



DS07: The Revolution of Digitised Study Designs:

Standards, Use cases and Tools

US Connect 22-26 March 2026



Content

- Introduction
- Use Cases
- Tooling



ClinLine

- Started in 2018
- Digital Data Flow
- Data Lineage
- Real-world Data Utilization
- Consultancy, Validation and Mapping

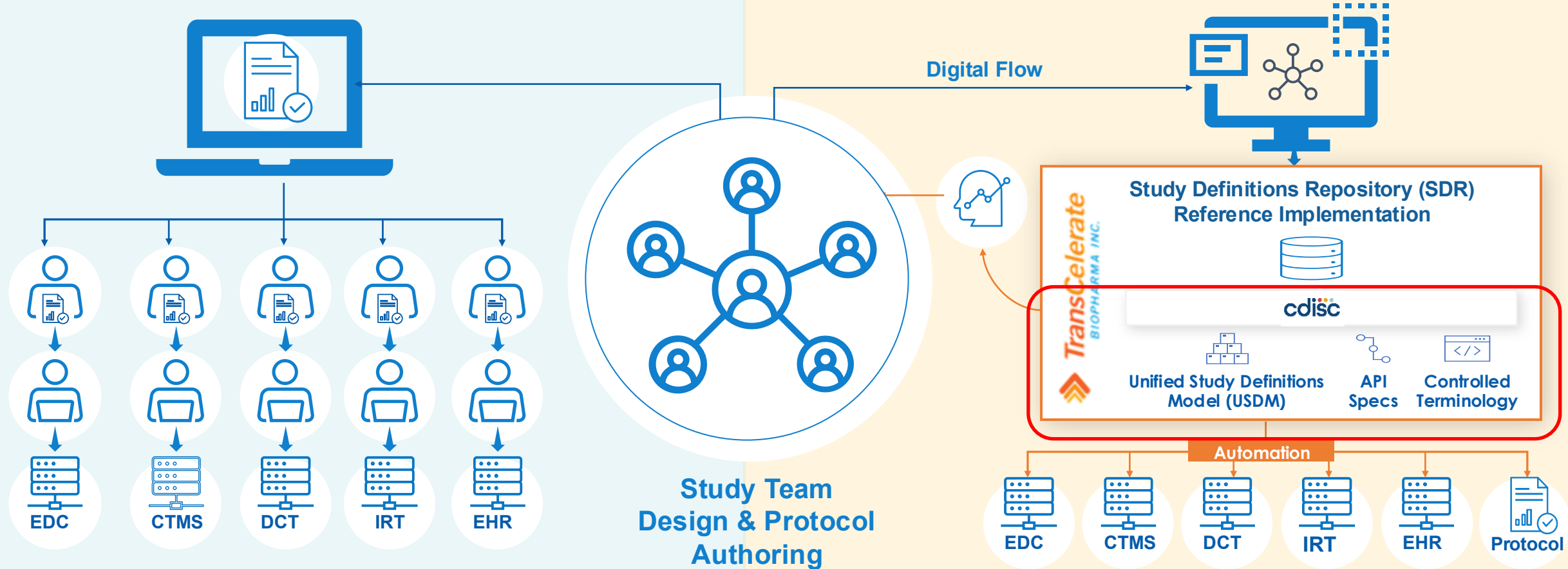
Our **aim** is to efficiently utilize knowledge and innovate technology for effective and efficient use of clinical data in order to reduce both time to market as well as costs for drug and device development.

TransCelerate Digital Data Flow (DDF) Ambition

Write Once, Read Many

TODAY: Document-based paradigm for protocol creation, interpretation, and transcription into consuming systems

TOMORROW: Digital paradigm for protocol creation, with fully automated data flow and interoperability between systems



M11 harmonized protocol



INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL
REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

**CLINICAL ELECTRONIC STRUCTURED HARMONISED
PROTOCOL
(CESHARP)**

M11

Draft version
Endorsed on 27 September 2022
Currently under public consultation

At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Assembly to the regulatory authorities of the ICH regions for internal and external consultation, according to national or regional procedures.



