CDISC Italian User Network TC

https://wiki.cdisc.org/display/ITAUG/Italian+User+Network+Home

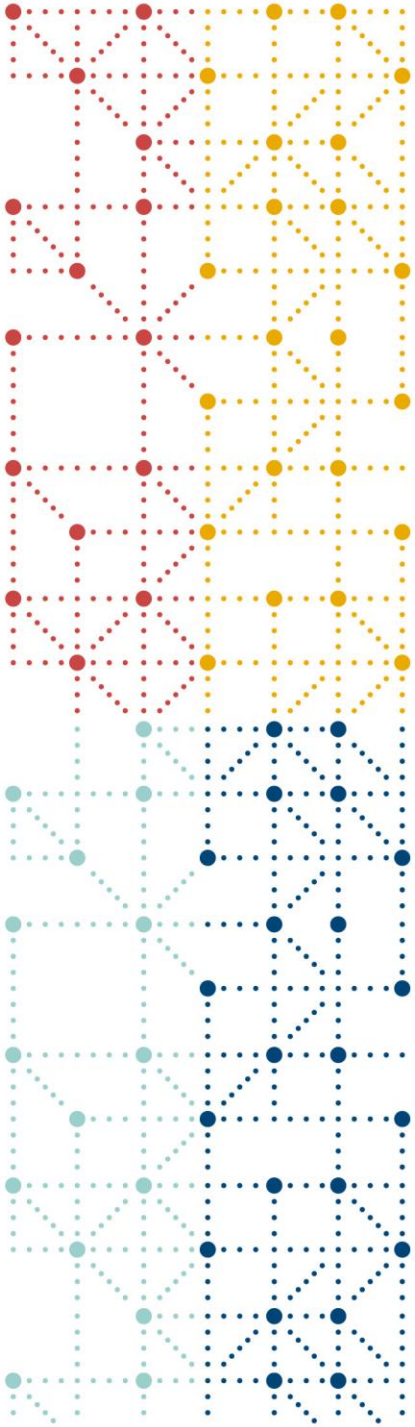
Presented by Silvia Faini (Cytel), Mauro Cortellini (Chiesi) and Angelo Tinazzi (Cytel)

25.10.2023

Agenda

1. CDISC EU Interchange 2024 Call for Abstracts
2. COSA / Open Source Overview
3. Dataset JSON
4. CDISC and Data Submission What's New
5. CDISC TMF Interchange
6. Other Topics and Q&A

https://wiki.cdisc.org/display/ITAUG/Italian+User+Network+Home



CDISC EU Interchange

EU CDISC Interchange 2024 – Call for Abstract

24-25 April 2024 – Berlin – Main Conference

Novelty in Clinical Trials and CDISC standards

- Modernization of clinical trial impact on CDISC standards: decentralized trials incl. digital endpoints, master protocols, patient and rare disease registries.
- Applications of AI to extract value from Clinical Trials and Real World Data
- Regulatory and CDISC positioning on usage of AI

CDISC in Academic Research

- Healthcare Data Systems
- eSource/Direct Data Capture (DDC) for e.g. using electronic health records and the FHIR standard
- Opportunities across the life sciences data sharing (FAIRified) ecosystem post anonymization of critical GDPR data

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EU CDISC Interchange 2024 – Call for Abstract

24-25 April 2024 – Berlin – Main Conference

Real World Data / Evidence

- Experiences of RWD/RWE in regulatory decision-making for drugs and biologics
- Use of CDISC and other industry standards (OMOP data model, HL7 FHIR, etc.) incl. conversions between standards
- Regulatory guidance, progress and barriers

Bringing data back to life, re-use and harmonisation of clinical trials

- Pool historic R&D data and harmonize.
- Utilize harmonized terminologies and vocabularies
- Combine RCT data with Omics, RWD, and Imaging to unlock the full potential of clinical data and improve R&D returns.

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EU CDISC Interchange 2024 – Call for Abstract

24-25 April 2024 – Berlin – Main Conference

Open Source usage, including CORE, OAK, ARS, COSMoS

- Experience in the use of CORE, Rules Authoring Tool and generation of Rules
- Experience of various validation tools for SEND/SDTM/ADaM/Define
- Experience in use of Open Source tools
- Implementation examples of ARS

Global Regulatory Submissions

- Submitting around the Globe learnings
- Achieving quality and efficiency in data submission
- Impact of new FDA guidance
- Experience integrating data from multiple studies in support of Integrated Summary of Safety (ISS) and Integrated Summary of Effectiveness (ISE)
- Imagine Data Submission in 2041: how technology, standards and industry initiative can fasten data submission

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EU CDISC Interchange 2024 – Call for Abstract

24-25 April 2024 – Berlin – Main Conference

DDF

- Implementation examples of DDF
- DDF impact on drug development
- DDF and integration with upstream and downstream process : challenges and advantages

Standards governance and MDRs

- Managing CDISC versions and handling (non) adherence in terms of submission to one or multiple regulatory agencies
- Metadata-driven governance and automation experiences
- How to ensure end to end connections between different CDISC standards: CDASH-SDTM-ADaM
- Pharma/Bio tech experiences with graph databases/linked data implementations

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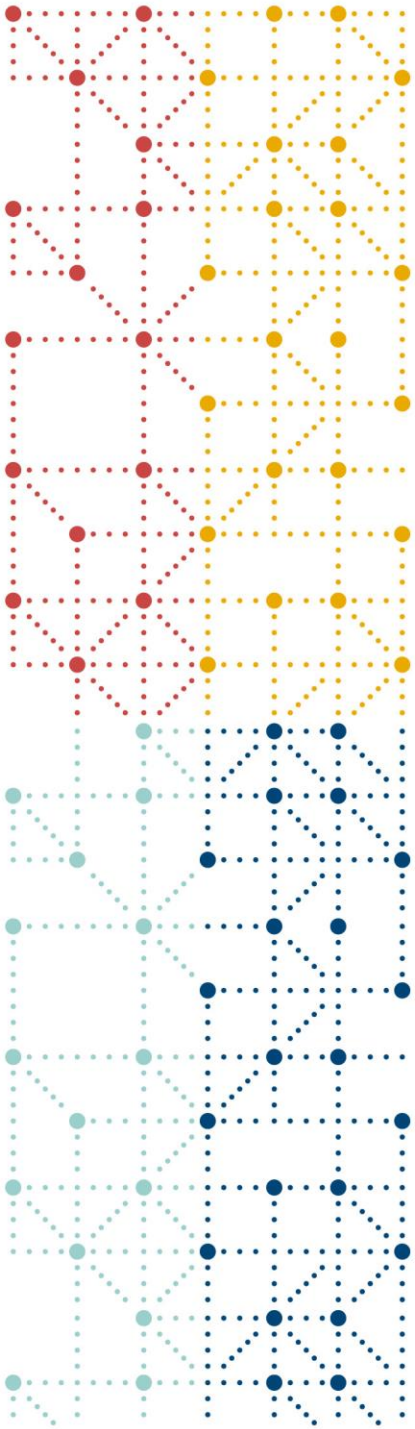
EU CDISC Interchange 2024 – Call for Abstract

