



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 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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	<ul style="list-style-type: none"> studies • Full document contribution permissions: create and edit documents, participate in workflows, track quality issues, manage expected documents 	
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	<ul style="list-style-type: none"> • Permissions to view study documents and 	Can be either blinded or unblinded



monitors)	<p>data but cannot make updates</p> <ul style="list-style-type: none"> • Can participate in document workflows as needed 	
External Inspector (reserved for external monitors/auditors/inspectors such as for the purpose of a FDA inspection)	<ul style="list-style-type: none"> • 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

Version	Effective Date	Brief Description of Change
1.0	01/05/2023	Initial
2.0	05/20/2024	Study manager functions revised to remove ability to make changes to organizations in global directory