

# ECOS User Guide: Audit Module

# Contents


## **Audit Module User Guide for:**

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

1. Audit Module General Interface
2. How to Locate the Audit Task
3. How to View and Access Study Audit Information
4. How to Draft Corrective Action and Preventive Action (CAPA) for Audit Findings
5. How to View/ Reply to CAPA Query

## 1) Audit Module General Interface - Columns

[illegible]

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** using  and click on **“Save”**.
3. To reset the columns to its default view, click on **“Clear”** and **“Save”**.
4. Study tasks are listed according to the **user’s assigned role**. Tab/tasks shown here may vary across the users.

# 1) Audit Module General Interface – Export Listing

ECOS

My Tasks

Download

84

User Icon

Homepage

Dashboard

My Tasks

My Notices

IRB

CRMS

Compliance

Audit

Monitoring

IRB

CRMS

FCOI

Monitoring

Compliance

Audit

PI (0)

Columns

Export

Filter

Form Type	ECOS Ref	Study Site	Audit Status	Task Due Date	Auditor Name	Date Sent to PI	Action
Site CAPA	2024-3708	Khoo Teck Puat Hospital	Closed	08-Dec-2024	A/Prof NHG_A3	06-Dec-2024	
Site CAPA	2024-3699	Khoo Teck Puat Hospital	CAPA Pending Completion	30-Nov-2024	A/Prof NHG_A2, A/Prof 何庆青	29-Nov-2024	

Download Original

Safe Download (PDF)

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

Audit Study Information							
Downloaded By: Ms KTPH_PISP1							
Downloaded Date and Time: 12-Dec-2024 14:52:04							
Form Type	ECOS Ref	Study Site	Audit Status	Task Due Date	Auditor Name	Date Sent to PI	Task Status
Site CAPA	2024-3708	Khoo Teck Puat Hospital	Closed	08-Dec-2024	A/Prof NHG_A3	06-Dec-2024	Completed
Site CAPA	2024-3699	Khoo Teck Puat Hospital	CAPA Pending Completion	30-Nov-2024	A/Prof NHG_A2, A/Prof 何庆青	29-Nov-2024	Terminated

# 1) Audit Module General Interface – Filter

ECOS

My Tasks

Download

84

Profile

Homepage

Dashboard

My Tasks

My Notices

IRB

CRMS

Compliance

Audit

Monitoring

IRB

CRMS

FCOI

Monitoring

Compliance

Audit

PI (0)

Form Type	ECOS Ref	Study Site	Audit Status	Task Due Date
Site CAPA	2024-3708	Khoo Teck Puat Hospital	Closed	08-Dec-2024
Site CAPA	2024-3699	Khoo Teck Puat Hospital	CAPA Pending Completion	30-Nov-2024

Filter

Form Type:

ECOS Ref:

Study Site:

Task Due Date:

Auditor Name:

Date Sent to PI:

Task Status:

