

# TMF Survey Report Out

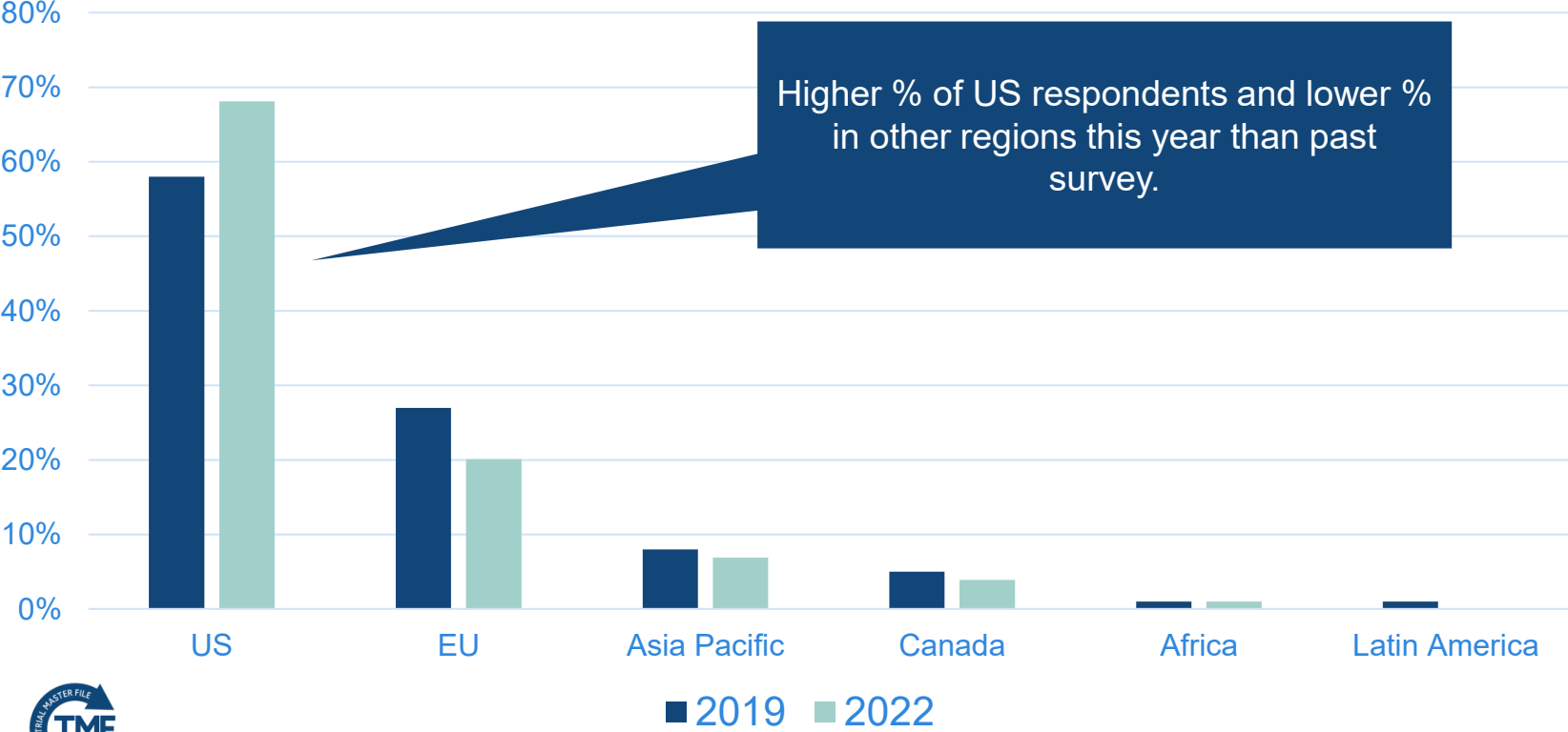
Allison Varjavandi

# TMF Reference Model Survey

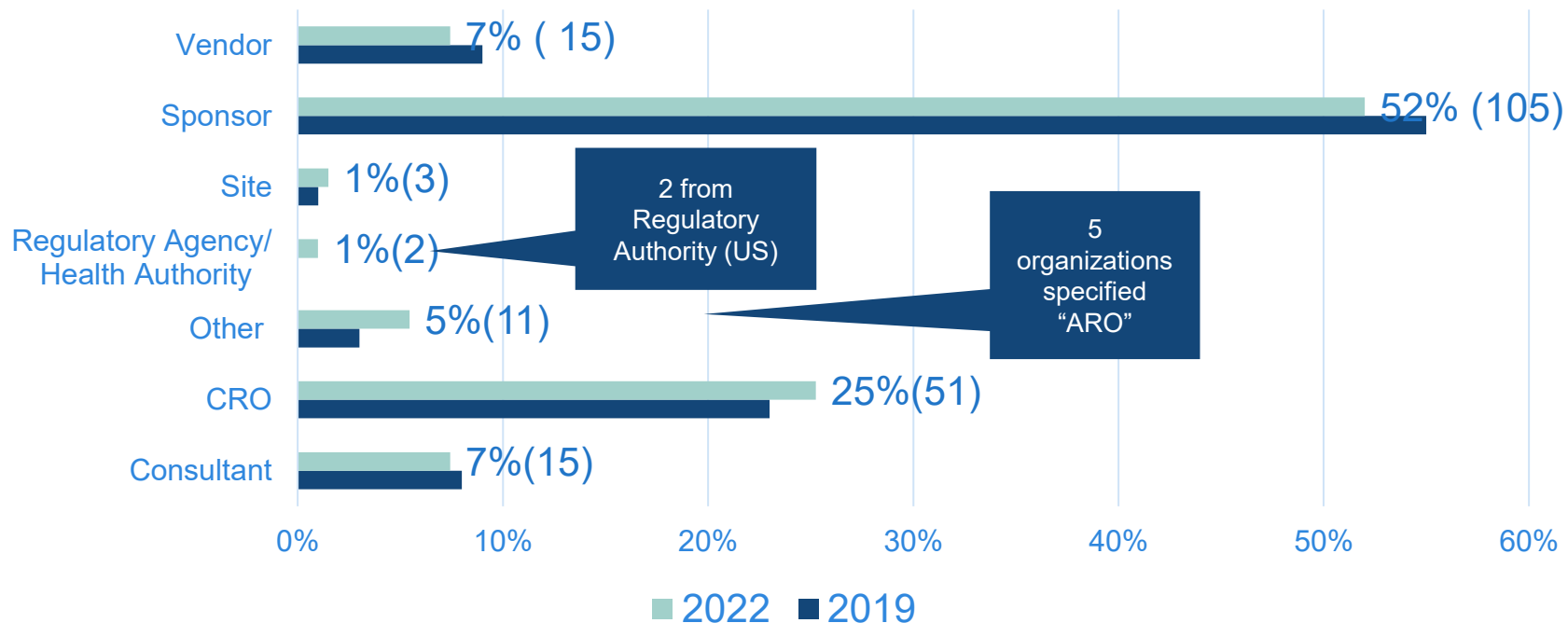
- Thank you to everyone who contributed to the Survey conducted June 2022!
- Many of the comments collected through the survey will be communicated to the Steering Committee and Change Control Board to determine where there is opportunity for enhancement to tools, model etc.
- Today, we will share some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



