ECOS

Navigating Ethics & Compliance Online System (ECOS) User Guide

Compliance Module:

Principal Investigator Self-Assessment Form – Study Closure Checklist (PISAF-SCC)

[ECOS User Guide – Compliance (PISAF)_SCC Ver 1, 26 Sep 2024]

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Principal Investigator Self-Assessment Form (PISAF) - Study Closure Checklist (SCC) User Guide for:

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

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1) When does the SCC Task occur

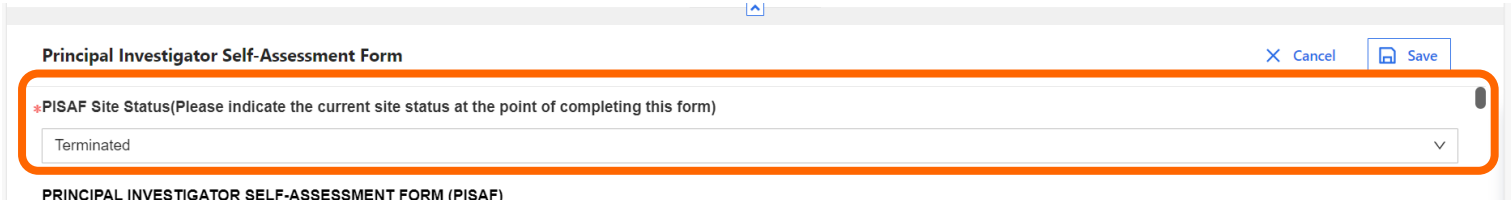
- The Study Closure Checklist (SCC) provides guidance to the PI/ Site PI, Co-I and study team during study completion.

- Completion of SCC is **required** for NHG researchers with studies monitored under the **NHG Monitoring Programme for HBR studies.**

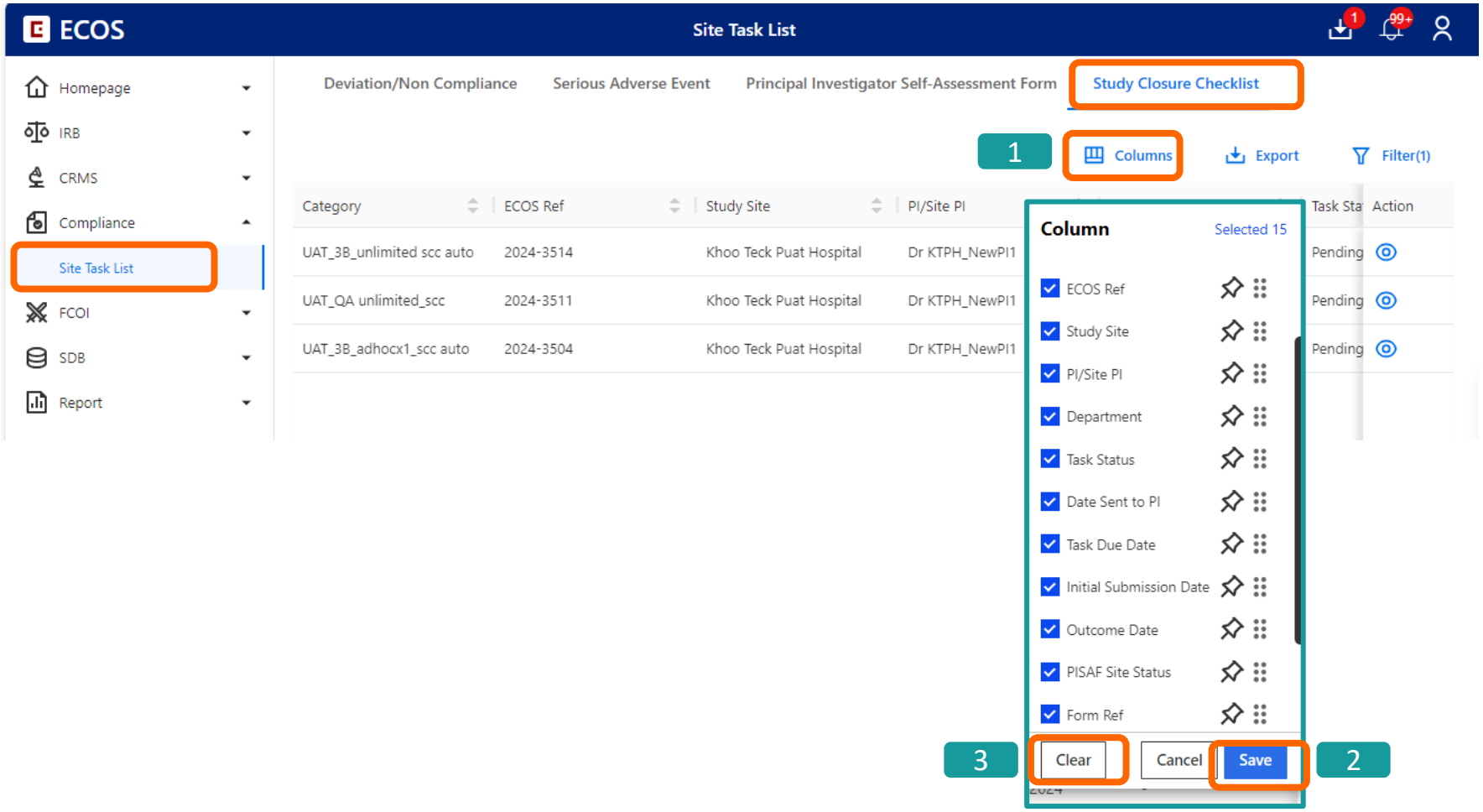
- The SCC task will be triggered on ECOS when:

1) The PI submits **Study Status Report (SSR)** in the **IRB module** to notify study completion/ termination.

2) The PI reports Study Site Status as **Completed/ Terminated** during the completion of the PISAF.



