

# ECOS User Guide: Compliance Module - Principal Investigator Self-Assessment Form – Study Closure Checklist (PISAF – SCC)

# Contents

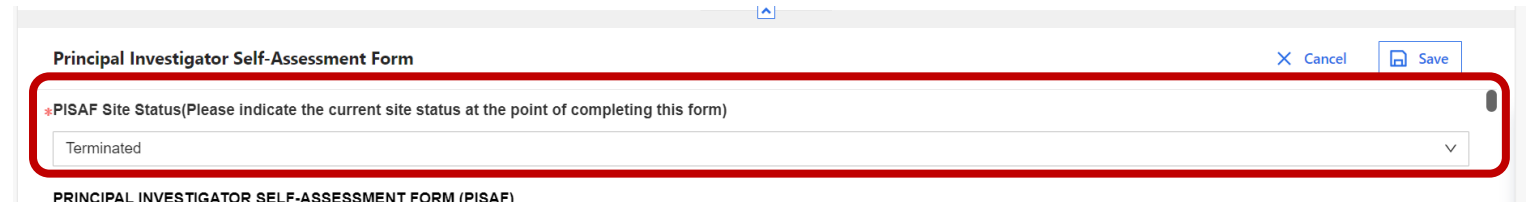
## **Principal Investigator Self-Assessment Form (PISAF) - Study Closure Checklist (SCC) User Guide for:**

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

1. When does the SCC Task occur
2. PISAF-SCC Module General Interface
3. How to Locate the SCC task
4. How to View/ Edit/ Submit the SCC
5. How to View/ Reply to Query
6. How to Export the SCC

# 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.



The screenshot shows a web form titled "Principal Investigator Self-Assessment Form". At the top right, there are "Cancel" and "Save" buttons. The main content area contains a dropdown menu labeled "PISAF Site Status (Please indicate the current site status at the point of completing this form)". The dropdown menu is open, and the selected option is "Terminated". Below the dropdown menu, the text "PRINCIPAL INVESTIGATOR SELF-ASSESSMENT FORM (PISAF)" is visible.

# 1) PISAF-SCC Module General Interface - Columns

The screenshot shows the ECOS Site Task List interface. The top navigation bar includes tabs for Deviation/Non Compliance, Serious Adverse Event, Principal Investigator Self-Assessment Form, and Study Closure Checklist. The left sidebar contains navigation options: Homepage, IRB, CRMS, Compliance, Site Task List, FCOI, SDB, and Report. The main content area displays a table with columns for Category, ECOS Ref, Study Site, and PI/Site PI. A 'Columns' dialog is open, showing a list of columns with checkboxes and drag handles. The 'Clear' button is highlighted with a red box and labeled '3', and the 'Save' button is highlighted with a red box and labeled '2'. A green box labeled '1' highlights the 'Columns' button in the top toolbar.

Category	ECOS Ref	Study Site	PI/Site PI	Task Sta	Action
UAT_3B_unlimited_scc auto	2024-3514	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Pending	🔍
UAT_QA_unlimited_scc	2024-3511	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Pending	🔍
UAT_3B_adhocx1_scc auto	2024-3504	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Pending	🔍

**Column** Selected 15

- ECOS Ref
- Study Site
- PI/Site PI
- Department
- Task Status
- Date Sent to PI
- Task Due Date
- Initial Submission Date
- Outcome Date
- PISAF Site Status
- Form Ref

**3** Clear **2** Save

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

The screenshot shows the ECOS interface for the Site Task List. The 'Site Task List' menu item is highlighted in red. The 'Study Closure Checklist' tab is selected. The 'Export' button is highlighted in red. A dropdown menu is open, showing 'Download Original' and 'Safe Download (PDF)' options, with a green arrow pointing from the 'Export' button to the dropdown. A green box labeled '2' highlights the dropdown menu.

