ECOS

Navigating the Ethics & Compliance Online System (ECOS)

National Healthcare Group
Adding years of healthy life

SingHealth
Defining Tomorrow's Medicine

Revised Version dated 10 May 2024

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Overview of ECOS & General

Overview of ECOS

Minimum Training

Institutional Review Board

Clinical Research Management System

Financial Conflict Of Interest
(For NHG DSRB review studies only)

Will be available from 10 May 2024*

IRB Reports for Institutions and IRB

Compliance – Study Deviation and Non-Compliance / Serious Adverse Event

Compliance – PI Self-Assessment Form

Quality – Monitoring & Audit

To be confirmed

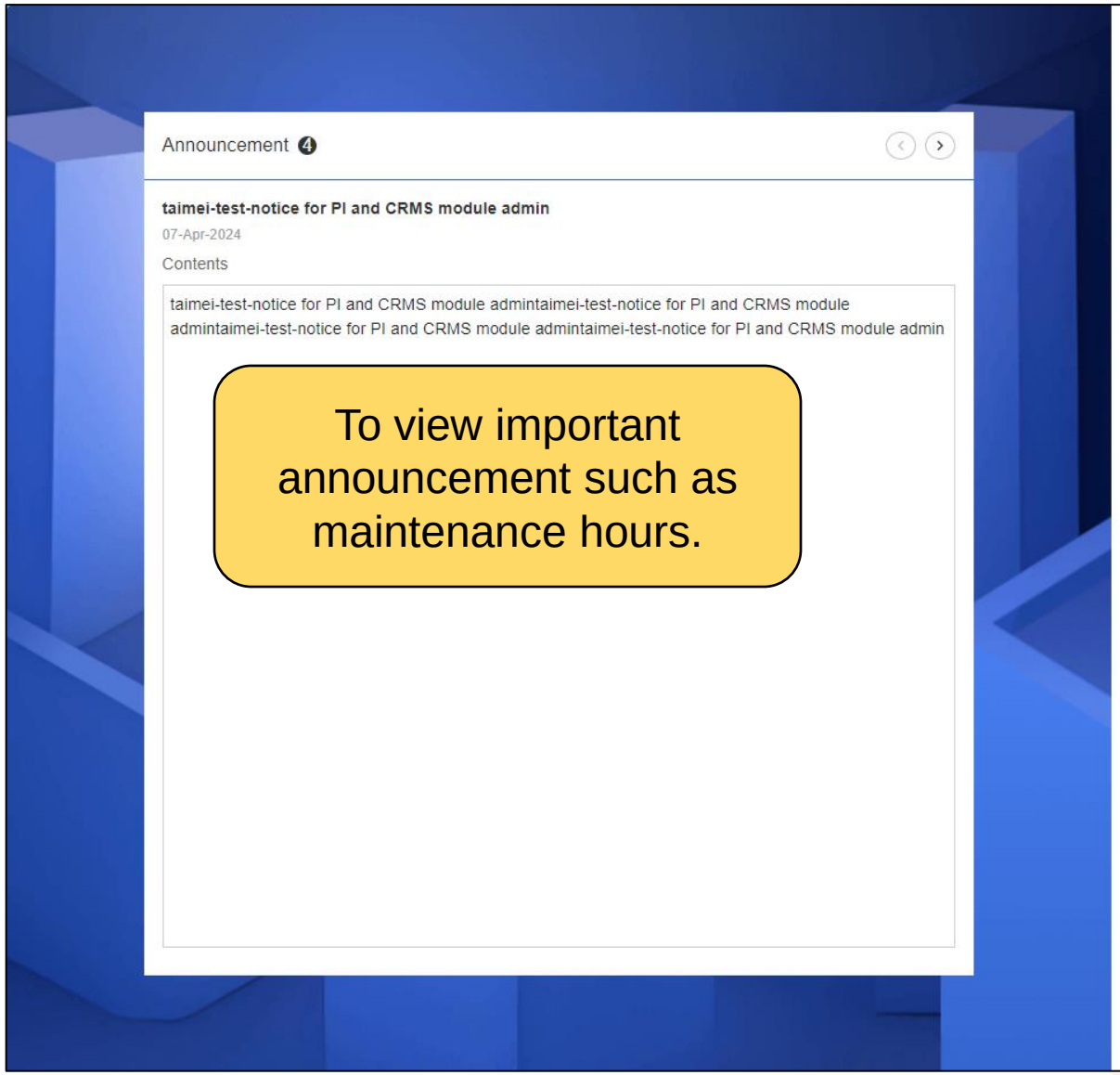
IRB Review

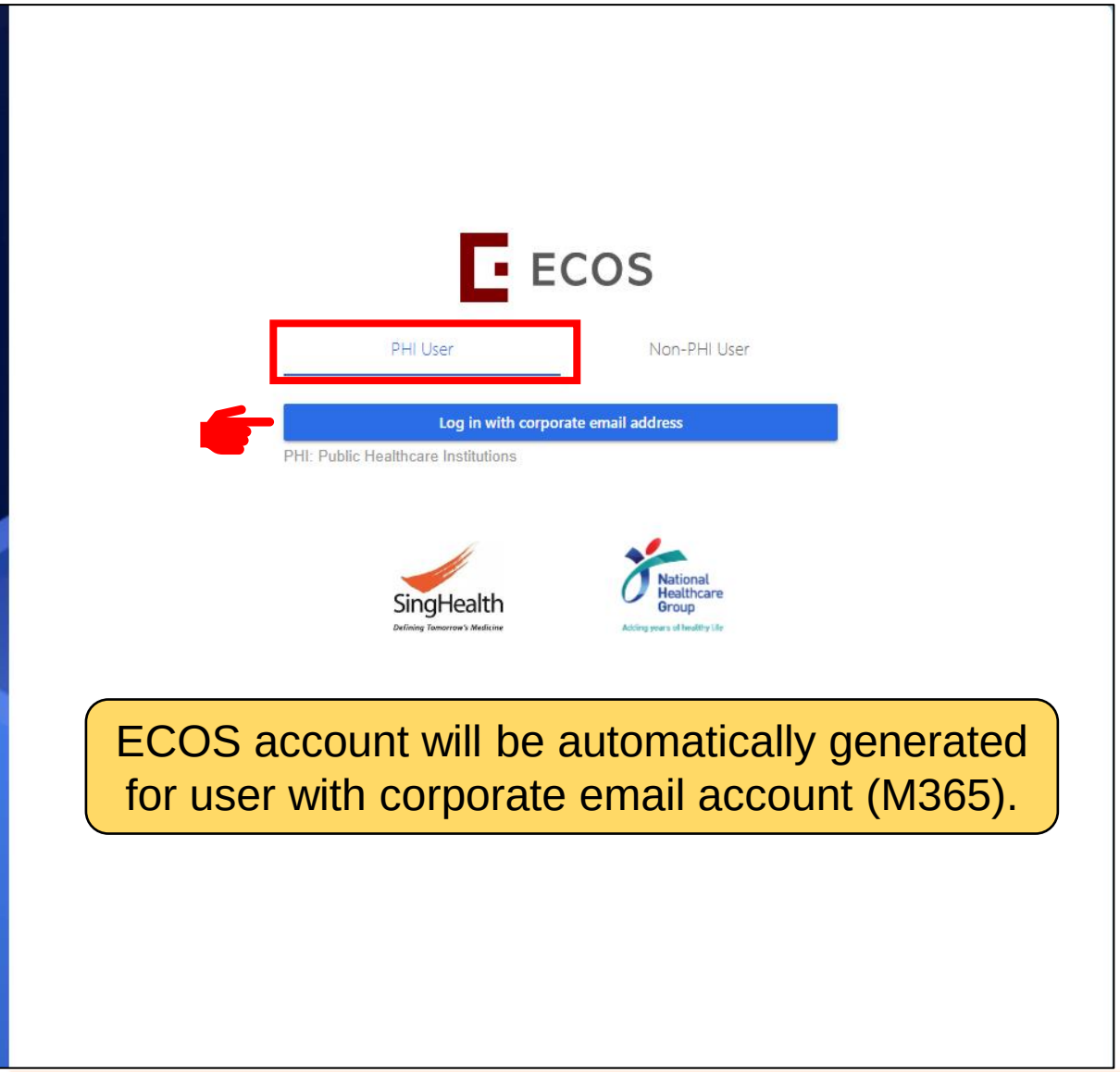
Submissions require Full Board Review in May, the application must reach CIRB by **17 May 2024, 5pm**.

An application is considered “Reached CIRB” only when Research Office Check, DR endorsement and IR endorsement are completed.

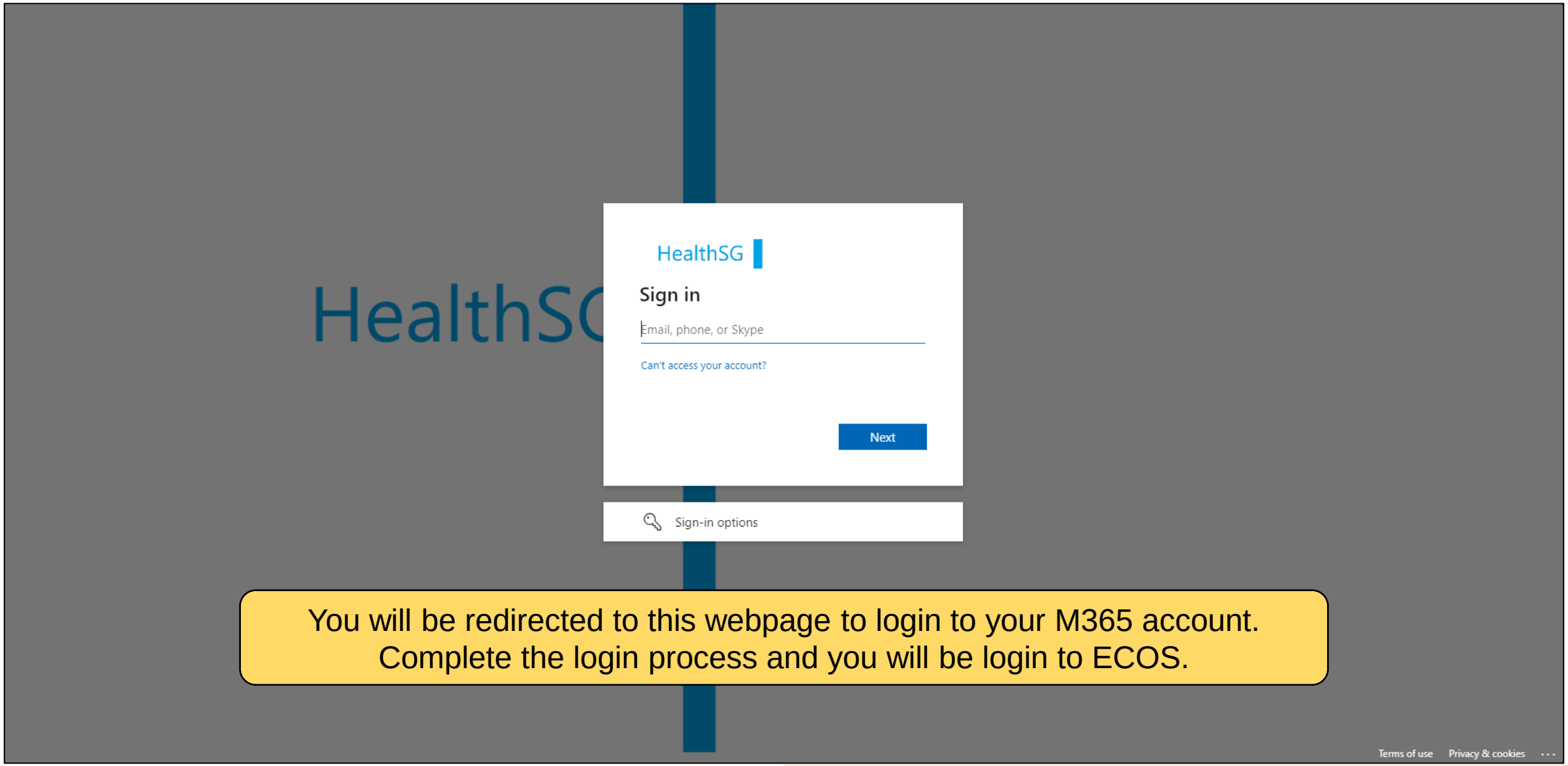
Full Board Meeting Dates						
	A	**B**	**C**	**D**	**E**	**F**
May	31 May	30 May	29 May	31 May	30 May	28 May
Jun	21 Jun	20 Jun	19 Jun	21 Jun	20 Jun	25 Jun

Account Login (For PHI Users)



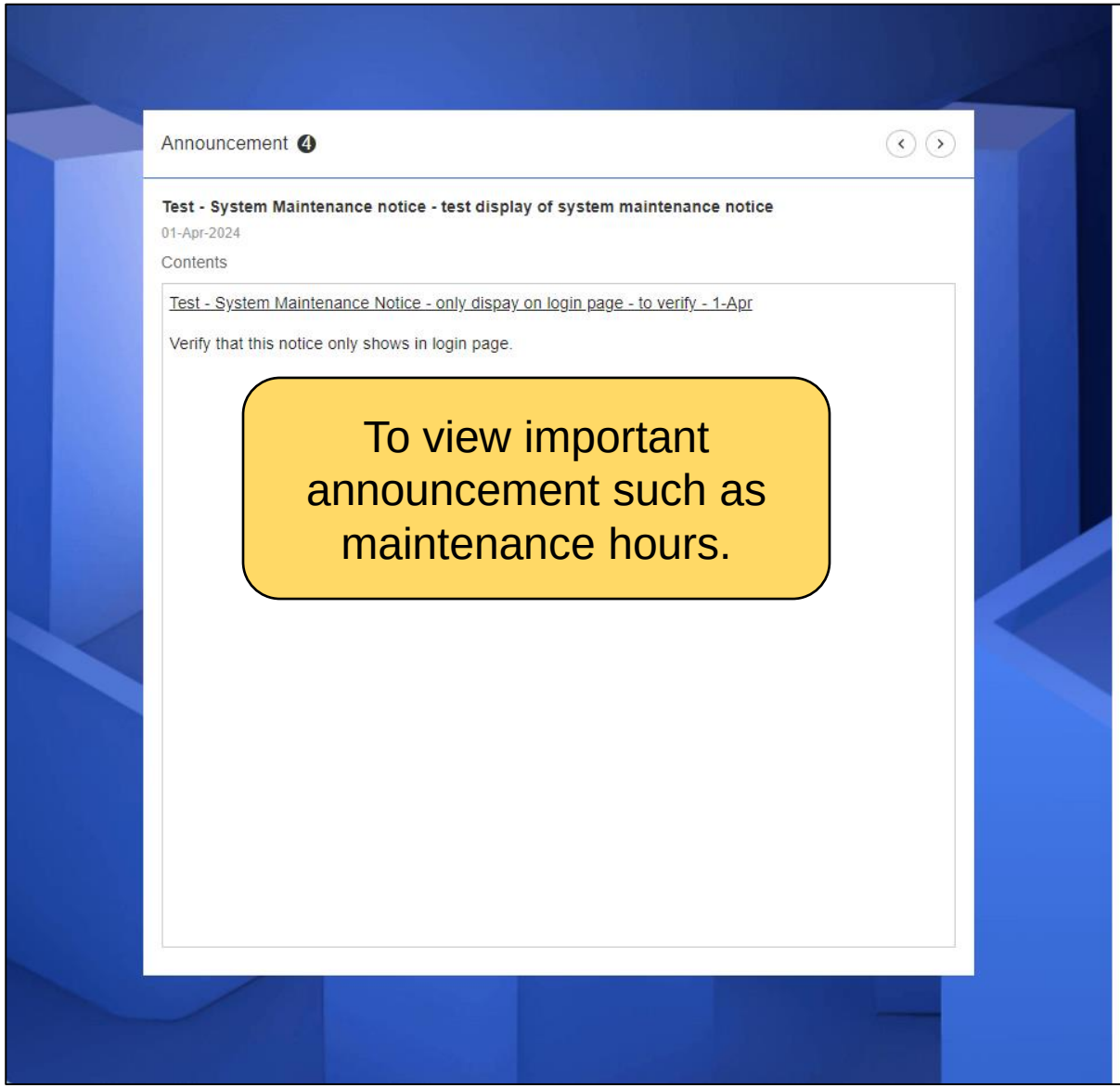


Account Login (For PHI Users)

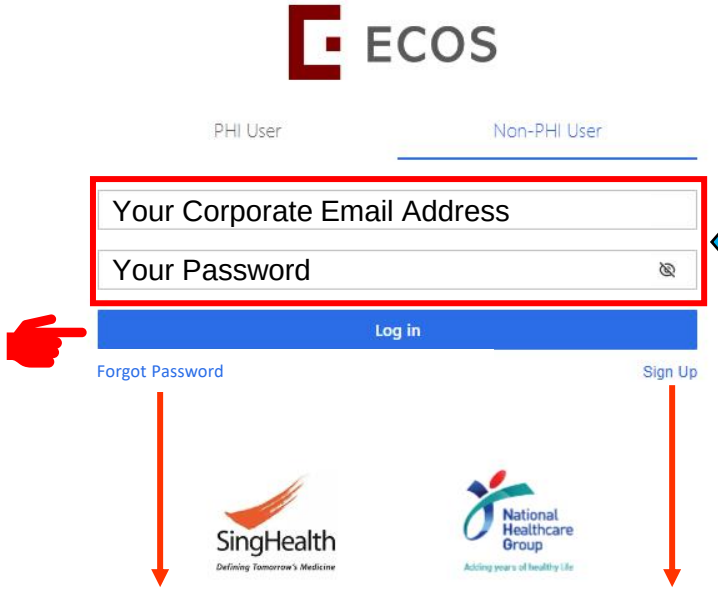


You will be redirected to this webpage to login to your M365 account.
Complete the login process and you will be login to ECOS.

Account Login (For non-PHI Users)



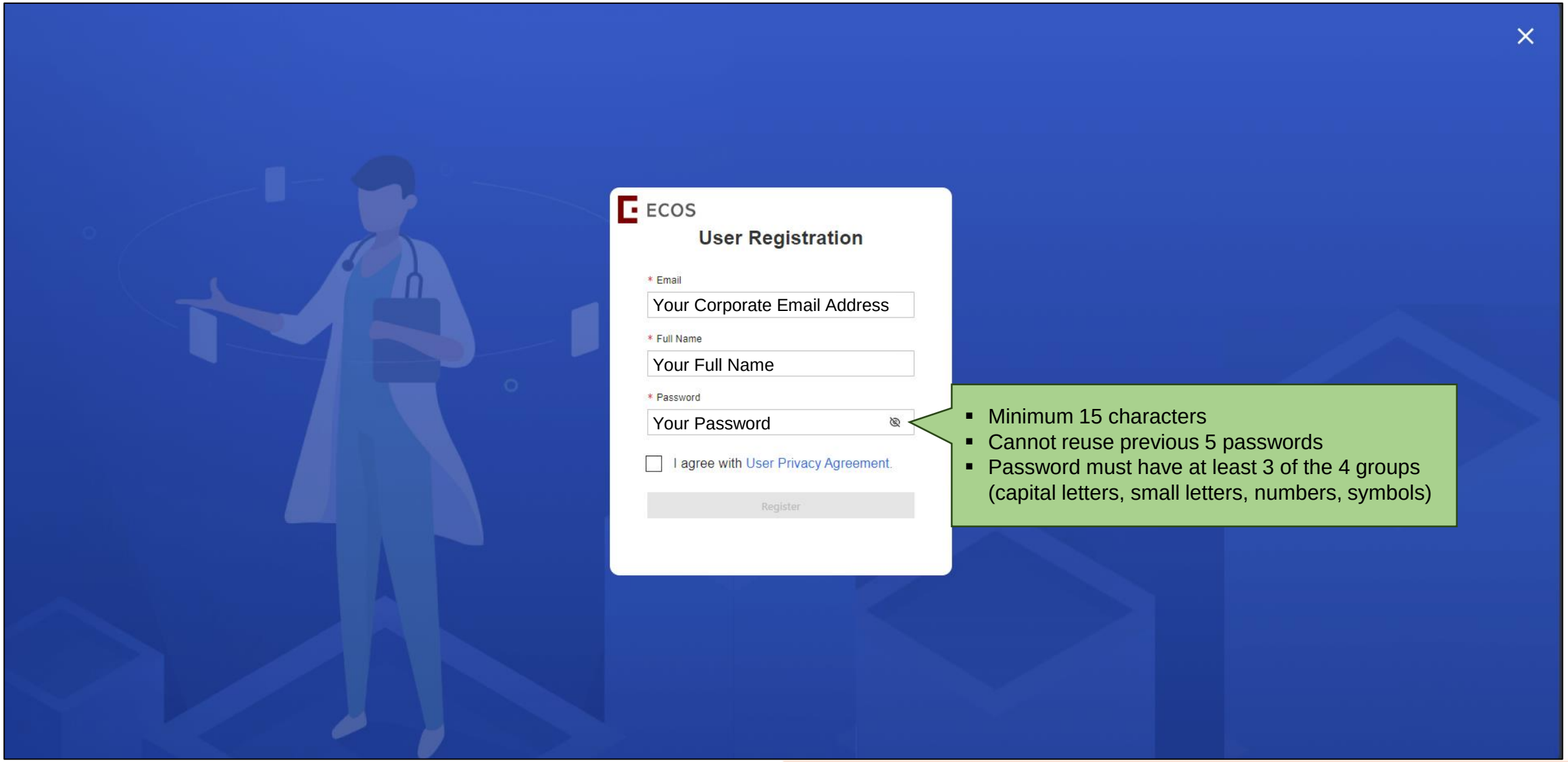
To view important announcement such as maintenance hours.



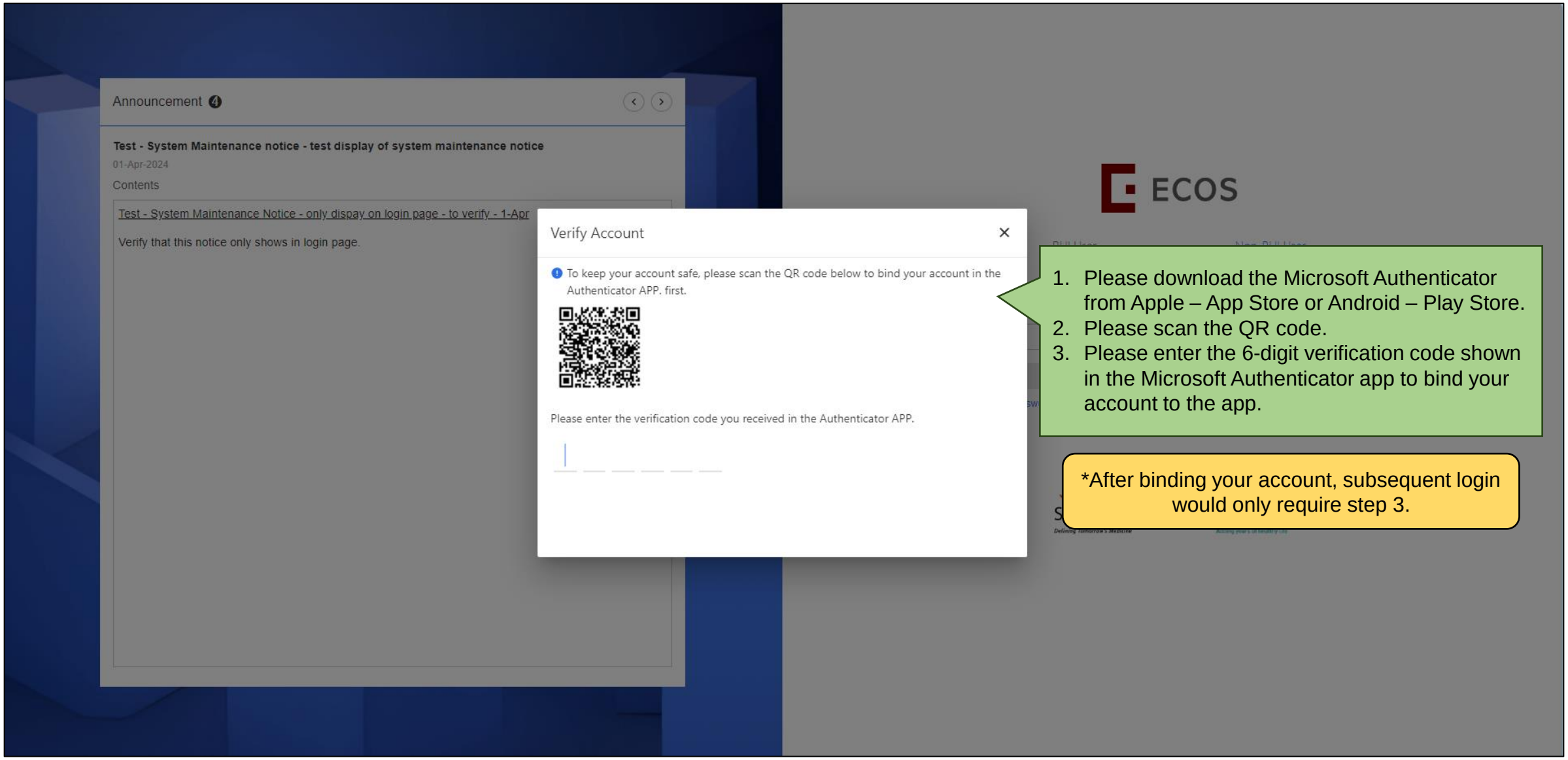
If you previously have an iSHaRe account, please use the email to login.

[Forgot Password] and [Sign Up] are only applicable for non-PHI Users.

Account Creation (For non-PHI users)



Account Login (For non-PHI Users)



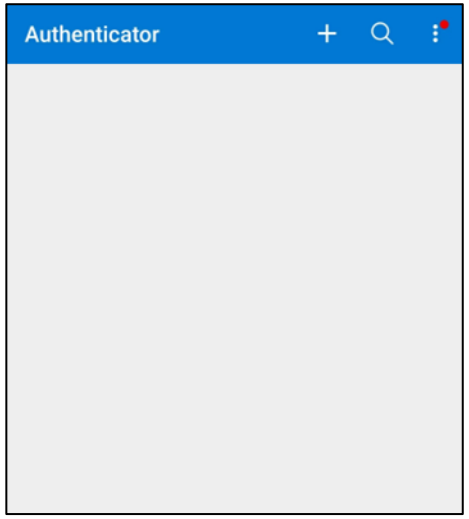
Account Login – Microsoft Authenticator

Step 1:
Download Microsoft Authenticator.

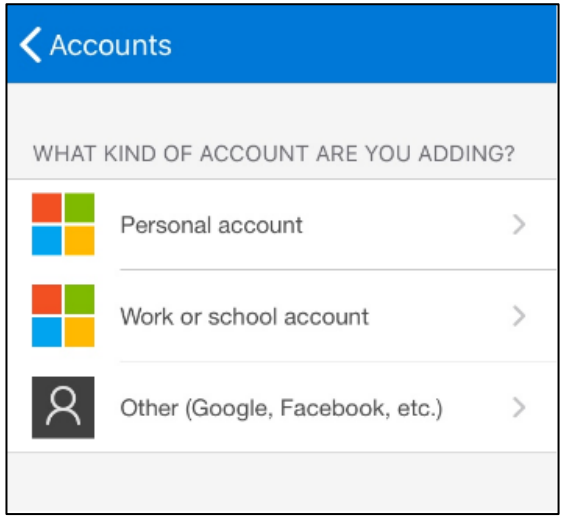
GET IT ON Google Play

Download on the App Store

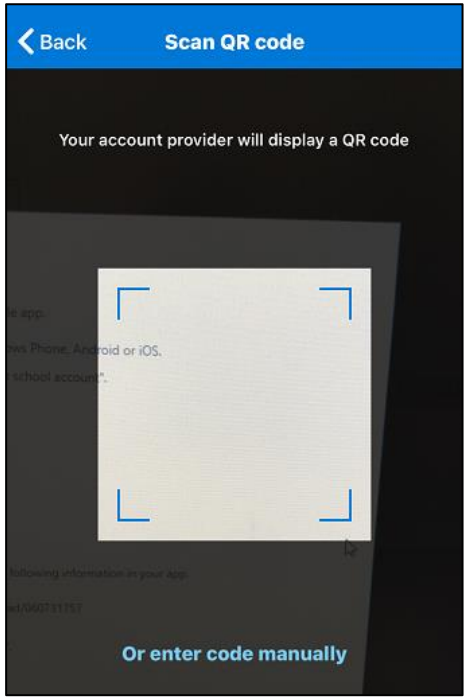
Step 2:
Click ‘+’ to add account.



Step 3:
Select ‘Other account (Google, Facebook, etc.)



Step 4:
Scan QR code to bind your account



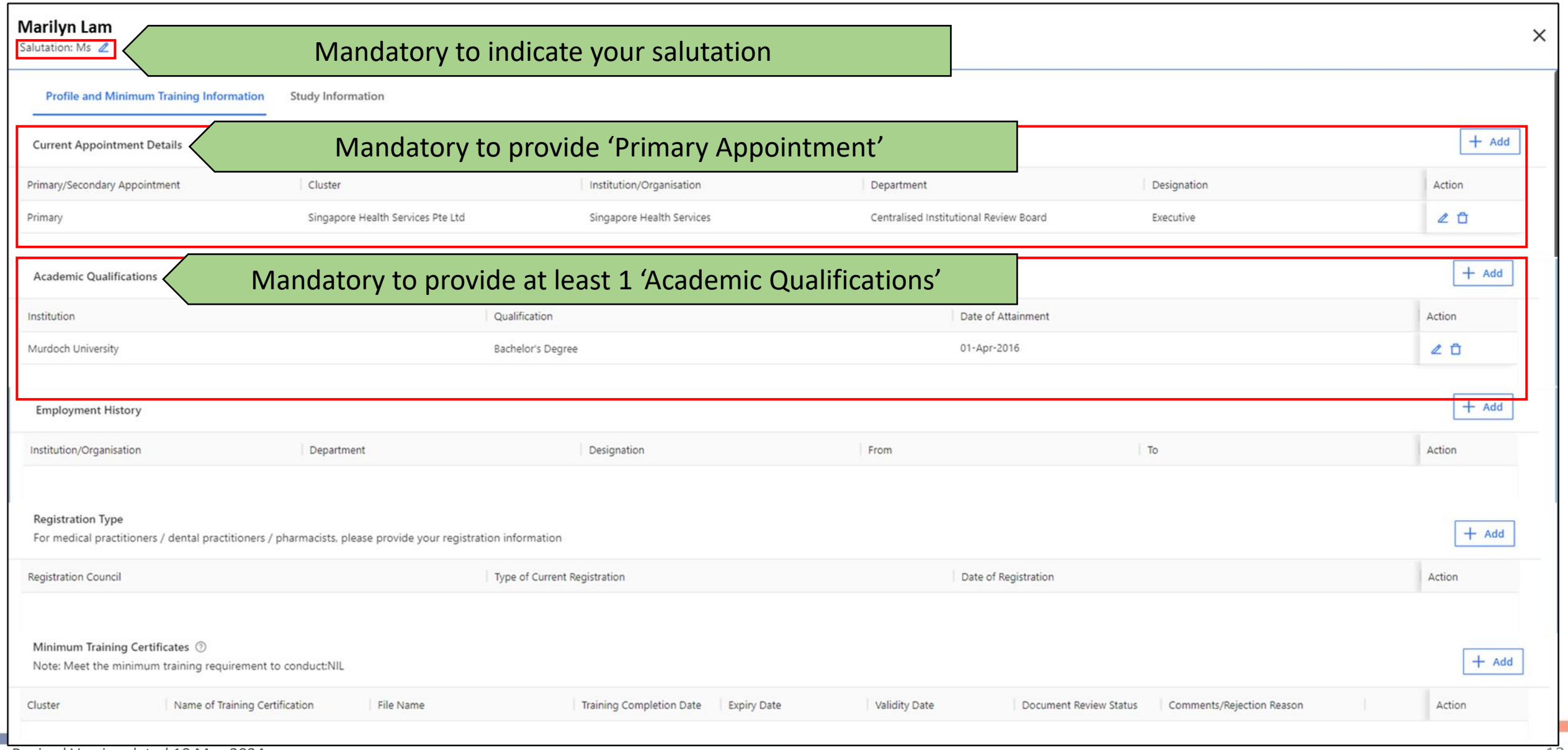
Account Status

- Locked Account: Locked after 5 consecutive failed logins.
  - PHI users: To unlock account, to send a request to it.helpdesk@singhealth.com.sg for SingHealth users. Other PHI users to approach their institution IT helpdesk.
  - Non-PHI users: To unlock account, to use ‘Forgot Password’ feature.

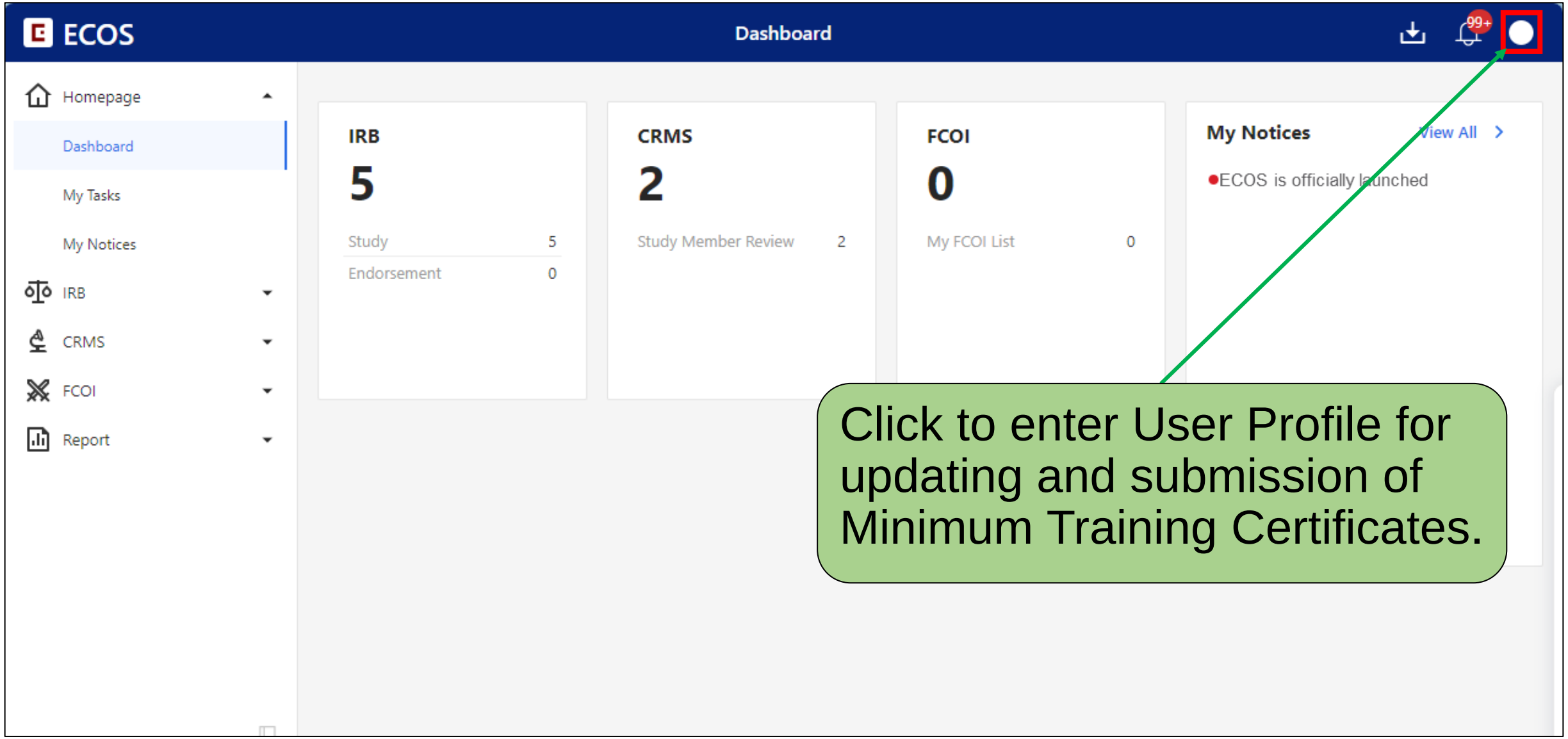
- Disabled Account: Disabled after 90 calendars days of user login inactivity.
  - All users: To reactivate account, send a request in https://for.sg/ecos-support-request.

- Forgot Password
  - For PHI users, the ECOS login password would be your corporate email address (M365) password. In the event that you have forgotten your password, please reset your password via M365 or contact your Institution’s IT helpdesk.
  - For non-PHI users, you may reset your password in ECOS using ‘Forgot Password’ feature.

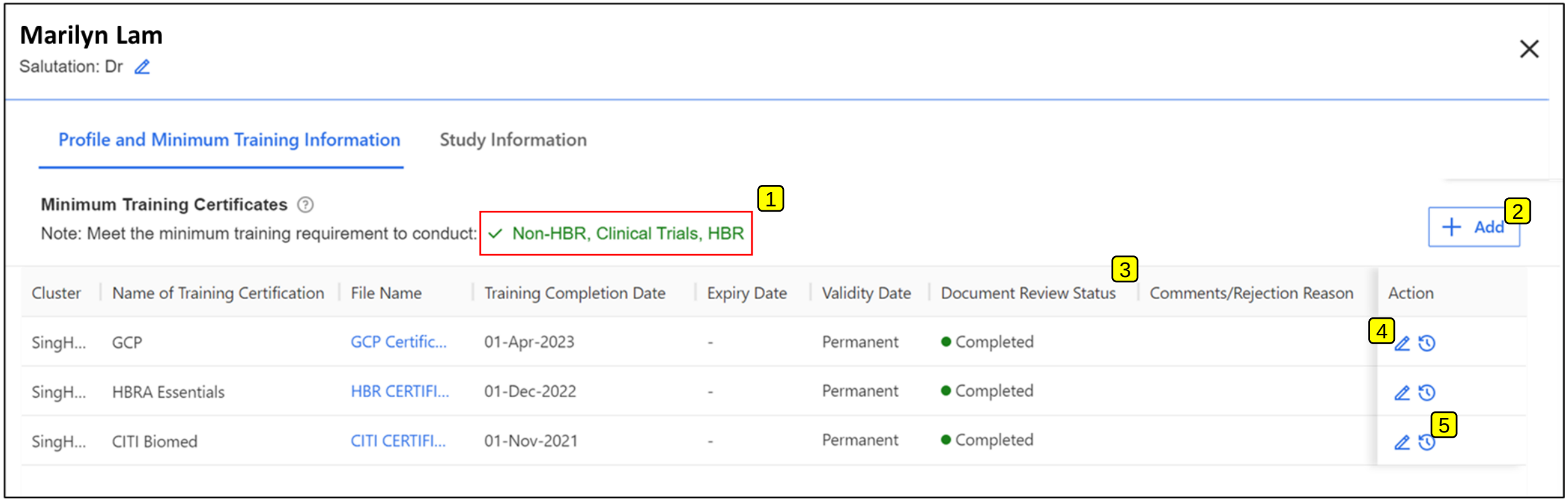
User Profile



Accessing to User Profile



User Profile: Minimum Training



1 Display the type of studies that you can conduct.

2 Click to add new training certification achieved.

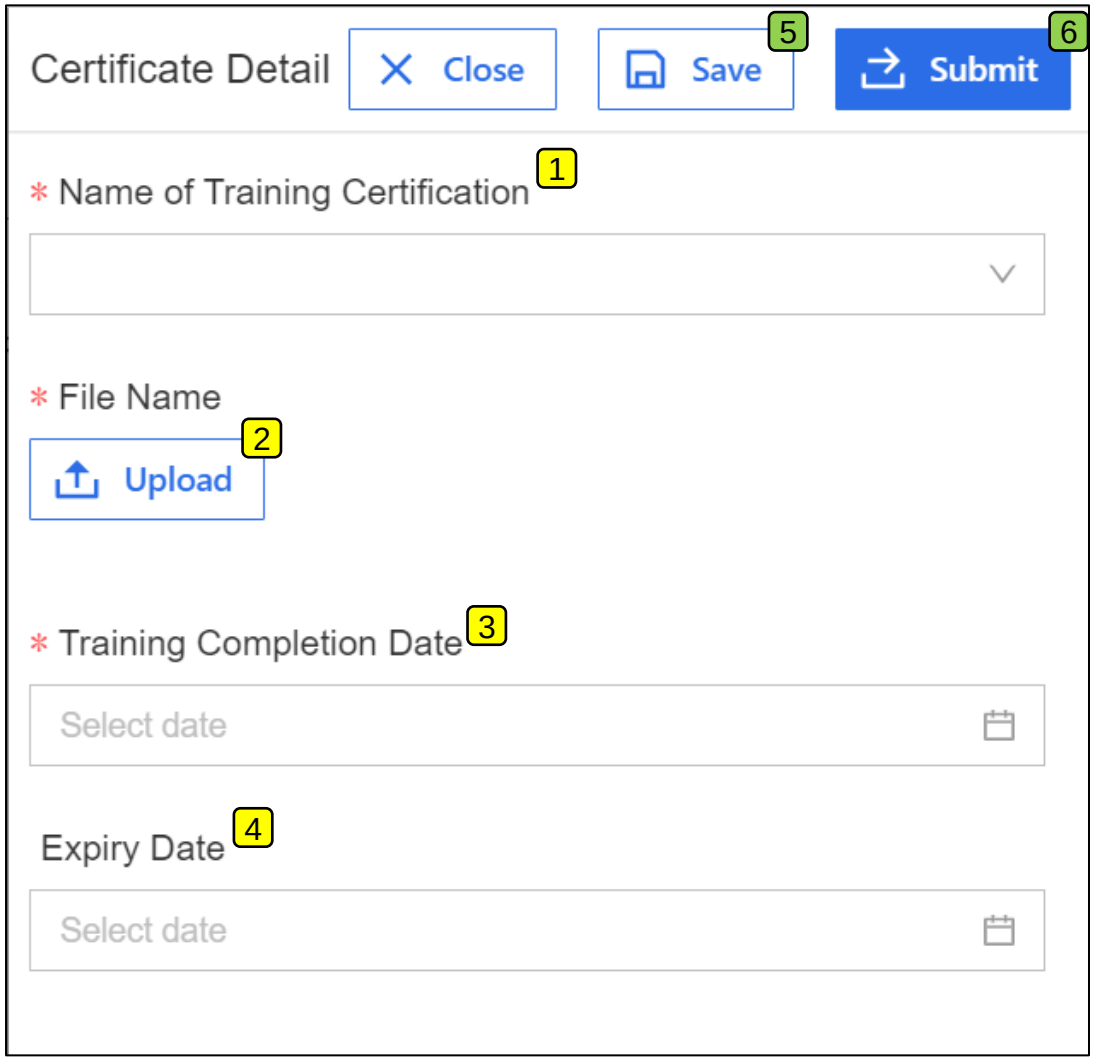
3 Check Document Review Status for latest update.
Type of Document Review Status: Draft, Pending Review, Completed and Rejected

4 Click to edit and update the training certification.

5 View the history of the submission of the training certification.

User Profile: Minimum Training

1. Choose the type of training certification to be submitted.
2. Upload the training certification.
   (Accepted File Format: pdf, doc)
3. Select Training Completion Date.
4. Expiry Date is not mandatory.
5. Click Save for more information to be included when available.
6. Click Submit and training certification will be reviewed by the Minimum Training Secretariat.



Minimum Training Requirement

Your Institution's Minimum Training Secretariat will review your training certification and update the type of studies that you can conduct based on the following criteria:

		Training Certification		
		Collaborative Institutional Training Initiative (CITI) Biomedical Research Investigators and Key Personnel	Human Biomedical Research Act (HBRA) Essential	Good Clinical Practice (GCP) Certification
Type of Studies That You can Conduct	Non-HBR	✓		
	HBR	✓	✓	
	Clinical Trials	✓		✓

User Profile – Study Information

Marilyn Lam

Salutation: Ms

Profile and Minimum Training Information | Study Information

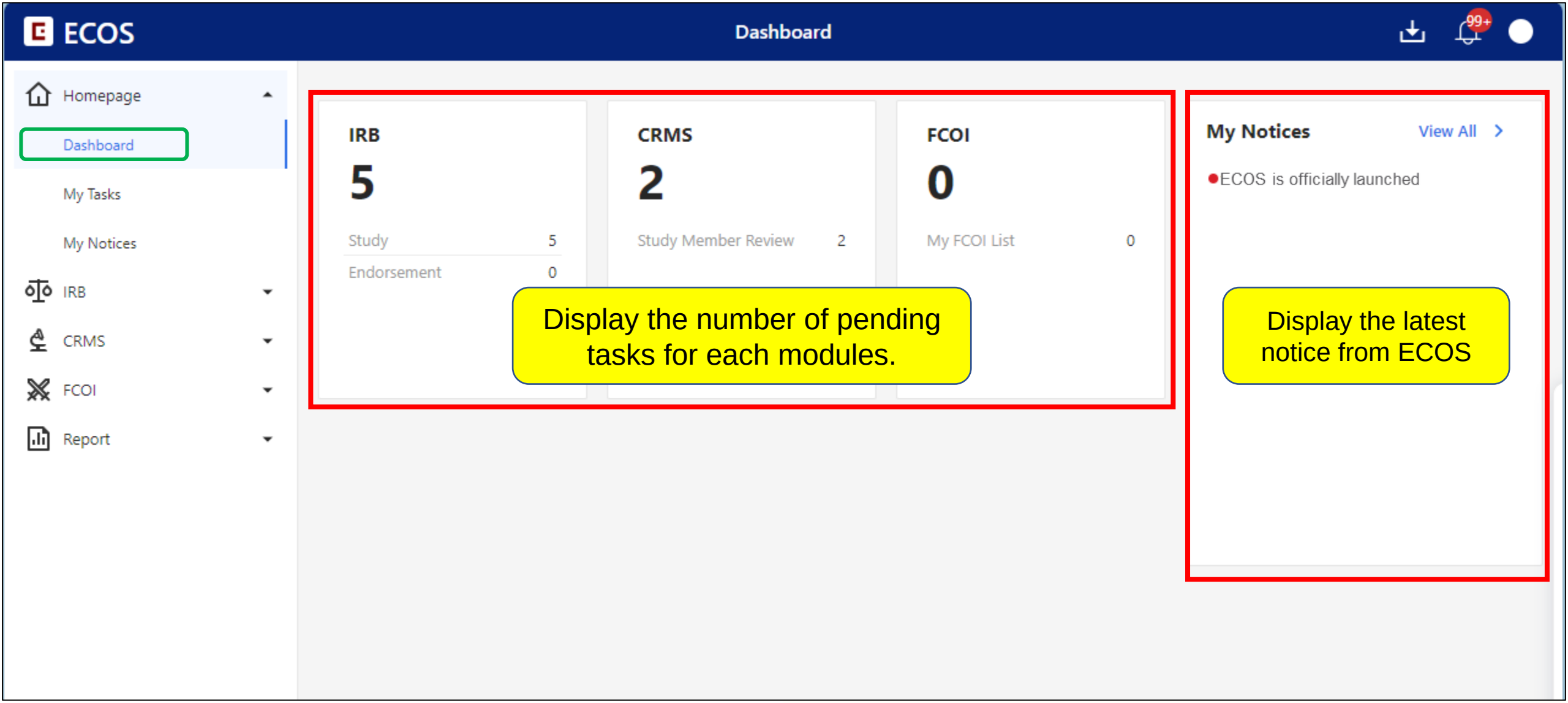
Study Information

Columns | Export | Filter

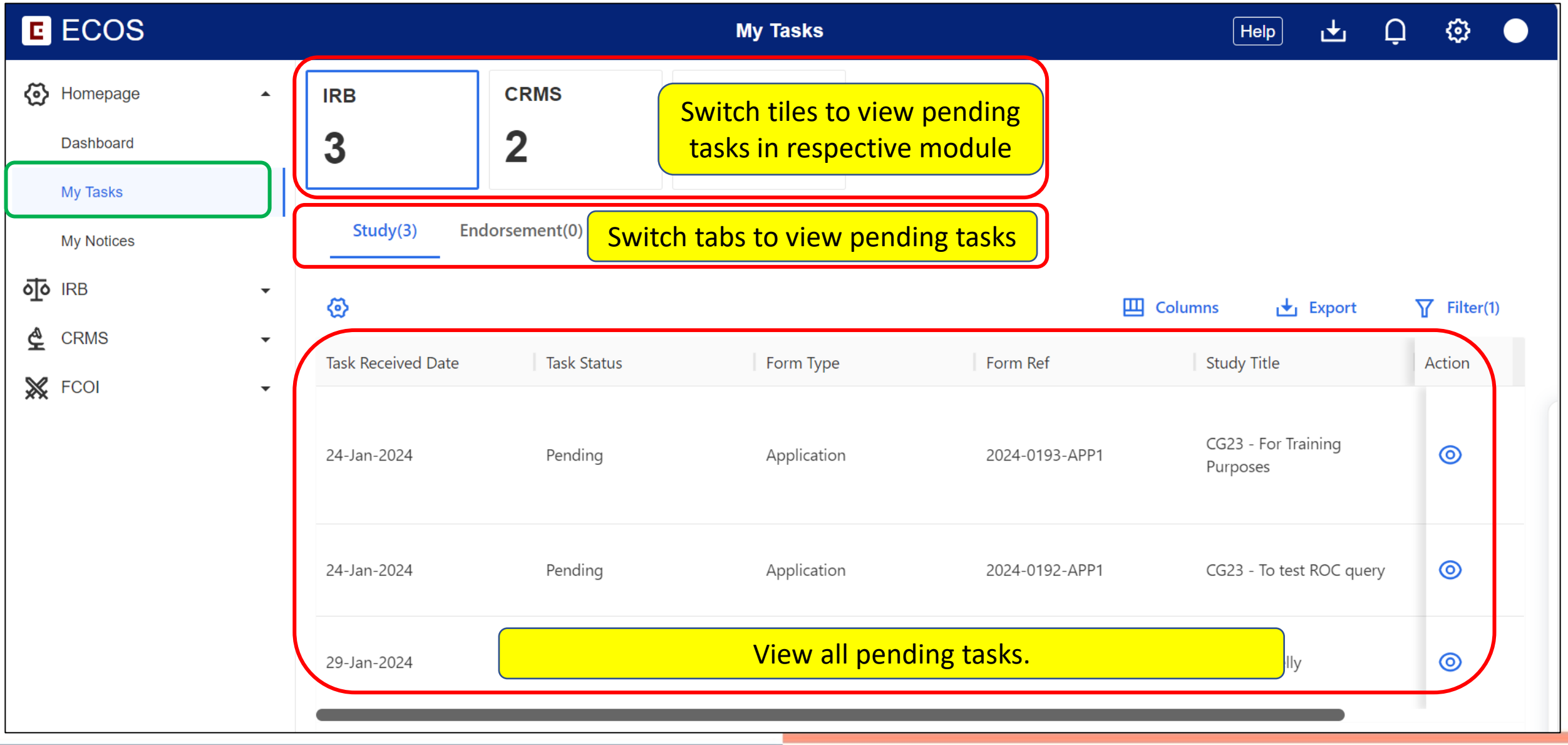
ECOS Ref	IRB	Site	Study Status	Initial Outcome Date	Valid Till Date	Study Classification	Study Role
2024-0193	CIRB - Board A	Singapore National Eye Centre (SNEC)	Pending Endorsement	-	-	(d) Others – The study is not regulated by Health Products Act/ Medicines Act (HSA) nor Human Biomedical Research Act (MOH)	Study Team Member
2024-0177	CIRB - Board A	Singapore National Eye Centre (SNEC)	Pending Review	-	-	(d) Others – The study is not regulated by Health Products Act/ Medicines Act (HSA) nor Human Biomedical Research Act (MOH)	PI
2024-0142	CIRB - Board A	Singapore National Eye Centre (SNEC)	Approved	16-Jan-2024	15-Jan-2025	(d) Others – The study is not regulated by Health Products Act/ Medicines Act (HSA) nor Human Biomedical Research Act (MOH)	Co-I

- View the list of studies that you are involved in.

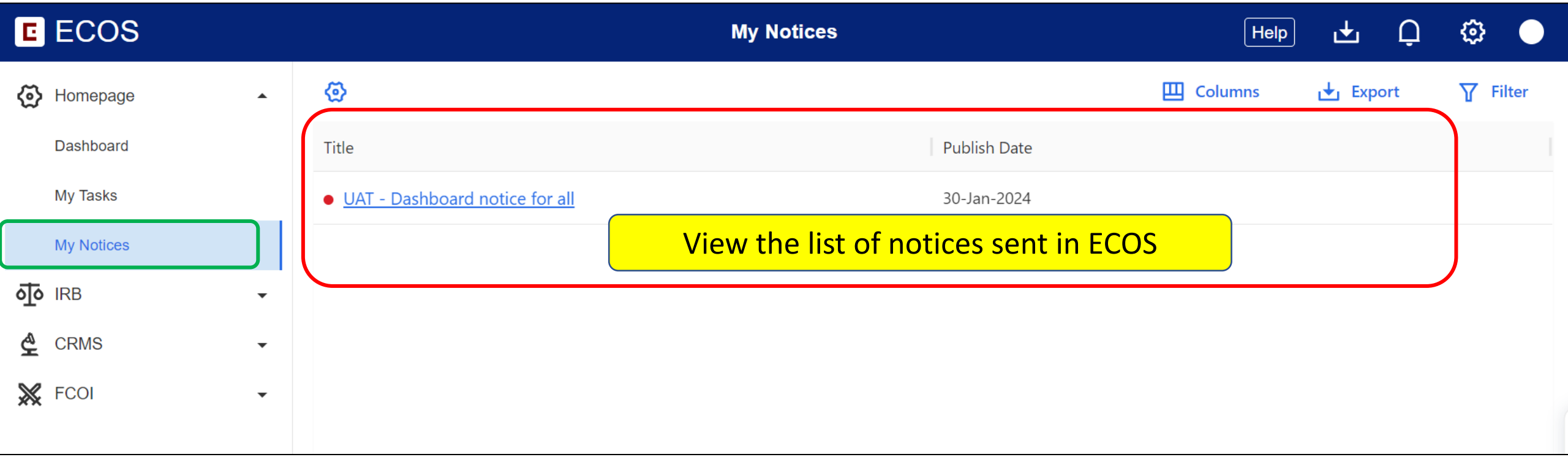
Dashboard – At a Glance



Dashboard – My Tasks

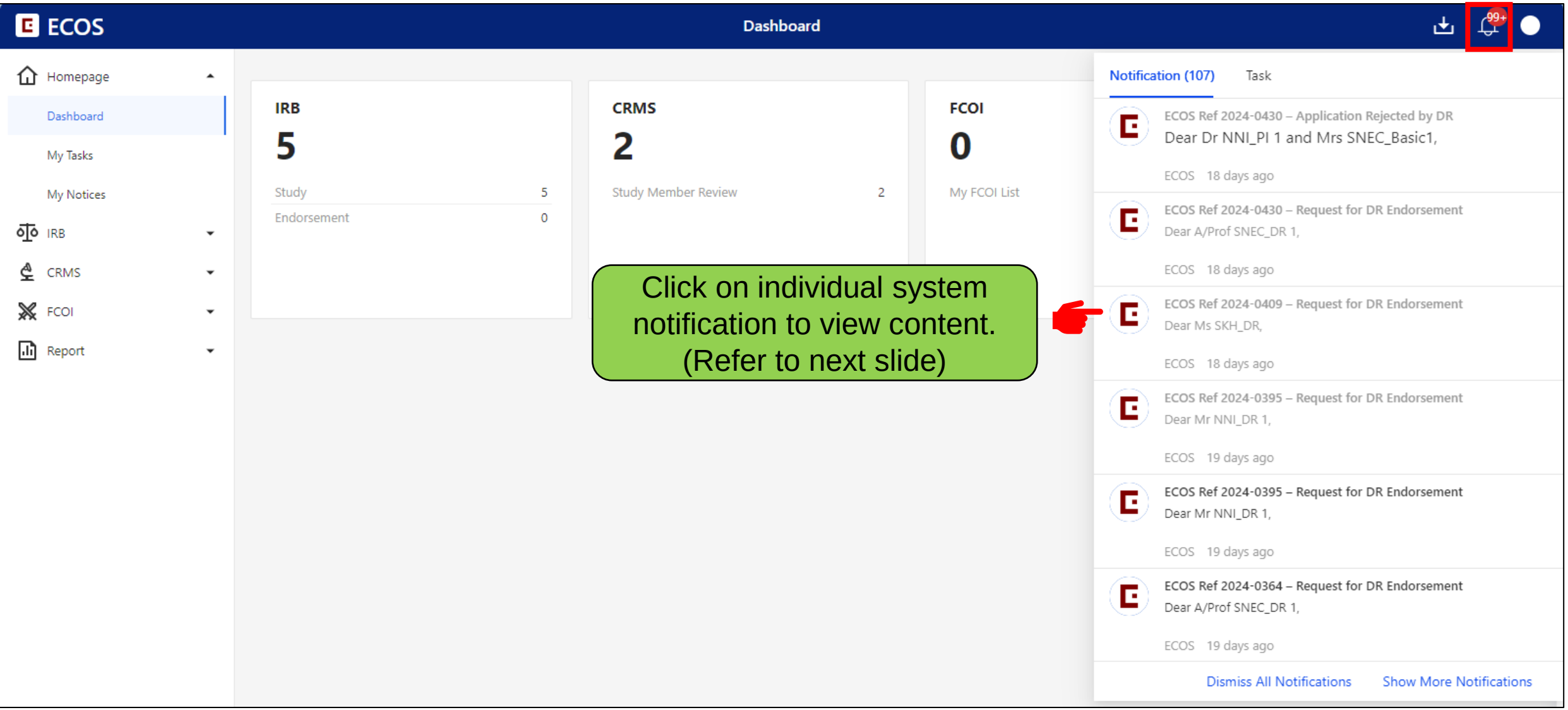


Dashboard – My Notices



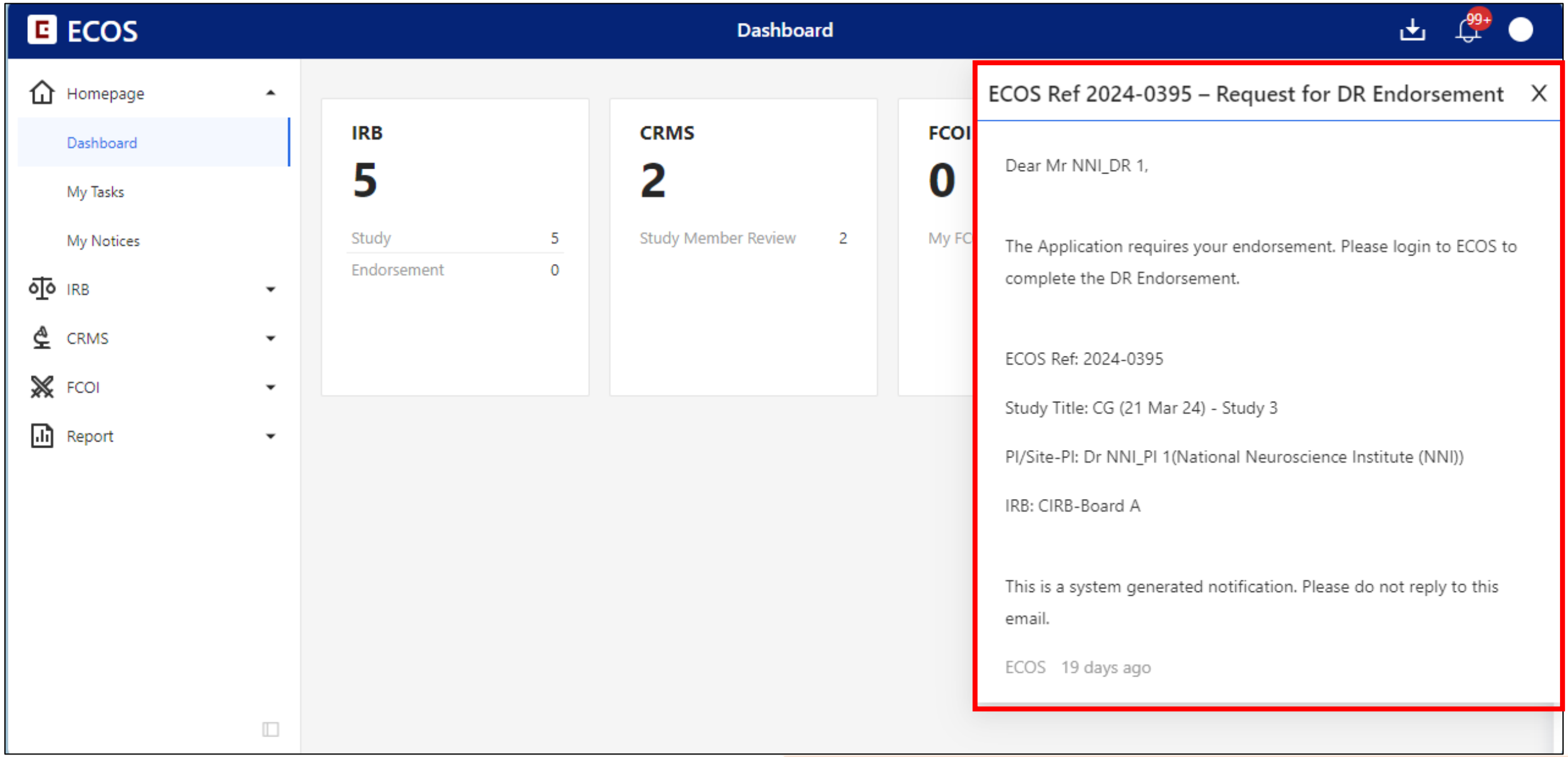
- The '●' shows that the notice had not been read.

