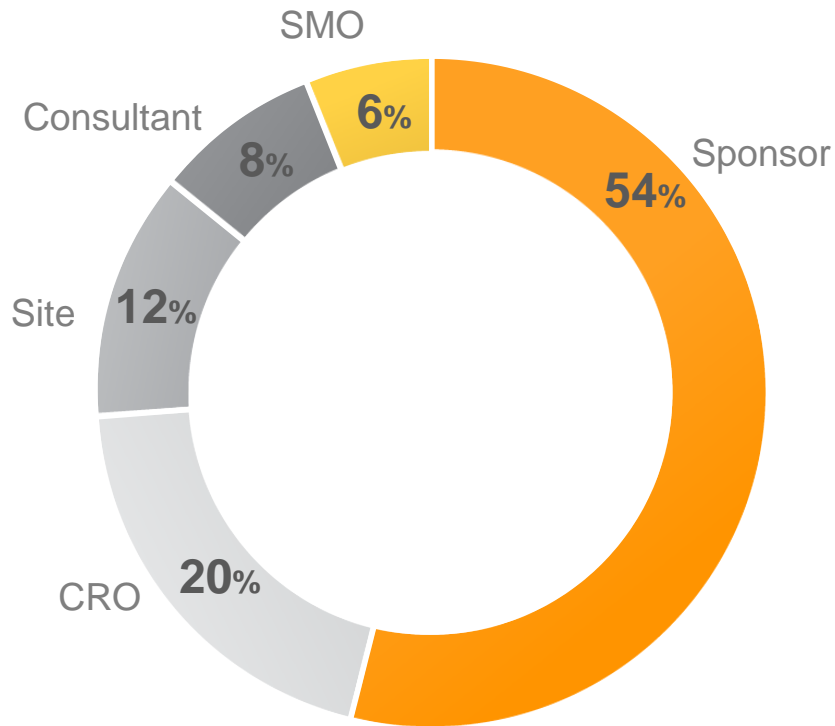**Rebecca Moraris**
Director,
Clinical Management

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Michael Burton
Director,
CRO Alliances

Veeva

Largest TMF Survey to Date

Type of Organization
n = 252

SMO — 6%
Consultant — 8%
Sponsor — 54%
Site — 12%
CRO — 20%
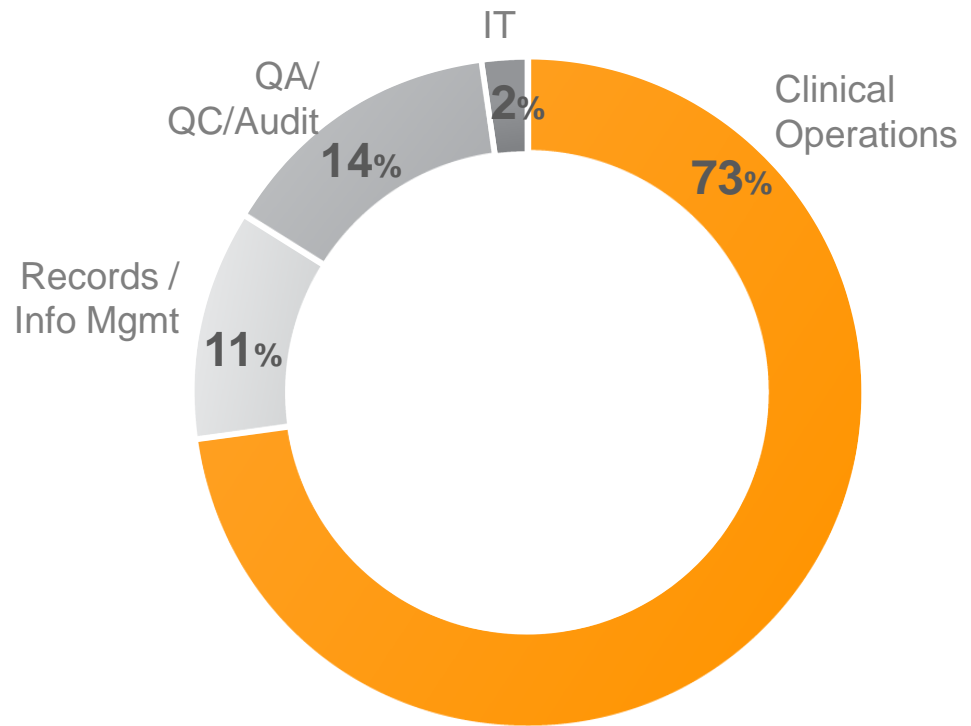
Functional Area
n = 252

