TRIAL INTERACTIVE

~~MYTI~~MYTI V2.2 - USER GUIDE V1.0~~0.1~~

TRANSPERFECT LIFE SCIENCES

APPROVALS

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CONTENTS

VERSION HISTORY

Author	Revision	Date	Change History
Janki Prajapati	1.0~~0.1~~	03-April-2025	Initial document creation

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HARDWARE AND SOFTWARE REQUIREMENTS

The following describes the hardware and software requirements to use the Trial Interactive v10.6 platform.

System Requirements	
iOS	• OS Version: iOS 14 and higher. • Tested and verified on iPhone 13, XS • **Supported Devices:** any iPhone device that supports iOS version 13 or higher.
Android	• OS Version: 11 and higher • Tested and verified on Samsung Galaxy S20, LG V30, Google Pixel • **Supported Devices:** any Android device that supports version 11 or higher, including Samsung Galaxy S9, Samsung Galaxy S8, LG V30, and Google Pixel.
Trial Interactive	Trial Interactive 10.4.2 and higher. Supports Multi-Tenant and Dedicated Instances of Trial Interactive.
CTMS	CTMS v2.0 and higher.
GlobalLearn	GlobalLearn v2.5, and higher.~~.~~

ABOUT THIS USER GUIDE

This guide provides a comprehensive overview of the features and components of the ~~myTI~~myTI v2.2 application, enabling users to work efficiently and securely manage their tasks within the platform.

It includes detailed instructions on the user interface, step-by-step processes, and visual aids to enhance understanding and ease of use. This guide is exclusively designed for clients who have purchased the Trial Interactive platform.

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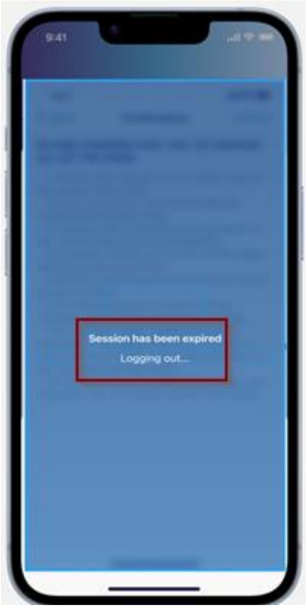
CHAPTER 1. NEW FEATURES IN ~~MYTI~~MYTI V2.2

This section highlights the new features and enhancements introduced in the ~~myTI~~myTI 2.2 version.

Auto Log Out Notifications

Log Out Notification

The system continuously monitors user activity while they are manually taking or signing a course within the application. If the user remains inactive for a configured period, a notification is automatically triggered to alert them of the upcoming log-out due to inactivity. This alert serves as a warning and, if applicable, allows the user to take action to remain logged in before the session ends.



Incorrect Credentials Notification

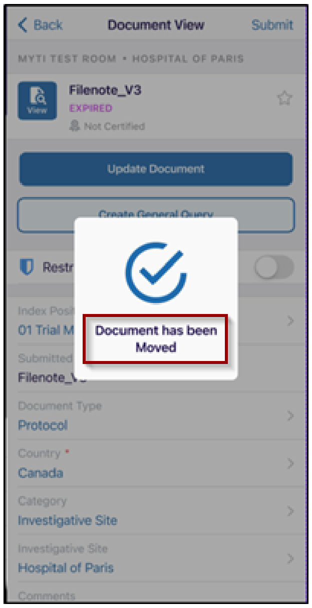
When a user enters incorrect credentials-such as during document submission or while performing an eSignature-a clear, contextual notification will be displayed. This message helps the user quickly identify and resolve the issue, ensuring a smoother and more intuitive experience during authentication-related tasks.

Editable Index Field for Existing Documents

This enhancement provides users with greater flexibility in managing documents and placeholders, resulting in a smoother workflow and ~~an improved~~an improved user experience.

Editable Index Position:

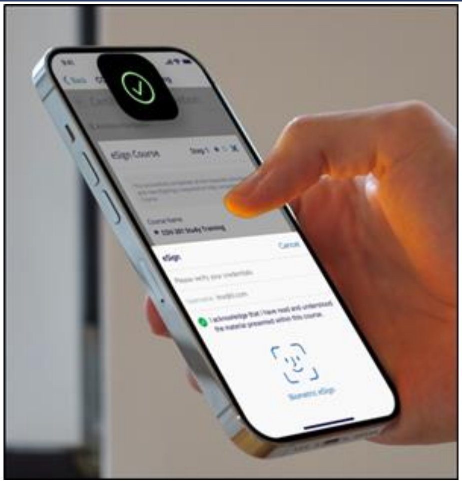
The Index Position field is now editable for both existing documents and placeholders on the Document View screen, allowing users to move document between folders even after creation and for more flexible and consistent content organization.



Error Alert:
To maintain proper permission controls, an error alert will be displayed if a user attempts to move a document between folders without having the necessary permissions. This alert will inform the user of the restriction, helping prevent unauthorized folder changes and maintaining data integrity.

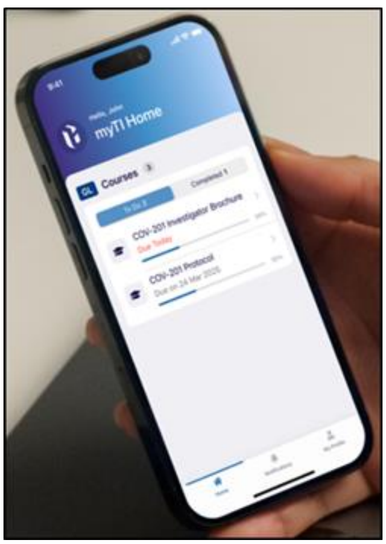
Cyber Security Testing Update

Cyber security testing identified minor issues in the application. These are being addressed to meet current security standards and maintain regulatory compliance.



Mobile-Friendly Viewer Enhancement for Documents and Videos

The document and video viewers have been improved for Android and iOS, allowing full-screen viewing in landscape mode for a better mobile learning experience and making it easier to take courses on the go.



eTMF Dashboard for Health Monitoring

Users can now view eTMF health metrics directly in the ~~myTI~~myTI app through the new Health Dashboard.

Consistent Data Synchronization
Dashboard data will remain consistent between the ~~myTI~~myTI app and web version, ensuring a smooth and unified user experience across platforms.

Single-Screen Data Display
All relevant eTMF information is shown on one screen in the app for quick and easy access.

Dedicated Dashboard Tab
A new eTMF Health Dashboard tab will be added in the ~~myTI~~myTI app for quick and easy access.

Drill-Down Functionality
Users can tap on any field in the dashboard to view more detailed information when needed.

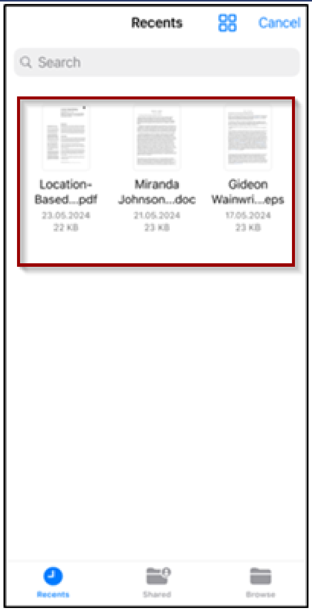
This update makes the eTMF Health Dashboard easier to use and helps users quickly see important information in the ~~myTI~~myTI app.

Rapid Scan Feature Enhancement

When Rapid Scan is enabled, users no longer need to enter the 'Index Position' field, making scanning faster and more efficient.

Display All Supported File Types in ~~myTI~~myTI

~~myTI~~myTI users can now view and upload more file types, such as .docx, .xlsx, .jpg, .png, .gif, and more-making it easier to work with different formats in the app.



Document Submission Popup Orientation

The popup will stay in portrait mode even when the device is turned sideways, ensuring a consistent and clear display.

CHAPTER 2. INTRODUCTION

Trial Interactive

TransPerfect's *Trial Interactive* has been used successfully by TransPerfect customers for over 15 years in hundreds of clinical trials to store critical trial documents as part of the Electronic Trial Master File. Trial Interactive's platform is a web-based and mobile-enabled software-as-a-service (SaaS) application that provides eClinical solutions for eTMF and content management, Study Start-Up, and various other tools used in conducting a clinical trial. Trial Interactive's products deliver a wide range of benefits to any organization looking to leverage new efficiencies and opportunities in their Trial Master File, clinical trial management, content management, and eLearning:

- An electronic Trial Master File archive that meets all regulatory, security, access, and storage requirements in all countries and regions.
- A Clinical Trial Management System (CTMS) that meets all eClinical requirements for managing and tracking clinical studies and works seamlessly with the eTMF, Content Management, Learning Management, Mobile app, and other Trial Interactive solutions.
- A fully hosted SaaS solution that is 21 CFR Part 11, Annex 11, ER/ES, GDPR, and GxP compliant.
- A single access point for all trial content as well as sponsor and site personnel documentation.
- Supports a series of TMF workflows, including document import and indexing, quality review, audit and inspection, document certification, remote monitoring, redaction, and the capture of other Clinical Trial documentation.
- Effective management of documents that are created internally or externally. Trial Interactive is the only solution that provides a best practice and validation-ready approach to creating, collecting, reviewing, and finalizing documents bound for the eTMF archive.
- A thin-client, consumer-grade user interface that supports most major browsers and a mobile app that supports iOS and Android devices.

- A powerful, flexible technical stack with many integration options, including an API, Event Service Bus, SFTP Dropbox, and Corporate Directory Integration with Single Sign On.
- Increases teamwork and collaboration via one global view of clinical trials, training, and supporting documentation.
- A flexible, configurable document management solution for Clinical, Quality, and Regulatory documentation that supports a series of reviews and authoring solutions.
- Dashboards and reports that provide KPIs, measurable metrics, simple Excel exports, as well as complex standardized and custom reports.
- Adaptable, built-in machine learning features such as auto-classification and metadata extraction enable AI auto-coding capabilities.
- A full-featured eLearning system designed for GxP compliance, study training, and virtual investigator meetings.
- Effectively manage the entire clinical trial process from protocol conception through closeout.

~~myTI~~myTI

CRAs spend a lot of their time on site manually handling paper documents for Regulatory Binders or ISF for Sites. This includes mailing boxes of documents, transporting them to scanning facilities, and photocopying them. Limited access to scanners, paired with technical issues while scanning or emailing documents, adds to their workload and could also lead to missed IRB reviews.

Trial Interactive addresses this problem through its ~~myTI~~myTI mobile application, which allows constant access to site statuses. It reduces the workload of CRAs or other site personnel, namely the CRO, main contact, and coordinator, by leveraging the Smartphone technology to access studies and sites and to search for documents in the eTMF. While on-site, it allows the CRAs or other site personnel to safely and securely use the camera interface of their Smartphone device to:

- Scan and upload images of paper documents to the TI eTMF.
- Update queried and expired documents to the TI eTMF.
- It also allows access to contact information for any central Lab, CROs, and contract facilities that its users might be working with.

eTMF

Trial Interactive's electronic Trial Master File (eTMF) is a secure, cloud-based solution enabling real-time collaboration for both sponsors and CROs, supplying value and ease of use for trial stakeholders across the board and now bringing enhanced transparency and visibility to the trial. Trial Interactive's eTMF can help an organization in multiple ways including the following.

- Ensure quality with the ability to have a customized workflow for indexing and approval powered by AI and machine learning.
- Stay current with required document lists and placeholders based on the TMF Reference Model. Placeholders and required document lists ensure that all expected and essential documents are captured in your final TMF.
- Track timeliness with KPI metrics dashboards that measure document intake from receipt to submission through QC and finalization.
- Encourage better compliance with an eTMF that tracks responsibility and actively requests documents when they are due, supporting queries for document corrections through email or upload.
- Confirm and maintain the validity of the eTMF before inspections using quality review audit capabilities to support oversight, periodic reviews, and inspection readiness.
- Ensure overall reportable eTMF Heath with Key Performance Indicator (KPI) metrics, reports, and portfolio dashboards for eTMF health, timeliness, quality, and completeness.
- Plan amendments, visits, and other key trial events and milestones while creating placeholders for the expected documents that need to be collected, including due dates and responsibility to help track eTMF health and timeliness.
- Automate the classification and metadata extraction of the TMF using powerful AI auto-coding with human-aided machine learning.
- eClinical platform interoperability provides a seamless connection and data flow between the eTMF and other critical applications such as a site portal, eISF and site binders, content management, document authoring, study startup, and clinical trial management systems.
- Email and study correspondence inbox with relevance checks captures all email correspondence for each study. Once a correspondence email is sent in, it is rendered to PDF and may be selected for inclusion in a separate interface by study staff. Attachments are checked for duplicates and are linked back to the original email. Emailing documents and site correspondence securely into the eTMF ensures GCP compliance.
- Document redaction, manipulation, and certification allow selected team members to remove personal information to meet data privacy requirements and repair, split, and merge documents. Additionally, document certification helps ensure proper paper disposal.

Additional features of the Trial Interactive eTMF include:

- A mobile content capture app that supports both iOS and Android, with support for CRA reconciliation, metadata classification, query management, training, redaction, and offline mode.
- Drag and drop emails and documents to import them automatically or drop them onto placeholders for auto-assignment.
- Full query and task management capability with three types of queries for requesting, verifying, and responding via email, web, and mobile apps.
- Automatic alerts and reminders with notifications and a daily digest.

- Built-in eSignature and digital signature solution for 21 CFR Part 11 and ER/ES compliance with pre-defined signature blocks, pages, and digital certificate.
- Universal document viewer that supports and renders over 300 document formats.
- Multi-document view with built-in document comparisons, bulk editing, page rotation, deletion, reordering, and annotations.
- Global search provides cross-study search results for documents, document types, full-text, contacts, sites, and other record types, with facets, filtering, and other advanced features.
- Configurable grid filters, column selection, saved public/private views, and built-in reporting tools for ad-hoc exports.
- Standard and ad-hoc reports that support all metadata fields and the ability to add columns to standard reports or fully customize your exports.
- Completeness view showing TMF structure, final documents, planned documents/placeholders, and required documents.
- Configurable support for the latest TMF reference model with full auto-routing and auto-naming rules.
- Automatic duplicate document detection and comparison verifies that a document is unique and does not have a duplicate in the eTMF archive based on identical metadata or an exact copy or duplicate scan.

Collaborate

Trial Interactive provides an online collaborative workspace, which enables collaborative and controlled document authoring, review, and approval. Designed to include 21 CFR Part 11 compliant workflows and approvals, the solution offers an end-to-end service platform for your organization's content management and document control requirements. These collaborative rooms allow users to benefit from the following solutions:

- Study Collaborate and the CTMS Collaboration Rooms are shared workspaces for clinical teams to manage and share documentation to be used in the clinical trial and ultimately shared with the eTMF.
- Site Collaborate/eISF and Remote Monitoring Rooms are shared workspaces for sites to manage, redact, reconcile, and share documentation with the sponsor and CRO to conduct the clinical trial and ultimately send it to the eTMF.
- The Quality Document Management solution provides controlled document workflows to an organization for use by clinicians, quality assurance, R&D, and other life sciences teams to collaboratively author, review, approve, sign off on, make effective, train, and distribute regulated content and documents.

TI Collaborate can provide your organization with:

- A single place to share and collaborate on clinical documentation.
- The ability to align document work streams with regulatory compliance practices for document authoring, approval, control, and related training.
- The ability to enforce quality document control workflows on policies, SOPs, work instructions, and other critical documentation and to fully automate the training management process through the LMS.
- The ability to co-author and collaborate with other authors in real time on new documentation both online and offline with MSWord®, Excel®, and PowerPoint®.
- The ability to complete the end-to-end document process with an electronic and digital signature for document approvals.
- The ability to send documents for certified translation through TransPerfect TransPort, track their status, and receive back the translated copies and certificates.
- The ability to work with clinical sites in a remote monitoring and collaboration room, supporting mobile document collection, reconciliation, expected and planned documents, eSignatures, and collaborative authoring with the clinical site.
- The ability to follow critical processes for metadata, approval, and signoffs by publishing or sharing directly with the TMF.

CTMS

Trial Interactive's Clinical Trial Management System (CTMS) is a secure, cloud-based solution that enables the collection and management of trial-related data in a single location. TI CTMS provides the ability for clinical studies team members, such as study managers and CRAs, to plan, collaborate, and track clinical data with specific attention to monitoring requirements. This is the industry's first CTMS with a modern user experience and a mobile-first interface. TI CTMS can help your organization:

- Provide a single source of truth for all trial-related data and information, with an intuitive planning and tracking structure,
- Track and view product, program, study, country, site, organization, contact, subject, and subject visit data in real-time,
- Ensure quality with support for adjustable, best-practice CTMS workflows that ensure completion of critical trial requirements. Reduce risk by confirming that plans are followed per SOP with controls in place to prevent issues,
- Track timeliness with KPI metrics dashboards that provide an integrated real-time view of Clinical Trial data,
- Confirm a fully updated CTMS before inspections with quality oversight, periodic reviews, and operational checks,
- Plan study-related activities such as site visits, communications, training, and other key trial Milestones with due dates and responsibilities using visit schedules and activity plan templates,
- Manage trial-related documentation with a built-in Content Management System and integrated eTMF, along with many other offerings,
- Support flexibly, company-specific workflows and SOPs with a full set of custom fields, record statuses, and field validation,
- Improve quality through standardized business practices and record-keeping,
- Provide trial insights through drill-down study and portfolio dashboards, and,
- Streamline clinical processes to reduce costs.

Additional features of the Trial Interactive CTMS include:

- A mobile visit report App that supports both iOS and Android, with support for questionnaires, activity tracking, CRA Reconciliation, training, document capture, and offline mode
- Pre-defined, best-in-class CTMS Activity Plans for consistent trial execution and operational checks
- Built-in Site and IRB correspondence tracking, Email capabilities to keep close track of all back-and-forth activity
- Automatic Notifications, Alerts, and Reminders with emails and a daily digest
- Standard and Ad-hoc reports that support all custom metadata fields and the ability to add columns to standard reports or fully customize
- Full support for clinical data integrations, including EDC, Payments, and IXRS, either directly or through a technical partner. Fields may be pulled from EDC and included in CTMS reporting.
- Well-developed classroom and lab training courses with an integrated LMS and eLearning for study and site training.
- Simpler and less administrative: Assign ownership to Studies, Sites, and Countries with central admin optional. Study and Site owners may then fully manage the record types they own, inviting and revoking access by start and stop date and by role.
- Track everything that is trial-related in the form of a configured set of activities with types and subtypes that may all have their own configured sets of fields and statuses.
- Event, Activity, and Document Sharing
- A Clinical Trial Management System can track all trial activities as well as the collection of documents and evidence that must ultimately be published to the eTMF. As site visits are completed, they result in final documentation that must be archived. Additionally, documents must often be associated with trial records for viewing and distribution to the study teams.
- All site visits are configured in the CTMS to trigger Site Events that are sent directly to the eTMF. These Events may then trigger required documents and placeholder creation in TI.
- Visit status changes can trigger Events, Required Documents, and Placeholders within Trial Interactive, including eTMF rooms but also Site Collaborate and the CTMS Collaborative Workspace.

GlobalLearn

Trial Interactive's Global-Learn is a compliance-focused learning management system that enables sponsors, CROs, and sites to experience exponential savings in study training logistics with compliance learning that is integrated with TI eTMF and clinical content collaboration solutions. The integrated experience creates a seamless flow from clinical document authoring, review, and approval to training delivery to archival in the eTMF. Key features:

- A single access point for a single view of compliance assurance.
- With the "My Transcript" feature, ~~Global Learn~~GlobalLearn users have a consolidated view of their complete training history, including reported external training outside of ~~Global Learn~~GlobalLearn.
- Visual dashboards help with quick insights. Learners can monitor their progress while managers benefit from a single view of learning compliance.
- Rather than enrolling staff in one course at a time, assign an entire collection of training specific to a defined training group.
- A fully hosted solution that is 21 CFR Part 11, ER/ES, and GxP compliant.

Global-Learn can help your organization:

- Track and manage live, in-person, and virtual training courses for blending training
- Get better insight into compliance and make actionable decisions through Visual Dashboards
- Designate due dates for each course (with training completion reminders) so learners move progressively through their training and have it completed in an appropriate timeframe
- Maintain a consolidated view of the complete training history, including reported external training outside of Global-Learn
- Streamline compliance training processes and reduce costs

Global-Learn supports core regulatory requirements, including:

- Comprehensive audit trails
- Record protection and their accurate and ready retrieval
- Security by design (including unique login credentials and levels of access)
- Course archival options

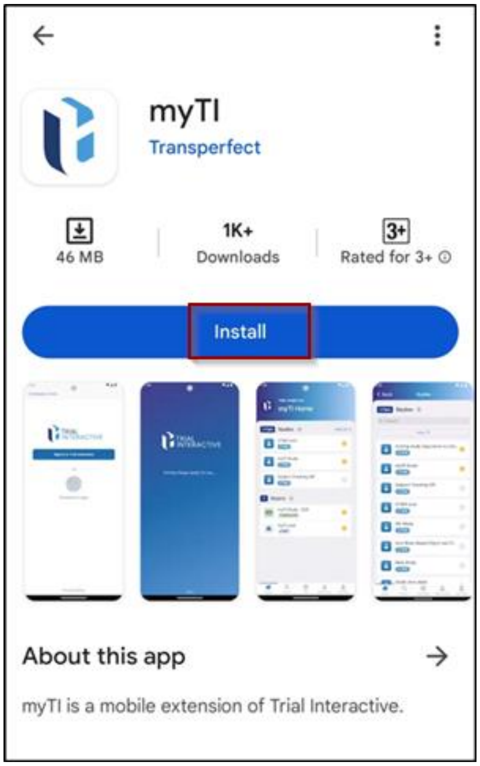
CHAPTER 3. GETTING STARTED

This section describes the step-by-step procedure on how to download, install, and set up the application.

Download ~~myTI~~myTI application

To download the ~~myTI~~myTI application, follow the steps below.

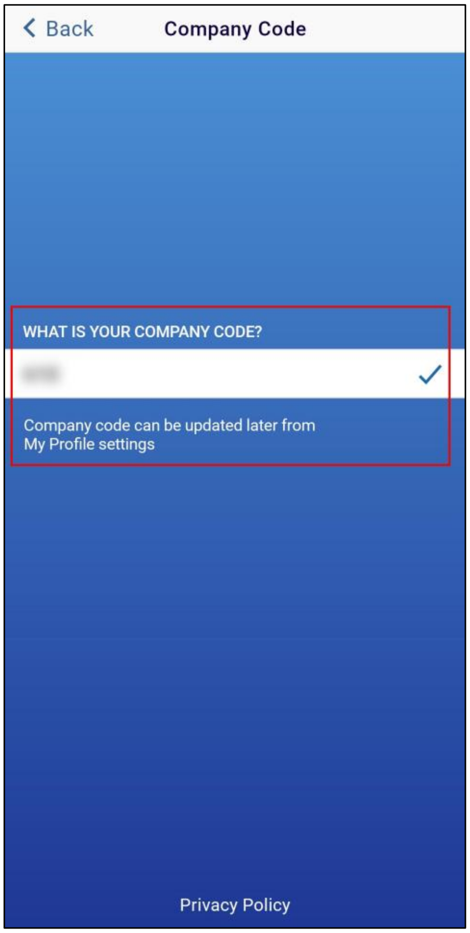
1. Search for the ~~myTI~~myTI application on the Google Play or App Store.
2. Click on the on the Install button.



Note: to download the application from the App Store, it is mandatory to download the TestFlight application.

Company Code

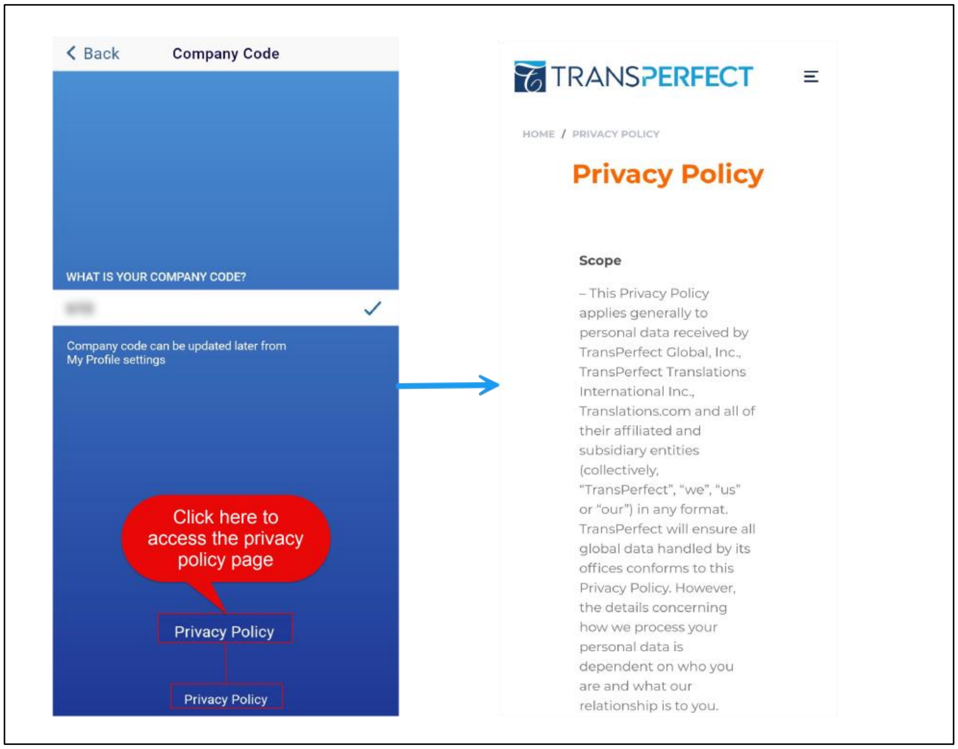
Once installed and opened, the application asks for the Company Code to be entered. If the company code is valid, a blue checkmark is displayed. If invalid, a red exclamation mark appears.



Note: Contact the Product Manager for the Company Code details.

Privacy Policy

Click on the Privacy Policy link to access the important privacy information.

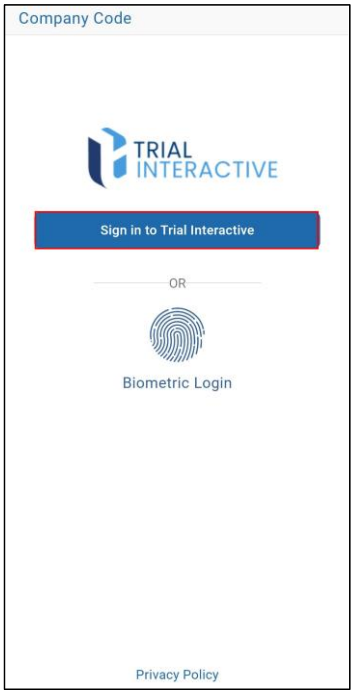


Manual Login

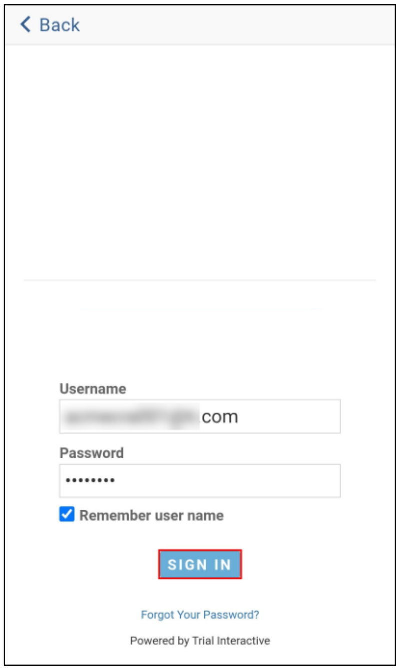
After entering the Company Code, users are redirected to the login page. First-time users must manually log in to the application.

To log into the application, follow the steps below.

1. Click on the **Sign in to Trial Interactive** button.

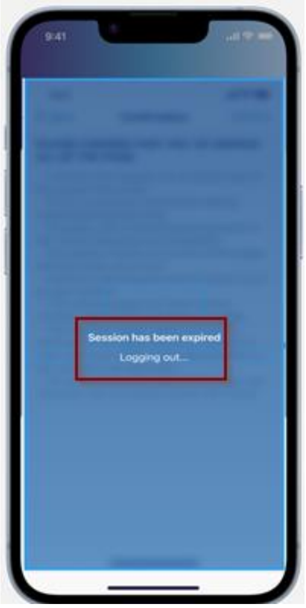


2. Enter the Username and Password into the designated fields.
3. Optionally check the **Remember user name** checkbox.
4. Click on the **SIGN IN** button.



Auto Logout Notification

The user remains inactive within the application for a defined period, a notification is displayed informing that they are logged out due to inactivity. This notification allows the user to remain logged in before the session ends automatically.



Incorrect Credentials Notification

When a user enters incorrect credentials-such as during login and document submission or while performing an eSignature-a clear, contextual notification will be displayed. This message helps the user quickly identify and resolve the issue, ensuring a smoother and more intuitive experience during authentication-related tasks.

CHAPTER 4. ~~MYTI~~MYTI HOME SCREEN

The Navigation bar at the bottom of the Home screen has the following tabs.

Tab Name	Description
Home	The Home tab provides access to the rooms assigned to the user and to which the user has access.
Search	The Search tab, also called Cross Room search, allows users to search for documents within any room they have access to without actually being in the room.
+Add	The +Add tab empowers users to scan a document or directly upload files into the application using the relevant options.
Offline Queue	This feature helps the user scan and upload the required documents when the user faces connectivity issues and keeps them in a queue while offline. The documents are saved for a few days in the offline queue mode. When the user is online again, the documents are automatically uploaded to the required room.
My Profile	The Profile tab enables users to view and configure their profile.

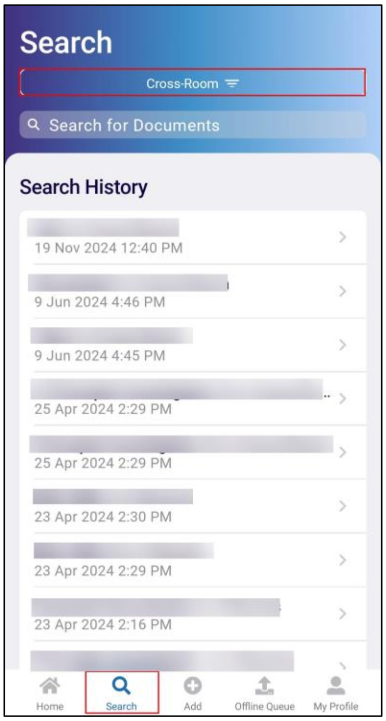
Home

Click on the Home Tab to view all the CTMS studies, TI Rooms, and assigned GlobalLearn courses.

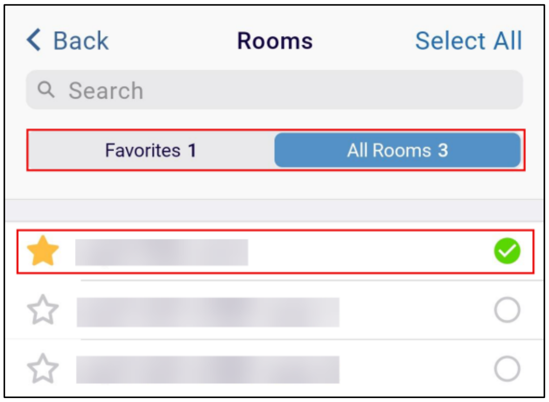
Search

To search for documents across rooms, follow the steps below.

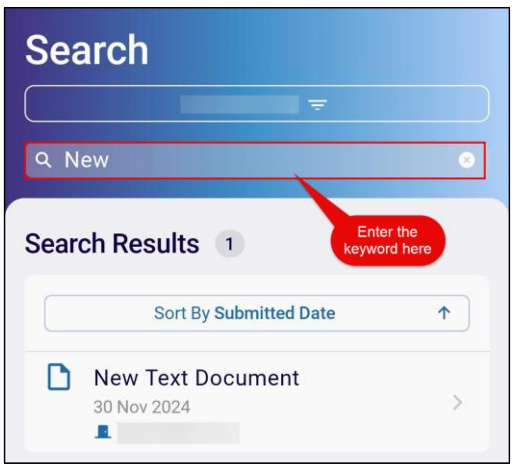
1. On the ~~myTI~~myTI home screen, click on the Search tab.
2. On the Search screen, click on the Cross-Room search tab.



3. Click on the All Rooms tab, select a room, and navigate back to the Search screen.



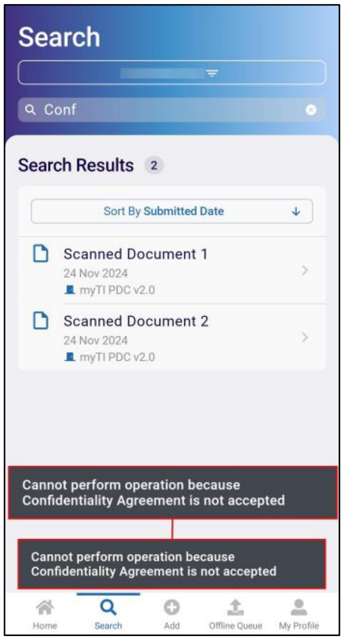
4. Depending upon the room selected, the search results will populate accordingly.
5. Optionally, enter a keyword in the 'Search for documents' search box to look for a specific document.



6. Select the required option and follow the document completion process detailed in the +Add section.

Important:

To ensure secured access to the document, the Search screen displays a notification when users attempt to open a Confidentiality Agreement document via the Cross Room search.



