# PointCROSS Life Sciences
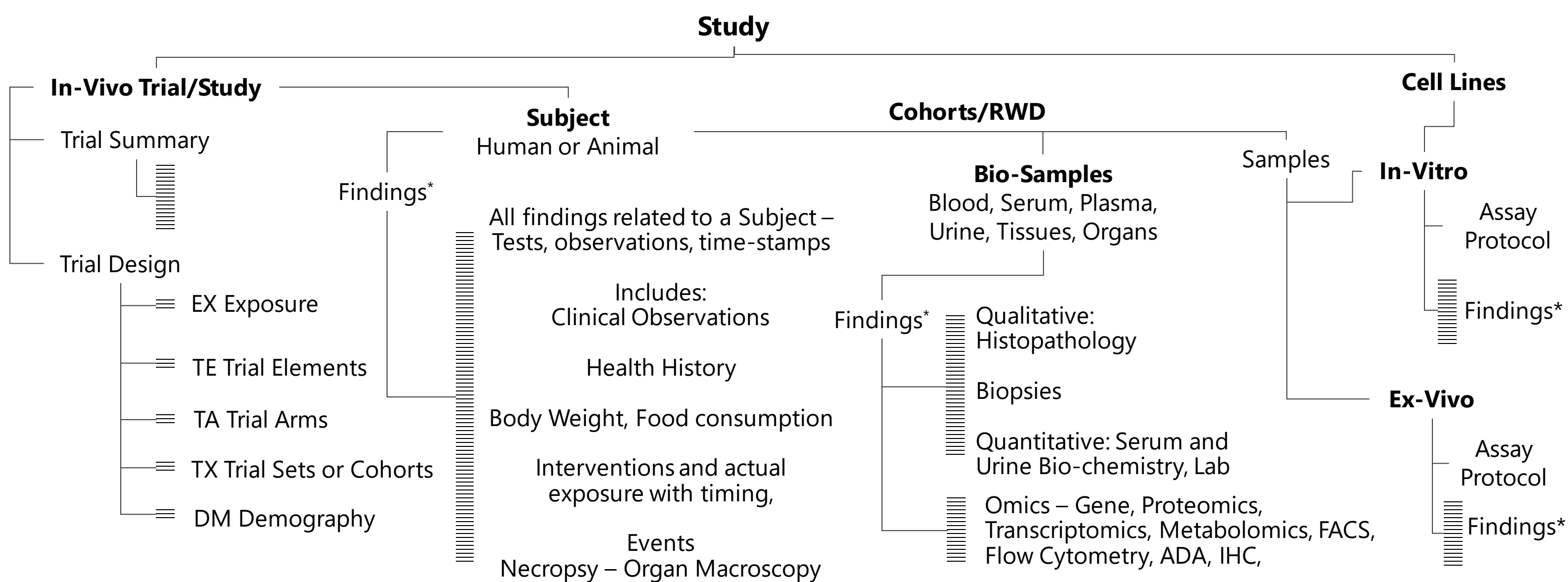
# CDISC 360 Mission: SDTM Design and Automation

## Input: Metadata & Raw Clinical Data

### Create End-to-Start Specification

❑ Produce a standards-based, machine readable specification

### Generate Start-to-End Metadata

❑ Use standards specification to generate study metadata artifacts
❑ Demonstrate the ability to generate study metadata given a specification

**Study**

**In-Vivo Trial/Study**
- Trial Summary
- Trial Design
  - EX Exposure
  - TE Trial Elements
  - TA Trial Arms
  - TX Trial Sets or Cohorts
  - DM Demography

**Subject**
Human or Animal

Findings*

All findings related to a Subject – Tests, observations, time-stamps

Includes:
Clinical Observations

Health History

Body Weight, Food consumption

Interventions and actual exposure with timing,

Events
Necropsy – Organ Macroscopy

**Cohorts/RWD**

**Bio-Samples**
Blood, Serum, Plasma, Urine, Tissues, Organs

Findings*
- Qualitative: Histopathology
- Biopsies
- Quantitative: Serum and Urine Bio-chemistry, Lab
- Omics – Gene, Proteomics, Transcriptomics, Metabolomics, FACS, Flow Cytometry, ADA, IHC,

