Ethics and Compliance Online System (ECOS)

Monitoring and PI Self Assessment

07-Jan-2025

Content – Monitoring Module

1. View/Locate Monitoring Tasks
2. View and Access Study Monitoring Information
3. Query and Endorse Monitoring Plan (MP)
4. Respond to Monitoring Issue
5. Reply to CAPA Query for Monitoring Issue
6. Export of Monitoring Report, Letters, Issue List

1) View/Locate Monitoring Task – Homepage

1. Locate your outstanding monitoring task via "**Homepage**" > "**Dashboard**" on the left navigation panel.

2. In the "**Monitoring**" tile, click on the → or listed items will lead you to "**My Tasks**".

1) View/Locate Monitoring Task – My Tasks

IRB 1	**CRMS** 6	**FCOI** [4] 0	**Monitoring** 2	**Compliance** 12	**Audit** 0

PI/Site-PI (0) Plan Reviewer (1) **Responsible Person (1)** [5]

☐ Columns   ⬇ Export   ▽ Filter(1)

Form Type	ECOS Ref	Task Due date	Monitor Name	PI/Site-PI	Date Sent to Site	Task Status	Action
Follow-up Letter/ Issue List	2024-3610	18-Dec-2024	A/Prof SHS_MON2	A/Prof CGH_PI11	18-Dec-2024	Pending	👁

3. You can also access "**My Tasks**" directly via the left navigation panel.

4. In "**My Tasks**", click on the the "**Monitoring**" tile.

5. The type and number of outstanding tasks are listed under the different tabs based on the user's role. Click on each tab to display the respective task listing.

6. To view the monitoring task, click on 👁 "View" icon in the "**Action**" column.

1) View/Locate Monitoring Task – My Tasks

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

2. The default settings for the filter show only **pending** tasks for your action **(Task Status = Pending)**.

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

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

1) View/Locate Monitoring Task – Monitoring Module

1. **My Issue**: As the assigned "**Responsible Person",** you will see all monitoring issues that were assigned to you.*

2. **Plan Review**: The "**Plan Reviewer**" (PI/Site-PI) will see all Monitoring Plans (MP) submitted by the Monitor for endorsement.*

3. **Study Monitoring Information**: To **access all monitoring information** (e.g. view monitoring plan, monitoring reports, issues list, confirmation and follow-up letters).

*The default settings for the filter show only tasks **pending** your action.

To view all tasks (including completed tasks), please update the filter parameters.

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2) View and Access Study Monitoring Information

1. This page is accessible by **Site Staff**
   (with some pages restricted to specific site staff, e.g. Plan Review is only accessible by PI/Site-PI)

2. Click on 👁 "**View Plan**" to enter "**View Monitoring Plan**" page**.**

2) View and Access Study Monitoring Information

1. PI/Site PI may view their **respective site's** Monitoring Plan.

2. To export a copy of the Monitoring Plan, click on "**Export**".

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

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

2) View and Access Study Monitoring Information

5. Click on 📅 "**View Schedule**" to enter Monitoring Schedule Detail page.

6. In "**Monitoring Schedule Detail**" page, all monitoring visits of that study are listed on the left navigation panel.

   You can view the past monitoring reports, issue list, confirmation and follow-up letters of each visit.

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3) Query/Endorse Monitoring Plan (MP)

Plan Reviewer will receive an email notification when the Monitor submits a MP for endorsement.

Via Dashboard > My Tasks

1. The Plan Reviewer can locate all assigned MPs for review/endorsement via "**Dashboard**"

2. Click on "**Plan Reviewer**" to enter "**My Tasks**" > "**Plan Reviewer**" page.

3. Click on 👁 "**View**" icon in the "**Action**" column to view the details of MP.

3) Query/Endorse Monitoring Plan (MP)

Plan Reviewer will receive an email notification when the Monitor submits a MP for endorsement.

Via Dashboard > My Tasks

1. The Plan Reviewer can locate all assigned MPs for review/endorsement via "**Dashboard**"

2. Click on "**Plan Reviewer**" to enter "**My Tasks**" > "**Plan Reviewer**" page.

3. Click on 👁 "**View**" icon in the "**Action**" column to view the details of MP.

3) Query/Endorse Monitoring Plan (MP)

Via Monitoring > Plan Review

1. You can also locate the list of MPs for review via the Monitoring Module > "**Plan Review**" menu on the left navigation panel.

