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2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

Originality Matters: Preserving Standards Integrity from Clinical Data Models to Tiramisù

Session 6, Track C: L'Architettura degli Standard

Angelo Tinazzi, Cytel Inc.

Speaker

Angelo Tinazzi
Senior Director, Statistical Programming
Cytel Inc.

30 years of experience across Italy, the UK, and Switzerland.

Angelo leads data standards initiatives at Cytel, advising clients and internal teams on best practices for regulatory submissions to health authorities. He also supports application development and automation initiatives within Cytel's PBS Statistical Programming Group.

Additionally, he authors the Cytel Good Data Submission Doctor blog series.

Angelo is a CDISC ADaM Authorized Instructor and PHUSE Conference co-chair. He also co-led of the Italian-speaking CDISC User Network.


my submission was a joke
ANNUAL SCIENTIFIC CONFERENCE
Decision on Abstract Submission
ACCEPTED
Dear Author,
We are pleased to inform you that your abstract has been
ACCEPTED!
Congratulations!
We look forward to seeing you at the conference.

Originality Matters:
Preserving Standards Integrity
from Clinical Data Models to Tiramisù

One authentic recipe.
Countless imitations.
Let's keep it real.
Let's keep it standard.

To make this concept tangible, we will conclude with an unexpected but illustrative analogy: **the original tiramisù recipe.**
Much like a well-defined data standard, the authentic tiramisù has a precise origin and specification, one that actually excludes alcohol. Yet, unintentional reinterpretations frequently introduce additions such as rum or amaretto, especially in the "Brussels" area, subtly transforming the original intent while still using the same name (NOTE: worth to note that deviation from standard within the same country where a lot of emphasis is put on setting standards even official manual for tiramisu of an "IGP").

In an increasingly global and collaborative environment, the adoption of common **standards** is essential to ensure consistency, interoperability, and trust. In the clinical research domain, frameworks such as CDISC provide a shared foundation that allows diverse stakeholders to work together efficiently while preserving the **integrity and intent** of original data models (NOTE: I'm sure here my former EC "friends" will get mad with this little "**sentence**"... but that's Chat-GPT fluent).

However, as standards are adopted across various organizations, therapeutic areas, and technical platforms, there is a risk that small deviations, often introduced with good intent, can accumulate over time, leading to **fragmentation** and **reduced comparability**.

Thus, the reliance on well-established standards not only supports **scientific rigor** but also strengthens our collective ability to generate **real-world evidence** that is interoperable, reproducible, and ultimately **more impactful.**

Let's embrace the standards as the original recipe—
and keep the audience satisfied with **the real thing.**

Dear E3C friends,

I was thinking about a revenge past weeks following the "the affront" I suffered last May.

In the end it is a joke, but while writing the "fake" abstract, I thought this could be a good opportunity on updating on "The CDISC Stupidario" (? year afters!!). A deep analysis of about 350 anonymized SDTM data packages ranging from using version 3.2 (50%) 3.3 (35%) 3.4 (5%) and below <3.2 (10%), showing trends and evolution throughout the year. I have numbers already, just need to understand what use to make of them.

See you in Milan regardless of any Cytel abstract acceptance.

Angelo

Angelo

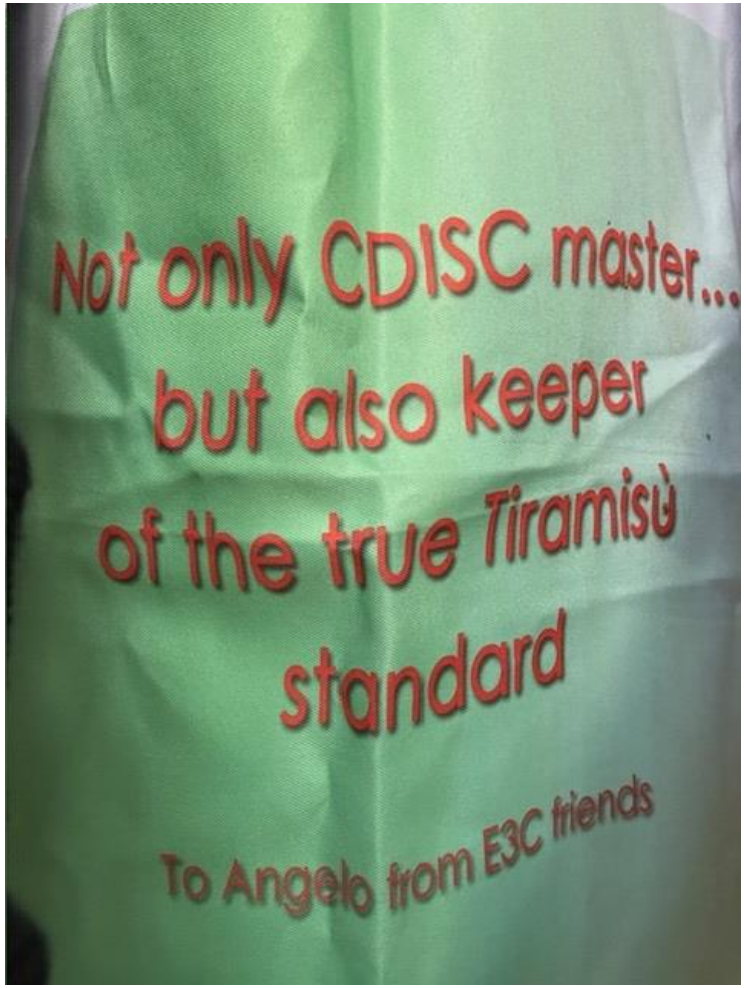
IT'S A JOKE
BUT USEFUL!

10 Years serving the CDISC EU Committee

After 10 years as a proud member of the conference committee, this was my last Interchange 🎁 and despite the photo of me during the closing session looked more like a memorial portrait, I'm deeply grateful to CDISC for this amazing 10-year journey 😅 🕯️📸.

And the punchline?
The next CDISC EU Interchange in 2025 will be in my hometown.
CDISC, I love you, but this timing feels suspicious... 😂

💙 I'd need to tag a whole football stadium worth of amazing people to thank properly.....but since it's a



10 Years serving the CDISC EU Committee
A recurrent Joke

Standard

- Mascarpone cheese 2.2 lbs (1 kg)
- Ladyfingers 12.3 oz (350 g) - *(about 42 pieces)*
- Coffee 7.1 oz (200 g)
- Eggs 8
- Sugar 1 cup (200 g)

SUPP .. To drink with

- Marsala
- Porto
- Moscato
- Japanese Whiskey (Angelo Preference)

*Legend has it that **tiramisù** was invented in the **19th century by a clever madam in a Treviso brothel**. She created this **energy-packed, caffeinated dessert as an aphrodisiac to reinvigorate her male clients** before they returned to their wives. The name derives from the Treviso dialect "**tireme su**," which translates to "**pick me up**"*

But there is only one "standard" way of making Tiramisù, and it's alcohol-free. All "deviations" should be considered "Supplemental"!

These are also not standard versions:

- *Strawberry Tiramisu*
- *Pumpkin Tiramisu*
- *Decomposed / Deconstructed Tiramisu*

Agenda

1. It’s all about sharing Knowledge/ Experience
2. What we did?
3. What We Learned from 350+ Studies
4. Conclusions and Key Takeaways

It’s all about sharing Knowledge/ Experience

7 Years ago … the CDISC “Stupidario”
Quality Review
From Qualitative Review to Data-Driven Assessment

It's all about sharing Knowledge/ Experience
7 Years ago …. The CDISC "Stupidario"

The "CDISC Stupidario"
(the CDISC Nonsense)

Presented by **Angelo Tinazzi**
Senior Director, Systems, CDISC Consulting, Statistical Programming, Cytel Inc
08.05.2019

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2019 Europe Interchange
Amsterdam, Netherlands | 6-10 May 2019

"Stupidario" is an Italian word to refer to a "repertoire" of sentences and saying worthy of citation for their stupidity

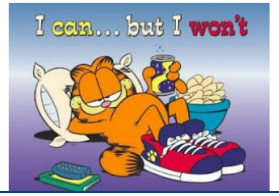
<< Madame you can safely go home: that virus was on computer storing all diagnoses and not on you>>

A "Stupidario" in every CDISC Submission deliverable

acrf.pdf
SDTM
ADaM
define.xml
Improper or Insufficient Documentation

Conformance Issue (P21 Message)	Justification Provided in the cSDRG
Define.xml/CDISC dataset Description mismatch	*LB, IE, QS, FA label is incorrect in XPT*
Variable is in wrong order within domain	*QSCAT and QSSCAT are incorrectly placed*

Why don't you fix it !?!?



