Metadata Matters: Standardizing Metadata in the TMF RM V4

Aaron Grant, Head of Innovation, Just in Time GCP

Meet the Speaker

Aaron Grant

Title: Head of Innovation

Organization: Just in Time® GCP

Aaron is the Head of Innovation at Just in Time GCP, leading the integration of advanced technologies to enhance clinical operations and ensure GCP compliance. With over 20 years of experience in regulatory and clinical research technology, he is focused on delivering practical, usable solutions that delight users and improve business practices. Aaron is a regular contributor to the CDISC TMF Reference Model helping shape the technical direction of the TMF industry including EMS, DDF and V4.

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What is this?

timestamp	latitude	longitude	altitude	speed	course
1760001941	40.16755	-75.1844	109		
1760001964	40.16748	-75.1837	107	0.1	0
1760002120	40.16758	-75.1837	106	0	0
1760002252	40.16757	-75.1836	85	0.5	0
1760002399	40.16757	-75.184	87	1.5	0
1760002550	40.16748	-75.1836	109	0	0
1760002700	40.16745	-75.1837	116	0.7	0
1760002850	40.1675	-75.1837	112	0.1	0
1760003000	40.16753	-75.1835	99	0.3	0
1760003150	40.16752	-75.1836	111	0.8	0
1760003304	40.1677	-75.1836	91	0.5	0
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1760003751	40.16785	-75.1835	105	0.4	0
1760003900	40.16798	-75.1835	103	0.2	0
1760004050	40.16818	-75.1833	94	0.3	0
1760004199	40.16829	-75.1831	105	0	0
1760004348	40.16816	-75.1831	113	0.2	0
1760004501	40.16819	-75.183	103	0	0
1760004658	40.16828	-75.183	94	0	0
1760004804	40.16827	-75.183	104	0	0
1760004950	40.16823	-75.1831	107	0	0
1760005099	40.1681	-75.1832	112	0.1	0
1760005253	40.16819	-75.1831	102	0	0
1760005399	40.16831	-75.183	135	0	0
1760005548	40.16826	-75.1831	101	0.2	0
1760005699	40.16818	-75.183	102	0	0
1760005848	40.16825	-75.1831	80	0.3	0
1760005999	40.16824	-75.1831	105	0.1	0
1760006149	40.1684	-75.1831	97	0.5	0
1760006301	40.16847	-75.1839	114	0.6	0
1760006449	40.16827	-75.1839	97	0	0
1760006609	40.1679	-75.1841	100	0.2	0
1760006751	40.16786	-75.1844	133	0.4	0
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1760007257	40.16787	-75.1841	92	0.3	0
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1760012360	40.16617	-75.1849	110	0.8	0
1760012523	40.16542	-75.1858	110	0.9	0

Does this help?

- **Location:** Campus Dr [redacted]
- **Recent Activity:**
  - **Timestamp:** 10/09/2025 – 9:34 AM
  - **Distance Traveled:** 0.95 miles
  - **Tracking Period:** From 10/09/2025 5:25 AM to 10/09/2025 9:36 AM
  - **Current Position:** 453 ft from starting point
  - **Environment:** Light, Sound, Fence detected

