

TMF Reference Model

Topline results of 2014 TMF Survey #4

August 2014

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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
 - Changes in TMF management and processes
 - Impacts of electronic TMF and e-Investigator Site File
 - Insight into health authority inspection trends
- Data for 2014 Survey #4 was collected in May to July of 2014
 - Previous surveys were conducted in 2010, 2012, and 2013
- A survey team will regroup for work on the fifth TMF Survey in 1Q2015. Your feedback, insight and participation are enthusiastically welcomed.

The TMF Survey sub-team and the Trial Master File Reference Model (TMF RM) initiative is a subgroup of the Document and Records Management SIAC of the Drug Information Association

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 2014 was collected from May to July 2014
- 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)

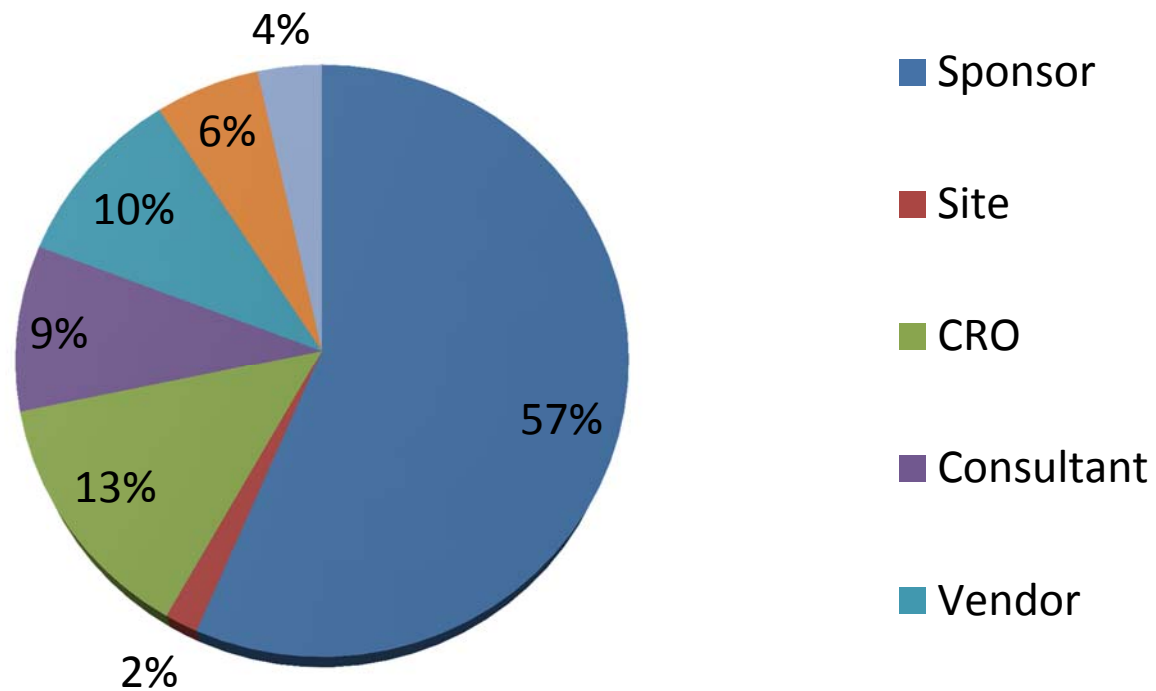


RESPONDENT DEMOGRAPHICS

Respondent Organization Type

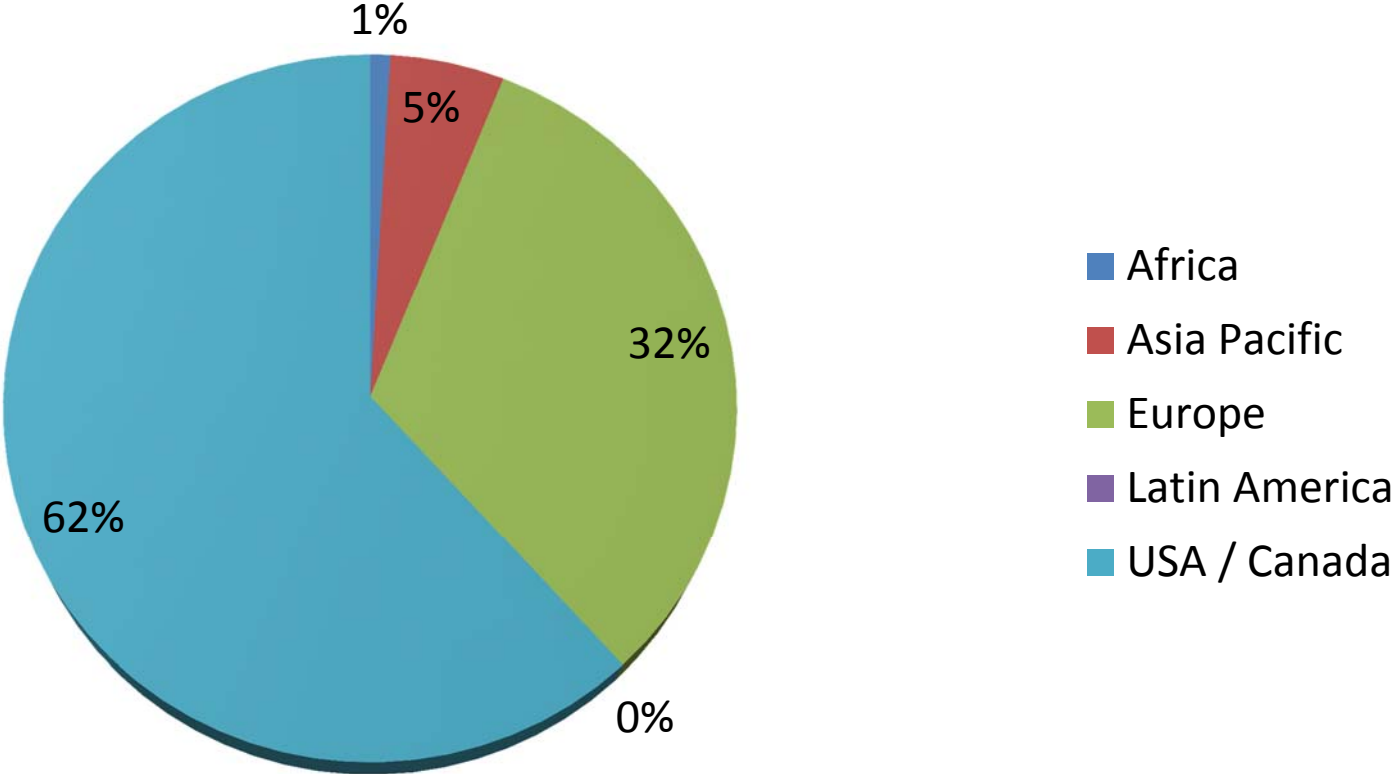
- 231 Evaluable Responses
- Sponsor organizations majority respondents (57%)

Your organization type:



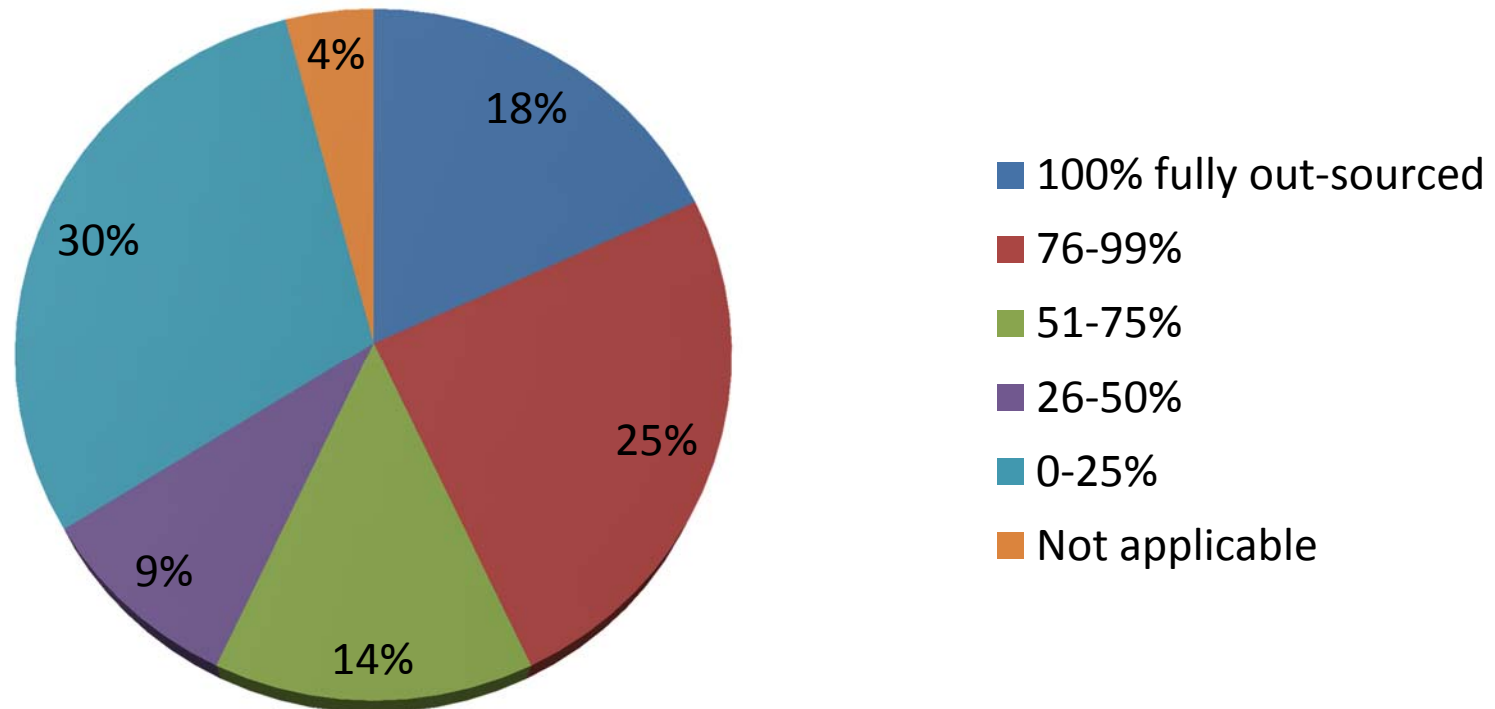
Respondent Location

Where are you located?



