2026 CDISC China Interchange

CDISC 360i Phase 2: Lessons Learned and Road Ahead

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The Burning Platform

The industry struggles to absorb the wave of AI, data, and regulatory change on the people, technology, and process infrastructure it has today.

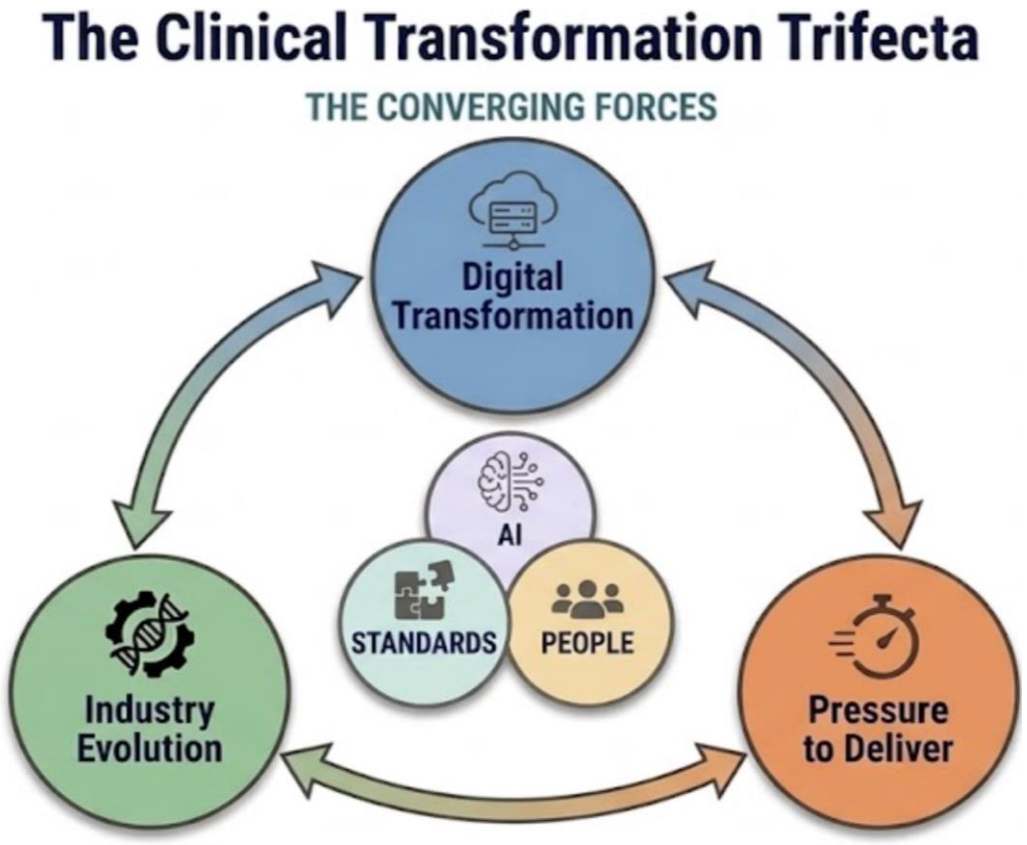
Three forces are converging — and within this convergence lies a transformative opportunity to rewire how we develop therapies.

"Clinical development is no longer constrained by science—but by our ability to connect data, people, and processes."

Industry Evolution

Converging Force:
R&D has become a competitive race. Portfolio decisions are strategic differentiators.

Opportunity (Standards):
Standards and interconnected information provide the competitive infrastructure to make faster, better-informed decisions.



Digital Transformation

Converging Force:
Two decades of digitizing paper without transforming the data flow. AI is maturing faster than the infrastructure can support.

Opportunity (AI):
Development of a connected infrastructure enabled by a fundamental shift in people and processes will set the foundation to utilize AI to its potential

Pressure to Deliver

Converging Force:
Significant growth in data volume and complexity per study without an increase in resources limits the ability to scale and rapidly deliver results

Opportunity (People):
Those who standardize and create well-structured connected information will realize significant and exponential returns. Every connected trial makes the next one faster, cheaper, and higher quality.

Standards: The Foundation of Trustworthy AI

If we have AI we don't need standards, right?

Yes, you absolutely need data standards—even (or especially) when using AI. AI **does not replace** the need for data standards—it **relies** on them. Think of AI as the engine, and data standards as the quality fuel it needs to run safely, smoothly, and at scale.

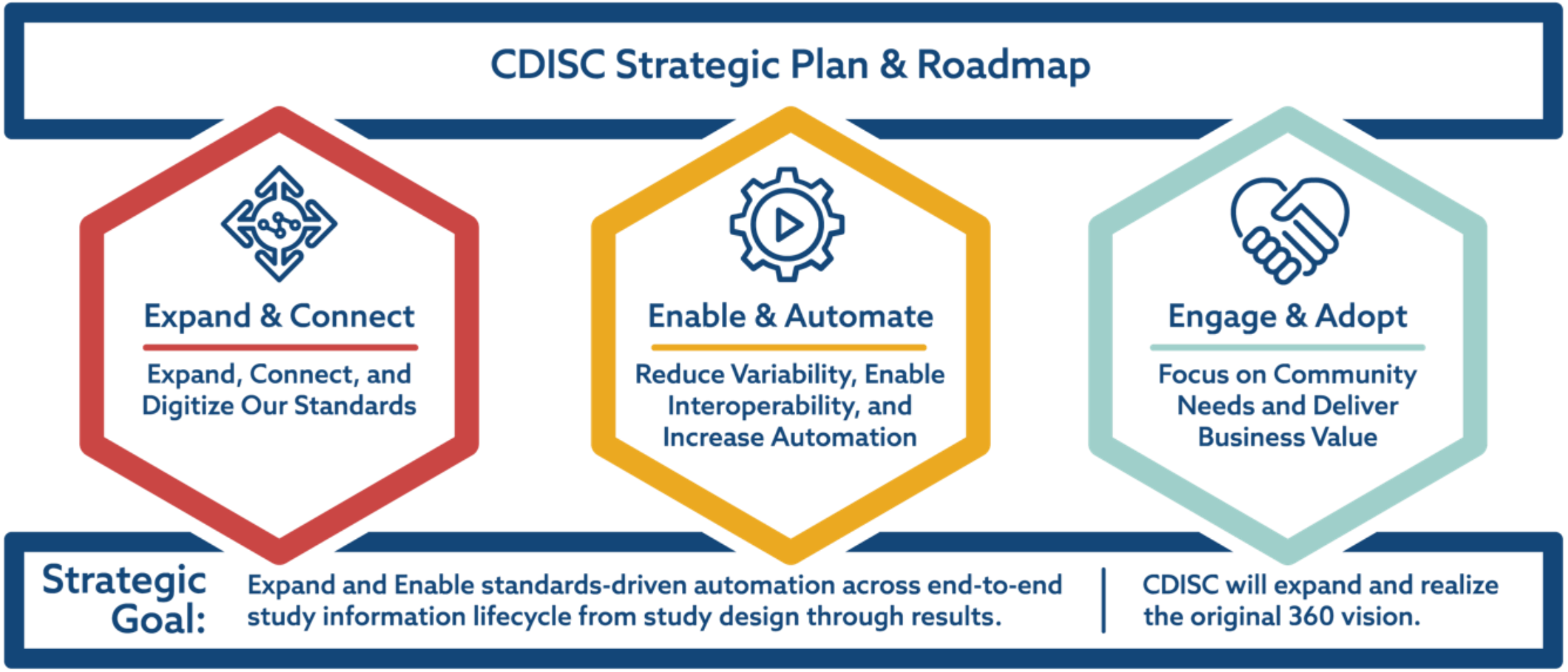
What type of data standards do we need to support AI?

