

Using the TDR Global Competency Framework for Clinical Research:

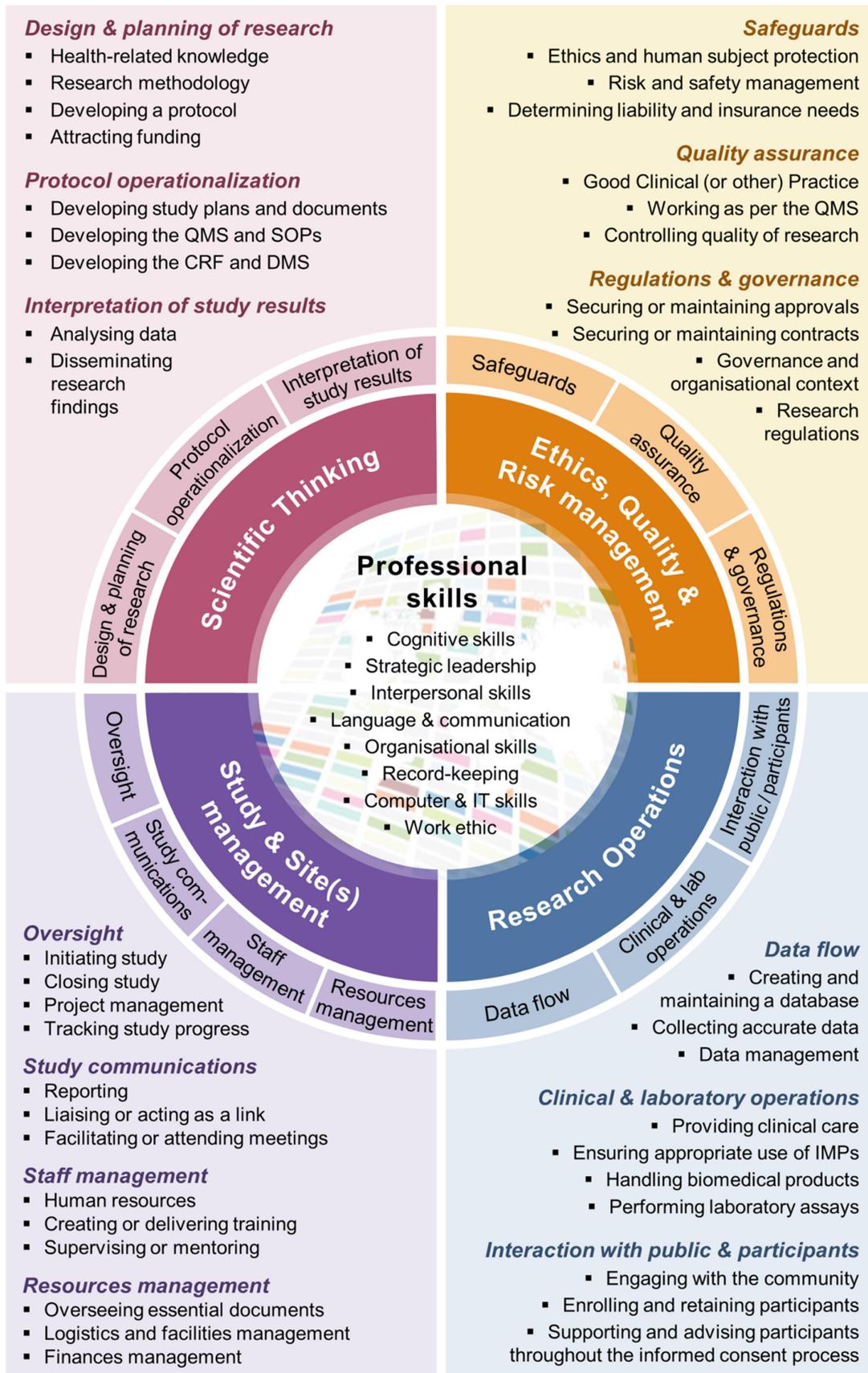
A set of tools to help develop
clinical researchers



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

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

Knowledge base: Health-related knowledge; Research methodology

Required skills: Language and communication skills (writing); Computer and IT skills

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	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
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	Set-up (site, steering committees); Start-up; Site initiation; Risk assessment; Feasibility; Selection (site, investigator); Preparing/preparedness; Kick-off; Launch; Piloting	
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>
----------------------	--

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
-----------	---

Competency	Project management
------------	--------------------

Type	Task-based
------	------------

Definition	<p>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.</p> <p>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.</p>
------------	---

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>
----------------------	--

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
------------	--	------------------------------

Type	Task-based
------	------------

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	Clinical; Medical; Care; Sample-taking; Anthropometric measures; Healthcare qualification (e.g. Nursing degree); Experience in a medical speciality (oncology, paediatrics, etc.); Delivering intervention	
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	<p>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.</p>
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 trouble-shoot 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