



Using the TDR Global Competency Framework for Clinical Research:

A set of tools to help develop
clinical researchers

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Researchers from The Global Health Network were selected to draft and test this framework. Tamzin Furtado, Amélie Julé, Liam Boggs, Francois van Loggerenberg, Victoria Ewing and Trudie Lang from The Global Health Network, University of Oxford, comprised the technical team. They identified the roles to be covered and performed a literature review to locate existing high-quality frameworks and documents outlining the responsibilities for certain clinical research roles. The information contained on the competencies and tasks required during a study was systematically categorised into themes. Initially, a few broad themes (inspired from the most generic pre-existing framework, developed by MRCT) were used to categorise the text data.

Job descriptions were then collected from global partners and from the internet, to cover a broad range of clinical study types and locations (including low- and middle-income countries). Those were analysed as described above, which led to the creation of new, more specific themes to cover all aspects of the rich data collected. The process continued until 116 job descriptions were included, alongside the 28 frameworks and guidelines. At this point, the analysts were satisfied no new theme was needed to describe the data.

All data was then re-examined for consistency of categorisation, and to create a synthesized description for each of the themes, which correspond to the competencies within the global framework. This work has since been refined by iterative expert review. In particular, it was presented at a TDR stakeholder meeting: this was the occasion for external clinical research experts to provide feedback and contribute to the current framework and tools.

The authors would like to thank the following individuals for their reviews and feedback on the framework during the workshop on the development of a global core competency framework for clinical research held at the WHO head quarter, Geneva, Switzerland on 29-30 September 2015: Barbara E. Bierer, Christian Burri, Núria Casamitjana, C. Padma Chandrasekaran, Roma Chilengi, Helen Demarest, Michäel Kaeser, David Laloo, Kamal Mansinho, Renata Mendizabal Sole de Cabrera, Wilfried Mutombo Kalonji, Jean Nachege, Raffaella Ravinetto, Morven Roberts, Nidia Rizzo, Nandi Siegfried, Nathalie Strub Wourgaft, Alfred Tiono, Jeremy Whitty. The authors would also like to thank Elizabeth Allen and Cordelia Reddy of the University of Cape Town, and Barbara Farrell of the UK Trial Managers Network, for their invaluable support and feedback in the initial stages of development.

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Abbreviations

AE	Adverse Event
CRF	Case Report Form
CRO	Contract Research Organisation
DMS	Document Management System
DSMB	Data Safety Monitoring Board
GCP	Good Clinical Practice
GCLP	Good Clinical Laboratory Practice
GXP	Good Practice guidelines and regulations
IMPs	Investigational Medicinal Products
IT	Information Technology
LMICs	Low- and Middle-Income Countries
MRCT	Multi Regional Clinical Trial Center of Harvard
R&D	Research and Development
QMS	Quality Management System
SAEs	Serious Adverse Events
SOPs	Standard Operating Procedures
SUSAR	Suspected Unexpected Serious Adverse Reaction

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Foreword

This document describes the tools that support the use of the TDR Global Competency Framework for Clinical Research. Competencies correspond to the ability to apply knowledge and skills to successfully perform an activity at work. This flexible framework lists all the competencies that should be demonstrated by the research team, to carry out a successful clinical study.

The Special Programme for Research and Training in Tropical Diseases (TDR) asked researchers from The Global Health Network based at the University of Oxford to lead the development of this framework, to bridge the lack of information about clinical research roles.

Why are they being developed? Many frameworks already exist.

Many high quality frameworks for roles within clinical research do indeed already exist, but they have several limitations that we tried to address by adopting a wide scope to development:

- Frameworks were usually developed for one single job role, and/or one location. However, teams vary considerably depending on the study, its location, and the size of the team. For example, a research nurse may specifically be involved in informed consent, sample taking and clinical care of study participants; while in another setting and smaller trials, they may commonly also take on trial coordination tasks. Therefore, it's interesting and useful to consider job roles together as a continuum rather than solely in isolation.
- Frameworks have been developed in different ways for different roles; and mostly rely on experts' opinion. Combining those viewpoints could help to standardise the information, and the resulting picture should be enriched with real-life examples of the tasks and competencies required for each role. There are also few frameworks which have been developed taking into account Low- and Middle-Income Countries (LMICs).
- Most frameworks have been designed to highlight competencies needed to run clinical trials¹, especially as performed to assess drug efficacy. This approach has some value, especially for when aiming at market approval of a drug, but it neglects other important types of clinical research such as observational studies. It is important to bridge the gap between the two, so that similarly high standards are applied to all, while researchers know when or not to abide by stringent regulations depending on the aim of their study.

¹ Glossary of Terms available at The Global Health Network: <https://globalhealthtrials.tghn.org/articles/global-health-glossary/>

What are the parts of the Competency Framework, and how does it work?

Competency wheel



The Competency Wheel shows on a single page all the 50 competencies that make the Framework, applying to the entire research team.

Competency dictionary

Competency Dictionary

Scientific thinking

Design & planning of research

Competency Health related knowledge

Task Theory knowledge based

Definition The individual has enough knowledge of a specific area related to health, either with a background in fundamental or social sciences. This knowledge enables them to understand the purpose, context and topic of a study. They have an appropriate education or experience in health sciences dependent on their role, which they are able to apply when to perform their research job assignments (e.g. to provide clinical care or deliver the intervention to participants, to set clinical research questions or to analyse quantitative and qualitative data). They maintain their understanding and knowledge of new advancements in their specific field by engaging with the professional community, i.e. by attending conferences or seminars or by reading relevant articles.

Research responsibilities Tasks based on this knowledge: Developing a protocol, Analyzing data, Disseminating research findings, Providing clinical care, Ensuring appropriate use of skills, Handling biomedical products, Performing laboratory assays

Related knowledge Research methodology

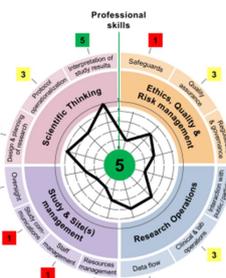
Required skills Cognitive skills, Work ethics

Keywords Degree in life sciences and related health background (including nursing and pharmacy), Medical qualifications (e.g. oncology, paediatrics, geriatrics), In-depth experience in a clinical research area (e.g. HIV/AIDS, malaria vaccines), Attending (academic) conferences and scientific writing, literature review.

The Competency Dictionary gives a full description of each competency, and its associated tasks and keywords. This should clarify what is meant by the competencies listed on the Wheel.

The Competency Wheel and Dictionary are very flexible, and can be used to determine how a team will break down responsibilities involved in a new study, or to perform analyses of gaps in resources at a site. The interactive Competency Dictionary can be found at: <https://globalhealthtrials.tghn.org/global-competency-framework-clinical-research>.

Grading system



The grading system includes a template for grading an individual's level of expertise for each area of competency; as well as a scale (0-5) to help grading consistently. Grades can be represented pictorially through the use of a radar diagram.

Role-specific frameworks

Design & planning of research

- Health related knowledge
- Research methodology
- Developing a protocol

Protocol operationalization

- Developing the CRF and SOPs
- Developing the CRF and DASH
- Interpretation of study results
- Analyzing data
- Disseminating research findings

Scientific Thinking

DATA STAFF

Research Operations

Study & trial management

- Study management
- Study communications
- Staff management
- Quality management
- Logistics and facilities management
- Finance management

Ethics, Risk Management & Compliance

- Ethics and human subject protection
- Good Clinical Practice (GCP)
- Regulatory & governance
- Insurance or warranty agencies
- Research or regulatory compliance
- Contract and organizational contract management
- Research registration

Professional skills

- Communication
- Teamwork
- Leadership
- Project management
- Time management
- Problem solving
- Decision making
- Conflict resolution
- Stress management
- Self-management
- Quality management
- Logistics and facilities management
- Finance management

Research Operations

- Collecting accurate data
- Data management
- Clinical & laboratory operations
- Ensuring appropriate use of NMPs
- Handling biomedical products
- Performing laboratory assays

Study & trial management

- Interaction with public & participants
- Engaging with the community
- Enrolling and retaining participants
- Supporting and advising participants throughout the informed consent process

[under construction] The role-specific frameworks are adapted from the generic framework for specific roles (research nurse, investigator, etc.). They contain examples of what a competency means for that particular role, and suggest a desired grade for junior/senior staff.

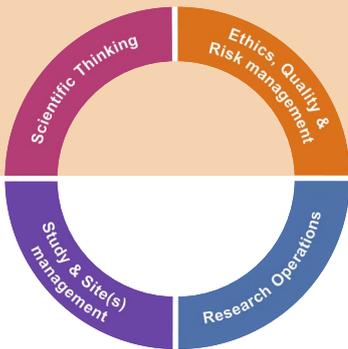
The Grading System and Role-Specific Frameworks can help while developing job descriptions, appraising staff, creating training curricula, etc.

We will keep working on making these documents more practical to use, and would like to hear from you if you have any suggestions². We have also developed a feedback form, which you can find at: <https://www.surveymonkey.co.uk/r/QH5NVZT>. We appreciate all feedback. We also developed a basic protocol for an evaluation of the framework. Please do get in touch if you would like to get involved: this could be the opportunity for a great collaboration and publication.

² Contact us at info@theglobalhealthnetwork.org

Using the TDR Global Competency Framework for Clinical Research:

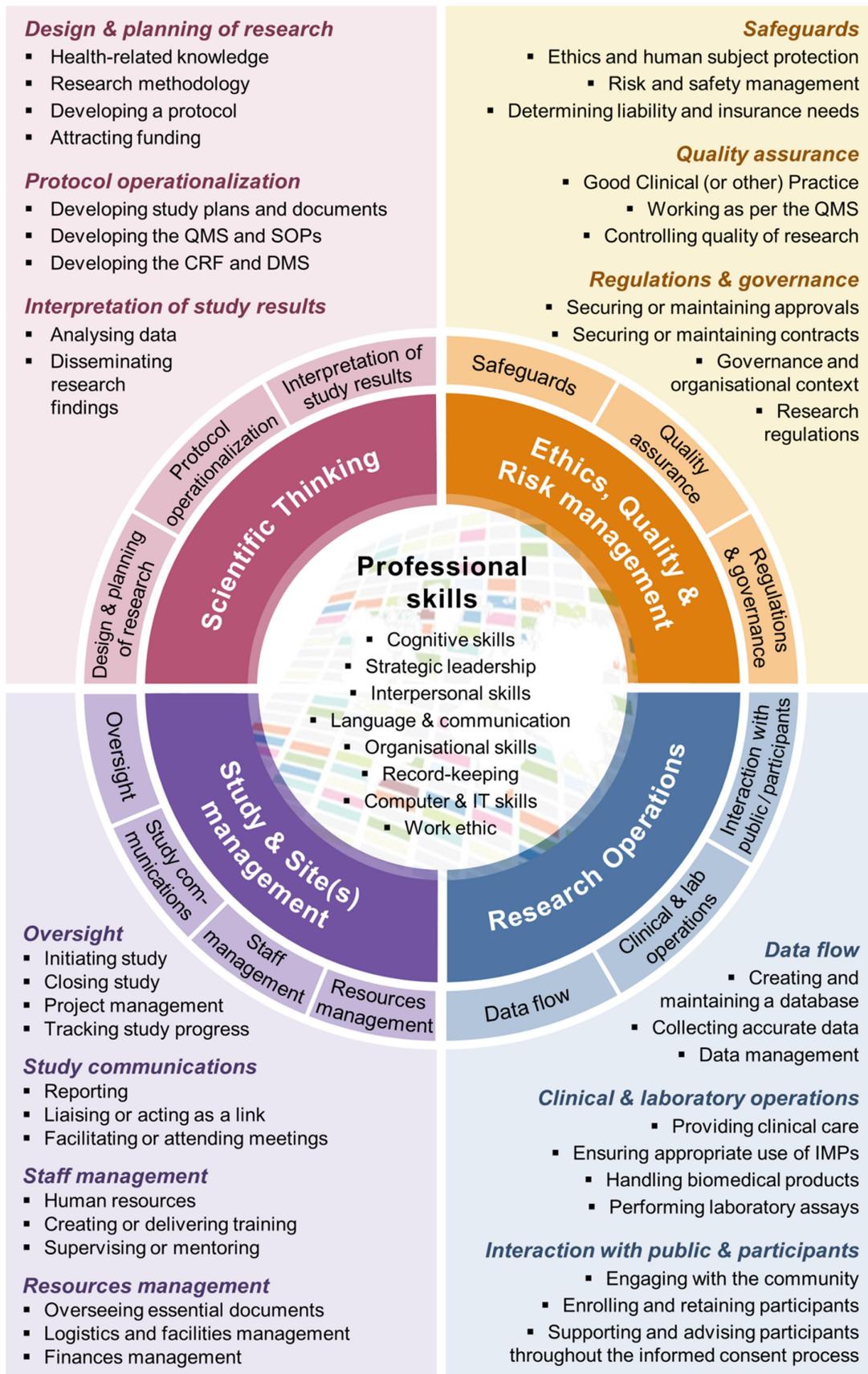
A set of tools to help develop
clinical researchers



Competency Dictionary

PART 1/3

The competency wheel: an overview of TDR Global Competency Framework for Clinical Research.



