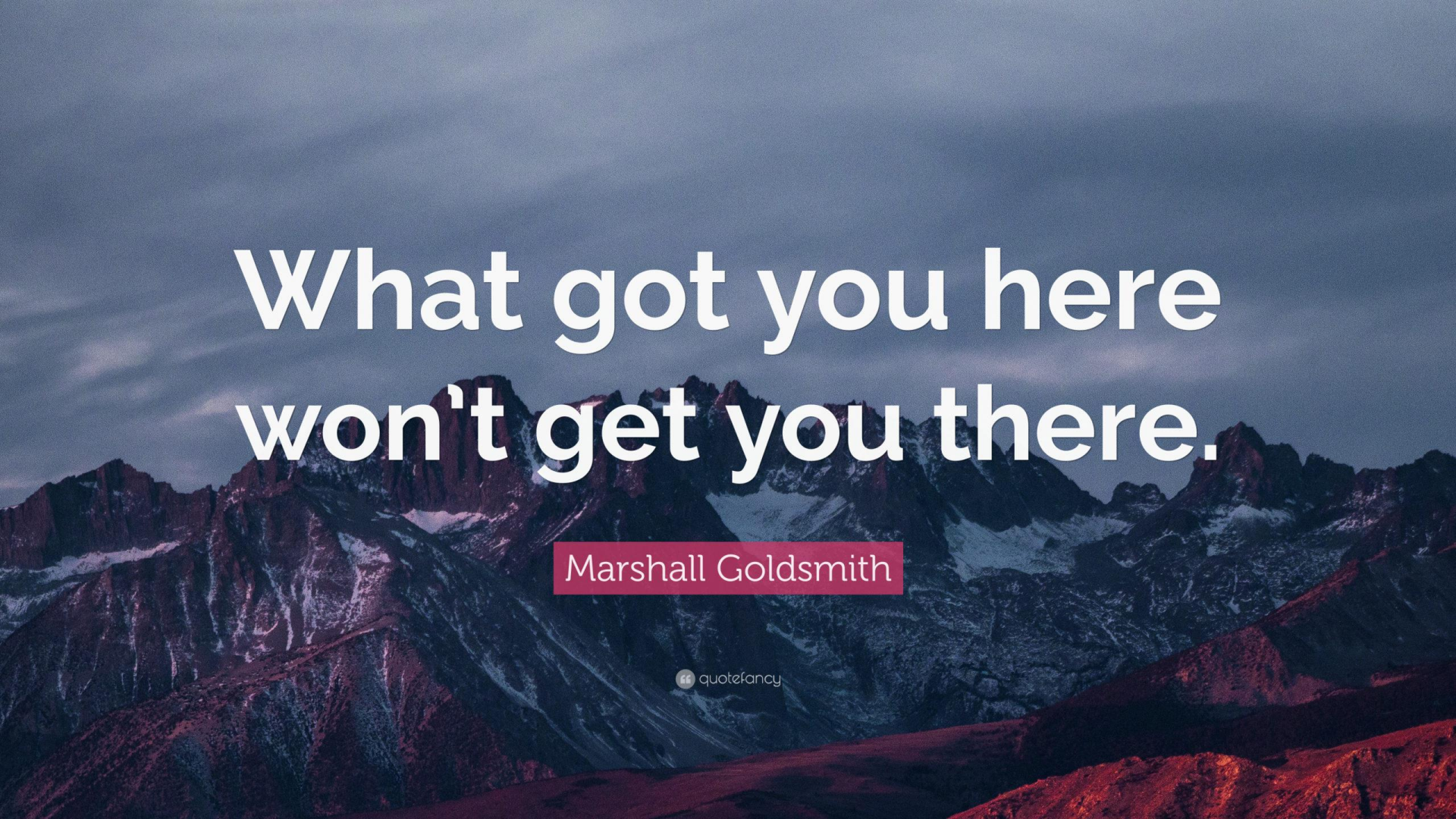
CDISC Strategy: Rebuilding our Foundation and Transforming the Standards Paradigm

Presented by Chris Decker, CEO and President, CDISC


What got you here won't get you there.
Marshall Goldsmith
quotefancy

Vision, Mission, and Imagine If….