IT — 2%
QA/QC/Audit — 14%
Clinical Operations — 73%
Records / Info Mgmt — 11%

Source: Veeva 2014 Paperless TMF Survey: An Industry Benchmark, June 2014

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Manual Processes Persist

Manual exchange of TMF documents between sponsors and CROs

57% paper

69% email

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Significant Opportunity for the Industry

Only half of eTMF systems have advanced process management

eTMF Application **13%**

N/A, only use paper **13%**

26% Local file system

18% Cloud file share

30% Content mgmt. system
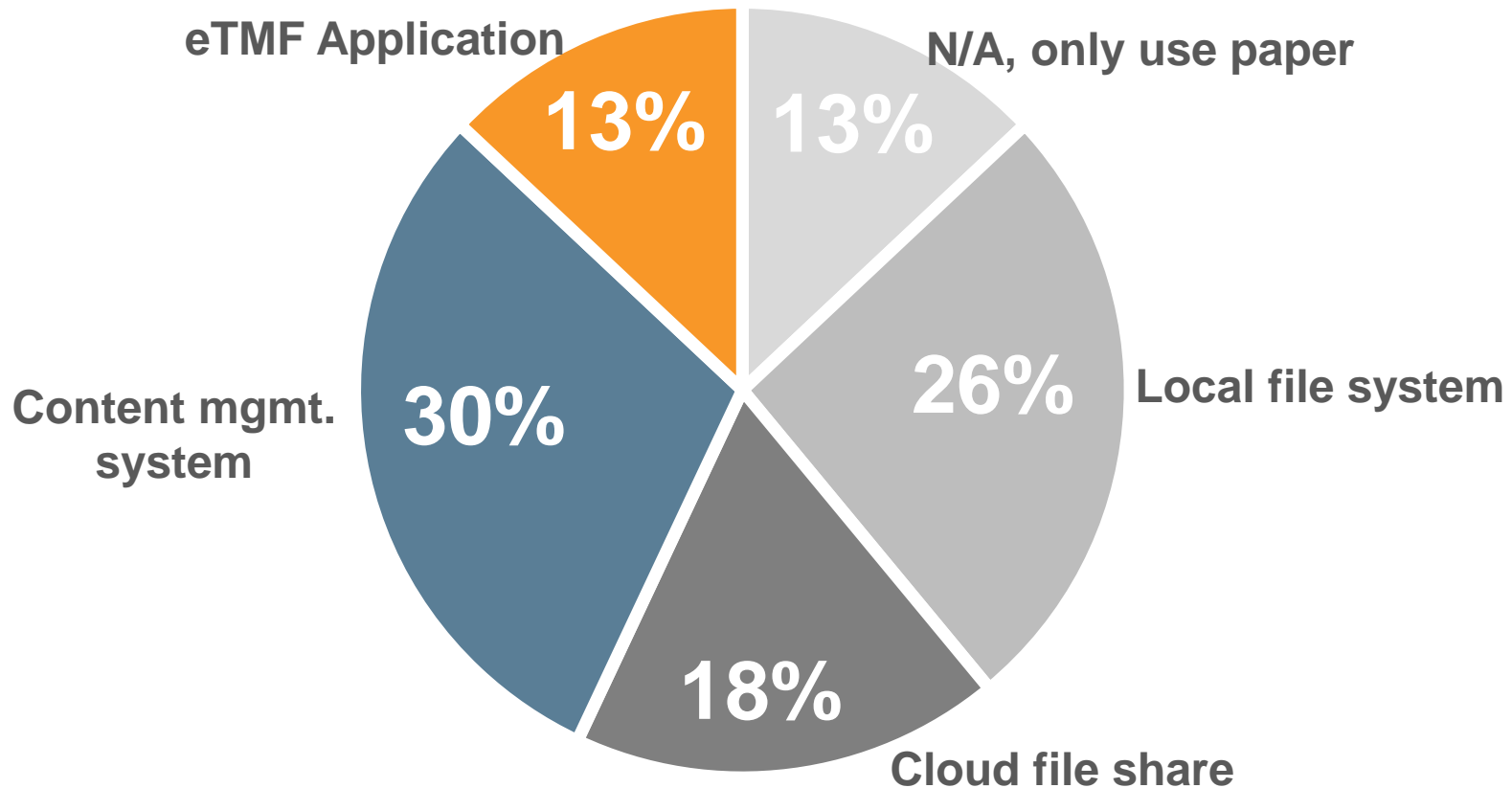
What type of eTMF solution did you most recently use? (n=135, Q.9) **Sponsor company responses only.**

