



Editor User Guide v10.1





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Chapter 1. Trial Interactive 10.1- Overview and Features Hardware and Software Requirements

The following describes the hardware and software requirements to use the Trial Interactive eTMF platform.

OS	 Windows Version 7 or higher All currently supported Mac OSX releases iOS and Android for myTI mobile app (see myTI release notes) 	
Browser	 Microsoft Edge: Version 20 or later (officially supported versions by Microsoft only) Google Chrome: Current release and earlier Mozilla Firefox: Current and ESR releases Apple Safari: Current release and earlier Internet Explorer: Version 11 or later NOTE: Microsoft® stopped supporting Internet Explorer™ 8 and Internet Explorer™ 9 in January 2016 and will stop support for Internet Explorer™ 10 in January 2020. Beginning with the release of TI 10, we expect slight degraded performance with Internet Explorer™ 11, and no longer support Internet Explorer™ 10. Users accessing TI with this and older browsers will see in some cases a degraded experience and may have trouble using certain features. 	
Client Software	 For Edit Online Support, Microsoft Office 2010 SP1 or higher is required Optional: Adobe Acrobat, Acrobat Standard, or Professional version 8 or higher may be installed in addition to the included PDF Viewer. For SAS Datasets, SAS Viewer or compatible software must be installed. The free version is available here: https://support.sas.com/downloads/browse.htm?fil=&cat=74 	
Optional Add-Ons	 DocuSign Standard and DocuSign 21 CFR Part 11 (Latest Cloud Versions) Adobe Sign (Latest Adobe Document Cloud Version) NOTE: The Snowbound Viewer is now deprecated in TI 10. All features of Snowbound are now available in the TI Viewer. 	



PLATFORM FEATURES

The improved version of Trial Interactive 10.1 comprises of following Platform features:

Multi-tenant SSO



Introduced in 10.1 is support for SAML Federated Single Sign-On for the TI multi-tenant platform. Now, all customer domains on multi-tenant can be configured with single sign-on through their own Corporate Directory, as well as third party IAM providers.

A change to the sign in page has been made to reflect the possibility of multiple providers.

The Trial Interactive sign in page will now first prompt the user for their email address, and based on the domain, will either prompt for a password or redirect to the configured Identity Provider. Users who do not have SSO configured will be directed to the normal login page where they will enter their password.

Please reach out to your Trial Interactive representative to discuss setting up SSO for your organization.



Three-Column Dashboard Layout



Trial Interactive 10.1 brings back the 2 and 3 columns look to the dashboards as well as the single column tabbed view introduced in TI 10. This provides more flexibility, allowing dashlets to be repositioned and configured to fit the needs of your team.

All standard TMF dashlets are available to show in different chart styles, such as donut, horizontal and vertical bar chart layouts.

If project training is required for access it is clearly shown in an eLearning dashlet with courses listed.

For Content Management customers, the in progress collaborative reviews are shown, as are popular documents, favorites, approvals, and required signatures. Finally, administrators can set the default dashlet layout for each major role directly from this page, defining it for all users of the eTMF or room.

In order to enable the multiple column layout, press the Edit Dashboard button on the dashboard and choose Setup Layout. This will enable you to choose the number of columns



visible on the dashboard. This can be customized for each of the available dashboards within TI.

Outlook Drag And Drop



10.1 now supports Microsoft Outlook[™] interoperability, fully supporting drag and drop of documents and mail messages in Windows 10[™]. This provides the following:

- You can drag and drop email messages from MS Outlook into TI and the email will import along with all document attachments. Once in TI, MSG files may be converted to PDF.
- You can drag and drop individual document attachments from an email into TI and the documents will import.
- You can drag and drop a single document or email message onto a folder or placeholder and it will auto-classify.
- You can drag and drop many documents or email messages into the import modal in TI and they will all load into the import box.

Certain browsers such as Mozilla Firefox[™] require an Outlook plug-in to fully support this feature. Chrome, Edge, and IE 11 do not require a plug-in. Links to download the required plug-ins will be provided in the online help.



Outlook File Drag

Drag and drop Outlook items as files into any application

Read This First!

Microsoft Edge (as of Windows 10 1709) and Google Chrome (as of version 76) natively support drag and drop from Outlook on Windows. If you use one of these browsers, then this plugin is not necessary.

Overview

Outlook File Drag is an add-in for Outlook 2013 and 2016 that allows you to drag and drop Outlook items (messages, attachments, contacts, tasks, appointments, meetings, etc) to applications that allow physical files to be dropped, such as web browsers.

How Does it Work?

When you try to drag and drop from Outlook, Outlook correctly identifies the format as virtual files (CFSTR_FILEDESCRIPTORW) since the files do not exist directly on disk. Instead, they are contained in a PST file, OST file, or on an Exchange server.

However, many applications do not support this format, such as web browsers and most .NET/Java applications.

To work around this issue, Outlook File Drag hooks the Outlook drag and drop process and adds support for physical files (CF_HDROP). When the receiving application asks for the physical files, the files are saved to a temp folder and those filenames are returned to the application. The application processes the files (such as uploading them). Outlook File Drag deletes the temp files later in a cleanup process.

Features

- Works with Chrome, Firefox, Internet Explorer, Edge, and other applications that accept files to be dropped
- Allows drag and drop into HTML5-based web applications
- Drag e-mails, attachments, contacts, calendar items, and more
- Drag multiple items at once
- Supports Unicode characters



CROSS-ROOM DOCUMENT SHARING



Content Management in life sciences is a very complex set of relationships that happen across multiple repositories of content, owned by different business units. Clinical needs content management and a TMF system that authors and captures content generated during the planning and execution of a Clinical Trial. Other repositories exist that are owned by Quality, Regulatory, R&D, Commercial, Training, Medical Writing, and many others. Finally, quite often, Clinical needs to keep unblinded content in a separate repository as well as the ability to access site documents from remote monitoring workspaces.

Each of these units broadly has its own workflows, approval cycles, and policies for the management of content. They also have separate owners who want control of the content management and metadata policies within. When it comes to a Clinical Trial, much of this content is archived and ends up in the Trial Master File.

10.1 introduces the capability to share documents easily, in a controlled fashion, between TI repositories called Rooms. This sharing is configured by room and may be enabled to many rooms, to allow for multiple content sharing scenarios, including: Sharing a single document to many eTMFs, sharing from many sites to a single eTMF, and sharing from an eTMF to other groups.

The 'chain of custody' of these documents is very important to maintain. As approved document versions are shared between rooms, the document source location and destination are tracked and can be viewed. Metadata that is common between two rooms will be shared



along with the content, and only users with permission may share content. However, users may not share content to rooms to which they do not have access, like the eTMF for example, to enforce a controlled document workflow between repositories.

Enabling Cross-Room Document Sharing

In order to enable cross-room document sharing, the rooms must be linked. The Settings menu in TI has a new section entitled Documents Distribution.

Clicking on the Linked Rooms sub-menu and pressing the Link Rooms button will bring up the Link Rooms window. From there the user needs to drill down or search for the required room and press Next and then Finish.



The Common Configuration sub-menu should then be opened, and the user can choose whether or not to Enable Documents Distribution. Other options include whether shared document should be sent to the receiving room's QC Workflow or if they should be counted as final once shared.





ETMF FEATURES

The improved version of Trial Interactive 10.1 comprises of following eTMF features

Responsible Department Views

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-	Document • A Manage Security • Import •		T Documents Cart
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	Q Search by	III Manage Filters O Create New Filter	
Ā	Clinical Operations	Submitted Name	
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	Principal Scientist	🗈 🚖 O Reg_Submission_Redacted - Copy (5)	
	Project Management	🗈 🔺 🗢 Reg_Submission_Redacted - Copy (3)	
.	Clinical Research Associate	🗋 🚖 🗢 permit to import - Copy (2)	
	Regulatory	🗈 🚖 🗢 CLIA-COPY	
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		🗋 🖄 🖈 🔍 test	
		🗋 🚖 🖈 💿 Site Initiation Visit Report	
C		Grid view Document view	Previous document

One of the business challenges with eTMF is the ability to ensure that documents are submitted in a timely fashion as the trial progresses. To ensure that this happens, it is important to know which person or department is responsible for authoring, collection, and submission of each required document and placeholder.

While CRAs are often responsible for document collection from the sites, many other documents must be collected from internal groups, regulatory authorities, IRBs/IECs, and partners.

10.1 introduces the definition of Responsible Parties and Owners to Trial Interactive. For each Document Type, the responsible group or person may be defined. These definitions may be set up using groups within the room for a flexible assignment of ownership. Once configured, an eTMF Completeness View is now available that shows the required documents, placeholders, collected, and final documents for each Responsible Department or Owner.

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Setting up Responsible Departments

In order to set Responsible departments, the user should navigate to the Users Management Module. There is a new icon present on the menu at the left side of the screen which represents the Responsible Department management area.

Clicking on this will open the Responsible Department management area.

Press the Add button in order to create a new department. The user could also pres button

in order to make changes to a preexisting department.

Enter the Department Name.

Select the Members tab to add users to the department.

Once the department members have been selected, change to the Document Types tab. From here, the user can drill down in the folder structure to assign specific document types to this department. Check the box next to the document type and press Add. If there is no box next to the desired document type, this indicates that the document type has already been assigned to another department.

Once all required members and document types have been assigned to the department, press the Create button in order to create the department.



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QUERY ANY DOCUMENT

	TI 10.1 eTMF Pre-release 1 eTMF / Documents	٥	t Search 💿 Add 👻 🌲 🕕 🚺 Jay Smith 🔹
	Document 👻 🔒 Manage Security 🖉 Move to Stud	y Start-Up 🔹 🛧 Import 👻 🕹 Export 👻 🖾 Email 🛛 🖨 Print	Compare 🛱 Documents Cart 0 -
æ	View by Index Filters Show Empty Folders	1 - 2 of 2 (1 selected) 🤝 🔻 Filters 💷 Select Colur	Expand More *
	Q Search by folder name	Submitted Name A	Copy Field
		🗹 🖹 ★ 🖉 🌣 011_Utterback_RecruitPlan	011_Utterback_RecruitPlai C Paste Field
	🔻 🗁 Index	🗌 📄 🚖 🖉 🌣 IRB application	Document Metadata Set Starting Version
≞	01 Trial Management 7		? Create General Query
	Country 3		File Name
8	D2 Central Trial Documents 3		Clinical Protocol Synopsis.pdf
	03 Regulatory 2		Not Applicable Reason
P	04 IRB or IEC and other Approvals		This is ok
	🔻 🗁 05 Site Management 27		Milestone Date
	🔻 🗁 Site - 011 Utterback 13		
	🔻 🗁 01 Trial Management 2		
	D1.01 Trial Oversight 2		Milestone
	01.01.06 Recruitment Plan 2		· · · · · · · · · · · · · · · · · · ·
	0 01.01.11 Debarment Statement		Milestone
	01.01.14 Audit Certificate		
	01.01.15 Filenote Master List		Category *
	01.05 General		Site 👻
	02 Central Trial Documents 1		Comments
	03 Regulatory 1		
$\overline{\mathcal{F}}$	04 IRB or IEC and other Approvals 1		Cancel Save Save & Next
0	D5 Site Management 8	Grid View Document Viewevious 1 of 1 Next ► M	Previous Document Next Document

Queries are a critical feature in TI, and in 10.1, Queries will become much more flexible. Currently, queries can only be used as part of eTMF Quality Control or Quality Review, but 10.1 changes all of that. Queries can now be opened regarding a document at any time for purposes of clarification or to prompt for document replacement.

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A room Admin or Document Manager can raise and resolve a query against a Collected or Final document **through** a simple right-click. This query may be sent to anyone in the room, including Readers and Editor roles. Once raised, the queries may be viewed by status from an All Queries view and are assigned by default to the submitter or the person who last progressed the workflow.

The standard query workflow process is then followed, allowing the responder to clarify the query, or respond with updated content. All back-and-forth is captured in the document audit trail as normal. Documents may be emailed in or attached directly to the query response from within Trial Interactive.

Users can see what queries are assigned to them just like they would their tasks, through a notification in the user menu, the query view, or the corresponding dashlet. They may be reminded about their queries through a message or newsletter. Documents with open queries will show with an icon in the index and working views, and queries may be filtered by site, country, issue type, and other configurable filters. Open queries against collected and final documents also show in the 'My Queries' and 'Queries by Status' dashboards alongside standard workflow and audit queries.

STAGING AREA PREVIEW



In TI 10, the Working Documents view was introduced to provide a simpler, more comprehensive index for eTMF Completeness, showing not just final documents, but also collected documents, placeholders, and required documents within a standard eTMF index

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structure. This view also introduced the Staging Area, a separate panel that shows documents waiting to be classified via the eTMF workflow.

TI 10.1 introduces a simpler way to preview these documents. Selecting a document in the Staging Area and double-clicking will open the document in a preview modal window alongside its metadata. Then the document can be dragged and dropped directly into the eTMF index, into a folder or onto a Placeholder, and have Trial Interactive intelligently prompt you for the correct Document Type and other classification metadata.

QUALITY REVIEW COMMENTS

Improvements were made to simplify the display of Audit Comments and Audit Responses during a Quality Review by adding comments and response comments to the quality review export.

The process here hasn't changed. The export is still performed in the same way but now the Audit Comments and Audit Response Comments are available for export along with the usual audit data.

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Name of Clinical Investigator JOHN DOE				Site •		
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AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY MARINE THE CHARTAL INITERTOLOGYNMELINE CONTINUETED				Site - John Doe	A ×	
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MACHINE LEARNING METADATA EXTRACTION

Auto-classification of eTMF documents is consistently accurate when enough document identification data has been collected and the machine learning model has been trained by



the clinical team. This functionality was introduced with TI10.

In TI 10.1 the ability to recognize documents by identifying the document type and then extracting the metadata embedded within the document has been improved. This capability will identify investigator names, relevant dates, etc. and then prompt the user to verify and correct the additional pre-filled information. This capability also correctly identifies the Document Type most of the time, when properly trained.

Trial Interactive has been trained on a set of common eTMF document formats with a focus on 12 primary Document Types out of 32 structured essential document formats. Nonstandard formats or customer-specific formats must be trained individually for best results. The key takeaway here is the the system will need to adequately trained to recognize documents that are new or customized for your organization or study.

IMPROVED METADATA SEARCH

In 10.1, additional items may be searched that go beyond documents, including queries, tasks, and users. These may be selected using a simple dropdown next to the search box.

A more advanced metadata search is also available that provides the ability to search on key fields that are most common. Rooms may still be configured to limit the global search to just a few metadata fields. This improvement provides more fine- grained control to a user. For Example, a user may search against all 1572 forms in a specific Country containing a specific piece of text. Other available search fields may include:

- Document ID
- Name
- Title / Submitted Name
- Submitted Date
- Investigative Site
- Country
- Within the text of the document
- Any other metadata field needed, configured in the search panel by each user.

In order to perform an Advanced search, the user would open the regular search function and press the Advanced button at the right of the search field.

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Doc	uments 🔻 Search			✓ Advanced
Limi	it search to the current room			
Searcl	ı			
Adv	anced Search - Docume	ıts		* Simple
Э	Responsible Department		•	Your recent searches
Ð	Current Workflow Stage			Document Status is "Final" and Document Type is "05 Site
9	Document Id			Management\05.02 Site Set-up\05.02.04 Principal Investigator Curriculum Vitae\PICV"
9	Document Date		≅ ×	Current Workflow Stage is "Final"
9	Generated Name			Document Status is "Final"
)	Document Status		•	Responsible Department is "Training"
9	Document Type		۲	
	Add more fields			
Inclu	ide Document Content			
ind the	se words in the documents context			

In the Advanced Search window, the user can then refine their search by adding specific metadata fields.

DUPLICATE CHECKS

Potential Duplicates			×
Search	Go to document Open in new window Download all s Ownload all s	Ill selected Mark as duplicate Mark as non-duplicate Mark as non-duplicate Search text Men you get this, would you please Reply All and let me know if you were able to access the document? Thank you	K X X
	-Steve 1. FDA 1572 montena	-Steve 1. EDA 1572.montena	
	Metadata Relation Test Communication @ Possible Duplicate File Name Testing this Function.pdf	RelevantComms_18May2020 Possible Duplicate File Name RelevantComms_18May2020.pdf	



TI10 introduces more flexibility around duplicate checks, improving the process in the following ways:

- Documents are now flagged as a possible duplicate if they are identical in every way to a document that already exists in the eTMF room (they have the same hash value which means the content is identical).
- Documents are now flagged as a possible duplicate if there is a document with an identical Generated Name at any step in the QC workflow process.
- These flagged documents can be identified through an icon. Once they are claimed, the user will be prompted to compare them. Note that the user may opt to ignore the flag, for example, if the document is known to be a duplicated site document.

Enabling Detection of Potential Duplicates

In order to enable detection of potential duplicates, an Administrator level user will need to go to the Settings menu and go to the Documents Module area of the Documents sub-menu. From here, the user can check the box labeled "Find document duplicates by hash."

-	Documents	attachments)
	Documents Module	C Regenerate Document Names V
	Document Replacement Reasons	Type of Document Link
	eTMF Health	O Link to Document
	Index Outline	Link to Document with Metadata
	Non-PDF to PDF Document Conve	Use document upload date as the document date for bulk upload and Inbox
	Document Certification	Use separator sheet for multiple documents print
•	Document Types	Enable View by Tag for Documents
•	Required Documents	 Enable coding on Mass Import window as default option Find document duplicates by hash

Once this setting is enabled, the room will be able to detect potential duplicates by hash value.

Reviewing Potential Duplicates

When a potential duplicate is detected, it will be indicated by a gray, Potential Duplicate icon. Clicking on that icon will open the window shown at the beginning of this section wherein the user can compare potential duplicate documents and indicate whether or not they are duplicates.

*			0	907410
*	ළු	8		964578
*	ළු	8		969017
\star	4			1009172
\star	2			1015491

Documents which have been marked as duplicates will be indicated by a red version of the potential duplicate icon.

CERTIFIED COPY



T R I A L INTERACTIVE

For situations where the original paper copy of a document may be destroyed or unavailable, TI 10.1 introduces the capability to ensure a certified copy workflow from eTMF, Collaborate, Remote Monitoring, and other room types in TI. With this feature:

- You can upload a document in a room that has enabled certified copy, and you can verify the document uploaded and review copy certification text before providing credentials to certify the document.
- You can review a certified document and view the details related to that certification.
- If you edit a certified document, the document will no longer be a certified copy.
- The text used as the certification criteria is configurable by room, as well as the ability to define a default reason.
- This feature also works in the myTI mobile app.

Enabling Certified Copy

In order to enable detection of potential duplicates, an Administrator level user will need to go to the Settings menu and go to the Documents Module area of the Document Certification sub-menu.

From here, the user can check the box labeled "Enable Certification."

Documents	*	Enable Certification	
Documents Module		Certified copy reason:	Contents Verified
Document Replacement Reasons			
eTMF Health			
Index Outline			
Non-PDF to PDF Document Conve	:		
Document Certification			

Marking a Document as Certified

T R I A L INTERACTIVE

Once the document has been uploaded, proceed to the Documents Module or Documents Library module and choose the Submission view under the My List column. Choose the document from the grid and open the Document Menu by clicking on the gearwheel icon or by right-clicking on the line item in the Grid.



Choose Certify Document from the menu that opens. This will open the Certify Document window.



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Certify Document

PLEASE CONFIRM THAT YOU'VE VERIFIED ALL OF THE ITEMS

- I confirm the image(s) are an exact copy of the original document
- Prior to scanning I removed all wallets/staples/binding/paperclips
- All pages were scanned and are present in the correct sequence and orientation
- No headers, footers, or corners of the pages and document are cut off
- Nothing in blocking document content, such as bent corners
- The scanned pages are clear and the content, signature(s) and all text is legible
- The scanned copies reflect all and any attributes of the paper document that are in color which
 are critical to the interpretation of the content in the document
- No content from the original document was removed such as the fax header information

_	
	Cancel Finish

The user will need to read and agree to the conditions shown. If the document meets all of the displayed criteria, they can press the Finish button. The user will be required to confirm their identity by entering their Username and Password.

Once this is done, the document will be given the status of Certified. This is indicated in the Grid by a green dot next to the file-type icon.

4	×	4	۲	0	05 Site Managemen
ß	×		۲		09 Third parties \09
۲	×				09 Third parties \09
ß	*	2			01 Trial Manageme
Þ,	*		٢	٠	05 Site Managemen



SCANNING AUTOMATION

Trial Interactive has always been about reducing, removing, and simplifying the need for paper documentation. Both CROs and Sponsors still often need to collect paper from investigative sites, and still need a built-in process for managing paper records.

With 10.1, Trial Interactive will make available our production scanning processing system. This system provides, through a simple QR code-based metadata solution, a way to quickly scan boxes of paper to be classified immediately and automatically into a Trial Interactive eTMF room. Metadata may be filled-out either at the point of scan or within the TI staging area, depending on your process, and where the classification is most easily done.

Please reach out to your Trial Interactive Representative for a demonstration and additional information about this feature.



STUDY START UP FEATURES

The improved version of Trial Interactive 10.1 comprises of following features:

Ability to mark sites as Closed

	★ Training Team eTMF Room → Start-Up / Sites		
	Site Activation	Hagrid's Animal Hospital Essent	tial Documents All Documents
••••	By Status 🔻 🏹 🔘 🗖	Required fields are marked with an ast	erisk (*)
0	🕶 🖕 Ali	Institution Name: *	Hagrid's Animal Hospital
	🗃 Active [7]	CRA:	× Editor 105
\bigcirc	Non Participating [1]	Start-Up Specialist:	× Admin 102
	💕 Pending [11]	Contacts	
Д		Create O Add existing	🖊 Edit 🛛 😑 Delete 🕴 🥝 Activa
		Last Name 🔺	First Name
		🗆 🗶 Ollivander	Edward
		Address	
		0	
8		── More	
		Edit History	Profile created by Editor 104
ø		Eur History.	Last updated by Admin 103 o
\sim			
E		⊘ Close Site ⊨ Save S Can	cel
		Grid Profile 🖌 <	Site 2 / 7 🔰 🕨

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As a Clinical Trial is completing, the investigative Sites must ultimately be closed. While not typically part of Study Start-Up, this process is very much a part of the Clinical Trial lifecycle. With Trial Interactive 10.1 the system shall have the ability to mark Sites as closed once the trials are completed for the Sites. Once closed, these Sites will be moved to a separate folder for closed sites. Advanced Validation for metadata fields is still available when Sites are marked as Closed.

Sites marked as Closed will still appear on eTMF completeness reports but documents from these sites will not be shown on expired/expiring documents reports or dashlets. Additionally, new amendments will not be applied to Closed sites.

Marking a Site as Closed

T R I A L INTERACTIVE

> If Study Start Up has been enabled in a room, any changes to a site's status must be made from the Study Start Up module. To do so, simply navigate to SSU in the Navigation Grid and open the Sites area. (See the screen shot above)

Select a site from the list of Active sites and double-click or select the site and click Edit in the menu-ribbon above the grid. This will open the site profile. As seen in the screen shot above, a user with sufficient privileges to edit the site (Editor or Admin) will be able to mark the site as closed.



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Support for Multiple Translations and Multiple IRB/EC Approvals



Quite often, the same Document Type requires a translated version, for example, a regulatory authority may require the document in French, German, and English. Additionally, there may be multiple IRB/ECs required in the regulatory approval workflow, and so the same Document Type may need to be recorded for each of these separate organizations.

For this reason, in SSU 10.1 a document type may now be set up as required document multiple times. They can now be set up as required documents more than once based on:

- Language
- IRB/EC

This improves support for European agencies, as well as supporting the process where more than one Ethics Committee may be required for a specific Country or Site's activation.

In order to perform this task, follow the standard procedure for designating a document as required. Simply select multiple languages from the drop down menu in the Required Documents window where possible.



Advanced Validation

When a site is created the Sponsor/CRO may have only limited information about the site, and often cannot complete all the required fields. However, the Sponsor/CRO will ultimately gather more information that must be included before the Site can be marked Active.

With SSU in 10.1, Sites can now be configured to require a set of fields to be filled out with initial site creation and require additional fields that must be filled out before the site can be marked Active. This allows a simplified creation process, and at the same time ensures that all required information is collected prior to the Investigative Site going live.

To set this up, an Administrator level user will need to go to the Settings menu and to the Forms Settings area of that menu.

From there, the user will need to select Investigative Site Profile from the drop-down menu above the Grid. It is likely that nothing will appear. If desired the user can click the option for System Fields above the Grid to display all fields.

Training Team eTMF Settings	Room	•					Q Search O A	dd 👻 🌲 🚺 Admin 103	13 🔻
Search	Q	About Metadata I	Fields ×						
Seneral	-	Investigative Site Profile	🝸 🖸 Add 🦯 Edit	Oelete	idation 🗖 Change Log	≣ System Fields	Custom Fields	All Columns Status	×
Milestones	- 1				Include in				
	- 1	Field Title	Searches	Coding	Grid	Mass Coding	Readonly	Required	
M INDOX	- 1	Status			✓				
Se Outbox	- 1	Regulatory Approval Status				(iii)			
Ø Documents Distribution	- 1	5 7 11		-	0				
Forms Settings		Site Status	\checkmark				\checkmark		
	-1	eFeasibility Status			\checkmark				
	- 1	Site Status Change Date							
Documents									

The user should select Advanced Validation. This will open the Edit Advanced Fields Validation window.

Pressing Add will begin the process of creating an advanced validation requirement.

Select the field (in this case, "Status") and the value ("Active").

Choose which metadata fields should be required upon site activation by clicking the



appropriate checkboxes. Then, press the Actions button and select "Make Required."

Edit Advanced Fields validation			×
Advanced Fields Validations	Validation Criteria		
🖸 Add 🗢 Delete 🚹 🕇	When Status	✓ Equals Active	v
Criteria Condition	Apply actions to fields listed below		
Status equals "Active"			Search Q
	Make Required:	Actions	
	On Off		A
	Apply		
	Closed Site		
	☑ Disable auto Site name		
	eFeasibility Status		
	Effective Closure Date		
	Expected Submission Date		
	✓ Fax		
	✓ IRB/EC Approval Date		
	☑ IRB/EC Name		
	✓ IRB/EC Submit Date		
			· · · · · · · · · · · · · · · · · · ·
			Save Close

Press Save to close the window.

The user will also have to press the Save button at the bottom-left of the Forms Settings window in order to keep the changes.



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Document History

	Anuj's Test Room + eTMF / Documents		c	λ Search	O Add 🔹 🌲	
	Document - A Manage Secu	All History		×	nt 🔲 Compare	Documents Cart 0
<i>6</i> 2	View by Index Q. Search by folder nam	Organization All	Activity Type All	•	pand ata Queries His 100	O More -
4	O1 EF 1 O3 Country Management 1	New File: TransPerfect Trial Interactive			nization 👻	Activity Type
•	 Image: Stee Management 63 Image	O Update security: TransPerfect Trial Intera	14 Oct 201 ctive 14 Oct 201	9, 10:54 AM	ch from	
Ŧ	Jay Smith 2	O Create document: TransPerfect Trial Inter	ractive 14 Oct 201	9, 10:54 AM	ew File: TransPerfect	t Trial Interactive 14 Oct 2019, 10:54 AM
					odate security: Tran	sPerfect Trial Interactive 14 Oct 2019, 10:54 AM
					eate document: Tra	14 Oct 2019, 10:54 AM
					View d	a misory
E		G	ancel	21 40	Th	is record is not editable

During the course of Study Startup, Documents must go through a standard process before they are considered approved. With SSU 10.1, Users now have the ability to view the complete history of the documents in SSU. This includes:

- Submitted By
- Submitted Date
- Start-up Specialist Approver
- Start-up Specialist Approval Date
- Regulatory Approval Date
- Regulatory Reviewer

This information will be accessible at the bottom of the metadata pane when a document has been highlighted in the Grid. Simply click the View all History button to see the expanded history.



Content Management Features

Trial Interactive 10.1 comprises of following Content Management features:

ROLE-BASED CONTENT VIEWS

🛧 Import 👻 🔸 Export 👻 Email 🛛 🖨 Print 🔲 Compare								
	•	1 - 6 of 6 (0 s	elected	i)		C T Filters		
c		Effective 🔹 🖽 Manage Filters 🖉 O Create New Filter						
				Title	Effective Version	Document Owner		
		🗆 🖪 ★ 🍕	9 0	Department3 SOP 002 - Create Cli	3.0			
	🗌 🖹 🚖 🔅 SOP 200 - Access Request		2.0	Ned Stark				
		🗆 🖪 ★ 🧉	0	Allergy Clinical SOP 1	2.0	c		
		🗆 🖬 ★		Allergy Clinical SOP 2	2.0	Ned Stark		
		🗆 🖬 ★		ATL SOP CAW test 3	2.0	Ned Stark		
es 15		🗆 🖪 ★		SOP 003182020	2.0	Ned Stark		

When Editors are looking for documents, they likely want to see the latest, most current, draft version so that they know what's in progress, what needs to be reviewed, and what is currently approved and effective.

Conversely, when Readers are looking at documents, they will see the current, effective version. In 10.1, the TI CMS will provide users with the most logical views for each role, showing Readers the effective version, and Editors the current version.



SIMPLIFIED WORKFLOW START

1 - 6 of 6 (Email Recipients			Expand	08
	Email Recipients CC				
0 *	Document Owner		-		
	Effective Period		\$		
		C Effective Immediately			
	Next Review Period	365	\$		
		Periodic Review not Required		N	D.
	Language		•		
	Tags	Study Start Up			
	is document ready for Appro	locument ready for Approval Workflow? *			
		Cancel Finish			

No longer will a document need to go through a round of editing prior to being able to start a workflow. With CMS 10.1, upon upload, the user will be able to set a document as ready for workflow and the workflow can be initiated right after saving. Immediate approvals and E-signatures can be obtained.

FLEXIBLE CONTROLLED DOCUMENT STATES


SOP- Create new study	
Document Owner	
Carrie Jahnson	+
Effective Date	
21 Jul 2020	⊞ ×
Effective immediately	
Next Review Date	
31 Jul 2020	m ×
Periodic Review not Required	
Language	
	-

For Controlled Documents, there may be a need to make a document Effective immediately or make a document Effective with or without a Periodic Review Period. With 10.1, Document managers will be able to control what does or does not apply

to a document providing the ability to meet the business requirements of the document with ease. Document owners will be able to:

- Control the duration of a document's Effective Period and Periodic Review Period; and
- Set a document to be Effective immediately after approval with or without a Periodic Review Period.



IMPROVED WORKSPACE NAVIGATION

	★ Training Team Collaborate Room ★ Collaborative Workspace / Docum	nents Library			
<i>6</i> 76	🖿 Document 👻 🔒 Manage Security	↑ Import	🝷 🔤 Email 🛛 🖨 Pri	nt 🔲 Compare	
	View by Index 👻	1 - 7 of 7 (0 selected)		e	T Filters
	Q Search by folder n: 2 ···· •		Document Id	Title	Working V
	🔻 🞥 Index	🗆 🖪 ★ 🥭 🏵 <	1124943	Acknowledgemen	1.1
ø	🔻 🗁 Training 9	🗆 🗟 ★ 🔎 🔺 <	1124944	IRB Approval Letter	1.3
_	🔻 🗁 Training Certificates 🛛 8	🗆 🗟 ★ 🥔 🖉	1172886	Version Demo	2.0
<u> </u>	Training Team 7		1186441	Demo for Eva	2.0
	Internal 13		1215032	FilenoteMasterLis	2.0
Ĕ	SC Folder 3		1275754	Standard Template	2.0
	QA Awesomeness 1		1381920	Test for Ashlev	1.0
Y	Upload 11				
	Share 2				

Now users can easily navigate between the Document Repository and Collaborative workspace or Document Lifecycle for a single document.

Within the Document Repository, users can click on the collaborative icon to take them to that document in the Collaborative workspace.

Users can click on the Workflow icon to go directly to the document and its status in the Document Lifecycle.

Within the Collaborative workspace click on the paper airplane icon on the document row to send the document immediately to a workflow review.

COLLABORATE WITHIN A CONTROLLED DOCUMENT WORKFLOW

You will add document(s) to V	tion 🗮 Documents Cart 0	
Workflows	Please select approvers who sl	ould review this document
WF with Clarif	Name Name	Email Metadata Versions History
Im wf1	🗹 🛔 Carrie Johnson	SOP Study Start Up Access Man
🕨 🖿 CC WF NO eSign stage		Is this a TMF document?
Controlled Document Review stage 1	in .	🔾 Yes:
Approval stage 1	·	. Document Metadata
e-Signature		Title *
		SOP Study Start Up Access Mar
		Document Name
		Disable auto Document Nam
	Minimum Number of Approve	Document Name last updated by
		Carrie Johnson
	Cancel Add Document) to Workflow
	10000000	

In CMS 10.1, Document Owners have more workflow choices for their Controlled document. Workflows can be created for business needs providing review steps that allow a document edit, approval steps which will provide an approval event in the document history as well as an E-Signature step to obtain signatures on the document.

Creating and initiating a workflow are covered more in-depth later in this document.



VERSION LABELS

	Periodic Review not Required	
Language		•
Tags		
Document Life Cycle Status		
Effective Version		
Starting Version	3.0	-
Is document ready for Appro	val Workflow? *	-
	Ves No	
	Cancel Finish	

Upon document upload, users will be able to set the initial version in Trial Interactive allowing the document in Trial Interactive to be able to inherit previously defined versions. Trial Interactive will allow for the initial version of a draft document to be set as 0.1. The control of the document version labels will allow organizations to easily follow their own procedure for document management.



ADDITIONAL DESIGNATION FOR TI E-SIGN

L-Signal	ure type Cristianer Obertai						
		Q		Name	Signer Role	Title	
	Name	Title		Admin 103	Training	▼ Trainer	•
	companyadmin2@ti.com		□ ▲	Admin 101	QA	 Directo 	r
	testeditor0418@ti.com			Reader 100	Management	▼ CEO	
	Editor 100						
	Eddie 101						
	Admin 101						
	Admin 102						
	Reader 100						
	Reader 101						
	Reader 102						
		÷					
		Previous 1 of 5 Next		4			

Roles can be defined and leveraged during the E-Signature step. The standard definitions will create consistency across all signatures. During the creation of the E-Signature request, each signer can be associated with a role for the document. This allows not only the user's title, and reason for the signature to be displayed as part of the E-Signature record but the role of the person in the lifecycle of the document. Title and Role inclusion in the E-signature step provide a high level of visibility and clarity for each signer of a controlled document. Roles can be enabled and defined from the E-Signature area of the Settings Menu as shown in the screen shot below.



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Training Team Collaborate Residual Settings	- m				
Search Q	About Signer Roles *				
Seneral Integration	Enable Role for TI signature				
Documents	OAdd / Edit ODelete				
Document Types	Role A	Description			
Required Documents	Management	This signer is from Management			
Countries	QA	This signer is from QA			
Investigative Sites	Training	This signer is from Training			
⊘ IRB/EC					
🕨 🏧 Email					
Document Templates					
🕨 🗹 Audit					
Workflows					
Periodic Review					
R Security					
▼ / E-Signature					
Vendors					
Signer Roles					
Reasons					
Purpose of the signature					

COLLABORATE WITH OUTSIDE USERS

ent Repository	1 - 6 of 6 (1 selected)	Check Out	Step 2 O • X
der name S ·····	Effective 💌 🔠 Mana	Select Collaborators	
		Q. Search Full Name	locu
Repository		Full Name Rob Stark	ffec
lideos 7	00* 0:	🗌 Arya Stark 🖌 🖌 🗌 Jon Snow	ffec
unit 13		Ned Stark Arya Stark	ffec
int2_0	5 🖻 🖈 🔹 /	🗌 Rob Stark 🖌	ffec
ent3 21		CRA User	ffec
rd Operating Procedures 15	0 4 0 :	testeditor@ti.com	ffec
nstructions 4		Admin 103	
1		carjohnson@transperfect.com	
ites 1		🗌 Jon Snow 🗸	
int4 1		Jon Stark	
4			
		·	
		Previous 1 of 1 Next	
		Previous Check Out	

This improvement will allow document collaboration to occur with room participants that may not have direct access to the document in the document repository.

Documents can be managed in a folder by one set of users and then, as needed for



collaborative review, new users can be invited and their edits limited to only within the collaborative review.

This provides an easy way to gain input from subject matter experts, outside organizations, or other departments in a controlled timeframe without leaving the document open and editable for all the editors at all times.



CANCEL CHECK-OUT

	Title	
□ 🖪 ★ 🏵 🌣	Check In ×	^
🗆 🖬 ★ 🔅	What kind of version would you like to check in?	
- 🗟 ★ 🔹	O Major 💿 Minor O No Changes	
🗆 🖬 ★ 🔹	Comments	
S 🗟 🖈 🖨 🌣		
🗆 🖄 ★ 🔹		
	Cancel Save	

This improvement will allow room administrators in a Content Management room to check back in a document checked out by another user. In cases where a user may unexpectedly be unavailable or unresponsive a room admin can free up the document locked by a collaborative edit or an individual edit.

SITE USER RESTRICTIONS

C Mo	ve to Study St	art-Up 🛧	import 👻 📢	🕨 Export 👻 🔤 Er	mail 🔒 Print 🖽 Co	mpare	🗮 Documents Cart (
1 -	8 of 8 (1 sele	cted)		0	T Filters III Select Col	umns 🐵 Default View 👻	🖌 Expand
	Select In	vestigative	Site			×	Metadata History
	Select Spec	tific Site					Subject Participation
	2 Sites 1 S	Selected				Search Q	Reason for not using auto Docu
		Site #	Principal Inve	estigator	Institution Name	Country Name	
	•		1 2		SWS IS 1	<u>^</u>	Comments
	- 🖂		Ben Tsai		SWS IS 2		
	Firs	it Name	Last r	name	Email	Contact Type	Document Date
	Ber	n	Tsai		btsaimd@elilink2648	Principal Investigator	DD MMM YYYY
							Category *
							Investigative Site
					4	Previous 1 of 1 Next 🕨	Investigative Site
				Cancel	Select		Document Type
		<					Cancel Sa
	Grid \	view	Docur	ment View	н 4	Previous 1 of 1 Next 🕨 🕅	Previous Document



This improvement will restrict users assigned to sites to only see their assigned sites in the Investigator site list when adding documents or updating document metadata. This provides an additional security measure eliminating other site names or numbers from site-specific users.

REPORTING FEATURES Improved TI Standard and Ad hoc Reports

In TI 10.1, all TI users will now have access to OOTB standard reports using Jasper Reports solution. TI Reports will no longer support reporting solutions based on legacy Izenda Reports. Additionally, ad-hoc reports would be enabled by default for all users with access to the TI Reports module.

The following reports have been added in 10.1:

- SSU Document History Report This new report provides a complete history from the time the document is uploaded in TI SSU module through various approval stages.
- Document Placeholder Report This new report provides the complete history of any placeholders created, modified, or deleted in the TI system.
- Quality Review Report This new report displays the history documents (passed and failed) through the Quality Review module in TI.
- Inventory and Completeness Report Site The new report shall display the inventory and completeness of all documents (essential documents, non-essential documents, and placeholders) for Site category. The report shall also provide the Zone, Section and Artifact details related to each document type.
- Inventory and Completeness Report Country The new report shall display the inventory and completeness of all documents (essential documents, non-essential documents, and placeholders) for Country category. The report shall also provide the Zone, Section and Artifact details related to each document type.
- Inventory and Completeness Report Trial The new report shall display the inventory and completeness of all documents (essential documents, non-essential documents, and placeholders) for Trial category. The report shall also provide the Zone, Section



and Artifact details related to each document type.

• Inventory Report - Staging and Upload - The new report shall display the inventory all documents for all categories that are available in the staging and inbox folder. This report will help take inventory of documents which are available in the system but have not been coded yet.

Chapter 2. Signing into Trial Interactive

This section includes basic information that will help you get started with Trial Interactive 10.1.

- System Requirements
- Receiving and responding to Room Invitation
- User Registration
- Multifactor Authentication
- Logging in on Subsequent Visits
- Requesting a Password Reset during Login
- Logging in without access to rooms

Receiving and Responding to Room Invitation

Once a Trial Interactive room Administrator has sent you an invitation, you will receive an email message with a welcome message and a Registration link.

Figure 1: Room Invitation Email



Click the **Registration link** near the bottom of the message, and you are directed to the Trial Interactive user account registration page. Follow on to the User Registration page (*page 36*) for the complete process.



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User Registration

🕛 Important:

- 1. You register to the application only once as a first-time user when you are invited to a room (page 36) through an email.
- 2. Once you register, you can sign into your room.
- 3. If you are invited to other rooms hereafter, you need not register again, but need to sign in to access the rooms.
- 4. For all subsequent invitations to rooms, you are notified by emails.

After you have received your invitation email with a welcome message and Registration link, you will need to follow the steps as below to register:

Step 1: Registration - Required Information

			-	
Registration	Step	1 000		
Required infor	mation			
Your user account	gives you to invintation-or	nly rooms		
hosted on Trial Inte	eractive			
First Name*	Last Name*			
Fire alle				
Email*				
Danswordt		F	assword requirement	s:
Password*			. Must have at least 8	characte
		Strong a	. Must contain one up nd digit OR one specia	percase al Chara
Confirm Password		3	. Valid special charact	ers are -
Jumproxs				
Place coloct the co	crot question and ancum	r for your	1.000	
password recovery	er er guesuur and answei	i ini yuur		
Question 1*			a little sea	
Question		~		
Answer*			in the second seco	
			P	

- 1. Click the Registration link near the bottom of the message, and you are directed to the Trial Interactive user account registration page.
- 2. Type in your first name, your last name, and your email address as requested on the page in the appropriate fields.



3. Create your secure password and confirm the password by re-typing it in the **Confirm password** field.

Note: Hover the mouse over the Password field to see the tooltip on password requirements.

- 4. Select your password recovery question from the dropdown list.
- 5. Type in your answer in the Answer field and click Next to take you to Step 2.

Step 2: Registration - Optional Information

On this page enter your contact address, phone number, and other details as required and click **Next** to take you to **Step 3** or **Previous** to take you to **Step 1** if you want to change some information.

Note: You can skip this page and fill it up later from your User Login after you have logged in.

Step 3: Registration - Custom Information

Enter your contact email ids. You may want to click **Previous** to go back and verify the information entered or click **Register** to be taken to a confirmation page.

Click the link to the secure Trial Interactive website to login and begin work.

Signing in on Subsequent Visits

To log in to Trial Interactive

- 1. Using your preferred internet browser, navigate to http://www.trialinteractive.com
- 2. Click the Client Login button located at the top right corner of the page.
- 3. The Trial Interactive Login page with links to a suite of e-clinical solutions offered by TransPerfect Life Sciences appears. Click the links to delve further into the solutions provided by TransPerfect Life Sciences or log in.
- 4. Enter the Username and Password. The Username is the full email address that was submitted by the client-appointed Administrator.
- 5. Click Login.

If you are logging in the first time, the Trial Interactive Homepage (page 40) for the

account associated with the

login username appears, else you are redirected to the same location in the application that you were in upon subsequent login.

Note: You can bookmark **http://www.trialinteractive.com** on your browser for easier access to the Trial Interactive corporate homepage. By accessing Trial Interactive through this site, you will consistently see news and new information about Trial Interactive.





Requesting a Password Reset

In the event that you have forgotten your password, click **Forgot Your Password?** at the bottom of the login window to initiate an account password reset.

Users do not need to contact the Help Desk. In most cases, the user can

We`ll email you a link to a create a new password.	page where you can easily
To assure our messages ar please add origami-suppo to your Address Book or Sa	e not accidentally filtered out ort-tilatest@protonmail.com afe Sender List.
Email	
Email vourmail@example.com	

perform the Password Reset operations without any outside help.

- 1. Enter your email address in the field provided.
- 2. Click Send Request. The next window in the Password reset wizard opens.
- 3. You will receive an email with the Reset Password link.
- 4. Click the link to lead you to the Password Reset page.
- 5. Respond to the security questions and click Next.
- 6. You are taken to the Change Password page. Enter the new password and confirm again.
- 7. Click Set new password.
- 8. The system confirms that the password was successfully reset. Click Back to the login page to login with your new password.

Signing in without access to rooms

If a user who does not have access to rooms in the system tries to log in, such a user is automatically logged off and redirected to a separate advisory page. A user might not have access to rooms if the user's access to the rooms has expired or revoked.

Refer to the screenshot below for a view of a typical advisory page.



←) → ♂ ଢ	Attps://secure.trialinteractive.com/origami/tix/#/no-access	🗵 🏚 🔍 Search	⊻ ⊪\ ⊡ ŝ
			Sign out
testsab2@ti.com do	esn't have access to any of the rooms.		

Click the Sign Out button to redirect to the standard login page.

Note: You can contact the helpdesk if you want to configure a different message to be displayed on the advisory page.

Chapter 3. The Trial Interactive Home Page

This section helps you access rooms as well as Overview and Detailed summary of rooms.

After signing in to Trial Interactive, you are landed on the Trial Interactive Home Page as shown in the screenshot below:

	Trial Interactive 👻 Home				Q Search 🌲	AS Arya Stark •
O OPEN	Search for Room		٩)		
A VEW	All 7 Favorite 0 Recent 4 eTMF 2 Study Start-Up 1 Collaborate 2	TI Docs 3				
SELECTOR	Last Visit Date Room Name Created Date Total Documents Expired	Documents	Expiring Documents	Open Queries		
	Sort Descending -				Overview	Detailed View
	* Training Room 1 206	8 Countries	🊠 10 Pending Sites	7 Active Sites	598 Total Documents	Add 🗸
	* TI Docs Master ALPHA 445				14 Total Documents	Add 🕶
	* TI Docs 335				396 Total Documents	Add -
	* Michael Demo	8 Countries	A 8 Pending Sites	3 Active Sites	901 Total Documents	Add 🗸

Click the required Room Name to enter a room.



	Trial Interactive + Home	Q Search 🌲 🛛 Arya Star)
(Search for Room Q	
P	All 7 Favorite 0 Recent 4 eTMF 2 Study Start-Up 1 Collaborate 2 TI Docs 3	
I	Last Visit Date Room Name Created Date Total Documents Expired Documents Expiring Documents Open Quite	eries
S	Sort Descending -	Overview Detailed View
	Training Room 1 206 & Countries 🚠 10 Pending Sites 🛱 7 Active S	tes 📑 598 Total Documents 💽 Add 🕶
	* TI Docs Master ALPHA 448	T4 Total Documents O Add -
	* TI Docs	📔 396 Total Documents 🛛 O Add 🗸
	★ Michael Demo 118 A 8 Pending Sites	tes 📑 901 Total Documents 📀 Add 🗸

Note: Once inside a room, you can reach this page from the Main Navigation (*page 53*) by clicking the Navigation Grid icon. Refer to the screenshot below:





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You can do the following from the Trial Interactive 10.1 Home Page:

- 1. View Rooms
- 2. Search for Studies, Sponsors, and Sites across all rooms
- 3. Cross Study Document Search
- 4. Get a Summarized Overview of rooms
- 5. Get a Detailed View of rooms
- 6. Upload Documents to a Room
- 7. Add Users to a Room
- 8. Filter and Sort Rooms
- 9. View and Mark favorite rooms

All the above are accessible from the left panel of this help.

Room View

TI Home page provides you with the different views through which you can filter rooms.

Filter categories are placed in the left pane. If it is closed then click on Open like shown in below screenshot to open it.

Trial Interactive + Home		
View by Category -	Search for Room	
View Rooms By		
Category	All 7 Favorite 0 Recent 5 eTMF 2 S	tuc
Status	Last Visit Date Room Name Created Date	2
Room Type	Open Queries	
Sponsor	Sort Descending	
Product	Training Room 1 206	8
Program	TI Docs Master ALPHA	
Country	* Michael Demo	8 (
Cancel Select	* Aa TI Docs Sandbox 419	
	★ TI Docs 335	



Viewing Room Details

You can also view the details of the room and the related information by clicking the '**Overview**' or '**Detailed View**' to the extreme right of the

All 7 Favorite 0 Recent 5	eTMF 2 Study Start-Up 1 Collaborate 2 TI Docs 3	
Last Visit Date Room Name	Created Date Total Documents Expired Documents	Expiring Documents
Open Queries Sort Descending		Overview Detailed View
Training Room 1 206	😡 8 Countries 🛔 10 Pending Sites 📋 7 Active Sites	615 Total Documents
★ TI Docs Master ALPHA		1 Total Documents Add -
Michael Demo 118	🐼 8 Countries 🛔 7 Pending Sites 🚔 4 Active Sites	∎ 847 Total Documents 🕢 Add 🕶
★ Aa TI Docs Sandbox		16 Total Documents 🔂 Add 🗸
* TI Docs		∎ 398 Total Documents

home page. Refer to the screenshot below:

Besides TI Home Page, the Room Details can also be viewed from the User Menu (*page 56*) after entering a room.

Note: This panel of Room Details is static and can be viewed irrespective of the view selected of the rooms.

Room Search and Accessing a Trial Interactive Room

Room Search

Trial Interactive allows you to search for rooms easily in

cases you have access to hundreds of rooms. To perform

a room search:

1. Enter the required room name in the Search box at the top of the page and press Enter on your keyboard.



2. Rooms matching the search criteria are displayed in the panel below the filters, else a message **No rooms found** is displayed. Refer to the

Training	×	
All 1 Favorite 0 Recent 1	eTMF 1 Study Start-Up 1	
Last Visit Date Room Name Open Queries	Created Date Total Documents Expired Documents	Expiring Documents
Sort Descending		Overview Detailed View
Training Room 1	🚱 8 Countries 🛔 10 Pending Sites 📋 7 Active Sites	615 Total Documents

screenshot below:

Accessing a Trial Interactive Room

Click on the required room name in the panel to enter the room. Refer to the screenshot below:

Last Visit Date Room Name	Created Date To	tal Documents Ex	pired Documents	Expiring Documents	
Open Queries					
Sort Descending				Overview De	etailed View
Training Room 1	8 Countrie	es 🛔 10 Pending Sites	🗿 7 Active Sites	615 Total Documents	🔂 Add 🗸

Cross Study Document Search

Documents Search

To perform a cross-study documents search, perform the following steps:

- 1. From the Home Page, or from within a room as appropriate, click the **Search** icon located at the top right corner of the screen.
- 2. The Search window appears, which consists of the following sections:
 - a. The Search textbox.
 - **b.** The **Documents**, **Queries**, and **Users** radio buttons (these are available only when a search is being performed from within a room)
 - c. The Limit search to the current room checkbox.
- 3. Select the Documents radio button. The documents grid appears below.

Search		
1572	×	
Documents Queri	es 🕜 Users	☑ Limit search to the current room
↑ Import	▼ 🖻 Email 🖶 Print 🔲 Compare	🐂 Documents Cart 0 🔹 🖬 Layout 🔹
1 - 50 of 875 (0 selected) 🗘 🕇 Filters 🖽 Select Columns 🛷 Views 🗸	r Expand
	Submitted Name	
🗆 🔄 🔶 🛧 🖉 💿	1572	
	Acknowledgement IB Signature Page_pdf-r	
🗆 🖪 🗙 🔶 ★ 🖉 🚳	Certificate of Liability Insurance_pdf-r	
	Certification _ Accrediation	No document selected
🗆 🖪 🔶 🛧 🖉 🌣	Clinical Protocol Synopsis	
	Confidentiality Agreement_pdf-r	
🗆 🖪 🔶 🛧 🖉 🔶	Contact Details_List_pdf-r	
🗆 🖪 🔸 📥 🔅	CTA .	
Grid View	Document View A Previous 1 of 18 Next M	Previous Document Next Document

You can perform the following action from the Search Window:

- 1. Code the document
- 2. Import and Export the document
- 3. Email document
- 4. Compare documents

TI Home Page Filters

TI Home Page provides a variety of filters through which you can filter the rooms. Refer to the screenshot below:

All 7	Favorite 0 Recent	eTMF 2 Study	Start-Up 1 Colla	borate 2 TI Doo	cs 3	
Last Ope	Visit Date Room Name	Created Date	Total Documents	Expired Documen	ts Expiring Documents	
Sort	Descending 🔻				Overview	Detailed View
*	Training Room 1	8 Cc	ountries 🔒 10 Pendin	g Sites 🔮 7 Active	Sites 615 Total Documents	Add 🗸

The filters consist of the following main filters:

- 1. All: This link displays all rooms that you have access to.
- 2. Favorite: This link displays the list of all rooms that you have marked favorite.
- 3. Recent: This link displays the list of rooms that have been visited recently with the latest visited room at the top.
- 4. eTMF: This link displays all eTMF rooms.
- 5. Study Start-Up: This link displays all Study Start-Up rooms.



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6. Collaborate: This link displays the list of all TI Collaborate rooms.

Below these main filters, TI Home Page provides **Additional Sortings** which allows you to sort the room as per the options in the sortings. *These Additional Sortings varies with every main filter*.

Summarized (Overview) View of Rooms

From the Home Page, click the **Overview** button located at the top right corner of the page to get a long-listing of rooms that you have access to with a count of the following metadata:

- 1. Countries where sites are located
- 2. Active Sites
- 3. Pending Sites
- 4. Total Documents

Refer to the screenshot below:

Sort Descending		Overview Detailed View
Training Room 1 206	🐼 8 Countries 🛛 🚠 10 Pending Sites 📋 7 Active Sites	total Documents
TI Docs Master ALPHA		■ 71 Total Documents
Michael Demo 118	🚱 8 Countries 🛔 7 Pending Sites 🔮 4 Active Sites	🖺 847 Total Documents 🚯 Add 🗸
* Aa TI Docs Sandbox		📔 16 Total Documents 🚯 Add 🗸
* TI Docs		S98 Total Documents 🚯 Add 🗸

Countries

The **number** next to **Countries** link shows the **total count** of the countries where clinical trial sites pertaining to a room are located.

Active Sites

The number next to Active Sites link shows the total count of sites that are activated.

Pending Sites

The number next to Pending Sites link shows the total count of sites that are pending for activation.

Total Documents

The number next to Total Documents link shows the total count of documents pertaining to a room.



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Detailed View of Rooms

From the Home Page, click the **Detailed** button located at the top right corner of the page to view rooms and studies as large cards with the following information:

- 1. Open Queries
- 2. Collected Documents
- 3. Missing Documents
- 4. Expired or Expiring Documents
- 5. Require Coding
- 6. Quality Control 1
- 7. Quality Control 2
- 8. Final Documents
- 9. Rejected Documents Refer to the

screenshot below:

Last Visit Date Room Name Open Queries	Created Date	Total Documents	Expired D	ocuments	Expiring Document	s
Sort Descending					Overview	Detailed View
Training Room 1 206	🔇 8 Countri	es 🛔 10 Pendin	g Sites 📑 7 /	Active Sites	616 Total Documents	🔂 Add 👻 😂
Created 24 Jun 2017	78 Collected Documents	187 Missing Documents	444 Required Coding	140	9 Expired Documents	
Project Code Sw3 training Koom	0 Expiring Documents	44 Open Queries	required county	- mar bocumenta	expired obtainents	
TI Docs Master AI PHA	-					-

Click the required tab next to the room name. The **Document** window opens which displays the list of documents. The screenshot below shows an example for the expanded view of the **Collected Documents** tab which displays the list of documents:

You can drill down the folders in the Index on the left to locate the required document.

Besides, you can also configure the columns in the **Document** window as required by clicking the **Update Columns** link at the top right corner of the

1 - 1 of 1 (1 selected)		C	T Filters	🔲 Select Columns	🛷 Views 🔻
	Submitted Name				
🗹 🖄 🔶 ★	Test Document 1 (1)				

window. Refer to the screenshot below:

Clicking the **Update Columns** link opens the **Grid Configuration** window which allows you to configure the columns in the document grid. You can add and delete the columns to display for a document in the **Document Grid** as required.

You can also change the order of the columns in the Selected Columns

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section by clicking the **Up** and **Down** buttons located to the right of the Selected Columns.

Similarly, you can view the list of documents for **Missing Documents**, **Documents that require** coding, Final Documents, Expired Documents, and Open Queries.

						Selec	ted Columns
							Title
elect Columns					×		Submitted Name
Available Columns	Selected Columns						Document Type
Q Enter Field Name or Title		Order By		💌 Asc 👻	Up		Document Id
Title	Title	Name	Width		Down		Description
Submitted Name	Submitted Name	Document_Title	100				Description
OCR							
Category							
Investigative Site							
Contact Name							
Z Document Type							
Document Id							
Description							
Comments							
Document Status							

Add Users to a Room

Follow the steps below to add users to a room from the Home Page:



- 1. Click dropdown at the extreme right of the Room Name on the home page.
- 2. Click the Add Users option from the dropdown list that appears. The Add Existing Users window opens. Refer to the screenshot below:



User Invitation		×
User Group Members	hip	
Email*	testUser@ti.com Q	Î
First Name	Last Name	
Title		
Role*	Administrator	
Expiration Date ?		
Actions	•	
Organization*	transperfect.com 🔹 🕇	
Mobile Number		
Phone Number		
A _1 _1		-
	Cancel Save	

- 3. You can choose to select multiple rooms to add users to by clicking Add button next to the Room textbox.
- 4. Enter the Email Address of the user, assign Role to the user, select Actions to assign to users.
- 5. Select the Groups to add users to the group. You can select multiple groups.
- 6. Click Create. The users get added to the room.



Upload Documents to a Room

Follow the steps below to upload documents to a room from the Home Page:

🔂 Add 🗸

- 1. Click dropdown at the extreme right of the Room Name on the home page to reveal the options.
- 2. Select the Document option from the dropdown list that appears.
- 3. Drag and drop the files OR click Browse at the bottom of the page to navigate to the required document to be uploaded. See below screenshots:

Training Room 1 - Start-Up / Docu	ments									1	Q Search	O Add -	
By Site	*			👻 🖾 E-Mail	🕈 Import 📷 I					*	Document		
101 Hamilton		^		Submitted	Generated	Q	Re	Added By	Submitted		Required fiel	Task	aster
102 Juliano		- 1										🛓 Site	

File Name	Size Upload Status	🗹 Documents Metadata	00
		Category	
			•
		Investigative Site	
			<u>م</u>
	→ ①	Country	
			•
	Drop Files and Folders Here - or -	Document Type	
	Use Browse Button Below		۲
		Comments 😧	
Upload Progress	Metadata Progress No files	Document Version	

4. Once the document is added, click on the **Import and Apply Metadata** button to import the document.

Import Documents		
File Name	Size	Upload Status
🗌 🔄 Test Copy.xlsx	53.1 KB	not uploaded



ſ

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🗹 Documents Metadata	o;
Category	
	•
Investigative Site	
	<u>گ</u>
Country	
	•
Document Type	
	•
Comments 😧	
Document Version	
Import and Apply Metadata	ancel

5. Once the document uploading is completed, the system displays a notification to the user regarding the same.



Marking Favorite Rooms

Many users are granted access to more than one Trial Interactive room. Users can make particular rooms easier to locate by marking the room or rooms as Favorites. This can be done in two ways.

1. From the home page by clicking the star which changes its color to golden on selection to the left of the room name. Refer to the screenshot below:



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Search for Room	٩
All 7 Favorite 0 Recent 5 eTMF 2 Study Start-Up 1 Colla	borate 2 TI Docs 3
Last Visit Date Room Name Created Date Total Documents Sort Descending	Expired Documents Expiring Documents Open Queries
Training Room 1	🥥 8 Countries 🛔 10 Pending Sites 🗒 7 Active Sites
TI Docs Master ALPHA	



- 2. On entering a study room, you can add it to Favorites by clicking the star at the top left corner of the page where the room name is displayed. The room can easily be removed from the list by clicking the star again. Refer to the screenshot below: The list of all rooms to which you are assigned is also available through the user profile.
 - a. Navigate to My Profile Settings from the User menu.
 - b. Select Notifications from the menu on the left.
 - c. Click the golden star to the right of the room names to mark the selected rooms as Favorites.

