TMF Reference Model General Meeting

Mary Emanoil, Head TMF & Registry Operations, Pfizer, TMF RM SC Member
Scott Feiner, Senior Manager, Trial Disclosure, AbbVie
Karen Roy, Chief Strategy Officer, Phlexglobal; Chair, TMF Reference Model Steering Committee
Jamie Toth, Global Head, TMF Management & Records, Beigene, TM RM SC Member
Alison Varjavandi, Director, TMF Management Office, Astellas, TM RM SC Member

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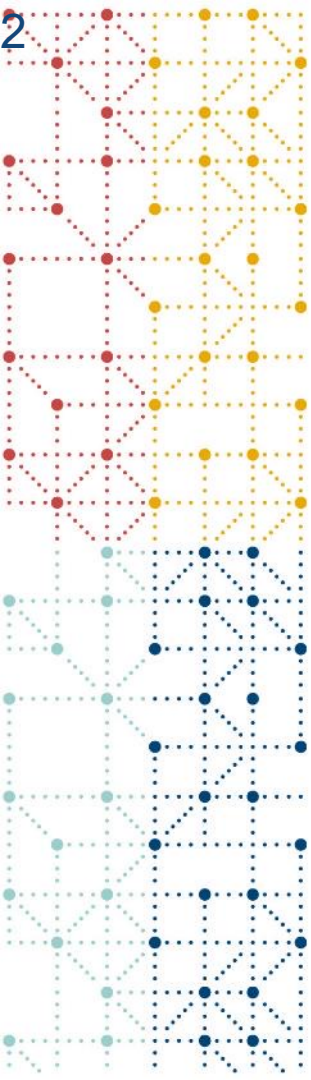
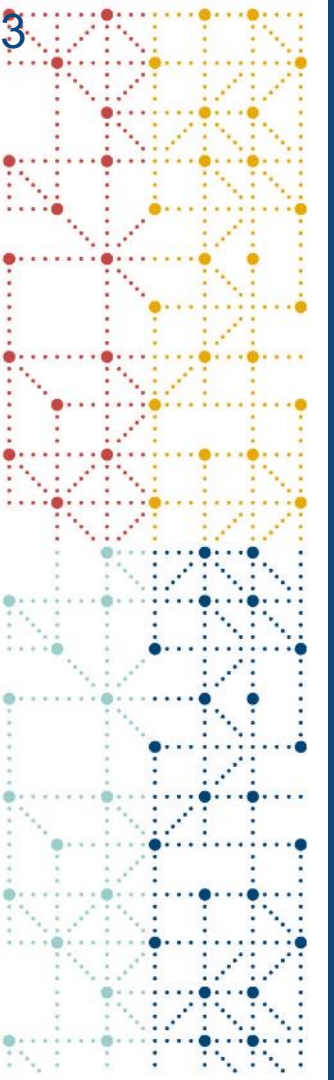
Thursday, 13 October
11:00AM – 12:30PM US ET



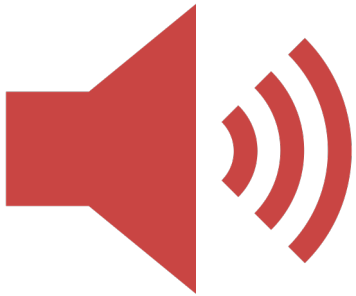
Today’s Agenda

1. Housekeeping
2. Feature Presentation
3. Upcoming Learning Opportunities & Events



Housekeeping

Housekeeping

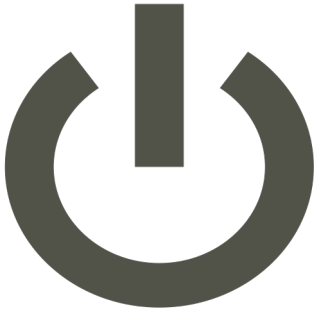


You will remain on **mute**

Housekeeping

Submit questions at any time via the Questions tool on your Zoom app

Housekeeping



Audio Issues?

First, close and restart your Zoom App
Second, check your local internet connection strength

Housekeeping

A recording of this webinar and the slides will be available in the **Public Webinar Archive.** Check under the “Events” tab on the CDISC homepage.

Our Presenters

Mary Emanoil Head TMF & Registry Operations Pfizer TMF RM SC Member	**Scott Feiner** Senior Manager, Trial Disclosure AbbVie
Karen Roy Chief Strategy Officer Phlexglobal Chair, TMF Reference Model Steering Committee	**Jamie Toth** Global Head, TMF Management & Records Beigene TM RM SC Member
Alison Varjavandi Director, TMF Management Office Astellas TM RM SC Member	

The TMF Reference Model
General Meeting 13-Oct-2022

Presenters:

- Mary Emanoil, Head TMF & Registry Operations, Pfizer, TMF RM SC Member
- Karen Roy, Chief Strategy Officer, Phlexglobal; Chair, TMF Reference Model Steering Committee
- Jamie Toth, Global Head, TMF Management & Records, Beigene, TM RM SC Member
- Alison Varjavandi, Director, TMF Management Office, Astellas,TM RM SC Member
- Scott Feiner, Senior Manager, Trial Disclosure, AbbVie

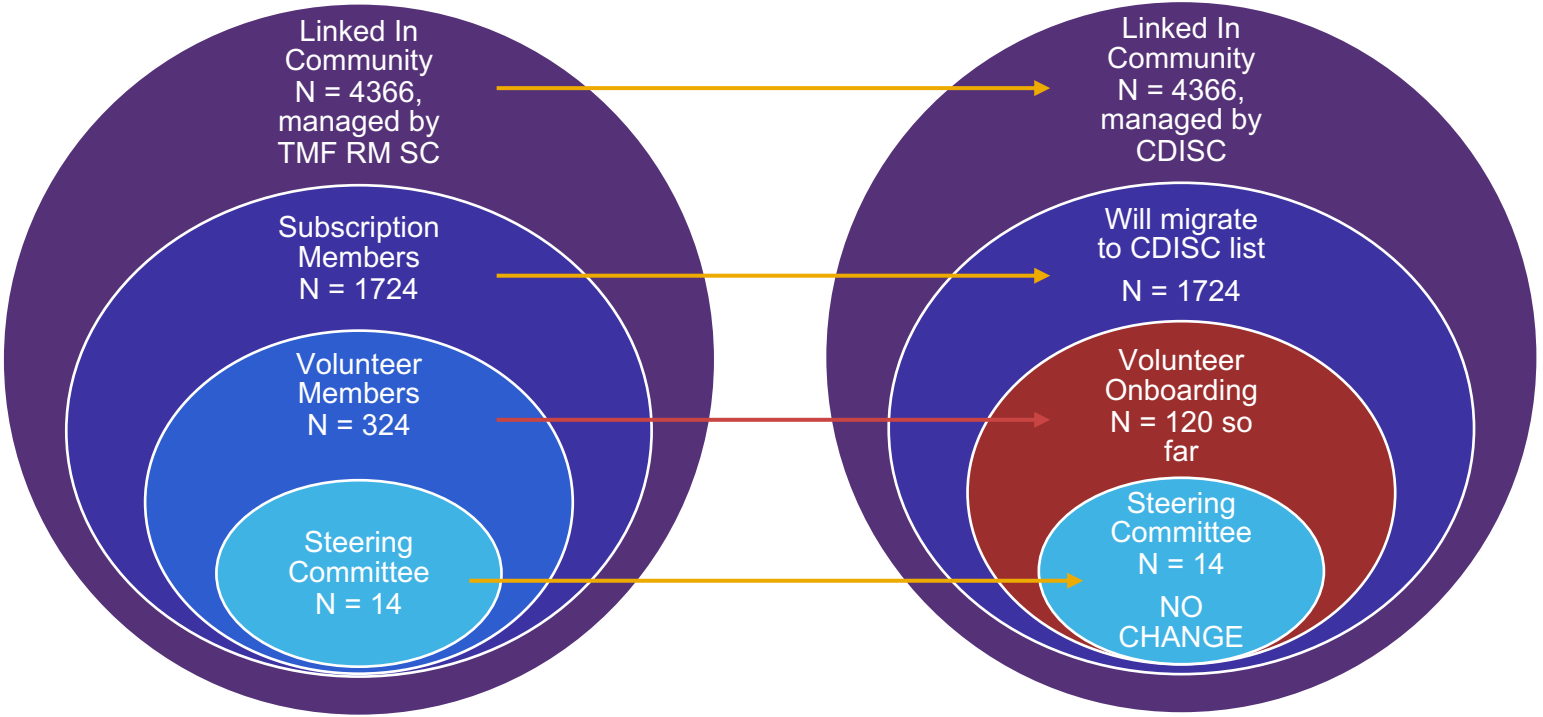
Introductions

Agenda

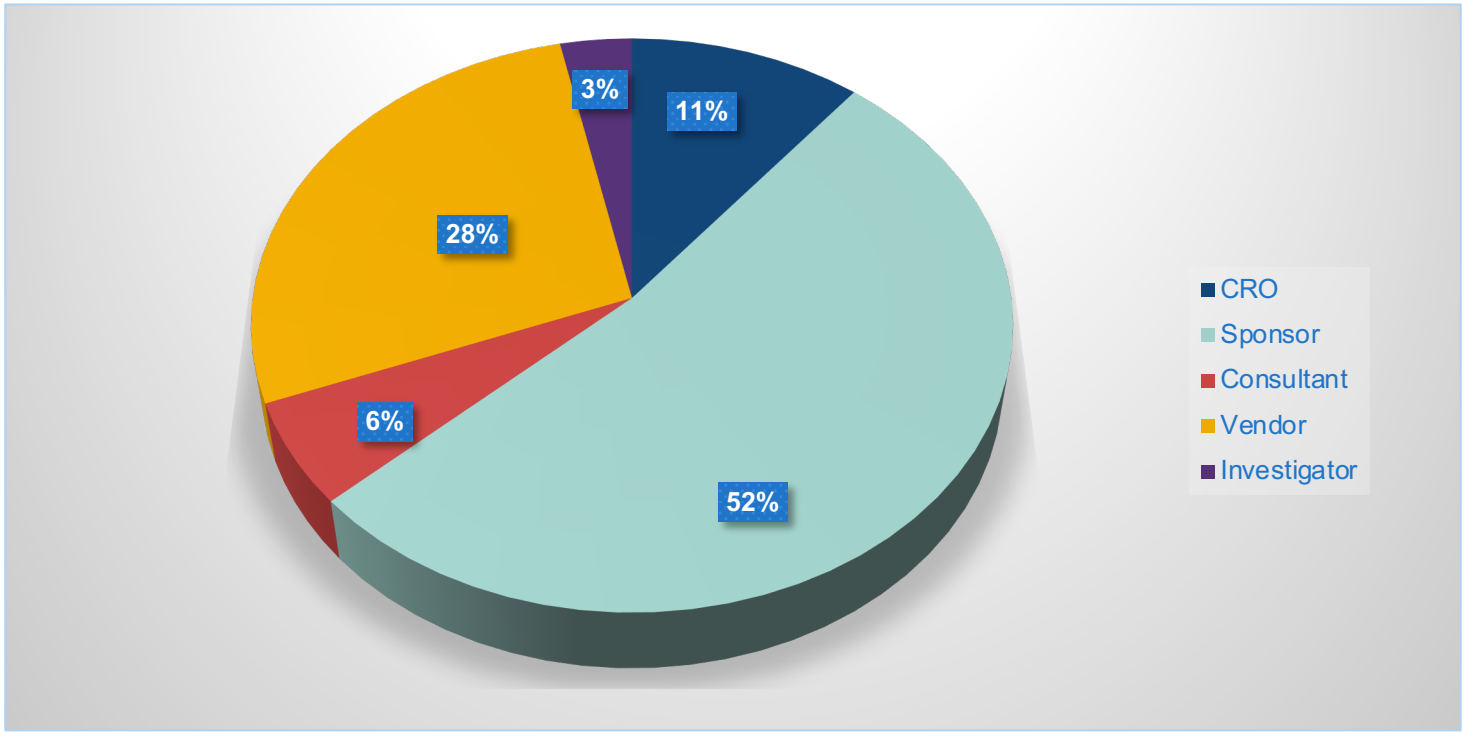
- Intros/Agenda – Mary Emanoil
- Membership Update – Karen Roy
- TMF Management Plan Template Update – Jamie Toth
- 2022 TMF RM Survey Report Out – Allison Varjavandi
- Special Topic: CTIS Update– Scott Feiner, Abbvie
- Upcoming Events: CDISC Interchange, EU TMF Summit – Mary Emanoil

