

# 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.

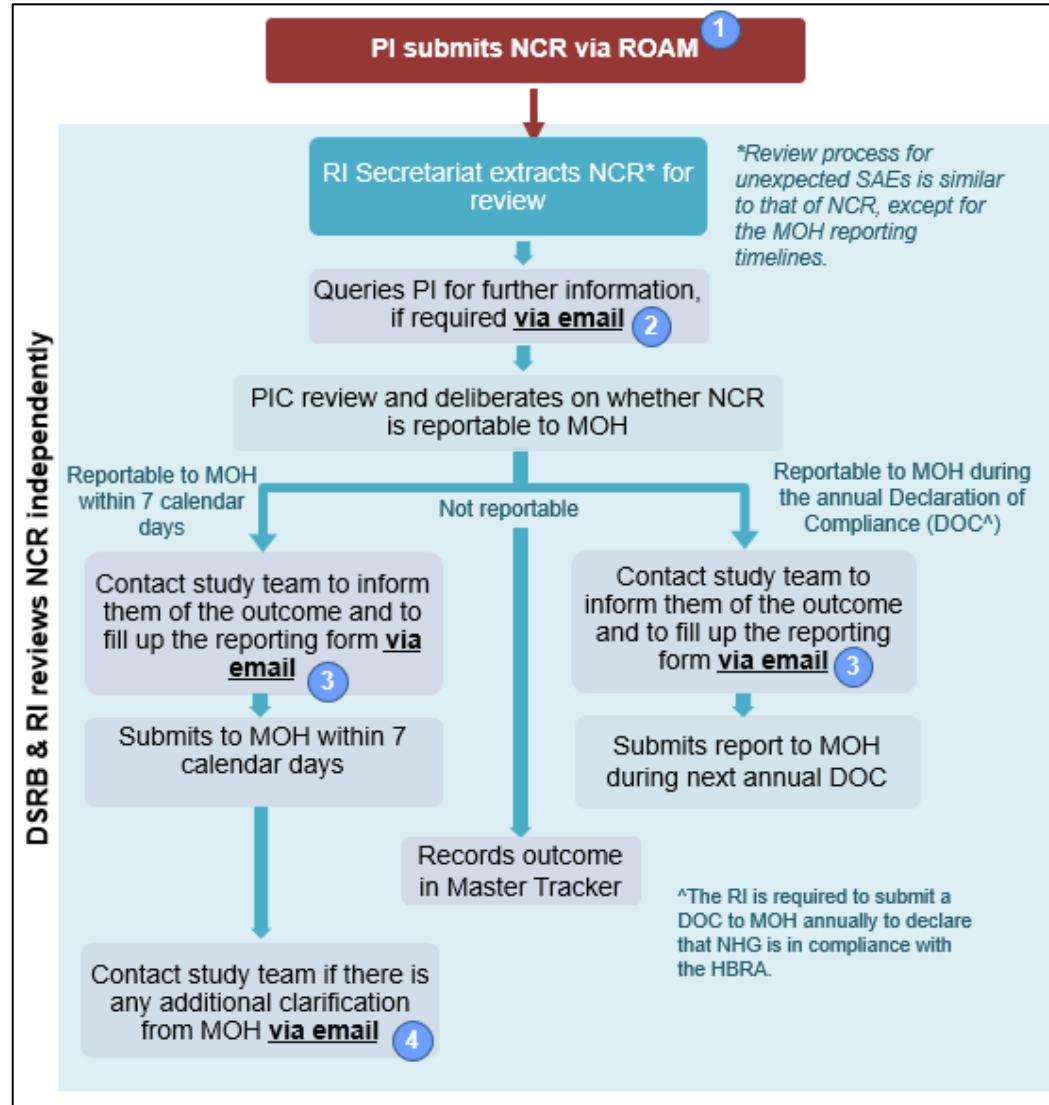
## In ECOS, researchers can:

- 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 with a blue navigation bar on the left and a white main content area. The navigation bar includes links for 'Homepage', 'Dashboard', 'My Tasks', 'My Notices', 'IRB', 'CRMS', 'Compliance', and 'FCOI'. The main content area has four main sections: 'IRB' (26 tasks, sub-tasks: Study, Endorsement), 'CRMS' (0 tasks, sub-task: Study Member Review), 'FCOI' (0 tasks, sub-task: My FCOI List), and 'Compliance' (11 tasks, sub-tasks: Deviation/Non Compliance - Site, Serious Adverse Event - Site). A sidebar on the right lists 'My Notices' with five entries, each with a red dot and a timestamp. A blue arrow points from the 'Dashboard' link in the navigation bar to the 'Dashboard' link in the main content area. A blue box with the text 'Step 1: This page may be accessed by clicking on “Homepage” followed by the “Dashboard” in the left navigation bar.' is overlaid on the navigation bar area. A blue box with the text 'Step 2: Outstanding tasks relating to Compliance (DNC/SAE) will be displayed here' is overlaid on the 'Compliance' section. A blue box with the text 'Step 3: Click to be directed to the “My Tasks” Page.' is overlaid on the 'My Tasks' link in the sidebar.

