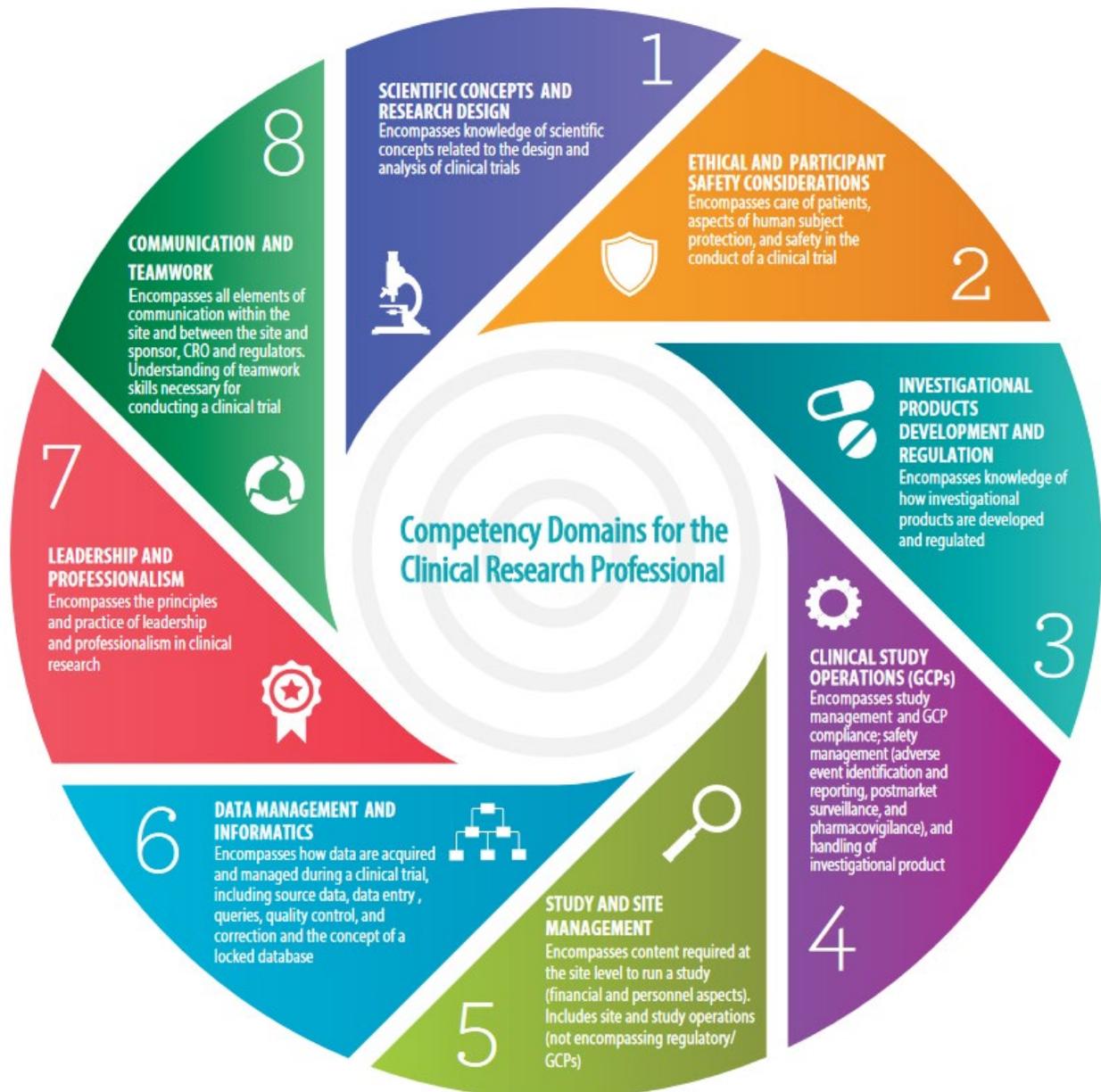


**Leveling the Harmonized Core Competency Framework for the Clinical Research Professional
Version 3.0**



A clickable, downloadable Harmonized Core Competency Framework, with links to leveled competencies, is posted on the JTF website (<https://mrctcenter.org/clinical-trial-competency/>). Please do not hesitate to provide feedback and further suggestions to mrct@bwh.harvard.edu. Any use of the Competencies should acknowledge the source.