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M11 TEMPLATE

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M11 TECHNICAL SPECIFICATION

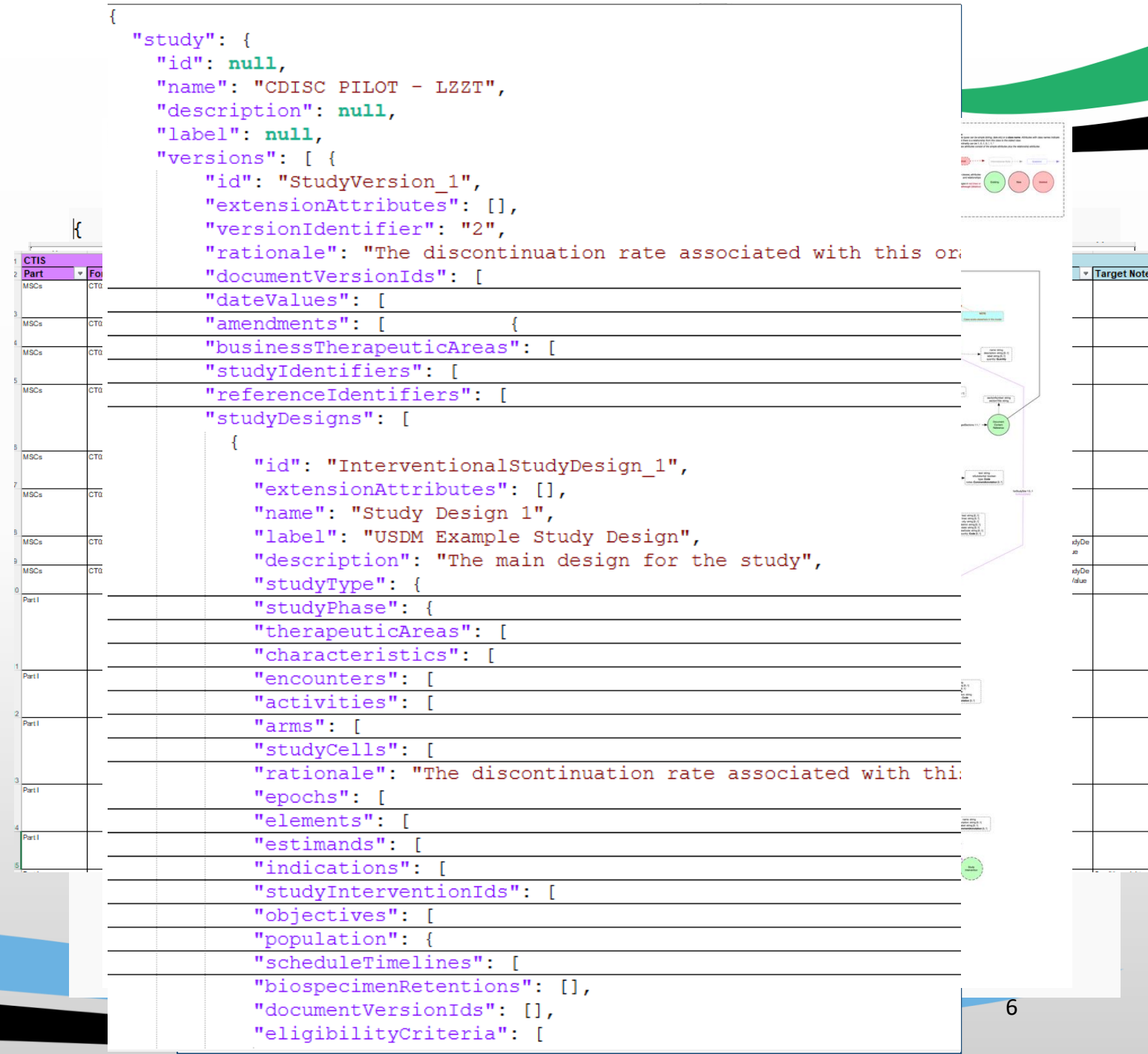
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USDM v4.0

- UML data model
- Controlled Terminology
- API definition
- Implementation Guide
- Conformance Rules
- Mapping information
- Informative Diagram
- Examples

<https://github.com/cdisc-org/DDF-RA>



The screenshot displays the CDISC USDM v4.0 API definition, which is a JSON schema. It defines the structure of a study and its associated study design. The schema is organized into two main sections: a 'study' object and a 'studyDesign' object. The 'study' object includes fields for 'id', 'name', 'description', 'label', 'versions', 'dateValues', 'amendments', 'businessTherapeuticAreas', 'studyIdentifiers', 'referenceIdentifiers', and 'studyDesigns'. The 'studyDesign' object includes fields for 'id', 'extensionAttributes', 'name', 'label', 'description', 'studyType', 'studyPhase', 'therapeuticAreas', 'characteristics', 'encounters', 'activities', 'arms', 'studyCells', 'rationale', 'epochs', 'elements', 'estimands', 'indications', 'studyInterventionIds', 'objectives', 'population', 'scheduleTimelines', 'biospecimenRetentions', 'documentVersionIds', and 'eligibilityCriteria'. The schema is presented in a table-like format with a left-hand column for the field name and a right-hand column for the field type and description. The 'study' object is defined as a 'Study' and the 'studyDesign' object is defined as a 'StudyDesign'. The schema is part of the CDISC Data Definition Framework (DDF) for Research Arm (RA).

```
{
  "study": {
    "id": null,
    "name": "CDISC PILOT - LZZT",
    "description": null,
    "label": null,
    "versions": [ {
      "id": "StudyVersion_1",
      "extensionAttributes": [],
      "versionIdentifier": "2",
      "rationale": "The discontinuation rate associated with this or",
      "documentVersionIds": [
        "dateValues": [
        "amendments": [
        "businessTherapeuticAreas": [
        "studyIdentifiers": [
        "referenceIdentifiers": [
        "studyDesigns": [
          {
            "id": "InterventionalStudyDesign_1",
            "extensionAttributes": [],
            "name": "Study Design 1",
            "label": "USDM Example Study Design",
            "description": "The main design for the study",
            "studyType": {
              "studyPhase": {
                "therapeuticAreas": [
                "characteristics": [
                "encounters": [
                "activities": [
                "arms": [
                "studyCells": [
                "rationale": "The discontinuation rate associated with thi",
                "epochs": [
                "elements": [
                "estimands": [
                "indications": [
                "studyInterventionIds": [
                "objectives": [
                "population": {
                "scheduleTimelines": [
                "biospecimenRetentions": [],
                "documentVersionIds": [],
                "eligibilityCriteria": [
```