1) PISAF-SCC Module General Interface - Columns

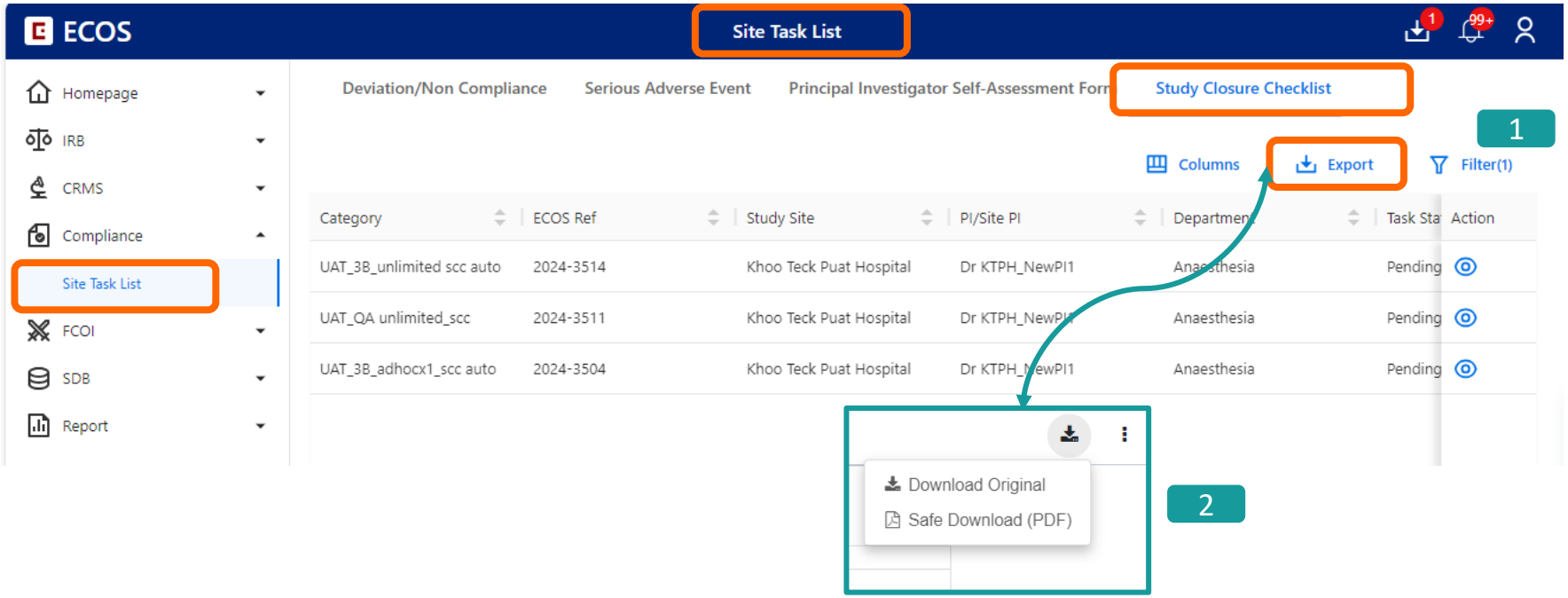


1. Click on **“Columns”** to **change the layout** of information presented.

2. You can adjust the **columns display order** by pulling the display information **up and down** and click on **“Save”.**

3. To reset the columns to its default view, click on **“Clear”**

1) PISAF-SCC Module General Interface – Export Listing



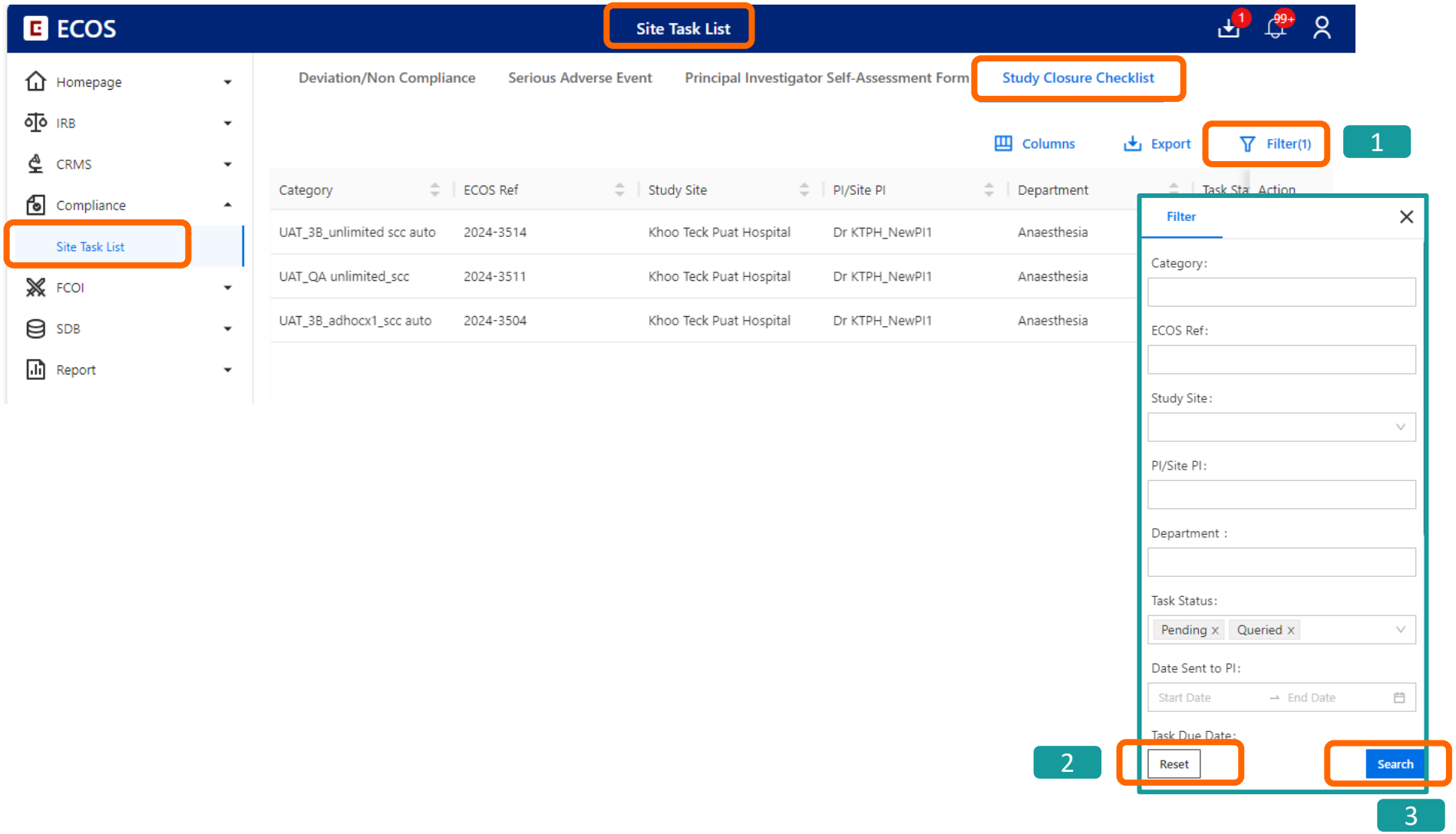
1. You can export the listing you are viewing by clicking on "**Export**".