24-25 April 2024 – Berlin – Main Conference

Call for Abstract: apertura nelle prossime settimane e chiusura 12 gennaio
Bozza programma: fine gennaio

Speriamo di ricevere un buon numero di abstract anche da voi Italian CDISC UN e così avere diversi **speaker italiani** al prossimo EU CDISC Interchange



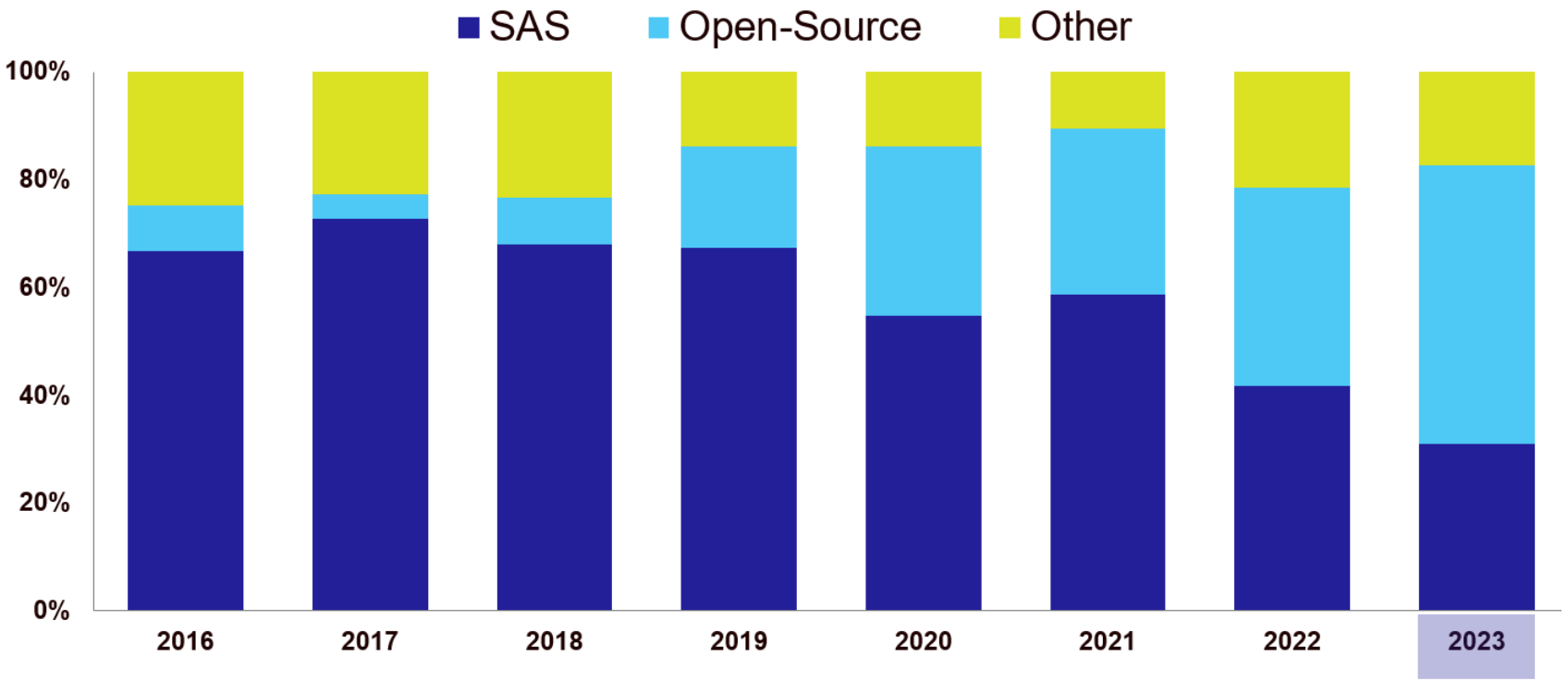
COSA / Open Source Overview

Open-Source Initiatives – FDA Statemet

Statistical Software Clarifying Statement

FDA does not require use of any specific software for statistical analyses, and statistical software is not explicitly discussed in Title 21 of the Code of Federal Regulations [e.g., in 21CFR part 11]. However, the software package(s) used for statistical analyses should be fully documented in the submission, including version and build identification.

Open-Source Initiatives – A Change is Already Taking Place



PHUSE EU 2016-2023 Presentations showing or discussing SAS, Open-Source or other tools

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Open-Source Initiatives – A Change is Already Taking Place

*"Why are we giving away code that we invested **millions** in for free?"*

Sponsor aim to get market approval for their products

- A new Device
- A new Drug

A software, a SAS macro, an R library is not what a sponsor wants to make money from

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Open-Source Initiatives – A Change is Already Taking Place

Supports and promotes open-source software projects that create tools for implementing or developing CDISC standards to drive innovation in the CDISC community

With permission from Peter Van Reusel, Chief Standards Officer, CDISC

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Open-Source Initiatives – R Pilot Submission

Pilot 1

Demonstrate data packages can be created using other software e.g., R

- XPT Datasets
- define.xml

Pilot 2

Sharing R Packages

- Include data visualization
- Provide tool the HA can re-use work with it
- Installing and using Sponsor R packages

Planned

- Pilot 3: Generation of ADaM Datasets
- Pilot 4: Alternative Submission Formats

First Publicly Available R-Based Submission Package Submitted to FDA (Pilot 3), Sep 11, 2023 https://www.r-consortium.org/announcement/2023/09/11/first-publicly-available-r-based-submission-package-submitted-to-fda-pilot-3

https://github.com/RConsortium/submissions-wg

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Open-Source Initiatives – R Pilot Submission

