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

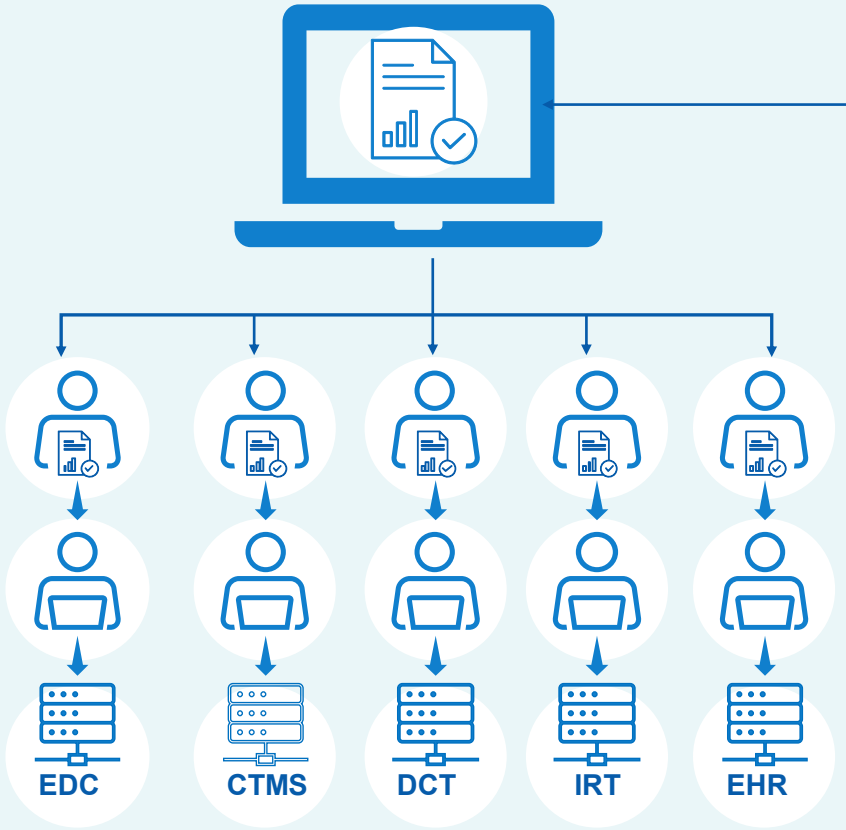
Our **aim** is to efficiently utilize knowledge and innovate technology for effective and efficient use of clinical data in order to reduce both time to market as well as costs for drug and device development.

https://www.transceleratebiopharmainc.com/assets/digital-data-flow-solutions/

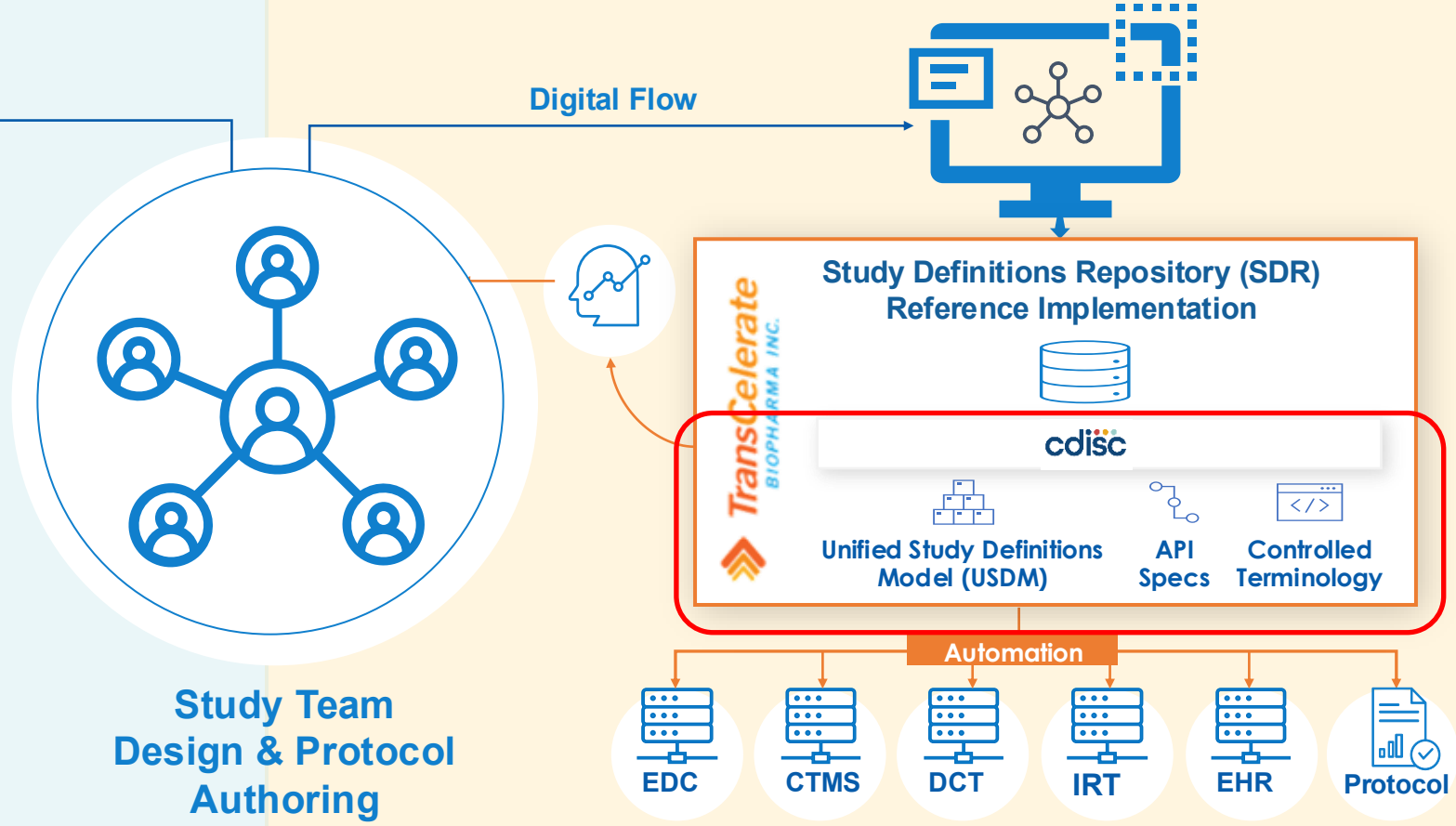
TransCelerate Digital Data Flow (DDF) Ambition