In short, enabling AI **requires** a **layered and evolving set of data standards** ranging from general frameworks to technical, **semantic**, ethical, and domain-specific norms, all ensuring AI's data is high-quality, trustworthy, interoperable, and aligned with regulations.

Good data leads to good AI, while bad data leads to bad AI

Realizing CDISC's Mission

*CDISC's **vision** is to amplify data's impact to advance research by…*
creating connected standards across the study information lifecycle to enable accessible, interoperable, and reusable data for more meaningful and effective research



Five Year Vision: CDISC 2030

By end of 2030, all CDISC standards are digital, linked, and easily consumable by users and systems.

- Digital, connected standards create the trusted foundation required for scalable automation and responsible AI.
- Digital standards empower experts across the clinical research ecosystem, reducing manual burden, increasing transparency, and enabling better, faster decisions for patients

Digital

Structured, machine-readable standards that reduce manual effort

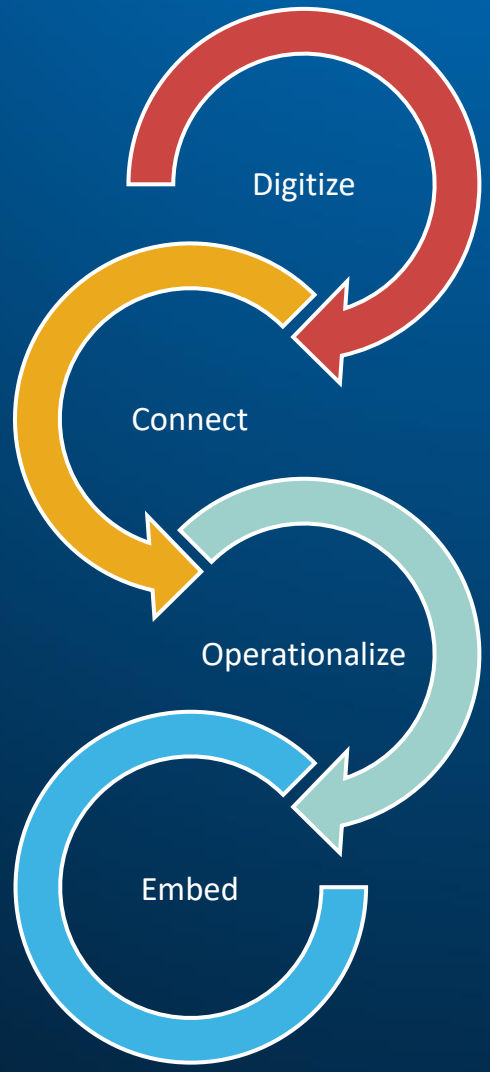
Linked

Unified semantic backbone that provides clarity and context

Accessible

Embedded in workflows to support informed, confident decisions

Path to 2030



CDISC 360i: Digital Standards that Power a Connected Clinical Development Ecosystem

What is CDISC 360i?

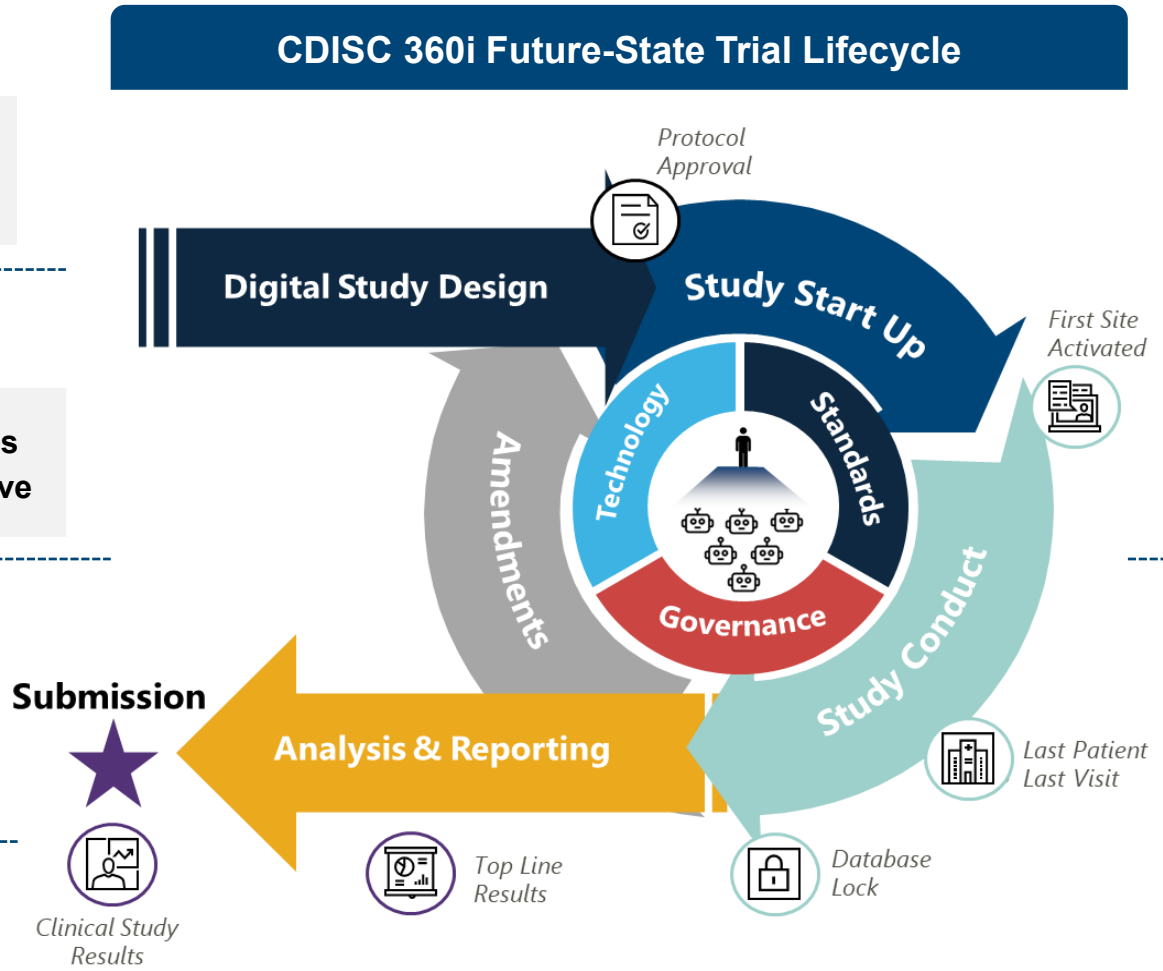
Standards are the foundation of automation. You cannot automate what you cannot standardize. Better data, better AI.

- **CDISC** has been the clinical research standard for over 25 years. 360i is the evolution of those standard from document to digital
- **CDISC 360i is** a digital implementation of the standards: seamless digital data flow throughout the entire clinical trial — from the moment a protocol is written through when a data point is analyzed. Eliminating manual, error prone handling. Enabling automation and AI at every step.

