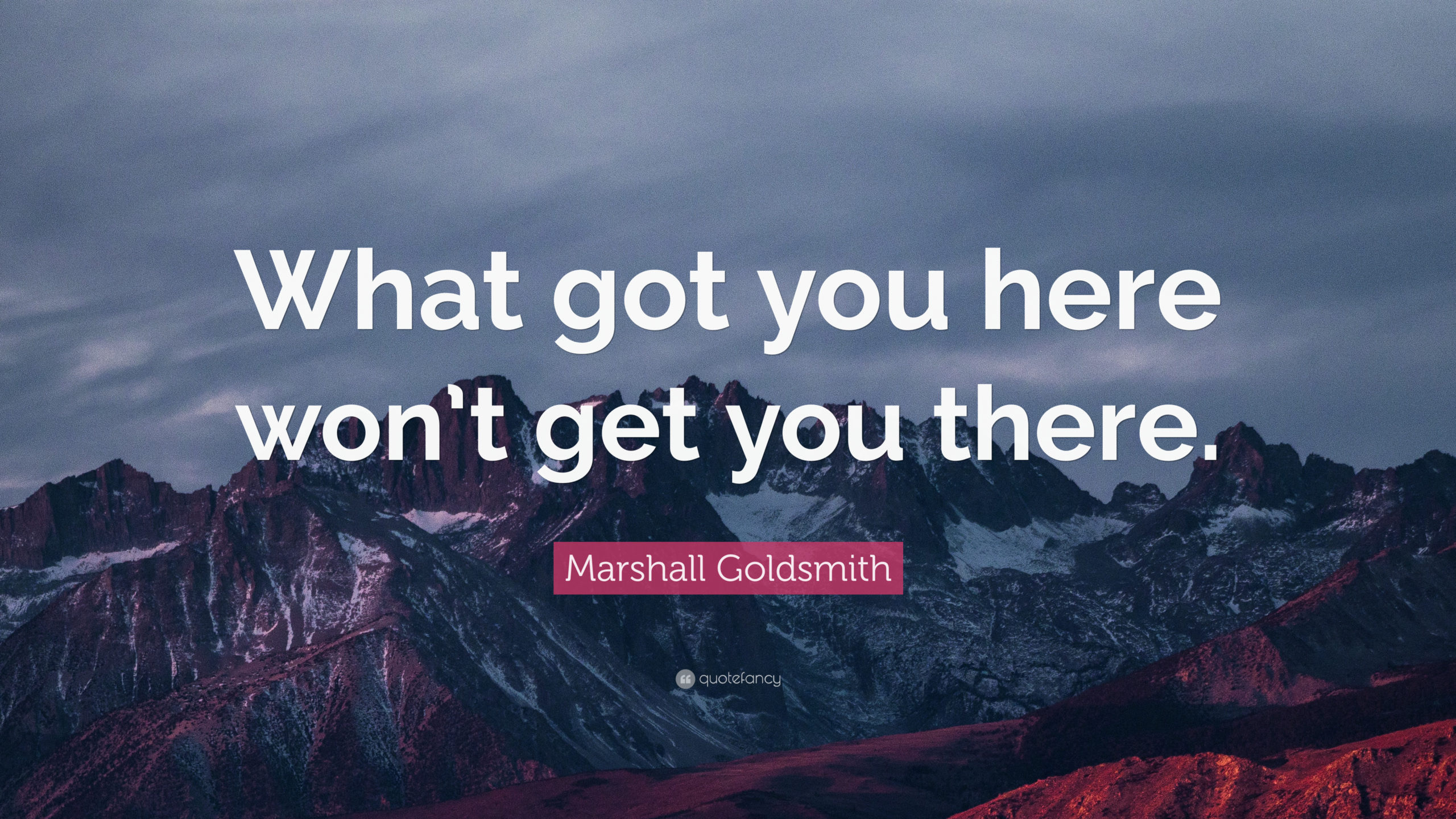




CDISC Vision: Rebuilding our Foundation and Transforming the Standards Paradigm

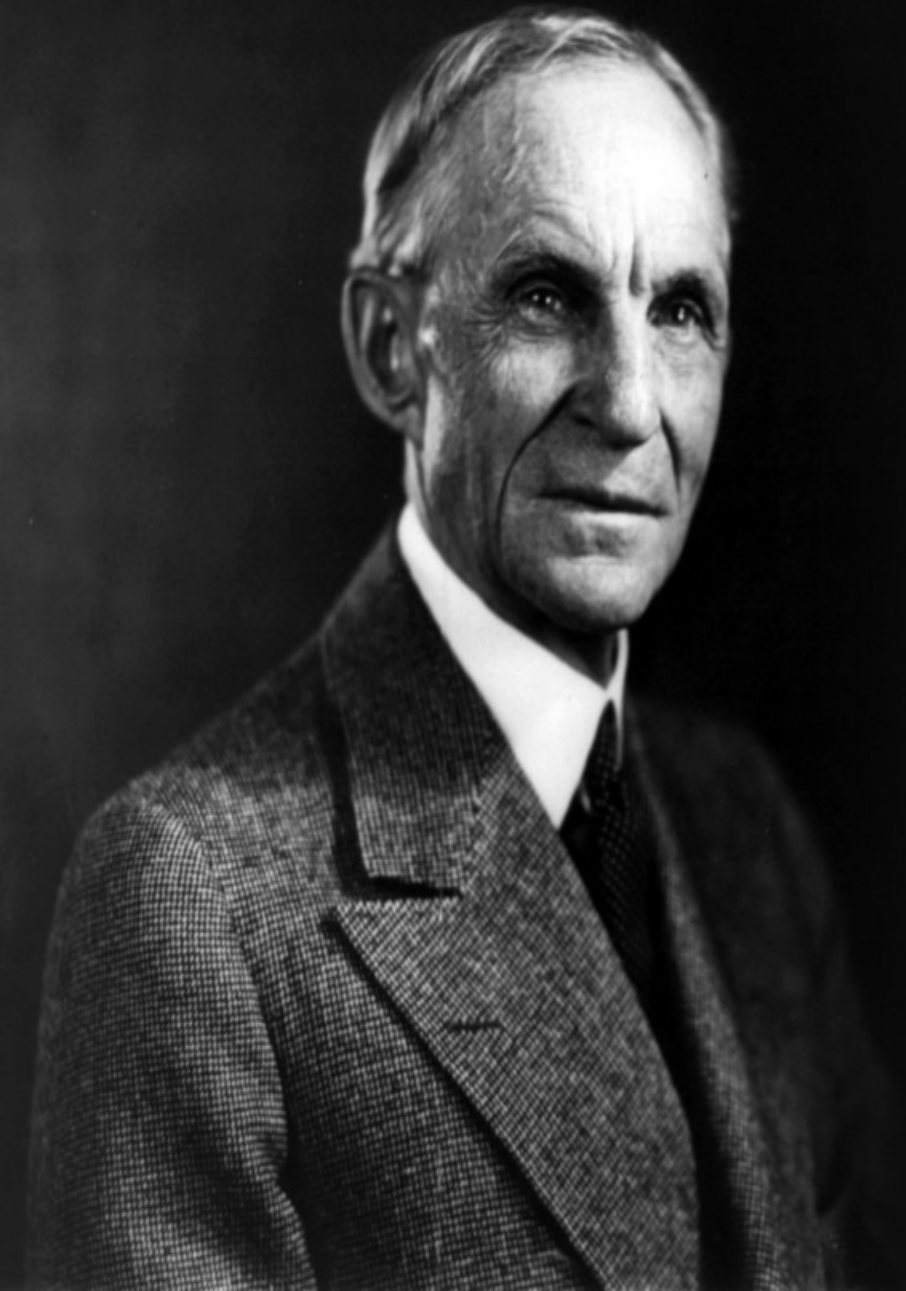
Chris Decker, CEO and President, CDISC





What got you here
won't get you there.

Marshall Goldsmith



“IF I HAD ASKED PEOPLE
WHAT THEY WANTED,
THEY WOULD HAVE SAID:
FASTER HORSES...”

Henry Ford



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....