Write Once, Read Many

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

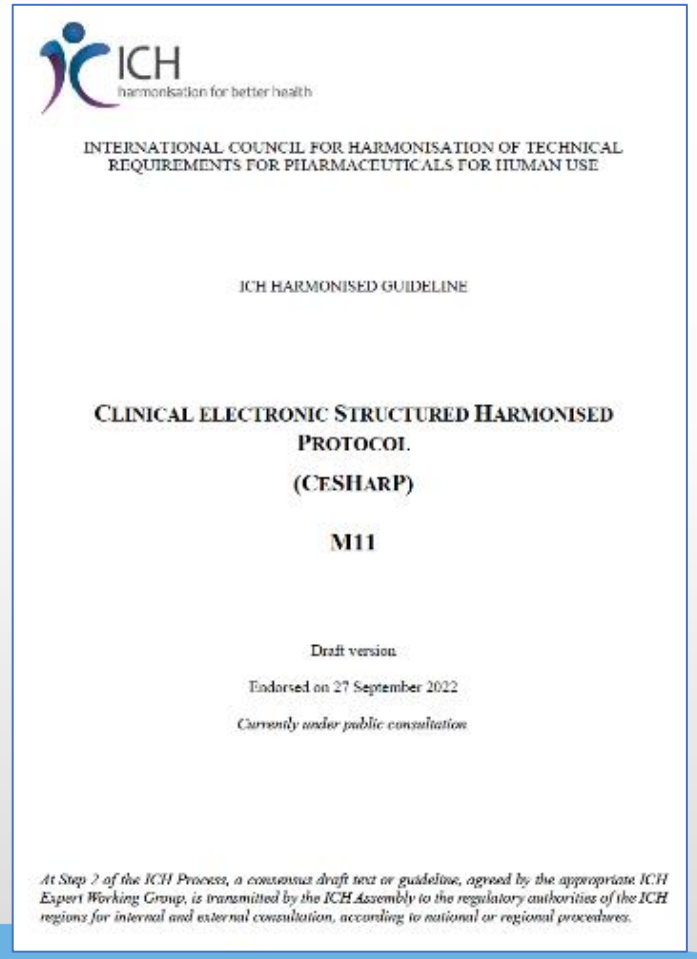


TOMORROW: Digital paradigm for protocol creation, with fully automated data flow and interoperability between systems



TransCelerate BIOPHARMA INC.

