



2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

CDISC 360i Phase 2: Lessons Learned and Road Ahead

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Speaker



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Chief Standards Officer
CDISC



Agenda

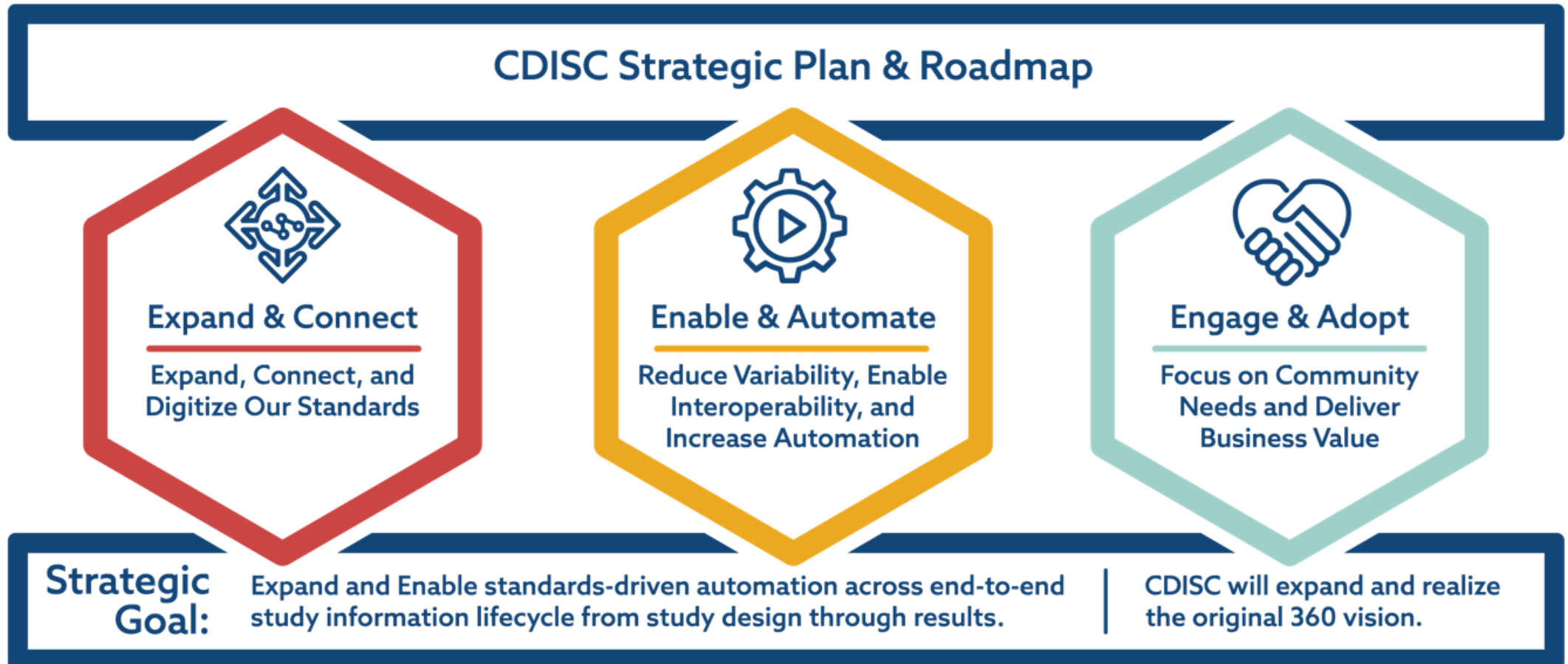
- CDISC Mission and 360i Goals
- 360i Phase 1 Achievements & Findings
- 360i Phase 2 Scope & Approach



CDISC Mission and 360i Goals

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

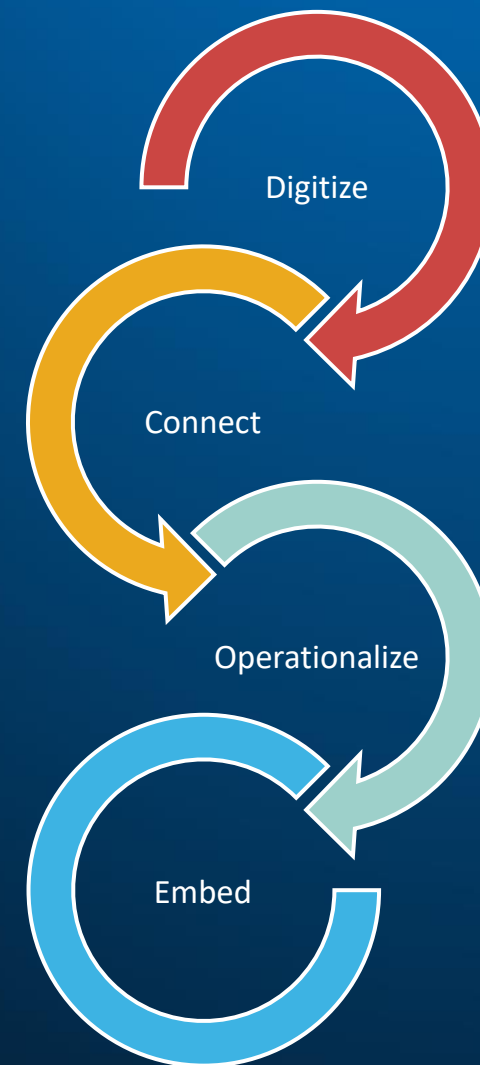
Unified semantic backbone that provides clarity and context



