies. Facilitators of the ClinOps program have undergone training in online andragogy and pedagogic innovation tools (SER 7.1.2).

CDT-Africa has an academic leader from the core faculty who oversees the program, supported by full-time scientific coordinators and student affairs personnel. Additionally, there are project leaders who coordinate the delivery of the course and communicate with instructors and students. Administrative staff, including center administrators, assistants, procurement officers, finance officers, and drivers, are responsible for the day-to-day operations of the teaching-learning process at the Center (SER 7.2.1).

Students enrolled in the program will have access to resources categorized as mandatory, recommended and in-depth for each lesson, enriching their learning journey. Mandatory resources, suggested by course facilitators, offer foundational understanding of key concepts through summaries, concise guides, informative websites, or brief videos. On the other hand, in-depth resources provide comprehensive coverage of topics, including textbooks, scholarly articles, research papers, or lengthy instructional videos, catering to those seeking deeper exploration or advanced study. Recommended resources have intermediate depth. These resources are tailored to accommodate varying learning preferences and goals, empowering students to engage with course material at their desired level of depth and understanding (SER 7.3.2).

The ClinOps training incorporated innovative pedagogical tools to deliver the course content and monitor trainee performance. VoiceThread (VT) was utilized as an online platform for uploading PowerPoint presentations, accompanied by recorded explanations from tutors for each slide. Trainees could engage with the material by posing questions or sharing comments via text or voice recordings directly on the slides. Additionally, the course leverages a Learning Management System (LMS), specifically Moodle, to centralize resources, tasks, forum discussions, and assignments. Trainees accessed VT links and course materials through the LMS, and could provide feedback directly within the platform. Live tutorials, conducted via Zoom, provided interactive sessions for further engagement. To facilitate course delivery, laptops and desktop computers were procured to ensure trainees had access to necessary technology resources (SER 7.3.3).

The main source of funding for the ClinOps program is the Bill and Melinda Gates Foundation. These funds cover expenses such as facilitator and support staff salaries, equipment procurement, and scholarships for both local and international students. Additionally, CDT-Africa receives funding from other sources, including the World Bank, the National Institute of Health Research UK (NIHR), and the European and Developing Countries Clinical Trials Partnership (EDCTP) (SER 7.3.4).

Judgement

New teaching staff is thoroughly briefed about the programs and their teaching responsibilities before they start teaching. Overall, the teaching and academic staff at the Addis Ababa University shows a very high level of commitment and potential for the execution as well as further development of the study program they are responsible for. The experts conclude that there is a strong corporate identity and positive group dynamics among the University and the faculty administration. The experts find the amount of human resources allocated to the program to be sufficient to carry out its functions. The experts inquire about the experiences of the teaching staff in clinical trials. The University confirms that the staff has extensive experience in Phase I, Phase II, and Phase III clinical trials. Additionally, they are involved in research ethics and inspections, with a strong background in project management. This ensures that the teaching staff is highly experienced and well-qualified to deliver the program.

Regarding additional training, the Ministry of Education requires all teachers to have a higher learning diploma. Specifically for the Clinical Trials Operations program, the head of the program briefs all staff on how to proceed before the course begins, ensuring everyone is well-prepared and aligned with the program's objectives.

Decision

From the experts' point of view, the requirements of this criterion are fulfilled.

4.6 Quality assurance

Summary

The ClinOps training program is structured around the competency framework of TDR/TGHN, ensuring trainees are equipped with the necessary competency

for the study coordinating role. To maintain quality, the program includes a monitoring and evaluation framework including pre-post course assessment. Prior to finalizing lesson plans, drafts are shared with Product Development Partners (PDPs) for their expertise and input. CDT tutors undergo comprehensive training on online andragogy, technical tools like Moodle Learning Platform & VoiceThread, and administrative aspects before the course begins. Flexibility is built into the curriculum to accommodate additional discussions or content based on student needs (SER 8.1.1).

Pre- and post-course assessments are conducted to gauge student progress and measure learning outcomes. Additionally, students are regularly evaluated throughout the course, and their engagement is closely monitored using inbuilt tools in Moodle. Those falling behind receive reminders and individualized support to ensure they stay on track. If needed, one-to-one assistance is provided to students who require additional help (SER 8.1.2).

The Monitoring and Evaluation (M&E) evaluation report for the 2021/22 cohort is accessible (see appendix 6) and highlights that students' confidence in various domains of clinical trials increased following the training. Additionally, students provided positive feedback on the course content and delivery, while also identifying areas for improvement (SER 8.1.3).

In the post-course assessment for the 2021 cohort, 85.5% of the graduates indicated that the course is relevant to their current role as clinical trial coordinators. While no formal assessment has been conducted to evaluate student workload, it's acknowledged that this intensive training typically requires 8-12 hours per week (SER 8.1.4).

The statistics for former students are given as follows:

Academic Year	*No. of students enrolled*			*Graduated*				
	Total	*Male*	*Female*	*Total*	*Male*	*Female*	*Local*	*International*
2021/22	*88*	*34*	*54*	*71*	*25*	*46*	*10*	*61*
2023/24	*90*	*49*	*41*	*83*	*44*	*39*	*12*	*71*
Total	*178*	*83*	*95*	*154*	*69*	*85*	*22*	*132*

Judgement

From the experts' point of view, the University has a well-structured system of quality assurance spread across all of its units. The University has developed and documented a concept of quality assurance in the education process, teaching and research, which serves as the basis for the quality-oriented development and implementation of the ClinOps training.