Competency dictionary

Scientific thinking

Design & planning of research

Competency	Health-related knowledge
Type	Theory (knowledge-based)
Definition	<p>The individual has enough knowledge of a specific area linked to health, either with a background in fundamental or social sciences. This knowledge enables them to understand the purpose, concept and topic of a study. They have an appropriate education or experience in health sciences dependent on their role, which they are able to apply daily to perform their research job appropriately (e.g. to provide clinical care or deliver the intervention to participants, to set clinical research questions or to analyse quantitative and qualitative data). They maintain their understanding and knowledge of new advancements in their specific field by engaging with the professional community, i.e. by attending conferences or seminars and by reading relevant articles.</p>
Related competencies	<p>Tasks based on this knowledge: Developing a protocol; Analysing data; Disseminating research findings; Providing clinical care; Ensuring appropriate use of IMPs; Handling biomedical products; Performing laboratory assays</p> <p>Similar knowledge: Research methodology</p> <p>Required skills: Cognitive skills; Work ethic</p>
Keywords	<p>Degree in life sciences and related; Health background (including nursing and pharmacy); Medical speciality (e.g. oncology, paediatrics); Epidemiology; Interest/experience in a clinical research area (e.g. HIV/AIDS, malaria vaccines); Attending (academic) conferences and scientific training; Literature review.</p>
Abilities	<ul style="list-style-type: none"> ▪ Have sufficient scientific knowledge for their role, e.g. understanding of medical terminology or HIV issues if the role warrants it ▪ Maintain up-to-date understanding in their area of expertise, e.g. pharmacology (pharmacodynamics and pharmacokinetics), epidemiology ▪ Be an expert or solid reference on health sciences for the team ▪ Contribute medical input into study designs and protocol

Competency	Research methodology
Type	Theory (knowledge-based)
Definition	<p>The individual has an understanding of the different types of research methods and study designs, the different sources of data (primary and secondary), and they recognise when each might be used. In particular, they are aware of methods that are being used in the study they are working in. They are also well aware of the processes within a clinical trial or research project and of how they differ from practice.</p> <p>Expert: Following conduction of a comprehensive literature review, the individual recognises the gaps in current knowledge and can suggest a suitable and practicable research question. They are able to turn the question into a feasible and appropriate trial design, adopting appropriate randomisation and blinding procedures. They suggest appropriate measures to answer the research question (primary and secondary outcomes, endpoints, etc.). They have a deep understanding of statistics as they relate to research design, including issues of validity, reliability and power calculations. They can suggest adaptations to the design or make appropriate allowances depending on the risk and setting of the trial, thus facilitating the research without inhibiting the validity of the results.</p>
Related competencies	<p>Tasks based on this knowledge: Developing a protocol; Developing study plans and documents; Developing the CRF and DMS; Analysing data; Initiating study</p> <p>Similar knowledge: Health-related knowledge</p>
Keywords	<p>(Systematic) literature review; Research design; Methodology; Source of data; Setting research question; Identifying gap in knowledge; Statistics (e.g. power calculations, null hypothesis); Bias; Randomisation; Blinding; Trial phase I-IV; Experience of clinical research; Endpoints; Outcome measures</p>
Abilities	<ul style="list-style-type: none"> ▪ Understand the importance of and how to access, critique and synthesize literature appropriately ▪ Be aware of/understand the elements (statistical, epidemiological and operational) of clinical and translational study design; and different stages of clinical trials <p>Expert:</p> <ul style="list-style-type: none"> ▪ Design an appropriate clinical trial, including: select a design for the research question, define outcome measures and endpoints, perform power calculations, design a randomisation and blinding system, etc. ▪ Develop cost effective risk-based strategies to run clinical research studies effectively in low-resource settings

Competency		Developing a protocol
Type	Task-based	
Definition	<p>The individual understands the different elements of a research protocol. They can write and/or review a protocol which operationalises the chosen research design appropriately for the disease and the setting in question.</p> <p>Developing the protocol (which may be for a pre-clinical, exploratory or clinical study) requires writing skills, combined with the ability to use theoretical knowledge of research methods and scientific concepts. The protocol development spans from drafting to approval, via review and then continuous updating.</p>	
Related competencies	<p>Similar tasks: Attracting funding; Developing study plans and documents; Developing the QMS and SOPs; Developing the CRF and DMS</p> <p>Knowledge base: Health-related knowledge; Research methodology; Ethics and human subject protection; Good Clinical (or other) Practice; Research regulations</p> <p>Required skills: Language and communication skills (writing); Organisational skills (planning)</p>	
Keywords	Protocol writing, review, approval; Draft; Proposal; Contribute to/coordinate protocol writing; Protocol development, amendment/updating	
Abilities	<ul style="list-style-type: none"> ▪ Be aware of the different elements that must be covered in a research protocol, including the specific requirements (e.g. regulatory, ethical) linked to the study type and/or setting ▪ Draft an appropriate protocol ▪ Contribute to relevant sections of a protocol ▪ Coordinate protocol writing and review; track inconsistencies, errors or omissions 	

Competency		Attracting funding
Type	Task-based	
Definition	<p>The individual understands the requirements of different funding sources, and can write an effective grant application which ensures maximum chances of success. Budget and resource requirements are planned thoughtfully and accurately. Attracting the necessary funding requires the individual to identify sources for funding, and to understand the current interests of donor agencies and global health stakeholders. Based on that information, the individual is able to plan a relevant study which will be attractive to the grant call, to evaluate study costs and necessary supplies, and to write effectively and in a persuasive manner.</p>	

Related competencies	<p>Similar tasks: Developing a protocol; Securing or maintaining contracts; Logistics and facilities management; Finances management</p> <p>Required skills: Strategic leadership; Language and communication skills (writing)</p>
Keywords	Grants; (Successful) funding application; Identifying funding sources; Assembling resources to run the study
Abilities	<ul style="list-style-type: none"> ▪ Have an understanding of major funding bodies, and that application requirements vary from one to another ▪ Understand the component parts of a grant application process ▪ Plan costings and resources for a grant application ▪ Independently write or contribute to grant application ▪ Seek to address funders' interests by developing original grants

Protocol operationalization

Competency		Developing study plans and documents
Type	Task-based	
Definition	<p>The individual has sufficient understanding of the protocol and research processes to make plans for, and to write documents to support the conduct of the study. They can contribute to or independently write the informed consent forms or other trial documents, as required for their role. They can design appropriate and pragmatic plans in relation to their role within the trial; for example how to project-manage the whole trial procedure, how to design the consent process and participant flow, etc.</p> <p>Developing plans and documents to support the study requires good writing skills together with a comprehensive knowledge and understanding of the study protocol, as well as of the constraints within which the study will be run (e.g. low-resource or particular cultural setting, infectious disease requiring constraining protection measures), with the ability to translate this high-level document into practical and reproducible operations.</p>	
Related competencies	<p>Similar tasks: Developing a protocol; Developing the QMS and SOPs; Developing the CRF and DMS; Initiating study; Project management</p> <p>Required skills: Language and communication skills (writing); Organisational skills (planning)</p>	

Keywords Document writing, review; Study plans; Planning; Development; Amendment/updating; Process; Systems; Programme; Process; Documentation; Manual; Tool; Investigator’s Brochure; Participant flow

- Abilities**
- Design overall operational plan for the study, e.g. project management plan
 - Design participant flow process, with visit schedules, appropriate documentation and time-points for sample taking, etc.
 - Design study processes related to ethics, such as community sensitisation plans, participant information leaflets, recruitment strategies and informed consent form
 - Design practical communication plans to circulate information within trial staff and to key stakeholders, e.g. participants groups
 - Coordinate/contribute to the writing of study documents, such as information leaflets for participants

Competency **Developing the quality management system (QMS) and standard operating procedures (SOPs)**

Type Task-based

Definition

The individual has sufficient understanding of the protocol, of the practicalities of its execution and of the risks associated to the study to design a quality management system and risk-mitigation strategies. They develop a quality assurance plan in accordance with Good Clinical Practice guidelines in order to deliver the best-quality science and study. They understand how to take account of pre-study assessments (feasibility, risk and site assessment) to develop study-specific quality management plans. The QMS should include plans for audits at different sites and contractor organisations, if applicable.

The individual also understands the structure and requirements that SOPs must fulfil, and knows how to write detailed, clear and pragmatic guidelines that will enable replicable performance of study activities between individuals, between sites, etc., thus enabling consistent execution of the QMS plan. Developing SOPs to operationalize study plans requires good writing skills together with detailed knowledge of the requirements of the organisation within which the individual is working and the standards it requires.

Related competencies

Similar tasks: Developing a protocol; Developing study plans and documents; Developing the CRF and DMS; Risk and safety management; Determining liability and insurance needs; Working as per the QMS; Controlling quality of research; Initiating study; Project management

Knowledge base: Good Clinical (and other) Practice; Governance and organisational context; Research regulations

Required skills: Organisational skills (planning); Language and communication skills (writing)

Keywords Document writing, review; Study plans; Planning; Development; Quality management, assurance, control; Risk (mitigation); SOP; Standard/standardized; Writing; Developing; Guidelines; Procedures/protocols; Manual of operations; Compliant

- Abilities**
- Develop quality management systems for the whole study, and for specific sites, laboratories or pharmacies, where appropriate
 - Develop and write procedures for quality assurance, e.g. how to track participants' information and check the accuracy of collected data without breaking confidentiality rules
 - Develop and write procedures to control compliance to protocol and SOPs on a daily basis and throughout the study
 - Design risk management and safety plans, e.g. adverse event reporting systems, safety management plans, etc.
 - Coordinate/contribute to the writing or drafting of SOPs
 - Write SOPs that are both GCP and regulations compliant
 - Develop guidelines to ensure study procedures will be consistently applied and adhered to
 - Plan and translate the quality management system into pragmatic SOPs

Competency Developing the case report form(s) (CRF) and data management system (DMS)	
Type	Task-based
Definition	The individual has sufficient understanding of the study and of data management constraints to suggest practical means for data capture and to write documents to collect study data. In particular, they design a suitable Case Report Form (CRF) and/or questionnaires, taking account of the outcomes to measure, of the study endpoints, etc. They also develop plans for the overall data management process, including methods for reporting and monitoring the safety data. They must ensure the CRF and planned data management system (DMS) will enable acquisition of appropriate and high quality data in order to answer the research question.
Related competencies	<p>Similar tasks: Developing a protocol; Developing study plans and documents; Developing the QMS and SOPs; Controlling quality of research; Creating and maintaining a database; Data management</p> <p>Knowledge base: Health-related knowledge; Research methodology</p> <p>Required skills: Language and communication skills (writing); Computer and IT skills</p>
Keywords	CRFs; Data Management Systems; Data Management Plan; Outcome measures; Endpoints; Source documentation form

Abilities

- Coordinate/contribute to the writing of CRFs or source documentation forms
- Develop health questionnaires
- Design a data management plan for the study
- Contribute to quality management systems for the study as they apply to data processes, such as monitoring of safety data and checking database requirements
- Investigate potential data management systems for the study

Interpretation of study results

Competency		Analysing data
Type	Task-based	
Definition	<p>The individual can extract and analyse quantitative data using appropriate software, applying their knowledge of biostatistics, trial design and medicine to draw valid conclusions from the data and outline limitations. The analysis stage may involve some modifications of the data (e.g. creating graphs, calculating rates) to clearly present results. The individual is able to perform statistical monitoring and interim analyses if required, including to validate the data.</p> <p>Data may also be qualitative, in which case the individual uses different software if necessary, and applies different knowledge related to social sciences methods to perform the analysis and draw accurate conclusions.</p> <p>Data analysis and interpretation requires analytical thinking and IT skills of the relevant software.</p>	
Related competencies	<p>Similar tasks: Disseminating research findings; Reporting; Collecting accurate data</p> <p>Knowledge base: Health-related knowledge; Research methodology</p> <p>Required skills: Cognitive skills (analytical skills); Computer and IT skills</p>	
Keywords	Statistics; Analysis; Interpretation	
Abilities	<ul style="list-style-type: none">▪ Extract data from database and conduct data analyses using statistical software packages; e.g. compute rate, ratio and percent, interpret bar graphs▪ Identify and articulate whether or not any conclusions drawn from analyses of data are valid and based on the material provided▪ Perform statistical monitoring of data and interim analyses▪ Interpret efficacy and safety data from clinical trials	

Specialist setting:

- Apply modelling and simulation knowledge using quantitative data and appropriate technology

Competency		Disseminating research findings
Type	Task-based	
Definition	<p>The individual is aware of the importance of reporting the results of research, and of the various dissemination formats available for different audiences. They can clearly communicate results in writing and speaking, in a manner suitable for the audience. They take appropriate steps to feed results back to the local community, and are able to prepare lay summaries for research participants and the public. They are able to submit an abstract for a conference, and subsequently prepare a suitable poster or oral presentation (or assist others to do so). They understand the component parts of a scientific publication or final report, and can draft, coordinate and write one confidently.</p> <p>Language and communication skills are of primary importance to disseminate findings, as is the ability to synthesise complex information to explain to others. The task may require coordination and managerial skills when the first author or leader is expected to collect contributions from various parties in their team.</p>	
Related competencies	<p>Similar tasks: Analysing data; Closing study; Reporting; Facilitating or attending meetings</p> <p>Knowledge base: Health-related knowledge; Research methodology</p> <p>Required skills: Cognitive skills; Language and communication skills; Organisational skills</p>	
Keywords	Scientific publication; Paper; Presenting at conferences; Disseminating/communicating results	
Abilities	<ul style="list-style-type: none"> ▪ Coordinate/contribute to/write a publication or final report ▪ Be aware of the differing requirements and formats of journals ▪ Be aware of the concept of plagiarism and of requirements for citations of others' work ▪ Write and submit abstracts to conferences or journals ▪ Assist in the preparation of and/or deliver oral or poster presentations at conferences/meetings ▪ Write, agree and work to a publication policy or dissemination plan ▪ Develop communication and awareness programmes for results 	

Ethics, quality and risk management

Safeguards

Competency		Ethics and human subject protection
Type	Theory (knowledge-based)	
Definition	<p>The individual understands how to apply ethical theory in the context of clinical research design and operations. They understand the rationale and value of research, but can also balance its harms and benefits by taking into account participants' interests. They are able to provide sound and poised review of the likely risks and benefits of a study to the participant, and to adapt this review based on the specific community and setting. They should particularly keep in mind populations which might be vulnerable in different ways, including children, populations living in low-resource settings or experiencing an emergency situation.</p> <p>On a daily basis, research staff and clinical professional must apply ethics and ensure that the confidentiality and privacy of the participant is respected at all times.</p>	
Related competencies	<p>Tasks using this knowledge: Developing a protocol; Risk and safety management; Engaging with the community; Enrolling and retaining participants; Supporting and advising participants throughout the informed consent process</p> <p>Similar knowledge: Good Clinical (or other) Practice; Research regulations</p>	
Keywords	<p>Ethics; History of research; Cultural (variations); Moral (conflicts); Value of research; Balance harms/benefits; Participants' perspectives; Human subject protection; Participants rights, well-being, dignity; Confidentiality; Integrity</p>	
Abilities	<ul style="list-style-type: none"> ▪ Describe and understand the history and evolution of the principles of ethical theory and the key documents related to human subjects in research ▪ Ensure that the research is necessary; take a balanced view of the likely harms and benefits of a research project on the subject ▪ Understand the need for ethical approval to be obtained before research activities are initiated ▪ Ensure that payments or compensations for subjects for taking part do not constitute a coercion or undue influence ▪ Demonstrate high integrity, and consistently respect and ensure confidentiality and privacy of research participants 	