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

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://mrctcenter.org/clinical-trial-competency/>) 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.

Leveling the Joint Task Force Core Competencies
<https://mrctcenter.org/clinical-trial-competency/> **March 2019**

mrct@bwh.harvard.edu 

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

<p>A1. Recognize the need to apply scientific principles to discovery and development of biomedical investigational products and health-related behavioral interventions</p> <p>A2. Explain the basic scientific principles that should be applied during development of biomedical investigational products and health-related behavioral interventions</p>	<p>B1. Apply scientific principles when implementing a clinical or behavioral study</p> <p>B2. Implement data collection according to scientific principles and based on protocol design</p>	<p>C1. Plan biomedical research according to scientific principles</p> <p>C2. Develop a data management plan according to scientific principles</p>
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1.2 Identify scientific questions that are potentially testable clinical research hypotheses

<p>A1. Articulate the purpose of the study</p> <p>A2. Describe the importance of the study</p>	<p>B1. Identify the research hypothesis in a study protocol</p> <p>B2. Identify endpoints (primary and secondary) that will be used in data analyses to measure outcomes</p>	<p>C1. Develop protocol or source document checklist language that identifies the scientific questions (hypotheses), primary objectives, secondary objectives, and associated endpoints</p> <p>C2. Align parameters for collecting data on endpoints with objectives</p>
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1.3 Identify the elements and explain the principles and processes of designing a clinical study

<p>A1. Identify the key elements of a clinical study protocol</p> <p>A2. Describe the general process of clinical study protocol development</p> <p>A3. Recognize the basic differences between the various types of clinical studies</p>	<p>B1. Review a clinical study protocol to ensure all needed elements are included</p>	<p>C1. Evaluate the clinical study design and make adjustments to the processes as needed</p> <p>C2. Develop protocols as applicable to the therapeutic area</p> <p>C3. Evaluate strengths and weakness of study designs and explain these to others</p>
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1.4 Critically analyze clinical study results

<p>A1. Identify the study results</p> <p>A2. Describe the relevance of the results to the research question</p>	<p>B1. Compare and assess the level of quality of results associated with study reports and publications</p> <p>B2. Understand descriptive and exploratory data analysis</p>	<p>C1. Assess the potential for application of findings</p> <p>C2. Identify trends and anomalies within the clinical study data</p>
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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

<p>A1. Explain that a clinical study is unconfirmed research and not accepted standard of care</p>	<p>B1. Demonstrate the importance of conducting clinical trial activities as per the protocol</p>	<p>C1. Develop a protocol that appropriately includes distinct research activities and standard of care</p>
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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		
<p>A1. Recognize that clinical equipoise and therapeutic misconception are fundamental ethical principles and concerns that underlie clinical research</p>	<p>B1. Explain the rationale of clinical equipoise and therapeutic misconception, and can demonstrate comprehensive knowledge and understanding of how they may impact patient understanding</p> <p>B2. Consistently apply knowledge of clinical equipoise and therapeutic misconception during the course of the study</p> <p>B3. Recognize, interpret, and seek assistance where required to address participant concerns regarding therapeutic misconception or clinical equipoise</p>	<p>C1. Act as an expert resource to potential study participants and staff in their understanding of clinical equipoise and therapeutic misconception</p>
2.3 Apply relevant national and international principles of human subject protections and privacy throughout all stages of a clinical study		
<p>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</p>	<p>B1. Critically appraise and implement within a clinical study protocol, the principles of human subject protection and privacy</p>	<p>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</p> <p>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.</p>
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		
<p>A1. Identify the historical events which have led to the development of the current informed consent regulations</p> <p>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.)</p>	<p>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</p> <p>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</p>	<p>C1. Implement processes and control measures to ensure human subject protection regulations requirements are met across studies</p> <p>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</p>