Accessible

Embedded in workflows to support informed, confident decisions

Path to 2030





360i Phase 1 Achievements & Findings

360i Focus

Data Sources



eDT



EDC

DHT



EHR

Data Standards
Biomedical Concepts
Analysis Concepts
Foundational Standards



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LIBRARY

Specifications



Data Collection

Tabulation

Analysis

Select
Biomedical
Concepts

Schedule of
Activities



Study Team



USDM



Protocol Outline

Build

Design

Extract



Tabulation
Datasets

Analyze



Analysis
Datasets

Output



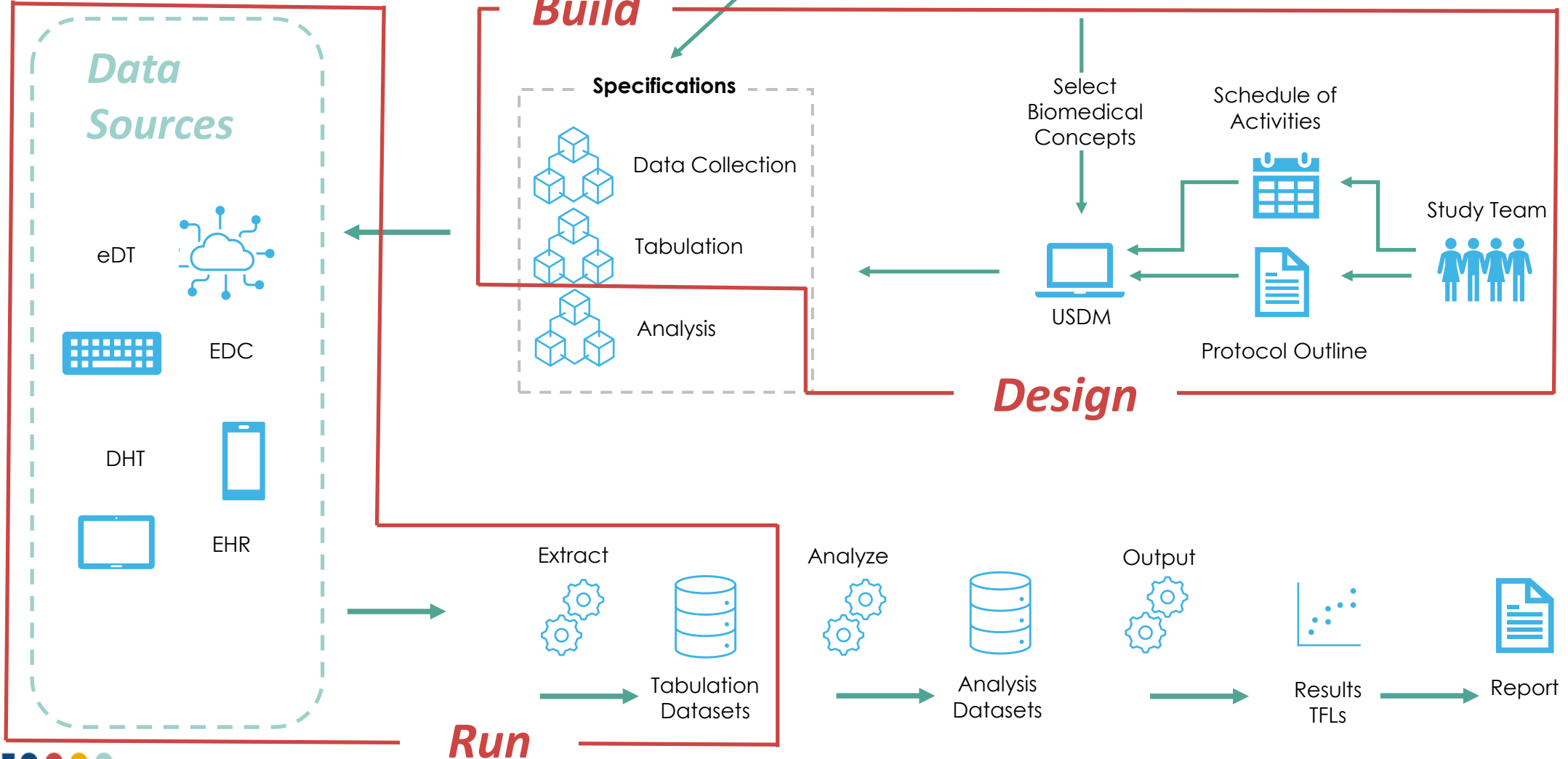
Results
TFLs



Report

Run

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

