Conventional Statistic and Programming Process for Clinical Data Analysis

Transforming Files through a Series of Stages

Data Management & Curation, Metadata Generation by Programmers

Programmers, Bio-Statisticians use Statistical Analysis Plan (SAP) & SDTM to generate ADaM files

Programmers, Bio-Statisticians run Scripts to follow SAP

Raw Source

SDTM

ADaM

TFLs

EDC Extract, aCRF, ODM, Biomarker Assays, Bio-Analytics raw data files

Files for exchange

ADSL, BDS, OCCDS files

Tables, Figures, Listings – results of Analysis & Visualization – for Clinical Study Report (CSR)

Statistical Computing Environment (SCE)
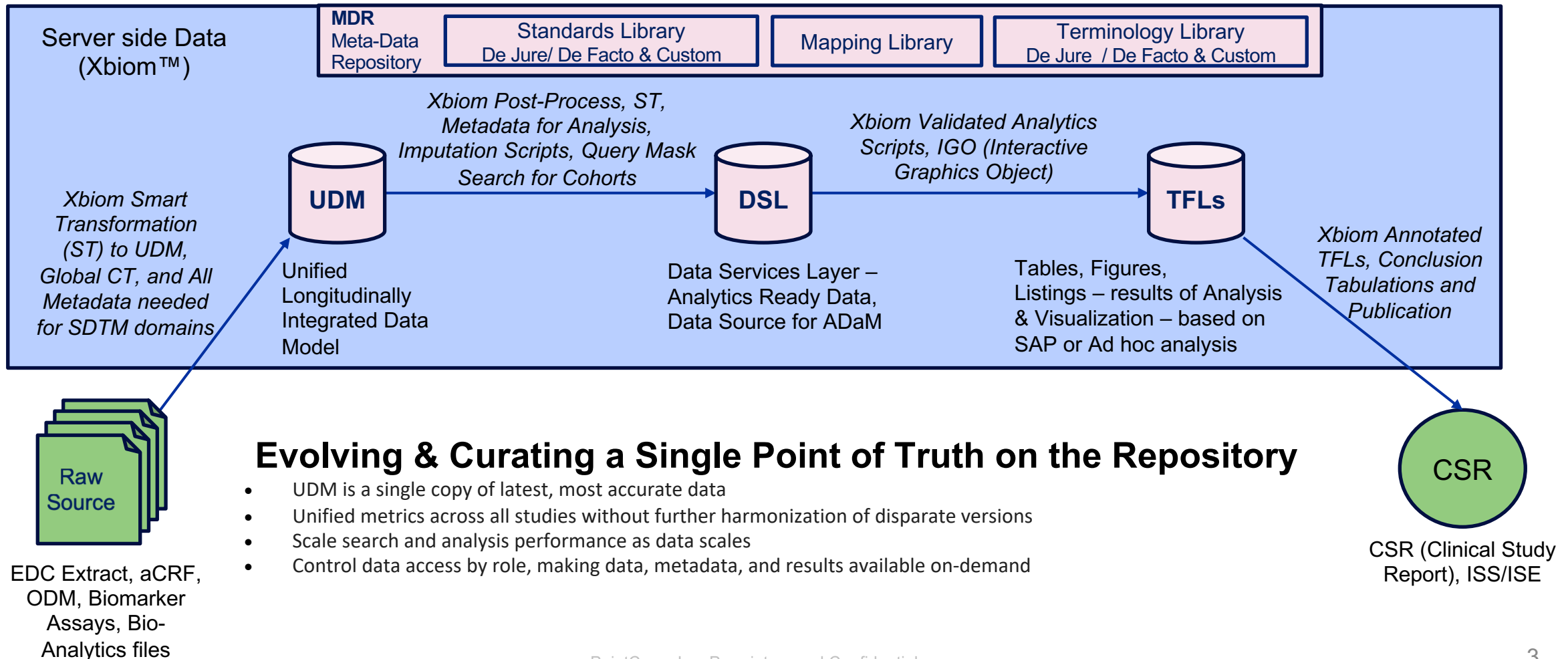
CSR

