

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
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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

The screenshot shows the ECOS Audit Module General Interface. The top navigation bar includes the ECOS logo, a 'My Tasks' button (highlighted with a red box), and a 'Columns' button (highlighted with a red box). The 'My Tasks' section displays various counts: IRB (1), CRMS (0), FCOI (0), Monitoring (0), Compliance (0), and Audit (0). Below this, a 'PI (0)' button is highlighted with a red box. A 'Columns' configuration dialog is open in the foreground, showing a list of columns: Form Type, ECOS Ref, Study Site, Audit Status, Task Due Date, Auditor Name, Date Sent to PI, and Task Status. Each column has a 'Select' checkbox and a 'Move' icon. The 'Selected' count is 8. At the bottom of the dialog are 'Clear', 'Cancel', and 'Save' buttons. The 'Save' button is highlighted with a red box. The background shows a table with two rows of data: Site CAPA (2024-3708, Khoo Teck Puat Hospital) and Site CAPA (2024-3699, Khoo Teck Puat Hospital). The table includes columns for Auditor Name, Date Sent to PI, and Action. A '1' is highlighted in a green box above the table.

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

The screenshot shows the ECOS Audit Module General Interface. The top navigation bar includes 'ECOS', 'My Tasks' (with a red box around it), '84 notifications', and user icons. Below the navigation is a summary bar with counts for IRB (1), CRMS (0), FCOI (0), Monitoring (0), Compliance (0), and Audit (0). A red box highlights the 'Audit' section. The main area is titled 'My Tasks' and shows a table of audit tasks. The table has columns: Form Type, ECOS Ref, Study Site, Audit Status, Task Due Date, Auditor Name, Date Sent to PI, and Action. Two rows are listed: Site CAPA (Ref 2024-3708) with status Closed, due 08-Dec-2024, by A/Prof NHG_A3, sent 06-Dec-2024; and Site CAPA (Ref 2024-3699) with status CAPA Pending Completion, due 30-Nov-2024, by A/Prof NHG_A2, A/Prof 何庆青, sent 29-Nov-2024. A red box highlights the 'Export' button in the top right of the table. A modal window is open, showing 'Download Original' and 'Safe Download (PDF)' options, with a red box around it and a green box labeled '2' pointing to it. The bottom of the interface shows a summary box for 'Audit Study Information' with download details and a table of audit study information.