Reset

Search

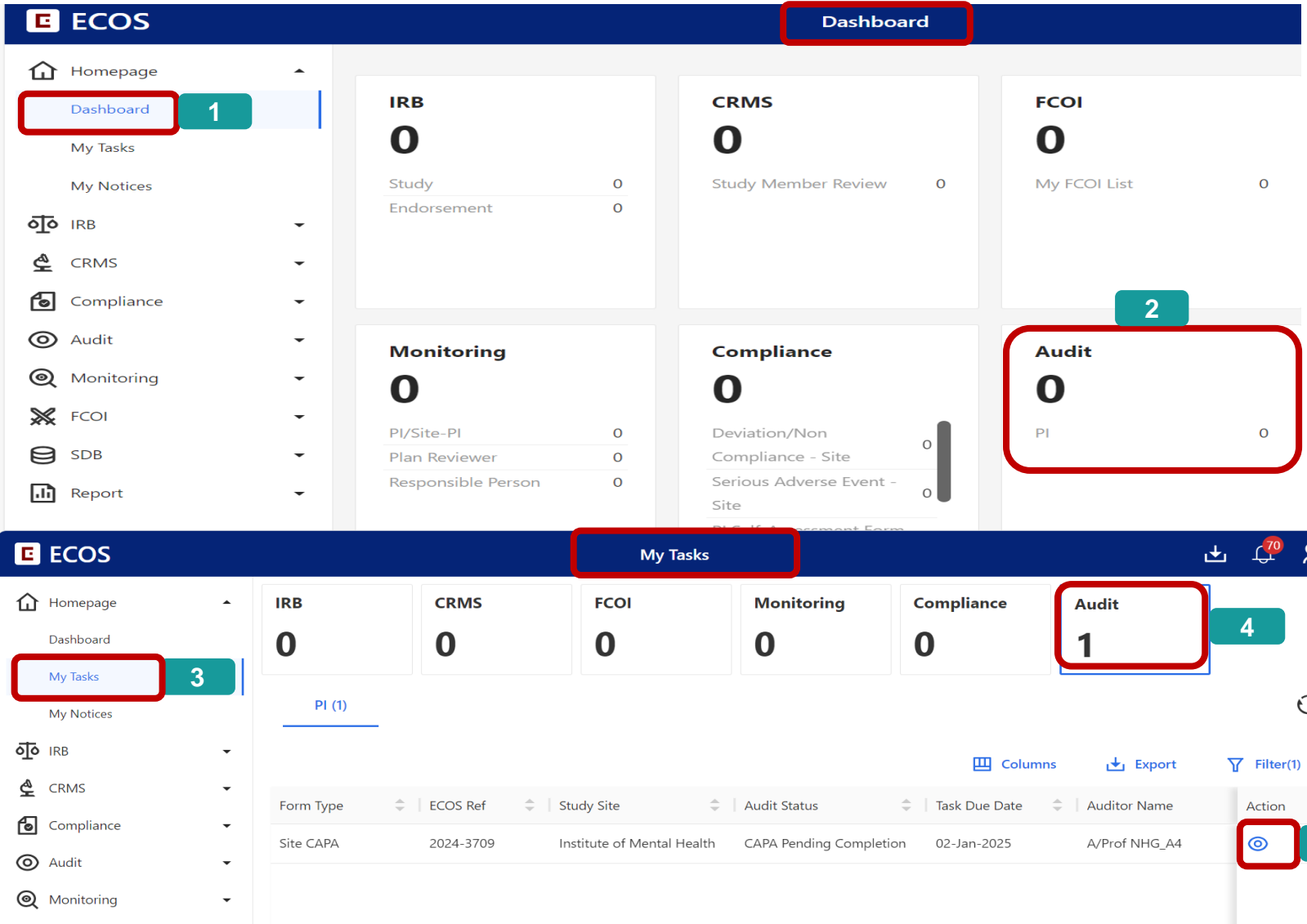
1. Click on “**Filter**” to tailor the listing you wish to view.

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 CAPA task (method 1) – via Homepage



## Via Homepage > Dashboard

1. You can locate your outstanding audit task via “Homepage” > “Dashboard” on the left navigation panel.
2. Locate the “Audit” tile and click on “Audit”. It will lead you to “My Tasks”.
3. You can also access “Homepage” > “My Task” via the left navigation panel.
4. Click on the “Audit” tile.
5. To view the audit task, click on “View” under the “Action” column. The page will be directed to the study audit details (audit report/audit observation list).

## 2) Locate your CAPA task (method 2)– via Audit menu

Study Audit Information										
Columns   Export   Filter										
ECOS Reference	Audit Number	Study Title	Study Site	No. of Findings	No. of Comments	CAPA Due Date	Audit Status	Actual Start Date	Action	
2024-3713	2024-3713-Khoo Teck Puat Hospital-AUD01	Audit UAT test 18 (Routine audit-COI)	Khoo Teck Puat Hospital	0	1	-	Audit Closed	06-Dec-2024		
2024-3699	2024-3699-Khoo Teck Puat Hospital-01	Audit UAT test 4 (Routine audit-COI)	Khoo Teck Puat Hospital	6	2	30-Nov-2024	Audit Closed	29-Nov-2024		
2024-3708	2024-3708-Khoo Teck Puat Hospital-AUD01	Audit UAT test 11 (Routine audit-COI)	Khoo Teck Puat Hospital	6	4	08-Dec-2024	Audit Closed	04-Dec-2024		

### Via Audit> Study Audit Information

1. PI/Site PI, Co-I and Study Team Member can:

- Locate the **audit report** sent by auditor
- **View the findings, comments and recommendations** that arise from the audit
- **Complete the corrective action and corrective action (CAPA)** if needed in findings.

2. To view the audit task, click on  under the “Action” column.

**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 reply to CAPA.

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

### 3) View and Access Your Study Audit Information

Back to Study Audit Information

Study Audit Information Detail

2024-3713-Khoo Teck Puat Hospital-AUD01 | Khoo Teck Puat Hospital

Audit Closed

ECOS Ref: 2024-3713

Plan Audit

1

Site Audit

Audit Report

Audit Report Observation

Plan Audit

Saved at 06-Dec-2024 10:41

Planned Start Date: 09-Dec-2024

Planned Start Time: 07:00

Planned End Date: 29-Dec-2024

Planned End Time: 07:00

Venue: KTPH

Audit Agenda: xx

Attachment: No file uploaded.

