



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

Role	Functions	Blinded/unblinded Role (Can vary per study)
Study Manager	<ul style="list-style-type: none"> • Permissions to manage Global Directory • 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 studies • Full document 	Can be either blinded or unblinded



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	<p>contribution permissions: create and edit documents, participate in workflows, track quality issues, manage expected documents</p>	
CTA	<ul style="list-style-type: none"> • 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 	Can be either blinded or unblinded
Study Document Contributor	<ul style="list-style-type: none"> • 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 monitors)	<ul style="list-style-type: none"> • Permissions to view study documents and data but cannot make updates • Can participate in document workflows as needed 	Can be either blinded or unblinded
External Inspector (reserved for external)	<ul style="list-style-type: none"> • Assigned to an inspector of a study 	



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monitors/auditors/inspectors such as for the purpose of a FDA inspection)	and provides them with access to the TMF. This will provide permissions to view the approved study documents and some key study data.	
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Contact

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

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Document History

Version	Effective Date	Brief Description of Change
1.0	01/05/2023	Initial