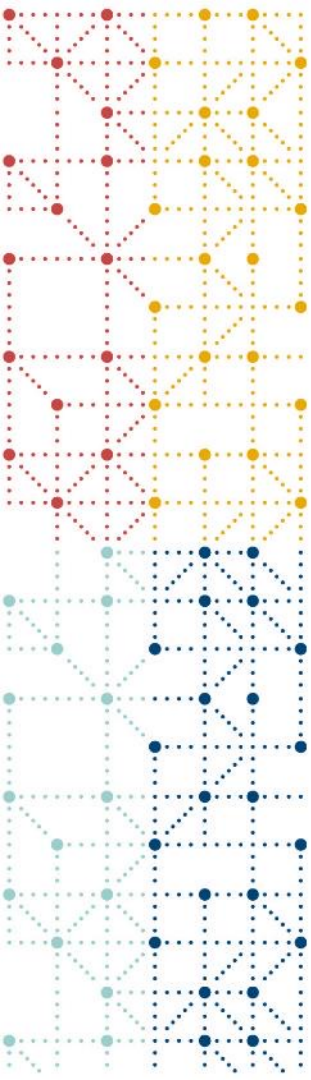
The TMF Reference Model General Meeting Feb 2023

Presenters:

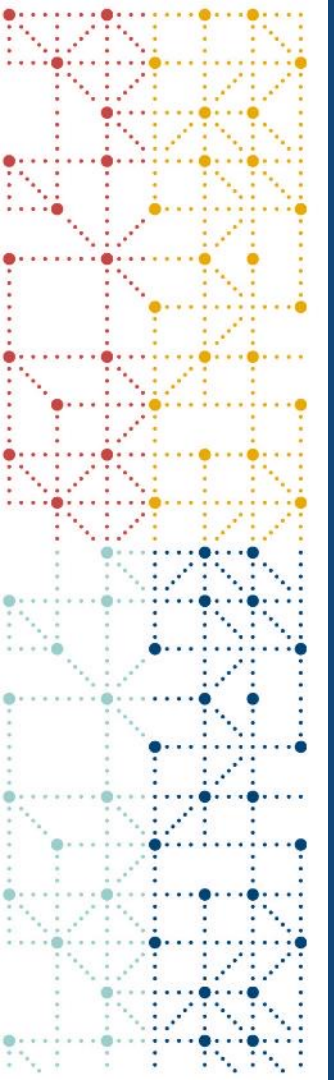
- Karen Roy, Consultant, CDISC; Chair, TMF Reference Model Steering Committee
- Leila Ponce, Sr Manager, Regional Clinical Trial Operations, Clinical Systems & Records Management, Seagen; Chair, Change Control Board
- Paul Fenton, CEO Montrium, TM RM SC Member
- Dawn Niccum, EVP, QA & Compliance, inSeption, TM RM SC Member
- Bernard Klinke, Manager, Events & Technology, CDISC
- John Owen, Head, Project Management Office, CDISC
- Gill Gittens, Director, eClinical Strategy & Solutions, TransPerfect, TM RM SC Member



Introductions

Agenda

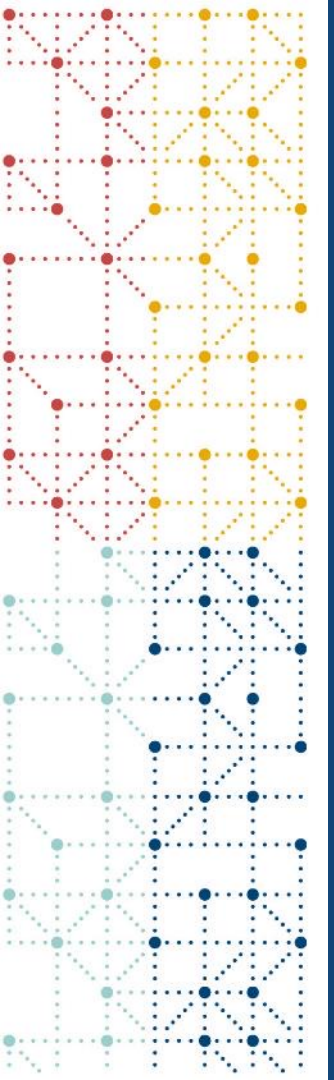
- Steering Committee Elections – Karen Roy
- Update on CDISC Transition – Karen Roy
- Change Control Board Update – Leila Ponce
- The new Standards Sub-group – Paul Fenton
- The new Education Sub-group – Dawn Niccum
- The all new TMF Interchange – Bernard Klinke
- Digital Data Flow and how it can affect the TMF – John Owen
- Webinar feedback ‘New ICH M11 Harmonised Guideline and Protocol template‘ – Gill Gittens
- Regulatory Updates, Upcoming Events and Q&A – Karen Roy



