THE biomarkers CONSORTIUM

Biomarker Qualification Workshop: Framework for Defining Evidentiary Criteria

Bethesda Marriott Hotel and Conference Center
Bethesda, MD
April 14-15, 2016

FNIH Foundation for the National Institutes of Health

FDA

DRAFT AGENDA

Day One -- Thursday, April 14, 2016

7:30 – 8:30 AM	**Registration and Breakfast**
8:30 – 8:40 AM	**Welcome** *Chris Leptak, MD, PhD, Biomarker and Companion Diagnostics Lead and Co-Director of the Biomarker Qualification Program, Office of New Drugs, CDER, FDA* *David Wholley, MPhil, Director of Research Partnerships, FNIH*
8:40 – 9:10 AM	**Keynote and Charge to Participants** *Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, FDA*
9:10 – 9:25 AM	**Presentation: Update on FDA Biomarker Development and Qualification Process** *Shashi Amur, PhD, Scientific Lead, Biomarker Qualification Program, Office of Translational Sciences, CDER, FDA*
9:25 – 10:25 AM	**Presentation: Overview of Proposed Framework for Evidentiary Criteria for Biomarker Qualification** *Chris Leptak, FDA* *John Wagner, MD, PhD, FCP, FAAPS, Senior Vice President and Head of Clinical and Translational Sciences, Takeda* (Audience Q&A: 10:10 – 10:25 AM)
10:25 – 10:40 AM	**Coffee Break**
10:40 – 11:25 AM	**Presentation: Statistical Design Considerations** *Lisa McShane, PhD, Mathematical Statistician, Division of Cancer Treatment and Diagnosis, NIH/NCI*

11:25 AM – 12:20 PM	**Panel Discussion and Audience Q&A: Statistical Design Considerations** *Lisa McShane, NIH/NCI – Discussion Leader* *Viswanath Devanarayan, PhD, Global Head & Senior Research Fellow, AbbVie* *Aloka Chakravarty, PhD, Director, Division of Biometrics, Office of Biostatistics, CDER, FDA* *Klaus Romero, MD, MS, Director of Clinical Pharmacology, Critical Path Institute* *Sue Jane Wang, PhD, Biostatistics Leader for Biomarker Qualification Program, CDER, FDA*
12:20 – 1:20 PM	**Lunch**
1:20 – 2:05 PM	**Presentation on Case Study 1: Biomarkers of Drug-Induced Kidney Injury** *Frank Sistare, PhD, Scientific Associate Vice President, Safety Assessment & Laboratory Animal Resources, Preclinical Development, Merck*
2:05 – 3:05 PM	**Panel Discussion and Audience Q&A: Case Study 1** *Frank Sistare, Merck – Discussion Leader* *Amanda Baker, PharmD, PhD, Research Scientist, Critical Path Institute* *Steve Hoffmann, MS, Scientific Program Manager, FNIH* *Paul Kimmel, MD, Program Director, Division of Kidney, Urologic, and Hematologic Diseases, NIH/NIDDK* *Romaldas Maciulaitas, MD, Clinical and Regulatory Expert, EMA* *Irene Nunes, PhD, Senior Director, Global Regulatory Affairs, Merck* *Aliza Thompson, MD, MS, Medical Officer and Clinical Team Leader, Division of Cardiovascular and Renal Products, CDER, FDA*
3:05 - 3:50 PM	**Presentation on Case Study 2: A Biomarker of Drug-Induced Liver Injury** *Jiri Aubrecht, PharmD, PhD, Senior Director, Safety Biomarkers, Pfizer*
3:50 – 4:10 PM	**Afternoon Break**
4:10 – 4:55 PM	**Panel Discussion and Audience Q&A: Case Study 2** *Jiri Aubrecht, Pfizer – Discussion Leader* *Elizabeth Hausner, DVM, DABT, DABVT, Senior Pharmacologist, Division of Cardio-Renal Products, CDER, FDA* *Joe Menetski, PhD, Deputy Director, Research Partnerships, FNIH* *John-Michael Sauer, PhD, Executive Director, Predictive Safety Testing Consortium, Critical Path Institute* *Shelli Schomaker, PhD, Principal Scientist, Pfizer* *Paul Watkins, PhD, Professor, University of North Carolina*

