

Using the TDR Global Competency Framework for Clinical Research:

A set of tools to help develop
clinical researchers



User Guide

PART 3/3

Protocol for pilot use and evaluation

The TDR Global Clinical Research Competency Framework is available in a paper, beta version and ready to be piloted by research groups to determine areas for improvement. The framework and all associated documents can be downloaded at <https://globalhealthtrials.tghn.org/articles/who-tdr-global-competency-framework-clinical-research-set-tools-help-develop-clinical-researchers/>: this includes a **Development Report** detailing why and how the framework came about; and the present document containing various supporting tools to help the user to fully understand the purpose of this framework. We recommend you to look at those, or to go back to the brief 'Foreword' section for quick reference.

The present protocol explains how to use the TDR Global Competency Framework in day to day work (Section A), and how to concurrently collect information so as to evaluate its practicality and usefulness to you (Section B). The framework is meant to be highly flexible: you can use it across different settings and situations, and a description of how to test it in four major situations is provided below. The suggested situations are:

1. When planning roles and responsibilities for a new study
2. When building job descriptions for studies
3. When conducting an appraisal
4. When creating a training curricula

Section A below details how to use the framework for each of those four situations. Please respond to the standardised feedback and questions provided in Section B, and send your feedback to the developers of the framework (info@theglobalhealthnetwork.org) for processing. We hope the framework is useful to you, and really appreciate your time providing feedback which will ultimately help to improve it.

Section A – Using the TDR Global Competency Framework for Clinical Research in practice

When planning roles and responsibilities for a new study

The framework aims to cover all competencies required by *your team as a whole* to perform a clinical study (interventional trial, observational study, etc.). You may want to use the **Competency Wheel** to first take some time to decide if *all* competencies will be required for your specific study: for example, you may cross out *Ensuring appropriate use of Investigational Medical Product (IMPs)* if you are performing an

observational study. When you are not sure whether a competency should be covered, please use the **Competency Dictionary** to get an in-depth description of that competency, as well as likely tasks.

You can then use your adapted framework (and the **Competency Dictionary**) to ensure that you have all responsibilities covered by at least one team member when planning a new study and distributing tasks. You may wish to do this by putting the relevant individual's role title(s) or names against each competency. Doing so will highlight to you if there are gaps in your proposed team in a certain area: for example, perhaps the issue of safeguards and safety has not been well covered.

Note: Each competency will be relevant to more than one individual, but this should still assist you in clarifying whether there are gaps in your team and whether you should consider hiring additional staff or training existing one.

When building role descriptions

Use the Competency Framework to assist you in creating role descriptions for staff, ensuring that you have a comprehensive overview of the role (e.g. data staff, research nurse, trial coordinator), and of the different levels at which that role could operate (junior, senior or specialist).

First use the **Competency Wheel**, marking each competency between 0 (no knowledge of the competency needed) and 5 (high level of expertise), relating to the level of competency your individual needs to perform that role, at the chosen level (see the guidance on the grading scheme for information on scoring; to do so, you can use either the **Competency Wheel**, or a **Radar Chart** if you prefer, which will give you a visual representation of the competency of the individual). For example, a research nurse will need a high level of knowledge about patient care and safety, as well as informed consent; their knowledge may be more limited about grant applications (depending on the study).

This exercise will give an overview of the level and type of staff that you require for your study: having the broad overview of the framework should also help you to think beyond the conventional boundaries of the role (your research nurse may well take on the role of trial coordinator as well), and thus to conduct more targeted staff search.

When you are not sure about the meaning of a competency, please use the **Competency Dictionary** to give you an in-depth description of that competency, as well as likely tasks.

Next, for each competency, consult the dictionary for some useful examples of the related tasks and the demonstration of the competency 'in practice', which you may choose to copy to create your job description.

Note: We have developed our own versions of those role descriptions for the role of data staff, and will in future create the other roles included in the project. The information and specific examples of tasks that those role-specific frameworks contain are derived from the data we systematically analysed (essentially, role-related guidelines and job descriptions). You may find them readily useful to you, work from there to adapt them to your setting, or wish to create new ones from scratch for additional roles not covered here.

When conducting an appraisal

The framework can be used to conduct staff appraisals, by working with the individual to grade them on each competency. Please check the guidance on the grading scheme for clarification on the 0-5 scale proposed for assessment using the framework. Use of the Competency Framework will assist in providing a comprehensive appraisal, and ensuring that the staff member has all the appropriate knowledge for their role (as described in their role description, see above).