Samples

**Cell Lines**

**In-Vitro**
- Assay Protocol
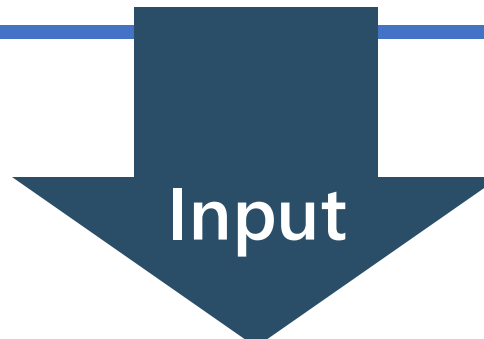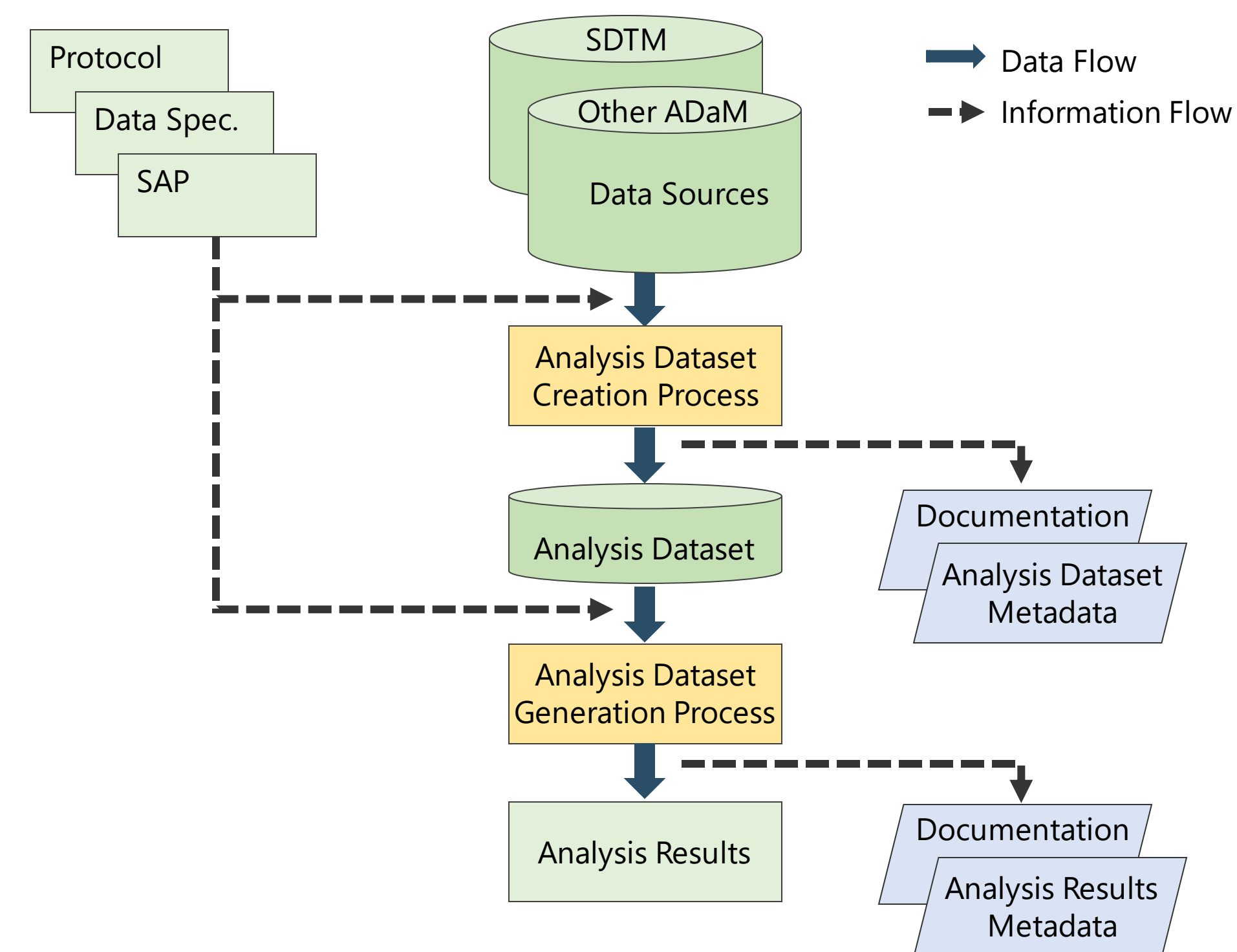- Findings*

**Ex-Vivo**
- Assay Protocol
- Findings*

*\* Findings are held in a common storage model with Observation/Testname, date-Time stamp, Units and other attributes*

## Output: SDTMs, ADaMs, Define.xml & TFLs

### Data Curation

❑ Repetitive Process to Optimize Data and Metadata to ensure Valuable use of Data



- Protocol
- Data Spec.
- SAP
- SDTM
- Other ADaM
- Data Sources
- ➡ Data Flow
- ⇢ Information Flow
- Analysis Dataset Creation Process
- Analysis Dataset
- Documentation / Analysis Dataset Metadata
- Analysis Dataset Generation Process
- Analysis Results
- Documentation / Analysis Results Metadata

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**Input ⬇**

## Transformation and Automation: Reusability & Repeatability

**Output ⬆**

### Transformation Data Start-to-End

❑ Use machine-readable metadata to generate study data artifacts
❑ Demonstrate the ability execute data transformations given the study

**Replication and Automation**
[Metadata and Data, Mapping and Transformation, Code Generation]

**Metadata-Driven Process & Intelligence**
[Global, Study Level, Raw Data (EDC,PK), Data Meaningful, Machine Readable]

**CDISC Metadata and Rules**
[Standards, Versions, Data Exchange]

### Replication and automation are the focuses

- Use or create utilities to replicate the process: Project Set Up, Mapping Specification, Mapping Creation
- Use analytics tool to identify the areas for replication and automation: Data Profiling & Data Rules for Source Data Review / Edit Checks

### Metadata-driven process is the key for automation

- Metadata makes data meaningful
- Metadata is machine readable
- Metadata is the base for automation

### Standard adoption is the key for code reusability

- Train people to understand the standards
- Define standard templates
- Build public libraries for code snippets and public transformation: Custom functions, procedures and packages; public data rules; and public Experts
- Group code snippets and functional transformation into modular mapping and transformation: pluggable maps
- Define workflow to govern the process: Workflow Manager and Process Flows

*Evolving CDISC to the Next Decades: The CDISC Proof of Concept, Peter Van Reusel, Sam Hume; Efficiency Comes From Reusability and Repeatability, Hanming Tu, Dave Evans*