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

# Assessment Report

**for the Application of the Addis Ababa University,**
**College of Health Sciences,**
**Center for Innovative Drug Development & Therapeutic Trials for Africa,**
**for the Accreditation of the Study Program "Clinical Trials",**
**Master of Science (M.Sc.)**

AHPGS Akkreditierung gGmbH
Sedanstr. 22
79098 Freiburg
Telefon: +49 (0) 761/208533-0
E-Mail: ahpgs@ahpgs.de

| | |
|---|---|
| Expert group | **Mr. Leopold Beham**<br>Technical University of Munich, Germany |
| | **Prof. Dr. Gerlinde Egerer**<br>Heidelberg University Hospital, Germany |
| | **Prof. Dr. Stephan Lehnart**<br>Georg-August-University Göttingen, Germany |
| | **Prof. Dr. Gerd Mikus**<br>Ruprecht-Karls-University of Heidelberg, Germany |
| | ***Nora Josefine Paulke***[1]<br>*London School of Hygiene and Tropical Medicine, Great Britain* |
| Decision | February 15, 2024 |

[1] *The experts in italics did not participate in the site visit but evaluated the study program on paper beforehand.*

## 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 law or economics. 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 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.

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 study program is carried out by the AHPGS Accreditation Commission based on the following accreditation criteria[2]:

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
7. Gender Equality and Equal Opportunities

[2] Approved by the AHPGS Accreditation Commission

## 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 this 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 study program with the applicable accreditation criteria. Consequently, the experts comprise a short summary regarding the study programs.

## III. 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 study program 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 fulfils the Assessment Report. This report is based on the results of the visit, the written review of the study programs, and the documents submitted by the University. Finally, the 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 accreditation 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 summary comprised by the AHPGS, the Assessment Report, as well as the University's response opinion. These documents represent the foundation for the commission's decision regarding the recommendation for accreditation of the study program. Consequently, the decision – together with all other documentation – is forwarded to the AHPGS Accreditation Commission for it to reach a decision regarding the accreditation of the study program.

## 2 Information about the University

Addis Ababa University (AAU) is the oldest and largest higher learning and research institution in Ethiopia, established in 1950 as the University College of Addis Ababa (UCAA). It has been a leading center in teaching, research, and community services since its inception. AAU started with 33 students and has now grown to accommodate 47,610 students and employs 8,709 staff members, including academics, administrative support staff, and health professionals. Over 222,000 students have graduated from AAU since its establishment. The University comprises ten colleges, four institutes that focus on teaching and research, and six research institutes that primarily conduct research. There are 55 departments, 12 centers, 12 schools, and one teaching hospital, with several other partner hospitals within these academic units. AAU offers 83 undergraduate and 417 graduate programs, including the MSc in Clinical Trials, which is offered at the College of Health Sciences campus. As of 2022, Addis Ababa University (AAU) has achieved notable rankings, being ranked #6 in Africa and #401-500 globally according to Times Higher Education Ranking. AAU has been successful in establishing over 200 partnerships with international and local institutions, highlighting its commitment to global collaborations.

The Center for Innovative Drug Discovery and Therapeutic Trials for Africa (CDT-Africa) was initially established in 2014 as a clinical trial unit of the College of Health Sciences (Addis Ababa University). In 2017, it evolved into a regional Center of Excellence as part of the Eastern and Southern Africa Higher Education Centers of Excellence (ACE II) initiative by the World Bank. The center's vision is to become a leading Africa-based institution for groundbreaking medical discoveries and development. In 2018, the center developed the curriculum for the MSc in Clinical Trials and launched the program. The curriculum development process followed standard procedures, including a needs assessment. The assessment confirmed the high demand for the program, which aims to improve access to interventions in Africa and accelerate regional development. To ensure the quality and relevance of the curriculum, the center conducted a validation workshop and incorporated feedback from stakeholders. Currently, the center is hosting its fifth cohort of MSc in Clinical Trial students (SER 3.1.1). The study program has also contributed to the development of an online training program to support study coordinators in carrying out their roles and responsibilities as essential members of the study team in conducting clinical trials.

CDT-Africa has emerged as a leading institution in the discovery and development of drugs, vaccines, and diagnostics. It is also recognized as a major center for complex interventions. Due to its reputation and expertise, CDT-Africa attracts a significant number of partners and funding agencies, fostering collaborative efforts in the field.

