

CLINICAL INVESTIGATOR TRAINING COURSE (CITC)

November 12-14, 2019 | College Park, MD

This course provides an intermediate-level study of clinical trial principles with in-depth coverage of clinical trial design, issues in safety and efficacy, investigator responsibilities, understanding the investigator brochure, and FDA requirements across Centers.

Upon completion, attendees should understand pre-clinical research, clinical trials, and FDA submissions for licensure of medical products.

Learning Objectives

- Explain the responsibilities of an investigator conducting a clinical trial.
- Describe what to look for in drugs being studied in a clinical trial.
- Describe the basic concepts of clinical trial design.
- Review clinical data for sources of bias and error.

Agenda

Day 1: Tuesday, November 12, 2019

7:30	Registration and Distribution of Course Material	
8:20	Welcome and Introduction	Leonard Sacks, MD Center for Drug Evaluation and Research (CDER) Office of Medical Policy (OMP) FDA
8:30	FDA Structure and Mandate	Leonard Sacks, MD CDER FDA
<i>SESSION 1: Trial Design</i> <i>Moderator: Leonard Sacks, MD</i>		
9:00	Design of Clinical Trials (Pt. 1)	Robert Temple, MD Deputy Center Director for Clinical Science and Acting Deputy Director of the Office of Drug Evaluation I (ODE-I) Office of the Center Director (OCD) CDER FDA

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9:45	Break and Exhibits	
	Discuss clinical research questions at exhibit tables.	
10:00	Design of Clinical Trial (Pt. 2)	Robert Temple, MD
10:30	Clinical Trial Endpoints	Elektra Papadopoulou, MD, MPH CDER FDA
11:00	Questions and Answers	Robert Temple, MD Elektra Papadopoulou, MD, PhD
11:15	New Trends in Clinical Trial Designs	
	Part 11 and Digital Health Tools	Leonard Sacks, MD
	Real World Evidence	David Martin, MD CDER FDA
	Decentralized Clinical Trials	Isaac Rodriguez-Chavez, PhD, MHSc, MSc CDER FDA
12:00	Questions and Answers	Leonard Sacks, MD David Martin, MD Isaac Rodriguez-Chavez, PhD, MHSc, MSc
12:15	Lunch and Exhibits	
	Discuss clinical research questions at exhibit tables for Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and Center for Devices and Radiological Health (CDRH)	
1:15	Issues in Clinical Trial Designs for Devices	Adam Donat Center for Devices and Radiological Health (CDRH) FDA
1:45	Issues in Clinical Trial Design for Companion Diagnostic Devices	Karen Bijwaard, MS, RAC, MB(ASCP), CQA CDRH FDA

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2:15	Questions and Answers	Adam Donat Karen Bijwaard, MS
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2:30	Break and Exhibits	Discuss clinical research questions at exhibit tables.
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SESSION 2: Issues in Clinical Trial Safety and Efficacy

Moderator: Leonard Sacks, MD

2:45	Safety Considerations in Phase I Trials	Ramya Gopinath, MD CDER FDA
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3:15	Safety Assessment in Clinical Trials and Beyond	Shabnam Naseer, MD CDER FDA
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3:45	Questions and Answers	Ramya Gopinath, MD Shabnam Naseer, MD
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4:00	The Analysis of Investigator Data: Sources of Bias and Error	Susan Ellenberg, PhD University of Pennsylvania
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4:45	Questions and Answers	Susan Ellenberg, PhD
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4:45	Adjourn	Networking Session in Lower Lobby
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Day 2: Wednesday, November 13, 2019

SESSION 2: Issues in Clinical Trial Safety and Efficacy (cont.)

Moderator: Leonard Sacks, M.D.