CDISC's Vision and Mission

VISION

Amplify Data's Impact to Advance Research

MISSION

Create connected standards across the study information lifecycle to enable accessible, interoperable, and reusable data for more meaningful and effective research

Imagine in the future we can….

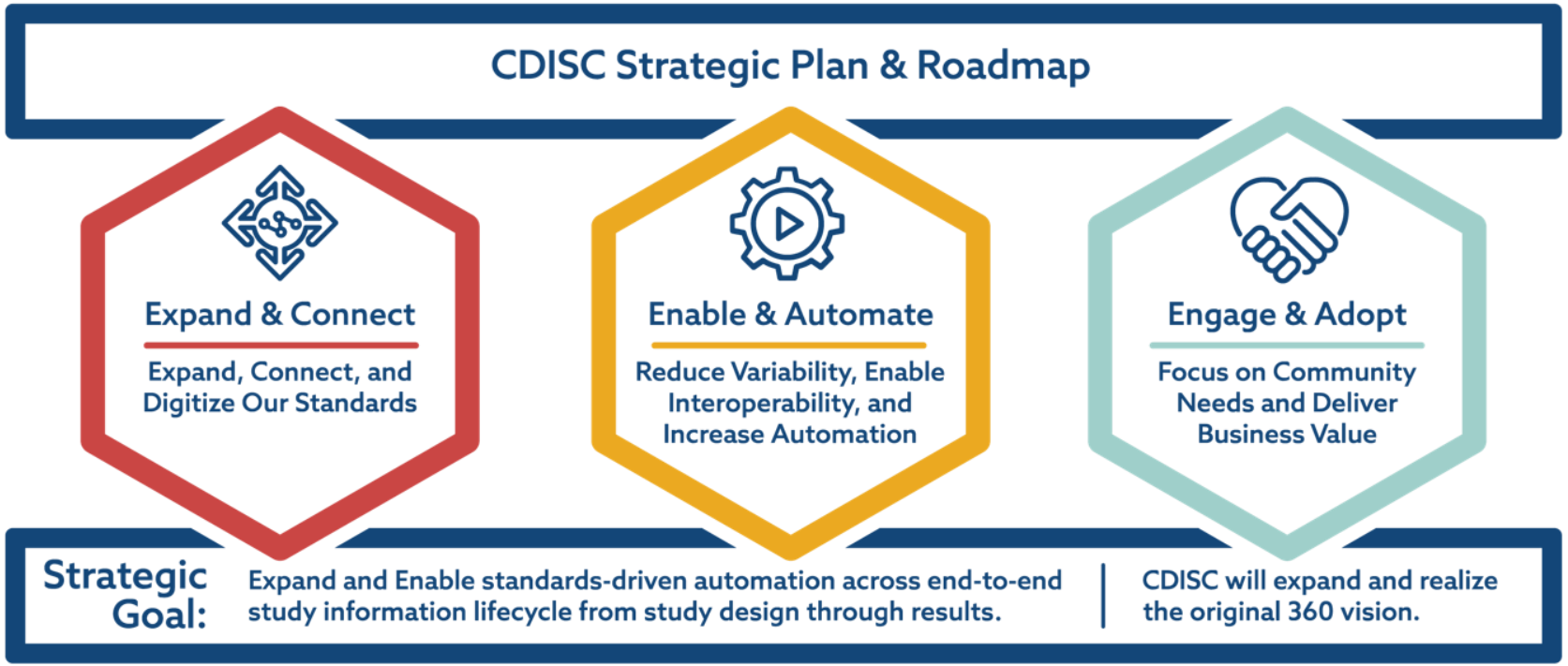
Leverage a **robust catalog of digital study information** along with AI to drive study design creating better studies and accelerating study execution.

Pull a ready to use **complete study package with all the connected standard metadata from design to analysis to submission** off the shelf making it easier to implement, consume, and automate.

