Program	Course Title	Course Description	Learner Level
The Legal Aspects of Conducting Clinical Trials (November 2019) 6 Course Series Complete 6 out of 6 Courses to earn a Badge 6.5 Total Contact Hours	**Program Overview**	Principal Investigators and regulatory professionals must stay abreast of legal requirements and compliance strategies when conducting clinical trials. This symposium offers perspectives from attorneys and regulatory experts to discuss U.S. and international regulations for pharmaceutical, biologic and medical device organizations, as well as sponsored and investigator-sponsored trials. This symposium is comprised of 6 courses which review the various legal requirements for principal investigators and regulatory professionals when conducting a clinical trial, including investigator's responsibilities, contracts, liabilities, indemnifications, invention protection, and privacy compliance. Participants earn contact hours for each session and at the completion of all 6 sessions earn a badge recognizing completion of the symposium. **Courses available in this program:** 1. Investigator Responsitilities: Industry Sponsored Trials 2. Investigator Responsibilities: Investigator Initiated 3. Clinical Trials Contracts. 4. Legal Considerations of Compassionate Use 5. Liability and Indemnification 6. Privacy and HIPAA: Concerns in Global Clinical Trials	Intermediate
	Investigator Responsibilities: Industry Sponsored Trials (0.75 CEU)	The first course in a 6-part series, examines selected updates from the "E6(R2): Good Clinical Practice: Integrated Addendum to ICH E6(R1): Guidance for Industry applicable to industry-sponsored trials" specific to industry-sponsored trials. Updated topics from the addendum include: resources, records and reports, quality management, trial management, data handling and recordkeeping.	Intermediate
	Investigator Responsibilities: Investigator Initiated Trials (0.5 CEU)	This course discusses key roles and responsibilities of individuals associated with investigator initiated trials pertaining to 21 CFR 312.50, FDA 1572. Core Competencies: Ethical & Participant Safety Considerations, Clinical Study Operations, Study & Site Management,	Intermediate
	Clinical Trials Contracts (1.25 CEU)	This course examines institutional clinical trial contractual agreements, and how budgets, regulations, and law compliance impacts study conduct. The session discusses specific research agreement terms, particular to pre-study initiation and post study activation, and their impact on successful contract and budget negotiations.	Intermediate
	Legal Considerations of Compassionate Use (1.5 CEU)	Over the last two decades, the FDA has permitted industry sponsors to broaden access to investigational products while they are still undergoing clinical trials for patients with serious or immediate life-threatening diseases with no comparable or satisfactory therapeutic alternatives eligible. This course examines the FDA's expanded access program, also referred to as compassionate use, and its regulations and requirements. Key factors in obtaining expanded access, including treating physician and manufacturer requirements, institutional review, and patient qualifications will also be discussed.	Intermediate
	Liability and Indemnification (1 CEU)	All parties to a clinical trial have a common purpose of conducting a successful trial but the parties also have competing perspectives. To protect each party from liability, contracts are created to typically include mutual indemnifications that exclude each party's liability for consequential damages. This course examines the complicated responsibilities, liabilities, purpose, intent, rights and indemnifications when numerous parties, such as drug manufacturer, study sponsor, CROs, study site, institutions, investigators, and various other entities comes together to run a successfully clinical trial.	Intermediate
	Privacy and HIPAA: Concerns in Global Clinical Trials (1.5 CEU)	This explores core concepts of privacy in clinical research including similarities and differences between the U.S. and E.U. Privacy protections under the U.S. Health Insurance Portability and Accountability Act (HIPAA) and the European Union General Data Protection Requirements (GDPR) will be discussed. Additional complex considerations such as privacy breaches, disclosure obligations, penalties for non-compliance, state-specific laws, and the impact from Brexit will be examined. Core Competencies: Ethical & Participant Safety Considerations, Study & Site Management, Data Management & Informatics	Intermediate

Clinical Trials with Medical Devices (May 2019) 7 Course Series Complete 5 of 7 Courses for a Badge 7 Total Contact Hours	**Program Overview**	Demonstrating the safety and effectiveness of new medical devices is a critical part of the medical product development process and requires significant resources to accomplish. This symposium provides perspectives from physicians and medical device experts to discuss the complex regulatory process of various medical device classifications, U.S. and international requirements, trial management, and pediatric needs within the framework of Good Clinical Practices. At the end of this symposium, participants will understand the various types of medical device classification and regulatory requirements, and gain knowledge of coordinating, monitoring, and managing a medical device clinical trial. **Courses available in this program:** 1. History, Terms, Definitions & Regulatory Requirements 2. IRB Reviews on Medical Device Trials 3. Quality at the Data Level 4. Medical Device Feasibility Clinical Trials - A Medical Case Study 5. Advanced International Trials with Medical Devices 6. Auditing of Medical Device Trials 7. Gaps & Opportunities in Pediatric Medical Device Trials	Beginner
	History, Terms, Definitions and Regulatory Requirements (2.0 CEU)	This course will explore core concepts of FDA regulations including: study risk categorization and device classifications, IDE application process for industry and investigated-initialed trials, requirements and responsibilities in IDE trials, trial types for commercialization, guidance in consulting FDA, and coordination on multi-site IDEs. Core Competencies: Ethical & Participant Safety Considerations, Investigational Products Development & Regulation, Study & Site Management	Beginner
