

# 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<sup>1</sup>:

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

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<sup>1</sup> Inspired from the Professional Membership Scheme offered on The Global Health Network – <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.

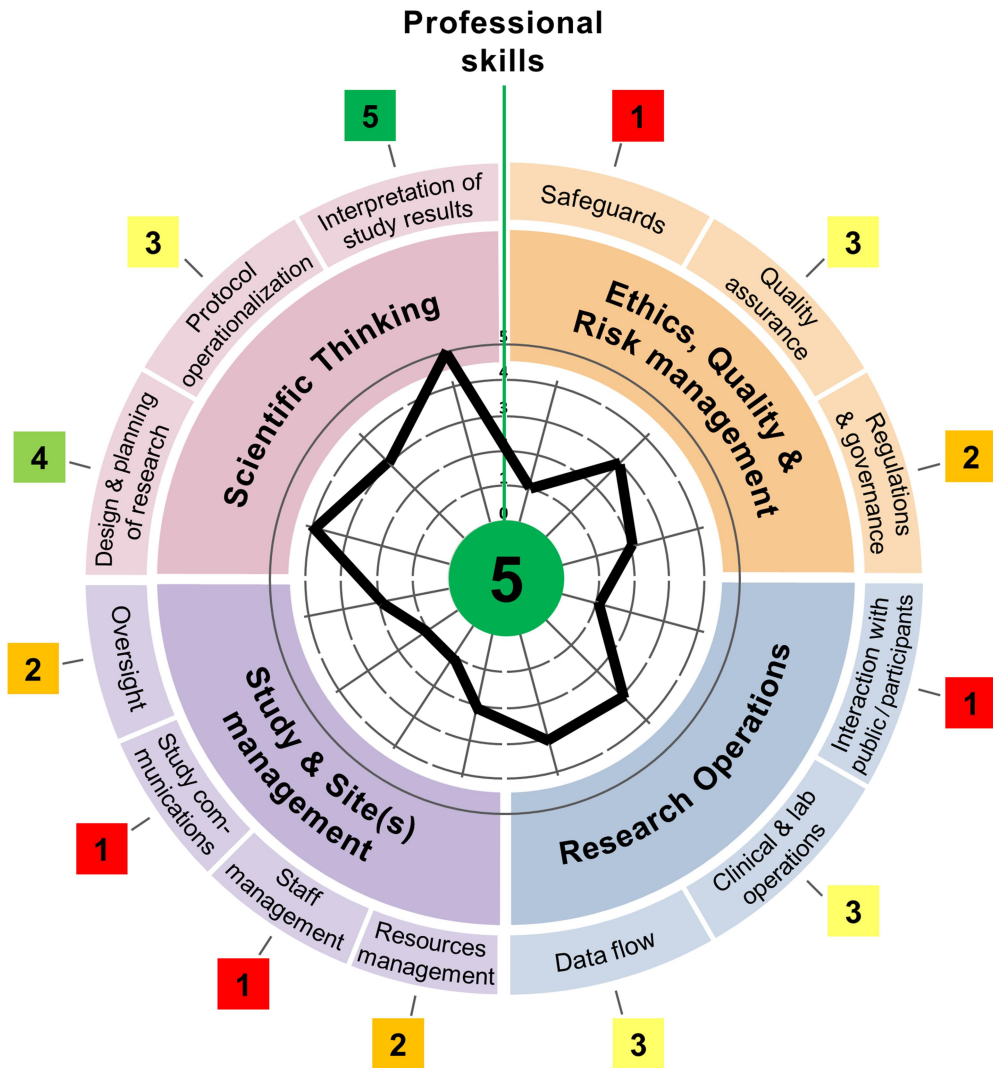
## **Grading radar chart**

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.