CSR (Clinical Study Report), ISS/ISE

Efforts that takes time, cost, and specialists

- Curation of Raw Data needs data managers, programmers and quality checks for every Data Lock
- Metadata for SDTM generation needs programmers and bio-statisticians for each Cycle
- Generation ADaM files for analysis readiness needs bio-statisticians & programmers to interpret SAP
- Generation of TFLs need bio-statisticians & programmers to develop and run scripts for analysis
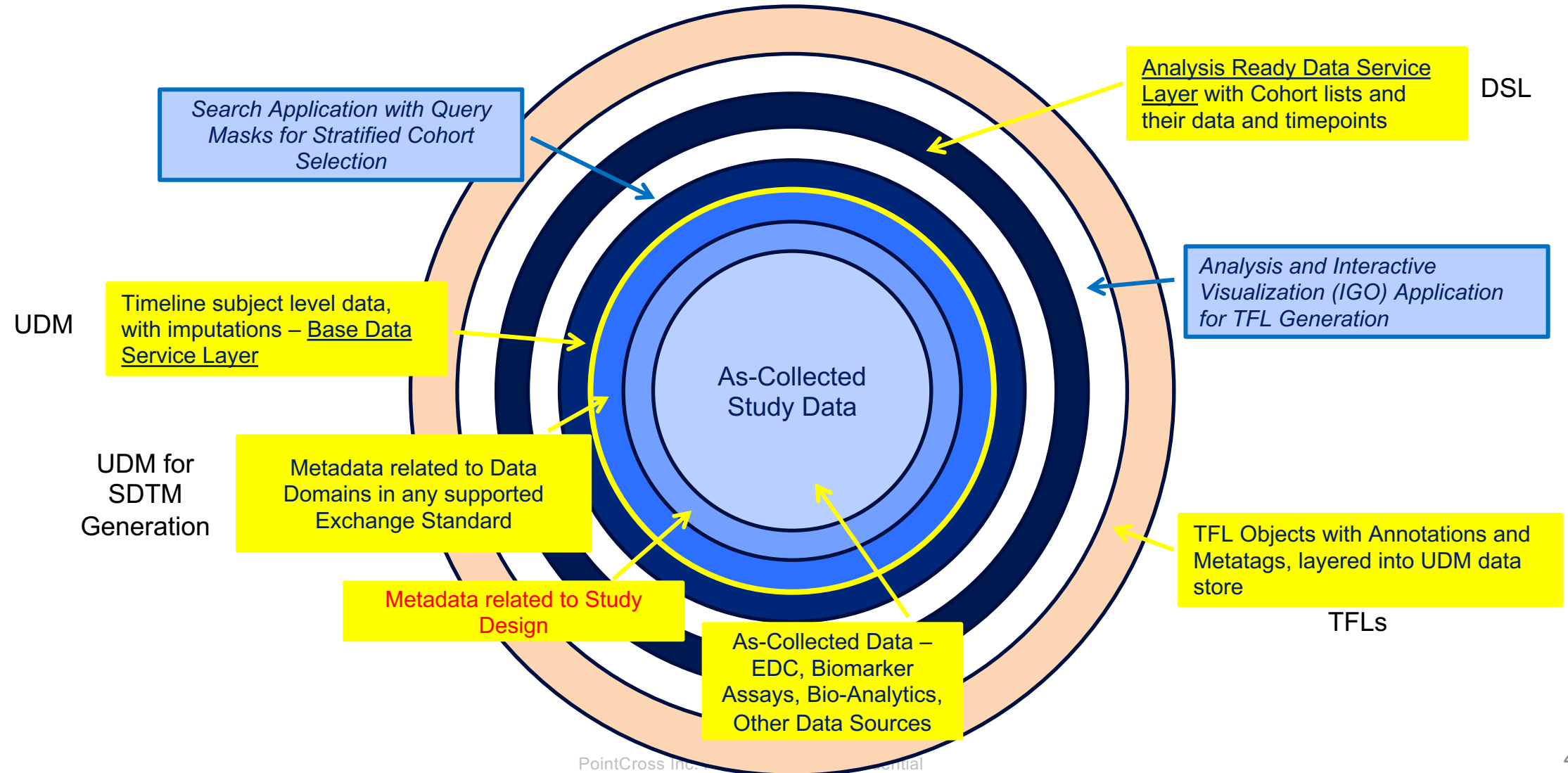
Clinical Data Phases Managed on a Server-side Platform

