TMF Reference Model

Results of
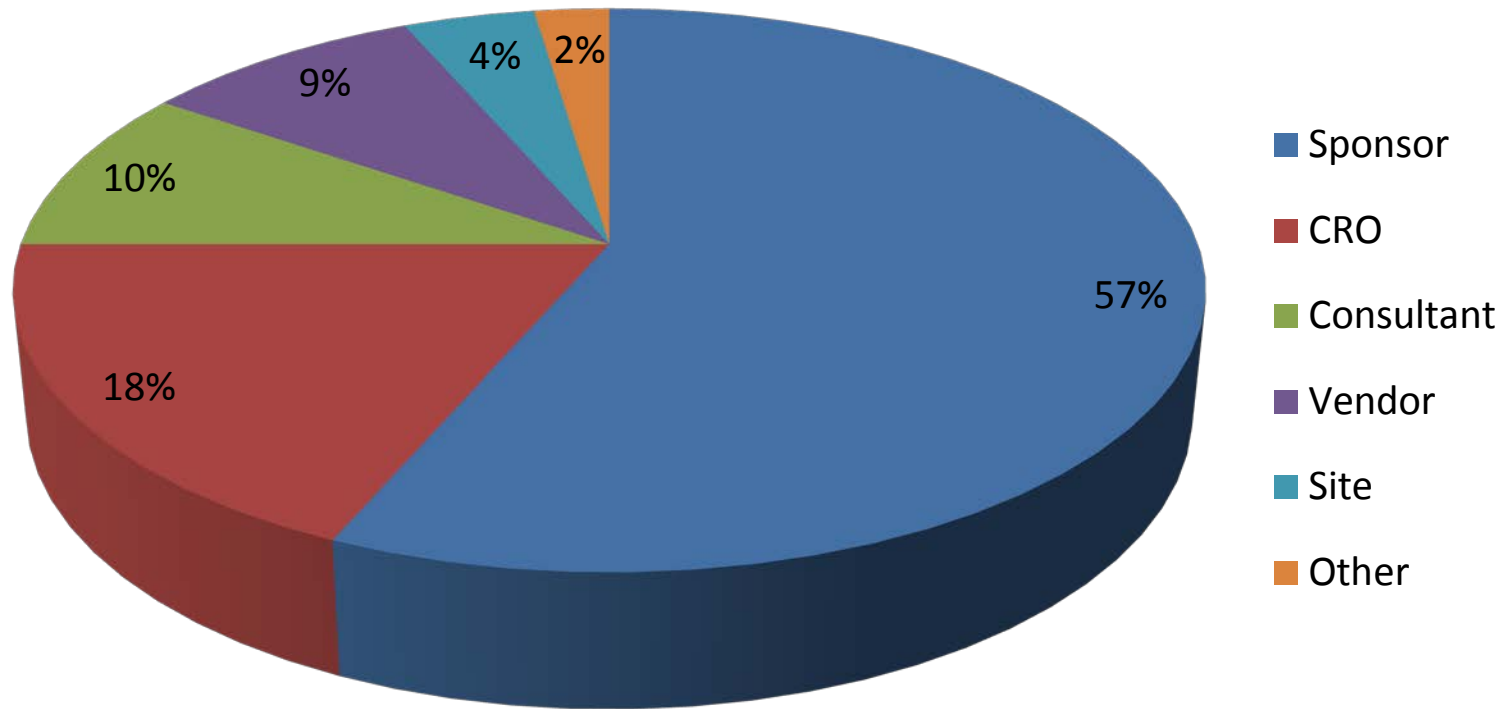## 2012 TMF Survey #2

November 2012

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
- The second TMF Survey replicates many questions from the successful first TMF survey in 2010, and included new topic areas such as electronic investigator site files (eISF)
- Survey #2 went live on 9th May 2012 and closed 5th June 2012
- The TMF Survey subteam 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
- The survey team plans to reconvene for work on the third TMF Survey in Q113. Your feedback, insight and participation are enthusiastically welcomed.

TMF Survey Analysis

- The following charts and data tables give interesting signals into the current state and direction of TMFs. From 2010 to 2012 data reveals:
    - Increase in eTMF uptake
    - Increase in reference model use
    - First signals about eISF uptake and details on drivers

- Please note, the size of the respondent pool precluded deep statistical analysis.
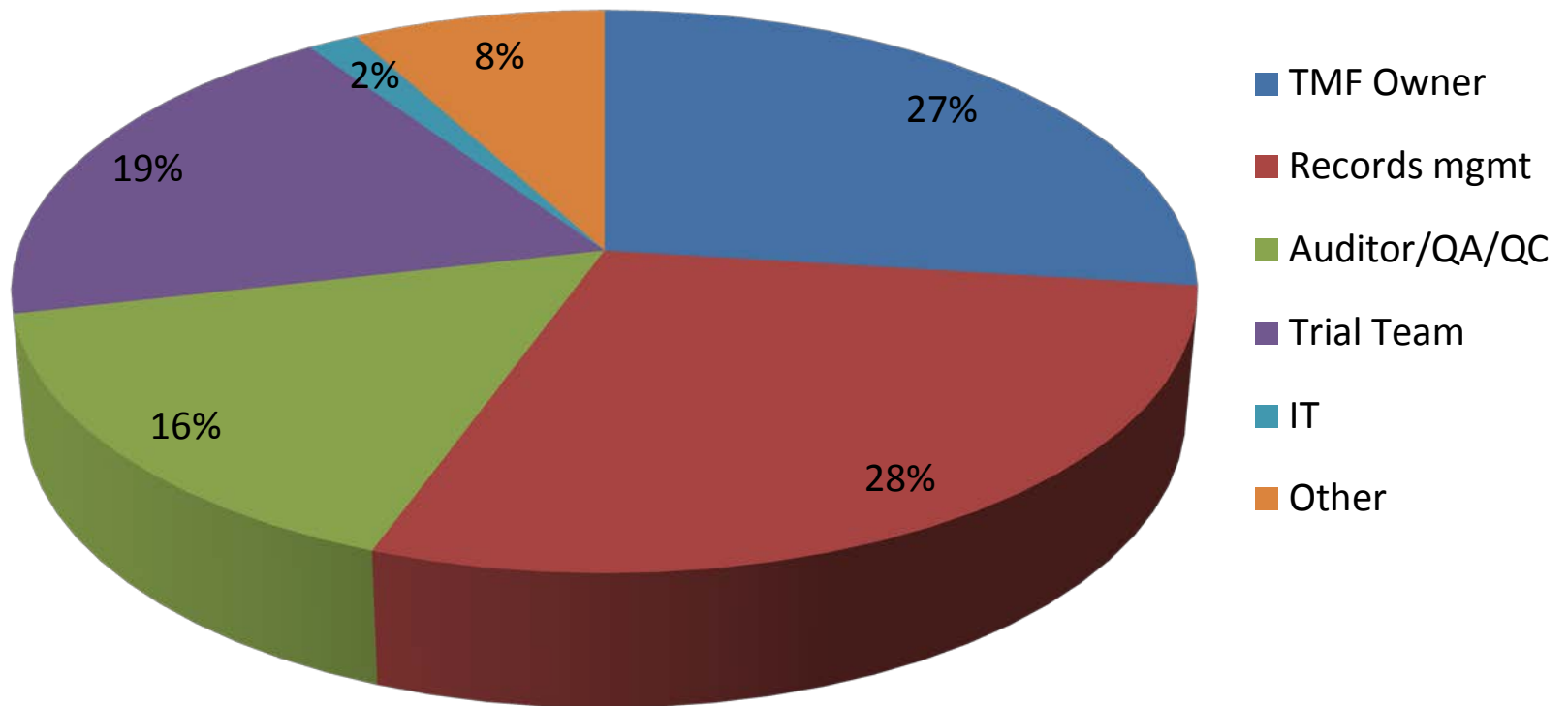
Respondents organization types

