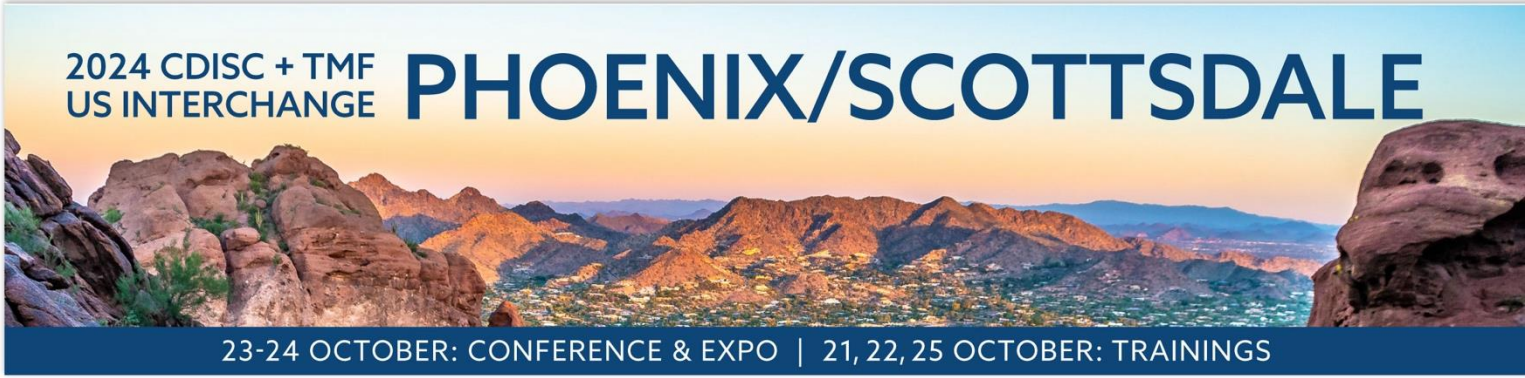
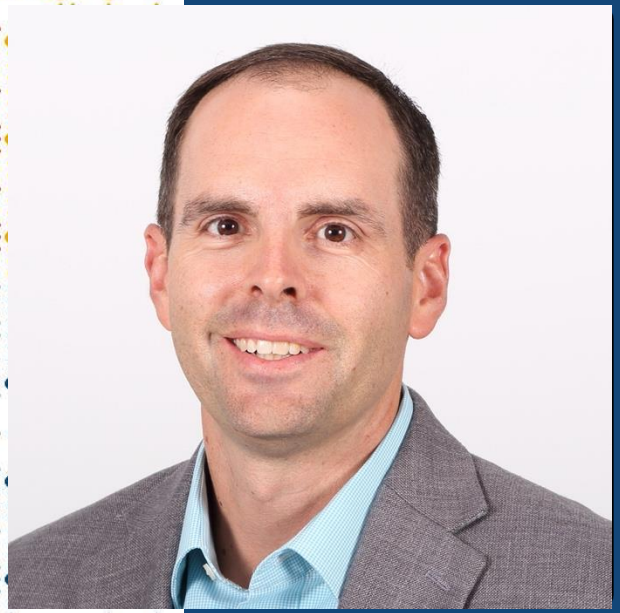


TMF Management through Metrics

Presented by Todd Tullis, Veeva Systems, Director of Product Management



Meet the Speaker

Todd Tullis

Title: Director, SiteVault Product Management

Organization: Veeva Systems

Todd Tullis has been a member of the TMF Reference Model Steering Committee for 10 years. His career mission is to improve human health through more efficient and more effective clinical trials.

When he’s not working on that goal, Todd coaches youth baseball and plays beach volleyball.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author(s) have no real or apparent conflicts of interest to report.*

Agenda

1. TMF Survey Overview & Demographics
2. State of the Reference Model
3. State of the Industry: Processes
4. State of the Industry: Technology
5. Next Steps

Trial Master File Survey

Overview & Demographics

Survey Purpose & History

- identify emerging TMF trends
- assess changes in industry directions
- measure the impact of TMF Reference Model

It is the only non-commercial TMF survey conducted by and for the TMF stakeholder community.

Survey History:

2024 Survey: About the (323) Survey Respondents

Mostly

North America & Europe

Your Region/Country		
North America	194	60%
Europe	94	29%
South-East Asia	22	7%
Western Pacific	8	2%
Africa	4	1%
South America	1	<1%

Mostly

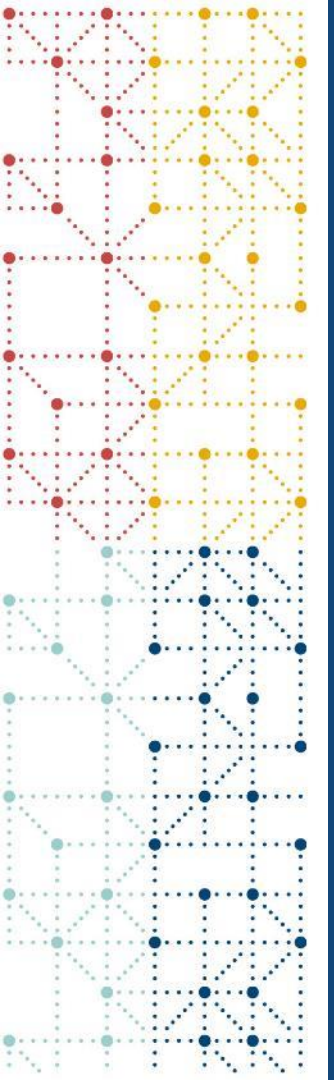
Sponsors & CROs

Your Organization Type		
Sponsor	164	51%
CRO	77	24%
Consultant	42	13%
Vendor	21	7%
Research Site/Institution	18	6%
Regulatory Agency / Health Authority	1	<1%

Mostly

4+ years of TMF RM awareness

When did you first become aware of the TMF RM?		
4-10 years ago	174	54%
10 or more years ago	92	28%
1-3 years ago	49	15%
Within the past year	8	2%