2. Select "**Download Original**" as an Excel file or "**Safe Download**" as PDF file.

Sheet1

Compliance Site Task - PISAF List						
Downloaded By: Dr TTSH_NewPI1						
Downloaded Date and Time: 25-Sep-2024 01:15:26						
Category	**ECOS Ref**	**Study Site**	**PI/Site PI**	**Department**	**Task Status**	**Date Sent to PI**
UAT Test reminders	2024-3493	Tan Tock Seng Hospital	Dr TTSH NewPI1	Geriatric Medicine	Closed with Satisfaction	23-Sep-2024
UAT QA unlimited scc	2024-3503	Tan Tock Seng Hospital	Dr TTSH NewPI1	Geriatric Medicine	Pending	23-Sep-2024
UAT 3B unlimited scc	2024-3490	Tan Tock Seng Hospital	Dr TTSH NewPI1	Geriatric Medicine	Closed with Satisfaction	23-Sep-2024

1) PISAF Module General Interface – Filter



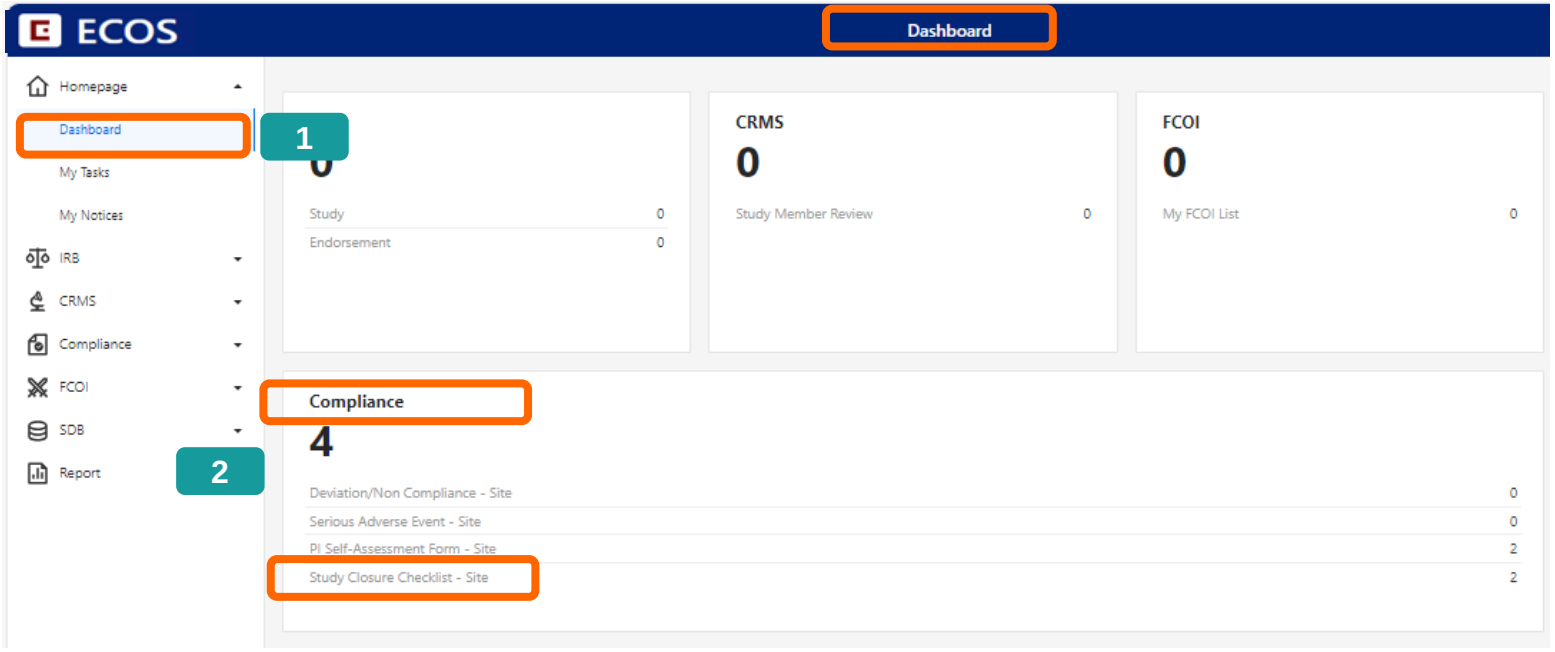
1. Click on "**Filter**" to tailor the listing you wish to view.

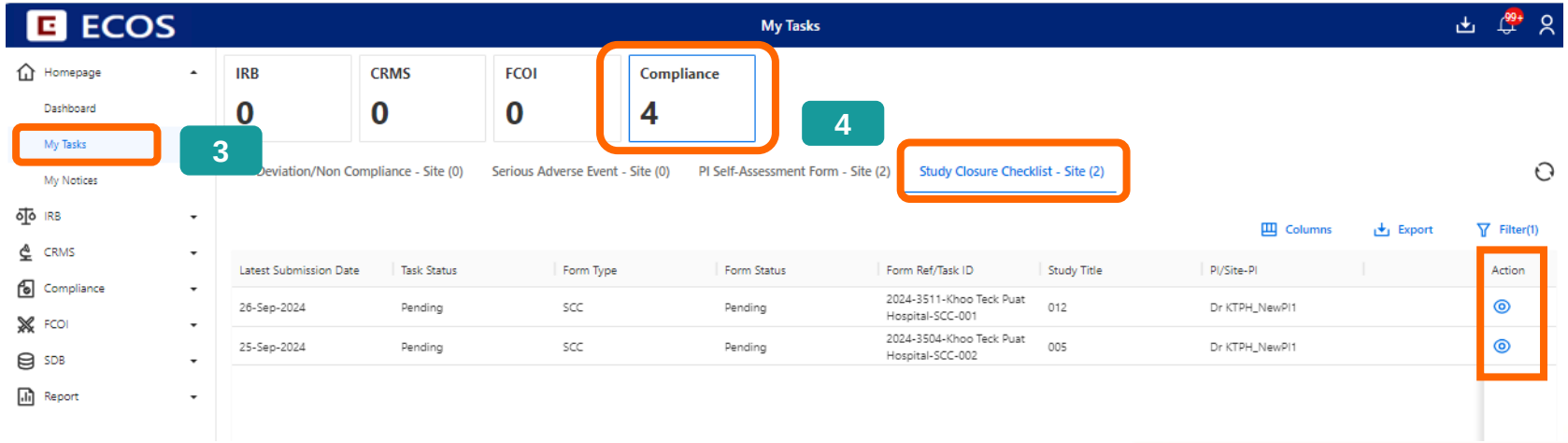
2. The default settings for the filter show only **pending** tasks for your action **(Task Status = Pending/ Queried)**. To reset to default filter settings, click on "**Reset**".

