EDCTP-TDR Clinical Research and Development Fellowship
Training Plan

1 Administrative information

Grant reference number *(To be filled in by EDCTP/TDR)*	
Name of Fellow	
Home organisation, country	
Supervisor at home organisation **Name** **Job title** **Email** **Telephone**	
Host organisation, country	
Supervisor at host organisation **Name** **Job title** **Email** **Telephone**	
Expected Start date of placement (dd/mm/yyyy) **Duration (months)**	
Funding organisation *(to be filled in by EDCTP/TDR)*	EDCTP ☐ TDR ☐

This training plan should be filled in **jointly** by the supervisor at the host organisation, supervisor at the home organisation and the Fellow.

2 Training programme

2.1 Goal and objectives

Please describe the Fellow's specific goals and objectives for the placement, making reference to the projects the Fellow will be involved in, the activities the Fellow will undertake and the clinical trials competencies (Section 2.2).

2.2 Clinical trials competencies

Please complete the table indicating the current competency level and whether the area is included in the training plan.

Notes: Please rate the level of competency from 0 to 5 according to the following categories*
Adapted from Global Health Trials Network core competencies categories

0. No experience
1. Trained (have received training but have no personal experience in the this task or activity)
2. Some experience (have performed this task or activity but not regularly or recently (less than one year's experience or occasional or past experience)

3. Capable (capable in this task or activity, it is part of my job and I am competent with approximately 1-2 years' experience)
4. Experienced (consistently competent at this task or activity. It is a normal part of my job and I can conduct it confidently with no supervision)
5. Highly experienced (have been performing this task or activity for many years, and play a leading role in it)

Clinical trials competencies *Adapted from CTTI*	**Level/Experience (0-5)**	**Included in training plan (X)**
Scientific concepts and research design		
• Clinical trial design		
• Statistics – sample size, data analysis		
• Clinical pharmacology		
• Protocol development		
• Molecular biology		
• Immunology		
• Microbiology		
• Systematic reviews		
• Other (please give details and add rows as needed)		
Ethical considerations and patient safety		
• Human subjects protection		
• Informed consent		
• Safety issues		
• Community engagement and feedback		
• Other (please give details and add rows as needed)		
Medicines development and regulation		
• Clinical development pipeline		
• Quality, safety and efficacy of medicines		
• Regulatory pathway to medicines approval		
• Other (please give details and add rows as needed)		
Clinical trials operations and study implementation		
• Good clinical practice		
• Good clinical laboratory practice		
• Trial governance (trial steering committee, data safety and monitoring board)s		
• Obtaining ethical approval		
• Obtaining regulatory approval		
• Recruitment study participants		
• Adverse event identification and reporting		
• Post marketing surveillance and pharmacovigilance		
• Handling investigational products		
• Quality control and clinical trial monitoring, including adherence		
• Trial master file and site investigator files		
• Other (please give details and add rows as needed)		
Study and site management		
• Financial management		
• Personnel management		
• Administration and document management		
• Other (please give details and add rows		

as needed)		
Data management and informatics		
• Clinical report forms and source data		
• Data entry and querying		
• Quality control and data correction		
• Clinical trial databases and database lock		
• Other (please give details and add rows as needed)		
Communication and team work		
• Interaction with sponsors		
• Working with clinical research organisations		
• Interactions with ethical and regulatory authorities		
• Chairing trial management meetings		
• Other (please give details and add rows as needed)		
Leadership and professionalism		
• Managing a team		
• Problem solving for trial site investigators		
• Clinical sponsor and sponsor representative role		
• Consortium agreements		
• Other (please give details and add rows as needed)		
Clinical trial reporting		
• Writing up completed trials		
• Clinical study reports		
• Manuscript writing (knowledge of CONSORT statement)		
• Manuscript writing – knowledge of STROBE statement (Strengthening the reporting of observational studies in epidemiology)		
• Other (please give details and add rows as needed)		

3 Supervision and monitoring arrangements

3.1 Departments and units

In which institutions/departments/units will the Fellow be placed? Will there be any rotation between different departments/units or offices, and what is the indicative timeline for such rotation? *Please note that any travel expenses associated with rotation should be covered by the host organisation.*

3.2 Supervision arrangements

Please describe the supervision arrangements at the Host Organisation.

3.3 Mentorship

Give details (name and job title) of a personal mentor assigned to the Fellow and the support/interaction provided by the mentor to the Fellow.

3.4 Monitoring of progress

How will the home organisation supervisor monitor the progress of the Fellow during placement? Describe the arrangements in place that will ensure and maintain contact and involvement during the placement.

3.5 Evaluation

How will the Fellow's acquisition of new skills and competencies be measured during the placement? E.g. will the participant receive progress reports or periodic reviews and if so how often will they occur? What documentation/evidence will be produced to verify the Fellow's training and performance?

4 Declarations

This training plan has been agreed by the following individuals:	**Signature and date**
Fellow [Name]	
Supervisor at Home Organisation [Name]	
Supervisor at Host Organisation [Name]	