FDA can receive submission with R code/packages

R Consortium R Submission Pilot 1

- Objective: to test the concept that an R-language-based submission package can meet the needs and the expectations of the FDA reviewers, including assessing code review and analyses reproducibility.
- Evaluating FDA's acceptance of system/software validation evidence is not in the scope of this pilot.
- All submission materials and communications from this pilot are publicly available. (Link)

Submitted Material

R Consortium R Submission Pilot 1

- What R consortium submitted:
  - ADaM datasets (.xpt files)
  - A pdf report with 4 analysis outputs
  - Analysis Data Reviewer's Guide (ADRG)
  - Analysis output programs (.r files)
  - Sponsor developed R package (.txt file)

Install Sponsor Packages and reproduced

R Consortium R Submission Pilot 1

- Receive electronic submission package in eCTD approved formats.
- Reconstruct and load the submitted sponsor-developed R package.
- Install and load open-source packages used in this submission.
- Reproduce the analysis results.
- Share potential improvements for submission deliverables and processes via written communications.

FDA Feedback

R Consortium R Submission Pilot 1

- Using R version 4.1.1, FDA was able to run the submitted code and confirm the submitted tables and figures.
- Using FDA developed code, FDA was able to independently generate tables and figures using the submitted data.
- There were minor issues.
  - Rounding issue
  - Important information was not given in the table

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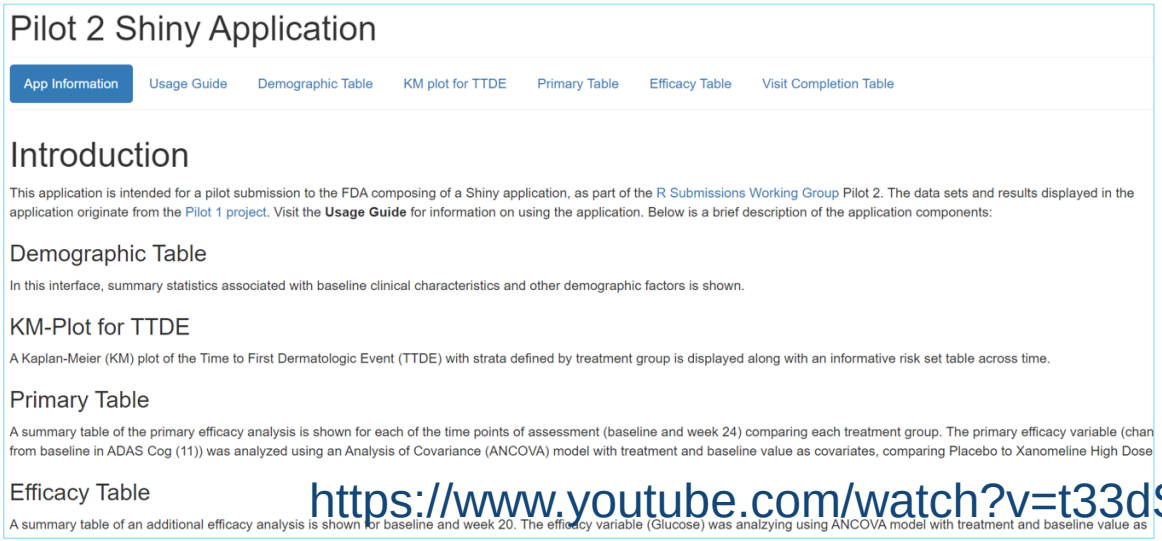
Open-Source Initiatives – R Pilot Submission



https://www.youtube.com/watch?v=t33dS17QHuA

Open-Source Initiatives – Novo Nordisk's Journey to an R based FDA Submission

https://www.youtube.com/watch?v=t33dS17QHuA

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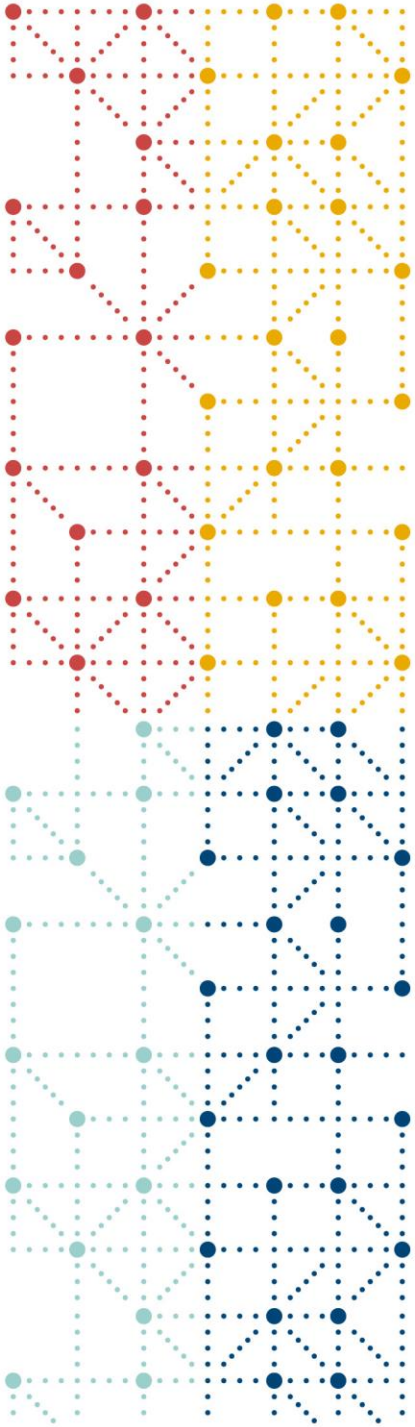

Dataset JSON

COSA – 2 Main Big Projects

- Conformance Rules – CORE

- Dataset JSON

Today we focus on Dataset JSON

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Dataset JSON – The Launch in US

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COSA Dataset-JSON Hackathon Results

Sam Hume, DSc
VP, Data Science CDISC
Session 6, Tack B: Business Optimization & Technical Topics

Dataset JSON – The Launch in EU

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State of the CDISC Standards
Beyond CDISC 360

Presented by Bess LeRoy, Head of Standards Innovation, CDISC

What is Dataset-JSON and Advantages

What is JSON?
An open standard file format and data interchange format that uses human-readable text to store and transmit data objects consisting of attribute–value pairs and arrays