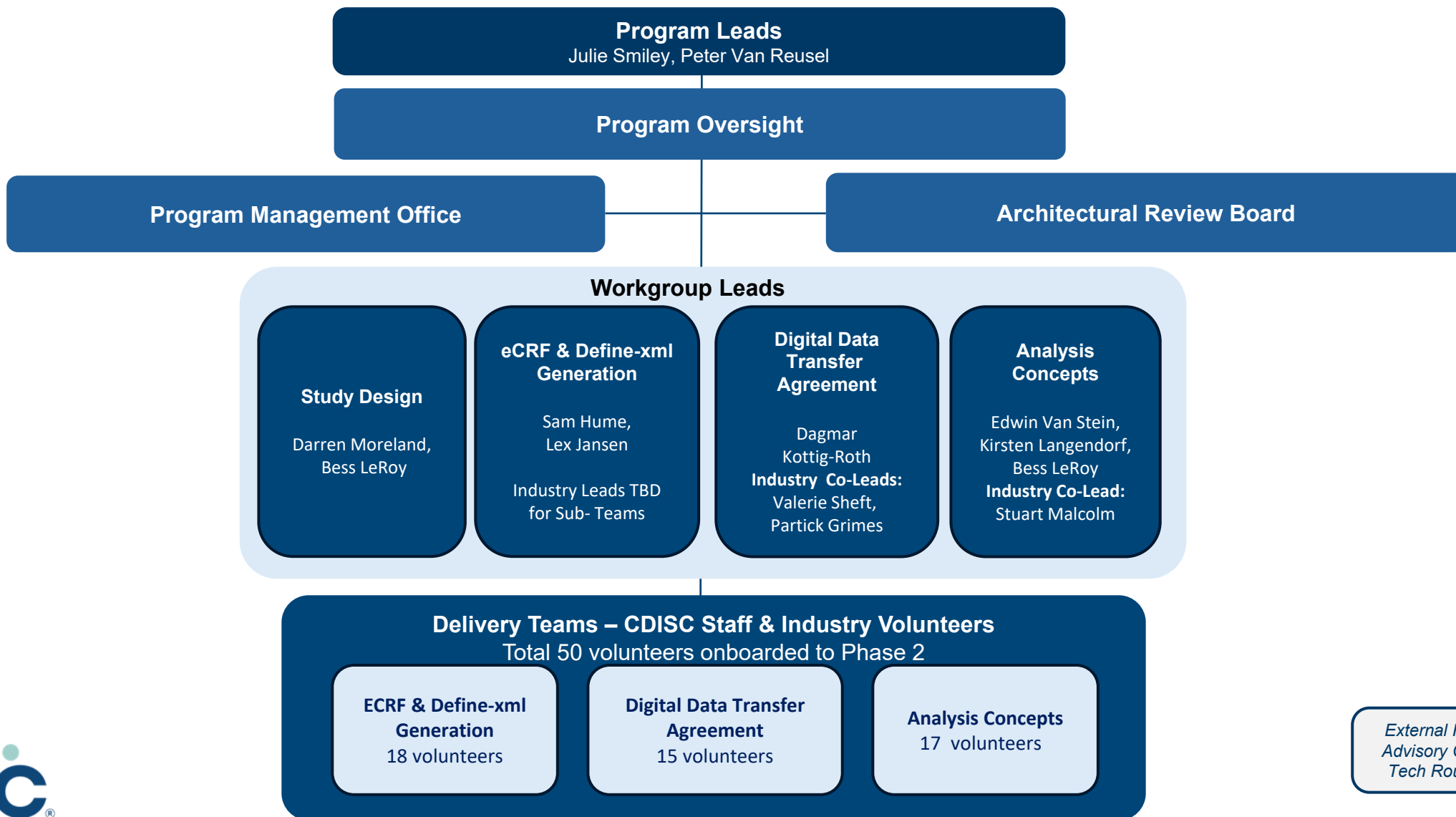
Automated eCRFs, Define & Dataset Generation: Generation of eCRFs, Define.xml and datasets integrated with study workflows

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 Program Structure



360i Phase 2 Focus

Data Standards
 Biomedical Concepts
 Analysis Concepts
 Foundational Standards

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 LIBRARY

Data Sources
 eDT
 EDC
 DHT
 EHR

Build
 Specifications
 Data Collection
 Tabulation
 Analysis

Select Analysis Concepts
 Select Biomedical Concepts
 Schedule of Activities
 Study Team
 USDM
 Protocol Outline

Run
 Extract
 Generate
 Analyze & Output
 Tabulation Datasets
 Analysis Datasets
 Results TFLs
 Report