To use the Competency Framework to conduct an appraisal, work with the individual using the **Competency Wheel** item-by-item to clarify the expected level for them for each competency. This will vary depending on the role and level; for example an investigator would be expected to have higher scores across the board than a data manager, whose knowledge would be more specialised. Assist your team member in comparing the theoretical expectations with their own current level, to highlight areas where they excel, and areas for improvement. You can use the **Competency Dictionary** and the **role-specific frameworks** as an accompaniment to the **Competency Wheel**, to clarify the specific tasks and responsibilities associated with each competency.

You may also wish to create a 'radar' or 'spider' diagram with them, which provides a visual representation of their skillset (see examples on pages 6 and 7), and can help to motivate them and track progress over time.

When creating a training curriculum

The Competency Framework can be used while creating a training curriculum, to ensure that the required competencies are comprehensively covered in the curriculum, and to provide guidance (via the **Competency Dictionary**) on the intended content and learning outcomes for each competency development course.

To use the Competency Framework to create a curriculum, first use the **Competency Wheel** to clarify the intended areas of the course, marking between 0 and 5 the level of knowledge expected by the end of the course, for each item (see guidance on the grading scheme).

Next, use the **Competency Dictionary** to go through each intended competency, to create a detailed overview of the knowledge that will be gained through taking the course. The detail for each item can be copied to create a comprehensive guide to the learning outcomes of the course, which can then provide the basis for the development of the material itself.

Note: You may also decide to 'grade' existing curricula against the framework, in order to see their strengths and weaknesses. This could help you to suggest appropriate training to your staff, after conducting their appraisal (see "*when conducting an appraisal*").

Section B – Your experience and evaluation

Please provide your feedback on the TDR Global Competency Framework for Clinical Research as you have used it, by emailing the form below to info@theglobalhealthnetwork.org. Thank you in advance for your valuable feedback!

We may use the responses from these questionnaires in reports and publications of the framework evaluation, but all responses will be anonymised.

Later, we may invite some individuals to collaborate on a closer evaluation of the framework. This may involve interviews to better understand your experience of using the framework; or some more systematic and guided use of the framework, to assess its effectiveness in supporting individuals through various aspects of the clinical research process. If you're interested in being further involved, please leave your contact details at the end of the form.

	Question	Your answer
	What did you use the framework for? Please tick all that apply to your experience.	<ol style="list-style-type: none">1. When planning roles and responsibilities for a new study2. When building job descriptions for studies3. When conducting an appraisal4. When creating a training curriculum5. To assess my own training needs6. Other (specify): _____
	Did you use the online version of the framework, or the downloadable word/pdf file?	<ol style="list-style-type: none">1. Online web application2. Downloaded pdf file3. Both
DESIGN	Did the layout appeal to you? What did you like or did not like about the layout?	
	What could we improve to increase readability of the framework?	
	Did the layout enable you to spot the different levels (competency areas, competency categories, detailed competencies) easily?	

CONTENT	Were there any competencies that you found hard to understand from the way they were phrased on the Competency Wheel? If so, please let us know which ones.	
	<p>Did you use the competency dictionary to clarify any of the competencies?</p> <p>If you used the Competency Dictionary, did it help you understand what the competency was about? Why or why not?</p>	
GRADING SYSTEM	Could you easily grade the competencies on a scale from 0 to 5 using the suggested grading scheme? Please explain.	
	Which competencies were easiest/hardest to grade? Why?	
	<p>Did you use the competency dictionary at any stage, to identify your competency level?</p> <p>Did it help? Why or why not?</p>	
ACCURACY	Were all the competencies you need to perform your job present in the framework? If not, which were missing?	
	Did you think that any of the competencies were superfluous? If any, please explain.	

CONCEPT	<p>The idea of this global framework is to bring together the competencies of the entire research team, and help clinical researchers to see what skills they could develop to progress and possibly take on more responsibility or a different role.</p> <p>Did you find it helpful or unhelpful to have a holistic view on the full research team skills? Please explain your answer.</p>	
GENERAL	<p>Would you recommend the framework to a colleague (why or why not)?</p>	
	<p>Did the framework make you think about an aspect of clinical research you would have forgotten to cover?</p>	
	<p>Anything else you would like to tell us about using the framework?</p>	
	<p>Which country are you based in?</p>	
	<p>We may contact some individuals about testing the competency framework more closely. Would you be interested in being involved in future studies? If so, please leave your name and email address here.</p>	