# 3 Overview

## 3.1 Procedure-related documents

The Self-Evaluation Report for accreditation (without the awarding of the official seal of the Accreditation Council of the Foundation for the Accreditation of Study Programs in Germany) of the above-mentioned study programs (hereinafter the SER) of the Center for Innovative Drug Development and Therapeutic Trials for Africa at Addis Ababa University (CDT-Africa or the Center) was submitted to the Accreditation Agency in Health and Social Science (AHPGS) in electronic format on February 03, 2023. The contract between the Center for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa) at Addis Ababa University and the AHPGS was signed on November 15, 2022. On May 24, 2023 the AHPGS forwarded the open questions and explanatory notes (hereinafter OQ) pertaining to the application for accreditation for the study programs to the University. On June 14, 2023 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 CDT-Africa follows the outline recommended by the AHPGS. Along with the application request towards accreditation of the Master study program "Clinical Trials", 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):

Documents for the study program "Clinical Trials"

| Annex | Description |
|---|---|
| 1 | Module Overview |
| 2 | Module Descriptions |
| 3 | Teaching Matrix |
| 4 | Teachers' CV |
| 5 | AAU Strategic Plan |
| 6 | AAU Senate Legislation |
| 7 | Student Handbook |
| 8 | AAU Guidelines for Program Design, Approval and Review |

| | |
|---|---|
| 9 | AAU Students Discipline Rules and Regulations |
| 10 | AAU Gender Policy |
| 11 | Cooperation Agreements |
| 12 | CDT-Africa Graduate Tracer Survey |
| 13 | Student Satisfaction Survey |
| 14 | Tracer Survey Summary |

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 within the University.

### 3.2 Structural data of the study program

| | |
|---|---|
| University | Addis Ababa University |
| College / Center | College of Health Sciences<br>Center for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa) |
| Cooperation partner | More than 20 public and private institutions e.g.<br>- Armauer Hansen Research Institute (AHRI)<br>- University of Gondar (UOG)<br>- Institute Pasteur Korea (IPK)<br>- University of California San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences<br>- Shanghai Jiao Tong University<br>- ViNS Bioproducts Limited Telangana, India |
| Title of the study program | „Clinical Trials“ |
| Degree awarded | Master of Science (M.Sc.) |
| Form of studies | Full-time, on-campus |
| Organisational structure | Monday to Friday, from 08:00 am to 05:00 pm |
| Language of Studies | English |
| Period of education | Three semesters |

<table>
<tr><td>Credit Points (CP) according to the European Credit Transfer System (ECTS)</td><td>99 CP</td></tr>
<tr><td>Hours/CP</td><td>27 Hours/CP</td></tr>
<tr><td>Workload</td><td>Total: 2.673 hours<br>Contact hours: 932 hours<br>Individual work: 931 hours<br>Master Thesis: 810 hours</td></tr>
<tr><td>CP for the Master Thesis</td><td>30 CP</td></tr>
<tr><td>Launch date of the study program</td><td>2018</td></tr>
<tr><td>Time of admission</td><td>Winter Semester</td></tr>
<tr><td>Number of available places on the program</td><td>Between 10 and 15 in the last two years</td></tr>
<tr><td>Number of currently enrolled students</td><td>27</td></tr>
<tr><td>Particular enrollment conditions</td><td>- Graduate Admission Test</td></tr>
<tr><td>Tuition fees</td><td>
<table>
<tr><th>Fee category</th><th>Ethiopian students<br><br>Academic year on and before 2021/2022</th><th>Ethiopian students<br><br>Academic year 2022/2023</th><th>IGAD members, Eastern African Countries</th><th>Others</th></tr>
<tr><td>Tuition Fee</td><td>718.4USD</td><td>1607.76 USD</td><td>4950USD</td><td>7920USD</td></tr>
<tr><td>Thesis Research Fees</td><td>520USD</td><td>548USD</td><td>1700USD</td><td>3400USD</td></tr>
</table>
</td></tr>
</table>

Chart 1: Structural data of the study program

## 4 Expert Report

The site visit was carried out on November 29-30, 2023 according to the previously agreed schedule. Representatives from the head office of AHPGS accompanied the expert group.

The expert group met on November 28, 2023 for preliminary talks prior to the on-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 site visit, experts conducted discussions with the University management, representatives of the College of Health Sciences and the Center for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa), the chair, vice chair and the teaching staff of the program "Clinical Trials" as well as with students currently studying in the program. Furthermore, they inspected the learning premises, such as lecture halls, seminar rooms, classrooms, library, and computer classes. Moreover, experts had the opportunity to examine the equipment and the capacity of the laboratories, including Phase I Clinical Trial Unit.

The expert 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 study program 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, the College of Health Sciences and the Center for Drug Discovery and Development (CDT-Africa), serve as the foundation for the statements made in the Assessment Report.

## 4.1 Program aims and their implementation

**Summary**

The „Clinical Trials" program aims to prepare competent individuals to work in various sectors like pharmaceutical industries, regulatory agencies, academia, and research centers. Graduates will be equipped to design, execute, and report clinical trials in compliance with ethical, legal, and regulatory requirements.