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Top Drivers of eTMF Adoption

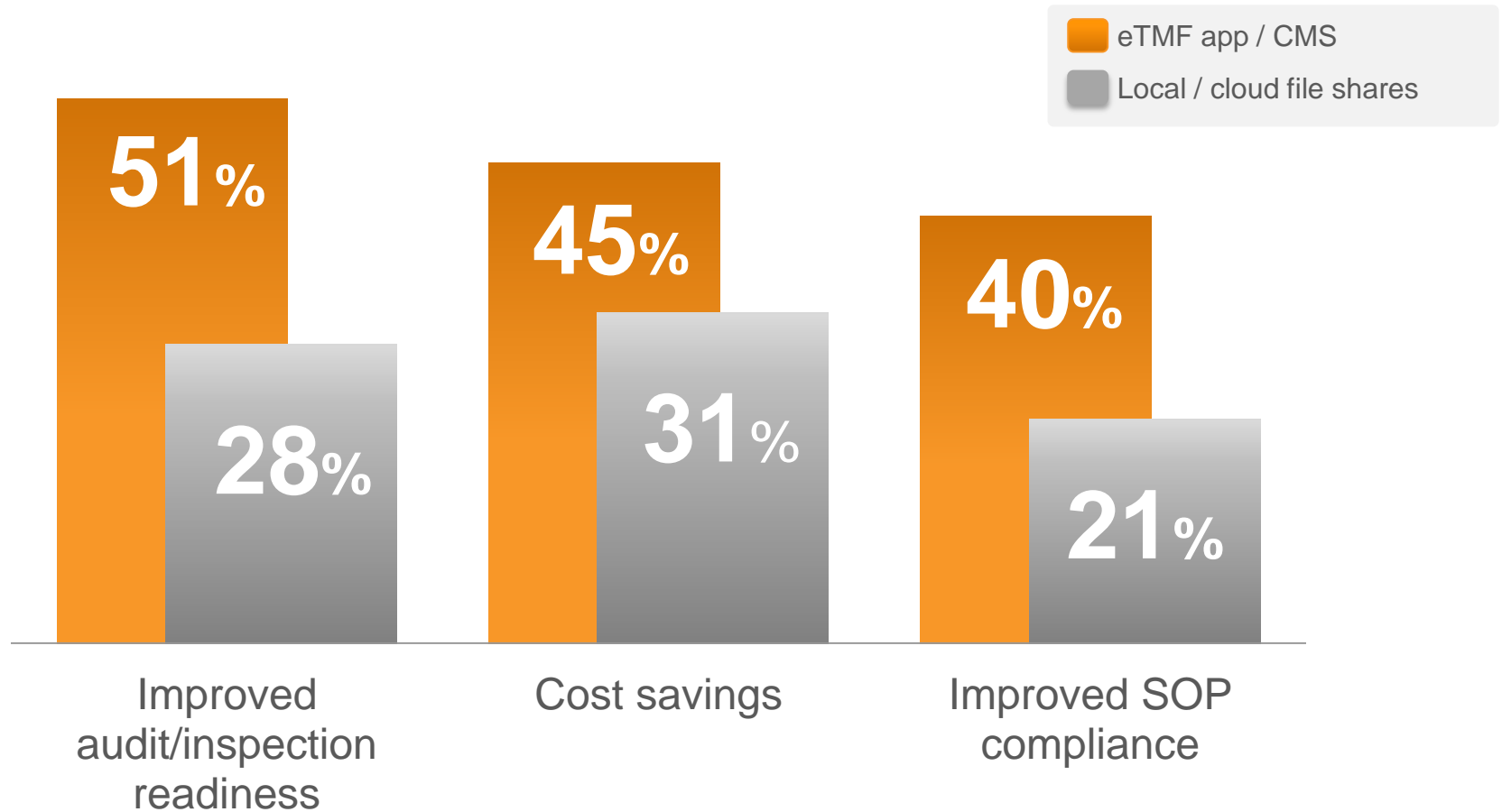| Driver	Percentage
Cost savings	56%
Speed study start-up	55%
Improve central and remote monitoring	49%
Audit and inspection readiness	45%
Improve collaboration with external parties	28%