Specialist setting (for vulnerable populations or emergency research during disease outbreaks):

- Conduct Rapid Ethical Appraisal if appropriate to weigh up the specific benefits and risks to a specific community, which may differ from place to place

Competency		Risk and safety management
Type	Task-based	
Definition	<p>The individual understands the breadth of safety and risk issues that participants may face within a trial, and knows how to mitigate them. They fully understand the importance of relevant and timely reports during any type of safety breach, as well as standard safety reporting such as data safety monitoring (DSMB) report writing. They know how to handle adverse events putting participants at risk, including how to break the masking code in an emergency situation and how to ensure that participants will be provided care timely and accordingly. More broadly, the individual understands and manages risk throughout the study, and knows when to suggest actions to amend the study in view of current information and associated uncertainty and risk.</p>	
Related competencies	<p>Similar tasks: Developing study plans and documents; Analysing data; Controlling quality of research; Collecting accurate data; Providing clinical care; Ensuring appropriate use of IMPs; Reporting</p> <p>Knowledge base: Research methodology (randomisation and blinding); Good Clinical (and other) Practice</p> <p>Required skills: Cognitive skills</p>	
Keywords	<p>Safety; Safety management; Adverse Events (AE); AE reporting; Risk management; AE management; Track AE; Unblinding/emergency code-breaking; Laboratory safety; Use of protective equipment; Hazard; Notification of trial change to reduce harm; Arrangement against long-term harm</p>	
Abilities	<ul style="list-style-type: none"> ▪ Describe the various methods by which safety issues are identified and managed during clinical research; understand different types of AEs (SAEs, SUSAR, etc.), AE management and reporting ▪ Set up Data Safety Monitoring Board (DSMB); write charter for Data Safety monitoring; write and submit report for DSMBs when applicable ▪ Coordinate unblinding and other emergency procedures when necessary ▪ Be responsible for risk mitigation strategies, associated action plan and issue resolution ▪ Understand that the protocol must be complied with, except to eliminate immediate hazards and in exceptional circumstances ▪ Immediately report protocol deviations or changes increasing risk to subjects 	

Competency		Determining liability and insurance needs
Type	Task-based	
Definition	The individual understands the requirements for liability and insurance which may be required for different types of research studies, and knows the responsibilities of those involved (sponsor, investigator, funder), whether the study is commercial or non-commercial. They are able to plan and ensure appropriate cover for research projects, and report accordingly if claims are required.	
Related competencies	<p>Similar tasks: Risk and safety management; Securing or maintaining contracts; Initiating study; Reporting.</p> <p>Knowledge base: Governance and organisational context; Research regulations.</p>	
Keywords	Liability, insurance, indemnity, sponsor	
Abilities	<ul style="list-style-type: none"> ▪ Understand when insurance is required for clinical research ▪ Understand the roles and responsibilities involved in planning appropriate liability/insurance cover ▪ Secure appropriate insurance/liability for a study ▪ Can report accordingly if a claim is required 	

Quality assurance

Competency		Good Clinical (or other) Practice
Type	Theory (knowledge-based)	
Definition	The individual knows and understands the GCP guidelines (both from the International Conference on Harmonization and their local/national adaptations). They understand the importance of human subject protection in clinical research, and how application of the relevant GxPs seeks to ensure human subject protection and quality of research. They understand the necessity of applying GxPs (e.g. Good Clinical Practice, Good Pharmaceutical Practice, Good Laboratory Practice) to their work, and how to achieve this practically. They are careful to ensure participant confidentiality throughout the research process.	

Related competencies	<p>Tasks using this knowledge: Developing the QMS and SOPs; Risk and safety management; Working as per the QMS; Controlling quality of research</p> <p>Similar knowledge: Ethics and human subject protection; Research regulations</p>
Keywords	GXP: Good Clinical Practice; Good Clinical Laboratory Practice; Good Manufacturing Practice
Abilities	<ul style="list-style-type: none"> ▪ Understand the requirements for human subject protection under relevant national and international regulations ▪ Has a thorough knowledge of the principles of GXP as it applies to their work (e.g. GCLP if they work in a laboratory) ▪ Ensure the study is run in compliance with the guidelines of Good Clinical Practice of the International Conference on Harmonization

Competency Working as per quality management systems	
Type	Task-based
Definition	<p>The individual understands the importance of compliance with the protocol and study procedures to ensure quality of research; and acts accordingly on a daily basis. This task requires a thorough knowledge of the protocol, SOPs and quality management system. The individual should seek to attend protocol-specific training to enhance their understanding of the study. They understand how to apply the protocol knowledge and SOP guidelines to their day to day work, and how to report concerns such as protocol non-compliance. They ensure that there is a full set of up-to-date SOPs at their workplace, and coordinate the review and distribution of these documents when required.</p>
Related competencies	<p>Similar tasks: Developing the QMS and SOPs; Controlling quality of research</p> <p>Knowledge base: Good Clinical (or other) Practice; Research regulations</p> <p>Skills required: Cognitive skills (attention to detail); Record-keeping</p>
Keywords	Compliance to protocol, SOPs; Quality assurance; Quality management
Abilities	<ul style="list-style-type: none"> ▪ Understand the importance of compliance with the protocol and study procedures/SOPs to ensure quality of research ▪ Ensure compliance with protocol and study procedures during day-to-day work, and raise concerns where appropriate when breaches are noticed ▪ Have a thorough knowledge of the specific protocol in question ▪ Ensure up-to-date SOPs are used at sites and coordinate review of these documents ▪ Maintain controlled reading and distribution lists for SOPs

Competency		Controlling quality of research (monitoring)
Type	Task	
Definition	<p>The individual understands the importance for quality control in research, and that monitoring is a tool to achieve this. They can take part in monitoring visits at sites, assisting others to resolve any discrepancies found. They understand the importance of documentation and record keeping, and as such keep clear reports of monitoring activities, findings and resolutions. They are able to plan a monitoring or quality control strategy, and coordinate the operationalising of it – which involves diverse activities such as checking source documentation or performing sites visits.</p> <p>Every individual involved in the daily activities of a study should ensure quality of research by consistently applying GxPs, complying with the protocol and to regulations, etc. Monitors will further ensure quality of research by performing audits.</p>	
Related competencies	<p>Similar tasks: Developing the QMS and SOPs; Risk and safety management; Working as per the QMS; Reporting; Overseeing essential documents; Collecting accurate data</p> <p>Knowledge base: Good Clinical (or other) Practice; Research regulations</p> <p>Required skills: Cognitive skills (attention to detail, problem-solving); Record-keeping</p>	
Keywords	<p>Quality assurance; Audits; Study visits (conduct and schedule); Consistency between site; Quality management/systems; Monitoring; Trouble-shooting; Resolve queries; Make recommendations; Solve issues; Data/documentation accurate/up-to-date/available for audit; Identify errors; Facilitate monitoring; Develop monitoring strategy; Monitoring reports; Review of research</p>	
Abilities	<ul style="list-style-type: none"> ▪ Understand that the purpose of monitoring/audit is to improve the quality of conduct of the study, and its integrity, consistency, timeliness, accuracy ▪ Promote self-regulation of academic clinical trials by conducting research on research, implementing internal quality management system and conducting audits ▪ Plan/Coordinate risk-based monitoring strategies, ensuring consistency across study sites ▪ Conduct study visit activities and on-site monitoring and ensure accuracy and completeness of source documents, case report forms, trial master file and other study related documents ▪ Identify errors and helps individuals resolve their issues in different ways depending on the situation ▪ Review others' monitoring reports ▪ Conduct central monitoring ▪ Ensure data and documentation is complete, up-to-date, and appropriately filed and ready for inspection if required 	

Regulations and governance

Competency		Securing or maintaining approvals
Type	Task-based	
Definition	<p>Trial staff should understand the relevant submissions required (trial registry, regulatory, ethics, and any others such as national or local requirements), and contribute to or write the submissions. The individual coordinates and maintains the required submissions and provides appropriate updates, for example in the case of protocol amendments or for annual reporting purposes. Those in charge of maintaining approvals must be aware of the regulations that apply to trials and know how to submit applications to regulatory bodies.</p> <p>Reviewing authorities should ensure submission dossiers are complete and should provide an appropriate and timely review of those dossiers. They must keep written records of their decisions and respond clearly to investigators regarding those decisions.</p>	
Related competencies	<p>Similar tasks: Determining liability and insure needs; Securing and maintaining contracts; Reporting; Liaising or acting as a link; Overseeing essential documents</p> <p>Knowledge base: Research regulations</p> <p>Required skills: Language and communication skills (writing); Record-keeping</p>	
Keywords	Submitting; Approvals (Ethics, Institutional Review Boards); Amendment; Maintaining; Registration	
Abilities	<ul style="list-style-type: none"> ▪ Understand application process for ethical/regulatory approvals ▪ Coordinate/write submission for ethics or regulatory approval ▪ Submit to trial registry ▪ Submit protocol amendments to relevant authorities ▪ Understand the importance of maintaining ongoing approval throughout study and the requirements for this, e.g. annual reports ▪ Understand other relevant approvals, e.g. local R&D department, marketing applications, local health authority permissions required <p>Reviewing authorities:</p> <ul style="list-style-type: none"> ▪ Provide timely review and approval of relevant documents, e.g. approval of protocol or protocol amendments ▪ Ensure that the right submission dossier documents or associated queries have been promptly sent 	

Competency		Securing or maintaining contracts
Type	Task-based	
Definition	<p>The individual understands the importance of, and manages, binding agreements and contracts. These could be with individuals or with sites or subcontractors. The individual ensures that all the relevant contracts are agreed and that they are signed, stored, and updated appropriately. Securing contracts requires good negotiation skills and a thorough understanding of responsibilities and liability within the clinical trial team. The individual should also be able to assess vendors and/or suppliers based on their claimed qualifications, experience, accreditation, etc. Contracts should define the distribution of roles, responsibilities and accountability within the contractors, and define the governance processes that apply.</p> <p>Sponsor specific: Sponsors should consider legacy after trial closure (e.g. issues relating to access to drug for a wider public, including participants outside the trial).</p>	
Related competencies	<p>Similar tasks: Determining liability and insurance needs; Securing or maintaining approvals; Initiating study; Liaising or acting as a link; Overseeing essential documents</p> <p>Knowledge base: Governance and organisational context; Research regulations</p> <p>Required skills: Interpersonal skills (negotiation); Record-keeping</p>	
Keywords	<p>Contract; Agreement; Initiating, reviewing, negotiating, securing agreements; Signing; Legacy; Division/delegation of responsibilities; Arrangements; Duty transfer; Liability; Accountability</p>	
Abilities	<ul style="list-style-type: none"> ▪ Manage contracts, including (but not limited to): investigator contracts, sponsor/site agreement, site agreements, agreement with CRO or subcontractors, data access and transfer agreements in compliance with confidentiality requirements, compensation in the event of harm ▪ Manage contracts, ensure they are signed appropriately, track deadlines for renewal and ensure timely update, etc. ▪ Read and review contracts to ensure they are comprehensive ▪ Ensure contract and documentation of specified responsibilities that are subcontracted (e.g. to a CRO) 	

Competency		Governance and organisational context
Type	Theory (knowledge-based)	
Definition	<p>The individual has an understanding of the roles and responsibilities of staff within relevant organisations, both in terms of practical application to their day-to-day role and of governance. The individual understands the roles and responsibilities of organisations involved in the trial (e.g. sponsor, regulatory authorities, contract research organisation, other sites), how organisations relate to groups involved in a trial, and understand how their own site/group fits into this framework.</p> <p>They understand their own roles and responsibilities and how their job fits into the overall research project, who they must report to, and when delegations are required. They also understand where the research study fits within the wider scientific aims of their organisation and what plans should be put in place for the future distribution of the product would it be proven safe and effective. They ensure that others in the team understand their own roles and responsibilities, and work within this remit.</p>	
Related competencies	<p>Tasks and skills using this knowledge: Determining liability and insurance needs; Securing or maintaining approvals; Securing or maintaining contracts; Human resources; Liaising or acting as a link; Strategic leadership</p> <p>Similar knowledge: Research regulations</p>	
Keywords	Structure; Function; Roles; Governance; Policies; How organisations work/are run; Work environment; Membership; Composition; Authority; (Delegation of) responsibilities	
Abilities	<ul style="list-style-type: none"> ▪ Be aware of the structure, roles and functions of regulatory and ethics review boards, sponsor, institutional and other organisations relevant to their research project (e.g. CRO) ▪ Understand the roles and responsibilities of key personnel within the research project, and how their own role fits in with this ▪ Consistently work within own role; adhere to the roles/responsibilities documents ▪ Contribute to the development of governance systems and documentation within the organisation <p>Specialist setting:</p> <ul style="list-style-type: none"> ▪ Understand how roles and responsibilities might differ in academia or not-for-profit research as opposed to industry 	

Competency		Research regulations
Type	Theory (knowledge-based)	
Definition	<p>The individual has an understanding of the relevant guidelines relevant to their work, whether local policies, international guidelines or regulatory authorities requirements; and applies them to their work. They report appropriately, especially in the case of breach of abidance, and work with the authorities when required such as during audits. They understand fraud and misconduct during research and seek to address them.</p> <p>All staff should consistently abide by regulations, and some hold particular responsibility to check that the study meets regulatory requirements, local policies, and applicable international guidelines.</p>	
Related competencies	<p>Tasks using this knowledge: Developing study plans and documents; Controlling quality of research; Securing or maintaining approvals; Securing or maintaining contracts</p> <p>Similar knowledge: Governance & organisational context</p>	
Keywords	<p>Regulation/regulatory; Law; Guidance; Marketing authorization; Drugs regulation; Policy; Political context; Procedures; Legislation; Guidelines; Compliance to (regulations); Funder/sponsor requirements</p>	
Abilities	<ul style="list-style-type: none"> ▪ Understand the processes and phases necessary for approval of a drug or other investigational medical product (diagnostic, device, gene therapy, etc.) through the different stages in a trial ▪ Keep up-to-date with relevant international, national, and local laws, policies and guidelines relating to clinical research (including ethical ones) ▪ Understand the laws relating to the use of animals in research, if applicable ▪ Be responsible for the study meeting regulatory requirements, local policies, and applicable international guidelines ▪ Have an understanding of fraud and misconduct in clinical research and raises concerns appropriately ▪ Ensure compliance with relevant guidelines, e.g. database, labelling, reporting of AEs and SUSARS, protocol amendments, etc. ▪ Work with regulatory authorities, e.g. during audits or when submitting reports <p>Expert:</p> <ul style="list-style-type: none"> ▪ Review and assess clinical trial regulatory documents 	