Enabling the digital data flow

Study Design

- Repository and reuse
- Study Design Tooling
- M11 protocol design
- Feasibility assessments
- Cost assessments

Study Set-up

- Data Management Plan
- Define.xml
- eDC set-up
- Data transfer specifications
- Analysis plan
- Trial Master File
- Registries

Clinical Phase

- Drug Supply
- Patient Selection
- Monitoring
- Data Validation
- Electronic Data transfer
- Instructions
- Patient Journey

Reporting Phase

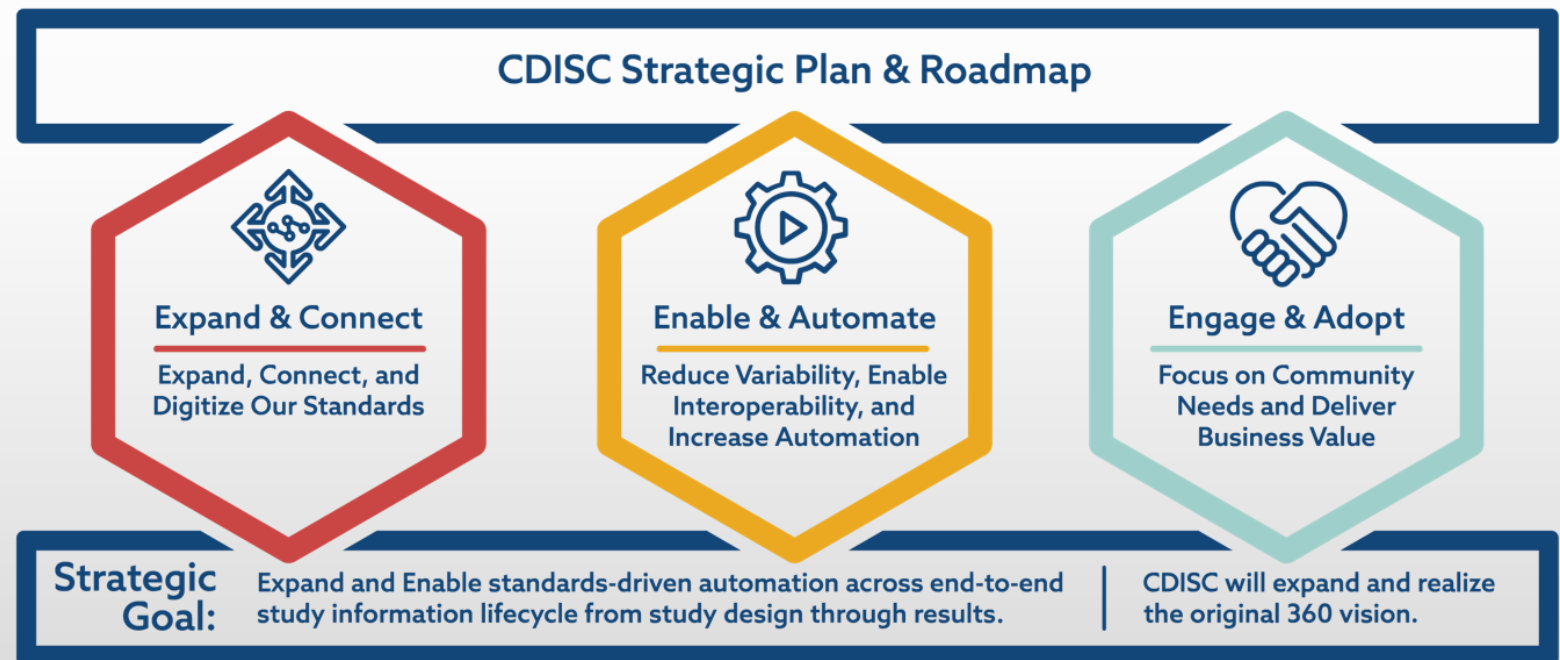
- SDTM data set creation
- ADAM and analysis
- Clinical Report

