

# ECOS User Guide: Compliance Module - Deviation / Non-Compliance & Serious Adverse Event (For PI)



# Introduction – Compliance Module

The **Compliance Module** in ECOS allows the review and processing of DNC<sup>^</sup> and SAE from HBR studies.

## In ECOS, researchers can:

- Respond to queries from the Research Institution (RI) directly and keep track of all queries on ECOS
- Upload supporting documents for a query
- Receive feedback directly from the RI on the MOH reporting forms (if any)
- Receive email and system notifications pertaining to pending tasks
- Endorse the MOH reporting form

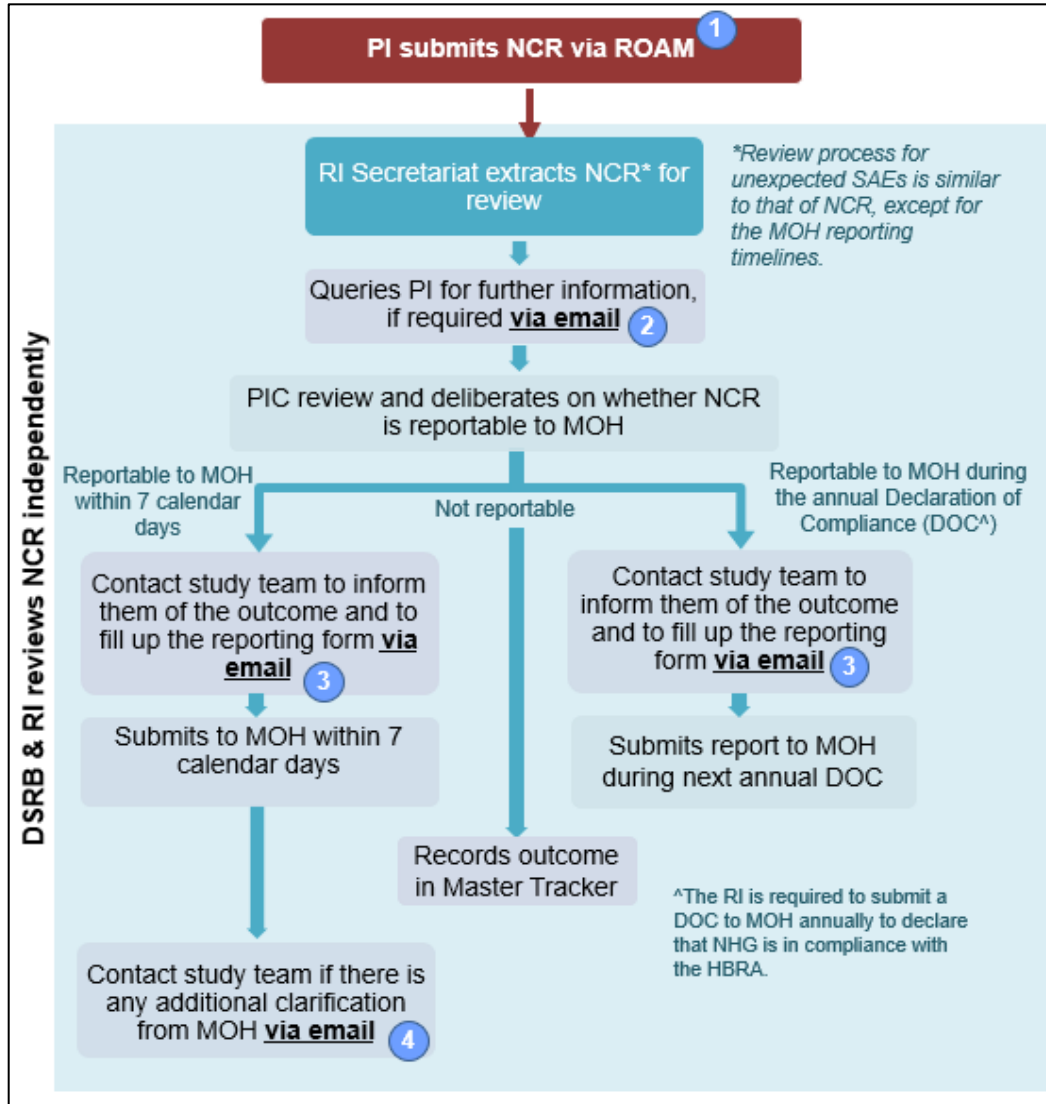
<sup>^</sup>DNC is the ECOS acronym for Deviations & Non-Compliances.