	IRB Reviews on Medical Device Trials (0.75 CEU)	Sound ethical practices must be applied in clinical trials using human subjects for medical device development. The 2nd course in a 7-part series, medical device review will be discussed from the perspective of the Institutional Review Board (IRB). Topics explored include FDA regulations and guidance for Significant Risk (SR) and Non-Significant Risk devices (NSR), Humanitarian Use Device (HUD), Emergency Use, custom device, exempt review, and local IRB application processes. Core Competencies: Ethical & Participant Safety Considerations, Investigational Products Development & Regulation, Clinical Study Operations	Beginner
	Quality at the Data Level (1.0 CEU)	In this course, critical concepts and practical methods in the planning, collection, storage, and dissemination of high-quality, reliable and statistically sound data will be discussed. Topics include how study design and case report form (CFR) specifications impact data quality, utilization of data quality indicators, and good documentation. Core Competencies: Scientific Concepts & Research Design, Study & Site Management, Data Management & Informatics	Beginner
	Medical Device Feasibility Clinical Trials – A Medical Case Study (0.75 CEU)	This course provides an overview of a feasibility trial for a novel active implantable device.The case study will demonstrate a private company's approach to feasibility trials, accomplishments, and lessons learned. Core Competencies: Ethical & Participant Safety Considerations, Investigational Products Development and Regulation, Study & Site Management	Beginner
	Advanced International Trials with Medical Devices (0.75 CEU)	The course provides an industry perspective on clinical studies.Topics will include considerations of study site selection, navigation in partnering with an industry sponsor, purpose of industry sponsored clinical studies, identification of stakeholders, explanation of study drivers, and outside pressures on public companies.	Beginner
	Auditing of Medical Device Trials (1.0 CEU)	Principles of auditing and monitoring in medical device clinical trials will be discussed.Topics unique to medical device trials will be examined, e.g., significant risks, IDE exemptions, and device modifications.Current issues identified by the FDA including warning letters, device trial monitoring and risk evaluation, and implementation of risk-based monitoring and auditing in medical auditing concepts will be explored.	Beginner
	Gaps and Opportunities in Pediatric Device Trials (0.75 CEU)	Historically pediatric health research and development has lagged behind health research for adults.This course will discuss barriers to the development of new pediatric medical devices, and special regulatory considerations in clinical trials for pediatric medical devices.Consideration is given to how the Consortium for Technology & Innovation in Pediatrics (CTIP) assists in advancing pediatric medical device innovation.	Beginner

Quality by Design in Clinical Trials 5 Course Series Complete 5 out of 5 Courses for a Badge 5.5 Total Contact Hours	**Program Overview**	Clinical trial data is critical to evaluating a medical product's efficacy and safety, and must be of sufficient quality and reliability to ensure valid analyses. The clinical trials enterprise has historically linked the gathering of more data with trial quality, 'more is better".Not only was it considered essential to gather detailed data on every aspect of a clinical trial, but also that data must be entered, reviewed, scrutinized, queried, and validated multiple times during the life cycle of a trial. This concept of over-collection and analysis is so entrenched, it is considered risky by investigators not to collect ever-increasing volumes of data and metadata. Growing evidence suggests a myopic focus on the accuracy of each data point, regardless of its criticality, adds little value (if anything) to trial quality and safety and, in fact adds to a trials significant expense and effort. This has prompted interest in more tailored approaches that are informed by trial design and how trial conduct influences quality. This program introduces Quality by Design (QbD) as a systematic approach to medical product development to ensure trial quality by applying analytical and risk-management methodologies to the design, development, and manufacturing of products. Program Outcome: At the end of the Quality by Design (QbD) program, participants will understand the principles of QbD and how quality issues encountered from clinical research sites/ contract research organizations/ pharmaceutical companies can be prevented by designing for quality at each critical junction. Participants will be prepared to use the Plan-Do-Check-Act cycle for risk-based monitoring to improve clinical trial quality. **Courses available in this program:** 1. What Do We Mean by Quality by Design 2. Clinical Trials Transformative Initiative (CTTI): Approach to Quality by Design 3. Developing Quality by Design tools for Clinical Researchers 4. Integrating Quality by Design into Team Science & Project Management for Research Success 5.Applying Design for Six Sigma	Intermediate /Advanced
	What Do We Mean by Quality by Design? (1.25 CEU)	This course provides a general overview of the history, principles and philosophy of Quality by Design (QbD). Perspectives from the FDA and ICH, quality focused guidance and activities, and a case study of a pharmaceutical company implementing QbD will be explored.	Intermediate/ Advanced
	Clinical Trials Transformative Initiative (CTTI) Approach to Quality by Design (QbD) (1.25 CEU)	The Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the FDA in 2007, resulted from a growing concern over the poor quality and inefficiency in clinical research as well as the increasing numbers of trials conducted outside of the United States where standards and practices greatly differ. The goal of the CTTI Quality by Design (QbD) project was to better understand the range of current practices, assess alternative approaches, understand barriers to change, and propose recommendations for improvement.The course will discuss the background, approach, and concepts from CTTI's QbD Project, including "The Principles Document" and a real-world example case study. Core Competencies: Scientific Concepts & Research Design, Study & Site Management, Data Management & Informatics	Intermediate/ Advanced
	Developing Quality by Design Tools for Clinical Researchers (1 CEU)	This course presents the experience of an academic health center's implementation of Quality by Design (QbD), including creation of the QbD working group, application of QbD principles on selected clinical trials in a 2-year pilot project, and collaborative efforts for national level QbD implementation. Core Competencies: Scientific Concepts & Research Design, Data Management & Informatics	Intermediate/Advanced