Submission

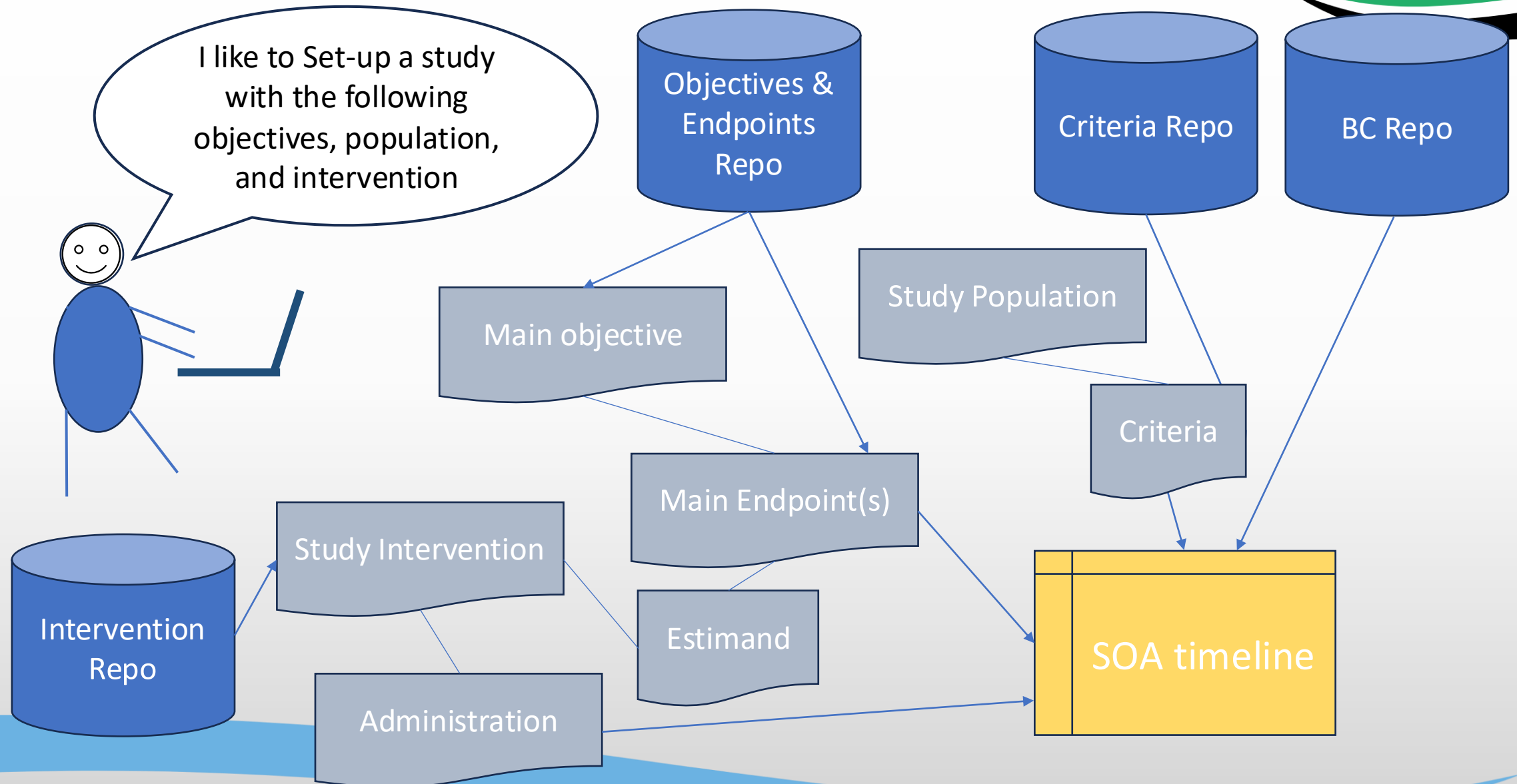
- Submission
- Regulatory Review

Enabling the digital data flow