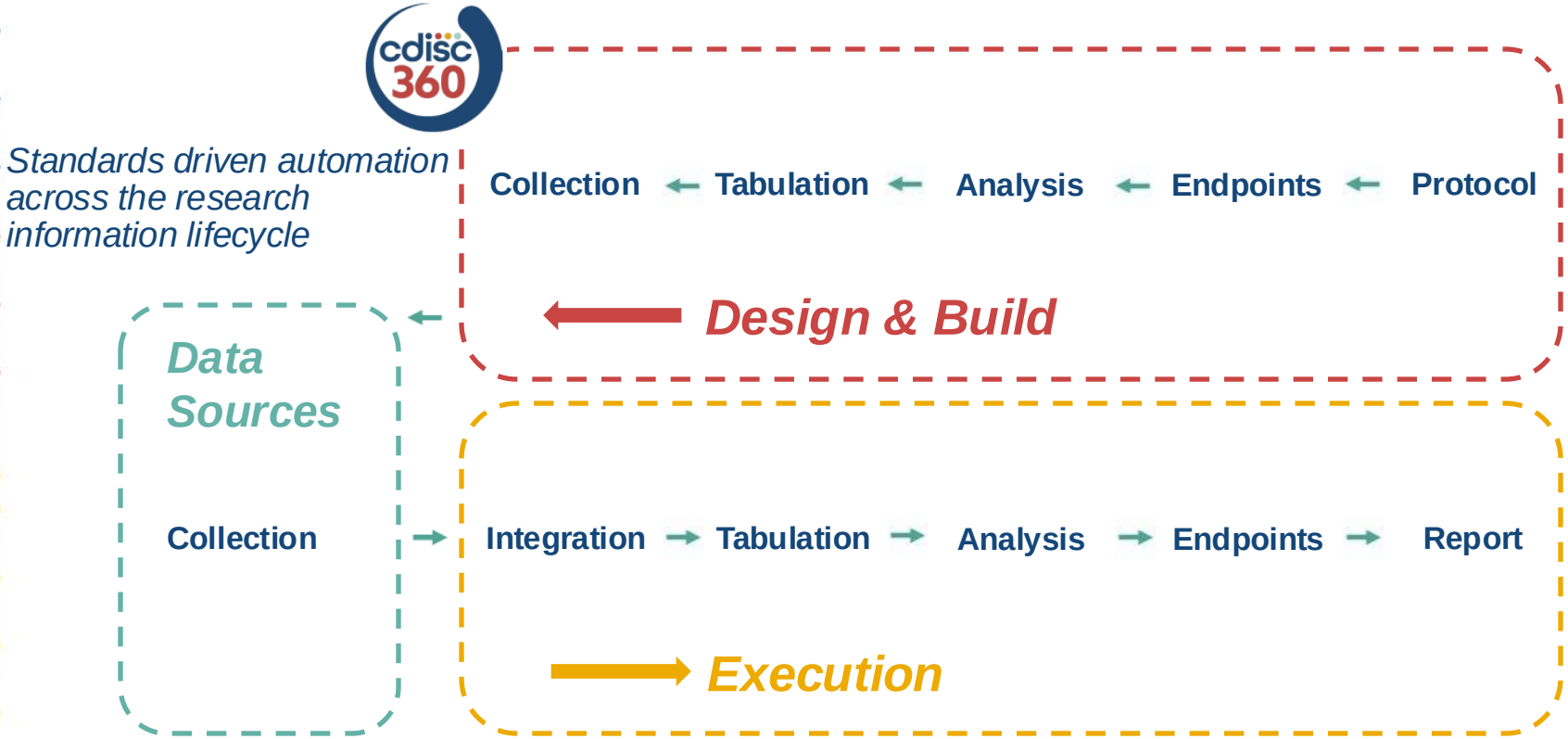
Provide regulatory agencies a **connected and traceable submission package** allowing reviewers to click their way from the clinical study report to analysis to data to protocol increasing confidence in the data and results.