Study & site(s) management

Oversight

Competency		Initiating study
Type	Task-based	
Definition	<p>The individual can plan the practical aspects of starting the study based on the protocol, including conducting early feasibility and risk assessment. They prepare study teams, including setting up and managing oversight committees, and they negotiate start dates and milestones with all parties. They conduct site selection activities, and understand the needs of the chosen sites to address before study start, for example recognising the need for specific training or equipment. They run launch meeting and site initiation meetings, and ensure that the sites have the relevant information and documentation, such as the investigator’s brochure (IB) and site specific information (SSI). Individuals managing study initiation should have a good knowledge of the planned study operations so as to be able to execute them appropriately from start, and a thorough understanding of the protocol.</p>	
Related competencies	<p>Similar tasks: Developing a protocol; Developing study plans and documents; Developing the QMS and SOPs; Working as per the QMS; Securing and maintaining approvals; Securing and maintaining contracts; Project management; Human resources; Overseeing essential documents; Logistics and facilities management; Engaging with the community</p> <p>Required skills: Strategic leadership; Interpersonal skills (negotiation); Organisational skills</p>	
Keywords	<p>Set-up (site, steering committees); Start-up; Site initiation; Risk assessment; Feasibility; Selection (site, investigator); Preparing/preparedness; Kick-off; Launch; Piloting</p>	
Abilities	<ul style="list-style-type: none"> ▪ Review protocols and conduct feasibility planning, risk assessments ▪ Recruit study teams, Quality Control teams, and oversight committees such as steering committee ▪ Plan and coordinate study initiation process (initial requirements in infrastructure and facilities, supplies, staff, training, etc.), in particular laboratory and pharmacy start-up activities ▪ Conduct site and investigator selection: identify, visit and recruit suitable sites, identifying training and technical assistance needs ▪ Test, document and pilot risk and mitigation strategies, such as code breaking procedure in emergencies (piloting) 	

Competency		Closing study
Type	Task-based	
Definition	<p>The individual is able to perform study close-out activities such as site close-out visits, and reconciliation of study supplies at the end of the study. They write and coordinate relevant notifications (e.g. to institutions, regulatory authorities). They have an understanding of the requirements of the sponsor, regulatory bodies, GCP and any other applicable standards for archive of trial data and documents, and make relevant arrangements. They arrange for database lock at an appropriate time-point. Performing study closure requires good knowledge of the relevant guidelines and good project management and reporting skills.</p>	
Related competencies	<p>Similar tasks: Disseminating study findings; Controlling quality of research (monitoring); Securing and maintaining approvals; Project management; Reporting; Overseeing essential documents; Data management</p> <p>Knowledge base: Research regulations; Good Clinical (or other) Practice</p> <p>Required skills: Organisational skills</p>	
Keywords	Archiving; Storage; Study completion; Study close-out/closure; Database lock	
Abilities	<ul style="list-style-type: none"> ▪ Perform study close out visits at sites, and audit as required ▪ Plan and coordinate data and source document archive for specified time period ▪ Maintain study documents archive inventory, and make arrangements for (selected) access to files after close-out ▪ Ensure unused trial supplies are accounted for, and appropriate disposal of trial materials once research is completed ▪ Send notifications of closures: inform and submit relevant reports to official bodies (regulatory authorities, EC, etc.) and to other people involved with the study (investigators, institution, trial subjects, etc.) ▪ Ensure and oversee close-out activities in case of premature termination of trial 	

Competency		Tracking study progress
Type	Task-based	
Definition	<p>The individual understands the project scope, milestones, budgets and timelines and can appropriately track the progress of these against the original planned targets. They review status reports from other members of the team in relation to meeting these milestones, and can analyse the progress sufficiently to anticipate problems in advance.</p>	

Tracking study progress requires good project oversight and managerial skills, along with good attention to detail and record-keeping, as the individual must constantly keep an eye on others' activities, on goals and targets and ensure they are met.

Related competencies	<p>Similar tasks: Working as per the QMS; Controlling quality of research; Closing study; Project management</p> <p>Required skills: Cognitive skills; Organisational skills; Record-keeping</p>
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Keywords Tracking; Progress; Milestones; Deadlines; Timely; Objectives/goals/targets

Abilities	<ul style="list-style-type: none"> ▪ Understand project scope, milestones, budgets, timelines; track these appropriately ▪ Track progress of study, using tracking tools or software if appropriate, and measures progress against planned objectives and targets ▪ Use progress tracking to anticipate potential issues, so initiative can be taken for resolution ▪ Ensure timeliness of reporting relevant milestones ▪ Review status reports from other team members in relation to milestones
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Competency	Project management
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Type Task-based

Definition The individual manages the study implementation and oversees the conduct of all activities from initiation to completion of the research project. They keep oversight of the project timeline, financing, human resources, other resources and logistics, in particular at and between groups and sites. They coordinate the relevant processes and teams, using project management tools if required.

Project management demands organisational and time management skills, and the ability to prioritise conflicting needs in order to successfully coordinate the activities of different parties (laboratories, research sites, etc.) involved in a clinical study.

Related competencies	<p>Similar tasks: Developing study plans and documents; Developing the QMS and SOPs; Working as per the QMS; Controlling quality of research; Securing or maintaining contracts; Initiating study; Closing study; Tracking study progress; Liaising or acting as a link; Human resources; Supervising or mentoring; Logistics and facilities management; Finances management</p> <p>Required skills: Strategic leadership; Cognitive skills (problem-solving); Interpersonal skills; Organisational skills</p>
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Keywords Project/study management; Coordination; Site management; Operations (overall); Coordinating (between sites); Overseeing; Implementation; Conducting; Planning

Abilities

- Oversee study and site management, including managing multiple sites/laboratories and ensuring consistency
- Oversee specified processes within the trial, e.g. recruitment, monitoring, follow-up
- Plan work schedules and timelines, review associated reports
- Coordinate or manage teams or CROs
- Understand how to use project management processes and tools

Study communications

Competency		Reporting
Type	Task-based	
Definition	<p>Reporting can take the form of oral or written accounts of activities, which may take place at scheduled meetings or upon request from team members or stakeholders. This might be a continuous task (regular updates) or a time-driven one (requested reports).</p> <p>This task requires language and communication skills (presentation and writing) as well as organisational skills, and aims to ensure that every party is aware of the progress of the study and that issues are escalated to relevant bodies. The individual understands the importance of escalating issues whether informally in the team or formally to authorities, and can do so as required. The individual understands the importance of reporting appropriately to relevant groups, for example keeping authorities and stakeholders informed of progress and issues. They can write and present reports according to the requirements of audience.</p>	
Related competencies	<p>Similar tasks: Disseminating study findings; Risk and safety management; Tracking study progress; Liaising or acting as a link; Facilitating or attending meetings</p> <p>Required skills: Language and communication skills (presentation and writing); Organisational skills; Record-keeping</p>	
Keywords	Escalating issues; Reporting; Report writing/drafting; Presentations	
Abilities	<ul style="list-style-type: none">▪ Report appropriately when required within the team (e.g. on workload, logistics, status of project); escalate issues or concerns appropriately▪ Write suitable reports according to audience, presenting information clearly	

- Understand specific and varying reporting requirements for diverse bodies (e.g. IRBs, sponsors, funders, regulatory authorities as opposed to trial management team, steering committees and safety monitoring boards)
- Have responsibility for the quality, coordination, medical and otherwise scientific accuracy and timeliness of relevant reports

Competency		Liaising or acting as a link
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Type	Task-based
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Definition

The individual maintains regular communications and interactions with study site(s), teams and relevant departments to ensure smooth and successful execution of trial activities. They make sure to constantly update and circulate new information to other parties in the trial, including protocol, SOPs, informed consent forms, etc. to study staff, and data or adverse events reports to review boards and sponsors.

In order to establish and maintain working communication between parties within a trial, point-of-contacts need interpersonal skills, good language and communication skills, as well as sound knowledge of the organisational context they are embedded in.

Related competencies

Similar tasks: Controlling quality of research; Securing or maintaining contracts; Project management; Tracking study progress; Reporting

Knowledge base: Governance and organisational context

Required skills: Interpersonal skills; Language and communication skills

Keywords

Liaison; Maintaining (regular) contact/communication; Point-of-contact; Collaboration; Coordination; Circulating information; Updating

Abilities

- Understand the communication and liaison required as part of a trial; for example communication with the sponsor, with sites, with PIs, stakeholders, monitors etc., to ensure smooth and successful execution of trial activities
- Liaise appropriately and regularly with the groups relevant to their role, keeping groups informed of progress, developments and issues.
- Be able to act as primary contact for authorities, media, CROs, etc.
- Process communications received and ensure a timely and complete response
- Ensure that relevant documents are communicated with the team; for example that the correct version of the investigator’s brochure/protocol is sent to groups, communicating amendments, etc.
- Interact with staff in other functional areas to ensure the highest level of collaboration across groups

Competency		Facilitating or attending meetings
Type	Task-based	
Definition	<p>Active participation in meetings encompasses multiple tasks, such as planning and organising, chairing and facilitating, as well as presenting or interacting with others. The individual has the ability to organise, plan, manage and record the outcomes of the meeting appropriately. They take detailed minutes of meetings to subsequently circulate discussed information and reached decisions to others, which necessitates good record-keeping skills. Senior individuals may chair meetings as required. This task requires interpersonal skills to facilitate active and useful discussions so as to achieve maximum efficiency.</p>	
Related competencies	<p>Similar tasks: Liaising and acting as a link; Reporting</p> <p>Knowledge base: Governance & organisational context</p> <p>Required skills: Interpersonal skills; Organisational skills; Language and communication skills; Record-keeping</p>	
Keywords	Meeting; Participating; Organising/planning; Facilitating; Presenting at meeting; Chairing	
Abilities	<ul style="list-style-type: none"> ▪ Organise meetings or teleconferences (ensuring correct attendees, making practical arrangements, preparing agendas, etc.) ▪ Prepare for, participate in and present clearly at meetings as required ▪ Take minutes, ensure they are reviewed and signed by the individual in charge ▪ Chair the meeting; have appropriate Chair training ▪ Facilitate meeting, ensuring agenda is kept to and decisions made 	

Staff management

Competency	Human resources
Type	Task-based
Definition	<p>The individual can recruit and select an appropriately qualified team. They hold CVs and training records of study and site staff, and update them as appropriate. They ensure that individuals have received sufficient instruction to carry out their research activities, and can direct them to training when required to bridge gaps in knowledge, or when needed (e.g. coordinating GCP refreshers).</p> <p>They must also ensure that staff will be equipped to perform their job safely and act in a sound and safe manner at the workplace (e.g. availability and consistent use of Personal Protective Equipment, up-to-date vaccinations).</p>
Related competencies	<p>Similar tasks: Initiating study; Project management; Creating or delivering training; Supervising or mentoring; Overseeing essential documents; Logistics and facilities management</p> <p>Knowledge base: Good Clinical (and other) Practice (safety rules); Research regulations</p> <p>Required skills: Strategic leadership; Record-keeping</p>
Keywords	Training requirements/planning; Staff recruitment; Maintaining delegation logs/CVs; Collecting staff; Safe workplace; Personal Protective Equipment; Infection prevention
Abilities	<ul style="list-style-type: none"> ▪ Recruit and select team, plan and coordinate their training as required ▪ Ensure that individuals have received and understood instructions to conduct their work both safely and as per the protocol ▪ Ensure the work environment is safe for staff, e.g. that laboratory equipment or infection control procedures are in place ▪ Ensure that individuals are qualified for their role; hold CVs, training records and logs of delegation, and ensure they are updated when appropriate

Competency		Creating or delivering training
Type	Task-based	
Definition	<p>The individual delivers relevant information in a meaningful way to others. They develop appropriate training objectives based on the needs of the group, and develop interesting and useful materials for training. When delivering training (e.g. in lectures or seminars), they are clear, effective and adapt their material and speech appropriately. The individual can also train individuals in a specific task or perform On-the-Job Training when needed.</p> <p>To deliver effective training, the individual requires excellent language and communication skills, and good interpersonal skills to respond to trainees. They already have, or seek to gain, a full understanding of the subject to be covered (e.g. the study protocol or SOPs).</p>	
Related competencies	<p>Similar tasks: Developing study plans and documents; Human resources; Supervising or mentoring</p> <p>Required skills: Interpersonal skills; Language and communication skills</p>	
Keywords	Training; On-the-Job training; Lecture; Seminar; Curriculum	
Abilities	<ul style="list-style-type: none"> ▪ Deliver effective training in front of groups, e.g. site training on study protocol/SOPs ▪ Produce materials such as manuals or presentations for training on a specific topic, e.g. the data management system or participant flow ▪ Be able to determine the appropriate subject topic, assess audience responsiveness to training, repeat and paraphrase source material (e.g. SOPs) in order to produce an effective training session ▪ Deliver effective On-the-Job (OJT) or Individual training ▪ Develop a training curriculum and/or manage a training programme 	

Competency		Supervising or mentoring
Type	Task-based	
Definition	<p>The individual has the ability to lead, motivate, mentor, supervise, monitor, train and advise staff in their work, acting as an expert resource on a specific topic if necessary. They supervise and line-manage staff, conducting appraisals when needed, and have skills in motivating and guiding their team. They can assign work appropriately depending on the interests and skills of individuals, so as to maximise the effectiveness of their team. They can oversee the activities of other staff members, identifying knowledge gaps and encouraging training if needed. The individual understands the different needs and management styles available and adapt appropriately to less experienced staff.</p>	

Supervision and mentorship requires good interpersonal skills, the ability to give clear instructions and feedback, and project management skills so as to assign tasks appropriately.