Membership Update

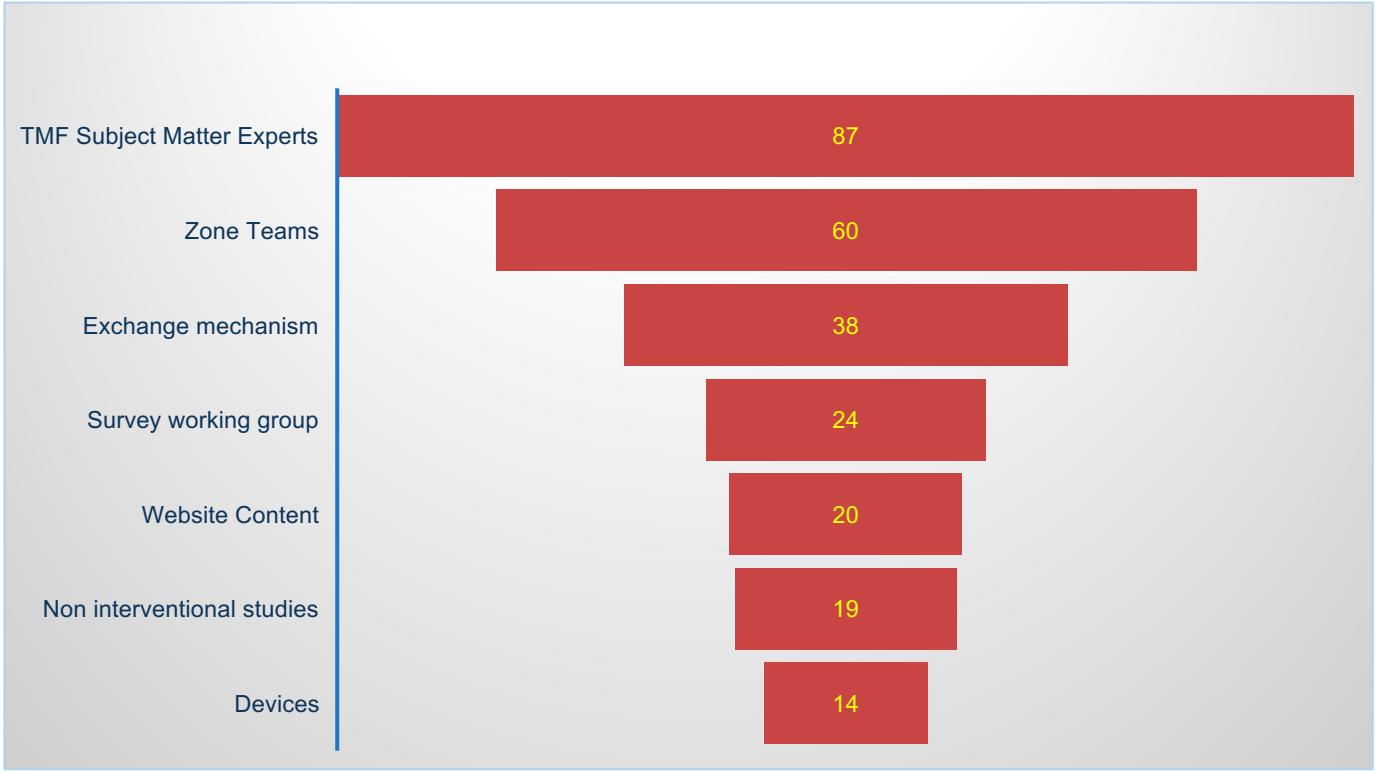
The TMF RM Community move to CDISC



Volunteer Demographics



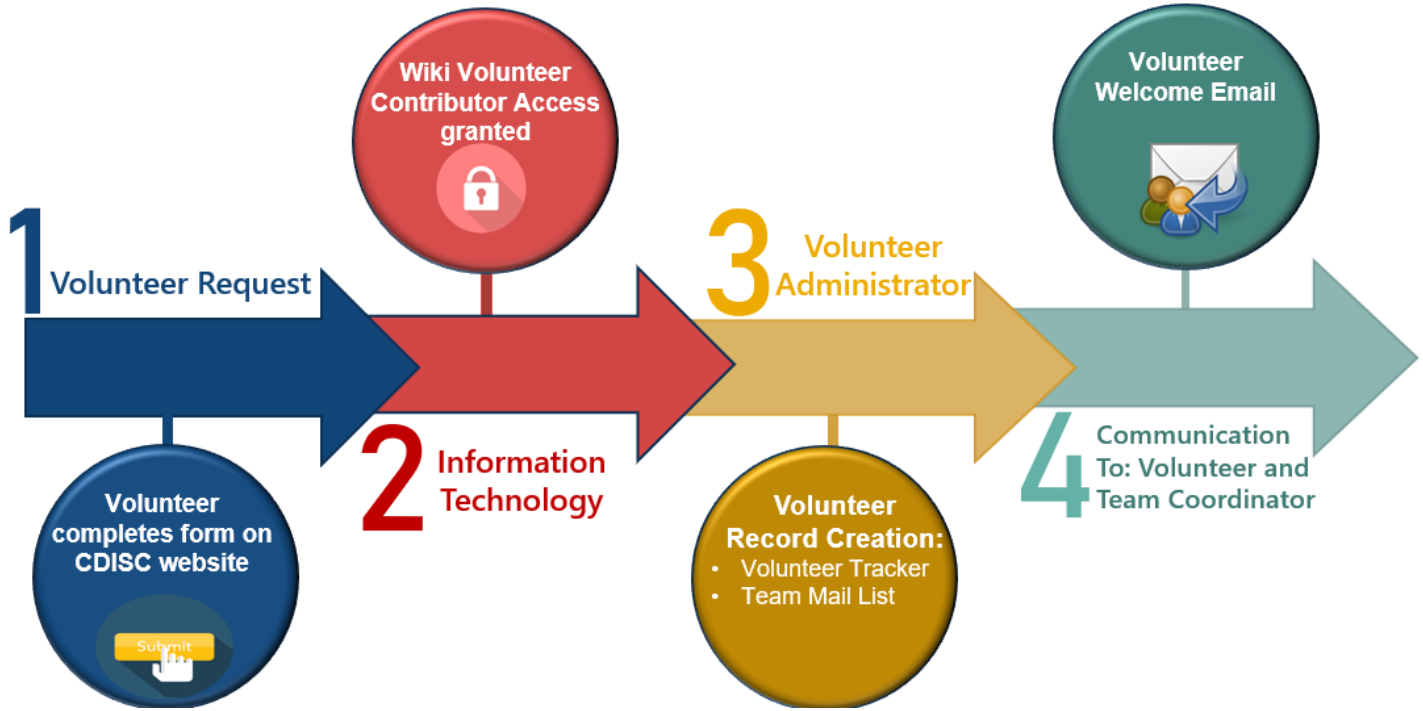
Special Interests of Volunteers



Registering as a Volunteer

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

Volunteer Onboarding



TMF Management Plan Template

Presenter:

Jamie Toth, Sr. Director TMF Management & Records at BeiGene; Member, TMF Reference Model Steering Committee

Agenda

1. Members & Charter
2. Summary of Revisions
3. Status to Go-Live

Members & Charter

Members

Name	Company
Jamie Toth - Workstream Lead	BeiGene
Marion Mays - Workstream CoLead, Subteam 2 Lead	JustIn Time
Gil Gittens	Transperfect
Mabel Ebot	Molecular Partners
Deb Oriez	Sarepta
Twanna Davis	FHI Clinical
Corunna Culver-Windham - Subteam 1 Lead	Relay Therapeutics
Debra Wells	Novartis
Donna Dorozinsky	JustInTime
Dawn Niccum - Subteam 3 Lead	Inseption Group
Allison Grosik	Arcus Bio

Charter

Brief description of project & objectives:	Objective: Review the template published in 2018 and incorporate changes due to regulations, technology, pandemic needs. Template must still be: a *cross-industry usable, simplistic TMF Management Plan template. Guidance provided on how to deal with variations depending on study size, phase, type.*
Scope - In:	Template to be used for all clinical research study/trial types.
Scope - Out:	Development of an SOP. Processes already created within a given company around the TMF.
Desired deliverables:	•An updated, simplistic Plan template that can be used within any company, where company specifics can be added. •Guidance on Plan usage and any variations and how to adapt Plan.
Target end date:	15-Dec-2022
Status:	•First meeting held 03-Mar-2022; 3 mini teams formed to work on Subteam 1 – Sections 0-4, Subteam 2 – Section 5 – 8, Subteam 3 – Sections 9-12. Teams had 3 months to work on suggested updates. •Biweekly meetings scheduled March to Oct 2022. •Beginning in July 2022, brought the 3 drafts together to finalize master draft. •25-Aug provided to TMF Ref Model SC for comment. •As of 10-Oct, SC had ~46 comments and we have 11 left to review/reconcile.

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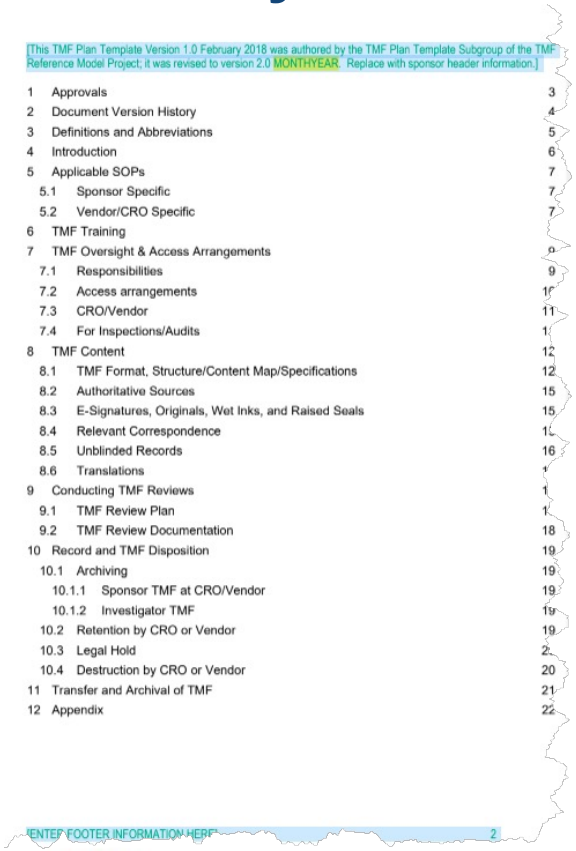
Summary of Revisions

Summary of Revisions – High Level

- Updated instructions, added additional instructions throughout.
- Re-arranged the order of the sections, i.e. Transfer/archive is section 11 now.
- Added in tables for SOPs, training, vendor responsibilities.
- Created activities table, removed RACI.
- Created subsections for TMF Review documentation, Archiving at Sponsor or CRO/Vendor and Retention and Destruction.
- Created table for Legal Holds section.
- Added Transfer Agreement language into section 11.

Summary of Revisions



[This TMF Plan Template Version 1.0 February 2018 was authored by the TMF Plan Template Subgroup of the TMF Reference Model Project; it was revised to version 2.0 MONTHYEAR. Replace with sponsor header information.]

1 Approvals 3
2 Document Version History 4
3 Definitions and Abbreviations 5
4 Introduction 6
5 Applicable SOPs 7
5.1 Sponsor Specific 7
5.2 Vendor/CRO Specific 7
6 TMF Training
7 TMF Oversight & Access Arrangements
7.1 Responsibilities 9
7.2 Access arrangements 1
7.3 CRO/Vendor 11
7.4 For Inspections/Audits 1
8 TMF Content 12
8.1 TMF Format, Structure/Content Map/Specifications 12
8.2 Authoritative Sources 15
8.3 E-Signatures, Originals, Wet Inks, and Raised Seals 15
8.4 Relevant Correspondence 1
8.5 Unblinded Records 16
8.6 Translations 1
9 Conducting TMF Reviews 1
9.1 TMF Review Plan 1
9.2 TMF Review Documentation 18
10 Record and TMF Disposition 19
10.1 Archiving 19
10.1.1 Sponsor TMF at CRO/Vendor 19
10.1.2 Investigator TMF 19
10.2 Retention by CRO or Vendor 19
10.3 Legal Hold 2
10.4 Destruction by CRO or Vendor 20
11 Transfer and Archival of TMF 21
12 Appendix 22

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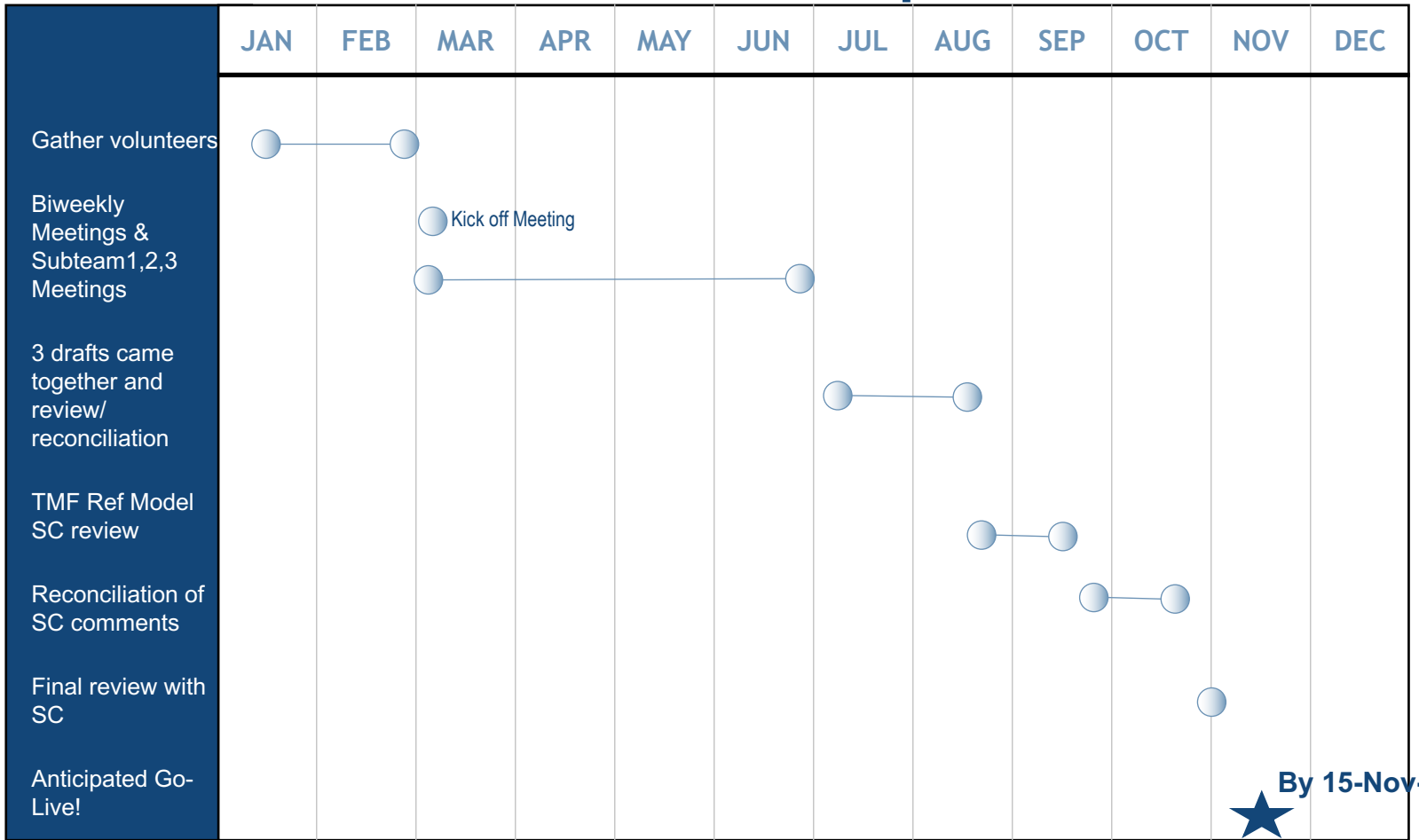
Section #	Section Topic	Page #	Revisions Made
0	Instructions	1	Updated Instructions for intention and the font written in
0	Table of Contents	2	Re-arranged the order for better flow
1	Approvals	3	No major changes
2	Document Version History	4	No major changes
3	Definitions and Abbreviations	5	Added additional instructional text
4	Introduction	6	Reworded section, ensure boxes were clickable
5	Applicable SOPs	7	Added tables for both Sponsor and CRO SOPs
5.1	Sponsor Specific	7	
5.2	Vendor/CRO Specific	7	
6	TMF Training	8	Reworded section, added table for type of training by Role
7	TMF Oversight & Access Arrangements	9	
7.1	Responsibilities	9	Removed the RACI, added an Activity table to state who is doing what at Sponsor or CRO (or other vendor)
7.2	Access arrangements	10	No major changes
7.3	CRO/Vendor	11	No major changes
7.4	For Inspections/Audits	11	No major changes
8	TMF Content	12	
8.1	TMF Format, Structure/Content Map/Specifications	12	Minor wording changes and major change by adding in table by vendor type
8.2	Authoritative Sources	15	Minor wording changes.
8.3	E-Signatures, Originals, Wet Inks, and Raised Seals	15	Minor wording changes
8.4	Relevant Correspondence	15	No major changes
8.5	Unblinded Records	16	No major changes
8.6	Translations	16	Wording changes
9	Conducting TMF Reviews	17	Wording changes
9.1	TMF Review Plan	17	Added wording into instructional text and updated table
9.2	TMF Review Documentation	18	Section added
10	Record and TMF Disposition	19	Updated Instructions
10.1	Archiving	19	No major changes
10.1.1	Sponsor TMF at CRO/Vendor	19	Sub section added, although text was there in past
10.1.2	Investigator TMF	19	Sub section added, although text was there in past
10.2	Retention by CRO or Vendor	19	Sub section added
10.3	Legal Hold	20	Table added to make clearer
10.4	Destruction by CRO or Vendor	20	Sub section added
11	Transfer and Archival of TMF	21	Added TMF Transfer Agreeement info into instructional text; added column to table for type of Documentation
12	Appendix	22	Minor wording

