

Agatha Clinical (eTMF)



Agatha Clinical is an electronic master file (eTMF) application that connects all trial participants and processes in a single, cloud-based application.

Leveraging the TMF Reference Model, Agatha Clinical includes standard templates to help you get up and running quickly, reducing ramp-up time to hours and days instead of weeks or months.

With configurable actions that allow you to capture processes in end-to-end workflows, Agatha Clinical provides a tool to enforce best practices, document all activities, and connect all study participants. The result is faster start-up, more consistent processes, and complete trial documentation ready for inspection at any time.

Benefits

Inspection Ready

Your Trial Master File is up-to-date at all times and ready for sponsors, CROs, sites, and most importantly, auditors and inspectors.

Fully Automated & Efficient

Document creation, review, and approvals are fully automated to ensure efficient and effective execution of all trial activities.

Connected to Everyone

Every authorized trial participant — sponsors, CROs, and sites — can connect to the eTMF without the need for cumbersome IT processes.

Fully Compliant

Agatha Clinical is built around the industry-standard eTMF reference model and ensures that every document expected in the file is present.

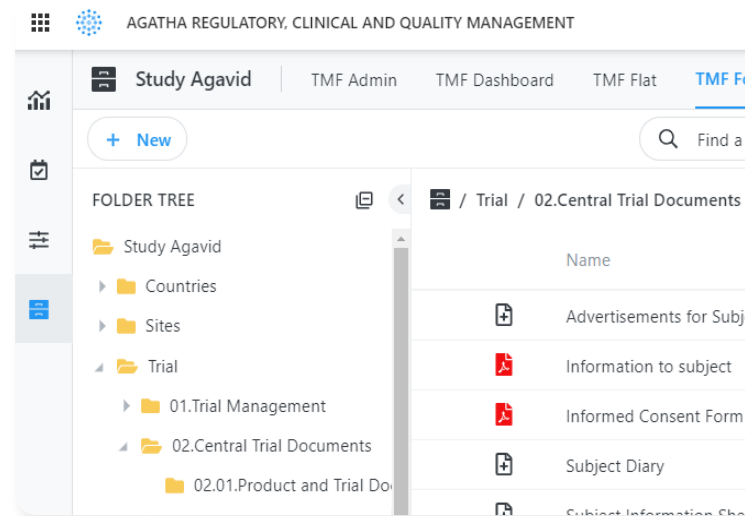
Features

Create and Manage Sites & Documents

Create and manage trial sites based on the TMF Framework. Combine documents and forms to accelerate study processes.

Access Workspaces and Tasks in the Dashboard

View all your workspaces for each clinical trial 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 expected eTMF contract at any time.



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 in a process. Reviews, approvals, and assignments for actions are also built-in.

Author and Edit Documents Directly in the App

Co-Author and edit Microsoft Word, Excel, and PowerPoint files directly in the application, without the need for a Microsoft Office license. Annotate PDF, Office documents, and images with a simultaneous review of documents.

Ensure Quality Checks Are Completed

Designate documents for the quality check process and track the quality review using custom views.

Complete Metrics and Reporting

Get all the reporting you need with built-in dashboards and reports, and export reports for external reporting requirements. You can also create views and reports across workspaces and export results to Excel for dashboard reports.

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.