Connected, machine-readable study design

The foundation that makes AI trustworthy and effective

End-to-end digital traceability across the trial



A framework for seamless data flow across the ecosystem

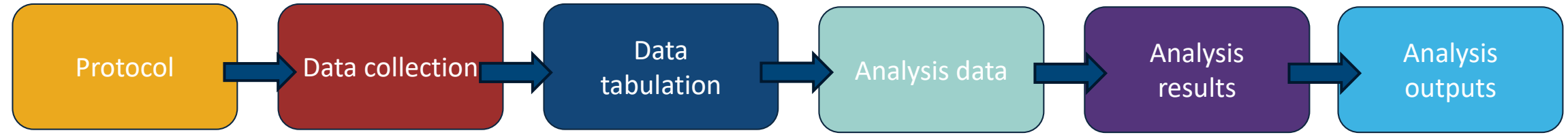
A strategic investment with compounding returns

Your standard enabling your portfolio, & competitive advantage

360i Goals

- Define and digitalize end to end standards from study design endpoints through the analyses
- Leverage those standards to accelerate the study design and build phase of the trial
- Demonstrate the automated data flow from raw data source to the generation of the targeted result

Using Digital Assets to Enable Seamless Data Flow



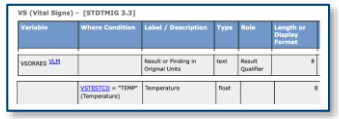
Conceptual Biomedical Concepts (BC)

Schedule of Activities

BC CRF Implementation

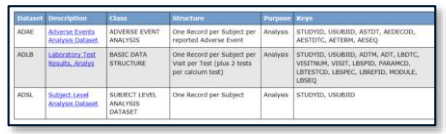
eCRF

BC SDTM Implementation



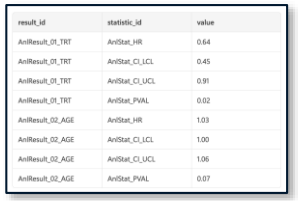
- *SDTM Define.XML*
- *Mapping Specifications*

Analysis Concepts



- *ADaM Define.XML*
- *Mapping Specifications*

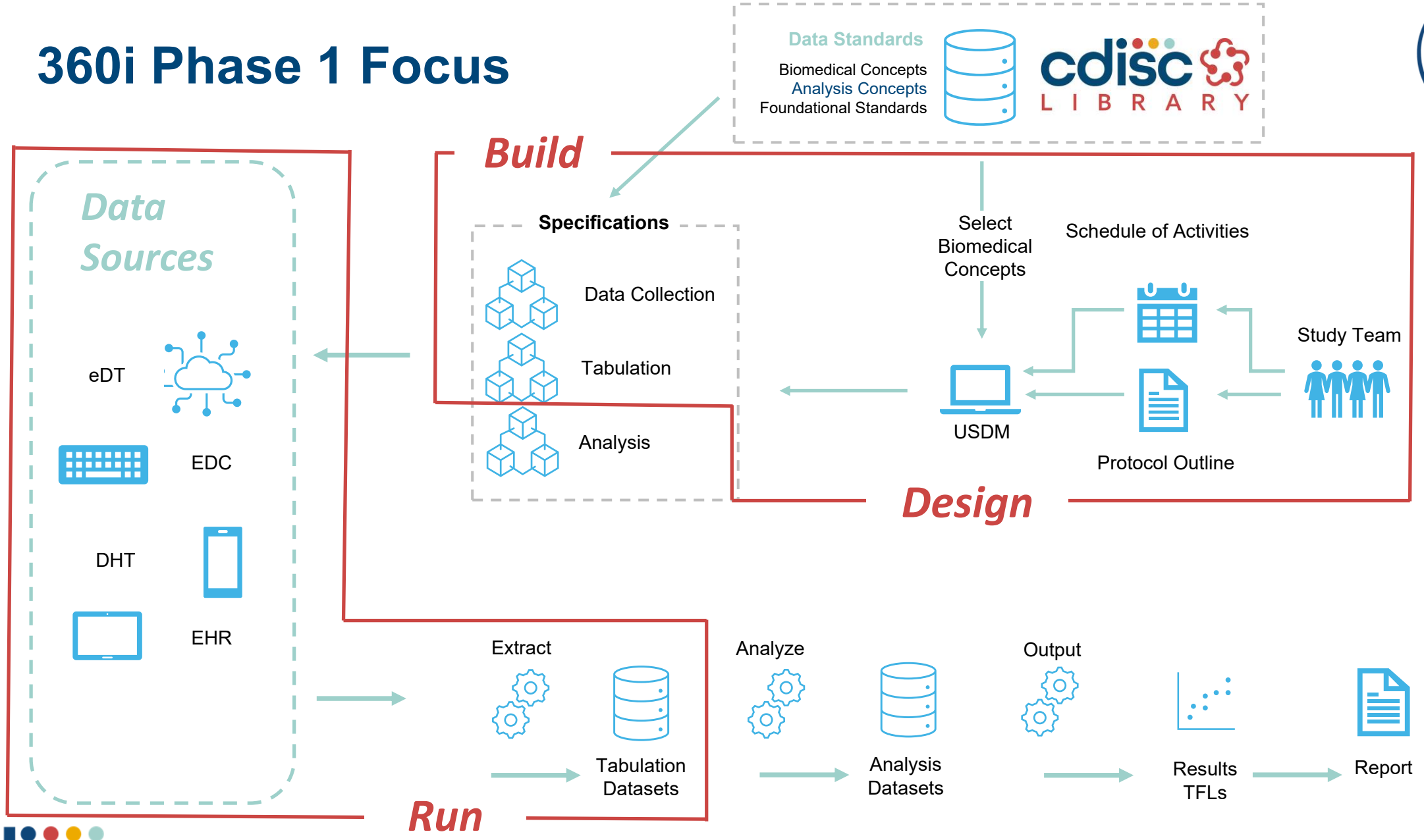
Analysis Results Metadata



Analysis Results Dataset

360i Phase 1 Achievements & Findings

360i Phase 1 Focus



360i Phase 1 – Consolidated Learnings

Achievements

- Digital Schedule of Activities linked to biomedical concepts via USDM
- Automated generation demonstrated for SDTM Datasets, define.xml, CRFs & annotated CRFs

Challenges

- Concept linking is insufficient
- Lack of study-specific operational metadata
- Some elements are missing (concept grouping, forms metadata, …)

Insights

Gaps are operational – not conceptual

To scale automation, we need

- Concept groupings
- Operational Metadata
- Transformation logic (tool agnostic)

