

ECOS User Guide: Monitoring Module

What the ECOS Monitoring Module is All About

ECOS (Ethics and Compliance Online System)

- Replacing ROAM and NHG Monitoring Platform and iSHaRe
- Allows both intranet and internet access

Monitoring module

- One of the modules within ECOS system
- Allows the monitoring process workflow to be carried out by the relevant individuals involved in the monitoring of the research.
 - Visit planning/confirmation
 - Monitoring Plan
 - Monitoring Report
 - Monitoring observations and follow-up
 - Generation of reports to retrieve monitoring activities

Contents

Monitoring User Guide for:

Principal Investigator (PI) / Site Principal Investigator (Site PI)/ Co-Investigator (Co-I) and Study Team Member (STM)

1. Monitoring Module General Interface
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3. How to View and Access Study Monitoring Information
4. How to Query and Endorse Monitoring Plan (MP)
5. How to Respond to Issue
6. How to View/ Reply to CAPA Query
7. How to View/Edit/Submit Study Closure Checklist (SCC)
8. How to Export the Monitoring Report/ Letters/ Issue List

1) Monitoring Module General Interface - Columns

The screenshot displays the ECOS Monitoring Module General Interface. The top navigation bar includes the ECOS logo, 'My Tasks', and user profile icons. The left sidebar contains navigation options: Homepage, Dashboard, My Tasks (highlighted with a red box), My Notices, IRB, CRMS, Compliance, Monitoring, FCOI, SDB, and Report. The main content area features summary cards for IRB (0), CRMS (0), FCOI (0), Monitoring (1, highlighted with a red box), and Compliance (0). Below these cards are summary rows for 'Responsible Person (0)', 'Plan Reviewer (0)', and 'PI/Site PI (1)'. A 'Columns' dialog box is open, showing a list of columns with checkboxes and drag handles. The dialog includes a search bar, a 'Select All' checkbox, and a list of columns: Form Type, ECOS Ref, SCC Form Ref No., Form Status, Monitor Name, PI/Site PI, Date Sent to PI, and Task Status. The 'Columns' button in the main interface is highlighted with a red box and a '1' callout. The 'Save' button in the dialog is highlighted with a red box and a '2' callout. The 'Clear' button in the dialog is highlighted with a red box and a '3' callout. The 'Responsible Person' column in the summary row is highlighted with a red box and a '4' callout.

NOTE: This screenshot was taken by using PI's account.

1. Click on “Columns” to change the layout of information presented.
2. You can adjust the columns display order by pulling the display information up and down and click on “Save”.
3. To reset the columns to its default view, click on “Clear”
4. Study tasks are listed accordingly to the user's assigned role. Tab/ tasks shown here may vary across the users.

1) Monitoring Module General Interface – Export Listing

The screenshot shows the ECOS 'My Tasks' interface. The 'Monitoring' tab is selected and highlighted with a red box, showing a count of 1. Below it, the 'PI/Site PI' count is also highlighted with a red box. The 'Export' button is highlighted with a red box and labeled with a green '1'. A dropdown menu is open, showing 'Download Original' and 'Safe Download (PDF)' options, with a green '2' next to it. A table below shows a single entry for 'Study Closure Checklist'.

| Form Type | ECOS Ref | SCC Form Ref No. | Form Status | Monitor Name | PI/Site PI | Date Sent to | Action |
|-------------------------|-----------|--------------------------------------|-------------|----------------------|--------------------|--------------|--------|
| Study Closure Checklist | 2024-3646 | 2024-3646-Tan Tock Seng Hospital-SCC | Draft | A/Prof TTSH_Monitor1 | A/Prof TTSH_NewPI3 | 11-Nov-2024 | 👁 |

1. You can export the listing you are viewing by clicking on “Export”.
2. Select “Download Original” as an Excel file or “Safe Download” as PDF file.

| Form Type | ECOS Ref | SCC Form Ref No. | Form Status | Monitor Name | PI/Site PI | Date Sent to PI | Task Stat |
|-------------------------|-----------|----------------------------------|-------------|----------------------|--------------------|-----------------|-----------|
| Study Closure Checklist | 2024-3646 | 2024-3646-Tan Tock Seng HosDraft | | A/Prof TTSH_Monitor1 | A/Prof TTSH_NewPI3 | 11-Nov-2024 | Pending |

1) Monitoring Module General Interface – Filter

The screenshot displays the ECOS Monitoring Module General Interface. The top navigation bar includes the ECOS logo, 'My Tasks', and user profile icons. The left sidebar contains navigation options: Homepage, Dashboard, My Tasks (highlighted with a red box), My Notices, IRB, CRMS, Compliance, Monitoring, FCOI, SDB, and Report. The main content area shows a dashboard with five categories: IRB (0), CRMS (0), FCOI (0), Monitoring (1, highlighted with a red box), and Compliance (0). Below this, there are counts for 'Responsible Person (0)', 'Plan Reviewer (0)', and 'PI/Site PI (1)'. A table lists monitoring tasks with columns for Form Type, ECOS Ref, SCC Form Ref No., Form Status, and Monitor Name. A 'Filter' dialog box is open, showing fields for ECOS Ref, Task Due date, Monitor Name, PI/Site-PI, Date Sent to Site, and Task Status. The 'Task Status' dropdown is set to 'Pending'. The dialog box has 'Reset' and 'Search' buttons at the bottom, and a 'Filter' button on the right side of the main interface.

| Form Type | ECOS Ref | SCC Form Ref No. | Form Status | Monitor Name |
|-------------------------|-----------|--------------------------------------|-------------|---------------|
| Study Closure Checklist | 2024-3646 | 2024-3646-Tan Tock Seng Hospital-SCC | Draft | A/Prof TTSH_M |

1. Click on “Filter” to tailor the listing you wish to view.

2. The default settings for the filter show only **pending** tasks for your action (**Task Status = Pending**). To reset to default filter settings, click on “Reset”.

3. After selecting the parameters to filter, click on “Search”.


Note: To view all assigned tasks (including completed tasks), ensure all filters are cleared.

2) Locate your Monitoring task – via Homepage

The screenshot shows the ECOS system interface. The top navigation bar is labeled "ECOS" and "Dashboard". The left navigation panel has "Dashboard" highlighted with a red box and a green "1". The main content area shows three summary cards: "IRB" (0), "CRMS" (0), and "FCOI" (0). Below these are "Monitoring" (0) and "Compliance" (0) cards. The "Monitoring" card is highlighted with a red box and a green "2". A second screenshot below shows the "My Tasks" page. The "My Tasks" header is highlighted with a red box and a green "3". The "Monitoring" tile is highlighted with a red box and a green "4". The sub-header "PI/Site PI (1)" is highlighted with a red box and a green "5". The "View" button for the task is highlighted with a red box and a green "6".

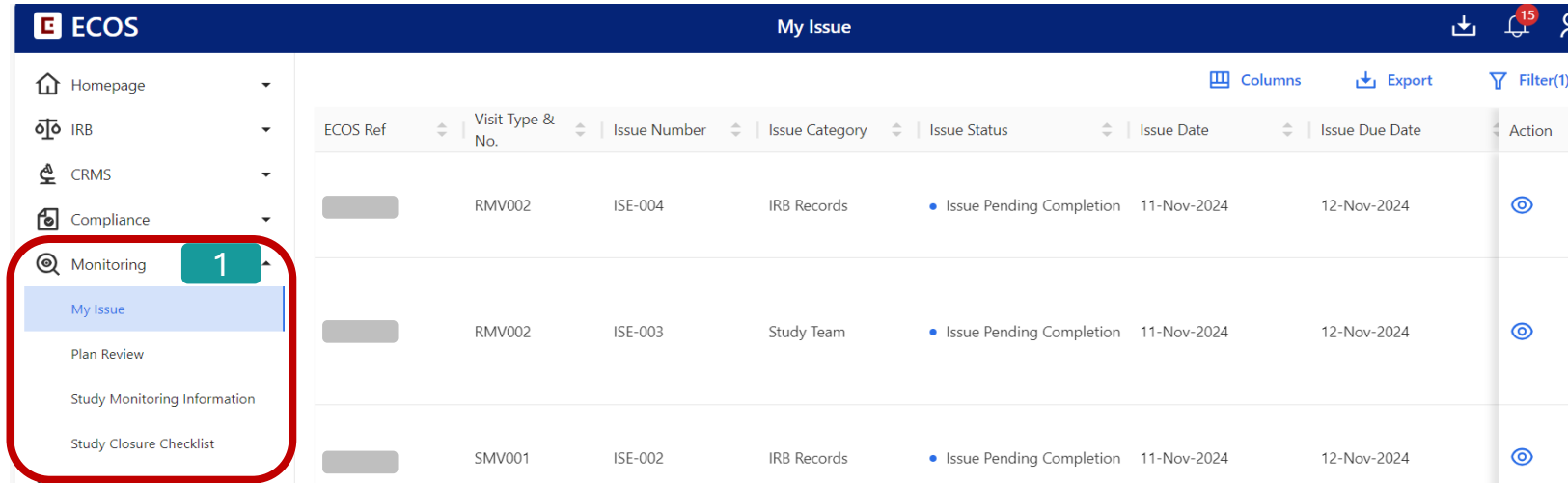
| Form Type | ECOS Ref | SCC Form Ref No. | Form Status | Monitor Name | PI/Site PI | Date Sent |
|-------------------------|-----------|--------------------------------------|-------------|----------------------|--------------------|-------------|
| Study Closure Checklist | 2024-3646 | 2024-3646-Tan Tock Seng Hospital-SCC | Draft | A/Prof TTSH_Monitor1 | A/Prof TTSH_NewPI3 | 11-Nov-2024 |

Via Homepage > Dashboard

1. You can locate your outstanding monitoring task via “Homepage” > “Dashboard” on the left navigation panel.
2. Locate the “Monitoring” tile and click on “Monitoring”. It will lead you to “My Tasks”.
3. You can also access “Homepage” > “My Task” via the left navigation panel.
4. Click on the “Monitoring” tile.
5. The type and number of outstanding tasks are listed under the different sub-headers based on the user’s role. Click on the sub-header to reveal the listing.
6. To view the monitoring task, click on  under the “Action” column.

