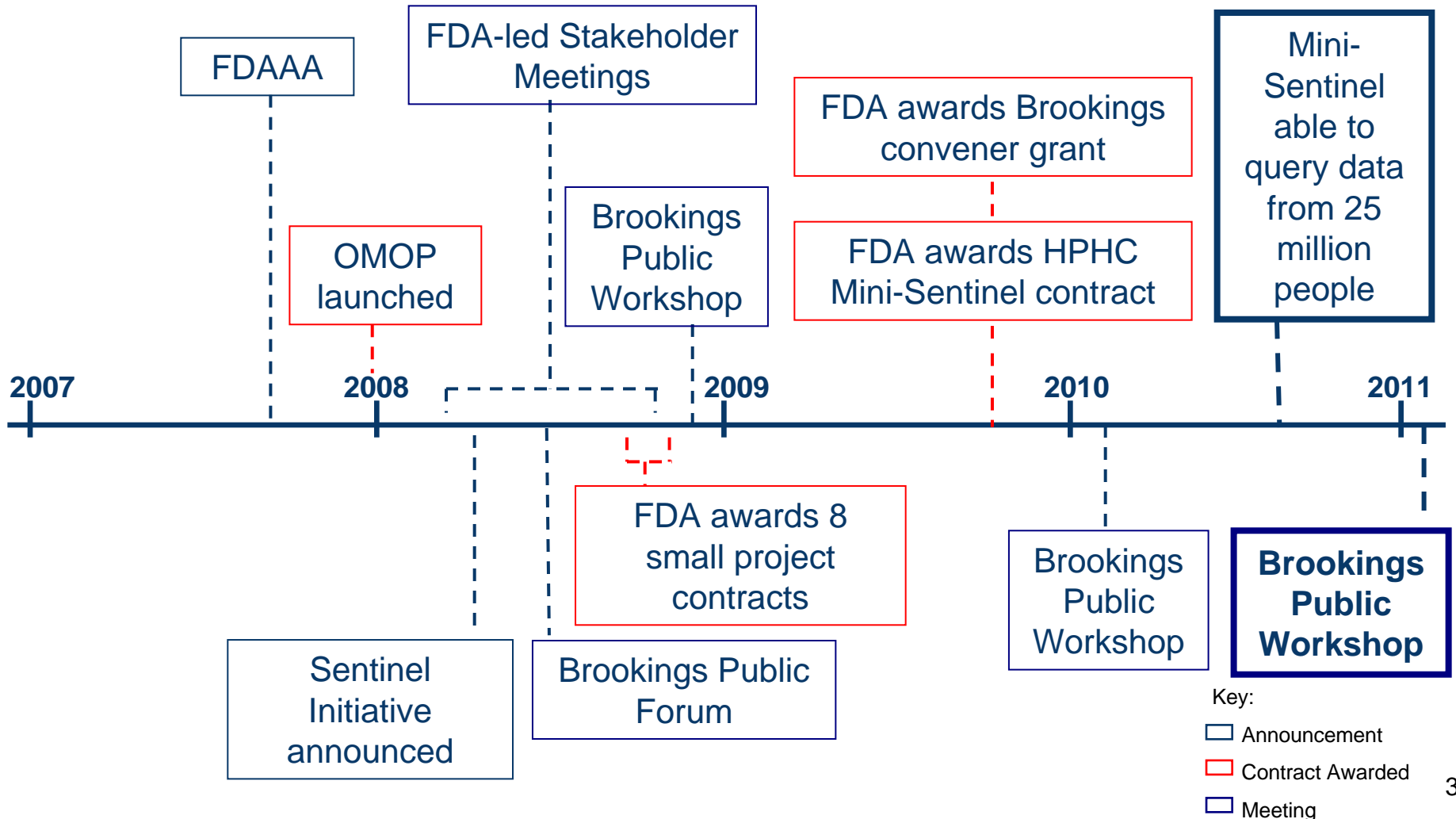


Keynote Address: Toward Better Post Market Evidence for Medical Product Safety

Mark McClellan
Engelberg Center for Health Care Reform at Brookings

The Sentinel System is being developed through public-private collaboration



Opportunities for stakeholder involvement

Activity	Description	Past Topics
Roundtable Webinars	Highlight pilot projects relevant to active surveillance	<ul style="list-style-type: none"> • Refer to: www.brookings.edu/health/projects
Expert Workshops	Focused discussions of technical topics	<ul style="list-style-type: none"> • Network Infrastructure • Privacy and Legal Issues • Methods • Communications
Implementation Meetings	Senior leaders of public and private organizations discuss strategic implementation issues	<ul style="list-style-type: none"> • Potential organizational models • Participation of private sector data and analytic partners
Public Stakeholder Workshops	Large, annual meetings provide a forum to engage the public in dialogue about the direction of Sentinel's activities	