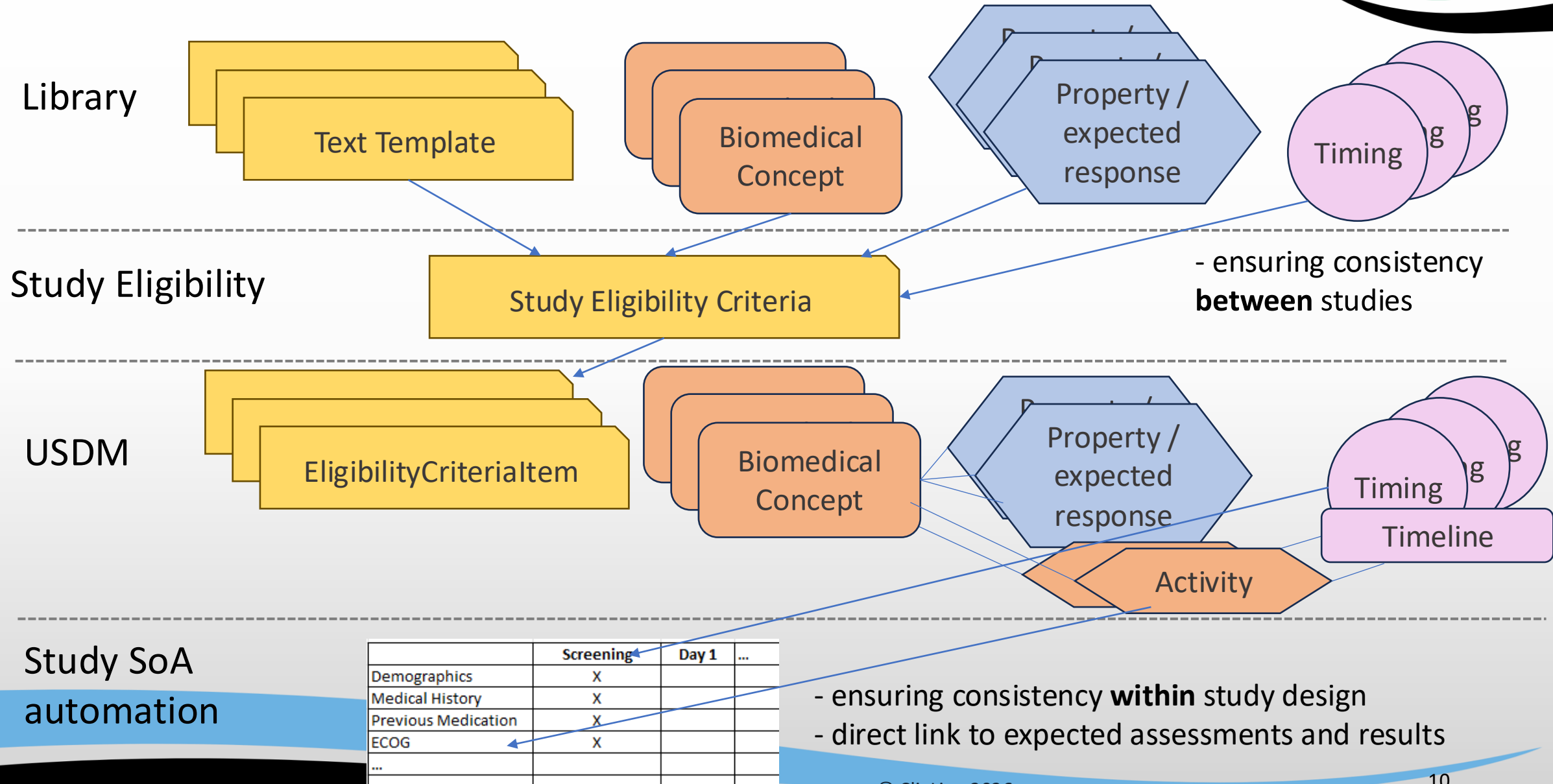
- Upstream standardization
- Downstream automation
- Connect the standards
 - CDISC 360i