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		
<p>A1. Identify which populations are considered vulnerable</p> <p>A2. Understand that regulations are in place to protect vulnerable populations</p>	<p>B1. Accurately apply the appropriate safeguards with research participants</p> <p>B2. Anticipate situations when research participants may be considered vulnerable</p>	<p>C1. Evaluate a study protocol to identify whether population is properly protected or additional safeguards are needed</p> <p>C2. Create strategies to engage vulnerable populations in research studies to allow them to make the best decision</p> <p>C3. Evaluate unique situations that affect participation of vulnerable patients</p> <p>C4. Evaluate whether vulnerable populations require special considerations from IRBs or regulatory authorities</p>
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		
<p>A1. Recognize the cultural variations which exist when conducting multi-regional clinical trials for new investigational product development</p> <p>A2. Explain the concept of cultural competency and how it relates to the conduct of clinical research in diverse population groups</p>	<p>B1. Compare and contrast the ethical principles guiding clinical research across different global regions (e.g., ICH guidelines vs. FDA regulations, other country regulations)</p> <p>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</p>	<p>C1. Assure that clinical trials incorporate concepts which recognize varying cultural perspectives and ethical issues across regions</p> <p>C2. Develop strategies to select clinical trial sites that appropriately balance the need to provide equal access to potential treatments</p>
2.7 Explain why inclusion, exclusion, and other criteria are included in a clinical protocol to assure human subject protection		
<p>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</p> <p>A2. Determine potential eligibility of study participants for a non-complex study (e.g., registries, survey studies)</p>	<p>B1. Articulate the necessity for a homogeneous patient population (based on criteria defined in the protocol) and the need for consistency in protocol recruitment</p> <p>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</p> <p>B3. Develop study materials (e.g., guidance documents, recruitment plans) to ensure appropriate application of inclusion/exclusion criteria</p> <p>B4. Determine potential eligibility of study participants for complex studies (e.g., biomedical or interventional)</p>	<p>C1. Develop and edit eligibility criteria for new protocol development</p> <p>C2. Explain the rationale for choosing inclusion and exclusion criteria based on evidence or previous experience</p>

A. Fundamental Level	B. Skilled Level	C. Advanced Level
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2.8 Summarize the principles and methods of distributing and balancing risk and benefit; through selection and management of clinical study subjects

<p>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</p>	<p>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</p>	<p>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</p> <p>C2. Illustrate the risk and benefits principles and methods while designing and/or providing oversight through the selection and management of clinical study subjects</p>
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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

<p>A1. Identify the key historical events that took place which influenced the current regulatory environment that exists today (both FDA and internationally)</p>	<p>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</p>	<p>C1. Predict and/or construct adaptation plans for the new releases of existing regulations and ICH Guidelines</p> <p>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</p>
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3.2 Describe the roles and responsibilities of the various institutions participating in the investigational products development process

<p>A1. Identify differences between responsibilities of investigators, sponsors, CROs and regulatory bodies</p> <p>A2. Demonstrate understanding of the role of IRBs in approving protocols, assessing risk, and determining exemptions</p>	<p>B1. List specific roles and responsibilities for each of the institutions participating in the investigational products development process, (investigators, sponsors, CROs and regulatory bodies)</p> <p>B2. Recognize the scope of responsibilities of monitoring organizations like Research Pharmacy, Data Safety Monitoring Boards</p>	<p>C1. Evaluate the study protocol to determine the need for collaboration between various institutions/organizations</p> <p>C2. Define the roles and responsibilities of the institutions required to complete a research project</p>
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3.3 Explain the investigational products development process and the activities which integrate commercial realities into the life cycle management of medical products

