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Workshop Overview

This workshop will explore the current state of the science in the field of therapeutic drug monitoring (TDM) for biologic products and current clinical practice in the United States and Europe. TDM of some small molecules is commonly performed to sustain target drug levels for efficacy and to minimize safety issues. TDM of large molecule biologics has been reported to improve clinical outcomes in some inflammatory diseases, by ensuring sustained therapeutic levels and reducing the probability of immunogenicity. The potential benefits, limitations, and future considerations for TDM of large molecule therapeutics will be discussed.

Objectives:

- Discuss the impact of TDM on patient outcomes in inflammatory and other diseases
- Discuss the challenges and enabling factors and best practices in the implementation of TDM for biologics as an end-to-end process from evidence generation to point-of-care implementation and evaluation (pre-analytical, analytical, clinical, regulatory, and health-economic considerations)
- Explore possible ways all stakeholders could work collaboratively to address these challenges and actualize identified opportunities

Programming Committee

Yow-Ming Wang, Ph.D., US FDA, Office of Translational Sciences, Office of Clinical Pharmacology (Chair)
Tara Altepeter, M.D., US FDA, Office of New Drugs, Division of Gastroenterology
Daphne Guinn, Ph.D., US FDA, Office of Translational Sciences, Office of Clinical Pharmacology
Mohsen Rajabi, Ph.D., US FDA, Office of Translational Sciences, Office of Clinical Pharmacology
Sophie Shubow, Ph.D., US FDA, Office of Translational Sciences, Office of Clinical Pharmacology
Michele Gunsior, Ph.D., Astria Therapeutics (co-chair)
Michael Partridge, Ph.D., Regeneron (co-chair)
Amy Rosenberg, M.D., EpiVax (co-chair)

AAPS Disclaimer

All scientific presentations at AAPS-sponsored events must adhere to the highest standards of scientific ethics, including acknowledgements or references to sources (both scientific and financial), and the absence of promotional content or endorsement of commercial products. Any conflict of interest must be disclosed prior to the meeting. Authors and speakers are responsible for the content and ideas stated in their oral and written presentations. AAPS is not responsible for, nor do we endorse, the material published in any final program materials, or any oral or written statements made by presenters at this meeting.

Handouts

All available handouts are posted on the workshop webpage through a password-protected PDF. Please enter password TDM2024 to access the files. Speakers’ handouts will remain online for registered attendees until May 26, 2024.
Travel Information

Getting to the FDA

Visitor parking is often limited. We recommend public transportation or a car service.

Several bus lines stop at the FDA White Oak campus and the FDA Shuttle runs between the White Oak campus and nearby Metrorail stations (see below). Always check the status of public transit before leaving. Taxis and ridesharing services are usually available. Mapping apps and online trip planners can help find the best route for you.

Free FDA Shuttle

The FDA shuttle stops at the following local Metro stations and drops off or picks up in the traffic circle in front of Building 1.

- College Park Metro
- Glenmont Metro
- Medical Center Metro
- Shady Grove Metro
- Silver Spring Metro
- Twinbrook Metro

View details on the FDA Shuttle Bus.

Airport Information

There are 3 airports local to the FDA White Oak campus in the Washington, D.C. metro area:

- Baltimore-Washington International (BWI)
  - 29 miles / 30-40 minutes
- Ronald Reagan Washington National (DCA)
  - 29 miles / 30-45 minutes
- Washington Dulles International (IAD)
  - 33 miles / 45-60 minutes

Recommended Hotels

AAPS does not have room blocks reserved for this event. However, below is a list of hotels close to the FDA White Oak campus:

- **Home2 Suites by Hilton Silver Spring**
  1701 Elton Rd, Silver Spring, MD 20903
  2 miles / 7 minutes

- **Hilton Garden Inn Silver Spring White Oak**
  2200 Broadbirch Dr, Silver Spring, MD 20904
  4 miles / 10 minutes

- **Courtyard by Marriott Silver Spring North/White Oak**
  12521 Prosperity Dr, Silver Spring, MD 20904
  4 miles / 10 minutes

- **Residence Inn by Marriott Silver Spring**
  12000 Plum Orchard Dr, Silver Spring, MD 20904
  4 miles / 10 minutes
Facility Information

FDA/CDER – AAPS Public Workshop will take place at the **FDA White Oak campus in Building 31 in the Great Room (Room 1503)**.