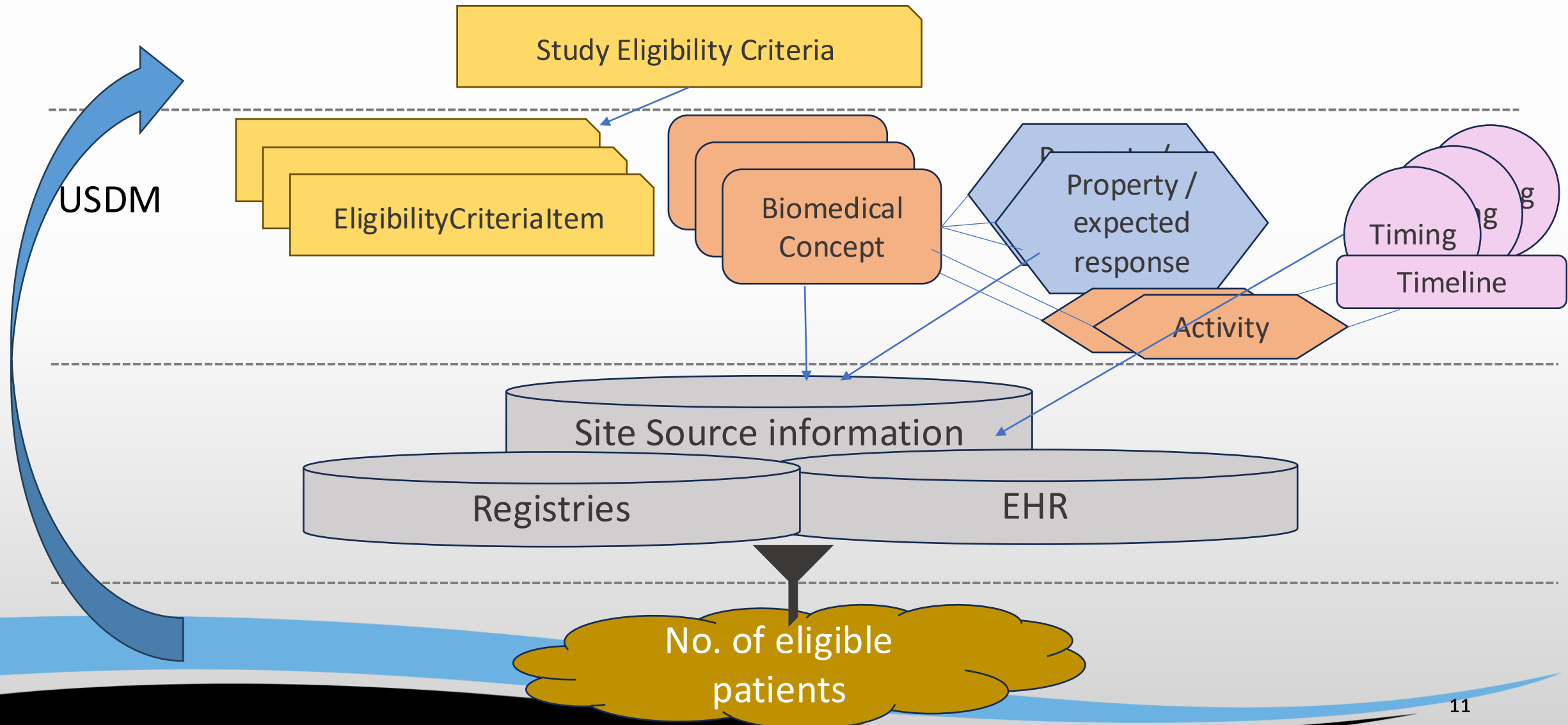
Use Case: Automated Design



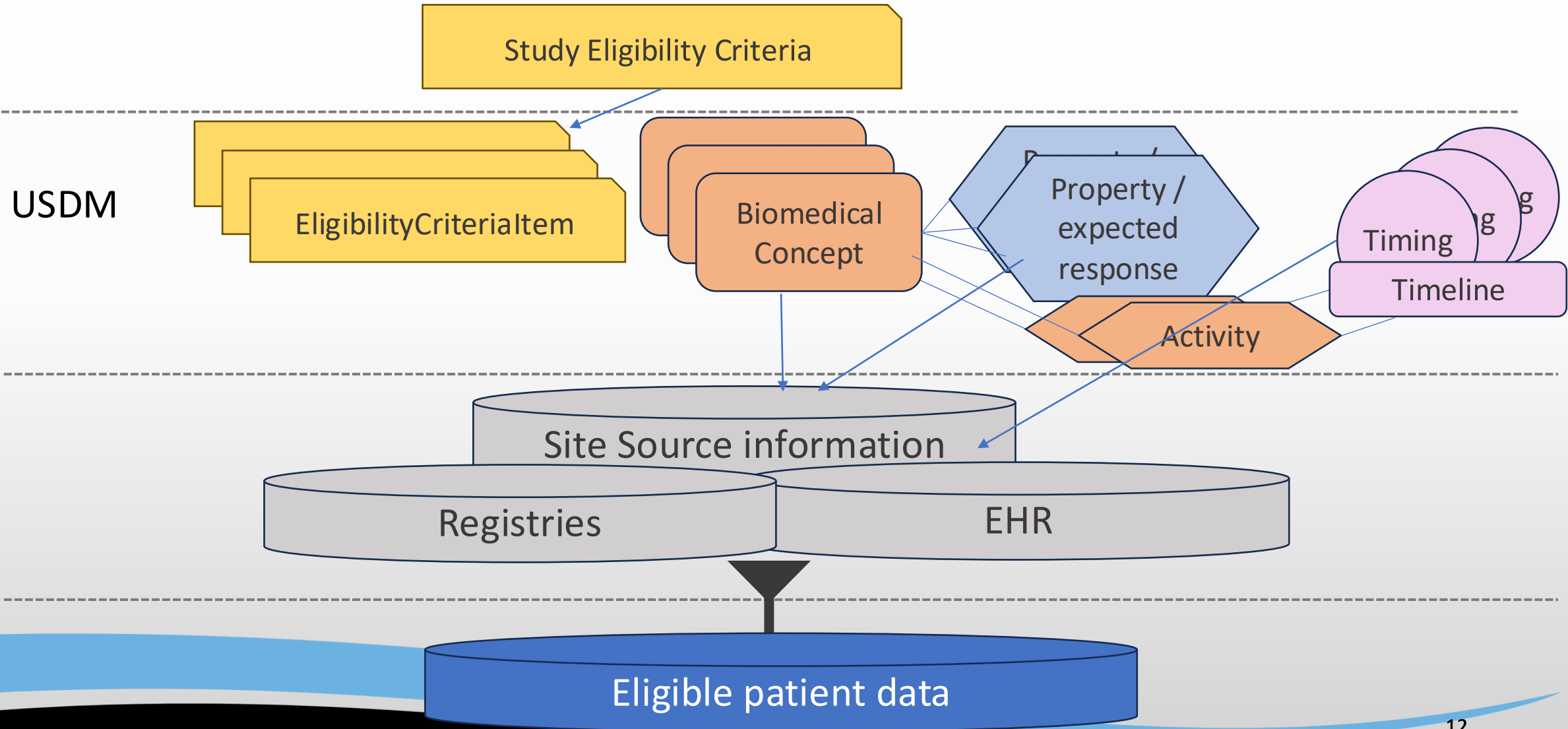
Use Case: Automated Design - eligibility