Remarks: yy

Audit Notification


Saved at 06-Dec-2024 10:41

Subject: NHG RQM Study Review (2024-3713)

To: KTPH\_PISP1<ktp\_h\_pisp1@taimei.com>

### Via Audit > Study Audit Information

1. Click on **“Plan Audit”** to view **Planned Audit Schedule Detail and Audit Notification.**

**Audit Notification**  Saved at 06-Dec-2024 10:42

---

**Subject:** NHG RQM Study Review (2024-3713) - Notice of Study Review Visit

**To:** KTPH\_PISP1<ktph\_pisp1@taimei.com>

**Cc:** NHG\_A3<nhg\_a3@taimei.com>, KTPH\_ROA1<ktph\_roa1@taimei.com>, baob9<nhg-site3-tester222@taimei.com>, BVH\_MTSec<shs-site16-tester6@taimei.com>, baob9<baob9@taimei.com>

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Dear Ms KTPH\_PISP1,

ECOS Reference: 2024-3713

Study Title: Audit UAT test 18 (Routine audit-COI)

Principal Investigator: Ms KTPH\_PISP1



### 3) View and Access Your Study Audit Information

< Back to Study Audit Information

Study Audit Information Detail

2024-3713-Khoo Teck Puat Hospital-AUD01 | Khoo Teck Puat Hospital

Audit Closed

ECOS Ref: 2024-3713

Plan Audit

Site Audit

Audit Report

1

Audit Report Observation

Site Audit

Closed

NHG RQM STUDY REVIEW REPORT

Default Section

Download List

3

Delete All

P NHG RQM STUDY REVIEW REPORT2024-  
3713.pdf  
230.23 KBDeleteDownload To Local

4

Export

2Attachments

Default Section

SECTION A – STUDY TEA...  
SECTION B - IRB DOCU...  
SECTION C – REGULATOR...  
SECTION D – SUBJECT RE...  
SECTION E- INFORMED ...  
SECTION F – INVESTIGA..  
SECTION G – SAFETY RE..

NHGRQMFor-Cause Study Review Report

Note: As the study review report is a restricted document, please do not retain a copy in the investigator file.

Date of Study Review: 13-Dec-2024

Date of Report: 13-Dec-2024

CAPA Due Date: 12-Jan-2025

Mode of Audit: Physical Audit

1. Executive Summary

Study Title	Audit UAT test 32 (For-cause audit)
ECOS Reference	2024-3835
Principal Investigator (PI)	Mv TTSH_PISPL
Contact Details of PI	Business Address: Business Email: thh_piisp1@taimci.com
Study Site	Tan Tock Seng Hospital
RQM Auditor(s)	A/Prof NHQ_A1
Audit Report Reviewer	Dr NHQ_ARR2
Observers (if any)	2
List of site staff present	S AA BB CC DD EE
Number of findings/comments	Critical Finding: 0 Major Finding: 2 Minor Finding: 1 Comment: 2

Version 3.1 dated 11 Dec 2024

RESTRICTED SENSITIVE NORMAL

[Document classification should be revised in accordance to the sensitivity of data collected]

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## Via Audit > Study Audit Information

1. PI/Site PI/Co-I/STM may view their respective study's Audit Report.
2. To export a copy of the audit report, 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 displayed, and you may save it to your computer local drive.

# 3) View and Access Your Study Audit Information

Home

Back to My Tasks

Study Audit Information Detail

2024-3833-Khoo Teck Puat Hospital-AUD02 | Khoo Teck Puat Hospital

Visit Completed

Submit

Reply Query

ECOS Ref: 2024-3833

Plan Audit

Site Audit

Audit Report

**Audit Report Observation**

Site Audit

CAPA Pending Closure

Audit Report Observation

CAPA Due Date: 15-Jan-2025

Finding

Comment

230.23 KB

Delete

Download To Local

Columns

Export

Filter

View

Comment Number	Comment Item	Category of Comment	Comment Summary	Comment Description	Reference
AUD-C02	General	Biological Materials	materials not stored properly	materials not stored properly	-
AUD-C01	General	Investigator File / Essential Documents	-	CV not filed	-

2024-366802-Dec-2024 09\_22...

