

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
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 displays the ECOS Monitoring Module General Interface. The top navigation bar includes the ECOS logo, 'My Tasks', and user icons. The left sidebar contains navigation links: 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 tabs: IRB (0), CRMS (0), FCOI (0), Monitoring (1, highlighted with a red box), and Compliance (0). Below the tabs, there are three yellow boxes: 'Responsible Person (0)', 'Plan Reviewer (0)', and 'PI/Site PI (1)'. The 'Monitoring' tab is active, showing a table with columns: Form Type, ECOS Ref, SCC Form Ref No., PI/Site PI, Date Sent to, and Action. A 'Columns' dialog box is open, showing a list of columns to be displayed. The dialog has a 'Column' header, a search bar, and a list of columns with checkboxes and drag handles. 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 'Clear' button is highlighted with a red box. The 'Save' button is highlighted with a red box. The 'Cancel' button is also visible. The dialog box is labeled 'Selected 8'.

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

Download

1

Profile

Homepage

Dashboard

My Tasks

My Notices

IRB

CRMS

Compliance

Monitoring

FCOI

SDB

Report

IRB

0

CRMS

0

FCOI

0

Monitoring

1

Compliance

0

Responsible Person (0)

Plan Reviewer (0)

PI/Site PI (1)

Columns

Export

1

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	<div><div>Download</div><div>More</div></div>

2

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.

PI/Site PI							
Downloaded By: A/Prof TTSH_NewPI3							
Downloaded Date and Time: 11-Nov-2024 13:20:00							
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 icons. The left sidebar contains navigation links: 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 cards: IRB (0), CRMS (0), FCOI (0), Monitoring (1, highlighted with a red box), and Compliance (0). Below these cards, there are filters for 'Responsible Person (0)', 'Plan Reviewer (0)', and 'PI/Site PI (1)' (highlighted with a red box). A table lists tasks with columns: 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' (highlighted with a red box). The dialog box has 'Reset' and 'Search' buttons at the bottom (both highlighted with red boxes). A 'Filter' button is also visible on the right side of the interface (highlighted with a red box). Numbered callouts 1, 2, and 3 are present: 1 points to the 'Filter' button, 2 points to the 'Reset' button, and 3 points to the 'Search' button.

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 displays the ECOS system interface. The top navigation bar is dark blue with the ECOS logo on the left and a 'Dashboard' button on the right. The left navigation panel is also dark blue and contains several menu items: 'Homepage', 'Dashboard' (highlighted with a red box and a green '1'), 'My Tasks', 'My Notices', 'IRB', 'CRMS', 'Compliance', 'Monitoring' (highlighted with a red box and a green '2'), 'My Issue', 'Plan Review', 'Study Monitoring Information', and 'Study Closure Checklist'. The main content area is white and features several task tiles: 'IRB' (0), 'CRMS' (0), 'FCOI' (0), 'Monitoring' (0, highlighted with a red box), and 'Compliance' (0). Below these tiles is a 'My Tasks' section with a table of monitoring tasks. The table has columns for 'Form Type', 'ECOS Ref', 'SCC Form Ref No.', 'Form Status', 'Monitor Name', 'PI/Site PI', and 'Date Sent'. A row is highlighted with a red box, showing a 'Study Closure Checklist' form with ECOS Ref 2024-3646, SCC Form Ref No. 2024-3646-Tan Tock Seng Hospital-SCC, Form Status Draft, Monitor Name A/Prof TTSH_Monitor1, PI/Site PI A/Prof TTSH_NewPI3, and Date Sent 11-Nov-2024. A 'View' button (highlighted with a red box and a green '6') is located at the end of this row. A green '3' is next to 'My Tasks' in the left panel, a green '4' is next to the 'Monitoring' tile, and a green '5' is next to the 'PI/Site PI (1)' link in the table header.

ECOS

Dashboard

Homepage

Dashboard

My Tasks

My Notices

IRB

CRMS

Compliance

Monitoring

My Issue

Plan Review

Study Monitoring Information

Study Closure Checklist

IRB

CRMS

FCOI

Monitoring

Compliance

My Tasks

Responsible Person (0)

Plan Reviewer (0)

PI/Site PI (1)

