

# Navigating Ethics & Compliance Online System (ECOS) User Guide

## Monitoring Module

*[ECOS User Guide – Monitoring Module Ver 1, 06 Dec 2024]*

# 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
2. How to Locate the Monitoring Task
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 shows the ECOS Monitoring Module General Interface. The top navigation bar includes 'My Tasks' and a user profile icon. The left sidebar contains a navigation menu with 'My Tasks' highlighted. The main content area displays a 'Monitoring' tab with a count of 1. Below the tab, there are summary cards for 'Responsible Person (0)', 'Plan Reviewer (0)', and 'PI/Site PI (1)'. A table of tasks is visible, with one task listed: 'Study Closure Checklist' with ECOS Ref '2024-3646' and SCC Form Ref No. '2024-3646-Tan Tock Seng Hospital-SCC'. A 'Columns' dialog box is open, showing a list of columns to be displayed. The columns listed are: Form Type, ECOS Ref, SCC Form Ref No., Form Status, Monitor Name, PI/Site PI, Date Sent to PI, and Task Status. The 'Columns' dialog has 'Clear', 'Cancel', and 'Save' buttons. Numbered callouts (1-4) indicate key actions: 1. Clicking 'Columns' in the top bar; 2. Dragging the 'PI/Site PI' column to the first position; 3. Clicking 'Clear' to reset columns; 4. Clicking 'Save' to apply changes.

**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

ECOS My Tasks

IRB 0 CRMS 0 FCOI 0 **Monitoring 1** Compliance 0

Responsible Person (0) Plan Reviewer (0) **PI/Site PI (1)**

Columns **Export** Filter

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	👁

Download Original  
Safe Download (PDF)

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 an orange box), My Notices, IRB, CRMS, Compliance, Monitoring, FCOI, SDB, and Report. The main content area features a dashboard with five cards: IRB (0), CRMS (0), FCOI (0), Monitoring (1, highlighted with an orange box), and Compliance (0). Below the cards, there are filters for 'Responsible Person (0)', 'Plan Reviewer (0)', and 'PI/Site PI (1)' (highlighted with an orange box). A table lists 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' (checked). The dialog box has a 'Filter' button (1), a 'Reset' button (2), and a 'Search' button (3).

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 includes 'ECOS' and 'Dashboard'. The left sidebar contains 'Homepage', 'Dashboard', 'My Tasks', 'My Notices', 'IRB', 'CRMS', 'Compliance', 'Monitoring', 'My Issue', 'Plan Review', 'Study Monitoring Information', and 'Study Closure Checklist'. The main content area displays several monitoring tiles: IRB (0), CRMS (0), FCOI (0), Monitoring (0), and Compliance (0). The 'Monitoring' tile is highlighted with a red box and a '2' callout. Below the tiles, the 'My Tasks' section is shown, with 'Monitoring' highlighted by a red box and a '4' callout. The 'Monitoring' section lists tasks under sub-headers: 'Responsible Person (0)', 'Plan Reviewer (0)', and 'PI/Site PI (1)'. The 'PI/Site PI (1)' sub-header is highlighted with a red box and a '5' callout. Below the list, a table shows task details. The 'View' button in the 'Action' column is highlighted with a red box and a '6' callout.

**ECOS Dashboard**

**Monitoring**

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

**My Tasks**

**Monitoring**

Responsible Person (0)	Plan Reviewer (0)	PI/Site PI (1)
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**View**

### 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

ECOS My Issue

Columns Export Filter(1)

ECOS Ref	Visit Type & No.	Issue Number	Issue Category	Issue Status	Issue Date	Issue Due Date	Action
2024-3650	RMV002	ISE-004	IRB Records	Issue Pending Completion	11-Nov-2024	12-Nov-2024	
2024-3650	RMV002	ISE-003	Study Team	Issue Pending Completion	11-Nov-2024	12-Nov-2024	
2024-3650	SMV001	ISE-002	IRB Records	Issue Pending Completion	11-Nov-2024	12-Nov-2024	

### Via Monitoring >

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 has 'Study Monitoring Information' highlighted with a red box and a '1' callout. The main table has columns: Monitoring Category, ECOS Ref, Study Site, PI/Site-PI, Current Study Site Status, and Action. The bottom row is highlighted, and its 'Action' column contains a 'View Plan' icon (a target symbol) highlighted with a red box and a '2' callout.

