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

Virtual Training Program
October 27 - 29, 2021

Wednesday, October 29, 2021 – Program Day 1 ***Session No.***
All Times Listed EDT

11:00 – 11:15 AM **PERI Welcome and Course Overview**
Lauren Kirk, PERI Education Director
The Pharmaceutical Education and Research Institute, Inc.

11:15 AM – 12:30 PM **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)

12:30 – 1:15 PM ***Extended Break***

1:15 – 2:30 PM **Clinical Development: Past, Present and Future** ***2***
Allan J. Weinstein, MD

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

2:30 – 2:40 PM ***Stretch Break***

2:40 – 3:25 PM **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

Wednesday, October 27, 2021 (continued)		***Session No.***
3:25 – 3:35 PM	***Afternoon Break***	
3:35 – 4:50 PM	**Workshop: Designing a Phase I Clinical Study** Allan J. Weinstein, MD • Introduction to Workshop • Participants may choose to work offline after introduction; faculty will be available for consult and questions until course ends	***4***
4:50 – 5:00 PM	***End of Day: Final Q&A, Review/Preview Agenda***	

Thursday, October 28, 2021 – Program Day 2		***Session No.***
11:00 – 11:05 AM	**Day Two Welcome and Overview** Lauren Kirk, PERI Education Director The Pharmaceutical Education and Research Institute, Inc.	
11:05 – 11:30 AM	**Workshop: Designing a Phase I Clinical Study** Allan J. Weinstein, MD • Participant presentations • Faculty Q&A	***4***
11:30 AM – 12:45 PM	**Statistical Considerations in Clinical Trials** Michael G. Wilson • Adaptive Designs in Early Phase • Hypothesis Testing Framework • Interpretation of Power Curves • Establishing Evidence in Main Study Types	***5***
12:45 – 1:30 PM	***Extended Break***	
1:30 – 2:30 PM	**Designing a Phase II Study** Allan J. Weinstein, MD • Understand key principles of Phase II drug development • Review different study designs and timing	***6***

Thursday, October 28, 2021 (continued)		***Session No.***
2:30 – 2:40 PM	***Stretch Break***	
2:40 – 3:40 PM	**Statistical Challenges in Clinical Trials** Michael G. Wilson • Proper differentiations of Primary and Secondary Endpoints • Alpha control for multiplicity • Missing Data Mechanisms • Interpretation of Statistical Output from a Hypothetical Clinical Trial	***7***
3:40 – 3:50 PM	***Stretch Break***	
3:50– 4:55 PM	**Workshop: Designing a Phase II Clinical Study** Allan J. Weinstein, MD • Introduction to Workshop • Participants may choose to work offline after introduction; faculty will be available for consult and questions until course ends	***8***
4:55 – 5:00 PM	***End of Day: Final Q&A, Review/Preview Agenda***	

Friday, October 29, 2021 – Program Day 3		***Session No.***
11:00 – 11:05 AM	**Day Three Welcome and Overview** Lauren Kirk, PERI Education Director The Pharmaceutical Education and Research Institute, Inc.	
11:05 – 11:30 AM	**Workshop: Designing a Phase II Clinical Study** Allan J. Weinstein, MD • Participant presentations • Faculty Q&A	***8***
11:30 AM – 12:30 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***

Friday, October 29, 2021 (continued)		***Session No.***
12:30 – 1:15 PM	***Extended Break***	
1:15 – 2:30 PM	**Workshop: Designing a Phase III Study** Allan J. Weinstein, MD • Introduction to Workshop • Participants may choose to work offline after introduction; faculty will be available for consult and questions until lunch break	***10***
2:30 – 2:40 PM	***Stretch Break***	
2:40 – 3:10 PM	**Workshop: Designing a Phase III Clinical Study** Allan J. Weinstein, MD • Participant presentations • Faculty Q&A	***10***
3:10 – 3:55 PM	**Pharmacoeconomics and Market Access** Allan J. Weinstein, MD • Pharmacoeconomics & Healthcare Outcomes Research • Measuring the value of pharmaceutical therapy • Healthcare Informatics: QoL, QALY • Pricing & payer reimbursement issues • Cost-minimization, benefit, utility, comparative effectiveness • Reimbursement linked to outcomes • PROs: Patient Reported Outcomes • Value evidence data generation	***11***
3:55 – 4:05 PM	***Afternoon Break***	
4:05 – 4:55 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	***12***
4:55 – 5:00 PM	***Course Conclusion***	

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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:

- Design 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