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

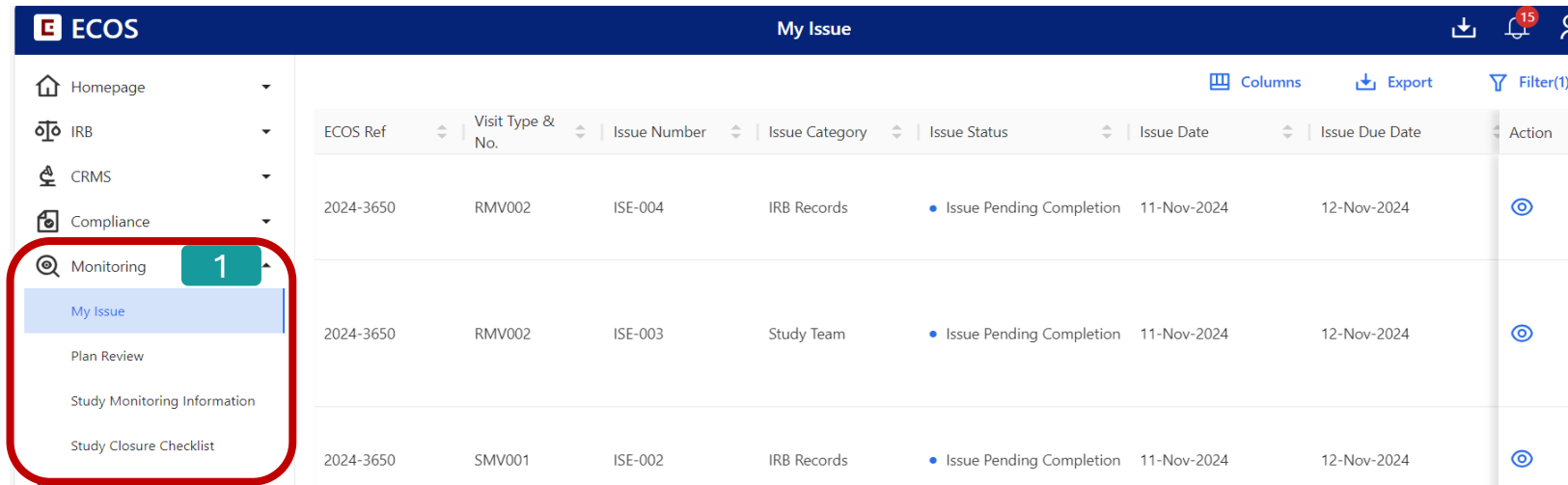
View

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

Via Monitoring >



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	

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

ECOS

Study Monitoring Information

Download

99+

User

Homepage

IRB

CRMS

Compliance

Monitoring

My Issue

Plan Review

Study Monitoring Information

Study Closure Checklist

Columns

Export

Filter

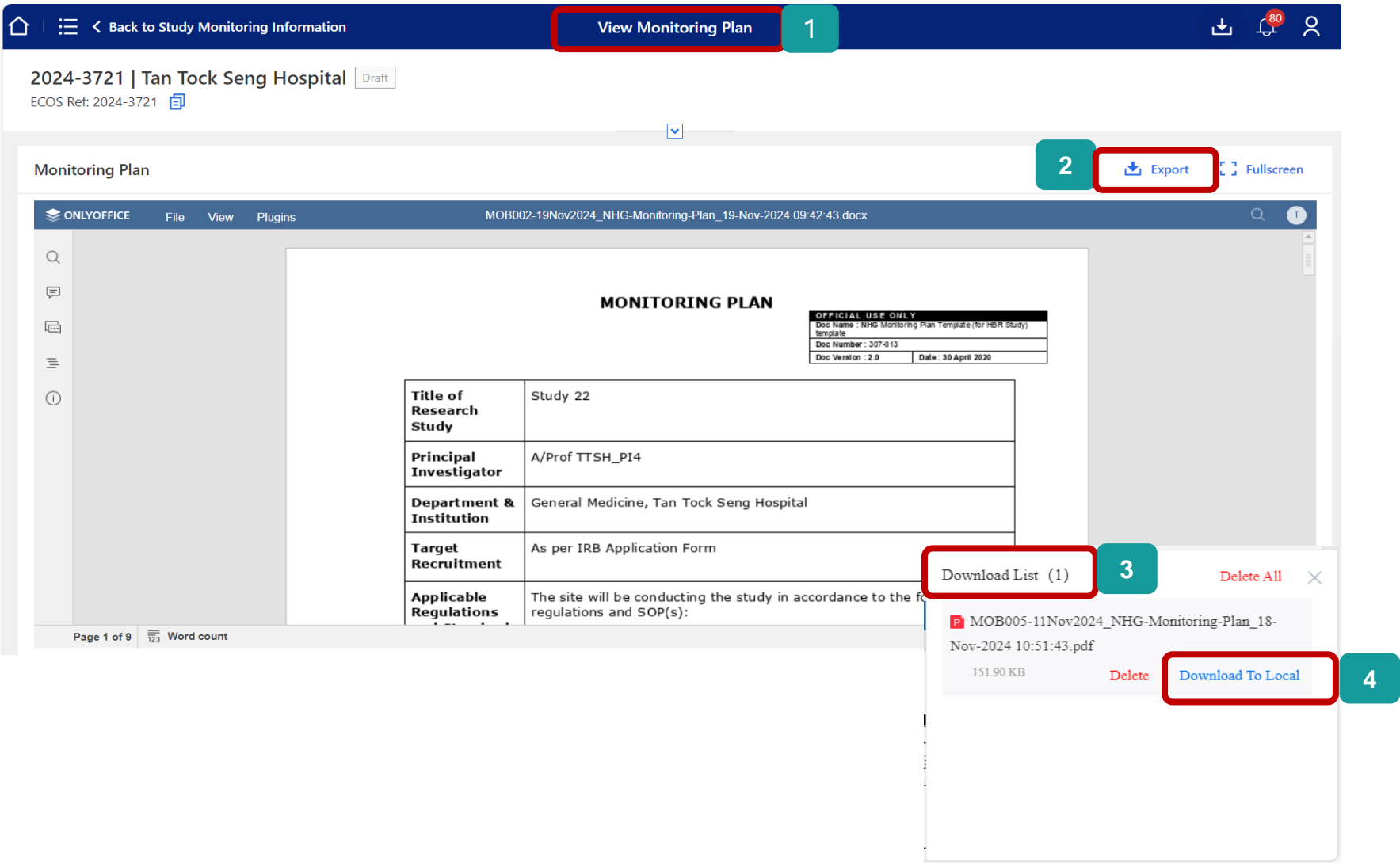
Monitoring Category	ECOS Ref	Study Site	PI/Site-PI	Current Study Site Status	Action
NHG 3A	2024-3649	Khoo Teck Puat Hospital	A/Prof KTPH_PI3	• Ongoing (Last Participant Last Visit Completed, On Data Analysis Ongoing)	<div>View Plan</div>
NHG 3A	2024-3645	Khoo Teck Puat Hospital	A/Prof KTPH_PI3	• Ongoing with active enrolment	<div>View Plan</div>
NHG 3A	2024-3645	Khoo Teck Puat Hospital	A/Prof KTPH_PI3	• Ongoing with active enrolment	<div>View Plan</div>
NHG 3A	2024-3644	Khoo Teck Puat Hospital	A/Prof KTPH_PI3	• Ongoing (Last Participant Last Visit Completed, On Data Analysis Ongoing)	<div>View Plan</div>

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



- 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

Homepage

IRB

CRMS

Compliance

Monitoring

My Issue


Plan Review

Study Monitoring Information

Study Closure Checklist

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_P13	Ongoing (Last Participa Last Visit Completed, Only Data Analysis Ongoing)	<div>5</div>
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).

