360i Program Kickoff: Enabling Standards Driven Automation from Study Design Through Results
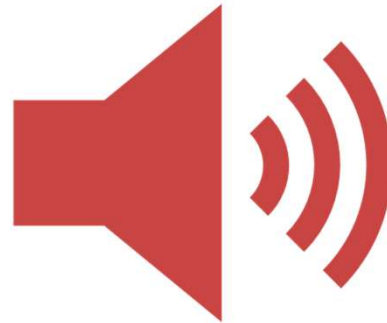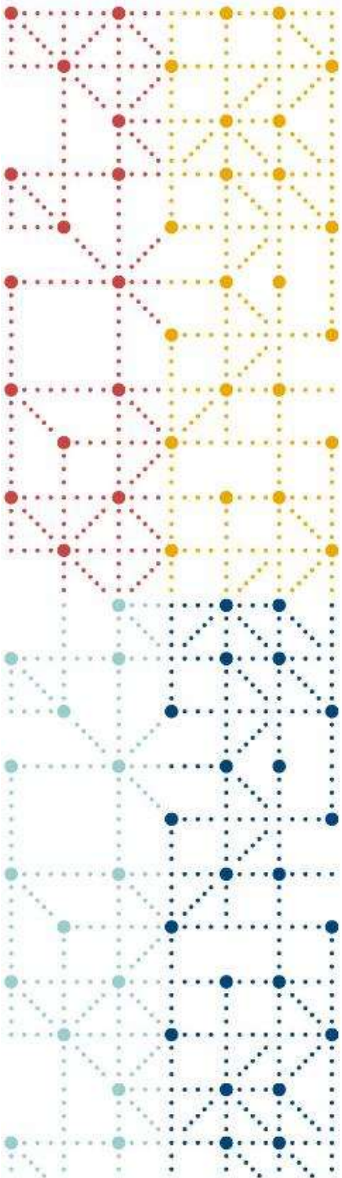
Joe Ben Clark / I.T. Director / Host

February 18, 2025
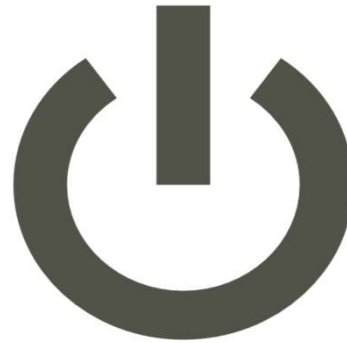
Housekeeping

Housekeeping

You will remain on **mute**

Housekeeping

Submit questions at any time via the Q&A section on your Teams app
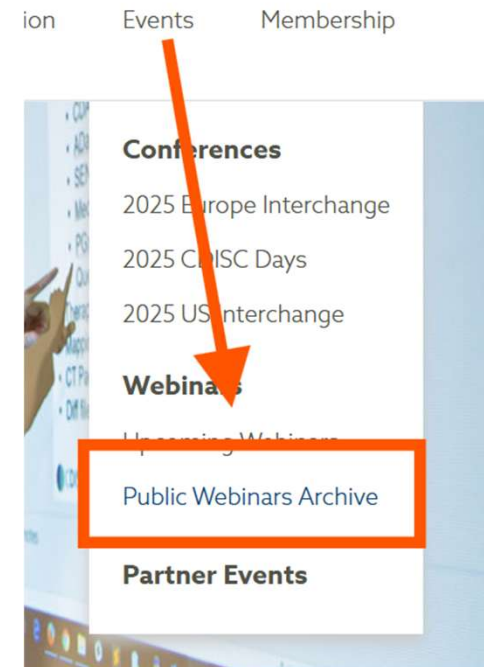
Housekeeping

Audio Issues?

First, close and restart your Teams App
Second, check your local internet connection strength
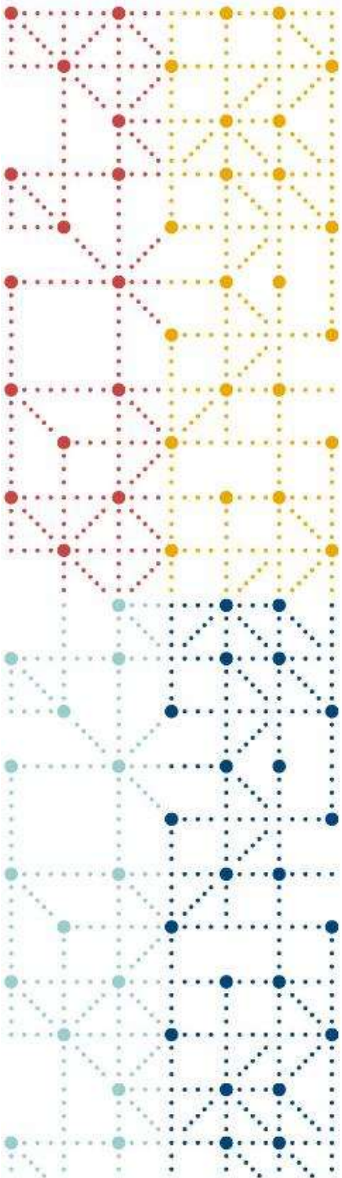
Housekeeping

Webinar Recording

A recording of this webinar and a PDF of the slides will be available in the Public Webinar Archive on the CDISC website.

Meet the Speakers

Chris Decker

Title: President and Chief Executive Officer

Peter Van Reusel

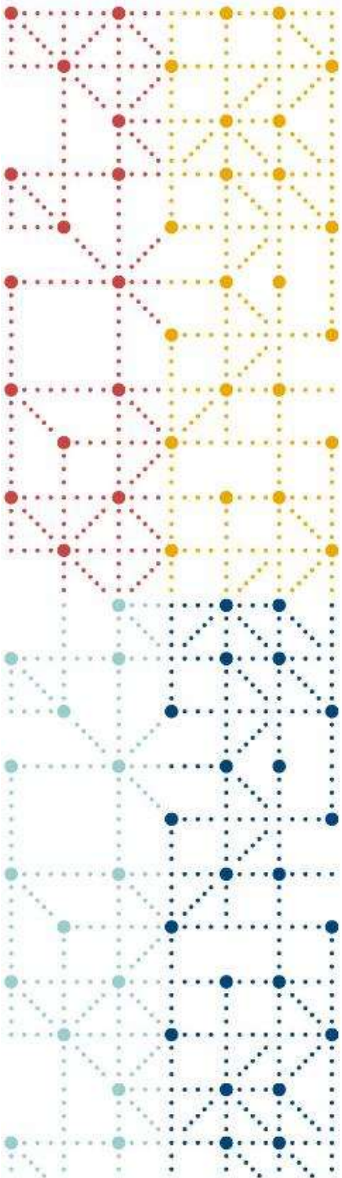Title: Chief Standards Officer

Sam Hume

Title: Principal Consultant

Charles Shadle

Title: Head of Data Science Operations

360i Program Kickoff
Enabling Standards Driven Automation from Study Design Through Results

