ECOS User Guide: Audit Module

Restricted, Sensitive - Normal

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Audit Module User Guide for:

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

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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

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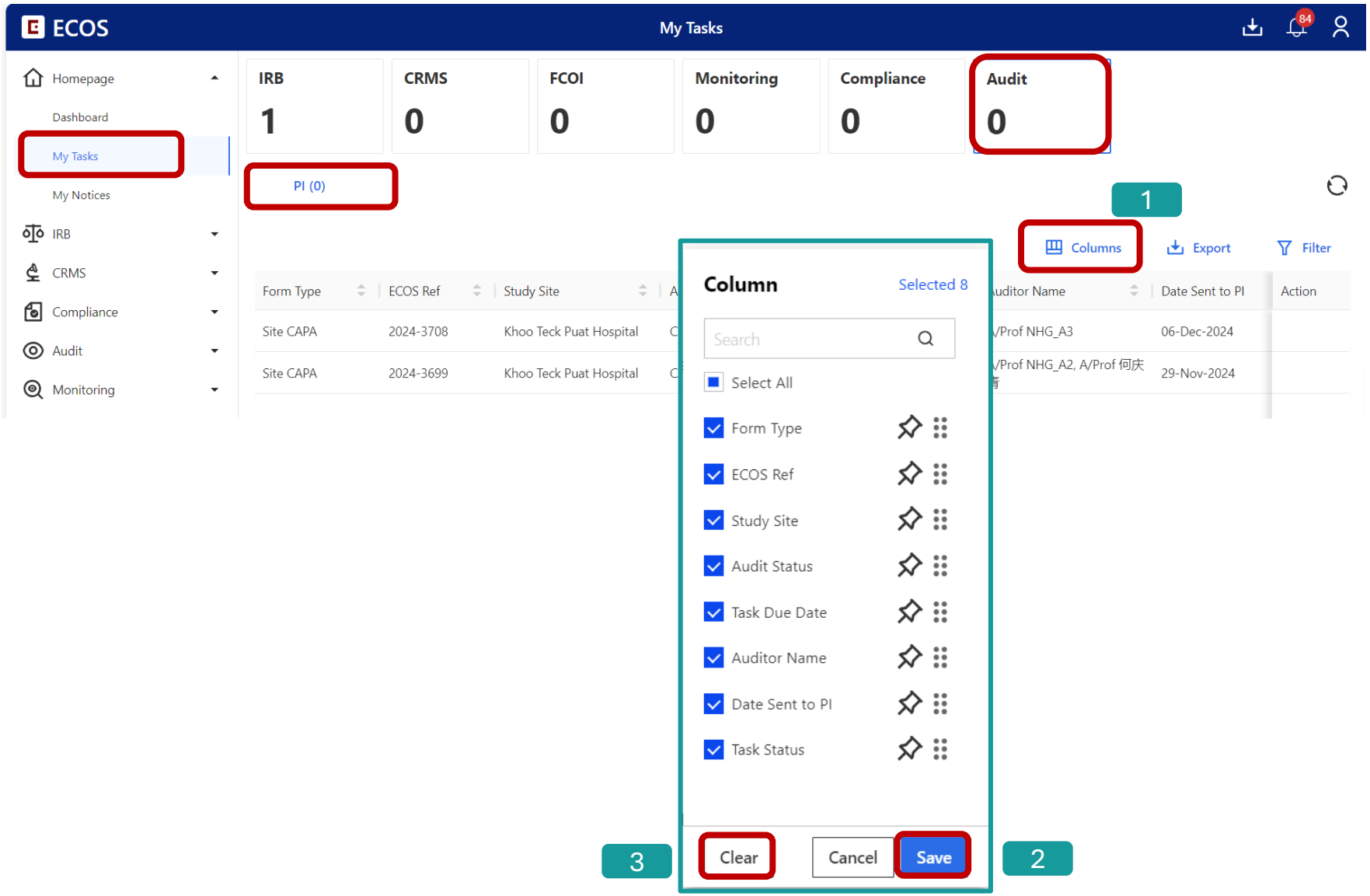
1) Audit Module General Interface - Columns



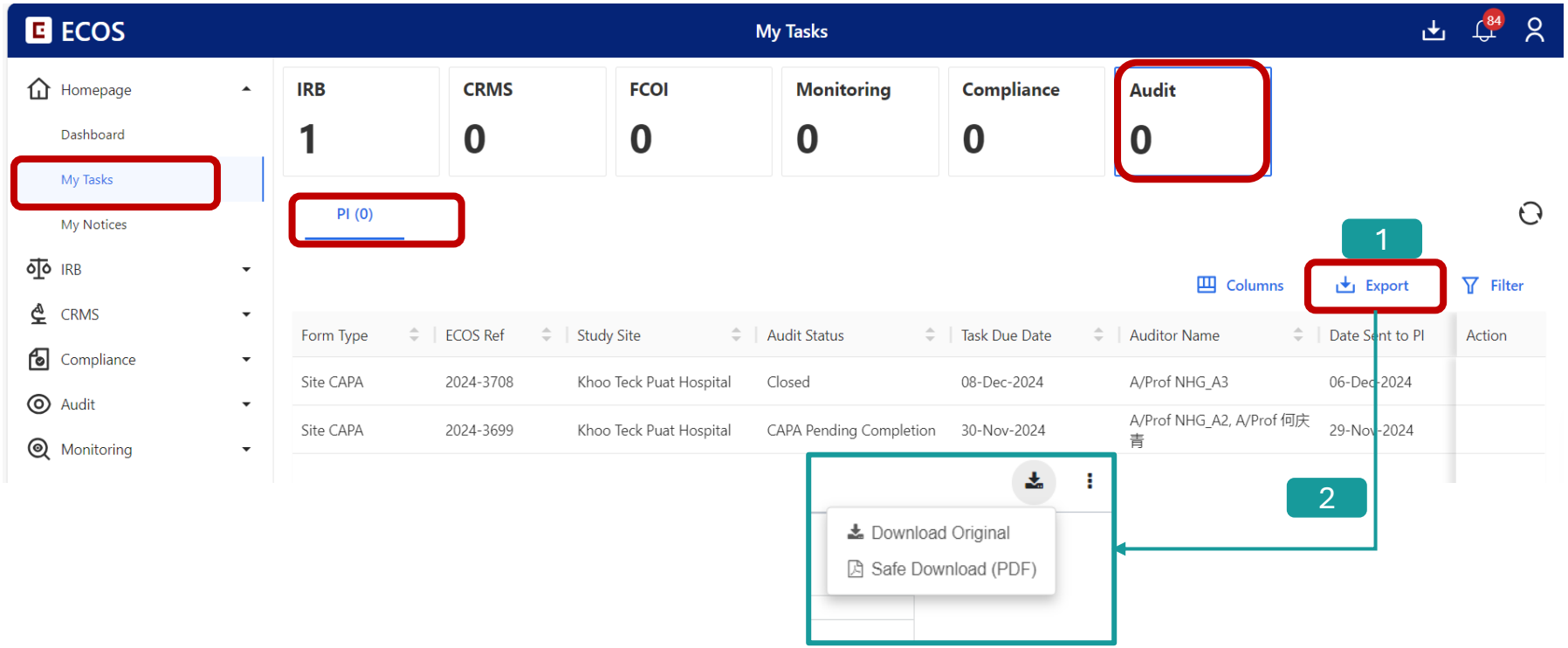
1. Click on **"Columns"** to **change the layout** of information presented.