System Notification

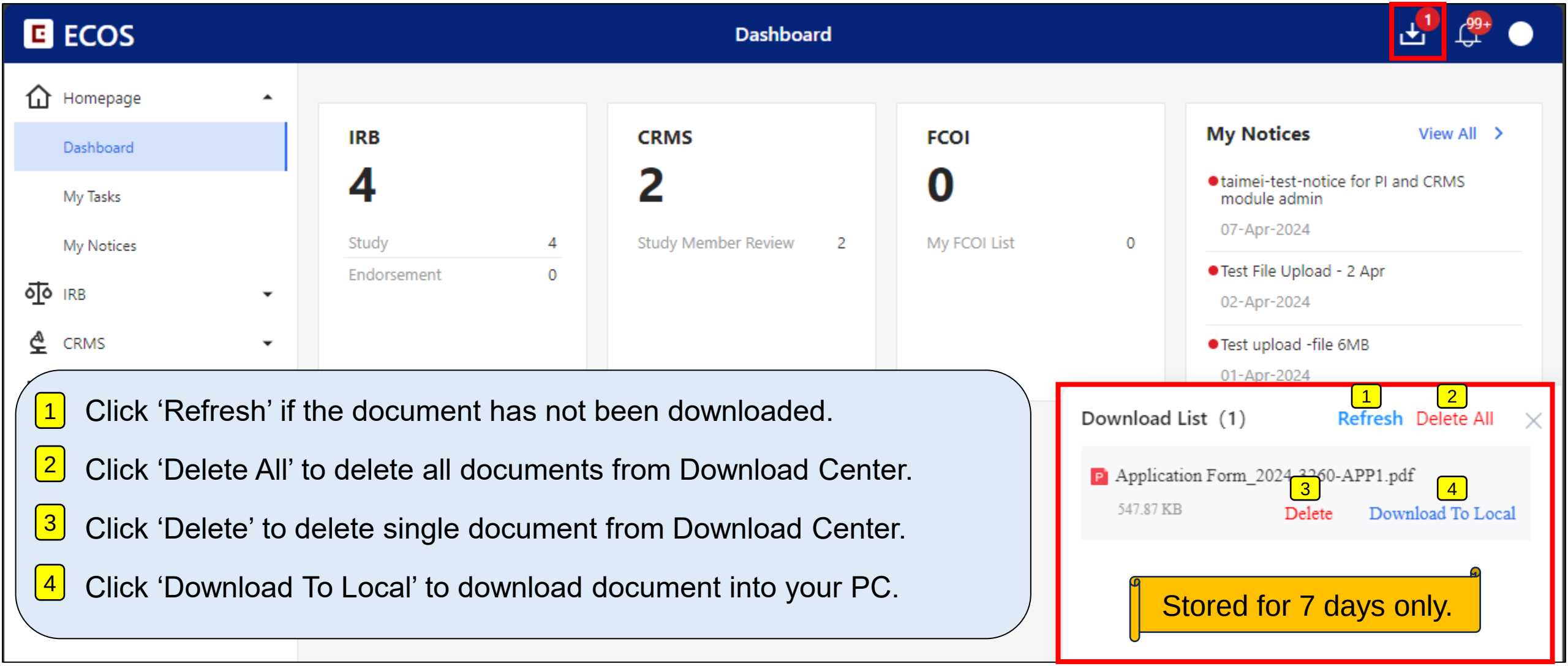


- Click on ‘ 🔔 ’ to view the list of system notifications

System Notification



Download Center

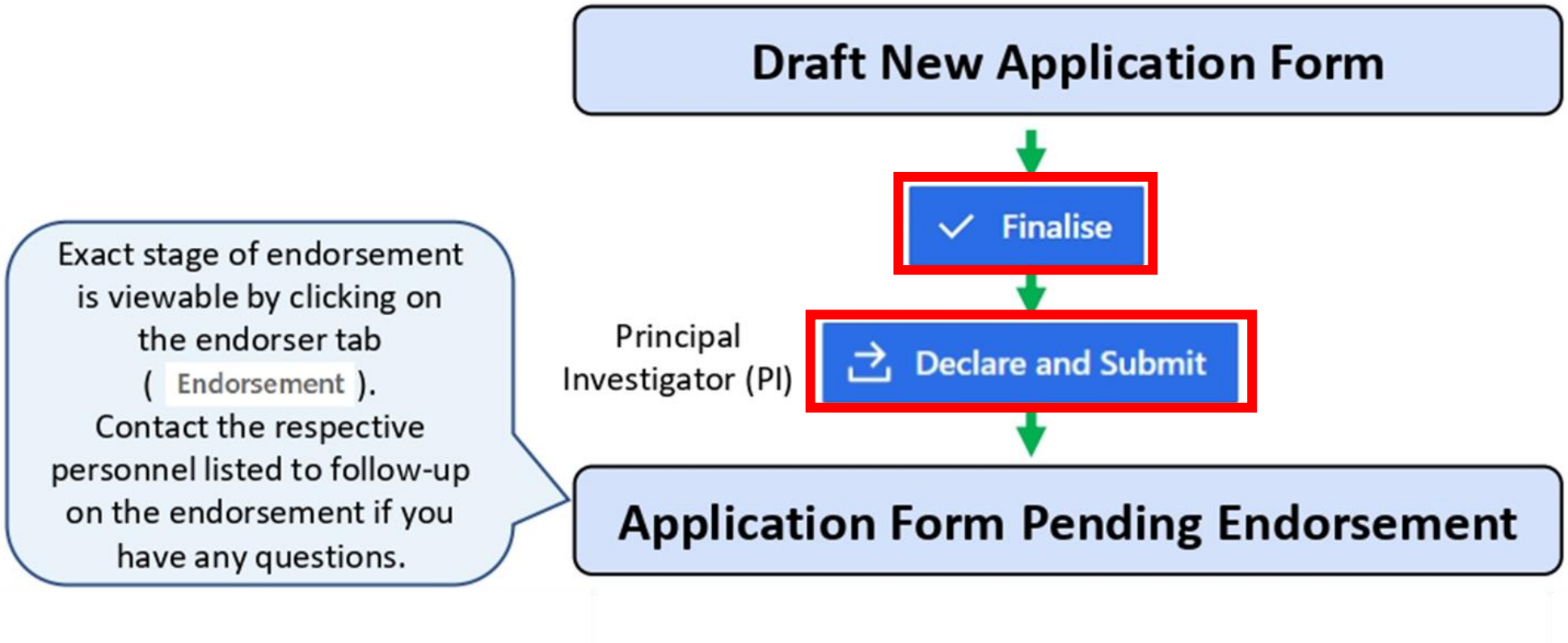


1. Click 'Refresh' if the document has not been downloaded.
2. Click 'Delete All' to delete all documents from Download Center.
3. Click 'Delete' to delete single document from Download Center.
4. Click 'Download To Local' to download document into your PC.

- Click on ' ' to view the list for documents downloaded

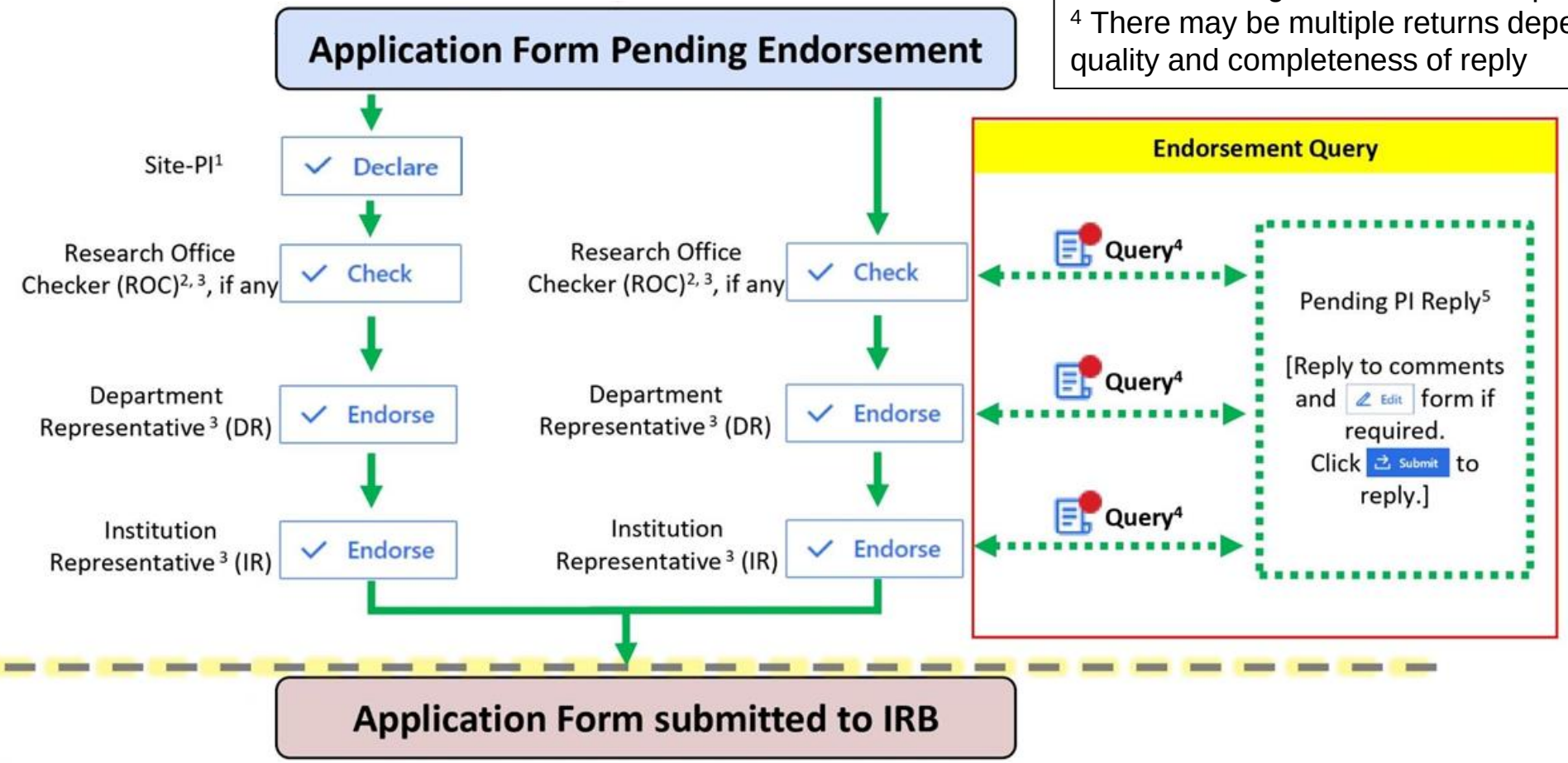
IRB Submission and Migrated Study

Submission Workflow

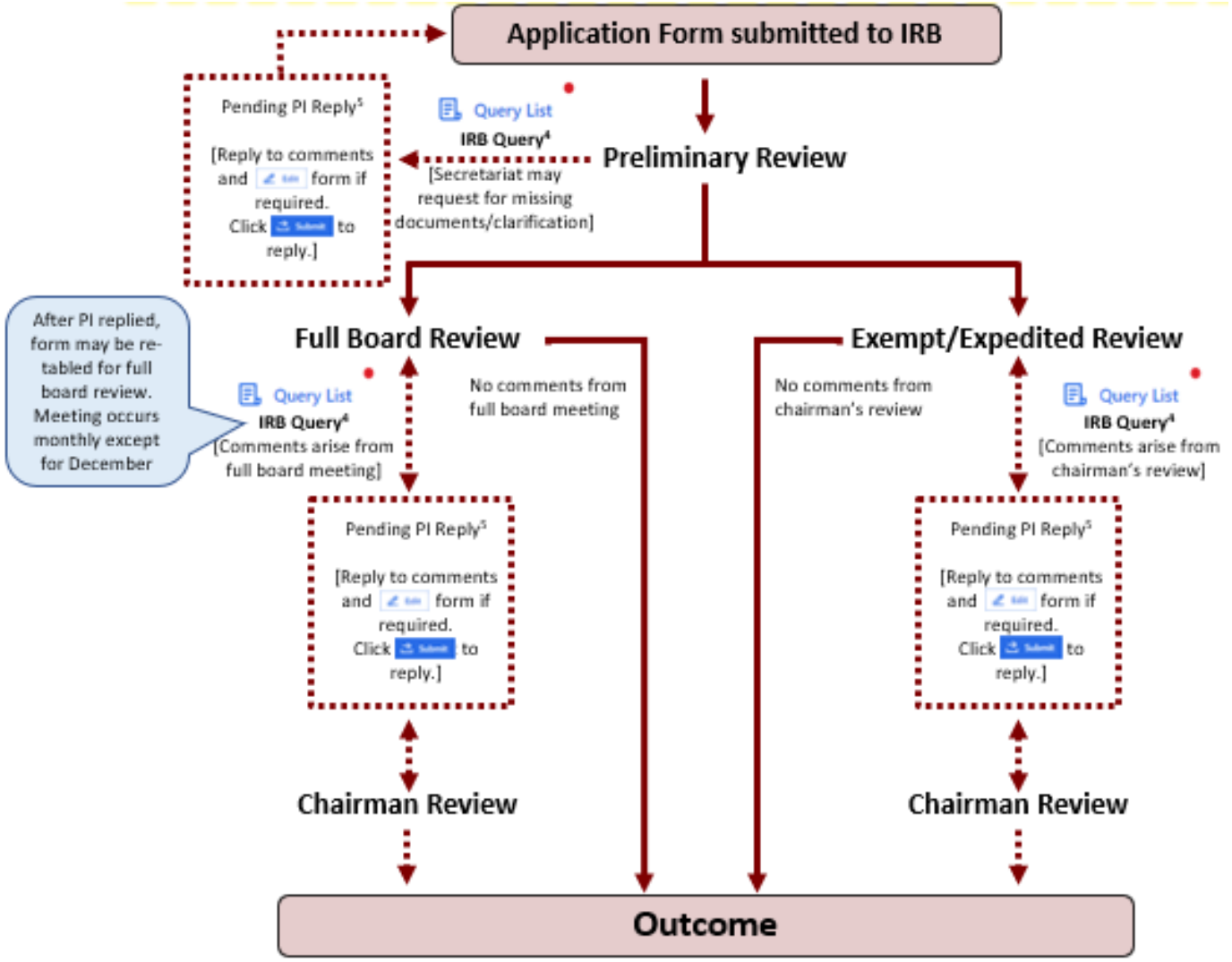


Submission Workflow

Note:
[1] This is only applicable for study involving multi-sites.
[2] ROC check is not applicable for all institutions
[3] Please note that there may be queries from ROC, DR or IR during the endorsement process.
[4] There may be multiple returns depending on the quality and completeness of reply

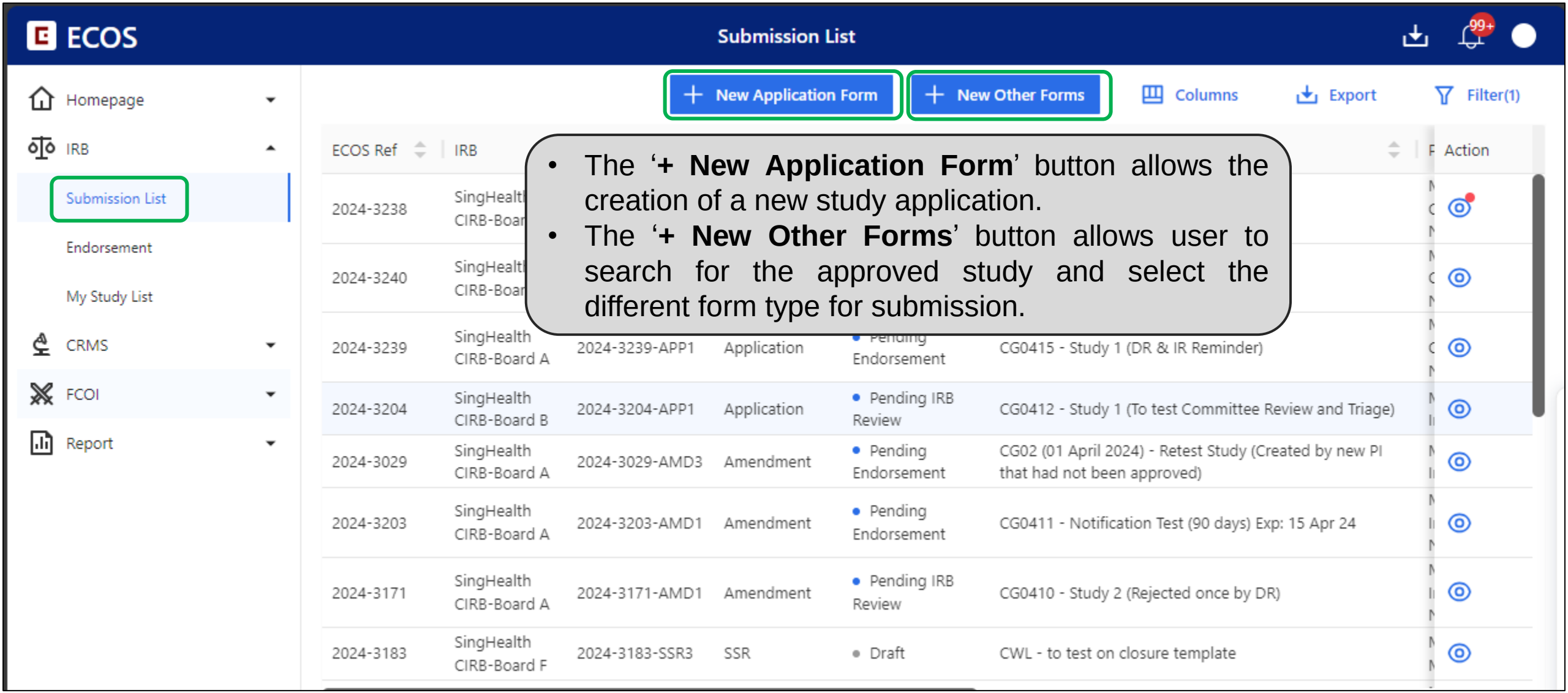


Submission Workflow



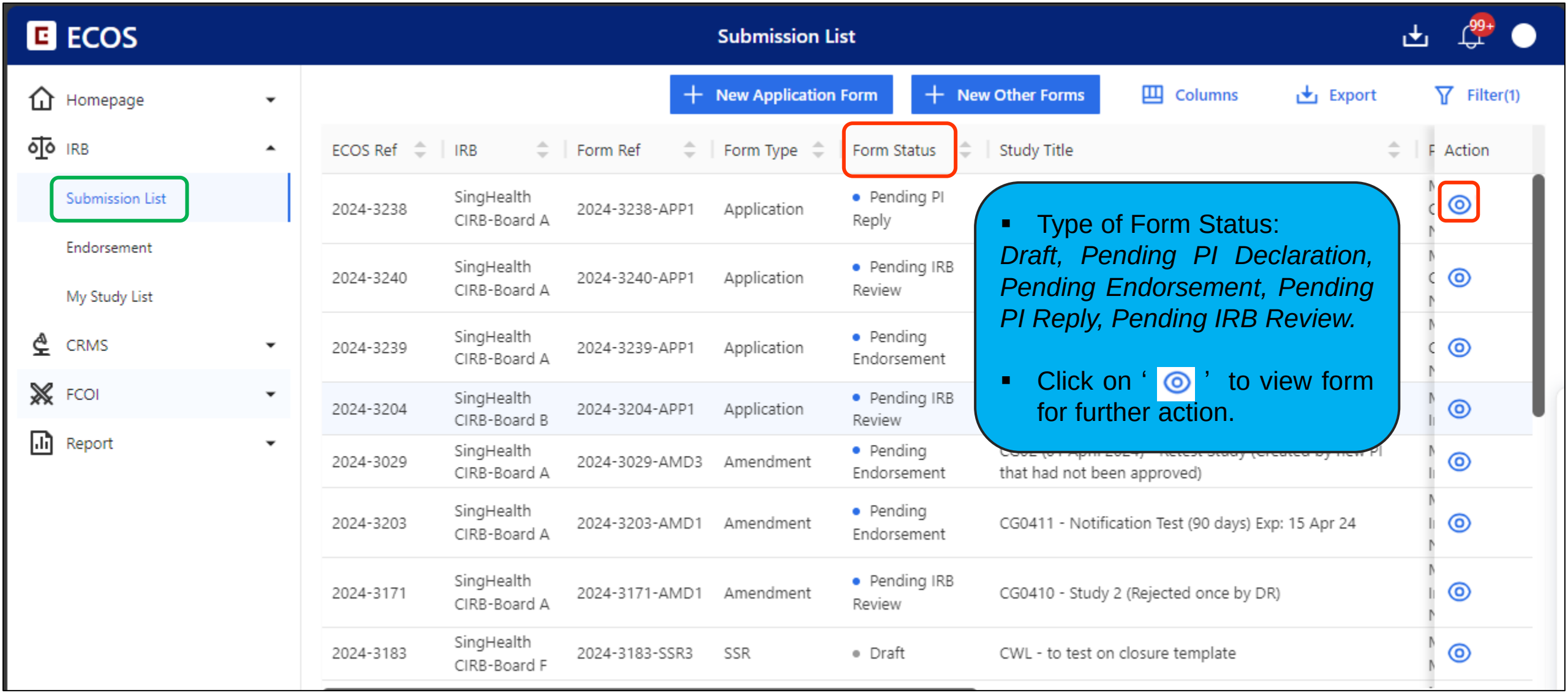
Note:
[4] There may be multiple returns depending on the quality and completeness of reply
[5] Re-declaration / Re-endorsement is required if there are major changes to the application form

IRB – Submission List

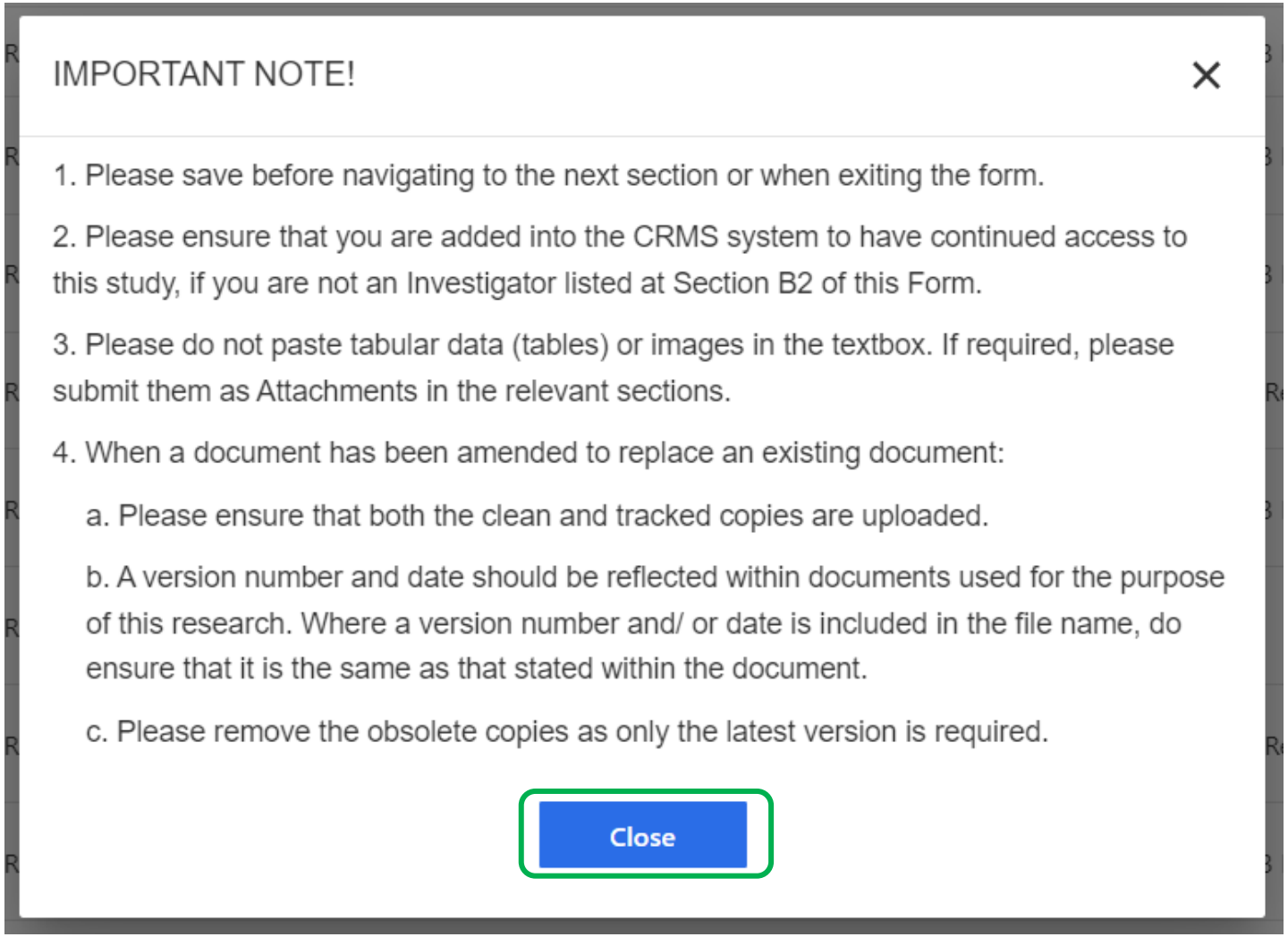


- The '**+ New Application Form**' button allows the creation of a new study application.
- The '**+ New Other Forms**' button allows user to search for the approved study and select the different form type for submission.

IRB – Submission List

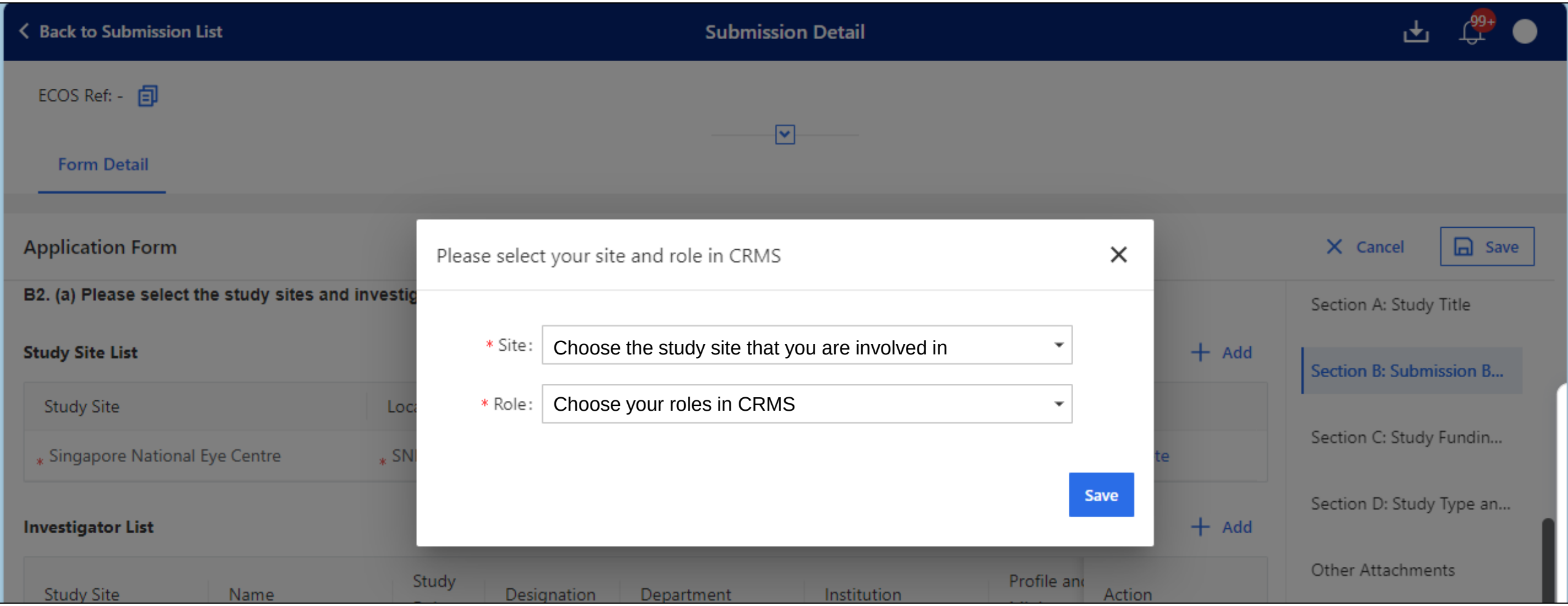


Creation of New Application Form



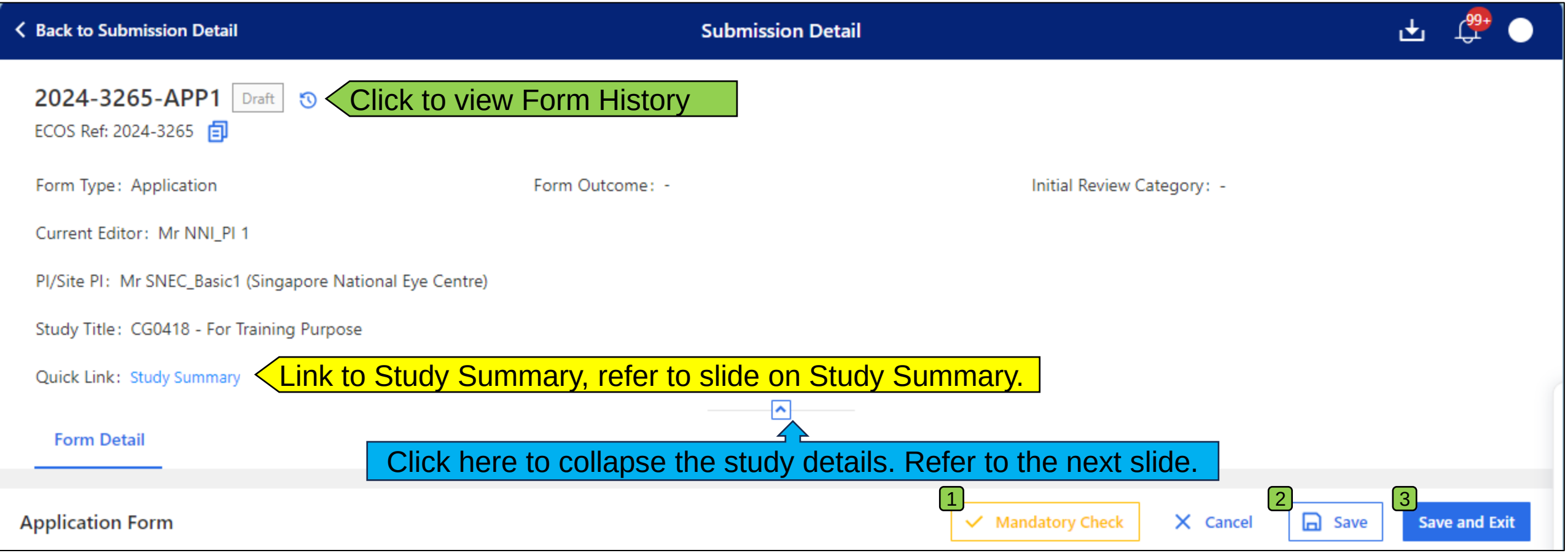
- Click on '**Close**' button to proceed with the creation of form.
- Complete **Section A: Study Title** and **B: Submission Board, Study Site, Study Investigator and Conflict of Interest** to save draft.

Creation of New Application Form



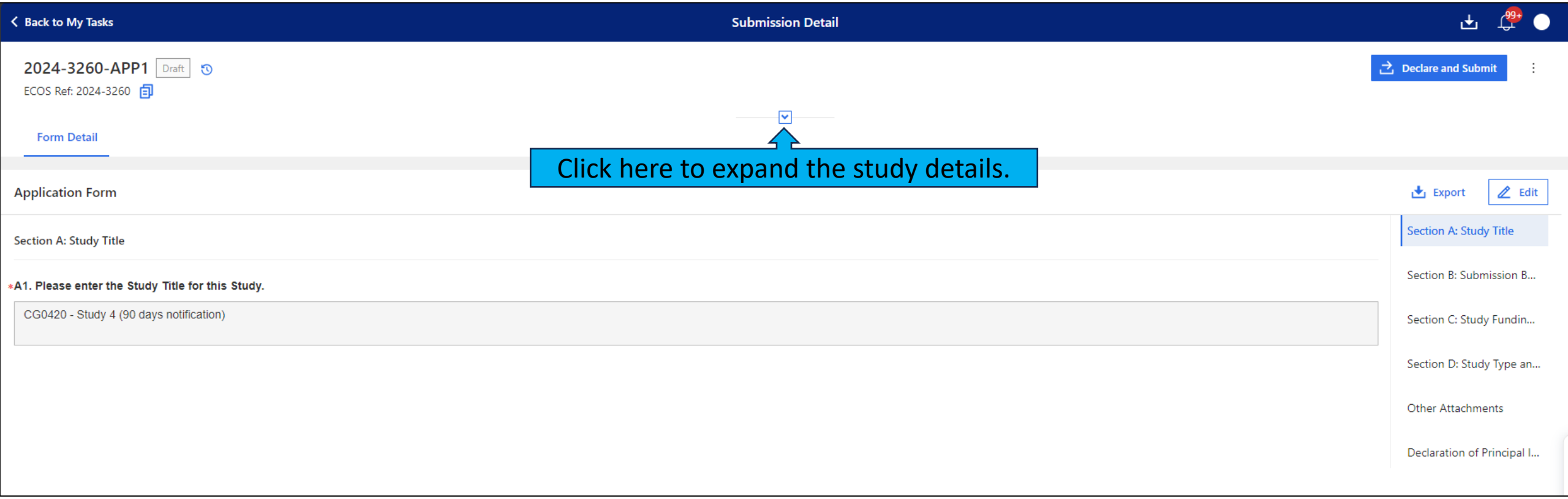
Note: This prompt will appear the first time you saved the form, and you are not part of the Investigator List in Section B2. (a).

Features of Forms



1. Click ‘Mandatory Check’ to ensure that all form fields are filled.
2. Use ‘Save’ frequently to ensure that all information are saved.
3. Use ‘Save and Exit’ to save and exit editing mode.

Features of Forms



Adding Study Investigator

Application Form

Study Site List + Add

Study Site	Location	Endorsement needed	Action
* Singapore National Eye Centre (SNEC)	SNEC Main Site	* Yes	Edit Delete

Investigator List + Add

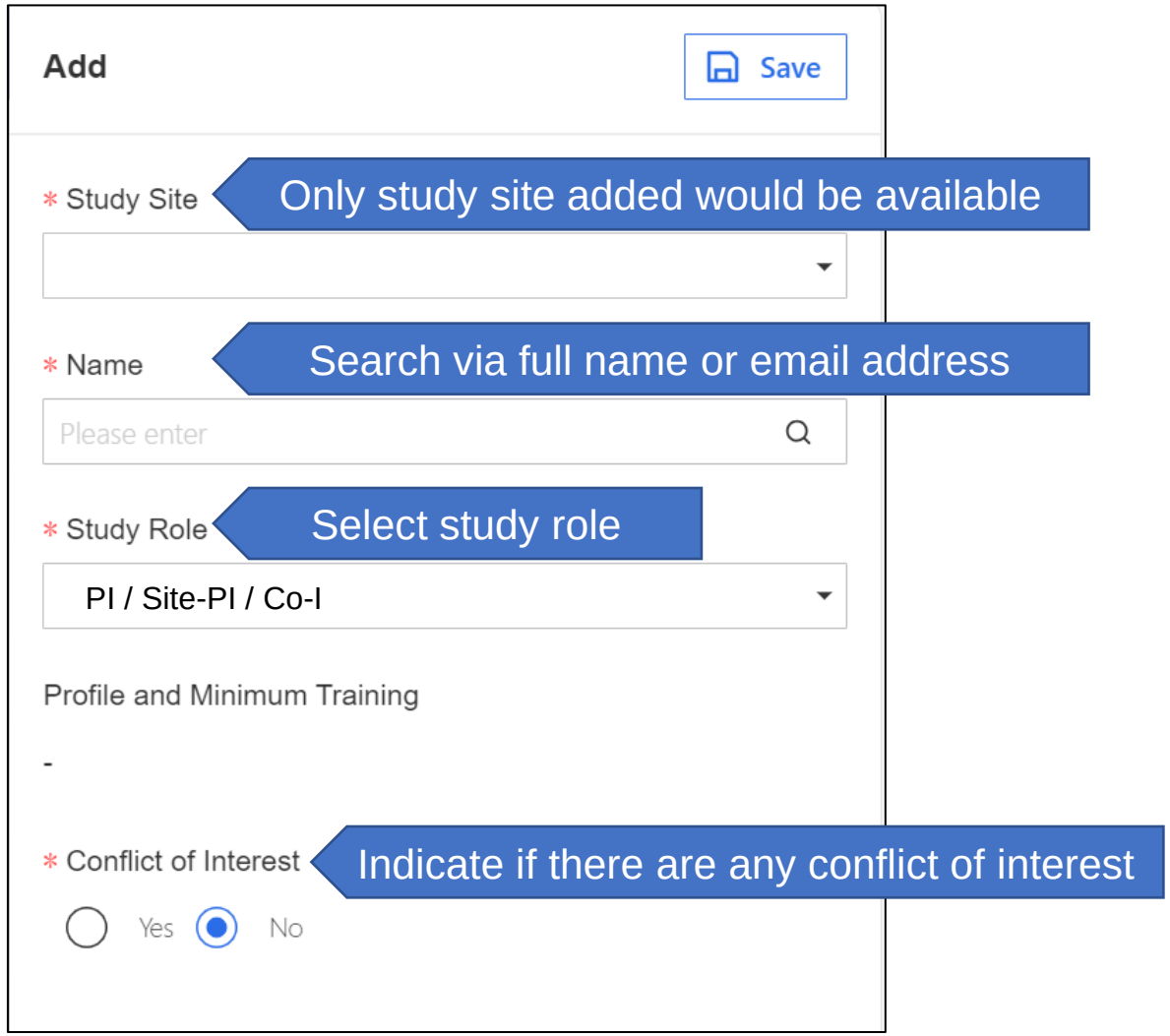
Study Site	Name	Study Role	Email	Designati

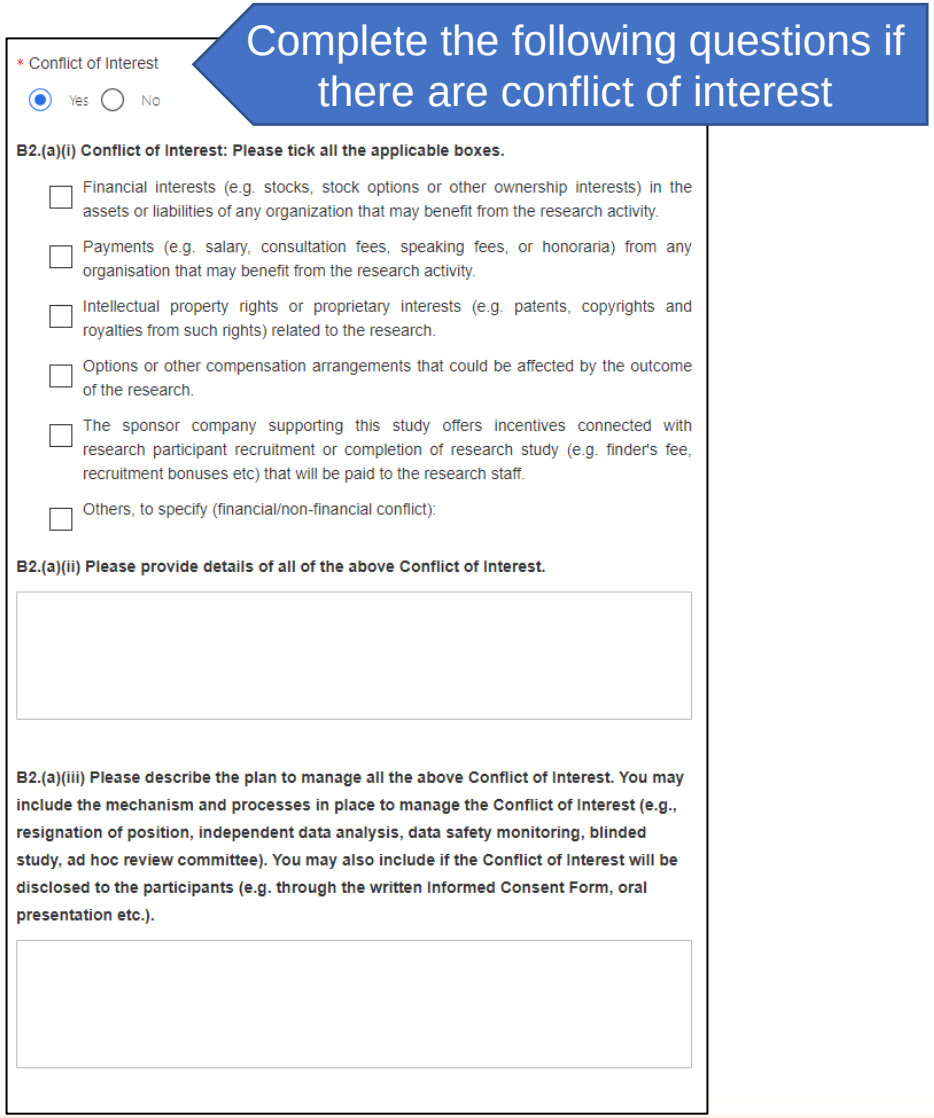
B2. (b) Study Sites (For Information Only) ⓘ

Note: Other local/ overseas site (The sites listed here is for the IRB's information only. IRB's approval will not include any of the sites. The sites should apply for their own IRB approval if required.)*

0 characters entered

Adding Study Investigator





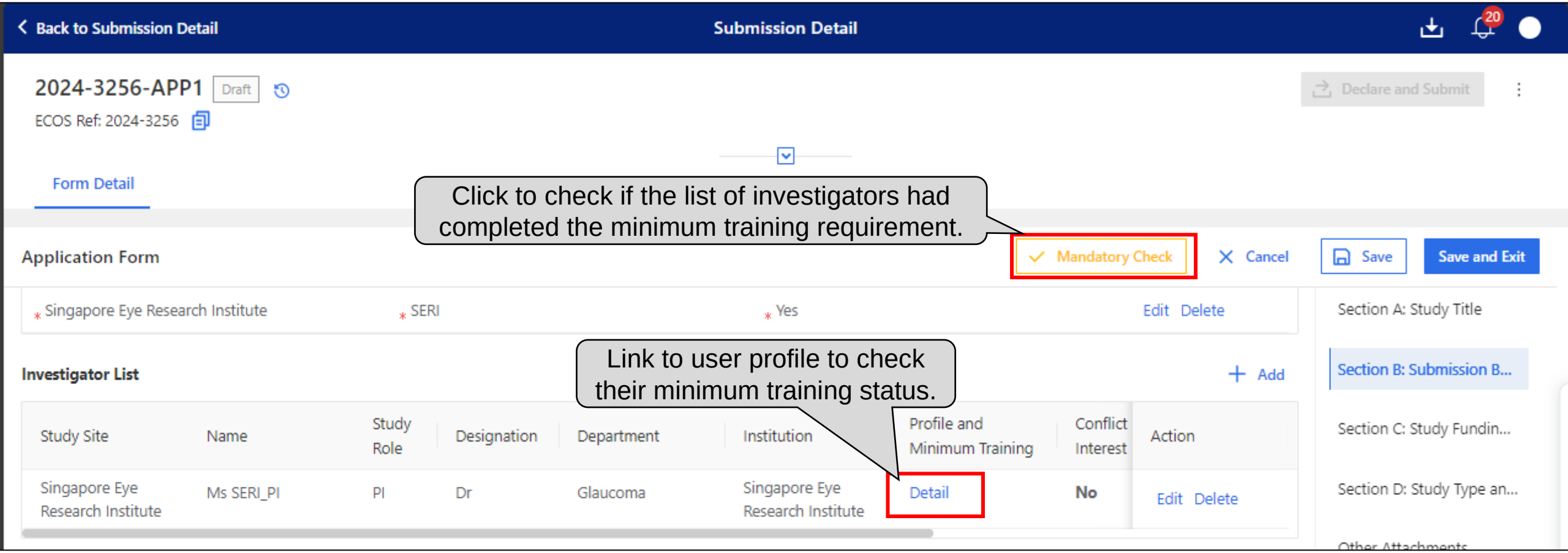
Adding Study Investigator

Application Form Export

Investigator List

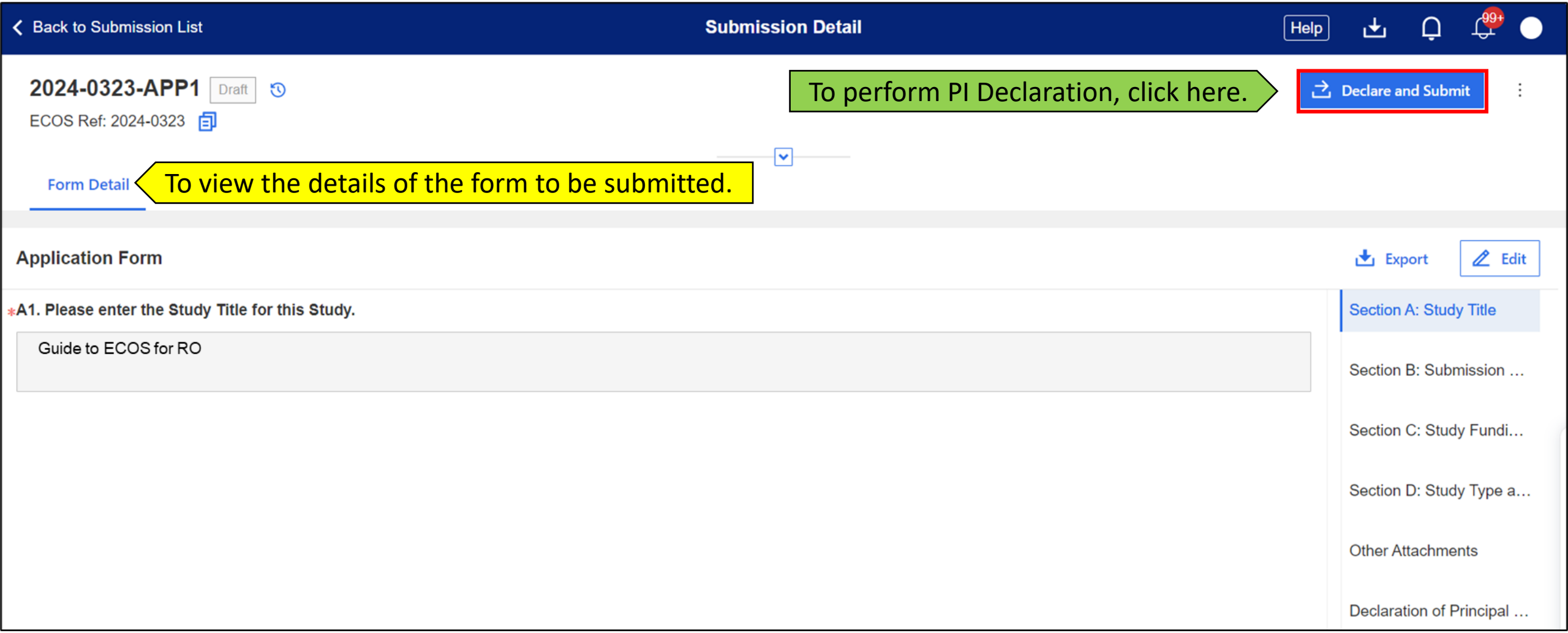
Study Site	Name	Study Role	Email	Designati
Singapore National Eye Centre (SNEC)	SNEC_Basic2	PI		Basic Us
Singapore National Eye Centre (SNEC)	SNEC_Basic1	Co-I		Basic Us
National Neuroscience Institute (NNI)	NNI_PI 1	Site PI		Senior C
National Neuroscience Institute (NNI)	NNI_PI 2	Co-I		Senior C

Minimum Training Requirement

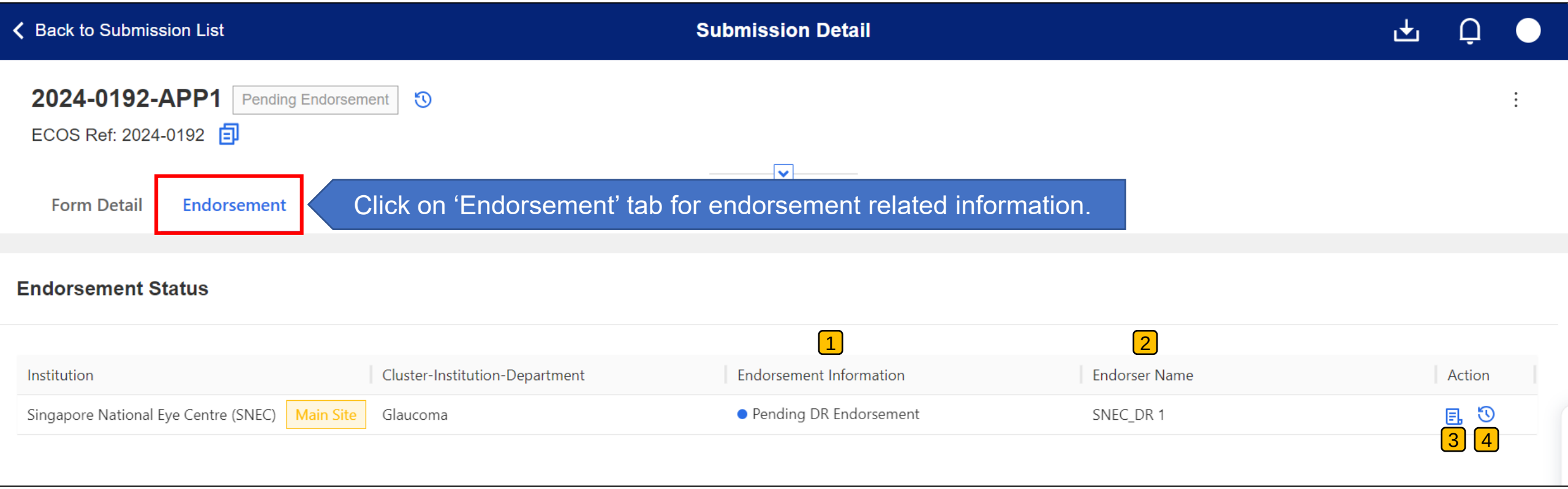


- ❑ Complete: The user had fulfilled the minimum training requirement.
- ❑ Incomplete: The user had not completed the minimum training requirement to conduct the type of study (e.g. Clinical Trials, HBR, non-HBR). Therefore, the form cannot be submitted.

PI Declaration



Endorsement Status



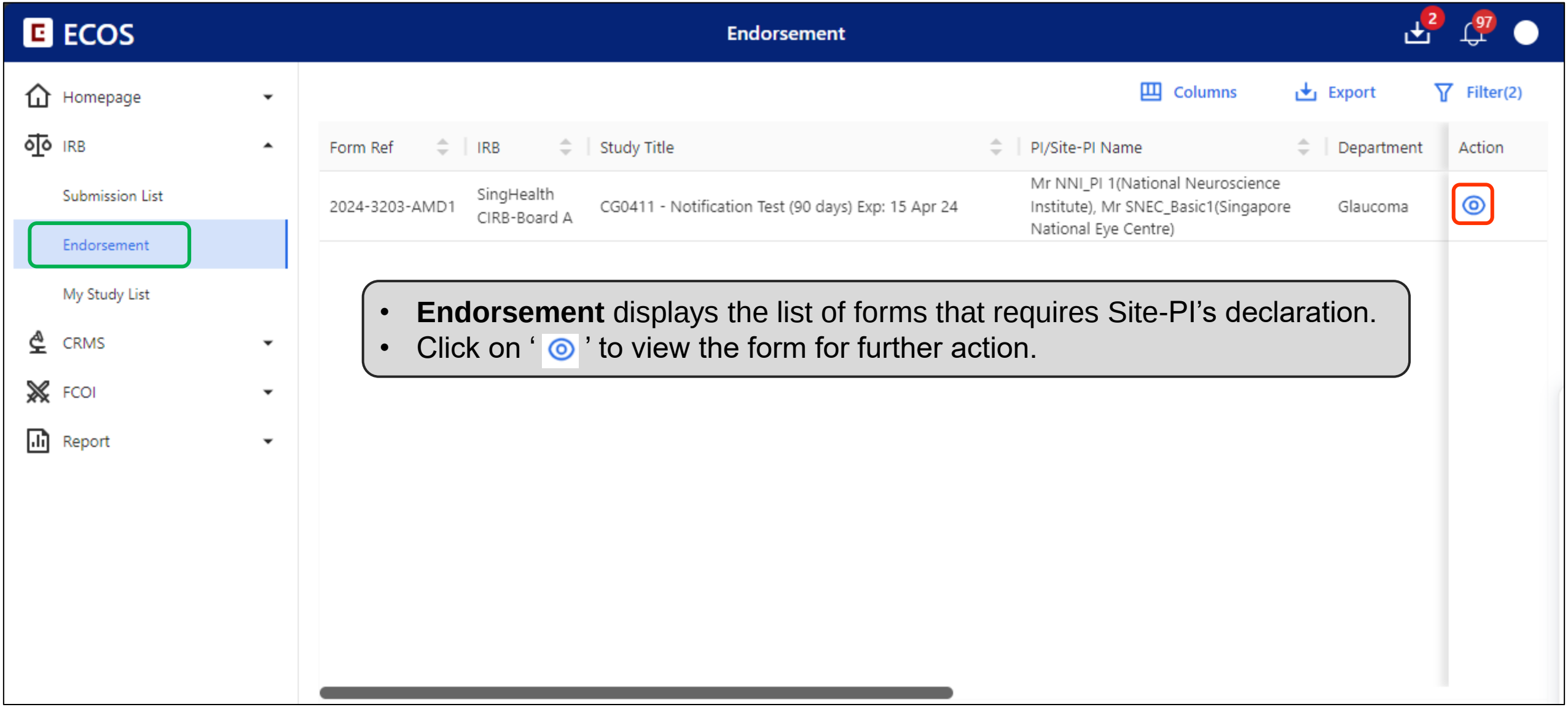
1 View the endorsement status.

2 View the name of endorser to complete the pending task.

3 Click to view query raised by endorsers.

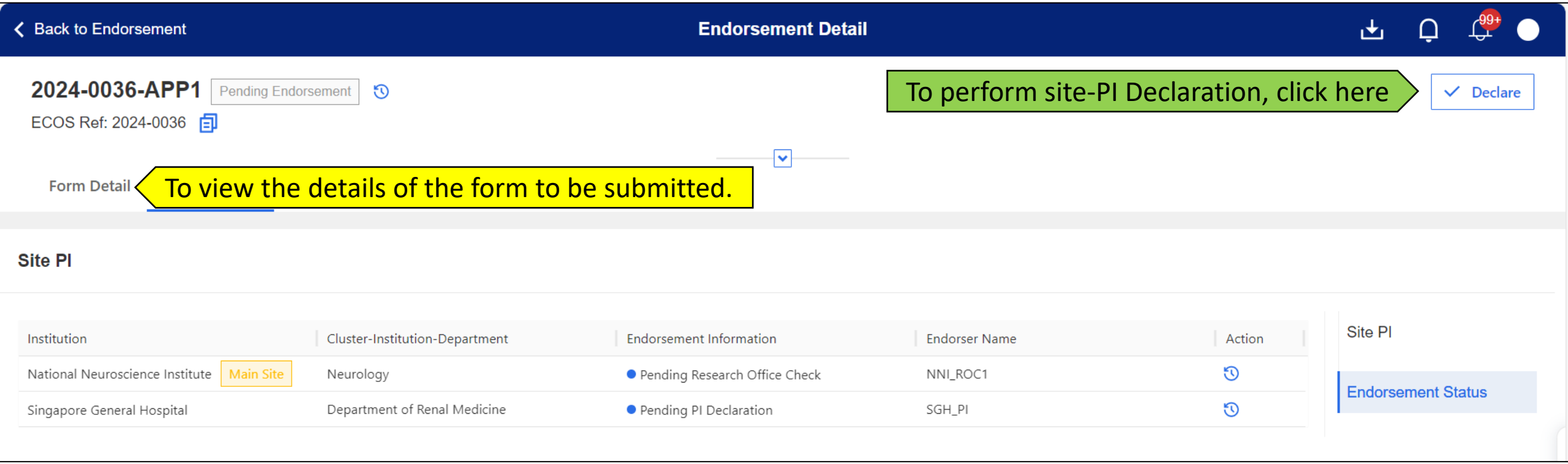
4 View the endorsement history.

IRB – Endorsement

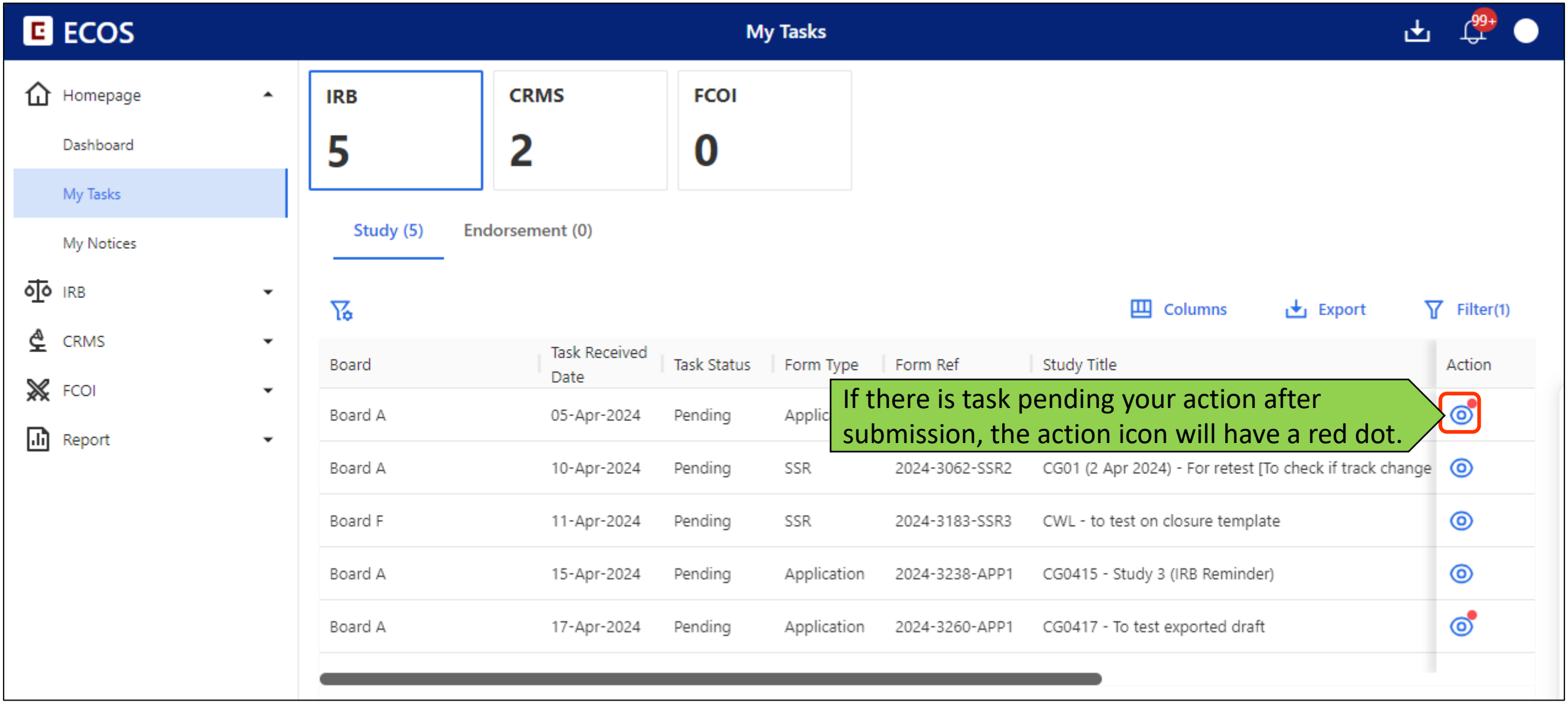


- **Endorsement** displays the list of forms that requires Site-PI's declaration.
- Click on ' ' to view the form for further action.

