CDER Small Business and Industry Assistance

Webinars 2024

Version 6 – Updated August 2, 2024

FDA | NIH:
Regulatory Do's and Don'ts: Tips from FDA

Wednesday, September 4, 2024

Add Event to Your Calendar

AGENDA

All times are Eastern (EST UTC-5)

View Start Time on World Clock

11:00 – 11:05 AM

Welcome from FDA

Brenda Stodart, PharmD, MS, BCGP, RAC
Captain, United States Public Health Service (USHPS)
Director, Small Business, and Industry Assistance (SBIA)
Division of Drug Information (DDI) Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)

11:05 – 11:15

Welcome from NCI

Monique Pond, PhD
Team Leader & Program Director
Small Business Innovation Research (SBIR) Development Center
National Cancer Institute (NCI) | National Institutes of Health (NIH)

SESSION I: Center for Drug Evaluation and Research (CDER)

11:15 – 11:20

Overview of CDER's Small Business & Industry Assistance (SBIA)

This presentation will provide an overview of CDER SBIA and different ways to leverage the resources this program offer, such as free conferences and webinars, recordings of these events, a podcast, webpages with a wealth of information, opportunities to have questions answered and to stay connected and up to date with the latest regulatory information.

Brenda Stodart, PharmD, MS, BCGP, RAC
Captain, United States Public Health Service (USHPS)
Director, Small Business, and Industry Assistance (SBIA)
Division of Drug Information (DDI) Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)

11:20 – 11:30

An Oncology Drug Development Mindset – First Steps

This presentation will focus on FDA's role at this early stage of Drug development and also provide a high-level overview of Resources and meetings.

Jeff Summers, MD
Associate Office Director
Office of Oncologic Diseases (OOD)
Office of New Drugs (OND | CDER

11:30 – 11:40

Overview of CDER Regulatory Resources CMC for pIND/IND Submissions

This presentation will:

- Focus on chemistry, manufacturing, and controls (CMC) resources and requirements to support submission of an IND.
- Provide an overview of the regulations that govern CMC requirements for an IND application and how the requirements change through clinical development.
- Address typical FDA interactions with IND sponsors (e.g., pre-IND meetings, Type C meetings), CMC challenges, and resources for products developed under expedited programs.

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

11:40 – 11:50

Overview of CDER Nonclinical Resources and Guidance for Approaching First-in-Human (FIH) Studies

This presentation will discuss CDER resources pertinent to early nonclinical development in oncology and recommendations for approaching FIH studies. Topics of discussion will include relevant nonclinical guidances, Good Laboratory Practice (GLP), nonclinical studies recommended to support the initiation of FIH studies, DHOT publications on FIH dose selection, potential pitfalls encountered by Sponsors, and pre-IND meetings.

Emily Wearne, PhD
Pharmacologist/Acting Nonclinical Team Leader
Division of Hematology Oncology Toxicology (DHOT)
OOD | OND | CDER

11:50 – 12:00

CDER's Clinical Consideration for First-in-Human Trials

This presentation will provide an overview of expectations and common pitfalls of First-in-Human trials and discuss resources available for protocol development, including templates and guidances.

Caitlin Tydings, MD
Pediatric Hematologist/Oncologist
Medical Officer, Division of Oncology 3
OOD | OND | CDER

All times shown are Eastern (EST UTC-4)

12:00 – 12:20

Session I Q&A Panel

Moderator:
Nora Lim, PharmD, BCPS
LCDR | USPHS | *Pharmacist*
SBIA | DDI | OCOMM | CDER

All CDER Speakers

12:20 - 12:35: BREAK

SESSION II: Center for Biologics Evaluation and Research (CBER)

12:35 – 12:40 PM

Overview of CBER's Manufacturers Assistance and Technical Training Branch (MATT)

This presentation will provide an overview of CBER's Manufacturers Assistance and Technical Training Branch which responds, via telephone and email, to inquiries from biologics industry/manufacturers.

Loni Warren Henderson
Public Affairs Specialist
Manufacturers Assistance and Technical Training Branch
Division of Manufacturers Assistance and Training
Office of Communication Outreach and Development | CBER

12:40 – 12:50

Regulatory Resources and Avenues for Obtaining Early Guidance from CBER/OTP

This presentation will provide an overview of the regulatory Resources and avenues for obtaining early guidance from CBER's Office of Therapeutic Products, including meetings, Webpages, webinars and additional resources.