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.

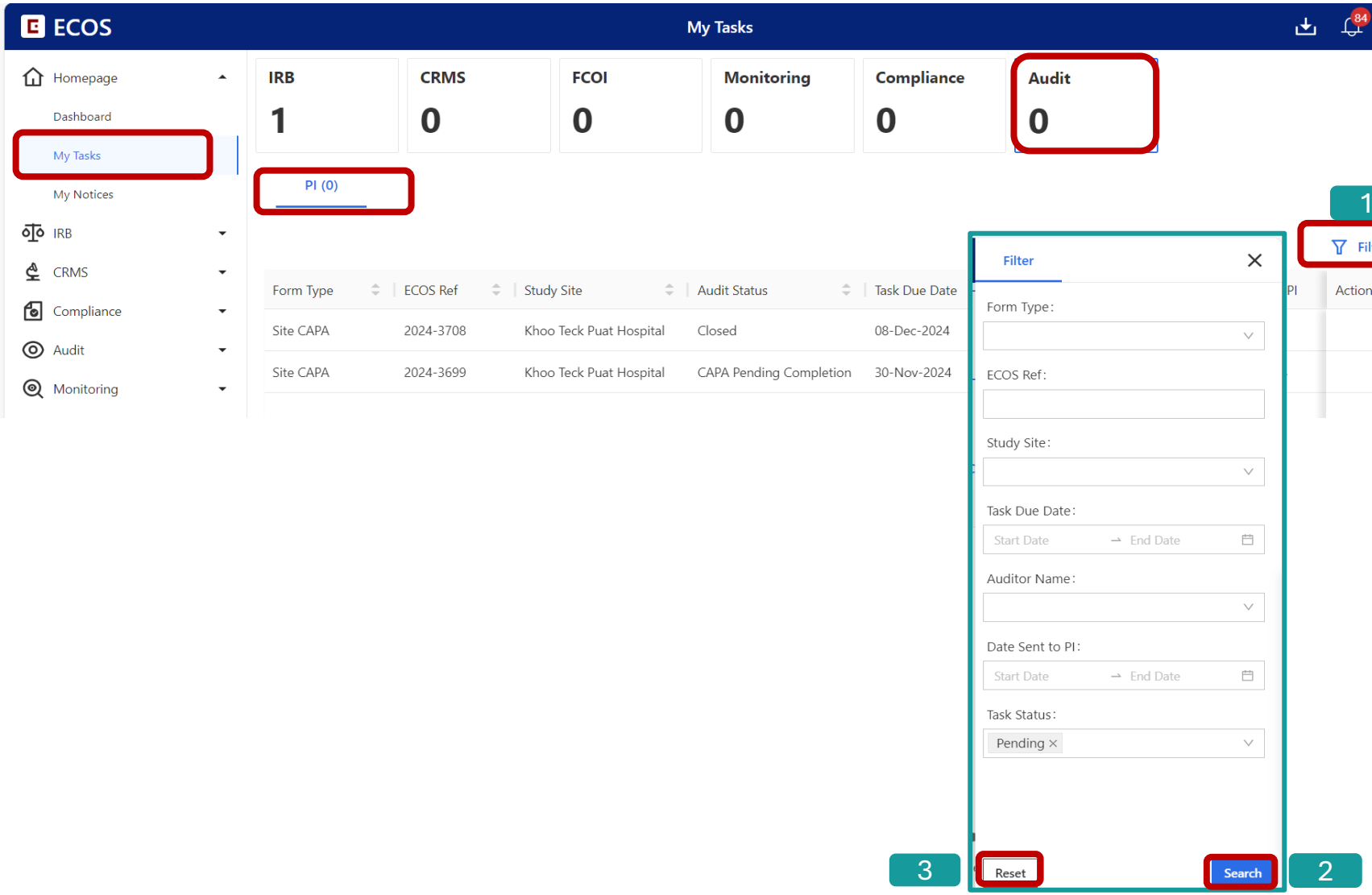
1) Audit Module General Interface – Export Listing