FDA White Oak Campus  
10903 New Hampshire Avenue  
Silver Spring, MD 20933
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<tr>
<th>Time</th>
<th>Session 1: Clinical Pharmacology Considerations</th>
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<tbody>
<tr>
<td>9:00 AM – 10:10 AM</td>
<td>Introduction and Welcome</td>
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<tr>
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<td>Yow-Ming C. Wang, Ph.D., U.S. Food &amp; Drug Administration</td>
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<tr>
<td>9:05 AM – 9:15 AM</td>
<td>Precision Dosing: From Aspiration to Application</td>
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<td>Issam Zineh, Pharm.D., M.P.H., FCP, FCCP, U.S. Food &amp; Drug Administration</td>
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<tr>
<td>9:15 AM – 9:35 AM</td>
<td>Scientific &amp; Technical Perspective</td>
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<td>Diane R. Mould, Ph.D., Projections Research Inc.</td>
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<td>9:35 AM – 9:55 AM</td>
<td>Drug Developer’s Perspective</td>
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<td>Honghui Zhou, Ph.D., FCP, FAAPS, Jazz Pharmaceuticals</td>
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<td>9:55 AM – 10:10 AM</td>
<td>Question &amp; Answer</td>
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<td>Yow-Ming C. Wang, Ph.D., U.S. Food &amp; Drug Administration</td>
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<td>10:10 AM – 10:20 AM</td>
<td>Coffee Break</td>
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<td>10:20 AM – 11:45 PM</td>
<td>Session 2: TDM in Clinical Practice</td>
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<td>10:20 AM – 10:50 AM</td>
<td>Proactive TDM: Its Time has Come</td>
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<td>Adam Cheifetz, M.D., Harvard Medical School, Beth Israel Deaconess Medical Center</td>
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<td>10:50 AM – 11:10 AM</td>
<td>TDM in Rheumatology</td>
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<td>Sandra Garces, M.D., PhD, Amgen Inc</td>
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<td>11:10 AM – 11:30 PM</td>
<td>TDM for the Well-Being of Children</td>
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<td>Rachel Chevalier, M.D., Children’s Mercy Kansas City</td>
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<tr>
<td>11:30 AM 11:45 AM</td>
<td>Question &amp; Answer</td>
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<td>Amy Rosenberg, M.D., EpiVax, Inc.</td>
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<td>11:45 AM – 12:45 PM</td>
<td>Lunch</td>
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<td>12:45 PM – 1:40 PM</td>
<td>Session 3: Health Economics</td>
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<td>12:45 PM – 1:05 PM</td>
<td>HEOR Data on TDM of Biologics</td>
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<td>Sean Gavan, Ph.D., MSc, The University of Manchester</td>
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<tr>
<td>1:05 PM – 1:25 PM</td>
<td>Translation of HEOR Findings on TDM of Biologics in the US Healthcare Landscape</td>
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Mark Trusheim, M.S., NEWDIGS Tufts Medical Center

1:25 PM – 1:40
Question & Answer
Sophie Shubow, Ph.D., U.S. Food & Drug Administration

1:40 PM – 1:45 PM
Coffee Break

1:45 PM – 3:00 PM
Session 4: Enabling Technologies

1:45 PM – 2:05 PM
Experience from TDM in Small Molecules
Joseph Kotarek, Ph.D., U.S. Food & Drug Administration

2:05 PM – 2:25 PM
TDM Operations: Perspective from a European CRO
Theo Rispens, Ph.D., Sanquin

2:25 PM – 2:45 PM
Developing FDA-Cleared TDM Tests for Biologics – A Manufacturer’s Perspective
Kurtis R. Bray, Ph.D., ProciseDx

2:45 PM – 3:00 PM
Question & Answer
Michele Gunsior, Ph.D., Astria Therapeutics

3:00 PM – 3:10 PM
Coffee Break

3:10 PM – 4:20 PM Panel Discussion
Moderated by Michael Partridge, Ph.D., Regeneron Pharmaceuticals, Inc.