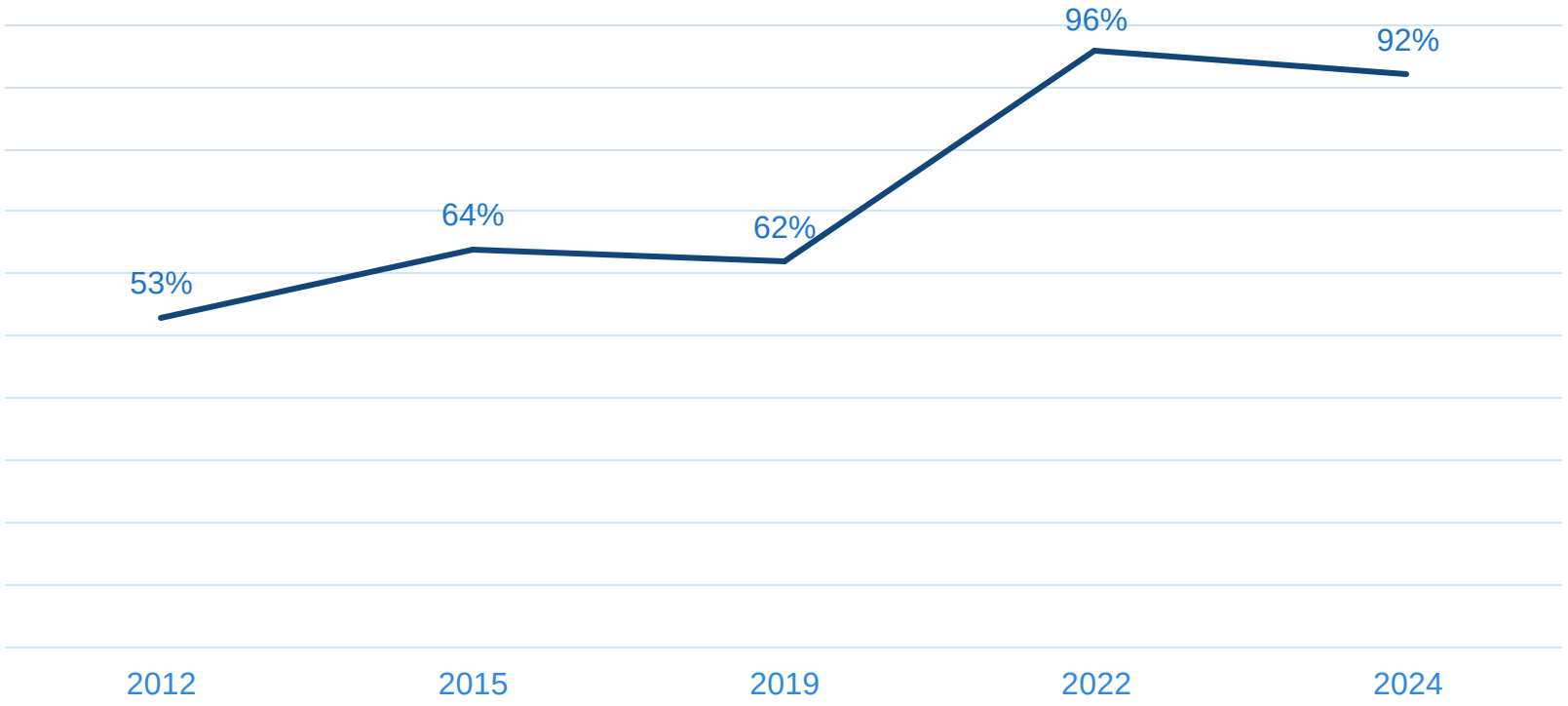


Survey Results & Implications

State of the Reference Model

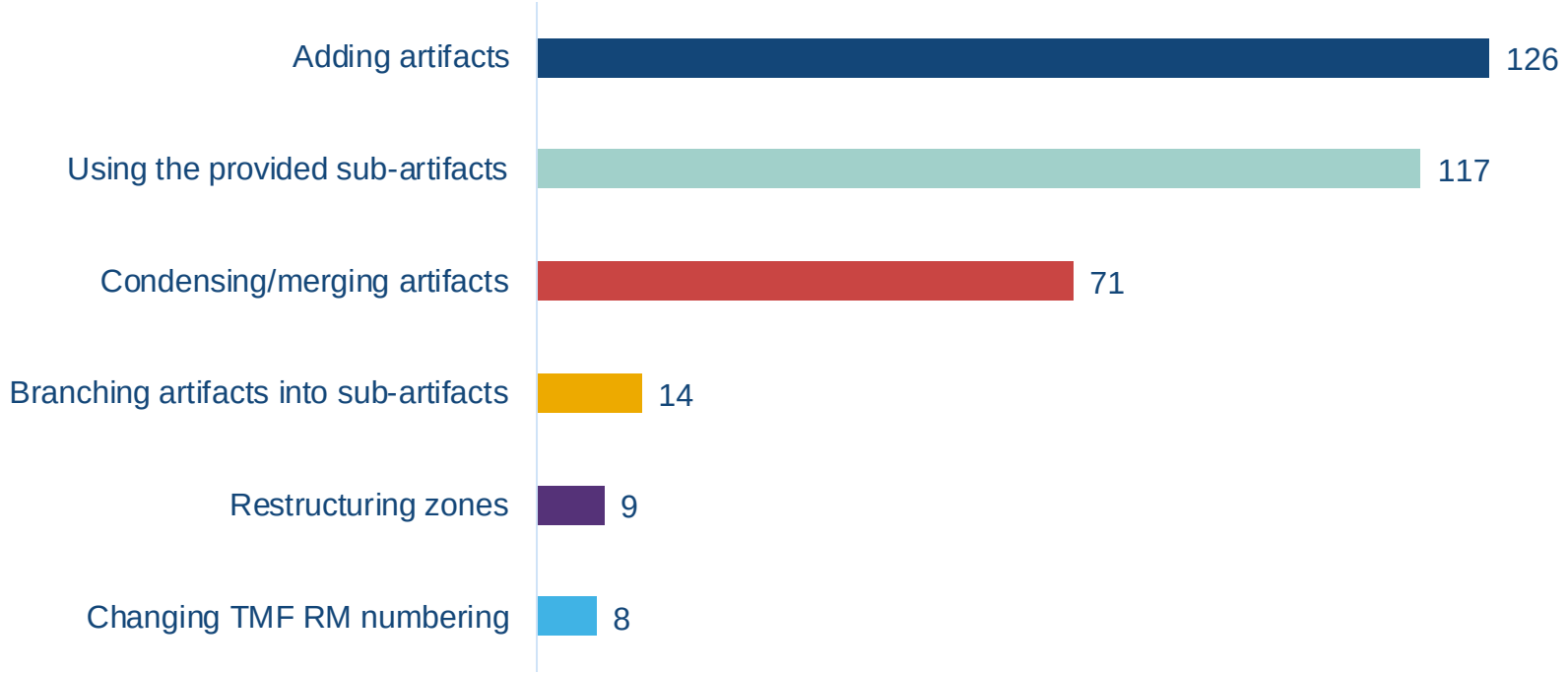
YES, my organization uses the TMF RM

323 responses



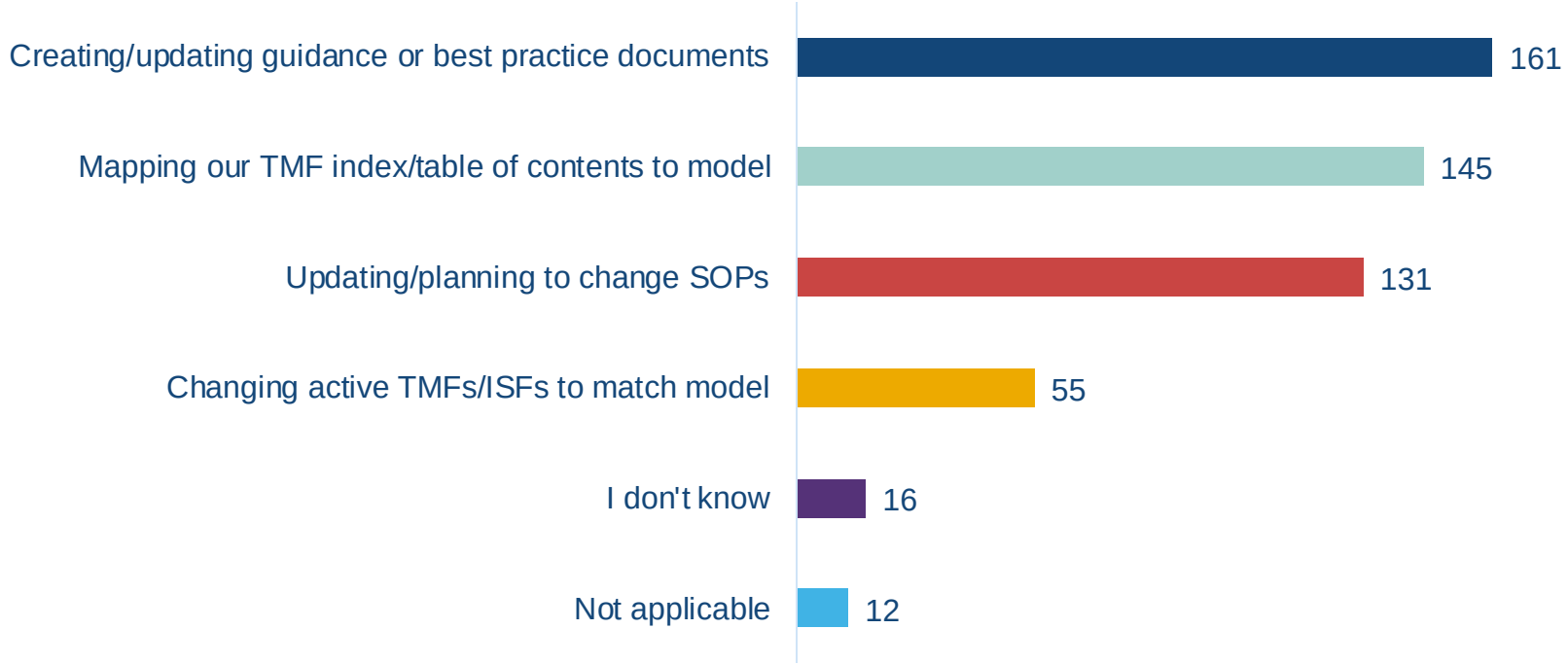
In adopting the TMF RM, my Organization is…