Related competencies **Similar tasks:** Project management; Human resources; Creating or delivering training
Required skills: Strategic leadership; Interpersonal skills

Keywords Supervision; Mentorship; Knowledgeable resource; Support; Advising; Line-managing; Appraising; Appraisal

- Abilities**
- Support and guide other researchers or a team and monitor their performance, developing their skills and capacity as needed
 - Mentor new staff; act as a technical advisor or expert to staff or researchers
 - Help and support other researchers (whether with work or personal issues, learning, etc.); provide comprehensive advice and guidance
 - Be aware of the various styles of supervision, and understand the principles of sound supervision/motivation techniques and their applications in the work environment
 - Line-manage and conduct appraisals for staff
 - Supervise and coordinate the work of the team
 - Evaluate and assign work/delegate to others, based on an individual’s strengths and interests

Resources management

Competency		Overseeing essential documents
Type	Task-based	
Definition	The individual ensures that all applicable essential documents and trial records exist and are accurate, complete, kept up-to-date and maintained – especially for those required by law and/or vital to the quality assurance of the study. They appropriately store and maintain restricted access to documents, where applicable.	
Related competencies	Similar tasks: Determining liability and insurance needs; Securing or maintaining approvals; Securing or maintaining contracts; Closing study (archiving); Reporting Knowledge base: Good Clinical (or other) Practice; Research regulations Required skills: Record-keeping	

Keywords Maintaining; File (Trial Master); Essential documents/documentation; Regulatory documentation

- Abilities**
- Ensure collection and maintenance of essential study documentation, e.g. up-to-date protocol, trial master file, site files, delegation logs, investigator’s brochure, official approvals, CVs, important correspondence
 - Update important documentation as required
 - Hold documents in a central location, filed in an organised manner and readily available for inspection
 - Maintain security of documentation by controlling access and physically protecting it from elements (e.g. water, fire)

Competency **Logistics and facilities management**

Type Task-based

Definition The individual supports the research process by managing logistical tasks and ensuring the infrastructure and facilities are in good working order. They are able to plan, coordinate, track and reorder the resources and generic supplies for the study. They maintain equipment inventory, prepare and perform trouble-shooting on assigned material (electronic devices, equipment and reagents in the laboratory, etc.).

Related competencies **Similar tasks:** Initiating study; Finances management
Required skills: Organisational skills; Record-keeping

Keywords Support; Resources; Logistics; Reagents (sourcing); Waste disposal

- Abilities**
- Coordinate the resources and supplies required for study, ordering things when required and within financial constraints
 - Create ways to plan, track and inventory study consumables
 - Plan logistics required for the trial materials, such as arranging shipments and accounting for materials
 - Equipment management: take care of and calibrate assigned equipment, perform basic trouble-shooting and report damages/required repairs
 - Space management: ensure appropriate facilities for study and clean environment
- Specialist setting:**
- Maintain a laboratory in running order by preparing reagents and disposing of biological and chemical waste appropriately

Competency		Finances management
Type	Task-based	
Definition	<p>The individual has an awareness of study budget and understands how to operate research projects within financial constraints. They manage the study budget, including preparing financial reports and cost forecasts. They keep accurate, up-to-date accounts, and assist in ensuring timely payments for stakeholders. They are involved in budget negotiations, and in preparing the associated funding agreements between groups. Managing financial resources requires good study tracking, record-keeping and organisational skills, including the ability to plan and operate within given limitations.</p>	
Related competencies	<p>Similar tasks: Attracting funding; Securing or maintaining contracts; Tracking study progress; Overseeing essential documents</p> <p>Required skills: Organisational skills; Record-keeping</p>	
Keywords	Budget; Finances; Payment; Accounts; Costs; Bills	
Abilities	<ul style="list-style-type: none"> ▪ Have an awareness of study budget and operate within financial constraints, and assist others in doing so ▪ Manage study budget and forecasting ▪ Alert relevant personnel to potential escalating consumable and other costs associated with a clinical research study ▪ Assist in budget negotiations and funding agreements ▪ Maintain accurate accounts, synthesise financial information from multiple sources to create report and ensure up-to-date financial information is available and circulated ▪ Manage expenses, e.g. preparing invoices and work orders, cash float, travel expenses, participant reimbursements 	

Research operations

Data flow

Competency		Creating and maintaining a database
Type	Task-based	
Definition	<p>The individual has a full awareness of the database requirements for a trial, including verification and query systems and audit trails, and of how this can be achieved practically. This involves applying both practical IT knowledge to create the physical database, and theoretical knowledge of the CRF and data analysis plan in order to integrate appropriate requirements and specifications. The individual can programme, test and implement an appropriate data management system, including using various devices for electronic data capture (e.g. PDAs, smartphones). They manage and troubleshoot the physical infrastructure of the database, as well as the software interface and the data itself. They must also pay attention to aspects of security of data, in particular during data transfer or archiving.</p>	
Related competencies	<p>Similar tasks: Developing the CRF and DMS; Data management Knowledge base: Research regulations Required skills: Computer and IT skills</p>	
Keywords	Database; Database specifications; Security; Storage	
Abilities	<ul style="list-style-type: none">▪ Collaborate with IT and implementation team(s) to address Clinical application requests and/or changes to Clinical database systems.▪ Operate data management system▪ Ensure safe and secure storage of data▪ Audit databases to validate programming and quality checks▪ Select, install and maintain data dictionary▪ Ensure that database supports an audit trail▪ Design database appropriately for data specifications, user requirements, edit rules, query logic and data validations; build and test database according to the above; develop test scripts	

Competency		Collecting accurate data
Type	Task-based	
Definition	<p>The individual understands the data collection, data entry and verification process. They recognise the importance of accurate and comprehensive source documentation, and of verifying this information before it is entered into the database. They are able to spot issues such as out-of-range values. They coordinate or otherwise participate in the data entry process, ensuring that reported trial data are accurate, complete, and verifiable from source documents. They can coordinate and produce data queries, keeping appropriate records of their findings and resolutions, and raising concerns when necessary. They recognise the need for confidentiality, and understand the relevant guidelines pertaining to this.</p> <p>Data may be collected from a range of sources including CRFs or health questionnaires that data collectors should be familiar with and able to appropriately fill in or retrieve information from, e.g. if the data has been directly generated by an electronic source. Collectors may work in the laboratory, or directly at the bedside.</p>	
Related competencies	<p>Similar tasks: Developing CRF & data management system; Providing clinical care (CRF completion); Performing laboratory technical operations (tests results); Controlling quality of research</p> <p>Required skills: Cognitive skills (attention to detail); Record-keeping</p>	
Keywords	Data entry; Data collection; Record data; Data queries (resolve); Review/verification of source documents	
Abilities	<ul style="list-style-type: none"> ▪ Manage data collection and insertion into Case Report Form (CRF) or other storage format, ensuring the data is accurate and complete ▪ Responsible for receiving and checking the data prior to data entry, maintaining a log of incomplete or missing data ▪ Enter CRF into database and produce data queries, keeping a log of discrepancies and resolving data queries ▪ Be familiar with electronic data collection processes or smartphone data collection ▪ Ensure all Adverse Events are entered into database 	

Competency		Data management
Type	Task-based	
Definition	<p>The individual manages the data process in the trial; they oversee the flow of data and the specifications for its regular backup and safe storage, in line with ethical requirements and respecting participants' confidentiality. They operate the data management system (DMS), and execute quality management strategies for the data. They check the timely resolution of database queries, and review reports generated from the databases, as required. Data management requires excellent knowledge of the data flow plan, processes and guidelines, and good project management skills.</p> <p>Expert: Experts may work with other sites to implement data management solutions during multicentre trials, and support the improvement of the data management process when necessary.</p>	
Related competencies	<p>Similar tasks: Developing CRF & data management system; Analysing data; Collecting accurate data; Creating and maintaining database; Project management; Safety & AEs management</p> <p>Knowledge base: Research regulations; Ethics & human subject protection (confidentiality); Good Clinical (or other) Practice</p> <p>Required skills: Computer and IT skills; Record-keeping</p>	
Keywords	Data management; Data flow; Data transfer	
Abilities	<ul style="list-style-type: none"> ▪ Manage the flow of data in the trial: how it is acquired, cleaned and stored ▪ Oversee quality of data management and data systems ▪ Operate data management system ▪ Assist in defining data specifications and summaries, and data listings ▪ Reconcile data transfers 	

Clinical and laboratory operations

Competency		Providing clinical care
Type	Task-based	
Definition	<p>Clinical care relates to the theoretical knowledge of medicine and the ability to apply it during the research process, for example assessing clinical history, taking relevant measurements and samples, and providing appropriate and safe care and treatment. The individual may be involved in care in different ways: as a performer (conduct participants' visits), as a coordinator (oversee or lead the clinical team) or as a controller (review participants' medical records).</p> <p>The individual understands the differences between research and standard clinical care, and has a good understanding of the clinical field of study. The individual may also carry out data collection tasks that involve direct interaction with participants, such as administering health questionnaires or taking samples and measurements. They also deliver the intervention, monitor the participant for toxicity of the intervention, control adherence to treatment and provide emergency care in case of Adverse Event (AE).</p>	
Related competencies	<p>Similar tasks: Risk and safety management; Collecting accurate data; Handling biomedical products</p> <p>Knowledge base: Health-related knowledge</p>	
Keywords	<p>Clinical; Medical; Care; Sample-taking; Anthropometric measures; Healthcare qualification (e.g. Nursing degree); Experience in a medical speciality (oncology, paediatrics, etc.); Delivering intervention</p>	
Abilities	<ul style="list-style-type: none"> ▪ Conduct study visits with participants, ensuring their care and safety ▪ Take blood and other study samples and measurements such as vital signs ▪ Conduct, record and/or review clinical assessments, e.g. on the CRF, to the satisfaction of the monitors, sponsor and regulators/auditors ▪ Diagnose participants through review of medical history, analysis of vital signs, biological samples etc. and recommended relevant treatments ▪ Carry out routine clinical services including ward rounds if required ▪ Immediately manage any medical emergency according to qualification 	

Competency		Ensuring appropriate use of investigational medical products (IMPs)
Type	Task-based	
Definition	<p>The individual demonstrates an understanding of pharmacology and of the appropriate use of drugs, including investigational medical products (IMPs). They have knowledge of drug toxicity, pharmacokinetics and pharmacodynamics issues, and know how those should influence the clinical research process and participants' clinical management. They apply their pharmacology knowledge to the IMP, ensuring safe use and dispensing of the IMP and of any appropriate comparators within the trial. They have a thorough knowledge of Good Manufacturing and Pharmacy Practices, and understand how to ensure the drug contains the appropriate active compound, especially in settings where counterfeit drugs occur frequently. They may assist in study design and implementation by providing pharmacological advice on the IMP and the comparators (placebos) to be used.</p> <p>The individual also understands the importance of pharmacovigilance, both throughout and beyond the study lifecycle, and suggests steps to continually monitor drug effects in both situations.</p>	
Related competencies	<p>Similar tasks: Developing a protocol; Risk and safety management; Providing clinical care; Handling biomedical products</p> <p>Knowledge base: Health-related knowledge; Research methodology; Good Clinical (or other) Practice</p>	
Keywords	Administering drug (dispensing); Use (safely and correctly); Dosage; Comparator/placebo; Pharmacy; Pharmacology; Monitoring toxicity; Pharmacokinetics/dynamics; Bioavailability; Pharmacovigilance; Market authorization	
Abilities	<ul style="list-style-type: none"> ▪ Understand pharmacology and toxicity as they relate to drugs and in particular to the IMP used in the research project ▪ Apply knowledge of pharmacy to control appropriate products are delivered to participants; in particular, check prescriptions for adverse interactions between drugs and with participants' existing conditions ▪ Ensure safe use of current IMP and any comparators ▪ Understand the importance of pharmacovigilance and post-market surveillance of all medical products ▪ Use detailed knowledge of pharmacology to write the investigator's brochure 	

Competency		Handling biomedical products
Type	Task-based	
Definition	<p>Biomedical products may be participants' biological samples (e.g. blood, tissues) as well as drugs or other medical devices used for treatment, and this competency relates to the ability to source, track and process these products safely and carefully within the trial environment. The individual has a good understanding of the requirements for storage, handling and tracking of the relevant biomedical products. They develop systems to handle these products appropriately, ensuring correct labelling and storage temperatures are maintained and documented. They ensure that they have the correct and completed paperwork for any samples taken and received.</p> <p>Handling biomedical products requires logistical skills (e.g. inventory and ordering of drug supplies, dealing with export/import permits) as well as technical knowledge (e.g. conditions for transport and storage, processing and reconstitution on receipt if applicable). Within the context of clinical trials, it also requires record-keeping skills as products need to be tracked, e.g. to identify participants from which a sample was taken or to ensure the drug labelling is made according to the code in blinded trials.</p>	
Related competencies	<p>Similar tasks: Logistics and facilities management; Collecting accurate data; Providing clinical care; Ensuring appropriate use of IMPs; Performing laboratory assays</p> <p>Knowledge base: Health-related knowledge</p> <p>Required skills: Cognitive skills (attention to detail); Record-keeping</p>	
Keywords	<p>Handling; Tracking; Storage; Sourcing (intervention); Procured; Returned; Disposed of/destruction; Labelling/packaging; Reconstitution (of drugs); Inventory; Processing (of samples); Receipt; Import/export permits; Transport; Coding/blinding</p>	
Abilities	<ul style="list-style-type: none"> ▪ Manage the log for the study intervention, including tracking expiry dates ▪ Understand and ensure the requirements for the safe storage, handling and tracking of relevant biomedical products (IMPs or study samples) ▪ Coordinate movement of lab samples during the trial and of resulting data ▪ Receive the samples and ensure that the correct and full supportive information is provided, including CRFs ▪ Ensure that there are robust written procedures in place relating to storage conditions, and what to do when some value is outside of the specified range (e.g. temperature of storage room) ▪ Check the acceptability of the packaging/labelling of the IMP (e.g. checking that it is child resistant) ▪ Ensure that relevant samples are taken, resolves discrepancies and communicates results ▪ Ensure processes are in place for import/export of IMPs or specimens in compliance with applicable legislation 	

