Using the TDR Global Competency Framework for Clinical Research:

A set of tools to help develop clinical researchers



Competency Grading System

PART 2/3

Competency grading scheme

Although other uses are anticipated, the framework is essentially intended to assist in the professional development of clinical researchers. The framework should enable to evaluate individuals in their own jobs and in light of other roles, thus facilitating the identification of required training based on existing capabilities, experience and career objectives. Templates for grading individuals and showing their areas of strengths and weaknesses in a visual manner have been developed (see below) to support this use of the framework.

For consistent grading (between staff, or over time), we recommend assessing the level of an individual in performing each of the competencies with the following scale¹:

Grade	Corresponding behaviour
5	Task: Highly experienced; able to train and guide others.Knowledge: Expert knowledge; able to teach and assess others.Skill: Use skill appropriately, consistently and confidently.
4	Task: Experienced; regularly perform the task in their job. Knowledge: Highly knowledgeable; use, reflect, critically evaluate information related to the topic. Skill: Use skill appropriately, in all relevant situations.
3	Task: Capable to perform the task. Knowledge: Knowledgeable; frequently apply knowledge of topic. Skill: Use skill appropriately, but only occasionally.
2	Task: Some experience; already performed the task at least once. Knowledge: Some exposure; already applied knowledge of topic in their job at least once. Skill: Use skill inconsistently and occasionally.
1	Task: Little experience, but received training. Knowledge: Little exposure, but followed courses or read about the topic. Skill: Use skill with difficulty and/or very rarely.
0	Task: No experience; never performed the task before. Knowledge: No exposure; never heard of the topic before. Skill: Unable to use skill.
NA	Not applicable (e.g. if the competency is not useful for the role of the individual assessed)

¹ Inspired from the Professional Membership Scheme offered on The Global Health Network – <u>https://globalhealthtrainingcentre.tghn.org/cpd/about/</u>

The definitions provided in the *Competency Dictionary* are meant to clarify situations in which the individual should apply the competency. The definition is mostly representative of the minimum level desirable for an individual to competently perform the task (i.e. Grade 3), unless otherwise stated (i.e. Expert/Specialist = Grade 5).

Specific situations may also need to be addressed by different job roles or individuals with more or less experience, in which case a different grade should be aimed for (e.g. Junior = Grade 2/3; Senior = Grade 4/5). The role-specific frameworks (see below) further map such Junior/Senior levels to different grades.

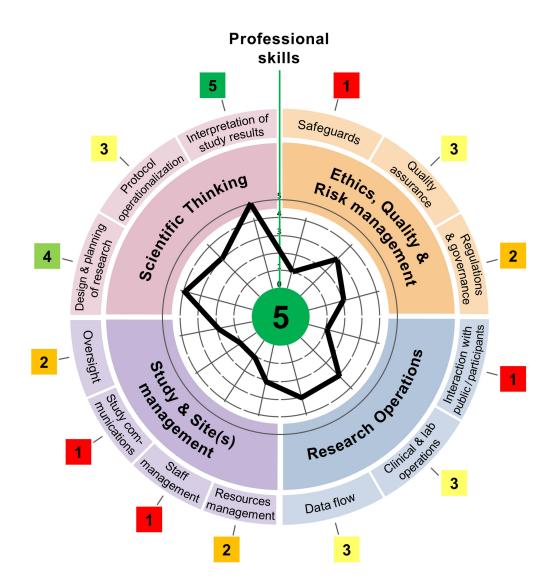
Grading radar chart

To facilitate the visualisation of one's areas of strengths or in need for improvement, the scores obtained for each competency can be averaged by area, and then reported on the following template radar chart (also known as web diagram). These charts are often used for mentoring; one would mark oneself on each competency out of five, and the circular structure allows a visual representation of the areas in which the individual has particular strengths, and/or areas one would need to improve.

We provide both an empty grading radar template, which can be photocopied and re-used at will, as well as a completed radar (Figure 1), to illustrate how this facilitates highlighting major skills.