Monitoring Category	ECOS Ref	Study Site	PI/Site-PI	Current Study Site Status	Action
NHG 3A	2024-3649	Khoo Teck Puat Hospital	A/Prof KTPH_PI3	• Ongoing (Last Particip... Last Visit Completed, On... 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 Particip... Last Visit Completed, On... 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 shows a web application interface for viewing and exporting a study monitoring plan. The interface includes a navigation bar with 'View Monitoring Plan' highlighted, a document viewer showing a 'MONITORING PLAN' form, and a download list at the bottom with 'Download To Local' highlighted.

**Navigation Bar:** Home icon, menu icon, 'Back to Study Monitoring Information', 'View Monitoring Plan' (highlighted), '1' (step indicator), download icon, notification icon (80), and user profile icon.

**Document Header:** '2024-3721 | Tan Tock Seng Hospital' (Draft), 'ECOS Ref: 2024-3721'.

**Monitoring Plan Form:**

MONITORING PLAN	
<b>Title of Research Study</b>	Study 22
<b>Principal Investigator</b>	A/Prof TTSH_PI4
<b>Department &amp; Institution</b>	General Medicine, Tan Tock Seng Hospital
<b>Target Recruitment</b>	As per IRB Application Form
<b>Applicable Regulations</b>	The site will be conducting the study in accordance to the f regulations and SOP(s):

**Download List (1):**

File Name	Size	Actions
MOB005-11Nov2024_NHG-Monitoring-Plan_18-Nov-2024 10:51:43.pdf	151.90 KB	Delete, Download To Local (highlighted)

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

Columns Export Filter

Monitoring Category	ECOS Ref	Study Site	PI/Site-PI	Current Study Site Status	Action
NHG 3A	2024-3649	Khoo Teck Puat Hospital	A/Prof KTPH_PI3	Ongoing (Last Participa Last Visit Completed, Only 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, 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\_PI3 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 components:

- Dashboard Overview:** IRB (2), CRMS (0), FCOI (0), Monitoring (1), Compliance (0), Audit (0).
- Monitoring Tile:** PI/Site-PI (0), **Plan Reviewer (1)**, Responsible Person (0).
- My Tasks Section:** Monitoring (1), Compliance (0), Audit (0).
- Table:** A table with columns: Form Type, ECOS Ref, Plan Status, Monitor Name, PI/Site-PI, Date Sent to Reviewer, and Action.

Form Type	ECOS Ref	Plan Status	Monitor Name	PI/Site-PI	Date Sent to Reviewer	Action
Monitoring Plan	2024-3651	Pending Review	A/Prof TTSH_Monitor1	A/Prof TTSH_NewPI7	18-Nov-2024	View

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, a navigation menu has 'Plan Review' highlighted with a red box and a green circle containing the number '1'. The main area displays a table with columns: Monitoring Category, ECOS Ref, Study Site, PI/Site-PI, Current Study Site Status, Monitor, Plan Reviewer, Monitoring Plan Status, and Action. The 'Monitoring Plan Status' column has a red box around it with a green circle containing the number '2'. The 'Action' column has a red box around it with a green circle containing the number '3'. The table contains one row with the following data: Monitoring Category: NHG 3A, ECOS Ref: 2024-3651, Study Site: Tan Tock Seng Hospital, PI/Site-PI: A/Prof TTSH\_NewPI7, Current Study Site Status: Approved, Monitor: A/Prof TTSH\_Monitor1, Plan Reviewer: A/Prof TTSH\_NewPI7, Monitoring Plan Status: Pending Review, and Action: View (represented by an eye icon).