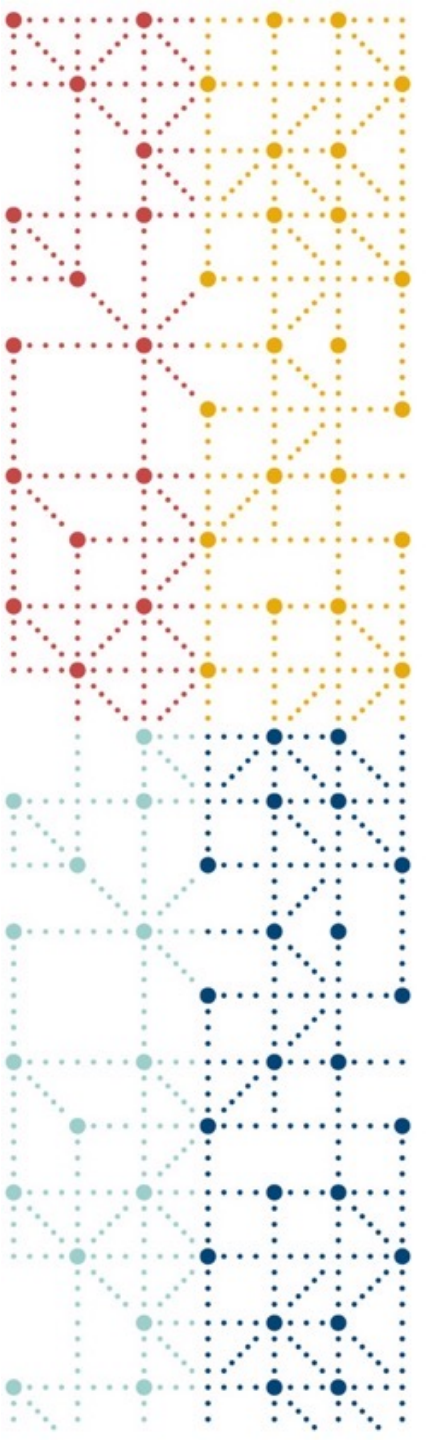


Leverage a **robust catalog of digital study information** along with AI to drive study design creating better studies and accelerating study execution.

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.



**Where will we be in the next
(INSERT # HERE) years?**

Realizing the CDISC Mission

STRATEGIC GOAL

Expand and enable standards driven automation across the end-to-end study information lifecycle from study design through results
(CDISC will expand and realize the original 360 vision)



