

# Navigating Ethics & Compliance Online System (ECOS) User Guide

## ***[Compliance Module]:*** **Deviation / Non-Compliance & Serious Adverse Event *[For PI]***

*[ECOS User Guide – Compliance Module: Deviation / Non-Compliance & Serious Adverse Event (For PI), Ver 1, 1 Aug 24]*

# 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:

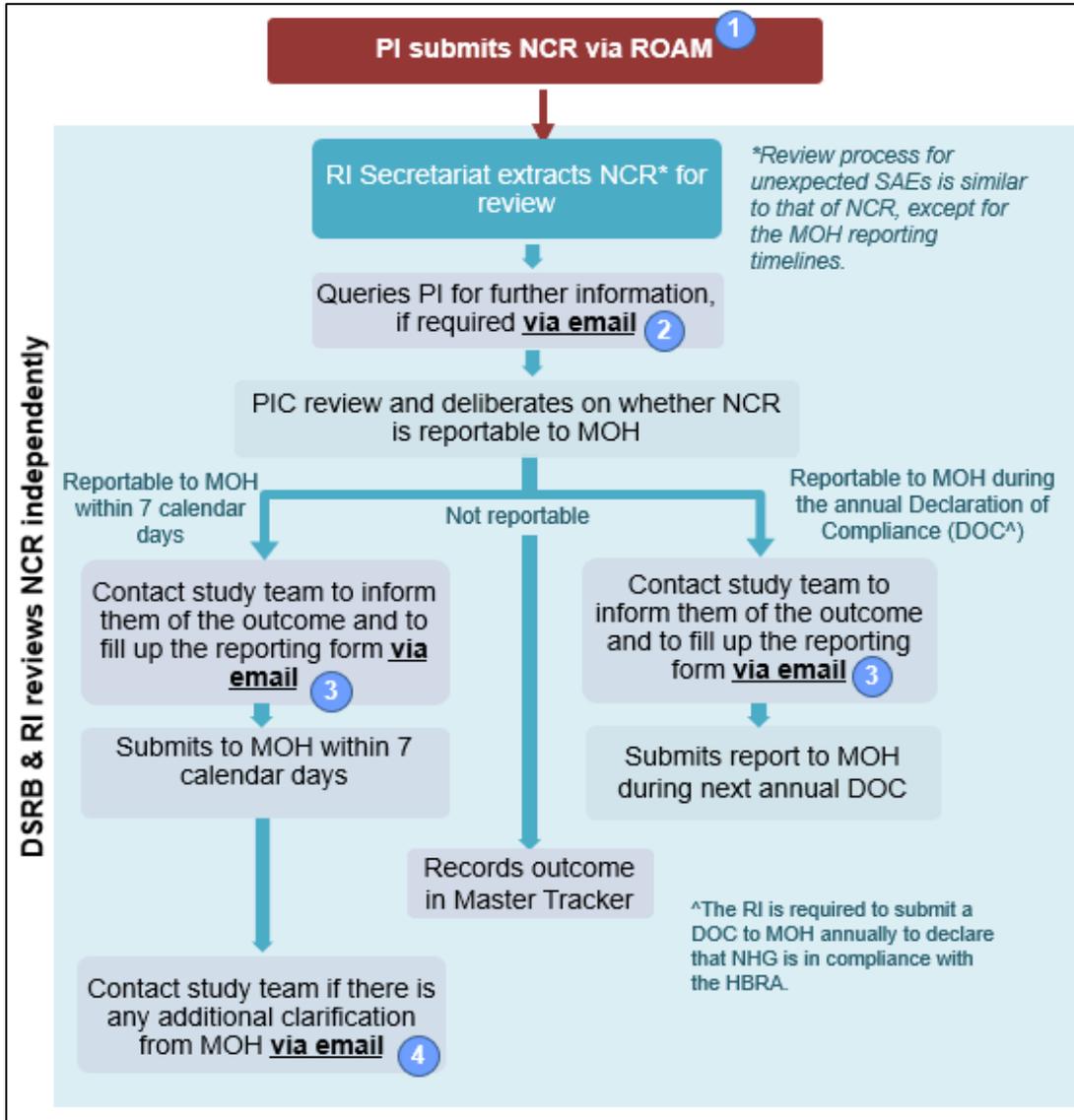
- Respond to queries from the Research Institution (RI) directly and keep track of all queries on ECOS
- Upload supporting documents for a query
- Receive feedback directly from the RI on the MOH reporting forms (if any)
- Receive email and system notifications pertaining to pending tasks
- Endorse the 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. On the left is a navigation bar with 'Homepage' and 'Dashboard' highlighted. The main content area is divided into several sections: IRB (26 total, with 26 Study and 0 Endorsement), CRMS (0 total, with 0 Study Member Review), FCOI (0 total, with 0 My FCOI List), and Compliance (11 total, with 8 Deviation/Non Compliance - Site and 3 Serious Adverse Event - Site). A 'My Notices' sidebar on the right lists five 'Service Disruption Broadcast Message' entries with dates from May 15, 2024, to June 3, 2024. Three orange callout boxes provide navigation instructions: Step 1 points to 'Dashboard' in the navigation bar; Step 2 points to the Compliance section; Step 3 points to the 'My Tasks' link in the navigation bar.

