

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)

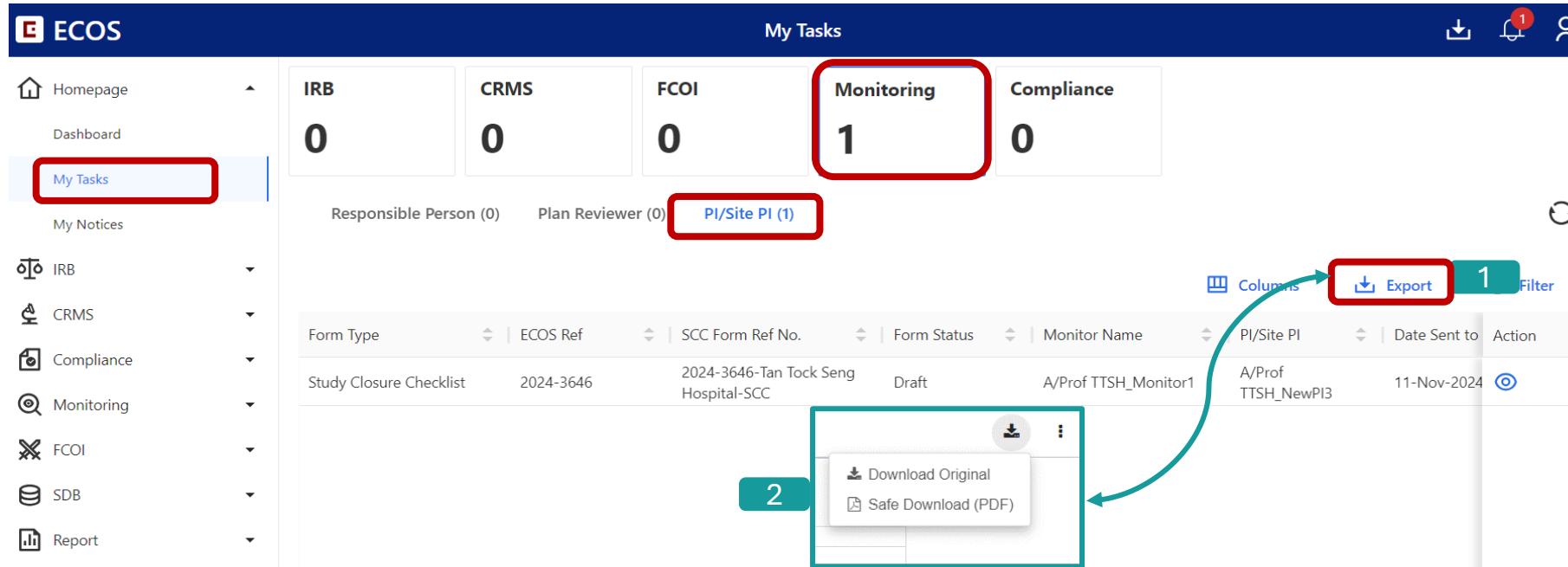
1. Monitoring Module General Interface
2. How to Locate the Monitoring Task
3. How to View and Access Study Monitoring Information
4. How to Query and Endorse Monitoring Plan (MP)
5. How to Respond to Issue
6. How to View/ Reply to CAPA Query
7. How to View/Edit/Submit Study Closure Checklist (SCC)
8.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

1) Monitoring Module General Interface - Columns

The screenshot shows the ECOS Monitoring Module General Interface. The top navigation bar includes 'ECOS', 'My Tasks' (highlighted with a red box), and icons for download, refresh, and user profile. Below the navigation is a summary section with tabs: IRB (0), CRMS (0), FCOI (0), Monitoring (1, highlighted with a red box), and Compliance (0). A red box highlights the 'Monitoring' tab and the '1' count. Below this, a sub-section shows 'Responsible Person (0)', 'Plan Reviewer (0)', and 'PI/Site PI (1)'. A green box highlights the 'PI/Site PI (1)' count. To the right, a modal window titled 'Column' lists 'Selected 8' columns: Form Type, ECOS Ref, SCC Form Ref No., Form Status, Monitor Name, PI/Site PI, Date Sent to PI, and Task Status. The 'PI/Site PI' column is highlighted with a red box. The 'Columns' button (highlighted with a red box) is at the top of the modal. At the bottom of the modal are 'Clear' (highlighted with a red box), 'Cancel', and 'Save' (highlighted with a red box) buttons. A green box highlights the 'Save' button. The bottom left of the interface has a note: '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)

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_Monitor1

PI/Site PI Date Sent to Action

A/Prof TTSH_NewPI3 11-Nov-2024

Export Filter

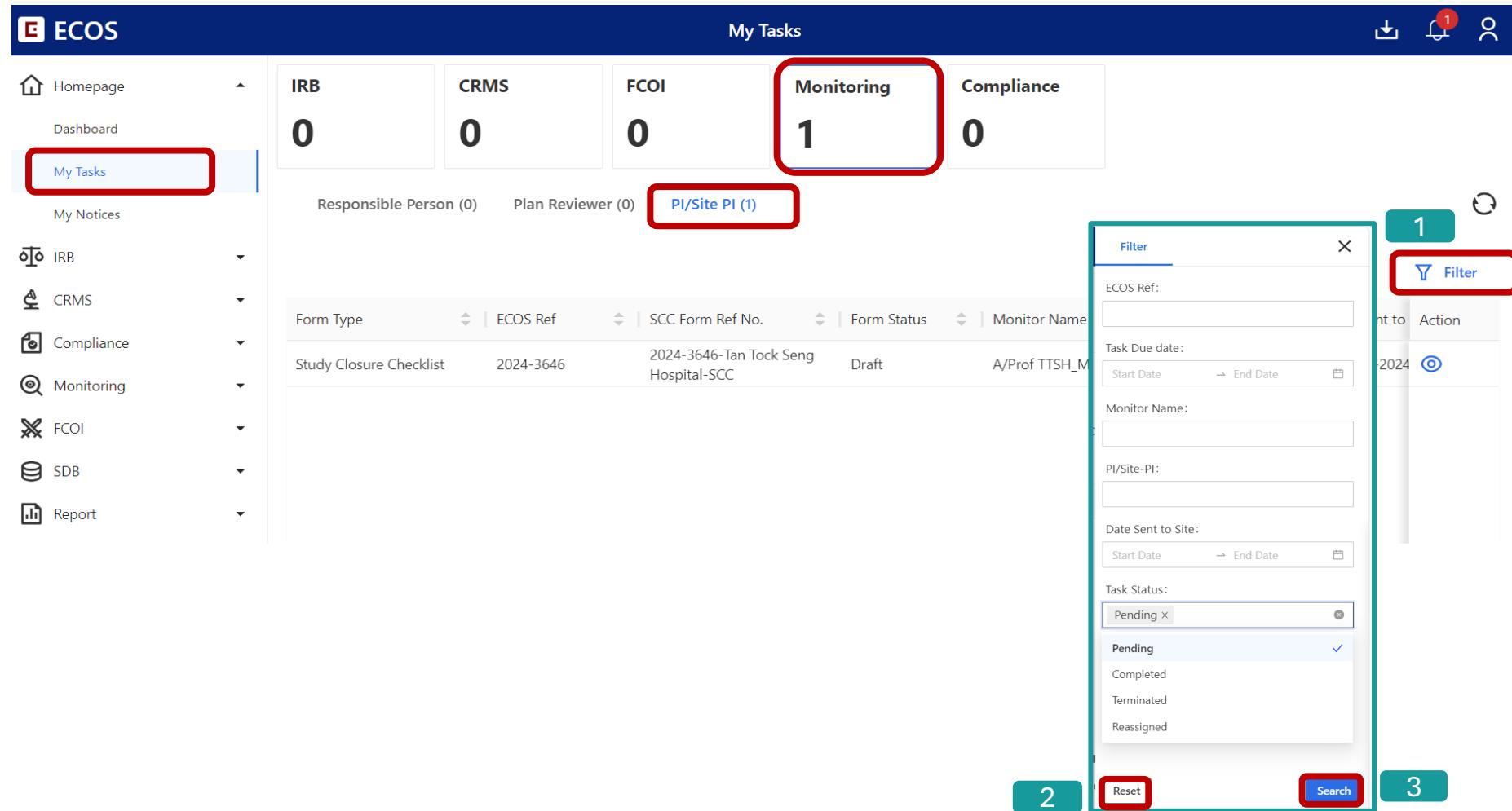
Download Original

Safe Download (PDF)

PI/Site PI							
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 Hos	Draft	A/Prof TTSH_Monitor1	A/Prof TTSH_NewPI3	11-Nov-2024	Pending

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.

