

Pharmacodynamic Biomarkers for Biosimilar Development and Approval

Virtual Public Workshop

September 20, 2021 | 10:00 am – 2:30 pm ET

September 21, 2021 | 10:00 am – 2:30 pm ET

Workshop Agenda | Day One

This public workshop is a forum for regulators, biopharmaceutical developers, academic researchers, and stakeholders to discuss the current and future role of pharmacodynamic (PD) biomarkers in improving the efficiency of biosimilar product development and regulatory approval.

10:00 am **Welcome and Overview**

Mark McClellan, Duke-Margolis Center for Health Policy

Janet Woodcock, Acting Commissioner of Food and Drugs

10:20 am **Session 1: Biosimilar Development Paradigms—Current and Future Perspectives**

Moderator: **Mark McClellan**, Duke-Margolis Center for Health Policy

Objective: This session will provide an overview of ongoing FDA and industry biosimilar development activities and participants will discuss opportunities to better utilize clinical pharmacology principles to facilitate biosimilar development.

Presentation: Overview of the FDA Perspective and Activities

- **Sarah Yim**, U.S. Food & Drug Administration

Presentation: Applying Clinical Pharmacology Principles to Selecting Pharmacodynamic Biomarkers for Biosimilar Development

- **Yow-Ming Wang**, U.S. Food & Drug Administration

Presentation: The Role of Pharmacodynamic Biomarkers for Biosimilar Development and Approval – An Industry Perspective

- **Leah Christl**, Amgen Inc.

Presentation: Learnings from Biosimilar Development Over the Last Decade and the Role of PD Biomarkers in Product Approvals

- **Abhijit Barve**, Viatrix Inc.

Panel and Moderated Discussion

- **Abhijit Barve**, Viatrix Inc.
- **Leah Christl**, Amgen Inc.
- **Yow-Ming Wang**, U.S. Food & Drug Administration
- **Elena Wolff-Holz**, European Medicines Agency
- **Sarah Yim**, U.S. Food & Drug Administration
- **Issam Zineh**, U.S. Food & Drug Administration

Audience Q&A

12:00 pm **Break**

12:50 pm **Session 2: Leveraging Pharmacology to Advance PD Biomarkers for Biosimilar Development**

Moderator: **Mark McClellan**, Duke-Margolis Center for Health Policy

Objective: This session will focus on the FDA's ongoing research and policy efforts to better inform utilization of PD biomarkers for biosimilar development and approval, including applicable guidance, interpretation of findings from the FDA's clinical studies evaluating PD biomarkers, and translating these studies' findings to advice for biosimilar developers. The session will also focus on how to determine if a PD biomarker is acceptable from clinical and regulatory perspectives, and how to identify the data necessary to support using PD biomarkers.

Presentation: Developing an Evidentiary Framework to Advance the Use of PD Biomarkers for Biosimilars

- **David Strauss**, U.S. Food & Drug Administration

Presentation: FDA-Sponsored Clinical Studies on Six Biologics to Characterize PD Biomarkers and Inform a General Evidentiary Framework

- **Jeffry Florian**, U.S. Food & Drug Administration

Panel and Moderated Discussion

Lead Reactants:

- **Martin Schiestl**, Sandoz Biopharmaceuticals
- **Gillian Woollett**, Avalere Health

Additional Panelists:

- **Jeffry Florian**, U.S. Food & Drug Administration
- **Ping Ji**, U.S. Food & Drug Administration
- **Stacey Ricci**, U.S. Food & Drug Administration

Additional Panelists (Continued):

- **David Strauss**, U.S. Food & Drug Administration

Audience Q&A

2:20 pm **Concluding Remarks**
Mark McClellan, Duke-Margolis Center for Health Policy

2:30 pm **Meeting Adjourns for Day One**

Pharmacodynamic Biomarkers for Biosimilar Development and Approval

Workshop Agenda | Day Two

10:00 am **Welcome and Day One Recap**

Mark McClellan, Duke-Margolis Center for Health Policy

10:10 am **Session 3: Emerging Experiences and Approaches Using PD Biomarkers in Biosimilar Development**

Moderator: **Jeffry Florian**, U.S. Food and Drug Administration

Objective: This session will focus on PD biomarker case studies, including methods, standards, and approaches used for PD biomarker selection, and approaches to pilot study designs and pharmacokinetic (PK)/PD similarity study designs.