ROAM users used to refer to this category of reports as “NCR (Non-Compliance Reports)”.



# Key Differences Between the Previous Workflow and ECOS

## Previous Workflow



## New Workflow in ECOS

- 1 PI submits NCR **via ECOS**
- 2 Queries will be sent to study team **via ECOS** if there is any clarification required
- 3 RI Secretariat will inform study team of the outcome and seek their assistance to fill up the reporting form **via ECOS**
- 4 RI Secretariat will send the additional clarifications from MOH to the study team **via ECOS**



# Navigating ECOS – Where to find the Compliance-Related Tasks?

## 1. On your “Dashboard”

The screenshot shows the ECOS Dashboard interface. The left navigation bar includes links to Homepage, Dashboard, My Tasks, My Notices, IRB, CRMS, Compliance, and FCOI. The main content area displays three summary cards: IRB (26), CRMS (0), and FCOI (0). The IRB card has sub-items: Study (26) and Endorsement (0). The CRMS card has a sub-item: Study Member Review (0). The FCOI card has a sub-item: My FCOI List (0). Below these is a Compliance card (11) with sub-items: Deviation/Non Compliance - Site (8) and Serious Adverse Event - Site (3). On the right, there is a 'My Notices' section with a 'View All' link and a list of five 'Service Disruption Broadcast Message' notifications with dates ranging from May 15, 2024, to June 3, 2024. Three blue callout boxes provide navigation instructions: Step 1 points to the 'Dashboard' link in the left bar; Step 2 points to the 'Compliance' card; Step 3 points to the 'My Tasks' link in the left bar.

**Step 1:** This page may be accessed by clicking on “Homepage” followed by the “Dashboard” in the left navigation bar.

**Step 2:** Outstanding tasks relating to Compliance (DNC/SAE) will be displayed here

**Step 3:** Click to be directed to the “My Tasks” Page.

Category	Count
IRB	26
CRMS	0
FCOI	0
Compliance	11

Category	Count
Study	26
Endorsement	0
Study Member Review	0
My FCOI List	0
Deviation/Non Compliance - Site	8
Serious Adverse Event - Site	3

**My Notices** [View All](#)

- Service Disruption Broadcast Message  
03-Jun-2024
- Service Disruption Broadcast Message  
31-May-2024
- Service Disruption Broadcast Message  
27-May-2024
- Service Disruption Broadcast Message  
23-May-2024
- Service Disruption Broadcast Message  
15-May-2024



# Navigating ECOS – Where to find the Compliance-Related Tasks?

## 2. On “My Tasks” page

Users will be directed to this page from the “Dashboard”

**Step 4:** This page may also be accessed by clicking on “Homepage” followed by the “My Tasks” in the left navigation bar

**Step 5:** Outstanding tasks relating to Compliance (DNC/SAE) will be displayed here

**Step 6:** Toggle between the tabs to view tasks for DNC or SAE

**Step 7:** Click here to view details of the task

Latest Submission	Compliance Status	Form Ref/Task ID	Study Title	PI/Site-PI	Action
31-Jul-2024	Pending	Tiered SOC	MOH Report Pending PI Response	Study with HBR-003	A/Prof TTSH_User_ID04
20-Jul-2024	Pending	SOC	MOH Report Pending PI Response	Study with HBR-004	A/Prof TTSH_User_ID04
18-Jul-2024	Pending	SOC	MOH Report Pending PI Response	Study with HBR-004	A/Prof TTSH_User_ID04
11-Jul-2024	Pending	SOC	MOH Report Pending Endorsement	Study with HBR-003	A/Prof TTSH_User_ID04
10-Jul-2024	Pending	DNC (IRB)	Pending PI Response	Study with HBR-003	A/Prof TTSH_User_ID04