	Trial Interactive - My Profile / Notifications
o:	Favorites All Rooms
	Search Q
	📄 Training Room 1 🛛 🔶

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Adding Tasks to a Room

To add documents to a room:

 Click the +Add dropdown to the right of the required room name and select the Add Task option. Refer to the screenshot below:

Training Room 1 - Start-Up / Docu	ments									Q Search	O Add ▼
sy Site	*	Document	👻 🖾 E-Mail	🕈 Import 🛛 📄 N	love to	the eT	MF		*	Document	
101 Hamilton			Submitted	Generated	Q	Re	Added By	Submitted		Required fiel	Task
102 Juliano											🛓 Site

- 2. The Create Task window opens.
- 3. Fill in the details as instructed on the screen.

Create Task	د
Subject	
Start Date	DD MMM YYYY
Due Date	DD MMM YYYY
Priority	Normal
Status	Not Started 🔻
Complete %	0
Description	
Assign To *	Arya Stark ×
Reminder	30 Jan 2020
Category	Not specified
	Cancel Save

4. Click Save when all the information is filled.

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Chapter 4. Main Navigation and Inter-Room Navigation

Know how to access applications from within Trial

Interactive and navigate between rooms. From here,

find more details on the following:

- 1. Main Navigation from Home Page
- 2. Main Navigation from Within a Room
- 3. Navigating between Rooms

Main Navigation from Home Page

Main Navigation from the Home Page can be accessed by clicking the Four Dots located at the top left corner of the page marked in Red box in the screenshot below:



You can access the **Home Page** and **Tasks** application from the Main Navigation. Besides applications, you can also access other **Application Links** from the Main Navigation of the Home Page. These application links take you to the website of the respective links.

Main Navigation from within a Room

On entering a room from the Home Page, you are landed on the **eTMF/Documents** Module.

In a room, as a user of Trial Interactive, you can choose which application to view in a

dashboard by clicking the Four Dots

located at the extreme top left corner of the page. Refer to the screenshot below:

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The different modules that can be viewed from a particular Main Module depend on the functionality that can be allowed from the particular Main module. Within Trial Interactive, you can view the following Main Modules:

- 1. Home (page 40)
- 2. Tasks (page 429)
- 3. Trial Interactive eTMF and the Documents Module (page 199)
- 4. Quality Control
- 5. Start-Up
- 6. Audit/Quality Review (page 346)
- 7. Communication (page 431)
- 8. Q&A (page 438)
- 9. FAQ (page 29)
- 10. Reports (page 498)
- 11. Collaborative Workspace (page 451)

Navigating between Rooms

With this version of Trial Interactive, you can now seamlessly change rooms from any location within the application without having to navigate back to the home page. Just click the dropdown next to the room name to open a popup window with the list of all the room names to which you have access. Refer to the screenshot below:

Click the arrow next to the room name. Select a room from the dropdown list that appears.

Refer to the screenshot below:

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Chapter 5. Document Types and Management

In this section, we discuss creating Document Types and various functionalities related to it. In the conduct of a clinical trial, scores if not hundreds of different kinds of documents need to be collected, categorized, and filed – some general documents, some documents that are specific to the countries in which studies are being conducted, and some documents that are specific to the investigative sites involved in the study.

All of these document types need to be set up and defined in the Trial Interactive room:

- 1. Navigate to Main Navigation -> Settings. The Room Settings page opens.
- 2. Select Document Types from the menu on the left.
- 3. The Document Types option expands to reveal two sub-options:
 - a. The Document Types Management and
 - b. The Common Configuration.
- 4. Click and view each panel separately. Refer to the screenshot below:



The Documents under the Document Types created from here can be viewed under the By

Document Type (page 232) view. Each view or panel are discussed in separate topics

accessible from the left pane of this help:

- 1. Document Types Management
- 2. Common Configuration



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Document Types Management

Note: Super Administrator users have the ability to turn On and Off Administrator access to Document Types Management Settings.

Attention: This tab may not be available in your data room. The Document Types Management tab, if enabled, for Administrator users, allows access to the auto-naming rules and to linking metadata fields to document types, enabling conditional metadata. Auto-naming settings are complex, and it is preferred that Administrators work with the Trial Interactive

Training Room 1 • Settings					Q Se	arch 🛛 💿 Add 👻	A AS	Arya Stark 👻
Search Q 🕷	About	Document Types Management *						
🕨 🌣 General 🔷	Nodify Doc	ument Types 🕴 🛧 Import 🛛 🕹 Expor	t 📲 Mass Coding (🗢 Delete 🛛 🖻 A		nts 🗖 Change Lo	g Type name	Q Select
Milestones	By Category	¥ 0 0	Document Type	Auto Nam	Profile	Metadata Fields E	ulk Fields Update	Default Values
🙆 Inbox	🕶 🖕 All Docu	ment Types			Document Type	: *		
Forms Settings	🕨 🖿 Gene	ral			Short Name			
✗ General Integration	🕨 🖿 Count	try						
Documents	Invest	tigative Site			Document Type	: Id: 🔞		
Document Types Document Types Management					Category:			
Common Configuration		1			Auto Name Rul	es:		
Required Documents Gountries								1
Investigative Sites					Related Folder:			
IRB/EC								٩
🕨 📼 Email					Due Date: 0			
Document Templates								
🕨 🔄 Audit					- Phases / Mile	estones		
Vorkflows					Study Milasto	nac	Sa	ve Cancel

Click the Document Types Management tab to open its dashboard on the right.

From this page, you can perform various actions as below. All of these are discussed in separate child-topics. Expand this topic from the left pane of this help to reveal the following child-topics:

- 1. Modify Document Types' Tree
- 2. Building the Document Type Profile
- 3. Specifying the Related Folder
- 4. Include Phases/Milestones
- 5. Adding Document Types to Required Documents
- 6. Include in Document Tracker Report
- 7. Auto Document Type Prediction Keyword(s)
- 8. Modifying Document Types Fields
- 9. Default Values

Modify Documents Types

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- 1. Click Modify Document Types option from the ribbon above the dashboard.
- 2. A new Modify Document Types' Tree window opens, displaying the folder structure of Document Types in a tree view. Document Types can be added to the category folders, edited in their current positions, and deleted through this view. In the figure below, the Investigative Site folder is open, displaying the document types that are added in that category.

Modify Document Types ↑ Import ↓ Export ■ Mass Coding O Delete 2 Add to Required Documents □ Change	Log Type nar
	16
By Category O Document Type Auto Nam Profile Metadata Fields	Bulk Fields Up
All Docu	×
Add / Edit O Delete	
The Course All Document Types	
General	
Inves	
O 02 Central Trial Documents	
Segulatory	
I 04 IRB or IEC and Other Approvals	
Site Management	
▶ 🦫 🗋 06 IP and Trial Supplies	
▶ 🎙 🗋 07 Safety Reporting	
▶ 🦫 🗆 08 Central and Local Testing	
Image:	
I 10 Data Management	-
Save	Cancel

Figure 43: Modify Document Types' Tree

- **a.** To add a new document type, click the main category into which the new document type is to be assigned. If the folder already contains document types, click the + sign next to the category's folder icon to see the document types already contained in the category. The categories are marked by the yellow folder icons and the actual document types by the blue document icon.
- **b.** Click the **Add** button near the top of the window, or right-click the folder where you want to add the new document type, or right-click the document type under which you want to add a sub-type. A new line appears with an editable field that reads **New Document Type**. Refer to the screenshot below:



Modify Document Types' Tree	×
O Add / Edit O Delete	
- All Document Types	<u>^</u>
🔻 📚 General	
🕶 💊 🗆 01 Trial Management	
Trial Oversight	
🕨 🔍 🗔 Trial Team	
Trial Committee	
🕨 🗣 🗖 Meetings	
Seneral	
New Document Type	
O 2 Central Trial Documents O 2 Central Trial Docu	
🕨 🍤 🖸 03 Regulatory	
I 04 IRB or IEC and Other Approvals	-
Hs	ave 🚺 😫 Cancel

- c. Type the name of the new document type to be added to the category folder.
- **d.** Press the Enter key. If you have more document types to add to this or other categories, you can repeat this process.
- e. When you have added all of the necessary new document types, click Save at the bottom of the window. That window closes, and you return to the primary Document Types view. The document types that you have just created has not been routed to a proper index position. Refer to the screenshot below:
- f. Similarly, you can also edit or delete document types.

Building the Document Type Profile

Source And America Modify Document Types	🗣 Exp	port	Ma Ma	ass Coding 🗢 Delete 🚦	Add to Required Documents	Change Log	Type name.	. Q Selec	t filter 🗙 🛪
By Category 🗸	0			Document Type	Auto Naming Rule	es Profile	Doc. Type Fields	Bulk Fields Update	Default Values
😑 늘 All Document Types			lidation	category 1 Category - 4	Document type(s)	Document Type	e: "		
🗉 🧰 General ed		10		validation type 1\sub v	lidation 1	validation type	3		
Country		-		validation type 1		Short Name:			
Investigative Site		-		validation type 1					
				validation type 2		IRB Document	Type Id:		
third category		14	- 7	validation type 3					
Field validation category				This document type is	listed in required documents	Desement Tem			
Field validation category 2						Document Type	e id:		
🗉 🛑 validation category 1									
🗉 🚞 validation category 2						Category:			
						validation cate	igory 1		0
						Auto Name Rul	les:		
									F
						-	-		
						Related Folder:			
						(Not Specified)		
									q
						Due Date 1			
						Disaster / Mil	les torner		
						Phases / Mil	restories		
						Study Mileste	ones: 💿		
									*
						Include in De	ocument Tracker Repor	t	
						Auto Documen	t Type Prediction Kevy	t vord(s): 0	



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About Document Types Management *	
Solution So	Add to Required Documents Change Log Type name Q Select
By Category	Nam Profile Doc. Type Fields Bulk Fields Update Default Values
✓ ► All Document Types	Document Type: *
🗸 🏲 General 🖉 📏 🚊 05 Site Management	05 Site Management
01 Trial Management	Short Name:
 © 02 Central Trial Documents © 03 Regulatory 	Document Type Id: 📀
 V 0 00 (regulatery) V 0 04 IRB or IEC and Other Ap 	Category:
05 Site Management	General
06 IP and Trial Supplies	Auto Name Rules:
▶ 🍆 07 Safety Reporting	×
🕨 💊 08 Central and Local Testinç	Related Folder:
▶ 💊 09 Third Parties	(Not Specified)
10 Data Management	Due Date: 0
11 Statistics	
Country	Phases / Milestones
Investigative Site	Study Milestones Save Cancel

- 1. Select the new document type by clicking the checkbox next to the icon and the document type name. The panel on the far right becomes active.
- 2. In the **Profile** tab, type in the **Short Name** for the document type. This can be the same as the **Document Type** name that you created in the previous steps, or it can be abbreviated if the original name is long.
- 3. The IRB Document Type ID is one of the fields besides Site ID and IRB Number that is required by the system for IRB Integration. This field will be available only if IRB Integration is enabled in the room.

This field can accept multiple values separated by semi-colon and should be unique

within the document type category.

- 4. The **Category** has already been assigned by your first steps of creating the new document type, so this field is not enabled.
- 5. Click the wrench icon next to the Auto Name Rules field. When the metadata gets filled out for documents of this type, the auto naming rules you set up here will be applied to these documents. The client typically supplies a file with prescribed document types and the auto naming rules that they want to be assigned to the document types. An Auto Name Rules window opens. Refer to the screenshot below:



Luto Name R	ules		
Rule Editor:			
Preview:			
			c
Available Temp	plates:	Field Incortions	
HardCoueu	PURCOURS	Field Inservoris	
Description			Insertion
PrincipalInvest	ågatorFirstNar	ne	##PrincipalInvestigatorFirstName##
PrincipalInvest	tigatorLastNan	ne	##PrincipalInvestigatorLastName##
SponsorName	8		##SponsorName##
ContactFirstN	ame		##ContactFirstName##
ContactLastNa	ame		##ContactLastName##
ProgramName	Ē		##ProgramName##
Insertion Desc	cription		
			and the second s
			OK Cancel

The following set of instructions describes the insertion of a standard set of fields for auto naming of documents of a particular type. For this example, the proposed naming rules include the study Principal Investigator's first and last name and Sponsor Name.

- **a.** Under the **Hardcoded** tab, double-click a description to be inserted as auto naming rule. The insertion appears in the **Rule Editor**.
- If you want to include fields present under the Field Insertion tab, doubleclick the description and further click the green arrow in the Select Fields Document Profile. This too gets appended in the Rule Editor. The order in which you select these naming elements is the order in which they will display.


Field Name	Field Title	
\$AmendmentitemNumber\$	Amendment Item Number	+
\$ClonedFrom\$	Cloned From	+
\$ClonedTo\$	Cloned To	+
\$CopiedToLinkedRoomsBy\$	Published to eTMF By	+
\$CopiedToLinkedRoomsDate\$	Published to eTMF Date	+
\$Country\$	Country	+
\$CraDocumentStatus\$	CRA Document Status	+
\$DocumentUrl\$	Document URL	+
\$EmailRecepients\$	Email Recepients	+
\$EmailRecepientsCC\$	Email Recepients CC	+
\$EmailSender\$	Email Sender	+

c. Click Close when you have included all of the necessary fields.

Note: The fields stored under the Hardcoded tab are fields typically used in building auto naming patterns. To include these, insert your cursor in the spot in the Rule Editor where you want this field to appear, then double-click the Description of the field and it will be inserted into the naming pattern.

d. Back in the **Auto Name Rules** window, click the white arrows icon to the right of the **Preview** box. The box populates with a generic preview of the selected Auto Naming pattern. Refer to the screenshot below.

Auto Name Rules	×
Rule Editor:	
##PrincipalInvestigatorFirstName##\$\$DP.\$AmendmentIte	emNumber\$\$\$
Preview:	
	0
Available Templates:	
Hardcoded Functions Field Insertions	
Description	Insertion

- e. Click OK at the bottom of the window. You return to the main Document Types view.
- f. Click Save at the bottom right of the Profile tab window.

Specifying the Related Folder

1. In the **Profile** tab in the panel on the right, click the magnifying glass icon next to the **Related Folder** box.



Related Folder:	
(Not Specified)	٩

A window opens, displaying the folders available for assigning the new document type.

2. Select the proper folder or subfolder for the document type.



In this example, we have chosen the Relevant Communications folder.

- 3. Click OK at the bottom of the window.
- 4. Back on the main Document Types view, click Save at the bottom of the panel on the right.



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Include Phases/Milestones

To add Document Types to Milestones in your room, click the Study Milestones dropdown in the Phases/Milestones section

of the Document Type Profile window. Refer to the screenshot below:

F	Profile	Doc. Type Fields	Bulk Fields Update Default Values		ues		
Sh	ort Name:						*
IR	B Document Typ	e ld: 🕜					
Do	ocument Type Id:	0					
	Milestone			Enabled	Auto		
Ca	room study mile	e 1					
G	Study dom 111					Η	
Αι	new study 1						
	milestone 3						
	milestone4						
Re	study 1						
(r	study 2						
	study 3						Е
D	domain study m	nile 1					
	domain study m	nile 2					
	domain study m	nile 3					
	room study mile	1, Study dom 111, r	new study 1, mile	stone 3		~	
	Include in Docu	ment Tracker Report					
Αι	ito Document Tv	pe Prediction Keywo	ord(s): 🕜				
E	nter keywords or	ne item per line					
							Ļ
			1	Save	Ca	ncel	

From the list of milestones that appear:

1. Tick the checkboxes to select the milestones that apply to the current document type

2. Click Save.

These milestones, when added to the document types, help to track the **eTMF Completeness** of documents associated with them, and generate **eTMF Completeness Reports**.



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Milestone Related Fields Auto Enabling

When a user selects one or more items in the Study Milestones, Investigative Site Milestones, or Country Milestones files in the Document Type Profile, the system will automatically mark the 'Milestone' and 'Milestone Date' document fields as visible and required. This will be reflected in the custom form fields list in the **Doc. Type fields window** of the selected Document Type; an

Profile	Doc. Type Fields	Bulk Fields Update	e Default Values	
Inherit from Ger	neral	🗡 Tools 🔻 🛛 Fie	ld name	Q
Title 🔺		Visible	Required	
кеуworaLooкup		×		
Material Item Deci	ision			
Material Item Num	nber			
Material Item Revi	sion Number			
Material Item Type	2			
Milestone			\checkmark	
Milestone Date		\checkmark		
Ongoing Review Id	đ			
Placeholder Id				
Popular Document	t			
Published By				
Published Date				
Published to eTMF	Бу			
Published to eTMF	Date			
Ready for eTMF				
Reason for not usi	ng auto Document Na	me 📃		
Recovered By Id				
Recovered Date				
Related Document	t			
Related Field				
Searchable Check	box #1			
Sender Address				
		[]		•
Grayed option	s cannot be changed d	lue to the mandato	ry system configurat	tion
			Save Cance	:

information message will also be shown. Refer to the screenshot below:

Besides the above, a document type can also be added to a milestone by either of the following ways:

- 1. From Required Documents window
- 2. From Sites Profile window while adding or editing sites

Adding Document Types to Required Documents

T R I A L INTERACTIVE

> You can know if a document type is added to the required documents list from the Required Documents icon that appears in the grid next to the document type category. Refer to the screenshot below:



A document type can be added to the required documents list from the Add to Required Documents button located on the toolbar above the Document Types Management window. Refer to the screenshot below:

About	Document Types Management *					
Nodify Docur	ment Types 🧪 Modify Categories	1 Import	🖶 Export 🕴 📲 Mas	s Coding 🔤 Delete	add to Required Documents	Change Log

Besides, you can also make a document type a required document from the Required Documents window.

Include in Document Tracker Report

To specify that any Document Type will specifically be included in the **Document Tracker Report**, tick the **Include in Document Tracker Report** checkbox from the **Document Types Profile** window. After making any changes, be sure to click **Save** at the bottom of the window. Refer to the screenshot below:



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Auto Document Type Prediction Keyword(s)

Out of the hundreds of potential document types that might be present in a study, many of those document types might be auto predicted. For example, Curriculum Vitae, the 1572 form, a financial disclosure form – practically any required regulatory pack document or any document for which a sponsor has a template to send to investigators. A Super Administrator user needs to activate this option in the room. When this feature is activated, and a document is uploaded, it goes into a queue. The system searches the first page of each document for the keywords entered for all of the document types for which keyword identifiers have been entered.

- 1. Open the Profile for the document type for which you want to add the Prediction Keywords in the **Document Types Management** settings.
- 2. Type Keywords into the field, one keyword per line.

Auto Document Type Prediction Keyword(s): 🝞	
STATEMENT OF INVESTIGATOR 1572 Vitae	

3. When all of the appropriate keywords have been entered, click Save at the bottom of the Profile panel.



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Modifying Document Type Fields

In some cases, you may need to change which metadata fields are available for a particular

document type.

1. To initiate a change in the availability of metadata fields, click the Doc. Type Fields tab next to the Profile tab in the panel on the right.

Profile	Doc. Type Fields	Bulk Fields Update	Default Values	
V Johert from	Investigative	Front - Funt	hame.	9
Title +		Visible	Required	
Cetegory		12	21	*
Dommenta		101	13	
Contact		393	- 221	
Copertor Inte	otroom date:			
Country		191	13	
Deleted By Id		22		
Deleted Date		12		
Disable auto I	locument Name	121	10	
Decement Cic	eied			
Document De	te:	581	-13	
Document No.	ma	12	12	
Document Sta	then.	50	13	÷.
Document Typ	ie.		11	

2. Uncheck the Inherit from {Category Name} box at the top

of the pane to break the inheritance. The pane becomes

active, no longer grey in appearance.

3. Click the boxes in the columns marked Visible and Required as dictated by the client request.

Note: If you have already established a standard set of metadata fields for the documents, you can use this shortcut:

- a. Click Tools.
- b. Select Clone Fields from.

Then select another document type whose metadata fields are the same.

4. When you have finished making the requested changes, click Save at the bottom of the pane.

Note: The Search box allows you to type in simple search criteria to help you find particular metadata fields in the list.



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Default Values

By implementing the **Default Values** options when defining a document type's profile coding, you can set a specific metadata field value to auto-populate based on the document type.

- 1. To use these new options, you must first create a custom metadata field in Form Settings. You must be sure to include the custom field in Coding before you save the final changes.
- 2. Select the specific document type to which you want to add the field that will auto-populate with the default value.
- 3. Click the Metadata Fields tab.
- 4. Click the necessary checkbox.
- 5. Click Save.
- 6. Click the Default Values tab.
- 7. Click the Add button.

The Field textbox activates. Click the dropdown arrow at the right end of the box.

- 8. Select the necessary custom metadata field from the list.
- 9. Press Tab on your Keyboard.
- **10.** Set the field's default value by typing the value in the textbox.

Profile	Doc. Type Fields	Bulk Fields Update	Default Values
🖸 Add 🤤 Del	lete		
Field		Default Value	

11. Click Save.

When any document is assigned to that document type, the custom field will auto-populate with the default value you established.

Common Configuration

Clicking Document Types Management opens its dashboard on the right. Refer to the screenshot below:

Search Q 🕷	About Common Configuration *
 Document Types Document Types Management Common Configuration Required Documents 	 Do not allow selection of main document type if there is a sub type for it Document Types Sorting Logical Alphabetical Order: Auto Name Separator: Allow edit fields with default value assigned
Required Documents	
Amendments	

• In the **Common Configuration** panel, you can make it so that users cannot select a main document type name if one or more sub-types exist for that



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type.

- In this panel, you also select whether Document Types are sorted by Logical order (the order in which they were entered) or sorted Alphabetically.
- Here, too, you select the default **Auto Name Separator**; you can choose any character, or you can make the auto separator a blank space.
- On enabling Allow edit fields with default value assigned, some document metadata fields will be filled automatically on creating a document and selecting a document type from the configured list.
- If you make any changes in this panel, click Save at the bottom of the panel.

Chapter 6. Trial Interactive eTMF and the Documents Module

The Trial Interactive eTMF Application acts as a central access point to not only Clinical Trial Documents (*page 222*) but also to eTMF Sites (*page 291*), Contacts, eTMF Completeness, and CRA Reconciliation Reports (*page 308*), reports in the form of **Dashlets** for all clinical trial activities, and also to IRB Integration and Potential Sites (*page 291*).

You can access this module from the Main Navigation (*page 53*). Refer to the screenshot below.



Once you enter the application, you have access to various modules within it and can toggle between the:

- 1. Dashboard Dashlet View
- 2. Documents
- 3. Sites
- 4. Contacts

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5. Milestones etc. from the menu bar on the left. Refer to the screenshot below

All these views can be enabled for you by the Super Admin through the Room Settings (page 85), and are discussed in separate topics.

Dashboard Dashlets

Know how to configure the dashboard and dashlets in a room.

All Trial Interactive dashboards are primarily composed of dashlets. As a user, you can configure your dashboards to suit your preferences, views, and convenience for efficient performance.

Individual users in Trial Interactive have the option to arrange their Dashboard views.

Arranging your dashboard views include deciding:

- 1. The layout of the dashlets on your dashboard by moving them around,
- 2. The dashlets to view along with their distribution on the dashboard, and
- 3. The configuration of each dashlet.

Dashlets

INTERACTIVE

A dashlet is a component in a dashboard with functionalities of its own. A dashlet may provide information on a particular feature in the form of a report, a graph, or a description on a particular topic. Dashlets are independent of each other and are contained in a dashboard. In a way of its own, they play a significant role in the look and feel of a dashboard.

To visit a Room Dashboard, click **Dashboard** from the left menu from the eTMF module.

Refer to the screenshot below:

ш	Training Room 1 → eTMF / Dashboard		Q Search O Add -	🜲 🚺 Arya S
436		Edit Dashboard	🗢 Edit Default Dashboard 🔻	O Dashlets
	eTMF			
프	eTMF Health Claimed & Unclaimed Documents Expiration Rejection & Clarification My Queries. Open Queries By Age			
4	Missing/Placeholders 👻			
Ŧ	50.0% Missing Placeholders		12 69,4% Missing Placehold	Sers 735

Dashboard Settings

As one of the sub-section of General room setting tabs, the Administrator will see the



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Dashboard Setup box. An Administrator can change the information that will be available to

users in the room when they access their Dashboard.

To modify the availability of dashlets to users, here are the steps to follow.

		S Edit Dashoo
etup Your Dashboard	· · · · · · · · · · · · · · · · · · ·	×
y Workflow locument processing Status in the locument Review Workflow	Search	Q
	Recent Communication Log Investigative Sites Common Cancel Save	

- 1. Navigate to Main Navigation-> Settings -> General -> Dashboard Setup.
- 2. Double-click any of the dashlet lines in the **Available for** column.

The field becomes active with a dropdown arrow at the right end of the field.

3. Click the dropdown arrow. A set of selections becomes available to the Administrator.

Dashlets		2
Title		-
Claimed & Unclaimed		Q,
Description		
Count of documents with the following workflow statuses of Unclaimed and In Progress (Claimed, Clarification Status)	Documents eTMF eTMF Health Claimed & Unclaimed	
Available for	Documents Expiration	
Editors and above	Rejection & Clarification	
	My Queries	
	Open Queries By Age	
	Users	
	Recent Communication Log	
	Investigative Sites	
	> Common	
	Cancel Save	

- 4. Select which users in the room will see any particular dashlet in their Dashboard views.
- 5. Click Save if you have made acceptable changes.

From the Dashboard Settings, the following activities are available:

- 1. Renaming a dashlet
- 2. Default Dashboard Setup

Above activities are discussed in details in the sections below.

Renaming a dashlet

To rename a dashlet follow the steps as below:

1. Double-click the name of a dashlet that you want to rename from the Dashlet column of the Dashboard Setup window.



- 2. Type in the new name into the activated field.
- 3. Click Save.

Default Dashboard Setup

You can set the default dashboard for the minimum level role by clicking the button at the bottom of the Dashboard Setup panel. The Default Dashboard Setup window opens. Make the appropriate choices as required and click OK.

Edit Dashboard	Edit Default Dashboard 🔻	Dashlets
	Reader	18
	Editor	1 2
	Administrator	





Configure Dashboard

The *Configure Dashboard* icon at the top right corner of the Dashboard page opens the **Setup Your Dashboard** window which lists out the dashlets available for a particular dashboard.

Refer to the screenshot below:



Setup Your Dashboard	? ×
Your dashboard includes the following dashlets. Use "Add" b "Remove" button to remove a dashlet from the dashboard.	Search > Documents Users Recent Communication Log > Investigative Sites Common ✓ About This Room Bulletin Board Project Links My Courses
Cancel	Save

The dashboard is divided into the following parent dashlets which have child dashlets associated with each of them:

- 1. Documents
- 2. Users
- 3. Recent Communication Log
- 4. Common

Click the arrow next to the required parent dashlets to revel the child dashlets to add them to the dashboard as shown in the screenshot above. On selecting the dashlets, click **Save** and the dashlets appear on the dashboard.

Laying Dashlets in your dashboard

To arrange the dashlets, simply drag-and-drop them to a location of your choice on your dashboard. This is demonstrated below:



	Training Room 1 👻 Start-Up / Dashboard				c	, Search 🔍 Add 👻 🌲 🤷 Arya Stark 🗸
20						Previous 1 of 1 Next
9						
⊘	X					
Δ.		Investigative Sites	÷			1
		Expiring Sites Milestone Type Rep	ort Recently Updated Sites Site A	ctivation Status E-Feasibility by Co	untry Study Monitoring Visits	C Distance @View
•		Site	Principal Investigator	Status	Main Contact	Main Contact Phone
,				No records av	vailable	
	Documents					
	Approved Submissio					Previous 0 of 0 N

Dashlet - Common Grouping

Common	0
About This Room Bulletin Board Project Links Tasks	
	St Edit
Welcome, Arya Stark,	
This is the training room for Ti10. The contents of the About This Room dashlet are configured by the room administrators from the Settings menu.	
Use this area to say whatever you would like about the ongoing study.	
I promise to use my powers for good.	

The Common Dashlet gives an overview of the room and the related information to the room.

Administrators can rename the dashlet by clicking the Edit icon from the top of the right corner of the dashlet and refresh the dashlet by clicking the Refresh icon.

The following tabs are available in the dashlets:

- 1. About The Room
- 2. Bulletin Board
- 3. Project Links
- 4. Tasks

Each of these is discussed in the separate topics. Click the topics on the left to open the topic.

About This Room

In this window, the user can see and change the information contained in the room's Welcome message, which is the message that all users see when they access the room. This space can be used to share important information about the study once the study is in full swing, and the welcome message is no longer necessary. Once you have made the desired



changes, click Save in the lower-left corner of the box.

You can view the Change Log History by using the Change Log button that is directly

available on the bottom right corner of the About this Room dashlet.

Abc	ut	About	This Room *															
\diamond	Times Ne	ew 👻	12pt	-	В	I	U	<u>A</u> -	<u>A</u> - 6		E	≣	Э	ŧΞ	łΞ	<u>.</u>	F	Insert ##UserName##
Welc	Welcome, ##UserName##.																	
The in techn	nformation ical ques	on conta stions a	ined in thi bout the us	s Trial Ir se of this	nterac s web	site p	oom o	send a	tes "Evalu in email to	Trial I	Materia nteract	l" and tive C	lient S	not b Servic	ces at	close test.	d to a <u>supp</u>	anyone, except as allowed under the Confidentiality Agreement(s). If you have any ort@trialinteractive.com
You v Read	/ill need . er.	Adobe	Acrobat so	ftware (versio	on 6.0	or lat	ter) to v	riew may o	f the d	locume	ents ir	n this :	site.	If you	l do n	ot ha	we Adobe Acrobat, please click <u>HERE</u> to download a free version of Acrobat
Some	of the d	locumer	nts in the s	ite may	have	been	encr	ypted.	You will or	ly be a	able to	view	these	docu	ument	ts onli	ine if	you get a <u>special browser plugin</u> .
This s	site was	develop	ed by Trar	nsPerfec	ct Tria	I Inter	ractive	e										

Dashlet Common - Bulletin Board

This is set up by the administrators to provide messages to the team which can be information regarding a room or problems within a study. It can be configured only by the administrators, and the reader can only see the information but could not edit.

Dashlet Common - Project Links

The Project Links tab displays the links to different systems that are used for the study and their contact information.

Common	# Z
About This Room Updates Project Li	nks My Courses
• Create	Private Shared
Title: CSS Url: https://www.w3schools.com Phone: Email: Description:	

Note: The project links are displayed in the tab only when you select the Shared button located at the right of the tab.

Following activities are available for the administrators in the Project Links tab:

- 1. Adding a new link
- 2. Editing a link
- 3. Deleting a link



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Each of these activities is discussed in the sections below:

Adding a new link

To add a new link:



- **© Create** button from the top left corner of the tab. 1. Click the Create
- 2. The Create Project Link window appears.
- 3. Enter the URL, Title, Contact details, Email, Logo, and any description.
- 4. Click Create at the bottom of the window. The link is added to the Project List. Refer to the screenshot below:

	https://www.w3schools.com	
Title:	CSS	
Phone:		
Email:		
Logo:		
٩		
	This is a personal project link	
Open Sar	ns ∨ 12 ∨ ♦ B I U 등 %	

Editing a link

Click the Edit icon next to the link. Follow the on-screen instructions and edit the required details.

Deleting a link



Click the **Delete** icon next to the link. Follow the on-screen instructions to delete the link.

Dashlet Common - My courses

This displays the courses you are assigned to and is configured by the administrator.

Dashlet - Documents Grouping

The Documents Dashlet gives an overview of the all documents and their related activities in a room. Refer to the screenshot below:

Docum	nents					<i>•</i> 2
← Docu	uments Expiration	by Workflow Status	Rejection & Clarification	Documents View	eTMF Health	∕ly Quer <mark>→</mark>
Expire	d V				1 bbA 🗲	New Version
0 Docu	iments					
	Document Date	Document Type	Title	Expiration Date	Comments	
	No records available.					
					<pre> Previous 0 of </pre>	0 Next >

The dashlet provides the Right and Left arrows to the extremes of the dashlet to allow you to navigate to the sub- dashlets dashlets contained in the Document Dashlet.

Besides, for every dashlet of the Documents Dashlets, you can also use the Previous and Next arrows to move among the documents in the dashlet as shown in the screenshot above.

The Documents Dashlet contains the following tabs related to documents:

- 1. Claimed & Unclaimed
- 2. Documents Expiration
- 3. By Workflow Status
- 4. Rejection and Clarification
- 5. Documents View
- 6. eTMF Health
- 7. My Queries
- 8. Documents Submissions
- 9. Open Queries by Age
- **10.** Popular Documents
- 11. Pending Documents Review
- 12. Unread



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- **13.** My Favorite Documents
- 14. Milestones Timeline
- 15. Milestone Type Report
- 16. Tasks

Each of these is discussed in separate topics. Select a topic from the left pane to open it.

Dashlet - Claimed & Unclaimed

The Claimed vs Unclaimed Documents dashlet provides a count of all documents that are in workflow and are either claimed, unclaimed, or in progress. You can further click on each slice of the interactive donut chart to obtain further detailed information.

The dashlet also provides the dropdown to select the workflow as required and displays the Donut Chart as per the selected workflow. Refer to the screenshot below:

Documents				d'	C
Claimed & Unclaimed	Documents Expiration 1 (3%) Click to see of	by Workflow Status	Rejection & Clarification	Documents View	÷ ✓

Dashlet - Documents Expiration

The Documents Expiration dashlet lists the expiring and expired documents as specified in the expiration period (N). The dashlet has two views that can be selected through an Expired dropdown. To set the views, click the **Expired** dropdown located on the top left corner. Refer to the screenshot below:

eTMF	Health Expired and E	Expiring Queries by A	ge My Queries		
Expired	~				Add New Version
10 Doci	uments				
	Document Date	Document Type	Title	Expiration Date	Comments
	13 Apr 2018	For Blue Flag and Milestone i	CDA AGREEMENT.pdf	09 May 2018	
	18 Apr 2018	custom amendment 1	Brochure	12 May 2018	

Click the Add New Version button from the top right corner of the dashlet to replace a document.



This opens the Add New Version window which provides the available methods to replace an attachment, or adds a new document and retain it alongside the older version or remove the older version if a new version is already submitted. Refer to the screenshot below:



Dashlet - Documents by Workflow Status

The Documents by Workflow Status dashlet displays the document processing status in the document review workflow through a donut chart. By changing the dropdown menu, you can view the document processing status:

- 1. As a complete Room Summary, or
- 2. As workflow stages defined.

Refer to the screenshots below:

Documents				Ø 2
Claimed & Unclaimed	Documents Expiration	by Workflow Status	Rejection & Clarification	Documents View Room Summary V
		2 219 Total docs	7	





Dashlet - Documents Clarification and Rejection

The Documents Rejection and Clarification dashlet displays the reason for rejections and also provides a count of each defined rejection type. This dashlet therefore can be used to determine the most common reason for rejection and need for clarification.

You can further double-click on the count to view the list of documents associated with a particular rejection or clarification reason. Refer to the screenshot below:

Documents								ø 2
 Documents E 1 Documents 	expiration	by Workflow Status	Rejec	ction & Clarificat	ion	Documents View	eTMF Health	My Queri 🕇
	Reason				Cou	nt		
~	Rejected				2			
	Rejected 2	2						
		Created Date		Submitted Name		Comments		
		20 Apr 2018		Doc_without_attach	nment			
	- a	27 Apr 2018		docu2				

Dashlet - eTMF Health

The eTMF Health dashlet displays a donut chart that indicates what percentage of required eTMF documents are either collected or currently missing. From the top right corner of the donut chart, Administrator users can manually set the chart type to be displayed. Hovering the mouse over the donut chart shows a popup with a more detailed progress percentage for the category of the documents.



Click a donut to drill down to the lowest level to list the missing/placeholder documents.

Additionally, you can use the Add Placeholder button to conveniently upload a missing



document/placeholder or to edit a placeholder right off the dashlet. To view any changes,

refresh the chart to update the missing documents list. Refer to the screenshot below:

Dashlet - My Queries

The **My Queries** dashlet gives a list of documents based on their query types. The query types could be All, Workflow, or Audit. Refer to the

C	ocu	ments					# C
÷	by	Workflow Status	Rejection & Clarification	Documents View	eTMF Health	My Queries	Documents Submi 🗲
		Title					Madellaw
	A	FormScreen(3)					Audit
	P	Important links					
	A	arabic_c2db99da14ad	l4bd5bfd347f4a8ce3987				
	A	french_e7cac3d85c09	4888a0bb5d5838aabd6b				
	A	german_d5efa2af836	c4a028515049596dfe665				

screenshot below:

Click the All dropdown to toggle between different views to view the queries.

Dashlet - Open Queries by Age

The Queries by Age dashlet conveniently displays those documents that are 30 days and older in age and also provides a documents count. The query types could be All, Workflow, or Audit. Click the arrow next to the age to reveal the queries listed in the query type. Refer to the screenshot below:

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Documents						ð O
esions Open (Queries By Ag	ge Popular Documents	Pending Do	ocuments Review	Unread	My Favorite Documen
All ~						
1 Open Queries By	Age					
	Age			Count		
~	30 days and old	der		29		
	Pending 25					
		Submitted Name				
		CDA AGREEMENT.pdf				
		ACM_userguide_en-US (2)				
		FormScreen(3)				

Dashlet - Popular

The **IP Release Documents** dashlet displays the list of documents that have been **marked as popular** (*page 289*) by an Admin or Editor through the Document Cart and which are used frequently.

To remove a document from the Popular list, click Remove

from Popular button on the dashlet. To view the

document, click the icon. Refer to the screenshot below:

Pop	ular I	Docu	ments	
0	Remo	ve fr	m Popular	
			Title	
	+	Ø	1	
		Le.	fgh	
			nv Site Local Docs_aaa aaa	
]	X	3434	
		x	mm1	
			3243	
M	4	Pa	ge1 of 1 ≫ ▶ Ø	Displaying documents 1 - 6 of 6

Dashlet - Pending Documents Review

The Pending Documents Review dashlet gives a list of all documents that are pending for review. You can choose to view the documents pending for review for All users, or only for yourself through My Review. Refer to the screenshot below:



			5
asks Unread Exp	ired and Expiring Docume	ents to be signed My Queries	Pending
		_	My Pending Documents 🖇
Pending Documents			My Pending Documents
Review Title	Due Date	Participants	All Pending Documents
No records available.			

Click the All Pending Documents dropdown from the top right corner of the dashlet to toggle between the views. Following views are available for the user through Pending Documents Review dashlet:

- 1. My Pending Documents: This displays the list of all pending documents that are assigned to you for review.
- 2. All Pending Documents: This displays the list of all pending documents that are pending for review in a room.

Dashlet - Unread

The Unread dashlet shows the three different views of documents in eTMF module - Unread, Pending, and Unclaimed. Refer to the screenshot below:

Docum	ients						00
← opula	r Documents	Pending Doc	uments Review	Unread	My Favorite Documents	Milestones Timeline	Milest 🗲
136 Ur	read Documents					Unread Unclaimed	Pending
	Document Date		Index		Title	Comments	
	13 Apr 2018		65 for activation with	out access	Stylesheet for Note.docx		
	13 Apr 2018		65 for activation witho	out access	Updates for 9.1.0.51389-51979		E
1	13 Apr 2018		65 for activation witho	out access	Tagging.docx		
	13 Apr 2018		65 for activation witho	out access	i106^cimgpsh_orig.png		

Click the Unread button to list any of the documents posted in the Trial Interactive site that has not yet been opened by the user logging in. This allows the users to get a sense, right from the Dashboard, as to what documents they still need to see, and whether any new documents have been posted that they may not have been aware of.



Click the Unclaimed button to get a list of documents that have not been claimed for review. Click the Pending button to get a list of documents that are yet to be reviewed.

Dashlet - Documents to be Signed

The Documents to be Signed dashlet gives a list of document pending for signature. Refer to the screenshot below:

Tasks	Tasks Unread Expired and Expiring Documents to be signed My Queries Pending								
Double	Double click a document to view and sign it								
5 Docu	ments to be Signed								
	Submitted Name	Signers							
	Multiplication6X	Nick Editor							
	hebrew	nakulich@elilink.com							
	Doc3	Swati B							
	Showing Swati	Swati B Amruta Maddel							
	Creating lists and nmbered headings in Word 2013	Amruta Maddel							

Dashlet - Milestone Type Report

The Milestone Type Report dashlet gives the percentage of missing/placeholder documents or collected documents for a particular milestone type associated with a site in the form of a bar graph.

Dashlet - Tasks

The Tasks dashlet displays the lists of tasks belonging to a particular user/s of a room. Select the Status and the Assignee from their respective drop-downs to get the task details.

All Tasks lists all the tasks belonging to the selected assignee.

My Tasks lists all the tasks pending recently, today, or are overdue.

Docu	iments					<i>•</i> C
←ndii	ng Documents Review	Unread N	ly Favorite Documer	nts Milestones Time	line Milestone Ty	ype Report Tasks
Statu	s	✓ Assignee	~	•		All Tasks My Tasks
12 Ta	asks					
	Subject		Start Date	Due Date		-
	Follow-Up: Annabot	Not Started			Normal	0%
	Research document	Not Started	20 Sep 2018	26 Sep 2018	Normal	0%
	Research document	Not Started	20 Sep 2018	26 Sep 2018	Normal	0%
	Follow-Up: TechWrit	Not Started	29 Jun 2018	29 Jun 2018	Normal	0%
	Follow-Up: Annabot	Not Started			Normal	0%

You can also export selected tasks or all tasks in the current grid by clicking the Tasks Export

icon located on the top right corner of the dashlet. After the export job is over, you can



retrieve the job result from the Notifications (page 64) by clicking Get Job Result which then downloads the export job as a .xlsx file on your hard disk.

Dashlet - Recent Communications Log

The Recent Communication Logs dashlet gives a list of all communications made during the site start-up and activation stage.

Clicking the View All Communication log link from the top right corner of the dashlet to view the list of all communication log. Refer to the screenshot below:

Recent Commu	Recent Communication Logs							
	View All Communication Lo							
1 Communicati	ion Logs							
Date	Туре	Description	Contact Name	Communication Entity				
27 Jun 2018	Regulat	E-Delivery of Reg. pack to the site	Amruta Auditor1 Maddel	Annabot				
				-				

You can also rename the dashlet by clicking the Pencil icon to the right of the dashlet and refresh the dashlet by clicking the Refresh icon.

Dashlet - Users

The Users dashlet provides a helpful option that lists new users or all users in a study with filters to sort users by organization and by their organization and access level (role). You can also invite a new user here by clicking the Invite button placed in the upper right corner. Double-clicking the icon next to the Last name opens the Edit User popup to allow editing of the user profile. Refer to the screenshot below:

Users				± #
Organization	∽ Role	~		O In
14 Users				
Name	Email	Phone	Organization	
🔒 Joe Joseph	schamberger@lavon.net	+1 123 456 789	ti.com	
🐣 Della Floyd	helga@lavon.net		ti.com	
🔒 Amanda Alvarado	schamberger@lavon.net		some organization	
🛔 Barry Padilla	schama@lavon.net		organization	
🚨 Harriett Hammond	schamberger@lavon.net		ti.com	
	and a second second second			

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Dashlet - Investigative Sites

The Investigative Sites dashlet display the overview of Sites in the form of Pie Chart. The dashlet contains the following tabs for the related to the sites:

- 1. Expiring: Display the details and count of expired sites in the form of Pie Chart.
- 2. E-Feasibility by Country: Display the count and details of sites based on E-Feasibility by Countries.
- 3. Study Monitoring Visits: Display the count of sites based on the Study Monitoring Visits.
- 4. Recently Updated: Display the count of all recently updated sites.



Dashlet - Expiring Sites

The Expiring Sites dashlet gives a list of all sites that are expiring in a future date. Refer to the screenshot below:

Investigative Sites							SP	0
Expiring Sites Milestone Type F	Report Recently Updated Sites	Site Activation Status	E-Feasibili	ty by Country	Study Monitoring \	lisits		
1 - 1 of 1 (0 selected)					c	Select Columns	Ø Views	•
Site	Principal Investigator	Status		Main Contact		Main Contact Phone		
107 Glass	Break Glass	Active		Break Glass; D	Daffy Duck	-		*
								-
						Previous	1 of 1 Nex	kt 🕨



Dashlet - Recently Updated Sites

The Recently Updated Sites gives the activation progress of all sites in a room. Hover the mouse over the Progress % column to view the list of documents that are missing to complete the site activation. Refer to the screenshot below:

Investigative Sites				10
Expiring Sites Milestone Type	Report Recently Updated Sites	Site Activation Status E-Feasibility by Country	Study Monitoring Visits	
1 - 10 of 10 (0 selected)			2 🛛 Select Columns	🕫 Views 🔻
Site	Principal Investigator	Status	Progress %	
107 Glass	Break Glass	Active	100	· · · ·
987 Applesauce	Johnny Applesauce	Active	100	
2145 Cornstalk	Jimmy Cornstalk	Pending	0	
530 Hydration	Cold Hydration	Active	67	
1040 Jackson	Samuel Jackson	Active	67	•
			Previous	1 of 1 Next

Dashlet - Site Activation Status

This dashlet offers three views – Sites By Country, e-Feasibility By Country, and Sites Activation Progress.

Select the Site By Country view to reveal the total number of active sites, sites pending for activation, and sites rejected from activation in each country in the form of a bar chart. Refer to the screenshots below:

Site Activation Progress Screenshot -

Investigative	Sites					٩	/ C
Expiring Sites	Milestone Type Report	Recently Updated Sites	Site Activation Status	E-Feasibility by Country All Sites	Study Monitoring Visits	Sites Activation Progress	•
2.2					-		
1.8 1.6 1.4							
1.2							



Sites by Country Screenshot -



Hover the mouse on any part of the chart to view the details of the site, see below -



Drilldown to the specific site, see below -

Investigative Sites									ø 2
Expiring Sites Milestone Type Repor	t Recently Updated Sites	Site Activatio	n Status	E-Feasibility by Count	ry	Study Monito	ring Visits		
Home 🕨 Canada						All Sites	•	Sites by Country	•
1 - 3 of 3 (0 selected)					C			2	
Site	Progress %	Si	ite Activatio	n Date			Total	D	
530 Hydration	66.67%	1	0 Jan 2020			A 3	Tota	Jica	
				Previous 1 of 1 N	Next 🕨				



Dashlet - Study Monitoring Visits

The dashlet Study Monitoring Visits provides two different views study monitoring visits – Monitoring Visits By Month, and Monitoring Visits By Country, in the form of a donut chart. This dashlet can be configured to display the Visit Date instead of the Created Date through the Configure Dashlet feature as discussed above. Refer to the screenshots below:

May 2018 🚔 - Dec 2018 🚔 by Month 🗸	Expiring Sites	Recently updated Sites	Site Activation Status	E-Feasibility by Country	Study N	Ionitoring Visits
all 1812validationIS all sites required doc1	May 2018 1812validationIS all sites required d	≝ - ○		+ Dec 2018	*	by Month 🗸 🗸

The dashlet provides the Date Ranges to filter the sites. Besides selecting dates in the date columns, you can also scroll the bar between the ranges to filter the sites.

When you select the 'By Country' option from the dropdown at the top right corner, you will finally be able to view the documents for the particular country. Click the section on the donut chart to delve further for the country documents.

The Study Monitoring Visits dashlet is connected to the Document Type Settings. Therefore, Administrator users can go to SettingsàDocumentTypesàDocumentTypesManagement, (*page 105*) and assign or modify document types. Through the configuration box, users can manually specify whether to include the document in the Monitoring Visits or not.

If you choose to include a new document type, the Study Monitoring Visits dashlet will be updated to reflect the change.



For your convenience, a search box and a filter option are also available in the Document Type Management section in the Settings. These features help users track which documents, and how many documents are needed to be collected for specific document types. Refer to the screenshot below:

ly Category *	C Document Type	Auto Naming Rules	Proble Doc. Type Fields Bulk Fields Update Default Values
All Document Types	U Investigative Site Calegory - 1 Document type(s)		Document Type *
🗇 🗰 General	2 . Manterine Valladiane Descentation		Monitoring Visit Follow-up Documentation
10 🗰 Country	(1) A Construction of a second		Short Name
Investigative Star			
Sub Monitoring Visit Follow-up Doc	ta-		189 Document Tune M
Interim Monitoring Visit Report			Landon and (Baran
FDA Form 1572			Channel .
Interim Monitoring Visit Confirmation	e .		Category
Protocol Signature Page			
C1 Trial Management			Auto Name Rules
Monitoring Visit Report			
Internet Monitoring Visit Follow Up I			
0 C2 Central Transpoorments			Related To:
A 199 or 100 and Other Annumeric			
Mandarian Mat Enline on Director			Related Folder
Clinical Trial Assessment			(Not Specified)
05 Six Management			
0 > 06 IP and Trial Suppliers	1		A 44 A
💿 🗣 07 Safety Reporting			DUE DATE O
S DY inv			
HIV Consent			Phases / Milestones
06 Central and Local Testing			Miestore 0
🗈 🗣 10 Deta Management			(H)
			Investigative Site Status
			1
			1
			El Include in Document Tracket Report
			12 Include in Monitoring Visits
			Auto Document Type Prediction Keywood(a)

Dashlet - Collaborative Review

The Collaborative Review dashlet gives you an overview of all the documents that are in a

Collaborative Review. Refer to the screenshot below:

The following dashlets are available in the Collaborative Dashlet:

- 1. Documents to Approve
- 2. Documents to Sign
- 3. Pending Documents Review
- 4. Collaborative Documents

Dashlet - Documents to Approve

This dashlet displays the list of all documents that are pending for approval in TI Collaborative. Click the document to open the document for approval.

Dashlet - Pending Documents Review

The Pending Documents Review dashlet gives a list of all documents that are pending for review. You can choose to view the documents pending for review for All users, or only for yourself through My Review. Refer to the screenshot below:



ocument			a de la companya de
asks Unread Expi	red and Expiring Docume	nts to be signed My Queries	Pending
			My Pending Documents 🗙
Pending Documents			My Pending Documents
Review Title	Due Date	Participants	All Pending Documents Own
Review Title No records available.	Due Date	Participants	Own

Click the All Pending Documents dropdown from the top right corner of the dashlet to toggle between the views. Following views are available for the user through Pending Documents Review dashlet:

- 1. My Pending Documents: This displays the list of all pending documents that are assigned to you for review.
- 2. All Pending Documents: This displays the list of all pending documents that are pending for review in a room.

Dashlet - Collaborative Documents

The Collaborative Documents dashlet displays the list of all collaborative documents. From this dashlet, you can also create a new Collaborative Profile by clicking the Create Profile button located at the top right corner of the dashlet.

Documents View

The Trial Interactive eTMF Documents is the central repository for all the clinical trial documents in their original digital format with Digital Signatures (*page 255*) wherever applicable, records, or documents converted from one format to another like paper documents, images converted to PDFs (*page 255*), besides videos and recordings pertaining to trials.

Here, you can configure and store trial master file 'essential documents' pertaining to clinical trials, view and edit documents attachments, manage security privileges on them, import and export documents and their metadata, mail them to other users besides many others. To comply with eTMF Completeness, you can track the progress right from documents collection to the finalization of a document through Milestones and assignments of Tasks to authorized personnel. Besides, this application also provides you with the facility to post



Questions and Answers along with the generation of FAQs for further insight.

The documents are then subjected to Quality Control, and Quality Review checks as specified by the FDA.

You can access the Documents View by clicking the Documents icon from the menu bar at the left of the dashboard. Refer to the screenshot below:



Clicking the **Documents icon** from the menu bar at the left leads you to the **Documents dashboard**. Refer to the screenshot below:



Refer to the table below for more description on each numbered part.

Table 1: The Documents View

No	Part Name	Descripti



-		on
1.	The Room Index (page 224)	The Room Index consists of folders organized into a tree-like structure starting with Index as the root folder.
2. Documents Grid.	The Documents Grid (page 24	1) Select a chid folder from the Index to populate and view its documents in the
3.	The Document Data Panel (page 261)	Tick a checkbox next to a document in the Documents Grid to populate the Document Data Panel.
4.	The Working Area (page 259)	Shows the record of the document currently working in.
5.	The Top Ribbon Bar (<i>page</i> 269)	Access various functionalities required for eTMF operations from here.



Click the links in the table below for more details on each part or section.

Documents Module Settings

🖖 Important:

- All documents added/imported to a room get populated in the Upload folder by default unless the Default index position is specified in the document settings.
- Documents emailed to the room will find its way to the Communication Inbox or the eTMF Inbox as per the room settings.

The settings that need to enable for a document are discussed in detail in the Settings

 \rightarrow Documents \rightarrow

Documents Module. (page 97)

The Room Index

- The Room Index consists of folders organized into a tree-like structure starting with **Index** as the root folder.
- The Index consists of **parent and child folders** and can either be cloned during room creation or created from scratch.
- The Index Folders are categorized as per the Document Types specified from the Room Settings and consist of three main categories – General, Country Management, and Site Management.
- Documents emailed to a room get stored in the room's Inbox folder.
- Similarly, all documents imported are populated in the Upload folder.
- If a folder contains subfolders, you can **expand** it to list its content by clicking the expand arrow collapsed folder.

icon next to a

>

- Similarly, you can **collapse** an Index folder by clicking the collapse arrow icon next to an expanded folder.
- To locate documents in a child folder, you drill down to the last child folder and click on it.
- The documents in the child folder populate in the **Documents Grid**.
- Tick a checkbox in the Documents Grid to view its metadata in the Metadata tab of the Right Panel.
- Besides the Metadata tab, the **Right Panel** also consists of the **Workflow**, **Queries**, **Versions**, **History**, and **eSignature tabs**.




From the Index Pane:

- View the room's folder structure (page 225)
- Search and navigate to sub-folders (page 241)
- Modify Index Structure (page 238)
- Export Index (page 240)
- Refresh Index (page 240)
- View Security on an Index Folder
- Export documents from an Index Folder
- Add documents to an Index Folder (page 297)
- Index Outline Settings and By Index View (page 101)

Choose View - Viewing the Room's Index Structure

You can view a room's index and its documents from the Index Pane of the room. From the Index Pane, you have access to various kinds of views to the folder structure. The default view provided by the system is By Index.

To toggle between the various views of the Index Structure:

- 1. Click the Choose View button on the Index Pane.
- 2. This opens the View Documents By popup with various view options. Refer to the screenshot below:

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≡	★ TechWritersDemoRoom ★ 1340						+ Ada
2	Ocument V Amage Securit	y 🙆 Move to Startup	↑ Import ~	🔶 Export 🗸 🔤 Em	ail 🔒 Print 🕼 Edit	Online ? Layout ~	Compare
	View by Index	Document. View Documents By	Title	Document Disa	ble au Document	Reason fo Comments	Documer
<u> </u>	🗸 🍃 Index						
4	 1 signature 2 6 2 eSignature 0 	etMF	Any List	Queries	Documents	Others	
4	b 3 Country Management_polly 0 (0) b 4 PleaseReview replacement 0 (0) b 5 Site Management 0 (16)	Index	Submission	Workflow	Sender	Posted Date	
	6 Complex criteria test 1 7 Complex criteria test 2 0 8 Mutual Nondisclosure Agreement For	Country	Reviews	Reviewer	Recipient	Security	
	9 Site Signed NDA 0 10 Site Language Changes 1 11 Additional PSV Package Documents 13 Partners Dark Pachage Sciences 1	Site		Status	Missing Documents	Group	
	12 Flocket Drate Flocket symplexs 13 CRA PSV Materials 1 14 Relevant Communications 0 15 Language Changes_Pearl Distributed			Document Type	Placeholders	Deleted Docs	
	 In 16 CNS_contracts and CDAs 0 (0) In 17 PT003006 US_SIte Contracts and Buc In 18 PT003007 US_Site Contracts and Buc 19 nick folder 1 125 20 a drims conv 1 			eSignature	Collected Documents	Processed Docs	
E	 21 SBV 0 (0) 22 export test 0 (0) 			Make Default	ect	-	

Tip: Select a view and tick the **Make Default** checkbox to make that view the default view. You will then see the documents sorted and grouped by the view you marked as default every time you visit the room.

Each of the view options are discussed in separate topics available from the left pane of this help.

By Index and Index Outline Settings

Important: Index Outline is a group of settings that Administrators should leave unchanged. The settings here are those chosen by the client during the initial room setup. Before making changes here, consult with the Project Manager and/or the Client Services Team.



On creating the index, as an administrator, you can decide on number of functions and appearances related to the Trial Interactive room's index from the Main Navigation ->Settings -> Documents Module -> Index Outline. You can change the names of the Upload folder, the Index folder, and the IRB Uploads folder if so, requested by the client. The following settings are configured from the Index Outline:

- By Index View
- Changing the Index Name
- Empty Folders Options
- Hide Index on add new document
- Auto Indexing

By Index View

Each of these sections is discussed in detail in the sections below.

	About Index	x Outline ×		
🕀 🧰 "Inbox	Upload folder name: *	*Upload		
🗉 🚞 *Upload [33]	Inbox folder name: *	*Inbox		
Show Empty Folders	IRB Uploads folder name: *	*IRB Integration		
	Index name: *	Index		
	Enable custom Index nam	e		
Document - R Print CE E-Mar R Manage Security	Import Show empty folders optio	n		
By Index	Show empty folders by de	efault		
🛛 🍉 Index 🖌	🖉 Use auto prefix			
O1 Trial Management Documents count	0 A.1.I	01.01.01	© I.A.1.i	
I 1.02 Trial Team [0]	A1.i.a	• 1.1.1		
Folde	x Show documents count			
() in 01.03 Trial Committee [0]	Enable auto indexing			
🗊 🚞 01.04 Meetings [0]	I Hide index on add new do	ocument		
🗊 🚞 01:05 General [0]	E Flue index on add new do	ocument		
O 2 Central Trial Documents [2]	Default index position for	19 nick folder 1		0
U = 03 Regulatory (4)	Add document:			Q
The second				

The All View(By Index) shows the full folder index of the room with child pages. If a folder contains sub-folders, it can be expanded to list its content by clicking the expand icon. If a user emails documents to the room, such documents get stored in the Inbox folder of the room. Similarly, all documents imported are populated in the Upload folder.

Note: A new Index sub-folder inherits the permissions from its parent folder.

Auto Prefix

The folders in a room index are numbered, and the subfolders follow a standard numbering system. These folder numbers are called as Folder Prefixes, whose settings can be decided from the **Auto Prefix** option in the **Settings -> Documents Module -> Index Outline**.



Activate or inactivate Auto Prefixing of folders in the room's index by ticking the **Use auto prefix** checkbox. If not selected, folder titles will appear in the index just as they were typed in during the creation of the room's index. Auto prefixing inserts the client's requested prefix of numbers or letters to identify the levels of the folders in the index. Click the radio button for the prefix pattern requested by the client.

Documents Count

Numbers in parentheses after the folder names indicate how many documents are available to you in each folder. Click a folder to open the documents contained in it in the Document Grid.

By showing Documents count, by ticking the **Show documents count** checkbox in the settings, users in the room will see a number in brackets that indicate how many documents are in each index folder.

Changing the Index Name

If the client has requested some unique name for the room's index besides the standard 'Index', then you have to first enable the custom index name, and then type the custom name in this field.

1. If the client wants to customize the name of the Index, click the box to activate it. The Index Name field then becomes active.

Index name:*	Custom Index Name	
Enable custom Ind	ex name	

- 2. Type in the custom name requested by the client.
- 3. If this is the only change requested for this panel, click Save at the bottom of the panel.

Empty Folders Options

In this next section of this panel, you make selections for the client regarding the

appearance of Empty Folders.

You can enable or disable the **Show Empty Folders Option**. By showing that option, users in the room will see this checkbox at the bottom of the room's folder index.

Another option sometimes called for by the client is to show empty folders all the time. If that is the case with the room you're configuring, click this box – **Show Empty Folders by default**. Then, the room's full index will always show in the documents view, whether the folders are empty or not.



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Hide Index on add new documents



If this setting is enabled:

- 1. Index position will be hidden in the new document window.
- 2. But in case if auto-routing logic can't determine index position, this control will be displayed, so the user will be able to specify index position manually.
- 3. A document cannot be copied or dragged to a different location/folder by editors.

Auto Indexing

In order to activate either of these next two options – **Enable Auto Indexing** or **Hide Index on add new document** – this Default Index Position for Add Document field must be completed.

