

Ethics and Compliance Online System (ECOS)

Monitoring and PI Self Assessment

07-Jan-2025

Content – Monitoring Module

1. View/Locate Monitoring Tasks
2. View and Access Study Monitoring Information
3. Query and Endorse Monitoring Plan (MP)
4. Respond to Monitoring Issue
5. Reply to CAPA Query for Monitoring Issue
6. Export of Monitoring Report, Letters, Issue List

1) View/Locate Monitoring Task – Homepage

The screenshot displays the ECOS Dashboard interface. The top navigation bar includes the ECOS logo, a 'Dashboard' tab (highlighted with an orange box), and user profile icons. The left sidebar contains a 'Homepage' menu (highlighted with an orange box and a green '1' badge) and a list of navigation items: My Tasks, My Notices, IRB, CRMS, Compliance, Audit, Monitoring, FCOI, SDB, and Report. The main content area features several tiles: IRB (1 Study, 0 Endorsement), CRMS (6 Study Member Review), FCOI (0 My FCOI List), Monitoring (2 PI/Site-PI, 1 Plan Reviewer, 1 Responsible Person), Compliance (12 Deviation/Non Compliance - Site, 0 Serious Adverse Event - Site, 12 PI Self-Assessment Form - Site, 0 Study Closure Checklist - Site), and Audit (0 PI). The 'Monitoring' tile is highlighted with an orange box and a green '2' badge. A blue arrow icon is located in the top right corner of the 'Monitoring' tile. The right sidebar shows 'My Notices' with a 'View All' link and a list of service disruption broadcast messages.

ECOS **Dashboard**

Homepage **Dashboard** **1**

My Tasks

My Notices

IRB

CRMS

Compliance

Audit

Monitoring

FCOI

SDB

Report

IRB
1
Study 1
Endorsement 0

CRMS
6
Study Member Review 6

FCOI
0
My FCOI List 0

Monitoring **2**
PI/Site-PI 0
Plan Reviewer 1
Responsible Person 1

Compliance
12
Deviation/Non Compliance - Site 0
Serious Adverse Event - Site 0
PI Self-Assessment Form - Site 12
Study Closure Checklist - Site 0


Audit
0
PI 0

My Notices [View All](#)

- Service Disruption Broadcast Message
03-Jun-2024
- Service Disruption Broadcast Message
31-May-2024
- Service Disruption Broadcast Message
27-May-2024
- Service Disruption Broadcast Message
23-May-2024
- Service Disruption Broadcast Message
15-May-2024

1. Locate your outstanding monitoring task via “Homepage” > “Dashboard” on the left navigation panel.
2. In the “Monitoring” tile, click on the or listed items will lead you to “My Tasks”.

1) View/Locate Monitoring Task – My Tasks

3. You can also access “My Tasks” directly via the left navigation panel.
4. In “My Tasks”, click on the the “Monitoring” tile.
5. The type and number of outstanding tasks are listed under the different tabs based on the user’s role. Click on each tab to display the respective task listing.
6. To view the monitoring task, click on  “View” icon in the “Action” column.

1) View/Locate Monitoring Task – My Tasks

The screenshot displays the ECOS 'My Tasks' dashboard. The top navigation bar includes 'ECOS', 'My Tasks', and user controls. The left sidebar lists navigation options: Homepage, Dashboard, My Tasks (highlighted with an orange box), My Notices, IRB, CRMS, Compliance, Audit, Monitoring, FCOI, SDB, and Report. The main content area features a summary of task counts: IRB (1), CRMS (6), FCOI (0), Monitoring (2, highlighted with an orange box), Compliance (12), and Audit (0). Below this, a table lists tasks with columns: Form Type, ECOS Ref, Plan Status, Monitor Name, PI/Site-PI, Date Sent to Plan Reviewer, Task Status, and Action. A 'Plan Reviewer (1)' link is highlighted with an orange box. A 'Filter(1)' button is also highlighted with an orange box and labeled with a green '1'. A green arrow points from this button to a 'Filter' modal on the right. The modal contains fields for ECOS Ref, Task Due date, Monitor Name, PI/Site-PI, Date Sent to Site, and Task Status. The 'Task Status' dropdown is open, showing 'Pending' (selected with a checkmark), 'Completed', 'Terminated', and 'Reassigned'. A green '2' is next to the dropdown. At the bottom of the modal, a 'Search' button is highlighted with an orange box and labeled with a green '3', and a 'Reset' button is also visible.

Form Type	ECOS Ref	Plan Status	Monitor Name	PI/Site-PI	Date Sent to Plan Reviewer	Task Status	Action
Monitoring Plan	2024-3130	Pending Review	Ms SHS_QMR1	A/Prof CGH_PI11	03-Jan-2025	Pending	

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

2. The default settings for the filter show only **pending** tasks for your action (**Task Status = Pending**).

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

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

1) View/Locate Monitoring Task – Monitoring Module

1

2

3

ECOS

My Issue

ColumnsExportFilter(1)

Homepage

IRB

CRMS

Compliance

Audit

Monitoring

My Issue

Plan Review

Study Monitoring Information

ECOS Ref	Visit Type & No.	Issue Number	Issue Category	Issue Status	Issue Date	Issue Due Date	Issue Description	Action
2024-3610	SMV001	ISE-001	Research Participant Recruitment	Query Pending Reply	09-Dec-2024	11-Dec-2024	Missing eligibility assessment documentation	
2024-3610	SMV001	ISE-002	Protocol Compliance	Query Pending Reply	09-Dec-2024	11-Dec-2024	CGH-A01 Visit 2 not done	
2024-3610	SMV001	ISE-007	Biological Materials	Issue Pending Completion	09-Dec-2024	11-Dec-2024	Missing HBM Management SOP	
2024-3610	SMV001	ISE-008	Investigator File/Essential Documents	Issue Pending Completion	09-Dec-2024	11-Dec-2024	Protocol not signed	
2024-3610	SMV001	ISE-009	Investigator File/Essential Documents	Issue Pending Completion	09-Dec-2024	11-Dec-2024	poster not filed	
2024-3610	SMV001	ISE-010	Investigator File/Essential Documents	Issue Pending Completion	09-Dec-2024	11-Dec-2024	IRB comments not filed	

- My Issue:** As the assigned “Responsible Person”, you will see all monitoring issues that were assigned to you.*
- Plan Review:** The “Plan Reviewer” (PI/Site-PI) will see all Monitoring Plans (MP) submitted by the Monitor for endorsement.*
- Study Monitoring Information:** To access all monitoring information (e.g. view monitoring plan, monitoring reports, issues list, confirmation and follow-up letters).

*The default settings for the filter show only tasks **pending** your action.

To view all tasks (including completed tasks), please update the filter parameters.

Content – Monitoring Module

1. View/Locate Monitoring Tasks
- 2. View and Access Study Monitoring Information**
3. Query and Endorse Monitoring Plan (MP)
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5. Reply to CAPA Query for Monitoring Issue
6. Export of Monitoring Report, Letters, Issue List

2) View and Access Study Monitoring Information

ECOS

Study Monitoring Information

Download

99+

User

Homepage

IRB

CRMS

Compliance

Audit

Monitoring

My Issue

Plan Review

Study Monitoring Information

Study Closure Checklist

FCOI

SDB

Report


Columns

Export

Filter(1)

ECOS Ref	Study Site	PI/Site-PI	Current Study Site Status	No. of Issues	Initial Monitoring Date	Last Monitoring Date	Monitor	Action
2024-3725	Changi General Hospital	A/Prof CGH_PI11	Approved	Total: 9 Closed: 9	03-Dec-2024	25-Feb-2025	A/Prof SHS_MON3	<div>2View Plan</div> <div><div></div><div></div></div>
2024-3610	Changi General Hospital	A/Prof CGH_PI11	Ongoing	Total: 18 Issue Pending Send: 2 Issue Pending Review: 5 Query Pending Reply: 1 Closed: 10	19-Dec-2024	03-Feb-2025	A/Prof SHS_MON2	<div></div> <div></div>
2024-3610	Changi General Hospital	A/Prof CGH_PI11	Ongoing	Total: 11 Issue Pending Completion: 5 Query Pending Reply: 3 Closed: 3	17-Dec-2024	19-Dec-2024	A/Prof SHS_MON3	<div></div> <div></div>

1. This page is accessible by **Site Staff**
(with some pages restricted to specific site staff, e.g. Plan Review is only accessible by PI/Site-PI)

2. Click on  **“View Plan”** to enter **“View Monitoring Plan”** page.

2) View and Access Study Monitoring Information

[Home](#) |
 [Menu](#) |
 [Back to Study Monitoring Information](#)
View Monitoring Plan
1

 ¹
 ⁹⁹⁺


2024-3610 | Changi General Hospital Endorsed

ECOS Ref: 2024-3610

Monitor: A/Prof SHS_MON3

PI/Site-PI: A/Prof CGH_PI11

Current Study Site Status: Ongoing

Plan Submission Date: 09-Dec-2024

Plan Endorsement Date: 09-Dec-2024

Plan Reviewer: A/Prof SHS_MRR1

Attachment: [0 files](#)

Endorsement Comment: [View](#)

Study Title: SHS_AUD-UAT_Study-A19_CGH_TB Collection

 [Query List](#)

Monitoring Plan

ONLYOFFICE File View Plugins MOB002-09Dec2024_SingHealth-Monitoring-Plan_09-Dec-2024 09:41:33.docx

ECOS MONITORING PLAN
 SINGHEALTH
 OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE

Restricted, Sensitive (Normal)

ECOS Reference:	2024-3610	IRB:	SingHealth CIRB-Board A
Regulatory Reference: (if applicable)		Monitor:	A/Prof SHS_MON3
Study Title:	SHS_AUD-UAT_Study-A19_CGH_TB Collection		
PI/ Site-PI:	A/Prof CGH_PI11		
Study Site:	Changi General Hospital		

Download List (1) Delete All X

MOB002-09Dec2024_SingHealth-Monitoring-Plan_09-Dec-2024 09:41:33.pdf
 194.94 KB Delete Download To Local

1. PI/Site PI may view their **respective site's** Monitoring Plan.
2. To export a copy of the Monitoring Plan, click on “Export”

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.