	Integrating Quality by Design into Team Science and Project Management for Research Success (1 CEU)	The experience of a second academic health center's approach to implementing Quality by Design is presented. Insights on implementation, intricacies of subject matter expert/ stakeholders' engagement, and the development and outcome of a tailored project plan will be discussed.	Intermediate / Advanced
	Applying Design for Six Sigma (1 CEU)	This course provides an in-depth discussion of Six Sigma process improvement strategies, tools, and concepts as applied to pharmaceutical research and manufacturing. Design for Six Sigma (DFSS) is a methodology of improvement that helps businesses create new products or services at a high level of quality. The technique aims to meet customer needs and utilize the company's capability to reduce the need to redesign/reintroduce a product multiple times.	Intermediate / Advanced

Patient-Centered Drug Development and Real-World Evidence/Data 5 Course Series Complete 5 out of 5 Courses for a Badge 5.25 Total Contact Hours	**Program Overview**	This five-course program provides an overview of real-world data (RWD) and real-world evidence (RWE). Collected through the routine delivery of health care, RWD and RWE are potentially powerful tools for enhancing the quality and efficiency of clinical trials and precision medicine. Traditionally, data from randomized clinical trial have been viewed as the gold standard in drug development. Over the last decade, new sources of data and innovative technologies have accelerated the shift toward individualized care and precision medicine, whereby providers can develop treatment plans targeted to specific patient needs and improved outcomes. Made possible by a number of U.S. Food and Drug Administration acts and developments, regulators and pharmaceutical developers have begun to view real-world data (RWD)/real-world evidence (RWE) as a more efficient way to evaluate drug approval and label expansion decisions. In this program, the concepts and development of RWD/RWE will be explored, including its usefulness in rare diseases, insights and challenges in data validity, and how RWD/RWE can accelerate clinical trials and the integration of precision medicine within standardized care. Program Outcome: At the end of this program, participants will understand the concept of patient-focused drug development and how real-world data and real-world evidence are applied to evaluation of rare diseases and the field of oncology, and how tools are developed in transforming data to applicable information to knowledge. **Courses available in this program:** 1. Patient Centered Drug Development: History, Terms, & Definitions 2. Patient-focused Drug Development: Patients & Patient Advocacy Organizations 3. Introduction ro Rare Diseases & Orphan Drugs 4. From Data to Information to Knowledge 5. Case Study: From Discovery to Practice & Survivorship	Intermediate / Advanced
	Patient Centered Drug Development: History, Terms and Definitions (1.25 CEU)	An overview of the history, terms, and definitions of patient focused drug development and real-world data (RWD) and real-world evidence (RWE) will be reviewed.The FDA's pivotal role in passing the Prescription Drug User Fee Act, the 21st Century Cures Act, and the Framework for the Real-World Evidence (RWE) and Real-World Data (RWD) Program will be highlighted. The impact on medical product developers utilizing RWE/RWD to support clinical trial designs and observation studies to generate innovative, new treatment approaches will be discussed. Core Competencies: Scientific Concepts & Research Design, Investigational Products Development & Regulation, Data Management & Informatics	Intermediate/ Advanced
	Patient-focused Drug Development: Patients and Patient Advocacy Organizations (1.0 CEU)	The importance of the FDA Patient-Focused Drug Development policy will be discussed, including patients' perspectives in determining the risk/benefit in areas of high, unmet medical need; and the role of a patient advisory committee for drug approval. Additionally, consideration on how this policy was scrutinized during drug approval evaluation for the treatment of rare disease.	Intermediate/ Advanced
	Introduction to Rare Diseases and Orphan Drugs (0.75 CEU)	This course discusses the legislative landscape and regulatory framework for novel treatments of rare diseases in the United States, European Union, and non U.S./E.U. regions.The significance and challenges of the Orphan Drug Act, rare disease advocacy, and the FDA's commitment to rare diseases will be examined. Core Competencies: Investigational Products Development & Regulation	Intermediate/ Advanced
	From Data, to Information, to Knowledge (1.25 CEU)	An overview of how clinical trial simulation is used to evaluate optimal design selections, trial criteria and execution, and strategies to eliminate early errors will be examined.Case studies highlight the integration of real-world data becoming real-world evidence that leads to cost effective labeling change of medical drugs/devices.Distinctions between physiologically based pharmacokinetic and pharmacodynamic models will be explored.	Intermediate/ Advanced
	Case Study - From Discovery to Practice and Survivorship (1.0 CEU)	The impact of molecular profiling and technologies in translating basic science research to human studies; and the translation of new interventions into clinical practice will be explored. We will discuss vital programs in the discovery of cancer genome mapping and the advancement of precision health and oncology, including The Cancer Genome Atlas, and the National Cancer Institute Genomic Data Commons.	Intermediate/ Advanced

Pharmacovigilance and Safety Reporting 6 Course Series Complete 6 out of 6 courses for a Badge 4.75 Total Contact Hours	**Program Overview**	Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or other drug related issues. To accurately assess the risk of potential harms, the FDA and other regulatory agencies developed broad sets of regulations and procedures that govern how researchers and the biomedical industry must gather, analyze, and report adverse events. This program will provide an in-depth understanding of adverse event regulatory definitions, processes, requirements, and analysis and investigation techniques to minimize risk in clinical research. This six (6)-course symposium explores the fundamentals of pharmacovigilance for drugs, medical devices and biologics including adverse event reporting and regulatory requirements, risks management, and case studies demonstrating practical approaches to adverse event reporting. Program Outcome: At the end of this program, participants will understand terminologies and definitions of adverse events and their reporting procedures and requirements. Participants will gain knowledge of how relationship and causality between medical products and adverse events are determined, and the value of pharmacovigilance in clinical trials. **Courses available in this program:** 1: Regulatory Requirements 2: Safety Reporting in Investigator-Initiated Trials 3: Safety Reporting from Other Sources 4: Safety Reporting in Industry-Sponsored Trials and Case Studies – Part 1 5: Safety Reporting in Industry-Sponsored Trials and Case Studies – Part 2 6: Adverse Event Reporting	Beginner/Intermediate
