Agatha

Your RFP Template for Selecting an eTMF Application

The processes around creating, gathering, and managing the files and documents related to a clinical trial are complicated and daunting. There are hundreds of types of documents, some based on specific forms, and these documents are authored by different people in different locations. Many go through specific review and approval processes, and many include signatures. They all need to be authentic versions of original documents and protected from unauthorized access.

An electronic trial master file (eTMF) application automates collecting documents from clinical sites, investigators, and the rest of the study team. It also ensures these documents adhere to regulatory rules and compliance requirements.

As you embark on your project to select the best eTMF application for your organization, it's critical to understand the features and functionalities you need to support your specific requirements.

We developed this RFP guide to help you do just that. Use this template as a guide - add things we may have missed and take out what doesn't apply to your situation.

And if you have any questions, please feel free to reach out. We're here to help.

[Company Name]

Request for Proposal for a for an **eTMF System for Managing Trial Master File Content and Processes**

Sections

1. Introduction

<Company> is a **[describe company].**

<Company> is seeking to implement a system for managing Trial Master File content and processes in order to **[describe high level goal]**.

The purpose of the Request for Proposal is to gather proposals from alternative solutions for managing Trial Master File content and processes in order to compare and contrast the capabilities of the systems, the qualifications of the vendors and the cost of the solution.

2. Scope

The scope of this RFP includes an eTMF system for managing Trial Master File content and processes as well as the services to implement the system, train users, ensure validation and begin production use. It also includes on-going support services for the duration of the use of the system.

The scope of use for the system is to manage the TMF content for approximately **[number of trials]** clinical trials. There will be approximately **[number of users]** of the system. This includes administrators, individuals responsible for creating and reviewing TMF content.

The system will be used by users in the following locations:

- [Location 1]
- [Location 2]

The relevant schedule for the activities described in this proposal are for the work to start on or around **[date]** and for the system to be in production use by **[date].**

3. Submission of Responses and Evaluation

Responses to the RFP are due no later than close of business on **[date].** They should be delivered as PDF documents in a format of the responders choosing, but including all information requested in this RFP.

Submissions will be evaluated according to the following criteria:

- Experience and qualifications of the vendor
- The functional match with the requirements documented in the RFP
- The cost of the solution over a three-year period
- The schedule for the implementation of the system
- The strength of the references provided by the vendor

4. Vendor Description

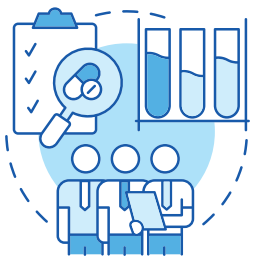
In your proposal, please provide a description of your company, including

- Location
- Years in Business
- Size of business in employees (full time and contractor, as two numbers)
- Where development is done
- Years in business
- Years the proposed solution has been available
- Approximate number of customers of the proposed system

5. Software Solution Description

In your proposal, please provide a description of your proposed software solution, including

- The basic functionality and capabilities of the system
- How the system addresses relevant regulatory requirements
- How the system is different than alternative solutions
- The required hardware and software environment
- Whether it is cloud-based or on premise
- Of cloud-based, whether it is multi-tenant
- If cloud-based, where and by whom it is hosted
- Who will be responsible for managing the system
- Where the software is developed
- Where the support organization is located



6. Vendor Description

In your proposal, please provide a description of your proposed approach to implementing the proposed solution and providing associated services, including

- Location
- The planned schedule for the implementation project
- The steps or phases of the implementation plan
- The date the system will be available for production use
- The resources (people) who will be assigned to the implementation
- The time and resources that will be required by our team members
- How you will communicate progress to us on the project
- How the system will be validated
- How you will train users
- How you will support us after the system is in production use

7. System Costs

In your proposal, please provide a listing of all the associated costs of the system, including

- Initial cost for the software
- Recurring annual cost of the software
- The costs for the proposed services
- How your services will be billed: fixed price, hourly or other
- Where the support organization is located

APPENDIX A

Please provide an analysis of your systems capabilities based on the attached requirements matrix.

