<table>
<thead>
<tr>
<th>Group</th>
<th>Feature</th>
<th>Requirements Criteria</th>
<th>Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>System</td>
<td>System Flexibility</td>
<td>All the off-the-shelf systems must meet requirements without customization or configuration</td>
<td>Must Have</td>
</tr>
<tr>
<td>Support</td>
<td>Training</td>
<td>The system must be capable of being trained by end users</td>
<td>Strongly Preferred</td>
</tr>
<tr>
<td>Support</td>
<td>System Validation &amp; Compliance</td>
<td>The system must be validated with controls for 21 part 11</td>
<td>Must Have</td>
</tr>
<tr>
<td>System</td>
<td>System Validation Deliverables</td>
<td>The following deliverables should be provided</td>
<td>Must Have</td>
</tr>
<tr>
<td>System</td>
<td>System Data Migration</td>
<td>The following deliverables should be provided</td>
<td>Must Have</td>
</tr>
<tr>
<td>System</td>
<td>System User Management</td>
<td>The system must be capable of managing and granting permissions based on users’ roles</td>
<td>Must Have</td>
</tr>
<tr>
<td>System</td>
<td>System Single Sign-on (SSO)</td>
<td>The system must support single sign-on (SSO)</td>
<td>Must Have</td>
</tr>
<tr>
<td>System</td>
<td>System Mobile Access</td>
<td>The system must be capable of being accessed from mobile devices or mobile apps or web</td>
<td>Must Have</td>
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<tr>
<td>System</td>
<td>System Ease of Use</td>
<td>The system must be user-friendly with a simple, clean, modern and friendly user interface</td>
<td>Must Have</td>
</tr>
<tr>
<td>System</td>
<td>System Environmental</td>
<td>System and Production environment must be provided</td>
<td>Must Have</td>
</tr>
<tr>
<td>System</td>
<td>System Connectivity To Other Systems</td>
<td>Capability to integrate with applications with on going to collect clinical trial data for the site</td>
<td>Must Have</td>
</tr>
<tr>
<td>Support</td>
<td>Support External Users</td>
<td>Only external user to participate (review, collaboration, edit)</td>
<td>Must Have</td>
</tr>
<tr>
<td>Support</td>
<td>Support Integration Governance and Procedures</td>
<td>The following deliverables should be provided</td>
<td>Strongly Preferred</td>
</tr>
<tr>
<td>Support</td>
<td>Support Technical Support</td>
<td>Technical support for periodic system updates</td>
<td>Strongly Preferred</td>
</tr>
<tr>
<td>Support</td>
<td>Support Training</td>
<td>Training materials and a hands-on training program for administrator and end users</td>
<td>Must Have</td>
</tr>
<tr>
<td>Reporting</td>
<td>Reporting Capabilities</td>
<td>The system provides robust and streamlined reporting capabilities</td>
<td>Must Have</td>
</tr>
<tr>
<td>Reporting</td>
<td>Reporting Trial Analytics and Dashboard</td>
<td>Reports can be printed as a part of the document and presentations</td>
<td>Must Have</td>
</tr>
<tr>
<td>Metrics</td>
<td>JIRA Quality Metrics</td>
<td>Study / TMF / IR metrics</td>
<td>Must Have</td>
</tr>
<tr>
<td>Metrics</td>
<td>Quality Metrics Performance</td>
<td>Meeting the following deliverables</td>
<td>Must Have</td>
</tr>
<tr>
<td>Metrics</td>
<td>Site Status Reporting</td>
<td>Site status reporting</td>
<td>Must Have</td>
</tr>
<tr>
<td>Metrics</td>
<td>Site Metrics Deviations</td>
<td>Site metrics deviations</td>
<td>Must Have</td>
</tr>
</tbody>
</table>

**Priority Scale**

- **Must Have**: Requirements that the organization views as a critical element but a vendor would not be eliminated if this criteria was not met.
- **Strongly Preferred**: Desirable requirements but does not rise to the level of Strongly Preferred or Must Have.
- **Must Have**: 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.
## Metrics

### EDC Quality Metrics
- % of data errors/omissions of CRF (only manual queries by DM and OA)
- Number of queries not answered by site > 15 days
- Number of queries / ppt
- Average # of days from visit to CRF completion
- Avg AEs /ppt enrolled at site
- Safety data metrics
- Quality of site level metrics
- Metrics data coming from QMS (only critical findings per audit)

### EDC Data site level metrics:
- % of data errors/omissions of CRF (only manual queries by DM and OA)
- Number of queries not answered by site > 15 days
- Number of queries / ppt
- Average # of days from visit to CRF completion
- Avg AEs /ppt enrolled at site
- Safety data metrics

### Safety data metrics:
- Total # of critical findings per audit
- Total # of major findings per audit
- % of Audit CAPA items closed within timelines

### Site Biorepository Management:
- Site visits for data cleaning (baseline) and CTMS will be visibility
- Sample data transfer from clinical lab to Clinical Biorepository Operations
- Data discrepancies between Clinical and Specimen data

### Site lab metrics:
- Samples collection metrics
- In Compliance with EQA programmed as per study
- In Compliance with Proficiency testing as per study

### Quality Metrics on Sample Management and Lab:
- Planned finish date, actual finish date, status e.g., completed, planned:
  - Examples of EQA compliance and completeness (pre EQA date), clinical trial set up, study site weaknesses etc.

### CW (LMS) Quality Metrics:
- % of protocol-specific training items overdue

### Process

#### Monitoring or other site visit management:
- Site Visit Tracking, which provides workflow-based tracking of the site report, confirmation and follow-up letters, and custom tracking needs
- Action items, PO, OA, CIC and SF tracking for site visits and study team activities with alerts field and Open action items to automatically populate site site report and PO letter

#### Risk Management:
- Assessment article, risk mitigations, review cycle, meetings info:
- Evidence report filed in eTMF

#### Site Management:
- Site status, site level findings, issues by type, issues open by site with aging, tracking participant visits to flag upcoming visits or missed visits for site to quickly take action, creation of contact reports

#### Issue Log:
- Combined site and study issue and tracking log for issue resolution and trending
- e.g. vendors, selection, issues tracking, meetings, documentation, output files in eTMF

#### Vendor Management:
- e.g. vendor selection, issues tracking, meetings, documentation, output files in eTMF

#### Protocol deviation and Issue Tracking:
- Site / Study protocol deviation listings review and follow-up
- Output files in eTMF

#### Medical Monitoring:
- Review of EDC output, monitoring CRF, status field output in eTMF

#### Protocol Amendment:
- Implementation of Protocol Amendment at site level (training, approval)

#### Document Management:
- Integration with eTMF e.g. site documents to issue tracker, attach documents to monitoring reports, letters, etc.