M11 harmonized protocol



ICH
harmonisation for better health

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

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

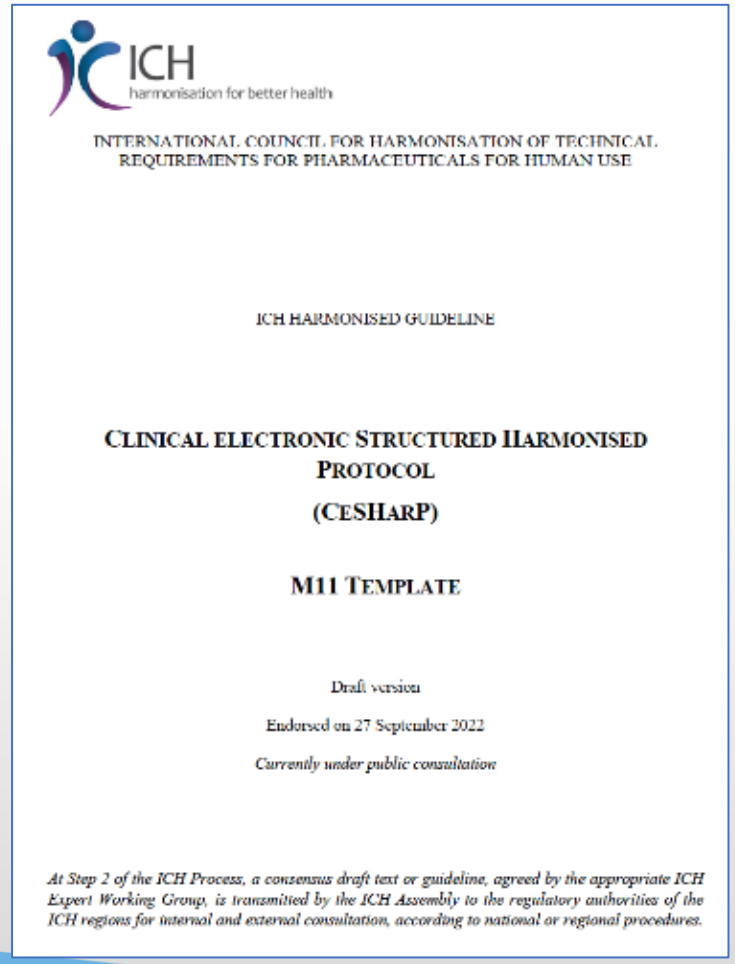
M11

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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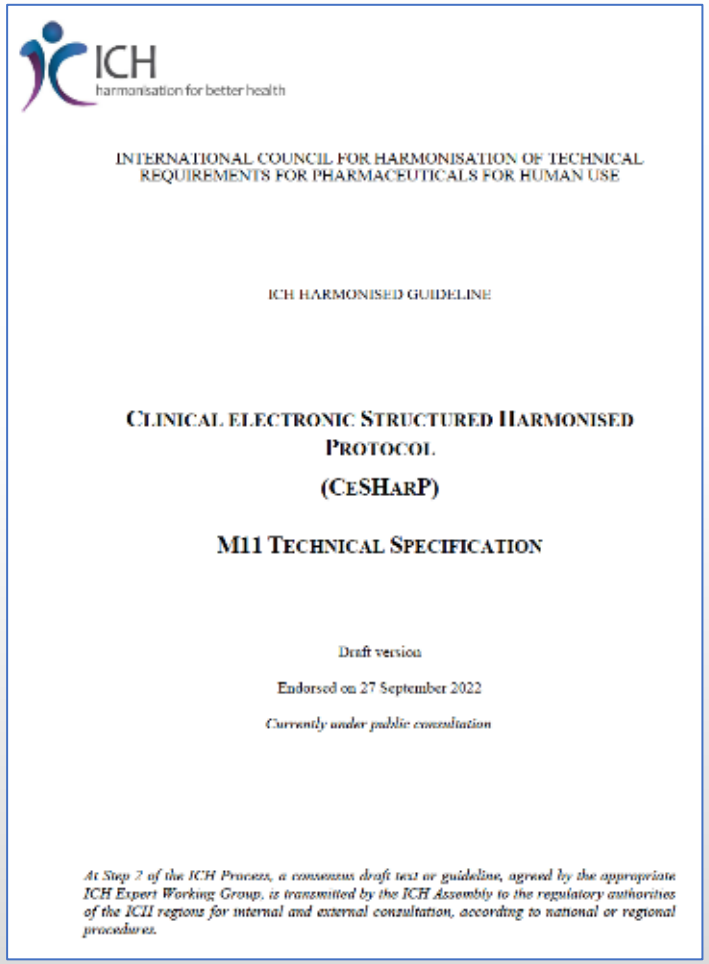

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(CESHARP)

M11 TECHNICAL SPECIFICATION

Draft version

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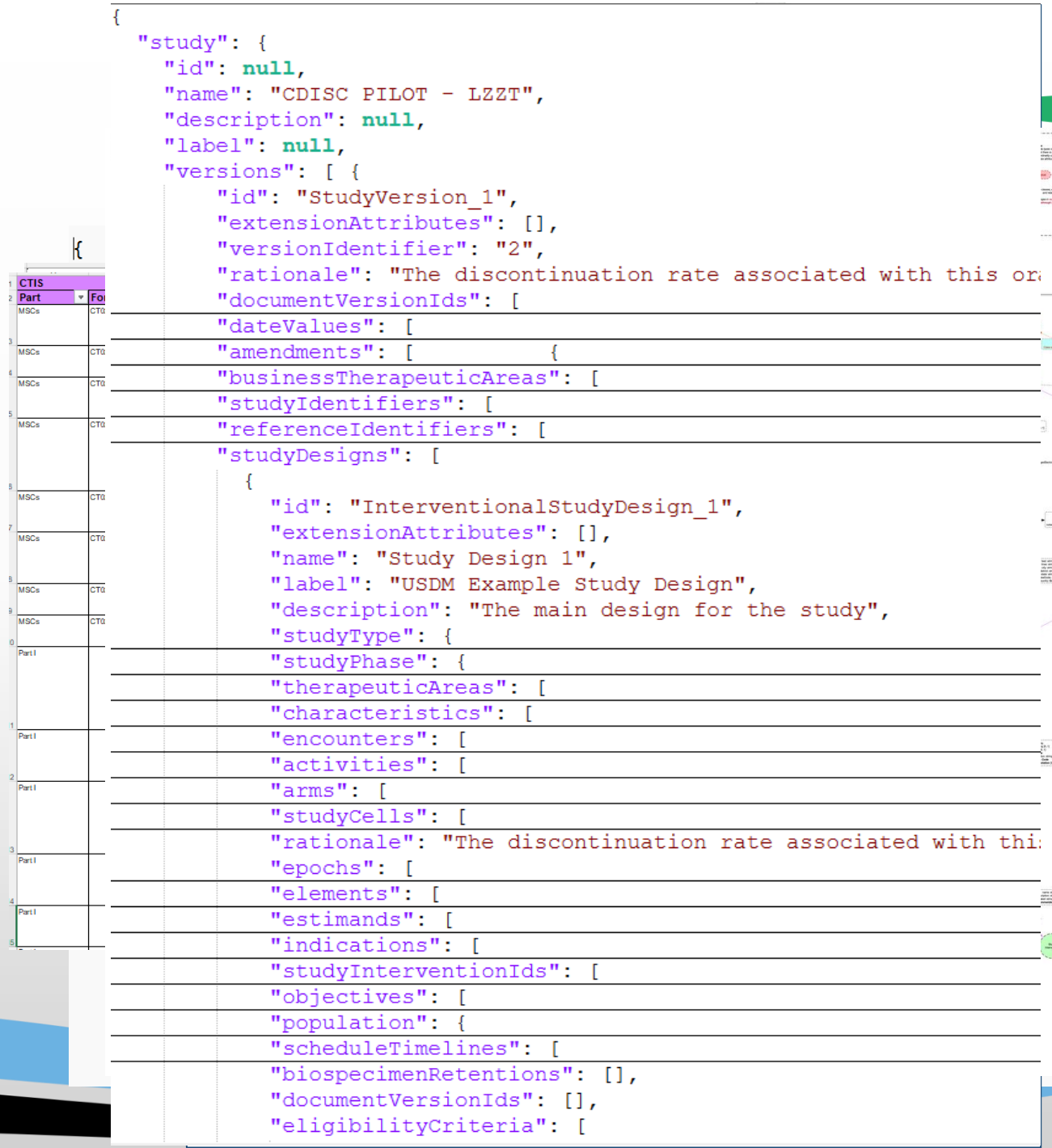
USDM v4.0