2) View and Access Study Monitoring Information

ECOS

Study Monitoring Information

Columns

Export

Filter(1)

Homepage

IRB

CRMS

Compliance

Audit

Monitoring

My Issue

Plan Review

Study Monitoring Information

Study Closure Checklist

FCOI

SDB

Report

ECOS Ref	Study Site	PI/Site-PI	Current Study Site Status	No. of Issues	Initial Monitoring Date	Last Monitoring Date	Monitor	No. of Visits	Action
2024-3725	Changi General Hospital	A/Prof CGH_PI11	Approved	Total: 9 Closed: 9	03-Dec-2024	25-Feb-2025	A/Prof SHS_MON3	5	<div>View Schedule</div>
2024-3610	Changi General Hospital	A/Prof CGH_PI11	Ongoing	Total: 18 Issue Pending Send: 2 Issue Pending Review: 5 Query Pending Reply: 1 Closed: 10	19-Dec-2024	03-Feb-2025	A/Prof SHS_MON2	3	
				Total: 11					

Back to Study Monitoring Information

Monitoring Schedule Detail

2024-3725 | Changi General Hospital

Study Site: Changi General Hospital

PI/Site-PI: A/Prof CGH_PI11

Monitor: A/Prof SHS_MON3

Current Study Site Status: Approved

Study Title: SHS MON UAT 2 - Study C

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

SMV002 Completed

Plan Visit

Confirmation Letter

Monitoring Report

Issue List

Follow-up Letter

Ad-Hoc SMV001 Completed

SMV001 Completed

Plan Visit


Saved at 18-Nov-2024 14:33

* Planned Start Date ~ Planned End Date:
02-Dec-2024 → 03-Dec-2024

Venue:

Phone

Visit Agenda:
aaa

5. Click on  “View Schedule” to enter Monitoring Schedule Detail page.

6. In “Monitoring Schedule Detail” page, all monitoring visits of that study are listed on the left navigation panel.

You can view the past monitoring reports, issue list, confirmation and follow-up letters of each visit.

Content – Monitoring Module

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- 3. Query and Endorse Monitoring Plan (MP)**
4. Respond to Monitoring Issue
5. Reply to CAPA Query for Monitoring Issue
6. Export of Monitoring Report, Letters, Issue List

3) Query/Endorse Monitoring Plan (MP)

ECOS

Dashboard

1

Dashboard

My Tasks

My Notices

IRB

CRMS

Compliance

Audit

Monitoring

FCOI

SDB

Report

IRB

1

Study 1

Endorsement 0

CRMS

6

Study Member Review 6

FCOI

0

My FCOI List 0

Monitoring

2

2

PI/Site-PI 0

Plan Reviewer 1

Responsible Person 1

Compliance

12

Deviation/Non Compliance - Site 0

Serious Adverse Event - Site 0

PI Self-Assessment Form - Site 12

Study Closure Checklist - Site 0

Audit

0

PI 0

ECOS

My Tasks

Homepage

Dashboard

My Tasks

My Notices

IRB

CRMS

Compliance

Audit

Monitoring

IRB

1

CRMS

6

FCOI

0

Monitoring

2

Compliance

12

Audit

0

PI/Site-PI (0)

Plan Reviewer (1)

Responsible Person (1)

Form Type

ECOS Ref

Plan Status

Monitor Name

PI/Site-PI

Date Sent to Plan Reviewer

Task Status

Action

Monitoring Plan

2024-3130

Pending Review

Ms SHS_QMR1

A/Prof CGH_PI11

03-Jan-2025

Pending

View

Plan Reviewer will receive an email notification when the Monitor submits a MP for endorsement.

Via Dashboard > My Tasks

1. The Plan Reviewer can locate all assigned MPs for review/endorsement via “Dashboard”
2. Click on “Plan Reviewer” to enter “My Tasks” > “Plan Reviewer” page.
3. Click on “View” icon in the “Action” column to view the details of MP.


3) Query/Endorse Monitoring Plan (MP)

PI/Site-PI only

The screenshot shows the ECOS Dashboard. On the left, a sidebar contains navigation links: Homepage, Dashboard (highlighted with a red box and a red '1'), My Tasks, My Notices, and a dropdown menu with IRB, CRMS, Compliance, Audit, Monitoring, FCOI, and SDB. The main dashboard area displays several metrics: IRB (1 Study, 0 Endorsement), CRMS (6 Study Member Review), FCOI (0 My FCOI List), Monitoring (2 PI/Site-PI, 1 Plan Reviewer - highlighted with a red box and a red '2'), Compliance (12 Deviation/Non Compliance - Site, 0 Serious Adverse Event - Site, 12 PI Self-Assessment Form - Site), and Audit (0 PI). At the bottom, there is a 'View Monitoring Plan' button and a 'Back to My Tasks' link.

Plan Reviewer will receive an email notification when the Monitor submits a MP for endorsement.

Via Dashboard > My Tasks

1. The Plan Reviewer can locate all assigned MPs for review/endorsement via “Dashboard”
2. Click on “Plan Reviewer” to enter “My Tasks” > “Plan Reviewer” page.
3. Click on  “View” icon in the “Action” column to view the details of MP.

The screenshot shows a web browser displaying a document titled 'Monitoring Plan' for '2024-3130 | Changi General Hospital'. The document is in a 'Pending Review' state. The browser window shows the 'ONLYOFFICE' interface with a menu bar (File, View, Plugins) and a toolbar (Export, Fullscreen). The document content includes the ECOS logo, the title 'MONITORING PLAN', the subtitle 'SINGHEALTH OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE', and the ECOS Reference: 2024-3130. The IRB is listed as 'SingHealth CIRB-Board E'. On the right side of the document, there is an 'Action' column with a 'View' icon (highlighted with a red box and a red '3') and a 'Filter(1)' button.

3) Query/Endorse Monitoring Plan (MP)

PI/Site-PI only

The screenshot shows the ECOS Plan Review interface. The left navigation panel has 'Monitoring' highlighted in yellow, and 'Plan Review' is selected under it. The main table displays a list of Monitoring Plans. Callout 1 points to the 'Plan Review' menu item. Callout 2 points to the 'Monitoring Plan Status' column, which shows 'Pending Review'. Callout 3 points to the 'Action' column, which contains a 'View' icon (an eye in a circle).

ECOS Ref	Study Site	PI/Site-PI	Current Study Site Status	Monitor	Plan Reviewer	Monitoring Plan Status	Initial Plan Submission Date	Plan Endorsement Date	Action
2024-3130	Changi General Hospital	A/Prof CGH_PI11	Approved	Ms SHS_QMR1	A/Prof CGH_PI11	Pending Review	03-Jan-2025	-	

Via Monitoring > Plan Review

1. You can also locate the list of MPs for review via the Monitoring Module > **“Plan Review”** menu on the left navigation panel.
2. By default, you will only see tasks which are pending your action (Monitoring Plan Status = Pending Review/ Query Pending Reply).
3. Click on “View” icon in the “Action” column to view the details of MP.

3) Query/Endorse Monitoring Plan (MP)

PI/Site-PI only

Home

Menu

Back to Monitoring Plan

View Monitoring Plan

1

99+

Profile

2024-3099 | Singapore General Hospital

Draft

ECOS Ref: 2024-3099

Icon

Monitor: A/Prof SHS_MON1

PI/Site-PI: Prof SGH_PI

Current Study Site Status: Approved

Plan Submission Date: -

Plan Endorsement Date: -

Plan Reviewer: Prof SGH_PI

Attachment: [0 files](#)

Study Title: CJL01 - 18 Jun 2024 UAT Sprint 1

Click on “Fullscreen” to expand the MP for easy viewing.