Back to Study Monitoring Information

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

Plan Visit

Confirmation Letter

Monitoring Report

Issue List

Follow-up Letter

Completed

RMV001

Plan Visit

Confirmation Letter

Monitoring Report

Completed

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

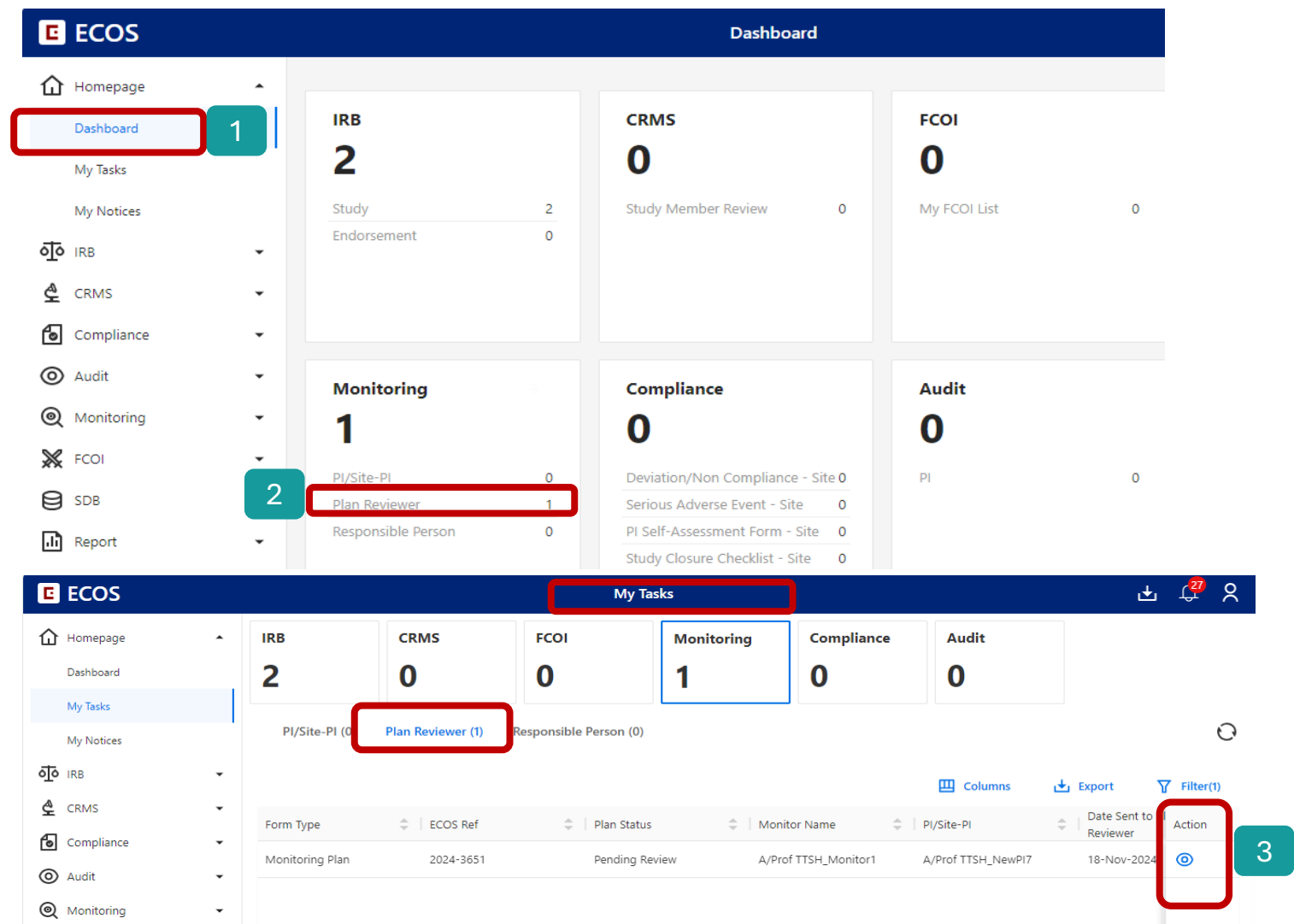
Remarks:

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

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)

ECOS

Plan Review

ColumnsExportFilter(1)

Homepage

IRB

CRMS

Compliance

Audit

Monitoring

My Issue

Plan Review

Study Monitoring Information

Study Closure Checklist

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	

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**.

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

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: -

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 × Close Query

QUERY1
 Test document_for uploading.pdf
 Query Round 1 A/Prof TTSH_NewPI7 18-Nov-2024 10:00:48

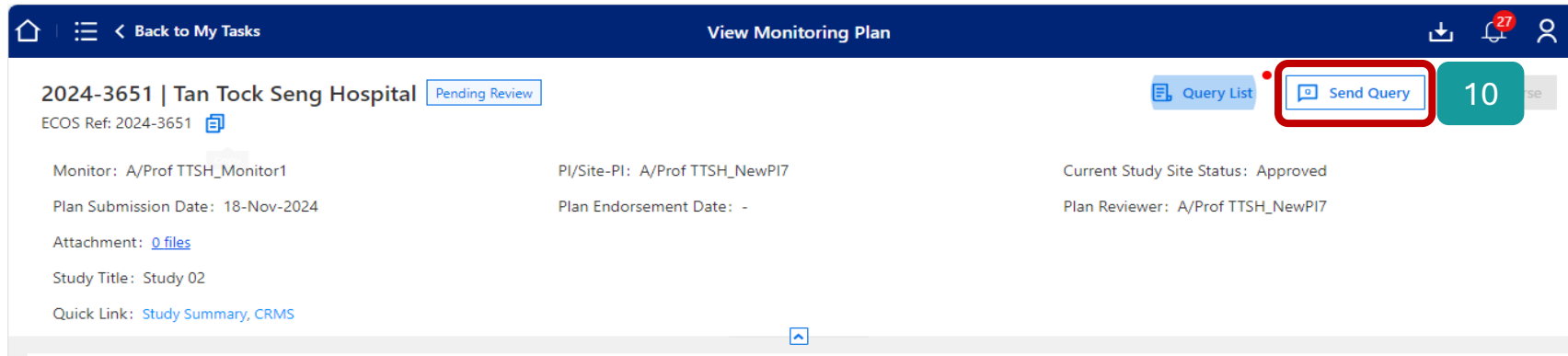
Reply to query
 Query Round 1 A/Prof TTSH_Monitor1 18-Nov-2024 10:05:01