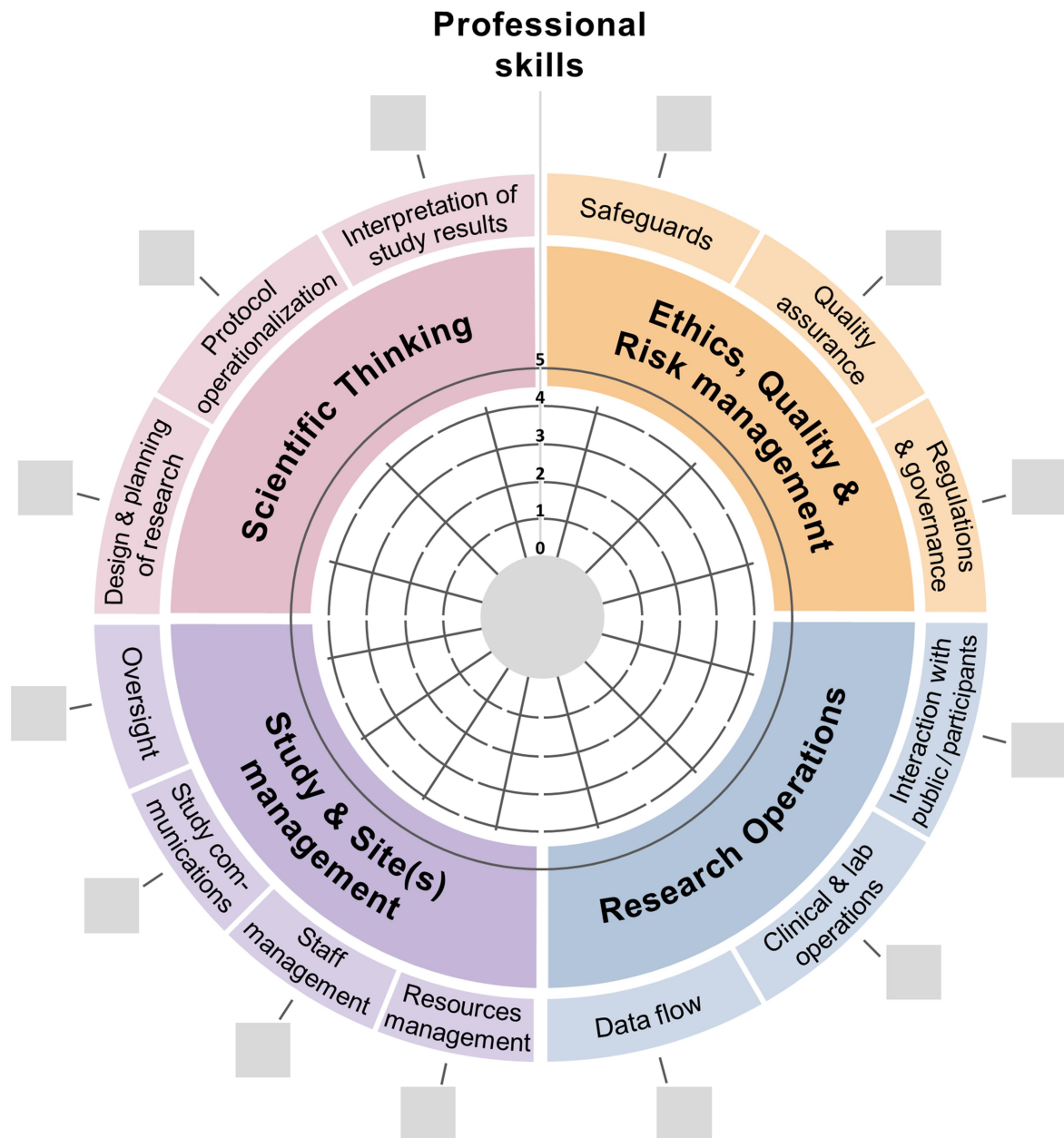
A web application is in development by The Global Health Network and TDR, which enables to record your grades online and keep track of your progress over time. We encourage you to use this online version if you can, as it provides a much more interactive interface that creates the radar picture automatically 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/>.

**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<sup>2</sup> 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.

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<sup>2</sup> Contact us at [info@theglobalhealthnetwork.org](mailto: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.