The specific objectives of the program are to develop students' knowledge and understanding of clinical trial design, execution, and interpretation, to foster critical and evaluative skills, teach practical tools for conducting clinical trials, and promote self-development and effective communication (SER 1.3.1).

After completing the program, graduates will be well-versed in research methods and clinical trial fundamentals, enabling them to conduct product evaluations for

licensing and marketing. They will have a comprehensive understanding of the regulatory and legal framework governing clinical trials and will be able to perform various duties related to trial design, management, analysis, and data integrity.

The program fosters an innovative mindset for research and clinical trials, and international and national students from diverse African countries develop strong social skills and teamwork abilities. Through ethical and intellectual practices, the program equips students for personal and career development in the field of clinical trials (SER 1.3.2).

As the University states, most graduates are currently working in academic institutions providing lectures, in regulatory offices such as Food and Drug Authorities, and in different research institutions across Africa. As the aim of the program is to stimulate clinical trial that has long been a critical gap, graduates are expected to harness the labor market by initiating clinical trials as principal investigators and facilitating large-scale implementation of clinical trials as regulatory leaders (SER 1.4.2).

**Judgement**

Currently, there are two study programs offered at CDT: The Master study program "Clinical Trials" as well as the Ph.D. program "Translational Medicine" in three tracks – Diagnostic Development, Drug Development and Vaccine Development. According to the University, the programs offered by CDT-Africa, including postdoctoral, Ph.D., MSc, short-term training, and research programs, hold great potential to advance translational medicine in Africa. From the experts' point of view, these initiatives demonstrate the center's dedication to transformative research and training in the region. On site the experts learned that both, the students and the leadership of CDT-Africa are striving to increase internationalization of the program through recruitment throughout the African continent and even from Europe. The experts positively acknowledge the latter vision as well as the clear description of the program aims and implementation.

From the experts' point of view the Master study program "Clinical Trials" focuses on specific qualification objectives. These objectives cover professional and interdisciplinary aspects and particularly refer to the domain of academic competences, competences necessary for a qualified employment, skills of social commitment and personal development. During the round of talks, it was

confirmed by all stakeholders that the competences gained during the "Clinical Trials" program are suitable for further employment.

**Decision**

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

## 4.2 Structure of the study program

**Summary**

The program comprises 15 modules, out of which two modules are general subjects and 13 modules are core specialized subject areas including targeted seminar and attachment modules. All modules have to be completed within one semester.

The list of modules offered:

**Year I - Semester I**

| Sequence | Module code | Module Title | No of ECTS | No of hours | Duration in weeks |
|---|---|---|---|---|---|
| 1 | CT6001 | Introduction to Research Methodology | 5 | 135 | 3 |
| 2 | CT6002 | Fundamentals of clinical trials | 5 | 135 | 3 |
| 3 | CT6003 | Trial designs | 5 | 135 | 3 |
| 4 | CT6004 | Clinical trials in practice | 5 | 135 | 3 |
| 5 | CT6005 | Clinical trials in global and special populations context | 5 | 135 | 3 |
| 6 | CT6006 | Reporting and reviewing clinical trials | 5 | 135 | 3 |
| | **Total** | | **30** | **810** | **18** |

**Year I - Semester II**

| | | | | | |
|---|---|---|---|---|---|
| 7 | CT6007 | Trial Protocol development | 5 | 135 | 3 |
| 8 | CT6008 | Advanced statistics for clinical trials | 5 | 135 | 3 |
| 9 | CT6009 | Project management and research coordination | 5 | 135 | 3 |
| 10 | CT6010 | Regulatory affairs, good clinical practice and ethics | 5 | 135 | 3 |
| 11 | CT6011 | Data management | 5 | 135 | 3 |
| 12 | CT6012 | Data monitoring | 4 | 108 | 2 |
| 13 | CT6013 | Seminar on advances in research and development of therapeutics | 2 | 54 | 1 |
| | **Total** | | **31** | **837** | **18** |

**Year II - Semesters I**

| | | | | | |
|---|---|---|---|---|---|
| 14 | CT6014 | Attachment | 8 | 216 | 6 |
| 15 | CT6015 | MSc project | 30 | 810 | 16 |
| | **Total** | | **38** | **1026** | **22** |

The module description covers the following aspects: Number, title, level/semester, credit hours distributed to lecture hours, practical hours, self-study hours, language, learning outcomes/goals/skills of the module, content of the module, examination (Annex 02).

The "Clinical Trials" program gives students a theoretical and practical understanding of the issues involved in the design and conduct of clinical trials and the analysis, interpretation and reporting of the study outcomes. Students who pass the core modules have had an essential introduction to a variety of methods, approaches and concepts in clinical trials. They have a sound grasp of

the fundamentals of clinical trials and understand the key principles of scientific analysis, writing and review.

