

# CLINICAL INVESTIGATOR TRAINING COURSE (CITC)

November 12-14, 2019 | College Park, MD

This course provides a 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	Breakfast, Registration and Distribution of Course Material	
8:20	<b>Welcome and Course Introduction</b>	<b>Leonard Sacks, MD</b> <i>Associate Director for Clinical Methodology</i> Office of Medical Policy (OMP)   Center for Drug Evaluation and Research (CDER)   FDA
8:30	<b>FDA Structure and Mandate</b>	<b>Leonard Sacks, MD</b> CDER   FDA
<i>SESSION 1: Trial Design</i>		
9:00	<b>Design of Clinical Trials (Pt. 1)</b>	<b>Robert Temple, MD</b> <i>Deputy Center Director for Clinical Science</i> Office of the Center Director (OCD) CDER   FDA

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9:45	<b>Break</b> <i>Visit FDA Exhibits</i>	
10:00	<b>Design of Clinical Trial (Pt. 2)</b>	<b>Robert Temple, MD</b>
10:30	<b>Clinical Trial Endpoints</b>	<b>Elektra Papadopoulos MD, MPH</b> CDER   FDA
11:00	<b>Questions and Answers</b>	<b>Robert Temple, MD</b> <b>Elektra Papadopoulos, MD,</b>
11:15	<b>New Trends in Clinical Trial Designs</b>	
	Part 11 and Digital Health Tools	<b>Leonard Sacks, MD</b>
	Real World Evidence	<b>David Martin, MD, MPH</b> CDER   FDA
	Decentralized Clinical Trials	<b>Isaac Rodriguez-Chavez, PhD, MHSc, MSc</b> CDER   FDA
12:00	<b>Questions and Answers</b>	<b>Leonard Sacks, MD</b> <b>David Martin, MD, MPH</b> <b>Isaac Rodriguez-Chavez, PhD, MHSc, MSc</b>
12:15	<b>Lunch Provided</b> <i>Visit FDA Exhibits</i>	
1:15	<b>Issues in Clinical Trial Designs for Devices</b>	<b>Adam Donat, MS</b> Center for Devices and Radiological Health (CDRH)   FDA
1:45	<b>Issues in Clinical Trial Design for Companion Diagnostic Devices</b>	<b>Karen Bijwaard, MS, RAC, MB(ASCP), CQA</b> CDRH   FDA

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2:15	<b>Questions and Answers</b>	<b>Adam Donat</b> <b>Karen Bijwaard, MS</b>
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2:30	<b>Break</b> <i>Visit FDA Exhibits</i>
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## *SESSION 2: Issues in Clinical Trial Safety and Efficacy*

2:45	<b>Safety Considerations in Phase I Trials</b>	<b>Ramya Gopinath, MD</b> CDER   FDA
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3:15	<b>Safety Assessment in Clinical Trials and Beyond</b>	<b>Shabnam Naseer, DO, MS</b> CDER   FDA
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3:45	<b>Questions and Answers</b>	<b>Ramya Gopinath, MD</b> <b>Shabnam Naseer, DO, MS</b>
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4:00	<b>Avoiding Bias and Random Error in Data Analysis</b>	<b>Susan Ellenberg, PhD</b> University of Pennsylvania
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4:45	<b>Questions and Answers</b>	<b>Susan Ellenberg, PhD</b>
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5:00	<b>Adjourn</b>  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.).*

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

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12:00	<b>Alan R. Shuldiner, MD, PhD</b> <b>Lei Xu, MD, PhD</b>
<b>Lunch Provided</b>	

## *SESSION 3: Investigator Responsibilities and Patient Perspective*

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

8:30	Quality Issues for Clinical Trial Materials: The CMC Review	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 K. Seo, PhD CDER   FDA
10:00	Questions and Answers	Erika Englund, PhD Shirley K. Seo, PhD 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>	Lawrence Allan CDER   FDA
11:30	Center for Biologics Evaluation and Research (CBER) <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 Galivo, MD, PhD CBER   FDA Deborah Belsky, MD, MPH, FAAFP CBER   FDA

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12:30	<b>Lunch Provided</b>	
1:30	<b>Center for Devices and Radiological Health (CDRH)</b> Medical Device Clinical Evidence: IDEs and Beyond	<b>Joshua Chetta, PhD</b> FDA, CDRH <b>Nadezda Radoja, PhD</b> FDA, CDRH
2:30	<b>Questions and Answers</b>	<b>Lawrence Allan</b> <b>Deborah Belsky, MD</b> <b>Joshua Chetta, PhD</b> <b>Donald Fink, PhD</b> <b>Feorillo Galivo, MD, PhD</b> <b>Nadezda Radoja, PhD</b>
3:00	<b>Patient and Investigator Perspective Panel</b> Patient Perspectives  Pulmonology, Epidemiology and Safety  Infectious Diseases and Pediatrics	<b>Pat Furlong</b> Founding President & CEO, Parent Project Muscular Dystrophy  <b>Lisa Salberg</b> CEO, Hypertrophic Cardiomyopathy Association  <b>Michael Terrin, MD, CM          MPH</b> University of Maryland <b>James Campbell, MD, MS</b> University of Maryland
4:00	<b>Questions and Answers</b>	<b>James Campbell, MD, MS</b> <b>Pat Furlong</b> <b>Lisa Salberg</b> <b>Michael Terrin, MD, MPH</b>
4:15	<b>Closing Remarks</b>	<b>Leonard Sacks, MD</b>
4:20	<b>Adjourn</b>	