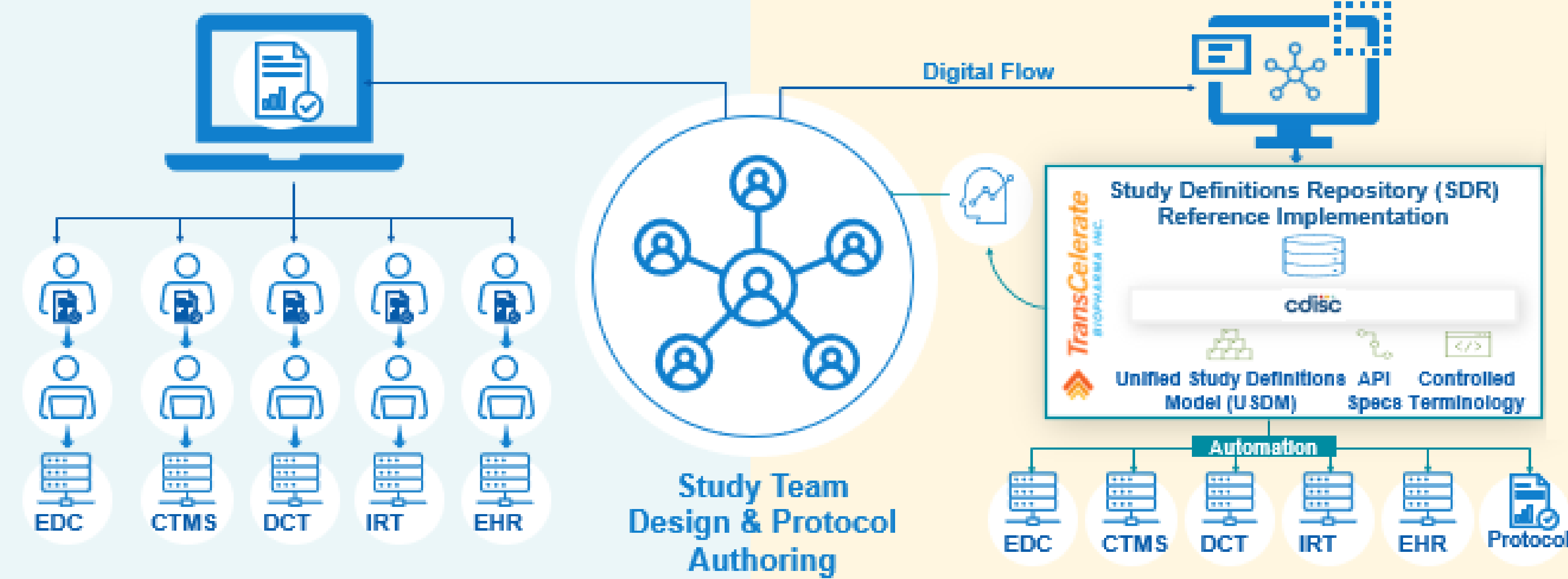


PP07 Digital Data Flow: Digitalizing Clinical Protocol Information to Accelerate Clinical Research and Pharma to Healthcare Interoperability