Expand & Connect

Expand,
Connect, and
Digitalize our
Standards



Enable & Automate

Reduce
Variability,
Enable
Interoperability,
and Increase
Automation



Engage & Adopt

Focus on
Community
Needs
Deliver
Business Value



CDISC Roadmap

End to End Study Information Lifecycle



*Standards driven automation
across the research
information lifecycle*

Collection ← Tabulation ← Analysis ← Endpoints ← Protocol

← **Design & Build**

**Data
Sources**

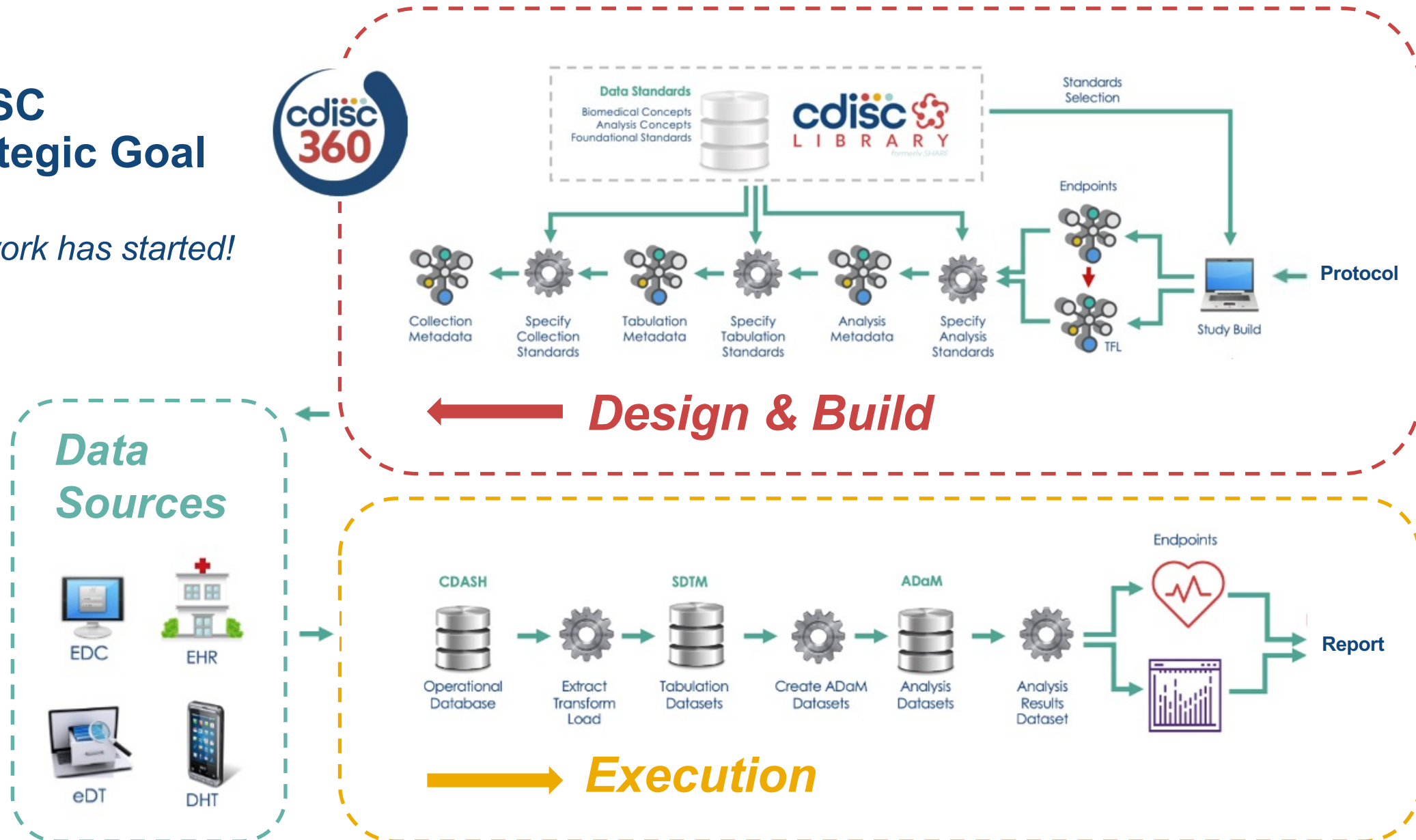
Collection

Integration → Tabulation → Analysis → Endpoints → Report

→ **Execution**

CDISC Strategic Goal

Our work has started!



CDISC Roadmap

Expand & Connect

- Embrace and adopt digital design
- Integrate data sources
- Connect design to results

Enable & Automate

- Ready to use standards
- Technology enabled standards
- Conformance framework

Engage & Adopt

Continuous feedback - User focused - Prioritize communication

CDISC Roadmap

Expand & Connect ★

- Embrace and adopt digital design
- Integrate data sources
- Connect design to results

Enable & Automate

- Ready to use standards
- Conformance framework
- Technology enabled standards

Engage & Adopt

Continuous feedback - User Focus - Prioritize communication

Expand & Connect



Three Year Roadmap

Embrace and Adopt Digital Design

Define study design upfront and leverage downstream to increase automation, improve data quality, and accelerate delivery

- ✓ Establish DDF USD M as industry standard and drive adoption across industry
- ✓ Partner with ICH, Regulatory, and other partners to make M11 standard for submission

← *Design & Build*

- ✓ Define and establish pilots with our community for downstream use

Expand & Connect



- ✓ Expand 360 initiative to implement the complete the end-to-end Pilot use case

- ✓ Refine the connected standards business case so stakeholders understand the value and put concepts in the hands of users
- ✓ Enrich concepts with definitions and semantics which will prevent AI from hallucinating



← *Design & Build*

Connect Design to Results

Connect standards and close gaps for automation to spend more time on science with confidence in the results

→ *Execution*

CDISC Roadmap

Expand & Connect

- Embrace and adopt digital design
- Connect design to submission
- Integrate data sources