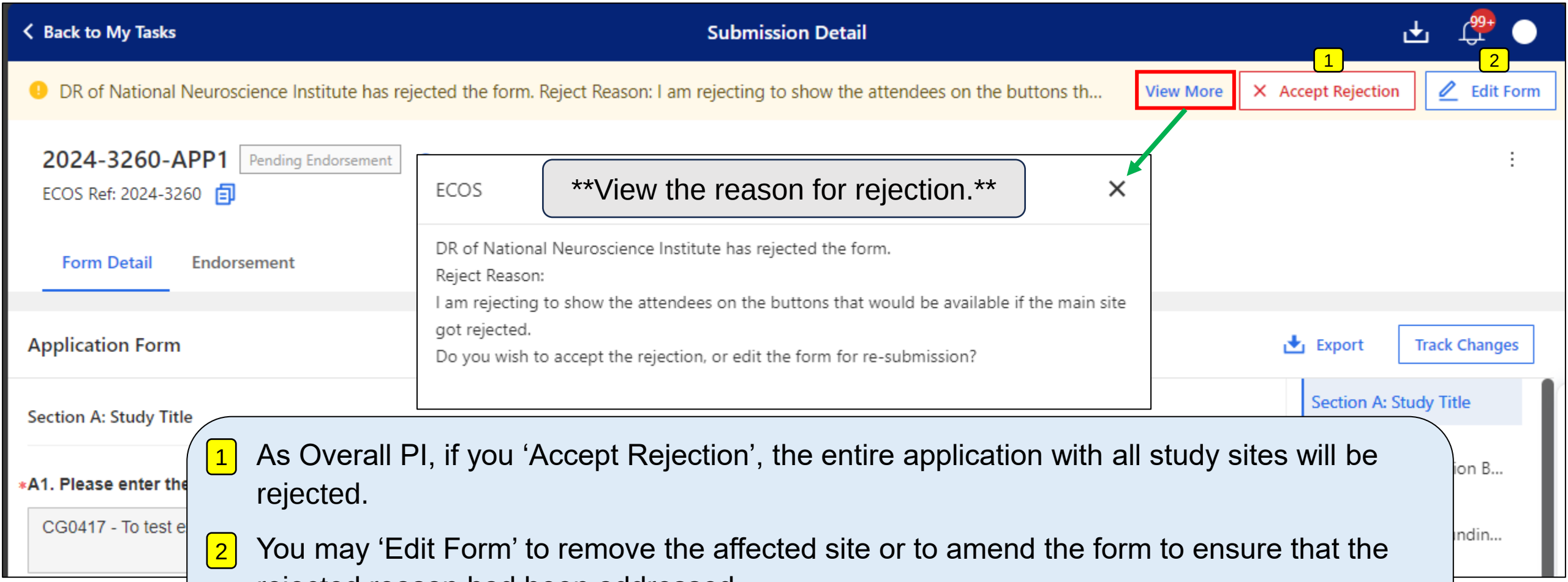
Endorsement by Site-PI



My Tasks – Rejected by DR / IR



Endorsement – Rejected by DR / IR (Main Site)

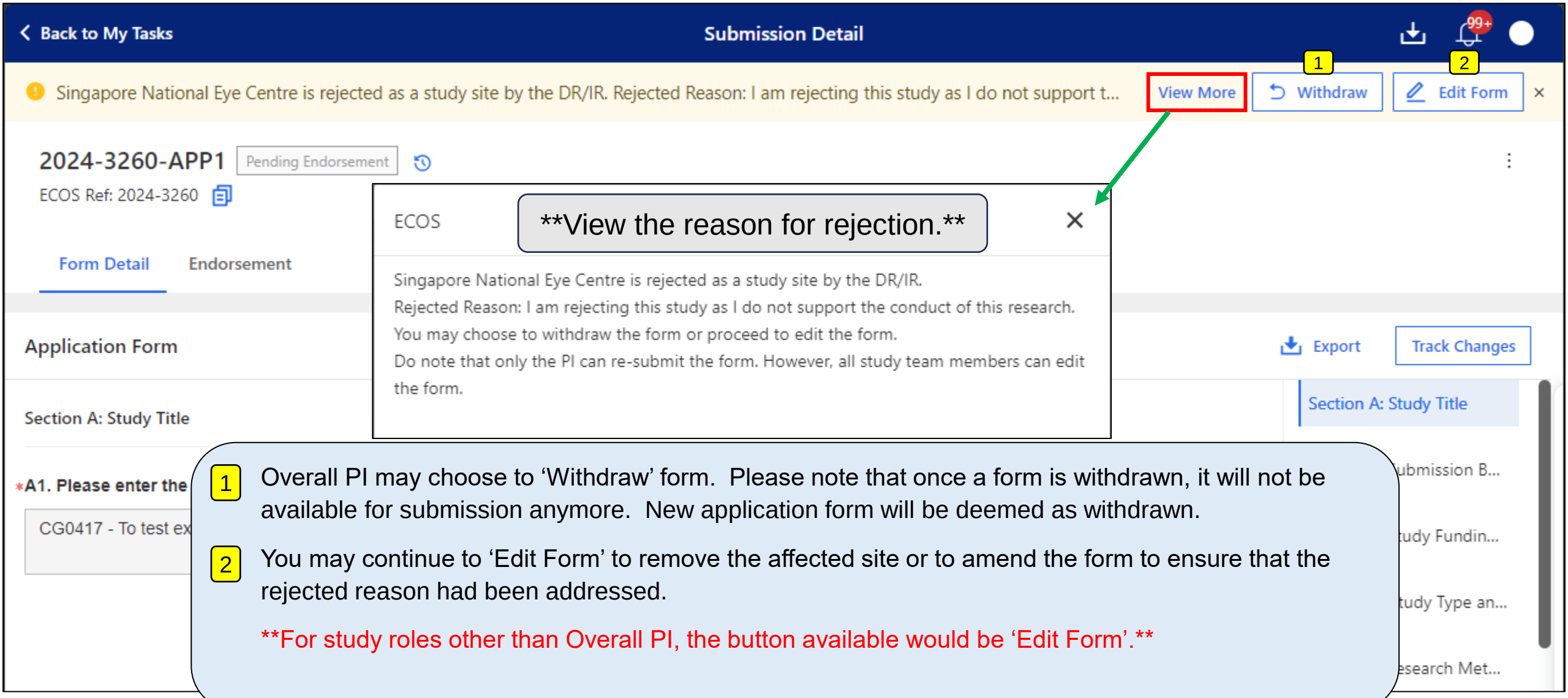


1 As Overall PI, if you ‘Accept Rejection’, the entire application with all study sites will be rejected.

2 You may ‘Edit Form’ to remove the affected site or to amend the form to ensure that the rejected reason had been addressed.

**For study roles other than Overall PI, they will only be able to view the reject reason.

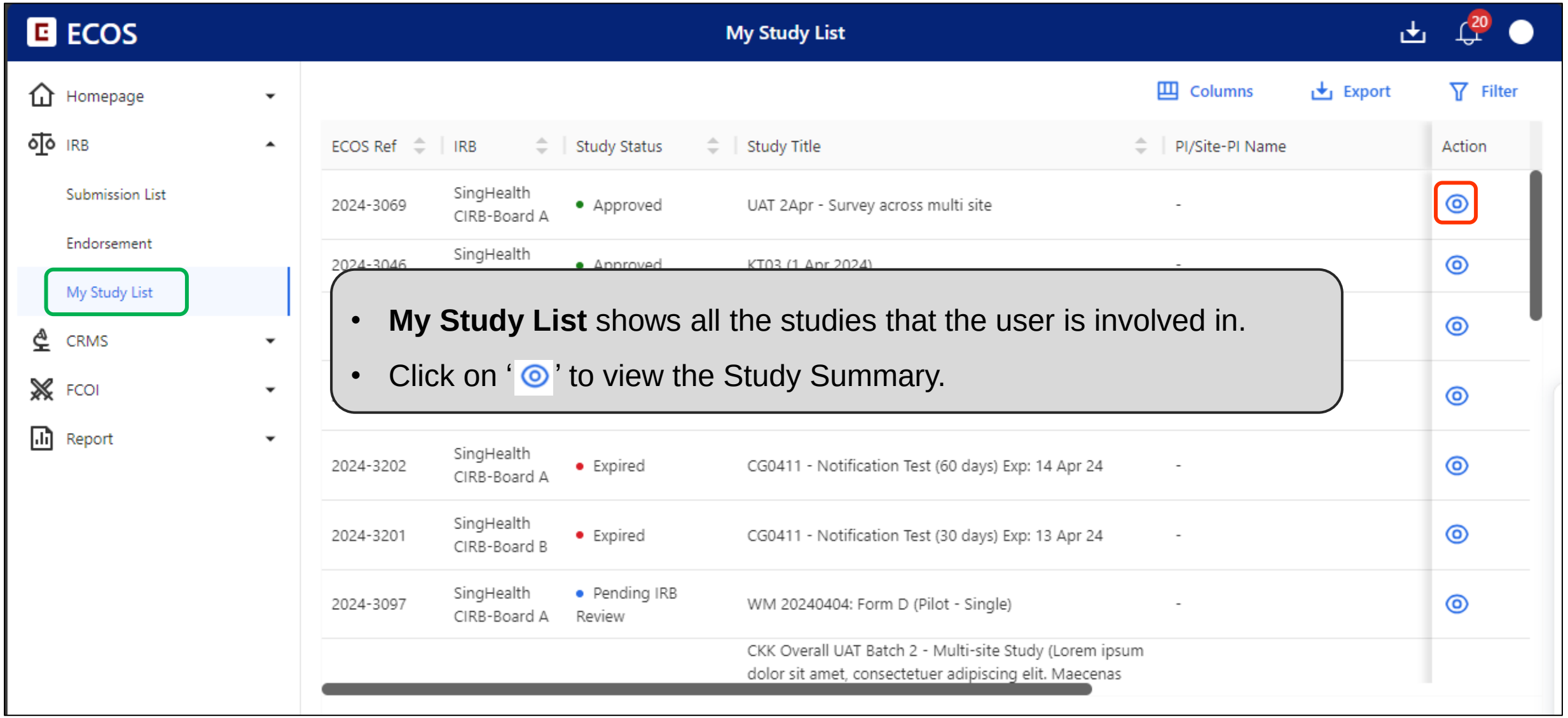
Endorsement – Rejected by DR / IR (Sub-Site)



1. Overall PI may choose to 'Withdraw' form. Please note that once a form is withdrawn, it will not be available for submission anymore. New application form will be deemed as withdrawn.
2. You may continue to 'Edit Form' to remove the affected site or to amend the form to ensure that the rejected reason had been addressed.

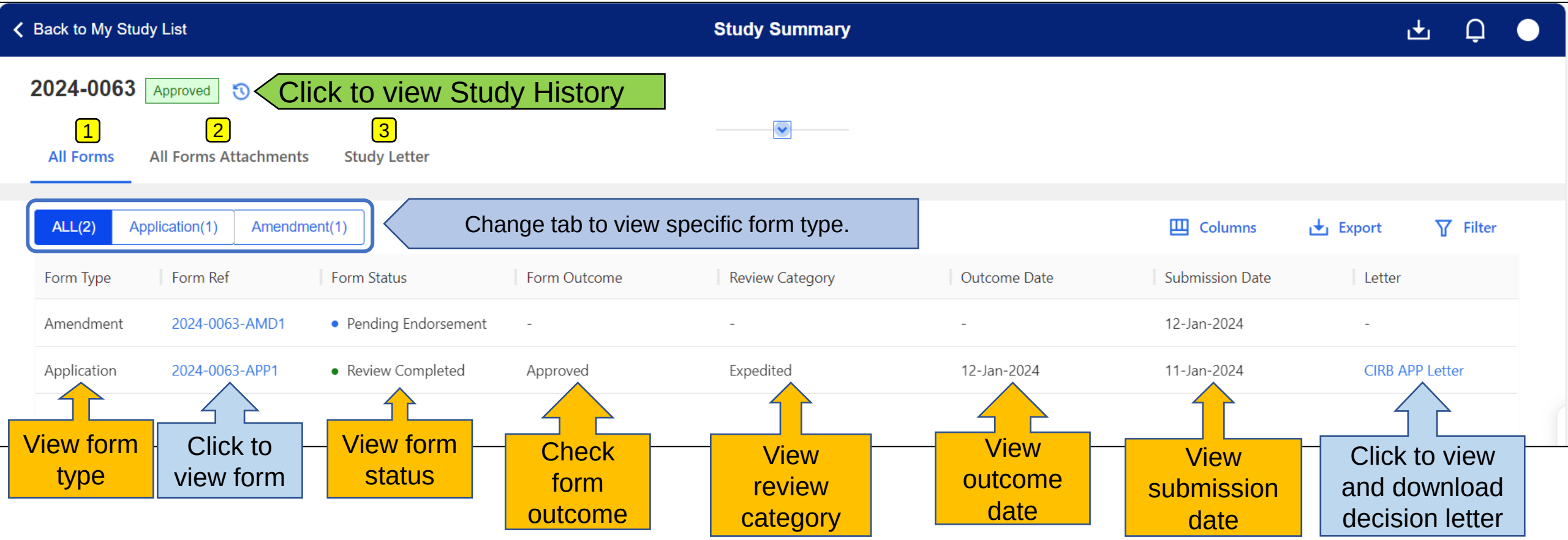
For study roles other than Overall PI, the button available would be 'Edit Form'.

IRB – My Study List



- **My Study List** shows all the studies that the user is involved in.
- Click on ‘ ’ to view the Study Summary.

Study Summary

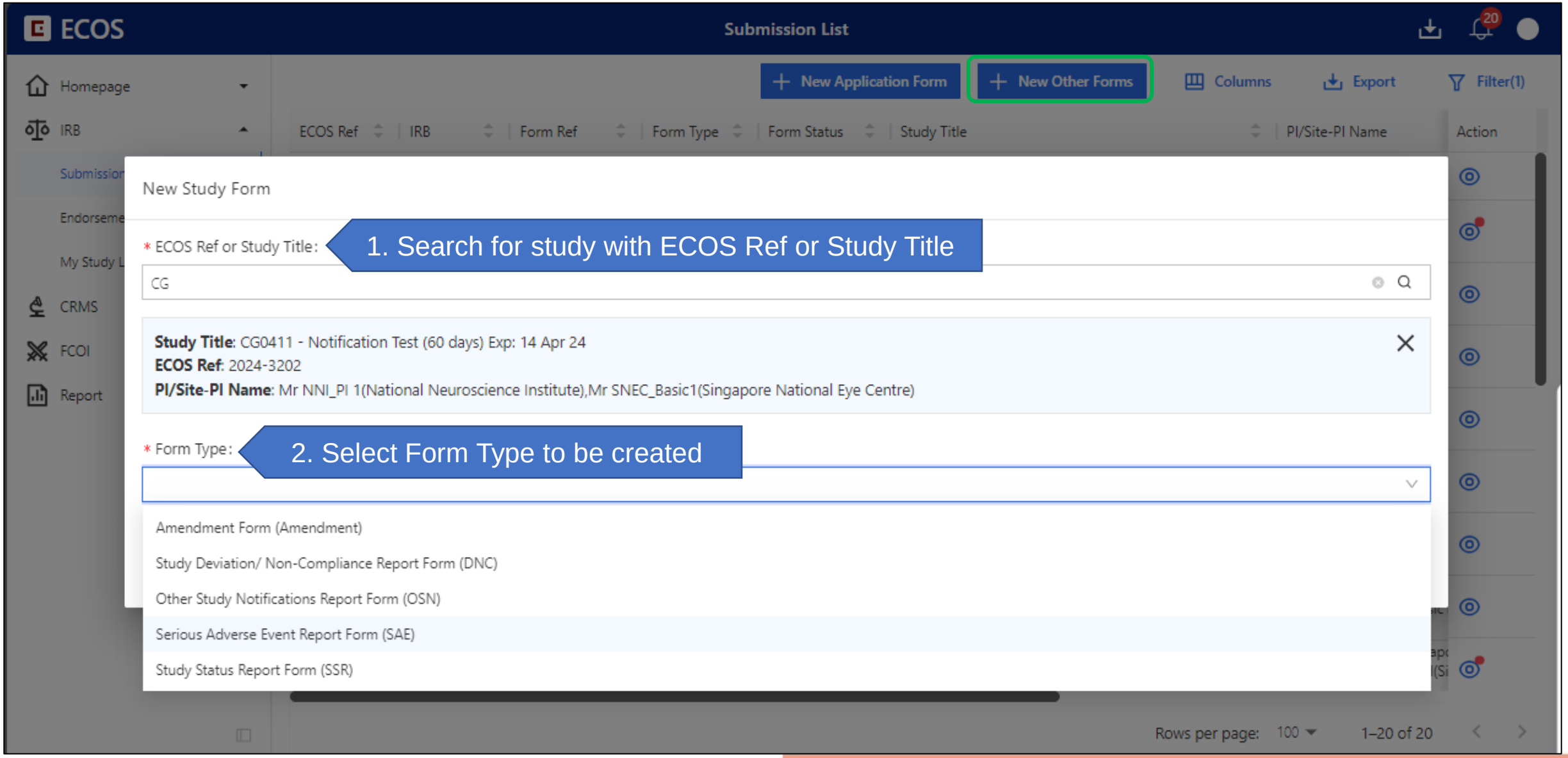


1 Display all forms that had been created for the study.

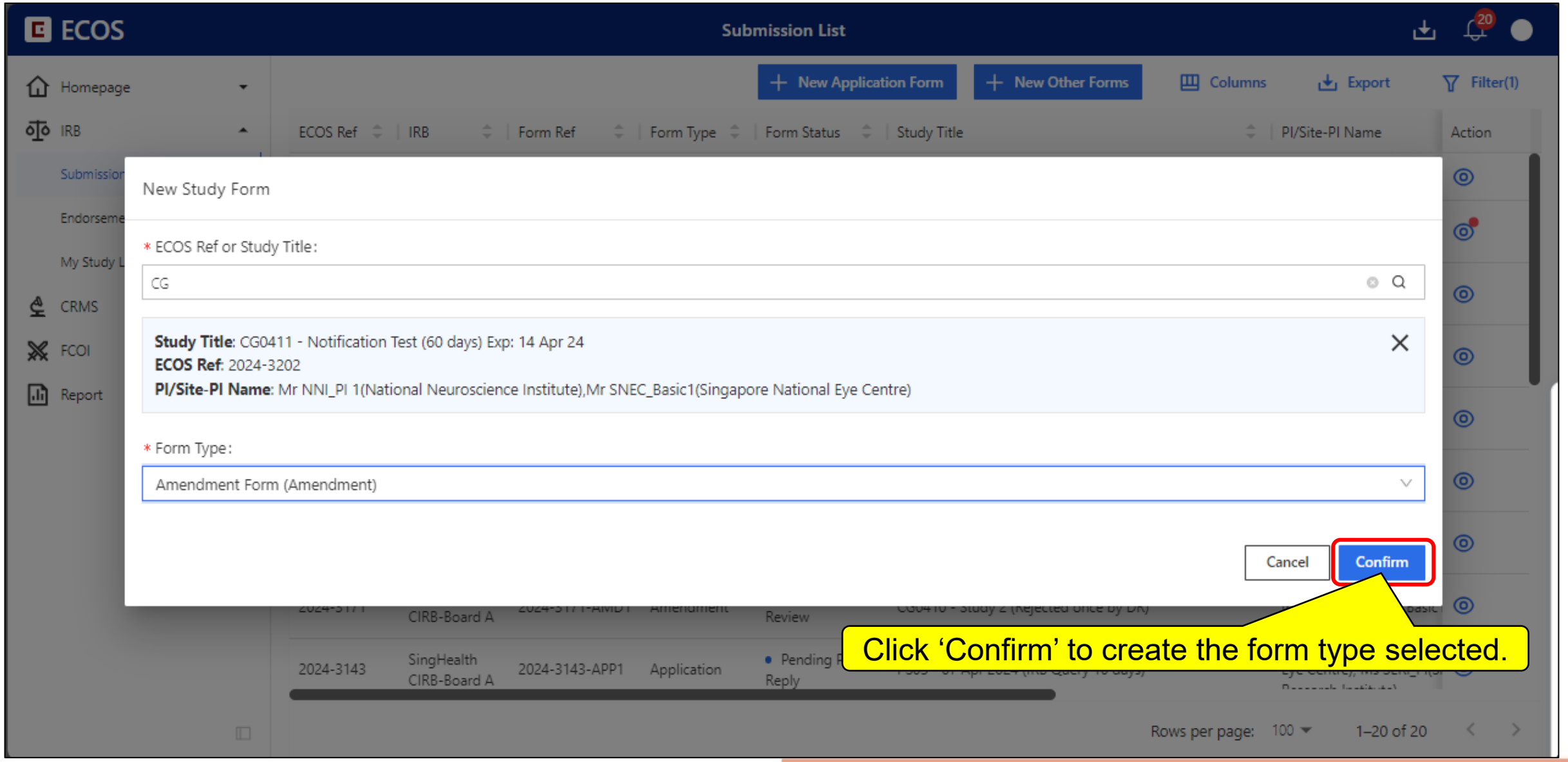
2 Display the list of attachments uploaded in all forms

3 Display the study letter issued by IRB (e.g. Suspension or Termination letter)

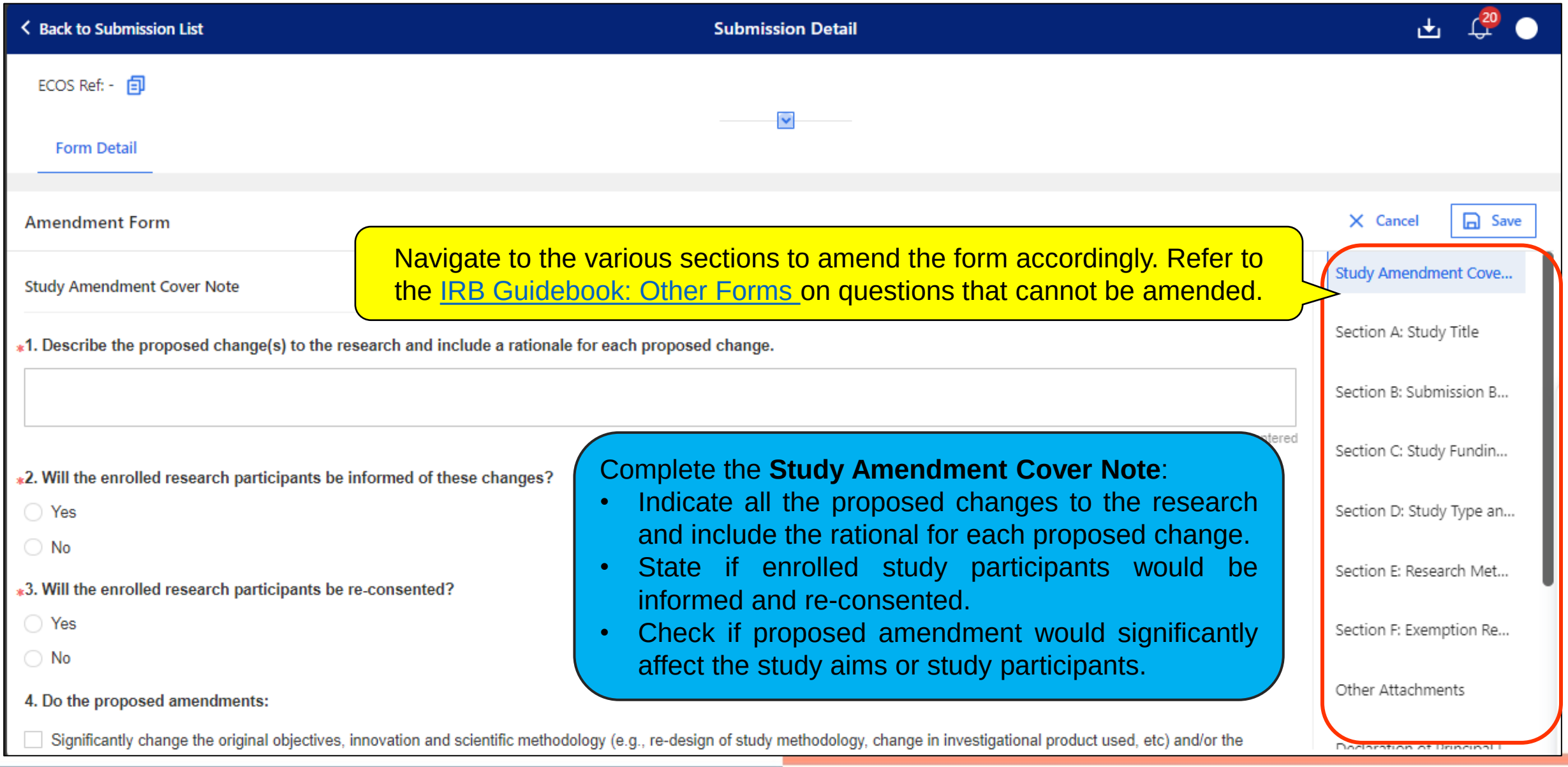
Creation of Other Forms



Creation of Other Forms



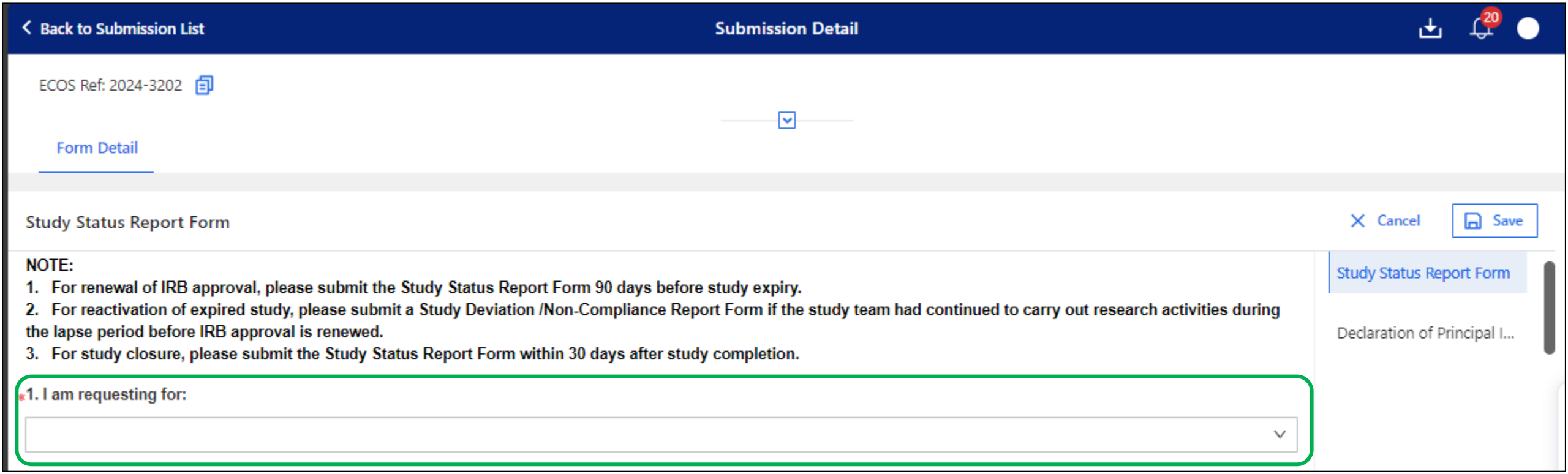
Amendment Form



Complete the **Study Amendment Cover Note**:

- Indicate all the proposed changes to the research and include the rational for each proposed change.
- State if enrolled study participants would be informed and re-consented.
- Check if proposed amendment would significantly affect the study aims or study participants.

Study Status Report Form (SSR)



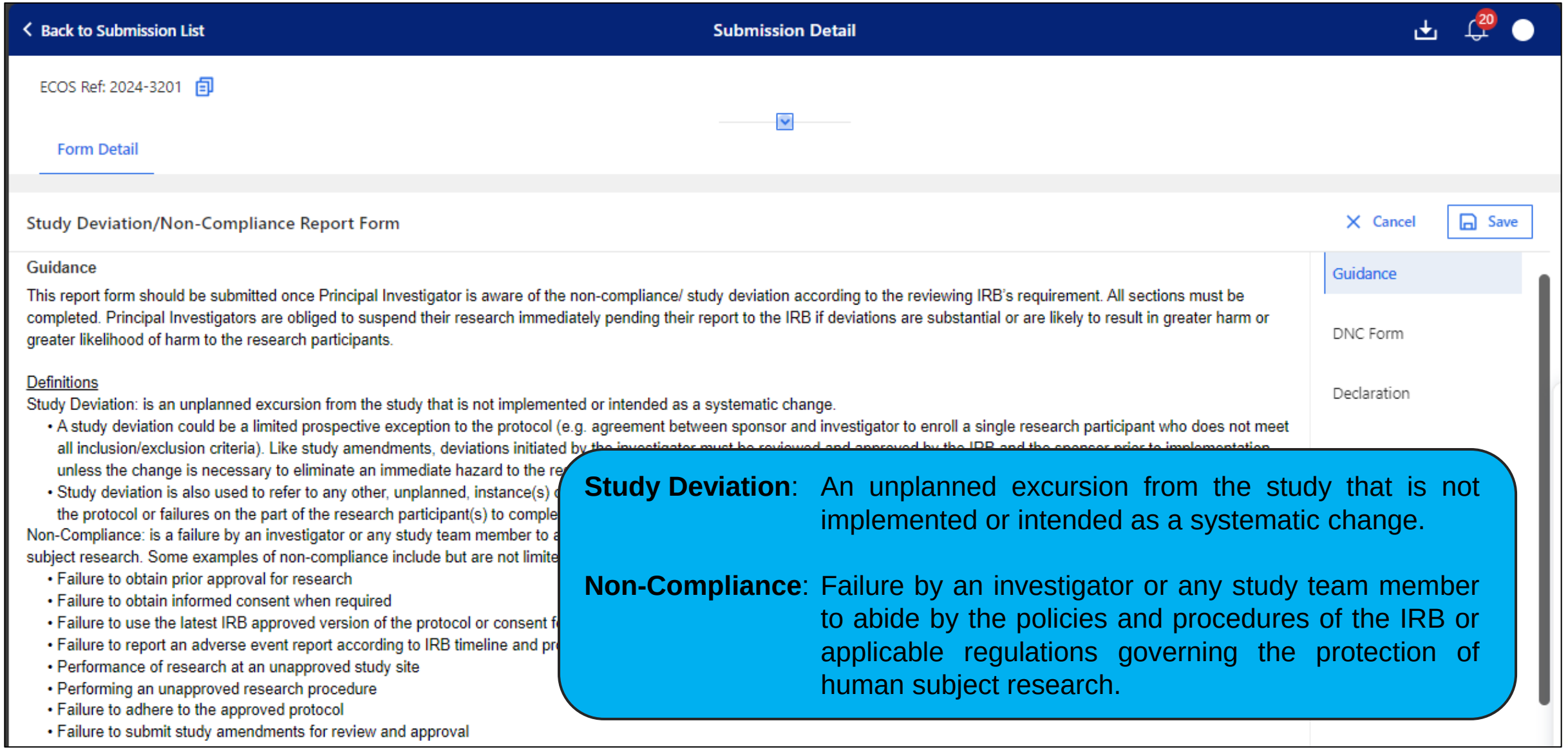
Select the request for submission of SSR as follows:

- ❑ Study Renewal
- ❑ Study Closure
- ❑ Study Status Update
- ❑ Study Reactivation

Study Status Report Form (SSR)

Type of SSR	Note
Study Renewal	For renewal of IRB approval. ➢ It is recommended for the form to be submitted at least 2 months (60 days) before expiry.
Study Status Update	For updating of study status such as change of study status from “Ongoing” to “Suspended”.
Study Closure	For reporting of study completion or termination. ➢ SSR should be submitted within 30 days for study completion. ➢ SSR should be submitted within 7 days for study termination.
Study Reactivation	For request to re-open a research study which is previously closed or where the approval has lapsed. ➢ For reactivation of expired study, please submit a DNC form if research activities were carried out during the lapse period.

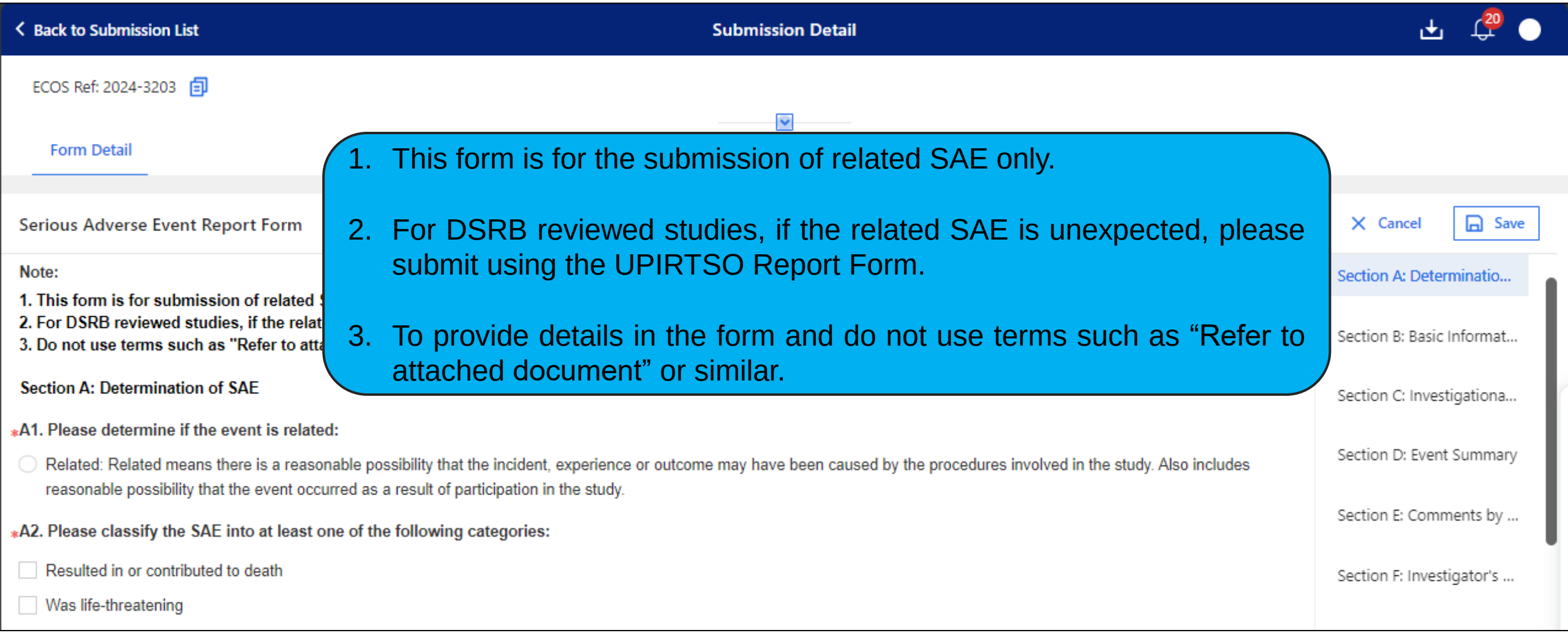
Study Deviation/ Non-Compliance Report Form (DNC)



Study Deviation: An unplanned excursion from the study that is not implemented or intended as a systematic change.

Non-Compliance: Failure by an investigator or any study team member to abide by the policies and procedures of the IRB or applicable regulations governing the protection of human subject research.

Serious Adverse Event Report Form (SAE)



1. This form is for the submission of related SAE only.
2. For DSRB reviewed studies, if the related SAE is unexpected, please submit using the UPIRTSO Report Form.
3. To provide details in the form and do not use terms such as “Refer to attached document” or similar.

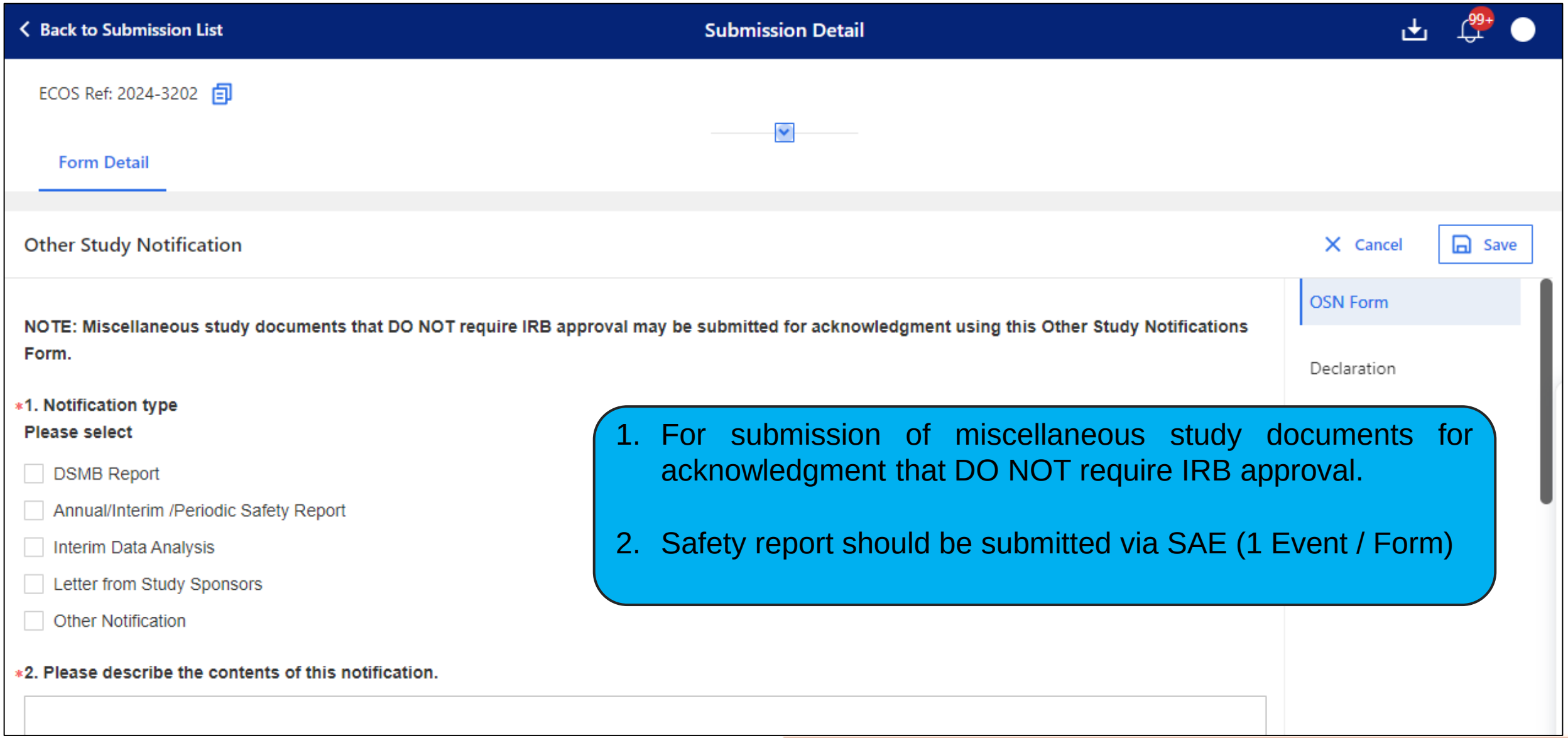
Serious Adverse Event Report Form (SAE)

Type of SAE	Note
Local SAE	Refer to SAE occurring in participants recruited by sites that were reviewed by IRB. If there is a specific location listed in Section B2. (a). of the application/amendment form, please specify it under Section D, question 2.
Non-local SAE (Overseas SAE)	Refers to SAE occurring in participants recruited by sites that were not reviewed by IRB. For non-local SAE, please select 'Others' and list the overseas study site in Section B1.

1. '**Initial Report**' should be selected if event is being reported for the first time. If information is incomplete at the point of initial report submission, PI should adhere to the reporting timeline and complete as much as possible.
2. '**Follow-up Report**' should be selected if there is any additional relevant information related to the initial report and to provide the Form Ref of the SAE Report that were submitted in relation to this event.

Note: If the event does not fulfil the submission criteria, you would not be able to submit the SAE.

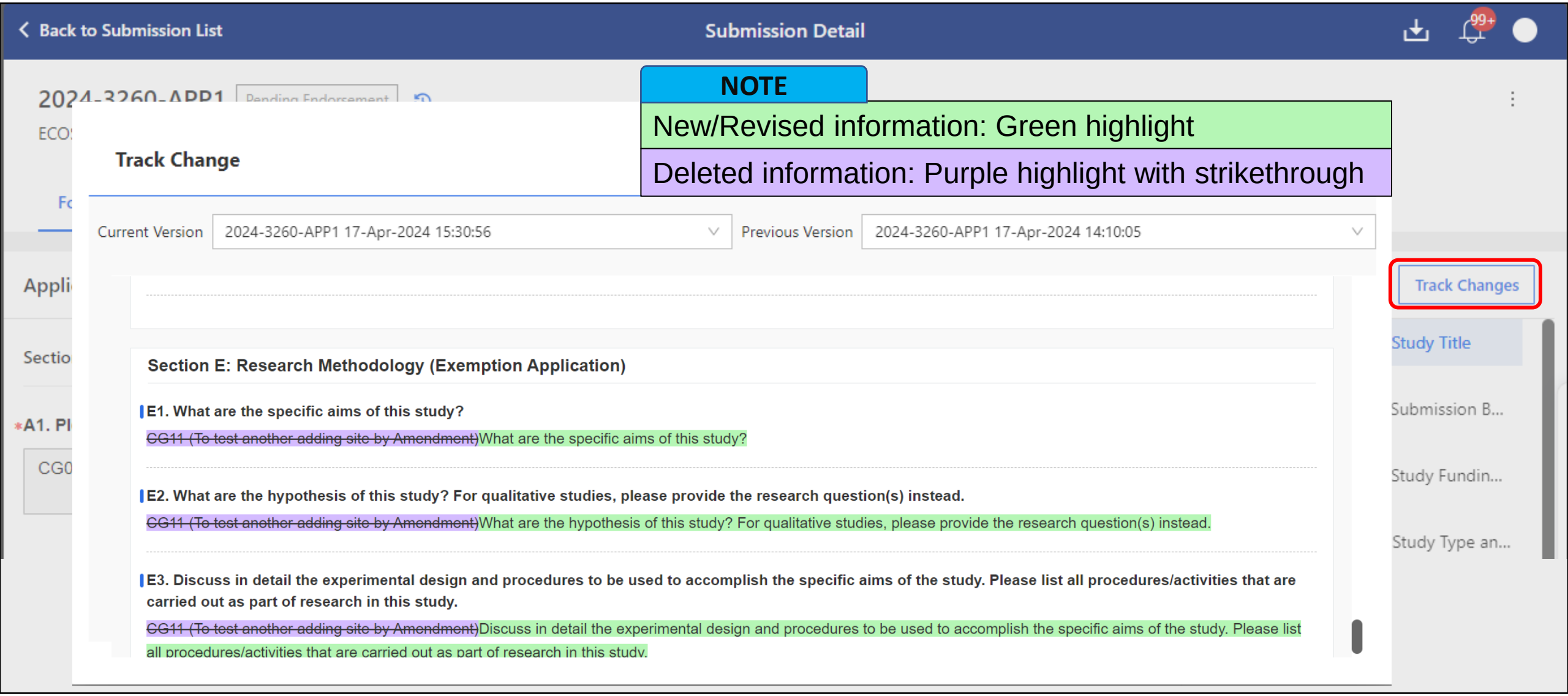
Other Study Notification Form (OSN)



1. For submission of miscellaneous study documents for acknowledgment that DO NOT require IRB approval.
2. Safety report should be submitted via SAE (1 Event / Form)

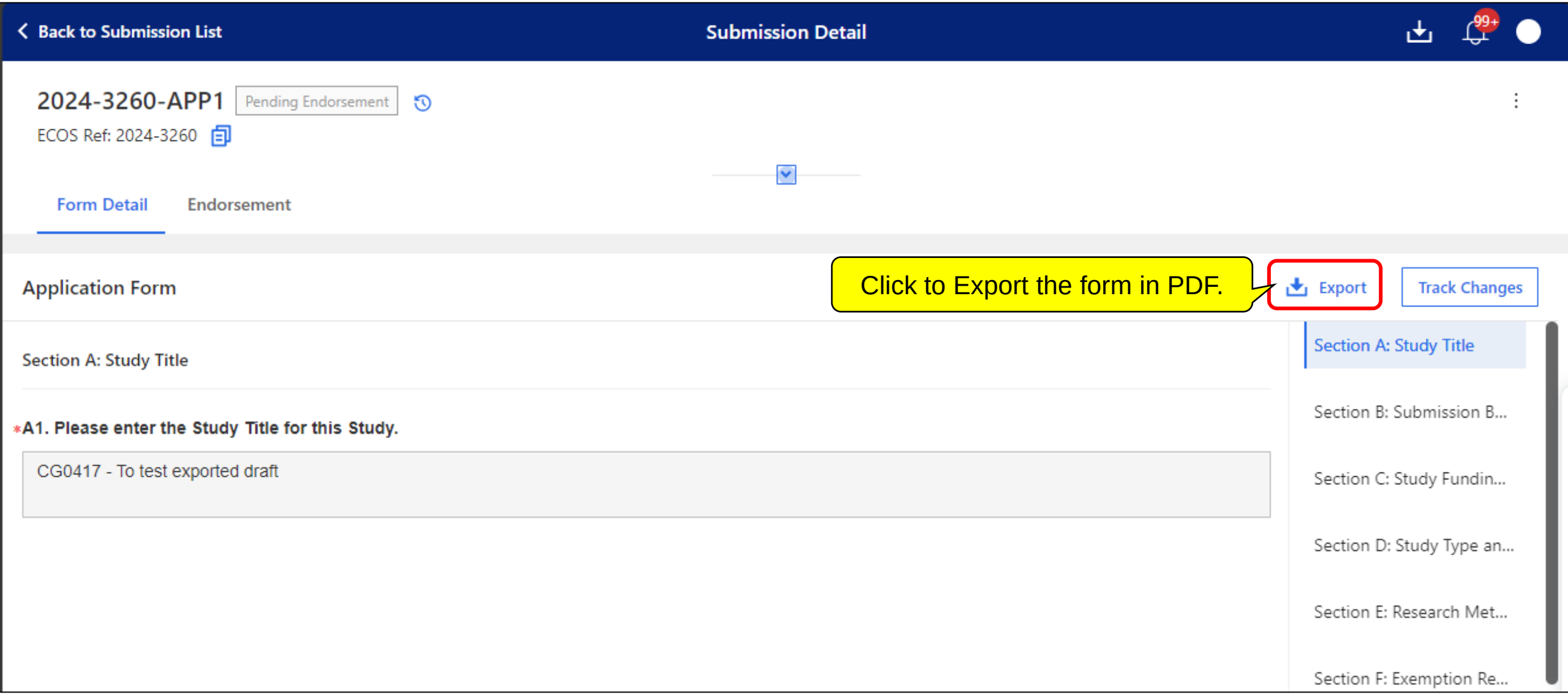
Track Changes

Still under development, please use at your own risk.

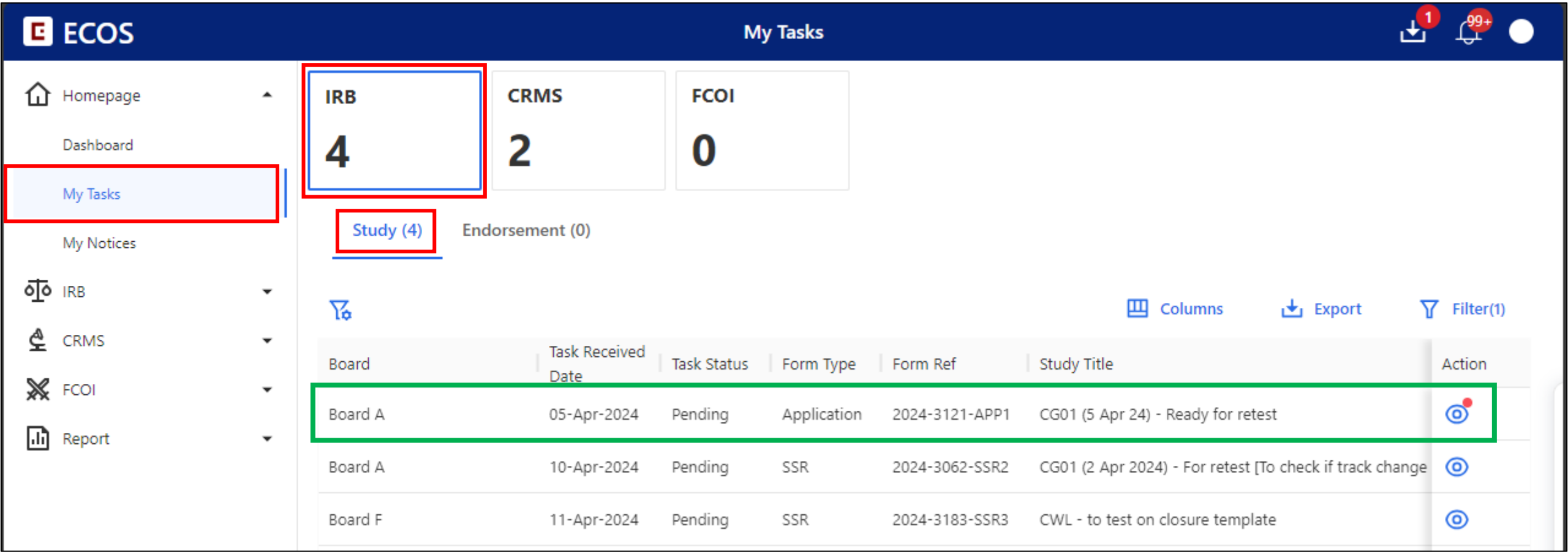


Export

Still under development, please use at your own risk.

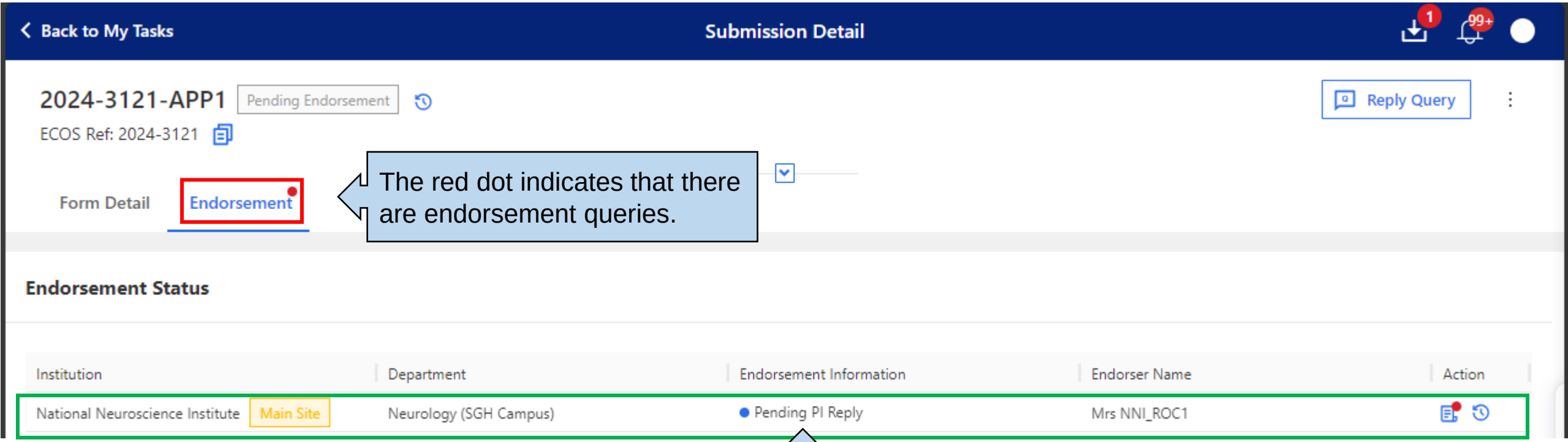


Endorsement Query - Pending PI Reply



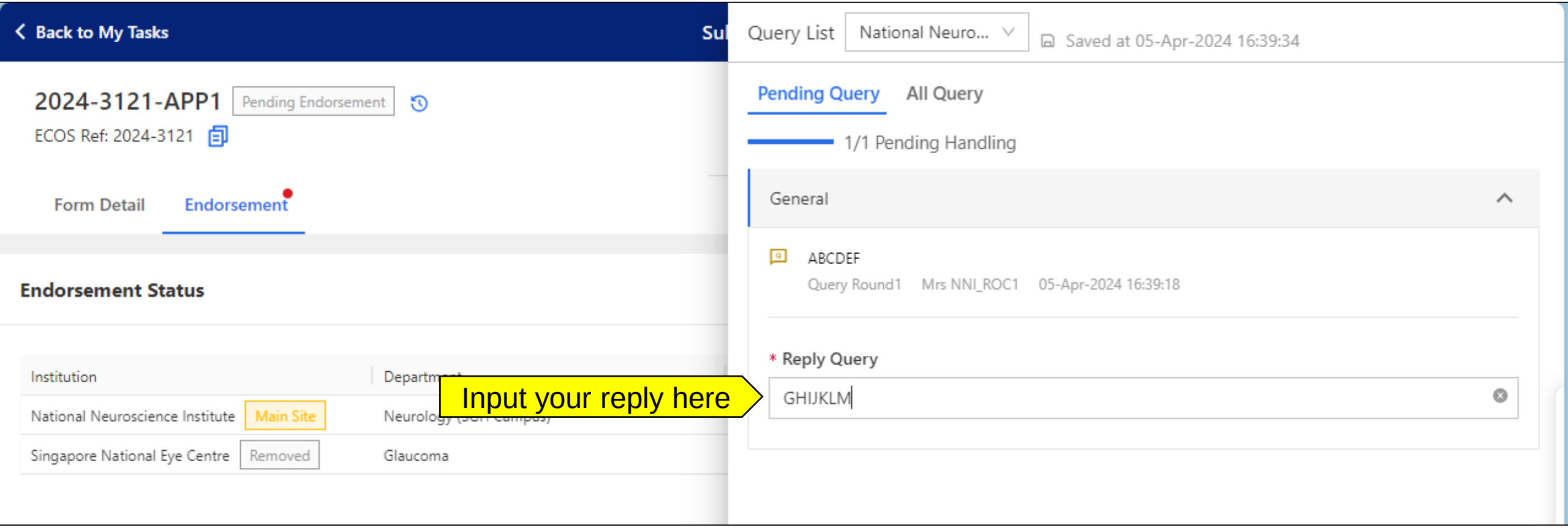
For PI, when there are endorsement query pending PI reply, the PI will receive a task in [My Tasks] and the action button would be with a red dot to symbolize that there are action required.

Endorsement Query - PI Reply



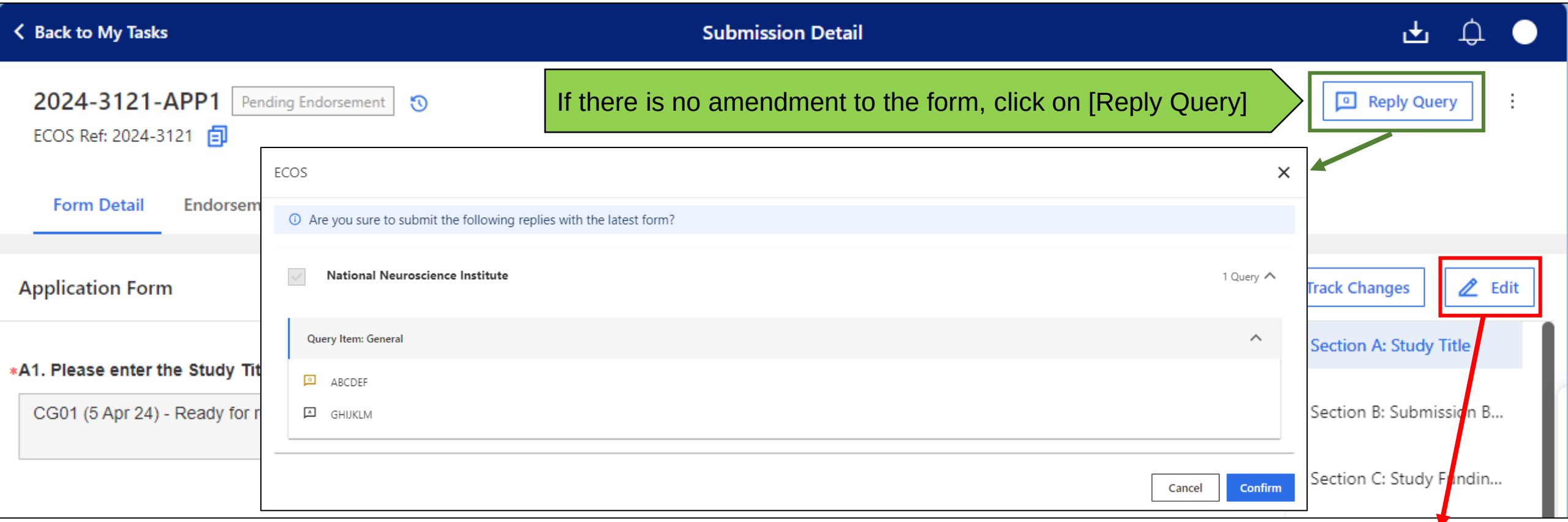
Click on the ‘ ’ icon to view and address the queries sent by ROC, DR or IR.

Endorsement Query - PI Reply



Note: Click the area outside to close the Query List.

