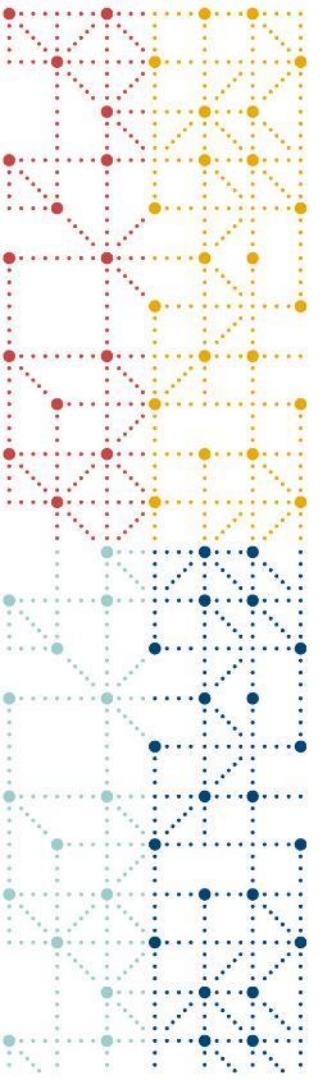


CDISC 360i: Implementing the CDISC Roadmap Connecting Standards from Design to Analysis

Chris Decker & Peter Van Reusel, CDISC







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

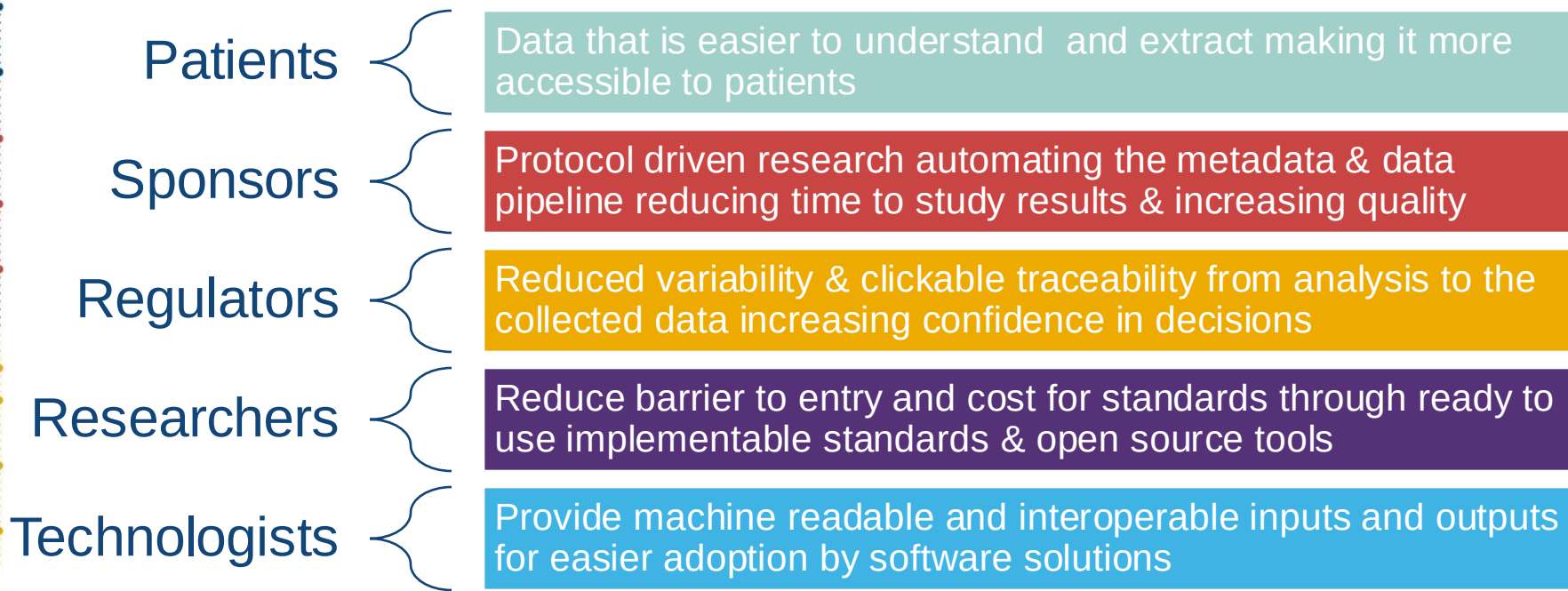
Strategic Goal:

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.