To exit full screen, click “Close Fullscreen”

Monitoring Plan

ONLYOFFICE

File View Plugins

MOB005-21Nov2024_SingHealth-Monitoring-Plan_03-Jan-2025 14:14:15.docx

Search

Share

Search

Messages

Comments

Tasks

Calendar

ECOS

MONITORING PLAN

SINGHEALTH
OFFICE OF RESEARCH INTEGRITY AND COMP

ECOS Reference: 2024-3099

Regulatory Reference: (if applicable)

Study Title: CJL01 - 18 Jun 2024 UAT Sprint 1

PI/ Site-PI: Prof SGH_PI

Study Site: Singapore General Hospital

MONITORING PURPOSE

Monitoring is performed to verify that

ONLYOFFICE

File View Plugins

MOB005-21Nov2024_SingHealth-Monitoring-Plan_03-Jan-2025 14:14:15.docx

Search

Share

ECOS

MONITORING PLAN

SINGHEALTH
OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE

ECOS Reference: 2024-3099

IRB: SingHealth CIRB-Board D

Regulatory Reference: (if applicable)

Monitor: A/Prof SHS_MON1

Study Title: CJL01 - 18 Jun 2024 UAT Sprint 1

PI/ Site-PI: Prof SGH_PI

Study Site: Singapore General Hospital

MONITORING PURPOSE

Monitoring is performed to verify that

(i) the safety, rights and well-being of the research participants are protected;

(ii) the reported research data are accurate, complete, and verifiable from source documents;

(iii) the conduct of the research is in compliance with the currently approved protocol/amendment(s), Good Clinical Practice (GCP), applicable regulatory requirements and SingHealth policies.

MONITORING SCOPE

Monitoring activities will be proportional to the specific human participant protection and data integrity risks of the research. The critical processes/ data specific to the study should be detailed in this monitoring plan. Any changes to the approved monitoring plan should be detailed in a Monitoring Plan Addendum.

MONITORING FREQUENCY AND DURATION

At least one monitoring visit will be conducted for the study. Subsequent visit may be required, depending on the risk of study and/or findings from previous monitoring/ audit. Determination of subsequent visit may be discussed with the Monitoring Visit Report (MVR) reviewer and/or line manager.

Each monitoring visit is expected to last approximately 1-2 days. Duration may differ, depending on factors such as visit type, nature and complexity of study, relative experience of the study team, findings during monitoring, etc.

VISIT TYPE	DESCRIPTION	PLANNED DATE(S) OF VISIT/ FREQUENCY (if applicable)
<input type="checkbox"/> On-site Monitoring	Monitoring activities conducted in-person by visiting the site where the study is conducted	
<input type="checkbox"/> Remote Monitoring	Monitoring activities conducted away from the study site location (e.g. at monitor's office)	

Page 1 of 5 Word count

15

3) Query Monitoring Plan (MP)

PI/Site-PI only

Home

Menu

Back to My Tasks

View Monitoring Plan

Download

1

99+

User

2024-3130 | Changi General Hospital

Pending Review

ECOS Ref: 2024-3130

Icon

1

Query List

Send Query

Endorse

Monitor: Ms SHS_QMR1

PI/Site-PI: A/Prof CGH_PI11

Current Study Site Status: Approved

Plan Submission Date: 03-Jan-2025

Plan Endorsement Date: -

Plan Reviewer: A/Prof CGH_PI11

Attachment: [0 files](#)

Study Title: 24618YP

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

Monitoring Plan

Export

Fullscreen

ONLYOFFICE

File

View

Plugins

MOB001-24Nov2024_SingHealth-Monitoring-Plan_24-Nov-2024 03:16:24.docx

Search

Close

ECOS

MONITORING PLAN

Restricted, Sensitive (Normal)

SINGHEALTH

OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE

ECOS Reference:

2024-3130

IRB:

SingHealth CIRB-Board E

Regulatory Reference:

(if applicable)

Monitor:

Ms SHS_QMR1

Study Title:

24618YP

PI/ Site-PI:

A/Prof CGH_PI11

Study Site:

Changi General Hospital

- Plan Reviewer may query the MP.
1. To query, click on the “**Query List**”. A window will appear.
 2. Click on “+ **General Query**” to add a query.
 3. Enter query description. Query description will be **auto-saved**.
 4. You can upload an attachment, if needed.
 5. To add another query, click on “+ **General Query**”.
 6. To exit Query List, click on the background page.

3) Query Monitoring Plan (MP)

PI/Site-PI only

The screenshot displays the 'View Monitoring Plan' interface for '2024-3130 | Changi General Hospital'. The interface includes a top navigation bar with 'Back to My Tasks' and 'View Monitoring Plan' buttons. A sidebar on the left shows the 'Monitoring Plan' document. The main content area displays the 'Monitoring Plan' document, which is a PDF titled 'MOB001-24Nov2024_SingHealth-Monitoring-Plan_24-Nov-2024 03:16:24.docx'. The document content includes the 'ECOS MONITORING PLAN' header and the 'SINGHEALTH OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE' logo. The document also lists the 'Monitor: Ms SHS_QMR1', 'PI/Site-PI: A/Prof CGH_PI11', 'Plan Submission Date: 03-Jan-2025', 'Plan Endorsement Date: -', 'Attachment: 0 files', 'Study Title: 24618YP', and 'Quick Link: Study Summary, CRMS, PISAF'. A 'Query List' window is overlaid on the right side of the document. The 'Query List' window has a 'Pending Query' tab and a 'Batch Close' button. It also features a 'General' dropdown menu and a 'Query Description' field with a placeholder 'Please enter'. An 'Attachment' section with an 'Upload' button is also visible. The interface is annotated with numbered steps: 1. Click on 'Query List' in the top bar. 2. Click on '+ General Query' in the 'Query List' window. 3. Enter the query description in the 'Query Description' field. 4. Click on the 'Upload' button in the 'Attachment' section.

Plan Reviewer may query the MP.

1. To query, click on the “**Query List**”. A window will appear.
2. Click on “+ **General Query**” to add a query.
3. Enter query description. Query description will be **auto-saved**.
4. You can upload an attachment, if needed.
5. To add another query, click on “+ **General Query**”.
6. To exit Query List, click on the background page.

3) Query Monitoring Plan (MP)

PI/Site-PI only

The screenshot displays the 'View Monitoring Plan' interface for '2024-3130 | Changi General Hospital'. The plan is in 'Pending Review' status. Key details include: Monitor: Ms SHS_QMR1, PI/Site-PI: A/Prof CGH_PI11, Current Study Site Status: Approved, Plan Submission Date: 03-Jan-2025, Plan Endorsement Date: -, Attachment: 0 files, Study Title: 24618YP, and Quick Link: Study Summary, CRMS, PISAF. The interface includes a 'Query List' button (1) and a 'Send Query' button (2). A 'Send Query' pop-up window (3) is shown, asking 'Do you want to proceed?' and displaying the 'Query Item: General' and 'Query Description: Will monitoring be performed at the pharmacy? IP is stored an managed by hospital pharmacy. IP records are maintained by delegated pharmacists.' The pop-up has 'Cancel' and 'Confirm' buttons.

1. A **red dot** indicates there is an action pending (i.e. to send the query).
2. After adding query, the “**Send Query**” button is enabled. Click on “**Send Query**”, a pop-up window with a list of query(ies) to be sent will be displayed.
3. Click “**Confirm**” to send the query, or “**Cancel**” to exit the pop-up window.

3) Query Monitoring Plan (MP)

PI/Site-PI only

2024-3130 | Changi General Hospital

ECOS Ref: 2024-3130

Query Pending Reply

1

Monitor: Ms SHS_QMR1

Plan Submission Date: 03-Jan-2025

Attachment: [0 files](#)

Study Title: 24618YP

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

PI/Site-PI: A/Prof CGH_P111

Plan Endorsement Date: -

Current Study Site Status: Approved

Plan Reviewer: A/Prof CGH_P111

View Monitoring Plan

1

99+

Query List

Monitoring Plan

ONLYOFFICE

File View Plugins

MOB001-24Nov2024_SingHealth Monitoring Plan_24-Nov-2024 03:16:24.docx

ECOS

MONITORING PLAN

RESTRICTED, SENSITIVE (Normal)

SINGHEALTH

OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE

ECOS Reference: 2024-3130

IRB: SingHealth CIRB-Board E

Regulatory Reference: (if applicable)

Monitor: Ms SHS_QMR1

Study Title: 24618YP

PI/ Site-PI: A/Prof CGH_P111

Study Site: Changi General Hospital

1. After sending query to the Monitor, MP status will be changed from “Pending Review” to “**Query Pending Reply**”.
2. When Monitor has replied to the query, MP status will be changed to “**Pending Review**”.
3. To re-query on a previous query, click on “**+ Further Query**”.
4. To add a new query, click on “**+ General Query**”.
5. To close a query, click on “**X Close Query**”.
6. To close query in batches, select the query box and click on “**Batch Close**”.