Appendix A: Analysis of Application Requirements

Please provide an analysis of your proposed solutions capabilities based on the requirements matrix below.

Use the following system to rate each requirement in comparison with your proposed solution:

1. Completely addressed

2. Partially Addresses

3. Addressed Differently

4. Not Addressed

System Requirements	Rating	How is the requirement addressed in your solution?
The solution is provided as a cloud-based service		
The system is a Multi-Tenant application, that is, the same core code is used by multiple customers		
The system is offered on an annual subscription basis, with payments due annually		
The system can be accessed by any user via a browser		
Provide different standard roles for individuals and groups		
Include disaster recovery, ensure business access within standard timeframes and include regular backups and administration		
The service includes disaster recovery, ensures business continuity within standard timeframes and includes regular backups and system administration		

Document-Related Requirements	Rating	How is the requirement addressed in your solution?
The system should allow new trials to be created based on the TMF Reference Model		
Track all expected items and easily identify missing items		
Create standard documents from templates		
Allow multiple users to collaborate on creating and edit documents in real time		
Allow creation and editing of documents without the need for external software application such as MS Word		
Allow related documents to be linked or related		
Store any type of file		
Automatically number and name new documents		
Allow external users to upload documents to the system		
Be easily searchable and sorted by their attributes, including keyword search		
Control access to documents by role		
Maintain archive for all retired documents and enforce archive rules such as allowing no changes		
Add custom fields (metadata) to further categorize and classify documents		
Create custom categories to manage and track documents		

Document-Related Requirements (cont'd)

	Rating	How is the requirement addressed in your solution?
Allow multiple users to comment and edit on a document while tracking comments and edits		
Allow preview of a document without the need for an external product (such as MS Word)		
Include the ability to search items by metadata or full text content		
Track and retain versions of all items		
Control check in and checkout processes		
Option to automatically name and number documents		
The system should have a possibility to link documents		

Workflow Requirements

	Rating	How is the requirement addressed in your solution?
Manage documents through life cycles from draft to final		
Create customizable workflow review/approvals based on document category		
Allow definition of specific workflows based on the type of document		
Upload and route a draft of a document to users for review and approval		
Provide notifications by eMail of tasks that are assigned to users		
Assign tasks to users		

Import, Export, Archive, Printing	Rating	How is the requirement addressed in your solution?
Import groups of documents in to the application while retaining metadata		
Export an entire study to a ZIP file while retaining folder structures		
Export any document to to a PDF		
Export table data to .csv		
Control access to printing		
Status and version of the document should be visible on printed document		
Apply watermarks to documents based on the stage of the document		
Choose any two drafts while in draft review and see differences between two documents		
The system will have the ability to assign tasks to users		
The system will allow users to set due-dates for assigned tasks		

Compliance Requirements

	Rating	How is the requirement addressed in your solution?
Capture and track creation dates and dates of any action on any item		
Provide special limited access to an auditor		
Provide an audit trail showing every change to every item in the system		
Support Electronic Signatures		
Track and retain all versions of every item in the system		
Provide an audit trail showing every access or attempted access to the system and access or attempted access to to an item		

List any additional capabilities not listed above:

	Rating	How is the requirement addressed in your solution?

About 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.

Learn more about our application
or Request a demo or free trial

About Agatha

Agatha, Inc. is a strategic software solutions provider to the healthcare and life sciences industry, providing SaaS-based business applications for managing SOP, regulatory documents, and clinical trial master file records.

With offices in the US, Europe, and Japan, Agatha is dedicated to helping the world's Hospitals, biotechnology, pharmaceutical, contract research organizations, and medical device firms optimize the management of their Quality, Regulatory and Clinical documentation and processes.

With lower costs and faster onboarding, Agatha delivers the best ROI on business applications for life sciences that are ready to use, fast to deploy, and easy to adopt.

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