Status to Go-Live

Status to Go-Live – Jan 2022 to present



Next Steps

Next Steps

- ✓ Version 1.0 to Version 2.0 comparison document.
- ✓ Listing of Revisions Made.
- ✓ Creation of feedback form for SC for ease of reconciliation and uploading into CDISC WIKI in future.
- Finish Reconciliation of all SC feedback (11 comments to go!) on 14-Oct.
- Review final reconciled version with SC on 19-Oct or 02-Nov.
- Share to industry via upcoming conferences (EU TMF Summit) and social media!

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Thank You!

Questions?

Jamie.Toth@beigene.com use subject *CDISC TMF Plan Template*

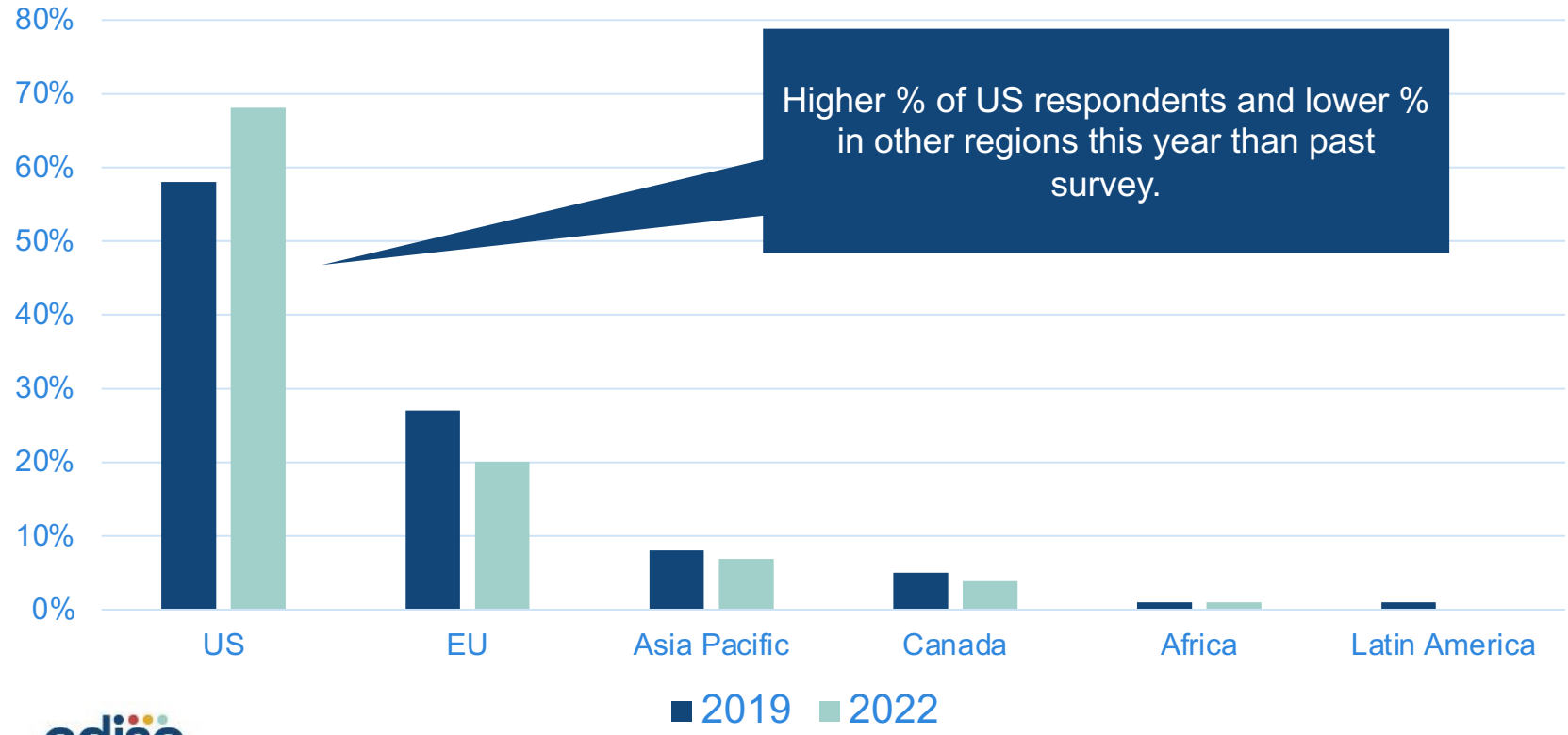
TMF Survey Report Out

Allison Varjavandi

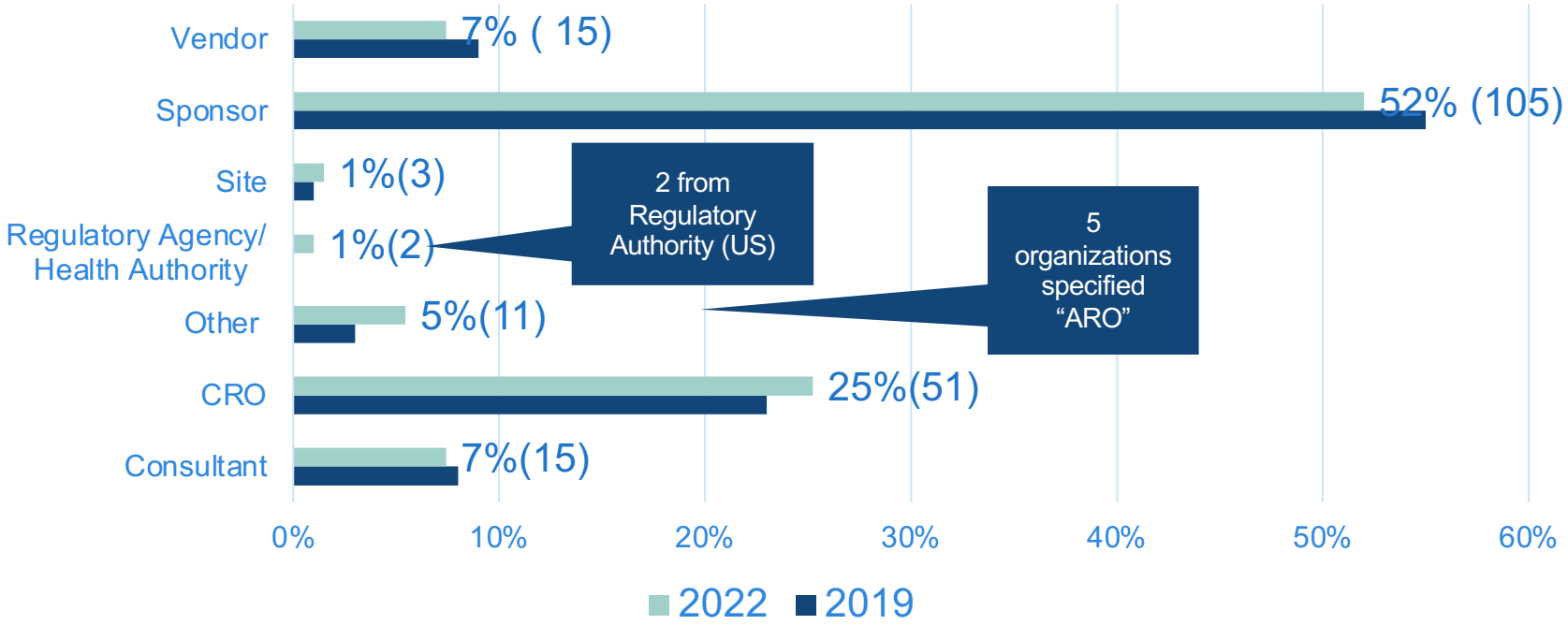
TMF Reference Model Survey

- Thank you to everyone who contributed to the Survey conducted June 2022!
- Many of the comments collected through the survey will be communicated to the Steering Committee and Change Control Board to determine where there is opportunity for enhancement to tools, model etc.
- Today, we will share some interesting takeaways we learned from the survey results.