Sponsors, CROs, Sites only | multi-select | 250 responses



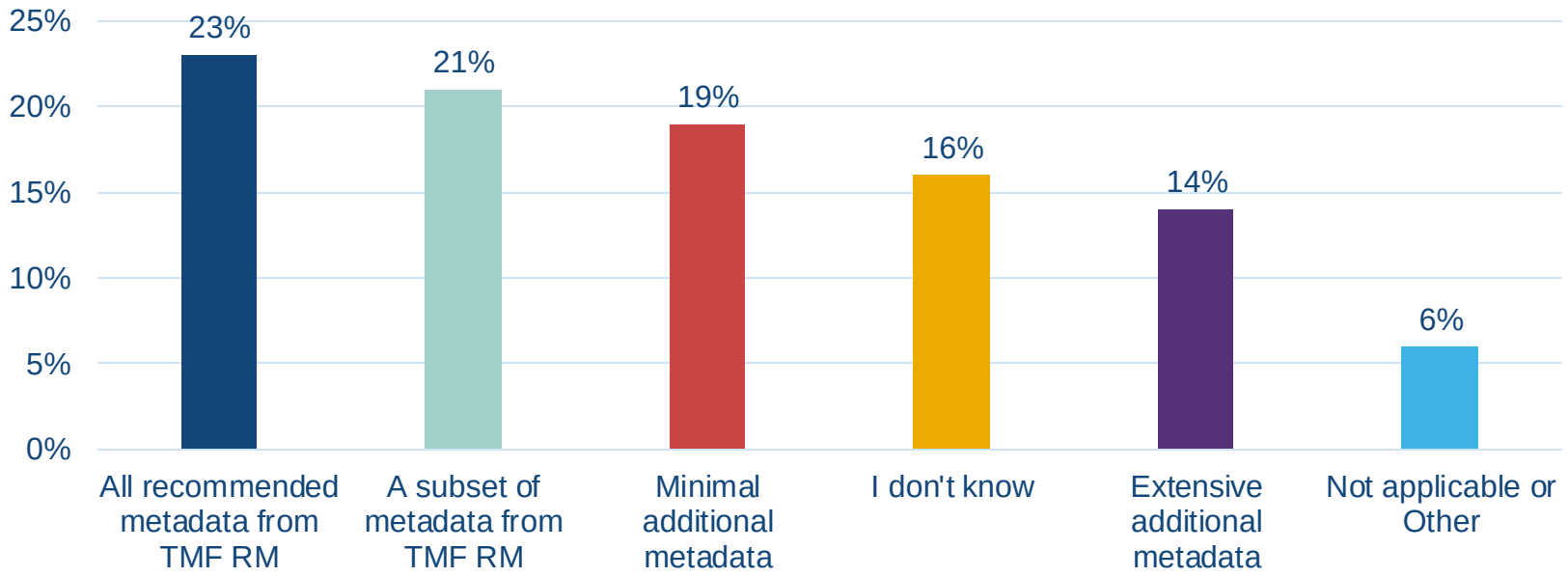
In adopting the RM, my Organization is…

Sponsors, CROs, Sites only | multi-select | 250 responses



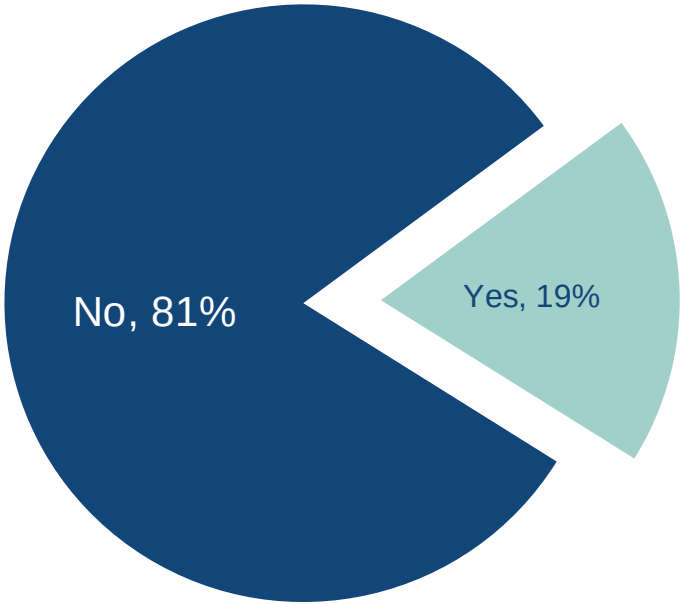
To what extent does your organization utilize additional metadata in your eTMF/eISF?

Sponsors, CROs, Sites only | 250 responses



Have you noticed any omissions from the TMF RM?

320 responses



If Yes, what omissions?

58 responses | free text

Specific record types:
- Investigator Statement
- GP letters
- (Blind) Data Review Meeting
- Site Transition CRA handoff
- Internal checklists
- Protocol deviation/IPD records

Other model considerations:
- File naming and organization
- Instructions for using the TMF RM
- Risk-score system for TMF records
- Highlighting unblinded records

Artifacts or sub-artifacts for/related to..
- Human factors testing
- Retrospective study types
- IVDR and CTIS regulations
- eCOA and ePRO data collection technologies
- Clinical events classifications
- Clinical systems validation
- Vendor governance, oversight, and management
- Data management & statistics
- CRO-specific considerations
- Medical device studies
- Sponsor oversight

Survey Findings: State of the Reference Model

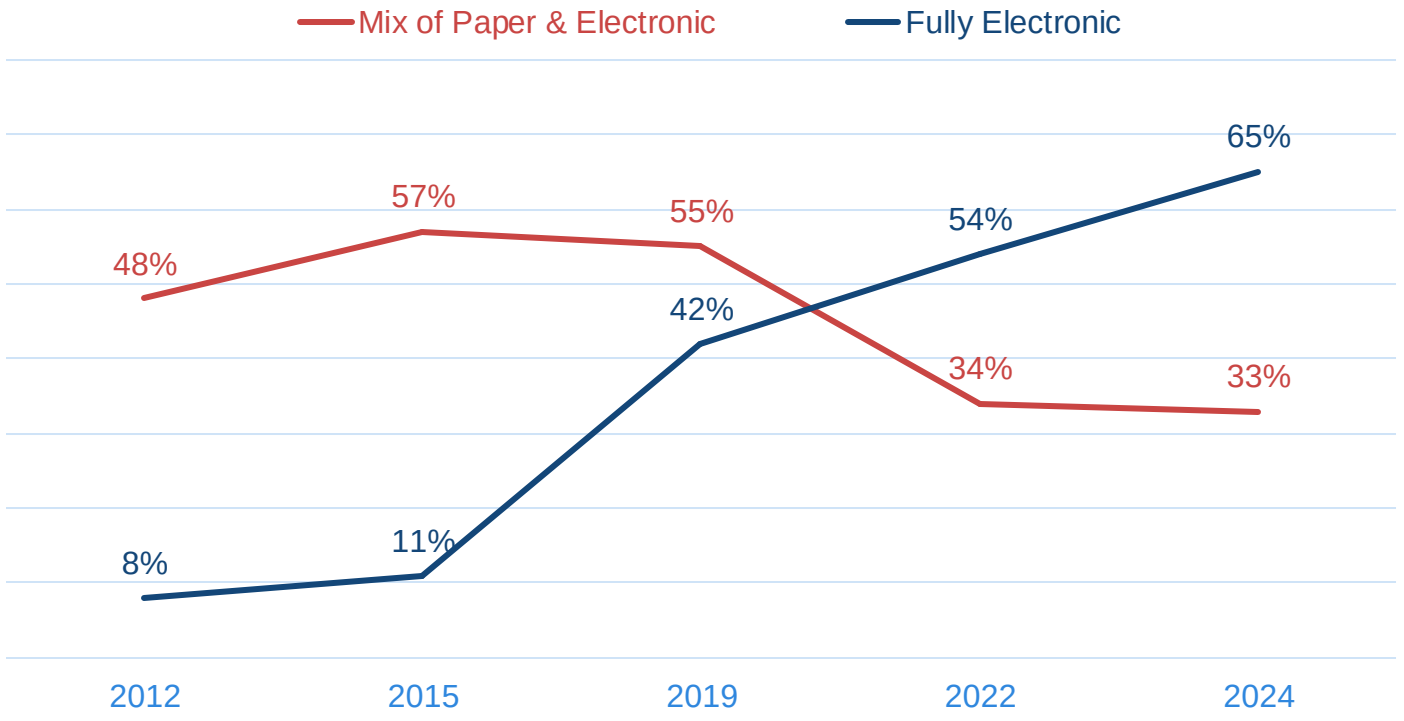
1. Has been very broadly adopted
2. Process & SOP changes still common
3. Opportunities for improvement remain

Survey Results & Implications

State of the Industry: Processes

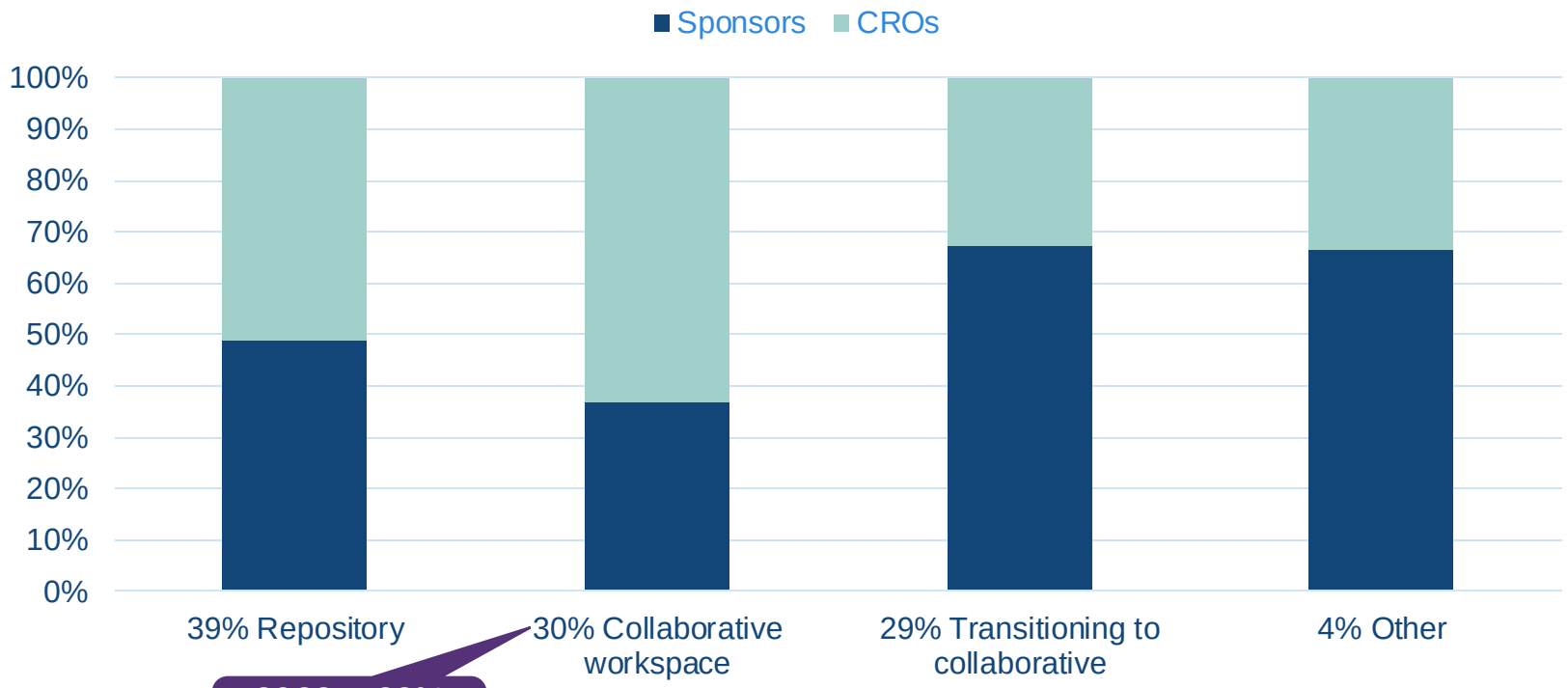
In which format are your organization's TMFs/ISFs?

Sponsors, CROs, Sites only | 249 responses



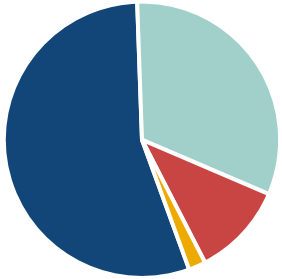
Which most closely describes your organization's view of TMF/ISF?