My Tasks

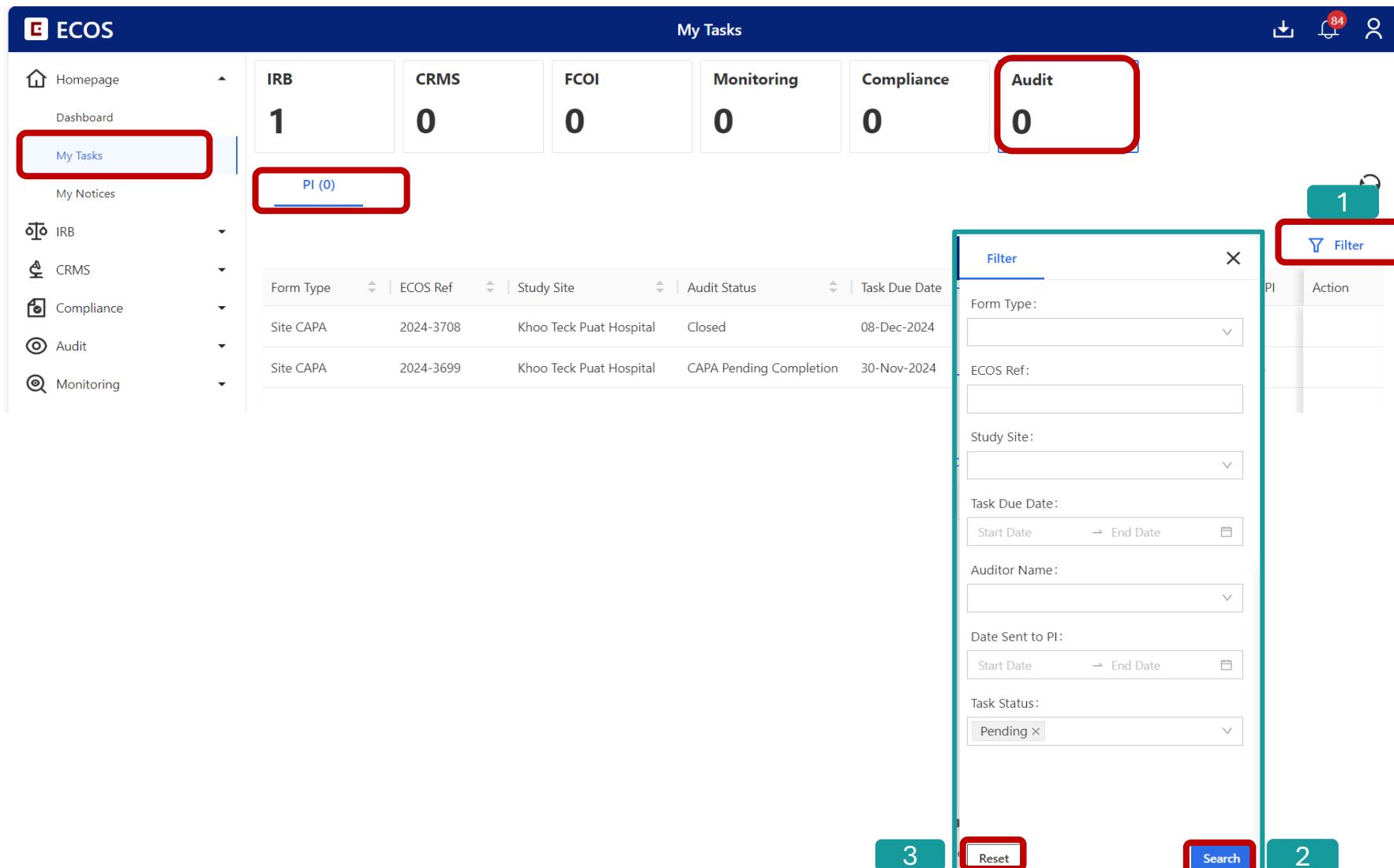
Form Type	ECOS Ref	Study Site	Audit Status	Task Due Date	Auditor Name	Date Sent to PI	Action
Site CAPA	2024-3708	Khoo Teck Puat Hospital	Closed	08-Dec-2024	A/Prof NHG_A3	06-Dec-2024	
Site CAPA	2024-3699	Khoo Teck Puat Hospital	CAPA Pending Completion	30-Nov-2024	A/Prof NHG_A2, A/Prof 何庆青	29-Nov-2024	

Audit Study Information

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. 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) Audit Module General Interface – Filter



The screenshot shows the ECOS Audit Module General Interface. The top navigation bar includes the ECOS logo, a download icon, a notification icon with '84' notifications, and a user icon. The main dashboard displays 'My Tasks' with categories: IRB (1), CRMS (0), FCOI (0), Monitoring (0), Compliance (0), and Audit (0). A red box highlights the 'My Tasks' link in the sidebar. Below the dashboard, a table shows two rows of audit tasks: Site CAPA (2024-3708) at Khoo Teck Puat Hospital with a Closed status and a due date of 08-Dec-2024; and Site CAPA (2024-3699) at Khoo Teck Puat Hospital with a CAPA Pending Completion status and a due date of 30-Nov-2024. A red box highlights the 'PI (0)' link. A large green box highlights the 'Filter' dialog box, which contains fields for Form Type, ECOS Ref, Study Site, Task Due Date, Auditor Name, Date Sent to PI, and Task Status. A red box highlights the 'Filter' button in the dialog box. A red box highlights the 'Reset' button at the bottom of the dialog box. A red box highlights the 'Search' button at the bottom of the dialog box. A red box highlights the 'PI' column header in the task table. A red box highlights the 'Action' column header in the task table. A red box highlights the '1' in the Audit category 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.