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Dataset JSON – The Launch in Italy

CDISC Key Initiatives for 2023 and beyond

Peter Van Reusel
Chief Standards Officer, CDISC

CDISC Italian UN, Milan, 12 May 2023

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Milestone 2: Long Term

- Enhance the CDISC SDTM and ADaM standards beyond XPT limitations (e.g. Variable names > 8, labels > 40, data > 200
- New Define-XML / Define-JSON based on ODM v2.0
- Enhanced conformance rules
- Collaborate with FDA to develop plan to retool their environment to natively consume JSON

➔ **Success Criteria: accept advanced Dataset-JSON as the only transport format option and deprecate XPT**

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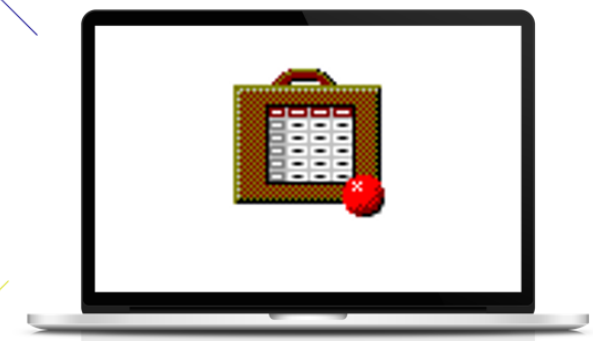
Dataset JSON – SAS XPT Limitations

Regulatory

Currently Mandated by Regulatory Agencies

Pre-history

Considered outdated and antiquated



Limitations of XPT v5

- Numeric limitations, antiquated format
- Stores data in its own numeric way
- Character limitations, no UTF-8 encoding
- No support for characters from other languages
- String & Column limitations (variable names > 8, labels > 40, data > 200)
- No metadata extensibility

No more public complaints

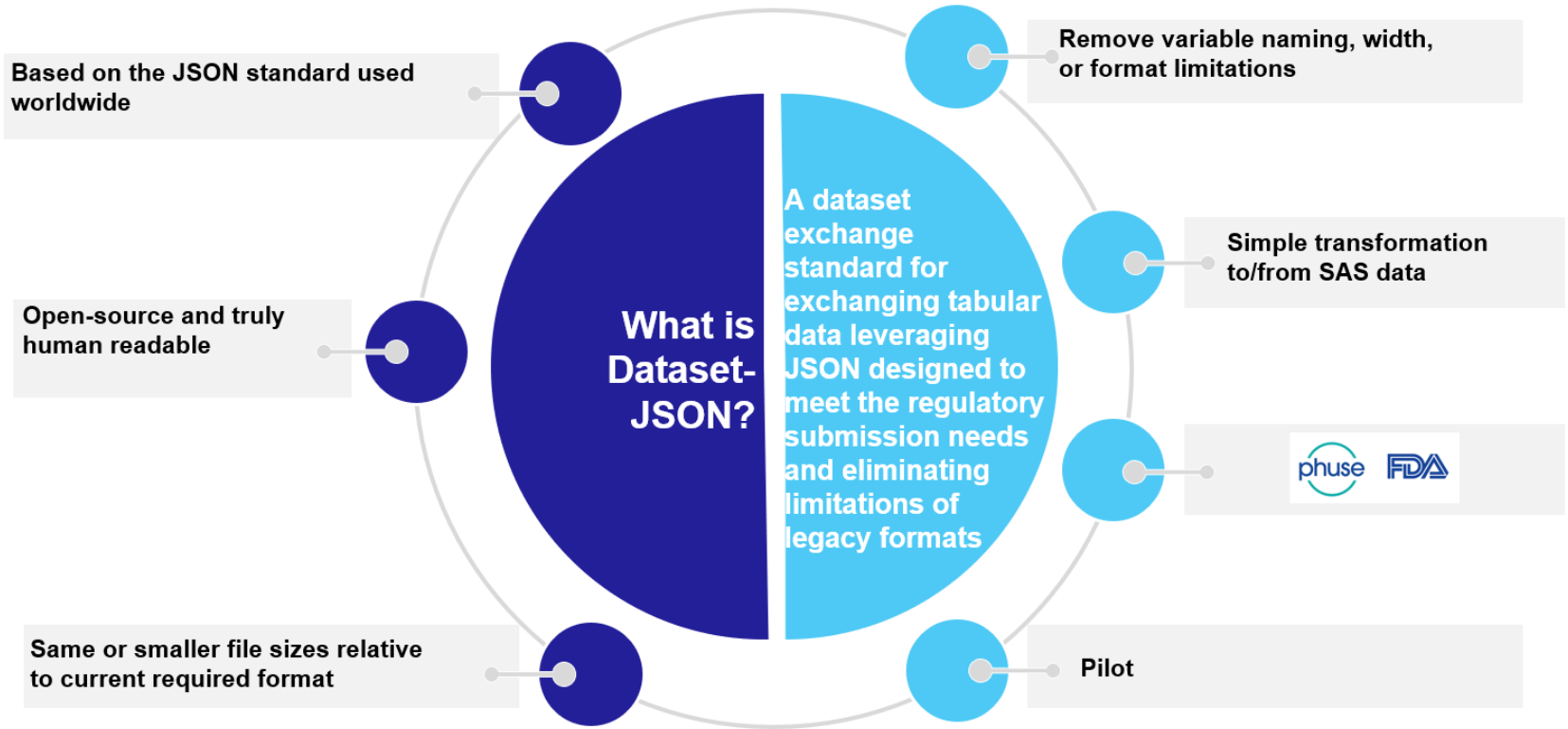
Transport for the Next Generation

Version 1.0
Created 30 Apr 2017

A White Paper by The PhUSE Alternative Transport Format Working Group - Part of the PhUSE Emerging Trends and Technologies Computational Science Symposium Collaboration.

https://www.cdisc.org/sites/default/files/2023-05/Transport-for-the-Next-Generation-Version-1.0.pdf

Dataset JSON in a Nutshell



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Dataset JSON

Dataset-JSON Pilot and Hackathon II Update

COSA Quarterly Spotlight – Q3 2023

Sam Hume, D.Sc.

