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 scale:\(^1\):

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

\(^1\) Inspired from the Professional Membership Scheme offered on The Global Health Network – [https://globalhealthtrainingcentre.tghn.org/cpd/about/](https://globalhealthtrainingcentre.tghn.org/cpd/about/)
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: [https://globalhealthtrials.tghn.org/global-competency-framework-clinical-research/](https://globalhealthtrials.tghn.org/global-competency-framework-clinical-research/).
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 touch 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 info@theglobalhealthnetwork.org
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.

<table>
<thead>
<tr>
<th>Role</th>
<th>Junior</th>
<th>Senior</th>
<th>Expert or Specialist setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data staff</td>
<td>Data clerk; Data assistant; Data entry and administration personnel</td>
<td>Data manager; Senior or Lead data manager</td>
<td>Biostatistician</td>
</tr>
<tr>
<td>Laboratory scientist</td>
<td>Laboratory (lab) technician; Scientific lab technician; Lab technologist; Lab research assistant</td>
<td>Assistant lab manager; Lab manager; Lab scientist; Head of laboratory (at site)</td>
<td>Head of laboratory(ies); Chief specialist scientist; Research scientist (medical); Senior lab analyst; Science lead; Clinical pharmacologist</td>
</tr>
<tr>
<td>Trial pharmacist</td>
<td>Pharmacy administrator/coordinator; Trial pharmacist; Pharmaceutical technologist; Pharmacy technician</td>
<td>Lead pharmacist</td>
<td></td>
</tr>
<tr>
<td>Community engagement staff</td>
<td>Fieldworker; Research assistant</td>
<td>Senior fieldworker; Field research officer; Community engagement or liaison officer; Community engagement and ethics coordinator</td>
<td>Counsellor</td>
</tr>
<tr>
<td>Research nurse</td>
<td>Nurse; Nurse assistant; (Clinical) research nurse; Study nurse; Vaccination nurse</td>
<td>Clinical research coordinator; Study coordinator</td>
<td></td>
</tr>
<tr>
<td>Study physician</td>
<td>(Clinical) research physician; Clinical development physician; Study physician; Medical officer; Research clinician; Clinical investigator</td>
<td>Sub-investigator; Lead clinical research physician</td>
<td>(Clinical) safety physician; Pharmacovigilance physician; Public health officer</td>
</tr>
<tr>
<td>(Principal) investigator</td>
<td>Investigator (at site); Co-investigator; Medical science physician</td>
<td>Principal Investigator; Head of clinical trials; Global clinical Leader; Senior director of clinical R&amp;D; Senior global clinical pharmacologist</td>
<td></td>
</tr>
<tr>
<td>Trial manager or Project coordinator</td>
<td>(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</td>
<td>Senior research coordinator; Chief trial manager</td>
<td></td>
</tr>
<tr>
<td>Quality Control monitor</td>
<td>Clinical trial monitor; Quality assurance manager; Quality control specialist; (Clinical) Research associate (industry)</td>
<td>Lead monitor; Monitoring senior associate; Monitoring team leader; Quality assurance officer</td>
<td>Data quality controller; Safety specialist; Regulatory affairs specialist; Regulatory coordinator Senior ethic clinical trials specialist</td>
</tr>
</tbody>
</table>
Table 1

<table>
<thead>
<tr>
<th>Role</th>
<th>Junior</th>
<th>Senior</th>
<th>Expert or Specialist setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECs and IRBs</td>
<td>Ethics Committee (EC) or Institutional Review Board (IRB) member</td>
<td>EC/IRB coordinator;</td>
<td>EC/IRB vice-chair or chair</td>
</tr>
<tr>
<td></td>
<td>(permanent or lay)</td>
<td>EC/IRB vice-chair or chair</td>
<td></td>
</tr>
<tr>
<td>Sponsor</td>
<td>Not applicable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
**Figure 2 (continued)**

- **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 findings

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**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**
  - 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
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**Data staff**

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**Data flow**
- Creating and maintaining a database
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**Interaction with public & participants**
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**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

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Not Applicable
Figure 2 (continued)

<table>
<thead>
<tr>
<th>JUNIOR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3</strong></td>
</tr>
</tbody>
</table>

- Have an awareness (certification) in human subject protection
- Maintain confidentiality of participants’ records at all times, from entry to storage

<table>
<thead>
<tr>
<th>SENIOR/SPECIALIST</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5</strong></td>
</tr>
</tbody>
</table>

- 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

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**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

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**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

**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
Figure 2 (continued)

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

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**Junior**
- Have knowledge of and consistently work in accordance with Good Clinical Practice
- Maintain data and study documentation as specified in SOPs

**Senior/Specialist**
- Propose suitable means to improve the data quality management systems within the organisation
- Audit databases to validate specifications, programming and quality checks
- Monitor and evaluate the activities of staff data in your team and/or at different sites

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**Oversight**
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- Project management
- Tracking study progress

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**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

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**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
Figure 2 (continued)

**Senior/Specialist**

- Develop data agreements between contractors (e.g. external laboratories, data vendors) and the research team
- Ensure that the data and data systems meet the sponsor, funder and regulatory requirements

**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

**Ethics, Quality & Risk management**

**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

**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