Category	Total	Sub-category	Count
IRB	26	Study	26
IRB	26	Endorsement	0
CRMS	0	Study Member Review	0
FCOI	0	My FCOI List	0
Compliance	11	Deviation/Non Compliance - Site	8
Compliance	11	Serious Adverse Event - Site	3

**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.

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

## 2. On “My Tasks” page

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

The screenshot shows the ECOS 'My Tasks' interface. On the left is a navigation bar with options: Homepage, Dashboard, My Tasks (highlighted), My Notices, IRB, CRMS, Compliance, and FCOI. The main content area has a 'Compliance' summary card showing '11' tasks. Below it are two tabs: 'Deviation/Non Compliance - Site (8)' (selected) and 'Serious Adverse Event - Site (3)'. A table lists tasks with columns for Latest Submission, Compliance Status, Form Ref/Task ID, Study Title, PI/Site-PI, and Action. An arrow points to the 'Action' column icon in the first row.

**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 Submi	Compliance Status	Form Ref/Task ID	Study Title	PI/Site-PI	Action
31-Jul-2024	Pending	DNC (IRB)	Pending PI Response	lands Health-01B	Study with HBR-003
20-Jul-2024	Pending	Tiered SOC	MOH Report Pending PI Response	lands Health-01	Study with HBR-004
18-Jul-2024	Pending	SOC	MOH Report Pending PI Response	lands Health-01A	Study with HBR-004
11-Jul-2024	Pending	SOC	MOH Report Pending Endorsement	lands Health-01	Study with HBR-003
10-Jul-2024	Pending	DNC (IRB)	Pending PI Response	lands Health-01	Study with HBR-003

# 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 interface with the 'Site Task List' page selected. The page has two tabs: 'Deviation/Non Compliance' (active) and 'Serious Adverse Event'. A table lists tasks with columns for 'Date of DNC reported', 'MOH Report Pending PI Response', 'User', 'Site', and 'Action'. Annotations point to the 'Compliance' dropdown menu (Step 8), the 'Site Task List' menu item (Step 9), the 'Action' column (Step 10), and the tabs (Step 11).

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

**Step 8:** Click to release dropdown menu

**Step 9:** Click to view all outstanding tasks assigned to you on the “Site Task List” page

**Step 10:** Click here to view details of the task

**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

**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.

# Navigating ECOS – Uploading of Attachment

## On “Site Task Detail” Page

The screenshot displays the 'Site Task Detail' page for a specific task. The main content area shows details for '2024-9999-DNC11-Woodlands Health-01B | Woodlands Health'. Below this, there are tabs for 'DNC (RI Query)' and 'Attachment'. The 'Attachment' tab is active, showing a table with one attachment: 'Attachment1.pdf' (Protocol) uploaded by 'TTSH\_User\_ID04' on '31-Jul-2024'. An 'Upload Attachment' button is visible in the top right of the attachment list. A modal window titled 'Upload Attachment' is open, showing a 'Document Description' text area and an 'Upload' button. Three callout boxes provide instructions: 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 16:** Users may include a **description** of the document before uploading