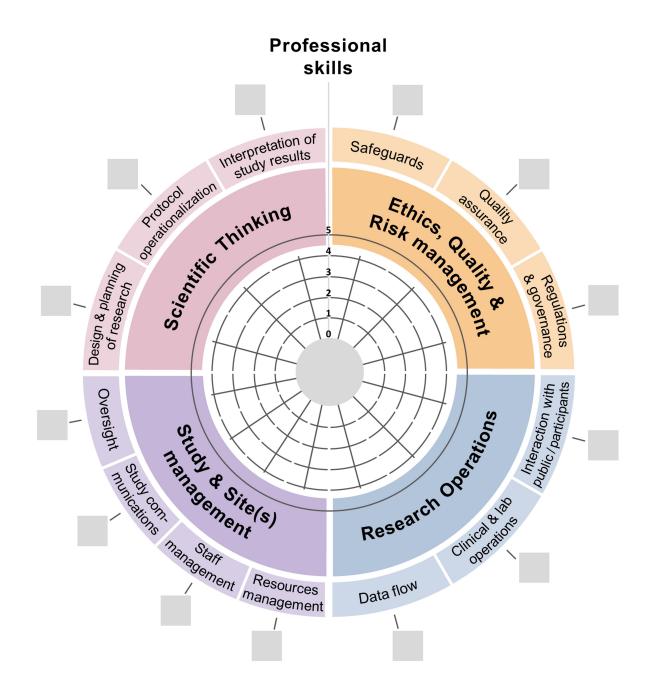
A web application is in development by The Global Health Network and TDR, which enables to record your grades online and keep track of your progress over time. We encourage you to use this online version if you can, as it provides a much more interactive interface that creates the radar picture automatically for you. It will also link to additional resources as the project unfolds, such as eLearning courses to develop your competencies of interest. You can find the web application at: <u>https://qlobalhealthtrials.tghn.org/global-competency-framework-clinical-research/</u>.

Figure 1 – Grading radar chart: an illustrative example. The empty radar template (see next page) has been completed with fictitious scores to provide this illustration. The professional skills' average score (here equal to 5) is recorded in the middle, and is surrounded by a 'radar' or 'web' recording scores in all 13 other areas of competency.



Re-usable template: Please record your average score for the corresponding competencies in the provided grey square, and draw your radar of competencies accordingly.

TDR Global Competency Framework for Clinical Research



Role-specific frameworks

[under construction]

The role-specific frameworks are a supportive tool we aim to provide in the future. They will be most useful in the web application format, and have been developed in a draft version for the 11 roles that were considered while gathering data for the initial development of the generic framework (Table 1). Owing to the broad coverage of the whole clinical research study's activities within the framework, we believe it can be derived for other roles as well, and we will keep working towards this as the framework evolves. Please get in touch² if you are interested in bringing further the development of a role-specific framework.

While creating those role-specific versions of the generic framework, it would be helpful to work with individuals in the concerned role and within different settings, to better define with them what it means in their context to be applying the competency suggested in the generic Competency Wheel and Dictionary, and to define expected grades for junior, senior or specialist staff.

As an early example, we created the data staff framework, which is presented over the following six pages. Of note and contrary to other roles (e.g. the research nurse or trial manager) for which the literature was abundant, no openly-accessible competency framework for data managers could be identified by the authors at the time the generic framework was being developed (last quarter 2014). We therefore decided to use this role as an illustration, in the hope to start filling an obvious gap.

It appeared from our analysis, and also from experience of working with clinical researchers worldwide, that in some settings, there is some strong crossover between the role of the statistician and the role of the data manager, while in other settings the roles are quite distinct. Therefore, some information on the role of the statistician has been given below as a 'specialist' option, which applies where crossover exists, and could help interested and experienced data managers in seeing how they could expand their skillset and get involved in statistical analyses.

Again, we would like to mention that the role-specific frameworks will be most practical to use in the web application for which they have been planned, and where examples of specific behaviours and activities can be shown in 'pop-up windows' by clicking on each and every competency. The following framework (Figure 2) is therefore more a proof of concept than a final product, and we invite the user to keep that in mind and send us their feedback when using this tool, still in its early-development stage.

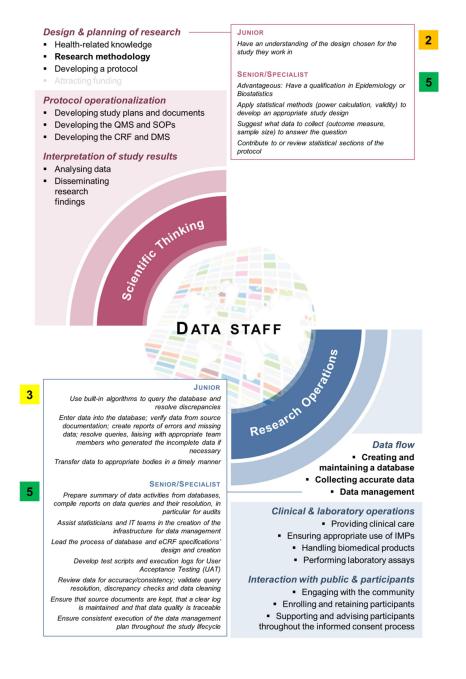
² Contact us at <u>info@theglobalhealthnetwork.org</u>

 Table 1 – List of roles and levels considered.
 Suggested job titles may vary from one team and setting to the next, and correspond to those found in the different job descriptions analysed.