Legend:
- Sponsor
- CRO
- Consultant
- Vendor
- Site
- Other

Sponsor 57%, CRO 18%, Consultant 10%, Vendor 9%, Site 4%, Other 2%

❑ 158 respondents, 57% were Sponsors
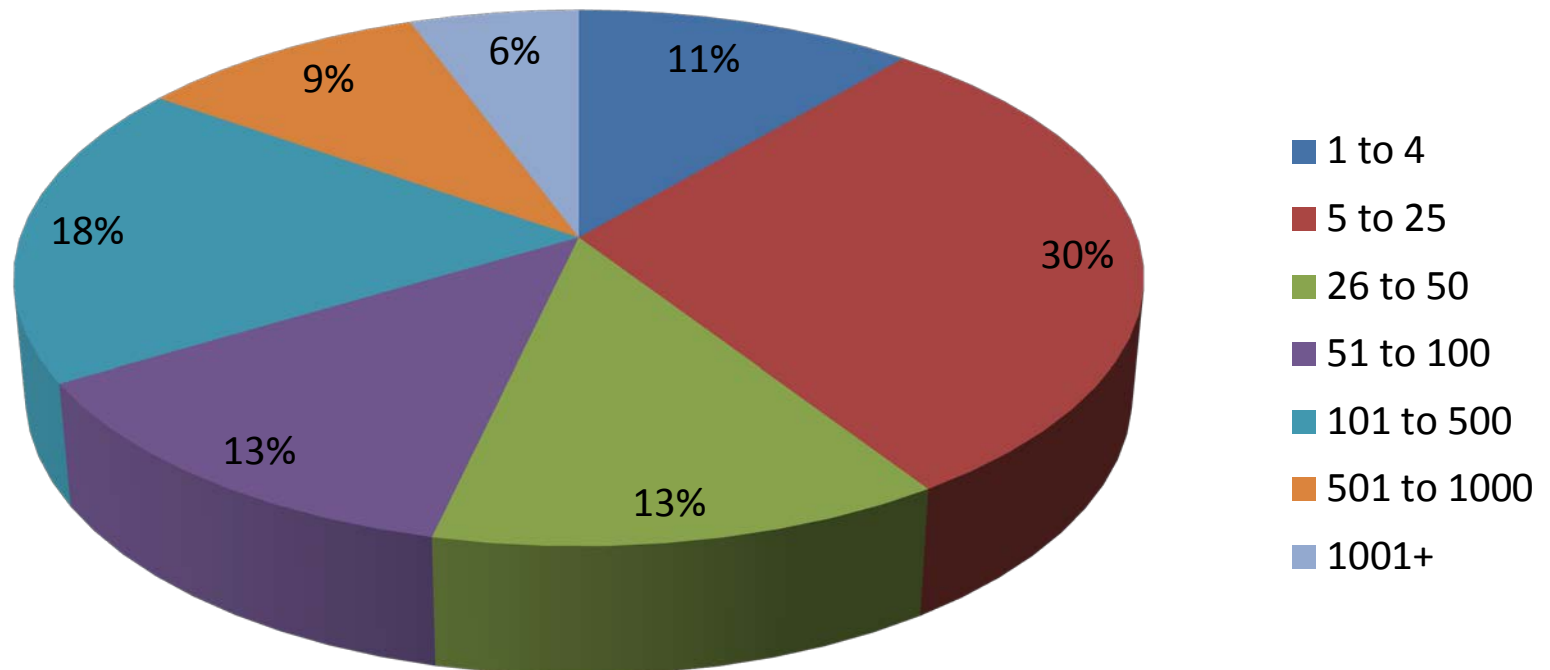
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Respondents roles

Select the role that best describes your relationship to TMF

2012 TMF Survey #2

Numbers of active trials

Indicate the number of active trials at your organization

Legend:
- 1 to 4 — 11%
- 5 to 25 — 30%
- 26 to 50 — 13%
- 51 to 100 — 13%
- 101 to 500 — 18%
- 501 to 1000 — 9%
- 1001+ — 6%

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TMF SOP adherence

Does your organization have and follow a TMF/ISF SOP?

- Other 5%
- Not required 13%
- No SOP 2%
- No, in development 11%
- Yes, inconsistently 22%
- Yes, consistently 47%
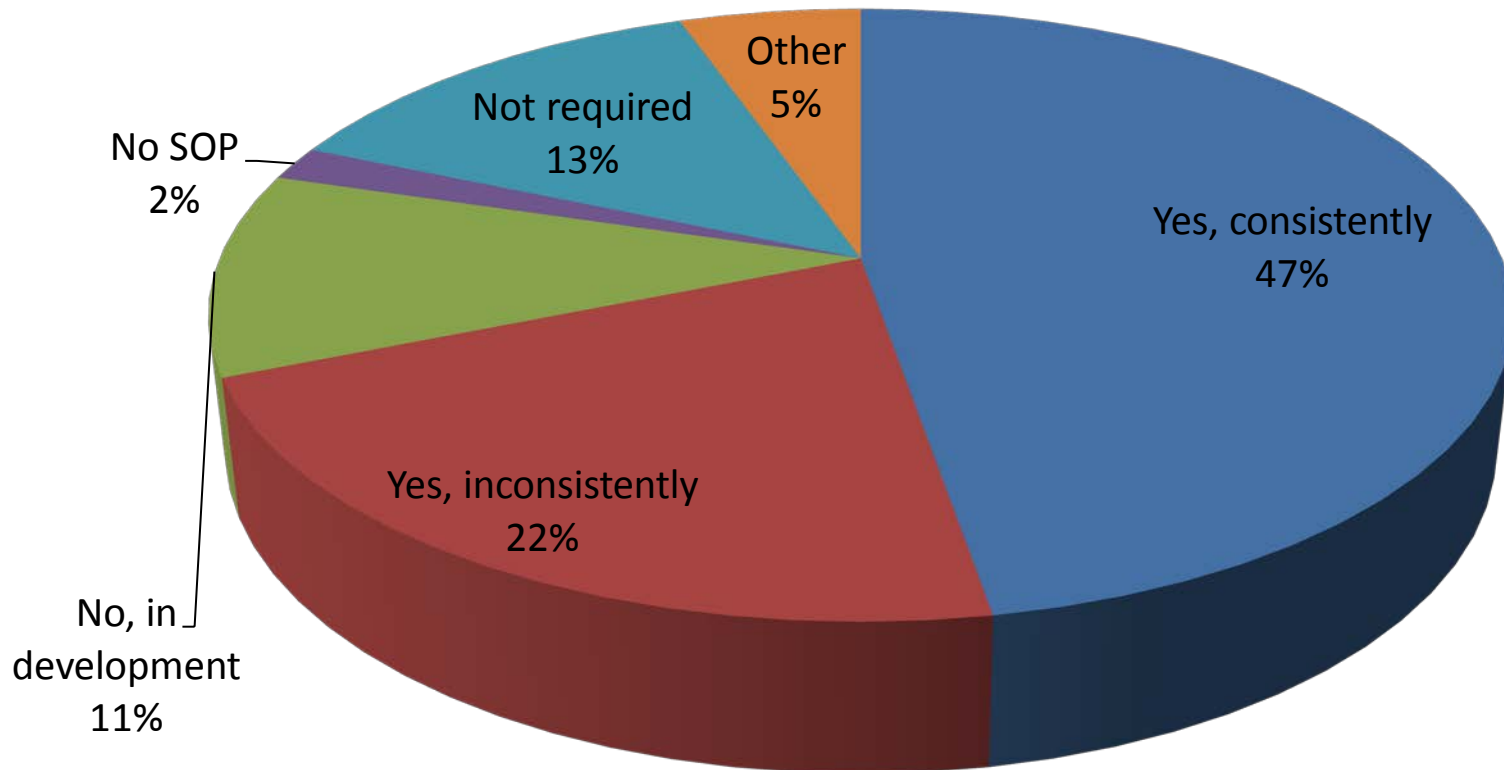
Paper and electronic TMF

What is your TMF file of record?