3) Query Monitoring Plan (MP)

PI/Site-PI only

The screenshot displays the ECOS Monitoring Plan interface. The top navigation bar includes 'Back to Plan Review' and 'View Monitoring Plan'. The main header shows '2024-3130 | Changi General Hospital' with a 'Query Pending Reply' status indicator (1). Below this, details for the monitor (Ms SHS_QMR1), plan submission date (03-Jan-2025), and study title (24618YP) are listed. The 'Monitoring Plan' section shows a document viewer with the ECOS logo and 'MONITORING PLAN' title. The 'Query List' panel on the right shows a 'Pending Query' status (2) and a '+ General Query' button (4). The 'Query List' table has columns for 'Batch Close' (6), '+ Further Query' (3), and 'X Close Query' (5). The table content includes two queries: 'Will monitoring be performed at the pharmacy?' and 'Yes, IP storage facility visit will be conducted and IP records must be made available for review during monitoring visit.'.

2024-3130 | Changi General Hospital **Query Pending Reply** 1

ECOS Ref: 2024-3130

Monitor: Ms SHS_QMR1
Plan Submission Date: 03-Jan-2025
Attachment: 0 files
Study Title: 24618YP
Quick Link: Study Summary, CRMS, PISAF

PI/Site-PI: A/Prof CGH_PI11
Plan Endorsement Date: -
Current Study Site Status: Approved
Plan Reviewer: A/Prof CGH_PI11

Monitoring Plan

ONLYOFFICE File View Plugins

MOB001-24Nov2024_SingHealth-Monitoring-Plan_24-Nov-2024 03:16:24.docx

ECOS MONITORING PLAN

SINGHEALTH OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE

ECOS Reference: 2024-3130 IRB: SingHealth CIRB-Board E

Query List Saved at 03-Jan-2025 17:09:34

4 + General Query

Pending Query All Query

0/1 Pending

6 Batch Close

3 + Further Query 5 X Close Query

0 Queries Selected

General

Will monitoring be performed at the pharmacy?
IP is stored and managed by hospital pharmacy. IP records are maintained by delegated pharmacists.
Query Round 1 A/Prof CGH_PI11 03-Jan-2025 16:57:26

Yes, IP storage facility visit will be conducted and IP records must be made available for review during monitoring visit.
Query Round 1 Ms SHS_QMR1 03-Jan-2025 17:09:34

Monitoring Plan

ONLYOFFICE File View Plugins

MOB001-24Nov2024_SingHealth-Monitoring-Plan_24-Nov-2024 03:16:24.docx

ECOS MONITORING PLAN

SINGHEALTH OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE

ECOS Reference: 2024-3130 IRB: SingHealth CIRB-Board E

Regulatory Reference: (if applicable)

Study Title: 24618YP

PI/ Site-PI: A/Prof CGH_PI11

Study Site: Changi General Hospital

1. After sending query to the Monitor, MP status will be changed from “Pending Review” to “**Query Pending Reply**”.
2. When Monitor has replied to the query, MP status will be changed to “**Pending Review**”.
3. To re-query on a previous query, click on “+ **Further Query**”.
4. To add a new query, click on “+ **General Query**”.
5. To close a query, click on “**X Close Query**”.
6. To close query in batches, select the query box and click on “**Batch Close**”.

3) Endorse Monitoring Plan (MP)

PI/Site-PI only

The interface displays the 'View Monitoring Plan' page for '2024-3723 | KK Women's and Children's Hospital' with a 'Pending Review' status. The top navigation bar includes a home icon, a menu icon, and a 'Back to My Tasks' link. The main content area shows a document viewer for 'MOB003-14Nov2024_SingHealth-Monitoring-Plan_14-Nov-2024 23:31:34.docx'. The document content includes the ECOS logo, 'MONITORING PLAN', and 'SINGHEALTH' branding. A 'Restricted, Sensitive (Normal)' label is visible. The bottom navigation bar also includes a home icon, a menu icon, and a 'Back to My Tasks' link. The 'Endorse' button is highlighted in the top screenshot, and the 'Close Query' button is highlighted in the bottom screenshot.

2024-3723 | KK Women's and Children's Hospital Pending Review

ECOS Ref: 2024-3723

Monitoring Plan

ONLYOFFICE File View Plugins MOB003-14Nov2024_SingHealth-Monitoring-Plan_14-Nov-2024 23:31:34.docx

ECOS MONITORING PLAN

Restricted, Sensitive (Normal)

SINGHEALTH

2024-3723 | KK Women's and Children's Hospital Pending Review

ECOS Ref: 2024-3723

Monitor: A/Prof SHS_MON1

Plan Submission Date: 15-Nov-2024

Attachment: [0 files](#)

Study Title: SHS MON UAT 2 - Study A

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

PI/Site-PI: A/Prof KKH_PI 1

Plan Endorsement Date: -

Current Study Site Status: Approved

Plan Reviewer: A/Prof KKH_PI 1

Monitoring Plan

ONLYOFFICE File View Plugins MOB003-14Nov2024_SingHealth-Monitoring-Plan_14-Nov-2024 23:31:34.docx

ECOS MONITORING PLAN

Restricted, Sensitive (Normal)

SINGHEALTH

OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE

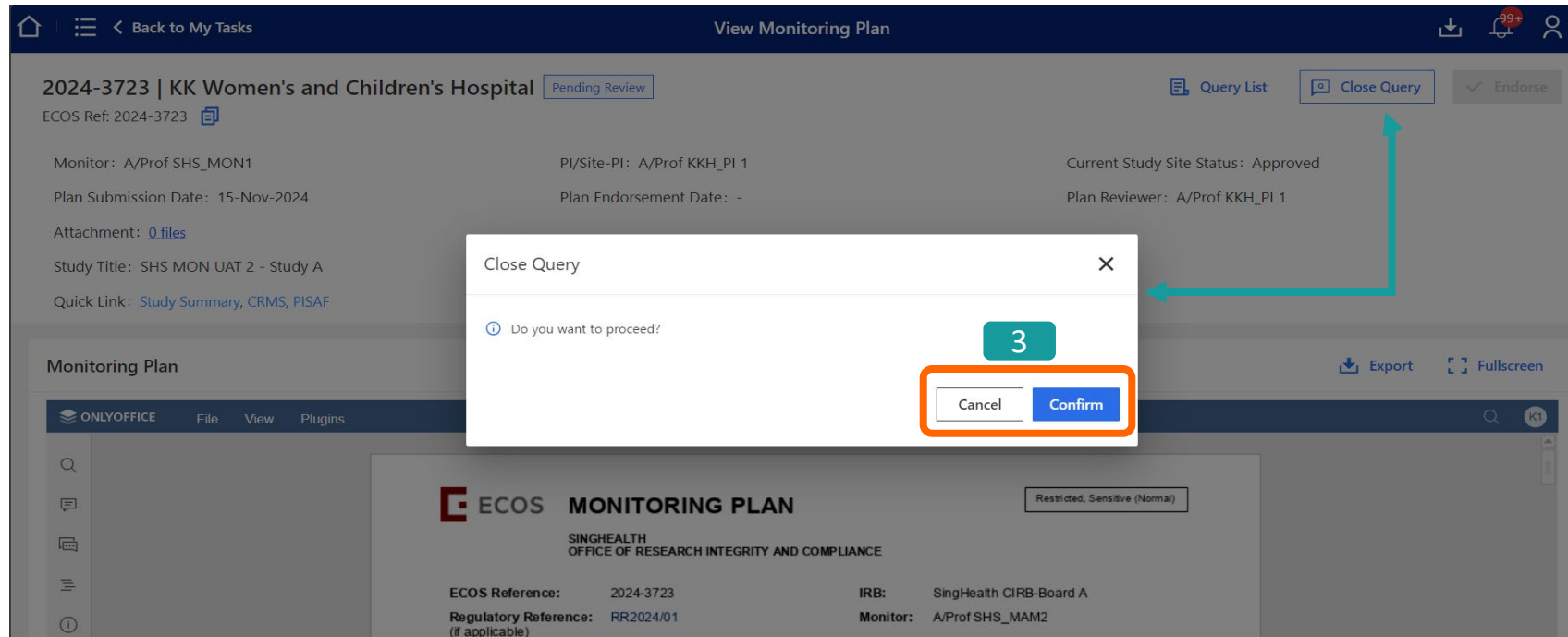
1. The MP can only be endorsed if there is no outstanding query.

2. After all query has been closed, the "Close Query" button is enabled.

A pop-up window to confirm the action will be shown.