8:30	Issues in Clinical Trial Design for Rare Diseases	Patroula Smpokou, MD, FACMG CDER FDA
9:00	Organ Specific Toxicities Roundtable	
	Oncology	Meredith Chuk, MD CDER FDA
	Hepatic	Kirti Shetty, MD University of Maryland
	Hematology	Ann T. Farrel, MD CDER FDA
	Renal	Aliza Thompson, MD CDER FDA
	Cardiac	Shari Targum, MD, MPH, FACC CDER FDA
	Oncology and Immunotherapies	Ashkan Emadi, MD, PhD University of Maryland
10:00	Break	
10:15	Personalized/ Precision Medicine	Alan R. Shuldiner, MD University of Maryland
10:45	Special Populations: Pediatrics, Pregnancy, Renal and Hepatic Impairment	Mario Sampson CDER FDA
11:15	Gene Therapy	Lei Xu, MD Center for Biologic Research and Evaluation (CBER) FDA
11:45	Questions and Answers	Mario Sampson

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12:00	Lunch	Alan R. Shuldiner, MD Lei Xu, MD
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SESSION 3: Investigator Responsibilities and Patient Perspective

Moderator: Cynthia Kleppinger, M.D.

1:00	Investigator Responsibilities-Regulation and Clinical Trials	Cynthia Kleppinger, MD CDER FDA
2:00	Questions and Answers	Cynthia Kleppinger, MD
2:15	Informed Consent and Ethical Considerations in Clinical Trials	Jon Mark Hirshon, MD, PhD, MPH, FACEP University of Maryland
2:45	Clinical Investigator Site Inspections- What to Expect	Michelle Anantha, MSPAS, PA-C, RAC CDER FDA
3:15	Questions and Answers	Michelle Anantha, MSPAS John Mark Hirshon, MD Cynthia Kleppinger, MD
3:30	Break	
3:45	Good Clinical Practice (GCP) and ClinicalTrials.gov	Bridget Foltz, MS FDA
4:15	FDA Perspective on International Studies	Kassa Ayalew, MD, MPH CDER FDA

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4:45	Questions and Answers	Kassa Ayalew, MD, MPH Bridget Foltz, MS
5:00	Adjourn	

Day 3: Thursday, November 14, 2019

SESSION 4: Understanding the Investigator Brochure: Non-clinical and Early Clinical Studies

Moderator: Shirley Seo, MD

8:30	CMC and the Investigator Brochure: Ensuring the Quality of a Drug is used in a Clinical Trial	Erika E. Englund, PhD CDER FDA
9:00	Pharmacology/Toxicology in the Investigator Brochure	Matthew Thompson PhD, MPH CDER FDA
9:30	Clinical Pharmacology	Shirley Seo, MD CDER FDA
10:00	Questions and Answers	Erika Englund, PhD Shirley Seo, MD Matthew Thompson, PhD
10:15	Break	

SESSION 5: INDs and IDEs – A Cross-center Perspective

Moderator: Donald Fink, PhD

10:30	Center for Drug Evaluation and Research <i>How to Put together an Investigational New Drug (IND) Submission</i>	Judit Milstein, D.Sc. CDER FDA
11:30	Center for Biologics Evaluation and Research <i>Putting Together Your IND Application (CBER): CMC, Preclinical Testing and Clinical Trial Design Expectations to Ensure Safety for a First-in-Human Clinical Investigation</i>	Donald Fink, PhD CBER FDA Feorillo Galvio CBER FDA Deborah Belsky, MD, MPH, FAAFP CBER FDA

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12:30	Lunch	
1:30	Center for Devices and Radiological Health (CDRH)	Joshua Chetta, PhD FDA, CDRH
	Medical Device Clinical Evidence: IDEs and Beyond	Nadezda Radoja, PhD FDA, CDRH
2:30	Questions and Answers	Deborah Belsky, MD Joshua Chetta, PhD Donald Fink, PhD Feorillo Galvio Judit Milstein, D.Sc. Nadezda Radoja, PhD
3:00	Patient and Investigator Perspective Panel	
	Patient Perspectives	Pat Furlong Founding President & CEO, Parent Project Muscular Dystrophy
		Lisa Salberg CEO, Hyperthrophic Cardiomyopathy Association
	Pulmonology, Epidemiology and Safety	Michael Terrin, MD, MPH University of Maryland
	Infectious Diseases and Pediatrics	James Campbell, MD, MS University of Maryland
4:00	Questions and Answers	James Campbell, MD, MS Pat Furlong Lisa Salberg Michael Terrin, MD, MPH
3:00	Closing Remarks	Leonard Sacks, MD
3:10	Adjourn	