Steering Committee Elections

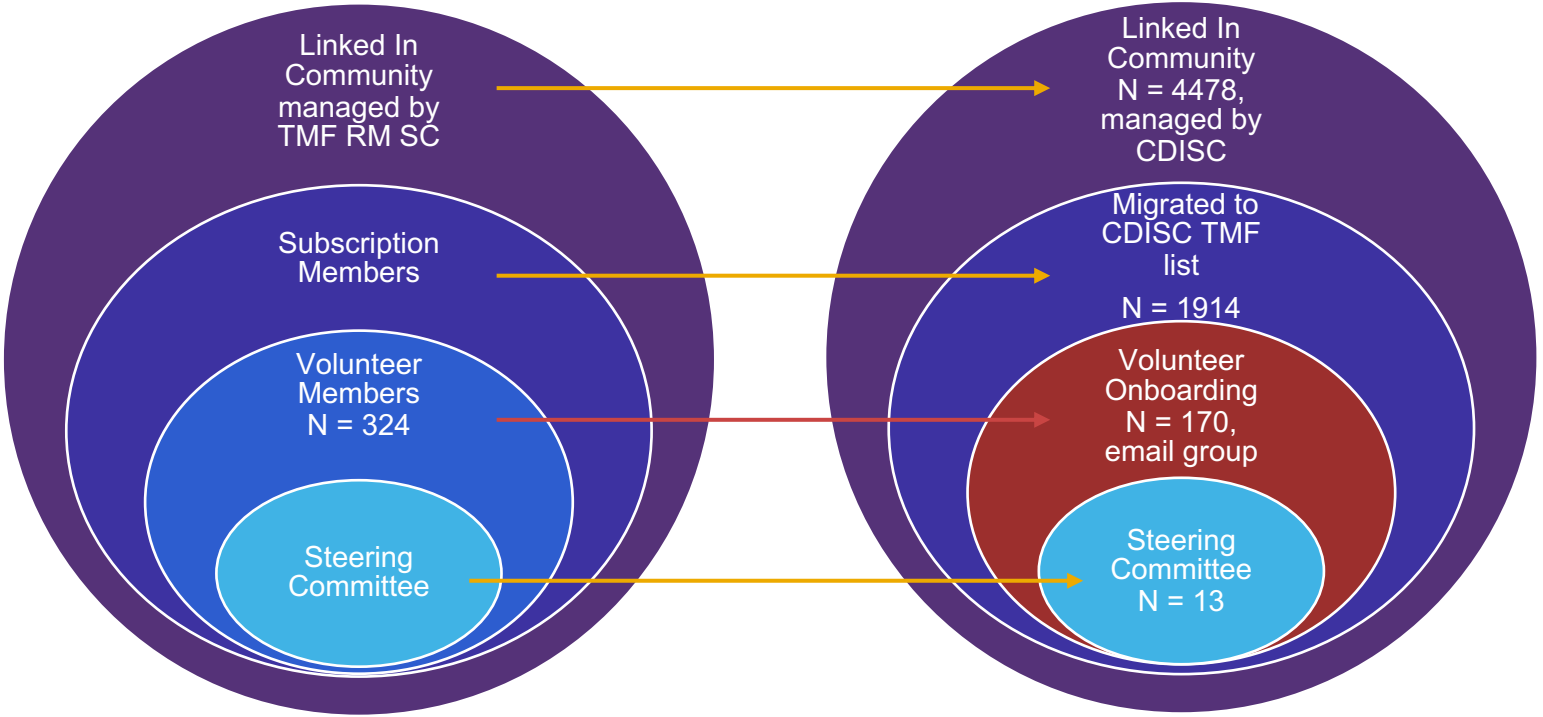
Steering Committee Elections

- Six positions for election or re-election – *Would love more CRO or Investigator Sites*
- Do you qualify?
  - Engaged in the TMF Reference Model for the past 12 months at a minimum
  - At least three years TMF-related experience
  - Currently registered as a CDISC Volunteer
- What does it take?
  - Two weekly calls
  - Leading or taking part in project teams
  - Presenting on behalf of the SC
- What do you do?
  - Submit a 150-word self-nomination on our Nomination Form.
  - For additional details, please refer to the Steering Committee Charter v4.0
  - Submission Deadline: 28 February 2023
- *Why serve on the CDISC TMF Reference Model Steering Committee?*



CDISC Transition

The TMF RM Community move to CDISC is COMPLETE!

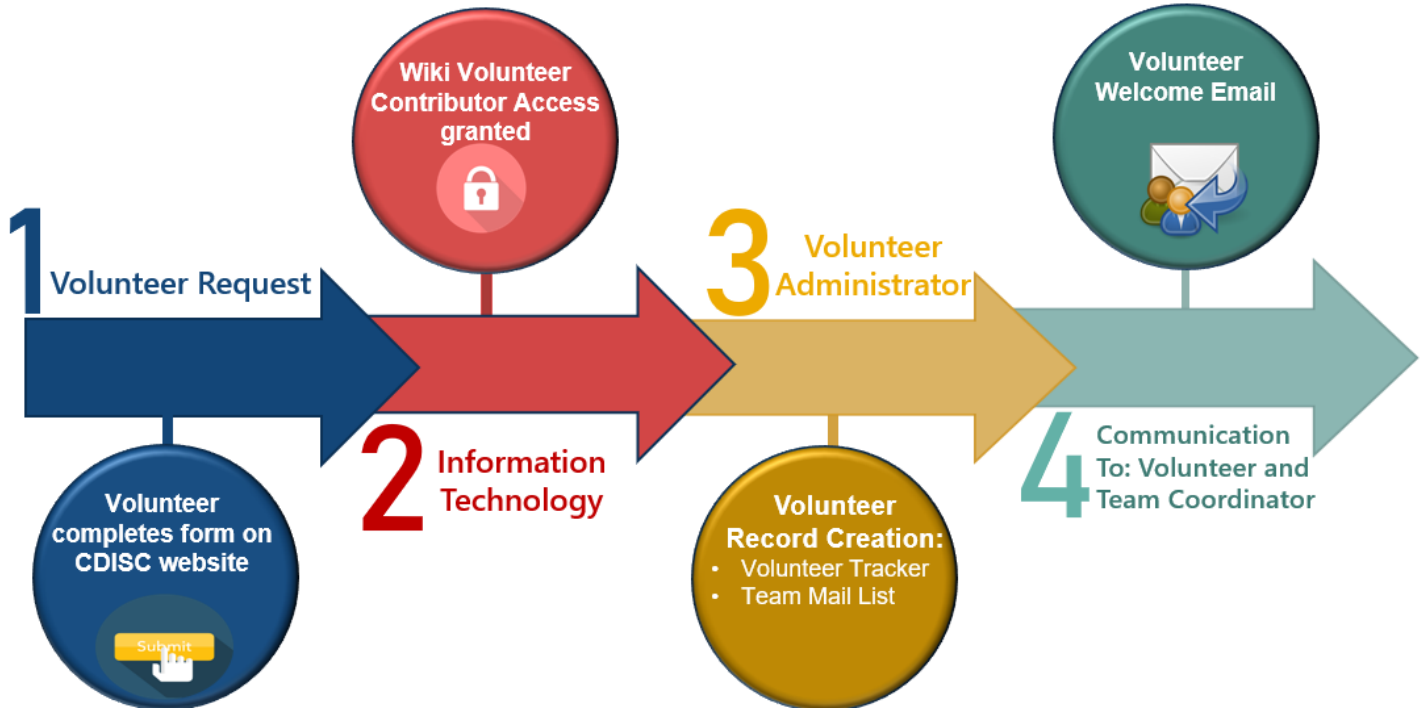


Registering as a Volunteer

- Navigate to https://www.cdisc.org/volunteer/tmf/form
- Review videos, CDISC policies, procedures, and CDISC and TMF charters
- Provide contact information
- Choose one or more TMF Volunteer Groups
- Submit form
- CDISC Volunteer Coordinator will begin onboarding process

https://www.cdisc.org/volunteer/tmf/form

Volunteer Onboarding



Technology Transition

TMF: New Mailing List, Call for Steering Committee Members

C

CDISC <info@cdisc.org> Unsubscribe

To: kazzajroy@icloud.com

Friday, 10 February 2023 at 16:00

Dear TMF Subscriber,

Welcome to the CDISC Mailing List! As part of the transition to CDISC, your details have been moved from the TMF Reference Model website. From now on, you will receive emails from CDISC, specifically for the TMF Community, about updates such as general meetings, new releases, reminders to volunteer.

Groups.io has been shut down. If you would like to continue (or start) volunteering, please complete the volunteer form.

Are you interested in serving on the CDISC TMF Reference Model Steering Committee?

Serving on the CDISC TMF Reference Model Steering Committee provides a unique opportunity to influence the direction of the TMF Reference Model as well as collaborate with fellow TMF experts.

No change yet, but will migrate to CDISC website

Groups.io has been shut down and content archived. Communication through email list

Subscribers moved to a CDISC mailing list

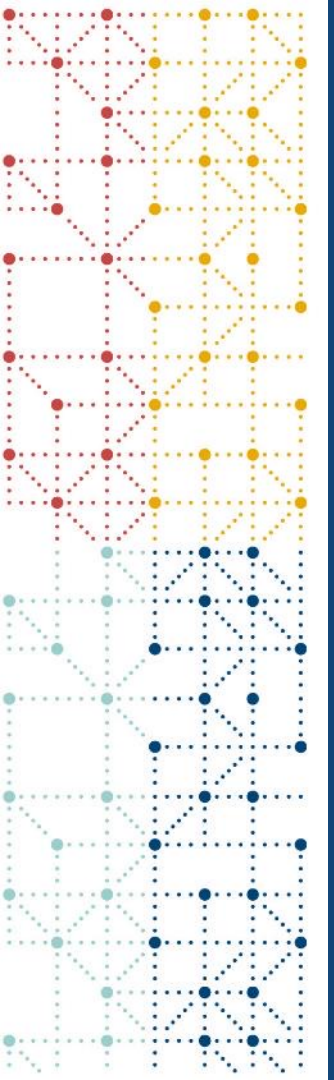
Wikis set up for document sharing and collaboration

The NEW Initiatives

- The Standards Team – Paul Fenton leading

- The Education Team – Dawn Niccum leading

- The CDISC TMF Interchange – We need you!