2023-10-05

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- Collaborate with FDA to develop plan to retool their environment to natively consume JSON

➔ **Success Criteria: Demonstrate the viability of Dataset-JSON as the primary transport option**

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Introducing Dataset-JSON

What is Dataset-JSON?
A dataset exchange standard for exchanging tabular data leveraging JSON designed to meet the regulatory submission needs and eliminating limitations of legacy formats

Dataset-JSON is…

- Part of the ODM v2.0 standard and based on the JSON standard
- Open-source and truly human readable
- An open-source MIT license
- Schema supporting any tabular format
- Extensible to support new metadata and new use cases
- Linked to Define-XML for complete metadata

Dataset JSON

JSON is nothing new, the format is already in use by CDISC Library.
For instance: call the Library asking for info about SDTMIG v3.3 structure

https://library.cdisc.org/browser/#/

Dataset JSON

Are SAS and R already able to work with JSON files? YES!

- See *'Yes, you can access the CDISC Library from SAS!'* presentation by Angelo Tinazzi at CDISC EU Interchange 2021

PDF

2021 EU Interchange pdf

- Check https://cran.r-project.org/web/packages/jsonlite/vignettes/json-aaquickstart.html for more resources about jsonlite package in R

Getting started with JSON and jsonlite

The jsonlite package is a JSON parser/generator optimized for the web. Its main strength is that it implements a bidirectional mapping between JSON data and the most important R data types. Thereby we can convert between R objects and JSON without loss of type or information, and without the need for any manual data munging. This is ideal for interacting with web APIs, or to build pipelines where data structures seamlessly flow in and out of R using JSON.

```
library(jsonlite)
```

Why JSON?

JSON is…

- The most widely used data interchange format
- An open standard that's human-readable
- Supported by nearly every programming language and technology framework
- Simple to implement - easy to read and write
- Used by other healthcare data standards (HL7 FHIR)

Why change transport formats?

- Numerous SAS V5 XPORT (XPT) limitations
  - Limited variable types
  - Limited to US ASCII encoding
  - 8-character variable names
  - 40-character labels
  - 200-character field widths
  - Lacks robust metadata
  - Not extensible
- Not truly vendor neutral
- Not broadly supported by new technologies

Dataset JSON

What are the goals of the pilot?

Milestone 1: Short Term

- Pilot submissions using JSON format with existing XPT ingress/egress to carry the same data
- Same content, different suitcase, no disruption to business process on either side
- In parallel, evaluate with FDA how their toolset can support JSON format and identify tool upgrade roadmap

➔ **Success Criteria: Demonstrate that Dataset-JSON can transport information with no disruption to business**

Milestone 2: Development of future strategy

- Evaluate how current and future industry standards can benefit without XPT limitations
  - e.g., Variable names > 8, labels > 40, data > 200
- Evaluate combining metadata with data
  - e.g., Define-XML / Define-JSON based
- Enhanced conformance rules
- Collaborate with FDA to develop plan to retool their environment to natively consume JSON

➔ **Success Criteria: Demonstrate the viability of Dataset-JSON as the primary transport option**

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Dataset JSON

Conversion Software Tools

- SAS
  - https://github.com/lexjansen/dataset-json-sas (submit issues)
  - The SAS conversion software by Lex Jansen
  - Dataset-JSON example files are included in the repository
  - Includes a macro for comparing libraries with SAS datasets
  - Includes a Python script for validating Dataset-JSON
  - Documentation is included
- R
  - https://github.com/atorus-research/datasetjson (submit issues)
  - https://atorus-research.github.io/datasetjson/index.html
  - https://cran.r-project.org/web/packages/datasetjson/index.html
  - R conversion package by Atorus Research and Johnson & Johnson
  - Documentation is included
- Python
  - https://github.com/dostiep/Dataset-JSON-Python (submit issues)
  - Python conversion software by Pierre Dostie
  - We will not cover the Python tooling in the workshop
  - The Dataset-JSON Pilot will focus on SAS and R, but any conversion tool can be used

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Dataset JSON – SAS (1/3)

SAS and JSON

- Starting in SAS© 9.4, you can use **PROC JSON to** write SAS data sets to JSON files

Writing Dataset-JSON with SAS

- PROC JSON in SAS© gives the user control over the JSON output:
  - through the utilization of options
  - through the ability to control containers (objects or arrays)
  - by writing directly to the output file
  - by choosing exactly what to include or not include in the resulting JSON file

```
PROC JSON OUT=fileref | "external-file" <options>;
  EXPORT <libref.>SAS-data-set <(data-set-options)> </options>;
  WRITE VALUES value(s) </options>;
  WRITE OPEN type;
  WRITE CLOSE;
RUN;
```

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Dataset JSON – SAS (2/3)

Reading Dataset-JSON with SAS

- Starting in SAS© 9.4TS1M4, you can use the **JSON engine** to read JSON files into SAS data sets
- A **JSON map** is a file that the JSON engine uses to define the data set structures that are created when reading JSON

```
FILENAME jsonfile "<path to the JSON file>";
FILENAME mapfile "<path to the MAP file to be created>";
LIBNAME data_out "<path to the output folder>";

LIBNAME jsonfile JSON FILEREF=jsonfile MAP=mapfile
        AUTOMAP=CREATE NOALLDATA ORDINALCOUNT=NONE;
PROC COPY IN=jsonfile OUT=data_out;
RUN;
```

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Dataset JSON – SAS (3/3)

Comparing SAS datasets

- Compare results in a summary
- Details for datasets that had differences

```
%macro util_comparedata(
  baselib=,
  complib=,
  dsname=,
  compareoptions=%str(listall criterion=0.00000001 method=absolute),
  resultds=,
  detailall=N
  );
```