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

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



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

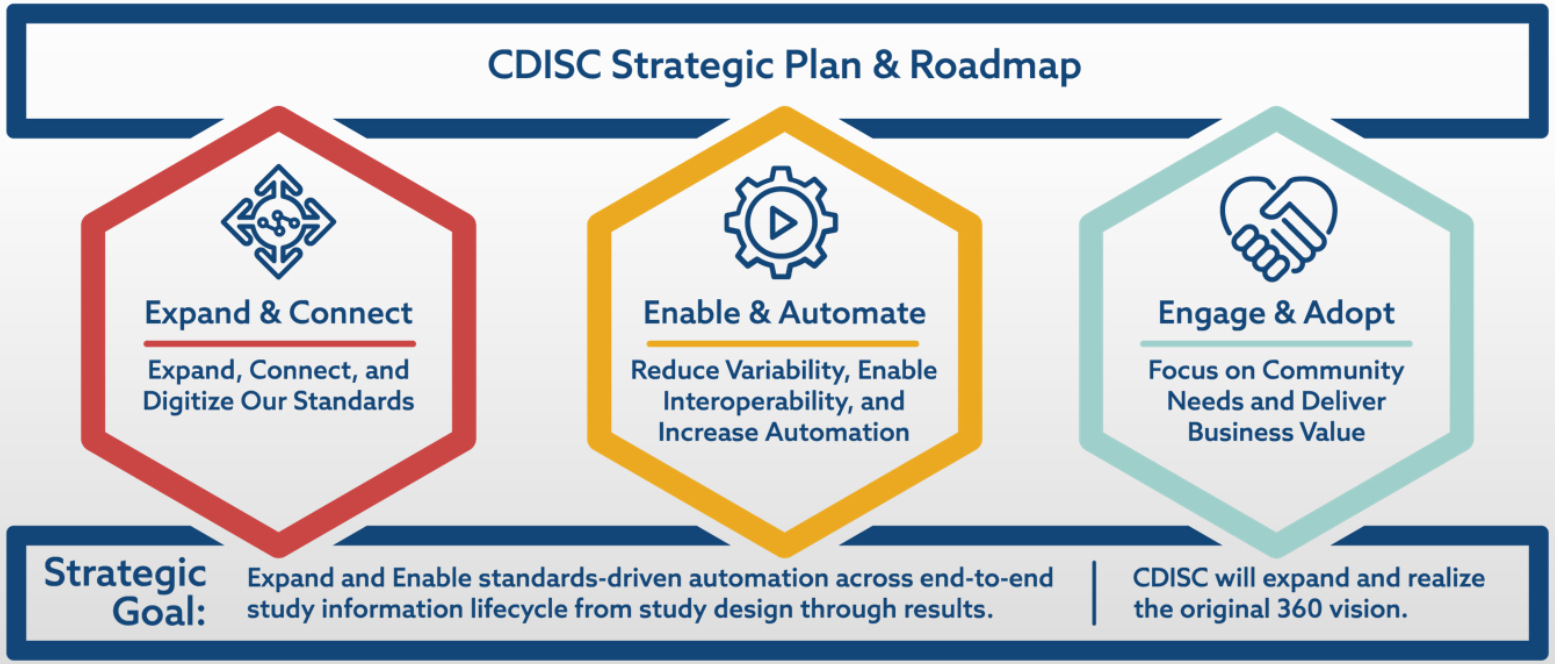
- SDTM data set creation
- ADAM and analysis
- Clinical Report

