Ready to Optimize KPIs with Xbiom?

Use Xbiom's Metadata Technology to Speed up SDTM Cycles!

CONVERT EDC RAW CLINICAL DATA WITH LOW CODE INTO CRITICAL STUDY DECISIONS

Time to Create SDTMs	Fourteen Days Instead of Months
SDTM Compliance	Integrated Standard Compliance Checks
Number of Programmers to SDTMs	Half the Normal Team Size
Study SDTM Expenses	Thirty percent under Budget
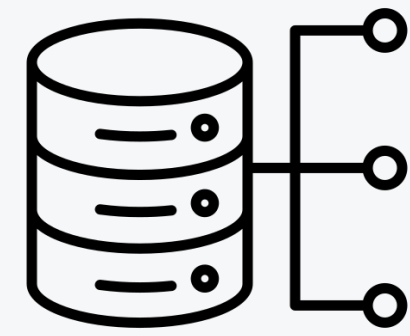
Data Ingestion

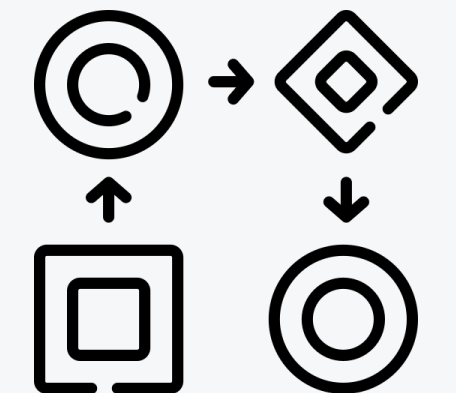System to load various sources and structures of raw data
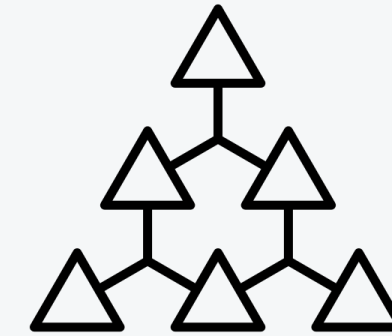
Data Aggregation

Categorize, organize and index raw data

Data Intelligence

Standardize raw data structure and values

Data Action Workflow

Validate SAP conclusions to make decisions

POWERFUL VISUAL AND USER FRIENDLY INTERFACE FOR ALL TYPES OF USERS

Statistical Programming Director

Manage Projects with Automation and Standards

- ✓ One SCE integrate tool for all Submission Deliverables
- ✓ Reduce Time and Budget per Clinical Study

Statistical Programmer

Manage Submission Process with Low-Code Programming
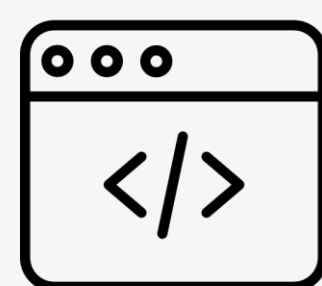
- ✓ Reduce writing SAS programs and macros
- ✓ Faster SDTMs, Define.xml and SDRG
- ✓ Auto Generate SDTM Mapping Specifications

Translational Scientist

Monitor Safety Data Issues with Early Alerts

- ✓ Faster Ingestion, Curation and Harmonization
- ✓ User Interface to create SAP Cohorts

Study Statistician

Explore with Pre-defined Templates

- ✓ Reduce Time to Tables, Lists and Figures
- ✓ Drill down from summary to patient level detail