The NEW ENGLAND JOURNAL of MEDICINE

Perspective
JANUARY 12, 2011

Developing the Sentinel System: A National Resource for Evidence Development

Rachel E. Behrman, M.D., Joshua S. Benner, Pharm.D., Sc.D., Jeffrey S. Brown, Ph.D., Mark McClellan, M.D., Ph.D., Janet Woodcock, M.D., and Richard Platt M.D., M.Sc.

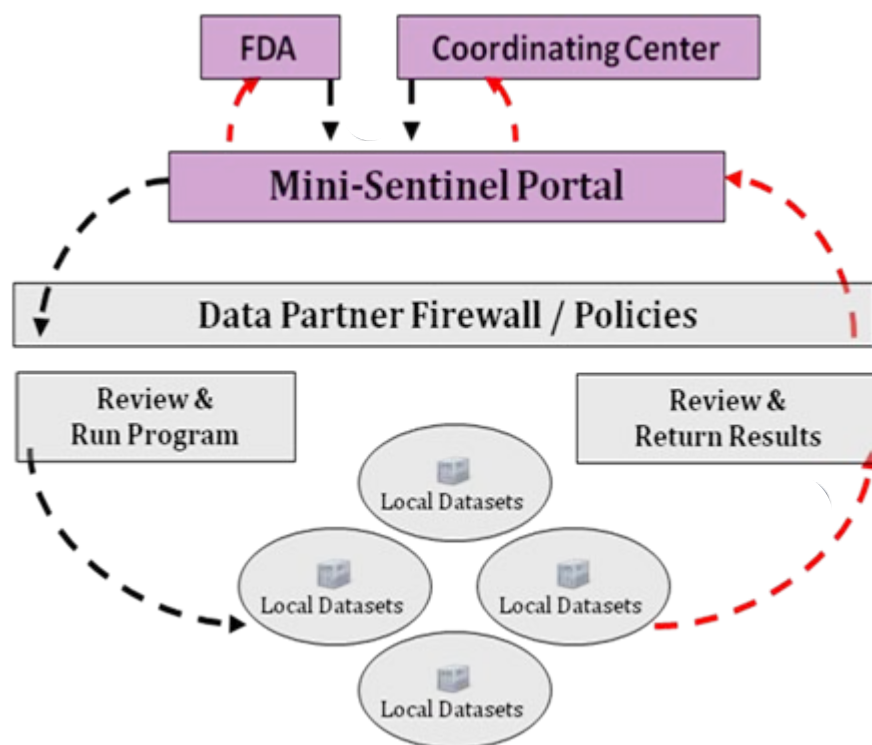
The Food and Drug Administration (FDA) now has the capacity to “query” the electronic health information of more than 60 million people, posing specific questions in order to monitor the safety of

approved medical products. This information to answer additional pilot program, called Mini-Senti- important questions about health

convening an ongoing series of discussions among stakeholders to address the near- and long-term challenges inherent in implementing the Sentinel System.³ In 2009, the FDA gave the Harvard Pilgrim Health Care Institute the lead role in fulfilling a 5-year contract to

Key features of Mini-Sentinel

- Distributed database network
- Privacy is priority
- Private sector collaboration as analytic partners



Elements of Mini-Sentinel in development

- Generalizable framework to refine safety signals
- Established protocols to answer common safety questions
- Expert and public input to ensure rigor and credibility of methods and results
- Education for healthcare professionals

Continued stakeholder involvement is vital to success

- Realistic expectations for patients, public, lawmakers
- Defining appropriate roles for
 - Medical product manufacturers
 - Health care professionals
 - Patients and consumers

Sentinel as a national resource for evidence development

- Creating a sustainable business model for the data and analytic partners
- Developing an effective public-private partnership to govern the activities of the network
- Extending our capacity to link and analyze different data sources while protecting patient privacy
- Ensuring all stakeholders have appropriate roles in these activities