Monitoring Category	ECOS Ref	Study Site	PI/Site-PI	Current Study Site Status	Monitor	Plan Reviewer	Monitoring Plan Status	Action
NHG 3A	2024-3651	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)

2024-3651 | Tan Tock Seng Hospital Pending Review  
ECOS Ref: 2024-3651

Monitor: A/Prof TTSH\_Monitor1  
Plan Submission Date: 18-Nov-2024  
Attachment: [0 files](#)  
Study Title: Study 02  
Quick Link: [Study Summary, CRMS](#)

PI/Site-PI: A/Prof TTSH\_NewPI7  
Plan Endorsement Date: -

Current Study Site Status: Approved  
Plan Reviewer: A/Prof TTSH\_NewPI7

Monitoring Plan Export Fullscreen

ONLYOFFICE File View Plugins MOB004-18Nov2024\_NHG-Monitoring-Plan\_18-Nov-2024 09:55:36.docx

Query List Saved at 03-Dec-2024 16:40:58 + General Query

Pending Query All Query  
0/1 Pending

0 Queries Selected Batch Close

General + Further Query X Close Query

QUERY1  
Test document\_for uploading.pdf  
Query Round 1 A/Prof TTSH\_NewPI7 18-Nov-2024 10:00:48  
Reply to query  
Query Round 1 A/Prof TTSH\_Monitor1 18-Nov-2024 10:05:01

General +

\* Query Description  
Please update Training information

Attachment  
Upload

Monitoring Plan ONLYOFFICE File View Plugins MOB004-18Nov2024\_NHG-Monitoring-Plan\_18-Nov-2024 09:55:36.docx

2024-3651 | Tan Tock Seng Hospital Pending Review  
ECOS Ref: 2024-3651

Monitor: A/Prof TTSH\_Monitor1  
Plan Submission Date: 18-Nov-2024  
Attachment: [0 files](#)  
Study Title: Study 02  
Quick Link: [Study Summary, CRMS](#)

PI/Site-PI: A/Prof TTSH\_NewPI7  
Plan Endorsement Date: -

Current Study Site Status: Approved  
Plan Reviewer: A/Prof TTSH\_NewPI7

Monitoring Plan Export Fullscreen

ONLYOFFICE File View Plugins MOB004-18Nov2024\_NHG-Monitoring-Plan\_18-Nov-2024 09:55:36.docx

Query List Saved at 03-Dec-2024 16:40:58 + General Query

Pending Query All Query  
0/1 Pending

0 Queries Selected Batch Close

General + Further Query X Close Query

QUERY1  
Test document\_for uploading.pdf  
Query Round 1 A/Prof TTSH\_NewPI7 18-Nov-2024 10:00:48  
Reply to query  
Query Round 1 A/Prof TTSH\_Monitor1 18-Nov-2024 10:05:01

General +

\* Query Description  
Please update Training information

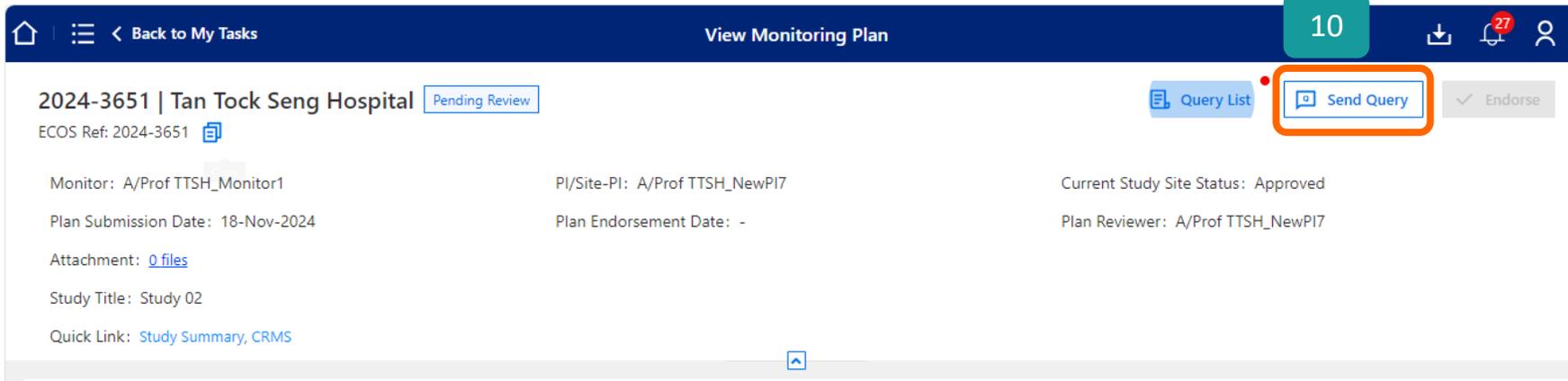
Attachment  
Upload

Monitoring Plan ONLYOFFICE File View Plugins MOB004-18Nov2024\_NHG-Monitoring-Plan\_18-Nov-2024 09:55:36.docx

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”.

