



Reflecting on the last 25 Years...Predicting the next 25

Presented by Chris Decker, CEO and President, CDISC

Innovation and Disruption in the Last 25 Years...





What Will the Next 25 Years Look Like...

Well let's ask <u>Chat GPT</u>....

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



What has OUR Last 25 Years Looked Like?











PDI











"The definition of insanity is doing the same thing over and over again expecting different results."

-Albert Einstein









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

Benjamin Franklin

🕜 quotefancy

Vision for the TMF Reference Model

Paul (Fenton) Carter CEO, Montrium; Chair, TMF Reference Model Steering Committee Chair





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A Vision for the Future

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Community Driven







Data & Process Driven







CDISC 360i and State of the Standards

Presented by Peter Van Reusel, Chief Standards Officer, CDISC



Meet the Speaker

Peter Van Reusel

Title: Chief Standards Officer Organization: CDISC

Peter Van Reusel provides executive leadership to the development and implementation of clinical standards in line with CDISC's strategy and operational plans, working closely with the President and CEO, as well as CDISC staff and stakeholders. He has over 20 years' experience in senior roles in pharma and at CROs, providing standards expertise and carrying out other standards work in various organizational settings. A long-time, CDISC-authorized instructor, Peter has helped significantly in developing CDISC training courses.

Peter is also an active PHUSE collaborator.

Agenda

1. CDISC 360i launch

2. State of the Standards



CDISC 360 Launch Activities





Phase 1 Milestones





360i Operational Team





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360i Early Progress

Logistics

- Initiative kicked off
- Team leads
 assigned
- Volunteers assigned
- Team meetings
- Tasks in Jira
- Project organization
- Team training

Deliverables/PoCs

- GitHub repo
- Code to load LZZT data
- Code to run pipeline
- CRF in ODM
- ODM-XML validation
- HTML version of CRF
- USDM Rules
- Synthetic data
- SDTM TDM datasets

Community engagement

- Tech vendor roundtable
- 360i Advisory Council
- TransCelerate DDF
- Call-to-vendors



Standards update 2025

Main activities and deliverables over the past 6~12 months





Foundational Standards

	Projects	Development	Internal Review (IR)	Resolving IR Comments	Public Review (PR)	Resolving PR Comments	Projected Publication
1	ADaM Oncology Examples v1					COMPLETE	2025
2	Unified Study Definitions Model v4				COMPLETE	ONGOING	Q2 2025
3	ADaMIG for Anti-drug Antibody Data v1 w/ Rules	ONGOING	Q2 2025		Q3 2025		Q4 2025
4	SDTMIG v4 w/ Rules		COMPLETE	ONGOING	Aug 2025		Q2 2026
5	SDTM v3		COMPLETE	ONGOING	Aug 2025		Q2 2026
6	SENDIG v4 w/ Rules	ONGOING	Jul 2025		Nov 2025		Q2 2026
7	ADaM Examples for Pharmacokinetic Parameters v1	ONGOING					
8	ADaM Examples for Drug-induced Liver Injury v1	ONGOING					
9	ADaM Examples for FDA Medial Queries v1	ONGOING					
10	ADaM & IG v3 w/ Rules	ONGOING	Q1 2026		Q2 2026		Q3 2026
11	SDTMIG-Medical Devices v2 w/ Rules	ONGOING	2026				2026
12	CDASH v2 & CDASHIG v3	ONGOING	2026				2026
13	TMF Reference Model v4	ONGOING					Q1 2027

Plus:

- Compressed Dataset-JSON
- Dataset-JSON v1.1 API spec
- ODM v2.0 JSON representation





QRS Portal (planning)

- Digitizing QRS Supplements
- QRS Package
 - Biomedical Concepts
 - Controlled Terminology
 - Digital CRF content PDF, metadata spreadsheet, ODM file
 - Digital SDTM & ADaM content
- Targeting 2025 for the first QRS package release
 - 6 Minute Walk Test



Biomedical Concepts

- Total BCs = 568; Total SDTM Specializations = 470
- Current focus

COIS

- Support for 360i
- QRS instruments
- Digital Health Technologies
- CDASH implementation layer
- FHIR implementation layer
- Initial planning for Collaborative Curation BCs from our community
- First BC Training Course in developed and delivered at the European Interchange

