

TMF Reference Model

Topline results of 2015 TMF Survey #5

September 2015

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TMF Survey Sub-team

Trial Master File (TMF) Survey Background

- TMF Survey purpose: industry-wide, gather insight into quality, cost and effectiveness drivers of TMF management, including:
 - Knowledge and use of TMF Reference Model
 - TMF management pain points
 - Paper vs electronic TMF
- Data for the 2015 was collected from May to July 2015
- This TMF Survey has been conducted as an initiative of the TMF Reference Model (TMF RM) and is performed annually. The TMF RM committee and leadership operate in coordination with the EDM Reference Model as initiatives of the Document and Records Management (DRM) Community in the DIA

Report Sections

- Respondent Demographics
- TMF / eTMF Insights
- TMF Metrics
- TMF Reference Model Use
- Inspection Trends
- electronic Investigator Site File (eISF)

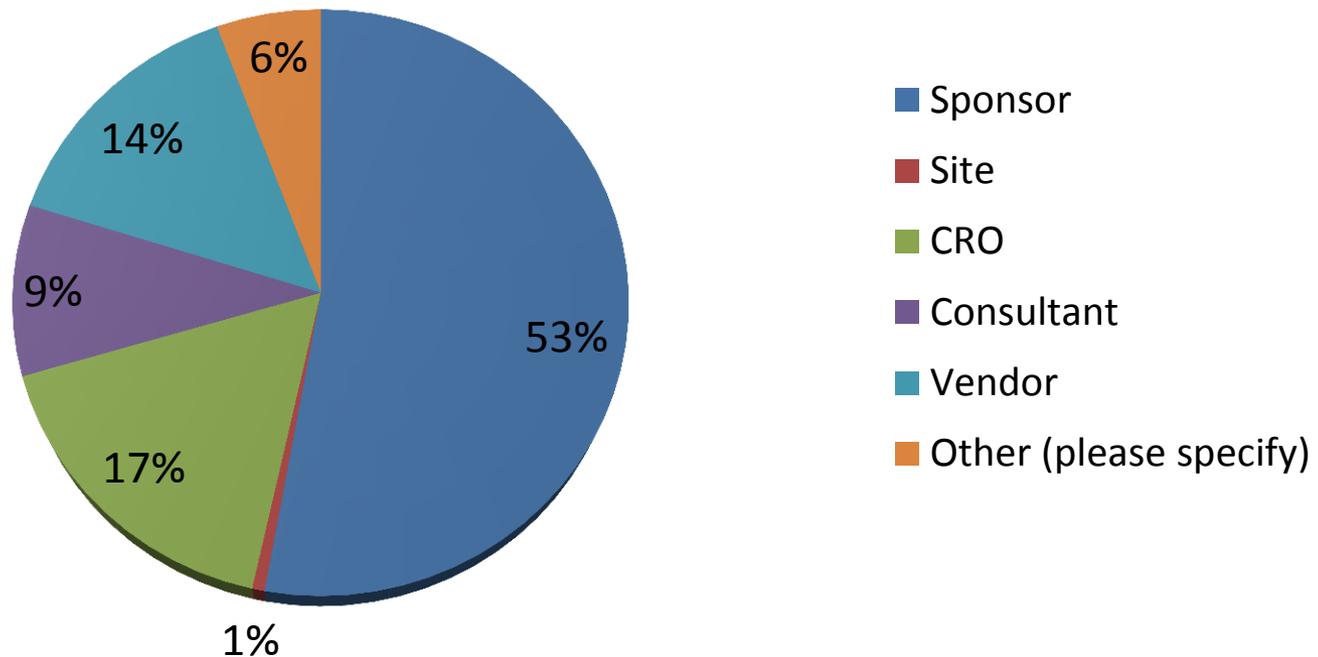


RESPONDENT DEMOGRAPHICS

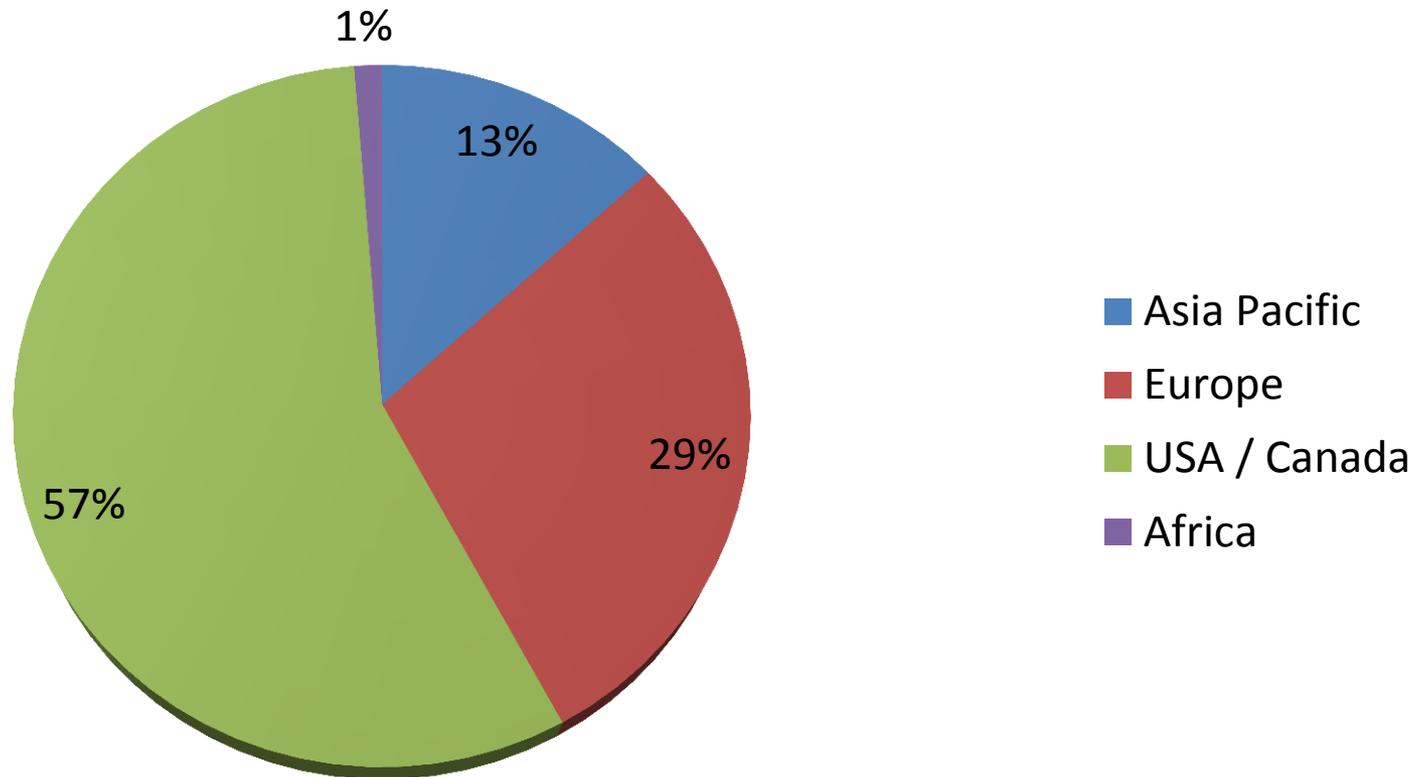
Respondent Organization Type

- 159 Evaluable Responses
- Sponsor organizations majority respondents (53%)

Your organization type:

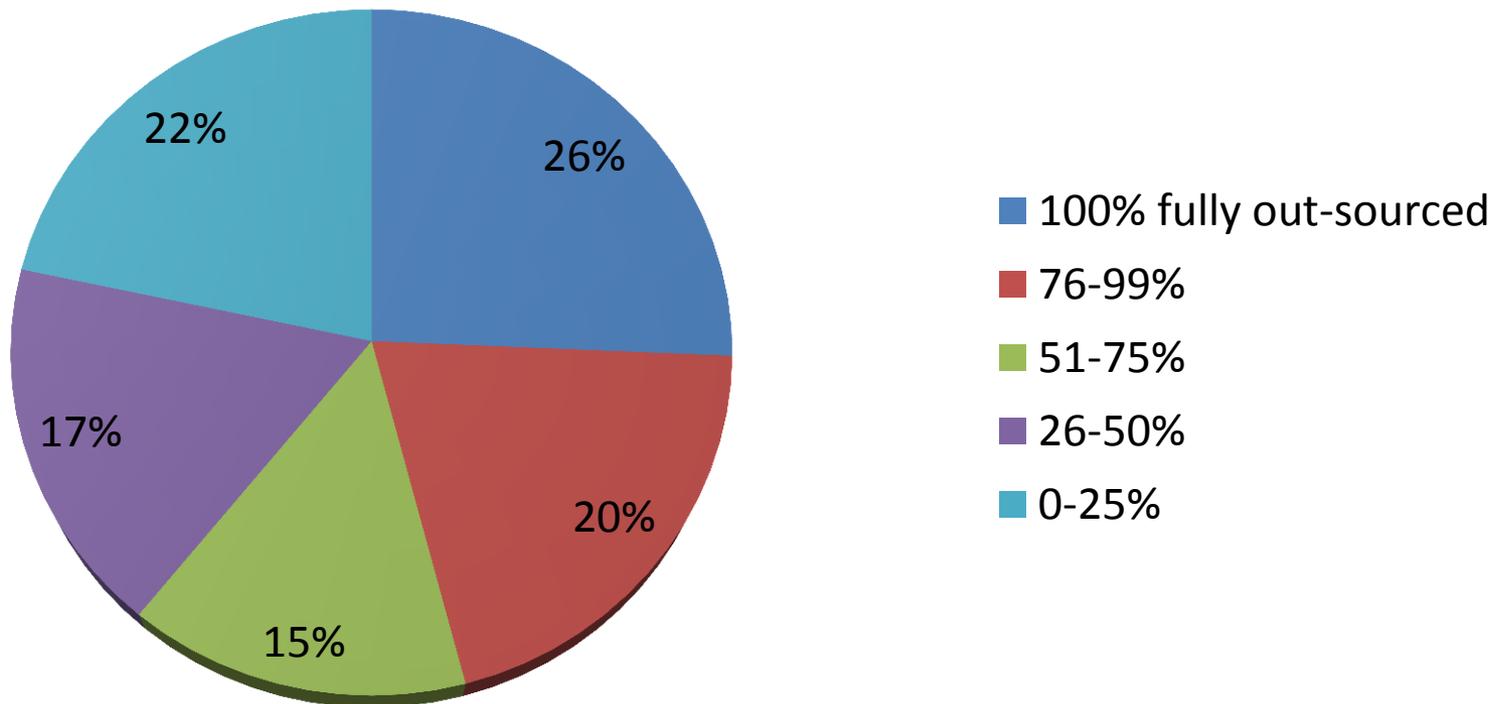


Where are you located?



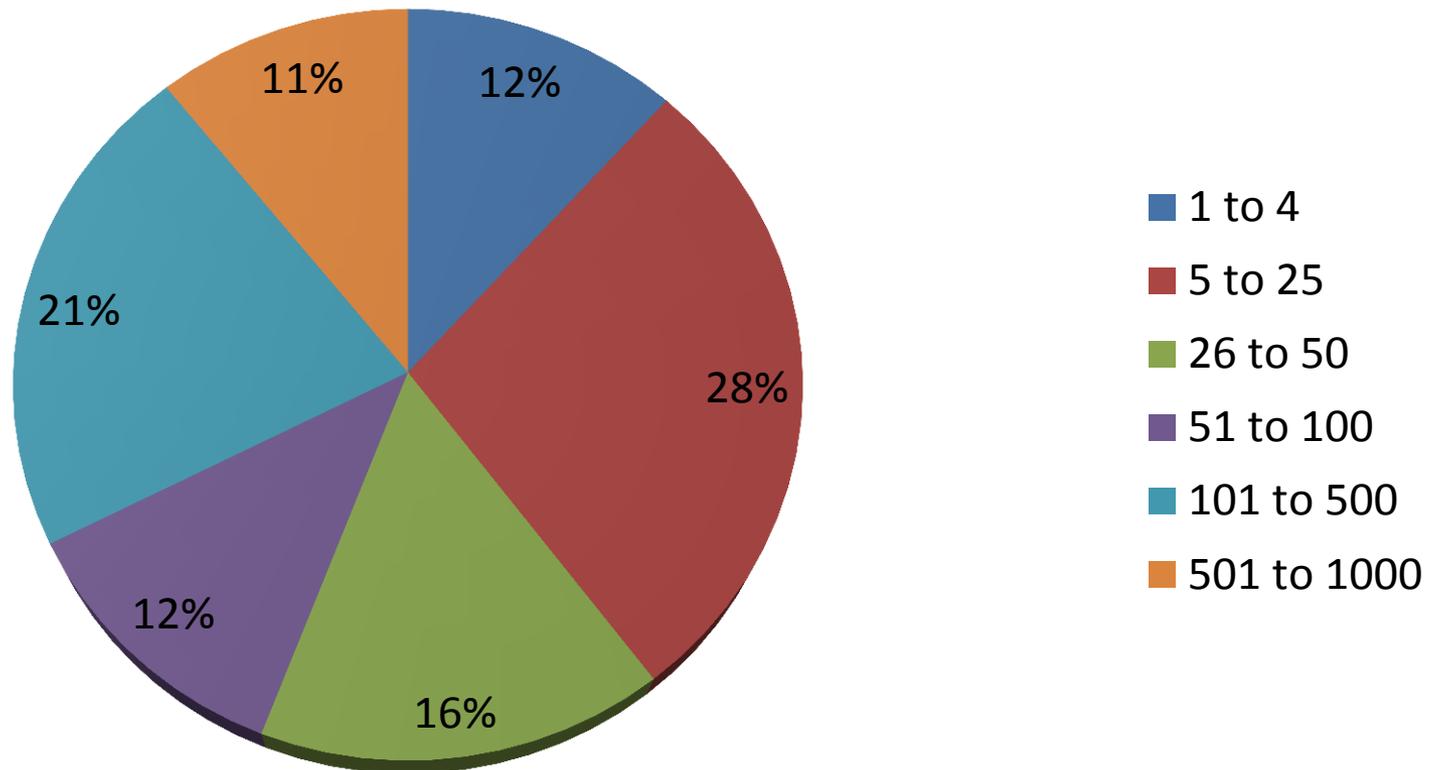
Trial Outsourcing Profile

What percentage of current Phase II/III trials are fully outsourced to CROs? (select closest percentage)