Enable & Automate ★

- Ready to use standards
- Technology enabled standards
- Conformance framework

Engage & Adopt

Continuous feedback - User Focus - Prioritize communication

Enable & Automate

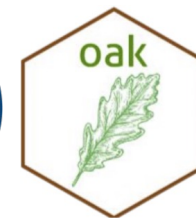


Ready to Use Standards

Deliver community centric standards to simplify management and adoption and reduce variability between studies

- ✓ Publish a complete preconfigured example study with all components from design to submission
- ✓ Demonstrate and test the example study in Connectathon events with technology providers
- ✓ Collaborate with regulatory to define use cases enabling better use of standards for review

Enable & Automate



Technology Enabled Standards

Embrace technology integrated as part of standards to automate the research data pipeline and realize the full value of the standards

- ✓ Develop set of COSA tools with the community to execute and consume the example study
- ✓ Make the complete example study available through the CDISC Library
- ✓ Publish all standards metadata in the CDISC Library and move away from PDF



Enable & Automate



Conformance Framework

Deliver a conformance framework as part of the standards to increase data quality and reduce variability

- ✓ Establish CORE as the foundation for defining and governing all CDISC conformance rules
- ✓ Define conformance rules for existing foundational standards including USDM/M11
- ✓ Deliver conformance rules as part of any CDISC standard going forward

CDISC Roadmap

Expand & Connect

- Embrace and adopt digital design
- Connect design to submission
- Integrate data sources

Enable & Automate

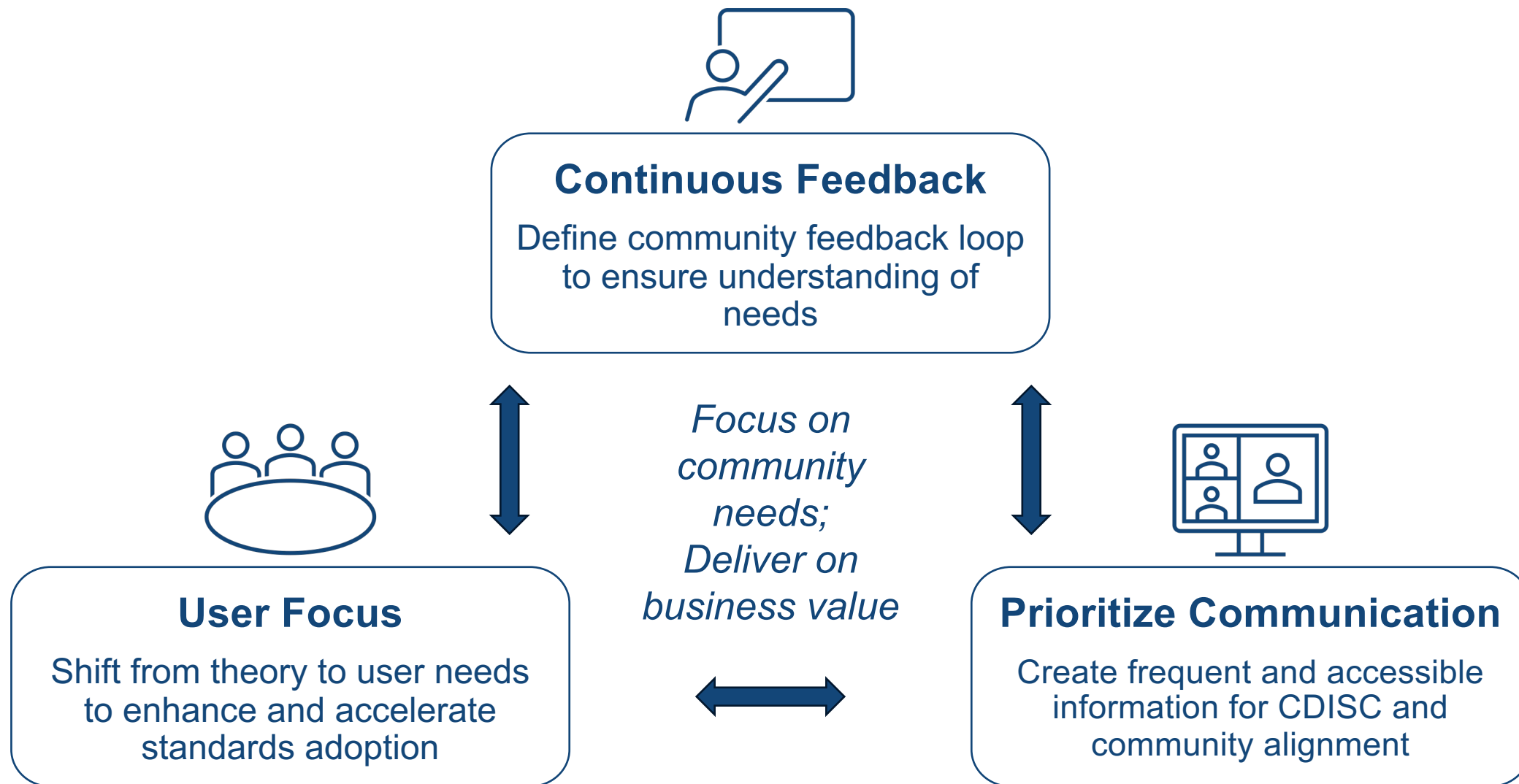
- Ready to use standards
- Conformance framework
- Technology enabled standards

