



Putting It All Together: How Safety Data Becomes a Signal

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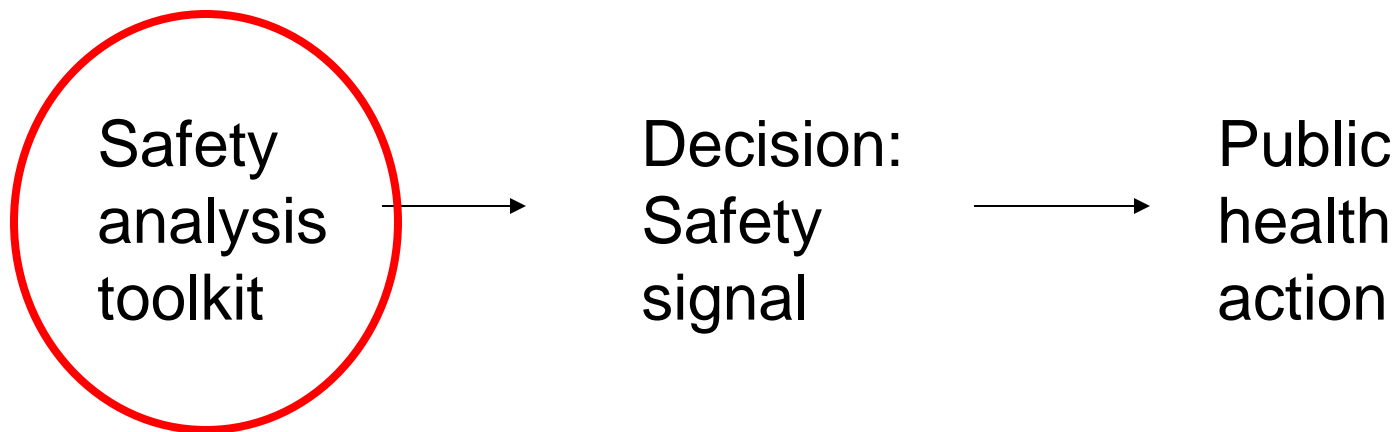
Office of Biostatistics and Epidemiology,

Center for Biologics Evaluation and Research, FDA

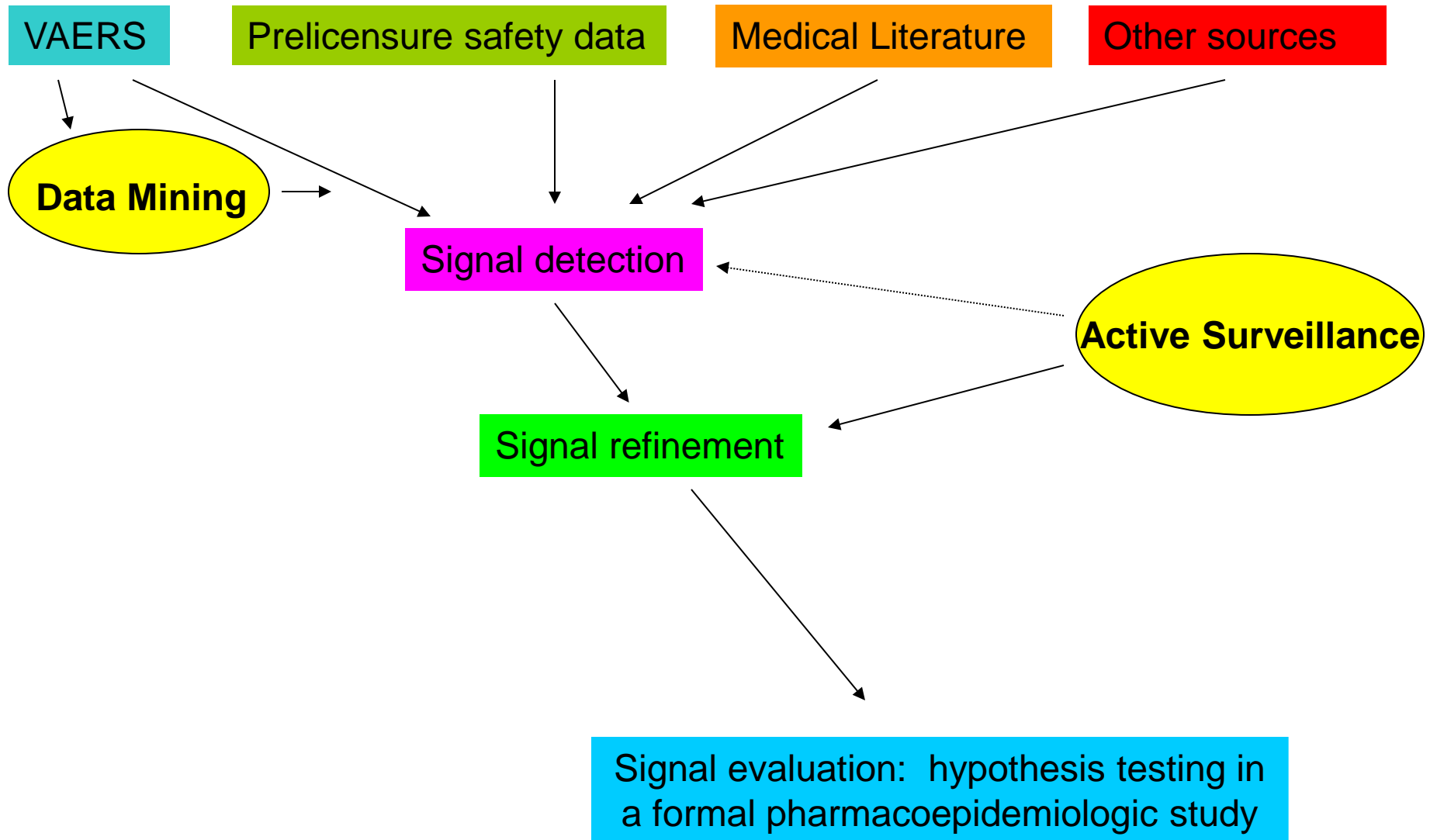
Objectives

- **Review tools for post-market safety surveillance and signal detection**
- **Discuss FDA's organizational approach to deciding if a signal is present**
- **Discuss risk management considerations**

Signal Decision Making



Consider the
“alert” source:
each has
strengths and
limitations



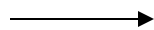
Signal Decision Making



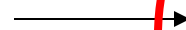
Place the “alert” source in context in order to determine if a safety signal is present

Signal Decision Making

Safety
analysis
Toolkit



Decision:
Safety
signal



Public
Health
Action

Examine
available options
and their
intended and
unintended
consequences

Discussion of CBER's signal adjudication process

- Pharmacovigilance and Pharmacoepidemiology, like clinical medicine, are both an art and a science
- An organized process within the Center enhances the acquisition and processing of vaccine safety information by reviewers
- Public health actions are taken after careful consideration by a multidisciplinary team at FDA