Value Of A Connected World

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



Harmonization With Industry Ask

Concepts

- *"Align on a standards-agnostic way to represent biomedical concepts used across clinical research and healthcare"*

E2E Standards

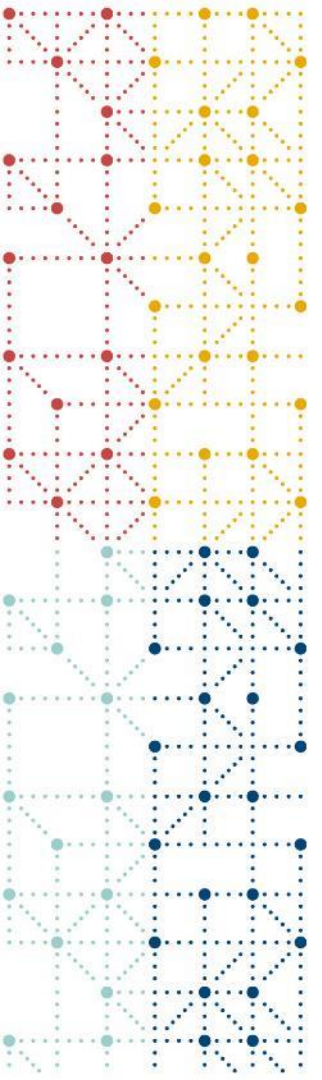
- *"Conceptualize standards and solutions from end to end...trial design, collection, tabulation, analysis and reporting"*

Collaboration

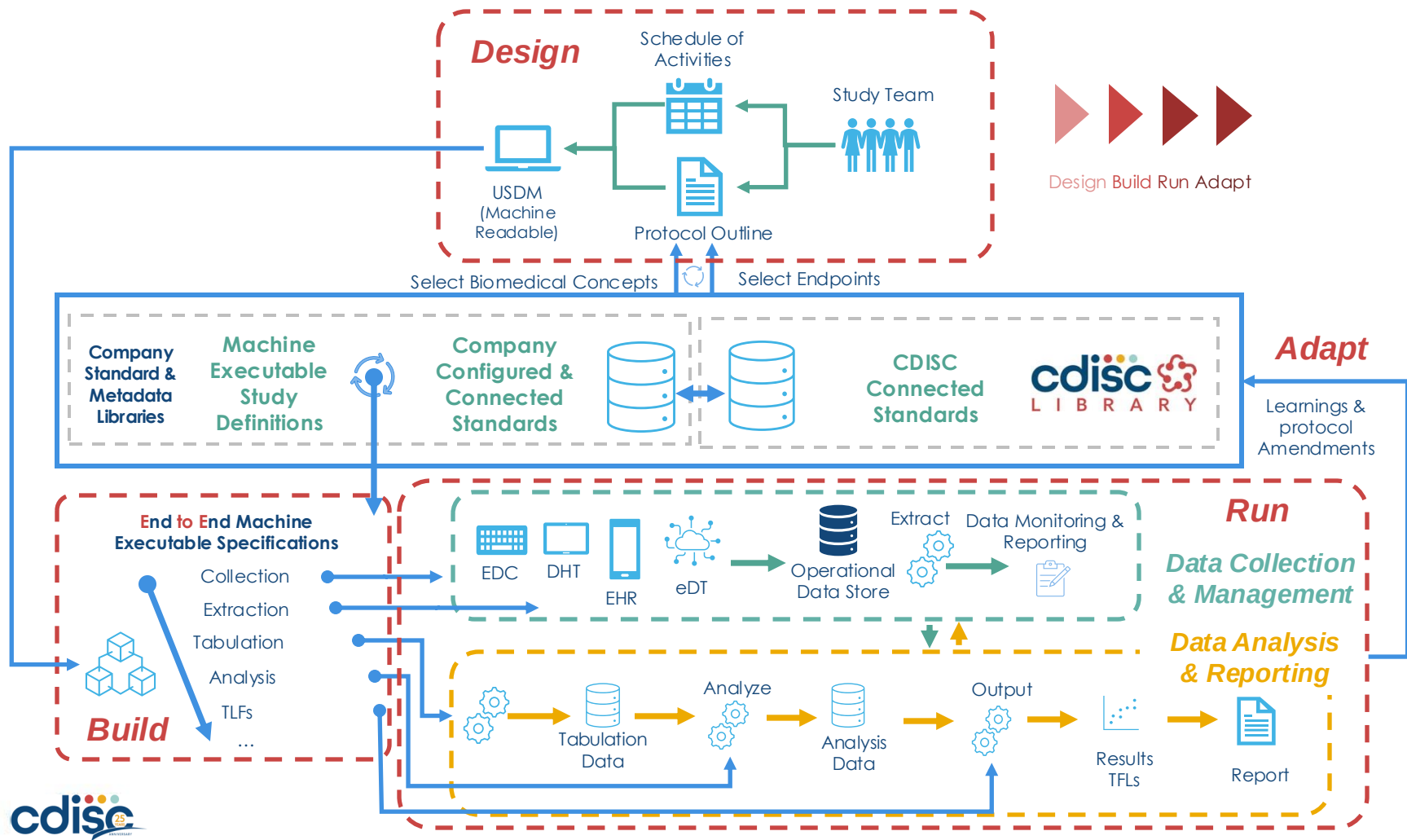
- *"Common vision and commitment to accelerate the development of novel data standards...require experts (resource commitment), partnerships, investing in proof of concept"*

Commitment

- *"Strong collaboration is needed between SDOs, regulators and biopharma representatives"*



