



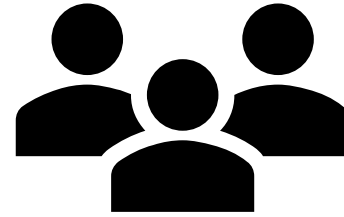
# **Trial Master File Reference Model**

## **TMF Reference Model 2019 Survey Overview**

David Ives

11 May 2020

# Overview of Respondents



307

Respondents

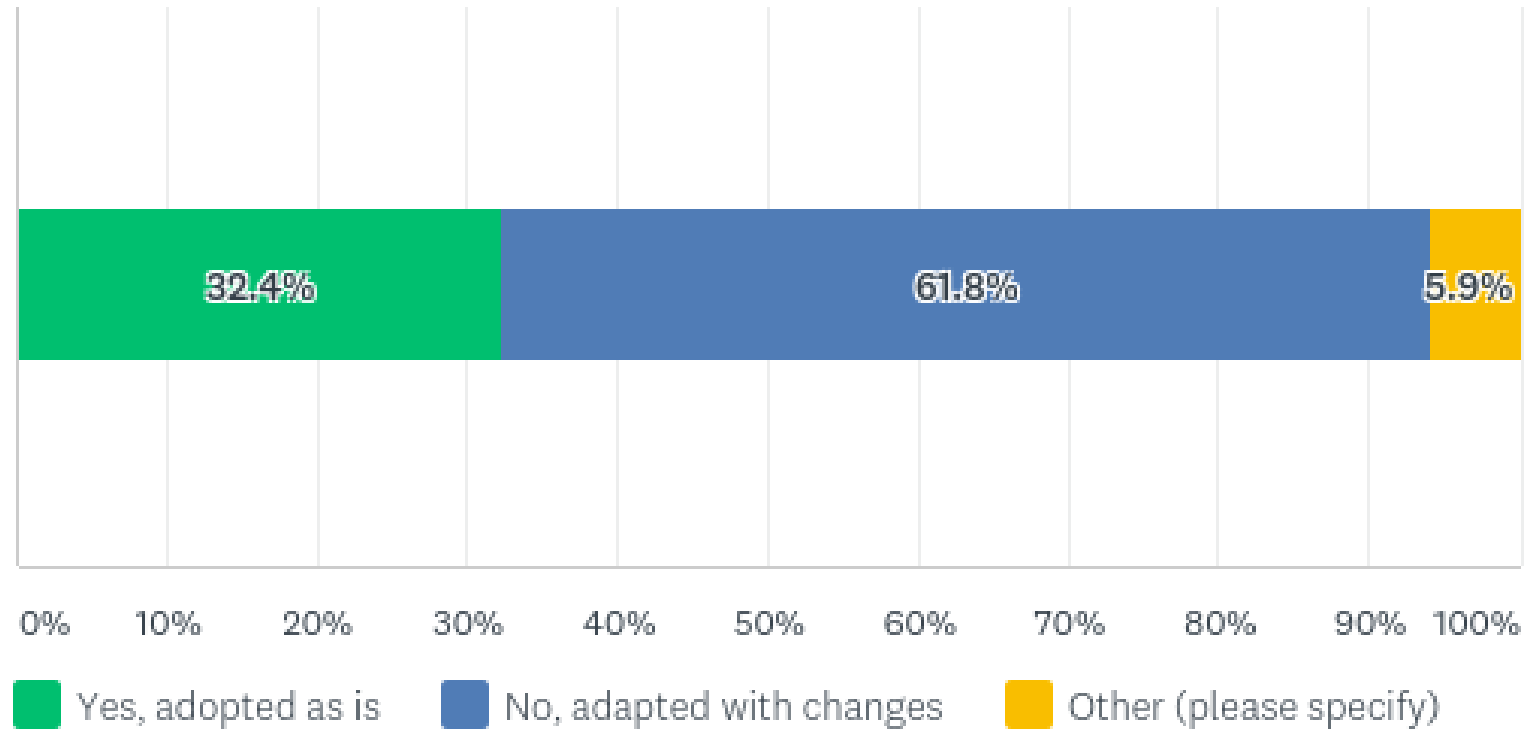


58% – US  
27% – EU  
8% – Asia Pacific  
5% – Canada  
1% – Africa  
1% – Latin America  
<1% – Middle East