Competency		Performing laboratory assays
Type	Task-based	
Definition	<p>The individual uses lab equipment to conduct routine diagnostics for the trial, and can interpret and document the results appropriately. Performing laboratory operations requires scientific background knowledge (e.g. to interpret biological tests) and record-keeping skills.</p> <p>Expert: The individual is also able to plan and set up new procedures and techniques within a laboratory.</p>	
Related competencies	<p>Similar tasks: Risk and safety management; Logistics and facilities management; Providing clinical care; Handling biomedical products</p> <p>Knowledge base: Health-related knowledge</p> <p>Required skills: Cognitive skills; Record-keeping</p>	
Keywords	Assays; Laboratory equipment (set-up, maintenance); Technical support; Method validation; Experiment set-up; Method development	
Abilities	<ul style="list-style-type: none"> ▪ Conduct routine diagnostics involving manual techniques or use of laboratory instruments, such as measuring hormone levels, STI testing, serology, PCR, CD4/CD8 counts, TB assays ▪ Conduct wet experiments, interpret and document results ▪ Generate data using relevant assays ▪ Monitor lab resources and inform relevant staff on the replenishment ▪ Provide technical laboratory based advice to researchers in designing experiments 	

Interaction with public & study participants

Competency		Engaging with the community
Type	Task-based	
Definition	<p>The individual understands the importance of community engagement in research activities and can design an appropriate community sensitisation strategy, adapting as required depending on the location and the needs of the study. They understand that different activities may be required at different sites for multi-centre studies, according to local variations. They can set up a Community Advisory Board, and know when to contact key opinion leaders and community chiefs or elders. They must ensure good communication is established in order to enable research/create a favourable context for research. Engaging with the community requires strong interpersonal skills and a good understanding of the area and culture where the research is to be held.</p>	
Related competencies	<p>Similar tasks: Disseminating research findings; Initiating study; Collecting accurate data; Enrolling and retaining participants</p> <p>Knowledge base: Ethics and human subject protection</p> <p>Required skills: Interpersonal skills; Language and communication skills</p>	
Keywords	<p>Public involvement; Sensitisation; Community engagement; Value of participants' contribution in all aspects of research; Reporting to research participants; Educating local community; Individual interviews/focus group discussions; Community awareness, preparedness, involvement; Knowledge of area and culture</p>	
Abilities	<ul style="list-style-type: none"> ▪ Design and coordinate community sensitisation plans, e.g. community meetings, educational plans, advertising, leaflets, letters to GPs ▪ Encourage, appreciate and value the contribution of study participants in all areas of research activity; promote patient and public involvement ▪ Set up and manage a Community Advisory Board ▪ Ensure that good relations are maintained at all times with locals ▪ Develop a network of Community Liaison Personnel (CLPs) who can facilitate ongoing community engagement ▪ Conduct Rapid Ethical Appraisal, or similar activities if necessary, which may involve interviews and focus group discussions 	

Competency		Enrolling and retaining participants
Type	Task-based	
Definition	<p>The individual who recruits and retains participants will be involved in outreach activities (informing potential participants about the study), screening potential participants (e.g. by administering health questionnaires for eligibility check), and executing strategies for retaining randomised participants.</p> <p>The individual needs a good understanding of the means for enrolling subjects in the trial, including the inclusion/exclusion criteria and participant recruitment strategies. They can manage participant recruitment, track figures and suggest trouble-shooting actions when recruitment figures are not met. They coordinate the visit schedules of participants in the trial, assisting in the follow-up of individuals and retention strategies, and monitoring withdrawals. They understand the importance of using local languages to interact with participants, and ensure the research team is equipped with translators if needed.</p>	
Related competencies	<p>Similar tasks: Tracking study progress; Providing clinical care; Collecting accurate data; Engaging with the community; Supporting and advising throughout the informed consent process</p> <p>Knowledge base: Ethics and human subject protection; Good Clinical (or other) Practice (confidentiality)</p> <p>Required skills: Interpersonal skills; Language and communication skills</p>	
Keywords	Inclusion/exclusion criteria; Screening; Recruitment (numbers); Eligibility; Enrolment (log); (Loss to) follow-up; Cohort retention; Visit schedule; Confidentiality; Privacy	
Abilities	<ul style="list-style-type: none"> ▪ Understand the application of inclusion and exclusion criteria, and can answer questions about enrolment when asked ▪ Coordinate participant visit schedules ▪ Randomise participants into trial ▪ Track recruitment figures and report to relevant groups when required ▪ Assist in follow-up of individuals to ensure trial data is complete ▪ Report withdrawals appropriately – if an individual withdraws from the study, make a reasonable effort to find out the reason 	

Competency		Supporting and advising throughout informed consent process
Type	Task-based	
Definition	<p>The individual is aware of the legal requirement to gain and maintain informed consent for participants in a trial, and of the reasons for doing so. They explain the study in ways a potential participant can understand, paying attention to factors that can influence decision-making. The individual uses their excellent interpersonal skills and communication skills to deliver information about the study in a clear, accessible, non-technical manner, and can use creative means to explain difficult concepts (e.g. using illustrations when necessary). They are particularly sensitive to the requirements of vulnerable participants, and know when an impartial witness is needed to ensure transparency and fairness of the process. They also document the informed consent suitably, e.g. by adding a copy of the form to the patient record.</p> <p>Once initial consent has taken place, the individual maintains good communication with the participant and continues to support them to ensure they are happy to continue, and ensures that they understand visit schedules, instructions on IMP or daily diary use, and any other trial procedures. Advising may also involve delivering general health advice to participants and their relatives.</p>	
Related competencies	<p>Similar tasks: Risk and safety management; Providing clinical care; Ensuring appropriate use of IMPs; Enrolling and retaining participants</p> <p>Knowledge base: Ethics and human subject protection; Good Clinical (or other) Practice</p> <p>Required skills: Interpersonal skills; Language and communication skills</p>	
Keywords	<p>Informed consent; Explaining; Obtaining/maintaining informed consent; Ethics; Counselling; Advising; Informing; Psychosocial support; Behavioural interventions; Providing support/information; Point-of-contact for participants</p>	
Abilities	<ul style="list-style-type: none"> ▪ Contribute to the informed consent process, ensuring that the participant fully understands the trial, including for children, young people and vulnerable adults; use consent material (e.g. pictures) if appropriate ▪ Understand that informed consent is an ongoing process, and continues to answer participants' questions and to support them throughout the trial ▪ Have an understanding of the issues that could occur during the informed consent process, and apply strategies to mitigate these risks ▪ Continuously ensure that participants have a full understanding of visit schedules and how to use the IMP ▪ Counsel participants and point out when to seek healthcare advice at study sites or non-study sites, if necessary ▪ Keep subjects informed of any relevant new information that comes to light during the trial and that might affect their decision to remain in the study 	

- Ensure that suitable arrangements are made in the case that a legally acceptable representative is giving consent, rather than the participant
- Ensure that the compensation or payment to trial subjects is clearly explained to subjects

Professional skills

Competency	Cognitive skills
Type	Skill-bases
Definition	Cognitive skills cover analytical, decision-making and problem-solving skills. The individual has cognitive abilities which complement their role. For example they give attention to detail, and are able to anticipate, define and resolve problems creatively. They have a methodical approach to their work and demonstrate sound decision-making. They can critique and analyse different types of information effectively, and apply common sense to work situations.
Related competency	Similar skill: Strategic leadership
Keywords	Problem identification/solving; Decision-making; Analytical thinking; Attention to detail
Abilities	<ul style="list-style-type: none"> ▪ Have an eye for detail/attention to detail ▪ Problem solving – define problems and find creative solutions to problems ▪ Analytical thinking – can break down information into manageable parts and systematically analyse it ▪ Integrative thinker – interprets and summarises complex issues (whether written or discussions) ▪ Anticipate problems and takes initiative to resolve them <p>Basic:</p> <ul style="list-style-type: none"> ▪ Ability to read and interpret documents, instructions or information

Competency		Strategic leadership
Type	Skill-based	
Definition	<p>Individuals demonstrating strategic leadership should be able to promote an appropriate culture for continued improvement, knowledge exchange and expansion of activities at the organisational, national or global level. Strategic leaders will promote research capacity building (both for their institutions and on a wider scale) by creating new opportunities for research activities, collaboration and knowledge sharing.</p> <p>Strategic leadership requires good problem solving skills and creative thinking to find new ways to enhance effectiveness, and excellent interpersonal skills in order to network, guide and motivate others.</p>	
Related competencies	<p>Similar skills: Cognitive skills; Interpersonal skills</p> <p>Useful knowledge: Governance and organisational context</p>	
Keywords	<p>Leadership; Global; Commercial/business; Change; Development of policies; Strategy; Institutional reputation; Professional networks; Representing profession; Collaborating (with colleagues around the world); Knowledge-sharing; Capacity-building; Driving innovation; Entrepreneurial</p>	
Abilities	<ul style="list-style-type: none"> ▪ Provide leadership and strategic vision to their organisation, encouraging the evaluation of current service and change where necessary ▪ Encourage a culture of continual improvements in the department, encouraging streamlining of processes; guide colleagues through the process of change ▪ Contribute to the development and updating of research policies and procedures, in department or nationally ▪ Seek to share best practice in clinical research to develop capacity, whether in the organisation or further afield ▪ Establish and maintain relationships with a strategic network of scientists and collaborators so as to facilitate the work of the department and building capacity 	

Competency		Interpersonal skills
Type	Skill-based	
Definition	<p>Interpersonal skills cover the ability to interact with other professionals at all levels. The individual understands the importance of teamwork in clinical research, and as such fosters a collaborative environment within their group, encouraging and motivating others, regardless of discipline, gender, professional level, and culture. They have good negotiation and diplomacy skills even in difficult situations, and are an active listener, encouraging open communication from others in the team. They also act with cultural appropriateness.</p>	
Related competencies	<p>Tasks requiring this skill: Liaising or acting as a link; Facilitating or attending meetings; Creating or delivering training; Supervising or mentoring; Engaging with the community; Supporting and advising participants throughout the informed consent process</p> <p>Similar skills: Language and communication skills; Work ethic</p>	
Keywords	Teamwork; Team; Negotiation; Networking; Mediation/facilitation; Listening	
Abilities	<ul style="list-style-type: none"> ▪ Understand the importance of teamwork in trial conduct, and how to work in a multidisciplinary and inter-professional team effectively (i.e. people with different backgrounds and different levels of training) ▪ Conflict management/mediation skills – ability to discuss issues with people who disagree on a topic ▪ Advocacy skills – enable articulation of the views of those who find it difficult to express themselves ▪ Listen effectively and encourage open communication ▪ Negotiation skills ▪ Effective networking skills, can build alliances and strategic partnerships ▪ Encourage diplomacy and sensitivity; promote respect and courteous treatment of others ▪ Tactful and good judgement when dealing with sensitive or personal information/issues 	

Competency		Language and communication skills
Type	Skill-based	
Definition	<p>The individual can communicate effectively in writing or orally, expressing ideas clearly and articulately. They adapt their communication depending on the audience, always ensuring to deliver their message coherently. This means that they have a strong knowledge of clinical terminology, as well as being able to clearly explain those technical terms. They can perform oral presentations confidently.</p> <p>Language skills include the ability to translate documents if required.</p>	
Related competencies	<p>Tasks requiring this skill: Disseminating research findings; Liaising or acting as a link; Facilitating or attending meeting; Reporting</p> <p>Similar skills: Interpersonal skills</p>	
Keywords	Written; Spoken/verbal; Languages; Communication; Presentation; Fluent	
Abilities	<ul style="list-style-type: none"> ▪ Communicate clearly in writing/orally, expressing ideas meaningfully and articulately ▪ Deliver effective presentation using oral and artistic skills to express ideas effectively ▪ Translate documents or organise translations ▪ Adapt communication as required depending on audience to coherently deliver message 	

Competency		Organisational skills
Type	Skill-based	
Definition	<p>The individual is highly organised and able to plan their work independently, taking into account deadlines and competing requirements that will arise over the course of the project. They have the ability to multitask and prioritise conflicting demands effectively, even under pressure, in order to deliver high-quality work, timely and as required.</p>	
Related competencies	<p>Similar skills: Cognitive skills; Work ethic</p>	
Keywords	Planning; Organisational skills; Prioritisation of projects; Multi-tasking; Self-management; Time/deadlines management; Work under pressure	
Abilities	<ul style="list-style-type: none"> ▪ Good time management – be able to multitask and prioritise competing deadlines, needs and demands from colleagues ▪ Deliver work at agreed time, and work effectively under pressure and in a stressful environment 	

Competency		Record-keeping
Type	Skill-based	
Definition	The individual creates and completes accurate study logs and records relating to any aspect of the study, thus creating and maintaining a clear audit trail. They update files as required and keep a record of any aspects, such as communication, which may be required in future. Good record-keeping requires attention to detail, organisation and good tracking skills to ensure information is appropriately and consistently documented in a readable, understandable and transparent manner.	
Related competencies	Tasks requiring this skill: Reporting; Overseeing essential documents Useful knowledge: Good Clinical (or other) Practice Similar skills: Cognitive skills (attention to detail)	
Keywords	Log; Record; Documentation (maintained and complete); Documented; Update	
Abilities	<ul style="list-style-type: none"> ▪ Complete accurate study logs and records e.g. relating to the study intervention, training records, funding, delegations ▪ Maintain updated files relating to study participants ▪ Keep records of communications; of regulatory submissions and responses ▪ Update documents as required, for example update central data on clinical research including dates, progress, numbers and documents 	

Competency		Computer and information & technology (IT) skills
Type	Skill-based	
Definition	<p>The individual is proficient using a computer and in particular with usual software of the Microsoft suite (Word, PowerPoint, Excel, etc.).</p> <p>They are proficient or willing and able to learn using other technical software (STATA, OpenClinica, etc.). IT skills include knowledge of hardware devices and ability to troubleshoot when necessary.</p>	
Related competencies	Tasks requiring this skill: Analysing data; Creating and maintaining a database; Collecting accurate data; Data management	
Keywords	Computer; Computing; Hardware; IT; Microsoft (Word, Excel, PowerPoint, Outlook); OpenClinica; STATA	
Abilities	<ul style="list-style-type: none"> ▪ Competency with computers and IT – can use the internet and email, Microsoft Office, etc. 	

