Johnson & Johnson

ASSURE | Active Safety Surveillance Using Real-world Evidence

Overview of ASSURE
OHDSI Symposium 2023

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Standardizing regulatory-grade real-world evidence generation

Standardized design

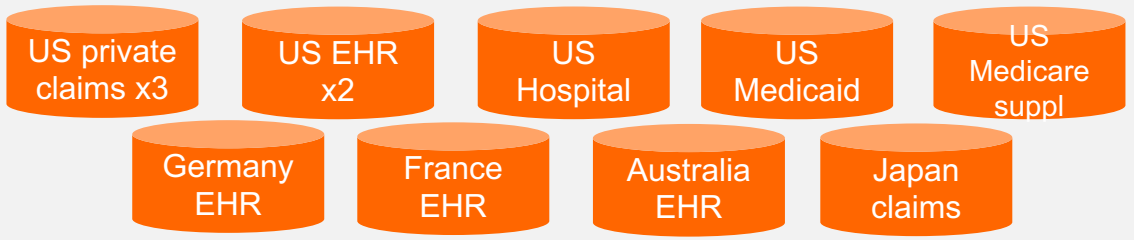
- Indication
- Target
- Outcome
- Comparator
- Time-at-risk

Standardized analytics

OHDSI
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

Open community data standards | Methodological research | Open-source development

JNJ/Epi standardized data network (OMOP CDM)



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

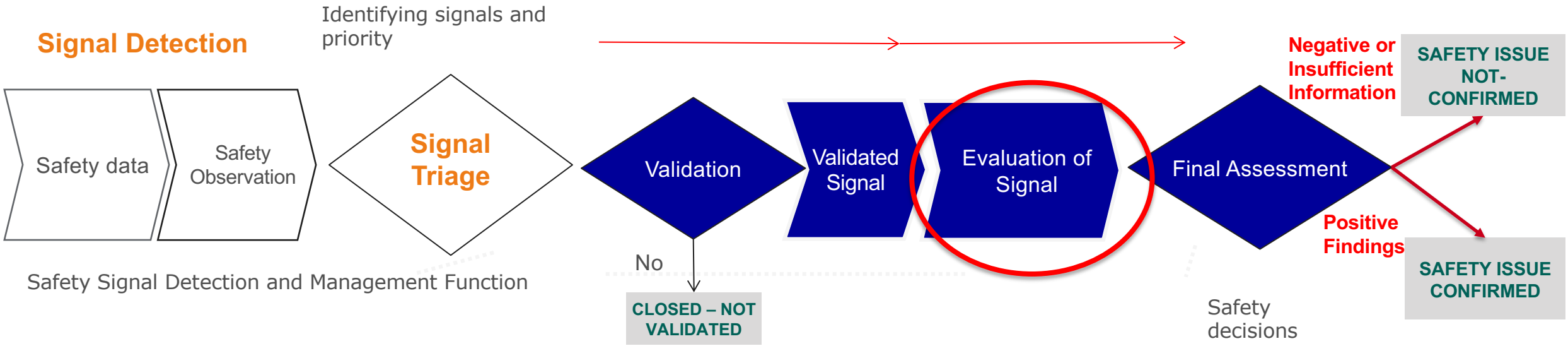
Current focus:
- Safety signal detection and evaluation
- Enhanced surveillance

Future opportunities:
- Comparative effectiveness
- Disease interception

Results delivered in 2023

- 23 Requests
- Impact on regulatory decision making

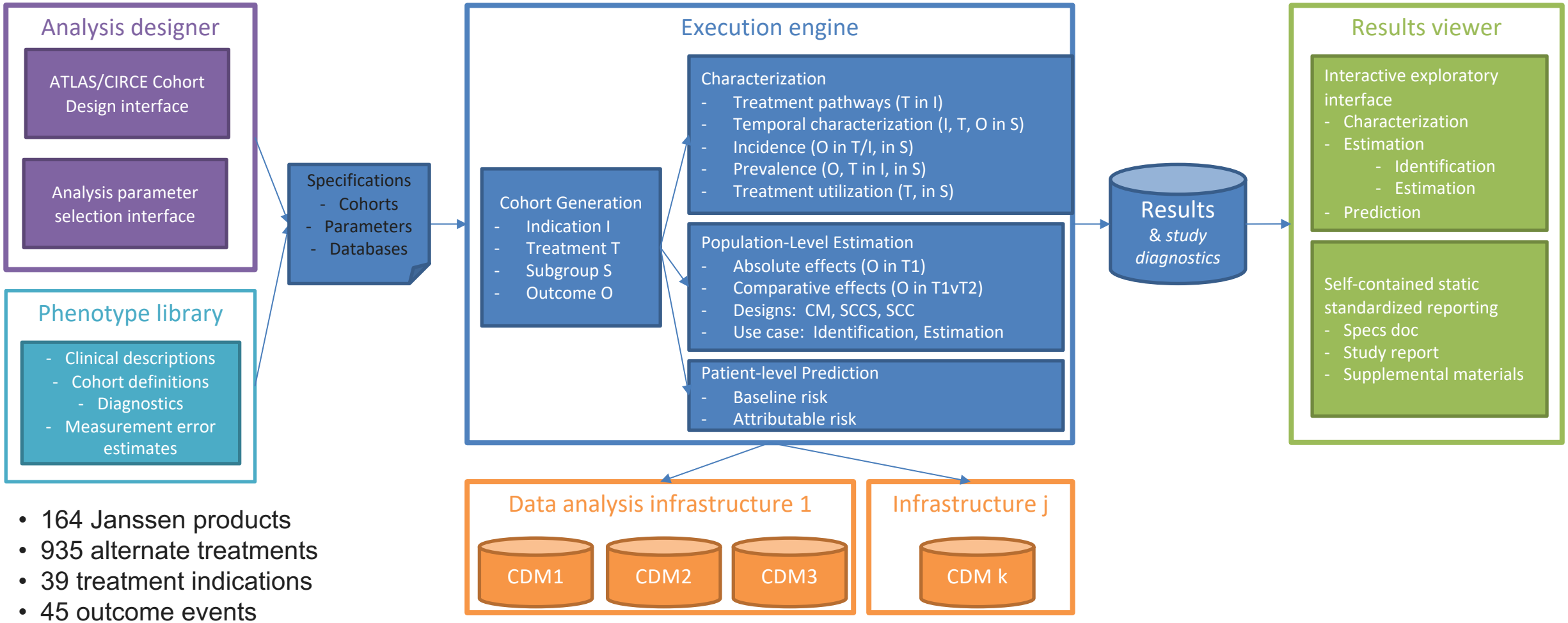
Where does ASSURE fit into the life of a safety signal?



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

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!”

```r
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
    )

sccsTi <- 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)
)
```

```r
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:
sccsTimeAtRisks <- 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
```

```r
54 # Probably don't change below this line ----------
```