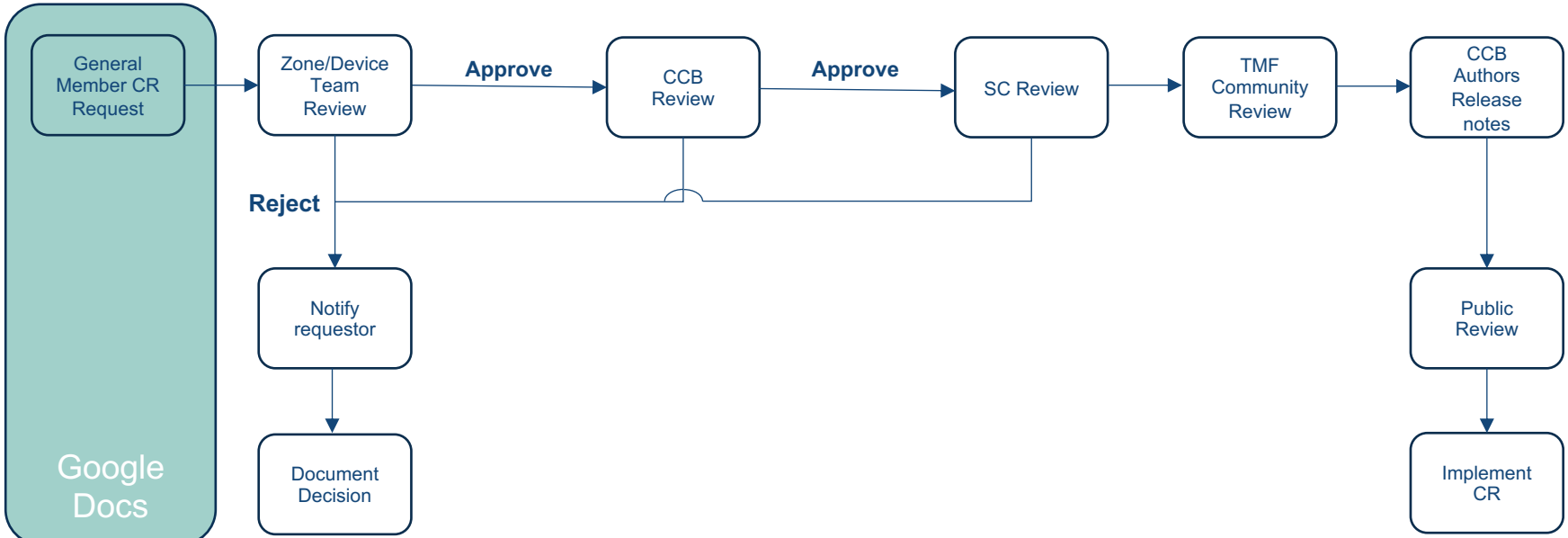


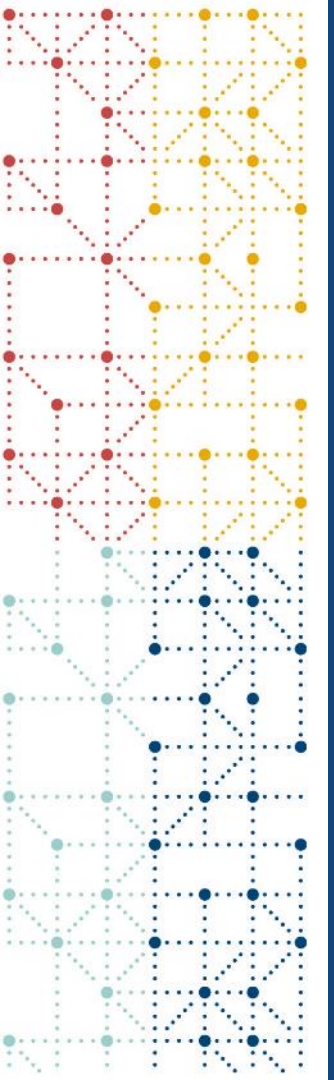
Change Control Board Update

CCB Members

- Leila Ponce (CCB Lead) - Seagen, Inc.
- Kate Santoro (CCB Co-Lead & Zone Team Lead) - Intellia Therapeutics
- Kelley Robinson – Sention Therapeutics
- Allison Grosik – Arcus Biosciences
- Emma Zuccaro – Sarepta Therapeutics
- Kristen Bretzius – Pharvaris
- Gift Tafadzwa Chareka – UZ-UCSF Collaborative Research
- Joanne Bilmazes – Device Representative
- Kim Songco – Pfizer
- Mary Ann Brooks – Baxter Healthcare
- Soraya Nossoughi – Regeneron
- Noreen Bouchard – Astellas
- Lori Braun (Administrative) - Mulcahy Consulting

CR Process


General Member CR Request
Google Docs
Zone/Device Team Review
Approve
CCB Review
Approve
SC Review
TMF Community Review
CCB Authors Release notes
Reject
Notify requestor
Document Decision
Public Review
Implement CR



The new TMF Standards Sub-group

TMF Standards Sub-Group

- Established in December 2022
- Will oversee the move of the TMF Reference Model from a de-facto standard to a formal standard
- 3 Initiatives:
  - Migration of TMF RM to CDISC Library
  - Evolution of EMS/Interoperability
  - TMF RM Standard Alignment and Management

TMF Standards Governance Committee

- Paul Fenton, CEO, Montrium Inc. – Chair
- Karen Roy, Chair TMF RM, CDISC – Secretary
- Jamie Toth, Global Head TMF Mgt and Records, BeiGene
- Sam Hume, VP Data Science, CDISC
- Kelley Robinson, Head of TMF Operations, Sention – CCB Representative
- Bess LeRoy, Head of Standards Innovation, CDISC
- Aaron Grant, VP Solutions Consulting, Phlexglobal
- Elizabeth Entwistle, Clinical Quality Manager, Novartis

Objective 1 – Migration of TMF RM to CDISC Library

- We want to move away from a Spreadsheet to a more dynamic format
- The CDISC library is a database where all CDISC standards are mapped and managed
- We will be able to search the library to find information on specific artifacts
- We should also be able to extract the model in Excel format
- Advantages to moving to the library include:
  - Ability to expand the RM (metadata)
  - Better control changes and version history
  - More easily map to other models and standards
  - Define sub-models for different types of trials

Team Leads: Kelley Robinson, Sam Hume

Objective 2 – Evolution of EMS / Interoperability

- EMS has been developed but has yet to be reduced to practice in a significant way
- Some vendors are adopting it, however, we need to re-engage with the vendor and business communities
- There are multiple use cases which we need to account for in future versions
- We need input form CDISC on how to better structure the initiative and promote its use
- The EMS should also be integrated into the CDISC library as part of the overall TMF RM standard
- We also need to ensure that we are aligned with the DDF initiative which has similar objectives

Team Leads: Jamie Toth, Aaron Grant

Objective 3 – TMF RM Standard Alignment and Management

Part 1 – Process implementation

- We will adapt and apply formal CDISC standards management processes to properly manage the CDISC TMF RM as a standard

Part 2 – Standards Alignment and Integration

- The CDISC vision is for TMF to be full integrated into the standards landscape
- As DDF and digital protocol standards evolve, we should align and integrate the CDISC TMF RM Standard
- We also need to ensure alignment with CDSISC controlled terminology and taxonomy

Team Leads: Bess LeRoy, Paul Fenton

Next steps

- Publish governance committee charter
- Start work on roadmap
- Form working groups for each initiative
- Get to work!

Interested in becoming a volunteer?

- We are looking for both technical and business focused volunteers
- You can work for either a sponsor, CRO, vendor or be a consultant – everyone welcome who feels they can contribute
- Time commitment should be at least 2-3 hours per week
- If you are interested, register as a volunteer on the CDISC website
- We will organize the workstreams to start in March so please register as soon as possible!

