# CTMS REQUIREMENTS CRITERIA

| Priority Scale | |
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| **The Priority Scale identifies the critical value of each criteria to the organization** | |
| **Must Have** | Requirements that the organization views as a critical element |
| **Strongly Preferred** | Requirements that the organization views as a critical element but a vendor would not be eliminated if this criteria was not met. |
| **Nice To Have** | Desirable requirements but does not rise to the level of Strongly Preferred or Must Have. |

| Group | Feature | Requirements Criteria | Priority |
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| **System** | **System Flexibility** | An off the shelf system to meet requirements without little or no customization | Strongly Preferred |
| **System** | **Cloud Readiness** | Hosted cloud solution where vendor performs all upgrades, backup etc. | Must Have |
| **System** | **Validation & Compliance** | The system must be a validated system with controls for 21 part 11 | Must Have |
| **System** | **Validation Deliverables** | The following deliverables should be provided:<br>-Validation Plan<br>-User Requirements Specifications (URS)<br>-Test Plan/Test Script (PQ)<br>-Configuration Specification | Must Have |
| **System** | **Data Migration** | The following deliverables should be provided:<br>-Data Migration Plan/Specifications<br>-Data Validation Plan and Summary Report | Must Have |
| **System** | **User Management** | The system must be have capabilities to manage and granted permissions based on users role | Must Have |
| **System** | **Single Sign-on (SSO)** | Ability to utilize Active Directory credentials for sign-on and setting permissions. | Must Have |
| **System** | **Multi-factor (MFA)** | The system supports enhanced security mechanisms by integrating with Identity Management offerings such as RSA, ADFS etc. (SAML 2.0 support) | Must Have |
| **System** | **Mobile Access** | The system has capability to access from mobile devices via native app or web | Must Have |
| **System** | **Ease of Use** | The system is easy to navigate with a simple, clean, modern and friendly intuitive interface | Must Have |
| **System** | **Environment** | Sandbox and Production environment must be provided | Must Have |
| **System** | **Connectivity To Other Systems** | Capability to integrate with applications IAVI is using to collect clinical trial data for the sites using:<br>-Vendor Electronic Data Capture (EDC) systems for metrics (see also details metric and process criteria)<br>-eTMF filing of documents collected at site and documents generated by CTMS and metrics (see also details metric and process criteria)<br>-Integration Governance and Procedures (templates, reference to SOPs, direct access of templates in CTMS etc.)<br>-Quality Management System for integration of deviation and audit management (reporting / review / follow-up) (see also details metric and process criteria)<br>-Any other future systems | Must Have |
| **System** | **External Users** | Invite external user to participate (review, collaboration, upload) | Nice To Have |
| **System** | **Document Review and Approval process** | Review and approval by eSignature in CTMS. Final signed off documents upload in eTMF | Must Have |
| **Support** | **Training** | The following deliverables should be provided:<br>-Training Materials<br>-Robust hands-on training program for Administrator and end users | Must Have |
| **Support** | **Validation** | Validation support after implementation | Must Have |
| **Support** | **Business Process Development Support** | IAVI driven SOPs and work instructions development supported by the vendor | Strongly Preferred |
| **Support** | **Technical Support** | Online help, help-desk and validation support for periodic system upgrade(s)<br>Add hoc support on issues | Must Have |
| **Reporting** | **Reporting Capabilities** | The system provides robust and streamlined reporting capabilities | Must Have |
| **Reporting** | **Trial analytics and dashboard** | Charts can be exported for use in external documents and presentations<br>Configurable reports with custom fields | Strongly Preferred |
| **Metrics** | **Trial analytics** | Possibility of analysis of data coming from EDC or other external source | Must Have |
| **Metrics** | **TMF Quality Metrics** | **Study TMF / ISF metrics**<br>-reconciliation eTMF / ISF<br>-missing document collection (transferred from eTMF) for example output EDLs for missing eTMF site documents linked to CTMS monitoring tool for collection of missing documents. | Strongly Preferred |
| **Metrics** | **Quality Metrics Performance** | **Monitoring:**<br>MVR follow-up and completion;<br>% SDV completed to date<br>%MVRs Final and submitted on time;<br>Avg # Action items open > 1 visit<br><br>**Monitoring /CRO oversight:**<br>Quality oversight visits documented and finalized within timelines (if able to create and track reports within CTMS). | Must Have |
| **Metrics** | **EDC Quality Metrics Site Status Reporting** | **Site Study Status:**<br>% pts enrolled against target per month<br>% screen failures<br>% of participants who discontinued early<br>% Missed visits and contacts<br>% Missed visits and contacts | Must Have |
| **Metrics** | **EDC Quality Metrics Deviations** | **Site Deviation:**<br>Number of eligibility criteria deviations (violations)<br>Total # major or critical deviations / ppt enrolled<br>Total # minor deviations / ppt enrolled | Must Have |

