The Vision for a Semi-Automated Surveillance System to Complement Protocol-Based Product Assessments

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An Analogy to Healthcare

- A comprehensive healthcare system includes both preventive health maintenance and also specialized health interventions
- A preventive program may include vaccines, cholesterol screening, colonscopy, mammograms, etc.
- Appropriate preventive program is chosen according to patient (age, gender, history, lifestyle, etc)
- May still be necessary to follow with specialized assessments and interventions

What constitutes a comprehensive safety surveillance system?

- Semi-automated routine surveillance, applying general tools with minor adaptations to address the specific product

But also…

- Ability to bring specialized expertise to bear on specific issue(s) that may arise in product lifecycle

Application of this Principle to the Sentinel System

At Present

- Infrastructure in place to capture product exposures
- Some experience in measuring a few outcomes (AMI, bleeding)
- Sufficient expertise available to develop programming to apply existing methodologies to specific product:outcome pairs

❖ Highly specialized system that supports important but restricted range of activities (e.g., the HPV and rotavirus vaccine and dabigatran evaluations described this morning)

Goal Capacities

- Increase current capabilities

But also…

- Create semi-automated routine surveillance capability
  - Need vastly expanded menu of measurable outcomes
  - Need adaptable modules that can apply general methodologies to many product:outcome pairs
  - Need improved understanding of appropriate application of statistical and epidemiology tools in this setting

❖ Comprehensive system capable of full range of safety surveillance

Relative Characteristics of Semi-Automated and Protocol-Based Surveillance

Semi-Automated	Protocol-Based
• Less resource intensive	• More resource intensive
• Less control of systematic biases	• Greater control of systematic biases
• Able to generate hypotheses	• Able to test hypotheses

The speakers that follow will describe the ongoing efforts to build the first generation of tools that will support semi-automated surveillance activities through the Sentinel Initiative