1) Monitoring Module General Interface – Filter



The screenshot shows the ECOS Monitoring Module General Interface. The top navigation bar includes 'ECOS', 'My Tasks' (highlighted with a red box), 'Dashboard', 'My Notices', and links for 'IRB', 'CRMS', 'FCOI', 'Monitoring' (highlighted with a red box), and 'Compliance'. The 'Monitoring' section shows 1 task. Below this, a 'My Tasks' summary shows 0 for IRB, CRMS, FCOI, and Compliance, and 1 for Monitoring. A sub-section shows 0 Responsible Persons and 1 Plan Reviewer (highlighted with a red box). A 'PI/Site PI (1)' link is also highlighted with a red box. The main content area displays a 'Study Closure Checklist' for '2024-3646-Tan Tock Seng Hospital-SCC' in 'Draft' status, assigned to 'A/Prof TTSH_M'. 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 a 'Filter' button (highlighted with a red box), a 'Reset' button (highlighted with a red box), and a 'Search' button (highlighted with a red box). A green box labeled '1' is positioned above the dialog box.

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

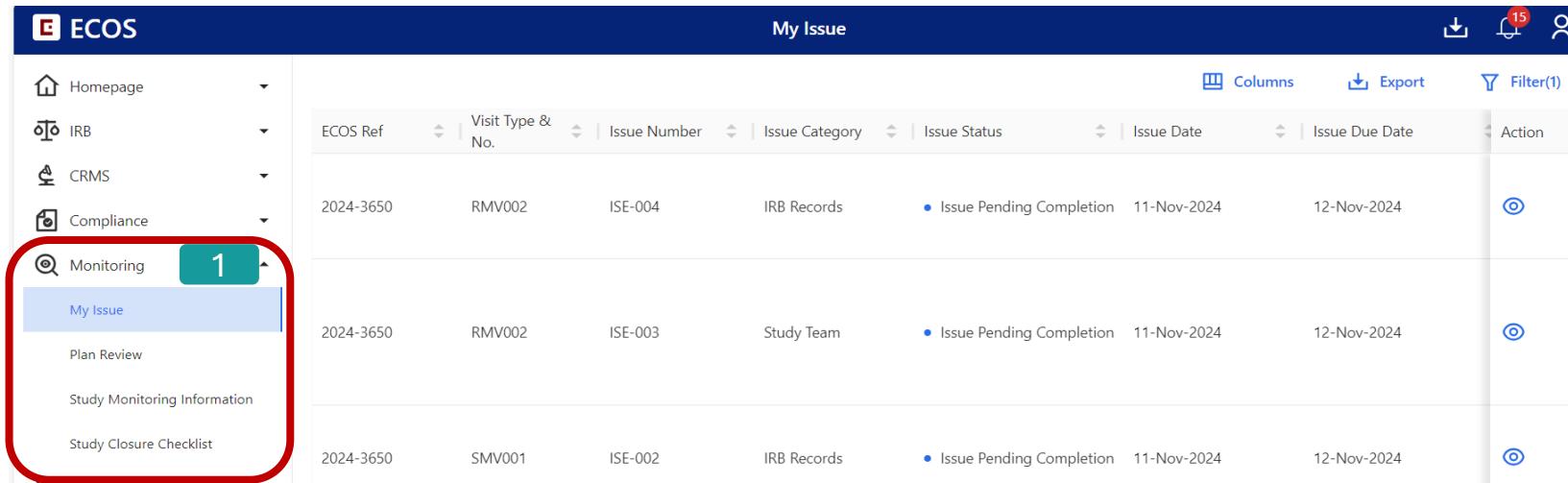
The image consists of two screenshots of the ECOS system interface. The top screenshot shows the 'Dashboard' page with a 'Monitoring' tile highlighted. The bottom screenshot shows the 'My Tasks' table, where a monitoring task is listed under the 'PI/Site PI' sub-header. Both screenshots include numbered callouts (1-6) pointing to specific UI elements.

- 1. Dashboard button in the left navigation panel.
- 2. Monitoring tile in the dashboard.
- 3. My Tasks button in the left navigation panel.
- 4. Monitoring tile in the 'My Tasks' table.
- 5. PI/Site PI sub-header in the 'My Tasks' table.
- 6. View button in the 'Action' column of the 'My Tasks' table.

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



The screenshot shows the ECOS system interface. The left navigation panel is open, showing 'Monitoring' as the active menu with a red box and a '1' badge. Under 'Monitoring', 'My Issue' is highlighted with a blue box. Other options in the list include 'Plan Review', 'Study Monitoring Information', and 'Study Closure Checklist'. The main content area is titled 'My Issue' and displays a table of monitoring tasks. The table columns are: ECOS Ref, Visit Type & No., Issue Number, Issue Category, Issue Status, Issue Date, Issue Due Date, and Action. The table data includes:

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	①
2024-3650	RMV002	ISE-003	Study Team	• Issue Pending Completion	11-Nov-2024	12-Nov-2024	①
2024-3650	SMV001	ISE-002	IRB Records	• Issue Pending Completion	11-Nov-2024	12-Nov-2024	①

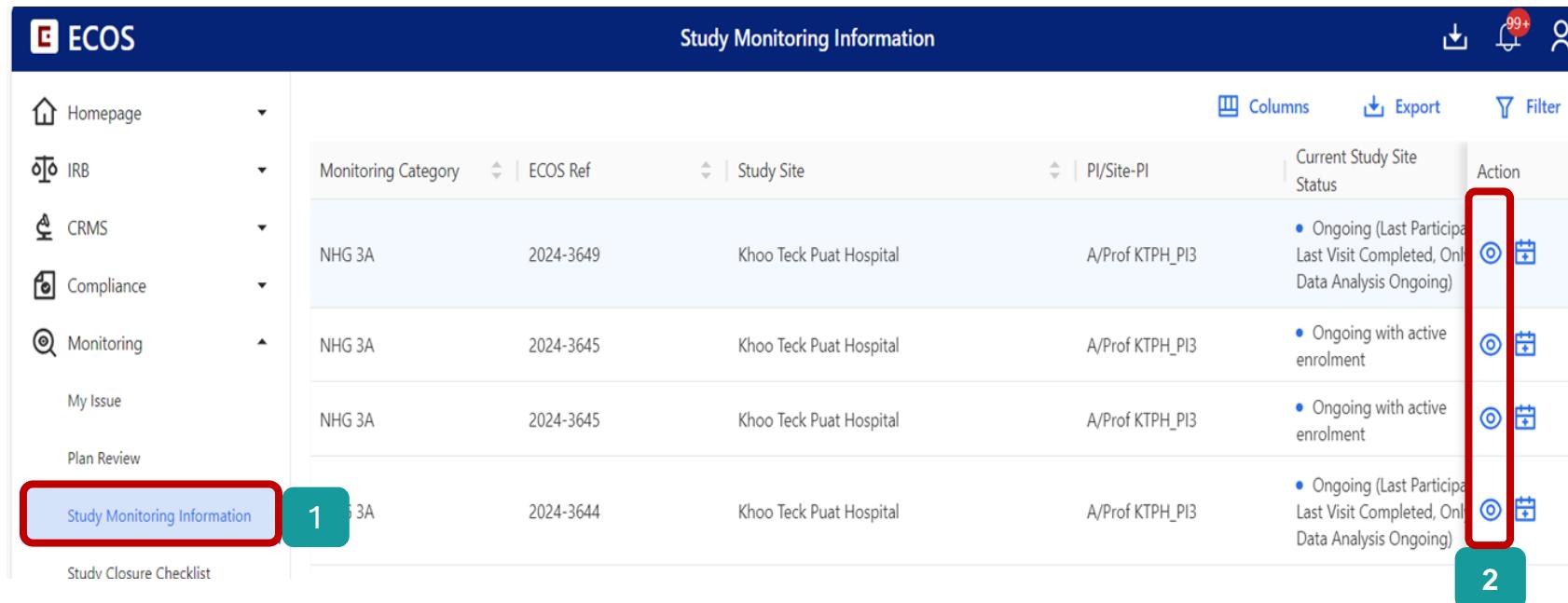
Via Monitoring >

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



Study Monitoring Information

ECOS

Homepage

IRB

CRMS

Compliance

Monitoring

My Issue

Plan Review

Study Monitoring Information

Study Closure Checklist

1

2

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	<ul style="list-style-type: none">• Ongoing (Last Participation: Last Visit Completed, Online Data Analysis Ongoing)	 
NHG 3A	2024-3645	Khoo Teck Puat Hospital	A/Prof KTPH_PI3	<ul style="list-style-type: none">• Ongoing with active enrolment	 
NHG 3A	2024-3645	Khoo Teck Puat Hospital	A/Prof KTPH_PI3	<ul style="list-style-type: none">• Ongoing with active enrolment	 
NHG 3A	2024-3644	Khoo Teck Puat Hospital	A/Prof KTPH_PI3	<ul style="list-style-type: none">• Ongoing (Last Participation: Last Visit Completed, Online 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-based application for managing study monitoring information. At the top, there is a navigation bar with a 'View Monitoring Plan' button (1) highlighted with a red box. Below the navigation bar, the study details are displayed: '2024-3721 | Tan Tock Seng Hospital' (Draft) and 'ECOS Ref: 2024-3721'. The main content area is titled 'Monitoring Plan' and shows a 'MONITORING PLAN' document. The document includes fields for '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), and 'Applicable Regulations' (The site will be conducting the study in accordance to the following regulations and SOP(s):). Above the document, there is an 'Export' button (2) with a red box around it. A 'Download List' (3) is open, showing a single PDF file: 'MOB005-11Nov2024_NHG-Monitoring-Plan_18-Nov-2024 10:51:43.pdf' (151.90 KB). The 'Download To Local' button (4) is highlighted with a red box.