CDISC Roadmap

Realizing the CDISC Mission



End to End Study Information Lifecycle



Roadmap Pillars and Objectives

Expand & Connect

- Embrace and adopt digital study design
- Expand and connect standards across the clinical research information lifecycle
- Define clear pipeline for integration of new data sources

Enable & Automate

- Develop ready to use implementation standards
- Create open-source technology enabled standards
- Establish and manage a conformance framework

Engage & Adopt

- Establish a continuous feedback loop across the CDISC community
- Shift focus to producers/consumers needs and lower the barrier to use
- Prioritize communication to enable our stakeholders

Roadmap Pillars and Objectives

Expand & Connect

- Embrace and adopt **digital** study **design**
- Expand and **connect standards** across the clinical research information lifecycle
- Define clear pipeline for integration of new **data sources**

Enable & Automate

- Develop ready to use implementation standards
- Create open-source technology enabled standards
- Establish and manage a conformance framework

Engage & Adopt

- Establish a continuous feedback loop across the CDISC community
- Shift focus to producers/consumers needs and lower the barrier to use
- Prioritize communication to enable our stakeholders

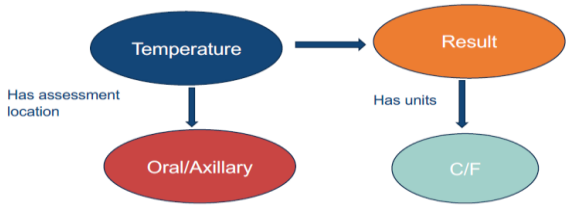
Expand & Connect: Digital Study Design

- Unified Study Definitions Model (USDM)
  - Holds many aspects of the study design
  - Facilitates interoperability between systems
  - Schedule of Activities = digital backbone of the protocol
    - Link Schedule of Activities to standard Concepts
  - Support study design activities

- ICH M11
  - Provide controlled terminology, aligned with USDM
  - Collaborate with ICH and Vulcan to create exchange mechanism
    - Utilizing Digital Protocol (UDP)
  - Support use cases and pilots (e.g. FDA PRISM)

Connect Design to Results

- Mapping data from various formats often breaks down
  - The meaning and terminology do not match (e.g. eHR to SDTM)
  - Mapping between common data models is only a part of the solution
- We need well defined Concepts
  - Standardize the meaning and semantics of data
  - Regardless of data representation
- Concepts will
  - Link to the **Schedule of Activities**
  - Provide consistent implementation
  - Facilitate automation
  - Prevent AI from hallucinating



Concept

VSTEST	VSTESTCD	VSORRES	VSUNIT	VSLOC
Temperature	TEMP	101.3	F	ORAL

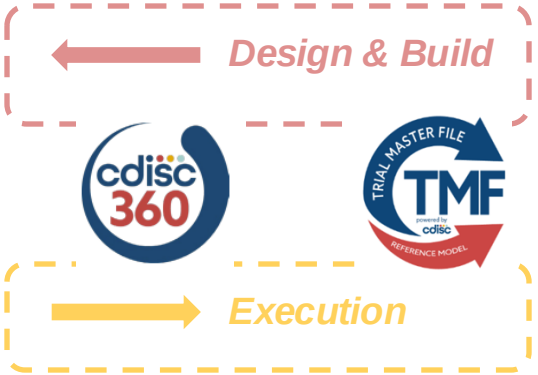
Representation

Close the gaps & Expand the standards

- Ensure standards can represent all data
  - Analysis Results Standards (launched March 2024)
  - Common electronic data transfers (to start)
  - Explore structures to represent objectives & endpoints (to start)

- TMF is now integrated with CDISC
  - Roll out form TMF standards development process
  - TMF Controlled Terminology (in progress)

- Digitalize Trial Master File
  - TMF Art of the Possible to TMF Roadmap
  - TMF systems will integrate digital protocol information
  - Enrich TMF with metadata to support automation