Improve vendor oversight	19%
Shorten study close-out	18%
Improve scalability	18%
Improve site satisfaction	13%
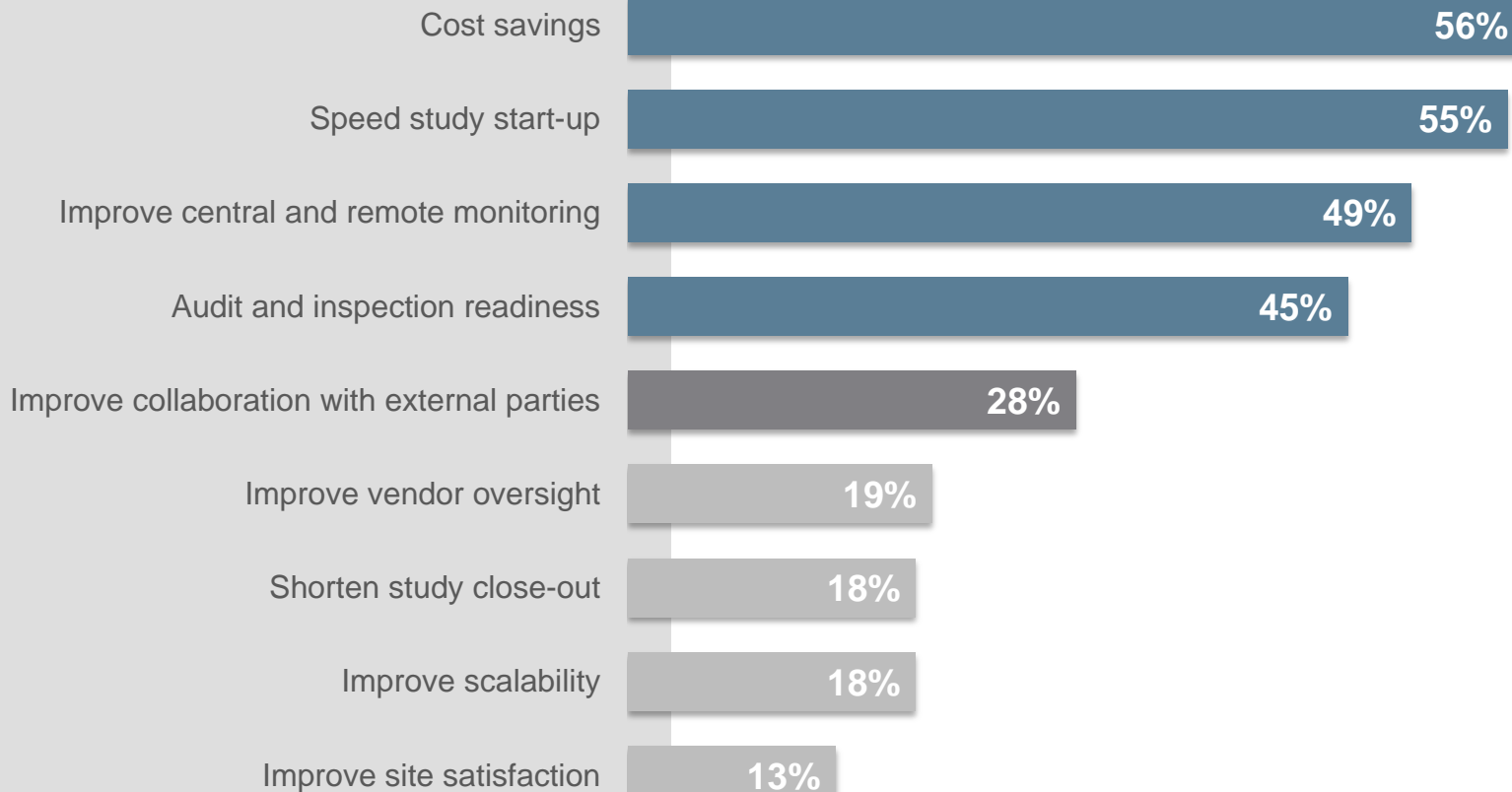
Which of the following business benefits are the most important in motivating your organization's adoption of electronic TMFs? Please select the top three benefits. (Q7)