Active Trials

Indicate the number of active trials at your organization

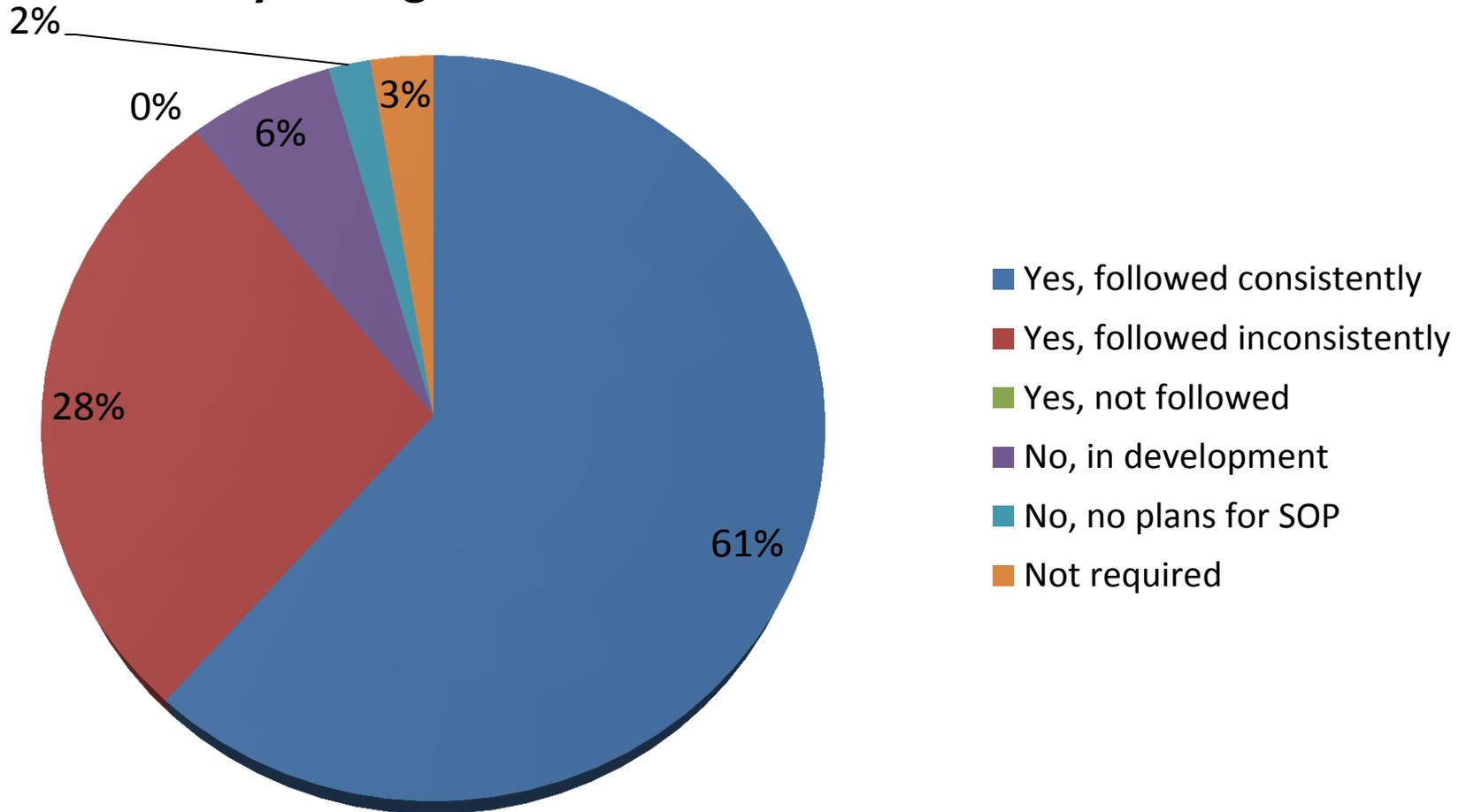




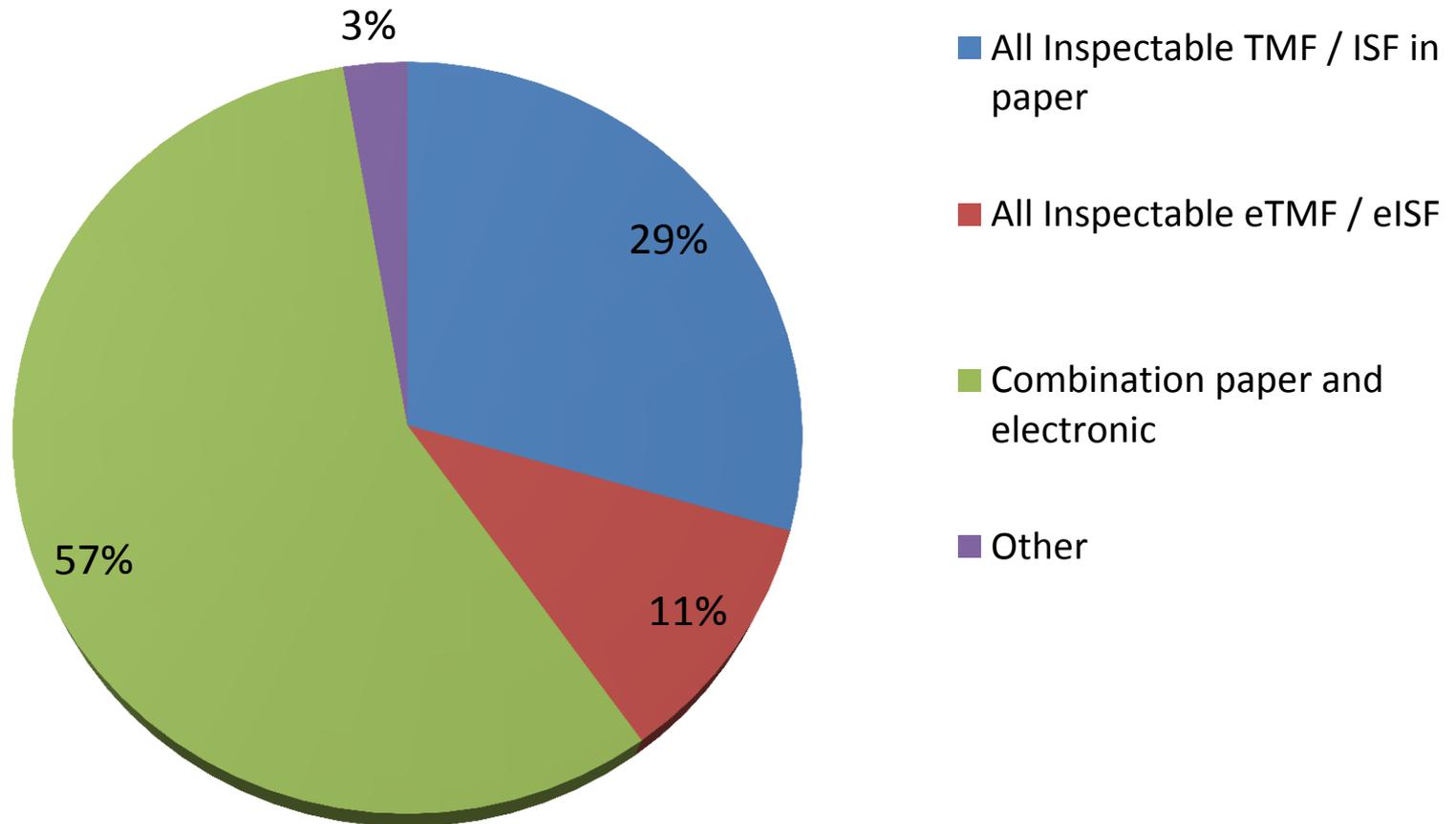
TMF / eTMF INSIGHTS

TMF SOP Adherence

Does your organization have and follow a TMF SOP?

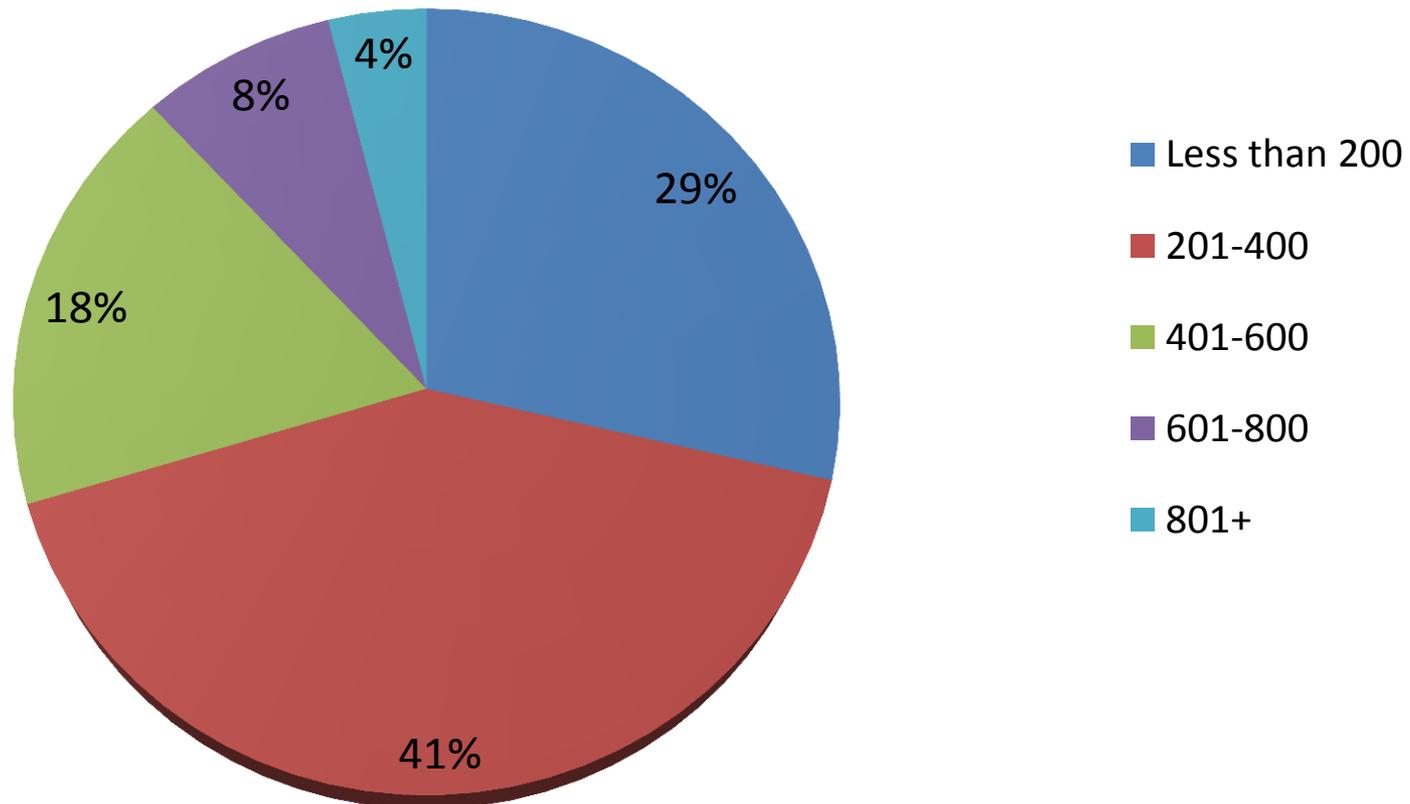


What format is your file of record?



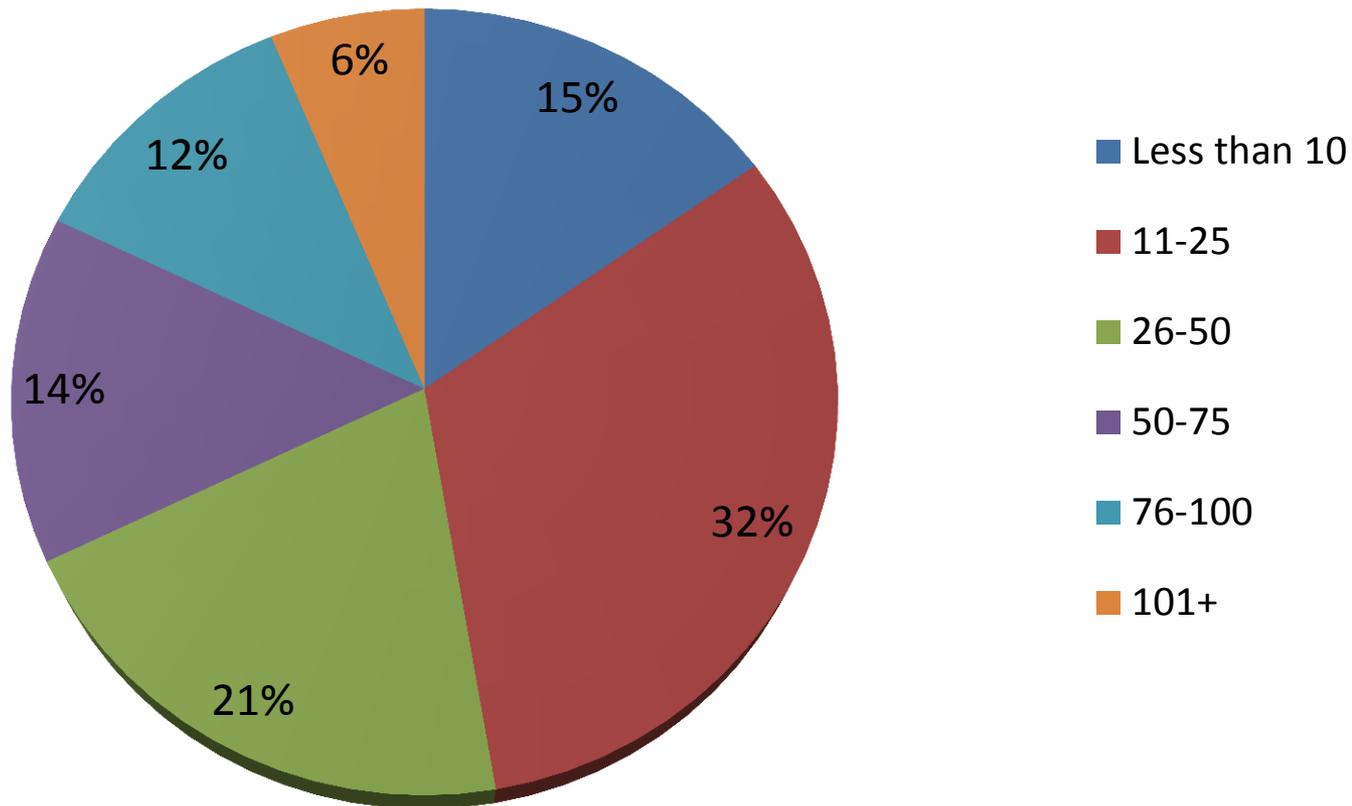
Numbers of unique artifacts

How many record types in the index / table of contents?

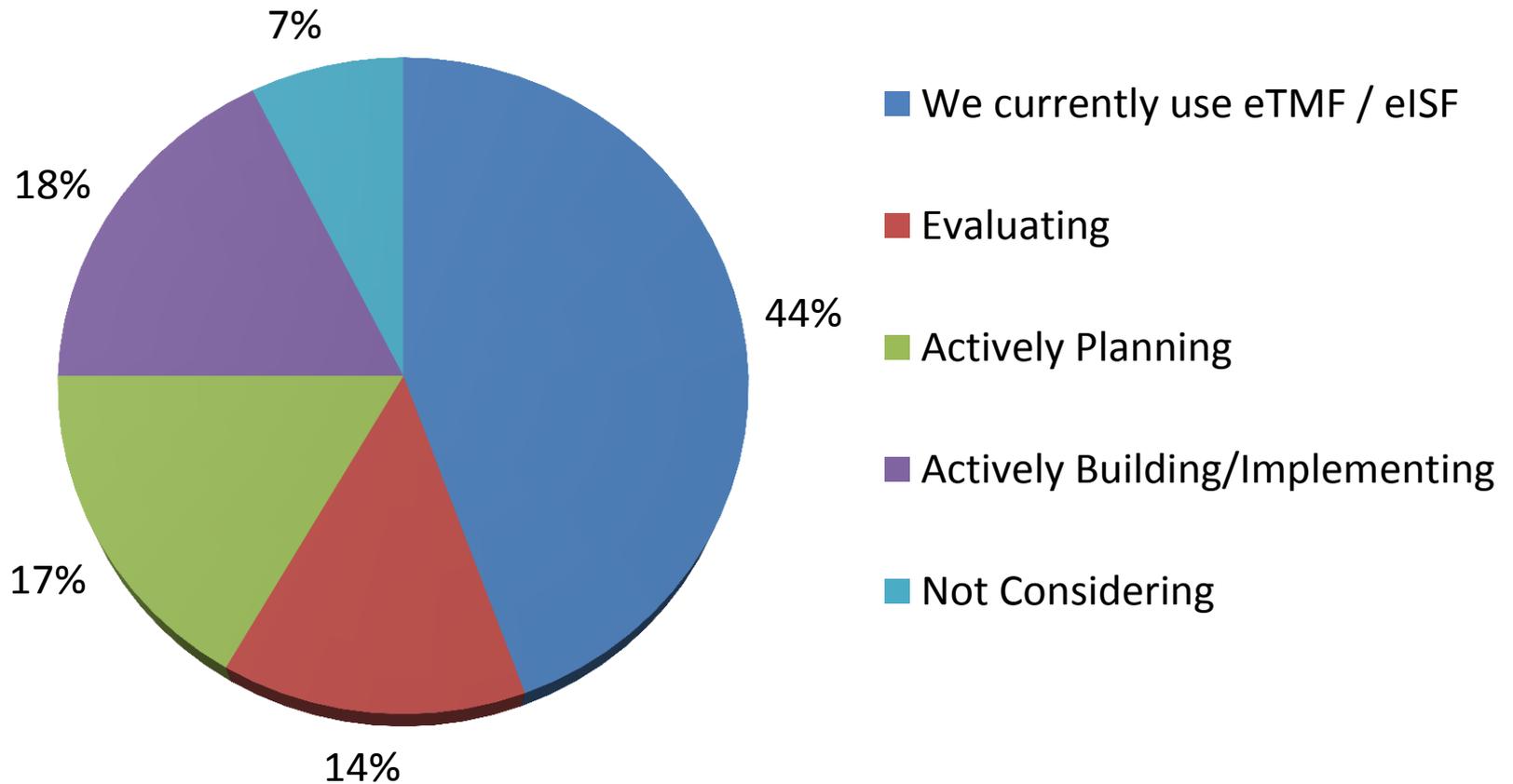


Documents requiring signature

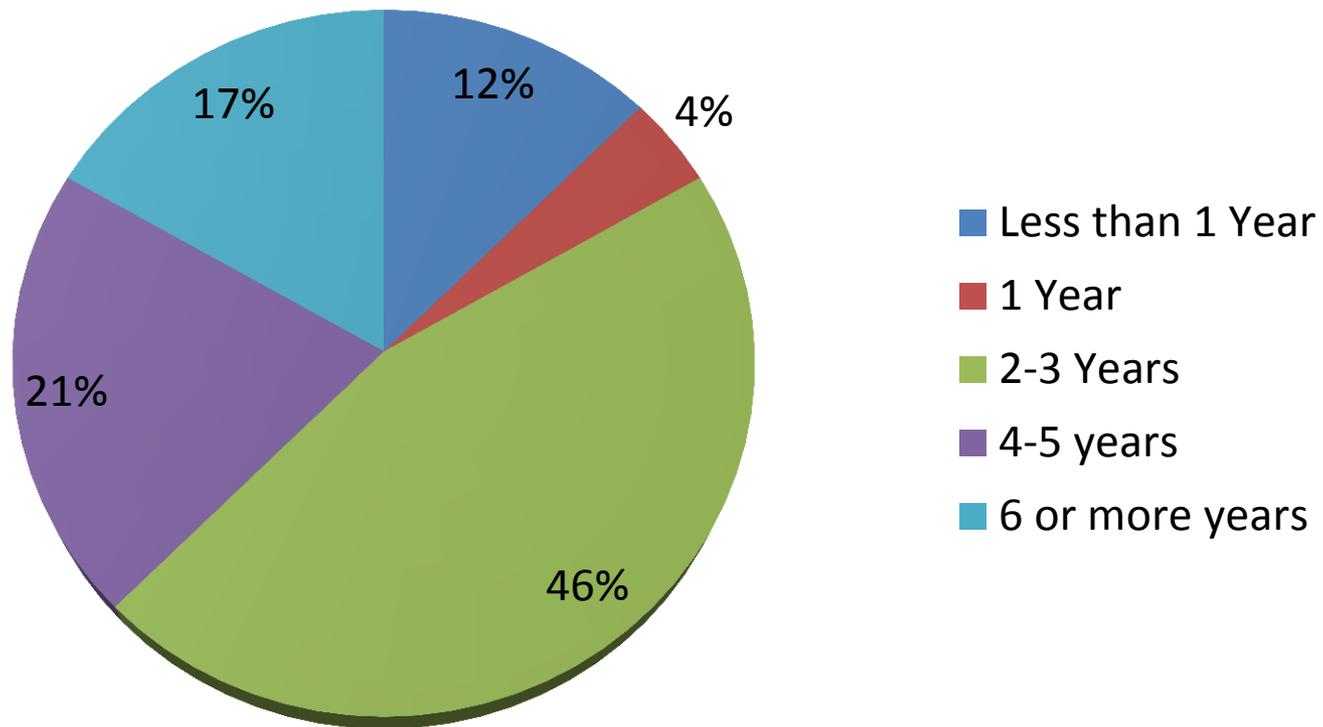
How many unique content types must be signed?