☐ General Query Description
 Please update Training information

Attachment Upload

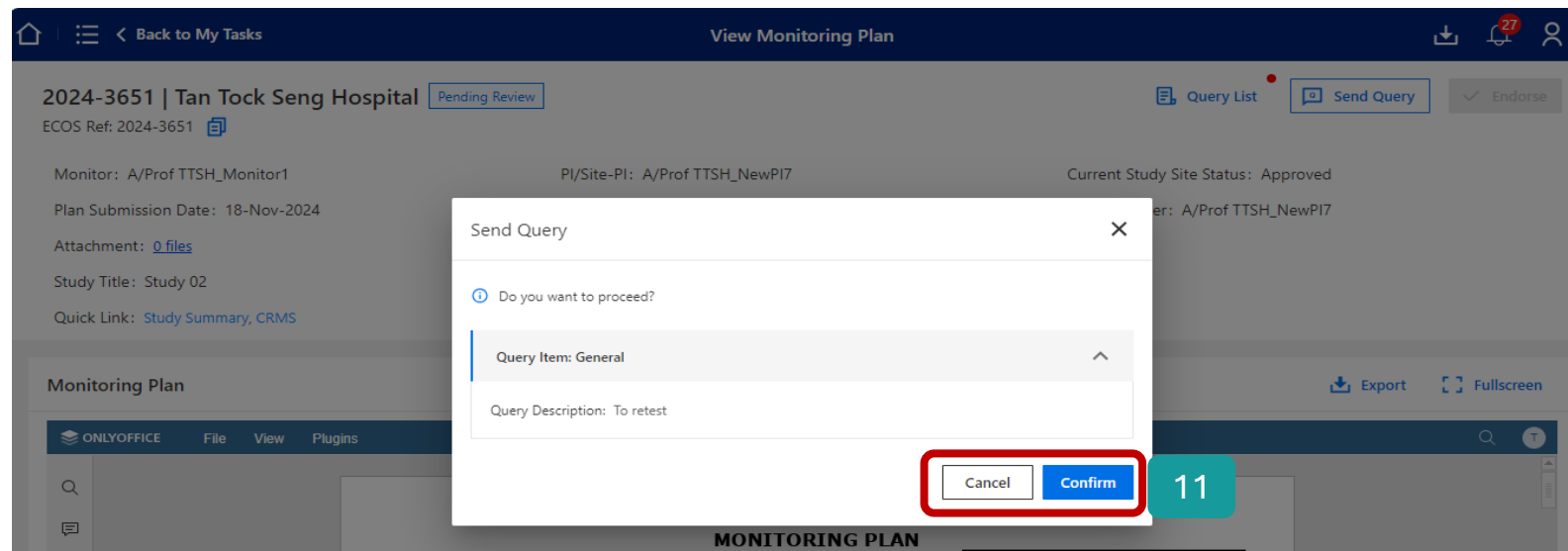
- Click on the background page to close the query sliding window.

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

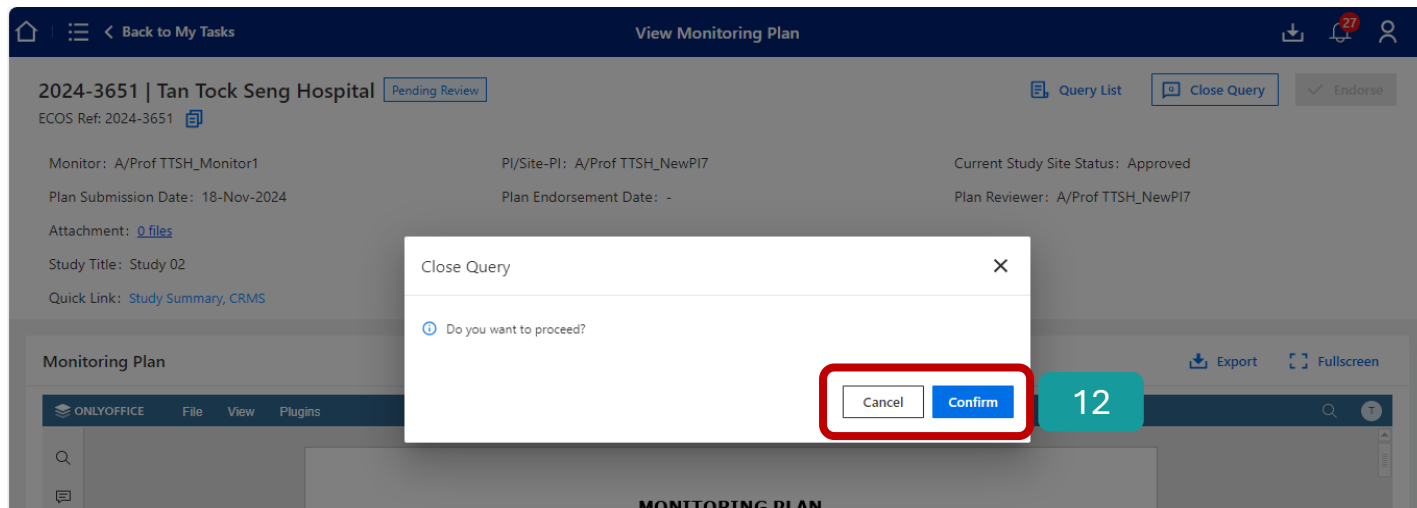


10. If there are outstanding query(ies) to the Monitor, the “**Send Query**” button will be activated. Click on “Send Query”.

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.