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



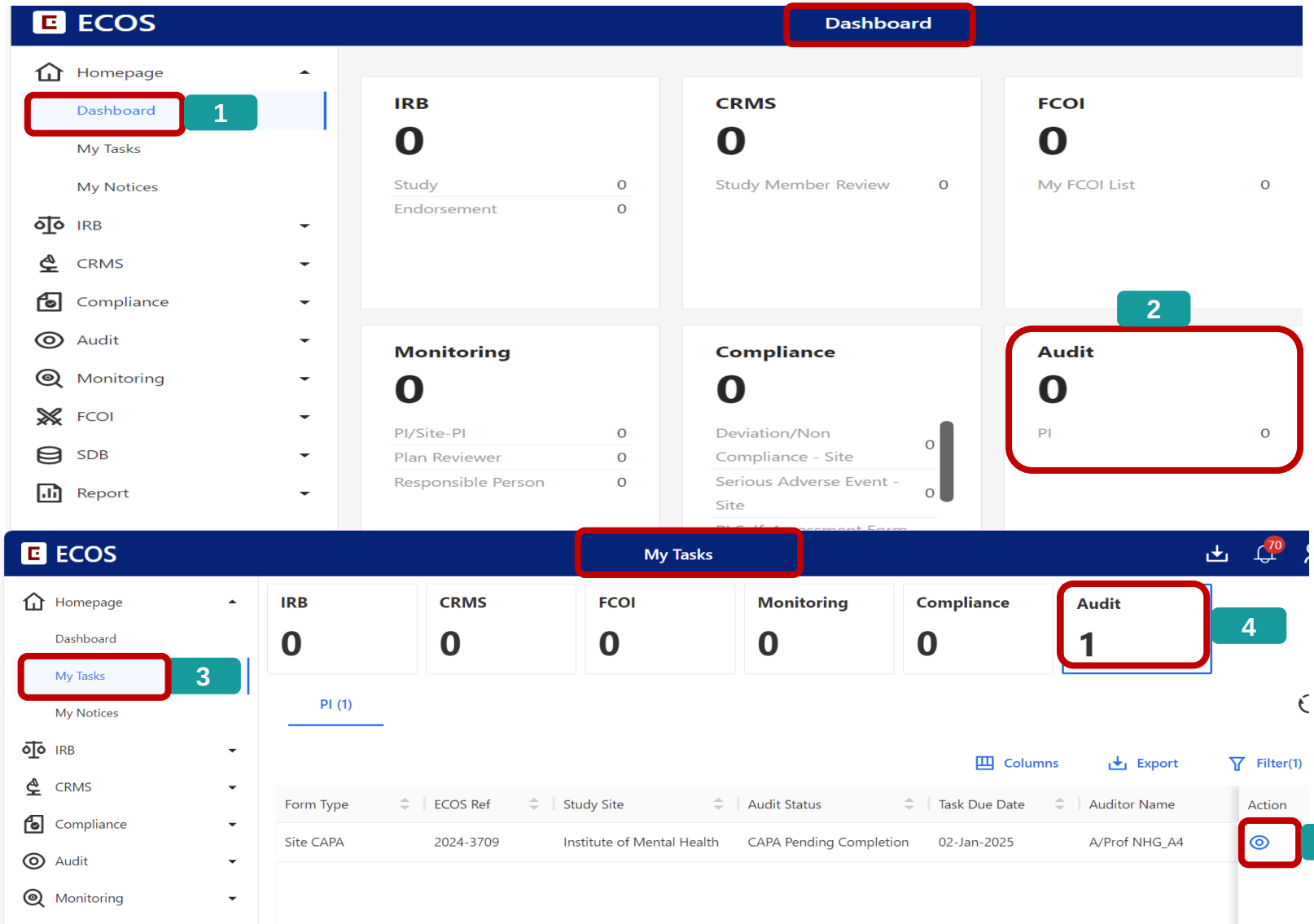
1. Click on "**Filter**" to tailor the listing you wish to view.

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.

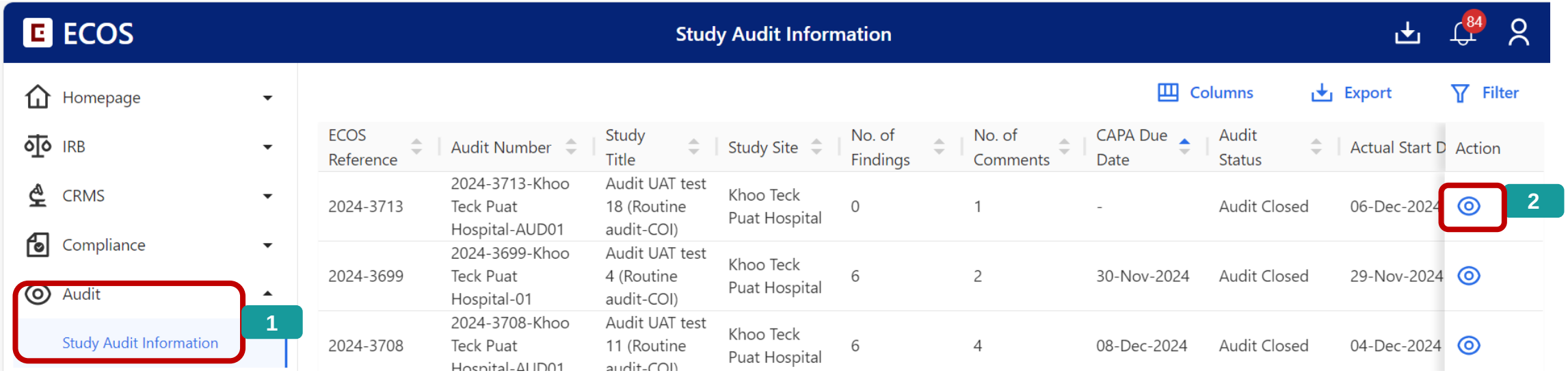
2. Locate the "**Audit**" tile and click on **" Audit".** It will lead you to **"My Tasks".**