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

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

3) Locate your SCC task – via Homepage





<u>Via Homepage > Dashboard</u>

1. You can locate your outstanding SCC task via "**Homepage**" > **"Dashboard"** on the left navigation panel.

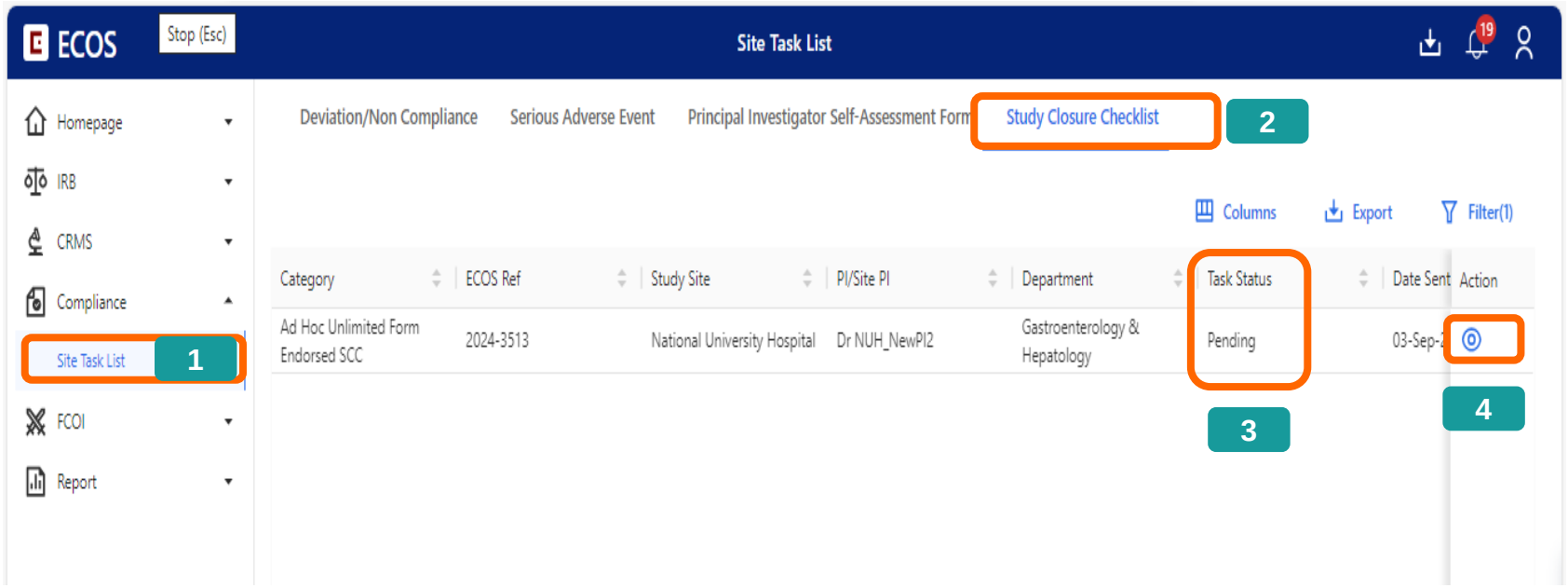
2. Locate the "**Compliance**" tile and click on **Study Closure Checklist - Site".** It will lead you to **"My Tasks".**

3. You can also access "**Homepage**" > "**My Task**" via the left navigation panel.

4. Click on the **"Compliance"** tile and locate the sub-tab **" Study Closure Checklist - Site".**

5. To view the **SCC** task, click on " " under the "**Action**" column.

3) Locate your SCC task – via Compliance module



PISAF and **Study Closure Checklist (SCC)** share the same navigation panel with **Compliance > Deviation/Non Compliance & Serious Adverse Event.**

<u>Via Compliance > Site Task List</u>

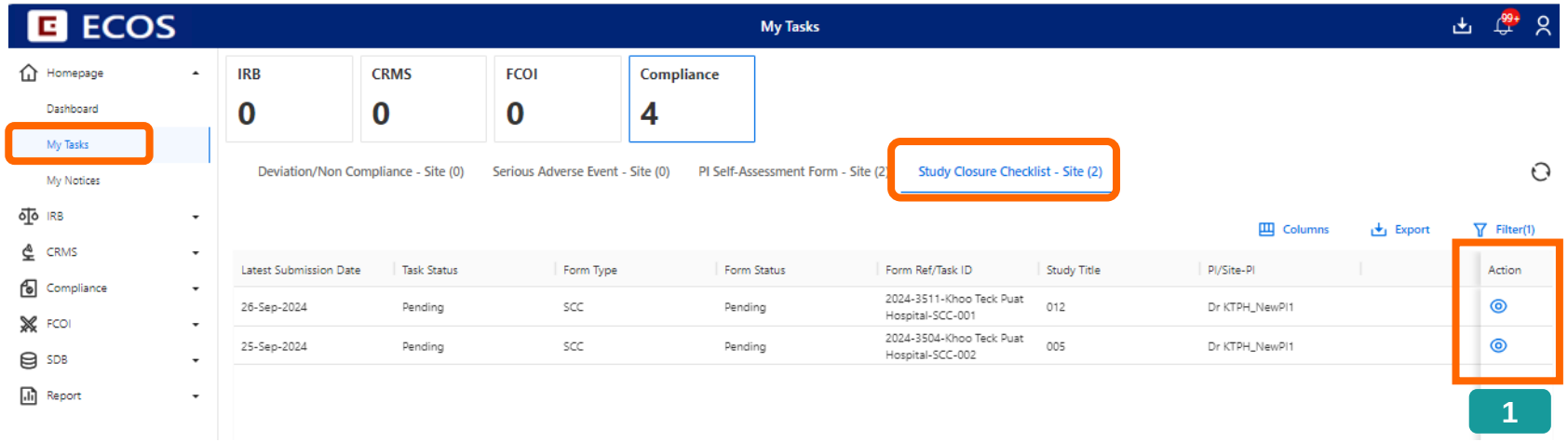
1. You can also locate **all assigned SCC tasks** via "**Compliance > Site Task List**".

2. Click "**Study Closure Checklist**" sub-header.

3. By default, you will see tasks which are pending your action (**Task Status = Pending/ Queried**).

4. Click on " " view button under the "**Action**" column to view the SCC form.

4) How to View/ Edit/ Submit SCC



Locate the SCC task through the methods described in Section 3.

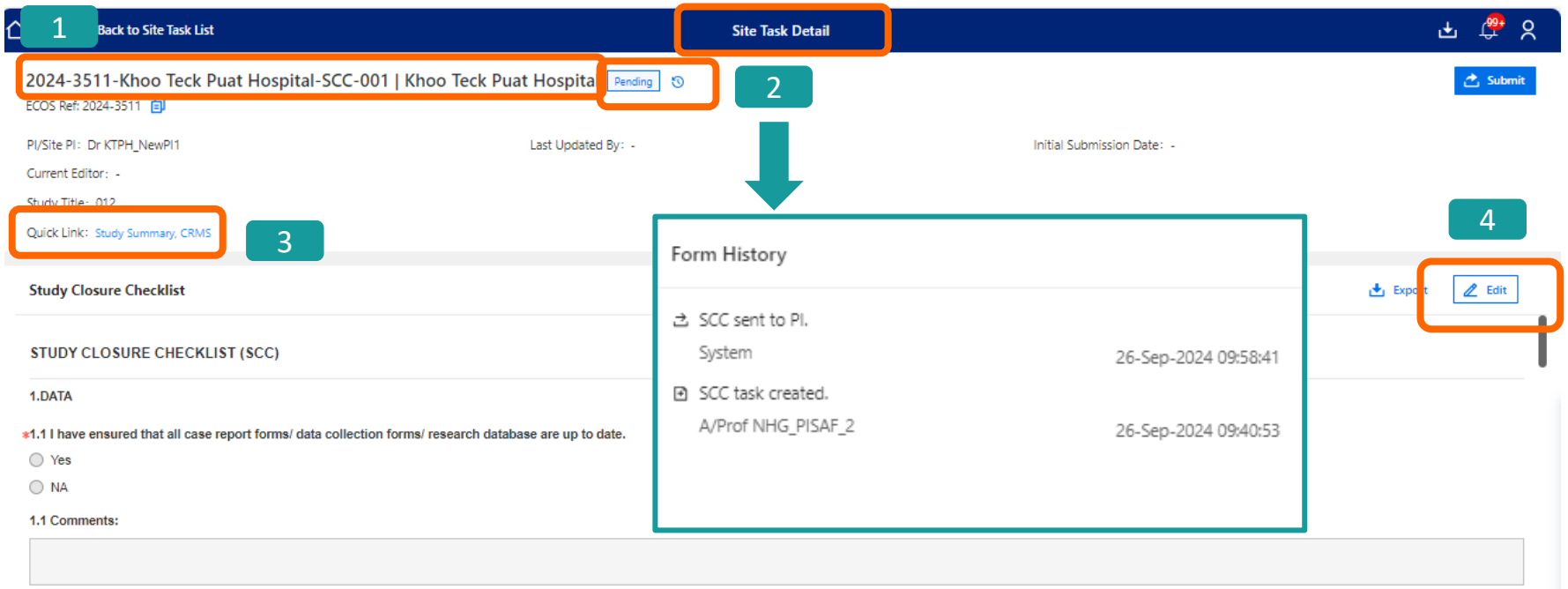
1. Click on the **View** button under **"Action"** column to edit the SCC Form.