2. By default, you will only see tasks which are pending your action (Monitoring Plan Status = Pending Review/ Query Pending Reply).

3. Click on ⊙ "View" icon in the "Action" column to view the details of MP.

3) Query/Endorse Monitoring Plan (MP)

Click on **"Fullscreen"** to expand the MP for easy viewing.

To exit full screen, click "Close Fullscreen"

3) Query Monitoring Plan (MP)

Plan Reviewer may query the MP.

1. To query, click on the "**Query List**". A window will appear.

2. Click on **"+ General Query"** to add a query.

3. Enter query description. Query description will be **auto-saved.**

4. You can upload an attachment, if needed.

5. To add another query, click on "**+ General Query**".

6. To exit Query List, click on the background page.

3) Query Monitoring Plan (MP)

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2. Click on "**+ General Query**" to add a query.

3. Enter query description. Query description will be **auto-saved.**

4. You can upload an attachment, if needed.

5. To add another query, click on "**+ General Query**".

6. To exit Query List, click on the background page.

3) Query Monitoring Plan (MP)

1. A **red dot** indicates there is an action pending (i.e. to send the query).

2. After adding query, the "**Send Query**" button is enabled. Click on "**Send Query**", a pop-up window with a list of query(ies) to be sent will be displayed.

3. Click "**Confirm**" to send the query, or "**Cancel**" to exit the pop-up window.

3) Query Monitoring Plan (MP)

1. After sending query to the Monitor, MP status will be changed from "Pending Review" to "**Query Pending Reply**".

2. When Monitor has replied to the query, MP status will be changed to "**Pending Review**".

3. To re-query on a previous query, click on "**+ Further Query**".

4. To add a new query, click on "**+ General Query**".

5. To close a query, click on "**X Close Query**".

6. To close query in batches, select the query box and click on "**Batch Close**".

3) Query Monitoring Plan (MP)

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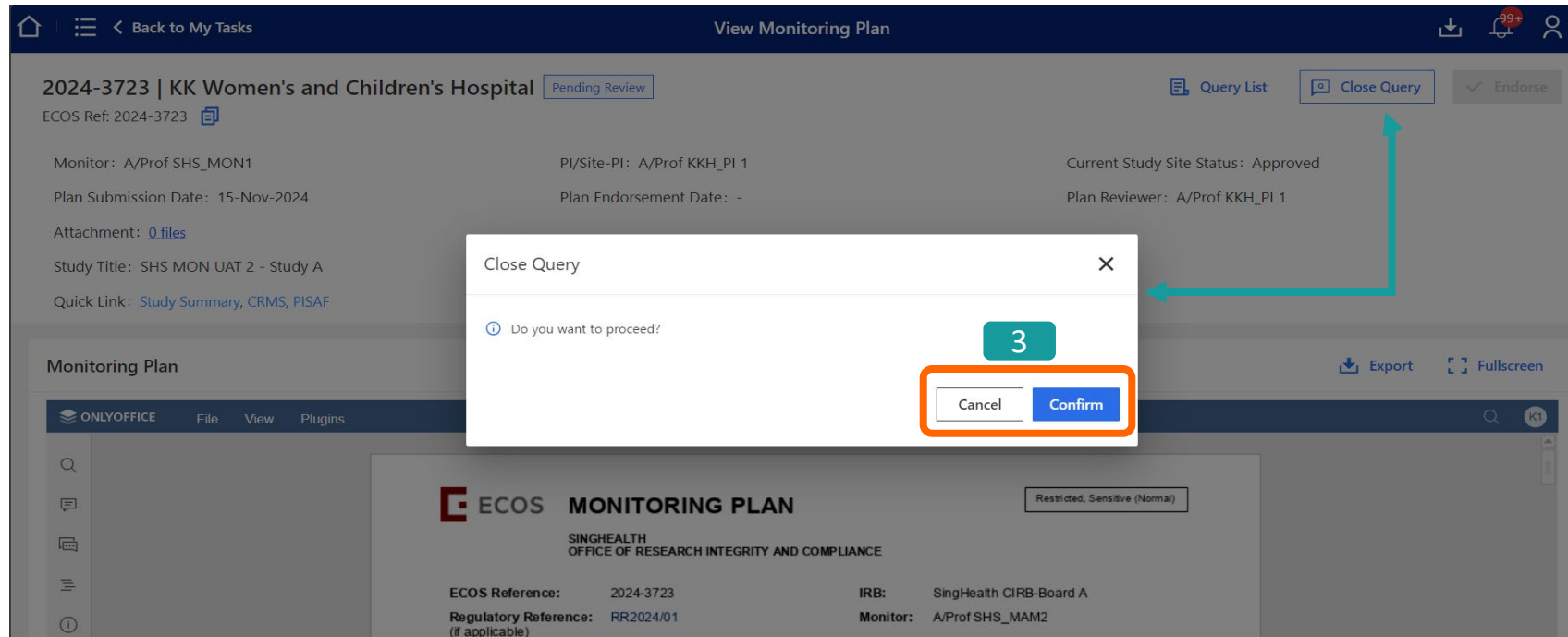
3) Endorse Monitoring Plan (MP)

