eTMF Study Roles Guideline

Security profile: Please indicate which of the following roles using the role table below:

- Study Manager
- CTA
- Study Document Contributor
- Study Document Viewer
- External Inspector: Please reach out to the contacts below directly for this type of account

**Study Staff Roles and Functions:**
Each time an individual is added to a study, they will need to be assigned one of the below roles

<table>
<thead>
<tr>
<th>Role</th>
<th>Functions</th>
<th>Blinded/unblinded Role (Can vary per study)</th>
</tr>
</thead>
</table>
| Study Manager      | • Permissions to create studies, countries, sites and products  
|                    | • Can manage their assigned studies, countries and sites and all necessary related study data (milestones, expected documents, personnel, communications, etc.)  
|                    | • Can create, modify and participant in workflows for documents in their assigned study  
|                    | • Can assign personnel and grant access as study persons  
|                    | • Can view and run reports and create their own  
|                    | • Ability to archive                                                                                           | Can be either blinded or unblinded |

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<table>
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<tr>
<th>Role</th>
<th>Permissions</th>
<th>Can be either blinded or unblinded</th>
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</thead>
<tbody>
<tr>
<td>studies</td>
<td>• Full document contribution permissions: create and edit documents, participate in workflows, track quality issues, manage expected documents</td>
<td></td>
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<tr>
<td>CTA</td>
<td>• Same roles as study manager except can’t change life cycle states of study, country and sites or archive studies; or can’t grant user access</td>
<td>Can be either blinded or unblinded</td>
</tr>
</tbody>
</table>
| Study Document Contributor | • Permissions to view studies, countries, sites and milestones related to specific studies  
  • Full document contribution permissions: create and edit documents, participate in workflows, track quality issues, manage expected documents  
  • Can view and run reports and has ability to create their own  
  • Can be designated as quality control reviewer | Can be either blinded or unblinded |
| Study Document Viewer (may be used for internal) | • Permissions to view study documents and | Can be either blinded or unblinded |
| monitors) | data but cannot make updates  
|   | ● Can participate in document workflows as needed |

| External Inspector  
(reserved for external monitors/auditors/inspectors such as for the purpose of a FDA inspection) | ● Assigned to an inspector of a study and provides them with access to the TMF. This will provide permissions to view the approved study documents and some key study data. |

**Contact**

Please contact either of the following for questions regarding this document:

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**Document History**

<table>
<thead>
<tr>
<th>Version</th>
<th>Effective Date</th>
<th>Brief Description of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>01/05/2023</td>
<td>Initial</td>
</tr>
<tr>
<td>2.0</td>
<td>05/20/2024</td>
<td>Study manager functions revised to remove ability to make changes to organizations in global directory</td>
</tr>
</tbody>
</table>