

Sentinel Initiative Public Workshop

The Brookings Institution Marriott at Metro Center • Washington, DC Tuesday, January 14, 2014







- Develop a coordinating center for a distributed system
 - Access three or more health data environments with varied attributes to conduct analyses
 - Convene a Planning Board to develop governing documents and establish a Safety Science Committee charged with the day-to-day operations
 - Develop a means for secure communication with contracted data holders
- Evaluate emerging methods in safety science
 - Develop epidemiological and statistical methodologies for signal detection, signal strengthening, and signal validation
 - Test such methodologies in the evaluation of FDA-identified medical product-adverse event pairs of concern
 J. Woodcock, Dec 16, 2009 2