**EDCTP-TDR Clinical Research and Development Fellowship**

## Clinical Trials Competencies

*Please complete the table indicating the current individual competency level and whether specific training would be required at a selected host organisation.*

*Note: Once the evaluation process has been completed and placements have been accepted, a comprehensive training plan will be completed by the successful fellow, host organisation and home organisation.*

Notes: Please rate your level of competency from 0 to 5 according to the following categories[[1]](#footnote-1)

0. No experience

1. Trained (I have received training but have no personal experience in this task or activity)

2. Some experience (I have performed this task or activity but not regularly or recently - less than one year’s experience or occasional or past experience)

3. Capable (I am capable in this task or activity, it is part of my job and I am competent with approximately 1-2 years’ experience)

4. Experienced (I am 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 (I have been performing this task or activity for many years, and I play a leading role in it)

|  |  |  |
| --- | --- | --- |
| **Clinical trials competencies**  *Adapted from* [*CTTI*](http://www.ctti-clinicaltrials.org/) | **Level/Experience**  **(0-5)** | **Mark (X) if training is required** |
| **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 other researchers including 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) |  |  |

1. Adapted from [Global Health Trials Network core competencies categories](https://globalhealthtrainingcentre.tghn.org/cpd/scoring/) [↑](#footnote-ref-1)