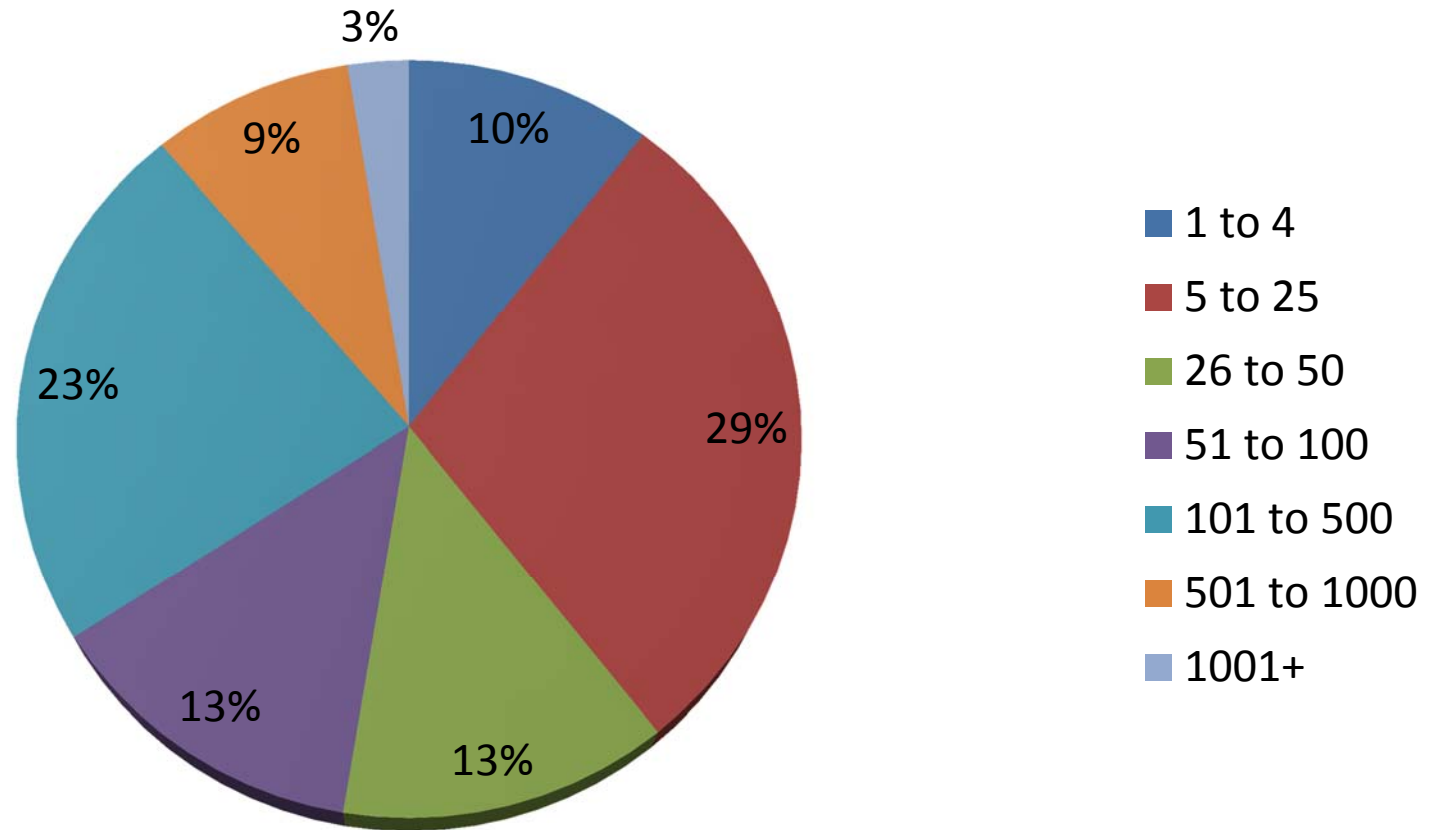
Trial Outsourcing Profile

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

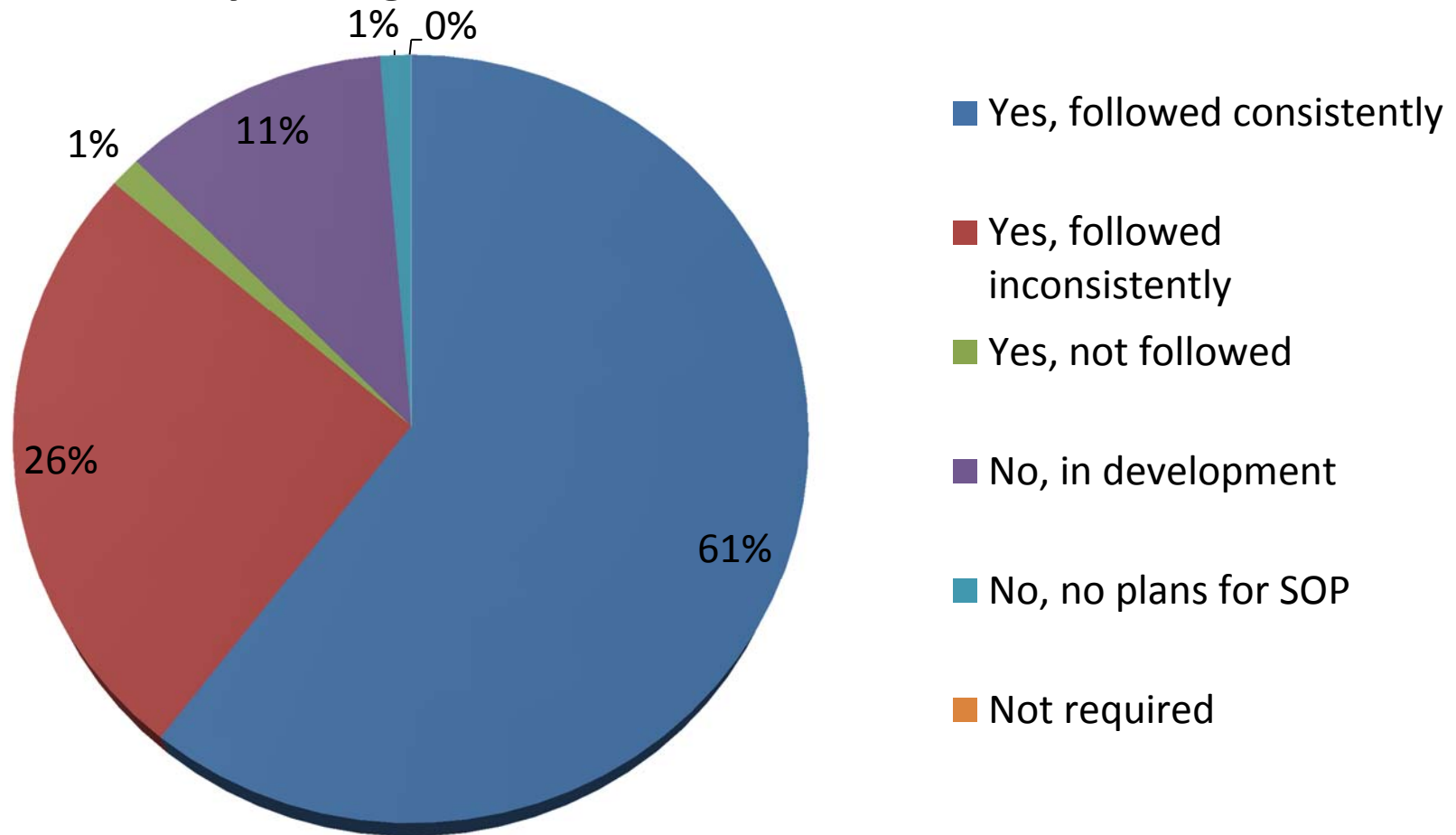




TMF / eTMF INSIGHTS

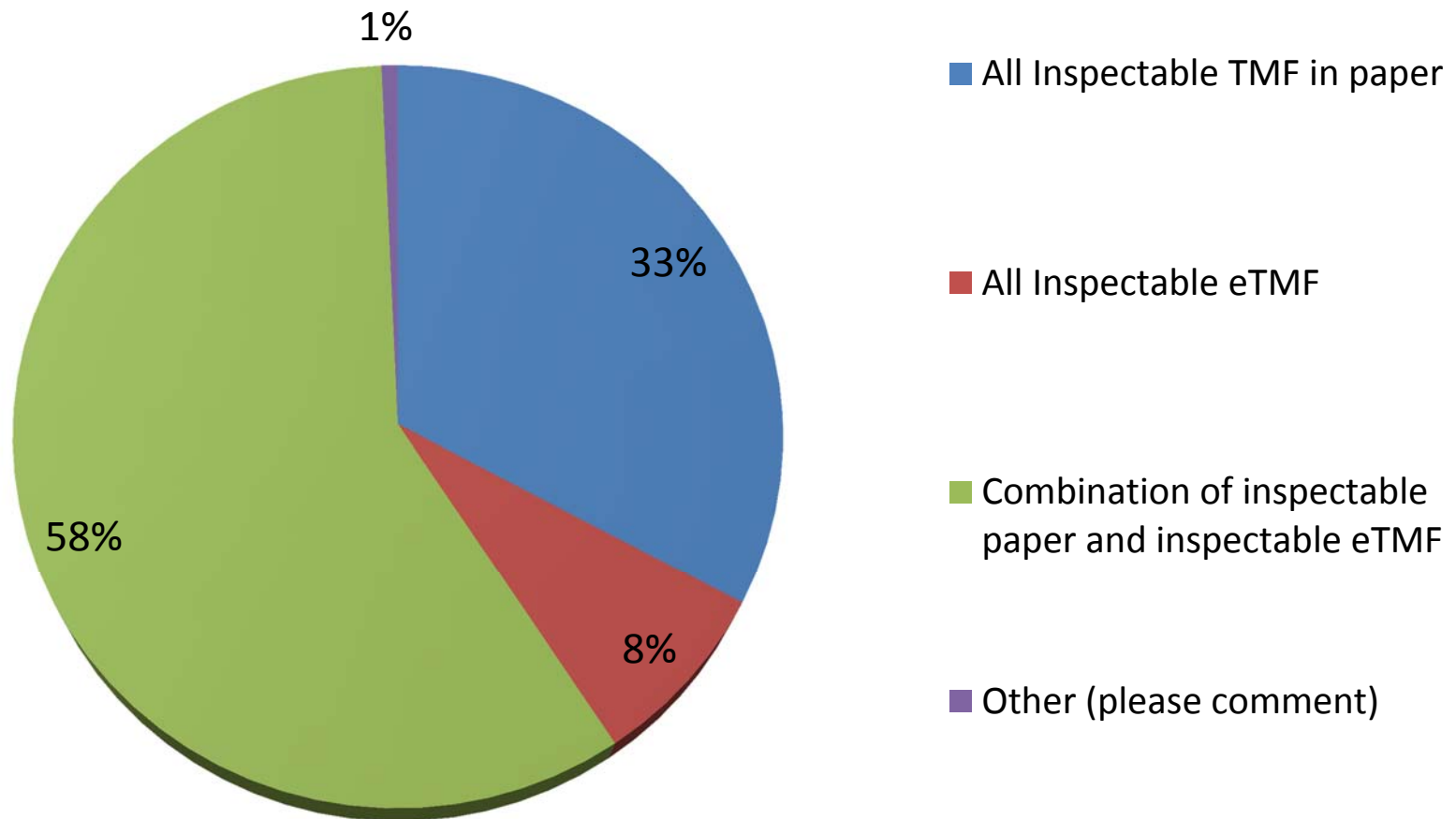
TMF SOP Adherence

Does your organization have and follow a TMF SOP?



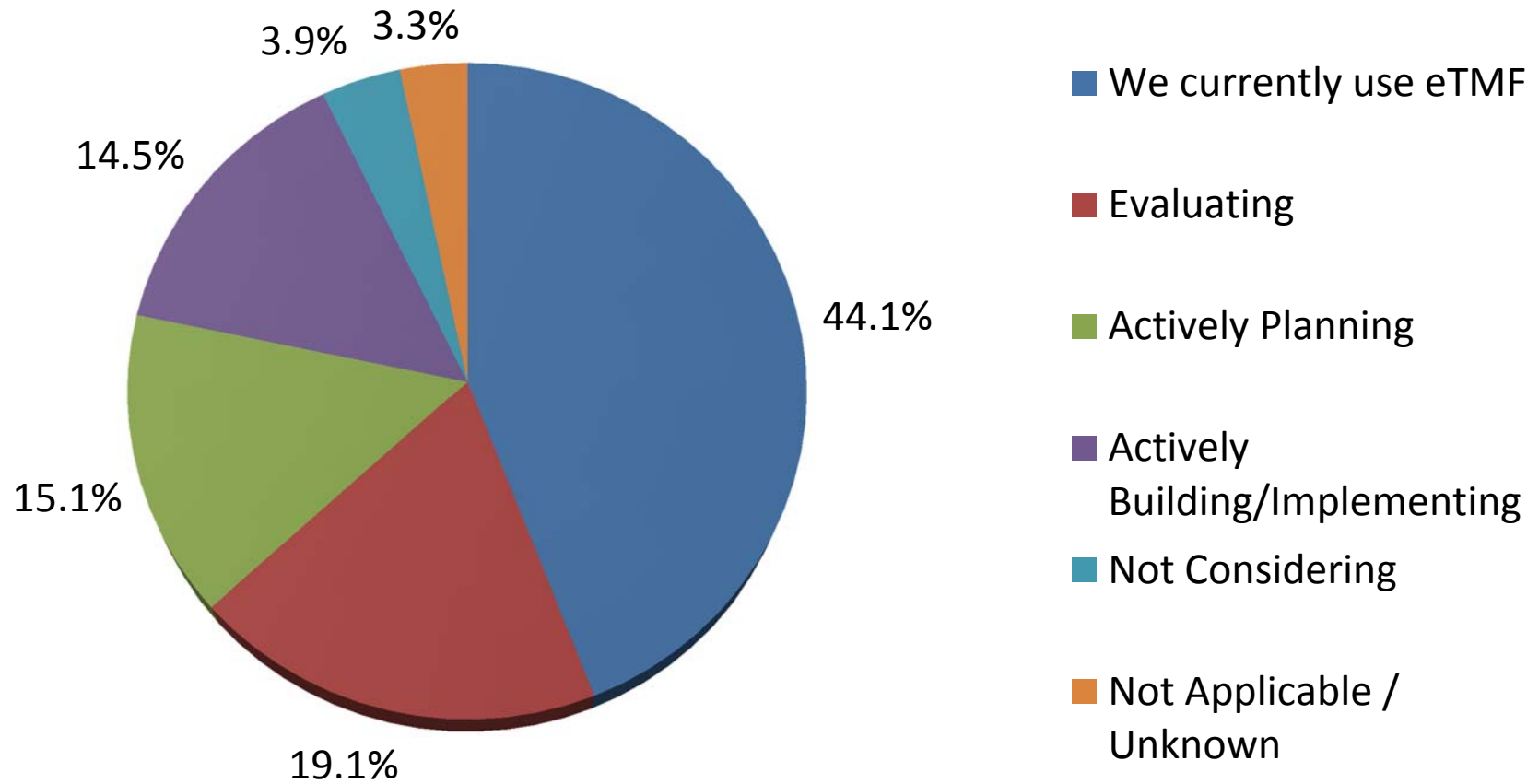
Paper TMF or Electronic TMF (eTMF)

What format is your TMF file of record?

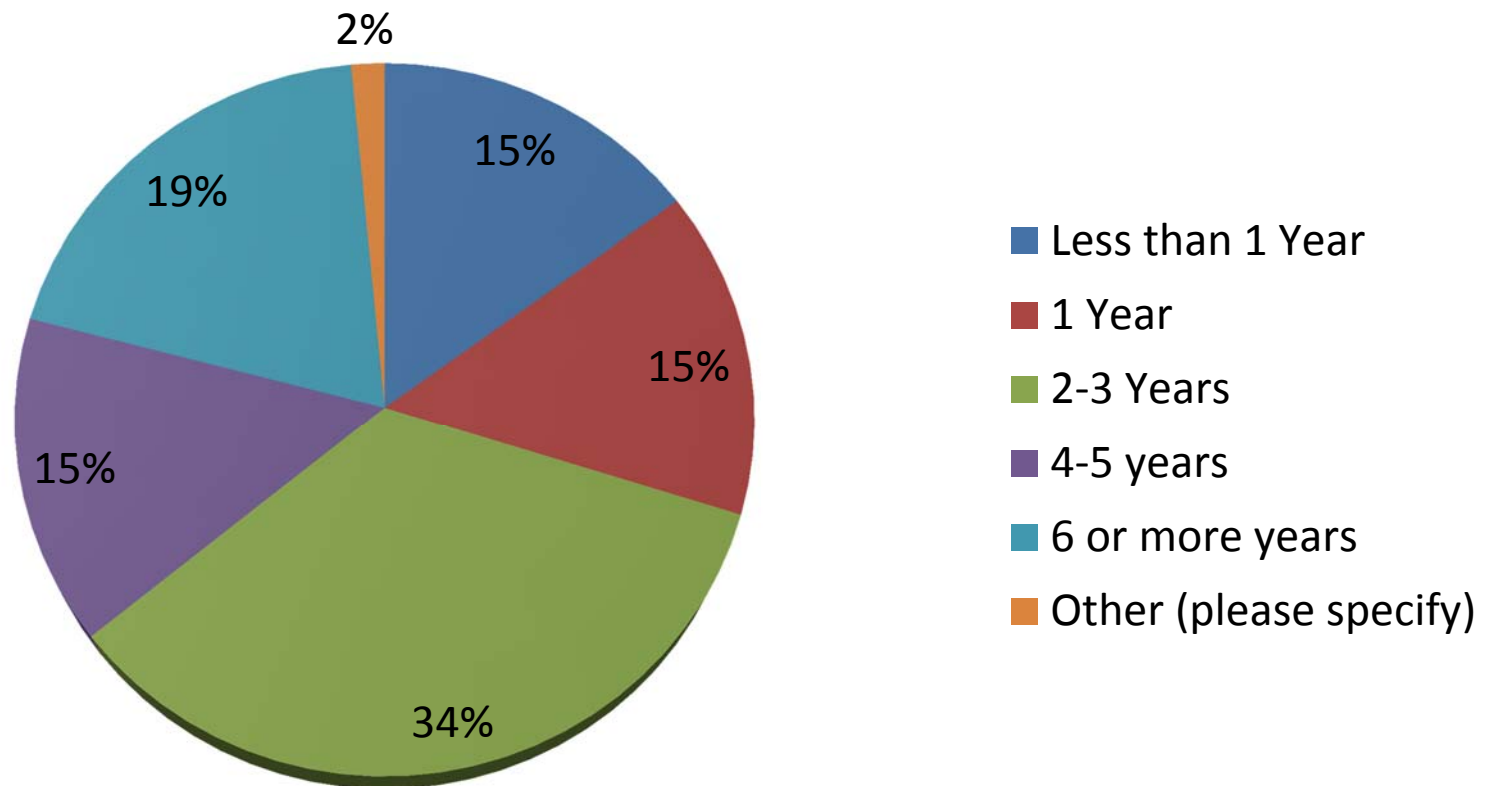


eTMF Status

What is the status of your organization's eTMF?

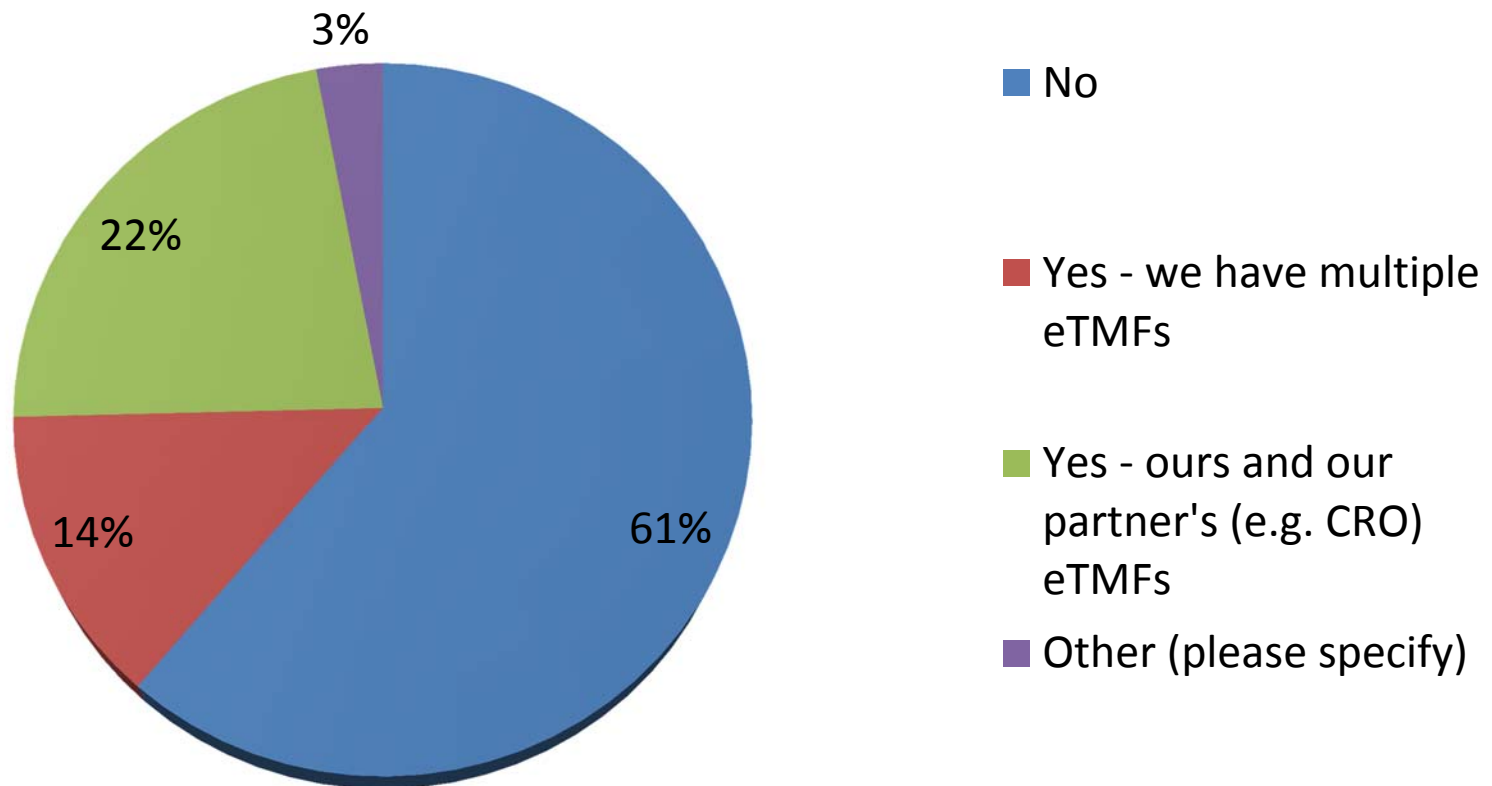


How long has your eTMF been in production?