Benefits Achieved by Type of eTMF

Legend:
- eTMF app / CMS (orange)
- Local / cloud file shares (gray)

Improved audit/inspection readiness: 51% / 28%
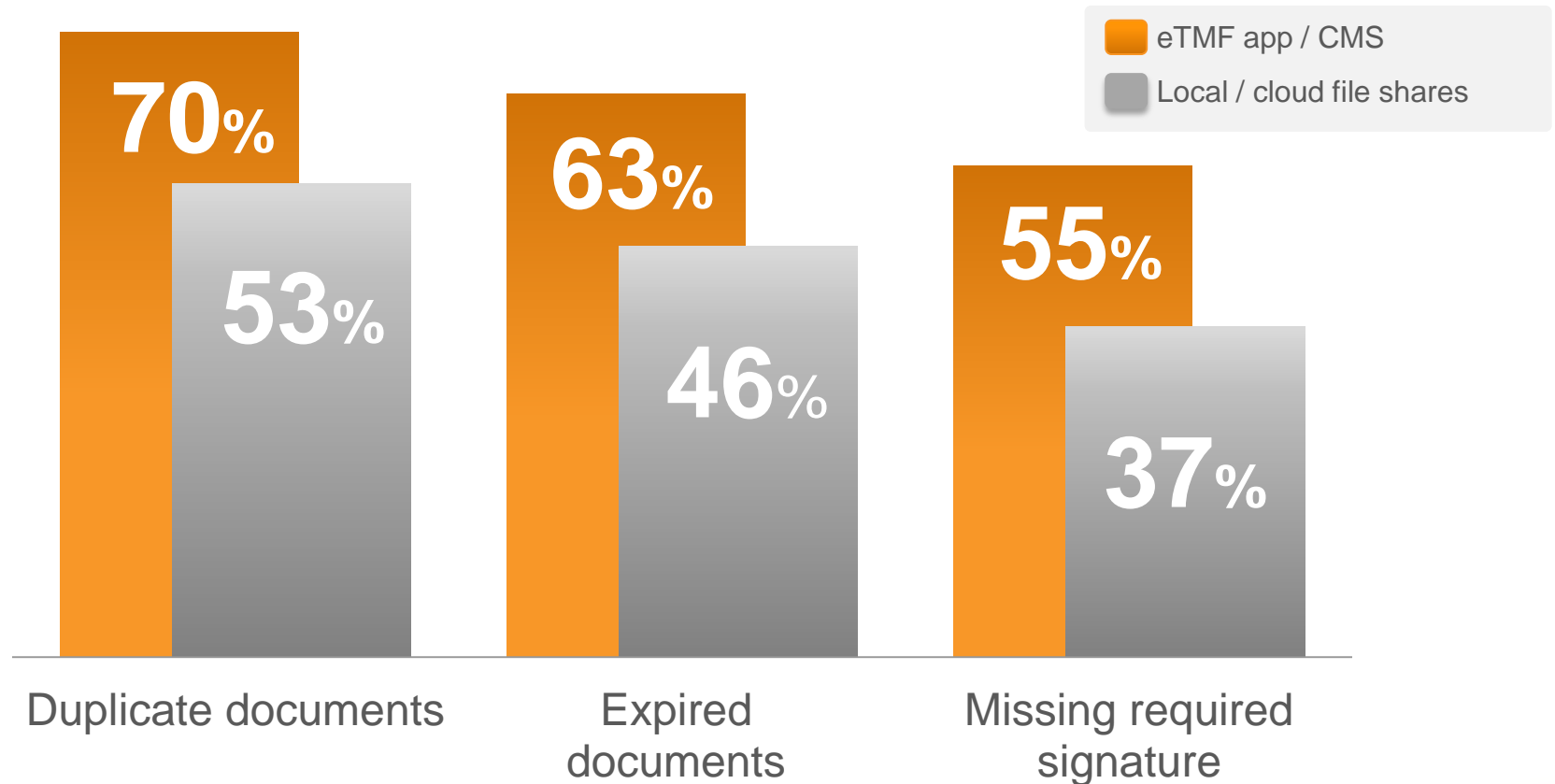
Cost savings: 45% / 31%

Improved SOP compliance: 40% / 21%

What benefits were achieved with your organization's implementation of the eTMF solution specified in . 0uestion 9? (Q.10).