You will arrive at **Site Task Detail** page.

Note: The **PI, Co-I and active Study Team Member (STM)** listed in **Clinical Research Management System User Authorization List (CRMS UAL)** can **view and edit** the SCC.

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

4) How to View/ Edit/ Submit SCC



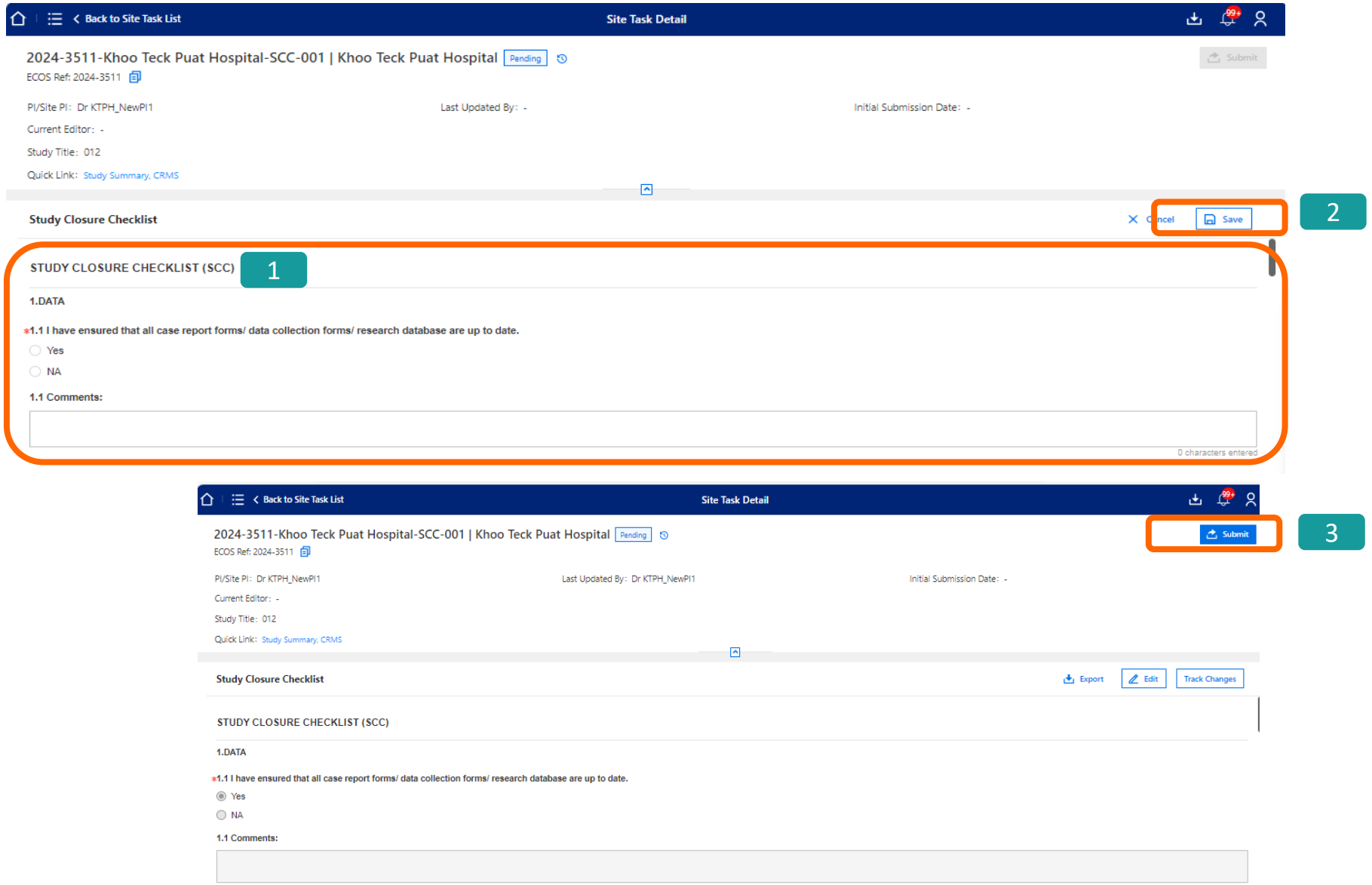
1. This is the SCC Form reference no.

2. The label indicates the task status of the SCC. Next to label is the **"Form History"** icon. You can click on the icon to view form history.

3. These quick links will bring you to **IRB Module - Study Summary** and **Clinical Research Management System (CRMS) information**.

