JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Leveling the Harmonized Core Competency Framework for the Clinical Research Professional
Version 3.0

A clickable, downloadable Harmonized Core Competency Framework, with links to leveled competencies, is posted on the JTF website (www.clinicaltrialcompetency.org). Please do not hesitate to provide feedback and further suggestions to mrct@bwh.harvard.edu. Any use of the Competencies should acknowledge the source.

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The Joint Task Force for Clinical Trial Competency (JTF) is a multi-stakeholder group hosted by the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center). The goal of the JTF is to develop clinical research professional competencies. A universal Core Competency Framework for the Clinical Research Profession was originally published in 2014. Since its release, the Framework has been utilized worldwide by organizations involved in clinical research, addressing a critical gap in clinical research.

In order to address the dynamic nature of clinical research enterprise, the JTF revised and released Version 2.0 of the Framework (https://www.clinicaltrialcompetency.org) in September of 2017. The JTF has now developed core competency expectations at different levels of experience. This 'leveling' enables the competencies to be used in the development of standardized role descriptions, assessment and evaluation (including potential self-evaluation), and potential promotion, development of educational and training resources, and individual portfolio creation. The JTF Version 3.0 Framework includes competency statements at the Fundamental, Skilled and Expert levels, with specific examples of each to guide the user in their application. The Framework was published in October 2018.*

The levels are defined as follows:

Fundamental - "Can perform the task/and or exhibit the knowledge at an essential or fundamental level; may require some coaching or supervision"

Skilled - "Can perform task or skill independently, consistently, accurately, and has a moderate level of expertise. Efficient and high-quality work; able to independently navigate resources and uses tools well"

Advanced - "Demonstrates advanced skills and knowledge and the ability to teach, coach, or supervise others. Consistently applies critical thinking and problem solving"

**See*: Sonstein SA, Namenek Brouwer RJ, Gluck W, Kolb HR, Aldinger C, Bierer BE, Jones CT. Leveling the joint task force core competencies for clinical research professionals. *Therapeutic innovation & regulatory science*. 2018 Oct 18:2168479018799291. *And* Sonstein SA, Jones CT. Joint Task Force for Clinical Trial Competency and Clinical Research Professional Workforce Development. Frontiers in pharmacology. 2018 Oct 16. doi.org/10.3389/fphar.2018.01148.

Core Competency Framework for the Clinical Research Professional, Version 3.0 FUNDAMENTAL, SKILLED and ADVANCED LEVEL		
A. Fundamental Level	**B. Skilled Level**	**C. Advanced Level**
DOMAIN 1: Scientific Concepts and Research Design: *Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials*		
1.1 Apply principles of biomedical science to investigational product discovery and development and health-related behavioral interventions		
A1. **Recognize** the need to apply scientific principles to discovery and development of biomedical investigational products and health-related behavioral interventions A2. **Explain** the basic scientific principles that should be applied during development of biomedical investigational products and health-related behavioral interventions	B1. **Apply** scientific principles when implementing a clinical or behavioral study B2. **Implement** data collection according to scientific principles and based on protocol design	C1. **Plan** biomedical research according to scientific principles C2. **Develop** a data management plan according to scientific principles
1.2 Identify scientific questions that are potentially testable clinical research hypotheses		
A1. **Articulate** the purpose of the study A2. **Describe** the importance of the study	B1. **Identify** the research hypothesis in a study protocol B2. **Identify** endpoints (primary and secondary) that will be used in data analyses to measure outcomes	C1. **Develop** protocol or source document checklist language that identifies the scientific questions (hypotheses), primary objectives, secondary objectives, and associated endpoints C2. **Align** parameters for collecting data on endpoints with objectives
1.3 Identify the elements and explain the principles and processes of designing a clinical study		
A1. **Identify** the key elements of a clinical study protocol A2. **Describe** the general process of clinical study protocol development A3. **Recognize** the basic differences between the various types of clinical studies	B1. **Review** a clinical study protocol to ensure all needed elements are included	C1. **Evaluate** the clinical study design and **make adjustments** to the processes as needed C2. **Develop** protocols as applicable to the therapeutic area C3. **Evaluate** strengths and weakness of study designs and explain these to others
1.4 Critically analyze clinical study results		
A1. **Identify** the study results A2. **Describe** the relevance of the results to the research question	B1. **Compare and assess** the level of quality of results associated with study reports and publications B2. **Understand** descriptive and exploratory data analysis	C1. **Assess** the potential for application of findings C2. **Identify** trends and anomalies within the clinical study data
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*		
2.1 Differentiate between standard of care and clinical study activities		
A1. **Explain** that a clinical study is unconfirmed research and not accepted standard of care	B1. **Demonstrate** the importance of conducting clinical trial activities as per the protocol	C1. **Develop** a protocol that appropriately includes distinct research activities and standard of care