	Pharmacovigilance & Safety: Regulatory Requirements (1 CEU)	Pharmacovigilance terminologies and adverse event definitions for drugs and medical devices will be reviewed.The adverse event reporting procedures and FDA requirements for drugs and medical devices during product development and post-marketing will be examined. Core Competencies: Ethical & Participant Safety Considerations, Investigational Products Development & Regulation,	Beginner/Intermediate
	Safety Reporting in Investigator-Initiated Trials (IIT) (0.5 CEU)	The intricacies of conducting various types of investigator-initiated trials (IITs), their adverse event reporting requirements, and documentation processes for all responsible parties will be discussed. Core Competencies: Ethical & Participant Safety Considerations, Clinical Study Operations, Data Management & Informatics	Beginner
	Safety Reporting from Other Sources (0.5 CEU)	The importance of collecting additional safety data from non-clinical trial sources, such as epidemiological investigations, public domain, foreign regulatory authorities, and animal and in-vitro data, to develop a comprehensive product safety profile will be discussed.	Beginner
	Safety Reporting in Industry-Sponsored Trials and Case Studies – Part 1 (1.5 CEU)	An expert medical safety officer will discuss the role of the sponsor in pharmacovigilance for adverse event collection and reporting, and criteria for reporting on drugs and medical devices. Core Competencies: Ethical & Participant Safety Considerations	Beginner
	Safety Reporting in Industry-Sponsored Trials and Case Studies – Part 2 (0.75 CEU)	In continuation with the fourth (4th) course, Safety Reporting in Industry-Sponsored Trials and Case Studies Part 1, of this 6-part program, two case studies exploring clinical trial adverse event reporting for drugs and medical devices will be presented. Core Competencies: Ethical & Participant Safety Considerations	Beginner
	Adverse Event Reporting (0.5 CEU)	The importance of adverse event (AE) reporting throughout the medical device product development process will be discussed. Focus will be on how individual patient adverse events (AE) become integral to final product labeling.	Beginner

Diversity in Clinical Trials in the Time of COVID-19 6 Course Series Complete 6 out of 6 courses for a Badge 5.0 Total Contact Hours	**Program Overview**	Inspired by current events unfolding worldwide, this program includes six courses of in-depth discussions on diversity, inclusion, and equality in human subjects research, and the importance of representation in clinical trials, especially in the time of COVID-19. Disease pattern, clinical presentation and therapeutic response can vary dramatically based on a number of factors including race, ethnicity, genetics, comorbidities, socioeconomic status, and gender. Clinical trials are necessary in the advancement of new therapies. While many individuals decide to participate, racial and ethnic minorities remain consistently underrepresented.It is vital to understand the significance of diversity in clinical trials, the barriers and facilitators to participation, the importance of community engagement, and education about clinical trials to ensure representation of clinical trials results relevant to diverse populations. At the end of this program, participants will be able to: 1. Define diversity, inclusion, and equity, and identify contributing factors to diversity disparities in clinical trials. 2. Gain an appreciation of the importance of diverse populations in research as well as strategies to implement tools for increasing representation for underserved and marginalized communities. **Courses available in this program:** 1: What Do We Mean by Diversity in Clinical Trials? 2: FDA Initiatives to Address Diversity in Clinical Trials? 3: Clinical Trials Participation: Understanding the Needs and Importance of Diverse Populations 4: Diversity, Equity and Inclusion in Clinical Research 5: Population on the Fringe of Clinical Trial Enrollment 6: Ensuring Participant Diversity and Engagement during COVID-19	Beginner/Intermediate /Advanced
	What Do We Mean by Diversity in Clinical Trials? (0.5 CEU)	This course focuses on the importance and dimensions of diversity, exploring the current landscape of diversity in clinical trials, and diversity in clinical trials of recently approved drugs. Core Competencies: Scientific Concepts & Research Design, Investigational Products Development & Regulation	Beginner/Intermediate/Advanced
	FDA Initiatives to Address Diversity in Clinical Trials (1.0 CEU)	An in-depth discussion of FDA initiatives and guidance documents addressing diversity in clinical trials will be examined, including the FDA Safety and Innovation Act, FDA Action Plan, Drug Trial Snapshots, Clinical Trials Transformation Initiative, and the establishment of the Office of Minority Health and Health Equity, and the Office of Women's Health. Core Competencies: Scientific Concepts & Research Design, Investigational Products Development & Regulation, Data Management & Informatics	Beginner/Intermediate/Advanced
	Clinical Trials Participation: Understanding the Needs and Importance of Diverse Populations (1.25 CEU)	The decision to participate in a clinical trial is a highly personalized decision and each pathway to that decision differs.This course focuses on the journey and factors that influence clinical trial participation, including challenges participants experience, patient perception, receptivity, and the impact of new and supportive technologies. Consideration is given to new clinical trial models and how clinical trial processes will evolve in the future. Core Competencies: Investigational Products Development & Regulation, Study & Site Management, Data Management & Informatics	Beginner/Intermediate/Advanced