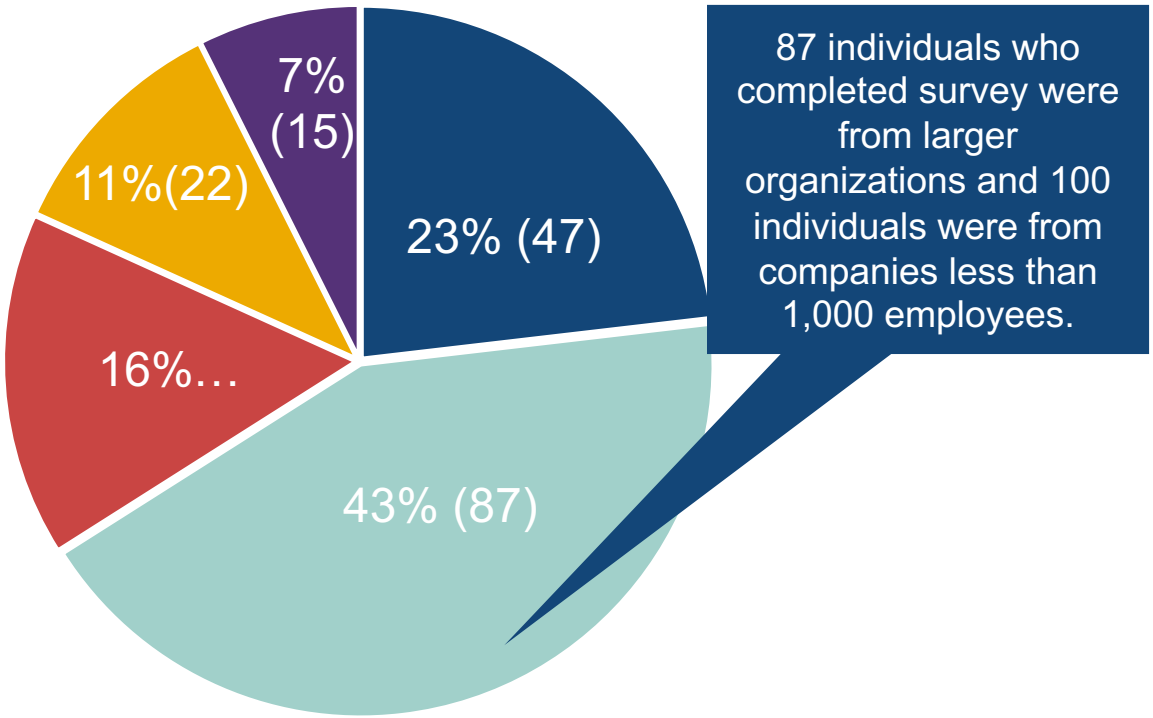
Location of the 206 Survey Respondents



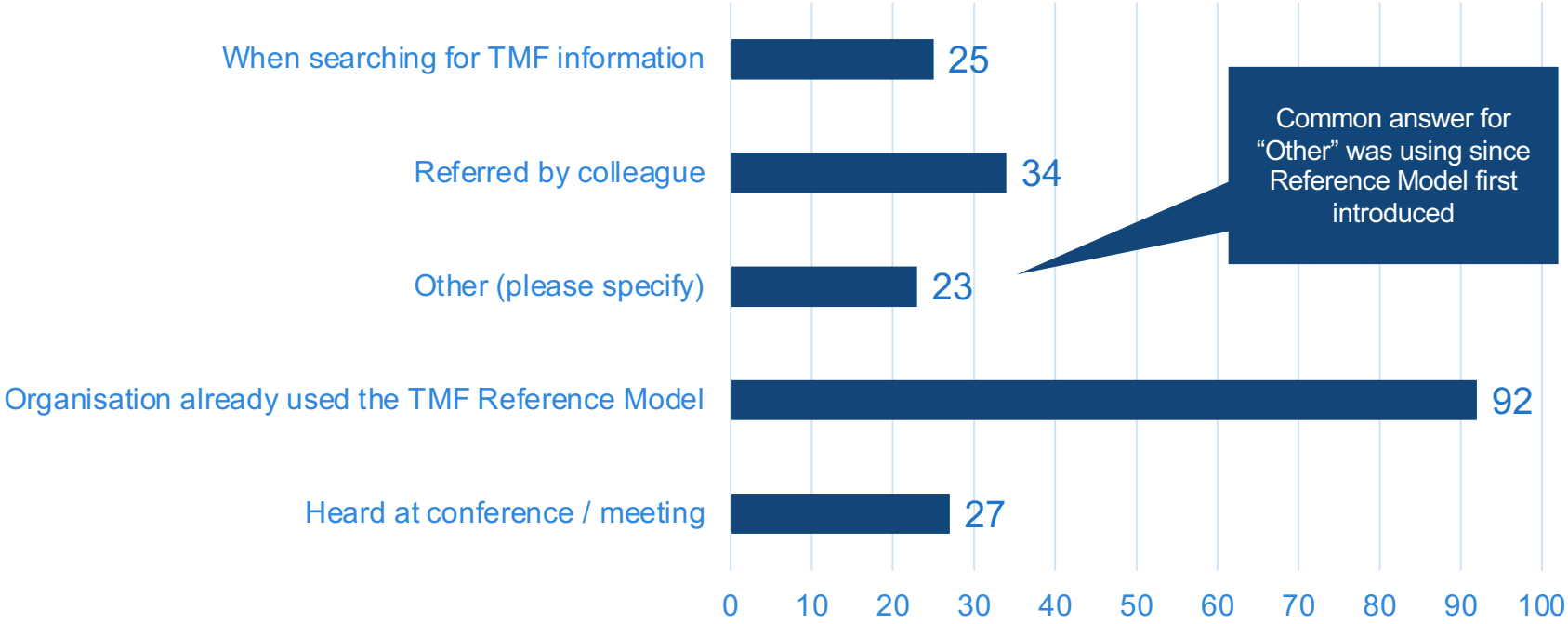
Organization Breakdown of Respondents



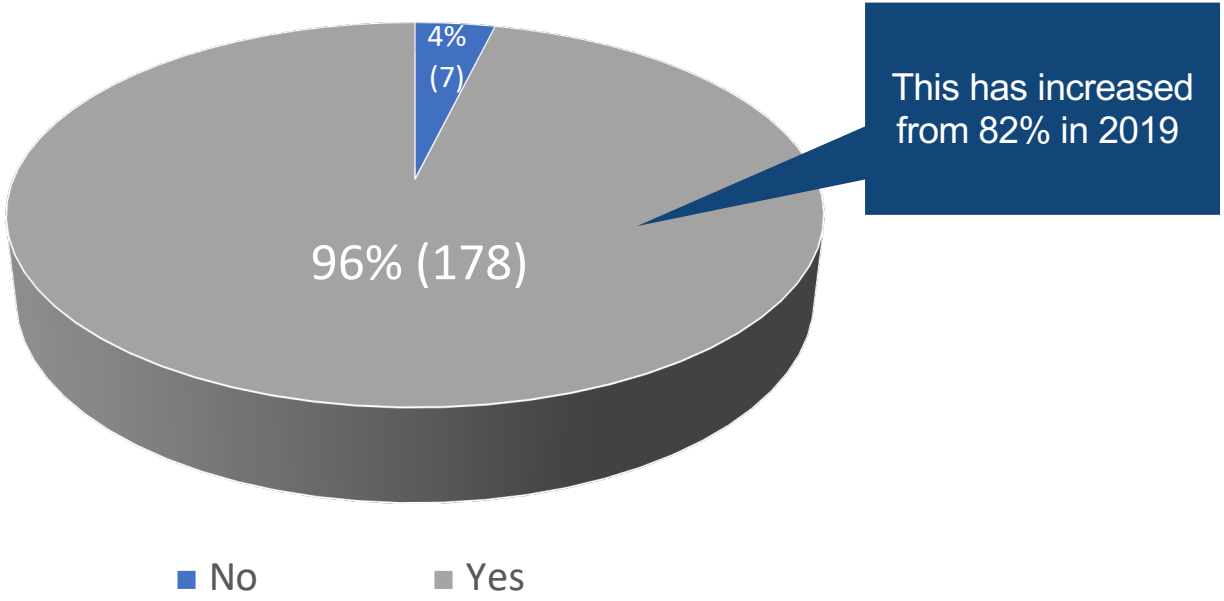
Organization Size for Survey Respondents



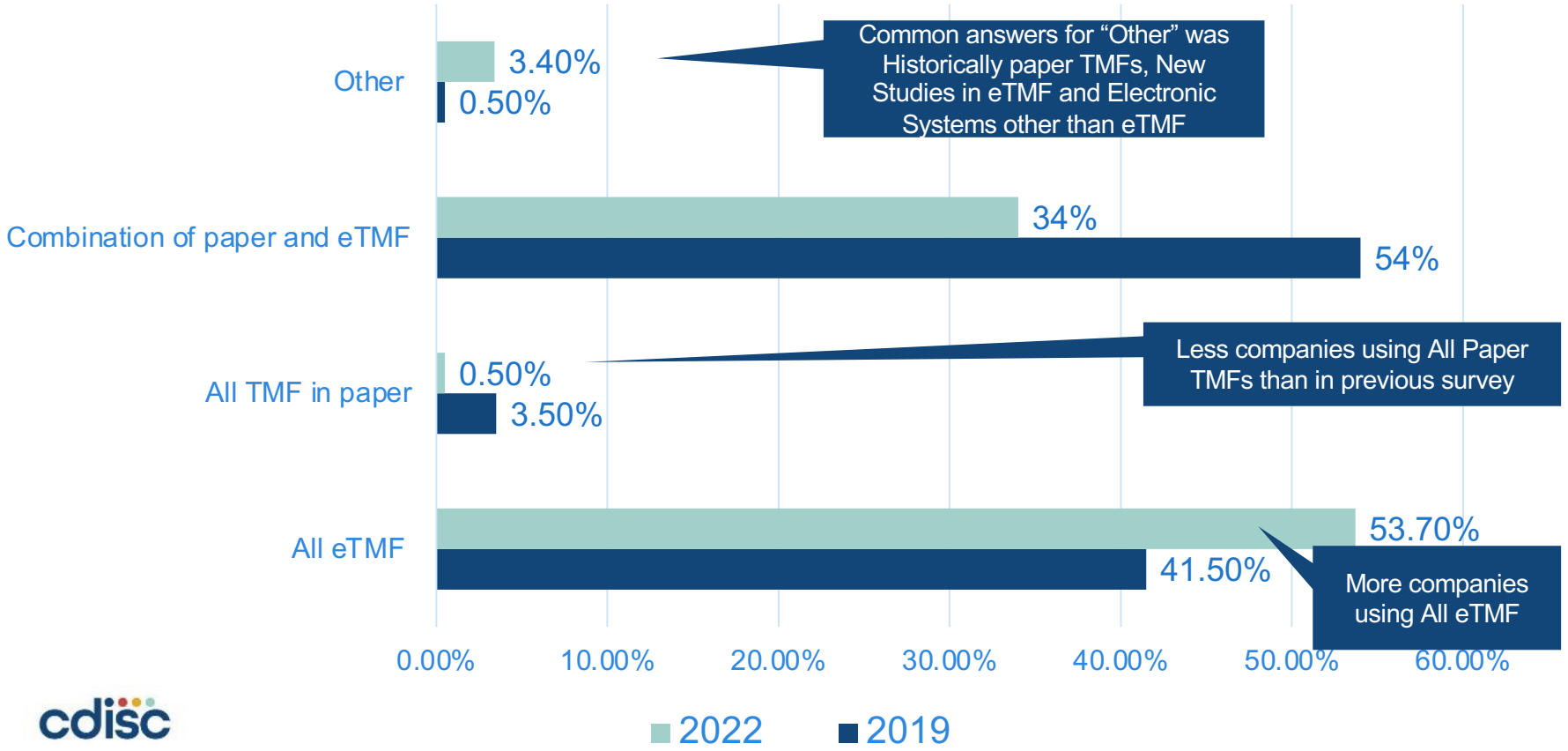
How did you hear about TMF Reference Model?



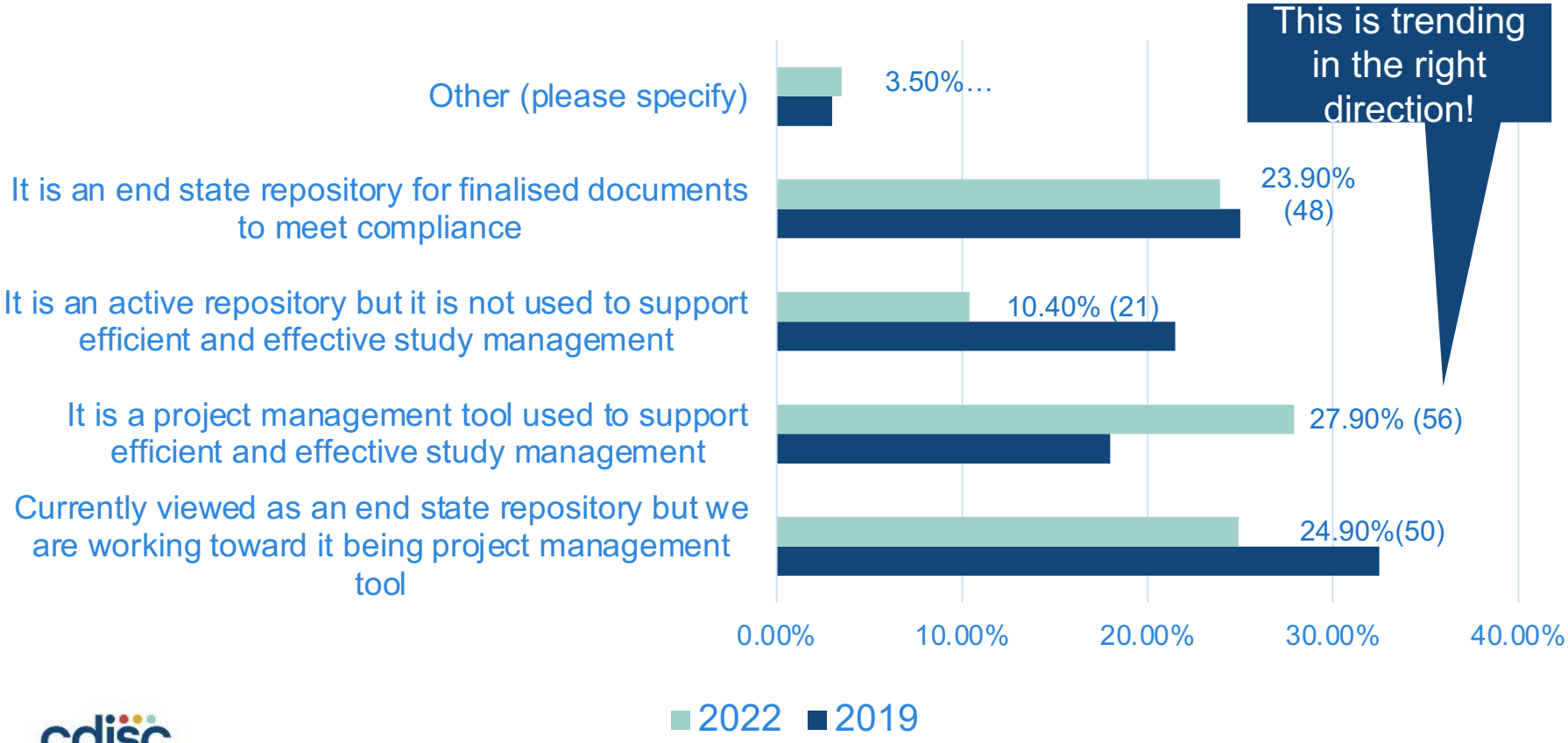
Organizations using TMF Reference Model



In which format is your organization's TMF?

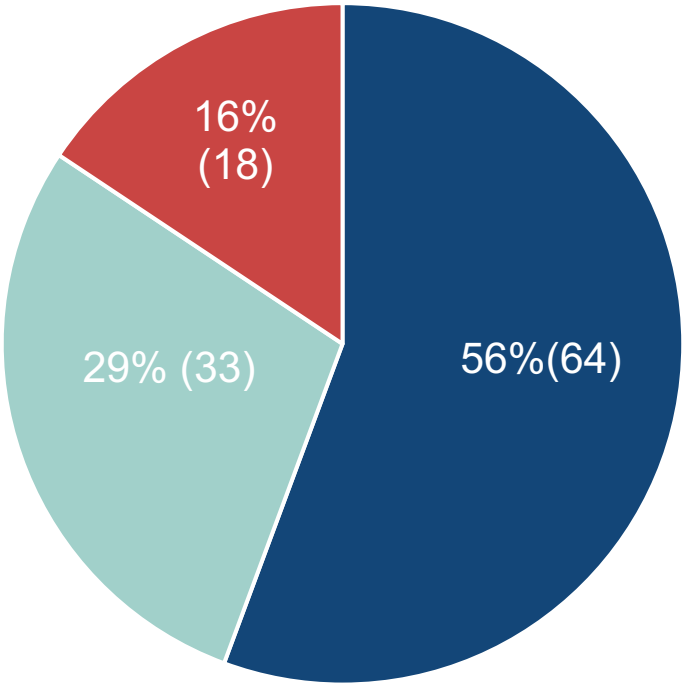


Overall, what is your organizational view of TMF?



If you are a Sponsor, do you utilize your own eTMF or do you use CRO's eTMF?

- Use our own eTMF solution and require CRO to use our eTMF
- Use our own eTMF solution only for sponsor-generated records and CRO eTMF for CRO / site-generated records
- We don't have an eTMF so use the CRO eTMF



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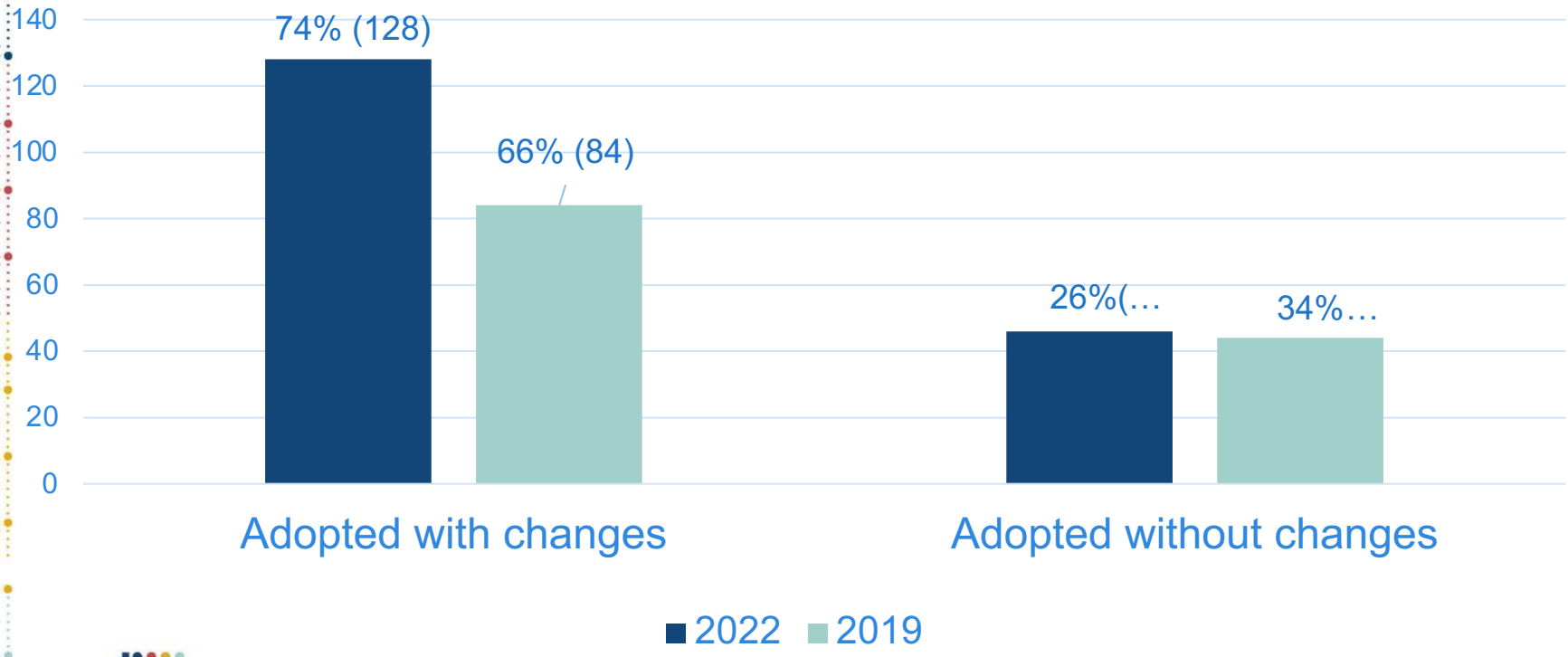
Has your organization adopted the Model without any change?