360i Vision and Overview

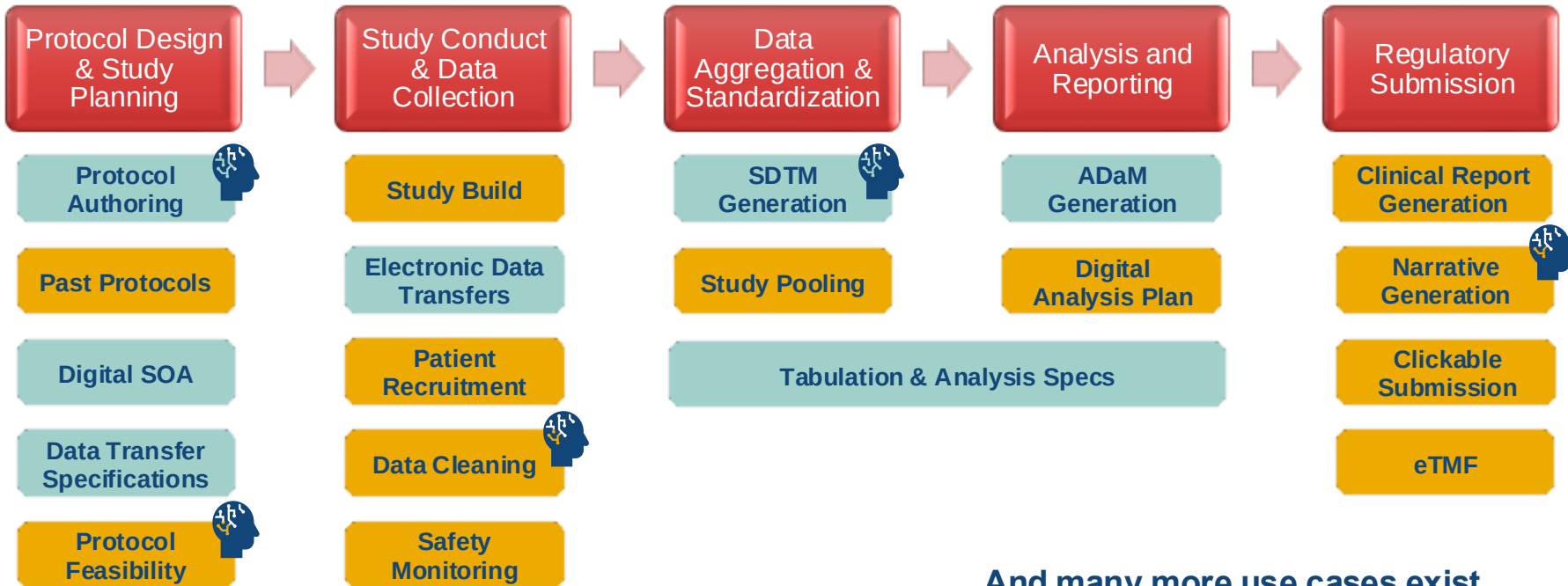


Use Cases 360i Can Enable

Potential AI
Use Cases

Initial 360i
Focus

Potential
future uses



And many more use cases exist...