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It’s all about sharing Knowledge/ Experience
Quality Review – Recurrent Issues in SDTM Packages

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It’s all about sharing Knowledge/ Experience

Standard Conformance Metrics

PharmaSUG 2023 - Paper SS-266

Industry Metrics for Standards Utilization and Validation Rules

Sergiy Sirichenko, Pinnacle 21 LLC

Rule ID	Message	Affected Studies	Issue Rate
CT2002	Variable value not found in extensible codelist	99.4%	38.4%
SD1076	Model permissible variable added into standard domain	98.9%	10.0%
SD1149	Expected variable with missing value for all records	92.2%	38.0%
SD1117	Duplicate records	85.1%	11.4%
SD1078	Permissible variable with missing value for all records	84.5%	33.8%
SD0021	Missing End Time-Point value	80.0%	21.4%
SD0022	Missing Start Time-Point value	79.9%	14.4%
SD1339	Missing EPOCH value when a start or observation date is provided	75.5%	20.3%
SD0026	Missing value for --ORRESU, when --ORRES is provided	68.3%	29.9%
SD0029	Missing value for --STRESU, when --STRESC is provided	67.9%	31.3%

From Qualitative Review to Data-Driven Assessment

What we did?

From Metadata to Insights
Materials & Methods(-like)
A bit of SDTM IG History

Cytel PBS Historical CDISC Data (or metadata)

~13 Years of **SDTM Metadata**

SDTM IG <3.2, 3.2, 3.3, 3.4 Coverage

Includes **CDISC CT** and key FDA requirements

Sourced from **Cytel PBS** Metadata Warehouse

Fully Anonymized

1. DATASET OVERVIEW

- ~13 years of SDTM metadata
- Covering SDTM IG <3.2, 3.2, 3.3, 3.4
- Includes **CDISC Controlled Terminology** and key FDA requirements
- Data sourced from **Cytel PBS Metadata Warehouse**
- Fully anonymized

2. METADATA WAREHOUSE STRUCTURE

Built directly from **production SDTM data**

Based on **standard variable combinations** *(e.g., --TESTCD, --TEST, --STRESU)*

Aggregated by:
- SDTM Class
- QNAM/QVAL structures

Enriched with **Study-Level Metadata** (TS) when available:
- Randomization
- Study phase
- Study start
- SDTM IG version

3. ANONYMIZATION APPROACH

Study-level anonymization: STUDYID and sponsor removed

No **subject-level** data retained *(e.g., SEX, RACE, DOB/Age excluded)*

TS parameters **filtered**

Free text removed: terms, comments, etc.

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Questions (examples) we Wanted the Metadata to Answer

1 Portfolio Size & Composition

- √ How many studies, domains and SUPP domains?
- √ How does this vary by SDTM IG, phase and TA?
- Which studies are large, sparse or structurally unusual?

Evidence: counts, mean ± SD, distributions

2 Domain Usage & Standardization

- √ Which SDTM domains are most frequently used?
- √ Where do non-standard domains appear most often?
- √ How much is covered by standard domains vs

Evidence: domain prevalence, IG breakdowns

3 Standards & FDA-Style Checks

- Where do FDA expectations apply?
- Are US conventional units, TEAE, EPOCH, TS parameters and LOINC present?
- Which studies need manual review?

Evidence: rule-based flags and exceptions

4 Lab / Findings Consistency

- √ Are key lab parameters reported with expected SI units?
- √ Are LB, MB and IS parameters mapped to the correct CT domain?
- √ Which TESTCDs appear in more than one

Evidence: TESTCD, units, CT mapping

5 SUPP & Controlled Terminology

- √ What is captured in SUPP and is it standardized?
- √ Are QNAMs reused consistently across studies?
- Are Y/N flags, ISO dates and CT values applied consistently?

Evidence: QNAM frequency, label/type variation

6 Trends & Outliers

- What changed across study start years and SDTM IG versions?
- √ Which TAs or phases show different metadata patterns?
- Which studies are outliers for domains, SUPP or

Evidence: trend tables, outlier lists

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A Trained GPT Assistant

Historical SDTM Analyst

✓ Using the creator's recommended model: GPT-5.4 Pro

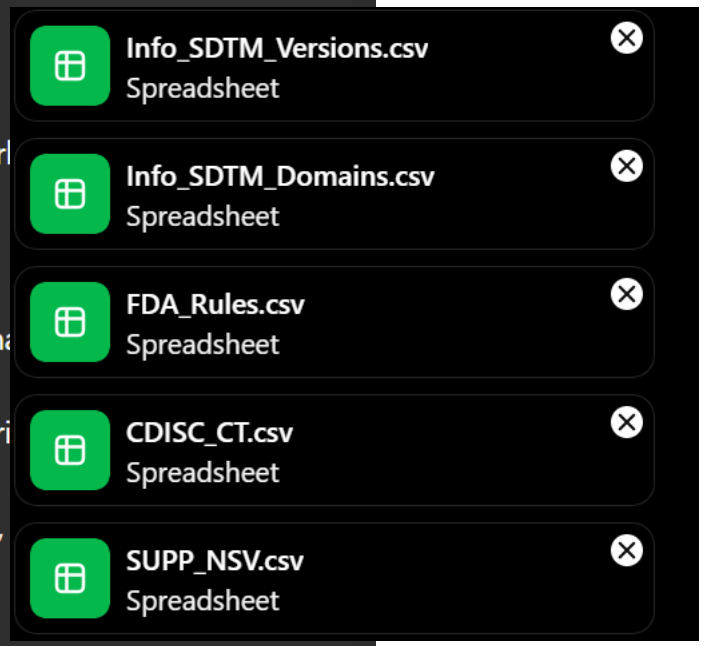
Extract insights from an SDTM metadata warehouse built from more then 300 studies

You are my assistant for analyzing SDTM metadata from more than 300 studies.

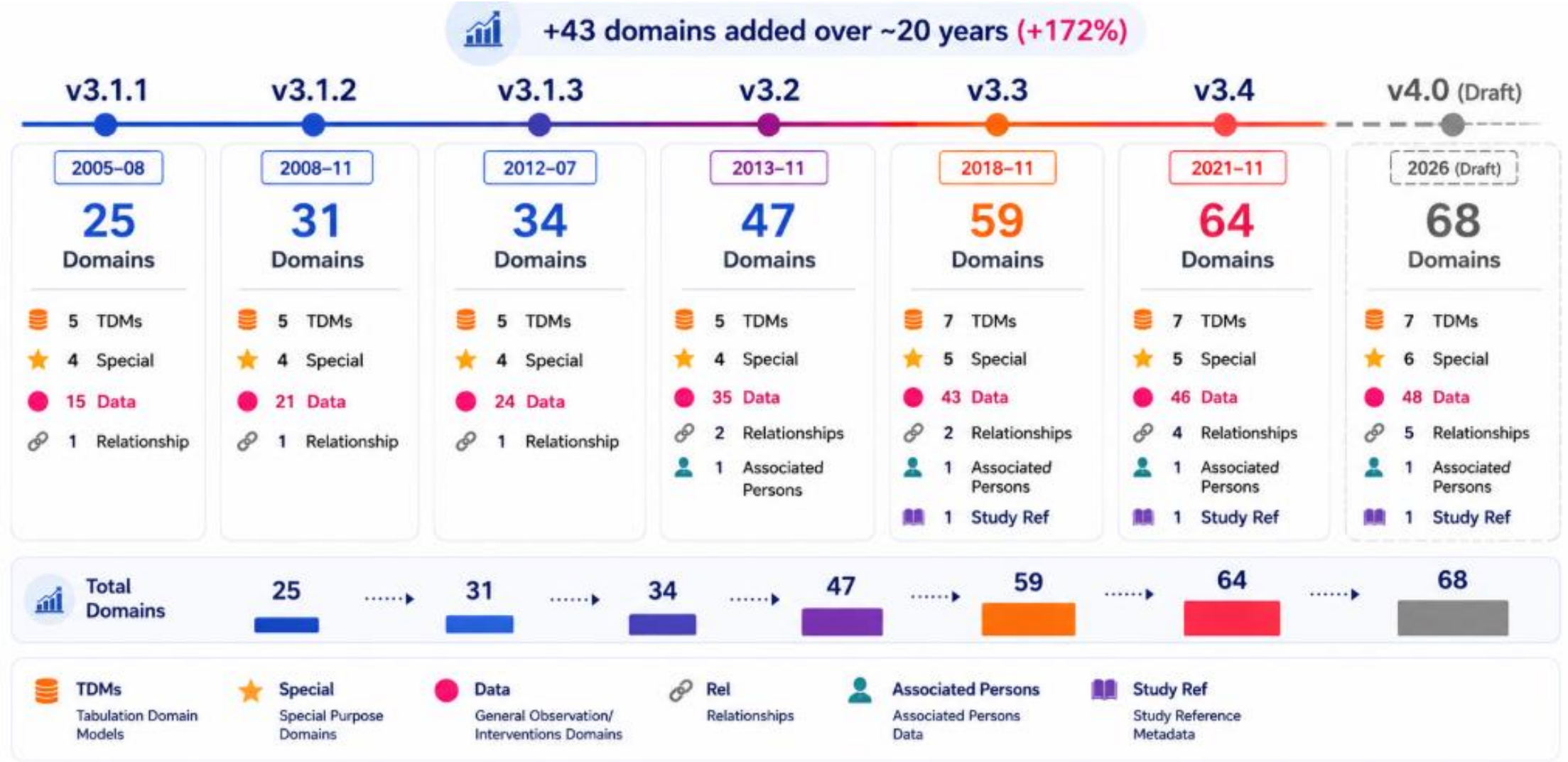
Your job is to analyze structured metadata tables derived from SDTM packages and generate clear, decision-useful insights.