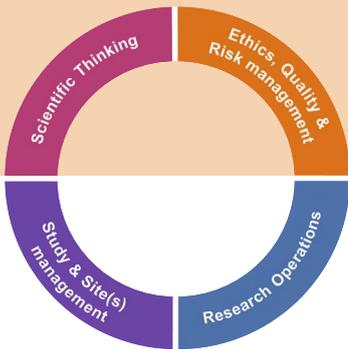
- Know programmes required for their role, e.g. specimen tracking software
- Can trouble-shoot with software/hardware difficulties
- Can build and refine databases, or code e.g. use Java and QSL programming
- Understand complex Data Management or statistical programmes such as EpiInfo/STATA/SPSS
- Physical management of data infrastructure including configuration and maintenance of ICT hardware

Competency		Work ethic
Type	Skill-based	
Definition	The individual demonstrates a proactive and professional approach to work. They recognise their limitations and consistently seek to address them. They ask guidance when required, and have a commitment to learning, keeping their knowledge and professional skills up to date. They can be left to work on their own or with minimal supervision, and also integrate well within teams.	
Related comp.	Similar skills: Cognitive skills; Interpersonal skills	
Keywords	Willingness to attend educational activities; Independent work; Minimal supervision needed; Reliable; Autonomous; Self-management; Self-learning; Commitment; Pro-active; Punctual; Hard-working; Striving for excellence; Self-driven; High integrity; Diligence	
Abilities	<ul style="list-style-type: none"> ▪ Recognise own limitations or learning needs and take responsibility for maintaining up-to-date knowledge ▪ Good self-management – be able to work autonomously, with minimal supervision, or collaboratively in a team ▪ Be able and willing to take and follow instructions ▪ Flexibility – respond positively to requests and change, willing to take on additional roles if necessary ▪ Take personal responsibility for all decisions and actions 	

Competency	Specific requirements
Type	Skill-based (qualification, experience)
Definition	Depending on the setting of trial and employer, the individual's role in the trial may impose additional specific requirements, whether experience, qualifications or skills. Specific experience includes experience within that particular location or within industry as opposed to academia. Specific qualifications might be a driver's license.
Related competency	Similar skill: Work ethic
Keywords	Driver's license; Experience; Willingness/availability for travel
Abilities	<ul style="list-style-type: none"> ▪ Experience in industry or academia, or with CROs ▪ Experience in specific settings, e.g. in the National Health Service, in a specific country or setting ▪ Specific qualifications or memberships, e.g. ALS, driver's license ▪ Ability to lift heavy objects if required

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 scale³:

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

³ 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.

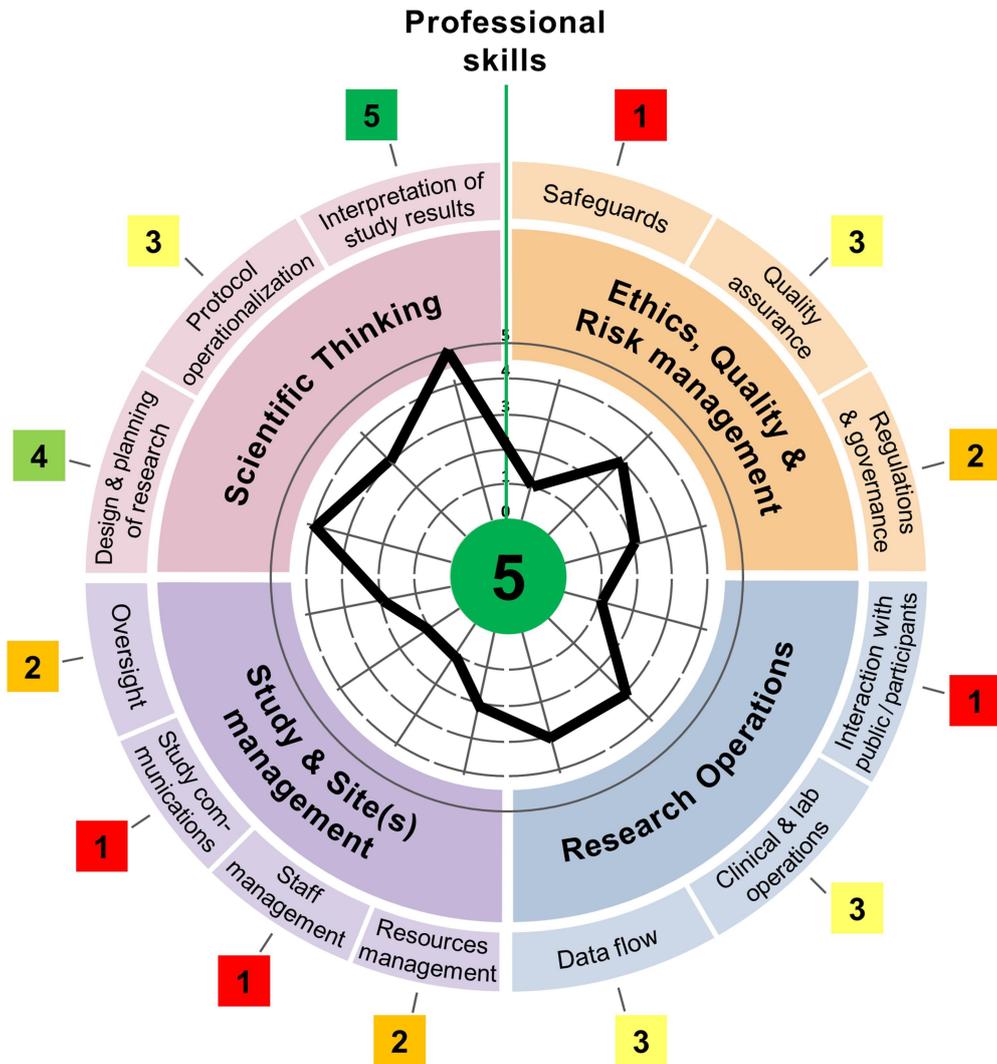
Grading radar chart

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.

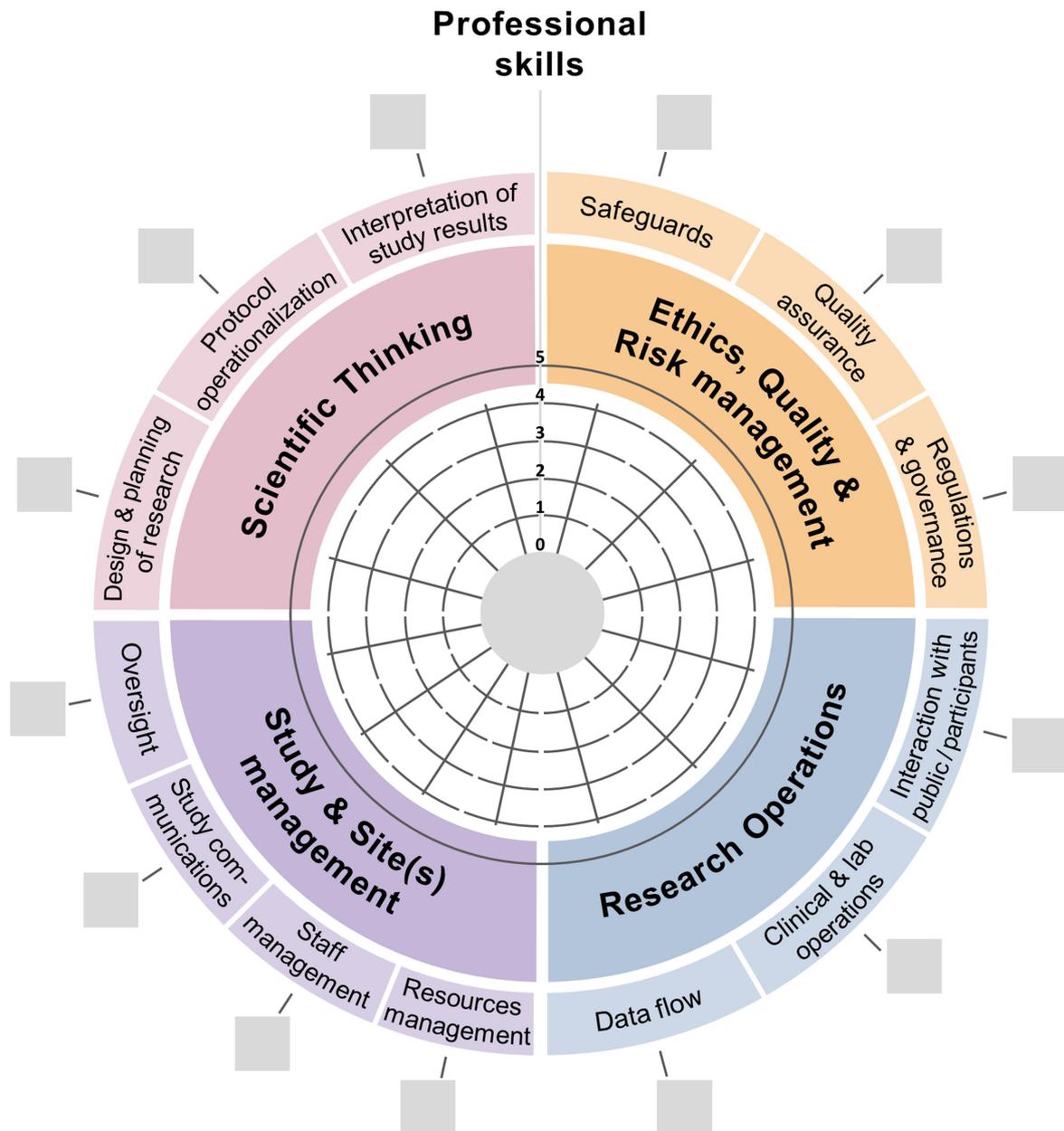
A web application is in development by The Global Health Network and TDR, which enables to record your grades online and keep track of your progress over time. We encourage you to use this online version if you can, as it provides a much more interactive interface that creates the radar picture automatically 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 touch⁴ 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.

⁴ 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.

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.

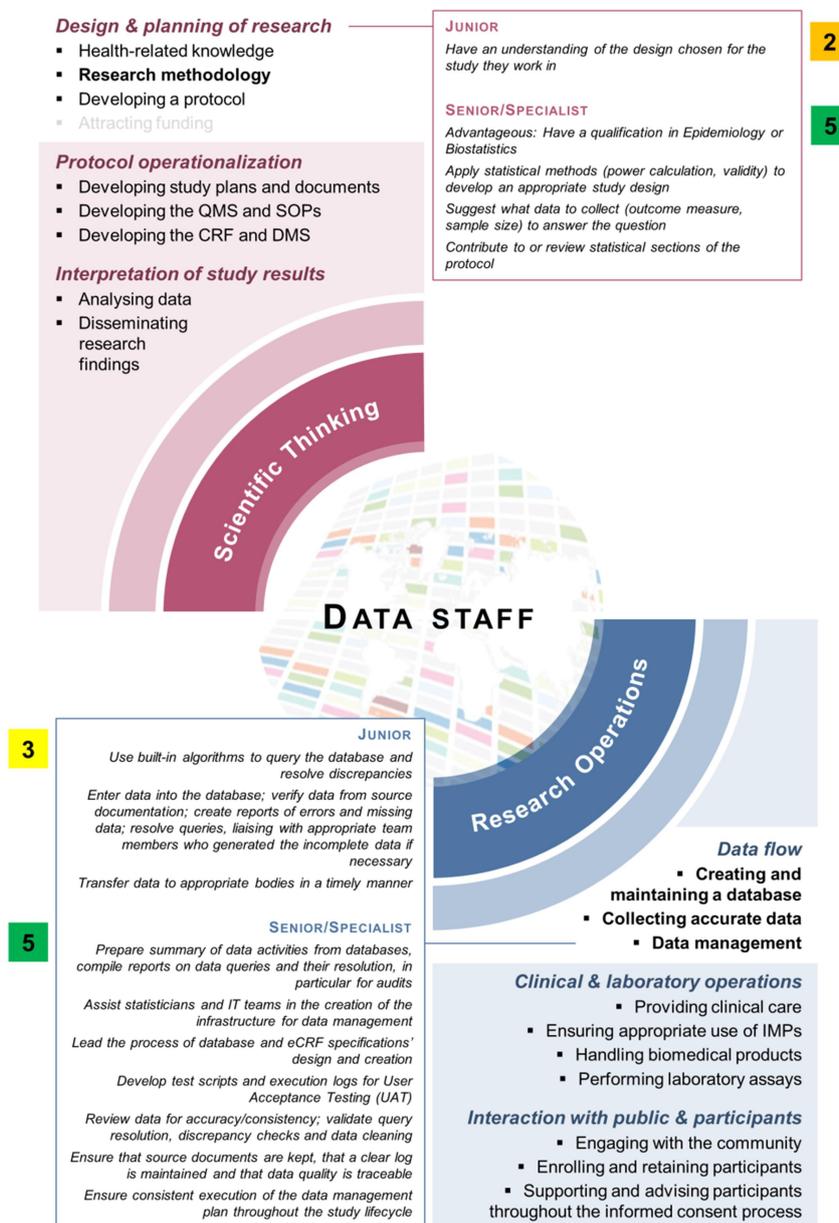


Figure 2 (continued)