The new Education Sub-group

Education Team

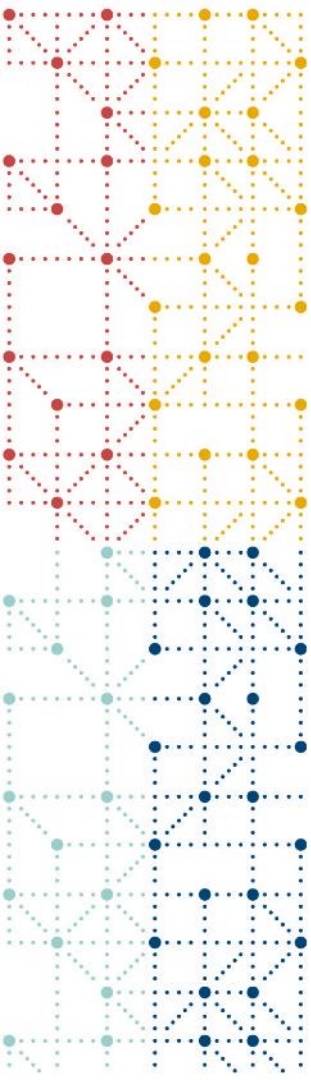
Members

Chair: Dawn Niccum, inSeption

Secretary: Karen Roy, Consultant

- Lisa Mulcahy, Consultant
- Jenn Stamper, Just in Time
- Lyndsey Kirwan, Montrium
- Noreen Bouchard, Astellas
- Jackie Morrill, LMK

- Purpose
  - Oversee the development of training courses through CDISC to increase and support the knowledge of the TMF RM.
- Trainings
  - Format: in-person, webinars, and eLearning
  - CEUs will be available
  - Supported by CDISC's education team
- First Deliverable:
  - In-Person Workshop (½ day) at the CDISC TMF Interchange – 27 Sep



The all new CDISC TMF Interchange

2023 CDISC Interchanges

Europe Interchange
26 – 27 April
Copenhagen
Denmark

Japan Interchange
10 – 11 July
Tokyo
Japan

China Interchange
25 – 26 August
Beijing
China

US Interchange
18-19 October
Washington, DC area
USA

Korea Interchange
11–14 December
Seoul
Korea

TMF / CDISC Conference – A New Tradition

27-28 September 2023
US East Coast

Call for Abstracts Opening Soon!

What to Expect from a TMF / CDISC Conference

Program Development

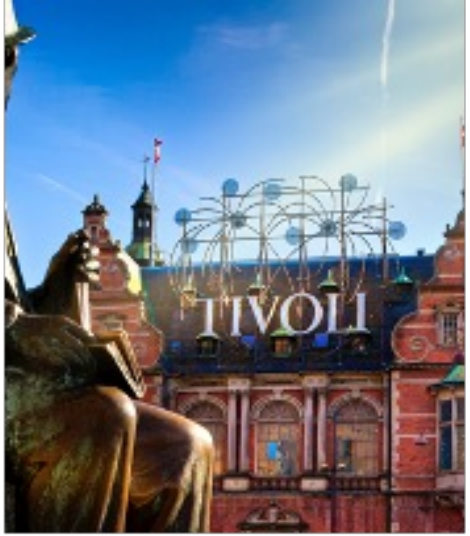
- Program committee
- Call for abstracts
- 60-day window
- Submission review based on merit

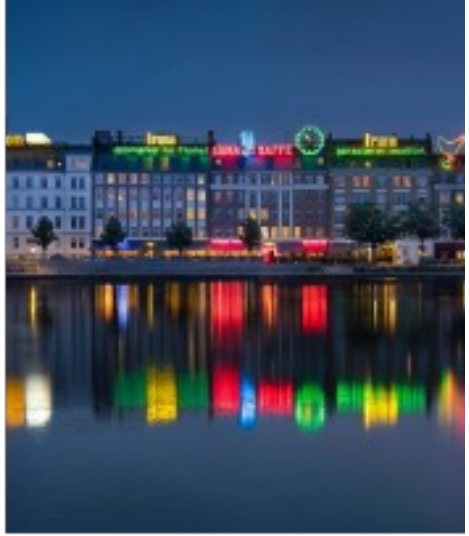
Abstract Acceptance Criteria

- Potential to educate audience
- Anticipated audience interest
- Timeliness of topic
- Uniqueness of the topic and approach
- Vendor neutrality

Sponsor & Exhibitor Opportunities

LIVE CONFERENCE SPONSOR & EXHIBITOR BENEFITS	Exhibitor (Check Availability)	Emerald (5 Available)	Sapphire (4 Available)	Ruby (3 Available)	Diamond (3 Available)
Exhibitor Booth(s)	1	0	1	1	2
Conference Passes	2	1	2	3	4
Evening Event Passes	2	1	2	3	4
Logo on CDISC Website	✓	✓	✓	✓	✓
Logo in Program	✓	✓	✓	✓	✓
Your Logo on Rotating Slides		✓	✓	✓	✓
Branded Sponsor Signage		Regular	Regular	Regular	Deluxe
Sponsor Flyer at Registration*		1-Page	1-Page	1-Page	2-Page
Thank You During Keynote		✓	✓	✓	✓
Logo in Email Communications		✓	✓	✓	✓
Thank You on Mobile App Sponsor Page		✓	✓	✓	✓
Basic Attendee List		✓	✓	✓	✓
Attendee Marketing List**				✓	✓
Featured Exhibitor on Mobile App				✓	✓
2 Mobile App Push Notifications				✓	✓
Advertisement on Rotating Slides					✓
1/2-Page Ad in Program					✓
Choice of Session Sponsorship				1	2





2023 CDISC Europe Interchange

Copenhagen, Denmark
26-27 April 2023

https://www.cdisc.org/events/interchange/2023-europe-interchange

2023 Europe Interchange Sponsors + Exhibitors

Sponsors

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OCS LIFE SCIENCES

CLYMB CLINICAL

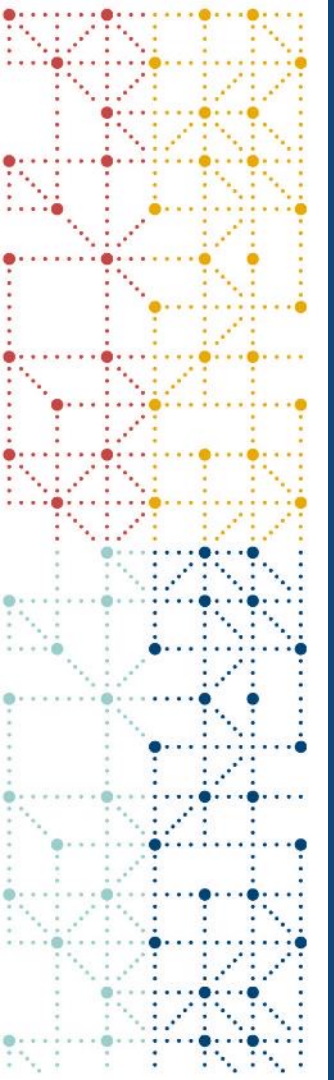
SGS

We hope to see you there for our first TMF / CDISC Conference!