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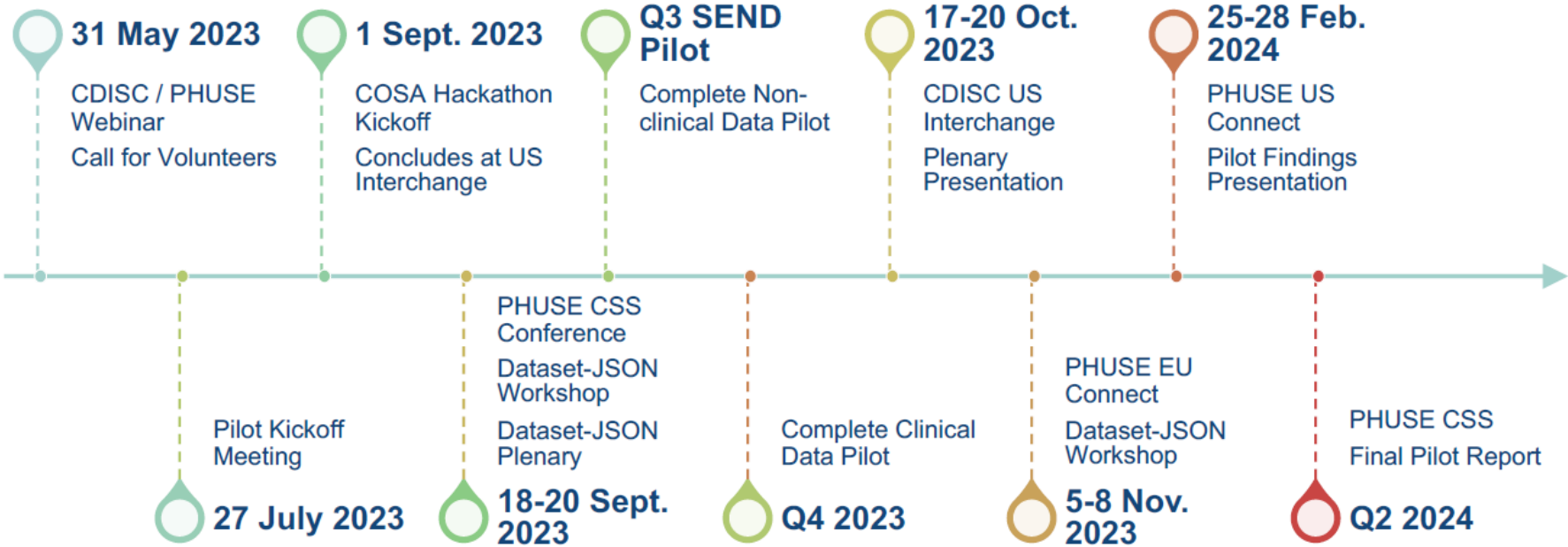
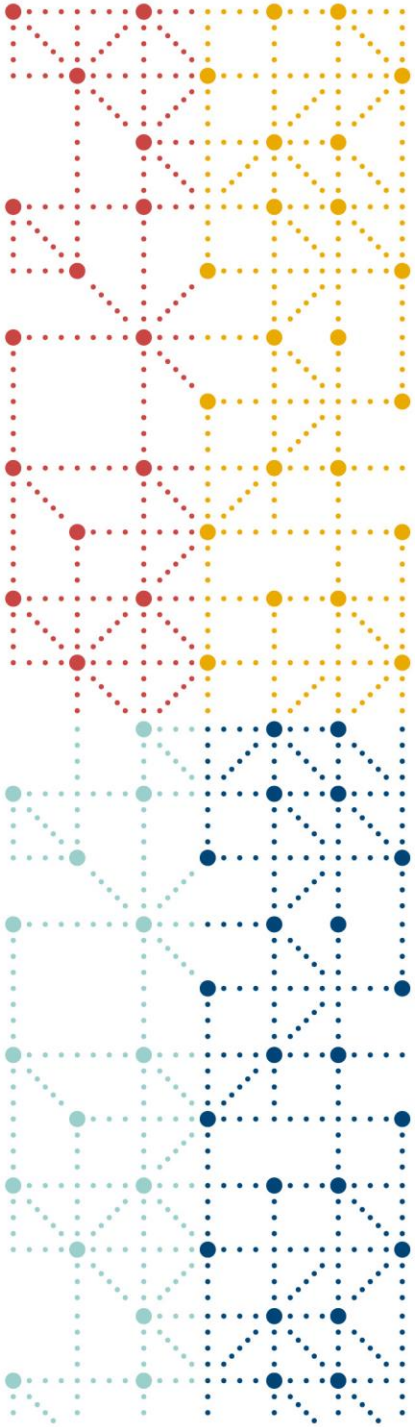
Current Status of Pilots

- Internal testing within FDA CDER OCS environment complete
- Successful conversion of nonclinical datasets from XPT to JSON without information loss
- Next steps: Accept test submissions from PHUSE Dataset-JSON working group members
- Preparing for clinical data testing

Dataset JSON

Dataset-JSON Pilot: Timeline





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TMF Implementation Plan

NEW ANNUAL CONFERENCE

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CDISC TMF
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28-29 SEPTEMBER
BALTIMORE

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What *is* the Trial Master File?

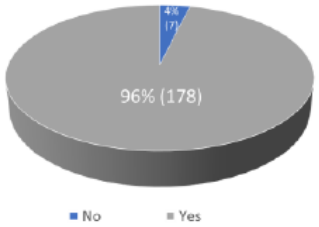
The sponsor and the investigator shall keep a clinical **trial master file**. The clinical trial master file shall at all times contain the **essential documents** relating to that clinical trial which allow verification of the conduct of a clinical trial and the quality of the data generated […]. It shall be readily available, and directly accessible upon request, to the Member States.

[EU Regulation 536/2014]

What *is* the Trial Master File Reference Model?

A Standardised structure, contents and naming of these Essential documents

2022 Survey:
Organizations using TMF Reference Model



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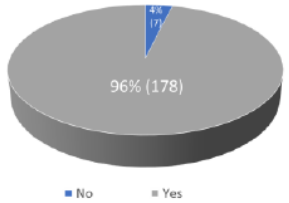

- ICH GCP did **NOT** provide a comprehensive contents list for the TMF
  - Examples of missing documentation:
    - Electronic systems
    - Data management and statistical methodology
    - Safety monitoring
- Everyone had their own customised structure – Sponsors, CROs and third parties

Development of the TMF Reference Model

DIA DEVELOP INNOVATE ADVANCE

Document & Records Management Community

2009 to 2010

Initial meeting in 2009 with first version being released in 2010

2011 to 2013

Multiple releases including Regulator feedback, Investigator Site Files, Devices, Process based metadata. Workgroups established

Separated from DIA

2014 to 2021

Formalization with a Steering Committee. **Release of the Exchange Mechanism Specification** and Version 3