What is the status of your organization's eTMF?

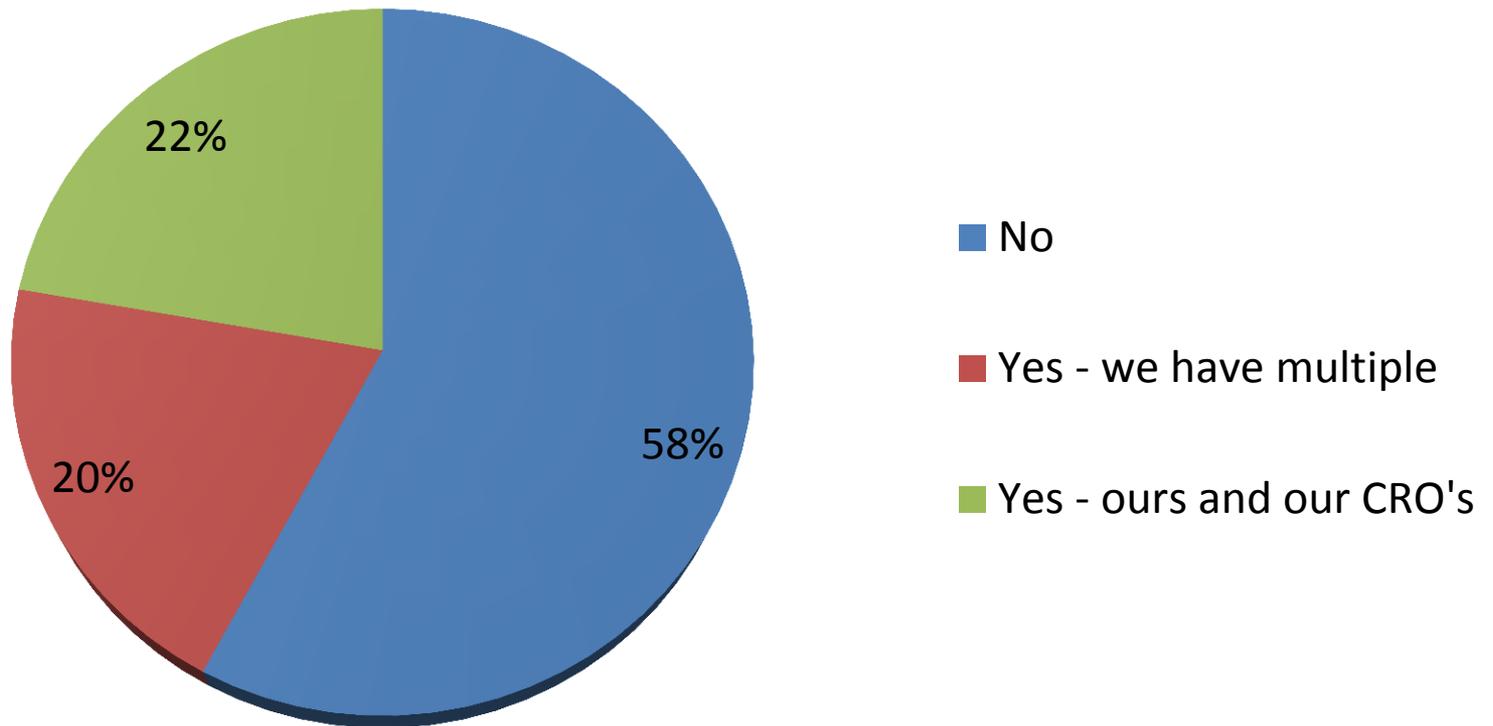


How long has your eTMF been in production?



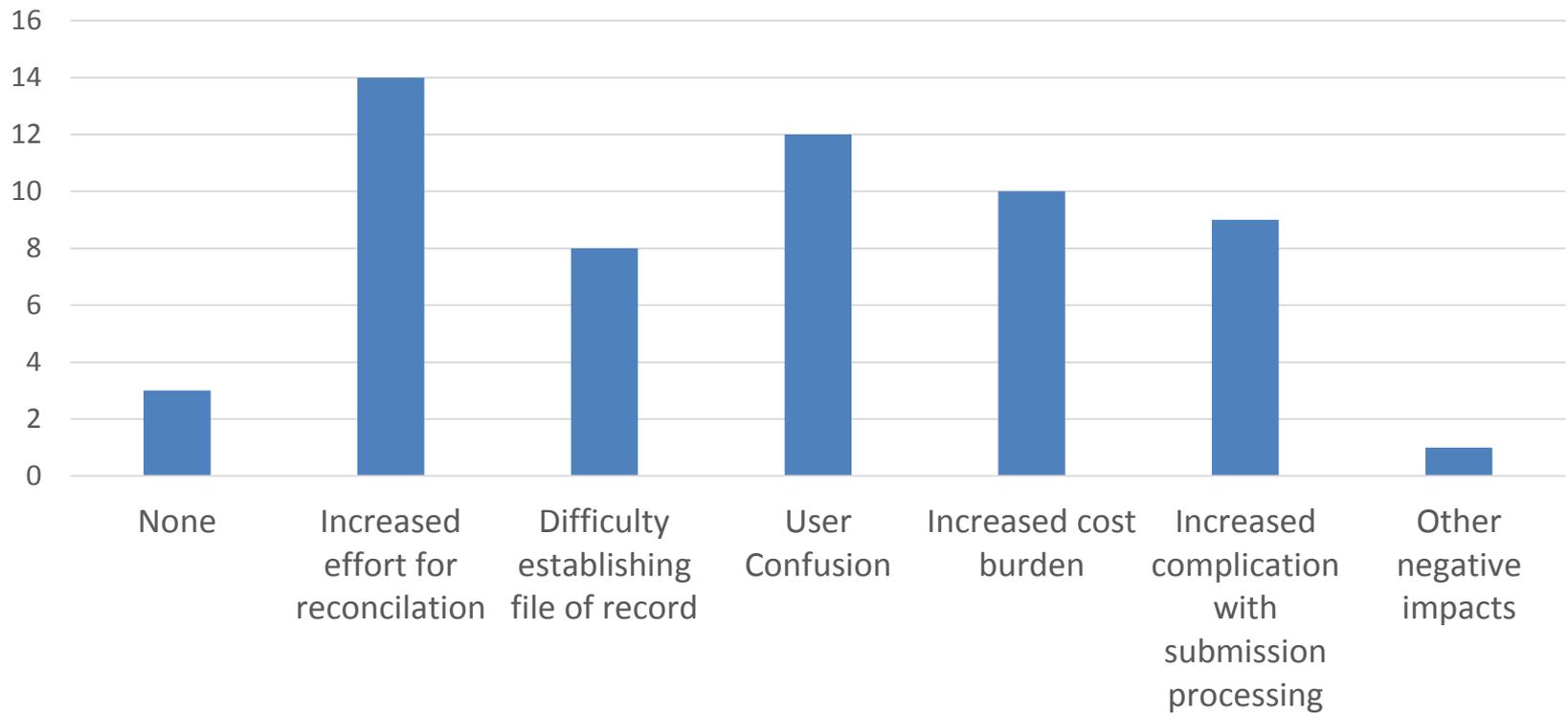
More Than One System?

Do you use more than one system?

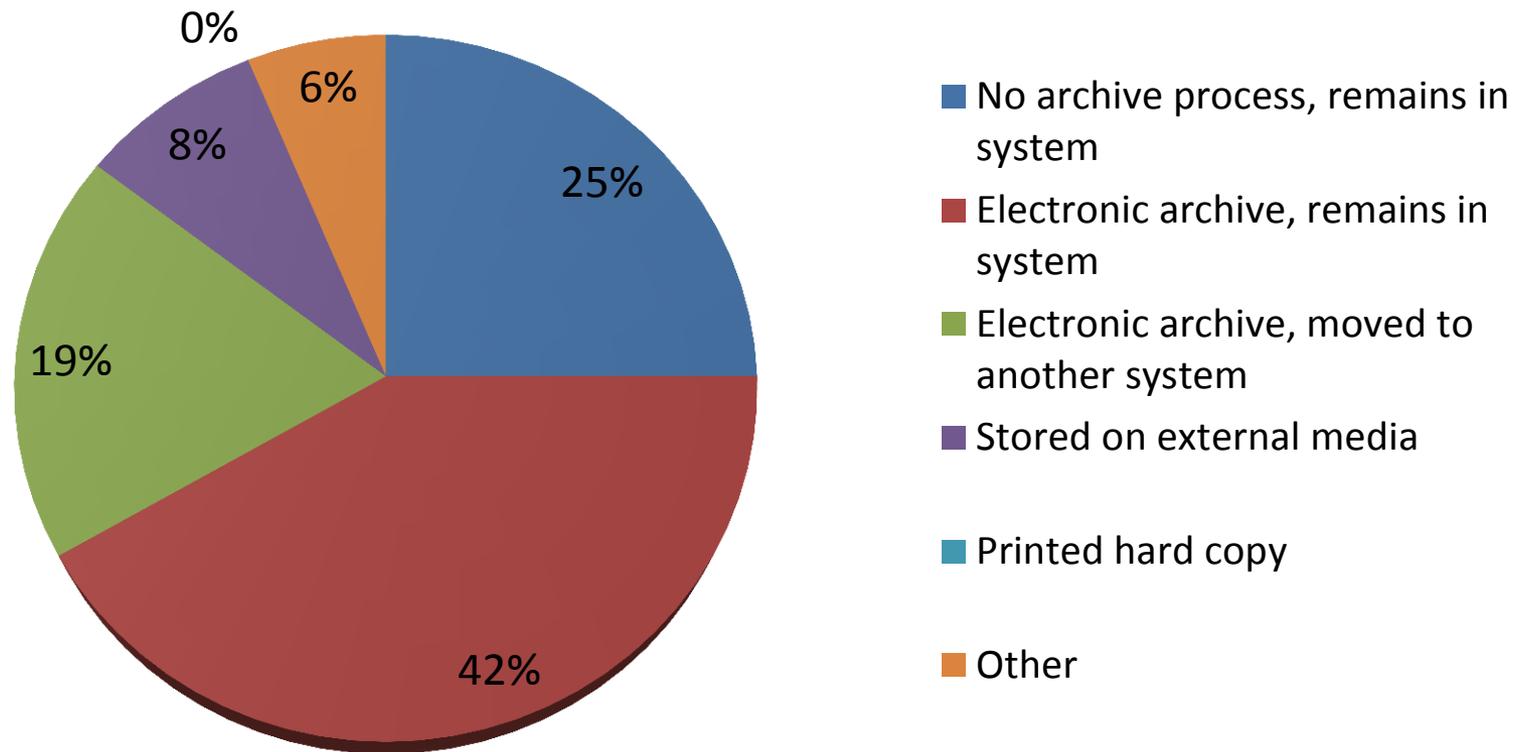


Issues When Using More Than One eTMF System

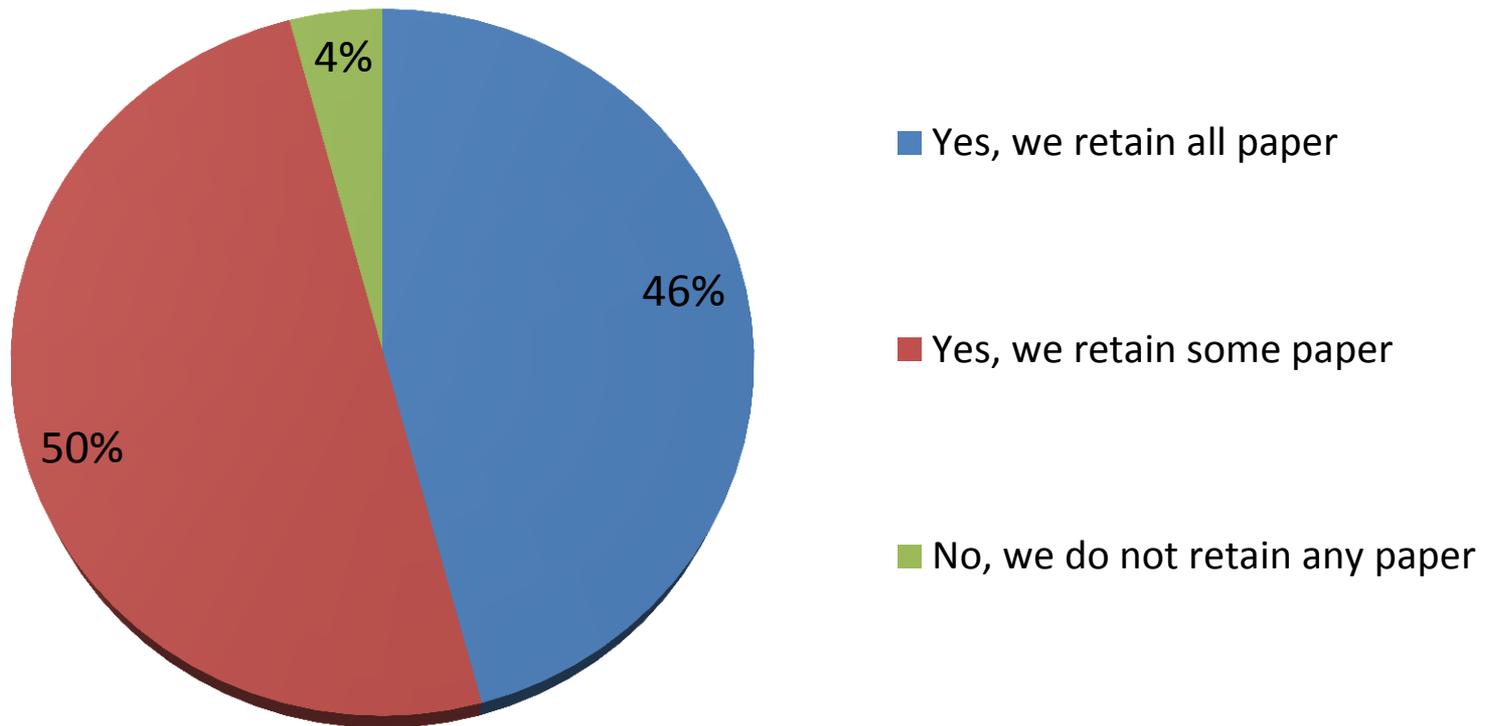
Which of the following do you encounter when using more than one system? (select all that apply)



What is the eTMF post-trial "archive" process?"

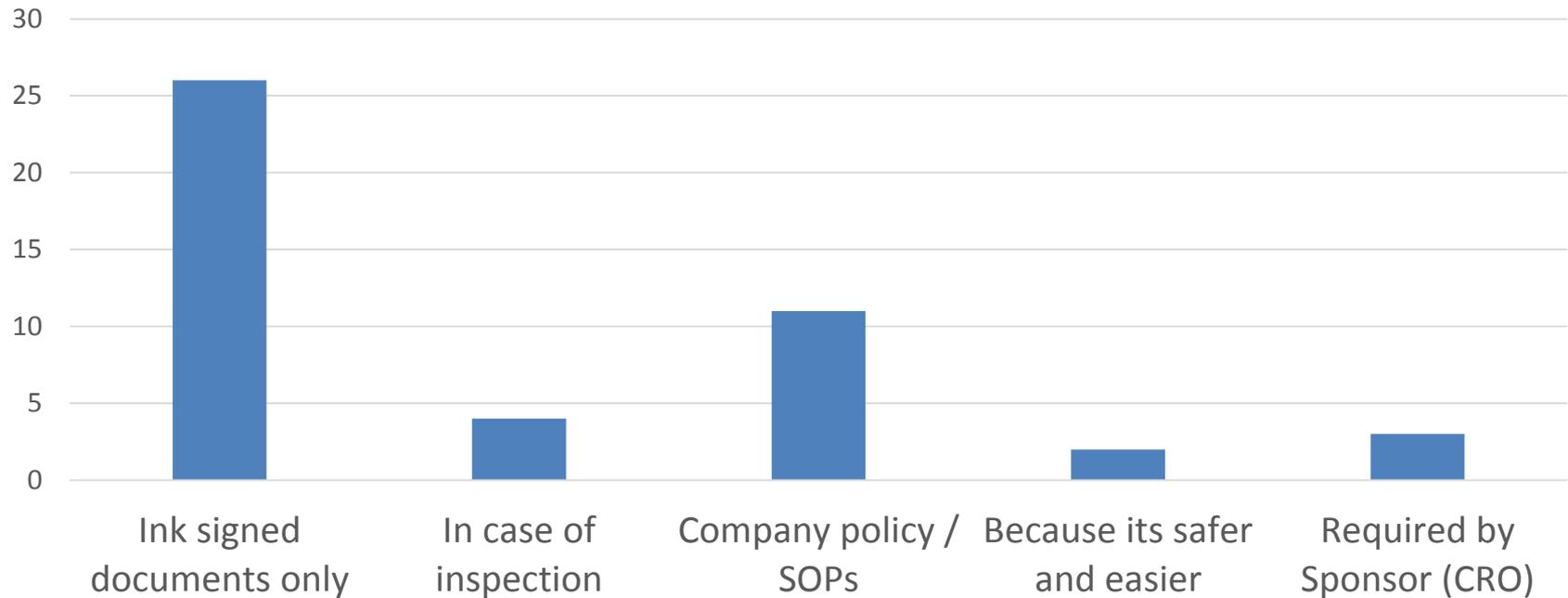


Do you retain scanned paper?



