

DON'T PANIC

How to Survive a TMF Inspection When You're Not Prepared



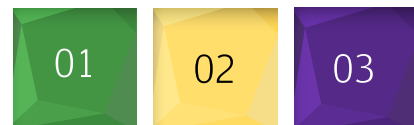
A PHLEXGLOBAL GUIDE

PRACTICAL
STEPS TO
REDUCE
YOUR RISK

You've just received an inspection notice, and the adrenaline is starting to kick in. While it's ideal that your studies and the Trial Master File should always be inspection-ready, we recognize the reality: teams get busy with fire drills, resources get shifted, staff turns over, and so forth. And even the most well-managed TMF can have errors that lead to inspection findings.

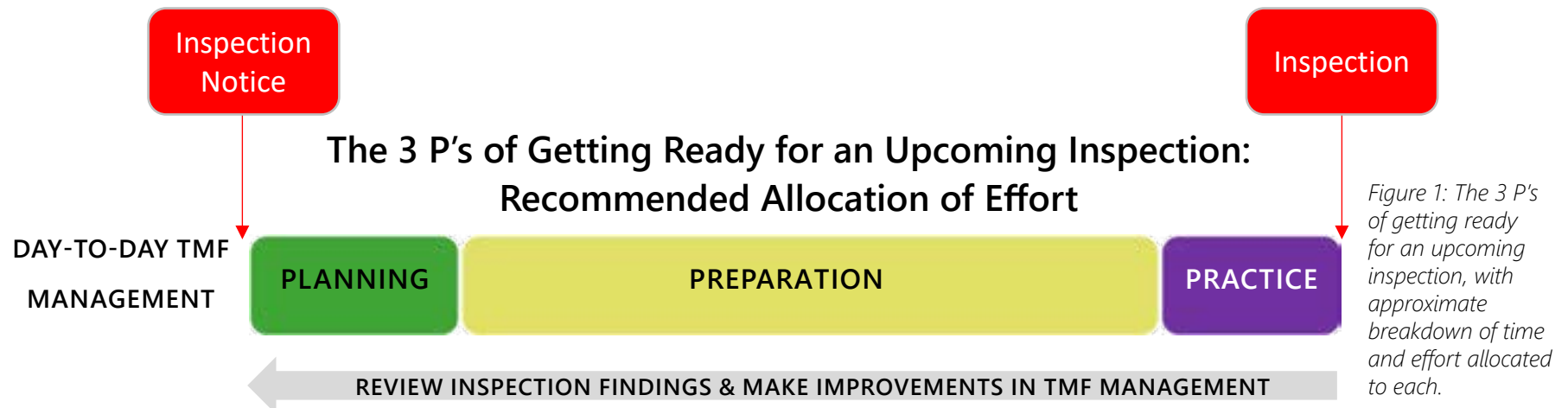
PHLEXGLOBAL'S TMF INSPECTION EXPERTS HAVE PUT TOGETHER THIS PRACTICAL GUIDE TO SPECIFICALLY ADDRESS THE TIME BETWEEN RECEIVING THE INSPECTION NOTICE AND THE INSPECTION ITSELF. WHILE NOT AN EXHAUSTIVE LIST, THESE BASIC STEPS SHOULD HELP YOU MAKE THE INSPECTION EASIER FOR ALL CONCERNED – REGARDLESS OF YOUR LEVEL OF PREPARATION.

Note: If you're feeling overwhelmed about an upcoming inspection even after reading this guide, [CONTACT](#) Phlexglobal's TMF readiness team for immediate support. Our global inspection-readiness team has extensive experience providing inspection expertise encompassing all major regulatory agencies - and can often be available at short notice.



Know the 3 P's of Getting Ready for an Inspection: Planning, Preparation, and Practice

In a word: Simplify. Based on lessons learned from supporting hundreds of TMF inspections, we have found that a simple framework (see Figure 1) helps teams focus time and resources in the most effective manner prior to an inspection.



First and foremost: Don't panic. While it may seem that there's no time to waste, rather than scramble from the start it is worth spending time up front to create an inspection plan (or review and update an existing one).

Take a deep breath and make sure your inspection plan includes some form of the following simple template:

PLANNING: Activity	Owner	Due Date	Status
Establish Inspection Team <ul style="list-style-type: none"> Internal: assign inspection lead plus internal representatives e.g. TMF staff, clin ops, QA, related departments/systems External: representatives from CROs and key vendors (if applicable) 			
Review & Summarize Inspection Notice <ul style="list-style-type: none"> Scope, timing, format e.g. remote or on-site or hybrid Questions for agency e.g. clarification of any points from the notice 			
Respond to Notice <ul style="list-style-type: none"> Provide official receipt of inspection notice, along with any questions for the agency e.g. whether they would like to receive online training on your eTMF system in advance, receive copies of your SOPs prior to the inspection, etc. 			
Create Inspection Project Plan <ul style="list-style-type: none"> Key milestones, roles & responsibilities, meeting cadence, communications requirements (i.e. who needs to be kept informed of what and when) 			

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BEST PRACTICE: Keep all documents related to the inspection in a single common site accessible to all stakeholders, with editing and access rights as appropriate.