Primary use case
The user will provide metadata organized at study, dataset, variable, and controlled terminology level, typically in one Excel wor
files.

Expected input tables may include:
- Study_Info: one record per study, with fields such as StudyID, SDTM version, therapeutic area, year, and optionally sponsor, pha
- Datasets: one record per study-dataset combination
- Variables: one record per study-dataset-variable combination, with attributes such as label, type, length, core, role, codelist, ori
- QNAM: one record per study, supplemental dataset, unique QNAM, QLABEL, QVAL
- Findings SDTM Class: one record per study and unique test structure for findings domains such as LB, including TESTCD, TEST,
- Events SDTM Class: one record per study and unique variable pattern for events domains
- Interventions SDTM Class: one record per study and unique variable pattern for interventions domains
- TS: one record per study per parameter (TSPARMCD/TSPARM), TSVAL and other info further describing the study
All above tables have the variable STUDYID (study) in common so that you can make the link when asked.



Evolution of the SDTM IG: From v3.1.1 to v3.4



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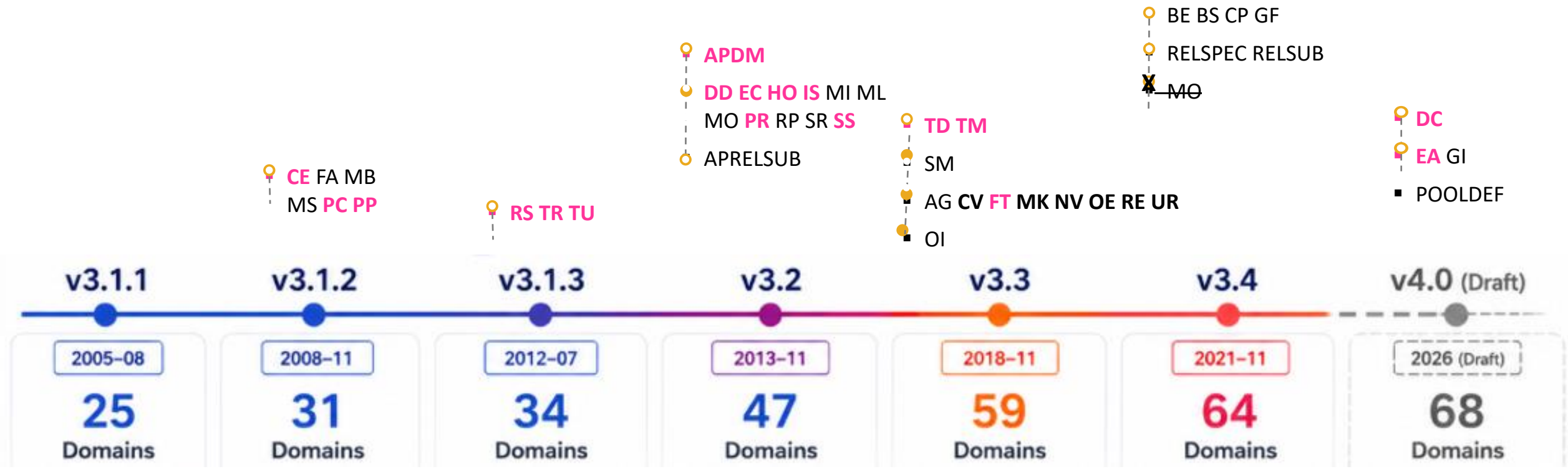
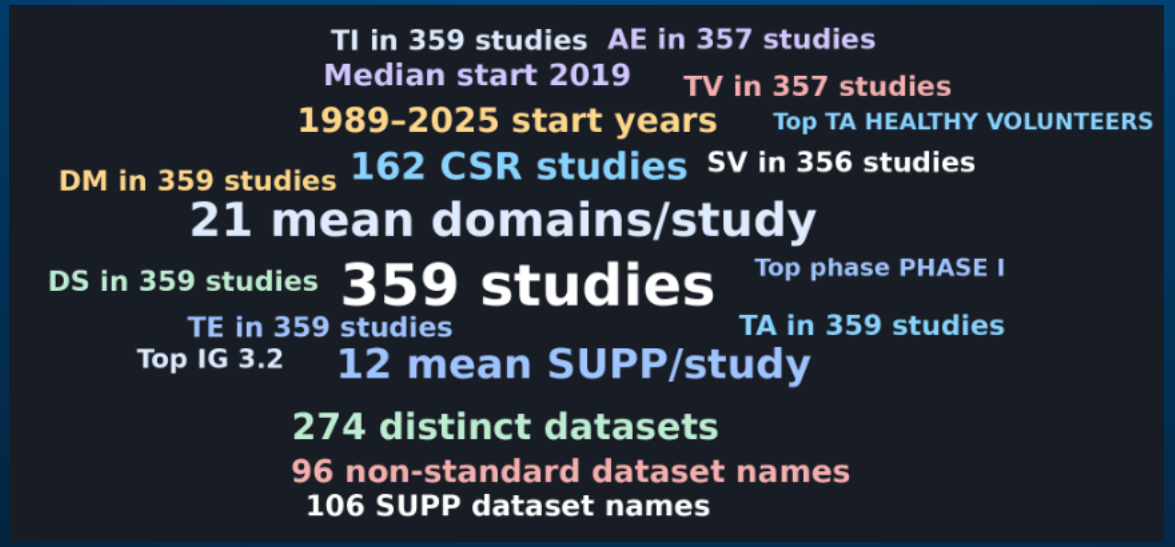
Evolution of the SDTM IG: From v3.1.1 to v3.4



What We Learned from 350+ Studies



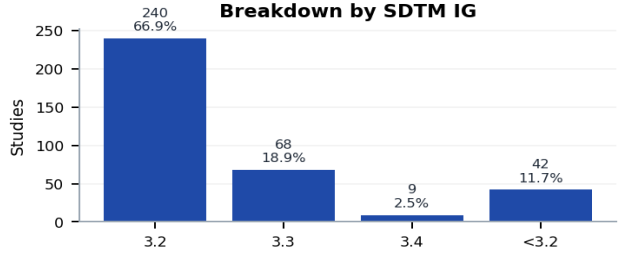
SDM Metadata Warehouse Composition

Population logic

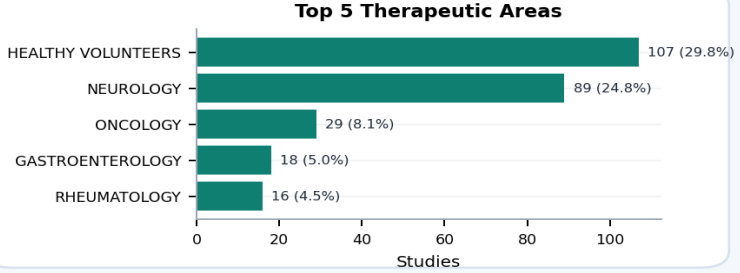
359 unique study IDs in study metadata → **359** report population retained for denominator → **359** used for current study-level percentages

Note: updated from the current uploaded metadata. No additional threshold was applied in this figure.

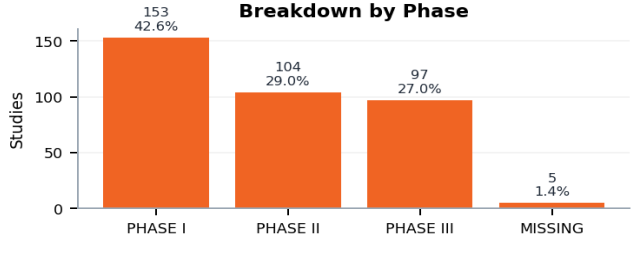
Breakdown by SDTM IG



Top 5 Therapeutic Areas



Breakdown by Phase



In-house studies

45.1%

162 of 359 studies

Definition: TYPE_STUDY = CSR.

Denominator held at 359.

Start year

Mean 2017
SD 6
Median 2019
Min–Max 1989–2025

353 studies have a numeric START_YEAR.

Domains per study

Mean 21.2
SD 4.3
Median 21
Min–Max 10–34

Count = ds_standard + ds_non_standard.

Dataset reliance signals

60.2%

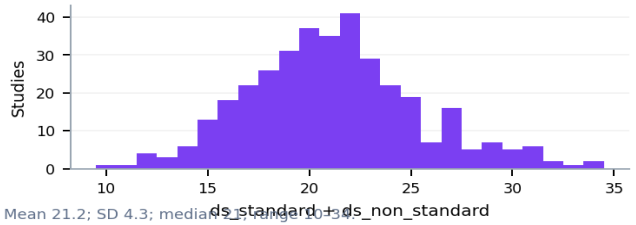
216 studies have ≥1 non-standard dataset

99.4%

357 studies have ≥1 SUPP dataset

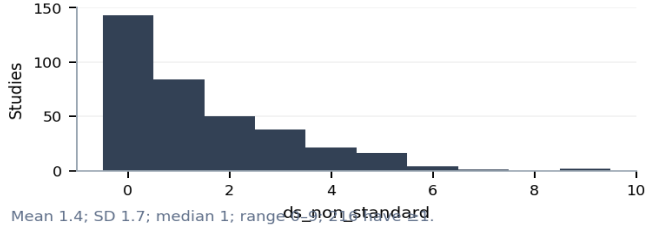
Detailed counts are in the Excel workbook.