4. Click on **"Edit"** to start completing the form.

4) How to View/ Edit/ Submit SCC



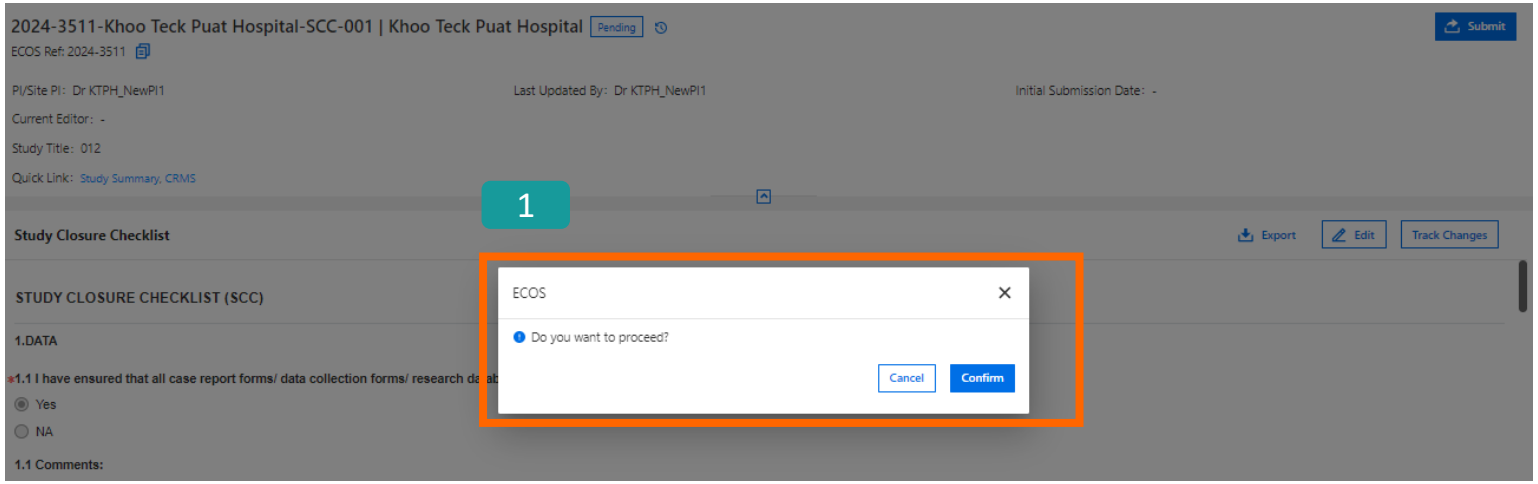
1. Scroll down to complete the rest of the SCC form. Fields marked with * are mandatory for completion.

2. Click on **"Save"** to ensure the edits have been saved successfully.

3. After the form has been saved, the **"Submit"** button will be enabled (color change from **grey to blue**).

4. By default, **only the PI** can be able to see and click on the **"Submit" button. Co-I and active STM listed in CRMS UAL** can **only view and edit** the SCC.

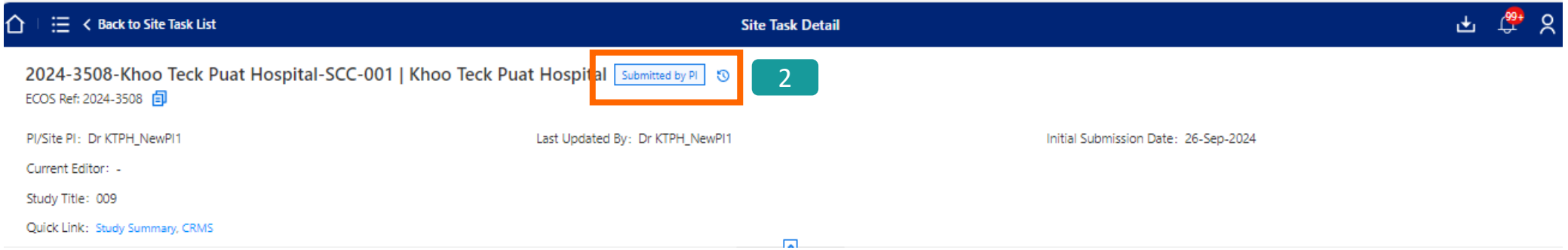
4) How to View/ Edit/ Submit SCC



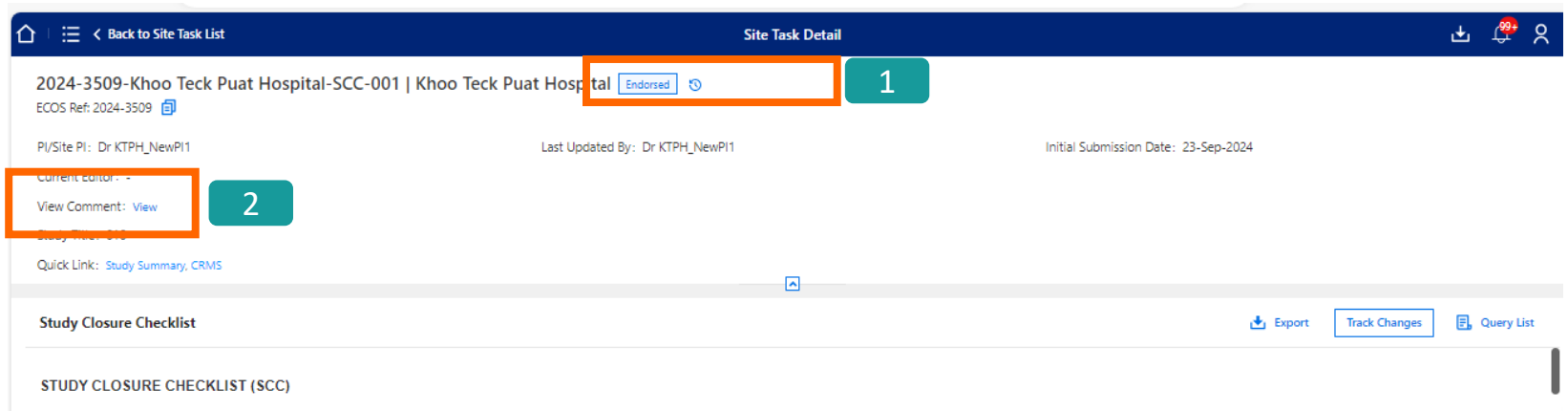
1. After the PI clicks on the **"Submit"** button, **a pop-up window** will appear for the user's confirmation to proceed with the task. Click on "**Confirm**" to proceed or "**Cancel**" to return to the Site Task detail page.

2. Click "**Confirm**" to proceed with the submission. The label will be changed from "**Pending**" to **"Submitted By PI".** The form **cannot** be edited further**.**

3. An email notification will be triggered after the SCC has been submitted. The task is now with the PISAF Reviewer to complete the review.



