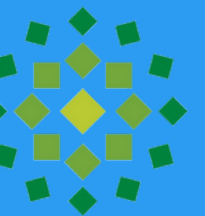


5 Steps to TMF Inspection- Readiness



What does it mean to be inspection ready?



Inspection readiness refers to the requirement to ensure that all clinical trial documentation and systems are up to date at all times. That means that every day, systems are updated, inspected, and maintained in a state that is ready for an external auditor to access the systems and conduct an inspection.

"It means your documents are up to date, deduped and organized, and your processes are in place. That means no notification, not "getting ready" for the audit...instead, it means you are ALWAYS ready. The result is higher quality and lower costs." - Ken Lownie, Head of North American Operations, Agatha





Ready to Get Started?

**5 STEPS TO INSPECTION-
READINESS**



1 Plan Ahead

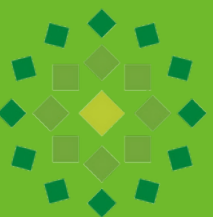
ALWAYS THE FIRST STEP

Don't wait for a letter from the FDA with an inspection date.



2 Dedicate Resources

Even if you are a small sponsor and do everything in-house, then you need person to own the TMF and ensure everything required for GCP compliance in in place



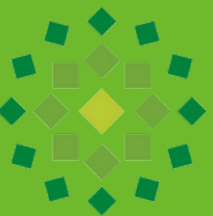


3 Create a Process

BREAK IT DOWN

If you already have a process for managing your documents in Dropbox or another space, that's a great start.

Now build on that process and make it into something that is going to help you migrate and maintain documents in a fully compliant eTMF system.



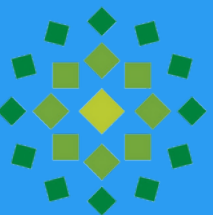
4

Select an eTMF that is right-size for you today

Select an eTMF that is right-sized for your needs.

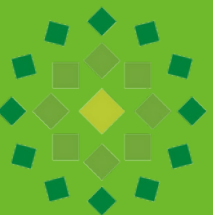
Compare its features with what you need and be sure to ask the vendor how long it will take to get to production.

Do a trial to test the application out and see if it works for you, the way you need it to.



If you need help planning the study and getting your TMF set up, find an expert who can provide these services and can help you get set up quickly.

5 Don't be afraid to get help





Watch the webinar 5 Steps to Inspection-Readiness for more details.

Watch it Now

Visit <https://www.agathahealth.com> to learn how we can help.

