Overview of ASSURE
OHDSI Symposium 2023

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OFFICE OF THE CHIEF MEDICAL OFFICER
Standardizing regulatory-grade real-world evidence generation

**Standardized design**
- Indication
- Target
- Outcome
- Comparator
- Time-at-risk

**Standardized analytics**
- Open community data standards
- Methodological research
- Open-source development

**JNJ/Epi standardized data network (OMOP CDM)**
- US private claims x3
- US EHR x2
- US Hospital
- US Medicaid
- US Medicare suppl
- Germany EHR
- France EHR
- Australia EHR
- Japan claims

**Standardized evidence**
- Characterization
  - Disease natural history
  - Treatment utilization
  - Outcome Incidence
  - Time-to-event
- Population-level estimation
  - Comparative cohort
  - Self-controlled case series
- Patient-level prediction

**Innovation**
Transforming RWE generation from bespoke studies taking months to a **systematic process** taking days, while enabling transparent reproducibility and ensuring **scientific best practices** in causal inference and machine learning

**Use cases**
Current focus:
- Safety signal detection and evaluation
- Enhanced surveillance

Future opportunities:
- Comparative effectiveness
- Disease interception

**Results delivered in 2023**
- 23 Requests
- Impact on regulatory decision making
Where does ASSURE fit into the life of a safety signal?

- Early awareness of signals enables preparation and validation of input specifications
- Standardization enables evidence generation within a short timeline

**Signal Detection**
- Safety data
- Safety Observation

**Signal Triage**
- Identifying signals and priority

**Validation**
- Validation of Signal
- No: Closed - Not Validated
- Yes: Evaluation of Signal

**Final Assessment**
- Positive Findings: Safety Issue Confirmed
- Negative or Insufficient Information: Safety Issue Not Confirmed

**Standardized inputs**

**Standardized analytics**

**Standardized databases**

**Standardized results**
ASSURE Analyses: Inputs and Outputs

- 164 Janssen products
- 935 alternate treatments
- 39 treatment indications
- 45 outcome events
1. Treatment/Comparator/Indication/Outcome
   • Comparator Selection Tool
2. Phenotype Development
   • Disease Advisory Board
3. Analytic Design and Implementation
   • Negative Control Selection
   • Time at Risk Selection
4. Result Interpretation
   • Shiny Dashboard
5. Documentation and Communication
   • Standardized Output

A Day in the Life of the ASSURE Team
Give me a “T”; Give me a “C”; Give me an “I”; Give me an “O”
What’s that spell… “Strategus!”

tcis <- list()
  list(
    targetId = 13771,
    comparatorId = 13774,
    indicationId = NULL,
    genderConceptIds = c(8507, 8532), # use valid
    minAge = 18, # Age 18+. Can be NULL
    maxAge = NULL, # No max age. Can be NULL
    excludedCovariateConceptIds = c(1154029,
                                      1103640)
  )

scctsTi <- list(
  list(
    targetId = 13771,
    indicationId = NULL, # NO INDICATION REQUIRED
    genderConceptIds = c(8507, 8532), # use valid
    minAge = 18, # Age 18+. Can be NULL
    maxAge = NULL # No max age. Can be NULL
  )
)

outcomes <- tibble(
  cohortId = c(12308),
  cleanwindow = c(90)
)

negativeConceptSetId <- 5749
timeAtRisks <- tibble(
  label = c("on-treatment"),
  riskwindowStart = c(1),
  startAnchor = c("cohort start"),
  riskwindowEnd = c(0),
  endAnchor = c("cohort end"),
)

# Try to avoid intent-to-treat TARs for SCCS:
scctsTimeAtRisks <- tibble(
  label = c("on-treatment"),
  riskwindowStart = c(1),
  startAnchor = c("cohort start"),
  riskwindowEnd = c(0),
  endAnchor = c("cohort end"),
)

# Try to use fixed-time TARs for PLP:
plpTimeAtRisks <- tibble(
  riskwindowStart = c(1),
  startAnchor = c("cohort start"),
  riskwindowEnd = c(365),
  endAnchor = c("cohort start"),
)

studyStartDate <- "" # YYYYMMDD
studyEndDate <- "" # YYYYMMDD