The curriculum provides foundational information in research design, ethics, good clinical trial practice, drug discovery, and local and international regulations governing drugs, diagnostics and device development. The program culminates in a capstone Master project in which the students perform a project at their job, participate in a mentored fieldwork experience, or write a systematic review for publication under the supervision of the faculty as partial fulfillment of the master's degree in Clinical Trials.

The modules are offered in the first and second semesters of the first year. The second year is devoted to clinical attachment, seminar preparation and presentations and development of the project protocol, research, and writing up of the Master thesis. Hence, in the first semester, students learn about research methods, fundamentals of clinical trials, trial designs, clinical trials in practice, clinical trials in global and special populations contexts, and reporting and reviewing clinical trials. In the second semester, students learn about trial protocol development, advanced statistics for clinical trials, project management and research coordination, regulatory affairs, good clinical practice and ethics, data management, and data monitoring.

In the first semester of year one, students take the course "Clinical Trials in Practice," which explores the practical implementation of a clinical trial. This includes clarifying and operationalizing trial objectives, the implications of design choices, trial governance, approvals, data collection methods, and recruitment techniques. Quality assurance and data management issues are also examined. The attachment module in the third semester builds on this course, providing students with further practical experience in clinical trials, aligning with the program's objectives. Instructors for the attachment or internship program are selected from the research sites where students are attached. The qualifications and experience of these practical instructors are assessed by the CDT-Africa academic team and communicated through a formal letter. Additionally, at the end of the attachment, the attachment coordinator gathers feedback from students to assess and ensure the quality of the attachment arrangement.

In the third semester, students undertake the "Attachment" module, which provides them with practical experience to complement their theoretical learning. In the final year of the program, students focus primarily on their research project, which is a compulsory module. This project aims to integrate knowledge from various Clinical Trials study modules. Students are encouraged to undertake original research in the field of Clinical Trials. They have the option to criticize specific aspects of a completed trial or conduct further analyses based on the provided data.

To begin their research project, students submit 2 or 3 potential research topics, from which one is selected by the CDT-Africa Academic Committee. The student then develops a research proposal with the guidance of two Advisors appointed by the Academic Committee. Once the proposal is completed and approved by the advisors, the student defends it publicly. This research project is a significant component of the program, allowing students to demonstrate their research skills and contribute to the advancement of knowledge in the field of Clinical Trials (SER 1.2.7).

The methods of teaching used in the program include: Illustrated and interactive lecture using PPT slides, collaborative learning through brainstorming, question and answer and group discussion, individual and group assignment, classroom student presentation and discussion, audiovisual simulation and animation (SER 1.2.4).

Instructors utilize audiovisual and multimedia platforms whenever appropriate to enhance the teaching process. For instance, when teaching statistical methods, students are provided with practical demonstrations of how analytical techniques are implemented on statistical software. Additionally, the program has adapted to challenging circumstances, such as the COVID-19 pandemic, by incorporating online teaching methods. This allows for continued learning and engagement, even in situations where the course professor may be located in a partner institution outside Ethiopia (SER 1.2.5).

**Judgement**

The study program aims to provide students with specialized and interdisciplinary knowledge as well as professional, methodological and general competences. The Master study program “Clinical Trials” has a course-based

structure and a course-related examination system. The combination and succession of the courses of the study program are consistent with the specified qualification objectives. Descriptions of the modules contain all necessary information and are well-structured. 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. A suggestion for possible further development could be to include elective courses e.g. in collaboration with the College of Health Sciences. Electives might cover cross-sectional topics of significance for the program, which are of relevance for all student batches within the "Clinical Trials" program.

From the experts' point of view, the practical and theoretical parts of the modules are well balanced. During the attachment module, the students intern at a clinical research site, either at Addis Ababa University or partner institutions, to observe and understand the actual conduct of trials. This firsthand experience allows them to appreciate the roles of investigators, sponsors, study subjects, and other stakeholders involved in clinical trials. Students are also assigned to appropriate data management units to witness and understand how clinical trial data are handled to maintain data integrity, including statistical analysis. The instructor or assigned supervisor of this course supports students in observing and gaining hands-on experience in clinical study activities at the selected institution, and their performance is evaluated at the end of the course. The experts appreciate that the students get supervised from both sides, the University as well as the clinical instructors.

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 admission requirements for the "Clinical Trials" program at Addis Ababa University (AAU) are in line with the university's general admission criteria. Admissions and enrolments into all graduate and undergraduate programs are overseen by the Admissions and Enrolment Committee (AEC) in consultation

with academic units. Priority is given to candidates from public higher education institutions as part of the national expansion of higher education.