Category	ECOS Ref	Study Site	PI/Site PI	Department	Task Sta	Action
UAT_3B_unlimited scc auto	2024-3514	Khoos Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia	Pending	👁
UAT_QA_unlimited_scc	2024-3511	Khoos Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia	Pending	👁
UAT_3B_adhocx1_scc auto	2024-3504	Khoos Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia	Pending	👁

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

The screenshot shows the ECOS interface with the 'Site Task List' menu item highlighted. The main content area displays a table of tasks with columns for Category, ECOS Ref, Study Site, PI/Site PI, and Department. A 'Filter(1)' button is visible above the table. A 'Filter' dialog box is open, showing fields for Category, ECOS Ref, Study Site, PI/Site PI, Department, Task Status (with 'Pending' and 'Queried' selected), Date Sent to PI, and Task Due Date. The 'Reset' and 'Search' buttons are highlighted in the dialog. Numbered callouts 1, 2, and 3 are placed near the filter dialog.

Category	ECOS Ref	Study Site	PI/Site PI	Department
UAT_3B_unlimited scc auto	2024-3514	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia
UAT_QA unlimited_scc	2024-3511	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia
UAT_3B_adhocx1_scc auto	2024-3504	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia

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

The screenshot shows the ECOS Dashboard. The 'Dashboard' link in the left navigation panel is highlighted with a red box and labeled '1'. The 'Compliance' tile in the main content area is highlighted with a red box and labeled '2'. Below the 'Compliance' tile, the 'Study Closure Checklist - Site' sub-tab is highlighted with a red box.

#### Via Homepage > Dashboard

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.

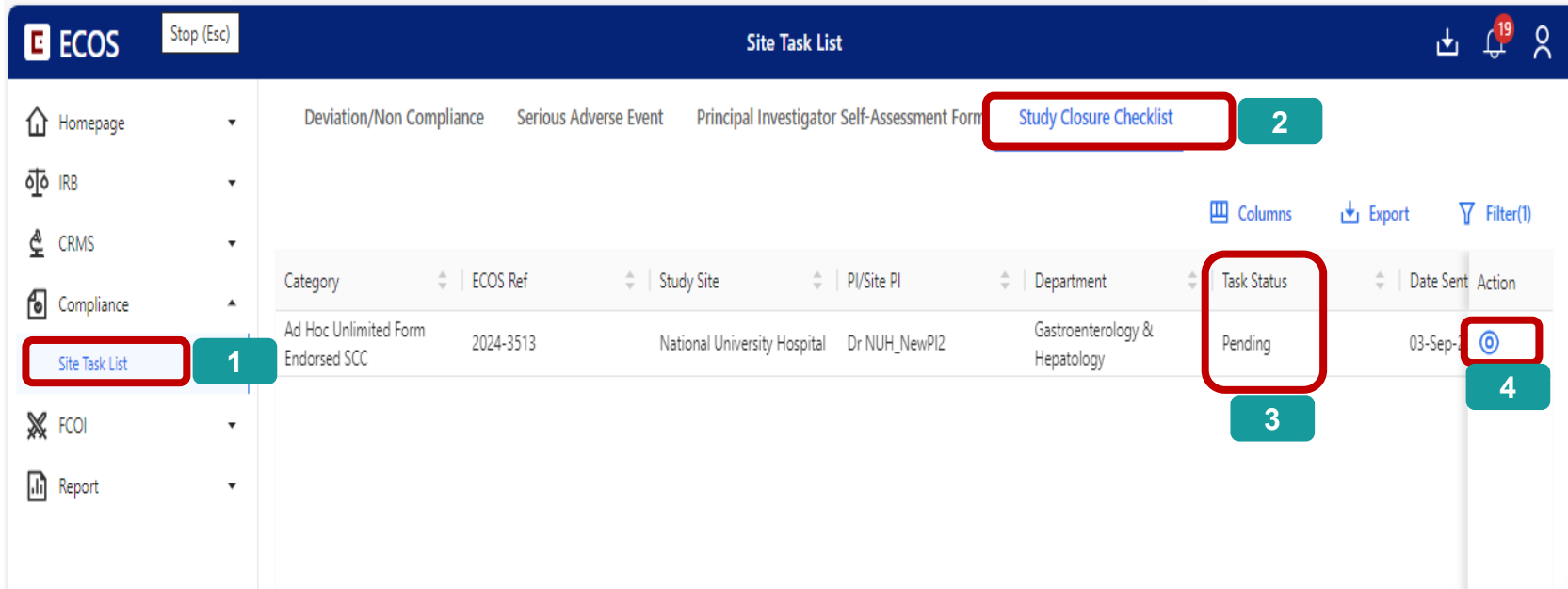
The screenshot shows the ECOS My Tasks page. The 'My Tasks' link in the left navigation panel is highlighted with a red box and labeled '3'. The 'Compliance' tile in the main content area is highlighted with a red box and labeled '4'. Below the 'Compliance' tile, the 'Study Closure Checklist - Site (2)' sub-tab is highlighted with a red box. A table of tasks is visible below, with the 'Action' column highlighted by a red box.