**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' page. The left navigation bar includes 'Homepage', 'Dashboard', 'My Tasks' (which is selected and highlighted in blue), 'My Notices', 'IRB', 'CRMS', 'Compliance' (which is expanded to show 'Latest Submi...', '31-Jul-2024', '20-Jul-2024', '18-Jul-2024', '11-Jul-2024', and '10-Jul-2024'), and 'FCOI'. The main content area is titled 'My Tasks' with a 'Compliance' tab selected, showing '11' tasks. Below this are tabs for 'Deviation/Non Compliance - Site (8)' and 'Serious Adverse Event - Site (3)'. The table lists tasks with columns for 'Compliance Status', 'Form Ref/Task ID', 'Study Title', 'PI/Site-PI', and 'Action'. Each task row has a blue circular icon with a white circle and a blue circular icon with a white circle. A callout box 'Step 4' points to the 'My Tasks' tab in the navigation bar. A callout box 'Step 5' points to the table header. A callout box 'Step 6' points to the tabs at the top of the table. A callout box 'Step 7' points to the 'Action' column of a task 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

Compliance Status	Form Ref/Task ID	Study Title	PI/Site-PI	Action
Pending PI Response	Health-01B	Study with HBR-003	A/Prof TTSH_User_ID04	
MOH Report Pending PI Response	Health-01	Study with HBR-004	A/Prof TTSH_User_ID04	
MOH Report Pending PI Response	Health-01A	Study with HBR-004		
MOH Report Pending Endorsement	Health-01	Study with HBR-003		
Pending PI Response	Health-01	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

**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**.

The screenshot shows the ECOS Site Task List page. At the top, there are tabs for 'Deviation/Non Compliance' (underlined) and 'Serious Adverse Event'. On the left, a dropdown menu is open over the 'Compliance' link, with 'Site Task List' highlighted. The main area displays a table of tasks with columns for 'Date of DNC reported', 'Task Description', 'Assigned To', 'Facility', 'Specialty', and 'Action'. The table contains four rows of data. A blue box labeled 'Step 10' points to the 'Action' column. A blue box labeled 'Step 9' points to the 'Site Task List' link in the dropdown menu. A blue box labeled 'Step 8' points to the 'Compliance' link in the dropdown menu. A blue box labeled 'Step 11' points to the 'Deviation/Non Compliance' and 'Serious Adverse Event' tabs.

Date of DNC reported	Task Description	Assigned To	Facility	Specialty	Action
18-Jul-2024	MOH Report Pending PI Response	A/Prof TTSH_User_ID04	Woodlands Health	Anaesthesia	<a href="#">View Details</a>
18-Jul-2024	Pending PI	A/Prof TTSH_User_ID04	Woodlands Health	Anaesthesia	<a href="#">View Details</a>
16-Jul-2024	MOH Report Pending PI Response	Dr NUH_IR01	Khoo Teck Puat Hospital	Acute & Emergency Care	<a href="#">View Details</a>
			Khoo Teck Puat Hospital	Acute & Emergency Care	<a href="#">View Details</a>

# 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

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

**c** Current Editor: -

**d** Study Title: Study wi

**e** Quick Link: Study Sum

**f** DNC (RI Query)

**Site Task Detail**

**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 shows the ECOS Site Task Detail page for a task titled "2024-9999-DNC11-Woodlands Health-01B | Woodlands Health". The page includes a "Pending PI Response" status and a "Save" button. The "Attachment" tab is selected, showing a table with one row: "Attachment1.pdf" (Protocol) uploaded by "TTSUser\_ID04" on "31-Jul-2024". A blue callout box labeled "Step 15: Documents can be shared with the RI Secretariat via the “Attachment” tab" points to the "Attachment" tab. Another blue callout box labeled "Step 16: Users may include a description of the document before uploading" points to the "Upload Attachment" overlay. The overlay has fields for "Document Description" and "Document" with an "Upload" button, and a "Save" button in the top right. A blue callout box labeled "Step 17: Users can only delete documents that they had uploaded" points to the "Delete" icon in the "Action" column of the table.

