Version 9 – Updated March 26, 2021

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AGENDA

All times are Eastern (EST UTC-4)
View Start Time on World Clock

DAY ONE: Tuesday, March 30, 2021

9:00 – 9:15

Administrative Overview

Brenda Stodart
CAPT, USPHS
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM) | CDER

9:15 – 9:20

Oncology Center of Excellence Introduction

Marc Theoret
Deputy Director
Oncology Center of Excellence (OCE)
Office of the Commissioner

9:20 – 9:35

Overview and Guide to the Workshop

Jeffrey Summers
Associate Director, Translational Sciences
Office of Oncologic Diseases (OOD) | CDER

9:35 – 10:30

Keynote: Innovation Mindset – Advancing Science to Therapies

Science is hard. With only a 1 in 10,000 likelihood of advancing a novel discovery to a commercial product, the process can be daunting, let alone difficult to navigate. Approaching each facet of this journey with an innovation mindset and clarity of purpose are key to improving both your odds of success and your experience (includes Q&A with presenter).

Keith Marmer
Chief Innovation & Economic Engagement Officer
University of Utah

View Speaker Biographies

DAY ONE: Tuesday, March 30, 2021

Your SBIA Host for Day One

Lisa Misevicz
Health Communications Specialist
SBIA | DDI | OCOMM | CDER

10:30 – 11:00

FDA Oncology Drug Development Overview - Past to Present

Provides a historical overview of oncology drug development past to present (includes Q&A with presenter).

John Leighton
Director
Division of Hematology, Oncology, Toxicology
OOD | CDER

11:00 – 11:15

Federal Resources for Innovative Cancer Startups: More than Just Funding!

In this talk, I will cover why SBIR funding is an attractive funding opportunity for startups, provide a primer on SBIR/STTR and discuss what makes a good SBIR application. I will discuss current funding opportunities, non-funding resources that can help accelerate commercialization and end with a few tips for a successful application.

Deepa Narayanan
Program Director & Team Lead
NCI Small Business Innovation Research Development Center
National Cancer Institute, NIH

11:15 – 11:35

Best Practices for Venture Capital Fundraising: Learn How Early-stage VCs Think

Two biotech venture capitalists will describe how investors think and what they are looking for in investment opportunities. They will also share tips for pitching to VCs and dos and don’ts of fundraising.

Colleen Cuffaro
Partner
Canaan Partners

Christy Shaffer
Partner
Hatteras Venture Partners

11:35 – 11:50

Funding Sources: Q&A Panel

Deepa Narayanan, Colleen Cuffaro, Christy Shaffer

11:50 – 12:50: LUNCH BREAK

DAY ONE: Tuesday, March 30, 2021

12:50 – 1:05

Considerations for Building Your Broader Network and Value to Obtaining External Input Prior to Interacting with FDA

As a former FDA reviewer, I will cover the limitations FDA has in providing detailed development strategy advice to programs and will share tips on getting the most out of your FDA interactions. With a view towards small companies with limited internal resources, I will share advice on how to broaden your advice network and what to look for in consultants and external partners to ensure product success.

Julie Bullock
Vice President
Integrated Drug Development
Certara

1:05 – 1:20

Assembling the Best Team to Navigate Through Preclinical Development

This session will highlight some of the early-stage development challenges for startups, including some of the common pitfalls in planning and executing IND-enabling studies. We will focus on how to effectively transition from academic research to preclinical development and where to seek guidance along the way. Examples and tips for working with CROs will also be discussed.

Christopher Scull
Senior Consultant
Biologics Consulting

1:20 – 1:35

Consulting Companies and FDA Limitations: Q&A Panel

Julie Bullock, Christopher Scull

1:35 – 2:05

CMC Considerations for CAR T Cell Product Development

This talk will outline the CMC requirements for CAR T cell product IND submissions. Specific aspects on early product development and product characterization will be discussed for both autologous and allogenic products (includes Q&A with presenter).

Kimberly Schultz
Gene Therapy Reviewer
Division of Cellular & Gene Therapies
Office of Tissues and Advanced Therapies (OTAT) | CBER

2:05 – 2:35

CMC Considerations for Oncolytic Viral Product Development

This talk will provide an overview of basic CMC requirements for oncolytic viral products. Specific topics will include recommendations on strategies and critical considerations for early phase product development, including control of the starting materials and reagents, the manufacturing process, and product testing (includes Q&A with presenter).

Bo Liang
Gene Therapy Reviewer
Division of Cellular & Gene Therapies
OTAT | CBER

2:35 – 2:45: BREAK

DAY ONE: Tuesday, March 30, 2021

2:45 – 3:35

Preclinical Considerations for Cell and Gene Therapy Products, An FDA Perspective

In this talk, I will describe the preclinical program to inform early clinical development for cell and gene therapy (CGT) products. Particularly, I will provide considerations for relevant animal models and assessments for proof-of-concept, safety, and biodistribution to support first-in-human studies of CGT products in oncology, as well as updates of pathways for early communication with FDA/CBER (includes Q&A with presenters).

Ying Huang
Pharmacology/Toxicology Reviewer
Division of Clinical Evaluation and Pharmacology/Toxicology
OTAT | CBER

3:35 – 4:15

FDA's Clinical Regulatory Perspective: Designing First-In-Human Trial for Cellular and Gene Therapy Products

This session outlines key issues in reviewing first-in-human clinical protocols for cellular and gene therapy products for the treatment of cancer and describes pitfalls to avoid when designing these studies. Lessons learned from successful oncology cellular and gene therapy products and questions about clinical development will be addressed (includes Q&A with presenter).