Latest Submission Date	Task Status	Form Type	Form Status	Form Ref/Task ID	Study Title	PI/Site-PI	Action
26-Sep-2024	Pending	SCC	Pending	2024-3511-Khoo Teck Puat Hospital-SCC-001	012	Dr KTPH_NewPI1	
25-Sep-2024	Pending	SCC	Pending	2024-3504-Khoo Teck Puat Hospital-SCC-002	005	Dr KTPH_NewPI1	

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.**

#### Via Compliance > Site Task List

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

The screenshot shows the ECOS 'My Tasks' dashboard. The top navigation bar includes 'ECOS' and 'My Tasks'. Below the navigation bar, there are four summary cards for IRB (0), CRMS (0), FCOI (0), and Compliance (4). The Compliance card is highlighted with a blue border. Below the summary cards, there are four task categories: 'Deviation/Non Compliance - Site (0)', 'Serious Adverse Event - Site (0)', 'PI Self-Assessment Form - Site (2)', and 'Study Closure Checklist - Site (2)'. The 'Study Closure Checklist - Site (2)' is highlighted with a red box. Below these categories is a table with columns: 'Latest Submission Date', 'Task Status', 'Form Type', 'Form Status', 'Form Ref/Task ID', 'Study Title', 'PI/Site-PI', and 'Action'. The 'Action' column contains two 'View' icons (eye with a magnifying glass), which are highlighted with a red box. A green badge with the number '1' is positioned below the 'Action' column.

Latest Submission Date	Task Status	Form Type	Form Status	Form Ref/Task ID	Study Title	PI/Site-PI	Action
26-Sep-2024	Pending	SCC	Pending	2024-3511-Khoo Teck Puat Hospital-SCC-001	012	Dr KTPH_NewPI1	
25-Sep-2024	Pending	SCC	Pending	2024-3504-Khoo Teck Puat Hospital-SCC-002	005	Dr KTPH_NewPI1	

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

The screenshot shows the 'Site Task Detail' page for SCC Form 2024-3511-Khoo Teck Puat Hospital-SCC-001. The interface includes a top navigation bar, a main content area with a 'Submit' button, and a 'Form History' table. Four numbered callouts highlight key elements: 1. The SCC Form reference number '2024-3511-Khoo Teck Puat Hospital-SCC-001 | Khoo Teck Puat Hospital'. 2. The task status 'Pending' and a refresh icon. 3. Quick links for 'Study Summary' and 'CRMS'. 4. The 'Form History' table and an 'Edit' button.

Form History		
📄 SCC sent to PI.	System	26-Sep-2024 09:58:41
📄 SCC task created.	A/Prof NHG_PISAF_2	26-Sep-2024 09:40:53

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

2024-3511-Khoo Teck Puat Hospital-SCC-001 | Khoo Teck Puat Hospital Pending Submit

ECOS Ref: 2024-3511

PI/Site PI: Dr KTPH\_NewPI1 Last Updated By: - Initial Submission Date: -

Current Editor: -

Study Title: 012

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

1 Prepare Checklist Cancel Save 2

STUDY CLOSURE CHECKLIST (SCC)

1.DATA

\*1.1 I have ensured that all case report forms/ data collection forms/ research database are up to date.