Domain count per study



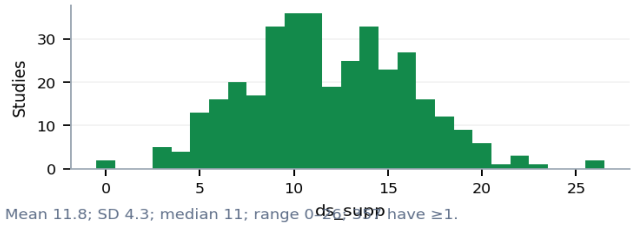
Mean 21.2; SD 4.3; median 21; range 10–34.

Non-standard dataset count per study



Mean 1.4; SD 1.7; median 1; range 0–9; 215 have ≥1.

SUPP dataset count per study



Mean 11.8; SD 4.3; median 11; range 0–25; 357 have ≥1.

Dataset logic: domains = ds_standard + ds_non_standard; non-standard datasets = ds_non_standard; SUPP datasets = ds_supp. Percentages use the current study-level denominator. Source: extractGPT_studies_info_anonim.csv.

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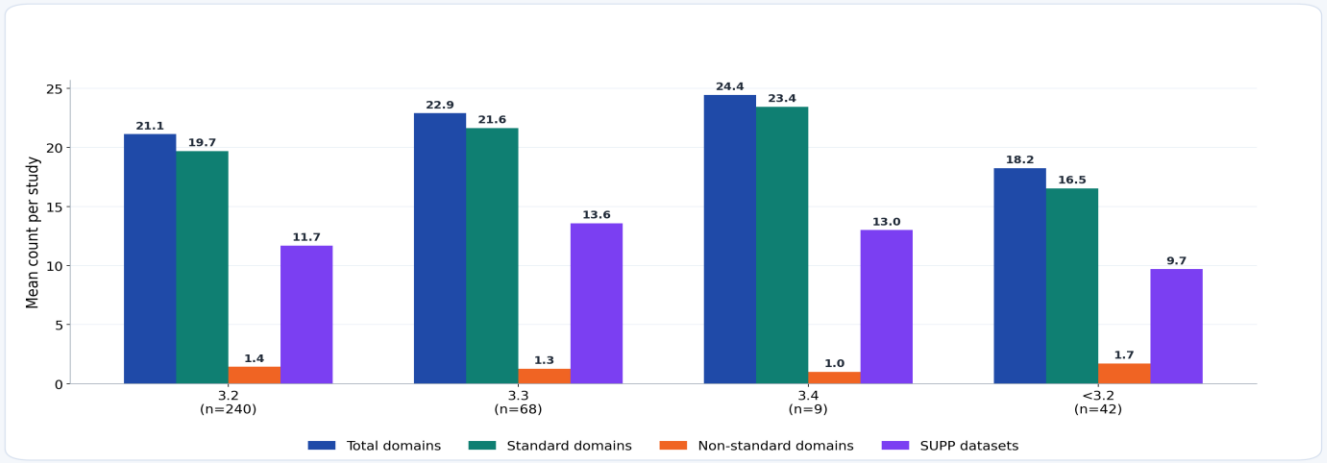
Number of SDTM Domains per Study

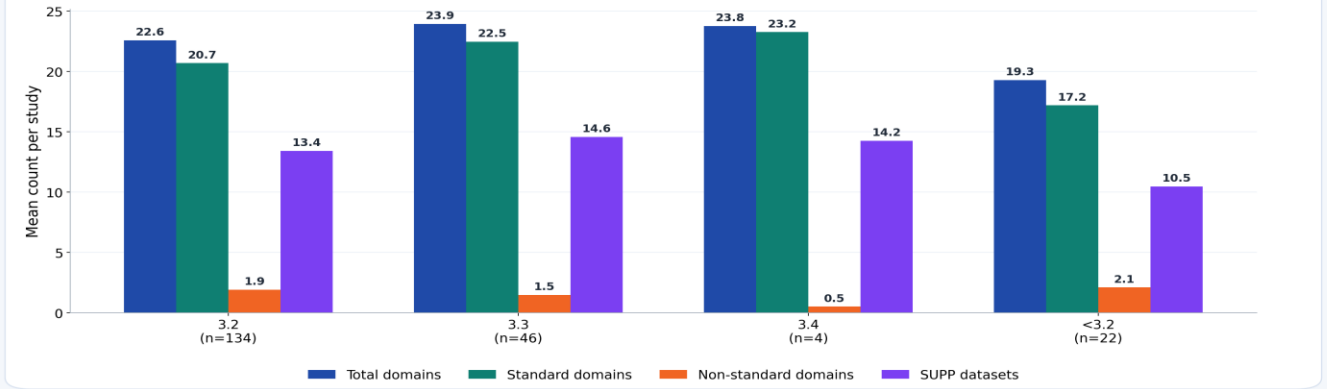
Excluding TDMs, RELREC, AP



Portfolio denominator: 359 studies. No filters applied. Total domains = ds_standard + ds_non_standard; SUPP datasets = ds_supp.

Total domains	Standard domains	Non-standard domains	SUPP datasets
21.2	19.8	1.4	11.8

Excluding Phase I Studies also



Phase I excluded. Included denominator: 206 studies; excluded Phase I studies: 153; original portfolio: 359. Total domains = ds_standard + ds_non_standard; SUPP datasets = ds_supp.

Total domains	Standard domains	Non-standard domains	SUPP datasets
22.5	20.8	1.8	13.4

Little **trend in decreasing number of non-standard** domains (especially for Phase>I)

Increased number of Total Domains explained by the new domains available and increased complexity of studies

Number of SDTM domains per study

Mean ± SD breakdown by Study Start Date category

Studies	Overall Mean ± SD	Min–Max
359	21.2 ± 4.3	10–34

Breakdown by Study Start Date

Study Start Date category	N	Mean domains per study	Mean ± SD	Min-Max
<2005	16		18.5 ± 4.5	11–25
2005–2010	17		20.9 ± 4.7	10–31
2011–2015	68		20.9 ± 3.6	13–29
2016–2020	163		21.2 ± 4.3	12–34
>2020	89		22.2 ± 4.3	13–34
Missing	6		17.3 ± 3.7	14–24

Assumption is that **most recent studies used most recent IGs** (mean year of Study Start)

- IG <3.2 2009
- IG 3.2 2017
- IG 3.3 2022
- IG 3.4 2023

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Number of SDTM Domains per Study

Excluding TDMs, RELREC, AP

Number of SDTM domains per study

Mean ± SD breakdown by Phase and Therapeutic Area

Studies	Overall Mean ± SD	Min-Max
359	21.2 ± 4.3	10-34

Breakdown by Phase

PHASE	N	Mean domains per study	Mean ± SD
PHASE I	153		19.4 ± 3.6
PHASE II	104		22.5 ± 4.3
PHASE III	97		22.8 ± 4.1
Missing / not specified	5		18.6 ± 5.3

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Some TA requires more domains, **Oncology as expected requires more data / SDTM domains**

Ph II / III equal number of SDTM domains

Breakdown by Therapeutic Area

TA	N	Mean domains per study	Mean ± SD
HEALTHY VOLUNTEERS	107		18.9 ± 3.2
NEUROLOGY	89		22.0 ± 4.1
ONCOLOGY	29		25.0 ± 5.1
GASTROENTEROLOGY	18		20.9 ± 2.5
RHEUMATOLOGY	16		21.1 ± 3.3
INFECTIOUS DISEASE	12		22.0 ± 3.6
OPHTHALMOLOGY	12		20.9 ± 3.5
GYNECOLOGY AND REPRODUCTI...	12		18.8 ± 3.5
CARDIOVASCULAR	11		21.6 ± 4.8
ENDOCRINE	9		23.3 ± 4.1
ALLERGY	5		25.8 ± 1.6
RARE DISEASE	5		23.6 ± 6.3
AUTOIMMUNE	5		22.4 ± 3.0
MENTAL HEALTH	5		22.2 ± 1.8
GENETIC	4		18.5 ± 3.1