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 HBR-003

Quick Link: [Study Summary](#)

DNC (RI Query) Attachment

Attachment

Document	Protocol	Uploaded by	Upload Date	Action
Attachment1.pdf		TTSUser_ID04	31-Jul-2024	

Upload Attachment

Document Description:

\* Document:

# Navigating ECOS – How to Respond to Queries?

The screenshot shows the ECOS Site Task Detail page for a task titled "2024-9999-DNC11-Woodlands Health-01B | Woodlands Health". The task status is "Pending PI Response". The "Reply Query" button is highlighted with a blue arrow. A modal dialog box titled "Reply Query" is open, asking "Do you want to proceed?". The "QUERY" option is selected in the "Query Item: General" dropdown. At the bottom of the dialog are "Cancel" and "Confirm" buttons, with blue arrows pointing to them. A callout box on the right says "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". Another callout box at the bottom says "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".

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

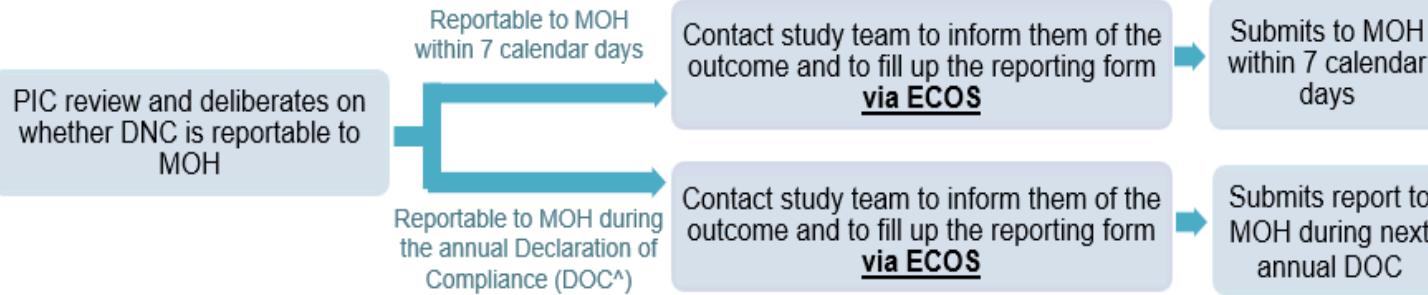
Confirm

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

**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.

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

The screenshot shows the ECOS reporting form interface. At the top, a blue header bar contains the title. Below it is a main content area with a dark blue header bar. The content area includes a 'Back to My Tasks' link, a study identifier '2024-9999-DNC11-Woodlands', and an ECOS Ref: '2024-9999' with a copy icon. It also shows the 'Date of DNC reported: 11-Jul-2024', 'Outcome: Reportable as Tiered SOC', 'Current Editor: -', and 'Study Title: Study with HBR-003'. A 'Reply Query' button is highlighted with a red box and a callout bubble. The main content area shows a 'Reply Query' dialog box with a message 'Do you want to proceed?'. Below the dialog is a 'Query Item: 12. No. of Subject(s) Affected' section with two options: 'PLEASE VERIFY THE NUMBER OF SUBJECT' (unchecked) and 'THIS IS CORRECT' (checked). At the bottom of the dialog are 'Cancel' and 'Confirm' buttons. A large blue callout bubble on the left side of the dialog contains the text: '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'. A blue callout bubble on the right side of the main content area contains the text: '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.' A blue callout bubble at the bottom right of the dialog contains the text: 'Step 24: Click here to view and respond to queries from RI Secretariat regarding the reporting form'. Arrows point from the text boxes to the corresponding UI elements.

**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

# Navigating ECOS – How to Endorse the Reporting Form?

Site Task Detail

2024-9999-DNC11-Woodlands Health-01B | Woodlands Health MOH Report Pending Endorsement

ECOS Ref: 2024-9999 

Date of DNC reported: 11-Jul-2024

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.

# 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, a blue header bar displays "Site Task Detail". Below it, the main content area shows a "Reply Query" dialog box. The dialog has a title "Reply Query" and a message "Do you want to proceed?". Below this, there are two buttons: "MOH QUERIES" and "REPLY QUERY". A callout box labeled "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" points to the "Confirm" button at the bottom of the dialog. In the bottom right corner of the main content area, there is a button labeled "e-Form Query List". A callout box labeled "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." points to this button. Arrows from the callout boxes point to the "Reply Query" button in the dialog and the "e-Form Query List" button respectively.