Reasons for retaining scanned paper

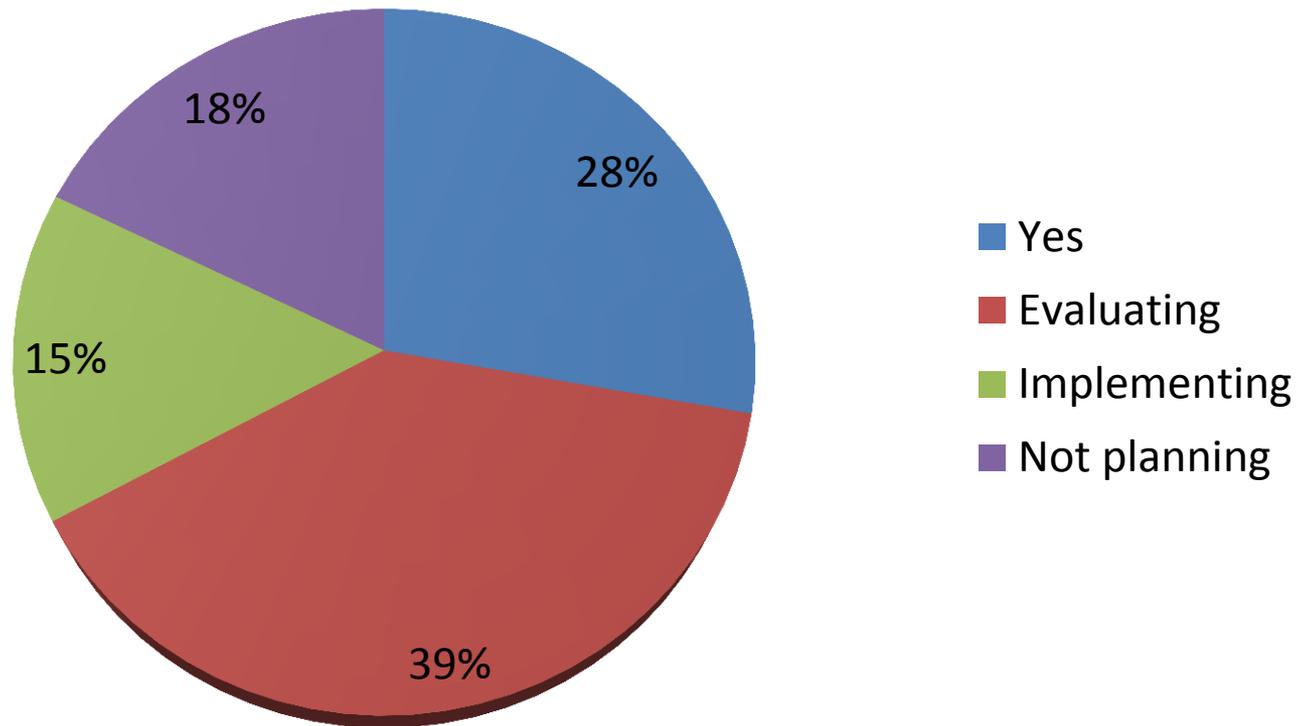
Why do you retain scanned paper?





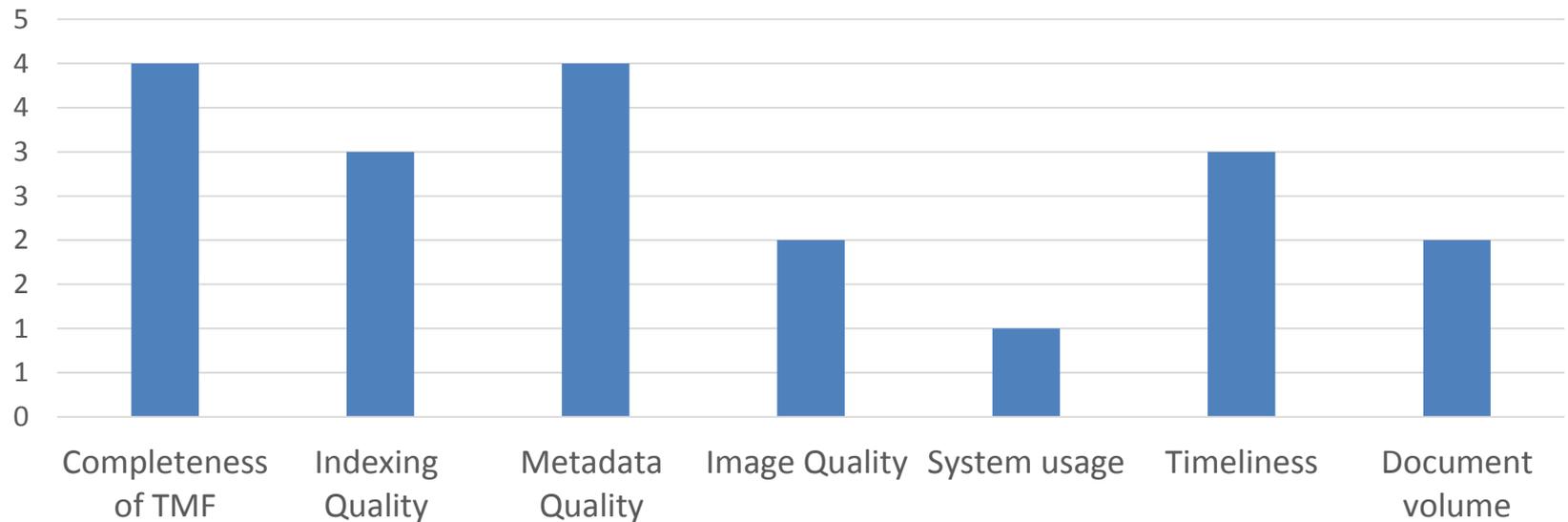
TMF METRICS

Do you have a TMF metrics program in place?

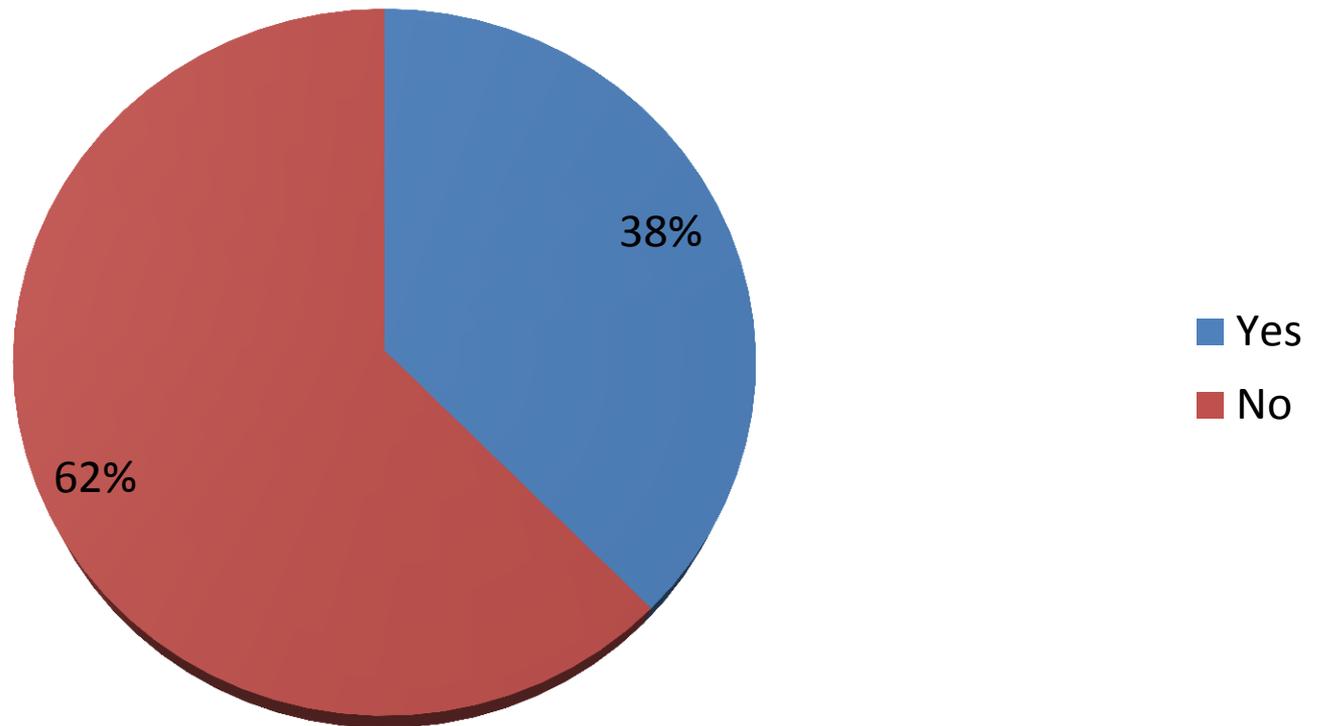


TMF Metrics Program Measurements

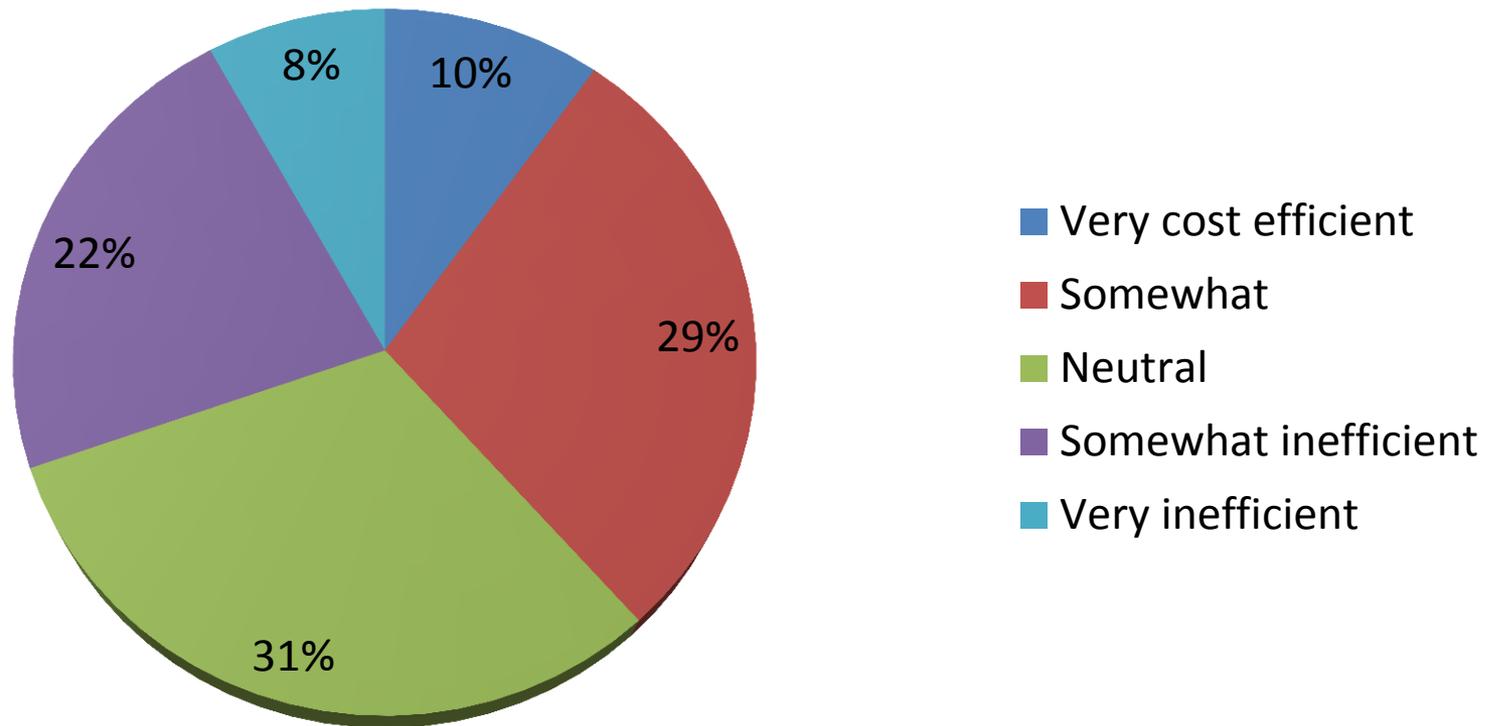
What do you measure in your TMF Metrics Program?
(select all that apply)



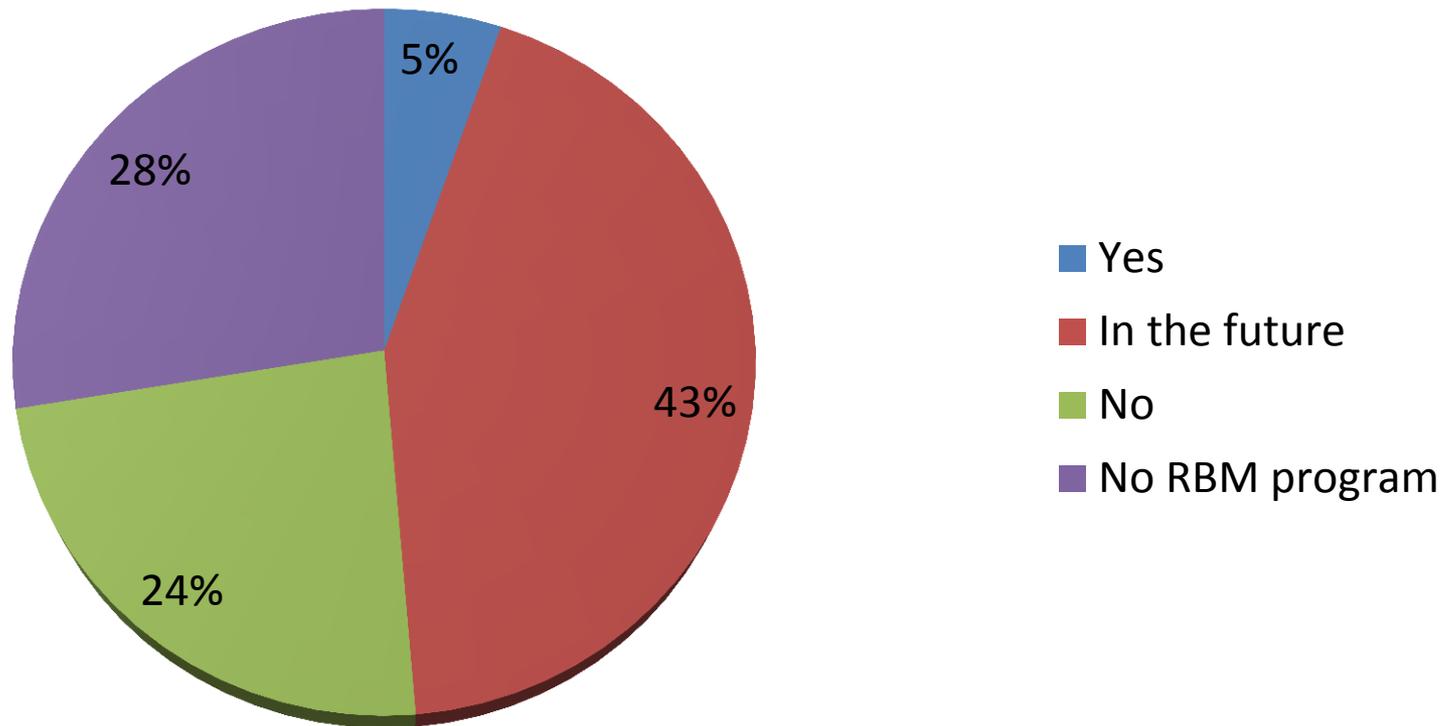
Do you measure TMF costs?



Do you believe your TMF is cost efficient?