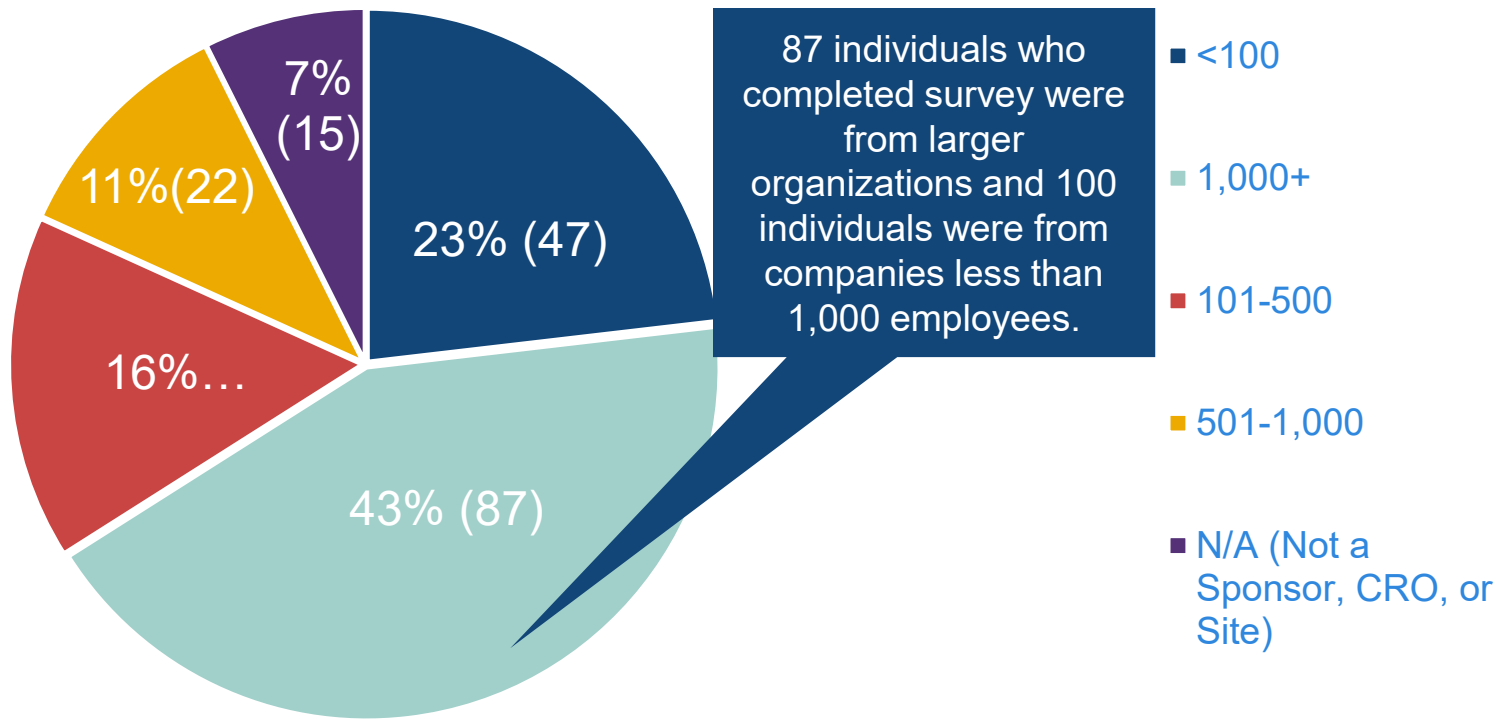
# Location of the 206 Survey Respondents



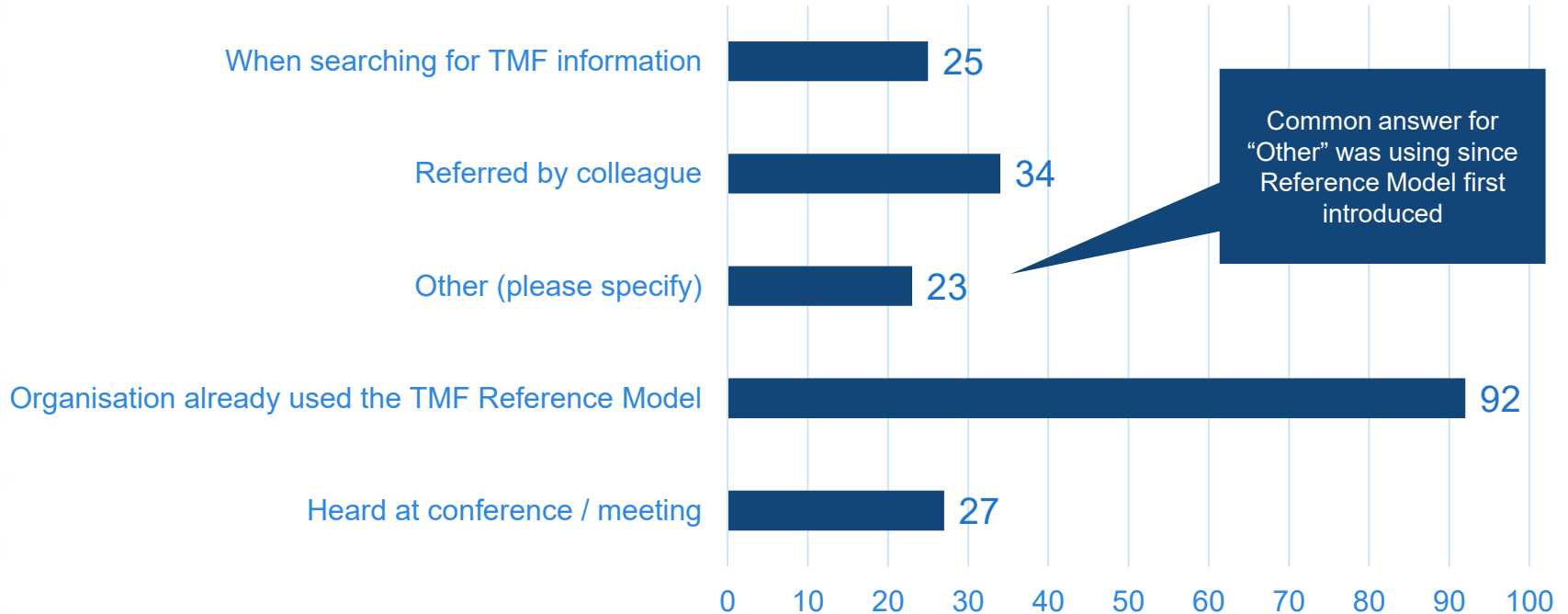
# Organization Breakdown of Respondents



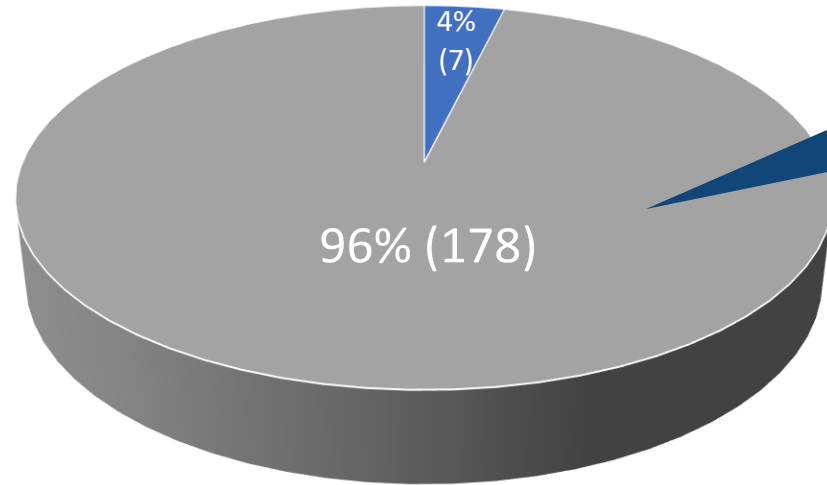
# Organization Size for Survey Respondents



