FDA-AACR Public Workshop on
OPTIMIZING DOSAGES FOR ONCOLOGY DRUG PRODUCTS: QUANTITATIVE APPROACHES TO SELECT DOSAGES FOR CLINICAL TRIALS

DAY 1 – Thursday, February 15, 8 a.m. – 5 p.m. | Grand Hyatt Washington

Welcome:
Pattricia M. LoRusso, DO, PhD (hc),
FAACR, Yale Cancer Center

Opening Remarks:
Marc Theoret, MD, FDA

Overview of Workshop:
Stacy S. Shord, PharmD, FDA

Session 1: Selecting Dosages for Dose-Escalation Portion of First-In-Human Trials

Session 1A: Utilizing Nonclinical Data and Modeling to Support Dosage Selection for First in Human Trials

Moderator:
Hao Zhu, PhD, FDA

Introductory Speaker:
Applications of Model-Based Approaches to Select the Starting Dosages for First-In-Human Trials: Alex Phipps, PhD, AstraZeneca

Additional Panelists:
• Matthew Thompson, PhD, FDA
• Jiang Liu, PhD, FDA
• Ralph Parchment, PhD, NCI Frederick National Laboratory
• Manish Gupta, PhD, Genmab

Session 1B: Alternative Designs for Dose-Finding Trials: Ending Reliance on Short-Term Safety

Moderator:
Hao Zhu, PhD, FDA

Introductory Speaker:
How to Pivot Beyond Rule-Based and Model-Based Determinations to Support Dosage Selection: Ying Yuan, PhD, MD Anderson

Additional Panelists:
• Jonathon Vallejo, PhD, FDA
• Jamie Brewer, MD, FDA
• Amit Roy, PhD, PumasAI
• Bruno Gomes DVM, PhD, Roche
• Brian Koffman, MDCM (retired), MSEd, CLL Society

Session 2: Selecting Dosages for Additional Exploration Based on Nonclinical and Early Clinical Data

Session 2A: Evaluating and Modeling All Early Data to Select Recommended Phase II Dose

Moderator:
Olanrewaju Okusanya, PharmD, MS, FDA

Introductory Speaker:
Modeling-Based Approaches Incorporating Emerging Clinical Data and Relevant Non-Clinical Data to Support Dosage Selection: Gabby Patilea-Vrana, PhD, Pfizer

Additional Panelists:
• Jerry Yu, PhD, FDA
• Atiqr Rahman, PhD, FDA
• Lillian Siu, MD, Princess Margaret Cancer Center
• Manju George, MVSc, PhD, COLONTOWN

Session 2B: Novel Trial Designs to Enhance Dose-Selection Decision Making

Moderator:
Timothy Yap, MBBS, PhD, MD Anderson

Introductory Speakers:
Using Novel Activity and Safety Endpoints in Clinical Trials to Support Dosage Selection: Anthony “Nino” Sireci, MD, MS, Loxo@Lilly

Utilizing Randomized Dosage Comparison and Controlled Backfill to Gain Greater Understanding of Dose- and Exposure-Response Relationships for Safety and Activity: Alexia Iasonos, PhD, Memorial Sloan Kettering Cancer Center

Additional Panelists:
• Mallorie Fiero, PhD, FDA
• Nicole Gormley, MD, FDA
• Vishal Bhatnagar, MD, FDA

Day 1 Wrap-Up and Day 2 Preview

Raj Madabushi, PhD, FDA
Welcome:  
Qi Liu, PhD, FDA

Section 3: Selecting Dosages for Registrational Trials

Session 3A: Considering the Totality of Efficacy and Safety Data to Aide Registrational Trial Designs

Moderator:  
Stacy S. Shord, PharmD, FDA

Introductory Speakers:
Using Modeling-Based Approaches to Understand Dose- and Exposure-Response Relationships for Activity: Jin Y. Jin, PhD, Genentech

Using Pharmacokinetic-Pharmacodynamic Modeling and Simulation to Understand Dose and Exposure-Response Relationships for Adverse Reactions: Scott Van Wart, PhD, Enhanced Pharmacodynamics

Additional Panelists:
• Youwei Bi, PhD, FDA
• Cara Rabik, MD, PhD, FDA
• W. Douglas Figg, PharmD, NCI
• Julia Maues, Patient Centered Dosing Initiative

Session 3B: Implementing Seamless and Adaptive Registrational Trial Designs

Moderator:  
Geoff Oxnard, MD, Loxo@Lilly

Introductory Speaker:
Adaptive Phase 2/3 Designs with Dose Selection: A Statistical Perspective: Cong Chen, PhD, Merck

Additional Panelists:
• Joyce Cheng, PhD, FDA
• Mirat Shah, MD, MHS, FDA
• Mehdi Lahmar, MD, PhD, Boehringer Ingelheim
• Debbie Pickworth, BRAF Bombers & American Lung Association

Closing Remarks, Lessons Learned and Next Steps

Moderator:  
Patricia M. LoRusso, DO, PhD (hc), FAACR, Yale Cancer Center

Additional Panelists:
• Atiqur Rahman, PhD, FDA
• Jin Y. Jin, PhD, Genentech
• Julia Maues, Patient Centered Dosing Initiative
• Geoff Oxnard, MD, Loxo@Lilly
• Alex Phipps, PhD, AstraZeneca
• Lillian Siu, MD, Princess Margaret Cancer Center