Realizing the CDISC Vision & Mission

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

CDISC Strategic Plan & Roadmap

Expand & Connect
Expand, Connect, and Digitize Our Standards

Enable & Automate
Reduce Variability, Enable Interoperability, and Increase Automation

Engage & Adopt
Focus on Community Needs and Deliver Business Value

Strategic Goal: Expand and Enable standards-driven automation across end-to-end study information lifecycle from study design through results. | CDISC will expand and realize the original 360 vision.

360i: Next Step to Realizing Standards Driven Research
Intelligent protocol-driven research to improve patient outcomes

Science & Innovation

Study Design & Conduct

Study Analysis & Review

Standards Driven Automation

Well-defined scientific concepts

With a connected data life cycle

For traceable, interactive, and AI driven results

Value Of A Connected World

Transition standards use from necessary requirement to valuable enabler through connected and ready to use implementable standards.

Stakeholder	Value
Patients	Data that is easier to understand and extract making it more accessible to patients
Sponsors	Protocol driven research automating the metadata & data pipeline reducing time to study results & increasing quality
Regulators	Reduced variability & clickable traceability from analysis to the collected data increasing confidence in decisions
Researchers	Reduce barrier to entry and cost for standards through ready to use implementable standards & open source tools
Technologists	Provide machine readable and interoperable inputs and outputs for easier adoption by software solutions

Harmonization With Industry Ask

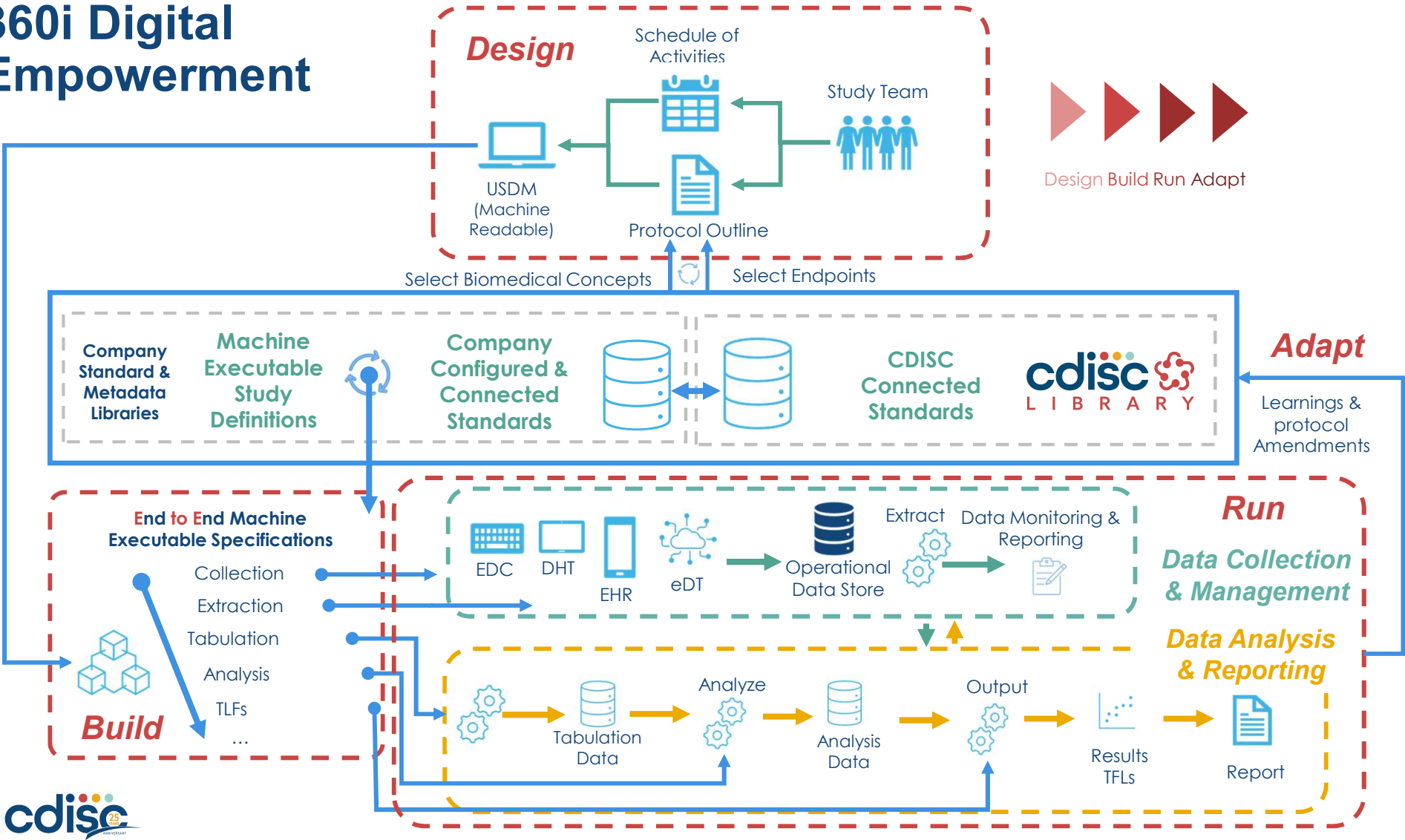| Concepts	E2E Standards	Collaboration	Commitment
• "Align on a standards-agnostic way to represent biomedical concepts used across clinical research and healthcare"	• "Conceptualize standards and solutions from end to end...trial design, collection, tabulation, analysis and reporting"	• "Common vision and commitment to accelerate the development of novel data standards...require experts (resource commitment), partnerships, investing in proof of concept"	• "Strong collaboration is needed between SDOs, regulators and biopharma representatives"