Engage & Adopt

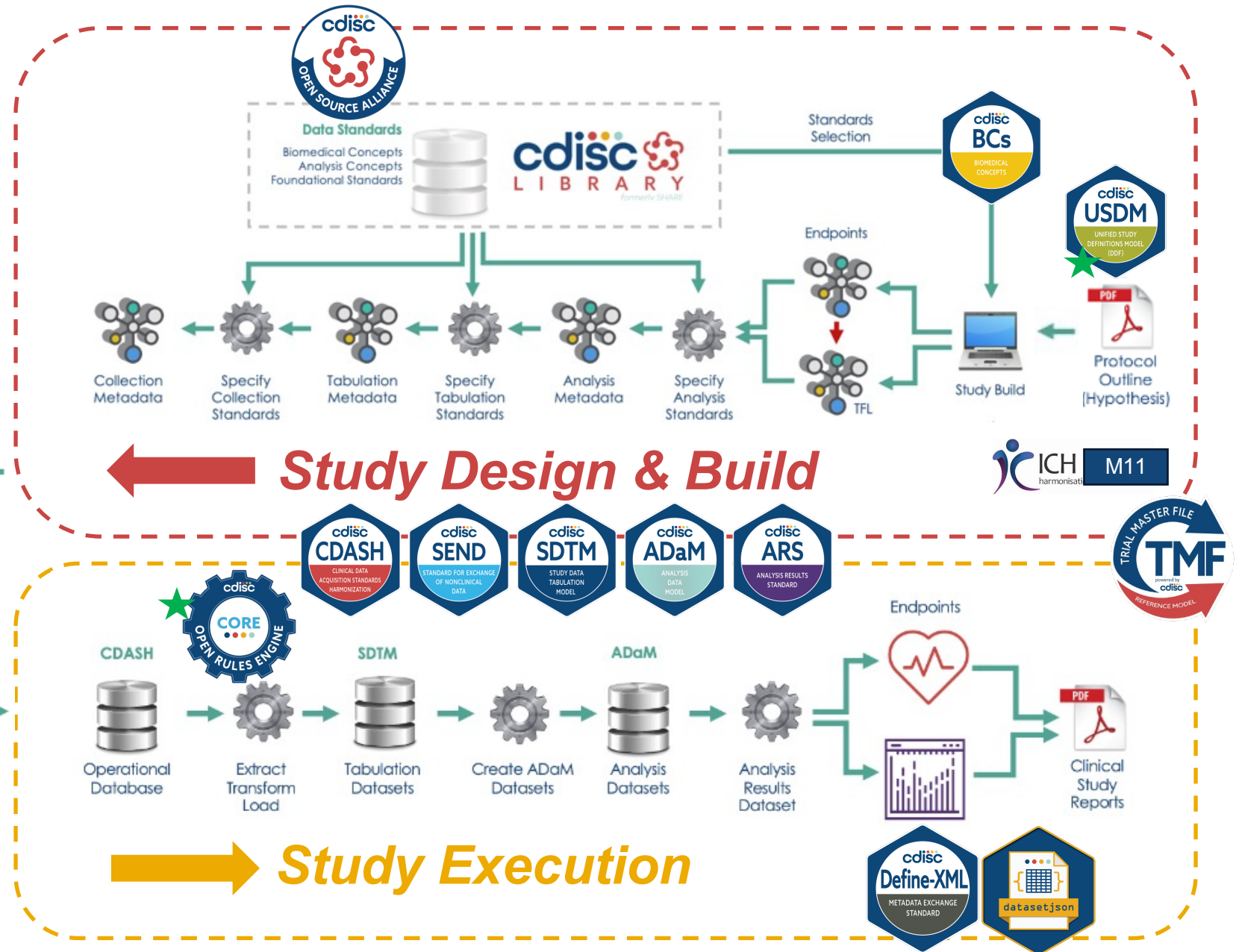


Continuous feedback - User Focus - Prioritize communication

Engage & Adopt



Expand and enable standards driven automation across the end-to-end study