Welcome Address: Reflecting on the Last 25 Years
欢迎词：回顾过去的25年

Chris Decker, CDISC CEO

Meet the Speaker

Chris Decker

Title: CEO & President

Organization: CDISC

Widely recognized in the industry, Chris has decades of experience leveraging technology and standards to optimize processes and help industry drive innovation forward. He has extensive experience in executive roles across software development, clinical research, and consulting and his 20-year engagement with CDISC includes roles as a volunteer, implementer, and board member. Chris is passionate about leading CDISC towards a technology-based standards future and expanding the organization's global impact in clinical research standards.

Reflecting on the last 25 Years…
Predicting the next 25

Innovation and Disruption in the Last 25 Years…

2000 | 2005 | 2010 | 2015 | 2020 | 2025

Digital Dawn

2001

facebook 2004

YouTube 2005

cdisc

Mobile & Cloud Boom

amazon web services 2006

2007

Dropbox 2008

2009

AI, Apps, & On-Demand

UC ubercab 2010

Siri 2011

amazon alexa 2014

2015

AI Expansion & New Realities

2016

5G 2018

zoom 2019

Generative AI & the Metaverse

2020

2021

2022

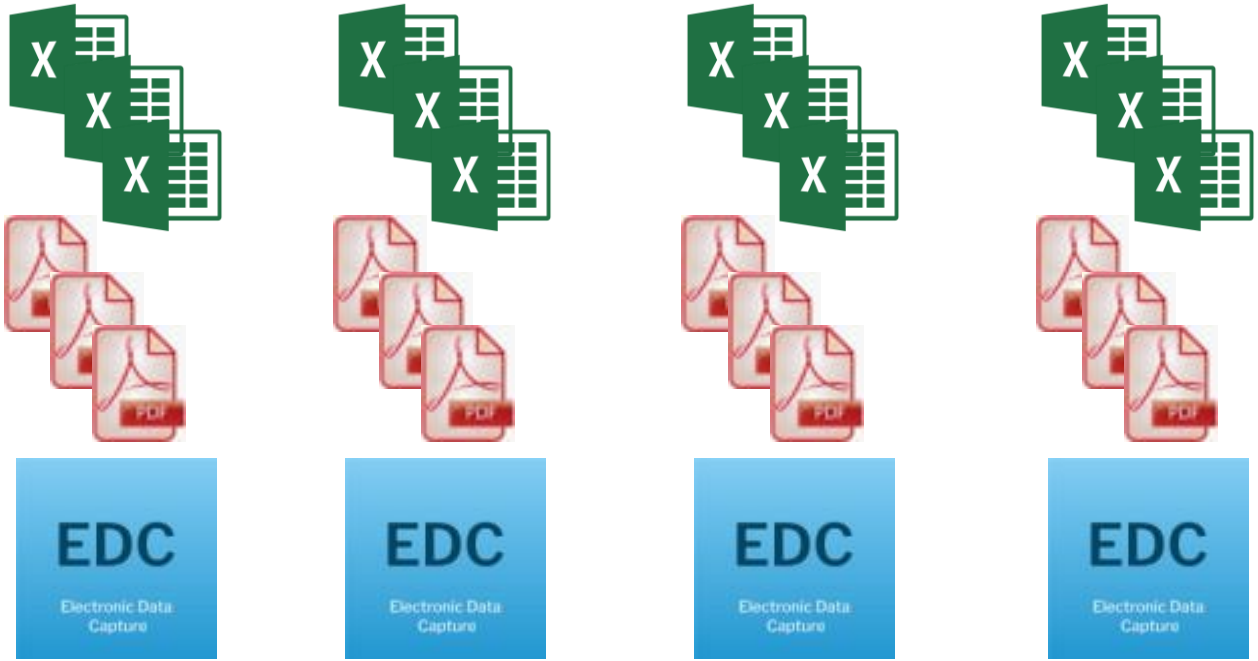
What Will the Next 25 Years Look Like…

Well let's ask Chat GPT….