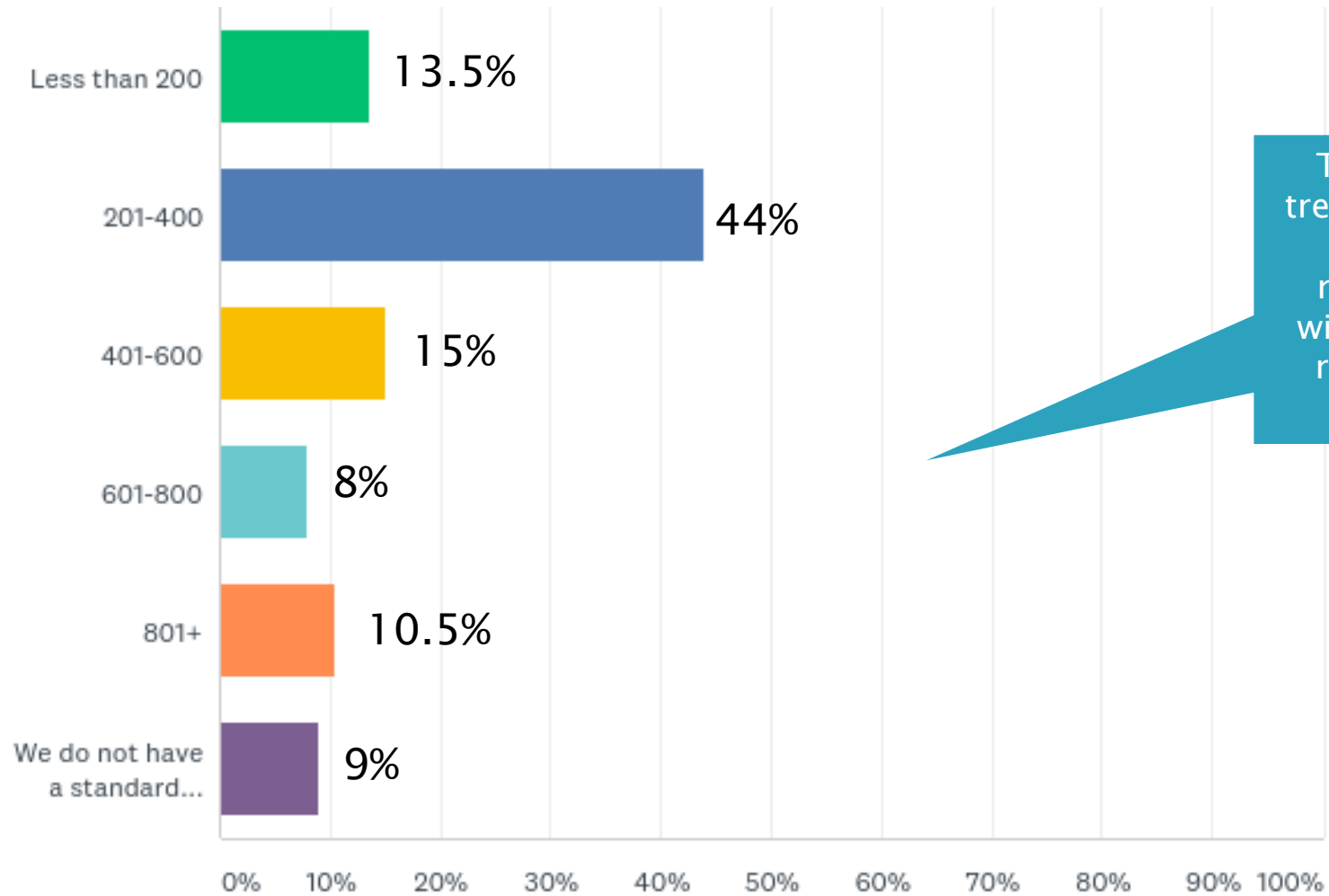
55% – Sponsor  
23% – CRO  
9% – Vendor  
8% – Consultant  
3% – Other  
1% – Site



Has your organization adopted the Model as is, without any change?

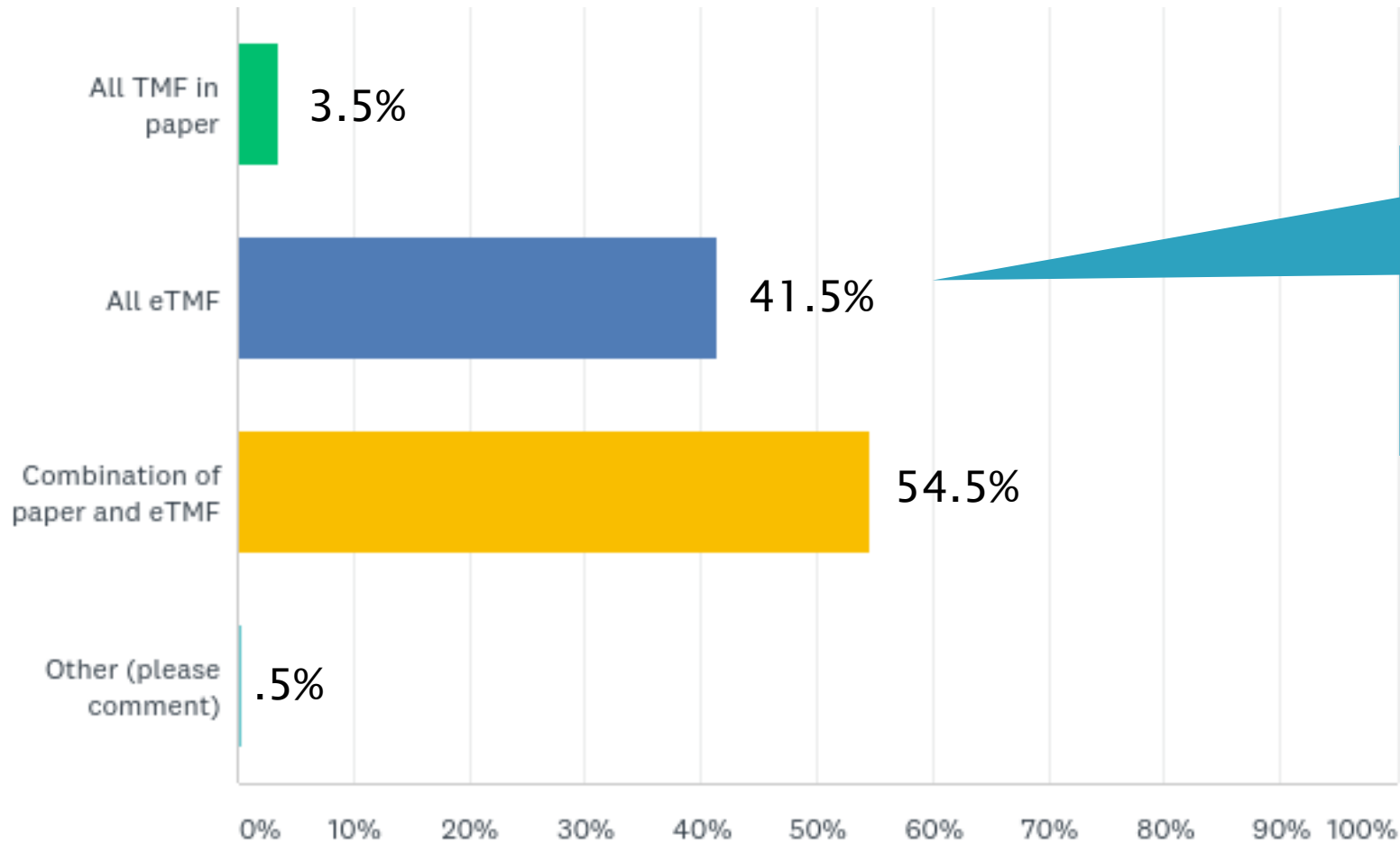


How many document types or artifacts are identified in your index / table of contents?  
In other words, how many unique document types or artifacts?



