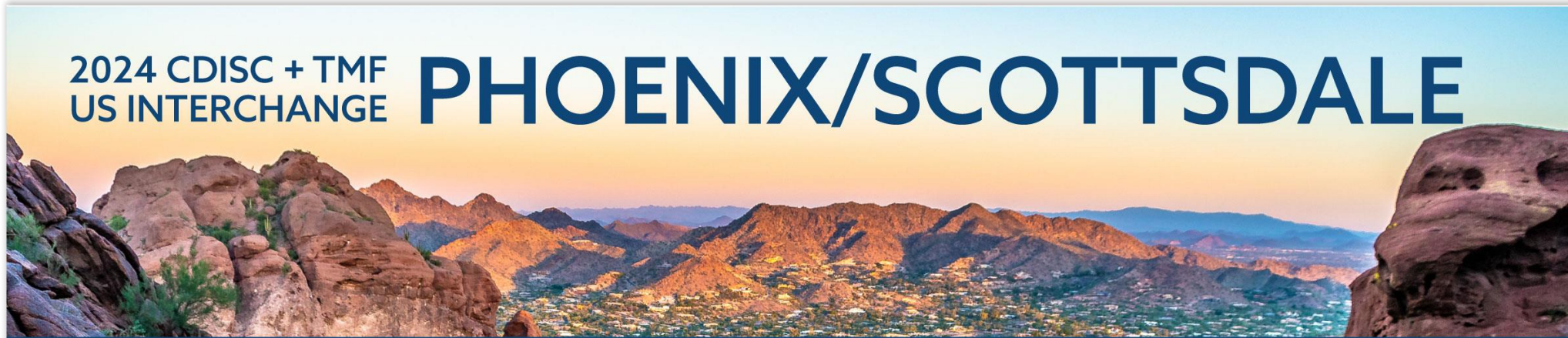




2024 CDISC + TMF
US INTERCHANGE

PHOENIX/SCOTTSDALE



23-24 OCTOBER: CONFERENCE & EXPO | 21, 22, 25 OCTOBER: TRAININGS



CDISC 360*i*

First Step to Realizing the CDISC Vision

CDISC's Vision and Mission



VISION

Amplify Data's Impact to Advance Research

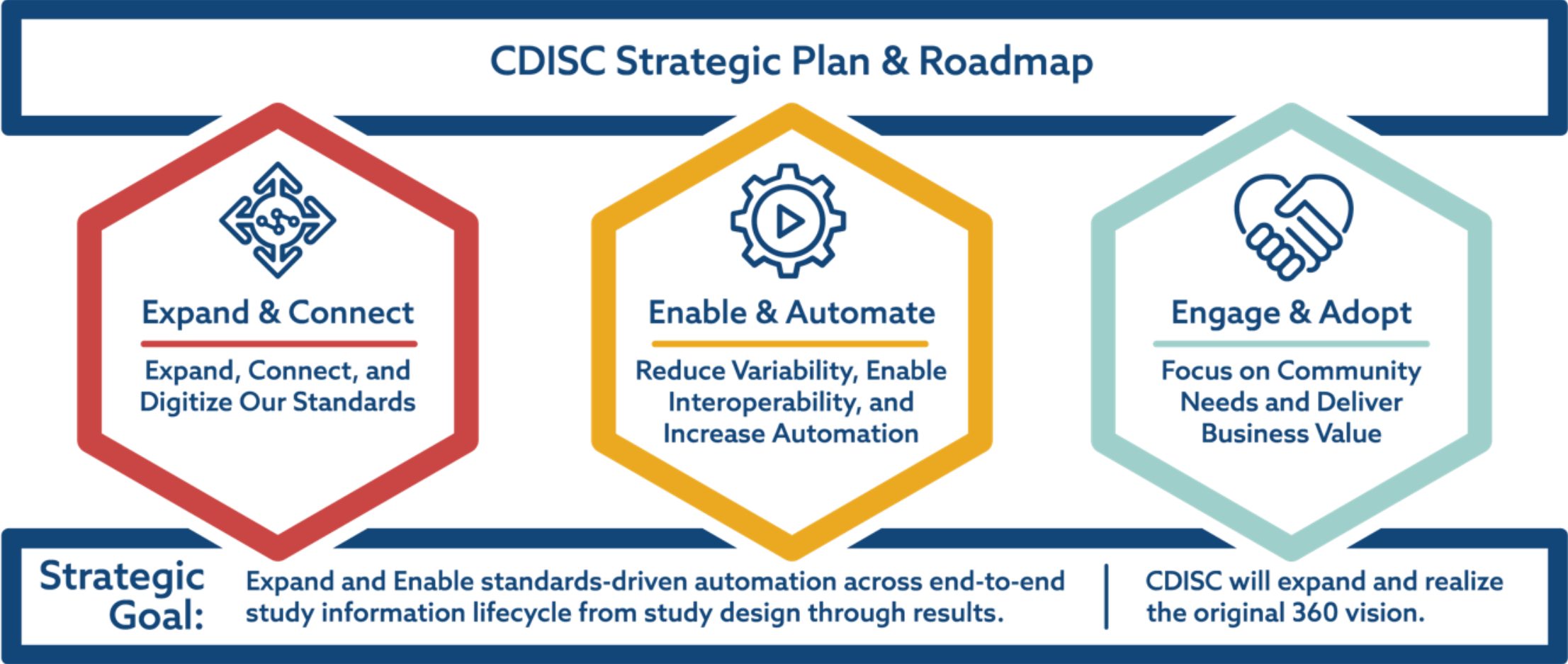


MISSION

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

“Align on a standards-agnostic way to represent biomedical

“Conceptualize standards and solutions from end to end, which includes but is not limited to trial design, collection, tabulation, analysis