Endorsement Query - PI Reply

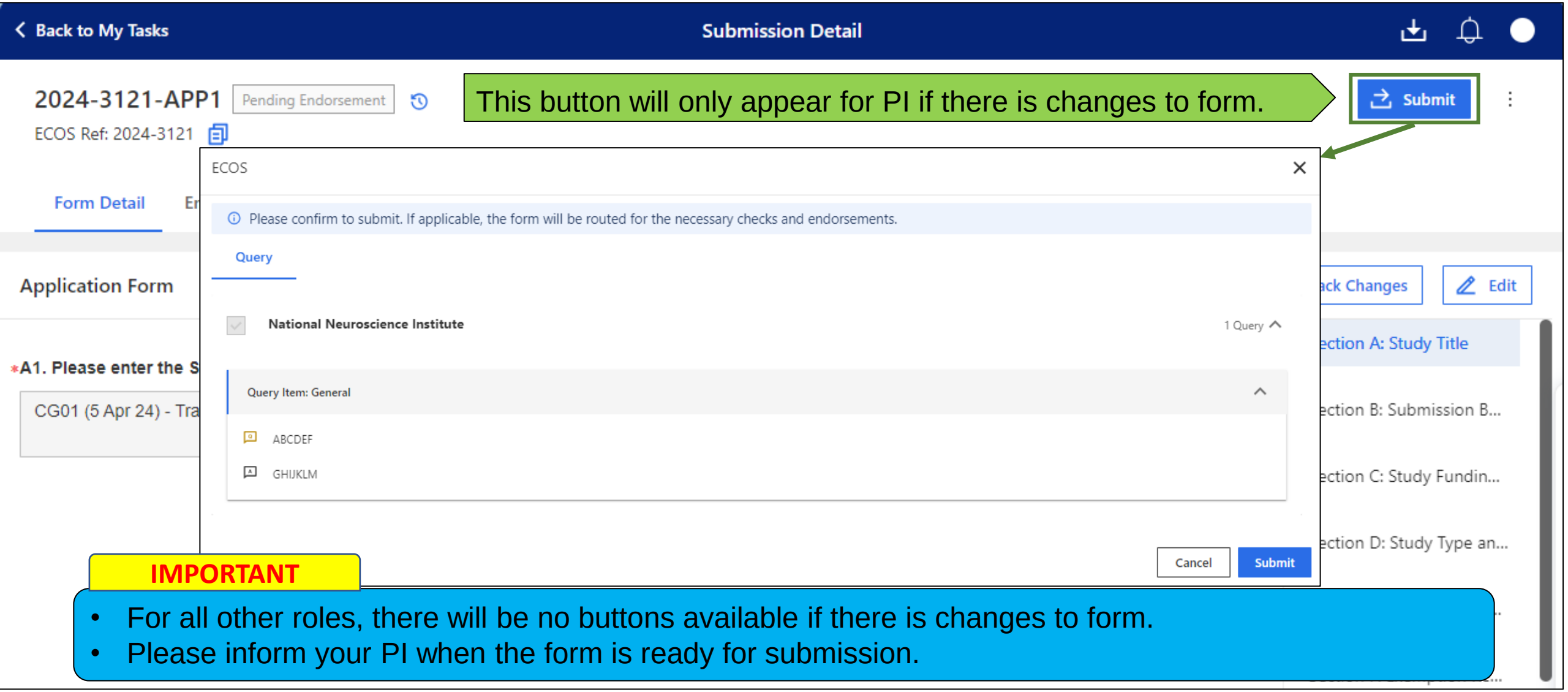


Click on [Edit] to amend the form if required.

IMPORTANT

- All roles will have the [Reply Query] button if there are no changes to the form.
- If there are changes to the form, only Overall PI will have the [Submit] button.

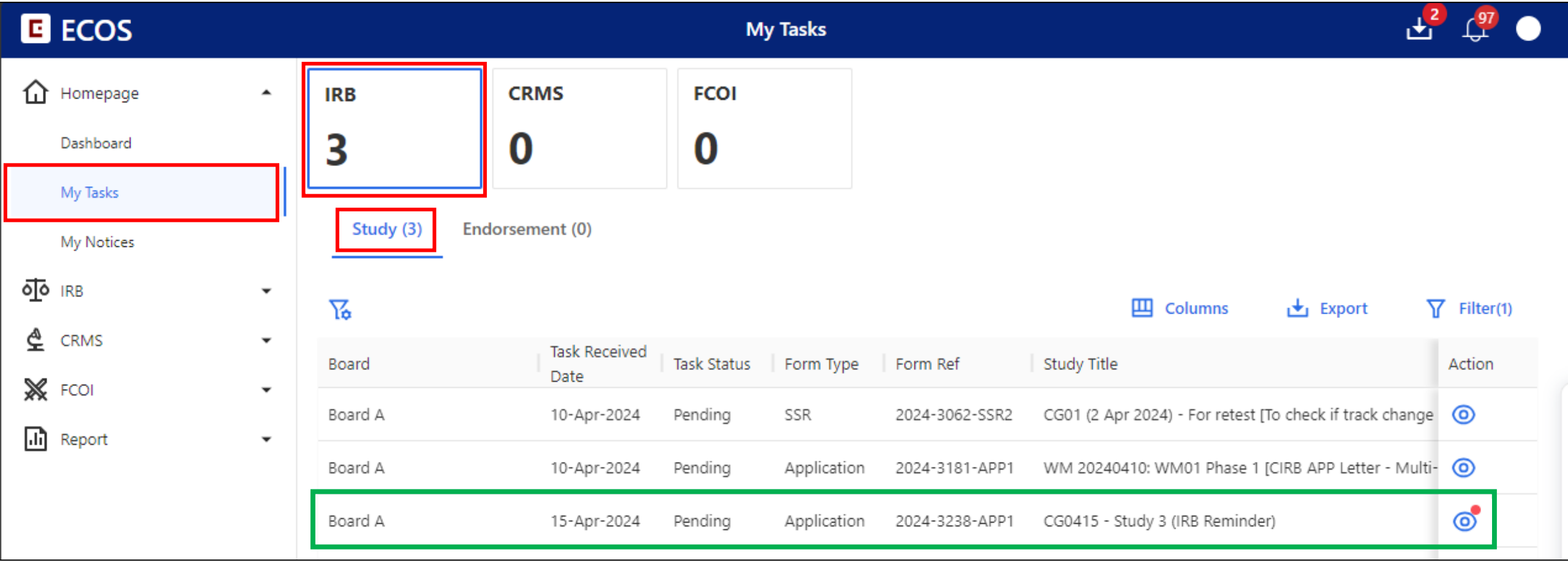
Endorsement Query - PI Reply with Amendment to Form



IMPORTANT

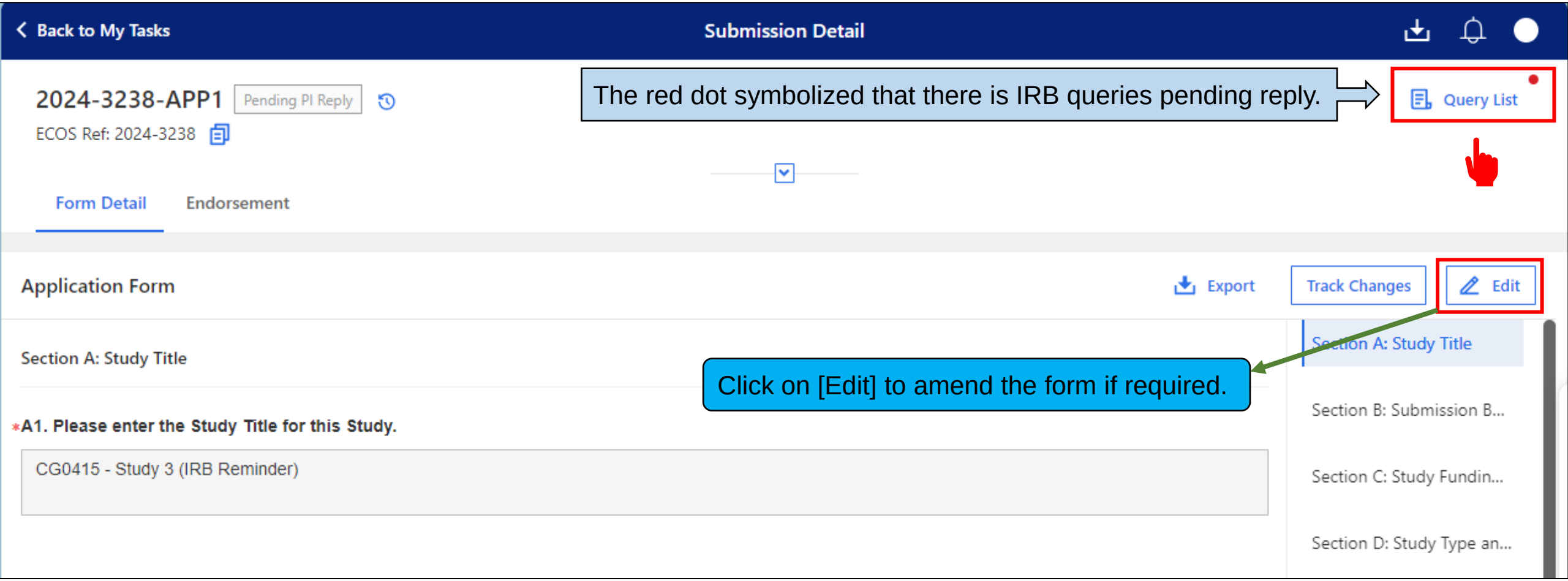
- For all other roles, there will be no buttons available if there is changes to form.
- Please inform your PI when the form is ready for submission.

IRB Query - Pending PI Reply

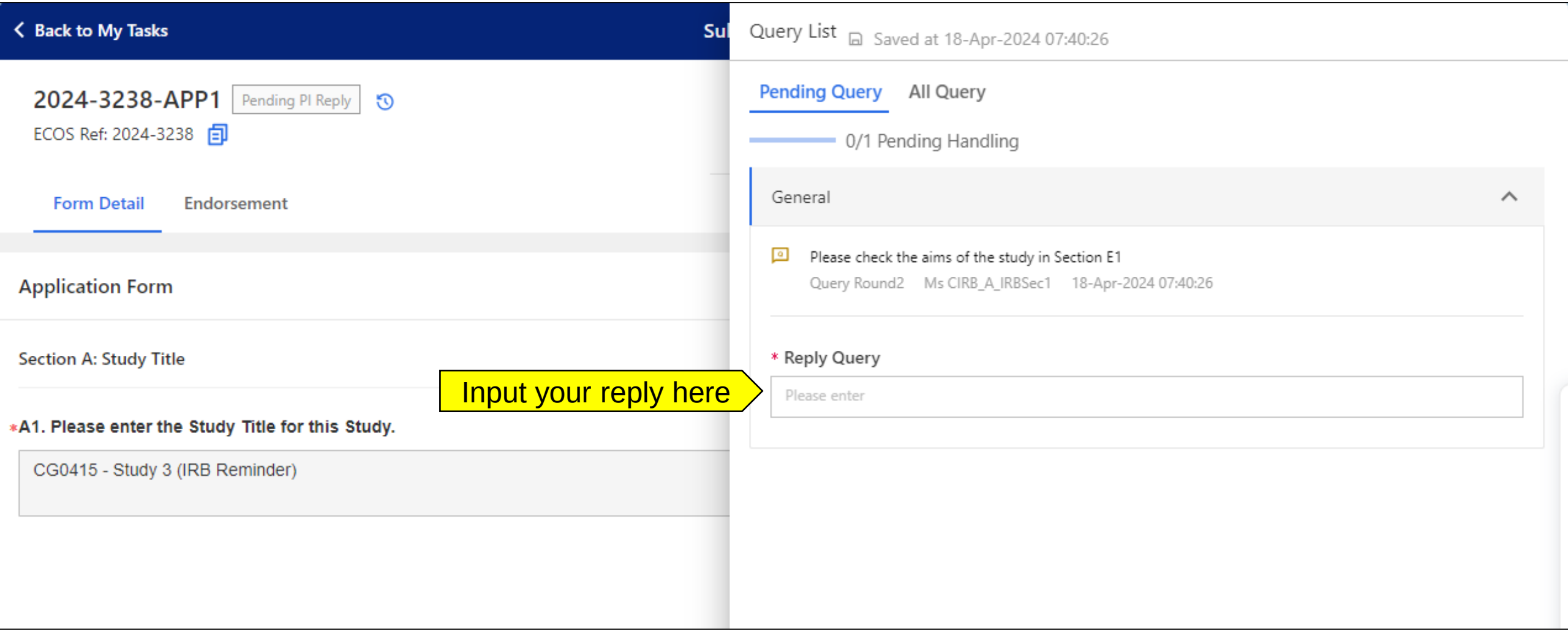


For PI, when there are IRB query pending PI reply, the PI will receive a task in [My Tasks] and the action button would be with a red dot to symbolize that there are action required.

IRB Query – PI Reply



IRB Query – PI Reply



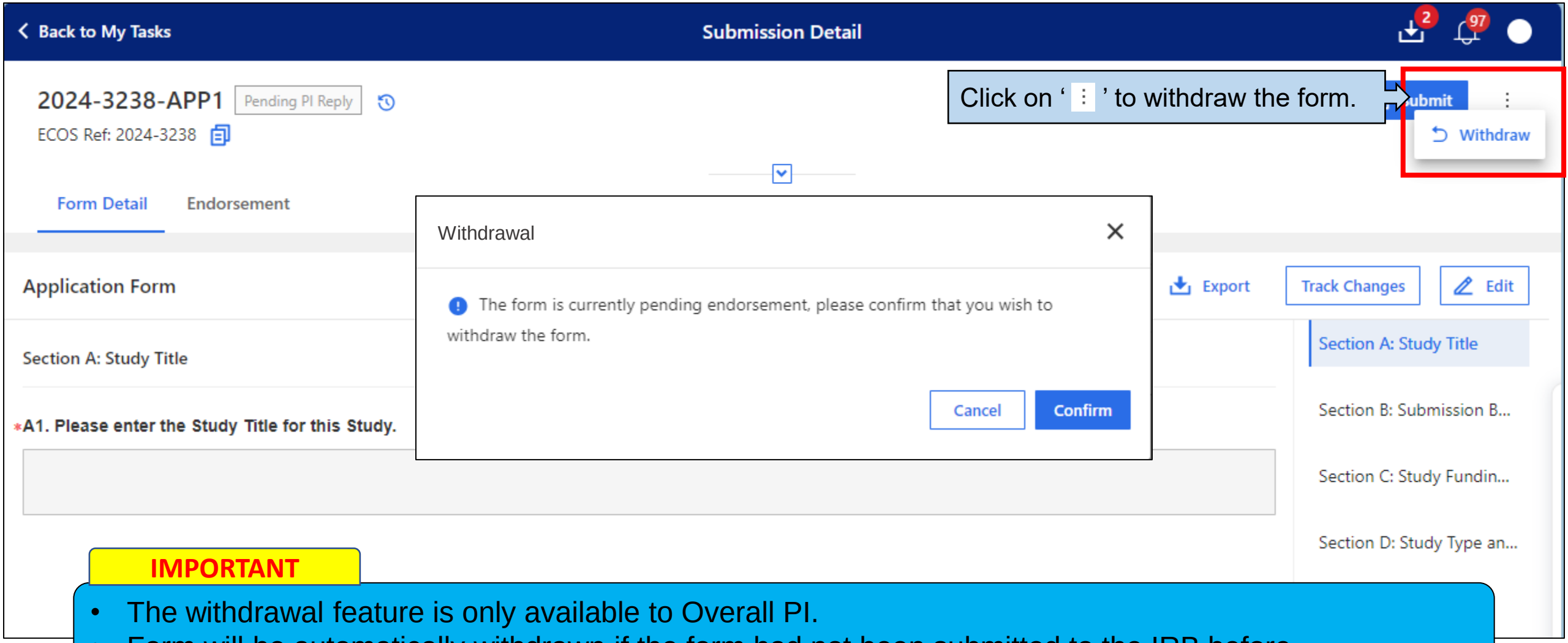
Note: Click the area outside to close the Query List.

IRB Query – PI Reply

IMPORTANT

- Only the Overall PI will have the [Submit] button.
- Please inform your PI when the queries had been addressed and is ready for submission.

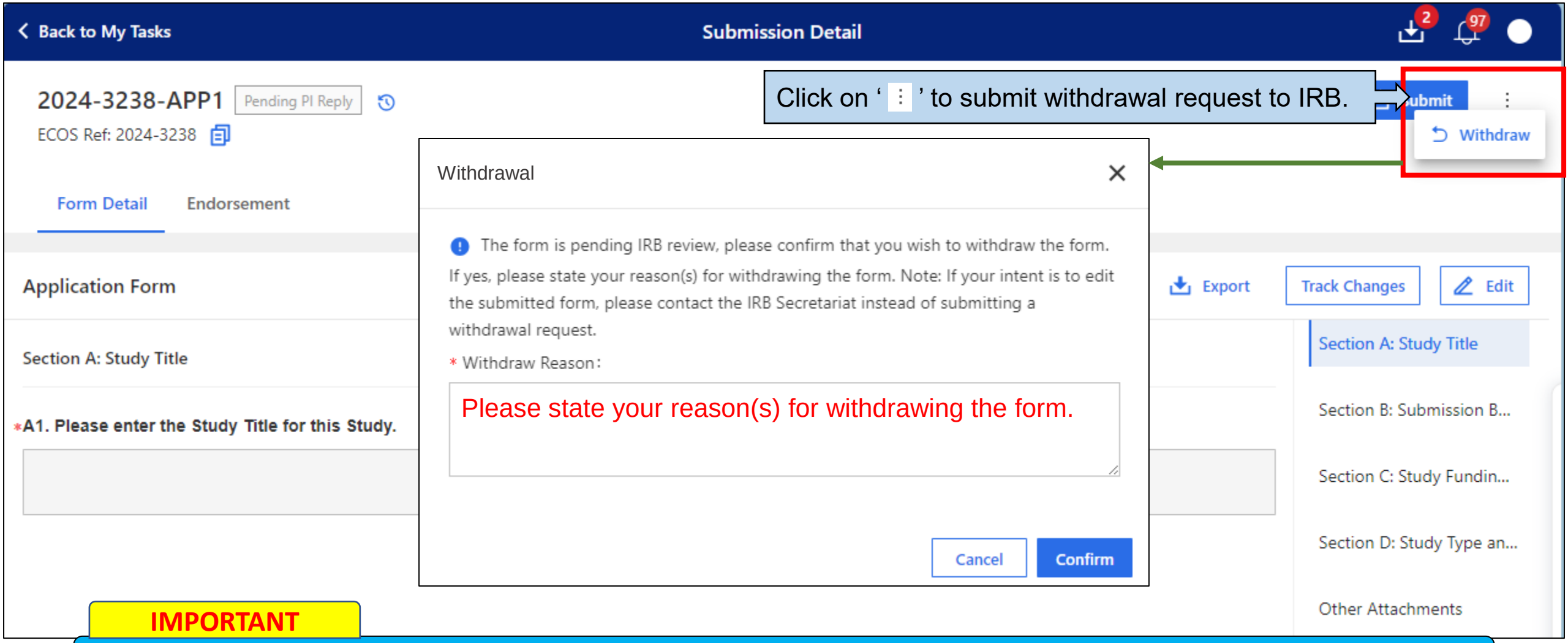
Withdrawal of Form – Pending Endorsement



IMPORTANT

- The withdrawal feature is only available to Overall PI.
- Form will be automatically withdrawn if the form had not been submitted to the IRB before.

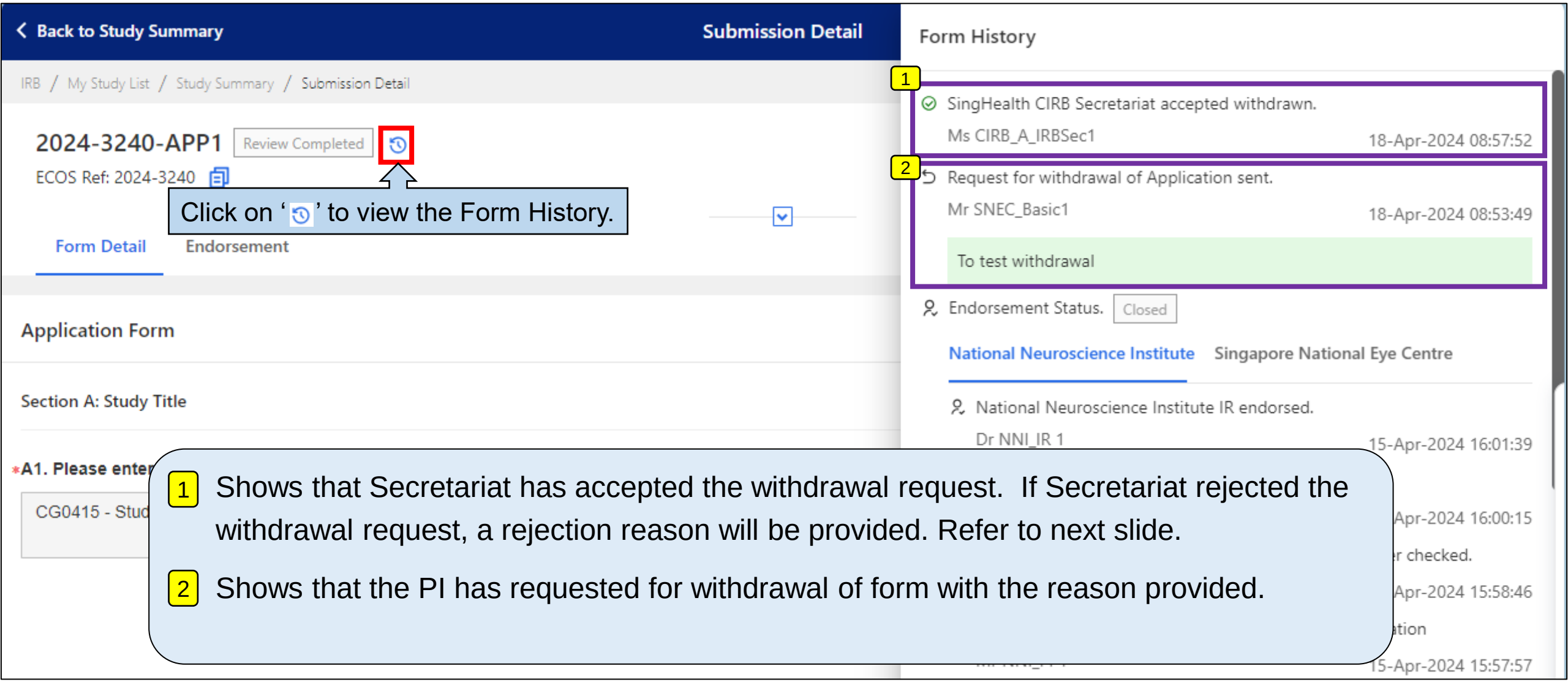
Withdrawal of Form – Pending IRB Review



IMPORTANT

- The withdrawal feature is only available to Overall PI.

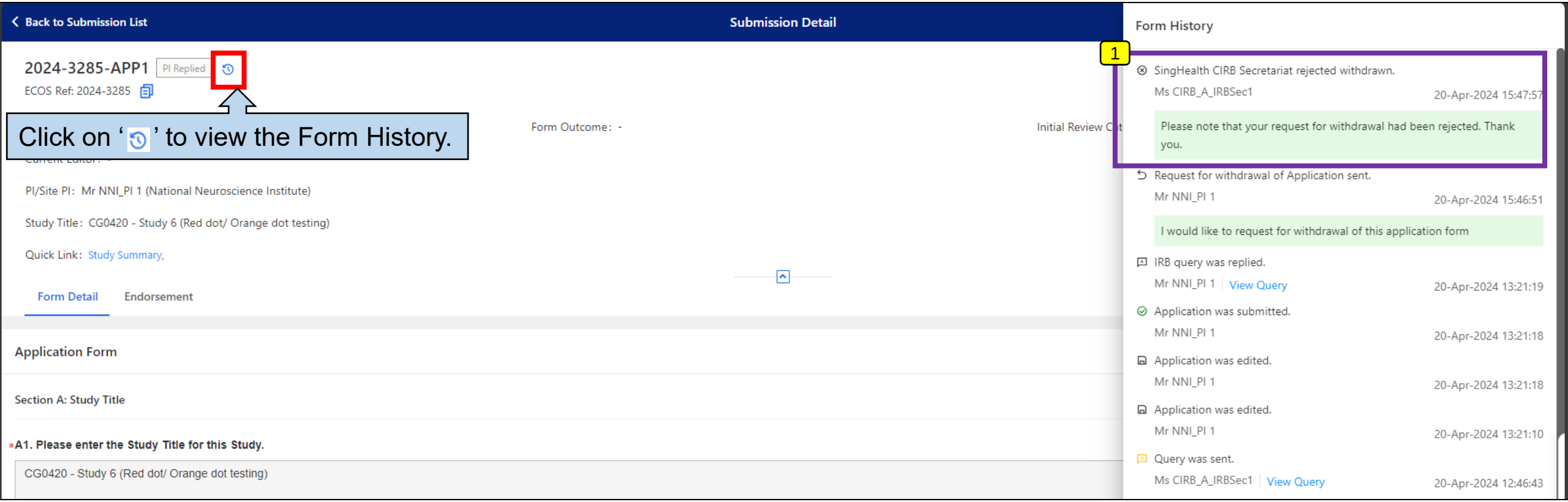
Withdrawal of Form – Pending IRB Review



1 Shows that Secretariat has accepted the withdrawal request. If Secretariat rejected the withdrawal request, a rejection reason will be provided. Refer to next slide.

2 Shows that the PI has requested for withdrawal of form with the reason provided.

Withdrawal of Form – Pending IRB Review



1 Shows that Secretariat has rejected the withdrawal request with a reason for rejection provided.

Application/ Amendment Form will be Routed for Re-Endorsement

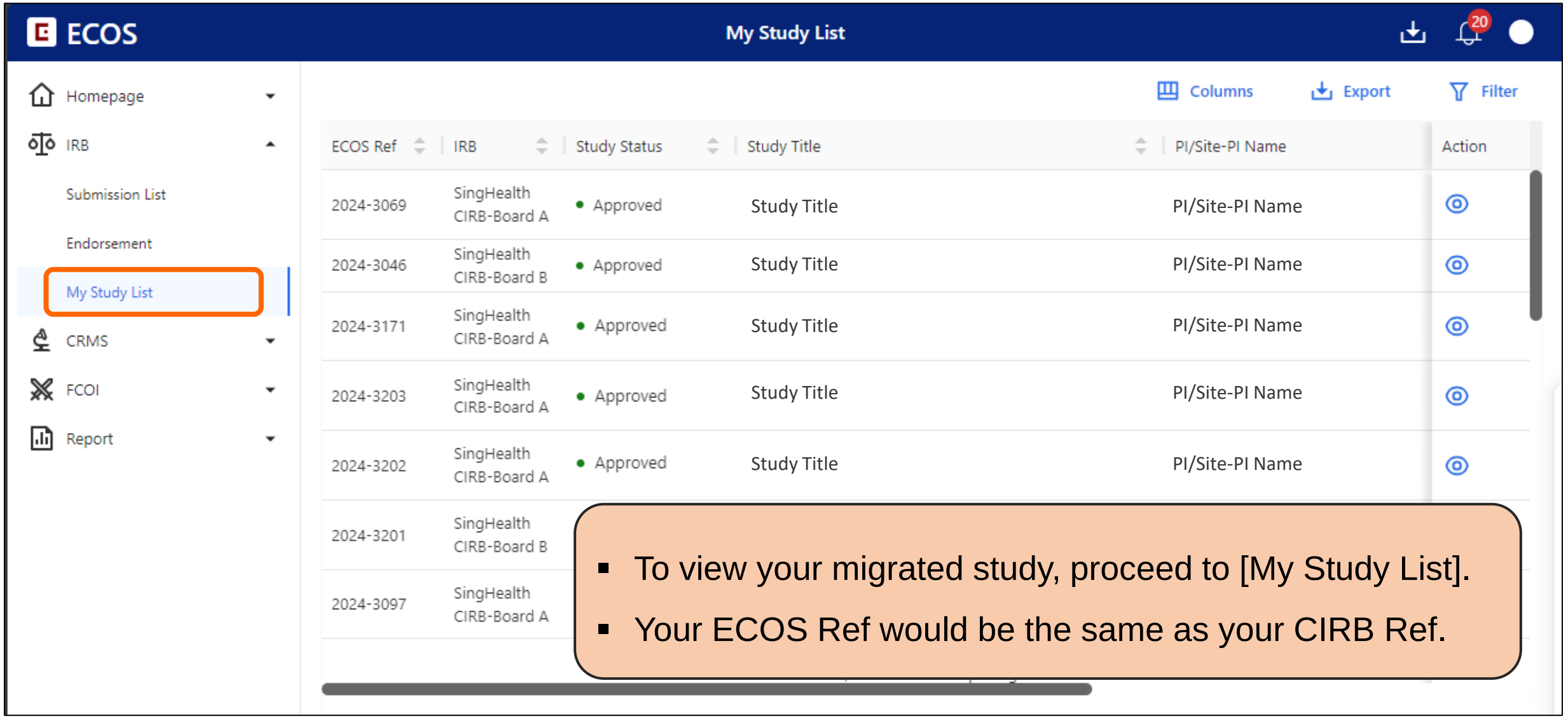
- Section B2: Addition of study sites (Endorsement for additional sites only)
- Section B2: Change/ Addition of PI/ Site-PI (Endorsement for additional sites only)
- Section D2: Change of study classification to ‘Clinical Trial’
- Section D3: Inclusion of Vulnerable Participants
- Section H4: Change to Placebo Controlled Trial
- IRB may unlock the Application/Amendment Form if there are major changes made besides the scenario described above.

Account – Migrated Users (iSHaRe)

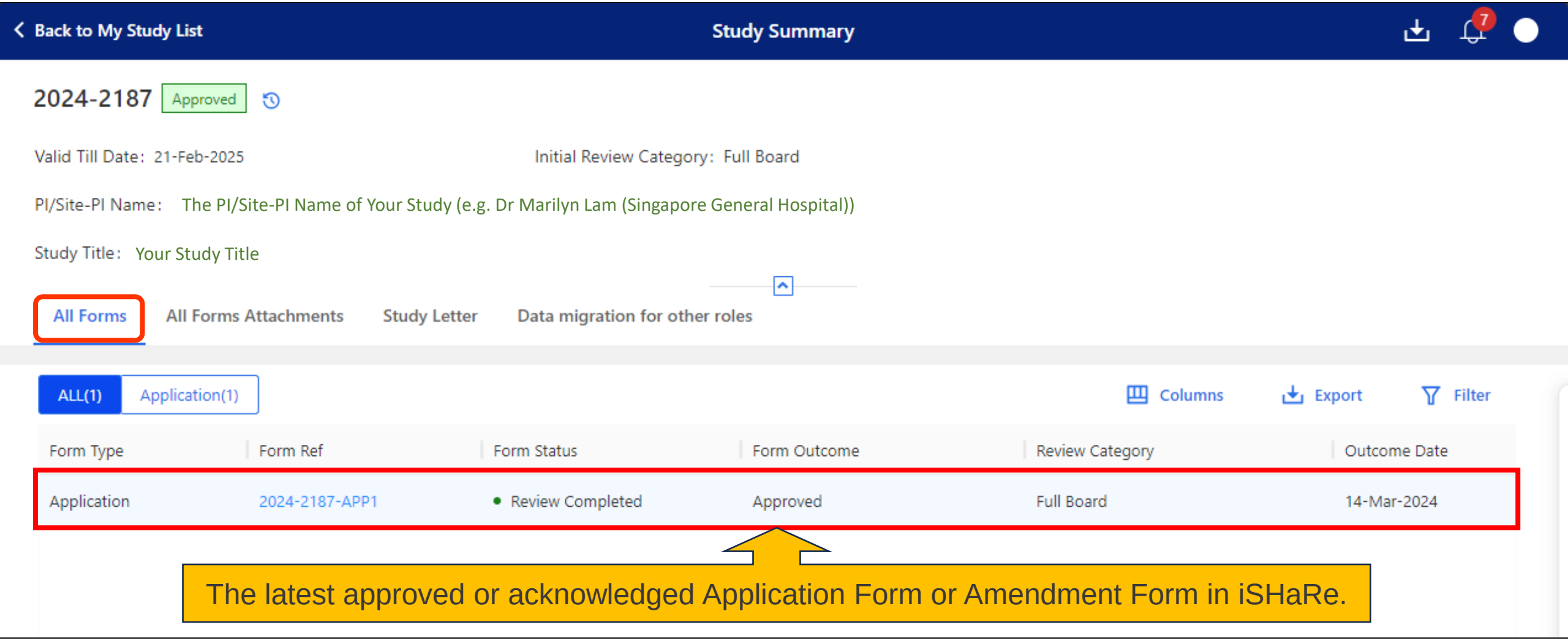
- PI, Site-PI and Co-I from existing ongoing studies in iSHaRe would be migrated to ECOS.
  - ➢Only iSHaRe profile with valid email address will be migrated.

- Study Team Members and Protocol Administrator will not be migrated to ECOS. You may add them in the Clinical Research Management System (CRMS) module.

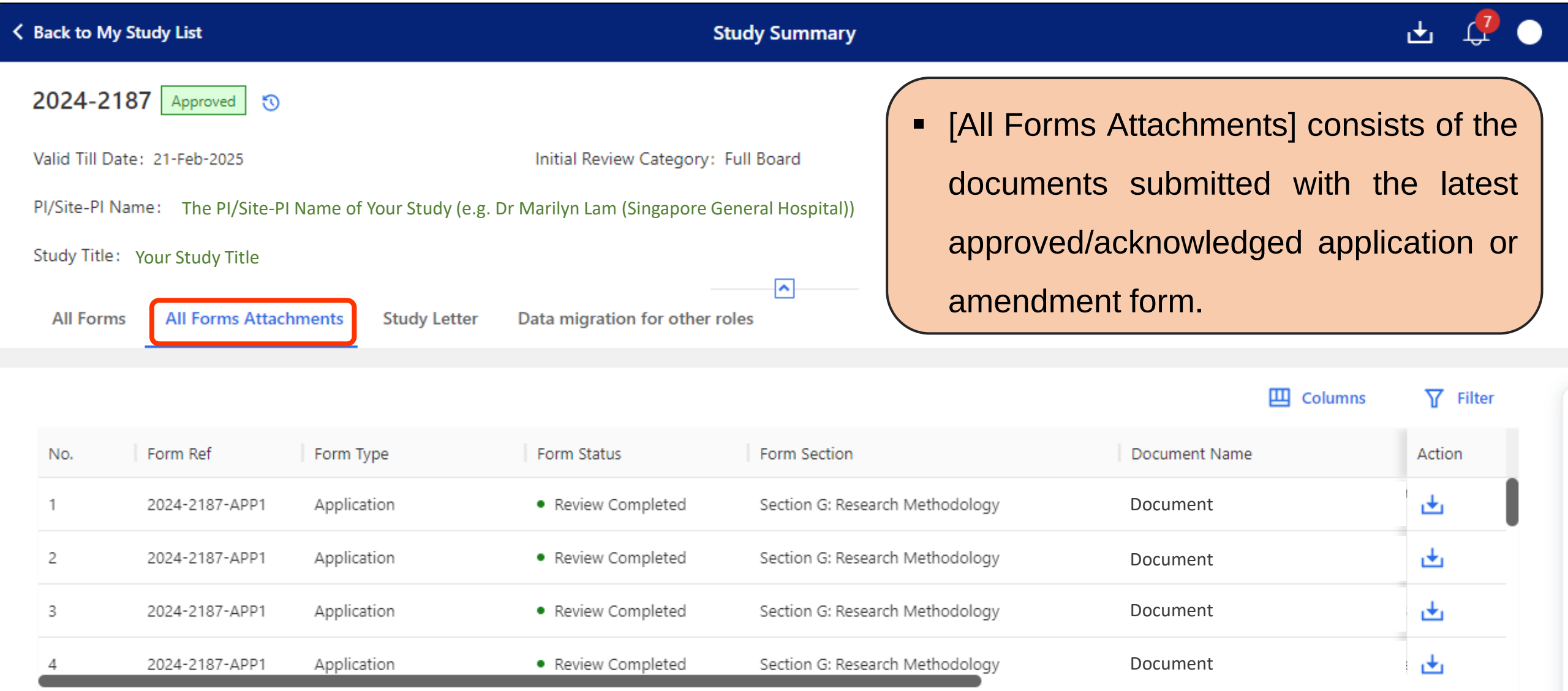
Migrated Study



Migrated Study

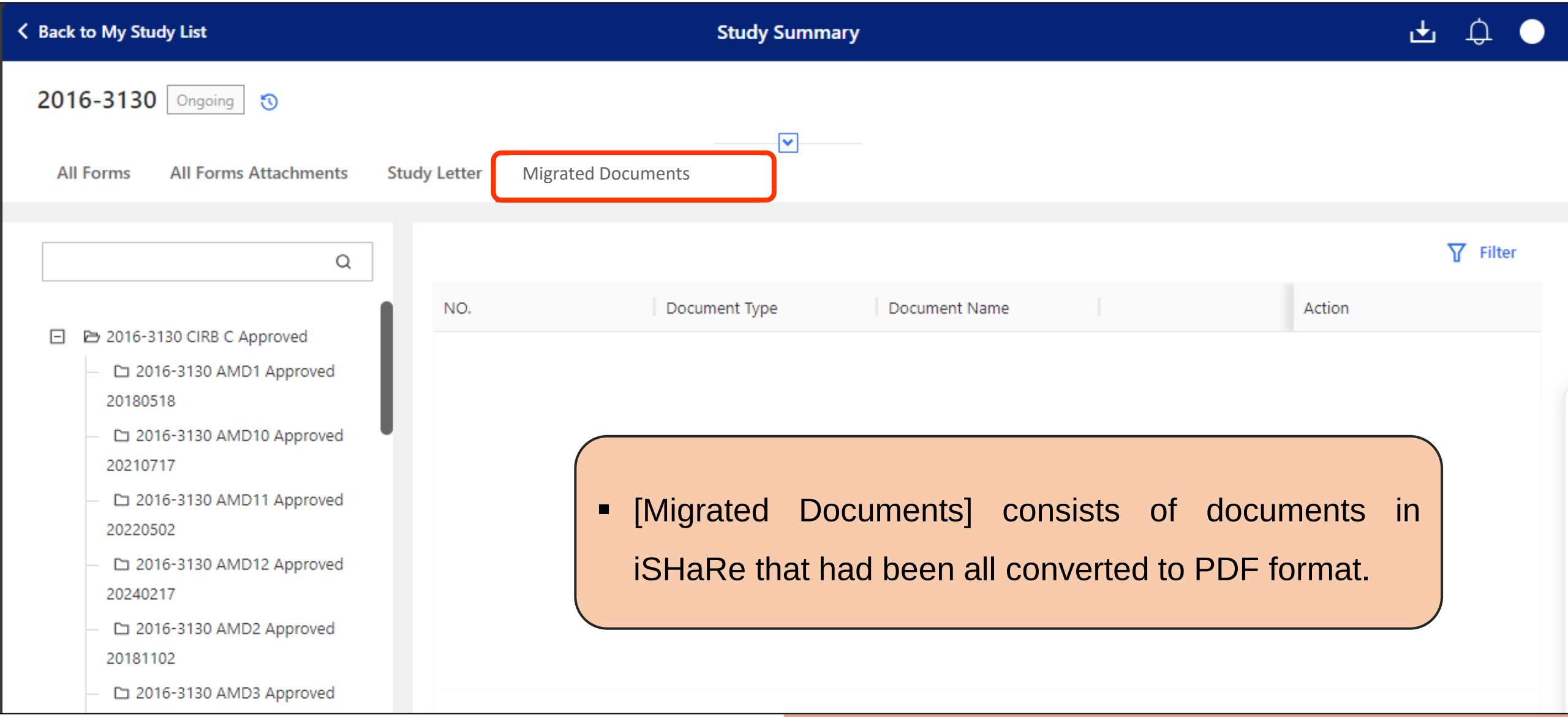


Migrated Study



- [All Forms Attachments] consists of the documents submitted with the latest approved/acknowledged application or amendment form.

Migrated Study



- [Migrated Documents] consists of documents in iSHaRe that had been all converted to PDF format.

Data Migration Studies Timeline (Updated)

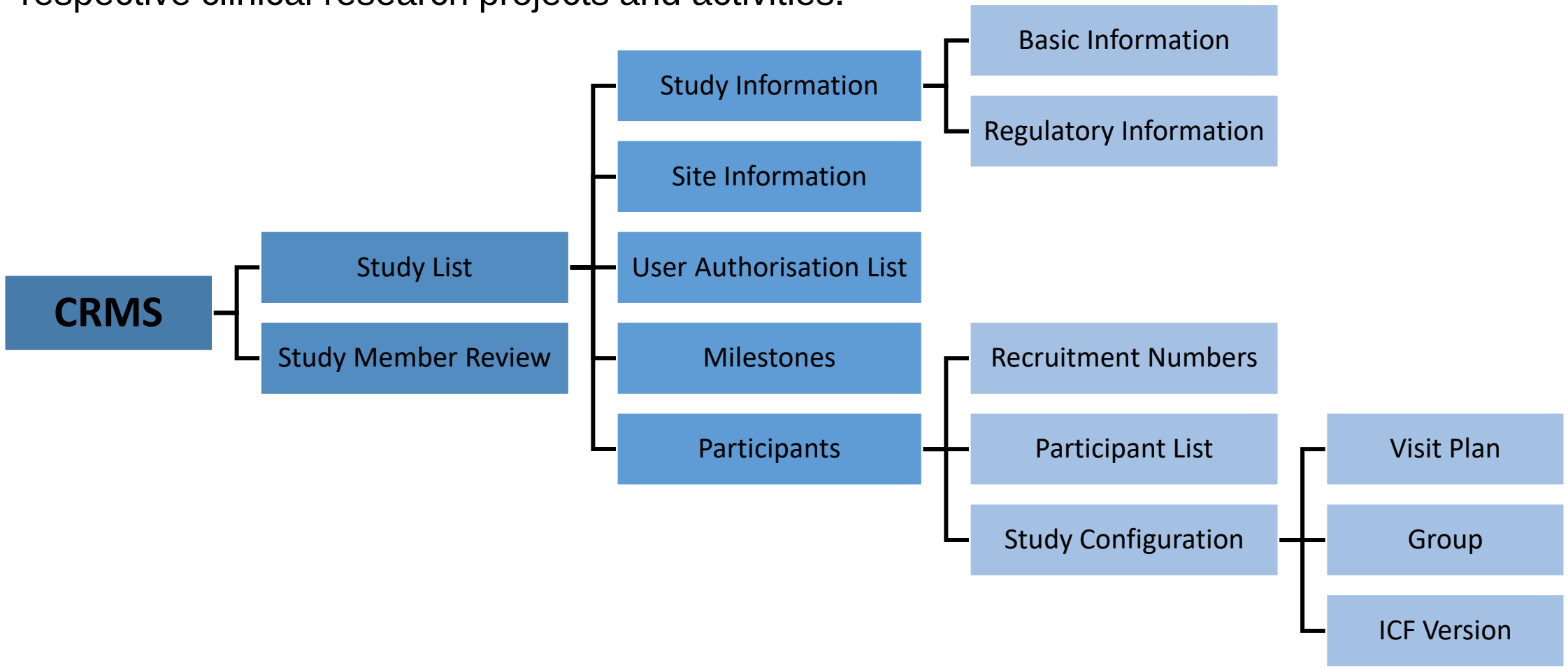
- All on-going IRB approved studies will be migrated to ECOS by **31 May 2024** and any action such as creation of forms for your migrated studies should start from **1 June 2024** onwards.
  - ➢If there are any reporting of DNC, SAE, ORE or Study Closure before 1 June 2024, please refer to CIRB Updates 1 Feb 2024, items 2 and 3.
  - ➢CIRB will cease to accept submissions via email from 1 June 2024. All submissions should be via ECOS for on-going IRB approved studies.

- For studies with Valid Till Date between 1 Aug 2024 and 31 Aug 2024. Please target to submit the Renewal in ECOS **by 21 Jun 2024, 5pm or earlier** to avoid lapse of renewal.

Clinical Research Management System (CRMS)

Clinical Research Management System (CRMS)

- New module created as a research toolkit to help researchers manage and track their respective clinical research projects and activities.



User Access Matrix

IRB APPLICATION Form Stage

Access Level	CRMS Sections	Type of Access		Roles					
				PI/ Site-PI	Co-I	STM	SA	SS	CRMS RO
Study Level	Study Information	Full Access	Limited Access	✓	✓	✓	✓	✓	✓
Site Level	User Authorisation List			✓	✓	✓	✓	✓	✓
	Site Information			✓	✓	✓	✓		✓
	Milestones			✓	✓	✓	✓		✓
	Participants			✓	✓	✓	✓		✓
	Participants – Study Configuration			✓	✓	✓	✓		
	Study Member Review			✓					

Legend

✓ Access (View & Edit) granted upon the addition of a user in the IRB Form or User Authorisation List

✓ Access (View & Edit) granted after IRB's approval or PI's endorsement in CRMS.

✓ Access (View & Edit) granted without any approval required.

PI: Principal Investigator; Site-PI: Site-Principal Investigator; Co-I: Co-investigator; STM: Study Team Member; SA: Study Administrator; SS: Study Sponsor; CRMS RO: RO administrator assigned with CRMS role.

User Access Matrix

IRB AMENDMENT Form Stage

Page Level	CRMS Sections	Type of Access		Roles					
				PI/ Site-PI	Co-I	STM	SA	SS	CRMS RO
Study Level	Study Information	Full Access	Limited Access	✓	✓	✓	✓	✓	✓
Site Level	User Authorisation List			✓	✓	✓	✓	✓	✓
	Site Information			✓	✓	✓	✓		✓
	Milestones			✓	✓	✓	✓		✓
	Participants			✓	✓	✓	✓		✓
	Participants – Study Configuration			✓	✓	✓	✓		
	Study Member Review			✓					

Legend

✓ Access (View & Edit) granted upon the addition of a user on the User Authorisation List

✓ Access (View & Edit) granted after IRB's approval or PI's endorsement in CRMS.

✓ Access (View & Edit) granted without any approval required.

PI: Principal Investigator; Site-PI: Site-Principal Investigator; Co-I: Co-investigator; STM: Study Team Member; SA: Study Administrator; SS: Study Sponsor; CRMS RO: RO administrator assigned with CRMS role.

CRMS Page Level

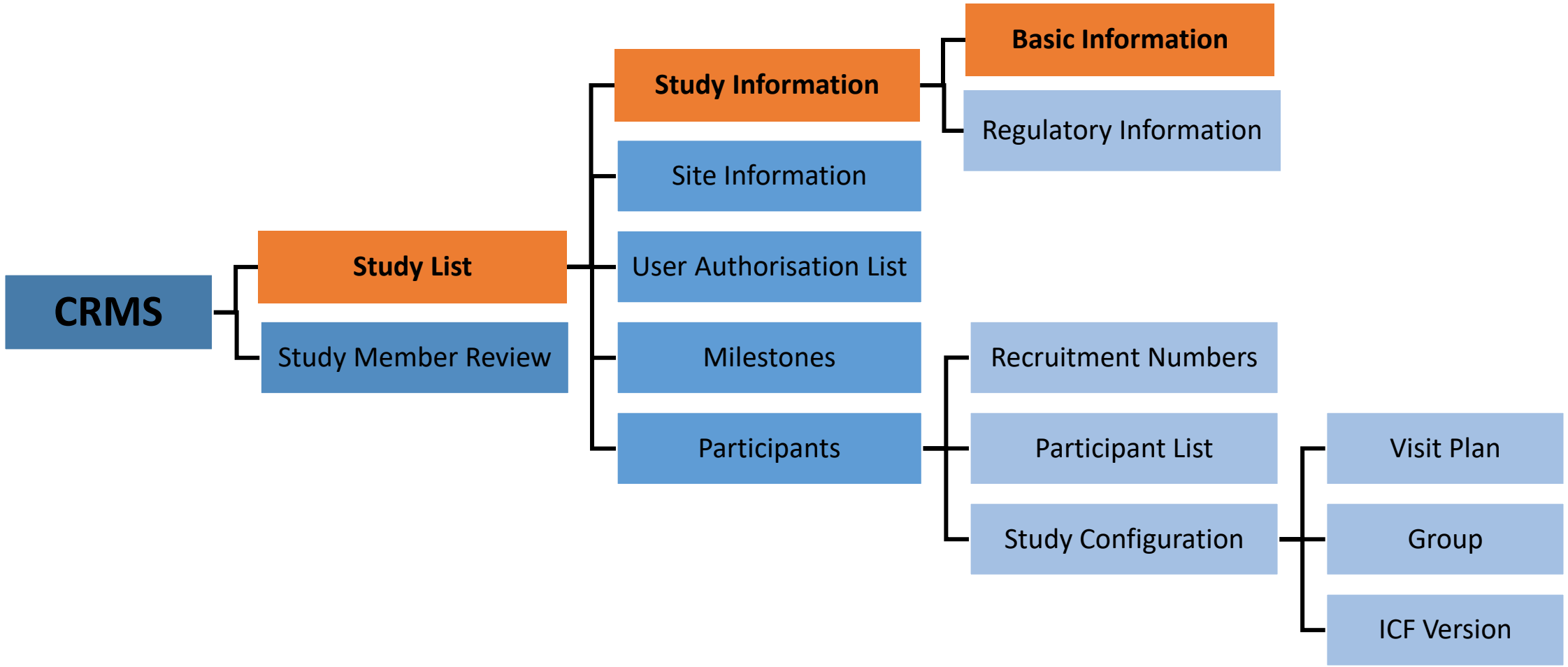
Page Level	CRMS Sections/ Pages	
Study Level	Study Information	Basic Information
		Regulatory Information
Site Level	Site Information	
	User Authorisation List	
	Milestones	
	Participants	Recruitment Numbers
		Participant List
		Study Configuration

Study Level

Information entered will be shared across all participating sites. E.g. data entered by 1 site will be seen by all sites. Similarly, data revisions made by 1 site will also be seen by the other sites.

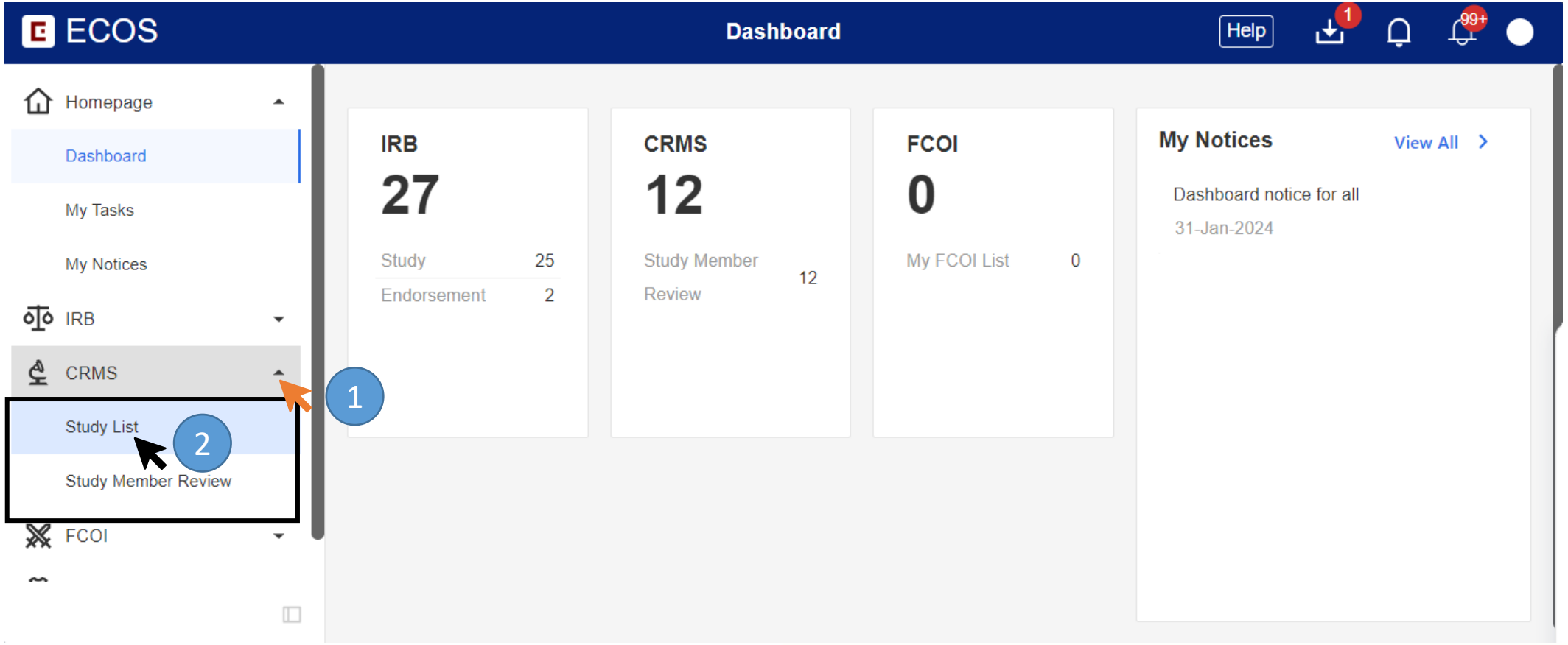
Site Level

Information entered is restricted to the specific site only. E.g. data entered by 1 site will not be shared nor seen by another site. Participating sites do not have access to each other's pages.

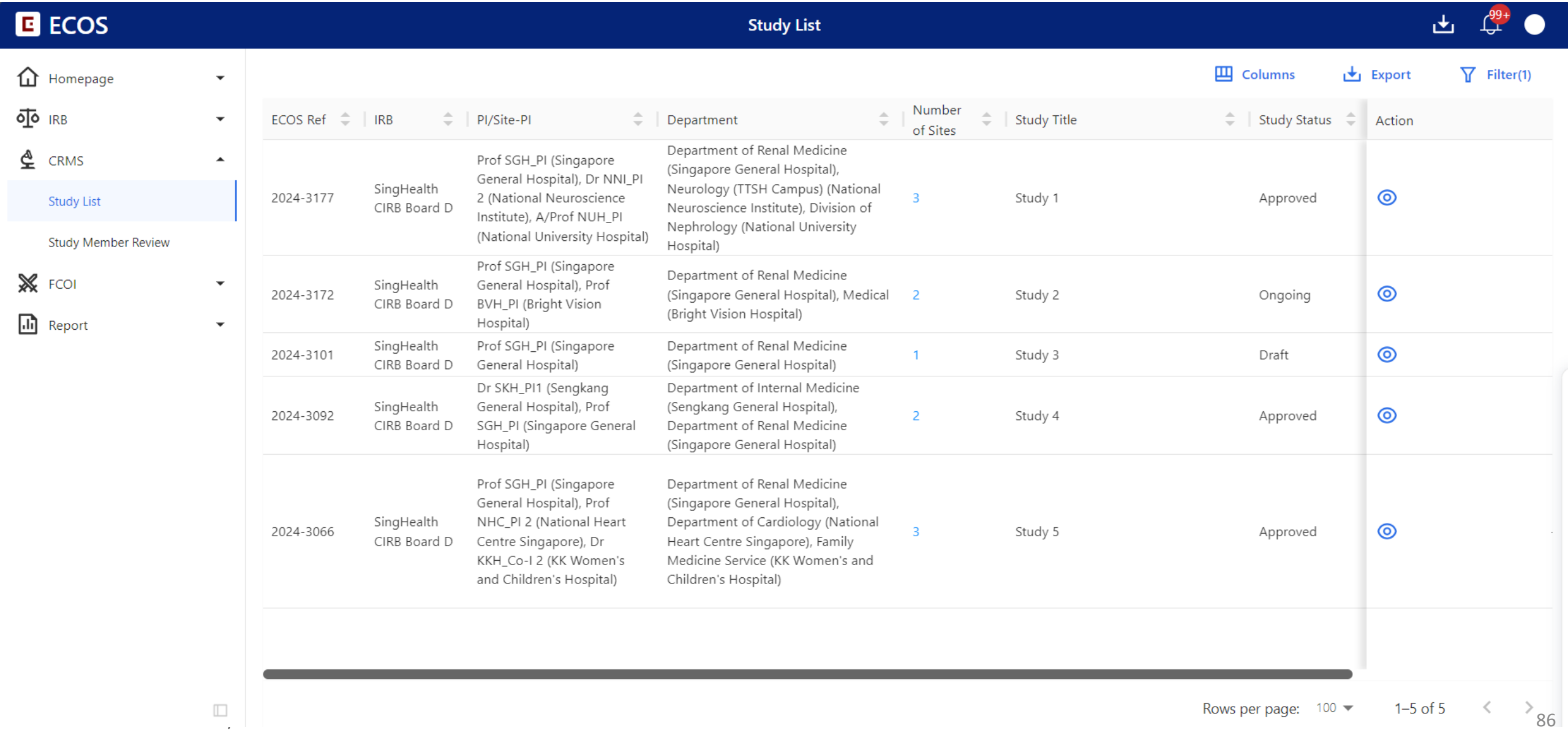

CRMS
Study List
Study Member Review
Study Information
Site Information
User Authorisation List
Milestones
Participants
Basic Information
Regulatory Information
Recruitment Numbers
Participant List
Study Configuration
Visit Plan
Group
ICF Version

CRMS Access

- There are 2 ways to access CRMS.
  1. ECOS Navigation Menu: CRMS



CRMS Access

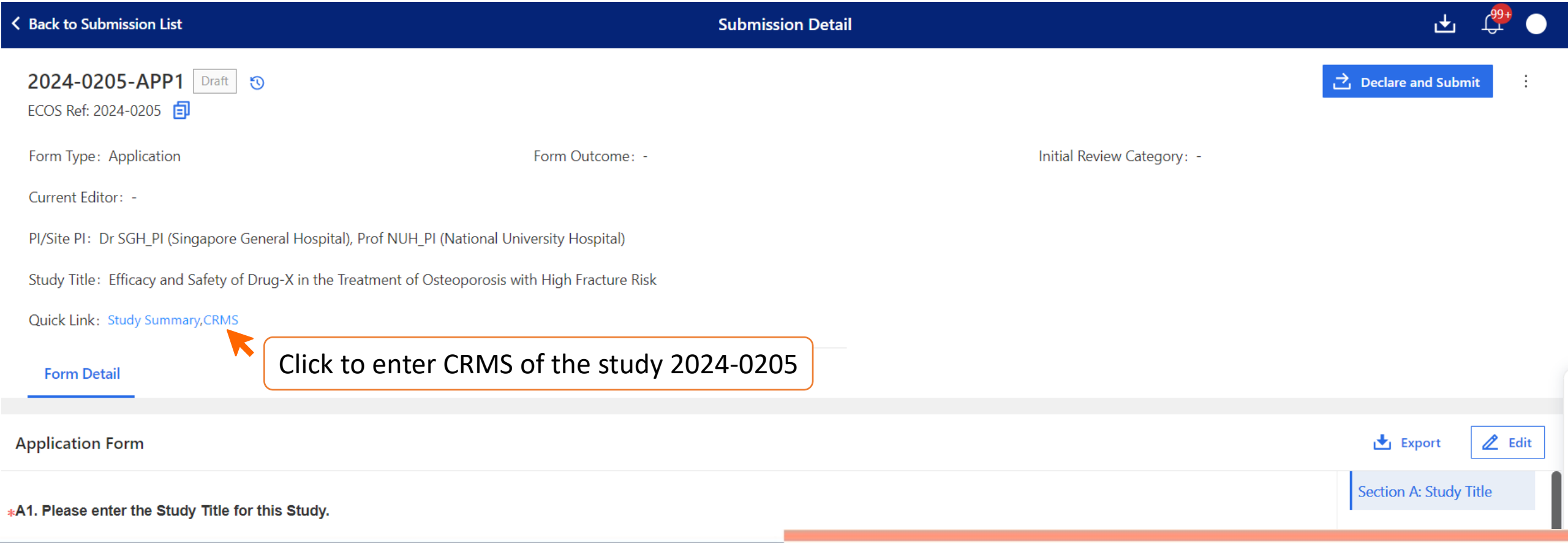

ECOS
Study List
99+
Homepage
IRB
CRMS
Study List
Study Member Review
FCOI
Report
Columns
Export
Filter(1)
ECOS Ref
IRB
PI/Site-PI
Department
Number of Sites
Study Title
Study Status
Action
2024-3177
SingHealth CIRB Board D
Prof SGH_PI (Singapore General Hospital), Dr NNI_PI 2 (National Neuroscience Institute), A/Prof NUH_PI (National University Hospital)
Department of Renal Medicine (Singapore General Hospital), Neurology (TTSH Campus) (National Neuroscience Institute), Division of Nephrology (National University Hospital)
3
Study 1
Approved
2024-3172
SingHealth CIRB Board D
Prof SGH_PI (Singapore General Hospital), Prof BVH_PI (Bright Vision Hospital)
Department of Renal Medicine (Singapore General Hospital), Medical (Bright Vision Hospital)
2
Study 2
Ongoing
2024-3101
SingHealth CIRB Board D
Prof SGH_PI (Singapore General Hospital)
Department of Renal Medicine (Singapore General Hospital)
1
Study 3
Draft
2024-3092
SingHealth CIRB Board D
Dr SKH_PI1 (Sengkang General Hospital), Prof SGH_PI (Singapore General Hospital)
Department of Internal Medicine (Sengkang General Hospital), Department of Renal Medicine (Singapore General Hospital)
2
Study 4
Approved
2024-3066
SingHealth CIRB Board D
Prof SGH_PI (Singapore General Hospital), Prof NHC_PI 2 (National Heart Centre Singapore), Dr KKH_Co-I 2 (KK Women's and Children's Hospital)
Department of Renal Medicine (Singapore General Hospital), Department of Cardiology (National Heart Centre Singapore), Family Medicine Service (KK Women's and Children's Hospital)
3
Study 5
Approved
Rows per page: 100
1–5 of 5

CRMS Access

This option may be available in Q3 2024.