	Diversity, Equity and Inclusion in Clinical Research (1.0 CEU)	The importance of diversity, equity, and inclusion in clinical research will be emphasized as well as obstacles to enrolling patients from diverse populations and implications for not enrolling patients from diverse populations. Core Competencies: Scientific Concepts & Research Design, Investigational Products Development & Regulation	Beginner/Intermediate/Advanced
	Population on the Fringe of Clinical Trial Enrollment (0.75 CEU)	Current efforts to address a lack of representation in clinical trials include Sec. 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA), FDA's Action Plan, and the FDA Drug Trial Snapshot.Diversity metrics and statistics collected from these combined efforts will be highlighted as well as, research projects conducted by the USC Undergraduate Research Associates Program. Core Competencies: Investigational Products Development & Regulation, Data Management & Informatics	Beginner/Intermediate /Advanced
	Ensuring Participant Diversity and Engagement during COVID-19 (0.5 CEU)	Current issues affecting clinical trial recruitment and barriers associated with clinical research access will be discussed. The main barriers include mistrust, lack of information of the research process and limited clinical trial awareness, logistical obstacles such as time and resource constraints, and a lack of cultural competency and knowledge among study staff. The importance of diversity in research, engagement strategies for minority populations and how the COVID-19 pandemic affects the research landscapes will be explored.	Beginner/Intermediate /Advanced

Regulatory Aspects of Clinical Trial Design 5 Course Series Complete 5 out of 5 courses for a Badge 5.35 Total Contact Hours	**Program Overview**	Clinical trials play a pivotal role in evaluating new interventions to prevent or treat disease in humans. The regulatory environment and strategy drive the development of drug and medical devices including design of clinical trials/programs. Topics include principles and methodologies used in study design, implementation, and analysis of clinical trials, ethical issues from medical device development, and an overview of the FDA's evolution to become the nation's leading authority for regulatory oversight.All study design elements including first-in-human studies (dose-finding, safety, proof of concept, and Phase I), Phase II, Phase III and Phase IV studies will also be explored. **Courses available in this program:** 1: Key Regulatory Terminology in Clinical Trial Design 2: Evolution of FDA's View of a Well-Designed Clinical Trial 3: Classical and Novel Designs Used in Regulatory Approvals 4: Unique Designs for Medical Device Trials 5: Case Studies and Future Trends	Beginner
	Key Regulatory Terminology in Clinical Trial Design (0.5 CEU)	Commonly used statistical and clinical trial design terminology will be discussed, highlighting the importance of the correct use of terminology. Core Competencies: Study & Site Management, Data Management & Informatics	Beginner
	Evolution of FDA's View of a Well-Designed Clinical Trial (1.85 CEU)	An in-depth overview and history of the FDA will include the legal framework that governs the FDA's regulatory oversight to ensure safe and effective medical products are approved and marketed.A comprehensive review of drug/product development from discovery phase to clinical trials and various pathways utilized by the FDA will be examined. Core Competencies: Investigational Products Development & Regulation, Clinical Study Operations	Beginner
	Classical and Novel Designs Used in Regulatory Approvals (1.5 CEU)	This course presents an in-depth review of the principles and application of statistics in randomized controlled trials, including basic terminologies, and fundamentals of research design and analysis. Core Competencies: Scientific Concepts & Research Design, Investigational Products Development & Regulation	Beginner
	Unique Designs for Medical Device Trials (1.0 CEU)	Differences between drug and device development and regulations, challenges with device clinical trials, utilization of sham surgery as a control for surgical medical devices, and changing requirements in the EU for clinical data and evaluation will be examined. Core Competencies: Scientific Concepts & Research Design, Ethical & Participant Safety Considerations, Investigational Products Development & Regulation	Beginner
	Case Studies and Future Trends (0.5 CEU)	Current trends in drug development and various regulatory approval pathways will be discussed.The different approaches in drug development and regulatory approval pathways are highlighted by two case studies. Core Competencies: Investigational Products Development & Regulation, Study Site Management	Beginner
Clinical Research Career Pathways 5 Course Series Complete 5 out of 5 courses for a Badge 4.25 Total Contact Hours	**Program Overview**	There are thousands of job opportunities in clinical research. For those seeking an initial career in this field or switching professions, how does one "get their foot in the door"? In this program, experts from the medical device industry and academic medical institutions will provide comprehensive insights to various clinical research fields, and necessary core competencies for professional growth and pathway advancement. At the end of this program, participants will gain perspectives and insights in various clinical research fields, and the required skill sets, background experiences, education, and resume building skills to acquire positions as a clinical research professional. **Courses available in this program:** 1: From Academics to Industry – A Physician Research Perspective 2: Clinical Supply Chain Management: Dude, Where's My Patient Benefit? 3: Understanding Clinical Research Management at Academic Institutions 4: Roads to the Human Subjects Protection Program (OPRS and IRB) 5: Knocking on HR's Door: Do you have what it takes to be a CRP?	Beginner/Intermediate /Advanced
	From Academics to Industry – A Physician Research Perspective (0.75 CEU)	A physician medical device expert will discuss the extensive research, development, and regulatory hurdles of the artificial pancreas device system, and the concerted team effort to bring one device from concept to commercialization.	Beginner/Intermediate /Advanced
	Clinical Supply Chain Management: Dude, Where's My Patient Benefit? (1.0 CEU)	An important factor for success in conducting clinical trials is the effective management of clinical trial products and supplies, especially in complex studies with detailed planning, extensive monitoring, and coordination between global enterprises. Core Competencies: Ethical & Participant Safety Considerations	Beginner/Intermediate /Advanced