Transform & Build Metadata Layers held in a Server-side Repository Model

Server side Data (Xbiom™)

MDR Meta-Data Repository

Standards Library De Jure/ De Facto & Custom	Mapping Library	Terminology Library De Jure / De Facto & Custom

Xbiom Post-Process, ST, Metadata for Analysis, Imputation Scripts, Query Mask Search for Cohorts

Xbiom Validated Analytics Scripts, IGO (Interactive Graphics Object)

Xbiom Smart Transformation (ST) to UDM, Global CT, and All Metadata needed for SDTM domains

UDM → **DSL** → **TFLs**

Xbiom Annotated TFLs, Conclusion Tabulations and Publication

Unified Longitudinally Integrated Data Model

Data Services Layer – Analytics Ready Data, Data Source for ADaM

Tables, Figures, Listings – results of Analysis & Visualization – based on SAP or Ad hoc analysis

Raw Source

CSR

Evolving & Curating a Single Point of Truth on the Repository

- UDM is a single copy of latest, most accurate data
- Unified metrics across all studies without further harmonization of disparate versions
- Scale search and analysis performance as data scales
- Control data access by role, making data, metadata, and results available on-demand

EDC Extract, aCRF, ODM, Biomarker Assays, Bio-Analytics files
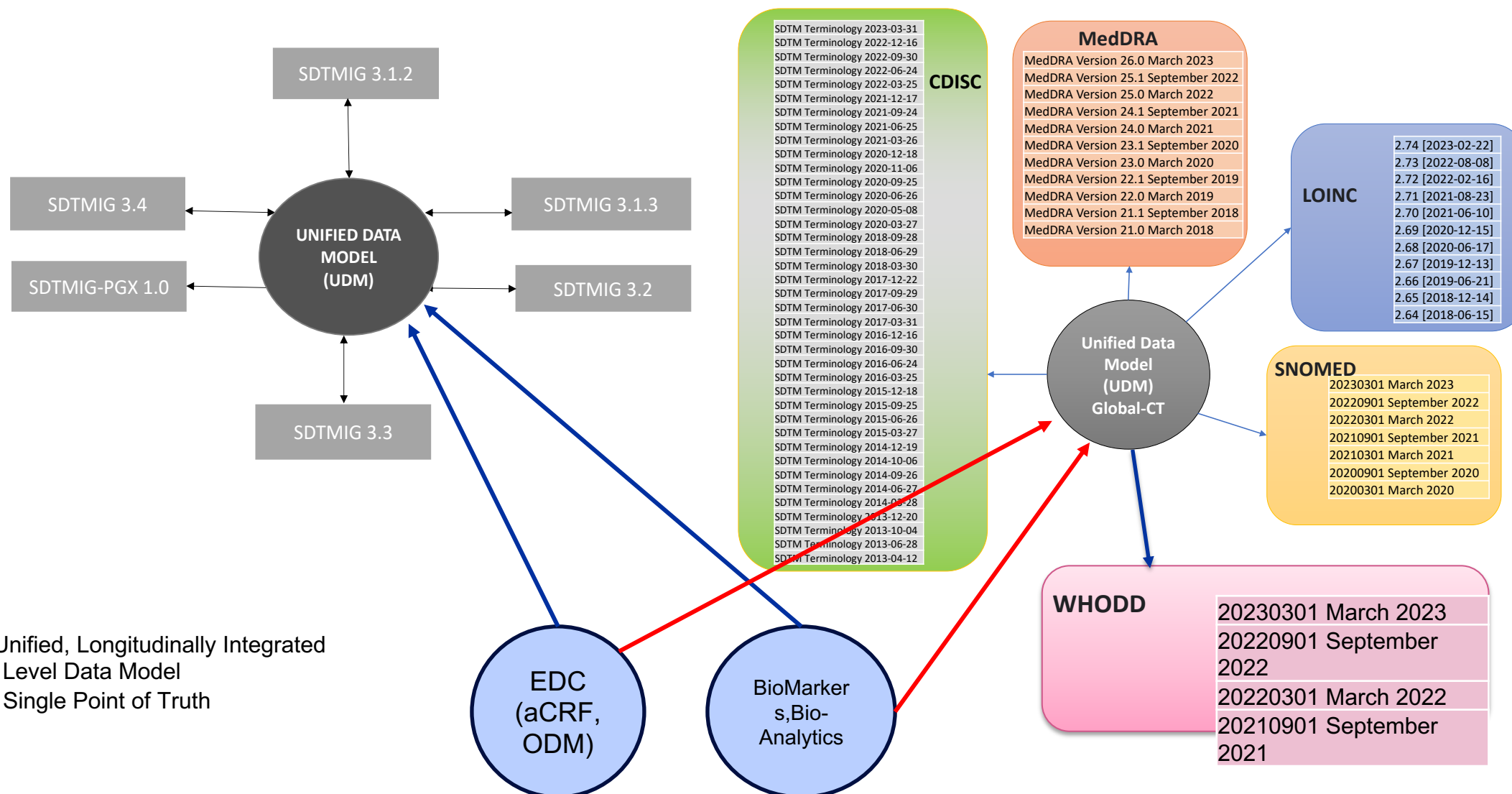
CSR (Clinical Study Report), ISS/ISE