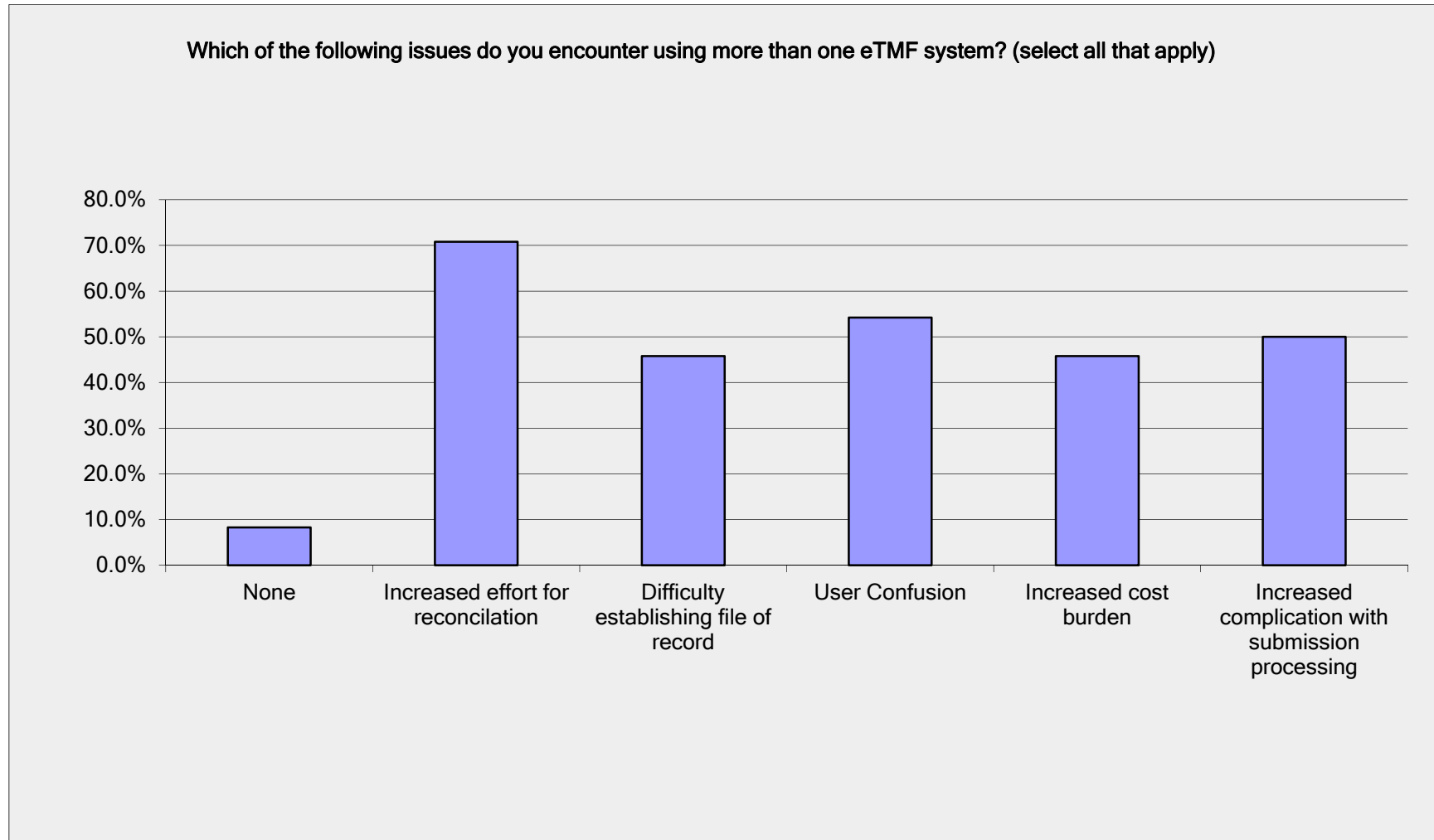


More Than One eTMF?

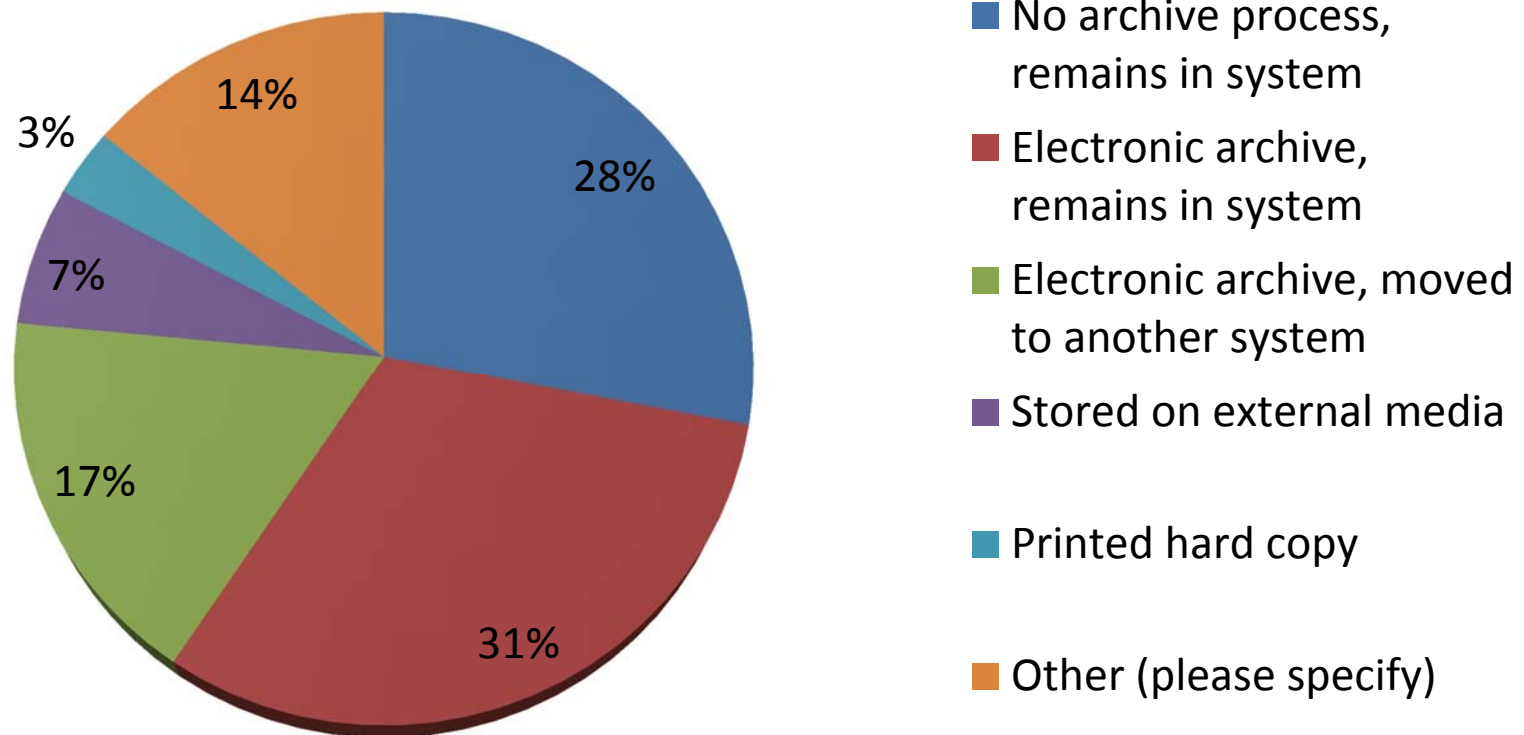
Do you use more than one eTMF system?



Issues When Using More Than One eTMF System



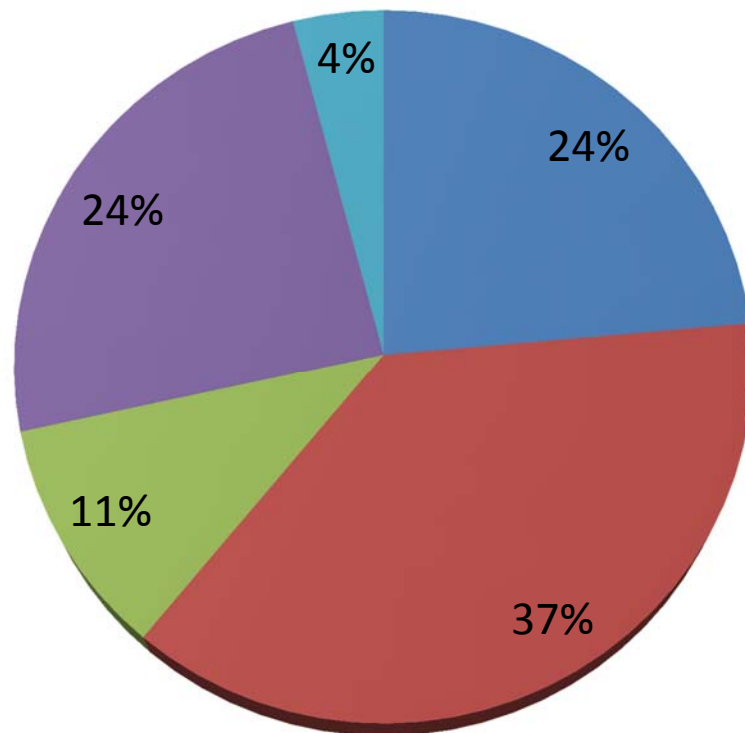
What is the eTMF post-trial "archive" process"?





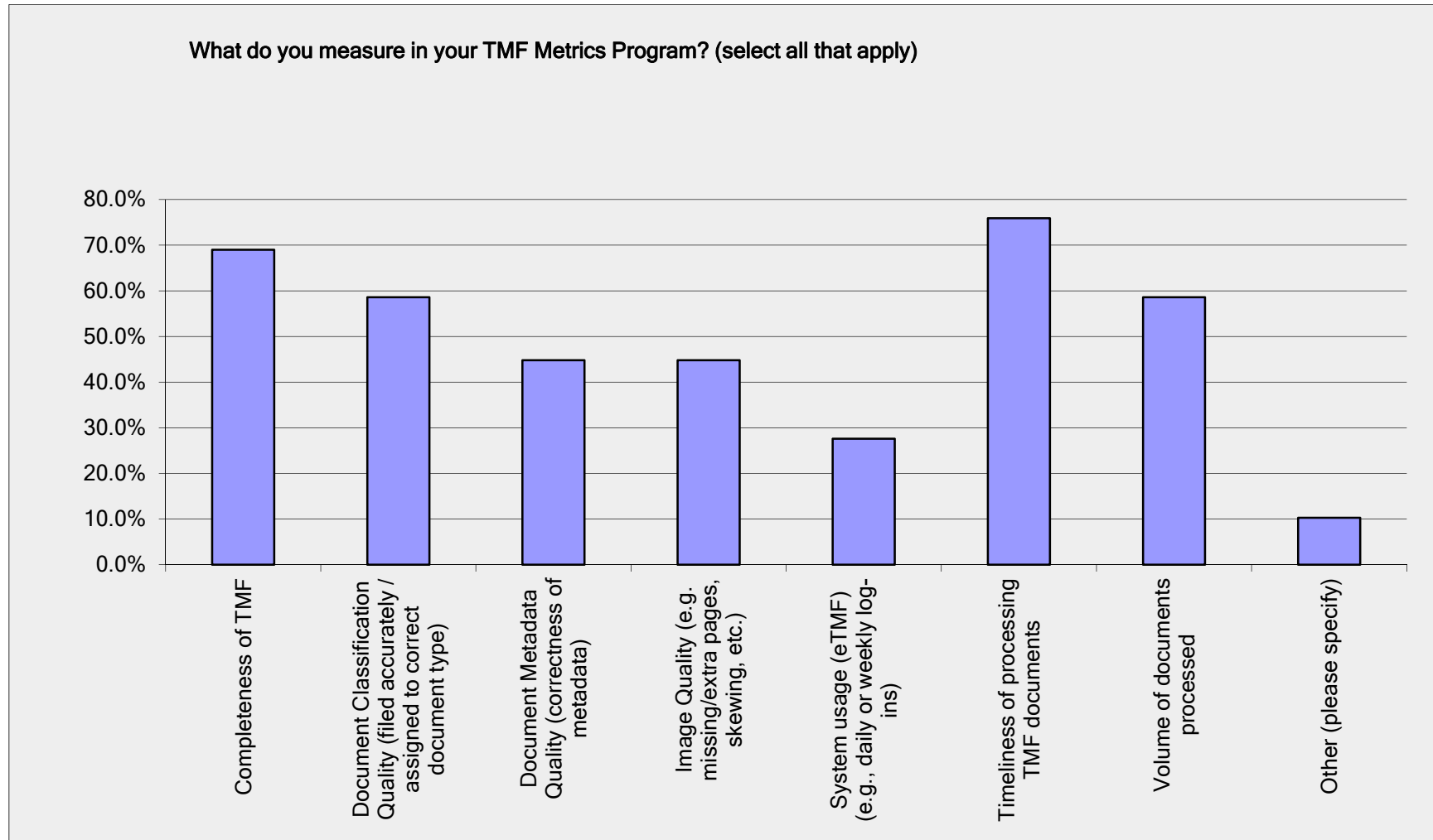
TMF METRICS

Do you have a TMF metrics program in place?

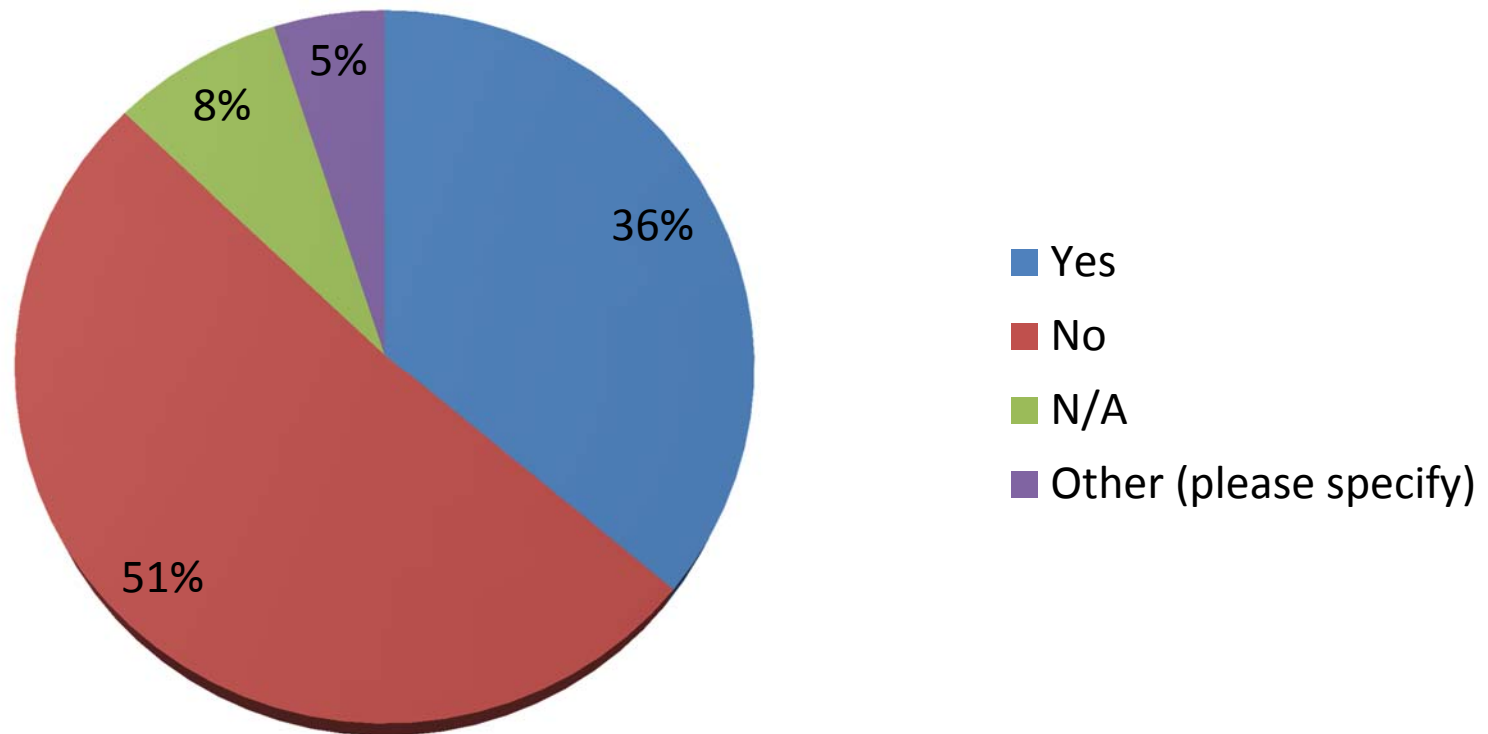


- Yes, we have a metrics program.
- No, but we are evaluating the need for a program.
- No, but we are implementing a metrics program.
- No, we are not planning a metrics program
- Other (please specify)