- Not applicable 12%
- Inspectable paper TMF 32%
- Combination paper and electronic 48%
- Inspectable electronic TMF 8%

2010 TMF Survey Results

- Combo 27%
- Unk 6%
- eTMF 7%
- Other 10%
- Paper TMF 50%

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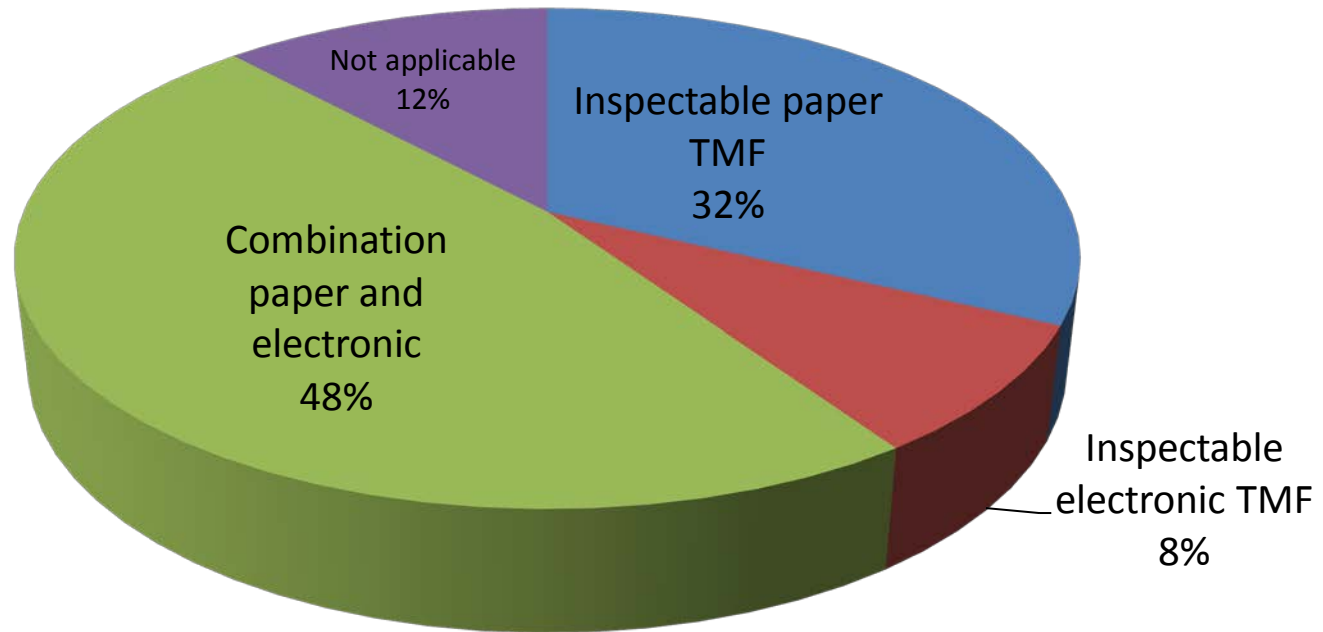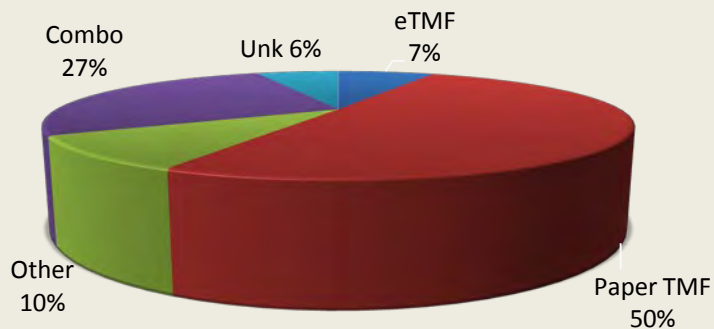
eTMF status

What is the status of your organization's eTMF?

Legend:
- We currently use eTMF
- Actively Building / Implementing
- Evaluating
- Actively Planning
- Not Considering
- Unknown/Not Applicable

Main chart values: 28%, 27%, 19%, 10%, 3%, 13%

2010 Survey Results
- We have an eTMF 31%
- Actively Building 17%
- Evaluating 28%
- Not considering 6%
- Other 9%
- Unknown 9%

2012 TMF Survey #2
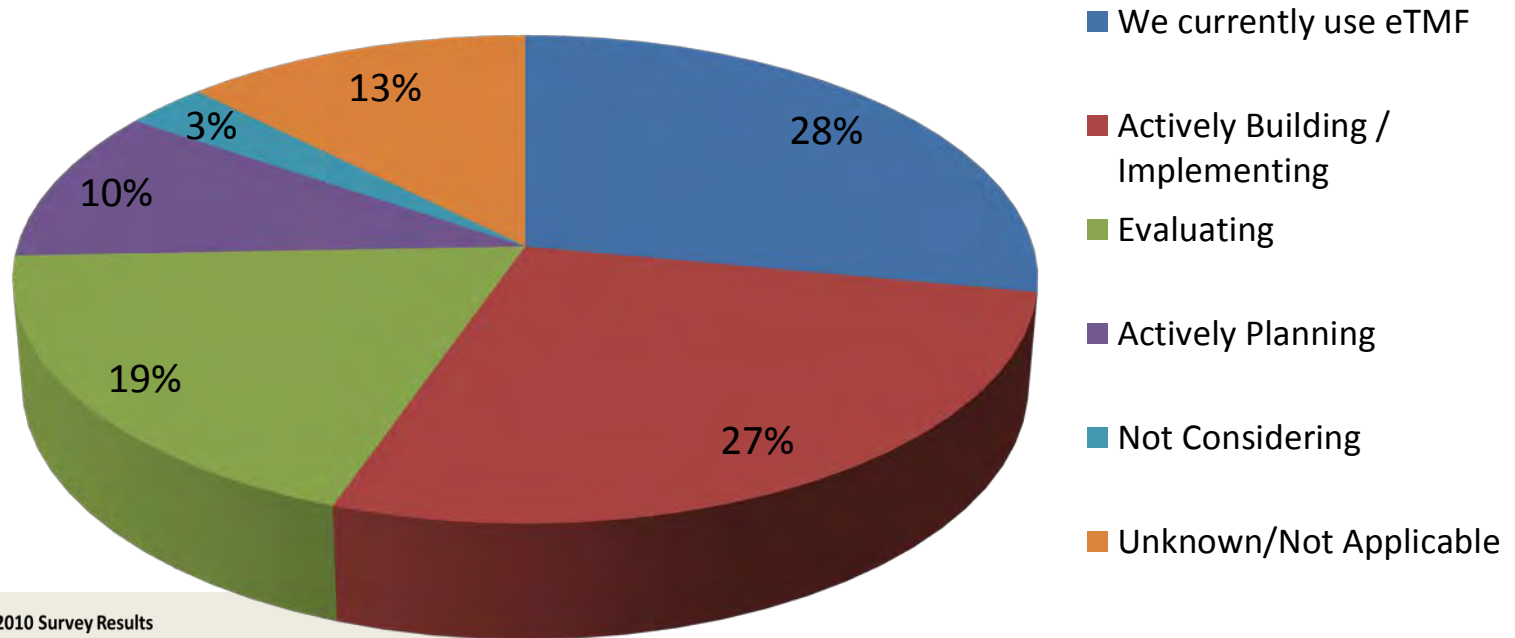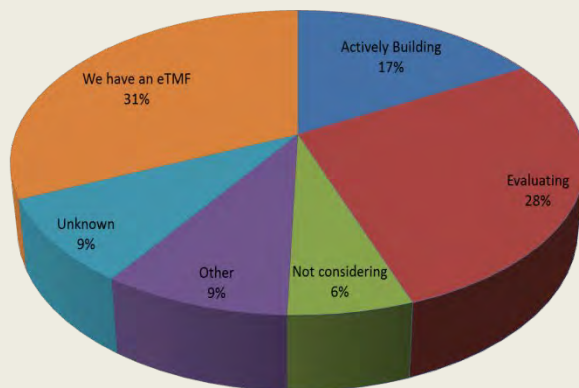
Reference Model Uptake

Is your organization using the TMF Reference Model?