Heather Erdman, MCPM, RAC, CQPA
Associate Director of Quality Assurance
Office of Review Management and Regulatory Review (ORMRR)
Office of Therapeutic Products (OTP) | CBER

12:50 – 1:00

CBER's CMC Considerations for Early Phase Studies of Cell and Gene Therapy Products

This presentation will discuss CBER's chemistry, manufacturing, and controls (CMC) resources and requirements to support submission of INDs for early phase studies evaluating cell and gene therapy products.

Karin Knudson, PhD
CMC Reviewer
Office of Cellular Therapy and Human Tissue CMC (OCTHT) | OTP | CBER

1:00 – 1:10

Nonclinical Assessment of Cell and Gene Therapy Products to Support an IND

This presentation will provide an overview of CBER's nonclinical assessment of early-stage cell and gene therapy (CGT) products. Discussion topics will include CBER resources for sponsors at early stages of product development such as the pre-IND and INTERACT meetings, critical considerations for nonclinical studies conducted to support the initiation of First-In-Human (FIH) studies, potential pitfalls encountered by sponsors and CGT-related guidance documents

Devaveena Dey, PhD
Pharmacology-Toxicology Reviewer
Office of Pharmacology-Toxicology (OPT) | OTP | CBER

All times shown are Eastern (EST UTC-4)

1:10 – 1:20

Clinical Consideration for Cell and Gene Therapy in Early Phase Study

This presentation will cover key clinical regulatory issues encountered during early-phase clinical development (especially first-in-human study) of cell and gene therapy (CGT).

Jessica Lee, MD, PhD
Branch Chief for the Oncology Branch 2 (OB2)
Division of Clinical Evaluation Oncology (DCEO)
Office of Clinical Evaluation (OCE) | CBER

1:20 – 1:35

Session II Q&A Panel

Moderator:
Nora Lim, PharmD, BCPS
LCDR | USPHS | *Pharmacist*
SBIA | DDI | OCOMM | CDER

All CBER Speakers
and
Peter F. Bross, MD
Chief, Oncology Branch
OTP | CBER

1:35 – 1:50: BREAK

SESSION III: Center for Devices and Radiological Health (CDRH)

1:50 – 2:10 PM

How Can DICE Help You?

This presentation will provide a brief introduction to CDRH's Division of Industry and Consumer Education (DICE) and will describe the educational and informational resources available to the medical device industry.

Giselle Blanco
Consumer Safety Officer
Premarket Programs Branch (PPB)
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE) | CDRH

2:10 – 2:20

Medical Device Development Tools Program

This presentation will focus on CDRH's qualification pathway through the Medical Device Development Tools Program (MDDT). The MDDT Program supports medical device manufacturers through qualification of regulatory science tools that are intended to assess safety, effectiveness, or performance of a medical device. The presentation will introduce the MDDT Program, types of MDDTs and details around how to access and use qualified tools to support marketing applications.

Jessica Mavadia-Shukla, PhD
Director | Medical Device Development Tools Program
Division of Partnerships and Innovation (DPI)
Office of Equity and Innovative Development (OEID)
Office of Strategic Partnerships and Technology Innovation (OST) | CDRH

All times shown are Eastern (EST UTC-4)

2:20 – 2:30

Medical Device Coverage Initiatives: Connecting with Payors via the Payor Communication Task Force

This presentation will provide an overview of the Early Payor Feedback Program, which allows sponsors to solicit feedback from both public and private payors thus providing an opportunity for sponsors to learn what data payors may need to make a positive coverage decision.

Danielle Fau, MSE
Senior Advisor for Technology and Innovation
Division of Health Equity (DHE)
OEID | OST | CDRH

2:30 – 2:50

Session III Q&A Panel

Moderator:
Nora Lim, PharmD, BCPS
LCDR | USPHS | *Pharmacist*
SBIA | DDI | OCOMM | CDER

All CDRH Speakers

2:50 – 3:00

Closing Remarks

Jeff Summers, MD
Associate Office Director
OOD | OND | CDER

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