UDM – Unified Data Model for Repository

Layers of As-Collected, Curated, Matured Data & Meta-Data Indexed and Searchable for Analysis and Visualization of TFLs

Search Application with Query Masks for Stratified Cohort Selection

Analysis Ready Data Service Layer with Cohort lists and their data and timepoints

DSL

Timeline subject level data, with imputations – Base Data Service Layer

UDM

Analysis and Interactive Visualization (IGO) Application for TFL Generation

UDM for SDTM Generation

Metadata related to Data Domains in any supported Exchange Standard

As-Collected Study Data

Metadata related to Study Design

As-Collected Data – EDC, Biomarker Assays, Bio-Analytics, Other Data Sources

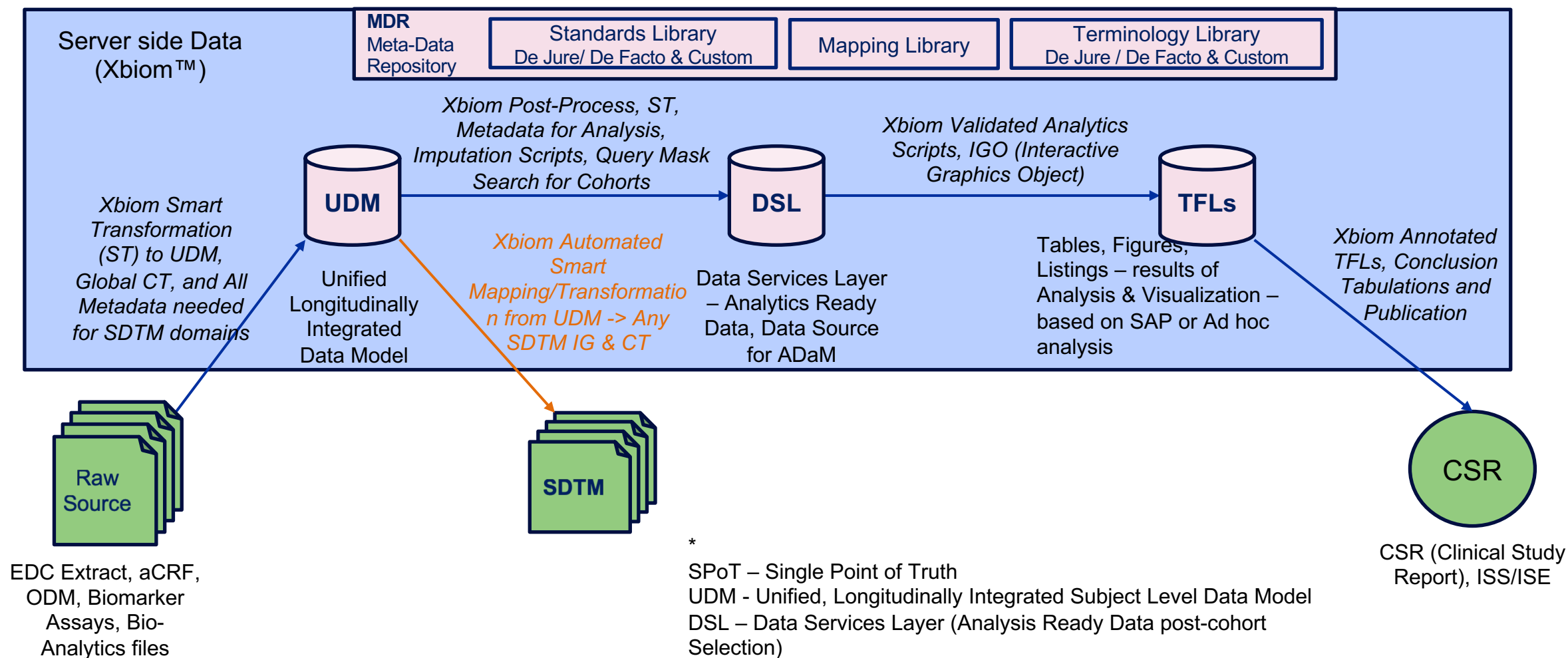TFL Objects with Annotations and Metatags, layered into UDM data store