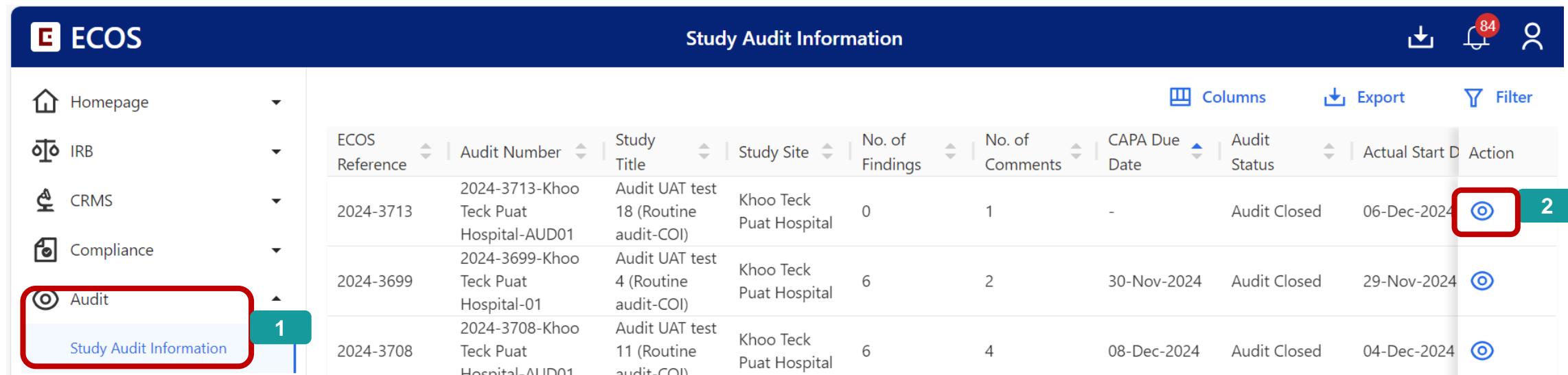
2) Locate your CAPA task (method 1) – via Homepage

The image consists of two screenshots of the ECOS system interface. The top screenshot shows the 'Dashboard' section. On the left, a navigation bar includes 'Homepage', 'Dashboard' (which is highlighted with a red box and a '1' in a teal box), 'My Tasks', 'My Notices', 'IRB', 'CRMS', 'Compliance', 'Audit', 'Monitoring', 'FCOI', 'SDB', and 'Report'. The main area has four large boxes: 'IRB' (Study: 0, Endorsement: 0), 'CRMS' (Study Member Review: 0), 'FCOI' (My FCOI List: 0), and 'Audit' (PI: 0). The 'Audit' box is highlighted with a red box and a '2' in a teal box. The bottom screenshot shows the 'My Tasks' section. The navigation bar is the same. The main area has six boxes: 'IRB' (0), 'CRMS' (0), 'FCOI' (0), 'Monitoring' (0), 'Compliance' (0), and 'Audit' (1). The 'Audit' box is highlighted with a red box and a '4' in a teal box. Below this, a table shows a single task: 'PI (1)'. The table has columns for 'Form Type' (Site CAPA), 'ECOS Ref' (2024-3709), 'Study Site' (Institute of Mental Health), 'Audit Status' (CAPA Pending Completion), 'Task Due Date' (02-Jan-2025), 'Auditor Name' (A/Prof NHG_A4), and 'Action' (a blue 'View' button). The 'View' button is highlighted with a red box and a '5' in a teal box.

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



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	View 2
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	View
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	View

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

[Home](#) [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 [Email](#)

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

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>

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

The screenshot shows the 'Study Audit Information Detail' page for a study audit. The audit is titled '2024-3713-Khoo Teck Puat Hospital-AUD01 | Khoo Teck Puat Hospital' and is marked as 'Audit Closed'. The audit report is listed under the 'Audit Report' section of the navigation menu. A modal window titled 'NHG RQM STUDY REVIEW REPORT' is open, showing a PDF file named 'NHG RQM STUDY REVIEW REPORT2024-3713.pdf' (230.23 KB). The modal has a 'Download List' button (1), an 'Export' button (2), and a 'Download To Local' button (4). A 'Delete All' button is also visible in the modal. The background shows sections for 'Default Section', 'SECTION A – STUDY TEA...', 'SECTION B – IRB DOCU...', 'SECTION C – REGULATO...', 'SECTION D – SUBJECT R...', 'SECTION E- INFORMED ...', 'SECTION F – INVESTIGA...', and 'SECTION G – SAFETY RE...'. The bottom of the page includes a note about the restricted nature of the document and a page footer.