A. Fundamental Level	B. Skilled Level	C. Advanced Level
2.2 Define the concepts of "clinical equipoise" and "therapeutic misconception" as they relate to the conduct of a clinical study		
A1. **Recognize** that clinical equipoise and therapeutic misconception are fundamental ethical principles and concerns that underlie clinical research	B1. **Explain** the rationale of clinical equipoise and therapeutic misconception, and can demonstrate comprehensive knowledge and understanding of how they may impact patient understanding B2. Consistently **apply** knowledge of clinical equipoise and therapeutic misconception during the course of the study B3. **Recognize, interpret,** and seek assistance where required to address participant concerns regarding therapeutic misconception or clinical equipoise	C1. **Act** as an expert resource to potential study participants and staff in their understanding of clinical equipoise and therapeutic misconception
2.3 Apply relevant national and international principles of human subject protections and privacy throughout all stages of a clinical study		
A1. **Explain** the importance of complying with global guidelines and recommendations, as well as local regulations regarding the safety, wellbeing, and rights of all subjects participating in a clinical trial anywhere	B1. Critically **appraise and implement** within a clinical study protocol, the principles of human subject protection and privacy	C1. **Supervise** the implementation of activities required to protect a clinical study participant´s privacy, safety, wellbeing, and rights in a clinical trial being conducted in any region C2. **Respond** to questions posed by a regulatory body (e.g. IRB.IEC) regarding the methods by which a clinical study protects the privacy and safety of participants.
2.4 Explain the evolution of the requirement for informed consent from research participants and the principles and content of key documents that help ensure the protection of human participants in clinical research		
A1. **Identify** the historical events which have led to the development of the current informed consent regulations A2. **Identify** the key documents that ensure the protection of human participants in clinical research (Declaration of Helsinki, Belmont Report, CIOMS, Nuremberg report, ICH guidelines, Investigators Brochure, product label, etc.)	B1. **Recognize** the critical nature of communicating the potential risks or hazards, as well as the benefits of a clinical study, using terminology and a manner that is understandable by the potential study participants during the informed consent process B2. **Apply** knowledge of the key doctrines and tenants for the regulations and guidelines coupled with available safety information when drafting an informed consent document for a clinical study	C1. **Implement** processes and control measures to ensure human subject protection regulations requirements are met across studies C2. **Evaluate** the informed consent document in relationship to the study protocol to assure that it not only meets current regulations and guidelines but also provides the information needed for a potential study participant to make an informed decision regarding their participation in the study

A. Fundamental Level	B. Skilled Level	C. Advanced Level
2.5 Describe the ethical issues involved when dealing with vulnerable populations and what additional safeguards should be in place for those populations		
A1. **Identify** which populations are considered vulnerable A2. **Understand** that regulations are in place to protect vulnerable populations	B1. Accurately **apply** the appropriate safeguards with research participants B2. **Anticipate** situations when research participants may be considered vulnerable	C1. **Evaluate** a study protocol to identify whether population is properly protected or additional safeguards are needed C2. **Create** strategies to engage vulnerable populations in research studies to allow them to make the best decision C3. **Evaluate** unique situations that affect participation of vulnerable patients C4. **Evaluate** whether vulnerable populations require special considerations from IRBs or regulatory authorities
2.6 Evaluate and apply an understanding of the relevant ethical issues and cultural variation as it applies to the commercial aspects of the clinical research and investigational product development process		
A1. **Recognize** the cultural variations which exist when conducting multi-regional clinical trials for new investigational product development A2. **Explain** the concept of cultural competency and how it relates to the conduct of clinical research in diverse population groups	B1. **Compare and contrast** the ethical principles guiding clinical research across different global regions (e.g., ICH guidelines vs. FDA regulations, other country regulations) B2. **Examine** the pros and cons of conducting clinical trials in low and middle-income countries and **differentiate** the potential types of exploitation and benefits that populations in these countries may face in the conduct of a global clinical trial	C1. **Assure** that clinical trials incorporate concepts which recognize varying cultural perspectives and ethical issues across regions C2. **Develop strategies** to select clinical trial sites that appropriately balance the need to provide equal access to potential treatments
2.7 Explain why inclusion, exclusion, and other criteria are included in a clinical protocol to assure human subject protection		
A1. **Recognize** the eligibility criteria for study participants (e.g., that include and exclude subjects) based on factors such as age, gender, the type and stage of a disease, treatment history, and other medical conditions that allows the research team to determine whether the subjects can take part in the study safely A2. **Determine** potential eligibility of study participants for a non-complex study (e.g., registries, survey studies)	B1. **Articulate** the necessity for a homogeneous patient population (based on criteria defined in the protocol) and the need for consistency in protocol recruitment B2. **Describe** the implications of deviations from inclusion/exclusion criteria on data quality and study validity and how results can be generalized to the public B3. **Develop** study materials (e.g., guidance documents, recruitment plans) to ensure appropriate application of inclusion/exclusion criteria B4. **Determine** potential eligibility of study participants for complex studies (e.g., biomedical or interventional)	C1. **Develop and edit** eligibility criteria for new protocol development C2. **Explain** the rationale for choosing inclusion and exclusion criteria based on evidence or previous experience

