



8:45 am-5:15 pm, PT

OCT. 6TH IN-PERSON WORKSHOP

Human PK and Dose Prediction for Small Molecules

Organizers: Li Di (Pfizer), Cuiping Chen (Jazz Pharmaceuticals), Shichang Miao (Consultant)



Li Di

PhD, Research Fellow,
Pfizer Worldwide Research
and Development

Human Clearance IVIVE and PK Prediction

Case Study: PAXLOVID™ Human PK and Dose Prediction



Ryota Kikuchi

PhD, Senior Principal
Research Scientist,
Quantitative,
Translational and
ADME Sciences, AbbVie

Allometry in Prediction of Human PK Parameters



Kishore Pasikanti

PhD, Senior Director,
DMPK, Grünenthal

Prediction of Human Volume of Distribution



Yurong Lai

PhD, FAAPS,
Executive Director,
Drug Metabolism
Gilead Sciences Inc.

Prediction of Transporter-Mediated Hepatobiliary and Renal Clearance



J. Cory Kalvass

PhD, Senior Research Fellow,
Quantitative, Translational
and ADME Sciences, AbbVie

Prediction of Human Oral Absorption



Tom De Bruyn

PhD, Senior Principal
Scientist, Genentech

PK/PD and Human Dose Prediction



Yuching Yang

PhD, PBPK Team Co-Lead,
Division of Pharmacometrics,
Office of Clinical
Pharmacology, Center for
Drug Evaluation and
Research, FDA

Regulatory Perspective on Design of First-in-Human Studies and Selection of Dosing Regimen

Sponsors



Registration:

<https://www.pbss.org.aspx/eventInfo.aspx?eID=816>



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OCT. 6TH IN-PERSON WORKSHOP
SAN FRANCISCO BAY AREA: CROWNE PLAZA FOSTER CITY

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Time (PT)	Topic
8:45-9:00 am	PBSS Welcome and Introduction (Cuiping Chen, PhD, Jazz Pharmaceuticals)
9:00-9:45 am	1. Human Clearance IVIVE and PK Prediction (Li Di, PhD, Pfizer Worldwide Research and Development)
9:45-10:30 am	2. Allometry in Prediction of Human PK Parameters (Ryota Kikuchi, PhD, AbbVie)
10:30-10:40 am	Major Sponsor's Presentation (Veloxity Labs/Patel Kwan Consultancy LLC)
10:40-11:00 am	Break and Vendor Show
11:00-11:45 am	3. Prediction of Human Volume of Distribution (Kishore Pasikanti, PhD, Grünenthal)
11:45-12:30 pm	4. Prediction of Transporter-Mediated Hepatobiliary and Renal Clearance (Yurong Lai, PhD, Gilead)
12:30-1:30 pm	Lunch (Sponsor TBD)
1:30-2:15 pm	5. Prediction of Human Oral Absorption (J. Cory Kalvass, PhD, AbbVie)
2:15-3:00 pm	6. PK/PD and Human Dose Prediction (Tom De Bruyn, PhD, Genentech)
3:00-3:10 pm	Major Sponsor's Presentation (Alturas Analytics)
3:10-3:30 pm	Break
3:30-4:00 pm	7. Case Study: PAXLOVID™ Human PK and Dose Prediction (Li Di, PhD, Pfizer Worldwide Research and Development)
4:00-4:45 pm	8. Regulatory Perspective on Design of First-in-Human Studies and Selection of Dosing Regimen (Yuching Yang, PhD, FDA)
4:45-5:15 pm	Panel Discussion (All Speakers)
5:15-6:15 pm	Happy Hour (Sponsor TBD)



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OCT. 6TH, IN-PERSON WORKSHOP

Human PK and Dose Prediction for Small Molecules



Molecule
to cure.
Fast.™



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