Governance & Reusability

Artifact Recommendations

Semantic Interoperability

Built In Traceability

Standards Conformance

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

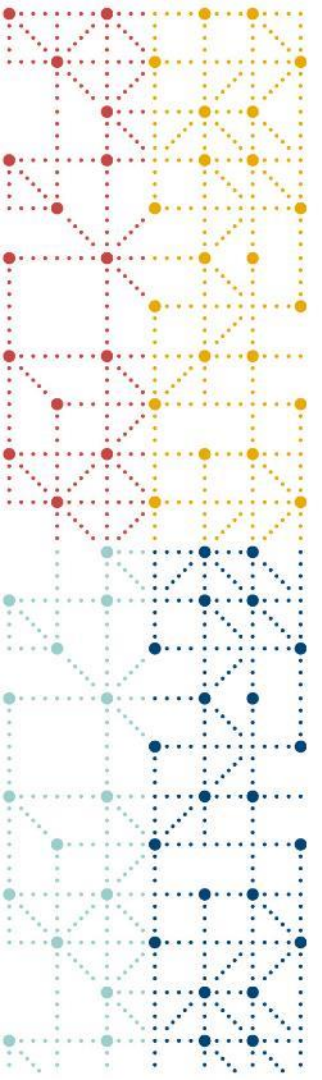
Implementation Cookbooks



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

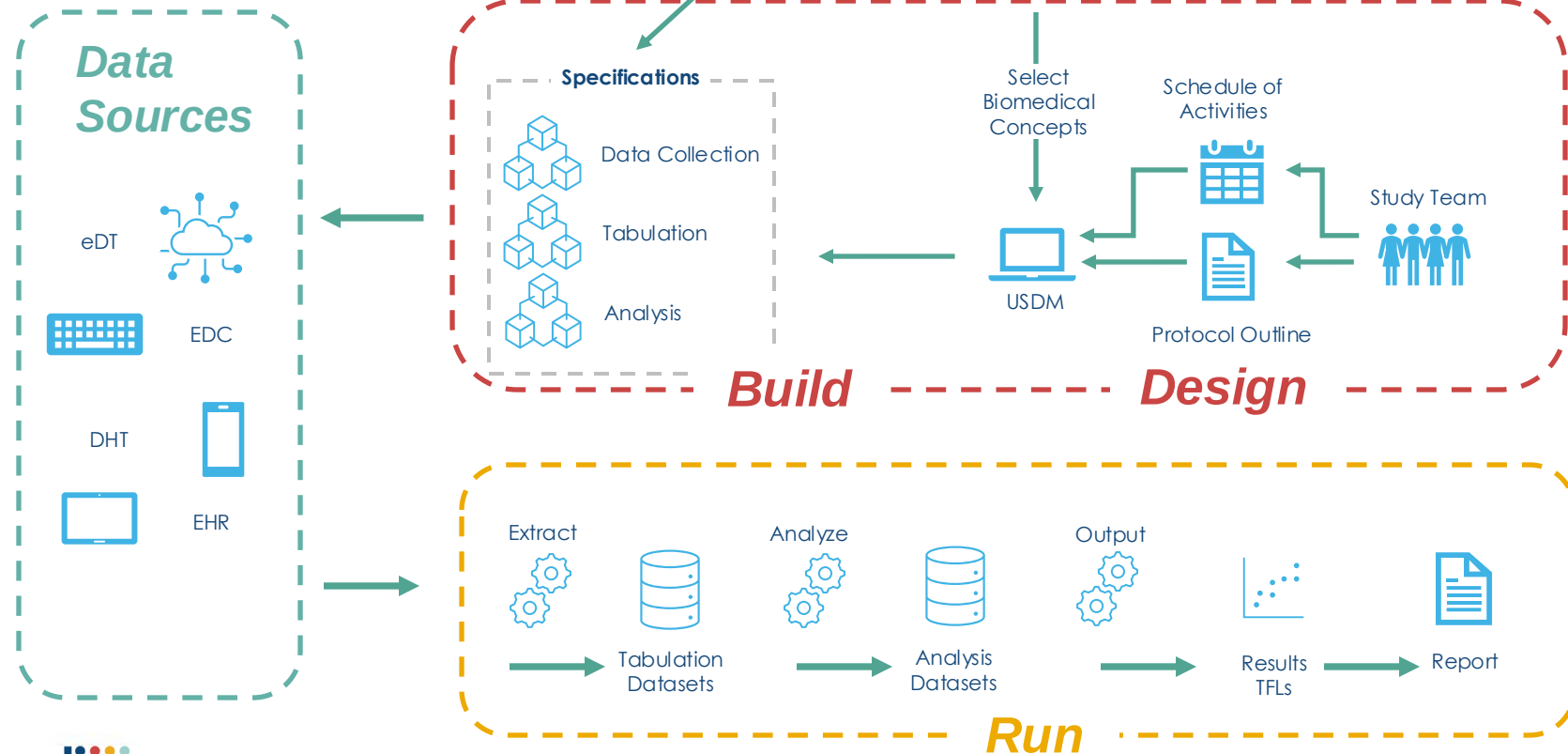
Example Implementations