1. The MP can only be endorsed if there is <u>no outstanding query</u>.

2. After all query has been closed, the "Close Query" button is enabled.

   A pop-up window to confirm the action will be shown.
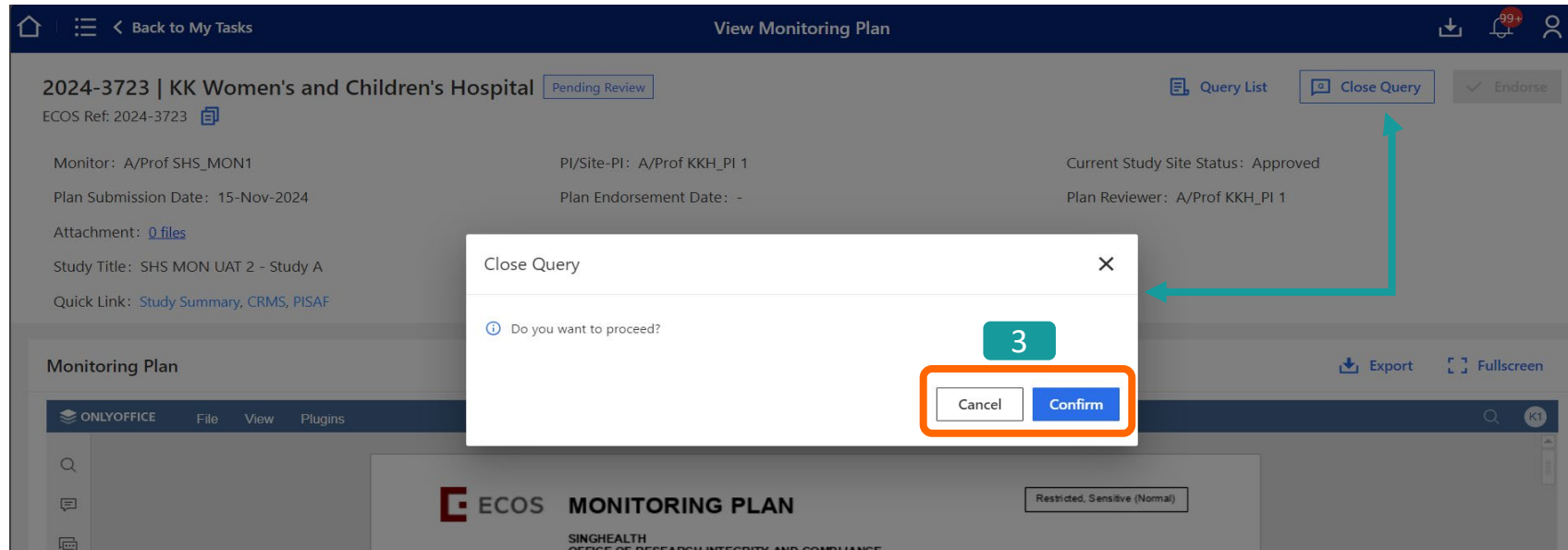
3) Endorse Monitoring Plan (MP)