3) Endorse Monitoring Plan (MP)

PI/Site-PI only

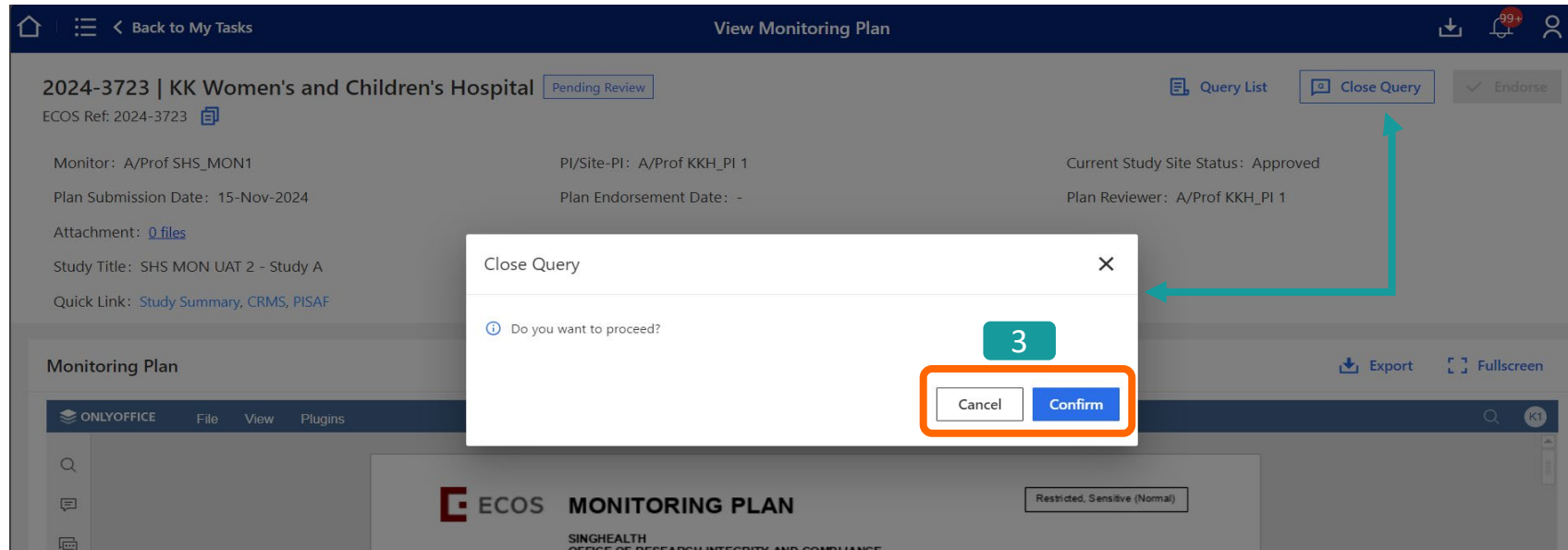


3. Click on “**Confirm**” to proceed, or “**Cancel**” to return to the previous page.

4. After clicking “**Confirm**” the “**Endorse**” button will be enabled.

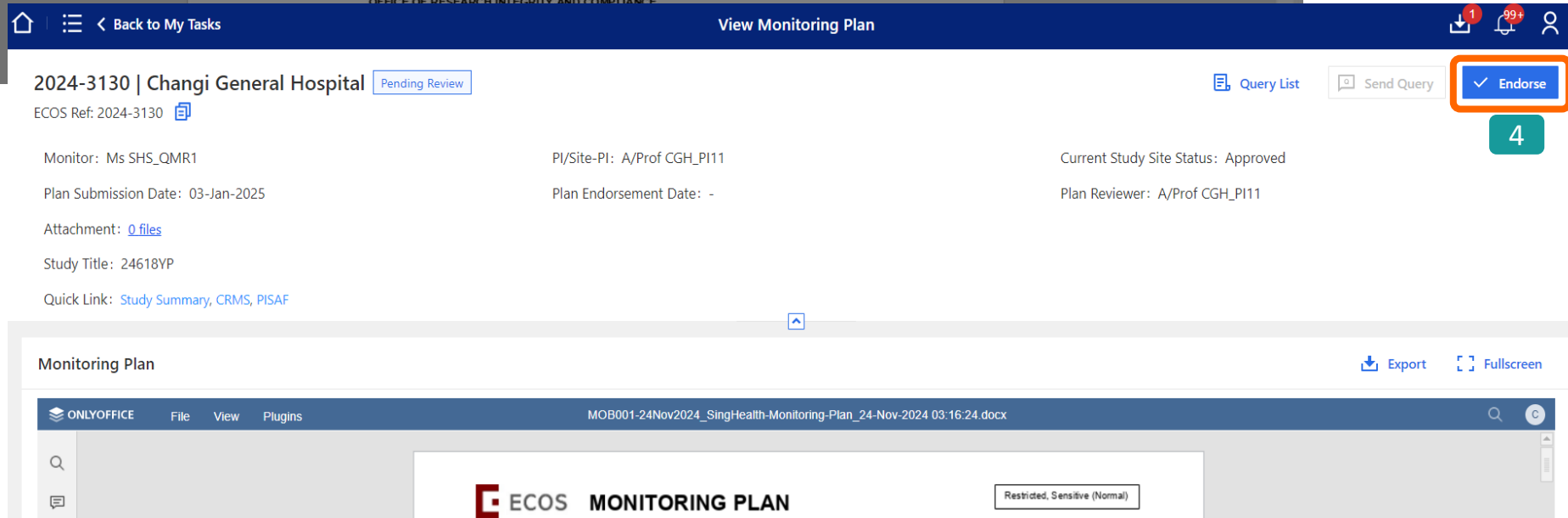
3) Endorse Monitoring Plan (MP)

PI/Site-PI only



3. Click on “**Confirm**” to proceed, or “**Cancel**” to return to the previous page.

4. After clicking “**Confirm**” the “**Endorse**” button will be enabled.



3) Endorse Monitoring Plan (MP)

PI/Site-PI only

The screenshot displays the 'View Monitoring Plan' page for monitoring plan 2024-3130 at Changi General Hospital. The page includes a header with navigation links and a top bar with a 'Back to My Tasks' button. The main content area shows details about the monitoring plan, including the monitor's name, submission date, attachment, study title, and quick links. A 'Monitoring Plan' section at the bottom contains a table with details such as ECOS Reference, Regulatory Reference, Study Title, PI/Site-PI, and Study Site. A red box highlights the 'Endorse' button in the top right corner, and a green arrow points from it to a pop-up dialog box. The dialog box asks 'Do you want to proceed?' and has 'Cancel' and 'Confirm' buttons. A green circle with the number '5' is next to the 'Endorse' button.

2024-3130 | Changi General Hospital Pending Review

ECOS Ref: 2024-3130

Monitor: Ms SHS_QMR1

Plan Submission Date: 03-Jan-2025

Attachment: [0 files](#)

Study Title: 24618YP

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

PI/Site-PI: A/Prof CGH_PI11

Plan Endorsement Date: -

Current Study Site Status: Approved

Plan Reviewer: A/Prof CGH_PI11

Query List Send Query ✓ Endorse

5

Endorse

Do you want to proceed?

Cancel Confirm

SINGHEALTH
OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE

ECOS Reference:	2024-3130	IRB:	SingHealth CIRB-Board E
Regulatory Reference: (if applicable)		Monitor:	Ms SHS_QMR1
Study Title:	24618YP		
PI/ Site-PI:	A/Prof CGH_PI11		
Study Site:	Changi General Hospital		

5. To endorse the MP, click on “**Endorse**”. A pop-up comment box will appear. Comments are **optional**.

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

MP cannot be edited once endorsed.

An email notification will be sent to the Monitor to notify on the MP endorsement.

3) Endorse Monitoring Plan (MP)

PI/Site-PI only

2024-3130 | Changi General Hospital Pending Review

ECOS Ref: 2024-3130

Monitor: Ms SHS_QMR1
Plan Submission Date: 03-Jan-2025
Attachment: [0 files](#)
Study Title: 24618YP
Quick Link: [Study Summary](#), [CRMS](#), [PISAF](#)

PI/Site-PI: A/Prof CGH_PI11
Plan Endorsement Date: -
Current Study Site Status: Approved
Plan Reviewer: A/Prof CGH_PI11

Endorse

Do you want to proceed?

Cancel Confirm

2024-3532 | Sengkang General Hospital Endorsed

ECOS Ref: 2024-3532

Monitoring Plan

ONLYOFFICE File View Plugins

MOB001-14Nov2024_SingHealth-Monitoring-Plan_14-Nov-2024 11:01:30.docx

ECOS MONITORING PLAN

SINGHEALTH OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE

Restricted, Sensitive (Normal)

5. To endorse the MP, click on “**Endorse**”. A pop-up comment box will appear. Comments are **optional**.

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

MP cannot be edited once endorsed.

An email notification will be sent to the Monitor to notify on the MP endorsement.

Content – Monitoring Module

1. View/Locate Monitoring Tasks
2. View and Access Study Monitoring Information
3. Query and Endorse Monitoring Plan (MP)
- 4. Respond to Monitoring Issue**
5. Reply to CAPA Query for Monitoring Issue
6. Export of Monitoring Report, Letters, Issue List

4) Respond to Monitoring Issue

Responsible Person

The screenshot shows the ECOS Dashboard with a sidebar on the left and a main content area. The sidebar includes links to Homepage, Dashboard (highlighted), My Tasks, My Notices, IRB, CRMS, Compliance, Monitoring, FCOI, SDB, and Report. The main content area has a top navigation bar labeled 'Dashboard'. Below this, there are five summary cards: IRB (0), CRMS (0), FCOI (0), Monitoring (2), and Compliance (0). The Monitoring card is highlighted with an orange border and contains a table with the following data:

Monitoring	
PI/Site-PI	0
Plan Reviewer	0
Responsible Person	2

Note:

- Issues noted during Monitoring Visit that require follow-up/resolution will be assigned to “**Responsible Person**” by the Monitor.
- For each Issue, one or more Responsible Person may be assigned.
- 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.