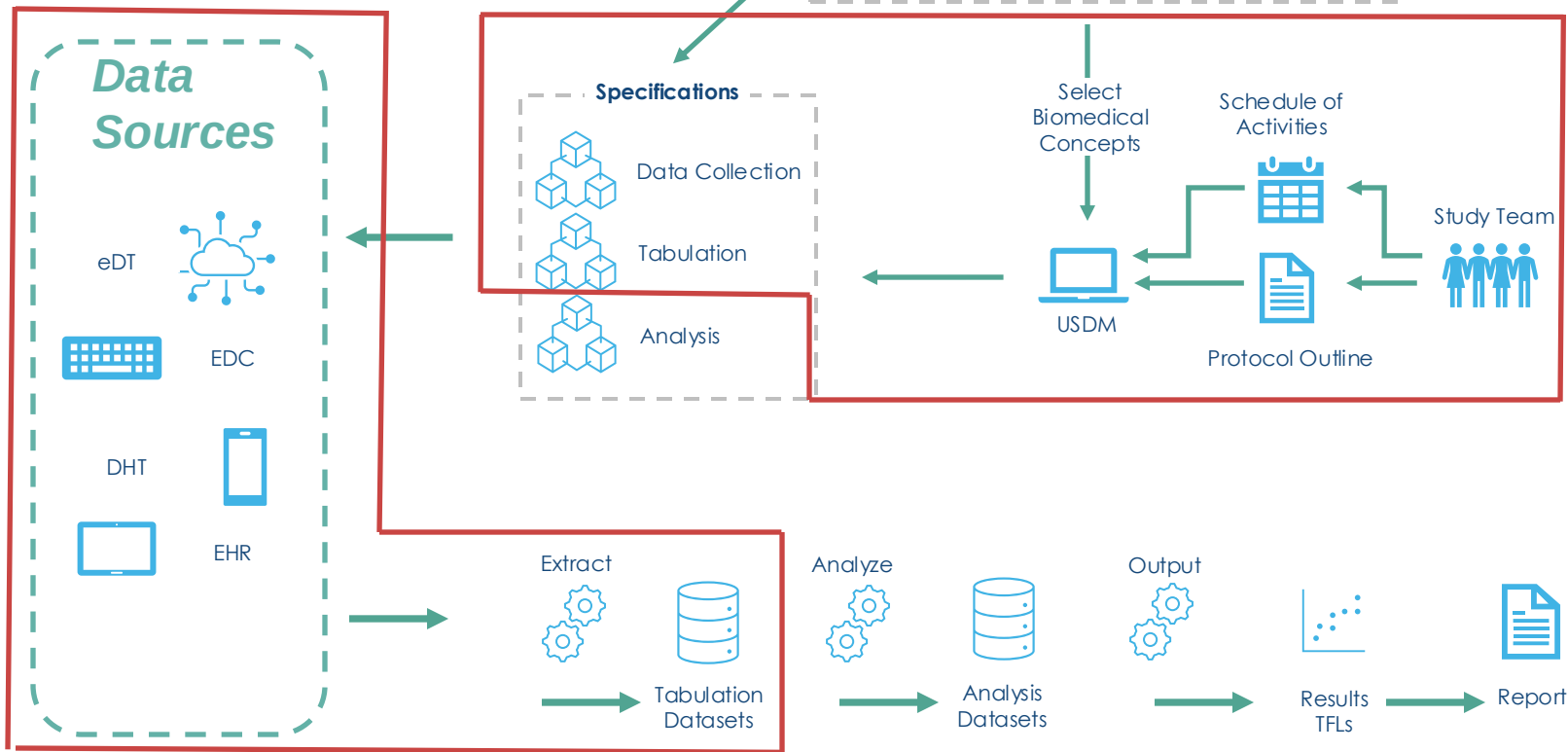


360i Phase 1: First Step in Realizing End to End Connected Standards

360i Focus



360i Phase 1



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

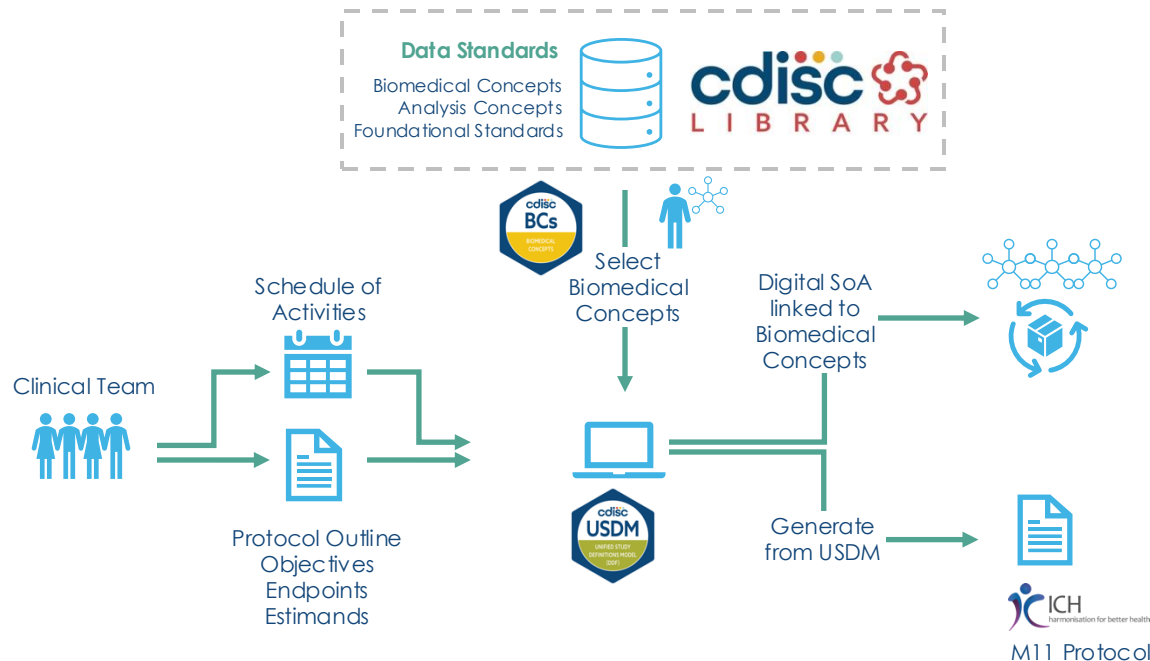
Efficacy Endpoint Assessments

- ✓ 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



Protocol Attachment LZTZ.1
Schedule of Events for Protocol H2Q-MC-LZTZ(c)