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



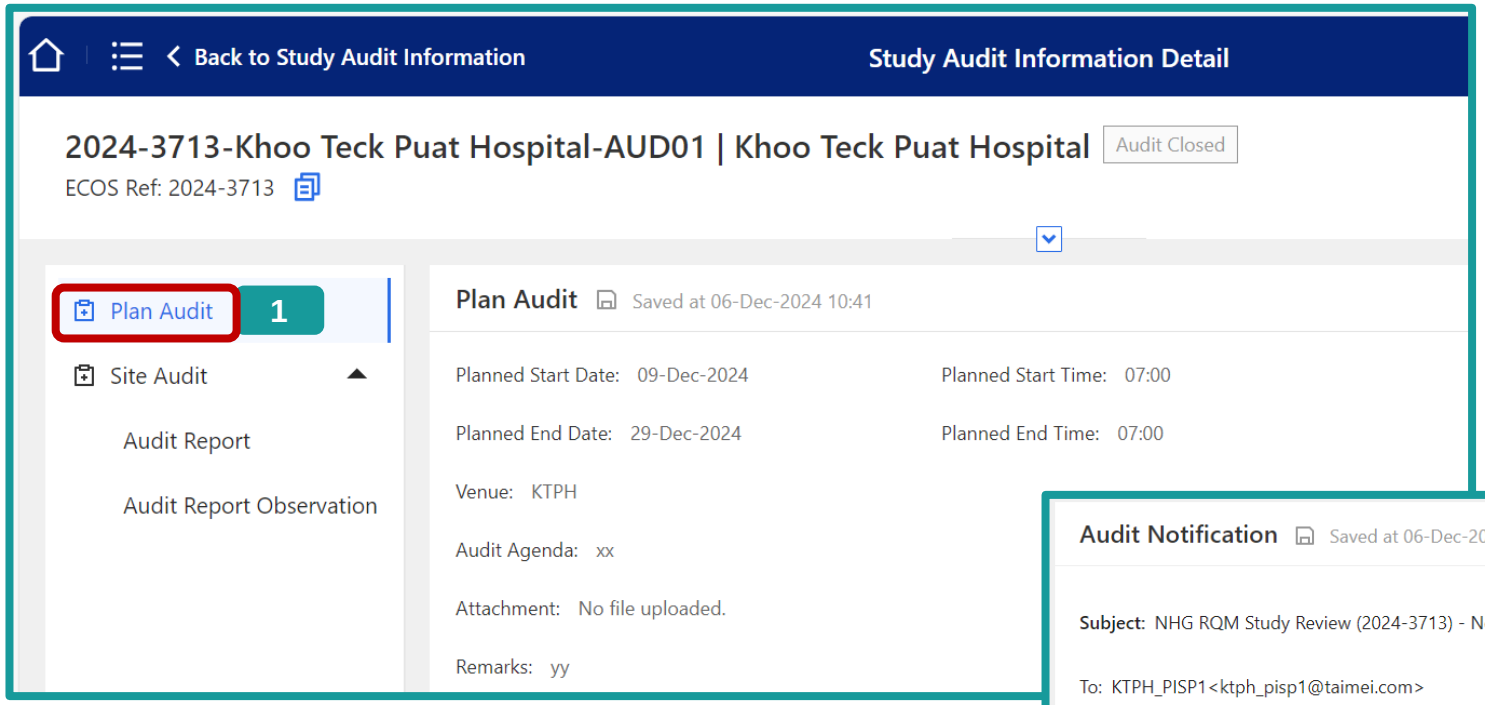
Via Audit> Study Audit Information

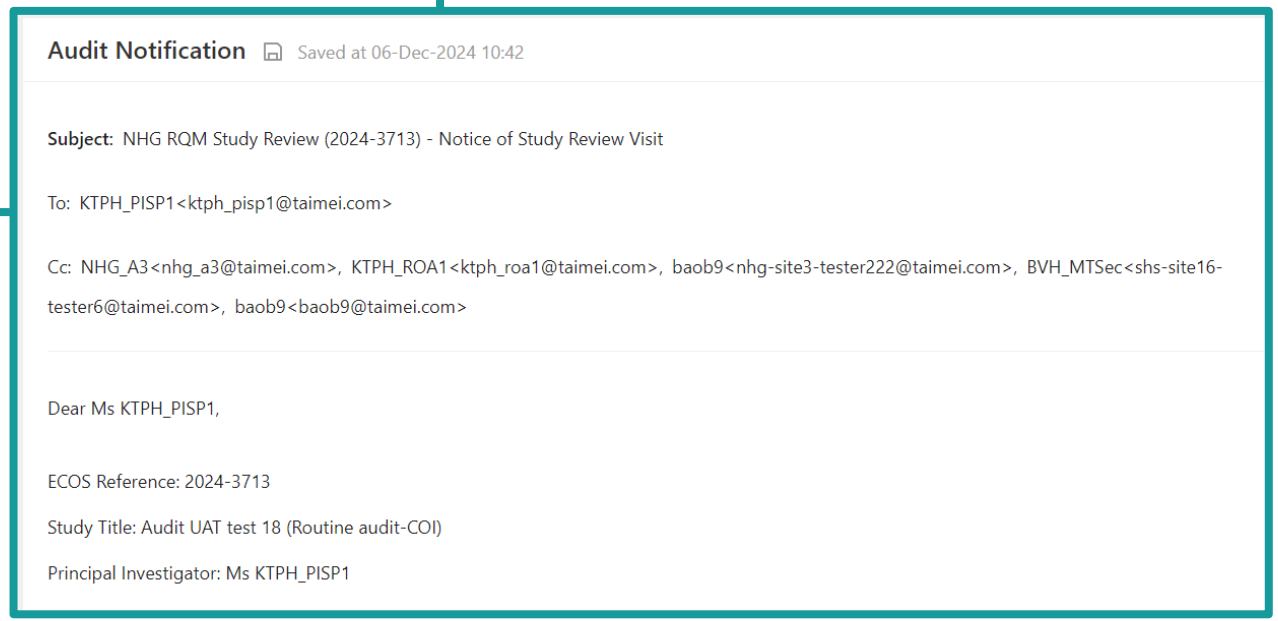
1. PI/Site PI, Co-I and Study Team Member can:
   - Locate the **audit report** sent by auditor
   - **View the findings, comments and recommendations** that arise from the audit
   - **Complete the corrective action and corrective action (CAPA)** if needed in findings.
2. To view the audit task, click 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