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As shown in Figure 1 above, inspection preparation should form the bulk of your time and effort, with the team following the project plan developed in Step 1.

PREPARATION: Activity	Owner	Due Date	Status
<p>Generate Current TMF and Related Reports</p> <ul style="list-style-type: none"> • Utilize your eTMF to provide reports into quality, completeness, and timeliness (the overall “health” of the TMF) • Leverage CROs/vendors/other systems to fill in any reporting gaps • Assess what system access beyond the eTMF may be needed, e.g. Quality Management or Learning Management systems • Determine whether you need additional resources / expertise (internal or external) to get a better picture of TMF health 			
<p>Conduct Risk Assessment</p> <ul style="list-style-type: none"> • Review current picture of TMF health • Identify areas of greatest risk – common reasons for inspection findings include but are not limited to: <ol style="list-style-type: none"> 1. missing and/or misfiled documents 2. documents have not been uploaded to the system on an ongoing basis 3. TMF plan not established and followed 4. inability to demonstrate effective oversight of outsourced studies 5. lack of clear audit trails 6. insufficient training on systems and SOPs 			
<p>Develop & Implement Risk-Based Remediation Plan</p> <ul style="list-style-type: none"> • Determine what can be reasonably remedied in the time prior to the inspection (e.g. lack of timeliness cannot be resolved by its very nature) • Prioritize remediation by greatest risk and ability to remediate in the time allowed • Create, track, and continuously measure remediation KPIs against progress • Allocate internal resources to remediation efforts • Determine whether you have sufficient resources and expertise to conduct effective remediation • Implement risk-based remediation plan 			

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BEST PRACTICE:

Leverage your eTMF system (and/or your CROs), which should be able to provide the reports you need. If your system can't do this, or if you don't have an eTMF, Phlexglobal's inspection experts can provide a more accurate picture of your TMF with proven tools and processes such as TMF Heatmaps, Quality Review, and Risk Assessments - regardless of source system or format.

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BEST PRACTICE:

The more comprehensive your remediation plan is, the better. Even if you are unable to implement all the actions you've identified, the inspector(s) will appreciate that you have made the effort to identify areas of greatest risk and have a plan to remediate them.

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Now comes the time to put all that planning and preparation to work in an inspection dry run. A practice inspection helps your team – especially those who have not been through one before – better understand the unique demands and dynamics of a TMF inspection.

PRACTICE: Activity	Owner	Due Date	Status
<p>Map Out the Inspection Workflow</p> <ul style="list-style-type: none"> • Based on the inspection notice and latest communications with the regulatory agency, create an end-to-end inspection workflow including: <ol style="list-style-type: none"> 1. Draft schedule for the inspection, with primary and backup team members assigned to each (see next box) 2. Set up dedicated real-time internal communications channel (e.g. Teams/Slack) to handle requests during the inspection 3. Create and test inspection access to necessary systems and facilities (on-site but also remote if requested by the agency) 4. Determine internal communication schedule to all stakeholders e.g. arrival of inspectors, location, duration, conclusion of inspection 			
<p>Choose Your Inspection Team and “Inspector”</p> <ul style="list-style-type: none"> • Delineate primary and backup responsibilities including: <ol style="list-style-type: none"> 1. Internal contact for the inspector(s) 2. Subject Matter Experts (SMEs) e.g. clinical documentation, GCP, TMF Reference Model 3. CRO/vendor representatives 4. System training & support 5. IT support 6. Operations support 7. Have an internal TMF expert play the role of the inspector <i>(Note: Since this person may have responsibility during the actual inspection, consider bringing in an independent third party with inspection experience to play this role)</i> 			
<p>Conduct Practice Inspection</p> <ul style="list-style-type: none"> • Walk through the inspection workflow you’ve created, beginning with the arrival of the inspector or the beginning of the remote inspection • Assess how easy it is for the “inspector” to access necessary files and reports, get answers to questions, and assess the quality, completeness, and timeliness of the TMF • Incorporate feedback into the inspection workflow 			

CONCLUSION

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REMEMBER: Inspectors are people too – so make sure you and your team are prepared to make their job as easy as possible, with attention to supporting their needs during the inspection. The more prepared you are in all areas, the better the experience will be for everyone.

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The planning, preparation, and practice steps outlined here have been proven effective in actual inspections across numerous regulatory agencies. We hope you find this guide useful in simplifying and focusing your approach to an upcoming inspection.

Still feeling alarmed by an upcoming inspection? Want help assessing any inspection findings or just learn how to get ahead of the inspection-readiness curve? [CONTACT](#) a Phlexglobal TMF expert today. We are seeing in the industry a positive move towards better TMF health as part of a drive for better study quality.