# How did you hear about TMF Reference Model?



# Organizations using TMF Reference Model

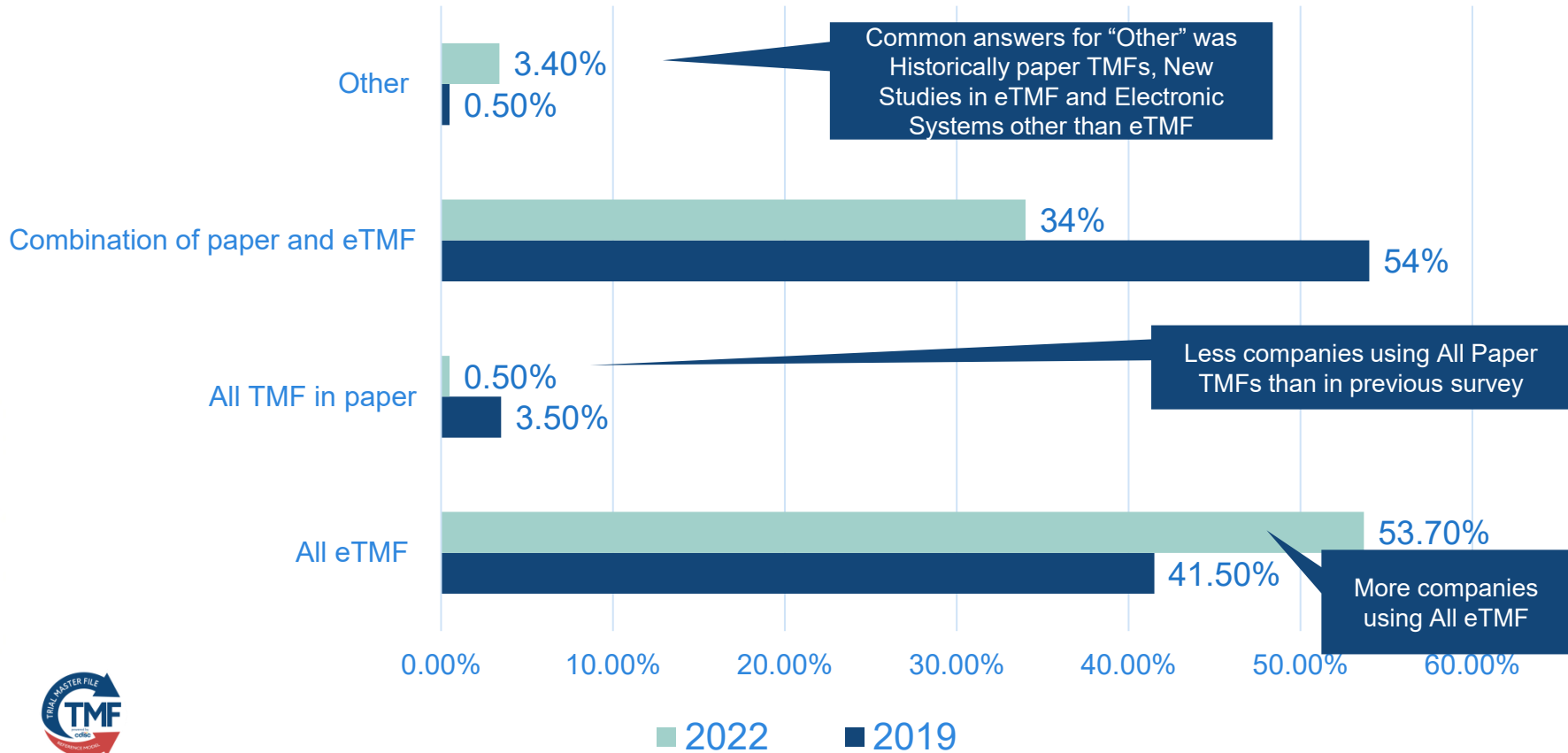


This has increased from 82% in 2019

■ No      ■ Yes

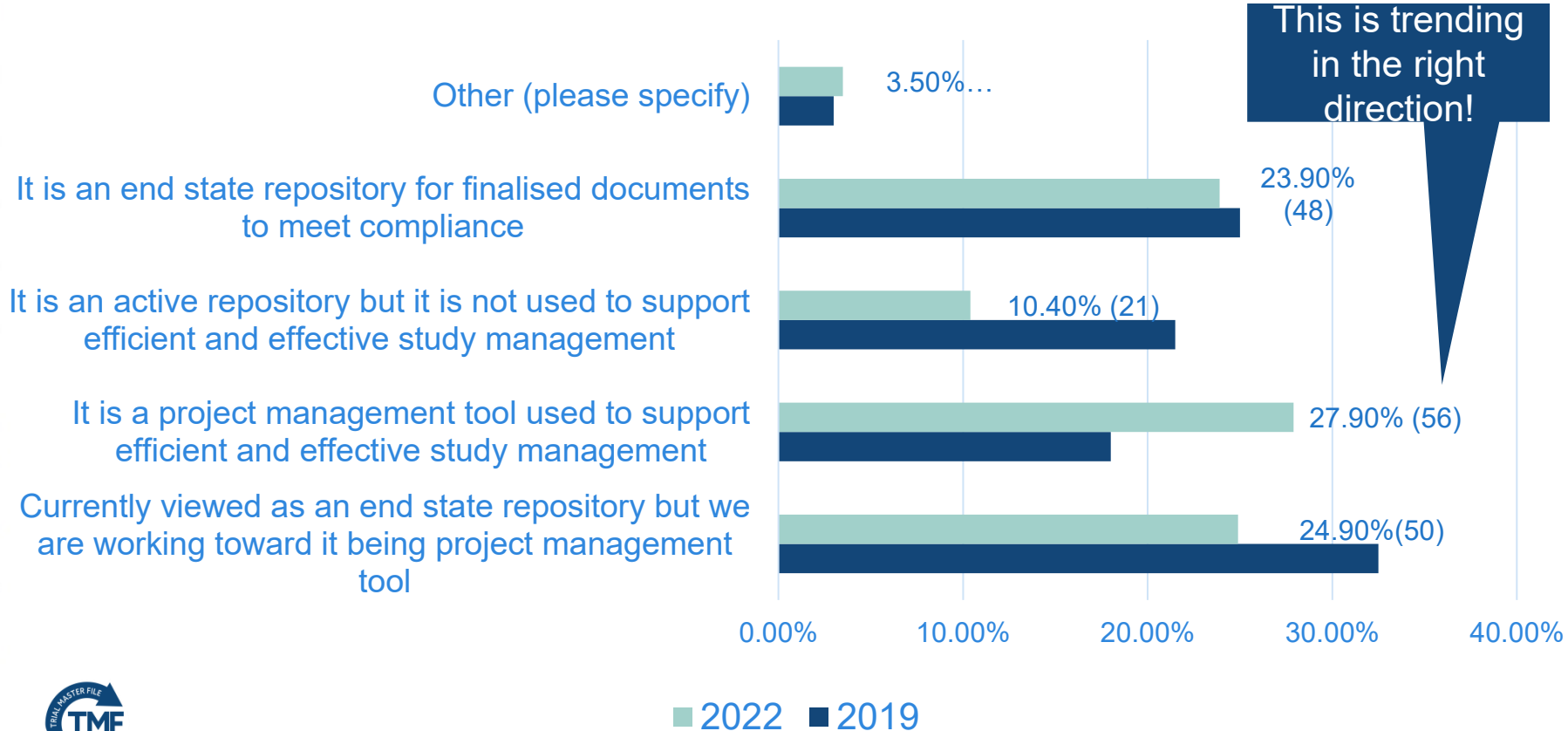


# In which format is your organization's TMF?



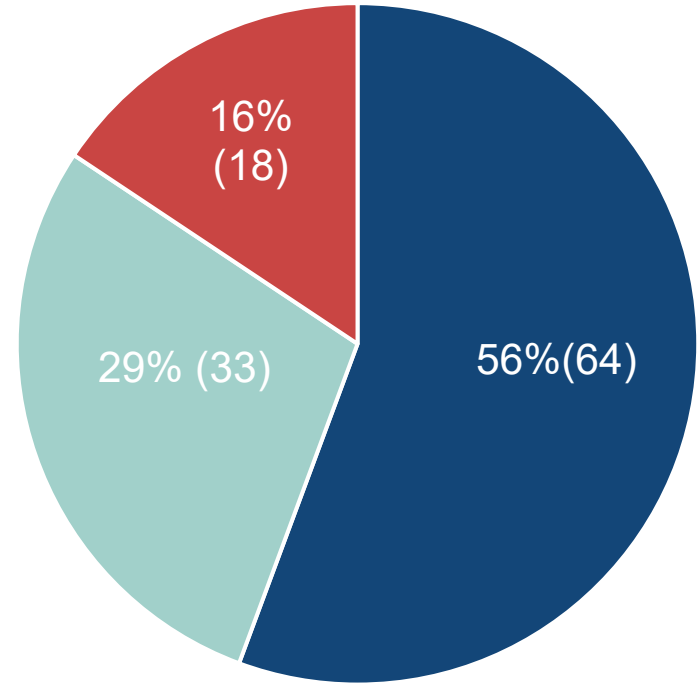


# Overall, what is your organizational view of TMF?

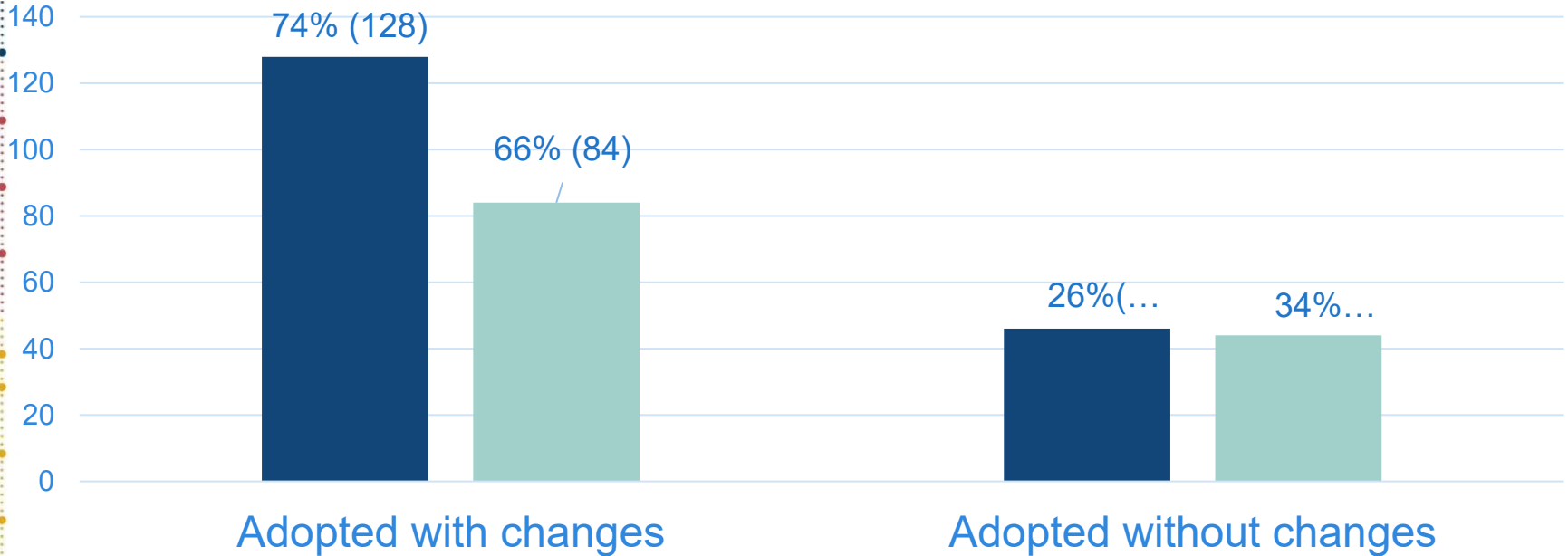


# If you are a Sponsor, do you utilize your own eTMF or do you use CRO's eTMF?

- 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