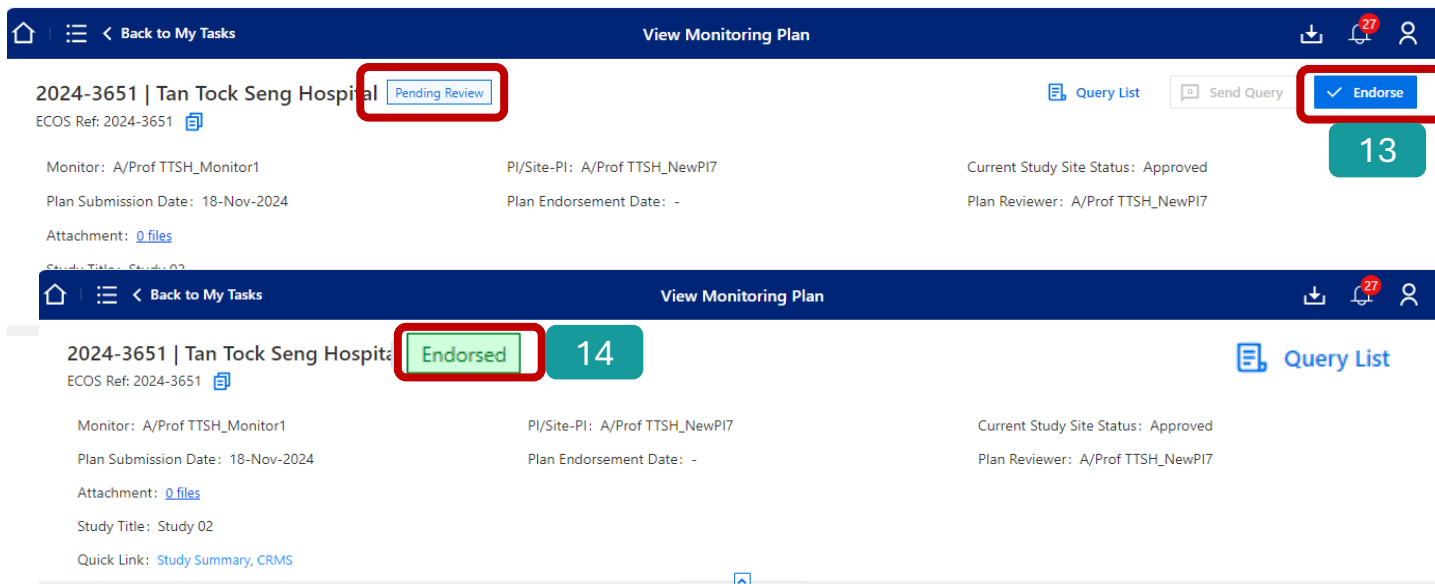


4) How to Query and Endorse the Monitoring Plan (MP)



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.

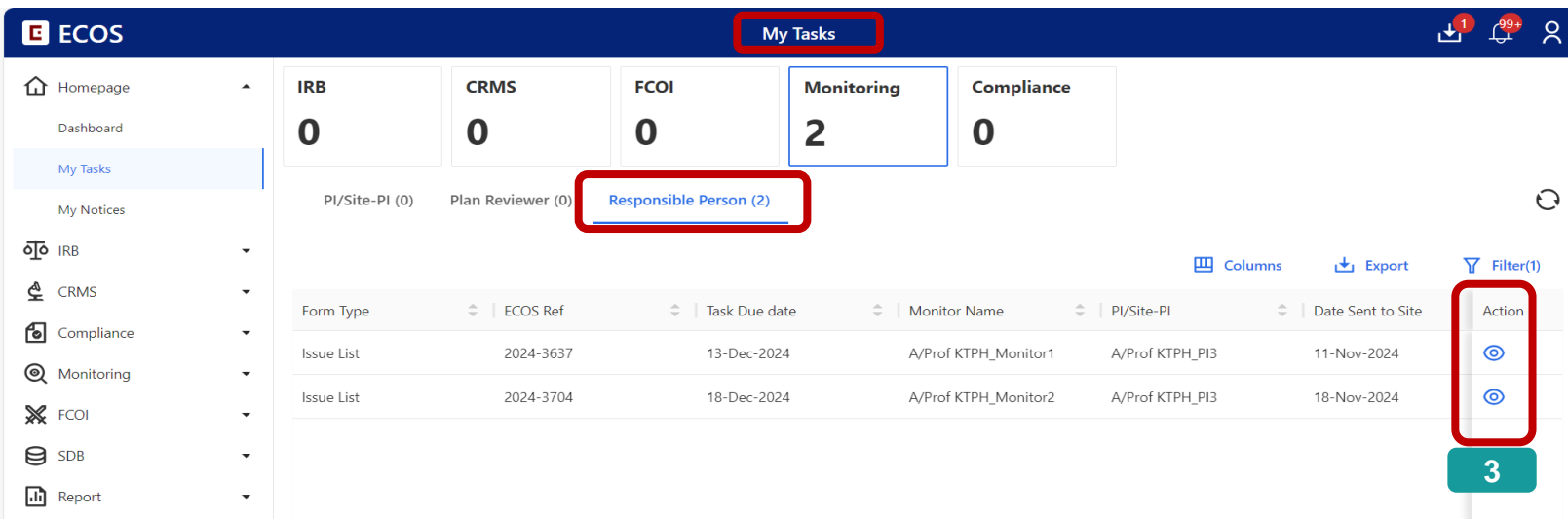
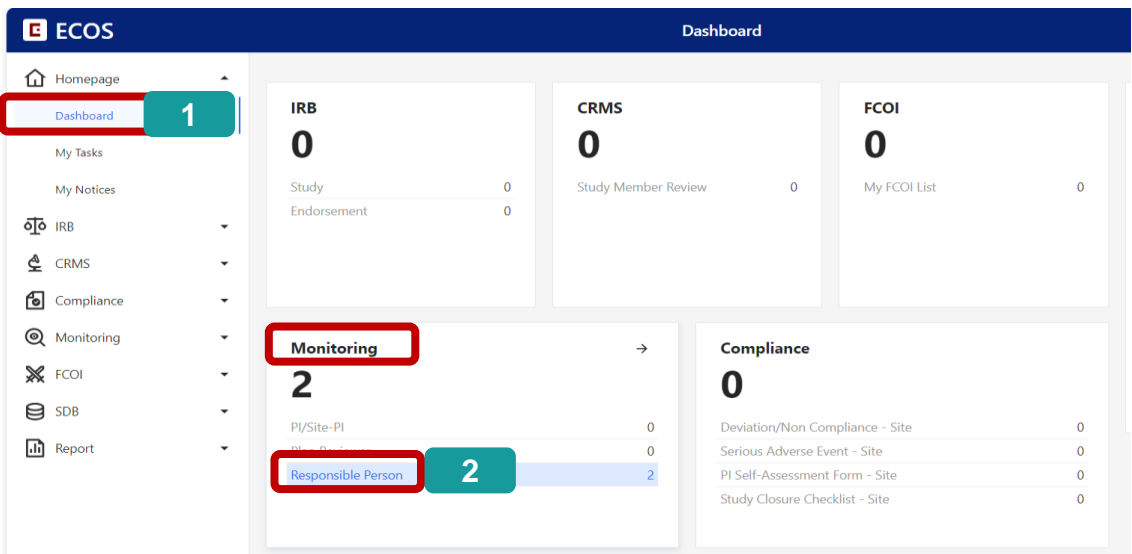
13. To proceed to endorse the MP, click on the **“Endorse”** button.



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

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.