A. Fundamental Level	B. Skilled Level	C. Advanced Level
2.8 Summarize the principles and methods of distributing and balancing risk and benefit; through selection and management of clinical study subjects		
A1. **Recognize** the processes (e.g., inclusion/exclusion, study procedures, adverse event identification and documentation, continuation of the study) that appropriately balance risk and benefit	B1. **Implement** the processes (e.g., inclusion/exclusion, study procedures, adverse event identification and documentation, continuation of the study) that appropriately balance risk and benefit	C1. **Develop** the processes (e.g., inclusion/exclusion, study procedures, adverse event identification and documentation, continuation of the study) that appropriately balance risk and benefit C2. **Illustrate** the risk and benefits principles and methods while **designing** and/or **providing oversight** through the selection and management of clinical study subjects
DOMAIN 3: Investigational Products Development and Regulation: *Encompasses knowledge of how investigational products are developed and regulated*		
3.1 Discuss the historical events that precipitated the development of governmental regulatory processes for investigational products		
A1. **Identify** the key historical events that took place which influenced the current regulatory environment that exists today (both FDA and internationally)	B1. Demonstrate an understanding of current events that have influenced guidelines and regulatory processes with regards to FDA regulations and guidelines as well as those on a global scale	C1. **Predict and/or construct** adaptation plans for the new releases of existing regulations and ICH Guidelines C2. **Support** cross-functional team efforts, provide teaching to internal staff, investigators, and other stakeholders about pending or current guidance or regulations, such as the documentation about training planned for updated ICH E6
3.2 Describe the roles and responsibilities of the various institutions participating in the investigational products development process		
A1. **Identify** differences between responsibilities of investigators, sponsors, CROs and regulatory bodies A2. **Demonstrate** understanding of the role of IRBs in approving protocols, assessing risk, and determining exemptions	B1. **List** specific roles and responsibilities for each of the institutions participating in the investigational products development process, (investigators, sponsors, CROs and regulatory bodies) B2. **Recognize** the scope of responsibilities of monitoring organizations like Research Pharmacy, Data Safety Monitoring Boards	C1. **Evaluate** the study protocol to determine the need for collaboration between various institutions/organizations C2. **Define** the roles and responsibilities of the institutions required to complete a research project
3.3 Explain the investigational products development process and the activities which integrate commercial realities into the life cycle management of medical products		
A1. **Understand** concepts, major elements and objectives of investigational products development life cycle management process for investigational products	B1. Interpret and **execute** the concepts, major elements, and objectives of investigational products development life cycle management process for medical products	C1. **Evaluate** an established or create a strategic investigational products development and life cycle management plan C2. **Coordinate** an IP development plan with regulatory authorities C3. **Distinguish** between the regulatory approval processes for drugs, biologics and medical devices