Sponsors, CROs, Sites only | 246 responses



Centralization of TMF Management: a pendulum?

Is your TMF/ISF managed centrally or disparately across functions/departments?

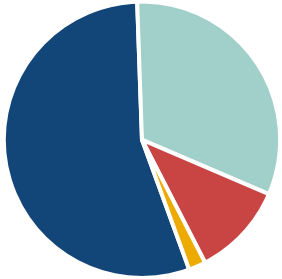


- Centrally (55%)
- Combination (32%)
- Functionally (11%)
- I don't know (2%)

2022 = 39%
2019 = 55%
2017 = 53%

Centralization of TMF Management: a pendulum?

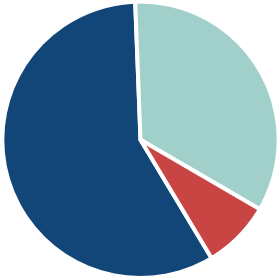
Is your TMF/ISF managed centrally or disparately across functions/departments?



- Centrally (55%)
- Combination (32%)
- Functionally (11%)
- I don't know (2%)

2022 = 39%
2019 = 55%
2017 = 53%

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

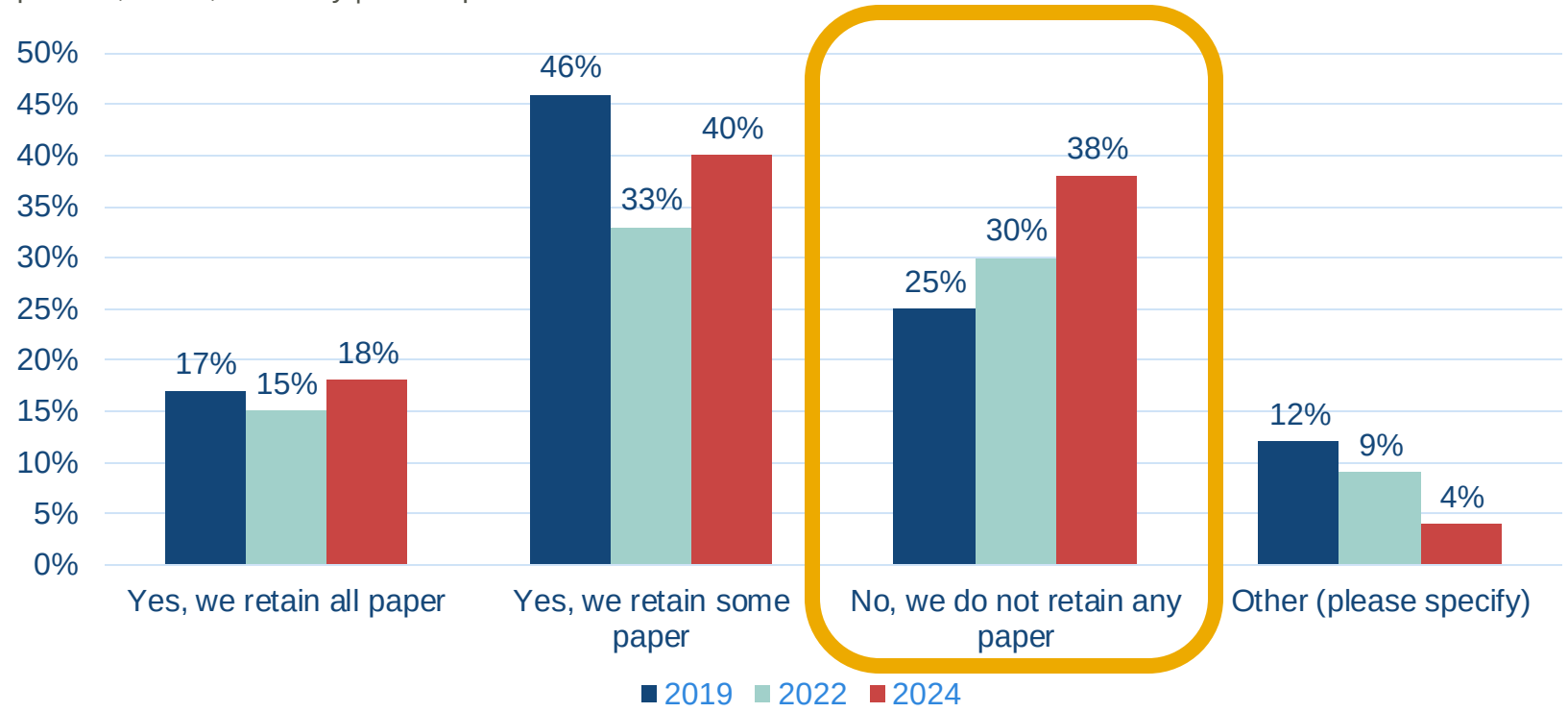


- Each function/department (58%)
- A central group (34%)
- I don't know/Other (8%)

2022 = 19%
2019 = 33%

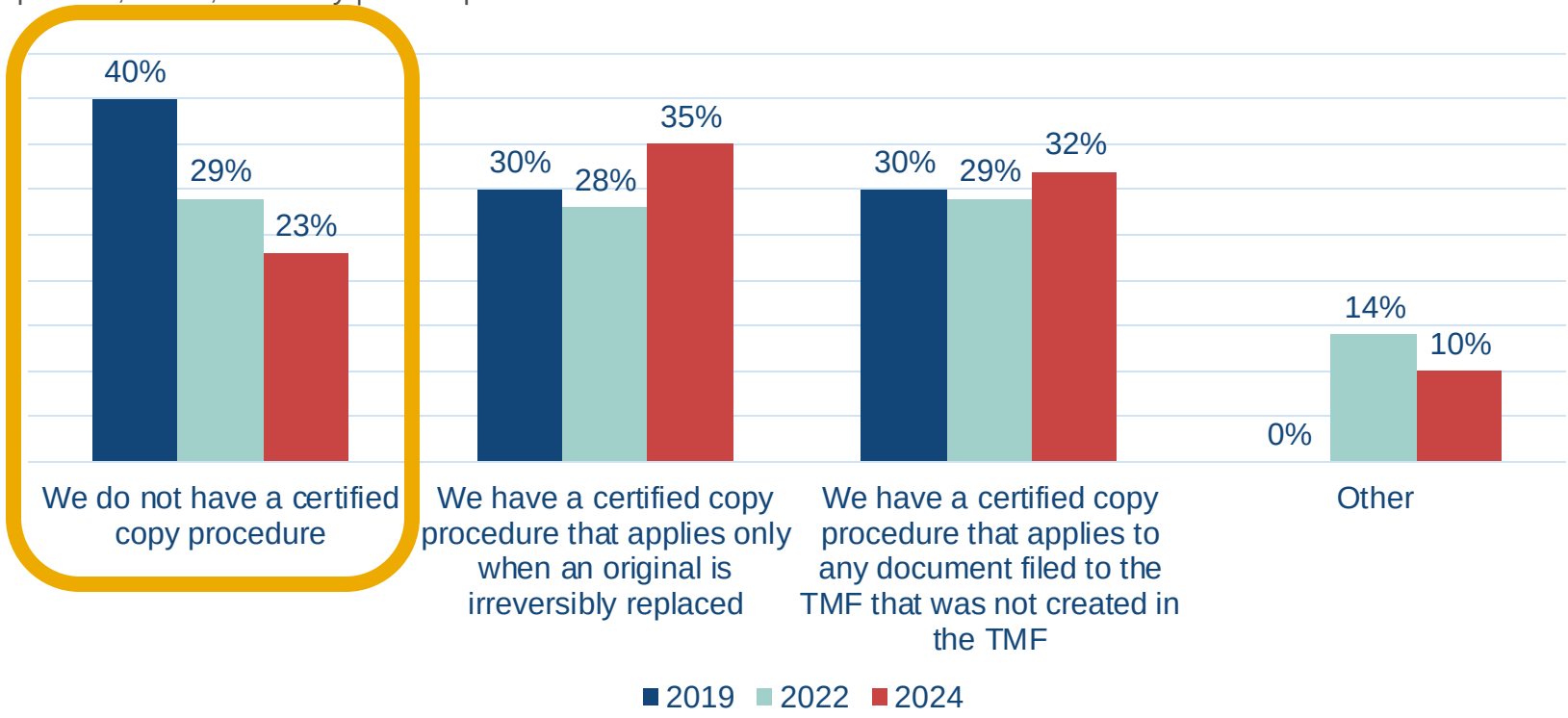
Does your organization retain paper records that have been scanned into your eTMF/eISF?