2) Locate your monitoring task – via Monitoring Module

Via Monitoring >



| ECOS Ref | Visit Type & No. | Issue Number | Issue Category | Issue Status | Issue Date | Issue Due Date | Action |
|----------|------------------|--------------|----------------|----------------------------|-------------|----------------|--------|
| | RMV002 | ISE-004 | IRB Records | • Issue Pending Completion | 11-Nov-2024 | 12-Nov-2024 | 👁 |
| | RMV002 | ISE-003 | Study Team | • Issue Pending Completion | 11-Nov-2024 | 12-Nov-2024 | 👁 |
| | SMV001 | ISE-002 | IRB Records | • Issue Pending Completion | 11-Nov-2024 | 12-Nov-2024 | 👁 |

1. You can also locate **all assigned monitoring tasks** via “**Monitoring**” on the left navigation panel. Expand the menu to view the various task types.

- “**My Issue**” > As the assigned “**Responsible Person**”, you will see all the **site issues pending** your response to the Monitor.
- “**Plan Review**” > The “**Plan Reviewer**” will see all **Monitoring Plans (MP) pending endorsements**. For NHG **Monitoring Programme for HBR study**, the **PI** is assigned as the Plan Reviewer.
- “**Study Monitoring Information**” > you will be able to **access all monitoring information** (e.g. view monitoring plan, monitoring reports, issues list, confirmation and follow-up letters).
- “**Study Closure Checklist (SCC)**” > you will be able to **draft/ submit** the SCC.

Note: The **PI, Co-I** and active **Study Team Member (STM)** listed in **Clinical Research Management System User Authorization List (CRMS UAL)** can **view and edit** the SCC.

By default, only the **PI** can submit the form.

3) View and Access Your Study Monitoring Information

The screenshot shows the ECOS interface for 'Study Monitoring Information'. The left sidebar contains navigation options: Homepage, IRB, CRMS, Compliance, Monitoring, My Issue, Plan Review, and Study Monitoring Information (highlighted with a red box and a green circle with '1'). The main content area displays a table with columns: Monitoring Category, ECOS Ref, Study Site, PI/Site-PI, Current Study Site Status, and Action. The table contains four rows of data for 'NHG 3A' at 'Khoo Teck Puat Hospital' with PI 'A/Prof KTPH_PI3'. The 'Action' column for the bottom row has a red box around the 'View Plan' icon (a target symbol) and a green circle with '2'.

| Monitoring Category | ECOS Ref | Study Site | PI/Site-PI | Current Study Site Status | Action |
|---------------------|-----------|-------------------------|-----------------|--|--------|
| NHG 3A | | Khoo Teck Puat Hospital | A/Prof KTPH_PI3 | • Ongoing (Last Participa Last Visit Completed, Onl Data Analysis Ongoing) | |
| NHG 3A | 2024-3645 | Khoo Teck Puat Hospital | A/Prof KTPH_PI3 | • Ongoing with active enrolment | |
| NHG 3A | 2024-3645 | Khoo Teck Puat Hospital | A/Prof KTPH_PI3 | • Ongoing with active enrolment | |
| NHG 3A | 2024-3644 | Khoo Teck Puat Hospital | A/Prof KTPH_PI3 | • Ongoing (Last Participa Last Visit Completed, Onl Data Analysis Ongoing) | |

Via Monitoring > Study Monitoring Information

1. This page is accessible by **Site Staff**(with some pages restricted to specific site staff, e.g. **Monitoring Plan (MP) review is only accessible by PI.**)
2. Click on **“View Plan”** to enter **“View Monitoring Plan”** page.

3) View and Access Your Study Monitoring Information

The screenshot displays a web application interface for viewing and accessing study monitoring information. The interface is divided into several sections:

- Navigation Bar:** A dark blue bar at the top contains a home icon, a menu icon, and a back button labeled "Back to Study Monitoring Information". A red box highlights the "View Monitoring Plan" button, with a green circle labeled "1" next to it.
- Document Header:** Below the navigation bar, the document title is "2024-3721 | Tan Tock Seng Hospital" with a "Draft" status. The ECOS Ref is "2024-3721".
- Monitoring Plan Viewer:** A light gray area contains the "Monitoring Plan" document. A red box highlights the "Export" button, with a green circle labeled "2" next to it. The document content includes a table with the following data:

| MONITORING PLAN | |
|-------------------------------------|--|
| Title of Research Study | Study 22 |
| Principal Investigator | A/Prof TTSH_PI4 |
| Department & Institution | General Medicine, Tan Tock Seng Hospital |
| Target Recruitment | As per IRB Application Form |
| Applicable Regulations | The site will be conducting the study in accordance to the regulations and SOP(s): |
- Download List:** A pop-up window at the bottom right shows a list of files. A red box highlights the "Download List (1)" header, with a green circle labeled "3" next to it. The list contains one file: "MOB005-11Nov2024_NHG-Monitoring-Plan_18-Nov-2024 10:51:43.pdf" (151.90 KB). A red box highlights the "Download To Local" button, with a green circle labeled "4" next to it.

1. PI/Site PI may view their respective site's Monitoring Plan.
2. To export a copy of the Monitoring Plan, click on "Export".
3. The "Download List" will appear at the bottom of the browser.
4. When the export is complete, click "Download To Local". The PDF copy of the form will be saved to your computer local drive.

3) View and Access Your Study Monitoring Information

ECOS Study Monitoring Information

| Monitoring Category | ECOS Ref | Study Site | PI/Site-PI | Current Study Site Status | Action |
|---------------------|-----------|-------------------------|-----------------|---|--------|
| NHG 3A | | Khoo Teck Puat Hospital | A/Prof KTPH_P13 | • Ongoing (Last Participa Last Visit Completed, Only Data Analysis Ongoing) | |
| NHG 3A | 2024-3645 | Khoo Teck Puat Hospital | A/Prof KTPH_P13 | • Ongoing with active enrolment | |
| NHG 3A | 2024-3645 | Khoo Teck Puat Hospital | A/Prof KTPH_P13 | • Ongoing with active enrolment | |
| NHG 3A | 2024-3644 | Khoo Teck Puat Hospital | A/Prof KTPH_P13 | • Ongoing (Last Participa Last Visit Completed, Only Data Analysis Ongoing) | |

Via Monitoring > Study Monitoring Information

5. You can also click on “View Schedule” to enter **Monitoring Schedule Detail** page to view the monitoring information of the study.
6. In the “**Monitoring Schedule Detail**” page under the left navigation panel, you can view the past monitoring reports, issue list, confirmation and follow-up letters according to the monitoring visits type (e.g. Site Monitoring Visit, Remote Monitoring Visit).

Monitoring Schedule Detail

2024-3720 | Khoo Teck Puat Hospital

Study Site: Khoo Teck Puat Hospital PI/Site-PI: A/Prof KTPH_P13 Monitor: A/Prof KTPH_Monitor1

Current Study Site Status: Ongoing with active enrolment

Study Title: Study 21

Quick Link: [Study Summary](#), [CRMS](#)

- SIV001 Completed
 - Plan Visit
 - Confirmation Letter
 - Monitoring Report
 - Issue List
 - Follow-up Letter
- RMV001 Completed
 - Plan Visit
 - Confirmation Letter
 - Monitoring Report

Plan Visit Saved at 19-Nov-2024 01:10

* Planned Start Date ~ Planned End Date:
19-Nov-2024 → 19-Nov-2024

Venue:
Please enter

Visit Agenda:
Please enter

Remarks:

4) How to Query and Endorse the Monitoring Plan (MP)

The screenshot shows the ECOS Dashboard with the following data:

| Category | Count |
|------------|-------|
| IRB | 2 |
| CRMS | 0 |
| FCOI | 0 |
| Monitoring | 1 |
| Compliance | 0 |
| Audit | 0 |

The 'Monitoring' tile is expanded to show:

| Task | Count |
|--------------------|-------|
| PI/Site-PI | 0 |
| Plan Reviewer | 1 |
| Responsible Person | 0 |

The 'My Tasks' view shows a table with the following data:

| Form Type | ECOS Ref | Plan Status | Monitor Name | PI/Site-PI | Date Sent to Reviewer | Action |
|-----------------|----------|----------------|----------------------|--------------------|-----------------------|--------|
| Monitoring Plan | | Pending Review | A/Prof TTSH_Monitor1 | A/Prof TTSH_NewPI7 | 18-Nov-2024 | View |

Red boxes and numbers 1, 2, and 3 highlight the 'Dashboard' menu item, the 'Plan Reviewer' task, and the 'View' button respectively.