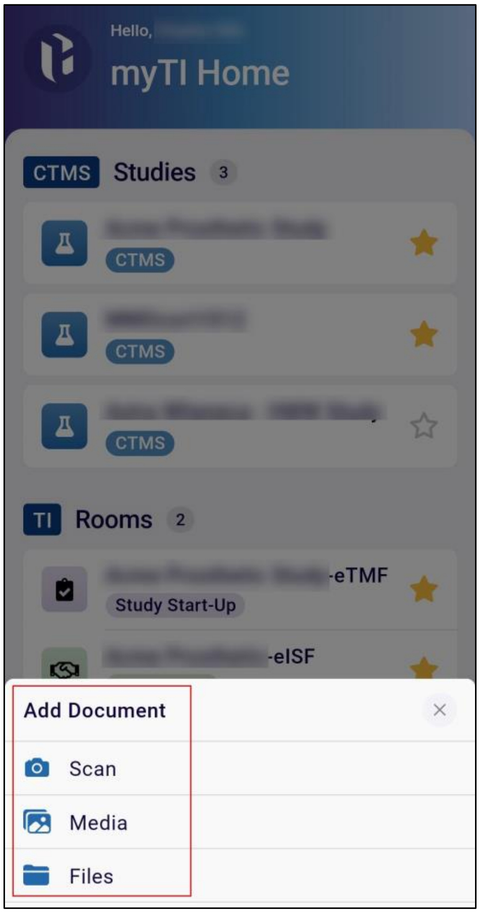
+Add

The **+Add** tab allows users to add documents, images, and other files to the application.

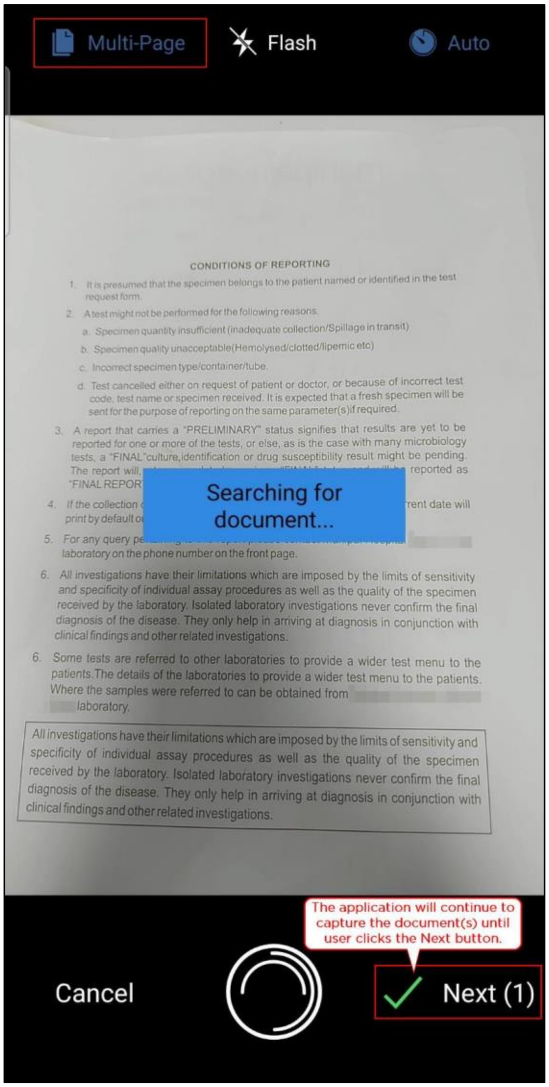
Scan

To scan and upload a document, follow the steps below.

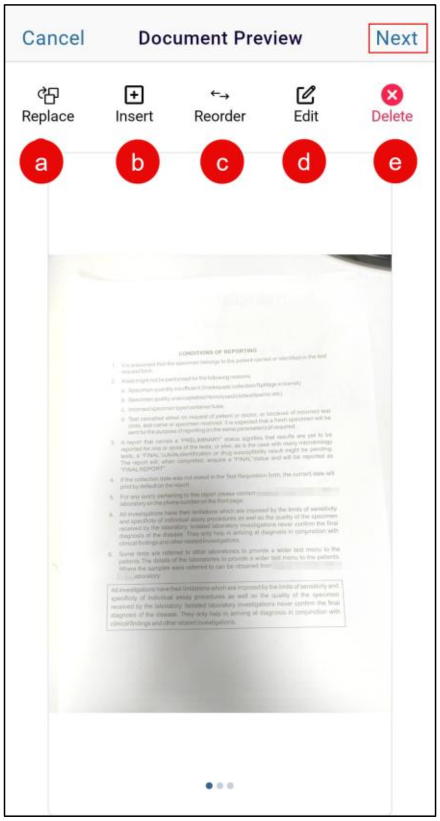
1. On the ~~myTI~~myTI home screen, click on the +Add tab.
2. Select the Scan option.



3. Scan the required document and click on the **Next** button. Select the Multi-Page option to scan multiple documents at a time.

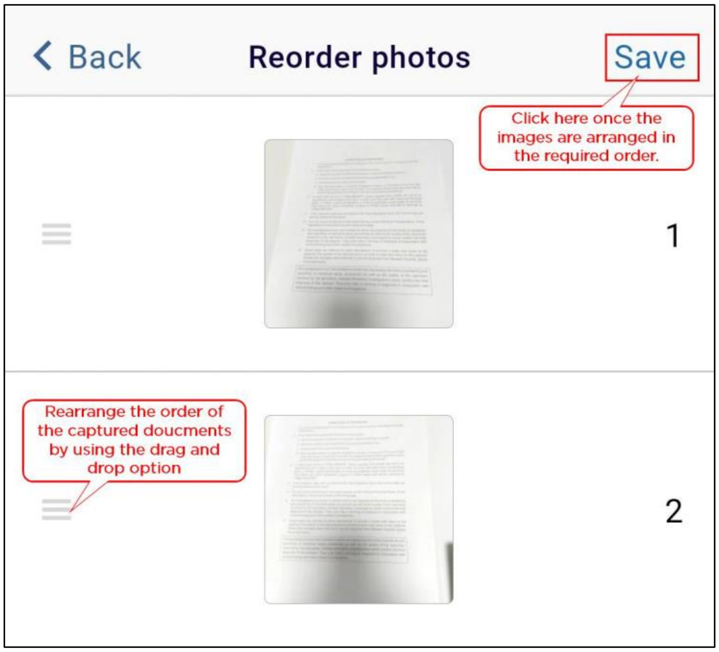


4. On the Document Preview page, perform the following actions if required else click on the Next button to proceed further.



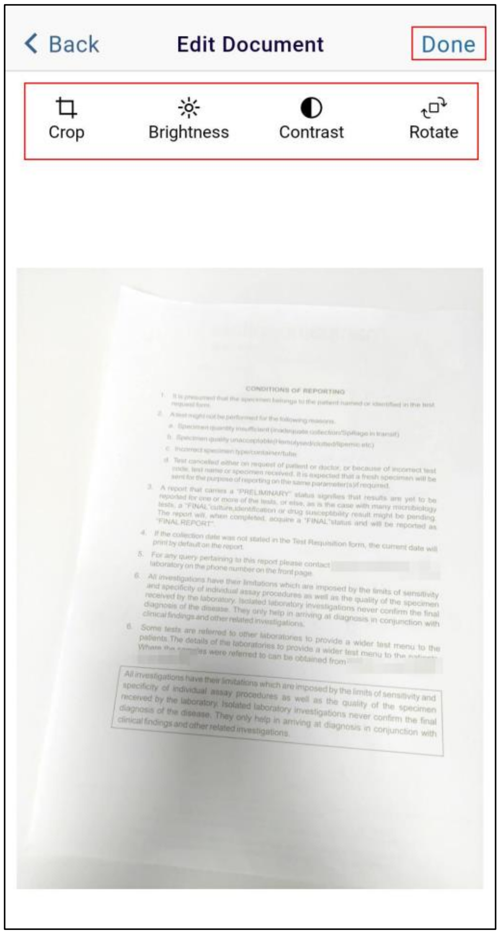
On the Document Preview, the following actions can be performed. (Refer to the sequence in the above image)

a. **Replace**: Selecting the **Replace** option will discard the initially captured document and allow users to capture another document in place of the initial one.
b. **Insert**: Selecting the Insert option will allow adding a document along with the initially captured document.
c. **Reorder**: The Reorder option allows rearranging the order of documents as per the user's requirements. On the **Reorder photos** screen, rearrange the order of documents by using the Drag and Drop option.

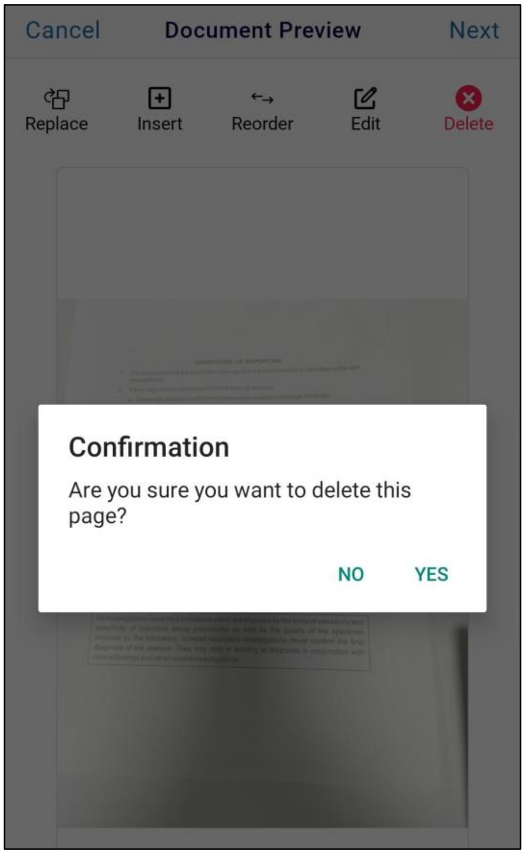


Note: The Reorder option becomes accessible if multiple documents are scanned, uploaded or inserted

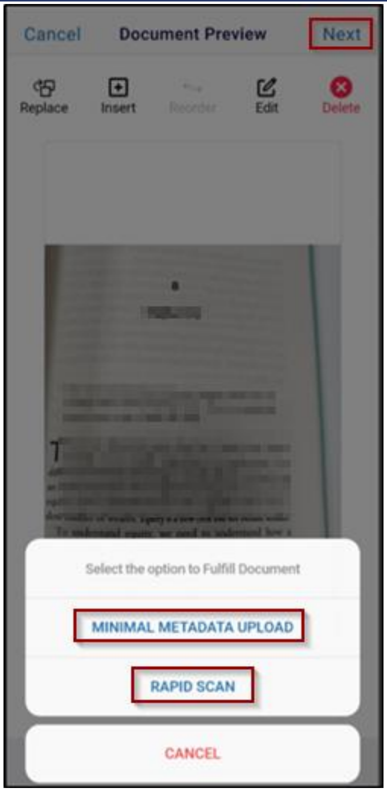
d. **Edit:** Selecting the Edit option will allow making aesthetic changes to the captured document(s) on the **Edit Document** screen such as:
   i. Crop
   ii. Brightness
   iii. Contrast
   iv. Rotate



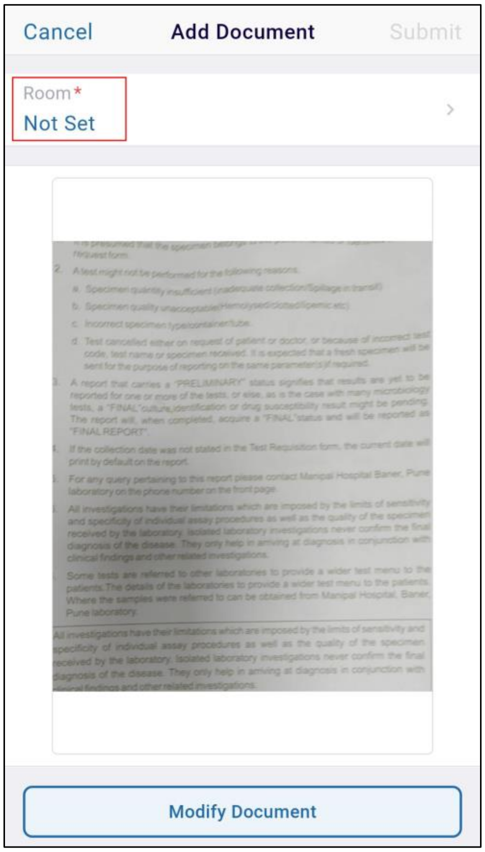
e. **Delete**: Selecting the Delete option will allow deleting the captured document. Click on **Delete** > **Yes** to delete the document.



5. Click on the **Next** button.

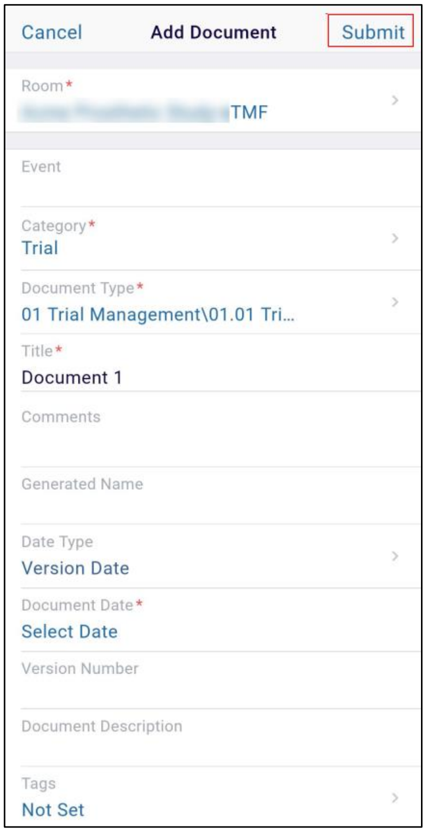


6. On the Add Document screen, click on the **Rapid Scan** or **Minimal Metadata Upload**, once the charges are made, click on the **Modify Document** button to make changes to the document and click on the Next button once the changes are made.
7. On the Add Document screen, click on the Room* field.

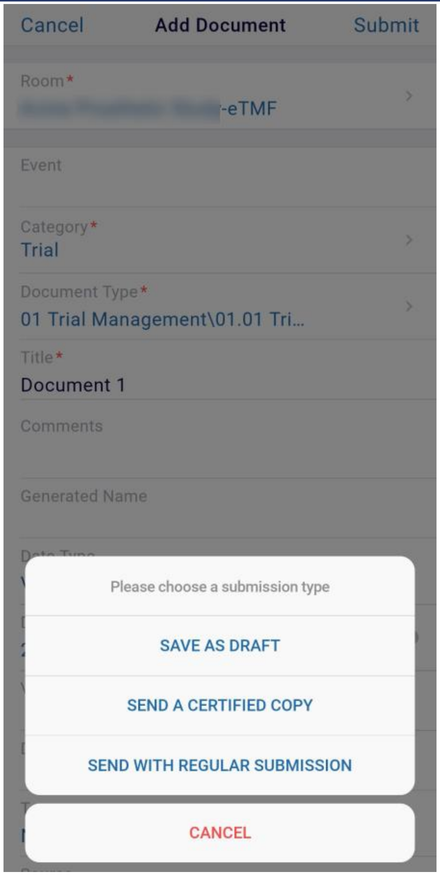


8. Select a Room from the available list to associate the document with and click on the **<Back** button.

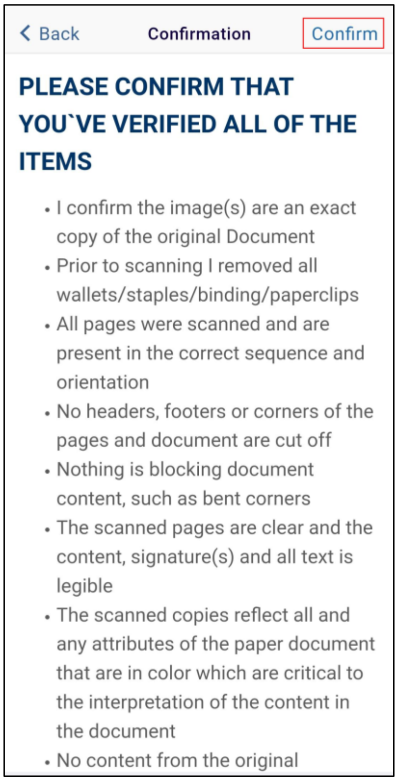
9. Fill in the mandatory metadata fields highlighted with a red asterisk (*) mark and click on the **Submit** button.



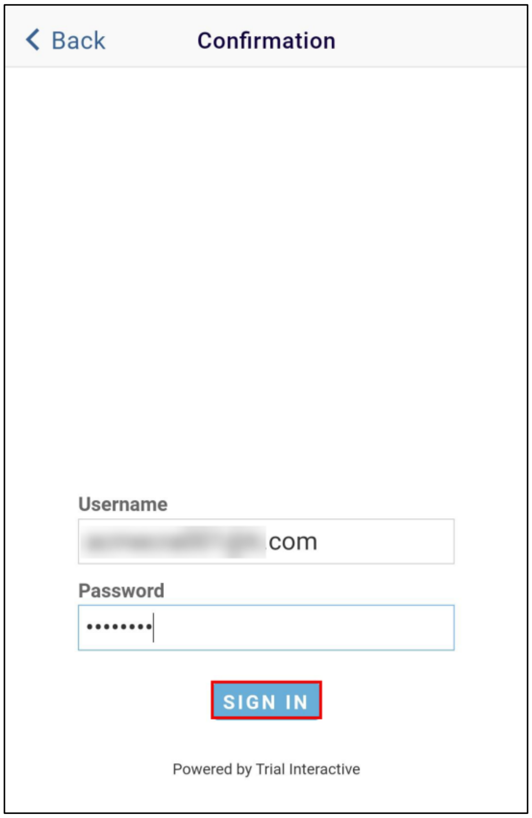
10. Select a submission type from the available options.
    a. SAVE AS DRAFT
    b. SEND A CERTIFIED COPY
    c. SEND WITH REGULAR SUBMISSION



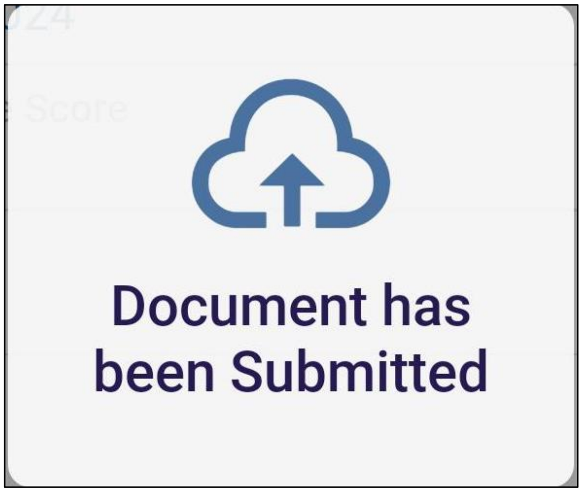
11. If the user selects **SEND A CERTIFIED COPY**, click on the **Confirm** button on the confirmation screen.



12. Enter the **Username** and **Password** and click on the **SIGN IN** button.



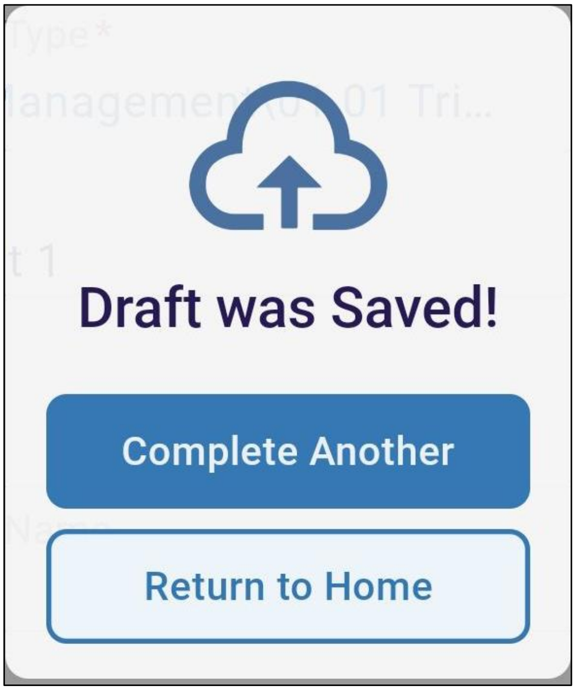
13. Upon successful submission, the application displays the corresponding notification message.



14. If the user selects the **SEND WITH REGULAR SUBMISSION**, the document is submitted without certifying and the application displays the corresponding success message.

Important

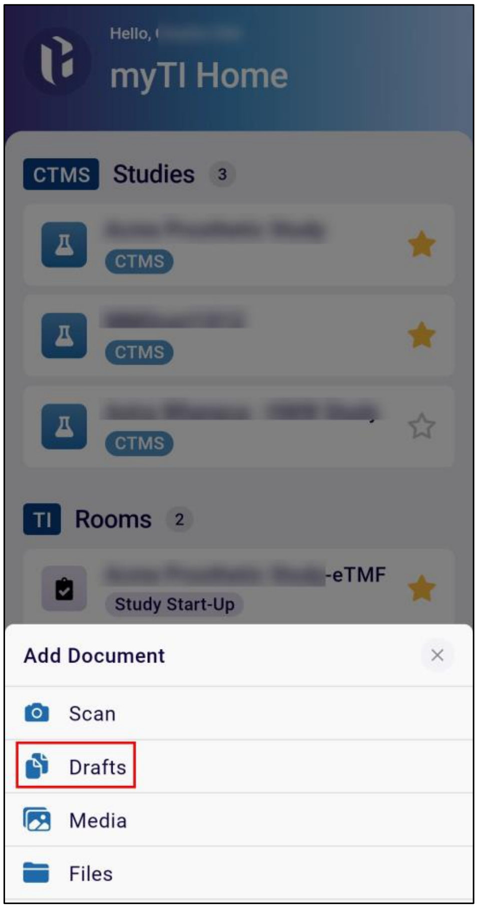
- If users select the **SAVE AS DRAFT** option, the application saves the document as a draft for future use.
- Once the document is successfully saved as a draft, users can select the **Complete Another** option to upload another document or select the **Return to Home** option to navigate back to the ~~MyTI~~myTI home screen.



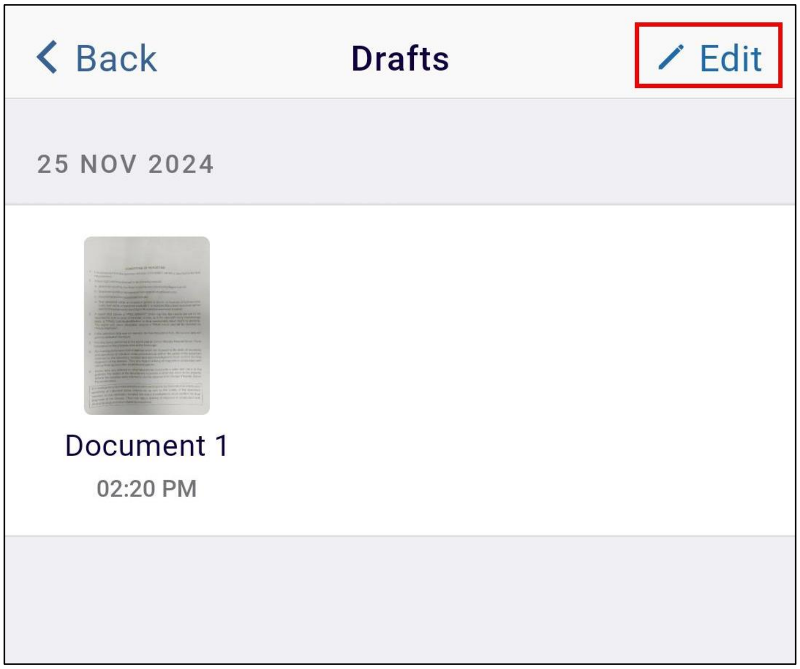
Drafts

To access documents saved as drafts, follow the steps below.

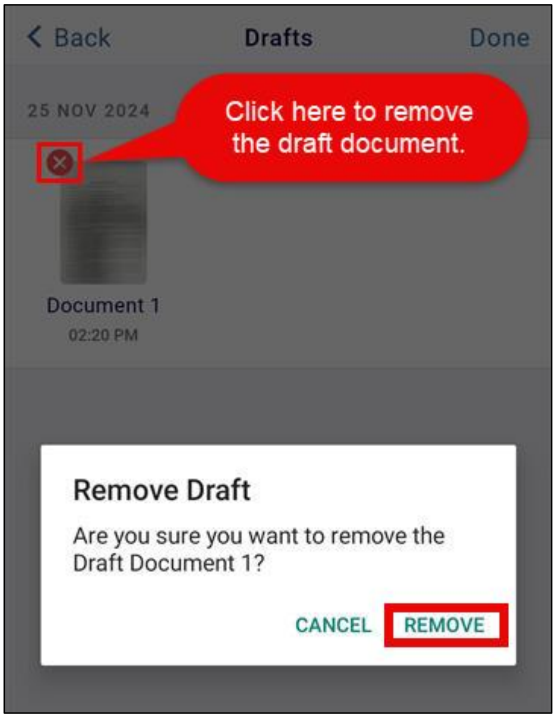
1. On the ~~myTI~~myTI home screen, click on the +Add tab.
2. Select the Drafts option.



3. Select the document and follow the standard document submission steps detailed in the Scan section.
4. Click on the Edit button to delete the document.



5. Click on a document cross mark and on the Remove Draft confirmation popup, select the **Remove** option.



Note: The +Add tab on the Home screen displays the Drafts option only if documents are saved in draft mode.

Media

To upload documents as images, follow the steps below.

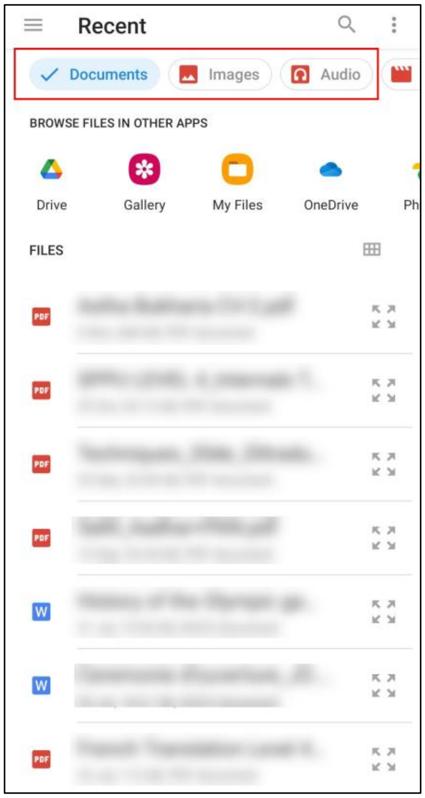
1. On the ~~myTI~~myTI home screen, click on the +Add tab.
2. Select the Media option.
3. Select the required documents.

4. Follow the standard steps to Edit and Submit the document detailed in the Scan section.

Files

To upload files as documents, follow the steps below.

1. On the ~~myTI~~myTI home screen, click on the +Add tab.
2. Select the Files option.
3. Select the required files.



4. Follow the standard steps to Edit and Submit the document detailed in the Scan section.

Offline Queue

The Offline Queue feature is designed to function in environments with limited or no network connectivity. The ~~myTI~~myTI application remains fully operational for tasks such as generating trip reports and capturing images, even in offline mode. In instances of weak or unstable connectivity, user responses, and documents are securely stored in encrypted, session-based memory on the device. Once connectivity is restored, users can access the Offline Queue for the documents and complete the document submission procedure in the TI rooms. For CTMS offline functionality, the data is automatically updated.

Types of Submission

The Types of Submissions determine whether users can submit documents with the default metadata fields or some additional metadata fields. The Types of submissions can be categorized as follows.

Submission Type	Description
Light Submission	If the Light submission is configured, users can submit documents with only the Study Name and Date.
Full Submission	With Full Submission configured, users need to fill out all the required metadata such as Study, Category, Investigative Site, Country, Document Type, and Date.

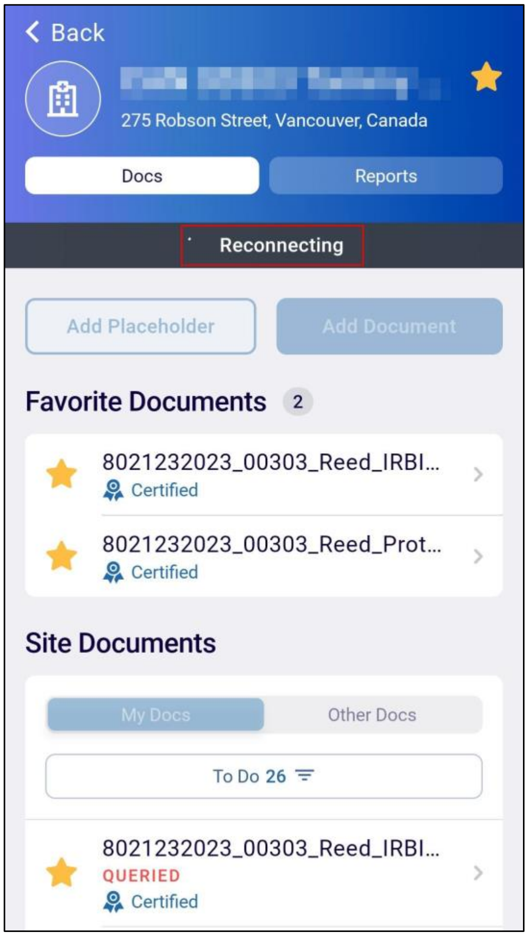
Important

- The submissions are linked to the Company Code Settings meaning one company code can have Light Submission while the other can have Full Submission.
- An individual company code cannot have both submissions configured.

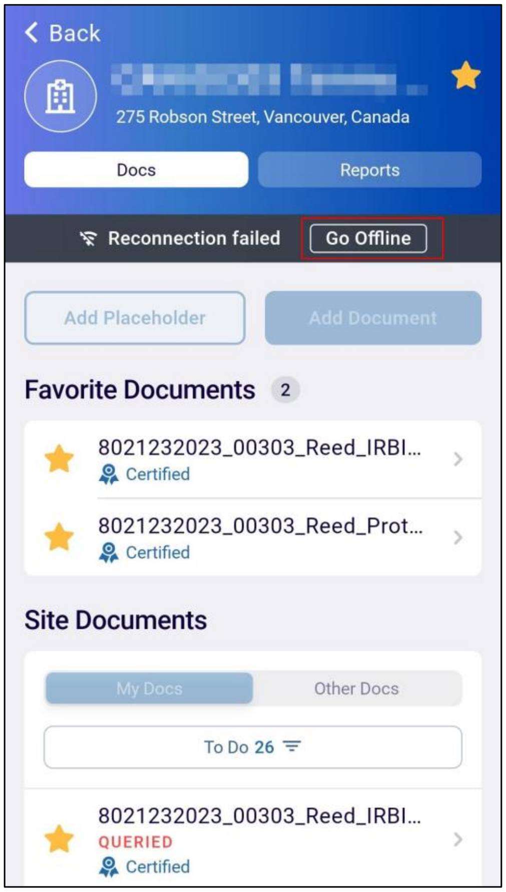
Accessing ~~myTI~~myTI in offline mode

To access ~~myTI~~myTI in offline mode, follow the steps below.

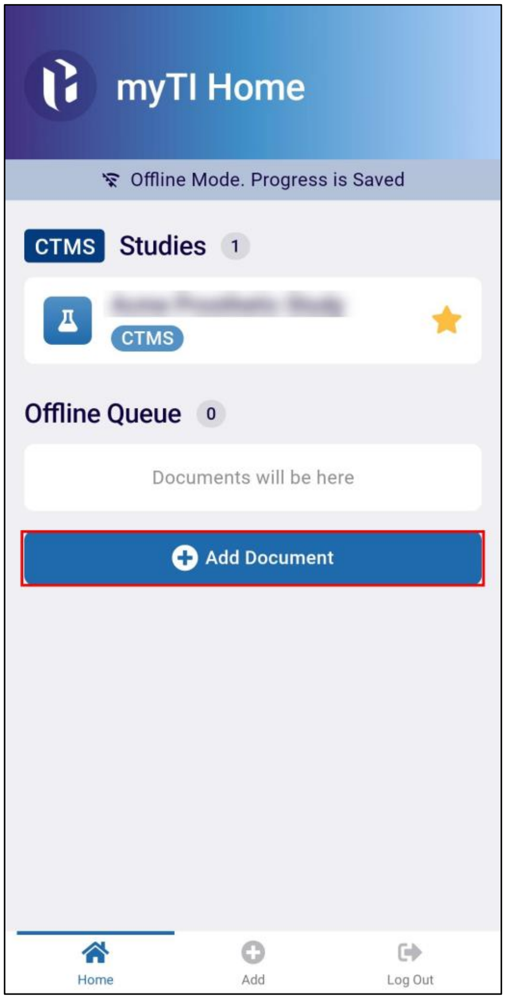
1. Without an active internet or wireless connection, the ~~MyTI~~myTI user interface displays the Reconnecting.



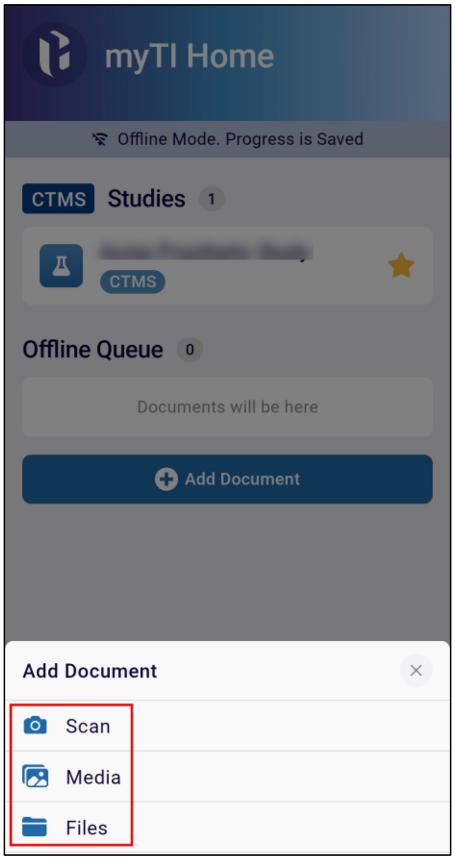
2. Click on the Go Offline.



