Governing the Ungovernable: Can a CRO Effectively Govern Its Standards?

Presented by Angelo Tinazzi, Senior Director, Statistical Programming, PBS, Cytel Inc.

Meet the Speaker

Angelo Tinazzi

Title: Senior Director, Statistical Programming

Organization: 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 a member of the CDISC European Coordinating Committee, where he leads the Italian-speaking User Network.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *I have no real or apparent conflicts of interest to report.*

- ***Spoiler: although there's no "magic" in my presentation, and no AI involved in my presentations, I will offer practical insights into the complexities of CRO data standard governance. Sponsors are also welcome to join to see what life looks like from the other side of the barricades!***

Agenda

1. The “Status Quo” of Data Governance in the Pharma Industry
2. What Truly Matters in CRO Data Governance?
3. The Cytel–PBS Approach to Data Governance
4. Conclusions

The Pharma Industry Data Governance “Status Quo”

PHUSE White Paper on Best Practice

Shared Sponsor / CROs Experience(s)

The Pharma Industry Data Governance "Status Quo"

What is Clinical Standards Data Governance?

A standard is a group of related assets such as forms, edit checks, datasets, mappings and terminologies. Using CDISC standards as a guide, ***you can design and refine organizational standards according to your company's internal governance process****. A* ***standards management team is required to create the standards and ensure compliance*** *with regulatory requirements.*

Standards management teams lead the development and management of standardized content*. They* ***work with key stakeholders*** *on data standards governance and support the technical* ***implementation*** *of standards and their* ***ongoing maintenance****.*

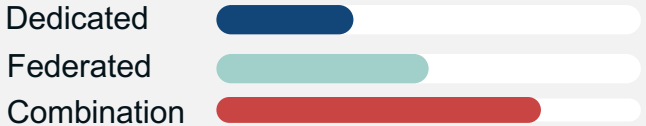
Ref: "The Complete Guide to CDISC Standards Management", Certara White Paper, 2024

The Pharma Industry Data Governance "Status Quo"

What is Clinical Standards Data Governance? Key Characteristics

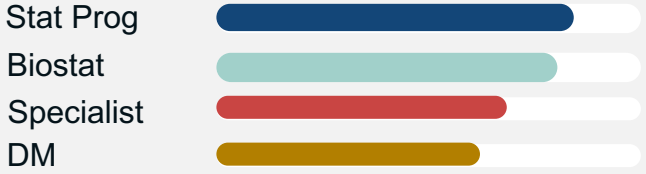
Organizational Structure

Employee working exclusively on data standards vs employee support standards



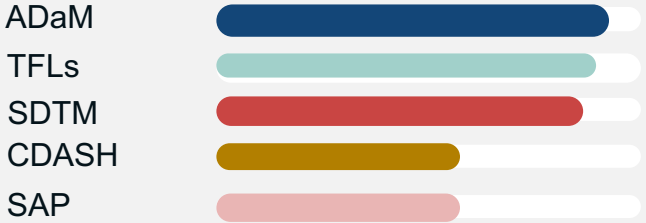
Composition

Diverse functional representation, different roles



What is Standardized?

Governed Standards

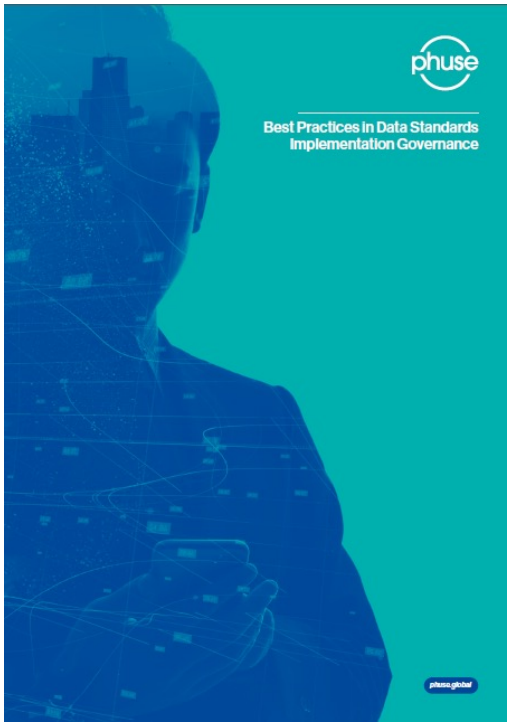


Key Items to set-up

- Scope
- Process
- Governance Model
- Technology (MDR?)
- "People" Engagement

The Pharma Industry Data Governance “Status Quo”

