NCI Drug Development Workshop
How to Advance a Therapeutic Candidate from Bench to Bedside

Agenda

July 23, 2021, 12 pm – 2:30 pm ET

Session I. Grand Overview

Introduction, *Rose Aurigemma, Ph.D., National Cancer Institute*

Topic 1: Clinical mindset to lead pre-IND activities: plan backward and develop forward
Rose Aurigemma, Ph.D., National Cancer Institute

Topic 2: Key milestones in drug development and components of an IND-package
Phil Jones, Ph.D., The University of Texas MD Anderson Cancer Center

Q&A

July 30, 2021, 12 pm – 2:30 pm ET

Session II. Pre-clinical Proof of Concept: Establishing Activity, Bioavailability, and Associated Effect, in Cancer Relevant Models

Topic 1: Establish therapeutic activity of an agent or a combination of agents
Melinda Hollingshead, D.V.M., Ph.D., National Cancer Institute

Topic 2: Preclinical pharmacology in IND-enabling studies and clinical pharmacology in clinical protocol development
Alex Sparreboom, Ph.D., The Ohio State University College of Pharmacy & Comprehensive Cancer Center

Q&A

August 6, 2021, 12 pm – 2:30 pm ET

Session III. Non-clinical Toxicology

Topic 1: Preliminary and IND-directed toxicology studies
Elizabeth Glaze, Ph.D., National Cancer Institute

Topic 2: Assays and endpoints for toxicology studies to assess immune-related adverse events
Marc Ernstoff, M.D., National Cancer Institute

Q&A

August 20, 2021, 12 pm – 2:30 pm ET

Session IV. Chemistry Manufacturing and Controls for Small Molecules

Topic 1: What is a certificate of analysis, and the assays and analytical methods needed for product release?
Donald Drinkwater, Ph.D., Albany Molecular Research Inc.
Andy Leyhane, Ph.D., Albany Molecular Research Inc.

Topic 2: Clinical formulations development and factors that influence small molecule product development
Esmail Tabibi, Ph.D., National Cancer Institute

Q&A

September 10, 2021, 12 pm – 2:30 pm ET

Session V. Development of Biological Products

Topic 1: Overview of product types and various applications in cancer
Jason Yovandich, Ph.D., National Cancer Institute

Topic 2: Process development: cell line development, upstream and downstream
Rachelle Salomon, Ph.D., National Cancer Institute

Topic 3: Characterization and quality control of biological product
Ray Harris, Ph.D., National Cancer Institute

Topic 4: Cellular therapy: special path from preclinical study to clinical testing
Anthony Welch, Ph.D., National Cancer Institute

Q&A

September 24, 2021, 12 pm – 2:30 pm ET

Session VI. Regulatory Considerations

Topic 1: FDA overview and perspective on regulatory requirements for an IND filing for oncology products
Rachel McMullen, M.P.H., M.H.A., Food and Drug Administration
May Tun Saung, M.D., Food and Drug Administration

Topic 2: FDA's regulatory requirements for an IND filing: preclinical data assessment
Amy Skinner, Ph.D., Food and Drug Administration

Topic 3: Overview of the process, workflows, timings for filings, and interactions with FDA
Bhanu Ramineni, M.B.A., M.S., National Cancer Institute
Tracy Lively, Ph.D., National Cancer Institute

Q&A

October 29, 2021, 12 pm – 2:30 pm ET

Session VII. Clinical Translation

Topic 1: Biomarkers and companion diagnostics in IND filing and clinical trial design
Tracy Lively, Ph.D., National Cancer Institute

Topic 2: Phase I trial design and considerations and CTEP clinical trial resource
Jeff Moscow, M.D., National Cancer Institute

Topic 3: Clinical development of immunotherapies
Marc Ernstoff, M.D., National Cancer Institute

Q&A

November 19, 2021, 12 pm – 2:30 pm ET

Session VIII. Entrepreneurship: Partnering and Advancing

Topic 1: Engaging with development partners
Jeremy Caldwell, Ph.D., Inception Sciences, Incorporated

Topic 2: Creating a data package for pharma/biotech
Carolyn Buser-Doepner, Ph.D., GlaxoSmithKline

Q&A

December 3, 2021, 12 pm – 2:30 pm ET

Session IX. NCI Translational Resources and Programs

NCI Experimental Therapeutics (NExT) Program, *Barbara Mroczkowski, Ph.D., National Cancer Institute*

Small Business Innovation Research (SBIR), *Kory Hallett, Ph.D., National Cancer Institute*

NCI DTP Resources and the Stepping Stones Program, *Rose Aurigemma, Ph.D., National Cancer Institute*

CTEP Formulary and Intellectual Property-related issues, *Jason Cristofaro, Ph.D., J.D., National Cancer Institute*

Clinical translation grant mechanisms, *Lori Henderson, Ph.D., National Cancer Institute*

NCI Patient-Derived Models Repository (PDMR), *Yvonne Evrard, Ph.D., Frederick National Laboratory for Cancer Research*

Q&A

December 10, 2021, 12 pm – 2:30 pm ET

Session X. Case Studies

Case study 1: Development of small molecule product
Jolanta Grembecka, Ph.D., University of Michigan
Mollie Leoni, M.D., Kura Oncology, Inc.

Case study 2: Development of biological products
Alice L. Yu, M.D., Ph.D., University of California in San Diego

Q&A