CDT AFRICA

AFRICAN SOLUTIONS
FOR GLOBAL PROBLEM

Clinical Trial Operations

FOR STUDY COORDINATORS
IN AFRICA

Course Begins June 2023

CDT AFRICA
Center for Innovative Drug Development and Therapeutic Trials for Africa (ሲዲቲ-አፍሪካ)

In Partnership with

FCD

FIND
Diagnosis for all

iavi

MMV
Medicines for Malaria Venture

PATH

TDR For research on diseases of poverty
UNICEF • UNDP • World Bank • WHO

TB Alliance

The Center for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa), Addis Ababa University has organized an online training program to support Study Coordinators (SCs) in carrying out their roles and responsibilities as essential members of the study team in conducting high quality, regulatory-compliant clinical trials. This course covers the essentials of study design and protocol development, bioethics, good clinical practice (GCP), data management, regulatory affairs, safety monitoring, and practical management skills. Importantly, this course offers three unique features:

- Real-time application - study coordinators actively work with their study teams to evaluate current processes, consult with fellow students and expert faculty, and implement improvements during and following completion of the courseEach student is an individual who has a preferred learning style
- Wide range of expertise and experience – self-directed learning enables participants with varying skill levels to increase their competency in areas of particular interest
- Addresses the specific challenges commonly encountered in resource-limited settings – moving beyond the didactic, participants engage in robust dialogue around real-world situations encountered in challenging geographic, cultural, and political settings

This course was developed from training tools and resources made available from The Global Health Network, TDR Regional Training Centers, University of Siena, and other similar institutions. The course has been delivered four times, in collaboration amongst the following organizations who have actively participated in its design, delivery, and continuous improvement through a formal measurement and evaluation framework: Faculty of Capacity Development (FCD), FIND, Medicines for Malaria Ventures (MMV), IAVI, PATH, and the Special Programme for Research and Training in Tropical Diseases (TDR).

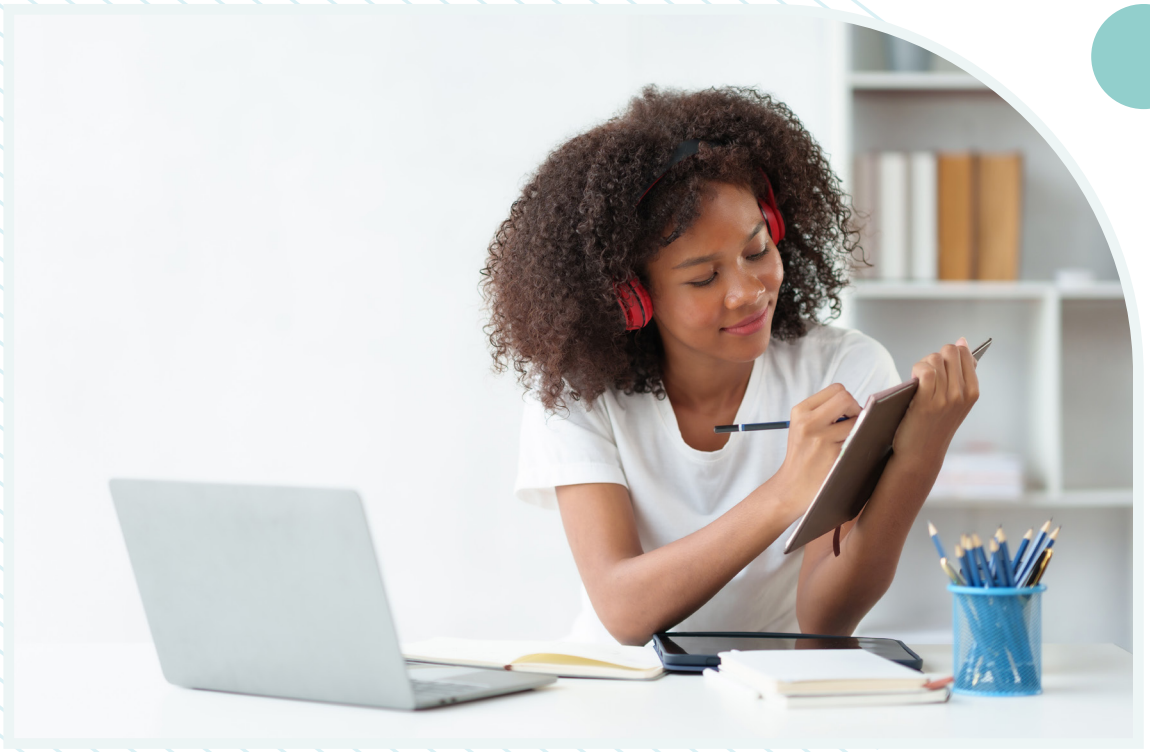
This course is supported through grant funding and financial support will be made available for those who require a scholarship. The training is an official executive course from CDT-Africa. Learners who complete the assignments will be awarded a certificate by CDT-Africa.

About CDT-Africa: CDT-Africa is a World Bank-supported Africa Centre of Excellence for education and research in medical discovery and development. Find out more at https://www.cdt-africa.org/

LEARNING Objectives

At the end of this course, successful participants will be able to::

- Have a broad vision and oversight of the whole conduct of a clinical trial at a site
- Prepare research sites for clinical trial start-up through an overall understanding of the clinical trial process from project management to trial design and protocol development.
- Demonstrate the ability to conduct GCP-compliant clinical trials in conformance with ethical principles using patient recruitment and retention approaches, data management, data monitoring, pharmacovigilance, and safety reporting.
- Design and maintain the quality system of a clinical trial through designing/implementing SOPs, risk management approaches, handling audits and inspections, as well as other aspects of quality control and quality assurance.
- Identify and address key challenges in managing the research sites including developing and maintaining capacity, retaining research staff, community engagement, and managing grants.
- Develop people management skills and techniques that are useful in working with internal colleagues and external partners.
- Efficiently close out clinical trials, handle post-trial responsibilities and report results in a timely manner.



