

Agatha Remote Monitoring

Remote Monitoring and Quality Management for Clinical Trial Sites



Sponsors and CROs are required to conduct regular reviews of clinical sites to monitor the execution of a trial and the integrity of the trial data. The traditional approach to monitoring and quality management of sites has been to send a Clinical Research Associate (CRA) to visit the physical office of each site. The travel required is expensive, time-consuming, and sometimes impossible.

Agatha provides a remote monitoring application that eliminates the need to conduct on-site monitoring visits. It ensures monitoring activities can continue even when travel is impossible, such as during the COVID-19 emergency, and can eliminate travel costs completely.

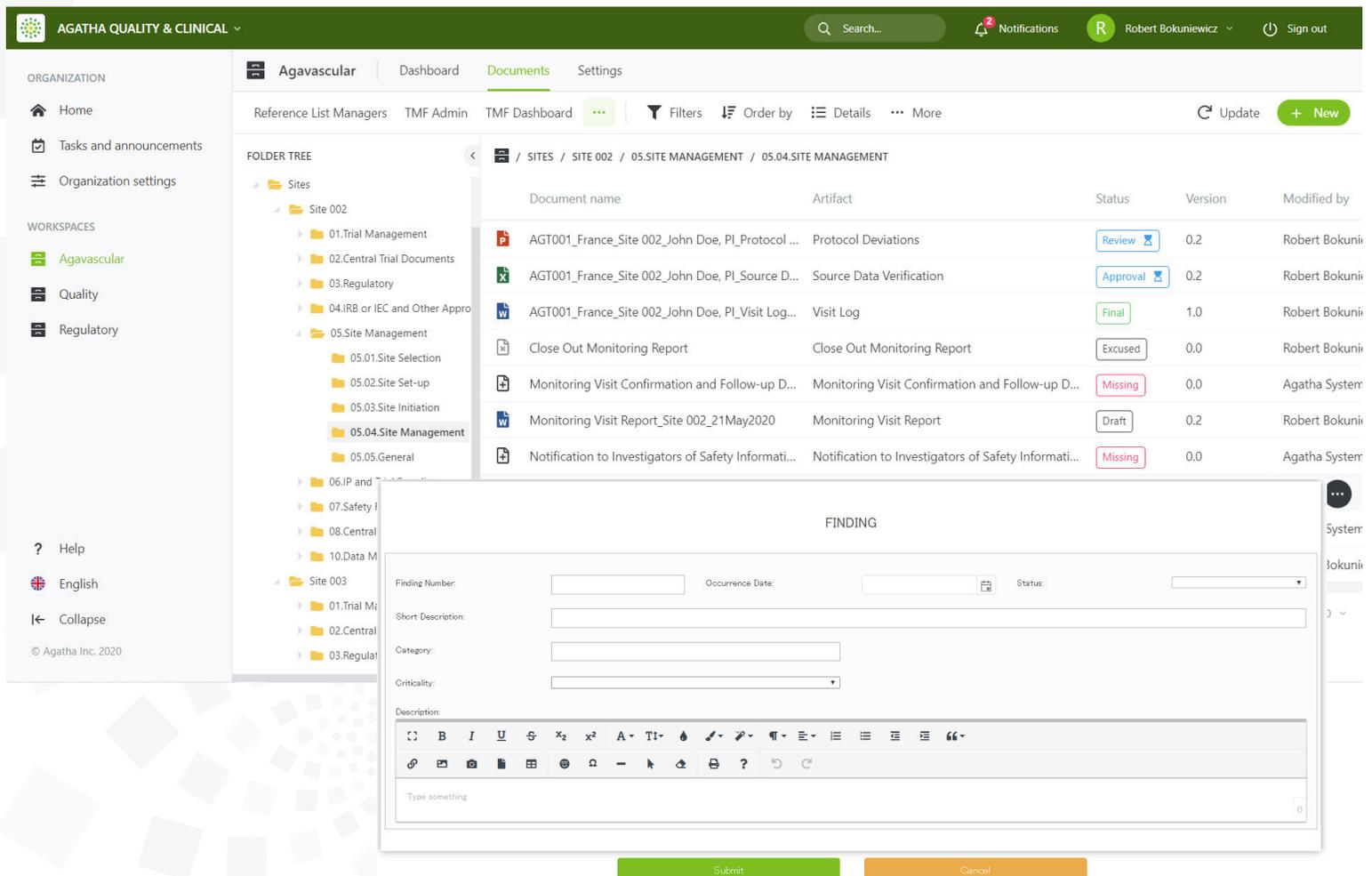
Agatha Remote Monitoring is a complete, ready-to-use, pre-validated cloud-based application that allows clinical sites to securely upload source files to a 21 CFR Part 11 and HIPAA compliant application. It enables monitors and inspectors to review the source files, make notes, and complete their monitoring tasks. The application also allows for the creation and assignment of tasks for site administrators, including notifications and tracking.

Key Capabilities

- Create separate, secure areas for each Site to manage their documentation
- Set up each new site and study with a complete set of placeholders for expected documents
- Configurable auto naming allows naming conventions aligned to study standards
- Share binder (investigator site files, or ISF) contents between monitors, sites, and sponsors to enable remote document review and quality check
- Use forms to share monitor notes and to assign tasks to site personnel
- Leverage workflows with electronic signatures to meet all compliance requirements
- Create and assign tasks for site administrators, including notifications and tracking
- Automatically move final documents to the Master TMF using automated

Remote Monitoring Benefits

- **Multi-Site Support:** Every site has its own secure space; Monitors can access multiple sites through a consistent interface.
- **Ready-to-Use.** A complete, pre-validated system in the cloud, ready for you to start using within days.
- **Follows Best Practices:** Leverages the TMF Foundations Model to embed best practices
- **Consistent.** Enforces and documents work processes with review and approval steps with complete, configurable workflows.
- **Compliant:** Full compliance with regulatory requirements including HIPAA and 21 CFR Part 11.
- **Secure:** Agatha ISF is hosted in a highly secure, compliant cloud service.



The screenshot displays the Agatha Quality & Clinical software interface. The top navigation bar includes the Agatha logo, a search bar, notifications, and user information (Robert Bokuniewicz). The main dashboard shows a folder tree on the left with categories like 'Sites', '01.Trial Management', and '05.Site Management'. The central area displays a table of documents with columns for Document name, Artifact, Status, Version, and Modified by. A 'FINDING' modal form is open in the foreground, containing fields for Finding Number, Occurrence Date, Status, Short Description, Category, Criticality, and a rich text editor for the Description. The form has 'Submit' and 'Cancel' buttons at the bottom.

Document name	Artifact	Status	Version	Modified by
AGT001_France_Site 002_John Doe, PI_Protocol ...	Protocol Deviations	Review	0.2	Robert Bokuni
AGT001_France_Site 002_John Doe, PI_Source D...	Source Data Verification	Approval	0.2	Robert Bokuni
AGT001_France_Site 002_John Doe, PI_Visit Log...	Visit Log	Final	1.0	Robert Bokuni
Close Out Monitoring Report	Close Out Monitoring Report	Excused	0.0	Robert Bokuni
Monitoring Visit Confirmation and Follow-up D...	Monitoring Visit Confirmation and Follow-up D...	Missing	0.0	Agatha System
Monitoring Visit Report_Site 002_21May2020	Monitoring Visit Report	Draft	0.2	Robert Bokuni
Notification to Investigators of Safety Informati...	Notification to Investigators of Safety Informati...	Missing	0.0	Agatha System