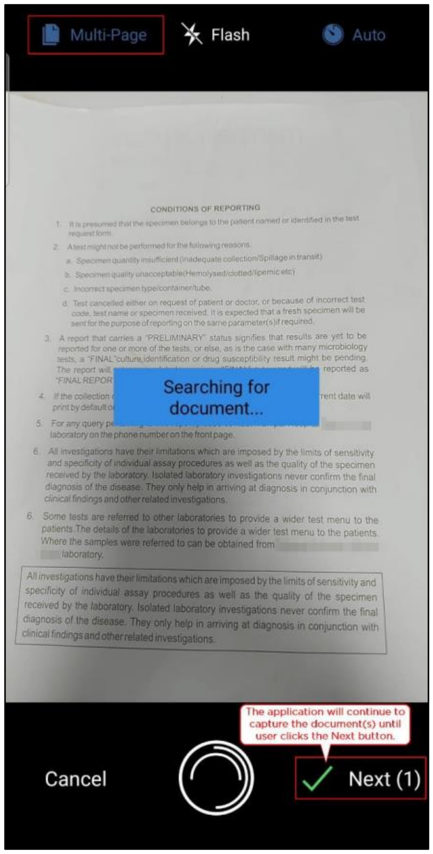
3. Click on the +Add Document button.



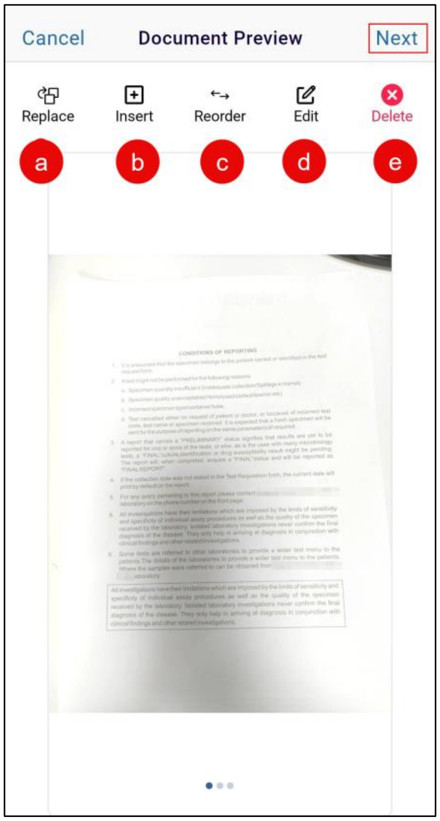
4. Select an option to add a document from the available list. i.e., **Scan**, **Media** or **Files**.



5. Select the Scan option and scan the required documents. Once all the required documents are scanned, click on the **Next** button.

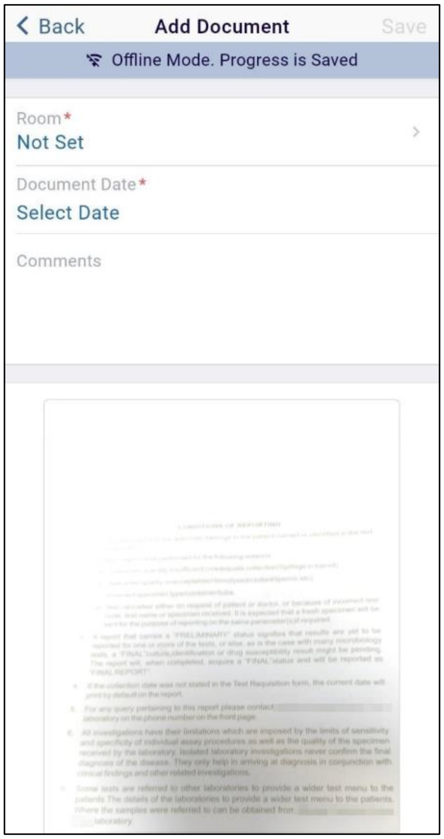


6. On the **Document Preview** page, perform the following actions, if required, or else click on the **Next** button to proceed further.

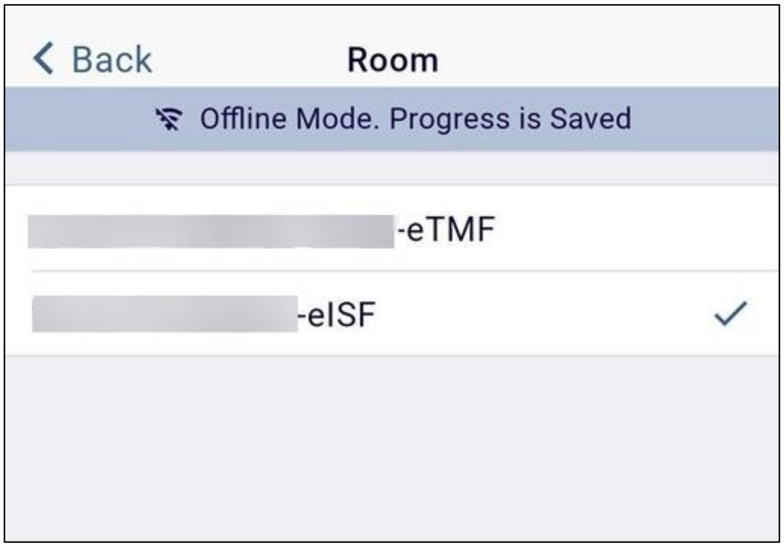


Note: Refer to Step 4 from the Scan section for the standard actions to be performed on the Document Preview page.

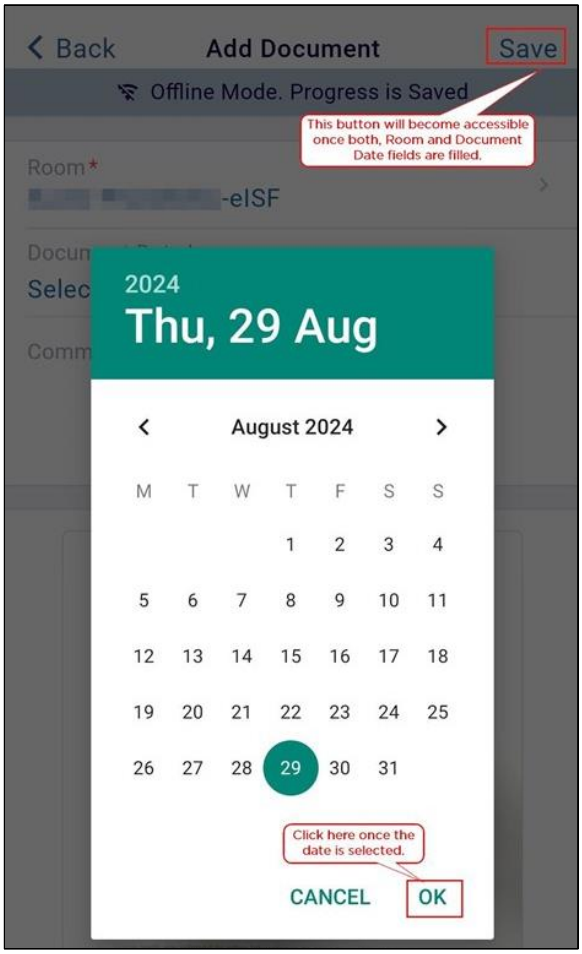
7. On the **Add Document** screen, add the following mandatory details and click on the **Save** button.



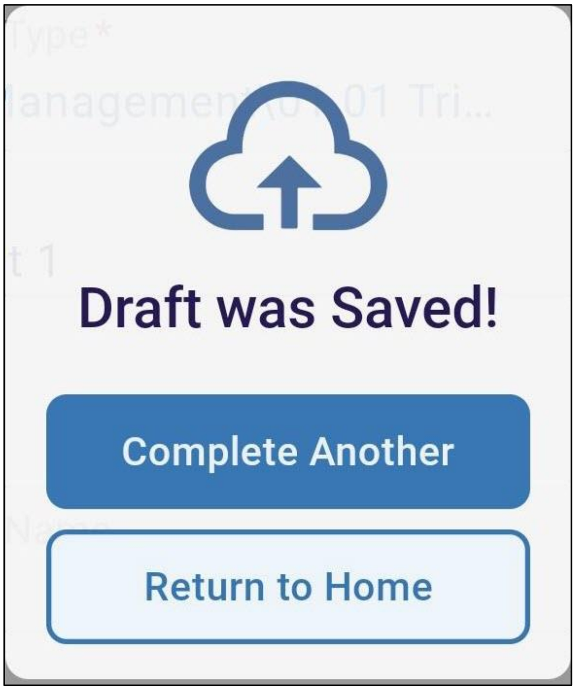
a. **Room***: Click on the field, select the required room, and click on the <Back button. The field will display Not Set unless a room is selected.



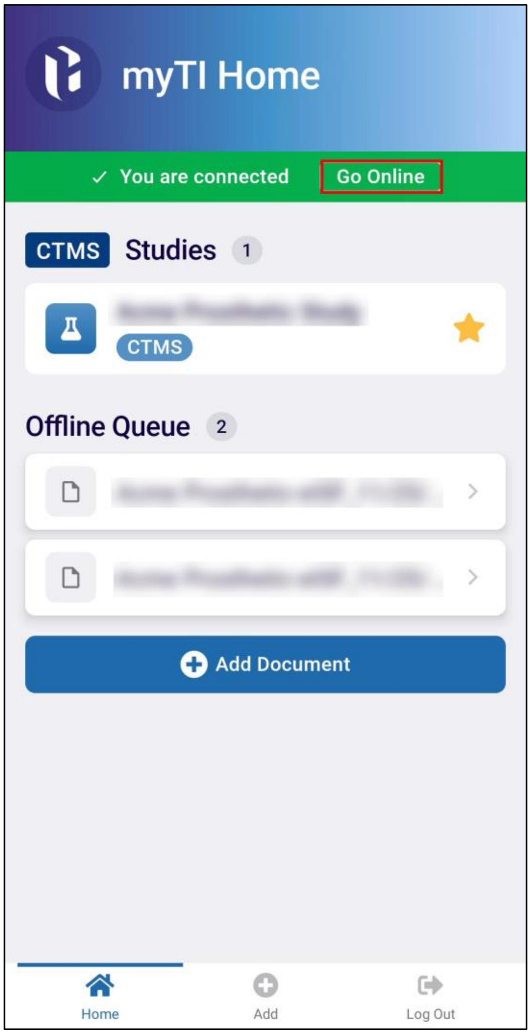
b. **Document Date***: Click on the field and select the appropriate date from the date selection tool.



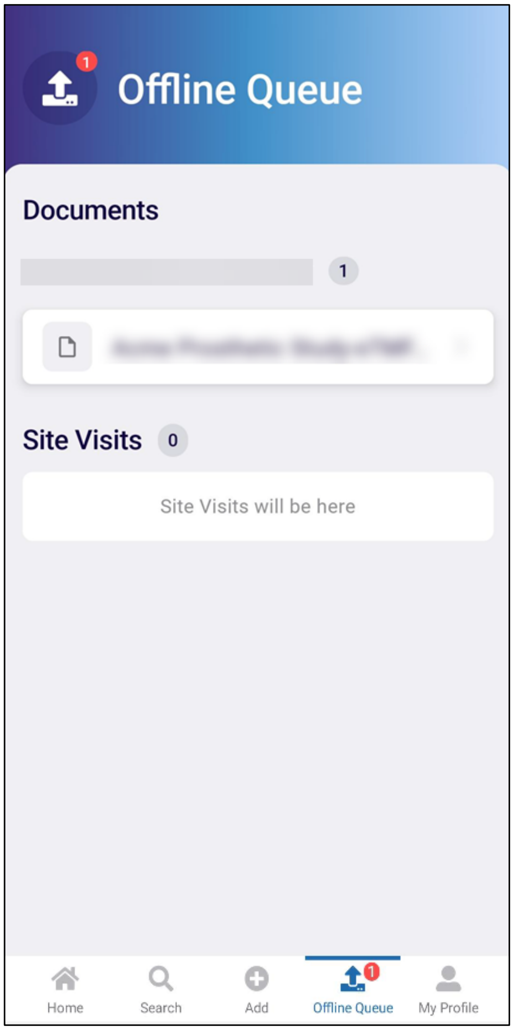
8. Once the document is successfully added, the application displays the success message with the following two options.
    a. **Complete Another:** Add another document by following the similar steps of accessing ~~myTI~~myTI offline mode.
    b. **Return to Home:** Navigate back to ~~myTI~~myTI Home page.



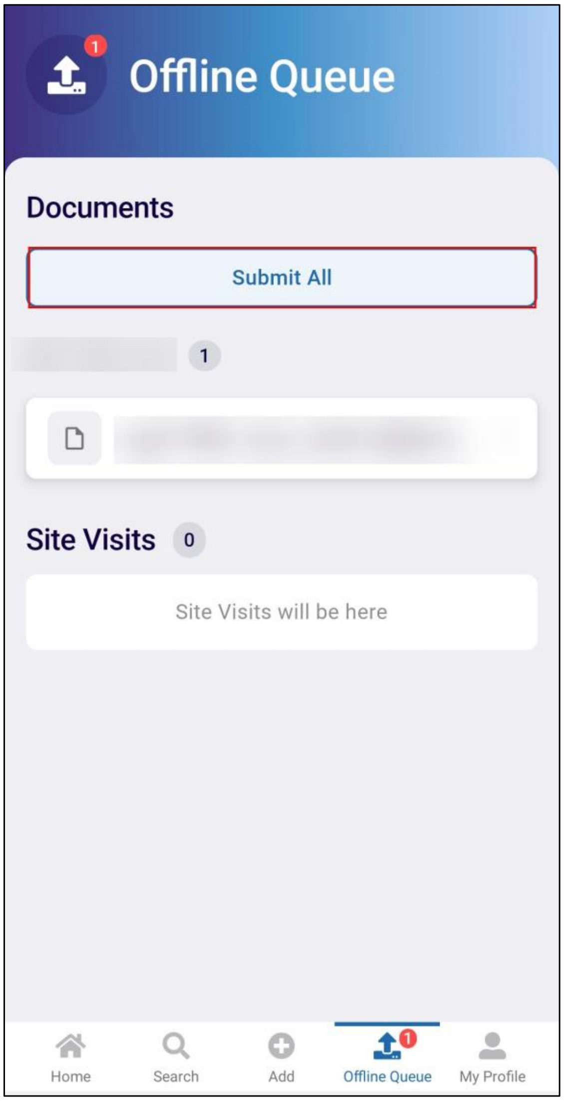
9. Click on the **Go Online** button once ~~myTI~~myTI displays a **'You are Connected'** message when an active internet or wireless connection gets reestablished.



10. Click on the **Offline Queue** tab to view the pending documents.



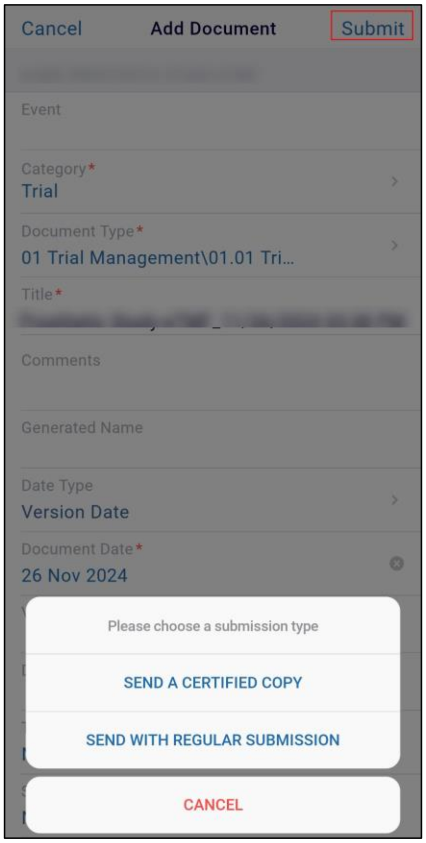
11. Click on the **Submit All** button (in case of Light Submission)



Note: If the company code is configured with Full Submission, the **Offline Queue** screen will not show the **Submit All** button.

Additional Steps for company code with Full Submission configured.

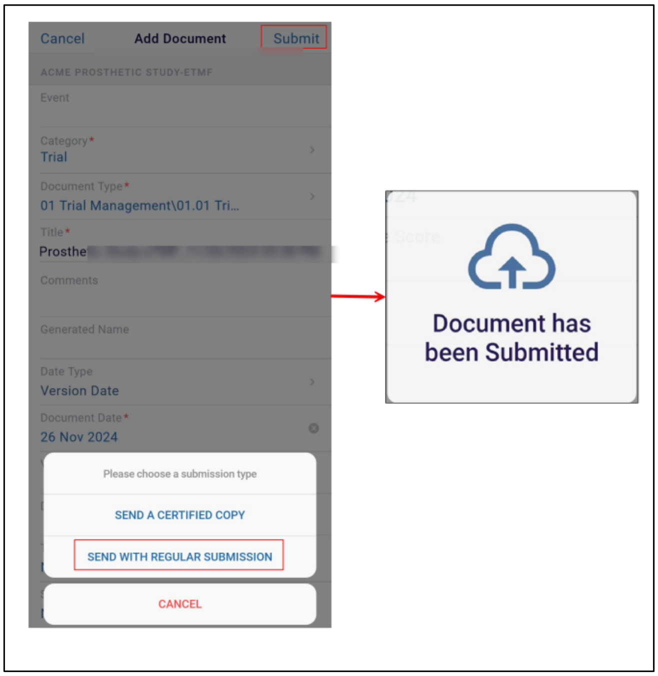
12. Click on the document to open the metadata panel.
13. Enter the mandatory metadata details into the respective fields and click on the **Submit** button.



14. Select a submission type from the available options.

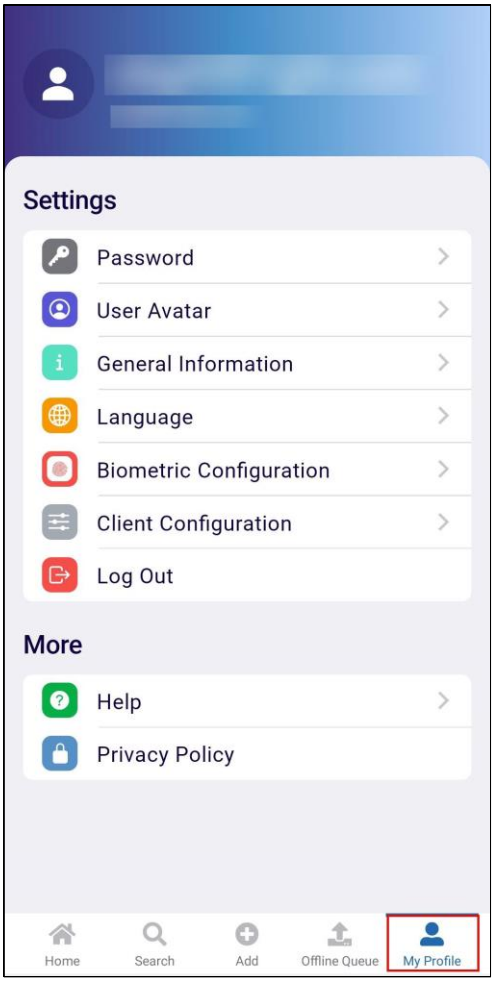
    a. Send a Certified Copy
        i. If this option is selected, click on the Confirm button on the Confirmation screen.
        ii. Enter the **Username** and **Password** and click on the **SIGN IN** button.
        iii. Once the document is submitted, the application displays the corresponding success message.

b. Send with Regular Submission
    i. If this option is selected, the document is submitted without certifying, and the application displays the corresponding success message.



My Profile

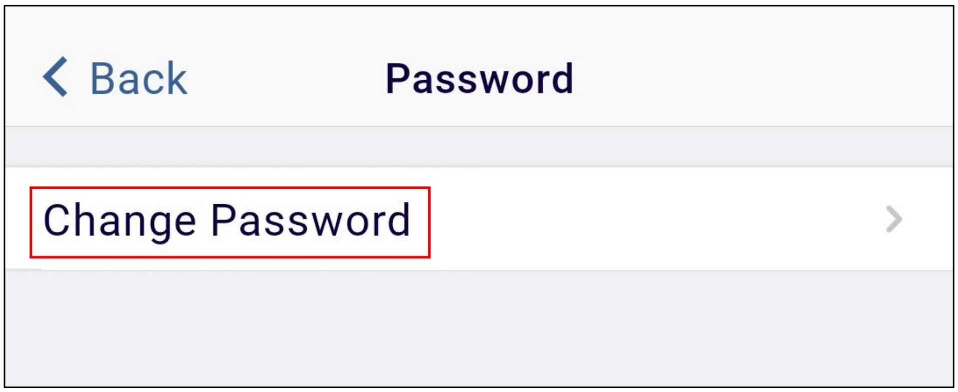
The **My Profile** section provides users with a centralized location to view and manage their personal account settings. It is designed to offer convenience and customization, enabling users to update key aspects of their profile to suit their preferences and requirements.



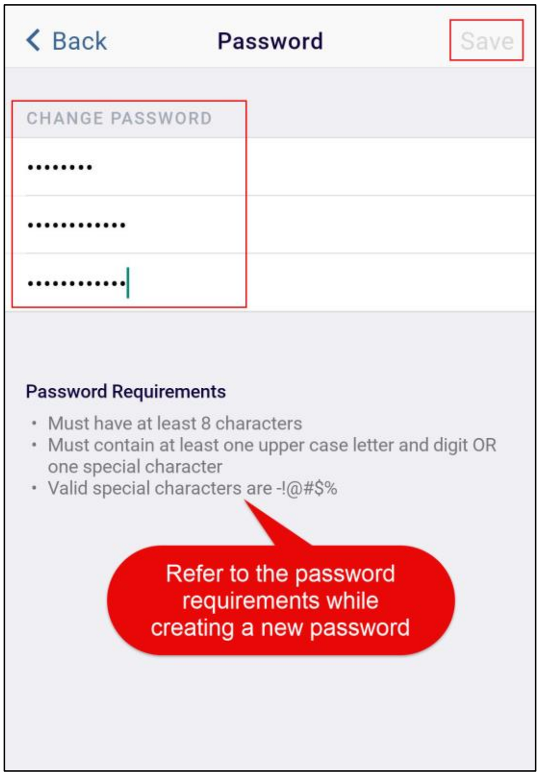
Password

To change the account password, follow the steps below.

1. Click on the **My Profile** tab on the ~~MyTI~~MyTI home page.
2. Click on the Password option located under the **Settings** section.
3. Click on the Change Password link.



4. On the Password screen, update the following fields adhering to the Password Requirements.
    a. **Current Password**: Enter the existing password in this field.
    b. **New Password**: Enter a new password adhering to the password requirements.
    c. **Confirm Password**: Re-enter the new password to confirm.
5. Click on the **Save** button.



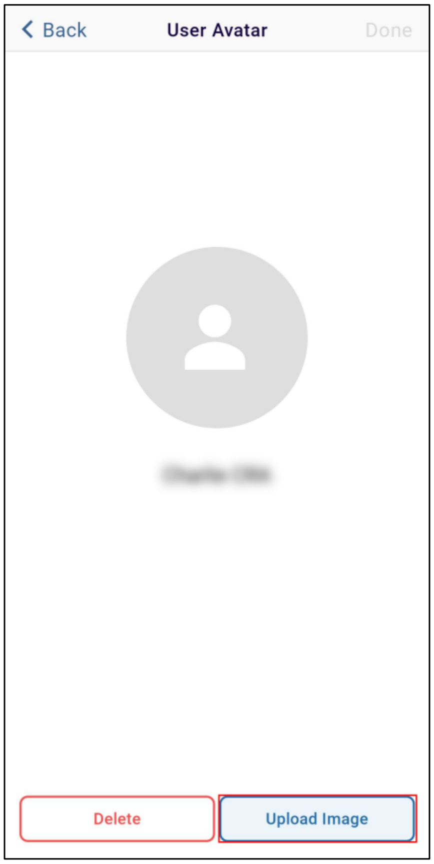
6. Log out from the application and log in again with the new password.

Note: By default, the password is set for the 1st time user.

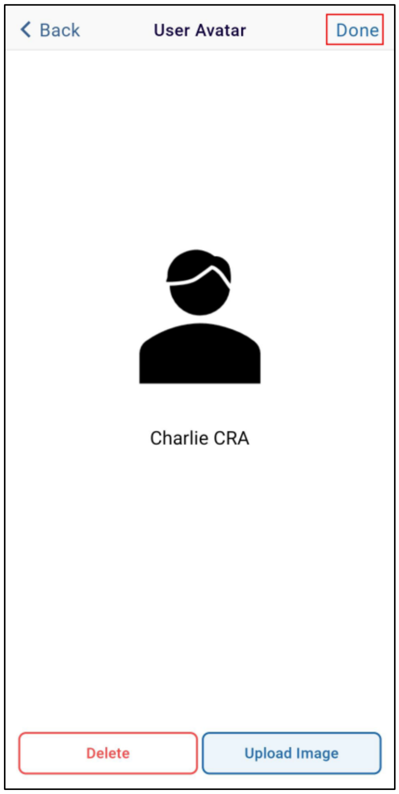
Use Avatar

To add or change the display profile picture, follow the steps below.

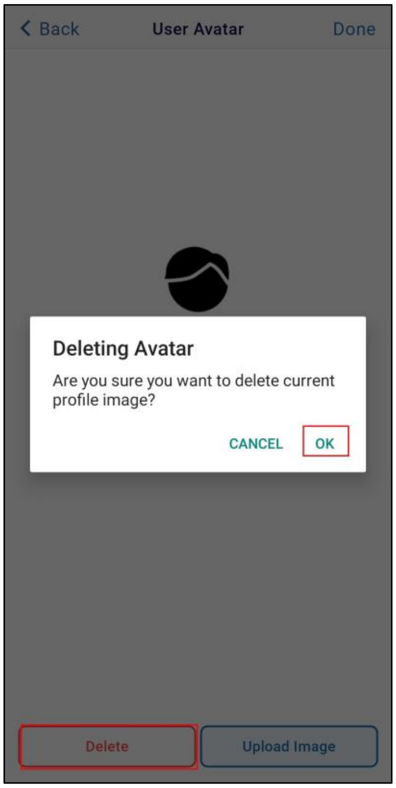
1. Click on the **My Profile** tab on the ~~MyTI~~myTI home page.
2. Click on the **Use Avatar** option located under the **Settings** section.
3. On the Use Avatar screen, click on the Upload Image.



4. Select the Camera option to click a photo or the Photo Library option to upload an image from the mobile device.
5. Click on the Done button once the image is uploaded.



6. Click on the Delete button to delete the current profile image and
7. Confirm the deletion by clicking on the **OK** button on the confirmation popup.

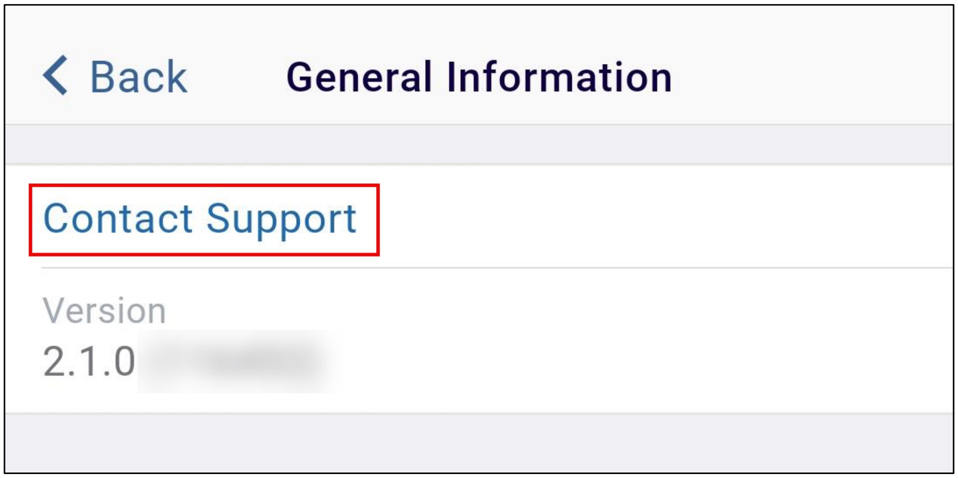


General Information

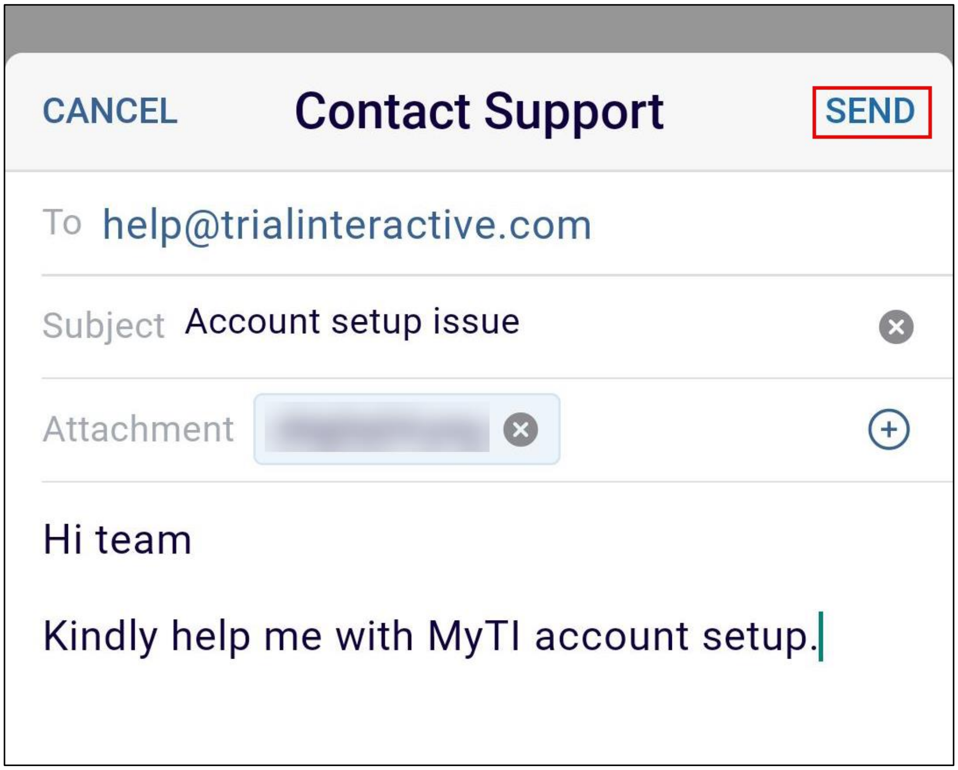
The General Information section displays the application version installed on the mobile device. Additionally, users have an option to reach out to the technical support team. After downloading the application, the company code will be linked to the company's instance and help desk email address. Click the **Contact Support** button if you come across any issues while working within the application. An email dialogue window pops up, allowing the user to enter issues, add an attachment (such as a screenshot of the issue), and click the **Send** button. The mail is sent to the helpdesk.

To access the General Information and contact support, follow the steps below.

1. Click on the **My Profile** tab on the ~~MyTI~~myTI home page.
2. Click on the **General Information** option located under the **Settings** section.
3. The General Information screen displays the app version along with an option to contact the support team.
4. Click on the **Contact Support** button.



5. Enter the subject line, attachments (if required), and email text describing the issue or requirement, and click on the **SEND** button.



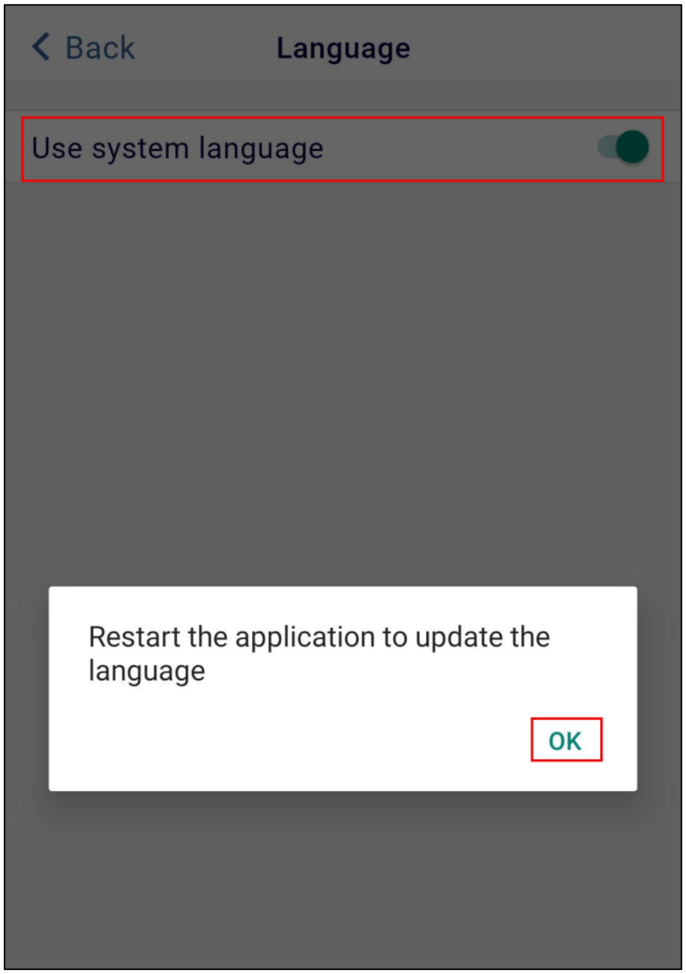
Language

Users can find the Language set for the application. The application automatically sets the language that the mobile device is set or configured. Users can enable the application to use the language settings selected in their mobile device setup. If a dialect is not available, the main language will be used.

Note: By default, the system language is US English.

To use the system language, follow the steps below.

1. Click on the **My Profile** tab on the ~~MyTI~~myTI home page.
2. Click on the **Language** option located under the **Settings** section.
3. Click on the Use System Language toggle switch.
4. Click on the **OK** button on the popup displaying a message prompting users to restart the application to update the language.