information lifecycle from study design through results

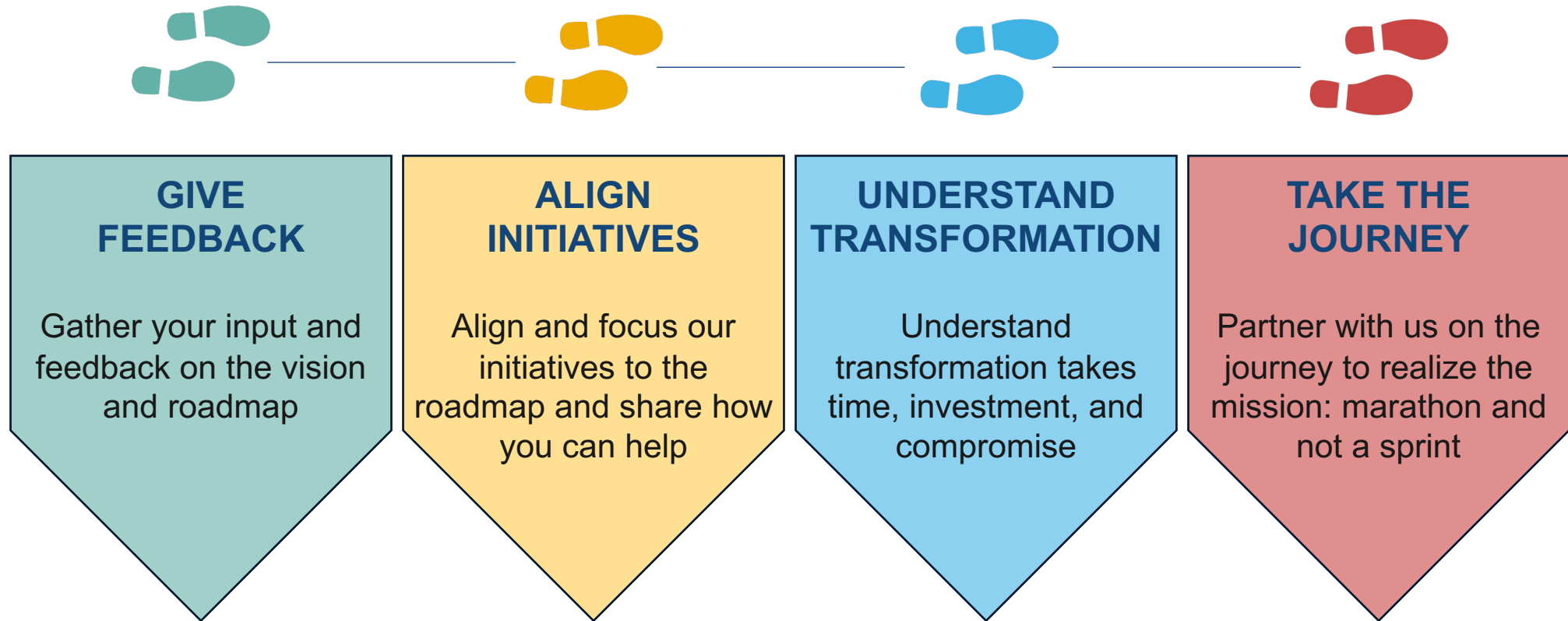




The journey of a
thousand miles begins
with a single step.

Lao Tzu

Where do we go next?





Thank You!