# Competencies of the Joint Task Force for Harmonized Core Competencies

| JTF Competencies | | | | | | | |
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| **I. Scientific Concepts and Research Design** | | | | | | | |
| 1. Demonstrate knowledge of pathophysiology, pharmacology and toxicology as they relate to medicines discovery and development | | | | | | | |
| 2. Identify clinically important questions that are potential testable clinical research hypothesis, through review of the professional literature | | | | | | | |
| 3. Explain the elements (statistical, epidemiological and operational) of clinical and translational study design | | | | | | | |
| 4. Design a clinical trial | | | | | | | |
| 5. Critically analyze study results with an understanding of therapeutic and clinical effectiveness | | | | | | | |
| **II. Ethical and Participant Safety Considerations** | | | | | | | |
| 1. Compare and contrast clinical care and management of research participants | | | | | | | |
| 2. Define the concepts of “clinical equipoise” and “therapeutic misconception” as they relate to the conduct of a clinical trial | | | | | | | |
| 3. Compare the requirements for human subject protection and privacy under different national and international regulations and ensures their implementation throughout the phases of a clinical study | | | | | | | |
| 4. Explain the evolution of informed consent from research participants and principles and content of key documents which ensure the protection of human participants in clinical research | | | | | | | |
| 5. Describe the ethical issues involved when dealing with vulnerable populations and the need for additional safeguards | | | | | | | |
| 6. Evaluate and apply and understanding of the past and current ethical issues, cultural variations and commercial aspects on the medicines development process | | | | | | | |
| 7. Explain how inclusion and exclusion criteria are included in a clinical protocol to assure human subject protection | | | | | | | |
| 8. Summarize the principles and methods of distributing and balancing risk and benefit through selection and management of clinical trial subjects | | | | | | | |

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| **III. Medicines Development and Regulation** | | | | | | | |
| 1. Discuss the historical events which precipitated the development of governmental regulatory processes for drugs, devices and biologics | | | | | | | |
| 2. Describe the roles and responsibilities of the various institutions participating in the medicines development process | | | | | | | |
| 3. Explain the medicines development process and the activities which integrate commercial realities into the life-cycle management of medical products | | | | | | | |
| 4. Summarize the legislative and regulatory framework which supports the development and registration of medicines, devices and biological and ensures their safety, efficacy and quality | | | | | | | |
| 5. Describe the specific processes and phases which must be followed in order for the regulatory authority to approve the marketing authorization for a medical product | | | | | | | |
| 6. Describe the safety reporting requirements of regulatory agencies both pre- and post- approval | | | | | | | |
| 7. Appraise the issues generated and the effects of global expansion on the approval and regulation of medicinal products | | | | | | | |
| **IV. Clinical Study Operations (GCPs)** | | | | | | | |
| 1. Evaluate the conduct and management of clinical trials within the context of a clinical development plan | | | | | | | |
| 2. Describe the roles and responsibilities of the clinical investigative team as defined by GCP guidelines | | | | | | | |
| 3. Evaluate the design, conduct and documentation of clinical trials as required for compliance with GCPs | | | | | | | |
| 4. Compare and contrast the regulations and guidelines of regulatory bodies related to the conduct of clinical trials | | | | | | | |
| 5. Describe appropriate control, storage and dispensing of investigational product | | | | | | | |
| 6. Differentiate the types of adverse events which occur during clinical trials, understanding the identification process for AEs and describe the reporting requirements to IRBs/IECs, sponsors and regulatory authorities | | | | | | | |
| 7. Describe how global regulations and guidelines assure human subject protection and subject protection and privacy during the conduct of clinical trials | | | | | | | |

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| 8. Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct | | | | | | | |
| 9. Describe the role and process for monitoring of the study | | | | | | | |
| 10. Describe the roles and purpose of clinical trial audits | | | | | | | |
| 11. Describe the safety reporting requirements of regulatory agencies both pre-and post-approval | | | | | | | |
| 12. Describe the various methods by which safety issues are identified and managed during the development and post-marketing phases of clinical research | | | | | | | |
| **V. Study and Site Management** | | | | | | | |
| 1. Describe the methods utilized to determine whether or not to sponsor, supervise or participate in a clinical trial | | | | | | | |
| 2. Develop and manage the financial, timeline, and cross-disciplinary personnel resources necessary to conduct a clinical or translational research study | | | | | | | |
| 3. Apply management concepts and effective training methods to manage risk and improve quality in the conduct of a clinical research study | | | | | | | |
| 4. Utilize elements of project management related to organization of the study site to manage patient recruitment, complete procedures and track progress | | | | | | | |
| 5. Identify the legal responsibilities, issues, liabilities and accountability that is involved in the conduct of a clinical trial | | | | | | | |
| 6. Identify and explain the specific procedural, documentation and oversight requirements of principal investigators, sponsors, CROs and regulatory authorities which relate to the conduct of a clinical trial | | | | | | | |
| **VI. Data Management and Informatics** | | | | | | | |
| 1. Describe the role that biostatistics and informatics serve in biomedical and public health research | | | | | | | |
| 2. Describe the typical flow of data throughout a clinical trial | | | | | | | |
| 3. Summarize the process of electronic data capture (EDC) and the importance of information technology in data collection, capture and management. | | | | | | | |

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| 4. Describe the ICH GCP requirements for data correction and queries | | | | | | | |
| 5. Describe the significance of data quality assurance systems and how SOPs are used to guide these processes | | | | | | | |
| **VII. Leadership and Professionalism** | | | | | | | |
| 1. Describe the principles and practices of leadership, management and mentorship and apply them within the working environment | | | | | | | |
| 2. Identify and implement procedures for the prevention or management of the ethical and professional conflicts that are associated with the conduct of clinical research | | | | | | | |
| 3. Identify and apply the professional guidelines and codes of ethics which apply to the conduct of clinical research | | | | | | | |
| 4. Describe the impact of cultural diversity and the need for cultural competency in the design and conduct of clinical research | | | | | | | |
| **VIII. Communication and Teamwork** | | | | | | | |
| 1. Discuss the relationship and appropriate communication between Sponsor, CRO and clinical research site | | | | | | | |
| 2. Describe the component parts of a traditional scientific publication | | | | | | | |
| 3. Effectively communicate the content and relevance of clinical research findings to colleague, advocacy groups and the non-scientist community | | | | | | | |
| 4. Describe methods necessary to work effectively with multidisciplinary and interprofessional research teams | | | | | | | |