Panelists:
Tara Altepeter, M.D., Division of Gastroenterology, Office of Immunology and Inflammation, U.S. Food & Drug Administration
Kurtis R. Bray, Ph.D., ProciseDx
Rachel Chevalier, M.D., Children’s Mercy Kansas City
Adam Cheifetz, M.D., Harvard Medical School, Beth Israel Deaconess Medical Center
Sandra Garces, MD., Ph.D., Amgen Inc
Sean Gavan, Ph.D., M.Sc., The University of Manchester
Ping Ji, Ph.D., U.S. Food & Drug Administration
Joseph Kotarek, Ph.D., U.S. Food & Drug Administration
Diane R. Mould, Ph.D., Projections Research Inc.
Theo Rispens, Ph.D., Sanquin
Mark Trusheim, M.S., NEWDIGS Tufts Medical Center
Honghui Zhou, Ph.D., FCP, FAAPS, Jazz Pharmaceuticals
Issam Zineh, Pharm.D., M.P.H., FCP, FCCP, U.S. Food & Drug Administration
Moderator and Speaker Biographies

Session 1: Clinical Pharmacology Considerations

Moderator: Yow-Ming C. Wang, Ph.D., U.S. Food & Drug Administration

Dr. Wang is the Associate Director for Biosimilars and Therapeutic Biologics in the Office of Clinical Pharmacology (OCP) of CDER, FDA. She leads the Therapeutic Biologics Program in the Immediate Office of OCP; the team has a mission to promote scientific and regulatory excellence in biologic product development through developing clear policies, enhancing excellence in review, facilitating knowledge sharing, and building collaboration and outreach. Dr. Wang joined the FDA in March 2011 in the role of a team leader with review focus on biologics. Prior to joining the FDA, she worked in the pharmaceutical industry for 18 years with experience in small molecules and large molecules. She received her Ph.D. degree from The Ohio State University College of Pharmacy with a research focus on Pharmacokinetics and Biopharmaceutics.

Speaker: Issam Zineh, Pharm.D., M.P.H., FCP, FCCP, U.S. Food & Drug Administration

Issam Zineh, Pharm.D., M.P.H., FCP, FCCP is Director of the Office of Clinical Pharmacology (OCP) at the U.S. Food and Drug Administration (FDA). He has held various leadership positions at the FDA including Associate Director for Genomics and Co-Director of the CDER Biomarker Qualification Program and serves on the CDER Medical Policy Council and other CDER-wide governance committees. Dr. Zineh received his Pharm.D. from Northeastern University and completed his residency at Duke University Medical Center. He completed a fellowship in cardiovascular pharmacogenomics at the University of Florida (UF) where he also obtained his M.P.H. in Health Policy and Management. Prior to joining FDA in 2008, Dr. Zineh was on faculty at the UF Colleges of Pharmacy and Medicine and Associate Director of the UF Center for Pharmacogenomics. He is a recognized expert in the fields of drug development and evaluation, clinical pharmacology, pharmacotherapy, and precision medicine. As Director of OCP, Dr. Zineh leads a staff of over 260 regulatory, research, program/project management, and administrative staff in FDA’s efforts to enhance drug development and promote regulatory innovation through clinical pharmacology and experimental medicine.

Session 1: Clinical Pharmacology Considerations

Scientific & Technical Perspective

This session will evaluate the use of therapeutic drug monitoring (TDM) data and dashboards for dosing monoclonal antibodies (Mabs). With inflammatory diseases, high failure rates have led to research that suggests efficacy may be improved with higher and/or more frequent dosing than the labeled dosing options. However, TDM data does not always provide all the information needed for the treating
physician to select a dose to achieve a desired Mab concentration, given that both dose and interval may need adjusting. Dashboards take TDM results and turn it into information allowing the physician to visualize the results of various dosing adjustments. Clinical trials of personalized dosing using TDM and a dashboard for Mabs have resulted in lower failure rates, better quality remission, and lower incidence of antidrug antibodies (ADA). Other therapeutic areas such as oncology may also benefit from the use of individualized dosing through TDM and dashboards.