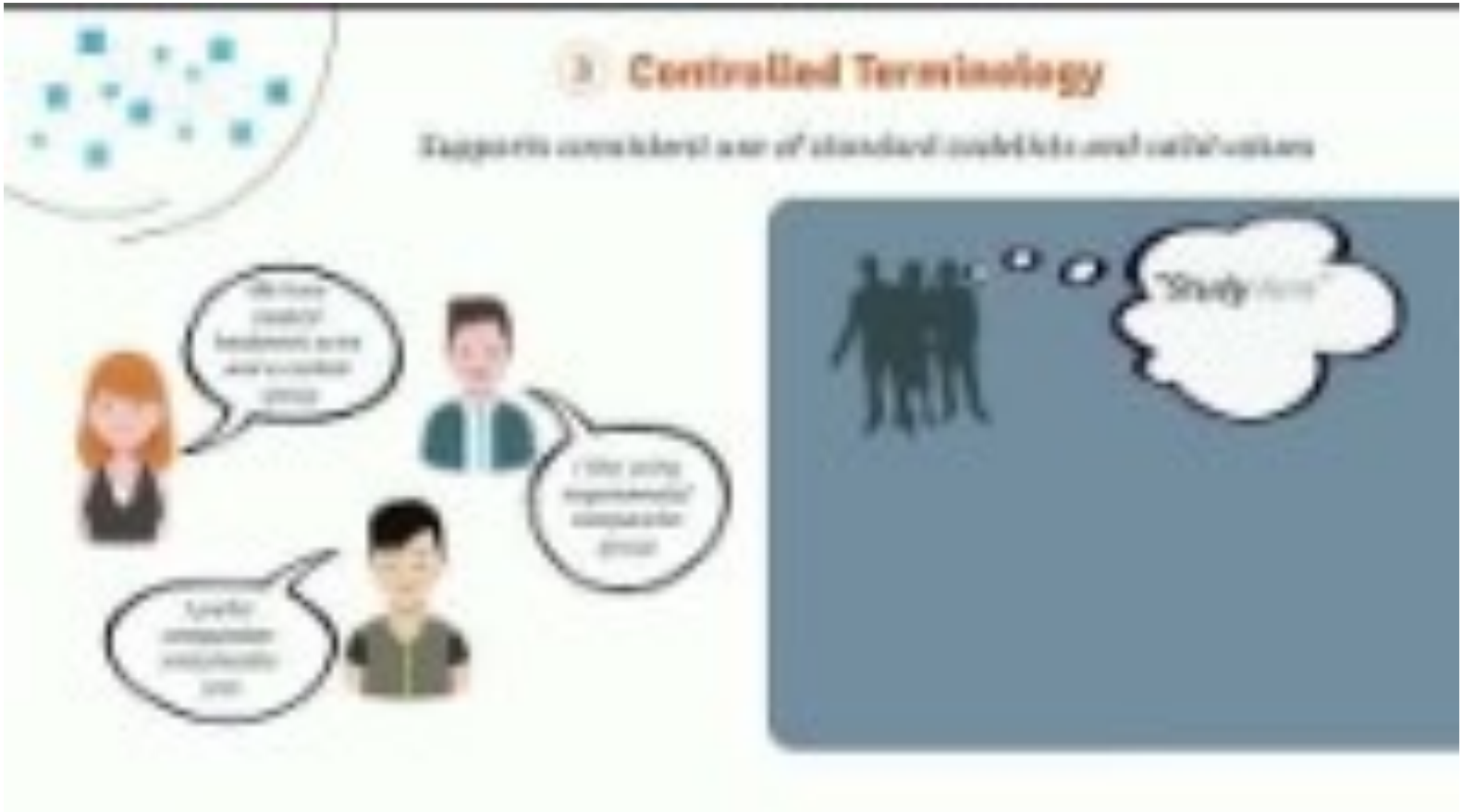
Contact Information:

CDISC Events Team: events@cdisc.org

Bernard Klinke: bklinke@cdisc.org

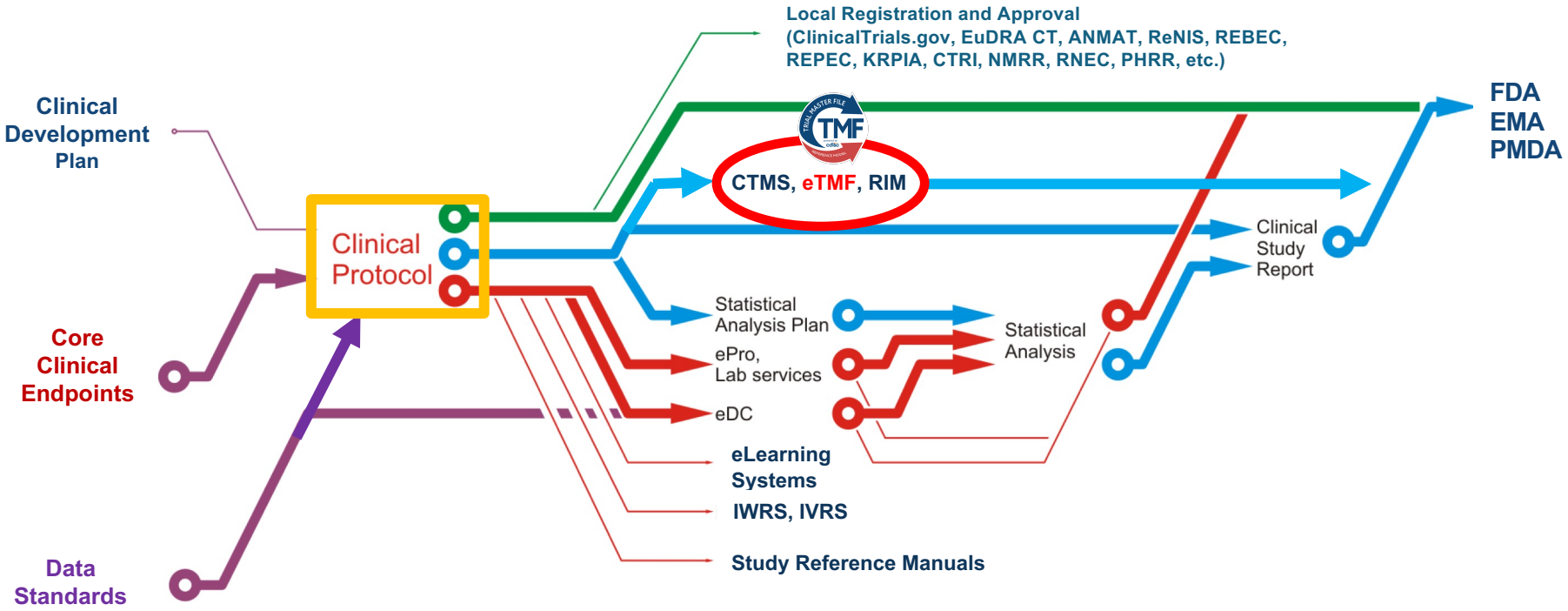


Digital Data Flow and how it can affect the TMF



https://www.transceleratebiopharmainc.com/assets/digital-data-flow-solutions/

The Clinical Trial Information Flow



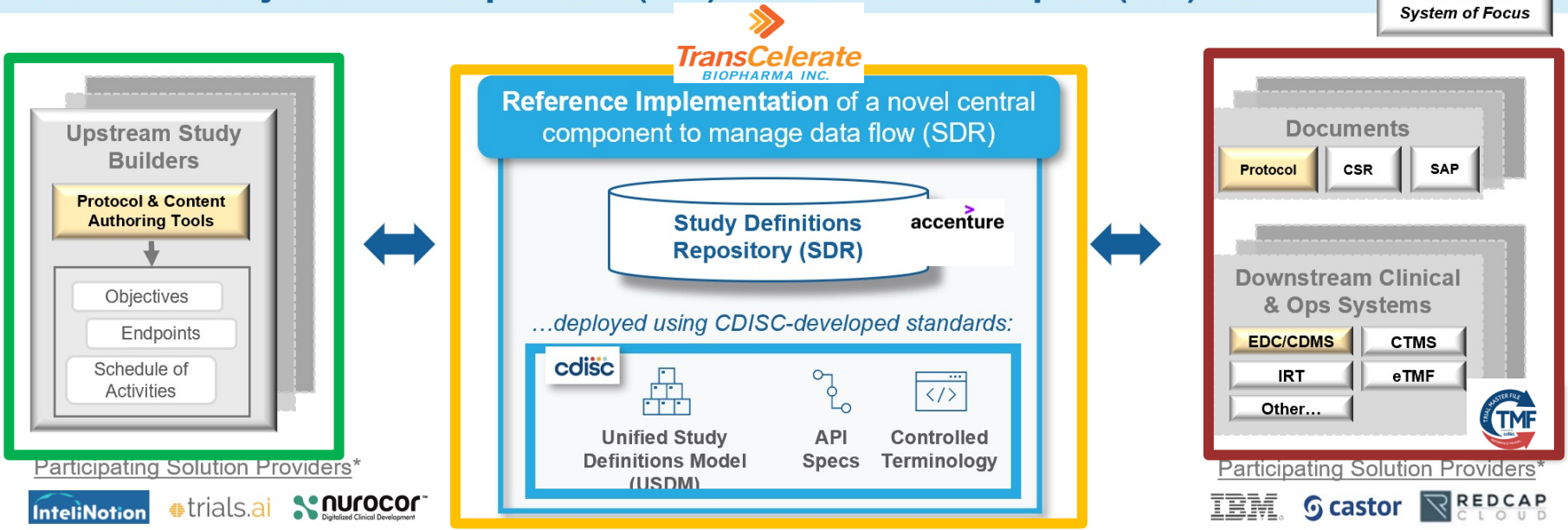
Minimum Viable Product (MVP) development underway

April 2022 Anticipated Release Date

The MVP release will focus on enabling flow of study definitions data from study builders to Study Definitions Repositories (SDR) to Electronic Data Capture (EDC)/CDMS

System or Tool of Focus for MVP

Potential Future System of Focus



* Solution Providers above have volunteered to participate in MVP development in anticipation of making use of DDF solutions in the future. Additional Solution Providers may volunteer in coming weeks/months. TransCelerate does not endorse nor recommend specific vendors or commercial products.

Minimum Viable Prod…lerway

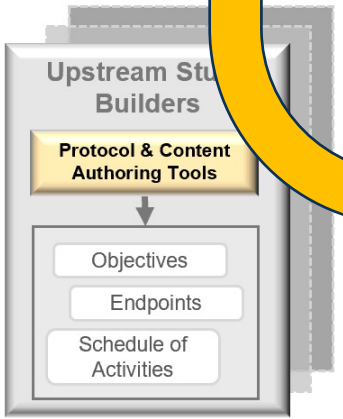
April 2022 Anticipated Release …ate

The MVP rele… will focus on …om study builders to S… Definitions R… …ture (EDC)/CDMS

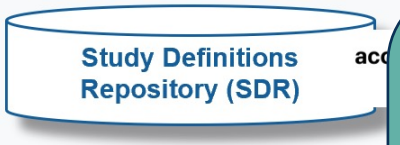
System or Tool of Focus for MVP

Potential Future System of Focus

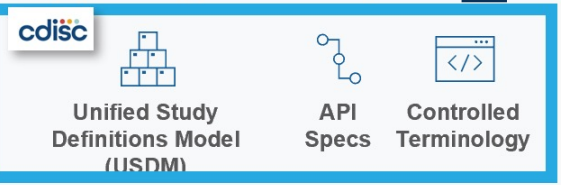
Reference Implementation
Accenture create a reference implementation based on the Reference Architecture that CDISC will develop



Reference Implementation of a novel central component to manage data flow (SDR)



…deployed using CDISC-developed sta…rds:



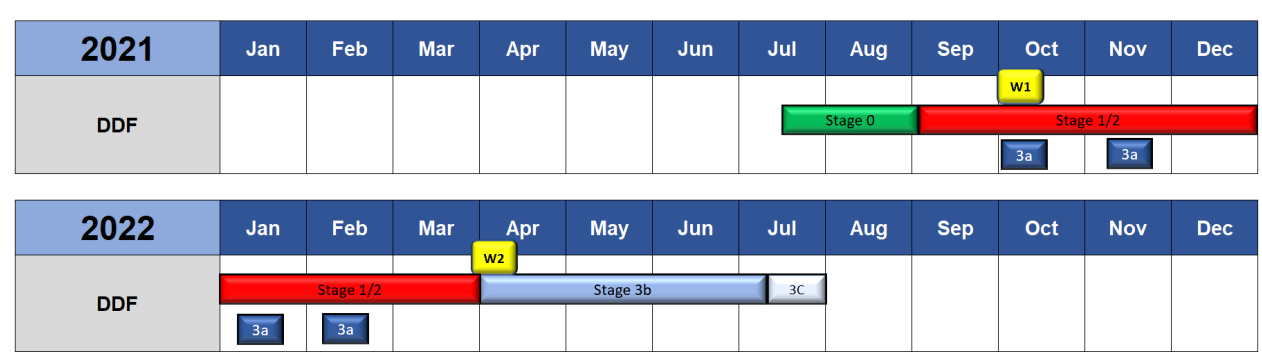
Reference Architecture
CDISC develop the standard model, API, and corresponding controlled terminology to support the model and API

Participating Solution Providers*

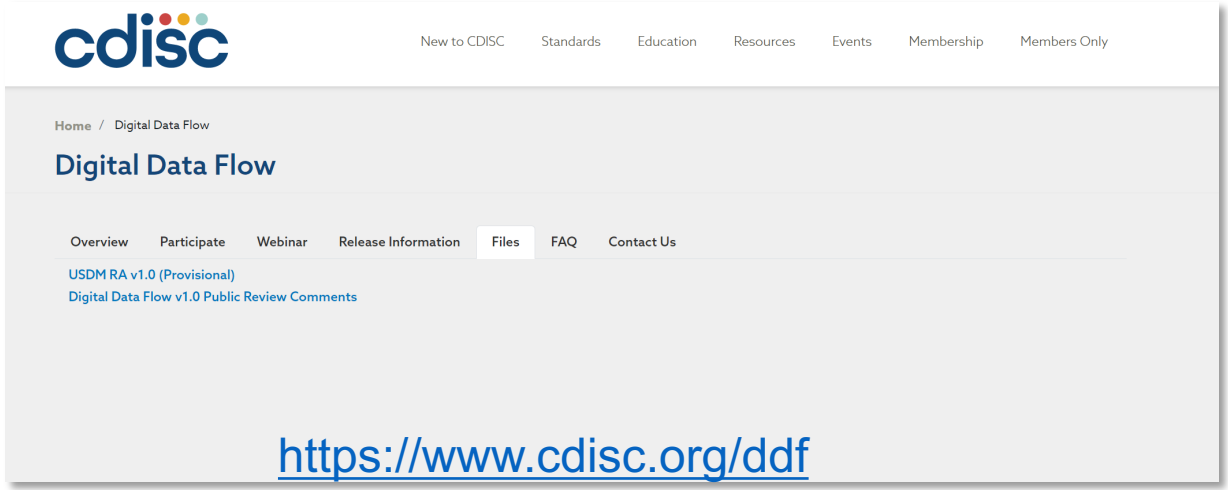
InteliNotion trials.ai nurocor Digitalized Clinical Development

* Solution Providers above have volunteered to participate in MVP development in anticipation of making use of DDF solutions in the future. Additional Solution Providers may volunteer in coming weeks/months. TransCelerate does not endorse nor recommend specific vendors or commercial products.