Content Scope

Disease endpoints to exercise the AC/DC Model

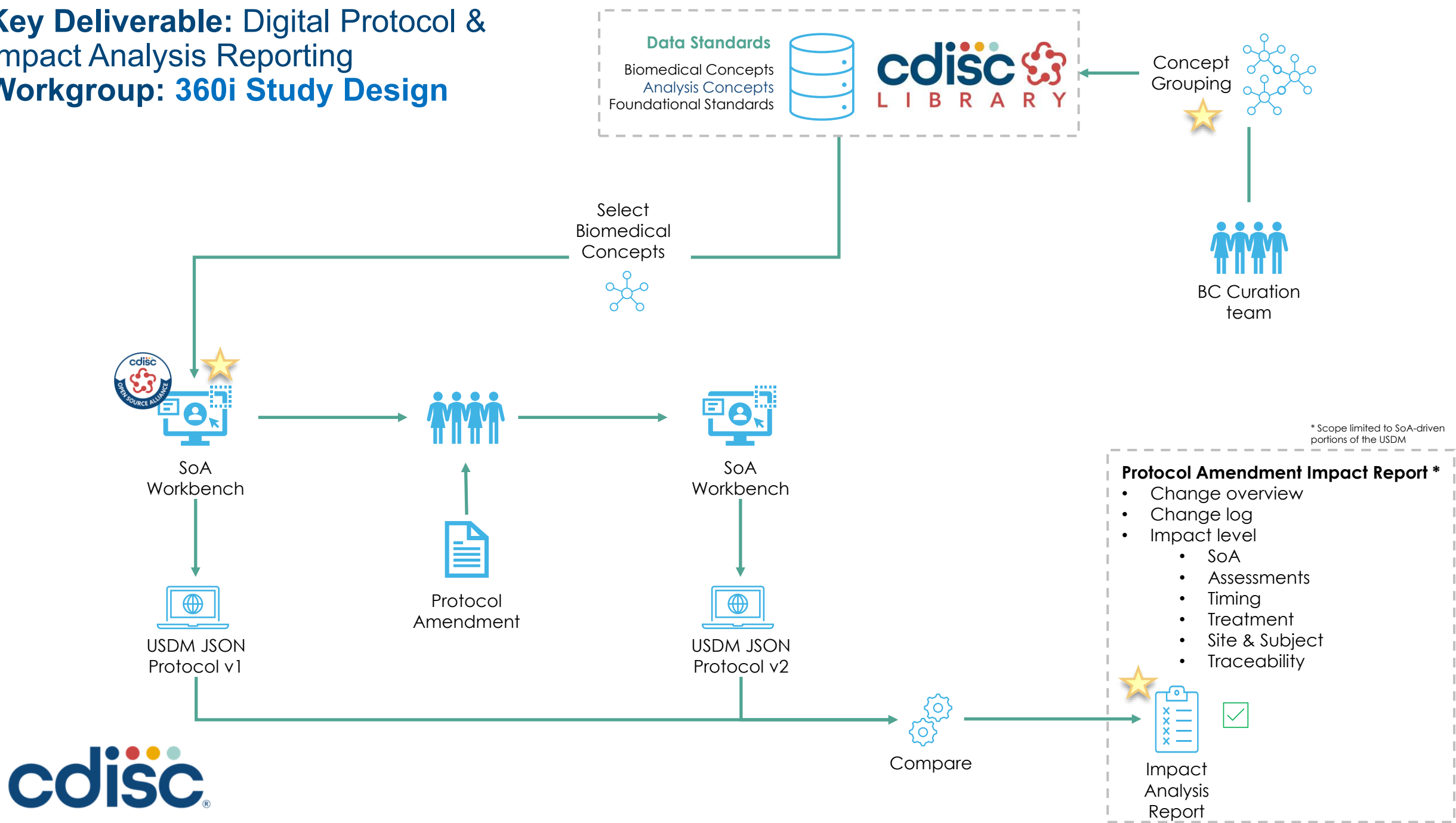
- Breast Cancer: Response Evaluation Criteria in Solid Tumors
 - Progression free survival
- Alzheimer's Disease: Alzheimer's Disease Assessment Scale-Cognitive Subscale
 - Change over time

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

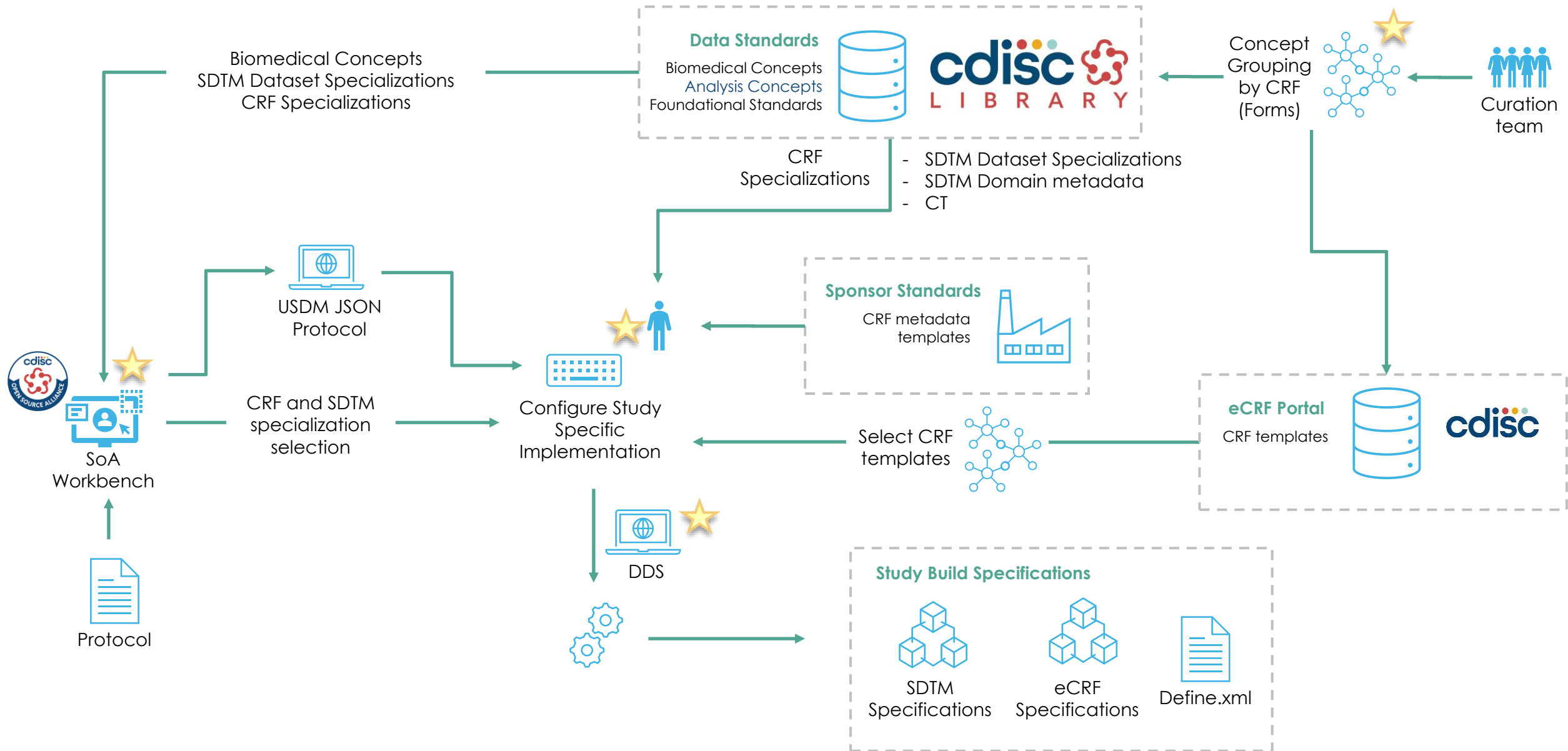
- Add and demonstrate BC groupings
- Develop and test the open-source SoA Workbench
- Generate protocol amendment impact assessment