4) Respond to Monitoring Issue


Responsible Person

The screenshot shows the ECOS Dashboard. On the left sidebar, the 'Dashboard' menu item is highlighted with a red box and a green '1' callout. In the main content area, the 'Monitoring' widget is highlighted with a red box and a green '2' callout. Within the 'Monitoring' widget, the 'Responsible Person' link is highlighted with a red box.


Category	Count
IRB	0
CRMS	0
FCOI	0
Monitoring	2
Compliance	0

Category	Count
Study	0
Endorsement	0
Study Member Review	0
My FCOI List	0
PI/Site-PI	0
Plan Reviewer	0
Responsible Person	2
Deviation/Non Compliance - Site	0
Serious Adverse Event - Site	0
PI Self-Assessment Form - Site	0
Study Closure Checklist - Site	0

Via Dashboard > My Tasks

1. The Responsible Person can locate all assigned Issues via “Dashboard”.
2. Click on “**Responsible Person**” to enter “**My Tasks**” > “**Responsible Person**” page.
3. Click on  “**View**” icon in the “**Action**” column will bring user to “**My Issue**” list.

The screenshot shows the ECOS My Tasks page. The 'My Tasks' menu item is highlighted with a red box. The 'Monitoring' widget is highlighted with a blue box. The 'Responsible Person (1)' link is highlighted with a red box. Below the widgets, there is a table of monitoring issues. The 'Action' column of the table is highlighted with a red box, and the 'View' icon is highlighted with a green '3' callout.

Form Type	ECOS Ref	Task Due date	Monitor Name	PI/Site-PI	Date Sent to Site	Task Status	Action
Follow-up Letter/ Issue List	2024-3610	18-Dec-2024	A/Prof SHS_MON2	A/Prof CGH_PI11	18-Dec-2024	Pending	

4) Respond to Monitoring Issue

Responsible Person

ECOS My Issue

Columns Export Filter(1)

2

1

3

ECOS Ref	Visit Type & No.	Issue Number	Issue Category	Issue Status	Issue Date	Issue Due Date	Issue Description	Action
2024-3610	SMV001	ISE-007	Biological Materials	Issue Pending Completion	09-Dec-2024	11-Dec-2024	Missing HBM Management SOP	
2024-3610	SMV001	ISE-003	Safety Reporting	Query Pending Reply	09-Dec-2024	11-Dec-2024	AE not assessed and not documented	
2024-3610	SMV001	ISE-002	Protocol Compliance	Query Pending Reply	09-Dec-2024	11-Dec-2024	CGH-A01 Visit 2 not done	
2024-3610	SMV001	ISE-001	Research Participant Recruitment	Query Pending Reply	09-Dec-2024	11-Dec-2024	Missing eligibility assessment documentation	

Via Monitoring > My Issue

1. You can also locate the Issue listing via the **Monitoring Module** > “**My Issue**” menu on the left navigation panel.
2. By default, you will see tasks which are pending your action (Issue Status = Issue Pending Completion/ Query Pending Reply).
3. Click on “**View**” icon in the “**Action**” column to view the **Issue Detail**.
4. To view another Issue Detail, toggle using the “<” and “>” arrows at the bottom of the Issue Detail page.

Issue Detail

ISE-011 Query Pending Reply

Query List

Monitoring Information

Study Title: SHS MON UAT 2 - Study F
ECOS Ref: 2024-3736
Visit Type & No.: SMV003
PI/Site-PI: Dr NNI_PI 2
Monitoring Category: ORIC Monitoring Category 2
Study Site: National Neuroscience Institute
Monitor: A/Prof SHS_MON2

Issue Information

Issue Item	Issue Category	Issue Description
H2b. Brief description of the MD transfer	Medical Device	Documentation on MD transfer, not available MD was transferred from NNI to TTSH. But documentation on MD transfer is not available.

Issue Date CAPA Needed Issue Due Date

4

4

ISE-012 Issue Pending Completion

ISE-010 Issue Pending Completion

4) Respond to Monitoring Issue

Responsible Person

The screenshot displays the 'Issue Detail' page for issue ISE-004, which is 'Issue Pending Completion'. The page is divided into two main sections: 'Issue Information' and 'Corrective Action Preventive Action'.

Issue Information:

Issue Item	Issue Category	Issue Description
N3	Study Team	Training records, not filed. Training materials, not filed.

Issue Date	CAPA Needed	Issue Due Date
22-Nov-2024	Yes	22-Nov-2024

Issue Closure Date	Responsible Person	Recommendation
	Dr NNI_PI 2	To file training records. To file training materials. Reminded site to perform training for all amended and approved protocols.

Monitor Comment

Corrective Action Preventive Action:

Root Cause ②

Corrective Action Preventive Action

Root Cause ②

Corrective Actions ②

Preventive Actions ②

CAPA Completion Date: ②

Attachment

Please ensure there are no personal identifiers in the attached document

Upload

The modal also contains buttons for 'Cancel', 'Save', and 'Save and Exit'.

Numbered callouts in the image:

- 4: Points to the 'Edit' button in the top right of the modal.
- 5: Points to the 'Corrective Actions' field.
- 6: Points to the 'Save and Exit' button.

Only assigned Responsible Person can edit the “Issue Detail” page.

- Click “**Edit**” to complete the Corrective Actions and Preventive Actions (CAPA).
- Fields marked with * (asterisk) are **mandatory** for completion.
- Click on “**Save**” to ensure the edits have been saved, or “**Cancel**” if you do not want to save the data.

After the form has been saved, click on “**Save and Exit**” to exit editing mode.

4) Respond to Monitoring Issue

Responsible Person

The screenshot shows the 'Issue Detail' page for issue ISE-004, which is in the 'Issue Pending Completion' state. The page includes sections for 'Issue Information', 'Monitor Comment', 'Corrective Action Preventive Action', 'Root Cause', 'Corrective Actions', and 'Preventive Actions'. A 'Submit' button is highlighted with a red box. A confirmation pop-up window is displayed in the center, asking 'Do you want to proceed?' with 'Cancel' and 'Confirm' buttons. The 'Confirm' button is highlighted with an orange box.

7. After clicking “**Save and Exit**”, the “**Submit**” button will be enabled. Click on the “**Submit**” button to proceed.

8. A confirmation pop-up window will appear. Click “**confirm**” to proceed.

9. If the mandatory fields are not completed, submission will not go through.

Click “**Confirm**” to return to the Issue Detail page and complete all necessary fields.

The ECOS pop-up window displays a warning message: "Your application is incomplete. You must complete all relevant sections before you can proceed to submit." Below the message is a table listing the mandatory fields that need to be completed:

Field	Reason	Action
CAPA Completion Date:	This is a mandatory field. Please fill in response.	Link
Corrective Actions	This is a mandatory field. Please fill in response.	Link
Preventive Actions	This is a mandatory field. Please fill in response.	Link



A 'Confirm' button is highlighted with an orange box at the bottom right of the pop-up window.

Content – Monitoring Module




1. View/Locate Monitoring Tasks
2. View and Access Study Monitoring Information
3. Query and Endorse Monitoring Plan (MP)
4. Respond to Monitoring Issue
- 5. Reply to CAPA Query for Monitoring Issue**
6. Export of Monitoring Report, Letters, Issue List

5) Reply to CAPA Query

Responsible Person

  [Back to My Issue](#)

Issue Detail

ISE-011 [Query Pending Reply](#)

1 [Query List](#)

Monitoring Information

Study Title: SHS MON UAT 2 - Study F

ECOS Ref: 2024-3736

Visit Type & No.: SMV003

PI/Site-PI: Dr NNI_PI 2

Monitoring Category: ORIC Monitoring Category 2

Study Site: National Neuroscience Institute

Monitor: A/Prof SHS_MON2

Issue Information

Issue Item	Issue Category	Issue Description
H2b. Brief description of the MD transfer	Medical Device	Documentation on MD transfer, not available
		MD was transferred from NNI to TTSH. But documentation on MD transfer is not available.

Issue Date	CAPA Needed	Issue Due Date
------------	-------------	----------------

[ISE-012](#) [Issue Pending Completion](#)

ISE-010 [Issue Pending Completion](#)

After submission of Issue CAPA, Monitor may raise query. Responsible Person will receive email notification on the Issue(s) with CAPA query.

1. To view query(ies), click on the “**Query List**” button. A 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. Enter your reply under “**Pending Query**” > “**Reply Query**”. Entry is auto-saved.

