



Federal Partners' Collaboration

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Safe Rx Project

- Collaboration between CMS and FDA
- Launched in 2008 at the time Medicare Part D data (prescription benefit) became available with support from HHS ASPE
- Evolved from earlier collaborations between CMS and FDA, primarily related to medical products covered by Medicare Part B
- Investigating ways to utilize Medicare and Medicaid medical product exposures and outcomes for active surveillance and full epidemiological studies

Federal Partners Collaboration

- An active surveillance initiative via intra-agency agreements with CMS, VA, DoD
- Small distributed system
 - Each Partner has unique data infrastructure
 - No common data model being utilized
- FDA proposes medical product – AE pairs to evaluate
- Develop a shared protocol
- Assess interpretability of query findings resulting from a decentralized analytic approach

Planning template

- CMS contractor Acumen has developed a template for planning the evaluation
 - Phase 1: Define treatments, outcomes, and related health circumstances and medical interventions for analysis
 - Phase 2: Describe analysis populations and compare populations for outcome events
- Template has been refined through discussions with Federal Partners and use in active surveillance evaluations

FPC Evaluations to date

- Antiviral drugs and neuropsychiatric adverse events
- Dronedarone and heart failure

Ongoing challenges

- Limits to analysis approaches with rare outcomes
- Develop approaches to make most of claims data to enhance outcome validation given limited access to source data
- Interpretation of evaluation findings given diverse Federal Partner populations and differences in clinical guidelines and practice