A. Fundamental Level	B. Skilled Level	C. Advanced Level
3.4 Summarize the legislative and regulatory framework that supports the development and registration of investigational products and ensures their safety, efficacy and quality		
A1. **Describe** how to access the appropriate regulatory guidance that applies to the development and registrations of IMPs, and the clinical trials process required to register such products in their geographical location. (US-FDA, Europe-EMA, UK-MHRA) A2. **Demonstrate** basic knowledge of Human Subjects Protection and ICH GCP guidelines	B1. **Describe and apply** federal (US, EMA, or other) regulatory laws and guidance during the performance of complex clinical research operations. B2. **Interpret** the requirements of ICH GCP, the approved study protocol and sponsor study related SOPs. B3. **Execute** the development or editing of study related SOPs, reports, and / or submission for the relevant regulatory approval of the study.	C1. **Provide oversight and train** others in relation to the relevant authority and associated regulatory frameworks, including how these harmonize with ICH GCP, the approved study protocol, and sponsor study related SOPs to ensure the safety and rights of study participants C2. **Monitor** the progress and assure that conduct of studies at site meets local, national and global regulatory frameworks, and support others to meet such requirements in the conduct of trials.
3.5 Describe the specific processes and phases that must be followed for the regulatory authority to approve the marketing authorization for a medical product		
A1. **Describe** the specific activities and purposes of preclinical and clinical research and how they contribute to the filing of an IND and an NDA/CTA/BLA A2. **Recognize** how Phase 1-3 data contributes to the filing of an IND and NDA	B1. Actively **participate** in the implementation of Phase 1-3 clinical trials B2. **Differentiate** between the purposes of the IND, NDA, BLA and each phase of clinical development and the relationship of research questions answered at each phase	C1. **Appraise** the potential and resources required for successful implementation of a preclinical or clinical research protocol C2. **Supervise** the development, clinical planning and implementation of a preclinical or clinical research protocol intended to contribute to a regulatory submission (e.g., IND, BLA, NDA) or clinical program
3.6 Describe the pre- and post- approval safety reporting requirements of regulatory agencies		
A1. **Identify** the differences between adverse event reporting requirements for studies pre- and post- marketing approval A2. **Understand** the reporting requirements for different types of adverse events	B1. **Assess** the occurrence and coordinate with investigator on classification of adverse events during the conduct of a clinical trial B2. **Complete and submit** adverse event reports, according to appropriate requirements and timeline	C1. **Identify** and **interpret** safety data (e.g., safety signals or data from surveillance systems) C2. **Mentor** and **teach** others to compare and contrast safety reporting requirements that may differ by region C3. **Comply** with a REMS program.
3.7 Appraise the issues generated and the effects of global expansion on the approval and regulation of medical products		
A1. **Recognize** that different national regulations may affect the medical product approval process	B1. Compare regional regulations and how their differences could impact the conduct of trials or the review of medical product approvals	C1. **Develop** and **implement** strategies for the conduct of multi-regional clinical trials C2. **Develop** and **implement** global strategies that optimize the required review and approval of a marketing application C3. **Analyze** the resources necessary to gain approval for medical products in multiple countries

A. Fundamental Level	B. Skilled Level	C. Advanced Level
DOMAIN 4: Clinical Study Operations (Good Clinical Practice): *Encompasses study management (adverse event identification and reporting, post-market surveillance, and pharmacovigilance), and handling of investigational product.*		
4.1 Explain how the design, purpose, and conduct of individual clinical studies fit into the goal of developing a new intervention		
A1. **Identify** the link between developing a new intervention and the interrelated trial goals and design by reading and comprehending a clinical trial protocol	B1. **Review** and **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 B2. **Provide** input and share ideas, proactively and reactively, on trial design	C1. **Design** a clinical trial independently to ensure an accurate link between the goal of developing a new intervention and the trial goal C2. **Train, supervise, and coach** junior trial designers
4.2 Describe the roles and responsibilities of the clinical investigation team as defined by Good Clinical Practice Guidelines		
A1. **Describe** basic principles of GCP A2. **Describe** own role and is aware of roles of others in the site clinical investigation team as set forth by the institution or organization, regulations and GCPs A3. **Understand** the concepts of delegation of authority and scope of practice	B1. **Describe** how GCP principles are incorporated into clinical research B2. **Describe** roles and responsibilities of IRB and sponsors as set forth in federal regulations and GCPs B3. **Performs** role in accordance with GCP guidelines	C1. **Apply** GCP Guidelines to the conduct of clinical research C2. **Review and assess** all roles in the clinical investigation team C3. **Supervise** clinical investigation team members C4. **Perform audits** of clinical research performance to ensure compliance with GCPs
4.3 Evaluate the design, conduct and documentation of clinical studies as required for compliance with Good Clinical Practice Guidelines		
A1. Following training, **describe** how the ICH Good Clinical Practice Guidelines are incorporated into the design of a research protocol, the procedures followed during the conduct of a clinical study and the collection of data relating to the study	B1. Successfully **participate in the implementation** of a clinical research protocol and **assure** that, with minimal supervision, the ICH Good Clinical Practice Guidelines are being followed during the conduct of research procedures and the collection of data	C1. **Ensure** that the operationalization of a clinical research study complies with ICH Clinical Practice Guidelines, C2. Appropriately **resolve** any compliance related issues which arise during the conduct of the clinical study, C3. **Ensure** that the personnel conducting the study are appropriately trained
4.4 Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical studies		
A1. **Describe** the role of global regulatory bodies in the conduct of clinical studies A2. **Identify** the various global regulatory agencies and their respective country-specific regulations A3. **Recognize** the differences in the global regulation of drugs, biologics, and medical devices	B1. **Assist** in the identification of country-specific regulations which apply during the conduct of a clinical study B2. **Apply** current processes and procedures for the global regulatory agency application requirements for clinical studies	C1. **Create** processes and procedures to determine feasibility for global studies C2. **Determine** and schedule the proper regulatory application requirements and timeframes for study applications C3. **Provide mentoring and educate** others on the global regulatory landscape with respect to the identification of potential clinical sites and the initiation and conduct of clinical studies