Benefits

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

Key Deliverable: Automated eCRFs, Define & Dataset Generation

Workgroup: 360i eCRF & Define.xml Generation



360i eCRF & Define.xml Generation

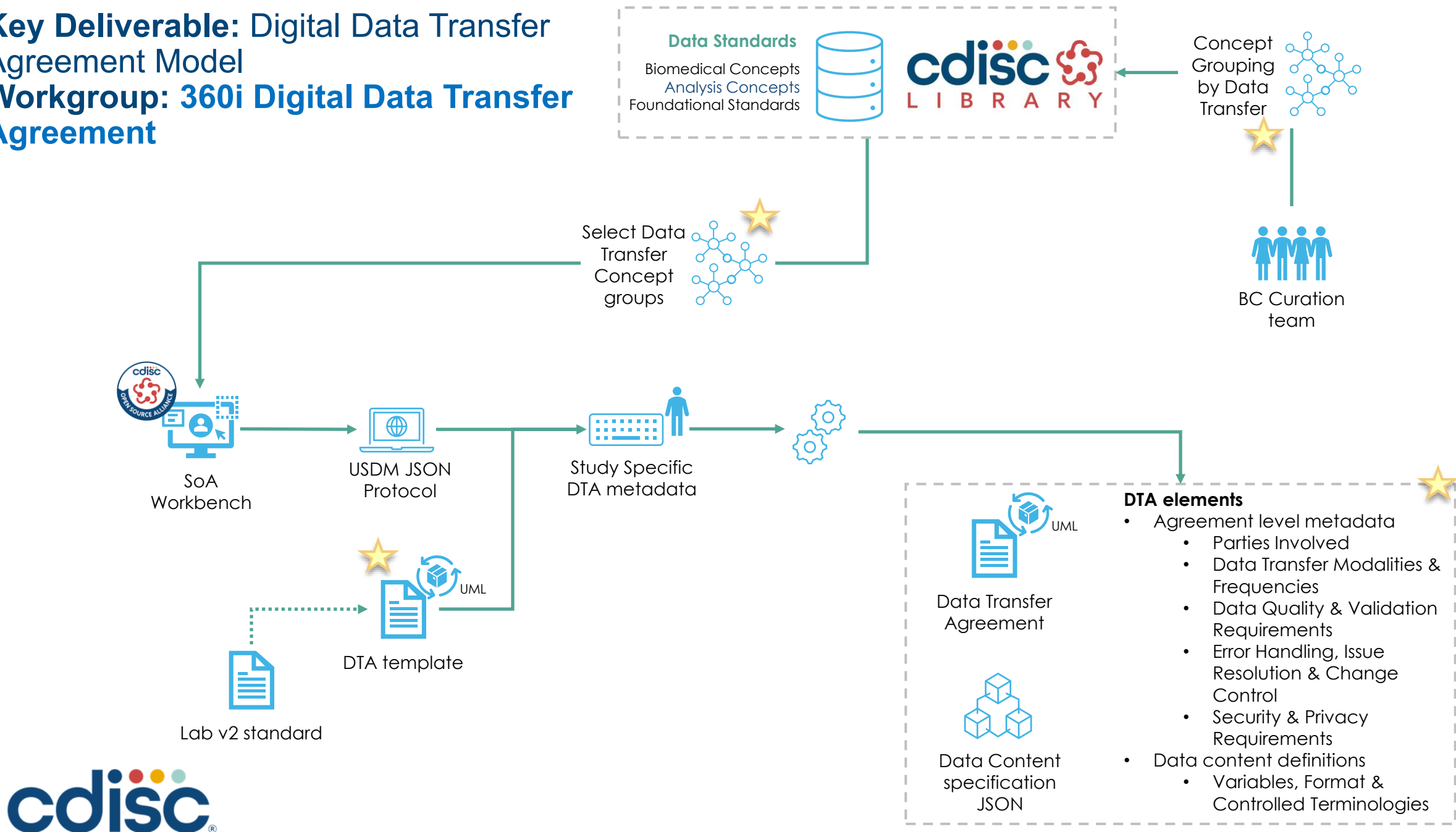
Main Activities

- 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)