Operational details need to be standardized and machine-readable

360i Phase 2 Scope & Approach

360i Phase 2: Operationalizing the Vision

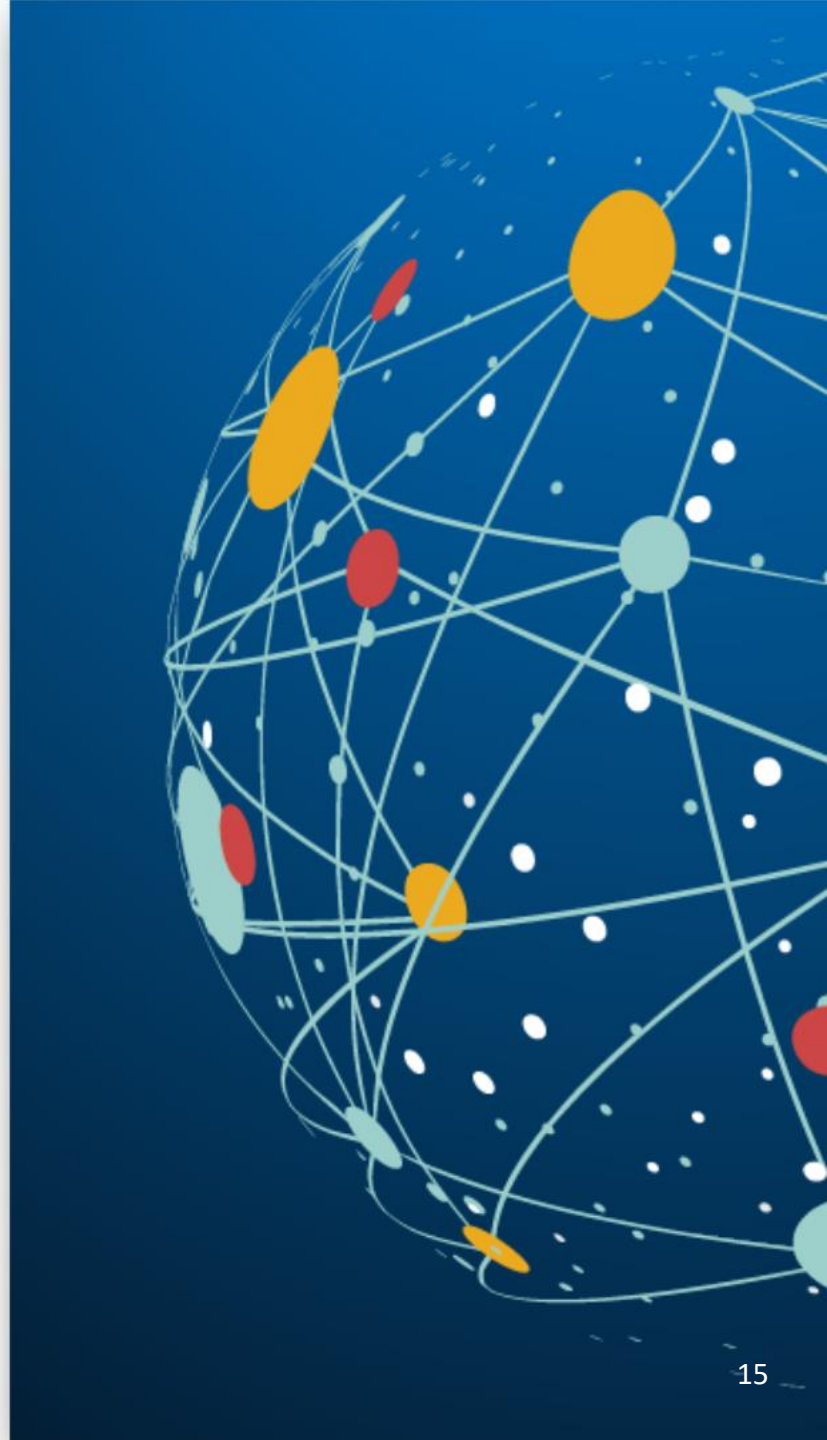
Key Deliverables

Digital Protocol & Impact Analysis Reporting: Machine-readable protocol model with automated amendment and impact analysis

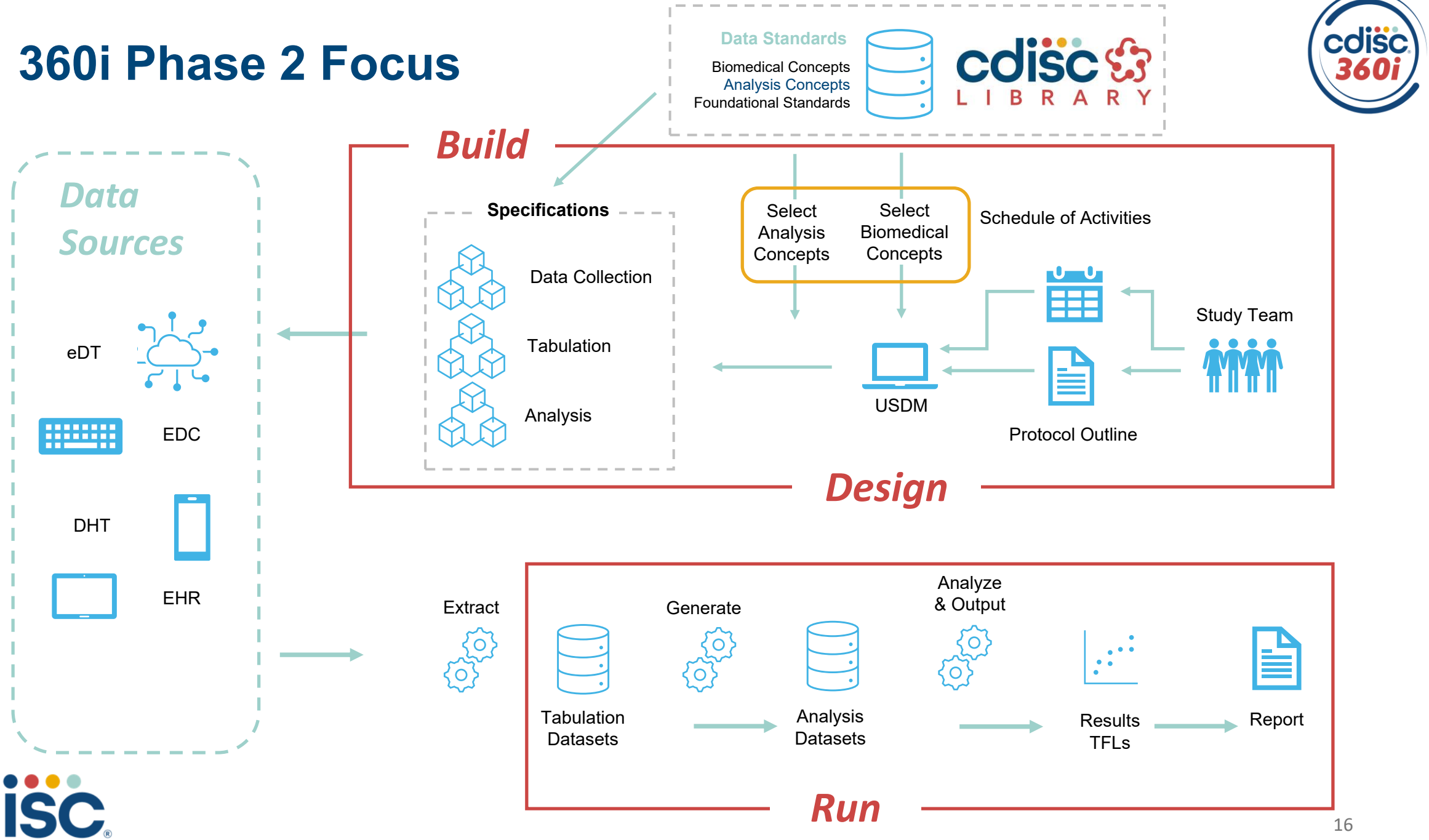
Automated eCRFs, Define & Dataset Generation: Generation of eCRFs, Define.xml and datasets integrated with study workflows

Digital Data Transfer Agreement Model: Technical DTA model and standardized template aligned with the digital protocol

Standardized Analysis Concept Model: Configurable, machine-readable analysis concepts driving automated analysis artifacts