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TMF Quality by Type of eTMF

Improvements rated good/major with eTMF adoption

Legend:
- ■ eTMF app / CMS
- ■ Local / cloud file shares

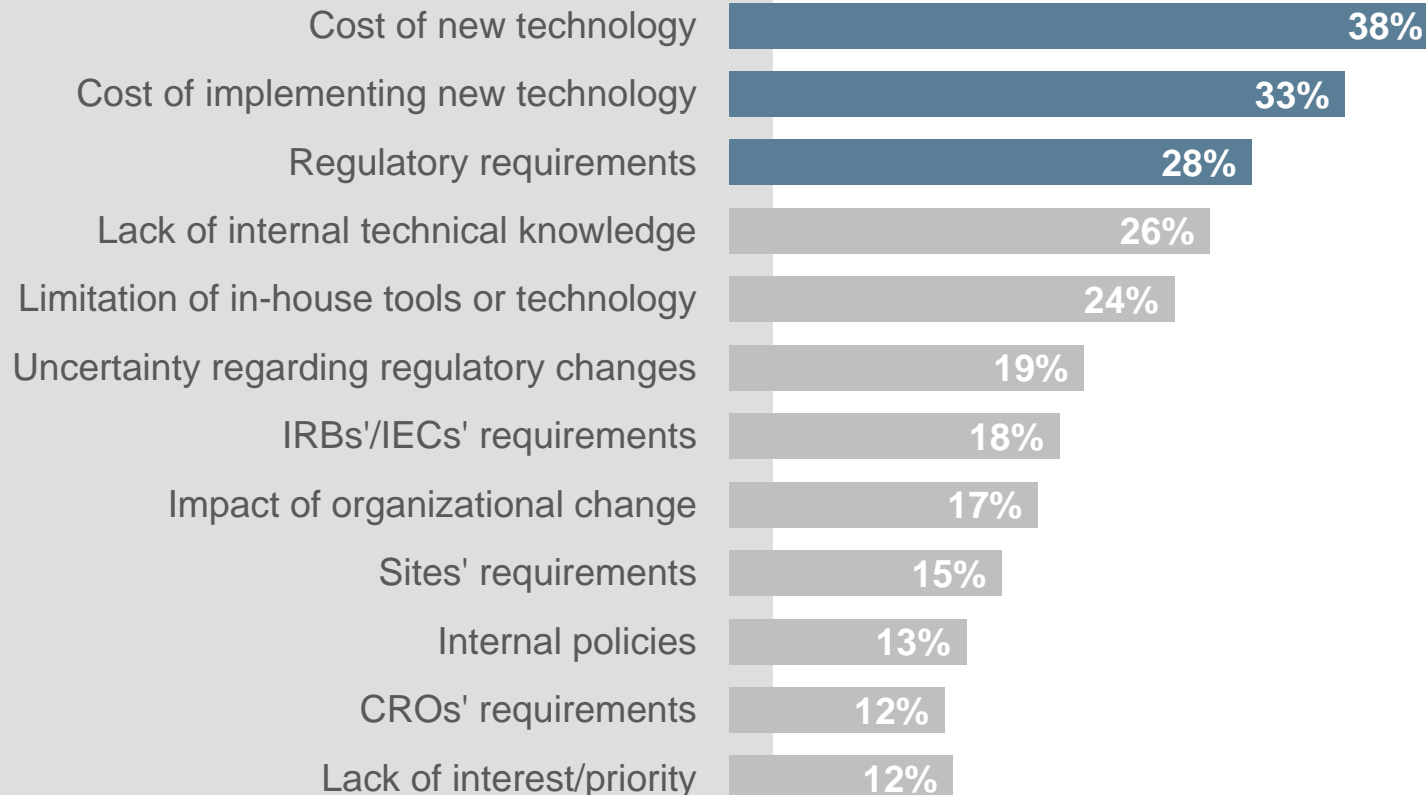|	eTMF app / CMS	Local / cloud file shares
Duplicate documents	70%	53%
Expired documents	63%	46%
Missing required signature	55%	37%