Specifically for the "Clinical Trials" program at CDT-Africa, candidates must have a Bachelor's Degree in healthcare or life sciences, such as pharmacy, public health, nursing, biology, medicine, dentistry, veterinary medicine, or statistics. Other qualifications may be considered if relevant further qualifications are obtained. Applicants are required to take and pass a written and/or oral examination. Additionally, they should have one to two years of relevant work experience after their last graduation.

The admission process involves taking the Graduate Admission Test (GAT) exam, passing it, and then undergoing an exam or interview conducted by CDT-Africa to select potential candidates. Once the successful candidates are confirmed, they proceed with the registration process through the AAU's online portal. After completing the required information and submitting authenticated documents, the main Registrar's Office admits the students into the MSc program, and the College of Health Sciences Registrar's Office handles further course-related matters for the program (SER 1.5.1).

Besides others, the following support mechanisms are available (SER 1.6.8): The Center ensures that students have easy access to support and guidance throughout their academic journey. Student affairs, the scientific coordinator, and the head of the center are available during office hours for any discussions or issues that students may have.

**Judgement**

The admission policies and procedures along with the requirements are properly documented and made publicly available. The experts determine the admission procedures and requirements to be appropriate, as they correspond to the standards of the study program and facilitates the high quality and motivation of the selected students.

The experts confirm that the University takes good measures to guarantee the feasibility of the study programs. The organization of the education process ensures the successful implementation of the study programs.

On site, it became obvious that the teaching staff follows an "open-door-policy". The person responsible for student affairs acts as a link between instructors and

students, facilitating communication and addressing concerns. During the first year, the scientific coordinator and instructors of each course act as mentors for the students, providing guidance and support for their coursework. In the final year, students have two advisors assigned to support them with their thesis work. These advisors monitor the progress of the students' projects and ensure that all requirements are met. Financial support is also provided to students by the center, covering their research costs, further facilitating their academic pursuits. From the experts' point of view, everyone is committed to ensuring that students have a conducive learning environment and the necessary resources to excel in their studies.

**Decision**

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

## 4.4 Examination system and transparency

**Summary**

The "Clinical Trials" program follows a structured assessment approach for each modular course. There are six exams for both the first and second semesters, and the final course seminar involves a presentation or seminar defense as an exam. Each final exam takes place at the end of its respective module, while quizzes and assignments that can be graded are given throughout the module's delivery. Exams are conducted only once during the academic year. However, in accordance with the Addis Ababa University Academic Standards, if a student has a legitimate reason for absence from the exam, such as disabilities or chronic illnesses, the professor who delivered the course may offer a second exam opportunity during the academic year.

Assessment methods for the coursework include various approaches, not limited to written examinations. Students may be evaluated through individual and group assignments, as well as seminars that may require written submissions or presentations. All examination processes adhere to the guidelines and regulations set forth by the Addis Ababa University Senate Legislation (SER 1.2.3).

The "Clinical Trials" program maintains comprehensive documentation of its curriculum and related materials, which are stored within the Academic Affairs Office of CDT-Africa. Student-related letters are archived in specific box files to

ensure organization and accessibility. Registration slips and grade reports are handled with strict confidentiality. Information about exam requirements is effectively communicated to the students through their respective instructors. The main registration documents are recorded and managed at the Registrar's Office of the College of Health Sciences to maintain accurate and up-to-date student records (SER 1.6.8).

Furthermore, all relevant information regarding CDT-Africa and the "Clinical Trials" program such as the admission criteria, the program description, application description, research activities etc. are published on the website.

**Judgement**

The University uses a continuous assessment process to ensure the quality of education for its students. As the students confirmed, the continuous assessments like quizzes, oral examinations etc. are helpful to prepare for the final exam. The study program has a course-related examination system. Its implementation, including the grading system, course load regulations, repetition of courses and exams is regulated and transparent for the students. 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.

The requirements to students' performance in examinations are regulated and published in the course descriptions. The frequency of examinations, as well as their organizations, is appropriate. The University guarantees within the regulations that students with disabilities or chronic illnesses receive compensation regarding time limits and formal requirements of the study process.

From the experts' point of view, the relevant information concerning the study program, the process of education, the admission requirements and compensation regulations are documented and published.

