Optimizing Oncology Therapeutics –
An Opportunity for Collaborative Multi-Dimensional Problem-Solving

• Emerging Therapeutic Modalities
• “-Omics” science – Pharmacoinformatics
• Precision Medicine – Patient Selection
• Combination Partner Selection
• Dose/ Schedule/ Sequence Optimization
• Safety/ Tolerability and Adherence
• Smarter & Efficient Clinical Trial Designs
Increasing Commitment to Optimizing Dose Selection

Optimizing Dosing of Oncology Drugs

Optimal Dosing for Targeted Therapies in Oncology: Drug Development Cases Leading by Example
Jeffrey R. Sachs1, Kapil Mayawala2, Satvik Gadamsetty3, Soonmo Peter Kang4, and Dinesh P. de Alwis2
Clin Cancer Res. 22(6); 1–7, 2016
SAFETY IMMUNO-ONCOLOGY
CLINICAL TRIAL SIMULATION
TRANSLATIONAL MEDICINE COLLABORATION
MOLECULARLY TARGETED AGENTS DOSING SCHEDULE
ADVANCING ONCOLOGY THERAPEUTICS
PERSONALIZED MEDICINE BIOLOGICS QUANTITATIVE PHARMACOLOGY
EDUCATION BENEFIT-RISK OPTIMIZATION
COMBINATION DEVELOPMENT TRANSLATIONAL PK-PD
TUMOR GROWTH MODELING
CANCER CELL SIGNALING DOSE SELECTION
8:30 AM – 8:40 AM
WELCOME AND INTRODUCTION

8:40 AM – 9:25 AM
Personalized Medicine
Razelle Kurzrock, MD

9:25 AM – 9:50 AM
Modeling Cellular Signaling Networks for Oncology Drug Development
Daniel Kirouac, PhD

9:50 AM – 10:15 AM
PK/PD Efficacy Modeling of Combinations to Guide Scheduling and Sequencing
Sonya C. Tate, PhD

10:15 AM – 10:35 AM
COFFEE BREAK

10:35 AM – 11:00 AM
Translational Safety Models in the Development of Oncology Compounds
Jay Mettetal, PhD

11:00 AM – 11:25 AM
Dose Optimization by Safety Guided Titration Approaches: Axitinib as a Case Example
Yazdi Pithavala, PhD

11:25 AM – 11:50 AM
Model-Based Integration of Clinical Safety/Tolerability of Oncology Drugs to Optimize Dosing
Lena E. Friberg, PhD

11:50 AM – 12:15 PM
Therapeutic Drug Monitoring in Oncology Improves Patient Outcomes
Jeannine McCune, PharmD

12:15 PM – 1:45 PM
LUNCH/NETWORKING/POSTERS
1:45 PM – 2:30 PM
Clinical Perspective: Immuno-Oncology
Suresh S. Ramalingam, MD

2:30 PM – 2:55 PM
M&S Approaches for Immuno-Oncology
Amit Roy, PhD

2:55 PM – 3:20 PM
Disease Models in Oncology: Optimizing Trial Designs to Maximize POS
Rene Bruno, PhD

3:20 PM – 3:45 PM
Special Considerations for Modeling Exposure-Response for Biologics
Yaning Wang, PhD

3:45 PM – 4:00 PM
BREAK

4:00 PM – 5:00 PM
ORAL SESSION FROM POSTERS

OPC1: PBPK-PD MODELING TO PROVIDE A TRANSLATIONAL RATIONALE BETWEEN DRUGS AND BETWEEN SPECIES: EXAMPLE OF TRAIL FUSION PROTEINS.
Michael Block, PhD

OPC2: A JOINT MODEL RELATING CHANGES IN PROSTATE SPECIFIC ANTIGEN (PSA) TO SURVIVAL IN CASTRATE RESISTANT PROSTATE CANCER (CRPC).
Tu Mai, PhD

OPC3: QUANTITATIVE ASSESSMENT OF THE EFFICACY OF TAK-385, AN INVESTIGATIONAL, ORAL GNRH ANTAGONIST IN PROSTATE CANCER PATIENTS (PTS) TO OPTIMIZE TRIAL DESIGN AND DOSE SELECTION.
Hélène Faessel, PharmD, PhD

OPC4: COMBINED POPULATION PK MODELING AND DISPROPORTIONALITY ANALYSES TO ASSESS THE ASSOCIATION BETWEEN KINASE INHIBITION AND ADVERSE EVENTS.
Jinzhong Liu, PhD

5:00 PM – 5:30 PM
CLOSING REMARKS
Pre-Conference Organizing Committee

• Co-Chairs
  – Karen Rowland-Yeo, PhD
  – Karthik Venkatakrishnan, PhD

• Planning Committee
  – R. Donald Harvey, PharmD, BCOP, FCCP, FHOPA
  – Julie Bullock, PharmD
  – Jin Y. Jin, PhD

• Scientific Program Committee Chair
  – Mark J. Dresser, PhD

THANK YOU!