Role	Junior	Senior	Expert or Specialist setting
<b>Data staff</b>	Data clerk; Data assistant; Data entry and administration personnel	Data manager; Senior or Lead data manager	Biostatistician
<b>Laboratory scientist</b>	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
<b>Trial pharmacist</b>	Pharmacy administrator/coordinator; Trial pharmacist; Pharmaceutical technologist; Pharmacy technician	Lead pharmacist	
<b>Community engagement staff</b>	Fieldworker; Research assistant	Senior fieldworker; Field research officer; Community engagement or liaison officer; Community engagement and ethics coordinator	Counsellor
<b>Research nurse</b>	Nurse; Nurse assistant; (Clinical) research nurse; Study nurse; Vaccination nurse	Clinical research coordinator; Study coordinator	
<b>Study physician</b>	(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
<b>(Principal) investigator</b>	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	
<b>Trial manager or Project coordinator</b>	(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	
<b>Quality Control monitor</b>	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.

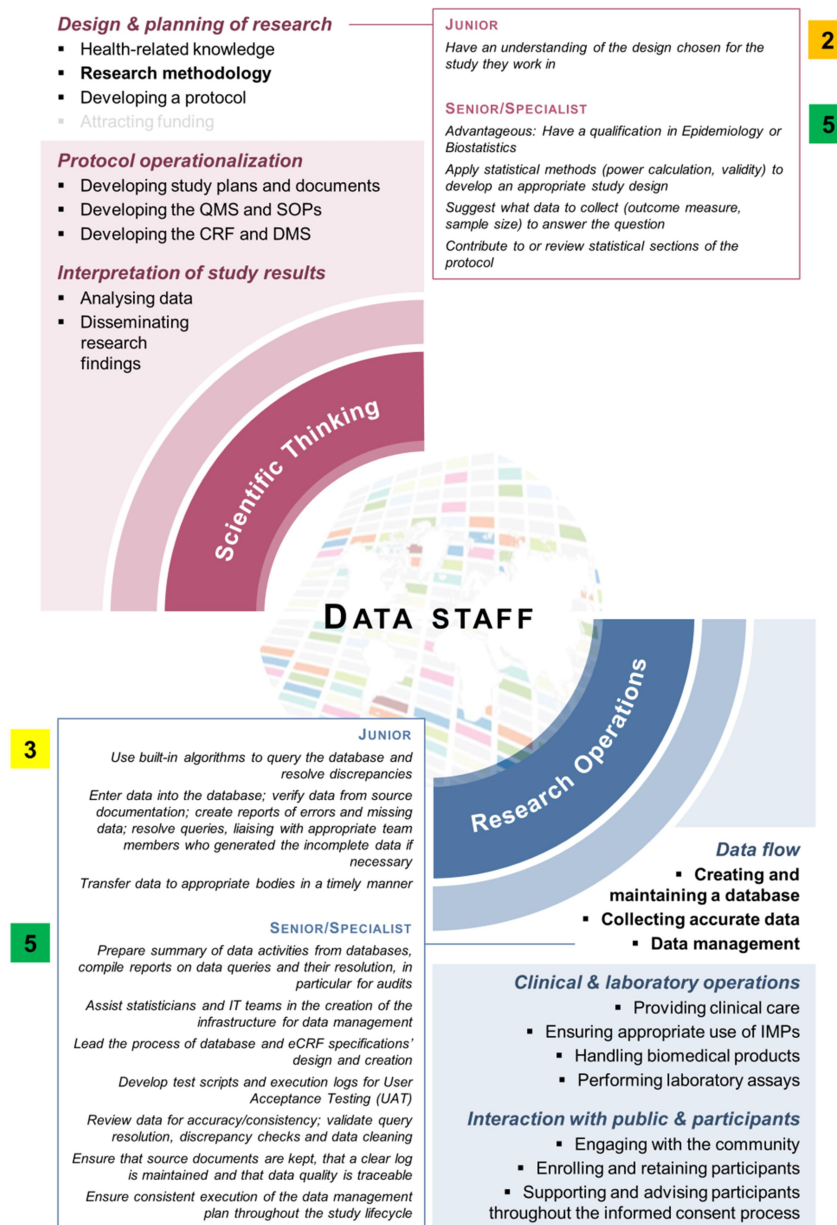




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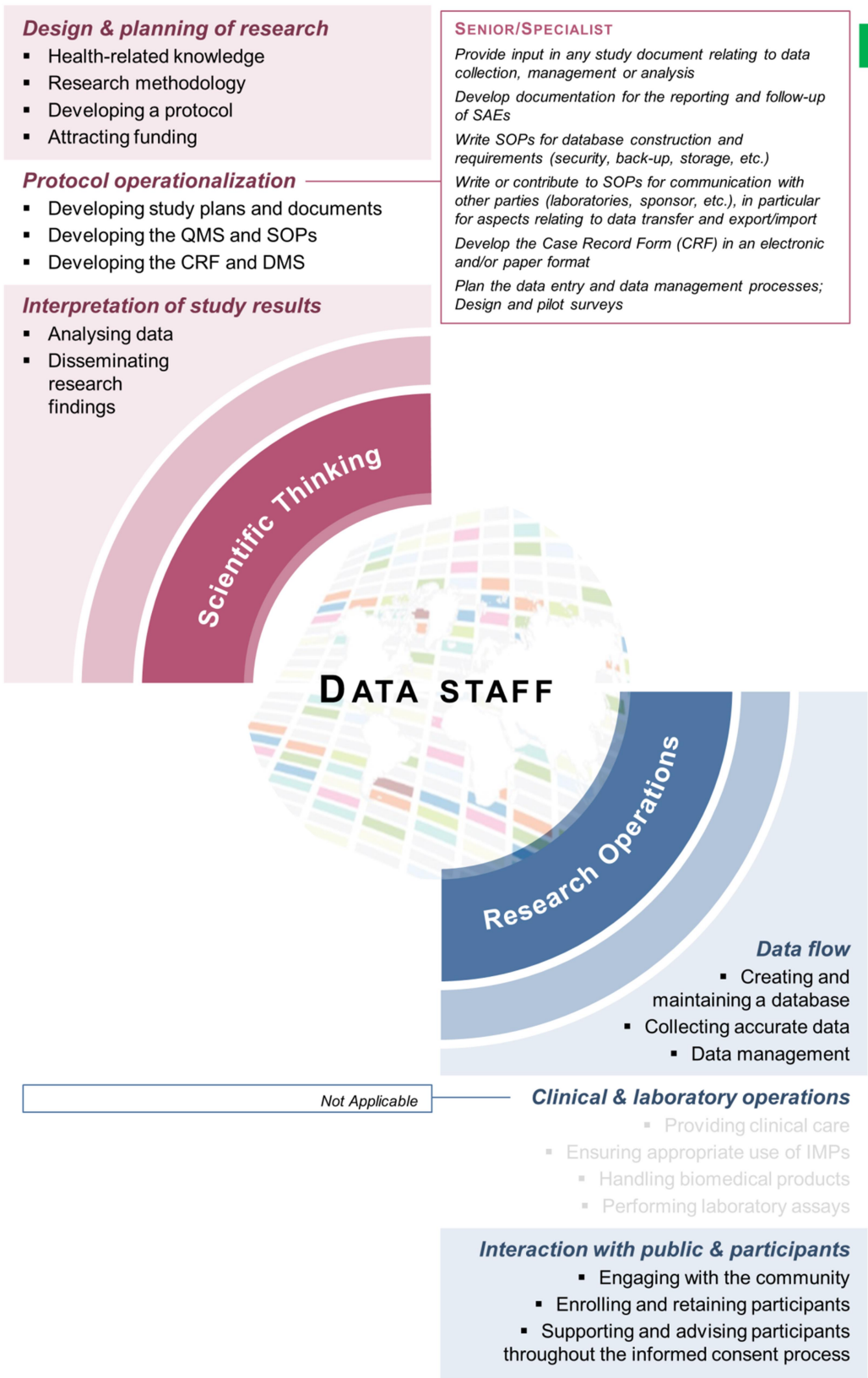