# Has your organization adopted the Model without any change?



■ 2022 ■ 2019

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

■ 201-400

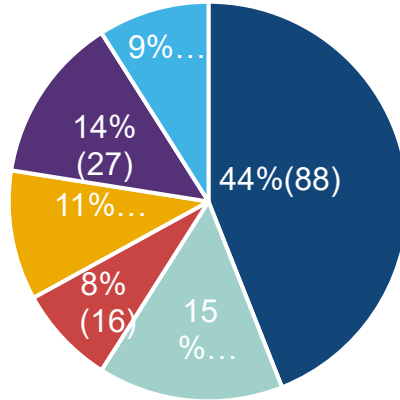
■ 401-600

■ 601-800

■ 801+

■ Fewer than 200

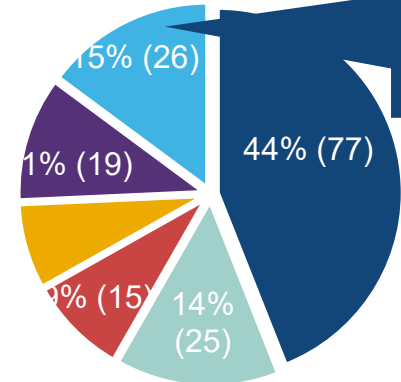
■ We do not have a standard content list / index



2019

■ 201-400

■ 401-600

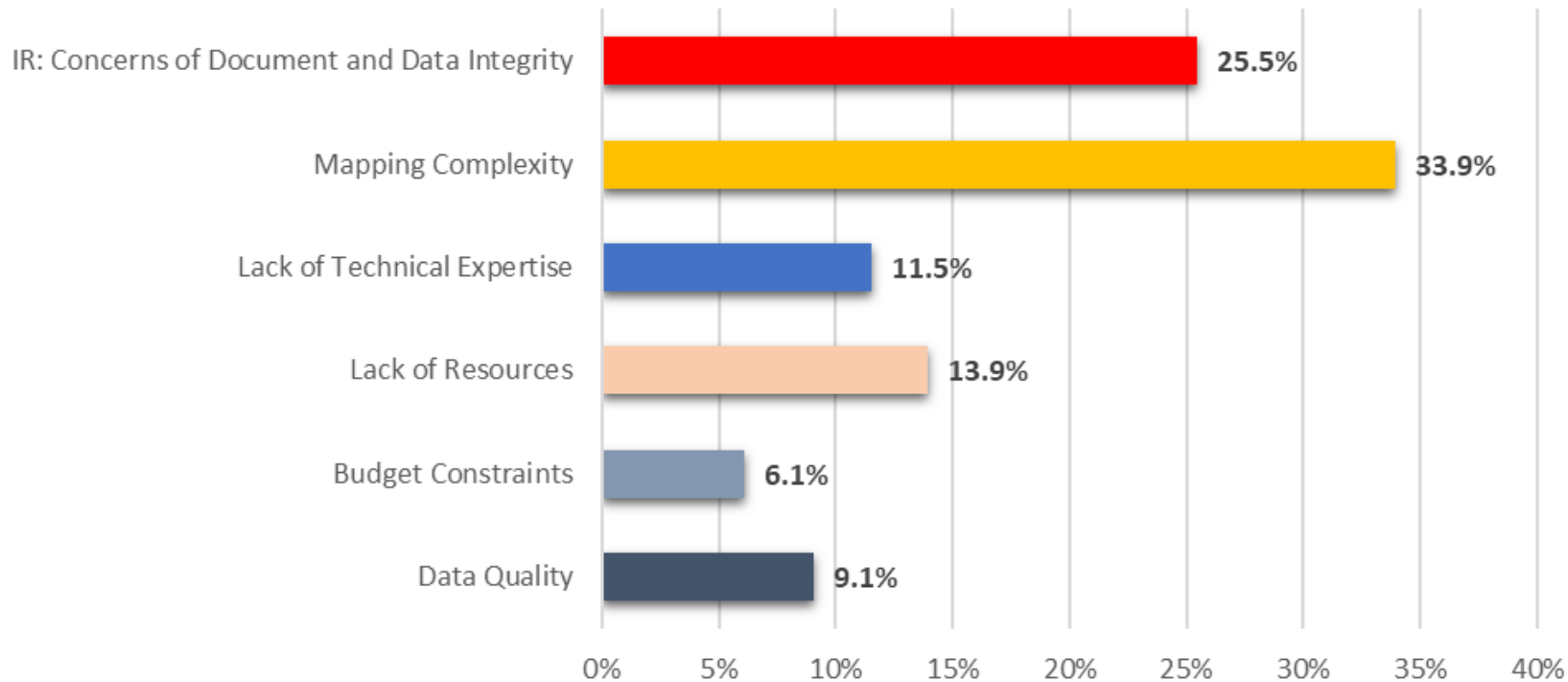


2022

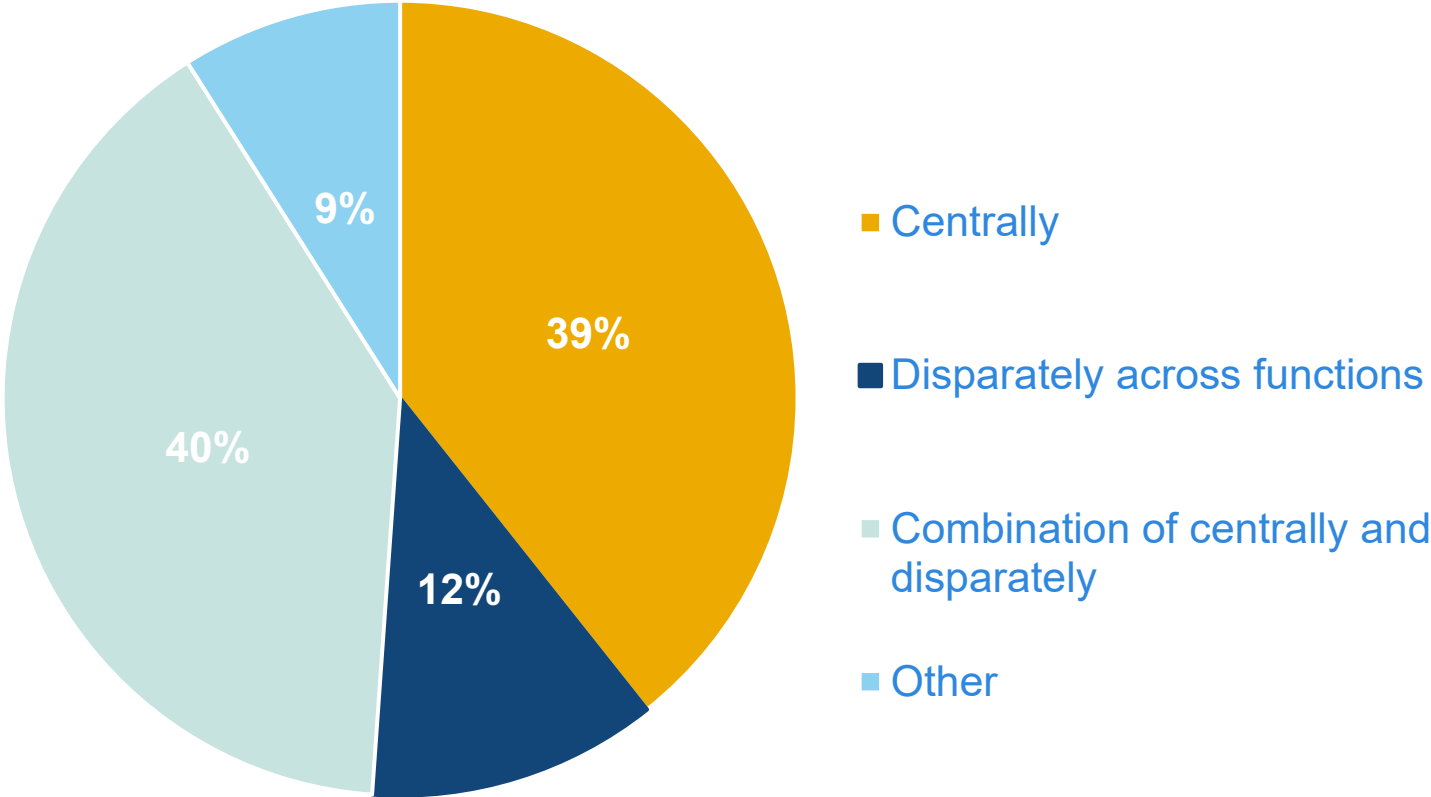
This could indicate there may be need for a subcommittee to create an Index template that can be shared for use.