43.5 % (54)

Yes
No
Don't know

3.2 % (4)

53.2 % (66)

2012 TMF Survey #2
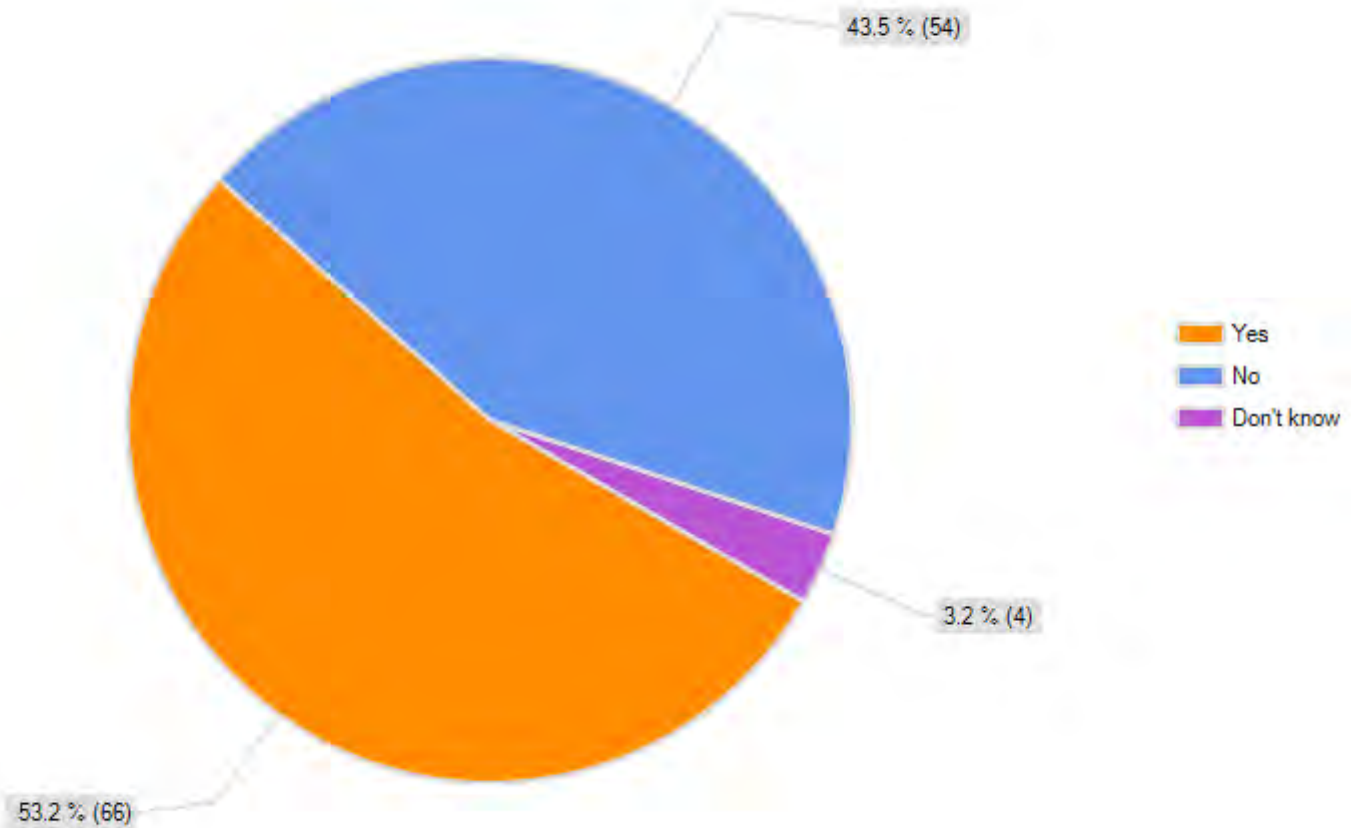
Reference Model use – paper and eTMF

My organization is using reference model for...

Category	Percentage (Count)
Paper TMFs only	16.7 % (11)
eTMFs only	24.2 % (16)
Both paper and eTMFs	40.9 % (27)
Don't know	—
Other (please specify)	18.2 % (12)

2012 TMF Survey #2
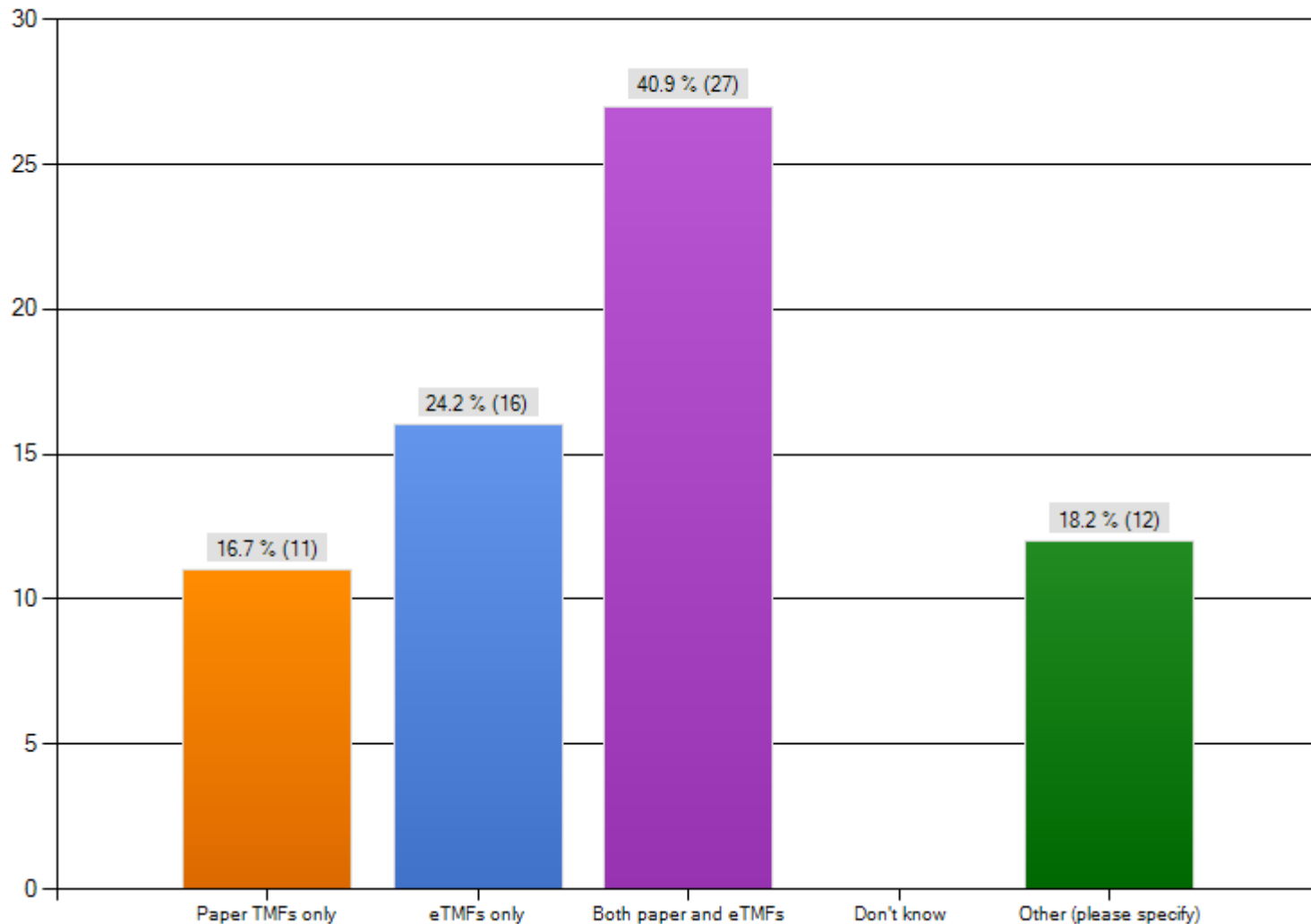
Reference Model use - trial status

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

Category	Percentage
New TMFs	83.3 %
Ongoing studies with restructured TMF	34.8 %
Ongoing studies with documents added to/removed from TMF	28.8 %
Closed TMFs	7.6 %