Reference: Data Standards White Paper
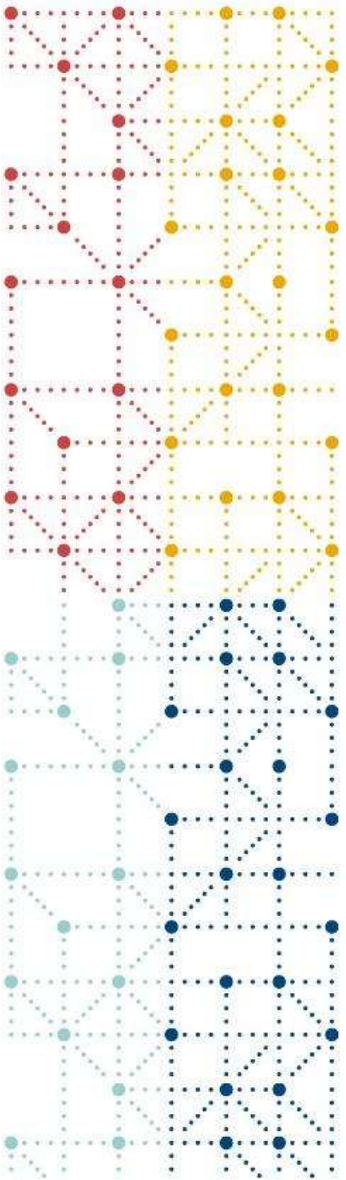
360i Vision and Overview

360i Digital Empowerment

Design

Schedule of Activities

Study Team

USDM (Machine Readable)

Protocol Outline

Design Build Run Adapt

Select Biomedical Concepts Select Endpoints

Company Standard & Metadata Libraries

Machine Executable Study Definitions

Company Configured & Connected Standards

CDISC Connected Standards

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Adapt

Learnings & protocol Amendments

End to End Machine Executable Specifications

Collection
Extraction
Tabulation
Analysis
TLFs
…

Build

Run

EDC DHT EHR eDT Operational Data Store Extract Data Monitoring & Reporting
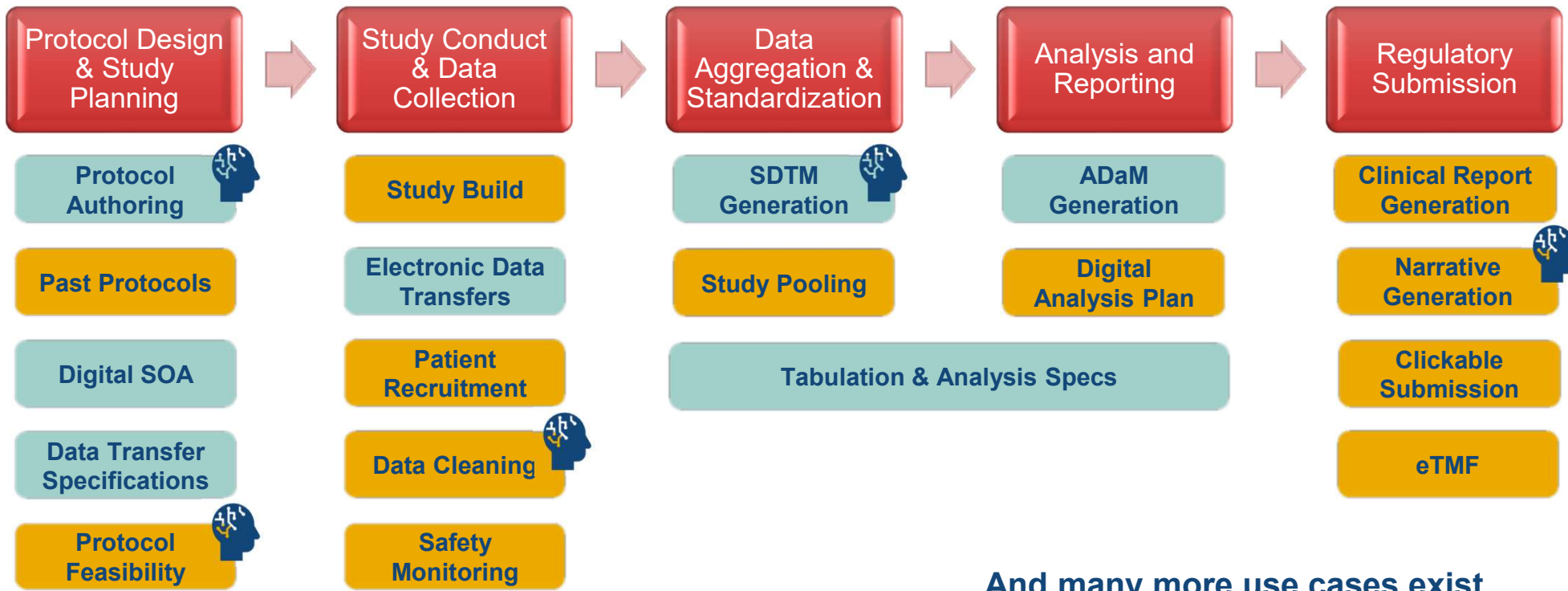
Data Collection & Management

Data Analysis & Reporting

Tabulation Data Analyze Analysis Data Output Results TLFs Report

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Use Cases 360i Can Enable

Potential AI Use Cases

Initial 360i Focus

Potential future uses

Protocol Design & Study Planning	→	Study Conduct & Data Collection	→	Data Aggregation & Standardization	→	Analysis and Reporting	→	Regulatory Submission
Protocol Authoring		Study Build		SDTM Generation		ADaM Generation		Clinical Report Generation
Past Protocols		Electronic Data Transfers		Study Pooling		Digital Analysis Plan		Narrative Generation
Digital SOA		Patient Recruitment		Tabulation & Analysis Specs				Clickable Submission
Data Transfer Specifications		Data Cleaning						eTMF
Protocol Feasibility		Safety Monitoring						

And many more use cases exist...