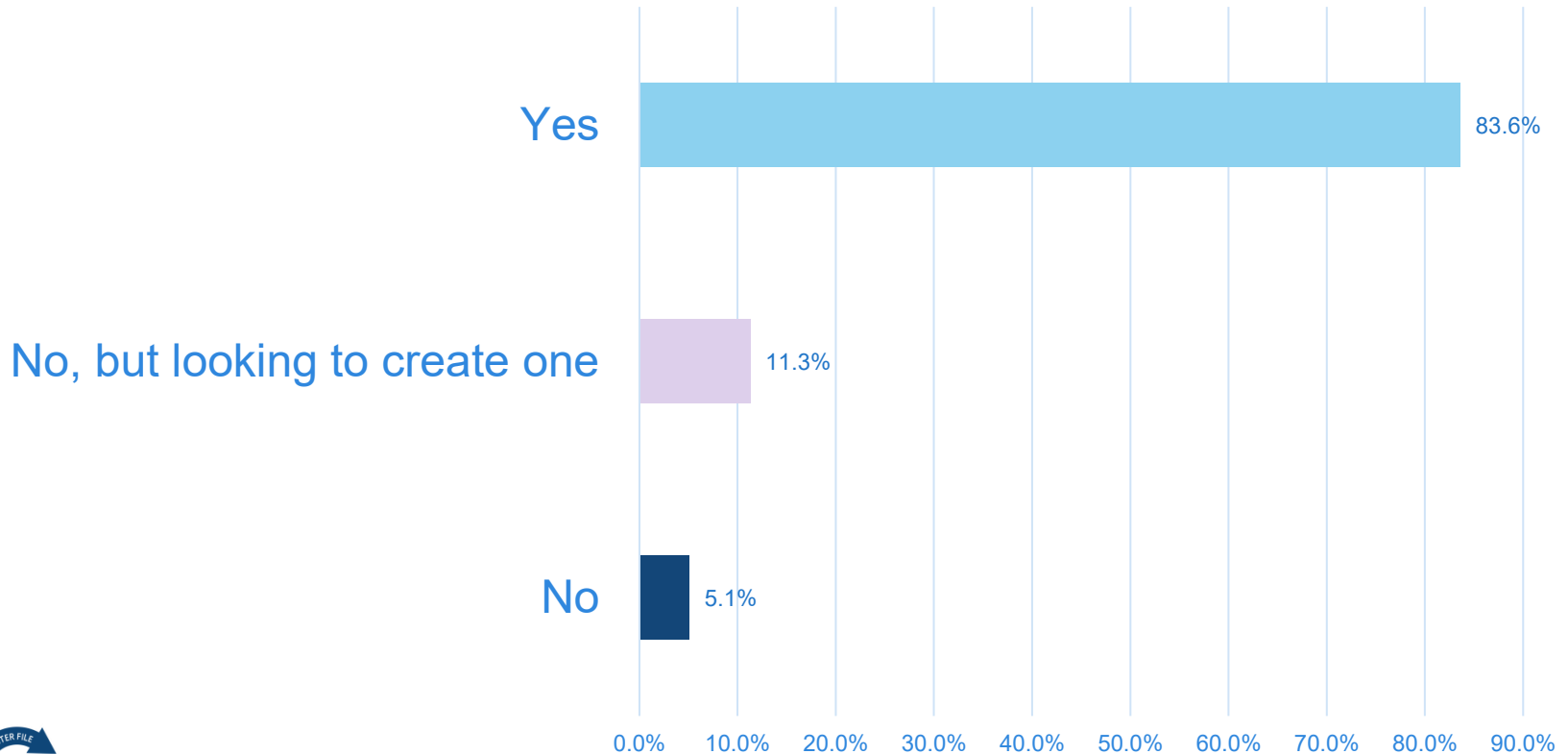
## Factors Impacting Electronically Transferred TMF Content between Systems/Organizations



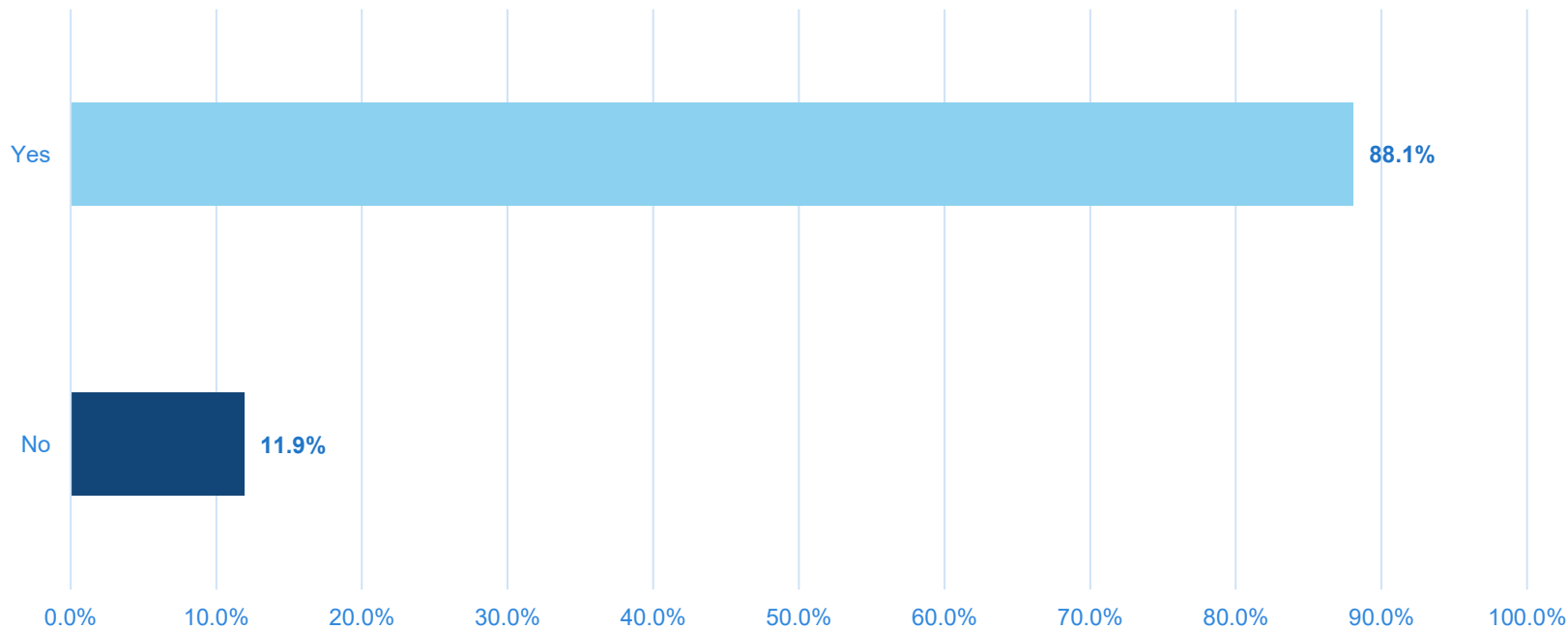
# How TMF is Managed In or Across the or Organization