1. Click the magnifying glass. The full index list appears.



- 2. Select the folder indicated by the client. In this example, the folder is named 19 nick folder 1.
- 3. Click OK. The window closes.
- 4. Click Save at the bottom of the Index Outline panel.

By Country

From this view, you can access all documents and placeholders of the Category Country having a country name metadata specified in its Country Field. When you access this view from within the Documents sub-module, you see all eTMF documents of the category Country. Refer to the screenshot below:



iew	by Country
Q,	
0	Afghanistan 2
0	Åland Islands 2
0	Albania 2
0	Algeria 1
0	Anguilla 1
0	Argentina 1
0	Armenia 2
0	China 1
0	India 4

Under each country as a parent folder, the documents are further categorized by its Document Types.

You can also view the category country documents in the By Index (page 225)view under the Country folder (the name that you provide to this folder depends on your room settings). For more details on how to set up this folder and its hierarchy follow on to Chapter Countries (page 380). To know more about Site-Specific Country Category documents proceed to Site -> By Country view.

By Site

From this view, you can access all documents and placeholders associated with the Investigative Sites. Sites are places where clinical studies are conducted. This view shows the segregation of Investigative Site as located in various countries.

All sites belonging to a particular country are listed under their specific country. Click a site name to list the documents belonging to the site in the Document Grid. Refer to the screenshot below:

Vie	ew by Site 📰
(Search by folder name
~ 1	Afghanistan
	A Charles River Lab [Site Management] 2
	Laz Institutes4 1
	Laz Institutes4 AFG[Site Management] AFC
	Laz Institutes4 AFG[Site Management] AFC
	AFG[Site Management] AFG
	Test_Swati AFG[Site Management] AFG 1
	TEST2 AFG[Site Management] AFG 7
> (China
> (🕽 India
> 1	*No Country specified



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The configurations for an Investigative Site can be setup from Settings ->

Investigative Sites (page 133). The dashlets related to Investigative Sites are:

- 1. Expiring Sites
- 2. Recently updated sites
- 3. Site Activation Status
- 4. Site Activation Progress
- 5. Sites Activation by Country
- 6. Study Monitoring Visits By Country

By Reviewer

Administrators can reassign documents claimed in the workflow to other reviewers.

- 1. From the Documents view, select By Reviewer as the Current view for the index.
- 2. Open the index folder of the reviewer whose claimed documents you want to reassign.
- Click the folder holding claimed document to reveal its contents. The list of that user's claimed documents populates the document grid.
- 4. Select the documents from the list that you want to reassign.
- 5. The Reassign reviewers button becomes active in the menu ribbon above the document grid.
- 6. Click Reassign reviewers. A Reassign reviewers window opens.
- 7. From the Workflow dropdown, select the workflow you want to adjust.
- 8. The Stage field auto-populates.
- 9. From the Reviewer dropdown, select the reviewer to whom you want to reassign the documents.
- 10. Click OK.

The documents are transferred to the folder for claimed documents of the new reviewer.

My Submissions

All the documents that the user imports, emails or adds to the room are populated in the My Submission folder. Refer to the screenshot below:

View by Submission				Document	Title	Document	Disable au	Document	Reason fo	Comments
My Submission 73		Ŵ	π	2070015	Tips for wr		True	Tiger Woo		
	0	Ŵ	*	2070130	Test Docu		True	Polly Chak		
		Ŵ	π	2070185	CDA AGRE		True	Amruta A		
		1	*	2070481	DMS proc		True	Tiger Woo		
		1	$^{\pm}$	2072057	Copy of D		True	Tiger Woo		
			$^{\pm}$	2072157	Important		True	Polly Chak		
		3	$^{\pm}$	2072158	Copy of C		True	Polly Chak		

My Reviews

Note: If you are the part of the reviewers group which you are assigned to the workflow, the My Reviews in the eTMF Documents module is automatically activated for you. You can have the same reviews as in My Reviews from the Quality Review module as well.



Depending upon your workflow settings, documents added to the room are automatically added to the workflow. You can view the documents added to the workflow from the My Reviews view or the Quality Review module in the folder with unclaimed documents under the workflow configured by you. Refer to the screenshot below:



For more details on workflow, refer to chapter Quality Control. (page)

By Workflow

From this view, you access the documents available to the user for review in the various

stages of workflow. Refer to the screenshot below:





By Status

This view displays the current workflow status of documents. Refer to the screenshot:



By Document Type

This view groups all documents by its Category as the parent folder. Each Category folder further holds documents grouped by document types as subfolders.

These Document Types are created from Document Types Management (page 105) in Room Settings.

Clicking each document type displays the documents of that type in the Document view. Refer to the screenshot below:





eSignature

This view groups all eSignature documents under Completed, Waiting, and Canceled category. Refer to the screenshot below:

View by eSignature	_
Canceled	
Waiting for Signatures	
Completed	

Click the folder to view the required documents. You can also choose to Cancel eSignature (*page 268*)by selecting a document from the Waiting for eSignatures.

By Sender

This view display documents grouped by reviewers who have raised queries on documents during a **Quality Review** or **Quality Control** and have sent them for clarification. Refer to the screenshot below:

View by Sender	+	Document	Title	Document	Disable au	Document	Reason fo	Comments	Documen	Metadata	Workflow C	Queries Ve	ersions H	listory
> *All 38	🗹 🖪 ★	2076933	docu3		True	Tiger Woo			20 Feb 20					^
V Tiger Woods 2		2370030	asdfgh		True	Tiger Woo				Query	[1340-232]	Per	nding	-
Pending 2										Descrip	ition			
> Polly Chakraborty 23										PLEAS	F DO NOT CH	ANGE THE	FFMAIL	
> Amruta Auditor1 Maddel 13										SUBJE	ст			
										The	following	issues w	vere	
										foun	d in the d	ocumen	nt,	
										plea	se attach	a revised	d	
										docu	iment in y	our repl	ly to	2
										this	email:			

From here the user can:

- 1. View the query.
- 2. Resolve a Query. (page 376)
- 3. Respond to a Query.

Click the links above to know more in detail about each topic.



By Recipient

This view display documents grouped by the recipients of the queries received by them for

Document 👻 🔒 Manage Security	🔒 Print	\geq	Email 🙆 Mo	ve to Startup	↑ Import ~		? Layout ∽	Compare	1 Bulk Upload	🕑 Edit o	Dnline 🛛 🙀 Add to Cart 🛛 🍞	Documents
View by Recipient			Document	Title	Document	Disable au	Document	Reason fo	Comments	Docun	Metadata Workflow Queries Versi	ons History
> Polly Chakraborty 7		6 *	2072157	Important		True	Polly Chak			20 Ap		
V Amruta Auditor1 Maddel 27		A *	2076502	german_d		True	Polly Chak			26 Api	Query [1540-175] Res	wed V
Pending 11		a *	2076503	nicksep27i	audit 1_10	True	Polly Chak			26 Api	Query [1340-180] Pen	ding
Responded 3		la *	2076511	turkish_e1		True	Polly Chak			26 Api	Description	
Resolved 13		D *	2076933	docu3		True	Tiger Woo			20 Fet		
Common Responder1 User 3		*	2076934	esign1		True	Polly Chak			20 Fet	PLEASE DO NOT CHANGE THE EM	IAIL
		D *	2081644	Tagging	303781_6	True	Amruta A				-	
		B *	2113023	Good Clini		True	Polly Chak			17 Jul	The following issues were	e
		R *	2232768	Import Do		True	Polly Chak			13 No	found in the document, p	olease
		•	2370030	asdfgh		True	Tiger Woo				attach a revised docume	nt in
		* 📾	2373028	CDA Agree			Polly Chak			21 Jan	your reply to this email:	
											TechWritersWorkflow: Approval s	tage 1



From here the user can:

- 1. View a query.
- 2. Respond to a query.
- 3. Resolve a query. (page 376)

Click the links above to know more in detail about each topic.

eTMF Completeness

This view lists collected, missing documents and acts as a placeholder for missing documents that do not fall under the required documents section.

From within the Document Grid or from the Add Placeholder dropdown on the top ribbon, placeholders can be created, edited, deleted for a document. Documents can be attached to placeholders or missing documents from the Add Document located on the top ribbon bar or by dragging and dropping them from the Windows Explorer.

The system:

- 1. Creates a new document from placeholder and missing documents
- 2. Does not allow to change the category and related metadata if placeholder ID is present for documents.
- 3. Allows the user to assign placeholders to milestone histories from the Create Placeholder window. Refer to the screenshot below:



By Posted Date

In the **By Posted Date** view, the documents are grouped as per the days they were **posted/imported/added**. Folders by posted dates are created. Clicking each folder displays the documents posted on that particular day. Refer to the screenshot below:

View by Posted Date	
02/15/2019	
02/11/2019	
02/07/2019	
01/20/2019	
12/24/2018	
12/18/2018	
12/10/2018	
12/03/2018	
11/14/2018	

By Security

The **By Security** view shows all the documents based on the security accesses provided to users and group of users. Documents are segregated under folders by the name of users showing the level of their access. Refer to the screenshot below:

v	iew by Security	_
>	Everyone	
>	Administrators Only	
>	1 01010 ed	
>	Index Manager Group	
>	Test	
>	auditors	
>	inVentiv Health Clinical	
>	Pearl Therapeutics	

Processed Documents

All the documents that traverse through various processes in a study can be viewed from here. Refer to the screenshot below.



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Some examples of processes in a study that the documents need to pass through are OCR, Optimization, PageCount, PDFConversion, PDFFixation, PublishtoeTMF, and DocumentTypeAutoPrediction. The documents are listed under each process in this. Under each process, the documents are further categorized into Not Submitted, Pending, Processed, and Error.

For example, as a user, you might want to submit documents for PDF Conversion. All the documents that were converted into PDF will appear under the **Processed->PDF Conversion** folder. If some documents could not be converted into PDF due to some error, they will appear under the **Error** folder. The documents that were not submitted for PDF Conversion will appear under the **Not Submitted** folder, and those that are still pending for conversion will appear under the **Pending** folder.

Similarly, all documents that are published from a Shared Workspace to its eTMF room get recorded under **Publish to eTMF** sub-folder in the **Processed** folder.

Deleted Documents

All documents that are deleted from a study by each user can be viewed from the Documents module under the **Deleted Documents view**. The documents are grouped under folders by the name of users who deleted documents. Refer to the screenshot below.





For more details on deleted documents proceed to Chapter Deleted and Expired

Documents. (page 303)

By Group

In the **By Group** view, the folders and documents belonging to a particular group can be viewed by clicking the group name in the index pane.

View Documents By					? ×
ener.	Ayutat	Queries	Documents	Chores	
By Index	By Submission	By Workflow	By Sender	By Posted Date	
By Country	By Reviews	By Reviewer	By Recipient	By Security	
By Site		By Status	eTMF Completeness	By Group	
		By Document Type		Deleted Docs	
		eSignature		Processed Docs	
		Make Default			
		Cancel Select			

Missing Documents

This view displays the list of all missing documents in a room. Refer to the screenshot below:

View by Missing Documents	
> E Country	
General	
Investigative Site	
> IRB/EC	

Click the folder from the left to view the documents. You can also edit the metadata of the documents from the **Metadata** Panel.



To edit the metadata, select the document from the appropriate folder and edit the metadata. Click Save to commit the changes.

Collected Documents

This view displays the list of all Collected Documents in a room. Refer to the screenshot below:



Click the folder from the left to open the list of sites. Select the required site to open the documents in the grid.

Modify Index

Configuring the Index Structure

Generally, a room index is created while creating a room from another room so that the index of the existing room is also copied into the new room. A client may opt to create a new room without any index, in which case the index structure needs to be created manually, and the documents and its types to be added to it. Creation of an index with its documents includes the following steps:

- 1. Adding main folders and sub-folders under the root folder of Index which is available by default.
- 2. Adding document types to the document categories. By default, the system provides three categories for the documents:
 - a. General
 - **b.** Country
 - c. Investigative site
- 3. If new categories are required for the documents, the super- administrator will need to add them.
- 4. Adding documents by importing or uploading and assigning them their categories and document types.



Adding Parent Folders / Child Folders

The administrator follows the process below to create the main folder structure:

1. Click the icon next to the View By Index search box. A popup appears. Refer to the screenshot below:



- 2. Click the Modify Index icon.
- 3. The Modify Index popup window opens. Refer to the screenshot below:



- 4. Select the root folder of **Index** from the popup to add a parent folder, else click a parent folder (or subfolder) into which you want to add a subfolder.
- 5. Click the '+' icon and type in the folder name in the textbox that appears. Press Enter.
- 6. The new folder appears under the root/parent folder.
- 7. Repeat the above steps to create another parent/child folder.
- 8. Click Save.



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Editing Folder Names

- 1. You can change the name of an existing folder.
- 2. Click the Modify index icon from the popup.
- 3. The Modify Index popup window opens.
- 4. Click the folder you want to rename.
- 5. Select the pencil icon.
- 6. The selected folder and its name appear in a highlighted box.
- 7. Make your changes, then press Enter.
- 8. Click Save.

Deleting Folder Names

1. To delete a folder, click the folder in the Modify Index window.



- 2. Click the Delete folder.
- 3. Click Save.

Note: Deleting a folder will delete all of its contents including documents and subfolders.

Umportant: If you have already clicked the Delete folder in error, you can still click Cancel at the bottom of the Modify Index window. The change will not be saved.

Exporting and Refreshing Index

Exporting Index

Export index allows you to export the index structure of the room. You can choose to export the index for the chosen folder, or only the index outline. The index can be exported in either HTML, or Microsoft Excel, or Microsoft Word formats. Besides these, you may also choose to export empty, or system folder as also documents unpublished to the eTMF.

To export index:

Export index

1. Click the **Export Index** from the popup and export the index as per the actions required. Refer to the screenshot below:



Export Index		?	×
Export Options Some information a	bout this window		
Options	Export Index Export Index Outline		
Туре:	HTML 🗸		
	Export Empty Folders		
	Export Empty Folders Only		
	Include Unpublished Documents		
	Include System Folders		
	Cancel Export		

Index Search

In the Search box below the View By Index pane, enter the name of the folder you want to search. Press **Enter** or click the magnifying lens icon to reveal matching contents.

View by Index		
् Inbox	×	:

Click the Cross next to the right of the search box to delete the search criteria.

The Documents Grid

You can perform the following from the Documents Grid.

- Preview and Viewing a document and its metadata (page 243)
- Access the Document Context menu on a document by the mouse right-click (page 249)
- Configure the Documents Grid (page 241)
- Copy or move documents (page 245)

Configuring the Document Grid

Through this option, you can decide which columns to display or hide from the Document, Workflow, or Audits Grid. Thus, you can decide exactly what information you want to see and configure the grids accordingly to suit your view.

- 1. Navigate to the eTMF/Documents module.
- 2. Click the Update Columns icon from the top right corner of the documents grid. Refer to the screenshot below:



Displaying do	e	т 🗉	● Views ~						
Disable au	Document	Reason fo	Comments	Document	Category	Category	Investigati	Investigati	Document
Yes	Polly Chak		This is ver	23 Apr 2018	1	General ed			2066000
Yes	Polly Chak			18 May 20	100	first categ			2065983
	Polly Chak			21 May 20	3	Country	2079443	Laz Institu	2065973
Yes	Polly Chak			24 May 20	0				
	Tiger Woo			03 Dec 2018	3	Country	2069250	Annabot I	2065973

- 3. The Grid Configuration window opens which displays the following panels:
 - a. Available Columns Panel: This panel display the list of all available columns in a room.
 - **b.** Selected Columns Panel: This panel displays the list of all columns that are selected and added from the Available Columns.
- 4. To add a column to the Selected Columns pane from the Available Columns pane, hover the mouse over the column name in the Available Columns. The + sign appears next to the column name.
- 5. Click the + sign to add the column to the Selected Columns. The column gets added to the list of Selected Columns. Refer to the screenshot below:

vailable Columns	Selected Columns			
Q Enter field name or title	Title	Name	Width	Up
Title	Contact	Document_ContactId	100	Down
Document Id	Contact Name	Document_\$\$ContactName\$\$	100	
Title	≘ File Name	Document_\$\$FileName\$\$	100	E
Document Name	Deleted By	Document_\$\$DeletedBy\$\$	100	
Disable auto Document Na	Delete Comments	Document_\$\$DeleteComments\$\$	100	
Document Name last upda	Index	Document_\$\$Index\$\$	100	
Reason for not using auto I	Last Updated By	Document_\$\$LastUpdatedBy\$\$	100	
Comments	Document Status	Document_DocumentStatusId	100	
Document Date	Document Status	Document_\$\$DocumentStatusName\$	100	
Category	Current Workflow	Document_\$\$CurrentWorkflow\$\$	100	
Category	Current Workflow Stage	Document_\$\$CurrentWorkflowStage\$	100	
Investigative Site	Published By	Document_PublishedBy	100	
Investigative Site Name	 Published By 	Document \$\$PublishedBv\$\$	100	-

- 6. Alternatively, you can also **double-click** the columns in the Available Columns to add to the Selected Columns.
- 7. After adding the columns to the Selected list, they are **greyed out** in the Available Columns list and a **small green tick**

appears to the next of the column name as shown in the screenshot below:



vailable Columns	
Q Enter field name or t	
Title	
Document Id	
Title	
Document Name	
Disable auto Document	Na
Document Name last up	da
Reason for not using aut	0
Comments	
Document Date	
Category	~
Category	4
Investigative Site	4

- 8. Similarly, you can remove the columns from the Selected Columns list by clicking the icon that appears next to the column name on hovering the mouse over the column OR double-click the column to remove it from the list.
- 9. Besides adding and deleting columns, you can also change the sequence of the columns by clicking the Up or Down



buttons located at the extreme right of the window.

10. Click Save to save to changes.

Previewing and Viewing a Document and its Metadata

This allows you to view the document metadata and the document in the separate panels in the eTMF / Documents module. These are discussed in the sections below:

Viewing Document Metadata

To access the Document Metadata, follow the steps as below:

- 1. From the **Documents** module, select the document from the grid.
- 2. Hover the mouse over the bar to the right of the grid. The **Metadata Viewer Open** text on it.
- 3. Click the viewer to open the Metadata Panel. Notice that when you open the metadata panel, the Metadata Viewer bar changes the Open text to Hide clicking which you can hide the metadata panel
- 4. The Document Data Panel opens which displays the Document Metadata by default. Refer to the screenshot below:

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display with the



iew by Index	60	docu	ments (1 se	lected)								0	Claim	Ø More
Q. Search by folder name			Document	Title	Document	Disable au	Document	Reason fo	Comments	Document	Category	Calife	Metadata Workflow Queries	Versions History
😂 Index	0	*	2070018	ACM_user	303781_6	True	Polly Chak		This is ver	23 Apr 2018	1	G	Document Metadata	-
1 signature 2 6	00	*	2085967	test		True	Polly Chak			18 May 20	100	fir M		
2 eSignature 0		*	2086013	adddocfro	-		Polly Chak			21 May 20	3	ADA	Document Id	
> a Country Management_polly 0(0)	20		2086077	etmf 10.pdf			Polly Chak			24 May 20		A	2086077	
> a PleaseReview replacement 0(0)	00		2237337	Showing S			Tiger Woo			03 Dec 2018	3	Cc	Title * 😧	
> is 5 Site Management 0 (16)	0.0	1.	2241062	TESTnew		True	Tiger Woo			10 Dec 2018			etmf 10.pdf	
6 Complex criteria test 1													Document Name	
7 Complex criteria test 2 0	A													
8 Mutual Nondisclosure Agreement For													Disable auto Document Name	
9 Site Signed NDA 0													Document Name last updated by	
10 Site Language Changes 1													Folly Chakraborty	
11 Additional PSV Package Documents	1												Reason for not using auto Docume	nt Name
12 Protocol Draft.Protocol Synopsis 0														
13 CRA PSV Materials 0														
14 Relevant Communications 0													Comments 0	
15 Language Changes_Pearl Distributed														
> 16 CNS_Contracts and CDAs 0(0)														
> 17 PT003006 US_Site Contracts and Buc													Document Date	
> 18 PT003007 US_Site Contracts and Buc													24 May 2018	8
													Category	
19 TICK TOIDER 1 125														~
20 admins only 1														
20 admins only 1													Investigative Site	

As an Administrator, you can not only view a document's metadata, but you can also change the content of some of the Metadata fields. The icons at the bottom of the panel provide access to several essential functions, such as saving changes and updates in the metadata panel as shown in the screenshot above.

Notice that you can manually enter dates in the format as preferred by you if you have enabled this option from your My Profile Settings -> General Information (page 58)section. Refer to the screenshot below:

Commen	ts 😧			
This is v	ersion 2 of	the docum	nent	
This is v	ersion 2 of t	the docum	nent	
This is v	rersion 2 of 1	the docum	nent	
This is v Documer	ersion 2 of 1 nt Date 2018	the docum	nent	Ĩ
This is v Documer 23 Apr 2 Category	ersion 2 of t nt Date 2018	the docum	nent	Ĩ

Previewing a document

To preview the selected document:

- 1. Select the checkbox next to the document.
- 2. Click the Document View button at the bottom of the grid.



Document Title Document Disable au Document * 2081023 12 Polly Chak Polly Chak * 2081024 VID-20180 True Tiger Woo * 2082068 SSU-4922 Polly Chak Polly Chak * 208208 SSU-4922 Polly Chak Polly Chak * 217883 For new q Polly Chak Polly Chak * 219714 Doct Polly Chak Polly Chak * 219963 Test Docu Polly Chak Polly Chak * 219963 Test Docu Polly Chak Polly Chak * 217729 DMS Docu Polly Chak Polly Chak * 217910 Doc3 True Polly Chak
2081023 12 Polly Chak 2081024 VID-20180 True Tiger Woo 20820608 S5U-4922 Polly Chak 2081024 Polny Chak Polly Chak 2081024 Polny Chak Polly Chak 2081025 Polny Chak Polly Chak 2081026 Text Docu Polly Chak 2081027 Doc1 Polly Chak 2081028 Text Docu Polly Chak 2081029 Doc3 True
* 2081024 VID-20180 True Tiger Woo * 2082608 SSU-4922 Polly Chak * 2178833 For new q Polly Chak * 218714 Doct Polly Chak * 2199633 Test Docu Polly Chak * 221729 DMS Docu Polly Chak
Image: state
<hr/>
Image: state
217910 Doc3 True Polly Chak
2232768 Import Do True Polly Chak
🗟 ★ 2373028 CDA Agree Polly Chak
2425559 For UAT 101010 ed Polly Chak
🗈 ★ 2425584 Review Do 101010 ed 🛛 Polly Chak

3. The document opens in the Arender view. Refer to the screenshot below with the sequence of

steps in number denoted:

Copying or Moving Documents

Follow the steps below to copy documents:

- 1. Select the document(s) to be copied or moved in the grid.
- 2. To move the document(s) to another folder, drag the document from the grid and drop it to the destination folder in the Index Pane.
- **3.** To **copy** the document/s to another folder, hold the *Ctrl or Shift key*, and drag and drop the document to the destination folder in the Index Pane.

While copying or moving a document you will be asked to re-code the document profile and will open the **Edit Document Profile** window to enter the details. Follow the instructions to complete the form. You may choose to replace the attachment at this time if required. If you replace the attachment you can view the version history in the document's metadata panel.

Note: Viewing of version history on replacing attachments is available only in Alfresco rooms. For more details follow on to section Replace Documents. (page)



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If the **Hide Index on add new document** option is on, editors will not be able to copy or move a document and will receive the warning as below.

Warning	
⚠	Cannot change index when Hide Index option is on
	ОК

Documents Grid Views

While in a specific folder, the user may want to filter the columns and view only the columns that are required. This can be done by customizing the grid view. You can create your own view and set that particular view as a default view so that you can view only that information which is required in the grid.

Besides, you can also apply filters to the grid and save the view for future use. To set and customize a view:

- 1. Navigate to the eTMF/ Documents view.
- 2. Select the required folder and update the columns (*page 241*) as needed. The documents grid gets updated as required.
- 3. Click the Views dropdown at the top right corner of the grid.
- 4. The list of options appears. Refer to the screenshot below:

	Document	Title	Document	Disable au	Document	Reason fo	Comments	Document	Category	Category	ies save view
*	2069982	DMS TEST			Polly Chak			16 Apr 2018			Default view Views
*	2070184	CDA AGRE		Yes	Polly Chak			19 Apr 2018	2	Investigati	I Show all vie
*	2081685	Script for		Yes	Amruta M			07 May 20			
*	2090205	For Query		Yes	Polly Chak			05 Jun 2018			
*	2090206	ieinstal.exe			Amruta M			05 Jun 2018			
*	2091588	Wildlife			Amruta M			11 Jun 2018			
*	2091589	3.New ap			Amruta M			11 Jun 2018			
*	2178885	For new q	audit 1_10	Yes	Tiger Woo			19 Sep 2018	1	General ed	
14	2348984	Creating li			Amruta M			18 Dec 2018			

- 5. You can perform the following actions:
 - a. Save View
 - b. Set Default View
 - c. Show all views
 - d. Share the Views

Each of these is discussed in the sections below:

Save Views



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After updating the columns in the grid, click **Views** → **Save View**. The **Save View** window opens. Refer to the screenshot below:

Save View			×
Name	My View]	
Make Default for Me			
Make Default for All			
		Cancel	Save

Enter the name of the view and enable the options by clicking the toggling buttons below for the default view. You can either make the view default for you or for all the users who accesses the folder to which the view has been set. Click **Save** to save the changes.

On saving, you can see the name of the view and columns also gets

Displaying documents 1 - 11 of 11 (0 selected)								
	Document Id	Title	Document Name	Disable auto Document Name	Version Date			
*	2069982	DMS TEST						
*	2070184	CDA AGREEMENT		Yes				
*	2081685	Script for myTl demo		Yes				

updated. Every time you visit the folder, you can select the view for the grid. Refer to the screenshot below:

Show All views

If the room has multiple views created in a room, and if they are visible

to all users, you can view all the views in a room. To display all views:

1. Click Show All Views from the from the Views dropdown. Refer to the screenshot below:



- 2. The Views window opens which contains the following tabs:
 - a. All: This displays the list of all the views in a room.
 - b. Created by me: This displays the list of all views that are created by you.
 - c. Shared by me: This displays the list of all the views that are shared by you to the other users.
 - d. Shared with me: This displays the list of all the views that are shared with you by the other users.
 - e. Default Views: This displays the list of all default views.



The screenshot below shows an example of the All views:

Viev	vs			×
	All	Created by me Shared by me Shared with me Default views	(Delete
	Title	Created By		
⊻	My View	Amruta Maddel		^
				÷
			Cancel	Select

Note: The Delete and Select buttons are enabled only when you select a view from the list.

To delete a view, select a view from the list and click the **Delete** button at the top right corner of the window.

Share Views

Note: This option is enabled in the Views dropdown only when you select a view created from the list.

To share view:

- 1. Select a view you want to share from the list of views. The selected name of the view displays.
- 2. Now, click the Views dropdown. The list of options appears.
- 3. Click Share View. Refer to the screenshot below:

۲	> My View ~
. 8	Save view
C	Share view
	Default views
	Views
	Recent views
۹	My View
	Show all views

4. The Share window opens.



- 5. Select the Groups or Users to whom you want to share the view. Double click the user from the left pane to add them to the Selected members pane.
- 6. After selecting Gorpus/Users, click Share. Refer to the screenshot below:

Shar	e							3
Gro	oups User	s				Selec	ted members	
						. 0	Name	
			Q	swa		· 0	Swati Auditor2 Pawar	
	Last Name	First Name	Email	Phone	Mobile			
	В	Swati	swatib008@gm			^		
	Pawar	Swati	swatipawar.pu			1		
~	Pawar	Swati Auditor2	swpawar@tran					
						Grou	ouble-click to add	
							Members pane.	
	21					-		
				< Previou	s 1 of 1 Ne	. >		
					_			
				C	ancel Sha	e		

7. This shared view now displays under the list of Shared by me in the Show All Views.

Documents Context Menu

You can perform the horde of activities on a document from the Document Actions (page 269) as well as by right- clicking on a document in the Document Grid.

Refer to the screenshot below to get a list of actions possible from the Documents Context Menu. Each of the functionalities is discussed in separate topics available from the left panel of this topic help.



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0	Add Document
C	Copy Link
×	Delete
	Manage Security
۲	Open Profile
Ø	Edit Profile
Ø	Replace Attachment
ľ	Add to Cart
*	Add to favorite
☆	Remove from favorite
¢	OCR
ß	Convert Non PDF to PDF
Ø	Send for E-Signature
Ø	Cancel E-Signature
4	Add to Review
P	Ask a question
ų	Related documents

Adding a Document

- 1. From the Documents Module, right-click on a document in the Document Grid.
- 2. Select the Add Document option and the New Document window opens. Enter the details as required to create a new Document profile. Refer to the screenshot below:

			Document	Title	Document	Disable au
	8	*	2070018	ACM_user	303781_6	True
2	B	*	2085967	test		True
	•	\pm	2086013	\rm \rm Add Docu	ment	
		$^{\pm}$	2086077	Copy Link		True
		$^{\pm}$	2237337	X Delete		
	A	*	2241062	A Manage S	ecurity	True

- 3. Select the appropriate Category from the dropdown list: General, Country, or Investigative Site.
- 4. Depending upon the category selected, the document's Submitted Name field would appear or disappear. Enter the Submitted Name as required.
- 5. Select the Document Type, and Document Date. Type in the date if that is configured for you.
- 6. Add pertinent Comments, if necessary. The Index position will populate



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automatically, based on the folder you selected from the index.

- 7. Click the Add button at the right end of the Attachment field to attach a document.
- 8. Click Save.

Deleting Documents Deleting Documents To delete a document:

- 1. Navigate to the Documents module.
- 2. Select the document(s) from the documents grid.
- 3. From the right-click menu, select Delete. Refer to the screenshot below:



Deleted Documents View

All documents that are deleted from a study by each user can be viewed from the Documents module under the **Deleted Documents view**. The documents are grouped under folders by the name of users who deleted documents. Refer to the screenshot below.

-	Document Manage Secu	rity 🍄 Move to Stu	udy Start-Up	🔹 🗣 Export 👻 🐸 Em	nail 😝 Print 🖽 Compar
\ \	/iew by Index	1 - 3 of 3 (1 selected)	C T Fil	ters 🔲 Select Columns
١	/iew Documents By				# X
	ETME	A MY LIST	WORKFLOW	DOCUMENTS	OTHER
	Index	Submission	By Status	eTMF Completeness	Security
	Show Empty Folders	Reviews	By Reviewer	Working Documents	Group
	Show Investigative Sites	Audit Findings	Workflow		Posted Date
	Show Countries	E-Signature	Query By Sender		Delete
	Document Type		Query By Recipient		Processed Documents
	Site		gaciy by recipient		Trocesses Bocamento
	Country				Documents Security
	Tag				

Copy Link

Clients might need to copy a document link through the Document



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dropdown in the eTMF module. They can choose the type of document link to copy through the**Copy Link Settings** option.

Once the Copy Links settings are made, follow the steps as below to copy a link:

- 1. Navigate to the Documents Module.
- 2. Select the required document from the grid and right-click on it.
- 3. Click Copy Link to copy the link to a document, or to copy the link to a document with metadata and anotification about the same is

NOTIFICATIONS			STICKY NOTES			📜 Documents Clear Al		
Actio	ons	Workflo						
	Cop	oy Link				Trial Interactive		
0	Link	has bee	en copied	to clipbo	ard	Trial Inter 04 May 15:3		

received. Refer to the figure below:

Paste the copied URL in a browser tab. Depending upon the option set up in Documents Settings, the document will either open up in the browser for you to read, or the link will take you to the eTMF room and open the document and its metadata for you to view. **Copying and pasting the link of an empty document shall display the message 'This document profile does not have an associated document'.**

Purging and Restoring Documents

Deleted documents can be restored or purged by clicking the required icon located on the top ribbon from the **Document dropdown** or he **right-click menu** on the document . Restored documents take the same place in the index they were located in before deletion. Refer to the screenshot below:

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	TechWritersDemoRoc 1340	om 🖌							🕇 Add
	Document 🗠 🔒 Manage Security	Print	Email 🖒	Move to Startup	↑ Import ~		? Layout	Compare	🌲 Bulk Upload
<i>6</i>	• Add Document		Document	Title	Document	Disable au	Document	Reason fo	Comments
			± 2072157	Important		True	Polly Chak		
	Restore Documents		* 2081644	Tagging	303781_6	True	Amruta A		
π	Purge		* 2091588	🛍 Restore Docum	ents		Amruta A		
	Replace Attachment			Durge					
4					2				
_	\bigcirc Ask a question								
2	♦ OCR								

Documents can also be **auto purged** if so required by the client. For such documents, the admin can enable the Auto Purge

(page 97) from the Room Settings.

Opening Document Profile

In the **Documents** module, select the document and click **Open Profile** from the right-click menu on the document. Refer to the screenshot below:

Print		Er	mail 🙆 Mov	ve to Startup	↑ Import ~		? Layout	Compare	🌲 Bulk Upload	
			Document	Title	Document	Disable au	Document	Reason fo	Comments	Docun
	•	$^{+}$	2070018	ACM_user	303781_6	True	Polly Chak		This is ver	23 Apı
0		$^{+}$	2085967	test		True	Polly Chak			18 Ma
	•	*	2086013	adit			Polly Chak			21 Ma
		$^{+}$	2086077	et C Add I	Document	Гrue	Polly Chak			24 Ma
		*	2237337	Sł Sł	LINK		Tiger Woo			03 De
		$^{\pm}$	2241062	TE Mana	age Security	ſrue	Tiger Woo			10 Dei
•		m		C Edit F S Repla	Profile Profile Ince Attachment	, hr				Þ
				😫 Add t	o Cart			< Previous	1 of 1	Next

On clicking Open Profile, you will see the Document Profile for the selected document. In this view, the fields are static. Refer to the screenshot below:



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Document Profile				×
Document Profile Activ	rity Log			
Organization: All	~	Activity type:	All	~
Date	Updated By	Activity	Description	
10 08 2017 07:23:19 EST	Polly Chakraborty (chak.polly@	Update security: gmail.c		
10 08 2017 07:23:19 EST	Polly Chakraborty (chak.polly@	Update security: gmail.c		
25 07 2017 14:34:10 EST	Polly Chakraborty (chak.polly@	Mass coding	LinkTopics	В
19 07 2017 10:56:58 EST	Polly Chakraborty (chak.polly@	Metadata field was upd		
12 07 2017 07:34:05 EST	Polly Chakraborty (pchakrabort	Mass coding	LinkTopics	
21 03 2017 06:25:07 EST	TymSA@tym.com	Update security: tym.com		
20 03 2017 11:18:50 EST	TymSA@tym.com	Update security: tym.com		
20 03 2017 11:18:50 EST	TymSA@tym.com	Update security: tym.com		
20 03 2017 11:18:50 EST	TymSA@tym.com	Update security: tym.com		
20 03 2017 11:18:50 EST	TymSA@tym.com	Update security: tym.com		
20 03 2017 11:18:50 EST	TymSA@tym.com	Update security: tym.com		
20 03 2017 11:18:49 EST	TymSA@tym.com	Update security: tym.com		
20 03 2017 11:18:49 EST	TymSA@tym.com	Update security: tym.com		
20 03 2017 11:18:49 FST	TvmSA@tvm.com	Undate security: tym.com		

Editing Document Profile

In the Documents module, select the document and click **Edit Profile** from the right-click menu on the document and the fields are no longer

Prin	t	E	mail	C Mov	e to Startup	↑ Import ∨	🗣 Export 🗸	? Layout	🔲 Compare	🌲 Bulk Upload	
			Do	cument	Title	Document	Disable au	Document	Reason fo	Comments	Docun
	W	*	207	70018	ACM_user	303781_6	True	Polly Chak		This is ver	23 Apı
C	A	$^{\pm}$	208	35967	test		True	Polly Chak			18 Ma
		*	208	36013	adddocfro			Polly Chak			21 Ma
C	A	$^{\pm}$	20	C Add D	ocument		True	Polly Chak			24 Ma
	A	$^{+}$	22	Copy I	Link			Tiger Woo			03 Dei
	A	*	22	DeleteManage Security			True	Tiger Woo			10 Dei
				👁 Open	Profile						
				🕑 Edit P	rofile						
				🕲 Repla	ce Attachment	<u> </u>					

static. Refer to the screenshot below:

By this route, an Administrator can edit the document profile. Editing profile is also possible

from the Metadata Panel.

(page 262)

Add Selected to Cart

Add Selected Document to Cart

Proceed to section Adding Selected Documents to Cart (page 282) for the detailed

information.



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Adding and Removing Favorites

Adding Favorites

Click Add to favorite from the Documents Context Menu menu to mark a document as favorite. Similarly, click **Remove from favorite** from the right-click menu to unmark document as favorite.

Besides, you can also click a Star to the left of a document to mark/unmark it as a favorite.

Ask a Question

This allows you to create a question related to a particular subject. Click the link Ask a Question to lead you to the topic

Note: You can also perform this action from the **Documents Actions** (page 269) dropdown on the top menu bar.

Convert Non PDF to PDF

Convert Non PDF to PDF and PDF fix

This allows you to convert the Non PDF documents to PDF. You can view these converted

PDF documents under the

Processed view of the documents.

e-Signature

This section discuss the various ways of e-Signature used to sign the documents.

Trial Interactive (TI) offers a feature to e-Sign your PDF, Word, PowerPoint, and Excel documents. This feature permits Administrator users to invite multiple signers to sign the required documents. The system facilitates the user with an option to designate a space within the document for the signers to sign. This feature also allows the user to decide the sequence in which the signers should sign the document.

OCR

This allows you to choose the language for OCR.

OCR can also be performed from the **Documents Actions dropdown** (page 269)

on the top ribbon bar. To specify languages for OCR:

- 1. Right-click on the required document from the grid. The Document Context Menu popup appears.
- 2. From the Context Menu, select OCR.
- 3. The Select OCR languages popup appears.
- 4. Click the textbox and select the languages as applicable from the dropdown.



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Select OCF	? ×	
Please specify lan	guages for OCR	
English 🗙	Swedish 🗙	×
Romany		*
Ruanda		
Rundi		
RussianOldSp	elling	
Russian		
Samoan		
Selkup		
SerbianCyrillio		
Corbian Latin		· · · · ·

5. Click Ok.

PDF Fix

Grid Filters

For a document grid, you can apply and save filters to

make the search for the documents easier. To apply

filters:

- 1. Click the Filter icon above the document grid.
- 2. The Filter options are enabled at the top left corner of the documents grid. Refer to the screenshot

Displaying	° 🔽 🗉	Views *				
0 ≔					_	
	Document	Title	Document	Disable au '	Category	Investigati
	No records ava	alabla				

below:

- 3. From the enabled options, you can perform the following:
 - a. Create New Filter
 - b. Add Existing Filter/Manage Filter

Each of these is discussed in the separate sections below:

Creating New Filter

- 1. Click the + ^osign above the documents grid.
- 2. The Create Filter window opens. The window displays the following:
 - a. A textbox that displays the Title for the filter selected.
 - b. The options for matching the filter records. Refer to the screenshot below:



Create filter		×
Include records that match all (any) (none) of the following filters		+0
	Cancel Add	Create

3. Notice that there are two + plus signs to the right of the window which allows you to create a single filter and group of filters.

Adding Single Filter

4. To add a single filter, click the first + sign. Refer to the screenshot below:

Create filter	×
Title Include records that match all (any) (none) of the following filters	Add Filter

- 5. A dropdown appears. Click the dropdown and select the fields to which you want to apply filters.
- 6. Select the operator and enter the value for the selected field. Refer to the screenshot below:

Title = TEST		
nclude records that match all	(any) (none) of the following filters	+0

- 7. Click Add if you wish to display the filter in the current view or click Create if you want to save the filter and use it later.
- After creating a filter, when you select the filter and apply it for the document grid, the search results display accordingly. The screenshot below shows an example of the filter result applied for the Title = Test.

Displaying	documents 1 -	9 of 9 (0 selec	ted)						¢		Views ~
Title = TEST	✓ 0 III										
	Document	Title	Document	Disable au	Document	Reason fo	Comments	Document	Category	Category	Investigati
🗆 🗟 ★	2072804	TEST	audit 1_10	Yes	Amruta M			25 Apr 2018	1	General ed	
. 🖻 \star	2081892	TEST	audit 1_10	Yes	Amruta M			08 May 20	1	General ed	
. 🛛 🖈	2085479	test		Yes	Polly Chak			17 May 20	2	Investigati	2069253
. 🗅 🖈	2085967	test		Yes	Polly Chak			18 May 20	100	first categ	
. 🖻 \star	2085986	test		Yes	Polly Chak			18 May 20	2	Investigati	2069281
*	2090128	Test		Yes	Polly Chak			01 Jun 2018	3	Country	
. 🖬 \star	2090144	test		Yes	Amruta M						
. 🖪 \star	2217728	Test		Yes	Polly Chak						
. 🛛 🖈	2423448	Test		Yes	Polly Chak				2	Investigati	2069253

9. Similarly, you can add group filters to apply for the document grid and search for the results by clicking the second +



Proceed further as discussed above to add group filters.

Add Existing Filters / Manage Filters

Manage filters allows you to view and share the created filters by you

and by others. When you click the Manage Filters icon above the documents grid, the **Filters** window opens. Refer to the screenshot below:

Filters		×
All Created by me Shared by m	ne Shared with me	
+ Add 🕲 Clone Delete	Only one filter must be selected	*
Test(Amruta Maddel)	A.	
Title = TEST(Amruta Maddel)		ш
	÷	٣
	Cancel Select	t

You can perform the following activities on the filters in Manage Filers window:

- 1. Share Filters
- 2. Clone Filters
- 3. Delete Filters Sharing Filters To share a filter:
- 1. Select the filters from the list of filters in the Filter window.
- 2. The selected filter appears in the right pane of the window and the buttons Clone, Delete, Share, Cancel, and Save are enabled. Refer to the screenshot below:

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Filters		×
All Created by me Shared by me	Shared with me	
+ Add 😰 Clone Delete	A Share D Cancel	Save
Filter	Test	<u>^</u>
Test(Amruta Maddel)	nclude records that match all (any) (none) of the following filters	+0
Title = TEST(Amruta Maddel)	Title (Title)	Ô.
		-
	Cancel	Select

- 3. After selecting a filter, click the Share button. The Share window opens.
- 4. Select the Users / Groups to whom you want

to share the filter and click Share. Deleting Filters

Similarly, select the filter from the list of filters and click **Delete** to delete the filter.

Viewing Shared Filters

You can view the filters that are **created by you**, **shared by you** and that are **shared with you** by clicking the required tabs in the Filters window.

The Working Area and Grid

When you open the eTMF/Documents module, the following appears:

- 1. The Room Index (page 224)
- 2. The Documents Grid (page 241)
- 3. The Working Area and Grid

In Trial Interactive 10, the eTMF index is separated from the working folders which include Working Documents, Rejected Documents, Uploaded, and Emailed documents. Users can perform various actions like document coding, document replacing and attaching, adding documents to workflow or auditetc. from this Working Area. The folders in the working area are hardcoded and any documents coming in the room, either by uploading or emailing are available for further process or actions from this Working Area. Refer to the screenshot below:
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=	TechWritersDemoRoom Y 1340							+ Ad	ld	Q Search	0 Polly Cha	akraborty 💙
	Document V 🔒 Manage Security	Print 🔤 Ema	ail 🖓 Move to	o Startup	↑ Import ~		? Layout 🗸	Compare	🌲 Bulk Upload	Edit Online	📔 Add to Cart	🗎 Documents cart '
æ	View by Index	No records ava	ilable.							Metad	ata Workflow Queries	Versions History
•	Q. Search by folder name											
1. 1. W.	V 🖕 Index											
4	1 signature 2 6											
da	Site Management 0 (16)											
	6 Complex criteria test 1											
	10 Site Language Changes 1	i										
	15 Language Changes_Pearl Distributed											
	20 admine ratu											
	20 aumins only 1											
	24 read only 1											
	25 New folder 3							< Previous	0 of 0	Next >		
					_				Arrest Const			
	Working Area	Working An	ea/Staging									
			Document	Title	Document	Disable au	Document	Reason fo	Comments	Docur		
	19 nick földer 1 123	🗹 🗈 \star	2231034	Updates f			Amruta A			30 Oc		
	Amruta Auditor1 Maddel 1											
	> Millioad 0 (50)											
\sim		*										
6								< Previous	1 of 1	Next >		

Besides working on documents, you can also drag and drop the documents from the Working Area to the required eTMF folders above like for the **Country** and **Site** views, the user can easily drag and drop documents from the working folders into **missing documents** and **placeholders** in the eTMF.

Note: Documents can be dragged only out of Working Area but not into the Working Area.

Hiding or Unhiding the Working Area/Staging panel

To hide or unhide the Working Area, hover the mouse over the bar above the Working Area. The Hide - Working Areabar appears. Refer to the screenshot below:

View by Index	9 d	locu	ments (9 se	lected)					
🔍 Search by folder name			Document	Title	Document	Disable au	Document	Reason fo	Comments
> 5.17 TEST2 AFG[Site Management] AF		π	2069982	DMS TEST			Polly Chak		
6 Complex criteria test 1		π	2070184	CDA AGRE		True	Polly Chak		
10 Site Language Changes		*	2081685	Script for		True	Amruta A		
15 Language Changes_Pearl Distributed		$^{+}$	2090205	For Query		True	Amruta A		
19 nick folder 1 123	0	$^{+}$	2090206	ieinstal.exe			Amruta A		
20 admins only 1	0	*	2091588	Wildlife			Amruta A		
23 test folder 2		*	2091589	3.New app			Amruta A		
24 read only 1		*	2178885	For new g	audit 1_10	True	Tiger Woo		
25 New folder 3		*	2348984	Creating li	_		Amruta A		
26 redaction 1	~	m		0					
al workflow 1								< Previou	is 1 of
Hide WORKING AREA									
Working Area	Worki	ng A	rea/Staging						
19 nick folder 1 123	No rec	ords a	vailable.						
* Inbox 0(1)									
*Upload 0 (50)									



Hiding the Working Area

You can also drag the Working Area/Staging to the extreme left to hide the Work Area.

Refer to the screenshot below:

<			F			
Working Area			Working Area/Staging			
19 nick folder 1 1	Drag to the I23 left to hide the		No records available.			
> 🖿 *inbox 0(1)	Working					
*Upload 0 (50)	-	-1				
]			
				Previous	0 of 0	Ne

Similarly, you can also drag the Working Area/Staging Area **up** to increase the size of the window and the number of documents count in the grid.

The Document Data Panel

The Right Panel opens by default in the eTMF Documents Module when you click Documents from the left pane.

From the **Right Panel** located at the right of the documents grid, you can view the following panels after you select a document from the grid:

- 1. Metadata panel
- 2. Workflow panel
- 3. Queries panel
- 4. Versions panel
- 5. History panel
- 6. eSignature panel

Each of the functionalities above is discussed in separate topics available from the left panel

of this help.

You can **hide** this panel by hovering the mouse to the right of the grid and clicking the **Hide** arrow. Refer to the screenshot below:

Prin	E)	🔽 Er	mail	街 Mov	e to Startup	↑ Import ~	🗣 Export 🗸	? Layout	Compare	🏂 Bulk Upload			😫 Add to Cart	📜 Documents car
			Docun	nent	Title	Document	Disable au	Document	Reason fo	Comments	Document	6 ₽	Metadata Workflow	Queries Versions Hi
	2	*	20700	18	ACM_user	303781_6	True	Polly Chak		This is ver	23 Apr 2018	Hide	Document Id	
		*	20859	67	test		True	Polly Chak			18 May 20		2,085,967	
C	1	*	20860	13	adddocfro			Polly Chak			21 May 20	+	Title * 😧	
C		*	20860	77	etmf 10.pdf		True	Polly Chak			24 hide/unhi	the arro	ight Panel	
C	Ø	*	22373	37	Showing S			Tiger Woo			03 Dec 2018		Document Name	
	D	*	22410	62	TESTnew		True	Tiger Woo			10 Dec 2018			
													Disable auto Document	

Besides, you can also hold the panel and drag it to the extreme left of the page. Refer to the

screenshot below:



	Document 🗸 🔒 Manage Security			Er	mail 🙆 Mov	e to Startup	↑ Import ∨	🔸 Export 🗸	? Layout	🔲 Compare	🍰 Bulk Upload	
Ð	View by Index				Document	Title	Document	Disable au	Document	Reason fo	Comments	Document
	Q Search by folder name	. 0	•	*	2070018	ACM_user	303781_6	True	Polly Chak		This is ver	23 Apr 2018
	ta P. Index	<u>^</u>		*	2085967	test		True	Polly Chak			18 May 20
	1 signature 2 6		•	$^{+}$	2086013	adddocfro			Polly Chak			21 May 20
	5 Site Management 0 (15)			$^{\pm}$	2086077	etmf 10.pdf		True	Polly Chak			24 May 20
	6 Complex criteria test 1			$^{+}$	2237337	Showing S			Tiger Woo			03 Dec 2018
	10 Site Language Changes 1		Ø	*	2241062	TESTnew		True	Tiger Woo			10 Dec 2018
	15 Language Changes_Pearl Distributed	1										
	19 nick folder 1 118											
	20 admins only 1								Hold a	nd drag to the loca	ition as	
	23 test folder 2								required. the e	You can drag the p atreme left of the	page.	
	24 read only 1				•							_

Metadata Panel

Metadata Panel is activated by default when you select a document.

As an Administrator, you can not only view a document's metadata, but you can also change the content of some of the Metadata fields. The buttons at the bottom of the panel provide access to several essential functions, such as saving changes and moving to the next document in the metadata panel. Refer to the screenshot below:

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Claim	🛱 More	~
Metadata Workflow Queries V	ersions History	e -)
Document Metadata	-	ſ
Document Id		
2086077		
Title * 😧		
etmf 10.pdf		
Document Name		
Disable auto Desument Name		
Document Name last updated by		
Polly Chakraborty		
Reason for not using auto Document	Name	
Comments 😧		
Document Date		
24 May 2018	#	
Category		
	~	
Investigative Site		
	Δ	
Cancel Save	Save and Nex	t
Previous Document	Next Document	>

Notice that you can manually enter dates in the format as preferred by you if you have enabled this option from your My Profile Settings \rightarrow General Information (page 60) section.

You can also shuffle back and forth between documents in the grid by clicking the Previous Document and Next Document links at the bottom of the Metadata panel.

The Metadata Panel also provides the Claim button and the More (Settings) icons at the top of the panel to allow you to claim documents in workflow and perform various actions on the document.

Workflow Panel

You can do the following from the Workflow Panel:

- 1. Claim Documents in a workflow
- 2. View the Workflow History
- 3. Initiate a Query
- 4. Release a document from a workflow'
- 5. Reassign Reviewer
- 6. Exclude document from a workflow

The Workflow panel displays all the details of the document workflow.



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		Document	Title	Document	Disable au	Document	Reason fo	Comments	Document	Category	Ca	Gaim	🌣 More 🗸
•	*	2069982	DMS TEST			Polly Chak			16 Apr 2018			Workflow History	^
	*	2070184	CDA AGRE		True	Polly Chak			19 Apr 2018	2	In	Q 17 Apr 2019	05:45 PM
2	*	2081685	Script for		True	Amruta A			07 May 20				
	*	2090205	For Query		True	Polly Chak			05 Jun 2018			0 17 Apr 2019	05:45 PM
0	*	2090206	ieinstal.exe			Amruta A			05 Jun 2018			0 08 Apr 2019	04:25 PM
0	*	2091588	Wildlife			Amruta A			11 Jun 2018				
	*	2091589	3.New app			Amruta A			11 Jun 2018			O 08 Apr 2019	04:19 PM
	*	2178885	For new q	audit 1_10	True	Tiger Woo			19 Sep 2018	1	Ge	O 08 Apr 2019	04:19 PM
	*	2348984	Creating li			Amruta A			18 Dec 2018				
A	*	2423443	Good Clini		True	Polly Chak						View All Histo	ory

Click the Date to view from the Workflow History section to view the full history of the

17 Apr 2019]	05:45 PM
Stage	Approval stage 1	
Status	Available for review	
Issues	÷.	
Activity	Release	
User Name	Polly Chakraborty	
Comments	-	
17 Apr 2019		05:45 PM
08 Apr 2019		04:25 PM
08 Apr 2019		04:19 PM
08 Apr 2019		04:19 PM
	View All History	_

document in a workflow as shown in the screenshot below:

Queries Panel

From the Queries tab, you can not only view the queries received but also can resolve them.

You can view queries in TI by various methods:

- 1. Query Email: By the Query Responder from the query email received in his/her inbox
- 2. By Recipient View: The Query Responder can view the queries received under the By Recipient view if the said query responder has access to such a TI room and documents related to the query.
- 3. By Sender View: The Reviewer can view the queries from the By Sender view if such a reviewer is the creator and sender of the query.
- 4. By Reviewer: This view is available only for admins and such a user can view the queries sent and responded by all the reviewers. (add to profiling for admins)



5. By Reviews: The reviewer can view all the queries from the By Reviews view which he/she has initiated.

Viewing a Query

To view a query, follow the steps as below:

- 1. From the eTMF/documents application, click Choose View next to the Index View.
- 2. The View Documents By popup appears.
- 3. Select the By Sender view and click Select at the bottom of the page.
- 4. The folders with the name of reviewers appear.
- 5. Click the required folder. The following folders are available for the query:
 - a. Pending: This folder contains all the queries sent and are awaiting the response.
 - b. In Progress: This folder contains all the queries which are responded.
 - c. Resolved: This folder contains all the queries which are resolved.
- 6. Select the required document from the grid and click Query tab from the metadata panel.
- 7. The queries display in the Queries panel.
- 8. Click the query to view the full query history.
- 9. The query displays the following:
 - a. The email body of the query that was initiated.
 - **b.** The responses and attachments to the query displayed by green sections. Refer to the screenshot below:

View by Sender	20 doo	uments (1 se	elected)									Claim
× 1 *All 41		Document	Title	Document	Disable au	Document	Reason fo	Comments	Document	Category	0 Ø	Metadata Workflow Queries Versions H
Pending 18	00*	2070129	CDA AGRE		True	Amruta M			18 Apr 2018			oc type
In Progress 3	🗆 🖬 \star	2070431	Test Docu		True	Amruta M			20 Apr 2018			VF Name TechWritersworknow
Resolved 20		2070480	Template		True	Amruta M		Given to P	20 Apr 2018			vr stage Approval stage i
> Tiger Woods 2	🗆 🖬 *	2070481	DMS proc		True	Tiger Woo			20 Apr 2018			Clarification
> Polly Chakraborty 26	□ 8 *	2070735	Tagging		True	Amruta M			20 Apr 2018			eviewer Comments
> 🖿 Amruta Maddel 13		2072157	Important		True	Polly Chak			20 Apr 2018			eviewer Name Polly Chakraborty
	□ 2 *	2072158	Copy of C		True	Polly Chak			20 Apr 2018			
		2076497	allinone1		True	Polly Chak			26 Apr 2018			
	🗹 @ ★	2076498	arabic_c2d			Polly Chak			26 Apr 2018			hank You.
		2076499	arabic_e7		True	Polly Chak			26 Apr 2018			No. State Prove Prese of
	0 . *	2076932	docu2		True	Amruta M			20 Feb 2018		3	arabic_c2db99da14
		2076934	esign1		True	Polly Chak			20 Feb 2018		Т	pchakraborty@tra
	0 0 *	2076943	hello		True	Polly Chak			20 Feb 2018		R	minders Sent 9 May 2018
		2080975	CDA AGRE	audit 1_10	True	Polly Chak			04 May 20	1	Ge	9 May 2018
	00 *	2081004	qewqwe		True	Polly Chak						9 May 2018
	- B *	2081685	Script for		True	Amruta M			07 May 20			New Document Created By 1 Jun 2018
	0.0 *	2081885	Conor eFe		True	Polly Chak		check to s	08 May 20			Polly Chakraborty
		2081892	TEST	audit 1_10	True	Amruta M			08 May 20	1	Ge	
	0 B *	2194384	Reference		True	Amruta M			26 Sep 2018		~	Query resolved by Polly 1 Jun 2018. Chakraborty
		2241052	TESTOON		True	Tiger Mee			10.0 2010			

c. Expand the required section to view the details for the sections.

Viewing Query History

To view the query history, open the required query and click the **Query History** button at the bottom of the Queries panel. This opens the history of the query in the **Query History** window. Refer to the screenshot below:



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Compa	re										T Documents cart 🕤
20 docu	iments (1 se	elected)								Claim	🗘 More 🗸
Q +	Document 2070129	Title CDA AGRE	Document	Disable au True	Document Amruta M	Reason fo	Comments	Document 18 Apr 2018	Category	Ca Metadata Worldic	w Queries Versions History e rsWorkflow
Query A	History	sorty			Description				; ×	Issues TechWritersW Clarification Reviewer Comment:	forkflow: Approval stage 1
New Doc Query re	cument Created E solved by Polly C	By Polly Chakrabor Shakraborty	ţ		PLEASE DO The foll please a this em TechWrite	o NOT CHANGE T owing issue: attach a revi ail: rrsWorkflow: Apj	HE EMAIL SUBJEC s were found sed documer proval stage 1	r in the docum t in your rep	ent, ly to	Thank You.	TechWritersDemoRoom arabic_c2db99da14ad4bd5bl
					Cla Site name	rification TechWritersDer	noRoom #		.,*	To Reminders Sent	pchakraborty@transperfect. 9 May 2018 9 May 2018 9 May 2018 9 May 2018
-					Close		1			New Document Polly Chakrabort	Created By T Jun 2018, 6:24 IV PM
8 *	2081892 2194384	TEST Reference	audit 1_10	True	Amruta M			08 May 20 26 Sep 2018	1	Gr Query resolved I Chakraborty	by Polly 1 jun 2018, 6:24 PM
	2241062	TESTnew		True	Tiger Woo			10 Dec 2018		-	

From the Query History window, select the required query activity from the left pane and the details of the history displays in the right pane.

Versions Panel

Versions Panel allows you to view and compare the different versions of a document.

Select a document from the grid and click **Versions** tab from the **Right panel**. The different versions of the document are displayed in the versions tab, if applicable. Refer to the

🛃 Metadata Workflow Qu	eries Versions History
• Version 2.0	Compare More info
Version Label	2.0
Status Date	10 Dec 2018, 11:59 AM
• Version 1.0	Compare
	More info
Version Label	1.0
Status Date	10 Dec 2018, 11:57 AM

screenshot below:

Clicking **More info** next to the version number opens the **Version History** which gives a detailed view of the document version history. Refer to the screenshot above.

History Panel



The History panel gives an overview of a document history. This panel displays the top four entries of the activities performed on the document. Here, you can apply filters to view the history of a document. Refer to the screenshot below:

Document History Filters

The History Panel provides the following filters to allow you to view a document history:

- 1. By Organization: Use this filter if you want to view the document history based on the organization.
- 2. Activity Type: Use this filter if you want to view the document history by the activity performed on it.
- 3. Date Filter: Use this filter if you want to view the document history within the set date range.
- 4. View All History: Click this button to view the full history of a document. The full document history opens in a popup. You can also apply the filters from the All History popup.

Viewing Document Activity

Every activity in the History panel is denoted by a node. Click the node to view the

description, date, time, and name of the person who performed the activity on the document.

