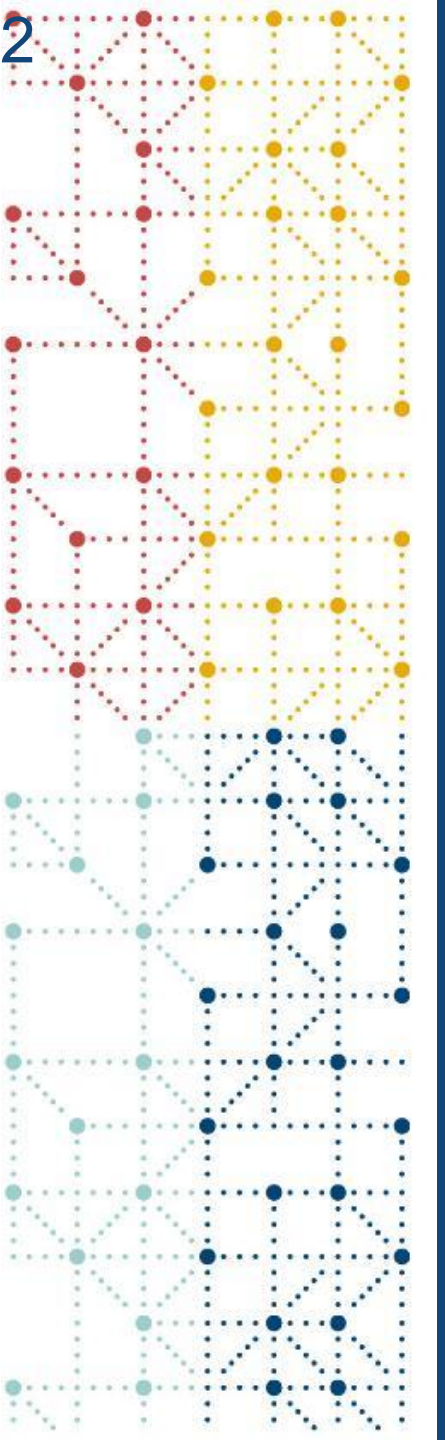
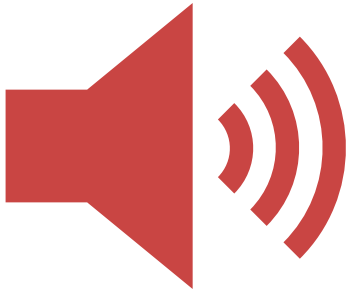
CDISC 360i: Transforming Clinical Research Through Standards-Driven Automation

Webinar will start shortly!



Housekeeping

Housekeeping

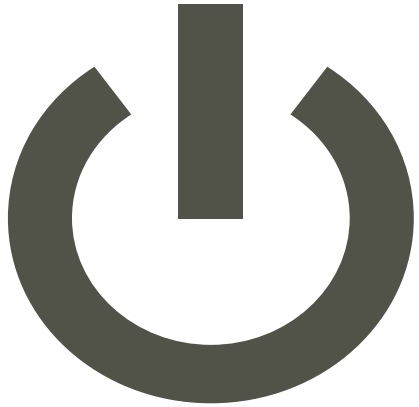


You will remain on **mute**

Housekeeping

Submit questions at any time via the Q&A section on your Teams app

Housekeeping

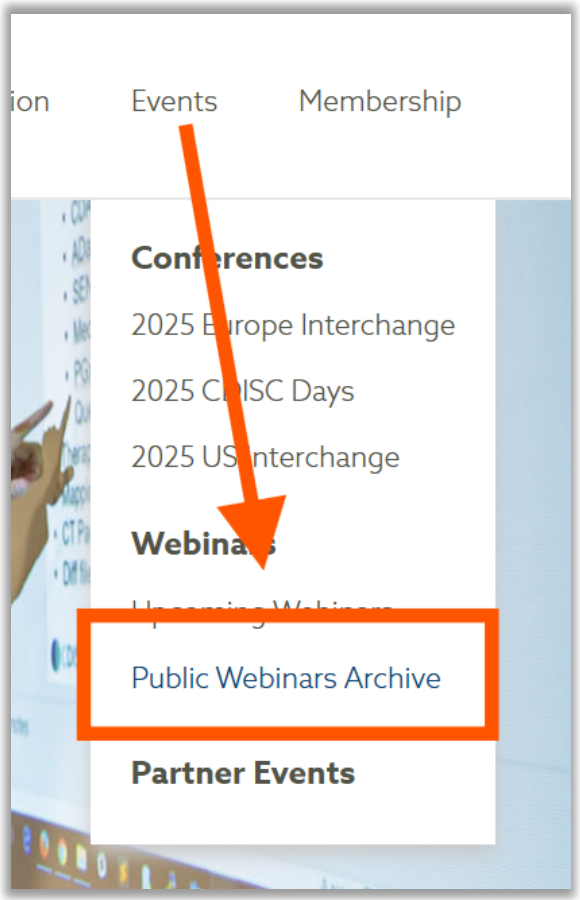


Audio Issues?