Only assigned “Plan Reviewer” will be able to access the task. For NHG Monitoring Programme for HBR study, the PI is assigned as the Plan Reviewer.

Via Dashboard > My Tasks


1. The Plan Reviewer can locate all assigned MPs for review via “Dashboard”
2. Locate the “Monitoring” tile, click on “Plan Reviewer” and you will enter “My Tasks” > “Plan Reviewer” page.
3. Click on “View” button under the “Action” column to view the Issue Details.

4) How to Query and Endorse the Monitoring Plan (MP)

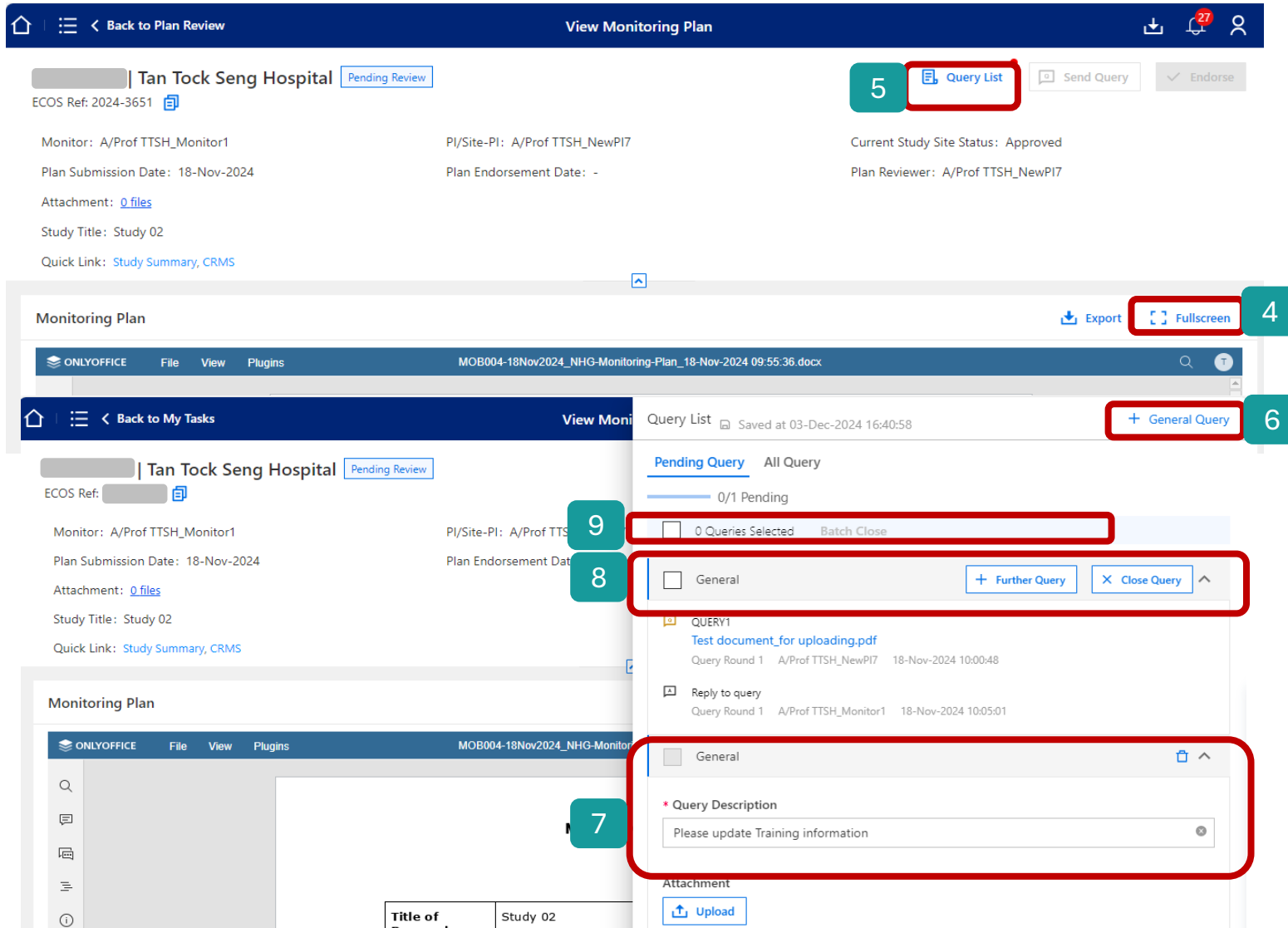
The screenshot shows the ECOS Plan Review interface. On the left is a navigation menu with 'Plan Review' highlighted and annotated with a red box and the number '1'. The main area displays a table of monitoring plans. The table has columns for Monitoring Category, ECOS Ref, Study Site, PI/Site-PI, Current Status, Monitor, Plan Reviewer, Monitoring Plan Status, and Action. A row is visible with 'Monitoring Plan Status' set to 'Pending Review', annotated with a red box and the number '2'. The 'Action' column for this row contains a 'View' icon (a blue circle with a white eye), annotated with a red box and the number '3'.

| Monitoring Category | ECOS Ref | Study Site | PI/Site-PI | Current Status | Monitor | Plan Reviewer | Monitoring Plan Status | Action |
|---------------------|----------|------------------------|--------------------|----------------|----------------------|--------------------|------------------------|--------|
| NHG 3A | 2 | Tan Tock Seng Hospital | A/Prof TTSH_NewPI7 | Approved | A/Prof TTSH_Monitor1 | A/Prof TTSH_NewPI7 | Pending Review | View |

Via Monitoring > Plan Review

1. You can also locate the list of MPs for review via the Monitoring Module > “**Plan Review**” sub-header.
2. By default, you will see tasks which are pending your action (**Monitoring Plan Status = Pending Review/ Query Pending Reply**).
3. Click on  “**View**” button under the “**Action**” column to view the **Monitoring Plan**.

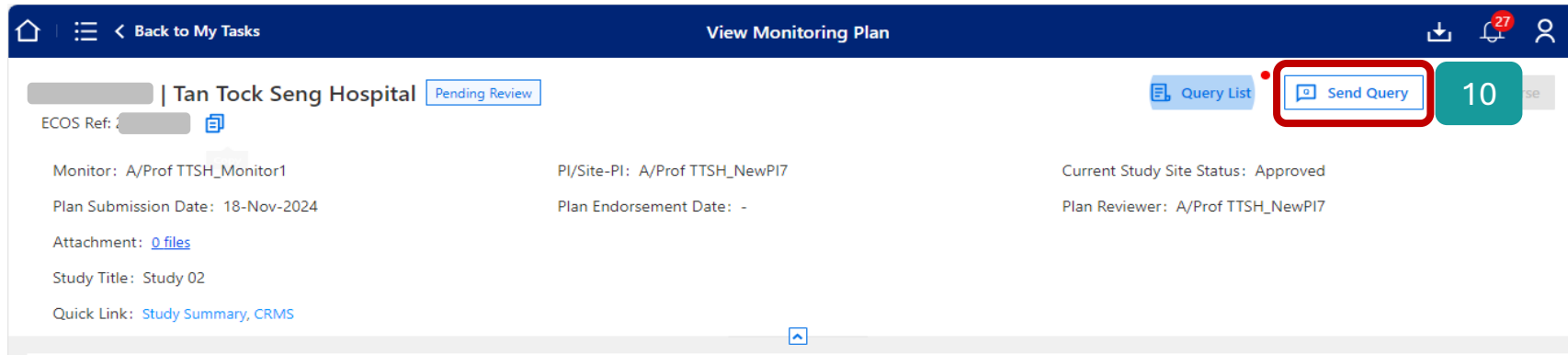
4) How to Query and Endorse the Monitoring Plan (MP)



4. Click on “Fullscreen” to expand the Monitoring Plan for easy viewing.
5. After reviewing the MP, the Plan Reviewer may **query** the Monitor. To query, click on the “Query List”. A **red dot** indicates that there is an action pending (i.e. to send the query).
6. A sliding window will appear, where you can add/ close the query(ies). Click on “+ General Query” to add a query.
7. Enter **query description**. You can upload an **attachment** if needed. Query description will be **auto-saved**.
8. To close a query, click on “X Close Query” or to re-query on a previous query, click on “+ Further Query”.
9. To close query in batches, check the query box and click on “Batch Close”.