Submission

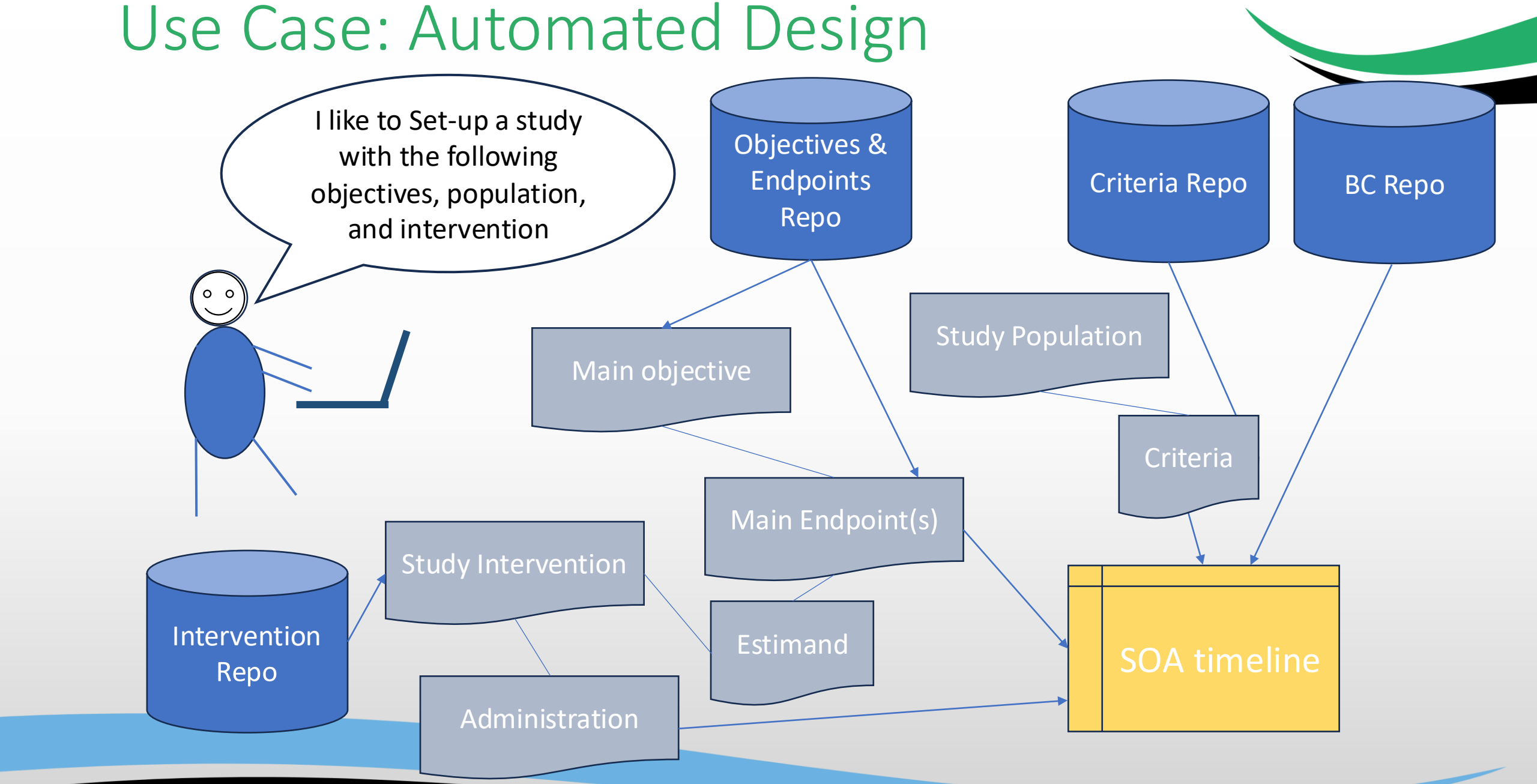
- Submission
- Regulatory Review

Enabling the digital data flow

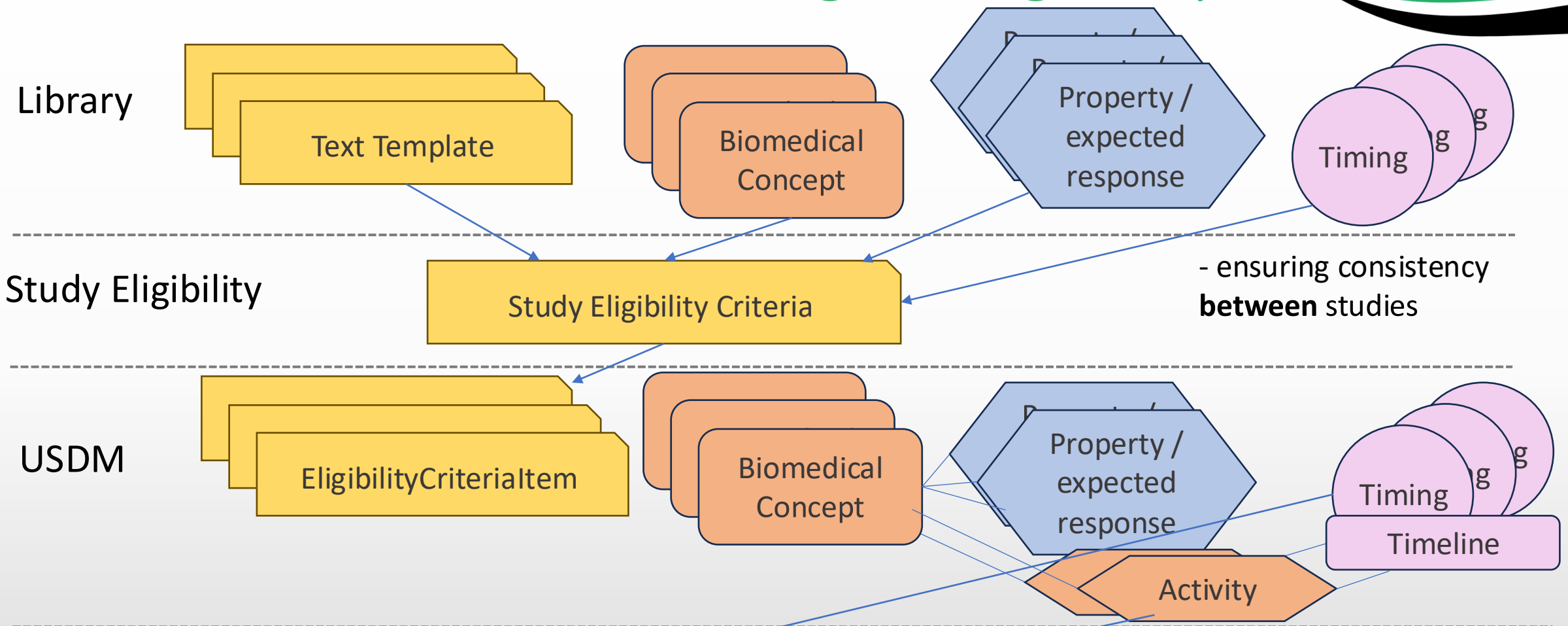
- Upstream standardization
- Downstream automation
- Connect the standards
  - CDISC 360i