A. Fundamental Level	B. Skilled Level	C. Advanced Level
4.5 Describe appropriate control, storage and dispensing of investigational product		
A1. **Understand** that investigational products require specific control, storage and dispensing A2. **Identify** and follow existing Standard Operating Procedures for control, storage, and dispensing of IP	B1. **Articulate** the specific procedures and elements for control, storage and dispensing of investigational product B2. **Determine** deviations in the process of handling study medication and report /solve the issue	C1. **Develop** SOPs that include specific procedures and elements for control, storage and dispensing of investigational product C2. **Develop** CAPAs when issues in the handling of study medication are detected in order to avoid further deviations
4.6 Differentiate the types of adverse events (AEs) that may occur during clinical studies and explain the identification process and reporting requirement to IRBs/IECs, sponsors and regulatory authorities		
A1. **Recognize** the differences between the different types of adverse events A2. **Recognize** when an SAE occurs during the conduct of a clinical trial and report it within the appropriate time frame per the regulatory regulations	B1. **Differentiate** the reporting timelines and requirements for an SAE and SUSAR across various international guidelines (e.g., FDA, EMA, ICH, etc.) B2. **Execute** the reporting of an SAE to the appropriate entity (sponsor, regulatory agency, IRB/IEC) based on their respective role (e.g., investigator, CRA, sponsor)	C1. **Critique** the SUSAR reporting requirements across various agencies and entities and **formulate** new recommendations to enhance the harmonization of reporting requirements
4.7 Describe how global regulations and guidelines assure human subject protection and privacy during the conduct of clinical studies		
A1. **Understand** that human research subjects are entitled to protection and privacy and that global regulations are in place to protect research subjects during the conduct of clinical studies A2. **Locate** the specific regulations associated with the protection and privacy of human research subjects	B1. **Apply** appropriate protection and privacy safeguards when conducting clinical studies B2. **Report** situations when human research subjects may require protection and privacy B3. **Recognize** the existing global regulations and local rules which differ among countries regarding to protect human research subjects and their privacy?	C1. **Create** strategies to protect human research subjects and guard their privacy in clinical studies C2. **Evaluate** whether protection and privacy strategies are appropriate C3. **Develop and implement** a global investigation strategy with global and local regulations to protect human research subjects and their privacy
4.8 Describe the role and process of monitoring a clinical study		
A1. **Recognize and understand** the rationale for clinical monitoring and the appropriate regulations and ICH guidance that applies A2. **Adhere to** the monitoring plan and applicable standard operating procedures A3. With guidance and oversight, **perform** monitoring tasks per the monitoring plan and inform others when confronted with issues not detailed in the monitoring plan	B1. **Employ and implement** the clinical monitoring plan to complete monitoring tasks/activities B2. **Address** complex monitoring issues with minimal supervision or guidance B3. **Provide guidance** to others to **resolve** simple and moderately complex monitoring issues	C1. **Lead** the monitoring effort by mentoring others in the planning and conduct of monitoring site visits C2. **Oversee the creation and planning** of study-specific monitoring plans that assure sufficient resources are allocated to ensure timely review of data while maintaining established standards for study participant safety and data integrity

A. Fundamental Level	B. Skilled Level	C. Advanced Level
4.9 Describe the role and purpose of clinical study audits		
A1. **Describe** the steps taken to prepare for an audit/inspection A2. **Name** the entities which have authority to conduct audits A3. **Locate and explain** the federal regulations governing audits and inspections	Researcher meets the Fundamental Level AND can: B1. **Distinguish** between scope of audits conducted by sponsors, IRB and regulatory authority B2. **Identify** research components inspected during a clinical study audit B3. **Distinguish** between routing and for-cause audits and inspections	C1. **Supervise** preparation for an audit/inspection conducted by a sponsor or regulatory authority C2. **Develop** policies and SOPs in response to audit/inspection findings
4.10 Describe the various methods by which safety issues are identified and managed in clinical studies		
A1. **Understand** that safety is a central issue in clinical trials and that lack of safety oversight can jeopardize participants in numerous ways A2. **Recognize** the tools and processes implemented in a clinical trial to protect participants A3. **Remember** to report suspicious activities or events which might compromise safety	B1. **Execute** safety reporting within required timelines through appropriate channels B2. **Classify** safety issues and report them to regulatory authorities and IRBs B3. **Implement** international guidelines and requirements across relevant agencies (e.g., FDA, EMA, ICH, etc.) B4. **Relate** safety issues according to monitoring and pharmacovigilance plans	C1. **Anticipate** possible safety issues during the clinical study implementation C2. **Institute** measures to minimize risks C3. **Critique and improve** monitoring and pharmacovigilance plans C4. **Recommend and conduct** safety training for study teams
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)*		
5.1 Describe the methods used to determine whether to sponsor, supervise or participate in a clinical study		
A1. **Demonstrate** a basic understanding of baseline determinants of new study selection process at a research site A2. **Understand** the purpose of pre-site evaluation visits A3. **Participate** in virtual or face-to-face pre-site visits	B1. **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 B2. Assist in **organizing and conducting** pre-site visits B3. Assist in **estimating** budgets for a potential study.	C1. **Guide** study selection on a program or institutional level C2. **Defend** study selection decision-making, including determination of scientific validity and value; favorable risk/benefit ratio, and operational (logistical and financial) feasibility C3. **Lead** the negotiation, creation of tools, guidance documents, and policies to **guide** the decision-making process in study selection and participation