**Decision**

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

## 4.5 Teaching staff and material equipment

**Summary**

The following table shows the faculty involved in the coordination, lecturers, as well as the advice and examination of students' thesis work within the Master study program "Clinical Trials":

| No. | Faculty Course Coordinators | Qualification | Name of the course | Semester | Weeks | Hours |
|---|---|---|---|---|---|---|
| 1. | Prof Charlotte Hanlon | Professor | CT6001: Introduction to research methodology | 1st | 3 | 135 |
| 2. | Prof Eyasu Makonnen | Professor | CT6002: Fundamentals of clinical trials | 1st | 3 | 135 |
| 3. | Prof Asrat Hailu | Professor | CT6003: Trial designs | 1st | 3 | 135 |
| | | | CT6007: Trial protocol development | 2nd | 3 | 135 |
| 4. | Dr Getnet Yimer | Associate Professor | CT6004: Clinical trials in practice | 1st | 3 | 135 |
| | | | CT6012: Data monitoring | 2nd | 2 | 108 |
| 5. | Prof Abebaw Fekadu | Professor | CT6005: Clinical trials in global & special populations context | 1st | 3 | 135 |
| | | | CT6006: Reporting and reviewing clinical trials | 1st | 3 | 135 |
| 6. | Dr Girmay Medhin | Associate Professor | CT6008: Advanced statistics for clinical trials | 2nd | 3 | 135 |
| | | | CT6011: Data management | 2nd | 3 | 135 |
| 7. | Dr Anteneh Belete | Associate Professor | CT6009: Project management & research coordination | 2nd | 3 | 135 |
| 8. | Dr Yimtubezinash Woldeamanuel | Associate Professor | CT6010: Regulatory affairs, good clinical practice & ethics | 2nd | 3 | 135 |
| 9. | Dr Tsegahun Manyazewal | Assistant Professor | CT6013: Seminar | 2nd | 1 | 54 |
| 10. | Dr Tsegahun Manyazewal | Assistant Professor | CT6014: Attachment | 1st (Yr 2) | 6 | 216 |

Furthermore, there are seven adjunct faculty involved in the lectures as well as the advice and examination of students' thesis. Moreover, twelve adjunct faculty are involved only in the advice and examination within the "Clinical Trials" program. When necessary, guest lecturers are invited to teach some of the courses as an additional back-up instructor (SER 2.1.1).

The faculty to student ratio ranges from 1:1 to 1:3, based on the enrolment year and the number of students enrolled:

| *Academic Year* | *No. of Faculty* | *No. of students enrolled* | *Faculty-student ratio* |
|---|---|---|---|
| *2018/19* | *9* | *26* | *1:3* |
| *2019/20* | *9* | *26* | *1:3* |
| *2020/21* | *9* | *15* | *1:1.5* |
| *2021/22* | *9* | *9* | *1:1* |
| *2022/23* | *9* | *7* | *1:1* |

CDT-Africa is led by an academic leader from the core faculty members who oversees the entire program. He or she is supported by a full-time scientific coordinator and student affairs personnel who handle the program's daily activities and communication with instructors and students, respectively. The Center also has a team of full-time administrative staff, including center administrators, admin assistants, procurement officers, finance officers, and drivers, who assist in the smooth functioning of the teaching-learning process (SER 2.2.1).

The human resources development and qualification for the teaching staff of the MSc program at CDT-Africa follow the guidelines of the Addis Ababa University's senate legislation. The Center chairs are responsible for initiating applications or nominations for staff promotions. Various staff development opportunities are available both within Ethiopia and internationally, allowing staff to enhance their expertise and competency based on their respective fields (SER 2.1.3).

The Addis Ababa University has two health campuses, Tikur Anbessa campus and Sefere Selam campus, primarily linked to the College of Health Sciences. Both campuses have lecture and seminar rooms, with two classrooms at Tikur Anbessa campus used for the „Clinical Trials“ program coursework. These classrooms can accommodate 30 to 40 students each, while the seminar room at Sefere Selam or other lecture rooms at Tikur Anbessa campus can hold 20 to 40 students for seminars.

Tikur Anbessa Specialized Hospital (TASH) serves as the teaching hospital of the University and is the largest specialized hospital in Ethiopia with over 700 beds. TASH plays a crucial role in training undergraduate and postgraduate students in various medical fields. The hospital also provides healthcare services to the community and the country.

Regarding clinical trial facilities, the program has phase I clinical trial units at the Tikur Anbassa campus, equipped with four beds each for men and women in separate rooms and a clinical laboratory. The program also collaborates with satellite clinical trial sites in different healthcare facilities within and outside of Addis Ababa. Previous clinical trials conducted by CDT-Africa were held at various health centers and hospitals in different locations, offering students the opportunity to visit these sites and even complete their attachments there during their MSc program.

The College of Health Science, where the Center is located, has two libraries. The first, located at Tikur Anbessa Specialized Hospital, is the largest and pioneer library with four floors. It offers internet access to students for their assignments, seminars, and projects. The second library is situated at Sefere Selam Campus. Currently, the library holds over 11,000 books and provides support for the education and research of five schools at AAU. In addition, it offers access to more than 27,000 eBooks across all departments. Addis Ababa University has strong and established connections with e-Journal companies and donors, which allows the library to obtain articles and books periodically. The library operates 24/7, including public holidays, and its spacious facilities can accommodate a large number of students at a time. Moreover, the library provides free access to selected databases such as PubMed and Scopus (Elsevier). It offers computer and internet services for students, including a separate internet room specifically for graduate students. The computer laboratories are available for use, except on public holidays (SER 2.3.2).