2012 TMF Survey #2
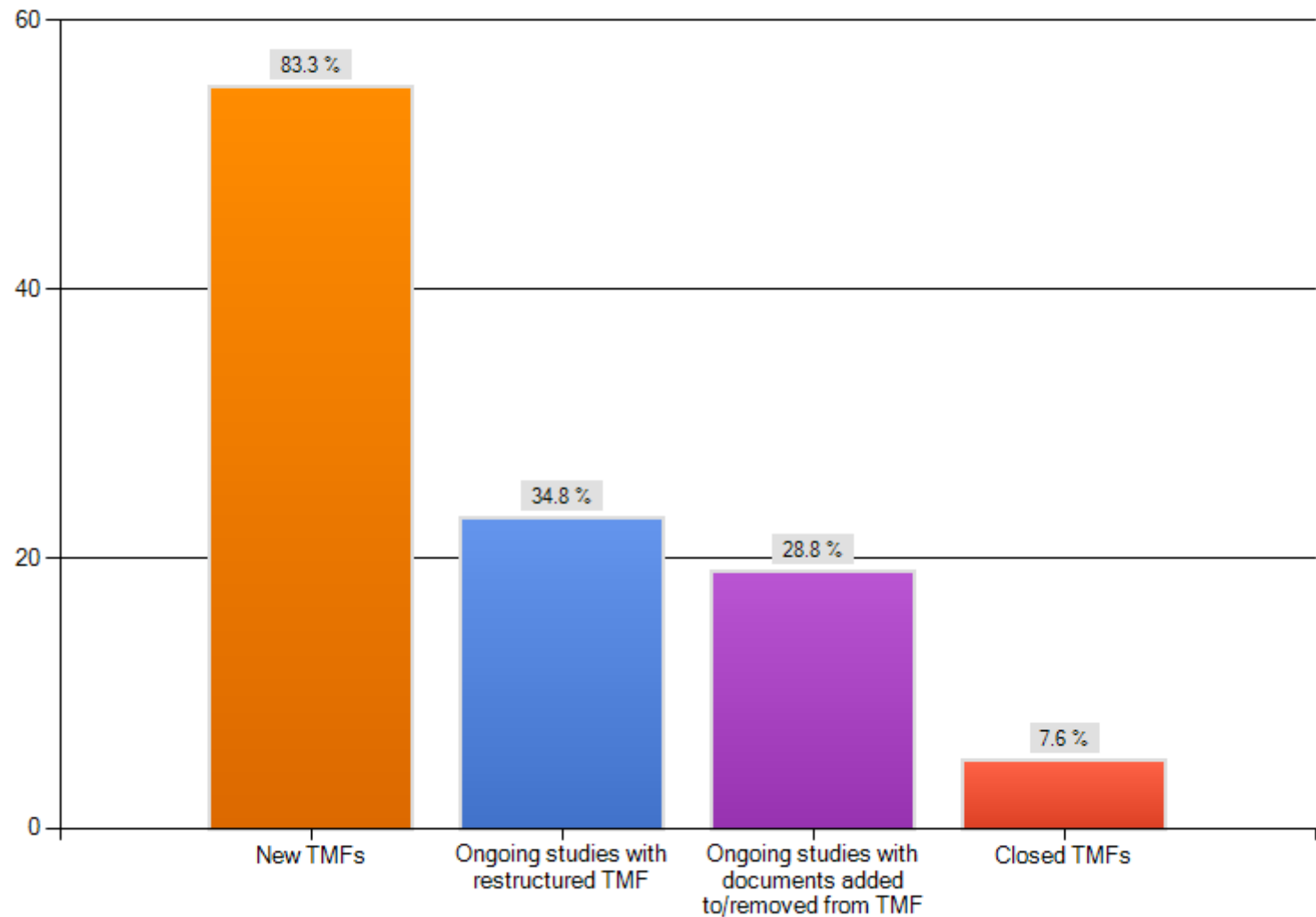
TMF Reference Model adaptions

In adapting the reference model, my organization is....

Bar chart showing responses to "In adapting the reference model, my organization is...."
- Changing artifact names: 40.0 % (20)
- Adding artifacts: 64.0 % (32)
- Condensing artifacts: 44.0 % (22)
- Changing the RM numbering system: 20.0 % (10)
- Restructuring the zones: 20.0 % (10)
- Other changes (please specify): 32.0 % (16)
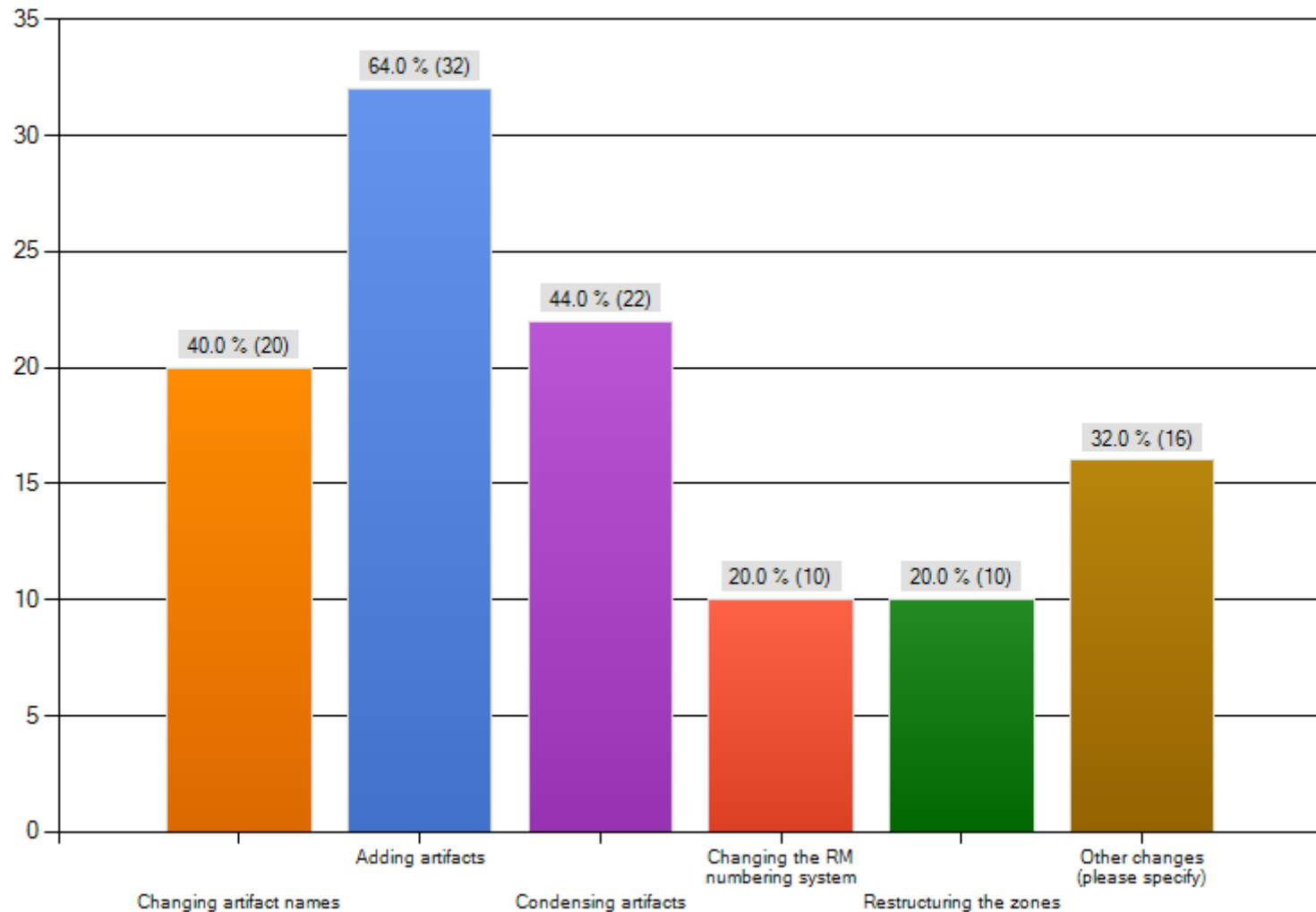
TMF Reference Model - Opinion