What will be the most disruptive changes in technology and innovation in the next 25 years?

What has OUR Last 25 Years Looked Like?

2000 > 2005 > 2010 > 2015 > 2020 > 2025



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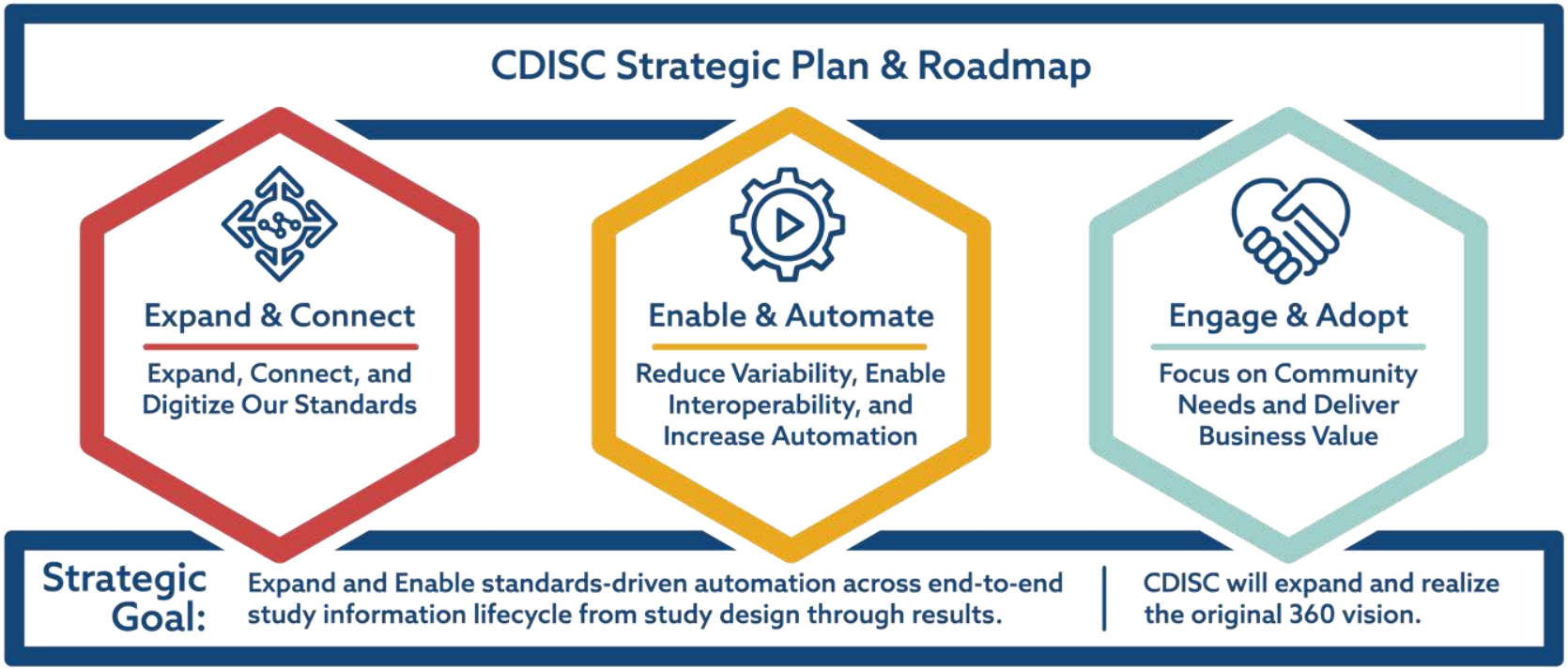
Realizing the CDISC Mission