# Does your Organization have a TMF Plan for each Study?

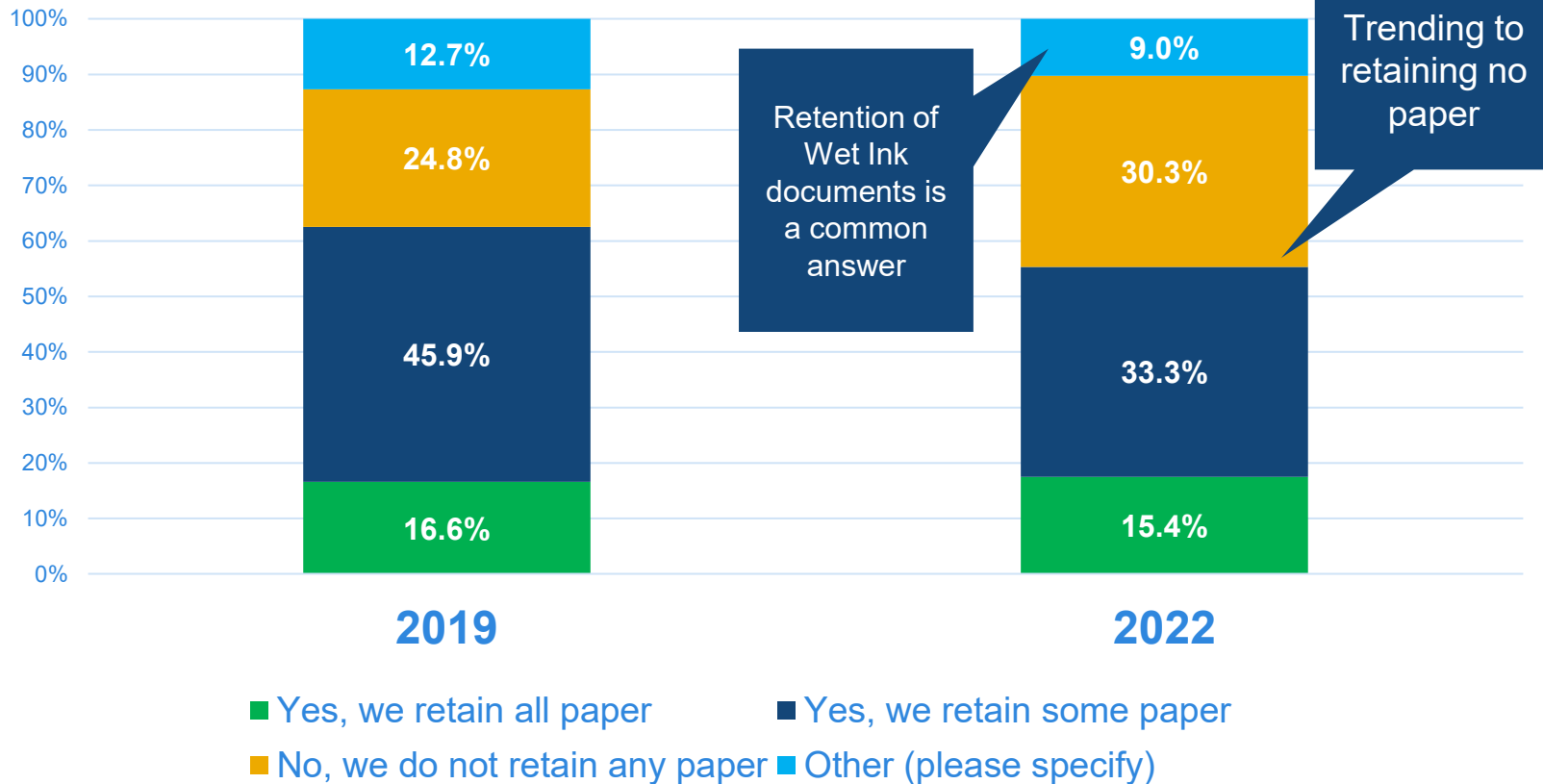


## Do you routinely capture / retain relevant e-mail communications in the eTMF?



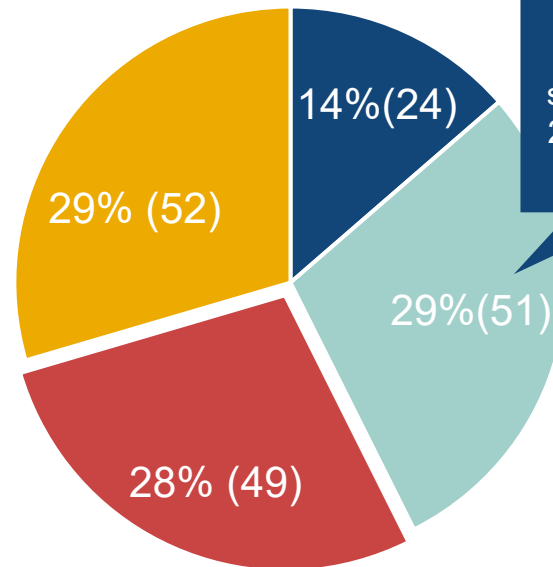


# Do you Retain Paper Content Scanned into your TMF?



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

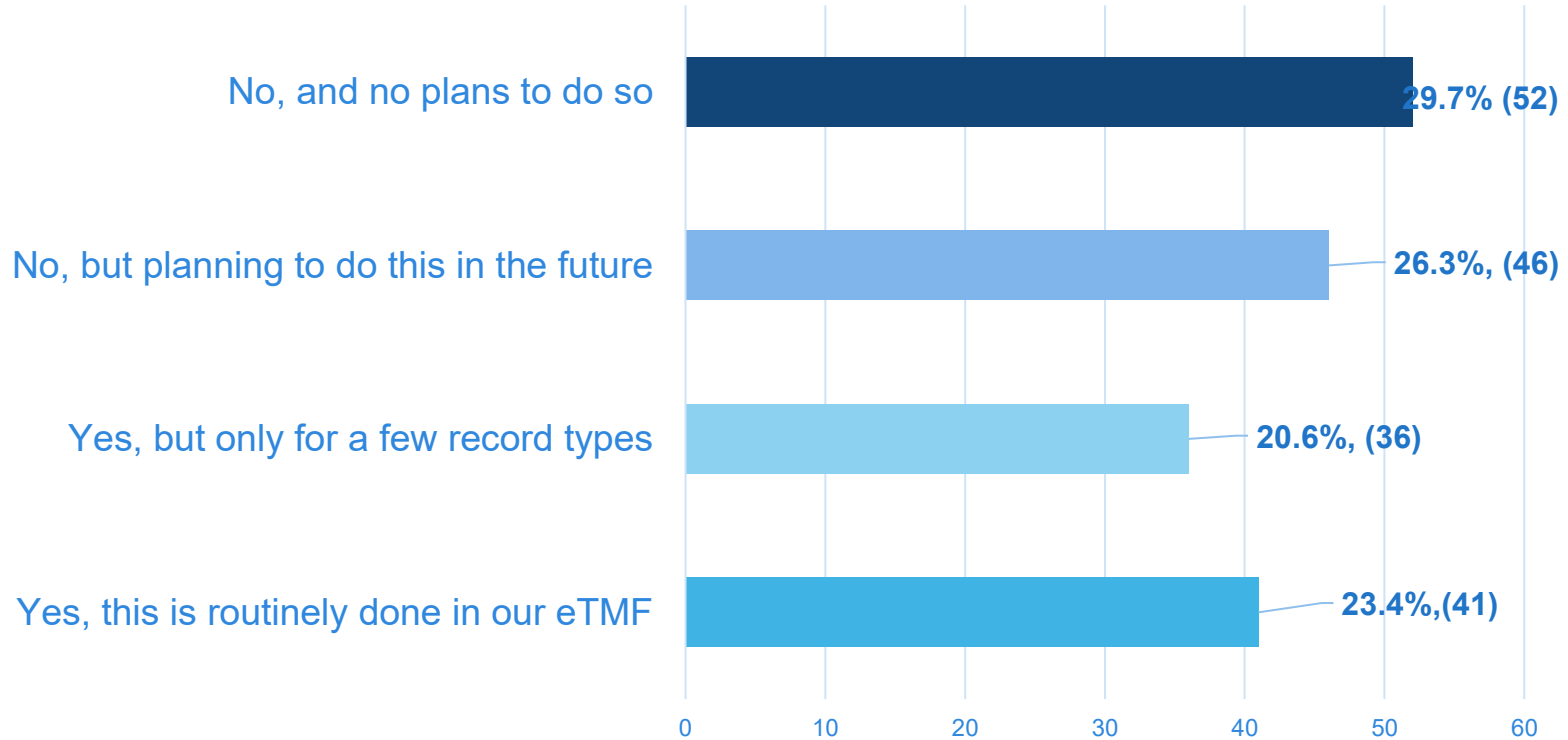
- Other
- We do not have a certified copy procedure
- We have a certified copy procedure that applies only when an original is irreversibly replaced



This had decreased significantly since 2019 when it was at 40.5%



## Does your Organization Author Documents in the eTMF?

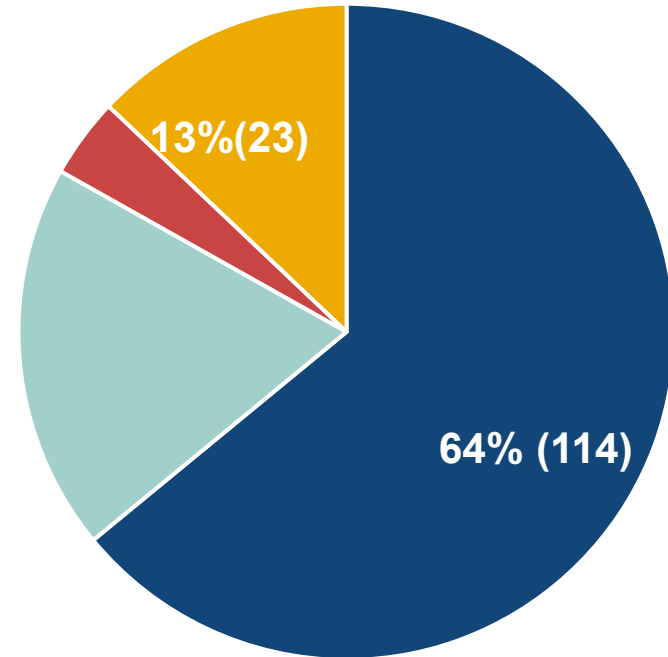


70% currently author in eTMF at some level or are planning to do so in future and about 30% do not and have no plans to author in future.