5) Reply to CAPA Query

Responsible Person

The screenshot displays the 'Issue Detail' page for ISE-011, which is in a 'Query Pending Reply' state. The interface includes a 'Monitoring Information' section with details like 'Study Title: SHS MON UAT 2 - Study F', 'ECOS Ref: 2024-3736', 'PI/Site-PI: Dr NNI_PI 2', 'Study Site: National Neuroscience Institute', 'Visit Type & No.: SMV003', 'Monitoring Category: ORIC Monitoring Category 2', and 'Monitor: A/Prof SHS_MON2'. A 'Query List' button with a red dot indicating a pending action is highlighted with a red box and labeled '1'. An arrow points from this button to a 'Pending Query' section, which is also highlighted with a red box and labeled '2'. This section shows a progress bar for '0/1 Pending' queries. Below, a 'Root Cause' section contains a notification: 'To test query to site email notification. Query Round 1 A/Prof SHS_MON2 29-Nov-2024 09:26:29'. At the bottom, a 'Reply Query' form with a red border and a 'Please enter' placeholder is highlighted with a red box.

ISE-011 [Query Pending Reply](#)

Monitoring Information

Study Title: SHS MON UAT 2 - Study F
ECOS Ref: 2024-3736
Visit Type & No.: SMV003

PI/Site-PI: Dr NNI_PI 2
Monitoring Category: ORIC Monitoring Category 2

Study Site: National Neuroscience Institute
Monitor: A/Prof SHS_MON2

Issue Information

Issue Item: H2b. Brief description of the MD transfer
Issue Category: Medical Device

Issue Date: CAPA Needed

[Back to My Issue](#) [Query List](#) [Pending Query](#) [All Query](#)

0/1 Pending

Root Cause

To test query to site email notification.
Query Round 1 A/Prof SHS_MON2 29-Nov-2024 09:26:29

*** Reply Query**

Please enter

After submission of Issue CAPA, Monitor may raise query. Responsible Person will receive email notification on the Issue(s) with CAPA query.

1. To view query(ies), click on the “**Query List**” button. A 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. Enter your reply under “**Pending Query**” > “**Reply Query**”. Entry is auto-saved.

5) Reply to CAPA Query

Responsible Person

ISE-011

Query Pending Reply

Monitoring Information

Study Title: SHS MON UAT 2 - Study F

ECOS Ref: 2024-3736

Visit Type & No.: SMV003

PI/Site-PI: Dr NNI_PI 2

Monitoring Category: ORIC Monitoring Category 2

Issue Information

Issue Item

H2b. Brief description of the MD transfer

Issue Category

Medical Device

Issue Date

28-Nov-2024

CAPA Needed

Yes

Issue Closure Date

Responsible Person

Query List

Pending Query

All Query

3

Query Status

Please select

Query Item

Please select

Queried/Replied By

Please select

Query Round

Please select

Corrective Actions

Please provide a copy of the file to the Monitor for review.
Query Round 2 A/Prof SHS_MON2 05-Jan-2025

Root Cause

To test query to site email notification.
Query Round 1 A/Prof SHS_MON2 29-Nov-2024

CAPA response updated.
Query Round 1 Dr NNI_PI 2 05-Jan-2025

ISE-012

Issue Pending Completion

3. You can view all queries for each issue under “All Query” tab.
4. If updates to CAPA response is required during the query process, click on “Edit” in the CAPA section.
- (Refer slide 25 for steps to edit and save CAPA response)

5) Reply to CAPA Query

Responsible Person

Issue Detail

ISE-011

Query Pending Reply

Monitoring Information

Study Title: SHS MON UAT 2 - Study F

ECOS Ref: 2024-3736

Visit Type & No.: SMV003

PI/Site-PI: Dr NNI_PI 2

Monitoring Category: ORIC Monitoring Category 2

Issue Information

Issue Item

H2b. Brief description of the MD transfer

Issue Category

Medical Device

Issue Date

28-Nov-24

CAPA Needed

Yes

Issue Due Date

22-Nov-2024

Issue Closure Date

Responsible Person

Dr NNI_PI 2

Recommendation

To file training records.

To file training materials.

Reminded site to perform training for all amended and approved protocols.

Monitor Comment

Corrective Action Preventive Action

Root Cause

STM not aware that printed copies of training record must be maintained in ISF.

Query List

Export

Pending Query

All Query

3

Query Status

Please select

Query Item

Please select

Queried/Replied By

Please select

Query Round

Please select

Corrective Actions

Please provide a copy of the file to the Monitor for review.

Query Round 2 A/Prof SHS_MON2 05-Jan-2025

Root Cause

To test query to site email notification.

Query Round 1 A/Prof SHS_MON2 29-Nov-2024

CAPA response updated.

Query Round 1 Dr NNI_PI 2 05-Jan-2025

Issue Detail

ISE-004

Query Pending Reply

Query List

Issue Information

Issue Date

22-Nov-2024

CAPA Needed

Yes

Issue Due Date

22-Nov-2024

Issue Closure Date

Responsible Person

Dr NNI_PI 2

Recommendation

To file training records.

To file training materials.

Reminded site to perform training for all amended and approved protocols.

Monitor Comment

Corrective Action Preventive Action

Root Cause

STM not aware that printed copies of training record must be maintained in ISF.

- 3. You can view all queries for each issue under “All Query” tab.
 - 4. If updates to CAPA response is required during the query process, click on “Edit” in the CAPA section.
- (Refer slide 25 for steps to edit and save CAPA response)

5) Reply to CAPA Query

Responsible Person

Home

Menu

Back to My Issue

Issue Detail

Download

99+

Profile

ISE-011

Query Pending Reply

5

Query List

Reply Query

6

Monitoring Information

Study Title: SHS MON UAT 2 - Study F

ECOS Ref: 2024-3736

Visit Type & No.: SMV003

PI/Site-PI: Dr NNI_PI 2

Monitoring Category: ORIC Monitoring Category 2

Study Site: National Neuroscience Institute

Monitor: A/Prof SHS_MON2

Issue Information

<div>Issue Item</div> <div>H2b. Brief description of the MD transfer</div>	<div>Issue Category</div> <div>Medical Device</div>	<div>Issue Description</div> <div>Documentation on MD transfer, not available</div>
<div>Issue Date</div> <div>28-Nov-2024</div>	<div>CAPA Needed</div> <div>Yes</div>	<div>Issue Due Date</div> <div>12-Dec-2024</div>
<div>Issue Closure Date</div>	<div>Responsible Person</div>	<div>Recommendation</div>

< ISE-012

Issue Pending Completion

ISE-010

Issue Pending Completion

 >

5. When all the query(ies) have been addressed, the red dot indicator will disappear.
6. Click on “**Reply Query**”, a **pop-up window** will appear for the user’s confirmation.
7. Click on “**Confirm**” to proceed or “**Cancel**” to return to the issue detail page.

5) Reply to CAPA Query

Responsible Person

The screenshot displays the 'Issue Detail' page for ISE-011, which is in a 'Query Pending Reply' state. The page includes sections for 'Monitoring Information' and 'Issue Information'. A red box highlights the 'Reply Query' button in the top right corner, with a green arrow pointing to it labeled '5'. Another green arrow points from the button to a 'Reply Query' pop-up window, labeled '6'. The pop-up window asks 'Do you want to proceed?' and lists the query item 'Root Cause' with a description 'To test query to site email notification.' and a status 'CAPA response updated.' At the bottom of the pop-up, the 'Confirm' button is highlighted with a red box, with a green arrow pointing to it labeled '7'. The 'Cancel' button is also visible next to it.

- When all the query(ies) have been addressed, the red dot indicator will disappear.
- Click on “**Reply Query**”, a **pop-up window** will appear for the user’s confirmation.
- Click on “**Confirm**” to proceed or “**Cancel**” to return to the issue detail page.

5) Reply to CAPA Query

All Responsible Person

ISE-014

Issue Pending Review

8

Query List

Send Query

Close Issue

Monitoring Information

Study Title: SHS MON UAT 2 - Study F

ECOS Ref: 2024-3736

Visit Type & No.: Ad-Hoc Others004

PI/Site-PI: Dr NNI_PI 2

Monitoring Category: ORIC Monitoring Category 2

Study Site: National Neuroscience Institute

Monitor: A/Prof SHS_MON2

Issue Information

9

Track Changes

Issue ID	Issue Item	Issue Category
	B. Purpose of Contact	Study Conduct/Management
Issue Description	Issue Date	CAPA Needed
test re-assignment	29-Nov-2024	Yes
Issue Due Date	Issue Closure Date	Responsible Person
30-Nov-2024		Ms NNI_STM, Asst Prof NNI_Co-I 1
Recommendation	Monitor Comment	

< ISE-015

Issue Pending Review

ISE-013

Issue Pending Completion

>

8. After Responsible Person has replied to query, Issue status will be changed from “Query Pending Reply” to “Issue Pending Review”.
- The form cannot be edited further.
9. If changes were made to the CAPA, you can view the changes using the “Track Changes” function.