2022 onwards

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Forward to Compliance

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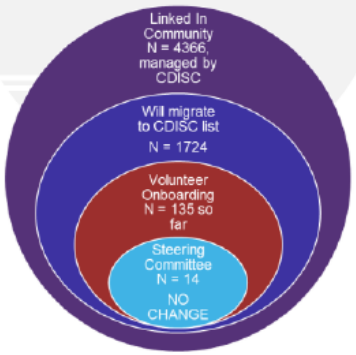
The Move to cdisc

H1 2022

- Final decision made with community input
- Memorandum of Understanding signed
- Implementation team created and plan produced
- SC attended CDISC Board meeting
- New Logo
- Press Release
- Presentations at US TMF Summit

H2 2022

- Volunteer onboarding process established (230 to date)
- Management of LinkedIn migrated
- General meetings moved to quarterly, CDISC managed
- Presentations at EU TMF Summit
- SC Chair attendance at CDISC Board
- CDISC Interchange presence (US)
- Update Charters
- Set-up Wiki and JIRA workflows
- Decommission Groups.io



H1 2023

- *Develop TMF RM Roadmap*
- *Standards governance and formalization plan*
- *Marketing plan and materials*
- *TMF Events*
- *TMF RM website in CDISC, incorporating forums*
- *TMF RM deliverables to Knowledge Base*
- *TMF RM spreadsheet to Wiki*
- *CDISC Interchange presence (EU)*

H2 2023

- *TMF RM to CDISC Library (database)*
- *Develop Education Offerings for TMF RM training accreditation*
- *Develop Accreditation for TMF RM Implementation*
- *Focus on Regulatory acceptance*

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

TAKE HOME MESSAGE:
CDISC ITA UN meetings no longer only for DMs, Stats, Stat/SAS Programmers!

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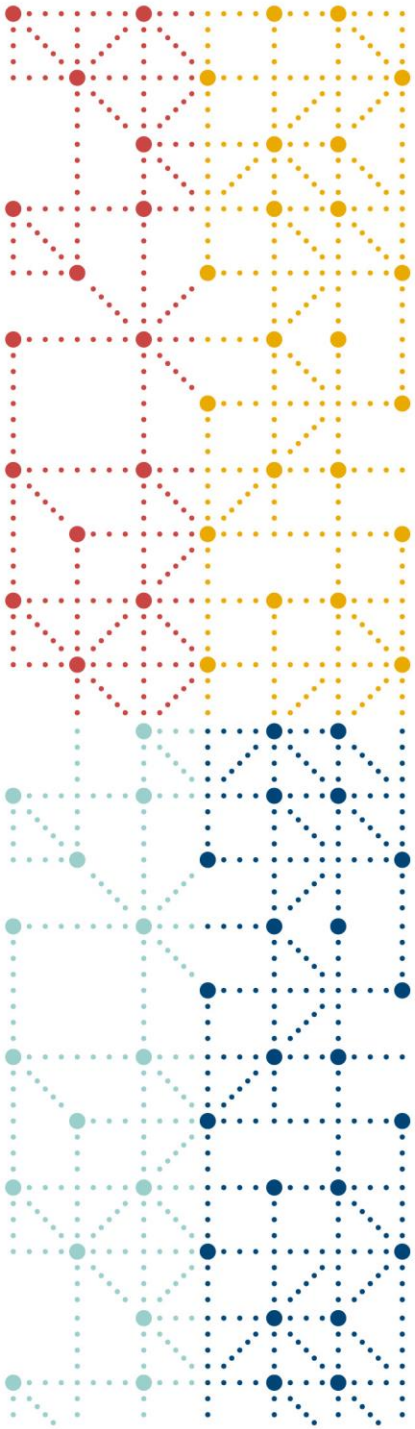


CDISC and Data Submission What's New

Standards publication

https://www.cdisc.org/standards/publications

Standard/Therapeutic Area Version	Published Date
Basic Data Structure for ADaM popPK Implementation Guide v1.0	6 OCT 2023
ADaM Conformance Rules v5.0	6 OCT 2023
CDASHIG v2.3	28 SEP 2023
CDASH Model v1.3	28 SEP 2023
COVID-19 Therapeutic Area User Guide v2.0	7 SEP 2023
Dataset-JSON v1.0	23 AUG 2023
ODM v2.0	23 AUG 2023
CT-XML v1.2 (Controlled Terminology)	23 AUG 2023
TMF Reference Model v3.3.1	15 AUG 2023

Standards under public review

https://www.cdisc.org/public-reviews

Standard/Therapeutic Area	Comments Due
Tobacco Implementation Guide v1.0 & SDTM v2.1	18 DEC 2023
Analysis Results Standard v1.0	11 DEC 2023
Controlled Terminology Relationships v1.0 (SDTM v1.7/SDTMIG v3.3/SDTMIG-MD v1.1)	31 OCT 2023
Controlled Terminology Package 56	23 OCT 2023

Standards in development

https://www.cdisc.org/standards/in-development

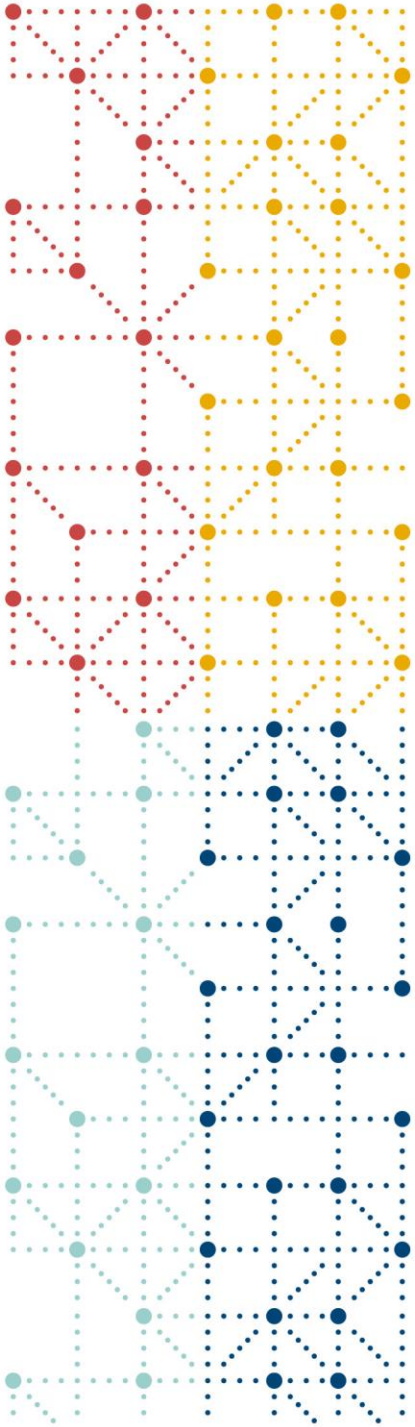
Standard	Release Notes
ADaM Oncology Examples	Resolving Public Comments
ADaM v3.0	In Development
Analysis Results Metadata (ARM) Conformance Rules	In Development
Analysis Results Standards v1.0	Public Review
CT Relationships for SDTM v1.7, SDTMIG v3.3, SDTMIG-MD v1.1	Public Review
Safety User Guide v1.0	In Development
SDTM for Observational Studies v1.0	Public Review
SDTM v2.1	In Public Review
SDTM v2.2	In Development
SDTMIG v4.0	In Development
SENDIG v4.0	In Development
Tobacco Implementation Guide v1.0	In Public Review