Sponsors, CROs, Sites only | 232 responses



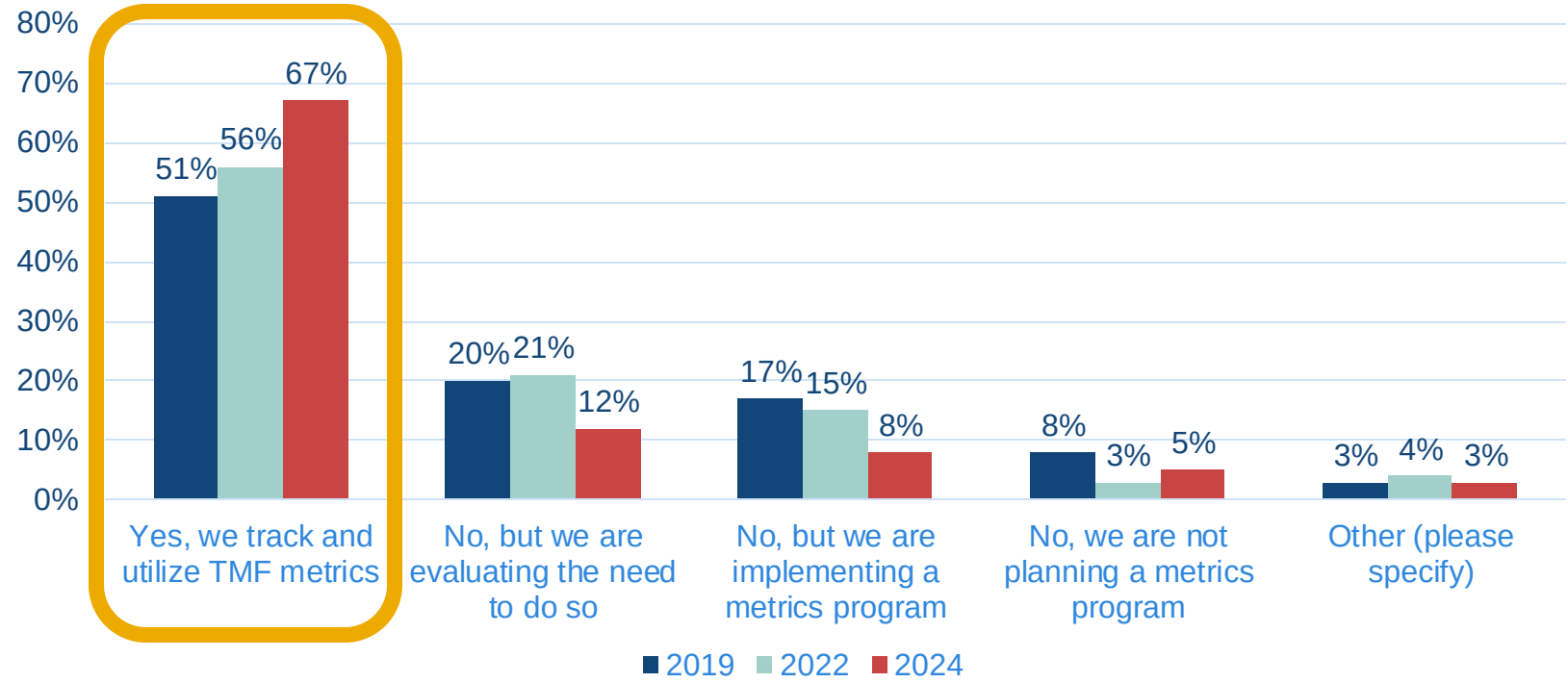
Which type of certified copy policy does your organization promote?

Sponsors, CROs, Sites only | 250 responses



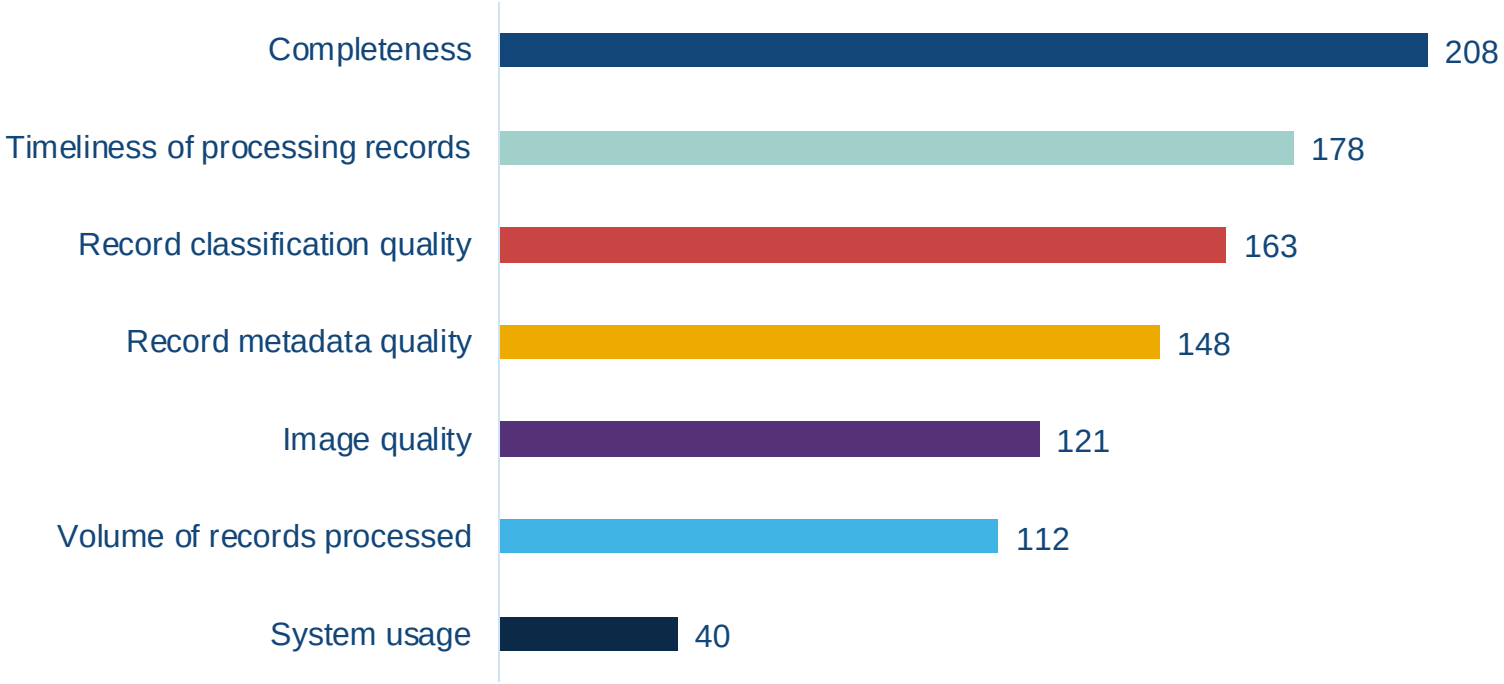
Does your organization have a metrics program to track and utilize TMF metrics in a systematic way?

Sponsors, CROs, Sites only | 250 responses



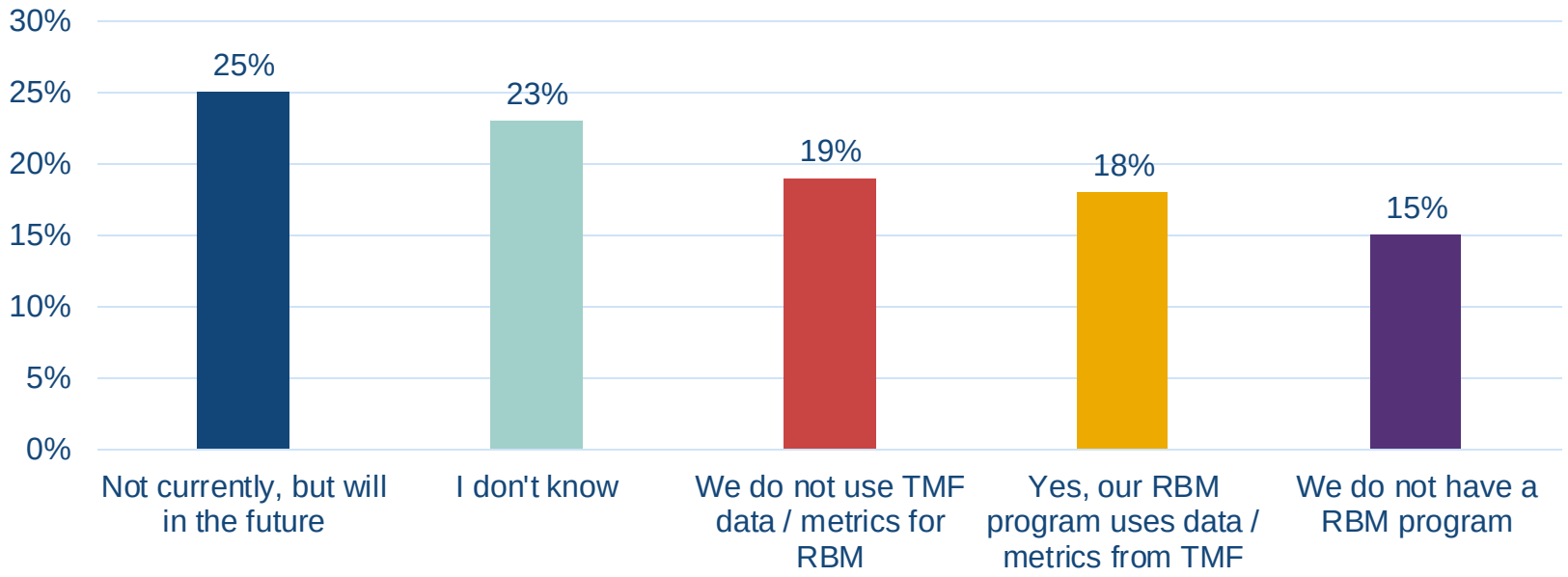
What does your organization track in your TMF Metrics?