Rate the Reference Model in the following categories..
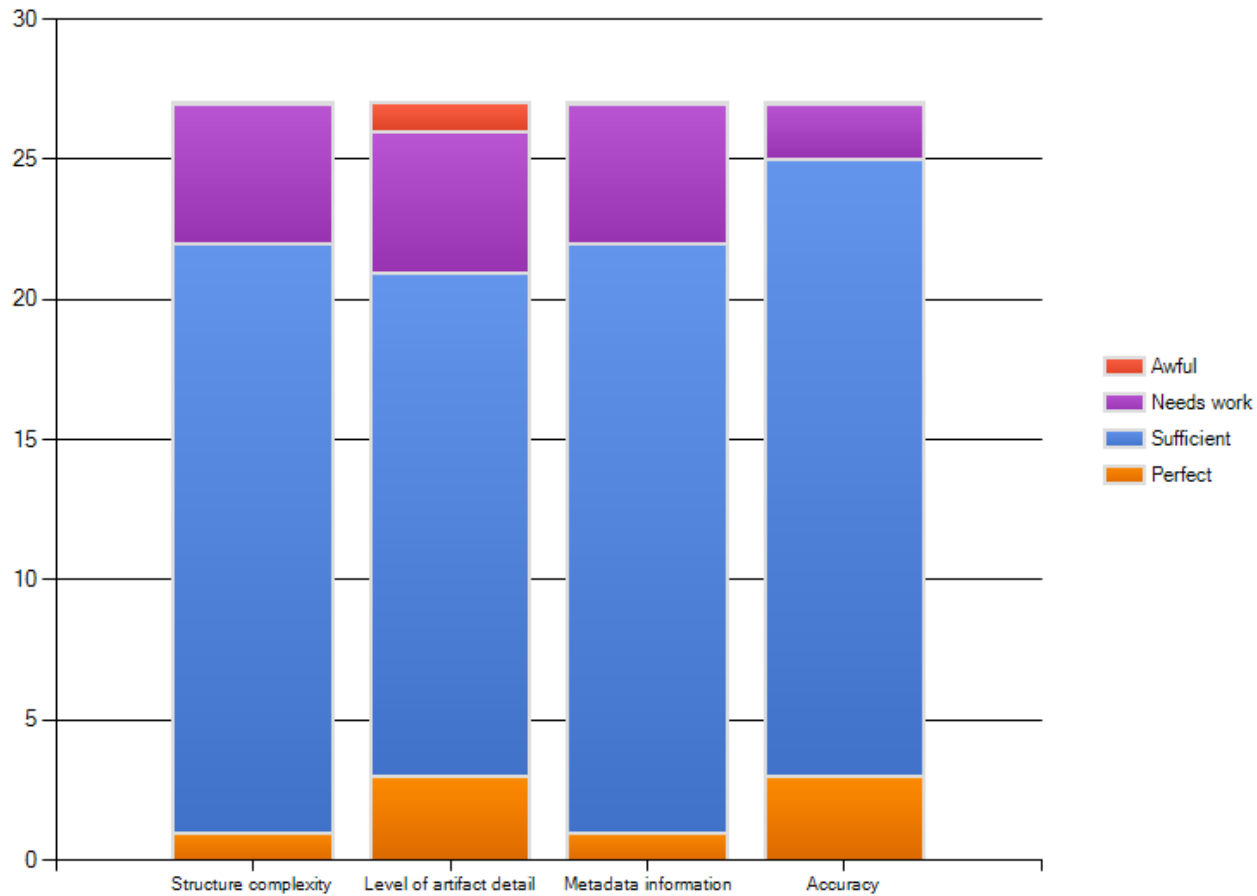
Impact of TMF Reference Model

Organizational Changes Since Implementing TMF RM

Chart legend:
- Changed active TMFs to reflect model
- Mapped TMF Structure to Model
- Created/updated guidance or best practice docs
- Updated/planning changes to SOP

Yes
- 35% — Changed active TMFs to reflect model
- 65% — Mapped TMF Structure to Model
- 62% — Created/updated guidance or best practice docs
- 70% — Updated/planning changes to SOP

No
- 49% — Changed active TMFs to reflect model
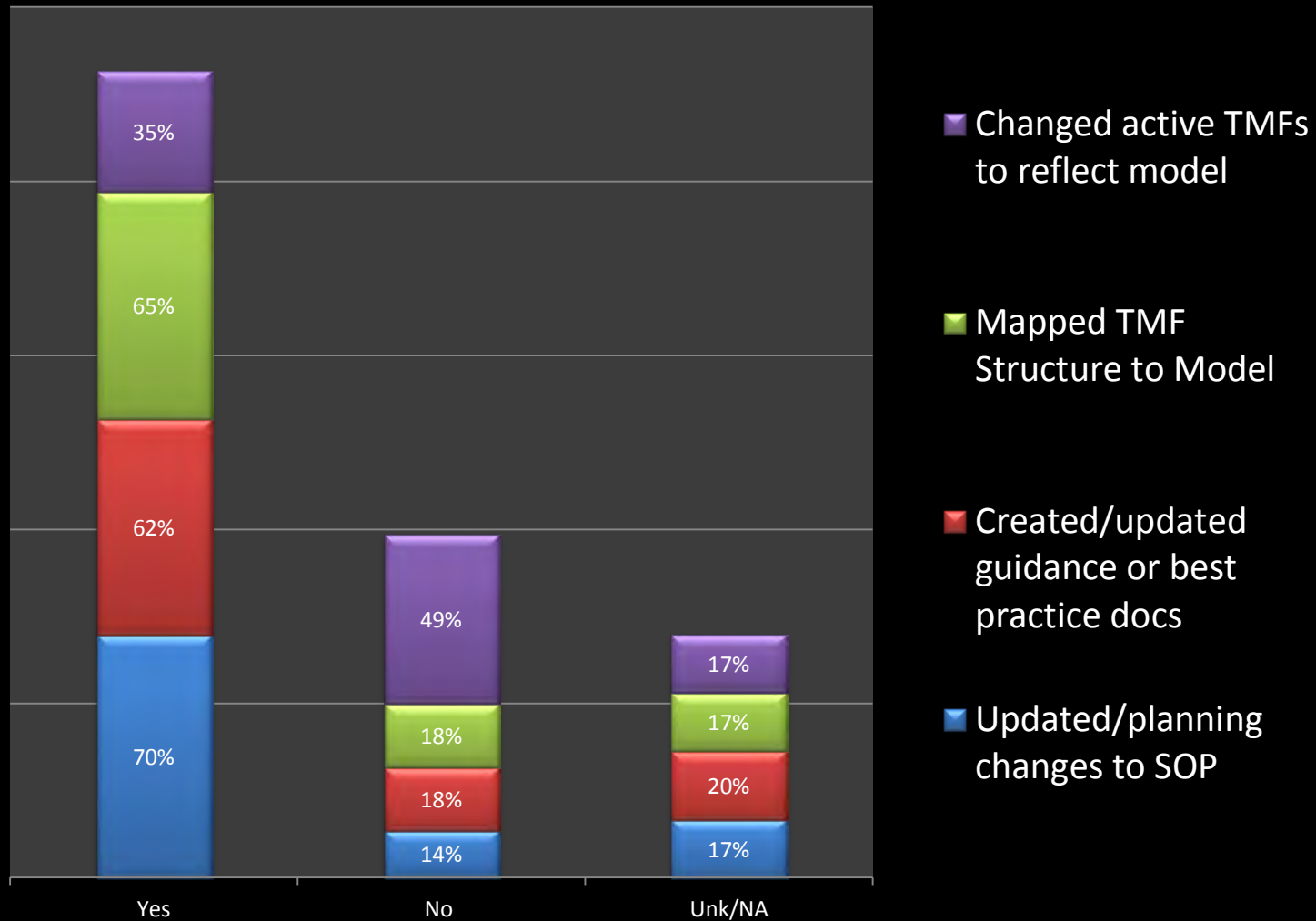- 18% — Mapped TMF Structure to Model
- 18% — Created/updated guidance or best practice docs
- 14% — Updated/planning changes to SOP

Unk/NA
- 17% — Changed active TMFs to reflect model
- 17% — Mapped TMF Structure to Model
- 20% — Created/updated guidance or best practice docs
- 17% — Updated/planning changes to SOP

Uptake of electronic Investigator Site Files (eISF)

What percent of your trials have an eISF?

