TRIAL INTERACTIVE

» CHECKLIST

15 WAYS
To Avoid Inspection Findings

CHECKLIST

- [ ] 1 Go paperless to ensure all TMF records are maintained electronically.
- [ ] 2 Conduct regular internal audits.
- [ ] 3 Train teams on your system's best practices and use cases.
- [ ] 4 Attend a TMF Inspection Readiness workshop to stay current on industry best practices and know what to expect from an inspection.
- [ ] 5 Utilize study owner services to supplement your in-house team.
- [ ] 6 Complete periodic reviews of TMFs.
- [ ] 7 Create standard operating procedures for trial-related activities.
- [ ] 8 Implement robust quality management solutions.
- [ ] 9 Obtain TMF expert certification through training.
- [ ] 10 Conduct and document investigator meetings in a 21 CFR Part 11 compliant system.
- [ ] 11 Use a clinical trial management system that integrates with the eTMF.
- [ ] 12 Centralize investigative site file management and monitoring.
- [ ] 13 Accelerate site activation.
- [ ] 14 Implement a solution for clinical study document collaboration.
- [ ] 15 Centralize training requirements for all studies through an LMS with real-time tracking.

15 WAYS
To Avoid Inspection Findings

TRIAL INTERACTIVE

1 ☐ Go paperless to ensure all TMF records are maintained electronically.

WHY IT MATTERS

Going paperless ensures that all records are easily accessible remotely and are retrievable and searchable in real time.

HOW IT PREVENTS INSPECTION FINDINGS

With a contemporaneous TMF, your TMF remains inspection ready instead of requiring active preparation ahead of inspections.

HOW TI'S PRODUCT HELPS

TI eTMF keeps all of your TMF records organized, accessible, visible, and controlled in real-time across all of your studies with reports and dashboards to monitor TMF health.

2 ☐ Conduct regular internal audits.

WHY IT MATTERS

An internal audit with a stronger GCP focus will assess procedures as well as the essential records expected to be reviewed during a GCP inspection. Mock TMF audits help identify and address potential compliance issues.

HOW IT PREVENTS INSPECTION FINDINGS

Allows companies to proactively address any issues before they become problems during an inspection.

HOW TI'S PRODUCT HELPS

TI's TMF review services can help you conduct effective internal audits.

3 ☐ Train teams on your system's best practices and use cases.

WHY IT MATTERS

Ensures that all trial-related activities are conducted in compliance with regulations.

HOW IT PREVENTS INSPECTION FINDINGS

Helps prevent non-compliance issues during inspections.

HOW TI'S PRODUCT HELPS

As part of our TMF Services, we provide best practices for using TI's systems, as well as use cases to support the training process.

4 ☐ Attend a TMF Inspection Readiness workshop to stay current on industry best practices and know what to expect from an inspection.

WHY IT MATTERS

Ensure that your organization's TMF inspection preparation practices are up-to-date and compliant.

HOW IT PREVENTS INSPECTION FINDINGS

Helps prepare for a pending inspection and prevents non-compliance issues during inspections.

HOW TI'S PRODUCT HELPS

TI's TMF workshops provide comprehensive training on the latest industry best practices and trends around GCP inspections.

5 ☐ Utilize study owner services to supplement your in-house team.

WHY IT MATTERS

Ensure that your organization has the necessary personnel and expertise to maintain a compliant TMF.

HOW IT PREVENTS INSPECTION FINDINGS

Helps prevent non-compliance issues during inspections.

HOW TI'S PRODUCT HELPS

TI's Study Owner Services provide experienced, qualified staff to supplement your in-house team.

6 ☐ Complete periodic reviews of TMFs.

WHY IT MATTERS

Periodic TMF quality reviews are massively important to avoiding inspection findings as they ensure ongoing TMF inspection readiness and a high-quality TMF.

HOW IT PREVENTS INSPECTION FINDINGS

Helps prevent findings related to TMF records during inspections.

HOW TI'S PRODUCT HELPS

TI's independent internal quality team is dedicated to TMF reviews, TMF health assessments, and inspection readiness reviews.

7 ☐ Create standard operating procedures for trial-related activities.

WHY IT MATTERS

Ensures consistency and compliance in all study-related activities and streamlines change management.

HOW IT PREVENTS INSPECTION FINDINGS

Helps prevent non-compliance issues during inspections.