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

The image shows two screenshots of the ECOS system. The top screenshot is the 'Study Monitoring Information' page, displaying a list of studies with columns for Monitoring Category, ECOS Ref, Study Site, PI/Site-PI, Current Study Site Status, and Action. The bottom screenshot is the 'Monitoring Schedule Detail' page for a specific study, showing details like Study Site, PI/Site-PI, Monitor, and a sidebar with visit types. Red boxes and numbers highlight specific features: 'Study Monitoring Information' in the left sidebar (3), the 'Monitoring Schedule Detail' tab (4), the 'Action' column in the list (5), and the sidebar on the 'Monitoring Schedule Detail' page (6).

Study Monitoring Information

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	<ul style="list-style-type: none">Ongoing (Last Participation: Last Visit Completed, Only Data Analysis Ongoing)	
NHG 3A	2024-3645	Khoo Teck Puat Hospital	A/Prof KTPH_PI3	<ul style="list-style-type: none">Ongoing with active enrolment	
NHG 3A	2024-3645	Khoo Teck Puat Hospital	A/Prof KTPH_PI3	<ul style="list-style-type: none">Ongoing with active enrolment	
NHG 3A	2024-3644	Khoo Teck Puat Hospital	A/Prof KTPH_PI3	<ul style="list-style-type: none">Ongoing (Last Participation: Last Visit Completed, Only Data Analysis Ongoing)	

Monitoring Schedule Detail

2024-3720 | Khoo Teck Puat Hospital

Study Site: Khoo Teck Puat Hospital
Current Study Site Status: Ongoing with active enrolment
Study Title: Study 21
Quick Link: Study Summary, CRMS

Plan Visit Completed

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

Venue: Please enter

Visit Agenda: Please enter

Remarks:

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

RMV001
Plan Visit
Confirmation Letter
Monitoring Report

6

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).

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

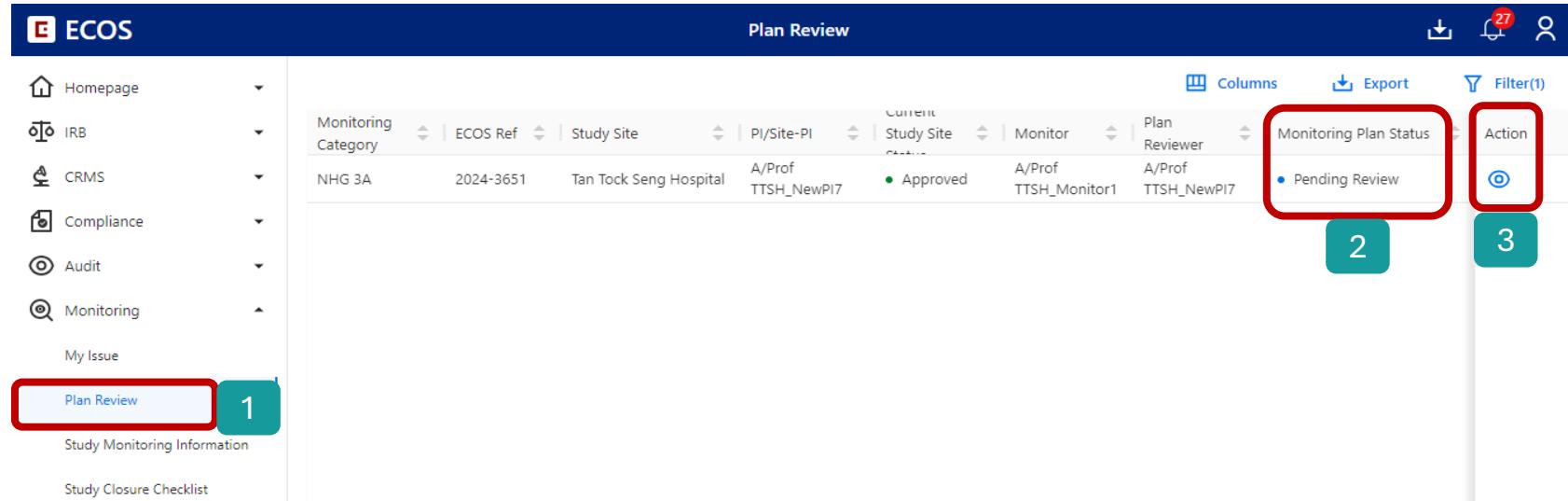
The screenshots show the ECOS dashboard and the 'My Tasks' page. The top screenshot highlights the 'Monitoring' tile, which shows 1 assigned MP for review. The bottom screenshot highlights the 'Plan Reviewer' section in the 'My Tasks' page, which shows 1 assigned MP for review. Both screenshots include a red box around the 'Plan Reviewer' section and a teal box around the 'Action' column, specifically the 'View' button.

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

Monitoring Category: NHG 3A, ECOS Ref: 2024-3651, Study Site: Tan Tock Seng Hospital, PI/Site-PI: A/Prof TTSH_NewPI7, Current Status: Approved, Monitor: A/Prof TTSH_Monitor1, Plan Reviewer: A/Prof TTSH_NewPI7

Monitoring Plan Status: Pending Review

Action: View

1

2

3

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)

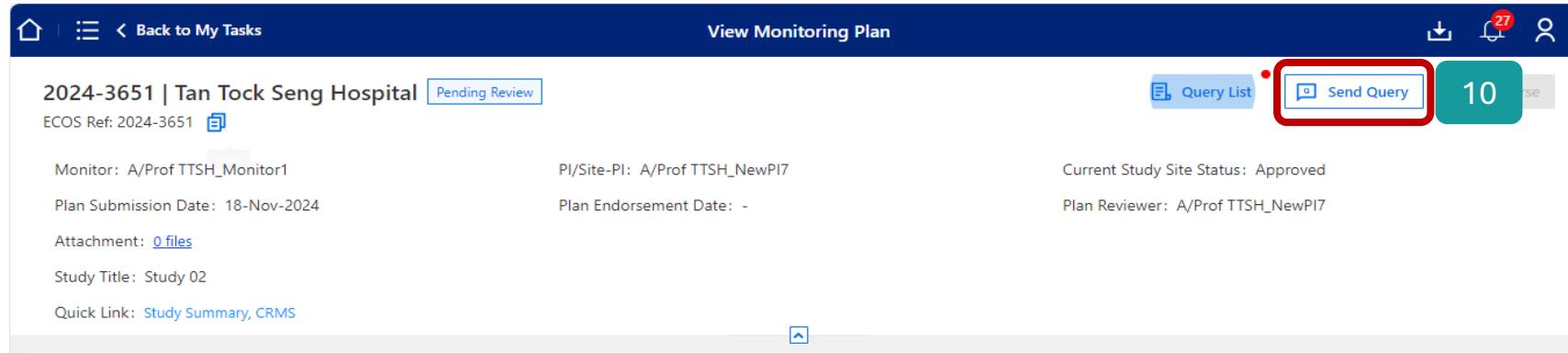
The image consists of three vertically stacked screenshots of a web-based application for viewing and managing monitoring plans. The top screenshot shows the main header 'View Monitoring Plan' and various status indicators. The middle screenshot shows a 'Query List' window with a 'Pending Query' tab and a 'General' query entry. The bottom screenshot shows a detailed view of a query entry with fields for 'Query Description' and 'Attachment'.

- 5
- 4
- 6
- 9
- 8
- 7

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.