ECOS

My Issue

ColumnsExportFilter(1)

Homepage

IRB

CRMS

Compliance

Monitoring

My Issue

Plan Review

Study Monitoring Information

Study Closure Checklist

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	

Back to My Issue

Issue Detail

Submit

Monitoring Information

Issue Information

Study Title: Study 18

ECOS Ref: 2024-3705

Visit Type & No.: Ad-Hoc RMV001

PI/Site-PI: A/Prof TTSH_P14

Monitoring Category: NHG 3A

Study Site: Tan Tock Seng Hospital

Monitor: A/Prof TTSH_Monitor1

Issue Item

Issue Date

Responsible Person

Monitor Comment

Issue Category

Issue Due Date

CAPA Needed

Issue Description

Issue Closure Date

Recommendation

5) How to Respond to Issue

The screenshot shows the 'Issue Detail' page for ISE-010. The page is divided into several sections: 'Monitoring Information', 'Issue Information', and 'Corrective Action Preventive Action'. The 'Issue Information' section contains fields for 'Issue Item', 'Issue Category', 'Issue Description', 'Issue Due Date', 'Issue Closure Date', 'Responsible Person', 'CAPA Needed', and 'Recommendation'. The 'Corrective Action Preventive Action' section contains a 'Root Cause' field and a 'Corrective Actions' field. A red box highlights the 'Submit' button in the top right corner, and a green box highlights the 'Edit' button in the bottom right corner. A large green arrow points from the 'Edit' button to the 'Corrective Action Preventive Action' section.

ISE-010 Issue Pending Completion

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
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 on-site remote monitoring?

Issue Category
Safety Reporting

Issue Description
Please confirm

Issue Due Date
06-Nov-2024

Issue Closure Date
13-Dec-2024

Responsible Person
A/Prof KTPH_P13

CAPA Needed
Yes

Recommendation

Monitor Comment

Corrective Action Preventive Action

Root Cause ⓘ

Corrective Actions ⓘ

Preventive Actions ⓘ

CAPA Completion Date: ⓘ Attachment

Select date 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.

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

The screenshot illustrates the process of viewing and replying to a CAPA query. It features two overlapping windows. The background window is the 'Issue Detail' page for 'ISE-006', which has a 'Query Pending Reply' status. A red box highlights the 'Query List' button in the top right, with a green callout '5' pointing to it. Another red box highlights the 'Reply Query' button next to it, with a green callout '2' pointing to it. The foreground window is the 'Query List' modal, showing a 'Pending Query' tab (highlighted with a red box and green callout '3') and an 'All Query' tab. It lists 'Query 1 (Monitor do not close)' with a status of 'Pending'. A red box highlights the 'Reply Query' button in the modal, with a green callout '4' pointing to it. A 'Reply Query' pop-up window is also shown, asking for confirmation to proceed, with a red box highlighting it and a green callout '1' pointing to the 'Confirm' button. The pop-up shows the query details and a 'Confirm' button.

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'. The monitoring information section includes the following details:

Field	Value
Study Title	Study 41
ECOS Ref	2024-3815
Visit Type & No.	RMV001
PI/Site-PI	A/Prof TTSH_P14
Monitoring Category	NHG 3A
Study Site	Tan Tock Seng Hospital
Monitor	A/Prof TTSH_Monitor1

The bottom screenshot shows the 'Track Changes' modal for ISE-006. The modal displays the current version (05-Dec-2024 14:20:01 ISE-006) and the previous version (02-Dec-2024 11:24:39 ISE-006). The modal includes sections for Root Cause, Corrective Actions, and Preventive Actions.


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)

The screenshot shows the ECOS Dashboard with the following components:

- Left Sidebar:** Contains navigation links. 'Dashboard' is highlighted with a red box and a green circle labeled '1'. Below it, 'My Tasks' is also highlighted with a red box.
- Dashboard Tiles:** Displays counts for various categories. The 'Monitoring' tile, which shows a count of 8, is highlighted with a red box. Below it, the 'PI/Site-PI' link is highlighted with a red box and a green circle labeled '2'.
- My Tasks Section:** At the bottom, the 'My Tasks' header is highlighted with a red box. Below it, the 'PI/Site-PI (3)' link is highlighted with a red box.
- Table:** A table titled 'Study Closure Checklist' is shown. It has columns: Form Type, ECOS Ref, SCC Form Ref No., Form Status, Monitor Name, PI/Site-PI, and Action. The 'Action' column contains 'View' icons (eye in a circle). The first 'View' icon is highlighted with a red box and a green circle labeled '3'.