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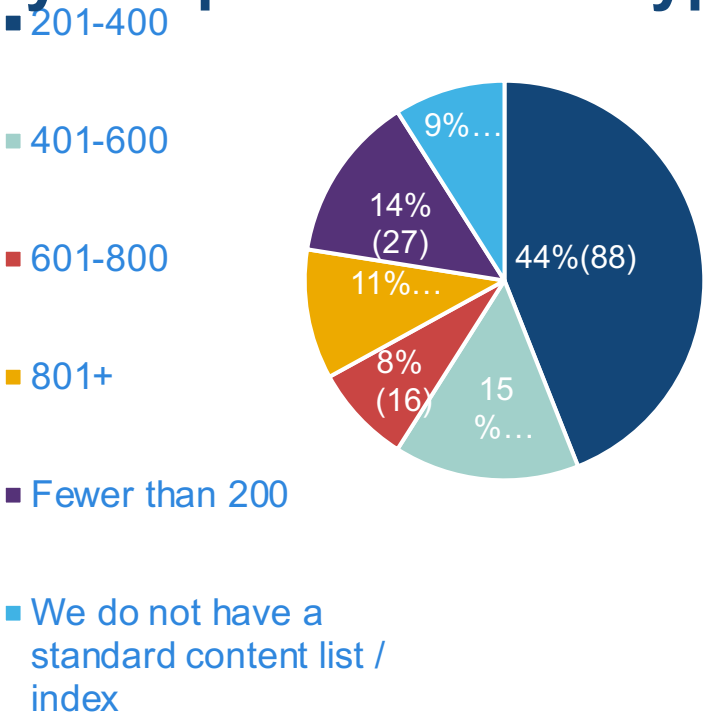
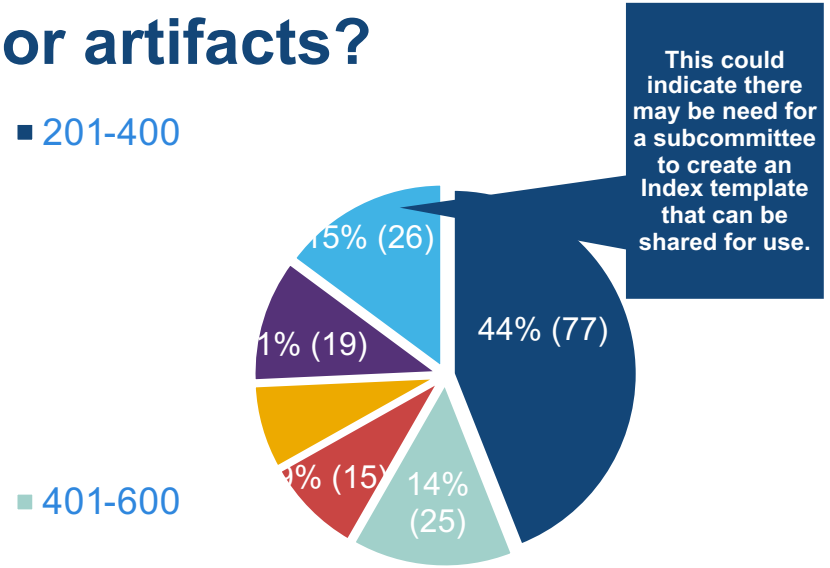
How many document types or artifacts are identified in your index / table of contents? In other words, how many unique document types or artifacts?

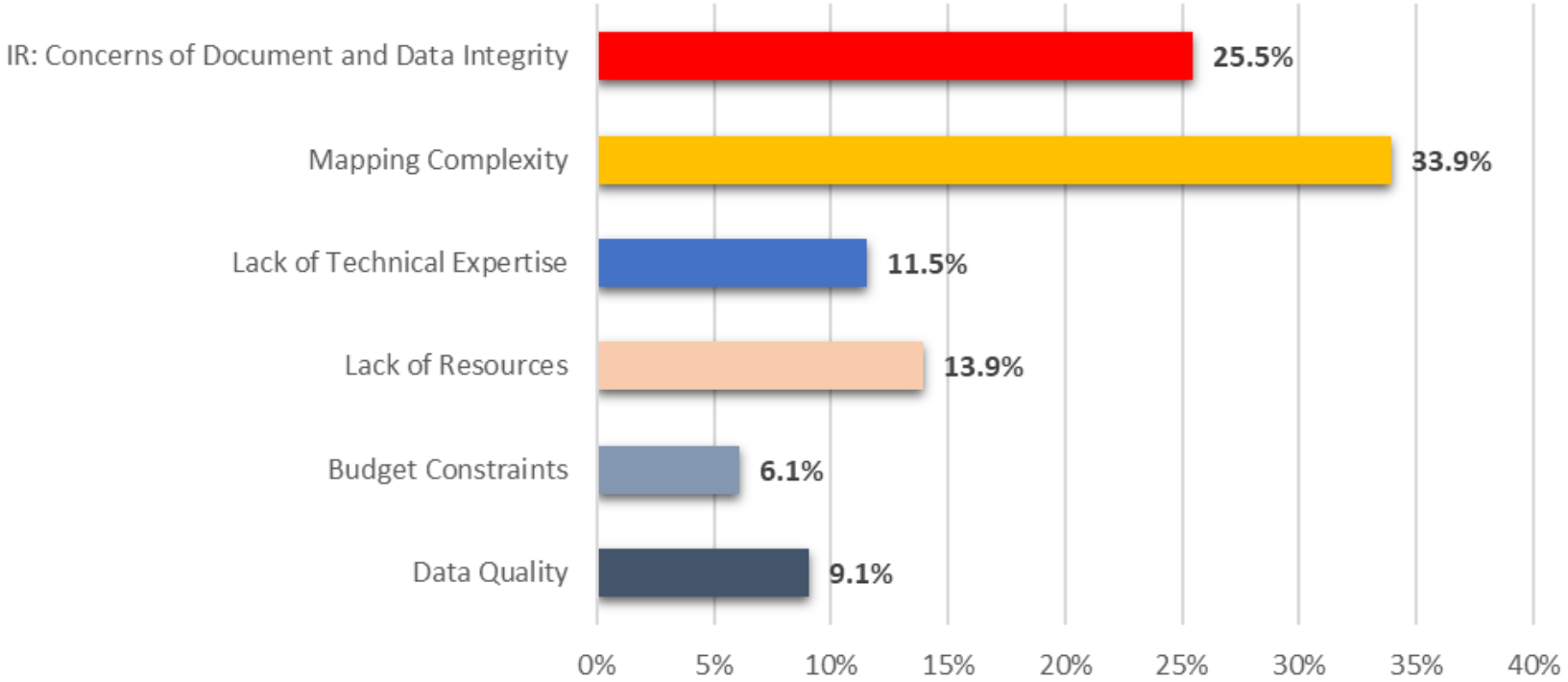


2019

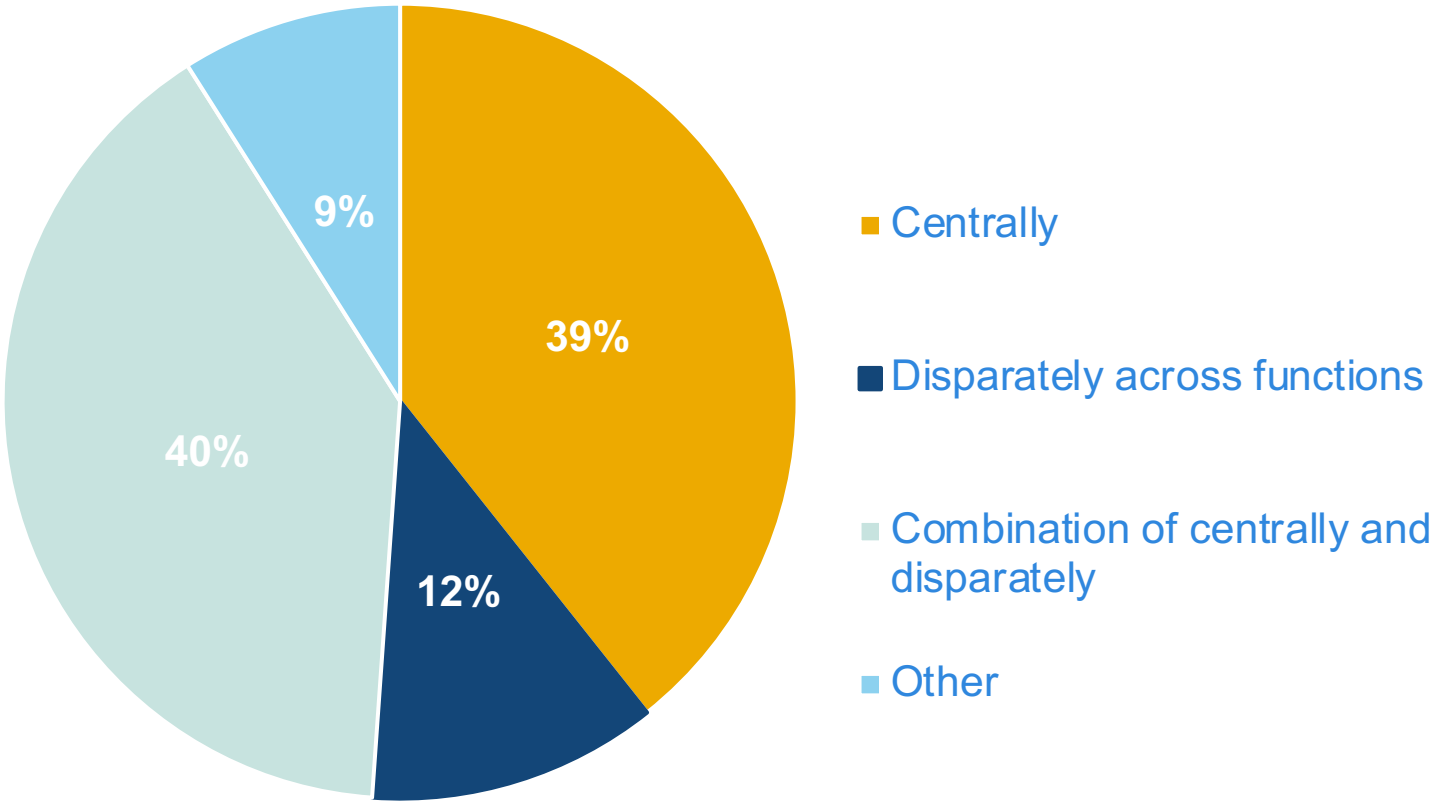


2022

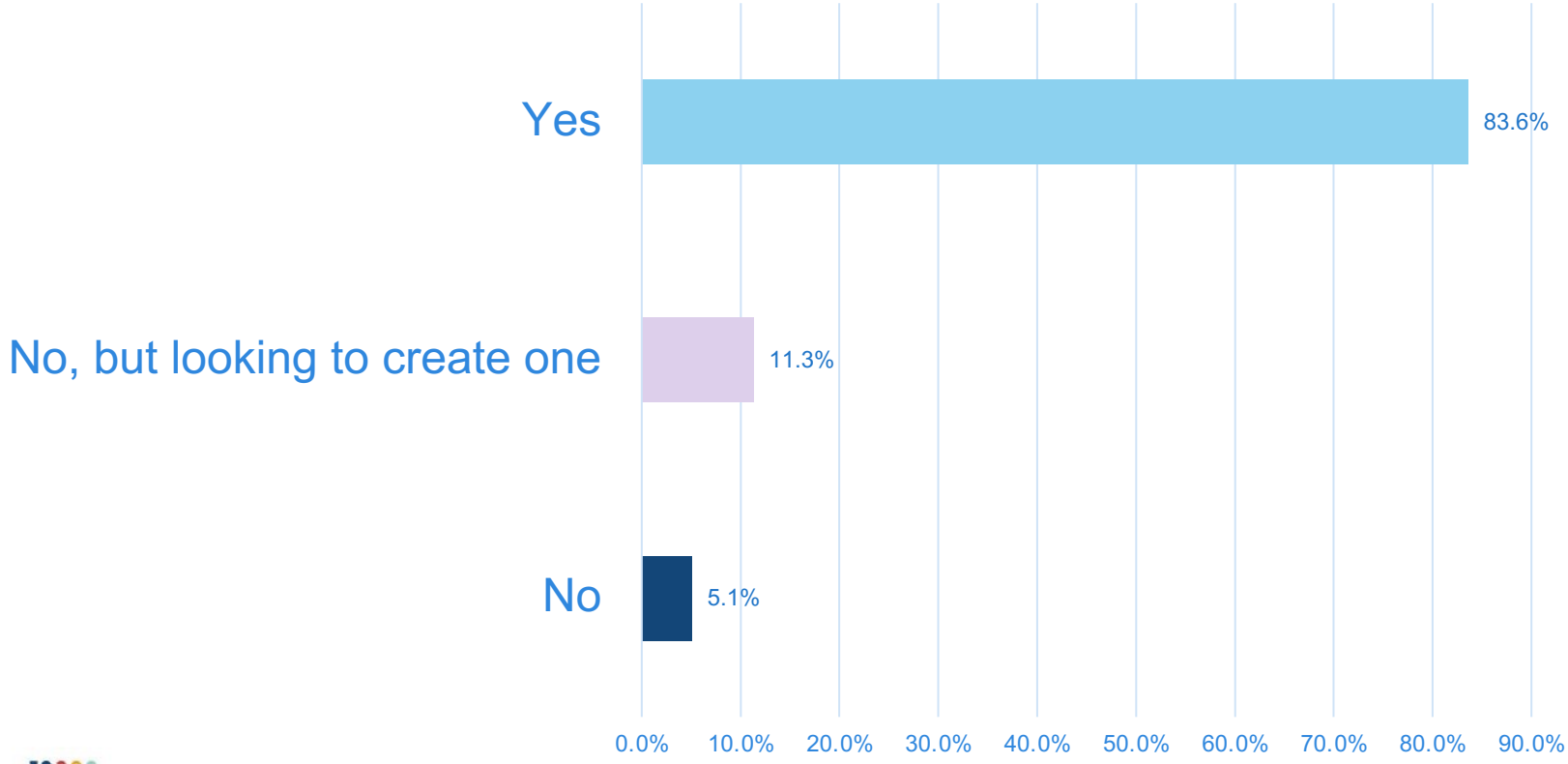
Factors Impacting Electronically Transferred TMF Content between Systems/Organizations