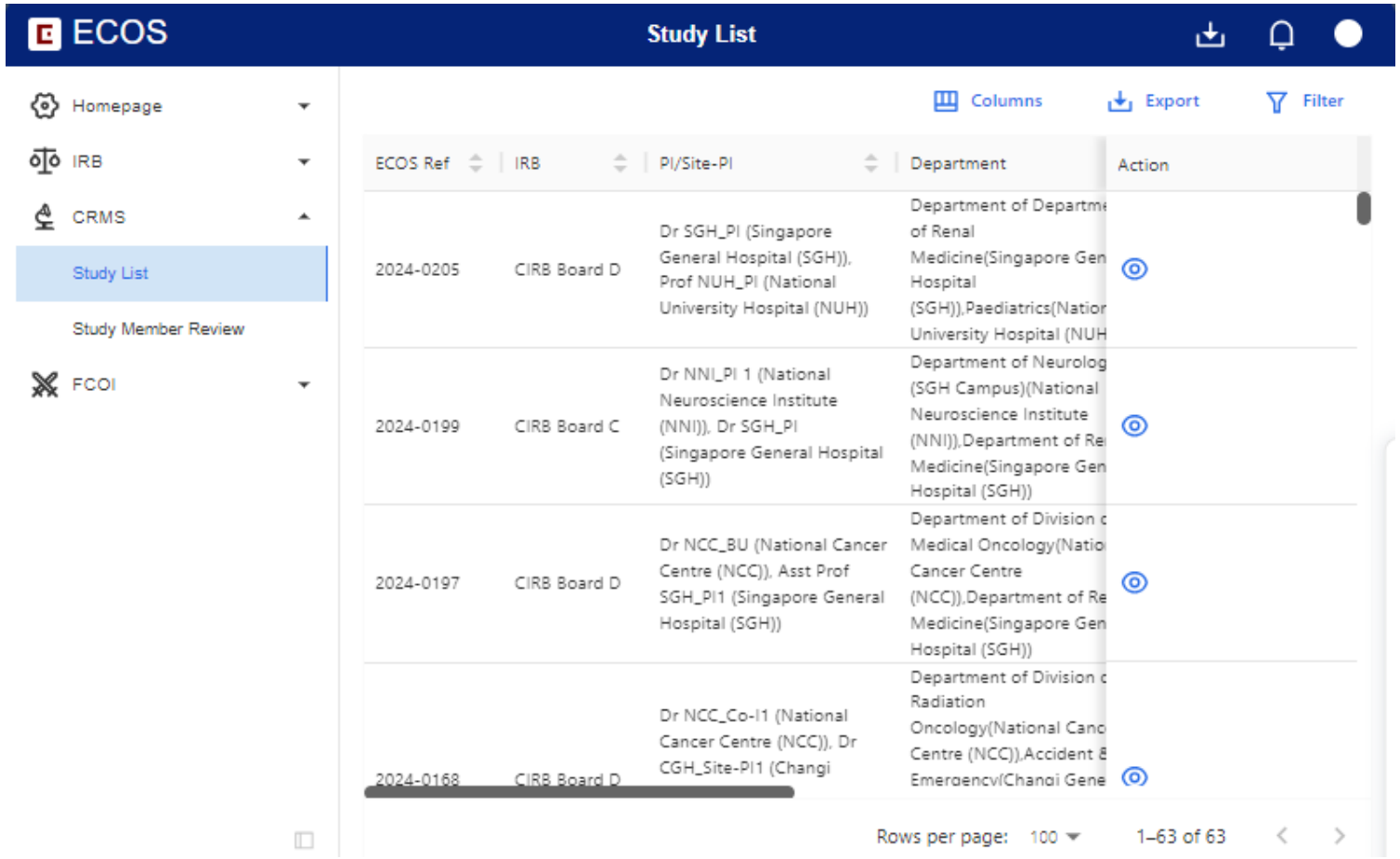
- There are 2 ways to access CRMS.

2. IRB Application or Amendment Form: Dashboard > IRB > My Study List > APP or AMD Form > Quick Link: CRMS



Study List

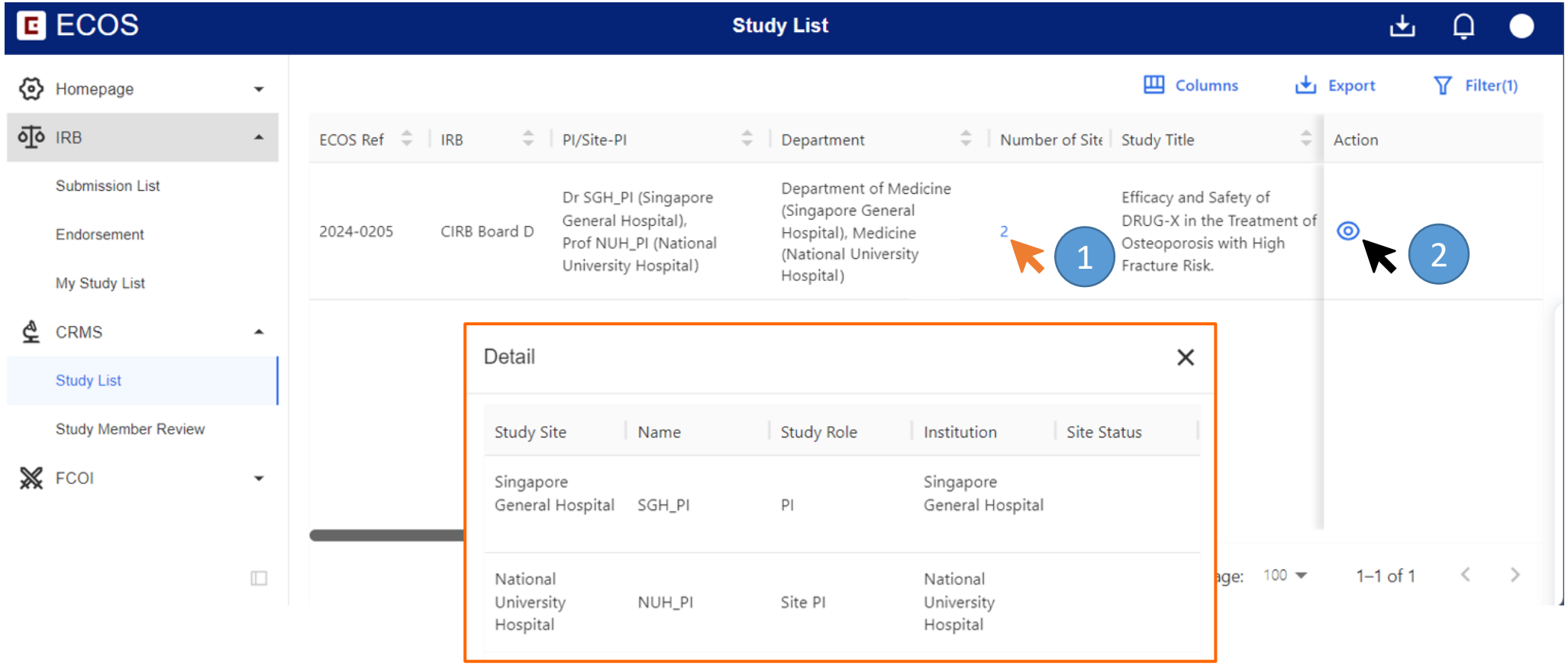
- Study List will only display the studies where a user has been added to the IRB forms or User Authorisation List.
- A new study will be created in CRMS once the IRB Application Form draft is saved for the first time.
- Relevant information from the IRB Application or Amendment Forms will be synced to CRMS.
  - Study details *(next slide).*
  - List of Investigators added in IRB form to User Authorisation List.
- Synchronisation points: -
  - Upon saving of IRB **Application** Form.
  - Upon IRB approval or acknowledgement.



Study List

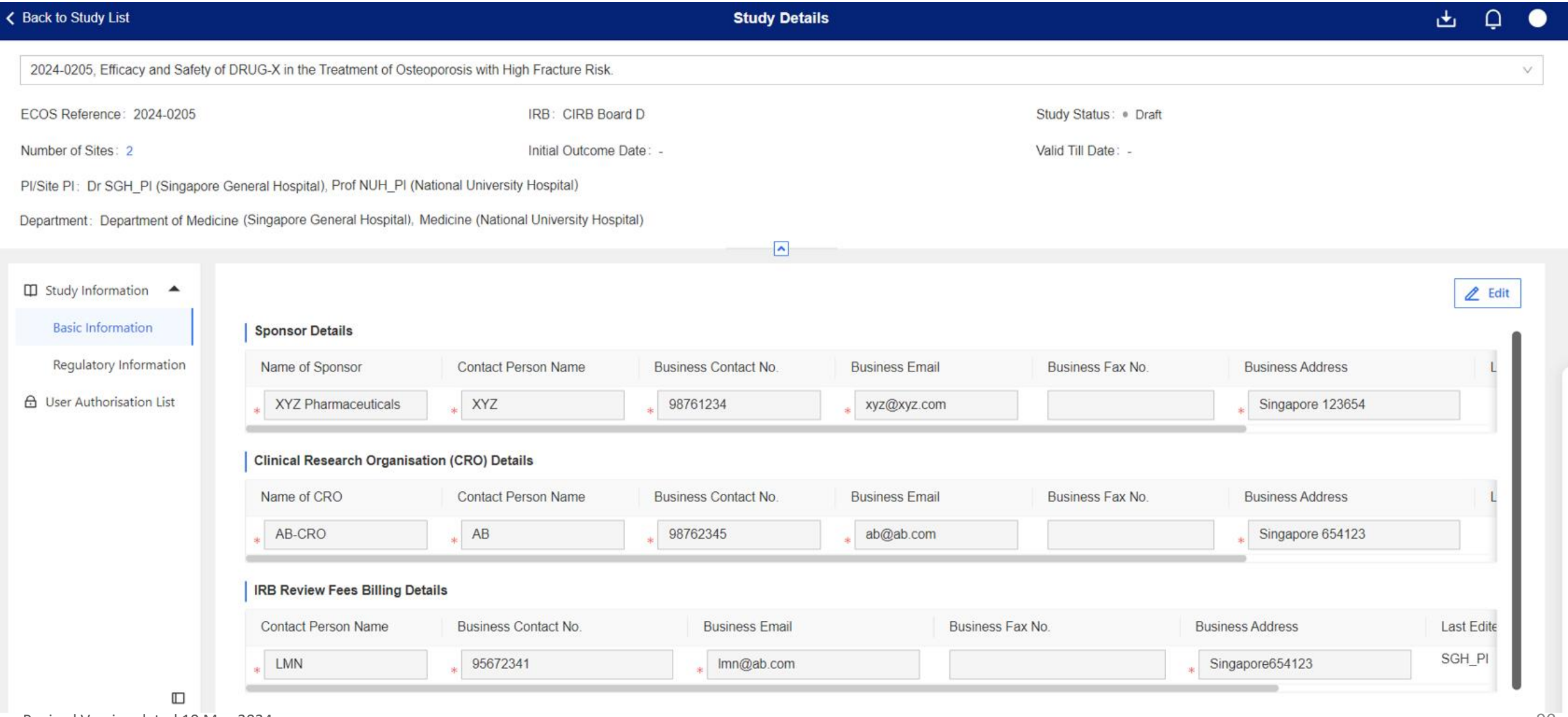
Study Details

- ECOS Ref
- IRB
- PI/Site-PI
- Department
- Number of Sites
- Study Title
- Study Status
- Initial Outcome Date
- Valid Till Date

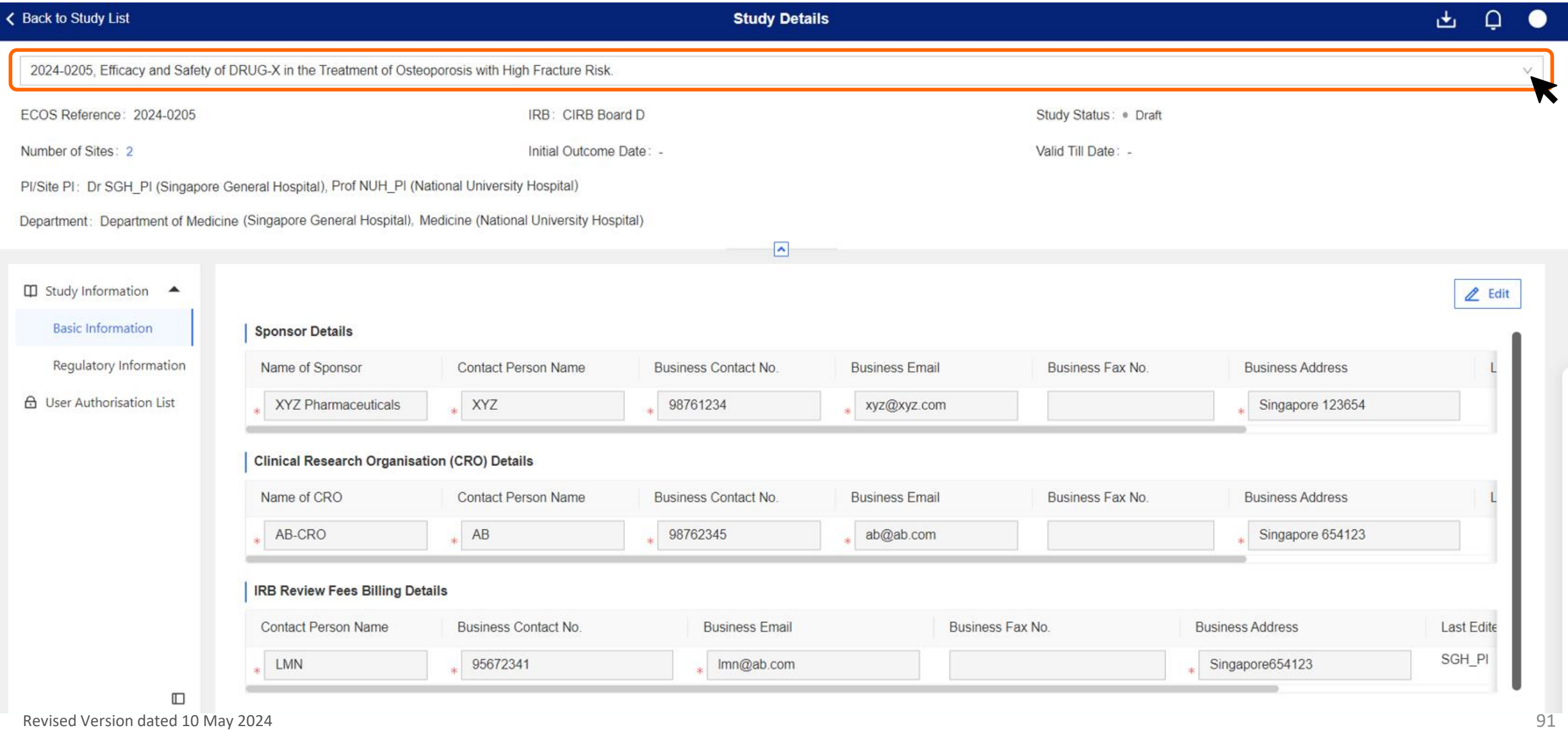


Study Information – Basic Information

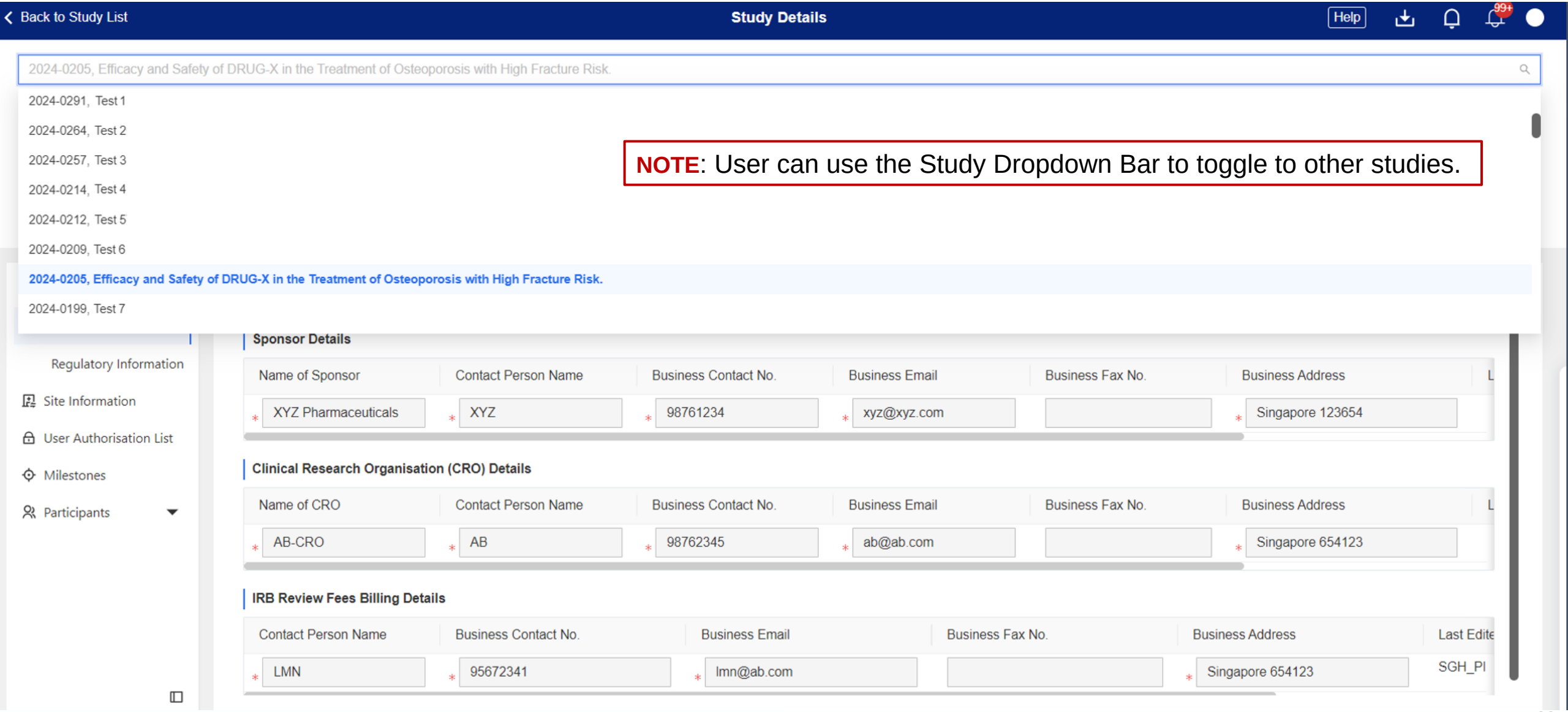
Study Level



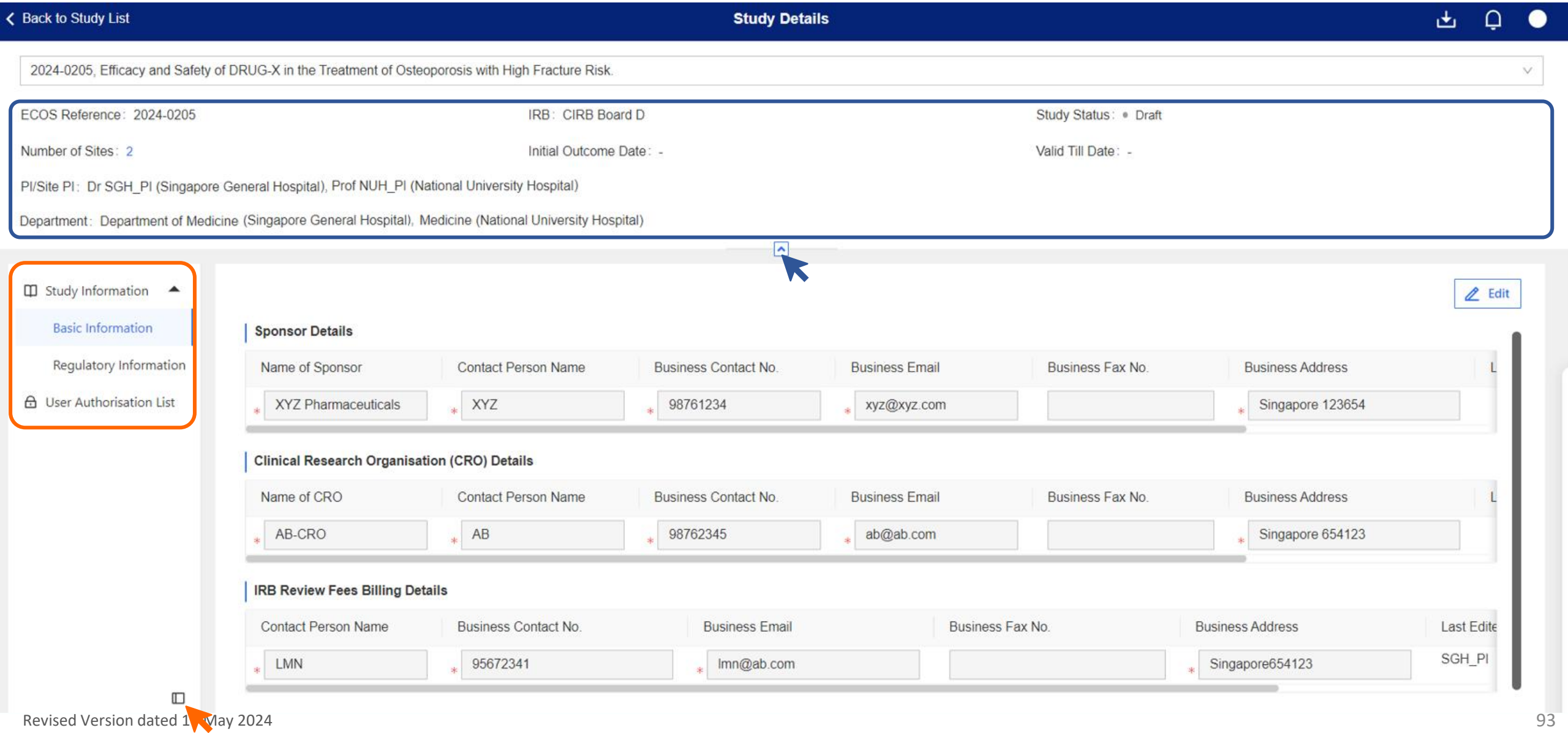
Page Function – Study Dropdown Bar



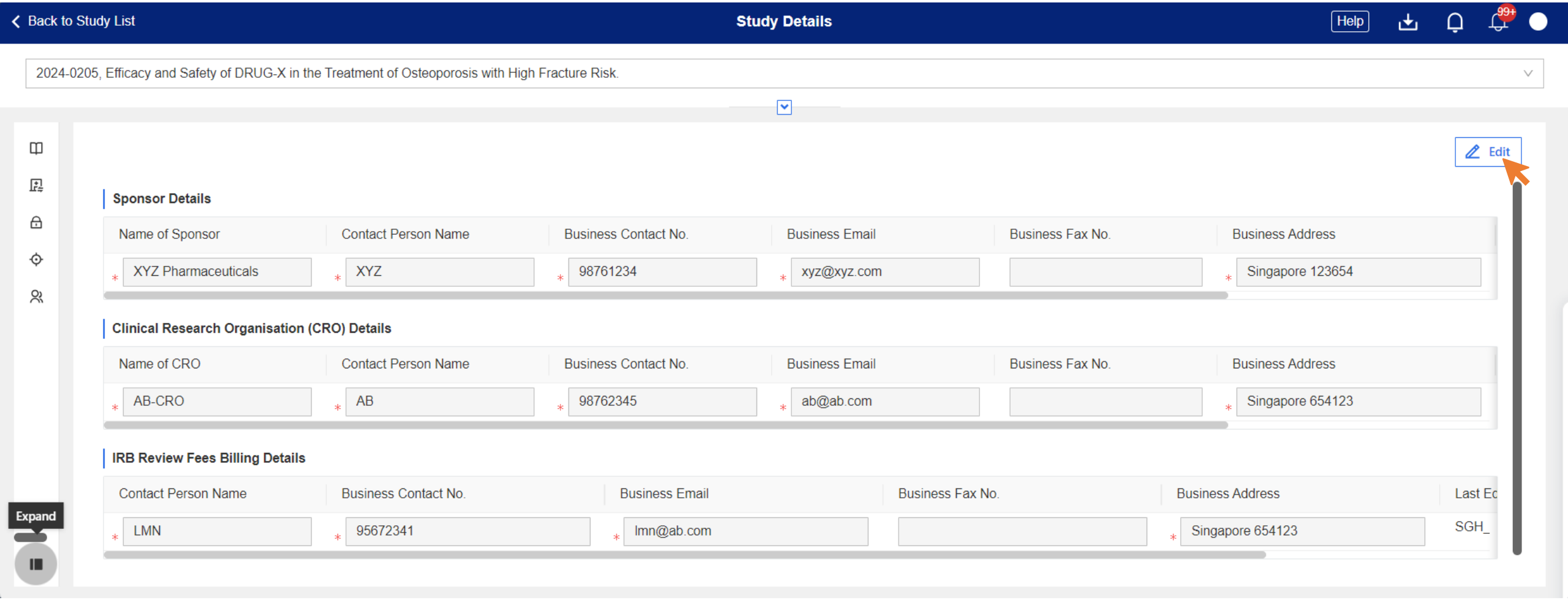
Page Function – Study Dropdown Bar



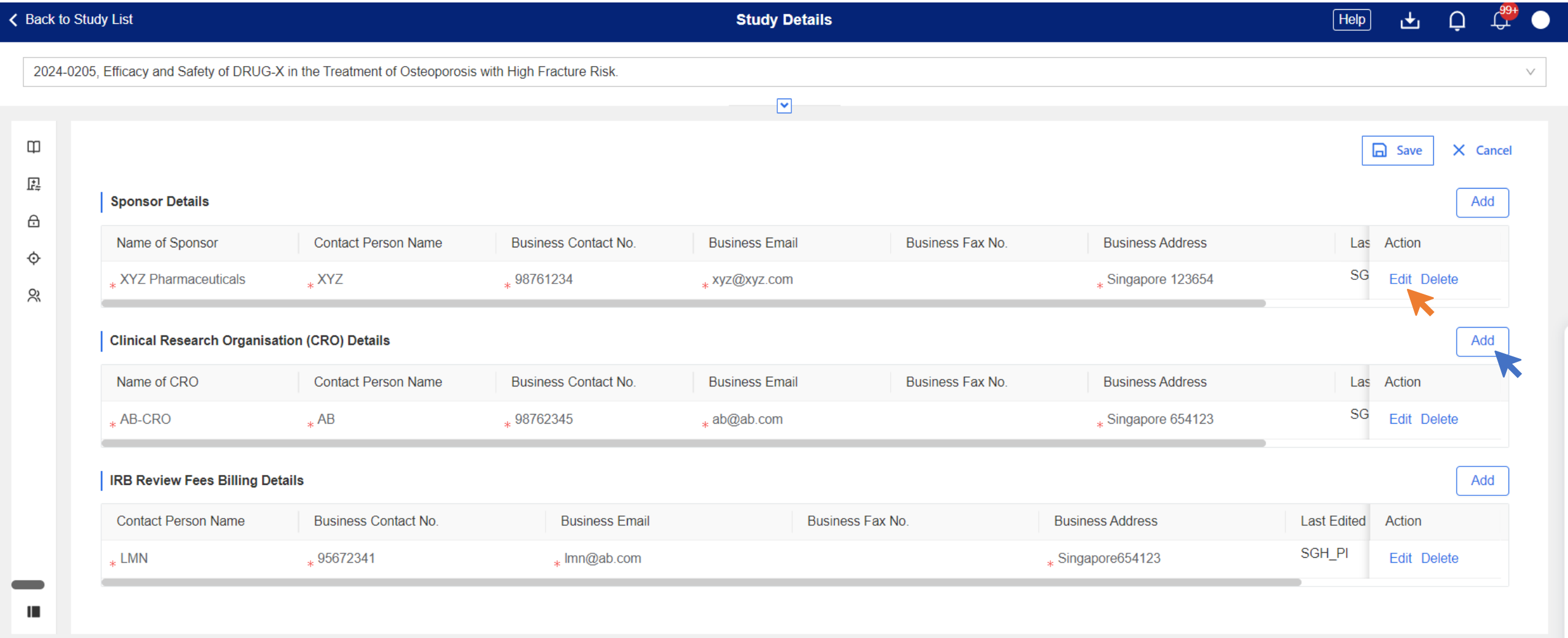
Page Function – Collapse/Expand



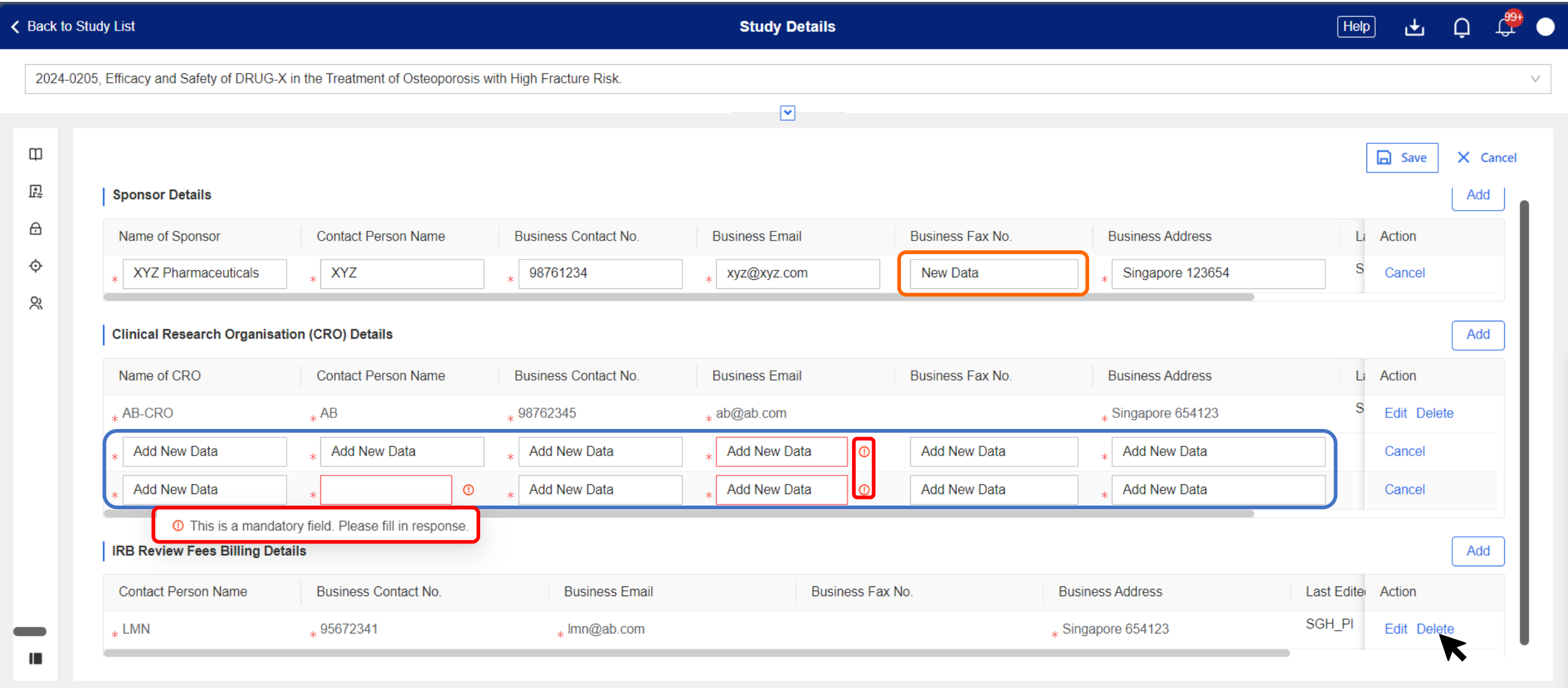
Page Functions – Edit, Add, Delete, Save Data



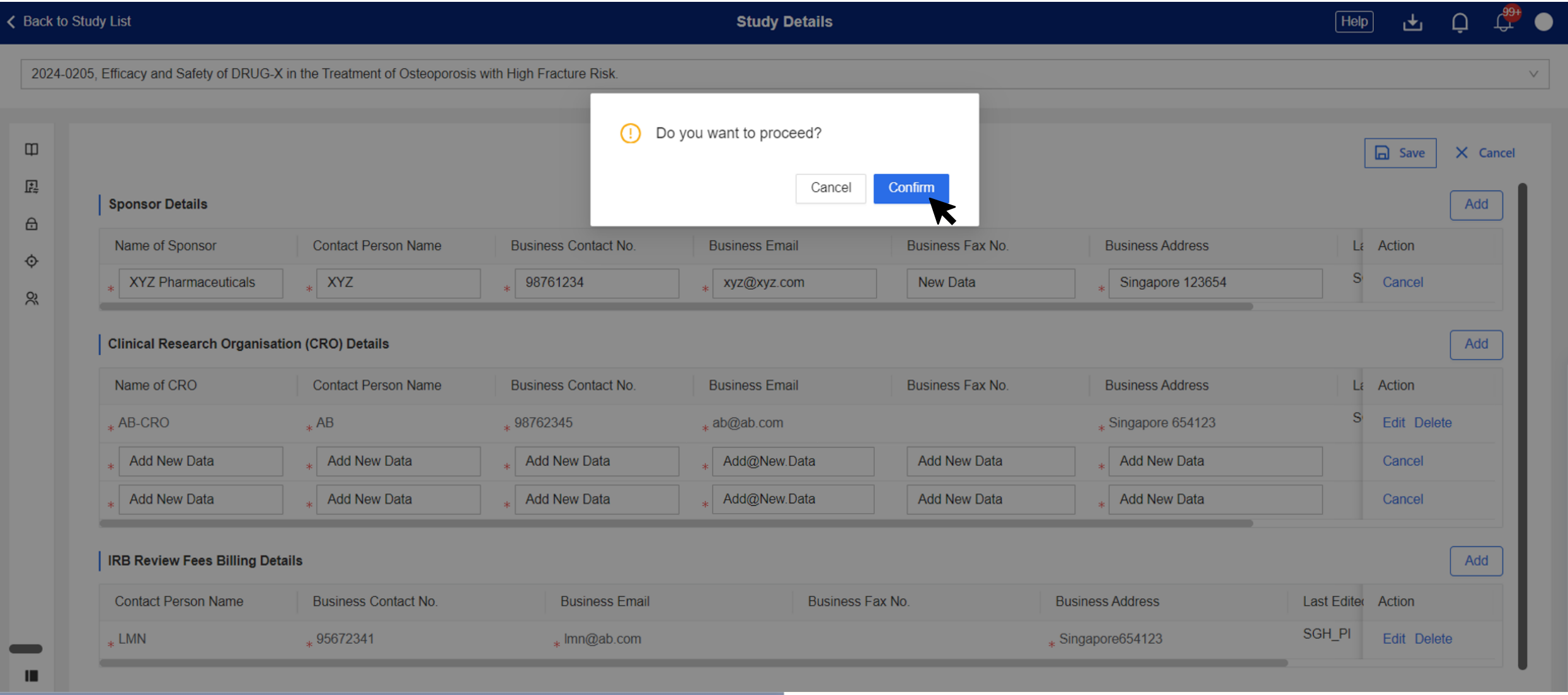
Page Functions – Edit, Add, Delete, Save Data



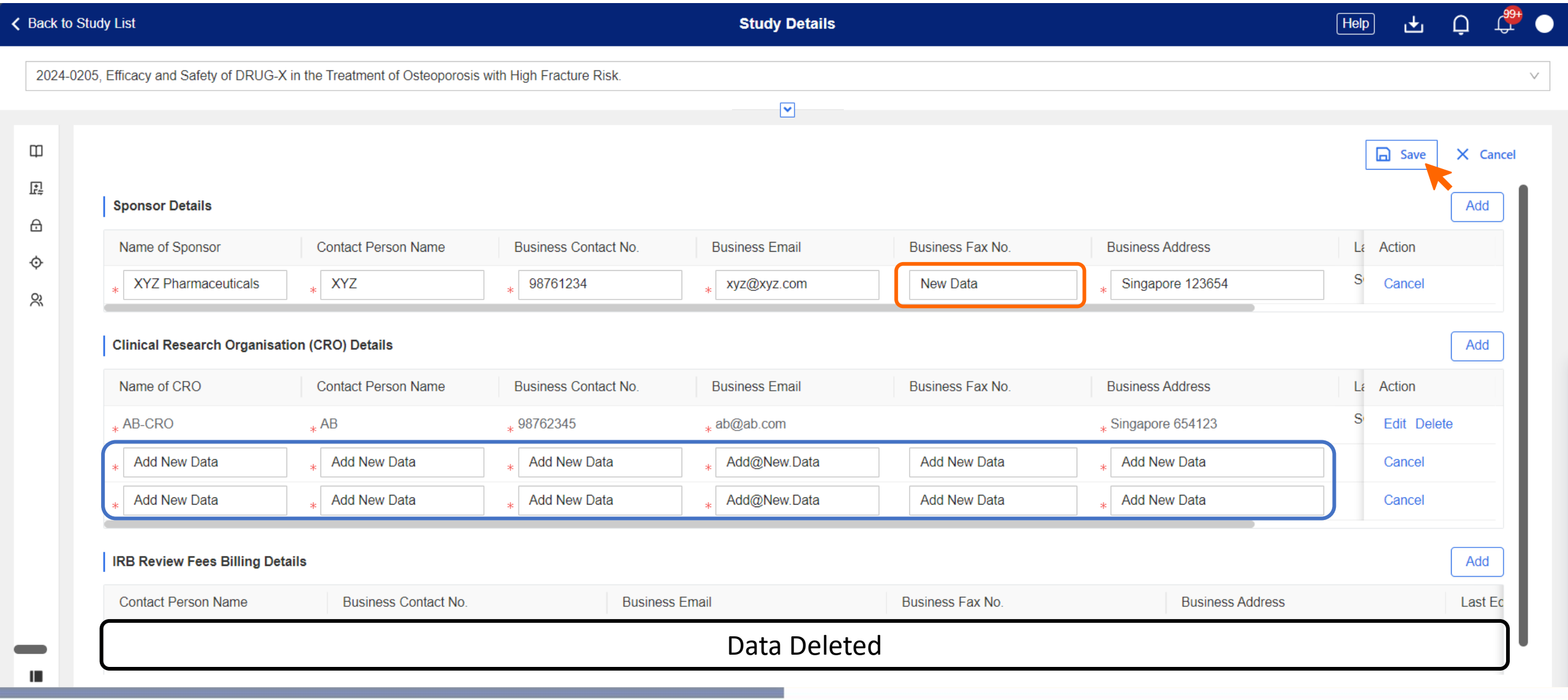
Page Functions – Edit, Add, Delete, Save Data



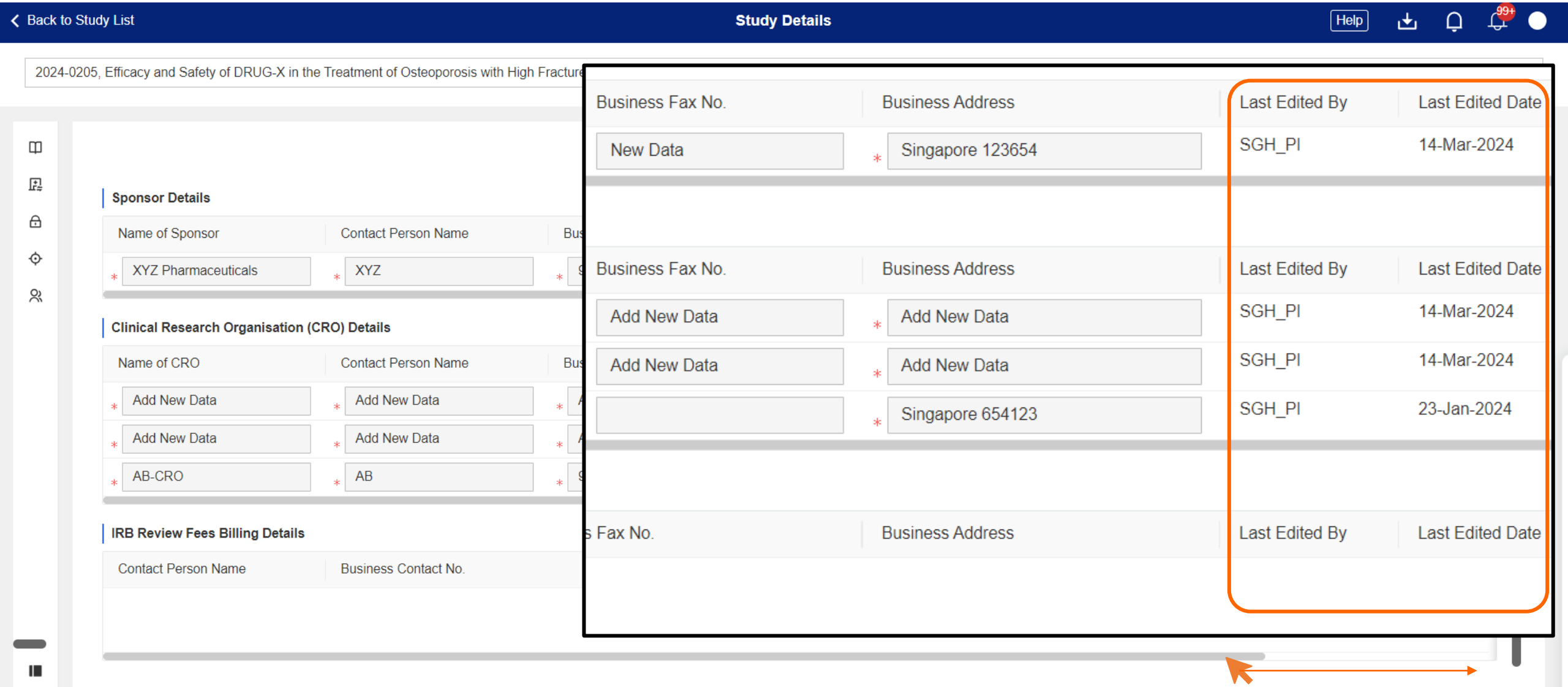
Page Functions – Edit, Add, Delete, Save Data



Page Functions – Edit, Add, Delete, Save Data



Record Tracking



Study Information – Basic Information

- On ECOS, Sponsor, CRO and IRB billing details will be entered on the **CRMS – Basic Information** page instead of the IRB Application Form.
- Subsequent changes to Sponsor/CRO and IRB billing details can be done via CRMS without submitting an IRB Amendment form.

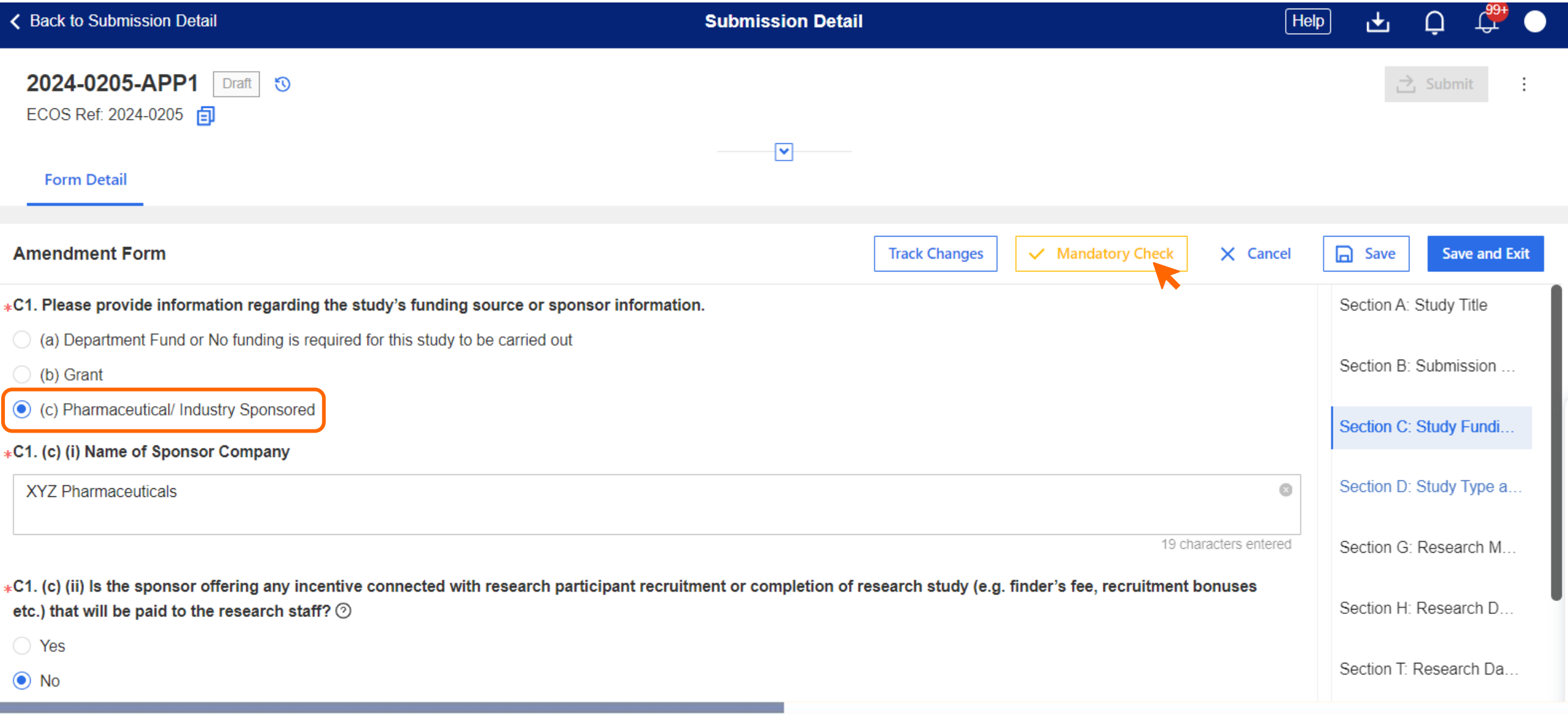
NOTE:

1. If a CRO is engaged for an Investigator-initiated study, CRO Details should be completed.
2. Business Address under IRB Review Billing Details will be reflected on the invoice. Sites should check with the sponsor and indicate the required information to ensure smooth invoice submission and payment processes.

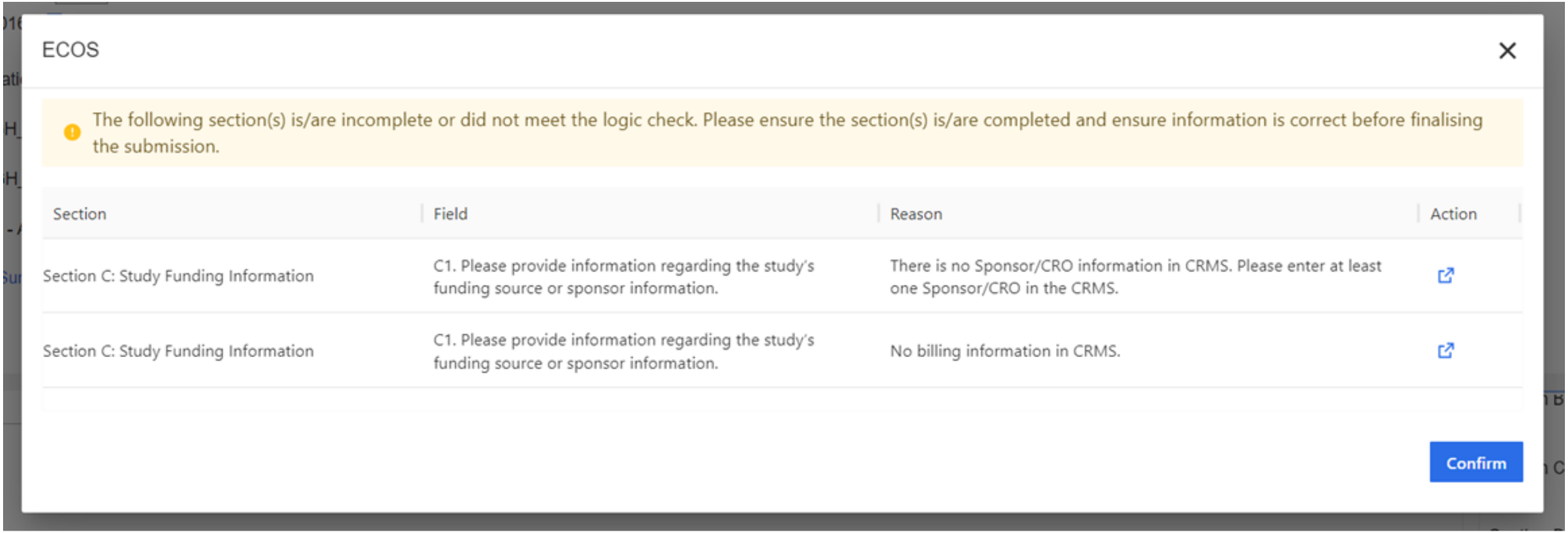
Study Information – Basic Information

- For Pharmaceutical/ Industry-sponsored studies, the following details must be provided for the IRB Application Form to be submitted successfully.
  a) Sponsor Details, **or**
  b) Clinical Research Organisation (CRO) Details, **and**
  c) IRB Review Billing Details.

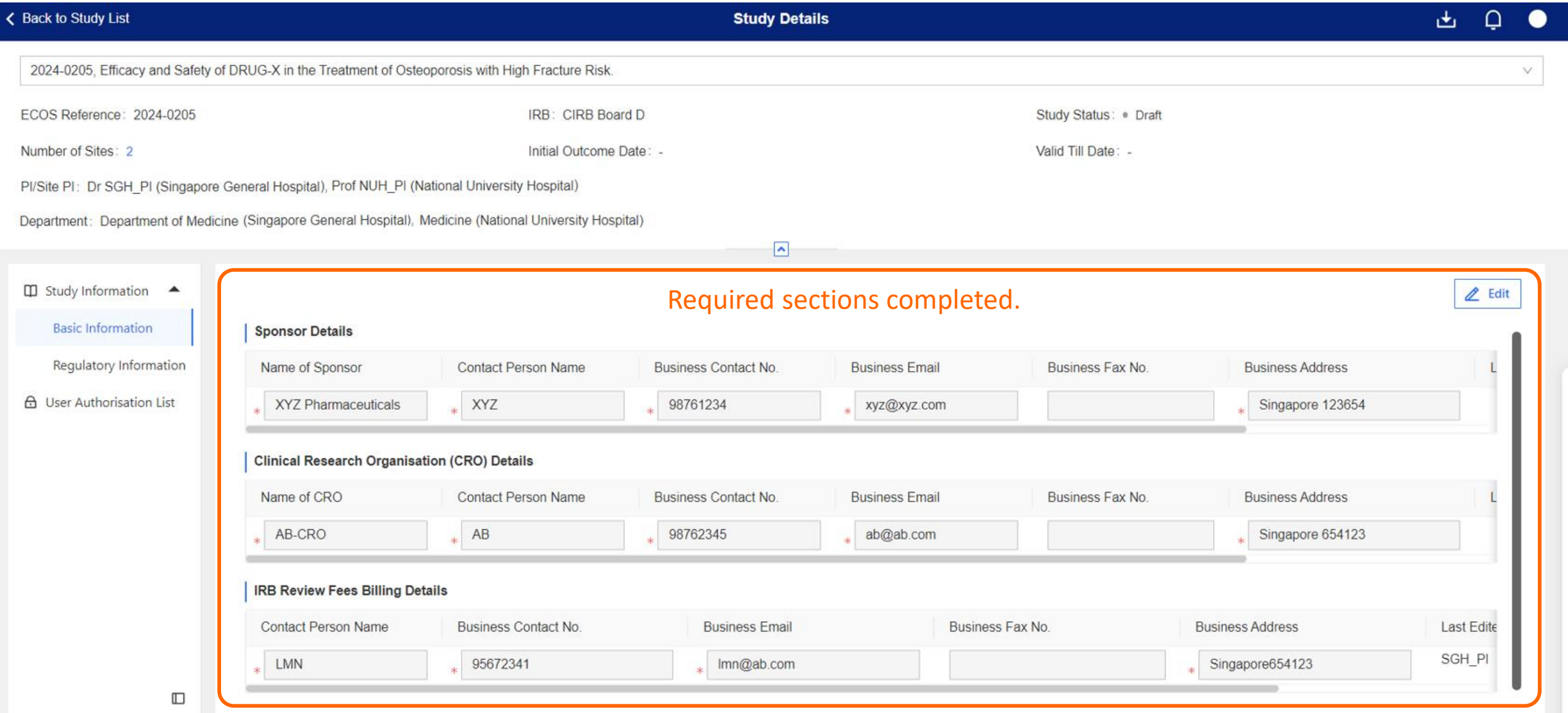
IRB Application Form – Section C1



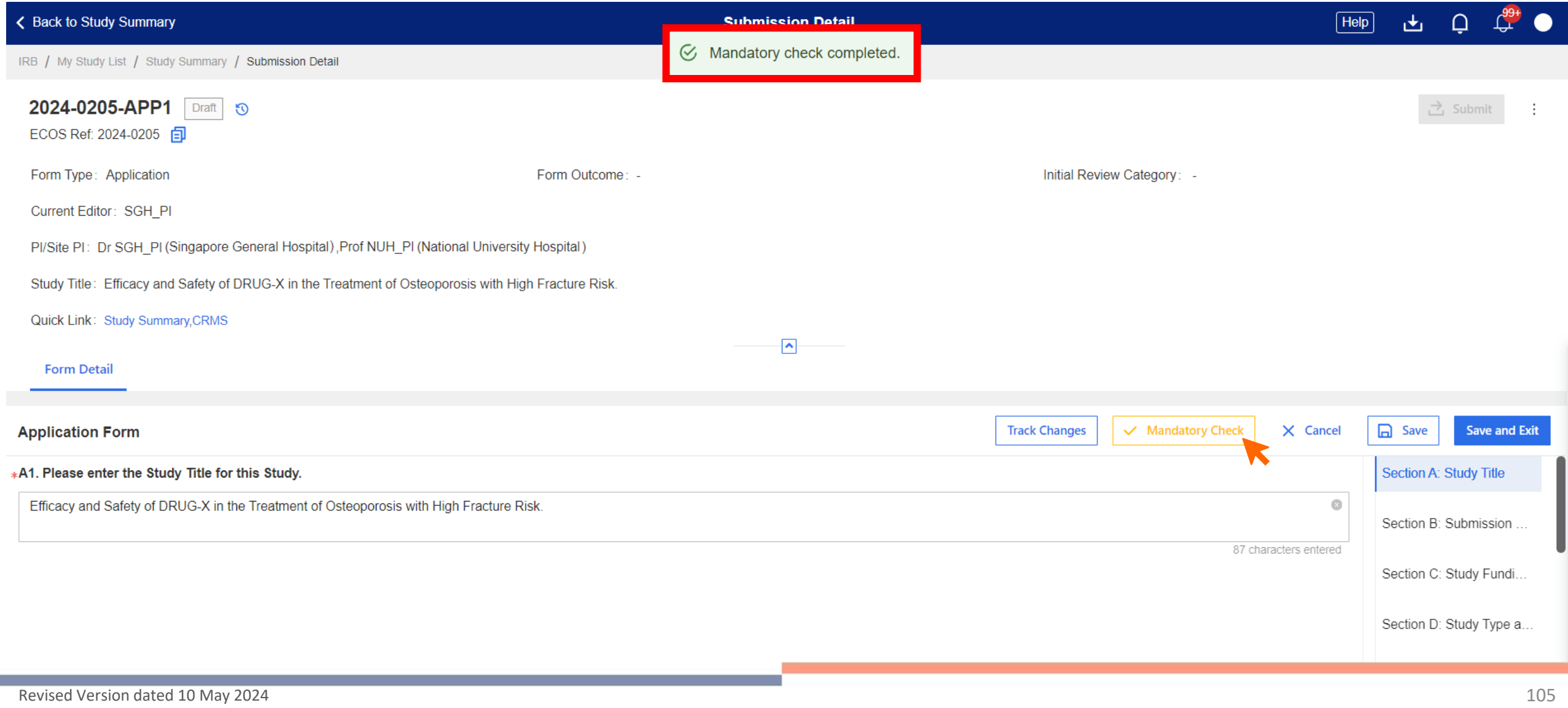
Mandatory Check Prompt From IRB APP Form



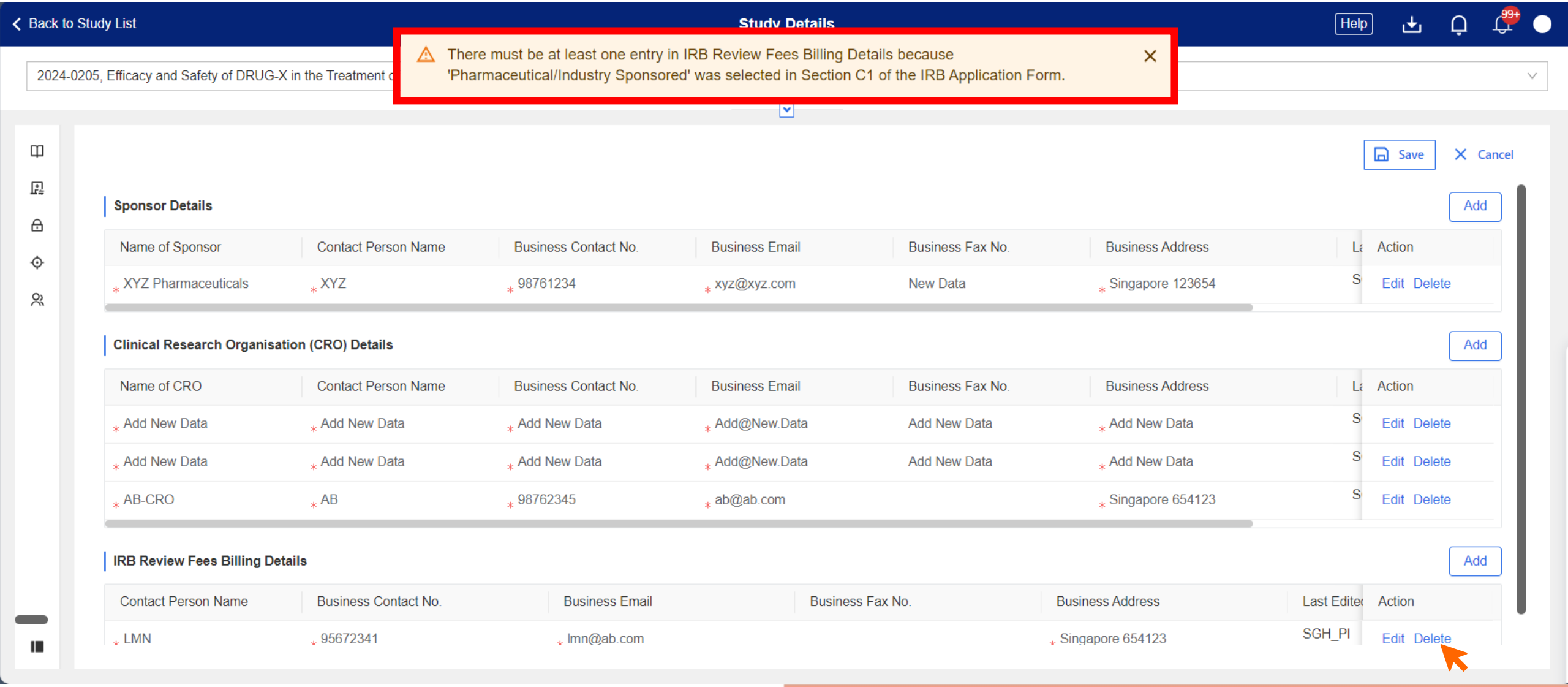
Complete Sponsor/CRO and IRB Details in CRMS