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

between SDOs, regulators and biopharma representatives”

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

A decorative graphic on the left side of the slide, consisting of a grid of dots connected by thin lines. The dots are colored in red, yellow, and blue, and the lines are dotted. The pattern is arranged in a grid that is roughly 10 columns wide and 15 rows high.

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



360i

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?



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

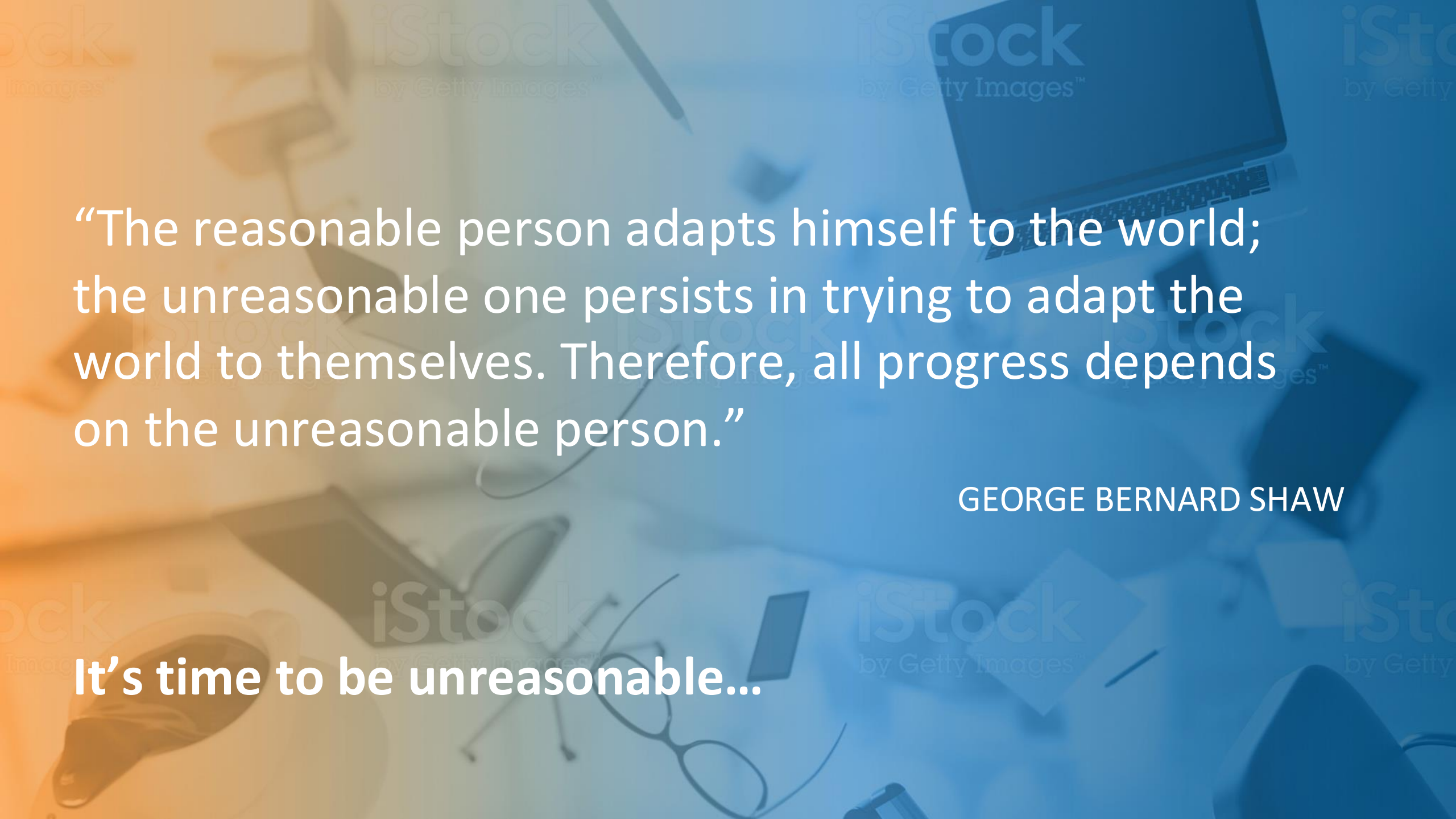


Invest in
Semantic
Layer to
Connect
Standards



Show and
Tell Early
and Often





“The reasonable person adapts himself to the world; the unreasonable one persists in trying to adapt the world to themselves. Therefore, all progress depends on the unreasonable person.”

GEORGE BERNARD SHAW

It's time to be unreasonable...