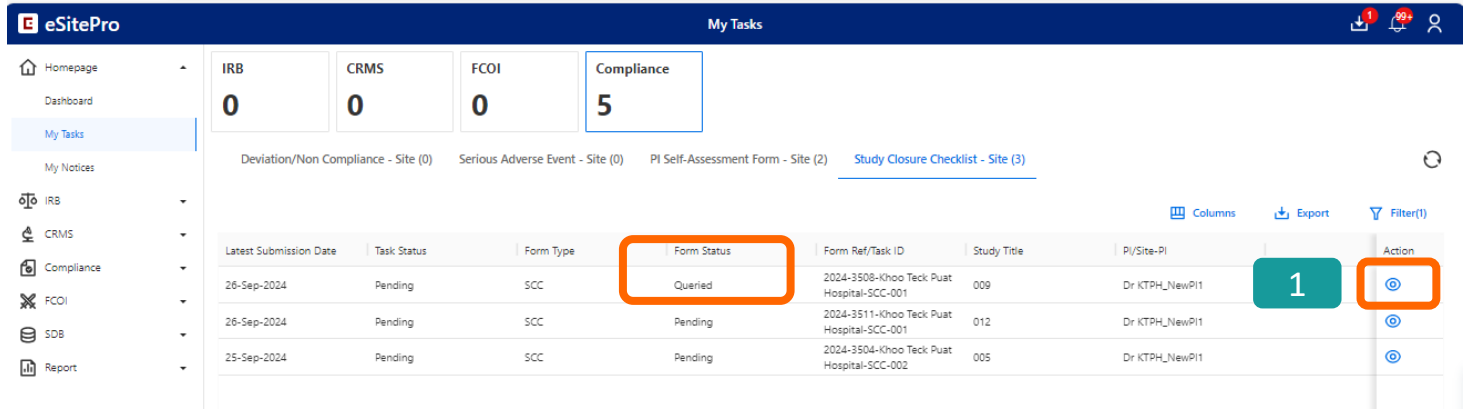
4) How to View/ Edit/ Submit SCC

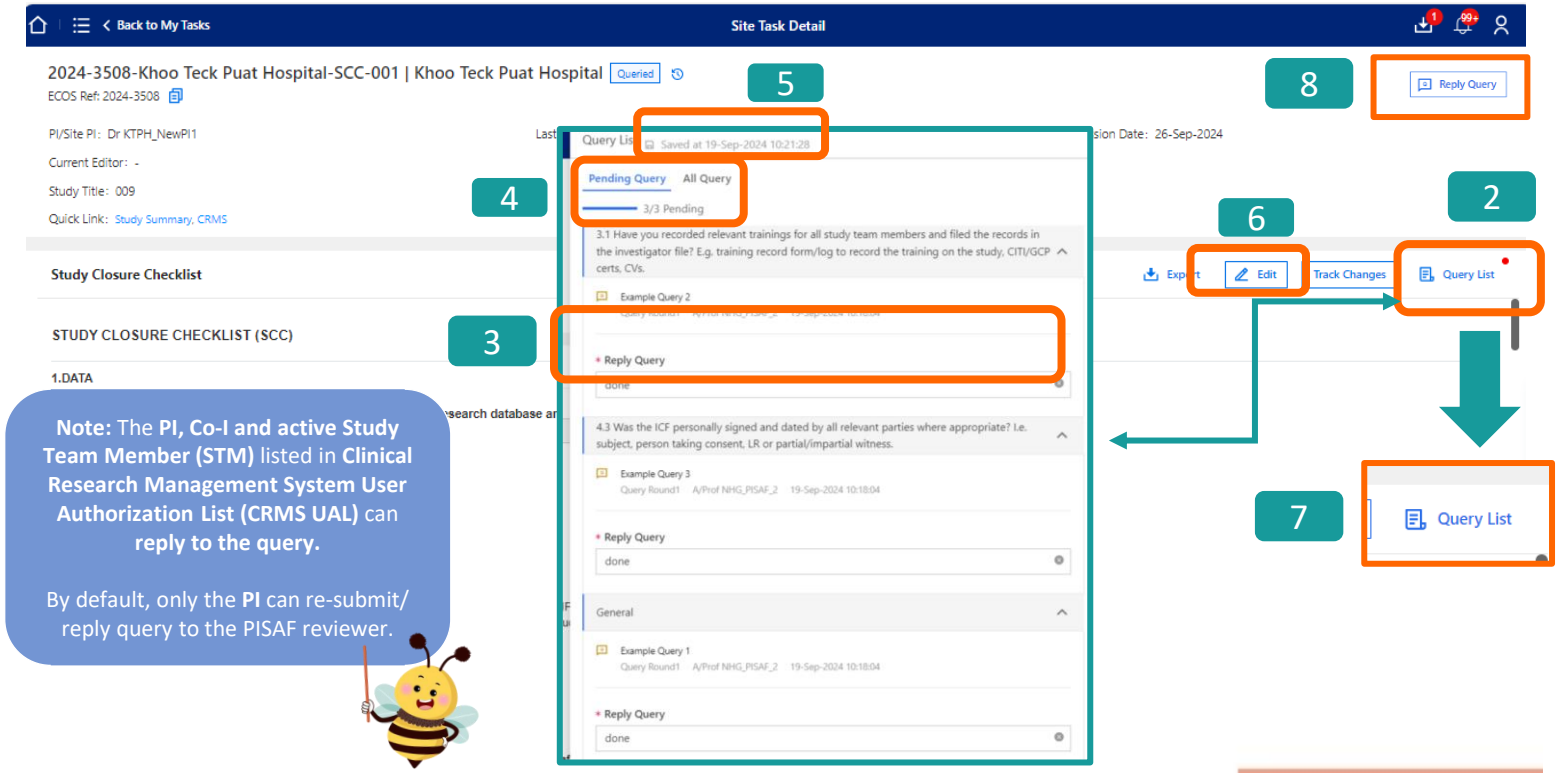


1. The PISAF reviewer will endorse the SCC if there is no query or all queries have been adequately addressed by the PI/ Study Team.

2. Click on "**View**" to see the comment from the PISAF reviewer (if any).

4) How to View/ Reply to Query





Note: The **PI, Co-I and active Study Team Member (STM)** listed in **Clinical Research Management System User Authorization List (CRMS UAL)** can **reply to the query.**

By default, only the **PI** can re-submit/ reply query to the PISAF reviewer.

1. Locate the SCC task from Home page or Compliance module. The status of the form will be reflected as "**Queried".** Click on **"View"** buttor to enter **Site Task detail** page to view the SCC.

2. To view query(ies)**, c**lick on the **"Query List"** button. A sliding window will appear**,** where you can **view and respond to** the query(ies). A **red dot** indicates that there is an action pending (i.e. to address the query).

3. Query(ies) are organised according to the respective sections of the SCC. 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 throughout the review under **"All Query"** tab.

