DIAMOND
Training and Assessment Digital Network

CLINICAL RESEARCH PROFESSIONAL CORE COMPETENCIES SELF-ASSESSMENT

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DOMAIN 1: Scientific Concepts and Research Design: *Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials.*				
Rating Scale *0 = N/A, 1 = Needs Development, 2= Appropriate to career stage, and 3= Strength*	*0*	*1*	*2*	*3*
Apply scientific principles when implementing a clinical or behavioral study.				
Implement data collection.				
Identify the research hypothesis in a study protocol.				
Identify primary & secondary endpoints for use in data analysis.				
Review a clinical study protocol to ensure all elements are included.				
Compare & assess the quality of results to study reports/publications.				
DOMAIN 2: Ethical and Participant Safety Considerations: *Encompasses care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial*				
Rating Scale *0 = N/A, 1 = Needs Development, 2= Appropriate to career stage, and 3= Strength*	*0*	*1*	*2*	*3*
Demonstrate the importance of clinical trial activities per protocol.				
Explain clinical equipoise & therapeutic misconception, on patient understanding.				
Consistently apply knowledge of clinical equipoise and therapeutic misconception.				
Recognize, interpret, & seek assistance to address participant concerns of therapeutic misconception or clinical equipoise.				
Critically appraise and implement the principles of human subject protection and privacy.				
Communicate potential risks/hazards, & benefits with terminology understandable to potential study participants in informed consent.				
Apply knowledge of key regulations/guidelines with safety information in drafting informed consent.				
Apply safeguards with research participants.				
Anticipate situations when research participants may be considered vulnerable.				
Compare/contrast ethical principles guiding clinical research across different global regions (e.g., ICH guidelines vs. FDA regulations, other country regulations).				

Examine conducting clinical trials in low and middle-income countries & differentiate the potential types of exploitation and benefits that populations in these countries may face in the conduct of a global clinical trial.				
Articulate the necessity for a homogeneous patient population and consistency in protocol recruitment				
Describe implications of deviations from inclusion/exclusion criteria on data quality and study validity & results generalizability.				
Develop study materials to ensure application of inclusion/exclusion criteria.				
Determine eligibility of study participants for complex studies (e.g., biomedical or interventional).				
DOMAIN 3: Investigational Products Development and Regulation: *Encompasses knowledge of how investigational products are developed and regulated*				
Rating Scale *0 = N/A, 1 = Needs Development, 2= Appropriate to career stage, and 3= Strength*	*0*	*1*	*2*	*3*
Demonstrate an understanding of current events that inform guidelines & regulatory processes with FDA regulations/guidelines and those on a global scale.				
List specific roles and responsibilities for each of the institutions participating in the investigational products development process (investigators, sponsors, CROs and regulatory bodies).				
Recognize the scope of responsibilities of monitoring organizations like Research Pharmacy, Data Safety Monitoring Boards.				
Interpret and execute the concepts, major elements, and objectives of investigational products development life cycle management process for medical products.				
Describe and apply federal (US, EMA, or other) regulatory laws & guidance during the performance of complex clinical research operations.				
Interpret the requirements of ICH GCP, the approved study protocol and sponsor study related SOPs.				
Execute the development or editing of study related SOPs, reports, and / or submission for the relevant regulatory approval of the study.				
Participate in implementation of Phase 1-3 clinical trials.				
Differentiate between the purposes of the IND, NDA, BLA & each phase of clinical development and the research questions answered at each phase.				
Assess occurrence & coordinate with PI on classification of adverse events during a clinical trial.				
Complete & submit adverse event reports, according to appropriate requirements & timeline.				

Compare regional regulations and how their differences could impact the conduct of trials or the review of medical product approvals.				
DOMAIN 4: Clinical Study Operations (Good Clinical Practice): *Encompasses study management and GCP compliance; safety management (adverse event identification and reporting, post-market surveillance, and pharmacovigilance), and handling of investigational product*				
Rating Scale *0 = N/A, 1 = Needs Development, 2= Appropriate to career stage, and 3= Strength*	*0*	*1*	*2*	*3*
Review & comment on trial protocols to ensure the links between the objective of developing a new intervention and the related trial goal and design is accurate.				
Provide input/share ideas, proactively/reactively, on trial design.				
Describe how GCP principles are incorporated into clinical research.				
Describe roles and responsibilities of IRB and sponsors as set forth in federal regulations and GCPs.				
Performs role in accordance with GCP guidelines.				
Participate in the implementation of a clinical research protocol & assure that, with minimal supervision, the ICH Good Clinical Practice Guidelines are being followed during the conduct of research procedures and data collection				
Assist in the identification of country-specific regulations that apply during a clinical study.				
Apply current processes/procedures for global regulatory agency application requirements clinical studies.				
Articulate the specific procedures & elements for control, storage & dispensing of investigational product.				
Determine deviations in the process of handling study medication and report /solve the issue.				
Differentiate the reporting timelines and requirements for an SAE and SUSAR across various international guidelines (e.g., FDA, EMA, ICH, etc.)				
Execute the reporting of an SAE to the appropriate entity based on their respective role .				
Apply appropriate protection and privacy safeguards when conducting clinical studies.				
Report situations when human research subjects may require protection & privacy.				
Recognize existing global regulations & local rules differ among countries in protecting human research subjects & their privacy.				
Employ and implement the clinical monitoring plan to complete monitoring tasks/activities.				
Address complex monitoring issues with minimal supervision or guidance.				