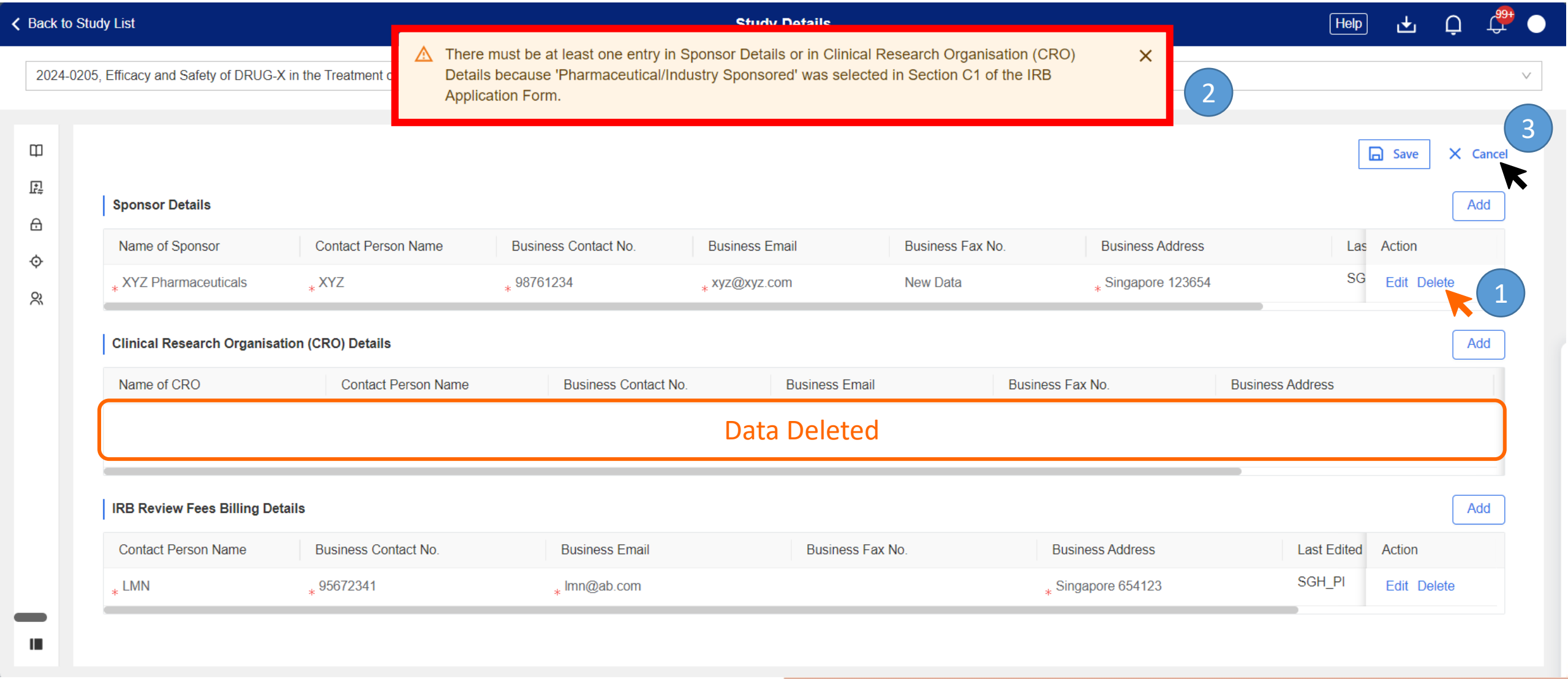
Return to IRB APP Form



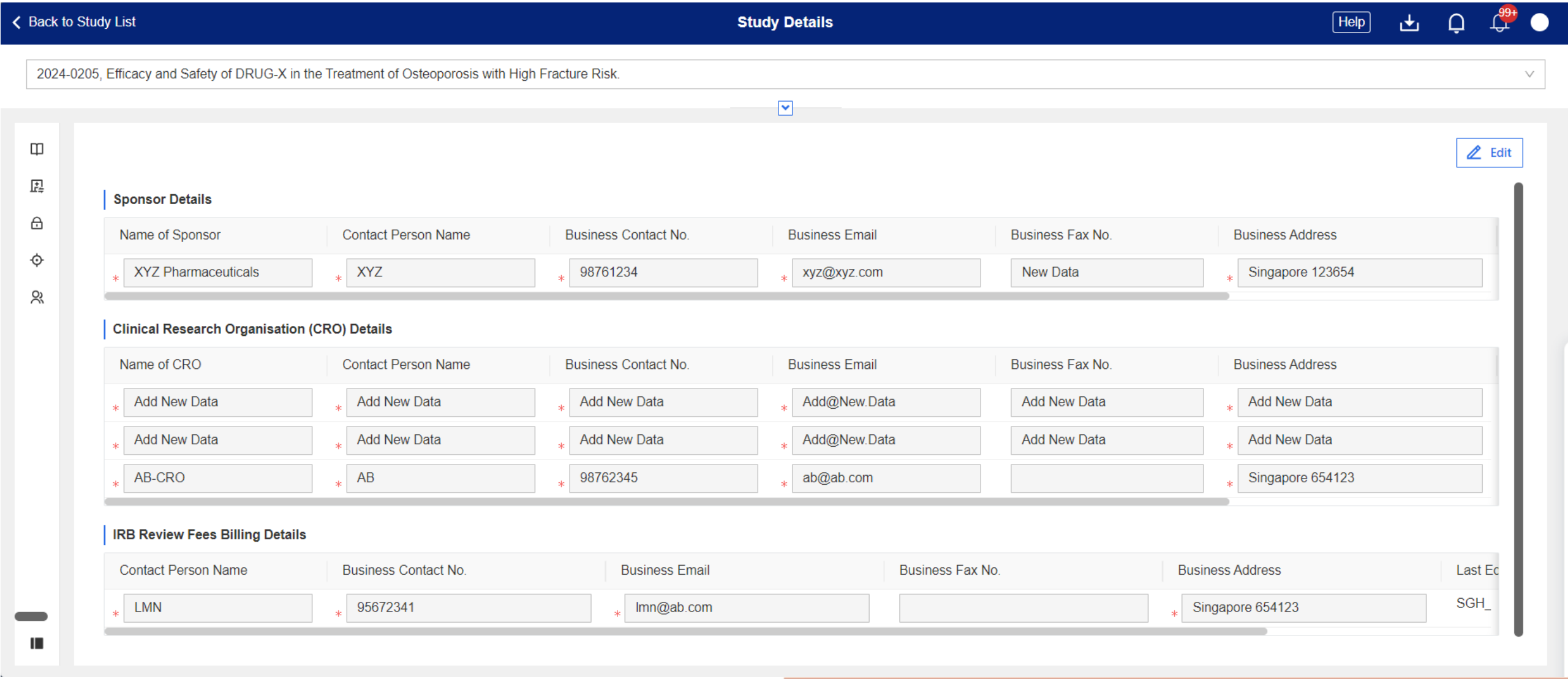
After IRB APP Form Approval



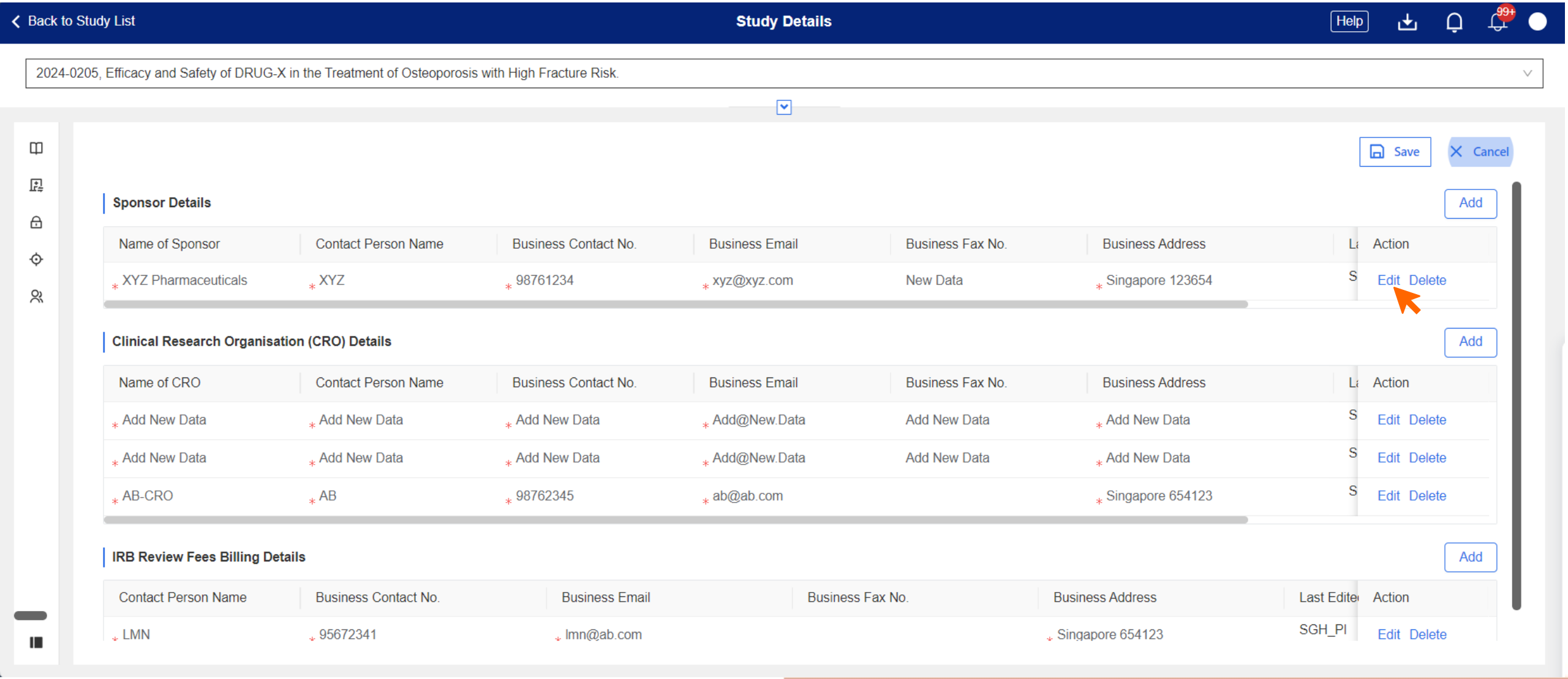
Applicable To Both Sponsor/CRO and IRB Details



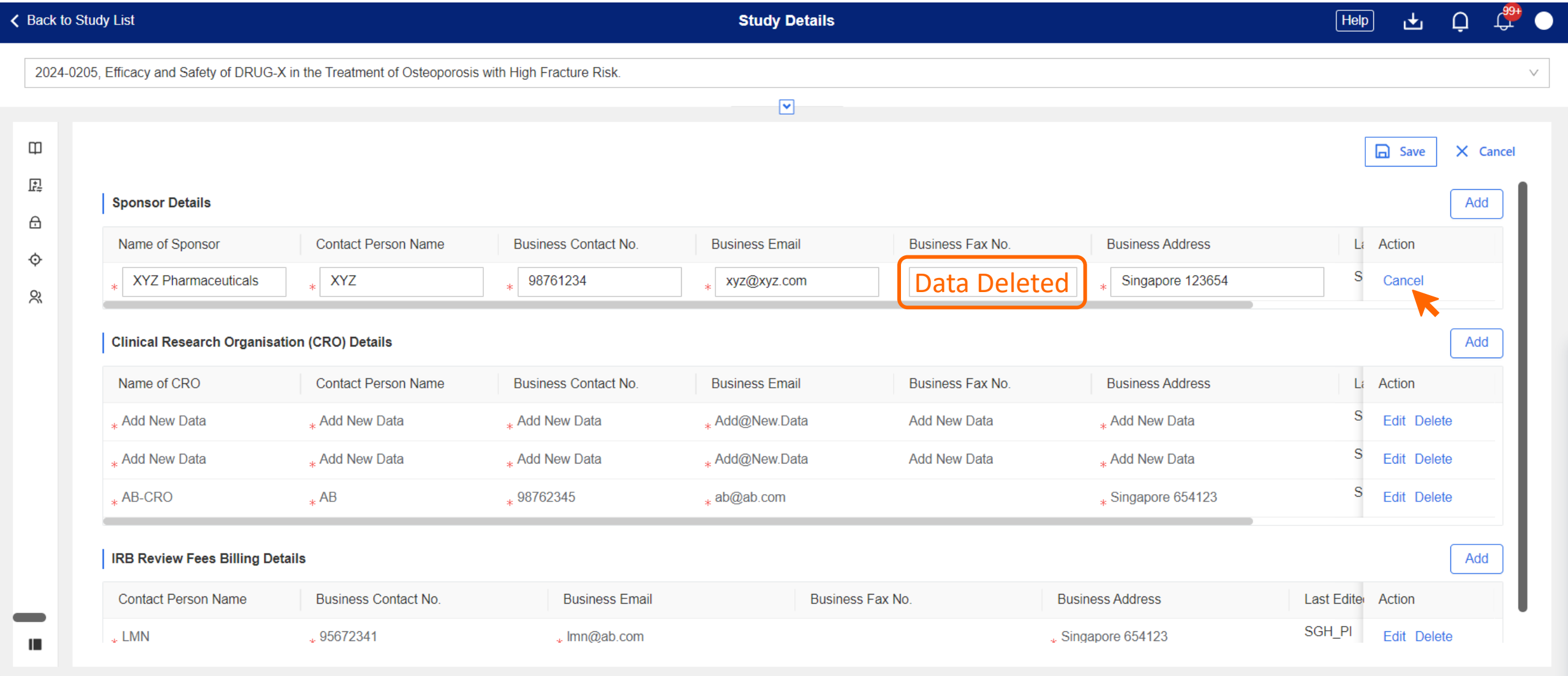
Original Data Reverted



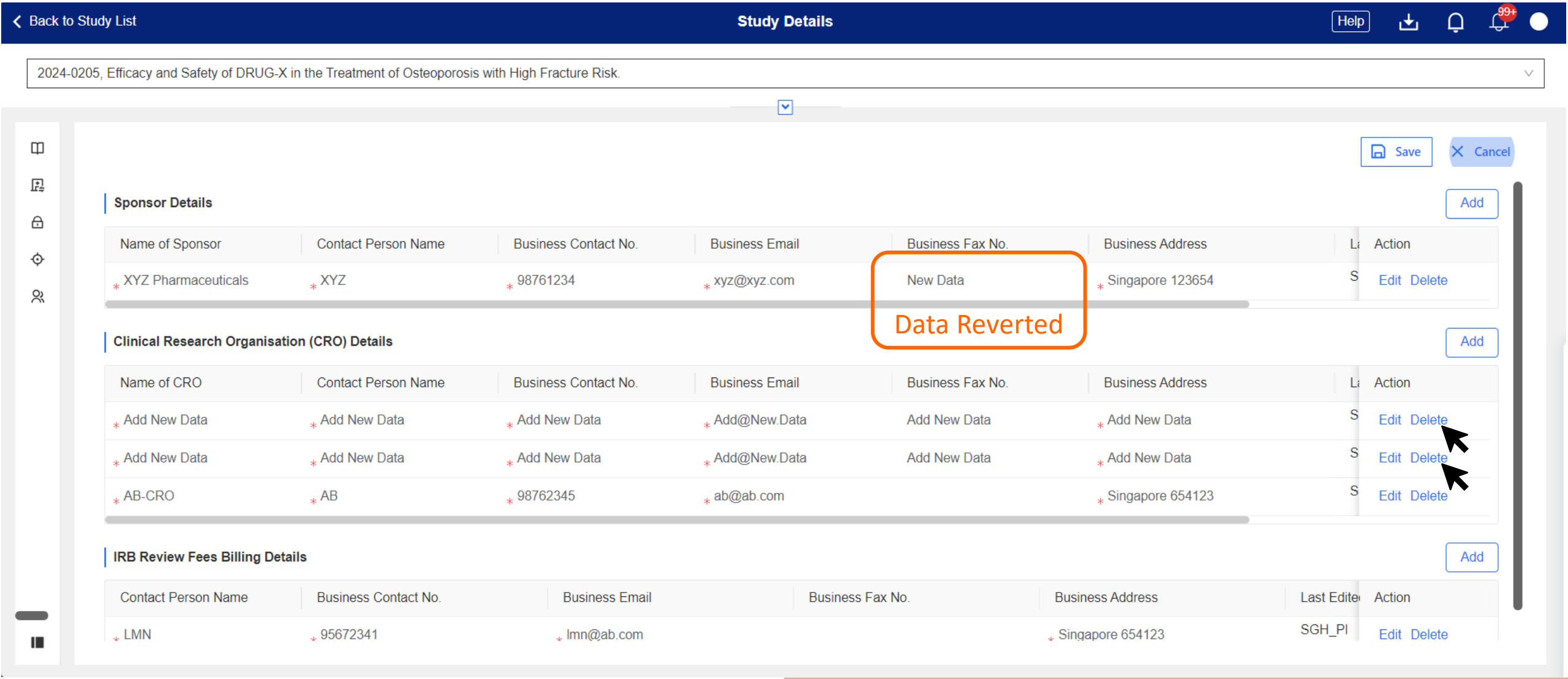
Page Functions – Cancel



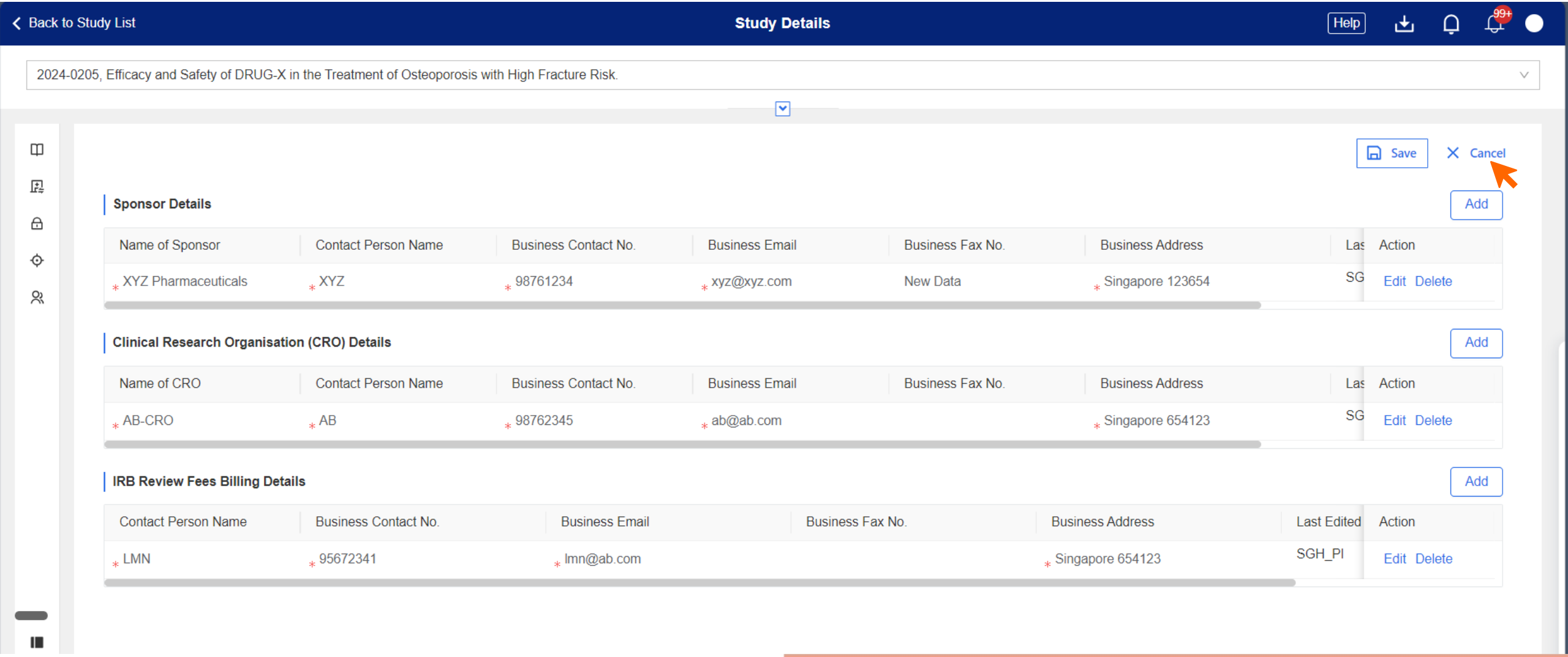
Page Functions – Cancel



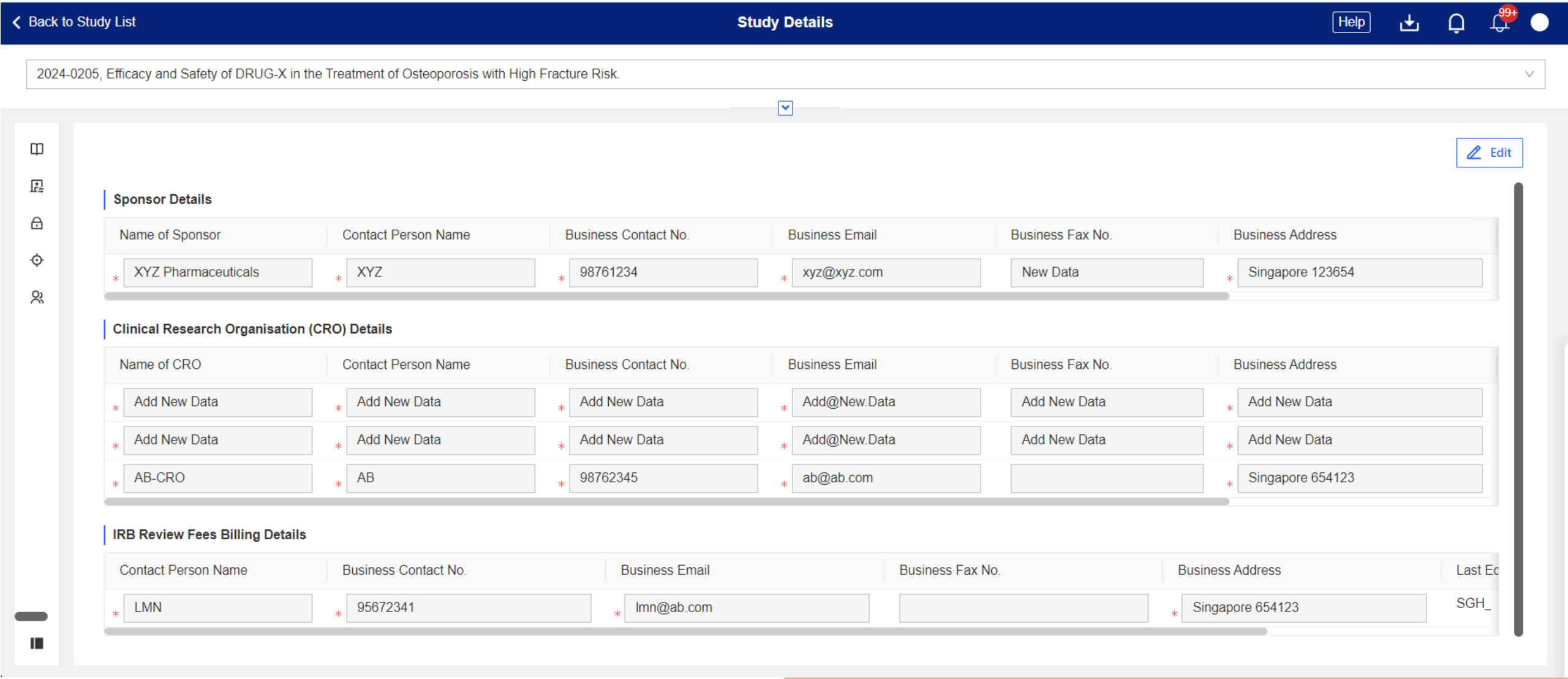
Page Functions – Cancel

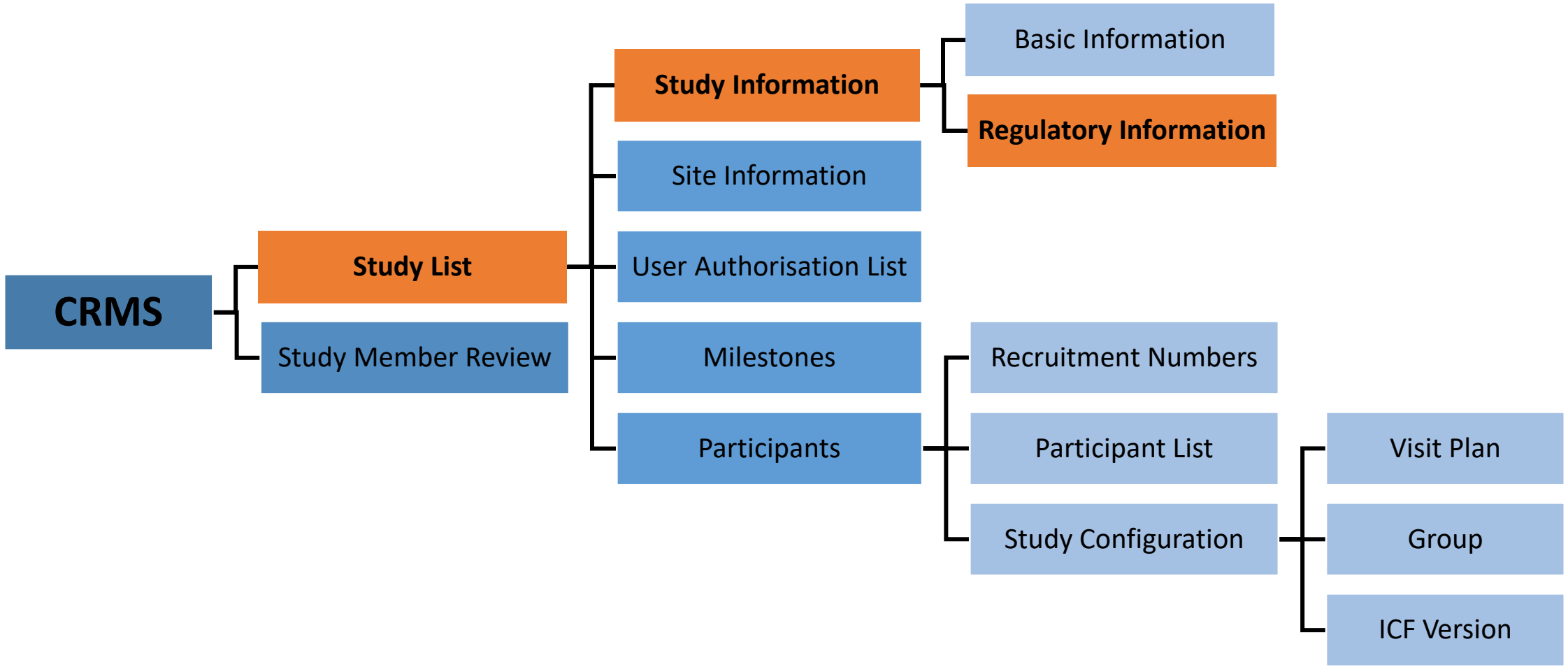


Page Functions – Cancel



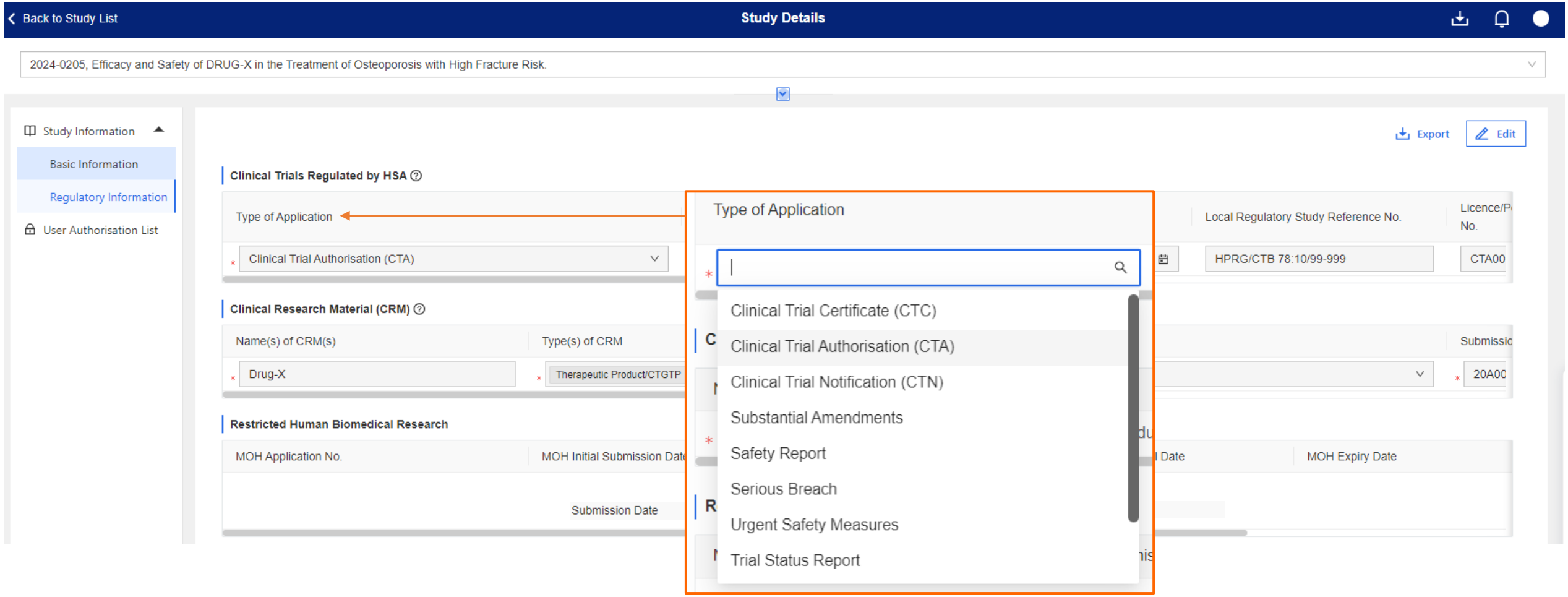
Original Data Reverted




CRMS
Study List
Study Member Review
Study Information
Site Information
User Authorisation List
Milestones
Participants
Basic Information
Regulatory Information
Recruitment Numbers
Participant List
Study Configuration
Visit Plan
Group
ICF Version

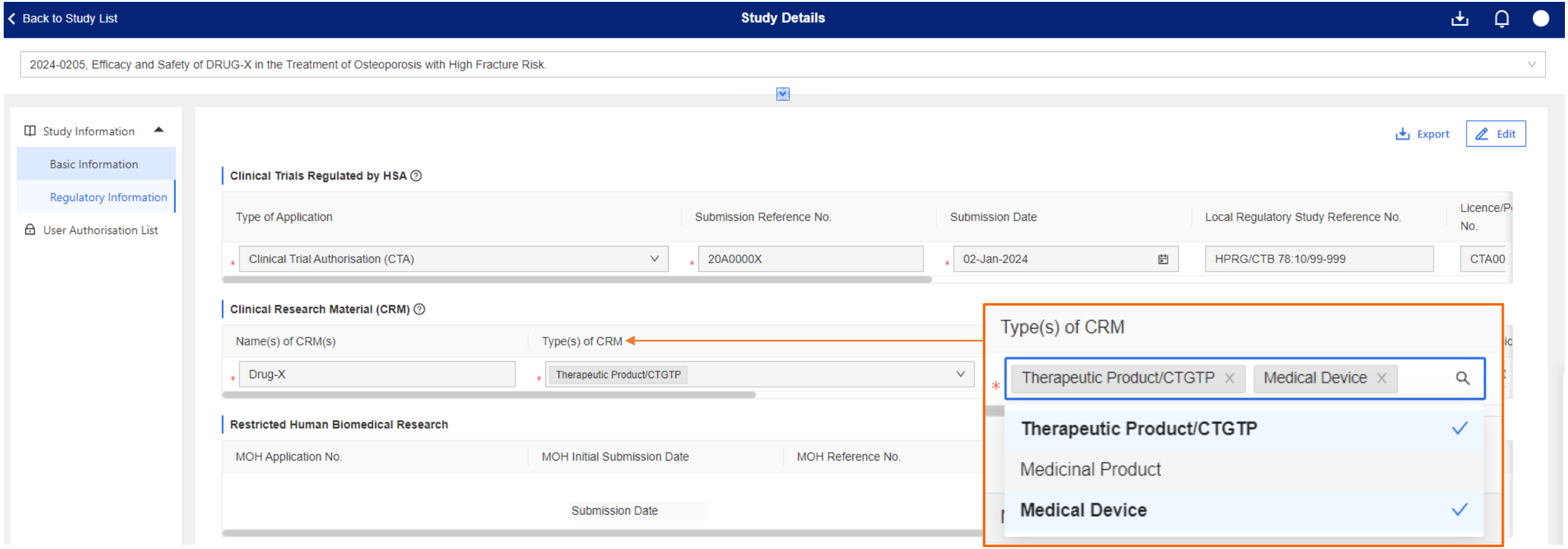
Study Information – Regulatory Information

Study Level



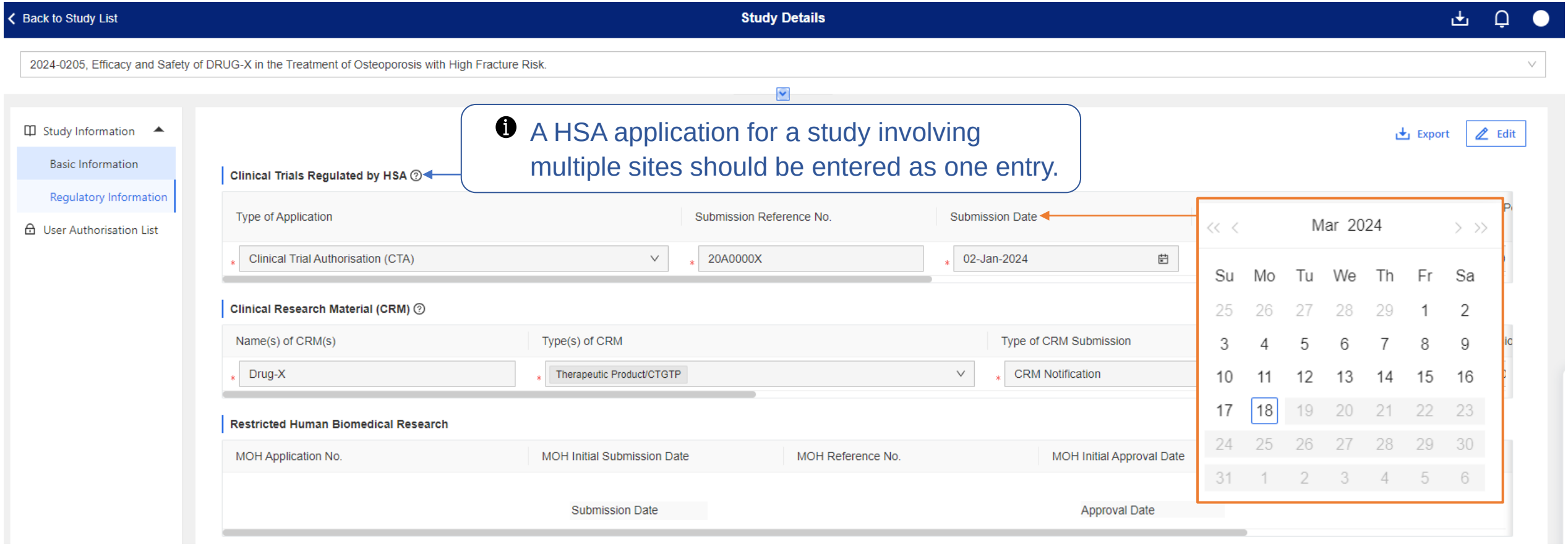
Study Information – Regulatory Information

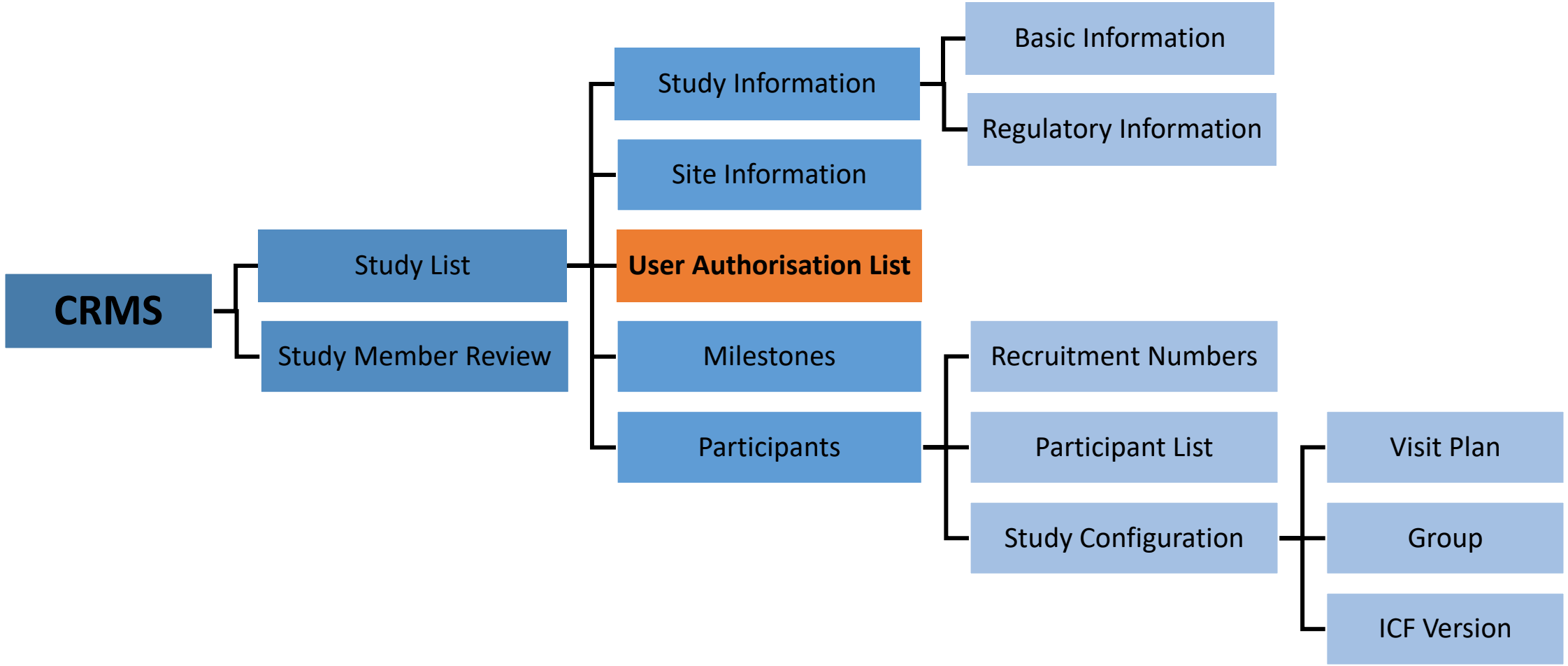
Study Level



Study Information – Regulatory Information

Study Level

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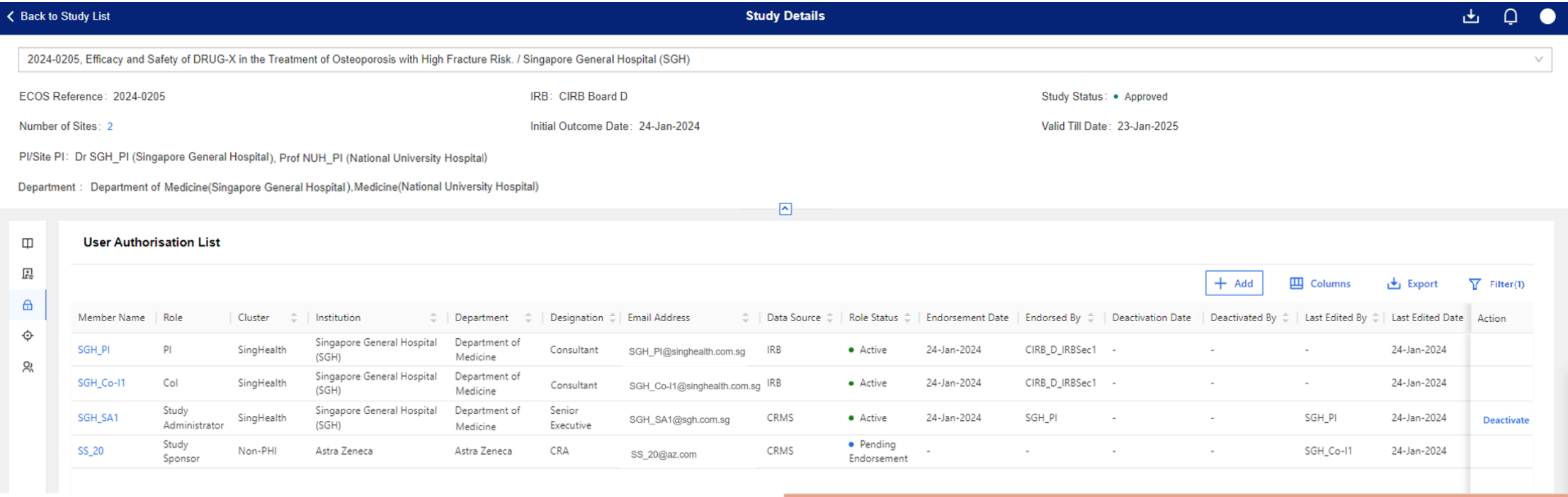
User Authorisation List (UAL)

Site Level

- User access management to CRMS and/or IRB modules on ECOS.
- PI/Site-PI, Co-I, Study Team Members, Study Administrators and Study Sponsor roles will be listed.
- But the UAL access management is for STM, SA and SS roles only.



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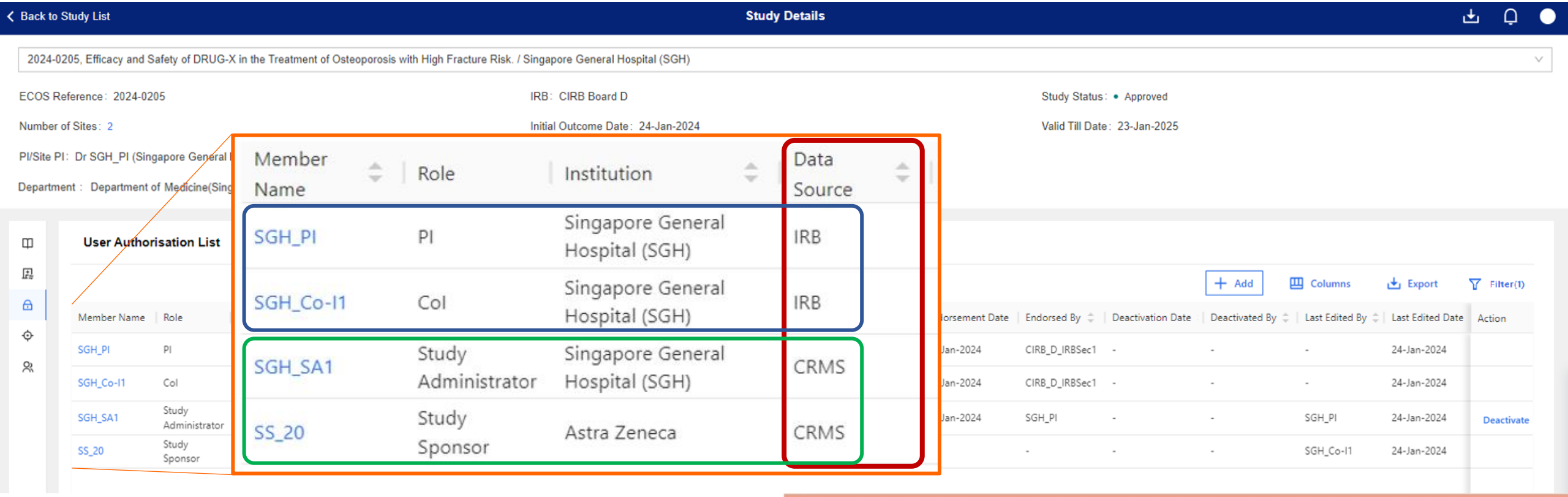


User Authorisation List (UAL)

<table>
<tr><th>Role</th><th>Definition</th><th>Comments</th></tr>
<tr><td>PI</td><td rowspan="3">Site investigators directly involved in the research.</td><td rowspan="3">Access management: IRB module > IRB APP or AMD Form > Section B2(a) Investigator List

• The list of investigators will be imported from IRB to CRMS module at each synchronisation point (as applicable) with IRB indicated as the data source.
• IRB approval is required to gain full CRMS access.
• Addition and deactivation will both go through the IRB module.

During IRB Application drafting:
➢ The addition or removal of any PI, Site-PI or Co-I in the draft IRB Application Form will be reflected on the CRMS UAL each time the IRB Application Form is saved.

In subsequent IRB Amendment Form(s):
➢ New PI, Site-PI or Co-I will only appear on the CRMS UAL after IRB has provided approval for the Amendment Form.
➢ Investigators to be removed will only be deactivated on the UAL after IRB’s review.</td></tr>
<tr><td>Site PI</td></tr>
<tr><td>Co-I</td></tr>
</table>

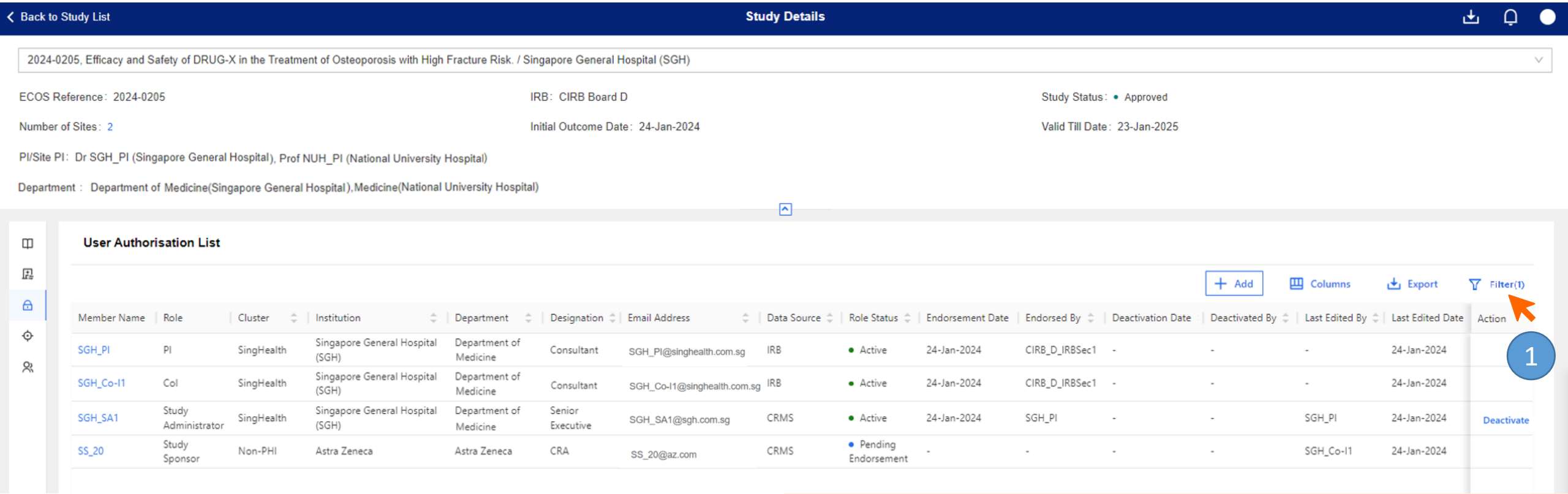
User Authorisation List (UAL)

Role	Definition	Comments
Study Team Member (STM) & Study Administrator (SA)	**STM**: Site personnel **directly involved** in the research e.g. CRCs, Study Nurses, Pharmacists etc. **SA**: Site personnel **not directly** involved in the research but provides administrative support only, e.g. Executives, CRCs not involved in the conduct of research.	**Access management: CRMS module > UAL** • Data source on UAL will indicate CRMS. • Any user on the UAL can add or deactivate a user. • New users added will require PI's endorsement in CRMS, endorsement is site-specific. • Addition of new user(s) by PI/Site-PI will automatically be endorsed upon submission. • User deactivation does not require endorsement from PI/Site-PI. • Once deactivated, access to CRMS and other related modules will be revoked, e.g. IRB. • Reactivation of the user is not allowed, i.e. a new entry needs to be added and endorsed to "reactivate" the user. • Number of users that can be added to the UAL is not capped, but please be mindful when performing this task as every addition and deactivation will be captured on this list. • Site will need to manage and keep the UAL updated, i.e. STM/SA/SS(s) no longer directly involved in the study should be deactivated in the list for IRB and CRMS accesses to be revoked.
Study Sponsor (SS)	Sponsor/CRO personnel, e.g. Clinical Trial Assistants, Clinical Research Associates, Clinical Trial Managers etc.	

Page Functions – Filter

NOTE:

- The UAL is pre-set to display only roles that are Active, Pending IRB Approval or Pending Endorsement.
- To view all Active, Pending and Inactive roles, remove the default filter configured.



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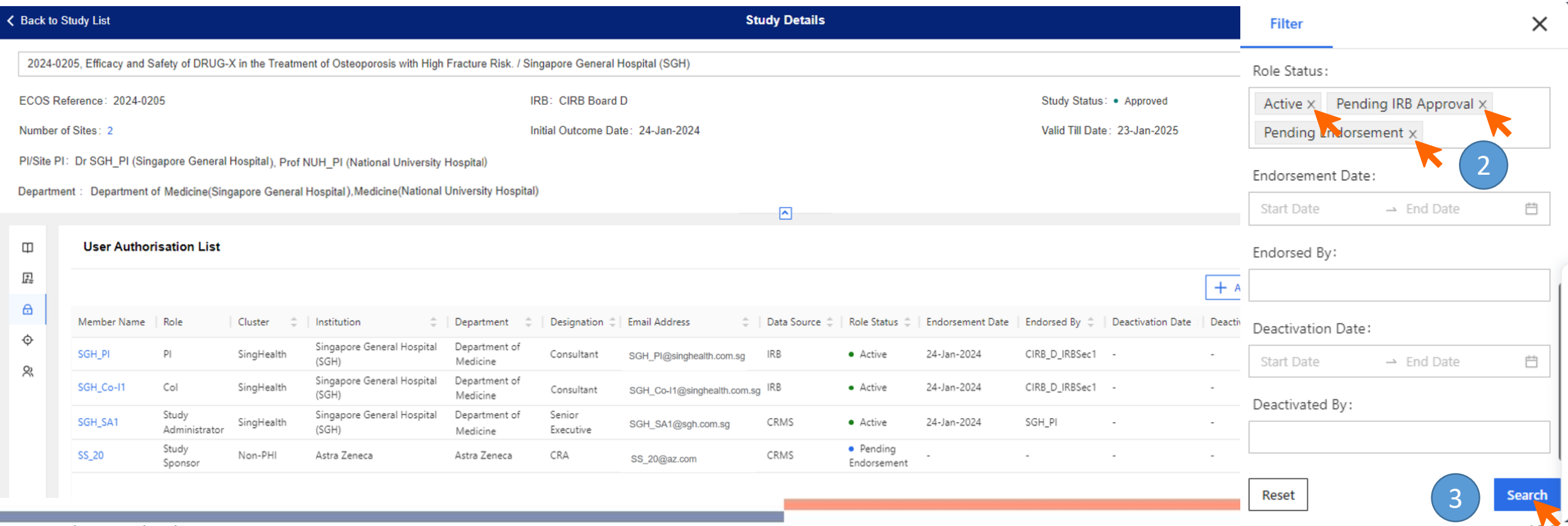
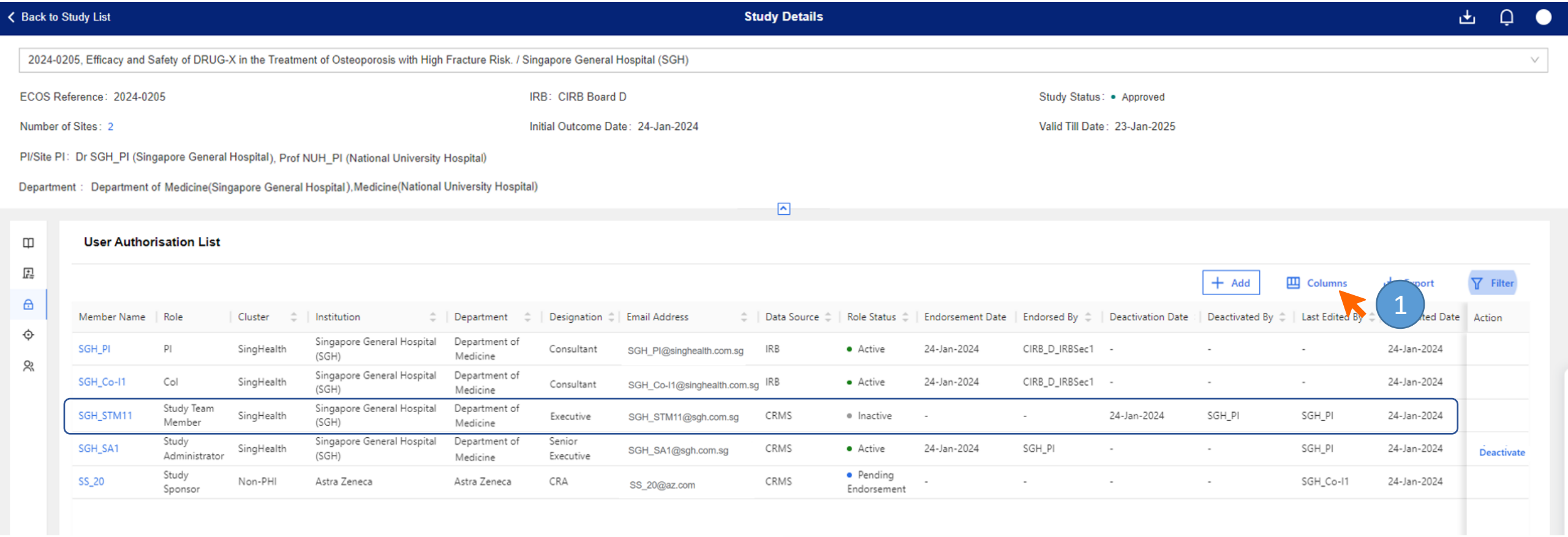


Page Functions – Columns

- With the filter removed, the UAL additionally displays SGH_STM11 (Role Status: Inactive).
- Use the Columns function to narrow the information to be displayed.



Page Functions – Columns

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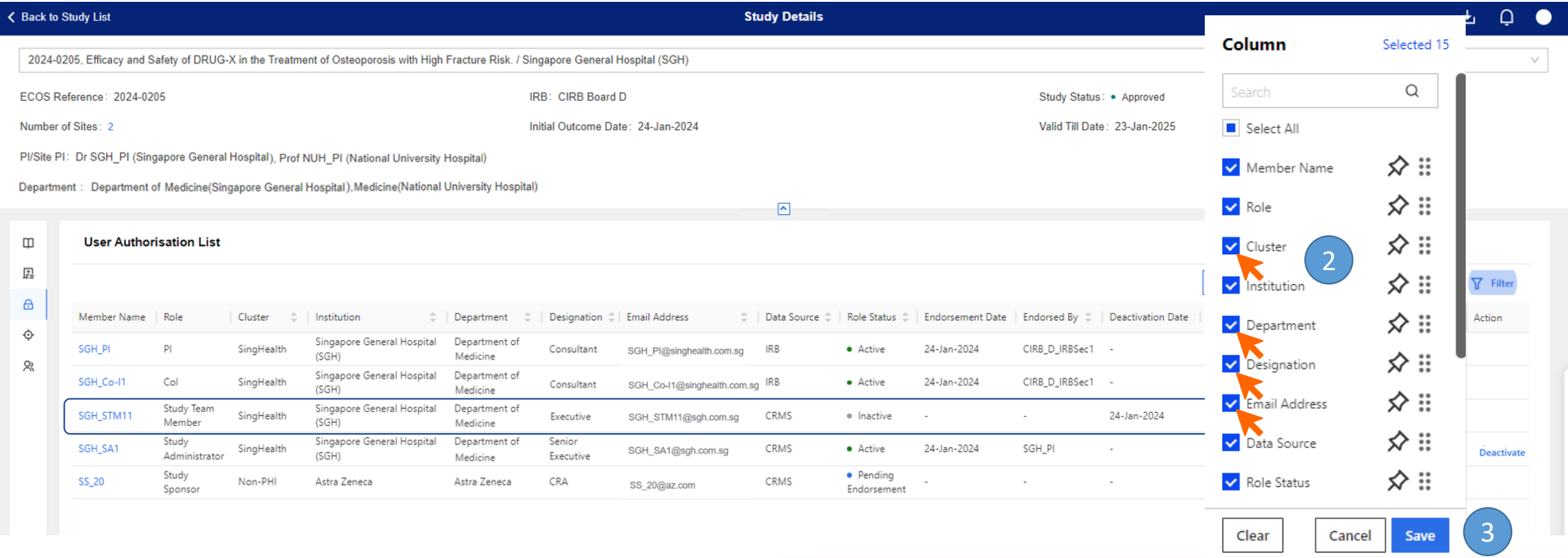
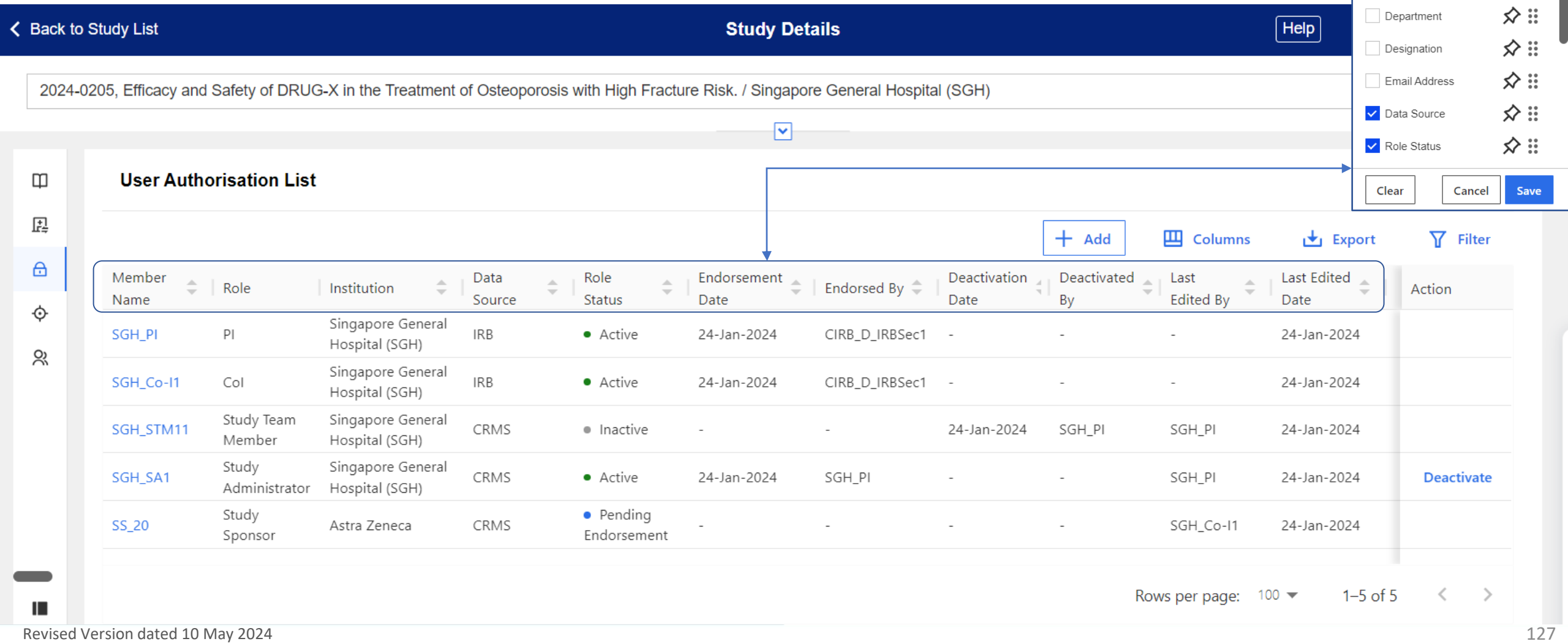


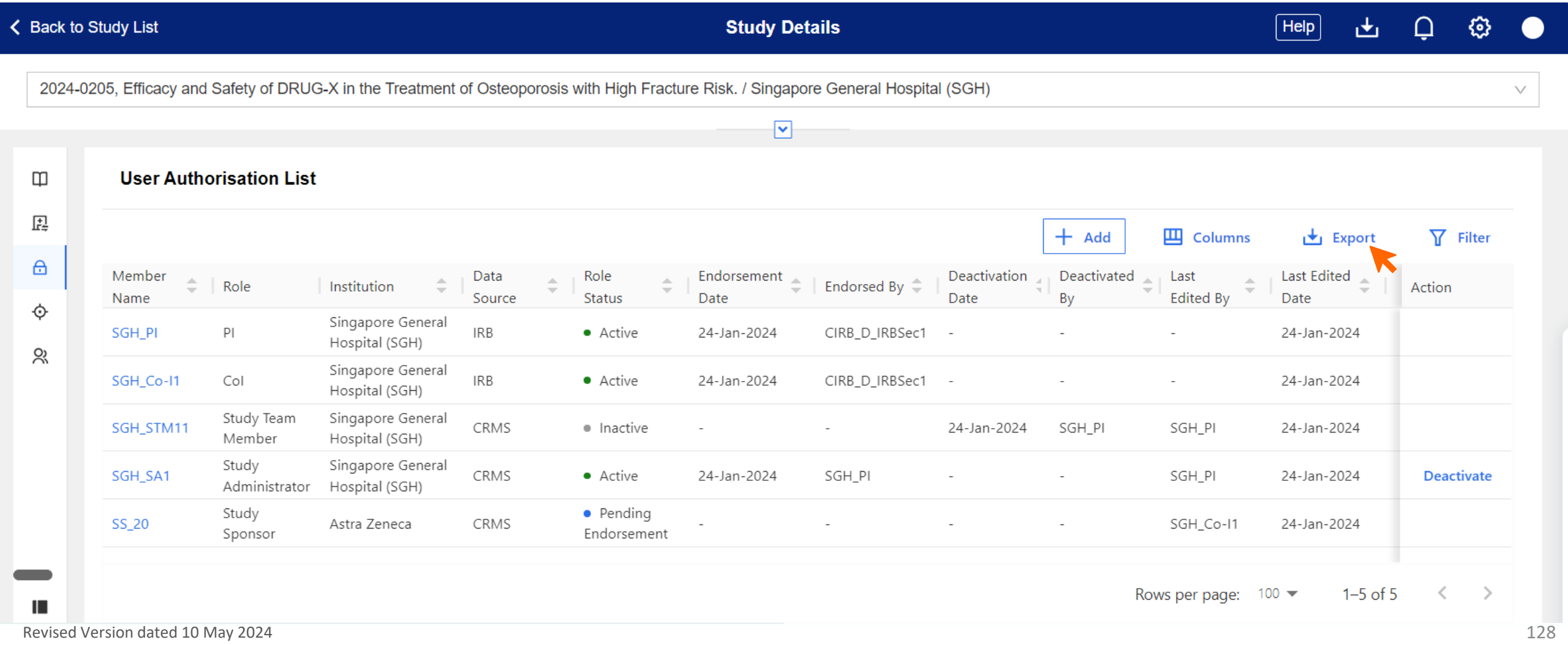
Page Functions – Export

- The 4 data columns unchecked will not be displayed.