Beau 3,720 min

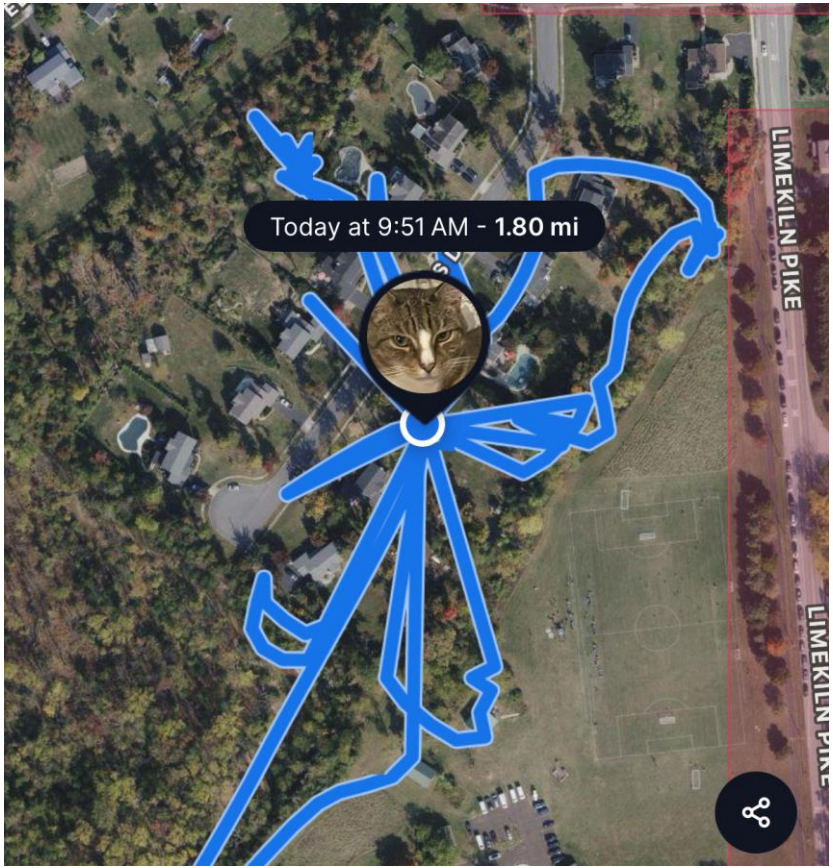
Mixed Breed

14 years ♂ Male

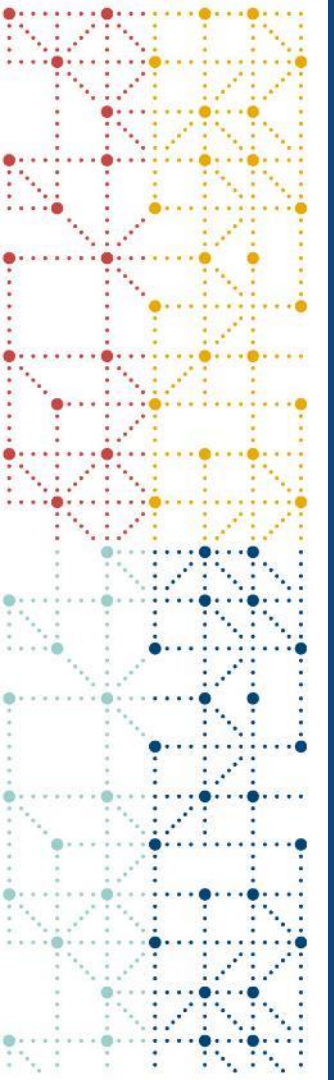
16 lb

4

Then of Obviously:



Source: Tractive. (n.d.). *GPS tracking for dogs and cats.* Tractive. Retrieved October 9, 2025, from https://tractive.com



What is Metadata?

What is metadata?