<p>A1. Understand concepts, major elements and objectives of investigational products development life cycle management process for investigational products</p>	<p>B1. Interpret and execute the concepts, major elements, and objectives of investigational products development life cycle management process for medical products</p>	<p>C1. Evaluate an established or create a strategic investigational products development and life cycle management plan</p> <p>C2. Coordinate an IP development plan with regulatory authorities</p> <p>C3. Distinguish between the regulatory approval processes for drugs, biologics and medical devices</p>
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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		
<p>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)</p> <p>A2. Demonstrate basic knowledge of Human Subjects Protection and ICH GCP guidelines</p>	<p>B1. Describe and apply federal (US, EMA, or other) regulatory laws and guidance during the performance of complex clinical research operations.</p> <p>B2. Interpret the requirements of ICH GCP, the approved study protocol and sponsor study related SOPs.</p> <p>B3. Execute the development or editing of study related SOPs, reports, and / or submission for the relevant regulatory approval of the study.</p>	<p>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</p> <p>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.</p>
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		
<p>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</p> <p>A2. Recognize how Phase 1-3 data contributes to the filing of an IND and NDA</p>	<p>B1. Actively participate in the implementation of Phase 1-3 clinical trials</p> <p>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</p>	<p>C1. Appraise the potential and resources required for successful implementation of a preclinical or clinical research protocol</p> <p>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</p>
3.6 Describe the pre- and post- approval safety reporting requirements of regulatory agencies		
<p>A1. Identify the differences between adverse event reporting requirements for studies pre- and post- marketing approval</p> <p>A2. Understand the reporting requirements for different types of adverse events</p>	<p>B1. Assess the occurrence and coordinate with investigator on classification of adverse events during the conduct of a clinical trial</p> <p>B2. Complete and submit adverse event reports, according to appropriate requirements and timeline</p>	<p>C1. Identify and interpret safety data (e.g., safety signals or data from surveillance systems)</p> <p>C2. Mentor and teach others to compare and contrast safety reporting requirements that may differ by region</p> <p>C3. Comply with a REMS program.</p>
3.7 Appraise the issues generated and the effects of global expansion on the approval and regulation of medical products		
<p>A1. Recognize that different national regulations may affect the medical product approval process</p>	<p>B1. Compare regional regulations and how their differences could impact the conduct of trials or the review of medical product approvals</p>	<p>C1. Develop and implement strategies for the conduct of multi-regional clinical trials</p> <p>C2. Develop and implement global strategies that optimize the required review and approval of a marketing application</p> <p>C3. Analyze the resources necessary to gain approval for medical products in multiple countries</p>



A. Fundamental Level	B. Skilled Level	C. Advanced Level
DOMAIN 4: Clinical Study Operations (Good Clinical Practice): <i>Encompasses study management (adverse event identification and reporting, post-market surveillance, and pharmacovigilance), and handling of investigational product.</i>		
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		
<p>A1. Understand that investigational products require specific control, storage and dispensing</p> <p>A2. Identify and follow existing Standard Operating Procedures for control, storage, and dispensing of IP</p>	<p>B1. Articulate the specific procedures and elements for control, storage and dispensing of investigational product</p> <p>B2. Determine deviations in the process of handling study medication and report /solve the issue</p>	<p>C1. Develop SOPs that include specific procedures and elements for control, storage and dispensing of investigational product</p> <p>C2. Develop CAPAs when issues in the handling of study medication are detected in order to avoid further deviations</p>
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		
<p>A1. Recognize the differences between the different types of adverse events</p> <p>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</p>	<p>B1. Differentiate the reporting timelines and requirements for an SAE and SUSAR across various international guidelines (e.g., FDA, EMA, ICH, etc.)</p> <p>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)</p>	<p>C1. Critique the SUSAR reporting requirements across various agencies and entities and formulate new recommendations to enhance the harmonization of reporting requirements</p>
4.7 Describe how global regulations and guidelines assure human subject protection and privacy during the conduct of clinical studies		
<p>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</p> <p>A2. Locate the specific regulations associated with the protection and privacy of human research subjects</p>	<p>B1. Apply appropriate protection and privacy safeguards when conducting clinical studies</p> <p>B2. Report situations when human research subjects may require protection and privacy</p> <p>B3. Recognize the existing global regulations and local rules which differ among countries regarding to protect human research subjects and their privacy?</p>	<p>C1. Create strategies to protect human research subjects and guard their privacy in clinical studies</p> <p>C2. Evaluate whether protection and privacy strategies are appropriate</p> <p>C3. Develop and implement a global investigation strategy with global and local regulations to protect human research subjects and their privacy</p>
4.8 Describe the role and process of monitoring a clinical study		
<p>A1. Recognize and understand the rationale for clinical monitoring and the appropriate regulations and ICH guidance that applies</p> <p>A2. Adhere to the monitoring plan and applicable standard operating procedures</p> <p>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</p>	<p>B1. Employ and implement the clinical monitoring plan to complete monitoring tasks/activities</p> <p>B2. Address complex monitoring issues with minimal supervision or guidance</p> <p>B3. Provide guidance to others to resolve simple and moderately complex monitoring issues</p>	<p>C1. Lead the monitoring effort by mentoring others in the planning and conduct of monitoring site visits</p> <p>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</p>