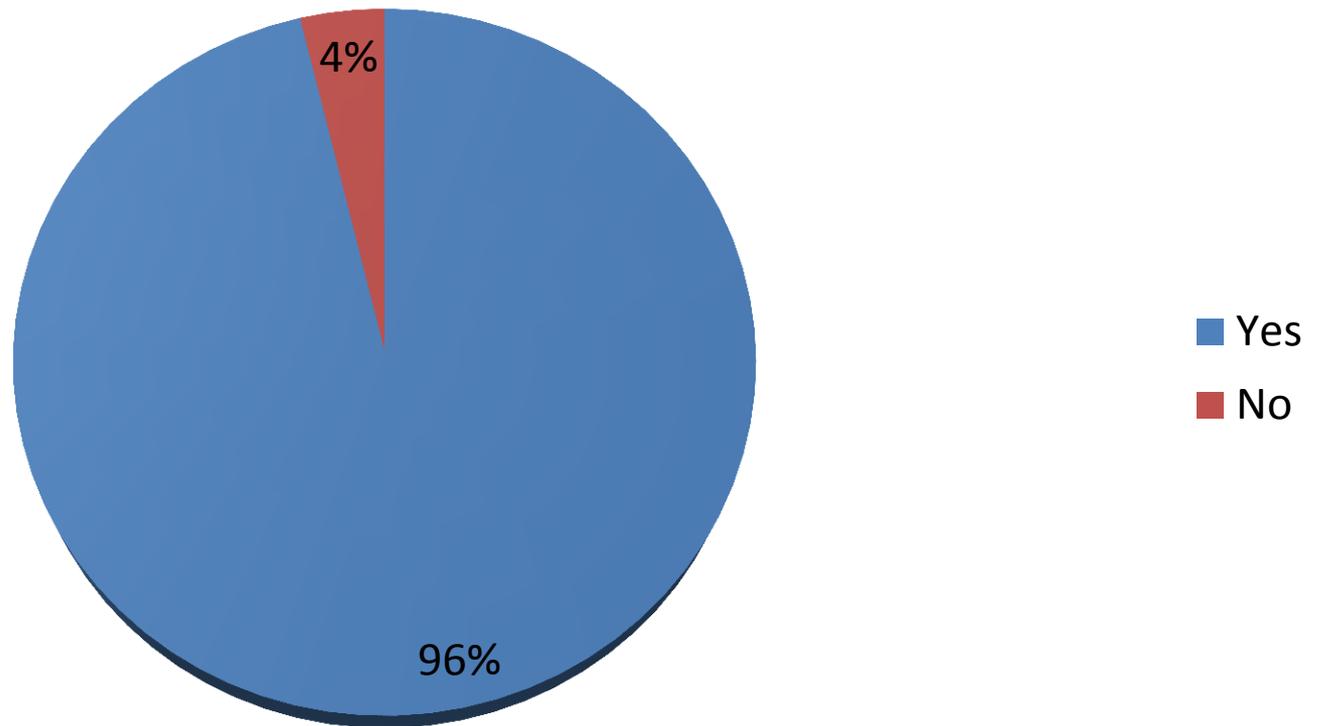
Are eTMF metrics used in your RBM program?



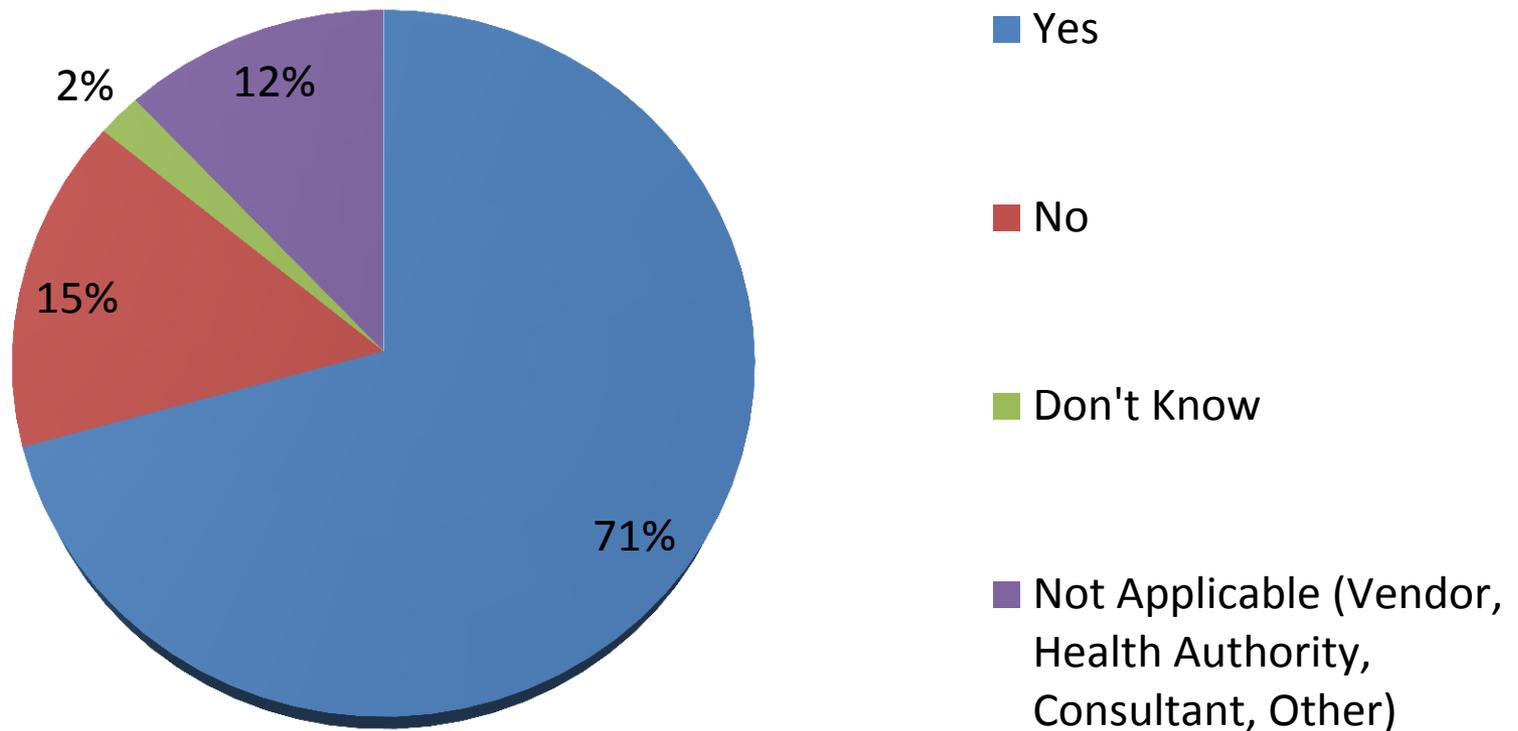


TMF REFERENCE MODEL USE

Are you aware of the TMF Reference Model?

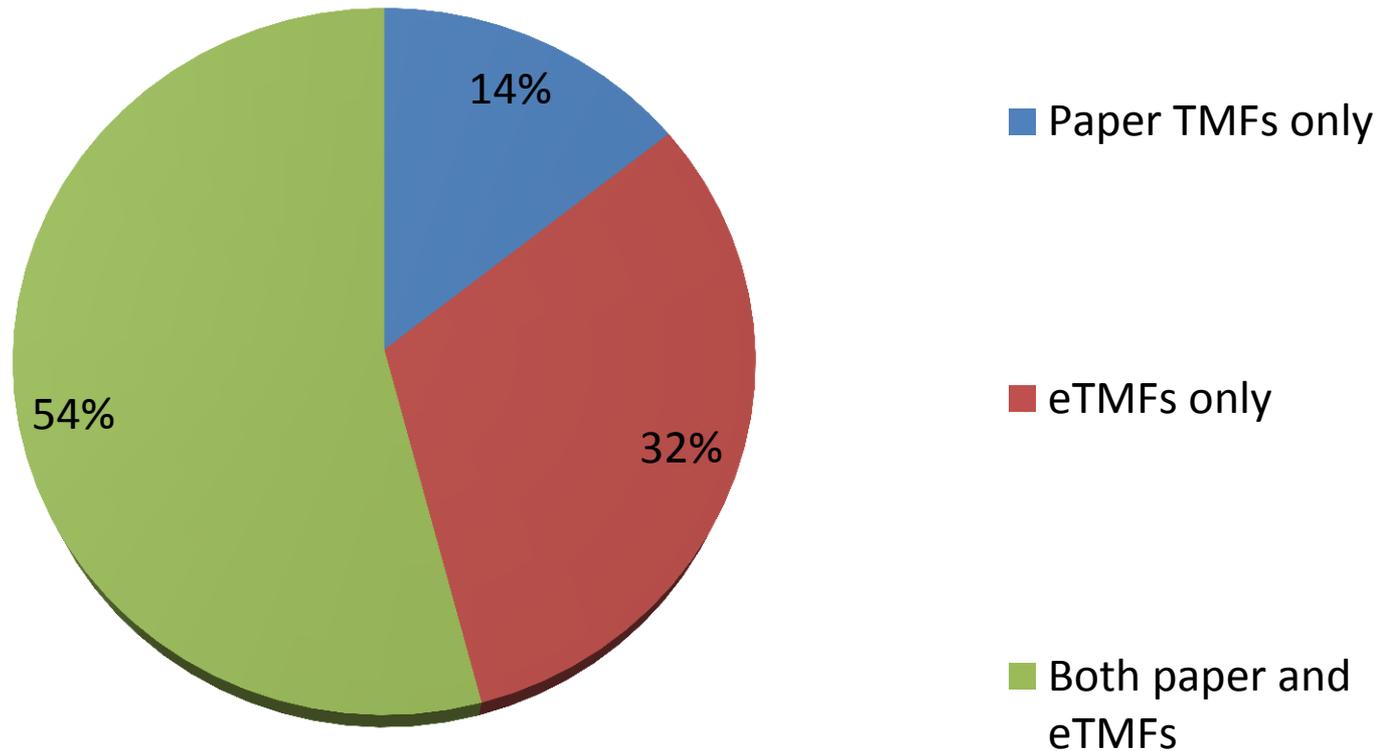


Is your organization using the TMF Reference Model?



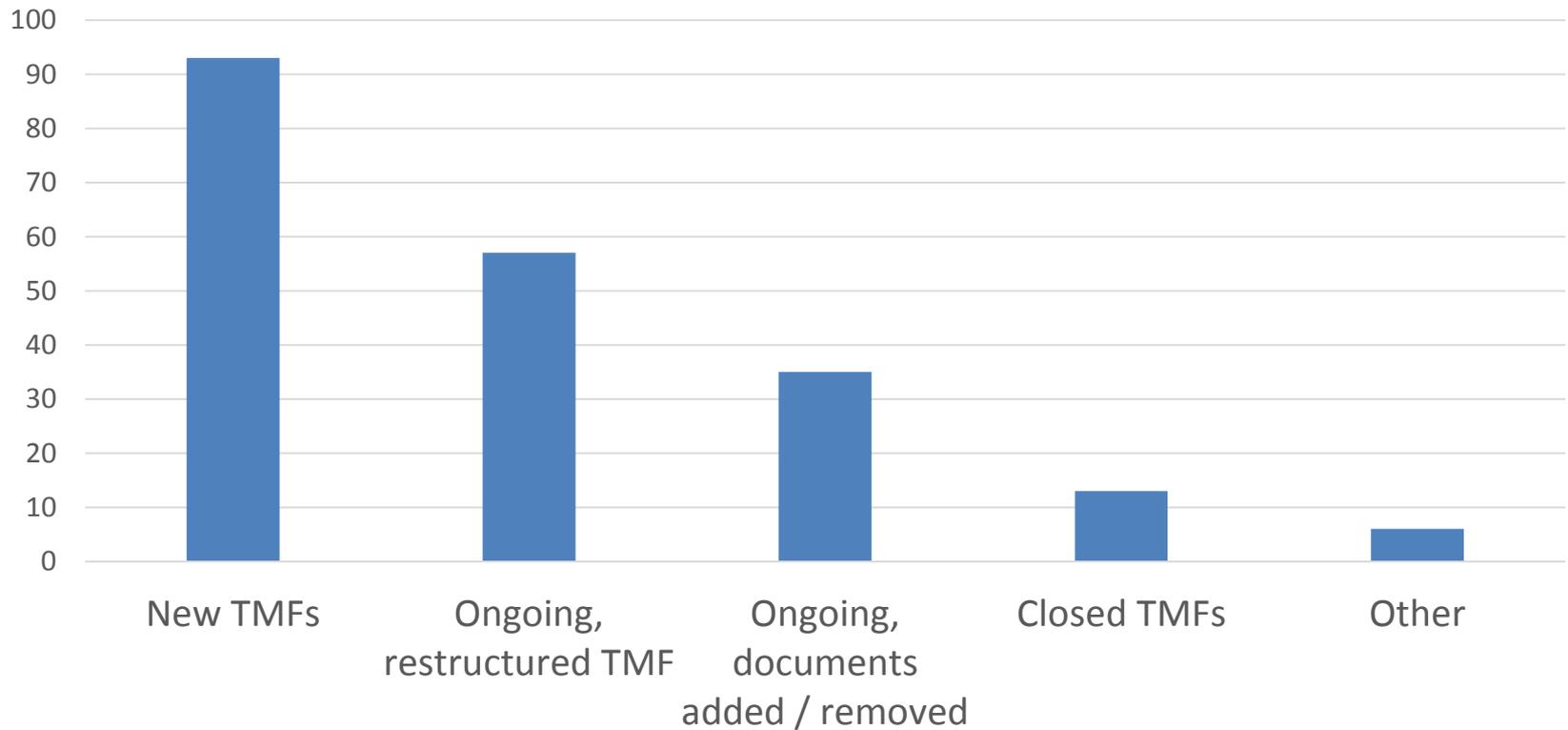
Applying the TMF Reference Model

My organization is using the Model for...

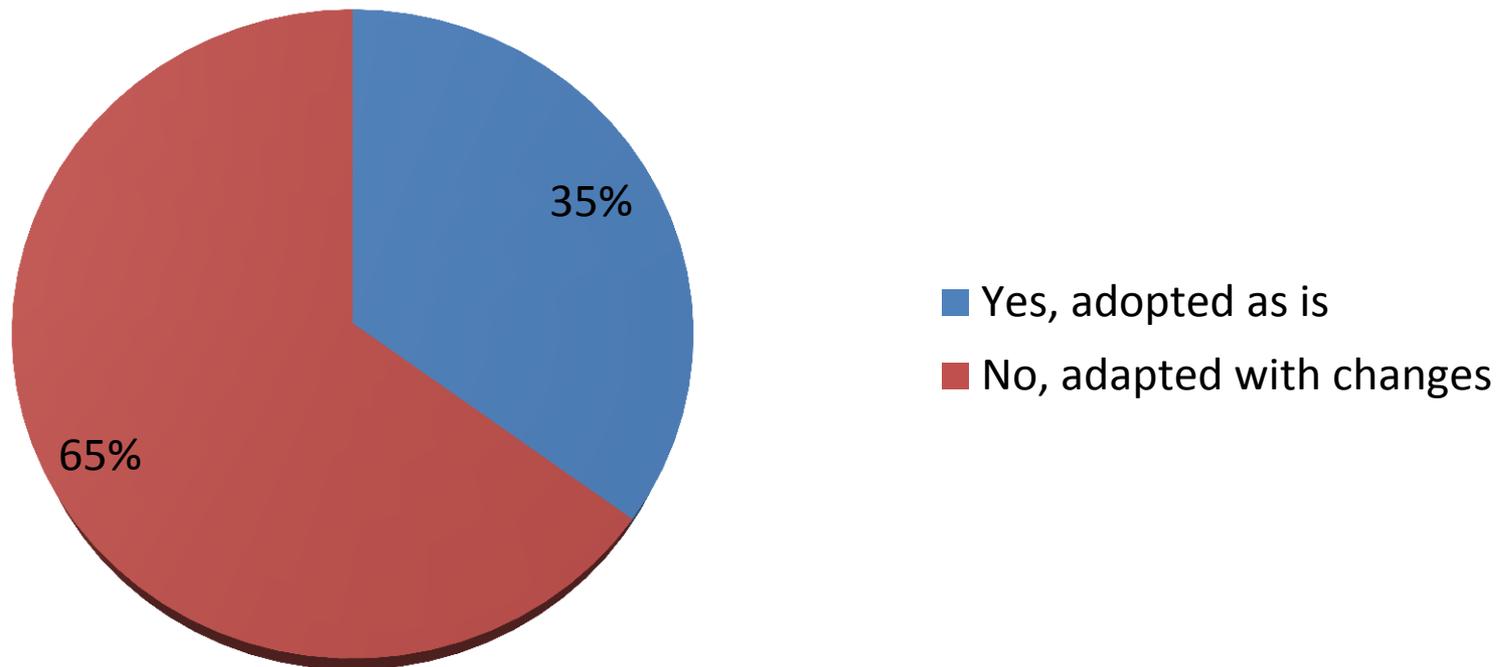


TMF Reference Model Use in New and Ongoing Trials

My organization is using the Model in... (select all that apply)