360i Phase 2 Focus



Content Scope

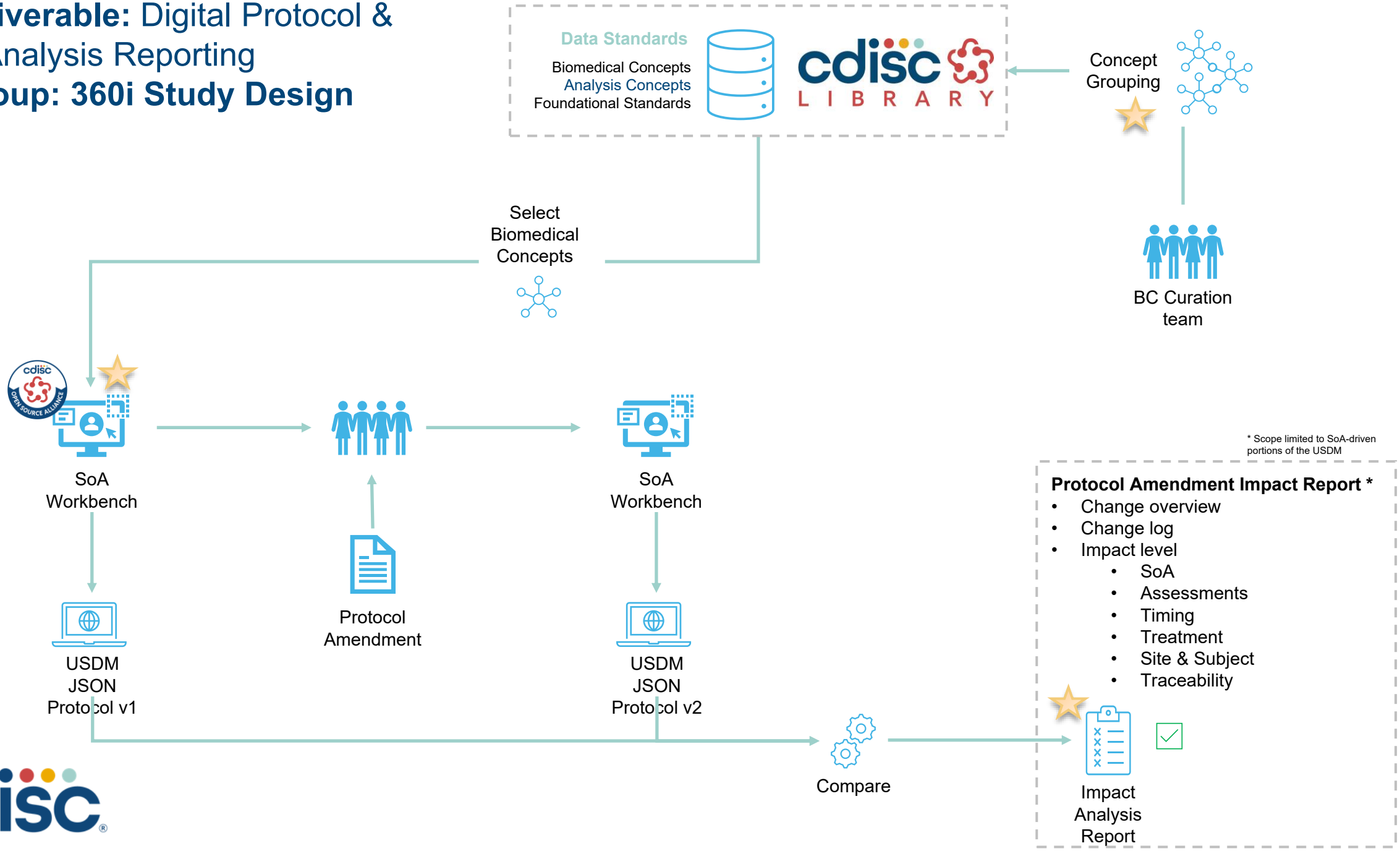
Disease endpoints to exercise the AC/DC Model

- Breast Cancer: Response Evaluation Criteria in Solid Tumors
  - Progression free survival
- Alzheimer’s Disease: Alzheimer's Disease Assessment Scale-Cognitive Subscale
  - Change over time

Safety concepts to illustrate biomedical concept groupings, CRF generation, Define.xml generation, data transfer agreements, and summary statistics

- Demography
- Death Details
- Adverse Events
- Disposition
- Labs
- Vital Signs

Key Deliverable: Digital Protocol & Impact Analysis Reporting
Workgroup: 360i Study Design



360i Study Design

Main Activities

- Add and demonstrate BC groupings
- Develop and test the open-source SoA Workbench
- Generate protocol amendment impact assessment

Benefits

- User-friendly concept selection
- Easy USDM SoA authoring
- Clearer change impact leading to more efficient design

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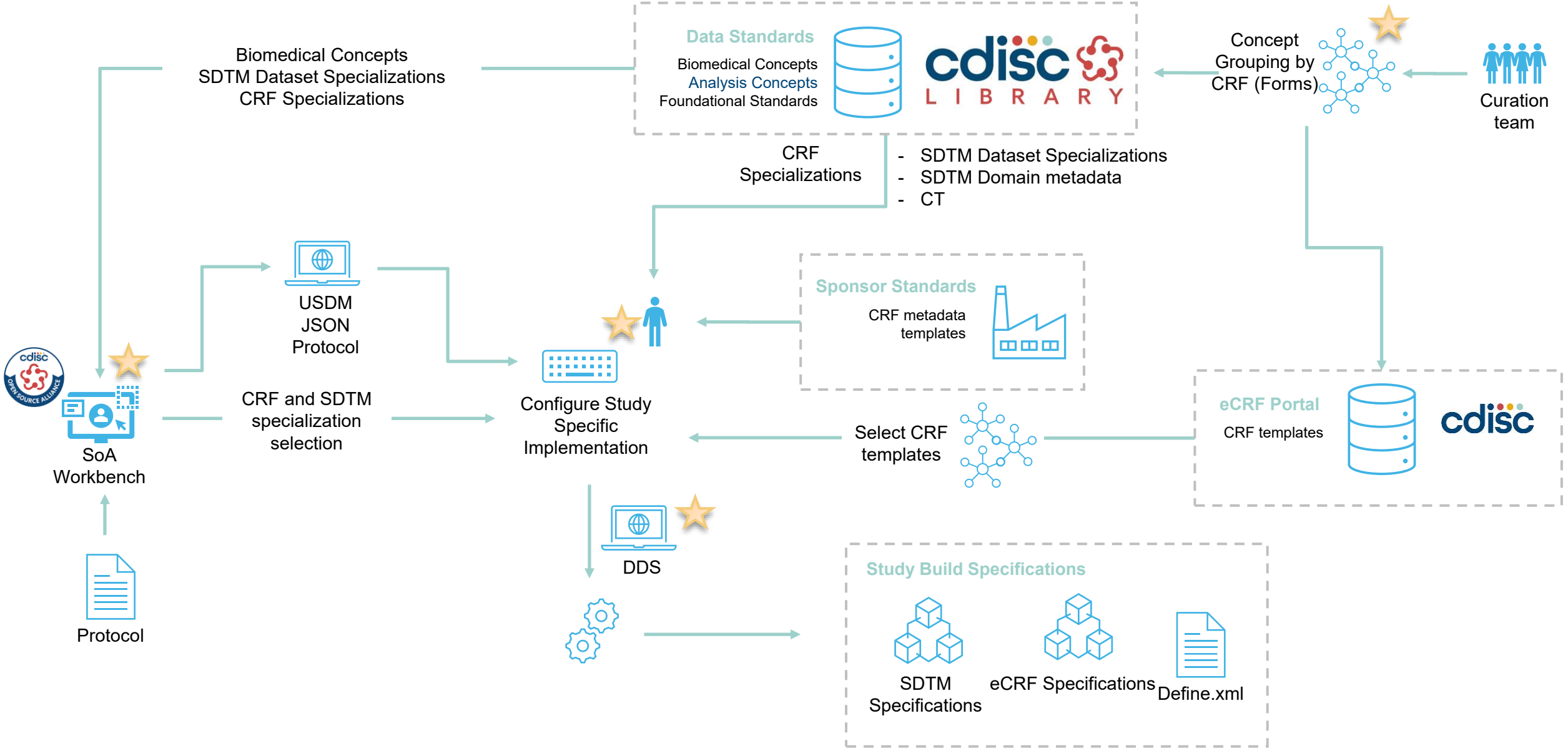
Key Deliverable: Automated eCRFs, Define & Dataset Generation
Workgroup: 360i eCRF & Define.xml Generation



360i eCRF & Define.xml Generation

Main Activities

- Leverage Biomedical Concepts to:
  - Generate eCRFs from CRF Specializations
  - Select eCRF Templates from the eCRF Portal
- Demonstrate the full automation of Define-XML creation
- Develop Data Definition Specification (Define-JSON)

Benefits

- Consistent CRFs across studies with harmonized structure and terminology
- Reduced manual effort via template selection in the eCRF portal
- Automated Define-XML creation reduces documentation workload and errors, and improves traceability and stronger regulatory readiness