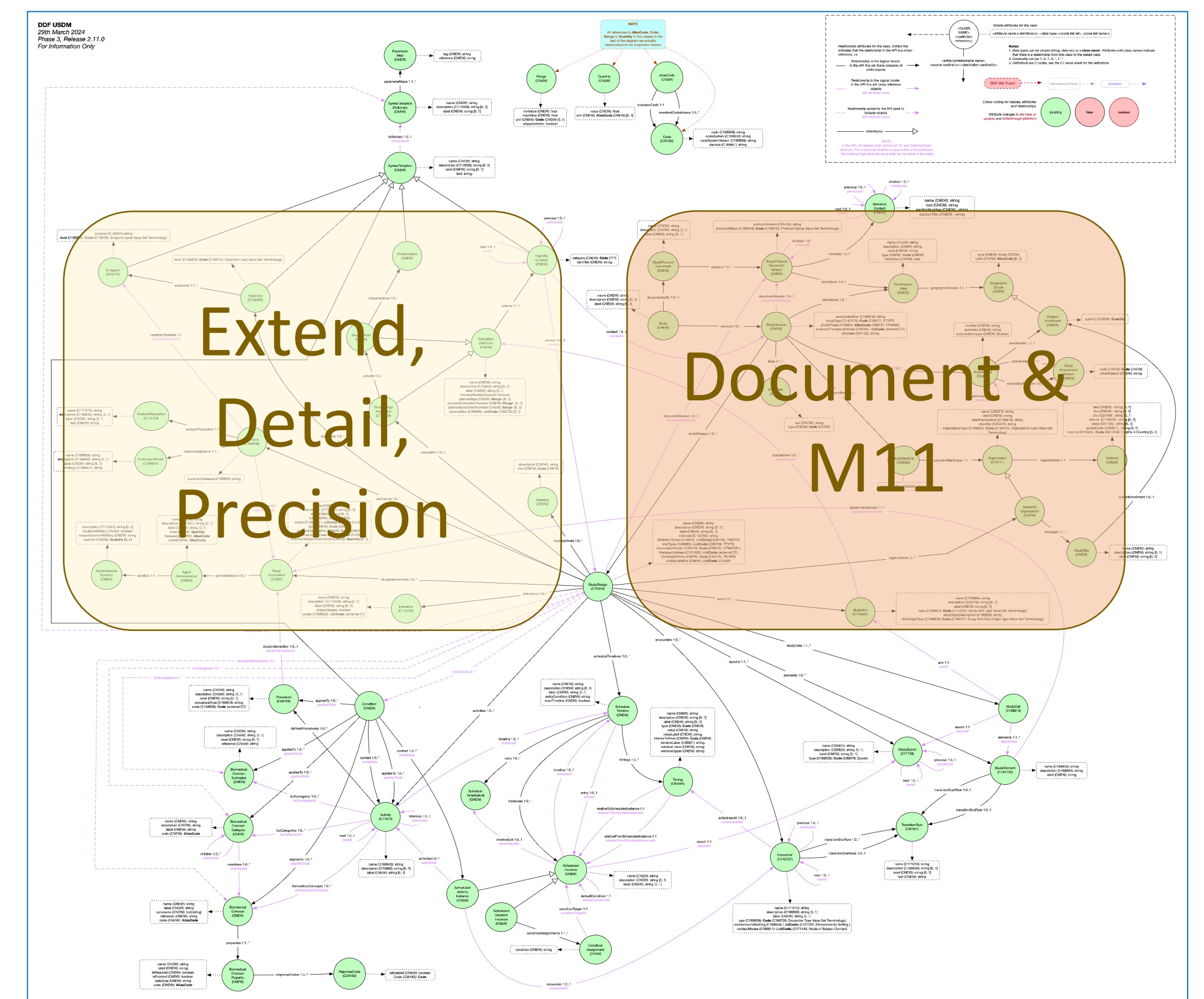
Documents to Data / Write Once, Read Many