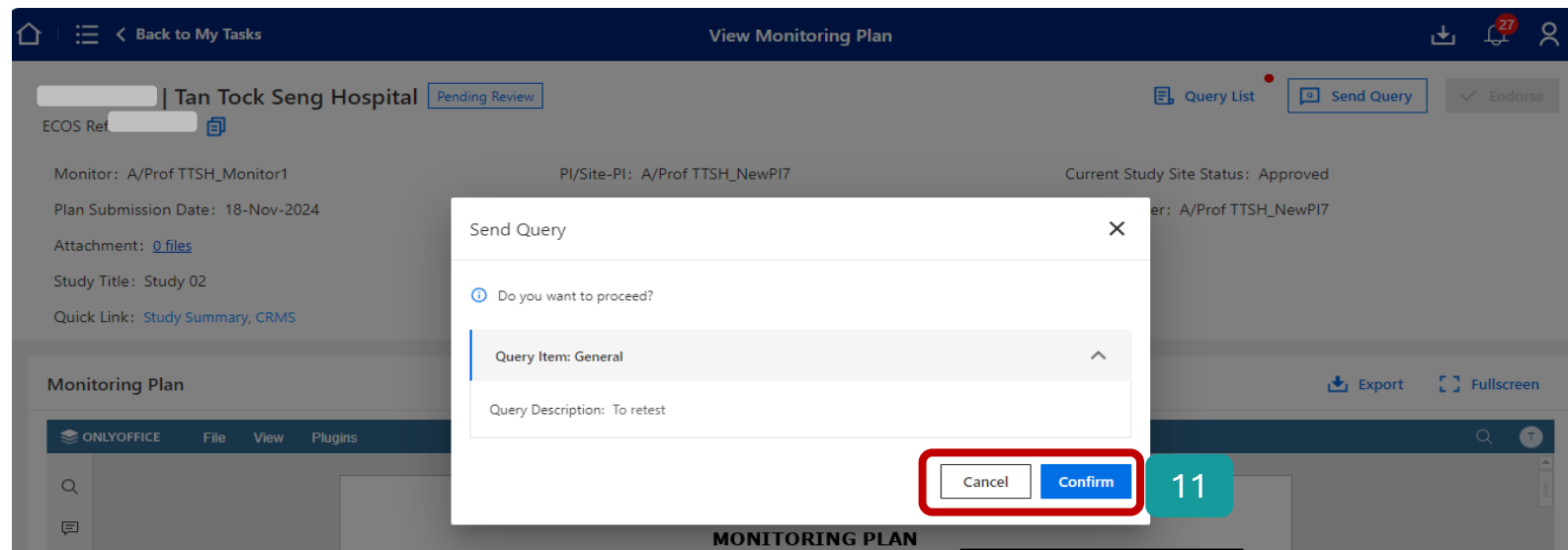
Click on the background page to close the query sliding window.

4) How to Query and Endorse the Monitoring Plan (MP)

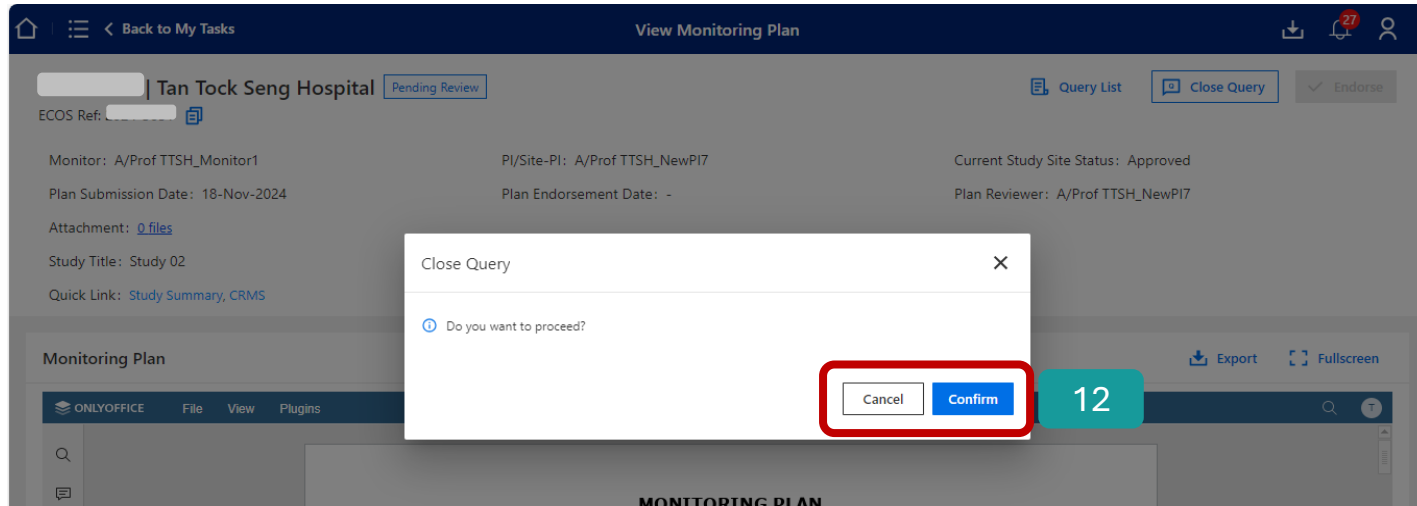


10. If there are outstanding query(ies) to the Monitor, the “Send Query” button will be activated. Click on “Send Query”.

11. A pop-up window with a list of query(ies) to be sent will be shown. Click “Confirm” to send the query or “Cancel” to return to the previous page.

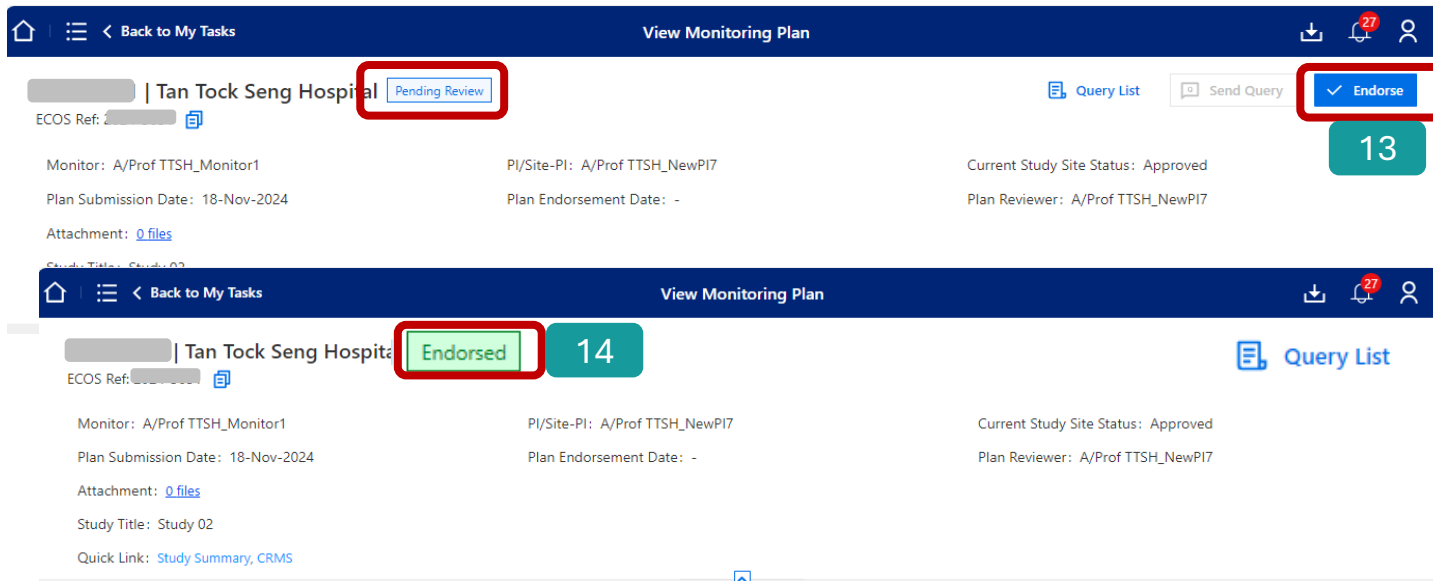


4) How to Query and Endorse the Monitoring Plan (MP)



12. The MP can only be endorsed if there is **no** outstanding query. After all query has been closed, a pop-up window to confirm the action will be shown. Click on **“Confirm”** to proceed or **“Cancel”** to return to the previous page.

