

Agatha Remote ISF



Empower Sites with Remote Monitoring

Agatha Remote Monitoring is a complete, ready-to-use, pre-validated cloud-based application that allows clinical sites to securely upload source files to a 21 CFR Part 11 and HIPAA compliant application.

It enables monitors and inspectors to review the source files, make notes, and complete their monitoring tasks. The application also allows for the creation and assignment of tasks for site administrators, including notifications and tracking.

Improve your Monitoring Processes with Agatha

Manage All Sites & Studies

Maintain a complete, pre-validated system with all sites and study documentation, following the TMF Reference Model.

Configured for You

Enforce and document work processes with review and approval steps with complete, configurable workflows.

Inspection Ready

Your Site Binder is up-to-date at all times and ready for sponsors, CROs, and, most importantly, auditors and inspectors.

Ensure Full Compliance

Maintain compliance with regulatory requirements including HIPAA, 21 CFR Part 11, and related regulations.

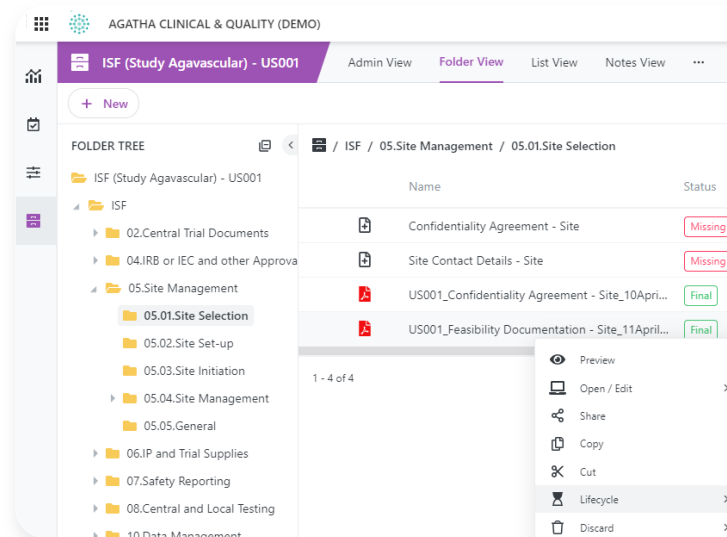
Features

Easy Site & Study Set-Up

Create separate, secure areas for each site to manage its documentation. Each site and study comes with a complete set of placeholders for expected documents. Use configurable auto naming to enable naming conventions aligned to study standards.

Access Workspaces and Tasks in the Dashboard

View all your workspaces for each site in the dashboard and quickly see and access tasks assigned to you. Use the configurable views to inspect, verify, and identify gaps in the eBinder at any time. Create views and reports across workspaces and export results to Excel for dashboard reports.



Share Binder Contents

Share binder (investigator site files, or ISF) contents between monitors, sites, and sponsors to enable remote document review and quality checks. Use forms to share monitor notes and assign tasks to site personnel.

Manage Quality Checks & Compliance

Designate documents for the quality check process and track the quality review using custom views. Leverage workflows with electronic signatures to meet all compliance requirements and set up automated workflows to move final documents to the Master TMF.

Advanced Forms

Work with ready-to-use standard forms and processes, or adapt them to support your needs. Forms include rich text fields that allow the addition of images and formatted text. Use the form designer to update the look and feel of your forms.

A single multi-part form supports all steps. Reviews, approvals, and assignments for actions are also built-in.

Preview, Edit, and Annotate

Review and edit Word, Excel, and PowerPoint documents directly in the application (does not require an Office license). Annotate PDF, Office documents, and images with a simultaneous review of documents.

Plus:

Extended Template Sets

Collect feedback from sites with Post Market Surveys and collect consent documents with Informed Consent.

Advanced Policy And Access Management

Manage policies, associated roles, and access controls easily.

Advanced Integration Toolkit

Use Agatha's Rest API to allow applications to upload or export items from Agatha (includes documentation & sample code).

Secure Cloud

Agatha Applications are cloud-based, hosted in Agatha's highly secure, highly reliant, high-performance, compliant, cloud environment.

Three Editions:

Standard, Extended, and Premium

Some features are only available in Extended or Premium editions.