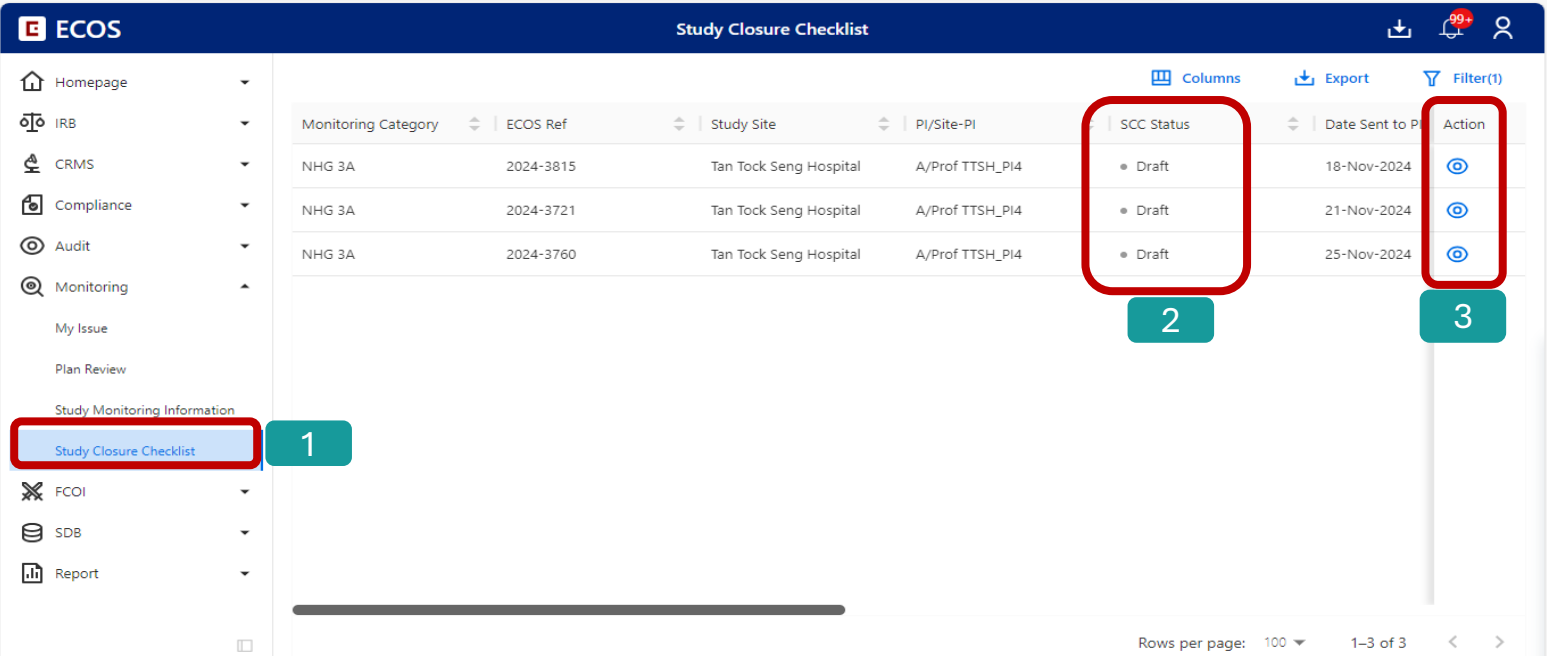
Via Dashboard > My Tasks

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)

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

Quick Link: Study Summary, CRMS

3

4

Edit

Study Closure Checklist (SCC)

Export

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)

< Back to My Tasks

Study Closure Checklist Detail

Download

Notification

User

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

2

3

Study Closure Checklist (SCC)

X 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:

0 characters entered

Attachment(s)

Upload

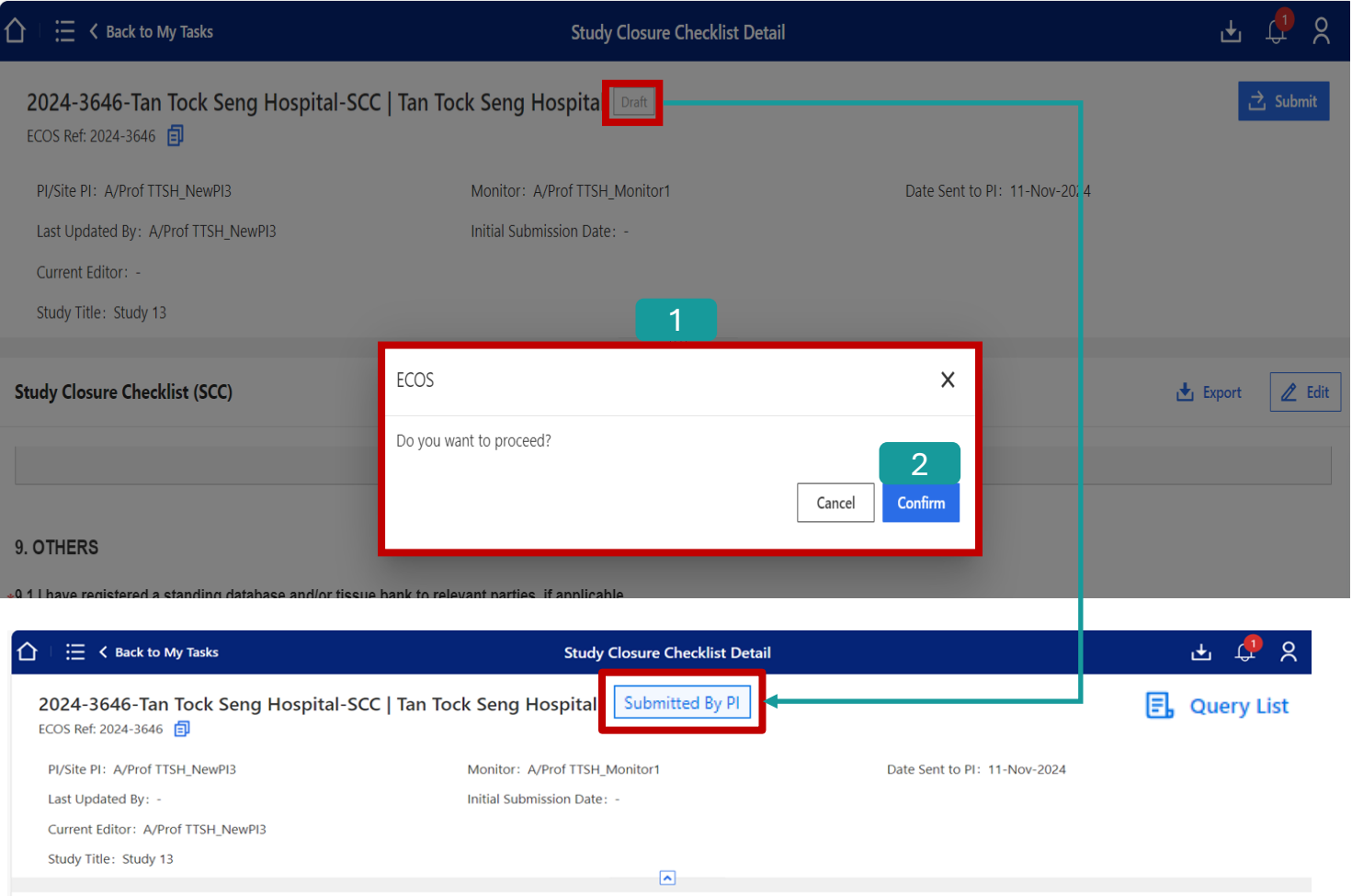
1. Scroll down to complete the rest of the SCC form. Fields marked with * are **mandatory** for completion.
2. Click on “**Save**” to ensure the edits have been saved successfully.
3. Click on “**Save and Exit**” to exit editing mode.