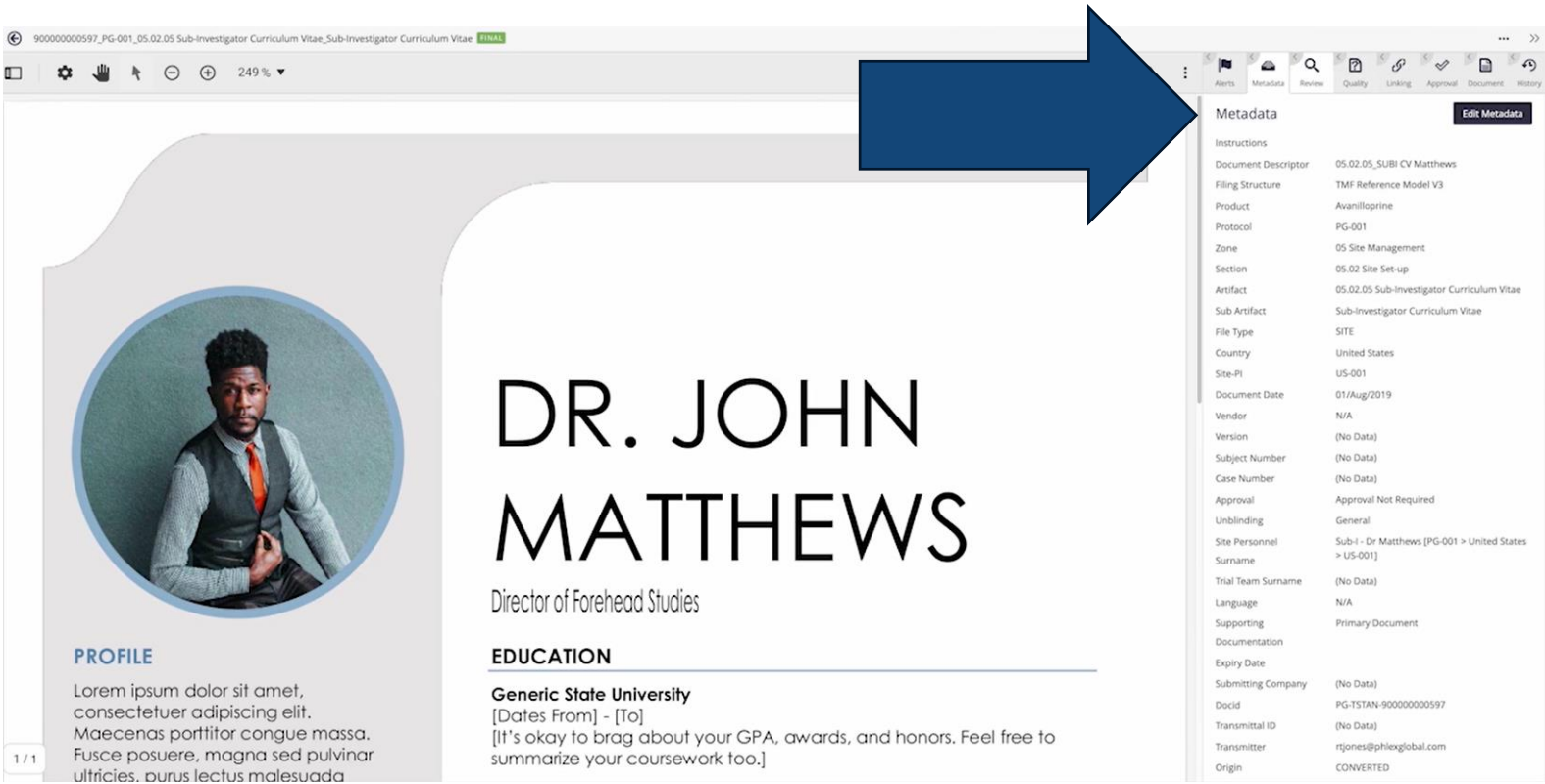
Merriam-Webster: "data that provides information about other data"

Acceldata.io: *"Metadata provides **context, structure, and meaning**. It tells us what data represents, how it was created, who can access it, and how it should be used."*

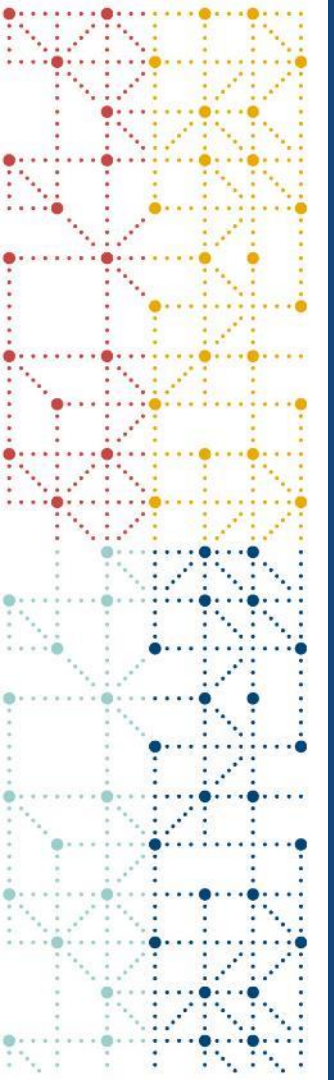
NISO: *"Metadata is structured information that describes, explains, locates, or otherwise makes it **easier to retrieve, use, or manage** an information resource."*

ChatGPT*: "I like my metadata like I like my coffee: abundant, rich, and well tagged."*

TMF Metadata

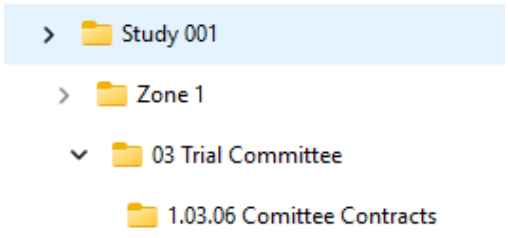


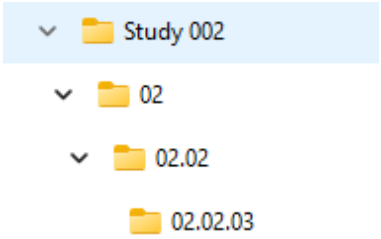
Source: Cencora. (n.d.). Retrieved October 9, 2025, from https://www.phlexglobal.com/etmf-software