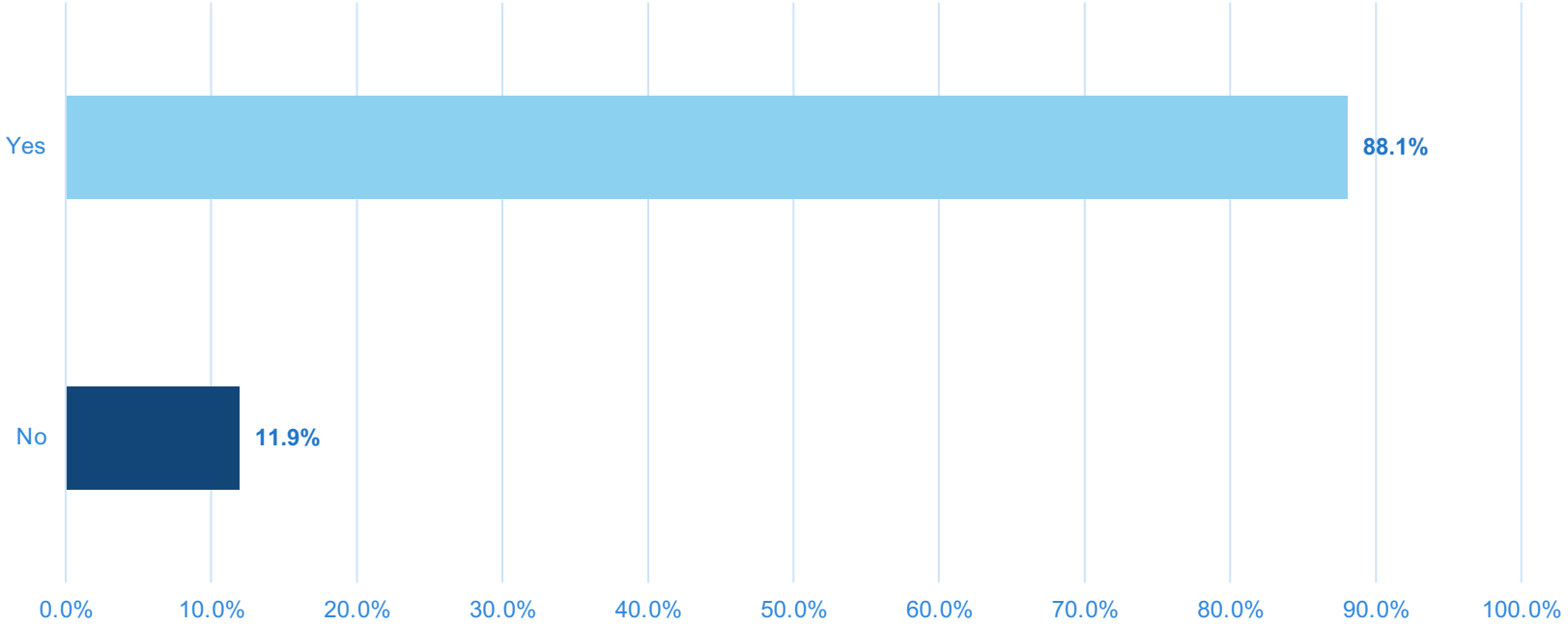
How TMF is Managed In or Across the or Organization



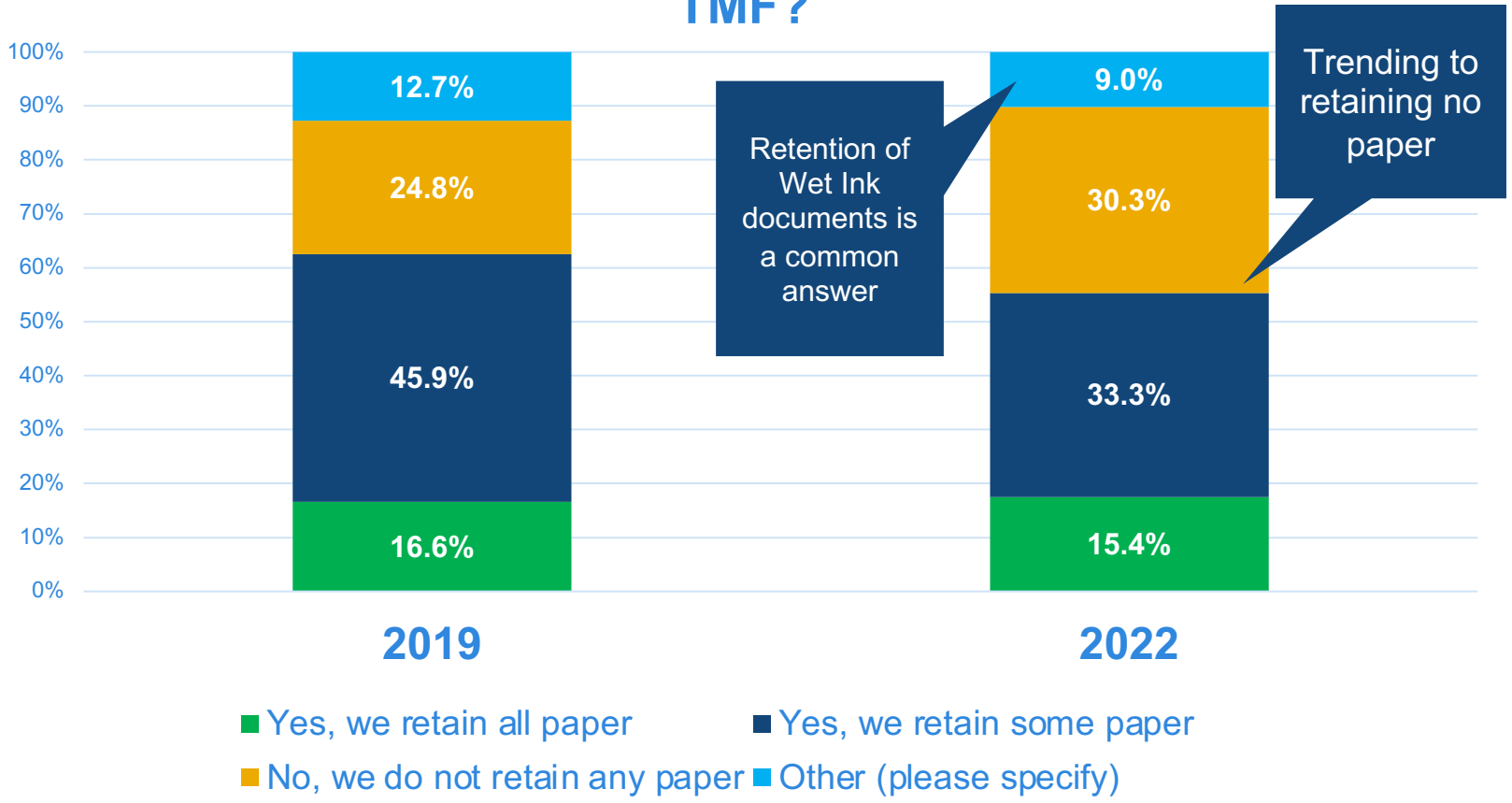
Does your Organization have a TMF Plan for each Study?



Do you routinely capture / retain relevant e-mail communications in the eTMF?

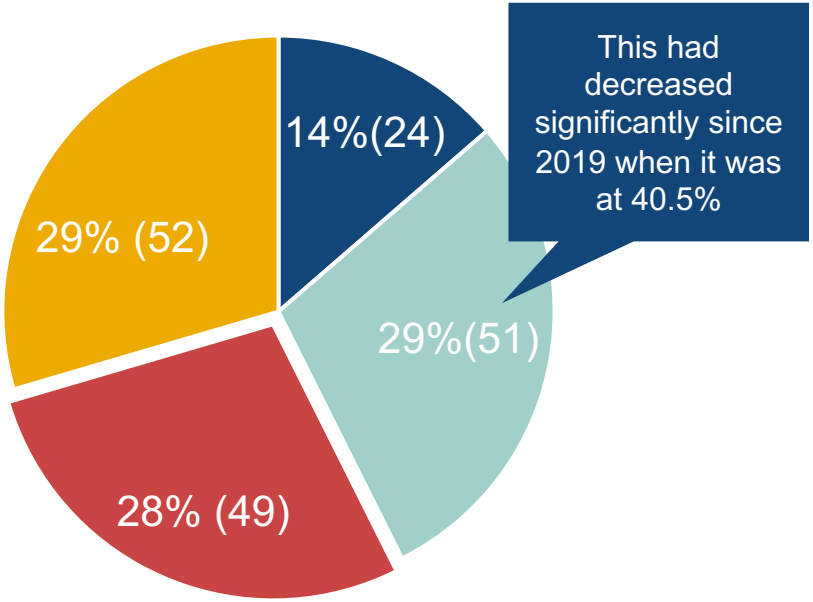


Do you Retain Paper Content Scanned into your TMF?

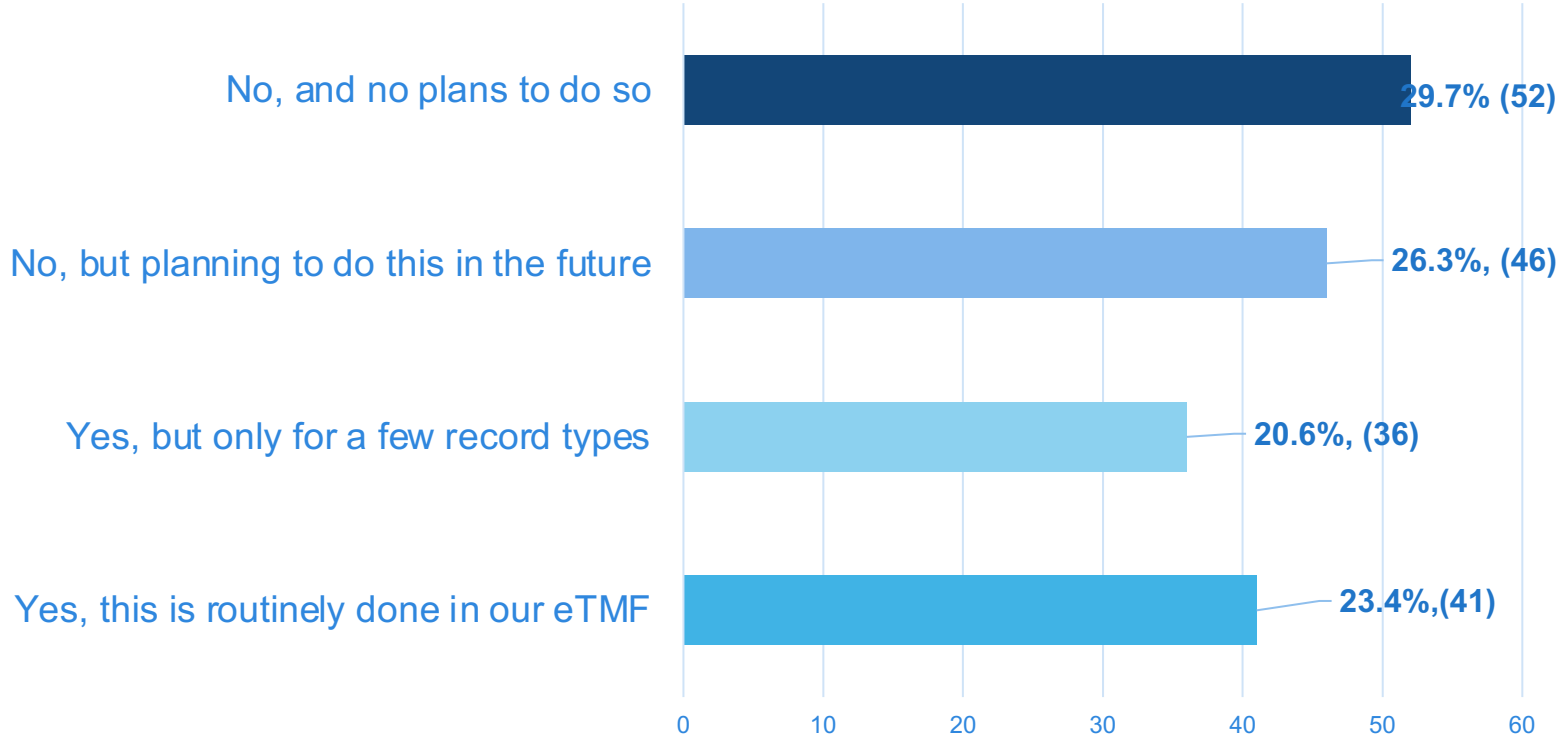


Which type of certified (true) copy policy does your organization promote?