TFLs

Simplifying, Streamlining SDTM Automation with a UDM SPoT*

*
UDM - Unified, Longitudinally Integrated
Subject Level Data Model
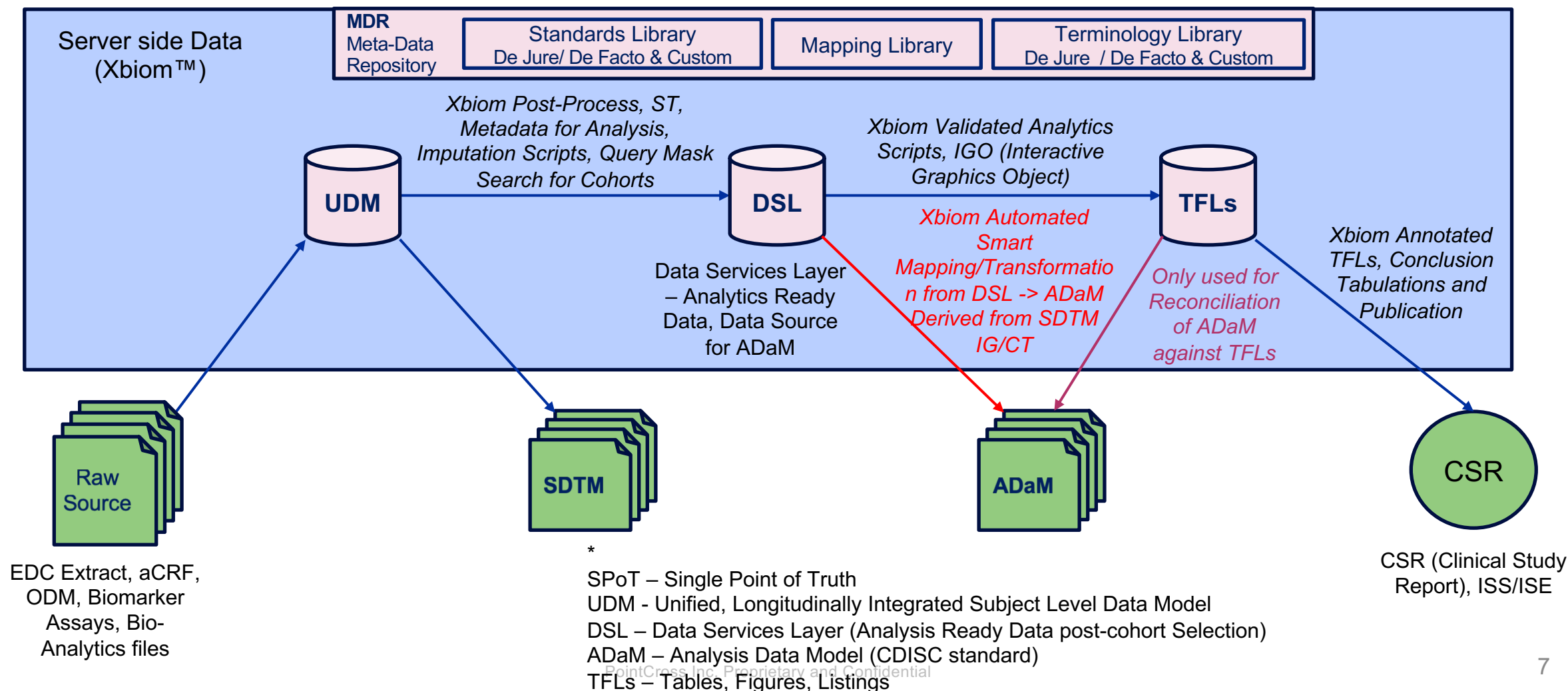SPoT – Single Point of Truth