Role	Junior	Senior	Expert or Specialist setting
Data staff	Data clerk; Data assistant; Data entry and administration personnel	Data manager; Senior or Lead data manager	Biostatistician
Laboratory scientist	Laboratory (lab) technician; Scientific lab technician; Lab technologist; Lab research assistant	Assistant lab manager; Lab manager; Lab scientist; Head of laboratory (at site)	Head of laboratory(ies); Chief specialist scientist; Research scientist (medical); Senior lab analyst; Science lead; Clinical pharmacologist
Trial pharmacist	Pharmacy administrator/coordinator; Trial pharmacist; Pharmaceutical technologist; Pharmacy technician	Lead pharmacist	
Community engagement staff	Fieldworker; Research assistant	Senior fieldworker; Field research officer; Community engagement or liaison officer; Community engagement and ethics coordinator	Counsellor
Research nurse	Nurse; Nurse assistant; (Clinical) research nurse; Study nurse; Vaccination nurse	Clinical research coordinator; Study coordinator	
Study physician	(Clinical) research physician; Clinical development physician; Study physician; Medical officer; Research clinician; Clinical investigator	Sub-investigator; Lead clinical research physician	(Clinical) safety physician; Pharmacovigilance physician; Public health officer
(Principal) investigator	Investigator (at site); Co-investigator; Medical science physician	Principal Investigator; Head of clinical trials; Global clinical Leader; Senior director of clinical R&D Senior global clinical pharmacologist	
Trial manager or Project coordinator	(Clinical) research/trial coordinator; Project/study coordinator; (Clinical) research/trial manager; Clinical research operations manager; Clinical research administrator; Trial clinical officer; Support officer; Clinical trials facility manager	Senior research coordinator; Chief trial manager	
Quality Control monitor	Clinical trial monitor; Quality assurance manager; Quality control specialist; (Clinical) Research associate (<i>industry</i>)	Lead monitor; Monitoring senior associate; Monitoring team leader; Quality assurance officer	Data quality controller; Safety specialist; Regulatory affairs specialist; Regulatory coordinator Senior ethic clinical trials specialist

Role	Junior	Senior	Expert or Specialist setting
ECs and IRBs	Ethics Committee (EC) or Institutional Review Board (IRB) member (permanent or lay)	EC/IRB coordinator; EC/IRB vice-chair or chair	
Sponsor	Not applicable		

Figure 2 – Example of role-specific framework derived from the TDR Global Competency Framework for Clinical Research: application to the case of data staff. For each sub-area of competency, specific examples of tasks and abilities are provided for the role considered (here, data staff). Expected scores are suggested for members of staff in a junior (data entry clerk or data assistant) or senior position (lead data manager) within that role. Competencies shaded in light grey apply little to the role: for example, the data personnel are not usually involved in clinical and laboratory operations.



Design & planning of research SENIOR/SPECIALIST Health-related knowledge Provide input in any study document relating to data collection, management or analysis Research methodology Develop documentation for the reporting and follow-up Developing a protocol . of SAEs Attracting funding Write SOPs for database construction and requirements (security, back-up, storage, etc.) Protocol operationalization Write or contribute to SOPs for communication with other parties (laboratories, sponsor, etc.), in particular Developing study plans and documents . for aspects relating to data transfer and export/import Developing the QMS and SOPs Develop the Case Record Form (CRF) in an electronic Developing the CRF and DMS and/or paper format Plan the data entry and data management processes; Interpretation of study results Design and pilot surveys Analysing data . Disseminating research Signific Thinking findings DATA STAFF Research Openio Data flow Creating and maintaining a database Collecting accurate data Data management **Clinical & laboratory operations** Not Applicable Providing clinical care Ensuring appropriate use of IMPs Handling biomedical products

5

Performing laboratory assays

Interaction with public & participants

Engaging with the community

Enrolling and retaining participants

 Supporting and advising participants throughout the informed consent process

Design & planning of research

- Health-related knowledge
- Research methodology .
- Developing a protocol .
- Attracting funding

Protocol operationalization

- . Developing study plans and documents
- . Developing the QMS and SOPs
- Developing the CRF and DMS .

