**FDA | NIH:**

**Regulatory Do’s and Don’ts: Tips from FDA**

Wednesday, September 4, 2024

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**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 NIH**

Monique Pond, PhD  
*Team Leader & Program Director*  
*Small Business Innovation Research (SBIR) Development Center*  
*National Cancer Institute | 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 offers, 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.
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*
### Session I Q&A Panel

**Moderator:**

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

**All CDER Speakers**

12:00 – 12:20

#### 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

**Preclinical 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*
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
### 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

#### Session II

**2:30 – 2:50**

**Session III Q&A Panel**

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

**All CDER Speakers**

#### Closing Remarks

**2:50 – 3:00**

**Closing Remarks**

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