Metadata and V4 CDISC TMF Reference Model

Historical Forms of TMF Metadata (What's happening to my spreadsheet)



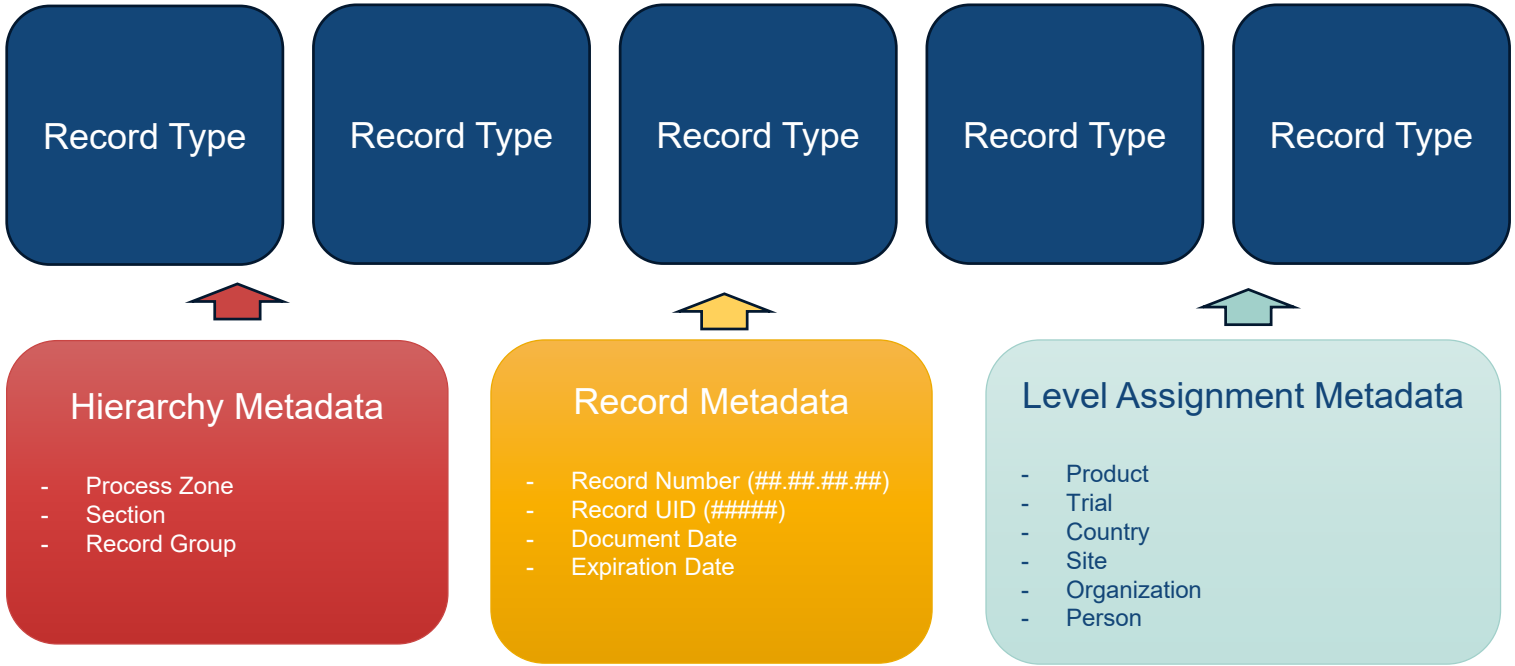


TMF Reference Model | **Version 3.3.1** | **11-AUG-2023**

X: applicable; NO* : Not applicable
*There may be some targeted exceptions based on local criteria (i.e. countries)