Sponsors, CROs, Sites only | multi-select | 235 responses



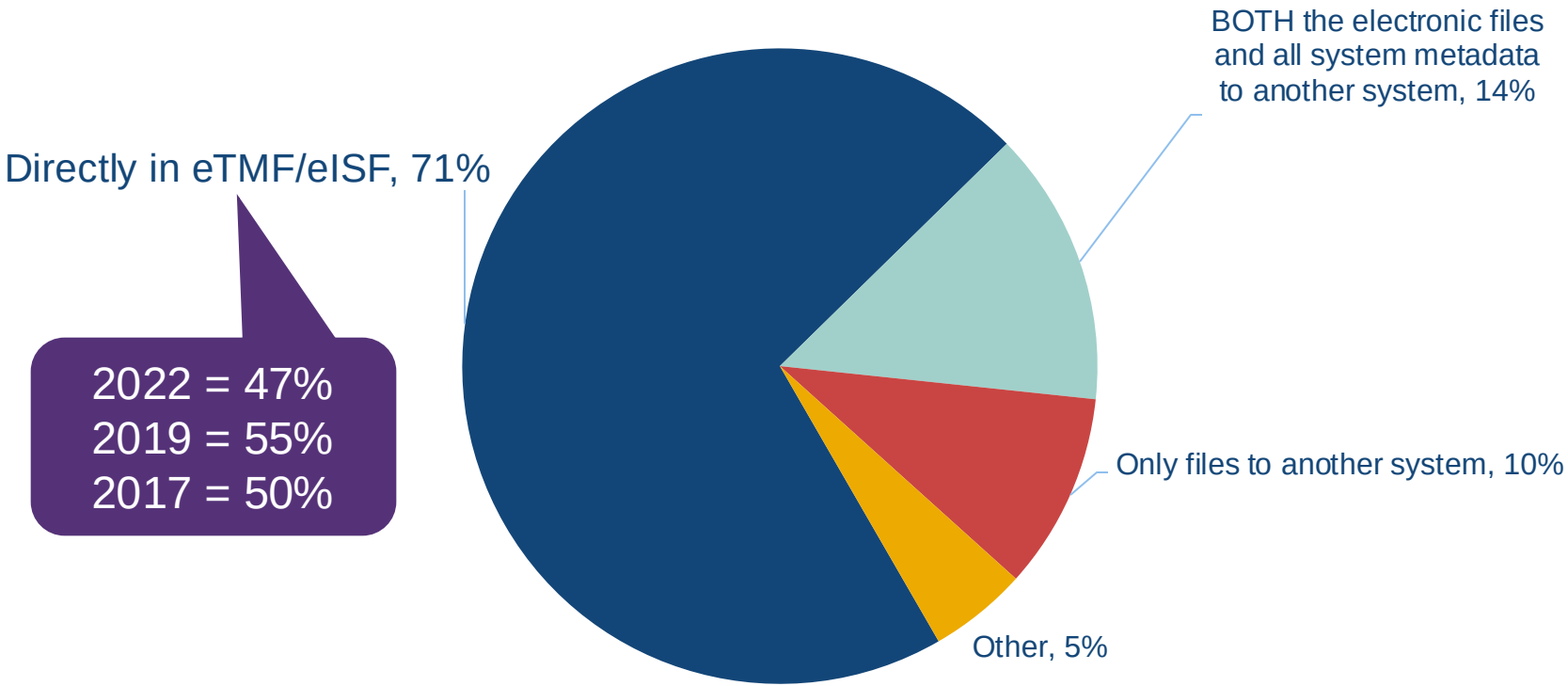
Are TMF data or metrics used by your organization's Risk Based Monitoring program?

Sponsors, CROs, Sites only | 250 responses



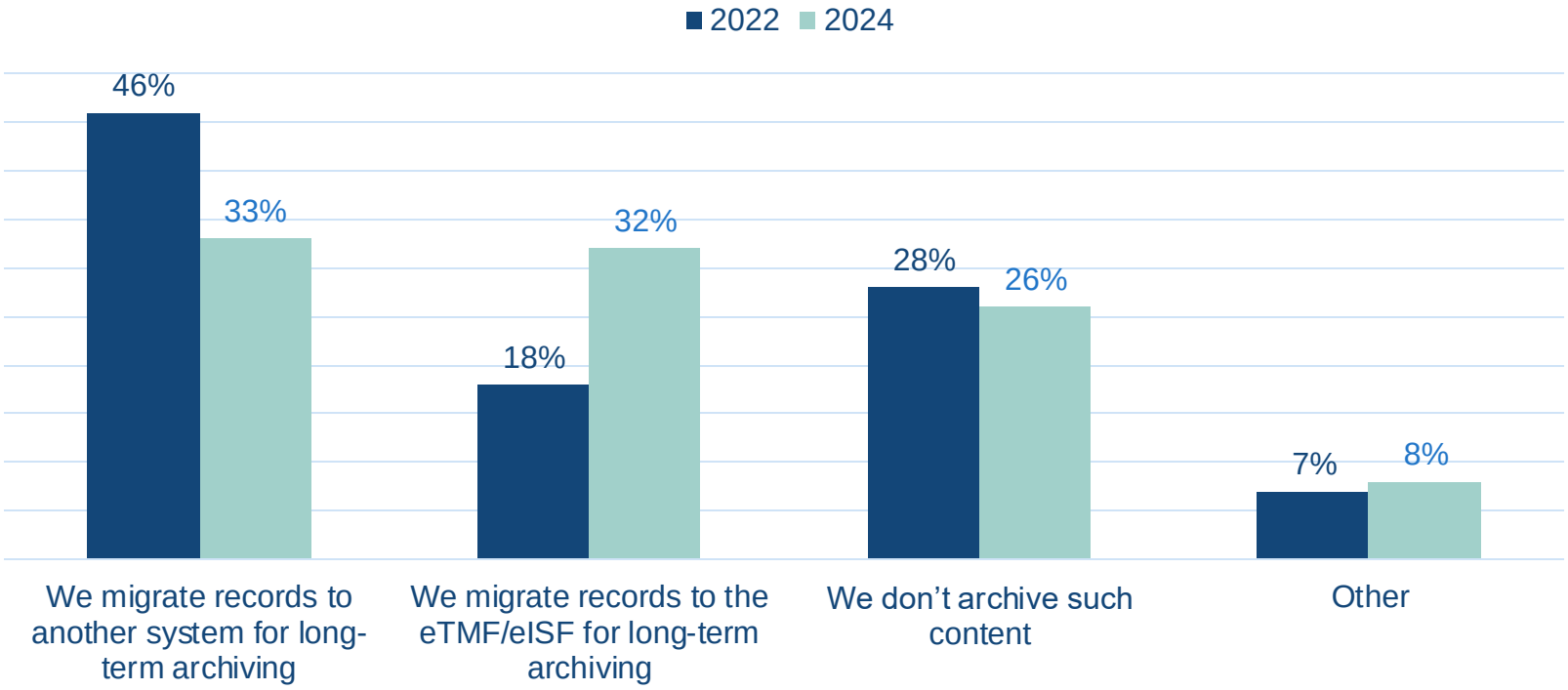
How do you archive records managed in your primary eTMF/eISF system?

Sponsors, CROs, Sites only | 221 responses



How do you archive content that was managed outside of the primary eTMF/eISF system during study conduct?

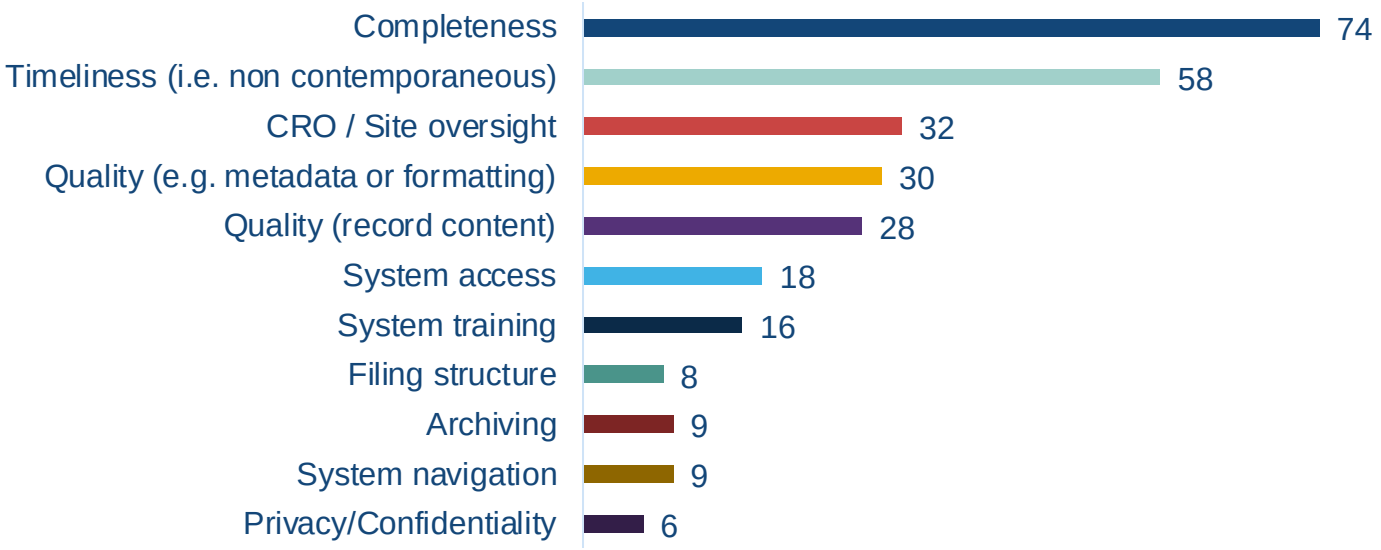
Sponsors, CROs, Sites only | 180 responses (excluding “I don’t know” answers)



In the previous 2 years, what types of findings have you received following an audit/inspection of your TMF/ISF?