Study Audit Information Detail

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

ECOS Ref: 2024-3713 [Email](#)

Plan Audit

Site Audit Closed

Audit Report 1

Audit Report Observation

NHG RQM STUDY REVIEW REPORT

Default Section

Download List 3

Export 2

Attachment

Default Section

SECTION A – STUDY TEA...

SECTION B – IRB DOCU...

SECTION C – REGULATO...

SECTION D – SUBJECT R...

SECTION E- INFORMED ...

SECTION F – INVESTIGA...

SECTION G – SAFETY RE...

NHG RQM For-Cause Study Review Report

OFFICIAL USE ONLY

Doc Name: NHG RQM For-Cause Study Review Report Template

Doc Number: 307-009

Doc Version: 3.1 Date: 11 Dec 2024

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): Mr TTSH_PSP1

Contact Details of PI: Business Address: Business Email: ttsh_psp1@aimrci.com

Study Site: Tan Tock Seng Hospital

RQM Auditor(s): A/Prof NHG_A1

Audit Report Reviewer: Dr NHG_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]

Page 1 of 6

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

The screenshot shows the 'Study Audit Information Detail' page for a study titled '2024-3833-Khoo Teck Puat Hospital-AUD02 | Khoo Teck Puat Hospital'. The left sidebar has a red box around 'Audit Report Observation'. The main content shows 'Site Audit' and 'Audit Report Observation' with a CAPA due date of 15-Jan-2025. A red box highlights the 'Export CAPA' button. A large green arrow points down to a CAPA report titled 'CORRECTIVE ACTION AND PREVENTIVE ACTION (CAPA) PLAN'. The report includes a table with one row:

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.	No informed consent process documentation for all the recruited 88 subjects.	To submit NCR.				

At the bottom, it says 'RESTRICTED - SENSITIVE - NORMAL DOCUMENT' and 'Version 4 dated 03 Oct 2023'.

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

The screenshots show the ECOS dashboard and 'My Tasks' page. The top screenshot highlights the 'Audit' section on the dashboard, which has 1 task for 'PI'. The bottom screenshot shows the 'Audit' section in 'My Tasks' with 1 task for 'PI'. The 'View' button in the table header is highlighted with a red box.

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.

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

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	-

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

Study Audit Information Detail

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

ECOS Ref: 2024-3831 Print

IRB: NHG DSRB-Domain A PI/Site-PI: A/Prof KTPH_SP2 Auditor: A/Prof NHG_A1

Current Study Site Status: Approved Audit Category: Routine Audit

Study Title: Audit UAT test 27 (Sytem audit)

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

Submit Reply Query

1 Plan Audit

2 Site Audit

3 Audit Report

4 Audit Report Observation

Site Audit CAPA Pending Closure

Audit Report Observation CAPA Due Date: 18-Jan-2025 Export CAPA

Finding Comment

2 Finding Number

AUD-F01 Finding Item

A1. List of study team members and responsibilities (in accordance to study delegation log and discussion with the PI/designated staff) Grading of Finding

Minor Category of Finding

Study Team Finding Summary

Responsibility log is not available. Finding Description

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 Recommendation

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 Action

3 Edit

4 Green Tick

The status will reflect the site audit report status.