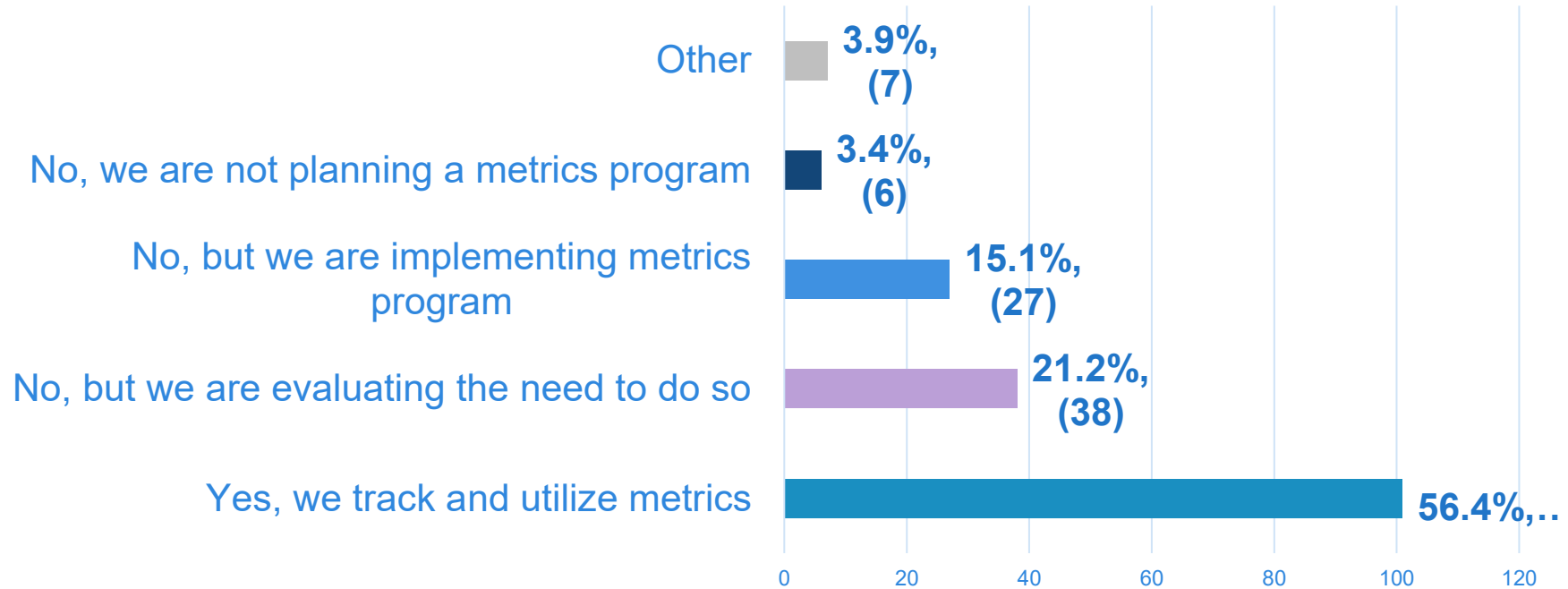


## Who is accountable for assessing the TMF completeness at your organization?

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



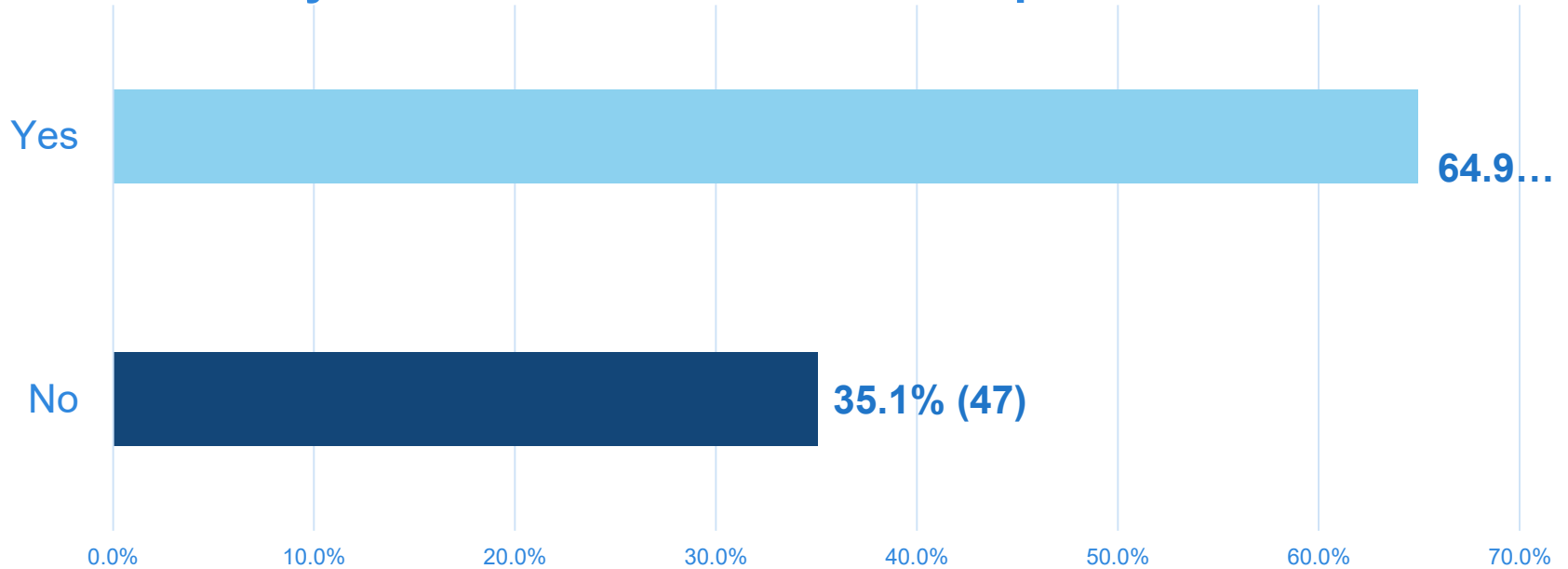
## Do you track and utilize TMF metrics in a systematic way (e.g. metrics program /measure TMF quality/efficiencies)?