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

The screenshot displays the 'Study Closure Checklist Detail' form. At the top, a green notification bubble states 'Saved successfully!'. The form title is '2024-3646-Tan Tock Seng Hospital-SCC | Tan Tock Seng Hospital'. Below the title, there are fields for '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'. A green box labeled '1' highlights the 'Submit' button, which is currently grey. A green arrow points to the right, where a second green box labeled '2' highlights the 'Submit' button, which is now blue and active. The bottom section of the form is titled 'Study Closure Checklist (SCC)' and contains a question: '9. OTHERS' followed by '*9.1 I have registered a standing database and/or tissue bank to relevant parties, if applicable.' with radio buttons for 'Yes' (selected) and 'NA'. At the bottom right, there are buttons for 'Cancel', 'Save', and 'Save and Exit'.

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)



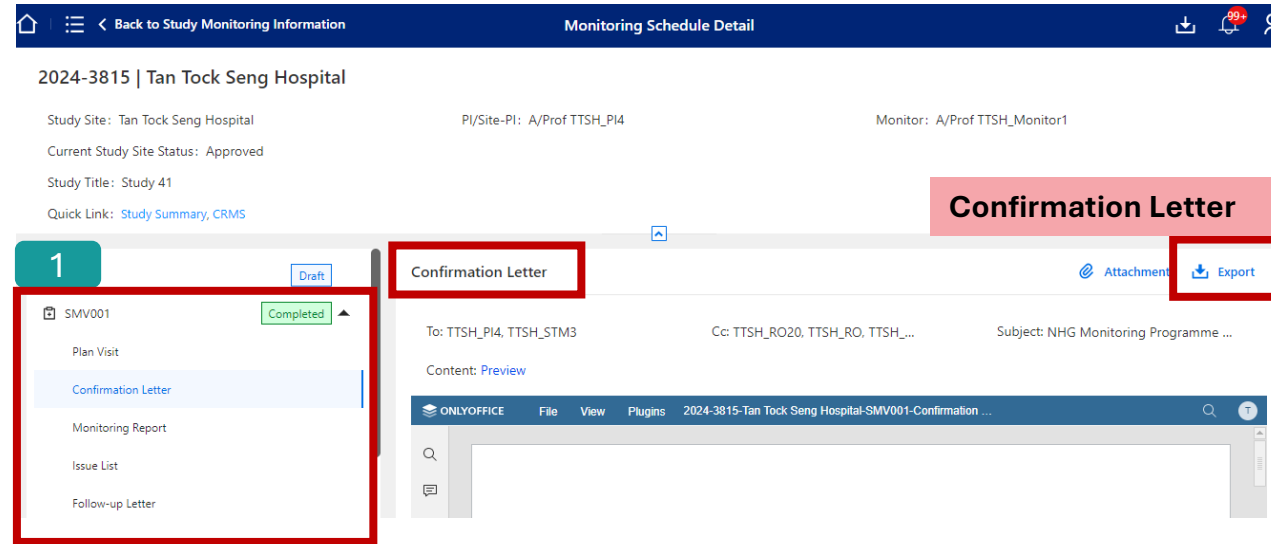
1. After the PI clicks on the “**Submit**” button, a **pop-up window** will appear for the user’s confirmation to proceed with the task. Click on “**Confirm**” to proceed or “**Cancel**” to return to the Study Closure Checklist Detail page.
2. Click “**Confirm**” to proceed with the submission. The label 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**.

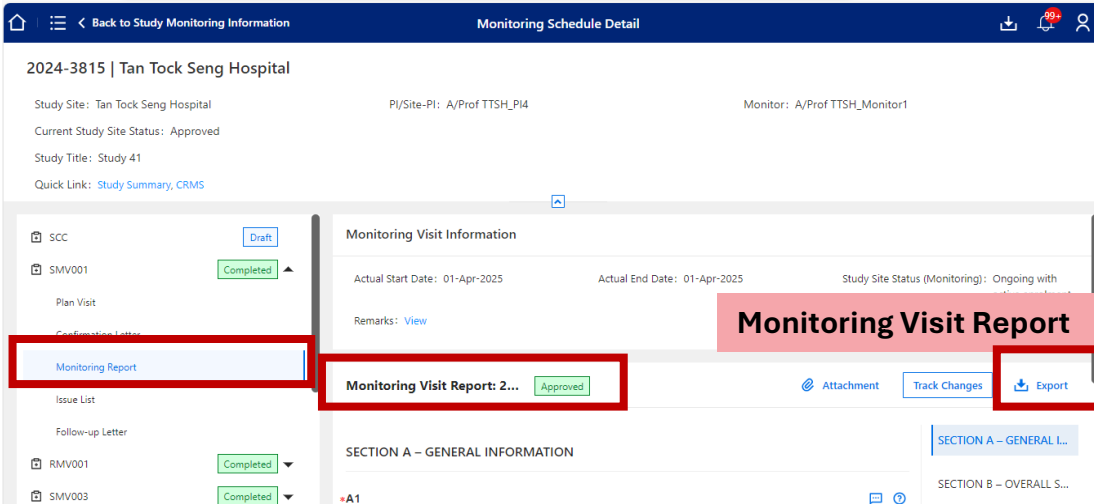
The monitoring of the study is now **complete**.

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



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.

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

The screenshot displays the 'Monitoring Schedule Detail' page for study 2024-3815 at Tan Tock Seng Hospital. The page shows details for a 'Follow-up Letter' document. A red box highlights the 'Follow-up Letter' tab in the left sidebar. Another red box highlights the 'Export' button in the top right corner of the document preview area. Below the document preview, a 'Download List (3)' is shown, with a red box highlighting the 'Download To Local' button for the first item, '2024-3815-Tan Tock Seng Hospital-SMV001-Follow-up Letter 02-Dec-2024 11:35:21.pdf'. A green box with the number '3' is placed next to the 'Download List (3)' header, and a green box with the number '4' is placed next to the 'Download To Local' 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

Follow up Letter

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 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 4

SMV Report Template.pdf

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.

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

Home

Back to Study Monitoring Information

Monitoring Schedule Detail

Download

99+

User

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](#)

SCC

Draft

SMV001

Completed

Plan Visit

Confirmation Letter

Monitoring Report

Issue List


Follow-up Letter


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.

 Issue List 04-Dec-2024.xlsx

Content scan completed

Download

5

Download Original

Safe Download (PDF)

6

Sheet1

Issue List

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 Date
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 (302-Dec	
ISE-004	General	Query Pending Reply	Dr TTSH_STM3	Study Team	Issue 4	Monitor queries issue CAPA (302-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