# Navigating ECOS – Where to find the Compliance-Related Tasks?

## 3. On “Compliance Site Task” Page

**Step 11:** Toggle between the **tabs** to **view tasks** for DNC or SAE

The screenshot shows the ECOS 'Site Task List' page. The left sidebar contains a navigation menu with 'Site Task List' highlighted. The main content area has two tabs: 'Deviation/Non Compliance' (active) and 'Serious Adverse Event'. Below the tabs is a table of tasks. Annotations with arrows point to specific elements: Step 8 points to the 'Site Task List' menu item; Step 9 points to the 'Site Task List' page title; Step 10 points to the magnifying glass icon in the 'Action' column; and Step 11 points to the tabs.

		Date of DNC reported					Action
MOH Report Pending PI Response	18-Jul-2024	A/Prof TTSH_User_ID04	Woodlands Health	Anaesthesia			
Pending PI	18-Jul-2024	A/Prof TTSH_User_ID04	Woodlands Health	Anaesthesia			
MOH Report Pending PI Response	16-Jul-2024	Dr NUH_IR01	Khoo Teck Puat Hospital	Acute & Emergency Care			
			Khoo Teck Puat Hospital	Acute & Emergency Care			

**Tips:** PIs may **appoint** their **study team members** to **respond to the queries** and/ or **fill up the MOH reporting form**:

- Ensure that they are **added** in the **Clinical Research Management System (CRMS)**.
- They will be able to **perform the tasks** mentioned in the **subsequent slides**.



# Navigating ECOS – Where to Find Queries Regarding the DNC?

## Workflow – Queries from RI

PI submits DNC  
via ECOS

RI Secretariat extracts  
DNC for review

Queries PI for further  
information, if required via  
**ECOS**

Users will be directed to this page from Steps 7 and 10

**a** 2024-9999-DNC11-Woodlands Health-01B | Woodlands Health Pending PI Response

ECOS Ref: 2024-9999

**b** Date of DNC reported: 11-Jul-2024

**c** Current Editor: -

**d** Study Title: Study wi

**e** Quick Link: [Study Sum](#)

**Step 13:** The “Site Task Detail” page would include the following information:

- a) Task ID** – This ID is unique to the Compliance (DNC/ SAE) module
- b) Date of DNC reported**
- c) Current Editor** – The current editor’s ID will be captured
- d) Study Title**
- e) Quick link** – Links to the study summary and CRMS page
- f) Task Status** – Task status for the Compliance (DNC/ SAE) module

**Step 14:** Under “DNC (RI Query)” tab, click here to view and **respond to queries** from RI Secretariat regarding the DNC.

[Query List](#)



# Navigating ECOS – Uploading of Attachment

## On “Site Task Detail” Page

The screenshot displays the 'Site Task Detail' page for '2024-9999-DNC11-Woodlands Health-01B | Woodlands Health'. The page includes a 'Pending PI Response' status and various details like 'ECOS Ref: 2024-9999', 'Date of DNC reported: 11-Jul-2024', 'Current Editor: -', 'Study Title: Study with HBR-003', and 'Quick Link: Study Summary'. The 'Attachment' tab is selected, showing a table with one attachment: 'Attachment1.pdf' (Protocol) uploaded by 'TTSH\_User\_ID04' on '31-Jul-2024'. An 'Upload Attachment' modal is open on the right, featuring a 'Document Description' text area and an 'Upload' button. Annotations highlight key steps: Step 15 points to the 'Attachment' tab, Step 16 points to the 'Document Description' field, and Step 17 points to the delete icon in the attachment table's action column.

