READY ROOM

PREP GUIDE

GCP Inspection Readiness Timetable

INTRODUCTION

A clinical program is inspection-ready when the inspection team can deliver documentation to the inspector that tells a quality story about its execution. Thus, inspection readiness involves three tangible elements—documents, people, and logistics—as well as the intangible "story" that is expressed through TMF contents, consistency with the information presented in interviews, and even the efficiency with which that information is delivered.

How do you get ready to tell a quality story in an inspection?

Prepare with this practical step-by-step guide to inspection readiness.

At study start-up

Ensure your registration study will capture documentation that shows adherence to GCP by making these key decisions early.

- Develop a **TMF map** to plan where the team intends to file documents. Typically there is one primary CRO or sponsor repository where essential documents are stored, but regulatory submission documents, safety case reports and submissions, IMP shipment records, datasets, and analysis deliverables may be filed in other controlled locations. Define these locations up front to save time in filing and QC.
- Determine a process for maintaining an **updated study team list**, including names, organizations, roles, and start and stop dates. This list will be central to future TMF QC efforts.
- Determine the process for defining **study-specific training requirements** and tracking completion of **study-specific training assignments**. A tracker will aid in QC efforts so the team can address gaps quickly.
- Determine how the sponsor will demonstrate **oversight of vendors**, how oversight will be documented, and where those documents will be filed. Training, meetings, and metrics are standard oversight measures; ensure all meeting types are documented and use the TMF map to define which of the many TMF "meetings" sections will be used for each meeting type.
- Standardize **version and naming conventions** for TMF documents. Imagine you are looking at a list of 50 IRB submissions or 20 protocol versions. Standardized metadata can help users scan long lists of documents quickly to locate a particular version or see at a glance what's missing.
- Set up **trackers**. After an initial investment of time, trackers for recurring activities or frequently-up-versioned documents are valuable tools for QCing the Trial Master File. During the inspection, they facilitate speedy answers to inspection questions. Consider trackers for ICF versions, monitoring visits, study plans and versions, financial disclosures, regulatory authority submissions, IRB/IEC submissions, investigator letter distribution, EDC specification and release versions, clinical samples, IMP shipments and returns, temperature excursions, vendor contracts, and systems used to perform regulated tasks. If other systems can provide reports of these activities, consider a regular schedule for generating reports to be used in TMF QC efforts.
- Document **vendor, site monitor, and site selection criteria** before selecting these participants and retain documentation that shows that all met criteria and were explicitly approved. Inspectors are keen to verify that vendors, site monitors, and sites met objective criteria for selection.
- Maintain records of each potential site's passage through the "**site selection funnel.**" Years from now, the team should be able to give an inspector a clear account of the numbers of sites that were initially contacted; completed feasibility questionnaires; underwent site qualification visits; had site qualification visits waived; dropped out through lack of interest; and were approved or not approved.
- **Qualify vendors** per your SOPs and retain questionnaires and audit reports.
- Ensure applicable studies are filed on **clinicaltrials.gov** on time.
- Conduct "**TMF awareness**" training for team members to ensure that everyone understands the concept of a TMF as a collection of repositories containing all the documentation required to reconstruct the trial and to cover data and document integrity.
- Develop a **phone tree** for notification in the event of an unannounced inspection.

If you've started inspection readiness well after study start-up, it's not too late to catch up on most of the items on the list above.

Quarterly after start-up

Start a regular cadence of maintenance activities:

- **Update all trackers** and the unannounced inspection phone tree, if they are not being updated on an ongoing basis.
- Write a **storyboard** for every deviation or unusual issue that occurs during the study. Storyboards are high-level talking points that interviewees can use to rehearse how they would explain an issue to an inspector. See the Storyboards blog post on the Ready Room website for more information on storyboard content.
- Conduct a **quarterly TMF completeness review** against other authoritative sources of information, including the trackers. Ensure that all sections of the TMF are reviewed, not simply the primary TMF repository.

Approximately one year before the planned regulatory submission

Build the project plan that will take you through to inspection.

Download a free project plan template.

- Perform an **initial risk assessment** to develop a list of sites that are at high risk for inspection and sites that are at high risk for inspection findings. Criteria typically include high enrollment, compliance issues, and prior inspection findings, but don't forget to compare sites for deviations per patient; adverse events, SAEs, and SUSARs per patient; screen failure rates; and other study-specific measures, flagging sites that are unusually high or low in each measure compared to other sites.
- Perform a similar **assessment for vendors** that are at high risk for inspection and for inspection findings.
- **Adjust** audit plans, monitoring activities, and oversight measures based on risk assessments.
- Identify a **project manager** for inspection readiness activities. Ideally, this resource is someone in Clinical Operations, Quality Assurance, or Program Management who is familiar with the registration study or studies but also has enough free time to drive inspection activities forward.
- Develop an **inspection readiness project plan**, including activities, timelines, and resources required to prepare the team for the inspection. The plan should include audits, inspection readiness visits, remediation activities, storyboard development, logistics set-up, training, interview coaching, rehearsal, mock inspection, the submission date, and the expected inspection range (typically, a four- to six-month window starting 30 days after the regulatory submission). Download a free Microsoft Project inspection readiness project plan.
- **Identify a repository** to hold storyboards, training materials, inspection plans, meeting minutes, and other non-TMF documents related to the inspection.
- **Kick off the inspection readiness team** by reviewing the project plan and adjusting as needed.