TMF Metrics Program Measurements

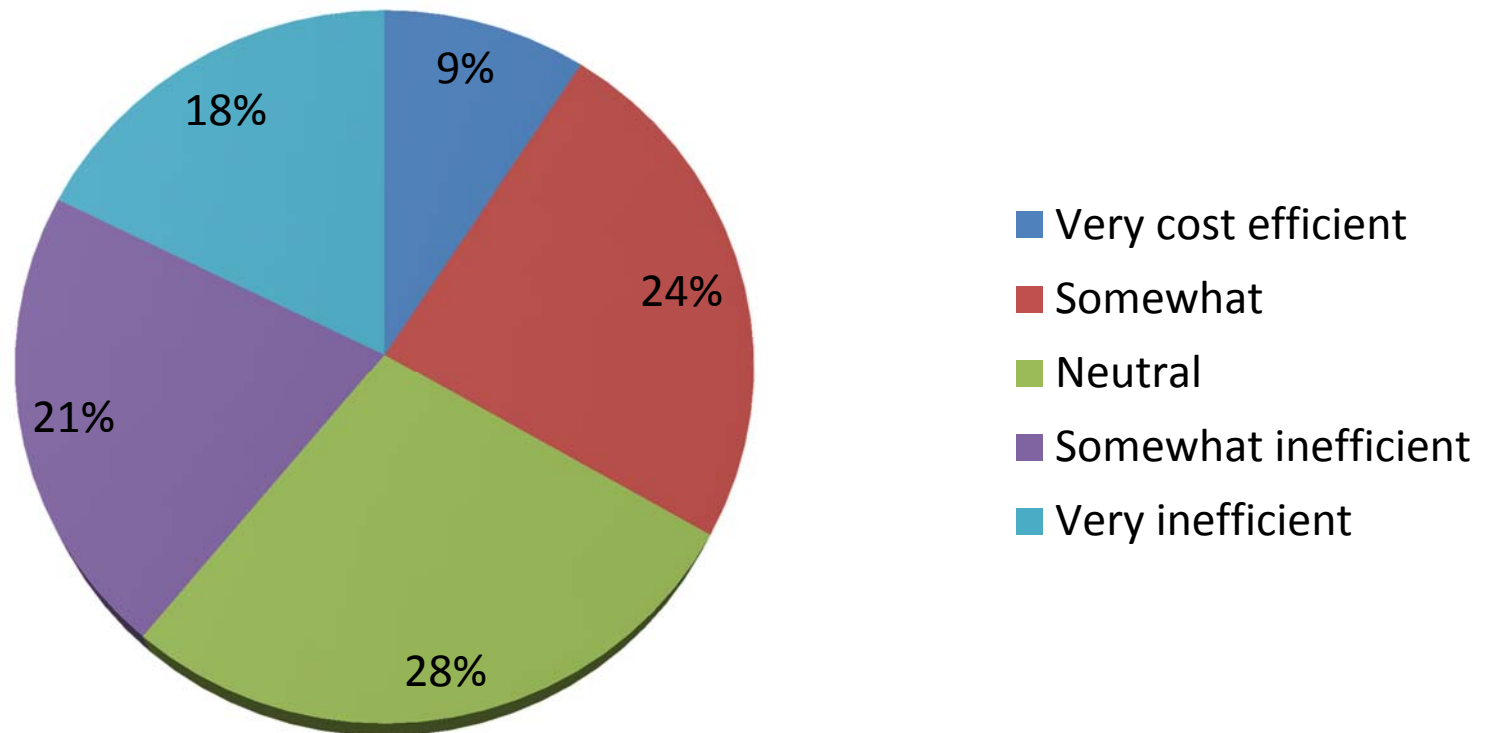


Do you measure TMF costs?



TMF Metrics – Cost Efficiency Opinion

Do you believe your TMF is cost efficient?

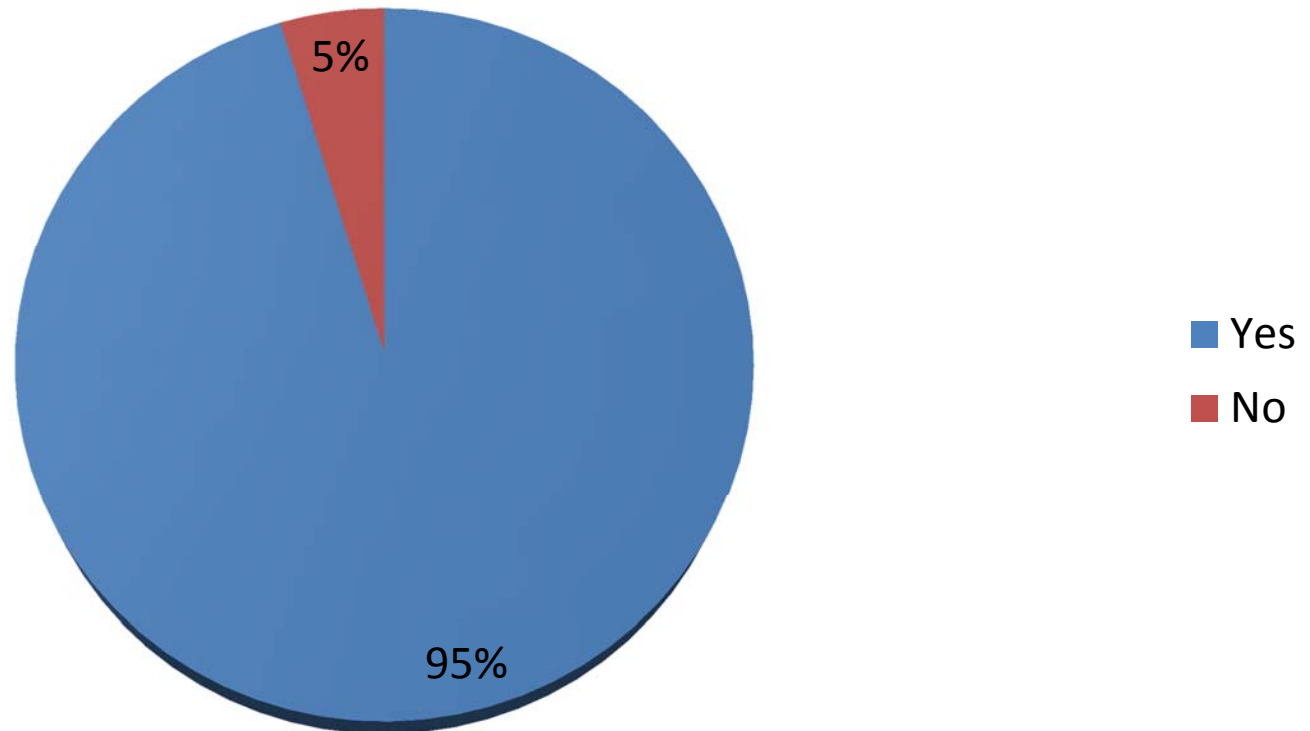




TMF REFERENCE MODEL USE

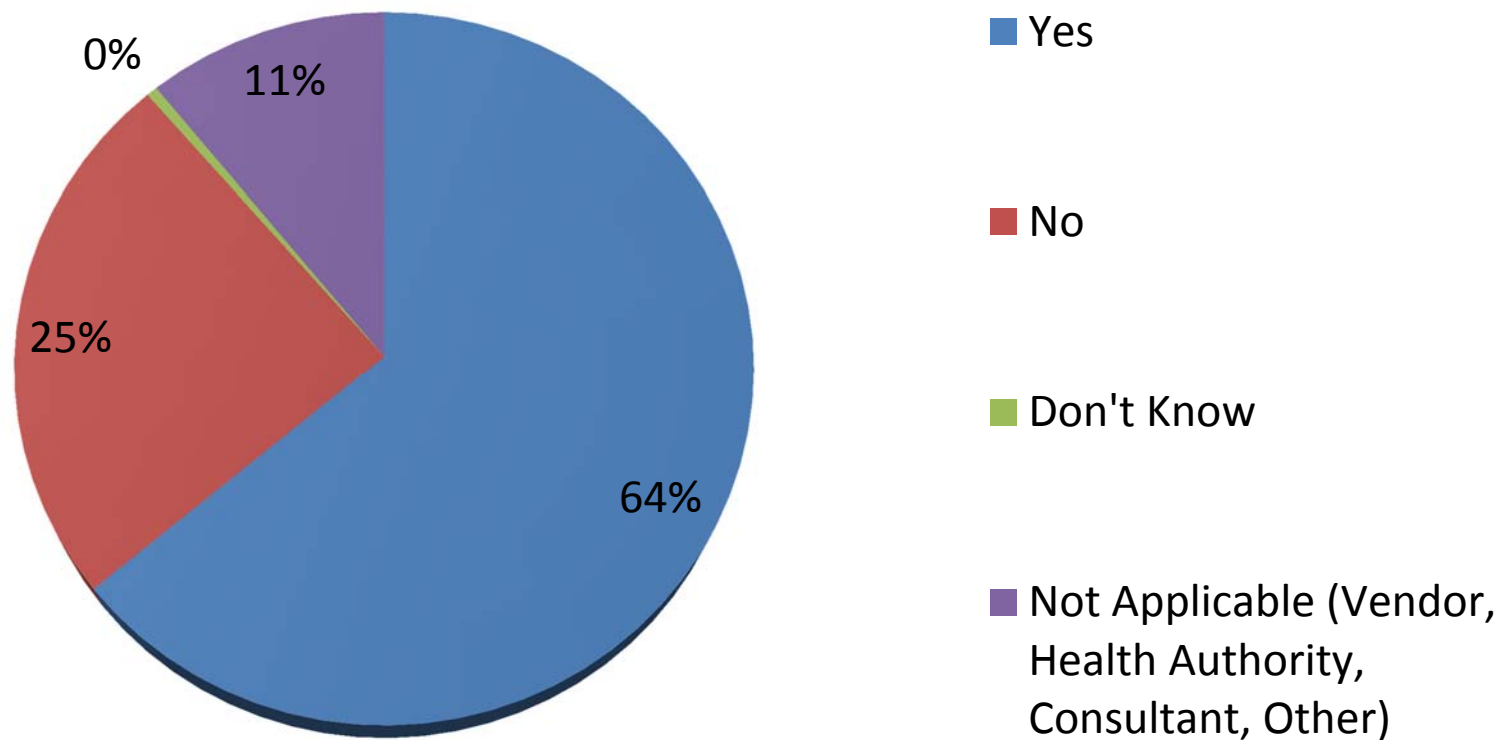
TMF Reference Model Awareness

Are you aware of the TMF Reference Model?



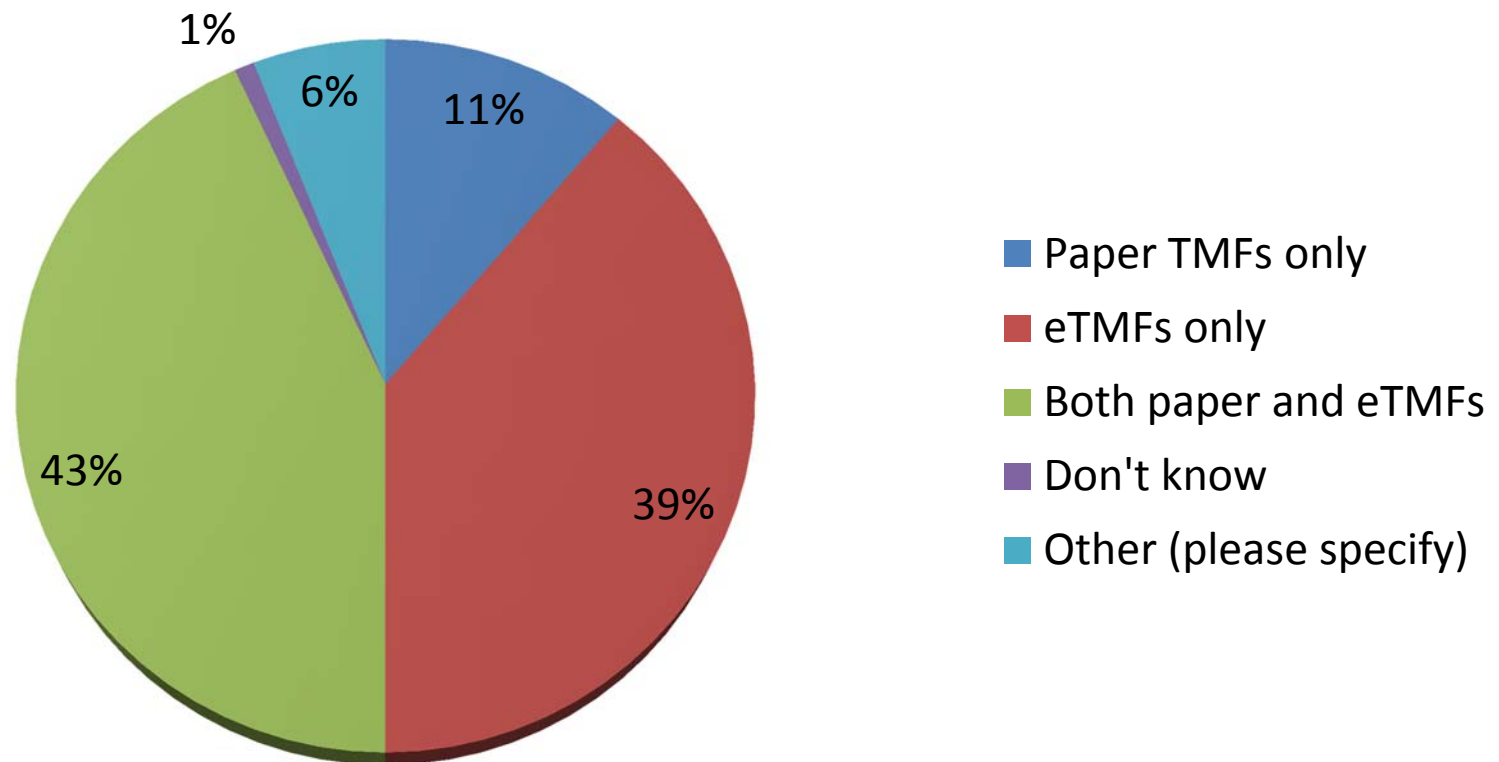
TMF Reference Model Use

Is your organization using the TMF Reference Model?

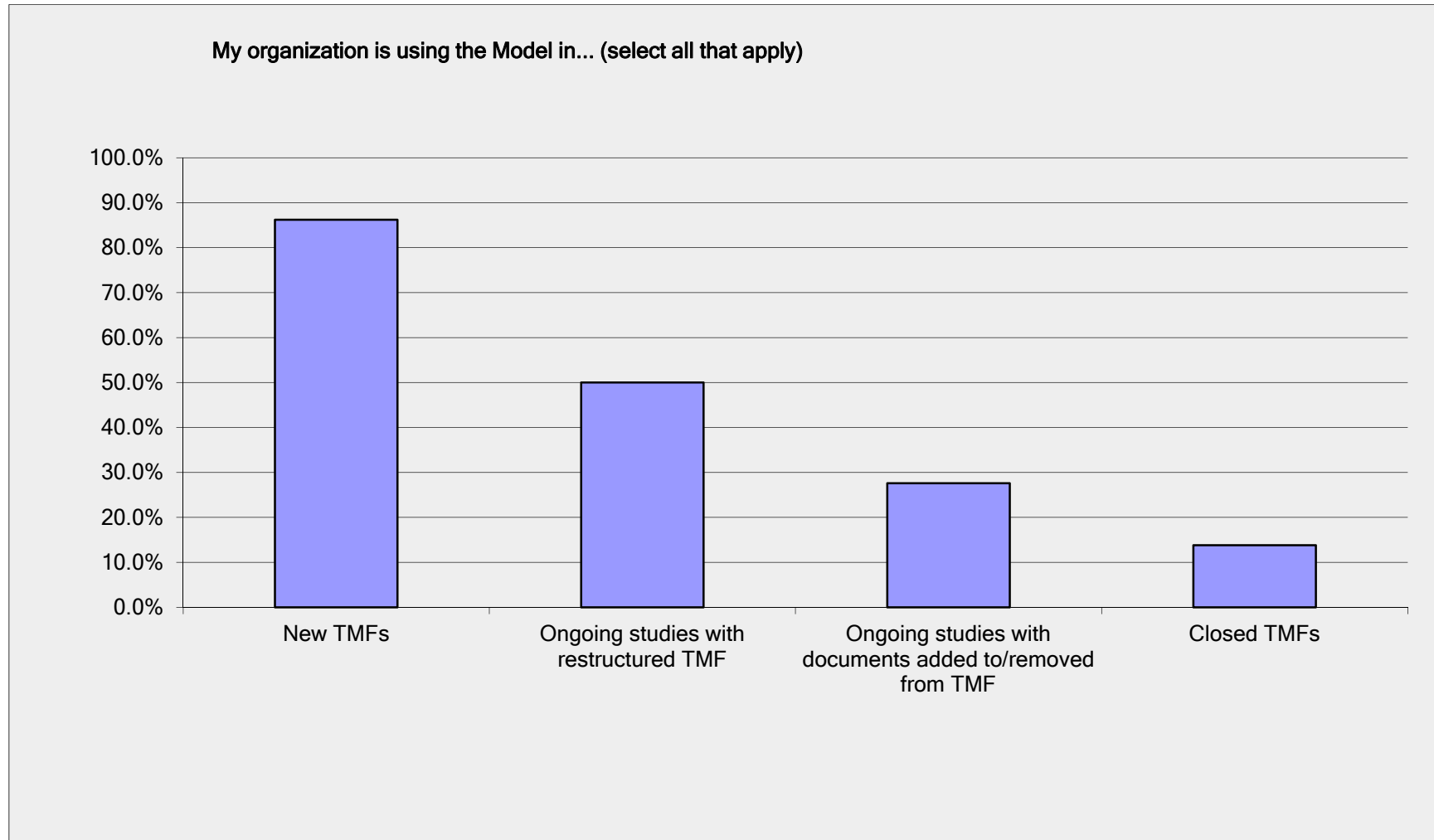


TMF Reference Model for paper or eTMF?