- Other
- We do not have a certified copy procedure
- We have a certified copy procedure that applies only when an original is irreversibly replaced



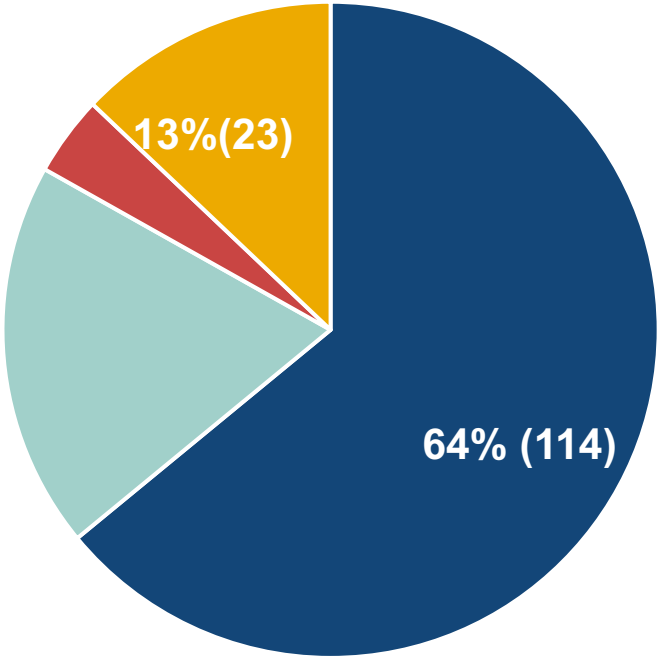
Does your Organization Author Documents in the eTMF?



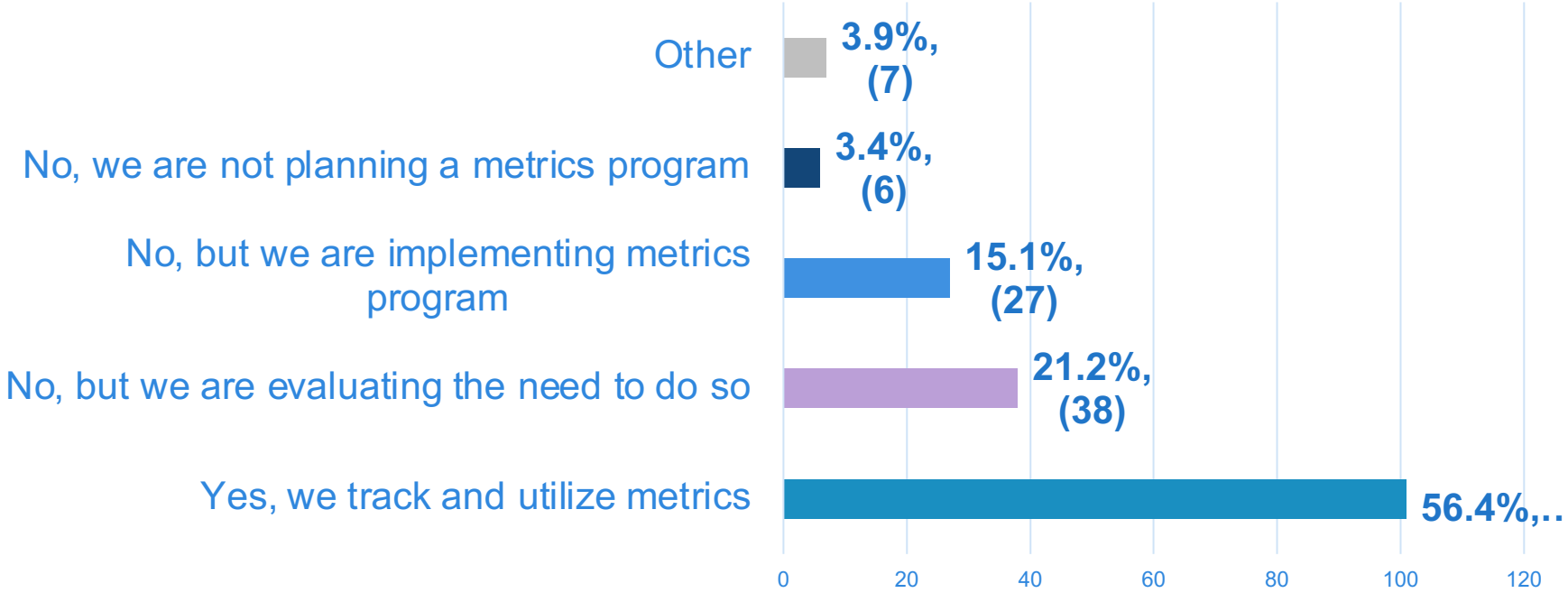
70% currently author in eTMF at some level or are planning to do so in future and about 30% do not and have no plans to author in future.

Who is accountable for assessing the TMF completeness at your organization?

- All contributing functions
- A central group
- Partnering organizations (e.g., CRO, Site)
- Other

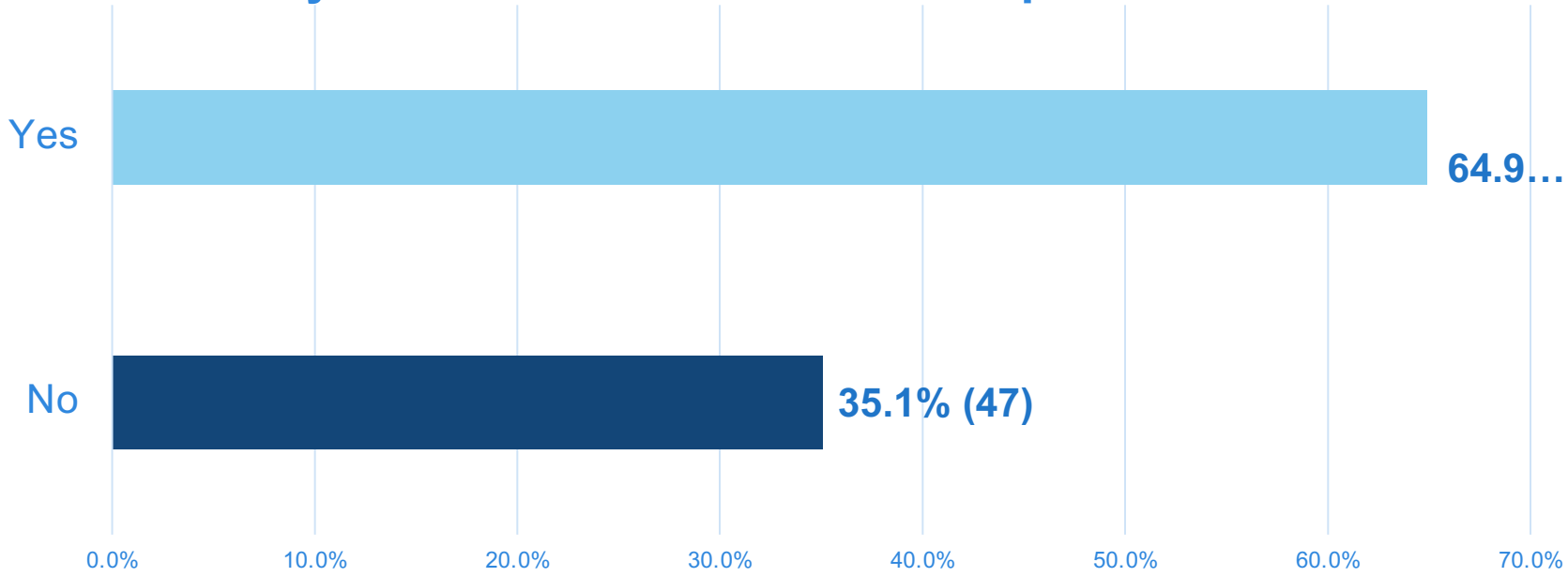


Do you track and utilize TMF metrics in a systematic way (e.g. metrics program /measure TMF quality/efficiencies)?



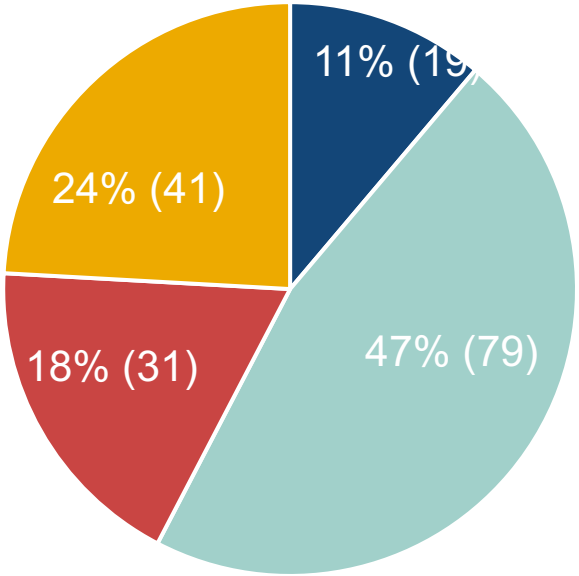
About 72% are tracking and utilizing metrics or are implementing a metrics program. This is slightly higher than 69% in 2019

Do you measure metrics on CRO performance?



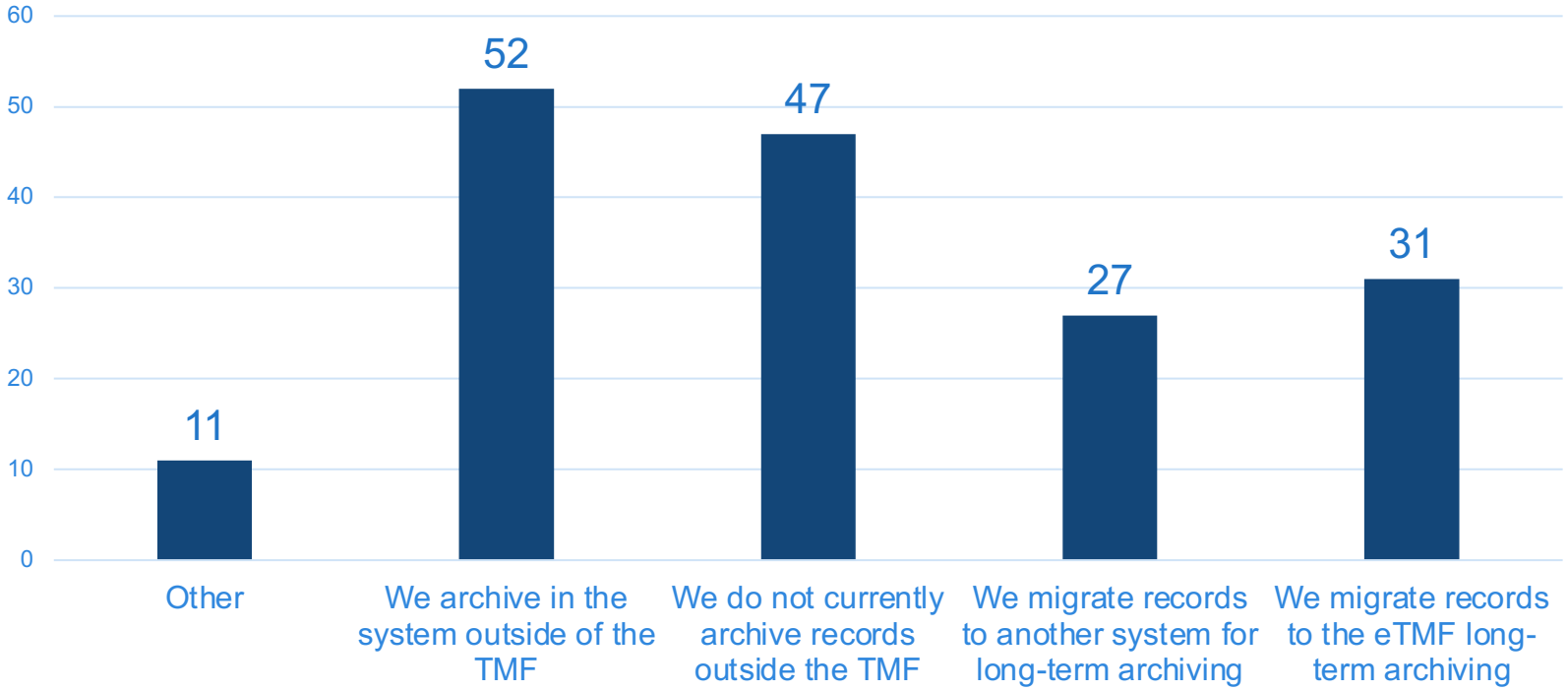
How do you archive records in your eTMF?

- Other
- We archive directly in the eTMF solution
- We do not currently archive the TMF
- We migrate records from eTMF to another system for long-term archiving

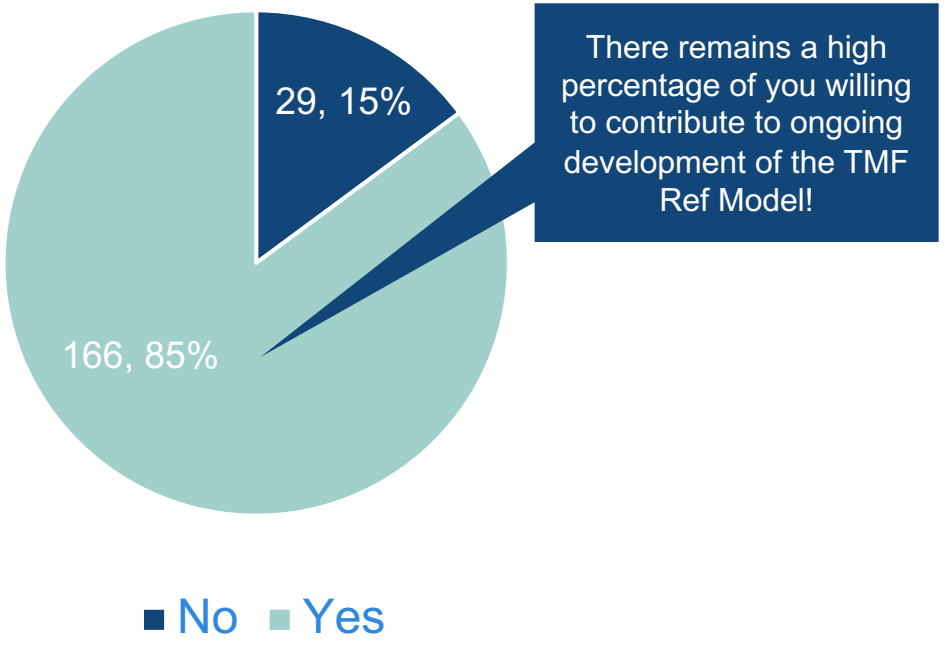


78% of respondents follow a formal TMF Archive process outlined in their company SOPs.