A. Fundamental Level	B. Skilled Level	C. Advanced Level
5.2 Develop and manage the financial, timeline, and personnel resources necessary to conduct a clinical study		
A1. **Identify** the component parts of a clinical trial budget	B1. **Critique** and recommend changes to proposed financial budgets, timelines, and amount/type of personnel necessary to conduct a clinical study B2. **Monitor** the progress of a clinical study towards milestones and **identify** trends or risks during study execution. Implements mitigation plans	C1. **Develop** the budget, timeline and/or personnel resources to conduct a clinical study; C2. **Identify** trends and **implement** mitigation plans C3. **Manage** personnel that is assigned to the clinical study
5.3 Describe the management and training approaches to mitigate risk to improve clinical study conduct		
A1. **Identify** the mechanisms used in a research study that have been put in place to mitigate risk A2. **Understand** how risk assessments are conducted for clinical study operations and patient safety	B1. **Identify and understand** the importance of the quality management plan (QMP) and **teach** others about the overall scope of the QMP B2. **Implement** risk mitigation steps as defined in the plan and **develop** a strategy to educate others on its content and application	C1. **Develop** both generalized and study-specific QMP training programs and delivers these programs to others. C2. **Define** key performance indicators for the clinical studies and **incorporate** them into the study specific QMP. C3. **Interpret** internal QA data on key performance indicators and **strategize** to mitigate risk through a corrective and preventive action (CAPA) plan.
5.4 Develop strategies to manage participant recruitment, retention, compliance and track study activities.		
A1. **Articulate** expected recruitment and retention rates A2. **Identify** and use tools, strategies, and procedures for implementation and tracking of participant recruitment and retention A3. **Describe** local and international regulatory requirements that impact the use of different recruitment tools	B1. **Interpret** subject recruitment and retention tracking data to determine if changes are needed B2. **Develop** basic methods for capturing and reporting on recruitment and retention B3. **Apply** local and international regulatory requirements to the use of different recruitment tools	C1. **Innovate** solutions to recruitment and retention challenges incorporating key ethical considerations. C2. **Propose** different recruitment tools based on regulatory requirements of each region / country
5.5 Identify the legal responsibilities, liabilities and accountabilities that are involved in the conduct of clinical studies		
A1. **Organize and maintain** study regulatory and grants/contracts documents for regulatory and institutional compliance audits A2. **Understand** purpose of study legal materials including: contract, budgets, indemnification, confidentiality disclosure agreements, conflict of interest reporting and IRB approvals in a compliant study site	B1. **Organize** and appropriately **process** contracts, materials transfer agreements, budgets, indemnification agreements, confidentiality agreements and conflict of interest reporting. B2. **Develop** and/or follow SOPs that mitigate legal risks in conducting clinical trials	C1. **Monitor** systems and **collaborate** with institutional bodies to ensure compliance with legal and ethical requirements in the conduct of clinical research at the organization. C2. **Develop and critique** risk mitigation strategies, associated action plans and issue resolution C3. **Negotiate** legal contracts (including budgets), confidentiality agreements, and conflict of interest documents

