Regulatory Science Competencies in 11 Core Thematic Areas

Regulatory Science Research Questions and Priorities

- Summarize current and emerging Regulatory Science priorities, including FDA Priority Areas and others
- Identify additional Regulatory Science questions via gap analysis of translational research pathway, considering current evaluation and approval process of medical products
- Critique Regulatory Science research questions and priorities
- Identify approaches and techniques to address areas of Regulatory Science; outline a vision for a research program
- Describe principles of decision science and evidence based decision making, considering the role of patients, patient advocates, clinicians, payors, and regulators
- Describe principles of Team Science, including the specific roles within a multidisciplinary network of individuals in and across organizations

Regulatory Policies and Process

- Understand current regulatory system and structure appropriate to the relevant field of study
- Evaluate and analyze laws, regulations, and guidance documents relevant to the field of studyyy5ocumentsÐ

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Analytical Approaches and Tools

- Explain potential applications of computational methods and in silico modeling to predict human efficacy, toxicity and risk-benefit and to inform regulatory decisions
- Evaluate applications of statistical approaches, biomedical informatics and models (e.g., missing data, multiple endpoints, patient enrichment, adaptive designs) to promote novel clinical trial design
- Describe basic statistical concepts (e.g., identify a research question, conceptualize hypotheses, identify sources of data, utilize appropriate study designs, determine appropriate analytical methods, draw valid and meaningful conclusions)
- Describe the process to identify, evaluate, and synthesize information from RCTs, observational studies, and other study designs
- Identify appropriate applications for various scientific methods to gather and validate information (e.g., systematic reviews, meta-analysis, etc.)
- Describe principles and applications of various analytic tools and techniques (e.g., bioinformatics, patient-reported outcomes, clinical effectiveness research, translational research, etc.)
- Discuss results from data mining techniques to explore existing clinical trial data (e.g., analysis of electronic health records from accessible large healthcare databases to identify sources of variation among studies, differentiate subsets of diseases, improve understanding of relationships between clinical parameters and outcomes, evaluate clinical utility of potential biomarkers and evaluate post-marketing data)
- Describe use of informatics to inform both clinical trials and pharmacometrics
- Outline current legal and policy requirements related to data storage, maintenance, access, privacy and security
- Discuss approaches to address data storage, access, sharing, privacy and confidentiality (including patient, industry, government and other data sources)
- Describe requirements and permissions associated with Biobanking tissue and others collections
- Describe use of novel strategies and existing data sets for repurposing

Communication

- Compare and contrast communication, evidence-based communication, and risk communication
- Explain approaches to risk communication and the underlying social and behavior sciences that inform these approaches
- Describe various research approaches that inform regulatory decisions (e.g., focus groups, surveys, experiments, etc.)
- Discuss results-oriented approaches, and corresponding evaluation criteria, to achieve short- and long-term goals of communication n achieve approved