Yes

NA

1.1 Comments:

0 characters entered

3 Submit

Study Closure Checklist Export Edit Track Changes

STUDY CLOSURE CHECKLIST (SCC)

1.DATA

\*1.1 I have ensured that all case report forms/ data collection forms/ research database are up to date.

Yes

NA

1.1 Comments:

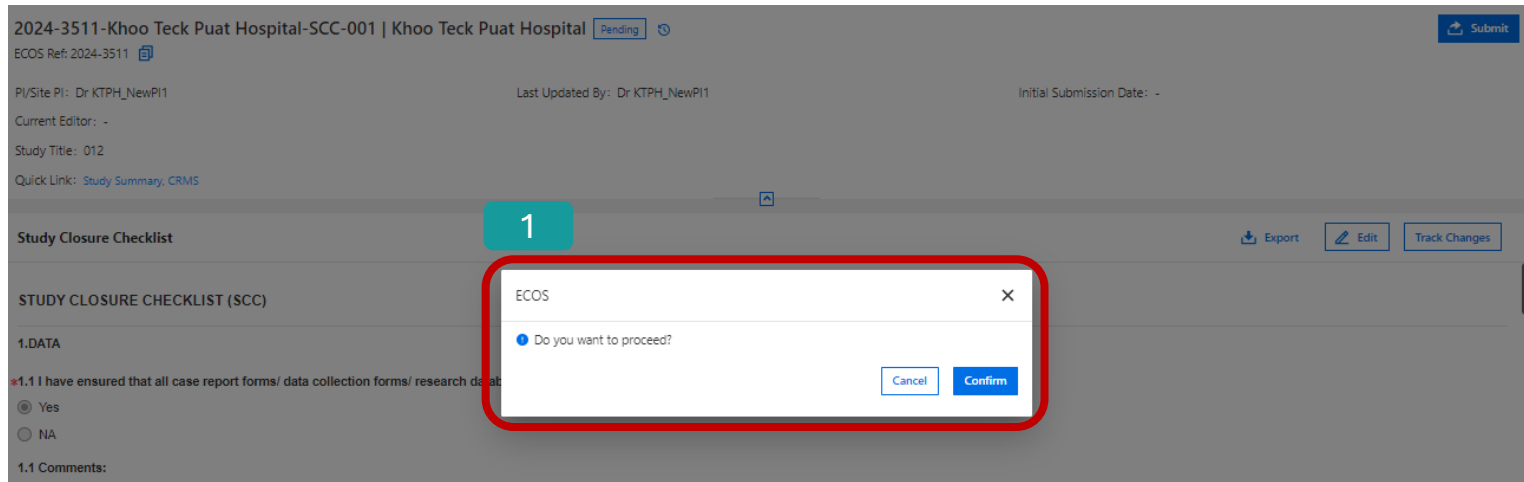
1. Scroll down to complete the rest of the SCC form. Fields marked with \* are mandatory for completion.