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2024-12-17	Abnormal Bleeding Indicator	C154889	C154889	C181043	Reproductive Findings;Clinical Finding	s Indicator;Indicator	BLEEDIND;Abnormal	Indicator
2024-12-17	Abnormal Bleeding Indicator	C154889	C154889	C181043	Reproductive Findings;Clinical Finding	s Indicator;Indicator	BLEEDIND;Abnormal	Indicator
2024-12-17	Abnormal Bleeding Indicator	C154889	C154889	C181043	Reproductive Findings;Clinical Finding	s Indicator;Indicator	BLEEDIND;Abnormal	Indicator
2024-12-17	Abnormal Bleeding Indicator	C154889	C154889	C181043	Reproductive Findings;Clinical Finding	s Indicator;Indicator	BLEEDIND;Abnormal	Indicator
2024-12-17	Abnormal Indicator	C93491	C93491		Clinical Findings Indicator;Indicator			
2024-12-17	Actively Menstruating Indicator	C204695	C204695	C25180	Reproductive Findings;Clinical Finding	s Indicator;Indicator	AMENSIND	
2024-12-17	Actively Menstruating Indicator	C204695	C204695	C25180	Reproductive Findings;Clinical Finding	s Indicator;Indicator	AMENSIND	
2024-12-17	Actual Date of Delivery	C178050	C178050		Reproductive Findings		ADLVRDTC	
2024-12-17	Actual Date of Delivery	C178050	C178050		Reproductive Findings		ADLVRDTC	
2024-12-17	Adrenarche Age	C189362	C189362	C69217	Reproductive Findings;Age		ADRNRAGE	
2024-12-17	Adrenarche Age	C189362	C189362	C69217	Reproductive Findings;Age		ADRNRAGE	
2024-12-17	Adrenarche Age	C189362	C189362	C69217	Reproductive Findings;Age		ADRNRAGE	
2024-12-17	Age at First Oral Sex	C201481	C201481	C25150	Reproductive Findings;Age		FSXOAGE	
2024-12-17	Age at First Oral Sex	C201481	C201481	C25150	Reproductive Findings;Age		FSXOAGE	
2024-12-17	Age at First Oral Sex	C201481	C201481	C25150	Reproductive Findings;Age		FSXOAGE	
2024-12-17	Age at First Sexual Intercourse	C201480	C201480	C25150	Reproductive Findings;Age		FSXIAGE	
2024-12-17	Age at First Sexual Intercourse	C201480	C201480	C25150	Reproductive Findings;Age		FSXIAGE	
2024-12-17	Age at First Sexual Intercourse	C201480	C201480	C25150	Reproductive Findings;Age		FSXIAGE	
2024-12-17	Age at Menarche	C19666	C19666	C25150	Reproductive Findings;Age		MENARAGE; Menarch	e Age

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SDTM Short Name	BC Sh	ort Name	Domain	Note: When applying one Use ctrl + click to do multi	filter, it appl ple selectior	ies to the other o ns in the same filt	fropdowns. er.				
Package Date	BC ID	SDTMIG	Start Version	SDTMIG End Version	Domain	VLM Source	VLM Group ID	SDTM	Short Name		SDTM Variat
2024-12-17	C106497	3-2			RP	RP.RPTESTCD	MENOAGE	Age at	Menopause		RPCAT
2024-12-17	C106497	3-2			RP	RP.RPTESTCD	MENOAGE	Age at	Menopause		RPDTC
2024-12-17	C106497	3-2			RP	RP.RPTESTCD	MENOAGE	Age at	Menopause		RPORRES
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2024-12-17	C106497	3-2			RP	RP.RPTESTCD	MENOAGE	Age at	Menopause		RPSTRESC
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2024-12-17	C106497	3-2			RP	RP.RPTESTCD	MENOAGE	Age at	Menopause		RPTEST
2024-12-17	C106497	3-2			RP	RP.RPTESTCD	MENOAGE	Age at	Menopause		RPTESTCD
2024-12-17	C106501	3-2			RP	RP.RPTESTCD	BCMETHOD	Birth C	ontrol Method		RPCAT
2024-12-17	C106501	3-2			RP	RP.RPTESTCD	BCMETHOD	Birth C	ontrol Method		RPDTC
2024-12-17	C106501	3-2			RP	RP.RPTESTCD	BCMETHOD	Birth C	ontrol Method		RPORRES
2024-12-17	C106501	3-2			RP	RP.RPTESTCD	BCMETHOD	Birth C	ontrol Method		RPSTRESC
2024-12-17	C106501	3-2			RP	RP.RPTESTCD	BCMETHOD	Birth C	ontrol Method		RPTEST
2024-12-17	C106501	3-2			RP	RP.RPTESTCD	BCMETHOD	Birth C	ontrol Method		RPTESTCD
2024-12-17	C106508	3-2			RP	RP.RPTESTCD	CHILDPOT	Childb	earing Potential		RPCAT
2024-12-17	C106508	3-2			RP	RP.RPTESTCD	CHILDPOT	Childb	earing Potential		RPDTC
2024-12-17	C106508	3-2			RP	RP.RPTESTCD	CHILDPOT	Childb	earing Potential		RPORRES
2024-12-17	C106508	3-2			RP	RP.RPTESTCD	CHILDPOT	Childb	earing Potential		RPSTRESC

Session 7A&B: AC/BC Highway to Automation

Analysis Concepts

- What is an Analysis Concept?
 - Collection of standardized configurable elements & methods that are needed to describe a final output or answer a clinical question
 - Standard definitions in a digital statistical analysis plan
- What is the purpose of an Analysis Concept?
 - Supports configuration and automation of analysis
 - Informs what needs to be collected to answer the clinical question



Why Develop Analysis Concepts?