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

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

Document	Uploaded by	Upload Date	Action
Attachment1.pdf	TTSH_User_ID04	31-Jul-2024	 

# Navigating ECOS – How to Respond to Queries?

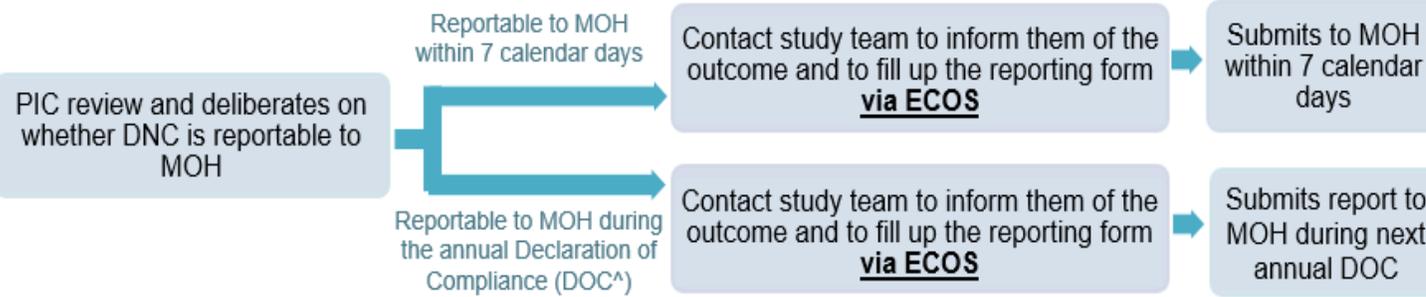
The screenshot displays the 'Site Task Detail' page for a task titled '2024-9999-DNC11-Woodlands Health-01B | Woodlands Health'. The task status is 'Pending PI Response'. A 'Reply Query' button is visible in the top right corner. A confirmation dialog box titled 'Reply Query' is open, asking 'Do you want to proceed?'. The dialog shows a 'Query Item: General' with a 'QUERY' status. At the bottom of the dialog are 'Cancel' and 'Confirm' buttons. An orange arrow points to the 'Reply Query' button, and another orange arrow points to the 'Confirm' button.

**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.

[Export](#) [Edit](#) [Track Changes](#) [e-Form Query List](#)

**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

Cancel

Confirm

# Navigating ECOS – How to Endorse the Reporting Form?

The screenshot shows the 'Site Task Detail' page in ECOS. The header includes a home icon, a menu icon, and a 'Back to My Tasks' link. The main title is '2024-9999-DNC11-Woodlands Health-01B | Woodlands Health' with a status badge 'MOH Report Pending Endorsement'. On the right, there are 'Reject' and 'Endorse' buttons, with an orange arrow pointing to the 'Endorse' button. The page content includes: 'ECOS Ref: 2024-9999', 'Date of DNC reported: 11-Jul-2024', 'Outcome: Reportable as Tiered SOC', 'Current Editor: -', 'Study Title: Study with HBR-003', and 'Quick Link: Study Summary'. Below this is a tabbed interface with 'DNC (RI Query)', 'Tiered SOC' (selected), and 'Attachment' tabs. A 'Tiered SOC' label is visible on the left side of the page.