Expand & Connect: Integrate Sources

- Study data is originating from many sources
  - Electronic Data Capture systems and eCRFs
  - Various Data Transfers such as eCOAs, ePROs, eHRs
  - Digital Health technologies
- Provide more standards to ingest data
- Digital Health Technologies initiative
  - Partnership with DiME – Library of digital endpoints
  - Link resources to concepts, device attributes, domains
  - Standardize analysis of DHTs where applicable

cdisc DHT DIGITAL HEALTH TECHNOLOGY

DiME DIGITAL MEDICINE SOCIETY

cdisc

Expand & Connect: Integrate Sources

- Real-world data provides valuable insights but…
- Concerns about
  - Data quality
  - Data integration issues (fidelity)
  - Traceability
- RWD Lineage
  - Exchange mechanism to represent lineage, traceability and quality
  - Together with the data
- Continue partnering with NIH, IMI and other SDOs
  - Define core data elements

Roadmap Pillars and Objectives

Expand & Connect

- Embrace and adopt digital study design
- Expand and connect standards across the clinical research information lifecycle
- Define clear pipeline for integration of new data sources

Enable & Automate

- Develop **ready to use** implementation standards
- Create **open-source technology** enabled standards
- Establish and manage a **conformance** framework

Engage & Adopt

- Establish a continuous feedback loop across the CDISC community
- Shift focus to producers/consumers needs and lower the barrier to use
- Prioritize communication to enable our stakeholders

Enable & Automate: Ready to Use Standards

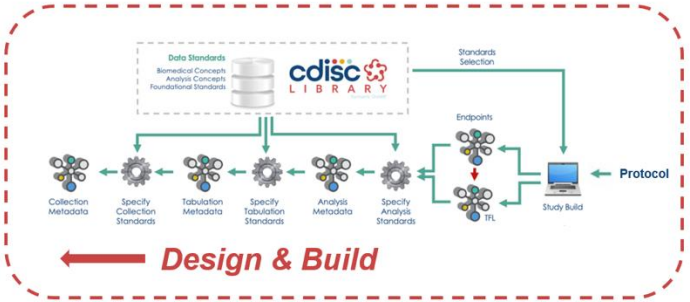
- Provide rich resources and examples
  - normative standards with informative content
  - ‘easy’ to implement and understand

- eCRF portal
  - https://www.cdisc.org/kb
  - 70 eCRF resources and growing
  - Ready to download and use in eDC systems

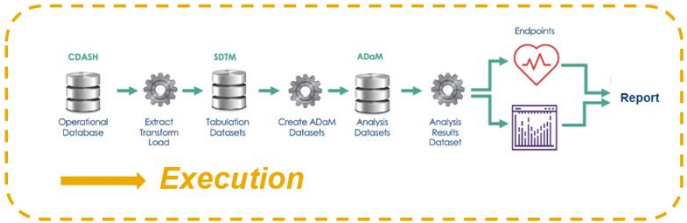
- eTLF portal
  - Based on the Analysis Results Standard
  - Analysis concept + ADaM metadata + ARS metadata + TFL example
  - Ready to download and implement

Enable & Automate: Preconfigured example study

- Complete preconfigured example study
  - Include all components from design to submission
  - Understand the normative gaps between standards



- Demonstrate and test the example study
  - Set-up Connectathon events with technology providers



- Collaborate with Regulatory to define use cases
  - Enabling better use of standards for review

Enable & Automate: Open-Source

- Consider technology and automation upfront

- CDISC Open Source Alliance
  - Support and promote development of open-source software
  - Drive innovation

- Examples
  - Oak Initiative: automate SDTM generation
  - Open Study Builder
  - CDISC Open Rules Engine
  - CDISC Rule Editor

Enable & Automate: Technology enables Automation

- Modernize data transport: Dataset JSON
  - Technology friendly, future proof

- Standards with logical models
  - Both USDM and ARS are published with logical models
  - Enables technical implementation, demonstrate use cases
  - Includes API specifications

- CDISC Library
  - Relevant standards are digitally available via APIs
  - Source for tools and automation

cdisc LIBRARY

Enable & Automate: Conformance Rules

- Complete conformance rules for all relevant foundational standards
  - SDTM, ADaM, SEND, ARS, …
- Expand to regulatory business rules
  - Current collaboration with FDA, other agencies to follow
- Expand to industry quality rules
  - Quality rules beyond standard conformance
  - Creating conformance rules for USDM to ensure compliance with USDM framework
    - This will enable checking conformance with M11 transport standard
- Going forward
  - Establish rules for all CDISC standards