	UNIT	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
ACTIVITY	WEEK	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Interest meeting																			
Patrol number assigned		X																	
Disinfect		X																	
MOORE 10-23		X																	
Physical inspection																		X	X
Medical history																			
Notes																			
Chart entry		X																	
April 4 emergency						X													
Patrol completed																			
UNIT clinic Coordinator		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Antibiotics (ECU) placed						X													
Antibiotics (ECU) removed																			
ECU						X	X	X	X	X	X	X	X	X	X	X	X	X	X
Recheck TTS test		X																	
CT test if not within last year and present (prior all other exams)						X	X	X	X	X	X	X	X	X	X	X	X	X	X
1. Cervical radiographs						X	X	X	X	X	X	X	X	X	X	X	X	X	X
2. Laboratory (Chemistry)						X	X	X	X	X	X	X	X	X	X	X	X	X	X
3. Laboratory (Immunology)						X	X	X	X	X	X	X	X	X	X	X	X	X	X
4. Plasma Specimen						X	X	X	X	X	X	X	X	X	X	X	X	X	X
5. (Chemistry)						X	X	X	X	X	X	X	X	X	X	X	X	X	X
Investigative Act						X	X	X	X	X	X	X	X	X	X	X	X	X	X
Study day record						X	X	X	X	X	X	X	X	X	X	X	X	X	X
Medication beyond Medication returned						X	X	X	X	X	X	X	X	X	X	X	X	X	X
TTS compliance forms						X	X	X	X	X	X	X	X	X	X	X	X	X	X
ASNA Org		X	X	X	X			X			X	X	X	X	X	X	X	X	X
EMMS		X	X	X	X			X			X	X	X	X	X	X	X	X	X
EMMS		X	X	X	X			X			X	X	X	X	X	X	X	X	X
SOH		X	X	X	X			X			X	X	X	X	X	X	X	X	X
ASNA		X	X	X	X			X			X	X	X	X	X	X	X	X	X
ASNA		X	X	X	X			X			X	X	X	X	X	X	X	X	X

360i Study Design



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



Objectives
Endpoints
Estimands



BC Curation
team

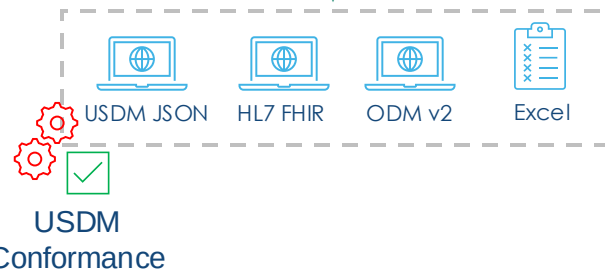
Select
Biomedical
Concepts



Link
Biomedical
Concepts
to SoA



Digital SoA
linked to
Biomedical
Concepts



360i Study Build



Digital SoA

Safety Assessments

- Demography
- Death Details
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 - By SOC and PT
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- Disposition
- Change from Baseline Lab
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Safety Assessments

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Efficacy Endpoint Assessments

- Breast Cancer (RECIST)
- Alzheimer's Disease

eCRF Portal



Select eCRF templates

Generate eCRF

Generate eDT



Electronic Data Transfer (eDT)

