MANA RBM
DELIVERING RISK BASED MONITORING SOLUTIONS

VENDOR SELECTION CRITERIA

ETMF_EISF V2 November 2020

Vender Selection Criteria

Vendor Name_____

Person Completing Assessment_____

Role of Person Completing Assessment_____

Date of Assessment

eTMF/eISF

Requirement	Describe how system meets requirement. Provide examples where prompted.	Does not meet	Comments
21 CFR Part 11			
Closed system? Describe process for adding users.			
eSignature functionality is present and meets requirements. Audit trail shows eSignature user.			
eSignature can be assigned to any user.			
eSignature can be added to any workflow.			
Documents can be electronically signed within the system.			
Audit trail is attached to any document with an eSignature, not a separate document with audit trail for the document.			
Documents are converted to PDF and are unalterable after eSignature.			
Audit trail is understandable to auditor.			
Audit trail is available throughout study.			
Study can be restored to active status for audit.			
Audit trail is exportable in CSV or other searchable/queryable format.			

PHI			
Does your system allow collection of documents with PHI? If so, how is that protected during study conduct and as part of the export and archive?			
Requirement	**Describe how system meets requirement. Provide examples where prompted.**	**Does not meet**	**Comments**
Role-Based Access			
Is role-based access configurable?			
Can role-based access limit visibility to different forms/fields?			
Can eSignature be added to a specific document or workflow (for making certified copies of paper documents)?			
Configuration			
Can system architecture be configured to collect documents for each site and also for the eTMF?			
Does the system have configurable metadata, and is it included in an export?			
Query functionality			
Describe workflow for documents that do not meet review requirements.			
Is documentation of that process exportable and searchable (CSV format or similar)?			
Can documents be downloaded at will?			
Notifications and Reports			
Provide details of the notification process (email, etc.) and how it is triggered.			
Provide examples of the reports available within the system.			
Configuration			
Provide details of process for configuring a study — who does it, timelines, and specifications.			
Describe process for denoting documents as essential documents and how status is communicated.			

Describe process for changing or adding documents to essential documents.			
Describe process for changes made to the system during study conduct, including internal testing.			
Requirement	**Describe how system meets requirement. Provide examples where prompted.**	**Does not meet**	**Comments**
Archive			
Describe the archive process, and provide an example of a PDF of the sample archive file. Be sure it includes the eSignature of the Investigator.			
Demonstrate how the archive is different for the Site and the Sponsor.			
Other Features			
Provide a list of all other features available. Note only those products that have been released to production, version, and date deployed.			
eConsent			
Other, Specify			

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