Learning Objectives:
- Acquire an understanding of the current difficulties of successfully treating patients with monoclonal antibodies (MAbs)
- Understand the complexity of MAb PK and identify one of the primary causes of antidrug antibodies (ADA)
- Recognize the potential benefit that therapeutic drug monitoring (TDM) can bring in MAb therapy
- Identify the associations between MAb PK and clinical response or failure
- Assess how PK guided dosing with dashboards can improve patient response

Speaker: Diane R. Mould, Ph.D., Projections Research Inc.
Dr. Mould obtained her bachelor’s degree in 1984 and her Ph.D. in 1989. She spent 30+ years as a pharmacokineticist in industry where she specialized in population pharmacokinetic/pharmacodynamic modeling. She has conducted population PK/PD analyses of hematopoietic agents, monoclonal antibodies, anti-cancer, anti-viral, antipsychotic, cardiovascular, and sedative/hypnotic agents.

Dr. Mould is president of Projections Research Inc., a consulting company offering pharmacokinetic and pharmacometrics services. She is the founder of Baysient LLC, a company developing systems to individualize doses of drugs that are difficult to manage. She published 112 peer-reviewed articles, 19 book chapters and co-edited one textbook. She made 138 national and international presentations and presented 6 podium sessions on advanced modeling and simulation approaches.

She is an adjunct professor at URI, OSU, and University of Florida, and teaches an annual class at NIH. Dr Mould taught 12 courses on specialized aspects of population PK/PD modeling. She is on the editorial board for JPKPD, CPT, and is on the Scientific Advisory Board for CPT-PSP. She is a Fellow of the American College of Clinical Pharmacology and an AAPS Fellow.

Session 1: Clinical Pharmacology Considerations

Drug Developer’s Perspective
This presentation will provide an industry clinical pharmacologist’s perspective on applying therapeutic drug monitoring (TDM) for biologic product development. Two case examples of applying TDM will be used to illustrate the potential utility and limitations of this approach. One is for therapeutic proteins in the treatment of immune-mediated inflammatory diseases, and another for an asparagine-specific enzyme for the treatment of acute lymphoblastic leukemia and lymphoblastic lymphoma. The opportunities and challenges of incorporating TDM in drug development of biologic products will be discussed.

Learning Objectives:
- Upon completion, the participant will be able to identify areas where TDM might be useful to support drug dose optimization for certain biological products
• Upon completion, the participant will be able to familiar with some case examples of applying TDM in biological products used in immune-mediated inflammatory diseases and hematological malignancies
• Upon completion, the participant will be able to better appreciate the benefits and challenges of applying TDM in optimizing the therapeutic effects of certain biological products

Speaker: Honghui Zhou, Ph.D., FCP, FAAPS, Jazz Pharmaceuticals
Dr. Zhou received his Ph.D. in Pharmaceutics from the University of Iowa. He spent most of his prior career at Johnson & Johnson (Janssen R&D and Centocor) with different roles including Head of Pharmacometrics, Clinical Pharmacology Immunology TA Head, and Head of Biotherapeutics PK/PD and M&S. He was Janssen Fellow, and the recipient of numerous Johnson & Johnson awards including the Spark Innovation Award, the Philip B. Hofmann Award, and Janssen Innovation Leadership Award. Honghui is board-certified by American Board of Clinical Pharmacology. He is a Fellow of the American College of Clinical Pharmacology (ACCP), and AAPS. He was a past ACCP Regent (2009-2013, 2016-2020) and is an Honorary Regent. He also served as past Co-Chairs of ACCP Annual Meetings (2013, 2016, 2020), and was a recipient of ACCP NTK Memorial Distinguished Service Award in 2022. He currently serves as Associate Editor for the Journal of Clinical Pharmacology and Assistant Editor for mAbs. He has published around 150 peer-reviewed manuscripts and book chapters, and co-edited three books (Wiley) in therapeutic protein ADME and translational PK/PD, drug-drug interactions, and individualized therapy strategy.