**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.

# 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

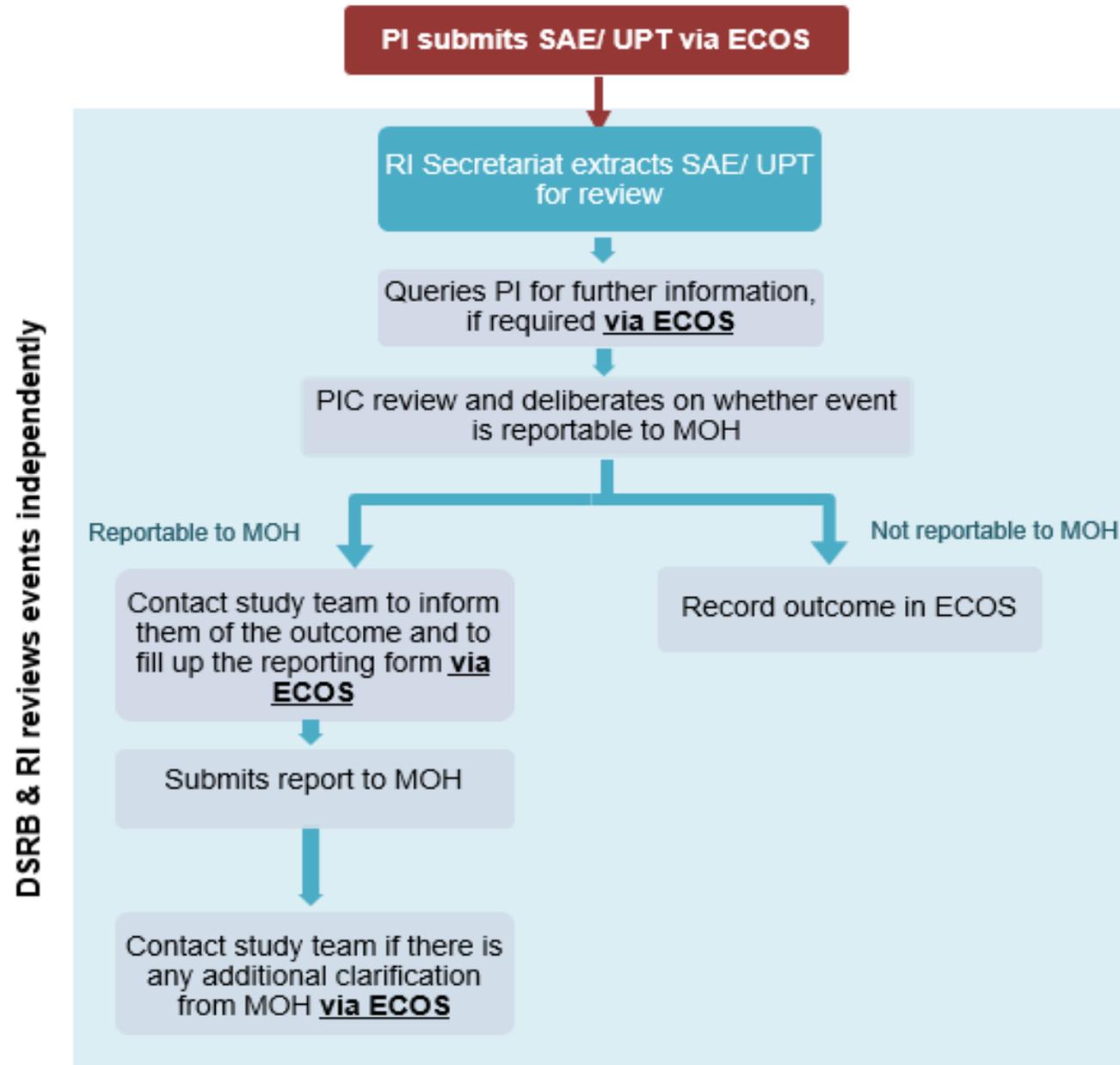
The screenshot shows the ECOS interface. At the top, there is a navigation bar with a home icon, a menu icon, and a link to 'Back to My Tasks'. The main header is 'Site Task Detail'. On the right side of the header, there is a 'Reply Query' button. Below the header, a 'Reply Query' dialog box is open. The dialog box has a title bar with a close button. Inside, it asks 'Do you want to proceed?' and lists 'Query Item: General' with two items: 'MOH QUERIES' and 'REPLY QUERY'. At the bottom of the dialog box, there are two buttons: 'Cancel' and 'Confirm'. An arrow points from the 'Reply Query' button in the header to the dialog box. Another arrow points from the 'Confirm' button in the dialog box to a text box on the right. A third arrow points from the 'MOH Query List' link in the bottom navigation bar to the same text box.

**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

# How to 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 [NHGRISecretariat@nhg.com.sg](mailto:NHGRISecretariat@nhg.com.sg)**