Page Functions – Export

- Click on the Export button to print the UAL in Excel or PDF.



Page Functions – Export

Export function will be soft-launched in May go-live. It may contain some errors that user will need to correct using the Excel version.

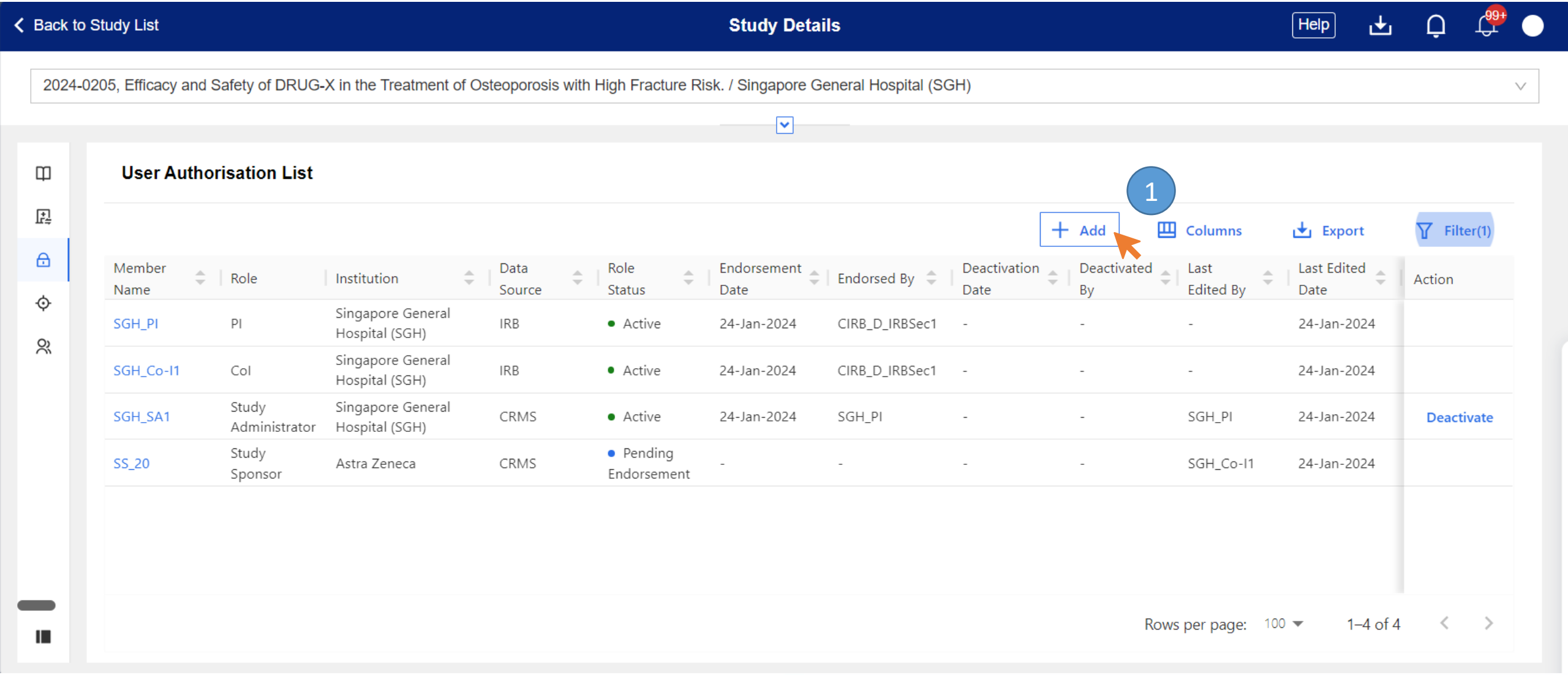
- The Export function will generate the UAL with the specific Columns and Filter selected (if any).
- Use can choose to export in Excel or PDF version.
  - ➢ Excel offers better flexibility to modify the column and row width/heights before saving as PDF.
- Steps to export are the same across all pages that can be exported.

ECOS Reference: 2024-0205
Unique Identifier: 2024-0205-Singapore General Hospital
Study Title: Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.
PI/Site-PI: Dr SGH_PI (Singapore General Hospital), Prof NUH_PI (National University Hospital)
Study Status: Approved
Initial Outcome Date: 24-Jan-2024
Valid Till Date: 23-Jan-2025
Downloaded By: SGH_PI
Downloaded Date and Time: 23-Feb-2024 17:54:46

Member Name	Role	Institution	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date
SGH_PI	PI	Singapore General Hospital	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1				24-Jan-2024
SGH_Co-I1	CoI	Singapore General Hospital	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1				24-Jan-2024
SGH_STM11	Study Team Member	Singapore General Hospital	CRMS	Inactive			24-Jan-2024	SGH_PI	SGH_PI	24-Jan-2024
SGH_SA1	Study Administrator	Singapore General Hospital	CRMS	Active	24-Jan-2024	SGH_PI			SGH_PI	24-Jan-2024
SS_20	Study Sponsor	Astra Zeneca	CRMS	Pending Endorsement					SGH_Co-I1	24-Jan-2024

Expected view of the exported UAL.

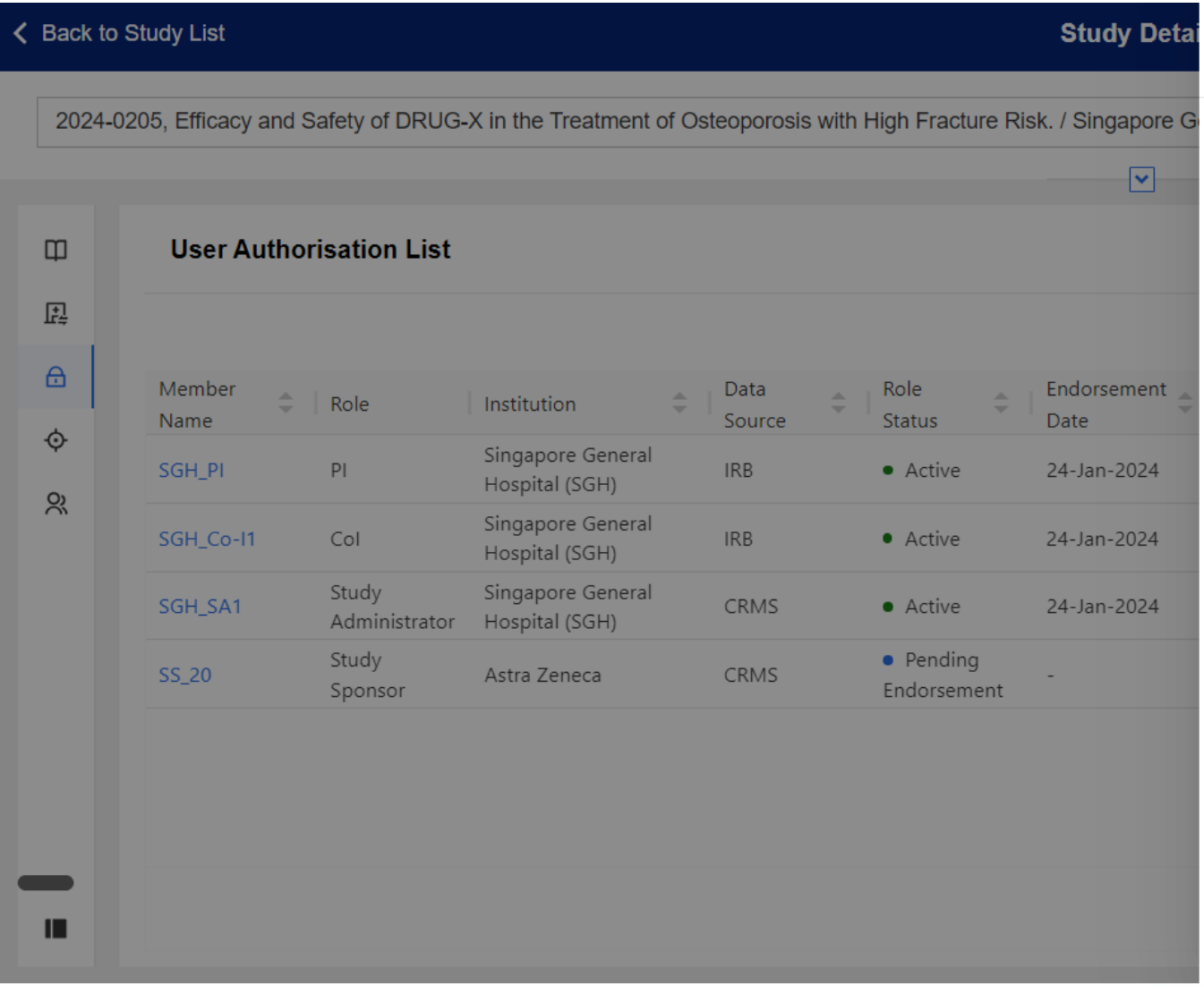
Page Functions – Add

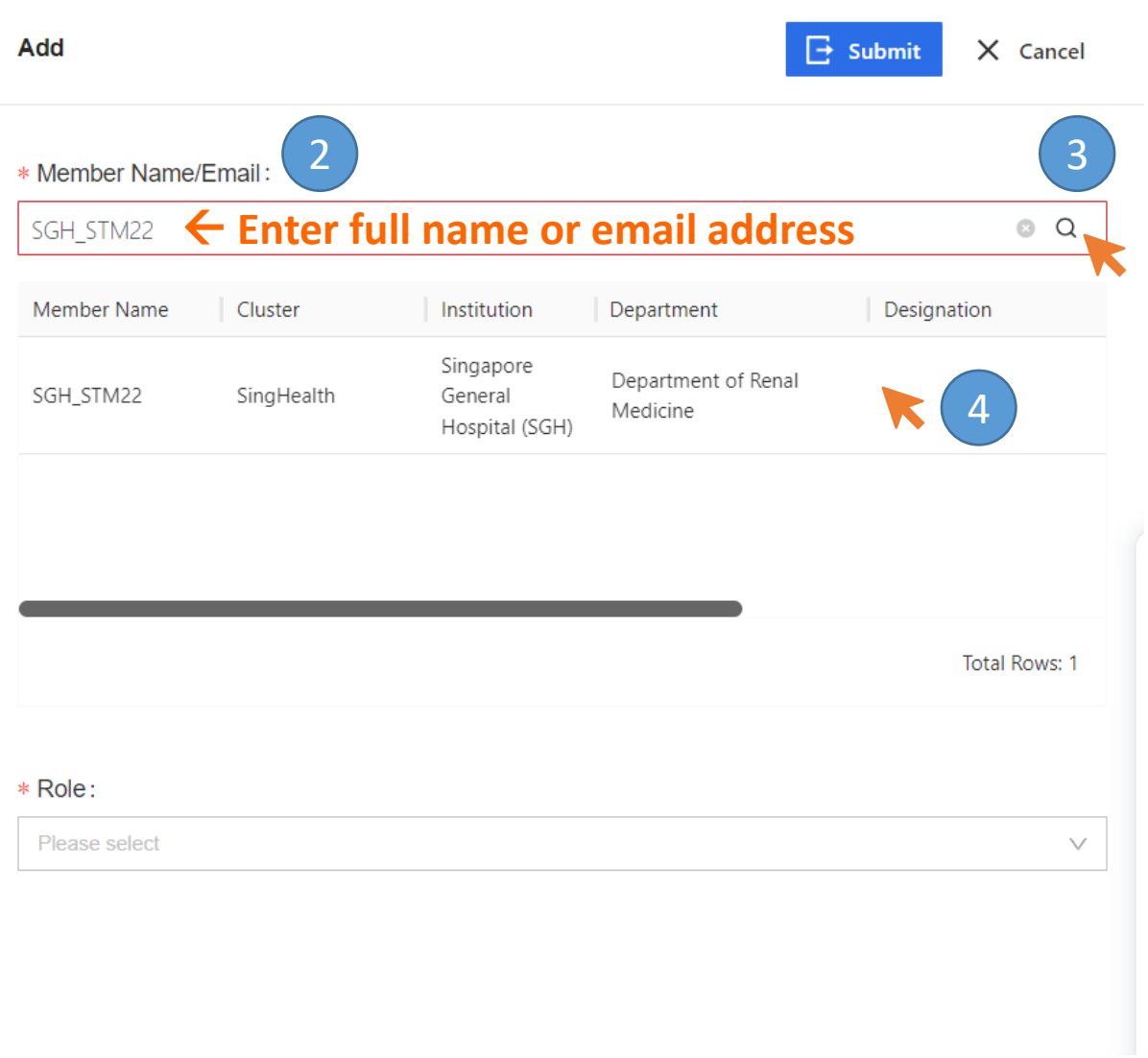


Page Functions – Add

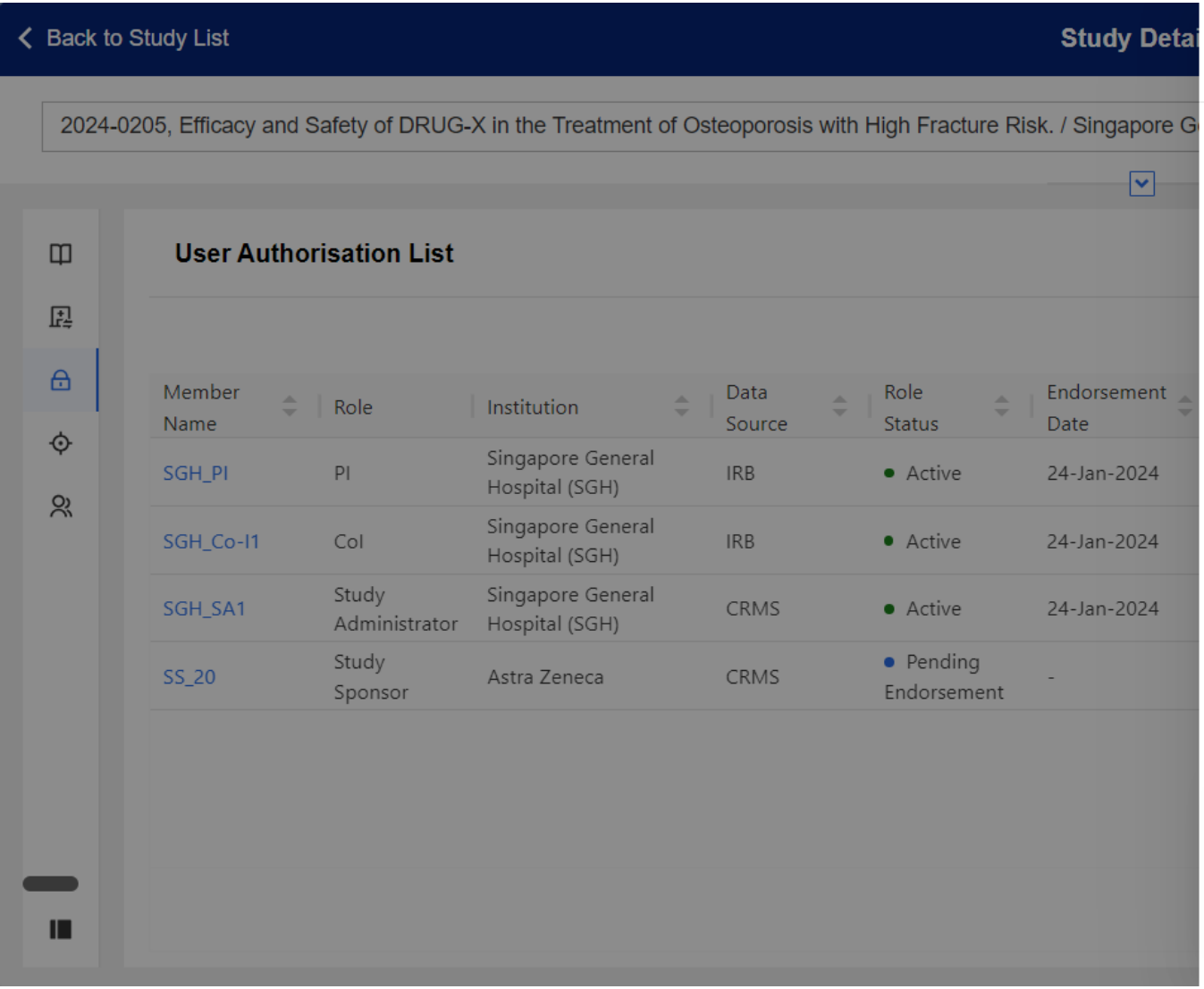
IMPORTANT

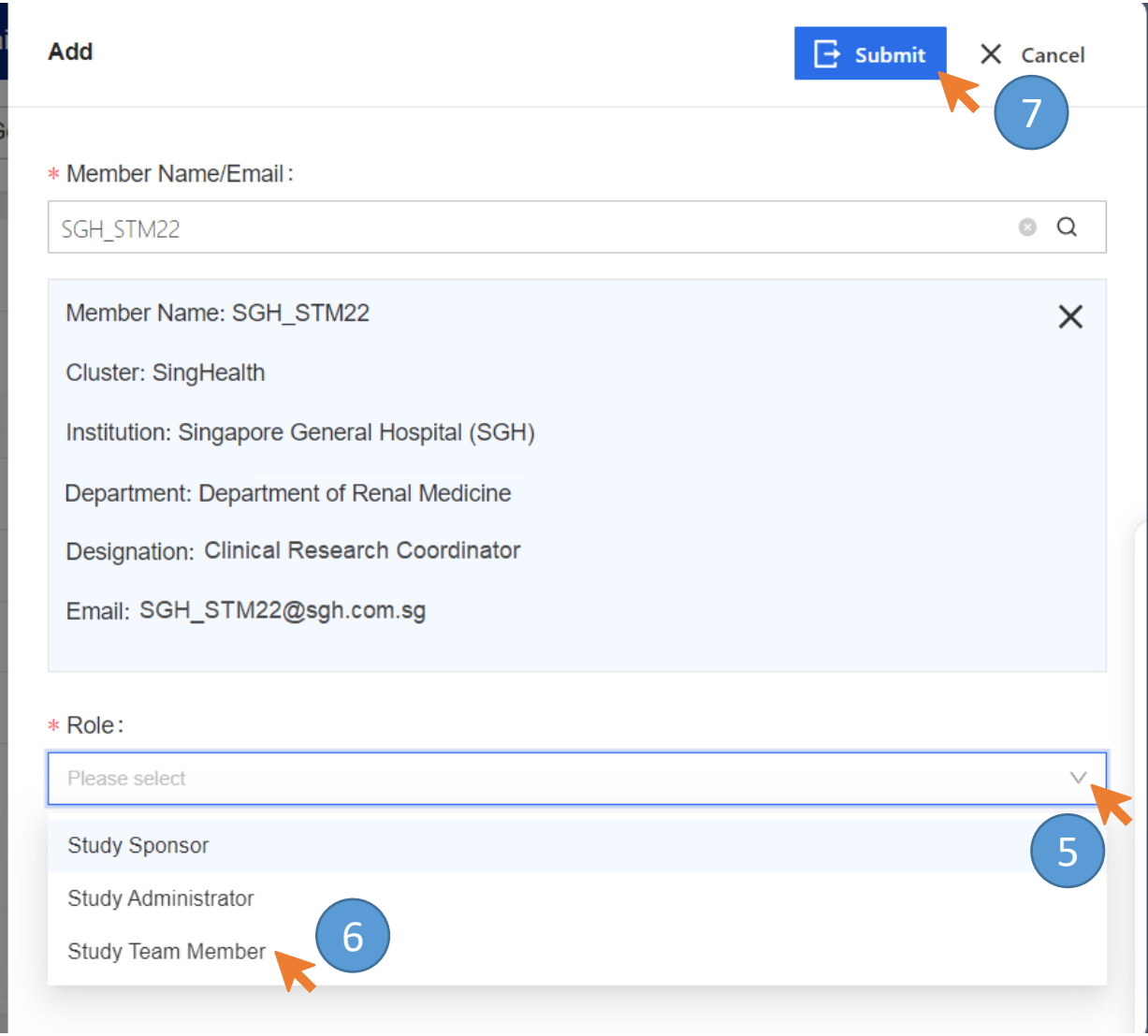
Fuzzy search is not allowed.





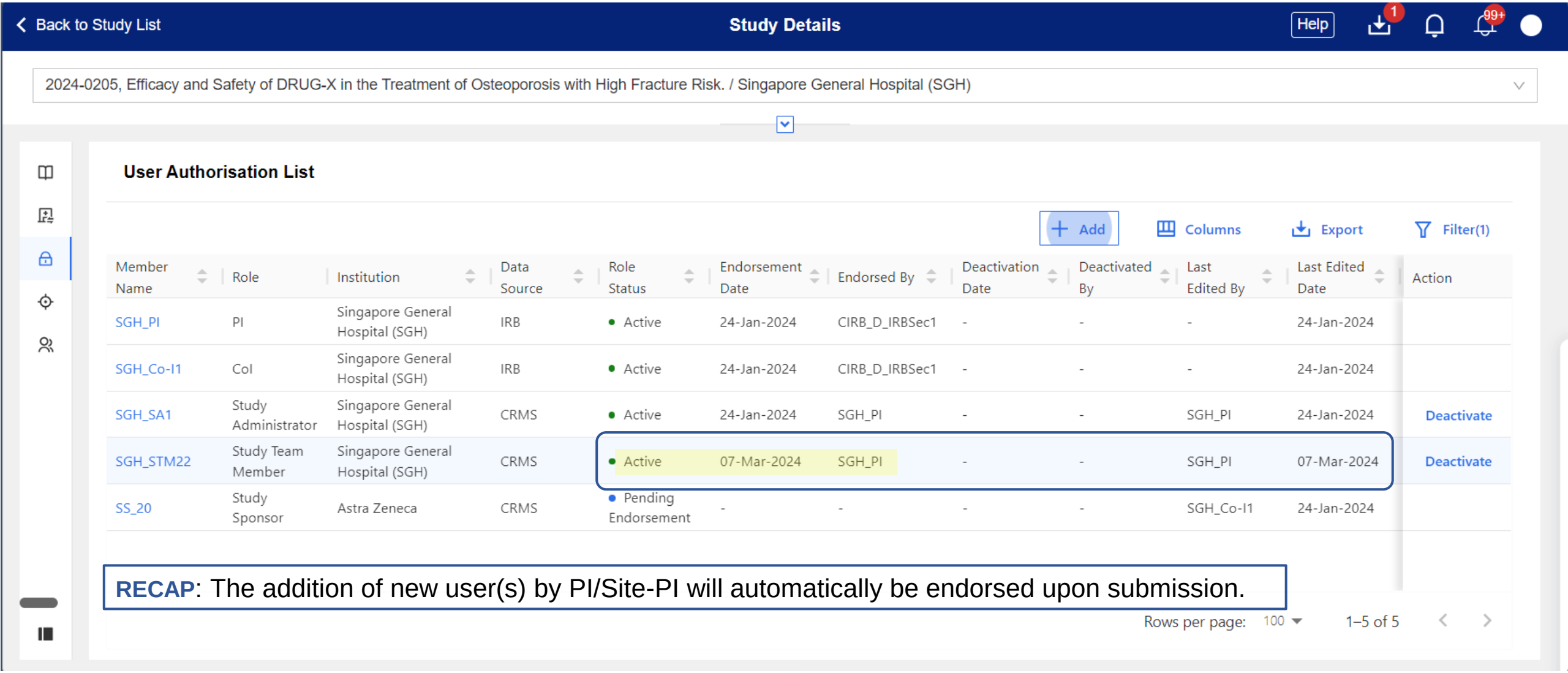
Page Functions – Add





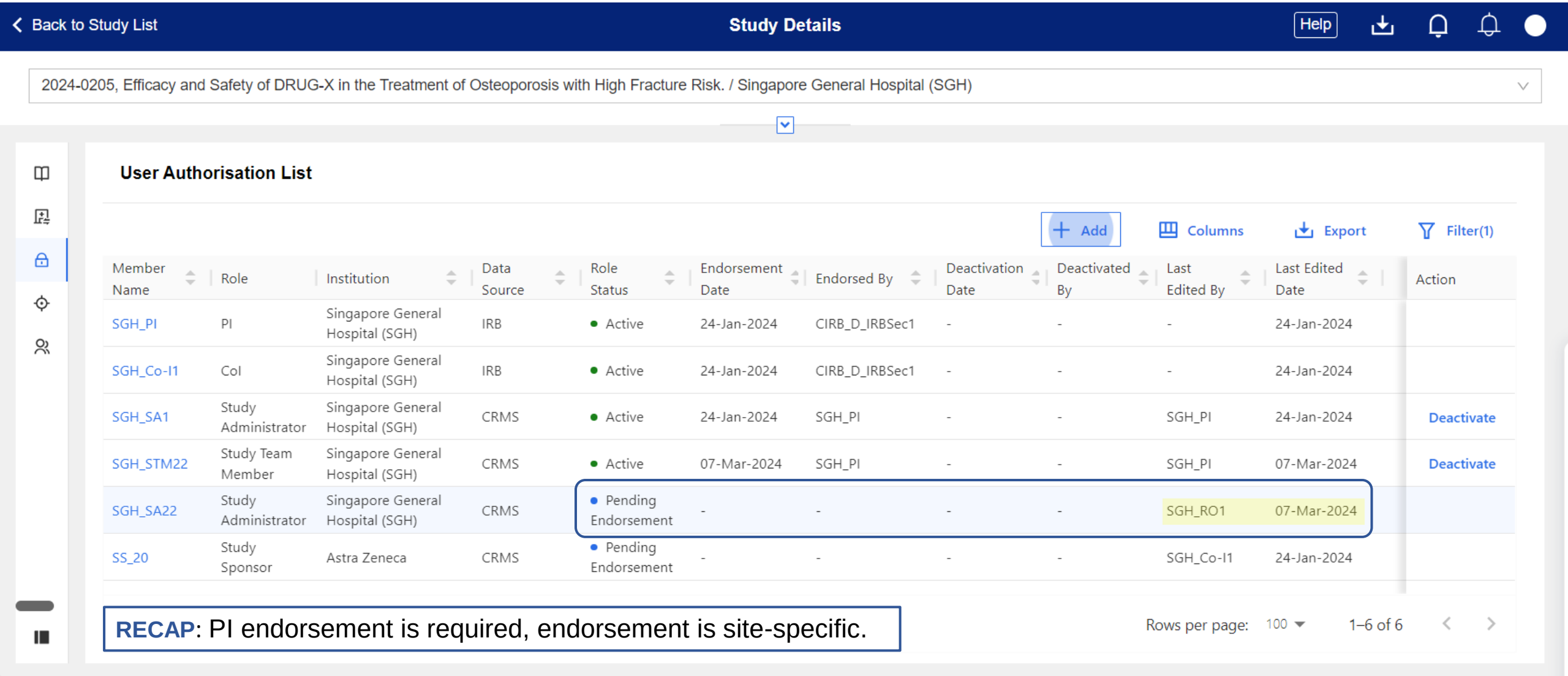
Page Functions – Add User

Role used: PI or Site-PI



Page Functions – Add User

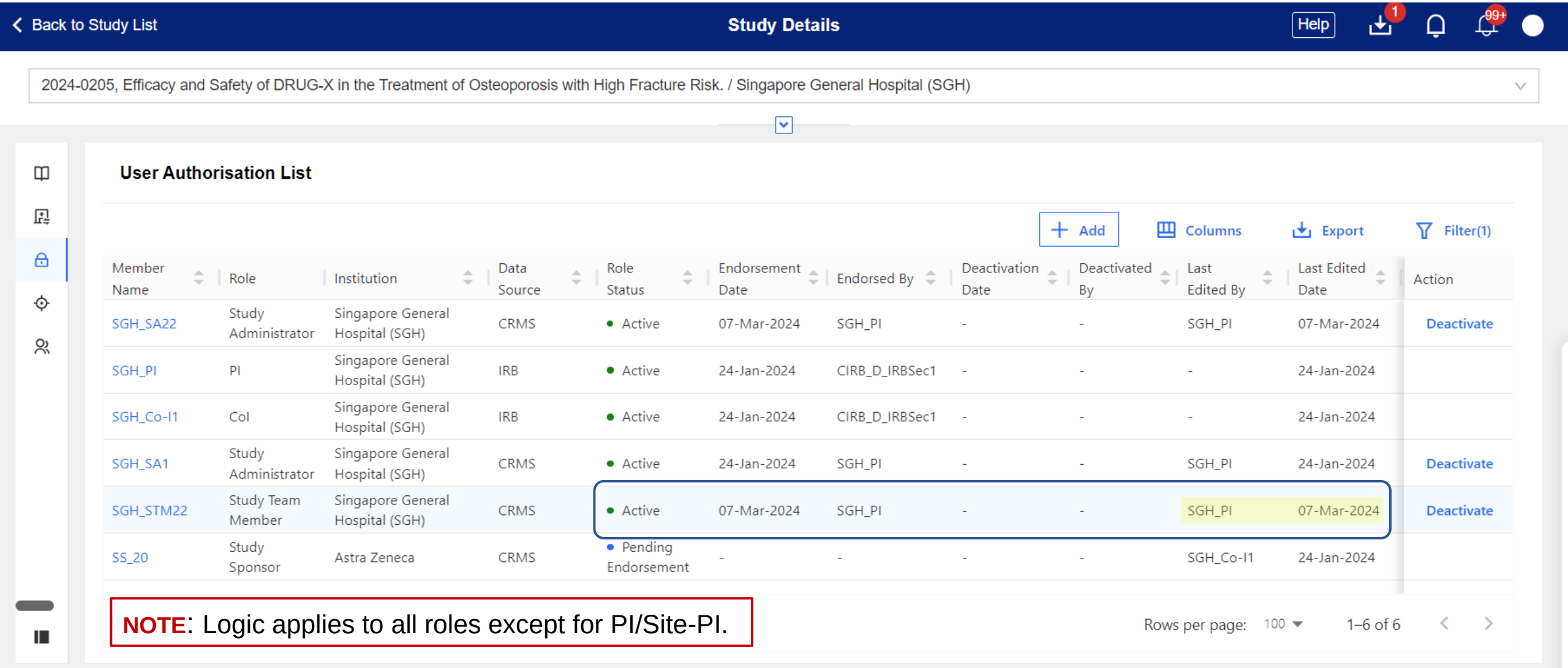
Role used: CRMS RO administrator



RECAP: PI endorsement is required, endorsement is site-specific.

Page Functions – Add User

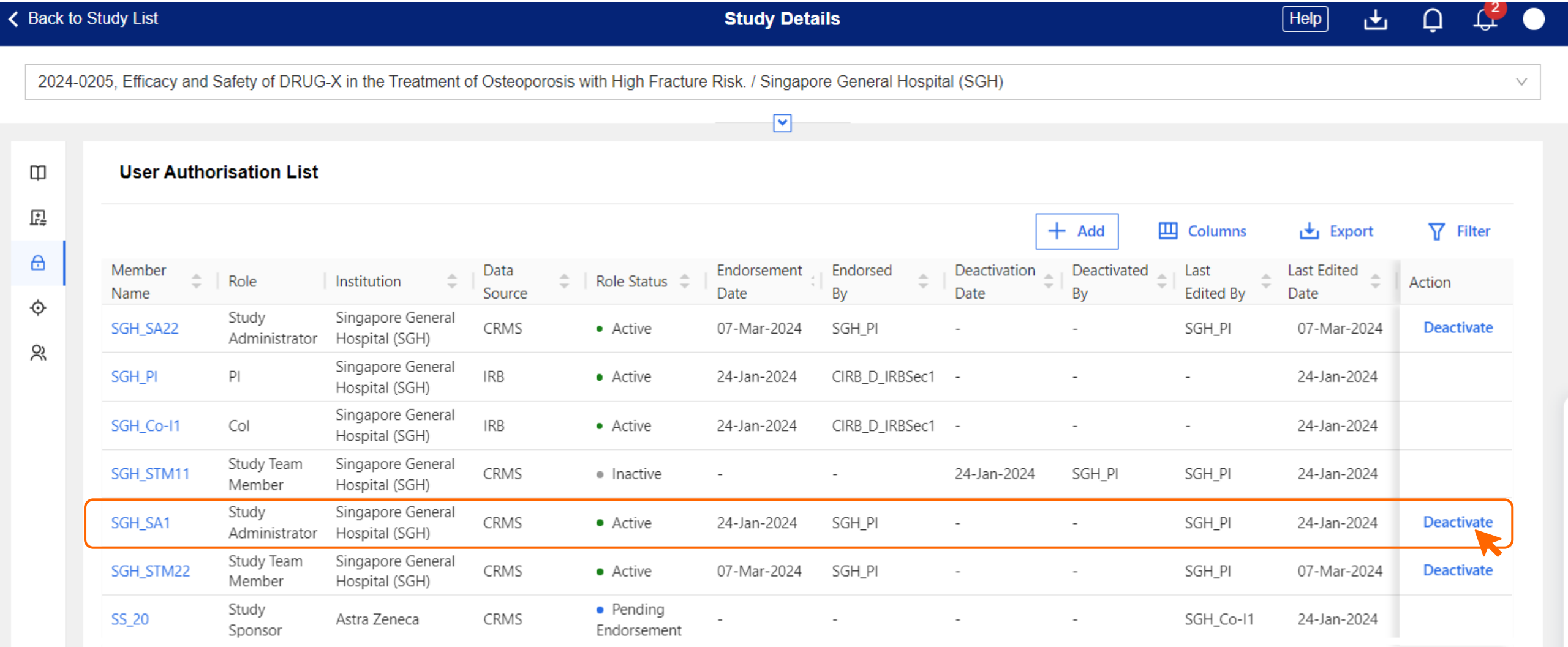
Updated page after PI or Site-PI's Endorsement in CRMS



NOTE: Logic applies to all roles except for PI/Site-PI.

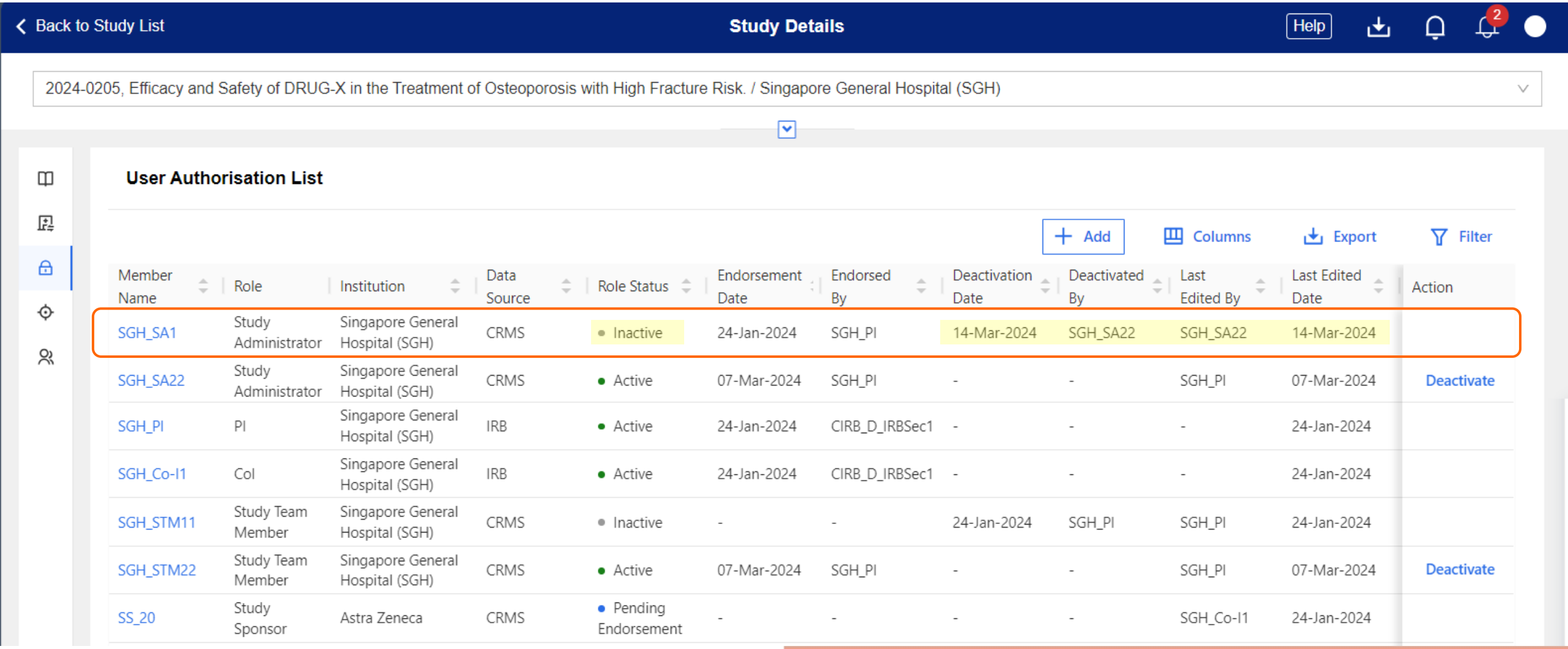
Page Functions – Deactivate User

Role used: Study Administrator



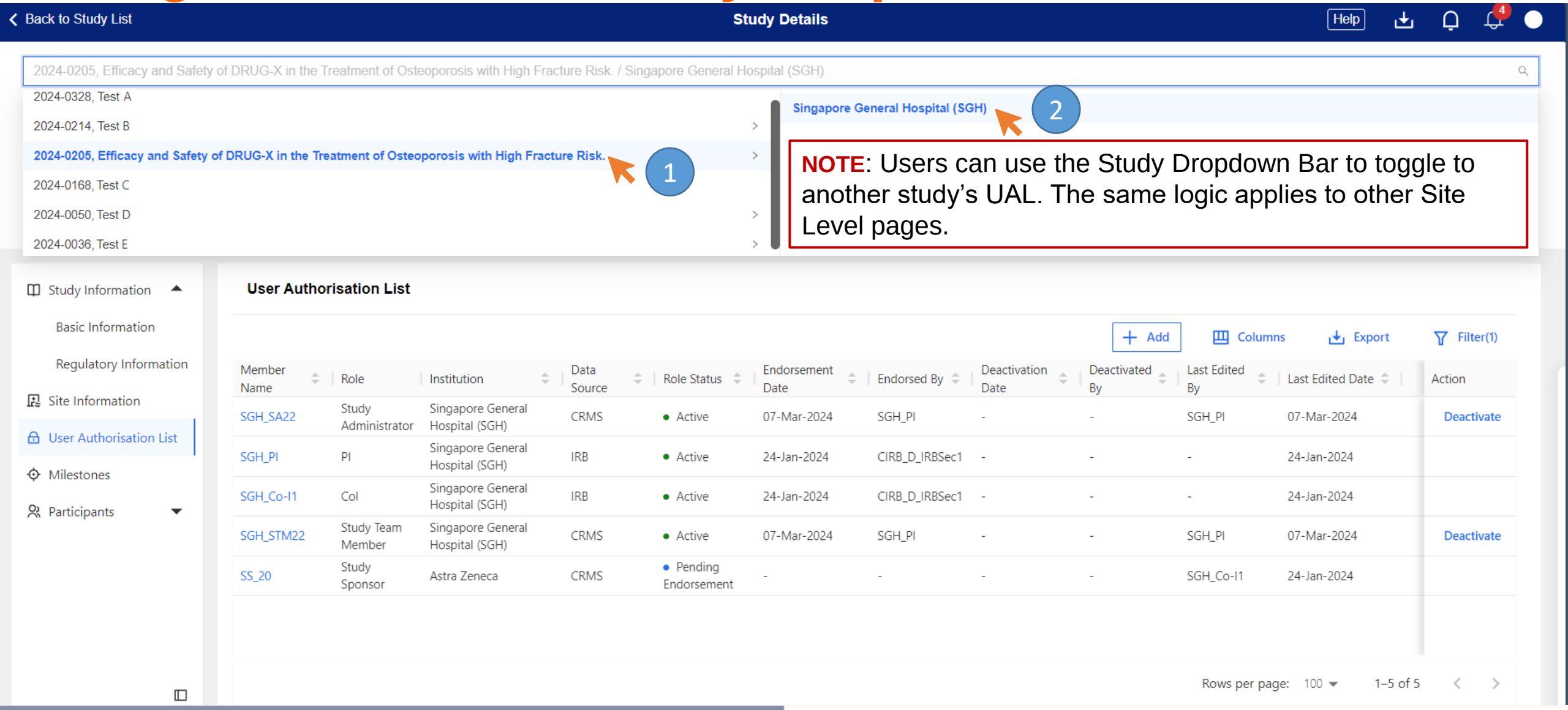
Page Functions – Deactivate User

Role used: Study Administrator



Member Name	Role	Institution	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date	Action
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	CRMS	Inactive	24-Jan-2024	SGH_PI	14-Mar-2024	SGH_SA22	SGH_SA22	14-Mar-2024	
SGH_SA22	Study Administrator	Singapore General Hospital (SGH)	CRMS	Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	Deactivate
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_Co-I1	CoI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_STM11	Study Team Member	Singapore General Hospital (SGH)	CRMS	Inactive	-	-	24-Jan-2024	SGH_PI	SGH_PI	24-Jan-2024	
SGH_STM22	Study Team Member	Singapore General Hospital (SGH)	CRMS	Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	Deactivate
SS_20	Study Sponsor	Astra Zeneca	CRMS	Pending Endorsement	-	-	-	-	SGH_Co-I1	24-Jan-2024	

Page Functions – Study Dropdown Bar



User Authorisation List (UAL)

- The UAL primarily functions to manage the access of **STM**, **SA** and **SS** to the CRMS and/or IRB modules on ECOS.
- This is one of the harmonised processes between SingHealth and NHG where non-investigator(s) will no longer require IRB's approval.

Limited access to Study Information and UAL on CRMS, once a STM/SA/SS has been added, would allow the new user to gain immediate access to IRB and CRMS modules for data entry, submission and reporting work.

- Only the PI's Endorsement in CRMS is required to fully activate the STM/SA/SS roles.

User Authorisation List (UAL)

The User Authorisation List does not replace a site delegation log.

- Site will need to create and maintain a proper site-specific delegation log in the Investigator Site Files.
- The delegation log should contain all personnel actively involved in the study conduct, e.g. Investigators, Study Coordinators, Study Nurses, Pharmacists etc.
- PI/Site-PI should ensure that each STM has received adequate and appropriate study-specific trainings and qualifications (HBRA, CITI Biomed, GCP etc).

Do I add everyone on the delegation log to the UAL?

Site Delegation Log

- PI
- Co-I_1
- Co-I_2
- Primary CRC
- Back-up CRC_1
- Back-up CRC_2
- Study Pharmacist_1
- Study Pharmacist_2
- Study Pharmacist_3
- Study Nurse_1
- Study Nurse_2
- Study Nurse_3
- Study Nurse_4

CRMS UAL

ECOS

User Authorisation List

Member Name	Role

?

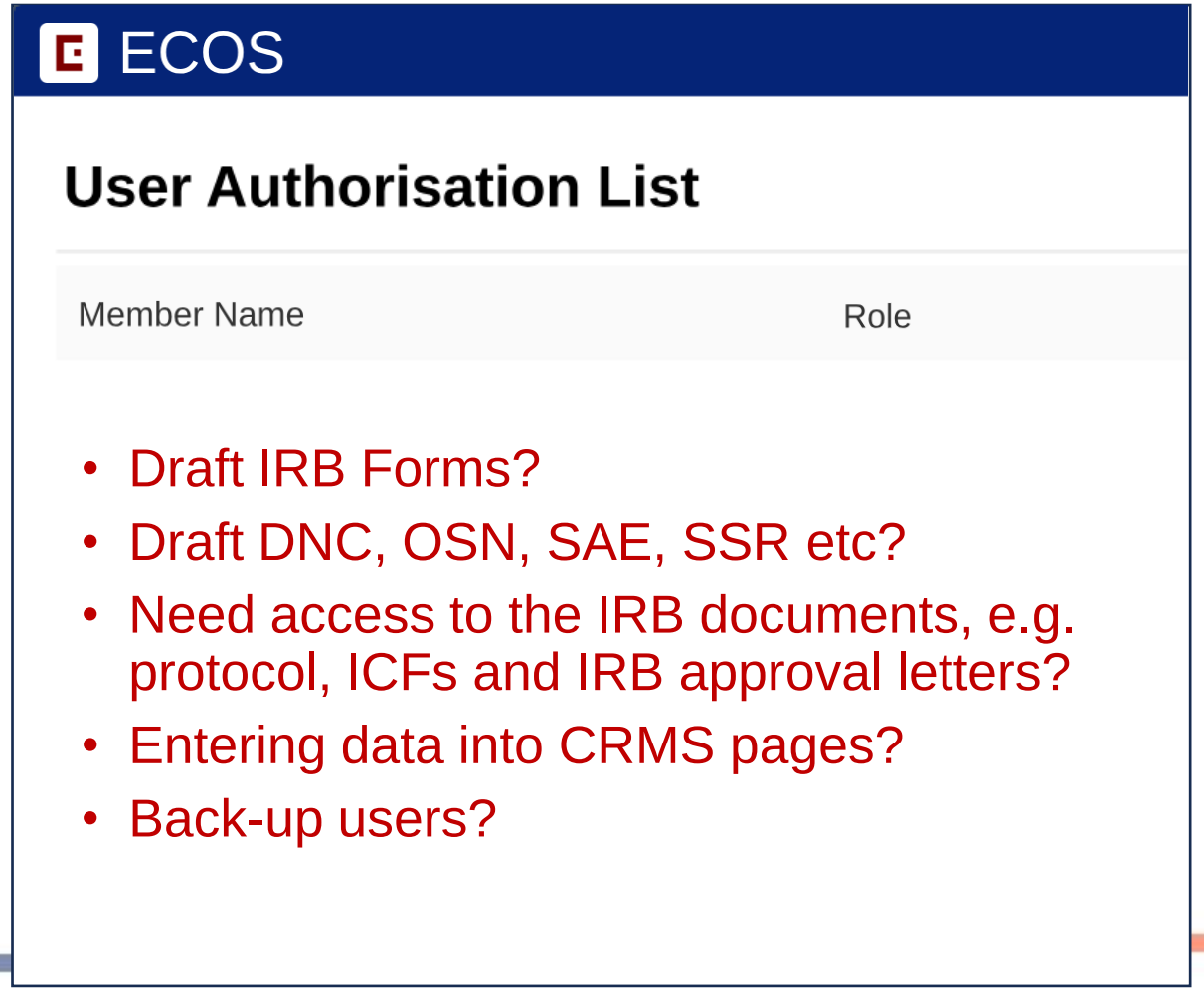
Does the user require access to IRB or CRMS modules?

Do I add everyone on the delegation log to the UAL?

Site Delegation Log

- PI
- Co-I_1
- Co-I_2
- Primary CRC
- Back-up CRC_1
- Back-up CRC_2
- Study Pharmacist_1
- Study Pharmacist_2
- Study Pharmacist_3
- Study Nurse_1
- Study Nurse_2
- Study Nurse_3
- Study Nurse_4

CRMS UAL



Do I add everyone on the delegation log to the UAL?

Site Delegation Log

- PI ✓
- Co-I_1 ✓
- Co-I_2 ✓
- Primary CRC ✓
- Back-up CRC_1 ✓
- Back-up CRC_2
- Study Pharmacist_1
- Study Pharmacist_2 ✓
- Study Pharmacist_3
- Study Nurse_1
- Study Nurse_2
- Study Nurse_3
- Study Nurse_4

If a Study Pharmacist/ Nurse requires IRB or CRMS access, add him/her to the UAL. If not, ok to omit from UAL.

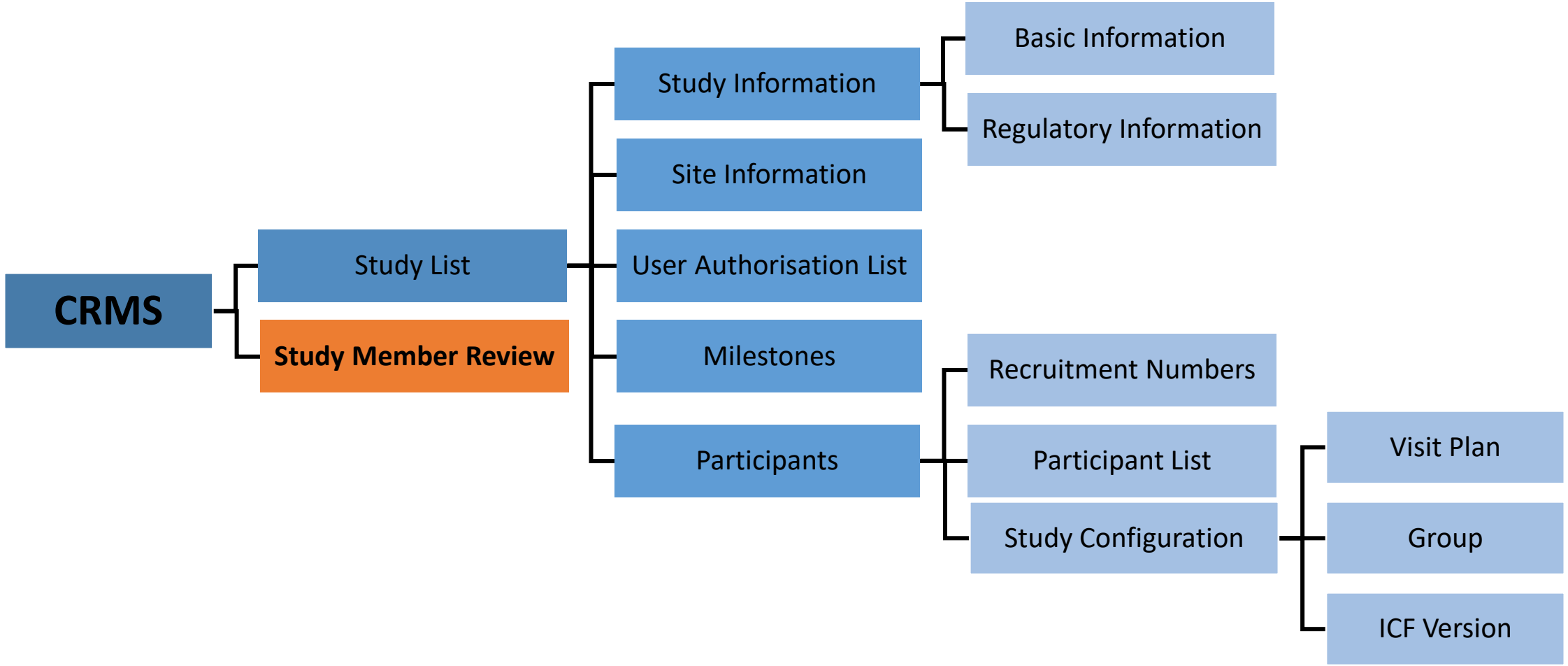
UAL can also contain sponsors or any other users outside the delegation log.