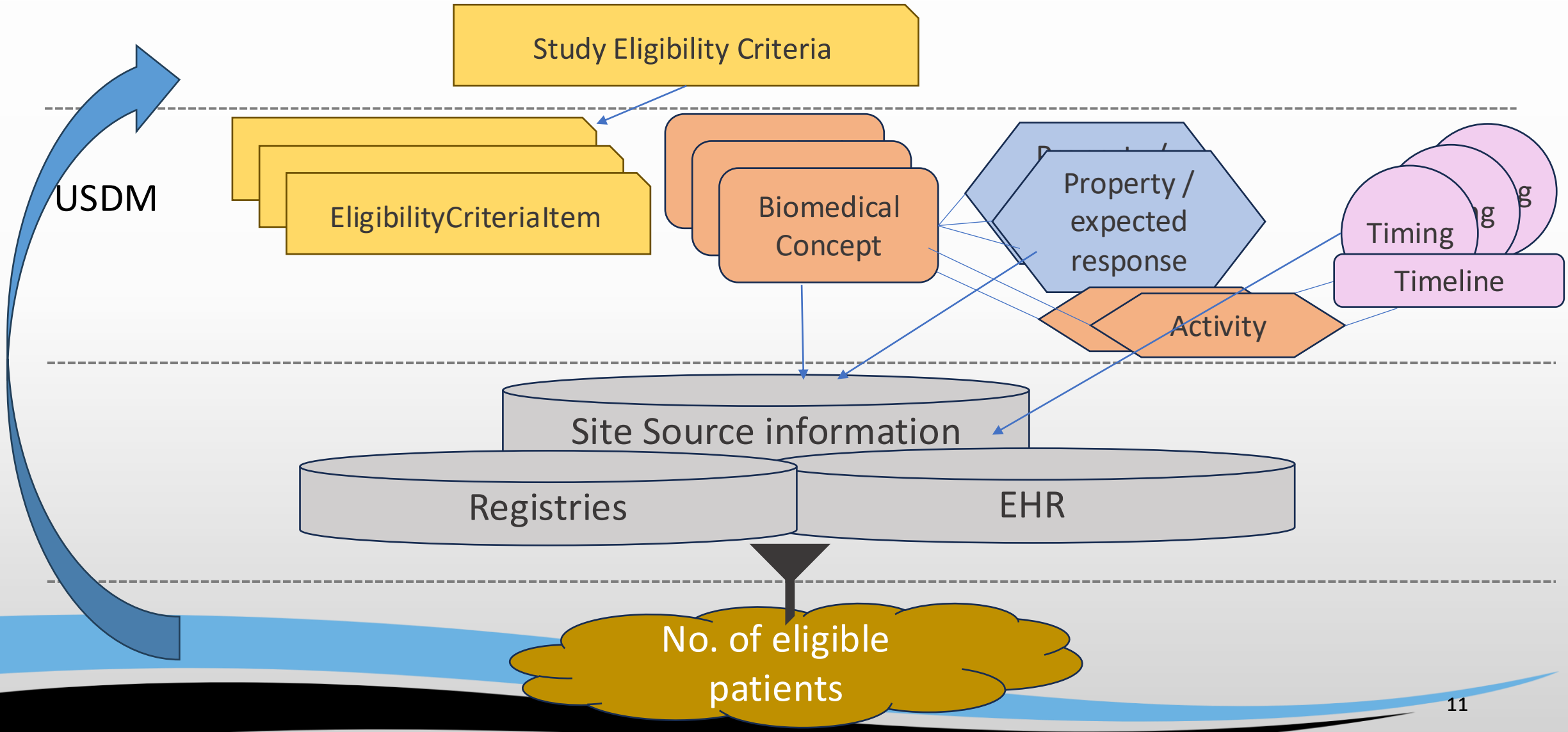
Use Case: Automated Design



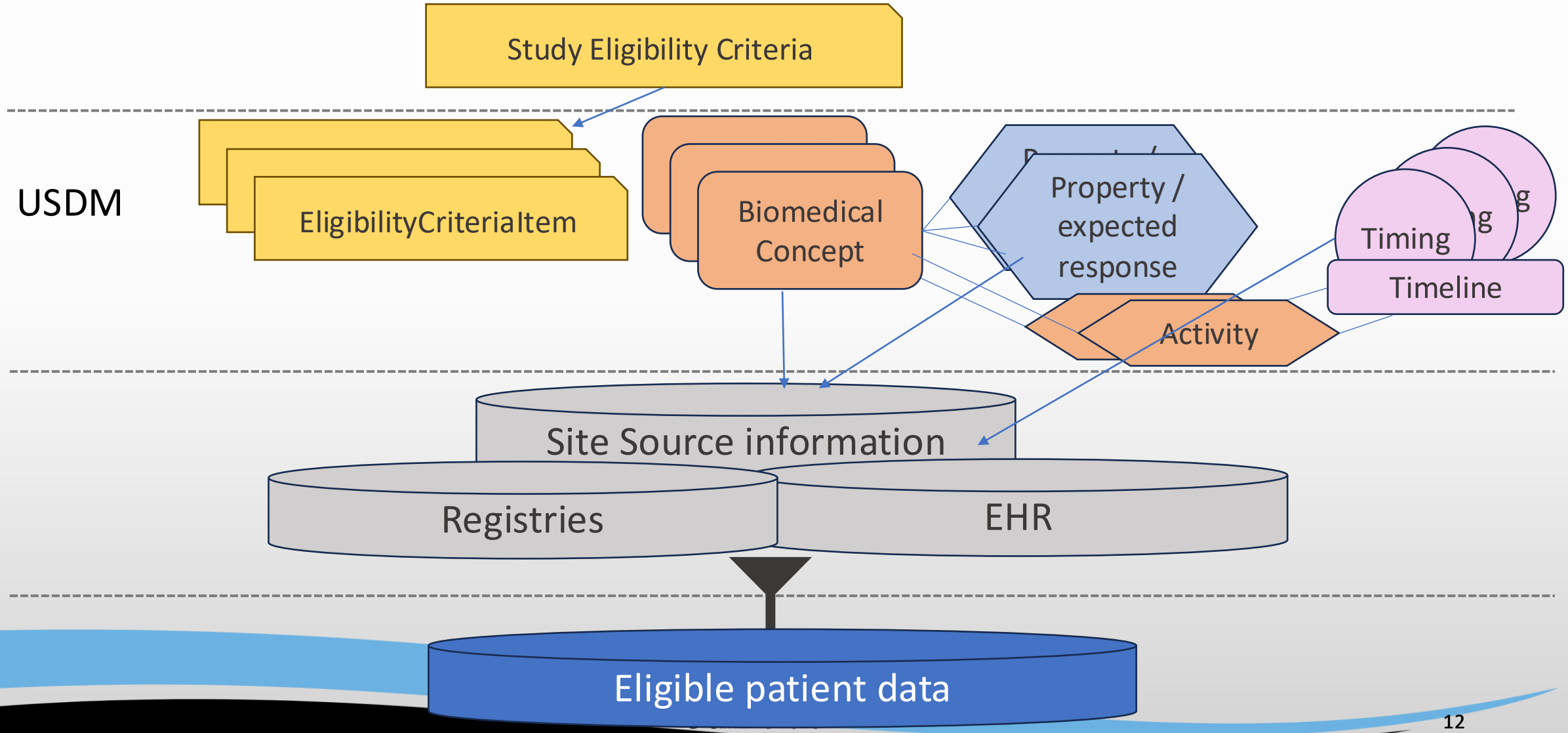
Use Case: Automated Design - eligibility