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Automated SDTM Generation from SPoT UDM*

MDR Libraries for Standards, Terminologies and Mappings

Server side Data (Xbiom™)

MDR Meta-Data Repository

| Standards Library De Jure/ De Facto & Custom | Mapping Library | Terminology Library De Jure / De Facto & Custom |

Xbiom Post-Process, ST, Metadata for Analysis, Imputation Scripts, Query Mask Search for Cohorts

Xbiom Validated Analytics Scripts, IGO (Interactive Graphics Object)

UDM

DSL

TFLs

Xbiom Smart Transformation (ST) to UDM, Global CT, and All Metadata needed for SDTM domains

Unified Longitudinally Integrated Data Model

Xbiom Automated Smart Mapping/Transformation from UDM -> Any SDTM IG & CT

Data Services Layer – Analytics Ready Data, Data Source for ADaM

Tables, Figures, Listings – results of Analysis & Visualization – based on SAP or Ad hoc analysis

Xbiom Annotated TFLs, Conclusion Tabulations and Publication

Raw Source

SDTM

CSR

EDC Extract, aCRF, ODM, Biomarker Assays, Bio-Analytics files

*
SPoT – Single Point of Truth
UDM - Unified, Longitudinally Integrated Subject Level Data Model
DSL – Data Services Layer (Analysis Ready Data post-cohort Selection)
TFLs – Tables, Figures, Listings

CSR (Clinical Study Report), ISS/ISE

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Automated ADaM Generation from SPoT UDM*

MDR Libraries for Standards, Terminologies and Mappings

Server side Data (Xbiom™)

MDR Meta-Data Repository | Standards Library De Jure/ De Facto & Custom | Mapping Library | Terminology Library De Jure / De Facto & Custom

Xbiom Post-Process, ST, Metadata for Analysis, Imputation Scripts, Query Mask Search for Cohorts

Xbiom Validated Analytics Scripts, IGO (Interactive Graphics Object)

UDM → DSL → TFLs

Data Services Layer – Analytics Ready Data, Data Source for ADaM

Xbiom Automated Smart Mapping/Transformation from DSL -> ADaM Derived from SDTM IG/CT

Only used for Reconciliation of ADaM against TFLs

Xbiom Annotated TFLs, Conclusion Tabulations and Publication

Raw Source

SDTM

ADaM

CSR

EDC Extract, aCRF, ODM, Biomarker Assays, Bio-Analytics files

*
SPoT – Single Point of Truth
UDM - Unified, Longitudinally Integrated Subject Level Data Model
DSL – Data Services Layer (Analysis Ready Data post-cohort Selection)
ADaM – Analysis Data Model (CDISC standard)
TFLs – Tables, Figures, Listings

CSR (Clinical Study Report), ISS/ISE

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phuse

The Global Healthcare
Data Science Community