My organization is using the Model for...

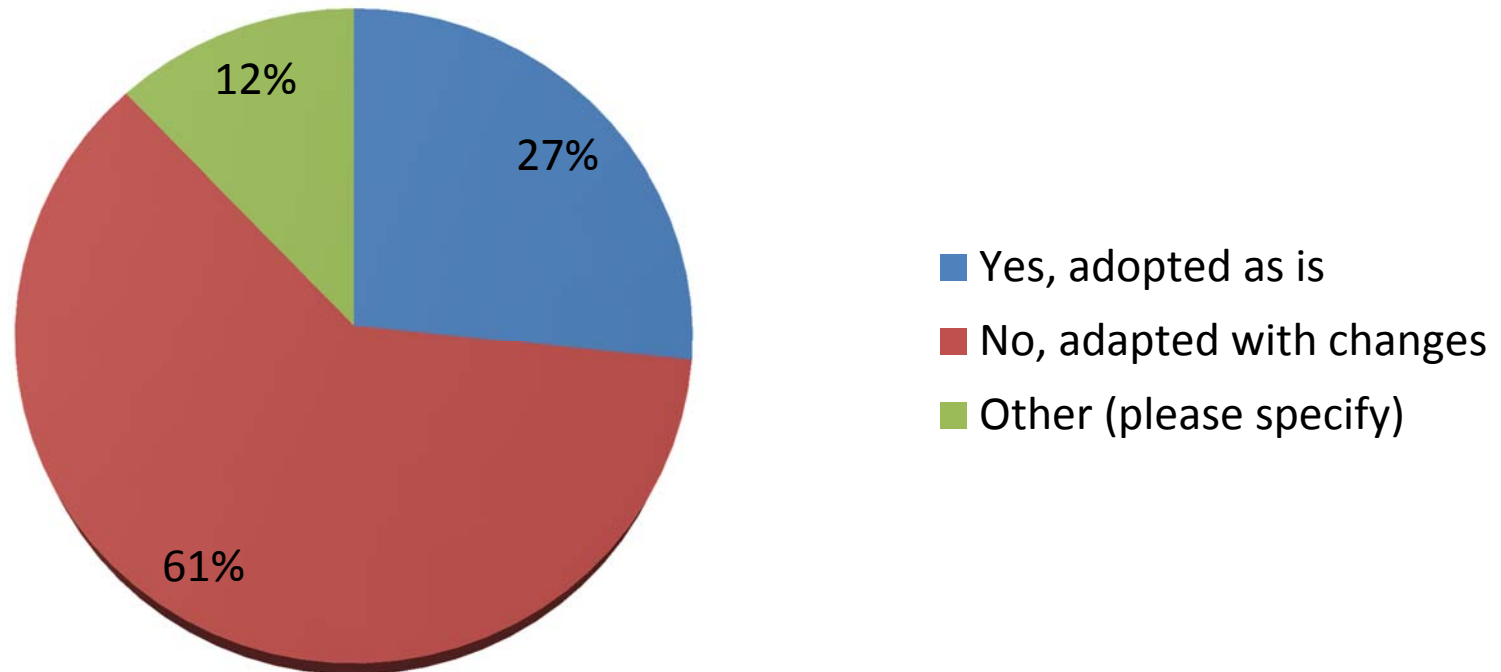


TMF Reference Model Use in New and Ongoing Trials

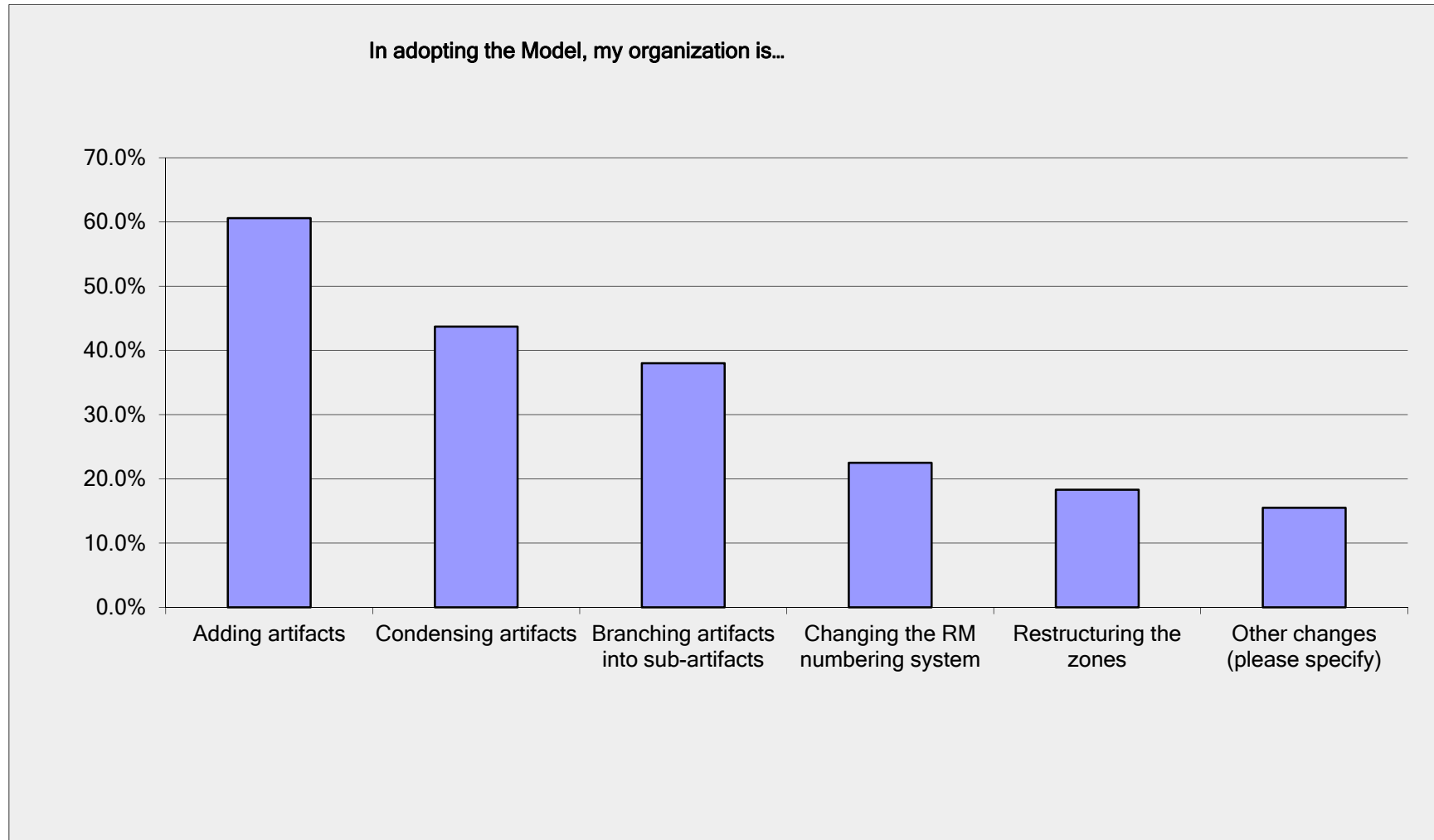


TMF Reference Model Adoption Practices

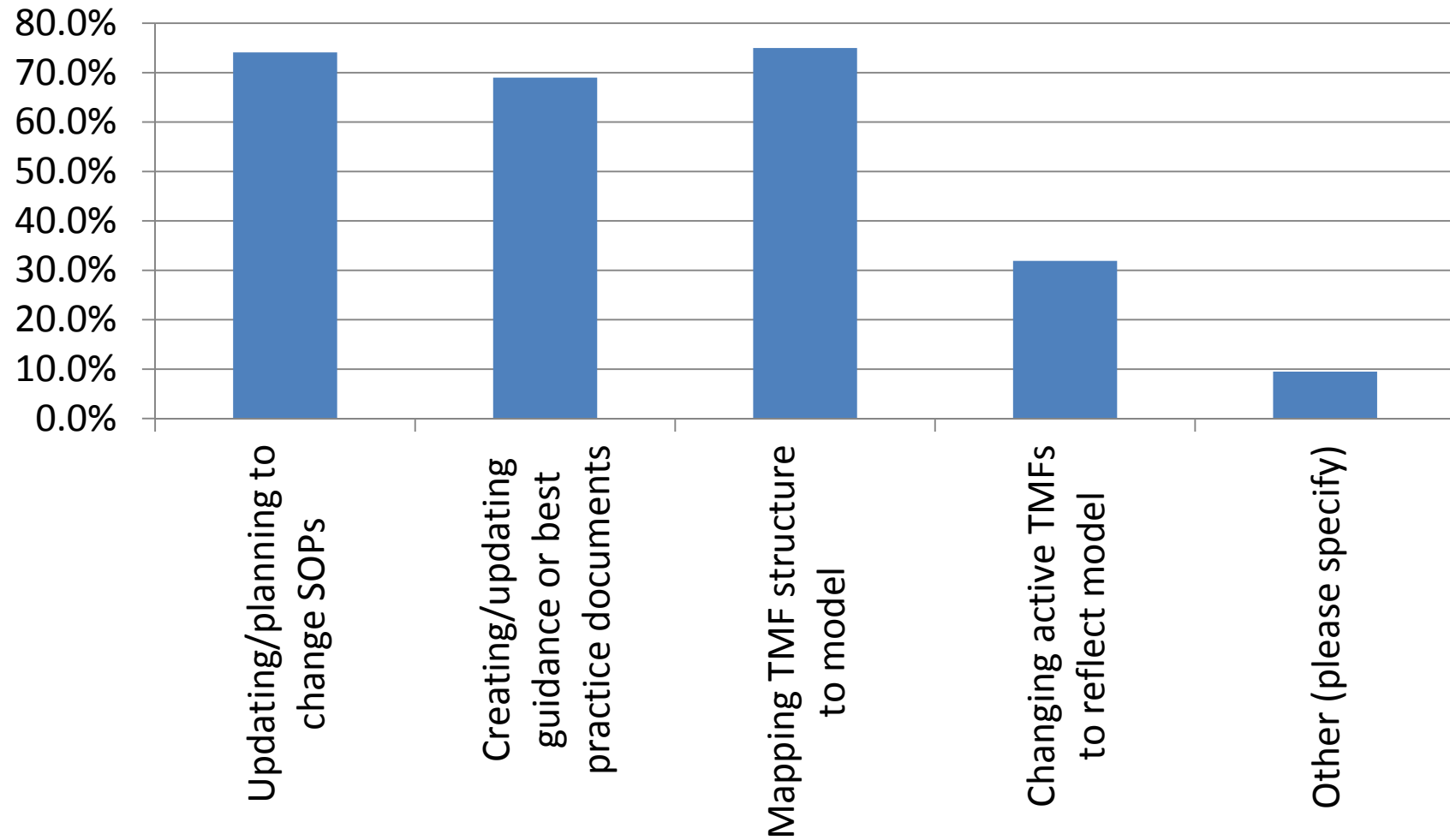
Has your organization adopted the Model as is, without any change?



TMF Reference Model Adoption Methods



TMF Reference Model Adoption Impacts

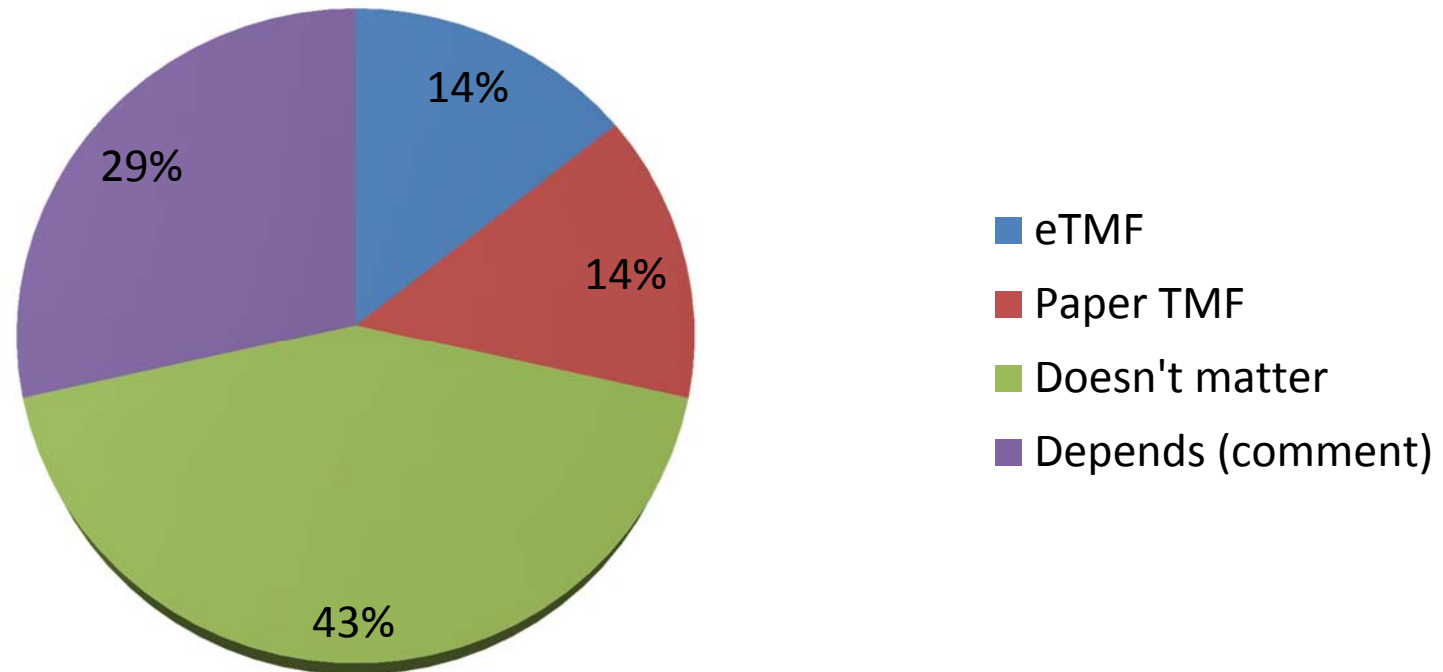




INSPECTION TRENDS

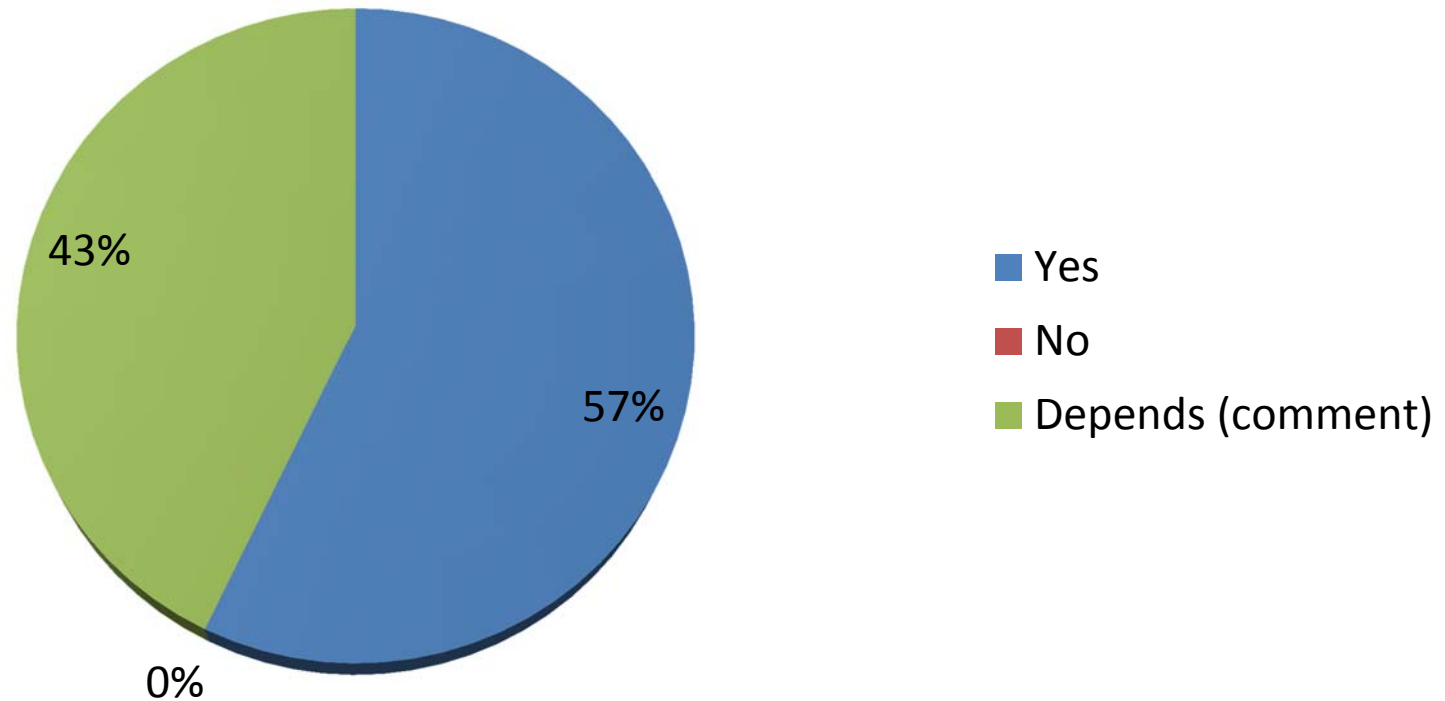
Inspector Opinion – TMF Modality

Do you have a preference for clinical trial documentation / TMF inspection modality?