Finding Number	Finding Item	Grading of Finding	Category of Finding	Finding Summary	Finding Description	Recommendation	Action
2 AUD-F01	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	3 Edit

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 **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

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

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

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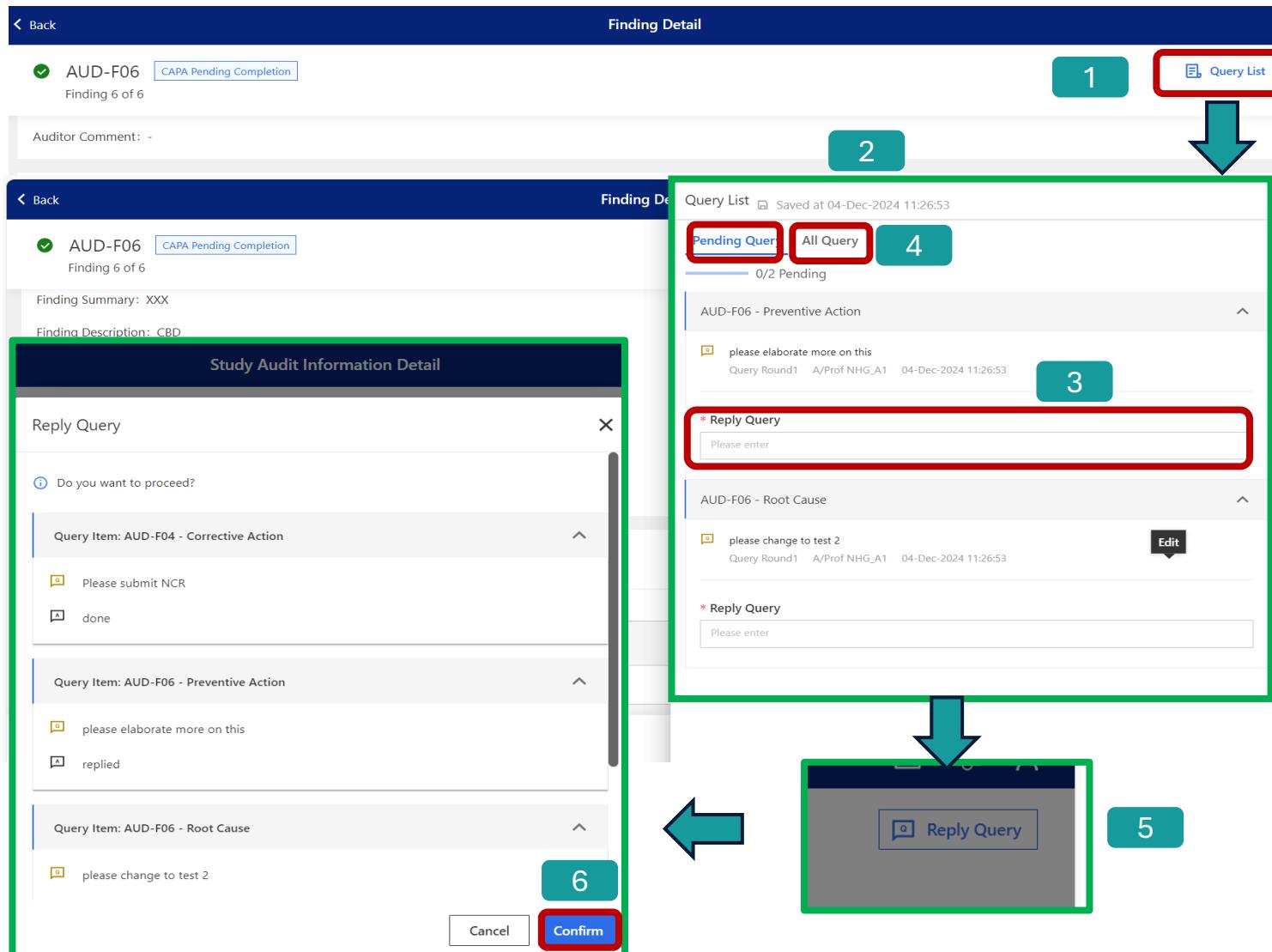
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5. Click “Edit” to start completing the form.
6. Fields marked with * are mandatory for completion.
7. The “Save” button will appear after you click the edit button. Click on “Save” intermittently to ensure the edits have been saved successfully.
8. 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



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
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