4:55 – 5:50 PM	**Panel Discussion and Audience Q&A: Understanding the General Framework** *David Wholley, FNIH – Discussion Leader* *Anna Barker, PhD, Director, Transformative Healthcare Knowledge Networks, Co-Director, Complex Adaptive Systems, Professor, Arizona State University* *Martha Brumfield, PhD, President and Chief Executive Officer, Critical Path Institute* *Chris Leptak, FDA* *Rajesh Ranganathan, PhD, Vice President, Scientific and Regulatory Advocacy, PhRMA* *Sharon Terry, MA, President and Chief Executive Officer, Genetic Alliance* *Thorsten Vetter, PhD, Senior Scientific Officer, EMA* *John Wagner, Takeda*
5:50 – 6:00 PM	**Summary of Day One** *Chris Leptak, FDA*
6:00 – 8:00 PM	**Reception**
	(Dinner on your own)

Day Two -- Friday, April 15, 2016

7:30 – 8:30 AM	**Registration and Breakfast**
8:30 – 8:40 AM	**Welcome – Day Two** D*avid Wholley, FNIH*
8:40 – 9:30 AM	**Presentation on Case Study 3: Biomarkers of Drug-Induced Vascular Injury** *Brad Enerson, PhD, Study Director, Manager/Project Team Leader, Drug Safety Research and Development, Pfizer* *Tanja Zabka, Veterinary Pathologist, Safety Assessment Group, Genentech*
9:30 – 10:25 AM	**Panel Discussion and Audience Q&A: Case Study 3** *Brad Enerson, Pfizer and Tanja Zabka, Genentech – Discussion Leaders* *Hobart Rogers, PharmD, PhD, Reviewer, FDA* *John-Michael Sauer, Critical Path Institute* *James Weaver, PhD, Division of Applied Regulatory Science, FDA* *Thorsten Vetter, PhD, Senior Scientific Officer, EMA*
10:25 – 10:45 AM	**Coffee Break**

10:45 – 11:30 AM	**Presentation: Analytical Validation** *Steve Piccoli, PhD, Research Fellow, Immunochemistry and Biomarkers, Bioanalytical Sciences – Biologics Department, Bristol-Myers Squibb*
11:30 AM – 12:30 PM	**Panel Discussion and Audience Q&A: Analytical Validation Considerations** *Steve Piccoli, Bristol-Myers Squibb – Discussion Leader* *Shashi Amur, CDER, FDA* *Steve Gutman, MD, MBA, Strategic Advisor, Myraqa* *Gary Kelloff, MD, Cancer Imaging Program, NIH/NCI* *Dan Krainak, PhD, Biomedical Engineer, CDRH, FDA* *Meena Subramanyam, PhD, Vice President, Translational Medicine, Biogen*
12:30 – 1:30 PM	**Lunch**
1:30 – 2:45 PM	**Panel Discussion and Audience Q&A: Defining Evidentiary Criteria for Safety Biomarker Qualification: Testing the Utility of the Framework and Refining the Model:** • COU • Benefit/Risk • Evidence "Map" *John Wagner, Takeda – Discussion Leader* *Martha Brumfield, Critical Path Institute* *Gary Kelloff, NIH/NCI* *Chris Leptak, FDA* *Frank Sistare, Merck* *Thorsten Vetter, EMA* *David Wholley, FNIH*
2:45 – 3:05PM	**Summary of Next Steps: Toward a Guidance for Safety Biomarkers** *Chris Leptak, FDA*
3:05 – 3:30PM	**Next Steps: Defining Evidentiary Criteria for Other Biomarker Classes—Meeting Wrap-Up** *David Wholley, FNIH*