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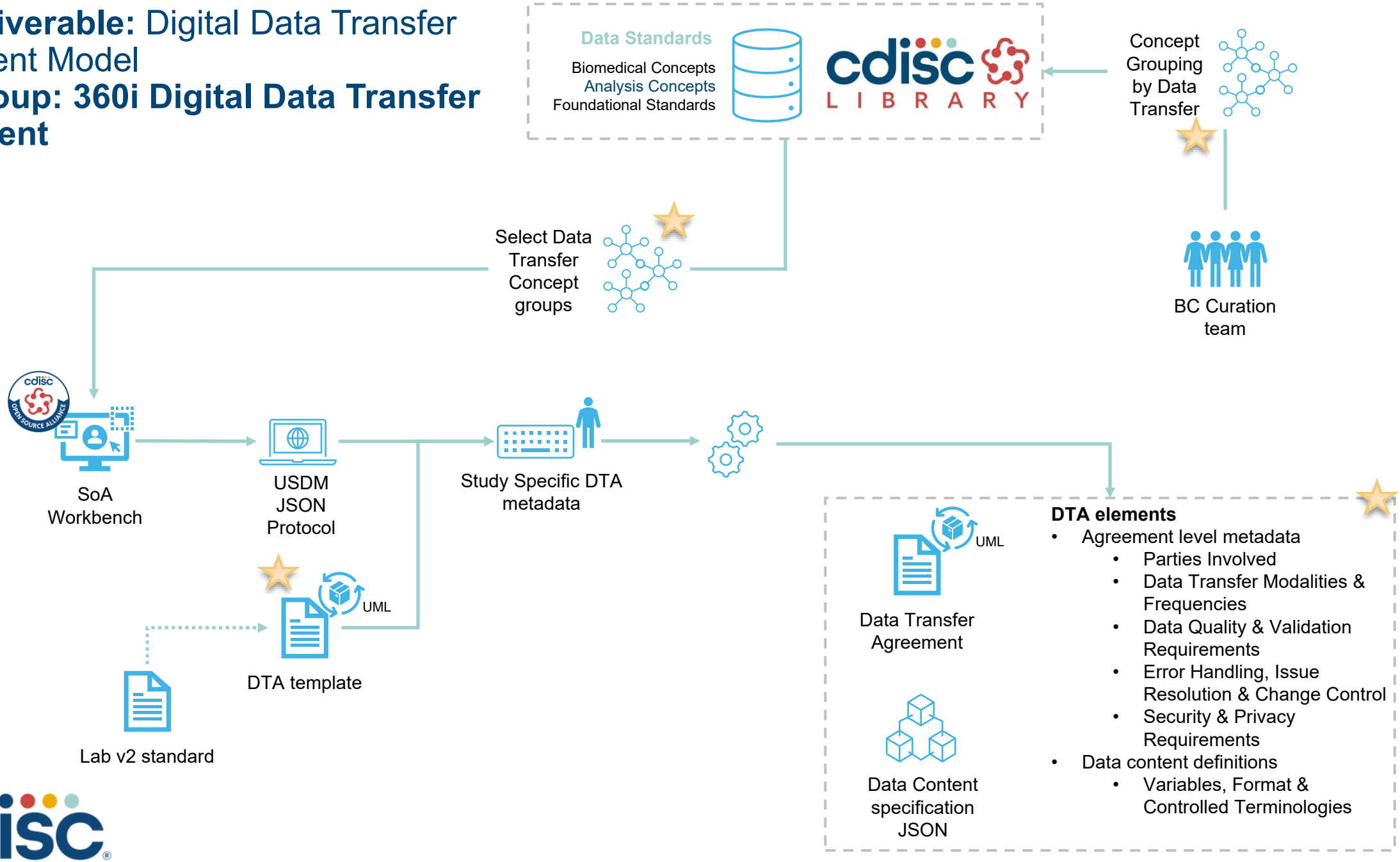
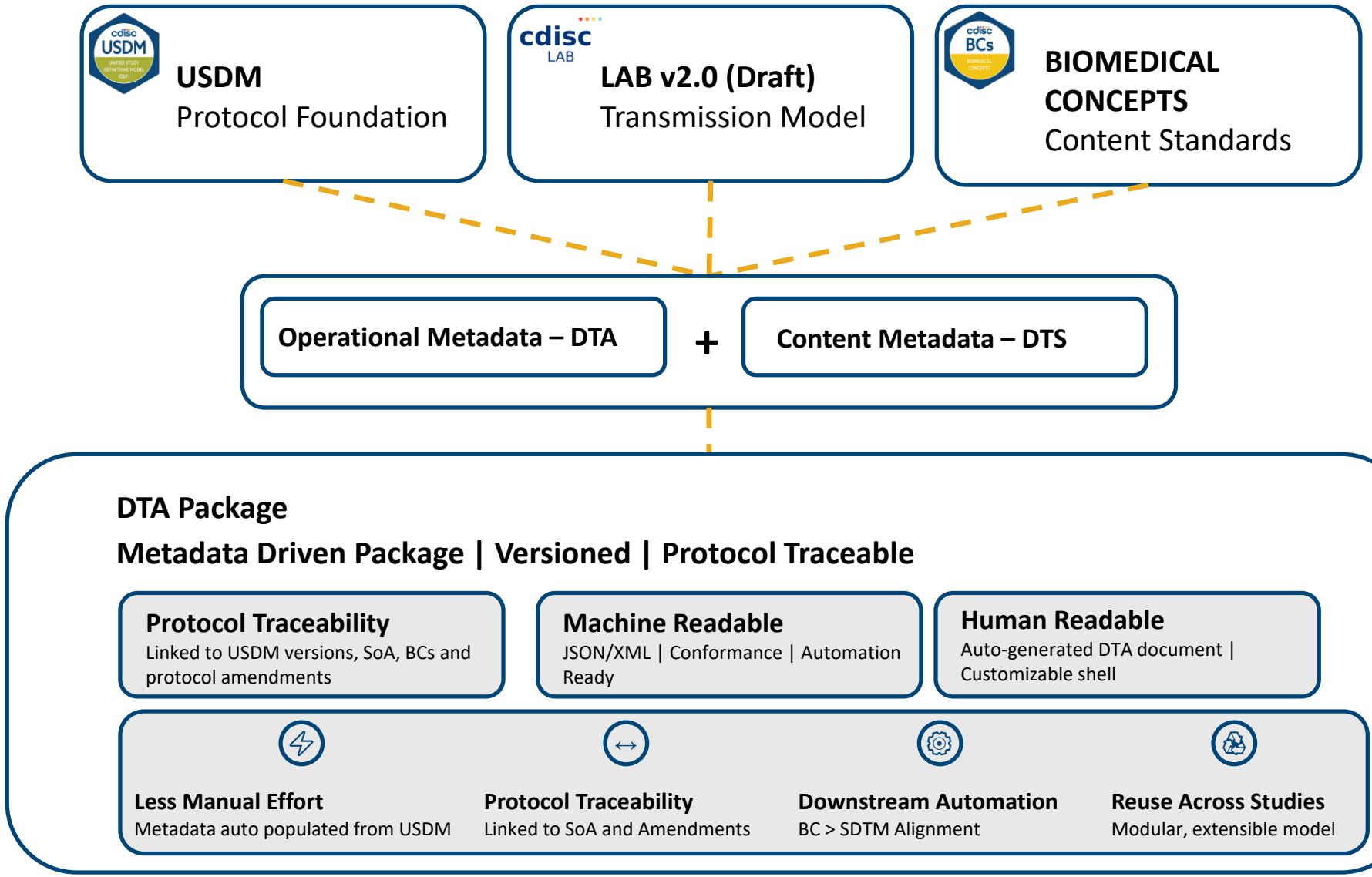
Key Deliverable: Digital Data Transfer Agreement Model
Workgroup: 360i Digital Data Transfer Agreement



DTA Framework



DTA – Data Transfer Agreement

How data is exchanged – operational metadata: parties, schedule, file conventions, transfer method

