FDA Clinical Investigator Training Course (CITC) 2022

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Add Event to Your Calendar

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
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>12:30 – 12:45</td>
<td>Q&amp;A Session</td>
<td>Leonard Sacks, Karen Hicks, and Lynne Yao</td>
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<td>12:45 – 1:00</td>
<td>BREAK</td>
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<tr>
<td>1:00 – 1:30</td>
<td>Statistical Principles for Clinical Drug Development</td>
<td>Mark Levenson, PhD</td>
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<td>Director, Division of Biometrics VII</td>
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<td>1:30 – 2:15</td>
<td>Safety Considerations in Clinical Drug Development</td>
<td>Shabnam Naseer, DO, MMS</td>
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<td>Medical Team Leader, Division of Anti-Infectives (DAI)</td>
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<td>2:15 – 2:30</td>
<td>Q&amp;A Session</td>
<td>Leonard Sacks, Mark Levenson, and Shabnam Naseer</td>
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<td>2:30 – 3:15</td>
<td>Special Topics: Gene Therapy, CarT Therapy, International Clinical Trials</td>
<td>Lei Xu, MD., PhD</td>
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<td>Branch Chief, General Medicine Brach 2 (GMB2)</td>
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<td>Lianne Hu, MD., PhD., MPH, MS</td>
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<td>Clinical Analyst, DCEPT</td>
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<td>Kassa Ayalew, MD., MPH</td>
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<td>Branch Chief, Division of Clinical Compliance Evaluation (DCCE)</td>
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**DAY ONE: Wednesday, December 7, 2022**

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<th>Time</th>
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<tr>
<td>3:15 – 3:30</td>
<td>Q&amp;A Session</td>
<td>Leonard Sacks, Lei Xu, Lianne Xu, and Kassa Ayalew</td>
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<tr>
<td>3:30 – 3:35</td>
<td>Day One Closing</td>
<td>Brenda Stodart, PharmD, MS, BCGP, RAC-US</td>
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<td>Office of Communications (OCOMM)</td>
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<td>3:35</td>
<td>DAY ONE ADJOURN</td>
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**Notes:**

- All times shown are Eastern (EST UTC-4)
- FDA Acronyms & Abbreviations
## 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*

## 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*

## Q&A Session

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

## Real World Evidence

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

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

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

## Q&A Session

**Leonard Sacks** and **John Concato**

1:00 – 1:15: BREAK
## DAY TWO: Thursday, December 8, 2022

### 1:15 – 2:15

**Early Drug Development**

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

### 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

### 2:40: ADJOURN