### DRAFT AGENDA

**Day One -- Thursday, April 14, 2016**

<table>
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<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>7:30 – 8:30 AM</td>
<td>Registration and Breakfast</td>
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| 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* |
*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* |
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| 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 Hauser, 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)*

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### Day Two -- Friday, April 15, 2016

#### 7:30 – 8:30 AM

**Registration and Breakfast**

#### 8:30 – 8:40 AM

**Welcome – Day Two**

*David 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**
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| 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 – 3:05 PM | **Summary of Next Steps:** Toward a Guidance for Safety Biomarkers  
Chris Leptak, FDA |
| 3:05 – 3:30 PM | **Next Steps:** Defining Evidentiary Criteria for Other Biomarker Classes—Meeting Wrap-Up  
David Wholley, FNIH |