Monthly, between finalization of the inspection readiness project plan and the first inspection

- **Meet with the inspection team** to review progress against plan and replan as needed.
- **Meet with senior management** to review progress against plan and ask for needed resources.
- If inspection readiness activities uncover significant quality issues, **develop a CAPA plan** to address the root cause of the issue according to your GCP CAPA SOP. This will help build the "quality story," demonstrating the company's responsiveness.

Nine months before the regulatory submission

Focus on the mock inspection and inspection-day logistics.

- Develop a **detailed inspection-day plan**, aligned with your inspection SOP, that includes identification of team members, roles and responsibilities, logistics for delivering requests, and set-up of inspection spaces. If your plan involves an inspection management system like Ready Room, contract with the system vendor.
- Select a mock inspector—ideally, a former agency inspector, or an auditor with extensive inspection experience—and **schedule a mock inspection**.
- Ensure **contracts with vendors** include provisions for inspection support, re-negotiating as needed.
- Schedule supportive **inspection readiness visits** at high-risk sites and vendors.

Six months before the regulatory submission

Plan third-party inspection activities and other logistics.

- **Reach out to high-risk clinical sites and vendors** to gauge what kind of support they require or will permit for an inspection. Some sites welcome sponsor attendance, while others will restrict communications to a daily debrief. Many vendors do not permit sponsors on-site for inspections, but Contract Research Organizations may welcome sponsor support.
- Develop a **plan for supporting third-party inspections**, incorporating the feedback received above.
- Hold the **first training and run-through of inspection logistics** involving the core inspection-day team members. Start slowly with a walk-through of a single inspection request, including communication of the request, fulfillment, QC, host review, and delivery to the inspector. Over the next few months, work up to overlapping requests and more complex requests.
- **Audit the internal team list** against job descriptions and curriculum vitae, remediating gaps where possible.
- **Audit general training records vs. requirements** for internal team members, remediating gaps where possible.

Three months before the regulatory submission

Start rehearsing.

- Schedule **monthly logistics practice** from now until the regulatory submission is complete.
- Train **potential interviewees** on useful frameworks for answering inspection questions using the storyboards.
- Prepare a short **storyboard for each high-risk site**, including details of any PI changes, key milestone dates, the start and stop dates for each sub-investigator, monitoring frequency compared to the monitoring plan, protocol deviation trends compared to other sites, and compliance issues and their resolutions. This will help team members prepare to support any clinical site inspections in addition to providing a useful cheat sheet for site questions during an HQ inspection.

At the time of regulatory submission

Congratulate the team and celebrate your accomplishment! Then:

- **Reach out** to all clinical sites and vendors and remind them notify you of any announced or surprise inspections.
- Provide **high-level training** to entire company on how to handle an inspection announcement or unexpected arrival of an inspector.
- Develop a **short introductory presentation** for the inspector highlighting the program history and short overview presentations for each function, including the organizational structure, key responsibilities, and key SOPs.
- **Increase frequency of practice for** request fulfillment logistics and interview questions to every other week.
- **Conduct supportive site and vendor inspection readiness visits**. Timing may vary, depending on the number of sites and vendors, but ideally these visits occur close to the actual inspection.

Approximately one month after submission

- **Hold the mock inspection**. Some teams prefer to conduct a mock much earlier in the process, or hold multiple mocks. An early mock inspection can conflict with submission activities and is of little use if the team is not fully prepared to fulfill requests and answer questions. On the other hand, early feedback gives the team time to remediate any findings. A mock inspection held as close as possible to the real inspection eliminates the gap in time that leads to loss of skills.
- **Adjust** presentations and the inspection-day plan based on learnings from the mock.
- If possible, **remediate** any compliance issues and documentation gaps identified during the mock. If it's not possible, develop storyboards and/or retrain interviewees to highlight the "quality story" of any compliance concern.

After formal notification of the inspection

Take a deep breath. You've prepared well for this. Now:

- **Notify** internal and external stakeholders, including vendors and clinical site personnel who may be called upon to answer questions during the inspection. If your office is in a building that is managed by an external party, notify facilities management and/or receptionists that may be on duty when the inspector arrives.
- **Make travel arrangements** for any team members who will be traveling to the inspection.
- Ensure that any **remote attendees have access** to solutions being used for logistics.
- **Update** the inspection-day plan with inspection-specific roles and responsibilities, including back-ups.
- **Set up rooms** according to the inspection-day plan.
- Plan **food orders** for the inspection team.
- **Print** the SOP inventory, key SOPs, protocols, and study-specific plans for quick distribution to the inspector.
- **Print signs** reminding personnel that an inspection is in progress.
- If desired, **print** trackers and other reference documents for the inspection team.
- **Redact** financials from key contracts so they can be provided to the inspector quickly.
- Conduct **final run-throughs** with back-up personnel.
- Conduct **final coaching sessions** with potential interviewees.

The day before the inspection

- **Check the room set-up** against the inspection plan.
- **Stock** the inspection room, ready room, and other consultation rooms with water, office supplies, and snacks.
- **Hang signs**.
- **Send a final notification** to all internal and external stakeholders.
- **Communicate the start time** to the inspection team.

NEXT STEPS

Get ready to tell a quality story with each inspection with complete documentation, well-prepared interviewees, and an efficient system to deliver information to the inspector.

Download a free Project Plan Template at ReadyRoom.net.

Review our Blog for helpful inspection readiness strategies.

Visit ReadyRoom.net to see how our powerful yet easy-to-use platform will help you prepare for your next inspection.