OFFICIALS USE ONLY

Study Title: Audit UAT test 6 (For-cause audit)

Approving IRB: NHG DSRB-Domain F1

Principal Investigator (PI): Mr TTSH\_PISP1

Department: Medical Oncology

Study Site: Tan Tock Seng Hospital

RQM Auditor: A/Prof NHG\_A1, A/Prof NHG\_A4

Date of Audit: 29-Nov-2024

CAPA Due Date: 29-Dec-2024

CAPA Submission Date:

CAPA Closed Date:

**CORRECTIVE ACTION AND PREVENTIVE ACTION (CAPA) PLAN**

Finding No.	Grading of Finding	Category of Finding	Finding Summary	Finding Description	Recommendation	Root Cause	Corrective Action	Preventive Action	CAPA Implementation Date
AUD-F03	Major	Informed Consent Process and Documentation	No informed consent process documentation for all the recruited 88 subjects.	No informed consent process documentation for all the recruited 88 subjects.	To submit NCR.				

RESTRICTED – SENSITIVE – NORMAL DOCUMENT

Version 4 dated 03 Oct 2023

Page 1 of 3

- Via Audit > Study Audit Information**
1. PI/Site PI/Co-I/STM may view **their respective study’s Audit Findings/Comments and Corrective Action Preventive Action (CAPA) Report** (if CAPA is already submitted to auditor).
  2. To export a copy of the audit CAPA report, click on **“Export CAPA”**.
  3. When the export is complete, click **“Download To Local”**. The PDF copy of the form will be displayed, you may save it to your computer local drive.

## 4) How to Draft CAPA

**ECOS Dashboard**

**Dashboard**

IRB: 0  
Study: 0  
Endorsement: 0

CRMS: 0  
Study Member Review: 0

FCOI: 0  
My FCOI List: 0

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

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

**Audit: 1** →  
PI: 1

**ECOS My Tasks**

IRB: 0, CRMS: 0, FCOI: 0, Monitoring: 0, Compliance: 0, **Audit: 1**

PI (1)

Form Type	ECOS Ref	Study Site	Audit Status	Task Due Date	Auditor Name	Action
Site CAPA	2024-3831	Khoo Teck Puat Hospital	CAPA Pending Completion	18-Jan-2025	A/Prof NHG_A1	<b>View</b>

### Via Dashboard > My Tasks

1. The PI/Co-I and STM can locate the task via **“Dashboard”**
2. Locate the **“Audit”** tile, click on **“PI”** and you will enter **“My Tasks”** > **“PI”** page.
3. By default, you will see tasks which are pending your action (CAPA Pending Completion/ Query Pending Reply).
4. Click on **“View”** button under the **“Action”** column which will direct the user to the study audit details page.

# 4) How to Draft CAPA

Home

Menu

Back to My Tasks

Study Audit Information Detail

1

1

Profile

2024-3833-Khoo Teck Puat Hospital-AUD02 | Khoo Teck Puat Hospital Visit Completed

Submit

Reply Query

ECOS Ref: 2024-3833

Plan Audit

Site Audit

Audit Report

Audit Report Observation

Finding

Comment

Site Audit

CAPA Pending Closure

The status will reflect the site audit report status.

Audit Report Observation

CAPA Due Date: 15-Jan-2025

Export CAPA

Comment Number

Comment Item

Category of Comment

Comment Summary

Comment Description


Reference

View

AUD-C02	General	Biological Materials	materials not stored properly	materials not stored properly	-	
AUD-C01	General	Investigator File / Essential Documents	-	CV not filed	-	

Rows per page: 100 1-2 of 2

## Via Audit > Study Audit Information Detail

1. Click “Audit Report Observation”, you will be able to see the “Finding” and “Comment” tabs.
2. In this page, you can see the detail breakdown of the **comments** which **do not require** Corrective Action and Preventive Action (CAPA). ). The comment number labelled as **AUD-Cxx**.
3. Click on view  to see the detail comments.

# 4) How to Draft CAPA

Home

Menu

Back to My Tasks

Study Audit Information Detail

Download

92

Profile

2024-3831-Khoo Teck Puat Hospital-AUD01 | Khoo Teck Puat Hospital

Visit Completed

Submit

Reply Query

ECOS Ref: 2024-3831

IRB: NHG DSRB-Domain A

Current Study Site Status: Approved

Study Title: Audit UAT test 27 (System audit)

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

PI/Site-PI: A/Prof KTPH\_SP2

Audit Category: Routine Audit

Auditor: A/Prof NHG\_A1

Plan Audit

Site Audit

Audit Report

1

Audit Report Observation

Site Audit

CAPA Pending Closure

The status will reflect the site audit report status.