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

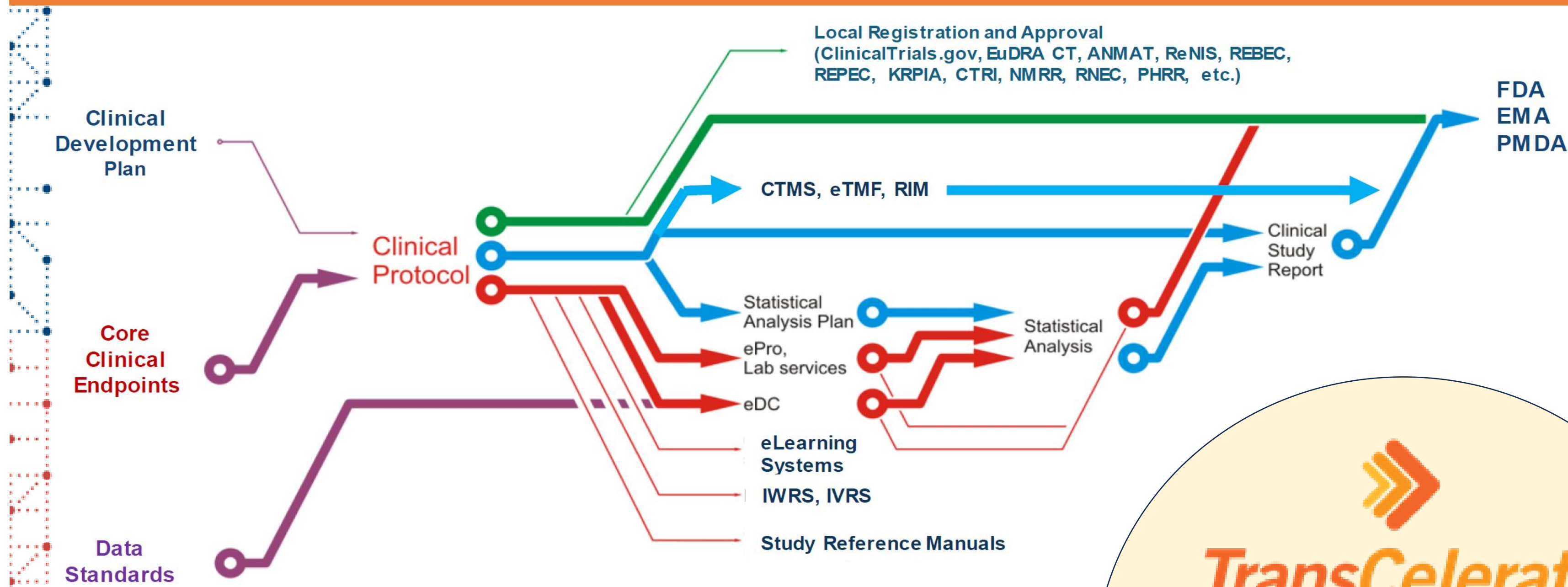
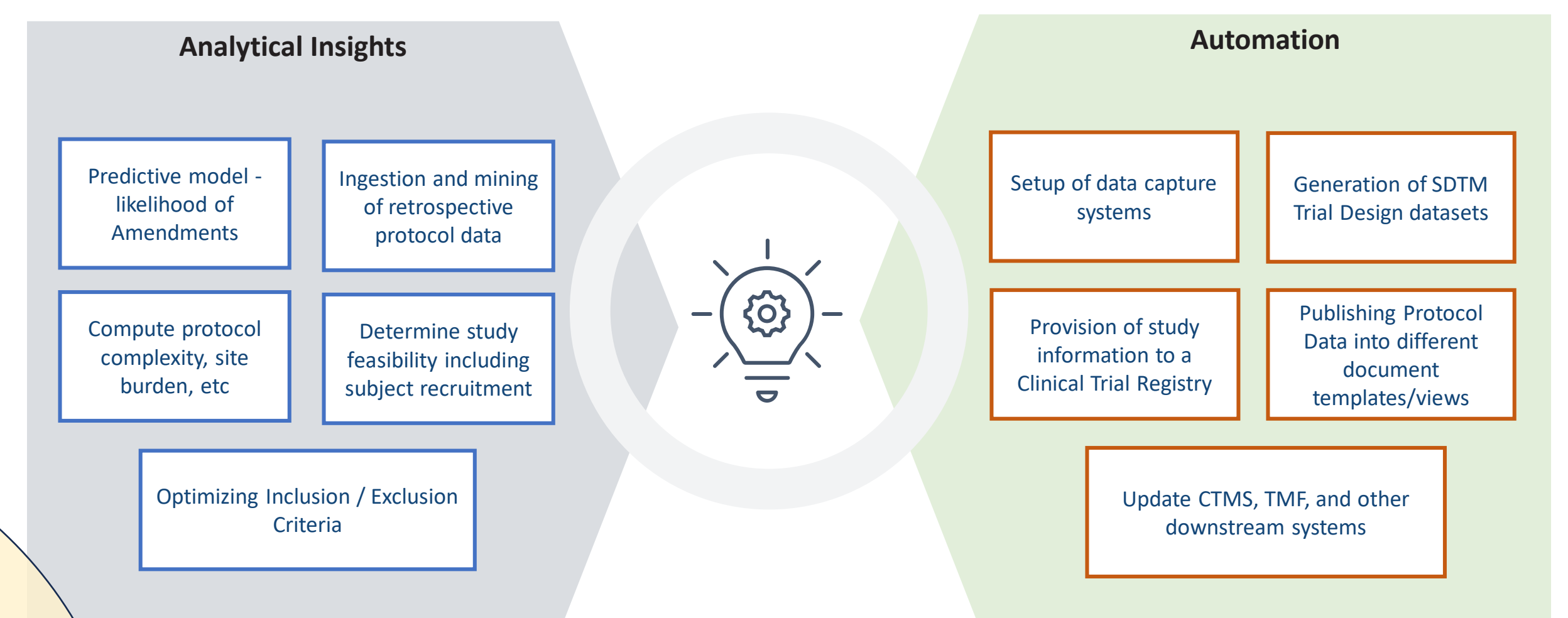
TOMORROW: Digital paradigm for protocol creation, with fully automated data flow and interoperability between systems