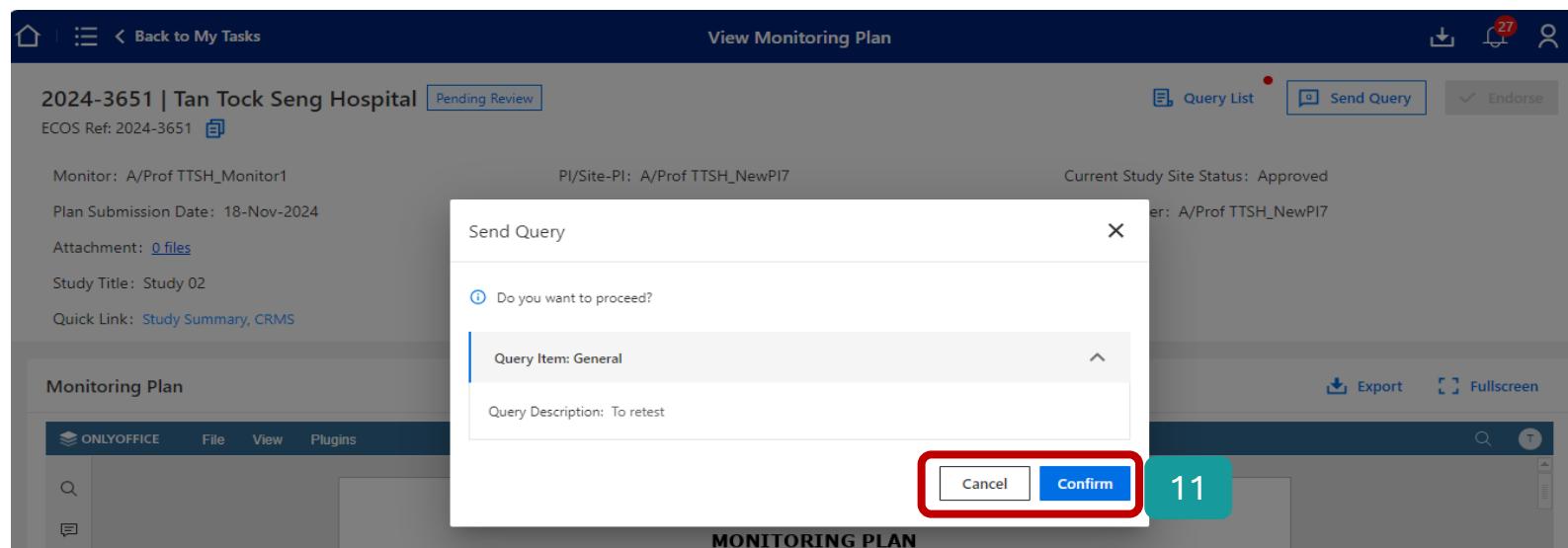
4) How to Query and Endorse the Monitoring Plan (MP)



This screenshot shows the 'View Monitoring Plan' page for study 2024-3651 at Tan Tock Seng Hospital. The page includes study details, a 'Pending Review' status, and a 'Send Query' button highlighted with a red box. A green box labeled '10' is in the top right corner.

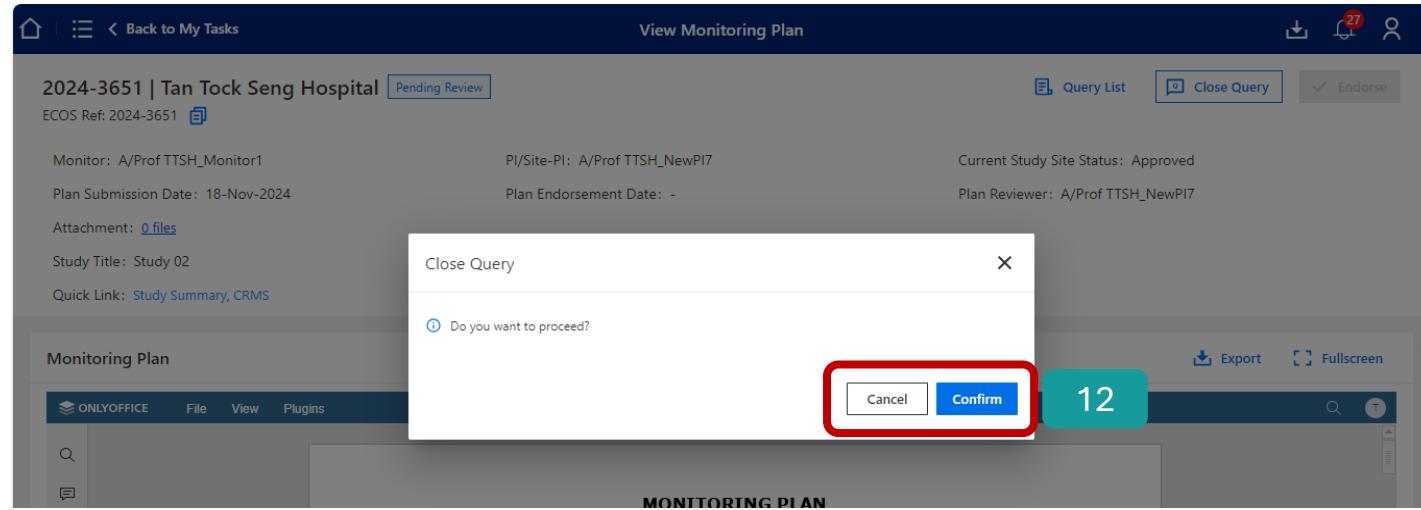
10. If there are outstanding query(ies) to the Monitor, the “Send Query” button will be activated. Click on “Send Query”.

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.

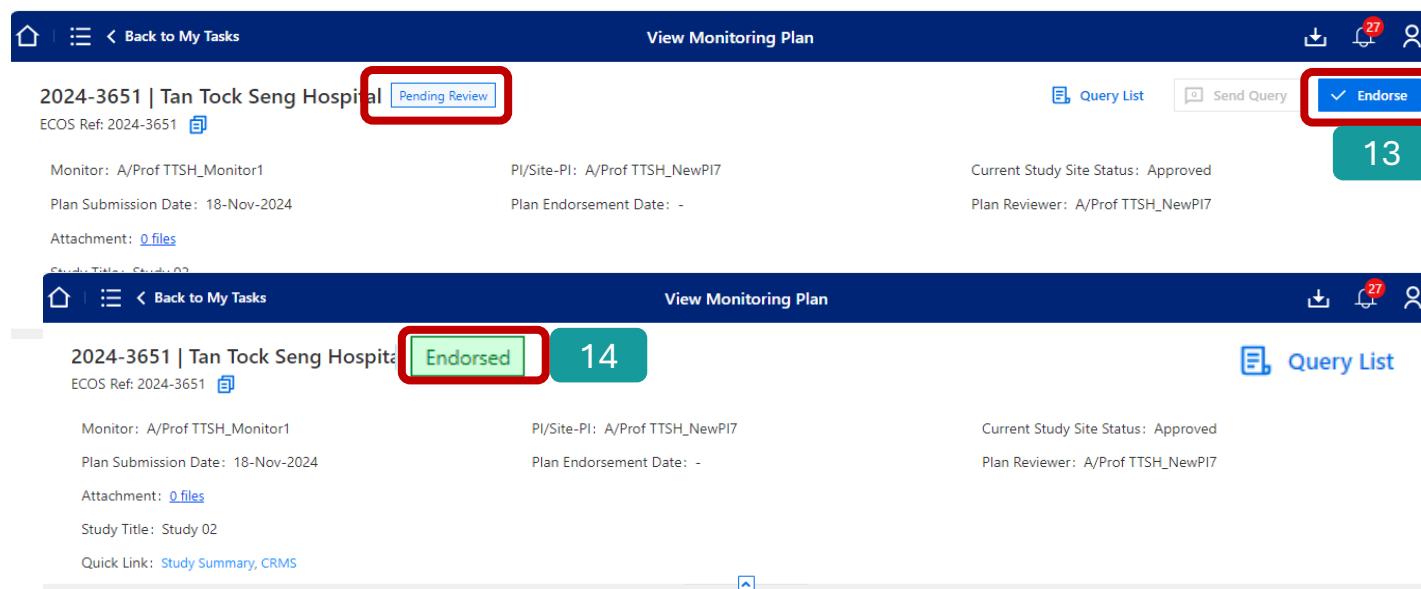


This screenshot shows a 'Send Query' pop-up window. It contains a confirmation message, a 'Query Item: General' section, a 'Query Description: To retest' field, and 'Cancel' and 'Confirm' buttons. The 'Confirm' button is highlighted with a red box. A green box labeled '11' is at the bottom center.

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 image shows two screenshots of the ECOS system. The top screenshot is the 'Dashboard' page. It features a sidebar with links like 'Homepage', 'Dashboard' (highlighted with a red box and a '1' in a teal box), 'My Tasks', 'My Notices', 'IRB', 'CRMS', 'Compliance', 'Monitoring', 'FCOI', 'SDB', and 'Report'. The main area has three tiles: 'IRB' (0 Study, 0 Endorsement), 'CRMS' (0 Study Member Review), and 'FCOI' (0 My FCOI List). Below these is a 'Monitoring' tile (2 PI/Site-PI, 0 PI-Review, 2 Responsible Person) and a 'Compliance' tile (0 Deviation/Non Compliance - Site, 0 Serious Adverse Event - Site, 0 PI Self-Assessment Form - Site, 0 Study Closure Checklist - Site). The bottom screenshot is the 'My Tasks' page. It has a similar sidebar and a header with 'My Tasks' (highlighted with a red box and a '2' in a teal box). It shows five summary boxes: 'IRB' (0), 'CRMS' (0), 'FCOI' (0), 'Monitoring' (2, highlighted with a red box and a '2' in a teal box), and 'Compliance' (0). Below is a table with two rows of data: 'Issue List' (2024-3637, 13-Dec-2024, A/Prof KTPH_Monitor1, A/Prof KTPH_PI3, 11-Nov-2024) and 'Issue List' (2024-3704, 18-Dec-2024, A/Prof KTPH_Monitor2, A/Prof KTPH_PI3, 18-Nov-2024). The table includes 'Columns', 'Export', 'Filter(1)', and an 'Action' column with two 'View' buttons (highlighted with a red box and a '3' in a teal box).