	Understanding Clinical Research Management at Academic Institutions (0.75 CEU)	An overview of the resources and infrastructure required to successfully operate industry-sponsored, grant-funded, and investigator-initiated clinical trials at an academic medical institution will be discussed.	Beginner/Intermediate /Advanced
	Roads to the Human Subjects Protection Program (OPRS and IRB) (0.75 CEU)	The course reviews one systems structure of the OPRS and IRB and program-wide policies for the conduct and review of human subjects research as well as training programs.	Beginner/Intermediate /Advanced
	Knocking on HR's Door: Do you have what it takes to be a CRP? (1.0 CEU)	There are thousands of job opportunities in clinical research, but for those seeking an initial career in this field or switching professions, how does one "get your foot in the door?" Focus will be on career path development for all learners. Core Competencies: Study & Site Management, Communication & Teamwork	Beginner/Intermediate /Advanced
Introduction to Clinical and Translational Research is a Course Introduction to Clinical and Translational Research Complete 4 out of 4 courses for a Badge 6.0 Total Contact Hours	**Program Overview**	This **4-part program** builds learner knowledge and expertise in the interpretation of the Clinical and Translational Research (CTR) literature using written and supplemental materials, videos, interactive graphics, and self-assessment. Part 1: Understanding the Translational Science Research Ecosystem Part 2: Basic Concepts Defining the Analytic Approach to Research Part 3: Elements of Clinical and Translational Research Studies Part 4: Clinical and Translational Research Study Design Types Development of this program was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award number UL1TR002378. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. At the end of this program the learner will be able to: 1. Identify the features that characterize translational research ecosystems: translational stages, developmental phase, clinical application, data types and collection methods, unit of analysis, and epistemological objectives. 2. Define the fundamental concepts of precision, accuracy, validity, causality, and types of associations. 3. Identify the steps from defining a target population to selecting a study sample. 4. Identify the processes of developing minimal important difference when defining study measures in causal inference CTR. 5. Describe the reasons for conducting power and sample size calculations in CTR study design. 6. Recognize the purpose, features, strengths, weaknesses, and optimization of observational study design, and its most commonly utilized styles. 7. Recognize the purpose, features, strengths, weaknesses, and optimization of experimental study design, and its most commonly utilized styles.	Beginner
Conducting Clinical Trials in the Era of Emerging Technologies and Treatments 5 Course Series Complete 5 out of 5 courses for a Badge 6.25 Total Contact Hours	**Program Overview**	This 6-course program explores the regulatory, scientific and logistical considerations in clinical trials involving emerging technologies, cutting edge devices, immunotherapies, gene therapies, and stem cell therapies. Rapid advances in science over the past decade have provided new technologies to innovate, manufacture and assess novel medical products, and to the discovery of life changing cures.Regulators have a key role in providing guidance to industry to ensure safe and effective use of these new scientific advances. In this program, scientific achievements will be highlighted along with their real-world impact. Consideration will be given to regulatory and logistical operations, and successes and consequences of failure. Program Outcome: At the end of this program, Conducting Clinical Trials in the Era of Emerging Technologies and Treatments, participants will understand basic terminologies associated with gene therapies, stem cell therapies, and immunotherapies, and the intricate process of harvesting, manufacturing and administrating cells for these therapies.Additionally, participants will gain knowledge of unique technologies including a fetal micropacemaker and the concept of decentralized clinical trials. **Courses available in this program:** 1: Regulatory Considerations 2: Gene Therapy Trials and Tribulations 3: Clinical Trials for Stem Cell Therapies 4: Clinical Trial Enabling Technologies – Decentralized Clinical Trials 5: Immunotherapy Trials 6: Cutting Edge Technologies and Humanitarian Devices	Advanced

	Regulatory Considerations (1.0 CEU)	Challenges to federal regulators in evaluating new and emerging therapies including gene therapy, cell therapy, tissue engineering, innovative medical devices, and innovative information technology (IIT) will be discussed. Core Competencies: Scientific Concepts & Research Design, Investigational Products Development & Regulation, Study & Site Management, Data Management & Informatics	Advanced
	Gene Therapy Trials and Tribulations (1.25 CEU)	A detailed overview of gene therapy focused on cell therapy, including its definition, clinical trial procedures and examples, and potential serious adverse events will be discussed.	Advanced
	Clinical Trials for Stem Cell Therapies (1.0 CEU)	Researchers have been unlocking the potential of stem cells to treat a variety of medical conditions and diseases; however, guidance and regulations for the stem cell manufacturing industry remains complicated and open to interpretation. This course examines the regulation, oversight and logistics of human cells, tissues, and cellular and tissue-based product manufacturing and administration.	Advanced
	Clinical Trial Enabling Technologies – Decentralized Clinical Trials (1.0 CEU)	Decentralization of clinical trials has been a growing field enabled further by advancement in emerging technologies. The experience of one company's decentralized approach to administering clinical trials, main benefits of decentralization, and an outline of key considerations when planning and designing elements of a decentralized trial will be explored.	Advanced
	Immunotherapy Trials (1.0 CEU)	Immunotherapy enables the immune system to recognize and target cancer cells that boost the body's natural defenses to fight cancer. Basic immunology terminologies and concepts, and an overview of immune-related adverse events and how they can be treated will be discussed.	Advanced
	Cutting Edge Technologies and Humanitarian Devices (1.0 CEU)	Complete heart block in the preterm fetus is a life-threatening emergency with no effective treatment options beyond watchful waiting or preterm delivery. More than a quarter of these fetuses do not survive. The design, development, engineering, testing, and implantation of a fetal micropacemaker for advanced fetal surgical intervention will be discussed.	Advanced