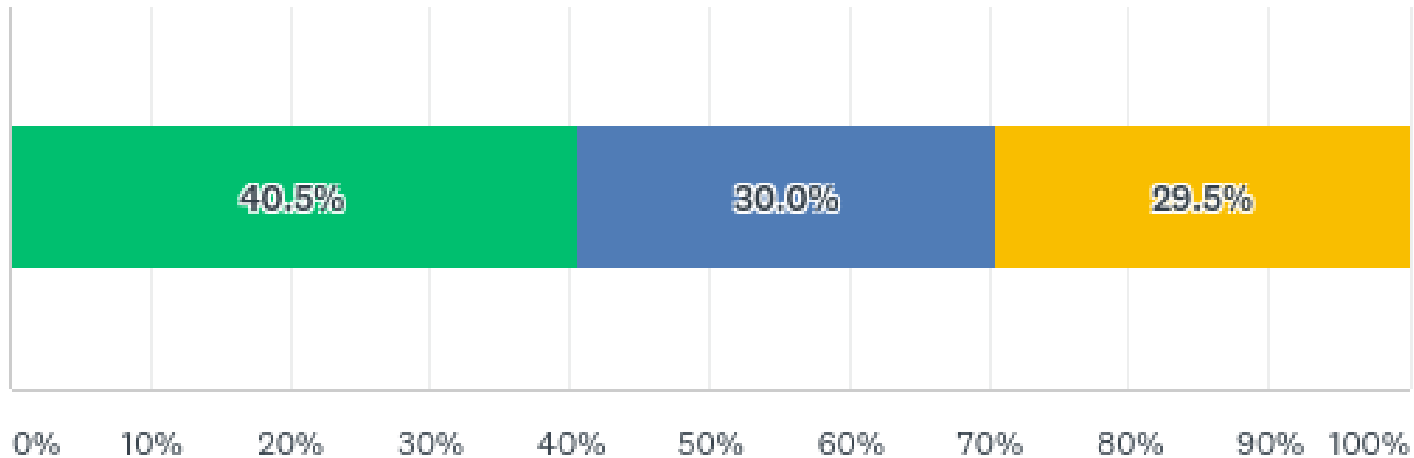
There continues to be a trending increase in unique artifacts although the number of respondents within the 201-400 range remains consistent with prior years .




## What format is your TMF of record?



**150%** Increase in all eTMF operations since the last survey!

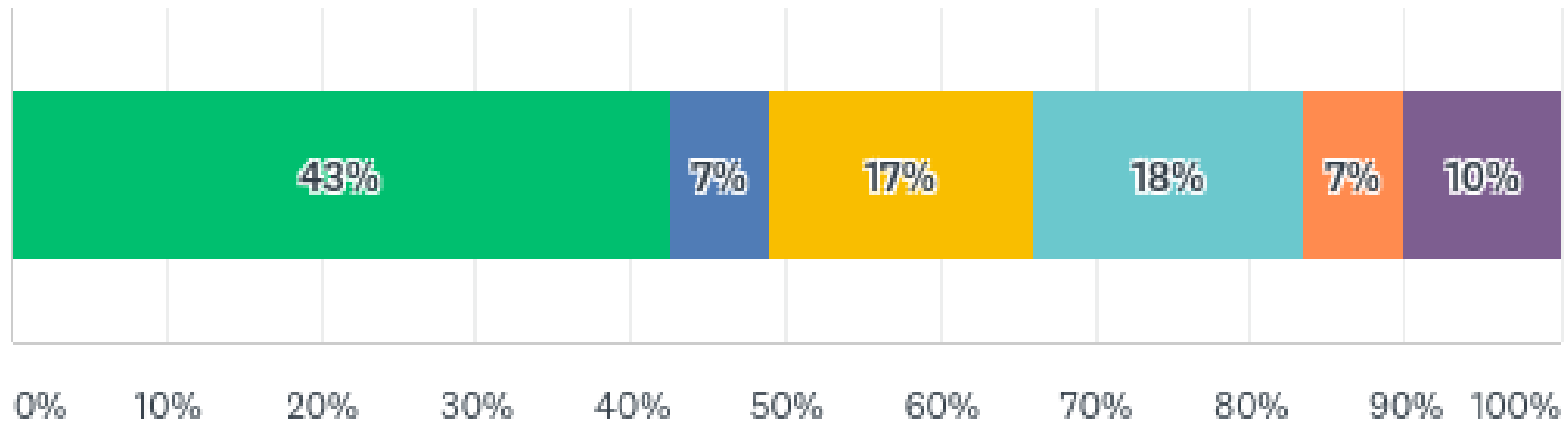
## How does your organization approach certified copy requirements?



	We do not have a certified copy procedure	40.5%
	We have a certified copy procedure that applies to any document filed to the TMF that was not created in the TMF	30.0%
	We have a certified copy procedure that applies only when an original is irreversibly replaced	29.5%