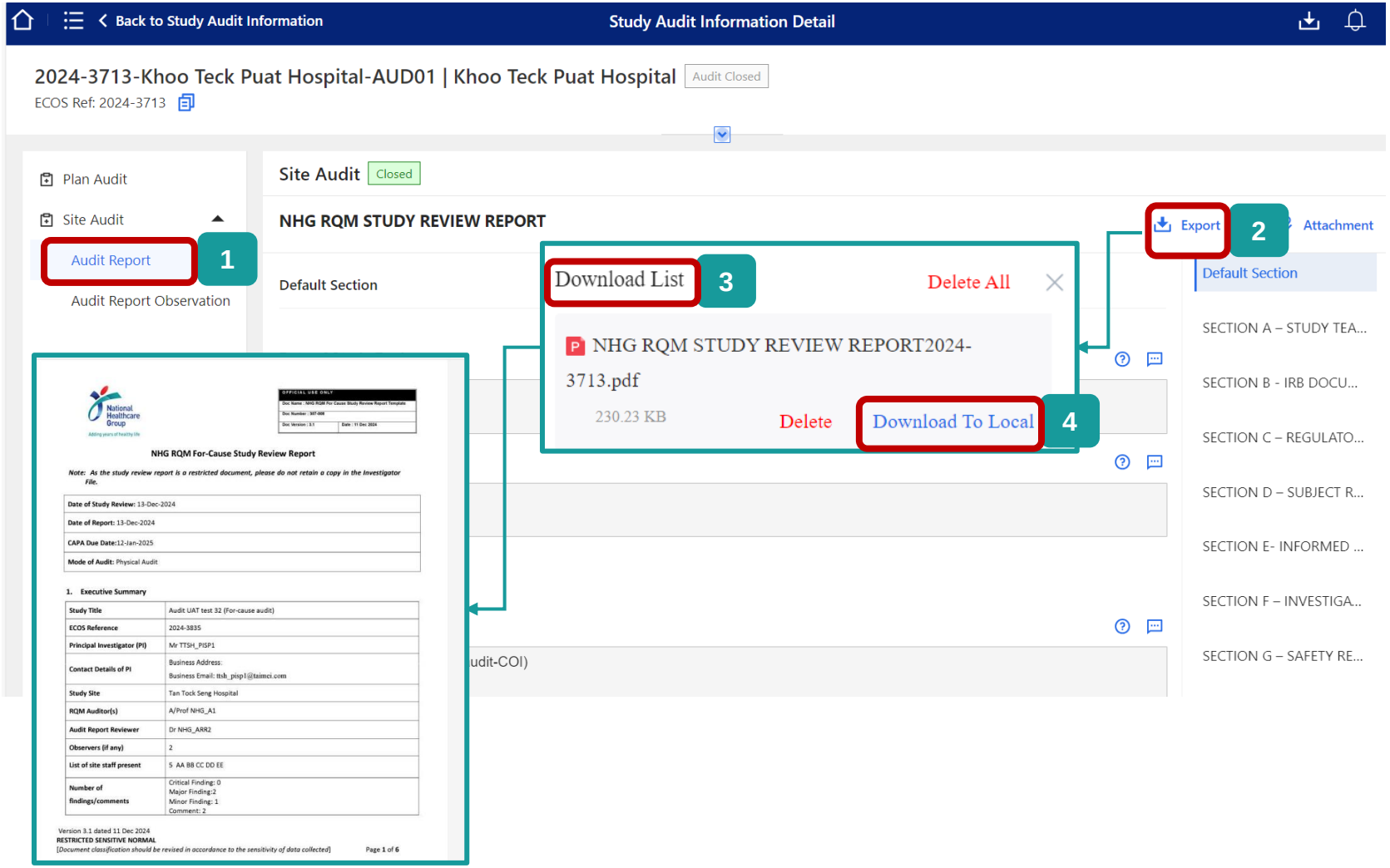




Via Audit > Study Audit Information

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

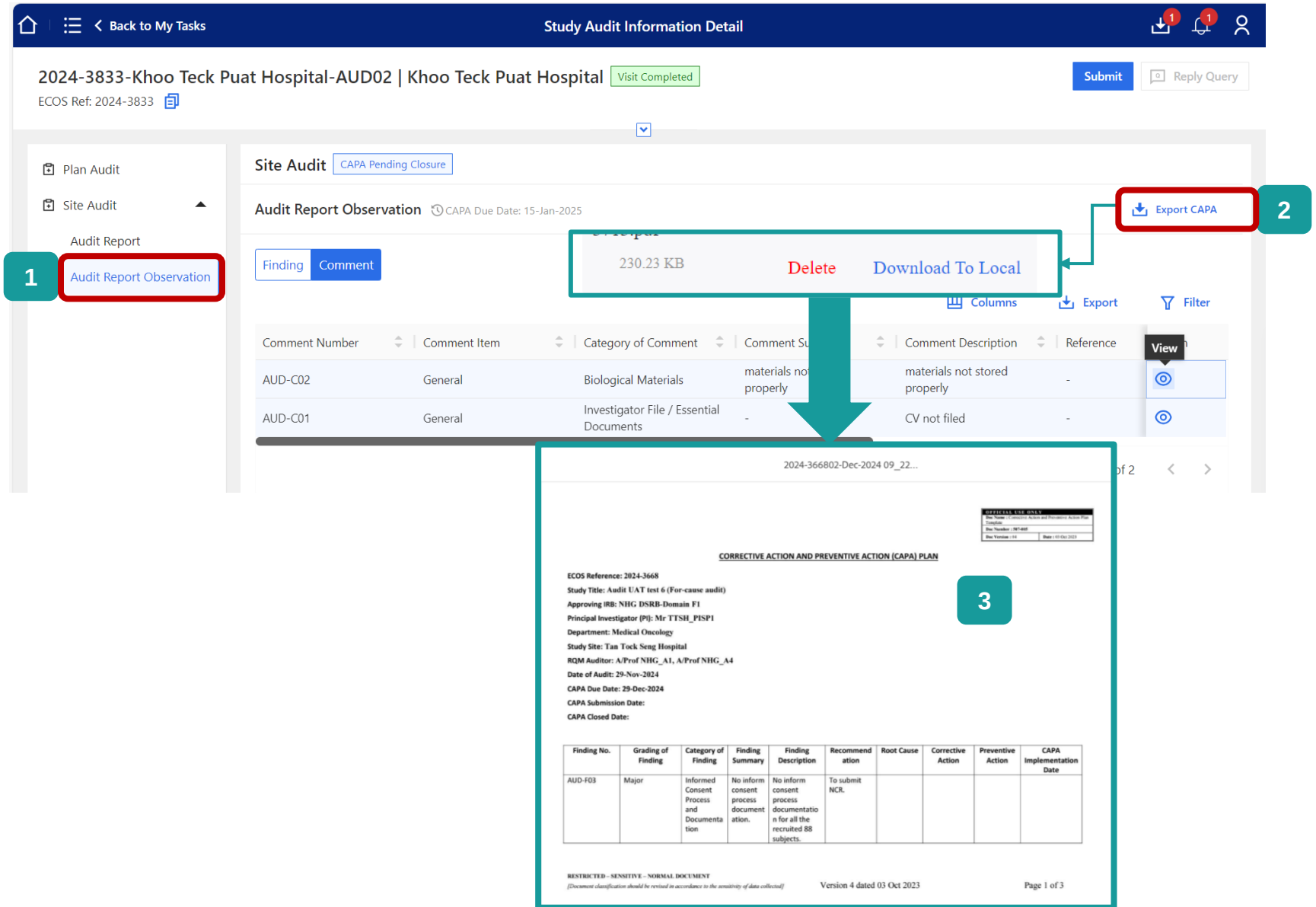
3) View and Access Your Study Audit Information