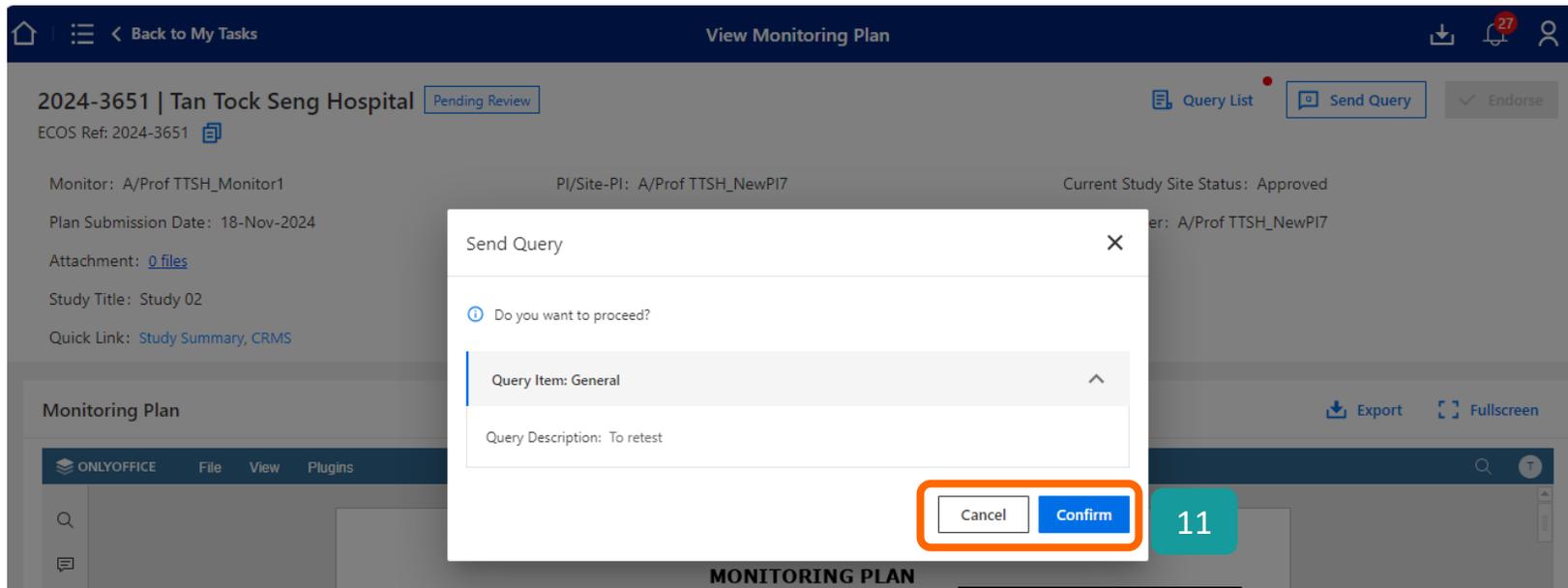
Click on the background page to close the query sliding window.

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



The screenshot shows the 'View Monitoring Plan' interface for '2024-3651 | Tan Tock Seng Hospital'. The page includes a navigation bar with 'Back to My Tasks', a 'View Monitoring Plan' title, and a notification badge with the number '10'. Below the navigation bar, there are buttons for 'Query List', 'Send Query' (highlighted with a red box), and 'Endorse'. The main content area displays details for the monitoring plan, including the monitor's name, submission date, and study title.