Session 2: TDM in Clinical Practice

Moderator: Amy Rosenberg, M.D., EpiVax, Inc.
A physician immunologist with extensive expertise in development and immunogenicity of therapeutic proteins and cellular products. As Division Director in the Office of Biotech Products, she was involved in the regulation and approval of numerous FDA regulated products, including therapeutic proteins (monoclonal antibodies and fusion proteins), enzyme replacement therapies, immunomodulators, hematologic and somatic cell growth factors, and combination device-biologics. She has extensive knowledge of product quality issues as well as clinical aspects of experimental investigations and am a leading expert in clinical risk assessment and mitigation strategies of immunogenicity of therapeutic proteins (Guidance for Industry: Immunogenicity Assessment for Therapeutic Protein Products). Dr. Rosenberg served as FDA expert consultant to NIAID's Immune Tolerance Network and to the ABIRISK Consortium and co-edited the AAPS/Springer Book Biobetters: Protein Engineering to Approach the Curative. In 2021, she left the Agency and is now Senior Director and Clinical Consultant, Immunology, at EpiVax, Inc, an immunoinformatics and vaccine development company based in Providence, RI. She received an M.D. from the Albert Einstein College of Medicine, trained at NYU in Internal Medicine and Infectious Diseases and in immunology in the Laboratory of Alfred Singer in the Experimental Immunology Branch of the NCI before joining the FDA.

Session 2: TDM in Clinical Practice

Proactive TDM: Its Time has Come
Anti-TNF antibodies and other biologics have transformed the care of patients with Inflammatory Bowel Disease (IBD). However, up to one-third of patients are primary nonresponders. Furthermore, many of
those patients who do initially respond to biologic therapies, unfortunately, lose response over time. Much primary and secondary loss of response and the lack of durability of biologics, may be due to inadequate optimization. Therapeutic drug monitoring (TDM), or checking drug concentrations and anti-drug antibodies, can aid in elucidating these unwanted outcomes. Currently, TDM is either not performed or obtained reactively when patients have symptoms of active inflammatory bowel disease. Reactive TDM is the assessment of drug concentration and antibodies when a patient is symptomatic – either in the case of primary non-response or, more commonly, for secondary loss of response. Studies have shown that reactive TDM for infliximab is cost-effective and better directs care. Importantly, there is recent data that suggests that proactive TDM with dose-optimization to a therapeutic window may lead to improved outcomes. The goal of proactive TDM is to prevent both primary and secondary loss of response by aiming for adequate drug concentrations. There is data from several studies that shows that proactive TDM with infliximab and adalimumab is associated with better outcomes than standard of care (empiric dose escalation or reactive TDM).

Learning Objectives:

- Describe the role of therapeutic drug concentration monitoring (TDM) with biologics
- Discuss reactive vs. proactive TDM
- Understand benefits of proactive TDM

Speaker: Adam Cheifetz, M.D., Harvard Medical School, Beth Israel Deaconess Medical Center
Dr. Cheifetz is Director of the Center for Inflammatory Bowel Disease and Medical Director of Infusion Services at Beth Israel Deaconess Medical Center, and Professor of Medicine at Harvard Medical School.

He is a well-recognized leader in the treatment of Crohn’s disease, ulcerative colitis, and other inflammatory bowel diseases. He is involved in multiple research projects relating to IBD and has published over 200 articles and chapters on the subject. His research currently focuses on therapeutic drug monitoring and optimizing the use of biologics through the proactive use of drug concentrations and antibodies, and he has published extensively in this area. Dr. Cheifetz was the first to demonstrate that proactive monitoring of infliximab and adalimumab concentrations and dosing to a therapeutic window improves outcomes when compared to standard of care.

Session 2: TDM in Clinical Practice

TDM in Rheumatology
No description available.

Speaker: Sandra Garces, M.D., Ph.D., Amgen Inc.
Sandra Garces is an Executive Medical Director and Global Development Lead at Amgen, where she has led cross-functional teams to advance the development of therapeutic drugs from 2019 to date. Previously, she worked at Eli Lilly, developing and executing global clinical development strategies for different programs. Dr. Garces also worked on Immunogenicity across the portfolio, assisting teams in designing tailored risk-based strategies to assess ADA’s clinical relevance and impact on biotherapeutics' benefit-risk profile.