3. Click on "**Confirm**" to proceed, or "**Cancel**" to return to the previous page.

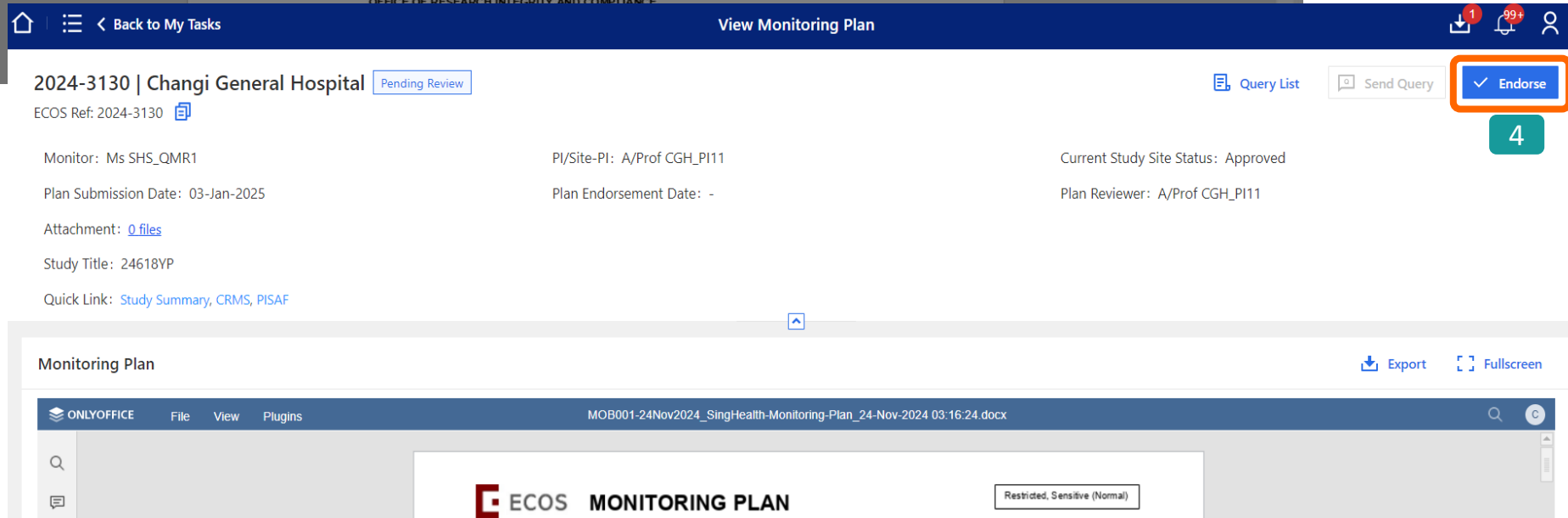4. After clicking "**Confirm**" the "**Endorse**" button will be enabled.

3) Endorse Monitoring Plan (MP)

3. Click on "**Confirm**" to proceed, or "**Cancel**" to return to the previous page.

4. After clicking "**Confirm**" the "**Endorse**" button will be enabled.

3) Endorse Monitoring Plan (MP)

5. To endorse the MP, click on "**Endorse**". A pop-up comment box will appear. Comments are **optional**.

6. The MP status will be changed to "**Endorsed**".

   MP cannot be edited once endorsed.

   An email notification will be sent to the Monitor to notify on the MP endorsement.

3) Endorse Monitoring Plan (MP)

5. To endorse the MP, click on "**Endorse**". A pop-up comment box will appear. Comments are **optional**.

6. The MP status will be changed to "**Endorsed**".

   MP cannot be edited once endorsed.

   An email notification will be sent to the Monitor to notify on the MP endorsement.

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4) Respond to Monitoring Issue

Note:

- Issues noted during Monitoring Visit that require follow-up/resolution will be assigned to "**Responsible Person**" by the Monitor.

- For each Issue, one or more Responsible Person may be assigned.

- The PI, Co-I and <u>active</u> Study Team Member (STM) listed in Clinical Research Management System User Authorization List (CRMS UAL) can be assigned as the "Responsible Person" to respond to the Issue.

4) Respond to Monitoring Issue

Via Dashboard > My Tasks

1. The Responsible Person can locate all assigned Issues via "Dashboard".

2. Click on "**Responsible Person**" to enter "**My Tasks**" > "**Responsible Person**" page.

3. Click on 👁 "**View**" icon in the "**Action**" column will bring user to "**My Issue**" list.

4) Respond to Monitoring Issue

Via Monitoring > My Issue

1. You can also locate the Issue listing via the **Monitoring Module** > "**My Issue**" menu on the left navigation panel.