XBIOM: LOW CODE USER INTERFACE AND VISUALIZATION TOOL

- Insights: Clinical & Biomarker
- Insights: Nonclinical
- Smart Transformation
- **Xbiom built on Metadata and Ontology Platform**
- eData Validator (SDTM, ADaM, Define.xml, SEND)
- Regulatory: Clinical
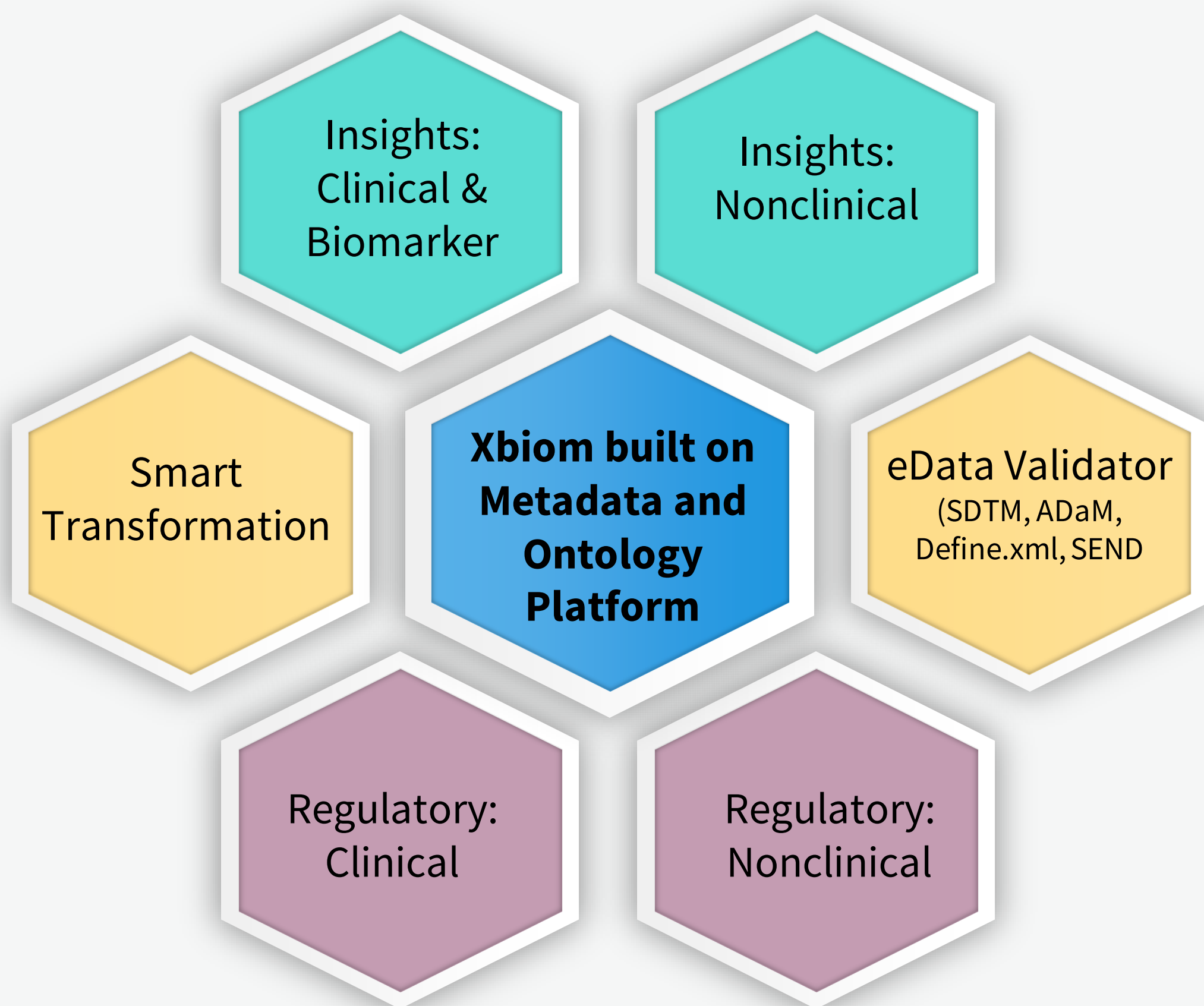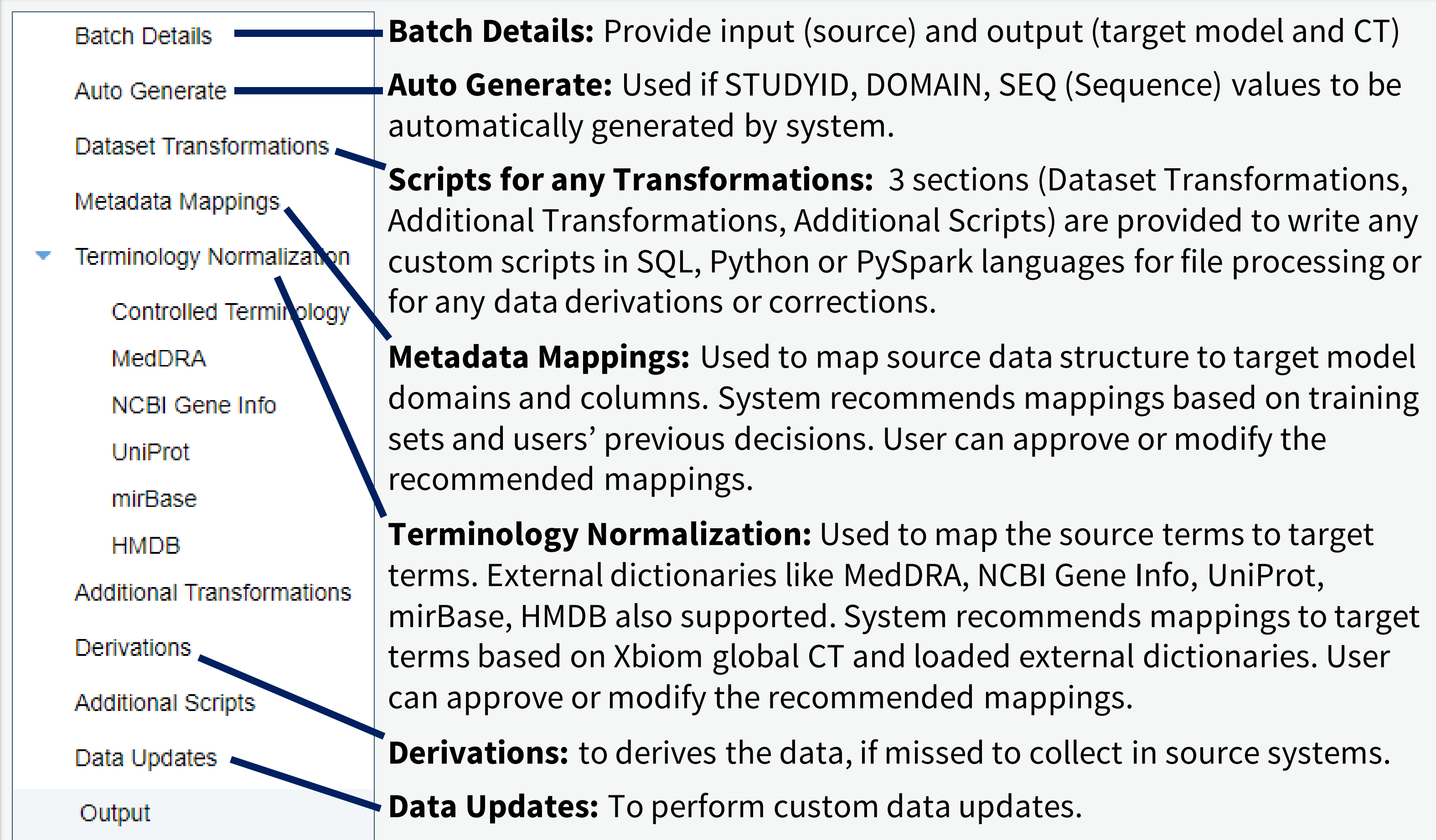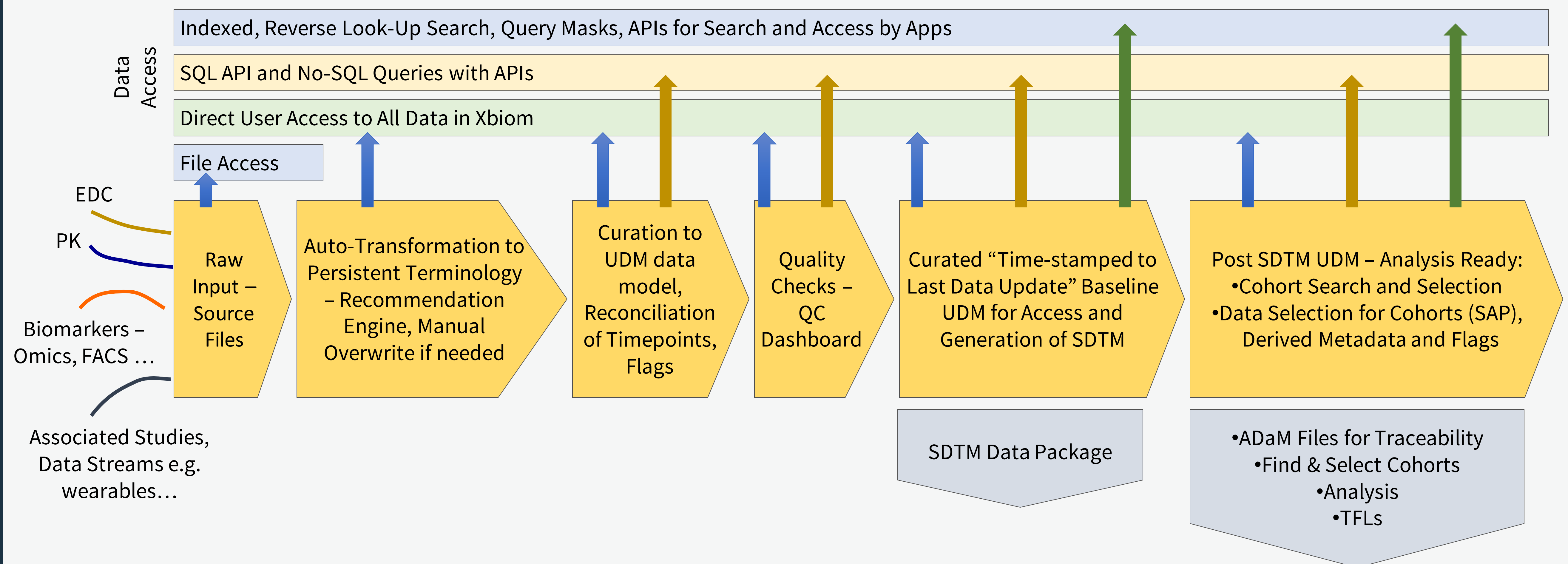- Regulatory: Nonclinical