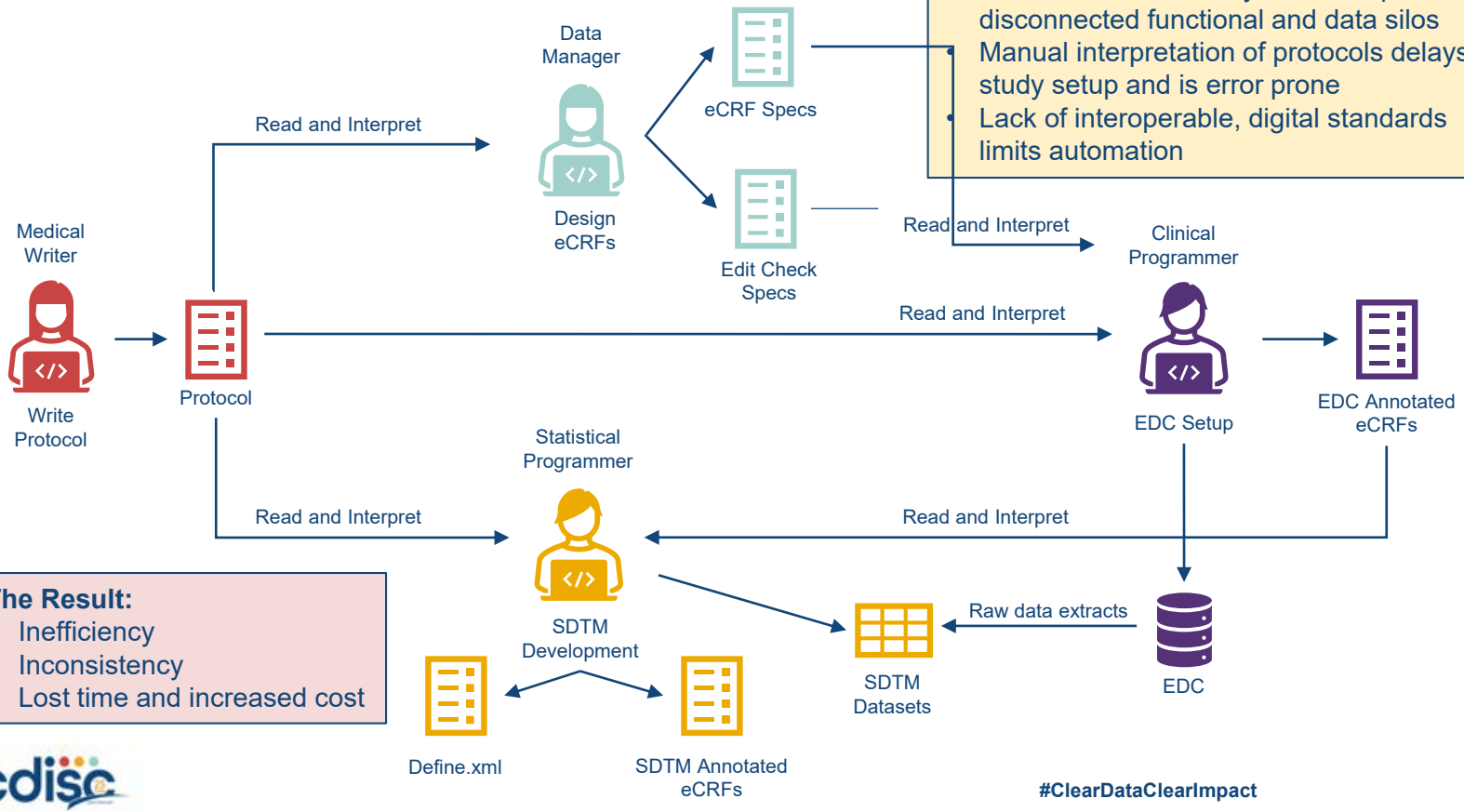
CDISC's vision is to amplify data's Impact to advance research by creating connected standards across the study information lifecycle to enable accessible, interoperable, and reusable data for more meaningful and effective research



CDISC 360i: Transforming the Way we Develop and Use Standards to Enable Standards-Driven Automation