Refer to the screenshot below:

All	✓ AI	I	~
Search from		earch to	
Update sec	urity 10) Dec 201	8, 1:27 F
Update sec	urity 30	Nov 2018	3, 3:50 F
Update sec	surity 30	Nov 2018	3, 3:50 P
Metadata f	ield was up	dated	
	11	Jun 2018	3, 11:06 A



Viewing All History

Clicking the **View All History** button opens the **All History** popup which displays the complete history of a document and also allows you to filter the document history based on the **Organization**, **Activity Type**, and **Duration**. Refer to the screenshot below:

rganization	Activity Type	
All 🗸	All	~
O Replace file	10 De	ec 2018, 11:59 AM
O Replace file	10 De	ec 2018, 11:59 AM
O Metadata field was updated	10 De	ec 2018, 11:59 AM
O Replace file	10 De	ec 2018, 11:59 AM
O Document was edited online	10 De	ec 2018, 11:59 AM
O Replace file		
Ca	ncel	

eSignature panel

10	doci	uments (1 se	elected)								← ata Workflow Queries Versions History eSignature
		Document	Title	Document	Disable au	Document	Reason fo	Comments	Document	Category	eSignature
•	$^{+}$	2069982	DMS TEST			Polly Chak			16 Apr 2018		This document has no eSignature yet, but you can start the
•	$^{+}$	2070184	CDA AGRE		True	Polly Chak			19 Apr 2018	2	eSignature workflow now.
•	*	2081685	Script for		True	Amruta A			07 May 20		Send for eSignature
•	*	2090205	For Query		True	Polly Chak			05 Jun 2018		
0	*	2090206	ieinstal.exe			Amruta A			05 Jun 2018		
0	*	2091588	Wildlife			Amruta A			11 Jun 2018		
	$^{\pm}$	2091589	3.New app			Amruta A			11 Jun 2018		
•	$^{\pm}$	2178885	For new q	audit 1_10	True	Tiger Woo			19 Sep 2018	1	
	$^{+}$	2348984	Creating li			Amruta A			18 Dec 2018		
	$^{+}$	2423443	Good Clini		True	Polly Chak					

The eSignature Panel:

- 1. Allows sending the document for eSignature if it is not initiated for eSignature yet.
- 2. Display the status of the document eSignature if it is initiated for eSignature.

Besides eSignature Panel, you can also send the documents for eSignature from the **Document Context Menu** (*page 249*) by right-clicking on a document.

Cancel eSignature

If the document is waiting for eSiganture, the eSignature Panel displays the status of the document as shown in the screenshot below:



🗲 ata Workflow Queries	Versions History eSignature
eSignature	
eSignature Type	Parallel
eSignature Status	Waiting for signers
O Amruta Maddel	Waiting for signers
Cancel	E-Signature

Select the eSignature and click the Cancel E-Signature button at the bottom of the eSignature Panel if you wish to cancel the eSignature of any document. Click Yes on the popup that appears to confirm the cancellation.

The Top Ribbon Bar

This bar is located at the top of the Documents Dashboard and allows access to various functionalities on documents:

- The Document Actions
- Manage Security on documents
- Print
- Email
- Move to Startup
- Import
- Export
- Comparing Documents
- Documents Cart
- Dashboard Layout

Refer to the screenshot below:

> 🕆 🖺 Document 🗸 🔒 Manage Security 🖓 Move to Startup 🔶 Import 🗸 🤟 Export 🗸 🖉 Email 🔒 Print 📍 Layout 🗸 🔲 Compare 📜 Documents cart 🗸

Each of the above functionalities is discussed in separate topics available from the left panel of this help.

Document Actions

You can perform the horde of activities on a document by from the Document Drop down located on the top ribbon bar of the eTMF

🖿 Document 🗸 🔒 Mana
🗞 Replace Attachment
Ask a question
OCR
Configuration
Add filter

Documents Dashboard.

Each of the functionalities is discussed in sections below:



Replace Attachment

To replace a document attachment or URL:

- 1. Select the required document from the grid and click the **Document Actions dropdown** from the top ribbon bar.
- 2. The dropdown appears.
- 3. Select Replace Attachment / Add URL.
- 4. The Replace Attachment / Add URL popup window opens.
- 5. Select the File radio button to replace an attachment, or select the URL radio button to replace the URL
- 6. To attach a document click **Browse** and select the required document from the Explorer, whereas to replace a URL ????
- 7. Enter the reason for replacement.
- 8. Click Apply
- 1. Click Ok.

Manage Security

The Trial Interactive platform allows for two different approaches for defining security rights in the Trial Interactive site. Security can be set on a **folder level** or on a **document level**.

Note: You can also Manage Security for Sites which is different from managing security for documents and is discussed in topic **Manage Security for Sites**.

Folder Level Security

This allows to assign security for the individual folders in the Index of the room. This automatically applies the security to the documents when they are uploaded in the assigned security folders.

To assign Folder Level Security:



- Manage Security
- from the top ribbon bar. The 1. Click Manage Security Manage Security window opens. Refer to the screenshot below:

Manage Security		?>
Select the Target	Select Folders	
Selected documents	Search	Q
All documents	🗸 🗸 🝃 Index	Â
	1 signature 2 6	
Subfolder Security	2 eSignature 0	
Apply same security as the parent folder	> a Country Management_polly 0 (0)	
	> a PleaseReview replacement 0 (0)	
Select the security update type	> 5 Site Management 0 (16)	
Update existing Security	6 Complex criteria test 1	
Overwrite existing Security	7 Complex criteria test 2 0	
Remove from existing Security	8 Mutual Nondisclosure Agreement Forms and Process	
Restrict access to Administrators only	9 Site Signed NDA	
	10 Site Language Changes 1	
	11 Additional PSV Package Documents 0	
	12 Protocol Draft Protocol Supposes 0	
	4 m	*

2. Select the Folders button from the Select a Target section in the left panel of the window. The panel on the right that displays the Index structure becomes active allowing you to select exactly to which folders you would like to apply the security change. You must select at least one folder from this list.

By leaving the Apply same security as the parent folder checkbox unchecked, you can select specific subfolders on which to modify the security settings. If you check the box, you need only to select the main folders whose security settings you want to modify.

- 3. Select the checkbox next to the folders to which the security is to be applied.
- 4. Select the Security Update Type for the folder from the following options.

Security Type	Description
Update existing security	This option leaves all current security definitions in place and adds on any new definitions set in step two of the manage security process.
Over write security	This option erases all current security definitions and replaces entirely with the definitions set in step two of the manage security process.
Remove from existing security	This option leaves intact any security definitions already assigned, but removes access for any group(s) or user(s) specified in step two of the manage security process.
Restrict access to Administrators only	This option erases all current security definitions in place and makes the target files/folders only viewable to administrators.

- 5. Click Next. The Access and Security step of the Manage Security opens.
- 6. Using the Groups and Users tabs on the left side of the control window, select the Groups and/or Users to update security rights. Refer to the screenshot below:



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coore and Cocurity								
elect group(s) and/or use	r(s) and set the desired l	levels of access						
Groups Roles	Users		Se	curity Grid				
				Full Name	a	۲	C	
All				Members		۲		5
Name ~				Ginger White		۲		
😁 Jackson			D	Mila Kunis		۲		6
Smith			Đ				 	
🐸 Monroe			0					
😬 Lambert			0					

- 7. Hover the mouse over the group/user name in the left pane. The Plus icon appears to the right.
- 8. Click the Plus icon to add the group and /or users to the Security Grid to the right pane. Notice that the group and /or user is grayed out when you add them to the Security Grid and a small green tick appears to the right of the selected group/user. This moves the Groups and/or Users into the Security grid on the right. Refer to the screenshot below:



lect group(s) and/or us Groups User	er(s) and set the desire	d levels of access.			
				Q	
Last Name	First Name	Email	Phone	Mobile	Organization
		vlad3101@ya.ru			
		qa+04@ecisys.com			
		auditresp2@test.cor			
		qa+03@ecisys.com			
Again	Try	try@demo.com			'ok
Auditor	First	auditor1@test.c			
Auditor	Second	auditor2@test.com			
в	Swati	swatib008@gmail.cc			'ok
Bob	Bob	123abc@elilink113.n			TransPerfect Trial In
Chakraborty	Polly	pchakraborty@trans			techwriters
					Previous 1 of 3 N

9. Select the required security definitions that you want to update for the selected group/user.

Security Option	Description
Full Access	Non Encrypted access allowing for full printing and saving rights
View Only Allows users to only view the PDF while restricting printing and	
No Watermark If the watermark is in use in the site, this access will provide the	
	access to a non-watermarked version of the PDF file
Redacted	Gives the users access to the redacted version of the file while
	preventing access to the original (non-redacted) version

10. Click Save. This applies the security permissions on the folders for the selected groups and/or users.

Note: By selecting the target as All documents in the top left panel of the Manage Security tool, you need only to Select the security update type before clicking Next and selecting which groups or users to include in the security modification.

Document Level Security

Note: To set the document level security, the option for document security needs to be enabled in the room by your Administrator.

This allows for security definitions to be set at the individual document level, allowing for the greatest control and flexibility on the security definitions as documents within a single folder can have different security/access rights. If document level security is used, each document will maintain its unique security settings, even as it is moved from one folder to another in the index outline, until its security definitions are changed.

1. Open a folder that contains documents from the Index outline.



- 2. Select one or more documents from the Document Grid whose security setting you want to modify.
- 3. Click the Manage Security button located in the upper toolbar. The Manage Security tool opens.
- 4. Click the button for Selected documents.
- 5. Select the security update type by clicking one of the four options, as described in the previous section of this guide.
- 6. Click Next. The second stage of the Manage Security tool populates the window.
- 7. Using the **Groups** and **Users** tabs on the left side of the control window, select the Groups and/or Users to update security rights for by double clicking on the listings. This moves the Groups and/or Users into the **Security grid** on the right.
- 8. Select which security definitions you want to update for the selected group/user, as described in the previous section of this guide.
- 9. Click Save, and the security definitions are in place.

By Security View

The By Security view shows the list of all the documents based on the security provided to the folders. To view the folders by security:



- 1. Click the three dots we next to View by Index. The View Documents By pop-up opens.
- 2. Select the By Security view.
- 3. Click Select. The Index displays the documents and folders based on the security level.



By group

The By Group view shows the list of all the documents and folders belonging to a particular group. To view the folders by group:

- 1. Click the three dots we next to View by Index. The View Documents By pop-up opens.
- 2. Select the By Group view.
- 3. Click Select. The Index displays the documents and folders based on the security level.

Email

To email a specific document as an attachment or as a link, click the **Email** option from the top ribbon and follow the on- screen instructions. You can save an outgoing email as a PDF document. On clicking **Send**, the **Save Conversation** dialog box opens up. Refer to the

Paginiant(a)*			
Kecipient(s)*	auditor1@test.com ×	Cc Bcc	
Subject*	Test		
Add Attach	ment		
Open Sans	v 12 v ♦ B I U S % ≣ v ≣ v ≡ v		

screenshot below:

If required, you may also opt to save the document as PDF and publish it to investigative sites. Upon selecting your option, the **Document Profile** dialog box pops up. Enter the details and click **Finish**. The email communication is now saved as a PDF document in the folder as mentioned in the **Default index position for Add document** in the **Settings -> Documents-> Index Outline**. (*page 225*)The email PDF has only Subject, date sent, and body of the email as its contents. You can view this email sent from the **Communications Outbox** module.

Print

The Print function is self-explanatory. You can order a printed hard copy of a document

through this menu option.

- 1. To activate the **Print** function, first, click a folder in the index so that documents populate on the document grid.
- 2. Select one or more documents from the grid that you want to print.
- 3. Click the Print icon from the top ribbon. The Print window opens.
- 4. Click the appropriate radio button, Selected Records, or All Records in Set.



- 5. Click Print.
- 6. Follow the usual steps of creating a printout from your computer.

If the user has opened a folder with documents and has not selected a document or particular set of documents from that view, the **Print** option is still available. When the user clicks the option without having selected a document, the default is to print all of the documents in the set. Follow the on-screen instructions to complete this operation.

Move to Start-Up

Note: The Move to Start-Up option is available only in rooms in which the Start-Up Module is active.

Move to the Start-Up option can be used to **move documents from the eTMF back to the appropriate Start-Up folder** in the case that documents have been delivered and deposited in the eTMF prematurely.

- 1. Navigate to Main Navigation-> eTMF module.
- 2. Select the required document/s from the grid and click the Move to Start-Up

button Move to Startup from the top ribbon bar.

Import

You can import multiple documents and metadata using just their metadata to a room. Click the Import

↑ Import ∨

dropdown to reveal the import options - Documents and Metadata.

Each of these is discussed in the separate topics and can be accessed from the left of this menu.

Export

Documents can be exported from:

- 1. The Export dropdown from the top ribbon bar
- 2. The Documents Cart
- 3. The Download documents when opening a document in the Original Viewer

Three options are available for Administrators from the **Export Dropdown** on the top ribbon bar - **Metadata**, **Documents**, and **Security**. Refer to the screenshot below:

All of these options are discussed in separate topics accessible from the left panel of this help.

Exporting Metadata

This function gives you a compressed file with the

information you requested in XLSX spreadsheet file To



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export metadata,

1. Click the Metadata option from the Export dropdown on the top ribbon bar. The Export Metadata window opens. Refer to the screenshot below:



- 2. Select the Source options as required and click Next.
- 3. In the next step, select the metadata fields you wish to export for the documents. This step provides the following filters:
 - a. Select All: Tick this checkbox if you wish to select all metadata fields.
 - **b.** Sort By: Select the options as required from this dropdown to view or select the metadata fields.
- 4. Also, Notice the two checkboxes below the metadata fields. Select the Save metadata selection checkbox if you wish to save the selection for the current user and Save selection for everyone if you wish to save the selection for all users. Refer to the screenshot below:



Export Metadata		Step 2 O •	?	>
Room Metadata Fields Select fieelds you want to export				
40 Fields Users 0 selected	Sort by	From A to Z		~
bool checkbox 1	Index	From A to Z		
Category	Investigative Site	Logical		
Comments	Investigative Site	e name		
Contact	key validation d	reckboy		

5. Click Export.



Exporting Documents

Exporting documents is the same as downloading documents from the Documents Cart.

You can **track an export**, **exclude previously exported documents**, or **include metadata during export**. Here too, you can select the logical or alphabetical order of the metadata fields for export, if you choose to include metadata to be exported with the documents.

Export Docu	ments	?	×
Export Options Some information	about this window		
Source:	 Selected records All documents in the current grid 		
Export Format	Excel Track Export Exclude previously exported documents Include metadata		
	Cancel Export		

The documents or selected documents get exported in a .zip file. The .zip will include the following:

- 1. A folder with the exported documents in it.
- 2. An excel worksheet with the metadata, if you happen to export metadata.
- **3.** A .log file which opens in Notepad to give the list of previously exported documents that were excluded during export. Here again, you have to select the option to exclude previously exported documents to enable this.
- 4. An ErrorsLog.xml file that includes details of documents that fail to export. To view the exported

file, navigate to the Notifications (page 64).

Exporting Security

This allows you to export all the security accesses for selected records for all documents in the grid, all documents in the room. The output of the export job is an .xlsx file that can be accessed from the **Notifications.** Follow the steps below to export documents security:

1. Click the Security option from the Export dropdown on the top ribbon bar. The Export Metadata window opens. Refer to the screenshot below:

Export Secur	ity	Step 1	• 0	?	×
Export Options Some information	about this window				
Source:	Selected records All documents in the current grid All documents in the room				
Export Format	Excel				
	Cancel Next				

- 2. Select the Source options as required and click Next.
- 3. In the next step, select the metadata fields you wish to export for the documents. This step provides the following filters:
 - a. Select All: Tick this checkbox if you wish to select all metadata fields.
 - **b.** Sort By: Select the options as required from this dropdown to view or select the metadata fields.
- 4. Also, Notice the two checkboxes below the metadata fields. Select the Save metadata selection checkbox if you wish to save the selection for the current user and Save selection for everyone if you wish to save the selection for all users. Refer to the screenshot below:

Export Security		Step 2	0 •	?	×
Room Metadata Fields Select fieelds you want to export					
46 Fields Users 0 selected	i Sort by	From	A to 7		~
BUCCEAN	Sorrby	From	A to 7		-
bool checkbox 1	Index	FION	740 4		
Category	Investigative Sit	Logic	al		
Comments	Investigative Site	e Name			
Contact	key validation cl	neckbox			
		Scr	oll to se	curity f	ield
Save metadata selection					
Save selection for everyone					
D	revious Export				

5. Click Export.

Layout

You can change the layout view of the grid by clicking the Layout option from the top



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ribbon bar. Follow the steps below to change the layout of the gird.

- 1. Navigate to eTMF Documents module.
- 2. Select the Layout option from the top ribbon bar. The Select Layout popup opens. Refer to the screenshot below:



3. Select the required layout and the document grid sets it layout as selected.

Compare

Documents can be compared from in the following ways:

- 1. From the top ribbon in the eTMF Documents module.
- 2. From the Documents Cart (page 285). To compare documents,
- 1. From the eTMF Documents module, select the folder from the Index to open the documents in the grid.
- 2. Select the required documents to compare and click the **Compare** option from the top ribbon bar.
- 3. The documents open in the **Compare Documents** window with each document side in a separate window of their own using the viewer chosen by you. You can also expand the metadata fields on the bottom using the double-caret bar to compare documents metadata conveniently at once.

Bulk Uploading

Besides Importing documents, you can also upload documents in a bulk to the room. Follow the steps below to bulk upload documents in a room.

- 1. Navigate to eTMF Documents module.
- 2. Click the Bulk Upload ^a Bulk Upload option from the top ribbon bar. The Import Documents window opens.
- 3. Following the on-screen instructions, either drag-and-drop files from your computer into the



upload panel or use the

Browse button on the window to select documents to upload. Refer to the screenshot

below:

Import Documents			? ×
File Name	Size	Upload Status	
Line	Top Files and Folders Here or Use Browse button below	0 Total Files 0 broks	
	-		
	Browse Clear Unpack Zip Archives ?		Import

- 4. Choose Unpack Zip-archives if you wish to extract files from an attached zip folder.
- 5. Tick the checkboxes for documents to be uploaded and click Import. These documents are uploaded to the upload folder. You can later edit the metadata of these documents from the Metadata Panel (*page 262*)as required.

Documents Cart

Perform various functions from here like copying documents to rooms or sites, comparing, merging, or linking

documents besides many more.

Users select documents to add to the Document Cart either from the Documents Context Menu (*page 249*) or by selecting documents from the grid and then clicking the **Add to Cart** button from the top ribbon menu.

The **Documents Cart** Cortect on the upper right-hand corner of the document grid and works just like a shopping cart.

Adding documents to the Documents Cart

- 1. Locate the document which is to be added to the Document Cart and select the checkbox next to it. Now the process of addition can be done in two ways.
 - a. Click Add to Cart from the upper right-hand corner.
 - b. Right-click and select Add Selected to the Cart option.



2. Once a document is added, it will automatically update to reflect the number of documents available in the cart. Refer to the screenshot below:

Print	Em	nail 🖓 Mov	e to Startup	↑ Import ∨		? Layout	Compare	🏦 Bulk Upload		😫 Add to Cart) Documents cart (1)
		Document	Title	Document	Disable au	Document	Reason fo	Comments	Docun Metadata	Workflow Queries	Versions History
Z 🖪	*	2090520	Doc3		True	Amruta A			06 Jun Docume	nt Id	Oper
		N:	34	100	- 14 	14	102		2 090 4	20	-

Removing documents from the Documents Cart

Follow the steps below to remove documents from the Documents Cart:

- 1. Click the arrow next to the Documents Cart. A popup window opens.
- 2. Select the checkboxes next to the documents and click Delete button to the right of the selected documents.
- 3. If you wish to remove all the documents, click the **Remove All** button. Refer to the screenshot below:

		+ Add	Q Search 2	Tiger Woods 🗸
+	Export 🛩 📍 Layout 🔲 Con	npare 🏦 Bulk Upload	🎦 Add to C	art 🛛 🐂 Documents cart (3) 🔽
7 3	Documents 2 selected			×
Se	lect All			Remove All
Ő	etmf 10.pdf		1 signature 2	阃
	Showing Swati	111 Country Special form	1 signature 2	圇
	TESTnew		1 signature 2	盦
		Copy ~	ctions ~	

Copying documents to Other Rooms

Trial Interactive allows Cross-Study **Copy** of Documents through this functionality. When users select the **Copy to Other Rooms** option from the Documents Cart, selected documents as well as their metadata will be copied to other rooms.

- 1. Add the required documents (page 282) to the Documents Cart.
- 2. Click the arrow next to the Documents Cart. A pop-up opens.
- 3. Select the documents which you wish to copy to other Rooms.



4. Click Copy and select to other Rooms. Refer to the screenshot below.

~ •	Export Y ? Layout	Compare 🌲 Bulk Upload	😭 Add to Cart	🐂 Documents cart (3)
	3 Documents 2 selected	ed		×
	Select All			Remove All
	etmf 10.pdf		1 signature 2	Đ
\checkmark	Showing Swati	111 Country Special form	1 signature 2	圇
	TESTnew		1 signature 2	Ŵ
		Copy V Actions		
		 P to other Rooms ⇒ to Investigative Sites 		

- 5. The Clone Document window will open up and prompts you to specify to which study rooms documents shall be copied.
- 6. Click the Select button which opens the Rooms window to allow you to select the rooms to copy the documents to.
- If you wish to publish documents to the index as final documents without going through the workflow, select the checkbox next to publish documents to the index as final documents.
- 8. Click Clone. The document type of the destination room will determine the auto-naming rule for the document. Refer to the screenshot below:

Clone Documents					
Following documents will be cl	oned. Please, select rooms				
Publish documents to inde	x as final documents		Select		
adddocfromindex	111 Country Special form	1 signature 2	Ŵ		
Showing Swati	111 Country Special form	1 signature 2	圇		

Copying documents to Investigative Sites

This option is helpful when Administrator users wish to distribute the same document, such as training documents, across different investigative sites. To avoid copying these documents one-by-one, you can simply use this option in Documents Cart.



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- 1. Add required documents to the Documents Cart (page 282).
- 2. Click the arrow next to the Documents Cart. A pop-up opens.
- 3. Select the documents which you wish to clone to other Investigative Sites.
- 4. Click Copy and select to Investigative Sites. Refer to the screenshot below.

↓ Export ~ ? Layout □	🗋 Compare 🏦 Bulk Upload	😫 Add to Cart	🃜 Documents cart (3) 🗸
3 Documents 2 select	ted		×
Select All			Remove All
etmf 10.pdf		1 signature 2	Ŵ
Showing Swati	111 Country Special form	1 signature 2	圇
TESTnew		1 signature 2	圇
	Copy ~ Actions	v)	
	 to other Rooms to Investigative Sites 		



- 5. The Clone Documents to Investigative Sites window opens up and asks you to select investigative sites. Click radio button next to your choices.
 - **a.** If you choose **All Sites**, just click **Next**, to select the folder to which the documents will be cloned.
 - **b.** If you choose **Specific Sites**, just click **Next**, and it will give you site choices on the next section.
 - c. If you choose By Country, a dropdown with the list of countries gets activated for you to choose from.
- 6. Click Next folder selection.
- 7. Once the folder is selected, click **Clone**. The documents are copied to the Investigative Site folder. Refer to the screenshot below:

Clone Documents to Investigative Sites	5 ×
Select Investigative Sites Choose Investigative Sites where Selected Documents will be cloned to:	Clone Documents to Investigative Sites ? X
All Sites Specific Sites By Country	Select Folder Please, select folder to which documents will be cloned
Cancel Next	✓ Index Root 123 > cloning test cloning test 2 Executed Mutual NDA final cloning 1 final cloning 2
	Previous Clone

Compare Documents

The **Compare Documents** tool in Documents Cart lets you view and compare two or three documents at the same time by placing those side by side. You can use the **ABBYY Optical Character Recognition** (if that is enabled for you) to support the comparison of documents from document scans and images.

- 1. Add required documents to the Documents Cart. (page 282)A pop-up window opens.
- 2. Select the documents from the list you wish to compare.
- 3. Click Actions at the bottom of the window and then select Compare. Refer to the screenshot below.

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↓ Export ~ ?	Layout 🔲 Com	pare 🏦 Bulk Upload		R AC	id to Cart	7	Docum	nents ca	rt (3) 🔽
3 Documents	2 selected								×
Select All							Rem	iove A	.11
etmf 10.pdf				1 signatur	e 2			I	<u>ال</u>
Showing Swati		111 Country Special form		1 signatur	e 2			ī	Ŵ
TESTnew				1 signatur	e 2			I	<u>ال</u>
		Сору 🗸	Actions						
			 Merge Link Add to Audit Create Audit Prot Add to Submissik Mark as Popular Download Add to existing reference Create new review 	file on Package eview w	lious	1	of 1	Next 3	•

- 4. The documents open in the Compare Documents window with each document side in a separate window of their own using the Arender view. Refer to the screenshot below:
- 5. To facilitate easy and seamless comparison of documents:
 - **a.** The differences on each page are highlighted showing actual differences in text between the two documents using **different color codes** which is useful if you need to maintain different versions of the document.
 - **b.** The **documents scroll at once in sync** with each other when you drag the scroll bar to facilitate easier viewing and comparison if you have activated the 'Synchronize document scrolling' from the toolbar.
 - c. The system displays appropriate messages when two documents are identical.
 - d. The print and download options for comparison are available to you only if you have Full Access to the documents.

Merging documents

An Administrator user can merge two or more documents into one document.

- 1. Add required documents to the Documents Cart. (page 282)
- 2. Select the documents from the cart you want to merge into one, either to use as a single document in the room or to download and print as a single document.
- 3. Click Actions and then select Merge. Refer to the screenshot below.

Linking documents

Administrator users can link documents together with this option.

1. Add required documents to the Documents Cart. (page 282)



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- 2. Select the documents from the cart.
- 3. Click Actions and then select Link. Refer to the screenshot below:

✤ Export ~ ? Layout ~	🔲 Compare 🏻 🏦 Bulk	Upload	🏋 Add to Cart	📜 Documents cart (2)
2 Documents 2 sele	ected			3
Select All				Remove All
 3.New app release download 			*Upload\Amruta Audit	or1 Maddel 🛛 🗎
For new query	audit 1		*Upload\Amruta Audit	or1 Maddel 🕅
Amruta A	Copy 、	Actions ~ Compare Merge Link Add to Audit Create Audit Pro Add to Submissi Mark as Popular Download Add to existing to Add to existing to Create new revio	ofile /ious on Package review ew	, 1 of 1 Next >

4. The Link Documents window opens. Select 2 or more than 2 documents to link and click Yes. Refer to the screenshot below:

Link Documents		? ×
Do you want to link all selected docur	nents?	
3.New app release download		*Upload\Amruta Auditor1 Ma
For new query	audit 1	*Upload\Amruta Auditor1 Ma
	No Yes	

- 5. A pop-up message appears to confirm the documents are successfully linked.
- 6. Afterward, whenever you right-click on one of the linked documents and click **Related Documents**, interrelated documents will all be displayed on the screen.

Adding documents to Audit

Admin can add documents to the cart from the grid and include them in an existing audit by

using the Add to Audit



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option.

- 1. Add required documents to the Documents Cart (page 282).
- 2. From the Documents Cart, select a document.
- 3. Click Actions and then select Add to Audit. Refer to the screenshot below:

4	• Export 👻 🔹 2 Layout 🗠	Compare	🌲 Bulk Uploa	d	🎦 Add	to Cart	📕 Docun	nents cart (2)
	2 Documents 2 selec	cted						>
Se	elect All						Rem	nove All
	3.New app release download				*Upload\An	nruta Audito	or1 Maddel	筪
	For new query	audit	:1		*Upload\An	nruta Audito	or1 Maddel	圇
	Amruta A		Сору ~	Actions ~				_
				Add to Audit	ofile / ion Package	ious	1 of 1	Next >
				 ★ Mark as Popula ▲ Download 	r			
				Add to existing Create new revi	review iew			

- 4. The Select Audit window opens.
- 5. Select the Audit to which you wish to add documents to.



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6. Click Select. Refer to the screenshot below:

Select Audit						? X
Some text or instruction						
1 Audits					Search	Q
Name 🗸	Status	Published only	Percentage	Access Lev	el	Reminder
+ 🕑 TWAudit	Active	No	100%	Full		No
		Cancel	Select			

Note: The Audits in the Select Window are displayed only when you select Add Documents to pool on Demand Basis (page 353) option while creating an Audit profile.



Create Audit Profile

Admins can add documents to the cart from the grid and create audit profiles using the **Create Audit Profile** option.

- 1. Add required documents to the Documents Cart (page 282).
- 2. From the Documents Cart, select a document.
- 3. Click Actions and then select Create Audit Profile. Refer to the screenshot below:

	✓ Export ✓ ? Layout ✓ □ C	ompare 🔒 Bulk Upload		🎦 Add to Cart	📕 Documents cart (2) 🗡
F	2 Documents 2 selected				×
	Select All				Remove All
	3.New app release download			*Upload\Amruta Audit	or1 Maddel 🗎
	For new query	audit 1		*Upload\Amruta Audit	or1 Maddel
	Amruta A	Copy ~	Actions L Compare ✓ Merge S Link Create Audit Pro Add to Audit Create Audit Pro Add to Submissi ★ Mark as Popular ▲ Download E Add to existing r Create new revie	file on Package review ew	1 of 1 Next >

- 4. The Create Audit Profile popup opens.
- 5. Follow the instructions on the form to create the audit profile as required.

Note: Creating Audit Profiles (*page 351*) are discussed under the Quality Review section in detail.

Adding documents to Submission Package

Admin can add documents to the cart from the grid to include them in a start-up submission

package by using this option.

- 1. Add required documents to the Documents Cart. (page 282).
- 2. Select the documents from the cart.
- 3. Click Actions and then select Add to Submission Package. Refer to the screenshot below:
- 4. The Select a Submission window opens.



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Marking documents as Popular

Administrator users can mark certain documents as popular using this option.

- 1. Add required documents to the Documents Cart.
- 2. Click Actions and then select Mark as Popular. Refer to the screenshot below.
- 3. A pop-up message- Documents successfully marked as popular appears.
- 4. The selected documents now appear on the dashboard- Popular Documents dashlet

Downloading documents

- 1. Add required documents to the Documents Cart. (page 282)
- 2. Click Actions and then select Download. Refer to the screenshot below.

Adding documents to existing review

Admin can add documents to the cart from the grid and include them in an existing review workflow by using the **Add to existing review** option.

- 1. Add required documents to the Documents Cart (page 282).
- 2. Click Actions and then select Add to existing review. Refer to the screenshot below.
- The Select a Review window opens. Select a review from the list of reviews and click Select. Refer to the screenshot below:

elect Specific Review Q Search Reviews Title Description Created Date Due Date For Review Test 11 May 2018	Select Specific Review Q Search 4 Reviews Title ^ Description Created Date Due Date For Review 26 Mar 2019	
Q Search Reviews Description Created Date Due Date For Review 26 Mar 2019 11 May 2018	Q Search Reviews Title ^ Description For Review 26 Mar 2019	
Reviews Created Date Due Date For Review 26 Mar 2019 11 May 2018	Reviews Created Date Due Date For Review 26 Mar 2019	
Reviews Description Created Date Due Date For Review 26 Mar 2019 11 May 2018	Reviews Title ^ Description Created Date Due Date For Review 26 Mar 2019	
Title ^ Description Created Date Due Date For Review 26 Mar 2019 11 May 2018	Title ^ Description Created Date Due Date For Review 26 Mar 2019	
For Review 26 Mar 2019 Test 11 May 2018	For Review 26 Mar 2019	ite
Test 11 May 2018		
	Test 11 May 2018	
20 Nov 2018	1est11 20 Nov 2018	
	User Guide Review 19 Sep 2018	
	Iser Guide Review 19 Sep 2018	

4. Confirmation pop-up opens. Select Yes.



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5. The review was added successfully message appears. The review can be accessed from the Collaborative Authoring module.

Creating a new review

Admin can also add documents to the cart from the grid to include them in a new review workflow by using the **Create new Review** option.

- 1. Add required documents to the Documents Cart. (page 282)
- 2. Click Actions and then select Create new review. Refer to the screenshot below:

Create review		? ×
Review Data:		
Complete general info about review		
Review type*	Co-Review V]
Title*		
Description		
Review Durations (days)*	10	
Review owner*	~	
Participants:		~
Documents:		~
2	itart Review Immediately	
G	ancel Save	

- 3. The Create review window opens. Fill in the details under New Review Info, Participants, and Documents.
- 4. Click Save. New review was successfully created message appears.

Potential Sites and IRB Integration

This allows you to locate the Unique Sites using the combination of Study Name and

Principal Investigator.

During IRB Integration sites are imported into Trial Interactive. The system uses a combination of the study name and the Principal Investigator Last Name to locate unique sites. If more than one site is found, it uses the Zip code of the site to uniquely identify an investigative site. When the investigative site is found, the site along with its IRB details and documents are imported into Trial Interactive.



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Note: If the system finds matching conditions like the site, IRB number and IRB document type in the Study Start- up Site Profile, the documents for the imported site will be uploaded into the Study Start-Up for the site, else the system will upload the documents to the eTMF module, the details of which are discussed below.

This section includes the following sections:

- 1. IRB Integration and Settings
- 2. Potential Sites and Modules

Chapter 7. Searches

In this section we discuss Document and Advanced Search, Cross Study Search, Search for Users, Sites, Clinical Data and Room Search

Each of the searches is discussed in separate topics available in the left panel of this help

topic.

Documents Search

We can perform two types of searches on documents:

- 1. Cross Room Search: When you search for documents across all studies that you have access to, you are performing across-study search. You can execute this search from the Home Page Search functionality.
- 2. Documents Search: When you search for documents from within a room or study, check the box Limit search to the current room. Refer to the screenshot below:

The process to execute both the types of searches is the same except for the location of

executing the search:

- 1. Navigate to the Home Page or a Trial Interactive room as required.
- 2. Click the Search icon from the blue bar located on the top of the dashboard.
- 3. The Search popup appears.
- 4. Select **Documents** from the options of Documents, Queries, and Users, Refer to the screenshot below:

Search				
Search				٩
Documents Queries Users				
↑ Import ▼ ↓ Export ▼ ■ Email ⊕ Print □ Compare				
0 - 0 of 0 (0 selected)	c	T Filters	III Select Columns	🕫 Views 🔻
Submitted Name				
				*

- 5. Enter the search criteria in the Search box.
- 6. As soon as the text is entered in the Search box, the search process starts.
- 7. Documents matching the search criteria are displayed in the Grid below the Search box else a message No records available is displayed. Refer to the screenshot below:



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	Ω 1.4		ocurit		PR Mousto Stud	lu Ctart Lin		ale Evenent a	Second Second	D. Delet	Company	J	Decuments Cart 0	
iment •		inage 5]	ecunio	y .	-El Move to Stud	iy Start-Op	T import •	◆ Export •	Ethali	e Print	LU Compan	1 2	E Documents cart u	
Ind Store	search													
ch l	1572										×			
ton 🧿	Docun	ients	Q	ueries	Users							🖂 Limit se	arch to the current roo	
01 Tr 02 Cr	↑ Impo	art 🕶	↓ E×	port •	🖌 🔤 Email	🔒 Print	Compare					🐂 Documents Cart 0	• 🗗 Layout •	
3 Ri	1 - 50 c	f 958 (() sele	cted)			c	▼ Filters	🖽 Select Colu	umns 🛷	views 🗸 🚺	🖌 Expand		
04 C					Submitted Nam	ne								
4 IR	o D.	* *			1572						â			
15 51		→ ★			Acknowledgem	ent IB Signatu	re Page_pdf-r							
7 5	0 0.	* *			Certificate of Lia	ability Insuran	ce_pdf-r							
8 6		+ *			Certification _ A	Accrediation						No document selected		
9 TI (+ *			Clinical Protoco	l Synopsis								
0 D		+ *			Confidentiality	Agreement_po	df-r							
1 St		+ *			Contact Details	_List_pdf-r								
rain		4 *			СТА						-			
	C	Cel	Line		De					- 1 of 20	North N	A Dravieur Desument		

- 8. Notice that the top ribbon bar is also available above the Documents Grid in the Search results window.
- 9. Hover the mouse over the Document icon \square_{\bullet} to get a preview of the documents.
- 10. Click the document icon. The document Metadata panel opens in the right pane.
- 11. Similarly, select the User option to perform the user search. When the results are displayed and the user selects any record, User Details are

Search										×
arya		2.0					×			
1 - 1 of 1 (1	s Queries	9 Users			c	🛄 Select Colum	ns 🛷 Views 🕶	Expand		
	Last Name 🔺	First name	Email	Phone	Mobile Phone	Organization	MFA Registered	User Details]	•
🖾 🛎 🌣	Stark	Arya	aryastark@ti.c			Trial Interactive	N/A	Email	aryastark@ti.com	^
								First Name	Arya	
								Last Name	Stark	
								Title	Manager of QA	
								Mobile Number	-	
								Phone Number		
								Address	-	
								City		
								State	-	
								Zip Code	-	
								Country	-	-
						Previou	us 1 of 1 Next 1	Previous User	Next Use	er 🕨
						Previou	us 1 of 1 Next 1	Zip Code Country	- Next Use	21

displayed in the right pane.

If more details are required then double click the record and **User** popup screen appears in which more **User Details**, **Group Membership**, **System Groups**, and **Activity Log** details are available.


Search										
arya							×			
O Docume	nts 🔿 Queries	 Users 								
1 - 1 of 1	(1 selected)				0	C Select Colum	nns 🐠 Views 🔻	12	Expand	
	Last Name 🔺	First name	Email	Phone	Mobile Phone	Organization	MFA Registered	U	ser Details	
🖾 🔺 🔅	Stark	Arya	aryastark@ti.c			Trial Interactive	N/A	-	Email	arya
			\sim $-$						First Name	Ary
			User						×	Sta
			User	Group Members	ship System Grou	ips Activity Log				Mai
				Email*	aryastark@ti.com				A	
				First Name	Arya	Last Name	Stark		51	
				Title	Manager of QA				5 1	
				Role*	Administrator				5	-
				Noie	Auministrator				•	
				Expiration Date 😯				ť	m ×	

Searching Users

To search for users, follow the steps as below:

- 1. From the Home Page, or from within a room as appropriate, click the **Search** icon located at the top right corner of the screen.
- 2. The Search window appears. Select Users from the options given.
- 3. Enter the user name in the Search textbox at the top of the window. This displays the user in the Records section if available. Refer to the screenshot

Search									×
amru	ta						×		
O Docum	ents 🕜 Queries 💽 U	sers							
1 - 2 of	2 (1 selected)					c = = =	Select Columns 🛛 🛷 Views 🔻	K Expand	
	Last Name 🔺	First name	Email	Phone	Mobile Phone	Organization	MFA Registered	User Details	0
🖾 🔺	Deshpande	Amruta	amdeshpande@tran			Trial Interactive	N/A	Email	amdeshpande@transperf
	Maddel	Amruta	amaddel@transperf			Trial Interactive	N/A	First Name	Amruta
								Last Name	Deshpande
								Title	
								Mobile Number	
								Phone Number	
								Address	
								City	
								State	
								Zip Code	
								Country	
								MFA Registered	N/A
								*	
							Previous 1 of 1 Next	Previous User	Next User 🕨

below:

4. Upon selecting a required user from the results grid, details of that user will



be displayed in the User Details section in the right pane.

Searching Sites

To search for sites, follow the steps as below:

- 1. From the Home Page, or from within a room as appropriate, click the Search icon located on the blue bar.
- 2. The Search popup appears.
- 3. From the Documents dropdown, click Sites. Refer to the screenshot below:

Search		
Documents 🗸	Q Search Go	
Documents	✓ Limit search to this (Site, Screen)	
Users	Save Search Advanced Search	
🖌 Clinical Data		

- 4. Enter the site name in the Search box next to the dropdown and click Go or press Enter.
- The sites matching the search criteria are displayed in the Grid below the Search box else a message No records available is displayed. Refer to the screenshot below:

Search							
Sites		~	QNew Sit	te		×	Go
			Limit search to	this (Site, Screen)			
Do	cum	ent 🕐 Docume	ent Details	Move to S	Startup	Layout	Compare
5 D	ocu	ment(s)					
		Investigative Site Na	Document Id	Title	Document	Reason for	Comments
•	*	New Site Tech Writers I	2070184	CDA AGRE	Polly Chakr		
□ ₩	*	New Site Tech Writers I	2113043	Doc1	Polly Chakr		
0 B	*	New Site Tech Writers I	2237347	rere	Tiger Woo		

6. Notice that the top ribbon bar is also available above the Documents Grid in the Search results window.



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 Notice that the top ribbon bar is also available above the Grid which provides the functionalities like Document, Document Details, Move to Startup, Layout, Compare, and Add to Cart.

Each of these functionalities is discussed in the respective sections.

Room Search

To search for a room, follow the steps as below:

1. The Search textbox is located on the home page to perform the room search. Refer to the screenshot below:



- 2. On the home page of the application, all the rooms are displayed and the user can use this search functionality to easily search for the desired room.
- 3. Enter the room name in the search textbox and search starts automatically as and when the text gets entered in it. Refer to the screenshot below:

Ттаі		×	
All 1 Favorite 1 Recent 1 eTMF 1 Study Start-Up 1			
Last Visit Date Room Name Created Date Total Expired Expired	Open Queries		
Sort Descending 💌			Overview Detailed View
Training Room 1 Room Id 206	🥥 9 Countries 🛛 🛔 11	1 Pending Sites 📋 10 Active Sites	🖹 836 Total 🔹 🔂 Add 👻 😂

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Chapter 8. Importing Documents and Metadata

Following are the various ways to add documents to a study room. Documents can be

added to a room by several means such as:

- 1. Uploading documents from the Home page
- 2. Adding a document from the Documents module using:
 - a. The Document Action dropdown
 - b. The Context Menu from the document grid
- 3. Importing documents using:
 - a. The Import dropdown in the Document module
- 4. By emailing and faxing documents to a room

Each of these is discussed in a separate topic and can be accessed from the left menu of this help.

Adding Documents to Index Folder

You can add Single or Multiple documents to an index folder. Each of these is discussed in the sections below.

Adding Single Document to Index Folder

To add a document directly to an index folder:

- 1. Navigate to the Documents module.
- 2. Select the folder from the index pane into which to add documents and right-click on it.
- 3. From the right-click popup, select Add Single Document. Refer to the screenshot below:





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4. This will open the Document Profile form for you to add the details and save. This adds documents directly to the selected folder and such an added document does not appear in the default index folder or Upload folder.

Adding Multiple Documents to Index Folder

- 1. From the Documents Module, select a folder in the index.
- 2. From the right-click popup, select Add Multiple Document. Refer to the screenshot below:



Adding Documents from the Documents Action or Context Menu

1. From the Documents Module, click the Document dropdown.



2. Select Add Document and the New Document window opens. Enter the details as required to



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create a new Document profile. Refer to the screenshot below:

3. Select the appropriate Category from the dropdown list; General, Country, or Investigative Site. Depending upon the category selected, the document's **Submitted Name** field would appear or disappear. Enter the Submitted Name as required.

- 4. Select the Document Type, and Document Date. Type in the date if that is configured for you.
- 5. Add pertinent **Comments**, if necessary. The Index position will populate automatically, based on the folder you selected from the index.
- 6. Click the Browse button next to the Attachment field to attach a document.
- 7. Complete other fields as necessary and click **Next** to take you to the **Document Security popup**. Here you can add group(s) and/or users(s) who would access the documents into the security grid and set the desired levels of access. A detailed description of each security access is given in *Manage Security (page 270)*.
- 8. Click Finish for the new document to take its place in the default index folder or the Upload folder as set in the room settings.

Note: You can also add/import documents by dragging and dropping them from the Windows Explorer to their relevant index folders. Upon dragging and dropping the document, the Document Profile window opens for you to code the document. The Title, Document type, and Category fields are automatically coded for you. The dragged document can be found in the Attachment/URL field of the Document Profile.

Importing Documents

Follow the steps below to import documents metadata to a room:

- 1. Navigate to the eTMF Documents module and select Documents from Import dropdown.
- 2. The Import Documents window opens. Refer to the screenshot below:
- 3. Following the on-screen instructions, either drag-and-drop files from your own computer into the upload panel or use the

Browse button on the window to select documents to upload.

- 4. After selecting documents to be uploaded, you can select the **Documents Metadata** checkbox on the right pane of the window to quickly code select metadata for these documents while the system is carrying out bulk-uploading. Therefore, if you are importing documents that are from the same investigative sites, are related to a particular contact person, or belong to the same document type, you can assign those at one go. This is also **Mass Coding** while importing documents.
- 5. While the documents are uploading, the user can monitor the **Upload Status** column in the display panel and view the progress of the upload in the progress bar at the bottom of the window. When the upload is complete, each document will display an **Upload Status** and the progress bar at the bottom of the window will read **Done**.
- 6. If you have specified the Documents metadata then click Import and Apply coding, and Close button placed on the bottom right corner. A confirm Mass Coding message will pop-up. Click Yes to confirm.
- 7. If you have not specified anything on Documents Metadata, then after the upload is finished, simply click the Import



for the process to begin.

Import Documents			? ×
File Name	Size	Upload Status	
	\odot		
	Drop Files and Folders Here -or- Use Browse button below		
	Ipload Progress	0 Total Files 0 bytes	
	Browse Clear Unpack Zip Arc	nives ?	Import

8. The Import functionality will not allow the import of erroneous files. During the import of several files, the files that were uploaded successfully will be removed from the list of files in the Import Document dialog box, but some

documents will remain in the grid due to some errors while uploading. The user can try to import the left out documents again. This will not re-import the already uploaded documents but will try to import the documents remaining in the grid only.

9. Once importing documents is over, click the Close button in the bottom right corner of the Import Documents window. The uploaded documents can then be found in the user's Upload folder in the folder index or the default index folder as specified in your room settings.

Importing Metadata

To import document metadata:

- 1. Select Metadata from the Import dropdown. The Documents Import popup opens.
- 2. Upload the .xlsx file containing data of sites and contacts by clicking the search icon. It is also possible to import multiple documents using just metadata. The wizard offers a link to the sample worksheet so the user can download it and fill it with actual data. Click **Next**. Refer to the

ocuments Import				Step 1 🌘	0 0	0	×
Upload File							
You can import multiple do with no content. Your Exce documents.	ocuments usi I spreadshee	ng just metada t should contai	ta. Imported do n one workshe	ocuments v et with you	vill be r list c	created of	
Metadata File (format: .xlsx)*:	C:\fakepath\	Book1.xlsx		Select			
See the sample worksheet ten	nplate						
	Cancel	Previous	Next				

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screenshot below:

3. Setup the mapping between metadata fields and uploaded file columns. It is possible to skip sheet selection in case you do not want to import investigative sites but only contacts. You can also specify the date format that should be used during import. Click **Next.** Refer to the screenshot below:

Documents Import			Step 2 🔘 🌘	00	×
Setup metadata fields m	apping				
Spreadsheet Column		Metadata field			
Flat # M wing		Amendment Item Number			*
Donation					
					-
Load file type	New data				
	Data overlay				
Unique ID fields*					
Date format*	MM/dd/moor				•
	www.daryyyy				
	Cancel Pro	evious Next			
	cuncer	NCAL			

4. You may choose incremental data or data overlay options for the import of metadata. Here, you will need to mention the Unique ID fields for incremental import or data overlay.

Click Next.

- 5. Observe the settings that were done during previous steps and probably return back and correct something. Click **Next** to confirm.
- 6. This will begin the actual import process. Upon completion, the user will get a short report on the issues that were occurred during import.

Uploading Videos

Trial Interactive supports the following types of video files as attachments to documents in the below mentioned browsers:

Browser Name	File Type
Internet Explorer	.mp4
Chrome	.mp4, .webm, .ogg
Firefox	.mp4, .webm, .ogg
Safari	.mp4
Opera	.mp4 (from Opera 25), .webm, .ogg



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To play a video file, select the document in the grid and click the **Document** tab at the bottom of the grid, or simply double- click it. The document opens in the viewer with the **PlayVideo** button on it. Refer to the screenshot below:

Open in New Window	% Start Redaction	🕲 Start Page Manipulations	Translate Document
		† ₁	
	AT	AD	
	Anuj Thaper	Amruta Deshoande	
 And Theory Dubies With App. ★ Box C C	4x42 × 4 (Vicken)14*/14/02/02/02/02/02/02/02/02/02/02/02/02/02/	v(155.080 🗰 🖏	- n × n ⊙ = a ≍ <mark>0 ≤ ⊠ é</mark> :
Biology) Real			Con 🛃 recent in
MIRIA		Set Due Onte	
(A) how	1	e der sont seder nort offe	
Conserver and Conserver	ne me cas	S 2011	of the States 0
States -	Configure Remindent	Seminder Emdit Template	
the second se		Mond: + <u>4</u> ■ / 1 C C 3 × 3 E E E 3 × 0 M 0 0 H	**-*
Ban Serv		Heads. White an Tradition server a consistent provides of a Charact Technologies and Technologies and Technologies and the to its consistent of the Self for any of the Latitude Self for an and the Self for the Se	en Weste
	No Reminders	Care to specify the care decision along. Neglet for the result of the comparison system of an electronic sector.	a west on our
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		Therefore the proceeding the Sciences	100 C
		TransFerRici	
Berta Der Dent			
Cesse		A-kd Herricker	The
			Witness and
	Demonstration		

It is possible to start/pause the video, control the sound, seek through the timeline, and switch to full-screen mode or back. Unsupported video files open in the viewer with the message **Media format is not supported. Click here to download the file.**

Chapter 9. Deleted and Expired Documents

This explains the places where

deleted and expired documents are

stored. This section includes the

following:

- 1. Deleting and Viewing Deleted Documents
- 2. Expired Documents
- 3. Deleting Queried Documents



The above is discussed in separate topics accessible from the left panel of this help.

Deleting Documents and Viewing Deleted Documents

Deleting Documents

To delete a document:

- 1. Navigate to the Documents module.
- 2. Select the document(s) from the documents grid.
- 3. From the right-click menu, select Delete. Refer to the screenshot below:



Please note, as an Editor you will only be able to delete documents which you submitted and which have not yet made it through the workflow.

Expired Documents

As an Administrator, you might want to specify the time by which a document will expire and require a new version. You can set up the settings of expired documents from the **Main Navigation -> Settings -** > **Documents -> Documents Module.**

You can view the expired documents from the Expired and Expiring Documents (page 210) dashlet.

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Chapter 10. CRA Reconciliation

This section helps you find the details about the CRA Reconciliation Reports that allows CRA to take decisions regarding further site visits.

Trial Interactive 10.1 helps the CRA to reconcile documents

during their site visits through the Site Report. You can reach

this page from Main Navigation – CRA Reconciliation. Refer

to the screenshot below: The module has the following

sections:

- 1. Documents: This module allows the CRA to mark the documents as verified, missing in eTMF, missing in ISF, or add the placeholder for an expected document as a part of the reconciliation process.
- 2. Reports: This module allows the CRA to create CRA Report which will include all the documents reviewed by the CRA since the last report created by him/her.

Each of the above modules is discussed in separate topics and can be accessed from the

left pane of this help.

Documents Reconciliation

For performing Site Visits, CRAs needs to take some important decisions regarding

documents for sites:

- 1. Which documents need to be added to both eTMF and site binder
- 2. Which documents need to be added to site binder from eTMF
- 3. Which documents need to be added from site binder to eTMF

CRAs can avail of this information from the **Site Report** so that they can verify the outstanding documents during their next site visit.

Note: Only **Pending** and **Active** sites are available for the reconciliation process

🖖 Important:

- Missing documents cannot be marked as reviewed.
- Only CRAs can perform this step. Admin users will not be able to mark documents as Reviewed.
- The CRA needs to have CRA Reconciliation Action enabled under the user profile.



Follow the steps below to reconcile documents:

- 1. Navigate to Main Navigation CRA Reconciliation Refer to the screenshot below:
- 2. The Document View opens as shown in the screenshot below:

	 Michael Demo - CRA Reconciliation / Docum 	ients												
	🗅 Placeholder 🔹 🖌 Reconcile	🔸 Ex	port	•	⊖ P	rint		🛙 Compare						
	View by eTMF Completeness		1	- 39	of 39	(1 se	lect	ed)				C	T Filte	rs 🔲 Select Colu
2		C						Submitted Name	Generated Name	Required By	Document Type	Language		Visit Status
	🔻 🍃 United States	Ŧ			*	8	•	(Country [United	FDA Form 1572			
	📄 Site 001 Thisis JustaTest			0	*		0			All Sites	Completed CRF			
				0	$^{\pm}$					All Sites	Completed CRF			
				0	*	8				All Sites	CLIA Certificate			
				0	*					All Sites	CLIA Certificate			
			C	0	*		ò.			All Sites	CAP Certificate			

3. Notice if you receive warning as shown in the screenshot below:



4. If the warning is displayed, click the Filter icon below the view and uncheck My CRA/SAS Sites or My favorite sites



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from the filter. Refer to the screenshot below:

View Documents By 🥒 🖋 🗙
eTMF Completeness
By Completeness Show Missing Show Placeholders Show Collected Show Empty Folders By My Sites My CRA/SUS Sites My Favorite Sites By Visit Status Wissing in eTMF Missing in ISF Verified Not Specified
Make default Make default for all rooms Cancel Select

- 5. Click Apply.
- 6. The list of folders appears in the view.
- 7. Click the appropriate folder to display the list of sites.
- 8. Select the appropriate site from the selected folder to get the list of missing, collected, and placeholder documents in the grid.
- 9. while reconciliation, each document will fall into one of the three scenarios as below:
 - a. If the document is in the ISF but not showing in the eTMF:
 - a. Click Add Placeholder (or if applicable, upload/email the document to the eTMF).
 - **b.** Complete the known required fields and click **Finish** (metadata can be added/edited once the document is collected).
 - c. Once all the actions are done, click the Reconcile button and proceed to step 11.
 - b. If a document is in the eTMF not present in the ISF:
 - a. Click the document(s) and click the Reconcile button.
 - c. When the document is in both eTMF and the ISF
 - a. Click the document and then click the Reconcile button.
- 10. Click the Reconcile button from the top ribbon bar to change the status of the document. The Change Status pop-up opens. Refer to the screenshot below:

	Dei	00.								
		Michael Demo + CRA Reconciliation / Docume	ents							
		Placeholder - Reconcile	◆ Ex	port 👻 🕴	🖯 Print	🗇 Compare				
		View by eTMF Completeness	•	1 - 39 o	f 39 (1 selec	ted)				
This	2		0			Submitted Name	Generated Name	Required By	Document Type	ret laws. Copyright
© 20		🔻 🍃 United States	Ŧ	00	* # 0			Country [United	FDA Form 1572	may be reproduced,
copi		🖺 Site 001 Thisis JustaTest		0.	* # 0			All Sites	Completed CRF	d by anyone in any
form				00	* # 0			All Sites	Completed CRF	ent and/or Product
Mana				🗹 🛛 '	* 🖩 🌣			All Sites	CLIA Certificate	
				00	* 🖉 🔅			All Sites	CLIA Certificate	



- 11. Choose the required status and click Select. 🗐 Note:
 - **Missing in ISF**: Select this status to indicate the document is missing in the site binder (ISF) but present in the eTMF.
 - Verified: Select this status to indicate the document is in both the eTMF & ISF.
 - Not specified Select this status to clear a previously assigned status.
- 12. Once the **Reconcile** process is complete, you can see the status of the document with the date. Refer to the screenshot below:
- 13. This site is then available for the creation of the CRA TMF Reconciliation Report in the **Report** view.

Creating and Viewing the CRA TMF Reconciliation Report

CRA TMF Reconciliation module is the repository of the CRA TMF Reconciliation reports generated by CRAs during site visits. You can access this page from Main Navigation \rightarrow CRA Reconciliation \rightarrow Reports View. On entering the dashboard, you can find the list of reports generated displayed in the grid. You can choose to view the reports By Site, By Visit Type, or By CRA from the current view panel on the left. Clicking a report from the grid populates the report metadata in Reconciliation Data panel located at the extreme right of the dashboard. You also have the option to Create edit, or delete a CRA Reconciliation TMF Report from the Create, Edit, or Delete icons located on the top ribbon. Refer to the screenshot below:



Creating CRA TMF Reconciliation Report

1. Once the Reconciliation process is complete, you can create the CRA TMF Reconciliation report



from the Reconcilia tion Report module.

- 2. Select the appropriate filter from the Current View. The Previous reports will populate in the grid.
- 3. Select the appropriate site and click Create from the top ribbon bar to run a new report.
- 4. The Create CRA TMF Reconciliation window populates with documents from the latest reconciliation. Complete the required fields.

Note: The Visit Type will be populated in the dropdown only if it is created from Settings \rightarrow Investigative Sites \rightarrow CRA Visit Types. (page 140) Refer to the screenshot below:

- 5. Fill in the appropriate details and click Create.
- 6. You will receive a notification that the Site Report is created successfully and displayed in the grid.

Editing CRA TMF Reconciliation Report

- 1. Select the required site from the Reports module and click the Edit button on the top ribbon bar.
- 2. The Modify CRA TMF Reconciliation popup opens.
- 3. Edit the required details and click Save when finished.

Deleting CRA TMF Reconciliation Report

- 1. Select the required site from the Current View and click the Delete button on the top menu bar.
- 2. Click Yes on the confirmation popup that appears if you wish to delete the report from the list.

Chapter 11. Quality Control

This section involves the quality check of the submitted documents in a room by Quality Reviewers who are the members of the Quality Control group.

Quality Control Process

This section gives the complete process of the Quality Control Workflow.

Activating My Reviews

If you are part of the reviewers group which you assigned to the workflow, the Reviews view in the eTMF Documents module is automatically activated for you. You can have the same view as in My Reviews from the Quality Control Review application as well.

Depending upon your workflow settings, documents added to the room are automatically added to the workflow. You can view the documents added to the workflow from the Reviews view or the Quality Control module in the folder with unclaimed documents under the workflow configured by you. Refer to the screenshot below:





Claiming a Document

To claim a document for review, click folder holding **unclaimed documents** under **Reviews** or the **By Document Status view** from within your eTMF room. This will list the documents on the right pane.

Select the document you want to claim for review and navigate to the right panel.

If Workflows have been activated in your trial room and you are a member

154	1 docu	uments (1 sele	cted)								🔒 Claim 🌣 More 🗸
		Document	Title	Document	Disable au	Document	Reason fo	Comments	Document	Category	Metadata Workflow Queries Versions History e
B	π	2072157	Important		True	Polly Chak			20 Apr 2018		Document Metadata
	*	2072158	Copy of C		True	Polly Chak			20 Apr 2018		Designed bil
	$^{\pm}$	2072804	TEST	audit 1_10	True	Amruta A			25 Apr 2018	1	2.076.500
	*	2076498	arabic_c2d			Polly Chak			26 Apr 2018		Title ± 2
	$^{\pm}$	2076499	arabic_e7		True	Polly Chak			26 Apr 2018		french_e7cac3d85c094888a0bb5d5838aabd6b
Z 🖪	*	2076500	french_e7		True	Polly Chak			26 Apr 2018		Document Name
	π	2076501	german_c		True	Tiger Woo			26 Apr 2018		
	*	2076502	german_d		True	Polly Chak			26 Apr 2018		Disable auto Document Name
B	*	2076503	nicksep27i	audit 1_10	True	Polly Chak			26 Apr 2018	1	Document Name last updated by
D	*	2076504	nicksep27i		True	Amruta A			26 Apr 2018	E	Polly Chakraborty

of a **Reviewers** or **Approvers** Group, you will see a **padlock icon** at the top of the metadata panel.

- 1. Click the padlock icon to claim the document for workflow review.
- 2. Then click Save.
- 3. Click the Next Document link at the bottom of the right panel to move to the next document in the current data grid. The process can be repeated as long as there are more documents available to be claimed. You may also select documents in bulk in the Documents Grid and claim them altogether.
- 4. All the claimed documents move to the folder for holding documents claimed for review in the Index Pane. Click the folder to view the claimed documents in the Documents Grid.



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Note: Once you claim a document for review, the padlock icon appears to be unlocked and changes its text to **Release** which allows you to release the claimed document.

5. Select the document from the grid and navigate to the **Workflow** panel to the right. From the Workflow panel, you can add the appropriate workflow status to the document.

Auto-Claiming a Document

In certain business scenarios, there can be only one reviewer assigned to a Quality Control stage. Under such circumstances, documents will be autoclaimed by the system and assigned to the lone reviewer for review. To enable auto-claiming of a document, the Administrator will need to enable the configuration from the Main Navigation ->Settings -> Workflows -> Common Settings -> Auto claim configuration. (page 153)

Note: If documents are present in the same stage of more than one Quality Review, and the Reviews have only one reviewer assigned to them, the documents will not be auto-claimed.

