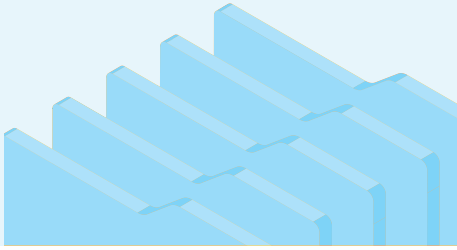
Archiving Checklist

This checklist is designed to ensure comprehensive preparation and implementation for eTMF archiving. It integrates industry best practices and regulatory requirements to guide the archiving process from planning to post-archival maintenance. Use as a guide to maintain compliance, data integrity, and long-term accessibility.



1. Planning and Preparation

1.1 Define Archival Objectives

- **Establish Archive Purposes and Scopes**
  - Regulatory Compliance
    - *Ensure documentation is archived to meet ICH-GCP, EMA, FDA 21 CFR Part 11*
    - *Other local regulations*
    - *Ensure documentation follows ALCOA+ principles*
  - Long-Term Data Retention: Archiving records for the legally required period, often 25+ years
  - Inspection Readiness: Guarantee that archived documents are structured and accessible to facilitate regulatory inspections.
  - Data Preservation: Protect against technological obsolescence by maintaining accessible data formats and metadata
  - Data Security and Integrity: Maintain secure and tamper-proof records for future audits or reviews.

1.2 Establish a Detailed Archival Plan

- **Regulatory Requirements:**
  - ICH GCP E6(R2): Specifies the retention of records in a way that ensures completeness and accessibility.
  - FDA 21 CFR Part 11: Governs the security and electronic signatures needed for eTMF systems
  - EMA Guidelines: Emphasizes traceability, accessibility, and audit trails for TMF documents
- **Clearly Laid out SOPS:**
  - TMF Structure SOP: Defining how documents are indexed and organized according to the TMF Reference Model
  - Archival Process SOP: Steps for preparing documents, conducting quality checks, and transferring documents into the archival system.
  - Access Control SOP: Procedures for managing permissions and maintaining data security during and after archiving.
  - Inspection Readiness SOP: Processes ensuring that the archived eTMF is always ready for audits and inspections
    - *Ensuring your data retention policies are aligned with regulatory requirements*
    - *Ensure your audit trail is accessible, and legible in case of inspection*

2. Data Organization and Validation

2.1 Ensure Metadata Completeness

- **Required Metadata Fields:**
  - TMF ID: Identifies the section and artifact.
  - Study Information: Includes study ID, site number, and country
  - Document Date and status: Essential for data integrity and tracking document versions
- **Data Validation Procedures:**
  - Use automated tools to verify metadata consistency
  - Cross-check against the TMF Reference Model for completeness

2.2 Check for Gaps in Documentation

- **Document Cross-Referencing:**
  - Conduct a thorough audit comparing the TMF inventory against the Expected Document List or predefined document index.
- **Gap Resolution Process:**
  - Identify and flag missing documents and initiate corrective actions such as obtaining or re-generating required files
- **Document Storage:**
  - Data should be stored within multiple cloud locations. A minimum of two different geographical locations, with the option of a third if required.

3. Archival System Requirements

3.1 Select a Validated eTMF Archival System

- **System Features:**
  - Document Locking: Ensures documents are uneditable once archived
  - Audit Trails: Maintain logs for each document action (upload, modification, access)
  - Encryption: Encrypt data at rest and in transit to protect against unauthorized access
  - Validation Checks
    - *Verify the the system is compliant with 21 CFR Part 11 Requirements, including secure electronic signatures*
    - *Ensure the system meets other validation standards, such as HITRUST and ISO 27001*
  - Formatting Requirements:
    - *Ensure documents meet formatting requirements such as PDF/A and CSV*
    - *Ensure archival solution can guarantee long-term legibility of digital content and reserve all common file formats*
  - Inspector Access: Ensure archival system can provide Inspectors access to the archive in the original eTMF presentation within a reasonable span of time
    - *The content of the clinical trial master file shall be archived in a way that ensures that it is readily available and accessible, upon request, to the competent authorities.*

4. Quality Control and Compliance Checks

4.1 Conduct Regular Audits

- **Audit Focus Areas:**
  - Document Integrity: Confirm that documents are complete and correctly indexed
  - Metadata Accuracy: Validate metadata for compliance with the TMF Reference Model and regulatory requirements
  - Data Accessibility: Test system capabilities for retrieving and viewing archived documents
- **Quality Assurance Procedures:**
  - Schedule periodic reviews and audits, utilizing automated tools for consistency and accuracy
  - Ongoing data integrity checks throughout the lifecycle of the data
  - Quickly identify data corruption or loss

For more information on audit preparedness, download our guide on effective auditing practices.

5. Final Archival Execution

5.1 Document the Archival Process

- **Process Documentation:**
  - Include details like the person responsible, timestamps, and approval logs for each archival activity
- **Record any deviations from the SOP and corrective actions taken**

5.2 Secure Storage and Retention

- **Data Retention Strategy:**
  - Ensure compliance with minimum storage periods (e.g., 25 years as per EMA guidance)
  - Vendor Assessment: If using external archives, verify vendor compliance and quality assurance processes

6. Post-Archival Monitoring and Maintenance

6.1 Set Up Periodic Review and Maintenance Plans

- **Data Integrity Reviews:**
  - Schedule regular checks to ensure documents remain accessible and audit trails are intact
- **System Updates:**
  - Monitor technology trends to anticipate necessary updates or data migrations

6.2 Establish a Continuous Training Program

- **Training Focus Areas:**
  - eTMF system use, regulatory requirements, and updates on archival processes
- **Cross-functional training for stakeholders to ensure compliance with SOPs**

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This detailed checklist provides a comprehensive guide for eTMF archiving, ensuring compliance, data security, and inspection readiness. It integrates best practices from multiple sources to help you prepare for and maintain a fully compliant eTMF archive.

If you're looking for more support, get in touch to find out how Trial Interactive can support your organization's eTMF archiving practice.