Roadmap Pillars and Objectives

Expand & Connect

- Embrace and adopt digital study design
- Expand and connect standards across the clinical research information lifecycle
- Define clear pipeline for integration of new data sources

Enable & Automate

- Develop ready to use implementation standards
- Create open-source technology enabled standards
- Establish and manage a conformance framework

Engage & Adopt

- Establish a continuous **feedback** loop across the CDISC **community**
- Shift **focus** to **user needs** and lower the barrier to use
- Prioritize **communication** to enable our stakeholders

Engage & Adopt: Feedback

- Ensure we are **solving the right problems**
  - Understand the needs of end-users
- Establish a transparent Community of Practice
- Reform the CDISC Advisory Council
  - Member input

Continuous Feedback

Define and manage community feedback loop to ensure understanding of needs

Engage & Adopt: User Focus

- Focus to enhance and accelerate standards adoption
  - A standard is only successful when used
- Include impact assessment to significant standard changes
  - Provide a rationale and value for the change
  - Provide implementation considerations where possible
- CDISC education
  - Shift from theory to hands-on experience trainings
  - I do, we do, you do

User Focus

Shift from development to user needs to enhance and accelerate standards adoption

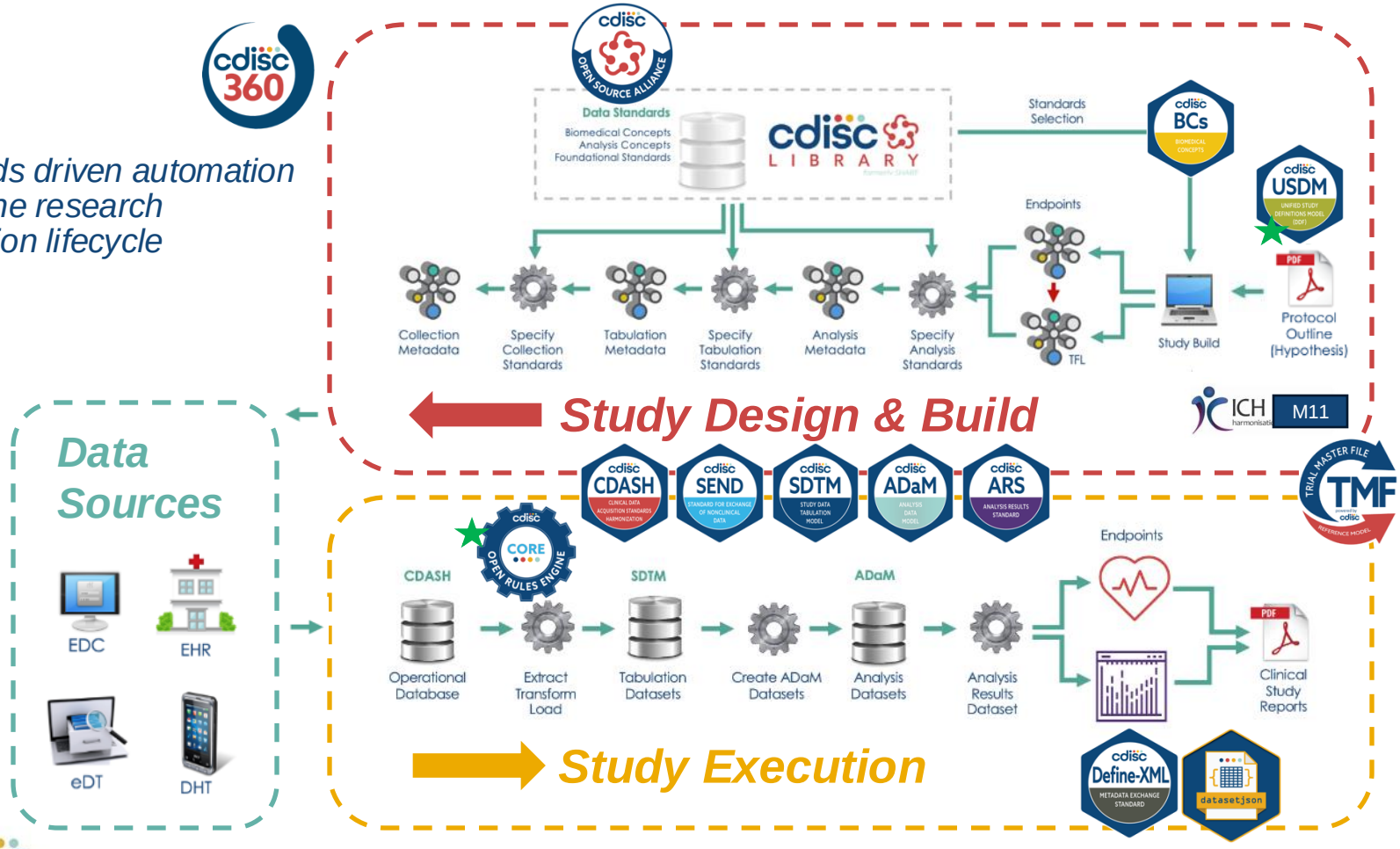
Engage & Adopt: Communication

- Evaluate on how we make content and information available
  - Website, Social Media, Github, CDISC Library
- Publish and maintain a dashboard with current CDISC activities and progress
- Publish the Annual Report
  - Summarize progress on strategic objectives
  - How is CDISC using membership fees to create value

Prioritize Communication

Create frequent and accessible information for CDISC and community alignment

Standards driven automation across the research information lifecycle



Harmonization with Industry and Future Transformation

"Align on a standards-agnostic way to represent biomedical

between SDOs, regulators and biopharma representatives"

"Conceptualize standards and solutions from end to end, which includes but is not limited to trial

accelerate the development of novel data Standards...require experts (resource commitment), partnerships, investing in proof of concept"