Assigning Quality Control Status

If you have been assigned to a Quality Review role, additional fields are available to you in the Metadata panel for documents in the Quality Control. Part of your assignment is to assign each document a Workflow Status.

- 1. Click Documents from the left menu.
- 2. Select **Reviews** or **Status** view from the views. Alternatively, you can also navigate to the Quality Control module from the Main Navigation.



3. Open the folder holding document claimed for the review by clicking the folder icon next to the folder name. A list of your claimed documents will



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populate the document grid.

- 4. Select a document.
- 5. View the document's contents by clicking the document's icon in the grid or by clicking the **Document View** button at the bottom of the grid.
- 6. Inspect the document.
- 7. From the Metadata panel, code the document as required.
- 8. Navigate to the Workflow panel. Refer to the screenshot below:

Release	More 🗸
Metadata Workflow Queries Versions Hi	story e 🗲
TechWritersWorkflow: Approval stage 1	-
Status*	
review in progress	~
Index	
1 signature 2	6
	×
Comments	
comments	
Send Issue	

9. Click the dropdown arrow to the right of the Status field to reveal the available Status selections.

- 10. Select the appropriate status based on your review of the document's contents.
- 11. Select the issue from the Issues field and select the Index Position for the document.
- 12. Add comments to the Comments field if appropriate.

Note: When you select the **Review Clarification** or **Review Declined** status, the **Create Query** button appears along with the **Send Issue button** as shown in the screenshot below.



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Release			🌣 More	~
Metadata Workflow	Queries	Versions	History	€ 🚽
TechWritersWorkflo	w: Appro	val stage	el '	-
Status*				
review clarification			~	
Issues				
Index				
1 signature 2			Ē	1
			×	
Comments				
Send Issue		Create Qu	uery	

- 13. Click the Save button at the bottom of the Workflow panel to save the workflow status you have assigned to the document, or click the Save and Next to continue reviewing the next document in the claimed documents queue.
- 14. Depending upon the status selected, the document moves to a corresponding folder under the Index Pane. For example, approved documents will move to the folder for holding documents approved in the workflow, rejected documents will move to the folder for holding declined documents, documents in progress will move to the folder for holding documents in progress, and so on.
- 15. You can also view the review history in the Workflow History section in the Workflow panel.

Releasing Claimed Documents Back

As a user with the Administrator role, you might find that you have claimed more documents for Quality Review than you can handle. If such a situation arises, you can release some or all of your claimed documents back into the Quality Review.

- 1. Click Documents from the left menu of the screen.
- 2. From the views, select Reviews or By Status, or navigate to Quality Control module.



View by Reviews	1 docun	nents (1 select	ed)								Release	Ø More ~
V 🍃 TechWritersWorkflow		Document	Title	Document	Disable au	Document	Reason fo	Comments	Document_	Category	Metadata Workflow Que	eries Versions History «
Available for review 153	2 0 *	2086077	etmf 10.pdf		True	Polly Chak	1		24 May 20	0	Document Metadata	-
Cverdue 0											Document Id	
review approved 3												
review approved with issues 0											Title * 🚱	
Treview claimed 1											etmf 10.pdf	
review clarification 0											Document Name	
review declined 1												
review in progress 0											Disable auto Document N	lame
> In TechWrites1											Document Name last updated	s by
											Polly Chakraborty	

All of the folders related to the Workflows in which you are an active reviewer populate the **Current view** index structure of the **eTMF/Documents Reviews view**.

3. Click the folder holding claimed documents from

which you want to release documents. The list of

documents in that folder populates the document grid.

- Click the checkbox above the list to select all of the items in the folder, or select individual documents by clicking the checkboxes for those individual documents.
- 5. Click the Release button from the Right Panel. Refer to the screenshot below:



- 6. A window opens asking for document release confirmation.
- 7. Click Release if you are sure you want to release the document or documents.



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8. Alternatively, you can also release the document by clicking Moredropdown at the top right corner of the Right Panel. From the dropdown options, click the **Release from Workflow** option to release the document. Refer to the screenshot below:

📴 Add to Ca	art 🛛 🃜 Documents cart 🗸
Release	🏶 More 🗸
Metadata Workflow C	📲 Reassign Reviewer
Document Metadata	🖋 Change Stage
Document Id	Exclude from Workflow
2,086,077	Release from Review
Title * 😧	
etmf 10.pdf	
Document Name	
Disable auto Document	t Name

That document or those documents return to the folder designated to hold **review unclaimed** documents. The documents are now available for other reviewers to claim.

Quality Control Query

The Workflow Query Resolution module must be enabled by a user who has Super Administrator access in Trial Interactive. When Query Resolution module is enabled, Query Reminder configuration is present in **Notification Preferences** and **Notification Columns** portlets in Email settings.

Quality Control Query involves the following processes:

- 1. Quality Control Query Initiation by a Reviewer
- 2. Quality Control Response by a Responder
- 3. Quality Review Query Resolution by Reviewer for Query Response without attachment
- 4. Quality Review Query Resolution by Reviewer for Query Response with attachment
- 5. Tracking Quality Control Queries
- 6. Excluding Documents from a Quality Review

Each of these processes are discussed in seperate topics. Click the topic from the left pane to

view it.

Quality Control Query Initiation by a Reviewer

- 1. As a user with Quality Control Reviewer assignment, go to the Documents module.
- 2. Select the **Reviews** view in the index panel on the left side of the screen, or navigate to **Quality Control** module.



- 3. Select an active Workflow main folder. The related subfolders open in the index view.
- 4. Select a document from the folder having unclaimed documents.
- Claim the document by clicking the Claim button located at the top of the right panel. The document moves to the folder containing claimed documents.
- 6. Navigate to the folder that contains documents claimed for workflow and select a document from the grid.
- 7. Navigate to the Workflow panel in the right.
- 8. Select either Rejected or Clarification as the workflow status.
- 9. Select one or more Issue from the Issue field.
- 10. Click the Create Query below the Comments field. Refer to the screenshot below:

Release	🏶 More
Metadata Workflow Querie	es Versions History
echWritersWorkflow: App	roval stage 1
Status*	
review clarification	~
Issues	
Clarification ×	
Index	
1 signature 2	6
	×
Comments	

An email window opens. Click Yes to the question Are you sending a Query? (add image)

11. Click the 'To' and/ or the 'CC' button at the top of the message to add recipient of the Query notification email message.

The party responsible for having sent the document to the room is an automatic recipient of

the outgoing message. Only room participants can be added to the 'To' and 'CC' fields. Other email addresses cannot be added.

The sender can include the associated workflow query document as an attachment or as a link.

12. Once all appropriate selections are made, click Send Query.



The email message will go out to all recipients indicated in the fields at the top. Recipients receive an email message like this:

Reply Reply All Forward T Im Wed 5.9/2018 6:38 PM TechWritersDemoRoom@trialinteractive.com (#QUERYID:1340-175##) TechWritersDemoRoom Important links To Poly Chakraborty Cc Amruta Maddel
Important links.txt
PLEASE DO NOT CHANGE THE EMAIL SUBJECT
The following issues were found in the document, please attach a revised document in your reply to this email:
TechWritersWorkflow: Approval stage 1
Clarification
Clarification
Site name TechWritersDemoRoom
Email pchakraborty@transperfect.com
Phone
Doc Name Important links
Doc Type
WF Name TechWritersWorkflow
WF Stage Approval stage 1
Issues TechWritersWorkflow: Approval stage 1
Clarification
Reviewer Comments Clarification

Each Query is assigned a unique Query ID number for easy tracking.

Note: A Query ID consists of the of the Room ID where the query was generated and the Query ID separated by a dash. For example, in the above screenshot, in the Query ID 1340-175, 1340 is the Room ID and 175 is the Query ID.

- 13. Click Save.
- 14. The Reviewer can also view the queries sent under two other views:
 - a. In the folder designated to hold documents sent for clarification under My Review view or Quality Control Reviews module where the document acquires a question mark to indicate that it is in query.





b. In the **Pending** folder under **Query By Sender** view from the eTMF/Documents module.



Quality Control Response by a Responder

The Quality Control Responder can do the following to respond to the query email received in his/her email inbox:

- 1. The responder can view the query email in the By Recipient view under the Pending folder.
- 2. The responder replies to the email query with/without attachments or links after examining the query closely.
- 3. Once the **Responder** replies to the query email, the query automatically moves to the **Responded** folder in the responder's room under the **By Recipient** view.
- 4. The <u>Responder may also choose to resolve the query</u> by clicking the **Resolve** button in the Queries panel in the **Pending** folder. Under such circumstances, the document moves to the **Resolved** folder of the **By Recipient view of the responder** and in the **By Sender view of the reviewer**.

Quality Control Query Resolution by Reviewer for Query Responses without Attachments

Once the responder replies to the query email, the reviewer can view the responded message in the room in **By Sender** view under the **In Progress** folder.

The reviewer needs to do the following to resolve the query:

- 1. From the In Progress folder, click the document and select the Query Panel from the right of the page.
- 2. At the bottom of the Query panel, two buttons are visible **Respond to Query** and **Resolve Query**. Refer to the screenshot below:

T R I A L

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	ל Tech י 1340	WritersDemoRoo	om 💙								🕇 Add	Q Searc	h
	🖹 Document 🗠	Manage Security	🖨 Print	🔽 Email	Move to	Startup	Import 🗠 🛛 🕈	Export Y ?	Layout 🔲 Co	ompare 🏦 B	ulk Upload		
a	View by Sender		î I		Document Id	Title	Document	Reason for	Comments	Document	Category	Category	Sit
	Choose View				2090144	test	Amruta Aud						En
	> 🖿 *All 38			🗟 \star	2090207	New Docum	Amruta Aud		For Mileston				Ph
₽	> Tiger Woods	2											Do
da	> 🖿 Polly Chakrabo	orty 23											Do
~	🗸 🖿 Amruta Audit	or1 Maddel 13	E										w
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	Kesolved	9											
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	*Inbox 0 (1)	,											
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													~
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(\mathcal{I})											Previous	0 of 0 Next >	

- 3. Click the Resolve Query button.
- 4. On clicking the **Resolve Query** button from the Query panel, the **Query** window opens to allow the reviewer to resolve the query. The reviewer will see the following window to resolve queries without attachments:

Resolve a query	? >
Please choose query resolution	
Resolve	
Resolve and replace using selected attachment	
Resolve and create new document Use selected attachment Copy metadata from original document	
Comments	
Rev Desument door	



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Note:

- On clicking the <u>Return back to Pending</u> button, the document returns back and is available for review again. It will then need to re-start the query process from the beginning. This can be used, for example, if the responder is Out of office and an automatic reply is sent from his/her email inbox due to which the document moves to the In Progress folder.
- The reviewer can also click the <u>Resolve</u> button from the <u>Query</u> <u>window</u> in <u>Pending</u> folder to mark a query as resolved without any additional actions or waiting for the responder to respond to the query email. This can be used if the reviewer decides that a response is not required or the documents will be received in some other way. For example, if a query was created by mistake and the reviewer decides to cancel the query thereby resolving it.
- 5. On clicking the Resolve button from the Query window, the query moves to the Resolved folder under the By Sender view for the reviewer and in the Resolved folder under the By Recipient view of the responder. The user can see the Query History in the History Panel to the right of the page.
- 6. On clicking the Resolve and create new document button and entering the Comments, the reviewer clicks the Next button to arrive at the Document Profile form. Refer to the screenshot below: (add

image)

- 7. Enter the document metadata details and provide the attachment.
- 8. Click the Resolve and create document button.
- 9. The document moves to the folder for documents available for review and is also available in the **Responded** folder in the **By Sender/By Recipient** view.

Quality Control Query Resolution by Reviewer for Query Responses with Attachments

Once the responder replies to the query email, the reviewer can view the responded message in the room in **By Sender** view under the **In Progress** folder.

The reviewer needs to do the following to resolve the query:

- 1. From the In Progress folder, click the document and select the Query Panel from the right of the page.
- At the bottom of the Query panel, two buttons are visible Respond to Query and Resolve Query. Refer to the screenshot below:

	1340	Room 👻								🕇 Add	Q Search
	Document 🖌 🧯 Manage Securi	ty 🔒 Print	🔽 Email	Move to	Startup	Import 🖌 🛛 🕹	Export ~ ? I	Layout 🔲 Co	mpare 🌲 Bu	ilk Upload	
<i>6</i> 78	View by Sender	<u> </u>		Document Id	Title	Document	Reason for	Comments	Document	Category	Category
	Choose View		₩ ★	2090144	test	Amruta Aud					E
			🗟 🖈	2090207	New Docum	Amruta Aud		For Mileston			P
л	> • *All 38										c
-	Della Chalashasha 2										c
<u>ل</u> ه	Manuta Auditor 1 Maddel 13	E									v
	Pending 2										v
ě.	In Progress 2										Ŀ
	Resolved 9										s
											c



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- 3. Click the Resolve Query button.
- 4. On clicking the **Resolve Query** button from the Query panel, the **Query** window opens to allow the reviewer to resolve the query. The reviewer will see

uery [1340-198]	()
Mease choose query resolution	
	Step 1 of 2: Query Resolution
Resolve	P Domain Level Description tif
 Resolve and replace using selected attachment ("Domain_Level Description.tif") 	• 1 K hello.pdf
Resolve and create new document	
Use selected attachment ("Domain_Level Description.tif")	
Copy metadata from original document	

the following window to resolve queries with attachments:

5. On clicking the **Resolve button** from the **Query** window, the query moves to the **Resolved** folder under the Query by Sender view for the reviewer and in the **Resolved** folder under the **Recipient** view for the responder. The user can view the Query History in the **Query** Panel from the right panel. It also moves back to the folder holding documents available for review and needs to follow the review process again. The following options are available for sending response with attachment:

Resolve and replace using selected attachment

On clicking Resolve and replace using selected attachment option:

- 1. The reviwer can choose from the right pane, the document as deemed fit. Two attachments are displayed at the bottom of the window (1) that was sent as an attachment by responder to allow the reviewer to resolve the query and (2) the document that is in the review process.
- 2. Before taking a decision, the reviewer can click the **Compare** icon from the right pane to compare between the document under review and the attachment sent by the responder in the **Compare documents** window, or click the attachment icon to open and view the attachment in the viewer.
- 3. Once done, the reviewer clicks the **Close** button on the Compare documents window and clicks the **Resolve and replace attachment** button after entering the **Comments**.



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- 4. The document moves to the folder for documents available for review and is also available in the **Responded** folder in the **By Sender/By Recipient** view.
- 5. The original document is still seen in the grid but the attachment from the query resolution can be seen under the Query History window.

Resolve and create new document

- Can choose whether to Use selected attachment below the option by ticking the checkbox next to it and also use Copy the metadata from the original document to create a new document, or
- 2. Untick both the above checkboxes and proceed to ignore the attachment and create a new document by providing another attachment.
- 3. Either ways, the reviewer clicks the Next button to arrive at the Document Profile form.
- 4. If the reviewer proceeds with option Use selected attachment, then he/she enters the metadata and clicks Resolve and create document button.
- If the reviewer proceeds with no option selected, then he/she enters the metadata, provides the attachment and clicks
 Resolve and create document button.
- 2. The document moves to the folder for documents available for review and is also available in the **Responded** folder in the **By Sender/By Recipient** view.
- 3. The original document is still seen in the grid but the attachment from the query resolution can be seen under the **History** panel.

Tracking Quality Control Queries

Users with Administrator access in a trial room can check the status of Quality Query

Queries.

- 1. Navigate to the Documents module.(add image)
- 2. Click the Choose View button and select **By Sender** or **By Recipient** view from the list. The Index panel populates with folders that contain the Quality Control Queries at their various stages of progress.

Select a specific folder and the contents of the folder populates the document grid.

- 3. Select a specific query from the grid and open the Right panel. The history of the selected query is available by clicking the **Query** panel. The stages of the query history populate the metadata panel.
- 4. Click the arrows to the left of stage description to see the details of each query stage.

If the user decides it is appropriate to create a new document in order to resolve the query, the user is required to complete the document profile, including uploading a new attached document.



Chapter 12. Quality Review

This section helps you understand the Quality Review/Audit application in Trial Interactive that allows creating Quality Review profile, recording auditor's review and comments on various documents added for audit in a trial.

As a Trial Interactive user, you can access the Quality Review Application from the Main Navigation:

Training Ro Quality R	oom 1 👻 eview / Quality Rev	riew	
TRIAL			
<mark>للے</mark> Start-Up	et MF	Communication	D Quality Review
Tasks	Legendre Reports	Users Management	Q & A
FAQ	CC Settings	A Home	

From here we discuss the following:

- 1. Performing Quality Review
- 2. Performing Quality Review Response
- 3. Responding to Quality Review Queries
- 4. Resolving Queries Raised during Quality Review

Performing Audits

If you are assigned the Auditor or Audit Manager action in your trial room, the audit feature is available to you when you click the **Quality Review** module in the toggling menu bar.

The Quality Review module has the following views:

- Audit: This allows you to perform audits
- Documents: This allows you to assign documents for audits
- Settings: This allows you to

configure settings for Quality

Review Follow the steps below to

perform audits:

1. As a user with Auditor duties, log in to a room and click the **Quality Review** icon from the Main Navigation. The user can access **Audits**, **Audit Documents**, and **Audit Settings** through the panel on the left.



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- 2. Click the Audit view from the left panel. The Audit view opens.
- 3. Click three dots from the left pane. The Choose View By popup appears as shown in the

View by Query By Sender	No records available.	
> (2) *All 21 > (2) Tiger Woods 1	Choose View By	?
 > O Nick Editor 10 > Nick Reader 6 	Quality Review 🥔 audit	query test 1 🗸 🗸
> 📀 Nick Akulich 4	Document Status Pending	~
	By Auditor	ditor 🗸 🗸
	Documents Queries	Others By Audit Findings
	By Document Type Query By Recipien	By Investigative Site
	By Country	
	Make Default	
	Consult of the	

screenshot below:

- 4. Click the Quality Review dropdown to select an active audit from the list.
- 5. The user can also choose to view the available audit documents *By Document Type, By Country, and By Investigative Site, Audit Findings, Query By Sender, and Query By Recipient.* Select views to be displayed.
- 6. The corresponding folders display based on the selection made by the user. Drill down and select the available folders.

Available documents will be displayed in the grid.

The Auditor has another means to filter the audit documents.

- 1. Once the Audit is chosen, click the Document Status dropdown.
- 2. Select Pending from the list.
- 3. Select the auditor from the By Auditor dropdown.
- 4. Click the Select button. Index folder containing documents Pending Audit populate in the Index View. Refer to the screenshot below:
- 5. Open folders to locate documents published and assigned for audit.
- 6. Notice the Quality Review Information icon next to the document icon in the document grid.
- 7. Click the icon to open the Audit Panel in the Metadata Panel. Also, notice that the Quality Review Information popup



displaying the audit status of the selected document. Refer to the screenshot below:

View by Index				Title		
			Qu	ality Reviews Inform	ation	
A Site Signed NDA 366	0.1		F	Review	Reviewer	Status
B Site Language Changes 38			1	123	NewTestUiUser_2@blabla	Pending
C Country Management 0 (2)		3 🖉	2	234	NewTestUiUser_2@blabla	Pending
D Additional PSV Package Documents 3		1 2	a	as1	NewTestUiUser_1477@bl	Pending
E Site Management 0 (1759)		1	a	as23!	NewTestUiUser_3@blabla	Pending
F Protocol Draft, Protocol Synopsis 3			-	as23!	NewTestUiUser_3@blabla	Excluded
G CRA PSV Materials 3		1		audit23!	NewTestUiUser_193@bla	Pending
H Relevant Communications 24	0.0	1	,	Auditing Round 3	testeditor@ti.com	Pending
I Mutual Nondisclosure Agreement Forms and Process		3 #	E	Brief Audit	NewTestUiUser_1000@bl	Pending
J Language Changes_Pearl Distributed 26	0.0			qwer	NewTestUiUser_2@blabla	Pending
K CNS_Contracts and CDAs 10 (11)	0.	3	,	brtygbtbt	NewTestUiUser_1675@bl	Pending
L PT003006 US_Site Contracts and Budgets 2 (459)	0.	1	4	Simple_audit	editor@tt.com	Pending
 Minimutodov op_site Contracts and Budgets 0 (353) Ninick folder 1, 12 		3 8		the best	NewTestUiUser 1002@bl	Pending
		3 8		vrfvfvfvffvf	NewTestUiUser 2@blabla	Pending
P export test 0 (12)	0.	3 🔊	-	rejedor_kichard_LSUHe	aith Center_CDA Language Changes	
Q test folder 1	0.	3 8	*	Calhoun_William_UnivT:	xMedBranch	
R DEFAULT FOLDER 173		3 🚇	*	Sciurba_Frank_Universit	ty of Pittsburgh/UPMC Emphysema/C	OPDResearchCenter_MUTUAL TEMPLATE
> Tredaction 15 (36)	-	a 🕫	*	Barbers Richard Health	ResAssoc CDA	

- 8. Open the document in the viewing panel.
- 9. Examine the document and its metadata to determine if it meets the established audit criteria.
- 10. From the Metadata panel to the right, click the dropdown

arrow at the right end of the Status field. The status options

appear.

11. Click the appropriate Status.

If the document contains **Protected Health Information** (PHI) and you want to delete and fail the document attachment for audit, tick the **Contains PHI?** checkbox.

Note: To enable the Contains PHI? field, you will need to enable the feature when setting up the Audit under Document Audit Settings (page 347)

On ticking this, the document automatically acquires a **failed** status and displays a warning regarding the removal of the attachment from the document.

Click **Remove file** to proceed. The system deletes the attachment in the backend and displays the **Refresh** icon next to the document in the grid.

On clicking the **Refresh** icon, the document disappears from the grid and moves to the

Audited folder.

- 12. Insert comments as appropriate.
- 13. Click the Save button, or the Save and select next button in the lower toolbar of the window.



Note: Add a comment to all documents with which you find issue. Comments can also be added to documents that have passed your Audit Criteria

- 14. To view audited documents, filter the documents by Audited from the panel on the left.
- **15.** The audited documents appear in the grid with their respective statuses. Documents failed due to the content of PHI appear in the grid without the attachment and acquire a failed status.

Exporting Audits

An Auditor or Audit Manager can export a report of the following directly related to the documents assigned to any particular audit:

- 1. Metadata
- 2. Documents
- 3. Security
- 4. Audit By View
- 5. All Audits

To export an audit report:

- 1. From the Quality Review module, click Audit from the left menu bar.
- 2. Select the audit on which you would like to run the audit report from the list of active audits.
- 3. Select the documents from the list and click Export on the top ribbon bar.

	Training Room 1 - Quality Review / Qualit	y Review						Q Sea	
	🖹 Document 🔹 🔤 Email	🕈 Export 🔹 🖪	Assign To					🖁 Add to 0	
	Quality Review 103 Test Audit	Metadata	of 2 (2 selected	(ל	C	T Filters	Select Columns	🕫 Views 💌	
	Auditor Admin 103	Security		Submitted Name		Index			
	View by Index	🕹 Audit By View	🛛 ★ 🌣	Protocol		02 Cen	tral Trial Documents\02	.01 Product 🛆	
Q°	🔍 Search by folder n:			🗐 ★ 🏟 Study Protocol			02 Central Trial Documents\02.01 Product		
	🔻 🖿 01.03 Trial Committee	2	18 166 COL 613						
	💼 01.03.02 Committee	Mem 1							
	🖿 01.03.05 Committee	Mem 1							
		121							

- 4. From the Export Dropdown, click the required option to generate an audit report.
- 5. Click the Export button. A Background Jobs window opens with the initial export results.
- 6. As instructed on the screen, click to get the export results. A zipped file downloads to your computer.
- 7. Follow the on-screen instructions to open the XLSX file.

Each option in the Export dropdown is discussed as below:

Metadata



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This is the same as discussed in Exporting Metadata in chapter Exporting Metadata (page 275).

Documents

This is the same as discussed in Exporting Documents in chapter Exporting Documents (page 277).

Security

This is the same as discussed in Exporting Security in chapter Exporting Security (page 278).

Audit by View

Select Audit by View from the Export dropdown menu. The Audit Data Export window opens.

Audit Data Exp	ort	2
Source:	Selected Records	
	All documents in the current grid	
Metadata: *	Category, Investigative Site Name, Counti	
	Save metadata selection	
	Save selection for everyone	

Follow the on-screen instructions to generate the audit report.

All Audits

Select All Audits from the dropdown menu. The Audit Data Export window opens.

Audit Data Export		
Audit's Source:	All AuditsSelected Audits	
Audits:*	Document Audit	~
Auditor's Source:	 All Auditors Selected Auditors 	
Auditors: *		*
Status: *	In Progress, Passed, Failed, Issues Resolve	*
Metadata: *	Contact Name, Country, Date of Visit, De	*
	 Save metadata selection Save selection for everyone 	

Follow the on-screen instructions to generate the audit report.

Performing Audit Response



To perform an audit response, you must be logged in the room as an Audit Responder.

- 1. Navigate to the eTMF/Documents module or the Quality Review/ Audit module.
- 2. If you are in the eTMF Documents module, select **Documents** from the menu icons at the top of the screen.

w Documents I	Ву			
eTMF	8 My List	Workflow	Documents	Other
Index	Submission	Status	Missing Documents	Security
Document Type	Reviews	Reviewer	Placeholders	Group
Site	Audit Findings	Workflow	Collected Documents	Posted Date
Country		Sender	eSignature	Deleted Docs
Tag		Recipient		Processed Doc
		Make Defaul	t	
		Cancel Se	lect	

3. From either of the modules, select Audit Findings view.

The active audits to which you are assigned that have audits with findings populate the Index panel.

- 4. Click the folder for one of the audits. The documents with audit findings populate the document grid. Documents in the list that are available for Audit Response show a padlock icon that is unlocked.
- 5. Select the document by clicking the checkbox.
- 6. Open the metadata panel for the document by clicking the Metadata button at the bottom of the document grid.
- 7. At the bottom of the Metadata panel, click the Audit button.

	Training Room 1 + Quality Review / Quality Review					Q Sea	rch 🛛 Add 🔹 🌲 🌔	Admin 106 *
8	Document 👻 🖾 Email 🛛 🔸 Export	 Assign To 				🕅 Add to C	art 🛛 🗮 Documents Cart 0 🔹	🗗 Layout 🔻
	Quality Review 103 Test Audit Document Status	1 - 1 of 1 (1 selected)	0 1	' Filters 🔲 Sel	lect Columns	🅫 Default View 🔻	🖋 Expand	🌣 More 🔻
	Auditor Admin 103		Generated Name	Index	Document St	Current Work	Metadata Audit Queries V	ersions
¢\$		☑ ☑ / / / ▲ ▲	101_Hamilton_Form FDA1572_2	05 Site Man	Final	<u>^</u>	Contains PHI? @	^72_20170628
7	A +Al 4 A Undained 1 A Editor 103 3		<			*	Grading/Finding Critical Major Minor Responsible Party Elsa Excluded from Audit Yes No Send Issue Audit History This re	Initiate Query
6		Grid View	Document View		H • Previous	1 of 1 Next ▶ ▶	Previous Document	Next Document 🕨



- 8. From the available options, click Claim document for Audit Correction.
- 9. Click **Document** at the bottom of the document grid to open the contents of the document for inspection.
- 10. From the Audit History panel, click View Full History button to view the comments included by the Auditor.
- 11. Appropriate actions on the part of an Audit Responder are based on the nature of the failure of the audit.
- 12. If the cause of the document's audit failure can be remedied by the Audit Responder, that action can be carried out.
- 13. In such cases, the Audit Responder then goes to the Audit button at the bottom of the metadata panel again and selects

Mark document as corrected.

14. If the cause of the document's audit failure cannot be remedied by the Audit Responder, the Audit Responder clicks

Email from the top ribbon bar or Initiate Query from the bottom of the Metadata panel.



- 15. The Email popup window opens. Click Yes to the question Are you sending a query?
- 16. Click To and select the appropriate party or parties from the room's users to notify about the discrepancy discovered in the audit.

Email	A WARN KROPW	×
Recipient(s)*	Add Cc.	- 1
Subject*	Training Room 1 - Form FDA1572 - FDA-1572_LMcNeil	2
R Add Attachment	t	
Open Sans	▼ 12 ▼ 6 BIUS % E E = E = E = E	
Auditor's comm	nents:	
New version re-	quired	
Thank You.		
) Files as Links	Files as Attachments 💿 None	y

- 17. Include something in the Subject line and enter the text of message to alert the recipients as to what action they need to take.
- 18. Select Files as Links at the bottom of the Email window to send the document along with the email message. Documents can also be sent as attachments.

Click Send.

The selected users will receive the email message regarding the Query raised.



19. Click **Audit** sub-module from the left menu bar. The queries raised during audit can be viewed from the **Query By Sender** current viewing the left index pane if you have sent queries to be resolved during audit. Refer to the



screenshot below:

Resolving Queries Raised during Audit

The user who receives the email responds back with an attachment to resolve the query. You can view the responded query in the **Responded** folder of **Query By Recipient** view under the selected audit. Refer to the screenshot below:

techwritersaudit	11	Do	cument *	E-Mail	Export *	📜 Documents Cart 💌	Document Data: ACM_userguide_en-US (2)
Query By Recipient				Que Que	ry Da Title	Query	Query [1340-188] (In Progress)
Polly Chakraborty [2] Anruta Maddel [7] Pencing [2] Rescolved [1] Rescolved [1] Rescolved [4]				134 30 M	Ary 2 ACM_userguide_en-US .	Please find the new attachment to resolve the query.	Response from Annula Maddel / 30 May 2018 18:51:57 Body: Please find the new attachment to resolve the query. Subject: To: pchakraborty@transperfect.com Attachments: Dim English links.door Reminders Sent: more Query from Polly Chakraborty / 30 May 2018 13:31:28 Metadata
		H.	Page	1 of 1	D H O	Displaying documents 1 - 1 of 1	Query [1340-170] (Pending) 4
		G	d Do	cument	Metadata 🛛 🖬 Layout 💌	Sa 🔟	Return back to Pending

To resolve queries raised during audit:

- 1. Navigate to the Query By Recipient view.
- 2. Select a query from the grid on the right.


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- 3. Click the Metadata button from the bottom of the grid. This will open the Document Data Panel.
- 4. Click the **Resolve** button from the bottom of the **Document Data Panel**. If the resolution is not acceptable, you can click the **Return to Pending**button from the bottom of the metadata panel. The document returns back to the **Pending** folder and can be resent for query again.
- 5. This will open the Query window to comment and resolve the query.
- 6. Enter the **comments** and click the **Resolve** button or **Resolve** and **replace attachment** button on the window as per your selection. Refer to the

Query [1340-188]	×
Please choose query resolution	Step 1 of 2: Query Resolution
 Resolve and replace using selected attachment ("English links.docx") 	Click to compare file with existing document
Comment: *	
	Resolve and replace attachment Cancel

screenshot below:

- a. Resolve: This option will just mark the query as resolved without any additional actions.
- **b.** Resolve and replace using selected attachment: This option allows you to replace the existing attachment with the one which is received as a part of the query response. Select the document from the right pane and click the **Compare** icon to compare the attachment received with the document in audit.

If you are satisfied with the response received, enter your comments and click Resolve and replace attachment button.

- 7. This will resolve the query and the query will now move automatically to the **Resolved** folder under the name of the auditor.
- 8. Click the **Resolved** folder from the **Index Pane** to view the resolved query. Refer to the screenshot below:

T R I A INTERACTIVE

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techwritenaudit			Dec	ument		+ Exp	w from		E Documents Cart 💌	Document Data: adobe2
Query By Recipient	(F) (B)	-				Quer	Query Date	Title	Query	Query [1340-187] (Resolved)
Polly Chakraborty [2] Amruta Maddel [7] Ponter [2]		-	8		*	1340	30 Apr 2018	french_e7cac3d85c094888	PLEASE DO NOT CHANGE THE EMAIL SUBJECT Auditor's comments For query techwritersaudit Tiger Woods twoodsigleimo.com french = 7ccs 2485c0P4888a/bb545838aabd/db Thank You	Query Resolved by Amruta Maddel / 30 May 2018 14:13:26 Commenta:
Resolved [4]		-		8	ŧ	1340	30 Apr 2018	adobe1	PLEASE DO NOT CHANGE THE EMAIL SUBJECT Auditor's comments sent for query techwritersaudit Tiger Woods twoodsliddemic.com adobet Thank You.	Replacing with English Links.doc
		0	8	5	R.	1340	04 May 2018	- 65	PLEASE DO NOT CHANGE THE EMAIL SUBJECT Auditor's comments: techwritersaude Tiger Woods amaddeligtransperfect.com ss Thank You,	14:13:26 File Name:
		120				1340	30 May 2018	adobe2	PLEASE DO NOT CHANGE THE EMAIL SUBJECTAuditor's comments send for query due to error in entry newwritteriudil? Polly Chaisaborty pchakraborty@transperfect.com adobe? Thank You.	English links.docs
										PLEASE DO NOT CHANGE THE EMAIL SUBJECT
										Thank You.

9. You can click the Query History icon at the bottom of the Document Data Pane for a query to view the Query History in a window that pops up.

~	Corr	pare											🏋 Do	cuments cart 🛩	
	20 do	cuments (1 s	elected)								1	Claim		🏟 More 🗸	
	Document Title Document Disable au E						Reason fo	Comments	Document 18 Apr 2018		Queries Versio Workflow ge 1 rkflow: Approval :	ns History eSig			
	Activ Query New [ity from Polly Chakra locument Created	borty By Polly Chakrabo	ty		Description PLEASE DO	D NOT CHANGE T	HE EMAIL SUBJEC	т	A B		Clarification Reviewer Comments Reviewer Name Polly (Chakraborty		
	Query resolved by Polly Chakraborty						 The following issues were found in the document, please attach a revised document in your reply to this email: TechWritersWorkflow: Approval stage 1 Clarification Site name TechWritersDemoRoom					Thank You. Subject TechWritersDemoRoom arabic_c2db99da14ad4bd5bf To pchakraborty@transperfect RemindersSent 9 May 2018 9 May 2018 9 May 2018			
						Close					_ ·	New Document Cro Polly Chakraborty	eated By 1 Jun	E 2018, 6:24 PM	
	 ★ ▲ ▲ ▲ 	2081892 2194384 2241062	TEST Reference TESTnew	audit 1_10	True True True	Amruta M Amruta M Tiger Woo			08 May 20 26 Sep 2018 10 Dec 2018	1	Gŧ	Query resolved by Chakraborty	Polly 1 Jun	2018, 6:24 PM	
4											. [Query History			

Note: To know how to view a deleted queried document, proceed to section Deleted Queried Documents.



Chapter 13. Sites, Required Documents, Countries and Contacts

In this section, we discuss the Sites, Required Documents that are required for site activation, Country Documents, and Contacts.

Sites

You can access the Sites module by clicking Sites icon on the left menu bar in the eTMF/Documents module. The Sites module is used for site management purposes and allows the administrator to track the progress of the sites. It gives detailed information on all investigation sites available in a room **By Status**, **By CRA**, **By Country**.

You can perform various other activities associated with a site, such as:

- 1. Retrieving Site Details
- 2. Adding, Editing, and Deleting sites
- 3. Importing, and Exporting Sites
- 4. Mass Coding metadata for sites
- 5. Managing Security.

Each of the above is discussed in the separate topics and can be accessed from the left

pane of this help.

Site Views

This section discusses about the various views of the Sites module.

By Status



Select By Status from the dropdown in the Index Pane of Sites Dashboard. Refer to the

screenshot below:



This will populate the data of all the sites available in the room based on their progress report in the right pane of the dashboard.

By CRA

Select By CRA from the dropdown in the Index Pane of Sites Dashboard. Refer to the





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screenshot below:

This will populate the Clinical Research Associate (CRA) for the available sites in the Index Pane on the left. Click the name of a CRA to populate the site details associated with that particular CRA in the right pane.

By Country

Select **By Country** from the dropdown in the Index Pane of Sites Dashboard. This will populate the countries where the studies are being conducted in the Index Pane on the left. Click the name of a country to

æ	🖸 Add 🛛 🗶 Delete 🔶 Import 🔶									
	View by By Status									
	Ø X									
∡	By Status									
-	By CRA									
Ŧ	By Country ✓ My CRA/Start-Up Specialist Sites ✓ My Favorite Sites									
	Make default Make default for all rooms Cancel									

populate the site details associated with that particular country in the right pane. Refer to the screenshot below.

Make a view default

To make any site view default and default for all rooms check one of the two options available in the index dropdown. Refer to the screenshot below.





Site Profile

Select a site from the grid and the Site Profile is displayed at the

ш	 Training Room 1 + eTMF / Sites 												Q Search	O Add - 4	Arya S	tark *
-	O Add x Delete ↑ Import	*	Export	🛢 Mas	ss Coding	a _e Manage Security *							B Er		17.00 B	Layout +
-	View by By Status	•	1 - 10	of 10 (1	selected)								C	Select Colum	ins 👁 Defaul	t View *
		0			Site N	Principal Investigator	Institution Name	Status	PI First Na	PI Last Name	CRA	IRB/EC Name	Main Contact	Reg. Pack S	Progress %	^
д	The All		₫ \$	*	530	Cold Hydration	Aquafina	Active	Cold	Hydration	Reader 103	279862	Cold Hydratio		100	
	Active 10	-		*	111	Stephanie Svoboda	Disney	Active	Stephanie	Svoboda		279864	Daffy Duck		100	_
8	Pending 11		0	*	1011	Minnie Mouse	Disney Express Medical	Active	Minnie	Mouse	Reader 102; R	279862	Minnie Mouse		100	
			<													,
Ŷ			_												Presidus I C	FI NEXT P
			🖍 Expe	and												
			Gener	al Info	Contacts									Site Specific Requ	irements Ins	titutions
			_		Start-Up Spe	cialist	3				🝽 View Milestone:	History	di.			
					Site Mr	mbor 530										l
					2100141	330										
			r i			Site 530 Hydration										
						Disable auto	Site name									l
			Reas	son for n	ot using auto S	ite na me *										
																l
					IRB/EC N	ame * Royal Brompto	n Hospital			-						I
			Addres	55						•						
			Securit	ty						•						
			More							•						
~			Canc	el.											Save Sav	e & Next
6															Previous Site	Vext Site 🕨

bottom of the grid. This will allow you to fill all the metadata related to the selected sites. Refer to the screenshot below:

The Site Profile window provides the following:

- 1. General Info tab
- 2. Contacts tab
- 3. Specific Requirements tab
- 4. Institutions



Each of the tabs is discussed in the separate topics.

Site Profile - General Info

This tab displays the general information of the site.

After selecting a site, click the General Info tab to edit the general details of the site. Click the arrow next to the required section of the General Info to update. Refer to the screenshot below:

General Info Contacts		Site Specific Requirements Institutions
Info		Edit History
Institution Name *	Anusting	Profile created by Editor 103 on 10 January 2020 13:28:09 EDT Last updated by Admin 103 on 10 January 2020 13:48:43 EDT
inscitution warne	Adomina	View Edit History
CRA	A Reader 103 ×	View Contacts History
Start-Up Specialist	Editor 103 ×	View Milestones History
Site Number	530	
Site	530 Hydration	
	Disable auto Site name	
Reason for not using auto Site name *		
IRB/EC Name *	Royal Brompton Hospital 👻	
Address	•	
Security	•	
More	-	
Cancel		Save Save & Next

When you click the arrow, the section fields get enabled and the arrow turns to - sign as shown in the screenshot below. Similarly, you can update the fields in the other sections of your choice.

Site Profile - Contacts

This section displays the list of contacts that are added to a site. From here, you can add, edit, delete, deactivate contacts and also change the contact to another level. Refer to the screenshot below:

1 - 10 of 10 (1 selected)								C 🗆 Selec	t Columns	Default View •		
	Site	Principal Investi	Institution Name	Sta	PI First	PI Last	CRA	IRB/EC Name	Main Con	Reg. Pa	Progress %	^	
2 🌣 🔺	530	Cold Hydration	Aquafina	Acti	Cold	Hydrati	Reader 103	279862	Cold Hydr		100		
• *	111	Stephanie Svob	Disney	Acti	Stepha	Svoboda		279864	Daffy Duck		100		
• *	1011	Minnie Mouse	Disney Express	Acti	Minnie	Mouse	Reader 10	279862	Minnie M		100		
•	107	Break Glass	Disney World Ca	Acti	Break	Glass	Michael S	279864	Break Gla		100	•	
												>	
Previous 1 of1 Next													
Expand													
General Info	Contact	s							Site Speci	fic Requirem	ents Instituti	ons	
🗢 Add 🧳	Edit 🛈	Delete 斗 Deact	ivate 🔒 Convert t	o User									
Las	t Name		First Name	2			Email		Contact Ty	Contact Type			
a 103	3		Reader				TIReader103	3@ti.com	Sponsor C	Sponsor Contact			
a 103	3		Editor	Editor				@ti.com	Site Activation Specialist			•	
🍰 Hy	dration		Cold	Cold			DrHydration	n@aquafinahospital.org	Principal Investigator 💌				



Double click the user to open the **Contact Profile** to the right of the contacts tab. This allows you to edit the contact details of the user. Once all the details are updated, click **Save** to save the changes. Refer to the screenshot below:

Ceneral	d Info <u>Contacts</u>	🌬 Deactivate 🛔 Convert	to User			Site Specific Requirements Institutions
	Last Name	First Name	Email	Contact Type	C	ontact Profile
M 🔺	103	Reader	TIReader103@ti.com	Sponsor Contact 🔹	^	Fmail
	103	Editor	ti_editor103@ti.com	Site Activation Specia 💌		TIReader103@ti.com
.	Hydration	Cold	DrHydration@aquafinah	Principal Investigator 🔻		Prefix
.	Star	Water	Drwaterstar@aquafinah	Sub-Investigator 🔹		
						First Name
						Reader
Cancel					~	Save Save & Next
					-	

Adding a Contact

- 1. Click Add from the menu bar of the Contacts tab.
- 2. The Add Contact window opens.



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3. Fill in the required details and click Finish. Refer to the screenshot below

Crea	te New Add Existing
	-mail *
	nedstark@ti.com
	Prefix
	First Name *
	Ned
1	Last Name *
	Stark
	Suffix
	2han - Number
1	none number
	Nobile Number
(Contact Type *
[Co-Investigator 🔻
	Same as investigative site address

Editing a Contact

Select an added contact and click Edit in the Contacts tab to edit the contact information entered as above. Refer to the screenshot below.



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it Contact		
Email *		
TIReader103@ti.co	m	
Prefix		
First Name *		
Reader		
Last Name *		
103		
Suffix		
Phone Number		
Mobile Number		
Contact Type *		
		-
Same as investig	ative site address	
Address		
		-
	Cancel Edit	

Deleting a Contact

Select an added contact and click **Delete** in the Contacts tab to delete a contact information.

Deactivating a Contact

Select an added contact and click **Deactivate** in the Contacts tab to deactivate the contact.

Convert to User(s)

You can assign a site contact the role of editor or reader and assign actions as appropriate

from the Convert to User(s)

utility in the Contacts tab.

Site Profile - Site Specific Requirements

This section displays the list of all the Site Specific Required documents. From here, you can Add required documents to a site, delete the documents, Assign Milestones to the documents, and view the Change Log History of the selected documents.



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Adding Required Documents

To add required documents to a site click the add button that opens Add Required Document Types popup. Fill up all the required information and click Save button to add required documents to a site. Refer to the screenshot below:

	Add Required Document Types	×
	Documents to be submitted by selected investigative site Required For	l
	To be submitted by	
	Select All Subfolder Contents	
	Search Q	
ts	↓ Investigative Site 12	
	👻 💊 01 Trial Management 2	
ur	👻 💊 Trial Oversight 4	
DC	👻 💊 Recruitment Plan 1	1
	– 🗹 🌭 Recruitment Plan	
	Debarment Statement 2	
	🕨 📎 Audit Certificate 1	
	Cancel Save	



Deleting a site-specific requirement

Delete a site-specific requirement that can be performed with the Pending and Non Participating sites only. To delete a site- specific

↓ E	Export S Mass Coding & Manage Security											Q Enter keywords or phrase			
	1 - 11 o	of 11 (1 se	elected)								C 🛛 Selec	t Columns	Default View •		
		Site Principal Investi I		Institution Name	Institution Name Sta F		PI Last	CRA	IRB/EC Name	Main Con	Reg. Pa	Progress %			
	M 🔹	*	101	David Hamilton	Alexander Park	Pe	David	Hamilton	Reader 10	279866		10 Feb	56		
		*	205	Poorva Kumar	Boston Medical	Pe	Poorva	Kumar		279866	Poorva K	10 Jul 2	83		
		*	251	John A. Sample	Central Park Car	Pe	John A.	Sample		279861	Poorva K	01 May	0		
		*	201	Momenta Pl	Central Park Car	Pe	Momen	PI		279866		10 Jul 2	38		
	<														
								_				Previo	ous 1 of 1 Next		
	🖋 Expa	ind													
	Genera	il Info	Contacts	5							Site Specif	ic Requireme	ents Institutions		
1	O Add	û De	lete	🛤 Assign Milestone	🗖 Change Log										
		Document Type Category			L	anguages		Contact	0	Required F	or				
		01 Trial Management Investigative Site				0	(Not Set) Clinical Research Progra			Manager					
	O2 Central Trial Documents Investigative Site (I					(Not Set) Clinical Research Progra			Manager						

requirement, tick the checkbox to activate the **Delete** button. Refer to the screenshot below.

Note: Site-specific requirements in the Active Sites can not be deleted.

Adding, Editing and Deleting Sites

Important: The following description is for adding Investigative Sites in an eTMF:

- Sites are added to the Study Start Up module by a slightly different method. If SSU has been enabled for the study, the user first clicks the Study Start Up icon at the top, then selects the Sites tab. The rest of the process of adding Investigative Sites is the same as the process described below.
- Sites added from the eTMF/Sites module also appear in the Study Start-Up, if that is enabled for you.



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Adding a Site

1. Click the Add button from the top ribbon bar. The New Investigative Site window opens. Refer to the screenshot below:

eneral Info Contacts	
Info	
Institution Name *	
CRA	
Start-Up Specialist	
Site Number	
Site	
	Disable auto Site name
Reason for not using a uto Site name *	
IRB/EC Name *	-
	This field is require
Address	

- 2. Either type the Institution Name in the available field or click the search icon to view the list of Available Investigative Sites. Investigative site information is stored in Trial Interactive's database. If a client has used an investigative site in a previous study, the site's information will be stored and easily accessed through this option.
- 3. Create or Add existing contacts from the Contacts panel in the window. This information will be supplied by the client and can be created under Contact Types in Investigative Site Settings. You can also add the Contact Type by clicking the contact type field which will then reveal the dropdown list to select your choice. Refer to the screenshot below:



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To make the Sponsor Contact ID a Required field proceed to **Settings -> Form Settings -> Investigative Site Profile**. Select the **Sponsor Site ID Field title** from the list **of System Fields** and tick the checkboxes under the **Coding** and **Required** column.

Note: The Sponsor Contact ID is used by the system as the unique identifier of sites used by third parties to enable their integration with Trial Interactive. Hence, the Sponsor Contact ID will need to be a Required field so that it can be passed to Trial Interactive. Similarly, to detect duplicate entries of site contacts, the email-id field is now case-insensitive.

- 4. Select an added contact and click Edit in the Contacts panel to edit the contact information entered above, or Delete to delete a contact information. You can also edit a contact by double-clicking the contact in the Contacts panel.
- 5. Click Activate or Deactivate to activate or deactivate a contact. This will either check or uncheck the Active Contact



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New Inve	stigative Sit	e			
General In	fo Contact	s			
• Add	🖋 Edit Last Name	🛍 Delete First Nam	X Deactivate	Convert to U	ser Cor
	Marvel	Dana	04a1d591		Er
					Pr
					Fi
					SL
					PI
					M
				~	C
			Cancel	Add	

- 6. You can assign a site contact the role of editor or reader and assign actions as appropriate from the Convert to User(s) utility (page 386) in the Contacts panel.
- 7. Click Address to reveal the fields to enter the site location details. Based on the address entered the system shall calculate the Geo Code of the site and populate it in the new field Geo Code.

Click **More** to open another array of data fields. Enter the investigative site information provided by the client. Refer to the screenshot below:

Note: The Geo Code needs to be enabled from the Settings Form Settings Investigative Site Profile

Geo Code. This is an important field for myTI mobile app to deteet site location $\; o\;$

 \rightarrow

- 8. Click Create at the bottom of the window.
- 9. Repeat this process until all investigative sites have been created for the room.



Editing a Site

Similarly, you can **Edit** a site by first selecting the site from the right pane and then clicking the **Edit** button from the top ribbon bar. You can also edit a site from the **Site Profile** window also. This is discussed under the **Site Profile**.

Deleting a Site

Select a site first and then click the Delete button from the top ribbon bar to delete a site.

Importing Sites

The metadata and contact information for an investigative site can be imported by using the **Import** icon located on the top ribbon bar. It runs the metadata import wizard where the user can upload a .xlsx spreadsheet, set up columns and metadata fields mapping, perform actual import, and observe the result.

1. Upload the .xlsx file containing data of sites and contacts by clicking the search icon. It is also possible to import just contacts so they will be mapped to existing investigative sites. The wizard offers a link to the sample worksheet so the user can download it and fill it with actual data. Click **Next.** Refer to the screenshot below:

Investigative Sites Impor	t	Step 1	• • • • • • •	×
Upload File				
This wizard supports the in The Excel spreadsheet sho	nport of multiple Sites at uld contain two separate	once using metada worksheets:	ta.	
Worksheet one shou Worksheet two shou	ıld contain the list of instit ıld contain the list of cont	tution names and a acts including the P	ddresses rincipal Investigator	
Metadata File (format: .xlsx)*:	C:\fakepath\SitesImport	Template.xlsx	Select	
See the sample worksheet ten	<u>nplate</u>			
	Cancel Previous	Next		

- 2. Setup the mapping between metadata fields and uploaded file columns for Investigative Sites. It is possible to skip sheet selection in case you do not want to import investigative sites but only contacts. You can also specify the date format that should be used during import. Click **Next**.
- 3. Setup the Contacts related metadata. Click Next.
- 4. Observe the settings that were done during previous steps and probably return back and correct something. Click **Next** to confirm.



- 5. This will begin the actual import process. Upon completion, the user will get a short report on the issues that were occurred during import.
- 6. It is also possible to download the full report as a text file. The import operation can be aborted at any time.

Manage Security for Sites

There are two site-level securities available for sites:

- 1. Editor
- 2. Reader

Administrators can use Manage Security to include users to any one of these groups:

- 1. Select the sites from the grid and click Manage Security dropdown from the top ribbon bar.
- 2. Select the type of users to add to the security groups. You can add either Editors or Readers. Refer to the screenshot below:



- 3. This will open either the Security Editors or Security Readers window as per your choice.
- Select the users in the Users tab to add to the security group, or/and click the Groups tab to select a group of users to be added to the security group. Click OK. An example of adding editors is shown below. The readers too would be

	Security - Editors		×
	Groups Users	Selected members	
oat 1	All Search	Auditor	^
	Name		
	Auditor	✓ ^	,
	Auditors		
	Cats		
	CRA - EU		
	CRA Recon- Tool		
	CRAs - US		
	CRO - Asia		
	Doc Editors	v	V
		Cancel	

added in a similar manner.

Mass Coding for Sites

Administrators are sometimes called upon to fill in or update the metadata of a number of sites in a room at once. When the metadata changes are consistent across a group of sites, the **Mass Coding** option saves a lot of time and keystrokes.

1. Select the sites to be coded in your grid.



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- 2. Click the Mass Coding tool from the top ribbon bar. The Mass Coding window opens.
- 3. Fill in the details by double-clicking the fields, and click **Save** to proceed with mass update of the sites' metadata. You can select multiple CRAs and Start-Up Specialists if required. Refer to the screenshot below.



Exporting Sites

You can also export site metadata through the Export window that appears on clicking the Export icon on the ribbon. You may export sites selected from the right panel, or all the sites in the current grid or room. To export site data, it is mandatory to select the **Site Metadata Fields** as shown below:

You can export the additional fields in either alphabetical or logical order of selection.



Similarly, to export site contact data, you need to select **Contact Metadata** fields as shown below:

Export Sites		Step 2	• • x
Document Metadata Fields Select fields you want to export			
Site Number × Address × City × Coun Active Contact × Contact Type × User N Mobile Number × Phone Number ×	ntry ×)[Geo Code ×)[Phone ×)[Site ×)[Stat lame ×][First Name ×)[Last Name ×)[Addre	e ×)[Zip Code ×)[Investigative Site Name ×)[SiteNumber ss ×)[City ×][State ×)[Country ×)[ZipCode ×]	r×
23 Fields 23 Selected			
Select All		Sort by From A to Z	-
Address	Geo Code	Site Number	
City	Phone Phone	State	
Country	Site	☑ Zip Code	
Additional Fields			
eFeasibility Status	🗌 PI Last Name	Projected Site Activation Date	
E Fax	Principal Investigator	Site Email Domains	~
		Scroll to Addition	al Fields
		Scroll to Contact Metada	ta Fields
		Scroll to Contact Addition	al Fields
	Previous		
pr Export Sites		Step 2	• • *
Export Sites		Step 2 -	• • ×
Export Sites Document Metadata Fields Select fields you want to export		Step 2	• • ×
Export Sites Document Metadata Fields Select fields you want to export Site Number × Address × City × Cou	intry ×] Geo Code ×] (Phone ×] (Site ×] (Stat	Step 2 - Step 2 - E ×] [Zip Code ×] [Investigative Site Name ×] [SiteNumber	• • ×
Export Sites Document Metadata Fields Select fields you want to export Site Number × Address × City × Court Active Contact × Contact Type × User Active Vectors Option Site Number × Contact Type × Cuser	intry X][Geo Code X][Phone X][Site X][Stat Name X][First Name X][Last Name X][Addro	Step 2 e ×) Zip Code ×) Investigative Site Name ×) SiteNumber rss ×) City ×) State ×) Country ×) ZipCode ×)	• • ×
Export Sites Document Metadata Fields Select fields you want to export Site Number × Address × City × Cou Active Contact × Contact Type × User Mobile Number × Phone Number ×	intry ×)[Geo Code ×)[Phone ×)[Site ×)[Stat Name ×)[First Name ×)[Last Name ×)[Addre	Step 2 <u>e ×)[Zip Code ×][Investigative Site Name ×][SiteNumber</u> <u>rss ×][City ×][State ×][Country ×][ZipCode ×]</u>	×
Frequencies Document Metadata Fields Select fields you want to export Site Number ×] (Address ×) (City ×) (Cou (Active Contact ×) (Contact Type ×) (User [Mobile Number ×] 23 Fields 23 Selected	intry ×)[Geo Code ×][Phone ×][Site ×][Stat Name ×][First Name ×][Last Name ×][Addre	Step 2 e ×)[Zip Code ×][Investigative Site Name ×][SiteNumber rss ×][City ×][State ×][Country ×][ZipCode ×]	×
Br Export Sites Document Metadata Fields Select fields you want to export Site Number × Address × City × Cou Active Contact × Contact Type × User Mobile Number × Phone Number × 23 Fields 23 Selected Select All	intry ×][Geo Code ×][Phone ×][Site ×][Stat Name ×][First Name ×][Last Name ×][Addre	Step 2 - e ×) [Zip Code ×] [Investigative Site Name ×] [SiteNumber rss ×] [City ×] [State ×] [Country ×] [ZipCode ×] Sort by From A to Z	
Frequencies Document Metadata Fields Select fields you want to export Site Number × Address × City × Cou Active Contact × Contact Type × User Mobile Number × Phone Number × 23 Fields 23 Selected Select All Contact Metadata Fields	intry ×][Geo Code ×][Phone ×][Site ×][Stat Name ×][First Name ×][Last Name ×][Addre	Step 2 e ×) Zip Code ×) Investigative Site Name ×) SiteNumber rss ×) City ×) State ×) Country ×) ZipCode ×) Sort by From A to Z	
Frequencies Document Metadata Fields Select fields you want to export Site Number × Address × City × Cout Active Contact × Contact Type × User Mobile Number × Phone Number × 23 Fields 23 Selected Select All Contact Metadata Fields ✓ Active Contact	intry ×) Geo Code ×) Phone ×) Site ×) Stat Name ×) First Name ×) Last Name ×) Addro Ø First Name	Step 2 - e × Zip Code × Investigative Site Name × SiteNumber sss × City × State × Country × ZipCode × Sort by From A to Z SiteNumber	
Frequencies Document Metadata Fields Select fields you want to export Site Number × Address × City × Cout Active Contact × Contact Type × User Mobile Number × Phone Number × 23 Fields 23 Selected Select All Contact Metadata Fields ✓ Active Contact ✓ Active Contact ✓ Address	intry ×) Geo Code ×) Phone ×) Site ×) Stat Name ×) First Name ×) Last Name ×) Addro Ø First Name Ø Investigative Site Name	Step 2 - e ×) Zip Code ×) Investigative Site Name ×) SiteNumber rss ×) City ×) State ×) Country ×) ZipCode ×) Sort by From A to Z Sort by SiteNumber SiteNumber State	
Frequencies Document Metadata Fields Select fields you want to export Site Number × Address × City × Cout Active Contact × Contact Type × User Mobile Number × Phone Number × 23 Fields 23 Fields Select All Contact Metadata Fields Active Contact Active Contact Address ✓ City	untry ×) Geo Code ×) (Phone ×) Site ×) (Stat Name ×) (First Name ×) (Last Name ×) (Addro Addro First Name ⊮ Investigative Site Name Investigative Site Name	Step 2 - e × Zip Code × Investigative Site Name × SiteNumber rss × City × State × Country × ZipCode × Sort by From A to Z Sort by From A to Z SiteNumber SiteNumber State User Name	
Fragment Sites Document Metadata Fields Select fields you want to export Site Number × Address × City × Cout Active Contact × Contact Type × User Mobile Number × Phone Number × 23 Fields 23 Selected Select All Contact Metadata Fields ✓ Active Contact ✓ Address ✓ City ✓ Contact Type	untry ×) Geo Code ×) (Phone ×) (Site ×) (Stat Name ×) (First Name ×) (Last Name ×) (Addre ♥ First Name ♥ Investigative Site Name ♥ Last Name ♥ Mobile Number	Step 2 - e × Zip Code × Investigative Site Name × SiteNumber rss × City × State × Country × ZipCode × Sort by From A to Z SiteNumber SiteNumber SiteNumber SiteNumber SiteNumber SiteNumber SiteNumber SiteNumber SiteNumber SiteNumber SiteNumber SiteNumber SiteNumber SiteNumber SiteNumber	
Finite State Document Metadata Fields Select fields you want to export Site Number × Address × City × Cou Active Contact × Contact Type × User Mobile Number × Phone Number × 23 Fields 23 Fields Select All Contact Metadata Fields ✓ Active Contact ✓ Address ✓ City ✓ Contact Type ✓ Contact Type ✓ Contact Type ✓ Country	untry ×) Geo Code ×) (Phone ×) Site ×) Stat Name ×) (First Name ×) (Last Name ×) (Addro ♥ First Name ♥ Investigative Site Name ♥ Last Name ♥ Mobile Number ♥ Phone Number	step 2 - e × Zip Code × Investigative Site Name × SiteNumber rss × City × State × Country × ZipCode × Sort by From A to Z SiteNumber SiteNumber SiteNumber SiteNumber SiteNumber ZipCode	× in
Frequencies Document Metadata Fields Select fields you want to export Site Number × Address × City × Cou Active Contact × Contact Type × User Mobile Number × Phone Number × 23 Fields 23 Fields Select All Contact Metadata Fields ✓ Active Contact ✓ Address ✓ City ✓ Contact Type ✓ Contact Type ✓ Country	Intry ×) Geo Code ×) (Phone ×) Site ×) Stat Name ×) (First Name ×) (Last Name ×) (Addre ♥ First Name ♥ Investigative Site Name ♥ Last Name ♥ Mobile Number ♥ Phone Number	Step 2 • • × Zip Code × Investigative Site Name × SiteNumber sss × City × State × Country × ZipCode × Sort by From A to Z SiteNumber SiteNumber SiteNumber SiteNumber ZipCode	
Finite State Document Metadata Fields Select fields you want to export Site Number × Address × City × Cou Active Contact × Contact Type × User Mobile Number × Phone Number × 23 Fields 23 Fields 23 Fields 23 Fields 23 Fields 23 Fields Contact Metadata Fields Image: Address Image: City Image: Contact Type	Intry ×) Geo Code ×) (Phone ×) Site ×) Stat Name ×) (First Name ×) (Last Name ×) (Addre Site of the second	step 2 - e × Zip Code × Investigative Site Name × SiteNumber ss × City × State × Country × ZipCode × Sort by From A to Z SiteNumber SiteNumber SiteNumber SiteNumber ZipCode Scroll to Additional Scroll to Additional Scroll to Additional	× n n n n n n n n n n n n n n n n n n n
Finite State Document Metadata Fields Select fields you want to export Site Number × Address × City × Court Active Contact × Contact Type × User Mobile Number × Phone Number × 23 Fields 23 Fields 23 Fields 23 Fields 23 Fields 23 Fields Contact Metadata Fields Image: Address Image: City Image: Contact Type Image: Contact Type Image: Contact Type Image: Contact Fields	intry ×) Geo Code ×) (Phone ×) Site ×) (Stat Name ×) (First Name ×) (Last Name ×) (Addre ♥) First Name ♥) investigative Site Name ♥ Last Name ♥ Mobile Number ♥ Phone Number	step 2 • • × Zip Code × Investigative Site Name × SiteNumber sss × City × State × Country × ZipCode × Sort by From A to Z SiteNumber	 A list A list
Frequencies Document Metadata Fields Select fields you want to export Site Number × Address × City × Court Active Contact × Contact Type × User Mobile Number × Phone Number × 23 Fields 23 Fields Select All Contact Metadata Fields ✓ Active Contact ✓ Address ✓ City ✓ Contact Type ✓ Country	Intry ×) Geo Code ×) (Phone ×) Site ×) (Stat Name ×) (First Name ×) (Last Name ×) (Addre ♥) First Name ♥) Investigative Site Name ♥ Last Name ♥ Mobile Number ♥ Phone Number	step 2 - e × Zip Code × Investigative Site Name × SiteNumber sss × City × State × Country × ZipCode × Sort by From A to Z SiteNumber SiteNumber State User Name ZipCode Scroll to Additiona Scroll to Contact Metadate Scroll to Contact Additiona	× In the second
Provide the state of the s	Intry × Geo Code × Phone × Site × Stat Name × First Name × Last Name × Addre V First Name V Investigative Site Name Last Name Mobile Number V Phone Number	step 2 - e × Zip Code × Investigative Site Name × SiteNumber sss × City × State × Country × ZipCode × Sort by From A to Z SiteNumber	× In A State of the state of th

The export result is also populated in the Notifications. Click GetJob Result to view the excel file.



