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
	SESSION 1: Trial Design *Moderator: Leonard Sacks, MD*	
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 Papadoplous, MD, MPH** CDER | FDA
11:00	**Questions and Answers**	**Robert Temple, MD** **Elektra Papadoplous, 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

2:15	**Questions and Answers**	**Adam Donat** **Karen Bijwaard, MS**
2:30	Break and Exhibits Discuss clinical research questions at exhibit tables.	

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
3:15	**Safety Assessment in Clinical Trials and Beyond**	**Shabnam Naseer, MD** CDER | FDA
3:45	**Questions and Answers**	**Ramya Gopinath, MD** **Shabnam Naseer, MD**
4:00	**The Analysis of Investigator Data: Sources of Bias and Error**	**Susan Ellenberg, PhD** University of Pennsylvania
4:45	**Questions and Answers**	**Susan Ellenberg, PhD**
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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		Alan R. Shuldiner, MD **Lei Xu, MD**
12:00	Lunch	

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

12:30	Lunch	
1:30	**Center for Devices and Radiological Health (CDRH)** Medical Device Clinical Evidence: IDEs and Beyond	**Joshua Chetta, PhD** FDA, CDRH **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 Cardiomyophathy 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	

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