Peter Bross
Chief (Acting)
Oncology Branch
Division of Clinical Evaluation and Pharmacology/Toxicology
OTAT | CBER

4:15 – 4:30

Day One Closing

Jeffrey Summers
Associate Director, Translational Sciences
Office of Oncologic Diseases (OOD) | CDER

4:30: DAY ONE ADJOURN

DAY TWO: Wednesday, March 31, 2021

9:00 – 9:05

Administrative Overview from Your Day Two Host

Lisa Misevicz
Health Communications Specialist
SBIA | DDI | OCOMM | CDER

9:05 – 9:10

Welcome and Overview for Day Two

Jeffrey Summers
Associate Director, Translational Sciences
Office of Oncologic Diseases (OOD) | CDER

9:10 – 10:10

Chemistry and Manufacturing Requirements for Early Clinical Development: What's in there? Prove it.

CMC reviewers will provide insight into the FDA's perspective when reviewing early development IND submissions. An emphasis will be placed on common missteps that can lead to clinical holds for CMC deficiencies and critical documentation expected in the original IND submission (includes Q&A with presenters).

Paresma Patel
Acting Branch Chief, Division of New Drug API

Olen Stephens
Chemist, Division of New Drugs Products 1

Office of Pharmaceutical Quality (OPQ)
Office of New Drug Policy (ONDP) CDER

10:10 – 11:10

CMC Considerations for Biotechnology Product Development: A Regulatory Perspective

This session provides an overview of regulatory expectations for biotechnology products, regulatory challenges, and strategies for success (includes Q&A with presenters).

Wendy Weinberg
Chief, Laboratory of Molecular Oncology

Kristen Nickens
Product Quality Team Lead

Office of Biotechnology Products (OBP)
Office of Pharmaceutical Quality (OPQ | CDER

DAY TWO: Wednesday, March 31, 2021

11:10 – 11:40

Getting to FIH for Small Molecules and Biologics

This talk will cover the main guidance documents and nonclinical expectations for initiating trials and developing small molecule and biologic products for oncology drugs in CDER, as well as some common misconceptions and stumbling blocks (includes Q&A with presenter).

Whitney Helms
Supervisor, Pharmacology/Toxicology
Division of Hematology, Oncology, Toxicology
OOD | CDER

11:40 – 12:20

Designing First-in-Human Trials for Small Molecules and Biologics

This presentation will provide an overview of the key design considerations for first-in-human trials of drugs intended to treat patients with cancer. Key topics include the approach to defining the patient population for eligibility, selection of the appropriate starting dose, dose escalation designs, protocol provisions to minimize patient risk, dose optimization, and initial assessment of antitumor activity for small molecules and biologics (includes Q&A with presenter).

Martha Donoghue
Acting Deputy Director
Division of Oncology 2
OOD | CDER

12:20 - 1:00: LUNCH BREAK

1:00 – 1:55

Planning for Co-development of Companion Diagnostics

This talk will provide an overview of points to consider when planning for companion diagnostics including the use of investigational tests, how trial strategies can impact the companion diagnostic indication, common pitfalls to avoid, and how to obtain regulatory feedback (includes Q&A with presenter).

Donna Roscoe
Deputy Director
Division of Molecular Genetics and Pathology
Office of In Vitro Diagnostics and Radiological Health
CDRH

1:55 – 2:40

Clinical Development of Radiopharmaceuticals as Theranostic Pairs and Dosimetry Considerations for Therapeutic Radiopharmaceuticals

Radiopharmaceuticals represent a growing portion of the armamentarium for treating cancer. In this context, theranostics refer to radiopharmaceutical therapies and nuclear medicine imaging drugs that share a mechanism of action and whose use may be coordinated during drug development, for pre-therapy dose and patient selection, and/or for post-therapy evaluation. This talk is focused on emerging pre-market pathways at FDA for theranostic co-development (includes Q&A with presenters).

Anthony Fotenos
Lead Medical Officer

Donika Plyku
Senior Staff Fellow

Division of Imaging and Radiation Medicine
Office of Specialty Medicine
Office of New Drugs (OND) | CDER

2:40 – 2:55: BREAK

DAY TWO: Wednesday, March 31, 2021

2:55 – 3:45

Getting the Best Dose: The Clinical Pharmacology Studies that Help Achieve this Goal

The main goal of clinical pharmacology is to get the optimal dose for patients. I will discuss how the various clinical pharmacology studies help better understand dose optimization for different patients (includes Q&A with presenter).

Brian Booth
Director, Division of Cancer Pharmacology 1
Office of Clinical Pharmacology (OCP)
Office of Translational Science (OTS) | CDER

3:45 – 4:05

Panel Discussion

Jeffrey Summers
Associate Director, Translational Sciences
Office of Oncologic Diseases (OOD) | CDER

Marc Theoret
Deputy Director
Oncology Center for Excellence (OCE) | CDER

4:05 – 4:10

Day Two Closing

Jeffrey Summers
Associate Director, Translational Sciences
Office of Oncologic Diseases (OOD) | CDER

4:10: ADJOURN