A. Fundamental Level	B. Skilled Level	C. Advanced Level
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4.9 Describe the role and purpose of clinical study audits

<p>A1. Describe the steps taken to prepare for an audit/inspection</p> <p>A2. Name the entities which have authority to conduct audits</p> <p>A3. Locate and explain the federal regulations governing audits and inspections</p>	<p>Researcher meets the Fundamental Level AND can:</p> <p>B1. Distinguish between scope of audits conducted by sponsors, IRB and regulatory authority</p> <p>B2. Identify research components inspected during a clinical study audit</p> <p>B3. Distinguish between routing and for-cause audits and inspections</p>	<p>C1. Supervise preparation for an audit/inspection conducted by a sponsor or regulatory authority</p> <p>C2. Develop policies and SOPs in response to audit/inspection findings</p>
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4.10 Describe the various methods by which safety issues are identified and managed in clinical studies

<p>A1. Understand that safety is a central issue in clinical trials and that lack of safety oversight can jeopardize participants in numerous ways</p> <p>A2. Recognize the tools and processes implemented in a clinical trial to protect participants</p> <p>A3. Remember to report suspicious activities or events which might compromise safety</p>	<p>B1. Execute safety reporting within required timelines through appropriate channels</p> <p>B2. Classify safety issues and report them to regulatory authorities and IRBs</p> <p>B3. Implement international guidelines and requirements across relevant agencies (e.g., FDA, EMA, ICH, etc.)</p> <p>B4. Relate safety issues according to monitoring and pharmacovigilance plans</p>	<p>C1. Anticipate possible safety issues during the clinical study implementation</p> <p>C2. Institute measures to minimize risks</p> <p>C3. Critique and improve monitoring and pharmacovigilance plans</p> <p>C4. Recommend and conduct safety training for study teams</p>
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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

<p>A1. Demonstrate a basic understanding of baseline determinants of new study selection process at a research site</p> <p>A2. Understand the purpose of pre-site evaluation visits</p> <p>A3. Participate in virtual or face-to-face pre-site visits</p>	<p>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</p> <p>B2. Assist in organizing and conducting pre-site visits</p> <p>B3. Assist in estimating budgets for a potential study.</p>	<p>C1. Guide study selection on a program or institutional level</p> <p>C2. Defend study selection decision-making, including determination of scientific validity and value; favorable risk/benefit ratio, and operational (logistical and financial) feasibility</p> <p>C3. Lead the negotiation, creation of tools, guidance documents, and policies to guide the decision-making process in study selection and participation</p>
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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
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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

<p>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</p> <p>A2. Describe roles of the site team members, including PI; sponsor, CRO, institution and FDA</p>	<p>B1. Understand and articulate applicable regulations and accurately follow established processes in place to ensure compliance</p> <p>B2. Describe the various team roles (Sponsor, PI) and their responsibilities in the compliant conduct of clinical research.</p> <p>B3. Describe the impact of compliance on the safe and ethical conduct of clinical research studies</p>	<p>C1. Apply advanced understanding of regulations and ability to accurately interpret regulatory guidance and mentor others in the translation of regulations into everyday practice.</p> <p>C2. Create strategies, policy and procedures to ensure regulatory compliance at a departmental or institutional level</p> <p>C3. Organize and manage regular study-related meetings with study staff and the principal investigators.</p>
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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

<p>A1. Understand the basic purpose of statistics and informatics as applied in clinical studies (e.g., randomization, sample size, adverse events, analysis, results)</p>	<p>B1. Perform randomization activities to ensure accurate designation of new study participants</p> <p>B2. Describe the statistical requirements to answer the study question (hypothesis) in a study protocol</p>	<p>C1. Develop a statistical analysis and data management plan for a clinical study</p>
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6.2 Describe the origin, flow, and management of data through a clinical study