She completed her medical degree in 2001 at the University of Lisbon, Portugal and practiced rheumatology for over ten years at Hospital Garcia de Orta, Portugal. Dr. Garces also completed a Ph.D. in Immunology with a thesis titled “The Clinical Relevance of Drug Immunogenicity.” She developed her Ph.D. work at the Gulbenkian Institute of Science in Portugal in collaboration with Sanquin Research
Institute in the Netherlands and worked as a clinician scientist developing multiple translational projects using TDM as a tool to understand patients’ heterogeneity within the same patient population with autoimmune conditions. She developed a TDM algorithm to guide therapeutic decisions towards personalized and more cost-effective strategies in patients treated with biologic therapies. In addition, she has authored/co-authored several publications in international peer-reviewed journals.

Session 2: TDM in Clinical Practice

TDM for the Well-Being of Children

In this presentation, TDM in pediatrics will be discussed. Children aren’t just little adults—they come with specific challenges. These challenges include different expectations for disease progression, treatment requirements, and psychosocial barriers. TDM is one way to keep children healthy and growing. Dr. Chevalier will discuss what treating these special patients is like in real world practice and how pediatric gastroenterologists are continually working against barriers.

Learning Objectives:
- Understand unique challenges in treating pediatric inflammatory bowel disease (IBD)
- Discuss how TDM is vital to treatment of pediatric patients with IBD

Speaker: Rachel Chevalier, M.D., Children’s Mercy Kansas City

Rachel Chevalier, M.D. is a pediatric gastroenterologist and physician researcher at Children’s Mercy Kansas City. She has expertise in inflammatory gastroenterological conditions (including inflammatory bowel disease) and clinical pharmacology associated with its treatments. She has presented her work at Digestive Disease Week, the American Society for Clinical Pharmacology, and the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition.

Session 3: Health Economics

Moderator: Sophie Shubow, Ph.D., U.S. Food & Drug Administration

Sophie Shubow joined the Office of Clinical Pharmacology (OCP) in FDA’s Center for Drug Evaluation and Research (CDER) in 2020. She serves as a program lead for biologic and biosimilar policy in OCP, and leads the CDER-wide Immunogenicity Review Committee, a forum for defining integrated multidisciplinary approaches to immunogenicity risk assessments. In the Fall of 2023, she completed a detail in FDA’s Office of Global Policy and Strategy, where she oversaw a program aimed at fostering inter-office collaboration on strategic global policy issues. Before joining FDA, Sophie served as a contractor for several agencies in the Department of Health and Human Services. Sophie holds a Ph.D. in Cell and Molecular Biology from the University of Bordeaux, France, and a master’s in International Project Management from ESCP Business School, Paris, France.

Session 3: Health Economics

HEOR Data on TDM of Biologics

TDM of biologics has the potential to improve health outcomes and the value of care to payers. Health economic data are vital to integrate TDM into routine care settings. This session will demonstrate how cost-effectiveness evidence can support the uptake of TDM. The recent health technology assessment of
TDM by the National Institute for Health and Care Excellence (NICE) will be used as a case study to highlight important future directions for generating health economic evidence.

Learning Objectives:
- Explain how health economic evidence informs decision-making
- Understand the health economic evidence supporting TDM of biologics
- Understand evidence generation strategies to support health technology assessment of therapeutic drug monitoring

Speaker: Sean Gavan, Ph.D., M.Sc., The University of Manchester
Sean P. Gavan, Ph.D., M.Sc., is a Research Fellow in Health Economics at The University of Manchester, United Kingdom. Dr Gavan is an experienced health economist with expertise in the cost-effectiveness and health technology assessment of TDM for biologic treatments in rheumatic conditions. He is a member of the European Network on Optimising Treatment with Therapeutic Antibodies in chronic inflammatory diseases (ENOTTA).