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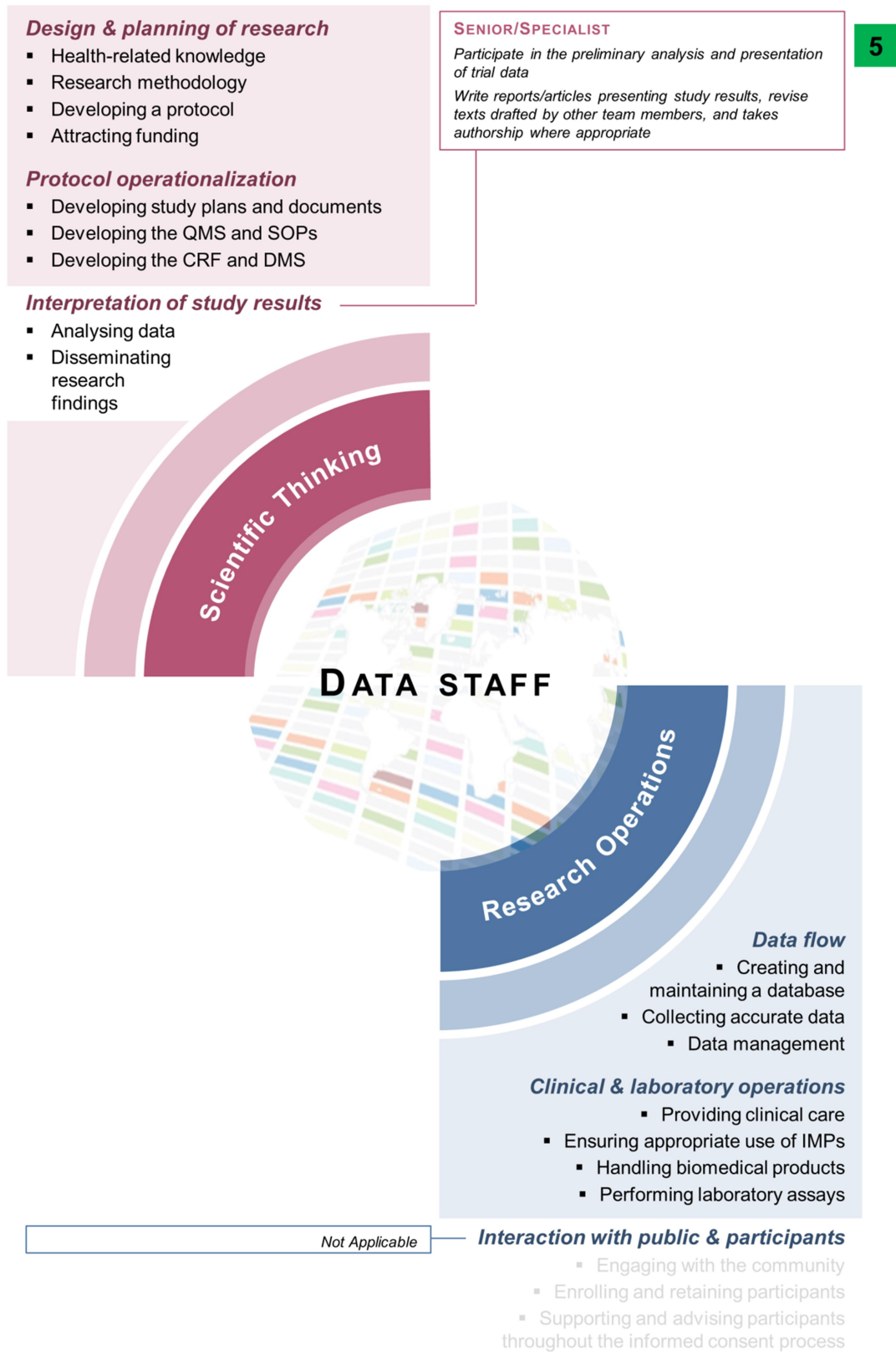