SMART TRANSFORMATION SECTION - APPLIES THE 80/20 PRINCIPLE

- Batch Details
- Auto Generate
- Dataset Transformations
- Metadata Mappings
- ▼ Terminology Normalization
  - Controlled Terminology
  - MedDRA
  - NCBI Gene Info
  - UniProt
  - mirBase
  - HMDB
- Additional Transformations
- Derivations
- Additional Scripts
- Data Updates
- Output

Batch Details: Provide input (source) and output (target model and CT)

Auto Generate: Used if STUDYID, DOMAIN, SEQ (Sequence) values to be automatically generated by system.

Scripts for any Transformations: 3 sections (Dataset Transformations, Additional Transformations, Additional Scripts) are provided to write any custom scripts in SQL, Python or PySpark languages for file processing or for any data derivations or corrections.

Metadata Mappings: Used to map source data structure to target model domains and columns. System recommends mappings based on training sets and users' previous decisions. User can approve or modify the recommended mappings.

Terminology Normalization: Used to map the source terms to target terms. External dictionaries like MedDRA, NCBI Gene Info, UniProt, mirBase, HMDB also supported. System recommends mappings to target terms based on Xbiom global CT and loaded external dictionaries. User can approve or modify the recommended mappings.

Derivations: to derives the data, if missed to collect in source systems.

Data Updates: To perform custom data updates.

DATA CURATION AND STANDARDIZATION STAGES TO SDTM AND BEYOND

Data Access

- Indexed, Reverse Look-Up Search, Query Masks, APIs for Search and Access by Apps
- SQL API and No-SQL Queries with APIs
- Direct User Access to All Data in Xbiom
- File Access

Sources:
- EDC
- PK
- Biomarkers – Omics, FACS …
- Associated Studies, Data Streams e.g. wearables…

Stages:
- Raw Input – Source Files
- Auto-Transformation to Persistent Terminology – Recommendation Engine, Manual Overwrite if needed
- Curation to UDM data model, Reconciliation of Timepoints, Flags
- Quality Checks – QC Dashboard
- Curated "Time-stamped to Last Data Update" Baseline UDM for Access and Generation of SDTM
  - SDTM Data Package
- Post SDTM UDM – Analysis Ready:
  - •Cohort Search and Selection
  - •Data Selection for Cohorts (SAP), Derived Metadata and Flags
  - •ADaM Files for Traceability
  - •Find & Select Cohorts
  - •Analysis
  - •TFLs

Leader in SEND Automation Tool for Top Pharma/CROs such as Roche, Sanofi, Bayer and Ipsen.