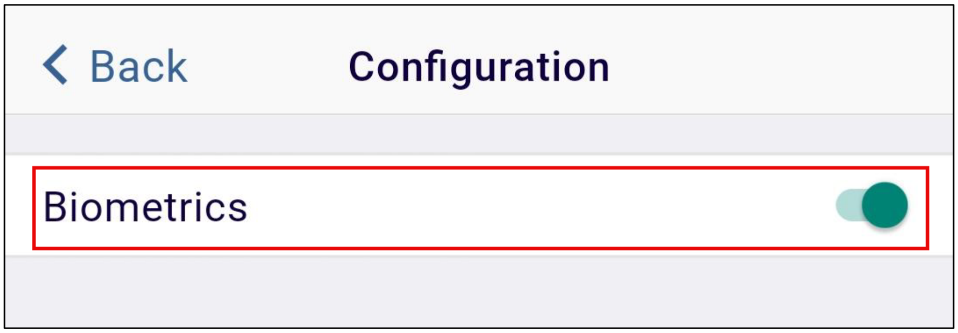


Biometric Configuration

Logging in via biometrics helps users save time from entering the username and password to log in to the application.

To enable the Biometric Configuration, follow the steps below.

1. Click on the **My Profile** tab on the ~~MyTI~~myTI home page.
2. Click on the **Biometric Configuration** option located under the **Settings** section.
3. Activate the **Biometrics** setting by clicking the toggle switch. When enabled, the toggle switch turns green.



4. Once this setting is enabled, users can sign into the application using biometrics. <Add Screenshot >

Note:
- Logging in via biometrics can be done only after the user manually logs in for the first time.
- The biometric settings can be done in the users' mobile '**Settings**.' Until then, the Biometric Configuration option will not be displayed in the Settings menu of the ~~myTI~~myTI application.

Client Configuration

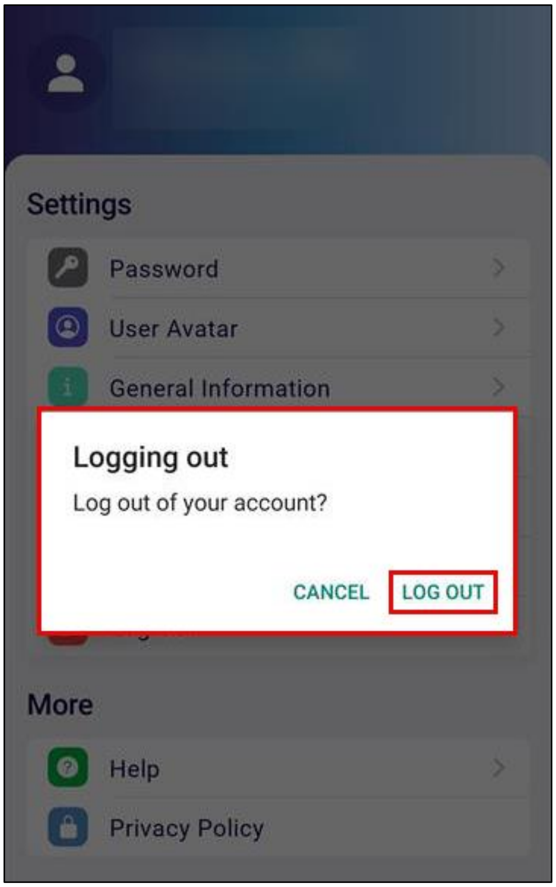
To access and configure the Client Configuration settings, follow the steps below.

1. Navigate to the My Profile tab on the ~~MyTI~~myTI home page.
2. Select the Client Configuration option under the Settings section.
3. Tap the Company Code field and enter the company code for the desired Trial Interactive instance.
4. Click on the Done button.
5. Once the new Company Code is successfully validated, the user will be logged out of the current Trial Interactive instance and redirected to the login screen to access the changed Trial Interactive instance.

Log Out

To log out of the application, follow the steps below.

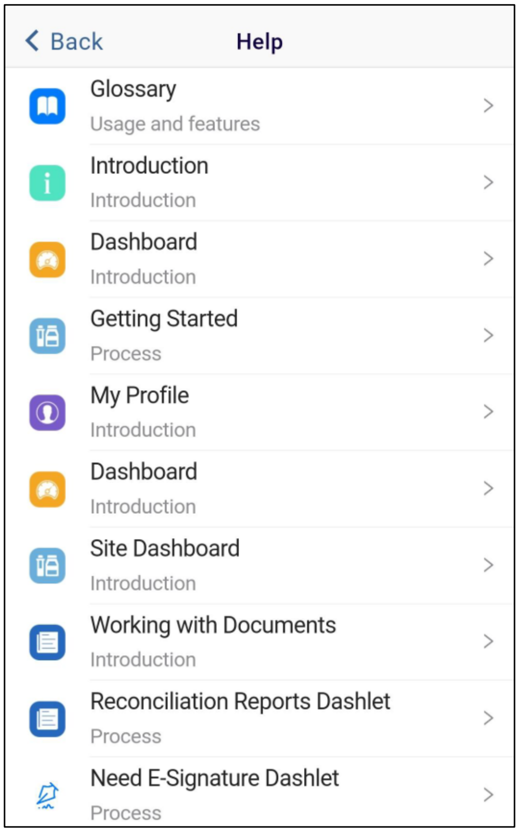
1. Navigate to the My Profile tab on the ~~MyTI~~myTI home page.
2. Select the **Log Out** option under the Settings section.
3. Click on the LOG OUT button on the Logging Out confirmation popup.



Help

To view the Help page comprising of help topics providing detailed insights into each topic, follow the steps below.

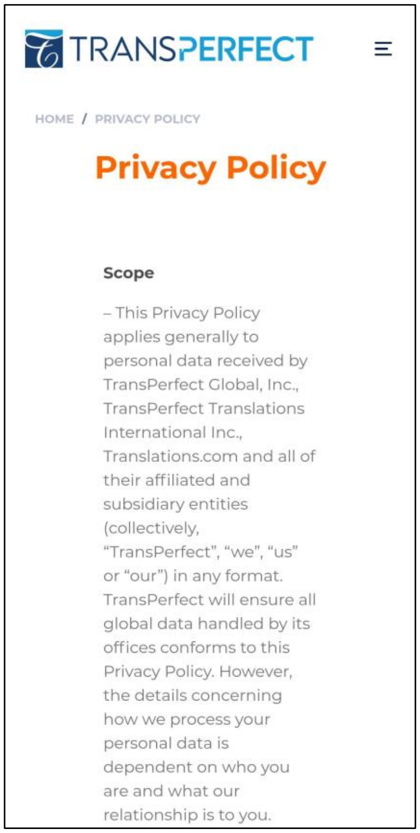
1. Navigate to the My Profile tab on the ~~MyTI~~myTI home page.
2. Select the Help option under the More section.
3. Select a specific topic to open a page displaying the relevant information or a list of subtopics related to the parent topic.



Privacy Policy

To access the privacy policy page, follow the steps below.

1. Navigate to the My Profile tab on the ~~MyTI~~myTI home page.
2. Select the Privacy Policy option under the More section.
3. The Privacy Policy page displays details regarding how an organization handles customers or client information gathered during the company operations.


TRANSPERFECT
HOME / PRIVACY POLICY
Privacy Policy
Scope
– This Privacy Policy applies generally to personal data received by TransPerfect Global, Inc., TransPerfect Translations International Inc., Translations.com and all of their affiliated and subsidiary entities (collectively, "TransPerfect", "we", "us" or "our") in any format. TransPerfect will ensure all global data handled by its offices conforms to this Privacy Policy. However, the details concerning how we process your personal data is dependent on who you are and what our relationship is to you.

CHAPTER 5. CTMS

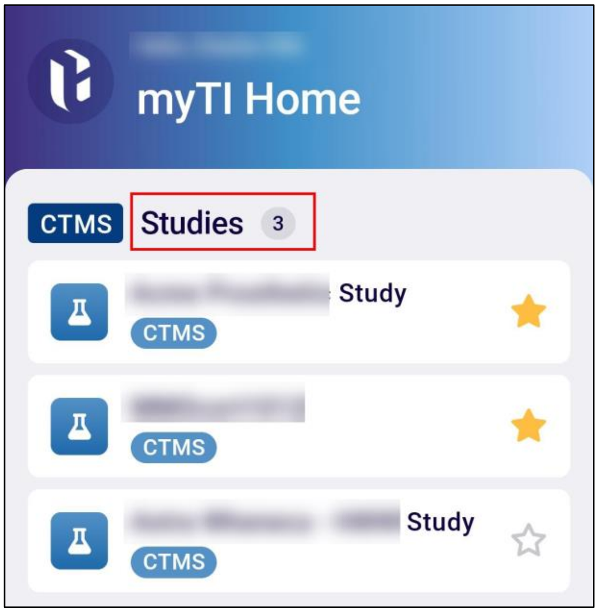
The ~~MyTI~~myTI home page displays all the studies the user is associated with.

Studies

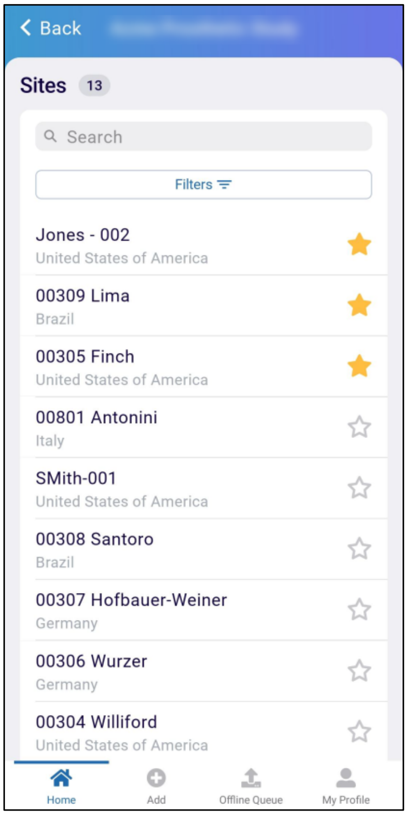
The CTMS-integrated application lists the studies associated with the user. Selecting a study redirects the user to the sites linked to that study.

To access and view the study details in ~~MyTI~~myTI, follow the steps below.

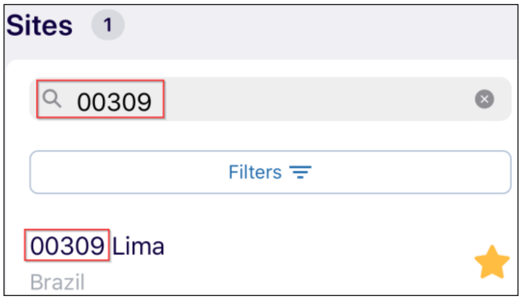
1. Click on a study name located under the CTMS – Studies on the ~~MyTI~~myTI Home Page. To mark a study as a favorite, click on the star icon.



2. The study displays the sites associated with its screen. Click on the star icon of a site to mark it as a favorite. Within the site, users can add Site Visits, Activities, Subjects, and Contacts from the application.



3. Enter the search term in the search box and click on the Search button to locate a particular site from the available list.

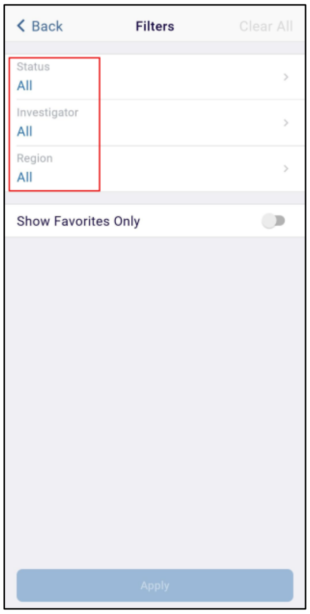


Filters

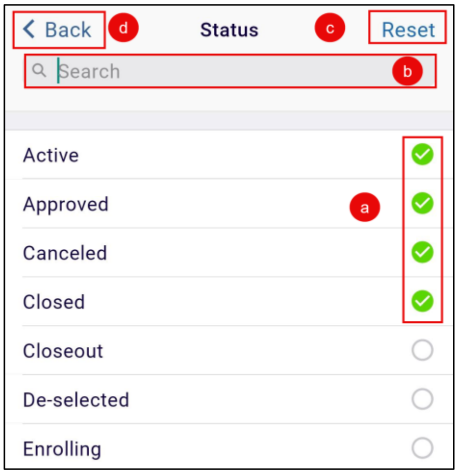
To apply filters to the sites in a study, follow the steps below.

1. Click on the Filters tab.

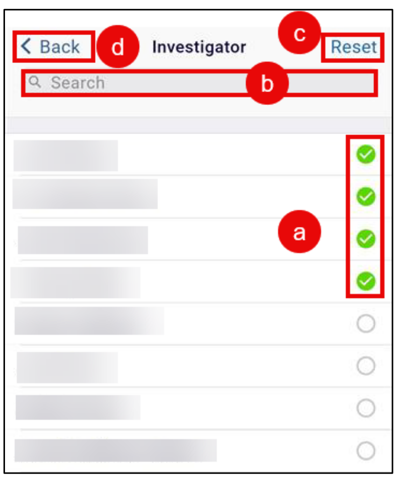
2. The filters tab displays the following filters
   a. Status
   b. All
   c. Region
3. Click on the All button of each filter to view and select the required filter options.



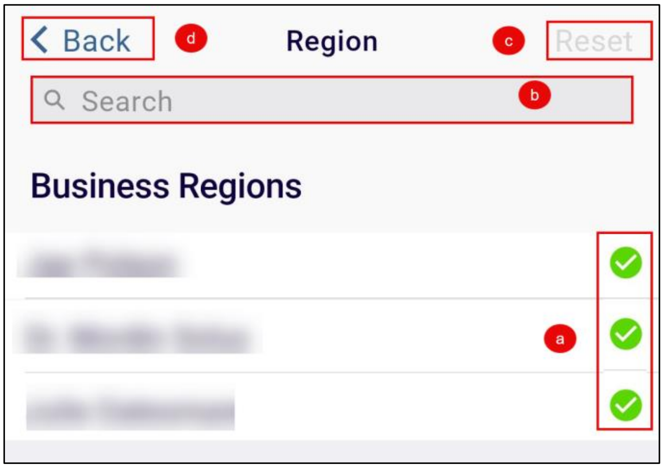
4. On the Status filter screen, perform the following
    a. Select the required status options by clicking on the radio button. A green checkmark is displayed to show the currently selected statuses.
    b. Enter the search term in the search box to search for specific statuses.
    c. Click on the Reset button to clear all the selected options.
    d. Click on the Back button once the required number of statuses is selected.



5. On the Investigator filter screen, perform the following
   a. Select the required investigators by clicking on the radio button. A green checkmark is displayed to show the currently selected investigators.
   b. Click on the Reset button to clear all the selected options.
   c. Click on the Back button once the required number of investigators are selected.

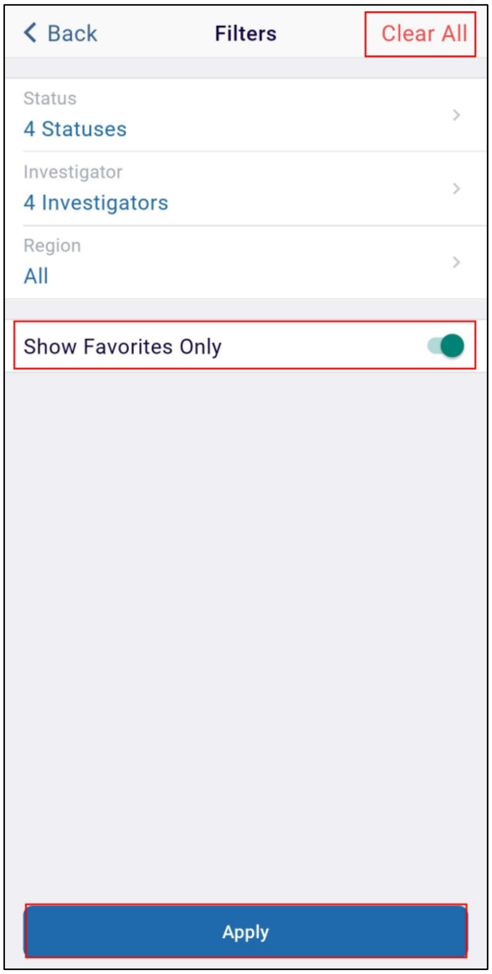


6. On the Region filter, perform the following
   a. Select the regions by clicking on the radio button. A green checkmark is displayed to show the currently selected regions.
   b. Click on the Reset button to clear all the selected options.
   c. Click on the Back button once the required regions are selected.



7. Optionally enable the **Show Favorites Only** toggle switch to display the sites marked as favorites.
8. Optionally click on the Clear All button to remove all the filters.

9. Click on the Apply button once the required filters are selected.



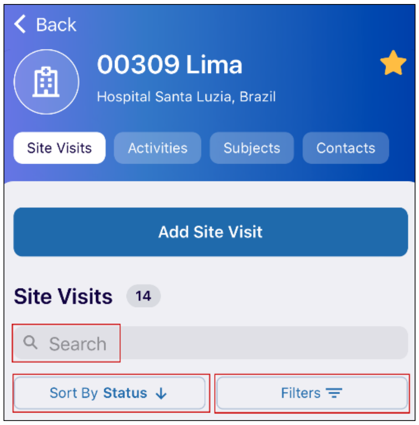
10. Click on the desired site to open the sites screen where users view the following tabs
    a. Site Visits
    b. Activities
    c. Subjects
    d. Contacts.

Site Visits

The Site Visits tab enables users to view existing site visits and provides the option to create a new one. Users can also sort and filter site visits based on their requirements.

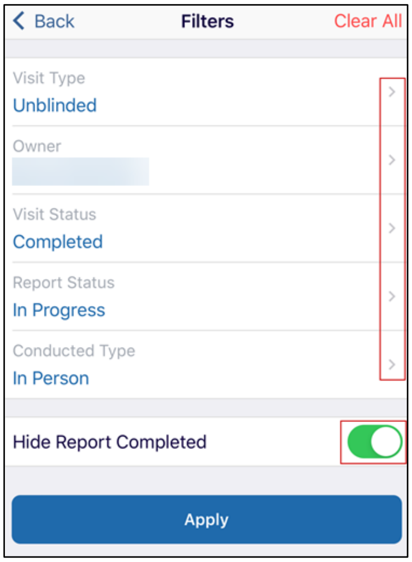
Customize Site Visit screen

Users can customize the Site Visit screen by applying filters, sorting criteria, and searching for a specific site visit.

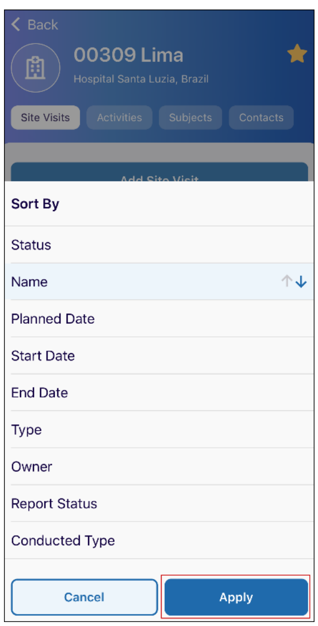


To apply filters, sort criteria, and search for a specific visit, follow the steps below.

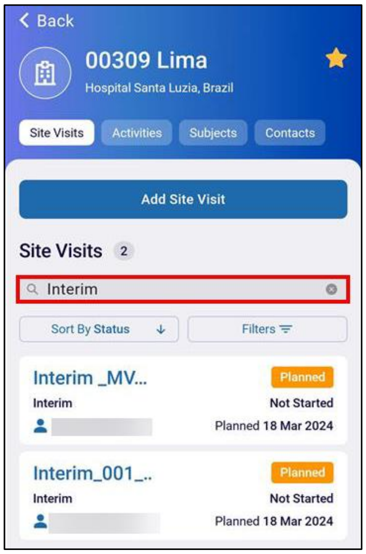
1. Click on the Filters tab and apply the following filters by clicking on the All button for each filter. Refer to the standard procedure of adding, removing, and applying filters detailed in the Filters section.
2. Optionally enable the Hide Report Completed toggle switch.
3. Click on the Apply button.



4. Click on the Sort By tab to apply specific sort criteria.
5. Select a criterion, and click on the Ascending and Descending arrows.
6. Click on the Apply button.



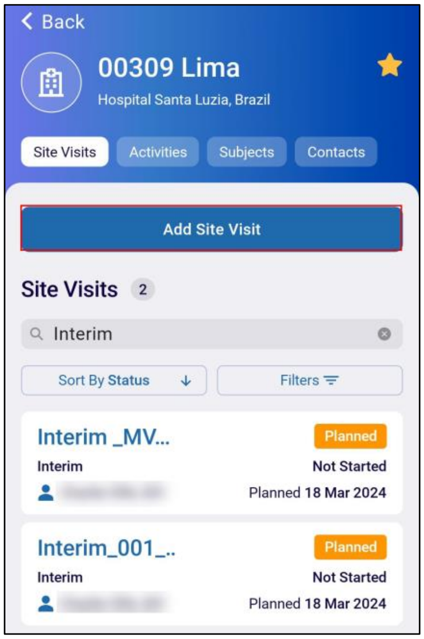
7. Enter a search term in the search box to search for a specific site visit record.



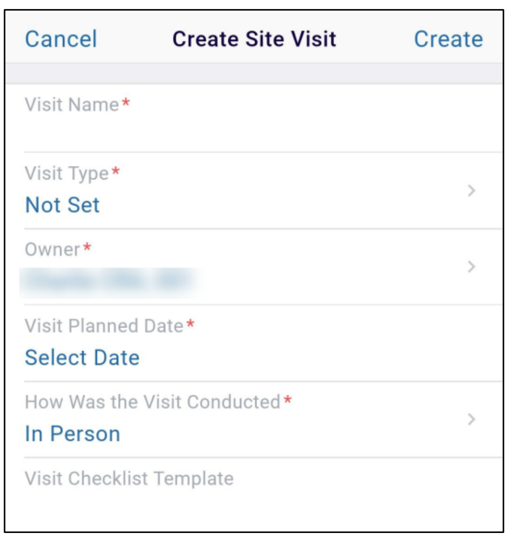
Add a Site Visit

To add a Site Visit, follow the steps below.

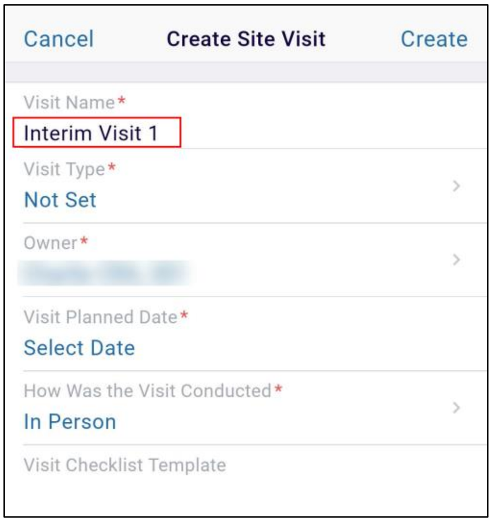
1. Click on the Add Site Visit button.



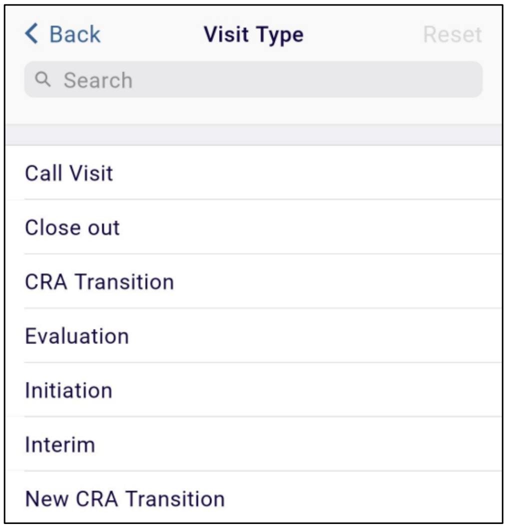
2. On the Create Site Visit screen, add the following mandatory details marked with a red asterisk mark (*).



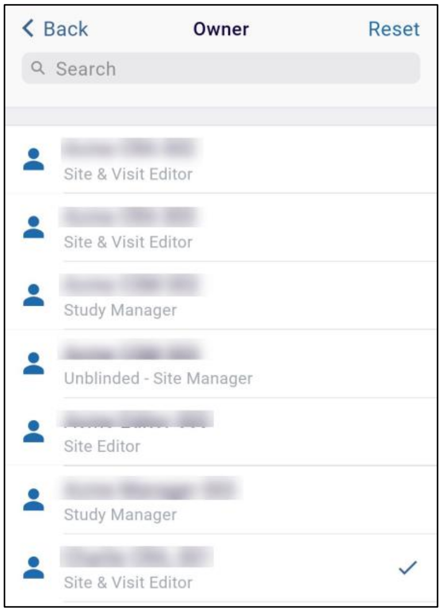
a. Visit Name*: Manually add a name to the visit



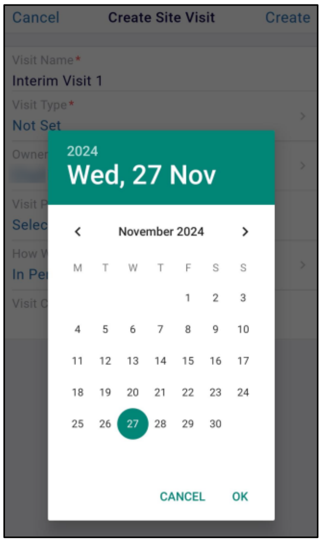
b. Visit Type*: Click on the '>' arrow and select a visit type from the available list.



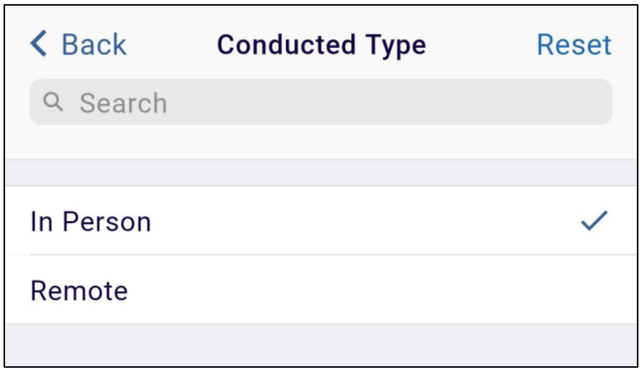
c. Owner*: Click on the > arrow and select an owner from the available list.



d. Visit Planned Date*: Add a visit planned date from the date picker.

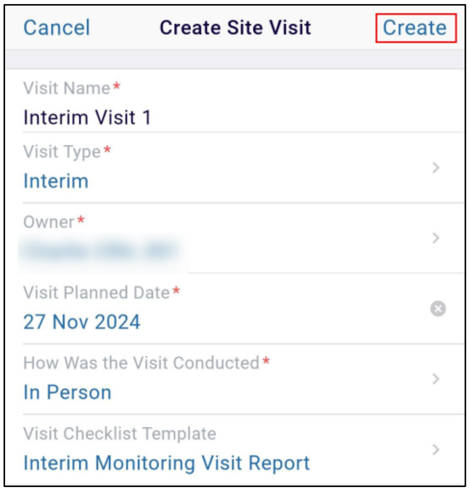


e. How was the Visit Conducted*: Select either In Person or Remote.



f. **Visit Checklist template**: Select a visit checklist template from the available options.

3. Click on the Create button once the required details are added.

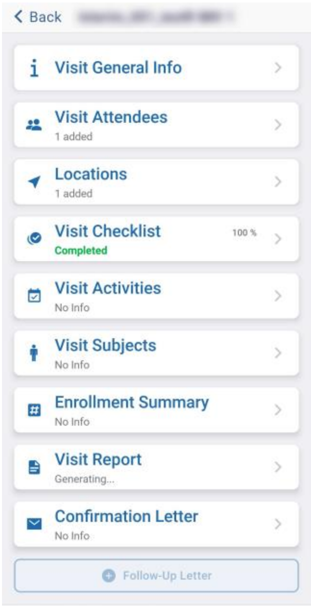


4. Upon successful creation, the success notification is displayed.

Complete a Site Visit

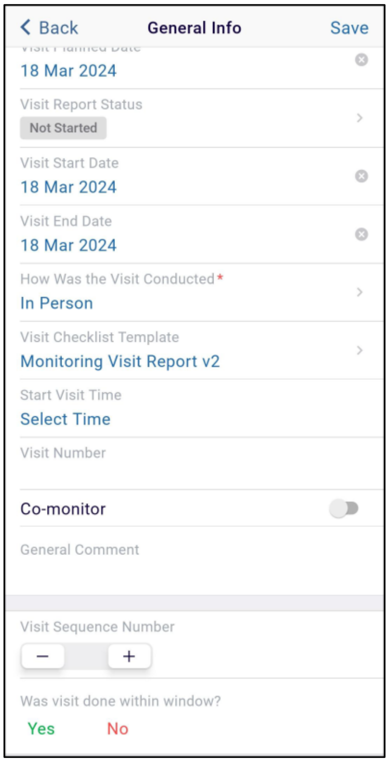
To complete a site visit, the user must complete all the steps in the site visit checklist. To complete a site visit, follow the steps below.

Click on the required site visit to be completed, which opens the Site Visit Information page.



Visit General Info

1. Update the fields by clicking the '>' arrow or manually entering the details.
2. If needed, enable the Co-monitor toggle.
3. Use the '+' or '-' icons to adjust the 'Visit Sequence Number' and select the appropriate response for whether the visit occurred within the window.
4. Once all changes are made, click the Save button in the top-right corner.



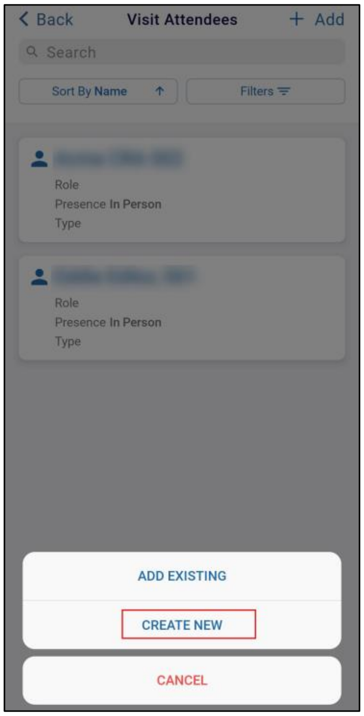
Visit Attendees

On the Visit Attendees screen, users can add and edit new as well as existing attendees,

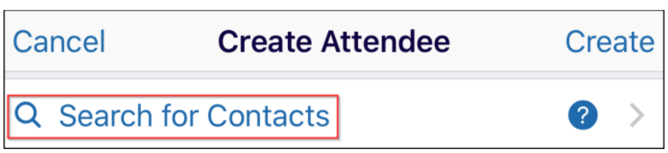
Create New Attendee

To create a new attendee, follow the steps below.

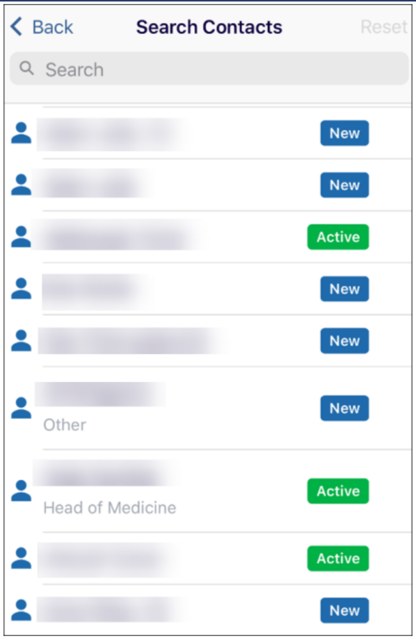
1. On the Visit Attendees screen, click on the +Add button and select the **CREATE NEW** option.



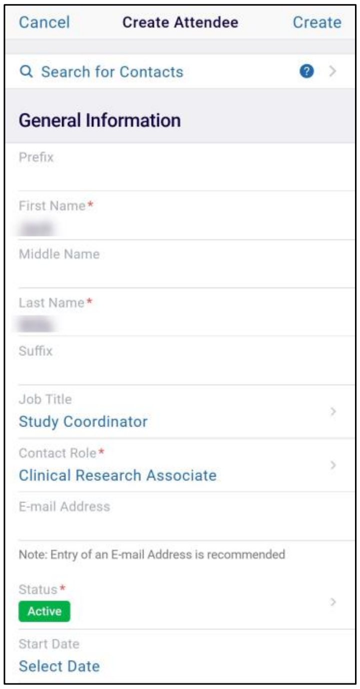
2. Click on the Search for Contacts.



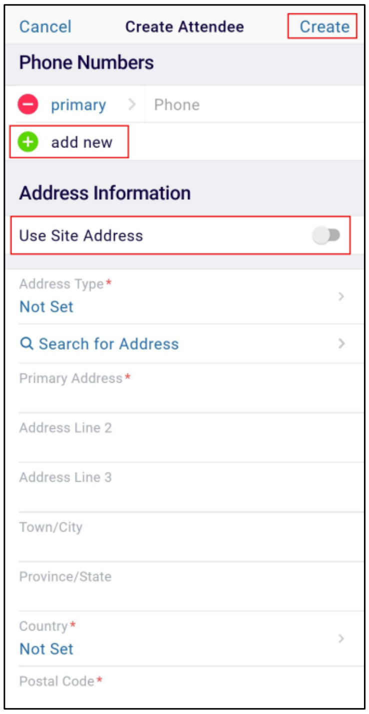
3. Select a name from the list. The user is navigated back to the create attendee screen, where the fields are auto-populated.



4. In the General Information screen, fill in the mandatory details highlighted with the red asterisk mark.



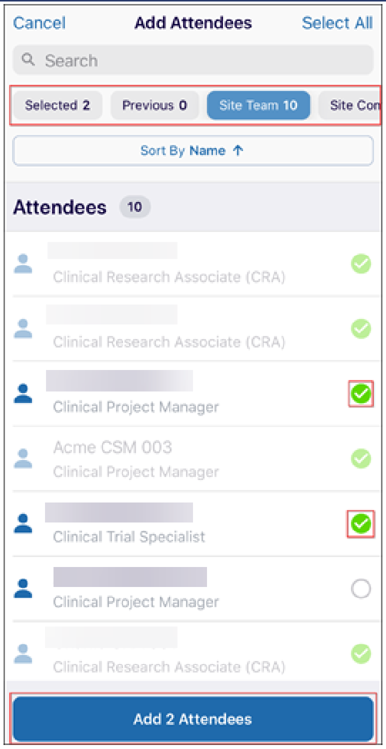
5. Optionally enter the Phone Numbers by clicking on the +add new button.
6. Enable the Use Site Address toggle switch to use the site address instead of adding new address details.
7. If the toggle switch is disabled, enter the mandatory information highlighted with a red asterisk mark in the Address Information section.
8. Click on the Create button once the necessary details are entered.