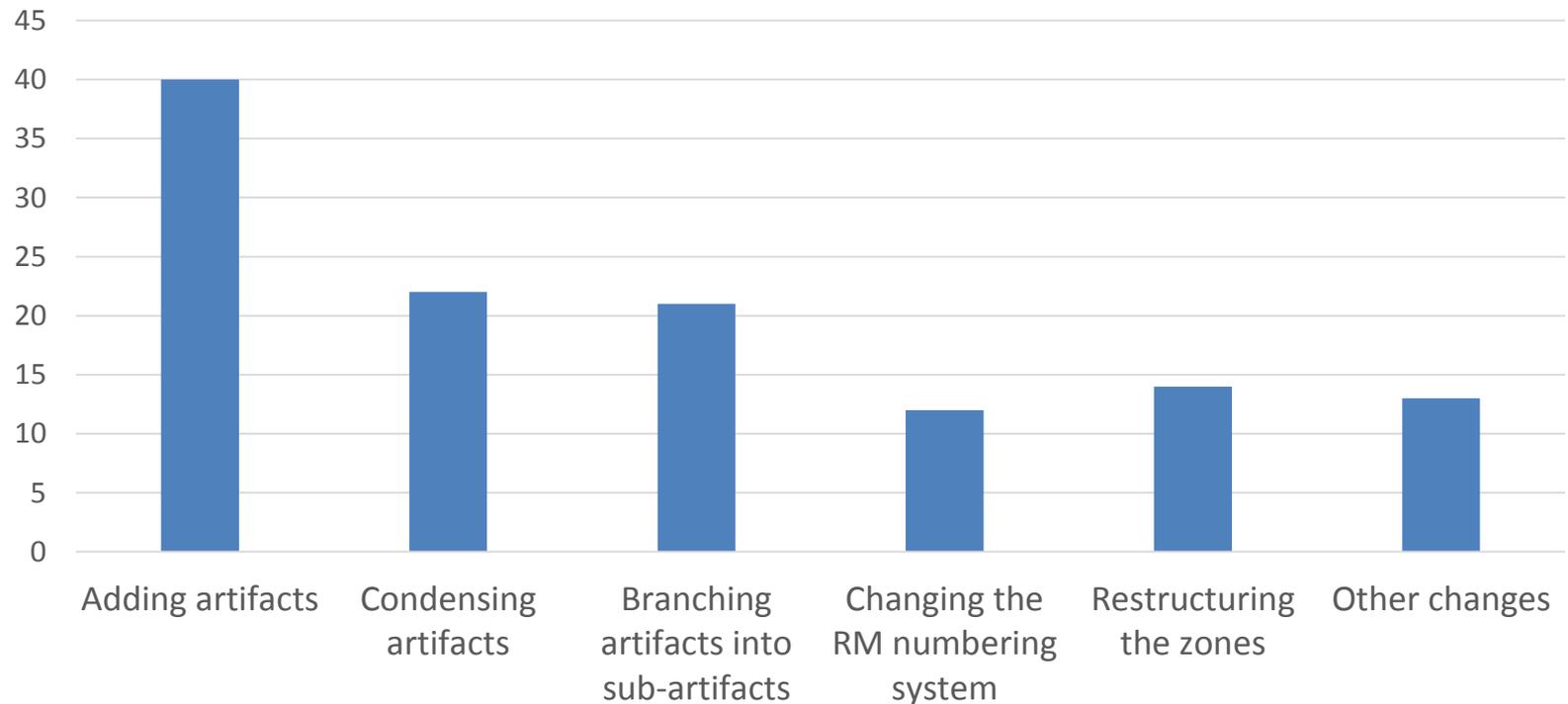


Has your organization adopted the Model as is, without any change?

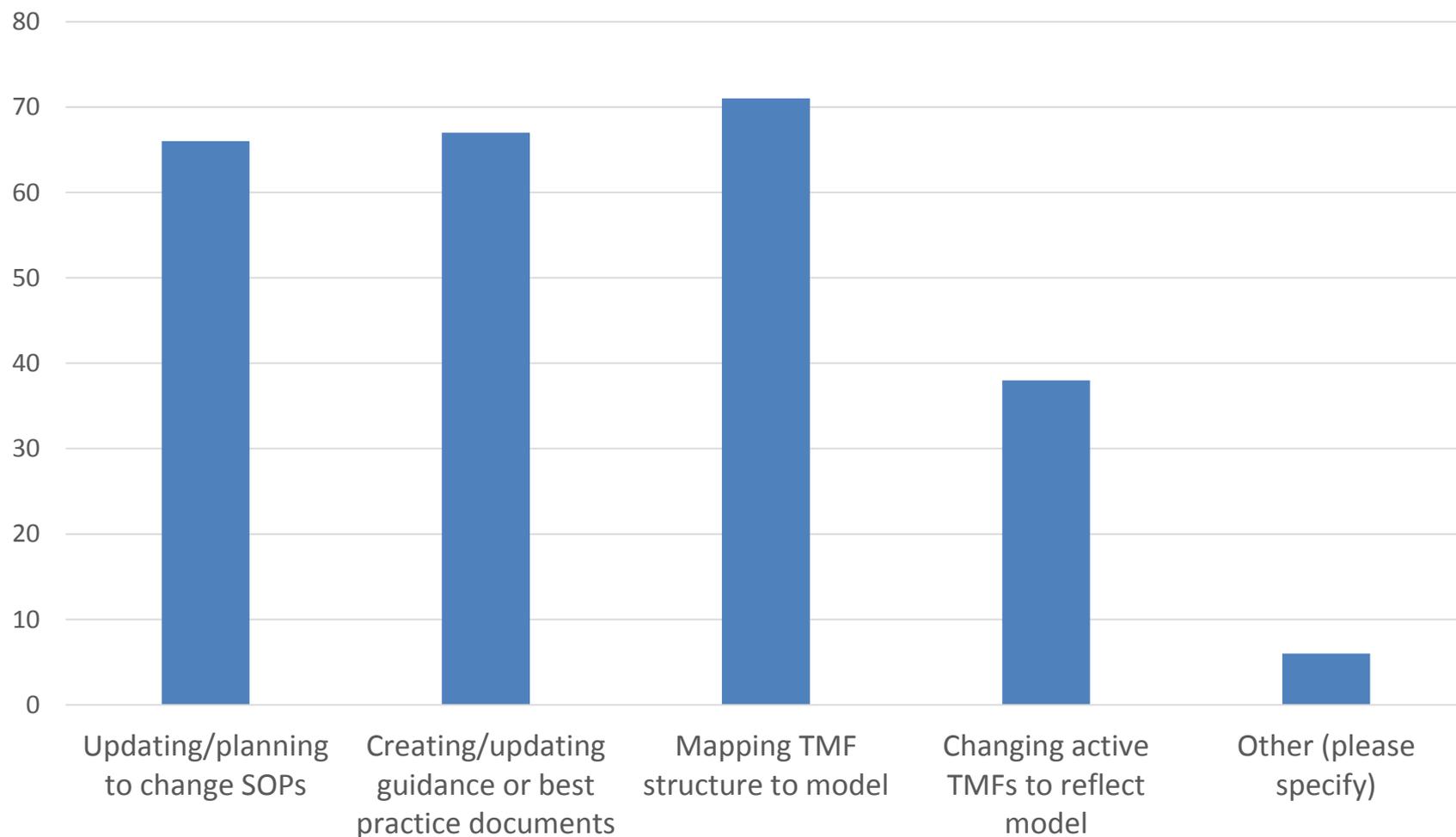


TMF Reference Model Adoption Methods

In adopting the Model, my organization is... (select all that apply)



Changes from Adopting TMF Reference Model

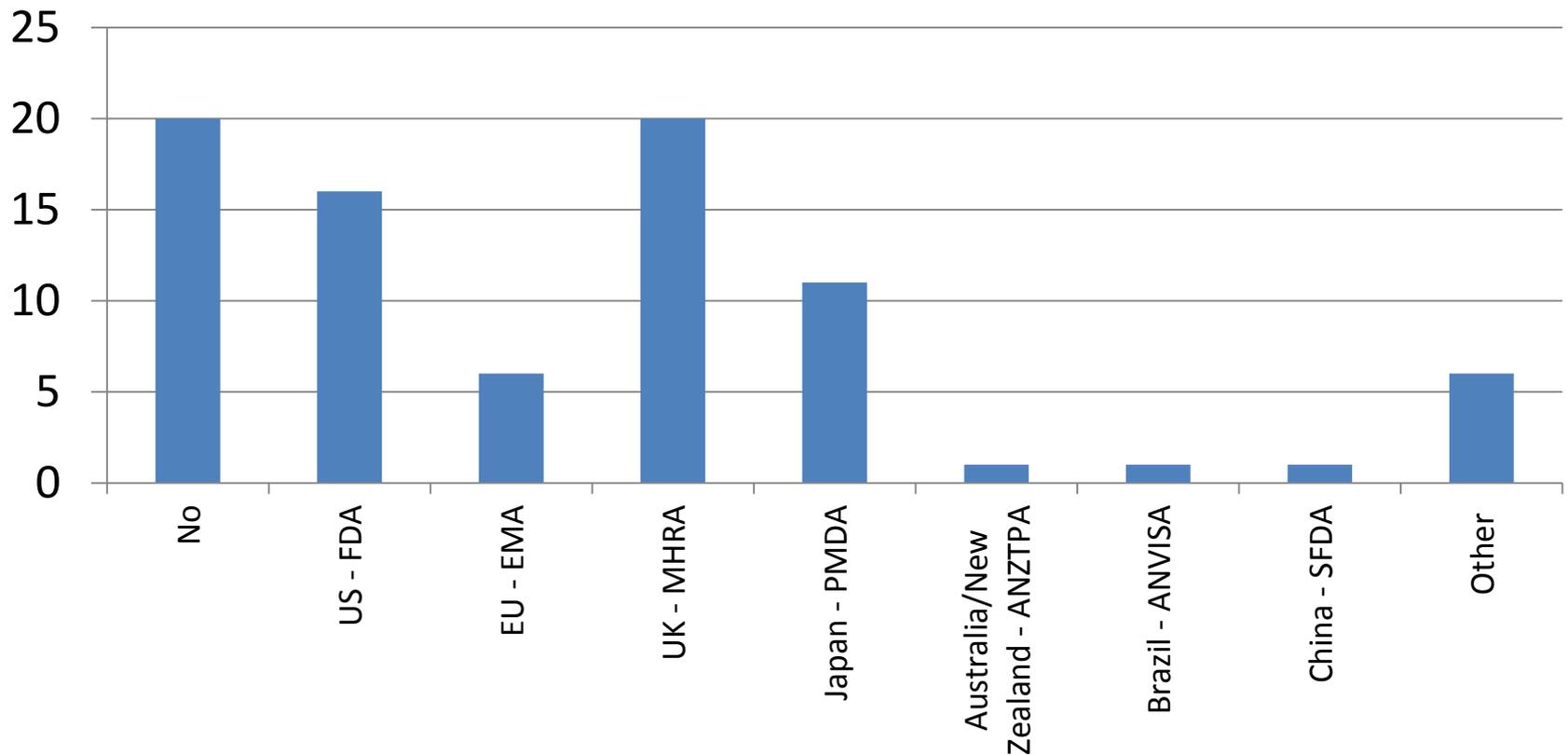




INSPECTION TRENDS

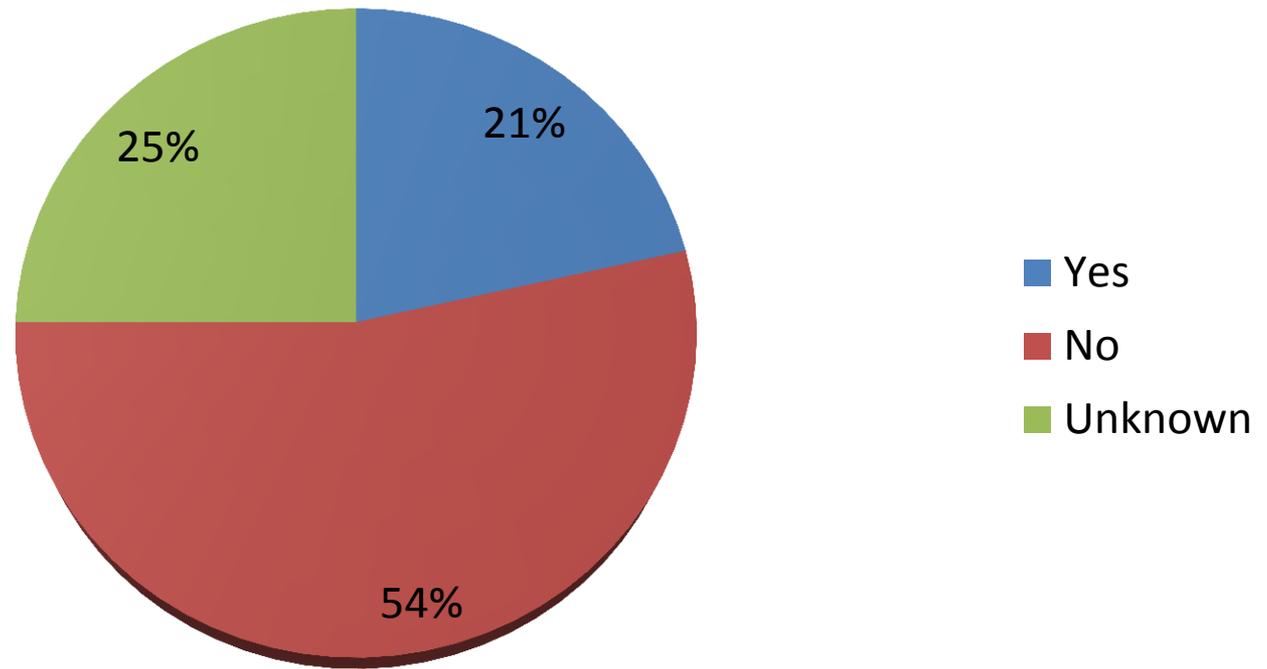
Inspection History

Have you had regulatory agency / health authority inspections of your eTMF? (select all that apply)



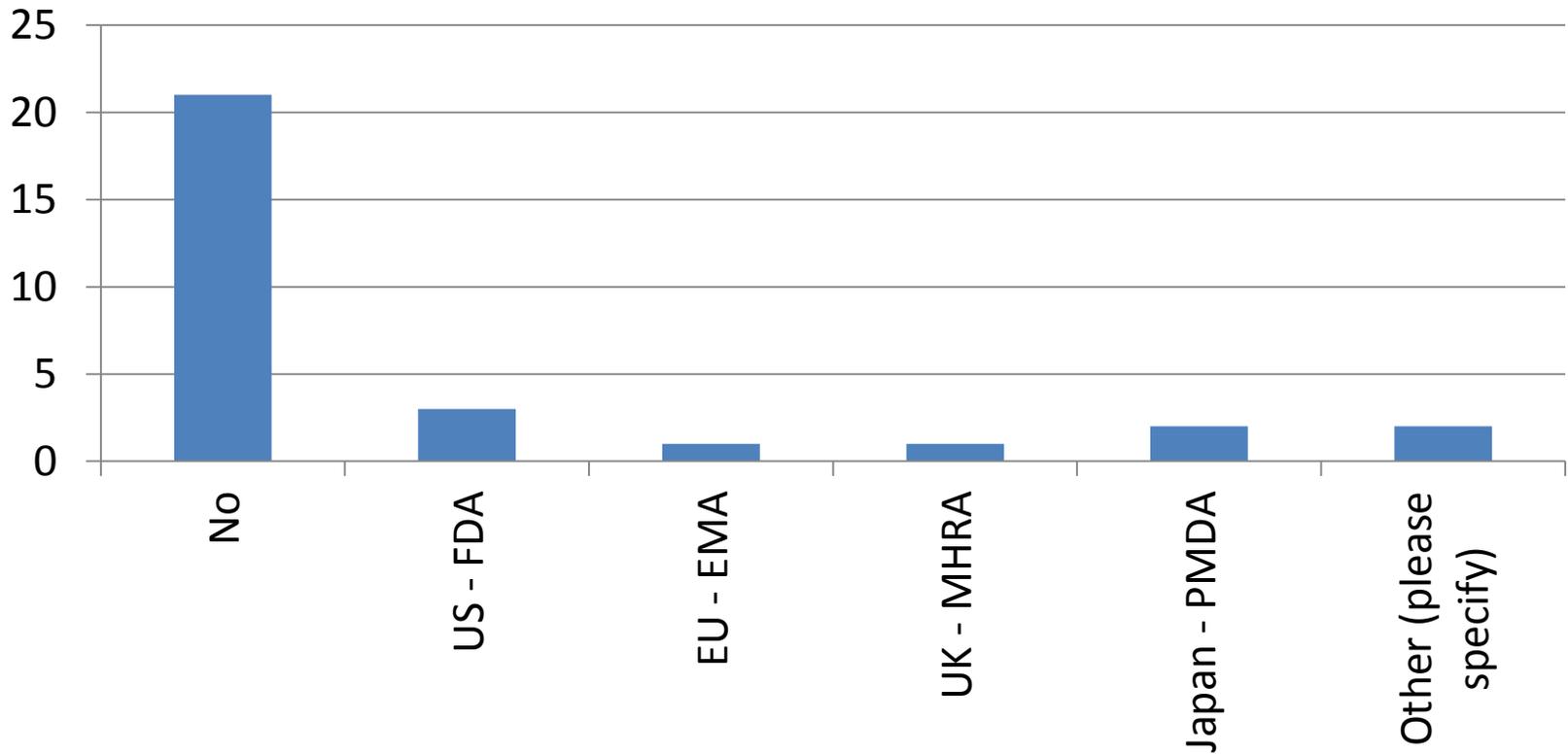
Remote Inspection History

Have you yet had a remote (off-premise) inspection by any regulatory agency / health authority?