Governance & Reusability

Artifact Recommendations **Semantic Interoperability** **Built In Traceability** **Standards Conformance**

The Possibilities Of AI…

Protocol Feasibility

- Extracts study definitions from non-digitized protocols using NLP
- Automated protocol review summary
- Standards: PRM, M11, USDM, and BCs

Business Benefits:
Faster protocol finalization
Reduced amendments
Optimized study design

Data Cleaning

- Analytics automation
- Discrepancy detection (i.e., Missing values, anomalies, gaps in traceability)
- Standards: CDASH, USDM, CT, and BC

Business Benefits:
Improved data quality
Reduced study costs
Better decision-making

Artifact Recommendation

- Analyze protocols, CRFs, SAPs, and historical data to recommend artifacts
- Extract study definitions to recommend previously used metadata/standards
- Standards: all

Business Benefits:
Faster artifact creation
Improved compliance
Better consistency

360i Journey: Ideas → Implementation → Common Practice

Define and digitize E2E standards

Accelerate study design and build through digitized standards

Demonstrate automated data flow from design to analysis

What Will 360i Deliver?

- Linked and executable metadata from study endpoint through analysis
- Includes concepts, rules, & sample data

Standards Packages

- Instructions to build standards packages
- Recipes to implement packages within your processes

Implementation Cookbooks

- Technology enabled example leveraging packages & recipes
- Library of community based open-source tools

Example Implementations
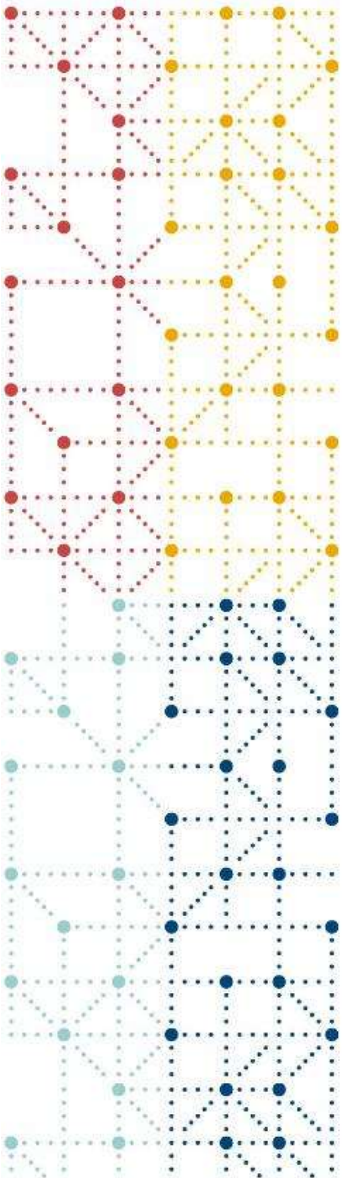
360i Phase 1: First Step in Realizing End to End Connected Standards

360i Phase 1 Objectives
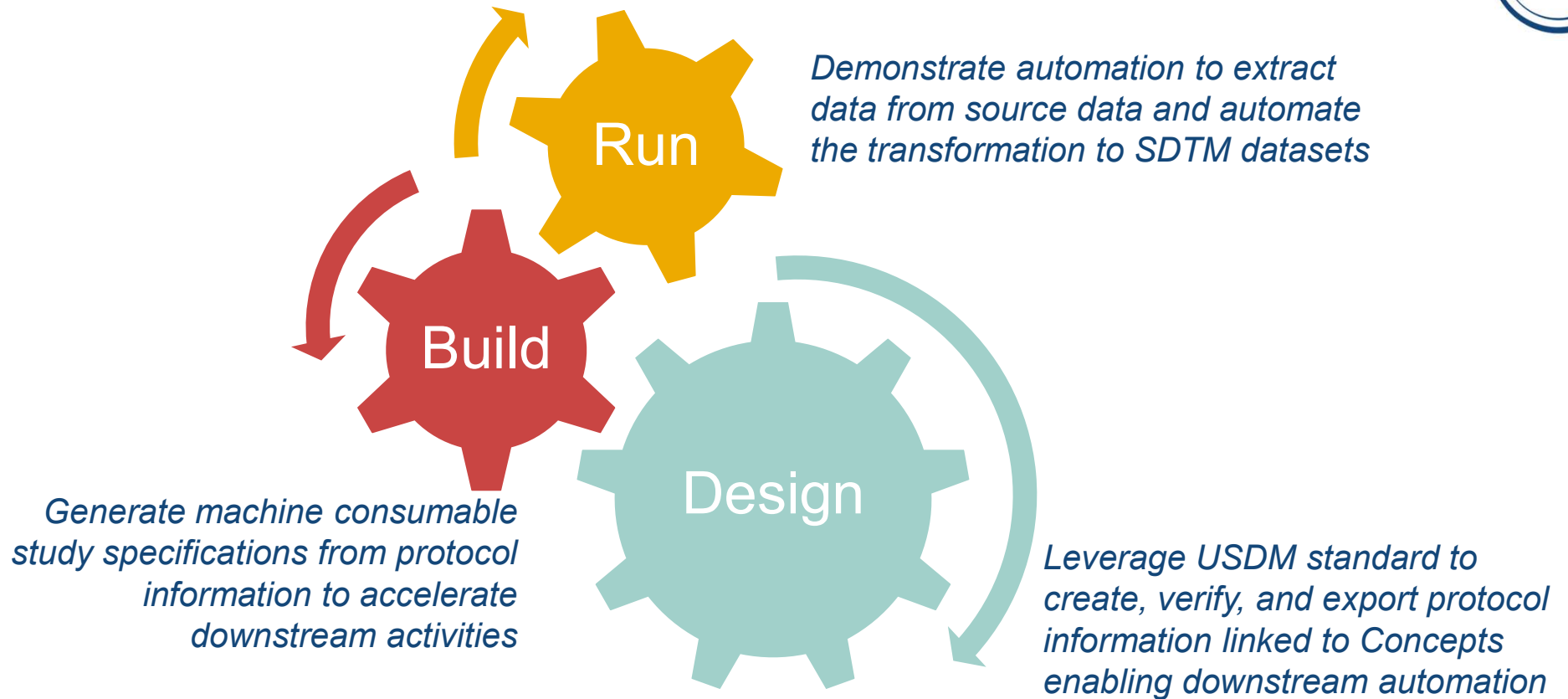
Run: Demonstrate automation to extract data from source data and automate the transformation to SDTM datasets