As the University states, feedback from students and teachers is collected through pre- and post-course assessments. This feedback is used to modify the course content based on recommendations and inputs from partners. Additionally, an independent evaluator from the social sciences department is responsible for making analysis of the feedbacks from the students and the synthesis of the M&E report.

The evaluation of the program includes both formative and summative assessments for students. An evaluation system is in place to gather feedback from all stakeholders, ensuring a comprehensive review of the course. Students also have the opportunity to evaluate the course themselves. For example, adjustments to lessons have been made based on student evaluations. Changes from the first batch to the second include a reduction in some materials and alterations to certain topics based on these recommendations. Therefore, the experts conclude that regular program reviews and revisions are conducted, actively involving students and other stakeholders in the process. The information collected from these reviews undergoes analysis, and program adaptations are made to ensure the program is up-to-date. Any actions planned or taken as a result of these reviews are communicated to all relevant stakeholders. Furthermore, the University ensures the publication of revised program specifications, fostering transparency and keeping stakeholders informed of changes resulting from the systematic review process. However, the experts suggest continuing to develop an alumni network to track where students go and how they can connect through their professional network.

Decision

From the experts' point of view, the requirements of this criterion are fulfilled.

4.7 Gender equality and equal opportunities

Summary

CDT-Africa prioritizes gender equality and equal opportunities for all students, admitting a significant number of female applicants. In the ClinOps course, 95 out of 178 participants (53.4%) were female, reflecting the center's commitment to inclusivity. The admission process is transparent and inclusive, ensuring fairness for all applicants.

Course materials and lectures are designed to be inclusive, creating a welcoming environment for all students. The course structure is flexible, accommodating the needs of students with special living situations. Interactive recorded presentations, live and asynchronous tutorials, discussion forums, and personalized mentoring allow students to complete the course at their own pace. Extended deadlines and material access are provided to support students facing potential disruptions.

Open communication and respect for diverse perspectives are encouraged in the virtual classroom. Students with disabilities or chronic illnesses are welcomed, and accommodations are available upon request. The center follows AAU's senate legislation on special support for students, ensuring provisions for female students, students with disabilities, and other disadvantaged groups. This information is communicated to students during orientation sessions, emphasizing the center's commitment to inclusivity and support (SER 9.1.1).

Judgement

The University demonstrates its commitment to the provision of equal opportunities for all students and shows openness for diversity and social development. Overall, the experts conclude that the University’s actions on the provision of gender equality and promotion of equal opportunities for students with particular living circumstances are implemented in a transparent manner.

Decision

From the experts’ point of view, the requirements of this criterion are fulfilled.

5 Conclusion

The experts commend the high quality of the written documents. Open questions were convincingly addressed during the assessment in four group sessions. While the experts highly appreciate the strong teacher engagement with the students, they also recognize the long-term need for trial-centred, state-of-the-art lifelong education.

Based on the information from written documents and the results of the virtual site visit, the experts came to the conclusion that the Certificate Course “Clinical Trial Operations” offered at the Addis Ababa University fulfils the above-described criteria. Hence, the experts recommended that the Accreditation Commission of AHPGS make a positive decision regarding the assessment of the Advanced Certificate Course “Clinical Trial Operations”

For the continuous development of the Certification Course “Clinical Trial Operations”, the experts have outlined the following recommendations:

- The concept on how to develop a risk-management-plan should be made more visible in the module descriptions.
- The topic of "Logistics" should be made more visible in the module descriptions.
- The relevant information concerning the study program, the process of education as well as the admission requirements should be published on the website.
- An alumni network should be developed to track where students go and offer them a possibility to (re-)connect through their professional network.

6 Decision of the accreditation commission

Decision of the accreditation commission September 20, 2024

This resolution of the Accreditation Commission of the AHPGS is based on the University's application, as well as the expert review and the site visit covered in the Assessment Report.

The virtual site visit of the University took place on June 25, 2024 according to the previously agreed-upon schedule.

The proceedings of the assessment procedure conform to the Accreditation Criteria developed by the AHPGS. The Accreditation Criteria are developed by the AHPGS in close accordance with the existing criteria and requirements valid in the Federal Republic of Germany and based on the "Standards and Guidelines for Quality Assurance in the European Higher Education Area" (ESG), established by the European Association for Quality Assurance in Higher Education (ENQA).

The Accreditation Commission of the AHPGS discussed the procedural documents and the vote of the expert group of the University regarding the Assessment Report.

The Certification Course comprises ten mandatory program-specific courses. Each module is delivered weekly for ten weeks. The language of instruction is English. The Certification Course "Clinical Trial Operations" is completed with awarding of the "Advanced Certificate". The first cohort of students was admitted in September 2021. The next batch is scheduled for September 2024.

The Accreditation Commission of the AHPGS considers that all Criteria described in the Assessment Report are fulfilled and adopts the following decision:

The positive assessment of the Certification Course "Clinical Trial Operations" (Advanced Certificate) is valid for the duration of five years until September 30, 2029.

For further development and enhancement of the Advanced Certificate, as well as of the University as a whole, the Accreditation Commission of the AHPGS supports the recommendation articulated in the Assessment Report.