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

ECOS

My Issue

1. My Issue

2. Issue Status

3. Issue Due Date

4. Action

5. Issue Detail

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	

Issue Detail

Monitoring Information

Issue Information

Issue Item: I1.1
Issue Date: 17-Nov-2024
Responsible Person: A/Prof TTSH_PI4, Dr TTSH_C1
Monitor Comment:

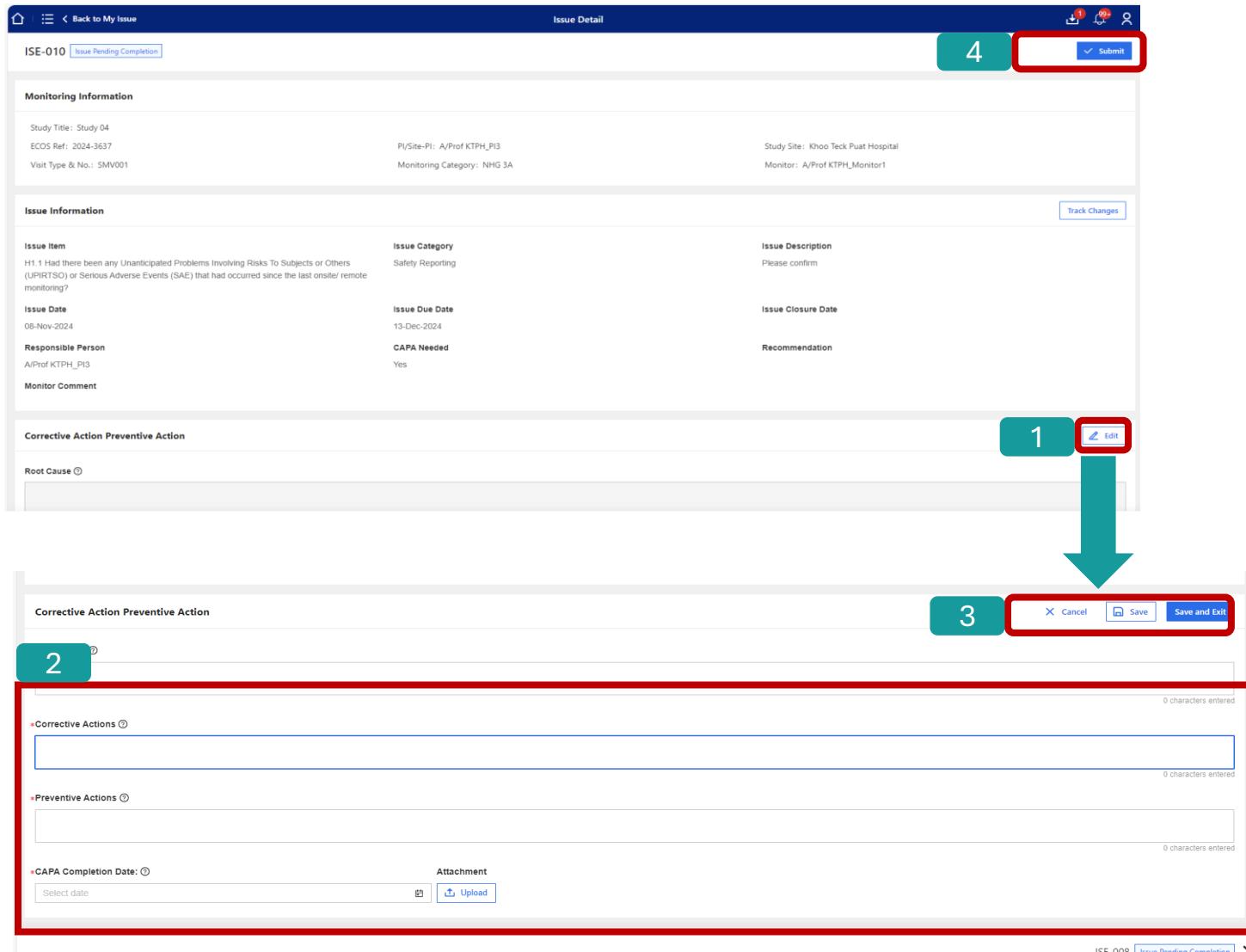
Issue Category: Other Study Supplies
Issue Due Date: 24-Nov-2024
CAPA Needed: Yes

Issue Description: Device prototype not available
Issue Closure Date:

Recommendation: TTSH_C1 to ensure that device prototype is available

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 with the following sections and data:

- Monitoring Information:** Study Title: Study 04, ECOS Ref: 2024-3637, Visit Type & No.: SMV001. PI/Site-PI: A/Prof KTPH_PI3, Monitoring Category: NHG 3A. Study Site: Khoo Teck Puat Hospital, Monitor: A/Prof KTPH_Monitor.
- Issue Information:** 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 onsite/ remote monitoring? Issue Category: Safety Reporting. Issue Description: Please confirm. Issue Due Date: 13-Dec-2024. Issue Closure Date: (empty). CAPA Needed: Yes. Recommendation: (empty). Responsible Person: A/Prof KTPH_PI3. Monitor Comment: (empty).
- Corrective Action Preventive Action:** Root Cause: (empty). Corrective Actions: (empty). Preventive Actions: (empty). CAPA Completion Date: (empty). Attachment: (empty).

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.



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 in the Clinical Research Management System (CRMS). The top section shows the 'Issue Detail' page for ISE-006, with a pending query. The bottom section shows the 'Query List' and a reply confirmation dialog.

Top Section: Issue Detail

- 1. Pending Query: ISE-006 (Query Pending Reply)
- 2. Action: Click on 'Reply Query' button.
- 3. Pending Query: 1 Pending
- 4. Confirmation Dialog: 'Do you want to proceed?' with 'Confirm' and 'Cancel' buttons.
- 5. Action: Click on 'Reply Query' button.