Making Informed Decisions: Key Statistical Principles in Clinical Trial Design 5 Course Program Complete 5 out of 5 courses for a Badge 4.1 Total Contact Hours	**Program Overview**	This 5-course program, features industry and academic experts discussing the integral role of statistics in medical product development, specifically in clinical trial design. This program provides a foundational understanding of statistical topics related to clinical research in an interactive forum. Statistical principles such as power, multiplicity, and P-values remain critical in designing successful clinical trials. Statistical techniques determine the number of patients needed for a study to meet a pre-set clinical endpoint and to generate meaningful results. While analyses can reveal mathematically significant, this does not always equate to clinical or medical value. Program Outcome: The learner will increase their understanding of basic statistical principles and their application to different clinical trial designs and populations, as well as how results are used to elucidate meaningful findings from raw clinical trial data. **Courses available in this program:** 1: Basic Statistical Principles: Validity and Sample Size 2: Designing Medical Devices 3: Pediatric Trials 4: CTSI Clinical Study Design Types 5: Gender, Race, and Ethnicity in Clinical Trials	Intermediate/ Advanced
	Basic Statistical Principles: Validity and Sample Size (1CEU)	The fundamental principles of statistics, including hypothesis testing, power, multiplicity, mathematical and data adjustments, and statistical confidence will be discussed. These principles applied to study design inform clinical endpoints, sample size, biases, validity, and missing data. At the end of this program the learner will: 1. Understand basic statistical principles relate to clinical research and how they affect clinical trial practices and study design. 2. Differentiate between statistical and clinical significance. 3. Evaluate different types of endpoints, e.g., continuous, ordinal, binary, survival, composite, surrogate). 4. Identify factors leading to missing data and biases and statistical techniques utilized to manage these factors.	Intermediate/ Advanced
	Designing Medical Devices (0.6 CEU)	Basic considerations for designing medical device trials such as device complexity and limitations, resource constraints, availability of a control group, and key stakeholders (i.e., hospital administration, radiologists, and clinicians) will be discussed. Characteristics unique to medical devices will be further explored via case studies using adaptive trial design for device testing. At the end of this course, the learner will: 1. Understand the basic considerations for designing medical device trials, e.g., proof of device safety and/or efficacy, device size, ethics, device costs, study controls, partnerships with hospitals and industry, and study endpoints. 2. Define adaptive trial design, identifying the advantages and disadvantages for using adaptive trial design for medical device studies.	Intermediate/ Advanced

	Pediatric Trials (0.75 CEU)	A general overview of pediatric trials, discussing pediatric subpopulations, laws related to pediatric research, the consent process, and clinical trial design considerations. The level of cognitive ability of developing children, ethics, the physiological changes associated with human growth, and data biases associated with age will be highlighted. A case study investigating the effects of caffeine on newborns and whether breast feeding versus formula feeding affected caffeine metabolism differently is presented. At the end of this course, the learner will be able to: 1. Identify the laws promoting pediatric participation in clinical research. 2. Distinguish between the diverse sub-populations that comprise the pediatric population. 3. Define terms related to pediatric participation in research (i.e., parental permission, assent, and consent). 4. Identify two complexities unique to pediatric clinical research and recruitment bias.	Intermediate/ Advanced
	CTSI Clinical Study Design Types (1 CEU)	This course provides an in-depth exploration of various clinical trial design types (i.e., cohort, case-study, quasi-experimental, etc.) along with the statistical methods often used respective to each type (i.e., Chi-square test, T-test, non-parametric Wilcox logistic regression, etc.). Other topics discussed include development of a testable research question using PICOT criteria, data collection, and brief explanations on the advantages and disadvantages of each trial design type. At the end of this course, the learner will be able to: 1. Define different clinical trial study designs (i.e., descriptive, analytic, observational, cohort, case-control, quasi-experimental, crossover, cluster randomized, non-inferiority trials). 2. Formulate a research question using PICOT criteria. 3. Understand how study designs should align with the research question, data collection, and statistical analyses. 4. Define different types of data (i.e., continuous, dichotomous, ordinal categorial, nominal, count, and survival).	Intermediate/Advanced
	Gender, Race, and Ethnicity in Clinical Trials (0.75 CEU)	Policies from the NIH and FDA on the inclusion and reporting practices related to gender, sex, race, and ethnicity in clinical trials as well as the rationale behind these policies will be discussed. Other topics in this course include subgroup reporting, the role of sex and gender in clinical trials and data implications associated with this topic, and the effects of racial misreporting and participation in clinical trials on data and healthcare outcomes. At the end of this course, the learner will be able to: 1. Identify NIH and FDA policies on inclusion and reporting practices by sex, race, and ethnicity. 2. Explain the importance of diverse, underrepresented groups in clinical trials. 3. Understand the statistical implications of the inclusion or lack of inclusion of sub-groups in clinical trials.	Intermediate /Advanced