Add Existing Attendee

To add an existing attendee, follow the steps below.

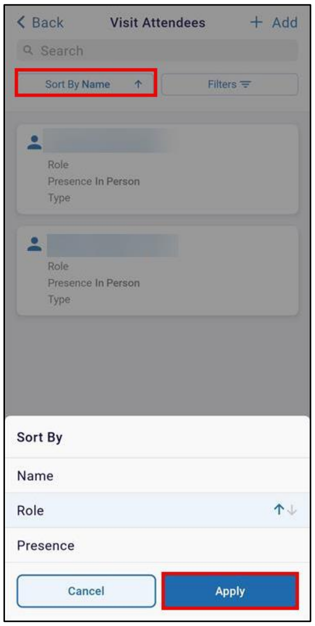
1. On the Visit Attendees screen, click on the +Add button and select the **ADD EXISTING** option.
2. On the Add Attendees screen, toggle between the tabs below the search box and select the required attendees. Attendees that are already selected are disabled with a green checkmark.
3. Click on the **Add (number of attendees) Attendee(s)** button.



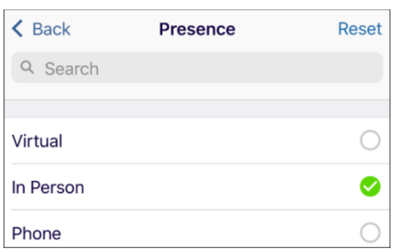
Sort and Filter

To Sort and Filter the attendees list, follow the steps below.

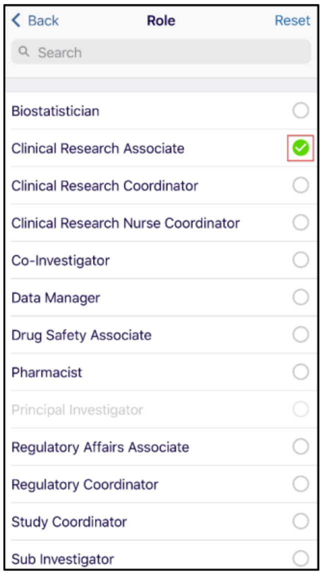
1. On the Visit attendees screen, click on the Sort By tab.
2. Select either Name, Role, or Presence as the Sort criteria.
3. Click on the Apply button.



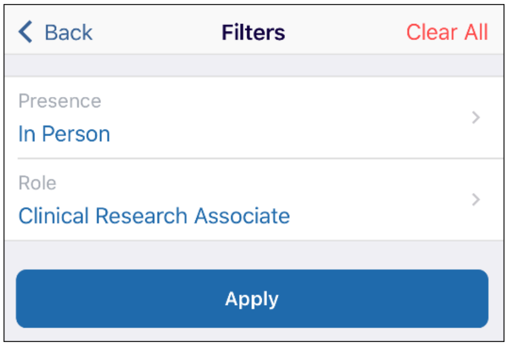
4. Click on the Filters tab which displays the following two options.
    a. Presence
    b. Role
5. Click on the Presence filter and select the required option from the available list.



6. Click on the Role filter and select the roles from the available list.



7. Click on Apply once the filters are added or select Clear All to remove the filters.



Locations

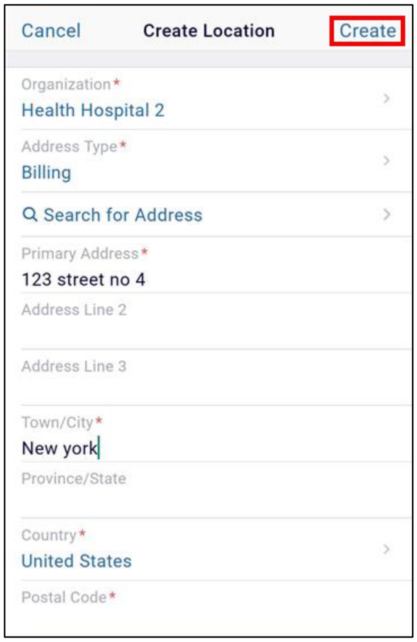
Select the locations tab on the Site Visit screen. On the Locations screen, users can create a new or add an existing location.

Add New Location

To add a new location, follow the steps below.

1. On the Locations screen, click on the +Add button and select the CREATE NEW option.

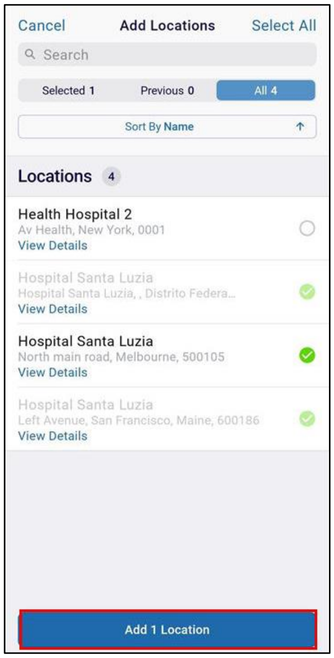
2. Fill in the mandatory details on the Create Location screen and click on the Create button.



Add an Existing Location

To add an existing location, follow the steps below.

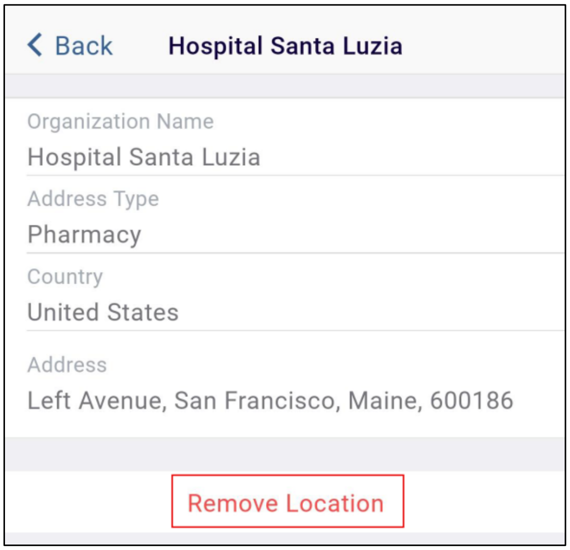
1. On the Locations screen, click on the +Add button and select the ADD EXISTING option.
2. Toggle between the tabs to select the required locations.
3. Click on the **Add (number) Location (s)** button.



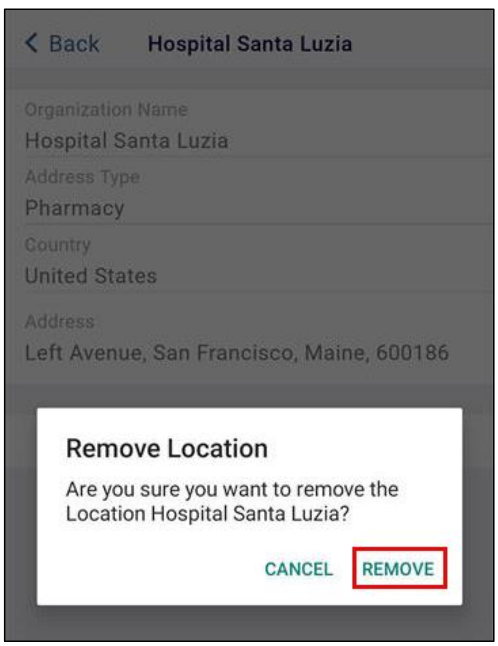
<u>Remove a Location.</u>

To remove a location, follow the steps below.

1. Click on a location to remove. This opens the location details page.
2. On the Locations' Details page, click on the Remove button.



3. On the Remove Location confirmation popup, click on the **Remove** button.

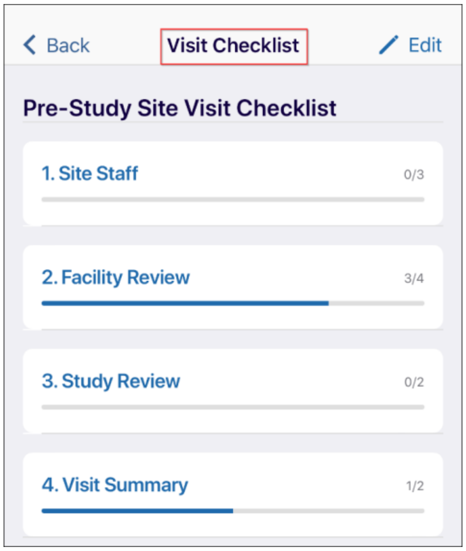


Visit Checklist

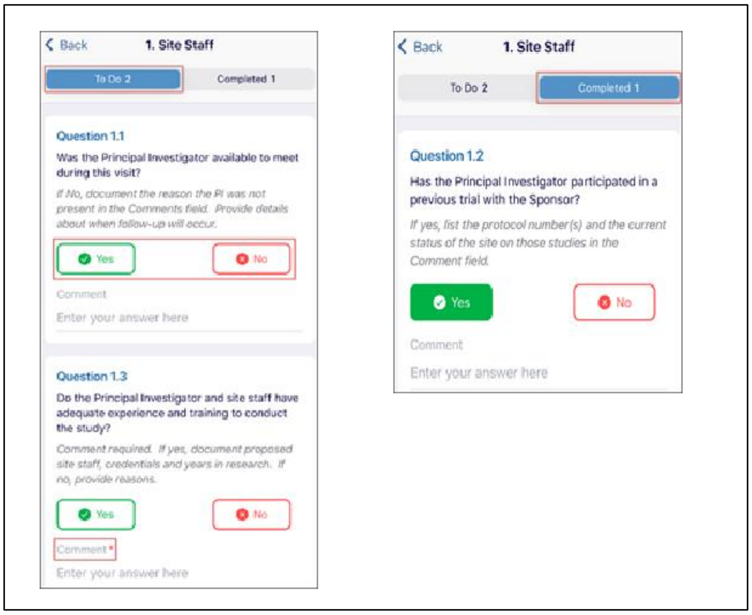
The Visit Checklist is a set of Yes/No questions to be selected. The user has to answer all the questions to display the 100% in the list and to proceed further to the next steps.

To complete the Visit Checklist, follow the steps below.

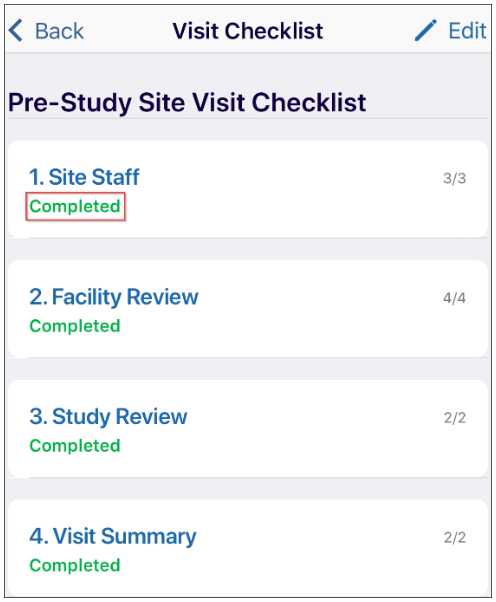
1. On the Site Visit screen, click on the **Visit Checklist** tab. This opens the Visit Checklist page.



2. Click on each tab and answer the questions by selecting Yes or No options.
3. Mandatorily enter a comment in the designated area.



4. After completing all the questions from all the tabs displayed, the visit checklist displays 'Completed' for all the tabs.

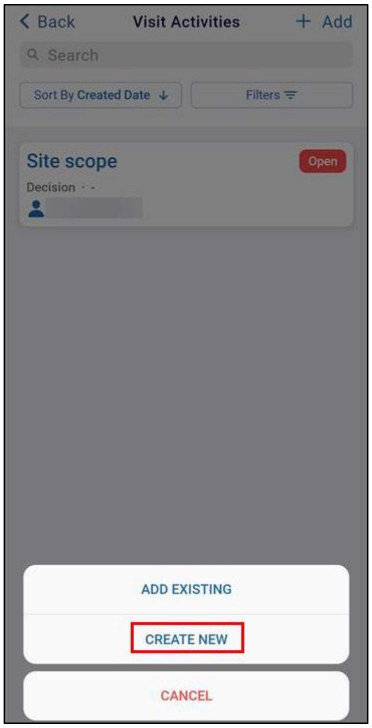


Visit Activities

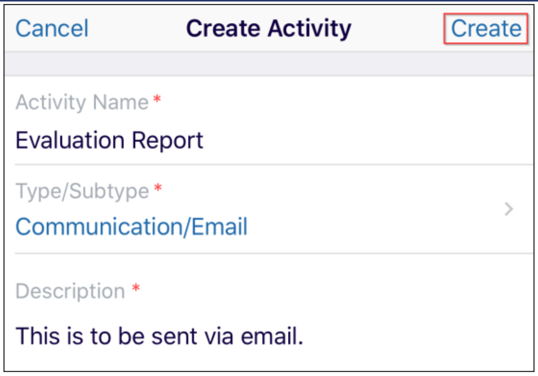
Users can add, edit, and remove new as well as existing activities.

Create New Activity

1. Select the Visit Activities tab from the Site Information screen.
2. Click on the +Add button and select the **CREATE NEW** option.



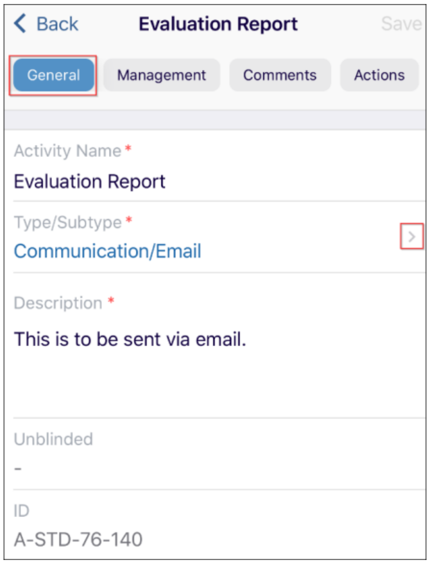
3. On the Create Activity screen, enter the following details and click on the Create button.



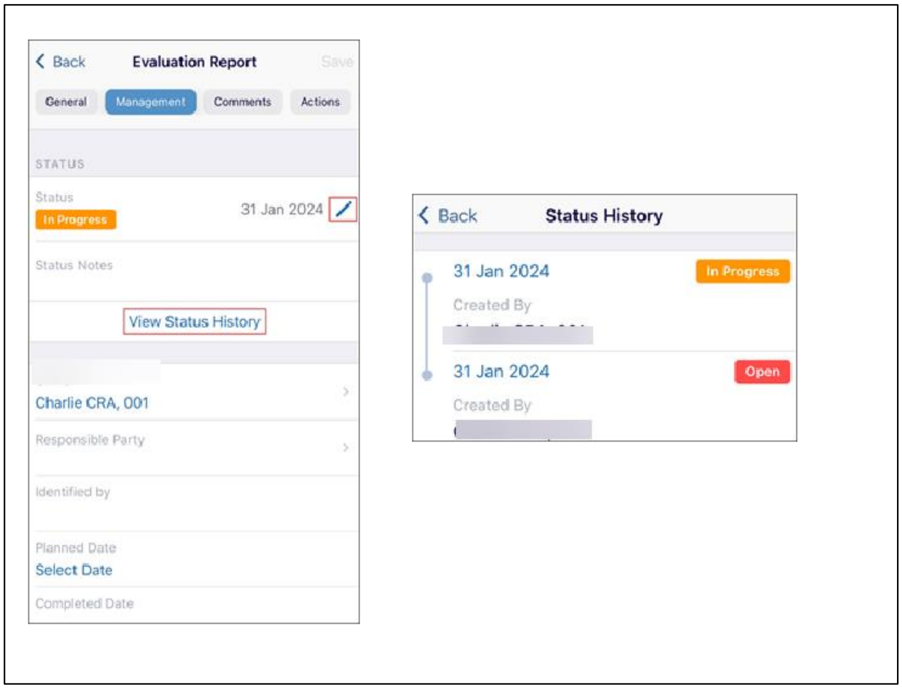
Edit a Visit Activity

To edit a visit activity, follow the steps below.

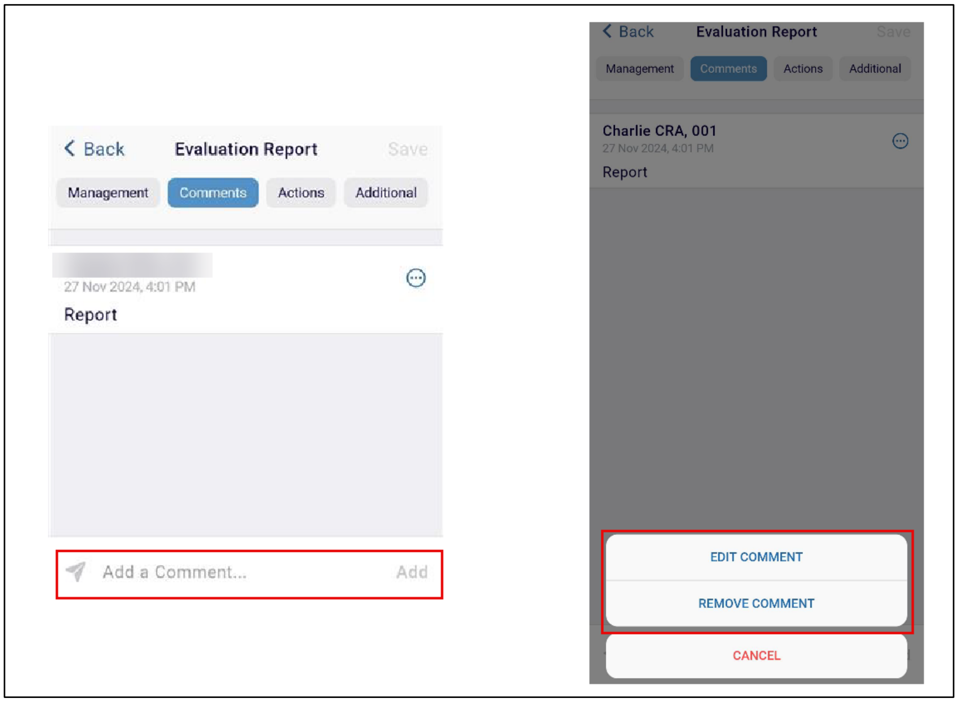
1. Click on a visit activity to edit. This opens the 'General' tab of the visit activity.
2. Make edits to the fields on the General tab.



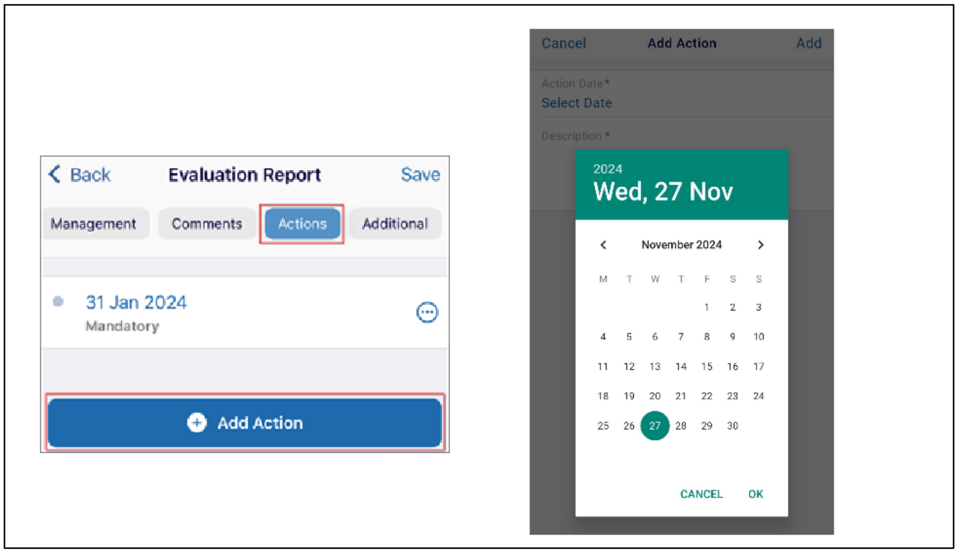
3. Click the **Management** tab to edit the Status, Owner, and other details displayed.



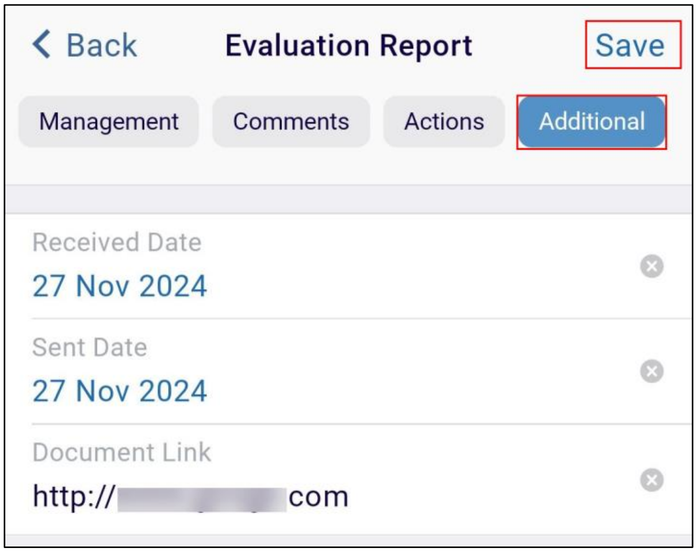
4. Click the **Comments** tab to add a comment. Click the three-dot menu to edit or remove an existing comment.



5. Click the **Actions** tab to add a new action. Click the **Select Date** link to add a date, and description and click the **OK** button.



6. Click the **Additional** tab to add the ‘Received Date’ and ‘Sent Date’ by clicking on the corresponding fields.



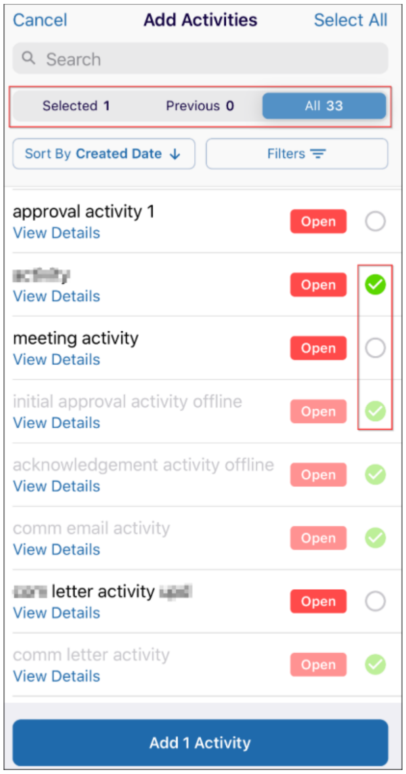
Note: The Additional tab is dynamic and is displayed as per the configuration of the application for each client

.

Add Existing Activity

To add an existing activity, follow the steps below.

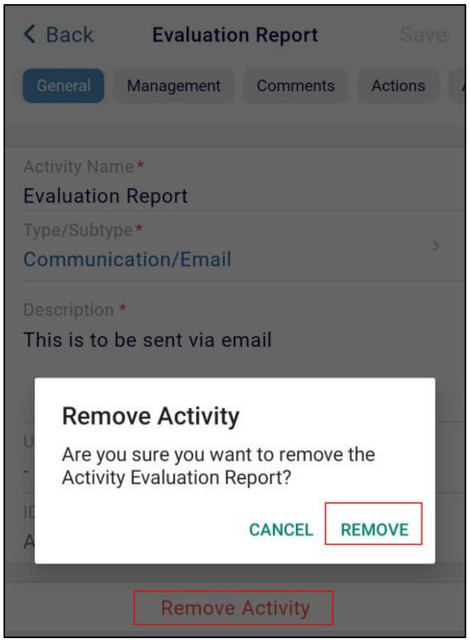
1. Click on the +Add button and select the **ADD EXISTING** option.
2. Toggle between the tabs displayed below the Search field and select the required attendees.
3. Click the **Add (number of activities) Activity** button displayed at the bottom of the screen.



Remove an Activity

To remove an activity, follow the steps below.

1. Select an activity and click on the Remove button.
2. Confirm the deletion by clicking on the Remove button on the Remove Activity confirmation popup.



Sort and Filter

To sort and filter the Visit Activities screen, follow the standard steps detailed in [the Customize Site Visit screen] section.

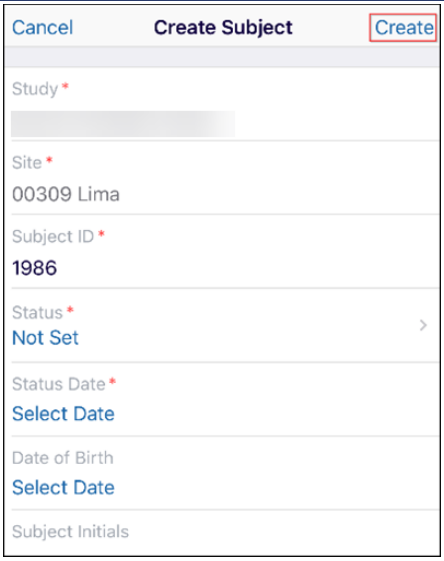
Visit Subjects

The Visit Subjects screen allows users to add, edit, and remove new and existing subjects.

Add New Subject

To add a new subject, follow the steps below.

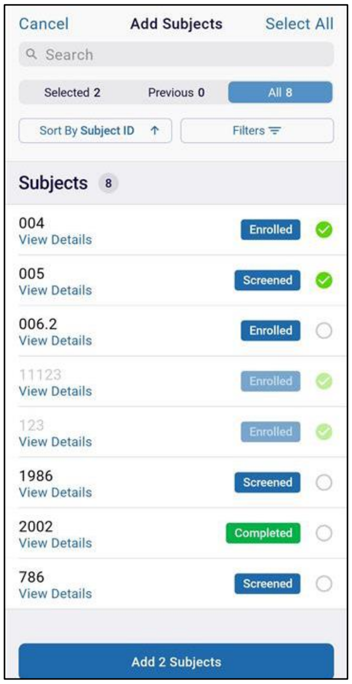
1. On the Subjects screen, click on the +Add button and select the **CREATE NEW** option.
2. On the Create Subject screen, fill in the mandatory details and click on the **Create** button.



<u>Add Existing Subject</u>

To add an existing subject, follow the steps below.

1. On the Subjects screen, click on the +Add button and select the ADD EXISTING option.
2. Toggle between the tabs and select the required number of subjects.
3. Click on the Add (number of subjects) Subjects button.



<u>Sort and Filter</u>

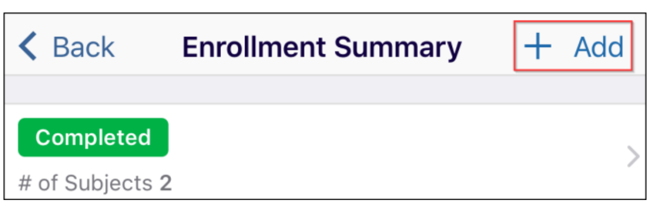
To sort and filter the Visit Subjects list follow the standard procedure detailed in the Customize Site Visit screen section.

Enrollment Summary

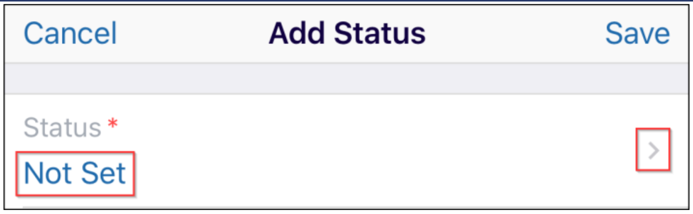
Users can 'Add' enrollment summary from this tab. Also, the added enrollment summaries can be edited and removed.

To add an enrollment summary, follow the steps below.

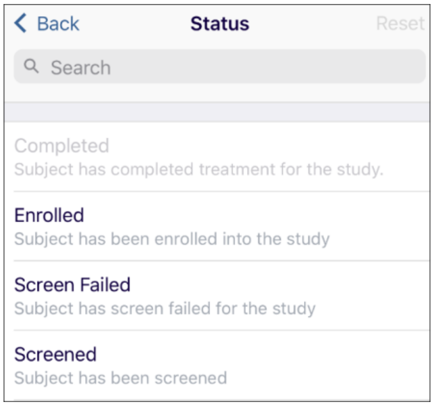
1. On the Site Information screen, click the **Enrollment Summary** option
2. On the Enrollment Summary button, click on the +**Add** button.



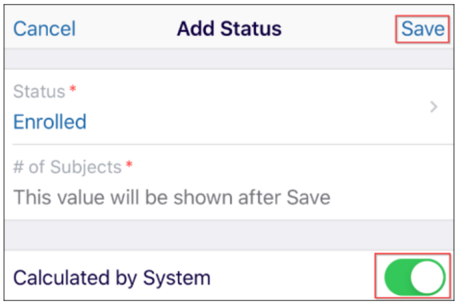
3. Set the status by clicking on the > arrow.



4. Select a status from the available list.



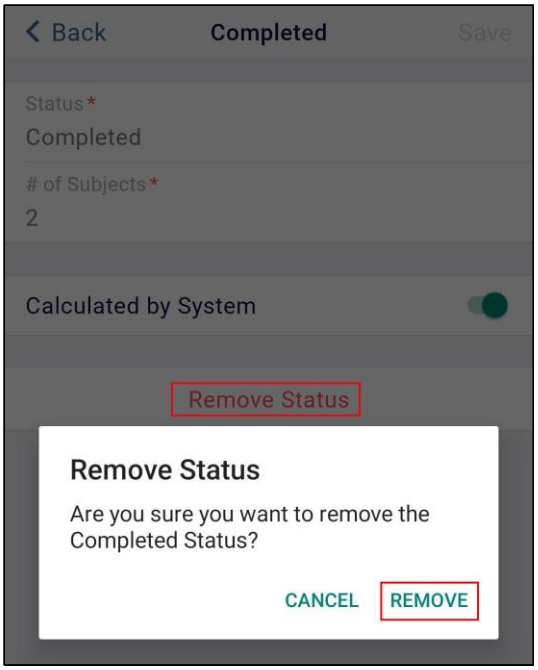
5. On the Add Status page, optionally enable the Calculate by System toggle button. If the toggle button is turned off, the user has to manually enter the site's enrollment statistics for the site at the time of the site visit.
6. Click on the Save button.



Remove the Status

To remove the status, follow the steps below.

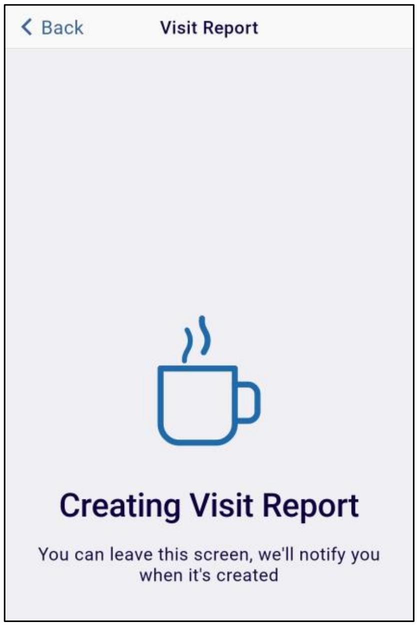
1. Click on the Enrollment Summary to remove.
2. Click on the Remove Status button.
3. On the Remove Status confirmation popup, click on the Remove button.



Visit Report

To generate a visit report, follow the steps below.

1. Click on the Site Visit report on the Site Information screen.
2. The page displays the creating visit report, and the system notifies once the report is generated.



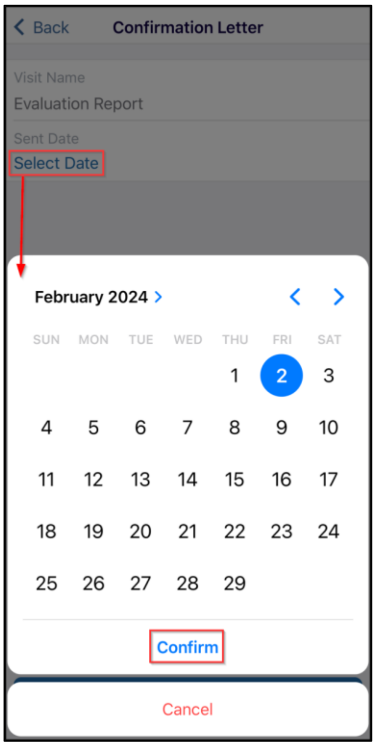
3. Once successfully created, users can see the Visit Report.

Generate Confirmation Letter

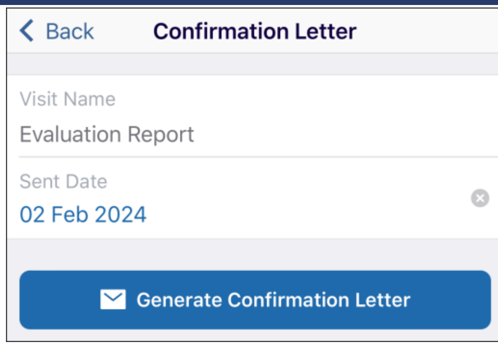
Users can create a confirmation letter for the site visit conducted.

To generate a Confirmation Letter, follow the steps below.

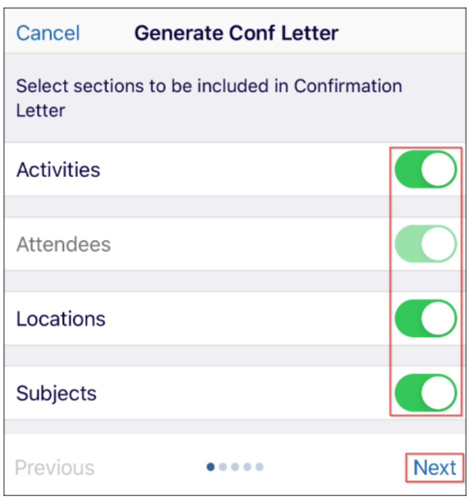
1. Select the site for which the confirmation letter needs to be generated.
2. Click the **Confirmation Letter** option displayed in the list. This opens the 'Confirmation Letter' page.
3. Click the **Select Date** link to display the calendar and choose the required date.
4. Click the **Confirm** button displayed at the bottom of the screen.