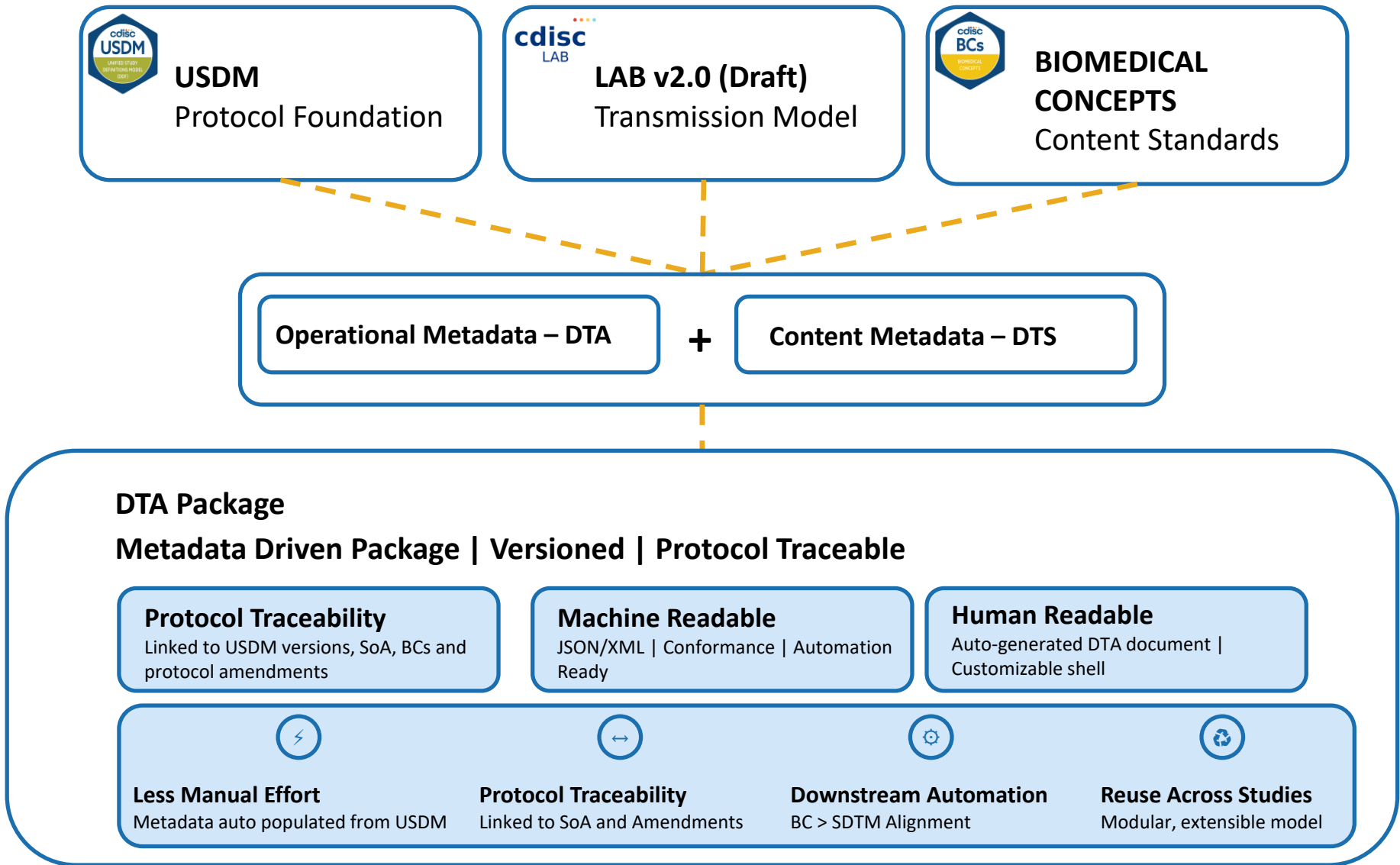
Benefits

- 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

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

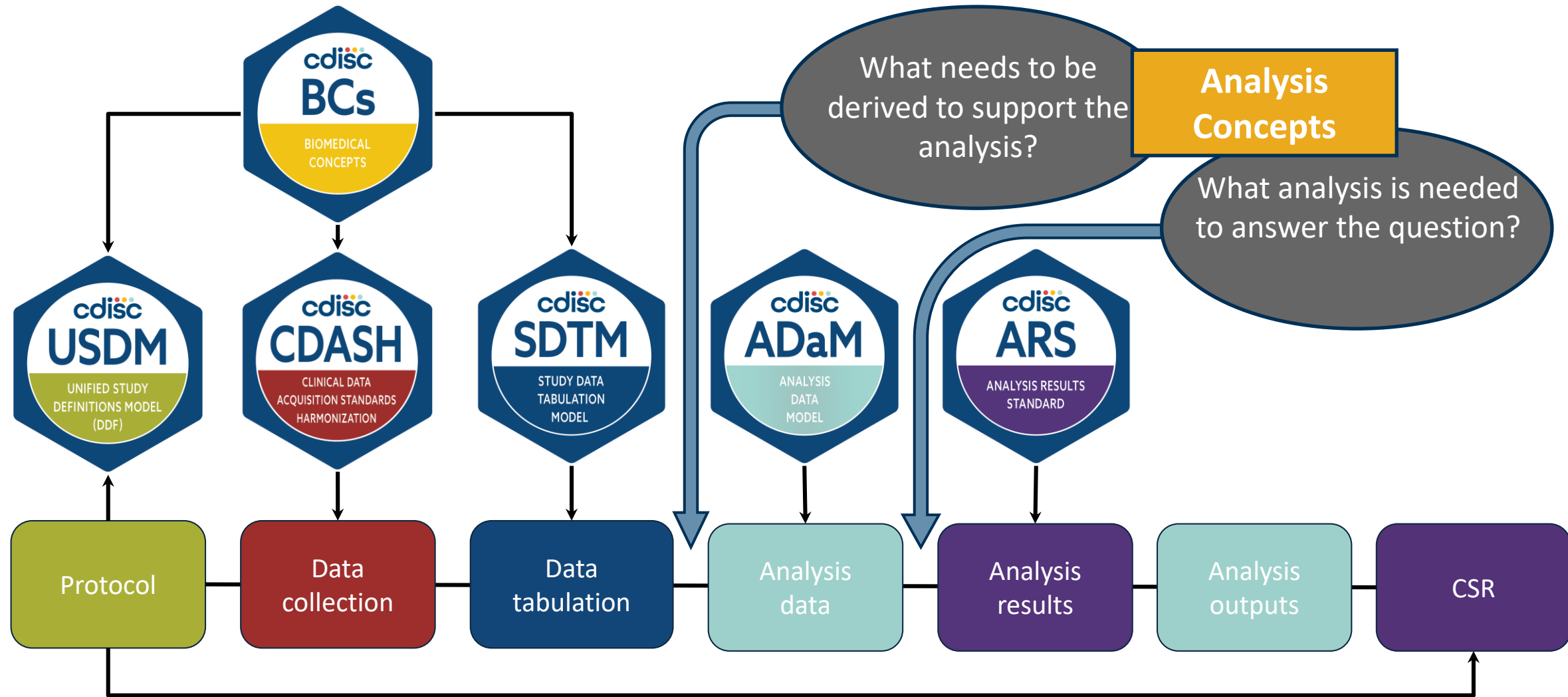
Main Activities

- 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