First, close and restart your Teams App
Second, check your local internet connection strength

Housekeeping

Webinar Recording



A recording of this webinar and a PDF of the slides will be available in the Public Webinar Archive on the CDISC website.

Meet the Speakers

Chris Decker

Title: President and Chief Executive Officer

Peter Van Reusel

Title: Chief Standards Officer

Julie Smiley

Title: Vice President of Data Science

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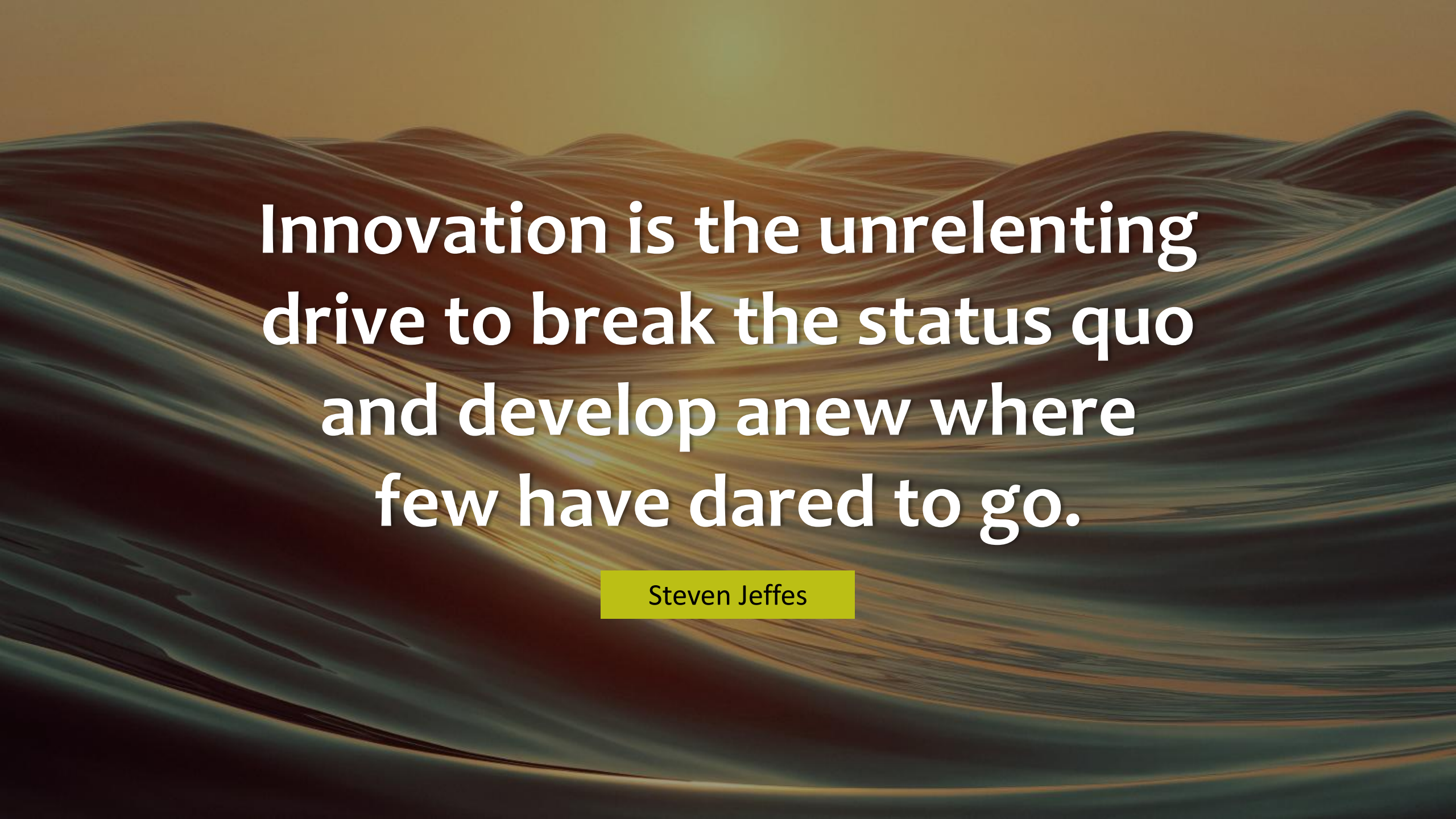
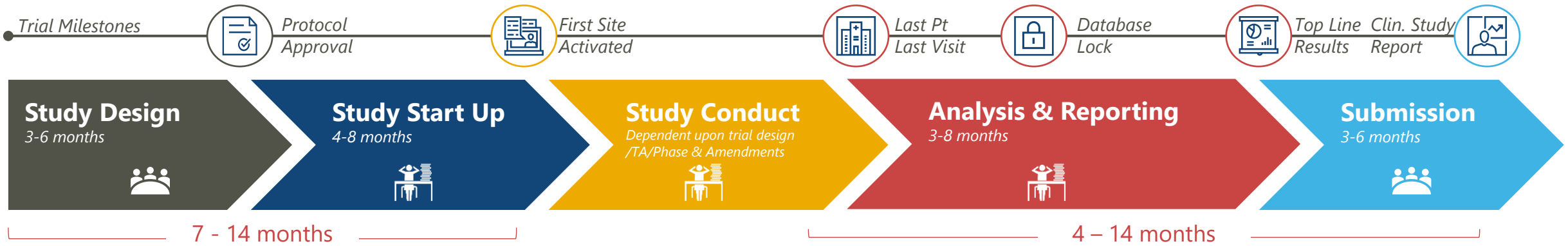