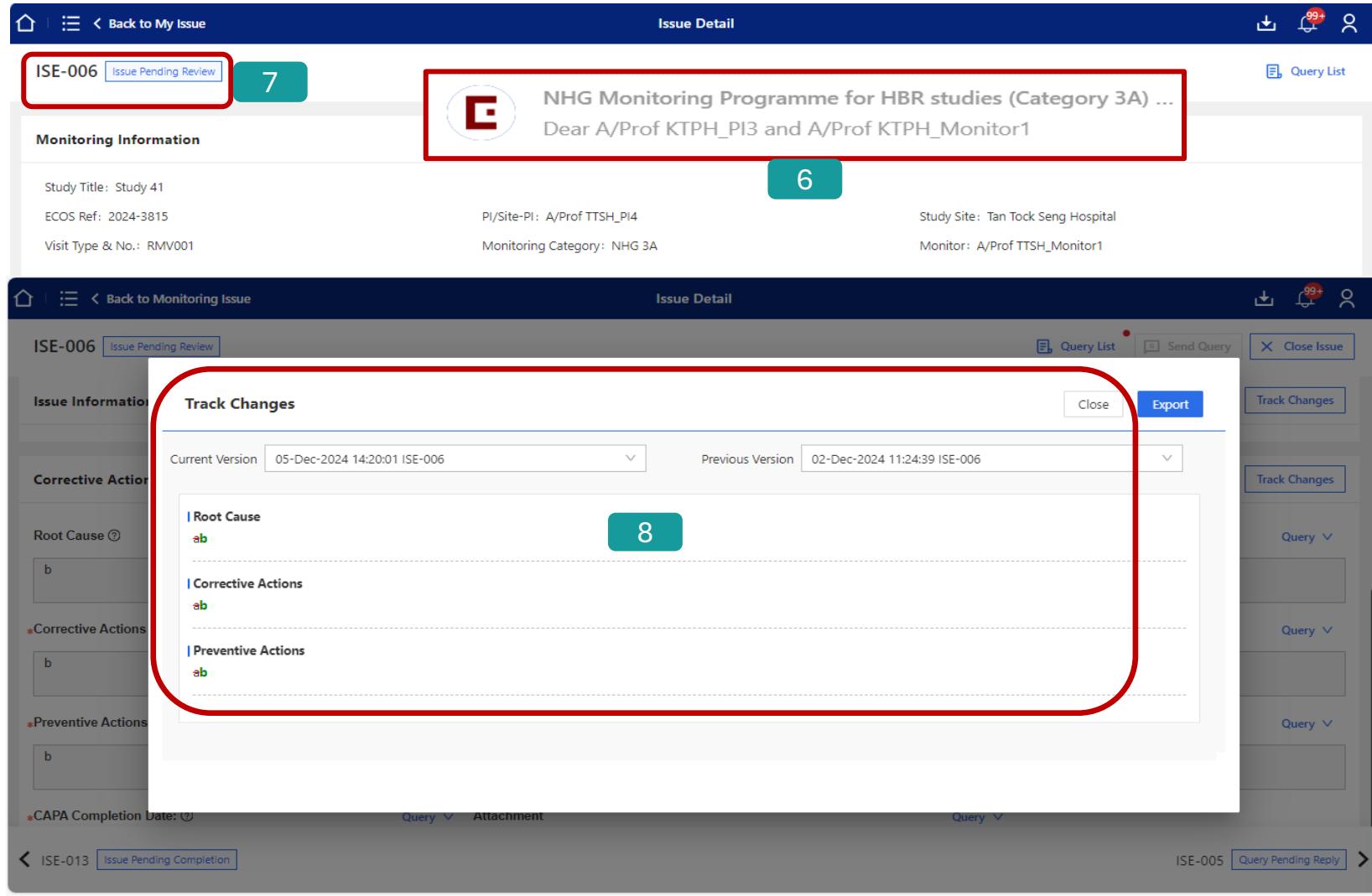
Bottom Section: Query List

- 1. Pending Query: 1 Pending
- 2. Confirmation Dialog: 'Do you want to proceed?' with 'Confirm' and 'Cancel' buttons.

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



Issue Detail

ISE-006 Issue Pending Review 7

NHG Monitoring Programme for HBR studies (Category 3A) ...

Dear A/Prof KTPH_PI3 and A/Prof KTPH_Monitor1

Monitoring Information

Study Title: Study 41

ECOS Ref: 2024-3815

Visit Type & No.: RMV001

PI/Site-PI: A/Prof TTSH_PI4

Monitoring Category: NHG 3A

Study Site: Tan Tock Seng Hospital

Monitor: A/Prof TTSH_Monitor1

Issue Detail

ISE-006 Issue Pending Review

Track Changes

Current Version 05-Dec-2024 14:20:01 ISE-006

Previous Version 02-Dec-2024 11:24:39 ISE-006

Root Cause

Corrective Actions

Preventive Actions

Query Attachment

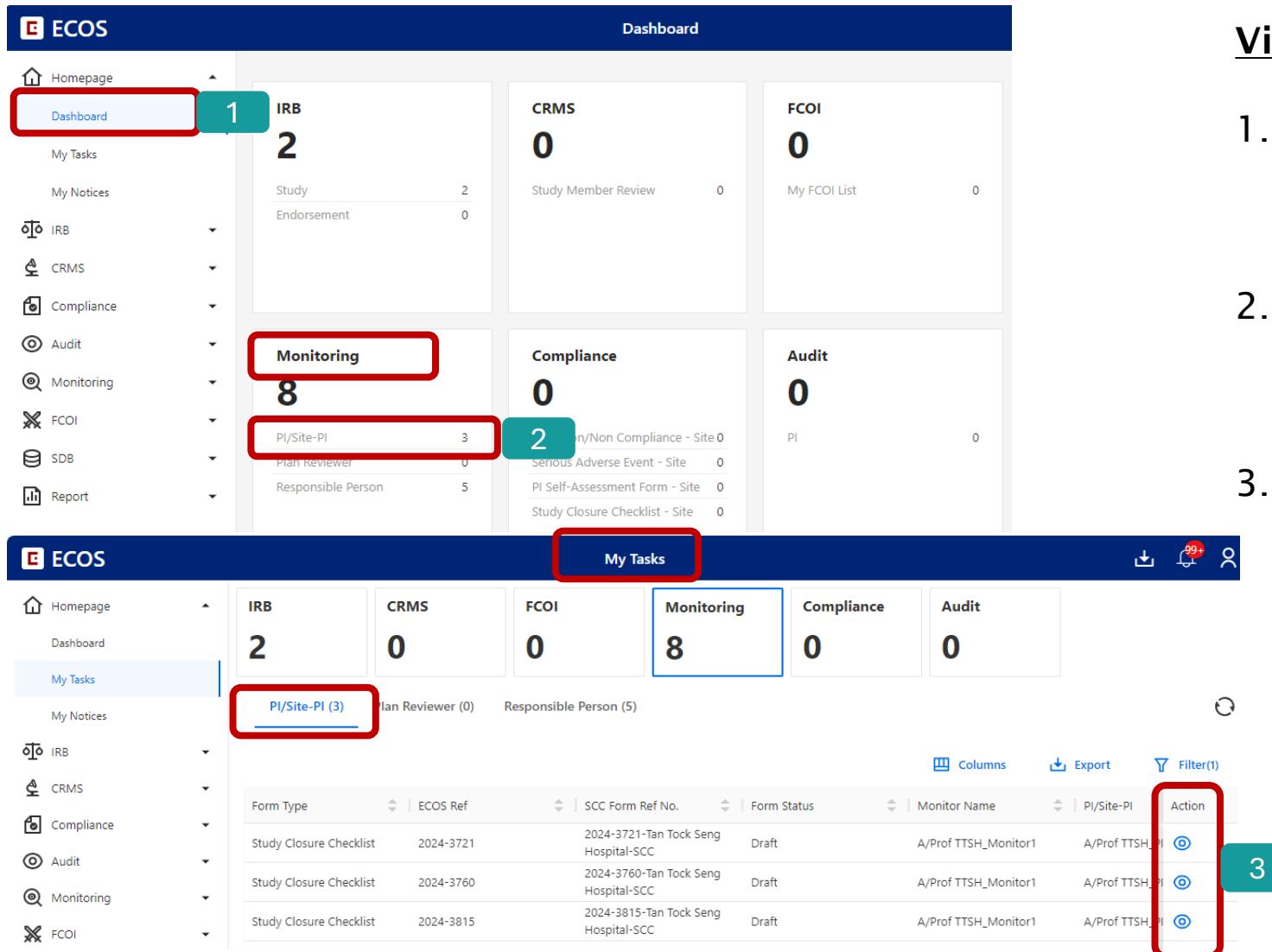
Query Attachment

ISE-013 Issue Pending Compliation

ISE-005 Query Pending Reply 8

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

1 IRB 2

CRMS 0

FCOI 0

Study Member Review 0

Study Endorsement 0

My FCOI List 0

Monitoring 8

Compliance 0

Audit 0

PI/Site-PI 3

Plan Reviewer 0

Responsible Person 5

ECOS

My Tasks

IRB 2 CRMS 0 FCOI 0 Monitoring 8 Compliance 0 Audit 0

PI/Site-PI (3)

Plan Reviewer (0) Responsible Person (5)

Form Type ECOS Ref SCC Form Ref No. Form Status Monitor Name Action

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

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)

Monitoring Category	ECOS Ref	Study Site	PI/Site-PI	SCC Status	Action
NHG 3A	2024-3815	Tan Tock Seng Hospital	A/Prof TTSH_PI4	Draft	View
NHG 3A	2024-3721	Tan Tock Seng Hospital	A/Prof TTSH_PI4	Draft	View
NHG 3A	2024-3760	Tan Tock Seng Hospital	A/Prof TTSH_PI4	Draft	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](#) “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, there is a header with a back button, a 'Study Closure Checklist Detail' title, and a user icon with a red notification badge. Below the header, the task ID '2024-3646-Tan Tock Seng Hospital-SCC | Tan Tock Seng Hospital' is displayed, with a 'Draft' status indicator. A 'Submit' button is located to the right. The main content area includes fields for 'PI/Site PI', 'Monitor', 'Date Sent to PI', and 'Initial Submission Date'. A 'Study Title' field shows 'Study 13'. A 'Quick Link' button (labeled 3) is highlighted with a red box, leading to 'Study Summary, CRMS'. A 'Edit' button (labeled 4) is also highlighted with a red box. The page content includes sections for '1. DATA' and '1.1 Comments', with radio button options for 'Yes' and 'NA'.