Approach to certified copies remains quite varied

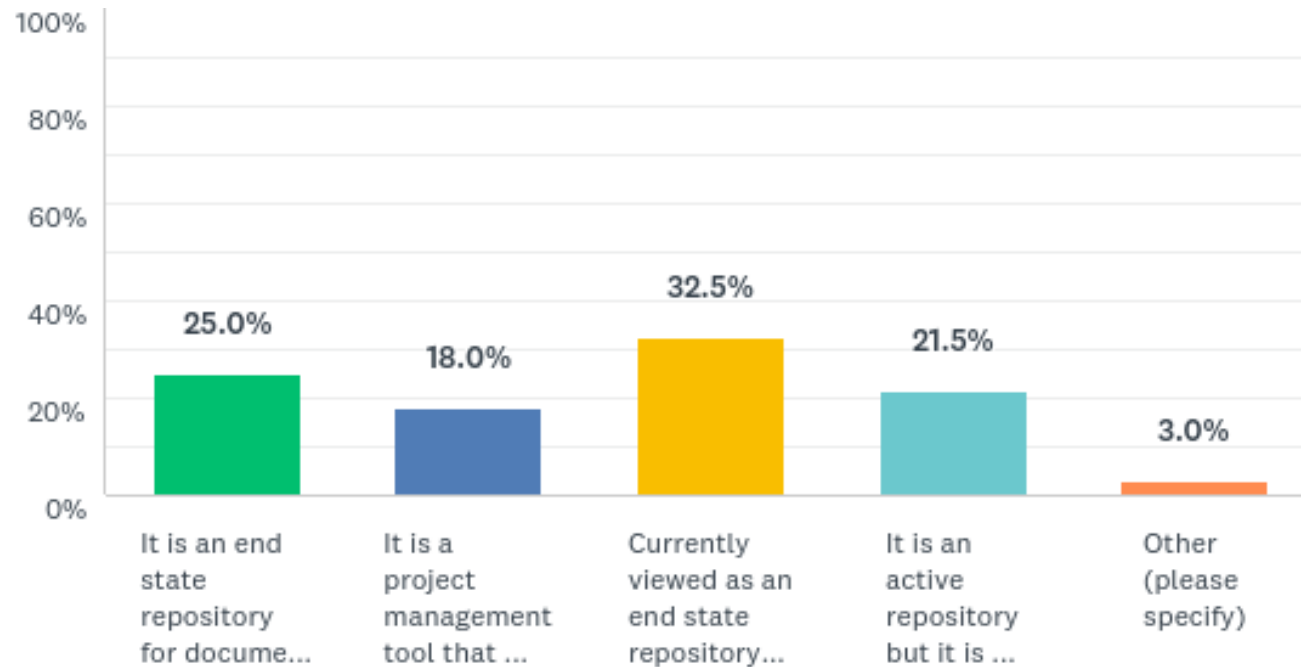
# How does your organization manage draft documents in the TMF as part of your change control process?



We do not retain any draft documents in the TMF	43%
We would only retain draft documents if the final was missing	7%
We maintain evidence of change control in other systems e.g. collaboration tools	17%
Our eTMF is a collaboration tool and maintains drafts of many documents as minor versions	18%
Our eTMF is a collaboration tool but minor versions are purged once a document is finalized.	7%
Other (please specify)	10%