PHUSE White Paper on Best Practice in Data Standards Governance

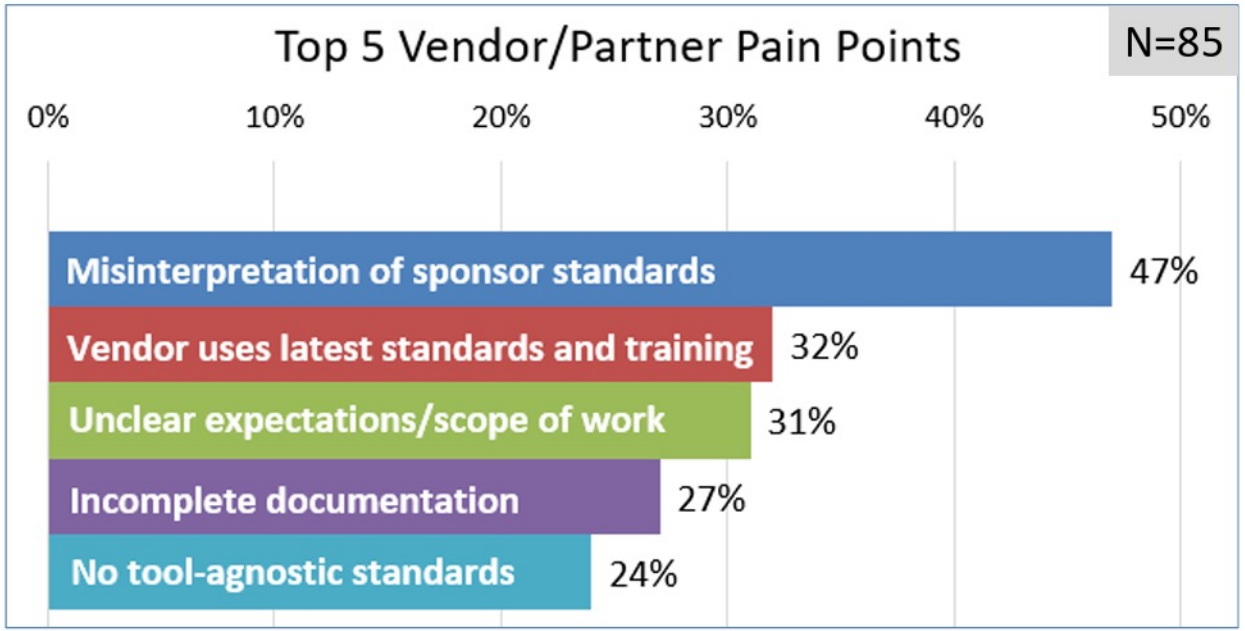


- How organizations are currently governing data standards? And how they are organized?
- Survey **14Feb2022-15Mar2022**
- Informal Discussion at **PHUSE CSS 2022 / 2023**
- Overview of Survey Results at PHUSE US 2023
- White Paper Published **Oct 2024**
- **48% centralized standards governance**
- **Significant variability in governance models**
- Sponsor **More Governance**
- CRO **More Automation**
- Lack of Resources
- **CRO-specific challenges: sponsor demands vs regulatory compliance**

The Pharma Industry Data Governance “Status Quo”

PHUSE White Paper on Best Practice in Data Standards Governance

Main “pain” points

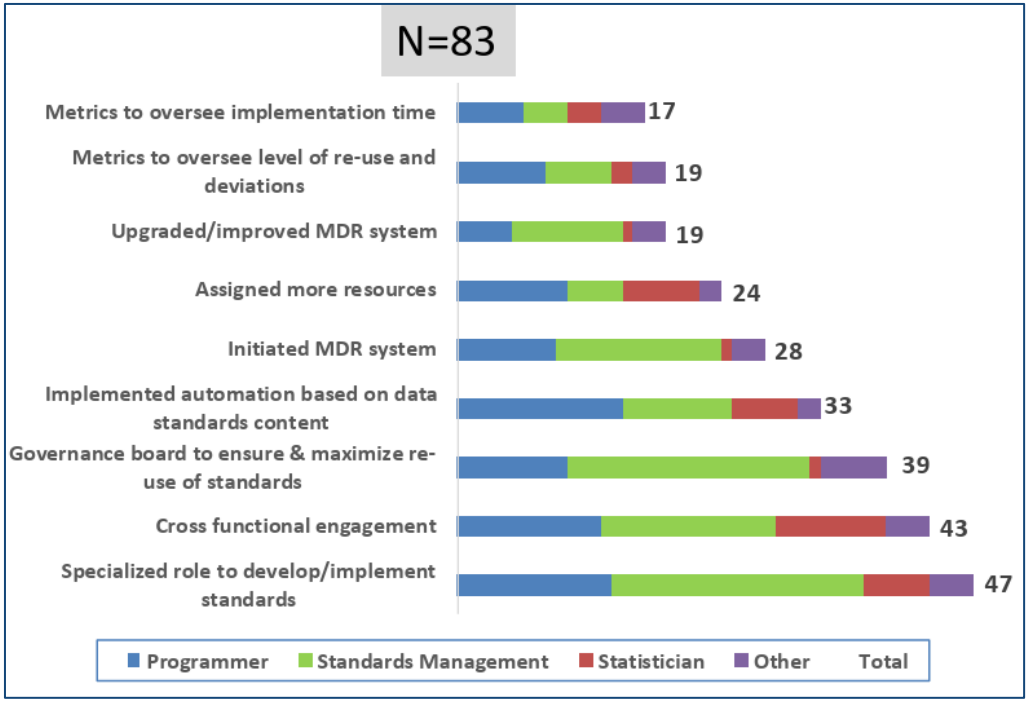


Ref: Data Standards Governance and Implementation Across Industry: Key Challenges and Benefits, G. Mahadevan and M. Baldwin – PHUSE US 2023