As a government-owned institution, the main faculty of the program at Addis Ababa University receives salaries from government sources. However, CDT-Africa also has additional funding sources that it utilizes for various purposes. These funds are used to hire both full-time and part-time staff, offer fellowships to local and international students of the „Clinical Trials“ program, and acquire necessary equipment and supplies for the program's operations. The main sources of funding for CDT-Africa come from organizations such as the World Bank, the National Institute of Health Research UK (NIHR), and the European and Developing Countries Clinical Trials Partnership (EDCTP). These funding sources play a crucial role in supporting the program's initiatives, promoting research, and enhancing the quality of education and training provided to students (SER 2.3.4).

**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 CDT 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. As motivations to teach at the CDT the faculty cites the good and family-like working environment, the small number of students as well as the development opportunities. The University informs its employees about opportunities for personal and professional development transparently, and actively encourages their participation in workshops, training courses and conferences intended to improve their abilities, which is confirmed during the talks with the staff on site. The experts positively acknowledge that all the staff members have the chance to improve their didactic competences within a workshop. For new colleagues without any didactic competences so far, this workshop is mandatory. The experts also suggest implementing a kind of coaching system in which more experienced teachers are present at lectures given by new colleagues and vice versa, so that they can help each other.

The experts consider the amount of human resources allocated to the program to be sufficient to carry out its functions. The teaching staff is well qualified and in possession of academic and technical credentials and experience adequate to their tasks.

The experts visited the premises of the CDT-Africa, where the skills labs of the Master study program "Clinical Trials" are located. The skills labs are equipped with all relevant devices. From the experts' point of view, the quality of the laboratories and clinical areas used to train students in the program are sufficient.

As a whole, it was ascertained by the experts that the Master study program "Clinical Trials" has ample teaching facilities at its disposal.

**Decision**

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

## 4.6 Quality assurance

### Summary

The „Clinical Trials“ program at CDT-Africa underwent a first process of quality assurance before being approved. It was assessed, reviewed, and enriched by internal and external experts in the field, and their input was incorporated into the program. The program was then reviewed and approved by various committees at the College and University levels. To ensure the program's ongoing quality, the center has a dedicated staff hierarchy, including an Academic Lead and Core Faculty members, responsible for decision-making and monitoring academic processes. Regular meetings with faculty, stakeholders, and guest lecturers have been held to assess the program's timeline and quality (SER 1.6.1).

The program also undergoes regular evaluations, both internal and external, including examinations by visiting scholars and graduating students. Addis Ababa University recognizes the importance of monitoring the quality of academic programs and advises the use of various methods, such as regular reviews, research ethics guidelines, involvement of external examiners, and gathering feedback from students and stakeholders. In its fifth year, the center plans to conduct a curriculum review in 2024 to further enhance the program's effectiveness. Additionally, the university advises the establishment of alumni networks to assess the graduates' career development and satisfaction with the program outcomes (SER 1.6.2).

To continuously evaluate the teaching-learning process, students are required to complete evaluation forms at the end of each course module. These forms cover various aspects such as meeting course objectives, course organization, use of practical examples, difficulty level, workload, and suitability of trainers. During COVID-19, the center shifted to virtual classes, and an assessment was conducted to address any gaps and maintain program quality. Additionally, each a graduate and a alumni survey are being developed to gather feedback from graduates, and the center plans to launch these surveys soon.

The program has received national recognition from the Ethiopian Ministry of Science and Higher Education (MoSHE) for its initial five-year period. The

Ministry of Education has subsequently renewed this accreditation for another five years. Moving forward, the program will undergo reaccreditation every five years to maintain its recognized status.

The following table shows the students enrolled in the „Clinical Trials“ program from 2018 to 2023:

| *Academic Year* | *No. of students enrolled* | *No of semester* | *Graduated* | | |
|---|---|---|---|---|---|
| | | | *Total* | *Male* | *Female* |
| *2018/19* | *26* | *Completed* | *22* | *11* | *11* |
| *2019/20* | *26* | *Completed* | *23* | *8* | *15* |
| *2020/21* | *15* | *3 and 4* | *4* | *1* | *3* |
| *2021/22* | *9* | *3* | - | - | - |
| *2022/23* | *7* | *1* | - | - | - |
| ***Total*** | ***83*** | ***20*** | ***49*** | ***20*** | ***29*** |

- not yet graduated

**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 study program "Clinical Trials".

The results of the internal quality assurance management are applied for the continuous development of the study program. In doing so, the University takes into close consideration the quality evaluation results as well as the analyses of students' workload, their academic accomplishments and feedback from graduates. The experts appreciate that regular meetings on different levels are held to improve the study programs. It was also well noted that students' feedback is taken seriously and leads to consequences within the program.

