Putting It All Together: How Safety Data Becomes a Signal

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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

Safety analysis toolkit → Decision: Safety signal → Public health action

Consider the “alert” source: each has strengths and limitations
Signal detection: hypothesis testing in a formal pharmacoepidemiologic study

Data Mining

VAERS

Prelicensure safety data

Medical Literature

Other sources

Signal refinement

Active Surveillance

Signal evaluation: hypothesis testing in a formal pharmacoepidemiologic study
Signal Decision Making

Safety analysis Toolkit → Decision: Safety signal → Public Health Action

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