Session 3: Health Economics
Translation of HEOR Findings on TDM of Biologics in the US Healthcare Landscape
The presentation will highlight:
1. Differences between the UK/EU healthcare landscape in which much of the TDM health economics and outcomes research (HEOR) has occurred and the US healthcare landscape
2. Nature of the evidence driving U.S. payers’ decisions
3. Differences in the evidence needed to modify practice of medicine (the “lower hanging fruit” for TDM of biologics) and the evidence needed for an FDA drug label change
4. Opportunities presented by innovative payment models to advance TDM adoption

Learning Objectives:
- Describe the evidence needs of U.S. payers to cover and reimburse TDM
- Differentiate between the evidence needed by U.S. payers versus the FDA or UK/EU payers to support TDM use
- Examine whether innovative payment models for diagnostics, therapeutics and/or medical services could accelerate the adoption of TDM

Speaker: Mark Trusheim, M.S., NEWDIGS Tufts Medical Center
Mark Trusheim is Strategic Director, NEWDIGS at Tufts Medical Center where he also co-leads the Financing and reimbursement of Cures in the US (FoCUS) Project. His research focuses on the economics of biomedical innovation, especially precision financing for patient access, precision medicine, adaptive pathways, platform trials, biosimilars, and digital health advances. Trusheim spent 18 years at MIT Sloan in Applied Economics and has served as a Special Government Employee for the FDA’s Office of the Commissioner. He is also President of Co-Bio Consulting, LLC. His career has spanned policy as the President of the Massachusetts Biotechnology Council, diagnostics as founder of Cantata Labs, genomics as President of Cereon Genomics, ehealth as Vice President of Monsanto Health Solutions, managed care marketing at Searle Pharmaceuticals, and big data at Kenan Systems. He holds degrees in Chemistry from Stanford University and Management from MIT.
Session 4: Enabling Technologies

Moderator: Michele Gunsior, Ph.D., Astria Therapeutics
Dr. Michele Gunsior is Senior Director and Head of Translational Sciences at Astria Therapeutics, responsible for delivering translational medicine and bioanalytical objectives to support all stages of a therapeutic drug program. Prior to joining Astria, Dr. Gunsior was in the TS/TM group at Viela Bio (acquired by Horizon Therapeutics, now Amgen) overseeing clinical and nonclinical bioanalytical work, managing toxicology studies, and incorporating TM objectives into clinical studies. She joined Viela Bio from AstraZeneca/MedImmune, first beginning her career in the pharmaceutical/biotech industry at Covance Laboratories (now LabCorp). Dr. Gunsior served as the first Chair of the Women in Pharmaceutical Sciences Community within AAPS, is currently leading the ADA Clinical Relevance sub team and is a member of the extended Biomarker and Precision Medicine Community Leadership Team within AAPS.

Session 4: Enabling Technologies

Experience from TDM in Small Molecules
This session will discuss the assessment of benefit and risk associated with TDM assays with a focus on the clinical considerations associated with device performance. Examples of market authorized small molecule TDM assays will be discussed, and how the clinical impact associated with the concentration (or concentration range) of any given drug informs TDM performance considerations and an overall benefit-risk assessment.

Learning Objectives:
• Upon completion, participants will be familiar with examples of small molecule TDM assays
• Upon completion, participants should better understand how the benefit-risk profile of any given drug impacts the benefit-risk profile of any associated TDM assay for that drug
• Upon completion, participants should better understand what types of clinical information could be used to support premarket submission for novel TDM assays

Speaker: Joseph Kotarek, Ph.D., U.S. Food & Drug Administration
Dr. Joey Kotarek is the Toxicology Branch Chief in the Division of Chemistry and Toxicology Devices at the Center for Devices and Radiological Health at FDA. Originally from Arkansas, he attended the University of Arkansas and later the University of South Carolina, where he received his B.S. and then Ph.D. in Chemical Engineering. He currently lives in the District of Columbia with his wife, daughter, and daughter's pet bunny.

Session 4: Enabling Technologies

TDM Operations: Perspective from a European CRO
No description available.