Innovation is the unrelenting drive to break the status quo and develop anew where few have dared to go.
Steven Jeffes


Innovation is the ability to see change as an opportunity – not a threat.
Steve Jobs
quotefancy

As biopharma pivots from research-oriented to competitive development models, cycle time and cost reductions are the new currency



The current trial lifecycle is linear resulting in sub-optimization of critical path activities. Key limitations under the current-state include:

Labor-Intensive Study Design & Start-up

Manual authoring and multiple review cycles of 70+ different study start-up artifacts

"~30% of participant and site burden is associated with non-essential procedures supporting core endpoints."[1]

Amendments

Amendments are time consuming costly, often result in system configuration updates and reversions

"Average of 4 amendments per trial and implementation cost of 500K per amendment"[2]

Trial Data Bottlenecks

Lack of data standardization requires significant effort & cycle time to transform data

"Each phase III protocol gathers, on average, 5.9 million datapoints, up 67% since 2020."[4]

Late SAP Finalization

Analysis requirements defined late in the trial life cycle complicate application of risk-based approaches

"1 day delay in asset development can result in $600K - $8M loss of revenue per day."[2]

Labor Intensive Analysis & Reporting

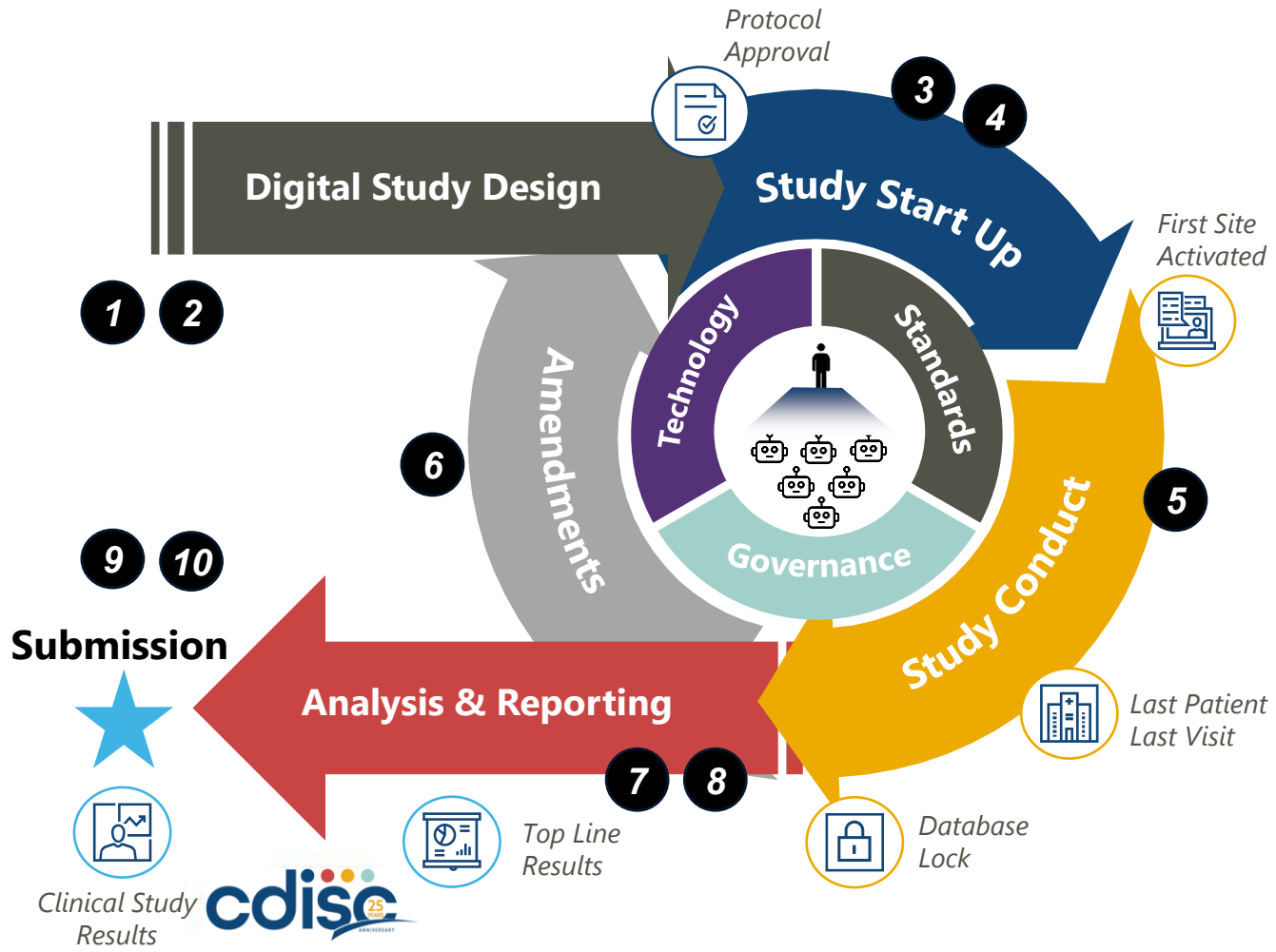
Authoring and review cycles of the CSR dependent upon full analysis & data

"25% of all data collected in a trial is not used in the CSR."[5]

Citations: 1, 2, 3 - Insights informing strategies for optimizing the collection of clinical trial data, Ken Getz Tufts, 4, 5 – PwC Research

Standards are not just a tool…combined with technology they are the foundation for reinventing the biopharma development process and enabling automation

Future-State Trial Lifecycle



AI & Automation Use Cases

1. Protocol Design Optimization
2. Full Text Protocol Generation
3. Study Artifact Generation
4. Site Budget and Contracting
5. Automated Clinical Data Flow
6. Generation & Implementation of Amendments
