Scientific Updates for Clinical Investigators

December 7, 2021

Add the Event to Your Calendar

AGENDA

View Start Time on World Clock

December 7, 2021 | 1:00 p.m. – 5:00 p.m. (Eastern, UTC-4)

1:00 pm	**Small Business and Industry Assistance (SBIA) Introduction**	**Brenda Stodart** *CAPT, USPHS* *Director, Small Business and Industry Assistance (SBIA)* Division of Drug Information (DDI) Office of Communications (OCOMM) Center for Drug Evaluation & Research (CDER) FDA	**10 mins**
1:10 pm	**CITC Overview**	**Leonard Sacks, MBBCh** *Associate Director* Office of Medical Policy (OMP) | CDER | FDA	**10 mins**
1:20 pm	**Gene Therapy**	**Lei Xu, MD, PhD** *Branch Chief* General Medicine Branch II | Office of Tissues and Advanced Therapies (OTAT) Center for Biologics Evaluation and Research (CBER)	**30 mins**
1:50 pm	**CarT Therapy**	**Lianne Hu, MD, PhD, MPH, MS** *Clinical Analyst* Division of Clinical Evaluation and Pharmacology/Toxicology OTAT | CBER | FDA	**30 mins**
2:20 pm	**Question and Answer Session**	Lei Xu Lianne Hu, Peter Bross, MD	**15 mins**
2:35 pm	***Break***		**15 mins**

The Small Business and Industry Assistance (SBIA) program in the Center for Drug Evaluation and Research provides guidance, education and updates for regulated industry.

- *Register for Upcoming Training*
- *Watch Learning Library Recordings on YouTube*
- *Subscribe to CDER SBIA Email Updates*
- *Follow on LinkedIn*

2:50 pm	**Innovations in the Design of Clinical Trials in Oncology**	**Sandra Casak, MD** *Acting Team Leader, Gastrointestinal Malignancies* Division of Oncology | Office of Oncologic Diseases (OOD) | Office of New Drugs (OND) CDER | FDA	**25 mins**
3:15 pm	**COVID-19 Treatment**	**Kirk Chan-Tack, MD and Sarita Boyd, PharmD** *Medical Officers* Division of Antivirals Office of Infectious Disease (OID) OND | CDER | FDA	**40 mins**
3:55 pm	**Question and Answer Session**	Sandra Casak Kirk Chan-Tack Sarita Boyd	**15 mins**
4:10 pm	**Trial Populations – Diversity, Sex Differences, Pediatrics**	**Mathilda Fienkeng, PharmD, MS, RAC** *CDR, USPHS* *Division Director* Division of Medical Policy Development Office of Medical Policy Initiatives (OMPI) OMP | CDER | FDA **Kaveeta Vasisht, MD, PharmD** *Associate Commissioner* Office of Women's Health (OWH) Office of the Commissioner (OC) | FDA **Lynne Yao, MD** *Director* Division of Pediatric and Maternal Health | Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORDPURM) OND | CDER | FDA	**30 mins**
4:40 pm	**Question and Answer Session**	CDR Mathilda Fienkeng Kaveeta Vasisht Lynne Yao	**15 mins**
4:55 pm	**Wrap up for the Day**		**5 mins**

Operational Updates for Clinical Investigators

December 8, 2021

Add the Event to Your Calendar

AGENDA

View Start Time on World Clock

December 8, 2021 | 1:00 p.m. – 4:30 p.m. (Eastern, UTC-4)

12:50 pm	**Introduction**	**Brenda Stodart**	**10 mins**
1:00 pm	**Master Protocols**	**Gregory Levin, PhD** *Deputy Director* Division of Biometrics III | Immediate Office | Office of Biostatistics (OB) | CDER | FDA	**15 mins**
1:15 pm	**Decentralized Clinical Trials (DCTs), Digital Health Technologies (DHTs)**	**Leonard Sacks, MBBCh** *Associate Director* Office of Medical Policy (OMP) | CDER | FDA	**15 mins**
1:30 pm	**Real World Evidence**	**John Concato, MD** *Associate Director of Real-World Evidence* OMP | CDER | FDA	**15 mins**
1:45 pm	**Drug Repurposing**	**Heather Stone, MPH** *Public Health Analyst* OMP | CDER | FDA	**15 mins**
2:00 pm	**Demo Session on Portal to Submit Research Investigational New Drugs (INDs)**	**Shoma Foss, MS, PMP** *Senior Business Informatics Program Manager* Office of Strategic Programs (OSP) Office of Business Informatics (OBI)	**15 mins**
2:15 pm	**Question and Answer Session**	Gregory Levin Leonard Sacks, John Concato Heather Stone, Shoma Foss	**30 mins**
2:45 pm	***Break***		**15 mins**
3:00 pm	**Investigator Responsibilities Including as Applied during Covid-19**	**Cynthia Kleppinger, MD** *Medical Officer* Good Clinical Practice Assessment Branch | Division of Clinical Compliance Evaluation | Office of Scientific Investigations (OSI) CDER | FDA	**60 mins**
4:00 pm	**Question and Answer Session**	Cynthia Kleppinger	**20 mins**
4:20 pm	**Wrap Up**	Leonard Sacks	**10 mins**