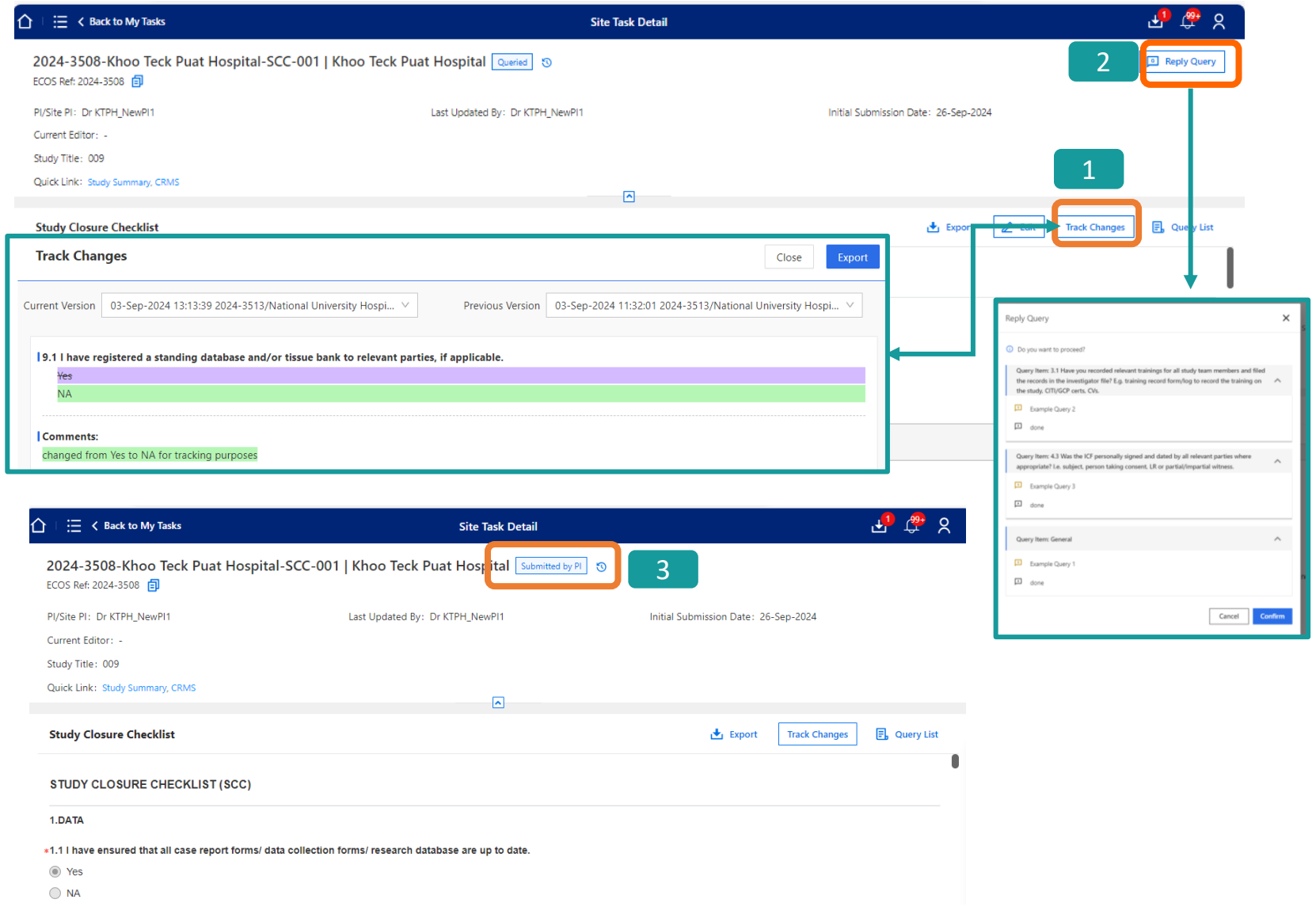
5. Query response will be **auto-saved.** Click on the background page, **Site Task Detail,** to close the sliding window.

6. Where needed, you will also need to make the edits onto the form directly. Click on "**Edit**" to make the changes and "**Save**".

7. When all the query(ies) have been **answered**, the red dot indicator will disappear.

8. The **"Reply Query"** button appears at the top of the form**.**

4) How to View/ Reply to Query



1. If changes were made to the SCC, you can see the **prior changes** when you click on the **"Track Changes"** function.

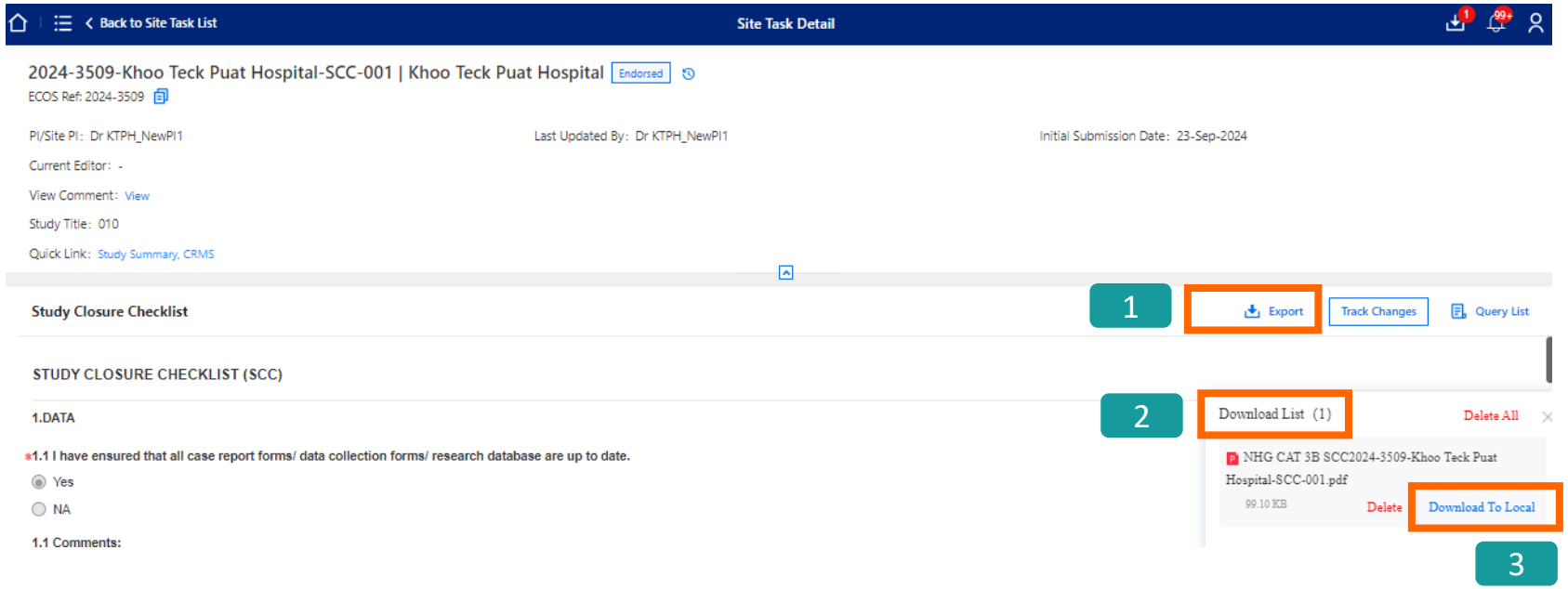
2. **Co-I and active STM** listed in CRMS UAL can **reply to query,** but **only the PI can re-submit the form/ reply query.** Click on **"Reply Query" button.**

   A confirmation pop-up window will appear with the list of query replies. Click "**Confirm**" to proceed or "**Cancel**" to return to **Site Task Detail** page.

3. The label will be changed from "**Queried**" to **"Submitted By PI".** The form **cannot** be edited further.

4. An email notification will be triggered after the SCC has been submitted. The task is now with the PISAF Reviewer to review the query response.

6) How to Export the SCC



1. To export a copy of the SCC for record keeping, click on "**Export**".

2. The "**Download List**" will appear at the bottom of the browser.

3. When the export is complete, click "**Download To Local**". The PDF copy of the form will be saved to your computer local drive.

Thank You

Please contact Research Quality (NHGHQ) researchquality@nhg.com.sg if you have any question about ECOS Compliance (PISAF-SCC) module.