2. By default, you will see tasks which are pending your action (Issue Status =Issue Pending Completion/ Query Pending Reply).

3. Click on 🎯 "**View**" icon in the "**Action**" column to view the **Issue Detail**.

4. To view another Issue Detail, toggle using the "<" and ">" arrows at the bottom of the Issue Detail page.

4) Respond to Monitoring Issue

Only <u>assigned Responsible Person</u> can edit **the "Issue Detail" page.**

4. Click "**Edit**" to complete the Corrective Actions and Preventive Actions (CAPA).

5. Fields marked with * (asterisk) are **mandatory** for completion.

6. Click on **"Save"** to ensure the edits have been saved, or "**Cancel**" if you do not want to save the data.

   After the form has been saved, click on **"Save and Exit"** to exit editing mode.

4) Respond to Monitoring Issue

7. After clicking "**Save and Exit**", the "**Submit**" button will be enabled. Click on the "**Submit**" button to procced.

8. A confirmation pop-up window will appear. Click **"confirm"** to proceed.

9. If the mandatory fields are not completed, submission will not go through.

   Click "**Confirm**" to return to the Issue Detail page and complete all necessary fields.

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5) Reply to CAPA Query

After submission of Issue CAPA, Monitor may raise query. Responsible Person will receive email notification on the Issue(s) with CAPA query.

1. To view query(ies), click on the **"Query List"** button. A 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).

2. Enter your reply under **"Pending Query"** > **"Reply Query"**. Entry is auto-saved.

5) Reply to CAPA Query

After submission of Issue CAPA, Monitor may raise query. Responsible Person will receive email notification on the Issue(s) with CAPA query.

1. To view query(ies), click on the **"Query List"** button. A 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).

2. Enter your reply under **"Pending Query"** > **"Reply Query"**. Entry is auto-saved.

5) Reply to CAPA Query

3. You can view all queries for each issue under "**All Query**" tab.

4. If updates to CAPA response is required during the query process, click on "**Edit**" in the CAPA section.

   (Refer slide 25 for steps to edit and save CAPA response)

5) Reply to CAPA Query

3. You can view all queries for each issue under "**All Query**" tab.

4. If updates to CAPA response is required during the query process, click on "**Edit**" in the CAPA section.

   (Refer slide 25 for steps to edit and save CAPA response)

5) Reply to CAPA Query

5. When all the query(ies) have been addressed, the red dot indicator will disappear.

6. Click on "**Reply Query**", a **pop-up window** will appear for the user's confirmation.

7. Click on **"Confirm"** to proceed or **"Cancel"** to return to the issue detail page.

5) Reply to CAPA Query

5. When all the query(ies) have been addressed, the red dot indicator will disappear.

6. Click on "**Reply Query**", a **pop-up window** will appear for the user's confirmation.

7. Click on **"Confirm"** to proceed or **"Cancel"** to return to the issue detail page.

5) Reply to CAPA Query

8. After Responsible Person has replied to query, Issue status will be changed from "Query Pending Reply" to "**Issue Pending Review**".

   The form cannot be edited further.

9. If changes were made to the CAPA, you can view the changes using the "**Track Changes**" function.

5) Reply to CAPA Query

8. After Responsible Person has replied to query, Issue status will be changed from "Query Pending Reply" to "**Issue Pending Review**".

   The form cannot be edited further.

9. If changes were made to the CAPA, you can view the changes using the "**Track Changes**" function.

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6) Export of Monitoring Report, Letters, Issue List

To export monitoring visit documents, go to **Monitoring** menu on the left navigation panel.
> **Study Monitoring Information > View Schedule.**

6) Export of Monitoring Report, Letters, Issue List

1. Click on the selected **Monitoring visit** and expand the menu to see the Confirmation Letter, Monitoring Report, Issue List and Follow up Letter.

2. To export a copy, locate the "**Export**" button within the respective menu.

6) Export of Monitoring Report, Letters, Issue List

Note
For Letters and Monitoring Visit Reports, the exported documents will be in PDF format.

6) Export of Monitoring Report, Letters, Issue List

For **Issue List** (table format), a pop-up window will be shown. Click on the download icon.

Select "**Download Original**" to save as an Excel file, or "**Safe Download**" to save as PDF file.

Need help?

SingHealth Users

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1800-666-7777

For Non-PHI Users

https://for.sg/ecos-support-request