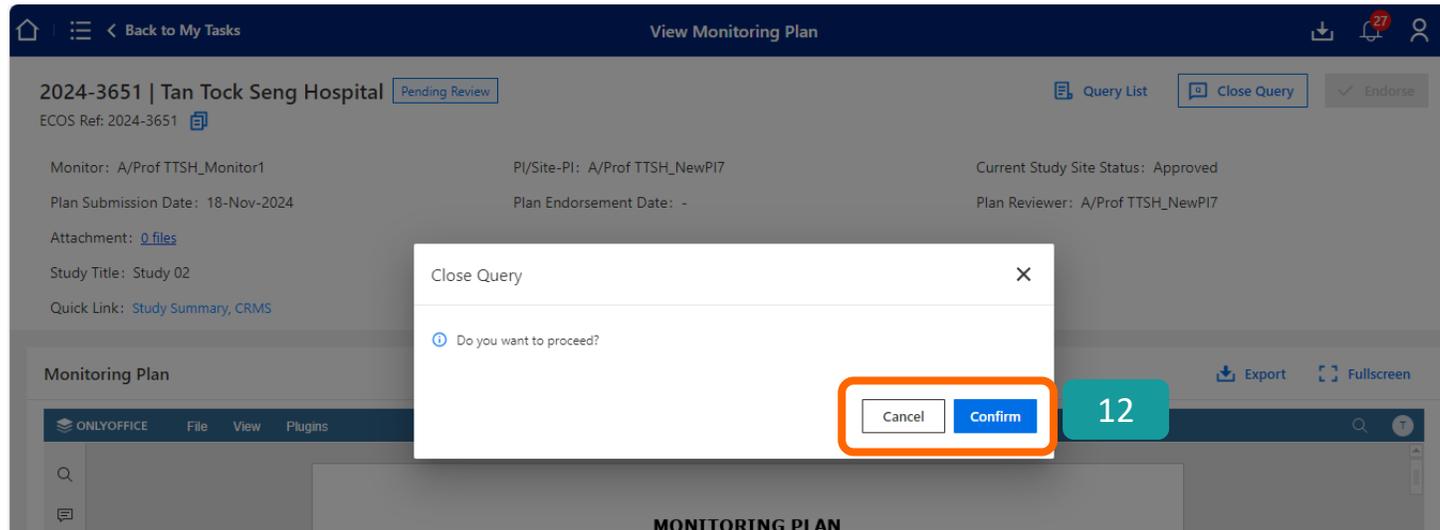
10. If there are outstanding query(ies) to the Monitor, the “Send Query” button will be activated. Click on “Send Query”.



The screenshot shows the 'Send Query' pop-up window. The window title is 'Send Query' and it contains a confirmation message: 'Do you want to proceed?'. Below the message, there is a dropdown menu showing 'Query Item: General' and a text field with 'Query Description: To retest'. At the bottom of the window, there are two buttons: 'Cancel' and 'Confirm' (highlighted with a red box). The background shows the same 'View Monitoring Plan' page as in the previous screenshot, but it is dimmed.