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



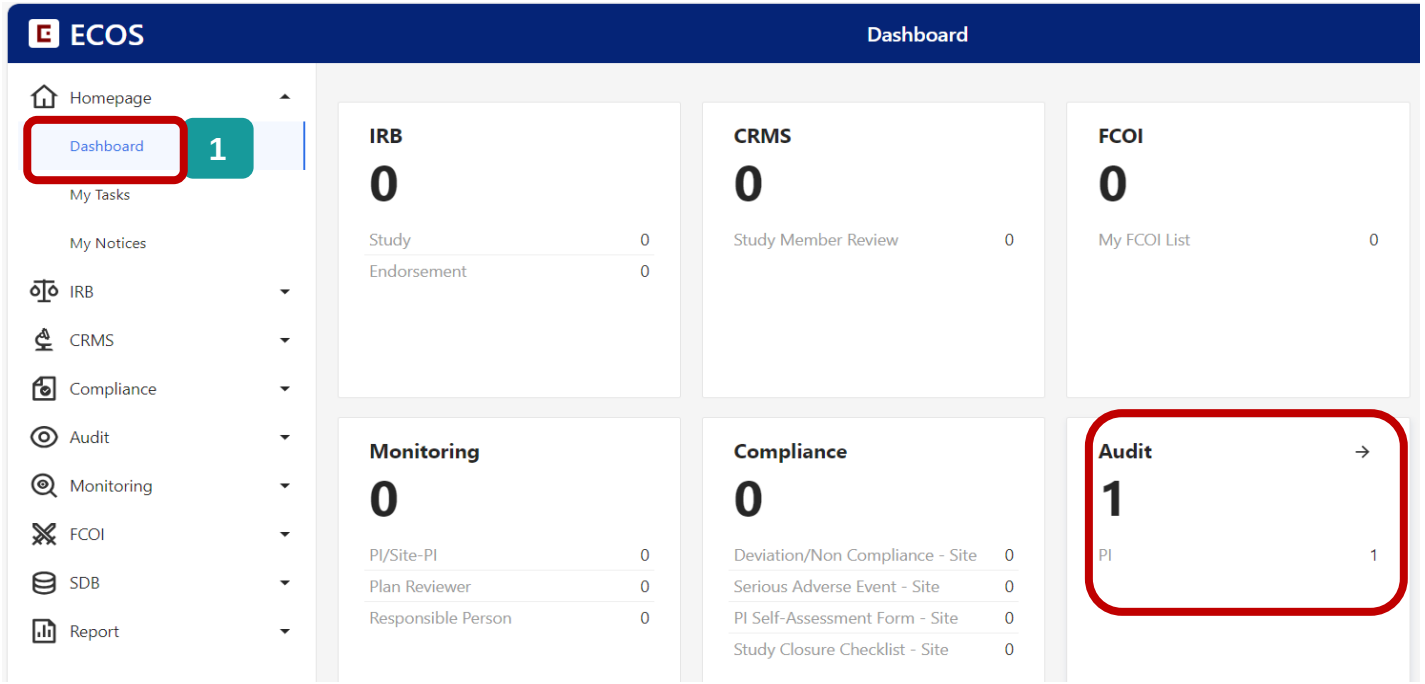
<u>Via Audit > Study Audit Information</u>

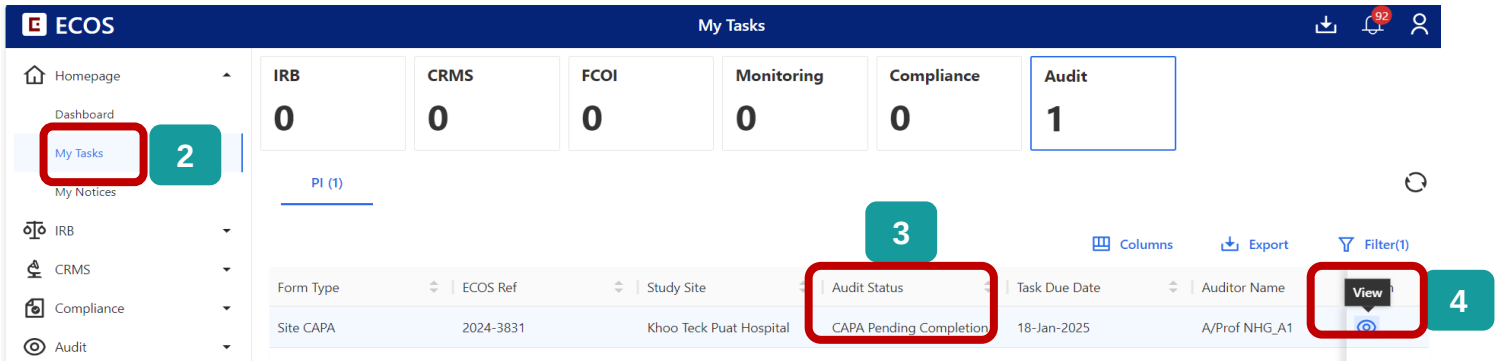
1. **PI/Site PI/Co-I/STM** may view **their respective study's Audit Findings/Comments and Corrective Action Preventive Action (CAPA) Report** (if CAPA is already submitted to auditor).

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





<u>Via Dashboard > My Tasks</u>

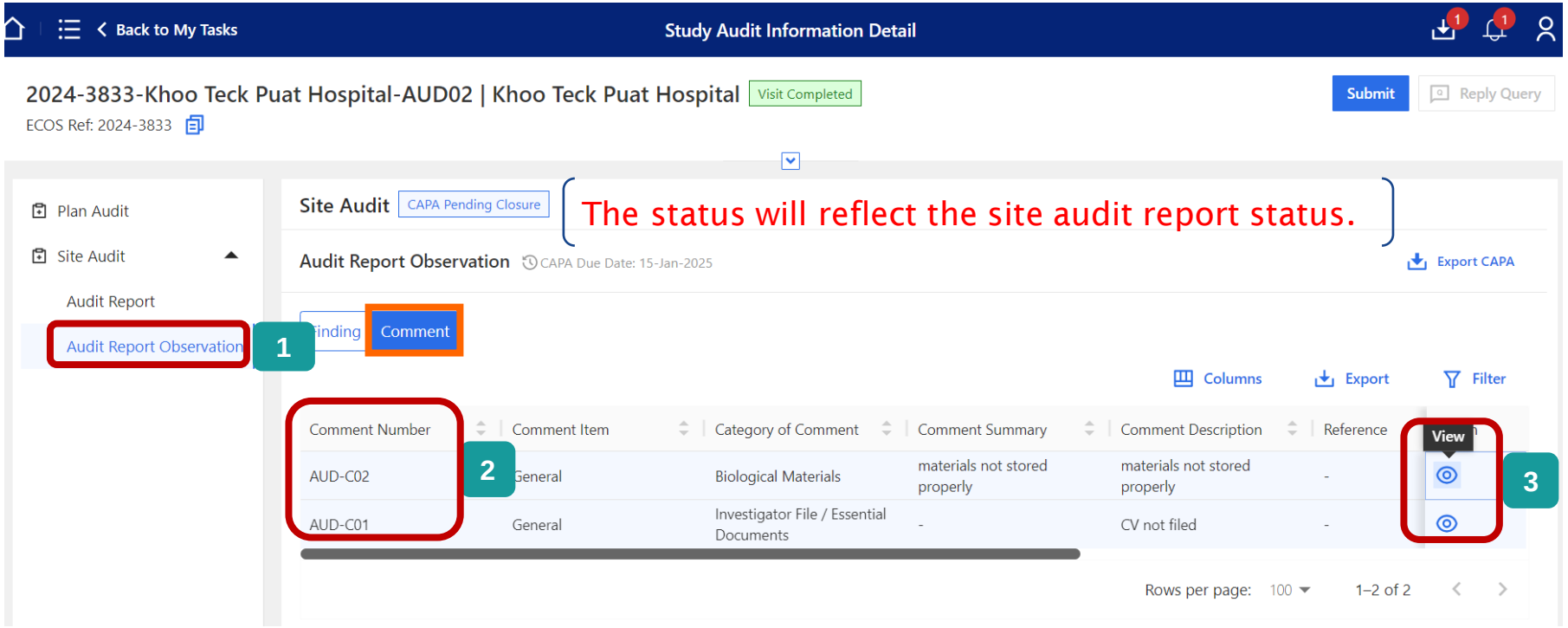
1. The PI/Co-I and STM can locate the task **via "Dashboard"**