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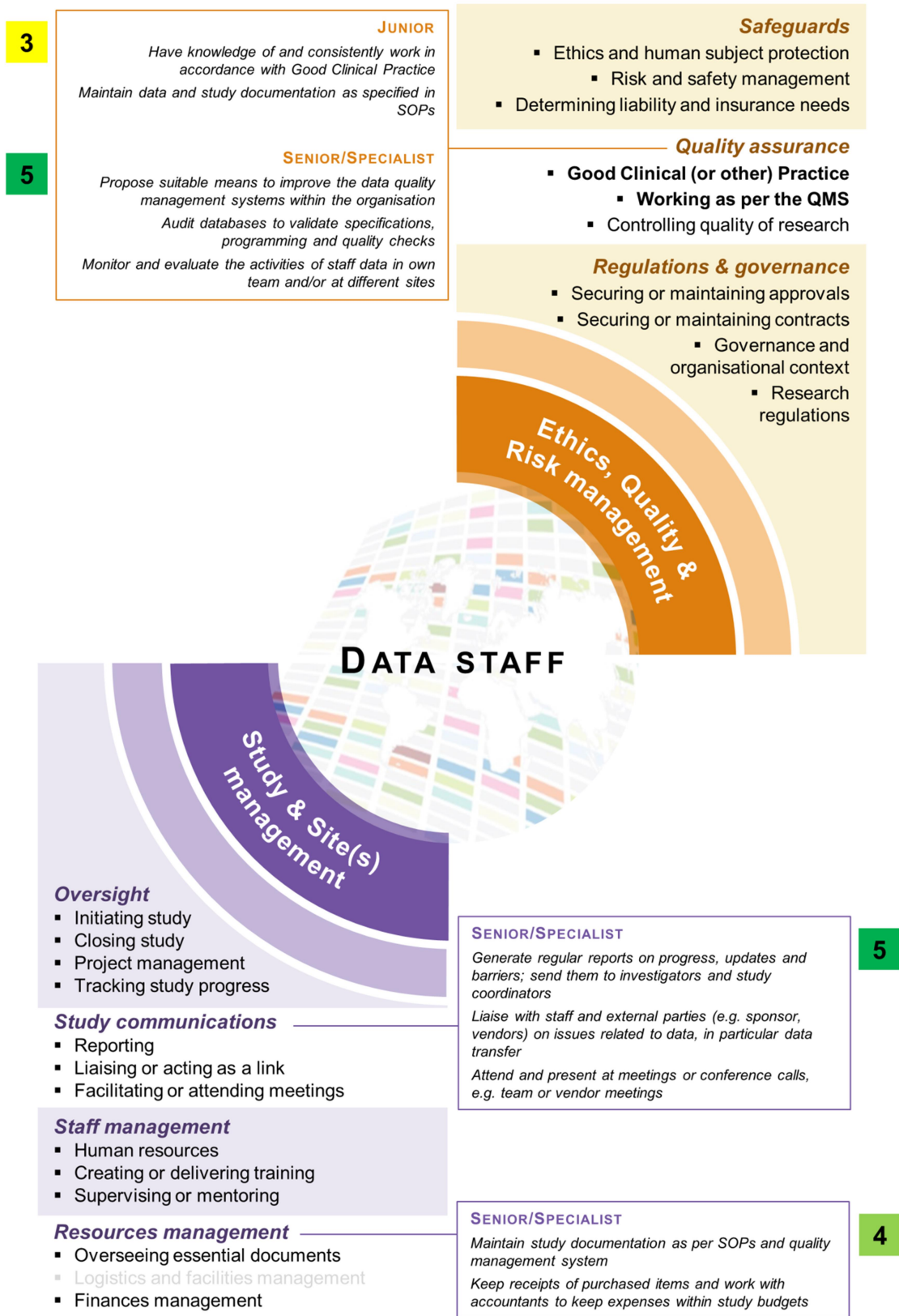


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