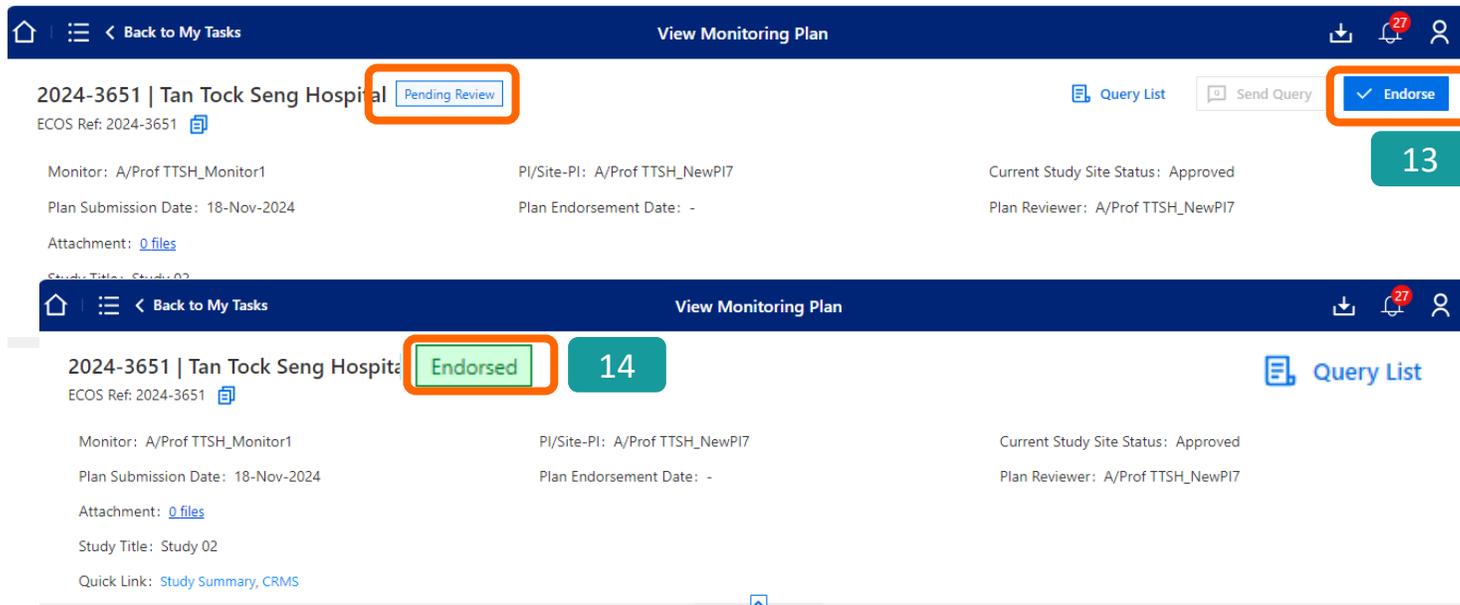
11. A pop-up window with a list of query(ies) to be sent will be shown. Click “Confirm” to send the query or “Cancel” to return to the previous page.

## 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

The screenshot shows the ECOS Dashboard. The left sidebar has a 'Dashboard' link highlighted with a green '1'. The main content area has several tiles: IRB (0), CRMS (0), FCOI (0), Monitoring (2), and Compliance (0). The Monitoring tile is highlighted with a green '2'. Below the Monitoring tile, there is a link for 'Responsible Person' with a count of 2, also highlighted with a green '2'.

The screenshot shows the ECOS 'My Tasks' page. The 'Monitoring' tile is highlighted with a green '2'. Below it, there is a link for 'Responsible Person (2)' highlighted with a green '2'. The main content area shows a table of issues with columns: Form Type, ECOS Ref, Task Due date, Monitor Name, PI/Site-PI, Date Sent to Site, and Action. The 'Action' column has a 'View' button (eye icon) highlighted with a green '3'.

Form Type	ECOS Ref	Task Due date	Monitor Name	PI/Site-PI	Date Sent to Site	Action
Issue List	2024-3637	13-Dec-2024	A/Prof KTPH_Monitor1	A/Prof KTPH_PI3	11-Nov-2024	View
Issue List	2024-3704	18-Dec-2024	A/Prof KTPH_Monitor2	A/Prof KTPH_PI3	18-Nov-2024	View

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' monitoring interface. The interface is divided into a sidebar on the left and a main content area. The sidebar contains navigation options: 'My Issue' (highlighted with a red box and labeled '1'), 'Plan Review', 'Study Monitoring Information', and 'Study Closure Checklist'. The main content 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 table contains three rows of issues, all with 'Issue Pending Completion' status. The table is sorted by 'Issue Due Date' (newest to oldest). A red box highlights the 'Action' column, and a red arrow points to the 'View' button (labeled '4'). The 'Issue Detail' page (labeled '5') is shown below the table, displaying monitoring information and issue details for issue ISE-002. The 'Issue Detail' page includes a 'Submit' button and a 'Track Changes' button.