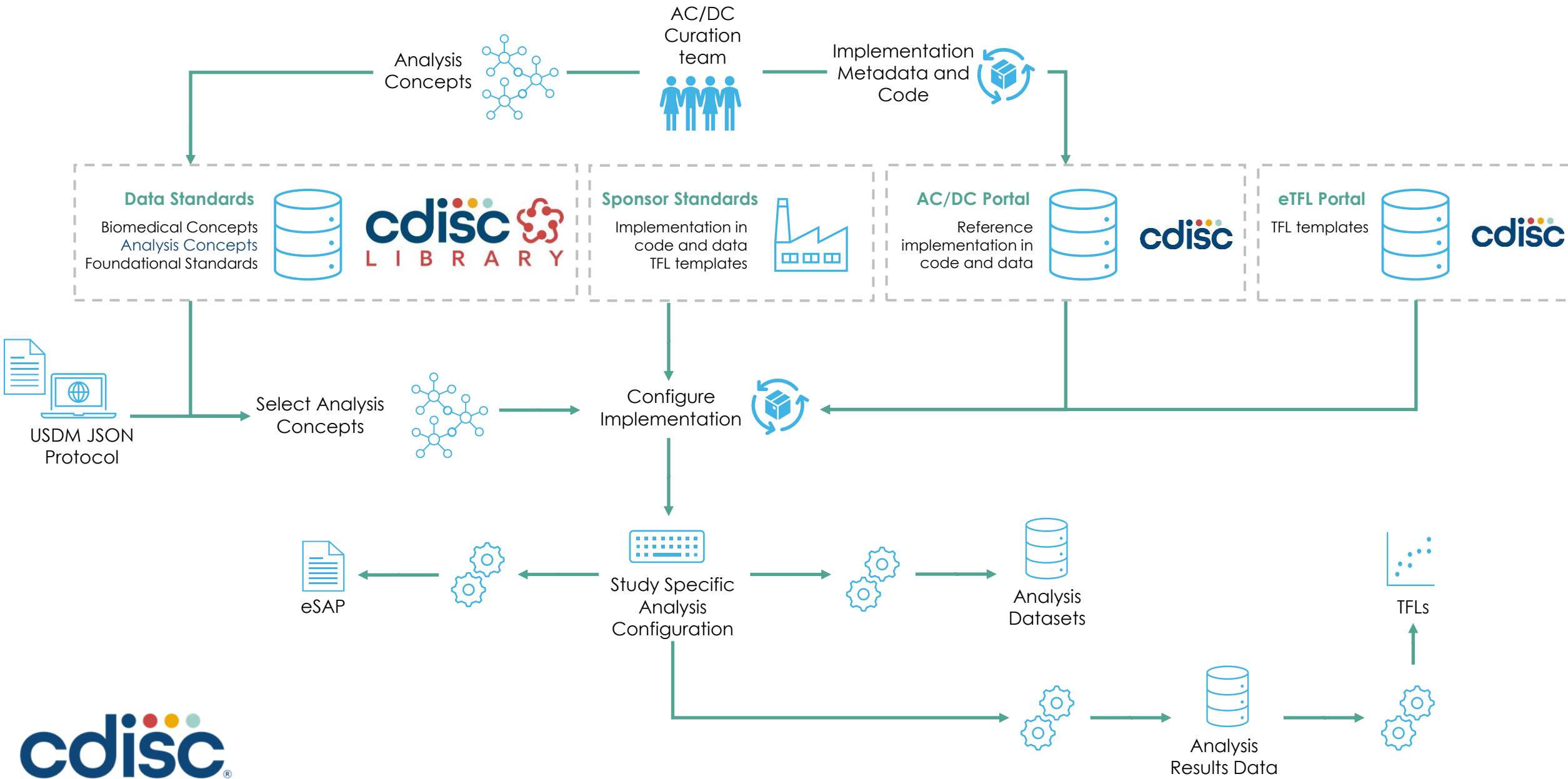
- Establish common DTA language and structure across the industry
- Provide faster, clearer, and more consistent data transfer agreements
- Reduce negotiation effort and automated specification generation