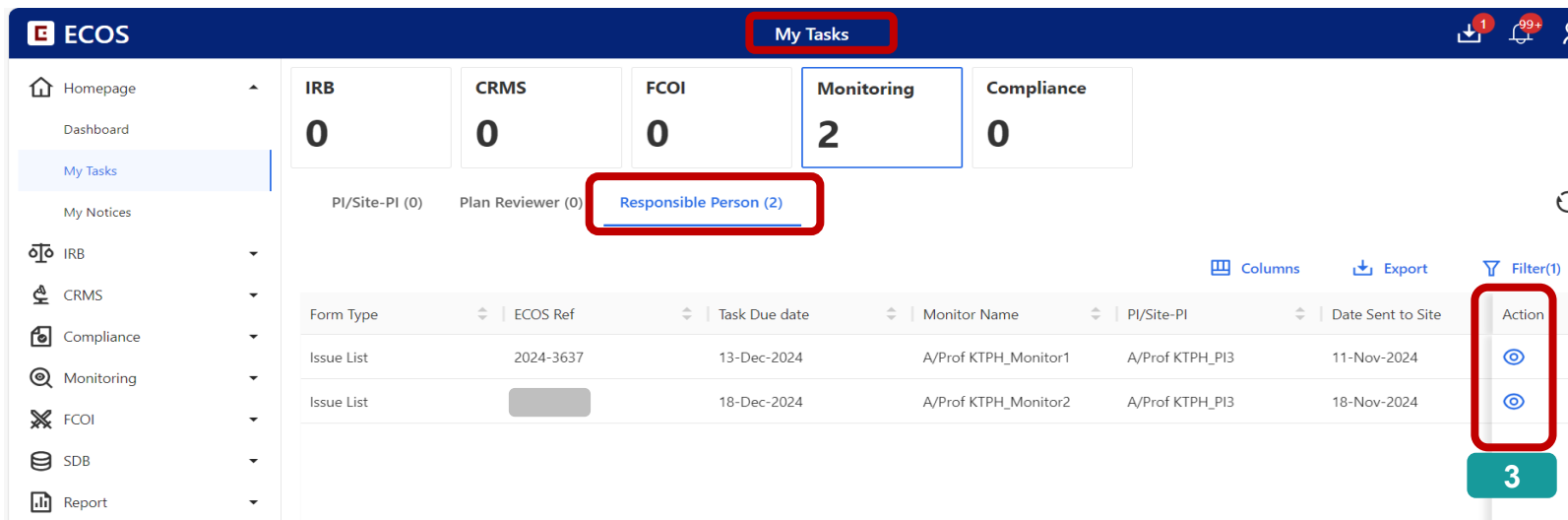
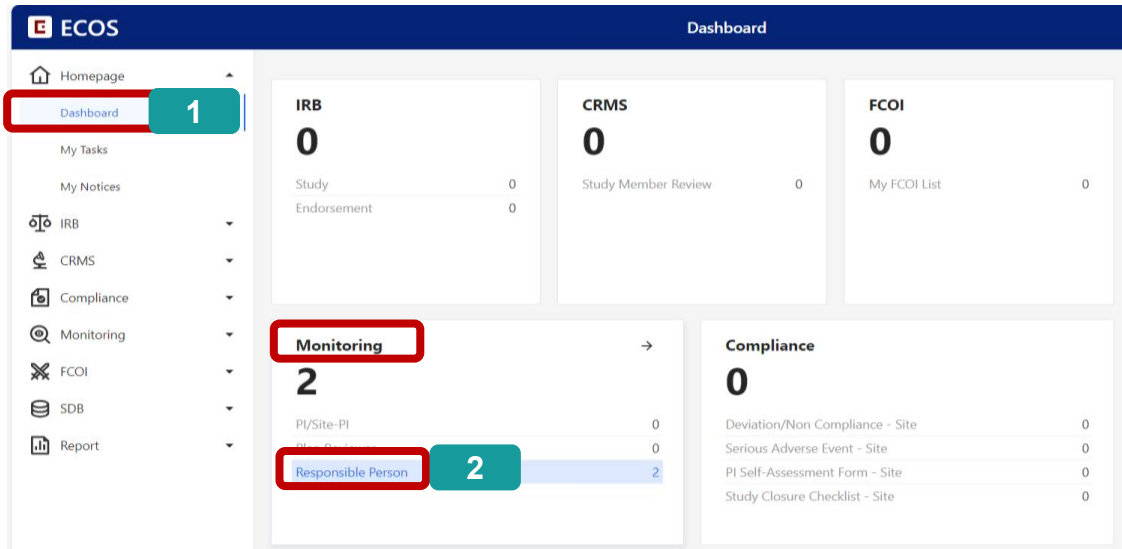
13. To proceed to endorse the MP, click on the **“Endorse”** button.



14. The MP status will be changed to **“Endorsed”**.

An email notification will be triggered to notify the Monitor of the endorsement.

5) How to Respond to Issue




Note: **Site issues** noted during the Monitoring visit that require resolution will be assigned to the **“Responsible Person”** by the Monitor.

Via Dashboard > My Tasks

1. The Responsible Person can locate all assigned Issues via **“Dashboard”**

2. Locate the **“Monitoring”** tile, click on **“Responsible Person”** and you will enter **“My Tasks” > “Responsible Person”** page.

3. Click on  **“View”** button under the **“Action”** column to view the Issue Details.

5) How to Respond to Issue

Via Monitoring > My Issue

The screenshot displays the ECOS 'My Issue' interface. On the left, a navigation menu has 'My Issue' highlighted with a red box and a green '1'. The main area shows a table of issues with columns: ECOS Ref, Visit Type & No., Issue Number, Issue Category, Issue Status, Issue Date, Issue Due Date, and Action. The 'Issue Status' column is circled in red with a green '2'. The 'Issue Due Date' column is circled in red with a green '3'. The 'Action' column contains 'View' icons, with one circled in red and a green '4'. A green arrow points from this icon to the 'Issue Detail' page below. The 'Issue Detail' page has a red box around the 'Issue Detail' header with a green '5'. The page shows monitoring information and issue details for ISE-002.

| ECOS Ref | Visit Type & No. | Issue Number | Issue Category | Issue Status | Issue Date | Issue Due Date | Action |
|------------|------------------|--------------|----------------|--------------------------|-------------|----------------|--------|
| [Redacted] | RMV002 | ISE-004 | IRB Records | Issue Pending Completion | 11-Nov-2024 | 12-Nov-2024 | View |
| [Redacted] | RMV002 | ISE-003 | Study Team | Issue Pending Completion | 11-Nov-2024 | 12-Nov-2024 | View |
| [Redacted] | SMV001 | ISE-002 | IRB Records | Issue Pending Completion | 11-Nov-2024 | 12-Nov-2024 | View |

| Monitoring Information | | |
|---------------------------------|-----------------------------|------------------------------------|
| Study Title: Study 18 | PI/Site-PI: A/Prof TTSH_P14 | Study Site: Tan Tock Seng Hospital |
| ECOS Ref: [Redacted] | Monitoring Category: NHG 3A | Monitor: A/Prof TTSH_Monitor1 |
| Visit Type & No.: Ad-Hoc RMV001 | | |

| Issue Information | | |
|--|---|---|
| Issue Item I1.1 | Issue Category Other Study Supplies | Issue Description Device prototype not available |
| Issue Date 17-Nov-2024 | Issue Due Date 24-Nov-2024 | Issue Closure Date |
| Responsible Person A/Prof TTSH_P14, Dr TTSH_C1 | CAPA Needed Yes | Recommendation TTSH_C1 to ensure that device prototype is available |
| Monitor Comment | | |

1. You can also locate the issue listings via the Monitoring Module > “My Issue” sub-header.

2. By default, you will see tasks which are pending your action (Issue Status = Issue Pending Completion/ Query Pending Reply).

3. The list is sorted by Issue Due Date (newest to oldest).

4. Click on “View” button under the “Action” column to view the Issue Details.

5. In the “Issue Detail” page, you can see the details of the monitoring observations which require a **Corrective Action and Preventive Action (CAPA)** plan from the PI/study team.

5) How to Respond to Issue

ISE-010 Issue Pending Completion 4 Submit

Monitoring Information

Study Title: Study 04
ECOS Ref: 2024-3637
Visit Type & No.: SMV001
PI/Site-PI: A/Prof KTPH_P13
Monitoring Category: NHG 3A
Study Site: Khoo Teck Puat Hospital
Monitor: A/Prof KTPH_Monitor1

Issue Information Track Changes

| Issue Item | Issue Category | Issue Description |
|--|------------------|-------------------|
| H1.1 Had there been any Unanticipated Problems Involving Risks To Subjects or Others (UPIRTSO) or Serious Adverse Events (SAE) that had occurred since the last onsite/ remote monitoring? | Safety Reporting | Please confirm |

| Issue Date | Issue Due Date | Issue Closure Date |
|-------------|----------------|--------------------|
| 08-Nov-2024 | 13-Dec-2024 | |

| Responsible Person | CAPA Needed | Recommendation |
|--------------------|-------------|----------------|
| A/Prof KTPH_P13 | Yes | |

Monitor Comment

Corrective Action Preventive Action 1 Edit

Root Cause

Corrective Action Preventive Action 3 Cancel Save Save and Exit

2 Corrective Actions 0 characters entered

Preventive Actions 0 characters entered

CAPA Completion Date: Select date Attachment Upload

ISE-008 Issue Pending Completion

Only assigned **Responsible Person** can edit the “**Issue Detail**” page. The PI, Co-I and active Study Team Member (STM) listed in Clinical Research Management System User Authorization List (CRMS UAL) can be assigned as the “**Responsible person**” to respond to the Issue.