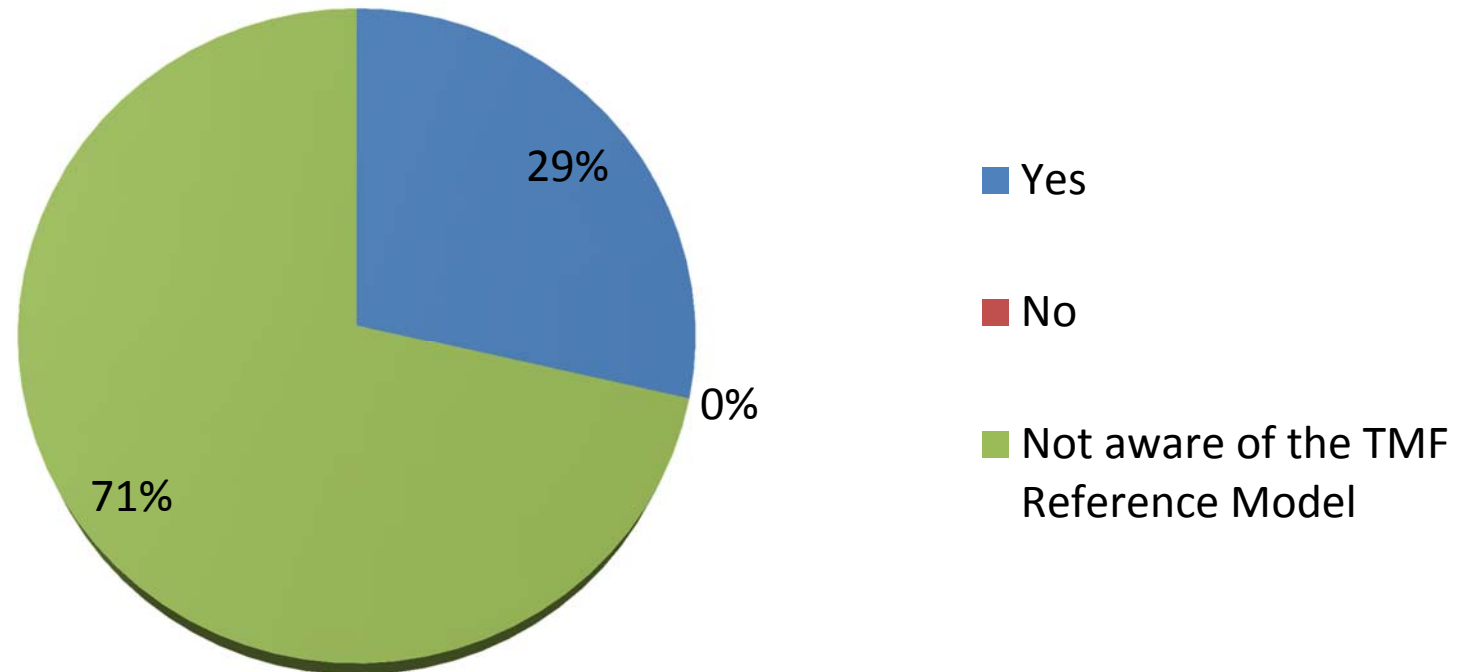
Inspector Opinion – eTMF Inspection Use

Are you / would you be comfortable completing an inspection in an eTMF?



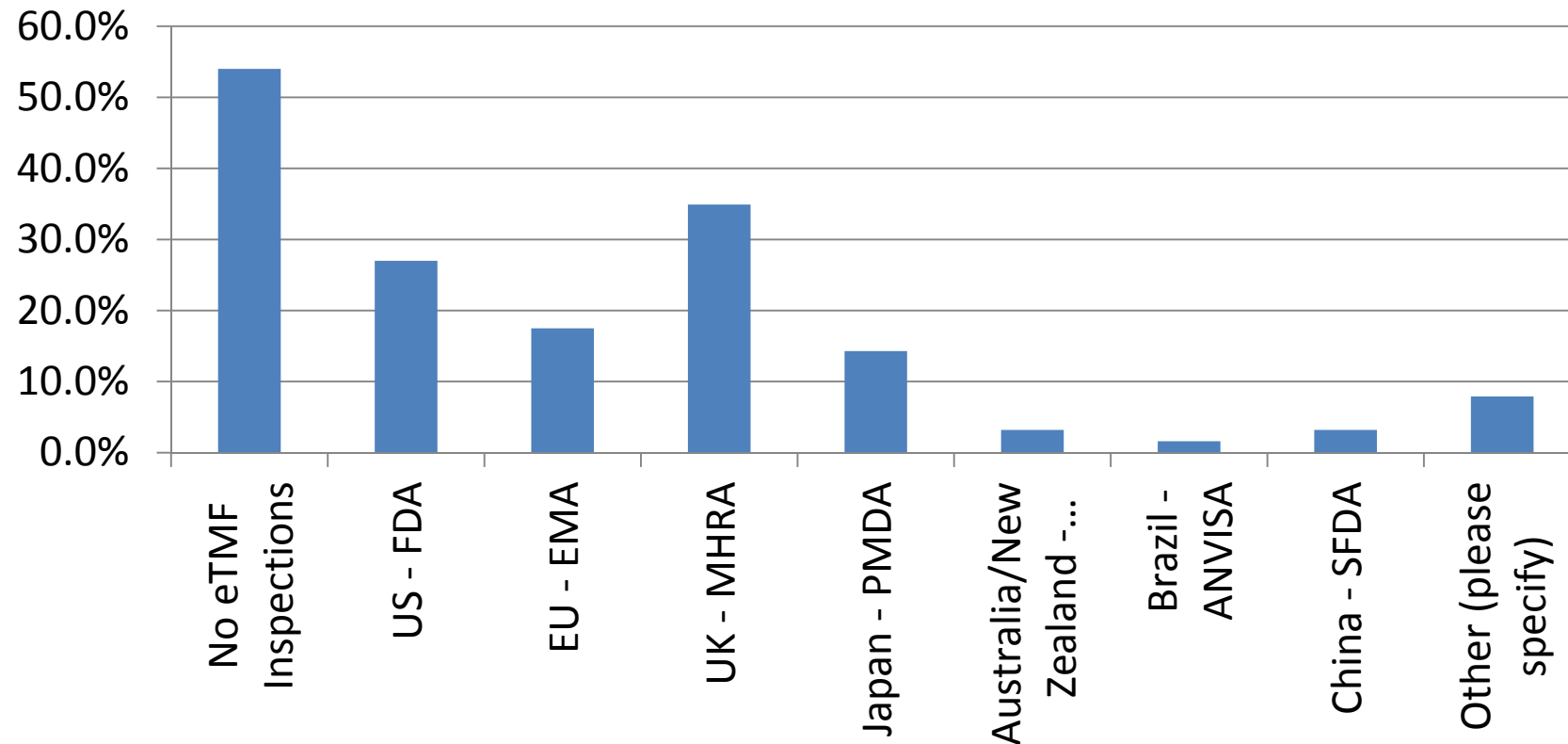
Inspector Opinion – TMF Reference Model

Do you find the TMF Reference Model supports activities in clinical trial inspections



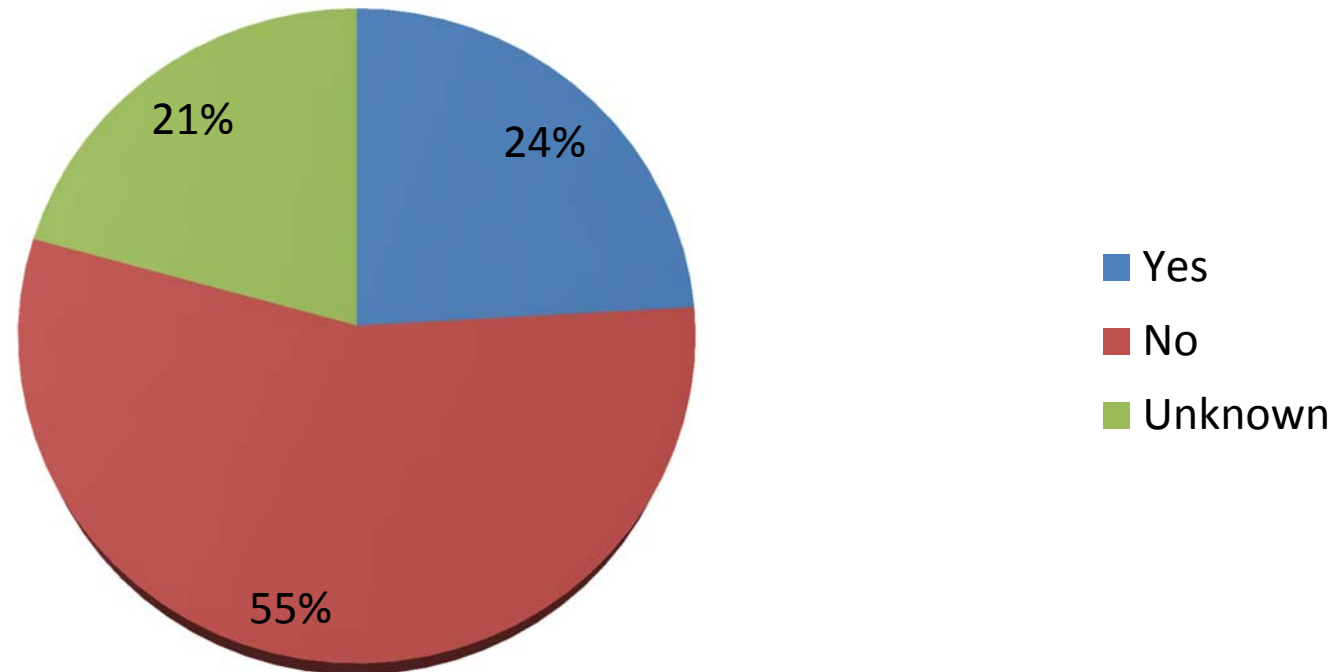
Sponsor Inspection History

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



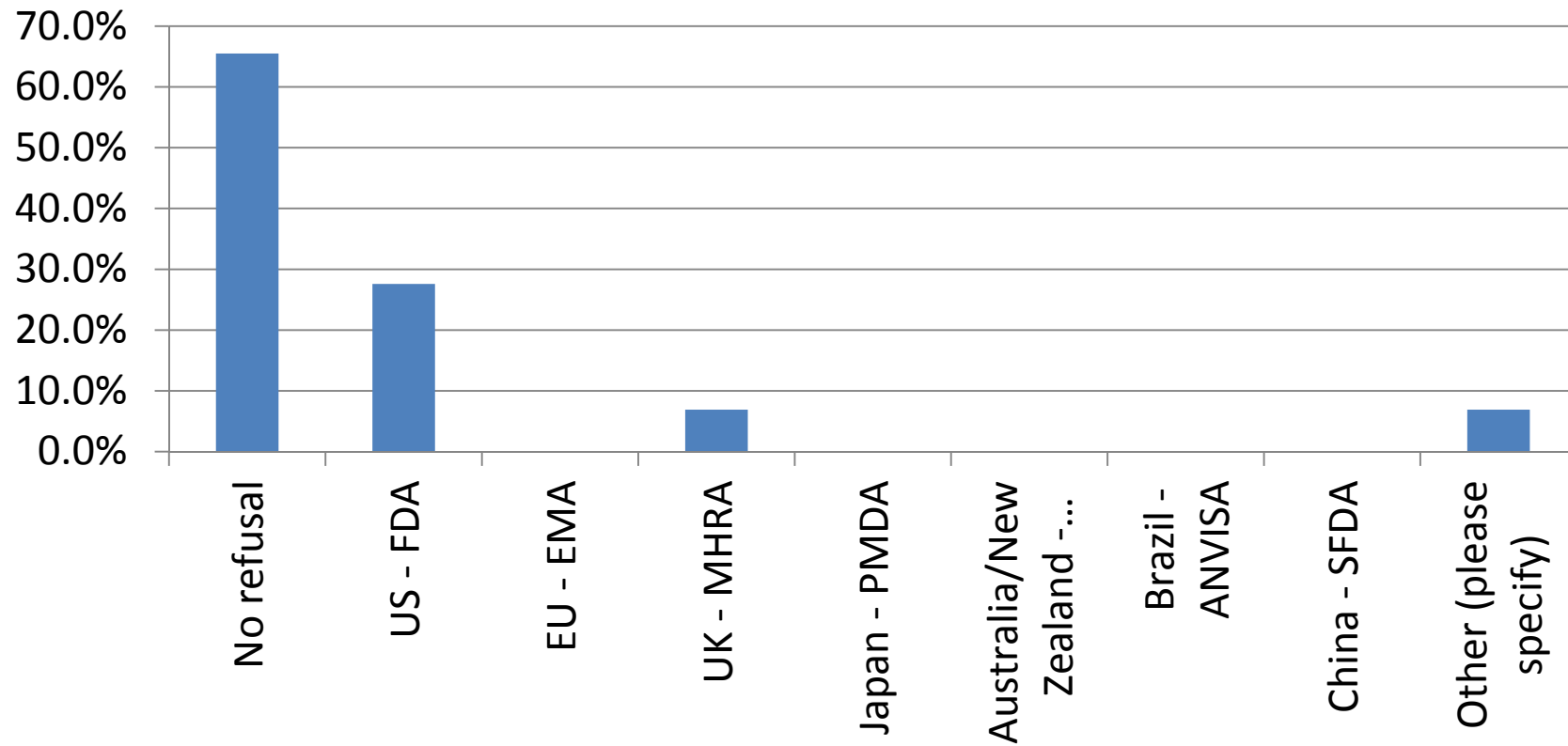
Sponsor Remote Inspection History

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



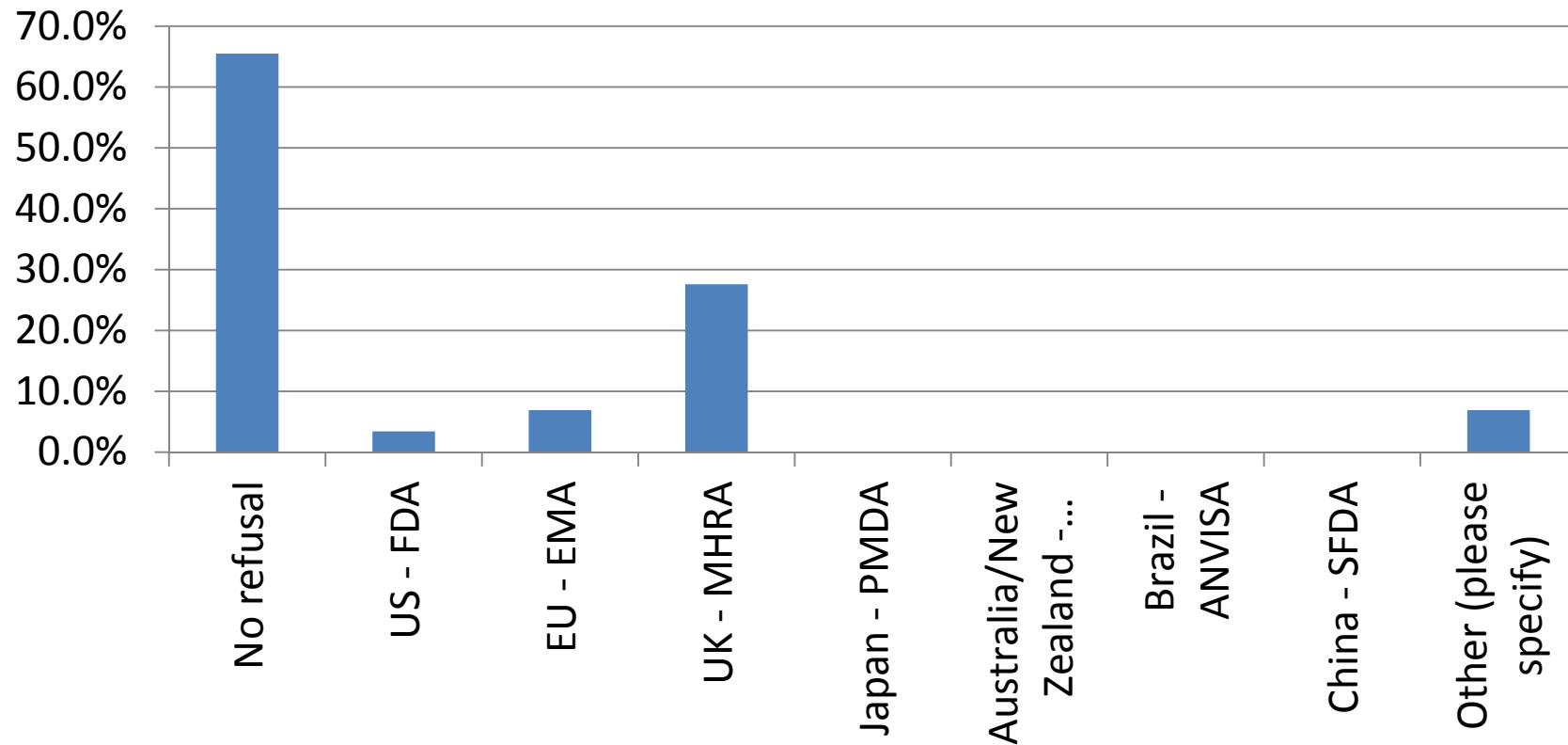
Sponsor Inspection History Paper Requests