Use Case: Feasibility Assessments



Use Case: Patient Selection



Use Case: Cost Assessment

Number of planned subjects:

<code>study.versions.studyDesigns.population.plannedEnrollmentNumber.value</code>
300

Cost for activity:

<code>study.versions.studyDesigns.activities.definedProcedures.extensionAttributes[url="http://MyCompany/usdm/extensions/ExtCost1/CostAttribute"].valueQuantity.value</code>	JSONata
350	2.1.0 ▼

Number of occurrences of activity:

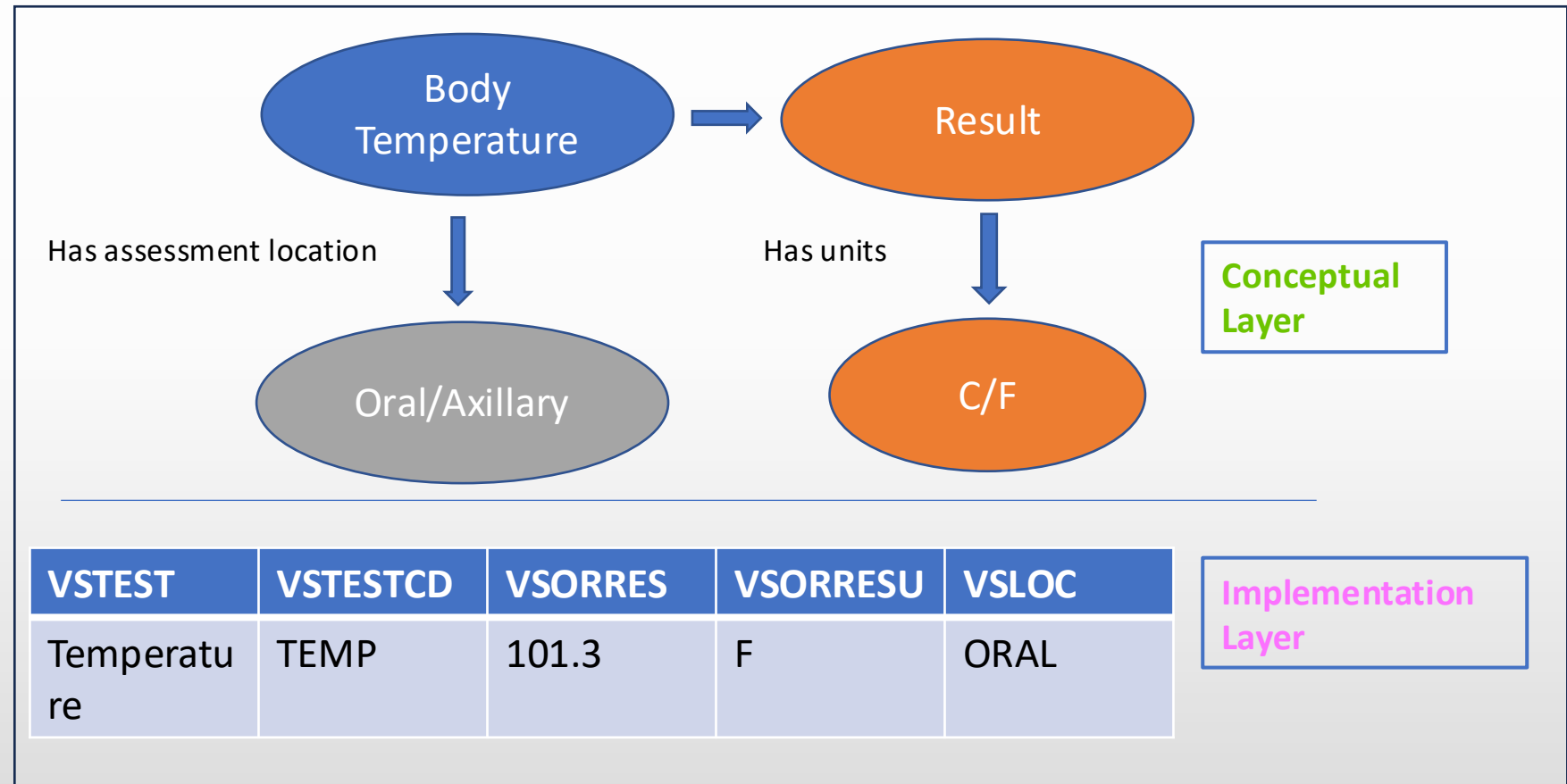
<code>\$count(\$filter(study.versions.studyDesigns.scheduleTimelines.instances.activityIds, function(\$v, \$i, \$a) {\$v="Activity_2"}))</code>
1

Total cost for activity:

<code>\$count(\$filter(study.versions.studyDesigns.scheduleTimelines.instances.activityIds, function(\$v, \$i, \$a) {\$v="Activity_2"}))</code> <code>* study.versions.studyDesigns.activities[id="Activity_2"].definedProcedures.extensionAttributes[url="http://MyCompany/usdm/extensions/ExtCost1/CostAttribute"].valueQuantity.value</code> <code>* study.versions.studyDesigns.population.plannedEnrollmentNumber.value</code>	JSONata
105000	2.1.0 ▼