Build: Generate machine consumable study specifications from protocol information to accelerate downstream activities

Design: Leverage USDM standard to create, verify, and export protocol information linked to Concepts enabling downstream automation

360i Phase 1

Data Standards
Biomedical Concepts
Analysis Concepts
Foundational Standards

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Data Sources

eDT

EDC

DHT

EHR

Specifications

Data Collection

Tabulation

Analysis

Select Biomedical Concepts

Schedule of Activities

Study Team

USDM

Protocol Outline

Extract

Tabulation Datasets

Analyze

Analysis Datasets

Output

Results TFLs

Report

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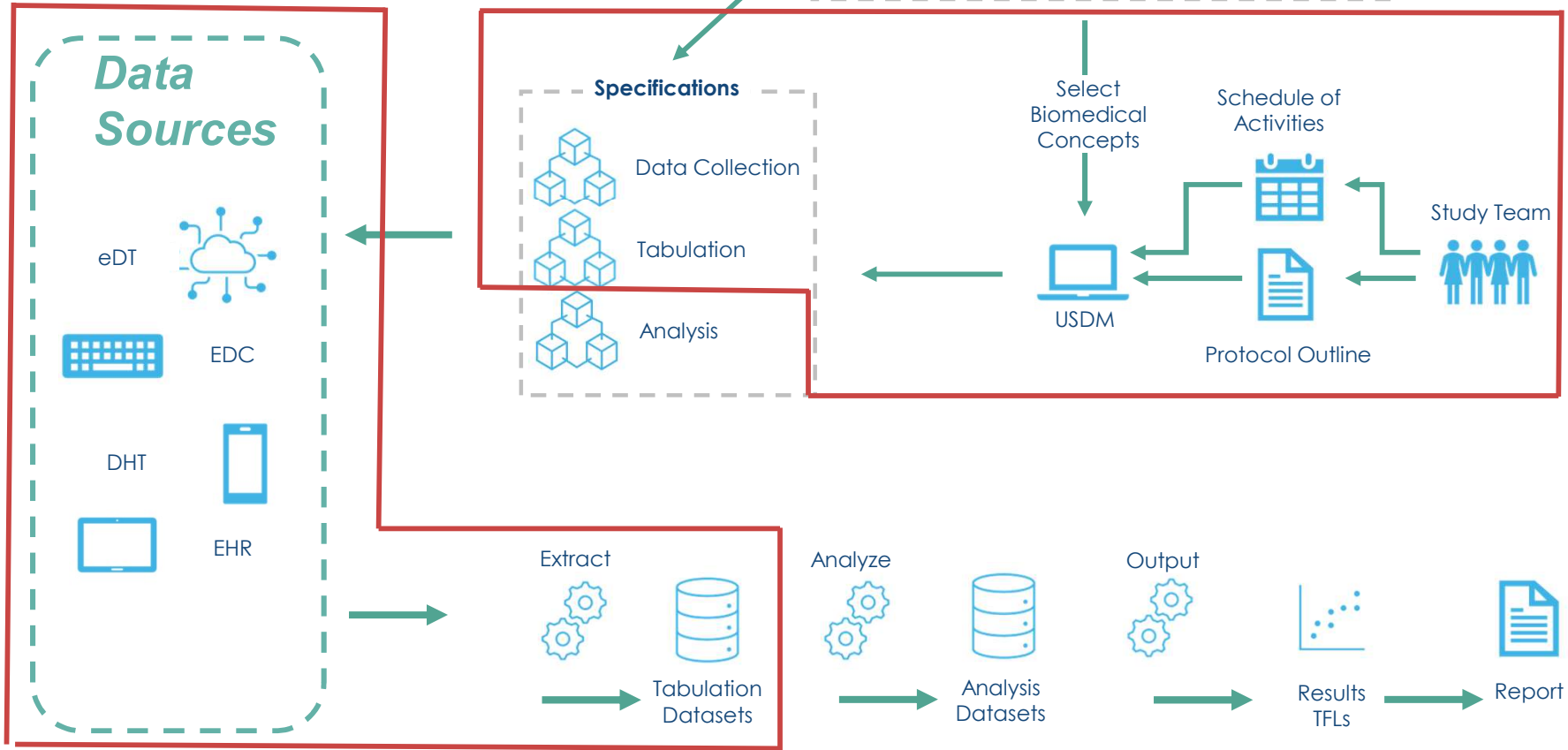
Content Scope: Implementing Breadth/Depth of Endpoints

Safety Assessments

✓ Demography

✓ Death Details

✓ Adverse Events

✓ Disposition

✓ Change from Baseline Labs

✓ Vital Signs

✓ Drug Induced Liver Injury (DILI)

Questionnaire

✓ ADAS-Cog

Digital Measure (DHT)