Still relatively few utilize eTMF for collaboration

# Overall what is your organizational view of TMF? (please select the one that most closely aligns)

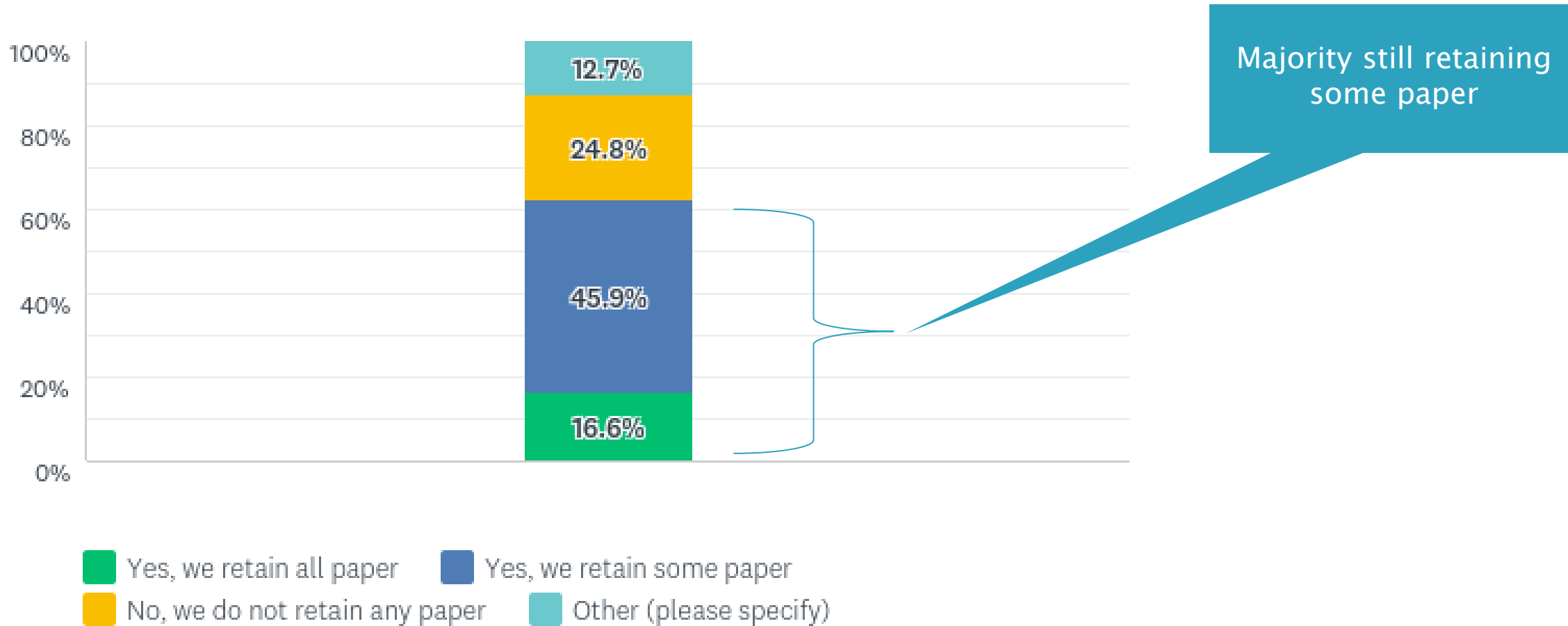


Majority still working toward eTMF being supportive of study management

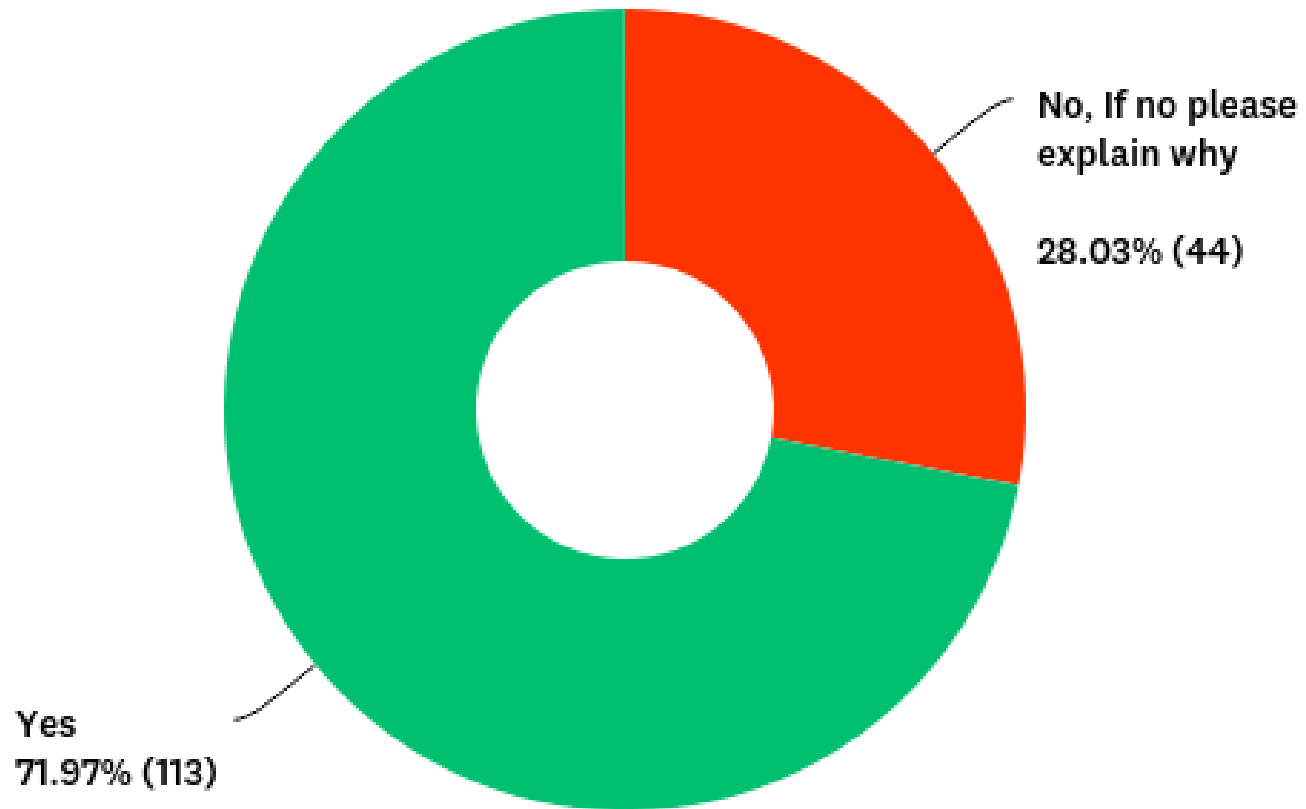
It is an end state repository for documents to meet compliance	25.0%
It is a project management tool that is used to support efficient and effective study management	18.0%
Currently viewed as an end state repository but we are working toward it being project management tool	32.5%
It is an active repository but it is not used to support efficient and effective study management	21.5%
Other (please specify)	3.0%