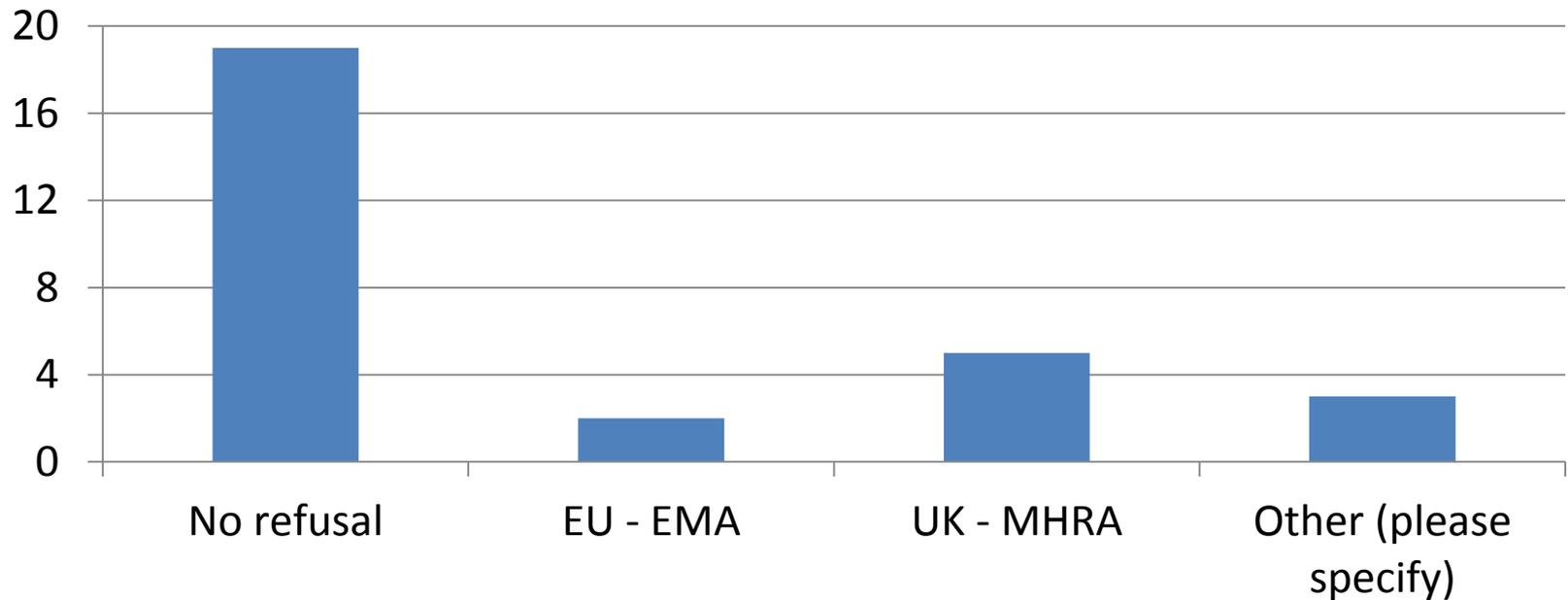
Sponsor Inspection History Paper Requests

Has any inspector refused to use eTMF and required paper print out of TMF?

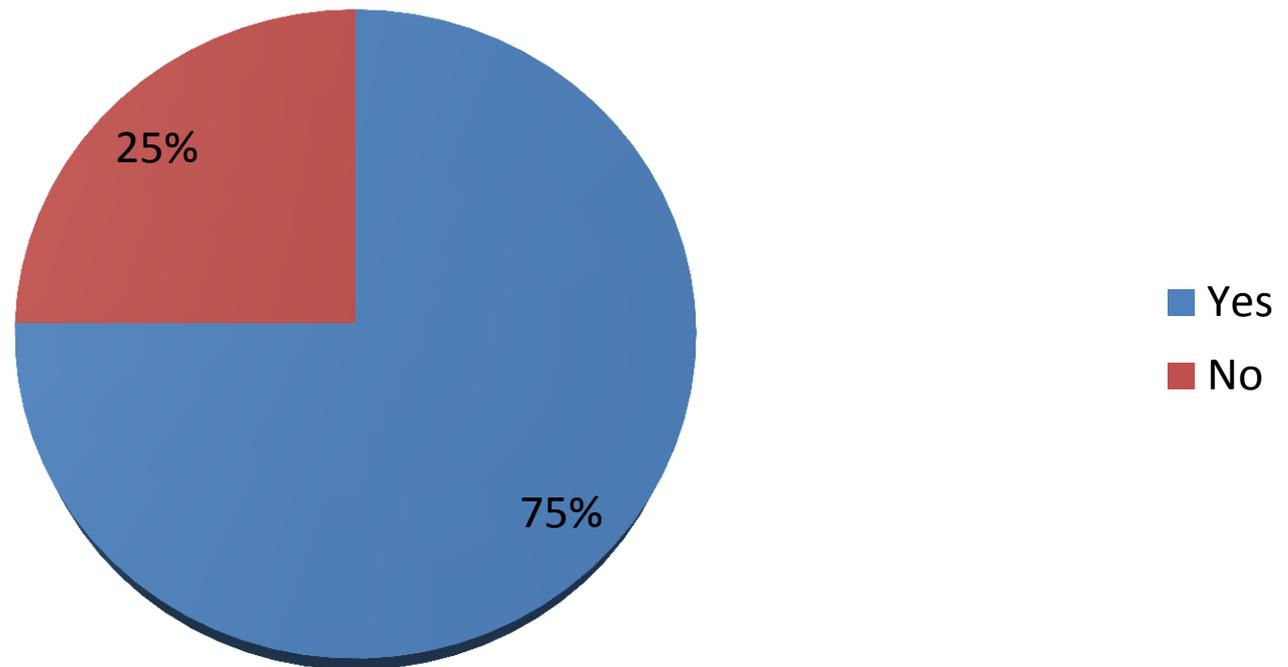


Sponsor Inspection History eTMF Resistance

Has any inspector refused to use paper and required access to eTMF?

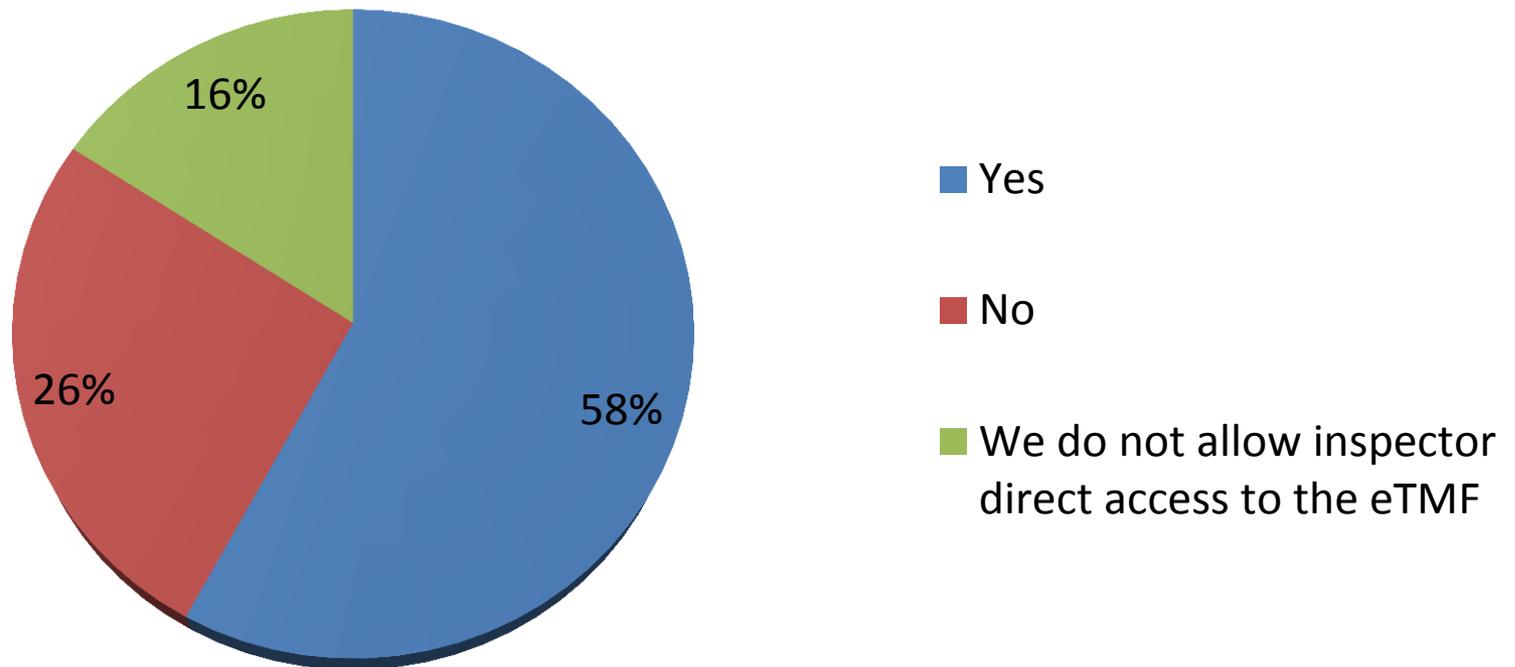


Has the eTMF helped ease burdens of audits / inspections?



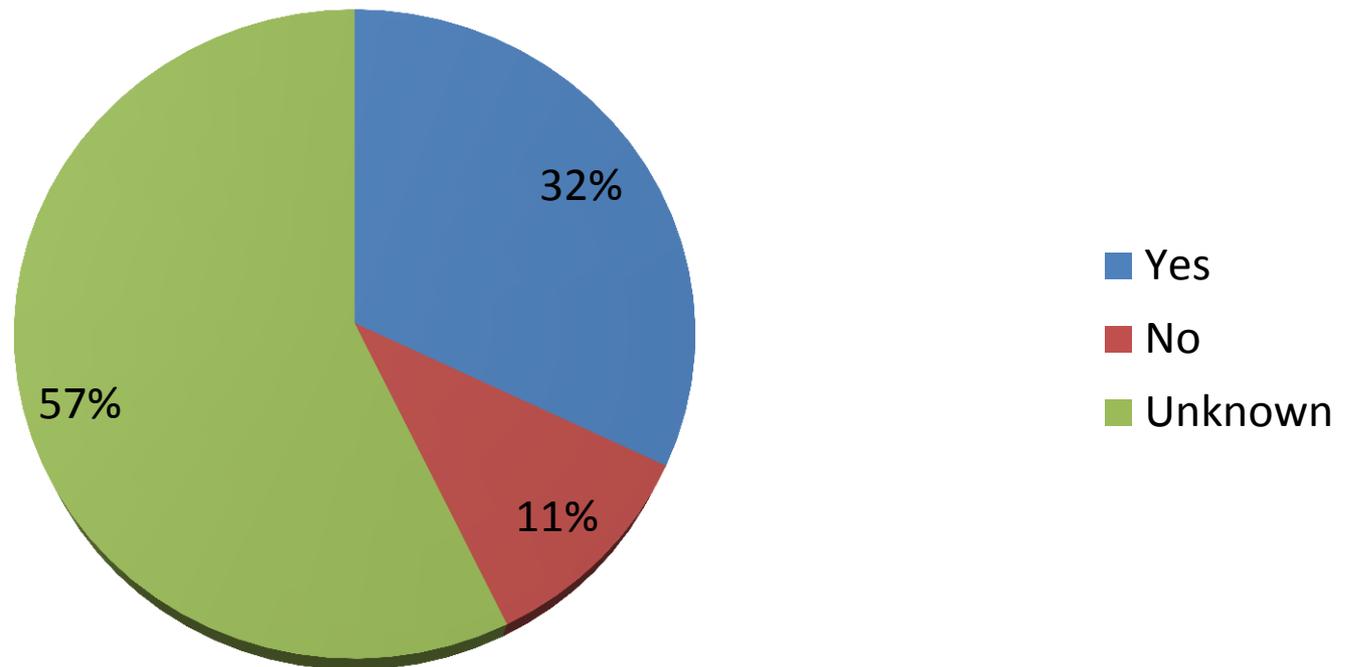
Sponsor Opinion - eTMF Inspection Impact

Have auditors or inspectors found the eTMF easier to inspect using your eTMF software?



Sponsor Opinion – eTMF Impact Unannounced Inspections

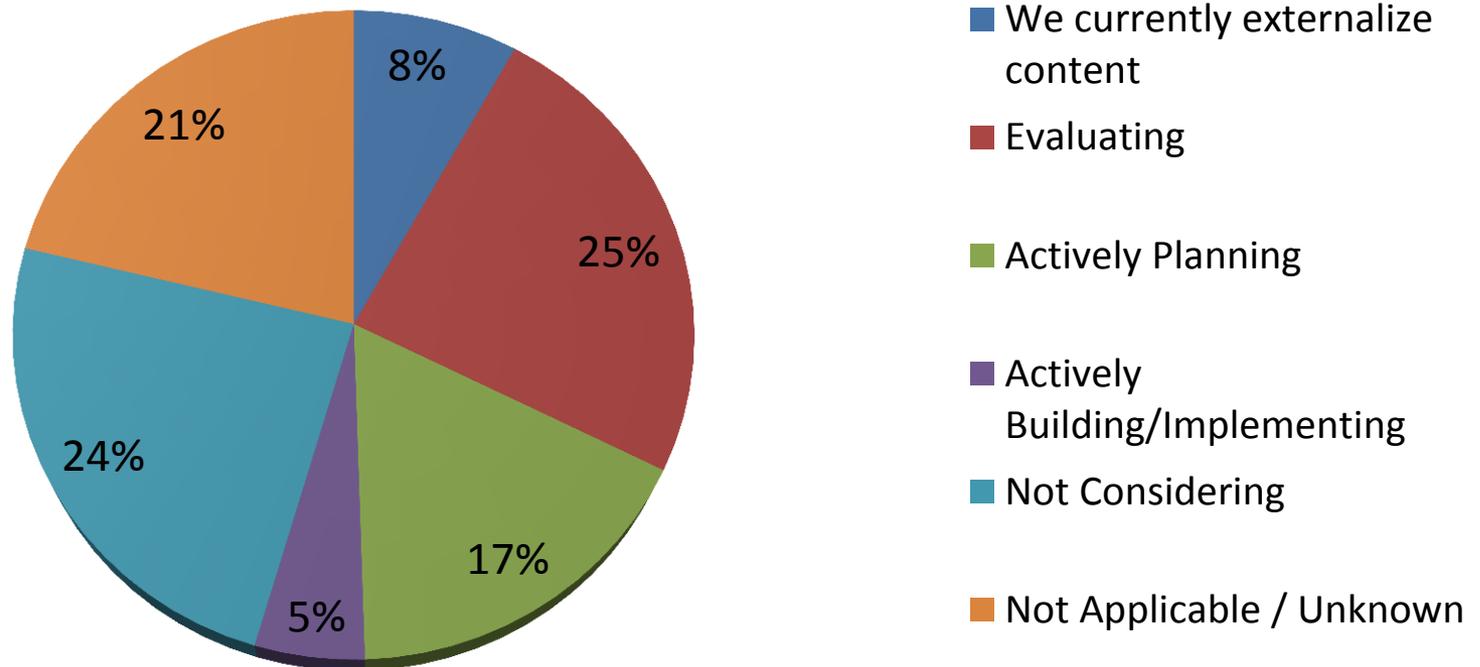
Has the eTMF proved a benefit in allowing you to support unannounced inspections?



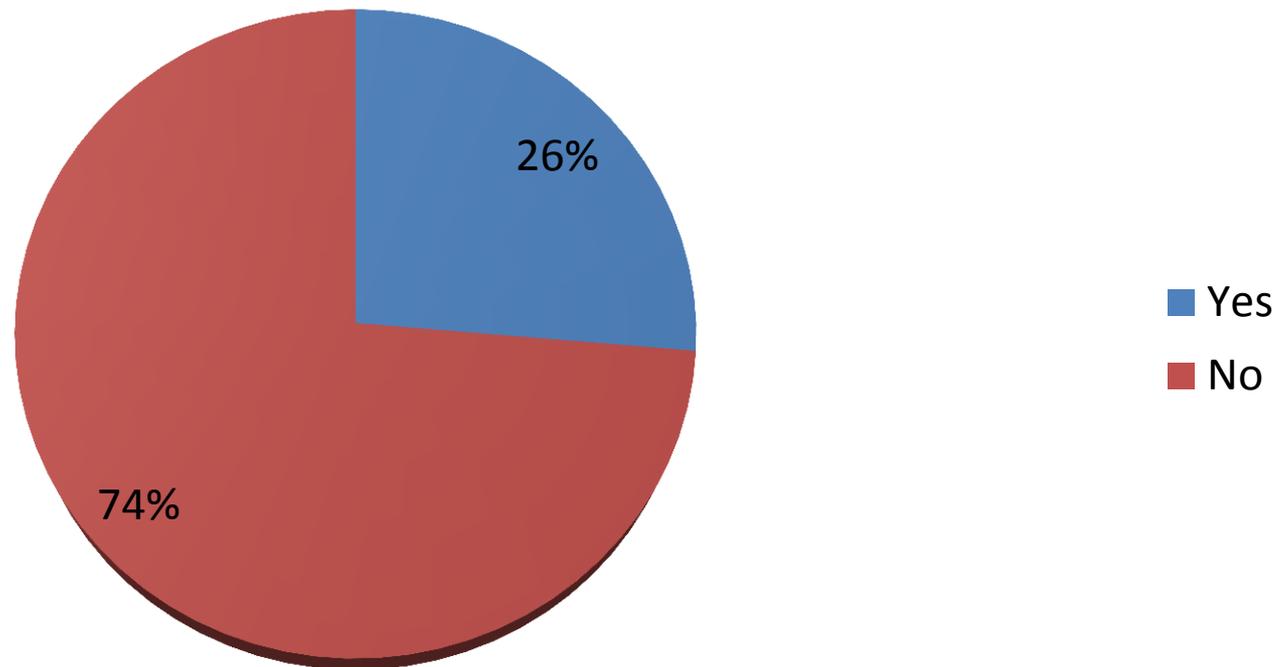


ELECTRONIC INVESTIGATOR SITE FILE (e-ISF)

Does your eTMF externalize content to clinical trial sites (e.g. Investigator Portal)?