												TMF Artifacts (Non-device)		TMF Artifacts (Device)			Process Based Metadata		
Zone	Zone Name	Section	Section Name	Artifact	Artifact name	Definition / Purpose	Recommended Subartifacts - Documents/documentation recommended to be filed to the artifact.	Core or Recommended for inclusion	ICH Code	ISO 14155 Reference (Device Studies	Artifact name in v1.3 EDM Reference Model	Unique ID Number	Sponsor Document	Investigator Document	Sponsor Document	Investigator Document	Investigator Initiated Study Artifacts M: mandatory, D: dependent upon the type of study, R: recommended	Process Number	Process Name	Trial Level Document
01	Trial Management	01.01	Trial Oversight	01.01.01	Trial Master File Plan	To describe how records for the trial will be managed and stored during and after the trial, including study-specific processes and documentation for archiving and destruction. To include TMF filing structure to be used. May include TMF content list, filing structure and chain of custody records. Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc.	Document Transfer Documentation Evidence of Quality Review Request to Lock TMF Trial Master File Plan Trial Master File Index Trial Master File Report	Recommended	5.5.7			001	X	NO	X	NO	R	12	Develop Trial Management Strategy	X
01	Trial Management	01.01	Trial Oversight	01.01.02	Trial Management Plan	To describe overall strategy for timelines, management and conduct of the trial and typically makes reference to other artifacts. Artifact can include details on contingency plan covering details for site start up planning.	Clinical Development Plan Project Management Plan Trial Management Plan	Recommended	2.2			002	X	NO	X	NO	R	12	Develop Trial Management Strategy	X

V4 Record Types



From Record Type to Record Instance

Record Type

Financial Disclosures (05.02.10)

Defines the metadata structure for all Financial Disclosure forms across studies.

Type Metadata

Level: Site
Zone: 05 Site Management
Section: 05.02 Site Set-up
Record UID: 00427
Dating Convention: Date of the Signature

Instance Metadata

Country: ISO-3166 Country Code
Site: String
Name: String
Date: Date

Instances created using this blueprint

Multiple Record Instances — each shares the same metadata blueprint.

V4 Metadata Goals

Make record retrieval simpler and more intuitive between studies, programs, sites, CROs and Sponsors

Make interoperability between processes and systems simpler

Make uploads easier and higher quality

Make TMF transfer smoother

What has is specifically going on at CDISC?

Vendor Group has been meeting since Jan

Key Goals

- Facilitate vendor understanding of the changes in V4
- Gather vendor input to ensure the model aligns with practical needs
- Support smooth adoption and implementation of V4 across vendor platforms and services

Outputs:

- Provided feedback and recommendations to technical changes in reference model structure
- Provide a harmonized minimum metadata suggestion for wider v4 team

Next: Assemble Metadata Team

Cross-functional representation from across the industry:

- Large, medium, and small sponsors
- CRO representatives
- Vendor representatives

Purpose

- Provide a collaborative forum for input across different stakeholders
- Advance vendor team outputs by shaping metadata standards for V4

Goals

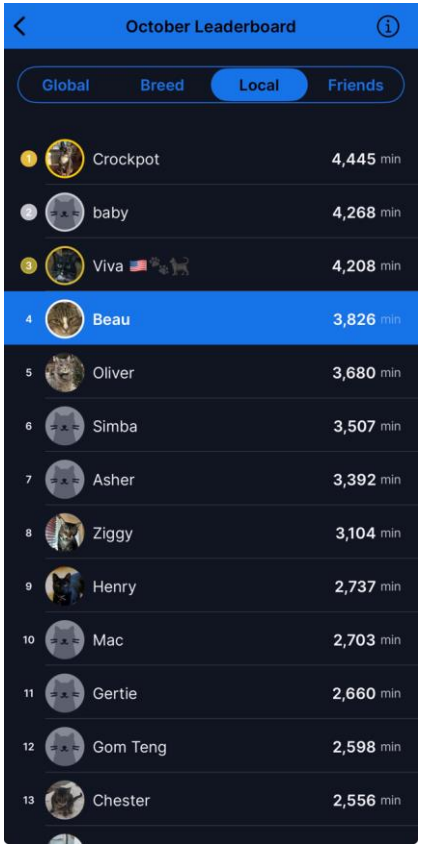
- Define metadata rules for V4
  - Establish clear principles governing metadata structure, consistency, and usability.
  - Ensure compatibility across systems and processes.

Conclusion

Metadata is getting more standardized in V4

This is a great opportunity for increased harmony in our the TMF community

There will still be change. We want to make sure we lay the right framework for the next 10 years



Thank You!