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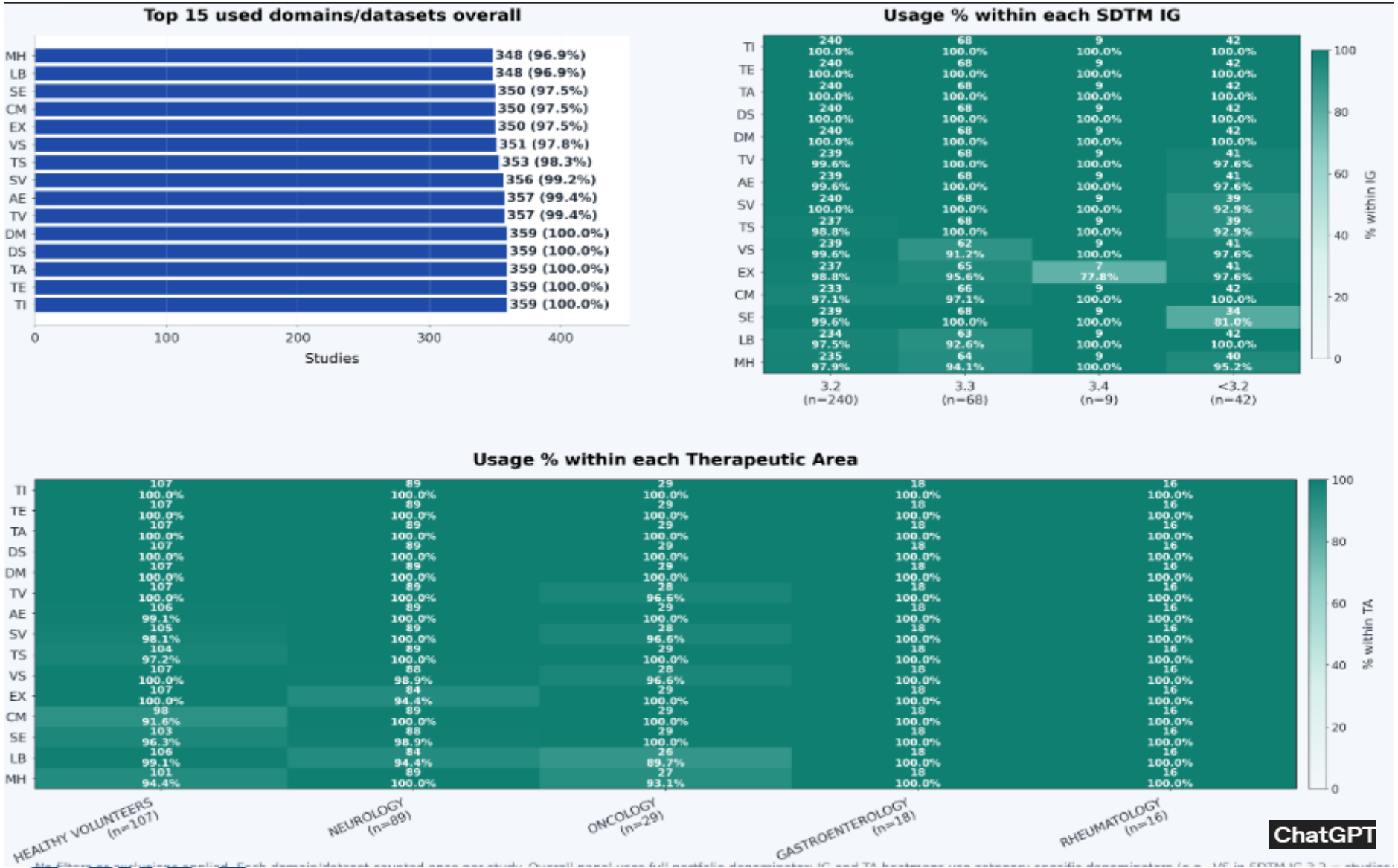
Most Used SDTM Domains



Some domains are essentially universal, forming the **core SDTM backbone**

Consistently across IG and TA

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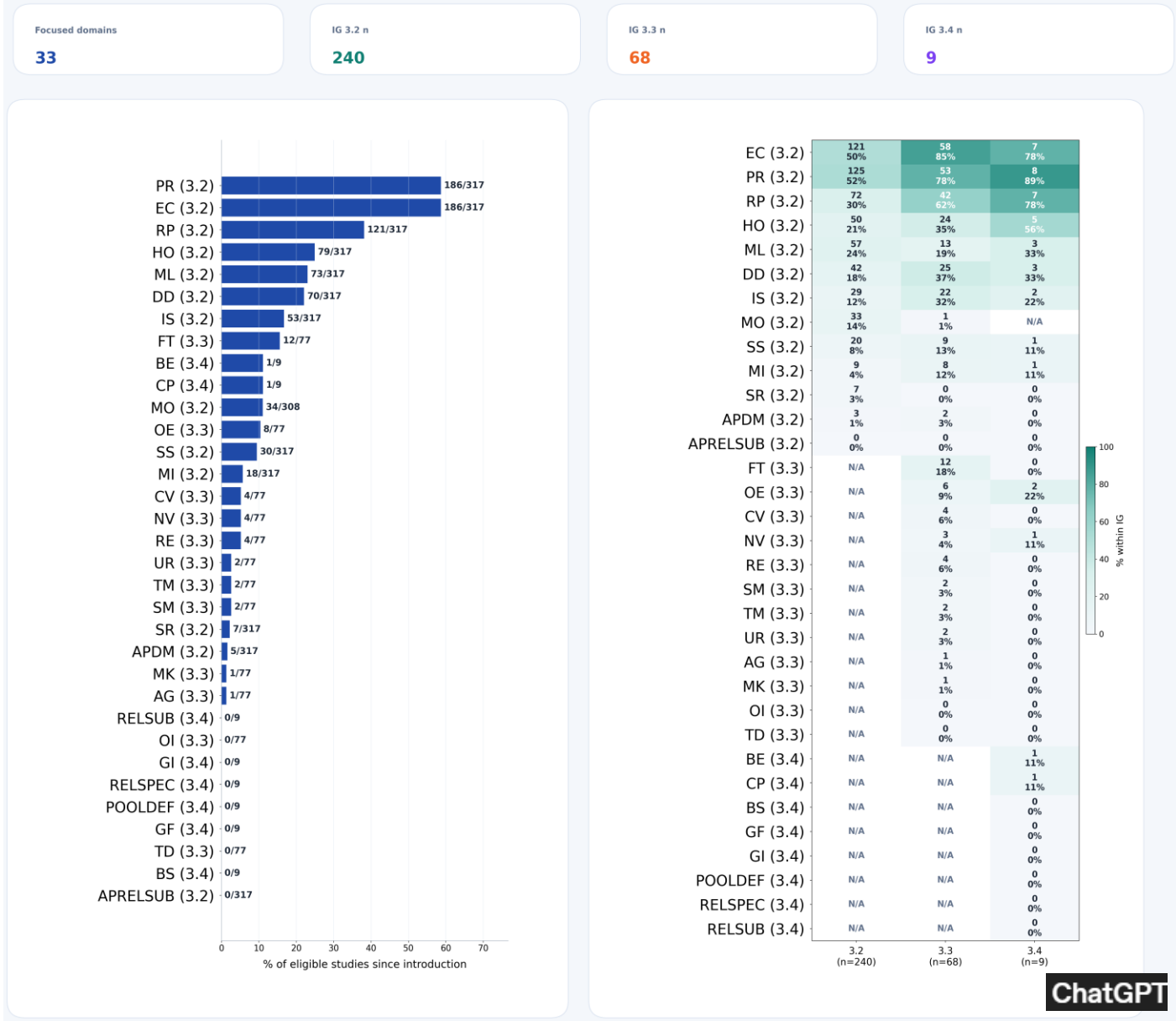
Was it worth adding that SDTM Domain?

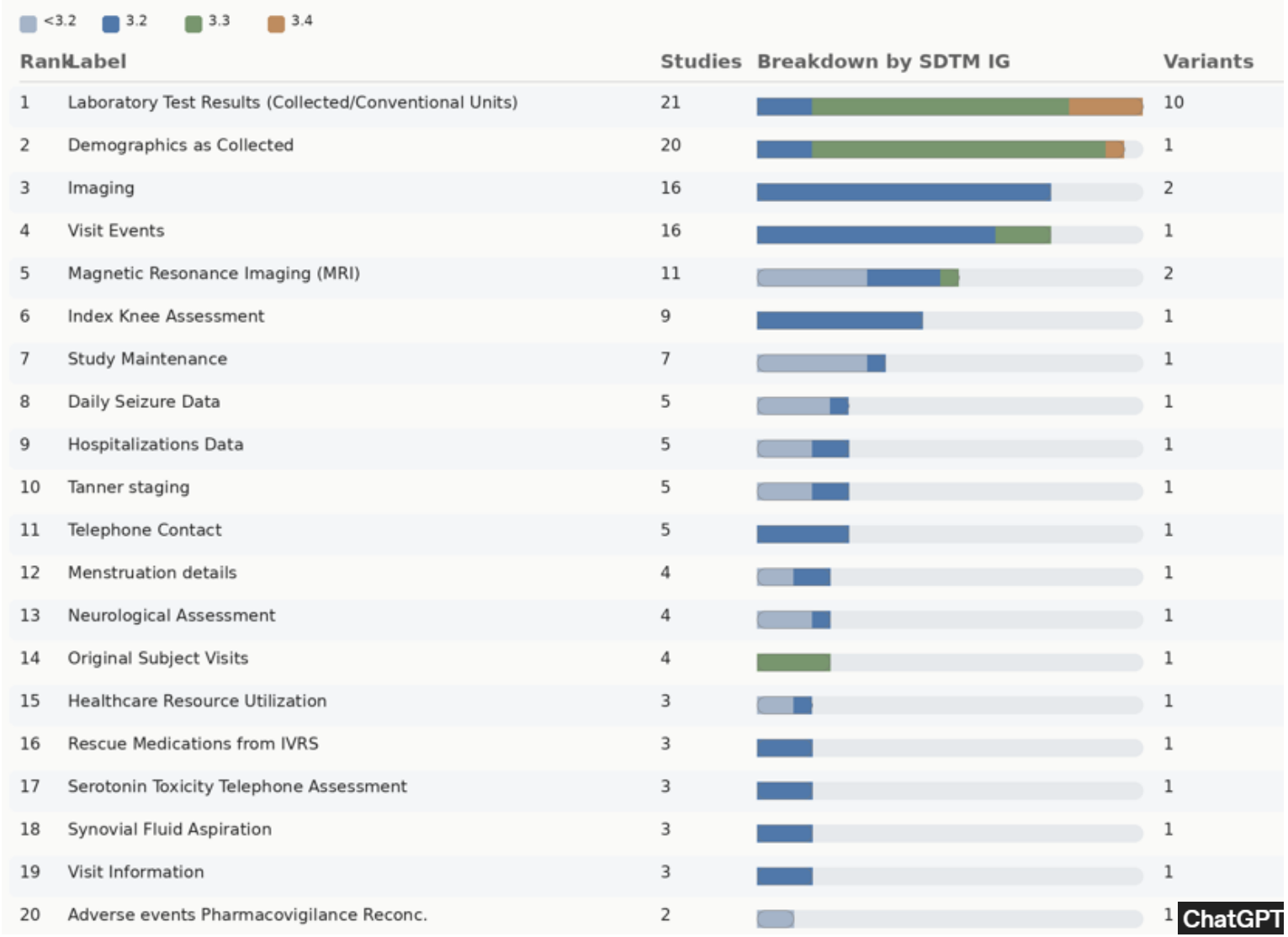
% of Usage since a new domain was introduced