DTS – Data Transfer Specification

What data is transferred – content metadata: data elements, formats, controlled terminology, units

DTA Package – Bound Metadata

DTA + DTS bound together with protocol traceability – generates machine-readable and human-readable artifacts

360i Digital Data Transfer Agreement

Main Activities

- Develop DTA industry standard template & specifications
- Add Data Transfer groupings to Biomedical Concepts
- Find and select data transfer BCs in the SoA Workbench
- Develop a study specific definitions utility

Benefits

- Establish common DTA language and structure across the industry
- Provide faster, clearer, and more consistent data transfer agreements
- Reduce negotiation effort and automated specification generation

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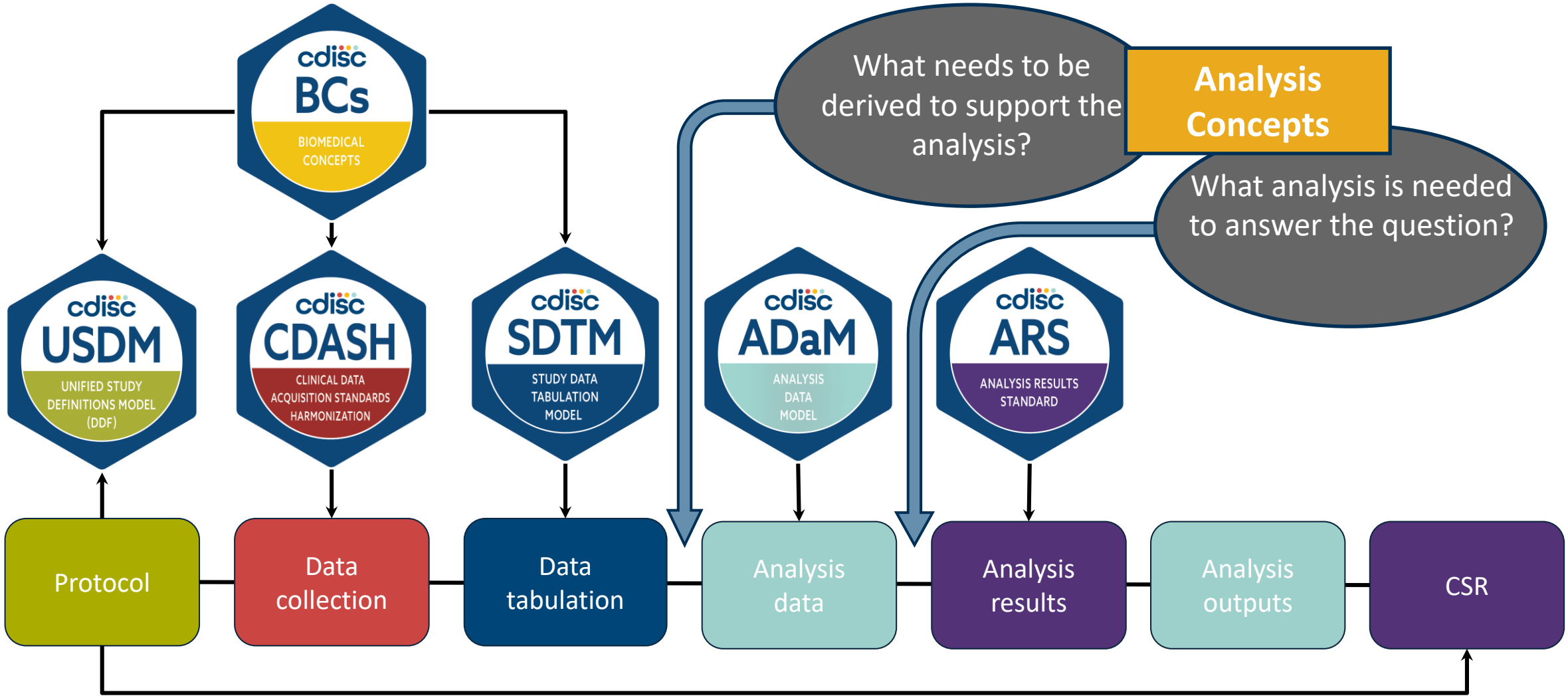
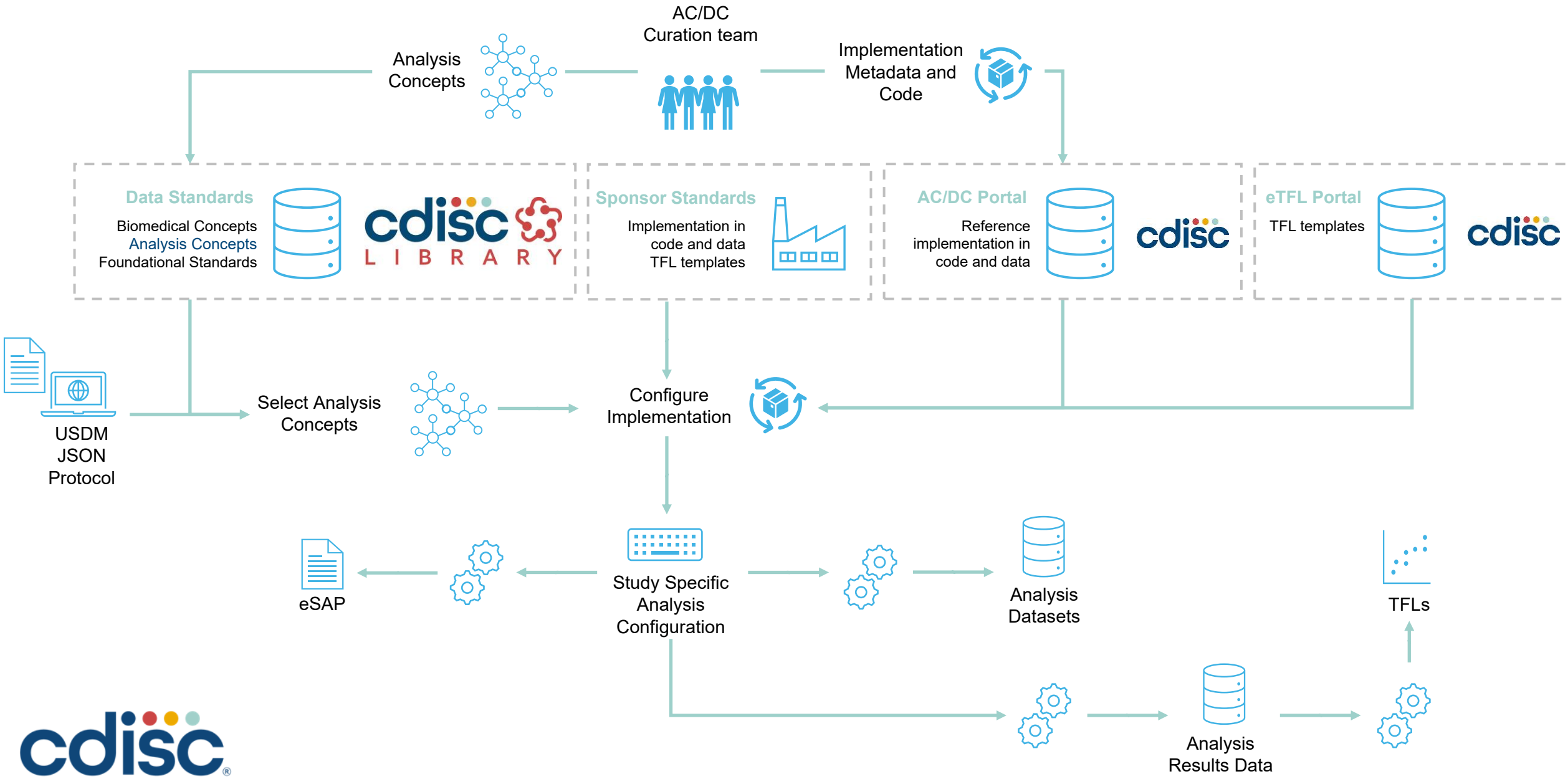
Where Analysis Concepts Fit