Timelines – Phase 1

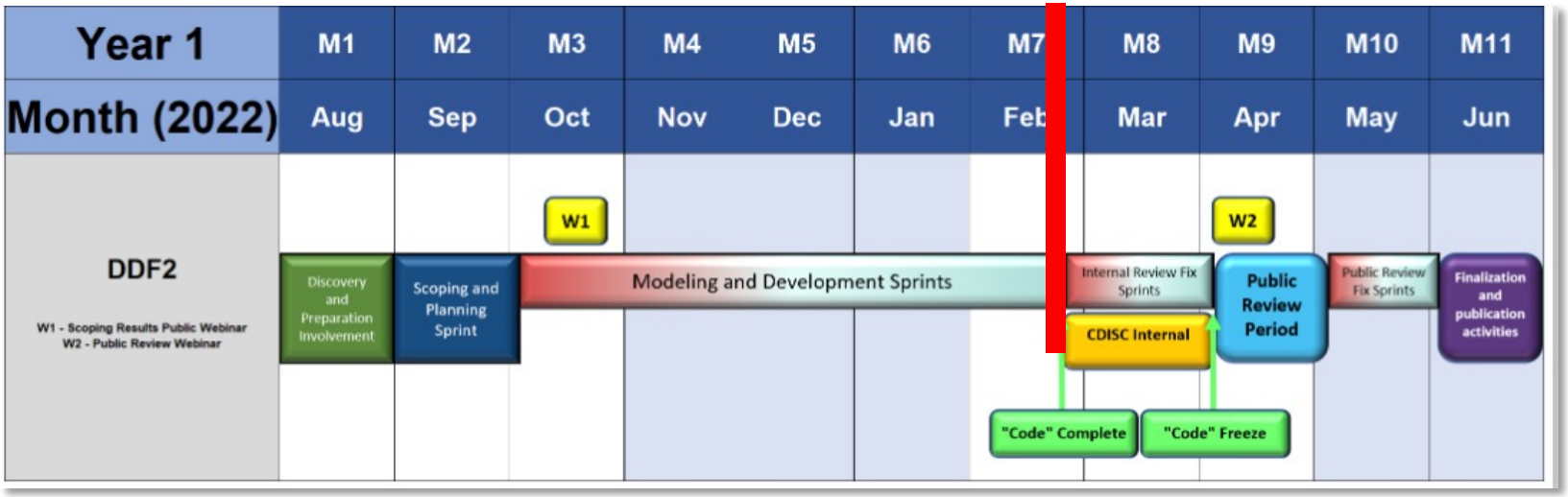


Stage 0	Scoping and Planning
Stage 1/2	Identification/Modeling of Concepts Standards Development
Stage 3a	Internal Review
Stage 3b	Public Review
Stage 3c	Publication
W	Public Webinars 1 - Scoping Results 2 - Public Review



https://www.cdisc.org/ddf

Timelines – Phase 2



https://www.cdisc.org/ddf

DDF Phase 2 Standards Strategy

- The primary goal of this phase of the project is enablement of EDC automation for sponsor adoption

- Secondary goals were additional updates to the model to enable greater population of study set-up elements, including selected structured eCPT data elements

Overview of Development Areas for DDF2

Enhancements/bug fixes from DDF1 Updates

Updates to accommodate Biomedical Concepts (EDC build)

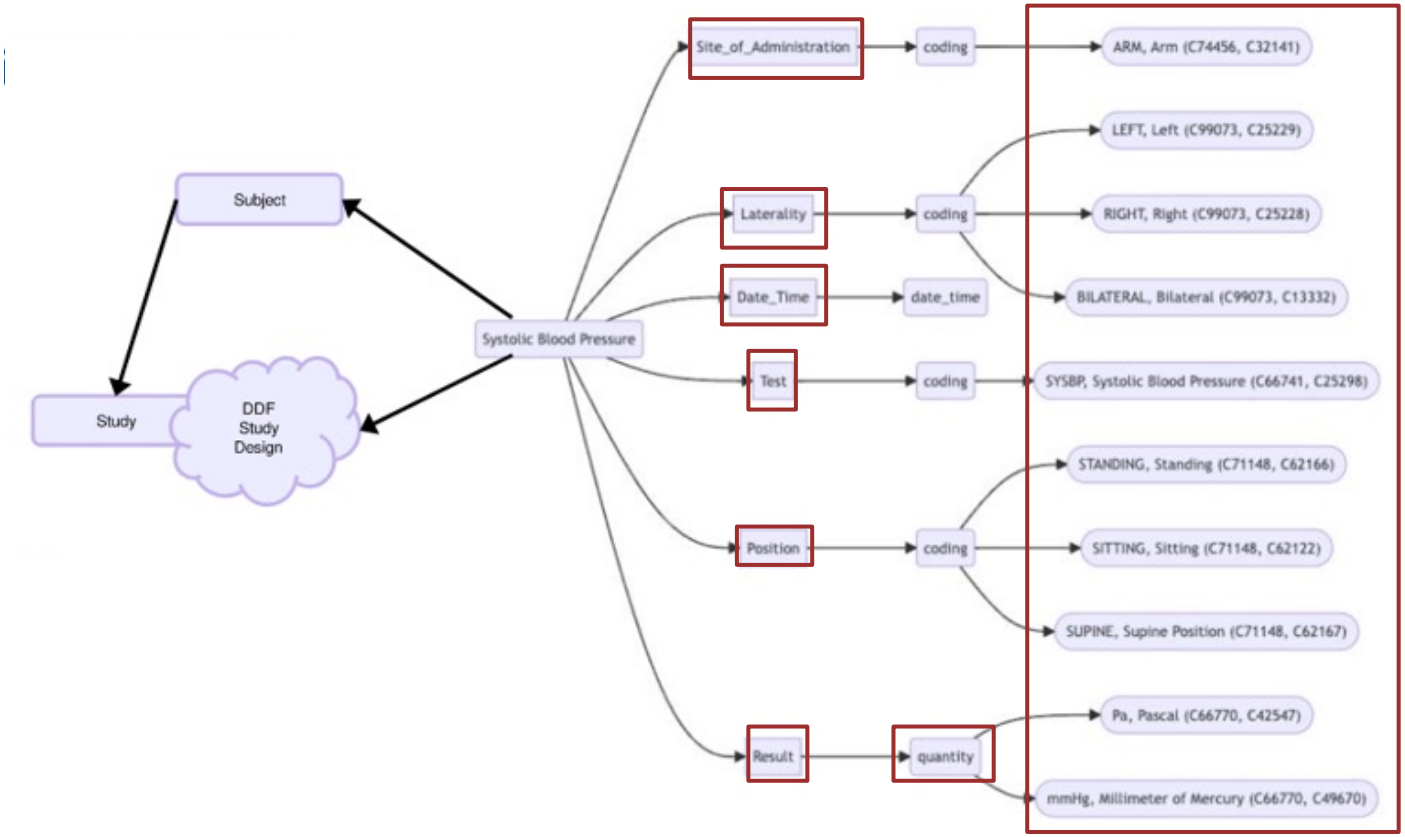
Updates for Common Protocol Template use case