HOW TI'S PRODUCT HELPS

TI's SOP development service can help you create effective, compliant SOPs. It helps you navigate the complexity of change management when new SOPs are needed for new processes.

8 ☐ Implement robust quality management solutions.

WHY IT MATTERS

Quality assurance teams can manage standard operating procedures, policies, guidelines, and any other records from approved frameworks for business processes as required by the quality management system.

HOW IT PREVENTS INSPECTION FINDINGS

Helps internal QA identify and address any potential compliance issues against a set of policies and procedures before they become problems during an inspection.

HOW TI'S PRODUCT HELPS

TI's configurable and connected Quality Management Solutions securely track and manage incidents, investigations, compliance documents and processes, and more to ensure compliance with regulations. We also help by tracking and overseeing your Quality Management System.

9 ☐ Obtain TMF expert certification through training.

WHY IT MATTERS
Ensures that your organization's TMF team members have the necessary knowledge and skills.

HOW IT PREVENTS INSPECTION FINDINGS
Helps prevent non-compliance issues during inspections.

HOW TI'S PRODUCT HELPS
TI's TMF University is the only accredited TMF University in the world and offers expert certified training.

10 ☐ Conduct and document investigator meetings in a 21 CFR Part 11 compliant system.

WHY IT MATTERS
Train investigators on clinical trial protocols and study records so they can prepare and carry out the protocol during clinical research. If your training is documented and signed with 21 CFR Part 11 e-signatures, findings can be prevented.

HOW IT PREVENTS INSPECTION FINDINGS
Late investigator training and missing qualifications are common inspection findings. By sharing data across training systems, you can easily track, validate and report completed participation.

HOW TI'S PRODUCT HELPS
TI Investigator Meetings improve training oversight and automatically file training completion certifications to the LMS/eTMF to easily prove compliance.

11 ☐ Use a clinical trial management system that integrates with the eTMF.

WHY IT MATTERS
Helps track and manage study data and timelines effectively.

HOW IT PREVENTS INSPECTION FINDINGS
Helps prevent issues related to data management and timelines during inspections.

HOW TI'S PRODUCT HELPS
TI CTMS enables a single source of truth across the entire life cycle, providing transparency into Trial Interactive solutions and any sponsor or CRO systems of record.

12 ☐ Centralize investigative site file management and monitoring.

WHY IT MATTERS
The ability to conduct remote site monitoring with paperless site file management helps CRAs work more efficiently and meet regulatory requirements.

HOW IT PREVENTS INSPECTION FINDINGS
Maintain digital site files that update in real time in one central location that supports inspection readiness.

HOW TI'S PRODUCT HELPS
TI's eISF reduces administration and improves speed and compliance for site personnel.

13 ☐ Accelerate site activation.

WHY IT MATTERS

Site activation is a highly regulated process. You need ways to efficiently collect the required records from sites, review and approve the collected records, and submit packages to regulatory authorities.

HOW IT PREVENTS INSPECTION FINDINGS

Reduces risk of noncompliance by using a study start up tool that shows oversight, which is an important part of inspections, and helps you reach drug approval faster.

HOW TI'S PRODUCT HELPS

TI's Study Start-Up solution accelerates site activation with process automation, obstacle mitigation, timeline projection, and simplified regulatory submission.

14 ☐ Implement a solution for clinical study document collaboration.

WHY IT MATTERS

Centralize collaborative authoring and approval processes for your clinical study records in an FDA 21 CFR Part 11 compliant system.

HOW IT PREVENTS INSPECTION FINDINGS

Helps reduce risk of inspection findings by aligning document work streams with regulatory compliance practices for document authoring, approval, control, and related training. It also adheres to FDA requirements for electronic records and signatures, 21 CFR Part 11.

HOW TI'S PRODUCT HELPS

It also adheres to FDA requirements for electronic records and signatures, 21 CFR Part 11.

15 ☐ Centralize training requirements for all studies through an LMS with real-time tracking.

WHY IT MATTERS

Ensure that all study-related training at site level are conducted and documented in compliance with regulations.

HOW IT PREVENTS INSPECTION FINDINGS

Helps prevent non-compliance issues during inspections.

HOW TI'S PRODUCT HELPS

TI's Site Training provides a regulatory compliant system to track training on regulatory requirements and best practices for site staff.