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

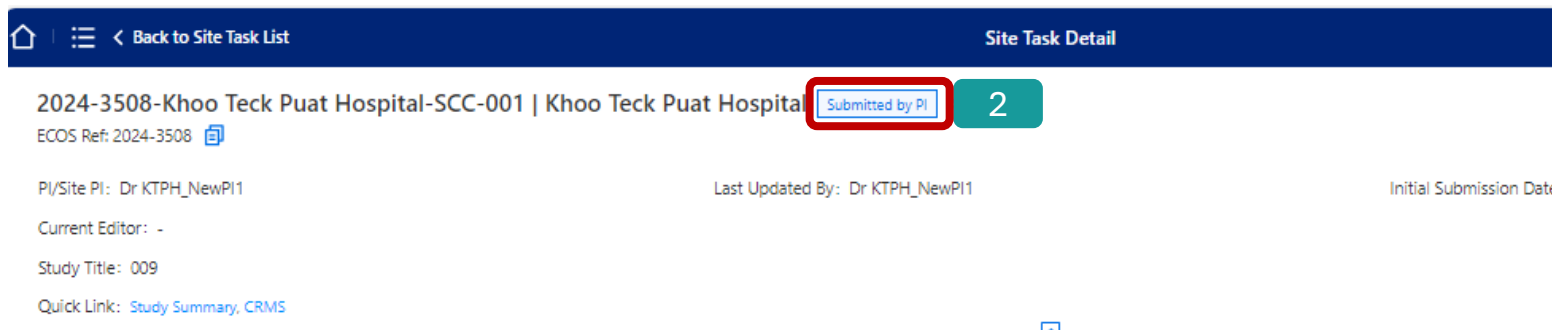


The screenshot shows the 'Study Closure Checklist' page for study 2024-3511. A red box highlights a confirmation dialog box titled 'ECOS' with the question 'Do you want to proceed?' and 'Cancel' and 'Confirm' buttons. A green box with the number '1' is placed above the dialog box. The background page shows a 'Pending' status and a 'Submit' button.

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.



The screenshot shows the 'Site Task Detail' page for study 2024-3508. The status is now 'Submitted by PI', which is highlighted with a red box and a green box with the number '2'. The page shows the study title, PI/Site PI, and other details.

## 4) How to View/ Edit/ Submit SCC

2024-3509-Khoo Teck Puat Hospital-SCC-001 | Khoo Teck Puat Hospital  
ECOS Ref: 2024-3509

PI/Site PI: Dr KTPH\_NewPI1  
Last Updated By: Dr KTPH\_NewPI1  
Initial Submission Date: 23-Sep-2024

Current Editor: Dr KTPH\_NewPI1  
View Comment: View

Study Title: 010  
Quick Link: [Study Summary, CRMS](#)

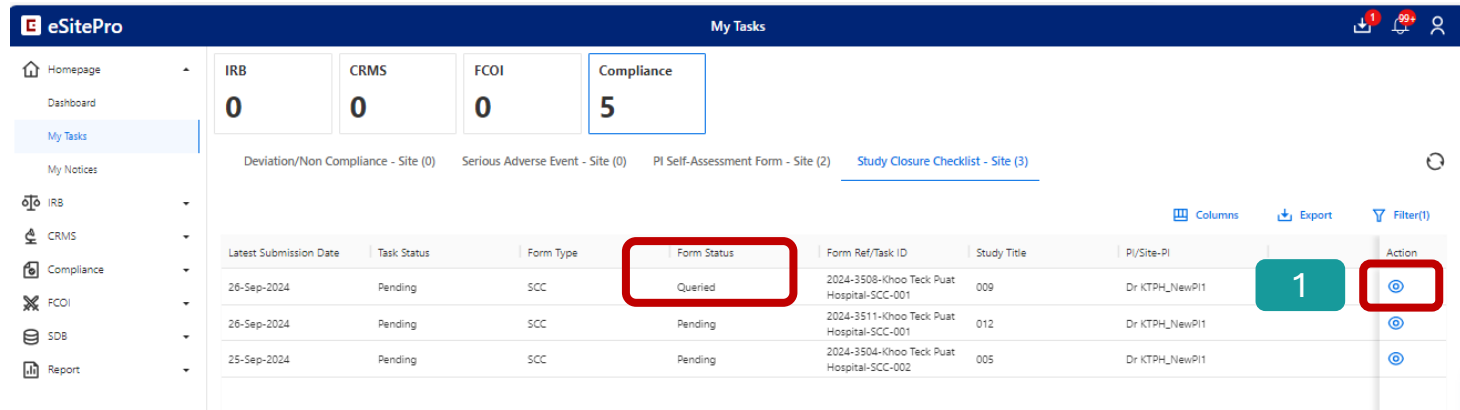
Study Closure Checklist


EXPORT TRACK CHANGES QUERY LIST

STUDY CLOSURE CHECKLIST (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



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

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). 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”**.