			Q Searc	h O Add	• " <mark>1</mark>	Arya Stark -
urit	٢	Exporting Investigative Sites Room: Training Room 1				×
		Finished Operation was successfully completed!				
		Get Job Result				27 Mar 17:13

Contacts

A clinical trial includes a varied range of people with different profiles, who

are a part of the study. Such people are a valuable source of information and are required at various stages of the study. Trial Interactive helps to maintain the detailed profile of such people as Contacts for a study. Some examples of contacts could be the Principal Investigator, Sponsor, Co-Investigator, regulatory authorities, authorities in the IRB.

You can access the Contacts module by clicking the Contacts icon on the menu bar at the left. The Contacts module

gives detailed information on all contacts available in a room By Site, By IRB/EC, By Country, and

By Contact Type. From this section you can do the following:

- 1. View Contacts
- 2. Mass Coding for Contacts
- 3. Convert to Users
- 4. Contact Data

Each of the above topics are discussed in seperate topics and can be accessed from the

left menu of this help.

View Contacts

This section gives you an overview of the different types of contacts:

By Site

Select **By Site** from the dropdown in the Index Pane on the left of the Contacts Module. This will reveal all the sites available in the room.

Click a site. This will populate the data of all the contacts available for the particular site in a room in the right pane of the dashboard.

By Country

Select By Country from the dropdown in the Index Pane of the Contacts Dashboard. This will list all the countries with the sites where the studies are being conducted in the Index Pane on the left. Clicking a country to expand the dropdown will reveal the sites under it. Click a site to populate the contact details associated with the site in the right pane.

By IRB/EC

Select By IRB/EC from the dropdown in the Index Pane of Contacts Dashboard. This will populate the IRBs associated with the sites in the Index Pane on the left. Clicking an IRB will expand the dropdown to reveal the sites associated with it.

Click a site to populate the contact details associated with the site in the right pane.

By Contact Type

Select By Contact Type from the dropdown in the Index Pane of Contacts Dashboard. This will populate the contact types associated in the room in the Index Pane on the left. Clicking a contact will list the contact details associated with a particular site in the right pane of the dashboard.

Mass Coding for Contacts

Administrators are sometimes called upon to fill in or update the metadata of a number of contacts in a room at once. When the metadata changes are consistent across a group of sites, the **Mass Coding** option saves a lot of time and keystrokes.

1. Click the Mass Coding *Mass Coding* tool from the top ribbon bar. The Contacts Mass Coding window opens. Refer to the screenshot below:

Contacts Mass Coding						
All Records in Set Sele	Clear 🔻					
Field	Value					
Main Contact						
Provide Documents						
	Save	Cancel				

- 2. You can choose to mass code for all the records in the grid, or a selected set of records.
- 3. Either way, double-click and select yes/no from the dropdown in the Value field for the required metadata to be mass coded.
- 4. Click Save.
- **5.** Confirm the message to proceed with mass coding. You will receive a confirmation about the job result which can also be retrieved from the Notifications.



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Contact Data

Selecting a contact in the grid will highlight the **Contact Data** window at the extreme right of the grid in the right pane. You can view the details of the contact here. Refer to the screenshot below.

Mass Coding L Convert to user(s)				Search			Contact Data	
	Name	Contact Type	Phone	Main Co	Provide		E-mail:	123@test.com
🖂 上	Anna Bravo	Clinical Researc		No	No		Prefix:	
	Dana Marvel	Backup Study C		No	No		First Name: *	Anna
- 1	jon snow	Principal Investi		No	No		Last Name: *	Bravo
							Suffix:	
							Phone number:	
							Mobile number:	
							Contact type: *	Clinical Research Program Manag
1							Address:	111 Eastman Drive
-							City:	Kansas City
							State:	MO
							ZipCode:	27555
							Country:	United States
							Clinical Trial	
							Experience:	
							Provide Documents:	
							Active Contact:	
						_	Main Contact:	

Note: Contacts can be added through the Sites Dashboard. They can also be added from the Documents Panel.

Countries

When a study includes investigative sites located in different countries, scountries need to be added to the room. In this way, country-specific folders will be set up in the room's folder structure to accept and store country-specific documents. To set up countries for investigative sites, navigate to:

- 1. The Trial Interactive room for which you want to set up countries.
- 2. Select the Settings option from Main Navigation.
- 3. Select **Countries** from the menu on the left. This option drops down to reveal the following options:
 - a. Countries
 - **b.** Template Folders
 - c. Common Settings

All of the above options are discussed in separate topics accessible from the left panel of

this help.



Chapter 14. e-Signature

This section discuss the various ways of e-Signature used to sign the documents.

Trial Interactive (TI) offers a feature to e-Sign your PDF, Word, PowerPoint, and Excel documents. This feature permits Administrator users to invite multiple signers to sign the required documents. The system facilitates the user with an option to designate a space within the document for the signers to sign. This feature also allows the user to decide the sequence in which the signers should sign the document.

e-Signature

The client can choose the required e-Signature vendor from Main Navigation \rightarrow Settings \rightarrow e-Signature \rightarrow Vendors.

Vendors

The e-Signature vendor available to you depends on the vendor chosen by your organization. This section discusses the following three e-Signature options:

- 1. DocuSign
- 2. Adobe Sign
- 3. TI e-Signature

Follow the steps below to select the e-Signature vendor:

- 1. Navigate to Main Navigation-> Settings-> E-Signature-> Vendors.
- 2. Click the Use E-Signature dropdown to select the vendor. Refer to the screenshot below:

About / E-Signature * E-Signature vendors *
Vendors
Use E-Signature: * TI E-Signature
🏲 Save 🛛 🖛 Undo 🗖 Change Log

Note: The e-Signature vendor available to you depends on the vendor chosen by your oraanization.

- An Administrator can choose to enable or disable the use of an e-signature for users in a room by selecting the None option from the dropdown.
- 4. Click Save if you make any changes here.



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Note: If the **E-signature** is enabled, the e-Signature Action is automatically added in the **Actions** pane as discussed in Edit User (page 72). To see the addition, refresh the room in the browser.

Reasons

While e-signing a document, the e-signers need to specify the reasons for approving or declining a document. Administrators can configure reasons for e-signature from here.

1. Navigate to Main Navigation-> Settings-> E-Signature-> Reasons. Refer to the screenshot below:

earch	Q 📧 🗈 About	Reasons ×	
◄ General Integration	↑ OAdd //E		
Documents	Reason		Description
Socument Types	Admin configu	es these choices	
Required Documents	I approve this	docultent	
Q Countries	I authored this	document	
A Investigative Sites	I have reviewe	d the changes in this revision	
IRB/EC			
🚥 Email		Create Reason Required fields are marked with an asterisk (*)	X
Document Templates		Person *	
👩 Audit		Description: *	
/ Workflows			Sava Cancel
R Security			Caller
/ E-Signature			
Vendors			
Reasons			
Purpose of the signature			

- 2. Click Add to create new reasons.
- 3. Select a reason from the list and click Edit to make changes in the existing reason.
- 4. Select a reason from the list and click **Delete** to delete the existing reason.

Purpose of the e-signature



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Purpose of the e-Signature is an additional text to display on the top of the send to e-signature form. Refer to the screenshot below:

Training Room 1 - Settings						_											¢
Search Q	۲	📄 At	oout	Purpo	se of the signature	🕒 Re	asons	×									
ズ General Integration	*	\diamond	Arial	-	12pt -	В	Ι	U	<u>A</u> -	<u>A</u> -	B	E	≣	∃	≣	Ξ	a a
Documents		Test	- eSigna	ature purp	oose												
Document Types																	
Required Documents	÷.																
Countries																	
Investigative Sites																	
IRB/EC																	
🕨 📼 Email																	
Document Templates																	
🕨 😰 Audit																	
🕨 🧪 Workflows																	
N Security																	
✓ F-Signature																	
Vendors																	
 Reasons Purpose of the signature 																	
Tasks																	

- 1. Navigate to Main Navigation-> Settings-> E-Signature-> Purpose of the signature.
- 2. In the Right Panel, you can write the Purpose of the e-signature.
- 3. Click Save.

Assigning Users to prepare an e-Signature Envelope

- 1. Click the desired room in your TI session. Click **Settings** from the Main Navigation to populate the room settings.
- 2. Navigate to Settings -> Security-> Users. A panel listing all users will be displayed in the right pane. Alternatively, you may arrive on the same page from the Main Navigation -> Users management.
- 3. Click the Invite dropdown located on the top left corner of the user list pane. Select the invite option from the list. A User Invitation form will be populated.

Fill in the fields marked with an asterisk (*), at minimum, to invite the desired user.



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From the **User Profile** tab click the **Actions** dropdown menu to select the **eSignature** option and click **Create** to assign your user to prepare the eSignature package. Refer to the screenshot below:

User views	O Hear h	witation		(9)	1
By organization	User	Profile Groups		0	
contact.ct	Requir	red fields are marked	with an asterisk (*)		hoo.com
Grail.com	Email			9	nai.com Iyahoo.com
ti.com	First	name: name:			
TransPerfect Tri	al Interactiv Role:	•		•	
a yahoo.com	Actio	ation Date: 🕥 ns:		×	nail.com n
	Orga Mobi Phon Addre City: State Zip ci Coun Invite Profe	nization: " le number: e number: ess: ess: tode: try: elater:	Reduction Study Startup Document Collaboration Document Collaboration Page Manipulations Page Manipulations Communications Publish to eTMF Milestones Assign Tasks	Reviewer Administrator	Pyahoo.com gmail.com om ntact.com oo.com 158-94ed-b5a96. sil.com om
e 👘 👘		Moviladi	Create Cancel Cr	eate and Invite Another	ail.com
By name By status	÷ •	Nerkar	Akshay	nerkar.akshay907(@yahoo.com
Div energies	(7)				

- 4. For existing users, select the user from the user list by clicking the checkbox adjacent to the list populated in the right pane.
- Click the dropdown next to the dots and click Edit option. An Edit User form will populate. Refer to the screenshot below:



- 6. Click the Actions dropdown menu and select the eSignature option by ticking the checkbox.
- 7. Click Save to prepare the existing user for the e Signature package.

The user added will receive an email from Trial Interactive asking them to register in order to comply with e Signature feature.



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Adding Groups with the eSignature Actions

Add Groups and activate the eSignature Action for the specified groups.

- 1. Navigate to Settings -> Security -> Groups. The Groups Panel opens.
- 2. From the Groups tab, click Add. The Create New Group window opens.
- 3. Name the group by typing its title into the Name field.
- 4. Add a Description.

The user making these additions or changes can choose to clone the security parameters already defined for another user group that has been established in the room. This cloning designation is not required.

5. Click the Actions dropdown. Refer to the screenshot below:

* * Regression Testing_Yug Settings	and Search for documents	s or select a filt	er v	Q -	
Search 💌 🕷	About de Groups	м			
Document Types	Groups		0	Add / Composition	
P 🛄 Required Documents	Name	Description			
Countries	a Site Activation Members	Create New Gr	oup		×
Investigative Sites	Auditor Esign_Yuga	Name: *	eSignature Group		
@ IRB/EC	4 Escalations	Description:	Users who eSign of	documents	
> 🥽 Email	4 QC 1	C1			
Document Templates	👛 Index Manager Group	Clone security fr	rom an existing group:		-
🗉 📅 Audit	Study Startup Team [Test	Actions:	1		¥.
Vorkflows			Study Startup		
• N Security			Document Coll Document Coll	aboration Reviewer aboration Administrator	
Ceneral Sector			Page Manipulat	tions	
L Users			🖻 eSignature		
a Groups			Communication	15	
> Tasks			Publish to eTM Milestones Assign Tasks	F	

6. Click the checkbox for eSignature and click Create.

The new user group displays in the list of Groups in the panel on the left.

TI eSignature

For many clients who do not want to use DocuSign or Adobe e-Sign as options for e-Signature, can now use the Trial Interactive e-Signature (TI e-Sign) to sign the documents.

This section includes the following sections:

- 1. Assigning signers to the documents (page 415)
- 2. Signing the documents in TI -eSignature if you are a signer (page 417)



TI eSignature - Assigning signers to the documents

- 1. Visit the desired room in Trial Interactive. Click the **Documents** tab. Open the appropriate folder from the index to display the documents in the documents grid.
- 2. Right-click the desired document and click Send for e-signature. Refer to the screenshot below:



Alternatively, you can also send the document for eSignature from the eSignature Panel (page 268) to the right.

- 3. The Send for eSignature dialog box opens.
- 4. Select the eSignature Type and assign the users for the document eSignature by clicking the Add button. Refer to the screenshot below:



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r eSignature	? ×
ire Settings	
tify the document is identical.	
eSignature Type Parallel Serial	
tifu the document is identical	
* Delete	
User Name	
No records available.	*
	In a set of the set of

Signing the documents in TI - eSignature

If you are assigned to electronically sign a document, you can sign the documents in the

following ways:

- From the Documents to be signed dashlet
- From the eTMF/Documents view

Each of the ways is discussed in the sections below:

Signing Documents from the Documents to be Signed Dashlet

- 1. When you are assigned a document for eSignature, navigate to the room Dashboard and scroll to find the Documents to be signed (page 215) dashlet.
- 2. Double click the document listed in the Documents to be signed dashlet. A new window to review and act on the document will display. Refer to the screenshot below:



You can also proceed to the **eTMF/Documents** module or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature Documents** view in the Index pane.

👁 👻 🖪 Create new review	🔽 Email	4	🔒 Prii	nt	? Layout ~	Compare									🚼 Add to Cart	🏋 Documents cart 🛩
View by eSignature			5 d	locur	ments (1 se	lected)									Metadata Queries Version	is History eSignature
Canceled		•	1		Document	Title	Document	Disable au	Document	Reason fo	Comments	Document	Category	Ca	eSignature	
Waiting for Signatures		2	۵	*	2107864	Multiplicat	Common		Polly Chak			29 Jun 2018	2	In	eSignature Type	Parallel
				*	2200056	hebrew			Nick Akulich			28 Sep 2018			eSignature Status	Waiting for signers
				*	2217910	Doc3		True	Polly Chak			05 Oct 2018			O Nick Editor	Waiting for signers
			Ø	$^{+}$	2237337	Showing S			Tiger Woo			03 Dec 2018	3	Cc		đ
				$^{\pm}$	2423443	Good Clini		True	Polly Chak						Cancel E-Sig	nature
		_														

Note:

- Completed signatures cannot be canceled.
- Administrators can cancel e-signature initiated by any user but editors can cancel only those that were initiated by themselves only.
- Once a document is canceled from e-signature, no one can sign the document until it is resent again.

Signing Documents from the eTMF/Documents view

- 1. Navigate to the eSignature view and click the Waiting for Signature folder to locate the document to be signed as shown in the screenshot above section.
- 2. Select a document and open the eSignature Panel to the right. The Waiting for eSignature status appears next to your name.



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3. Click the username to expand the details. Refer to the screenshot below:

eSignature Type	Parallel
eSignature Status	Waiting for sign
Amruta Maddel	Waiting for signers
Purpose of the signat	ure:
Approval Needed	
Reasons:	
Approval Signature	~
Comments *	
Approval Signature	ĺ
Order *	
123	

- 4. Enter all the required details and click Sign Document button.
- 5. A window opens asking you for Authenticating your credentials opens.
- 6. Click OK to authenticate your credentials. Refer to the screenshot below:



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Authentication X	User authentication
Please provide you credentials	T R I A L INTERACTIVE
	LOG IN
	Benutzername
	amazakov.dev@gmail.com
	Kennwort
	Meine Haben Sie Ihr Passwort Anmeldeinformationen auf vergessen? diesem Computer speichern.
	I am an INC Research Employee
	Anmelden
	€ Log In with SAML Auth

- 7. Once you are authenticated, you are directed to the confirmation dialog box asking for signing.
- 8. Click OK.



9. The Sign Document window opens which allows you to sign the document. Refer to the

-g seament		
Adobe Sign		0
Options 🗸	[DEMO USE ONLY] sample - Copy (37)	🦻 Completed 🕑
	test Click to change	
	Adobe Sign Test Document Not for commercial use	
l agree to	the Terms of Use and Consumer Disclosure of this document	Click tijssign

screenshot below:



- 10. Click the Blue button at the bottom right corner of the window to sign the document.
- **11.** If you are assigned to sign using the **Serial** signature, the status of the document will be updated as signed by the name of the signer who has signed the document and will still be waiting in **Waiting for Signatures** folder till all

👁 👻 🚯 Create new review	Email	8	Print	? Layout ~	Compare									PR Add to Cart	📜 Documents cart 🛩
View by eSignature			5 doc	uments (1 se	lected)									Claim	🗘 More 🗸
Canceled				Document	Title	Document	Disable au	Document	Reason fo	Comments	Document	Category	Ca	Metadata Queries Version	ns History eSignature 🗲
Waiting for Signatures		0	B *	2107864	Multiplicat	Common		Polly Chak			29 Jun 2018	2	In	eSignature	
				2200056	hebrew			Nick Akulich			28 Sep 2018			eSignature Type	Parallel
			ia *	2217910	Doc3		True	Polly Chak			05 Oct 2018			eSignature Status	Waiting for signers
			a *	2237337	Showing S			Tiger Woo			03 Dec 2018	3	Ca	Q Swati B	Waiting for signers
			1à *	2423443	Good Clini		True	Polly Chak						O Amruta Maddel	Waiting for signers
														Cancel E-Sig	gnature

the signers have finished signing. Refer to the screenshot below:

12. Open the signed document to find that a page with the signer's name and contact details, date of e-signing the document is appended as the last page to the document. In the case of multiple e-signers, a page for every signer is appended.

Note: Signature Page will be added to PDF documents only after all signers have finished signing the document.

13. Once all the signers have finished signing, the document will automatically move to the **Completed** folder under e- Signature Documents view. You can see the status of the eSignature as **Completed** in the eSignature Panel.

Adobe eSignature

This sections includes the following sections:

- 1. Assigning signers to the documents
- 2. Signing the documents in Adobe Sign if you are a signer

Adobe eSignature - Assigning signers to the documents

- 1. Visit the desired room in Trial Interactive. Click the **Documents** tab. Open the appropriate folder from the index to display the documents in the documents grid.
- 2. Right-click the desired document and click Send for e-signature. Refer to the screenshot below:



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10	doci	ume	ents (1 se	elected)				
		Do	ocument	Title	Document	Disable au	Document	
M	*	20	69982	DMS TEST			Polly Chak	
Z 🕅	*	2	G Add Do	ocument		True	Polly Chak	
2	*	2	Copy L	ink		True	Amruta A	
2	*	2	X Delete			True	Polly Chak	
0	*	2	A Manage	Security			Amruta A	
0	*	2	👁 Open I	Profile			Amruta A	
	*	2	🕑 Edit Pr	ofile			Amruta A	
	*	2	Replace	e Attachment	audit 1_10	True	Tiger Woo	
	*	2	R Add to	Cart			Amruta A	
	*	2	★ Add to	favorite		True	Polly Chak	
			 ☆ Remov Initiate Share I Share I OCR Conver Conver Send f Add to Ask a c P Related 	t Non PDF to PDF or E-Signature Review question documents				

Alternatively, you can also send the document for eSignature from the eSignature Panel

(page 268) to the right.

- 3. The Send for eSignature dialog box opens.
- 4. Select the eSignature Type and assign the users for the document eSignature by clicking the Add button. You may add one or more signers to the document. Refer to the screenshot below:



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Send fo	r eSignature	? ×
eSignatu	re Settings	
Please cert	ify the document is identical.	
	eSignature Type Parallel Serial	
Users Please cert	ify the document is identical.	
O Add	× Delete	
O Add	× Delete User Name	
O Add	× Delete User Name No records available.	*

If you wish to assign a sequence in which your signers should sign the document, select the **Serial** option to decide the sequence.

- 5. Click the OK button after adding the desired signers.
- 6. Recipient window with the list of email ids of signers enlisted opens.
- 7. Tick the **Preview & Add Signature Fields** checkbox located at the end of the page to determine the placement of signatures on the document.
- 8. Click Next. Refer to the screenshot below:

Documents for e-Signature		
	Recipients Complete in Order	What's New Add Me Add Recipient Group
	1 🔗 * chak.polly@gmail.com	🖾 • Brnall 🛛 🖂
	2 Ør * Enter recipient email	
	Shew CC	
	Message	
	Please Review W	Options Password Protect Set Reminder
	Files	Recipients' Language
	dtstgUploads1Demo16676_697_396996_2385888 Lab7048647647643baex02889462359194ease Review_add96029463bd56927691	English: US -
	Preview & Add Signature Fields	


- **9.** From the Recipients field select the signer and, drag and drop the fields on your document from the right menu option that you wish to include in the signature.
- 10. Repeat the above step for every e-signer.



11. Click the **Send** button located on the bottom right corner of the window to complete the signer assignment process. The system will trigger an email to the signers designated by you with a link to the document for

eSignature.

You may also review the documents to be signed, along with the signer details, in your dashboard under the **Documents to be signed** dashlet. Refresh the page to view the latest updates.

Signing the documents in Adobe Sign

If you are assigned to electronically sign a document, follow the steps mentioned here:

- 1. When you are assigned a document for eSignature, you should receive an email containing the link to the room where the document is stored. Click the **Review Document** link to access the document. Alternatively, click the **Dashboard** tab and navigate to the **Documents to be signed** dashlet.
- 2. Double click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display.

You can also proceed to the **eTMF/Documents** or **SWS/Documents** module (depending from where you need to e-sign documents) and select the required document from the **Waiting for Signatures** folder under **e-Signature** view in the Index pane. Either way, click **Sign Document** to begin the review and signing process.

If you are assigned to sign using the **Serial** signature, a place where you are supposed to sign will be highlighted in the document. Refer to the screenshot below:

T R I A L INTERACTIVE



- 3. You will be prompted with a signing validation dialog box. Enter the login and password that you used to log into Trial Interactive. The validation process will be skipped if you proceed to sign a document from within your email inbox.
- 4. After validation, you will now be lead to the Adobe Sign interface called embedded signing, for you to review and sign the document. Refer to the

Adobe Sign		٥
Alternative actions. +	[DEMO USE ONLY] Please Review	Direct required field
5	<page-header><image/><image/><list-item><list-item><list-item><image/><image/><list-item><list-item></list-item></list-item></list-item></list-item></list-item></page-header>	
		the second

screenshot below:

- 5. Hit Click here to sign box. You will be prompted to choose your style for the signature (font, size, etc.)
- 6. Enter your signature and other details as required. Click Apply.
- 7. This will insert your signature. Hit Click to Sign. Refer to the screenshot below:



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Adobe Sign		0
Abstration actions +	[DEMO USE ONLY] Please Review	💬 Campirtus 🕲
Alexandre actions +	<text></text>	Company &
	Cot Sure Extra constraints of a copyrers in the Cohever heading later. A new request in the Cohever heading later. A new request in the Cohever heading later.	

8. The document will move to the Completed folder under e-Signature Documents.

DocuSign eSignature

This section includes the following sections:

- 1. Assigning signers to the documents
- 2. Signing the documents in Adobe Sign if you are a signer

DocuSign - Assigning Signers to the Documents

- 1. Visit the desired room in Trial Interactive. Click the **Documents** tab. Open the appropriate folder from the index to display the documents in the documents grid.
- 2. Right-click the desired document and click Send for e-signature. Refer to the screenshot below:



			Do	cument	Title	Document	Disable au	Document
	1	*	2069982		DMS TEST			Polly Chak
~	1	*	2	G Add Do	cument		True	Polly Chak
	1	*	2	Copy L	ink		True	Amruta A
	1	*	2	🗙 Delete			True	Polly Chak
	0	*	2	A Manage	Security			Amruta A
	0	*	2	👁 Open I	Profile			Amruta A
		*	2	🕑 Edit Pr	ofile			Amruta A
	1	*	2	Replace	e Attachment	audit 1_10	True	Tiger Woo
		*	2	R Add to	Cart			Amruta A
		*	2	★ Add to	favorite		True	Polly Chak
				 ☆ Remov Initiate ☆ Share I ☆ OCR ☆ OCR ☆ Convert ✓ Send for ☆ Add to ♀ Ask a co 	e from favorite Workflow Document t Non PDF to PDF or E-Signature			

Alternatively, you can also send the document for eSignature from the eSignature Panel

(page 268) to the right.

- 3. The Send for eSignature dialog box opens.
- 4. Select the eSignature Type and assign the users for the document eSignature by clicking the Add button. You may add one or more signers to the document. Refer to the screenshot below:



Send fo	r eSignature	? ×
eSignatu	re Settings	
Please cert	ify the document is identical.	
	eSignature Type Parallel Serial	
Users		
Please cert	ity the document is identical.	
O Add	× Delete	
O Add	× Delete User Name	
O Add	× Delete User Name No records available.	

If you wish to assign a sequence in which your signers should sign the document, select the **Serial** option to decide the sequence.

- 5. Click the OK button after adding the desired signers.
- 6. A document preview window to determine the placement of the signatures with the designated recipient list on the left will display.



Select the desired recipient. Then drag and drop the fields on your document from the left menu option that you wish to be included in the signature. Repeat the above step for every e-signer. Refer to the screenshot below:

Click the **Send** button located on the top right corner of the window to complete the signer

	s "Untralated assessment of the Attract of December 2012				012016
•	new Contact *	ち d 「G C 124% *			
	Standard Fields		1	🛗 Date Signed	
	Z Signature	Date Signed		Formatting	
	DS Initial			Data Label	
	Date Signed Drag and Drop from here	Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive	*	AutoPlace	
	🔔 Name 🔹	Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive			
	🚰 Email	Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive			
	Company	Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive	11		
	Title	Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive		De	
	T Text	Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive			
	Checkbox	Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive			
	Dropdown	Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive			
	Badio	Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive			
	×	Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive			
	C. Samula	Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive		Save As Custo	om Fiel
	In romute .	Transperfect DealInteractive Transperfect DealInteractive Transperfect DealInteractive			

assignment process.

The system will trigger an email to the signers designated by you with a link to the

document for eSignature.

You may also review the documents to be signed, along with the signer details, in your dashboard under the **Documents to be signed** dashlet. Refresh the page to view the latest updates.

Signing the Documents in DocuSign

If you are assigned to electronically sign a document, follow the steps mentioned here:

- 1. When you are assigned a document for eSignature, you should receive an email containing the link to the room where the document is stored. Click the **Review Document** link to access the room. Alternatively, click the **Dashboard** tab in the eTMF module and scroll down to find the **Documents** to be signed dashlet.
- 2. Click the document listed in the **Documents to be signed** dashlet. A new window to review and act on the document will display.
- 3. You can also proceed to the eTMF/Documents or SWS/Documents module (depending from where you need to e-sign documents) and select the required document from the Waiting for Signatures folder under e-Signature



Documents view in the Index pane. Either way, click Sign Document



to begin the review and signing process. Refer to the screenshot below:

Click **Continue.** If you are assigned to sign using the **Serial** signature, a place where you are supposed to sign will be highlighted in the document. Click the **sign** icon. You will be prompted to choose your style for the signature (font, size, etc.). Refer to the screenshot below:

🕖 🕖 🖨 Doudign, Inc. 105) - https://domo.docusign.net/Signing/NorTheced9cR1e341236c1416x8e13e13e1			
Select the sign field to create and add your signature.		FINISH	OTHER ACTIONS •
	ơơ∓ <u>-</u> ⊕ ©		
Nor Nor Nor Nor Nor Nor Nor Nor Nor Nor	Casado fisicho documento de la comparisona de la		

Click Finish to complete the eSignature process.



Chapter 15. Tasks

This section explains the tasks application that allow users to manage their Trial Interactive

tasks for their rooms.

They are given an option to add, edit, delete, and export tasks. Additionally, administrators can adjust the number of days before a task's deadline for a user to receive an email message as reminder of the task's due date. They can thus set up the reminders from the Reminder section of the metadata panel of a task.

As a Trial Interactive administrator, you can access Tasks as mentioned below:

- 1. Enter the room for which you want to create tasks from the Home page
- 2. Click the Main Navigation >App switcher.
- 3. The popup with all the applications appear
- 4. Click Tasks icon.
- 5. You are taken to the Tasks page. Refer to the screenshot below:



The Task Module is explained in detail in separate section.

Tasks

The Administrator would need to set up certain configurations for tasks in a room from Main Navigation → Room Settings

→Tasks. These configurations are listed below:

- 1. Tasks
- 2. Tasks Category

Each of the options above is discussed in separate topics which can be accessed from the

left panel of this help.



Tasks

- 1. Navigate to Main Navigation->Settings->Tasks->Tasks
- 2. Define a number of days from IRB/EC submission reminder task [field] day(s) option. Refer to the screenshot below:



3. This defines the number of days before the due date that the user will receive a reminder email regarding any task related to the IRB/EC.

Task Category

Task categories need to be specified while creating a task. These task categories need to be created so that the user may select the appropriate category from the dropdown of the **Task Creation** window.

Tasks can be created, edited, or deleted through the buttons on the Task Category dashlet.

Refer to the screenshot below:

🕒 About 📄 Tasks 🎽 睯	Task Category ×
🕒 Add 📝 Edit 😑 Delete	
Category 🔺	
Client specific	
Internal team	
Misc	
Training	

- 1. Click Add to add a task and press Enter.
- 2. Double-click a task, or select an existing task and hit the Edit button to edit a task. Press Enter after editing.
- 3. Select a task and hit the Delete button to delete it.



Chapter 16. Communications

This section explains the Communications module that automatize the manual process of managing emails and thereby reduce unnecessary workload.

The **Communications** module was introduced to cater to issues related to managing of emails in the Outlook mailbox that required teams with dedicated people to sift through the mailbox, pick out relevant mails, download them, convert them to PDF and then file them to the TMF. It incorporates the features of both the *Inbox* and the *Outbox* and comes with two views – **Outbox** and **Inbox**. You will have access to this module if it is activated for you.

You can access the Communications Dashboard from the Main Navigation by clicking the **Communications** icon. Refer to screenshot below:



Click the links below for more details on each topic:

- 1. The Communications Dashboard
- 2. The Communications Inbox
- 3. The Communications Outbox
- 4. Exporting Mails



Communications Dashboard

Once you enter the **Communications** Dashboard, you will have access to both the **Inbox** and the **Outbox** views from the left menu. Refer to the screenshot below:

	★ Training Room 1 ★ Communication / Inbox				
4	Inbox				
\mathbf{N}	Outbox				

Communication Inbox

From this section, you can perform the following:

- 1. The Inbox Settings
- 2. The Inbox Process

Each of the above topics is discussed in the separate topic and can be accessed from the left menu of this help.

Communication Inbox Process

Below is the process for communication inbox:

- 1. After enabling the feature from the Inbox Settings (*page 93*), all the emails sent to the Communications Inbox are deposited here whereas emails sent to the eTMF inbox will be deposited to inbox.
- 2. Depending on the settings of the Communications Inbox, the email processing service converts the email into a PDF file; the Subject and date of the email are used to form the Submitted Name of the file.

 $\stackrel{\blacksquare}{\Rightarrow}$ Note: The settings that need to be activated to convert an email to PDF is Convert email body.

3. If there are any attachments to the email. They are also converted into PDF files (based on room settings) and automatically linked to the email PDF.

Note: The Settings that need to be activated to link attachments to the email PDF is Merge attachments.

- 4. Any attachment that cannot be rendered into PDF is left in its original format.
- 5. The email PDF file, along with its attachment(s), if any, are stored in the Communications Inbox



folder.

6. In the Communications Inbox, the email document is stored in the **Pending** sub-folder from where the editor can mark them as **Relevant** or **Non-Relevant**. Refer to the screenshot below:

5	× Delete									🗗 Layout 🔻
		a 1-1 of 1	(1 selected)					0	La Expand	
	By Date		Sent Date	Title	Sender Name	Sender Address	Status	Comments	TUE 21/01/2020, 8:56 PM	
	By User	🗹 % 1 🔅	21 Jan 2020	test	steli@transperf	steli@transperf	Pending		steli@transperfect.com	
	💌 👺 By Status								test	
	Pending								8	
	Relevant								test.pdf	
	Mon-relevant									
									1	
Y									Relevant Non-Relevant	

- 7. The documents that are marked as **Relevant** are coded by the editor in the **Document Profile** form with data such as category, document type, site, and other relevant data based on the document type selection.
- 8. Once the editor codes the document and saves it, the document will move to the **Relevant** folder in the Inbox View. The Metadata fields are now non-editable. Refer to the screenshot below:

					+ Add	Q Search	💿 Polly Chakraborty 🗙
O Delete							
 Comparison of the second secon	• • 961 • 961	Title For Communication SSU-5632 For communication Inb	Sender Name amaddel@transperfect pchakraborty@transpe amaddel@transperfect	Sender Address amadtlel@transperfect pchakraborty@transpe amaddel@transperfect,	Status Relevant Relevant	Comments	Email Message

- 9. Based on the room settings, the document will be published as final or will go to the default folder and the Quality Review Workflow where the reviewers will claim the documents, approve them, and file them to the eTMF.
- 10. The documents that are marked as **Non-Relevant** are moved to the **Non-Relevant folder** of the Communications Inbox module and can be deleted by the Administrators, if required.



Communication Outbox

Documents or messages emailed from a Trial Interactive room are stored in the Communication Outbox. Details on how to email is discussed in detail in section Email (page 143)

The Communication Outbox is the holding area of messages or emails that are sent out from a Trial Interactive room. The left pane of the Outbox module gives the views of the emails By Date and By Type.

Besides, you can also export communication emials.

Communication Outbox Email Message Window

Double click a message in the grid, or check the checkbox to display the Email Message window at the extreme right of the dashboard. This window gives the complete metadata of a message including its body, sender, receiver, subject, sent date, and attachments. Refer to the screenshot below:

You can also change the layout of the email message window by clicking

Q Enter key		Layout *
Expand		
MON 10/02/2020, 10:25 PM		
<tladmin103@ti.< td=""><td>com></td><td></td></tladmin103@ti.<>	com>	
Training Room 1 : Re	g. Pack	
To 'dhamilton@med	ical.org'	
1572.pdf FDF.pdf		
Re: Study: Training Room	1; Site: 101	
Dear Dr. David Hamilton	and Site Staff,	
Your response to questio	nnaires and addition	al
communication indicate	your site meets the re	equirement
necessary for this import	ant study. DIA is plea	esed to extend
the offer of participation	in the DIA Reference	Model study to
you. On benair of the Div	overd to working with	to warmiy
months ahead. This is a	system generated em	ail so please do
not reply to this but follo	w the instructions list	ed below.
Included you will find nee	essary documents re	quired for start-
up. To enable a quick sta	irt-up we would like to	o work with you
in the most efficient man	ner possible to ensur	e your site is
ready to participate in the	e registry. Before ope	ning your site to
participation we will need	to collect the followi	ng essential
aocuments.		
alles (se l'all')	8 91	
	Previous Ema	il Next Email 🕨
	10-10-10-10-10-10-10-10-10-10-10-10-10-1	

the **layout** buttons at the top right corner of the message window.

Communications Outbox Views

You can sort the emails in the following ways:

- 1. By Date
- 2. By Type



- Each of these is
- discussed in the
- sections below:

By Date

This section provides the segregation of mails by the period of:

- 1. Today
- 2. Last 7 days
- 3. This month, and
- 4. All mails.



Click a period to view the communications for that period in the right pane of the dashboard.

	✤ Export					
45	✔ 🏥 By Date	Sent Date	From	То	сс	Subject
	🔁 Today	11 Feb 2019	pchakraborty@transpe	amaddel@transperfect		Site Correspondence
\bigcirc	🕒 Last 7 days	 For UAT.pdf 	borty@transpe			
	🗢 This month	07 Feb 2019	pchakraborty@transpe	amaddel@transperfect		TechWritersDemoRoo
	All	07 Feb 2019	pchakraborty@transpe	swatipawar.pune@gma		Test Email
	> By Type					

The screenshot below shows all the communication for the current month.

The **link** icon ¹ with a number next to the **Sent Date** shows the number of attachments in the mail. Hover the mouse on the icon to view the attachment name.

Ву Туре

This section provides the segregation of mails by their types:

- 1. General Communication
- 2. Regulatory Packet





Export Communication Emails

You can export mails by clicking the **Export** icon on the top ribbon bar. This will open the **Export messages** window. You can export all

		1-8 0	9 (1 selected)				
	0	1-00	b (1 selected)				÷
🕨 🏥 By Date			Sent Date	From	То	сс	Subject
🔻 🗁 By Type		⊠ % 2	10 Feb 2020	Tladmin103@ti.com	dhamilton@medical		Training Room 1 : Re
📄 General Communication		□ % 2	02 May 2018	pkumar@transperfec	pkumar@transperfe		Training Room 1 : Re
Regulatory Packet		□ % 2	02 May 2018	pkumar@transperfec	pkumar@transperfe		Training Room 1 : Re
	Export Export By Date By Type General Communication Regulatory Packet	Export Export By Date By Date General Communication Regulatory Packet	Export Export 1 - 8 of 1 By Date Date General Communication Q Regulatory Packet Q		Export 1 - 8 of 8 (1 selected) Sent Date Sent Date	Export	 ▶ Export ■ By Date ■ Sent Date<

Export messages ×	_
Export Options	
Source Selected messages	
Cancel Export	

messages in the current grid, or only selected messages. Refer to the screenshot below:

The confirmation of the export job is displayed in a popup at the top of the grid.

You can **GetJob Result** from the **Notifications**. *(page 64)* The export job result is saved as a .xlsx file. Refer to the screenshot below.





Chapter 17. Collaborative Workspace

Collaborative Workspace is repository for the project management related documents, some of the documents in this room will be moved to eTMF room. Collaborative workspace have a reference to a study room.

The Trial Interactive Collaborate solution, also known as Shared Workspace, is a Clinical Collaborative Workspace Solution for clinical teams to provide Sponsors, CROs, and Sites a place to share and author documentation to be used in the Clinical Trial and ultimately archived in the eTMF.

An integral part of TI Collaborate, TI Collaborative Authoring will provide end-users the capability of directly editing MS Word, Excel, and Powerpoint documents in the browser, and allowing multiple authors to simultaneously work on a document, or components of a document, at the same time, much like Google Docs. Reviewers can annotate the document with responses and comment threads as well as integrated online chat. No local software installation is necessary. Using Edit Online, authors also have the ability to instantly open MS Office documents within their native editors and save them seamlessly back to the Shared Workspace.

There are two types of rooms associated with Collaborative Workspace

TI Docs

TI Collaborate

TI Docs and TI Collaborate both have the ability to edit the documents online. TI Collaborate

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acts as Content management tool that is linked to the TMF . TI Collaboarate asks 'Is this a TMF document?' while publishing the documents. With TI Collanorate the users can also publish the documents to any other room that is not associated to Collaborative Workspace. While TI Docs doesn't have any link to TMF, nor it can publish the same to any other room. However, the documents can be copied to other rooms.

🕛 Important: To enable Collaborative Workspace room, contact the Helpdesk.

Content Editing and Versioning

Content editing and versioning helps the users with the the capability of directly editing MS Word, Excel, and Powerpoint documents in the browser, and allowing multiple authors to simultaneously work on a document, or components of a document, at the same time, much like Google Docs. Reviewers can annotate the document with responses and comment threads as well as integrated online chat. No local software installation is necessary. Using Edit Online, authors also have the ability to instantly open MS Office documents within their native editors and save them seamlessly back to the Shared Workspace. The content editing is performed with check-in and check-out with the documents available in a collaborative room. The detailed process is explained in the subsequent topics.



Check Out

The editing of a document initiates with the check out process. To check out a document, go to the collaborative room and open the document index. Click the gear icon available in the document grid. This will open a dropdown as shown in the screenshot below.



Clicking the Check out option will populate a checkout window as shown in the screenshot below.

Check Out		×
Select the Edit mode	● My Edit 🔘 Collaborative Edit	
How do you want to edit the document?	 Using built-in online editor Using my local office application Edit content offline 	
Cancel	Check Out	

From here, you can initiate My Edit and Collaborative Edit choosing the editor options like Using built in editor, using local office application, and



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editing content offline. The edit mode 'My Edit' is explained in the subsequent topics.

My Edit

My Edit is performed under Check out. Click My Edit Rdio button and choose Using built-in online editor as shown in the screenshot below

Check Out	×
Select the Edit mode	My Edit Collaborative Edit
How do you want to edit the document?	 Using built-in online editor Using my local office application Edit content offline
Cancel	Check Out

Clicking the check ou button with using built-in online editor will open the document editor as shown in the screenshot below.

	*	Training T Collabo	ream Collabo rative Wor	orate Room 👻 kspace / Documents Libr	ary				Q Searc	h 🛛 Add 👻 🌲	Admin 106	-
<i>6</i> 26		Document	 A Mar 	nage Security 🔷 🛧 Import	▪ ↓ Export ▪	🗷 Email 🛛 🖨 Print	Compare			📜 Documents Ca	rt 0 👻 🗗 Lag	yout 👻
	Θ	🗗 Open in	n New Wind	ow ≫ Start Redaction	街 Start Page Mar	ipulations O Ti	anslate Document	Check In	₽ Ve	r Expand	O N	∕lore +
-	OPEN	File	Plugins		Test_9e3a933aac40430aal	058a14593e5a31.pdf		⊜ ±		Metadata Queries Ver	rsions History	
	5	a								Test		
ø	NEW SELEC	e								Is this a TMF document	17	-
₽	TOR	ē								O Yes	No	
		3								Document Metadata		-
					RACTIVE 10.		ELP		1	Title *		
										Test		
									10	Document Name		
					3				¥	Disable auto Docu	ment Name updated by	Next
Y		Page 1 o	of 116					Zoom 100%	•			
6			Grid View	Docu	ment View			8		Previous Document	or i Next Doci	ument 🕨

The document can be edited by clicking Checkin button available in the ribbon bar.



This allows you to edit the document online with the things like comments and track changes. Once you make the cdits, the system will poulate a Check in window as shown in the screenshot below.



Check In		×
What kind of	version would you like to check in?	
Comments	Need improvement	6 9
	Cancel Save	G

The edited document gets its version up in the metadata. The versioning can be seen in under the Vesrions button in the Metadata pane.

BNote: Editing a document offline is explained in the subsequent topic.

Offline Edit

To edit a document offline, the system prompts you to download the document.

Select the edit mode to My Edit and check the 'Edit Content Online' button as shown in the screenshot below

Check Out		×
Select the Edit mode How do you want to edit the docume	 My Edit Collaborative Edit Using built-in online editor Using my local office application Edit content offline 	
Cancel	Check Out	

Clicking the Check out button will download the document to your machine. Make the edits in the document and click Check in from the gear icon dropdown from the documents grid as shown in the screenshot below.





The check in button opens up a Check In pop up that prompts you to attach the edited document. Make your comment in the comment box

Check In		×
Attachment*	Test.pdf	e
What kind of	version would you like to check in?	
	Major Minor No Changes	
Comments	Attached edit	•
		_
	Cancel Save	

to save the edit. The edit will be vesrioned up same as the online edit.

Collaborative Edit

Collaborative edit is performed within a team of editors. The edit initiator can include the editors from this operation. The users can also set the due date to complete the collaborative edit. To initiate a collaborative edit, click the gear icon available in the document grid and click check out. The check-out po up has the selection option 'Collaborative edit'. Enter the due date and collaborative edit title to proceed. Refer the screenshots below for the steps to initiate a collaborative edit.

☑ 🗳	*		A \$	993050		Test		3.2		3.0	^
Che	ck (Dut						Step	1 •	0 x	
Selec	t the	Edit	mode mplete th	ne collaborative edit	31	My Edit 💽 Co	llabora	ative Edit	,		
Colla	Due date to complete the collaborative edit Collaborative profile title					Test Review 1					
	_	_		Cancel		Next			_		

Once you click the Next button, the system takes you to the Step 2 window. This allows you to select the collaborators. To select a collaborator click the 'plus' icon available near the name of the

				O Search 🚭
Che	ck Out			Step 2 🔘 🗮 🗙
Selec	t Collaborators			
Q			Full Name	3
	Full Name		Editor Training	A
	Editor Training	✓ ▲	Editor 104	
	Editor 104	v -		1
	Editor 105	9		
	Editor 106			
	Editor 107]
	Editor 108			
	Editor 109			t
	Editor 100			
	Eddie 101			
	Pres	vious 1 of 3 Next 🕨		- -
		Previous	Check Out	

collaborator. The selected collaborators will be displayed in the right side of the window. Also a green tick is seen in the list available at the left side.



Once you select all the collaborators, click Check out. The system will prompt you for a confirmation with a question 'A Collaboration Review has been created. Would you like to open the collaboration review profile now?' Select the appropriate option to proceed further.

The initiated collaborative edit is seen under my reviews folder under the subfolder 'Pending'. Refer the screenshot below



The collaborators can be added to the review via add button under the profile tab of metadata pane.refer the screenshots below.

Clicking the Add button will open the Add Collaborators popup. Here you can select collaborators available from the list. Refer the screenshot below.

15 11029						Q. Enter keywords or phrase	🗗 Layout
1 - 2 o	f 2 (1 selected)			0	r Expand		
	Title	Description	Created D	Last Updat	Profile Collab	oorate Status Versions	
🗹 🖬	Trial Intera		18 Aug 2020	18 Aug 2020			
	Test Revie		19 Aug 2020	19 Aug 2020	Source	TI Document	
					Title*	Trial Interactive Global Learn v2.0	.1 Patch Re
					Collaboration Review Owner*	💄 Admin 106	•
					Document Owner	Profile Collaborate Status Versions Source TI Document Title* Trial Interactive Global Learn v2.0.1 Patch Review Collaboration Admin 106 Review Admin 106@ti.com Document Tladmin106@ti.com Review Due 8/24/2020 Collaborators* Editor Training × Add	*
					Review Due Date*	8/24/2020	🗎 ×
				C Enter keywords or phrase C Expand Profile Collaborate Status Versions O20 18 Aug 2020 020 19 Aug 2020 Source TI Document Trial Interactive Global Learn v2.0.1 Patch Re Collaboration Review Document Admin 106 Collaborators* Review Due Date* Review Due Date* Collaborators* Editor Training × Add	Add		
					Reference Documents		Add



Add (Collaborators					3
Select u	isers by clicking the checkbox					Q
26	5 Users 1 Selected					
	Last Name	First Name	Email	Phone	Organization	
✓	<u> </u>	Admin	Tladmin101@ti.com		ti.com	Â
	å 102	Admin	Tladmin102@ti.com		ti.com	
	å 103	Admin	Tladmin103@ti.com		ti.com	
	å 104	Admin	Tladmin104@ti.com		ti.com	
	å 105	Admin	Tladmin105@ti.com		TransPerfect Trial Int.	
	å 106	Admin	Tladmin106@ti.com		ti.com	
	• 407		T: 1 : 40701	045 004 7050	A Previous 1 of 4 Nex	•
					T Previous 1 014 ives	XU 🕨
			Cancel Selact			

A collaborator can add status by clicking the button available under Collaborate Status tab in the metadata pane. Clicking Add Status button will open the add status window. Here the collaborate can choose the status as Pending/In Progress/ Completed and put in the comments to update and save the collaorate status. Refer the screenshot below.

🖌 Expan	1
Profile	Collaborate Status Versions
🔵 Aug	g 19, 2020
	UserName
	Admin 106
	Status
	In Progress
	Comments
	Will be completed by Friday
	Cancel Update and Save

A notification will be available for the executed update





Close Review Session and Check In

Once you are done with the check-out process with all the collaborators updates and edits, you can close the review and check in the collaborative edit. To close the review session and check in. click the button available under the Collaborate status tab in the metadata pane. Clicking the Close Review Session and Check In button will open the following popup window.

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Choose the kind of version from the options (Major/Minor/ No changes) and insert your comments to save the review. The closed review notification will be seen in the notifications. The collaborate status will be updated with the closed status in the metadata pane as shown in the screenshot below.

Close Review Session and Check In					
What kind of	version would you like to check in? Major Minor No Changes				
Comments	¢				
	Cancel Save				



Chapter 24. Reports

This section helps you know about getting the Reports for the room activities.

Room Administrators have the option to turn on **Reports** and make them available to other users. If Reports are activated, you will see an icon in the Navigation Grid.

Reports Dashboard

As an Administrator user, you have an option to turn on Reports for other level users to access and view.

You can reach this page by clicking the **Reports** application from the Main Navigation. Refer to the screenshot below:



The Reports Dashboard consists of the various dashlets which gives a summary of the reports of the room. Refer to the screenshot below:



	★ Training Room 1 ★ Reports		۵	Search O Add -	Admin 106 -
	Reports		Q Search	n Reports	<i>c</i>
Þ.	Favorite 0 Main Reports 13 Audit Reports	4 KPI Reports 5 Missing and Inventory Rep	orts 12		
		No Favo	ite reports		
		To add report to f	avorites list press 👚		
	AdHoc Reports		Q Ser	arch Reports	2 ? 0
	Templates 3 MyReports 5				
	Audit Template	Thu Jul 23 2020	Mon Feb 17 2020		
	Template for Audit	Template for Document	Template for Workflow		
	Create	Create	Crea	ate	
E					

From the Reports Dashboard you can do the following:

- 1. Generate Reports from the Reports List.
- 2. Export the Reports.
- 3. Design a new dashboard
- 4. Update Results

Each of these is discussed in the separate topics in this help.

Viewing Reports from the Report List

From the Reports Dashboard, click the reports category marked in red in below screenshot. The below list of the reports is from the **Main Reports** category.

Reports		Q Search Reports			
avorite 0 Main Reports 13 Audit Reports 4	KPI Reports 5 Missing and Inventory Reports 12				
All Expiring Documents	Occument Not Reviewed By Users	Document Submission By Status	Document Submission By Submitter		
To display the documents, 30 or 60 or 90 days before the date mentioned in the 'Expiration Date' custom field	To display the documents, with their 'Status' of the document - 'Not Reviewed' custom field	To display the documents, with their 'Status' of the document, also displaying their 'Submitter Name' custom field	To display the documents, that has been upload by every 'Submitter' shown in their 'Submitter Name' custom field		
🚖 Favorite 🜔 Run	👚 Favorite 🜔 Run	👚 Favorite 🔘 Run	👘 Favorite 🔕 Run		
Document Submission Inventory - Workflow	Documents Requiring Clarification	eTMF - Inventory by Sites	Expired Documents In 60 days		
To display the list of submitted documents with	To display the documents, with their 'Status' of the	To display the eTMF essential documents	To display the documents has crossed the date		

Select any report and click on Run button to view the desired report.





Typically, report builds are based on specific sponsor requests.

Note: For further assistance on other features of reports, please get in touch with the Support team of Trial Interactive.

Generating Reports

Reports are categorized by their types at the top and users can choose the category to view the list of reports available in that category. Below screenshot shows an example of **Main Reports**. From the Reports List page, choose the report to be run and click on the **Run** button to open it.

Any report can also be made favorite by clicking on the Favorite button.

Reports			2		
Favorite 0 Main Reports 13 Audit Reports 4 I	KPI Reports 5 Missing and Inventory Reports 12				
All Expiring Documents	Document Not Reviewed By Users	Document Submission By Status	Document Submission By Submitter		
To display the documents, 30 or 60 or 90 days before the date mentioned in the 'Expiration Date' custom field	To display the documents, with their 'Status' of the document - 'Not Reviewed' custom field	To display the documents, with their 'Status' of the document, also displaying their 'Submitter Name' custom field	To display the documents, that has been uploat by every 'Submitter' shown in their 'Submitter Name' custom field		
👚 Favorite 🔘 Run	👚 Favorite 🔘 Run	👚 Favorite 🔘 Run	👘 Favorite 🔕 Run		
Document Submission Inventory - Workflow	Documents Requiring Clarification	eTMF - Inventory by Sites	Expired Documents In 60 days		
To display the list of submitted documents with workflow related details	To display the documents, with their 'Status' of the Tasks displaying ' Clarification' and other essential	To display the eTMF essential documents (Required documents) and their Workflow status	To display the documents has crossed the date mentioned in the 'Expiration Date' custom field		

🔶 Favorite 🔘 Run

For a particular report, you can do the following:

- 1. Apply Filters
- 2. Adding and deleting fields in a report
- 3. Print Reports
- 4. Download Reports

Each of these is discussed in the sections below.



Applying Filters

You can apply filters for a report if you wish to view and generate the report with only specific information. You can apply filters for a report by clicking the **Show Filters** button in the menu bar. This enables the **Filter Field, Operator**, and **Value(s)**, **Blank** fields to allow you to select the filters for a report.

Select the single or multiple filter fields for which you want to get the

Options	Document Submission By	Status Data refreshed Ma	ar 22, 2020 at 07:32:57 (GMT	T+0000) 49						
* Status Available: 9 Selected: 1	B. 5 + 0					Tra	- + 100% -	search report 🔍 🗸]◀▶ ‹‹ < Pag	a 1 of 3 🕨 I
Search list Q,						Document Si	ubmission By Status			
Finel A QC 1 Approved QC1 Clarification	Category	Document Type	Document Title	Index Folder Location	Country	Site	Submitter Name	Document Date	Expiration Date	Document Status
QC1 In Progress		_							_	
QC1 Rejected QC2 Clarification DC2 In Progress	Investigative Site	FDA Form 1572	107_Glass_Glass_B_201 80109	05 Site Management\107 Glass\05.02 Site Set-up Documentation\05.02.08 Form FDA1572	US	0	Roger Stear	26Apr2018		Final
QC2 Rejected Not Snecified ✓ Select All X Deselect All I II Invert	Investigative Site	Indemnity	107_Glass_Indemn_2019 0117	05 Site Management\107 Glass\05.02 Site Set-up Documentation\05.02.13 Indemnity	US		Roger Stear			Final
SubmitterName Available: 47 Selected: 2 Search list	Investigative Site	PI Curriculum Vitae	107_Glass_PICV_Glass_B _20180104	05 Site Management\107 Glass\05.02 Site Set-up Documentation\05.02.04 Principal Investigator Curriculum Vitae	US	0	Roger Stear			Final
Admin 101 Admin 102 Admin 103 Admin 103 Admin 104	Investigative Site	PI Medical License	Glass_PIMedLic_Glass_B	05 Site Management107 Glass\05.02 Site Set-up Documentation\05.02.07 Site and Staff Qualification Supporting Information	US		Roger Stear			Final
Admin 105 Admin 107 Admin 108 Akshay Nerkar	Investigative Site	Qualified Investigator Undertaking	104_Fantini_QIU_Fantini _S_20171005	05 Site Management\104 Fantin\05.02 Site Set- up Documentation\05. 02.09 Investigator Regulatory Agreement	CA		Roger Stear			Final
Amruta Maddel	Approval stage 2									
Andu Guinto ✓ Select All X Deselect All II Invert	Investigative Site	Clinical Trial Agreement	102_Juliano_CTA_Juliano _N_20170616	05 Site Management\102 Juliano\05.02 Site Set- up Documentation\05. 02.12 Clinical Trial Agreement	us		Roger Stear			Final
	Investigative Site	Clinical Trial Agreement	101_Hamilton_CTA_Ham liton_A_20170713	05 Site Management\101 Hamilton\05.02 Site Set-up Documentation\05.02.12 Clinical Trial Agreement	HU		Roger Stear			Final
Angly Reset	Investigative Site	Confidentiality Agreement	102_Juliano_CDA_ABC_2 0130112	05 Site Management\102 Juliano\05.01 Site	US		Roger Stear			Final

reports. An example below shows a filter applied for generating a report for the open queries of a particular **Status** and **Submitter**:

You can also apply multiple filters as well by using the operator conditions to view the required results.

Exporting Reports

You can export the reports in the following formats:

- 1. CSV
- 2. Microsoft Excel
- 3. Microsoft Word
- 4. XML
- 5. Open Office Document



6. Rich Text Format (RTF)

All Expiring Documents	Data refreshed	i Mar 22, 2020 at 10:36:27 (GMT +0000)				
B. < > >			- + [100% 🔻	search report	Q -
ASPDF			Training Room 1			
As Excel (Paginated) As Excel			All Expiring Documents			
As CSV	nt Type	Document Title	Index Folder Location	Country	Site#/ PI	Docu
As RTF	tificate	201_PI_CLIA_20200324	08 Central and Local Testing\08.01 Facility Documentation\08.01.01 Certification or Accreditation		201 PI	
As XLSX (Paginated)	tificate	Canada_112_Libby_CLIA_20200325	Staging		112 Libby	
849643 CLIA	Certificate	1040_Jackson_CLIA_20200331	08 Central and Local Testing\08.01 Facility Documentation\08.01.01 Certification or Accreditation		1040 Jackson	

Chapter 25. Study Start Up

The Start-up module is available to users who have the Study Start-up action selected in user profile, who are members of the data room's Study Start-up Team group, and who are Start-up Specialists in the data room.

The Study Start Up Process in Trial Interactive

The Study Start Up Process in Trial Interactive

The sequence of steps enlisted below gives you a glimpse of the study start-up process

followed within Trial Interactive:

- 1. Creating/Editing/Viewing/Deleting Sites
- 2. Adding contacts to sites. This includes adding:
- a. Principal Investigator and other contacts
- b. Start-Up Specialists
- c. Regulatory Approvers
- d. Site Activation Specialists
- 3. Sending Regulatory Packets and Submission Packages submit to IEC
- 4. Collecting Essential/Required documents for sites, countries, and IRB/ECs
- 5. Review of documents by a Start-up Specialist
- 6. Review of documents by Regulatory Approver
- 7. Site Activation and publishing documents to the eTMF
- 8. Adding essential/required documents after site
- activation through amendments Each of the
- processes mentioned above are discussed in detail

in subsequent sections.