**Step 15:** Documents can be shared with the RI Secretariat via the “Attachment” tab

**Step 16:** Users may include a **description** of the document before uploading

**Step 17:** Users can only delete documents that **they** had uploaded



# Navigating ECOS – How to Respond to Queries?

The screenshot displays the 'Site Task Detail' page in the ECOS system. The top navigation bar includes a home icon, a menu icon, a 'Back to My Tasks' link, the page title 'Site Task Detail', and user notification icons (download, 99+ notifications, and profile). The main content area shows task details for '2024-9999-DNC11-Woodlands Health-01B | Woodlands Health' with a 'Pending PI Response' status. A 'Reply Query' button is visible in the top right corner. A modal window titled 'Reply Query' is open, displaying a confirmation message: 'Do you want to proceed?'. Below the message, the 'Query Item: General' is listed with two options: 'QUERY' and 'REPLY QUERY'. At the bottom of the modal are 'Cancel' and 'Confirm' buttons. Two callout boxes provide instructions: 'Step 18' points to the 'Reply Query' button, stating it appears after a query is responded to; 'Step 19' points to the 'Confirm' button, stating it sends the task back to the RI secretariat for review.

Site Task Detail

2024-9999-DNC11-Woodlands Health-01B | Woodlands Health Pending PI Response

ECOS Ref: 2024-9999

Date of DNC reported: 11-Jul-2024

Current Editor: -

Study Title: Study with

Quick Link: [Study Sum](#)

[DNC \(RI Query\)](#)

DNC (RI Query)

Reply Query

Do you want to proceed?

Query Item: General

QUERY

REPLY QUERY

Cancel Confirm

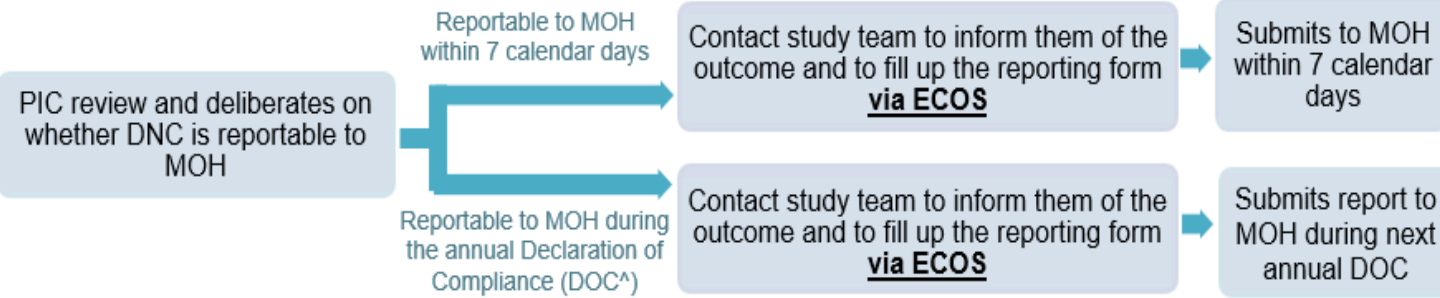
**Step 18:** A button “Reply Query” will appear once queries had been **responded** to. Click on the button and a prompt message will pop up

**Step 19:** Click “confirm” to **send the task back** to RI secretariat for their review or “cancel” if **further edit** to the response is required



# Navigating ECOS – How to Fill Up Reporting Form?

## Workflow – Reportable Outcomes



**Step 20:** Study team will be notified of the outcome of the DNC and (if required) will need to **complete the reporting form** soonest possible.

**Step 22:** The study team could either:

1. **Edit** the form.
2. **Save** the form as draft.
3. Compare with older version of the form via **Track Changes**.
4. **Export** the form for reference.
5. **Submit** the form to the RI Secretariat for further action.

After the **PI or study team submits the reporting form**, the **RI Secretariat will review the form** to ensure completeness of the form.

**Step 21:** Under the “**SOC**” or “**Tiered SOC**” tab, the study team will be able to **view and complete the reporting form**



# Navigating ECOS – Where to Find Queries Regarding the Reporting Form?

**Step 23:** If the RI Secretariat requires **additional information**, they will raise **query on the relevant section(s)** and **send the form back to the study team** to provide the required information

**Step 25:** A button “**Reply Query**” will appear once queries had been **responded** to. Click on the button and a prompt message will pop up.

