



**INSTITUTE OF MEDICINE**

OF THE NATIONAL ACADEMIES

**IOM ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE**

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**MEMBERS MEETING**  
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SEPTEMBER 26, 2013  
THE NATIONAL ACADEMY OF SCIENCES  
LECTURE ROOM  
2101 CONSTITUTION AVENUE, NW  
WASHINGTON, DC

**Meeting goals**

1. Explore the future of clinical research and regulatory science in the context of rapidly changing research resources and tools.
2. Discuss ongoing collaborative efforts among NIH, FDA, CMS, AHRQ, PCORI, and beyond.
3. Consider the rate-limiting factors to fully capturing the opportunities for improvement in regulatory science and practice.
4. Identify ways the Institute of Medicine might help foster the progress possible.

8:30 am **Coffee and light breakfast available**

9:00 am	<b>Welcome and introductions</b>
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**Opening remarks**

*Mark McClellan*, Roundtable Chair, The Brookings Institution

*Harvey Fineberg*, President, Institute of Medicine

9:15 am	<b>IOM Roundtable and Innovation Collaboratives: a brief update</b>
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*Michael McGinnis*, Institute of Medicine

9:45 am

**Emerging opportunities shaping the future of clinical research**

Opportunities for clinical research advancement and innovation, from key stakeholder perspectives.

*Ralph Horwitz*, GlaxoSmithKline, moderator and overview comments

- *Joe Selby*, Patients-Centered Outcomes Research Institute
- *Gary Gottlieb*, Partners HealthCare System
- *Jamie Heywood*, PatientsLikeMe
- *Amy Abernethy*, Duke University

*Q&A and open discussion*

10:45 am

**Break**

11:00 am

**Big data, the changing knowledge landscape, and regulatory innovation**

Evolving clinical knowledge generation resources and tools, and the prospects and priorities for regulatory innovation.

**Perspective from NIH**

*Kathy Hudson*, National Institutes of Health

*Belinda Seto*, BD2K, National Institutes of Health

**Perspective from FDA**

*ShaAvbrée Buckman-Garner*, Food and Drug Administration

*Q&A and open discussion after each*

12:00 pm

**Lunch**

**Opportunities and priorities for collaborative innovation**

*Dr. McClellan, Dr. Hudson, and Dr. Buckman-Garner*

*Q&A and open discussion*

1:00 pm

**Regulatory science and practice**

Prospective methodologic advances for innovation in regulatory science and practice.

**Distributed approaches to learning from care**

*Rich Platt*, Harvard Pilgrim Health Care Institute and Harvard Medical School

**Adaptive approaches to approval and use**

*Edmund Pezalla*, Aetna

**Progressive evidence generation: dealing with uncertainty**

*Patrick Ryan*, Janssens Research and Development and Observational Medical Outcomes Partnership

**Advances in understanding and communicating risks and benefits**

*Shannon Brownlee*, Lown Institute

*Q&A and Open Discussion*

2:45 pm	<b>Break</b>
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3:00 pm	<b>Opportunities and strategies</b>
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General discussion to identify opportunities and strategies, including those that could benefit from collaborative engagement under IOM Roundtable auspices.

4:00 pm	<b>Summary and next steps</b>
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**Comments from the Chair**

*Mark McClellan*, The Brookings Institution

**Comments and thanks from the IOM**

*Michael McGinnis*, Institute of Medicine

4:15 pm **Adjourn**