Study Start-Up Contacts

This section describes in detail the various user roles available in SSU module:



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- Clinical Research Associate (CRA)
- Start-Up Specialist
- Regulatory Approver
- Site Activation Member
- Other Site Contacts
- Site Activation Member

After site information is entered in TI, the regulatory packet is subsequently sent out to the site members. If you are added to the Site Activation Member group, you are able to submit Essential/Required Documents to the SSU module for the Start-Up Specialist and Regulatory Reviewer

to review. As a Site Activation Member, you can see and track the progress of Essential/Required Documents collection, and activate the site when required.

Clinical Research Associate (CRA)

A CRA is responsible to conduct a clinical trial, and oversee various important site related functions like initiation, compliance with protocols, site visits, adherence to good clinical practices, integrity of the data collected, and protection and safety of the human subjects of the study. A CRA adds documents to a site as a part of site visits. A CRA needs to be an editor in the room to be added as a CRA in a site.

Start-Up Specialist

The Start-Up Specialist is a part of the Site Activation Member group and is the first reviewer of the SSU documents. Documents can be mailed into the specific SSU email address, imported, or attached individually in Trial Interactive. The Start-Up Specialist will review and approve, or reject the document(s) and push them to the Regulatory Reviewer for final review. The Start-Up Specialist will also activate the site after the Regulatory Reviewer approves all Essential/Required Documents at each site. A Start-Up Specialist can be an Editor, or Admin in the room.

Regulatory Approver

The Regulatory Approver is the second and last reviewer of the SSU documents. (Email notifications can be set up to notify the Regulatory Approver that there are documents pending for review). The Regulatory Approver will review and approve or reject the document(s) in the Regulatory Review section in the SSU module.

Other Site Contacts

Besides the ones mentioned above, there are various other site contacts that can be added to a site. Some of them are mentioned below:

- 1. Principal Investigator
- 2. Sub-Investigator
- 3. Pharmacy Contact
- 4. Laboratory Contact
- 5. Contracts Contact
- 6. Finance/Budget Contacts
- 7. Co-Investigator



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8. Research Specialist

Note: A Principal Investigator is the most important contact for a site as sites cannot be created without a Principal Investigator.



Note: A SSU specialist cannot be a site contact and a SSU specialist at the same time. Except for the CRA, all the contacts discussed in this section can be viewed from the Contacts module. You can view sites in the By CRA view from the Sites module.

The Study Start Up Module

Once you set up the basic configurations and contacts for Study Start Up, you can now move forward to operate the module. The Study Start Up Module comprises of the following topics.

- 1. Accessing the Study Start Up Module
- 2. The SSU Interface
- 3. Sites
- 4. Countries
- 5. IRB/EC
- 6. Regulatory Packets
- 7. Collecting Essential and non-Essential Documents
- 8. Documents
- 9. Regulatory Review
- 10. Communication
- 11. Contacts
- 12. Steps to Site Activation
- 13. Amendments
- 14. Overview Dashboard
- 15. Reports

Each of these topics with their subtopics is described in details in the subsequent.

Accessing the Study Start-Up Module

To access the Start-Up Module (SSU), click the Navigation Grid and then





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the Start-Up icon. This will lead you to the Study Start-Up dashboard. Refer to the screenshot below:

The SSU User Interface

The SSU Module is a platform in Trial Interactive (TI) which allows users to Create, Monitor and Activate sites required for Clinical Trial purposes. Through this interface users can add, upload, and keep track of the progress of the documents collected for site activation, besides reviewing them.

Log in to the Trial Interactive and select the Study Startup room. You'll be taken directly to the Start-Up Overview. This room dashboard has a toggling menu bar on the left with access to various modules and the dashlets on the right. It also has a title bar on the top. Refer to the screenshot below for further insight into functionalities allowed from within the SSU:

ш	™ Training Team eTMF Room Start-Up / Dashboard	Q Search	8 Add * 💧 🧐	Yogesh Inamda
•		12 * Edit Dashboard	Celt Default Dashboard	• Ø Das
°2	Common			
°3	About this Room Bulletin Board Project Links My Courses My Tasks			
4				JEdit
-				
4	Welcome Yogesh Inamdar,			
~ 6	Welcome to the Training Team eTMF Room. This Trial Interactive room is a place for secure eTMF and Study Information. You will be able to access	ss the documents according to the partic	ipation privileges assigned to yo	u.
20	You will need Adobe's Acrobat Reader software version 7.0 or later to view many of the documents in Trial Interactive. Click here to get i			
-5 /8	lf you require technical assistance accessing a site, please email admin@ti.com. Hil			
	Welcome to Admin 104's room			
	Users			er i
	Users			
$\overline{\boldsymbol{z}}$	All Organizations All Roles All New O Invite			

The table below describes each numbered section in the screenshot:

Sr. No.	Part	Description
01	Sites	Here the users can create sites and contacts; view them based on status, country, start-up specialist, IRB/EC, CRA. It also allows to export, import, delete, and edit sites, Mass code metadata for sites, add documents, send regulatory packets, and manage security for the contacts in the sites.
02	Countries	Here the users can view and edit the country profile, collecting and reviewing documents for countries.
03	IRB/EC	Here the users can view and edit the IRB/ECs profile, collecting and reviewing documents for IRB/ECs.
04	Documents	Here the users can view, add and keep the track of all the documents collected in the SSU site.
05	Contacts	Here the users can view the contact details based on the User access level in the site.
06	Communication	Here the users can view, add, delete and edit the communication log based on SSU User Access level in the site.



07	Dashboard	Here the users can view variuos dashlets.
08	Regulatory Review	Allows the users with an access as a regulatory reviewer to review the documents assigned to them.
09	Add	From this tab the users can add Documents/ Users/Task/ Sites.
10	Username Dropdown	The users can manage user settings, language, can redirect to the guide and so on.
11	Notifications	The users can view the notifications here.
12	Edit Dashboard	The users can manage and edit the dashboard by this button.

Sites

The Sites tab comprises of the following functionalities in Study Start Up

- 1. Create Sites and adding contacts to them
- 2. Viewing sites
- 3. Editing site profile and deleting sites
- 4. Adding additional IRB/ECs
- 5. Exporting Site Metadata
- 6. Mass Coding for sites
- 7. Managing Security

Clicking the Sites tab from the toggling menu bar leads you to the Sites section. This is where the Start-up Specialists will perform their functions and the users of the sites are allowed to submit and approve documents specific to sites.

The Sites section consists of the Current view on the left and the Grid pane on the right. Besides these, it also allows you to perform various functionalities from the menu bar on the top of the grid pane, and the buttons on the Current View window. Clicking a folder in the

current view opens a list of sites in the grid pane. Refer to the screenshot below.

Besides the above, you can also add essential documents, or regulatory approvers specific only to a particular site, and add room users to sites by providing them appropriate security accesses. These will be discussed in subsequent sections.

ш	Training Team eTMF Room + Start-Up / Sites	0 6	0 0			8 9	Q Search O Add 👻 🐥	Yogesh Inamda
-	Site Activation	Add / Edit	🗢 Delete 🛧 Import 🔸 E	xport 🛛 📲 Mass Coding 🕴 🚥	Send Reg. I	Packet 🎠 Manage Security 👻		Search
	By Status Y	Site Nu	Principal Investigator	Institution Name -	Status	Site	IRB/EC Name	Progress %
0	- All		Edward Ollivander	Hagrid's Animal Hospital	Active	Site - 1777 Ollivander Edward	Hickory Hollow IRB	100%
	a' Active [5]	123456	Mary Anderson	St. Joe's University Hospital	Active	Site - 123456 Anderson Mary	Chesapeake IRB	100%
\odot	Non Participating [1]	D * 1	Delores Umbridge	Test Site #1	Active	Site - 1 Umbridge Delores	SCHULMAN Associates IRB	100%
	Pending [10]	0*	Harry Potter	Test Site #2	Active	Site - Potter Harry		100%
Ā		•	Doby The House Elf	Test Site #3	Active	Site - The House Elf Doby		100%
•								
۵								
1								



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Sr No	Part	Description
01	Site Activation	Here the user can choose the current view.
02	Add	Allows to add New Investigative Site and Contacts one at a time.
03	Edit	Allows to edit the sites.
04	Delete	Allows to delete the Investigative Site.
05	Import	Allows to import multiple Sites and Contacts at once in the room.
06	Export	Allows to export the sites in the room.
07	Mass Coding	Allows to add Metadata to the multiple selected sites.
08	Sending Regulatory Packet	Allows to send the regulatory packets to the specific sites.
09	Manage Security	Allows to provide security roles to users in the site.

Creating Sites and Adding Contacts

You can create sites by either of the methods:

- 1. Importing Sites and Site Contacts
- 2. Adding each site and its contacts individually

1 Importing Sites and Site Contacts

This feature is especially helpful if you want to create many sites at once. This is done by entering the site details in an excel worksheet and uploading them during the import process. A sample worksheet is provided by the system on clicking the Import button. The worksheet consists of two sheets – Investigative Sites, and Contacts. You can download the worksheet, fill it with the site metadata and upload it. Once the worksheet is uploaded, the system will map the metadata of sites and its contacts, and create the sites. The sites thus created appear in the grid for you to view.

Note: For sites to be imported, the following rules should be adhered to:

1. The Investigative Sites sheet cannot be left blank.

2. While importing sites, it is compulsory to specify the Principal Investigator without which sites will not be imported.

3. Start-Up Specialists and CRA cannot be imported. You will need to add these later and can use Mass Coding for the same.

4. Sites with same names cannot be imported.

5. Fields such as First Name and Last Name in the Contacts sheet cannot be left blank, as the system will verify the email id of the user with the user's credentials from the database. If they do not match an error will be thrown.

6. Main contact/s should be specified as they are the ones to receive the email when the regulatory packets are sent.

7. If you want a contact to be an Active Contact, Main Contact, or Provide Documents, enter numerical '1' in the Contacts sheet for the fields. The system will automatically map the data and set the actions allowed for the user. On editing the contact from the site profile, you will find the checkboxes for these actions ticked (find more on this in the next section).

8. If 'Active Contact' field is left blank, the contact will be deactivated by the system. You may


choose to activate the contact later if, required.

9. If a site and its contacts are already imported, then more contacts can be added to the site only manually or through the API.

10. Data that was not imported can be mass coded for multiple sites later (follow on to Mass Coding of Sites for further details).

Given below, is an example of the worksheet as guidelines to the import process:

X	ILE HOME INSERT	PAGE LAYO	UT FC	RMULAS	DATA	RE	VIEW	Site /IEW	slmportTest - Excel				? 🖻 — 🗖 🗙 Yogesh Inamdar 🕶 🌉
Pa	te v pboard ⊊ Fo	• 11 • A • 23 • 1 nt	A [*] ≡ □	= <mark>-</mark> 8	&≁ ≣ ∰≣ Alignme	🔐 Wra 📰 Mer ent	p Text ge & Cente	Gen 	eral + + % + €0 .00 Number r	Conditio Formattir	nal Format as Cell ng * Table * Styles * Styles	Insert Cells	∑ AutoSum * 2 ¥ Fill * Sort & Find & Clear * Filter * Select * Editing *
J7	• : ×	√ <i>f</i> x											v
2	A	В	С	D	E	F	G	Н	Ĩ	J	к	L	М
1	Investigative Site Name	Site Number	Address	City	Phone	State	Website	ZipCode	Expiration Date	Country			
2	Test Site 1	1234	Test	Pune	989898	MH		333333		India			
3	Test Site 2	5678	Test	Mumbai	878787	MH		555555		India			
4	Test Site 3	10122	Test	Chennai	767676	TN		444444		India			
5	Test Site 4	14566	Test	Kolkata	656565	WB		222222		India			
6 7	Test Site 5	19010	Test	Delhi	545454	DL		111111		India			

1. Click Import from the menu bar. The Sites and Contacts import window opens.

Sites and	Contacts Import
This wizard Step 1 (I helps to import metadata from the XLSX-file of 3: upload the Excel spreadsheet (.xlsx) file containing sites and contacts information
File:*	Select metadata file
	It should be a .xlsx file
Excel spre - Workshe - Workshe <u>See the s</u>	eadsheet should contain two separate worksheets: eet 1 with the list of institution name and address set 2 with the list of contacts including the Principal Investigator ample worksheet template
	< Previous Next > Cancel

2. Upload the .xlsx file containing data of sites and contacts by clicking the search icon.

a. The excel document should contain two separate worksheets – Worksheet1 with the list of institution name and address, and Worksheet 2 with the list of contacts including the Principal Investigator.

3. Click Next.



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Sites and	d Contacts Import	X
This wizar Step 1	d helps to import metadata from the XLSX-file of 5: upload the Excel spreadsheet (.xlsx) file containing sites and con inform	ntacts
File:*	C:\fakepath\SitesImportTest.xlsx	٩
	It should be a .xlsx file	
- Worksh - Worksh <u>See the s</u>	eet 1 with the list of institution name and address reet 2 with the list of contacts including the Principal Investigator sample worksheet template	

4. Setup the mapping between metadata fields for Investigative Sites and uploaded file columns. It is possible to skip sheet selection in case you do not want to import investigative sites but only contacts. You can also specify the date format that should be used during import. Click **Next**.

Sites and Contacts Import	×
This wizard helps to import metadata from the	e XL\$X-file Step 2 of 5: setup metadata fields mapping
Select the worksheet containing Inve	estigative Sites
Spreadsheet Column	Metadata field
Investigative Site Name	Investigative Site Name
Site Number	Site Number
Address	Address
City	City
Phone	Phone 💌
Date format: * MM/dd/yyyy	v
Unique ID For sites, site numb fields: without the site num	er should be unique. Site can be imported ber.
	< Previous Next > Cancel

5. As in the above step, setup the mapping between metadata fields for Contacts and uploaded file columns. Click



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N I	- · · +
IN	ехь

Sites and Contacts Import	X
This wizard helps to import metadata from th	e XLSX-file
	Step 3 of 5: setup metadata fields mapping
	0 0 0 0
Select the worksheet containing Con	tacts:* Contacts × •
Spreadsheet Column	Metadata field
Investigative Site Name	Investigative Site Name
User Name	User Name
Contact Type	Contact Type
Active Contact	Active Contact
Main Contact	Main Contact
Date format: * MM/dd/yyyy	×
Unique ID For sites, site numb fields: without the site num	er should be unique. Site can be imported ber.
	< Previous Next > Cancel

6. Observe the settings that were done during previous steps and probably return back and correct something. Click

Next to confirm.

7. This will begin the actual import process. Upon completion, the Administrator will get a short report on the issues that were occurred during import.

2. Adding each site and its contacts individually

Sites can be created afresh, or added from a list of previously created sites in other rooms related to the same sponsor in a domain. This is especially helpful if the sites are located in multiple locations. So you might want to create sites with the same name but different metadata like contacts, address, IRB/EC, and other details. It can also happen that a site is conducting different types of clinical trials, hence you might want to keep the same name but the rest of the data can differ. Metadata such as the country, and IRB/EC will be added to the new site only if the room has them configured and available.

To create sites follow the procedure below:



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•	Site Activation	🚍 💽 Add 📝 Edit 💿 Delete 🛧 Import 🔸 Export 💕 Mass Coding 📼 Send Reg. Pad	sket 🏋 Manag
~~	By Status Y	Site Nu Principal Investigator Institution Name - Status	Site
۲	🕶 📚 All		
	💕 Active [5]	New investigative site	×
\odot	💕 Non Participating [1]	Required fields are marked with an asterisk (*)	
	💕 Pending [10]	Institution Name: *	٩
프		CRA:	×
		Start-Up Specialist:	×
		A Contacts	
		Create OAdd existing / Edit ODelete OActivate Convert to user(s)	
ø		Address	
		- V More	

2. Either type the Institution Name in the available field or activate the 'Available Investigative sites' window by clicking the magnifying lens at the right end of the field.

Investigative site information is stored in Trial Interactive's database. If a client has used an investigative site in a previous study, the site's information will be stored and easily accessed through this window. If you choose from an existing list of sites, the 'Create' button in the 'New investigative site' window is replaced by the 'Add site to room' button. Refer to the screenshot below:



stitution	Name:*	test 1			Q
RA:					~
art-Up S	pecialist:				~
Com	tacts				
O Cre	ate 🛛 🔂 Add existing	g 📝 Edit 🛛 😑 Dele	ete 🛛 🥝 Activate 🛛 💄 Co	onvert to user(s)	
				Contract Taxa	
	Last Name 🔺	First Name	E-mail	Contact Type	
	Last Name 🔺	First Name	E-mail	Contact Type	
	Last Name 🔺	First Name	E-mail	Contact Type	
	Last Name 🔺	First Name	E-mail	Contact Type	
	Last Name 🔺	First Name	E-mail	Contact Type	
	Last Name ~	First Name	E-mail	Contact Type	
Addr	Last Name ~	First Name	E-mail	Contact Type	
Address	Last Name ~ ress	First Name	E-mail	Contact Type	
Address: City:	Last Name ~ ress	First Name	E-mail	Contact Type	
Address: City: State:	Last Name ~ ress	First Name	E-mail	Contact Type	
Address: City: State:	Last Name ~	First Name	E-mail	Contact Type	

3. Select the CRA from the field's dropdown menu.

4. Select the Start-Up Specialist from the field's dropdown menu.

5. From the Contact panel of the Site Profile window, the administrator can either create, or add existing contacts, edit/delete contacts, activate/deactivate them, or convert them to room users:

a. Click Create in the Contacts panel to add a new contact to the site. This information, too, is supplied by the client. At minimum, a site must have a contact designated as the Principal Investigator and one of the contacts must be designated as the Main Contact by selecting the Main contact checkbox for the site. If a contact would be responsible to add documents to the site then tick the 'Provide Documents' checkbox. Refer to the screenshot below:



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New contact	×
Email: *	Q
Prefix:	
First Name: *	
Last Name:*	
Suffix:	
Phone number:	
Mobile number:	
Contact type: *	×
	Former Principal Investigator
Address:	IT Contact
Address.	Laboratory Contact
City:	Pharmacy Contact
State:	Principal Investigator
ZipCode:	Study Coors ator
Country:	Sub-Investigator
Clinical Trial	
Experience:	,
Provide	
Documents:	
Active Contact:	
Main Contact:	
	Create Cancel



b. Click the **Add existing** button to add contacts from a list of existing contacts. Tick the checkboxes next to the contact names to add them to the site. Refer to the screenshot below:

New investigative site						X
Required fields are marked with an aste	risk (*)					
Institution Name:*						Q
CRA:	Choose Existing Contacts				×	~
Start-Up Specialist:				Search	٩	~
Contacts	E-mail	First Name	Last Na	ame		
Create Add existing	😨 123@ti.com	123	678		^	
Last Name 🔺	2707e260-4b7c-409f-a69	Jane	Doe			
	560783e7-62c2-4f1c-a89	Robert	Crews			
	abora@transperfect.com	Ankita	Bora			
- V Address	🕑 batman@ti.com	Batman	Wayne		-	
	batwoman@ti.com	Waynetta	Batwon	ian		
- More	Page 1 of 1	MIO	Dis	playing contacts 1 - 99 o OK Cancel	▼ f 99	
				Create	Car	icel

c. You might want to deactivate a contact, if a contact is unavailable for a considerable period of time and assign the role to another user, or would be of use at a later time. You can activate or deactivate a user by clicking the Activate /

Deactivate icon in the Contacts panel after selecting the user. This icon toggles from Activate to deactivate state and vice versa depending upon its state.

d. You can edit the profile of a contact by clicking the Edit icon on the Contacts panel.

e. Similarly, you can also delete a contact by clicking the Delete icon on the Contacts panel. A reason of deleting a contact could be that the user is no longer attached to the organization.

If a contact who has added documents, is later deleted, the contact name will be appended with '(undefined)' in the metadata of the documents added by the contact.

f. Contacts can also be converted to Editors or Readers by clicking the Convert to user(s) icon on the Contacts panel. This functionality is available from the Contacts section and is discussed in detail there.

6. Click Address to open the array of data fields for entering the address where the site is located. Here, you can specify the Country which is important when filtering for a site.

7. Click More to open another array of data fields. Here you enter important site information like the site expiration date, status of the site, its email domains, preferred communication mode, and the eFeasibility Status.

a. Besides the above, you also specify the IRB/EC details here. Select the IRB/EC Type from the dropdown. The IRB/EC type could be Any, Local, or Central.

b. Select the IRB/EC Name from the dropdown. This dropdown will list the IRB/ECs that have been added to the room, or domain.

If the required IRB/EC does not appear in the dropdown, you can create/add an IRB/EC on



the fly by clicking the plus sign at the right end of the field.

c. You may enter the Expected Submission Date, and IRB/EC Submit Date for the submission of essential/required documents of the IRB/EC.

8. Click Create or Add site to room at the bottom of the window as per the process.

9. Repeat until all investigative sites have been created for the room.

Viewing Sites

Sites can be viewed from the list of sites appearing in the grid pane. The user can choose to filter the sites appearing in the grid by selecting the filters from the current view dropdown as shown below.





The Current View Dropdown offers five views:

- **By Status**: The Site status could be Not Specified, Active, Pending, Rejected. When an investigative site is added to a data room, it has Pending status. After all documents for the Investigative site are collected, and appropriate country and IRB documents are approved by the start-up specialist and by regulatory approvers, the site can be activated and it moves to Active status. If the site is rejected during activation process, it is assigned Rejected status.
- By Country: This view reveals a list of countries, and when you select a particular country from the list, you see all investigative sites related to this country. Not Specified status indicates that a country is not specified in investigative site's profile.
- By Start-Up Specialist: This view displays a list of data room users with Start-Up Specialist designation. When you select a particular user from this list, you will see all sites where this user is set as start-up specialist. If you select Not Specified status you will see the list of investigative sites that have no start-up specialist specified in their profiles.
- **By IRB/EC**: IRBs can be of two types: Central or Local. Central type will show you all investigative sites with a central IRB specified in their profiles. Local type will show you all investigative sites with local IRB specified in their profiles.
- By CRA: This view displays a list of data room users with CRA designation. When you select a particular user from this list, you will see all sites where this user is set as CRA. If you select Not Specified status you will see the list of investigative sites that have no CRA specified in their profiles.

Buttons on the Current View

Some studies require that a data room house hundreds of sites. The user can toggle the display between the sites where the user is a CRA or a Start-Up Specialist, or All Sites.

The user can refresh the current view by clicking the Refresh Current View button. Through



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the Configure Grid button, the room administrator can decide the columns that team members need to display in the grid on the right, or choose the default sorting column. Users can show or hide columns in the grid, but only room administrator can make additional columns available for viewing.

1. Toggle Display Button.



2. Refresh Current View Button.



3. Configure Grid.

Moairy Gria Config				
Grid Config			Ξ	Columns List
Column Title	Column Na	Wi	Hidd	Column Title
Site Number	SiteNumber	40		Expiration Date
Principal Investigator	SSPrincipalI	100		PI First Name
Institution Name	TopicName	100		PI Last Name
Status	StatusId	40		CRA
Site	SAutoSiteN	150		Start-Up Specialist
IRB/EC Name	SSIRBNam	150		Main Contact
Progress %	SSEssential	120		Main Contact Phone
				Reg. Pack Sent Date
				Expected Submission Date
				IRB/EC Submit Date
Default Sorting Column	Y O See not	0		IRB/EC Approval Date

Viewing or Editing Site Profiles

After selecting the required view as shown above, the user can edit a site profile as follows:

1. Select a site from the grid.

2. Click Edit in the menu ribbon to open Site Profile of the site selected. The site profile opens, or Double-click a site from the grid to open its Site Profile window.



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ш	Training Tear Start-Up / 1	m eTMF Room 👻 Sites				Q Se	arch O Add	• A YOgesh Inamo
	Site Activation	=	Hagrid's Animal Hospital Esse	ntial Documents All Documents	Communication Log Institutions			
639	By Status	- T 0 0	Required fields are marked with an a	sterisk (*)				Essential Documents Progress
•	🕶 🖕 All		Institution Name: *	Hagrid's Animal Hospital				Investigative Site Hagrid's Anima
	Active [5]		CRA:	* Reader 103 * Editor 10	4 x Editor 105 x Editor 100 x Eddie 101 x	Editor 102	~	100%
	Non Parti	icipating [1]	Start-Up Specialist:				~	Site Activation Date:
	Rending I	[10]	Contacts					07 Apr 2020
л	- Chung	[10]	O Create O Add existing	🖌 Edit 🙁 Delete 🛛 🔘 De	eactivate 🛛 💄 Convert to user(s)			
			Last Name 🔺	First Name	E-mail	Contact Type		
			🔄 🗶 Ollivander	Edward	owandmaker@ollivander.com	Principal Investigator		
100								
æ								
			- Mddress					
8			- More					
1			Edit History:	Profile created by Editor 10 Last updated by Admin 104	4 on 4/7/2020 9:26:26 AM EST on 8/14/2020 7:19:13 AM EST			
To			⊘ Close Site ⊨ Save O Ca	incel		🖻 Requirements	🛚 Ҟ Security 👻	Legulatory Approvers: 1
9		aatomatican	Grid Profile	Site 1/5 > H	ai - i i i i i i i i i i i i i i i i i i			

Besides these, based on the Projected IRB/EC Approval Date and Start-Up Processing time (specified in the Study Start-Up Settings), the system will also display the Projected Site Activation Date on the right panel. Refer to the screenshot below:

T R I A L INTERACTIVE

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quired fields are marked with an a	asterisk (*)				Essential Documents Progress
Last Name 🔺	FIRST Name	E-maii	Contact type	*	Investigative Site country test 2
🔲 🔔 Chakraborty	Polly	pchakraborty@tra	nsperfect Principal Investigator		0%
🔲 💄 User	New	nwuser2017@gma	ail.com Study Coordinator		
					100%
Addross					Country India
Address					100%
Maria		IRB/EC			Reg. Pack Sent Date:
more		Profile Committee			09 Oct 2017
xpiration Date:		IRB/EC Name: *	SCHULMAN Associates IRB	× 🛅	Expected Submission Date:
Status:	Pending test	IRB/EC Type: " Address: "	Central 4445 Lake Forest Drive, Suite 300		18 Jan 2018
Site Email Domains:	example: mail-1.	City: "	Cincinnati		IDB/EC Submit Date
		State: *	OH		22 Jan 2018
		Zip Code:	45242 United States		
Reason for not using auto:*	test	Region:	North America		Projected IRB/EC Approval Date:
		Approval Cycle:	⇔ week ¥		22 Feb 2018
Preferred Communication Mode		Buffer Time:	Sefect x Every 2 day from 10 Oct 2015 to	~	Projected Site Activation Date:
RB/EC Type:	Local	Submission Deadline:	Select × Every week on the following occurrence: 11.0472017	~	24 Feb 2018
RB/EC Name:	Karthick Test	About	Study Start Up settings *	* +	
Reg. Pack Sent Date:	09 Oct 2017	Do not publish the	documents on eTMF when the site	×	
Expected Submission Date:	18 Jan 2018	_ Essential documents.	Publish to Index	×	
RB/EC Submit Date:	22 Jan 2018	Non-essential docum	ents: Publish to eTMF ¹	×	
nvestigative Site Name1:		Do not allow addit	ion of new documents for a site afte		
eFeasibility Status:		Allow paper docur	nents 🔞	~	
Cita Nama		Regulatory approvers	Select 1 user(s) se		
site name:		Start-Up processing	time (days): 🚺 2 🗘 🤤 🕘		

But if there are no IRB/EC Submit Date and Expected Submission Date specified in the site profile, the system will not display them in the right panel. Instead it will project the Next Pre-Submission Deadline Date based on the meeting

schedule specified in the IRB/EC profile. To display the Projected IRB/EC Approval Date, the system will use the Next Pre-Submission Deadline Date. The process to project the Projected Site Activation Date remains the same as mentioned above. The projected Next Pre-Submission Deadline Dates can be viewed by clicking the last calendar icon next to the Expected Submission Date field.

6. Make necessary additions or changes to the data fields in the profile. Refer to Adding sites and sites contacts in case of clarifications.

7. Click Save at the bottom of the panel.

Exporting Sites

Here the users can export

- Selected Records
- All Sites in the current grid
- All Sites in the data room

1. To Export a single site or a specific set of selected sites, select the site or sites by clicking the check box or boxes at the left side of the grid.



- 2. Click Export in the menu ribbon above the site grid. The Export window opens.
- 3. Choose the Source from the radio buttons. The export Format is preselected as Excel and cannot be altered.

Export	×
Source:	 Selected Records
	 All Sites in the current grid
	 All Sites in the room
Format: *	Excel
Metadata:*	Site Number, Site, Principal Investig ¥
Contact Metadata:*	Investigative Site Name, SiteNumbe
	Export Cancel

- 4. Activate the Metadata dropdown menu to the right of the metadata field.
- 5. Select which metadata fields you want to include in the export. By not activating the dropdown, you will leave all metadata fields active and the

Export			×	Anderson wary
Source:	 Selected Rec 	ords		idge Delores
	 All Sites in th 	e current grid		Harry
	 All Sites in th 	e room		use Elf Doby
Format: *	Excel	¥		use Eli Doby
Metadata:*	Site Number, Site	e, Principal Inv	/estig 💙	
Investigative Site I	Data			Deselect All
N Site Number		Principal I	Investigator	
Site				
Additional Fields	Field Sort Order	: Alphabetica	al Logica	Select All
Closed Site		Non Parti	cipating Site	e
CRA		PI First N	ame	
eFeasibility Sta	atus	PI Last Na	ame	
Expected Subr	mission Date	Progress	96	
Expiration Date	e	Reg. Pad	k Sent Date	
IRB/EC Approv	val Date	Site Activ	ation Date	
IRB/EC Name		Site Emai	l Domains	
IRB/EC Submi	t Date	Start-Up Sta	Specialist	
Main Contact		Status		
Main Contact F	Phone			+

export will include all fields.

6. By the same method, select which contact metadata fields you would like to include in the data export.



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Export			
Source:	 Selected Red 	cords	idge Delores
	 All Sites in the current grid 		Harry
	 All Sites in th 	ie room	use Elf Dobv
Format: *	Excel	¥	,
Metadata:*	Site Number, Sit	e, Principal Investic 🌱	
Contact	Investigative Site	e Name, SiteNumbe 🌱	
Contact Metadata			Deselect All
Investigative Sit	e Name	Address	
SiteNumber		City	
Active Contact		State	
Contact Type		Country	
User Name		ZipCode	
First Name		Mobile Number	
Last Name		Phone Number	-

7. Once you have made the appropriate selections, click Export. When the export is complete, you are notified about the Get Job Result in a popup.

8. To view the exported file, navigate to the Notifications .

Mass Coding for Sites

During the initial room configuration, the metadata fields that are available for mass coding are marked in the room's Form Settings (*page* 93)by the room's administrators. Once that process is done, it is possible to use mass coding for metadata fields of Investigative sites.

To mass code sites:

1. Select the investigative sites from the list in the grid that have common metadata fields that need to be coded by clicking the check boxes to the left of the Investigative sites grid.

Mass Coding			X
 Selected Records 		Clear	*
Country	India		
CRA	Editor Training		
Start-Up Specialist	Admin 102		
Reg. Pack Sent Date	01 Sep 2020		
Expected Submission Date	30 Sep 2020		
IRB/EC Submit Date	15 Sep 2020		
IRB/EC Approval Date	21 Sep 2020		
•		l F	-
	Save	Cancel	

2. Click the Mass Coding button in the menu ribbon. The Mass Coding window opens.

3. Double-click the fields in the Value column that you intend to code for all of the selected sites. The field becomes active.



4. Fill in the data that is common to all of the selected sites. Some of the fields are associated with calendar selections and some with dropdown menus.

5. When you have completed entering the common metadata, click Save at the bottom of the window. A Confirm? Window opens.

Confirm	n? 🗶
8	Are you sure you want to proceed with Mass Update?
	Yes No

6. The coding changes will be added to the site profiles. Note that if the requested coding additions or changes conflict with existing Investigative site profile metadata, the user will see a warning message.

In such cases, the coding requests will not be completed. The previously existing metadata will remain as part of the site profile. To make such changes to the site profile, the user must use the Edit function described earlier in this guide.

Searching for Sites

To search for sites from the grid pane, enter the search pattern in the Search textbox in the top ribbon bar and click the magnifying lens icon or hit Enter. Sites matching the search pattern will be displayed. The system will not only select sites that match the pattern from the columns in the Grid Pane, it will also display sites that have matching searches from the

ш	★ Training Team e Start-Up / Site	eTMF Room 👻								Q Search 🛛 Add 👻 🌲	Yogesh Inamdar -
	Site Activation		=	OAdd	/ Edit	🗢 Delete 🕴 🕈 Import 🛛 🐥	Export 📲 Mass Coding 📾 !	Send Reg. I	Packet 🎋 Manage Security 👻		Mary ×
	By Status	~ Y	00		Site Nu	Principal Investigator	Institution Name *	Status	Site	IRB/EC Name	Progress %
0	- 🖻 All			0 *	123456	Mary Anderson	St. Joe's University Hospital	Active	Site - 123456 Anderson Mary	Chesapeake IRB	100%
	💕 Active [5]										
0	💕 Non Participa	ating [1]									
	🞽 Pending [10]										
<u>×</u>											

site profiles. For example, if a site has a contact that matches the search pattern, it will be displayed.

Deleting Sites

1. Select a site from the list.

2. Click Delete in the menu ribbon. A window pops up, asking for confirmation that you want to delete the site. It also prompts you to enter the reason for deletion.

Confirmation needed	X
Delete investigative site Becky Site? Please enter the deletion reason:*	
Delete Cancel	

3. Enter the reason and click Delete.

4. Sites cannot be deleted if they have already collected documents and you will receive a message warning you about the same in a popup.



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1	Warning		ßX
	Some issues occurred dur	ing deletion:	
	Site	Issue	
	Cauldron Cake University Hospital	14110 - There are documents associated to the site. 14111 - There are documents associated to the site folders. 14114 - It is used in audit profile configuration	
		Clos	e

Ξ

Note: To delete a site, its documents must first be deleted.

Setting up Site Specific Required Documents

The required / essential documents specific only for a particular site can be set up through the Requirements button located at the bottom of the Sites Profile dashboard. This is discussed as below:

1. Double-click the site from the Grid Pane to open the Sites Profile window.

2. Click the Requirements button located in the lower toolbar of the Sites Profile window. This opens the Required Documents window.

3. Click Add from the menu bar in the window.

- 4. Select the document types as required from the collapsible tree.
- 5. Tick the checkbox for 'Site Activation' and select the contacts from 'To be submitted by' dropdown.
- 6. Click Save to add the required document type and continue adding, else click Save & Close to add and exit the window.

Institutions or Additional IRB/ECs

Although clinical trial organizations today adhere to protocols from a central IRB/EC, at times it might be required to adhere to protocols of more than one IRB/EC. For example, an organization may have one central IRB/EC, and one or more local IRB/ECs.

In the Site profile, you will be able to specify only one IRB/EC of any type. In case you need to provide additional IRB/ECs, proceed with the steps as below:

1. From the Grid Pane, double-click the site for which you want to specify additional IRB/ECs

- 2. The Site Profile window opens.
- 3. Click the Institutions tab.
- 4. Click Add from the top menu bar.



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5. The rest of the procedure is the same as specified in sections Adding or Creating New IRB/ECs (*page 512*) and Adding Existing IRB/ECs to Data Rooms (*page 513*)

6. The procedure to add from existing IRB/ECs is also the same, with the only difference that from within a site, the Add Existing functionality will only display the IRB/ECs available in the data room.

Viewing History

From a site profile window, you can also view histories related to site edit, contact activities,

and milestone.

Site Edit History

1. Double-click a site name from the Grid Pane to open the site profile.

2. Click the Show Edit History icon located on the toolbar at the bottom.

🖻 Requirements	🎙 Security 👻 💄 Regulatory Approvers: 1 🔤 📮 🖡	
	Show dit histo	ny j

3. This opens the Investigative Site Edit History window which contains information on the site creator and also the last updated by user.

Investigative Site	Edit History			C X
Date	Updated By	Activity	Description	
04 Sep 2020 2	Yogesh Inamdar (yinam	Investigative site was updated		-
03 Sep 2020 1	Admin 103 (Tladmin103	Access Topic		
03 Sep 2020 1	Admin 103 (Tladmin103	Access Topic		
03 Sep 2020 1	Admin 103 (Tladmin103	Access Topic		
14 Aug 2020 1	Admin 104 (Tladmin104	Investigative site was updated		
14 Aug 2020 1	Admin 104 (Tladmin104	Access Topic		
14 Aug 2020 1	Admin 104 (Tladmin104	Access Topic		
10 Jul 2020 02	Admin 103 (Tladmin103	Access Topic		
10 Jul 2020 02	Admin 103 (Tladmin103	Access Topic		-
			Clos	e

4. The information here cannot be edited. Click Close when you are done with viewing.

Site Contact Activities History

1. Double-click a site name from the Grid Pane to open the site profile.

2. Click the Show contacts history icon located on the toolbar at the bottom.





- 3. This opens the Contact Activities window which contains information on the site contacts and also their activities.
- 4. Select All contacts, or a specific contact from the dropdown to retrieve the details of only that ______ contact.

Contact Activities					ßX
⁶ All contacts	*				
All contacts	ontact Type	Updated By	Activity	Description	
Eddie 101 Editor 100		Admin 104 (Tlad	Investigative Site Secu	Replace	*
Editor 102	RA	Admin 104 (Tlad	User added as contact	Sponsor Contact	
Editor 104 Editor 105	RA	Admin 102 (Tlad	User added as contact	Sponsor Contact	
Edward Ollivander	RA	Admin 102 (Tlad	User added as contact	Sponsor Contact	
Reader 102 Reader 103	RA	Admin 102 (Tlad	User added as contact	Sponsor Contact	
Reader 104	RA	lahu gonde (lgon	User removed from inv	Sponsor Contact	
30 Apr 20 Editor 105	CRA	lahu gonde (lgon	User added as contact	Sponsor Contact	
29 Apr 20 Editor 102	CRA	Karthick Arul (kar	User added as contact	Sponsor Contact	-
				Clos	se

5. The information here cannot be edited. Click Close when you are done with viewing.

Managing Security

We have already seen in section Accessible functionalities for SSU Users (*page 520*) the types of security privileges provided by Trial Interactive system to the users and contacts of investigative sites. The security privileges can be provided for all sites in a data room, as well as from within the Study Start-Up Sites section.

Access to users for all sites can be provided by adding the site users to Default editors/readers group, or by making them Default access members of sites.

From within the SSU Sites section, the administrator can view and provide security privileges to users for site/s from two locations:

Note: The administrator has to be site members like a SSU Specialist, or Co-Investigator, or Site Activation Member to be able to manage security of sites from within the SSU Sites section.

1. The Manage Security dropdown on menu bar above the Grid Pane:



From the Grid Pane the administrator can assign Editor and Reader accesses to users/group of users, thereby making them contacts of multiple sites. By selecting the checkboxes next to the site names in the grid the administrator can make the selected users/groups member to multiple sites at one time. This is helpful if contacts will have same privileges in multiple

O Ado	📝 Edit	🗢 Delete 🕴 🛧 Import 🛛 🕹 Ex	port 💕 Mass Coding 📋 🎫 S	end Reg. P	acket 🛛 🕅 Manage Security 👻
	Site Nu	Principal Investigator	Institution Name -	Status	Site L Editors
≥ ★	1777	Edward Ollivander	Hagrid's Animal Hospital	Active	Site - 1777 Oniversed dward
≥ ★	123456	Mary Anderson	St. Joe's University Hospital	Active	Site - 123456 Anderson Mary
≥ ★	1	Delores Umbridge	Test Site #1	Active	Site - 1 Umbridge Delores
		Harry Potter	Test Site #2	Active	Site - Potter Harry
•		Doby The House Elf	Test Site #3	Active	Site - The House Elf Doby

sites.

2. The **Security** dropdown from within a site profile window:

From within a Site Profile, the administrator can assign Editor, and Reader accesses to users/group of users for only the particular site whose profile he/she is accessing at the moment.

Securit	Security - Readers											
Users		*			Search		Q	Sele	cted U	Jsers		
	Last	First	Email	Ph	Мо	Orga			Nar	me	Email	
•			Test121			ti.com		•	Del	ores Umbridge	umbridge@ti.com	
• 1			testedito			ti.com		•	Rea	ader 102	TIReader102@ti.com	
• 1			testread			ti.com						
•			jtrouble			Hog						
•	100	Reader	TIReade			ti.com						
• 1	100	Editor	ti_editor			ti.com						
•	101	Reader	TIReade			ti.com						
							*					
	C Page	1 of 1	\gg \mathbb{N}	O Di	splaying	users 1 - 41	of 4	Select	the us	ers by double clicking	or drag the entries to this pa	ane.
											OK Cancel	

Besides these, the administrator can also view the contacts who are assigned Editor, and Reader privileges in the site/s, from the right pane of the Security dialog box. Refer to the screenshot above.

Note: The procedure to add users to default editors/readers groups is described in details in the User Management (*page 67*)section .



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Countries

Since studies can be conducted in multiple countries across the globe, it is important for the administrator to add the countries where the clinical trial is taking, and the investigative sites located in the country during its initial setup and configuration. The following section discusses:

- 1. Viewing and editing country profiles
- 2. Viewing documents

Note: Adding countries, and essential/required documents to countries are discussed in sections Adding Countries to Data Rooms (*page 511*), and Setting up Required Documents for Countries (*page 514*) respectively

The Start-Up **Countries** tab accessed from the toggling menu bar on the left, allows you to set up documents for countries associated with sites. The Countries dashboard consists of the Current view on the left and the Grid pane on the right.

Viewing Countries

Countries in which the sites are located can be viewed from the list of countries appearing in the grid pane. The list of countries appearing in the grid and current view pane depends on the filter selected by the user in the current view panel. Refer to the screenshot below.

	Site Activation	Country Name	Language	Progres
•••	Current View	India	Hindi, English	0%
0	- All	North Macedonia	Macedonian	0%
	🖹 India			
\odot	North Macedonia			
즈				
The	e Countries Current Vie	W		



Site Activation	- Ober
A Site Activation	
Agency Submission	
No. 1 and a second s	

The Current View of the Countries associated with sites is based on:

1. Site Activation

2. Agency Submission (this section is used for Submission Packages)

Site Activation



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Choose **Site Activation** as your Current View. This view reveals a list of countries for which specific documents need to be submitted and

Site Activation						
Current View						
🗕 🖿 All						
🖺 India						
🖺 North Macedonia						

approved. Refer to the screenshot below.

A country name will be visible in the Current View listing only if the **essential documents** required for site activation for that country have been set up.

The Countries Grid Pane

The Grid Pane on the right provides a list of countries for which documents are required along with the Progress % bar to the extreme right showing the percentage of the essential documents submission

Country Name	Language		Progress %
India	Hindi, English	Missing Documents	
North Macedonia	Macedonian	 15.1 Hippo T6	0%

progress. Hover the mouse pointer over the Progress % bar to get a popup with a list of Missing Documents. Refer to the screenshot below.

Viewing or Editing Country Profiles

1. Click the country name in the Current View panel, or double-click the name of the country in the display grid in the middle of the screen.

2. The editable fields of the country profile become available in the center of the screen. The Essential Documents Progress graph also appears on the right side of

Site Activation	India Essential Documents Al	Documents Communication Log	
Current View	Country:*	India	Essential Documents Progress
▼ 🖕 All	Expected Approval Date:	30 Sep 2020	Country India
India	Status:	Completed	
North Macedonia	Approved Date:	× 🗎	
	Comments:		
	Room Contact #:		

the screen for that single country.

3. Click the data fields in the profile to add or edit profile information.

4. Click the Members dropdown at the bottom right corner of the Profile window. From here you can select users who will have Full Access, or Read Only access to the sites under the specified country.





5. Click one of the options from the Members dropdown. This will either open the Full Access Members window, or the Read Only Members window for you to select the members. Click **Ok** after you are done.

6. Select Users/Groups from the dropdown.

7. You can select the users/groups by double-clicking them from the left panel to transfer them to the right pane, or dragging a user/group from the left pane to the right pane.

8. Click **Save** at the bottom of the panel to save your changes, or click Cancel to reset the changes you have made.

Submission Packages

It is common practice to associate health agencies with sites and send submission packages to them for their approval. Sites can't be activated for the clinical study unless the agency approval is received. A study may have multiple health agencies located in various countries. These agencies may have more comprehensive site activation submission packages involving hundreds of documents and that need to be reviewed and approved. Since the agencies are related to countries, submission profiles and packages for them are accessed from the **Countries** Section.

This module allows you to prepare submission profiles where the user can provide the details such as agency name, country, status of submission, documents to be included in the submission profile, date when the package was submitted, and also the status of the submission package.

A submission package can contain documents from the eTMF, SSU, Site, Country, and IRB, or any document from the disk. For instance, the IB and protocol are already filed in the eTMF but are required for the submission package. The clinical trial organization downloads the submission package to perform QC Review as in other documents and then forwards it for regulatory review. All the actions from creating, and editing submission profiles to downloading submission packages for health agencies can be performed by an **admin or editor**.

Through the Agency Submission section in Trial Interactive, the organization can track multiple submission packages for the same country in case one submission package is rejected. Once a site is activated, these documents are not transferred to the eTMF and are left in the submission package.

Defining Health Agencies

Before adding submission profiles and downloading packages, it is essential to define health agencies to be associated with sites. Health agencies need to be defined at domain level.



Note: Contact the helpdesk to create Health Agencies, if they are not already created.



Agency Submission

Select Countries from the toggling menu bar. Choose Agency Submission as your Current View. This view reveals a list of countries where health agencies are available with their details. Refer to the screenshot below, which shows the view of the left pane.

Agency Submission	
Current View	oU
T 🔁 All	
Argentina	

The Grid pane on the right reveals the country-wise submission profiles that are submitted to the agencies. Through this pane you can Add, Edit, Delete submission profiles, add packages to the profiles, and download them for further processing. Refer to the screenshot below:

OAd	🛿 🧪 Edit \ominus Delete 🛛 🖶 Download Package		Search	ρ
	Title •	Country	Agency	
	Test	India	Indian Drug Agency	

Adding or Creating Submission Profiles

To create a submission profile, follow the steps below:

- 1. Select Agency Submission as your Current View.
- 2. Select the Country where you want to add submission profiles.

3. Click +Add from the menu bar located on top of the Grid Pane. The Create Submission Profile window opens. Refer to the screenshot below:

Create Submission Profile							
Required fields are marked	d with an asterisk (*)						
Agency Name:*							
Country:*	Argentina						
Agency: *	Not specified						
Submission Date:	× 🖬						
Submission Status:	Pending 💌						
Comments:							
Attachments:	O Add O Delete Document Name						
Download Packag	e Save Cancel						

4. Enter the Agency Name, Country of its location, and other details as asked in the form.

5. Click +Add , to upload documents as a part of the submission package of the profile you are creating. Kindly note that the Submission Status has to be Pending to submit documents.

6. Click Save.



Adding Site/Country/IRB Documents to Submission Packages

To add site, country, or IRB/EC documents to a submission package, follow the steps as

below:

1. Navigate to Documents section from within the SSU module.

2. From the Current View, select 'By Site' for adding site related documents, 'By Country' for adding country related documents, and 'By IRB/EC' for adding IRB/EC related documents to a submission package.

- 3. Selecting an option, will list the sites, countries, or IRB/ECs in the Current View pane as per your choice.
- 4. Select a site, country, or IRB/EC as required.

5. This will list all essential/required documents, as well as non-essential documents in the Grid Pane.

6. Select the document/s as required for adding to a submission package.

7. Add the documents to the Documents Cart by selecting Add Selected to the Cart option from the right-click menu, or Documents dropdown, or by dragging and dropping the selected documents to the Document Cart.

8. You can continue adding documents to the cart from as many filters in the Current View dropdown.

9. Once you have completed adding documents to the cart, click Documents Cart -> I want to...Add to Submission Package to add documents to add them to the required submission package. Refer to the screenshot below:

arch for documents or sele 🗸 🔍 🤜	👻 Documents Cart (1) 🔻	Document Data
lev 🖉 FDF_Sub_l.pdf	Remove All	Required fields are marked with an
		Document URL:
		Milestone Date:
Sieve Glain	I want to 👻	Milestone:
Steve Clark	Link Docume Add to Strong Downloa	ents nission Package All documents will be processed.

10. The Select a Submission window opens. Select a submission package as required from the list and click Add document(s) to Submission. The number in a red circle with a blue link is the number of attachments already uploaded to the submission package/profile. Refer to the screenshot below.

11. Navigate to Start-up -> Countries. Reload the page for the uploaded documents to be updated to the package.

12. Open the country under Agency Submission from Current View pane on the left and notice the change in the number of attachments besides the profile name on the Grid pane.

Adding Documents to Submission Packages from the eTMF

As an admin or editor, besides adding documents to submission packages through the processes described above, you can also add documents from the eTMF.

To add documents to a submission package from the eTMF, follow the steps as below:



- 1. Navigate to eTMF -> Documents.
- 2. Select the folder which contains the document you want to upload from the left pane.
- 3. Select the documents to be uploaded from the right pane.

4. Add the documents to the Documents Cart by selecting Add Selected to the Cart option from the right-click menu, or Documents dropdown, or by dragging and dropping the selected documents to the Document Cart. Refer to the

Inbox	*		Do	cument	👻 📼 E-Mail 🛧 Impo	ort 📓 Move to the eTMF	Search for do	cuments or sele •	Q +	🐏 Documents Cart (2) 💌
Steve Clark					Submitted Name	Generated Name	QC Review	Reg. Revie	Added By	
		_		*	DataPrivacyAgreem				Steve Clark	
				\star	Dr. A-CV.pdf				Steve Clark	
			•		FDF_Sub_I.pdf				Steve Clark	
			•	*	Feasibility Documen				Steve Clark	
				\star	IEC-IRBRoster_pdf				Steve Clark	

screenshot below:

5. Add the documents to the submission package by clicking Documents Cart -> I want to. Add to Submission Package,

and select the submission package as required from the 'Select a Submission' window.

6. The rest of the procedure is the same as described in earlier section.

Downloading Submission Package

Once the documents are uploaded to the required submission package, you may download the package for further processing.

To download a package:

- 1. Select the required profile from the Grid Pane.
- 2. Click Download Package from the menu bar on the top of the Grid Pane, or
- 3. Click Edit from the menu bar and click Download Package.
- 4. You will receive a notification regarding the documents downloaded. The documents are downloaded in a .zip format.



Editing a Submission Profile

Once the documents are downloaded, you can edit the submission profile and change the Submission Status to Submitted and click Save.

Edit Submission Profi	le: Trial				×
Required fields are mark	ed with an asteris	< (*)			
Agency Name: *	Trial				Î
Country: *	Canada			*	
Agency: *	Candian He	athcare Agency		¥	
Submission Date:			×		
Submission Status:	Submitted			~	
Comments:					
Attachments:	O Add	Delete			
4	C	ocument Name			
	📄 🔼 t	est doc 4			
🔸 Download Package			Save Cano	el	

Refer to the screenshot below:

After the Submission Status is changed to Submitted, the profile is locked from further additions of documents to it. Notice that the **+Add** and **-Delete** buttons are now disabled, which means further additions to/deletions from the submission package is now prohibited.

To add further documents you have to create another submission profile. Kindly note that you can use **Edit** to also make other changes in a submission profile as required.

Deleting a Submission Profile

To delete a submission profile, select the required profile from the Grid Pane and click the Delete button from the top menu bar.





A message asking you to confirm the deletion appears in a popup. Click Yes to delete the profile. Refer to the screenshot below:

Delete	Agency Submission	×
?	Do you really want to	o delete Agency Submission?
8	Yes	No

IRB/EC

It is essential for sites to adhere to the protocols as set by the IRB/ECs for more efficient and effective performance of clinical trial operations. Today organizations are encouraged to use central IRBs as opposed to multiple local IRBs. But the decision to use central or local IRBs or more than one IRB of any type for a clinical trial depends upon the clinical research enterprise, especially if it intends conducting multi-site trials.

Trial Interactive supports the use of both central and local IRBs. Although it is advisable to use a single central IRB for multi- site trials, sites may need to use more than one IRB/EC. Trial Interactive not only allows you add IRB/ECs as required, it also allows you to specify additional IRB/ECs. In this section we will discuss the following:

- 1. Adding additional IRB/ECs to data rooms
- 2. Viewing IRB/ECs
- 3. Editing IRB/EC profile

Adding additional IRB/ECs

You can specify more than one IRB/EC for a site from within the Sites module of SSU. Proceed to section Institutions or Additional IRB/ECs (*page 538*) for more details on this.

Viewing IRB/ECs



Clicking the IRB/EC tab from the toggling menu bar on the left, will list IRB/ECs available to the room. The IRB/EC dashboard consists of the Current view on the left and the Grid pane on the right with the progress bar showing the percent of essential documents collected for each IRB. It

	Training Room 1 - Start-Up / IRB/EC	
	Site Activation	
• • •	Current View	IRB/EC Name -
0	- All	Local IRB
	SCHULMAN Associates IRB	SCHULMAN Associates IRB
\odot	Local IRB	The Swedish Institutional Review Board
	The Swedish Institutional Review Board	
쓰		

also has a Search textbox in the top right corner to search for IRB/ECs. Refer to the screenshot below.

The IRB/EC Current View

The Current View panel on left lists the IRBs that have accumulated one or more of the essential IRB documents for the study. An IRB/EC

Site Activation
Current View
- All
SCHULMAN Associates IRB
Local IRB
The Swedish Institutional Review Board

name will be visible in the Current View listing only if the essential documents required for site activation for that IRB/EC have been set up.

The IRB/EC Grid Pane

The IRB/EC Grid Pane on the right provides a list of IRBs for which documents are required along with the Progress % bar to the extreme right showing the percentage of the essential documents collected. Hover the mouse pointer over the Progress % bar to get a popup with a list of Missing Documents.

Viewing and Editing IRB/EC Profile

1. Click the IRB name in the Current View panel, or double-click the name of the IRB in the Grid Pane.

2. The editable fields of the IRB profile become available in the center of the screen. The Essential Documents Progress graph also appears on the extreme



right of the screen for that single IRB.

- 3. Click the data fields in the profile to add or edit profile information.
- 4. Click Save at the bottom of the panel to save your changes, or click Cancel to reset the changes you have made.

Regulatory Packets

When all required documents are collected, the Start-Up Specialists, or the sponsor, or CRO forwards an initial regulatory documents packet for collecting the documents from various contacts in the site. Main contacts receive emails with a list of regulatory documents required. If no main contacts are specified for a site, then the Principal Investigator of the site will

receive the email. The administrator can set up the email template that would be sent out with regulatory packets. The email can also include document templates as attachments for specific document types if the clinical research

enterprise wants to adhere to specific formats for the documents. The Main contacts, on receiving the email, go about the task of collecting the documents, getting them approved from the Principal Investigator, and submitting them to the site. They can submit documents to the site by logging into the site and adding them, or by emailing them to the room. If the documents are emailed into the room, it is the SSU Specialists' responsibility to add them to the sites.

You can choose to send regulatory packets for one or multiple sites. Before sending regulatory packets, admins can set up email templates and document templates for specific document types as required.

Setting Up Email Templates

The administrator can set up the body of the email template from the room's settings. By default, the system provides a template body with the insertions needed to tell the system to send the names of essential/required documents, and the name and contact details of the



SSU Specialist.

All the administrator needs to do is insert the email text description. To set up the template,

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proceed as follows:

- 1. Navigate to Settings.
- 2. Select Email from the left panel and click the arrow next to it.
- 3. Select Email Templates from the collapsed dropdown.
- 4. The Email Templates window opens in the right.
- 5. Select Reg. Packet Email from the Template type dropdown.
- 6. The default template populates itself.
- 7. Click the appropriate location in the editor and insert the email body as per the format provided by your organization.

8. Besides the insertions already provided by default, you can insert your own insertions in the email body for the PI name, Domain Name, Room Name, and Investigative Site details by choosing appropriate options from the Insertions dropdown and clicking Insert next to the dropdown.

9. Click Save to commit the changes.



Setting up Document Templates

To set up document templates, follow the procedure as below:

- 1. Navigate to Settings.
- 2. Select Document Templates from the left panel.
- 3. The Document Templates window opens in the right.
- 4. Click Add from the top menu of the window to create a template.
- 5. The Create Template window opens.
- 6. Enter the details as required. You can choose to create templates for General



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category documents, for All Sites, or for specific country or site from the Category section of the window. One document template can be created for any one of the categories mentioned above. Hence select a radio button as required.

7. Select the Document type and provide the attachment specifying document template for the document type.

8. To include the template in regulatory packets, tick the Include In Reg. Packet checkbox. Document templates included in regulatory packets will be sent even for non-essential/required documents for the selected investigative sites.

Refer to the screenshot below:

Search	Q	About	Document Templ	ates *			
La Canaral		O Add /					
, General		Temp	olate Name		Description	Category	
OP Milestones		Image: 1572				All Sites	
🗳 Inbox		O 🛄 Other	r CV	Create Template		×	
la Outbox				Required fields are m	arked with an asterisk (*)		
Ø Documents Distribution				Template Name:*	Regutaory Package Sampl	e	
E Forms Settings				Description:	This will be the template fo	r Regulatory Packages	
) 🛪 General Integration							
Documents				Category:*	General All Sites		
Document Types					O Specific Country		
B Required Documents					Select No countries se	ected	
Countries					 Specific Site 		
M Investigative Sites					Select 1 investigative	site selected 😧	
C intestigative Sites				Document Type:	Oversight\01.01.02 Trial M	anagement Plan\SiteSelectStrat	
Ø IRB/EC				Attachment *	No Attachments selected	Q	
Email							
Document Templates							
🕨 🗾 Audit							
Vorkflows				Include in Reg. i	Packet 👔	Create Cancel	
Security							
E-Signature							

Sending Regulatory Packets

It is possible to send docs within a regulatory pack with the following options:

1. None

2. Links

3. Attachments.

This is similar to the Email documents functionality and can be configured from Settings -> Investigative Sites -> Regulatory packet Options. Refer to the screenshot below:



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	a	ADOUT	Regulatory Pa	cket Options		
Investigative Sites General Settings Study Start-Up settings	•	Regula	Send packet as: tory packet default	None Links Attachment Reg. Packet		
 Submission Profiles Status Template Folders Investigative Sites Status CRA Visit Types CRA Visit Status 		You have	to update titles of all re	ulatory packet related fields in the	forms settings after regula	tory packet rena
 Regulatory Approval Status list Communication Types Issues 						

To send regulatory packets follow as below:

- 1. Select the site/s for which you want to send regulatory packets from the Grid Pane.
- 2. Click the Send Reg. Packet button from the top menu bar in the Grid Pane.
- 3. A Confirmation needed pop up opens asking you to confirm your action. Click Yes to continue.

Confirm	ation needed	X
2	Are you sure you want to send Reg. Packet to the following site(s)?	
· ·	Site - Potter Harry	
	Yes No	

4. Once the regulatory packet emails are sent to the main contacts in the site, you will receive a status message stating the issues faced by the system while sending the emails, or stating that the process was completed successfully.