**Step 24:** Click here to **view** and **respond to queries** from RI Secretariat regarding the reporting form

**Step 26:** Click “**confirm**” to **send the task back** to RI Secretariat for their review or “**cancel**” if further **edits** to the response is required

The screenshot displays the ECOS system interface. At the top, a dark blue header bar contains navigation icons and the text 'Back to My Tasks'. Below the header, the main content area shows details for a task titled '2024-9999-DNC11-Woodlands'. Key information includes 'ECOS Ref: 2024-9999', 'Date of DNC reported: 11-Jul-2024', 'Current Editor: -', 'Study Title: Study with HBR-003', and 'Outcome: Reportable as Tiered SOC'. A 'Reply Query' button is visible in the top right corner. A dialog box titled 'Reply Query' is open, asking 'Do you want to proceed?'. Below the dialog, a 'Query Item' section is visible, titled 'Query Item: 12. No. of Subject(s) Affected'. It contains two response options: 'PLEASE VERIFY THE NUMBER OF SUBJECT' and 'THIS IS CORRECT'. At the bottom of the dialog, there are 'Cancel' and 'Confirm' buttons. A 'Query Item' section is also visible in the background, showing a list of queries with columns for 'Query Item', 'Status', and 'Action'. The 'Action' column includes buttons for 'Export', 'Edit', 'Track Changes', and 'e-Form Query List'.



# Navigating ECOS – How to Endorse the Reporting Form?

Home

Menu

Back to My Tasks

Site Task Detail

Download

99+

User

2024-9999-DNC11-Woodlands Health-01B | Woodlands Health

MOH Report Pending Endorsement

ECOS Ref: 2024-9999

Document

Date of DNC reported: 11-Jul-2024

Outcome: Reportable as Tiered SOC

Current Editor: -

Study Title: Study with HBR-003

Quick Link: Study Summary

DNC (RI Query)

Tiered SOC

Attachment

Tiered SOC

Step 28: After the reporting form has been **endorsed**, the task status will become “MOH Report Pending Submission/Completion” and it will be **locked**.

No further edits will be allowed on the form.

Step 27: PI is required to **endorse the MOH** reporting form after it has been finalized by RI

The PI could either:

1. **Endorse** the reporting form.

2. **Reject** the reporting form if they wish to make further edits to it. The RI Secretariat would then review the form before seeking endorsement again.

If the MOH reporting form is **completed by the study team members**, the form would be **routed to the PI for endorsement**.

Step 29: For DNCs that are deemed to be **not reportable to MOH**, an email will be **sent to the PI and study team** to inform them of the outcome.

Reject

Endorse

12

Restricted, Sensitive - Normal



# Navigating ECOS – How to Response to MOH Queries?

## Workflow – Queries from MOH after submission of reporting form

Contact study team if there is any additional clarification from MOH **via ECOS**

**Step 31:** A button “**Reply Query**” will appear once queries had been **responded**. Click on the button and a prompt message will pop up



Site Task Detail

Back to My Tasks

Reply Query

Do you want to proceed?

Query Item: General

MOH QUERIES

REPLY QUERY

Cancel Confirm

Export Track Changes e-Form Query List MOH Query List

**Step 30:** If there are **queries from MOH** after submitting the reporting form, RI Secretariat will **convey the queries** to the study team **via ECOS** using the **query list**.