The Pharma Industry Data Governance "Status Quo"

PHUSE White Paper on Best Practice in Data Standards Governance

Actions That Improved Development / Implementation Time

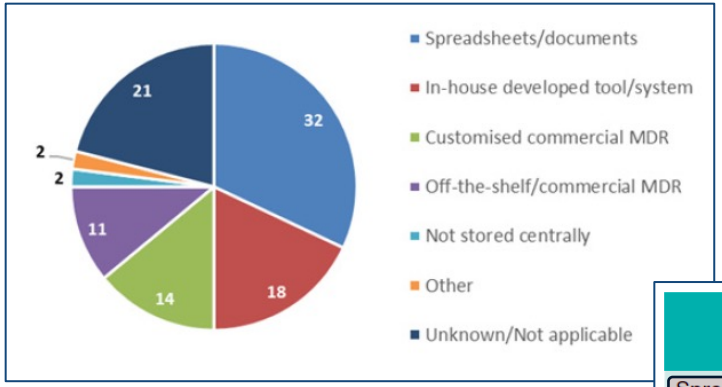


Ref: Data Standards Governance and Implementation Across Industry: Key Challenges and Benefits, G. Mahadevan and M. Baldwin – PHUSE US 2023

The Pharma Industry Data Governance "Status Quo"

PHUSE White Paper on Best Practice in Data Standards Governance

Standards Metadata Libraries/Repositories



Primary Standards Metadata Storage Method	N	
	CRO	Pharma/Biotech
Spreadsheets/documents	12	18
In-house developed tool/system	10	8
Customised commercial MDR	1	13
Off-the-shelf/commercial MDR	2	9
Other	2	0
Not stored centrally	0	2
Unknown/not applicable	16	2

Ref: PHUSE Data Standards White Paper (PHUSE White Paper 2024)

The Pharma Industry Data Governance “Status Quo”

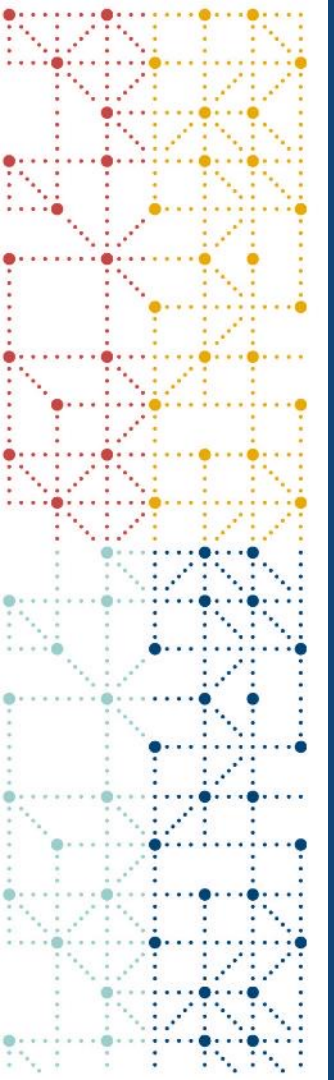
Shared Sponsor/CRO Experiences for Improving the Use of and Adherence to Standards

Sponsor 1 - Reference 6
- Big Pharma
- Dedicated end-to-end SMEs to projects

Sponsor 2 - Reference 4 / 5
- Growing Biotech
- The importance of setting expectations
- Different CRO mapping approaches

Sponsor 3 – Reference 4
- Big Pharma
- Centralized Governance “Body”
- Dedicated SMEs

Global CRO – Reference 8
- Use of MDR
- Governance Process, approval requests, etc.



What Truly Matters in CRO Data Governance

Current Challenges with Standards and Data Submissions

What Might Be Unique at a CRO Like Cytel?

What Truly Matters in CRO Data Governance

Current Challenges with Standards and Data Submissions

- **Continuously Evolving** Standards
- **Interpretation** Variability
- Versions Alignment for Future **Data Integration**
- Global **Harmonization**
  - Ongoing **Regulatory Refinement** e.g., FDA
  - Individual agency/division **Preferences**

What Truly Matters in CRO Data Governance

Current Challenges with Standards and Data Submissions

Ongoing Regulatory Refinement … and individual agency/division preferences

For clinical studies, 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 called LC structured identically to LB should

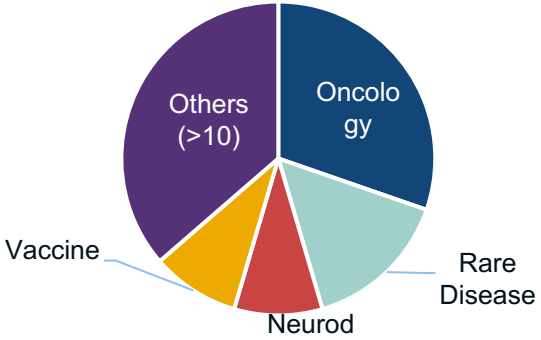
For subjects with multiple screenings and no subsequent enrollment, include the primary screening in DM with additional screenings in a custom domain with a structure similar to DM.

