



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



December 10-12, 2024

Version 7 – Updated November 7, 2024

## FDA Clinical Investigator Training Course (CITC) 2024

For files and resources, please visit  
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### AGENDA

All times are Eastern (EST UTC-4)

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#### 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

**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)  
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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 Cardiomatabolic 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**

## 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

### mRNA Vaccines

**Karin Bok, MS, PhD**

*Deputy Director | Office of Vaccines Research & Review (OVR)*  
*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**

**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)  
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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**

## 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

### FDA's Use of Alternative Approaches to Evaluate GCP Compliance

**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