

Scientific Updates for Clinical Investigators

December 7, 2021

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AGENDA

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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 <i>CAPT, USPHS</i> 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 <i>Associate Director</i> Office of Medical Policy (OMP) CDER FDA	10 mins
1:20 pm	Gene Therapy	Lei Xu, MD, PhD <i>Branch Chief</i> 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 <i>Clinical Analyst</i> Division of Clinical Evaluation and Pharmacology/Toxicology OTAT CBER FDA	30 mins
2:20 pm	Question and Answer Session	Lei Xu Lianne Hu	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.

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2:50 pm	Innovations in the Design of Clinical Trials in Oncology	Sandra Casak, MD <i>Acting Team Leader, Gastrointestinal Malignancies</i> 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 <i>Medical Officers</i> Division of Antivirals Office of Infectious Disease (OID) OND CDER FDA	30 mins
3:45 pm	Question and Answer Session	Sandra Casak Kirk Chan-Tack Sarita Boyd	15 mins
4:00 pm	Trial Populations – Diversity, Sex Differences, Pediatrics	Mathilda Fienkeng, PharmD, MS, RAC <i>CDR, USPHS</i> <i>Division Director</i> Division of Medical Policy Development Office of Medical Policy Initiatives (OMPI) OMP CDER FDA	
		Kaveeta Vasisht, MD, PharmD <i>Associate Commissioner</i> Office of Women’s Health (OWH) Office of the Commissioner (OC) FDA	30 mins
		Lynne Yao, MD <i>Director</i> Division of Pediatric and Maternal Health Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORDPURM) OND CDER FDA	
4:30 pm	Question and Answer Session	CDR Mathilda Fienkeng Kaveeta Vasisht Lynne Yao	15 mins
4:45 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)

1:00 pm	Master Protocols	Gregory Levin, PhD <i>Deputy Director</i> 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 <i>Associate Director</i> Office of Medical Policy (OMP) CDER FDA	15 mins
1:30 pm	Real World Evidence	John Concato, MD <i>Associate Director of Real-World Evidence</i> OMP CDER FDA	15 mins
1:45 pm	Drug Repurposing	Heather Stone, MPH <i>Public Health Analyst</i> OMP CDER FDA	15 mins
2:00 pm	Demo Session on Portal to Submit Research Investigational New Drugs (INDs)	Shoma Foss, MS, PMP <i>Senior Business Informatics Program Manager</i> 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 <i>Medical Officer</i> 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