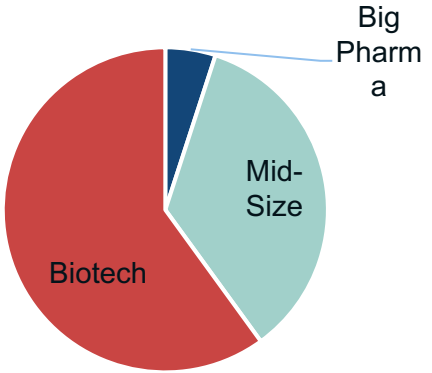
Only AEs that begin after xxxxx administration should be reported in AE, otherwise they should be reported in MH

What Truly Matters in CRO Data Governance

What Might Be Unique at a CRO Like Cytel? (Service Group Only)

- Sponsor-Specific Standards vs. **Lack of Direction**
- Multiple Standards **Versions**
- **Multiple Therapeutic Areas and Indications**
- Sponsor Size: Big Pharma vs. Mid-Size vs. Biotech
- **Partial** vs Full “Portfolio” Involvement
- Decisions need to be made quickly
- Greater Exposure to Innovative Trial Designs?
- **MDR too cumbersome**?
- **Sponsor Audit-Findings**





What Truly Matters in CRO Data Governance

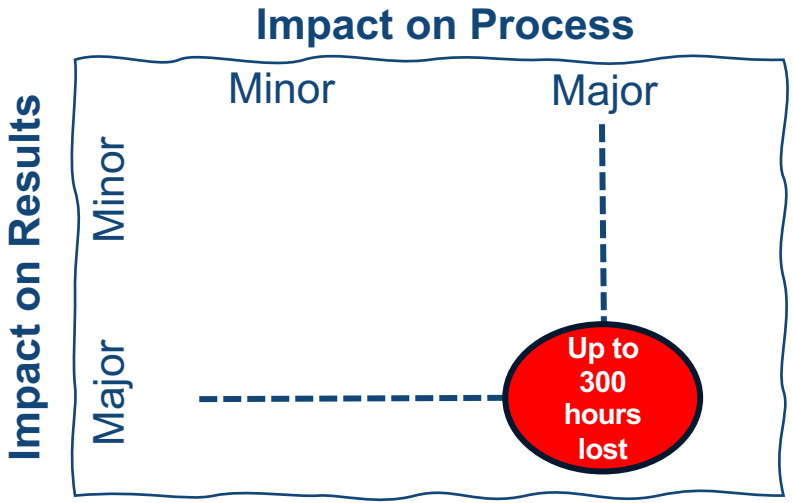
What Might Be Unique at a CRO Like Cytel?

Preventive Action

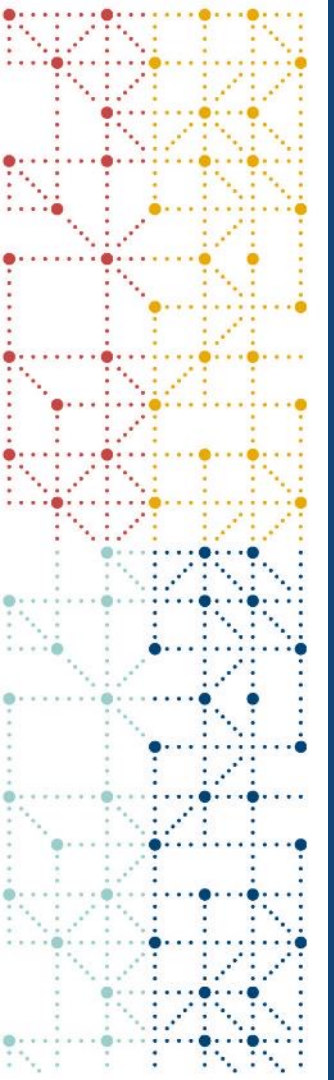
CAPA

Corrective Action

The “Cost” of a CAPA



- CAPA Handling
- Discussion
- Corrections / re-run
- Change in Process
- Re-training of the team (>100)



The Cytel–PBS Approach to Data Governance

Our Data Governance Journey

Automation / Cytemation Approach

Anything “Magic”?

The Cytel–PBS Approach to Data Governance

Our Data Governance Journey

2015 - 2019

cySDTM IG 3.2

(9 revisions 2019-2022)

cyADaM Ig 1.x

(7 revisions)

MDR-like Tool for issues Management + SDTM Team

2020 / 2021

Cytemation Effort

cySDTM IG 3.3

(9 revisions 2021-2025)

cyCDISC Guidance v1.0*

cyCDASH-like Library

(12 domains / 23 forms)