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



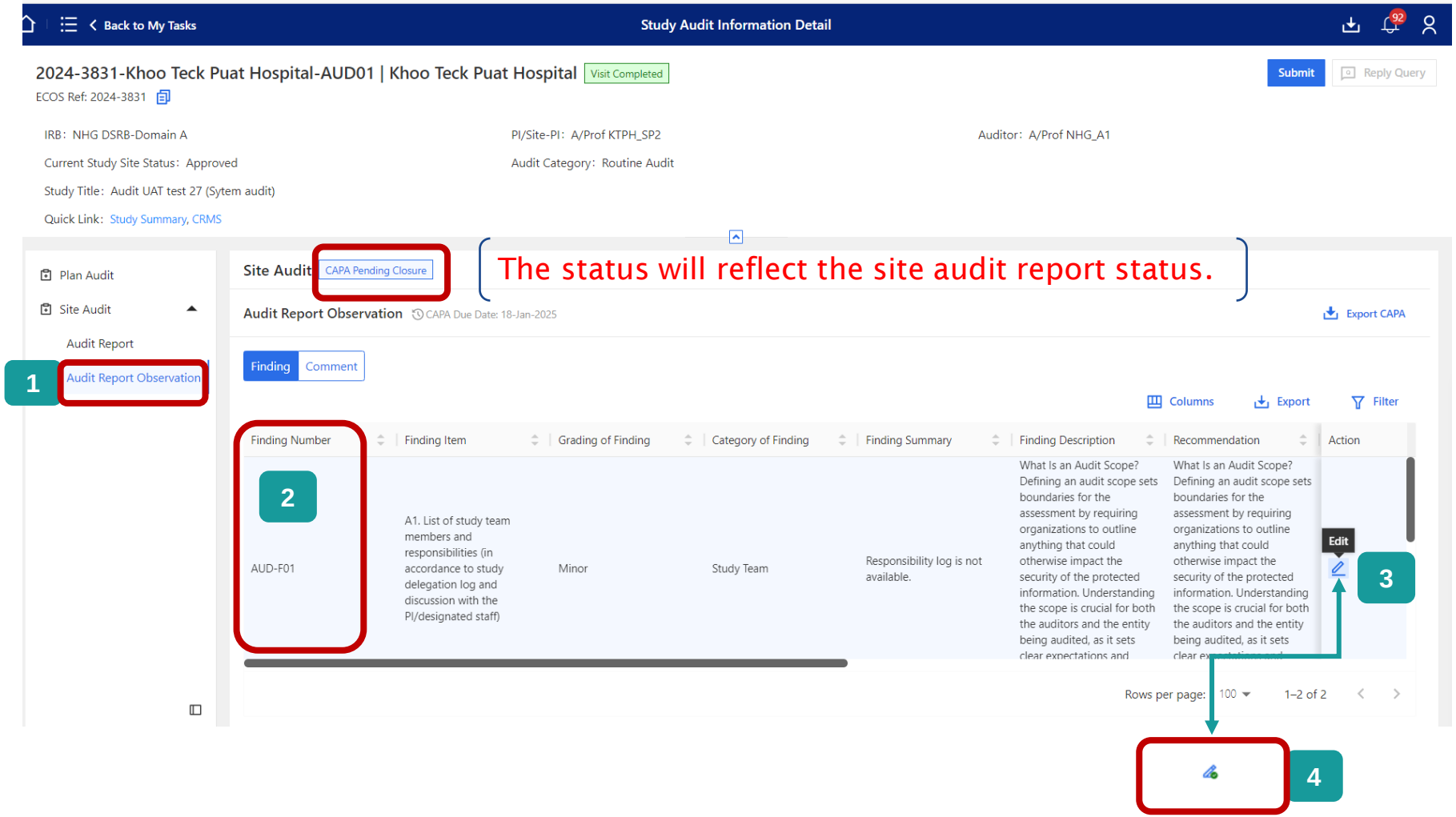
<u>Via Audit > Study Audit Information Detail</u>

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 **<u>do not require</u>** 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



