



TMF & ISF: What is keeping sites up at night?



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Insomnia-inducing, TMF-affecting issues

What are sites facing?

- Lack of transparency
- Communication
- Duplication of work
- Lack of consistent and/or compatible systems used between sponsors/CROs



Lack of Transparency



- What does a sponsor expect from a site for a healthy TMF?
- How often will the sponsor/CRO monitor our ISF?
- How often will the sponsor/CRO audit their TMF and contact the site about missing documents, documents that didn't pass QC, etc?
- How will the ISF from the site populate the TMF?

Communication

- There's a definite lack of communication.
- Who does the site reach out to?
- Are we communicating with the right people when it comes to the TMF?



Duplication of Work



Sites deal with multiple requests for documents from multiple sources, especially during and after the COV.

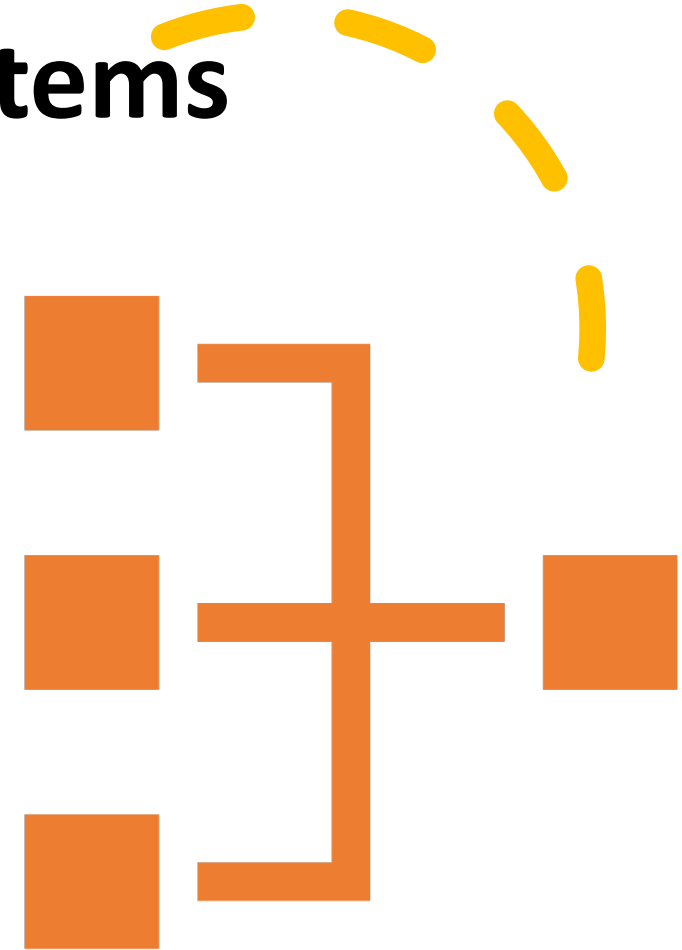
Since these deficiencies are identified during TMF audits, why aren't TMFs audited regularly but certainly before the COV?

“The main issue we are having with the TMF currently is that the study teams are contacting us months after the close-out visit requesting loooooooooong lists of documents that should have been collected at or prior to the COV.”

~ SCRS Member Site

Lack of Consistent/Compatible Systems

- The systems used varies between sponsors and CROs.
- Even if the same system is used, it seems that it's used differently between sponsors and CROs.
- Even if a sponsor or CRO uses the same system across multiple studies, it seems as though it's used differently between the studies.



HOW DO WE FIX IT?



TMF points of contact between the site and sponsor/CRO



Defined workflow with the site



Periodic TMF check-ins and query reports with site = meeting contemporaneous requirements

**Let's
talk
about
it!**

TMF **WEEK**
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