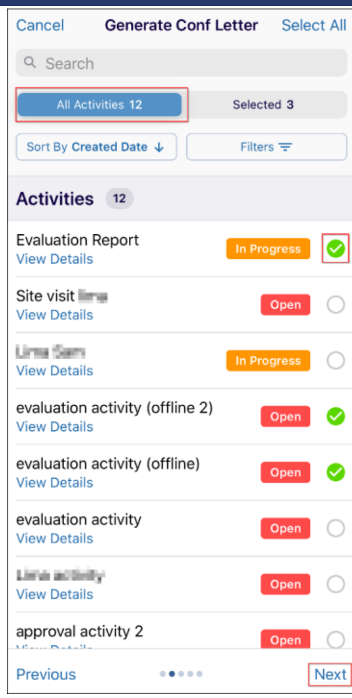
5. Click on the **Generate Confirmation Letter** button.



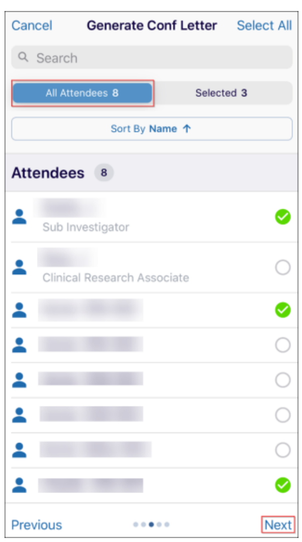
6. Select the **Toggle buttons** for the sections that need to be included in the confirmation letter – Activities, Locations, and Subjects. The Attendees toggle button is disabled by default. After selecting, click the **Next** button displayed at the bottom of the screen.



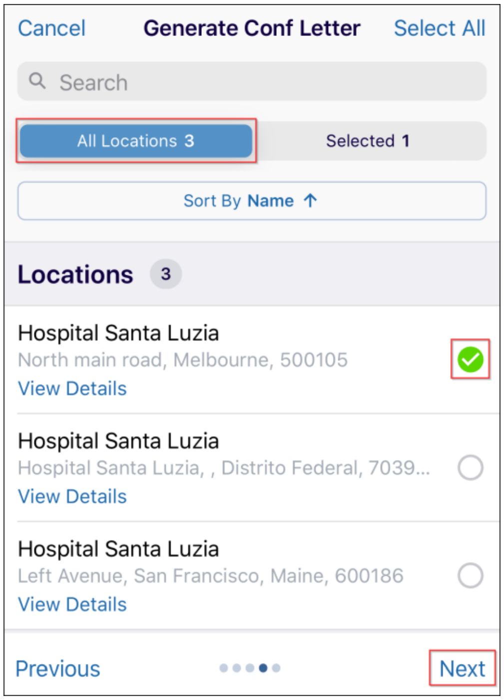
7. Select the required **Activities** by clicking on the circle displayed on the right side for each activity. Click the **Next** button displayed at the bottom of the screen.



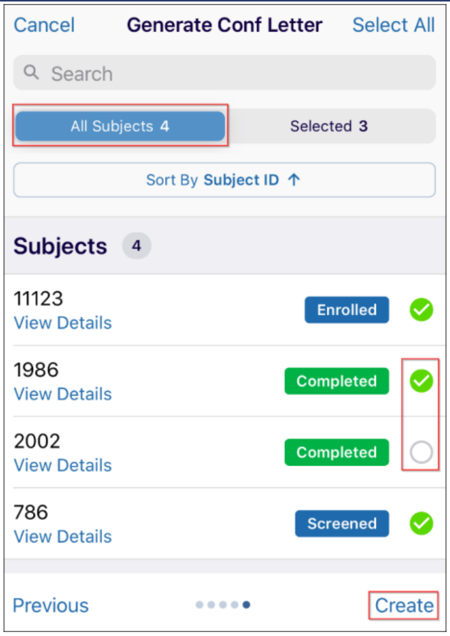
8. Select the required **Attendee(s)** by clicking on the circle displayed on the right side for each attendee. Click the **Next** button displayed at the bottom of the screen.



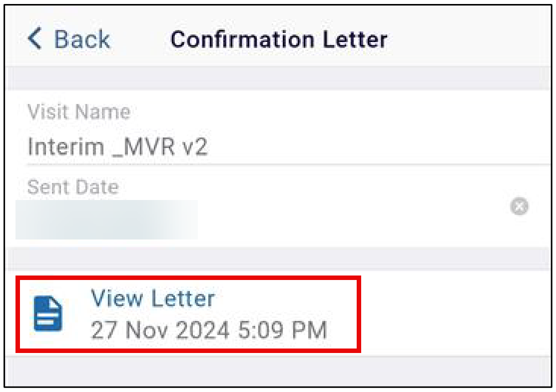
9. Select the required **Location(s)** by clicking on the circle displayed on the right side for each location.



10. Select the required **Subject(s)** by clicking on the circle displayed on the right side for each subject. Click the **Create** button displayed at the bottom of the screen after making the required selections for all the fields.



11. Once the letter is successfully generated, click on the View Letter hyperlink.



Follow up Letter

To generate a Follow-up Letter, follow the steps below.

1. On the Site Information screen, click on the +Follow-Up Letter.
2. Follow the steps similar to the Confirmation Letter steps to generate a follow-up letter.

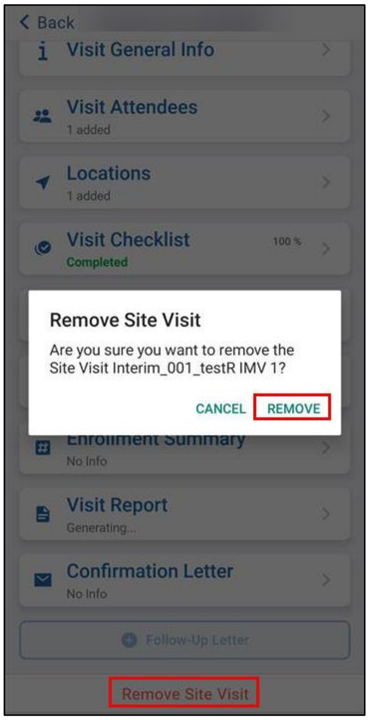
Note

- The Follow-up Letter button is enabled only after the 'Visit Report and the 'Confirmation Letter' is generated.
- Users can turn off any section that is not relevant to a visit-related follow-up letter.
- Regardless of user selection, a letter will only display content that there is a location within the template to display that data.

Remove a Site Visit

To remove a Site Visit, follow the steps below.

1. On the Site Visit Information screen, click on the Remove Site Visit button.
2. On the confirmation popup, click on the Remove button.

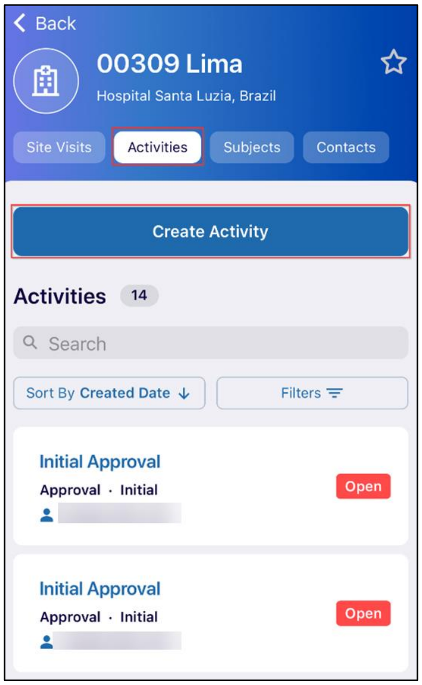


Activities

Add Activity

To add an activity, follow the steps below.

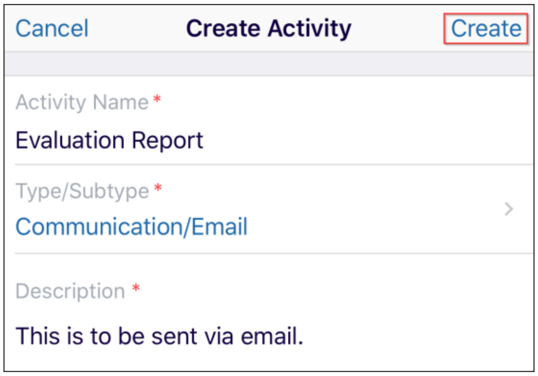
1. Select the Activities tab on a particular site and click on the **Create Activity** button.



2. Add details to the following fields on the Create Activity screen.
   a. Activity Name*: Add a name to the activity
   b. Type/Subtype*: Click on the > arrow and select the type and subtype from the available list.

c. Description*: Add a description to the activity.

3. Click on the Create button once all the details are entered.

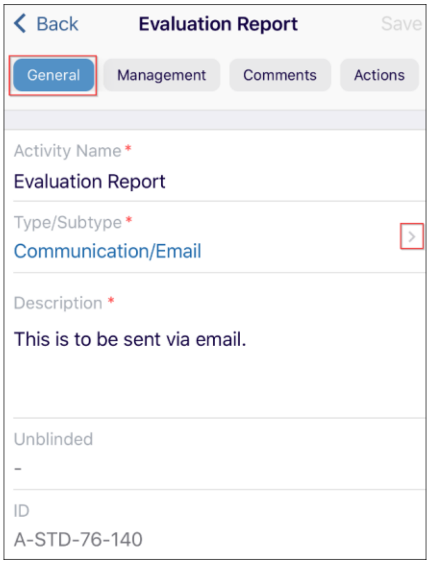


4. Once the activity is successfully created, it is displayed on the main page of the Activities tab.

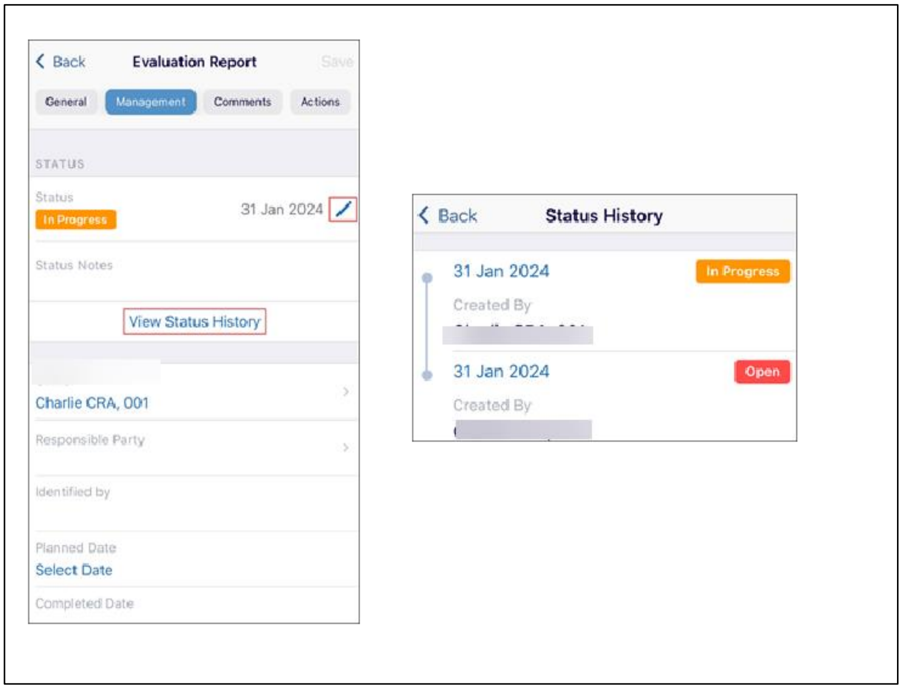
Edit Activity

To edit an activity, follow the steps below.

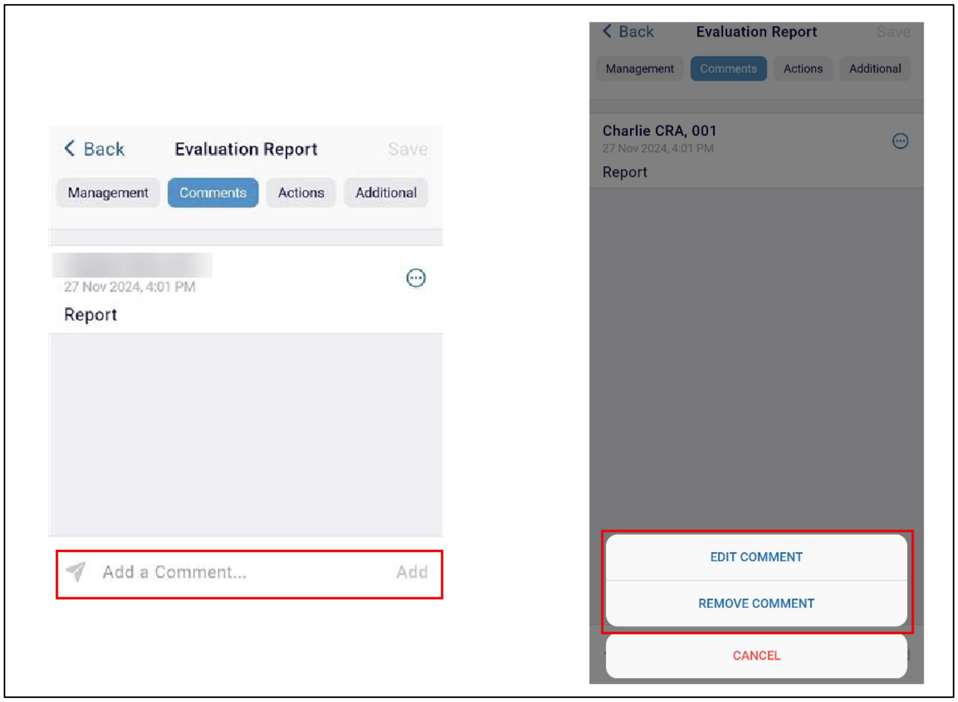
1. Select an activity on the **Activities** tab to edit.
2. Make edits to fields on the General tab.



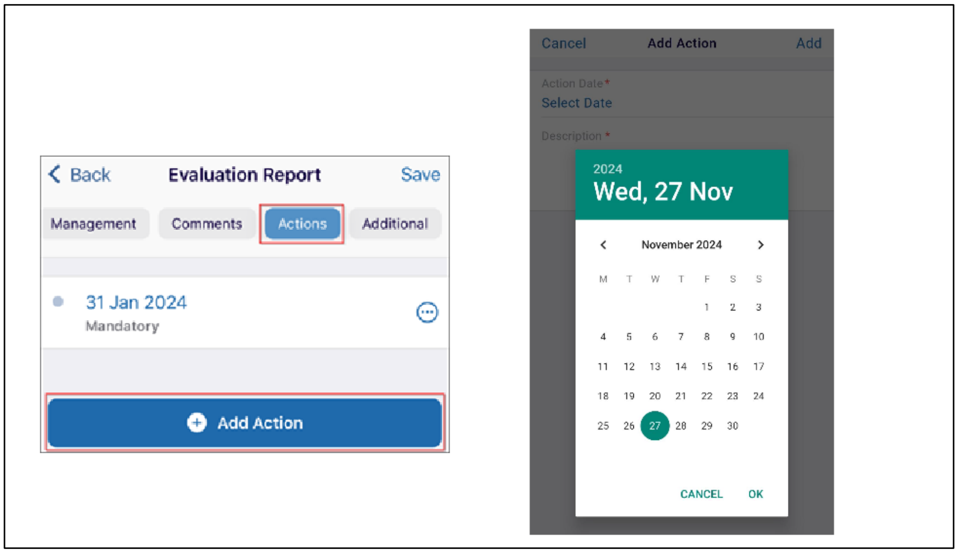
3. Click the **Management** tab to edit the Status, Owner, and other details displayed.



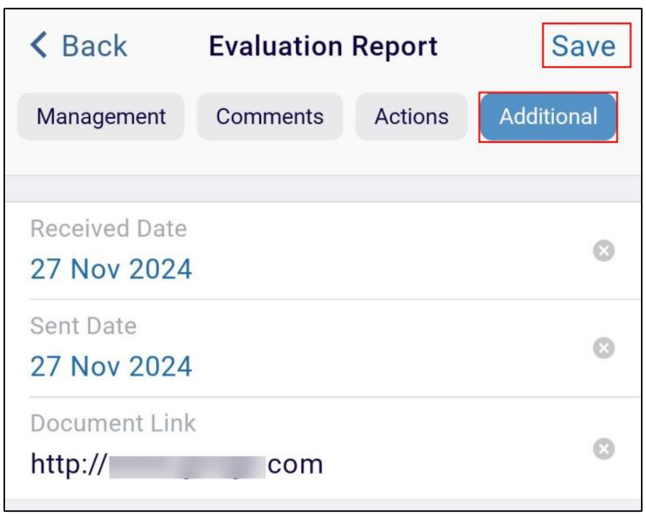
4. Click the **Comments** tab to add a comment. Click the three-dot menu to edit or remove an existing comment.



5. Click the **Actions** tab to add a new action. Click the **Select Date** link to add a date, enter the description and click the **Add** button.



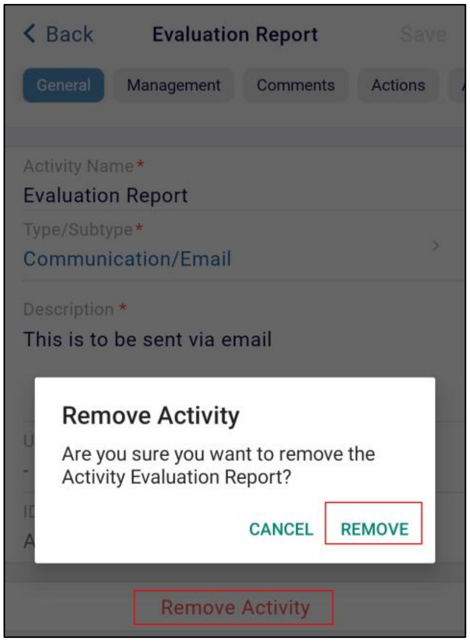
6. Click the **Additional** tab to add the ‘Received Date’, ‘Sent Date’, and the Document Link.
7. Click on the Save button once all the updates are made.



Remove Activity

To Remove an activity, follow the steps below.

1. On the Activities tab, select an activity to remove.
2. Click on the Remove Activity button.
3. Confirm the deletion by clicking on the Remove button on the Remove Activity confirmation popup.



Search, Sort, and Filter Activities

To search, sort, and filter activities, follow the standard steps detailed in the Customize Site Visit screen section.

Note: Types of Filters and Sort criteria differ per section but the process of applying filters and sort criteria remains the same.

Subjects

The user can create a subject and search for existing subjects. Also, the user can 'Sort by,' apply 'Filters' for subjects, and make a subject favorite by clicking on the grey star icon. Refer to the screenshot below.

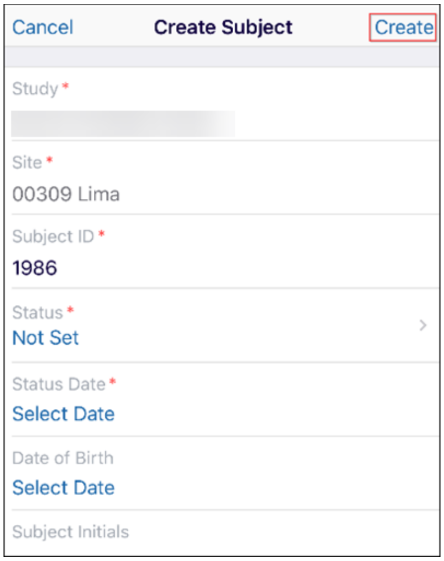
Add Subject

To create a new subject, follow the steps below.

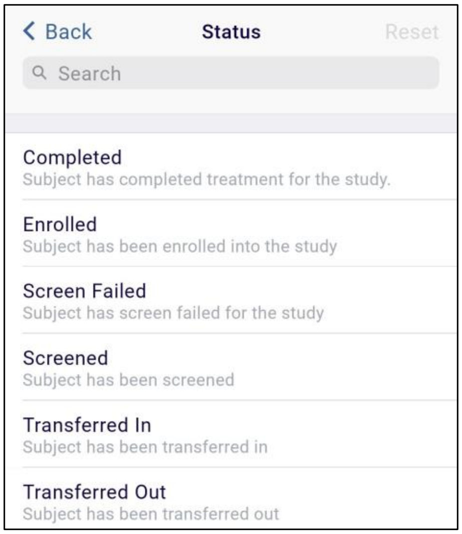
1. Select the Subjects tab on a particular site and click on the Create Subject button.

2. On the Create Subject screen, fill in the following mandatory details.

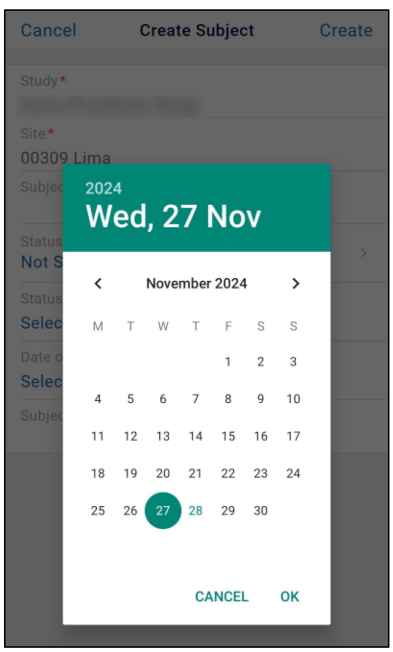
    a. **Subject ID***: Enter a value in the Subject ID field.



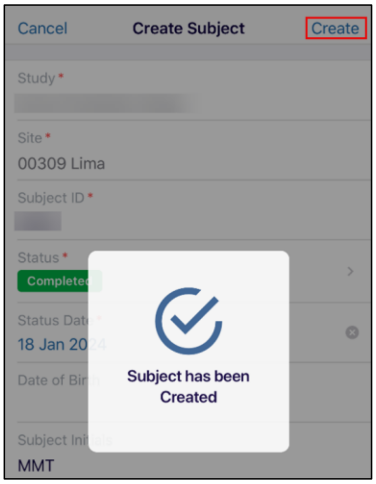
    b. Status*: Click on the > arrow and select a status from the available options. Search for a specific status by entering the term in the search box.



c. Status Date*: Click on the Select Date link and select a date from the date selection tool.



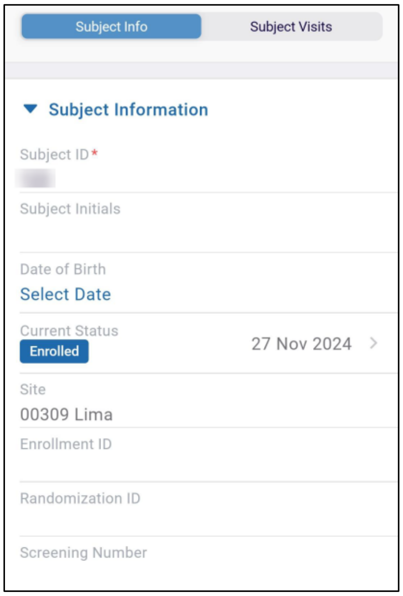
3. Optionally add the **Date of Birth** and the **Subject Initials**.
4. Click on the Create button once all the details are entered.
5. The success notification is displayed once the subject is successfully created.



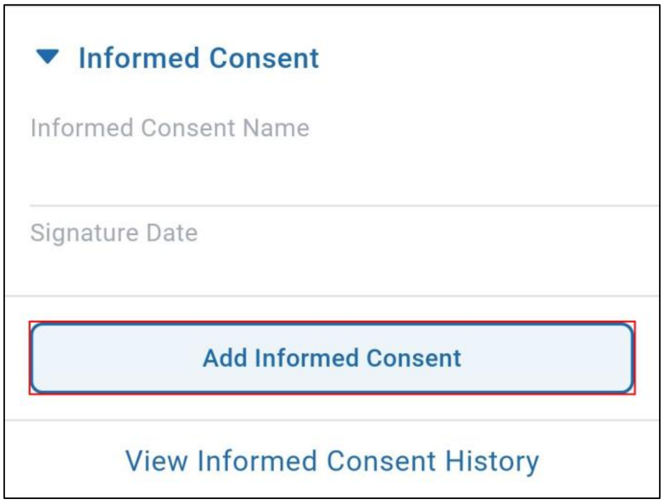
Edit Subject

To edit a subject, follow the steps below.

1. On the Subjects tab, click on a subject to edit.
2. On the Subject Info tab expand the following sections and make the required changes.
    a. **Subject Information**: Edit the information in the required fields.

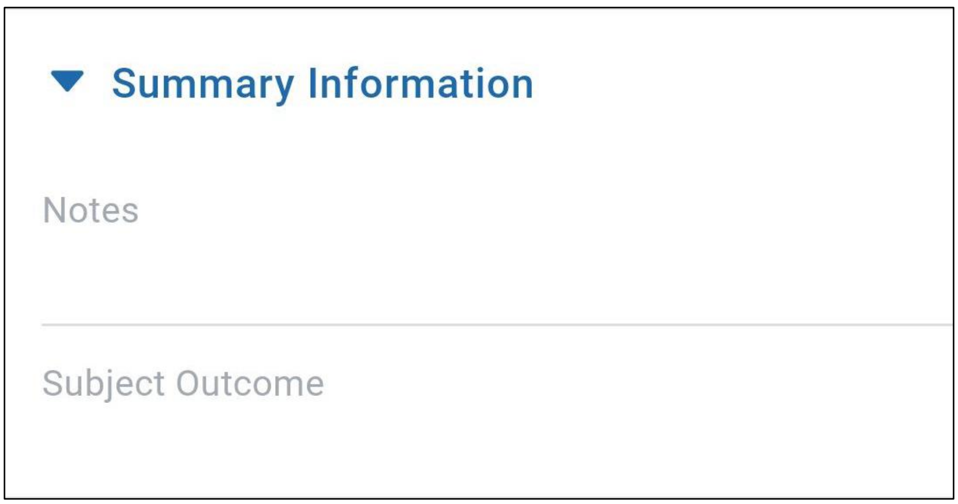


b. **Informed Consent:** Enter the informed consent form by clicking the **Add Informed Consent** button.

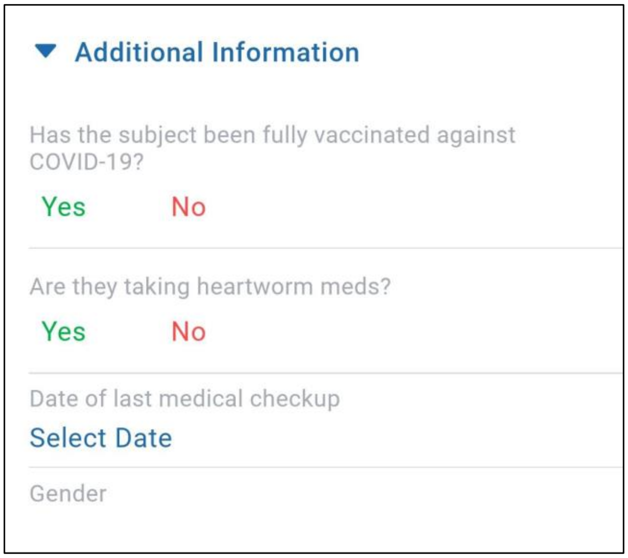


c. **Subject History:** Select the screening failure and early termination reason by clicking the **'>'** arrow.

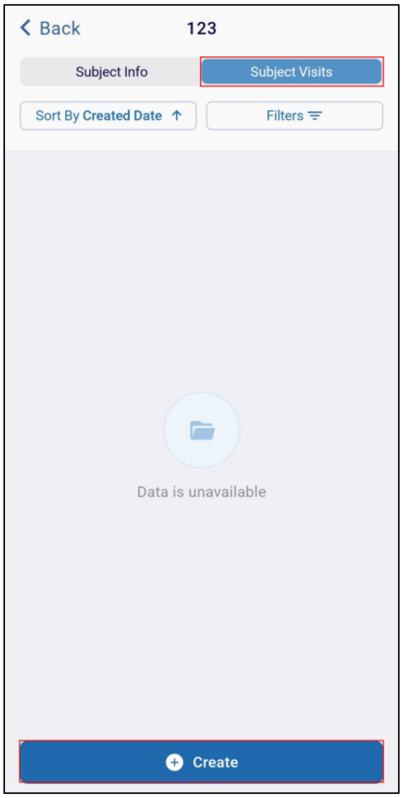
d. **Summary Information:** Enter the details of the information as a summary.



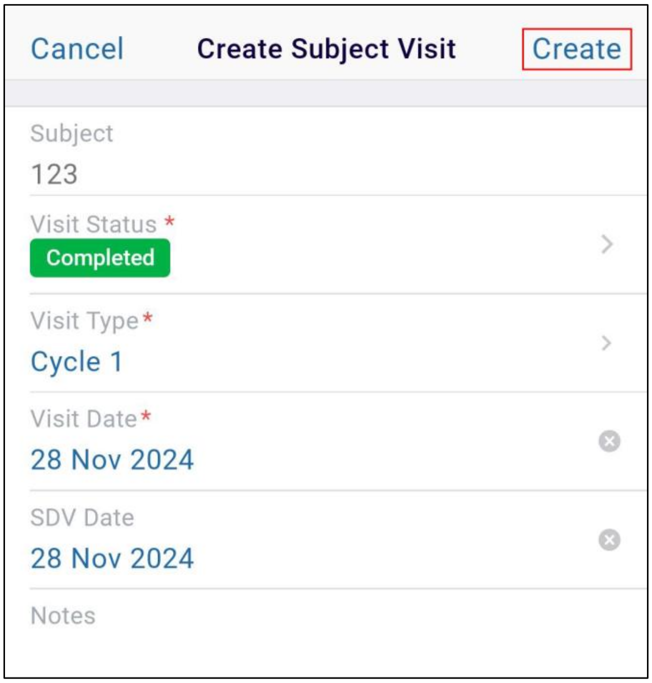
e. **Additional Information:** Answer the questions by selecting **Yes** or **No** options and enter the last date of the medical checkup.



3. Click on the Subject Visit tab, and click on the +Create button.



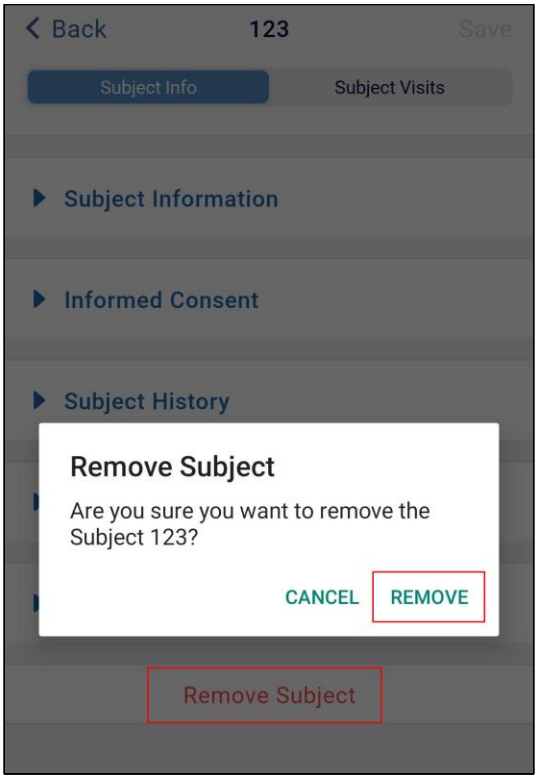
4. Once all the changes are made, click on the Save button.
5. On the Create Subject Visit screen, fill in the required details and click on the **Create** button.



Remove Subject

To remove a subject, follow the steps below.

1. On the Subjects tab, select a subject to remove.
2. On the Subject Info tab, click on the Remove Subject button.
3. On the Remove Subject confirmation popup, click on the **REMOVE** button.



Search, Sort, and Filter Subjects

To search, sort, and filter subjects, follow the standard steps detailed in the [Customize Site Visit screen] section.

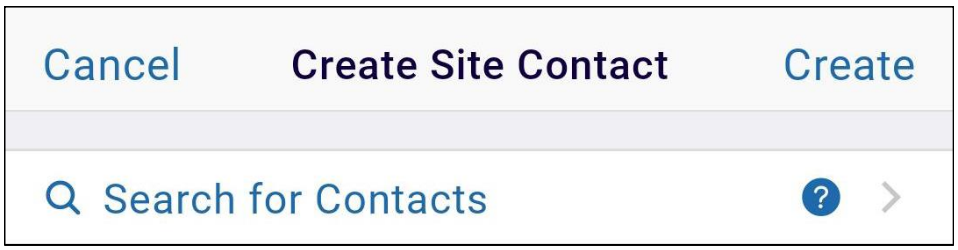
Note: Types of Filters and Sort criteria differ per section but the process of applying filters, sort criteria, and searching remains the same.

Contacts

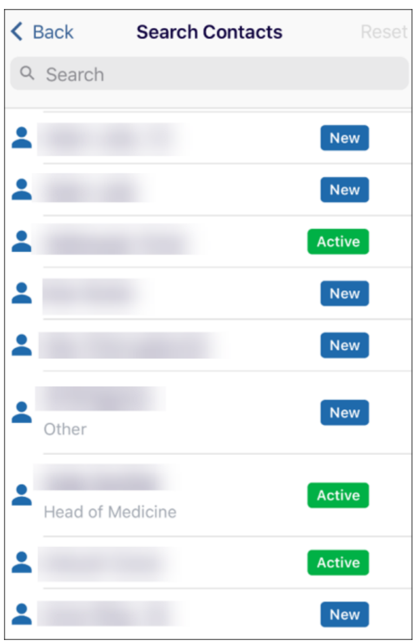
Create Site Contact

To create a site contact, follow the steps below.