<u>Via Audit > Study Audit Information Detail</u>

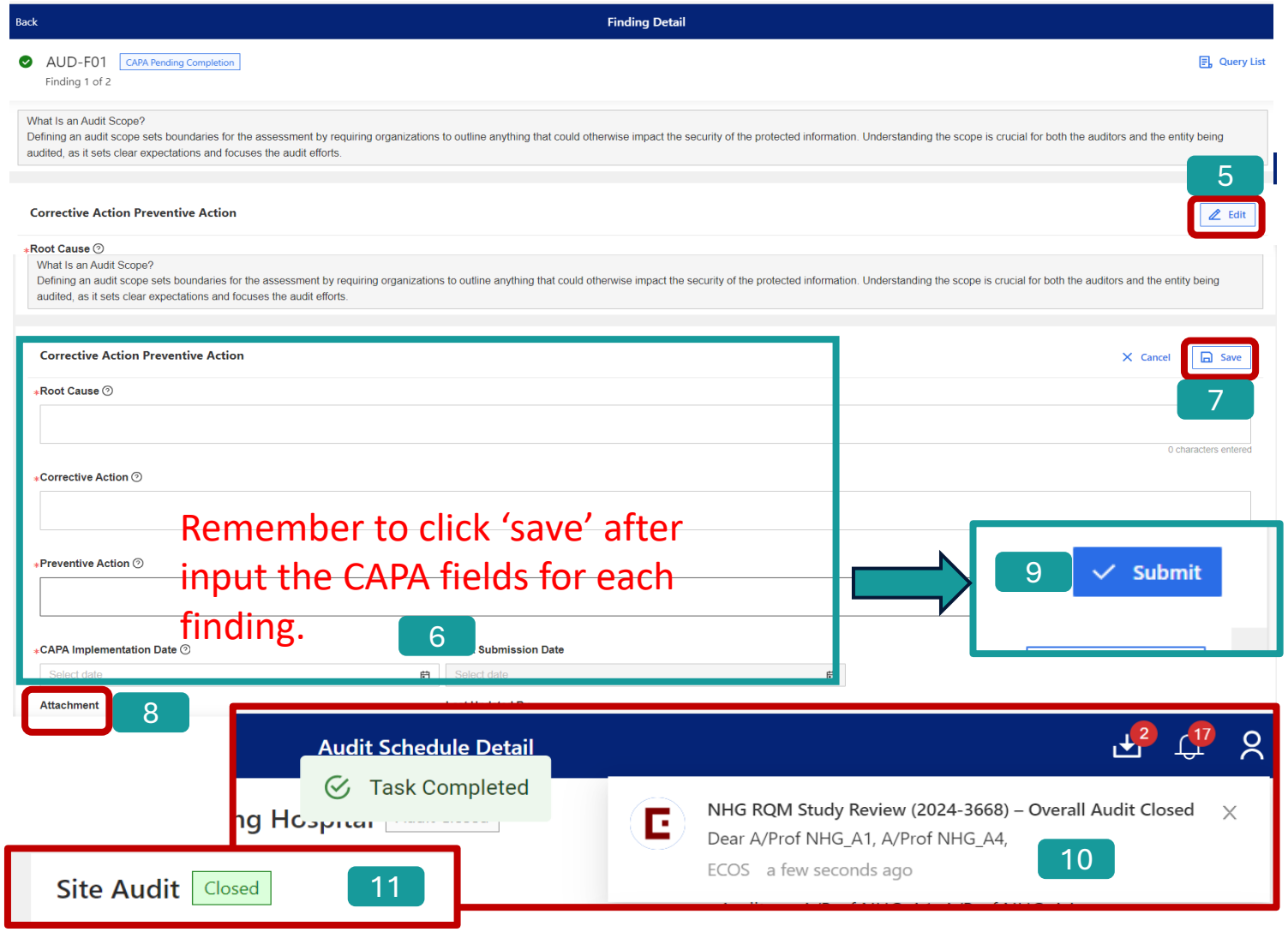
1. **Click "Audit Report Observation",** you will be able to see the **"Finding" and "Comment" tabs.**

2. In this page, you can see the detail breakdown of the **audit findings** which **<u>require</u> 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



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".**

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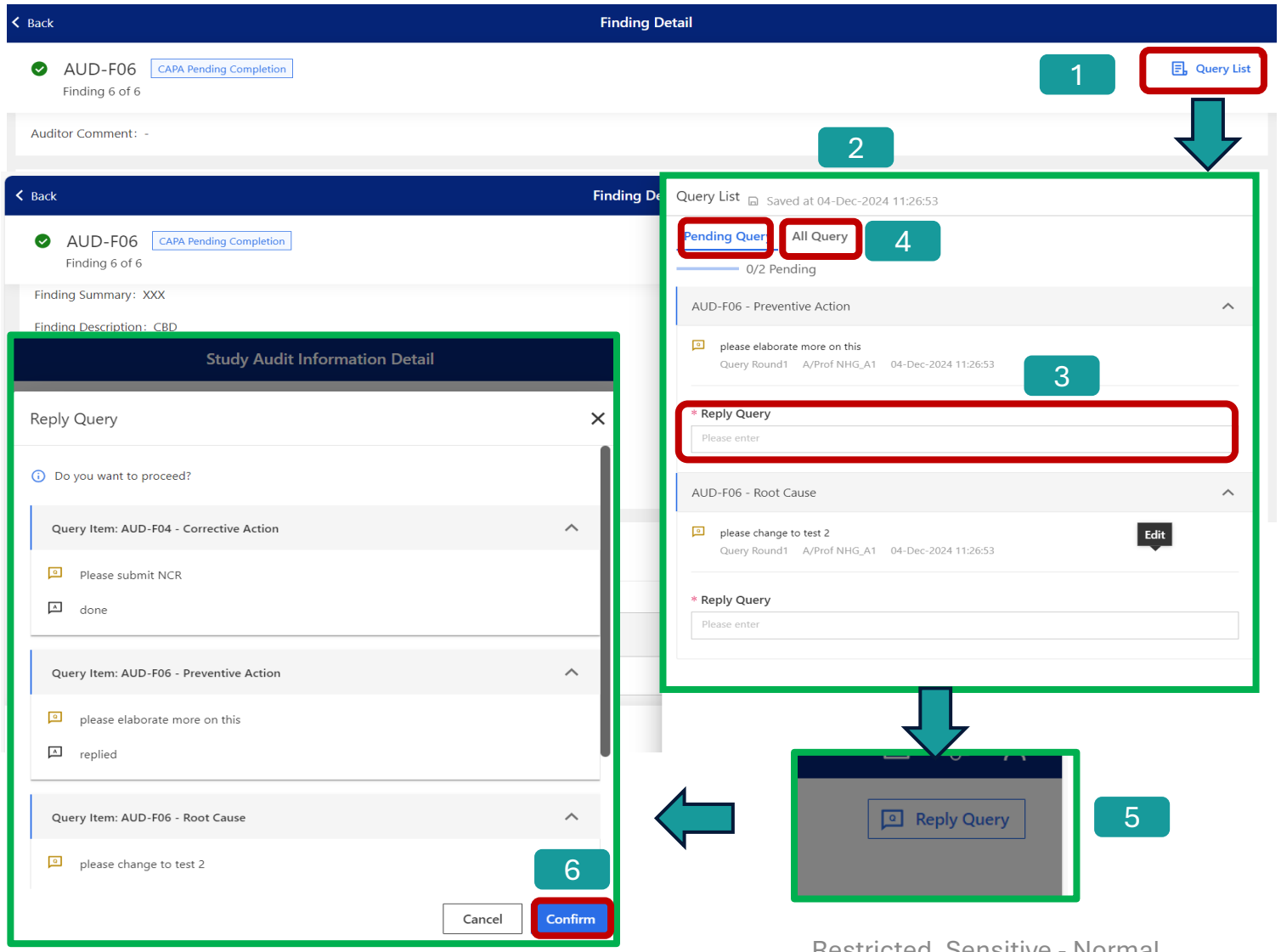
5) How to View and Reply CAPA Query



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