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

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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