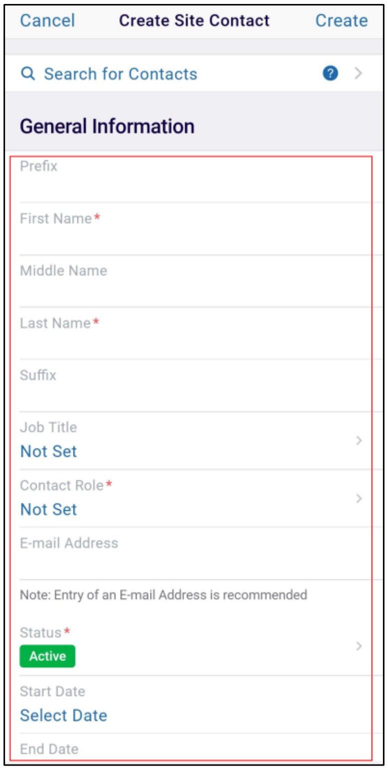
1. Select the Contacts tab on a particular site and click on the **Create Site Contact** button.
2. On the Create Site Contact screen, click on the Search for Contacts link.



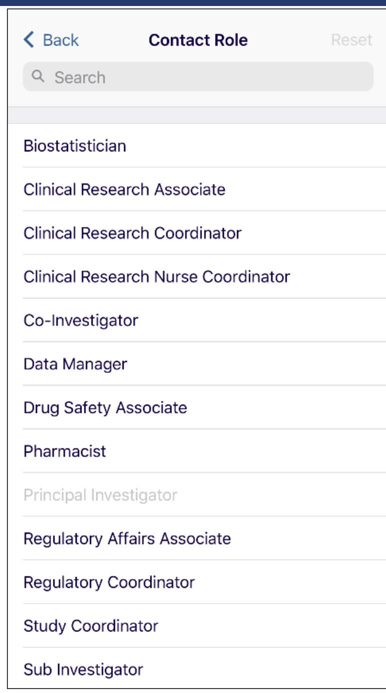
3. On the Search Contacts screen, select a contact from the available list. Enter the search term in the search box to search for a specific contact.



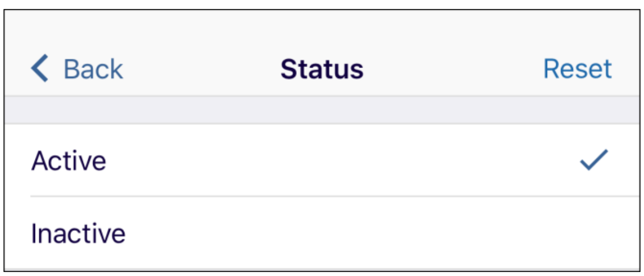
4. If the Search for Contacts option is not used, enter the mandatory details in the General Information section.



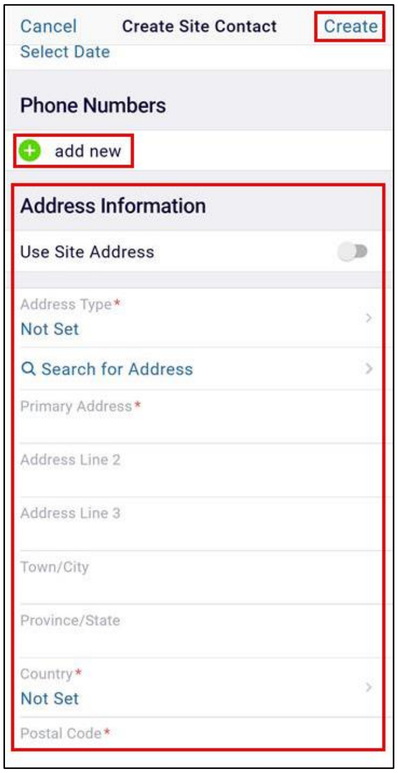
5. Manually enter the First Name and Last Name.
6. Click on the Not Set link in the Contact Role field and select a contact role from the available options.



7. Click on the > arrow in the Status field and set the status to Active or Inactive.



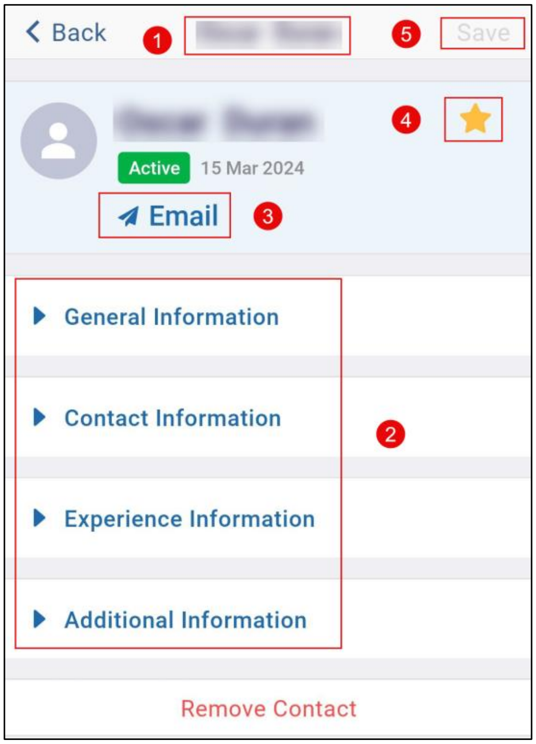
8. Add phone numbers in the respective section by clicking on the +add new button.
9. Enter the address details in the Address Information section.
10. Click on the **Create** button once all the details are entered.



Edit Site Contact

To edit a site contact, follow the steps below.

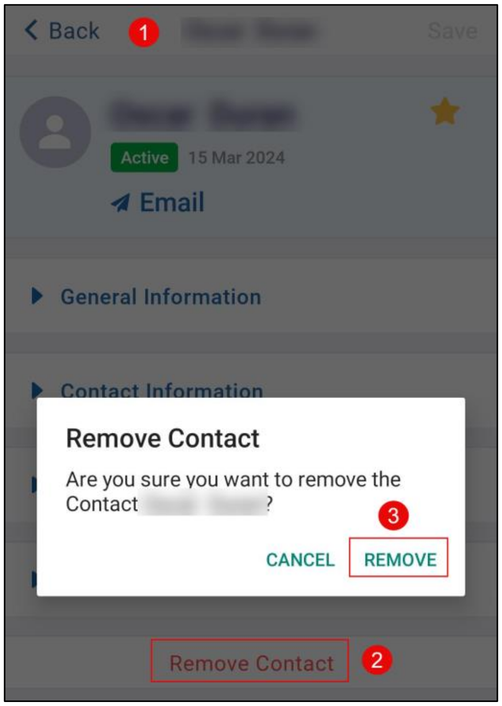
1. On the Contacts tab, select a contact to edit.
2. Make the required edits by accessing the General Information, Contact Information, Experience Information, and Additional Information tab.
3. Click on the Email link to send an email to the contact.
4. Click on the star icon to mark the contact as a favorite.
5. Once all the changes are made, click on the **Save** button.



Remove Site Contact

To remove a site contact, follow the steps below.

1. Select a contact to remove.
2. Click on the Remove Contact button.
3. On the confirmation popup, click on the REMOVE button.



Search, Sort, and Filter Contacts

To search, sort, and filter contacts, follow the standard steps detailed in the [Customize Site Visit screen](#) section.

Note: Types of Filters and Sort criteria differ per section but the process of applying filters, sort criteria, and searching remains the same.

CHAPTER 6. TRIAL INTERACTIVE ROOMS

The ~~myTI~~myTI home page displays the TI Rooms the user has access to.

eTMF Room

Click on the eTMF room, which opens the Site tab by default and displays all the sites linked to the room. Users can navigate to the Sites, Docs, To-dos, and More tabs to access and perform the relevant information and actions, respectively.

Dashboard

The **Dashboard** is the main landing page within the **eTMF Room** of the application it provides a high-level summary and quick access to critical data or features such as **Sites**, **Docs**, **To-dos.**

eTMF Health

This is a visual summary of the completion status of documents within different categories of the TMF. It shows:

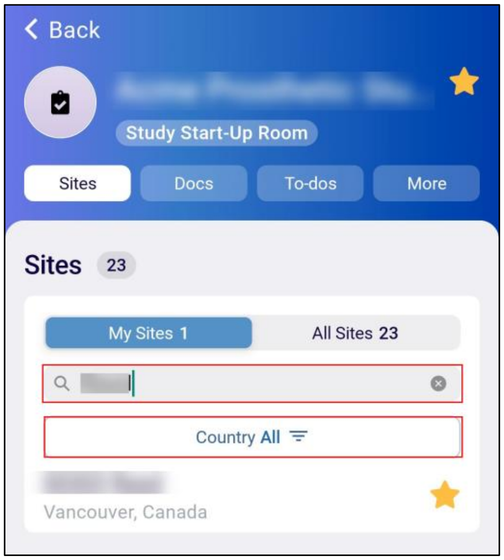
1. **Overall** progress of the TMF documents (e.g., 0% of 207 Complete).
2. Progress broken down by key categories:
    - **Trial**
    - **Country**
    - **Investigative Site**
    - **IRB/EC**
3. Each section shows the percentage and number of documents completed out of the total expected.
4. At the bottom, a legend explains the color-coded indicators:
    - **Fulfilled** – Document requirements are met.
    - **Overdue** – Documents are past their expected completion date.
    - **Unfulfilled** – Documents are not yet completed.

Search and Filter

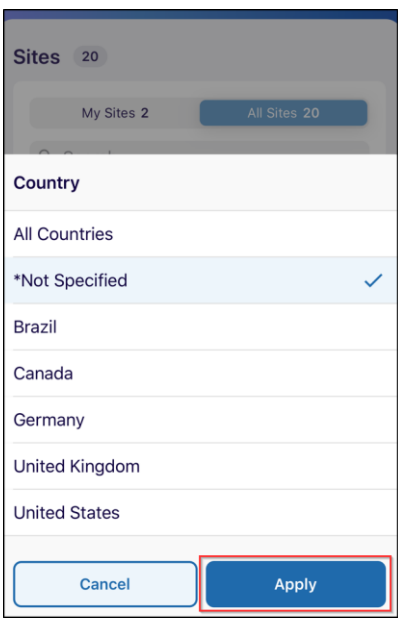
Users can customize the site tab by applying filters and searching for a specific site by accessing the search box.

To customize the Site tab, follow the steps below.

1. On the Sites tab, click on the My Sites tab and enter the search term in the search box to retrieve a specific site.
2. Click on the star icon to mark the site as a favorite.
3. Click on the Country Filter.



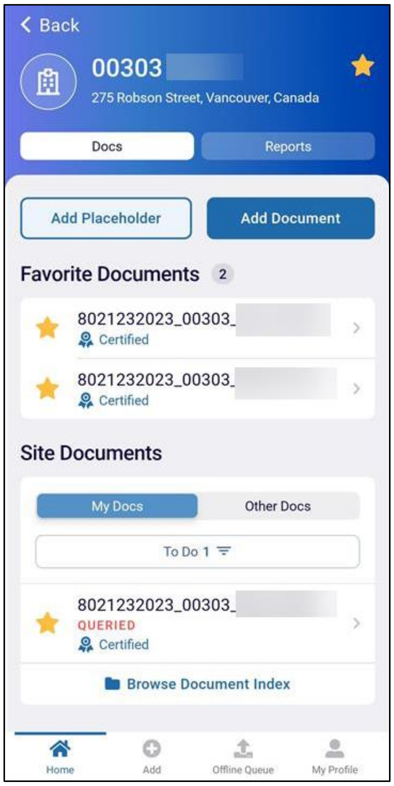
4. Select a country and click on the Apply button.



5. Click on the All Sites tab and follow the similar steps of searching and filtering.

Sites

To access a site, click on the Sites tab and select a site by toggling between the My Sites and All Sites tab. The site displays the address along with options to add documents and place holders, view favorite documents, site documents, and browse document index tabs.



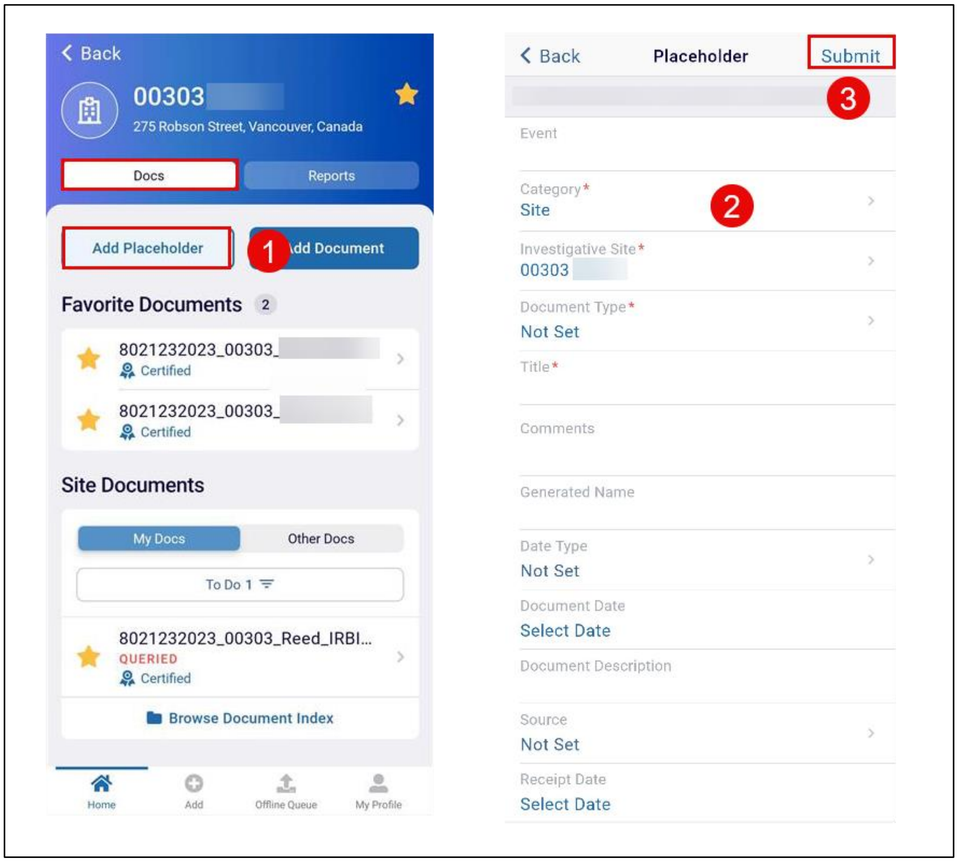
Docs tab

The docs tab allows users to add placeholders and documents.

Add Place Holder

To add a placeholder, follow the steps below.

1. On the Docs tab on a particular site, click on the **Add Placeholder** button.
2. O the Placeholder screen, add the mandatory details.
3. Click on the Submit button.



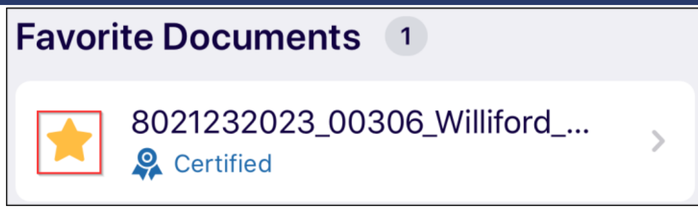
A notification 'Placeholder is Uploaded' is displayed and the document is visible under the Site Documents tab.

Add Document

To add a document, click on the Add Document tab and follow the standard steps detailed in the +Add section.

Favorite Documents

Click on the **Star** icon displayed before the name to make it a favorite room, site, or document. If the star is yellow, the room, site, or document is already added as a favorite.

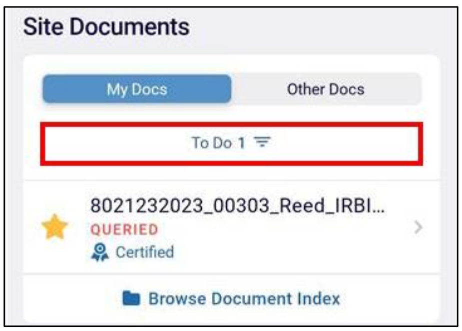


Site Documents

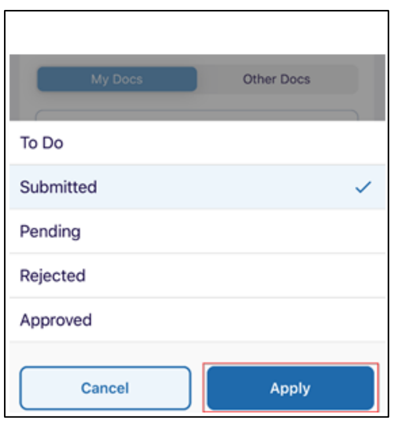
This section displays the My Docs and Other Docs tabs.

My Docs

The My Docs section displays documents that are certified by the user. Click the To-Do button to apply another filter and view the documents with other available statuses.



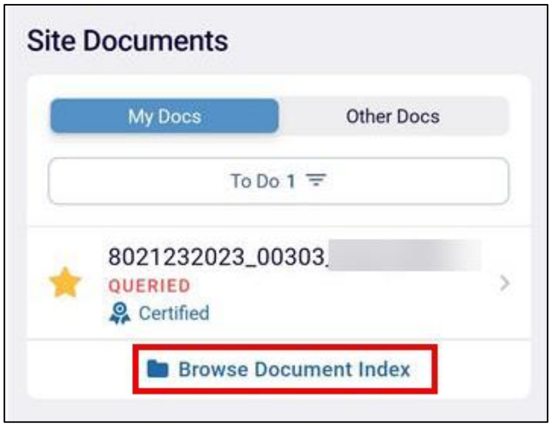
Click on the required status option and click the **Apply** button displayed at the bottom of the screen. The document(s) available for the selected status are displayed.



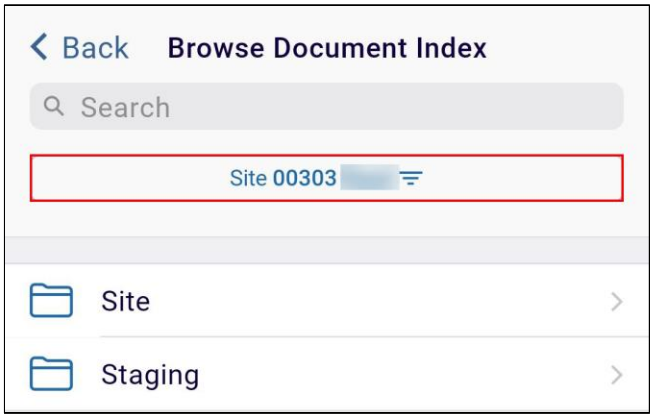
Browse Document Index

To browse the document index, follow the steps below.

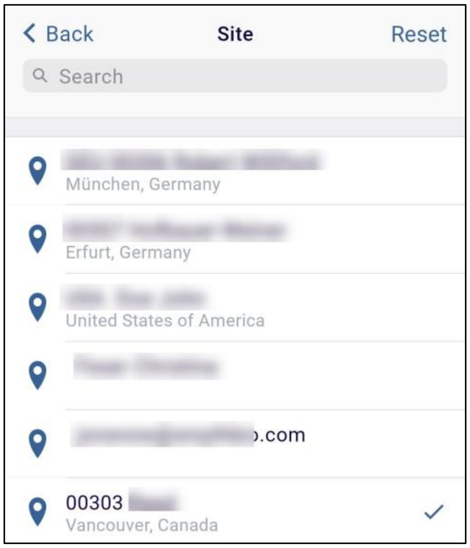
1. Click on the Browse Document Index button to view the list of available document indexes



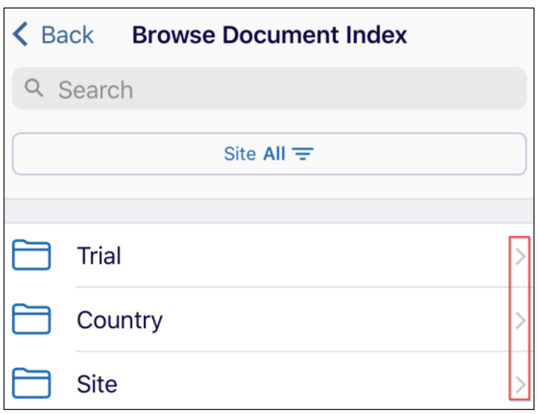
2. By default, the selected site's index is displayed. To change the site and its index, click on the site displayed on the screen.



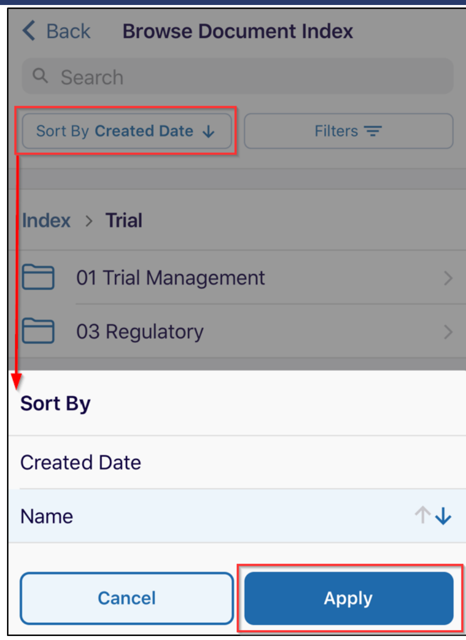
3. From the list of available sites, select the required site. Click on the **Reset** button displayed in the top right corner to clear all selections.



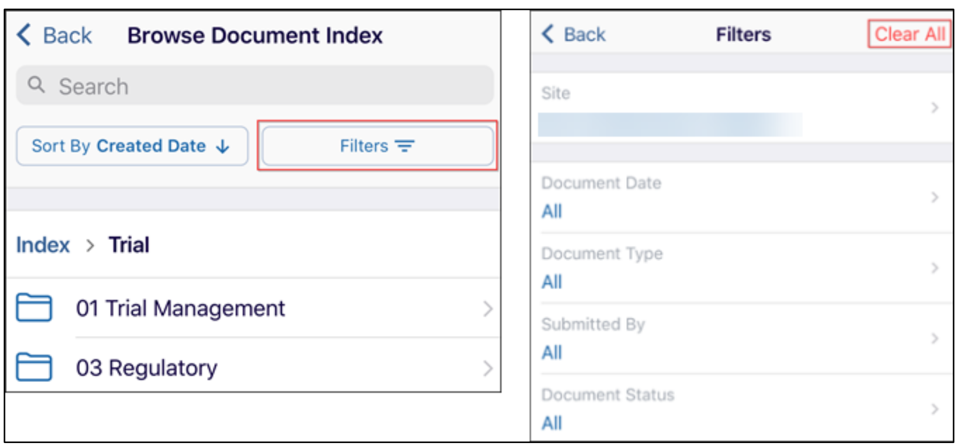
4. Click on the Back button, and on the Browse Documents Index screen, click on the '>' arrow to access the folders and select a subfolder to set as a document index.



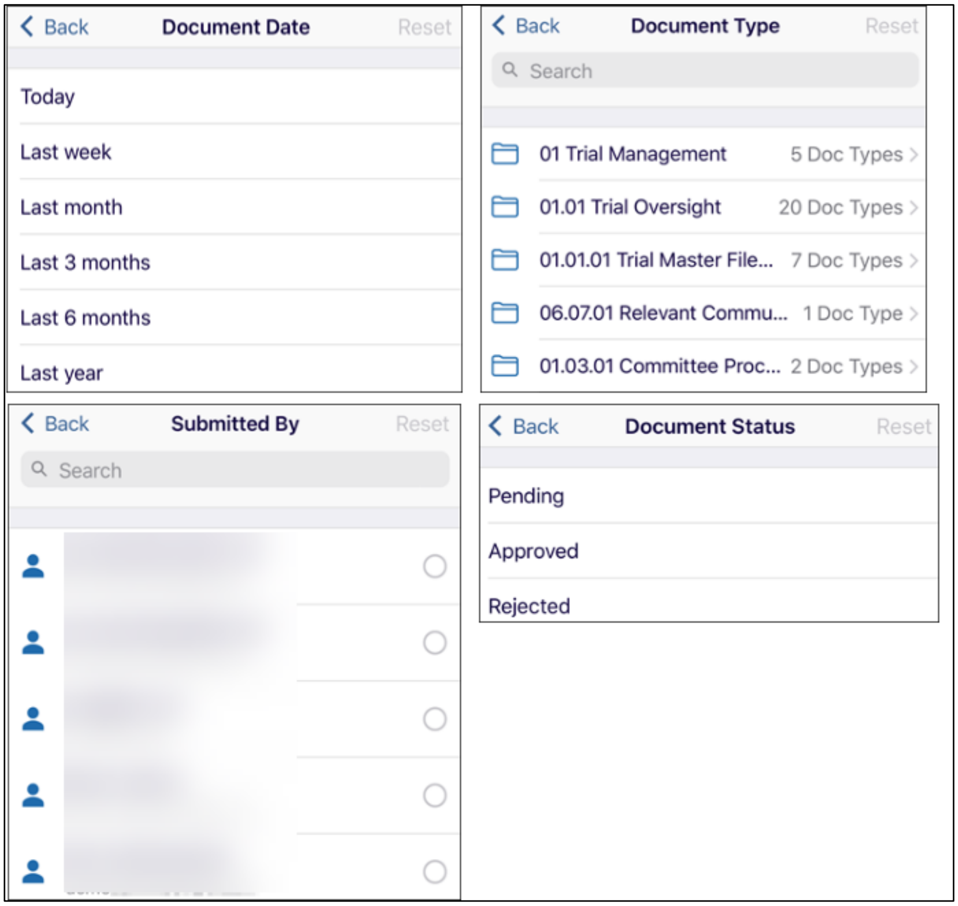
5. Click on the Sort By button, select any one sort criterion, and click the Apply button.



6. Click on the Filters tab to apply filters for Trial, Country, and Site and sub-filters for Document Date, Document Type, Submitted By, and Document Status.



7. Apply the filters by clicking on the > arrows and selecting the required filter criterion.

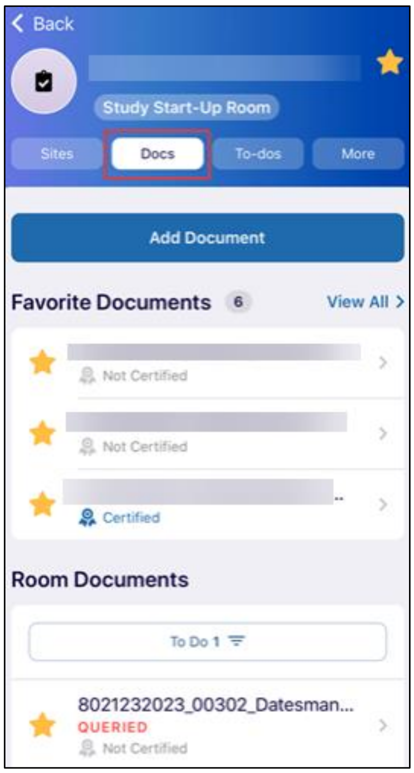


Other Docs

The other docs tab displays documents that are not certified by the user. Apply the filters to the other docs tab mentioned in the section above.

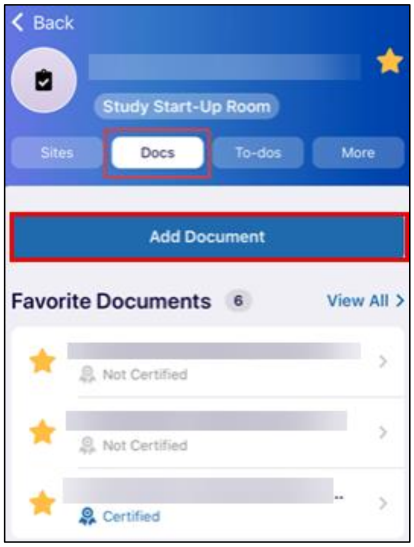
Docs

The Docs page helps the user add a document and also displays the Favorite Documents, Room Documents – Browse Document Index, Workflow Documents – Claimed and Unclaimed, and Need E-Signature documents.



Add Document

To add a document, click on the Add Document button and follow the standard steps detailed in the [+Add](#) section.



Favorite Documents

Click the grey star next to the document, site, or room name to mark it as a favorite. The star will turn yellow to indicate it is marked as a favorite. Click the yellow star again to remove it from the favorites.

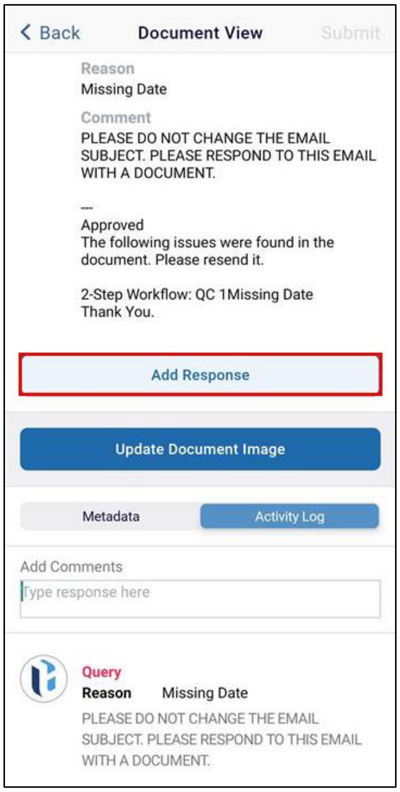
Room Documents

This displays the documents that are available in the room. The user can filter the documents with the below-displayed options. Select a document from the available list to make any changes in the document, mainly to update the document image, create a general query, or make any other changes in the fields mentioned.

Add Response and Update Document image.

To add a response and update the document image, follow the steps below.

1. Click the document that needs to be added with a response. This opens the Document View page.
2. Click the **Add Response** button. The user is redirected to the ‘Activity Log’ on the same page.
3. Enter the required response in the ‘Add Comments’ section and click the **Submit** button displayed at the top right corner.

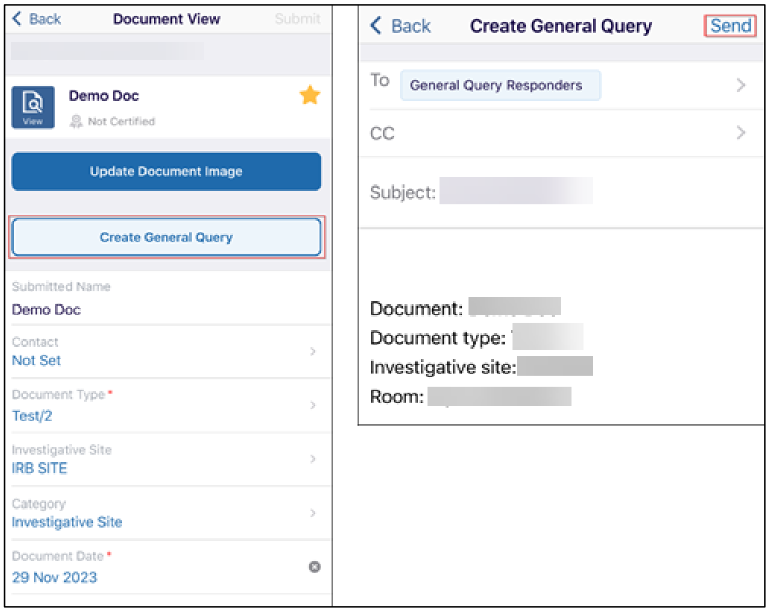


4. Click on the Update Document Image button and follow the steps to make the required modifications detailed in the +Add section.

Create General Query

To create a general query, follow the steps below.

1. Click the **Create General Query** button displayed on the mobile screen.
2. This opens the email window. Click the **Send** button displayed in the top right corner.



Restricted Documents

The Restricted Documents section displays the Waiting for Redaction and Redacted tab.

Workflow

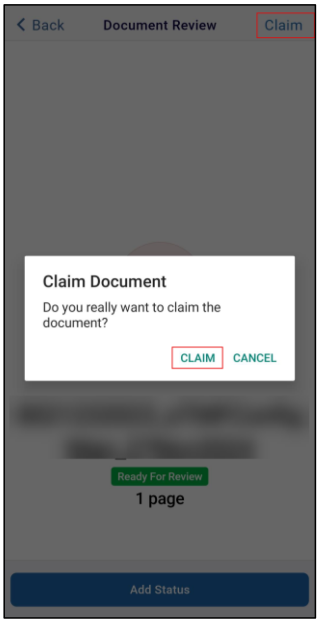
The Workflow section displays Unclaimed and Claimed documents that are currently in the workflow.

Note: To view the documents in this section, the user requires appropriate access permissions granted by the Super Administrator.

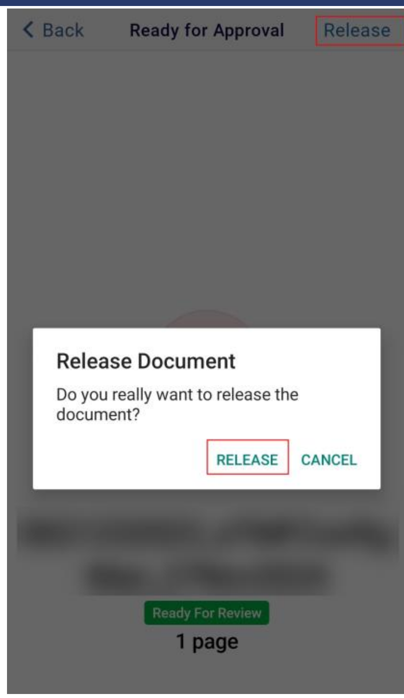
An Unclaimed document, once Claimed, is reflected under the Claimed tab.

Follow the steps below to Claim a document.

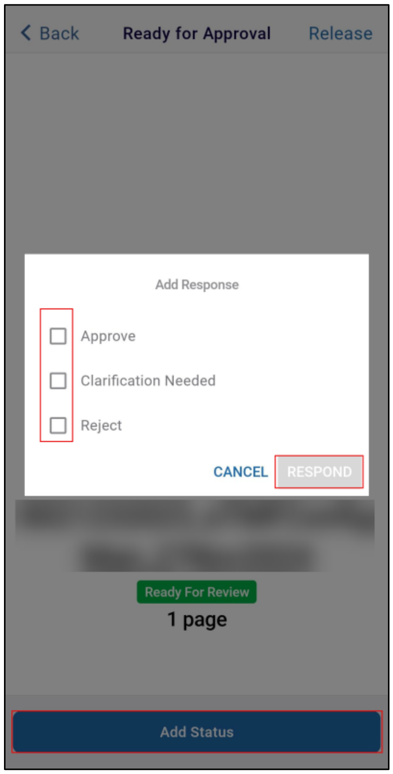
1. Click the View All button in the top-right corner to view and claim the required documents.
2. Select a document to open it on the Document Review page.
3. Click the Claim button in the top-right corner, then confirm by clicking the Claim button in the confirmation window. A 'Document Claimed' notification will appear on the screen.



