# CDISC 360*i*
# First Step to Realizing the CDISC Vision

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# CDISC's Vision and Mission

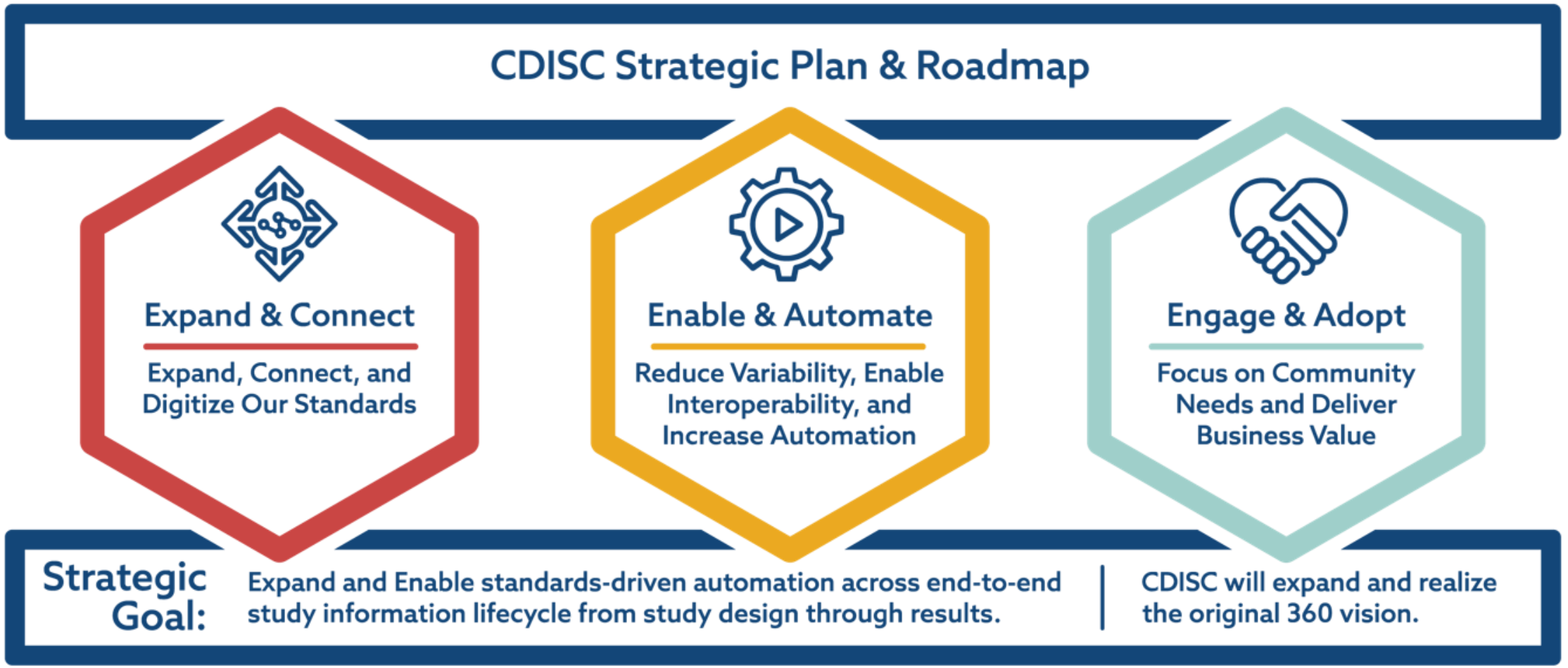
**VISION**

*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*

# Realizing the CDISC Mission



# 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.

# Harmonization with Industry and Future Transformation

| | |
|---|---|
| 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, which includes but is not limited to 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"* |

*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*

cdisc

Reference: Data Standards White Paper

# Realizing the CDISC Roadmap
# Establishing 360i

# 360 POC to 360i: What did we show and what questions do we need to answer?

## 360 POC

- ✓Identified gaps in normative standards
- ✓Confirmed concepts are path forward
- ✓Can define digital standards, i.e. analysis results, digital protocol
- ✓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 deliver tangible assets quickly?
- Engage (and sell) stakeholders on this approach?

# 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