Structure

This is an online program that has 10 consecutive lessons delivered via interactive recorded presentations, live and asynchronous tutorials, discussion forums, and personalized mentoring.

Lessons

Week	Lessons
1	Introduction to Clinical Trial Operations
2	Data Management and Biostatistics
3	Study Design and Protocol Development
4	Conducting a Trial 1
5	Conducting a Trial 2
6	Closing out and Reporting a Trial
7	Project and Financial Management
8	Working with External Partners
9	Quality Systems, Audits & Inspections
10	Pharmacovigilance

Is the Course for You?

This is a practical course where learning can be applied immediately.

Apply if you currently work in clinical research as a Study Coordinator (SC) or wish to work in this field.

Applicants should ideally have an academic qualification in one of the following fields: nursing, medicine, pharmacy, biomedical sciences, statistics, or a related subject. However, applicants with relevant experience or motivation without formal academic qualifications will also be considered.

Please note, applicants could be working in any disease area.

However, as the course measures its outcomes based on the degree to which participants apply their learning, those who are not actively working as SCs (or in a similar role) may not immediately realize the intended benefits from the course.

To better understand the proposed course, you may view an open-access version of the 2021/22 course for Africa-based Coordinators here

https://lms.cdt-africa.org/login/index.php

Log in as a 'guest' and click on 'open access study coordinators course'.

Time Commitment

The course is an intensive 10-week training program. Depending on your knowledge and experience expect to spend between 8-12 hours per week on the course.
A typical week will look like:

Week	Lessons
2 hrs	Studying interactive presentations & completing learning tasks
1 to 2 hrs	Forum Discussions
1hr	Live Video Conference
2 to 3 hrs	Preparing for Assessment
2 hrs	Independent Study

You will be given three weeks after the course ends to finalize your assessment if not already completed during the course.

Further Study

Learners who perform well in the course will be invited to enroll in a two-year MSc course in Clinical Trials at CDT Africa. CDT Africa has dedicated two positions in the 2023/2024 MSc program for the best-performing students in this 10-week course.

Who is Eligible?

This will be a cohort of Africa- based participants.
The criteria for selection in the course include:

- Experience working as a study coordinator, investigator, co-investigator, study manager, or assistant
- Applicants from sites with minimal clinical trial capacity will be given priority
- Applicants from sites initiating a trial soon will be given priority

The course is in English. Non-native English speakers may be asked to show proof of proficiency in English before they are accepted into the course.

If your application for the course fails or you need to access the course sooner than its start date, you may access the free-to-access version of the course here: https://lms.cdt-africa.org/login/index.php and access as a guest. Alternatively, you may access a similar course from the TGHN webiste here: https://tinyurl.com/54zjwzpk

Fees

The cost of the course for the whole 10 modules, including synchronous and asynchronous tutorials, group work, forum discussions, and certification, is $4,500 USD per participant; applicants offered a spot for the course will have access to funding support based on their need.

Key Dates

- Between now and 10th March 2023 please register your interest here: https://tinyurl.com/2p97adtv
- Formal applications, with supporting documents, will be accepted from 6th March to 7th April 2023. An online application will be sent to those who registered.
- The course will run for 10 weeks starting from 5th June 2023.

Please Note: You must be able to commit 8 to 12 hours to study each week starting from 5th June 2023.

Application Process

Applicants will need to submit items indicated under appendix I. The application will be online and the link to the application will be sent to those who registered their interest as indicated under "key dates"

Assessment

The assessment consists of a group assignment where risk management plan related to the lessons is drafted. Participation in the forum discussions and live tutorials as well as performance on quizzes in the lessons will also contribute to your assessment.

Most of the assessment will be completed during the online lessons and you will have three weeks after the course ends to complete and submit the remainder of outstanding assignments.

Further details

For more information, please contact us at info.clinops@cdt-africa.edu.et

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Appendix 1: Application Process

Applicants will need to submit the following:

- Curriculum Vitae detailing your academic and professional achievements using a template provided on the online application page.
- A 400 to 500-word letter of motivation outlining how your participation will benefit you and your organization. (Please note, the letter of motivation will be partly used to assess your level of proficiency in English. You may be asked to provide additional evidence.)
- Proof of identity (copy of passport, driver's license, or other valid IDs with photo).
- Endorsement from a senior manager in your organization

To show proof of endorsement please print the following Letter of Endorsement (LOE), discuss it with your line manager, Principal Investigator, or another colleague authorized to sign on behalf of your organization, and ask them to discuss the course with you and how it will benefit you and your organization by either closing a skills gap or meeting training needs. Ask them to sign the LOE and then please upload it as part of your application.

……..……..……..……

I have discussed the course with (Applicant's name) _____ and endorse their application to participate in the Clinical Research Operations for Study Coordinators course delivered by CDT Africa in collaboration with PDPs (FIND, MMV, IAVI, PATH), and TDR. I understand on completion of the course they should be able to do the following:

- Have a broad vision and oversight of the whole conduct of a clinical trial at a site
- Prepare the research sites for clinical trial start-up through an overall understanding of the clinical trial process from project management to trial design and protocol development.
- Demonstrate the ability to conduct GCP-compliant clinical trials in conformance with ethical principles using patient recruitment and retention approaches, data management, data monitoring, pharmacovigilance, and safety reporting.
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I will support (Applicant's name) _____applying these skills when possible.

Signed: _____ Print Name: _____

Job Title: _____ Date: _____