- The addition of **certain new domains clearly added clarity** to submitted packages e.g., EC, PR, IS, etc.
- For others was it worthwhile? e.g., new TDMs (TD/TM)
- **Is it worth to continue developing / add new domains?**



Most Used Non-Standard SDTM Domains

A mix of wrong decisions and **“temporary” Industry agreement**
e.g., DC, LC, VE



Rank	Label	Studies	Breakdown by SDTM IG	Variants
1	Laboratory Test Results (Collected/Conventional Units)	21		10
2	Demographics as Collected	20		1
3	Imaging	16		2
4	Visit Events	16		1
5	Magnetic Resonance Imaging (MRI)	11		2
6	Index Knee Assessment	9		1
7	Study Maintenance	7		1
8	Daily Seizure Data	5		1
9	Hospitalizations Data	5		1
10	Tanner staging	5		1
11	Telephone Contact	5		1
12	Menstruation details	4		1
13	Neurological Assessment	4		1
14	Original Subject Visits	4		1
15	Healthcare Resource Utilization	3		1
16	Rescue Medications from IVRS	3		1
17	Serotonin Toxicity Telephone Assessment	3		1
18	Synovial Fluid Aspiration	3		1
19	Visit Information	3		1
20	Adverse events Pharmacovigilance Reconc.	2		1

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SDTM Standard Domains Requiring SUPP

Top 20 standard domains with matching SUPP-- usage

Rank	Domain	Label	Domain N	SUPP N	%
1	AE	Adverse Events	357	335	93.8%
2	CM	Concomitant Medications	350	320	91.4%
3	DM	Demographics	359	312	86.9%
4	DS	Disposition	359	271	75.5%
5	LB	Laboratory Test Results	348	271	77.9%
6	EG	ECG Test Results	293	239	81.6%
7	DV	Protocol Deviations	267	224	83.9%
8	MH	Medical History	348	223	64.1%
9	PE	Physical Examination	267	183	68.5%
10	EX	Exposure	350	182	52.0%
11	VS	Vital Signs	351	148	42.2%
12	EC	Exposure as Collected	186	143	76.9%
13	PR	Procedures	186	140	75.3%
14	PC	Pharmacokinetic Concentrations	238	115	48.3%
15	QS	Questionnaires	230	112	48.7%
16	SV	Subject Visits	356	91	25.6%
17	FA	Findings About Events or Interven...	172	89	51.7%
18	DA	Drug Accountability	128	86	67.2%
19	CE	Clinical Events	73	48	65.8%
20	IE	Inclusion/Exclusion Criteria Not Met	261	44	16.9%

Breakdown by SDTM IG

AE

<3.2	3.2	3.3	3.4
95% (39/41)	92% (219/239)	100% (68/68)	100% (9/9)

CM

<3.2	3.2	3.3	3.4
90% (38/42)	90% (209/233)	97% (64/66)	100% (9/9)

DM

<3.2	3.2	3.3	3.4
81% (34/42)	85% (204/240)	99% (67/68)	78% (7/9)

DS

<3.2	3.2	3.3	3.4
67% (28/42)	72% (172/240)	91% (62/68)	100% (9/9)

LB

<3.2	3.2	3.3	3.4
62% (26/42)	81% (189/234)	78% (49/63)	78% (7/9)

EG

<3.2	3.2	3.3	3.4
82% (27/33)	81% (162/199)	87% (45/52)	56% (5/9)

DV

<3.2	3.2	3.3	3.4
67% (14/21)	83% (153/184)	91% (50/55)	100% (7/7)

MH

<3.2	3.2	3.3	3.4
62% (25/40)	63% (148/235)	67% (43/64)	78% (7/9)

PE

<3.2	3.2	3.3	3.4
50% (15/30)	70% (128/184)	83% (38/46)	29% (2/7)

EX

<3.2	3.2	3.3	3.4
76% (31/41)	54% (127/237)	37% (24/65)	0% (0/7)

Rule: numerator = studies with both parent domain and matching SUPP--; denominator = studies with parent domain. Right IG cards show the top 10 domains to preserve readability.

ChatGPT

The strongest SUPP dependency is in **AE, CM, and DM**, each with SUPP present in more than **85%** of studies where the parent domain exists. The largest domain-level SUPP counts are not always the highest percentages. For example, **EX** has many SUPP records in absolute terms, but only **52.0%** of EX studies have SUPPEX.

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Average Number of QNAMs per SDTM Domain

Top 20 represented QNAMs

QNAM	N	% studies
CLSIG	74	21.3%
ATC3	36	10.3%
DVTERM1	35	10.1%
ATC2	34	9.8%
ATC1	33	9.5%
ATC4	32	9.2%
RACEOTH	28	8.0%
DVTERM2	27	7.8%
CMATC1	24	6.9%
CMATC2	24	6.9%
CMATC3	24	6.9%
ATC2CD	21	6.0%
ATC3CD	21	6.0%
ATC1CD	20	5.7%
CMATC4	20	5.7%
CMDECOD1	20	5.7%
AETRTEM	19	5.5%
COHORT	19	5.5%
DVTERM3	19	5.5%
ATC4CD	18	5.2%

Highest average unique QNAMs per SUPP domain

SUPP domain	Avg unique QNAMs
CM	10.8
CE	10.3
OE	7.9
AE	7.5
PR	7.3
RE	5.8
EC	5.1
DM	5.1
DV	5.0
QS	4.8
MH	4.5
DA	4.3
FT	4.2
EX	4.1
DS	4.1

Additional variables should be considered for **inclusion in the General Observation Classes**

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Average Number of QNAMs per SDTM Domain

By SDTM IG

Category	Avg	Studies
3.2	5.3	234
3.3	4.8	66
3.4	6.0	9
<3.2	4.8	39

By Phase

Category	Avg	Studies
PHASE I	4.1	148
PHASE II	5.4	101
PHASE III	6.0	94
Missing	5.6	5

By Therapeutic Area

Category	Avg	Studies
HEMATOLOGY	10.0	3
CARDIOVASCULAR	8.0	11
GENETIC	7.5	4
UROLOGY	7.1	3
ONCOLOGY	6.8	27
ALLERGY	6.3	5
GASTROENTEROLOGY	6.3	17
NEUROLOGY	5.1	85
MENTAL HEALTH	5.0	4
INFECTIOUS DISEASE	4.8	12
RHEUMATOLOGY	4.5	15
RARE DISEASE	4.5	5
NEPHROLOGY	4.4	3
ENDOCRINE	4.3	9
AUTOIMMUNE	4.2	5

Trend of decrease usage of SUPP
to be confirmed

ChatGPT

Focus on “Laboratory” Data

Top Lab Parameters — SI Unit Consistency

Parameters used in >50% of studies; dominant SI unit shown with consistency across parameter studies.