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| **Metrics** | **EDC Quality Metrics Other** | **EDC Data site level metrics:**<br>% of data errors/omissions / CRF (only manual queries by DM and CRA)<br>Number of queries not answered by site > 15 days<br>Number of queries / ppt<br>Average # of days from visit to CRF completion<br>Avg AEs /ppt enrolled at site<br>Avg SAEs /ppt enrolled at site<br>Enrolment data<br>Safety data metrics | Must Have |
| **Metrics** | **QMS Quality Metric** | **Metrics data coming from IAVI QMS**<br>Internal deviation metrics coming from IAVI QMS<br>**Audit metrics**<br>Total # of critical findings per audit<br>Total # of major findings per audit<br>% of Audit CAPA items closed within timelines | Must Have |
| **Metrics** | **Quality Metrics on Sample Management and Lab** | **Site Biorepository Management: (not sure if integration between biorepository system and CTMS will be possibility - probably not?)**<br>Specimen Data transfers from clinical Lab to Clinical Biorepository Operations<br>Data Discrepancies between Clinical and Specimen data<br><br>**Site lab metrics**<br>Samples collection metrics<br>% Compliance with EQA programmed as per study<br>% Compliance with Proficiency testing as per study | Nice To Have |
| **Metrics** | **Metrics on Milestones / Timelines** | For each milestone e.g.<br>Planned finish date, actual finish date, status e.g. complete, planned.<br>Examples: eTMF compliance and completeness (Use EDL data), clinical trial set-up, study site readiness etc... | Strongly Preferred |
| **Metrics** | **CW (LMS) Quality Metrics** | % of protocol-specific training items overdue | Must Have |
| **Process** | **Monitoring or other site visit management** | Site Visit Tracking, which provides workflow-based tracking of the visit report, confirmation and follow-up letters, and custom tracking needs<br>Action items, PD , SAE, ICF and ISF tracking for site visits and study team activities with alerts<br>SAEs and Open action items to automatically populate into next report and FU Letter | Must Have |
| **Process** | **Contact Management** | Staff contact details set-up<br>Creation of contact list | Must Have |
| **Process** | **Risk Management** | Assessment details, risk mitigations, review cycles, meetings etc.<br>Outcome (report) filed in eTMF | Strongly Preferred |
| **Process** | **Site Management** | Site status, MVR quality findings, issues by type, issues open by study-site with aging, tracking participant visits to flag upcoming visits or missed visits for site to quickly take action, creation of contact reports. | Must Have |
| **Process** | **Issue Log** | Combined (Site and or Study) issue and tracking log for issue resolution and trending. | Must Have |
| **Process** | **Vendor Management** | e.g. Vendor selection, issues tracking, metrics, meetings, documentation. Output filed in eTMF | Must Have |
| **Process** | **ERB / RA submission and approval progress** | ERN submission / approval / follow-up management | Strongly Preferred |
| **Process** | **Protocol deviation and Issue Tracking** | Site / Study protocol deviation listings review and follow-up. Output filed in eTMF | Strongly Preferred |
| **Process** | **Medical Monitoring** | Review of EDC output monitoring in CTMS upload final output in eTMF | Must Have |
| **Process** | **Protocol Amendments** | Implementation of Protocol Amendment at site level (training, approval) | Nice To Have |
| **Process** | **Document Management** | Integration with eTMF e.g. link documents to issue tracker, attach documents to monitoring reports, letters, etc. | Nice To Have |