Where Analysis Concepts fit



Key Deliverable: Standardized Analysis Concept Model

Workgroup: 360i AC/DC Automation



360i AC/DC Automation

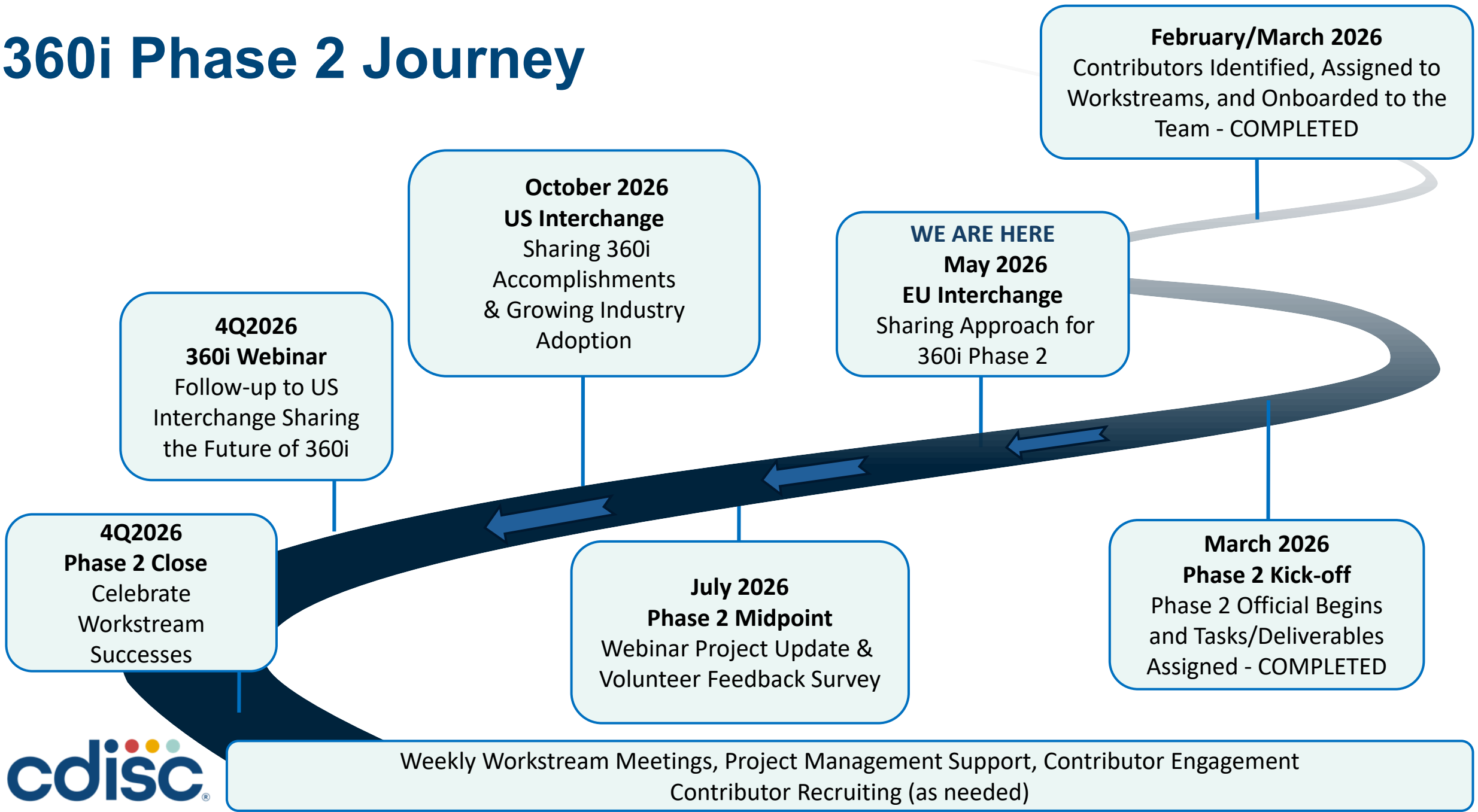
Main Activities

- 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

360i Phase 2 Journey





Thank You!