✓ Glucose Monitoring

✓ Steps / Movement / Sleep

Efficacy Endpoint Assessments

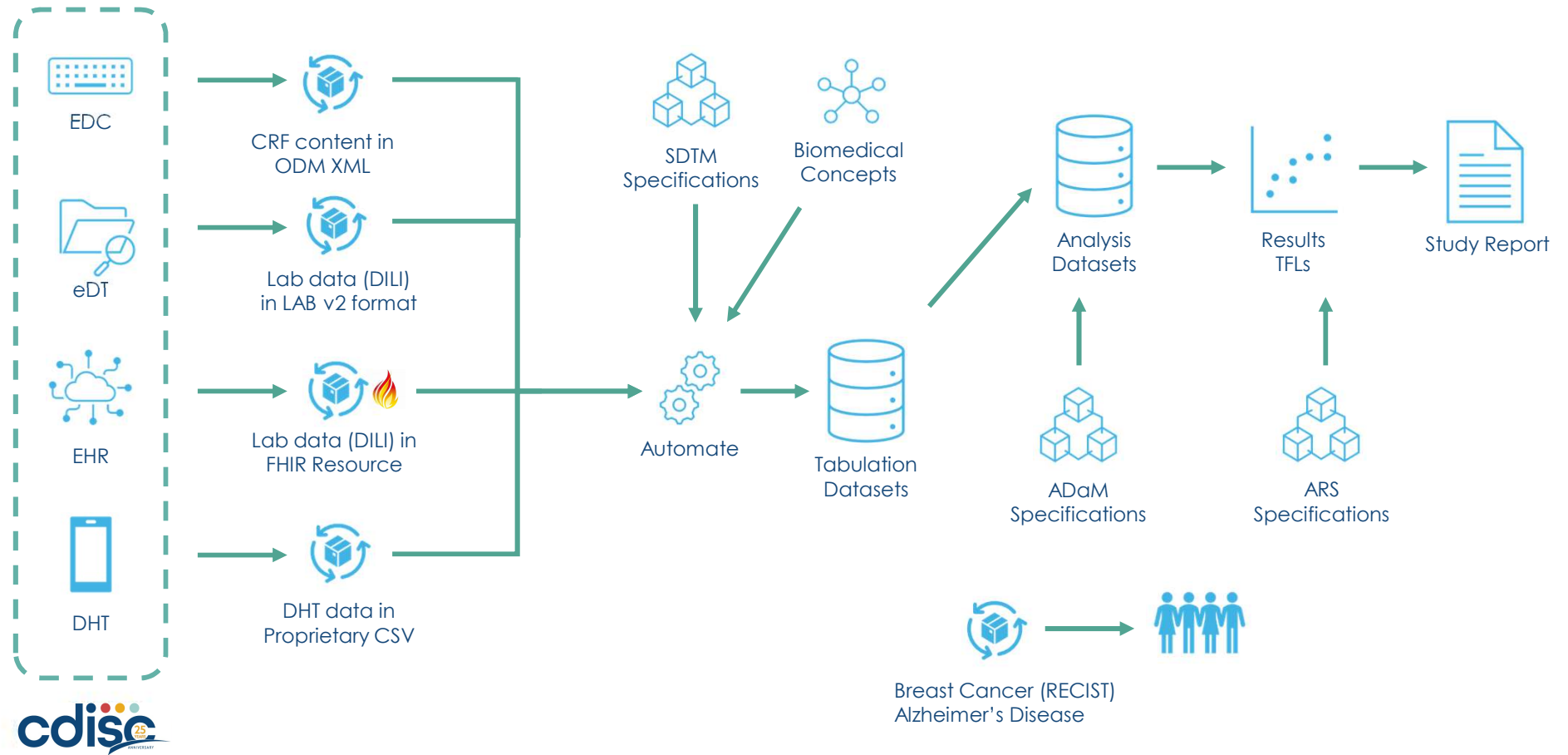✓ Breast Cancer (RECIST)

✓ Alzheimer's Disease

Why This Scope?

➢ *Leverage what is well known and a set of artifacts already available*

➢ *Use diverse set of data sources to demonstrate different data pipeline flows*

➢ *Focused and doable – need to get it right and build the playbook*

360i Study Design

360i Study Build

eCRF Portal

Data Standards
Biomedical Concepts
Analysis Concepts
Foundational Standards

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Safety Assessments
- Demography
- Death Details
- Adverse Events
  - Overview
  - By SOC and PT
  - By Freq
- Disposition
- Change from Baseline Lab
  - Chemistry
  - Hematology
  - Vital Signs

Safety Assessments
- DILI

Questionnaire
- ADAS - COG

Digital Measure (DHT)
- Glucose Monitoring
- Steps / Movement / Sleep

Efficacy Endpoint Assessments
- Breast Cancer (RECIST)
- Alzheimer's Disease

Digital SoA

Select eCRF templates

Generate eCRF

Generate eDT

Electronic Data Transfer (eDT)

eCRF Template

eCRF Specifications

FHIR observation resource

Select eDT

Predefined eDT

Define.xml

SDTM Specifications

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360i Phase 1 Activities

Create connected standards (packages) from study endpoints through SDTM and demonstrate automation

Build and broaden biomedical concepts community to operationalize curation and accelerate content

Establish industry think tank to align on definition and scope of analysis concepts by EOY for implementation in 2026

Deliver on CDISC Open Rules scope, Engine 1.0, and plan for inclusion of conformance rules in all future standards

Continue to partner with TransCelerate and industry to drive digital protocol adoption

Define roadmap and scope for digitizing the Trial Master File (TMF)
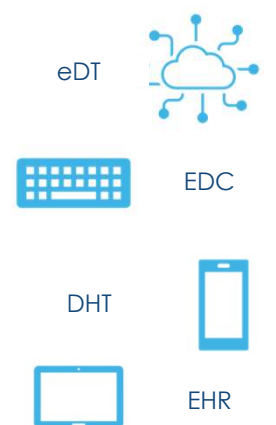
360i Phase 2 Workflow

Data Standards
Biomedical Concepts
Analysis Concepts
Foundational Standards
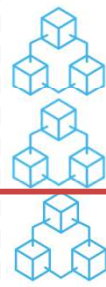
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Data Sources