Setting the Stage: The Problem

Today's Clinical Research Landscape:
- Study Design, Data Collection, Tabulations, and Analysis often operate in disconnected functional and data silos
- Manual interpretation of protocols delays study setup and is error prone
- Lack of interoperable, digital standards limits automation



The Result:
- Inefficiency
- Inconsistency
- Lost time and increased cost

360i: Next Step to Realizing Standards Driven Research

Intelligent protocol-driven research to improve patient outcomes

Science & Innovation

Study Design & Conduct

Study Analysis & Review

Standards Driven Automation

Well-defined scientific concepts

With a connected data life cycle

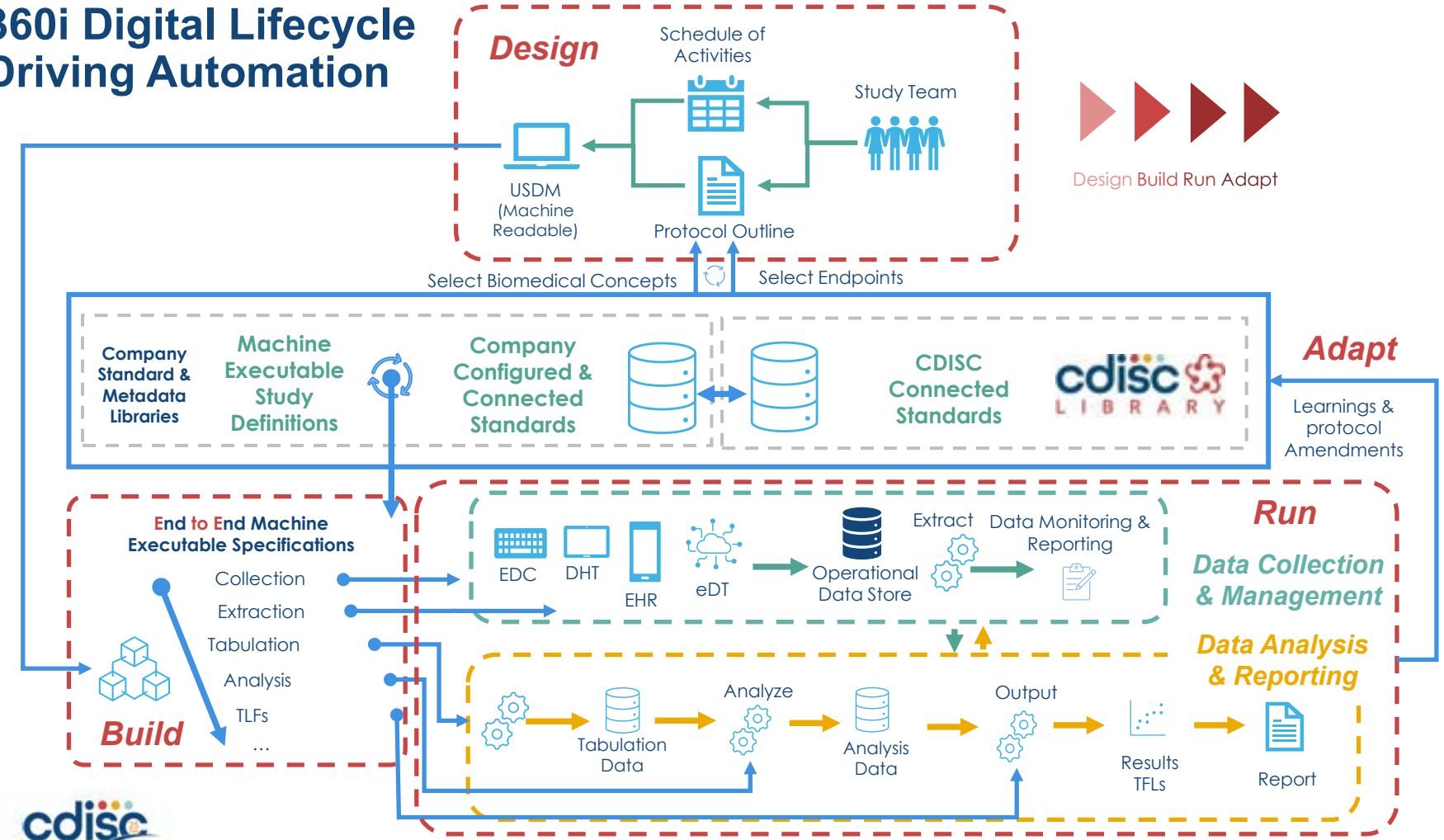
For traceable, interactive, and AI driven results

