



ClinOps clinical research operation training program in LMICs

**Dawit E, Eyasu M,
Abebaw F. Nov 25,
2022**

Introduction

Addis Ababa University



- The biggest & oldest univ. in Ethiopia
- One of the top univer. In Africa
- Has 14 colleges and institutes

College of Health Sciences



- The biggest college in AAU
- Hosts CDT Africa

CDT Africa

Training programs

- Short courses
- MSc
- PhD
- Post-doc

Research Activities

- Drug
- Diagnostic
- Vaccine development

Introduction...

- Ensuring the two common goods of GCP requires well trained trial staff
- Competency-based training in CTs should be given due attention to prepare site staff for effective clinical trial conduct
- The aim of ClinOps training program was to address this issue



Unique features of ClinOps training program

- Participatory approach for syllabus development
 - Developing draft curriculum by local team
 - Providing comments by PDPs
 - Taking care of comments for the final syllabus ppn
 - Developing competency framework set jointly by TDR/TGHN
- Alignment to local priorities
 - Focussing on practical problems in African trial sites
 - Involving local tutors with trial site experience
- Addressing all relevant domains for effective trial conduct
- Making an intensive on job training for 10 wks
- Making M&E effort to meet course objectives
- Following Innovative training approaches



Innovative Approaches

1. Employing Moodle LMS

- Using online tool for uploading power points
- Giving trainees opportunity to get PowerPoint online
- Enabling tutors to record inputs on slides
- Allowing trainees to put questions and comments on slides either as a text or voice record



Innovative Approaches....

2. Voice Thread Recording *Interactive Platform*



VOICETHREAD



Innovative Approaches...

3. Creating Discussion Forum

- Sharing opinions
- Giving comments/feedback
- Asking questions
- Getting responses



Task 1;



Task 2;



Task 3;

4. Conducting Live tutorial with Zoom

- Every week for one hour
- Summary presentation on each lesson
- Q & A



Live Tutorial; Thursday, January 20, 2022

Innovative Approaches...

5. Providing Reading Materials Online

- Mandatory
- Recommended
- In-depth

6. Designing strategy to motivate trainees

- Providing scholarships for top scoring trainees to be enrolled in an MSc program in CT hosted by CDT Africa



Innovative Approaches ...

7. Preparing Risk Management Plan

- Group work
- Identification and analysis of Risks
- Development of Risk Management Plan

RISK MANAGEMENT PLAN TEMPLATE

Title of the clinical trial				Comment
Risks Identified				
Risk analysis for risks identified	Average Likelihood (out of 10)	Average Gravity (out of 10)	Criticality (Likelihood x Gravity)	
Risk Mitigation plan				
Risk Management Document				



Contents of ClinOps Course

- Lesson 1: Introduction to Clinical Research Operation
- Lesson 2: Data Management & Biostatistics
- Lesson 3: Study Design & Protocol Development
- Lesson 4: Project & Financial Management
- Lesson 5: Conducting a Trial (Part 1)
- Lesson 6: Conducting a Trial (Part 2)
- Lesson 7: Closing out & Reporting a Trial
- Lesson 8: Working with External Partners
- Lesson 9: Quality Systems, Audits & Inspections
- Lesson 10: Pharmacovigilance



ClinOps tutors with rich experience in clinical trials



Prof. Eyasu Makonnen



Dr. Dawit A. Ejigu



Prof. Asrat Hailu



Dr. Anteneh Belete



Dr. Getnet Yimer



Dr. Birkneh T. Tadesse



Prof. Abebaw Fekadu



Prof. Charlotte Hanlon



Dr. Yimtubezinash W/Amanuel



Dr. Solomon Mequanente



Major Achievements

- Creating strong collaborations with FCD and Enovation, Ireland
- Networking with trial coordinators in Africa
- Creating opportunity for sharing experience among trainees
- Building capacity of over 80 trainees
- Establishing virtual platform system for future training



Challenges & Mitigation Strategies

Challenges

- Falling behind the course & high dropout rate
- Low participation
- Technology challenges

Mitigation strategies

- Following trainees up
- Encouraging trainees to participate
- Seeking IT support from CHS & Enovation, Ireland

Free to access version of the course

<https://lms.cdt-africa.org/login/index.php>,
access as guest
and click on
“Open Access
Study
Coordinator's
Course”



Open Access Study Coordinator's Course

Home / Courses / Open Access / Open Access Study Coordinator's Course

-  About this course
-  Related Courses
-  How to use this course

Lesson 1. Introduction to Clinical Trials Operations

Lesson 2. Data Management and Biostatistics

Lesson 3. Study Design and Protocol Development

Conclusion and Recommendation

- ClinOps training program helped trainees acquire relevant knowledge in coordinating/conducting CTs in LMICs
- We recommend the training to continue to develop critical mass of trained trial staff in Africa
- The training could also be given in other languages like French

Acknowledgment

*Bell &
Melinda
Gate's
Foundation*



Enovation



THANK YOU!