During the round of talks, the experts inquire on how the study program handles conflicts related to data handling. As the University states, these conflicts are considered as part of medical education. Although such incidents have never occurred, it is acknowledged that they need to be handled with care. A specific course on research ethics addresses this topic. Students are required to sign confidentiality agreements. Currently, there is no guideline available, but any such cases will be dealt with on an individual basis. It is recommended by the

experts to implement a guideline for handling such conflict situations in the worst-case scenario.

The establishment of an alumni association is currently in progress and is considered a high priority. The experts endorse efforts to create an alumni network, emphasizing that it enhances interaction between study programs and external stakeholders. Although each batch of students is already engaged in alumni activities individually, systematic support from the Center is encouraged. Notably, there is a CDT-Africa alumni mail group, and graduate surveys have been conducted. Furthermore, international clinical attachment days are organized, where graduates are invited to participate.

**Decision**

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

## 4.7 Gender equality and equal opportunities

**Summary**

The Center for Clinical Trials in Africa (CDT-Africa) places a strong emphasis on supporting female applicants and foreign exchange female students in the MSc program. Foreign exchange female students receive full scholarships and are provided with dormitory accommodations at either Addis Ababa University-6 killo Campus or Sefere-Selam Campus. The center also covers their living costs by providing a stipend of 13,000 Ethiopian Birr per month while they are in Ethiopia. Additionally, medical expenses are covered up to a maximum of 10,000 Ethiopian Birr per year, including hospital expenses, medical services, prescribed drugs, eyeglasses, and dental treatments (SER 1.6.9).

Similarly, foreign male fellows receive similar benefits, except their stipend is set at 10,000 Ethiopian Birr per month. For both national and regional students, the center allocates up to 3,000 USD for each student to cover the costs associated with their MSc research project work. The center is committed to supporting students with disabilities and other socially disadvantaged groups, in line with the regulations of Addis Ababa University. Such information is communicated to the students during their orientation session to ensure they are aware of the support available to them (SER 1.6.10).

Students who have disabilities and/or chronic illnesses are welcome to take part in the program. Addis Ababa University hosts the largest referral teaching in Ethiopia (Black Lion Teaching Hospital) so that students with any challenging health conditions can be followed-up and treated.

**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. The experts positively emphasize the support for female staff and students.

**Decision**

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

## 5 Conclusion

From the experts' point of view, the Master study program "Clinical Trials" is well-structured. The admission processes meet high standards. All relevant documents are well prepared and transparent. Within the study program, an effective examination system as well as a student-centred quality assurance process are implemented. The teaching staff is motivated, and the material resources are deemed sufficient. The unique gender equality scheme is appreciated. Overall, the program's internationalization efforts and commitment to quality education are acknowledged positively.

Based on the information from written documents and the results of the site visit, the experts came to the conclusion that the study program "Clinical Trials" offered at the Addis Ababa University, CDT-Africa, fulfils the above-described criteria. Hence, the experts recommended that the Accreditation Commission of AHPGS make a positive decision regarding the accreditation of the study program.

For the continuous development of the study program, the experts have outlined the following recommendations:

- A guideline/process description for handling conflicts related to data handling, sharing and storage is recommend.
- An alumni network should be systematically implemented as a potential resource for Africa-wide attachment electives and job opportunities, as well as to enable growth of the study program, i.e., through increased student recruitment.
- Elective courses in collaboration with the College of Health Sciences could be implemented in a cross-sectional thematic strategy.
- A coaching system in which more experienced teachers are present at lectures given by new colleagues and vice versa could be implemented, so that they can help each other.

# 6 Decision of the accreditation commission

**Decision of the accreditation commission February 15, 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 site visit of the University took place on November 29-30, 2023, according to the previously agreed-upon schedule.

The accreditation procedure is structured according 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 Master study program requires the obtainment of 99 Credit Points according to the European Credit Transfer System (ECTS). The regulated study period in the Master study program "Clinical Trials" is three semesters. The program comprises 15 modules, out of which two modules are general subjects and 13 modules are core specialized subject areas including targeted seminar and attachment modules. The language of instruction is English. The Master study program "Clinical Trials" is completed with awarding of the academic degree "Master of Science". Admission takes place every winter semester. The first cohort of students was admitted to the study program in the academic year 2018/2019.

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

The Master study program “Clinical Trials” is accredited for the duration of five years until September 30, 2029.

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