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

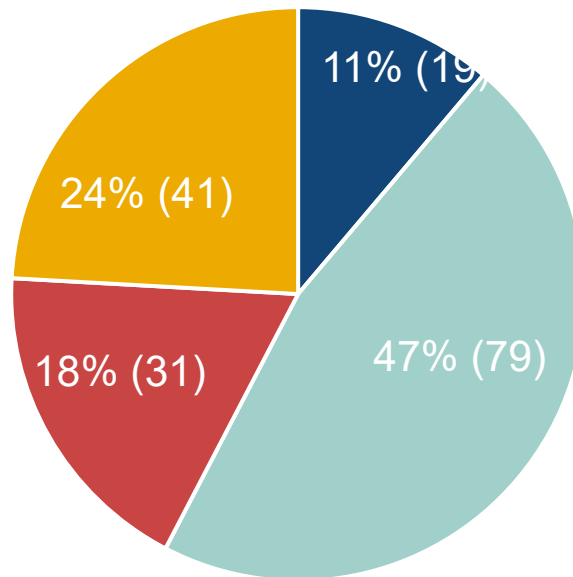


## Do you measure metrics on CRO performance?



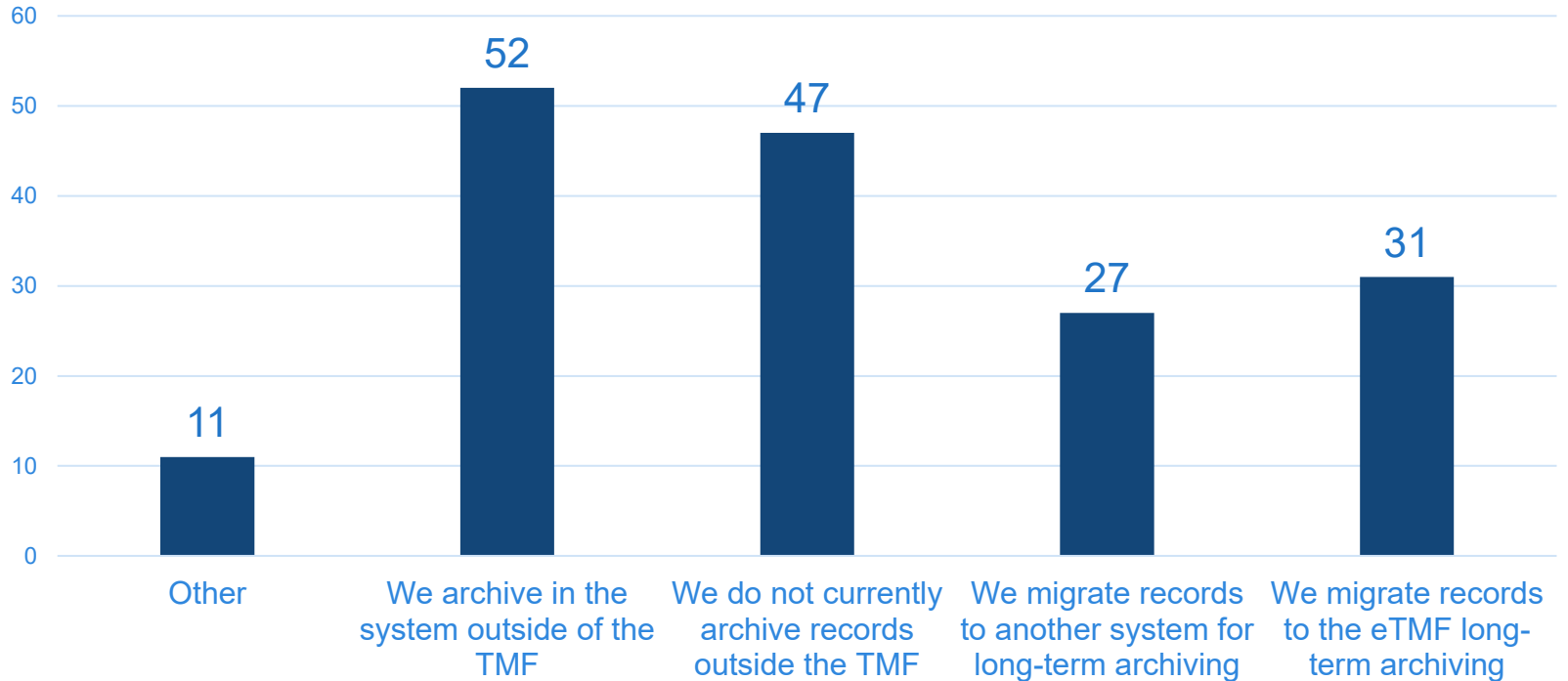
# How do you archive records in your eTMF?

- 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



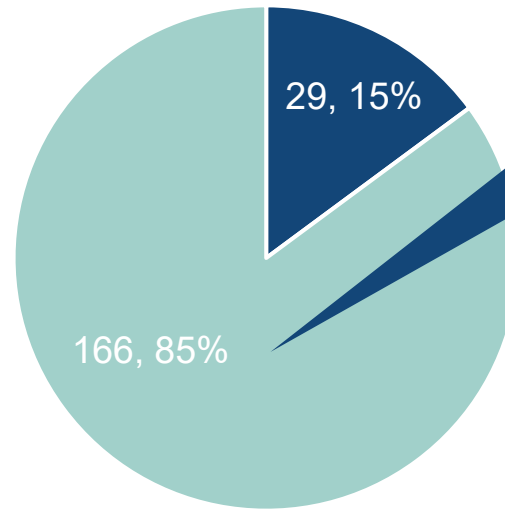
78% of respondents follow a formal TMF Archive process outlined in their company SOPs.

# 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?



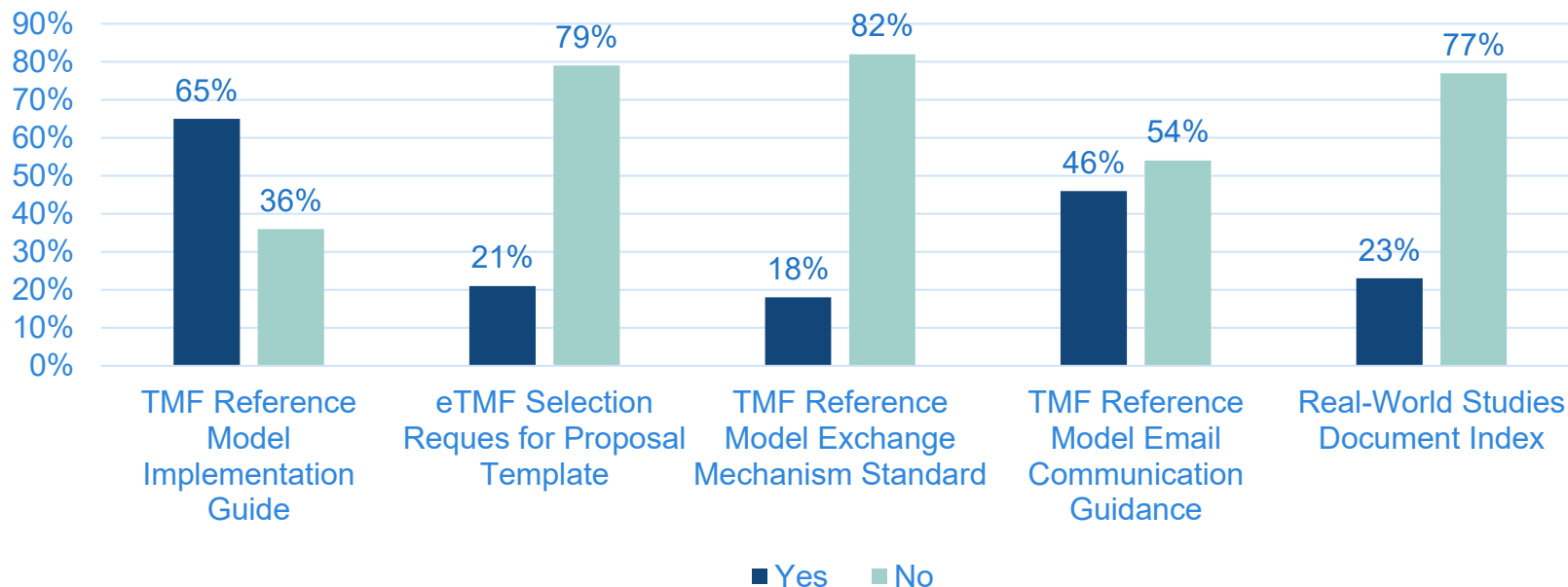
There remains a high percentage of you willing to contribute to ongoing development of the TMF Ref Model!

■ No ■ Yes



# Use of TMF RM Tools/Templates

Have you used these tools?

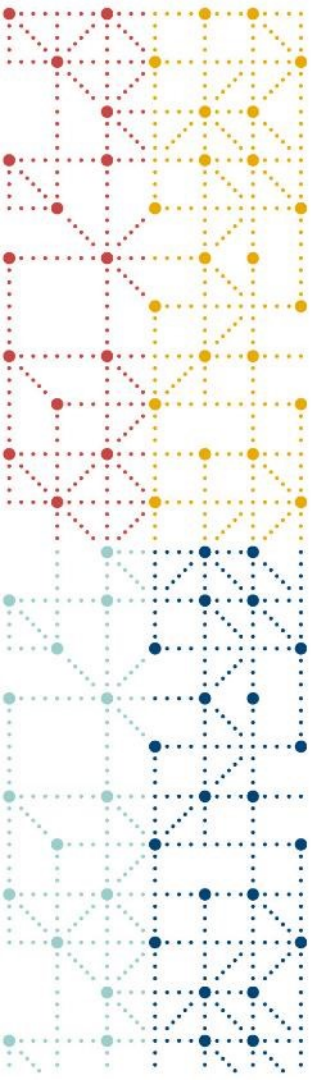


**Why not? Most common response was they didn't know it existed. A few commented they didn't have a need to use it and few didn't know or were not responsible for that part of the business.**

Here is a link to where you can locate these tools and templates:

<https://tmfrefmodel.com/resources>





**Thank You!**