eDT

EDC

DHT

EHR

Specifications

Data Collection

Tabulation

Analysis

Select Analysis Concepts

Select Biomedical Concepts

Schedule of Activities

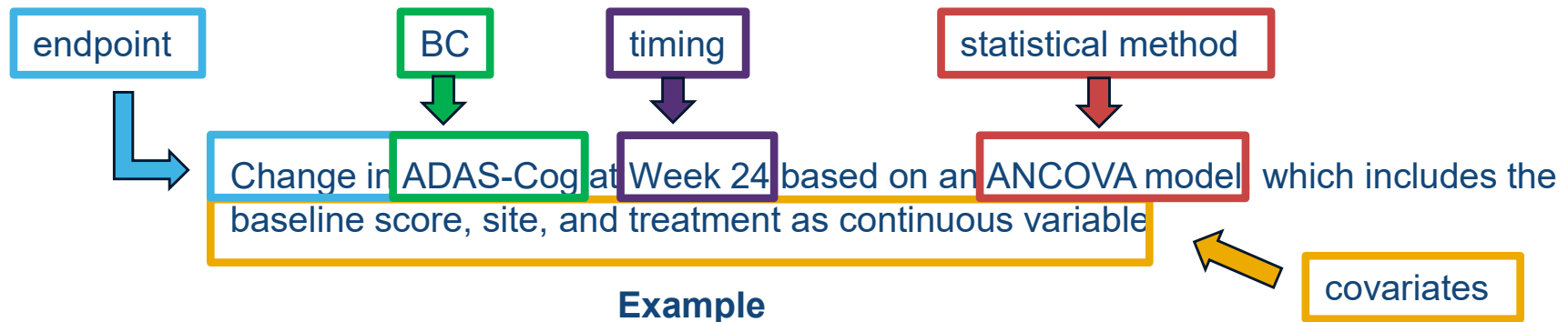Study Team

USDM

Protocol Outline
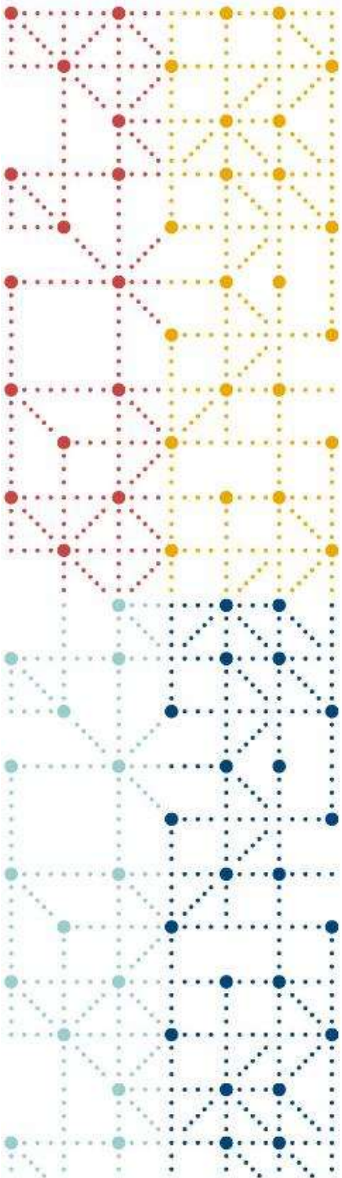
Extract

Tabulation Datasets

Analyze

Analysis Datasets

Output

Results TFLs

Report

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Analysis Concepts

- What is an Analysis Concept?
  - Collection of standardized configurable elements & methods that are needed to describe a final output or answer a clinical question
  - Standard definitions in a digital statistical analysis plan

- What is the purpose of an Analysis Concept?
  - Supports configuration and automation of analysis
  - Informs what needs to be collected to answer the clinical question

endpoint   BC   timing   statistical method

Change in ADAS-Cog at Week 24 based on an ANCOVA model which includes the baseline score, site, and treatment as continuous variable

covariates

Example

360i Phase 1:
Technology Enabled Standards

What's Changed Since CDISC 360 POC?

New Standards:

- DDF USDM

- Analysis Results Standard

- Biomedical Concepts and Dataset Specializations

- sdtm.oak transformations

- Dataset-JSON for dataset exchange

- Open conformance rules

New Software Tools:

- Open Study Builder

- TLF Designer

- admiral

- CORE

- sdtm.oak

- Dataset-JSON conversion tools

- Other COSA tools

- Other Pharmaverse tools

These lists are examples and not intended to be comprehensive

Software Tools Since CDISC 360 POC*

Study Design	Data Collection	SDTM	ADaM	Define-XML	ARS
Open Study Builder	odmlib	sdtm.oak	admiral	OpenCST	siera
Study Definitions Workbench	ODM XML Stylesheet	Dataset-JSON Tools	Dataset-JSON Tools	defineR	cards
BC Browser	XMLMAP	CORE	carver	odmlib	gtsummary
DDF SDR	Open Study Builder	datacutr	Dataset-JSON Viewers	Define XSL Stylesheet	tidyCDISC

* Examples listed – not a comprehensive listing

What Is A 360i Package?

360i has published a complete pre-configured study package with all the components defined in metadata from study design to submission, test data for the study, and open-source software to run the study data pipeline to generate analysis results

High Level Roadmap
Phase 1

Roadmap does not need to be completed sequentially in all cases

1. Study Design

2. CRFs & eDTs

3. SDTM Define-XML

4. aCRFs

5. Shell Datasets

6. Populate CRFs

7. ODS

8. oak.sdtm Algorithms

9. SDTM Datasets

10. Open Rule Set

11. Conformance Report

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Timeline, Team Structure, and How You Can Support 360i!

Phase 1: High Level Roadmap

Kickoff
Scope, methodology, onboarding of industry contributors and program kickoff

Summer Pulse Check
Semi-Automated Pipeline (Protocol – SDTM shell datasets)

Publication
Automated Study Data Pipeline Package
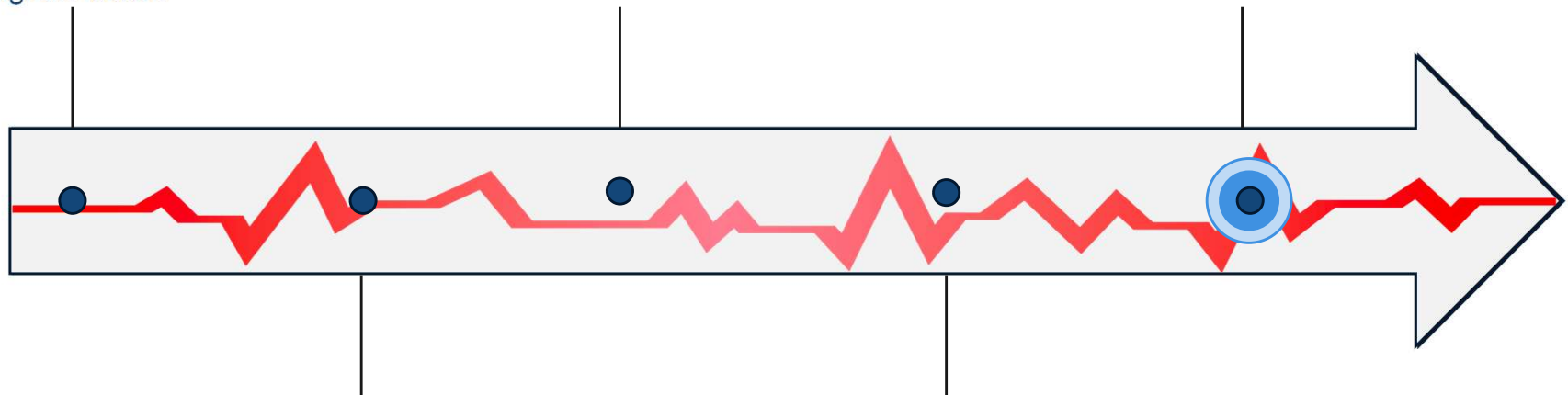
EU Interchange
Manually integrated Pipeline (some automation links)