- 48% of respondents have had an on-premise inspection
- 41% have had a **remote** inspection

Sponsors, CROs, Sites only | multi-select | 111 responses



Survey Findings: State of the Industry – Process

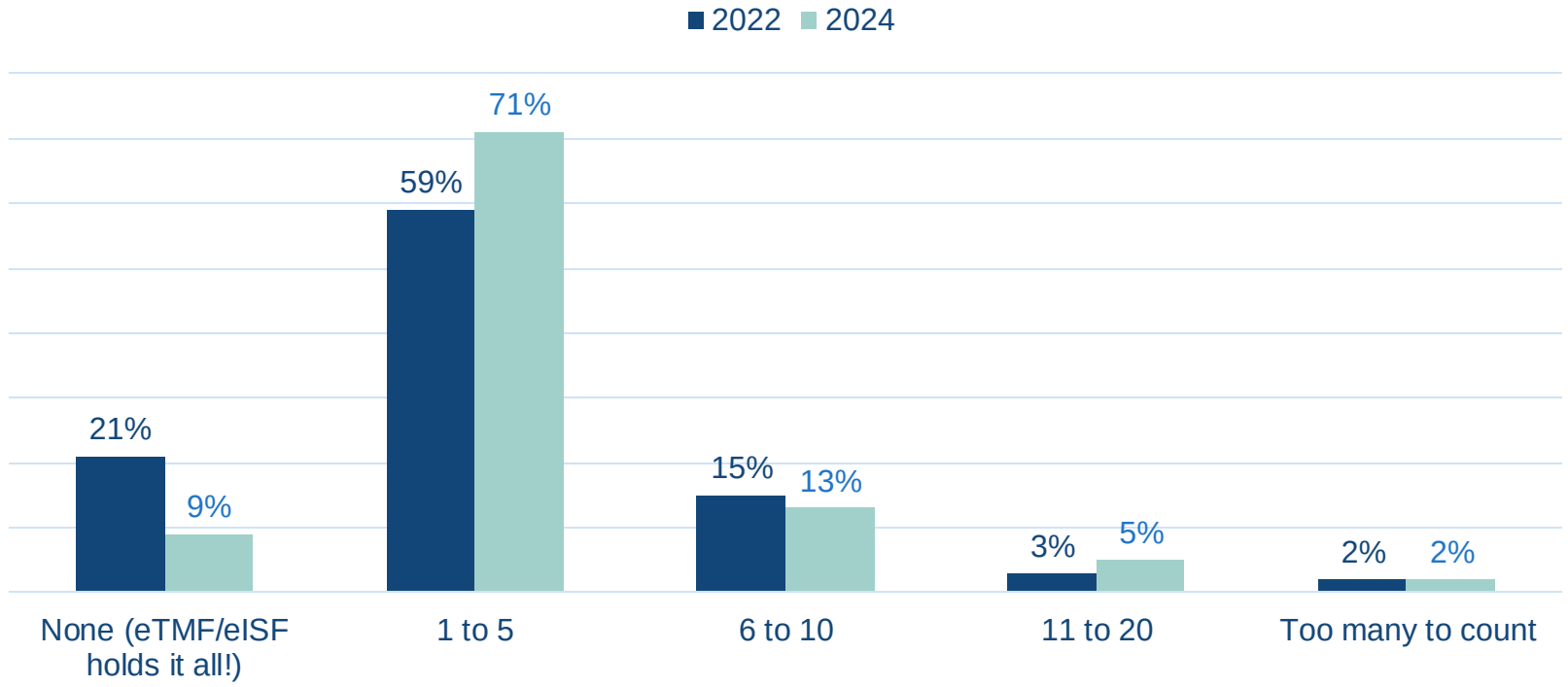
1. eTMFs rule, but process/operating models still vary
2. Certified copy holdouts remain
3. Metrics are tracking the most important things
4. Archiving-in-place becoming easier and more common
5. Remote inspections should be expected

Survey Results & Implications

State of the Industry: Technology

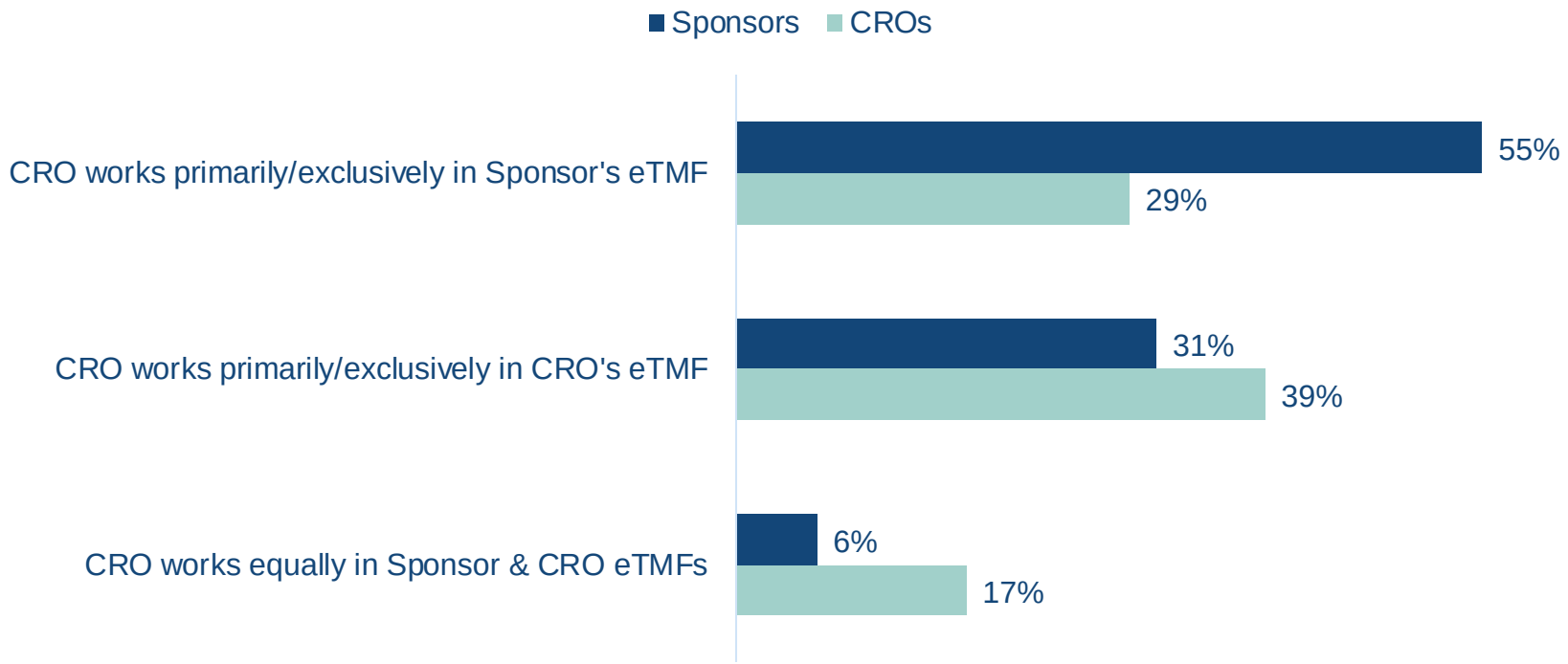
How many other systems (besides eTMF/eISF) does your organization use to hold authoritative source records that would be subject to inspection?

Sponsors, CROs, Sites only | 231 responses (excluding “I don’t know” answers)



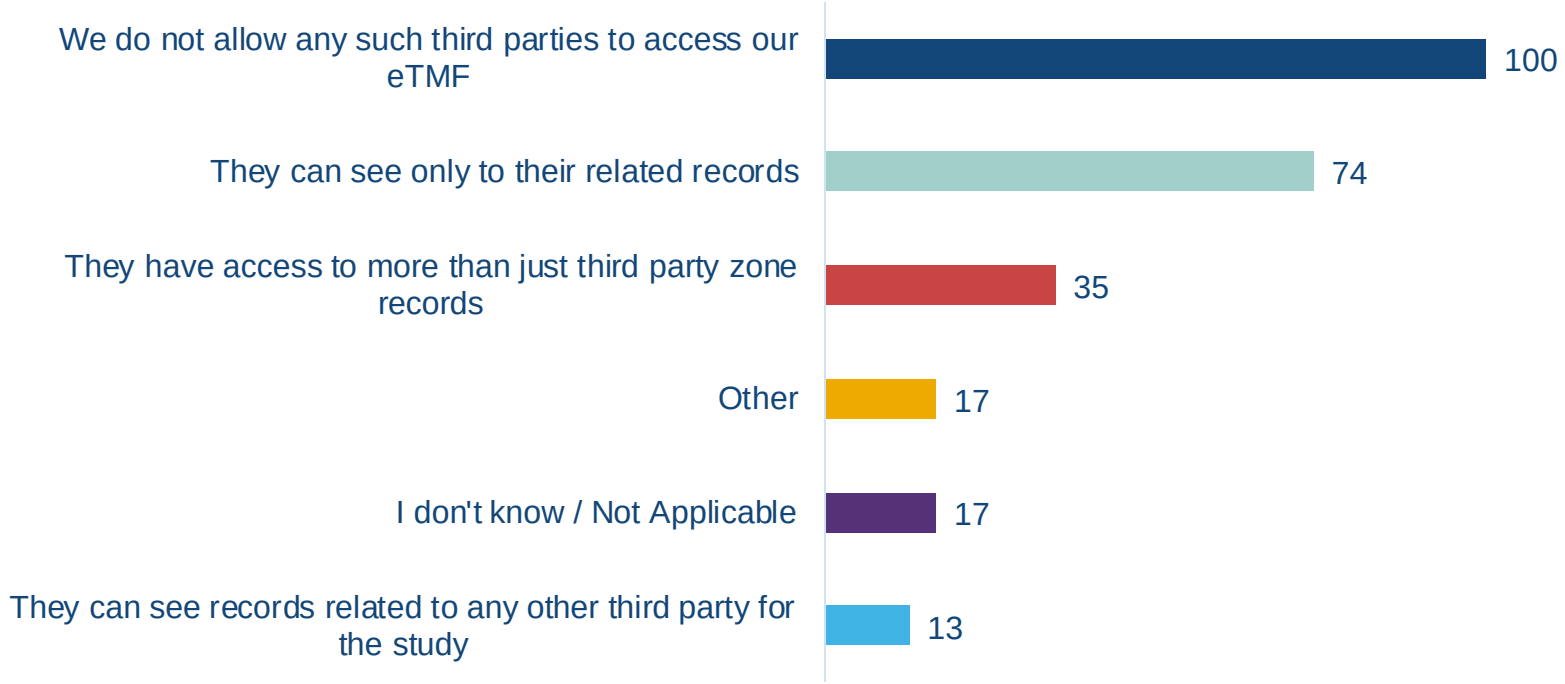
Which of the following best describes CRO use of eTMF systems during study conduct?