Audit Report Observation

CAPA Due Date: 18-Jan-2025

Export CAPA

Finding

Comment

Finding Number	Finding Item	Grading of Finding	Category of Finding	Finding Summary	Finding Description	Recommendation	Action
<div><div>2</div><div>AUD-F01</div></div>	A1. List of study team members and responsibilities (in accordance to study delegation log and discussion with the PI/designated staff)	Minor	Study Team	Responsibility log is not available.	What Is an Audit Scope? Defining an audit scope sets boundaries for the assessment by requiring organizations to outline anything that could otherwise impact the security of the protected information. Understanding the scope is crucial for both the auditors and the entity being audited, as it sets clear expectations and	What Is an Audit Scope? Defining an audit scope sets boundaries for the assessment by requiring organizations to outline anything that could otherwise impact the security of the protected information. Understanding the scope is crucial for both the auditors and the entity being audited, as it sets clear expectations and	<div><div>3</div><div>Edit</div></div>

Rows per page: 100


1-2 of 2

Previous

Next

4

## Via Audit > Study Audit Information Detail

1. Click “Audit Report Observation”, you will be able to see the “Finding” and “Comment” tabs.
2. In this page, you can see the detail breakdown of the audit findings which **require Corrective Action and Preventive Action (CAPA)**. The finding number is labelled as AUD-Fxx.
3. Click the pen icon  to view and edit the details of each finding.
4. After responded to the CAPA, the green tick will appear.

# 4) How to Draft CAPA

Back Finding Detail

AUD-F01 CAPA Pending Completion Query List

Finding 1 of 2

What Is an Audit Scope?  
Defining an audit scope sets boundaries for the assessment by requiring organizations to outline anything that could otherwise impact the security of the protected information. Understanding the scope is crucial for both the auditors and the entity being audited, as it sets clear expectations and focuses the audit efforts.

Corrective Action Preventive Action

Root Cause What Is an Audit Scope?  
Defining an audit scope sets boundaries for the assessment by requiring organizations to outline anything that could otherwise impact the security of the protected information. Understanding the scope is crucial for both the auditors and the entity being audited, as it sets clear expectations and focuses the audit efforts.

Corrective Action Preventive Action

Root Cause

Corrective Action

Preventive Action

CAPA Implementation Date Submission Date

Attachment

Remember to click 'save' after input the CAPA fields for each finding.

Audit Schedule Detail

Task Completed

NHG RQM Study Review (2024-3668) – Overall Audit Closed  
Dear A/Prof NHG\_A1, A/Prof NHG\_A4,  
ECOS a few seconds ago

Site Audit Closed

- 5. Click “Edit” to start completing the form.
- 6. Fields marked with\*are mandatory for completion.
- 7. The “Save” button will appear after you click the edit button. Click on “Save” intermittently to ensure the edits have been saved successfully.
- 8. Site staff can upload supporting document for CAPA. There will be a reminder not to attach document containing personal identifiers.
- 9. After the CAPA form has been saved for one finding, the user can navigate to next finding to continue drafting CAPA. After CAPA is completed for all findings, the PI can click the “Submit” button to send the CAPA to auditor.
- 10. The PI will receive an email notification if CAPA is acceptable and when auditor closes the audit.
- 11. The site audit status changed to “Site Audit Closed”.

## 5) How to View and Reply CAPA Query

The process is shown in three sequential screenshots:

- Step 1:** The 'Finding Detail' page for finding AUD-F06. A 'Query List' button is highlighted in the top right corner.
- Step 2:** The 'Query List' modal is displayed. It shows two tabs: 'Pending Query' (active) and 'All Query'. A 'Reply Query' input field is highlighted in the 'Pending Query' section.
- Step 3:** The 'Reply Query' modal is displayed. It shows a list of queries with their details and a 'Confirm' button at the bottom right.

1. If the CAPA is queried by auditor, a **red dot** will appear beside the ‘**Query list**’ button to indicate that there is an action pending (i.e. to address the query).

2. 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).

3. Query(ies) are **organised according to the respective sections of the findings**. To address each query that is currently pending response, you will need to **enter your reply under “Pending Query” tab > “Reply Query”**.

4. You can view all queries under “**All Query**” tab.

5. Remember to revise the CAPA before clicking “**Reply Query**” to auditor.

6. Click “**Confirm**” to proceed with reply query.

**Note:** The study team can view the track changes after the CAPA is submitted.

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