FDA’s Perspective on the Current Status and Future of Active Surveillance and Safety Science

Janet Woodcock
U.S. Food and Drug Administration
Sentinel Initiative Vision*

• System will be able to refine safety signals in near real-time. This will require the following capabilities:
  – rapidly defining exposed cohorts;
  – establishing algorithms to capture health outcomes of interest;
  – using sophisticated modular programs capable of running evaluations with minimal input from epidemiologists and clinicians and limited or no ad hoc programming; and
  – developing a framework to guide methodological approaches for safety surveillance evaluations that include confounding adjustment.

• Approaches for signal generation will be under development.

* Within the next 3 years