US Interchange
Automated Pipeline (Protocol – SDTM)

360i Operational Team

Operational Steering Committee

Business Sponsor	Technical Sponsor	Program Management
Business Delivery	Technical Delivery	Community Engagement

Industry Delivery Leads

✓ Steer the program
✓ Engage the community
✓ Deliver on scope
✓ Collaborate as integrated team
✓ Iterate and solve problems

Design, Build, and Run Delivery Teams

Delivery Leadership Team
CDISC Business & Technical Leads
Industry Co-Leads

Business/SME Team
CDISC Business Leads &
Industry Co-Leads
- Design
- Build
- Run

Technology & Modeling Team
CDISC Technical Leads
Industry Co-Leads

Industry Contributors

Parallel Focus Teams

BC Curation CDISC Lead	Analysis Concepts CDISC Lead
Industry Co-Leads	Industry Co-Leads

CDISC Open Rules CDISC Lead	TMF Digital Model CDISC Lead
Industry Co-Leads	Industry Co-Leads

41

360i Industry Ask: We Need Contributors, Not Observers

Team Co-Leads

- Request 40% commitment for 1 year
- 3 Leads for Business Delivery Team
- 2 Leads for Technical Team
- 2 Leads for each of the focus teams

Team Contributors

- Request 20% commitment committed to one or more teams for 6 month minimum
- Expertise in key areas of the 360i initiative
- Commitment from company to support your contribution

Co-Lead & Contributor Requirements

- ✓ CDISC Member
- ✓ Company commitment over individual commitment
- ✓ Innovative and flexible
- ✓ Collaborative and willing to compromise
- ✓ Hands on keyboards
- ✓ Follow CDISC Core Values:
  #FullyCommit
  #FocusOnCommunityNeeds
  #SolutionsMindset
  #AccountableForResults
  #LivetheGoldenRule

CDISC 360i Community Engagement Model

CDISC Community Engagement Team

Business Liaison	Tech Liaison	Engagement Manager	Communications Lead

Business, Technology, and Standards SMEs as Needed

Business Advisory Council
- 6-8 members Meeting Quarterly
- Industry Business/Standards Leaders from CDISC members
- Focus: 360i Strategy and progress Feedback , Business need/process

Technical Advisory Council
- 6-8 members Meeting Quarterly
- Technology Leaders from CDISC members (non-vendors)
- Focus: 360i Strategy and progress Feedback, Technology Roadmap

Technology Vendor Roundtable
- Open meeting quarterly
- CDISC Member Vendors
- Extract Technology Requirements
- 360i Readout & Feedback Sessions

✓ Continuous feedback with industry leaders ensuring 360i is pointing in the right direction and aligning with CDISC community needs
✓ Members will be selected and serve minimum of 1 year (business and technology committees)
✓ Technology roundtable engaging with vendor community to share and gather feedback on whether 360i outputs are meeting vendor needs

Contributor Expertise Desired

Standards	Foundational: CDASH, SDTM, Terminology
	Interchange: ODM, Define.xml, and Dataset JSON
	Models: USDM, ARS, Open Rules
Business	Business process, change management, study execution
	Data management, programming, and analysis
	Breast Cancer & Drug-Induced Liver Injury
Technology	Data modeling and biomedical concepts
	APIs, Python, R, GitHub
	JSON, FHIR, YAML

Next Steps

Webinar

- Share the 360i Roadmap
- Call for Action for team contributors

Kickoff: March

- Assemble contributors
- Define detailed charters
- Kickoff meeting with contributors

CDISC Interchange: May

- First Milestone: SOA to Specifications for targeted content
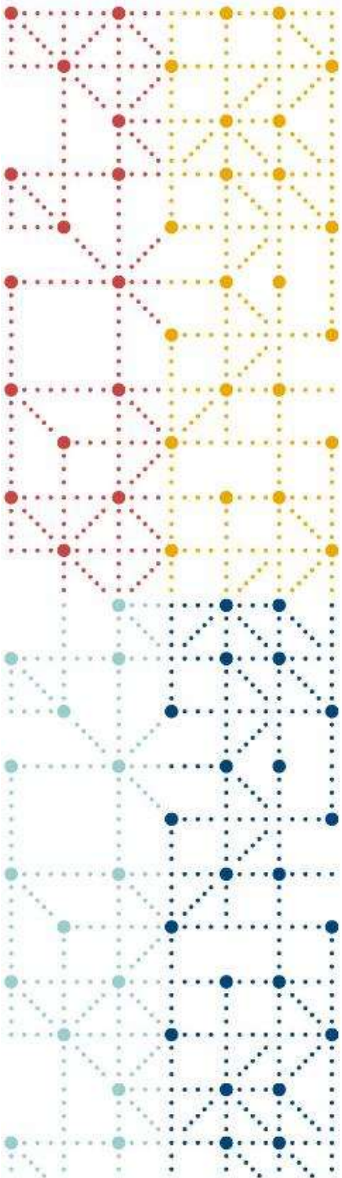- F2F 360i Working meeting to define next Iteration

We Need You!

- Be part of the team to drive this forward

- We need committed contributors AND…companies that support the goals

- Click on QR Code below to volunteer

- Make sure to select 360i from the list!

https://www.cdisc.org/volunteer

✓ Complete CDISC Volunteer Form
✓ Complete 360i Contributor Survey

Thank You!

360i Operational Team

Operational Steering Committee

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Business Delivery	Technical Delivery	Community Engagement

Industry Delivery Leads

✓ Steer the program
✓ Engage the community
✓ Deliver on scope
✓ Collaborate as integrated team
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Design, Build, and Run Delivery Teams

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Industry Co-Leads

Business and SME Team
CDISC Business Leads & Industry Co-Leads

Design	Build	Run

Technology & Modeling Team
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