Version 5 – Updated October 24, 2022

FDA Clinical Investigator Training Course (CITC) 2022

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The Event Page on SBIAevents.com

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AGENDA

All times are Eastern (EST UTC-4)

View Start Time on World Clock

DAY ONE: Wednesday, December 7, 2022

11:00 – 11:15

SBIA Welcome

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

11:15 – 11:30

FDA Structure and Mandate

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

11:30 – 12:00

Endpoints in Cardiovascular Trials

Karen A. Hicks, MD., FACC
Deputy Director
Office of Medical Policy (OMP)
CDER | FDA

12:00 – 12:30

Special Populations in Clinical Trials

Lynne Yao, MD
Director
Division of Pediatric and Maternal Health (DPMH)
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORDPURM)
Office of New Drugs (OND) | CDER | FDA

DAY ONE: Wednesday, December 7, 2022

12:30 – 12:45

Q&A Session

Leonard Sacks, Karen Hicks, and **Lynne Yao**

12:45 – 1:00: BREAK

1:00 – 1:30

Statistical Principles for Clinical Drug Development

Mark Levenson, PhD
Director
Division of Biometrics VII | CDER | FDA

1:30 – 2:15

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

2:15 – 2:30

Q&A Session

Leonard Sacks, Mark Levenson, and **Shabnam Naseer**

2:30 – 3:15

Special Topics: Gene Therapy, CarT Therapy, International Clinical Trials

Lei Xu, MD., PhD
Branch Chief
General Medicine Brach 2 (GMB2)
Division of Clinical Evaluation & Pharmacology/Toxicology (DCEPT)
Office of Tissues and Advanced Therapies (OTAT) | CBER | FDA

Lianne Hu, MD., PhD., MPH, MS
Clinical Analyst
DCEPT | OTAT | CBER | FDA

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

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DAY ONE: Wednesday, December 7, 2022

3:15 – 3:30

Q&A Session

Leonard Sacks, Lei Xu, Lianne Xu, and **Kassa Ayalew**

3:30 – 3:35

Day One Closing

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

3:35: DAY ONE ADJOURN

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DAY TWO: Thursday, December 8, 2022

10:55 – 11:00

Administrative Overview

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

11:00 – 11:45

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

11:45 – 12:00

Q&A Session

Leonard Sacks and **Ann Meeker-O'Connell**

12:00 – 12:15

Real World Evidence

John Concato, MD
Associate Director of Real-World Evidence
Office of Medical Policy (OMP) | CDER | FDA

12:15 – 12:45

Innovative Trial Designs (Decentralized Clinical Trials, Digital Health Technologies)

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

12:45 – 1:00

Q&A Session

Leonard Sacks and **John Concato**

1:00 – 1:15: BREAK

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DAY TWO: Thursday, December 8, 2022

1:15 – 2:15

Early Drug Development

Topics:

- Chemistry Manufacturing and Controls (CMC)
- Pharmacology & Toxicology
- Clinical Pharmacology

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

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

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

2:15 – 2:30

Q&A Session

Leonard Sacks, Paresma Patel, Matthew Thompson, and **Shirley Seo**

2:30 – 2:40

Day Two Closing

Leonard Sacks, MBBCh
Associate Director
Office of Medical Policy (OMP) | CDER | FDA

2:40: ADJOURN

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