1. Click “**Edit**” to complete the CAPA.
2. Fields marked with * are **mandatory** for completion.
3. Click on “**Save**” to ensure the edits have been saved successfully. After the form has been saved, click on “**Save and Exit**” to exit editing mode.
4. The “**Submit**” button will be enabled. Click on the “**Submit**” button to proceed.
5. A **confirmation pop-up window** will appear. Click “**confirm**” to proceed.

5 ECOS ×

Do you want to proceed?

Cancel Confirm

Note: To respond to query on Issue, refer to Section 6. 19

6) How to View/ Reply to CAPA Query

Note: The PI, Co-I and active Study Team Member (STM) listed in Clinical Research Management System User Authorization List (CRMS UAL) can reply to the query.

1. To view query(ies), click on the “**Query List**” button. A sliding window will appear, where you can **view and respond** to the query(ies). A **red dot** indicates that there is an action pending (i.e. to address the query).
2. To address each **CAPA query** that is currently pending response, enter your reply under "**Pending Query**" tab > "**Reply Query**"
3. You can view all queries throughout the review under “**All Query**” tab. Query response will be **auto-saved**. Click on the background page to close the sliding window.
4. A **pop-up window** will appear for the user’s confirmation to proceed with the task. Click on “**Confirm**” to proceed or “**Cancel**” to return to the issue detail page.
5. When all the query(ies) have been **answered**, the red dot indicator will disappear.

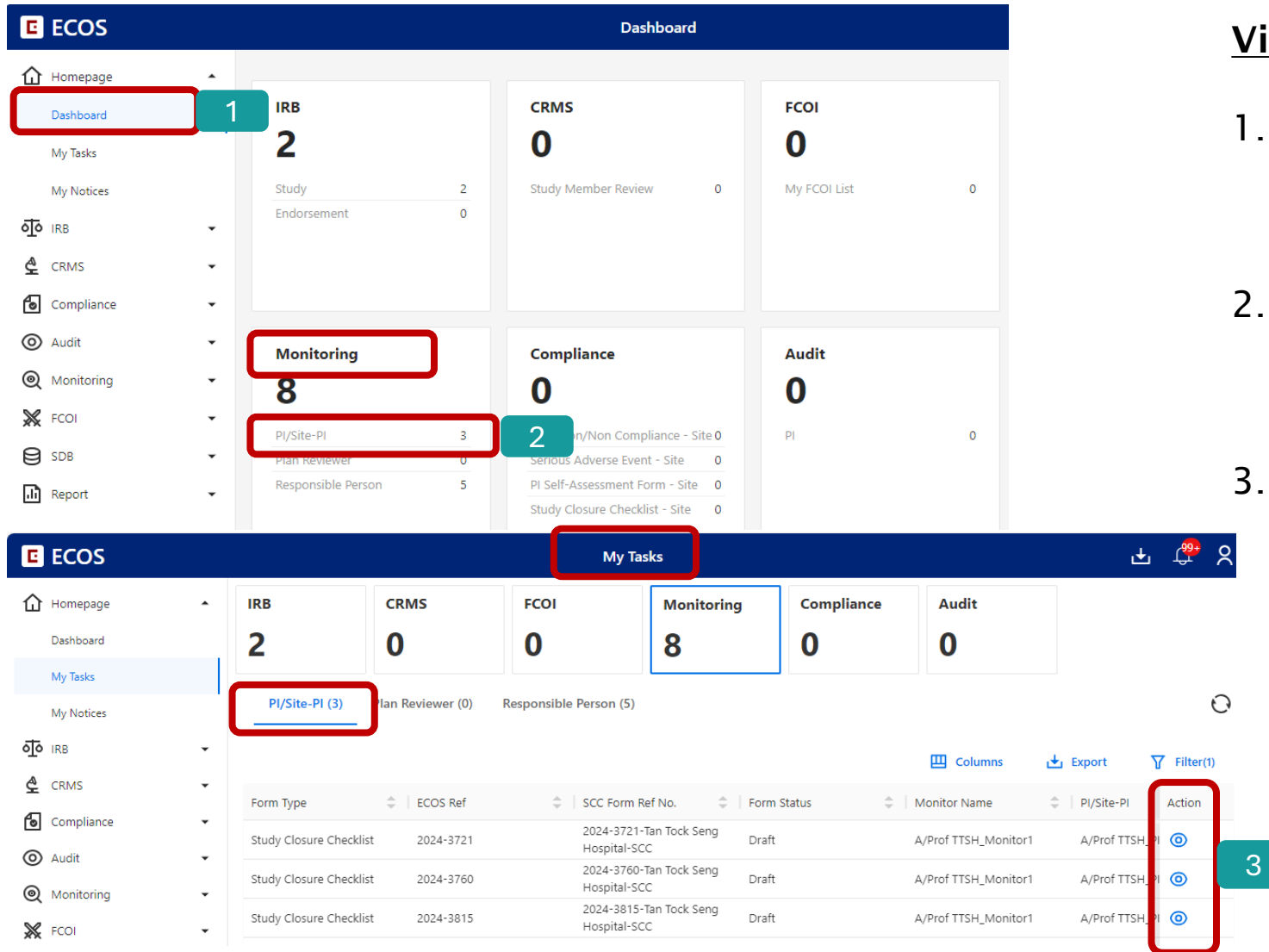
6) How to View/ Reply to CAPA Query

The top screenshot shows the 'Issue Detail' page for 'ISE-006' with a status of 'Issue Pending Review' (7). A red-bordered box highlights the email notification header (6) which reads: 'NHG Monitoring Programme for HBR studies (Category 3A) ... Dear A/Prof KTPH_PI3 and A/Prof KTPH_Monitor1'. The 'Monitoring Information' section includes details like 'Study Title: Study 41', 'ECOS Ref: 2024-3815', 'PI/Site-PI: A/Prof TTSH_PI4', 'Study Site: Tan Tock Seng Hospital', 'Visit Type & No.: RMV001', 'Monitoring Category: NHG 3A', and 'Monitor: A/Prof TTSH_Monitor1'.

The bottom screenshot shows the 'Track Changes' modal open, displaying a comparison between two versions of the CAPA response (8). The modal shows 'Current Version' (05-Dec-2024 14:20:01 ISE-006) and 'Previous Version' (02-Dec-2024 11:24:39 ISE-006). The modal content includes sections for 'Root Cause', 'Corrective Actions', and 'Preventive Actions', each with a small 'ab' icon indicating changes.

6. An **email notification** will be triggered after the form has been submitted. The task is now with the **monitor to review** the query response.
7. The label will be changed from **“Query Pending Reply”** to **“Issue Pending Review”**. The form cannot be edited further.
8. If changes were made to the CAPA, you can see the **prior changes** when you click on the **“Track Changes”** function.

7) How to View/ Edit/ Submit Study Closure Checklist (SCC)