Use Case: Feasibility Assessments



Use Case: Patient Selection



Use Case: Cost Assessment

Number of planned subjects:

```
study.versions.studyDesigns.population.plannedEnrollmentNumber.value
```

```
300
```

Cost for activity:

```
study.versions.studyDesigns.activities.definedProcedures.extensionAttributes[url="http://MyCompany/usdm/extensions/ExtCost1/CostAttribute"].valueQuantity.value
```

JSONata 2.1.0

```
350
```

Number of occurrences of activity:

```
$count($filter(study.versions.studyDesigns.scheduleTimelines.instances.activityIds, function($v, $i, $a) {$v="Activity_2"}))
```

```
1
```

Total cost for activity:

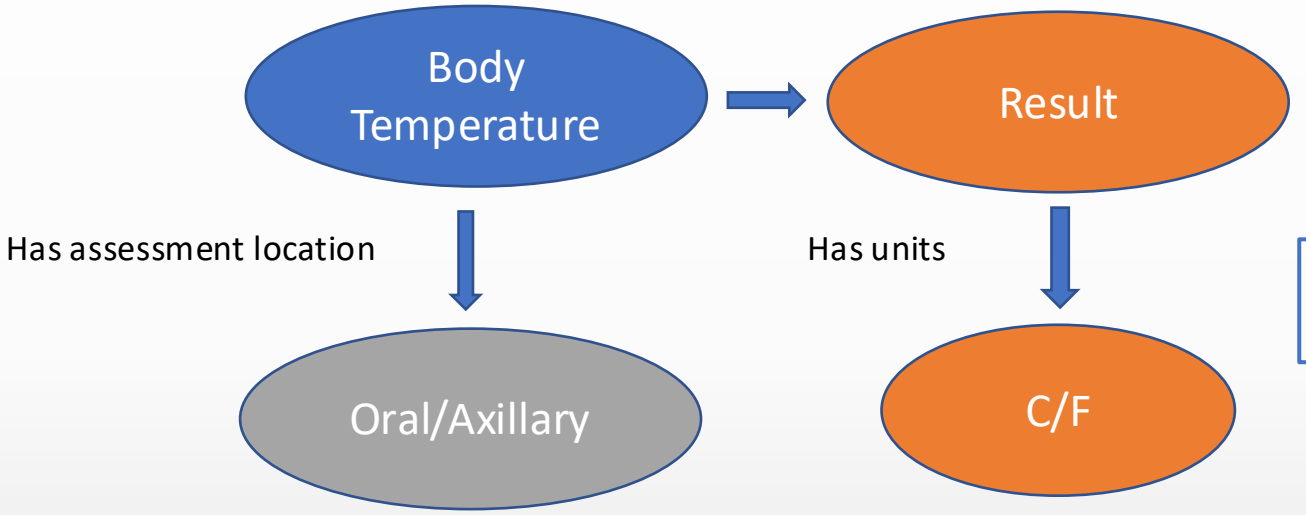
```
$count($filter(study.versions.studyDesigns.scheduleTimelines.instances.activityIds, function($v, $i, $a) {$v="Activity_2"}))
* study.versions.studyDesigns.activities[id="Activity_2"].definedProcedures.extensionAttributes[url="http://MyCompany/usdm/extensions/ExtCost1/CostAttribute"].valueQuantity.value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

JSONata 2.1.0