Select eDT



Predefined eDT

Data Standards

Biomedical Concepts
Analysis Concepts
Foundational Standards



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LIBRARY



eCRF Template

eCRF Specifications



FHIR observation resource



Define.xml



SDTM Specifications

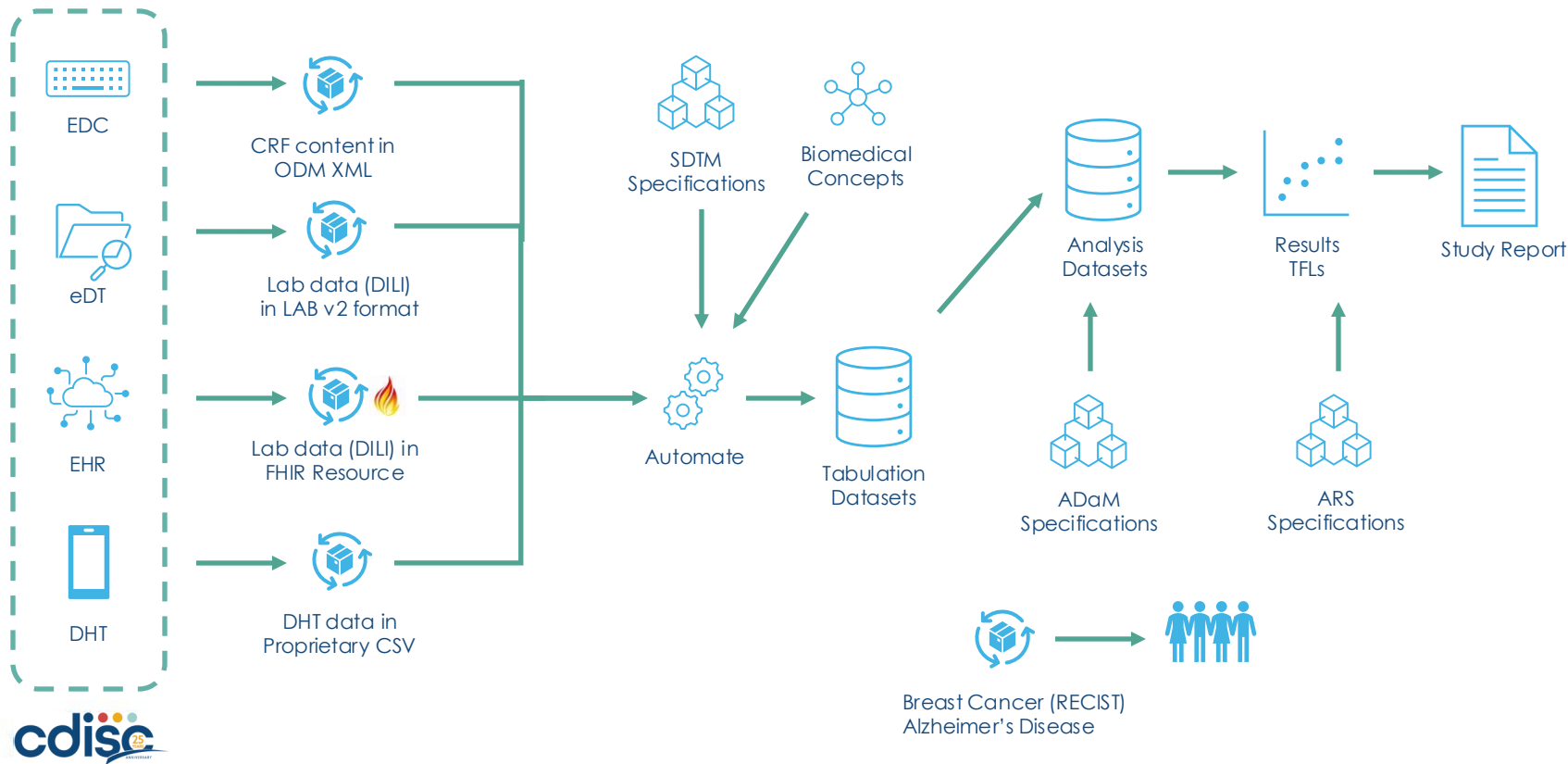
360i Study Run

Data Sources

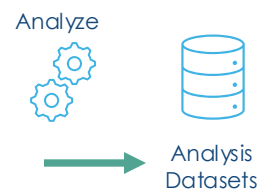
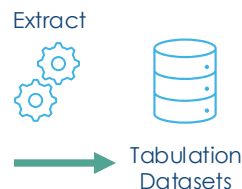
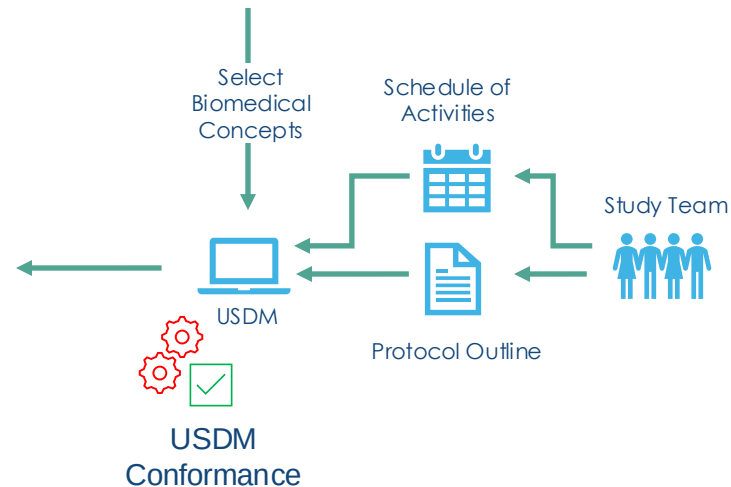
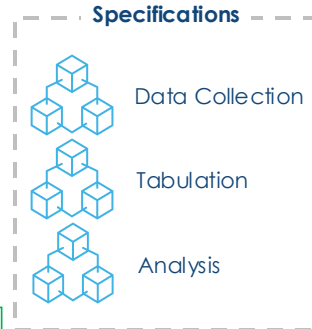
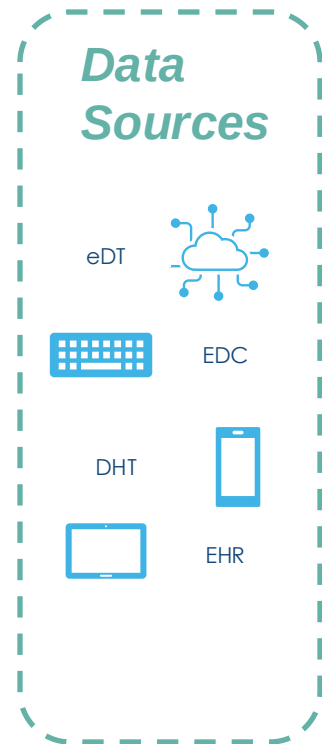
Data Standards
Biomedical Concepts
Analysis Concepts
Foundational Standards



