



QUANTITATIVE TRANSLATIONAL APPROACHES IN ONCOLOGY
PRE-CONFERENCE

March 8, 2016

ASCPT 2016 ANNUAL MEETING

MARCH 8-12, 2016

HILTON BAYFRONT, SAN DIEGO, CA

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

L. Minasian¹, O Rosen², D Auclair³, A Rahman⁴, R Pazdur⁴ and RL Schilsky⁵

Clin Pharmacol Ther. 2014 Nov;96(5):572-9



American Association
for Cancer Research
FINDING CURES TOGETHER™

Dose-finding of Small Molecule Oncology Drugs

May 18-19, 2015

Washington Court Hotel, Washington, DC

Review

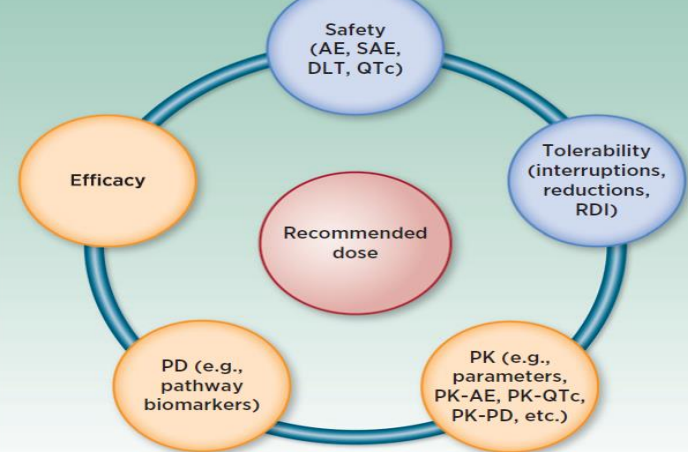
Clinical
Cancer
Research

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

Clin Cancer Res. 21(20): 4527-35, 2015



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CCR Focus

AAGR

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!