A. Fundamental Level	B. Skilled Level	C. Advanced Level
5.6 Identify and explain the specific procedural, documentation and oversight requirements of principal investigators, sponsors, CROs and regulatory authorities that relate to the conduct of a clinical study		
A1. **Identify** the regulations and guidelines that describe the requirements that apply to principal investigators, sponsors, CROs, and regulatory authorities in the conduct of clinical research A2. **Describe** roles of the site team members, including PI; sponsor, CRO, institution and FDA	B1. **Understand and articulate** applicable regulations and accurately follow established processes in place to ensure compliance B2. **Describe** the various team roles (Sponsor, PI) and their responsibilities in the compliant conduct of clinical research. B3. **Describe** the impact of compliance on the safe and ethical conduct of clinical research studies	C1. **Apply** advanced understanding of regulations and ability to accurately interpret regulatory guidance and mentor others in the translation of regulations into everyday practice. C2. **Create** strategies, policy and procedures to ensure regulatory compliance at a departmental or institutional level C3. **Organize and manage** regular study-related meetings with study staff and the principal investigators.
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*		
6.1 Describe the role and importance of statistics and informatics in clinical studies		
A1. **Understand** the basic purpose of statistics and informatics as applied in clinical studies (e.g., randomization, sample size, adverse events, analysis, results)	B1. **Perform** randomization activities to ensure accurate designation of new study participants B2. **Describe** the statistical requirements to answer the study question (hypothesis) in a study protocol	C1. **Develop** a statistical analysis and data management plan for a clinical study
6.2 Describe the origin, flow, and management of data through a clinical study		
A1. **Describe** the basic concepts of clinical data management. A2. **Identify** the various sources of data that contribute to a clinical study and can distinguish the different industry standards to be used in their handling.	B1. **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. B2. **Manage** queries and recommend whether the flow and quality of the clinical data meets the standards set in the CDMP.	C1. **Create** the clinical data management plan for a clinical study C2. **Analyze** and **modify** standard operating procedures, when necessary to accommodate the inclusion and implementation of new technology in the data management process or new industry-wide initiatives (e.g. data transparency and clintrials.gov requirements or the MRCT initiatives on data sharing, etc.). C3. **Educate** and **mentor** others concerning their role and responsibility in the conduct and management of clinical data across each aspect of the clinical research enterprise.

A. Fundamental Level	B. Skilled Level	C. Advanced Level
6.3 Describe best practices and resources required for standardizing data collection, capture, management, analysis, and reporting		
A1. **Identify and apply** standard and best practices for data management in clinical research. A2. **Identify** documents and resources related standards and best practices associated with the collection, data capture, data management, data analysis, and data reporting in clinical research.	B1. **Implement** industry, federal and GCP accepted standards and best practices for data management in a clinical study. B2. **Perform** data management activities across clinical studies from creation of protocol specific source documents, collection and entry of data and performing quality audits	C1. **Develop** a data management plan for a clinical study that includes standardized plans for data collection, data capture, data management, data analysis, and data reporting that use industry-accepted standards or best practices.
6.4 Describe, develop, and implement processes for data quality assurance		
A1. **Identify and understand** processes that assure data quality. A2. **Recognize** whether individual pieces of data collected in a clinical study are attributable, accurate, complete and verifiable from the source data.	B1. Independently **ensure** compliance with data quality related SOPs B2. **Provide** input and share ideas, pro- and reactively, related to data quality and the related processes.	C1. **Create/define** data quality related SOPs or study-specific procedures for the conduct of a clinical trial. C2. **Advise** the data management team on data quality related processes that impact the clinical trial team, ensuring a smooth and constructive collaboration and communication between both. C3. **Train** trial staff on data quality related procedures and provide **oversight** and **support** in cases of doubt or risk for non-compliance.
DOMAIN 7: Leadership and Professionalism: *Encompasses the principles and practice of leadership and professionalism in clinical research*		
7.1 Describe and apply the principles and practices of leadership, management and mentorship in clinical research.		
A1. **Display** professionalism in the workplace, in attire, attitude, work-ethic and quality products A2. **Identify** the leadership structure of the organization A3. **Locate, comprehend, and adhere to** the standard operating procedures in the research department A4. **Demonstrate** initiative and team cooperation in performing research duties	B1. **Assist** others with various aspects of study management using effective communication methods and documentation B2. **Train and mentor** Fundamental Level staff B3. **Demonstrate** effective time management and organizational skill when managing multiple research related projects	C1. **Serve in leadership roles** in the research department C2. **Train and mentor** new staff members and team members. C3. **Manage multiple** complex study operations C4. **Set strategic planning goals** and objectives for study performance

