Agatha Clinical

Ready-to-Use eTMF Application for Clinical Trial Management

Agatha Clinical is a powerful application that connects Clinical Trial sponsors, CRO staff, and site resources with automated processes for creating, managing, and tracking the Trial Master File (TMF).

Clinical trials are complex projects, with multiple participants in multiple locations and different roles. That complexity is amplified by the process itself, which includes extensive document creation, review, and approval activities. To make it even more challenging, access to systems is often complicated by cumbersome IT processes, including the use of private networks.

Agatha Clinical provides an immediately-available solution that connects all trial participants and processes in a single, cloud-based application. Leveraging the TMF Reference Model, Agatha Clinical includes standard templates that ensure you get up and running quickly, reducing ramp up time to hours instead of weeks.

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.

Key Capabilities

- Build new trial sites instantly, based on the TMF Reference Model.
- Determine “what’s missing” - identify gaps in expected eTMF content at any time.
- Automate review, approval, and signature tasks with configurable workflows.
- Ensure availability of all trial documents, in one location, with baked in quality review processes.

Agatha Clinical

Benefits

- Fully Standard and Compliant: Meets all 21 CFR Part 11 requirements and is built around the industry-standard eTMF reference model and ensures that every document expected in the file is present.
- Connects everyone: Every authorized trial participant -- sponsors, CROs, and site --- can connect to the cloud-based TMF without the need for cumbersome IT approval or connection processes.
- Automates processes: Document creation, review, and approvals are fully automated and based on best practices to ensure efficient and effective execution of all trial activities.
- Inspection ready: Your TMF is up-to-date at all times for sponsors, CROs, sites, and auditors.