Sendin	ng Reg. Packet	X
•	Sites were processed with issues	
100 %	6	
Details Test 5 site	s: Site #2: Cannot send Reg. Packet to activated investigative	
	Close	

5. The document templates, if created and specified for the selected sites, will be included as attachments in the emails. Below is the screenshot of a sample

Rev 188-121-01-00 Study		leal
Dear Innectigator and Site Staff.		buil@hielintasictive.com
Your response to questionnaires and additional communication indicate your with reveals the requirement indicatery fills important study. XXX is pleased to satend the offer of participation in the MM-12 of CP XXX team we would like to earnly net zero you and look formad to variety with you the motific alread. Tables a system generalized email so please do not reply to this but fallow the inductions it	21-01-02 study to you. On behalf sted below	113 - Store defails
Included you will find recessary documents required to start-go. To estable a quick start-go ve would like to work with you in the incut efficient manner possible to ensure your affe in ready to performe in to participation we will noted to collect the following occential documents.	t the registry. Befare opening your elle	6
SAE Depend Programme of Recording IP Despend Construction Expendence CRF Expendence CRF Sale Cart from the Sale Cart from the Sale Cart from the Sale Cart from the		
Piece submit the documents lated above to 1/31/121-07-070-070-070-070-070-070-070-070-070	2	
This study will be managed by XXX and tenting details will be provided in the sear fears. If you have any questions or concerns, please do not besite to context as. Then Eyru for your time and comes MM-121-01-22-28 Auty and boot fermini to waiting with you?	ferefice. We welcome people to this	
Thereix		
The Faste		
Tanggitsinitaterarchive.com	4-52 PM (19 hours ago) 🖄 🔸	•
2 Attachments		0
W Mathematica		

email:

When the regulatory packet is sent, and the site status is 'Pending', the system will automatically create a task for the SSU Specialist for the next submission deadline. The task thus created can be viewed in the Tasks module accessible from the Navigation Grid.

Collecting Essential and Non-Essential Documents

Once the document requirements are configured, documents can enter the room through three methods depending on preference and access:

1) Via a unique SSU email address



2) Via mass Import (follow to Documents section for import of documents).

3) Via individual document attachment

As mentioned earlier, all the sites, countries, and IRB/ECs require addition of essential and

non-essential documents to them.

The Grid Panes of sites, countries, and IRB/ECs allow you to add Essential Documents, non-essential documents, and add / edit communication logs. The procedure to add documents is the same for sites, countries, and IRB/ECs, and is discussed below.

Essential Documents

Setting up of Essential Documents for Sites, Countries, and IRB/ECs involve the following steps:

1) Adding Required/Essential Documents from Settings for Sites, Countries, and IRB/ECs.

2) Adding, editing, and reviewing documents of each Essential Document type from the menu bar.

The Top Menu Bar

	Training Team eTMF Room - Start-Up / Sites							Q Search O Add •	۰ 💕	Yogesh Inamdar 🕶
	Site Activation	=	O Add / E	dit 😄 Delete 🛧 Import 🔮	Export 📲 Mass Coding 🚥	Send Reg.	Packet 🔰 隆 Manage Security 👻			Search
••••	By Status 👻 🍸	00	Site N	Principal Investigator	Institution Name .	Status	Site	IRB/EC Name		Progress %
0	🔫 🖕 All		□ ★ 1777	Edward Ollivander	Hagrid's Animal Hospital	Active	Site - 1777 Ollivander Edward	Hickory Hollow IRB		100%
	Active [5]		12345	6 Mary Anderson	St. Joe's University Hospital	Active	Site - 123456 Anderson Mary	Chesapeake IRB		100%
	Training Team eTMF Room + Start-Up / Countries							Q Search O Add -	۰ 🚺	Yogesh Inamdar 👻
	Site Activation	=	Country Nam	e			Language			Progress %
	Current View	0	India				Hindi, English			0%
	- 🖻 All		North Macedo	nia			Macedonian			0%
	🖺 India									
	Training Room 1 - Start-Up / IRB/EC							Q Search O Add	- + (A1 Admin 106 -
	Site Activation	=								Search
	Current View	00	IRB/EC Name	*						
0	- 🗢 All		Local IRB							
	SCHULMAN Associates IRB		SCHULMAN A	ssociates IRB						
	Local IRB		The Swedish I	nstitutional Review Roard						

Refer to the screenshot above:

Notice that documents for sites, countries, and IRB/ECs can be added and edited from the menu bars located on top of the Grid Panes of Sites, Countries, and IRB/ECs. You can also add documents as attachments. The procedure is the same for all and is described below.

Add Essential/Required documents

Note: Documents can be added for contacts such as Sub-Investigator or Study Coordinator only if they are added as contacts to the site, have the 'Provide Documents' functionality enabled for them, and specified as contacts in the essential documents from room settings for site specific documents.

1. Navigate to the module to which you want to add documents as required. The



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modules here are Sites, Countries, or IRB/ EC.

2. Select the document type to which you want to add the document from the Grid Pane.

3. Click Add from the menu ribbon above the documents grid.

The Document Profile window opens. Complete the required

fields, marked by a red asterisk *, including the attached file.

4. Screenshots for each module are provided as below:

Document Profile	Document Profile						
Please enter the docume	nt profile data						
Required fields are marked with	h an asterisk (*)						
Category:*	Site	*					
Comments:							
	Not specified						
Contact:	Not specified						
Date Type:	¥						
Document Date:*	x 🗎						
Document Description:							
Generated Name:							
Document Type:*	•						
Investigative Site:*	Not specified						
Published By:		-					
1	Finish Cancel						

5. You can either attach a file to a document type by clicking the magnifying lens at the end to

6. Click Finish at the bottom of the window. The document takes its place in the grid with a Pending status.

You can also add documents by double clicking the Attachment field in the grid for the required document type for which you want to attach a file. This will activate the magnifying lens and dots to upload

acme loony tunes	research Es	sential Documents	All Documents	Communication	Log Institu	itions	
🛇 Add 🛛 🕹 Exp	ort @App	rove/Reject 🛛 🗳 S	Submit To Review	Not Applie	cable 🕴 📼 E	E-Mail 📙 Save	O Cancel
	Attachment	Document	Required By	Document	Language	Contact Type	Contact
2	۹.		All Sites	Clinical Trial		Principal Inv	simon kouz
2	2)	All Sites	Confidentiali		Principal Inv	simon kouz
i i			IRB [Hickor	Federal wid			
3			IRB [Hickor	GCP Compl			

attachments. Refer to the screenshot below:

Once the documents are uploaded, click the Save button, without which the document would appear in the grid with a red mark but will not acquire the Pending Status.



A document uploaded by this method is not complete in its profile unlike uploading it through the Add button and acquires the warning symbol next to it. Refer to the screenshot above. Clicking the warning symbol will open the Edit Document Profile window for you to complete the details. Click Finish on completing. The warning symbol now disappears.

Export documents

1. Click the Export^{Export} button in the menu above the grid. The Export window opens.

Export	×
Source:	 Selected Records All documents in the current grid
	Export Cancel

2. You can either export selected documents from the grid, or all documents from the current grid.

3. Click Export at the bottom of the window. An Exporting Documents window opens.

Exporting Documents (Lab Certification _CLIA) Finished: Export: 1 of 1 completed (1/1) 08 Sep 11:17	
Get Job Result	

4. Following the on-screen instructions, click the **Get Job Result** button to get the results that are delivered in a zipped folder.

QC Review by SSU Specialist

The documents are reviewed and approved by the Start-Up Specialists and then by the Regulatory Reviewer. Both these roles are assigned to users within the TI SSU module. Notifications within TI can be sent out to notify both these roles when they have pending tasks to complete.

A Start-up Specialist can approve

documents only for his or her own

sites. To approve documents:

- 1. Select a document from the grid.
- 2. Select the Approve button from the menu ribbon above the grid. The Approve / Reject Documents window opens.
- 3. You can select the Status to be Approved or Rejected as you deem fit.
- 4. Select the appropriate approval date.
- 5. Click Approve to save changes. The document's status changes to Approved or Rejected as selected by you.

You can also approve the documents by double-clicking the Status field in the grid for the required document. This will activate the Status dropdown. Select a status as appropriate. Click Save. Refer to the screenshot below:



You can approve several documents simultaneously.

- 1. Select several documents from the grid.
- 2. Select the Approve button from the menu ribbon above the grid. The Approved/Reject Documents window opens.
- 3. Click Approve/Reject at the bottom of the window to save changes.
- 4. The Attachment field or Attach URL by clicking the dots.

Submitting documents for Regulatory Review

Once documents are collected and approved by a start-up specialist, the documents should be submitted for regulatory review. Rejected documents or documents in pending status cannot be submitted to review.

1. Select the approved document or documents to be submitted to review by clicking the appropriate check boxes in the Essential Documents grid.

2. Click the Submit To Review button in the menu ribbon directly above the grid.

Note: Rejected documents cannot be submitted for Regulatory Review and need to be re-submitted again, if required. Paper documents are also submitted for Regulatory Review in the same way as mentioned above.

Not Applicable

A document type can be marked Not Applicable if such a document is not required for

the study start-up.

E-Mail

1. To send an Email message about a particular document to another party associated with the study, the site, the country, or the document, select the document in question from the grid by clicking the appropriate check box.

2. Click the E-Mail button in the menu ribbon directly above the grid. An Email window opens.


Email									×
То									
CC									
Subje									
Attachments									
Times New • 12pt •	B <i>I</i>	<u>U</u> A	- A	• 8	Ξ	∃	≣ ≣	<u> </u>	≣
○ Files as Links ○ Files as Attachments	 None 						Send	Can	cel

Files can be sent either as links or as attachments as shown in the screenshots above.

Choos	e the ema	il recipie	nts								×
Users		*			Search		Q	Email	Recipients		
	Last	First	Email	Ph	Mo	Orga			Name	Email	
• 1			Test121			ti.com					
• •			testedito			ti.com					
• 1			testread			ti.com					
• 1			jtrouble			Hog					
• •	100	Reader	TIReade			ti.com					
• •	100	Editor	ti_editor			ti.com					
• 1	101	Reader	TIReade			ti.com					
	Page	1 of 1	 > ⊳	O Di	splaying	 users 1 - 41	▼ I of 4	Select t	he users by double click	king or drag the entries to	o this pane.
										ОК	Cancel

3. Click the To / CC button to activate the list of room users to whom you can send the message.

4. Select the users or groups you want to send the message to by dragging and dropping the recipients' names into the Email recipient's grid or by double-clicking the names.

5. Click OK. The view returns to the Email window.

6. Complete the required Subject field.

7. Either add attachments to the message or click the Files as Links radio button at the bottom of the window. Note that the user can also select the



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None radio button to send a message without files attached.

8. Add a custom message in the message field.

9. Click Send. The designated recipients receive the email message.

Editing Essential/Required Documents

Once a document is added to a document type, its profile is available for editing, if

required. To edit a document:

1. Select a document from the grid

2. Click the Edit button from the menu bar.

3. The Edit Document Profile window opens. Make changes and click Finish to commit the changes made to the document profile.

Viewing Document Profile

To view the profile of a document you can click the Open

Document Profile		×
Document Profile Activi	ty Log	
Dr. A-CV.pdf		
Doc date : Not specified		Filesize : 144.4 KB
Attachment:	Dr. A-CV.pdf	*
Comments:		
Document URL:		
Milestone Date:		
Milestone:		
Category:	Trial	
Date Type:		
Document Date:		
Document Description:		
Generated Name:		
Document Type:		-
		Edit Close

Profile button from the menu bar. This opens the Document Profile window. Refer to the screenshot below:

This window consists of two tabs: Document Profile and Activity Log.

The Document Profile tab shows the profile of the document. Refer to the screenshot above.

The Activity Log tab shows all the activities performed by users on the document. Refer to the screenshot below:



Document Profile				X
Document Profile Activ	rity Log			
Organization: All	*	Activity type:	All	*
Date	Updated By	Activity	Description	
7/2/2020 3:50:13 P	Steve Clark (stclark@tra	New Essential Doc		
7/2/2020 3:50:09 P	Steve Clark (stclark@tra	New File: ti.com		
7/2/2020 3:50:08 P	Steve Clark (stclark@tra	Create document: t	AddDocumentFromSsul	
			Edit Close	

All Documents

The view presented to users in the All Documents tab for each site, country, and IRB/EC shows both the Essential Documents and the non-Essential Documents associated with the site, country or IRB/EC selected.

The All Documents tab for each of the modules consists of a menu bar



which allows various functionalities. Refer to the screenshot below:

The functionalities of this menu bar are the same as in the Documents section of the SSU

and can be referred there.

Review of Non Essential Documents

If the Study Start-Up Settings specify that the documents will need to be approved through the 'Two pass workflow in Study Start-Up' the documents automatically acquire the Pending status under QC Review. The documents will then have to be approved under QC Review and



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submitted for Regulatory Review.

The process for reviewing and approving the documents is as follows:

1. From the Grid Pane select the non-essential document to approve/reject.

2. From the menu bar on the top of the grid, click the Approve/Reject button.

3. Once the document is approved, the Submit To Review button is activated; clicking which you can submit the document for QC Review. A document that is rejected by the SSU Specialist cannot be submitted for Regulatory Review.

Documents

Clicking the Document tab from the toggling menu bar leads you to the Documents dashboard. Typically, the Documents module is the route through which most Editors will access and view documents for a Start-Up study. This module acts as a central repository for all documents added to the various components of a study start-up.

The Documents dashboard consists of the Current view on the left and the Grid pane on the right. Besides these, it also allows you to perform various



functionalities from the menu bar on the top of the grid pane, and the buttons on the Current View window. Clicking a current view opens a list of documents in the grid pane. Refer to the screenshot below.

Current View





The Current View Dropdown offers five views:

• **By Site**: Selecting the By Site option lists out the sites to which documents have been added. Clicking a site will display the documents submitted to the site along with their review status in the grid pane. Refer to the screenshot below:

By Site	🕒 🔘 📄 Docum	ent 👻 🥶 E-Mail 🕴 🛉 Import 📑 Move	e to the eTMF Sea	rch for documents	s or sele 🗸 🔍	 Documents Cart
Site - Potter Harry		Submitted Name	Generated Name	QC Review	Reg. Revie	Start-Up Rejection
Site - The House Elf Doby		Tracking Documents_Transmitta	The House Elf_TrackingInfo_28	Approved	Approved	
Site - 1 Umbridge Delores		Tracking Documents_Transmitta	The House Elf_TrackingInfo_26	Approved	Approved	
Site - 123 Owl Snowy	□ 🖾 ★	OtherCV	The House Elf_PIMedLicense	Approved	Approved	
Site - 123456 Anderson Mary		FDF_19Jan2013	The House Elf_PIFDF_The Hou	Approved	Approved	
Site - 1472 Fakefrog Tadpole	□ 🛛 🖈	Dr. A-CV	The House Elf_PICV_The Hous	Approved	Approved	
Site - 1777 Ollivander Edward	08*	InformedConsent_sample1	The House Elf_ICF_26Feb2020	Approved	Approved	

• By Country: Selecting the By Country option lists out the countries to which documents have been added. Documents added through the Countries tab can be located here. Clicking a country will display the documents submitted to the country along with their review status in the grid pane. Refer to the screenshot below:

By Country 💌 🐨 🖸 🗖	📄 Document 👻 📼 E-Mail 🛧 Import 📄	Move to the eTMF Search for doc	uments or sele 🗸 🔍 🗸	👿 Documents Cart 💌
🗈 India	Submitted Name	Generated Name	QC Review Status	Reg. Review Status
	Context Sensitive Help Topic			

• By IRB/EC: Selecting the By IRB/EC option lists out the IRB/ECs to which documents have been added. Clicking an IRB/EC will display the documents submitted to the institution along with their review status in the grid pane. Refer to the screenshot below:

By IRB/EC	*	 Documen	t 👻 📼 E-Mail 🕴 🛧 Im	port 👘 Move	to the eTMF	Search for do	ocuments or sele 🗸 🔍	🔍 👻 🛛 😇 Documents Cart 👻
🗈 Test		0	Submitted Name	Index	Document	QC Review Status	Status	Start-Up Rejection
			ti_10.0_online_help		Site Activation			
			SitesImportTest		Site Activation			



• By Document Type: Selecting the By Document Type options lists out the various document types available to the study start-up. Clicking a document type will display the documents submitted by that type along with their review status in the grid pane. Befer to the screenshot below:

By Document Type 👻 🕒 🖸	Docum	nent	💌 🚥 E-Mail 🛛 🕍 Move to the eT	MF Search for docu	iments or sele 👻 🔍 💌	👿 Documents Cart 👻
*Not Specified	0		Submitted Name	Generated Name	QC Review Status	Reg. Review Status
Acceptance of Investigator Brochure	□ ₪, *	8	InvestigatorAgreement_29Se	The House Elf_AcceptIB_The House Elf_D_2	Approved	Approved
Clinical Trial Agreement	0 *	-	1777_Ollivander_AcceptIB_O	1777_Ollivander_AcceptIB_Ollivander_E	Approved	Approved
Confidentiality Agreement		iii'	Protocol Signature Page	123456_Anderson_AcceptIB_Anderson_M_11	Approved	Approved
Form FDA 1572						

• By Posted Date: Selecting the By Posted Date option lists out the dates on which documents were submitted to the sites, countries, and IRB/ECs. Clicking a date will display the documents submitted on that day along with their review status in the grid pane. Refer to the screenshot below

Note: Apart from the above mentoned views you can also view the deleted documents and inbox documents if the room has set these documents attributes.

By Posted Date	*	Docur	Document 👻 📼 E-Mail 📄 Move to the eTMF			Search for docu	iments or sele 👻 🔍 💌	😇 Documents Cart 👻
9/8/2020			3	Submitted Name	Generated Name		QC Review Status	Reg. Review Status
9/3/2020			k a	Context Sensitive Help To	opic			
8/11/2020			h I	ti_10.0_online_help				
7/2/2020			k I	SitesImportTest				

The Documents Grid Pane

The Grid Pane displays the details of the documents and provides various other functionalities through the Menu Bar on the top, the Document Data Panel, and the Selections at the bottom of the panel.

The Top Menu Bar

The Menu Bar above the Grid Pane holds buttons for various functionalities. Refer to the

screenshot below:



Document Dropdown





Add documents

- 1. Select Add from the dropdown menu. The Document profile window opens.
- 2. Complete as many of the fields in the Document profile as you can. The fields marked with a red asterisk (*) are required
- Title, Category, Index Position, Document Type, Document Date, and Name.
- 3. The Category could be General, Country, or Investigative Site.
- 4. If you select Investigative Site as Category, the document added will be available from the Site to which it has been added. Such a document can be viewed from

Document Profile		X				
Please enter the document profile data						
Required fields are marked with an asterisk (*)						
Country:*	India	1				
Language:	Not specified					
Milestone Date:	×					
Milestone:	X 🗸	-				
Category:*	Country					
Comments:	Trial					
	Country					
Date Type:	Site					
Document Date:*	×	1				
Document Description:						
Generated Name:						
Document Type:*	•	-				
	Finish Cance	1				

the By Site Current View in the Document Tab or from the Sites Tab.

5. Click Finish.

Copy Link

Using this option you can copy the link of a document, or copy the link of the document

with its metadata.

The administrator needs to configure the option that the users would like to use:



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- 1. Navigate to Settings
- 2. Click Documents from the left pane.
- 3. Click Documents Module from the dropdown.
- 4. Go to the tab 'Type of document link'.
- 5. Observe that there a two options:
- a. Link to document
- b. Link to document with metadata
- 2. Select the option as required.
- 3. Click Save.

Search	۹ 🕷 🖿 ۸	About Documents I	Module ×	
o, General		Enable auto purge	: 🗆	
O Milestones		Days to auto purge	1	
🗳 Inbox	Do	ocument Expiration		-
	1	Expiration Dashboard View	60	 days before
Outbox		Expiration reminder	10	 days before
Ø Documents Distribution		Notification Recipients	Select 2	users 0 groups selected
🛅 Forms Settings				
General Integration		utomatic Document Name	e Generation	
General Integration		utomatic Document Name	e Generation ument name a	s output name (export, download, ema
General Integration	-Al	utomatic Document Name Use auto generated docu achments) Regenerate Document N	e Generation ument name a	s output name (export, download, ema
General Integration Comments Comments Module		utomatic Document Name Use auto generated docu achments) Regenerate Document Na	e Generation ument name a ames	is output name (export, download, ema
General Integration Documents Documents Module Document Replacement	Reasons	utomatic Document Name Use auto generated docu achments) Regenerate Document Na pe of Document Link	e Generation ument name a ames	is output name (export, download, ema
 General Integration Documents Documents Module Document Replacement eTMF Health 	Reasons	utomatic Document Name Use auto generated docu achments) Regenerate Document Na pe of Document Link	e Generation ument name a a mes	is output name (export, download, ema
 General Integration Documents Documents Module Document Replacement eTMF Health Index Outline 	Reasons	utomatic Document Name Use auto generated docu achments) Regenerate Document Na pe of Document Link Link to Document	e Generation ument name a ames etadata	is output name (export, download, ema
General Integration Comments Comments Module Document Replacement Comment Replacement Co	Reasons	utomatic Document Name Use auto generated docu achments) Regenerate Document Na pe of Document Link Link to Document	e Generation ument name a a mes etadata	is output name (export, download, ema
General Integration Cocuments Cocuments Cocuments Module Cocument Replacement Cocument Replacement Cocument Replacement Cocument	Reasons	utomatic Document Name Use auto generated docu achments) Regenerate Document Na pe of Document Link Link to Document Link to Document with Me Use document upload date	e Generation ument name a ames etadata e as the docum	is output name (export, download, ema
 General Integration Documents Documents Module Document Replacement eTMF Health Index Outline Non-PDF to PDF Docum Document Certification 	Reasons	utomatic Document Name Use auto generated docu achments) Regenerate Document Na pe of Document Link Use to Document Use document upload date Use separator sheet for mu	e Generation ument name a ames etadata e as the docume ultiple docume	is output name (export, download, ema
 General Integration Documents Documents Module Document Replacement eTMF Health Index Outline Non-PDF to PDF Docum Document Certification Document Types 	Reasons	utomatic Document Name (Use auto generated docu achments) (Regenerate Document Name (Pe of Document Link) (Link to Document Link to Document with Me Use document upload date Use separator sheet for mu Enable View by Tag for Do	e Generation ument name a ames etadata e as the docume ultiple docume cuments	is output name (export, download, ema nent date for bulk upload and Inbox ents print
General Integration Documents Documents Module Document Replacement eTMF Health Index Outline Non-PDF to PDF Docum Document Certification Document Types Required Documents	Reasons	utomatic Document Name Use auto generated docu achments) Regenerate Document Name Period Document Link Link to Document Link to Document with Me Use document upload date Use separator sheet for mu Enable View by Tag for Do Enable coding on Mass Im	e Generation ument name a ames etadata e as the docume ultiple docume cuments port window a	is output name (export, download, ema nent date for bulk upload and Inbox ents print



- 1. Select a document from the grid of the Documents section, or from the All Documents tab in Sites section.
- 2. Right click the document or activate the Document dropdown.
- 3. Select option Copy Link.
- 4. The document URL gets copied to the clipboard.
- 5. A notification about the same is received.





- 6. Paste the copied URL in a browser tab.
- 7. The document opens in the browser for you to read.

Edit Profile

- 1. Select a document from the grid.
- 2. Activate the Document dropdown menu and click Edit Profile. The Edit Document Profile window opens.
- 3. Make the necessary changes to the profile data fields as required.
- 4. Click Finish.

Open Profiile

To view the profile of a document, activate the Document dropdown and

Document Profile	×
Document Profile Activity Log	
Dr. A-CV.pdf	
Doc date : Not specified	Filesize : 144.4 KB
Attachment: Dr. A-CV.pdf	A
Comments:	
Document URL:	
Milestone Date:	
Milestone:	
Category: Trial	
Date Type:	
Document Date:	
Document Description:	
Generated Name:	
Document Type:	-
	Edit Close

click the Open Profile button from the menu bar. This opens the Document Profile window. Refer to the screenshot below:

This window consists of two tabs: Document Profile, and Activity Log.

The Document Profile tab shows the profile of the document. Refer to the screenshot above.

The Activity Log tab shows all the activities performed by users on the document. It allows you to select the Organization, and the Activity Type



as filters to view the log. Refer to the screenshot below:

Document Profile				×
Document Profile Activ	rity Log			
Organization: All	*	Activity type:	All	*
Date	Updated By	Activity	All	
6/5/2020 7:17:00 AM	Admin 103 (Tladmin103	Restore document	Restore document Delete document	
6/5/2020 7:15:20 AM	Admin 103 (Tladmin103	Delete document: ti	Metadata field was updated	
6/5/2020 7:14:26 AM	Admin 103 (Tladmin103	Metadata field was	Edit document Regulatory Review	
6/5/2020 7:14:25 AM	Admin 103 (Tladmin103	Metadata field was	Modify Essential Document	
4/7/2020 9:43:54 AM	Admin 103 (Tladmin103	Edit document: ti.com	QC Review	
4/7/2020 9:41:48 AM	Admin 103 (Tladmin103	Regulatory Review	New File	
4/7/2020 9:40:32 AM	Admin 103 (Tladmin103	Regulatory Review	Create document	
4/7/2020 9:34:22 AM	Editor 104 (Tleditor104	Modify Essential D		
4/7/2020 9:34:22 AM	Editor 104 (Tleditor104	QC Review		
4/7/2020 9:29:08 AM	Editor 104 (Tleditor104	New Essential Doc		-
			Close	

Clicking the Edit button leads you to the Edit Document Profile window.

Replace Attachment / Add URL

You can replace the attachment to a document type if it is not approved by using this feature.

- 1. Select the document from the grid.
- 2. Activate the Document dropdown.
- 3. Click the option Replace Attachment / Add URL.
- 4. The Replace Attachment / Add URL window opens.
- 5. Change the attachment as required and provide the reason for the same.
- 6. Click Save.

Add Selected to the Cart

You can add a document selected from the grid to the cart to compare documents, link them, add them to the submission package, or download documents.

Related Documents

1. Select a single document in the Document Grid.

- 2. Click the Document dropdown menu.
- 3. Select Related Documents from the available options. A Related Documents window opens.



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Related Documents		S
Title	No related d	locuments found
	Metadata relation	
		CTA
	File Name	CTA.pdf
	Category	Site
	Contact	Harry Potter
	Document Date	26 Feb 2020
	Generated Name	Potter_CTA_Potter_H_26Feb2020
	Document Type	Site\05 Site Management\05.02 Site Set-up\05.02.12 Clinical Trial Agreement\CTA

The top part of this window shows the documents located in the search through the room's default viewer. The left panel lists the related documents by title. The right portion of the window carries the Metadata Fields of the related documents. The metadata fields that have common content are highlighted in green.

E-Mail

The procedure to send out emails is the same as described under Essential Documents.

Import

1. Click Import

↑ Import ∨

from the menu ribbon. An Import Documents window opens.

2. The Upload Options depend upon the view selected - By Site, By Country, or By IRB/EC.

3. Select your choice from the dropdown menu in the field in the 'Upload Options' panel.

4. You can add documents to the window by using Browse and selecting the appropriate files for upload, or the user can drag-and-drop appropriate files, en masse, directly from a document library. You can tick the 'Unpack Zip-archives' if you have uploaded a zip file and want to import the documents in the zip as separate documents.

5. Once you have deposited all of the desired files into the Import Documents window, click Import.



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Import Documents			×
File Name	Size	Upload Status	Upload Options
SSU_overview_v9_2 (2).docx	33.4 KB		If you are uploading the documents related to a specific site, please select the name of the site from the drop down
			Site:*
			Site - 007 Batwoman Waynetta
			Protocol:
			Site Activation
	_		
Upload Progress	Files total 1	1 (33.4 KB)	
Browse - Browse - Clear Clear	Zip Archives (the Non-PDF	Documents to PDF 🕢	Import Close

6. The tool moves to the next stage of the document upload.

Import Documents Please select document type and cor	ntact for the documents you just uploa	ded		×
File Name	Document Type	Contact	Language	
SSU_overview_v9_2 (2).docx	Double click here to select t	Double click here to select t	Double click here to select t	
			Save Close	

7. Following the on-screen instructions, double-click the Document Type field



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Import Documents							X
Please select documer	nt type and con	tact for the documents you just uploa	ded				
File Name	_	Document Type	Contact		Language		_
SSU_overview_v9	_2 (2).docx	ment Type	Double click here to s	elect t	Double click here	e to select t	
	Select Docu	intent type					
	Site			Search	. Q		
	👆 01 Tria	I Management			<u>^</u>		
	🔖 02 Cen	tral Trial Documents					
	💊 03 Reg	julatory					
	🔖 04 IRB	or IEC and Other Approvals					
	💊 05 Site	Management					
	💊 06 IP a	nd Trial Supplies					
	🔖 07 Safe	ety Reporting					
	💊 08 Cen	ntral and Local Testing					
	A 10 Dat	Management			•		
				ОК	Cancel		
					_	_	_
					Sav	e Close	

8. Select the document type that matches the actual document for each uploaded document.

9. Click Save. You return to the Documents view.

Move to eTMF

You can move a document selected from the grid in the eTMF by clicking the Move to eTMF button on the menu bar. This opens the Select index



position to place the document window. Refer to the screenshot below.



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Select the appropriate folder to move the document to and click Ok.

Document Data Panel

The **Document Data Panel** at the extreme left lists out the metadata of the document that was entered in the **Document Profile** at the time of adding the document. Instead of opening the **Edit Document Profile** window, you can also edit the profile of a selected document from its

Document Data	Y >
Required fields are marked with an asterisk (*)	
Milestone Date:	
×	
Milestone:	
××	
Milestone:	
Category:*	
Site	~
Comments:	
Date Type:	
Version Date	
Document Date:*	
×	
Document Description:	_
Generated Name:	
Document Type:*	
Site\01 Trial Management\01.01 Trial Oversight\01.01.06 Recruitment Plan\RecruitPlan	•
Investigative Site:*	-

Document Data Panel. A screenshot of the panel is provided below:

The contact of the documents is the username of the login that was used to upload the documents. As shown in the screenshot below, documents for country **India** were uploaded. These documents now appear in the **By Country view** for **India**. Refer to the screenshot below:

By Country	~	Document	t 👻 🧰 E-Mail 🕴 🛉 Impor	Move to the eTMF	Search for documents or sele 🕶	Q 👻 🛛 🔚 Documents (
🕒 India			Submitted Name	Generated Name	QC Review Stat	us Reg. Review State
			Context Sensitive Help T	opic		

Regulatory Review



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Clicking the **Regulatory Review** tab from the toggling menu bar leads you to the **Regulatory Review** dashboard. From this module the regulatory reviewer can view the review statuses of the documents put up for regulatory review as well as review and approve the documents. The procedure to approve the documents by the regulatory reviewer is discussed after a brief summarization of the dashboard.

The **Regulatory Review** dashboard consists of the **Current view** on the left, the Grid pane in the center, and **Document Data** panel on the right. Refer to the screenshot below.

ш	Training Team eTMF Room - Start-Up / Regulatory Review				Q Sea	arch 🛛 Add 🔹 🔺 🚺 Yogesh Inamdar 🗸
	Site Activation	E		Search for documents or sele	🖌 🔍 👻 📜 Documents Cart 👻	Document Data
	By Site 💌 🕒 🖸	Submitted Name	Index	Status Start-	Up Rejection Reason	Required fields are marked with an asterisk (*)
	🕶 🖕 Approved	🛛 📕 ★ CTA	05 Site Management\Si	Approved		File Name:
۲	Site - Potter Harry	🗆 🖪 🛨 Confidentiality Agreement odf-r	05 Site Management\Si	Approved		CTA.pdf
	Site - The House Elf Doby	FDA 1572 montana	05 Site Management\Si	Approved		Not Applicable Reason:
v	Site - 1 Umbridge Delores	□ [2], ★ InformedConsent_sample1	- 05 Site Management\Si	Approved		
A	🖺 Site - 123456 Anderson Mary	🗆 🙋 🖈 Dr. C-CV	05 Site Management\Si	Approved		Milestone Date:
	Site - 1472 Fakefrog Tadpole					
	📔 Site - 1674 Scott Michael					Milestone:
A	Site - 1777 Ollivander Edward					Category:*
	🖺 Site - Carol Juvenal Carol					Site
4						Comments:
1						Contact:*
						Harry Potter (Principal Investigator)
						Date Type:
						Latest Signature Date
						Document Date:*
						26 Feb 2020
						Document Description:
$\mathbf{\tilde{z}}$		H C Page 1 of 1 D H Q			Displaying documents 1 - 5 of 5	Generated Name:
6		Grid Document Metadata				+

Adding Regulatory Approvers

A Regulatory Approver can be a Global Regulatory Approver, Country, or Site Regulatory Approver. As a Global Regulatory Approver, you are able to perform the functions at all sites within a study room. As a Country Regulatory Approver, you are able to perform the functions at all sites in a specific country (ies). Lastly, as a Site Regulatory Approver, you are able to only perform the functions at the site(s) a room Administrator assigns.

To add Global Regulatory Approver follow the steps as below:

- 1. Navigate to Settings.
- 2. On the left-side panel, navigate to Investigative Sites \diamond Study Start-Up settings.
- 3. Next to Regulatory approvers, click on Select. Add user(s) by either double



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clicking on the user on the left-hand side to move to the Selected Members on the right-hand side, or by dragging and dropping the user from the left-hand side to the Selected Members on the right-hand side.

Search	Q (#	About	Study Start-Up settings *
 General Integration Documents Document Types Required Documents Countries Countries Investigative Sites General Settings Study Start-Up settings Contact Types Submission Profiles State Template Folders Investigative Sites Status CRA Visit Types CRA Visit Status 	S	 Allow use Do not picture Essee Non-essee Do not al Do not respective Allow pair Regund Start-Upicture Site Complete and Site 	ers to select the documents which should be published to the eTMF ublish the documents on eTMF when the site is activated ential documents: Publish to eTMF Workflow Publish to Index without the eTMF Workflow ential documents: Publish to eTMF Workflow Publish to eTMF Workflow Publish to eTMF Workflow Two-pass workflow in Study Start-Up How addition of new documents to a Site after activation eset Amendments status on Site Edit per documents Latory approvers: Select 0 user(s) selected processing time (days): e activation email Select 0 user(s) selected, 0 contact type(s) selected mendment email recipients: mendment email Select 0 user(s) selected, 0 contact type(s) selected activation title: Site Activation

Users added as Regulatory Approvers added from here will be available as Regulatory

Approvers to all the sites in the room.

To add a Country Regulatory Approver follow the steps as below:

- 1. Navigate to Settings -> Countries -> Countries.
- 2. Check the box next to the country and then click Edit. (If the Country is not listed, click Add to create a new country).

3. Next to **Regulatory Approvers**, click **Select**. Add user(s) by either double clicking on the user on the left-hand side to move to the **Selected Members** on the right-hand side or dragging and dropping the user from the left-hand side to the **Selected Members** on the right-hand side.

4. Click Save.



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5.Click Select to open the Regulatory Approvers

windows and add the users. Click OK. To add a Site

Regulatory Approver follow the steps as below:

1. Navigate to the SSU module \diamond Sites.

2. Double click on the site you wish to add a Site Global Regulatory Approver.

3. At the bottom right-hand corner, click on **Regulatory Approvers**. Add user(s) by either double clicking on the user on the left-hand side to move to the **Selected Members** on the right-hand side or dragging and dropping the user from the left- hand side to the **Selected Members** on the right-hand side.

4. Click Save.



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	Training Team eTMF Room - Start-Up / Sites									Q Search	n O Ad	id 🔹 🌲 📢 Yogesh Inamdar 🗸
	Site Activation	Dunder-Mifflin Pap	er Company	Essential Docum	ents All Do	ocuments Comm	nication L	og Institutions				
e2	By Status 👻 🔻 🤨	Required fields are n	arked with an a	asterisk (*)								Essential Documents Progress
0	- 🖕 All	Institution Name:		Dunder-Mifflir	Paper Com	npany						Investigative Site Dunder-Mifflin Paper
¥	Active [6]	CRA:		H Editor 102							~	100%
	Non Participating [1]	Start-Up Specialis	t.	R Editor 103							~	Site Activation Date:
~	Develop (40)	Contacts M	embers							(X)		08 Sep 2020
	Pending [10]	O Create	sers	~		Search	Q :	Selected Users				
4		Las C	Last	. First Em	ail Ph	Mo Orga.	. 0	Name	Email			
		🗆 🗶 Sco	12	test	edito	ti.com	<u>^</u>					
			1 100	Editor ti e	ditor	ti com						
				Adaption Theor								
		- 🖸 Address	101	Aumin Had		u.com						
		- Moro -	101	Eddie ti_e	ditor	ti.com						
-		() more	102	Admin Tlac	imin	ti.com						
		Edit History:	102	Editor ti_e	ditor	ti.com						
1			103	Admin Tlac	dmin	ti.com						
				- er - e			-					
			🕘 🌾 🕴 Pag	e 1 of 1 >	MIO	Displaying users 1	26 of 2	elect the users by dou	uble clicking or drag the entrie	s to this pane.		
									ок	Cancel		
											1	
	-	Q Class Site	Saus 00	anoal						Doquiromonto 🛛	Convitu	
Ć	2		file							requirements T	accurity	Regulatory Approvers. 0 G E P
		-010	1111	JUE ITO	-		_					

Current View

Training Team eTMF Roor Start-Up / Regulatory	n 👻 Revi
Site Activation	
By Site 👻	S
By Regulatory Approval Status	
By Site	
By Country	
By IRB/EC	oby
By Document Type	res

The Current View Dropdown offers five views:

• By Site: The By Site option groups all the sites based on the review status of its documents. The review statuses of the documents could be Pending, Rejected, and Approved. Clicking a site under a particular review status will

Site Activation	=		Search for doc	uments or sele 🛩	Q.+	E Docum	
By Site 💌		Submitted Name	Index	Status	Start-Up	Rejectio	on Reason
🕶 🖕 Approved		* CTA	05 Site Management\Si	Approved			
Site - Potter Harry		Confidentiality Agreement_pdf-r	05 Site Management\Si	Approved			
Site - The House Elf Doby		FDA 1572_montana	05 Site Management\Si	Approved			
Site - 1 Umbridge Delores		InformedConsent_sample1	05 Site Management\Si	Approved			
Site - 123456 Anderson Mary	0 🙋	Dr. C-CV	05 Site Management\Si	Approved			



- **By Country**: The By Country option lists out the countries to which documents are added. Clicking a country from the left pane will display the documents submitted to the country along with their review status in the grid pane.
- By Regulatory Approval Status: The By Regulatory Approval Status groups all the documents as per their review status i.e. Approved, Rejected and Pending. Clicking a review status group from the left panel will display the documents belonging to the particular review status group in the grid pane.

Site Activation	=						Search for doc	uments or sele 🗸 🔍 💘 📜 Do
By Regulatory Approval Stati					Submitted Name	Index	Status	Start-Up Rejection Reas
Approved			囚	*	Confidentiality Agreement_pdf-r	05 Site Management\Si	Approved	
		D	囚	*	InformedConsent_sample1	05 Site Management\Si	Approved	
				*	CTA	05 Site Management\Si	Approved	
		0	因	*	FDA 1572_montana	05 Site Management\Si	Approved	
		0	m		IP Accountability Record	05 Site Management\Si	Approved	

• By Document Type: The By Document Type options lists out the various document types available to the study start- up. Clicking a document type will display the documents submitted under that type along with their review statuses in the grid pane. Refer to the screenshot below:

Site Activation	=				Search for doc	cuments or sele 🗸 🔍 👻 💟 Docun
By Document Type 💙			Submitted Name	Index	Status	Start-Up Rejection Reason
Acceptance of Investigator Brochu	ire	0 0,	InvestigatorAgreement_29Sep2014	05 Site Management\Si	Approved	
Clinical Trial Agreement		0 1	1777_Ollivander_AcceptIB_Ollivan	05 Site Management\Si	Approved	
Confidentiality Agreement			Protocol Signature Page	05 Site Management\Si	Approved	
Eorm EDA 1572						

• **By IRB/EC:** The By IRB/EC option lists out the IRB/ECs to which documents have been added. Clicking an IRB/EC from the left pane will display the documents submitted to the institution along with their review status in the grid pane. Refer to the screenshot below:



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Document Data Panel

The Document Data Panel is located on the extreme right of the dashboard and can be activated by clicking a document from the grid pane. Depending on the user's security settings and access rights and

Site Activation	=		Search for docu	ments or sele 🗸 🔍 👻 🖢 Documents Cart	Document Data
By Site 💌 💌	5 Submitted Name	Index	Status	Start-Up Rejection Reason	Required fields are marked with an asterisk (*)
👻 🖕 Approved	🜌 📳 ★ CTA	05 Site Management\Si	Approved		File Name:
Site - Potter Harry	🗆 🖪 🛨 Confidentiality Agreement_pdf-r	05 Site Management\Si	Approved		CTA.pdf
Site - The House Elf Doby	🗇 🛛 🗮 🛨 FDA 1572_montana	05 Site Management\Si	Approved		Not Applicable Reason:
Site - 1 Umbridge Delores	InformedConsent_sample1	05 Site Management\Si	Approved		
📔 Site - 1066 Doctor Test	🖸 💯 🜟 Dr. C-CV	05 Site Management\Si	Approved		Milestone Date:
💄 Site - 123456 Anderson Mary				_	
Site - 1472 Fakefrog Tadpole					Milestone:
Site - 1674 Scott Michael					Category:*
Site - 1777 Ollivander Edward					Site
📔 Site - Carol Juvenal Carol					Comments:
					Contact.*
					Harry Potter (Principal Investigator)
					Date Type:
					Latest Signature Date
					Document Date:*
					26 Feb 2020
					Document Description:
	K K Page 1 of 1 > H O			Displaying documents 1 - 5 of	/5 Generated Name:
	Crid Document Metadata				L

roles, this panel might be static to a user. If the user is given appropriate SSU User access rights, the data fields are editable and all changes made here must be saved.

In the screenshot above, observe that the fields are non-editable. The user can switch between the Grid and the Document Data Panel by clicking any of the buttons located at the bottom of the Grid pane.

How to Regulatory Review a Document with Attachments

Once the regulatory reviewer receives an email stating about a pending review, he/she logs into TI to locate the documents waiting for review in the Regulatory Review section. The easiest way to find out all the documents in the study start-up waiting for regulatory review is to activate the **By Regulatory Approval Status** view from the left panel which lists out all the documents in the SSU pending for approval.

To review a document, the regulatory reviewer selects a document with pending status and clicks the Document button at the bottom of the Grid Pane, or the icon next to the document name. The Grid Pane will disappear and the document will open for review in the center of dashboard. Refer to the screenshot below:

T R I A L INTERACTIVE

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The regulatory reviewer reads the documents for review. If he/she finds a document

appropriate, the reviewer clicks the

Approve button from the top ribbon bar, else he/she clicks the Reject button.

If the reviewer approves a document, a popup appears asking the reviewer to confirm the same. Click **Yes** to confirm the same.





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If the reviewer rejects a document, a popup appears asking the reviewer to state the reason for rejection. Fill in the reason and click **Reject** to

commit.

Depending upon the decision taken, a message will pop up indicating that the change is now

committed to the database.

The document is now locked and cannot be opened for review again. The Regulatory Approval Status of the documents throughout the SSU will now reflect the appropriate status from Pending to Approved, or Rejected. The Document button at the bottom of the dashboard, and the Approve or Reject buttons are now disabled to prevent further changes.

Regulatory Review of Paper Documents/Documents without attachments

As discussed in earlier sections, paper documents go without attachments. In such a case, the Approve, and Reject buttons will be placed above the Regulatory Review documents grid, so it will not be required to open the document in a viewer to approve/reject it. The rest of the approval/rejection process remains the same.

Communication

Note: The Communication Log section from Sites, Countries, and IRB/EC provides the same functionality as that available in the Communication section.

The **Communication** tab, accessed from the toggling menu bar on the left, holds all the messages sent and received with a study start-up for the purpose of activating a site. Opening the Communication tab, the user can see three panels: **Current View, Grid Pane,** and **Communication Data.**



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Current View

The Current View Dropdown offers four views:

- **By Site**: Selecting the By Site option lists out the contacts added to the sites. Clicking a site will display the contacts of the particular site in the grid pane. If a Principal Investigator (PI) was deleted, and a new one added, the previous PI will appear greyed out. Similarly, if a contact is deactivated, it too will appear greyed out, but if a contact is deleted, it will not appear in the grid.
- By Country: Selecting the By Country option lists out the countries which have sites added to them. Sites for which countries are not added will appear under the Not Specified category. Clicking the + next to a country will display the sites belonging to the country. Clicking the site will list the contacts of that site in the grid pane.
- **By IRB/EC**: Selecting the By IRB/EC option lists out the sites by IRB/ECs. The sites for which IRB/ECs are not specified get listed under Not Specified category. Clicking a site will display the contacts of the particular site in the grid pane.
- By Contact Type: Selecting the By Contact Type option lists out the various contact types added to the sites in a study start-up. Clicking a contact type will display the names of all the people under the contact type.

The Contacts Grid Pane

The Grid Pane displays the details of the contacts and provides various other functionalities through the Menu Bar on the top.

The Top Menu Bar

The Menu Bar above the Grid Pane holds buttons for various functionalities. Refer to the

screenshot below:



Mass Coding Contacts Metadata

Clicking the Mass Coding option from the top menu bar will enable you to set the all contacts in the grid pane, or only selected contacts in the grid pane as Main Contact at one go for all the sites in the study startup. Refer to the screenshot below:



By Contact Type	Mess Coding 💄 Convert to user(s)				Seuros Q
17 Contact	Manue Name	Investigative filts	Phone	Main Contact	Provide Documente
Principal investigator	😢 🗶 James Morgan	Optimizia University Medical Center		Yes	Yes
Regulatory Contait Regulatory Contait	11 £ James Smith	Ony Multipuplie Hospital #2 Depart		Yesi	Yes
 swali coordinatori 	🛅 🛓 Jene Doe	Example Hospital		No	Ves
	🖾 🗶 Jane Smith	Clinica Devila: Depto de Neurología	Yes	Yes	
	🗄 🗶 John Doe	Charite Universitatumed [2n Berlin-N	Yes	Yes	
	📃 🗶 Michael Smyth	Obscal Center of Settia, Obsc of N.	Yes	Yes	
	🗄 🗶 Steven Allen	Clinical Research Unit Montreal Neu	Yes	Ves	
	🗍 🗶 TestPl	Partral Phrinal Madion Sactano Bob	Yeo -	Yes	
	🗄 🗶 Ten Pi	Contects Mess Coding	X	Yes Yes	Yes
		Field Value Main Contact Yes Provide Documents Yes No	sve Cancel		

You can also decide whether the contacts can be mass coded to provide documents Click

Save to commit the changes.

Convert to user(s)

You can choose to assign selected contacts the roles of Editors, or Readers in a site by clicking the Convert to user(s) button from the menu

Convert selec	cted site con	tact(s) to user(s)	×			
Role:*			~			
Actions:	Editor					
Actions.	Reader					
Convert to user(s) Cancel						

bar. Refer to the screenshot below:

Click the Convert to user(s) button at the bottom of the popup to commit the changes.

Refer to the screenshot below:

The user will receive an invitation email to register and access the room with the role and actions ticked by the administrator enabled for him/her. This feature can be used in conjunction with Create/Add existing functionality in the Contacts panel of the Site profile to add a new contact not belonging to any room/site, or to add a contact who belongs to a site, or a room respectively. To

know the functionalities that would be accessible to such a user

proceed to the table for Accessible functionalities for SSU contacts.

Contact Data

You can view the contact metadata in this panel. The contacts cannot be edited from here. To edit contact information you will need to navigate to the Sites tab.

Select a contact from the grid to activate the Contact Data panel located to the extreme right of the dashboard and view contact information.



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≣° Ma	ss Coding 💄 Convert to u	iser(s)		Search		Q	Contact Data	
	Name	Contact Type	Phone	Main Co	Provide		E-mail:	123@test.com
☑ 上	Anna Bravo	Clinical Researc		No	No		Prefix:	
	Dana Marvel	Backup Study C		No	No		First Name:*	Anna
01	jon snow	Principal Investi		No	No		Last Name:*	Bravo
	2						Suffix:	
							Phone number:	
							Mobile number:	
							Contact type: *	Clinical Research Program Manag
							Address:	111 Eastman Drive
4							City:	Kansas City
							State:	MO
							ZipCode:	27555
							Country:	United States
							Clinical Trial	
							Experience:	
							Provide Documents:	
							Active Contact	
							Main Contact:	

Steps to Site Activation

To activate a site in the Trial Interactive Study Start-Up module a series of steps must be

followed.

The site information and users specific to the SSU site can be imported by TI if information is provided in a formatted excel. In addition, sites and users can be added in the site grid.

Activating a Site

Once all essential/required documents are sent by the sites to the trial room and approved by appropriate authorities, the site can be activated. Only Site Activation Members will access the site profile to activate the site. Upon site activation, documents can be auto-named, auto-routed, and auto-filed to the appropriate location within the finalized eTMF. To note, Administrator role can place preference on these automated setting features from the Study Start-Up settings.

Once all the required documents are approved by both the Start-Up Specialist and the Regulatory Reviewer, the Essential Documents Progress bar shows as 100% in the Site Profile and the Activate/Reject button at the bottom of the Site Profile dashboard appears.

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Site Activation	Essential Documents	All Documents Communication	Log Institutions						
By Status 💌 🍸 🔟	Required fields are marked with an	asterisk (*)				Essential Documents Progress			
🕶 🖕 All	Institution Name:*	Carol				Investigative Site Carol			
🛋 Active [7]	CR4:				*	100%			
	Start. Un Specialist				*				
Non Participating [1]									
📑 Pending [11]	O Create O Add eviatin		eliunte I						
		First Name	E-mail	Contact Type					
		Carol	Carol@ti.com	Principal Investigator					
		Caro	Caroliga.com	Finicipal investigator					
	- Address								
	- 💌 More								
	Edit History:	Profile created by Admin 10 Last updated by Admin 103	04 on 8/24/2020 2:21:48 PM EST 8 on 9/8/2020 11:55:35 AM EST						
	Activate/Reject Save	U Cancel		Z Requirements	T Security	🛚 🚣 Regulatory Approvers: 0 🙆 😫 🟴			
	Grid Profile 📕	< Site 5 / 11 🔰 射							

To activate the site:

- 1. Click the Activate/Reject button.
- 2. The Set Investigative Site Status window opens
- 3. Select the Status as Active.
- 4. Enter the comments
- 5. Click the Activate button

Set Investigative Site Status	×
Site activation / rejection summary	Step 3 of 3: Summary
Activate	
No comment provided.	
There are no Investigative site's documents to be published to th	le eTMF.
< Previous	Activate Cancel



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To reject the site:

- 1. Click the Activate/Reject button
- 2. The Set Investigative Site Status window opens
- 3. Select the Status as Rejected.
- 4. Select the reason for rejection.
- 5. Enter the comments.
- 6. Click the **Reject** button.

Set Investigative Site Status	×
Site activation / rejection summary	Step 2 of 2: Summary
Reject	
No reasons selected.	
Comment: Reject	
	< Previous Reject Cancel

The site will then be activated and the documents will be published to the eTMF or workflow as per your settings. You will receive a confirmation about the same. You can also specify the users, and contacts who will receive email confirmation on site activation from Study Start-Up settings.

The Activate/Reject button will then disappear, and the site name will now appear under the Active folder in the Current window. Refer to the screenshot below:

Note: If during site activation system cannot move the documents to eTMF for some reason, such documents will not be moved and user will be warned about it. In that case site will not be activated. The reasons of why docs cannot be moved to eTMF are: duplications found, cannot determine Index position.

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Site Activation	Dunder-Mifflin Paper Company	Essential Documents All Doc	uments Communication Log Institutions					
By Status 💌 🍸 🔟 🗖	Required fields are marked with an a	asterisk (*)				Essential Documents Progress		
🕶 🔂 All	Institution Name:*	Dunder-Mifflin Paper Comp	any			Investigative Site Dunder-Mifflin Paper		
🛋 Active [7]	CRA:	× Editor 102			×	100%		
Non Participating [1]	Start-Up Specialist:	# Editor 103			×	Site Activation Date:		
Danding [11]	Contacts					08 Sep 2020		
Pending [11]	O Create O Add existing	Create OAdd existing / Edit ODelete OActivate 2 Convert to user(s)						
	Last Name -	First Name	E-mail	Contact Type				
	🗆 🗶 Scott	Michael	michaelscott@ti.com	Principal Investigator				
	- 💽 Address							
	- More							
	Edit History							
	Eait History.							
	🕝 Close Site 🗎 Save 🟮 C	ancel		2 Requirements	K Security	Approvers: 0 C II		
	Grid Profile 4	Site 1/7 > N		The second second	THOMAS IN			

Amendments

After a site is activated and the clinical trial begins, it is very common to have amendments to the study protocol, depending on the nature of the amendments many more essential/required documents needs to be submitted by the sites. Such documents cannot be added to the site directly and can be specified only through Amendments. Amendments can be created for Investigative Sites, Country Amendments, and IRB/EC.

Creating Amendments

To create amendments, the administrator needs to do the following:

- 1. Navigate to Settings.
- 2. Click the arrow next to Required Documents in the left panel.
- 3. Select Amendments from the dropdown.



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4. The Amendments Management window opens in the right panel.

Training Team eTMF	Room +		Q Search 🛛 Add 👻 🌲 📢 Yi	ogesh Inamo
Search	Q 🗷 About	gement ×		
🚖 Outbox	Add / Edit Opelete			
Ø Documents Distribution	Title	Description	Amendment Date Num	ber of Requ
Eorms Settings	Dummy	Ammend 1	11 Sep 2020 1	
 General Integration 	NM Protocol Amendment		08 Sep 2020 3	
Documents	D > summer		31 Aug 2020 2	
Document Types	Becky Amendment		17 Aug 2020 3	
▼ 2 Required Documents	Monday Amendment		18 Aug 2020 1	
Required Documents	Slytherin		31 Aug 2020 1	
Amendments	AA protocol amendment		11 Aug 2020 0	
+ Export	Protocol Amendment		29 Jul 2020 1	

5. The Create Amendment window opens.

Create Amendment					×
Required fields are marked with an	sterisk (*)				
Title:*					
Description:					
Amendment Date:*					-
Required Documents					
OAd Oelete					
Quired For A Entity Na	me Category	Document T	Languages	Contacts	0
			C	reate Ca	ancel

a) Fill in the details as required.

b) Click Add in the Required Documents panel in this window.

c) The Required Documents window opens.

d) From the Required For dropdown in the left panel select an option as required (All Sites, Specific Site, Specific IRB/EC, or Specific Country).

- e) From the right panel select the essential/required documents that are needed after the site activation.
- *f)* The procedure to add the documents is same as described in earlier section Basic Configurations for SSU (*page 502*)
- 6. Click Create to create the amendment.



Viewing Amendments and Adding Documents

To view amendments for a site/s and countries, navigate to the Sites section. From the Current View in the left, click the three yellow bars above the panel to activate the Filter By Amendment dropdown. Choose the amendment as required. Refer to the screenshot below:

NM	Protocol Amendment
4	Dummy
	NM Protocol Amendment
Δ	summer
4	Becky Amendment
4	Monday Amendment
4	Slytherin
4	Protocol Amendment
Δ	Site Activation

Double-click a site name from the Grid Pane to open the site profile window for amendments. Like the Sites, and Country section, this window also has three tabs – Essential Documents, All Documents, and Communication Log. The procedure to add documents and communications are the same as described in section Collecting Essential and Non-Essential Documents (page 552)

Amendments for IRB/ECs can be viewed from the IRB/EC section. Here too, you will be able to select the required amendment from the Filter By Amendment dropdown in the Current View panel. The rest of the procedure is the same for Sites and Countries as described above.

QC Review and Regulatory Approval of Amendments

After the documents for amendment are added, essential documents will need to pass the QC Review and Regulatory Approval.

The non-essential documents will need to pass through the approval process only if it is specified in the Study Start-Up settings. The settings in this section also apply to the amendments.

The process to review and approve the documents for both the processes is the same as

described in earlier sections.

To Regulatory Review the documents, the Regulatory Approver will need to log in to the system and enter the Regulatory Review section. Here too, the Regulatory Approver selects the required amendment from the Filter By Amendment dropdown in the Current View panel and selects the documents to approve/reject them from the Grid Pane.

Completing an Amendment

Once all the documents (essential and non-essential) are approved, the amendment profile window acquires the **Complete Amendment** button at the bottom. Click the button to complete the amendment. You will need to confirm the process by clicking Yes on the dialog box that



appears on clicking the button.

On clicking 'Yes', the amendment will be completed, and the documents will be published on the eTMF. Whether they will take the place in the default folder to be picked up for the workflow process, or they will be auto-routed to their respective positions in the eTMF index depends once again on your settings in the Study Start-Up section. On completing the amendment, you will receive a confirmation for the same. Click Ok to accept the confirmation.

Overview Dashboard

The Overview Dashboard, which consists of a number of different dashlets, can be made available to users by room Administrators, depending on the needs of the client and the particular study room. The dashlets are described here in the subsequent topics.

Dashlet-Documents Expiring in N Days/Expired Documents

The Documents expiring in N days/expired documents dashlet lists the expiring and expired documents as specified in the expiration period (N). The dashlet has two views that can be selected through two buttons, Expiring and Expired on the top left corner. To set the views click the Dashlet icon located on the top right corner. The header of the dashlet changes as per the view selected. To set the expiration period for the documents, click the configure icon on the top right corner of the dashlet. Refer to the screenshot below:





The columns can be selected from the Expiring or Expired button in the above screen and also through Modify Grid Config. To view Expiring or Expired documents, click the Expiring button or Expired button from the dropdown on the dashlet.

Refer to the screenshot below:

eTMF					13
eTMF Healt	h Claimed & Unclaimed Expired D	Documents Rejected and In-Clar	ification Documents My Queries Open Querie	is By Age	Add New Version Export Documents Metadata
Expired Expiring	ed)				C 🖾 Select Columns 🕫 Views *
ù i	Submitted Name	Document Date	Document Type	Expiration Date	Comments
	СТА	22 Apr 2020	Form FDA 1572	29 Sep 2020	
	PI Medical License	17 Jun 2020	PI Medical License	19 Oct 2020	
	InvestigatorAgreement_29Sep2014	26 Feb 2020	Acceptance of Investigator Brochure	02 Oct 2020	
					H 4 Previous 1 of 1 Next > H

Dashlet-Recent Communication Logs

The **Recent Communication Logs** dashlet gives a list of all communications made during the site start-up and activation stage. Click the **View All Communication Log** to go the Communications module of **Start-Up dashboard**.



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Recent Communication Log						
Recent Communicatio	Recent Communication Log					
				View All Communication Log		
2 Communication Logs	2 Communication Logs					
Date	Туре	Description	Contact Name	Communication Entity		
8 Sep 2020	Email	Sent welcome email in anticipation of the reg packet.		A		
9 Sep 2020	Regulatory Pac	E-Delivery of Reg. pack to the site	Test Doctor	Test Site #1		

Dashlet – Recently Updated Sites

The Recently Updated Sites dashlet is available under the **Investigative** sites dashlet. This gives the activation progress report of all sites in a room. Hover the mouse over the Progress% column to view the list of

Investigative Sites Recently Updated Sites Site Activation	Status		Bill and EC contributions Approval No Bill and EC constraints Approval No Bill and EC constraints of Non Bill and EC constraints of Non Forderal Inde Assurance Statement Bill Registration Number Bill Registration Number Bill Ref. Kasarance Bill Aff.C Attestation Form Recruitment Plan Bill and EC Approval	otification Voting Status current
1 - 2 of 2 (0 selected) Site	Principal Investigator	Status	Confidentiality Agreement PI Medical License Pi Financial Disclosure Form Progress Clinical Trial Agreement	Views 🔻
Site - 1010 kouz simon	simon kouz	Pending		
Site - 123456 Anderson Mary	Mary Anderson	Active		

documents that are missing to complete the site activation.

Dashlet – Site Activation Status

This dashlet offers two views - Sites By Country and Sites Activation Progress. Select the

Site By Country view to reveal the total number of active sites, sites pending for activation,

Investigative Sites			Ø 2
Recently Updated Sites Site	Activation Status		
35		All Sites	 ▼ Sites Activation Progress ▼ Sites Activation Progress
3			Sites Activation Progress
2			- e 1
1			
0.5			

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and sites rejected from activation in each country in the form of a bar chart. Refer to the screenshot below.

Select the Site Activation Status view to reveal the number of sites activated per month. Drag the bar further to scroll down the chart.

By default, the charts reflect results from all sites; however, if you wish to view only your own sites, click the All Sites button next to the chart type



to change it to My Sites. Clicking a high point on the line graph or a bar in the bar graphs reveal the sites for the particular status.

Double-clicking a site name will open the Edit investigative site popup to allow you to edit

the details of the site.