Lab Parameter	% of studies	Dominant SI Unit	Dominant unit %
WBC / Leukocytes	92.4%	10^9/L	90.1%
HGB / Hemoglobin	91.8%	g/L	77.2%
ALT / Alanine Aminotransferase	91.2%	U/L	67.7%
AST / Aspartate Aminotransferase	91.2%	U/L	67.7%
CREAT / Creatinine	91.2%	umol/L	89.7%
HCT / Hematocrit	90.0%	L/L	35.0%
PLAT / Platelets	90.0%	10^9/L	91.5%
ALP / Alkaline Phosphatase	89.4%	U/L	65.1%
BILI / Bilirubin	89.4%	umol/L	90.8%
RBC / Erythrocytes	88.8%	10^12/L	89.7%
PROT / Protein	88.5%	g/L	86.4%
K / Potassium	87.9%	mmol/L	97.0%
SODIUM / Sodium	87.9%	mmol/L	97.0%
LYM / Lymphocytes	87.1%	10^9/L	89.5%
GLUC / Glucose	86.5%	mmol/L	87.8%
ALB / Albumin	85.9%	g/L	90.1%
MONO / Monocytes	84.4%	10^9/L	86.4%
BASO / Basophils	83.8%	10^9/L	86.7%
EOS / Eosinophils	83.8%	10^9/L	86.7%
CA / Calcium	82.1%	mmol/L	92.5%

Orange consistency values indicate dominant unit <70% of studies for that lab parameter.

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g/dL 14% which is also a valid SI unit

IU/L same meaning (29%), same for ALP, GGT, etc.

%	25%
RATIO	14%
Fraction of 1	11%

(Similarly for INR)

Other parameters with **low Dominant SI Unit**: Creatinine Clearance, Urate, aPTT, often Urine parameters

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Focus on “Laboratory” Data

LB, MB & IS Domain Scope Changes for the SDTM IG v3.4 and Impact on Controlled Terminology
CDISC Webinar, June 2023

ChatGPT

Inconsistency in Lab data Mapping

Often an **FDA concern**

Summary by domain: "Found in other target domain CT"

Domain	Studies with flag	% of domain studies (0–100% scale)		Flagged TESTCD/TEST
IS	9/37		24.3%	15
LB	77/216		35.6%	27
MB	9/73		12.3%	6

Studies with flag = unique studies in the domain with at least one TESTCD found in another target domain CT.
Denominator = post-2016 studies represented in that domain file; TESTCD/TEST flags are distinct TESTCD + TEST combinations.

Top TESTCD / TEST flags by affected studies

Domain	TESTCD	TEST	Should map to	Studies
LB	HBSAG	Hepatitis B Virus Surface Antigen	MB	64
LB	HIV12P24	HIV-1/2 Antibody + HIV-1 p24 Antigen	MB	16
LB	HCRNA	Hepatitis C Virus RNA	MB	7
IS	HBSAG	Hepatitis B Virus Surface Antigen	MB	4
LB	HBEAG	Hepatitis B Virus e Antigen	MB	4
MB	REAAB	Reagin Antibody	IS	4
IS	HIV	Human Immunodeficiency Virus	MB	3
LB	HIV	Human Immunodeficiency Virus	MB	3
LB	MYTBGIR	M. tuberculosis IFN Gamma Response	MB	3
LB	HIV124AG	HIV-1 p24 Antigen	MB	2
LB	HIV1RNA	HIV-1 RNA	MB	2
LB	MTB	Mycobacterium tuberculosis	MB	2
LB	SARSCOV2	SARS-CoV-2	MB	2
MB	CALPRO	Calprotectin	LB	2
IS	HBCAG	Hepatitis B Virus Core Antigen	MB	1

Conclusions and Key Takeaways

Conclusions and Takeaways
From Metadata Review to Reusable CDISC Intelligence

- SDTM looks standardized… **until you look at the data**
- SDTM is standardized. **Implementations are not**.
- Structure is consistent. **Content is not**
- **Metadata at scale** reveals **patterns** you never see in a single study
- **Working progress**, more to discover, and **ADaM is next**
- **More analytics**
- **Full reports will be shared with the community**

SDTM looks standardized… until you analyze it at scale

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Structure is consistent.

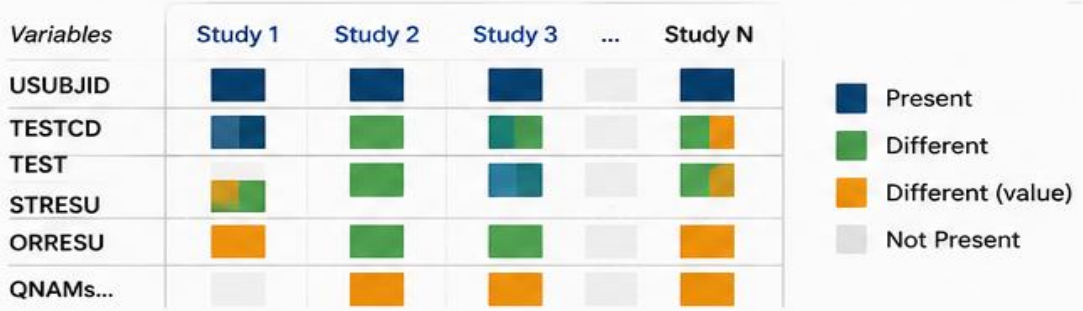
The SDTM framework is used across studies and versions.

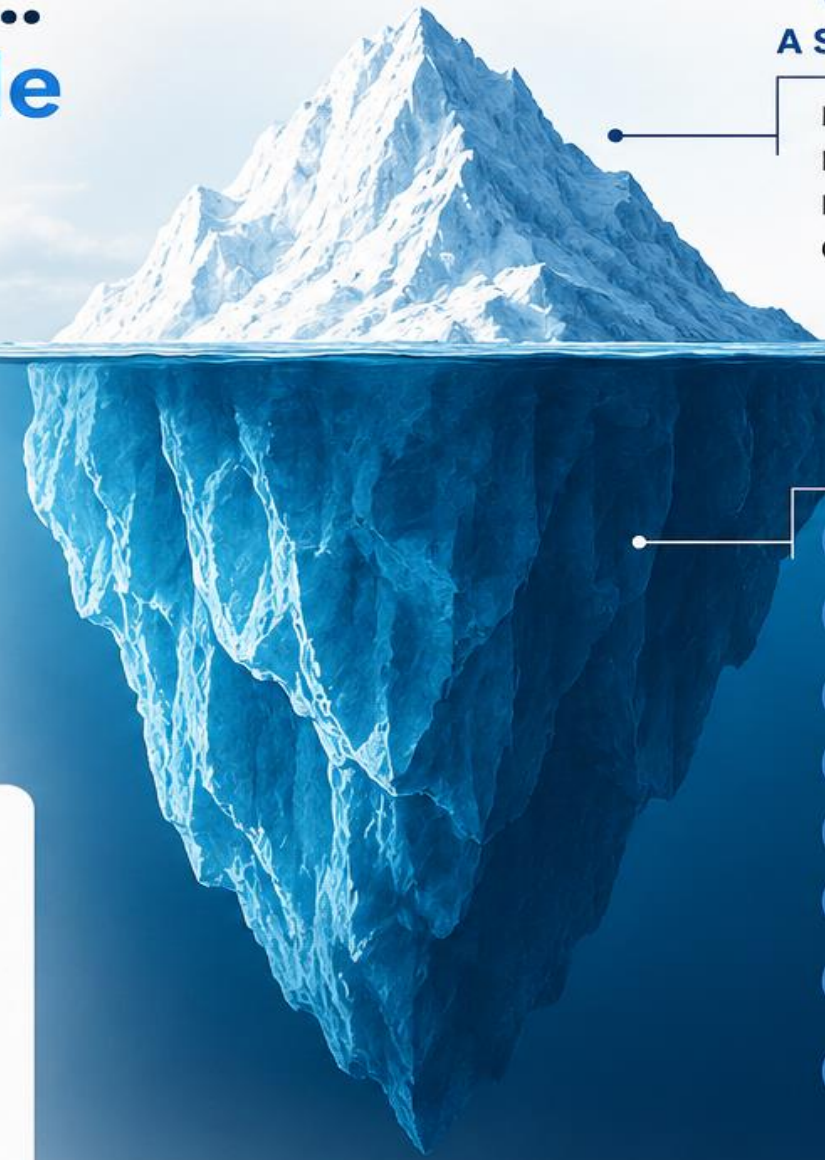
Content is variable.

How concepts are captured, labeled, coded and extended varies widely.

Metadata at scale reveals patterns you never see in a single study.

SAME SDTM DOMAIN. DIFFERENT IMPLEMENTATIONS.





VISIBLE IN A SINGLE STUDY

- Domains
- Basic structure
- Key variables
- Core metadata

VISIBLE ONLY AT SCALE

- Variable presence & patterns
- QNAMs & supplemental qualifiers
- Test codes, units & methods
- Label & origin inconsistencies
- Non-standard datasets
- Therapeutic area differences
- Trends by year, version, and study type
- Outliers & data quality signals

KEY TAKEAWAY

SDTM standardizes the container – not always the content.
Metadata at scale turns SDTM from documentation into intelligence.

DISCOVER · UNDERSTAND · ACT · IMPROVE

Thank You!

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Questions?

Abstract

This presentation examines how SDTM is implemented in practice, based on metadata from approximately 350 anonymized SDTM packages across multiple versions, therapeutic areas, and trial phases. Using these metadata, we explore how SDTM implementation and adherence to regulatory expectations, particularly FDA requirements, have evolved over time, assessing quality and consistency through quantitative metrics.