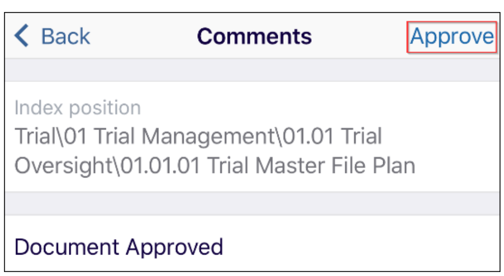
4. Click on the Release button on the top right of the screen. Select the RELEASE option of the confirmation popup.



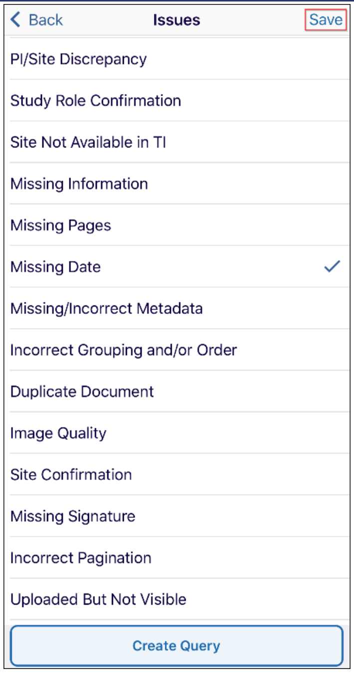
5. Click the **Add Status** button displayed at the bottom of the screen. This displays the Workflow Approval options at the bottom of the screen.
6. Select a response and click on the **RESPOND** button.



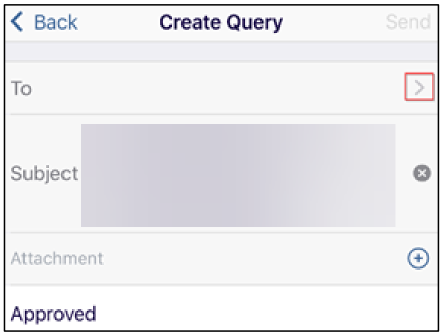
7. If approve is selected, enter the comments in the empty field if required. Click the **Approve** button displayed in the top right corner.



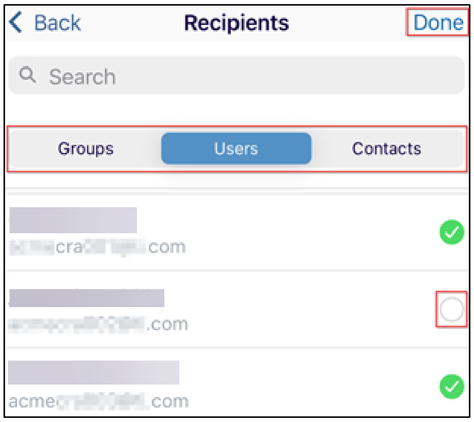
8. If the **Clarification Needed** button is selected, select the appropriate issue from the list available. Click the **Save** button displayed in the top right corner.



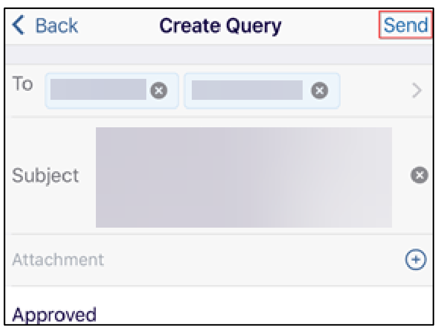
9. Additionally, click on the Create Query button. This opens the Create Query page. Click the **'>'** arrow for the 'To' field. Select the recipient to whom the query needs to be mailed.



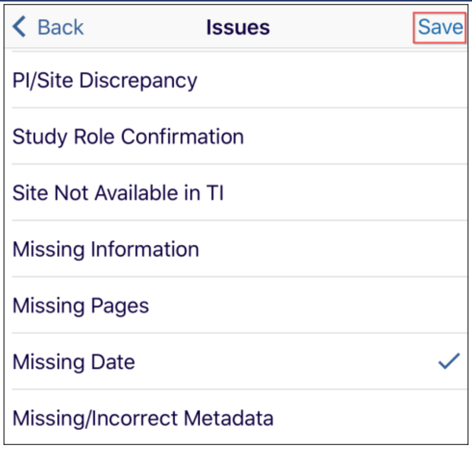
10. The 'Users' tab is displayed by default. Select the required tab – Group, Users, or Contacts as per requirement.
11. Click the **Done** button displayed in the top right corner.



12. On the Create Query screen, enter attachments or comments if required and click on the Send button.

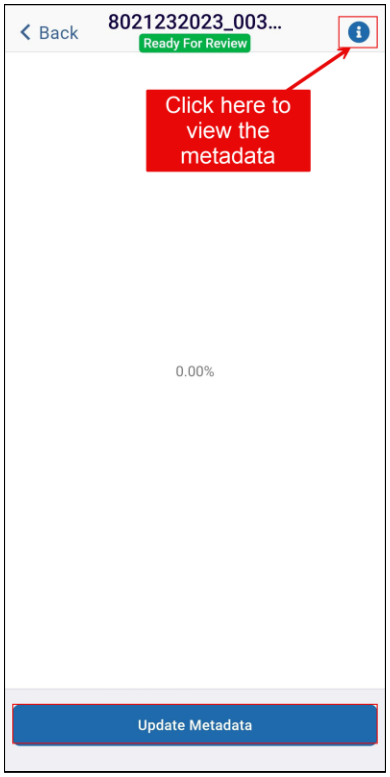


13. If the **Reject** is selected, select the issue from the list available and click the **Save** button. The ‘Document Rejected’ notification is displayed on the screen. The user is redirected to the Workflow page.



Important

- To change the metadata of the selected document, click anywhere on the screen OR the **Ready for Review** button displayed in the center of the mobile screen.
- Click the **Update Metadata** button displayed at the bottom of the screen. This opens the metadata of the document. Make the required changes and click the **Save** button displayed in the top right corner.
- The 'i' icon is displayed in the top right corner; by clicking this button, the user can only view the metadata of the document and cannot edit any fields.



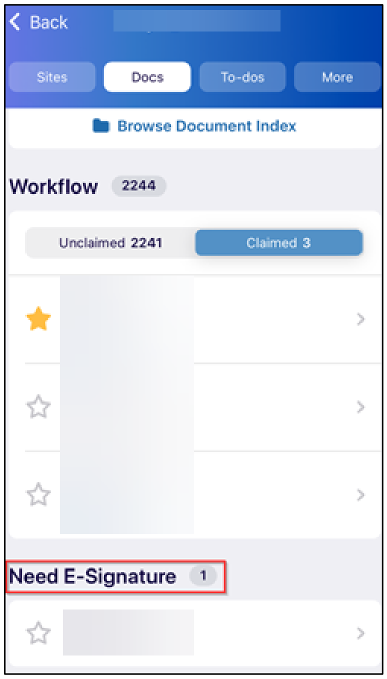
Need E-Signature – Sign

This tab displays all the documents that require an e-signature of the user. Click on the document that is to be signed electronically.

Note: To view the documents in this section, the user requires appropriate access permissions granted by the Super Administrator.

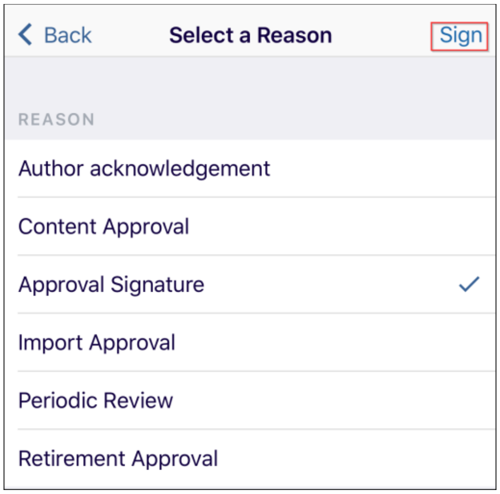
Follow the steps below to e-sign a document.

1. Click on the document that requires e-signature from the Need E-Signature section.



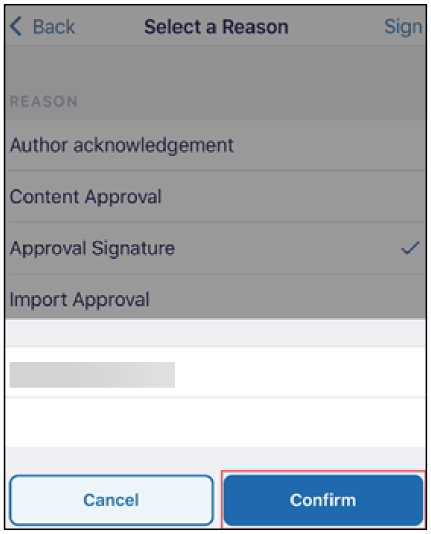
2. The E-Signature page opens with the Reject and Sign button at the bottom of the window.
3. Click the **Sign** option.

4. The Select a Reason window is displayed. Select the appropriate reason to e-sign the document. The selected reason displays a blue tick mark.
5. Again, click the **Sign** button displayed in the top right corner.



6. The application asks the user to verify themselves by entering the username and password.

7. Click the **Confirm** button.

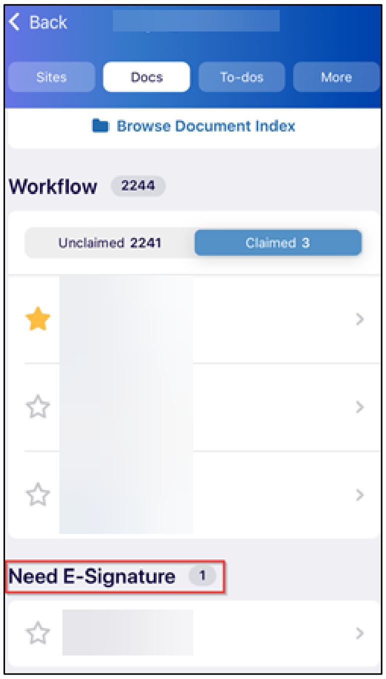


8. The ‘Document was signed’ is displayed on the screen.

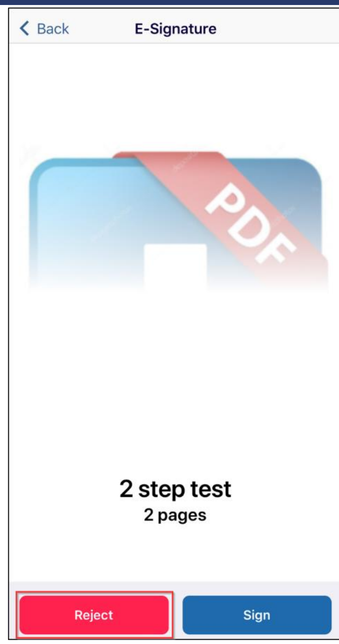
Need E-Signature – Reject

Follow the steps below to reject a document for E-Signature –

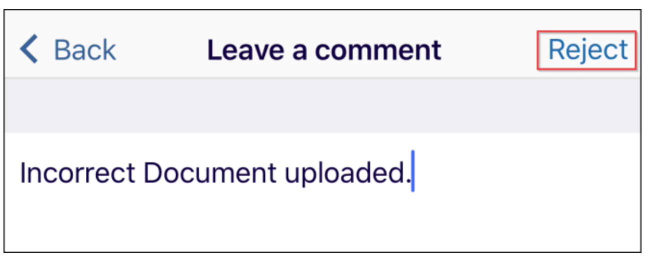
1. Click on the document that requires e-signature from the Need E-Signature section.



2. The E-Signature page opens with the Reject and Sign button at the bottom of the window.
3. Click the **Reject** option.

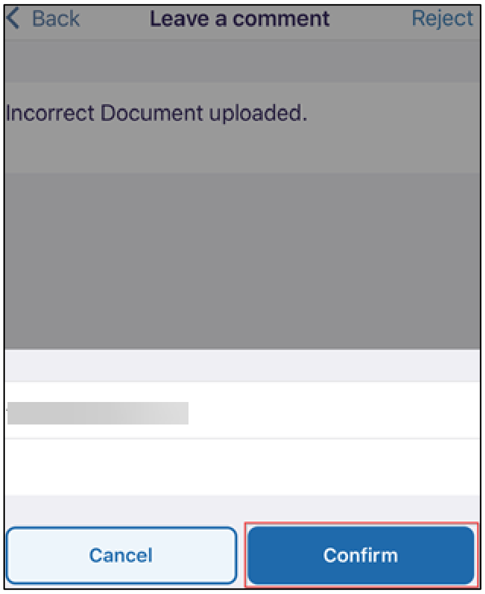


4. This opens the ‘Leave a Comment’ page. Enter a comment in the field displayed to enable the Reject option.



5. The application asks the user to verify themselves by entering the username and password.

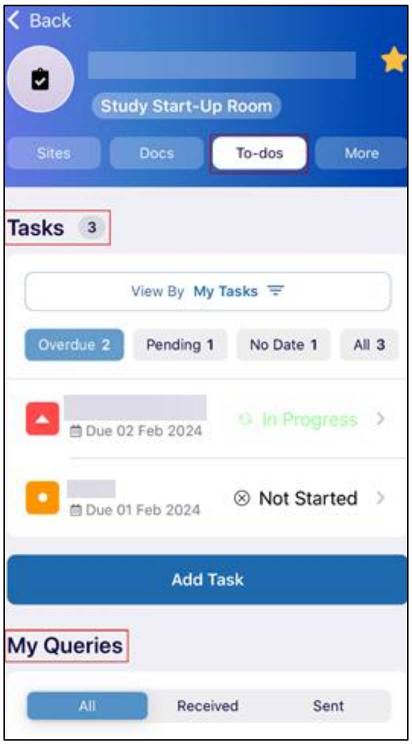
6. Click the **Confirm** button.



7. A notification ‘Document is rejected’ is displayed on the screen.

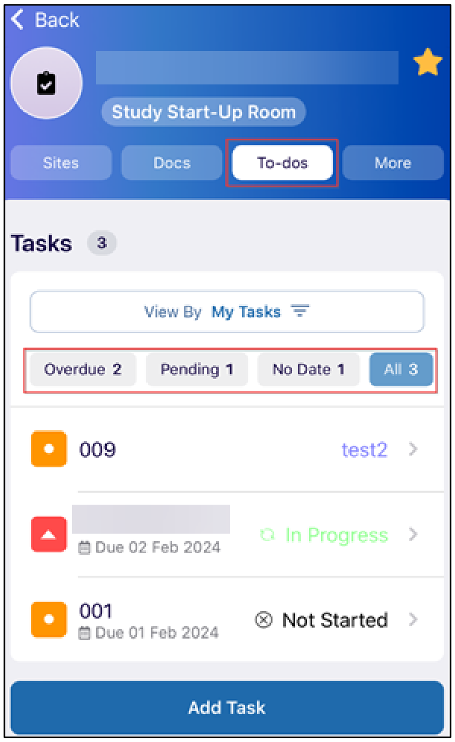
To-dos

The To-dos tab displays the Tasks and Queries assigned to the user.



Tasks

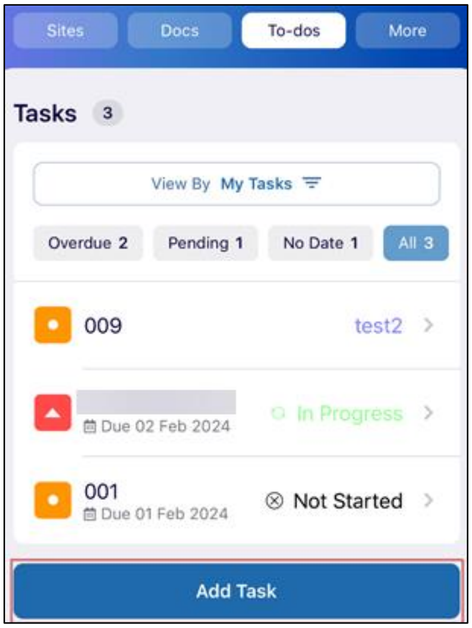
This tab displays the tasks assigned to the user. The user can select the options displayed to view details of the tasks assigned. Click a task to view its details.



Add Task

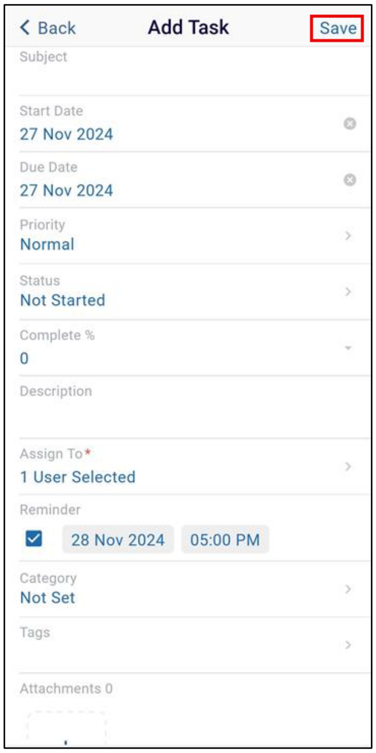
To add a task, follow the steps below.

1. Click on the Add Task button under the Tasks section.



2. On the Add Task screen, add the following details into their respective fields.
    a. Subject
    b. Start Date
    c. Due Date
    d. Priority
    e. Complete %
    f. Description
    g. Assign To*
    h. Reminder
    i. Category
    j. Tags
    k. Attachment

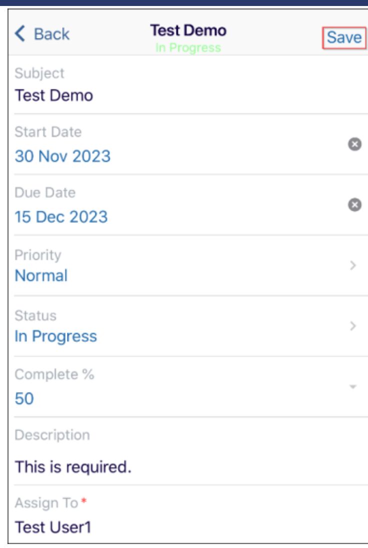
3. Once the required details are added, click on the **Save** button.



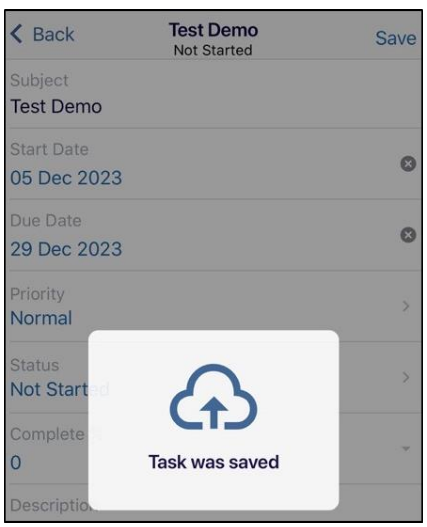
Edit Task

To edit a task, follow the steps below.

1. Select a task to edit under the Tasks section.
2. Make the required changes to the task and click on the **Save** button.

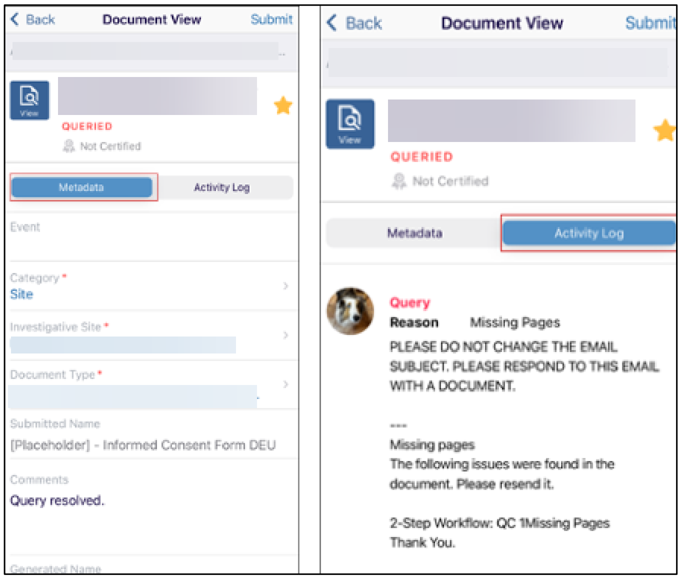


3. The success notification is displayed once the task is successfully saved.



My Queries

This tab displays the queries assigned to the user. The document can be viewed by clicking the View or magnifying glass icon displayed in the top left corner. The user can view the Metadata and the Activity Log on this page.

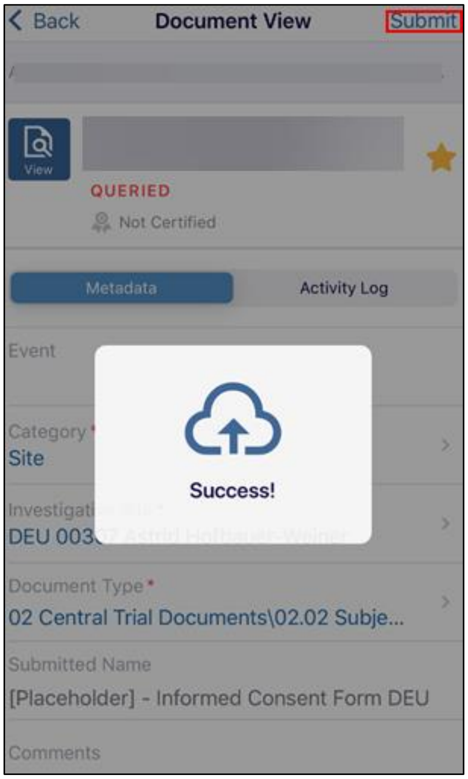


Note: Additionally, users can add a response and update the document image as well. Refer to the Room Documents description detailed in the Docs section.

Edit the query

To edit the query, follow the steps below.

1. Select the Metadata tab and make the required edits
2. Add Response by clicking on the Add Response button.
3. Change the document image by clicking on the Update Document Image
4. Click on the Submit button once all the changes are done.
5. Once the changes are saved, the success notification is displayed.

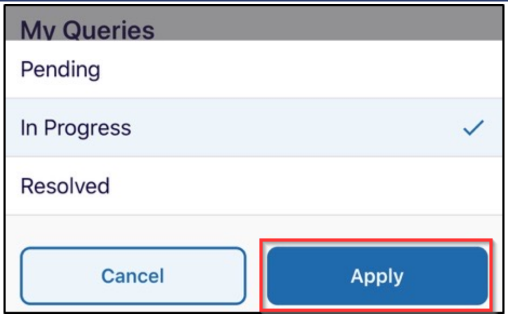


Apply Filters

To apply filters to the queries section, follow the steps below.

1. Toggle between the Received and Sent tabs and click on the Pending filter.

2. Select the required options and click on the Apply button.

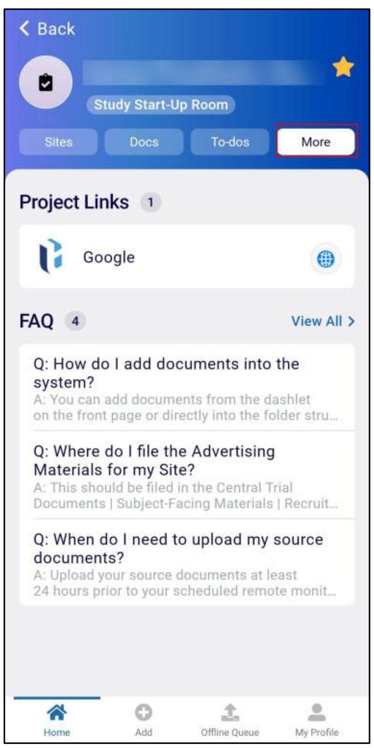


More

The More tab displays the Project Links and FAQs related to the application.

- **Project Links**: The Project Links section displays all the links associated with the project. Click on a project link to redirect to the required web address.

- **FAQ**: The FAQ section displays a list of the frequently answered questions. Click on the View All button to view the entire list of FAQs.



Collaborate room

The Collaborate room has a similar user interface to eTMF. Refer to Chapter 6 Trial Interactive Rooms section, for the features and functionalities.

CHAPTER 7. GLOBALLEARN

The GlobalLearn integrated application page displays all the courses assigned to the user.

My Courses

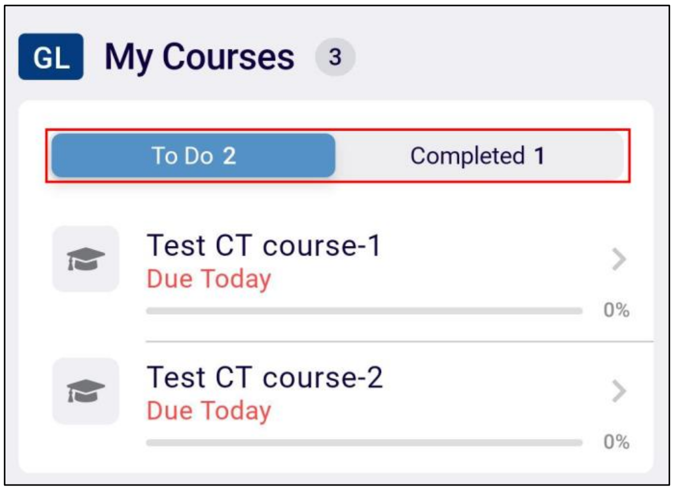
The My Courses section displays pending and completed courses by the user.

To-Do

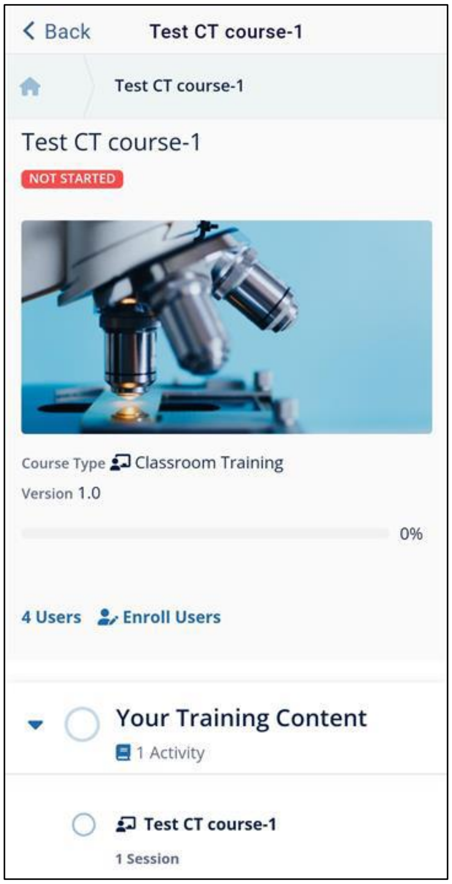
The To-Do tab displays the courses that are yet to be completed by the user.

To complete a particular course, follow the steps below.

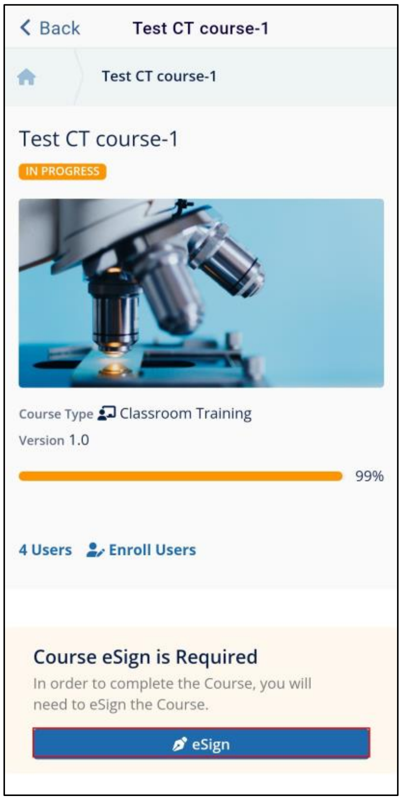
1. Click on the To-Do tab and select the course to complete.



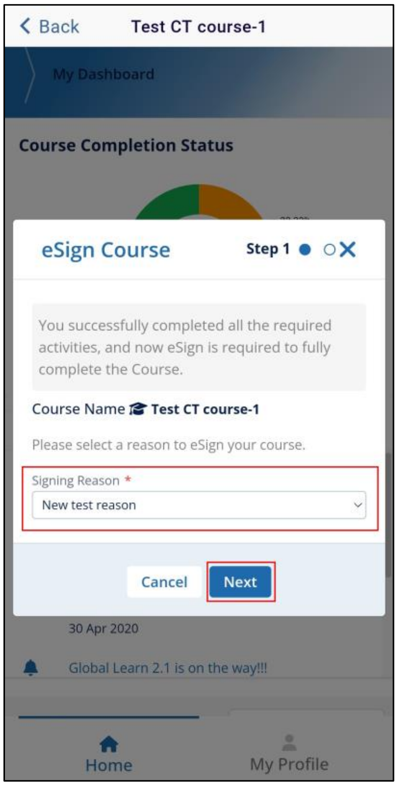
2. The course screen displays the training content assigned to the user. Click on the section to complete the activities within it.
3. Complete all the activities with the course.



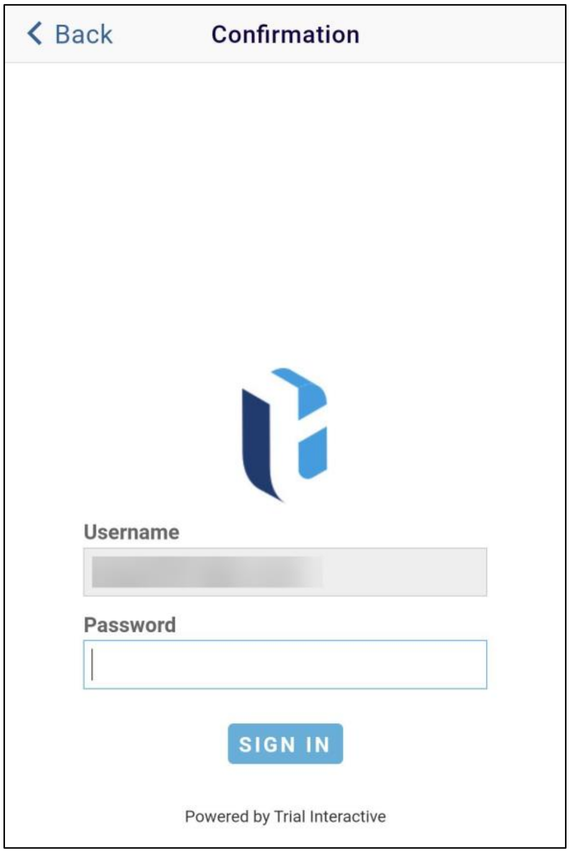
4. Once the course is completed, users are prompted to electronically sign the course.
5. Click on the eSign button.



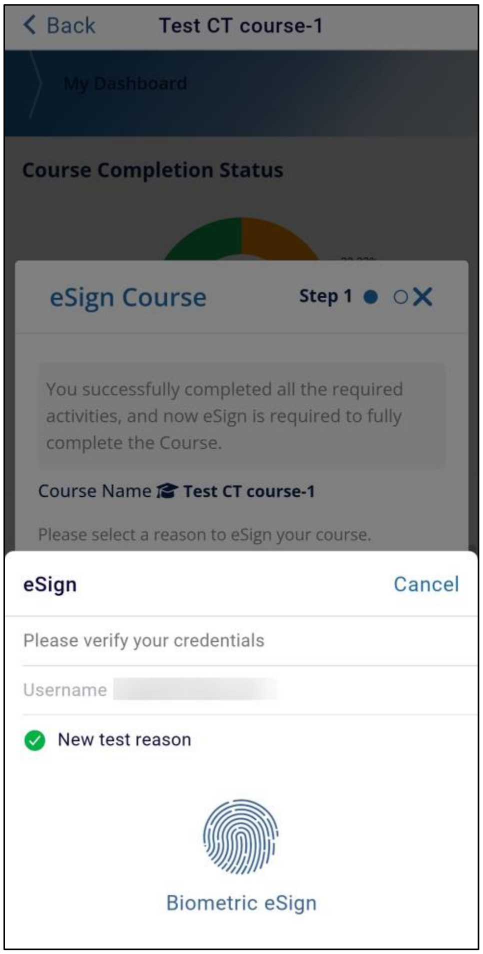
6. On the eSign Course popup, mandatorily add a signing reason by accessing the dropdown options and click on the **Next** button.



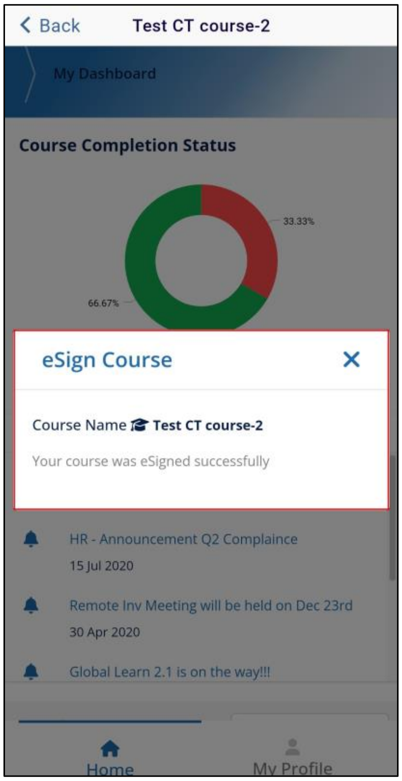
7. Users can complete the eSignature either manually or using the biometrics. If the biometrics setting is disabled, enter the Username and Password on the Confirmation screen and click on the **SIGN IN** button.



8. If the Biometrics setting is enabled, the ESign screen prompts the user to scan the fingerprint and complete the eSignature process.



9. A success notification appears once the eSignature process is complete.



Completed Courses

To view the completed courses, follow the steps below.

1. Click on the Completed tab to view all the completed courses.

2. The completed courses display a green progress bar with the completion percentage.