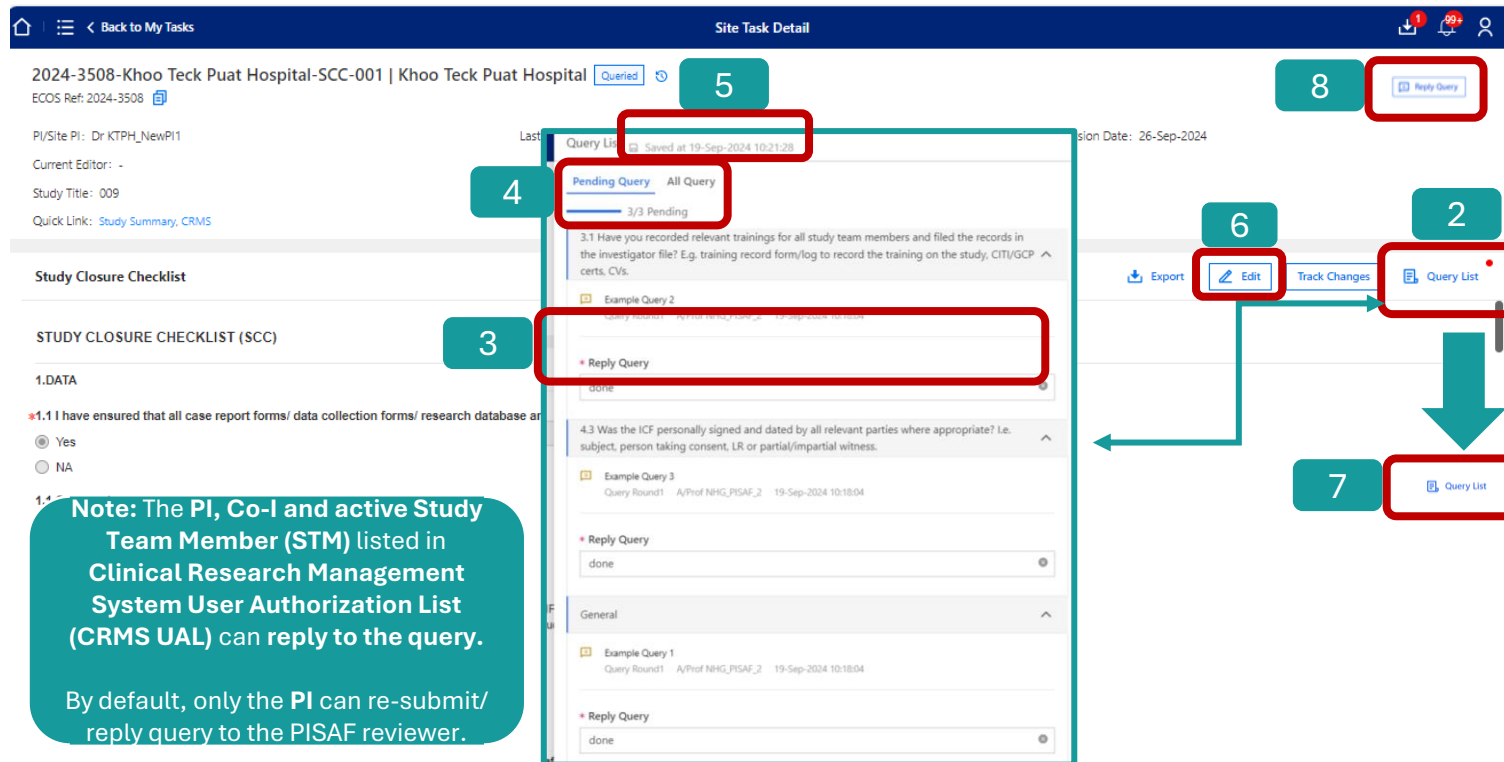
4. You can view all queries throughout the review under **“All Query”** tab.

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.