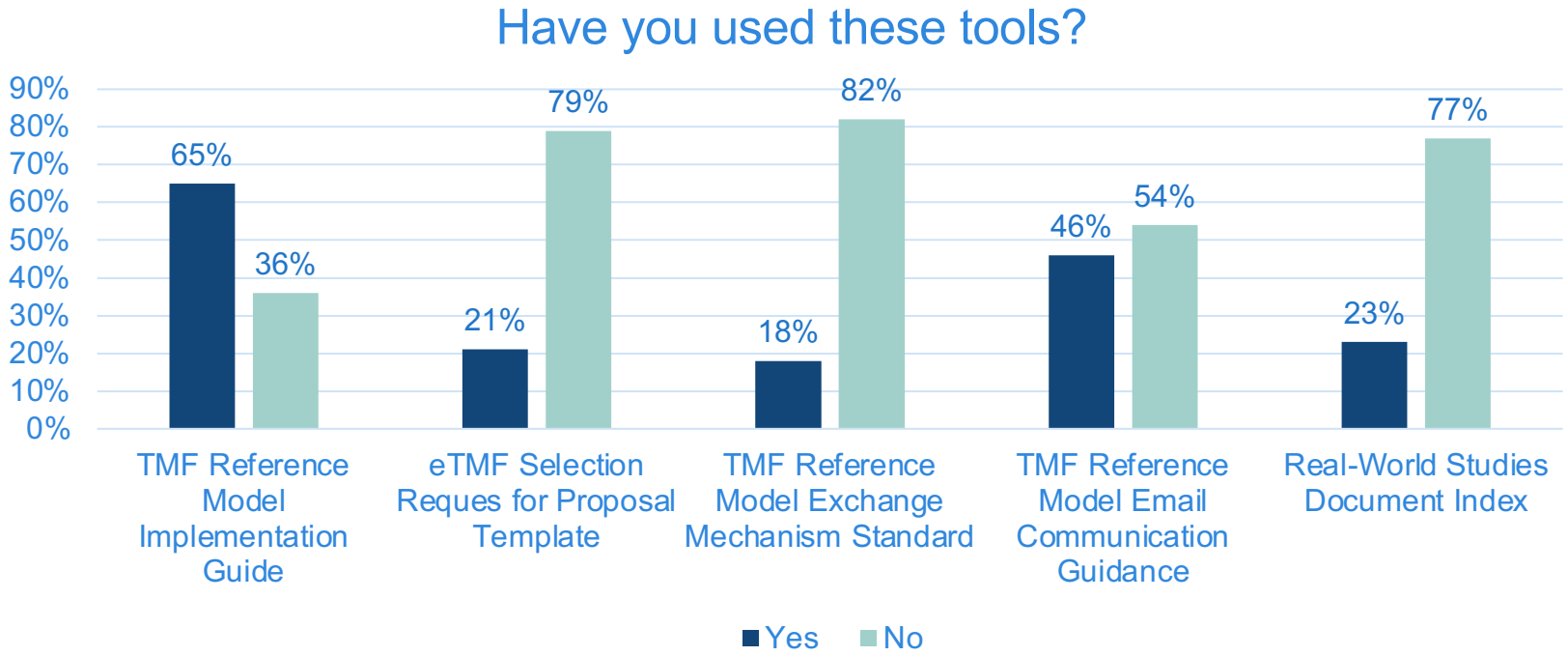
How do you archive TMF content kept outside of the primary TMF?



Would you be willing to contribute to ongoing development of the TMF Reference Model?



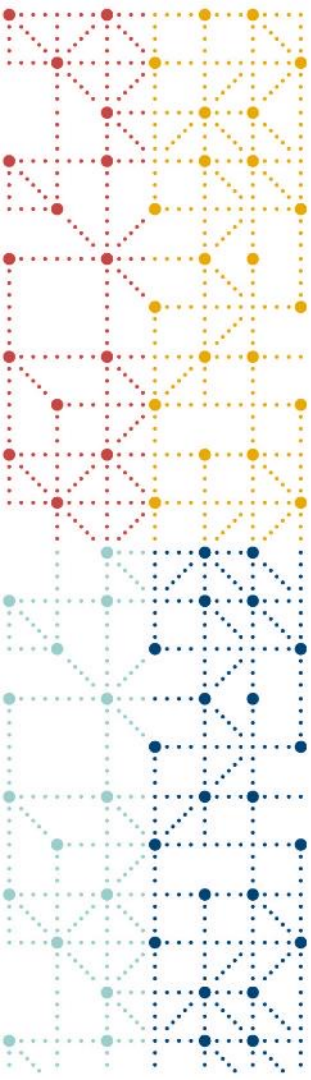
Use of TMF RM Tools/Templates

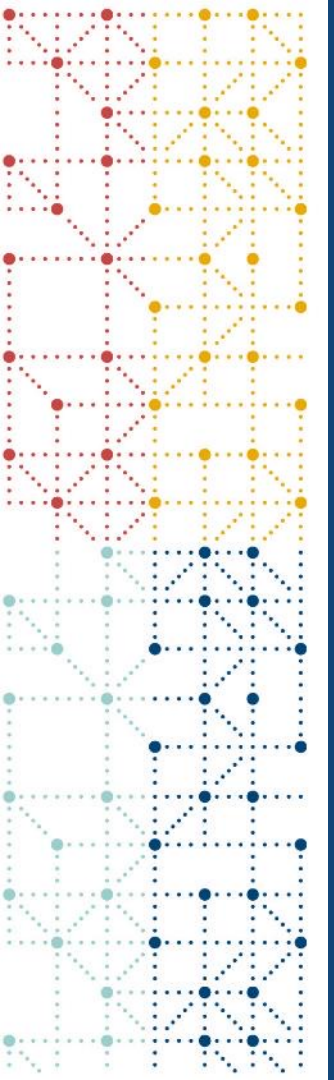


Why not? Most common response was they didn't know it existed. A few commented they didn't have a need to use it and few didn't know or were not responsible for that part of the business.

Here is a link to where you can locate these tools and templates:
https://tmfrefmodel.com/resources

Thank You!





CTIS

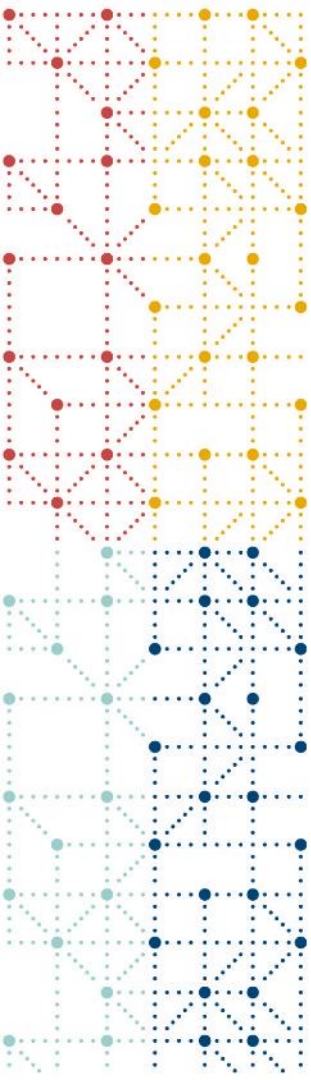
Scott Feiner, Abbvie

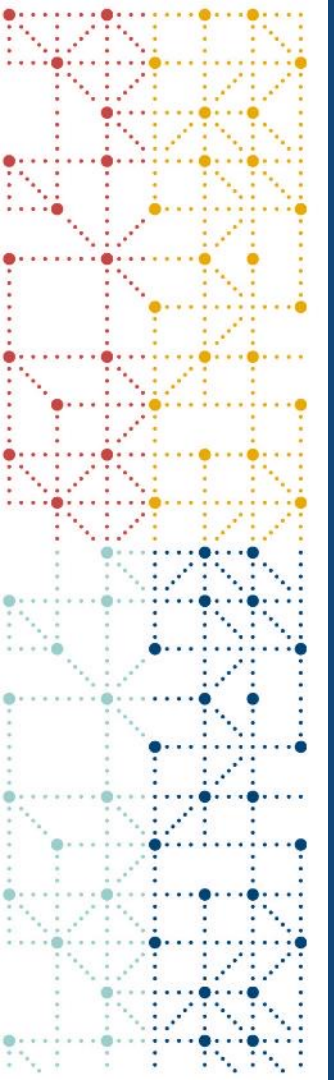
Upcoming Events

Upcoming Events

- 26-27 October; Austin, TX: **CDISC 2022 US Interchange**
- 14-16 November; London: **Fierce European TMF Summit**

Thank You!





Questions & Answers

Audience Questions

Is there a plan to include standardization of metadata within the TMF Index template?

Audience Questions

How do you differentiate between different phases in tmf index?

Audience Questions

How can the documents to be submitted be filed in the future if they are submitted jointly via CTIS and no longer separately?

Audience Questions

What are the potential changes or issues since the Ref. model moved over to CDISC as CDISC has their own processes?

Audience Questions

What is expected to filed in 11.03.07 through 11.03.10 - the data sent and outputs can be many files with large amounts of data?

Audience Questions

What is going to be the TMF review model recommended in this revision? I cannot see any standard model across companies to ensure TMF readiness.

Audience Questions

If there are multiple TMFs for a particular study, e.g., CRO TMFs and Sponsor TMFs - what is the standard transfer plan at the end of the study and factors to consider when merging all TMF s to one at the end of study ? end of study QC, system to system transfer etc ?

Audience Questions

As the use of technology (i.e., clinical systems) increases, we are seeing more documents related to systems beyond EDC. The current 10.04 section seems to be limited to EDC management. Is there any plan to add additional types/subtypes/classifications for other clinical data systems? In the interim, do you have a recommendation if we were to customize our company-specific TMF index to accommodate the non-EDC systems related documents?

Audience Questions

How does an organization utilize the TMF Metrics within the system?

Audience Questions

Can you explain why Date and Version would typically NOT be included in the title of the protocol document?

Audience Questions

Audience Questions

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Upcoming Events

Upcoming Trainings

SDTM Changes & Updates (SDTM v1.7 - 2.0 and SDTMIG ...
online
09/26/2022 @ 13:00 EDT

Training Schedule Options *(click on 'Read more...' to view all*

CDISC for Newcomers (Virtual)
online
01/09/2023 @ 09:00 EDT
$420.00

Description:New to CDISC Standards? Attend our workshop

Controlled Terminology
online
01/10/2023 @ 09:00 EDT

$420.00

Training Schedule Options
The Controlled Terminology virtual

CDASH Fundamentals and Implementation
online
01/11/2023 @ 09:00 EDT
$840.00

Training Schedule Options (click on 'Read more...' to view all

SDTM Theory and Application for Human Clinical Tri ...
online
01/23/2023 @ 09:00 EDT

Training Schedule Options (click on 'Read more...' to view all

SEND Implementation
online
01/23/2023 @ 09:00 EDT

$725.00

Training Schedule Options (click on 'Read more...' to view all

ADaM Core Theory and Application
online
01/30/2023 @ 09:00 EDT
$840.00

Training Schedule Options (click on 'Read more...' to view all

Define-XML
online
02/06/2023 @ 09:00 EDT

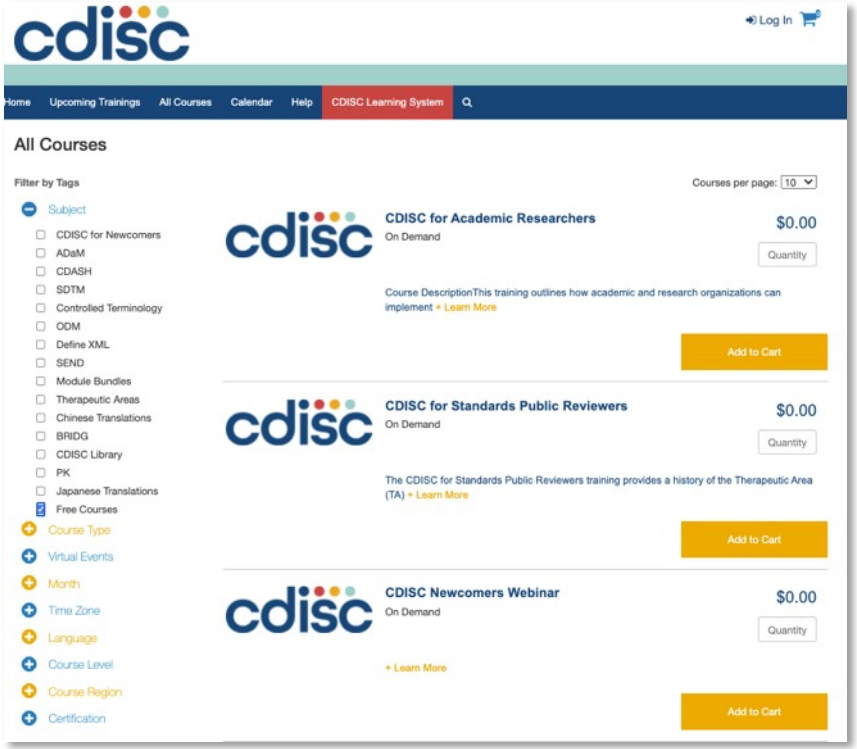
$840.00

Training Schedule Options (click on 'Read more...' to view all

- Information available at: www.cdisc.org
- Register at: https://learnstore.cdisc.org/
- Contact us at: training@cdisc.org

cdisc

Free CDISC Courses



Http://learnstore.cdisc.org

Upcoming Webinars

Date	Title
18 OCT	CORE Volunteer Onboarding Training Webinar
8 DEC	COSA Spotlight for Q4 – Dataset-JSON Hackathon Solutions
20 DEC	Controlled Terminology Updates: P52 Publication / P53 Public review
30 MAR 2023	Genomics Findings Office Hours

In 2023:

QRS, Controlled Terminology, and COSA quarterly updates

Office Hours with the ADaM, CDASH, CT, QRS, and SDTM teams, and more to come.

2022 CDISC US Interchange

Austin, TX, 26-27 October

cdisc

CDISC Events in 2023

2023 Japan Interchange
10 – 11 July
Tokyo
Japan

2023 US Interchange
October
Washington, DC
USA

2023 Europe Interchange
26 – 27 April
Copenhagen
Denmark

2023 China Interchange
25 – 26 August
Beijing
China

2023 Korea Interchange
11 – 14 December
Seoul
Korea

cdisc

Thank you!

Contact the Events inbox:
events@cdisc.org

Contact Education inbox:
training@cdisc.org

Contact Bernard directly:
bklinke@cdisc.org