

DMPK/Clinical Pharmacology Studies for IND/NDA Filings



Tuesday, October 1, 2024
8:45 am-5:30 pm Pacific Time

Organizers: Jan Wahlstrom, PhD (Amgen), Jennifer Yang, PhD (Consultant),
Barbara Saechao (BMS (Mirati)), Simon Wong, PhD (Aditum Bio)



Hilton San Diego/Del Mar, 15575 Jimmy Durante Blvd, Del Mar, CA 92014

Workshop Registration Fee: \$295 - Regular; \$45 - Paying out-of-pocket or Academic



Jan Wahlstrom, PhD
Executive Director, **Amgen**

Overview of sections 2.6.4, 2.6.5,
2.7.1, 2.7.2, Modules 4/5; Drug-
Drug Interactions: Perpetrator
and Victim



Simon Wong, PhD
Vice President, **Aditum Bio**

Overview of Sections 2.6.4, 2.6.5,
2.7.1, 2.7.2, and Modules 4/5



Jennifer Yang, PhD
Independent DMPK/Clinical
Pharmacology Consultant

DMPK Best Practices



Shinji Yamazaki, PhD
Senior Director, **Certara UK**

Transporter-Mediated DDI



Sekhar Surapaneni, PhD
Executive Director, DMPK
Nimbus Therapeutics

In Vitro Metabolism, Clinical
MetID and MIST



Natalie Hosea, PhD
Vice President, **Amgen**

Overview of IND/NDA Experiences



Xinning Yang, PhD
Policy Lead of Clinical
Pharmacology, **FDA**

Review Experiences and
Expectations for IND/NDA
ADME Studies



Naveed Shaik, PhD
Senior Director, **Pfizer**

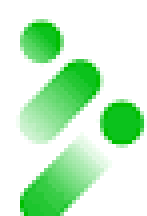
Clinical Pharmacology Studies to
Support NDA Submission and Inform
Drug Label



Cornelius Cilliers, PhD
Director, **BMS**

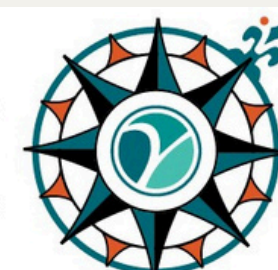
ADME Package of KRAZATI®
(adagrasib) and DMPK/Clin Pharm
Challenges

Major Sponsors



Fortrea

BioAgilytix



Sponsorship Opportunities for Lunch, Happy Hour and Vendor Show still Available

Registration: <http://www.pbss.org.aspx/homeSD.aspx>

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| Time (PST) | Topic & Presenter |
|---------------------|---|
| 8:45 - 9:00 am | PBSS Welcome and Introduction (Barbara Saechao, BMS (Mirati)) |
| 9:00 - 9:30 am | Overview of Sections 2.6.4, 2.6.5, 2.7.1, 2.7.2, and Modules 4/5 (Simon Wong, PhD, Vice President, Aditum Bio & Jan Wahlstrom, PhD, Executive Director, Amgen) |
| 9:30 - 10:10 am | DMPK Best Practices (Jennifer Yang, PhD, Independent DMPK/Clinical Pharmacology Consultant) |
| 10:10 - 10:20 am | Major Sponsor Presentation (Fortrea) |
| 10:20 - 10:40 am | Break & Vendor Show |
| 10:40 - 11:20 am | Drug-Drug Interactions: Precipitant and Object (Jan Wahlstrom, PhD, Executive Director, Amgen) |
| 11:20 am - 12:00 pm | Transporter-Mediated DDI (Shinji Yamazaki, PhD, Sr. Director, Certara UK) |
| 12:00 - 1:00 pm | Lunch (Sponsor - TBD) |
| 1:00 - 1:40 pm | In Vitro Metabolism, Clinical MetID and MIST (Sekhar Surapaneni, PhD, Executive Director, DMPK, Nimbus Therapeutics) |
| 1:40 - 2:25 pm | Overview of IND/NDA Experiences (Natalie Hosea, PhD, Vice President, Amgen) |
| 2:25 - 3:10 pm | Review Experiences and Expectations for IND/NDA ADME Studies (Xinning Yang, PhD, Policy Lead of Clinical Pharmacology, FDA) |
| 3:10 - 3:20 pm | Major Sponsor Presentation (BioAgilityx) |
| 3:20 - 3:40 pm | Break and Vendor Show |
| 3:40 - 4:20 pm | Clinical Pharmacology Studies to Support NDA Submission and Inform Drug Label (Naveed Shaik, PhD, Sr. Director, Pfizer) |
| 4:20 - 5:00 pm | ADME Package of KRAZATI® (adagrasib) and DMPK/Clin Pharm Challenges (Cornelius Cilliers, PhD, Director, BMS) |
| 5:00 - 5:30 pm | Panel Discussion (All Speakers) |
| 5:30 - 6:30 pm | Happy Hour (Sponsor TBD) |

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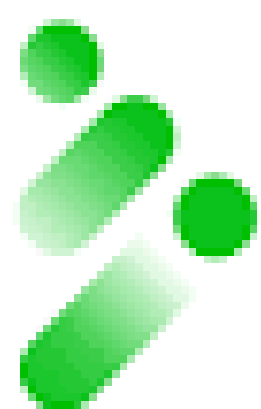
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Exhibitors



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