Clinical Trials in the Pharmaceutical Industry: Designing and Managing Phases 1, 2 and 3

Virtual Training Program
December 12 - 13, 2022

Monday, December 12 – Program Day 1 **Session No.**
All Times Listed EDT

8:00 AM — ***Registration & Continental Breakfast***

8:30 – 8:45 AM — **PERI Welcome and Course Overview**
Lauren Kirk, PERI Education Director
The Pharmaceutical Education and Research Institute, Inc.

8:45 AM – 10:00 AM — **Regulatory Overview** — ***1***
Allan J. Weinstein, MD
Clinical Research and Regulatory Affairs Consultant

- Regulations for new drug approval
  - Overview of regulatory process
  - Understanding the regulatory agencies' role in clinical development: US, EU, Japan
  - Regulatory Update: changes in last 10 years
- Emerging Regulatory Landscape (PDUFA VI)

10:00 – 10:15 AM — ***Morning Break***

10:15 – 11:00 AM — **Clinical Development: Past, Present and Future** — ***2***
Allan J. Weinstein, MD

- Protocol Writing
- Adaptive design
- Bayesian statistics
- Big Data

11:00 – 11:45 AM — **Designing a Phase I Study** — ***3***
Allan J. Weinstein, MD

- Understand basic principles of initial Phase I clinical studies
- Review different study designs and timing
- Compare strategies in big pharma vs. biotech

Monday, December 12, 2022 – Program Day 1 (continued)		***Session No.***
11:45 AM – 12:30 PM	**Workshop: Designing a Phase I Clinical Study** Allan J. Weinstein, MD • Introduction to Workshop • Group exercise	***4***
12:30 – 1:30 PM	***Lunch Break***	
1:30 –2:00 PM	**Workshop: Designing a Phase I Clinical Study (continued)** Allan J. Weinstein, MD • Group Presentations • Lessons Learned	***4***
2:00 – 3:00 PM	**Designing a Phase II Study** Allan J. Weinstein, MD • Understand key principles of Phase II drug development • Review different study designs and timing • Workshop Introduction	***5***
3:00 – 3:15 PM	***Afternoon Break***	
3:15 – 4:15 PM	**Statistical Challenges in Clinical Trials** • Proper differentiations of Primary and Secondary Endpoints • Alpha control for multiplicity • Missing Data Mechanisms • Interpretation of Statistical Output from a Hypothetical Clinical Trial	***6***
4:15 – 4:45 PM	**Workshop: Designing a Phase II Clinical Study** Allan J. Weinstein, MD • Introduction to Workshop • Group exercise	***7***
4:45 – 5:00 PM	***End of Day: Final Q&A, Review/Preview Agenda***	

Tuesday, December 13, 2022 – Program Day 2		***Session No.***
8:00 AM	***Registration & Continental Breakfast***	
8:30 – 8:45 AM	**Day Two Welcome and Course Overview** Lauren Kirk, PERI Education Director The Pharmaceutical Education and Research Institute, Inc.	
8:45 – 9:45 AM	**Workshop: Designing a Phase II Clinical Study (continued)** Allan J. Weinstein, MD • Group Presentations • Lessons Learned	***7***
9:45 – 10:00 AM	***Morning Break***	
10:00 – 11:15 AM	**Statistical Considerations in Clinical Trials** • Adaptive Designs in Early Phase • Hypothesis Testing Framework • Interpretation of Power Curves • Establishing Evidence in Main Study Types	***8***
11:15 – 11:20 AM	***Stretch Break***	
11:20 AM – 12:35 PM	**Conducting Phase III Trials** Allan J. Weinstein, MD • Forces that shape a Phase III development program • Key elements in a Phase III protocol • Additional factors to consider for a Phase III protocol and late-stage development program	***9***
12:35 – 1:45 PM	***Lunch Break***	
1:45 – 3:15 PM	**Workshop: Designing a Phase III Clinical Study** Allan J. Weinstein, MD • Introduction to Workshop • Group exercise • Participant presentations • Lessons Learned	***10***

Tuesday, December 13, 2022 – Program Day 2 (continued)		***Session No.***
3:15 – 3:30 PM	***Afternoon Break***	
3:30 – 4:30 PM	**Clinical Safety Monitoring & Pharmacovigilance** Allan J. Weinstein, MD • Good Clinical Practices • Overview of Pharmacovigilance • Safety issues throughout stages of clinical drug development • Adverse events and requirements for safety reporting • Key safety elements in individual and integrated clinical trial safety reports • Pharmacovigilance and Signaling • REMS and Benefit / Risk Management	***11***
4:30 – 5:00 PM	***Course Conclusion***	

Clinical Trials in the Pharmaceutical Industry:
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Fairfax, Virginia December 12 - 13, 2022

COURSE DESCRIPTION

PERI's *Clinical Trials* intermediate-level course explores the three key phases of clinical development of pharmaceuticals and addresses the skills needed to effectively and safely conduct global clinical trials. Presentations and workshops address the functions and critical decisions made through the clinical development process, from First in Human (FIH) to submission of a New Drug Application (NDA) or Biologics License Application (BLA). In addition to exploring Phases I-III, this course discusses regulatory guidelines, pharmacovigilance, good clinical practices (GCP), and key roles and responsibilities. Over the course of two days, PERI expert faculty presents key factors to consider in the daily operations aspects of clinical trial conduct, organizational tips, resource planning ideas, financial implications, timeline concerns, regulatory implications, and cross-function communication.

COURSE OBJECTIVES

Upon completion of this course, participants should be able to:

- Describe the benefits and key steps of an adaptive clinical trial
- Identify the responsibilities of main personnel in clinical trials
- Utilize Good Clinical Practices when developing clinical programs
- Analyze the key decision points in each phase of development
- Describe regulations for conducting global clinical trials

CONTINUING EDUCATION CREDIT

Pharmaceutical Education & Research Institute, Inc. (PERI) is pleased to make continuing education credit available to you for attendance at this program. To receive credit, you must attend the entire program and submit the Continuing Education Application form directly to a PERI on-site coordinator. Additional $35 fee applies for students who are applying for continuing education credit.

Continuing Pharmacy Education

Pharmaceutical Education & Research Institute, Inc. (PERI) is approved by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Continuing Medical Education

PERI, Inc. is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.