Role of Genomics in Medical Product Development (Fall 2021) 5 Course Series Complete 5 out of 5 couses to earn a Badge 5.75 Total Contact Hours	**Program Overview**	This program is comprised of five courses featuring industry experts discussing the role of genomics in medical product development, a rapidly evolving field of science with new technologies and emerging applications. Genomics science continues to play a major role in generating new knowledge in the basic research arena. How these learnings translate into product development involves the integration of genomics data, including pharmacogenomics and “Big Data,” and data extraction for mathematical models, such as drug-disease-trial models, into the regulatory decision-making process. This program will introduce and examine all of these topics in an interactive forum with an emphasis on innovation and translation. This course is designed to increase understanding of regulatory framework and policies for FDA regulated genomics products. Courses available in this program: 1. Genomics and Regulations 2. Genomics and Personalized Medicine 3. Pharmacogenomics Considerations for Clinical Research and Implementation 4. Big Data and Genomics 5. Applied Genomics and Target Identification	Intermediate /Advanced
	Genomics and Regulations (1 CEU)	The fundamentals of genomics testing will be discussed along with the FDA and FDA guidelines on the incorporation of data from genomic tests.	Intermediate /Advanced
	Genomics and Personalized Medicine (1.25 CEU)	This course discusses the FDA’s Critical Path Initiative (CPI), a national strategy developed to improve the methods used to move therapies from the laboratory to the patient in a more efficient manner. The goal is to use innovative methods to ensure that researchers developing new medical products are able to leverage the latest technology, along with existing knowledge culled from relevant clinical trials, scientific expertise, and collaborative interaction between industry, academia, regulatory agencies, and patient advocacy groups. These groups, known as C-Path Consortia, ask big-picture questions about drug development. What are the best methods for testing drug safety and efficacy in a therapeutic area? Are there any biomarkers that can be used as suitable endpoints to expedite the development process? How can we share clinical trial data without compromising patient privacy?	Intermediate/ Advanced

	Pharmacogenomics Considerations for Clinical Research and Implementation (1 CEU)	This course explains how genetic variation influences the response to drug therapy. From discovery of pharmacogenetic associations to the evaluation of utility in clinical practice. Discussed will be a summary of CYP2C19 genetic variability in acute coronary syndrome (ACS) patients receiving clopidogrel post-percutaneous coronary intervention (PCI). Additionally, a review of available resources and guidelines to design best practices for discovering and translating pharmacogenetic (PGx) research.	Intermediate/ Advanced
	Big Data and Genomics (1.25 CEU)	The first human genetic blueprint has just turned 20; the era of exorbitant costs to analyze one genome has now evolved to the use of digital bar codes to sequence DNA. Because of the sizeable quantity of complex data associated with human genomes, genomics is now considered a "big data" field. Genomics data involves the curation of data that cuts across cancer datasets, COVID-19, pediatrics, Canine Data Commons to mention a few. Each genomics data point is potentially a patient's hope and wish. How do we test the feasibility of these emerging technologies and make the data sets publicly available yet meet the highest standards of patient protection and respect? There are trade-offs between data utility and data privacy protection.	Intermediate/ Advanced
	Applied Genomics and Target Identification (1.25 CEU)	What is the role of technological innovation in drug development for specific neurodegenerative diseases such as Huntington's (HD)? This deep dive into HD provides an overview of applying genomics within the drug discovery process and how it relates to diagnosis, target identification, prognosis, and stratification target identification.	Intermediate/ Advanced
Energing Technologies in the Medical Device Industry (Fall 2022) *Complete 5 out of 5 Courses to earn a Badge* *5.5 Total Contact Hours*	***Program Overview***	*This program, comprised of five courses, features industry and academic experts discussing the role and impact of technological advancements in the medical device industry. The courses are designed to increase understanding of medical device types and applications along with the security and regulatory considerations necessary to manage these emerging technologies.* *1. What is Digital/AI/Machine Learning? How is it Used?* *2. Clinical Virtual Reality: Seven Ways that Virtual Reality Will Change the World of Mental Healthcare!* *3. Regulatory Framework for the Digital World* *4. Use of AI in Drug Development* *5. Cybersecurity*	*Beginner/Intermediate / Advanced*
	What is Digital/AI/Machine Learning? How is it Used? (.75 CEU)	*The use of technology in the medical device industry facilitates data capture and analysis. An overview of technological systems such as artificial intelligence and machine learning and the way individuals interact with these systems, and the results of those interactions, will be discussed.*	*Beginner/Intermediate /Advanced*
	Clinical Virtual Reality: Seven Ways that Virtual Reality Will Change the World of Mental Healthcare! (1.75 CEU)	*Virtual reality offers non-traditional approaches to therapeutic development and delivery. Different therapeutic approaches that use virtual reality simulations for mental and physical health are discussed. This course also presents results of randomized clinical trials validating the effectiveness of these approaches.*	*Beginner/Intermediate / Advanced*
	Regulatory Framework for the Digital World (1 CEU)	*Limitations of data sharing result from the lack of a global regulatory framework. Insights on how data can be compiled into a framework that is interchangeable, while still confidential for clinical trial participants and submissible to regulatory agencies will be discussed. Current approaches to interchangeable data formats (e.g., xml, jpg, mpg, ASCII, etc.), data structures, and blockchain technology will be covered.*	*Beginner/Intermediate / Advanced*
	Use of AI in Drug Development (1 CEU)	*This course provides an overview on the ways artificial intelligence (AI) and machine learning (ML) are applied to facilitate drug development and clinical trials as well as the need for regulatory policies in industry.*	*Beginner/Intermediate / Advanced*
	Cybersecurity (1CEU)	*The increasing demand for securing emerging technologies in the healthcare field has implications for standards, frameworks, and regulations for implementing cybersecurity, particularly in the areas of patient care and medical product development.*	*Beginner/Intermediate / Advanced*