5) Reply to CAPA Query

All Responsible Person

The screenshot displays the CAPA system interface. At the top, a blue header bar contains navigation icons, a 'Back to Monitoring Issue' link, the 'Issue Detail' title, and user notification icons. Below the header, a white bar shows 'ISE-014' with a status of 'Issue Pending Review' and a green badge with the number '8'. To the right are links for 'Query List', 'Send Query', and 'Close Issue'. The main content area is divided into sections: 'Monitoring Information' (Study Title: SHS MON UAT 2 - Study F, ECOS Ref: 2024-3736, PI/Site-PI: Dr NNI_PI 2, Study Site: National Neuroscience Institute, Visit Type & No.: Ad-Hoc Others004, Monitoring Category: ORIC Monitoring Category 2, Monitor: A/Prof SHS_MON2) and 'Issue Information' (Issue ID, Issue Item, Issue Category). A green badge with the number '9' is next to a 'Track Changes' button. A modal window titled 'Track Changes' is open, showing 'Current Version' (05-Jan-2025 16:10:04 ISE-012) and 'Previous Version' (05-Jan-2025 16:05:55 ISE-012). It includes a 'CAPA Completion Date' section with a red strikethrough date '01-Nov-2024' and a green date '02-Dec-2024'. The modal has 'Close' and 'Export' buttons. The background shows a list of issues with columns for Issue ID, Issue Item, and Issue Category.

8. After Responsible Person has replied to query, Issue status will be changed from “Query Pending Reply” to “**Issue Pending Review**”.

The form cannot be edited further.

9. If changes were made to the CAPA, you can view the changes using the “**Track Changes**” function.

Content – Monitoring Module

1. View/Locate Monitoring Tasks
2. View and Access Study Monitoring Information
3. Query and Endorse Monitoring Plan (MP)
4. Respond to Monitoring Issue
5. Reply to CAPA Query for Monitoring Issue
- 6. Export of Monitoring Report, Letters, Issue List**

6) Export of Monitoring Report, Letters, Issue List

ECOS

Study Monitoring Information

99+

Homepage

IRB

CRMS

Compliance

Audit

Monitoring

My Issue

Plan Review

Study Monitoring Information

Study Closure Checklist

Columns

Export

Filter

ECOS Ref	Study Site	PI/Site-PI	No. of Issues	Initial Monitoring Date	Last Monitoring Date	Action
2024-3735	National Neuroscience Institute	Mr NNI_PI 1	Total: 9 <ul style="list-style-type: none">Issue Pending Send: 2Closed: 7	25-Nov-2024	01-Jan-2025	<div>View Schedule</div> <div></div>
2024-3592	National Neuroscience Institute	Mr NNI_PI 1	Total: 29 <ul style="list-style-type: none">Issue Pending Completion: 5Closed: 24	16-Dec-2024	20-Dec-2024	<div></div> <div></div>
2024-3534	National Neuroscience Institute	Mr NNI_PI 1	Total: 12 <ul style="list-style-type: none">Issue Pending Review: 6Closed: 6	18-Nov-2024	19-Nov-2024	<div></div> <div></div>

To export monitoring visit documents, go to **Monitoring** menu on the left navigation panel.
> **Study Monitoring Information** > **View Schedule**.

6) Export of Monitoring Report, Letters, Issue List

Home

Menu

Back to Study Monitoring Information

Monitoring Schedule Detail

Download

1

99+

Profile

2024-3610 | Changi General Hospital

Study Site: Changi General Hospital

PI/Site-PI: A/Prof CGH_PI11

Monitor: A/Prof SHS_MON3

Current Study Site Status: Ongoing

Study Title: SHS_AUD-UAT_Study-A19_CGH_TB Collection

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

SMV001

Completed

1

Plan Visit

Confirmation Letter

Monitoring Report

Issue List

Follow-up Letter

Confirmation Letter

Attachment

Export

To: CGH_PI11

Cc: CGH_RO7, SHS_MON3, SHS_MRR1

Subject: [Revised] ECOS Ref. 2024-3610 | ...

Content: [Preview](#)

ONLYOFFICE

File

View

Plugins

2024-3610-Changi General Hospital-SMV001-Confirmation Letter 09-D...

Search

ECOS

SINGHEALTH
OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE

Dear A/Prof CGH_PI11

MONITORING VISIT BY SINGHEALTH OFFICE OF RESEARCH INTEGRITY & COMPLIANCE

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 “**Export**” button within the respective menu.

6) Export of Monitoring Report, Letters, Issue List

2024-3610 | Changi General Hospital

SMV001 Completed

Plan Visit

Confirmation Letter

Monitoring Report

Issue List

Follow-up Letter

Follow-up Letter

Attachment **Export**

To: CGH_PI11 Cc: CGH_RO7, SHS_MON3 Subject: [For Action] ECOS Ref. 2024-361...

Content: [Preview](#)

ONLYOFFICE

File View Plugins 2024-3610-Changi General Hospital-SMV001-Follow-up Letter 09-Dec-20...

Restricted, Sensitive (Normal)

ECOS
SINGHEALTH
OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE

< Back to Study Monitoring Information

Monitoring Schedule Detail

1 99+

Dear A/Prof CGH...

MONITORING VI

2024-3610 | Changi General Hospital

ECOS Referenc

Study Title: Study Site: Changi General Hospital PI/Site-PI: A/Prof CGH_PI11 Monitor: A/Prof SHS_MON3

Study Site: Current Study Site Status: Ongoing

Study Title: SHS_AUD-UAT_Study-A19_CGH_TB Collection

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

Note
For Letters and Monitoring Visit Reports, the exported documents will be in PDF format.

SMV001 Completed

Plan Visit

Confirmation Letter

Monitoring Report

Issue List

Follow-up Letter

Monitoring Visit Information

Actual Start Date: 17-Dec-2024 Actual End Date: 19-Dec-2024 Study Site Status (Monitoring): Ongoing with active enrolment

Remarks: [View](#)

Monitoring Visit Report: 202... Approved Attachment **Export**

Visit Date(s)

17-Dec-2024 18-Dec-2024 19-Dec-2024

Monitor

A/Prof SHS_MON3

General Info

A. Visit Attendees

6) Export of Monitoring Report, Letters, Issue List

Home

Menu

Back to Study Monitoring Information

Monitoring Schedule Detail

199+

Profile

2024-3610 | Changi General Hospital

Study Site: Changi General Hospital

PI/Site-PI: A/Prof CGH_PI11

Monitor: A/Prof SHS_MON3

Current Study Site Status: Ongoing

Study Title: SHS_AUD-UAT_Study-A19_CGH_TB Collection

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

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-011	P15	Issue Pending Completion	A/Prof CGH_PI11	Study Conduct/Management	
ISE-010	P4e	Issue Pending Completion	A/Prof CGH_PI11	Investigator File/Essential Documents	
ISE-009	P4b	Issue Pending Completion	A/Prof CGH_PI11	Investigator File/Essential Documents	

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

Select **“Download Original”** to save as an Excel file, or **“Safe Download”** to save as PDF file.

synapxe

Issue List_05-Jan-2025.xlsx

Sheet1

Issue List

Downloaded By: A/Prof CGH_PI11

Downloaded Date and Time: 05-Jan-2025 16:39:59

Issue Number	Issue Item	Issue Status	Responsible Person	Issue Category	Issue Description	Recommendation	Issue Date
ISE-011	P15	Issue Pending Completion	A/Prof CGH_PI11	Study Conduct/Management	Research Study Self-Assessment to test tracked change content	to submit annually	2024-12-09 11:4
ISE-010	P4e	Issue Pending Completion	A/Prof CGH_PI11	Investigator File/Essential Doc	IRB comments not filed	to file IRB comments	2024-12-09 11:3
ISE-009	P4b	Issue Pending Completion	A/Prof CGH_PI11	Investigator File/Essential Doc	poster not filed	to file poster	2024-12-09 11:3
ISE-008	P2c. Comments	Issue Pending Completion	A/Prof CGH_PI11	Investigator File/Essential Doc	Protocol not signed	to sign	2024-12-09 11:3
ISE-007	O2	Issue Pending Completion	A/Prof CGH_PI11, Dr CGH_Co	Biological Materials	Missing HBM Management S	to create SOP	2024-12-09 11:3
ISE-006	O1	Closed	A/Prof CGH_PI11	Biological Materials	Missing HBM tracking log	to create HBM tracking log	2024-12-09 11:3
ISE-005	O1	Closed	A/Prof CGH_PI11	Biological Materials	HBM amount collected exceed	to report DNC	2024-12-09 11:3
ISE-004	N3	Closed	A/Prof CGH_PI11	Study Team	STM not trained	To report DNC	2024-12-09 11:3
ISE-003	F. Comments	Query Pending Reply	Dr CGH_Co-I22	Safety Reporting	AE not assessed and not docu	To report DNC	2024-12-09 11:3
ISE-002	E1. Brief description of the D	Query Pending Reply	A/Prof CGH_PI11, Dr CGH_Co	Protocol Compliance	CGH-A01 Visit 2 not done	To report DNC	2024-12-09 11:2
ISE-001	B6. Comments	Query Pending Reply	A/Prof CGH_PI11, Dr CGH_Co	Research Participant Recruitm	Missing eligibility assessment	To create NTF for clarification	2024-12-09 11:2

Need help?

SingHealth Users

it.helpdesk@singhealth.com.sg

1800-666-7777

For Non-PHI Users

<https://for.sg/ecos-support-request>