How much improvement did you observe in the following inspection areas after your organization implemented the eTMF specified in Q9? (n varies, Q.11)

Top Barriers

Percent reporting as major or insurmountable barrier

Barrier	Percent
Cost of new technology	38%
Cost of implementing new technology	33%
Regulatory requirements	28%
Lack of internal technical knowledge	26%
Limitation of in-house tools or technology	24%
Uncertainty regarding regulatory changes	19%
IRBs'/IECs' requirements	18%
Impact of organizational change	17%
Sites' requirements	15%
Internal policies	13%
CROs' requirements	12%
Lack of interest/priority	12%

To what extent is each of the following a barrier to TMFs going paperless in your organization? (Q.4)
Percent of respondents rating each as a major barrier or barrier that cannot be overcome.

# Updated definition of
CRITICAL GCP inspection finding

…where provision of the **TMF does not comply with Regulation** 31A 1-3, as the TMF is not readily available or accessible, or the TMF is incomplete to such an extent that it cannot form the basis of inspection and therefore impedes or obstructs inspectors carrying out their duties in verifying compliance with the regulations.

35%

of inspections over the past year resulted in **extra days** to complete inspections where difficulties ensuring the TMF is complete and readily available

25 April 2014

Where We Were

STUDY DESIGN

Phase 4 medical device

Post marketing

Regulatory commitment
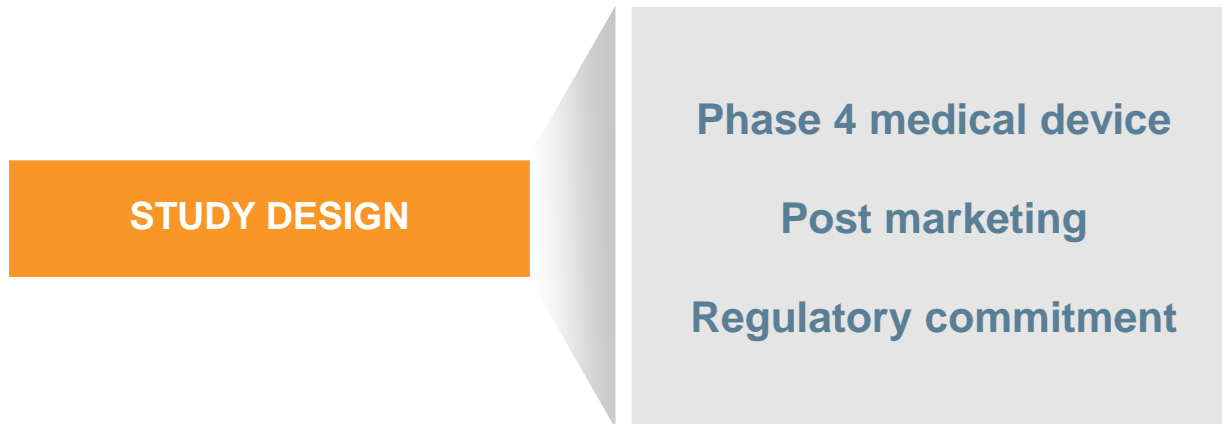
- **Recently purchased by new sponsor**

- **Transfer of information from previous sponsor, including "legacy" paper TMF**

- **Ensure smooth transition from previous sponsor to new sponsor**

Why Implement an eTMF

Cloud-based Technology

Efficiency

Accessibility

- ▪ "Green" philosophy

- ▪ Zero IT footprint

- ▪ Paperless

- ▪ Minimal end-of-study document reconciliation

- ▪ Real-time access to study documents

- ▪ Real-time document approval from anywhere

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Implementation Challenges

- **"Newness" factor**

- **System validation alignment with SOPs**

- **21 CFR Part 11 compliance**

- **Differences in interpretation of regulations**

- **Team training and usage of system**

- **Definition of original records**

  - Disposition of "legacy" paper?

  - Disposition of paper generated moving forward?

Current Status

✔ System validated and in use

✔ All study team members trained

✔ Documents approved in a timely manner

✔ Study tracking accessed and updated via eTMF

✔ Legacy documents uploaded and classified

✔ Site files set up and permissions set

Lessons Learned

eTMF Implementation	User Adoption
Bring QA and regulatory in early	In-person, hands-on training at study start
Define process upfront	Encourage usage of system by all team members
	Utilize system during team meetings

Questions