# Do you retain paper content scanned into your eTMF?

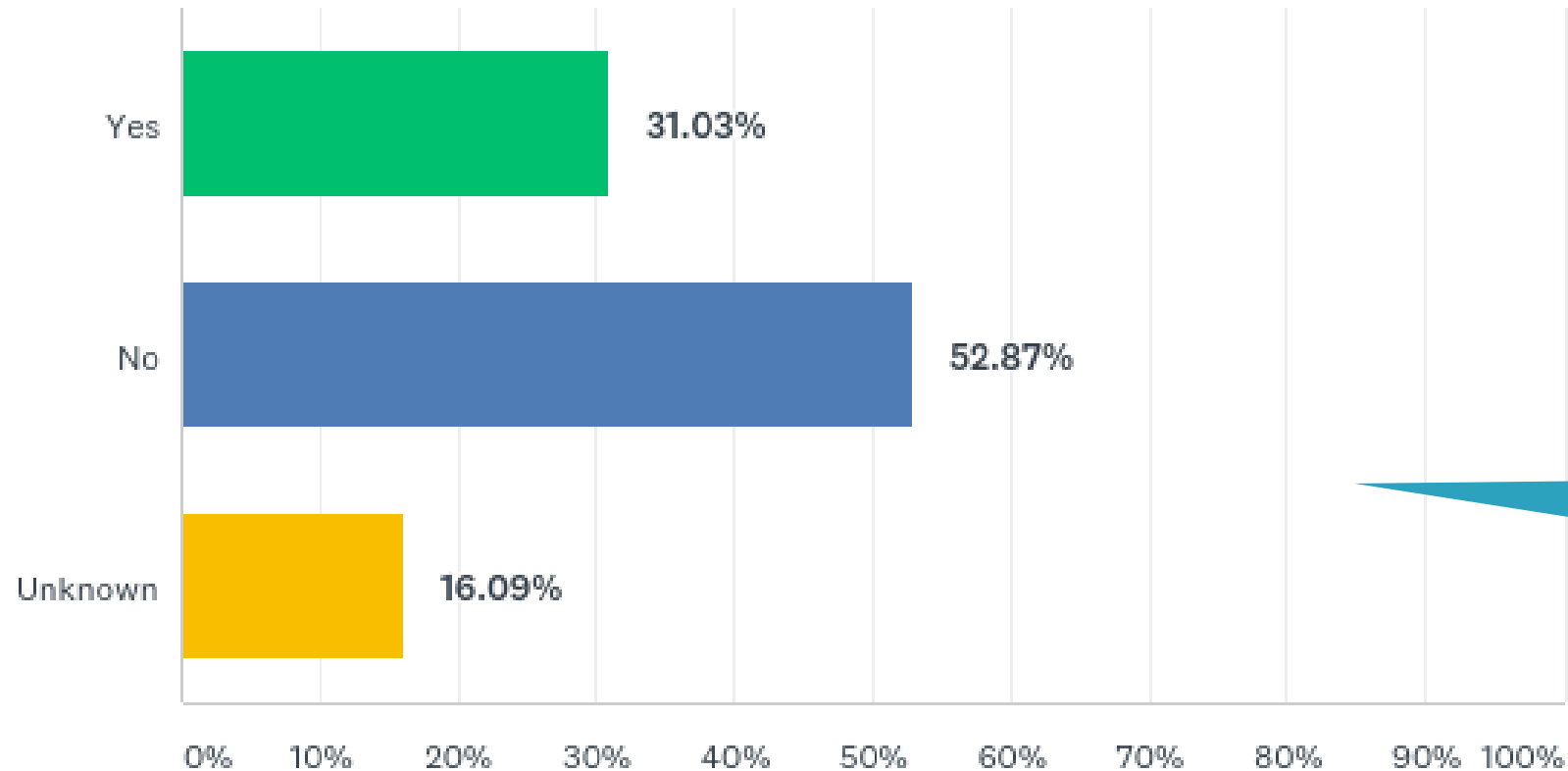


## Do you maintain blinded records in your eTMF?



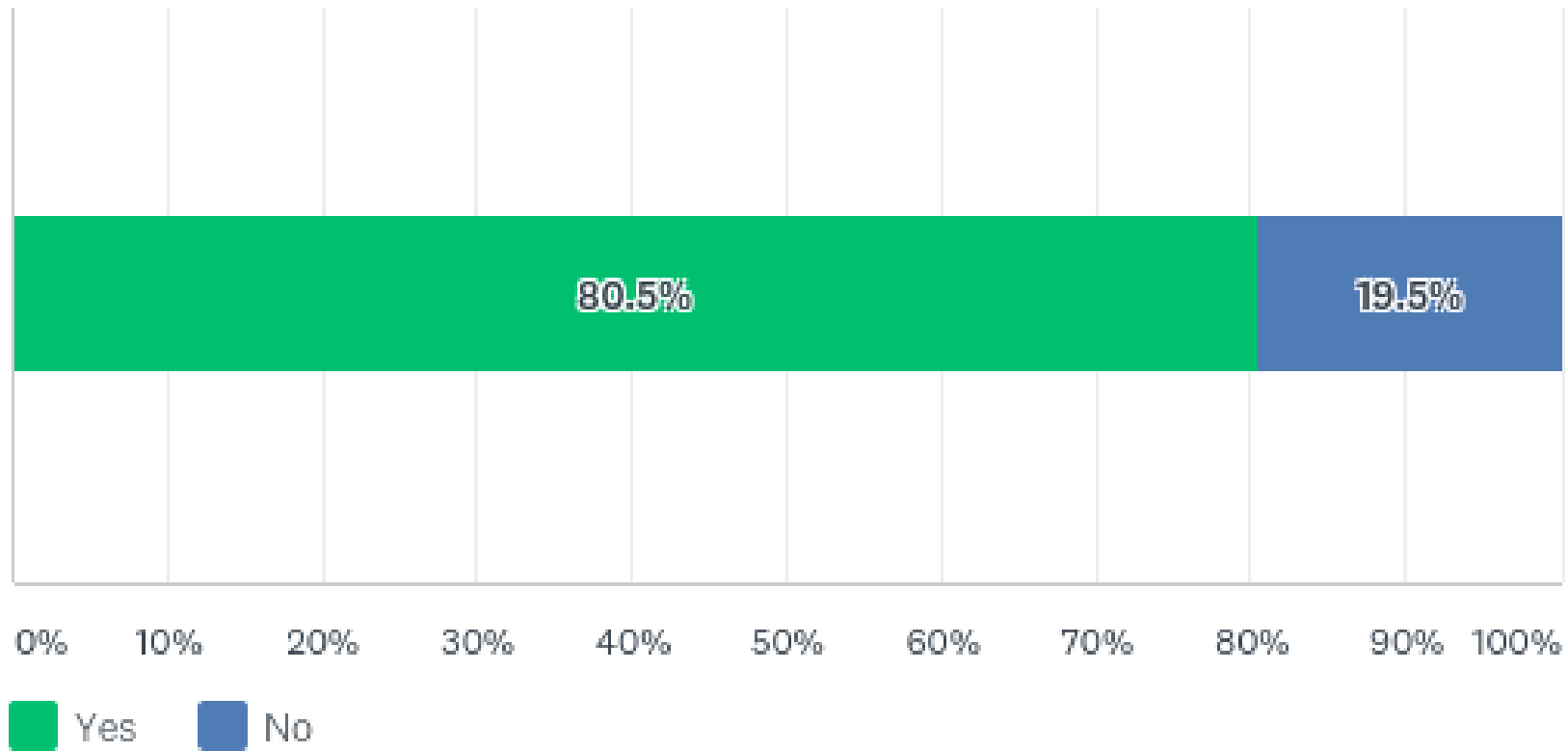
The primary reasons listed for not filing blinded records in eTMF was related to not comfortable with risk and system security or workflows

Have you had a remote (off-premise) inspection by any regulatory agency / health authority where the agency conducting the inspection remotely from their office?

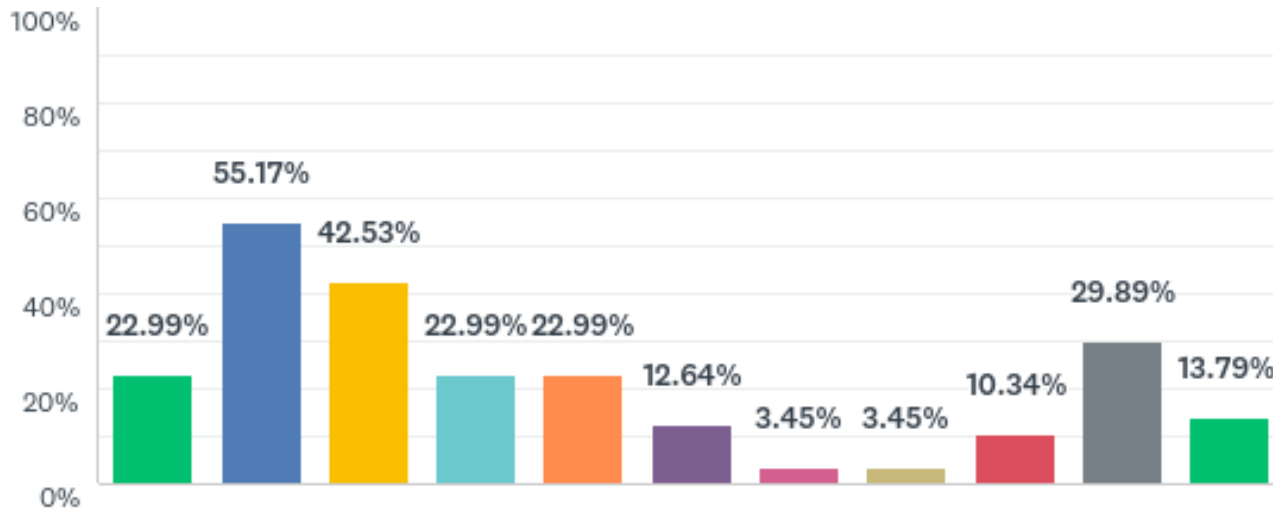


COVID-19 Impact will continue to accelerate the shift

Do you require inspectors to complete training prior to issuing credentials?

