Center for Health Policy at BROOKINGS

Improving Productivity in Pharmaceutical Research and Development: The Role of Clinical Pharmacology and Experimental Medicine

The Embassy Row Hotel • Washington, DC
July 29, 2015

Private Roundtable – Invitation Only

9:00 a.m. **Welcome, Recap from Day One, and Meeting Objectives**

- Mark McClellan, Senior Fellow and Director, Health Care Innovation and Value Initiative, The Brookings Institution
- Gregory Daniel, Managing Director for Evidence Development & Innovation, Center for Health Policy and Fellow, Economic Studies, The Brookings Institution

9:15 a.m. **Session I: Exploring Opportunities for Pre-Competitive Data Sharing and Collective Learning**

This session will focus on outlining key takeaways from discussions that took place on the first day, with a specific emphasis on exploring opportunities for academic researchers, product sponsors, and regulators to work together to share data and reach mutually beneficial conclusions.

Perspectives:

- Klaus Romero, Director, Clinical Pharmacology, Critical Path Institute
- Dalvir Gill, Chief Executive Officer, TransCelerate BioPharma Inc.
- Cornelis Hop, Senior Director, Drug Metabolism & Pharmacokinetics, Genentech

10:30 a.m. **Break**

10:45 a.m. **Session II: Regulatory and Policy Considerations for the Application of Clinical Pharmacology Tools in Drug Development Programs**

This session will focus on relevant regulatory and policy issues and map out a strategy to overcome barriers to the successful implementation of clinical pharmacology in drug development and review. Discussion will also focus on topics that may require further exploration in subsequent workshops, as well as on identifying concrete next steps for industry, FDA, and other stakeholders.

Perspectives:

- Rob Califf, Deputy Commissioner for Medical Products and Tobacco, U.S. Food and Drug Administration
- Akintunde Bello, Executive Director Oncology and Immuno Oncology, Bristol-Myers Squibb
- Issam Zineh, Director, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

12:00 p.m. **Adjournment**

Convened by the Center for Health Policy at Brookings and supported by a cooperative agreement with the U.S. Food and Drug Administration.

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Participant List

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Deputy Commissioner for Medical Products and Tobacco, U.S. Food and Drug Administration

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