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)

Study Closure Checklist Detail

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

ECOS Ref: 2024-3646 [Edit](#)

PI/Site PI: A/Prof TTSH_NewPI3
Monitor: A/Prof TTSH_Monitor1
Last Updated By: -
Initial Submission Date: -
Date Sent to PI: 11-Nov-2024

Study Title: Study 13

Study Closure Checklist (SCC)

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

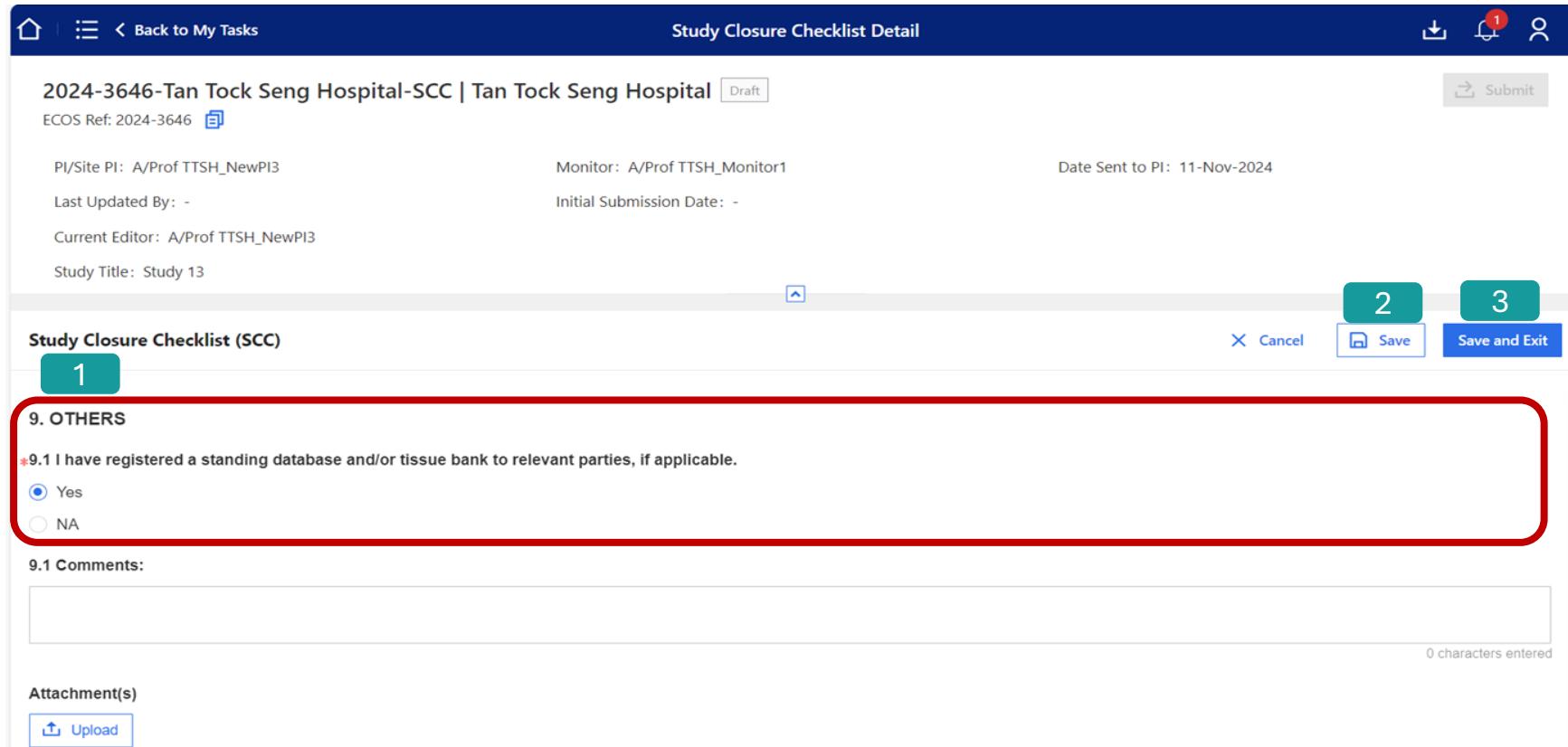
2. **Save**

3. **Save and Exit**

9.1 Comments:

0 characters entered

Attachment(s)
[Upload](#)

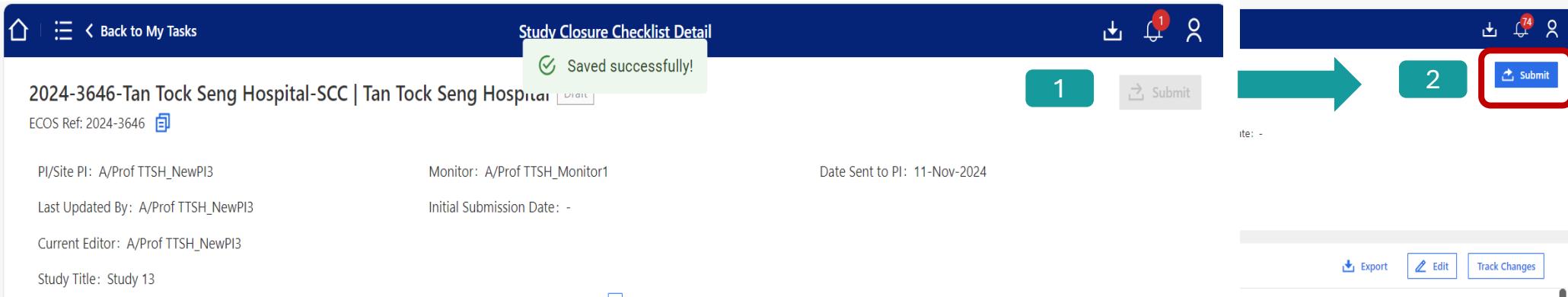


1. Scroll down to complete the rest of the SCC form. Fields marked with * are mandatory for completion.

2. Click on “Save” to ensure the edits have been saved successfully.

3. Click on “Save and Exit” to exit editing mode.

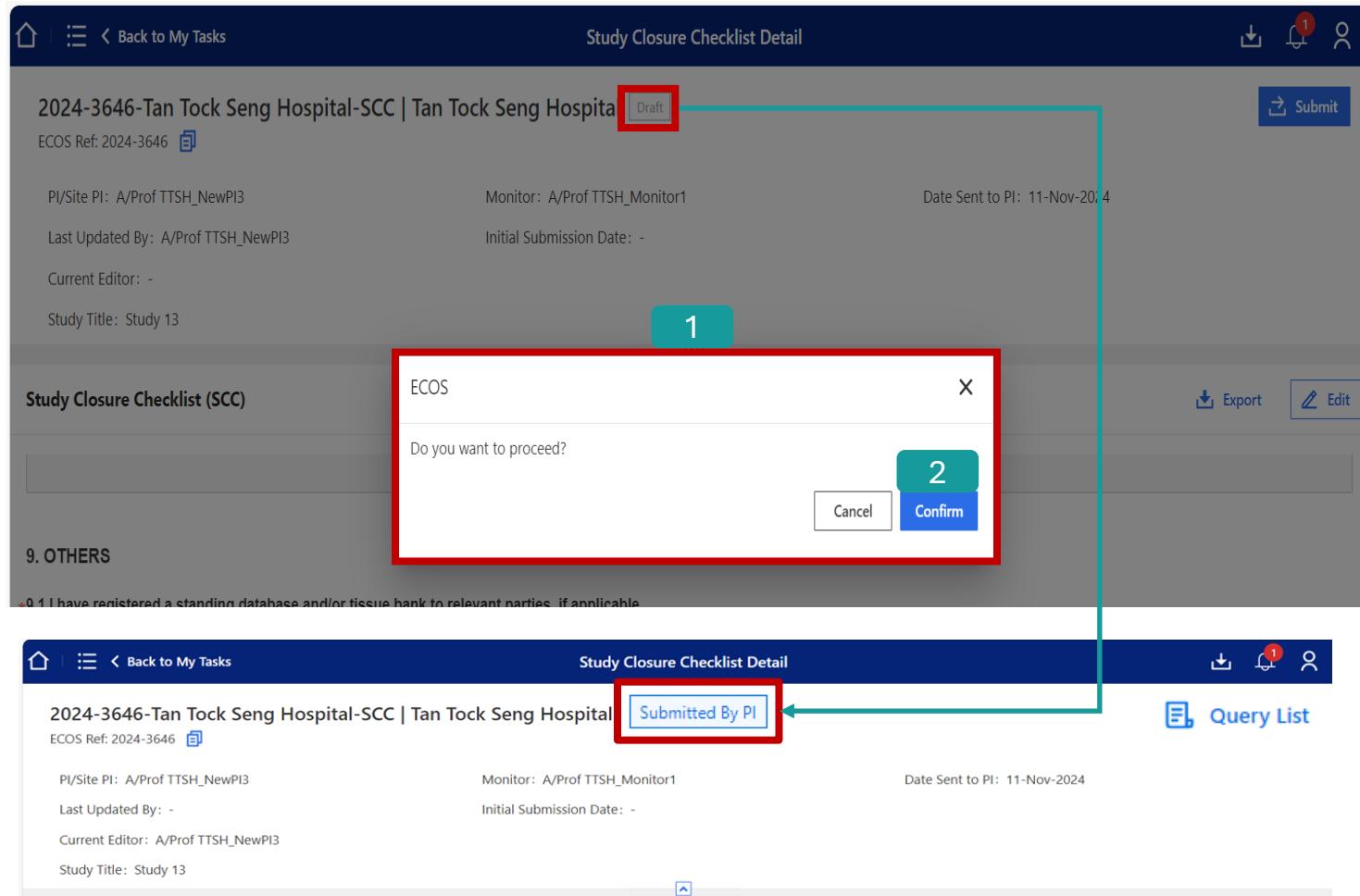
7) How to View/ Edit/ Submit Study Closure Checklist (SCC)