The breadth and depth of data available will continue to grow. Putting fundamental steps in place to accurately define this data, starting at the biomedical concept level, is essential for achieving seamless data interoperability across the clinical research and healthcare ecosystem, maximizing the use and reuse of data, automating data transformation and analysis, and fully realizing the vision of a data-driven relationship between biopharma companies and health authorities around the world

Reference: Data Standards White Paper

Realizing the CDISC Roadmap
Establishing 360i

360 POC to 360i: What have we proved and What questions do we need to answer?

360 POC

- ✓Identified gaps in normative standards
- ✓Confirmed concepts are a path forward
- ✓Can define digital standards, i.e. analysis results, USDM
- ✓Protocol pieces can be digitized
- ✓Can bring community together behind a cause

360*i*

How do we…

- Start putting concepts into practice?
- Continue to close original 360 gaps?
- Slow down existing standards changes and transition siloed teams to cross functional E2E teams?
- Define, prioritize, and roll out solutions?
- Engage (and sell) community/stakeholders behind this approach?

cdisc

cdisc 360

cdisc 360i

Starting the Transition from Current State to 360i

Complete Art of the Possible

Build Stakeholder Business Cases

Slow Down Current Changes

Develop & test E2E Standards Playbook

Invest in Semantic Layer to Connect Standards

Show and Tell Early and Often


The journey of a thousand miles begins with a single step.
Lao Tzu
quotefancy

Meet the Speaker

Chris Decker

Title: CEO and President
Organization: CDISC

Chris Decker is the President and CEO of CDISC. Widely recognized in the industry, Chris is an expert in technology and standards for complex process and technology solutions. He has extensive experience in executive roles across software development, clinical research, and consulting. Chris was previously at Instem (d-wise) for fifteen years, most recently as Vice President, Clinical Solutions.

Chris's 20-year involvement with CDISC includes roles as a volunteer, implementer, and board member, with a focus on innovation through standards. Chris is enthusiastic about leading CDISC towards a technology-based standards future and expanding the organization's global impact in clinical research standards.