Sponsors, CROs only | 240 responses



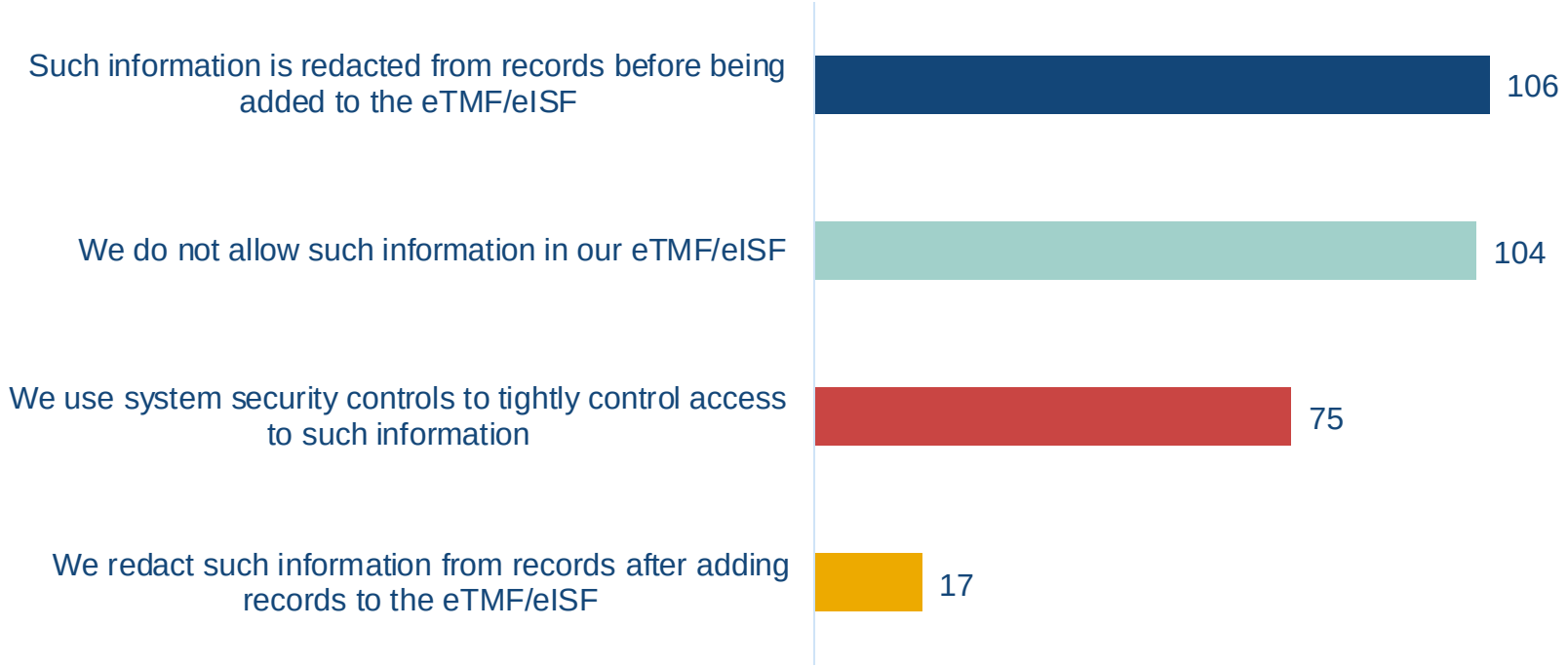
What eTMF access permissions are granted to "third parties" outside of your Sponsor/CRO & your study sites?

Sponsors & CROs only | multi-select | 222 responses



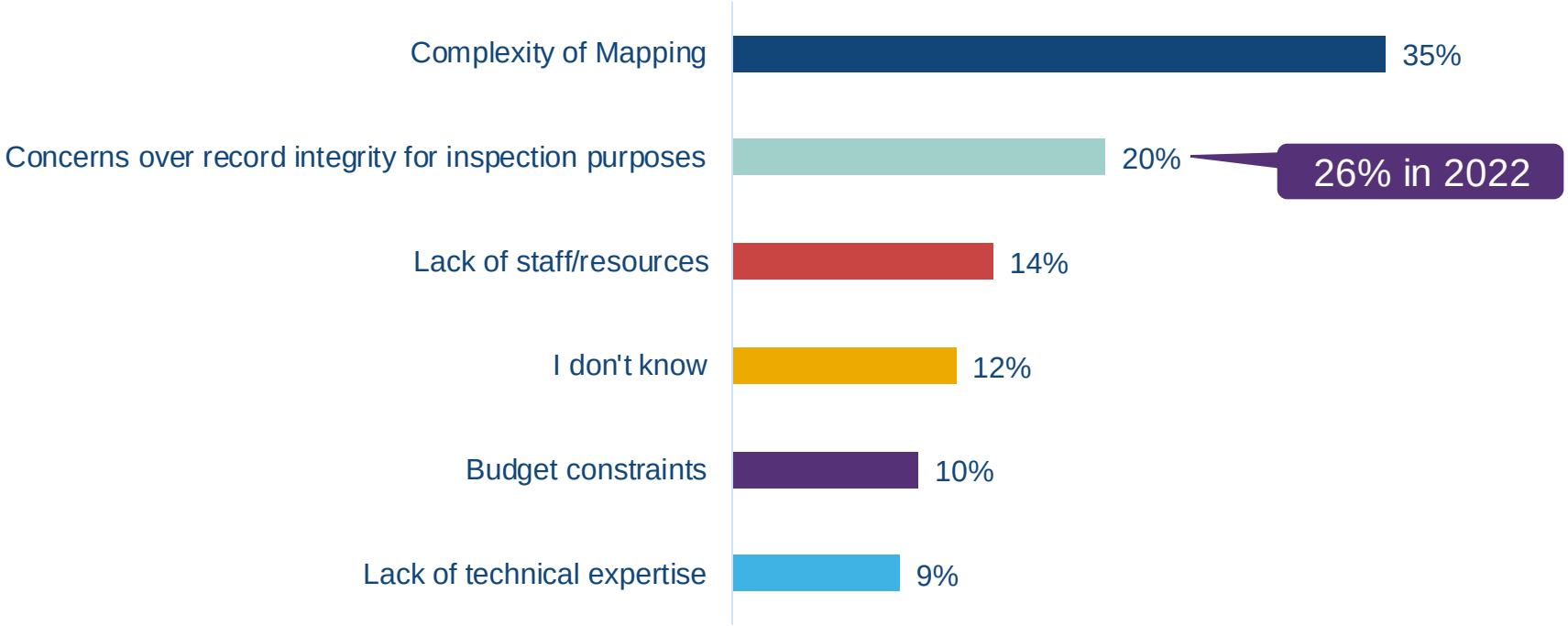
How does your organization handle confidential or sensitive information in your eTMF/eISF?

Sponsors, CROs, Sites only | multi-select | 232 responses



If you have transferred TMF/ISF content between systems or organizations, which of the following factors impacted most on the transfer?

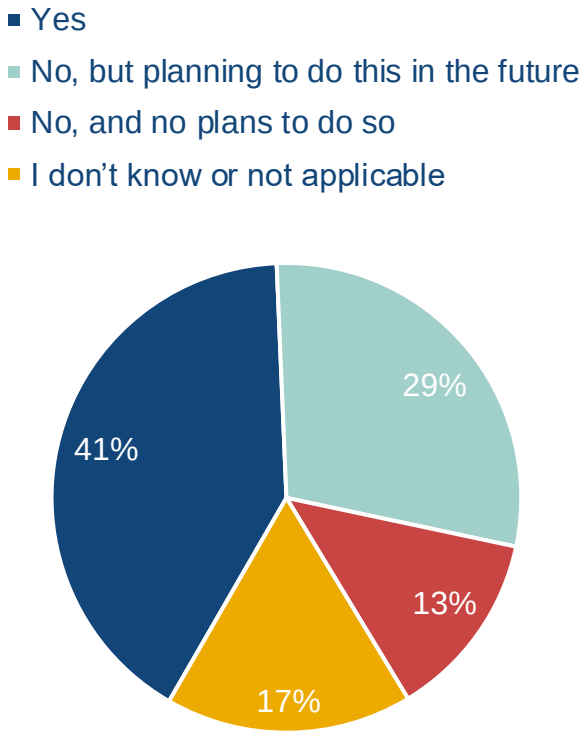
Sponsors, CROs, Sites only | 232 responses



Does your organization conduct proactive/ongoing reviews of your eTMF/eISF audit trail?

Sponsors, CROs, Sites only | 232 responses

- This question is based on the "*EMA Guideline on computerised systems and electronic data in clinical trials" (9 Mar 2023)*.
- We were curious if any organizations consider eTMF/eISF systems high risk enough to warrant such procedures.



Survey Findings: State of the Industry – Technology

1. Source records in more than just eTMF/eISF
2. Spectrum of experience sharing eTMF/eISF with partners & vendors
3. Interoperability still seen as biggest hurdle to TMF/ISF transfers

Next Steps

Coming soon to the CDISC TMF RM Resources Page:

- PowerPoint summary of 2024 questions and responses

Available by request: raw 2024 survey response data

Coming in 2025: TMF Reference Model Version 4

Next Survey: 2026 ???

Thank You!