Legend:
- Yes - 100%
- Yes - 75%
- Yes - 50%
- Yes - 25%
- None

Pie chart values: 7%, 2%, 6%, 13%, 72%
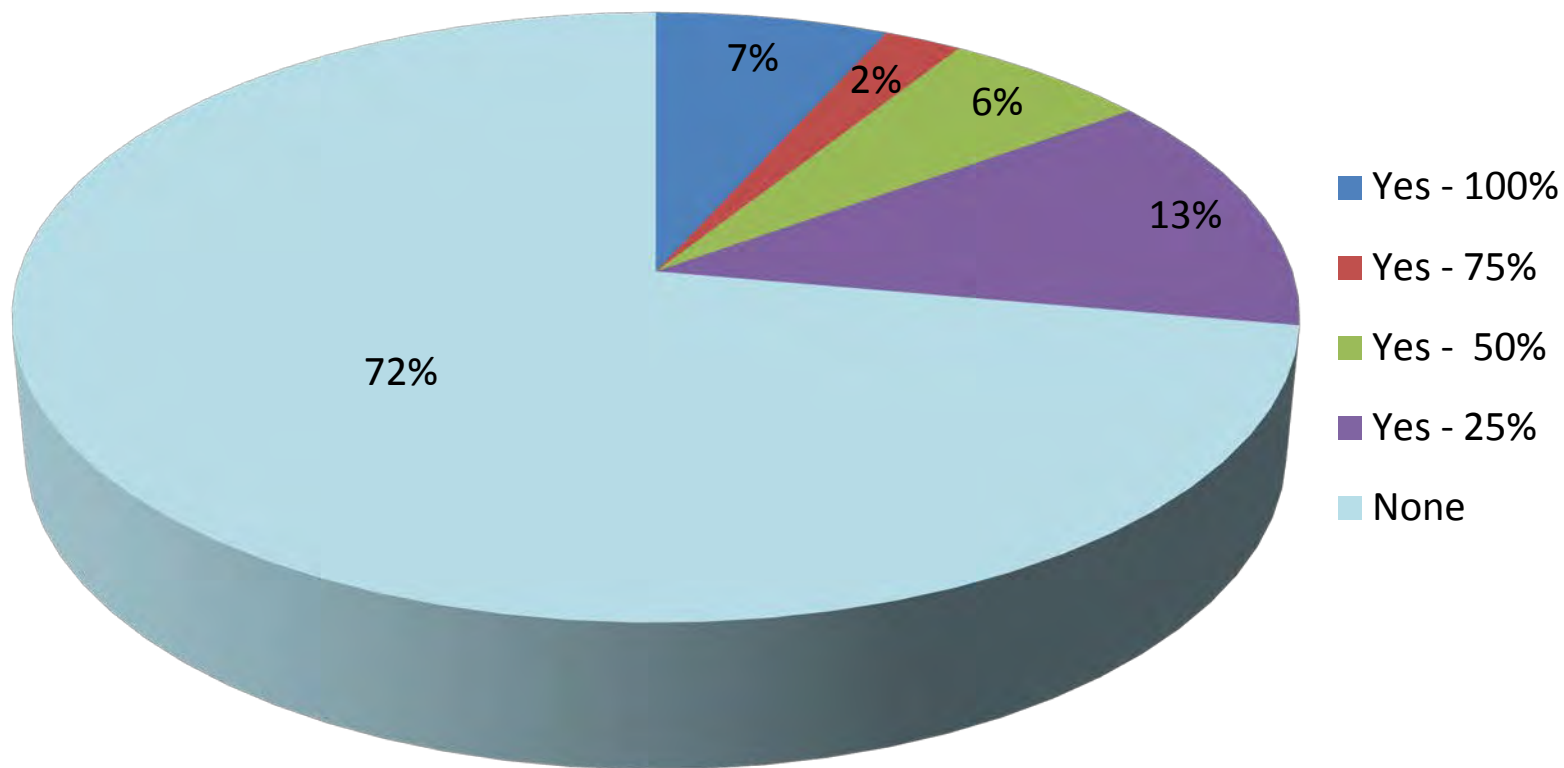
Barriers to eISF uptake

If no electronic Investigator Site File, why not?

Legend:
- Technical Constraints
- Regulatory Concerns/Barriers
- Legal Concerns/Barriers
- Local Country Concerns
- Site Refusal
- Not Considered
- Other