"Failed" MDR Vendor Selection

2022

Internal Checker

Internal regular-QA

2023

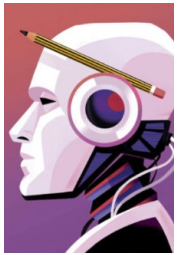
From excel to Ticketing System

2024

cySDTM IG 3.4

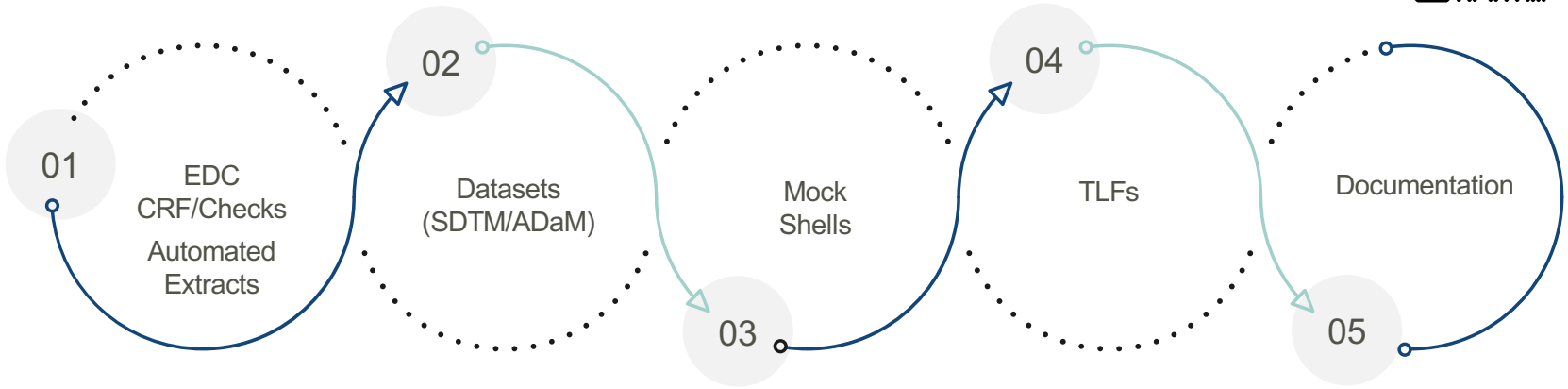
(2 revisions)

Formal Data Governance



The Cytel–PBS Approach to Data Governance

Automation / Cytemation Approach



DM tools	ALPS	Lighthouse	PRISM-TAB Macros	CytelDocs
Creation of standard library CRFs/checks to streamline EDC design and set up Automation of manual repeating tasks for data extract.	Generate SDTM and ADaM mapping code using the standard Cytel Metadata file.	Automate the creation of TLF shells faster and with consistent layout.	Streamlines the TLFs process by capturing metadata embedded in TLFs shells created using Lighthouse.	Library of Standard documents with metadata.

The Cytel–PBS Approach to Data Governance Anything "Magic"? Not really….

Lightweight yet **structured governance** model (no bureaucracy)

Established **simple but stable standards**

Flexible alignment with **sponsor expectations**

Foster a **win–win** partnership between sponsor and CRO

Cross-functional collaboration, DM, BS and PROG

Increased Number of **SMEs**

Targeted SMEs support involvement

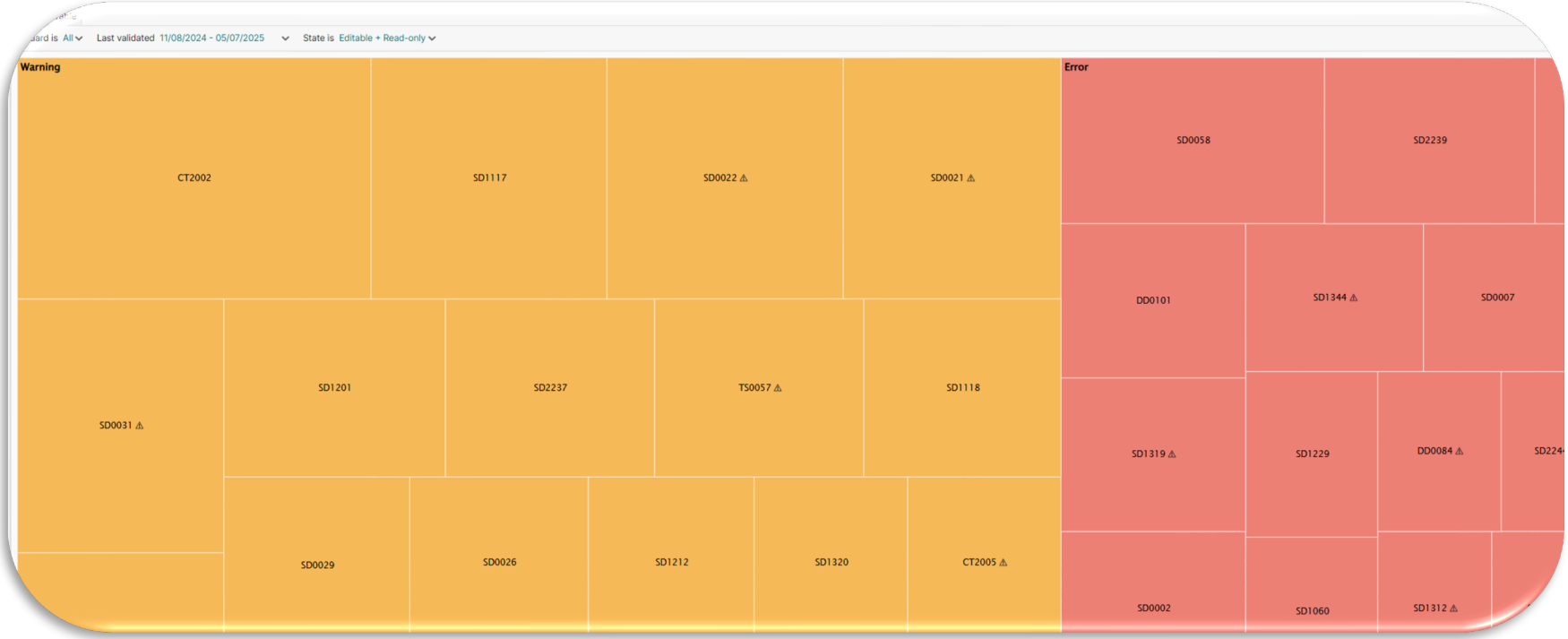
- **Support at "start"** e.g., SDTM key mapping decision review
- **Support at the "end"** e.g., full SME CDISC package review for critical projects at final dry-run
- Dedicated **HelpDesk**