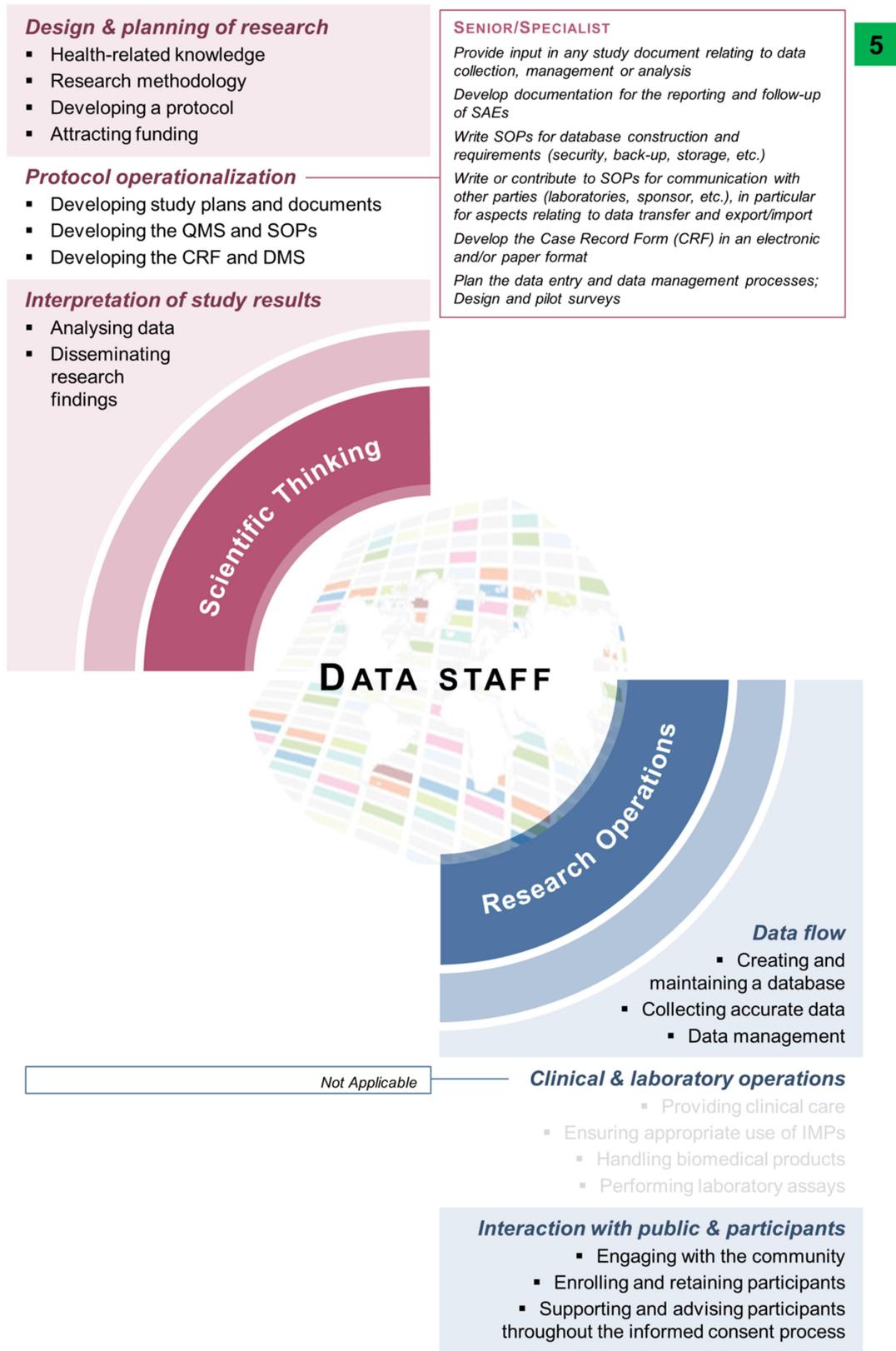


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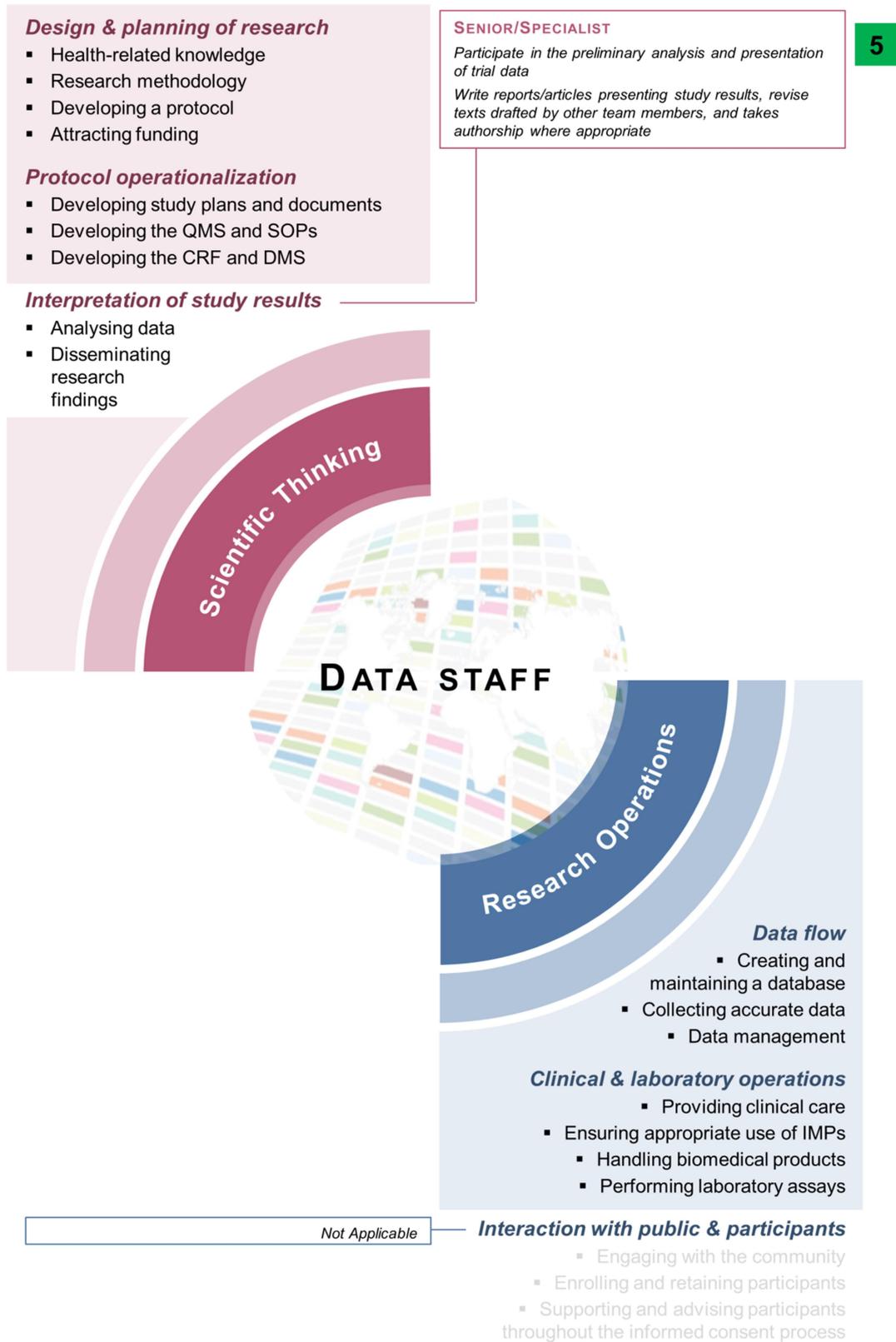


Figure 2 (continued)



Figure 2 (continued)

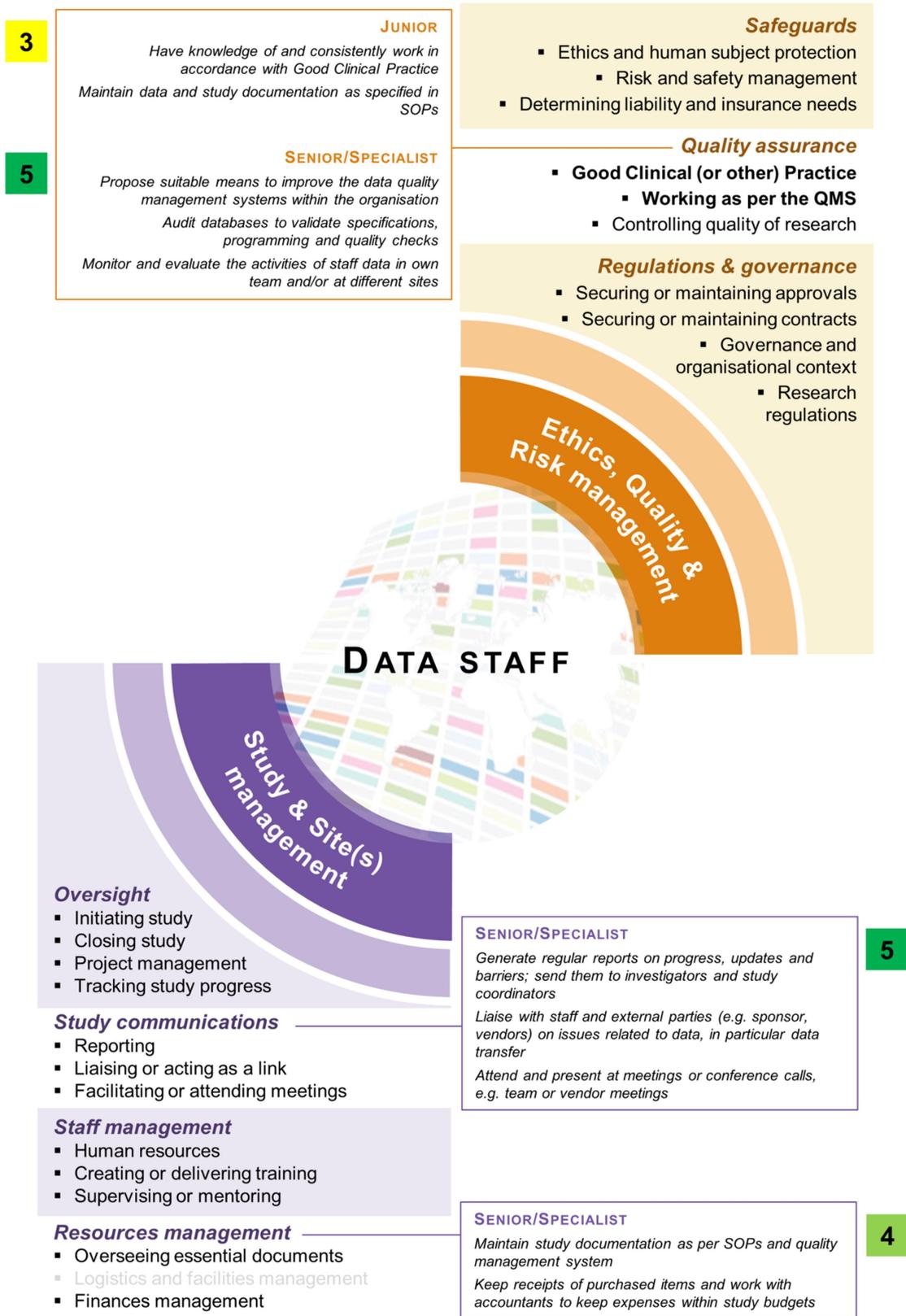
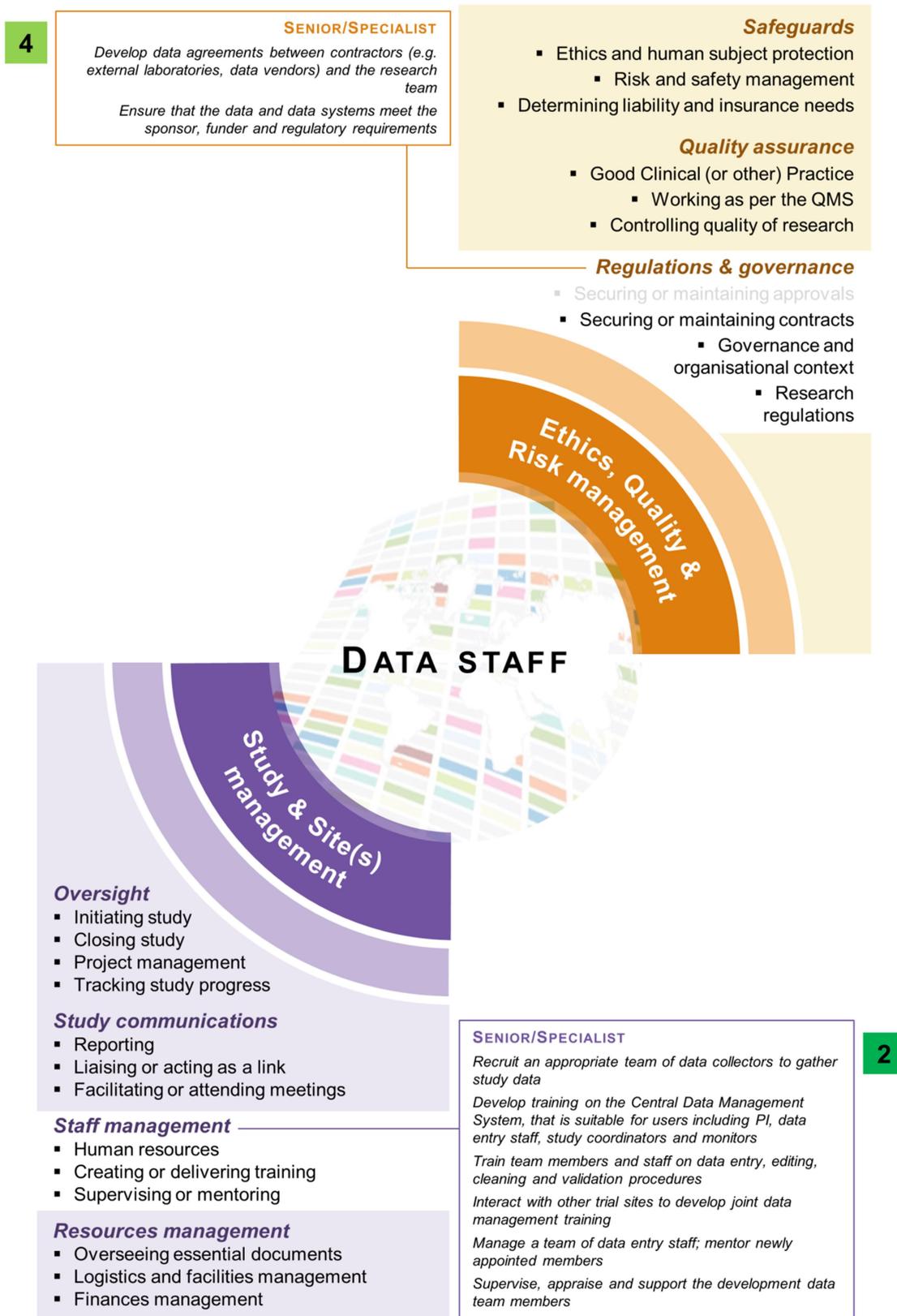
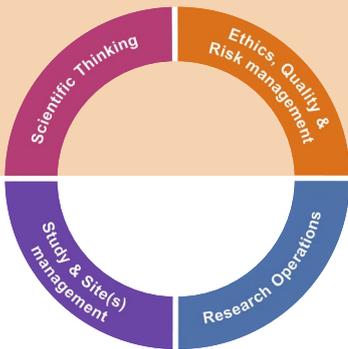


Figure 2 (continued)



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 study 2. When building job descriptions for studies 3. When conducting an appraisal 4. When creating a training curriculum 5. To assess my own training needs 6. 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 application 2. Downloaded pdf file 3. 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>	



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