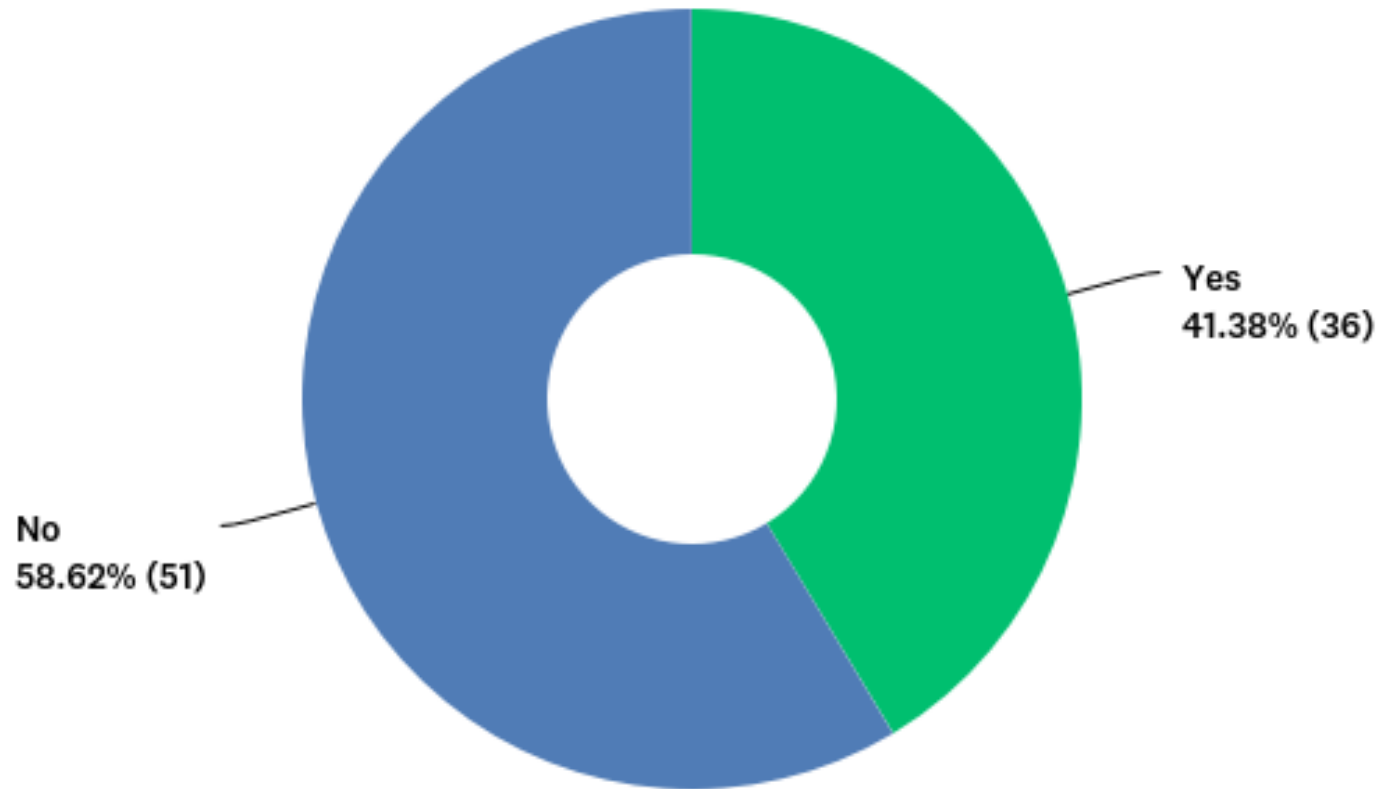


Please share some insight regarding the types of findings you have received following an Audit/Inspection using your eTMF or (select all that apply)