The Cytel–PBS Approach to Data Governance Anything “Magic”? Not really….

- Internal “Tools” for **Gap-analysis**
- Checklists prior to final package production
- **Regular review** common issues and requests (tool-driven approach)
- Provide ongoing **re-training**
- **Enhances Sponsor Understanding** of Standards
- **Regular assessment of the impact of new regulatory guidelines, standards, and requirements**

The Cytel–PBS Approach to Data Governance

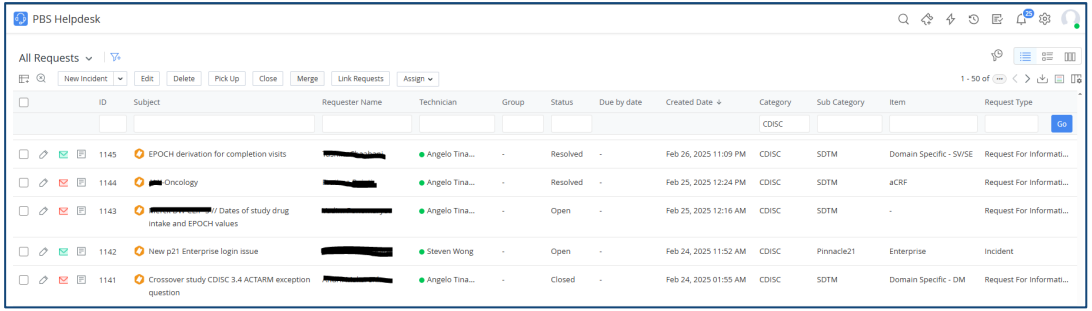
Anything “Magic”? Not exactly... Support Commercial Off-the-Shelfs Tools – Insights into Top conformance Issues

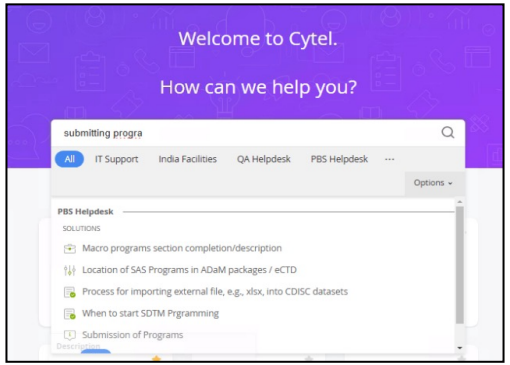


The Cytel–PBS Approach to Data Governance

Anything "Magic"? Not really….Ticketing System (HelpDesk)