Interpretation of study results

• Analysing data

Disseminating research Signific Thinking findings

SENIOR/SPECIALIST

Participate in the preliminary analysis and presentation of trial data

Write reports/articles presenting study results, revise texts drafted by other team members, and takes authorship where appropriate

Research Operation

DATA STAFF

Data flow

 Creating and maintaining a database Collecting accurate data Data management

Clinical & laboratory operations

 Providing clinical care Ensuring appropriate use of IMPs

- - Handling biomedical products
 - Performing laboratory assays

Interaction with public & participants Not Applicable

Engaging with the community Enrolling and retaining participants

Supporting and advising participants

5

3

5

- Safeguards

Ethics and human subject protection Risk and safety management

Determining liability and insurance needs

Quality assurance

- Good Clinical (or other) Practice
 Working as per the QMS
 - Controlling quality of research

Regulations & governance

Securing or maintaining approvals
 Securing or maintaining contracts

 Governance and organisational context
 Research regulations

DATA STAFF

Oversight

- Initiating study
- Closing study
- Project management
- Tracking study progress

Study communications

- Reporting
- Liaising or acting as a link
- Facilitating or attending meetings

Study & Site(s)

Staff management

- Human resources
- Creating or delivering training
- Supervising or mentoring

Resources management

- Overseeing essential documents
- Logistics and facilities management
- Finances management

JUNIOR

Archive CRFs as laid-down in SOPs

SENIOR/SPECIALIST

Coordinate the archiving of study database; perform database-lock as required by PI

Perform close-out audits; ensure future availability of data

Demonstrate ability to coordinate and oversee research activities

Manage CROs or other groups that execute statistical analyses for the trial, if applicable

Check and track timelines for data management with study coordinators and managers

5

times, from entry to storage

JUNIOR

protection

Report on AEs and inform relevant staff of any potential harm suspected from data analyses Ensure appropriate entry and follow-up on status of AEs/ SAEs into database

Have an awareness (certification) in human subject

Maintain confidentiality of participants' records at all

3

5

Safeguards

Ethics and human subject protection
Risk and safety management
Determining liability and insurance needs

Quality assurance

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DATA STAFF

JUNIOR

SOPs

SENIOR/SPECIALIST

Have knowledge of and consistently work in

Maintain data and study documentation as specified in

Propose suitable means to improve the data quality

Monitor and evaluate the activities of staff data in own

management systems within the organisation Audit databases to validate specifications,

Study & Site(s)

programming and quality checks

team and/or at different sites

accordance with Good Clinical Practice

Oversight

- Initiating study
- Closing study
- Project management
- Tracking study progress

Study communications

- Reporting
- Liaising or acting as a link
- Facilitating or attending meetings

Staff management

- Human resources
- Creating or delivering training
- Supervising or mentoring

Resources management

- Overseeing essential documents
- Logistics and facilities management
- Finances management

SENIOR/SPECIALIST

Generate regular reports on progress, updates and barriers; send them to investigators and study coordinators

Liaise with staff and external parties (e.g. sponsor, vendors) on issues related to data, in particular data transfer

Attend and present at meetings or conference calls, e.g. team or vendor meetings

SENIOR/SPECIALIST

Maintain study documentation as per SOPs and quality management system

Keep receipts of purchased items and work with accountants to keep expenses within study budgets



5

4

Safeguards

Ethics and human subject protection
 Risk and safety management

Determining liability and insurance needs

Quality assurance

- Good Clinical (or other) Practice
- Working as per the QMS
- Controlling quality of research

Regulations & governance

Securing or maintaining approvals

Securing or maintaining contracts

 Governance and organisational context
 Research regulations

 Risk model of the second s

DATA STAFF

SENIOR/SPECIALIST

team

Develop data agreements between contractors (e.g.

external laboratories, data vendors) and the research

Ensure that the data and data systems meet the sponsor, funder and regulatory requirements

Oversight

- Initiating study
- Closing study
- Project management
- Tracking study progress

Study communications

- Reporting
- Liaising or acting as a link
- Facilitating or attending meetings

Study & Site(s)

Staff management

- Human resources
- Creating or delivering training
- Supervising or mentoring

Resources management

- Overseeing essential documents
- Logistics and facilities management
- Finances management

SENIOR/SPECIALIST

Recruit an appropriate team of data collectors to gather study data

Develop training on the Central Data Management System, that is suitable for users including PI, data entry staff, study coordinators and monitors

Train team members and staff on data entry, editing, cleaning and validation procedures

Interact with other trial sites to develop joint data

management training

Manage a team of data entry staff; mentor newly appointed members

Supervise, appraise and support the development data team members

2