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



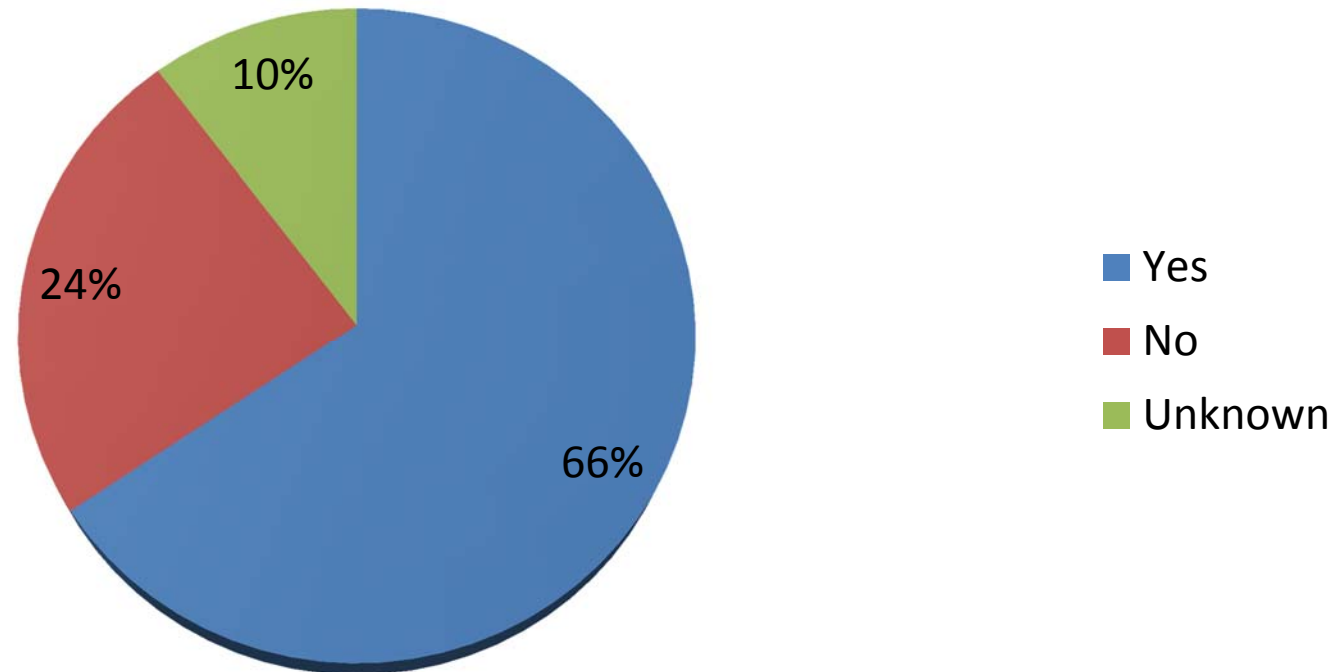
Sponsor Inspection History eTMF Resistance

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



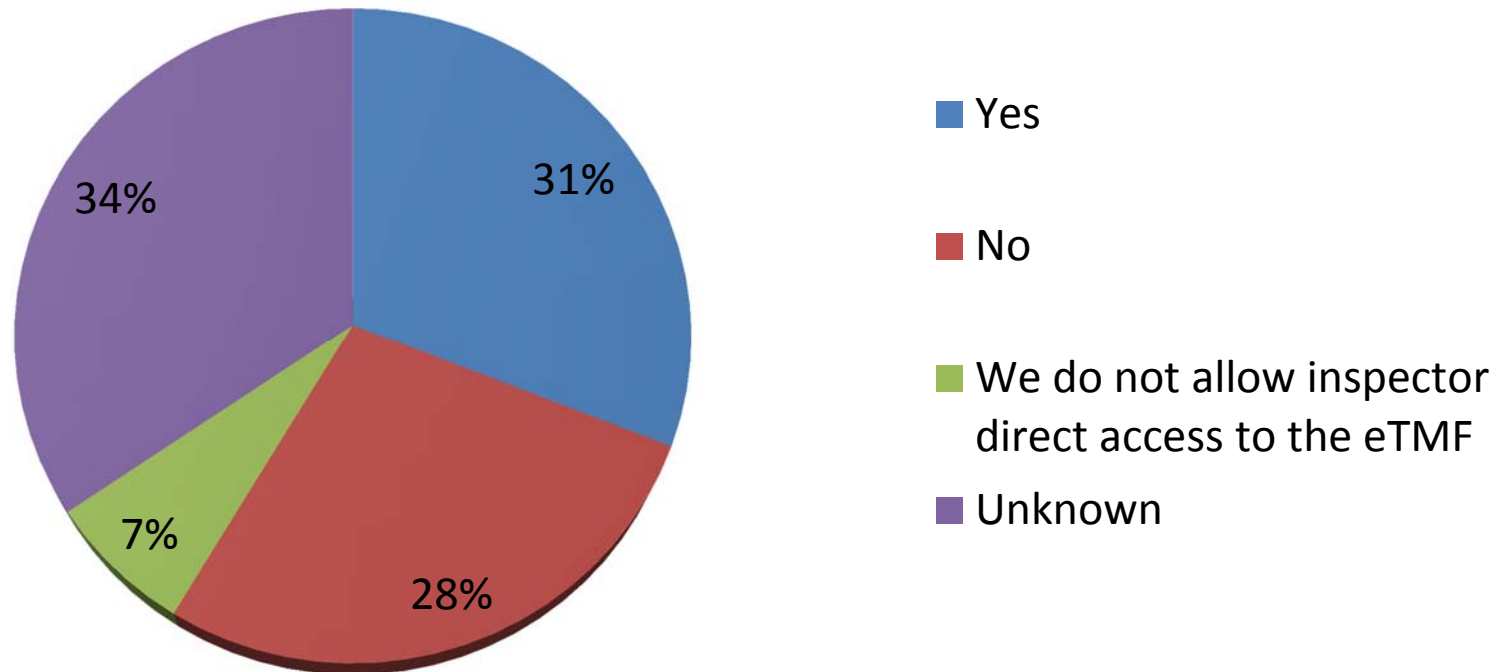
Sponsor Opinion - Inspection Preparation Impact

Has the eTMF helped ease burdens of audits / inspections?



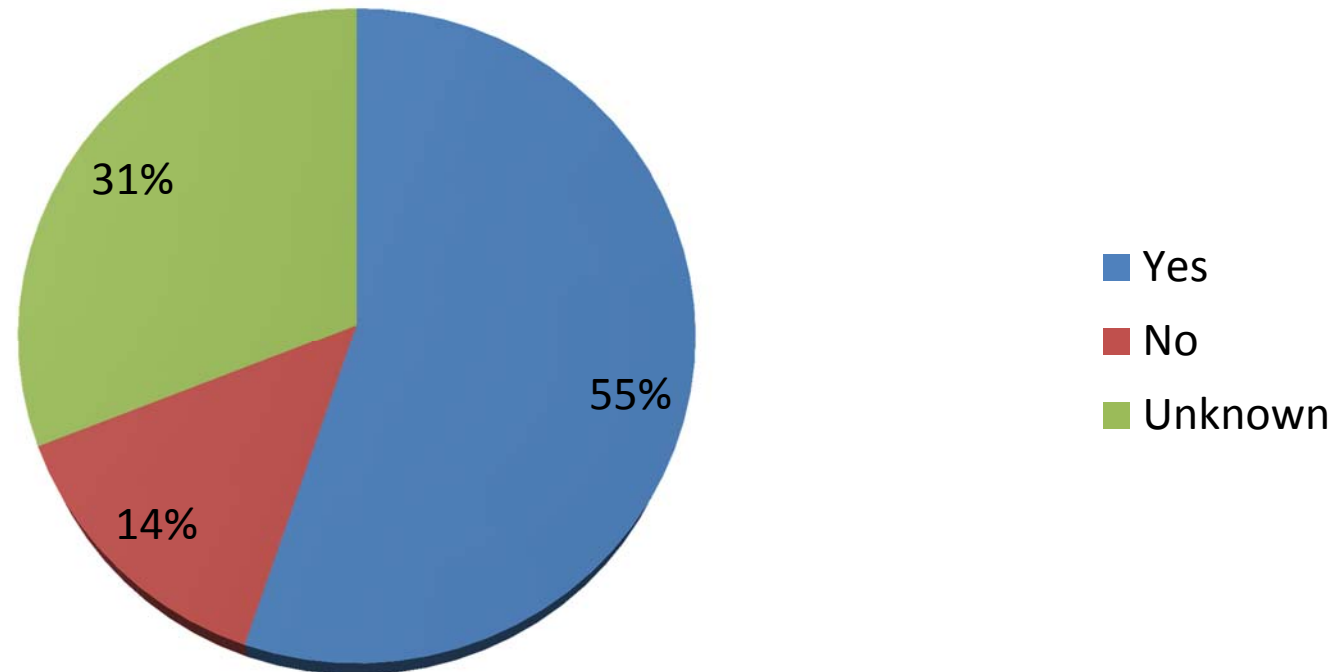
Sponsor Opinion - eTMF Inspection Impact

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



Sponsor Opinion – eTMF Impact Unannounced Inspections

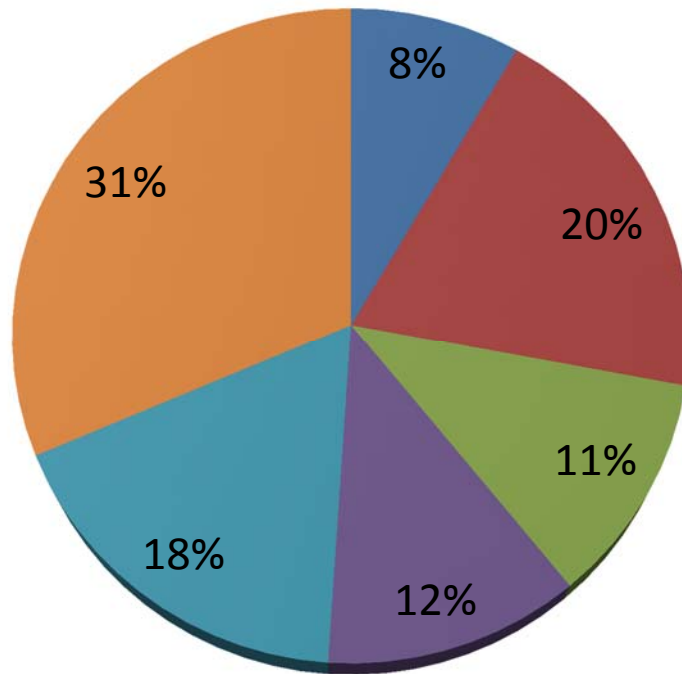
Has the eTMF proved a benefit in allowing you to support unannounced inspections?





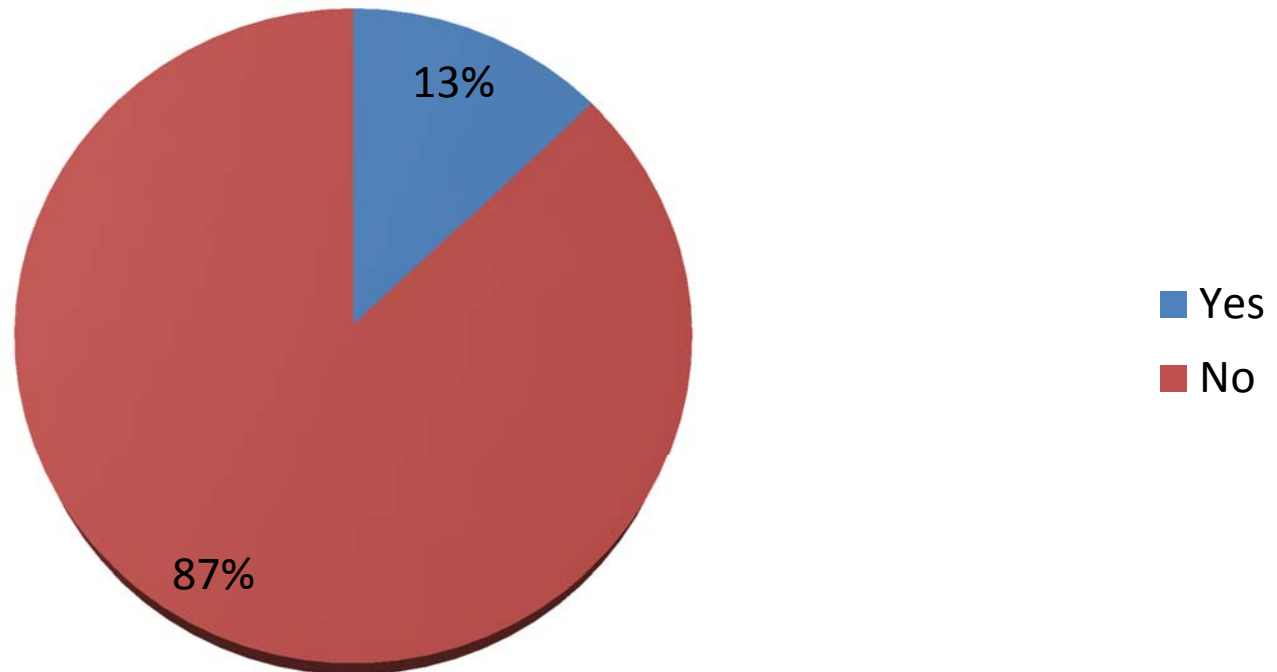
ELECTRONIC INVESTIGATOR SITE FILE (e-ISF)