Phase Three



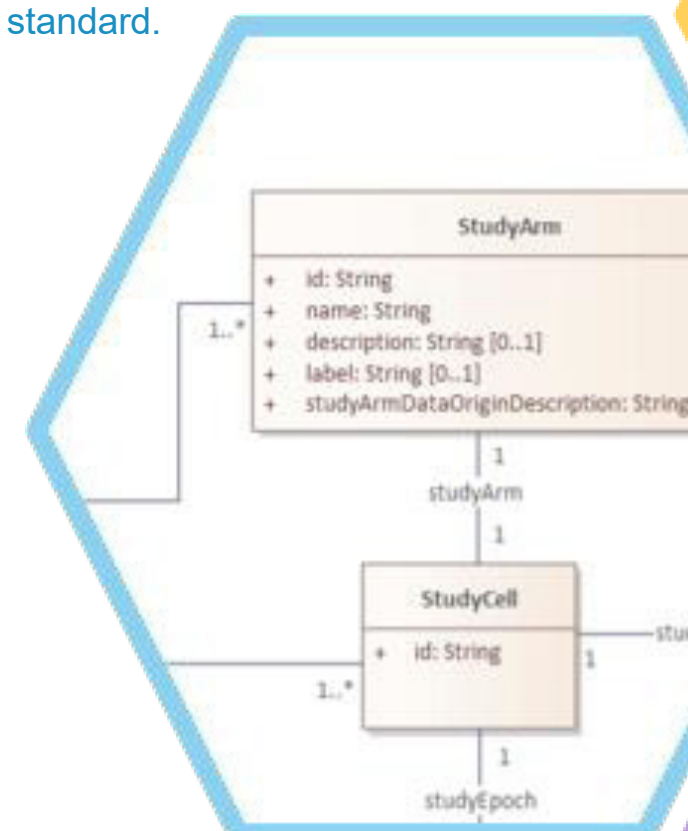
Use Cases



The USD M Standard

Logical Model

The UML logical model (a class diagram) that provides the basis for the USD M standard.



API Specification
Provides the means to exchange a single study between machines using a JSON API

CDISC Controlled Terminology

Provides further semantics, complementing the UML model. Includes the definition of classes and attributes along with the definition of value sets

Code	Study Arm	Description
C174447	Study Arm	
C170984	Study Arm Name	
C93728	Study Arm Description	
C188827	Study Arm Type	
C188828	Study Arm Data Origin Description	
C188829	Study Arm Data Origin Type	
C171398	Study Epoch	
C93825	Study Epoch Name	
C20604	Study Epoch Description	
C188830	Study Epoch Type	
C188831	Study Epoch Label	
C188832	Study Epoch Description	
C188833	Study Epoch Label	

Examples

Example protocols implemented in the USD M with associated JSON files and visualisations

```

{
  "id": "StudyItem",
  "name": "StudyItem",
  "description": "StudyItem",
  "label": "StudyItem",
  "type": "StudyItem",
  "dataOrigin": "StudyItem",
  "dataOriginType": "StudyItem",
  "studyArm": "StudyItem",
  "studyEpoch": "StudyItem",
  "studyCell": "StudyItem"
}
    
```

Implementation Guide
Guidance on using the USD M model and ensuring conformance with the standard

Where are we going?

ENGAGEMENT GOALS

- Increase Solution Provider Engagement**
Continue to grow Solution Collaboration Forum and provide opportunity for providers to showcase how they are applying DDF solutions
- Publish Sponsor Case Studies to share experiences among industry peers**
Includes case studies in exploration and execution of protocol digitization value and/or adoption
- Strengthen industry understanding of DDF via congresses, webinars, and training**
Workshops, panels/presentations, and modular education that can provide hands-on experience and showcase case studies
- Prepare for long-term governance transition**
Design long term governance model and prepare for a future transition of the DDF initiative to a 3rd party(ies) by year-end 2025



Sponsor Engagement



Health Authority Engagement



Solution Provider Engagement



Communications & Pulse on Industry

Scan QR Code to explore DDF GitHub

- Review the videos, newsletters and other archived materials available
- Find links to the USD M RA, and other assets
- Download the SDR RI source code available
- Contribute and interact on the open discussion forums
- If you work for a TransCelerate member company, volunteer to join our core team
- If you work for a technology vendor join our Solution Collaboration Forum
- Volunteer to join the CDISC USD M team (via CDISC website)



<https://transcelerate.github.io/ddf-home/>

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