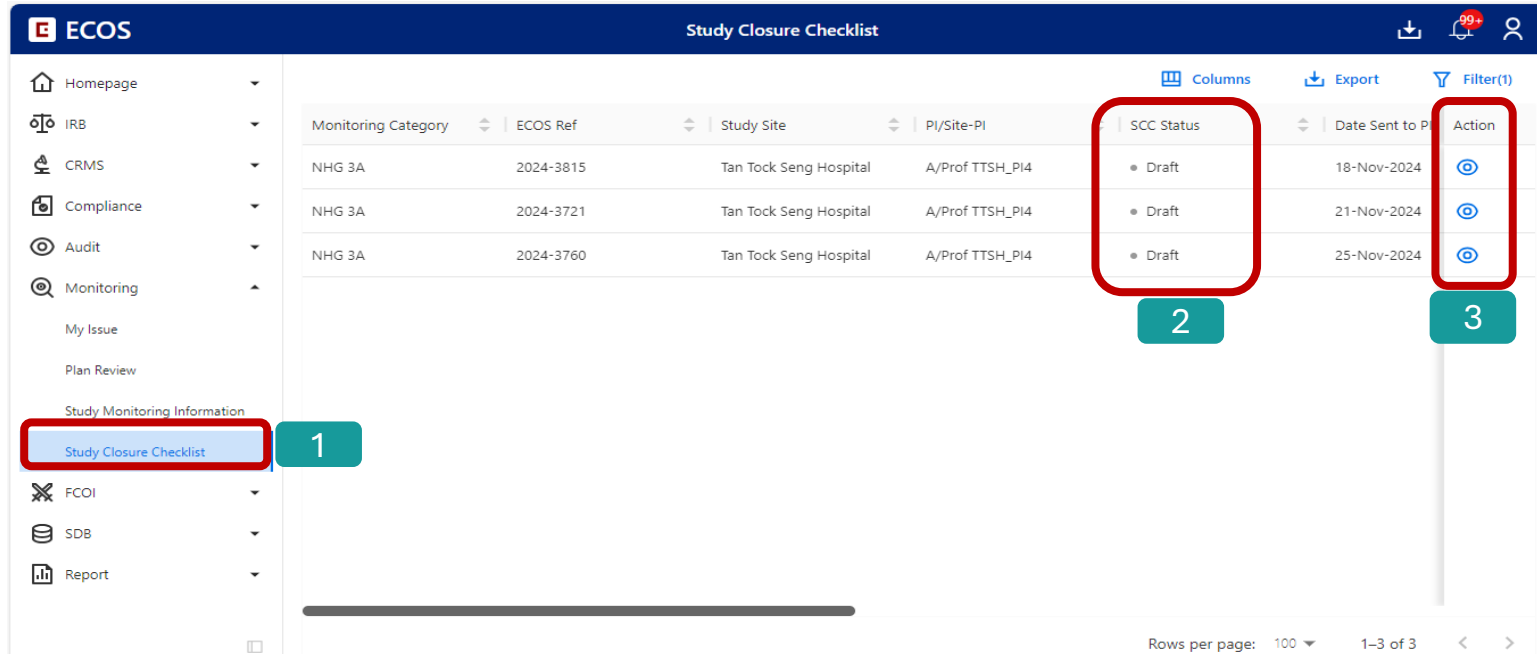
Via Dashboard > My Tasks

1. The PI/ Site-PI/ Co-I/ Study Team Members can view all SCC tasks via **“Dashboard”**.
2. Locate the **“Monitoring”** tile, click on **“PI/Site PI”** and you will enter **“My Tasks”** > **“PI/Site-PI”** page.
3. Click on **“View”** button under the **“Action”** column to view the **“Study Closure Checklist Detail”** page.

Note: The PI, Co-I and active Study Team Member (STM) listed in **Clinical Research Management System User Authorization List (CRMS UAL)** can view and edit the study closure checklist.

By default, only the PI /Site PI can submit the SCC form.


7) How to View/ Edit/ Submit Study Closure Checklist (SCC)



Via Monitoring > Study Closure Checklist

1. You can also locate the SCC task via the Monitoring Module > “Study Closure Checklist” sub-header.

2. By default, you will see tasks which are pending your action (SCC Status =Draft/ Queried by Monitor).

3. Click on  “View” button under the “Action” column to view the “Study Closure Checklist Detail” page.

7) How to View/ Edit/ Submit Study Closure Checklist (SCC)

The screenshot shows the 'Study Closure Checklist Detail' page. At the top, a blue navigation bar contains a home icon, a 'Back to My Tasks' link, and the page title 'Study Closure Checklist Detail'. Below the navigation bar, the form title '2024-3646-Tan Tock Seng Hospital-SCC | Tan Tock Seng Hospita' is displayed in a red-bordered box, followed by a 'Draft' status label and a 'Submit' button. The form includes fields for 'PI/Site PI: A/Prof TTSH_NewPI3', 'Monitor: A/Prof TTSH_Monitor1', 'Date Sent to PI: 11-Nov-2024', 'Last Updated By: -', 'Initial Submission Date: -', and 'Current Editor: -'. A 'Study Title: Study 13' field is also present. A 'Quick Link: Study Summary, CRMS' is highlighted with a red-bordered box. At the bottom right, there are 'Export' and 'Edit' buttons, with the 'Edit' button highlighted by a red-bordered box. The main content area is titled '1. DATA' and contains two sections: '*1.1 I have ensured that all case report forms/ data collection forms/ research database are up to date.' and '*1.2 I have resolved all data queries to the extent possible.' Each section has radio buttons for 'Yes' and 'NA' and a text area for comments.

1. This is the SCC **Form reference no.**
2. The label indicates the **task status** of the SCC.
3. These quick links will bring you to **IRB Module - Study Summary and Clinical Research Management System (CRMS) information.**
4. Click on **“Edit”** to start completing the form.

7) How to View/ Edit/ Submit Study Closure Checklist (SCC)

2024-3646-Tan Tock Seng Hospital-SCC | Tan Tock Seng Hospital Draft Submit

ECOS Ref: 2024-3646

PI/Site PI: A/Prof TTSH_NewPI3 Monitor: A/Prof TTSH_Monitor1 Date Sent to PI: 11-Nov-2024

Last Updated By: - Initial Submission Date: -

Current Editor: A/Prof TTSH_NewPI3

Study Title: Study 13

Study Closure Checklist (SCC) Cancel Save Save and Exit

1

9. OTHERS

*9.1 I have registered a standing database and/or tissue bank to relevant parties, if applicable.

Yes

NA

9.1 Comments:

Attachment(s) Upload

0 characters entered

1. Scroll down to complete the rest of the SCC form. Fields marked with * are **mandatory** for completion.
2. Click on **“Save”** to ensure the edits have been saved successfully.
3. Click on **“Save and Exit”** to exit editing mode.

7) How to View/ Edit/ Submit Study Closure Checklist (SCC)

Study Closure Checklist Detail

2024-3646-Tan Tock Seng Hospital-SCC | Tan Tock Seng Hospital

ECOS Ref: 2024-3646

PI/Site PI: A/Prof TTSH_NewPI3 Monitor: A/Prof TTSH_Monitor1 Date Sent to PI: 11-Nov-2024

Last Updated By: A/Prof TTSH_NewPI3 Initial Submission Date: -

Current Editor: A/Prof TTSH_NewPI3

Study Title: Study 13

Study Closure Checklist (SCC)

9. OTHERS

*9.1 I have registered a standing database and/or tissue bank to relevant parties, if applicable.

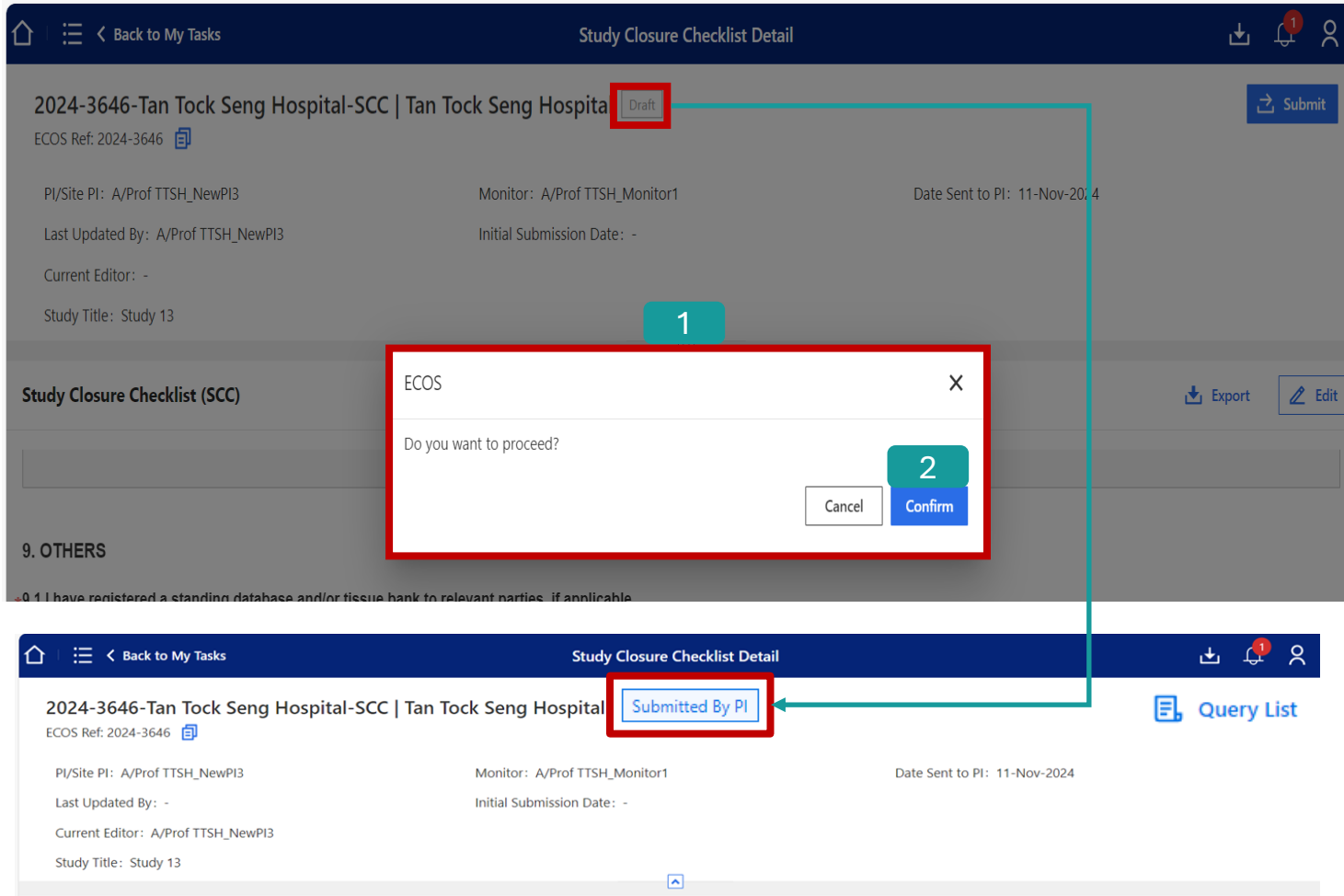
Yes

NA

Submit

1. After the form has been saved, the **“Submit”** button will be enabled (colour change from **grey to blue**).
2. By default, **only the PI/Site PI** is able to see and click on the **“Submit”** button. **Co-I and active STM listed in CRMS UAL** can **only view and edit** the Study Closure Checklist (SCC).