Ticketing system inspired by IT support models



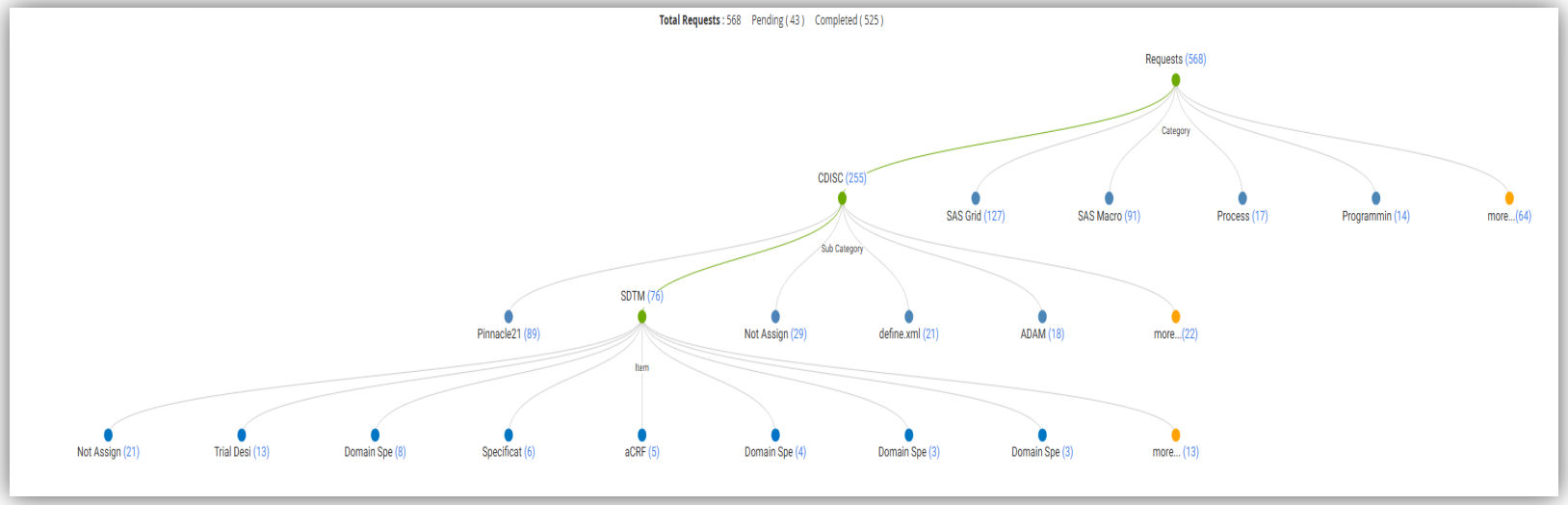


Centralized knowledge sharing and documentation

Dashboards for tracking issues and trends

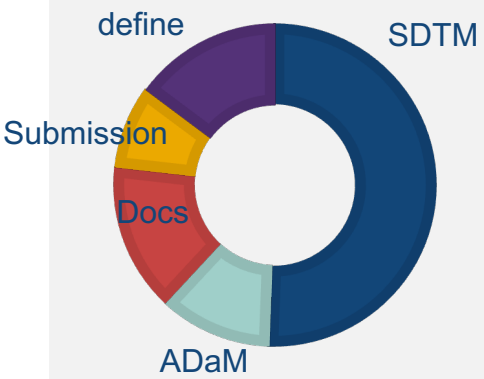
The Cytel–PBS Approach to Data Governance

Anything “Magic”? Not really….Ticketing System (HelpDesk)



The Cytel–PBS Approach to Data Governance

Anything “Magic”? Not really….Ticketing System (HelpDesk)– Regular Insight into Requests



Focus on SDTM

Top Ranked SDTM Requests

18%	10%	5%	3%	3%
Trial Design	LB	SV/SE	DM	DS

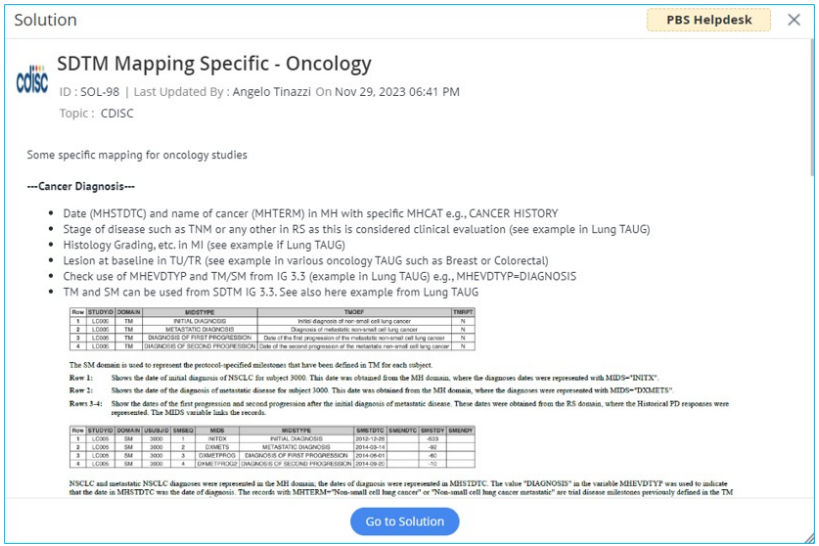
re-screening / multiple participation

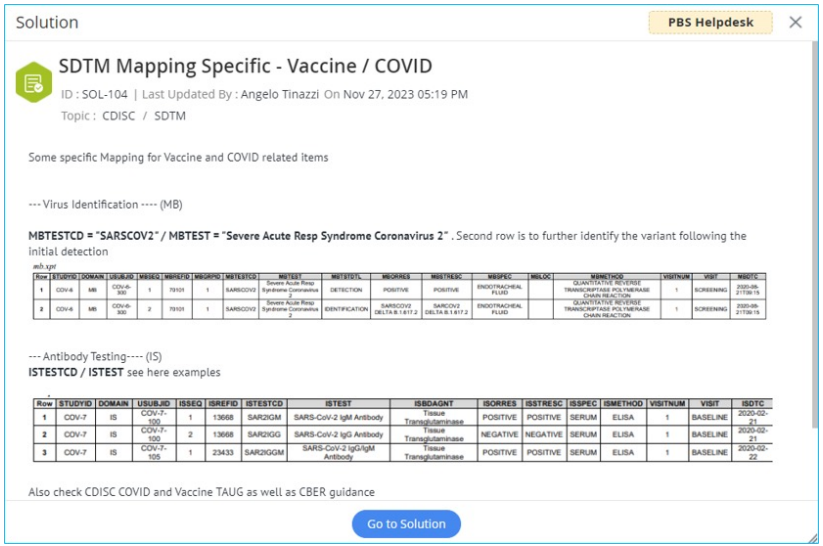
Scope of “Laboratory Data” Domains e.g., LB vs IS vs MB