Site Task Detail

Reply Query

Do you want to proceed?

Query Item: General

MOH QUERIES

REPLY QUERY

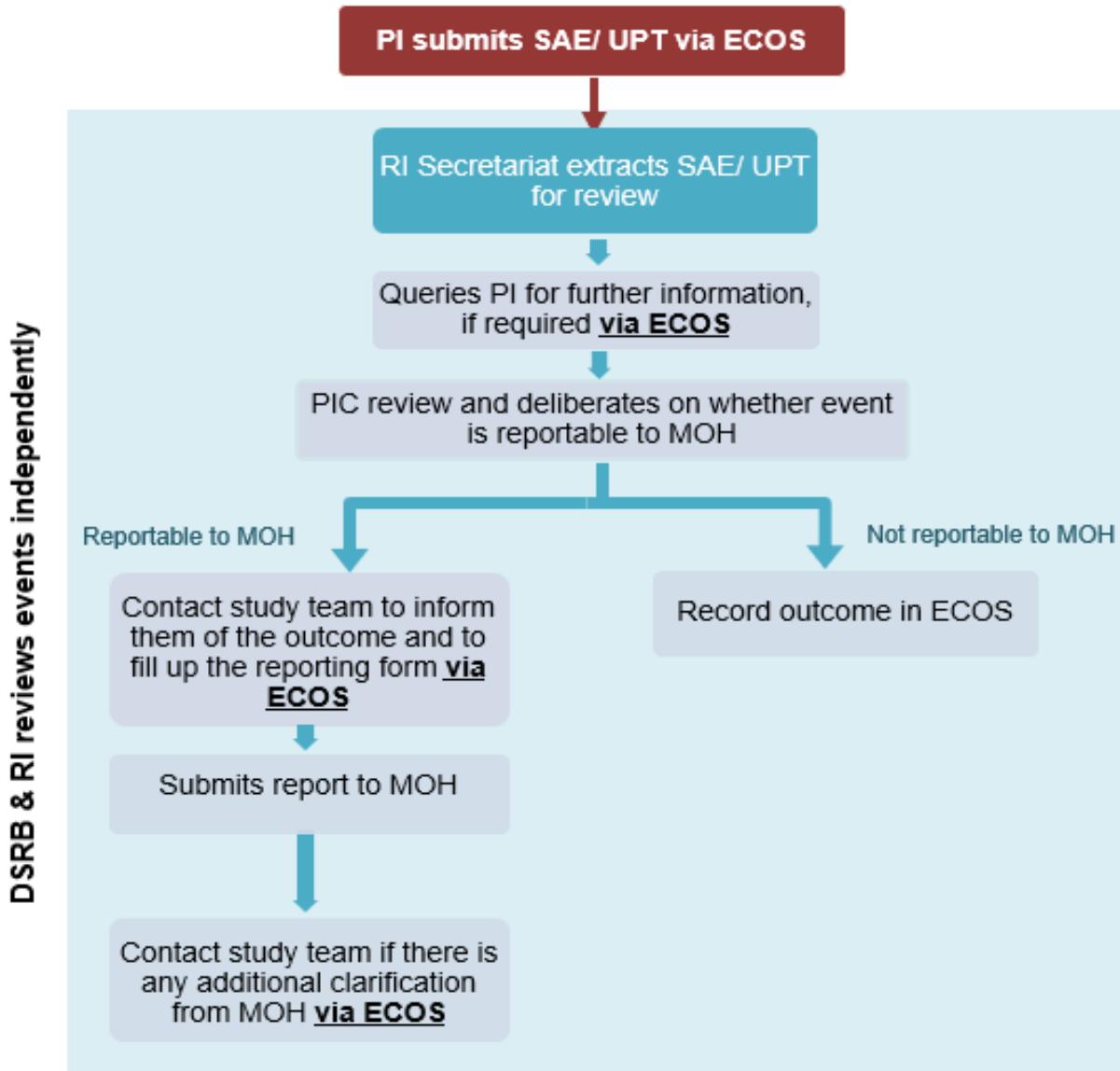
Step 32: Click “confirm” to send the task back to RI Secretariat for their review or “cancel” if further edits to the response is required

Cancel Confirm

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.

Export Track Changes e-Form Query List MOH Query List

# 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