FDA Technical Conformance Guide

v5.4 - June 2023
From “Section 4.1.1.3 (SDTM Domain Specification)”

Important clarification – submit in LB SI units and a separate domain for other conventional units (e.g. US units)

“ […] For clinical studies, please submit two separate domains for lab results. The LB domain should contain SI units in LBSTRESU for the SI results in the LBSTRESC and LBSTRESN fields. An additional custom domain structured identically to LB should contain conventional units in --STRESU for the results in conventional units in the --STRESC and --STRESN variables. It is ideal if both conventional and SI units come directly from the lab vendor.”



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2023
CDISC TMF
INTERCHANGE

28-29 SEPTEMBER
BALTIMORE

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What *is* the Trial Master File?

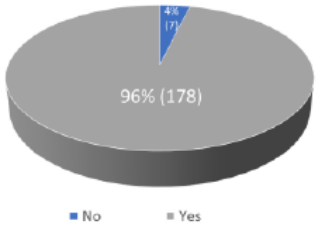
The sponsor and the investigator shall keep a clinical **trial master file**. The clinical trial master file shall at all times contain the **essential documents** relating to that clinical trial which allow verification of the conduct of a clinical trial and the quality of the data generated […]. It shall be readily available, and directly accessible upon request, to the Member States.

[EU Regulation 536/2014]

What *is* the Trial Master File Reference Model?

A Standardised structure, contents and naming of these Essential documents

2022 Survey:
Organizations using TMF Reference Model



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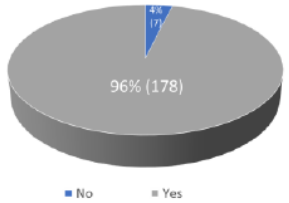

- ICH GCP did **NOT** provide a comprehensive contents list for the TMF
  - Examples of missing documentation:
    - Electronic systems
    - Data management and statistical methodology
    - Safety monitoring
- Everyone had their own customised structure – Sponsors, CROs and third parties

Development of the TMF Reference Model

DIA DEVELOP INNOVATE ADVANCE

Document & Records Management Community

2009 to 2010

Initial meeting in 2009 with first version being released in 2010

2011 to 2013

Multiple releases including Regulator feedback, Investigator Site Files, Devices, Process based metadata. Workgroups established

Separated from DIA

2014 to 2021

Formalization with a Steering Committee. **Release of the Exchange Mechanism Specification** and Version 3

2022 onwards

TRIAL MASTER FILE TMF powered by cdisc REFERENCE MODEL

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Forward to Compliance

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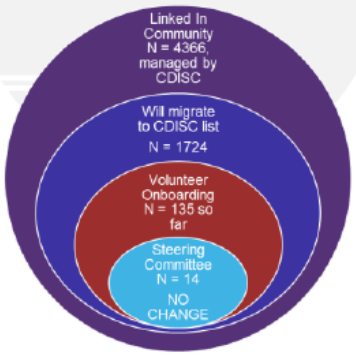
The Move to cdisc

H1 2022

- Final decision made with community input
- Memorandum of Understanding signed
- Implementation team created and plan produced
- SC attended CDISC Board meeting
- New Logo
- Press Release
- Presentations at US TMF Summit

H2 2022

- Volunteer onboarding process established (230 to date)
- Management of LinkedIn migrated
- General meetings moved to quarterly, CDISC managed
- Presentations at EU TMF Summit
- SC Chair attendance at CDISC Board
- CDISC Interchange presence (US)
- Update Charters
- Set-up Wiki and JIRA workflows
- Decommission Groups.io



H1 2023

- *Develop TMF RM Roadmap*
- *Standards governance and formalization plan*
- *Marketing plan and materials*
- *TMF Events*
- *TMF RM website in CDISC, incorporating forums*
- *TMF RM deliverables to Knowledge Base*
- *TMF RM spreadsheet to Wiki*
- *CDISC Interchange presence (EU)*

H2 2023

- *TMF RM to CDISC Library (database)*
- *Develop Education Offerings for TMF RM training accreditation*
- *Develop Accreditation for TMF RM Implementation*
- *Focus on Regulatory acceptance*

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

TAKE HOME MESSAGE:
CDISC ITA UN meetings no longer only for DMs, Stats, Stat/SAS Programmers!

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CDISC Webinars and Events 2023/24

Upcoming Webinars

https://www.cdisc.org/events/webinars/upcoming

- Tobacco Implementation Guide v1.0 Public Review Webinar – 09NOV23
- TMF Reference Model General Meeting - Q4 – 05DEC23
- COSA Quarterly Spotlight - Q1 2023 – 12DEC23

Recent Past Webinars

https://www.cdisc.org/events/webinars/members-only

- Digital Data Flow Project Phase 3 Informational Webinar – 14SEP23
- 2023 COSA Dataset-JSON Hackathon II – 29AUG23
- ADaM Office Hours – 10OCT23

TMF Interchange

- Primo TMF Interchange 28-29 SEP 2023 a Baltimora
- Dal EU CDISC Interchange 2024, il TMF Interchange si svolgerà parallelamente ad EU CDISC

The CDISC TMF Interchange

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

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https://wiki.cdisc.org/display/ITAUG/Italian+User+Network+Home

Thank You!

Silvia Faini

silvia.faini@cytel.com

Mauro Cortellini

m.cortellini@chiesi.com

Angelo Tinazzi

angelo.tinazzi@cytel.com