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Open Rules



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

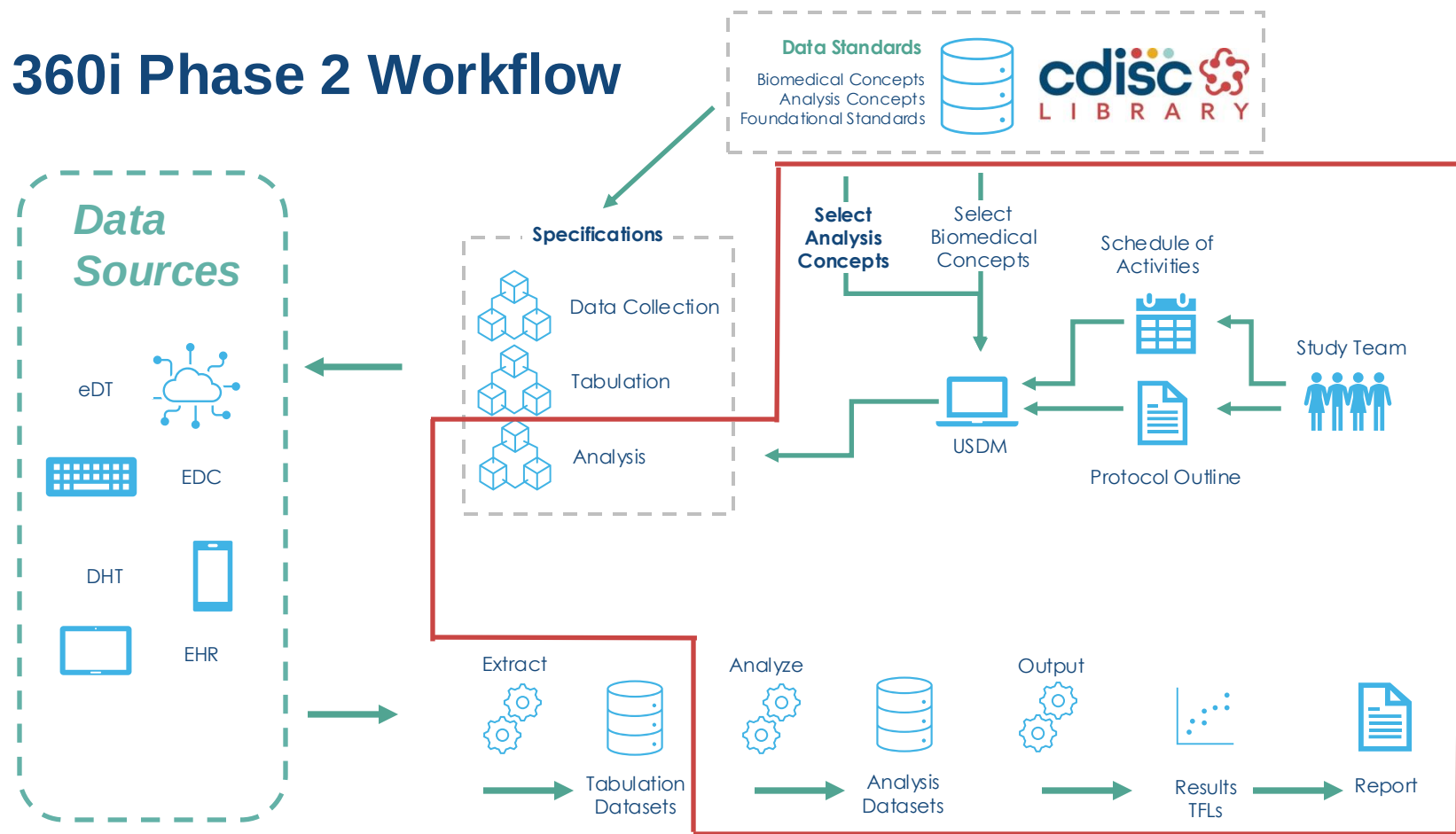


Continue to partner with TransCelerate and industry to drive digital protocol adoption



Define roadmap and scope for digitizing the Trial Master File (TMF)

360i Phase 2 Workflow



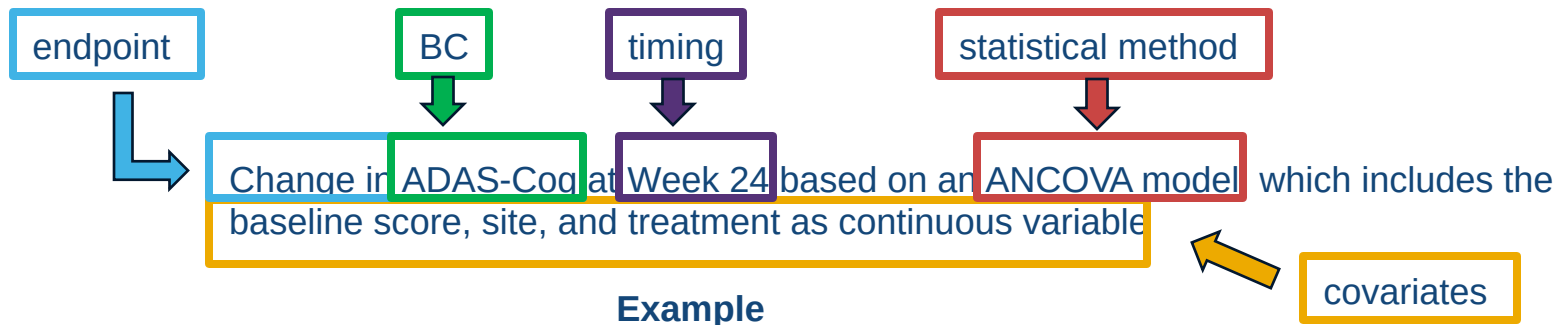
Analysis Concepts

- 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



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!