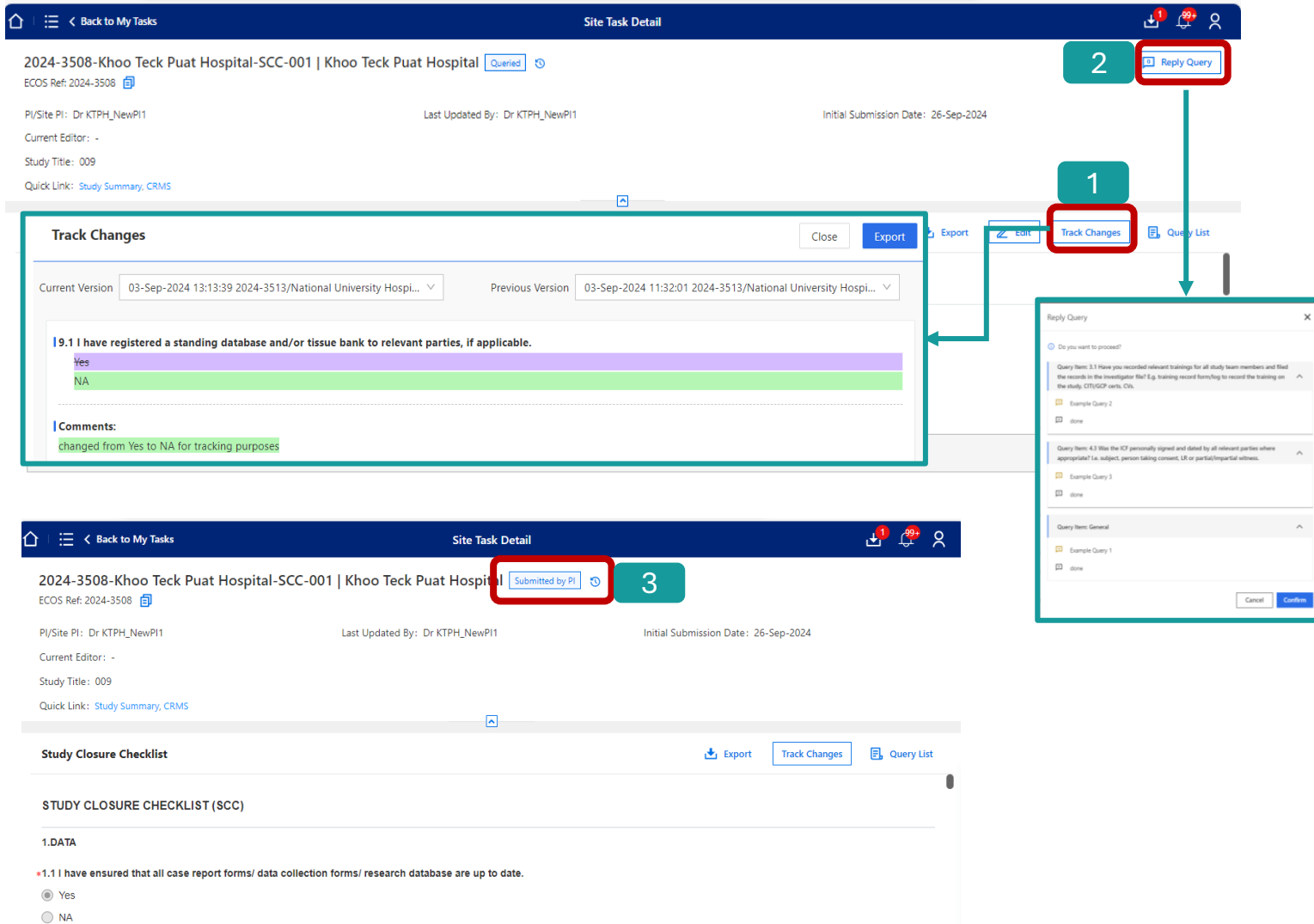
8. The **“Reply Query”** button appears at the top of the form.



**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.

# 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

The screenshot shows the 'Site Task Detail' page for 'Khoo Teck Puat Hospital-SCC-001'. The page includes a header with navigation and user information, a main content area with a checklist, and a bottom section with an 'Export' button and a 'Download List' dropdown. Red boxes and numbers 1, 2, and 3 highlight the 'Export' button, the 'Download List' dropdown, and the 'Download To Local' button respectively.

Study Closure Checklist

STUDY CLOSURE CHECKLIST (SCC)

1.DATA

\*1.1 I have ensured that all case report forms/ data collection forms/ research database are up to date.

Yes

NA

1.1 Comments:

1 Export Track Changes Query List

2 Download List (1) Delete All

NHG-CAT 3B SCC2024-3509-Khoo Teck Puat Hospital-SCC-001.pdf 99.10 KB Delete Download To Local

3

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.

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