Small Business and Industry Assistance
Clinical Investigator
Training Course (CITC)

DECEMBER 6 – 7, 2023
Webcast

Version 3 – Updated October 13, 2023

FDA Clinical Investigator Training Course (CITC) 2023

For files and resources, please visit
The Event Page on SBIAevents.com

Add Event to Your Calendar

AGENDA

All times are Eastern (EST UTC-4)

View Start Time on World Clock

DAY ONE: Wednesday, December 6, 2023

11:00 – 11:15

SBIA Welcome

Brenda Stodart, PharmD, MS, BCGP, RAC-US
Captain, United States Public Health Service (USPHS)
Director, Small Business, and Industry Assistance (SBIA)
Division of Drug Information (DDI)
Office of Communications (OCOMM) | CDER | FDA

Day 1 - Part 1: Trial Design Considerations

11:15 – 11:30

FDA Structure and Mandate

Kimberly Smith, MD, MS
CAPT | USPHS
Real World Evidence Analytics
Office of Medical Policy (OMP)
CDER | FDA

11:30 – 12:15

Basics of Clinical Trial Design – Design, Population, Intervention, Outcomes

Fortunato Fred Senatore, MD, PhD, FACC
Lead Physician
Division of Cardiology and Nephrology (DCN)
Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN)
Office of New Drugs (OND) | CDER | FDA

DAY ONE: Wednesday, December 6, 2023

12:15 – 1:00

New Trends in Trial Design – Decentralized Clinical Trials (DCT), Digital Health Technologies (DHT), Real-World Evidence (RWE)

Leonard Sacks, MBBCh
Associate Director for Clinical Methodologies
OMP | CDER | FDA

John Concato, MD
Associate Director of Real-World Evidence
OMP | CDER | FDA

1:00 – 1:15

Q&A Session

Leonard Sacks (Moderator) — **Kimberly Smith, Fred Senatore, Leonard Sacks,** and **John Concato**

1:15 – 1:30: BREAK

1:30 – 2:00

Trial Design Considerations in Rare Diseases

Scott Winiecki, MD
Lead Physician
Rare Diseases Team (RDT)
Division of Rare Diseases and Medical Genetics (DRDMG)
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORDPURM)
OND | CDER | FDA

2:00 – 2:30

Special Populations in Clinical Trials

Lynne Yao, MD
Director
Division of Pediatric and Maternal Health (DPMH)
ORDPURM | OND | CDER | FDA

2:30 – 2:45

Q&A Session

Leonard Sacks (Moderator) — **Scott Winiecki** and **Lynne Yao**

2:45 – 3:00: BREAK

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DAY ONE: Wednesday, December 6, 2023

Day 1 - Part 2: Safety and Statistical Considerations

3:00 – 3:45

Safety Considerations in Clinical Drug Development

Shabnam Naseer, DO, MMS
Medical Team Leader
Division of Anti-Infectives (DAI)
Office of Infectious Diseases (OID)
OND | CDER | FDA

3:45 – 4:15

Statistical Principles for Clinical Drug Development

Mark Levenson, PhD
Director
Division of Biometrics VII (DBVII)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS)
CDER | FDA

4:15 – 4:30

Q&A Session

Leonard Sacks (Moderator) — **Shabnam Naseer** and **Mark Levenson**

4:30 – 4:35

Day One Closing

Leonard Sacks

4:35: DAY ONE ADJOURN

All times shown are Eastern (EST UTC-4)

DAY TWO: Thursday, December 7, 2023

11:00 – 11:15

Administrative Overview

Forest "Ray" Ford, PharmD, BCPS
Captain | United States Public Health Service (USPHS)
Pharmacist | Small Business, and Industry Assistance (SBIA)
Division of Drug Information (DDI)
Office of Communications (OCOMM) | CDER | FDA

Day 2 - Part 1: Considerations for Early Drug Development

11:15 – 11:45

Chemistry, Manufacturing, and Controls

Paresma Patel, PhD
Director | Division of New Drug API (DNDAPI)
Office of New Drug Products (ONDP)
Office of Pharmaceutical Quality (OPQ) | CDER

11:45 – 12:15

Pharmacology & Toxicology

Matthew Thompson, PhD, MPH
Supervisory Pharmacologist
Division of Hematology Oncology Toxicology (DHOT)
Office of Oncologic Diseases (OOD)
Office of New Drugs (OND) | CDER | FDA

12:15 – 12:45

Clinical Pharmacology

Shirley K. Seo, PhD
Director
Division of Cardiometabolic and Endocrine Pharmacology (DCEP)
Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS) | CDER | FDA

12:45 – 1:00

Q&A Session

Leonard Sacks (Moderator)
Associate Director for Clinical Methodologies
Office of Medical Policy (OMP) | CDER | FDA

Paresma Patel, Matthew Thompson and **Shirley K. Seo**

1:00 – 1:15: BREAK

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DAY TWO: Thursday, December 7, 2023

Day 2 - Part 2: Investigator Responsibilities

1:15 – 2:15

Investigator Responsibilities - Regulation and Clinical Trials and Clinical Trial Quality

Ann Meeker-O'Connell, MS
Director
Office of Clinical Policy (OCLiP)
Office of Clinical Policy and Programs (OCPP)
Office of the Commissioner (OC) | FDA

2:15 – 2:45

Clinical Investigator Site Inspections – What to Expect

Stephanie F. Coquia, MD
Good Clinical Practice Assessment Branch (GCPAB), Team 1
Division of Clinical Compliance Evaluation (DCCE)
Office of Scientific Investigations (OSI)
Office of Compliance (OC) | CDER | FDA

2:45 – 3:15

International Clinical Studies

Kassa Ayalew, MD, MPH
Branch Chief
Division of Clinical Compliance Evaluation (DCCE)
OSI | CDER | FDA

3:15 – 3:45

Q&A Session

Leonard Sacks (Moderator) **Ann Meeker-O'Connell, Stephanie F. Coquia,** and **Kassa Ayalew**

3:45 – 4:00

Wrap Up and Thank You

Leonard Sacks, MBBCh
Associate Director for Clinical Methodologies
OMP | CDER | FDA

4:00: ADJOURN

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