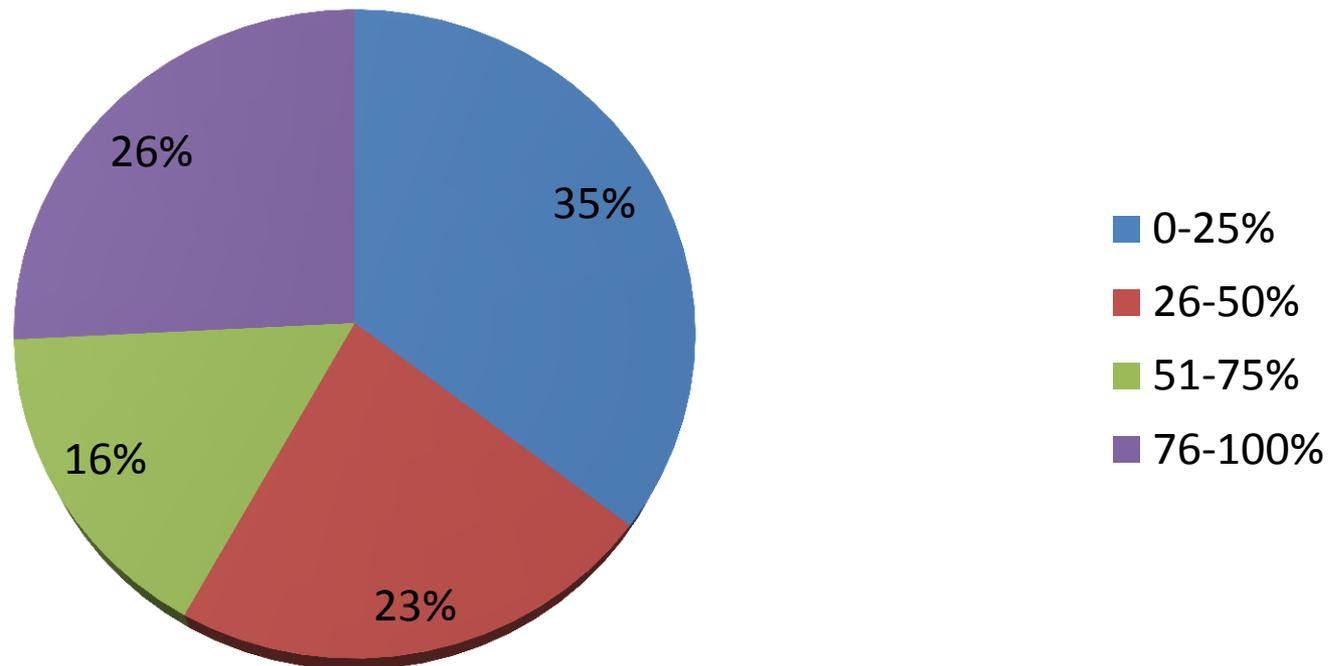


Are electronic Investigator Site Files (eISF) being used in your trials?



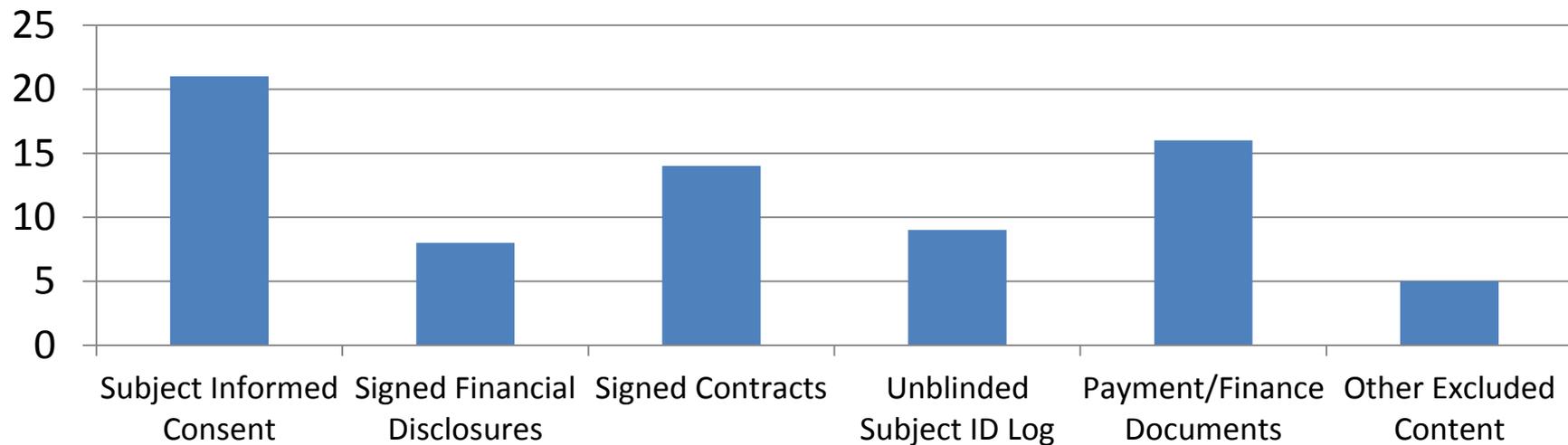
Percentage of Trials with eISF

What percent of your trials have an electronic Investigator Site File (eISF)?

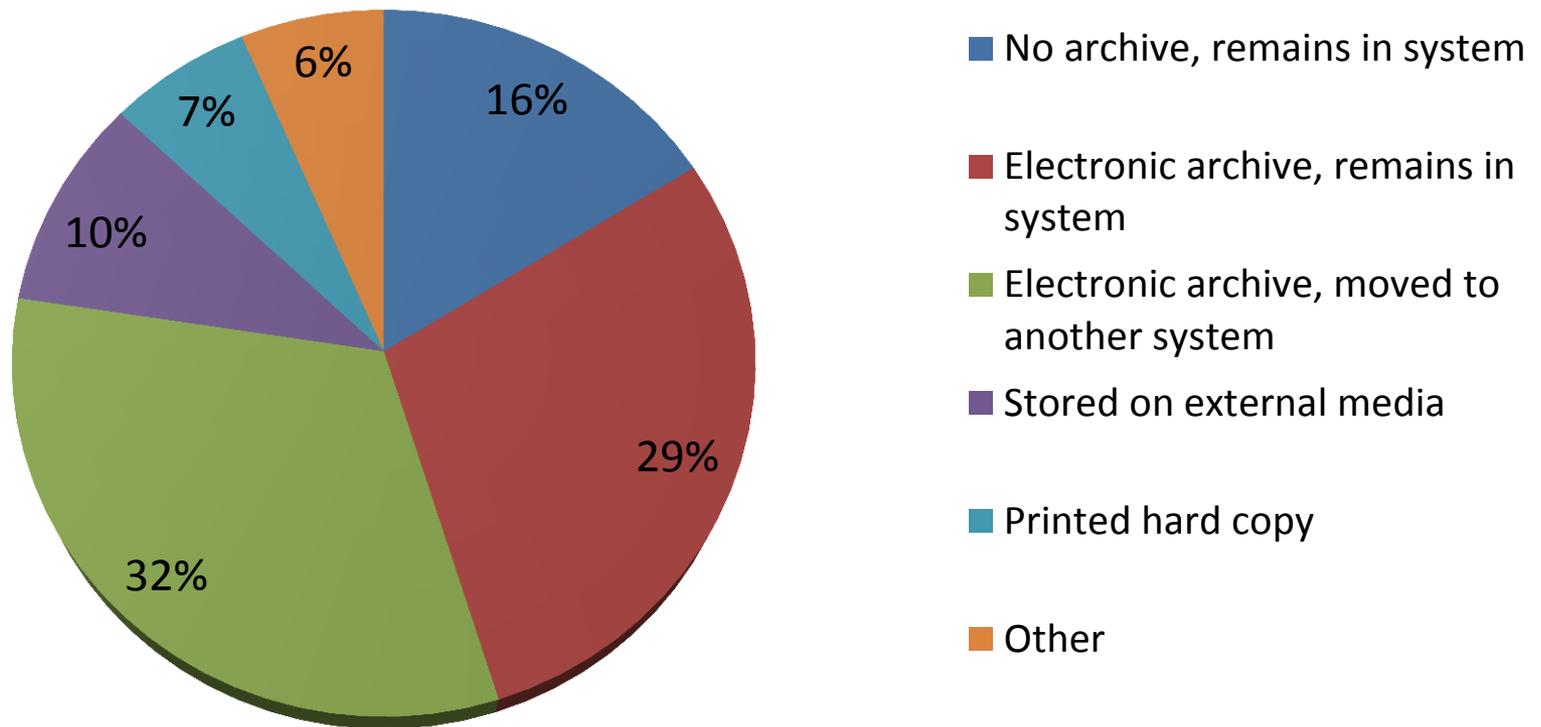


eISF Excluded Content

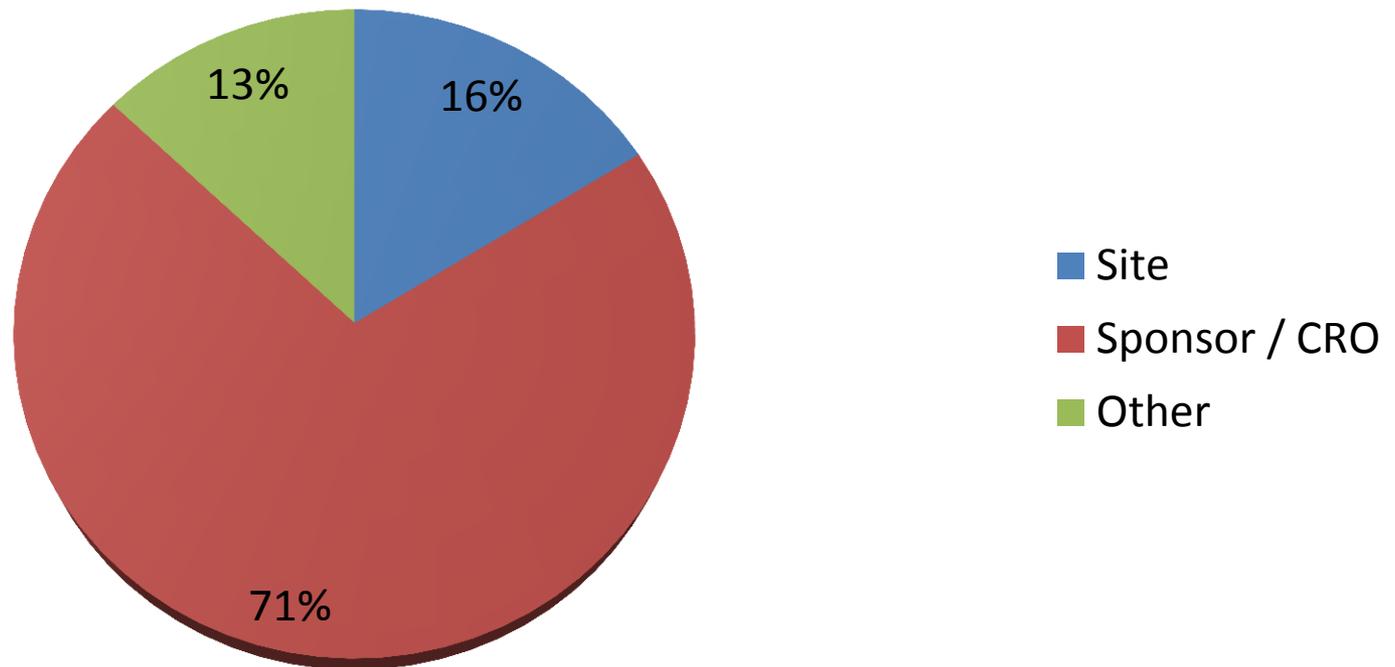
**Which of the following documents, if any, are NOT stored in the eISF
(select all that apply)**



What is the eISF post trial "archive" process?

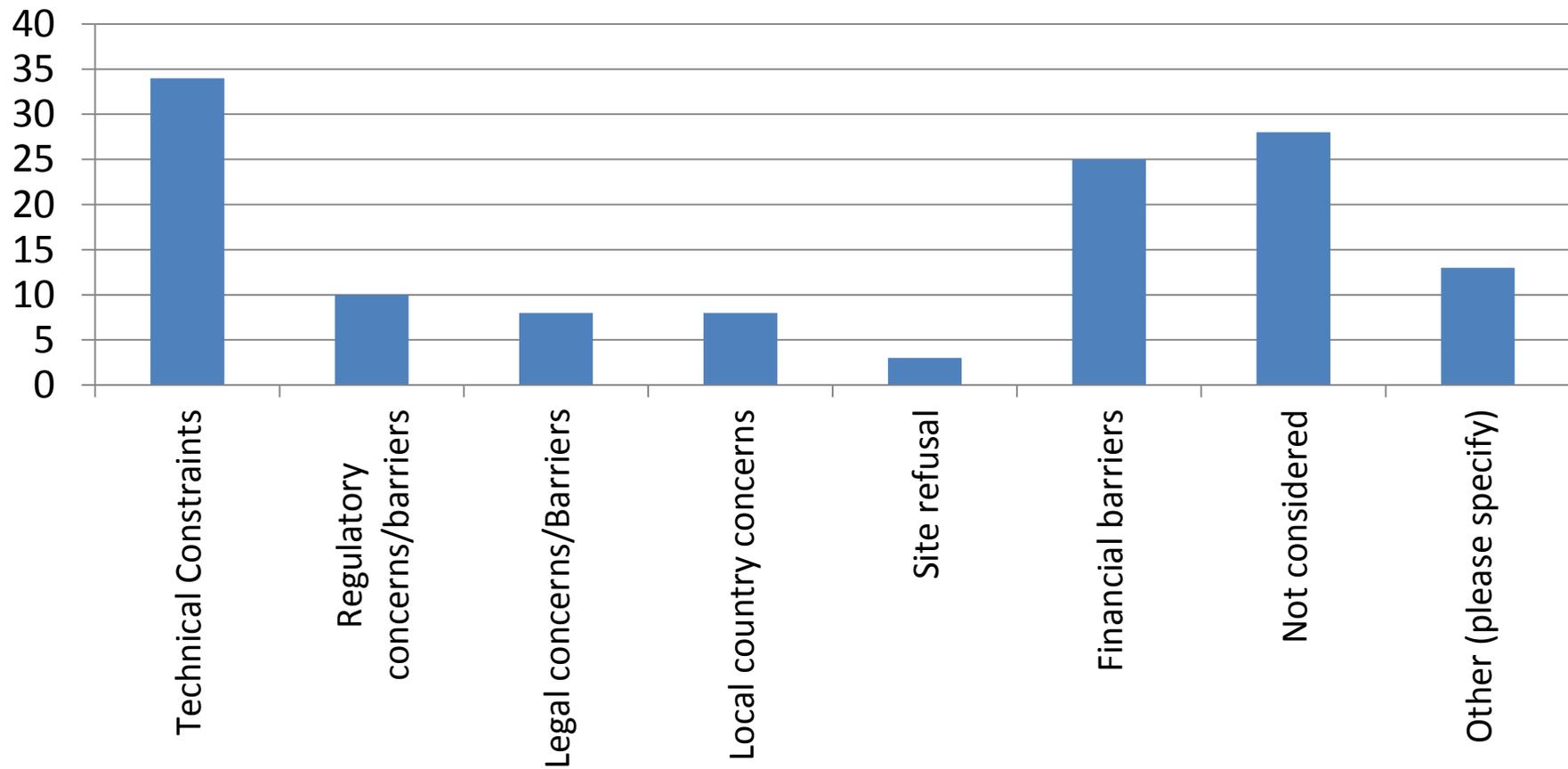


Is the eISF the site's technology or sponsor / CRO's technology?



Barriers to eISF uptake

If no eISF, why not? (choose all that apply)



TMF Reference Model – Participate!

To join the TMF Ref Model, register on the website:

<http://tmfrefmodel.com/>

Visit the website for up to date information too!

Join **Linked ** group “TMF Reference Model”

http://www.linkedin.com/groups?home=&gid=2663204&trk=anet_ug_hm

TMF 2015 Survey Team – THANK YOU!

- Shah Ashraf
- Andrew Mitchell
- Penny Jegede
- Betsy Fallen
- Sholeh Ehdaivand
- Steve Scribner