Value Of A Connected World

Transition standards use from necessary requirement to valuable enabler through connected and ready to use implementable standards.

Patients	Easier access to trials, better engagement in those trials, and faster life saving products to market
Sponsors	Protocol driven research automating the metadata & data pipeline reducing time to study results & increasing quality
Regulators	Reduced variability & clickable traceability from analysis to the collected data increasing confidence in decisions
Researchers	Reduce barrier to entry and cost for standards through ready to use implementable standards & open-source tools
Technologists	Provide machine readable and interoperable inputs and outputs for easier adoption by software solutions

360i Digital Lifecycle Driving Automation



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Use Cases 360i Can Enable

Key
- Initial Focus
- Future Use
- AI Use Case

Study Planning & Design	Study Conduct & Data Collection	Data Aggregation & Standardization	Analysis & Reporting	Regulatory Submission
Protocol Authoring	Electronic Data Transfers	Tabulation & Analysis Specs		Clinical Study Report Generation
Digital SOA	Study Build	SDTM Generation	ADaM Generation	Narrative Generation
Data Transfer Specs	Patient Recruitment	Define.xml	TFL Generation	Clickable Submission
Past Protocols	Data Cleaning	Study Pooling	Digital Analysis Plan	eTMF
Protocol Feasibility	Safety Monitoring			

And many more...

Governance & Reusability

Semantic Interoperability

Standards Conformance

Artifact Recommendations

Built-In Traceability

Example Use Cases: Digital Connected Information Accelerating Trials and Increasing Quality

	Current State *Siloed and manual handoffs across the study lifecycle*	Future State *Upfront digital design information driving downstream activities*	Benefits
Study Setup	• Manual, document-based study design • 6-8 months to start up a study • Labor intensive and error prone	• AI-driven intelligent study design informed by structured digital information • Easier adoption by sites and patients • Automated generation of study build, specifications, and data/analytical artifacts	✓ Focused study design leading to higher quality decisions ✓ Reduce 'start up' by 50-75% accelerating time to study start ✓ Significant reduction in manual transcription errors
Patient Recruitment	• Cycles flat over 10 years, >50% screening failures, >40% dropout • Most critical and expensive area within clinical trials	• Digital information can help assess patient burden and feasibility • More structured and standardized IC/EC targets the right patients	✓ Easier to enroll and better patient experience means less dropouts ✓ Significantly reduce cost of recruitment
Study Amendments	• Average 4 amendments per study • Each amendment costs ~$500K • Labor intensive and error prone	• Better study design reduces amendments • Digitally linked information enables impact analysis of proposed change • Automated implementation of changes reduces efforts by 50%	✓ Save $1.5M per study ✓ Accelerate study exceution by eliminating or reducing effort ✓ Higher quality outputs

What Will 360i Deliver?

- Linked and executable metadata from study endpoint through analysis
- Includes concepts, rules, & sample data

Standards Packages

- Instructions to build standards packages
- Recipes to implement packages within your processes

Implementation Cookbooks

- Technology enabled example leveraging packages & recipes
- Library of community based open-source tools

Example Implementations

Change is the only constant in life.
One's ability to adapt to those changes
will determine your success in life.
Benjamin Franklin
quotefancy

Thank You!
谢谢