Use case: EDC set-up

- Biomedical Concept Specializations
- Granular timing details
- Encounter/Visit details
- Informing EDC Form definitions



See CDISC Biomedical Concepts Training

Use Case SDTM domain creation

■ Trial Summary Domains

- Direct from USDM exchange file
- JSONata queries

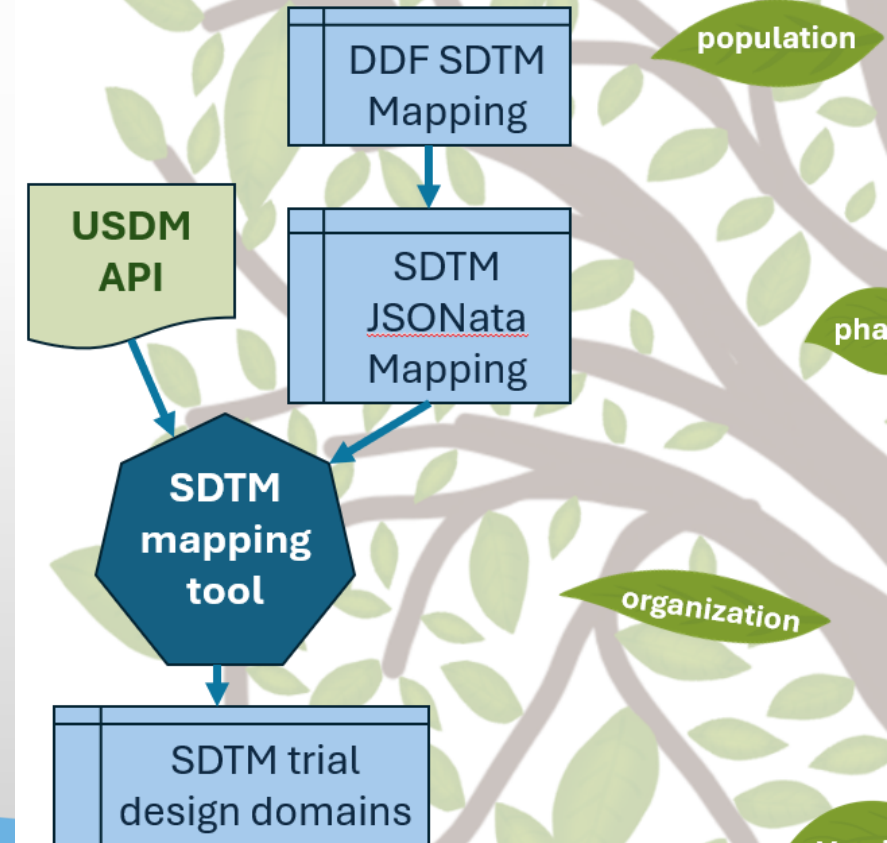
■ Patient data domains

- Based on Biomedical Concept SDTM Specializations



SDTM Mapping Tool

The python Open-Source tool is designed to pick up JSONata queries and subsequently to create the corresponding SDTM trial design domains. The tool is available via our Github: https://github.com/ClinLine/USDM_SDTM_mapper



Tooling

- Vendors and Pharma companies are in the stage of adopting
- Open-Source tools are being developed to showcase the USDM implementation and the digital data flow (CDISC 360i)
- See CDISC COSA website for currently available USDM tools.

View 34		
All		
ADaM 12		
Define-12 XML		
SDTM 10		
ODM 7		
USDM 6		
ARS 5		
CDASH 5		
Dataset-4 XML		
ARM 4		

	Digital Data Flow The DDF initiative aims to modernize clinical trials by enabling a digital workflow that allows for automated creation of study content and configuration of study systems to support clinical trial execution.
	OpenStudyBuilder The OpenStudyBuilder is a new approach to working with studies that once fully implemented will drive end-to-end consistency and more efficient processes.
	soa_workbench A Python web app for easily creating and versioning USDM-compliant Schedules of Activities with linked CDISC Biomedical Concepts.
	Study Definitions Workbench (SDW) The Study Definitions Workbench provides a set of tools to assist users and developers in adopting USDM, M11 and the associated FHIR messages. It will also bring together some of the early tooling develop to show the USDM into one place.
	USDM OSB Uploader USDM OSB Uploader is a Python-based tool that automates clinical trial setup by seamlessly uploading and managing USDM files in OSB platforms, reducing manual work and errors.
	USDM to SDTM TS domains This applicaiton processes jsonata commands with a USDM JSON file to generate the corresponding data items.

<https://www.cdisc.org/cosa>

Questions and contact

- Questions?
- Thank you to CDISC for using their content
- Like to learn more?
 - www.CDISC.org/DDF
 - Berber Snoeijer, ClinLine: b.snoeijer@clinline.eu