Bar values: 25%, 9%, 5%, 7%, 0%, 55%, 22%

"Other" response themes
- Implementing eTMF first
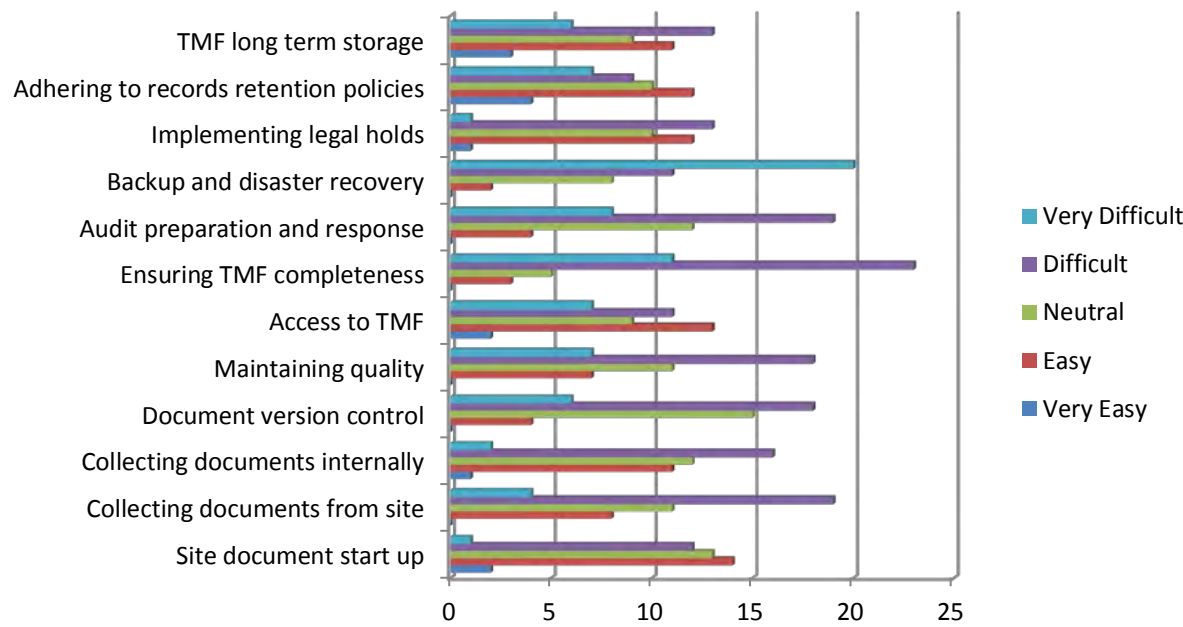- Still evaluating / planning
- No perceived value
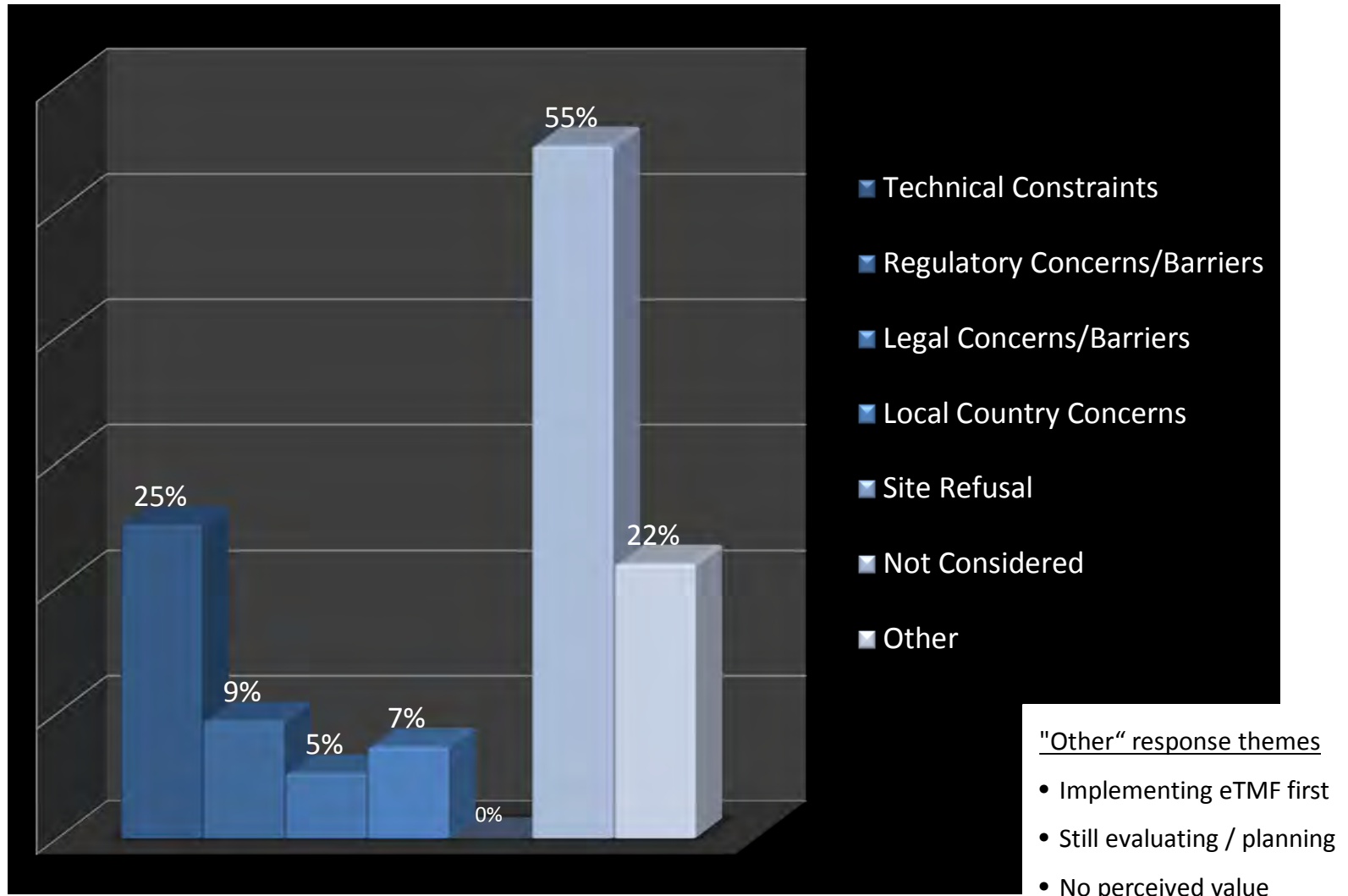
2012 Survey - Electronic TMF
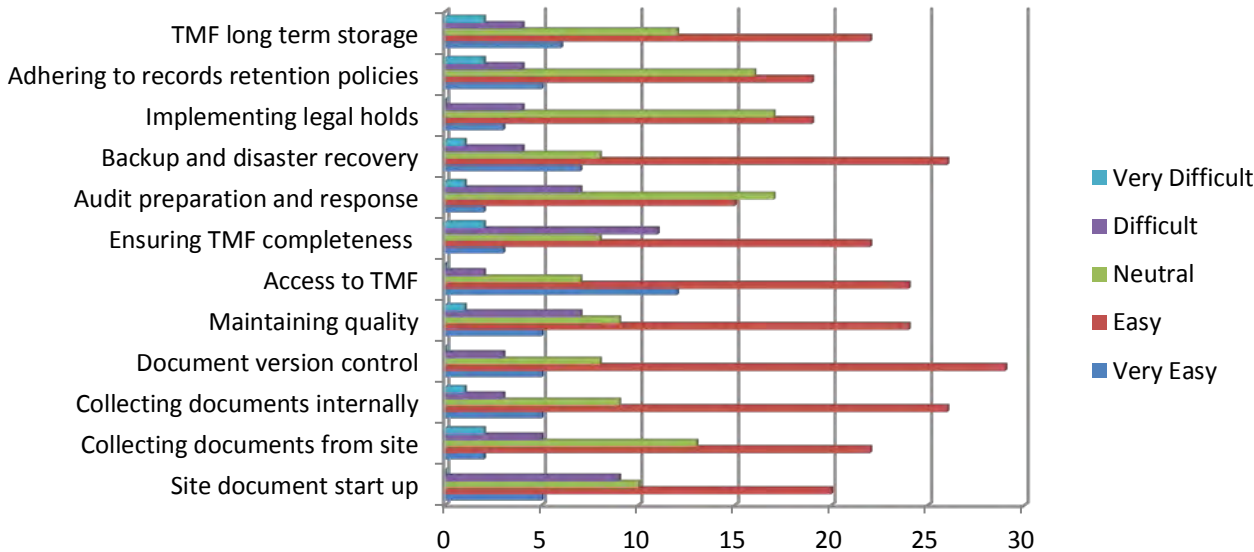

Data indicates efficiencies increase when using eTMF
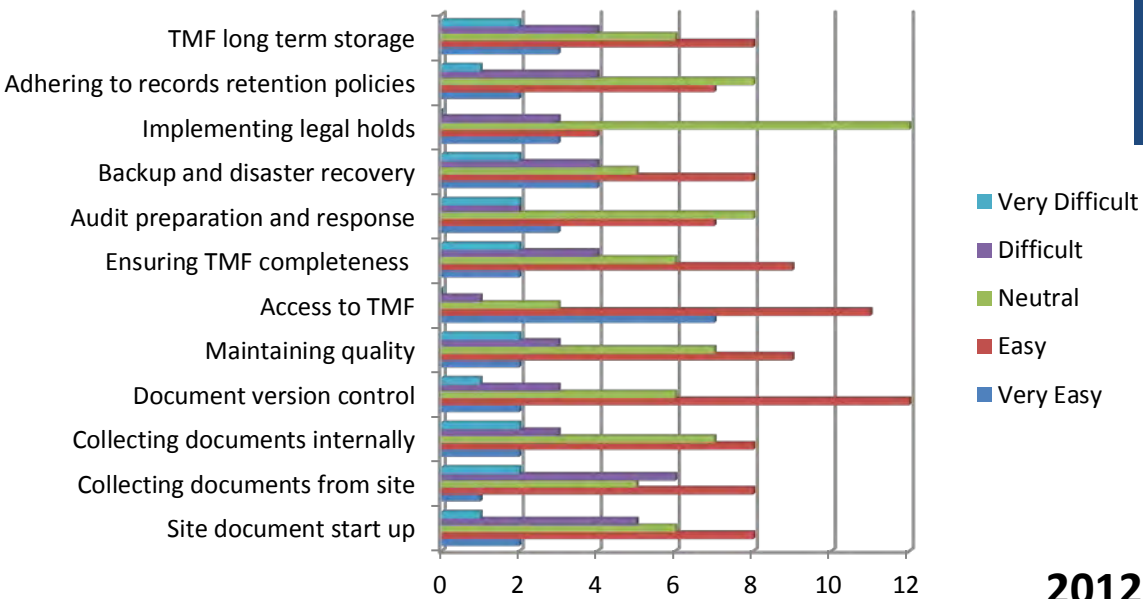
2012 Survey - Paper TMF

Rating TMF processes, paper vs electronic TMF, with level of difficulty (very easy to very difficult)

2012 TMF Survey #2

2012 Data - Using TMF RM and eTMF

Categories (top to bottom):
- TMF long term storage
- Adhering to records retention policies
- Implementing legal holds
- Backup and disaster recovery
- Audit preparation and response
- Ensuring TMF completeness
- Access to TMF
- Maintaining quality
- Document version control
- Collecting documents internally
- Collecting documents from site
- Site document start up

Legend:
- Very Difficult
- Difficult
- Neutral
- Easy
- Very Easy

X-axis: 0, 5, 10, 15, 20, 25, 30

Data indicates additional benefits in using both eTMF and TMF Ref Model

2012 Data - Not Using TMF RM and Paper

Categories (top to bottom):
- TMF long term storage
- Adhering to records retention policies
- Implementing legal holds
- Backup and disaster recovery
- Audit preparation and response
- Ensuring TMF completeness
- Access to TMF
- Maintaining quality
- Document version control
- Collecting documents internally
- Collecting documents from site
- Site document start up

Legend:
- Very Difficult
- Difficult
- Neutral
- Easy
- Very Easy

X-axis: 0, 5, 10, 15, 20, 25

2012 TMF Survey #2