7. Automated Generation of Analysis Dataset
8. Automated Generation of TLFs
9. eCTD Population and Automatic Linkage
10. Draft CSR Generation

Anticipated Net Cycle Time Reduction

Protocol Approval → First Site Activated	Last Patient Last Visit → Database Lock	Top Line Results → Clinical Study Report
4-12 months reduction	***4-8 weeks reduction***	***2-4 months reduction***

CDISC 360i Elevator Pitch…

CDISC 360i is transforming clinical research by digitalizing study design through analysis making metadata interoperable across the entire study lifecycle. With connected standards and end-to-end automation, 360i eliminates manual tasks, enables AI, ensures traceability and consistency, and empowers the industry to deliver results faster, with better quality, and at a lower cost accelerating the delivery of new therapies to patients

Future standards provide the foundation to reinvent the process and enable automation

Accelerates Clinical Study Start-Up & Reduces Time to Insight

- Automated workflows and eliminating error prone tasks results in moving from **months long setup to streamlined processes** in weeks
- Faster, machine-readable digital study information **improves speed and accuracy**

Drives Quality & Consistency Across the Data Lifecycle

- Standards driven automation **ensures clinical data is consistent, traceable, and reusable**
- Real-time, embedded validation **reduces risk of costly errors and regulatory compliance issues**

Enables Seamless Interoperability & Future-Proofed Data Ecosystem

- Connected study through analysis information in a single framework **empowers industry for greater interoperability**
- Supports growing complexity of trials with **scalable and future-ready data architectures** based on connected standards

Improves Stakeholder Engagement & Regulatory Compliance

- **Industry benefits from faster & smarter study designs**, improved cross-functional alignment, and a streamlined data flow
- Regulatory agencies **receive more consistent, high-quality 'clickable' data submissions**


There's nothing efficient about innovation.
Simon Sinek
quotefancy