ECOS Ref	Visit Type & No.	Issue Number	Issue Category	Issue Status	Issue Date	Issue Due Date	Action
2024-3650	RMV002	ISE-004	IRB Records	Issue Pending Completion	11-Nov-2024	12-Nov-2024	View
2024-3650	RMV002	ISE-003	Study Team	Issue Pending Completion	11-Nov-2024	12-Nov-2024	View
2024-3650	SMV001	ISE-002	IRB Records	Issue Pending Completion	11-Nov-2024	12-Nov-2024	View

**Issue Detail**

ISE-002 Issue Pending Completion Submit

**Monitoring Information**

Study Title: Study 18  
ECOS Ref: 2024-3705  
Visit Type & No.: Ad-Hoc RMV001  
PI/Site-PI: A/Prof TTSH\_PI4  
Monitoring Category: NHG 3A  
Study Site: Tan Tock Seng Hospital  
Monitor: A/Prof TTSH\_Monitor1

**Issue Information** Track Changes

**Issue Item**  
I1.1

**Issue Date**  
17-Nov-2024

**Responsible Person**  
A/Prof TTSH\_PI4, Dr TTSH\_C1

**Issue Category**  
Other Study Supplies

**Issue Due Date**  
24-Nov-2024

**CAPA Needed**  
Yes

**Issue Description**  
Device prototype not available

**Issue Closure Date**

**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

The screenshot shows the 'Issue Detail' page for ISE-010. The page is divided into three main sections: Monitoring Information, Issue Information, and Corrective Action Preventive Action. The 'Issue Information' section contains a table with the following data:

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

The 'Corrective Action Preventive Action' section contains a table with the following data:

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

The 'Corrective Action Preventive Action' section also contains a table with the following data:

Responsible Person	CAPA Needed	Recommendation
A/Prof KTPH_PI3	Yes	

The 'Corrective Action Preventive Action' section also contains a table with the following data:

Root Cause

The 'Corrective Action Preventive Action' section also contains a table with the following data:

Corrective Actions

The 'Corrective Action Preventive Action' section also contains a table with the following data:

Preventive Actions

The 'Corrective Action Preventive Action' section also contains a table with the following data:

CAPA Completion Date
Select date

The 'Corrective Action Preventive Action' section also contains a table with the following data:

Attachment
Upload

The 'Corrective Action Preventive Action' section also contains a table with the following data:

Attachment
Upload

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.

ECOS  
Do you want to proceed?  
Cancel Confirm

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

## 6) How to View/ Reply to CAPA Query

The screenshot illustrates the process of viewing and replying to a CAPA query. It is divided into five numbered steps:

- Step 1:** A red dot indicator on the "Query List" button in the top right corner of the "Issue Detail" page, indicating a pending query.
- Step 2:** The "Query List" button is clicked, opening a sliding window.
- Step 3:** The "Pending Query" tab is selected in the sliding window, showing a list of pending queries. One query is visible: "Query 1 (Monitor do not close)".
- Step 4:** A "Reply Query" pop-up window appears, asking for confirmation to proceed. It shows the selected query details: "Tan Tock Seng Hospital", "Query Item: General", and "Query 1 (Monitor do not close)".
- Step 5:** The "Confirm" button is clicked in the "Reply Query" window to submit the response.

Additional details from the interface include the "Issue Detail" page for ISE-006 (Query Pending Reply) and the "Monitoring Information" section with fields for Study Title, ECOS Ref, PI/Site-PI, and Study Site.

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. The status is 'Issue Pending Review' (7). The recipient information is 'Dear A/Prof KTPH\_PI3 and A/Prof KTPH\_Monitor1' (6). The bottom screenshot shows the 'Track Changes' dialog box (8) with the following details:

- Current Version: 05-Dec-2024 14:20:01 ISE-006
- Previous Version: 02-Dec-2024 11:24:39 ISE-006
- Root Cause: ab
- Corrective Actions: ab
- Preventive Actions: ab

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)

ECOS Dashboard

- IRB: 2 (Study: 2, Endorsement: 0)
- CRMS: 0 (Study Member Review: 0)
- FCOI: 0 (My FCOI List: 0)
- Monitoring: 8 (PI/Site-PI: 3, Non Compliance - Site 0: 2, Serious Adverse Event - Site 0: 0, PI Self-Assessment Form - Site 0: 0, Study Closure Checklist - Site 0: 0)
- Compliance: 0
- Audit: 0