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



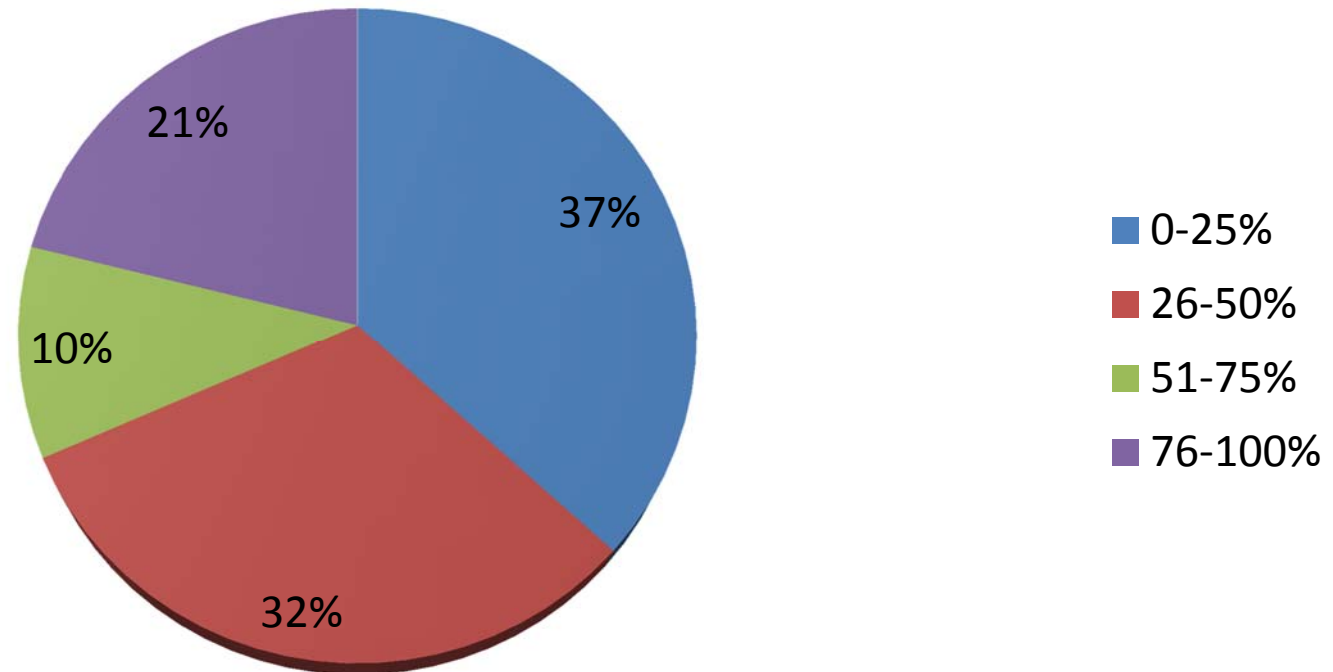
- We currently externalize content
- Evaluating
- Actively Planning
- Actively Building/Implementing
- Not Considering
- Not Applicable / Unknown

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



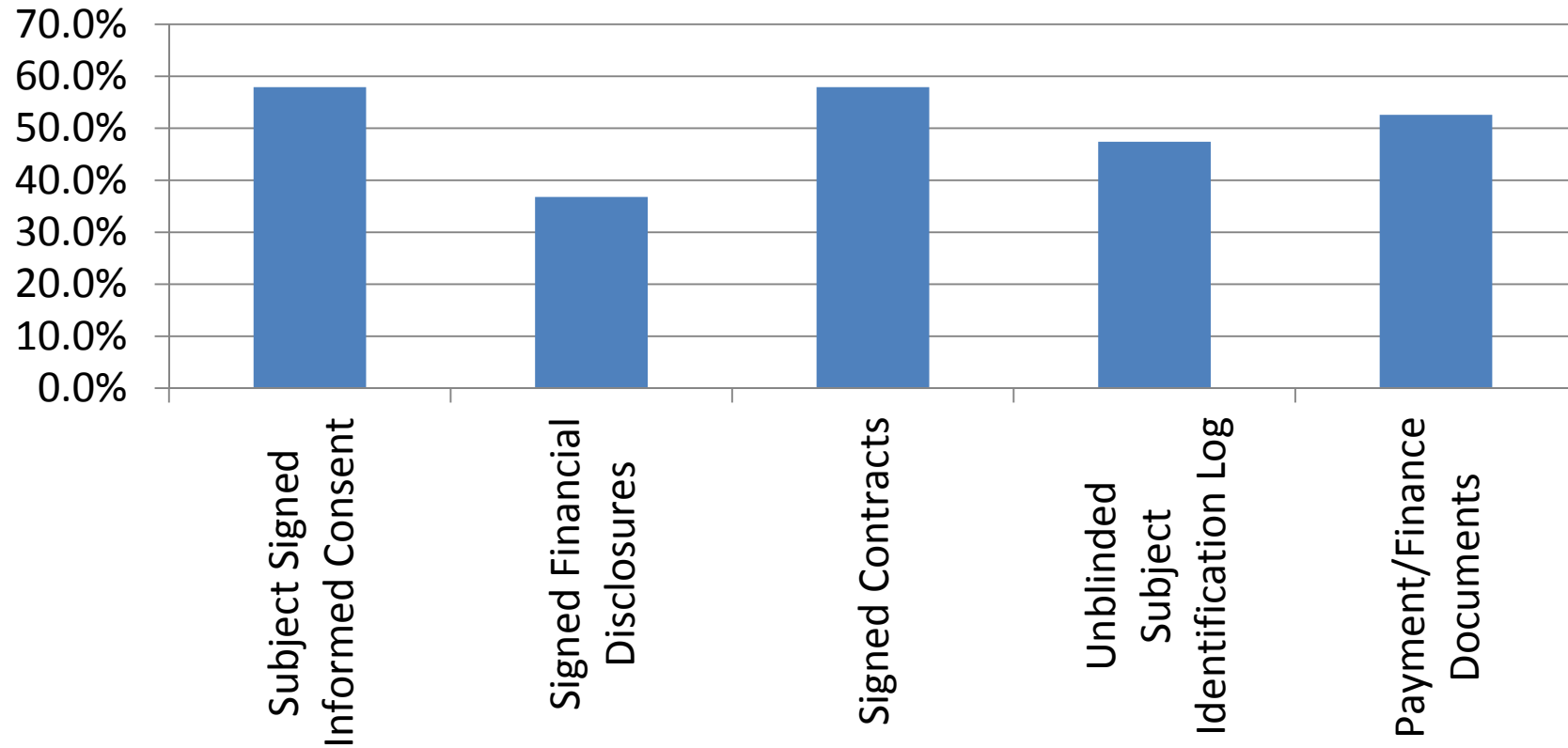
Percentage of Trials with eISF

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

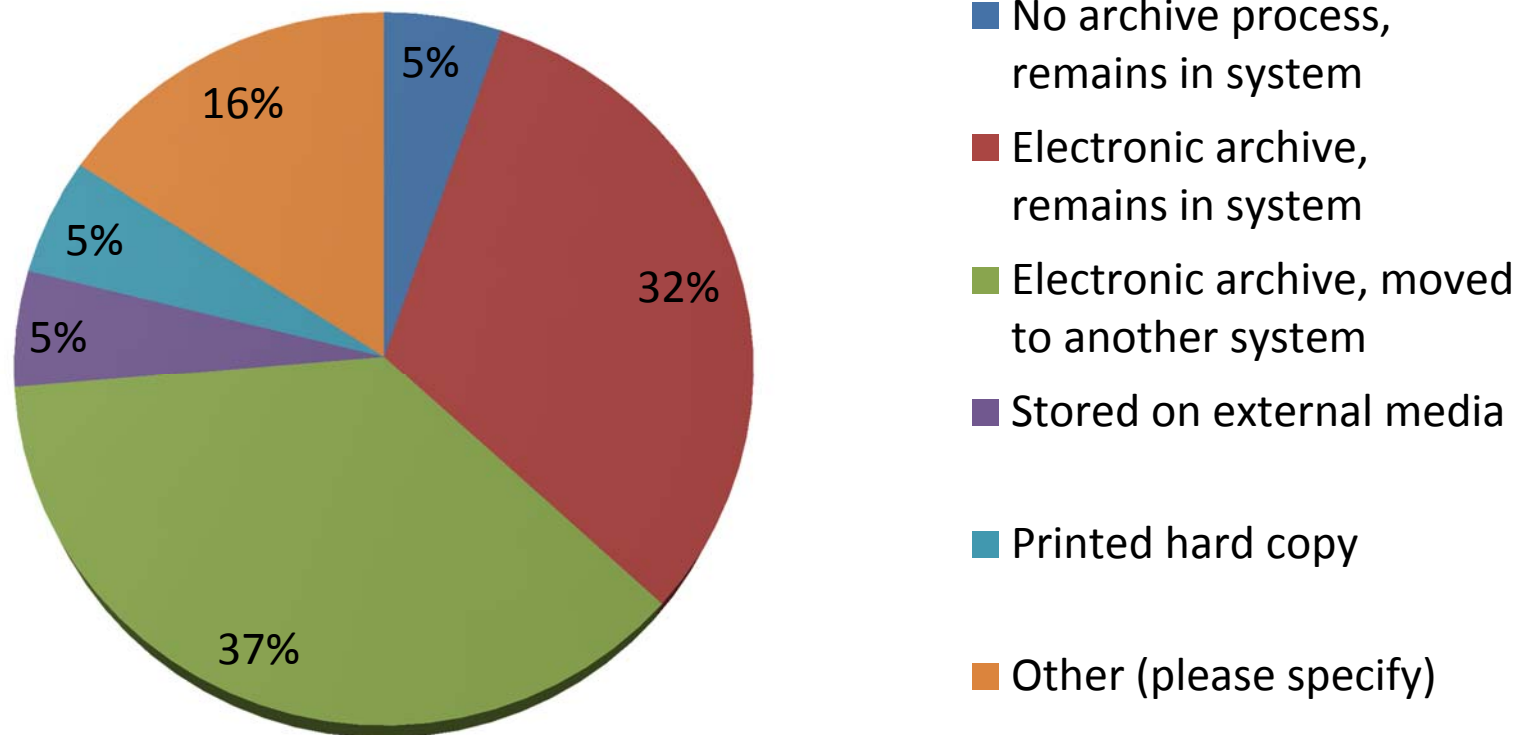


eISF Excluded Content

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

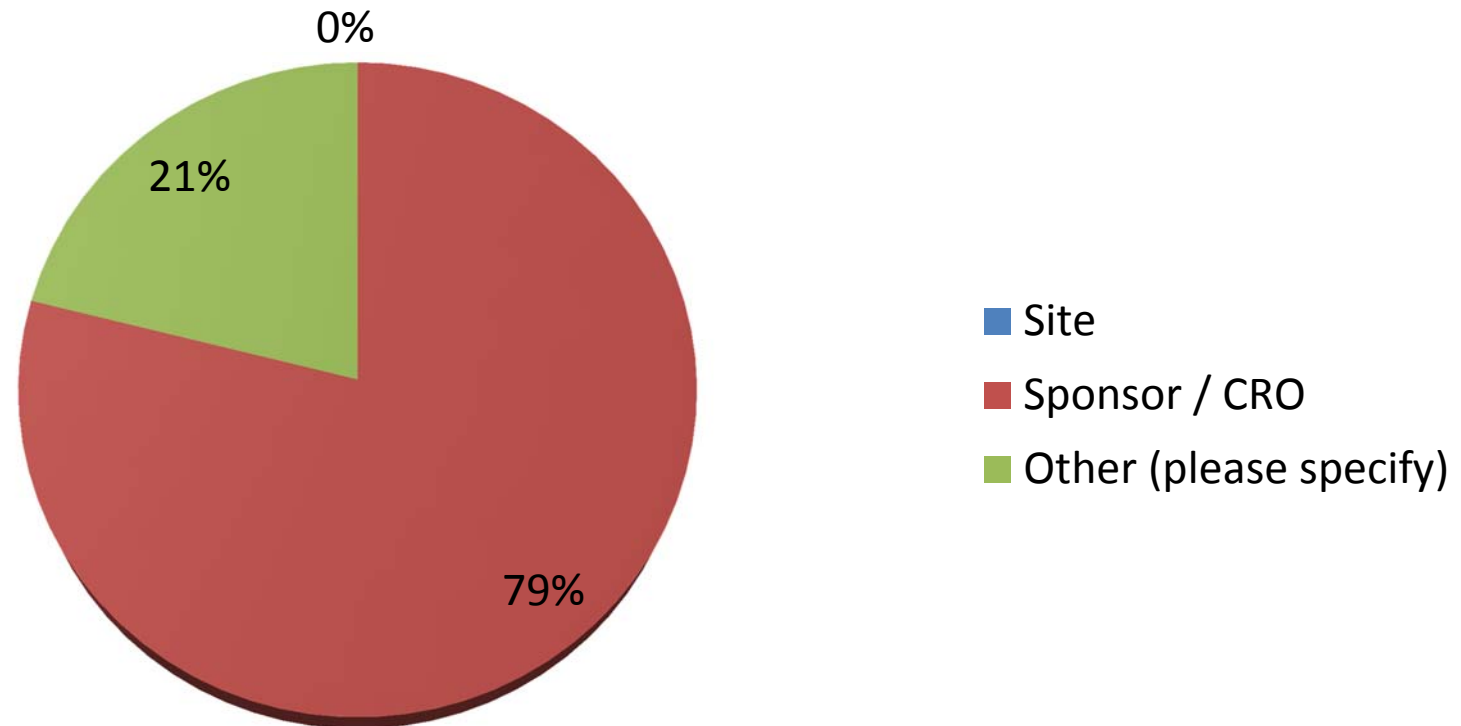


What is the eISF post trial "archive" process?



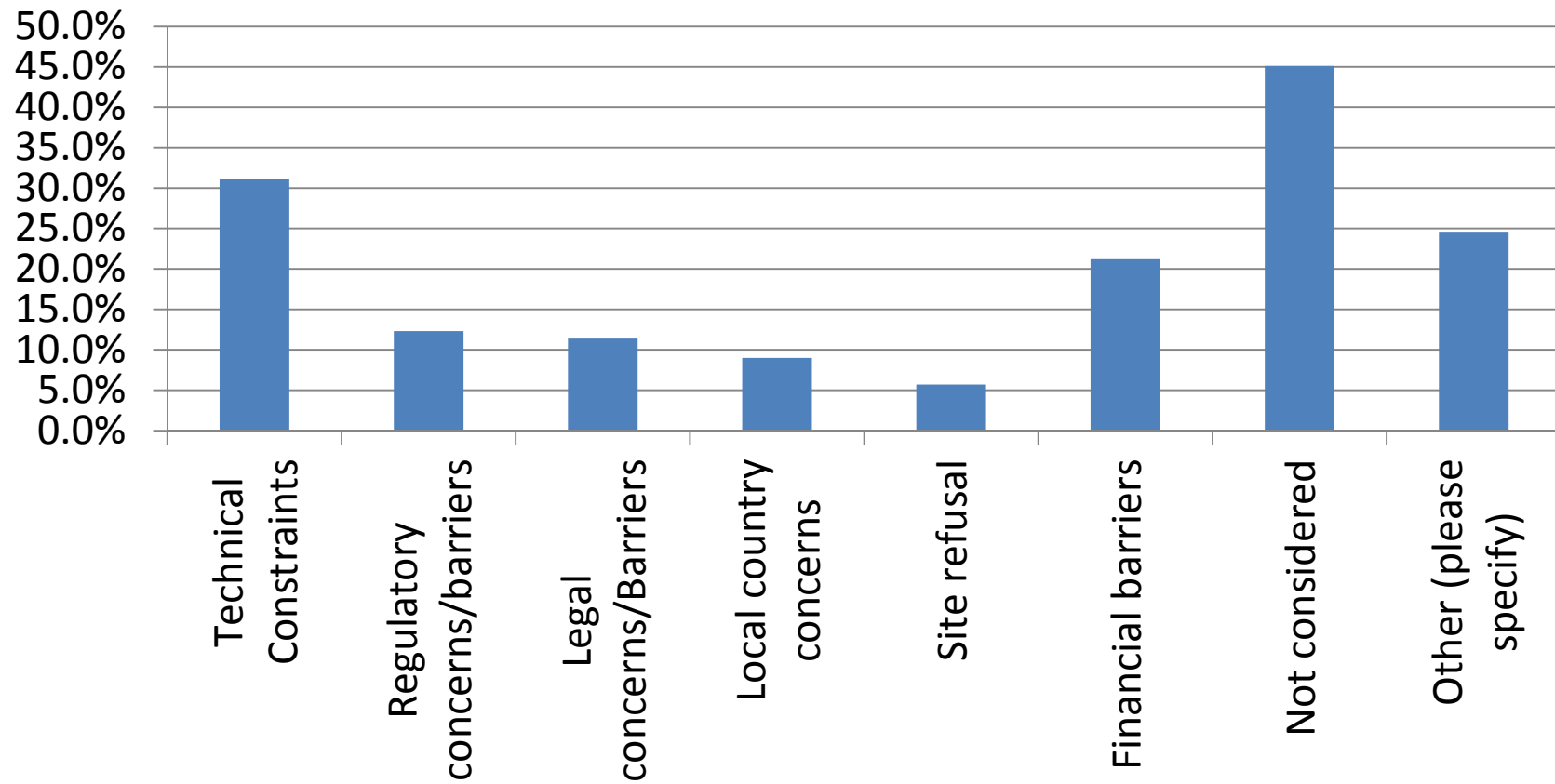
eISF Technology Control

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!

Contact co-chairs to join TMF Ref Model Team:

- Karen Roy, kroy@phlexglobal.com
- Lisa Mulcahy, mulcahy67@comcast.net

To stay up to date on TMF Ref Model team progress and active discussions, read the blog: <http://tmfrefmodel.com/>

Join **Linked ** group “TMF Reference Model”
http://www.linkedin.com/groups?home=&gid=2663204&trk=anet_ug_hm

The TMF Ref Model and overview information is free and available here <http://www.diahome.org/en/News-and-Publications/Publications-and-Research/EDM-Corner.aspx>

TMF 2014 Survey team – THANK YOU!

- Shah Ashraf
- Kathie Clark
- Fran Ross
- Steve Scribner

Thanks to Chris McSpiritt for preliminary results deck support!