The screenshot shows the 'Study Closure Checklist Detail' page. At the top, there is a success message: 'Saved successfully!' with a green checkmark icon. Below the message, the study identifier is '2024-3646-Tan Tock Seng Hospital-SCC | Tan Tock Seng Hospital' and the ECOS Ref is '2024-3646'. The page displays various details: PI/Site PI: A/Prof TTS defence, Monitor: A/Prof TTS defence, Date Sent to PI: 11-Nov-2024, Last Updated By: A/Prof TTS defence, Initial Submission Date: -, Current Editor: A/Prof TTS defence, and Study Title: Study 13. On the right, there are navigation icons for 'Back to My Tasks', 'Home', and 'Logout'. A large teal arrow points from step 1 to step 2. Step 1 is labeled '1' and has a 'Submit' button. Step 2 is labeled '2' and has a 'Submit' button, which is highlighted with a red box. Below the main content, there is a sub-section titled 'Study Closure Checklist (SCC)' with buttons for 'Cancel', 'Save', and 'Save and Exit'. At the bottom, there is a section titled '9. OTHERS' with a question: '9.1 I have registered a standing database and/or tissue bank to relevant parties, if applicable.' with two radio button options: 'Yes' (selected) and 'NA'.

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 image consists of two screenshots of a software interface for managing Study Closure Checklists (SCCs).
Top Screenshot: The title is "Study Closure Checklist Detail". It shows a list of details: "2024-3646-Tan Tock Seng Hospital-SCC | Tan Tock Seng Hospital" (status: **Draft**), "ECOS Ref: 2024-3646", "PI/Site PI: A/Prof TTSH_NewPI3", "Monitor: A/Prof TTSH_Monitor1", "Initial Submission Date: -", "Date Sent to PI: 11-Nov-2024", and "Study Title: Study 13". A "Submit" button is visible. A red box highlights the "Draft" status. A modal dialog box is overlaid, titled "ECOS", with the question "Do you want to proceed?". It has "Cancel" and "Confirm" buttons. The number "1" is in a green box above the dialog, and "2" is in a green box next to the "Confirm" button.
Bottom Screenshot: The title is "Study Closure Checklist Detail". It shows the same details as the top screenshot, but the status is now **Submitted By PI**. A "Query List" button is visible. A red box highlights the "Submitted By PI" status. A green arrow points from the "Submitted By PI" status in the bottom screenshot to the "Confirm" button in the top screenshot's dialog box.

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

Monitoring Schedule Detail

2024-3815 | Tan Tock Seng Hospital

Study Site: Tan Tock Seng Hospital

PI/Site-PI: A/Prof TTSH_PI4

Monitor: A/Prof TTSH_Monitor1

1

2

Confirmation Letter

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

Attachment Export

Monitoring Schedule Detail

2024-3815 | Tan Tock Seng Hospital

Study Site: Tan Tock Seng Hospital

PI/Site-PI: A/Prof TTSH_PI4

Monitor: A/Prof TTSH_Monitor1

1

2

Monitoring Visit Report

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

Attachment Track Changes Export

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.

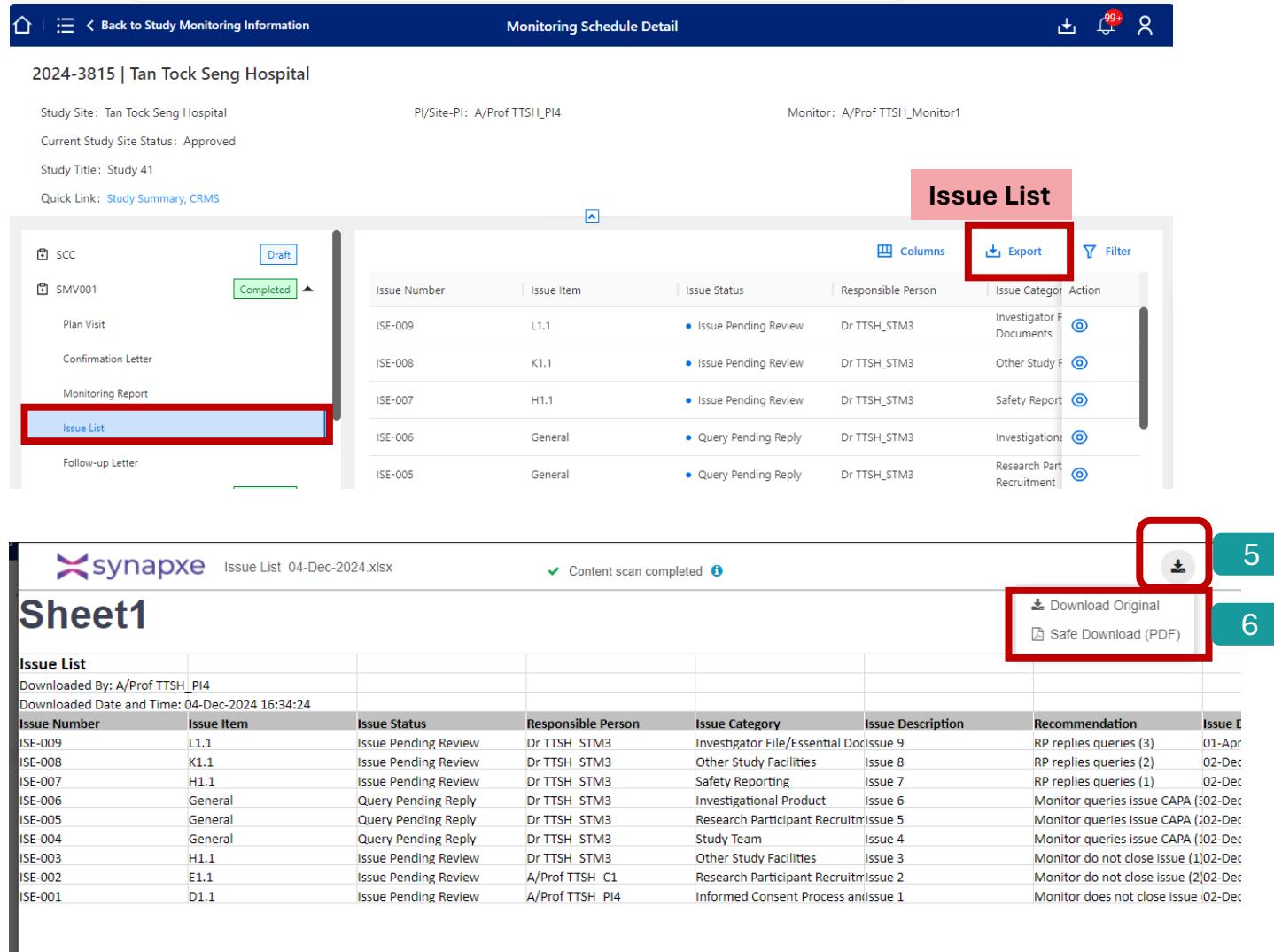
8) How to Export the Monitoring Report/ Letters/ Issue List

The screenshot shows the 'Monitoring Schedule Detail' page for study 2024-3815 at Tan Tock Seng Hospital. The left sidebar lists 'Follow-up Letter' (highlighted with a red box), 'SCC', 'SMV001' (status: Draft, Completed), 'Plan Visit', 'Confirmation Letter', 'Monitoring Report', and 'Issue List'. The main content area shows a 'Follow-up Letter' window with a red box around the title. It includes fields for 'To', 'Cc', 'Subject', and 'Content: Preview'. Below this is an 'ONLYOFFICE' editor window. A red box highlights the 'Follow-up Letter' button in the bottom right of the editor. The top right of the page shows a 'Follow up Letter' button with a red box, and the top right corner has a '99+' notification icon.

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



Monitoring Schedule Detail

2024-3815 | Tan Tock Seng Hospital

Study Site: Tan Tock Seng Hospital

PI/Site-PI: A/Prof TTSH_PI4

Monitor: A/Prof TTSH_Monitor1

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/Essential 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	@

Issue List 04-Dec-2024.xlsx

Content scan completed

Download Original

Safe Download (PDF)

- For Issue List (table format), a popup window will be shown. Click on the download icon 
- Select “Download Original” as an Excel file or “Safe Download” as PDF file.

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