A. Fundamental Level	B. Skilled Level	C. Advanced Level
7.2 Identify ethical and professional conflicts associated with the conduct of clinical studies and implement procedures for their prevention or management.		
A1. **Explain** the nature and historical instances of ethical and professional conflicts which occur in the conduct of clinical research A2. **Describe** the procedures which are implemented to prevent ethical conflicts and support risk management strategies	B1. **Recognize, implement, and manage** the procedures in a clinical research study which minimize the risks of ethical and professional conflicts B2. **Implement** risk management strategies within their role responsibilities	C1. **Assess** the risk of ethical and professional conflicts inherent in a clinical study C2. **Develop** strategies and policies to implement and manage risk of ethical and professional conflicts across a project team as well as functional domains
7.3 Identify and apply the professional guidelines and codes of ethics that apply to the conduct of clinical research.		
A1. **Recognize** the key documents which make up the foundation of the regulations that ensure clinical studies are conducted ethically and in a professional manner A2. **Identify and understand** the meaning of ethical and professional behaviors found in both federal regulations and international guidelines addressing ethical conduct in clinical studies.	B1. **Apply** professional and ethical regulations and international guidelines in each facet of clinical research B2. **Demonstrate** through actions and documentation of tasks during the conduct of clinical research an understanding of how appropriate procedures and processes assure professional and ethical conduct throughout clinical research	C1. **Evaluate, and modify** when required, internal policies and procedures to ensure that the organization's code of ethical conduct is in compliance with local law/regulations and/or international guidelines C2. **Mentor (educate) and provide guidance** to all study team and staff members concerning internal processes and procedures which ensure that all aspects of clinical studies are conducted within the bounds of ethical conduct.
7.4 Describe the impact of regional diversity and demonstrate cultural competency in clinical study design and conduct		
A1. **Describe** why it is important to incorporate strategies that account for regional and cultural diversity in the conduct of clinical research A2. **Classify** examples of potential impact that are related to diversity or cultural competency	B1. **Apply** regional/country and cultural considerations during study design and conduct B2. **Incorporate** the appropriate regulatory requirements during the implementation of multi-country trials	C1. **Develop specific strategies** or methods for considering culture and region/country when designing and conducting studies in multiple regions/countries C2. **Validate** that regulatory requirements are incorporated into the study design for 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*		
8.1 Discuss the relationship and appropriate communication between Sponsor, CRO and clinical research site.		
A1. **Understand and describe** the relationships and appropriate communication channels between regulators, sponsors, CROs and research sites	B1. **Apply** appropriate professional communication practices in written and verbal interactions with other parties in order to maintain legal and productive relationships during the conduct of a research study	C1. **Establish and maintain** productive long-term relationships with all participating parties across the research enterprise to sustain efficient, effective and sustainable clinical trials currently and in the future

A. Fundamental Level	B. Skilled Level	C. Advanced Level
8.2 Describe the components of a traditional scientific publication.		
A1. **Identify** the component parts of a scientific publication and the general purpose of each part A2. **Comprehend** that a traditional scientific publication describes the outcomes of a research study in a structured and ordered format to contribute to generalizable knowledge and evidence-based practice	B1. **Describe** the methods for a study that has been published and appreciates the basis for the conclusions made from the results obtained. B2. **Search** the literature using key terms to find articles on specific subjects B3. **Explain** the difference between a primary source and a secondary source when citing the professional literature	C1. **Navigate, appraise and assess** the content of all component parts within a traditional scientific publication and communicate a both detailed understanding to staff C2. **Describe** the relationship of the findings from a clinical study to the relevant human population and current practice context C3. **Write and edit** manuscripts as well as **apply** varying journal citation styles when formatting a manuscript
8.3 Effectively communicate the content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientist community.		
A1. **Explain** the structure and contents of a scientific publication. A2. **Identify and utilize** reliable sources of information which communicate clinical research findings to the scientific and non-scientific communities	B1. **Relate** the content and value of clinical research studies to colleagues and the non-scientific community through professional presentations and other verbal and written means	C1. **Design** reports for scientific and non-scientific communities which interpret and explain clinical trial data and appraise the significance of clinical study reports C2. **Facilitate** the awareness and further understanding of clinical research protocols and their results to colleagues, advocacy groups and the non-scientific community
8.4 Describe the importance of team science and methods necessary to work effectively with multidisciplinary and inter-professional research teams.		
A1. **Describe and understand** the importance of an interdisciplinary team and the values each member can bring to clinical studies A2. **Identify and recognize** each member of the team and their respective roles and responsibilities and understand that communications within a clinical study team is vital to the success of the study	B1. **Identify and facilitate** the activities of the key contacts essential to ensuring effective team operations during a clinical study B2. **Demonstrate** an understanding of the cross-functional team in developing a communication plan	C1. **Mentor** others how to work best on a multi-functional clinical study team C2. **Establish** the core infrastructure of the clinical study team and ensure effective and efficient communication and teamwork C3. **Incorporate** multidisciplinary skills into research teams

JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Joint Task Force for Clinical Trial Competency Levelling Workgroup

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