Presentation: How PD Biomarkers Have Contributed to Biosimilar Approvals

Salaheldin Hamed, U.S. Food & Drug Administration

Presentation: Clinical Pharmacology Feasibility Assessment of PD Biomarkers for Immunology Biosimilars

Andrej Skerjanec, Sandoz Inc.

Presentation: Impact of Tolerance Effect on AUEC for Hematological Biomarkers

Wojciech Krzyzanski, State University of New York at Buffalo

Panel and Moderated Discussion

- **Patrick Archdeacon**, U.S. Food and Drug Administration
- **Salaheldin Hamed**, U.S. Food and Drug Administration
- **Wojciech Krzyzanski**, State University of New York at Buffalo
- **Andrej Skerjanec**, Sandoz Inc.
- **Hong Zhao**, U.S. Food and Drug Administration

Audience Q&A

11:15 am Session 4: Extending PD Biomarker Opportunities Across Therapeutic Areas and Advancing PD Biomarker Use in Future Biosimilar Development

Moderator: **Yow-Ming Wang**, U.S. Food and Drug Administration

Objective: This session will focus on ongoing research and regulatory efforts to identify and advance PD biomarkers in therapeutic areas where traditional PD biomarker approaches may not apply. Participants will also discuss how research and other efforts can help health care providers better understand and adopt biosimilars approved on the basis of PD biomarkers.

Presentation: Use of Multiple Biomarkers in Assessing Pharmacodynamic Similarity
Qin Sun, U.S. Food and Drug Administration

Presentation: Use of Novel Approaches in Identifying PD Biomarkers for Biosimilar Development
Paula Hyland, U.S. Food and Drug Administration

Presentation: Clinician Concerns with PD-Based Data in Oncology Biosimilar Approvals
R. Donald Harvey III, Emory University

Presentation: Added Value of Using PD biomarkers over Non-Discriminative Clinical Endpoints
Bernd Meibohm, University of Tennessee

Panel and Moderated Discussion

- **R. Donald Harvey III**, Emory University
- **Paula Hyland**, U.S. Food and Drug Administration
- **Bernd Meibohm**, University of Tennessee
- **Sarah Schrieber**, U.S. Food and Drug Administration
- **Qin Sun**, U.S. Food and Drug Administration

12:20 pm Break

1:10 pm **Session 5: Regulatory Perspectives and Efforts to Advance PD Biomarkers for Biosimilars**

Moderator: **David Strauss**, U.S. Food and Drug Administration

Objective: This session will discuss regulatory and developer perspectives on opportunities to advance PD biomarkers in characterizing PD similarity. Additionally, stakeholders are encouraged to react to the FDA's presentations from Day One and highlight opportunities to work together, and advance the utility of PD biomarkers in biosimilar development.

Presentation: The Role of Pharmacodynamic Biomarkers in the Assessment of Biosimilar Drugs: Some Regulatory Considerations

Peter Stein, U.S. Food and Drug Administration

Presentation: Canadian Perspectives on Using Pharmacodynamic Markers for Biosimilar Development and Approval

Jian Wang, Health Canada

Presentation: EMA: Current Thinking on the Role of Pharmacodynamic Biomarkers for Biosimilar Development and Approval

- **Elena Wolff-Holz**, European Medicines Agency

Panel and Moderated Discussion

- **Abhijit Barve**, Viatrix Inc.
- **Janet Franklin**, Amgen Inc.
- **Shiew-Mei Huang**, U.S. Food and Drug Administration
- **Shinichi Okudaira**, Japan Pharmaceuticals and Medical Devices Agency
- **Peter Stein**, U.S. Food and Drug Administration
- **Jian Wang**, Health Canada

2:25 pm **Concluding Remarks**

David Strauss, U.S. Food and Drug Administration

Mark McClellan, Duke-Margolis Center for Health Policy

2:30 pm **Meeting Adjourns**

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