Provide guidance to others to resolve simple & moderately complex monitoring issues.				
Distinguish between scope of audits conducted by sponsors, IRB and regulatory authority.				
Identify research components inspected during a clinical study audit.				
Distinguish between routing and for-cause audits and inspections.				
Execute safety reporting within required timelines through appropriate channels.				
Classify safety issues and report them to regulatory authorities and IRBs.				
Implement international guidelines and requirements across relevant agencies (e.g., FDA, EMA, ICH, etc.).				
Relate safety issues according to monitoring and pharmacovigilance plans.				
DOMAIN 5: Study and Site Management: *Encompasses content required at the site level to run a study (financial and personnel aspects). Includes site and study operations (not encompassing regulatory/GCPs)*				
Rating Scale *0 = N/A, 1 = Needs Development, 2= Appropriate to career stage, and 3= Strength*	*0*	*1*	*2*	*3*
Provide input and guidance in the study selection process, including the ability to assess financial and logistical feasibility of conducting a study at the research site.				
Assist in organizing and conducting pre-site visits.				
Assist in estimating budgets for a potential study.				
Critique and recommend changes to proposed financial budgets, timelines, and amount/type of personnel necessary to conduct a clinical study.				
Monitor the progress of a clinical study towards milestones and identify trends or risks during study execution. Implements mitigation plans.				
Identify and understand the importance of the quality management plan (QMP) and teach others about the overall scope of the QMP.				
Implement risk mitigation steps as defined in the plan and develop a strategy to educate others on its content and application.				
Interpret subject recruitment and retention tracking data to determine if changes are needed.				
Develop basic methods for capturing and reporting on recruitment and retention.				
Apply local and international regulatory requirements to the use of different recruitment tools.				

Organize and appropriately process contracts, materials transfer agreements, budgets, indemnification agreements, confidentiality agreements and conflict of interest reporting.				
Develop and/or follow SOPs that mitigate legal risks in conducting clinical trials.				
Understand and articulate applicable regulations and accurately follow established processes in place to ensure compliance.				
Describe the various team roles (Sponsor, PI) and their responsibilities in the compliant conduct of clinical research.				
Describe the impact of compliance on the safe and ethical conduct of clinical research studies.				
DOMAIN 6: Data Management and Informatics: *Encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database*				
Rating Scale *0 = N/A, 1 = Needs Development, 2= Appropriate to career stage, and 3= Strength*	*0*	*1*	*2*	*3*
Perform randomization activities to ensure accurate designation of new study participants.				
Describe the statistical requirements to answer the study question (hypothesis) in a study protocol.				
Apply all aspects of the clinical data management plan (CDMP) to an active clinical study with regards to the flow of data from the site to the clinical database as well as the flow of data from other sources, for example laboratory electronic uploads, EMR transfers, etc.				
Manage queries and recommend whether the flow and quality of the clinical data meets the standards set in the CDMP.				
Implement industry, federal and GCP accepted standards and best practices for data management.				
Perform data management activities across clinical studies from creation of protocol specific source documents, collection and entry of data and performing quality audits.				
Independently ensure compliance with data quality related SOP.				
Provide input and share ideas, pro- and reactively, related to data quality and the related processes.				
DOMAIN 7: Leadership and Professionalism: *Encompasses the principles and practice of leadership and professionalism in clinical research*				
Rating Scale *0 = N/A, 1 = Needs Development, 2= Appropriate to career stage, and 3= Strength*	0	1	2	3
Assist in study management using effective communication methods and documentation.				

Train and mentor Fundamental Level staff.				
Demonstrate effective time management and organizational skill when managing multiple research related projects.				
Recognize, implement, and manage the procedures in a clinical research study to minimize the risks of ethical/professional conflicts.				
Implement risk management strategies within role responsibilities.				
Apply professional/ethical regulations and international guidelines in each facet of clinical research.				
Demonstrate through actions & documentation of tasks during the conduct of clinical research an understanding of how procedures/processes assure professional/ethical conduct.				
Apply regional/country and cultural considerations during study design and conduct .				
Incorporate the regulatory requirements during the implementation of multi-country trials.				
DOMAIN 8: Communications and Teamwork: *Encompasses all elements of communication within the site and between the site and sponsor, CRO, and regulators. Understanding of teamwork skills necessary for conducting a clinical trial.*				
Rating Scale *0 = N/A, 1 = Needs Development, 2= Appropriate to career stage, and 3= Strength*	**0**	**1**	**2**	**3**
Apply professional communication practices written & verbal interactions with other parties to maintain legal/productive relationships during the research study.				
Describe methods of a published study and basis for the conclusions made from the results obtained.				
Search literature using key terms to find articles on specific subjects.				
Explain the difference between a primary source and a secondary source in professional literature.				
Identify & facilitate the activities essential to ensuring effective team operations during a clinical study.				
Demonstrate an understanding of the cross-functional team in a communication plan.				

References

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