Small Business and Industry Assistance
FDA Clinical Investigator Training Course (CITC)
December 10-12, 2024

Version 5 – Updated October 15, 2024

FDA Clinical Investigator Training Course (CITC) 2024

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: Tuesday, December 10, 2024

11:00 – 11:10

SBIA Welcome & Logistics

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)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

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

11:10 – 11:30

FDA Structure and Mandate

Kimberly Smith, MD, MS
CAPT | USPHS
Senior Medical Advisor
OMP | CDER | FDA

11:30 – 12:15

Clinical Trial Design Basics

James P. Smith, MD, MS
Director | Office of New Drug Policy (ONDP)
Office of New Drugs (OND) | CDER | FDA

DAY ONE: Tuesday, December 10, 2024

12:15 – 1:00

Statistical Principles for Clinical Development

Mark Levenson, PhD
Acting Deputy Director | Office of Biostatistics (OB)
Office of translational Sciences (OTS) | CDER | FDA

1:00 – 1:20

Q&A Session

Kimberly Smith (Moderator) — **James P. Smith** and **Mark Levenson**

1:20 – 1:45: BREAK

1:45 – 2:30

Safety Considerations in Clinical Drug Development

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

2:30 – 3:00

Specific Populations in Clinical Trials

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

3:00 – 3:20

Q&A Session

Leonard Sacks (Moderator) — **Shabnam Naseer** and **Lynne Yao**

3:20 - 3:30

Day One Closing

Brenda Stodart

3:30: DAY ONE ADJOURN

All times shown are Eastern (EST UTC-4)

DAY TWO: Wednesday, December 11, 2024

11:00 – 11:10

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)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

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

11:10 – 11:40

Chemistry, Manufacturing and Controls: Regulatory Considerations Through Clinical Development

Paresma Patel, PhD
Director | Division of Product Quality Assessment XIX (DPQAXIX)
Office of Product Quality Assessment (OPQA) III
Office of Pharmaceutical Quality (OPQ) | CDER | FDA

11:40 – 12:10

Pharmacology/Toxicology in the Investigator's Brochure

Nikolett Biel, PhD
Senior Biologist
Division of Hematology Oncology Toxicology (DHOT)
Office of Oncologic Diseases (OOD)
Office of New Drugs (OND) | CDER | FDA

12:10 – 12:40

Why Clinical Pharmacology is Essential in Drug Development

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

12:40 – 1:00

Q&A Session

Leonard Sacks (Moderator) **Paresma Patel, Nikolett Biel** and **Shirley K. Seo**

1:00 – 1:30: BREAK

All times shown are Eastern (EST UTC-4)

DAY TWO: Wednesday, December 11, 2024

1:30– 2:00

New Trends in Trial Designs: Digital Health Technologies and Decentralized Trials

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

2:00 – 2:30

Informed Consent and Ethical Considerations in Clinical Trials

Ann Meeker-O'Connell, MS
Director | Office of Clinical Policy (OCP)
Office of the Chief Medical Officer (OCMO)
Office of the Commissioner (OC) | FDA

2:30 - 2:40

Q&A Session

Mili Duggal (Moderator)
Health Science Policy Analyst
OMP | CDER | FDA

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

2:40 - 3:10

(Title Under Development)

Karin Bok, MS, PhD
Deputy Director | Office of Vaccines Research & Review (OVRR)
Center for Biologics Evaluation and Research (CBER) | FDA

3:10 - 3:40

Innovative Therapeutics: Gene Therapy

Nicole Verdun, MD
Super Office Director
Office of Therapeutic Products (OTP) | CBER | FDA

3:40 – 3:50

Q&A Session

Leonard Sacks (Moderator)

Karin Bok and **Nicole Verdun**

3:50 - 4:00

Day Two Closing

Brenda Stodart

4:00: DAY TWO ADJOURN

All times shown are Eastern (EST UTC-4)

DAY THREE: Thursday, December 12, 2024

11:00 – 11:10

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)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

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

11:10 – 11:40

Clinical Trial Quality as Fitness for Purpose

Cheryl Grandinetti, PharmD
Associate Director for Clinical Policy
Division of Clinical Compliance Evaluation (DCCE)
Office of Scientific Investigations (OSI)
Office of Compliance (OC) | CDER | FDA

11:40 – 12:10

Investigator Responsibilities - Regulation and FDA Expectations for the Conduct of Clinical Trials

Miah Jung, PharmD, MS
Senior Pharmacologist
Division of Enforcement and Post-marketing Safety (DEPS)
OSI | OC | CDER | FDA

12:10 – 12:30

International Clinical Trials

Kassa Ayalew, MD, MPH
Division Director
DCCE | OSI | OC | CDER | FDA

12:30 – 12:50

Q&A Session

Leonard Sacks (Moderator) **Cheryl Grandinetti, Miah Jung** and **Kassa Ayalew**

12:50 – 1:15: BREAK

All times shown are Eastern (EST UTC-4)

DAY THREE: Thursday, December 12, 2024

1:15 – 1:45

FDA's Good Clinical Practice (GCP) Compliance Review for NDAs and BLAs

Cara Alfaro, PharmD
Senior Pharmacologist
DCCE | OSI | OC | CDER | FDA

1:45 - 2:05

Clinical Investigator Inspection Readiness

Michelle Anantha, MSPAS, PA-C, RAC
Senior Pharmacologist
DCCE | OSI | OC | CDER | FDA

2:05 - 2:35

Current and Innovative Alternative Approaches to Evaluating Compliance with GCP and FDA Regulations Approach

Emily Gebbia, JD
Associate Director for Regulatory Development
OSI | OC | CDER | FDA

2:35 - 2:55

Q&A Session

Kimberly Smith, MD, MS
(Moderator)
CAPT | USPHS
Senior Medical Advisor
OMP | CDER | FDA

Cara Alfaro, Michelle Anantha, and **Emily Gebbia**

2:55 - 3:05

Wrap Up and Thank You

Brenda Stodart

3:05: ADJOURN

All times shown are Eastern (EST UTC-4)