```
105000
```

Use case: EDC set-up

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



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Temperature	TEMP	101.3	F	ORAL

Implementation Layer

See CDISC Biomedical Concepts Training

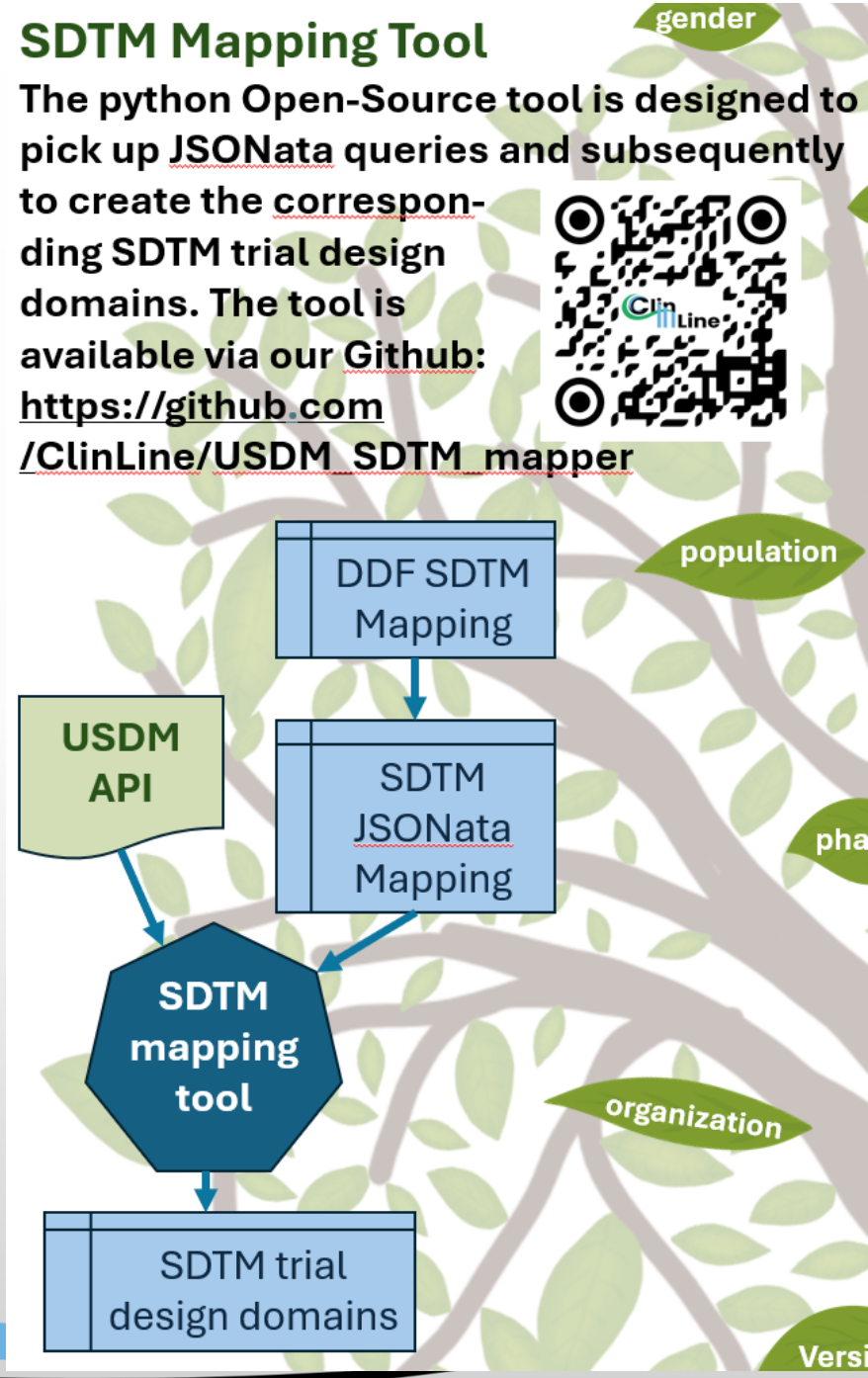
Use Case SDTM domain creation

- Trial Summary Domains
  - Direct from USDM exchange file
  - JSONata queries

- Patient data domains
  - Based on Biomedical Concept SDTM Specializations

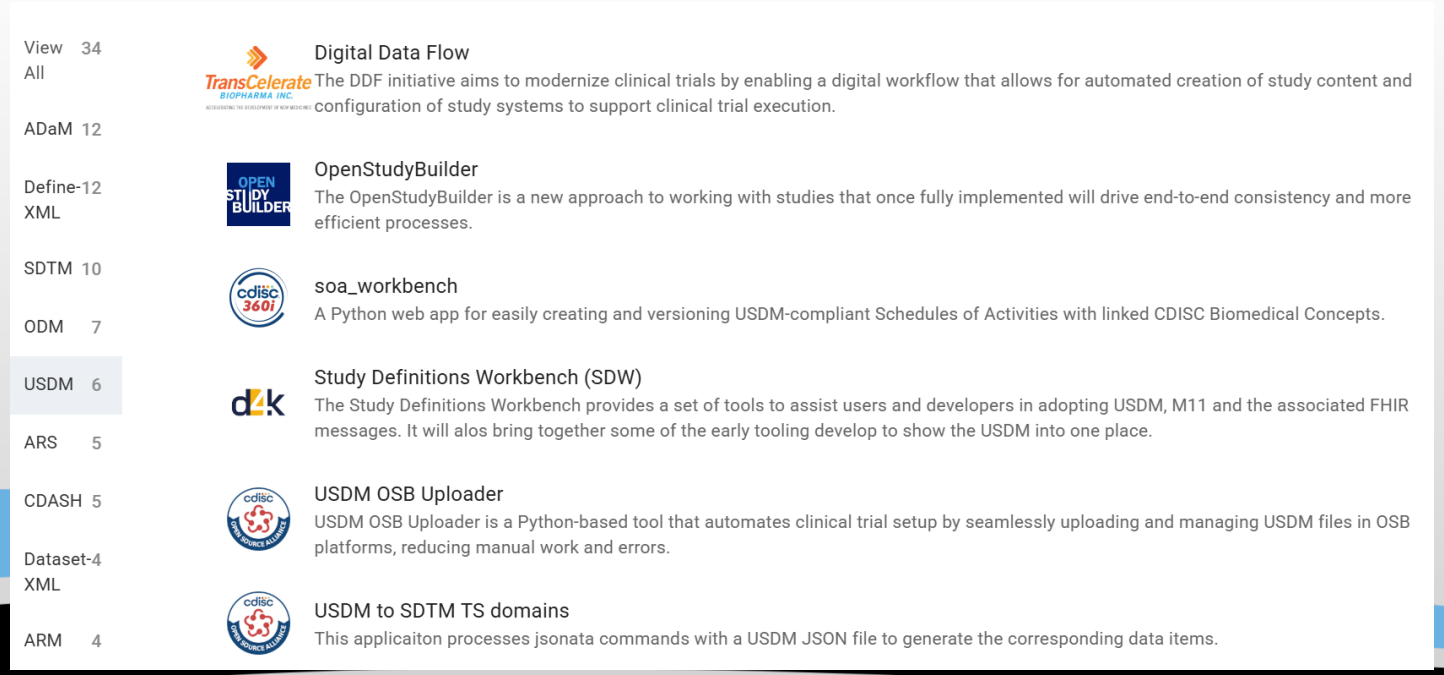
SDTM Mapping Tool

The python Open-Source tool is designed to pick up JSONata queries and subsequently to create the correspon-ding 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.



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