

Glossary of User Roles and Actions

TI version 10.7



APPLICABLE TO: ● **Admin** ○ **Manager** ○ **Editor** ○ **Reader**



Admins have rights to all documents and site settings. They can also add and modify documents, and invite users.



Managers have similar access rights as Admins with the exception of Users and Group Management, Security and Workflow Settings, Inbox, Email and Investigative Site Configuration, Folder & Document Security.



Editors have the ability to add documents directly to the room, apply metadata to documents, and perform Workflow functions.



Readers have basic view-only access to files. These users can only submit documents to a room via email.

Action	Applicable to	Description
Redaction	Admin, Manager, Editor	This action allows the user to apply redaction to a document.
Study Startup	Admin, Manager, Editor, Reader	This action allows the user to access the Start-Up Module, if enabled in the current room.
Page Manipulations	Admin, Manager, Editor	This action allows the user to make changes to a document's layout (e.g., page rotation and deletion).
eSignature	Admin, Manager, Editor	This action Allows the user to prepare the E-signature documents and assign the signees.
Communications	Editor	This action allows the user to access the Communication Module.
Event Manager	Admin, Manager, Editor	This action allows the user to access the Event Manager Module, accessible from the Navigation Grid.
Assign Tasks	Admin, Manager, Editor	This action allows the user to view/assign tasks in the Tasks Module.
Document Manager	Manager, Editor	This action allows the user to update metadata and/or change the index location of a document with Final status.
Mobile CRA	Reader	This action allows the user to submit documents via the <i>myTI</i> application but limits their role in the eTMF to Reader access.
CRA Reconciliation	Admin, Manager, Editor, Reader	This action allows the user to access the CRA Reconciliation Module.
Document Distribution	Admin, Manager, Editor	Allows the user to distribute documents to linked rooms.

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Action	Applicable to	Description
Acknowledgement	Admin, Manager, Editor, Reader	Allows a user to send requests for Read & Acknowledge of documents in Collaborate/eISF rooms.
Enroll for GL Courses	Groups	This action is available for groups when LMS Integration is enabled. The group gains interoperability with Global Learn and becomes a training group in that system.
Translation Request	Editor, Reader	This action is available when TransPort Integration is enabled. It allows users to request certified translations.
Quality Records	Admin, Manager, Editor, Reader	This action gives the user visibility of the Quality Records module in a Collaborate room.

System Groups	Applicable to	Description
Sites Team	Admin, Manager, Editor, Reader	Users in this group gain access to the Sites Module and all site folders in the Index.
Site Activation Members	Admin, Manager, Editor	A subgroup of the Study Start-Up Team group. Editors and Administrators in this group become selectable users to assign to the Start-Up Specialist group (see below).
myTI Access	Admin, Manager, Editor, Reader	Users added to this group gain access to the respective room within the myTI mobile application.
QC Groups (1 -10)	Admin, Manager, Editor	These are approval stage groups in a QC workflow. Users in this group can claim, code, and QC newly uploaded documents.
Query Manager Group	Admin, Manager, Editor	Group of users who can respond to all workflow queries
General Query Responders	Admin, Manager, Editor	Group of users who can respond to all general queries
Index Manager Group	Editor	Editor users assigned to this group gain privileges to modify the Index, an action normally reserved for Administrators only.
CRA	Editor, Reader	Editors and Readers can be assigned as CRAs to sites. Users have to be assigned per site to gain access to the site(s) in the myTI mobile application.
Start-Up Specialist	Admin, Manager, Editor	First approval stage group in the Study Start-Up QC workflow. Users in this group can code, review, approve, or reject documents. Users can also activate the site once the site achieves Regulatory Approval.
Regulatory Approvers	Admin, Manager, Editor	Second approval stage group in a Study Start-Up QC workflow. Users in this group can review, approve, or reject the documents previously approved by the Start-Up Specialist. Once all documents are approved, the site is ready for Site Activation.