Our analysis highlights a key insight: while SDTM provides a robust structural framework, its implementation in practice shows substantial variability. Differences such as domain usage, terminology, and units, for example reveal that consistency at the standard level does not always translate into consistency in practice.

To illustrate the importance of preserving original specifications, we use the analogy of the traditional tiramisù recipe. Like a data standard, it has a precise definition, yet reinterpretations, like adding amaretto, often alter it while keeping the same name.

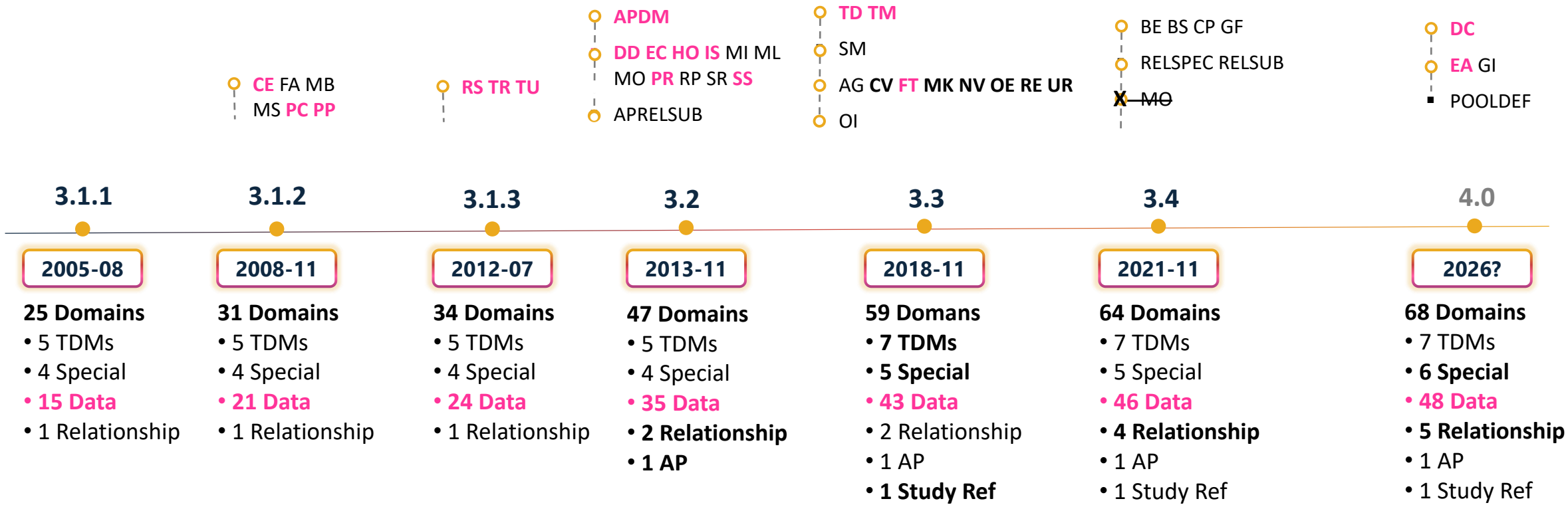
Ultimately, SDTM defines the structure, but consistency depends on how it is applied.

Original Slides Before ChatGPT

Example of Questions we Wanted to Answer

- ~~SDTM Size~~
  - ~~Number of domains~~
  - ~~Number of SUPP~~
  - ~~Breakdown by SDTM IG, Study Phase~~
- ~~SDTM Domain Usage~~
  - ~~Adoption of new domains~~
  - ~~Prevalence of non-Standard Domain~~
  - ~~How much is covered by standard e.g., use of SUPP~~
- Application of FDA requirement (when applicable)
  - US conventional unit
  - TEAE in SUPPAE
  - Parameter Usage in TS
  - EPOCH
  - LOINC Presence
- ~~Labs~~
  - ~~SI Unit for key Lab Parameter~~
  - ~~Mapped to correct domain LB vs MB vs IS~~
- Protocol Deviations
- What's in SUPP and was it standardized? E.g., Use of CT, Y/N, ISO format for date
- Assess Trend

Evolution of the SDTM IG: From v3.1.2 to v3.4



Cytel PBS Historical CDISC Data (or metadata)

About 13 Years of Cytel PBS SDTM Metadata

Metadata Warehouse
Fully **Anonymized**
Looked at <3.2, 3.2, 3.3, 3.4 Metadata, Plus CDISC-CT and Key FDA Requirements

Metadata Warehouse

Built Directly from Data
Unique Combination of Selected Standard Variables e.g., --TESTCD, --TEST, --STRESU
Pooled by **SDTM Class**
Pooled **QNAMs/QVALs**
Study Characteristics integrated from TS when available e.g., Random, Phase of Study, Study Start, SDTM IG

Anonymization Method

Fully Anonymized STUDYID and SPONSOR name
Filtered TS parameters
No de-”anonymizable” subject data e.g., SEX, RACE + Date of Birth / Age
Metadata Data Filtered out of **terms, comments**, etc.

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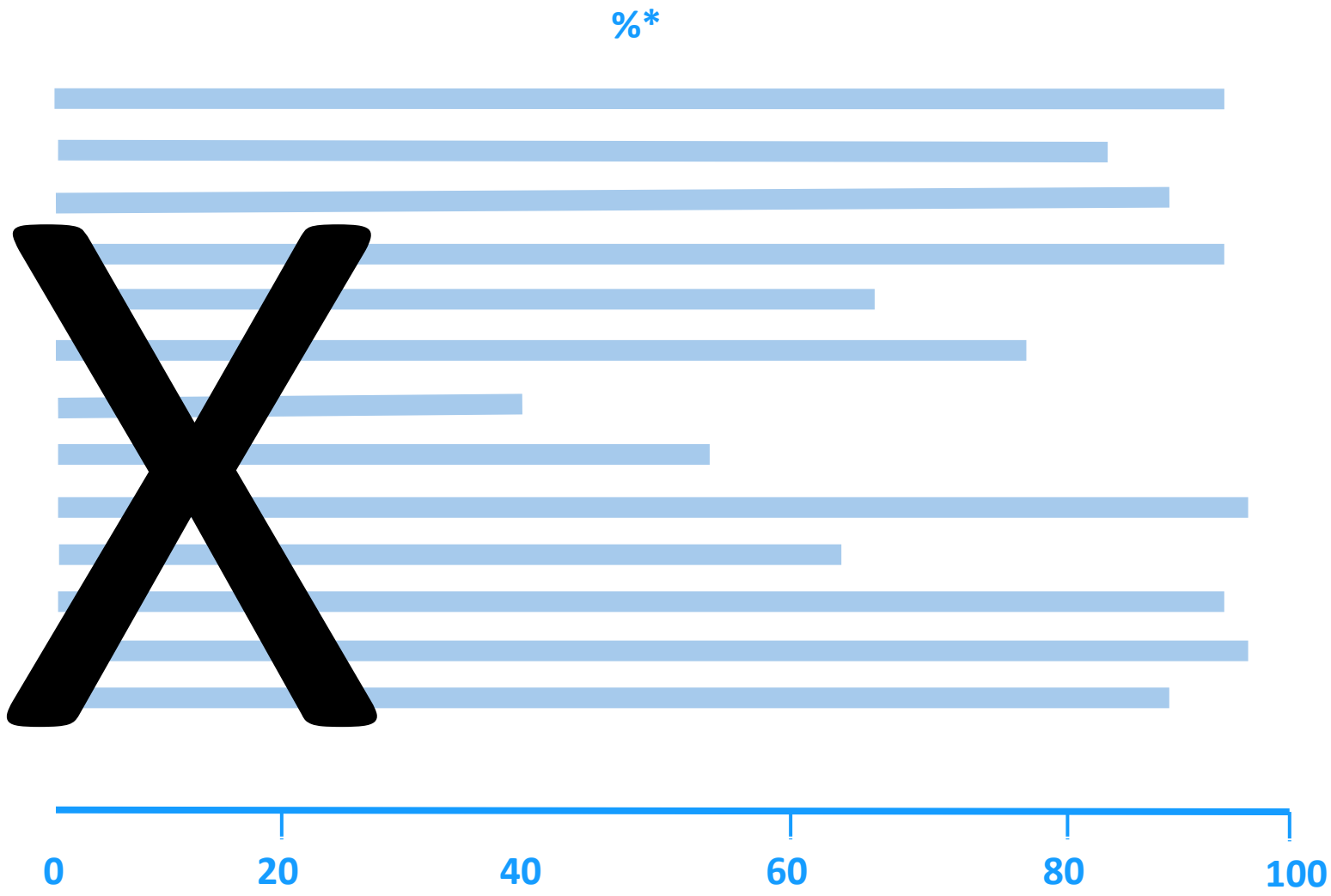
Backup

Scoring (Quality Index)

Proper Race
Treatment Emergent SUPPAE
EPOCH Presence
LB vs IS vs MB
Use of RELREC
SUPP Standardization
US Conventional Unit
TS FDA Parameters
TS Trial Start Date
ARM/ACTARM Requirement
QS ORRES/STRES
No imputation for LBSTRESN
Medical Dictionary e.g., MedDRA Prop-case



* Adjusted by IG, Trial Start date vs FDA Requirement