Speaker: Theo Rispens, Ph.D., Sanquin
No biography available.
Session 4: Enabling Technologies

Developing FDA-Cleared TDM Tests for Biologics – A Manufacturer’s Perspective

The presentation consists of a brief company and technology introduction followed by:

1) Processes followed to develop and validate our TDM tests for biologic drugs
2) Technical and regulatory challenges and barriers encountered in the validation and regulatory process
3) Recommendations for drug companies, in-vitro diagnostic companies, and FDA to consider enhancing the process

Learning Objectives:

- Recognize the technological and clinical characteristics of a potentially successful TDM test,
- Understand some of the problems and challenges that might be encountered through the development and regulatory processes and strategies to address them,
- Understand how the development and implementation of biologic TDM tests might be improved going forward.

Speaker: Kurtis R. Bray, Ph.D., ProciseDx

Kurt Bray, Ph.D. is the Senior Director of Clinical Development and Regulatory Affairs at ProciseDx Inc. Trained originally as an immunologist, he has worked in biotech for over 30 years, primarily in in-vitro diagnostics (IVD), including for large companies such as Beckman Coulter, and for small startups as in his current role. He has also worked on the pharmaceutical side for established main line firms such as Eli Lilly and also for smaller technology pioneers such as Hybritech Inc.

Dr. Bray began his career developing new products in R&D and over the decades has transitioned in clinical research, primarily designing and executing clinical trials to demonstrate clinical utility and achieve regulatory approvals for IVD tests. Has led or been a part of teams that have brought multiple new analytes across several disease states through the regulatory process and onto the market, employing PMA, De Novo, and 510(k) FDA submissions.

Panel Discussion

Moderator: Michael Partridge, Ph.D., Regeneron Pharmaceuticals, Inc.

Michael Patridge received his Ph.D. from Sydney University. He moved to the United States for a post doc at Columbia University where he investigated integrin-mediated cell signaling and motility and went on to study tumorigenesis, eventually developing immunoassays to detect biomarkers of radiation exposure. Dr. Partridge left academia to work at Regeneron where he led a group of scientists developing and validating PK, ADA, Nab, and biomarker immunoassays for nonclinical and clinical studies. He is currently a Director in the Bioanalytical Sciences Dept and is the BA and immunogenicity strategic lead for multiple therapeutic areas, interacting directly with clinical teams including physicians, clinical pharmacology and regulatory departments.
Panelists:

Tara Altepeter, M.D., Division of Gastroenterology, Office of Immunology and Inflammation, U.S. Food & Drug Administration
Dr. Tara Altepeter is an Associate Director for Therapeutic Review in the Division of Gastroenterology, in the Center for Drug Evaluation and Research at FDA. She has been with the Agency for the past eight years. She previously completed training in general pediatrics at Advocate Childrens Hospital in Chicago, followed by fellowship in Pediatric Gastroenterology at Alfred I Dupont Hospital for Children in Wilmington, DE. As a clinician, her passion was providing excellent care to pediatric patients with IBD. In her time at FDA, she has worked across many areas of Gastroenterology, but continues to enjoy and focus upon drug development in IBD.

Ping Ji, Ph.D., U.S. Food & Drug Administration
Ping Ji, Ph.D., is a Master Pharmacokineticist in the Division of Inflammation and Immune Pharmacology (DIIP), Office of Clinical Pharmacology at the FDA. Before joining the FDA in 2008, she had worked in the industry on clinical discovery and research for five years. She received her Ph.D. from the University of Minnesota Department of Pharmaceutics with a research focus on pharmacokinetics and pharmacodynamics.

Kurtis R. Bray, Ph.D., ProciseDx
Rachel Chevalier, M.D., Children's Mercy Kansas City
Adam Cheifetz, M.D., Harvard Medical School, Beth Israel Deaconess Medical Center
Sandra Garces, M.D., PhD, Amgen Inc
Sean Gavan, Ph.D., M.Sc., The University of Manchester
Joseph Kotarek, Ph.D. U.S. Food & Drug Administration
Diane R. Mould, Ph.D., Projections Research Inc.
Theo Rispens, Ph.D., Sanquin
Mark Trusheim, M.S., NEWDIGS Tufts Medical Center
Honghui Zhou, Ph.D., FCP, FAAPS, Jazz Pharmaceuticals
Issam Zineh, Pharm.D., M.Ph., FCP, FCCP, U.S. Food & Drug Administration