Key Deliverable: Standardized Analysis Concept Model
Workgroup: 360i AC/DC Automation



360i AC/DC Automation

Main Activities

- Develop AC/DC model
- Design study specific analysis configuration
- Create controlled terminology
- Generate eSAP
- Demonstrate automation from ADaM datasets through Analysis Results Datasets (ARD)

Benefits

- Allows exchange of analysis specifications
- Enforces precision in specifying analysis setting and assumptions
- Establish common language to express derivations and analysis
- Analysis automation and reuse

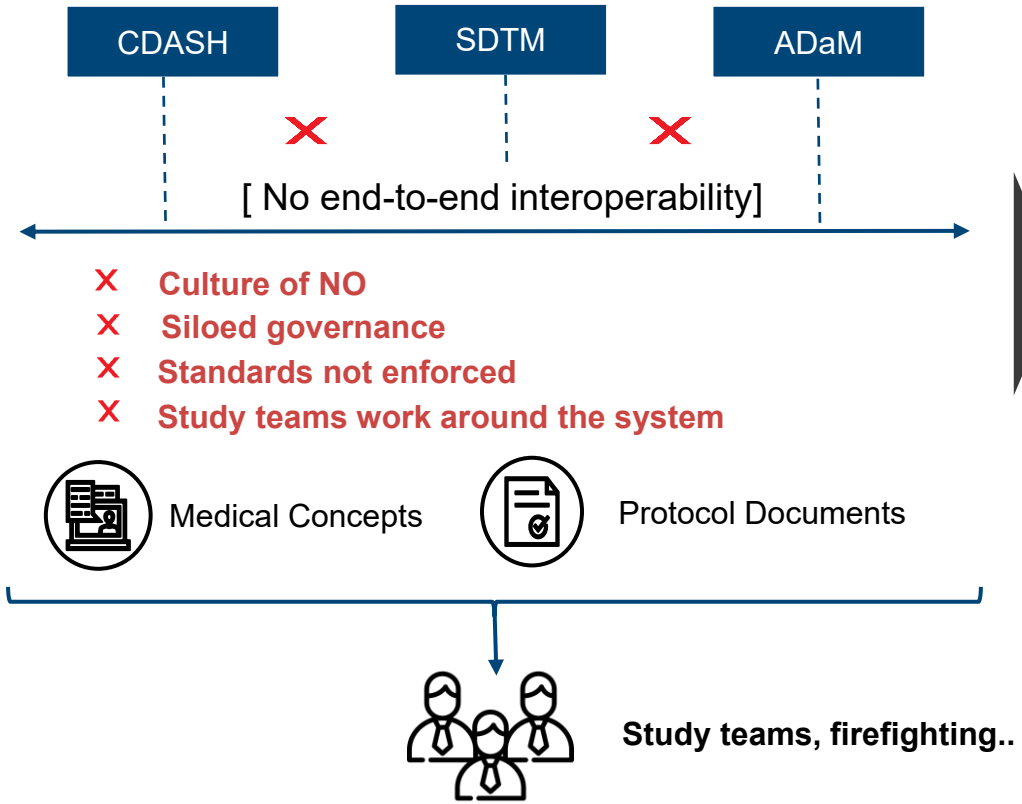
Connected Standards Future

From Disconnected Standards to a Connected Foundation

CDISC's original promise was standards. CDISC 360i's promise is the connected foundation that standards enable; with the study team at the center.

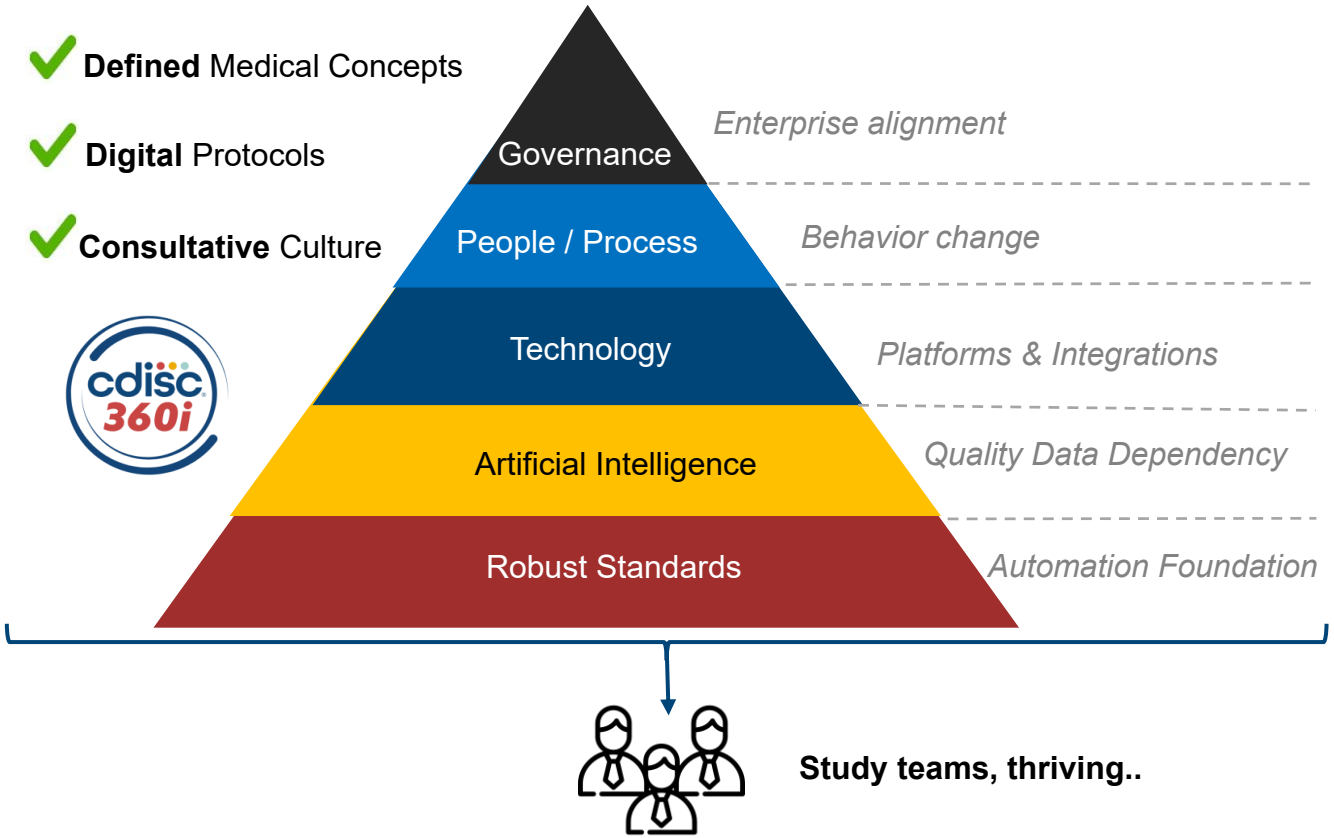
From – Today: Disconnected Information

- **Disconnected governance** — varying ownership models across the standards stack
- Standards exist but are **not enforced end-to-end**; no interoperability across the pipeline
- AI and automation **bolted on** after the fact, on an unstable foundation



To – CDISC 360i: Connected Foundation

- **Medical concepts → digital protocol → driving** downstream collection and analysis
- **End-to-end governance** across the full standards stack
- **People, process, governance, technology, AI** all working because the standards beneath them are connected
- **Study team at the center** — every layer serves them; 360i gets work off their plates



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Thank You!

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