Creating Consensus Science
New Tools and Tactics for Next-Gen Drug Development

November 30 - December 1, 2011
Crowne Plaza Hotel
8777 Georgia Avenue
Silver Spring, MD

Collaborations between industry, regulatory agencies, and academia are generating consensus on the value of innovative tools for drug development (data standards, open databases, biomarkers, patient-reported outcome measures, quantitative disease progression models, clinical imaging, and others). These tools will accelerate the development of efficacious medicines with optimal risk profiles. This cross-sector conference will feature state-of-the-art drug development tools while reviewing the lessons learned from Public Private Partnerships (PPPs) and scanning the landscape for the most pressing needs in drug and diagnostic development.

November 30, 2011

8:00 a.m.  Welcoming Remarks  Dr. Lynn Hudson, Chief Science Officer, Critical Path Institute
8:15 a.m.  Keynote  Dr. Margaret Hamburg, Commissioner, FDA

SESSION I: DATA STANDARDS AND CLINICAL TRIAL DATABASES AS TOOLS

Discussion Topics Include:
- The Data Standards Initiative – the five-year program to develop clinical data standards for the top 50 therapeutic areas.
- The explosion of clinical data repositories – meeting the challenge to integrate and harmonize data repositories using standards.
- What are the rate-limiting steps in developing and implementing data standards?

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8:45 a.m.  Introduction and Overview Presentation by Session Co-Chairs
       Dr. Rebecca Kush, Clinical Data Interchange Standards Consortium
       Enrique Aviles, Critical Path Institute

9:10 a.m.  Initial comments by panelists
       Dr. Chuck Cooper, FDA
       Margaret Haber, National Cancer Institute, NIH
       Dana Pinchotti, American College of Cardiology
       Dr. Frank Rockhold, GlaxoSmithKline
       Mary Ann Slack, FDA

9:35 a.m.  Open discussion of topics and Q&A

10:30 a.m. COFFEE BREAK

**SESSION II: BIOMARKER QUALIFICATION**

Discussion Topics Include:

- Is the precompetitive space ideal for biomarker qualification? Or is qualification of a biomarker as part of an NDA the most efficient route?
- Can biomarker qualification facilitate subsequent clearance of a companion diagnostic?
- How can we measure the utilization and value of newly qualified biomarkers?
- What factors should be used to prioritize which biomarkers are submitted for qualification? Who should set the priorities?

11:00 a.m. Introduction by Session Co-Chairs
       Dr. Eslie Dennis, Critical Path Institute
       Dr. Marc Walton, FDA

11:05 a.m. Individual Speakers and Panelists
       Dr. Rich Miller, GlaxoSmithKline
       Dr. Frank Sistare, Merck
       Dr. Ron Perrone, Tufts University
       Dr. Gary Romano, Johnson & Johnson
       Dr. Chris Leptak, FDA

12:45 p.m. LUNCH

**SESSION III: QUALIFIED PATIENT-REPORTED OUTCOME INSTRUMENTS AS DRUG DEVELOPMENT TOOLS**

Discussion Topics Include:

- What are the most pressing PRO measurement gaps in drug development?
- How can the processes for PRO instrument development and qualification be accelerated?
- What are the barriers to implementing electronic PRO data collection technologies in clinical trials?

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2:00 p.m. Introduction by Session Co-Chairs
Capt. Laurie Burke, FDA
Dr. Stephen Joel Coons, Critical Path Institute

2:05 p.m. Individual Speakers
Capt. Laurie Burke, FDA
Dr. Elektra Papadopoulos, FDA
Dr. Stephen Joel Coons, Critical Path Institute
Dr. Clarice (Risa) Hayes, Lilly
Dr. Wilhelm Muehlhausen, eResearch Technology, Inc.

3:05 p.m. Open discussion of topics and Q&A

3:45 p.m. COFFEE BREAK

SESSION IV: QUANTITATIVE DISEASE PROGRESSION MODELS AS TOOLS

Discussion Topics Include:
- Modeling and simulation of clinical trials as drug development tools; what is the impact for the drug development process?
- How can modeling and simulation support the qualification of additional drug development tools such as biomarkers?
- How can C-Path Consortia contribute to the development of best practices for use of modeling and simulation in drug development?

4:00 p.m. Introduction by Session Co-Chairs
Dr. Klaus Romero, Critical Path Institute
Dr. Pravin Jadhav, FDA

4:05 p.m. Individual Speakers
Dr. Brian Corrigan, Pfizer
Dr. Mahesh Samtani, Johnson & Johnson
Dr. J.F. Marier, Pharsight
Dr. Marc Pfister, Quantitative Solutions

5:05 p.m. Open discussion of topics and Q&A

6:00-8:00 P.M. NETWORKING SOCIAL
Creating Consensus Science
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December 1, 2011

ROUND TABLE I: GLOBAL PARTNERSHIPS TO SPUR DEVELOPMENT OF MEDICAL PRODUCTS

10:00 a.m. Introduction by Chair Dr. Janet Woodcock, FDA

10:15 a.m. Roundtable Participants
- Dr. Michel Goldman, Innovative Medicines Initiative
- John Castellani, PhRMA
- Dr. Garry Neil, Johnson & Johnson
- Myrl Weinberg, National Health Council
- Senator Robert Bennett, Critical Path Foundation
- Dr. ShaAvhree Buckman-Garner, FDA
- Dr. Jan Gheuens, Bill & Melinda Gates Foundation

12:15 p.m. Keynote Dr. Kathy Hudson, Deputy Director for Science, Outreach, and Policy, NIH

12:45 p.m. LUNCH

ROUND TABLE II: THE DEVELOPMENT PATH FORWARD

Discussion Topics Include:
- How can drug development tools support a new regulatory framework?
- How can the process for the co-development of drugs and diagnostics be enhanced by new tools such as quantitative disease progression models?
- How can combinations of drugs be efficiently evaluated?
- What regulatory path can incentivize the development of anti-infectives and medical countermeasures?
- How can the development of interventions for rare diseases be accelerated?
- Can partners help the FDA by drafting guidances to optimize the use of new drug development tools?

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2:00 p.m.  Introduction by Session Chair  Dr. Raymond Woosley, Critical Path Institute

2:05 p.m.  Roundtable Participants:
            Dr. Janet Woodcock, FDA
            Dr. Alberto Gutiérrez, FDA
            Dr. Chris Austin, Director, NIH Center for Translational Therapeutics
            Dr. Thorir Bjornsson, Critical Path Institute
            Dr. John Orloff, Novartis
            Dr. Sean Tunis, Center for Medical Technology Policy
            Dr. Timothy R. Coté, Chief Medical Officer, National Organization for Rare Disorders
            Mara Aspinall, Ventana Medical Systems, Inc. (invited)

4:00 p.m.  Meeting adjourns