## 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.

ECOS My Tasks

Form Type	ECOS Ref	SCC Form Ref No.	Form Status	Monitor Name	PI/Site-PI	Action
Study Closure Checklist	2024-3721	2024-3721-Tan Tock Seng Hospital-SCC	Draft	A/Prof TTSH_Monitor1	A/Prof TTSH_Monitor1	
Study Closure Checklist	2024-3760	2024-3760-Tan Tock Seng Hospital-SCC	Draft	A/Prof TTSH_Monitor1	A/Prof TTSH_Monitor1	
Study Closure Checklist	2024-3815	2024-3815-Tan Tock Seng Hospital-SCC	Draft	A/Prof TTSH_Monitor1	A/Prof TTSH_Monitor1	

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)

Monitoring Category	ECOS Ref	Study Site	PI/Site-PI	SCC Status	Date Sent to PI	Action
NHG 3A	2024-3815	Tan Tock Seng Hospital	A/Prof TTSH_PI4	Draft	18-Nov-2024	View
NHG 3A	2024-3721	Tan Tock Seng Hospital	A/Prof TTSH_PI4	Draft	21-Nov-2024	View
NHG 3A	2024-3760	Tan Tock Seng Hospital	A/Prof TTSH_PI4	Draft	25-Nov-2024	View

### 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)

1

Study Closure Checklist Detail

2024-3646-Tan Tock Seng Hospital-SCC | Tan Tock Seng Hospita Draft 2 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: -

Study Title: Study 13

3 Quick Link: Study Summary, CRMS 4

Export Edit

Study Closure Checklist (SCC)

1. DATA

\*1.1 I have ensured that all case report forms/ data collection forms/ research database are up to date.

Yes

NA

1.1 Comments:

\*1.2 I have resolved all data queries to the extent possible.

Yes

NA

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)

The screenshot displays the 'Study Closure Checklist Detail' form. At the top, there is a navigation bar with 'Back to My Tasks' and a 'Study Closure Checklist Detail' title. A green notification bubble says 'Saved successfully!'. Below the title, the form fields are: '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', and 'Study Title: Study 13'. At the bottom of the form, there are buttons for 'Cancel', 'Save', and 'Save and Exit'. The 'Submit' button is highlighted in blue, indicating it is enabled. A green arrow points to the 'Submit' button, and a red box highlights the 'Submit' button in the top right corner of the form.

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)

The screenshot shows the 'Study Closure Checklist Detail' page for '2024-3646-Tan Tock Seng Hospital-SCC | Tan Tock Seng Hospital'. The status is 'Draft'. A 'Submit' button is visible in the top right. A confirmation pop-up window is overlaid on the page, asking 'Do you want to proceed?' with 'Cancel' and 'Confirm' buttons. A red '1' is placed above the pop-up, and a red '2' is placed above the 'Confirm' button.

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 screenshot shows the 'Study Closure Checklist Detail' page after submission. The status is now 'Submitted By PI', which is highlighted with a red box. The 'Submit' button is no longer visible, and a 'Query List' button is present in the top right. The page content remains the same as in the previous screenshot.

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\_PI4  
Monitor: A/Prof TTSH\_Monitor1

**Confirmation Letter** (Draft)

To: TTSH\_PI4, 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 ...

Export

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\_PI4  
Monitor: A/Prof TTSH\_Monitor1

**Monitoring Visit Report** (Approved)

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

Remarks: [View](#)

ONLYOFFICE File View Plugins 2024-3815-Tan Tock Seng Hospital-SMV001-Monitoring Visit Report

Export

1

2

## 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

**Follow up Letter**

Follow-up Letter

To: TTSH\_P14, 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...

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

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**

Columns    Export    Filter

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

Sheet1

Downloaded By: A/Prof TTSH\_PI4  
Downloaded Date and Time: 04-Dec-2024 16:34:24

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 (3)	02-Dec
ISE-005	General	Query Pending Reply	Dr TTSH_STM3	Research Participant Recruitment	Issue 5	Monitor queries issue CAPA (2)	02-Dec
ISE-004	General	Query Pending Reply	Dr TTSH_STM3	Study Team	Issue 4	Monitor queries issue CAPA (1)	02-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 an	Issue 1	Monitor does not close issue	02-Dec

Download Original    5

Safe Download (PDF)    6

# Thank You

Please contact Research Quality (NHGHQ)  
[researchquality@nhg.com.sg](mailto:researchquality@nhg.com.sg) if you have any question  
about ECOS Monitoring module.