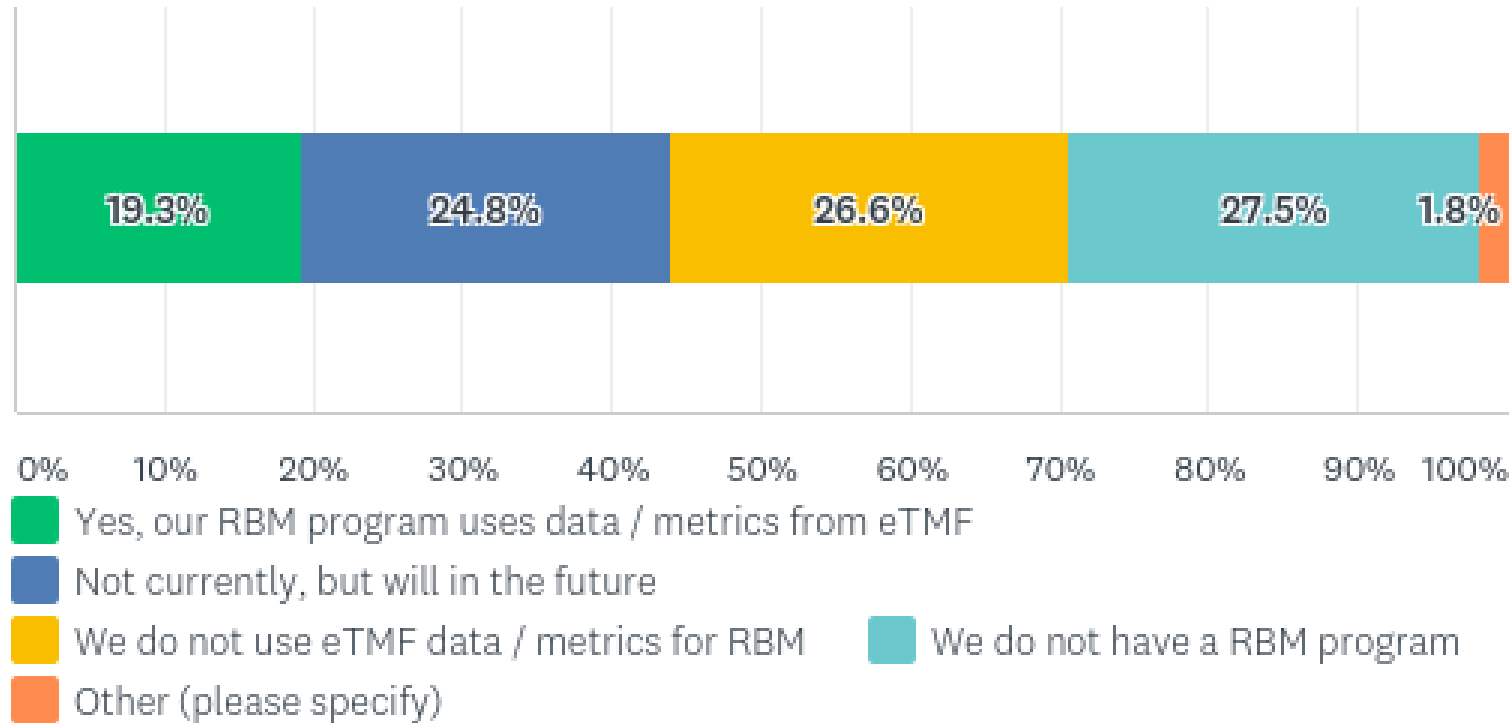


Not Applicable (no findings or findings not yet received)	22.99%
Finding regarding TMF Completeness	55.17%
Finding regarding TMF Timeliness (i.e. non contemporaneous TMF)	42.53%
Finding regarding TMF Quality (document content)	22.99%
Finding regarding eTMF Quality (e.g. metadata or formatting)	22.99%
Finding regarding eTMF System navigation	12.64%
Finding regarding eTMF System access	3.45%
Finding regarding eTMF System training	3.45%
Finding regarding TMF Filing Structure used	10.34%
Finding regarding CRO Oversight	29.89%
Other (please comment)	13.79%

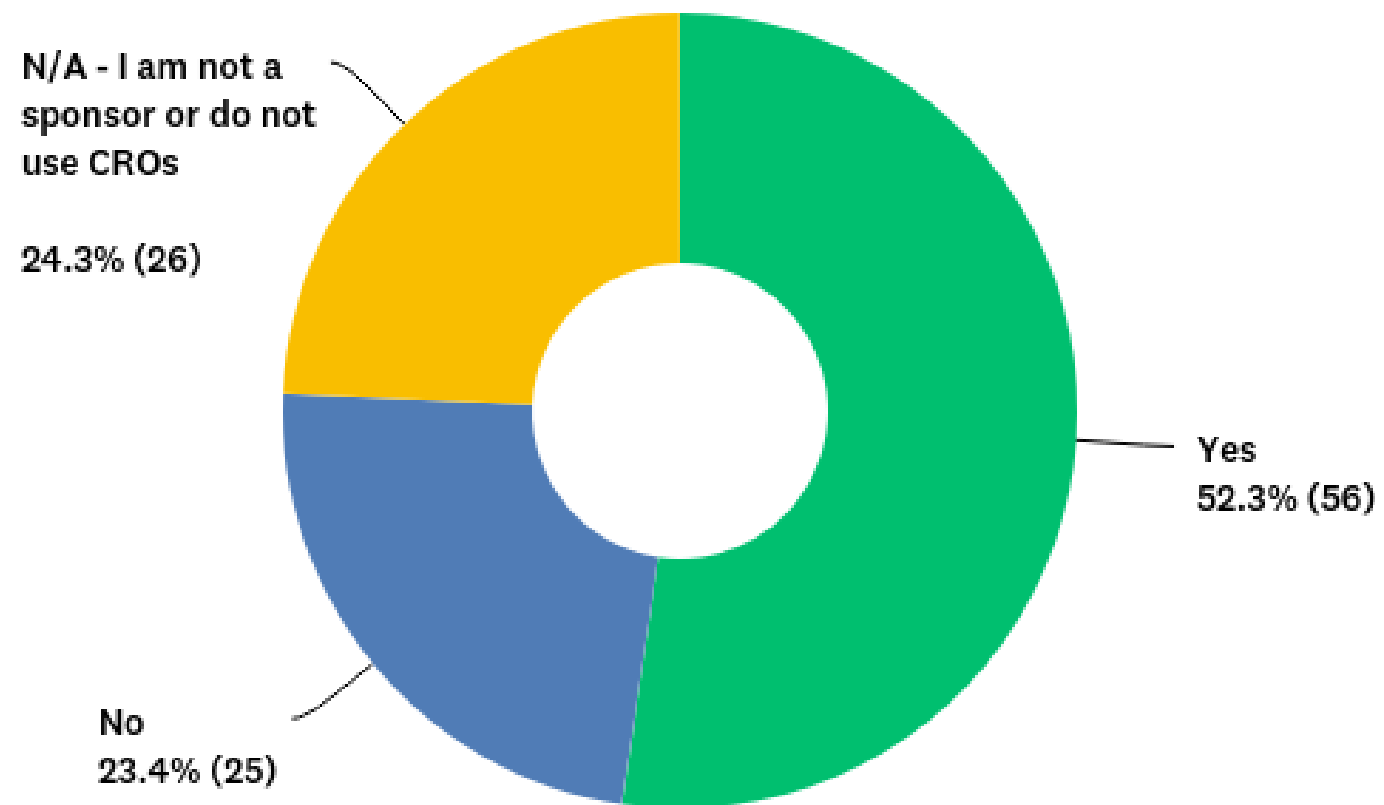
Have you undergone a joint inspection with a partner (sponsor/CRO) where both organizations were equally subject of the inspection?



## Is eTMF data or metrics used by your Risk Based Monitoring (RBM) program?



## Do you measure metrics on CRO performance too?





# Questions?