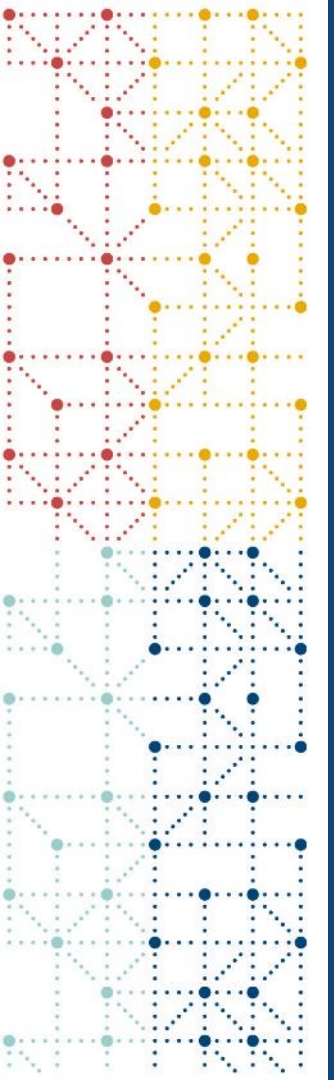
TA/Indications mapping e.g., oncology disease characteristics

The Cytel–PBS Approach to Data Governance

Anything “Magic”? Not really….Ticketing System (HelpDesk) – Regular Insight into Requests







Conclusions

Conclusions

Anything Special in the end?

Flexibility

SME+SME+SME … “Develop” SME

Learn (and Share) from requests …. and mistakes

Track Requests (Ticketing System) and Share Solutions

AI Soon to come….

Thank You!

Angelo Tinazzi

Sernior Director, Statistical Programming

Cytel Inc., Geneva (CH)

angelo.tinazzi@cytel.com

References

1	“PHUSE Data Standards White Paper“ (PHUSE White Paper 2024) https:/phuse.s3.eu-central-1.amazonaws.com/Deliverables/Special+Projects/WP086.pdf
2	“PHUSE Best Practices in Data Standards Implementation Governance” (PHUSE White Paper 2024) https://phuse.s3.eu-central-1.amazonaws.com/Deliverables/Optimizing+the+Use+of+Data+Standards/WP-89.pdf
3	“Clinical study oversight: different approaches to using data standards” (PHUSE EU 2017) https://www.lexjansen.com/phuse/2017/ds/DS09.pdf
4	“Developing, Implementing and Governing End-to-End Standards at Gilead” (PHUSE US 2019) https://www.lexjansen.com/phuse-us/2019/ds/DS01.pdf
5	“Standardisation in a fast growing environment; MDR, EDC and other abbreviations” (PHUSE EU 2024) https://www.lexjansen.com/phuse/2023/ds/PAP_DS04.pdf
6	“Enhancing the standard utilization by creating a new pivotal role: The Standard Implementation Lead” (PHUSE EU 2024) https://phuse.s3.eu-central-1.amazonaws.com/Archive/2024/Connect/EU/Strasbourg/PAP_DS07.pdf
7	“Standards Subject to Change Data Standards Flexibility in an Evolving Landscape” (PharmSUG 2017) https://pharmasug.org/proceedings/2017/DS/PharmaSUG-2017-DS06.pdf
8	“Standards Governance Strengthened by MDR Technology” (PHUSE US Connect 2022) https://www.lexjansen.com/phuse-us/2022/ds/PRE_DS08.pdf
9	“Data Standards Governance and Implementation Across Industry: Key Challenges and Benefits” (PHUSE WG) https://phuse.s3.eu-central-1.amazonaws.com/Archive/2023/Connect/US/Florida/PRE_DS02.pdf

Abstract

A recent **PHUSE White Paper**, reporting the outcome of an Industry survey, highlighted **significant variability in data governance structures among sponsors and CROs**, as well as challenges in governing the implementation of standards. These and other challenges are particularly pronounced in CROs, where governance must **balance regulatory compliance with sponsor and study-specific requirements, and preferences**.

At Cytel, we implemented a light yet effective governance structure supported by **cross-functional teams**. A **ticketing system**, inspired by IT support frameworks, enables efficient issue resolution, continuous improvement, and knowledge sharing. Subject Matter Experts provide specialized support, while dashboards track ticket trends, identifying recurring issues and misconceptions. **This enables proactive updates to processes, internal guidance, templates, and standards**.

This presentation will offer practical insights into the **complexities of CRO data governance**, showcasing how a structured yet flexible approach—backed by efficient tools and collaboration—streamlines operations, enhances quality, and ensures compliance with industry standards.