Updates for more complex studies

Updates from Connectathon feedback

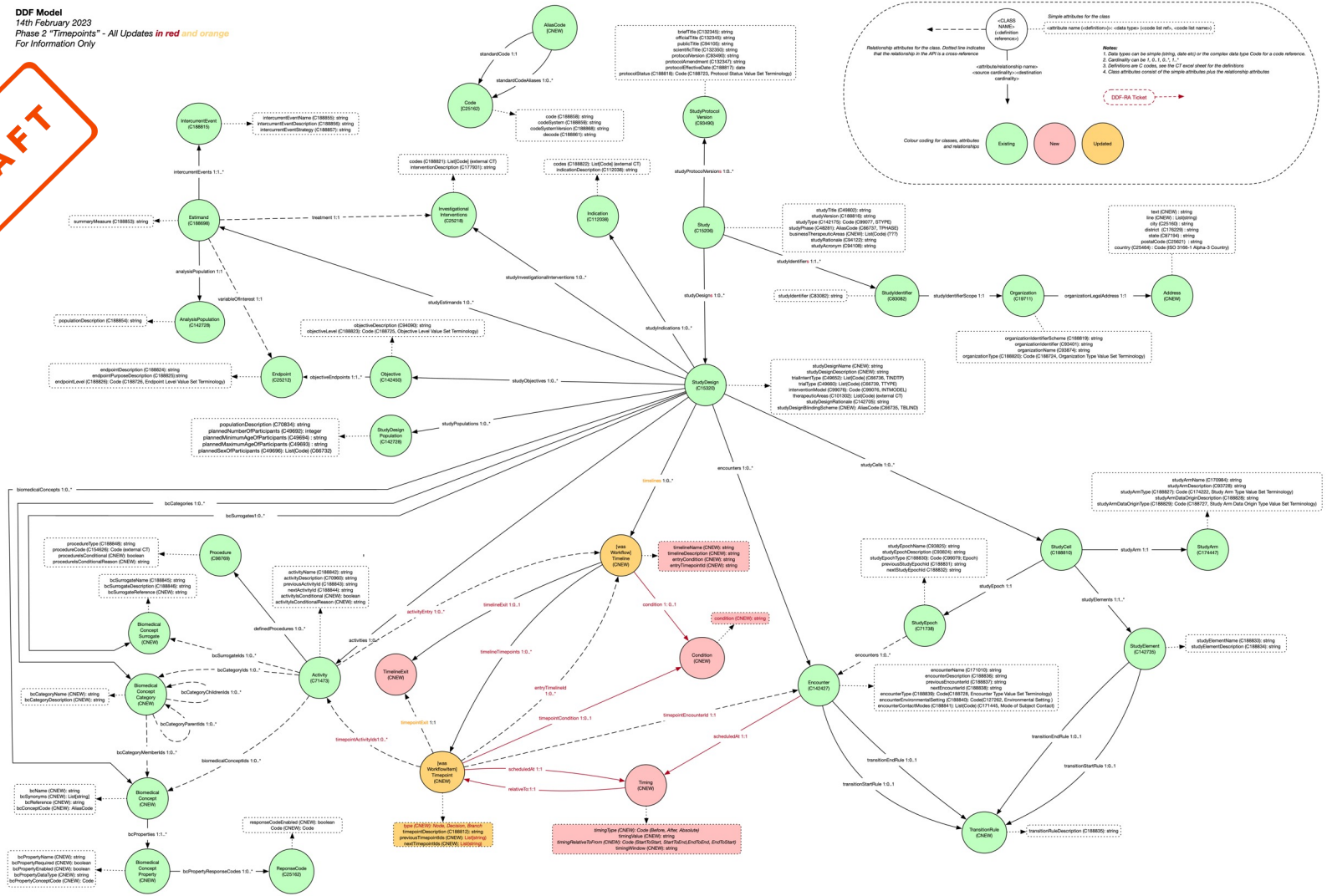
A Biomedical Concept is …

- A small model that defines a clinical concept in a standardized and reusable manner



DDF Model
14th February 2023
*Phase 2 "Timepoints" - All Updates **in red** and orange*
For Information Only

DRAFT



Use Cases: USDM with BCs allows for …

Data Capture	*Automate the setup of data capture systems ,incl. RWE, and capture the data.*
SoA	*Use the study design to build the FHIR SoA message.*
Data Import	*Import data from a variety of sources . Can be re-exported thus allowing for conversion across versions.*
Common Protocol Template (CPT)	*Generation of the CPT from a study design.*
Data Decay	*Re-import data using the USDM as a framework to rebuild a study design & data using the SDTM Trial Design Domains.*
Scoring	*The "scoring" of a study for such purposes as site impact, subject impact, environmental impact etc.*
Feasibility	*The use of the design to determine study feasibility including subject recruitment. A study data template.*
CT Registry	*The provision of study information to a CT registry.*
FAIR Data	*The use of the design to aid Findability, Accessibility, Interoperability, and Reusability.*
CTMS, TMF …	*The provision of protocol information to down stream systems needing "study" information.*
Query	*Having multiple studies that have a common structure allows for data export and query across the set of studies*
SDTM	*Automate the generation of SDTM datasets using the study design and BCs*

And many more …

Next Steps

- Phase 3
  - Strategic direction for DDF
  - Use Cases
  - Phase 3 Implementation Planning

Webinar feedback ‘New ICH M11 Harmonised Guideline and Protocol template‘

What is ICH M11?

- The ICH guideline on the clinical protocol that specifies organization with standardized content
- Deliverables :
  1. A Protocol Template to include identification of headers, common text and a set of data fields and terminologies
  2. A Technical Specification that uses an open, nonproprietary standard to enable electronic exchange of clinical protocol information

Applicable to interventional trials of medicinal products across all phases and therapeutic areas of clinical research

Why is it being developed?

- To support consistency and exchange of information across organizations
- Enables the electronic exchange of protocol content
- There are inconsistencies in the quality of protocols, resulting in:
  - Delayed timelines for product development, delaying access to medicines
  - Resource-intensive manual activities, which increase the cost of R&D
  - Inefficient use of knowledge and duplication of effort
  - Inability to leverage tools that allow reuse, review, analysis, and reporting

Steps in the Process

Status: Step 3

Public consultation dates:

- **ANVISA, Brazil** - Deadline for comments by 6 March 2023
- **EC, Europe** - Deadline for comments by 26 February 2023
- **FDA, United States** - Deadline for comments by 21 February 2023
- **HSA, Singapore** - Deadline for comments by 28 February 2023
- **Health Canada, Canada** - Deadline for comments by 17 February 2023
- **MHLW/PMDA, Japan** - Deadline for comments by 17 March 2023
- **NMPA, China** - Deadline for comments by 15 March 2023
- **SFDA, Saudi Arabia** - Deadline for comments by 15 February 2023
- **Swissmedic, Switzerland** - Deadline for comments by 26 February 2023
- **TFDA, Chinese Taipei** - Deadline for comments by 28 February 2023

Regulatory Updates

Regulatory Updates

- https://www.ema.europa.eu/en/news/facilitating-decentralised-clinical-trials-eu
- https://www.ema.europa.eu/en/documents/report/annual-report-good-clinical-practice-inspectors-working-group-2021_en.pdf

		# Inspected deficiencies			Total
Deficiency category name	**Deficiency sub-category name**	**Minor**	**Major**	**Critical**	
General	Contracts/Agreements	1	5	0	**6**
	Direct Access to Data	1	0	0	**1**
	Essential Documents	25	12	3	**40**

- https://www.ich.org/page/multidisciplinary-guidelines
- FDA Omnibus Reform Act (FDORA) - Expansion of FDA Inspection Authorities

Upcoming Events

Upcoming Events

- 20th to 22nd March, Palm Beach, Florida: US TMF Summit
- 24th to 27th April, Copenhagen: CDISC EU Interchange
- 27th to 29th September, East Coast: CDISC TMF Interchange
- 3rd to 5th October, Dublin: HSRAA Conference
- Late November, London: EU TMF Summit

- General Meetings:
  - 23rd May
  - 7th September
  - 5th December

Opening for Questions (and hopefully Answers!)

Thank you

https://www.cdisc.org/events/webinar/tmf-reference-model-general-meeting-q1