<p>A1. Describe the basic concepts of clinical data management.</p> <p>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.</p>	<p>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.</p> <p>B2. Manage queries and recommend whether the flow and quality of the clinical data meets the standards set in the CDMP.</p>	<p>C1. Create the clinical data management plan for a clinical study</p> <p>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.).</p> <p>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.</p>
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A. Fundamental Level	B. Skilled Level	C. Advanced Level
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6.3 Describe best practices and resources required for standardizing data collection, capture, management, analysis, and reporting

<p>A1. Identify and apply standard and best practices for data management in clinical research.</p> <p>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.</p>	<p>B1. Implement industry, federal and GCP accepted standards and best practices for data management in a clinical study.</p> <p>B2. Perform data management activities across clinical studies from creation of protocol specific source documents, collection and entry of data and performing quality audits</p>	<p>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.</p>
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6.4 Describe, develop, and implement processes for data quality assurance

<p>A1. Identify and understand processes that assure data quality.</p> <p>A2. Recognize whether individual pieces of data collected in a clinical study are attributable, accurate, complete and verifiable from the source data.</p>	<p>B1. Independently ensure compliance with data quality related SOPs</p> <p>B2. Provide input and share ideas, pro- and reactively, related to data quality and the related processes.</p>	<p>C1. Create/define data quality related SOPs or study-specific procedures for the conduct of a clinical trial.</p> <p>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.</p> <p>C3. Train trial staff on data quality related procedures and provide oversight and support in cases of doubt or risk for non-compliance.</p>
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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.

<p>A1. Display professionalism in the workplace, in attire, attitude, work-ethic and quality products</p> <p>A2. Identify the leadership structure of the organization</p> <p>A3. Locate, comprehend, and adhere to the standard operating procedures in the research department</p> <p>A4. Demonstrate initiative and team cooperation in performing research duties</p>	<p>B1. Assist others with various aspects of study management using effective communication methods and documentation</p> <p>B2. Train and mentor Fundamental Level staff</p> <p>B3. Demonstrate effective time management and organizational skill when managing multiple research related projects</p>	<p>C1. Serve in leadership roles in the research department</p> <p>C2. Train and mentor new staff members and team members.</p> <p>C3. Manage multiple complex study operations</p> <p>C4. Set strategic planning goals and objectives for study performance</p>
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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.		
<p>A1. Explain the nature and historical instances of ethical and professional conflicts which occur in the conduct of clinical research</p> <p>A2. Describe the procedures which are implemented to prevent ethical conflicts and support risk management strategies</p>	<p>B1. Recognize, implement, and manage the procedures in a clinical research study which minimize the risks of ethical and professional conflicts</p> <p>B2. Implement risk management strategies within their role responsibilities</p>	<p>C1. Assess the risk of ethical and professional conflicts inherent in a clinical study</p> <p>C2. Develop strategies and policies to implement and manage risk of ethical and professional conflicts across a project team as well as functional domains</p>
7.3 Identify and apply the professional guidelines and codes of ethics that apply to the conduct of clinical research.		
<p>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</p> <p>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.</p>	<p>B1. Apply professional and ethical regulations and international guidelines in each facet of clinical research</p> <p>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</p>	<p>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</p> <p>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.</p>
7.4 Describe the impact of regional diversity and demonstrate cultural competency in clinical study design and conduct		
<p>A1. Describe why it is important to incorporate strategies that account for regional and cultural diversity in the conduct of clinical research</p> <p>A2. Classify examples of potential impact that are related to diversity or cultural competency</p>	<p>B1. Apply regional/country and cultural considerations during study design and conduct</p> <p>B2. Incorporate the appropriate regulatory requirements during the implementation of multi-country trials</p>	<p>C1. Develop specific strategies or methods for considering culture and region/country when designing and conducting studies in multiple regions/countries</p> <p>C2. Validate that regulatory requirements are incorporated into the study design for multi-country trials</p>
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.		
<p>A1. Understand and describe the relationships and appropriate communication channels between regulators, sponsors, CROs and research sites</p>	<p>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</p>	<p>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</p>



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





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Leveling the Joint Task Force Core Competencies

<https://mrctcenter.org/clinical-trial-competency/> March 2019

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