**The reporting form will remain locked.**



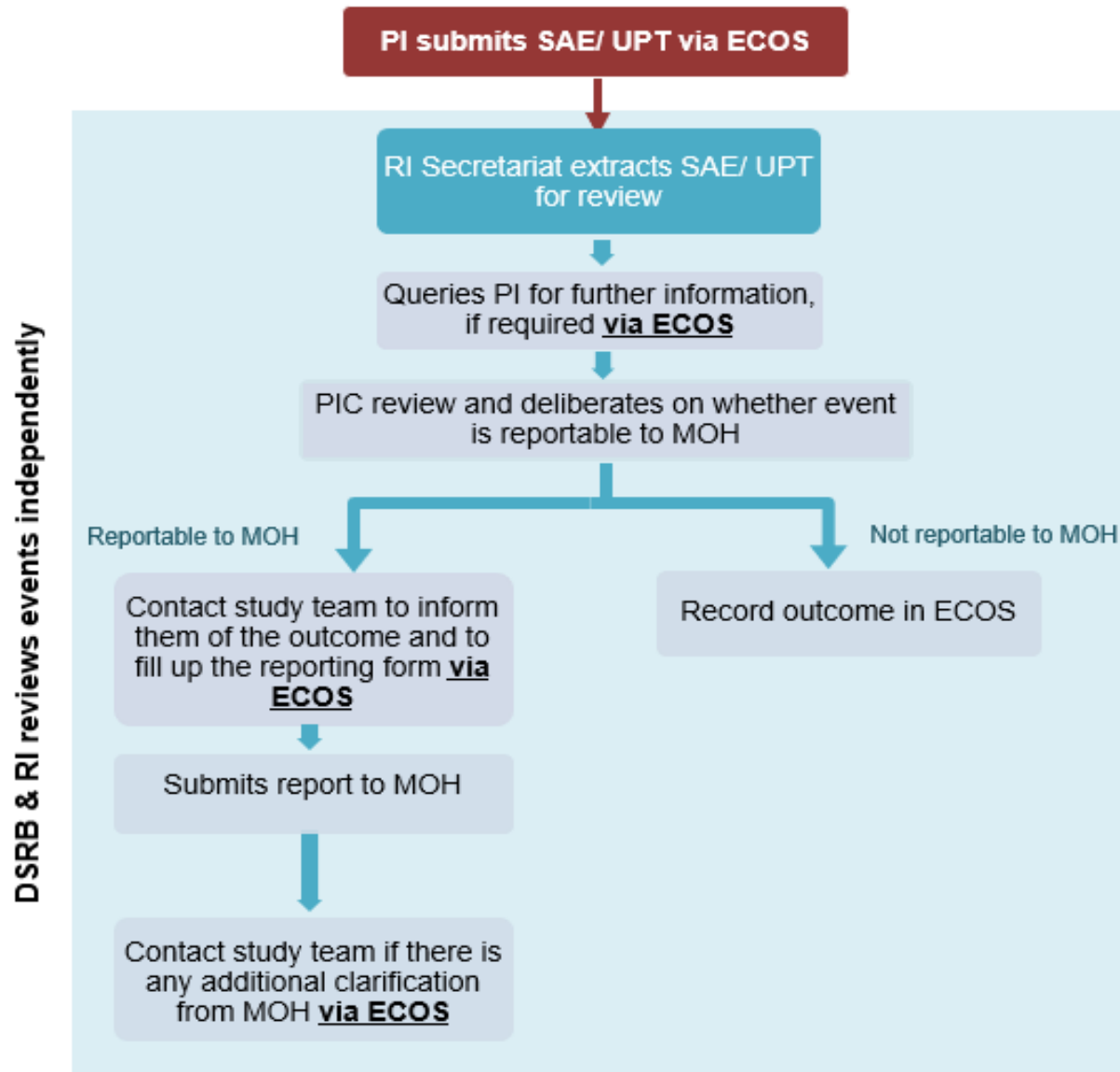
**Step 32:** Click “**confirm**” to **send the task back** to RI Secretariat for their review or “**cancel**” if further **edits** to the response is required

Cancel

Confirm



# Navigate ECOS – Serious Adverse Event/ UPIRTSO



The workflow for SAE & UPT are similar to DNC, except for the content of the reporting form.





**Need help navigating the system?**

**Write to:**

**[NHGGroup.RISecretariat@NHGHealth.com.sg](mailto:NHGGroup.RISecretariat@NHGHealth.com.sg)**





# 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