7) How to View/ Edit/ Submit Study Closure Checklist (SCC)



1. After the PI clicks on the “**Submit**” button, a **pop-up window** will appear for the user’s confirmation to proceed with the task. Click on “**Confirm**” to proceed or “**Cancel**” to return to the Study Closure Checklist Detail page.
2. Click “**Confirm**” to proceed with the submission. The label will be changed from “**Draft**” to “**Submitted By PI**”. The form **cannot** be edited further.

An email notification will be triggered after the SCC has been submitted. The task is now with the Monitor to complete the review.

The SCC will be further reviewed by the Monitoring Report Reviewer. If there is no further query from **both** Monitor and Monitoring Report Reviewer, the SCC will be **approved**.

The monitoring of the study is now **complete**.

8) How to Export the Monitoring Report/ Letters/ Issue List

2024-3815 | Tan Tock Seng Hospital

Study Site: Tan Tock Seng Hospital
Current Study Site Status: Approved
Study Title: Study 41
Quick Link: [Study Summary, CRMS](#)

PI/Site-PI: A/Prof TTSH_P14
Monitor: A/Prof TTSH_Monitor1

Confirmation Letter

To: TTSH_P14, TTSH_STM3
Cc: TTSH_RO20, TTSH_RO, TTSH_...
Subject: NHG Monitoring Programme ...

Content: [Preview](#)

ONLYOFFICE File View Plugins 2024-3815-Tan Tock Seng Hospital-SMV001-Confirmation ...

1

2

You can export a copy of the monitoring visit information via **Monitoring > Study Monitoring Information > View Schedule**.

1. Click on the selected **Monitoring visit** and expand the menu to see the Confirmation Letter, Monitoring Report, Issue List and Follow up Letter.

2. To export a copy, locate the respective document **“Export”** button.

2024-3815 | Tan Tock Seng Hospital

Study Site: Tan Tock Seng Hospital
Current Study Site Status: Approved
Study Title: Study 41
Quick Link: [Study Summary, CRMS](#)

PI/Site-PI: A/Prof TTSH_P14
Monitor: A/Prof TTSH_Monitor1

Monitoring Visit Report

Actual Start Date: 01-Apr-2025
Actual End Date: 01-Apr-2025
Study Site Status (Monitoring): Ongoing with

Remarks: [View](#)

Monitoring Visit Report: 2... Approved

SECTION A – GENERAL INFORMATION

SECTION B – OVERALL S...

Monitoring Report

Export

8) How to Export the Monitoring Report/ Letters/ Issue List

2024-3815 | Tan Tock Seng Hospital

Study Site: Tan Tock Seng Hospital
Current Study Site Status: Approved
Study Title: Study 41
Quick Link: [Study Summary, CRMS](#)

PI/Site-PI: A/Prof TTSH_PI4
Monitor: A/Prof TTSH_Monitor1

Follow up Letter

Attachments: [Export](#)

To: TTSH_PI4, TTSH_C1, TTSH_STM3
Cc: TTSH_RO20, TTSH_RO, TTSH_...
Subject: NHG Monitoring Programme ...

Content: [Preview](#)

ONLYOFFICE File View Plugins 2024-3815-Tan Tock Seng Hospital-SMV001-Follow-up Lett...

3. The **“Download List”** will appear at the bottom of the browser.

4. When the export is complete, click **“Download To Local”**. The PDF copy of the form will be saved to your computer local drive.

3 Download List (3) Delete All

| | | |
|--|---------------------------|--------------------------|
| 2024-3815-Tan Tock Seng Hospital-SMV001-Follow-up Letter 02-Dec-2024 11:35:21.pdf | Preparing for download... | Delete |
| 2024-3815-Tan Tock Seng Hospital-SMV001-Confirmation Letter 02-Dec-2024 11:29:33.pdf | 60.45 KB | Delete Download To Local |
| SMV Report Template.pdf | | |

4

8) How to Export the Monitoring Report/ Letters/ Issue List


2024-3815 | Tan Tock Seng Hospital

Study Site: Tan Tock Seng Hospital PI/Site-PI: A/Prof TTSH_PI4 Monitor: A/Prof TTSH_Monitor1

Current Study Site Status: Approved
Study Title: Study 41
Quick Link: [Study Summary, CRMS](#)

Issue List

| Issue Number | Issue Item | Issue Status | Responsible Person | Issue Category | Action |
|--------------|------------|----------------------|--------------------|----------------------------------|--------|
| ISE-009 | L1.1 | Issue Pending Review | Dr TTSH_STM3 | Investigator File/ Documents | |
| ISE-008 | K1.1 | Issue Pending Review | Dr TTSH_STM3 | Other Study Facilities | |
| ISE-007 | H1.1 | Issue Pending Review | Dr TTSH_STM3 | Safety Reporting | |
| ISE-006 | General | Query Pending Reply | Dr TTSH_STM3 | Investigational Product | |
| ISE-005 | General | Query Pending Reply | Dr TTSH_STM3 | Research Participant Recruitment | |

5. For **Issue List (table format)**, a popup window will be shown. Click on the download icon 

6. Select **“Download Original”** as an Excel file or **“Safe Download”** as PDF file.

synapse Issue List 04-Dec-2024.xlsx Content scan completed

Download Original 5

Safe Download (PDF) 6

| Issue Number | Issue Item | Issue Status | Responsible Person | Issue Category | Issue Description | Recommendation | Issue I |
|--------------|------------|----------------------|--------------------|----------------------------------|-------------------|--------------------------------------|---------|
| ISE-009 | L1.1 | Issue Pending Review | Dr TTSH_STM3 | Investigator File/Essential Doc | Issue 9 | RP replies queries (3) | 01-Apr |
| ISE-008 | K1.1 | Issue Pending Review | Dr TTSH_STM3 | Other Study Facilities | Issue 8 | RP replies queries (2) | 02-Dec |
| ISE-007 | H1.1 | Issue Pending Review | Dr TTSH_STM3 | Safety Reporting | Issue 7 | RP replies queries (1) | 02-Dec |
| ISE-006 | General | Query Pending Reply | Dr TTSH_STM3 | Investigational Product | Issue 6 | Monitor queries issue CAPA (302-Dec | |
| ISE-005 | General | Query Pending Reply | Dr TTSH_STM3 | Research Participant Recruitment | Issue 5 | Monitor queries issue CAPA (202-Dec | |
| ISE-004 | General | Query Pending Reply | Dr TTSH_STM3 | Study Team | Issue 4 | Monitor queries issue CAPA (202-Dec | |
| ISE-003 | H1.1 | Issue Pending Review | Dr TTSH_STM3 | Other Study Facilities | Issue 3 | Monitor do not close issue (1)02-Dec | |
| ISE-002 | E1.1 | Issue Pending Review | A/Prof TTSH_C1 | Research Participant Recruitment | Issue 2 | Monitor do not close issue (2)02-Dec | |
| ISE-001 | D1.1 | Issue Pending Review | A/Prof TTSH_PI4 | Informed Consent Process and | Issue 1 | Monitor does not close issue (02-Dec | |

Please contact Research Quality (NHGHQ)
researchquality@nhghealth.com.sg
if you have any question about ECOS
Monitoring module.



Thank You

Tan Tock Seng Hospital • Khoo Teck Puat Hospital • Woodlands Hospital • Yishun Community Hospital • TTSH Integrated Care Hub
Institute of Mental Health • National Skin Centre • National Centre for Infectious Diseases • NHG Cancer Institute • NHG Eye Institute • NHG Heart Institute
Population Health • NHG Polyclinics • Diagnostics • Pharmacy • Community Care • NHG College • Centre for Healthcare Innovation