- Reduces ambiguity
 - Analysis Concepts with standardized metadata structure enforce precision in specifying analysis settings and assumptions
- Enables machine-readable analysis plans
 - Analysis Concepts structured as metadata rather than narrative text, can be directly linked to statistical programming code

Supports traceability

Analysis Concepts help maintain clear linkage between protocol objectives, endpoints, and the specific analytical methods applied

Streamlining collaboration

Analysis Concepts provide a common language between statisticians, clinicians, data managers, and other stakeholders



Working Towards a Logical Model



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eTFL Portal

- Launched in October 2024 in collaboration with Clymb Clinical
- 12 initial packages
- Based on safety analysis displays from the ARS v1.0 User Guide and and the FDA Standard Safety Tables and Figures Integrated Guide.
- Each Package contains
 - Analysis overview, design considerations, and TFL preview
 - Download
 - ADaM Dataset and Metadata
 - ARS Metadata
 - Analysis Results Dataset
 - Display



Baseline Demographic and Clinical Characteristics	Deaths	Duration of Treatment Exposure
FDA STF-IG	FDA STF-IG	FDA STF-IG
Overview of Adverse Events FDA STF-IG	Subject Disposition FDA STF-IG	Subjects With Adverse Events by System Organ Class and Preferred Term FDA STF-IG
Subjects With Common Adverse Events Occurring	Subjects With Serious Adverse Events by System	Subjects With Serious Adverse Events by System
at ≥X% Frequency	Organ Class and Preferred Term	Organ Class and Preferred Term
FDA STF-IG	FDA STF-IG	FDA STF-IG
Summary of Observed and Change from Baseline	Summary of Observed and Change from Baseline	Summary of Observed and Change from Baseline
by Scheduled Visita - Chemistry Laboratory Test	by Scheduled Visits - Hematology Laboratory Test	by Scheduled Vinits - Vital Signs
ARS Release Package	ARS Release Package	ARS Release Package



Session 5B: Analysis Results Standards

TIG Submission Pilot Project

CDISC Tobacco Implementation Guide (TIG) Team: FDA CTP, Industry, and CDISC



Enable standards adoption and realization of efficiencies through hands-on experience & support.



Digital Health Technologies (DHT) Initiative

Alignment of Digital Medicine Society (DiMe) and CDISC Resources

Library of Digital Endpoints

https://dimesociety.org/get-involved/library-of-digital-endpoints/

Dirt	Endpoint positioning $\scriptstyle \smallsetminus$	Endpoint description (per trial registration record) $$	Health concept/s ${\scriptstyle \lor}$	Technology \vee
DIGITAL MEDICINE SOCIETY	Primary	Amount of Daily Walking/Activity Level, Collected by the usage log of the device(s), measured in steps per day, Day 0, from enrollment to end of treatment at 12 weeks, post-intervention at Week 16	Physical activity	Wearable

Glossary

https://dimesociety.org/glossary/

Core Measures

Sensor-based digital health technologies (sDHT)

/'sɛnsər-beɪst 'dɪʤətəl hɛlθ tɛk'naləʤiz/

Connected digital medicine products that process data captured by **mobile** sensors using **algorithms** to generate measures of behavioral and/or physiological function, also referred to as biometric monitoring technologies.

<u>V3+ Framework</u>



https://datacc.dimesociety.org/digitalmeasures-physical-activity/all-coremeasures/



Digital Health Technologies (DHT) Initiative

Deliverables

- 1. Key Concepts
- Common in research
- Visualization with relationships, controlled terminology

2. Best Practices

• For using aligned resources with DHTs

- **3. Informative Examples**
- Community reference & comment
- Use cases
 - Continuous glucose
 monitoring
 - Physical activity
 - Sleep
 - Heart rate
 - Nocturnal scratch
- Provisional biomedical concepts
 and controlled terminology

Digital Health Technologies (DHT) Portal

Q4 2025

CDISC Knowledge Base





CDISC Open Rules & CORE

- New release: v0.10.0 05MAY
- Most important enhancements
 - Almost full support for TIG
 - Full functional support for custom rules execution
 - PyPi and Docker Implementation Support
 - Robust Test Suite integrated within CI/CD pipelines to ensure reliability



- SDTMIG 3.3, 3.4 (n=509)
- SENDIG 3.1.1 (n=312)
- FDA Business Rules (n=292)
- TIG v1.0*(n=487)
- USDM v4.0*(n=208)











Thank You!

Join Us in Building the Future:

- Engage with CDISC 360i working groups
- Test, pilot, and provide feedback on new models and tools
- Support the adoption of open digital standards

Together, we are breaking down silos to deliver faster, smarter, more connected clinical research.

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