CRMS UAL

ECOS

User Authorisation List

Member Name	Role
PI	PI
Co-I_1	Co-I
Co-I_2	Co-I
Primary CRC	STM
Back-up CRC_1	STM
Study Pharmacist_2	STM
Study Monitor	SS
Dept's Executive	SA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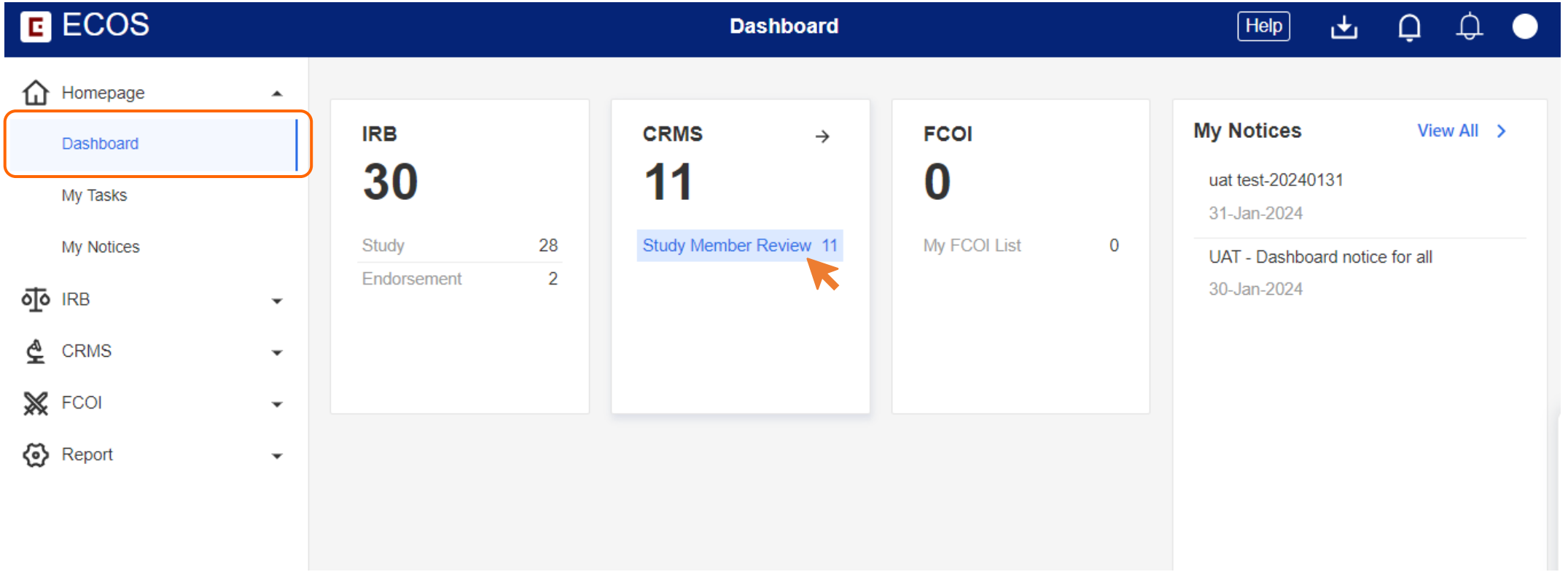
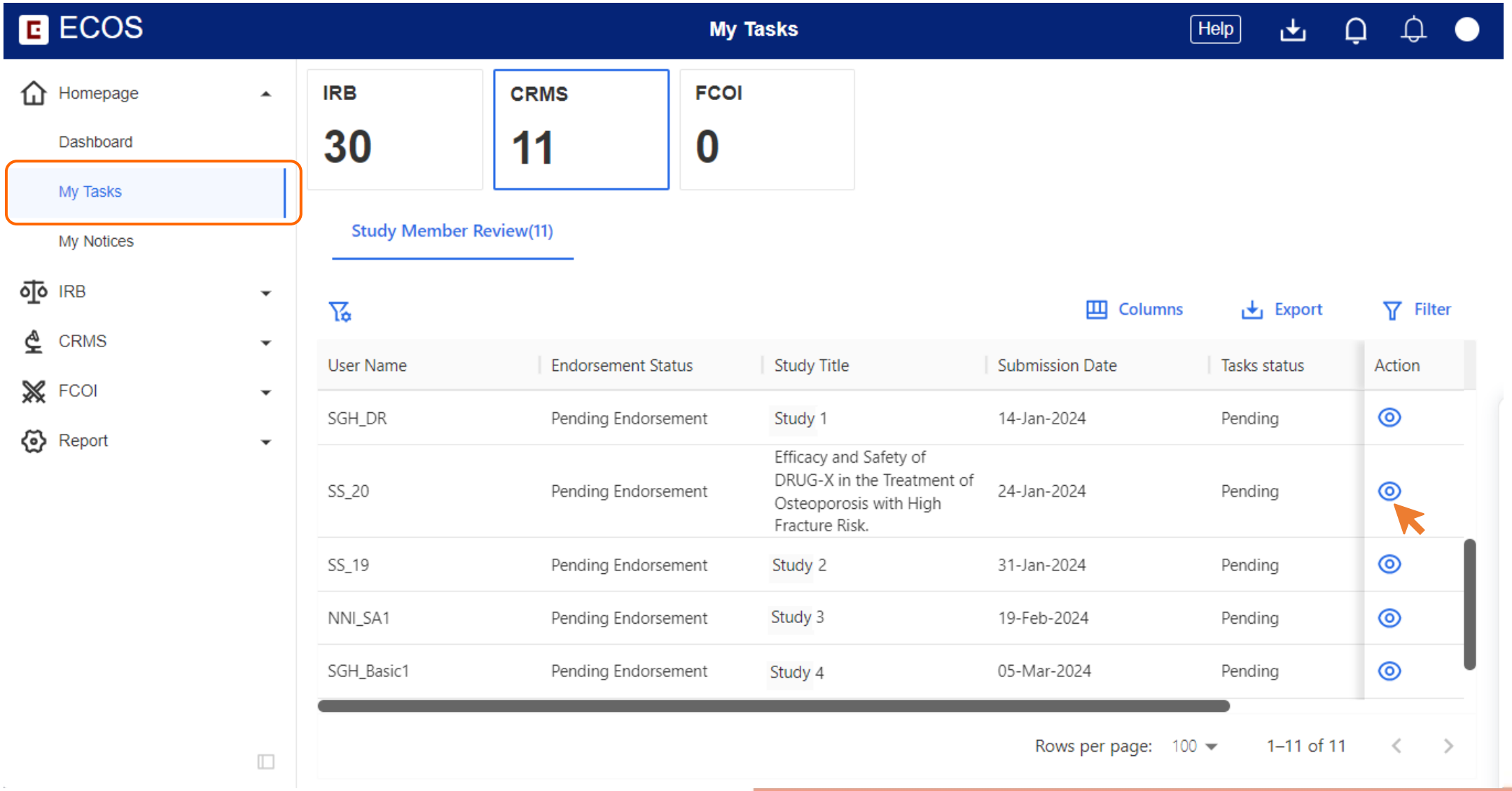
Study Member Review

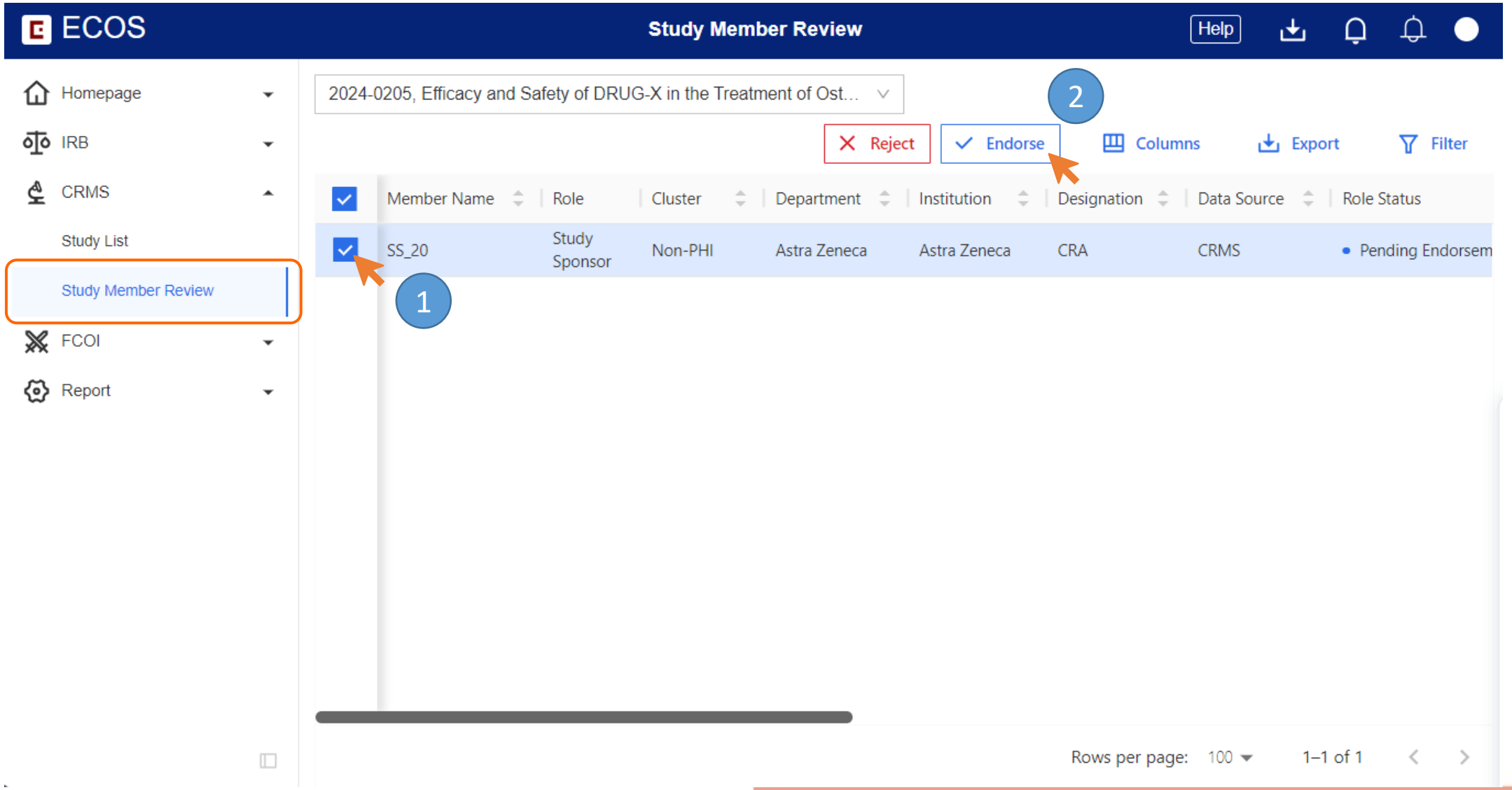
- PI/Site-PIs can access the Study Member Review Page via 2 ways.
  1. ECOS Navigation Menu: Dashboard > CRMS Card > Study Member Review



Study Member Review

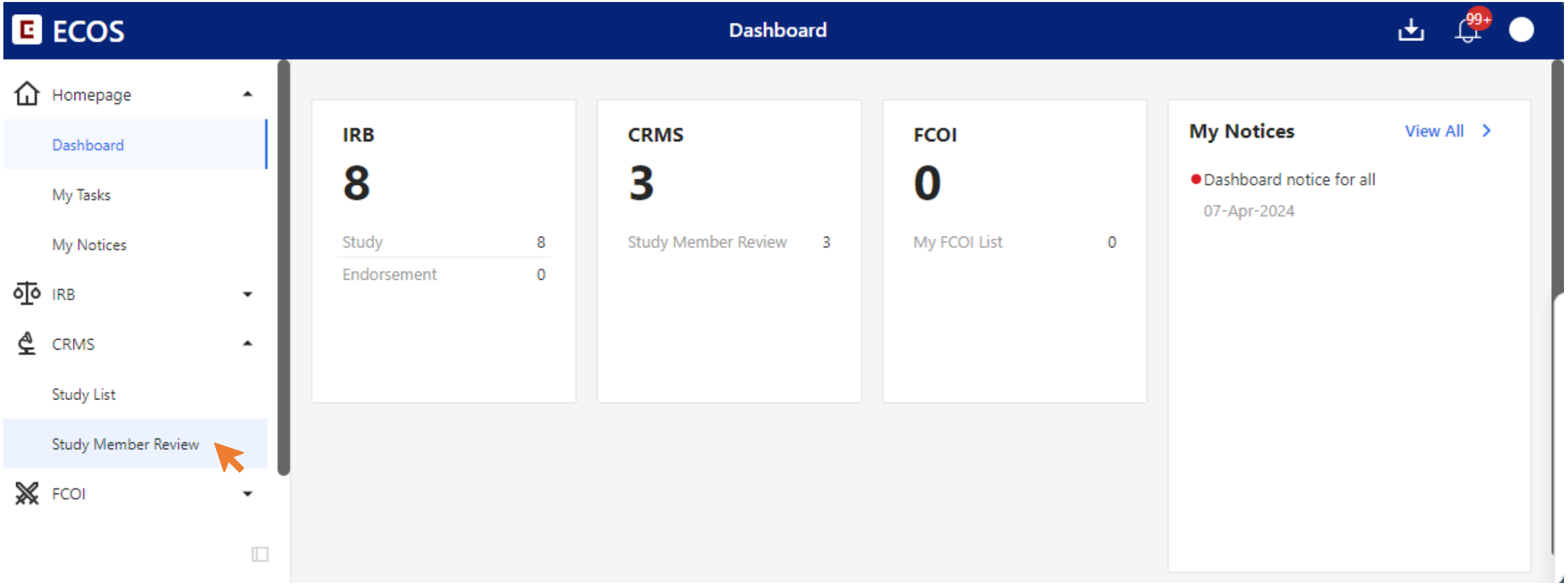


Study Member Review

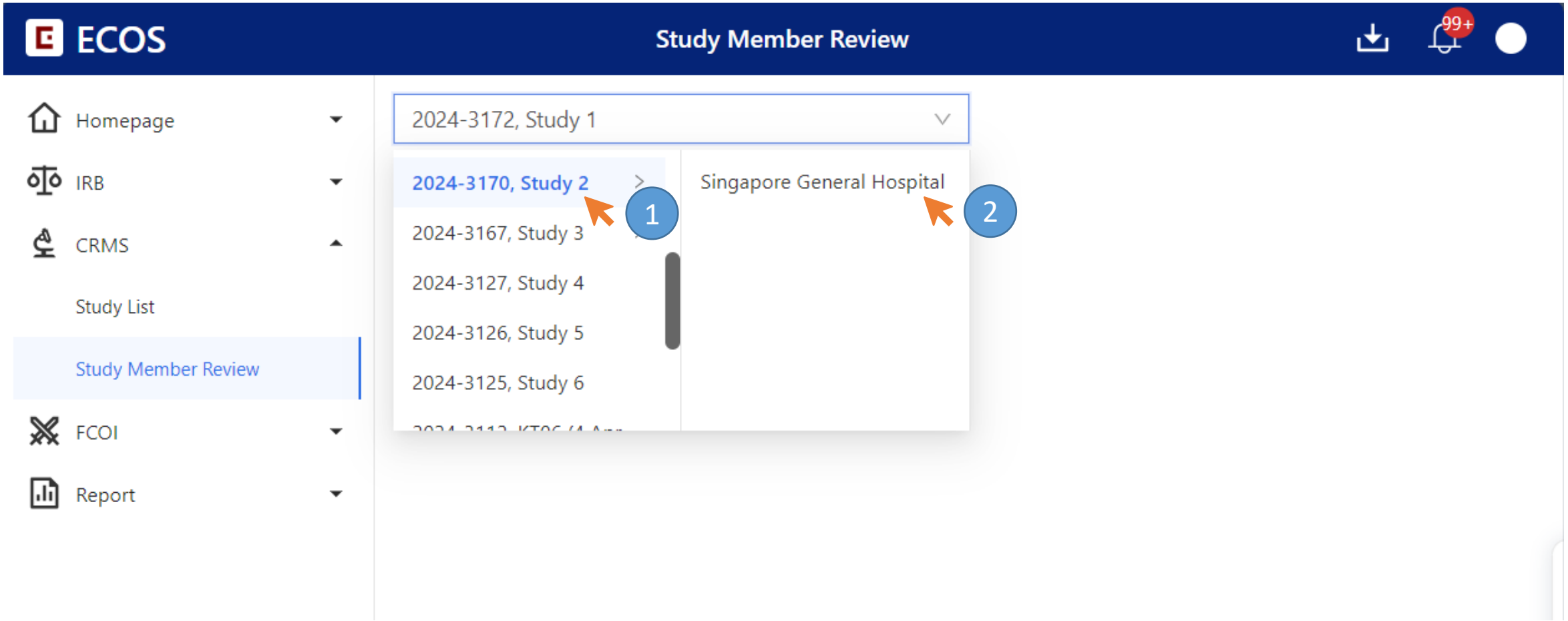


Study Member Review Access

- PI/Site-PIs can access the Study Member Review Page via 2 ways.
    2. ECOS Navigation Menu: CRMS > Study Member Review



Study Member Review Access



Study Member Review

Site Level

- Endorsement page exclusive to PIs/Site-PIs.
- PI/Site-PI can start performing the user endorsement once his/her PI status is Active on the User Authorisation List.
- Multiple users can be selected for PI/Site-PI to endorse or reject.
- User Authorisation List will be updated accordingly.

Study Member Review

Site Level

- Action: **ENDORSE**

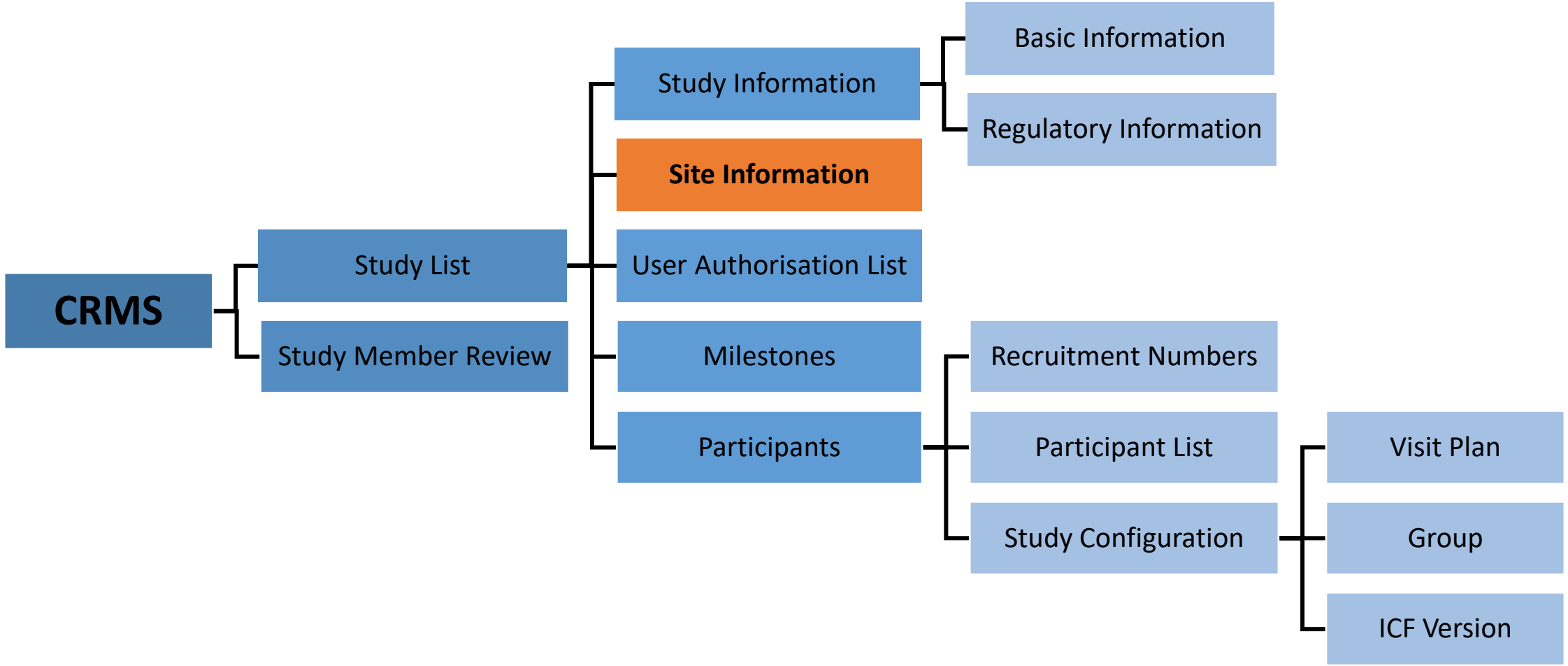
Member Name	Role	Institution	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date
SGH_STM22	Study Team Member	Singapore General Hospital (SGH)	CRMS	Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024

  - Role Status, Endorsement Date, Endorsed By, Last Edited By and Last Edited Date will be updated.
  - Full access to CRMS granted to STM/SA.

- Action: **REJECT**

Member Name	Role	Institution	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date
SGH_STM11	Study Team Member	Singapore General Hospital (SGH)	CRMS	Inactive	-	-	24-Jan-2024	SGH_PI	SGH_PI	24-Jan-2024

  - Role Status, Deactivation Date, Deactivated By, Last Edited By and Last Edited Date will be updated.
  - Limited access to CRMS will be revoked.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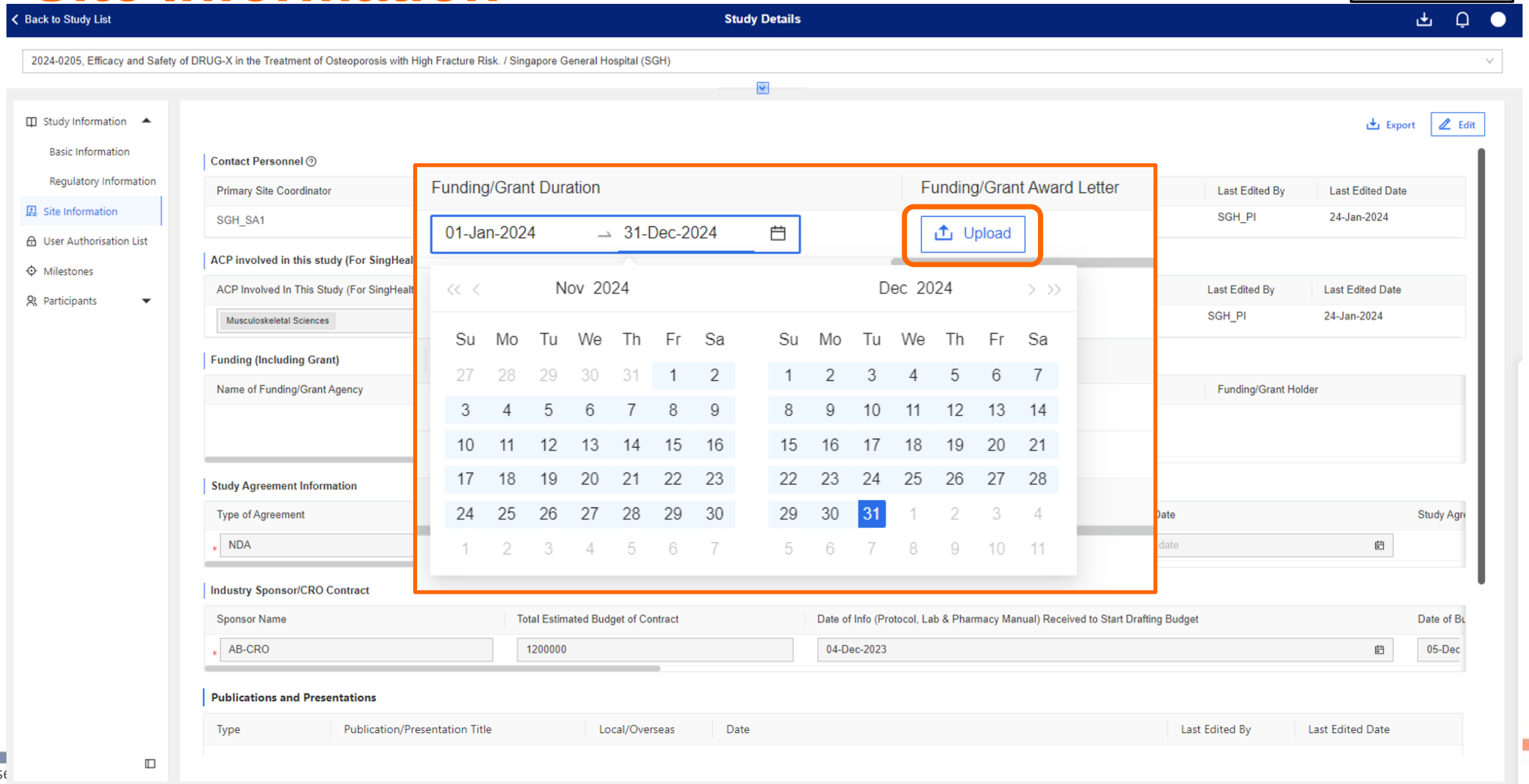
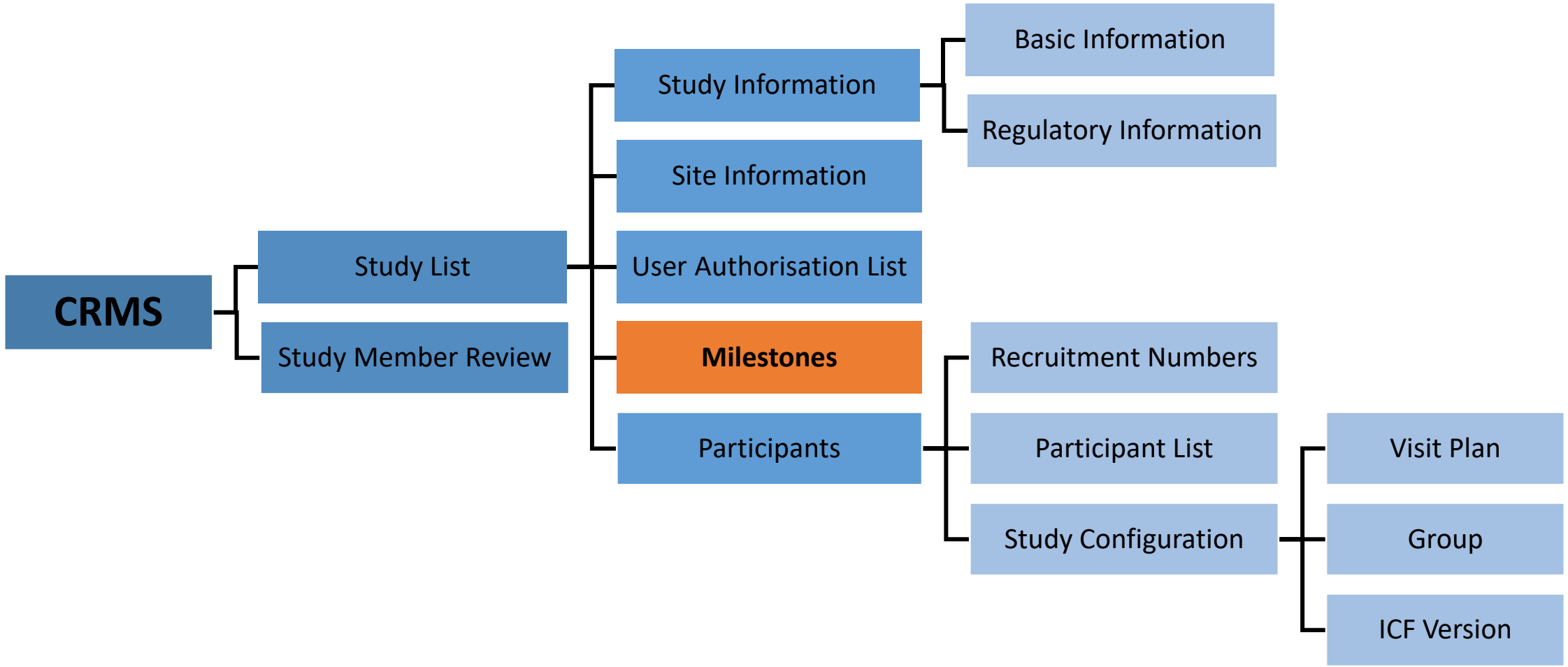
Site Information

Site Level

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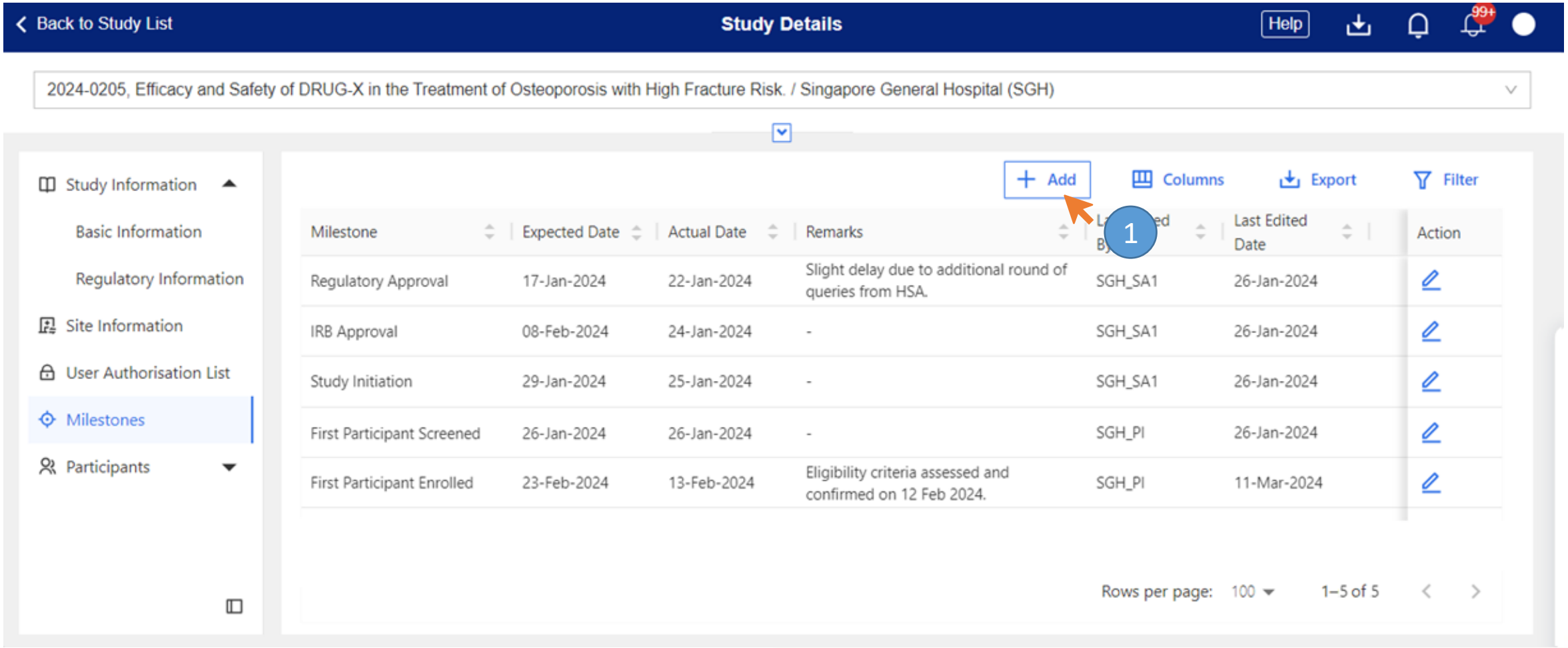
Milestones

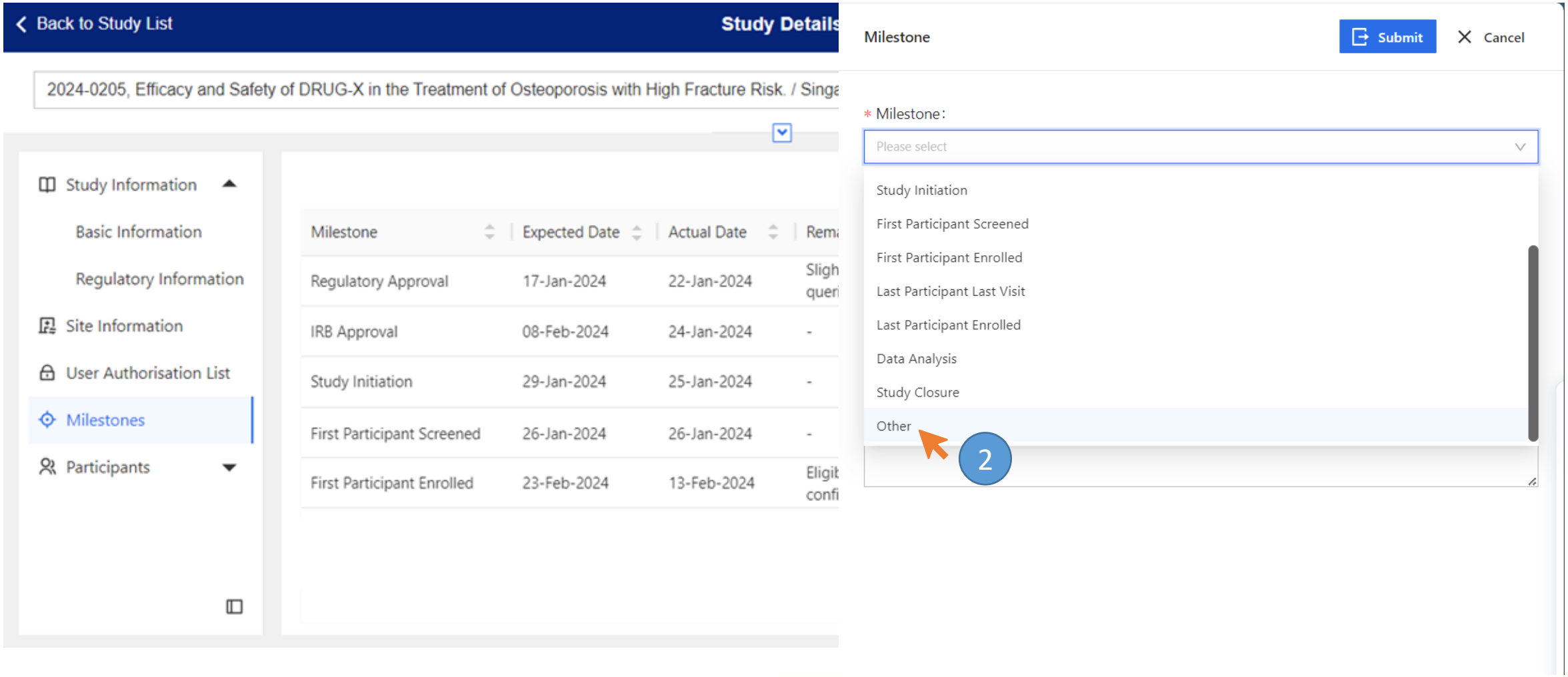
Site Level

If you have a unique milestone not part of the dropdown list..



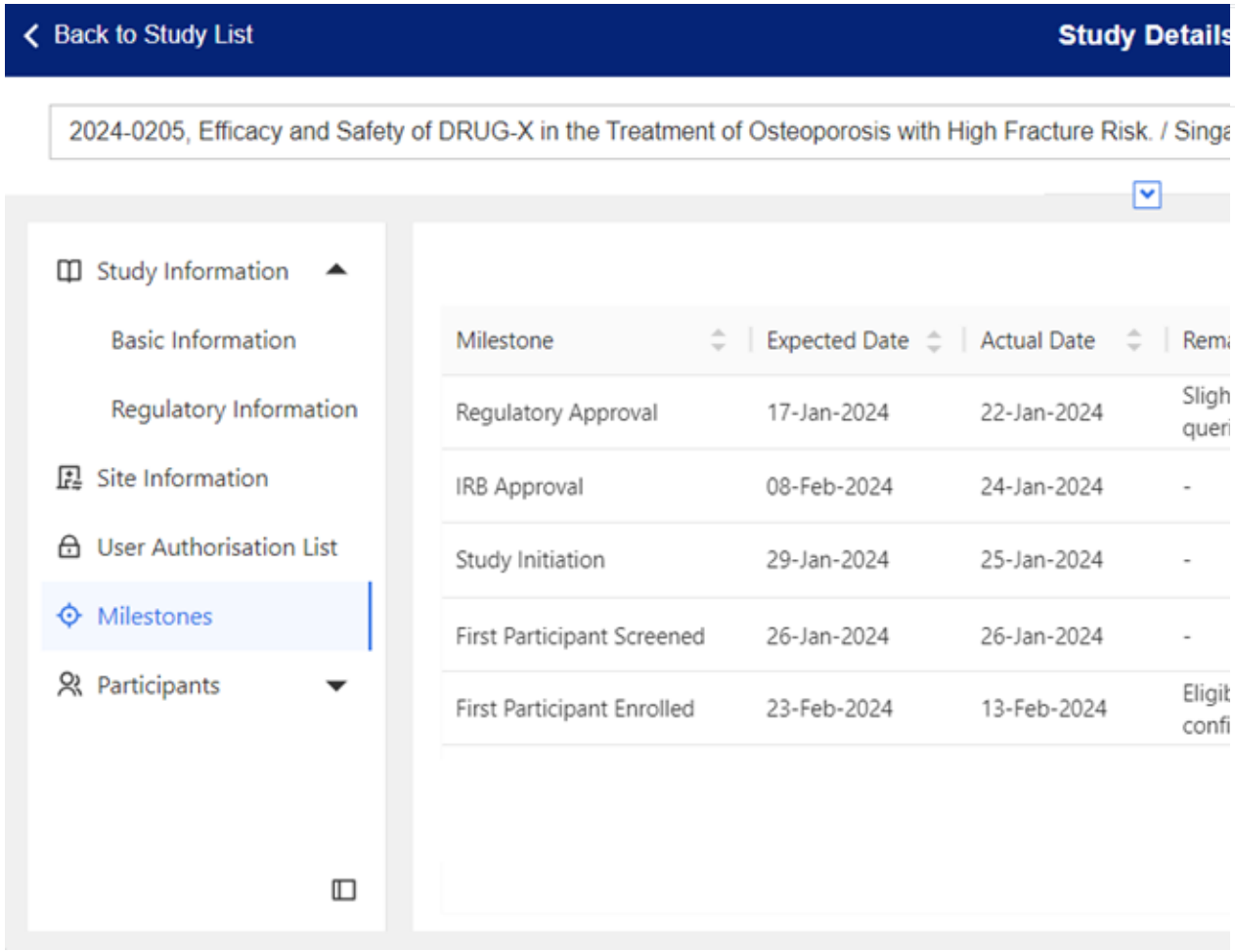
Milestones

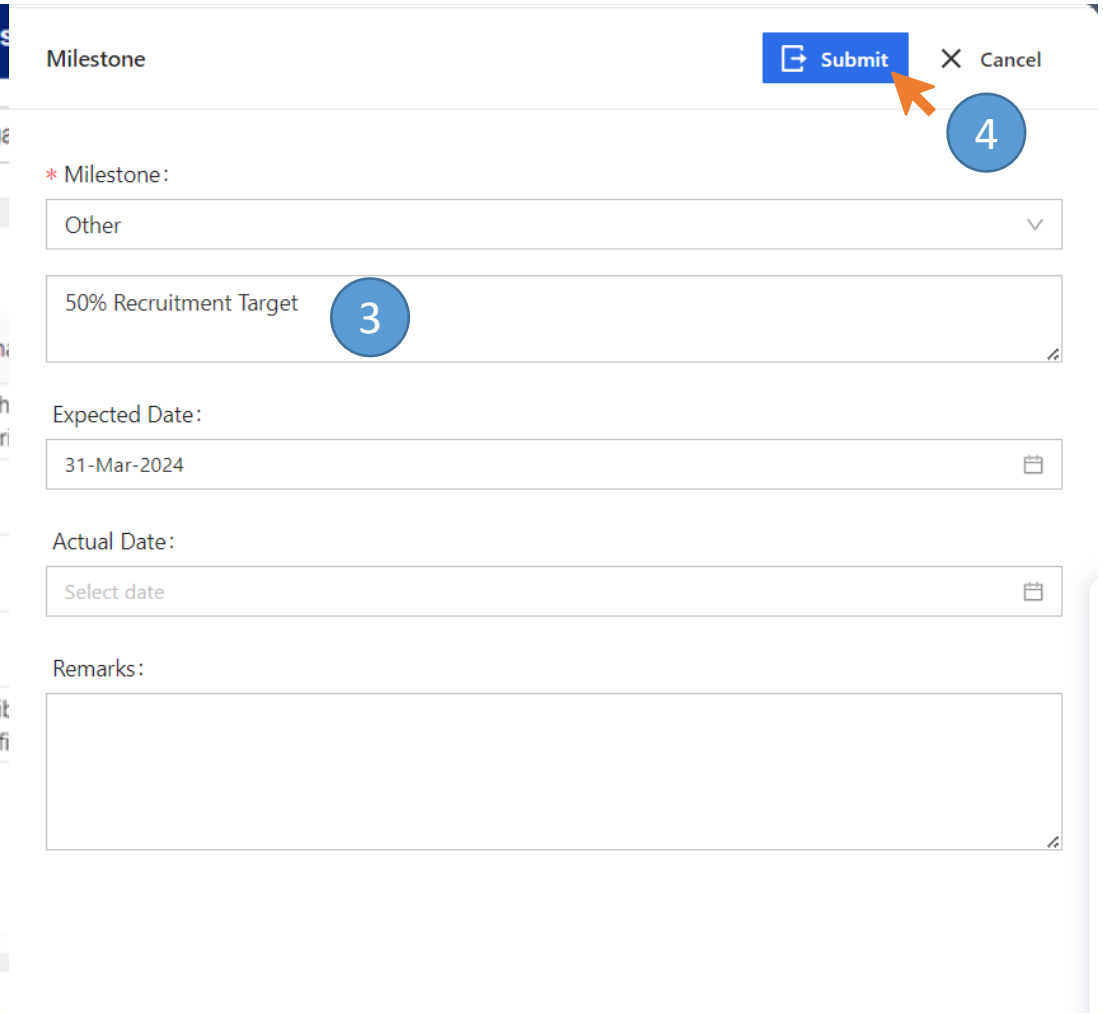
Site Level



Milestones

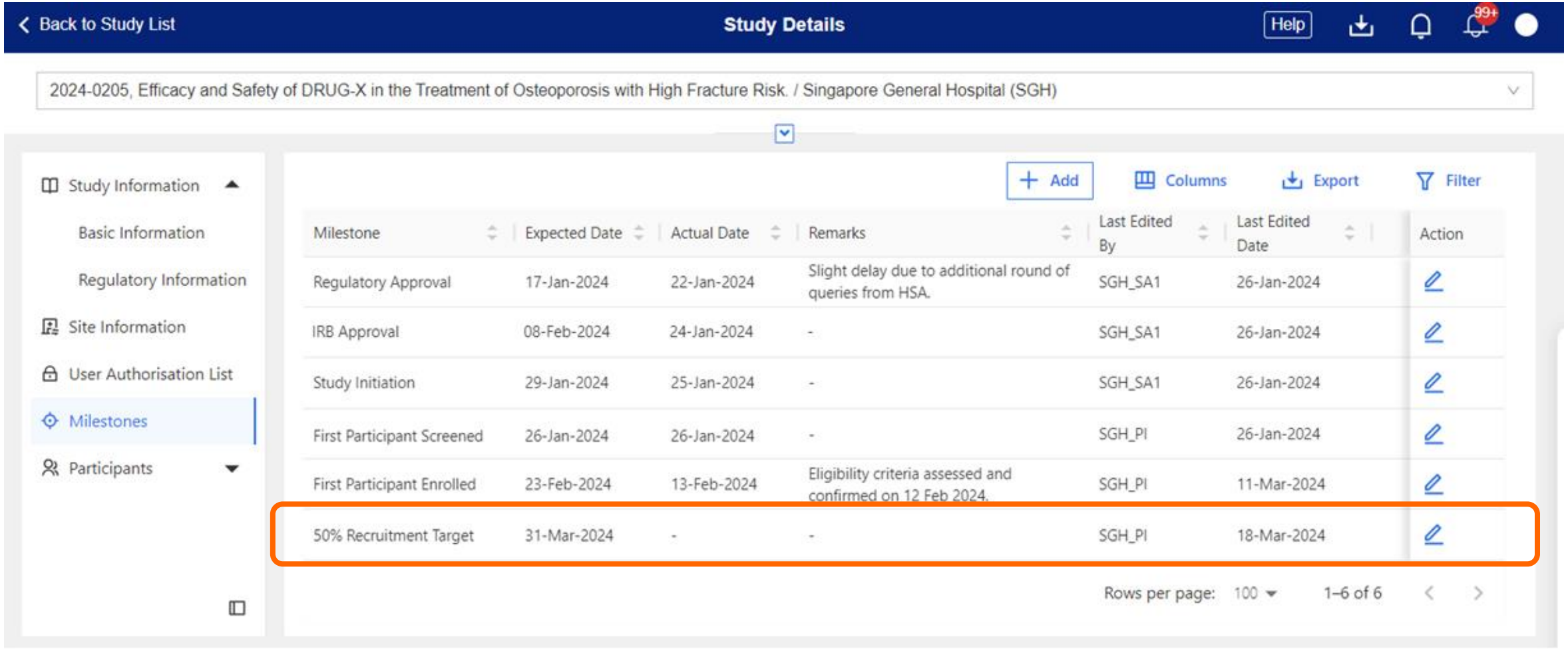
Site Level



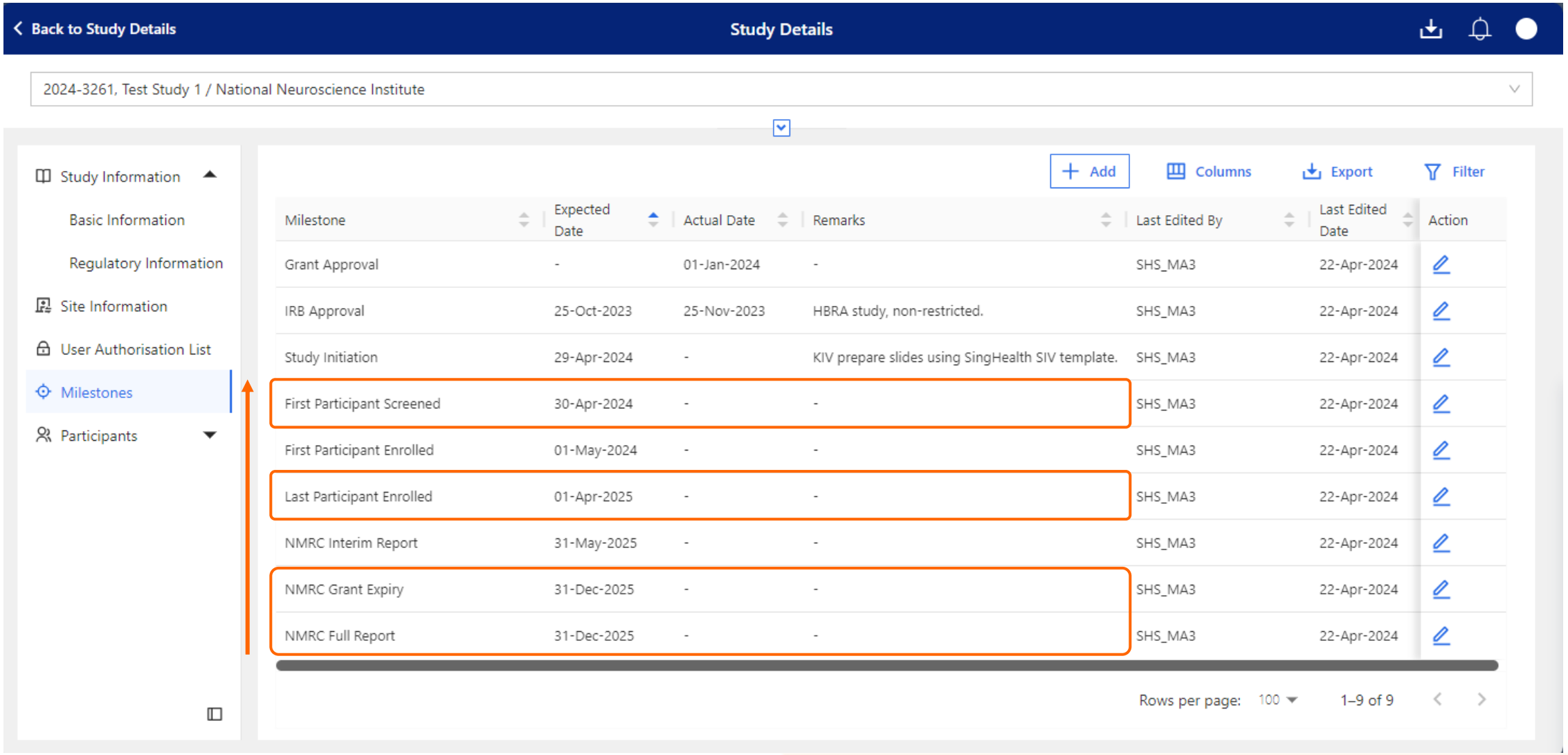


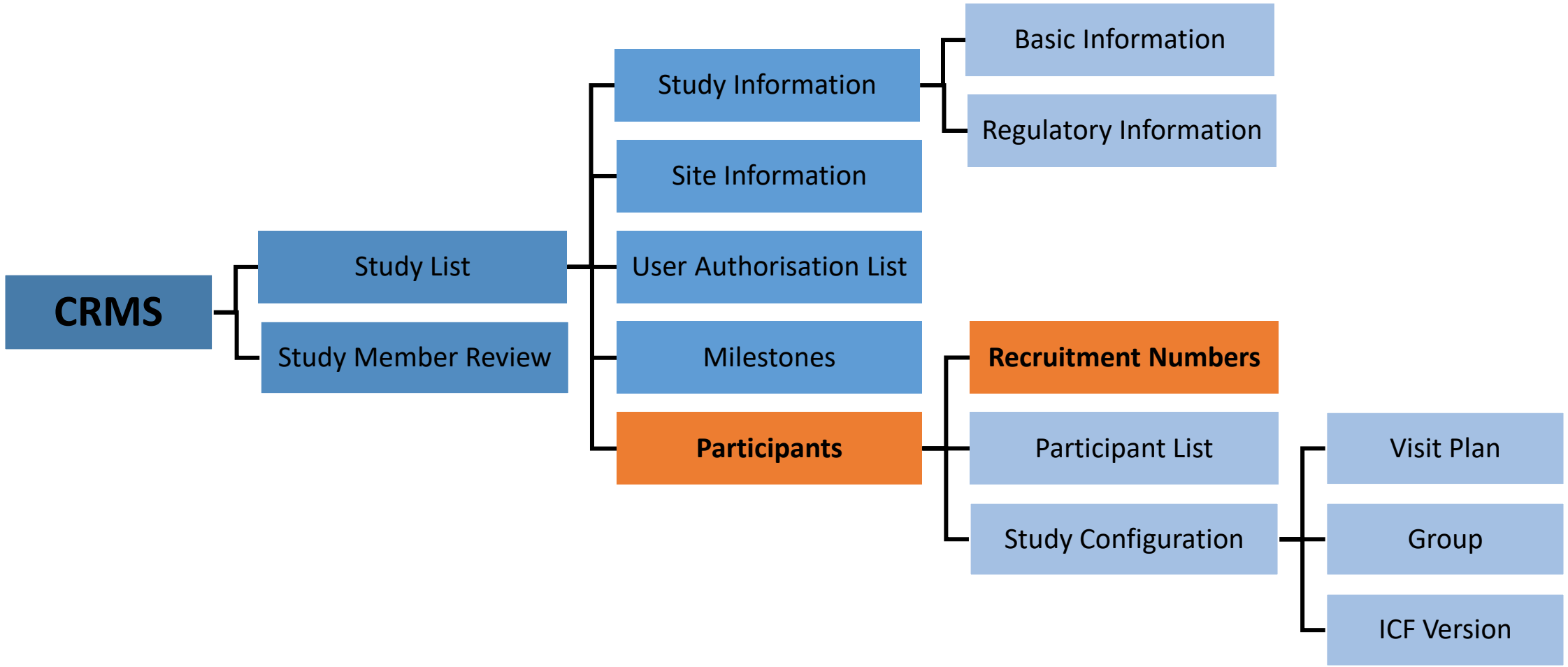
Milestones

Site Level



Project Management Tool – Reverse Planning

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Participants – Recruitment Numbers

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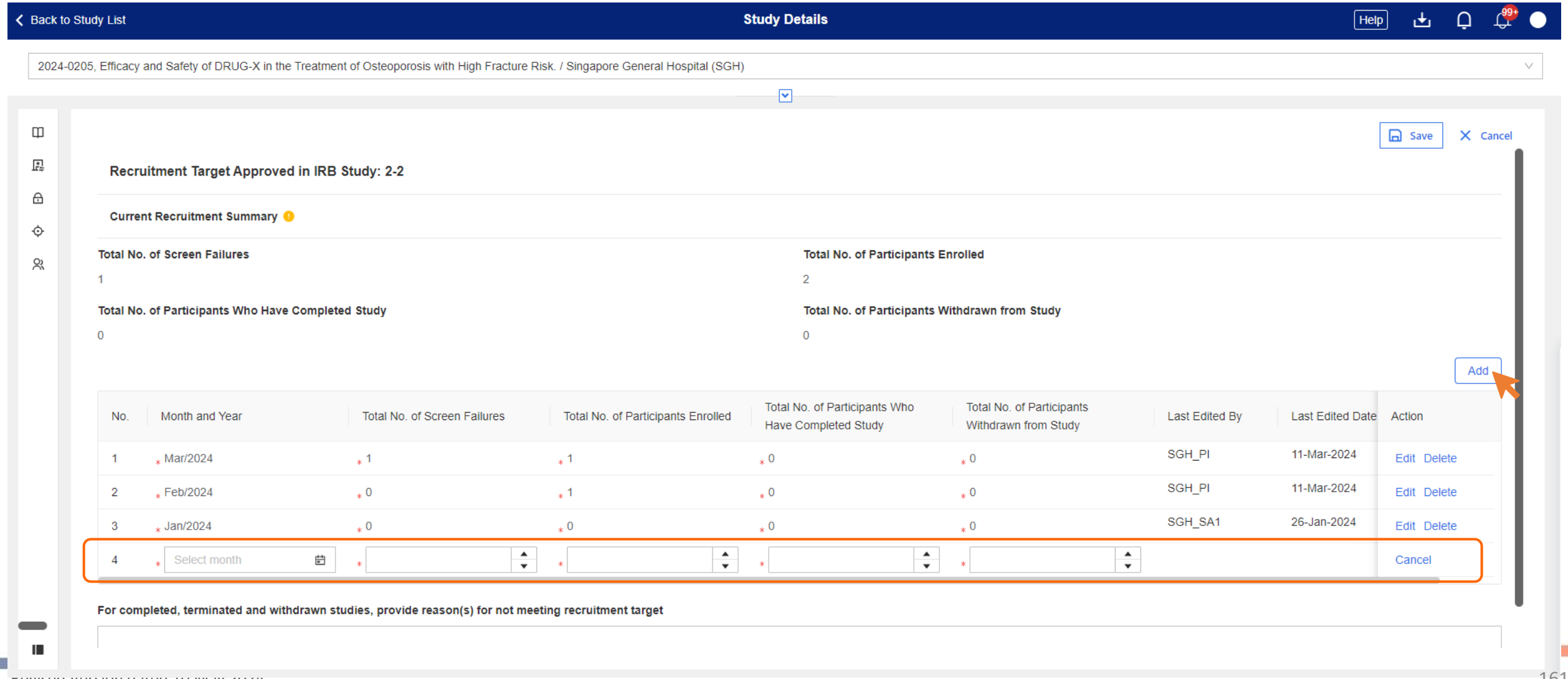
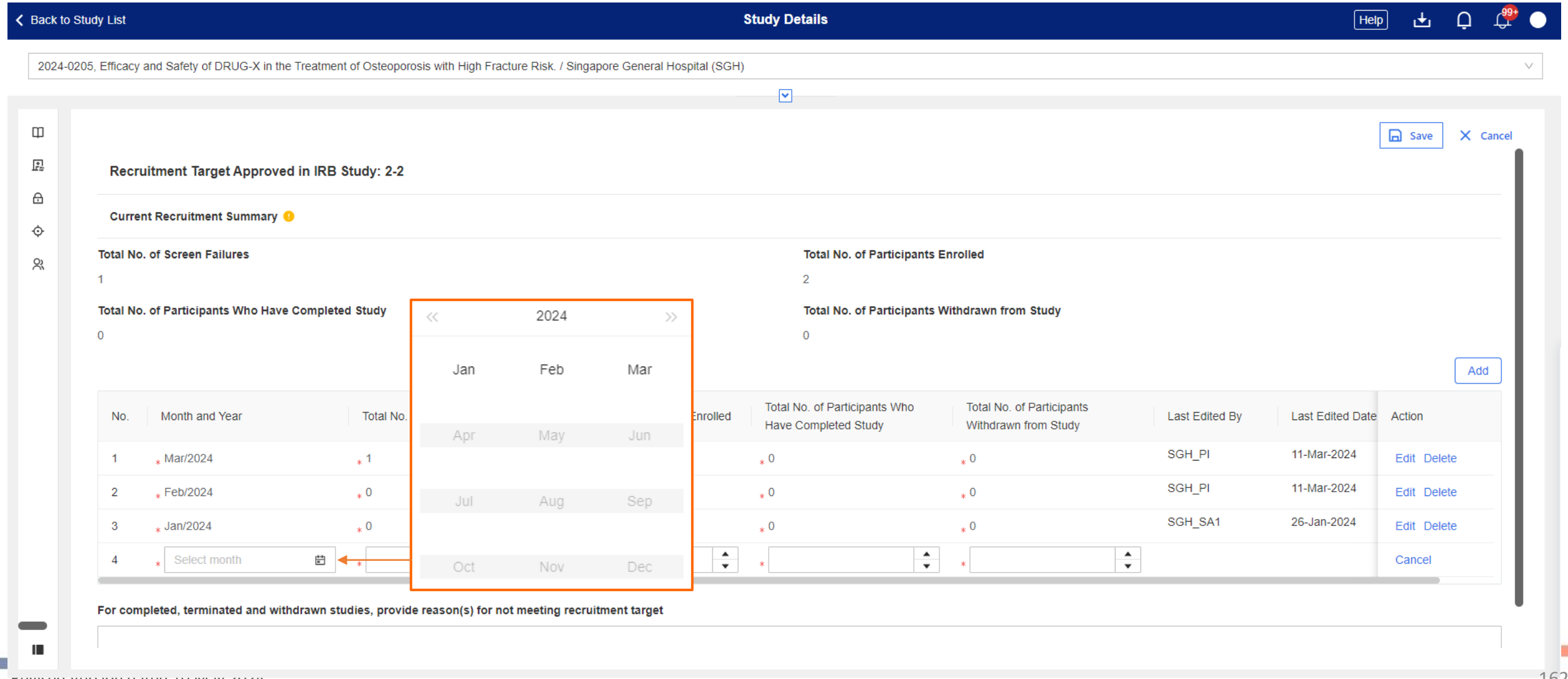


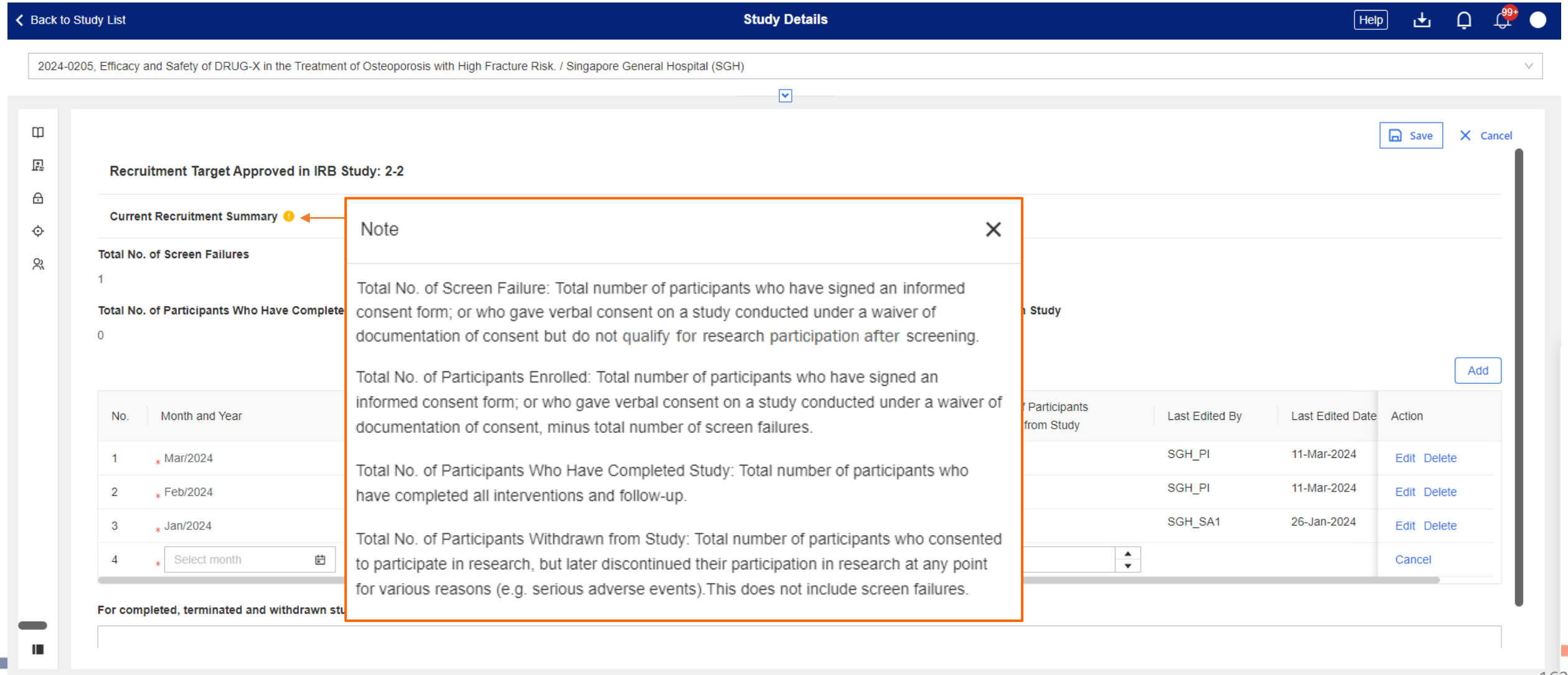
Participants – Recruitment Numbers

Site Level



Participants – Recruitment Numbers

Site Level



Participants – Recruitment Numbers

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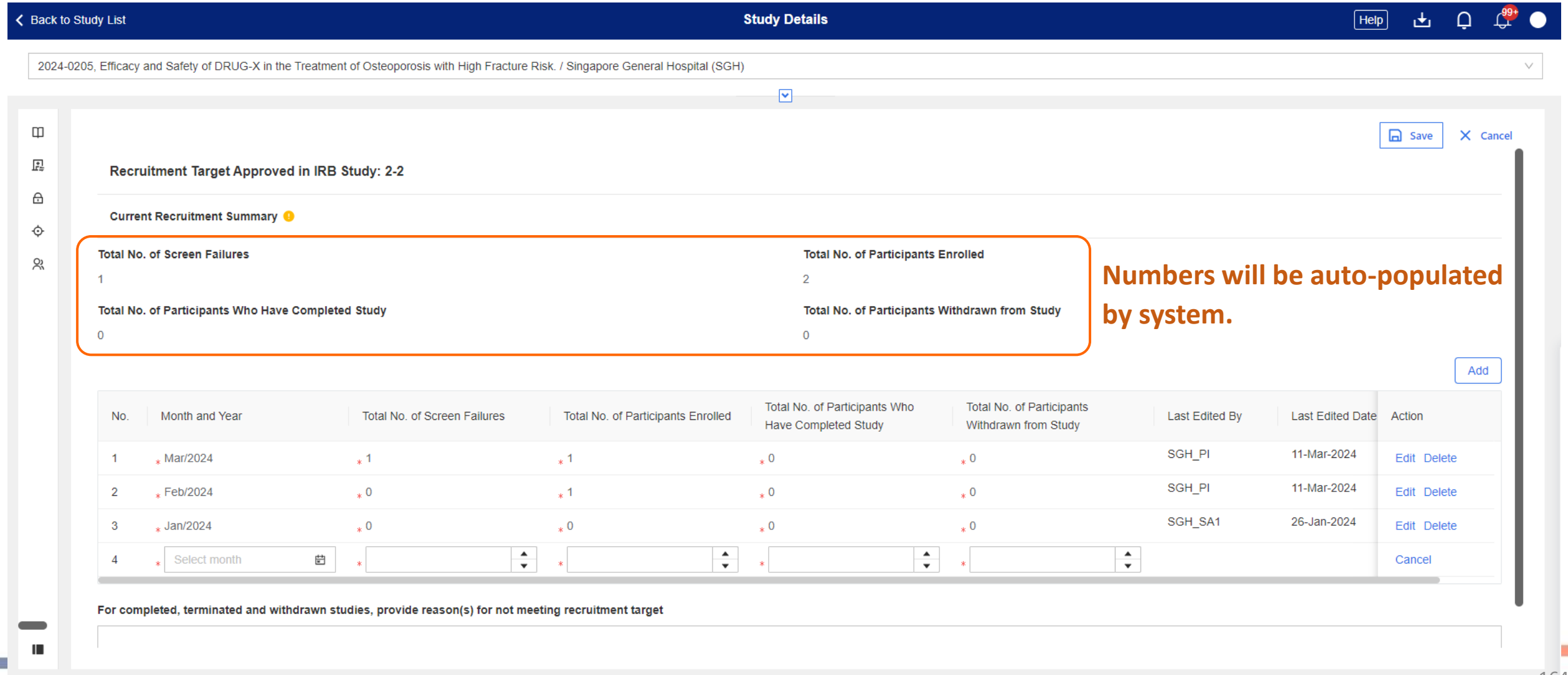
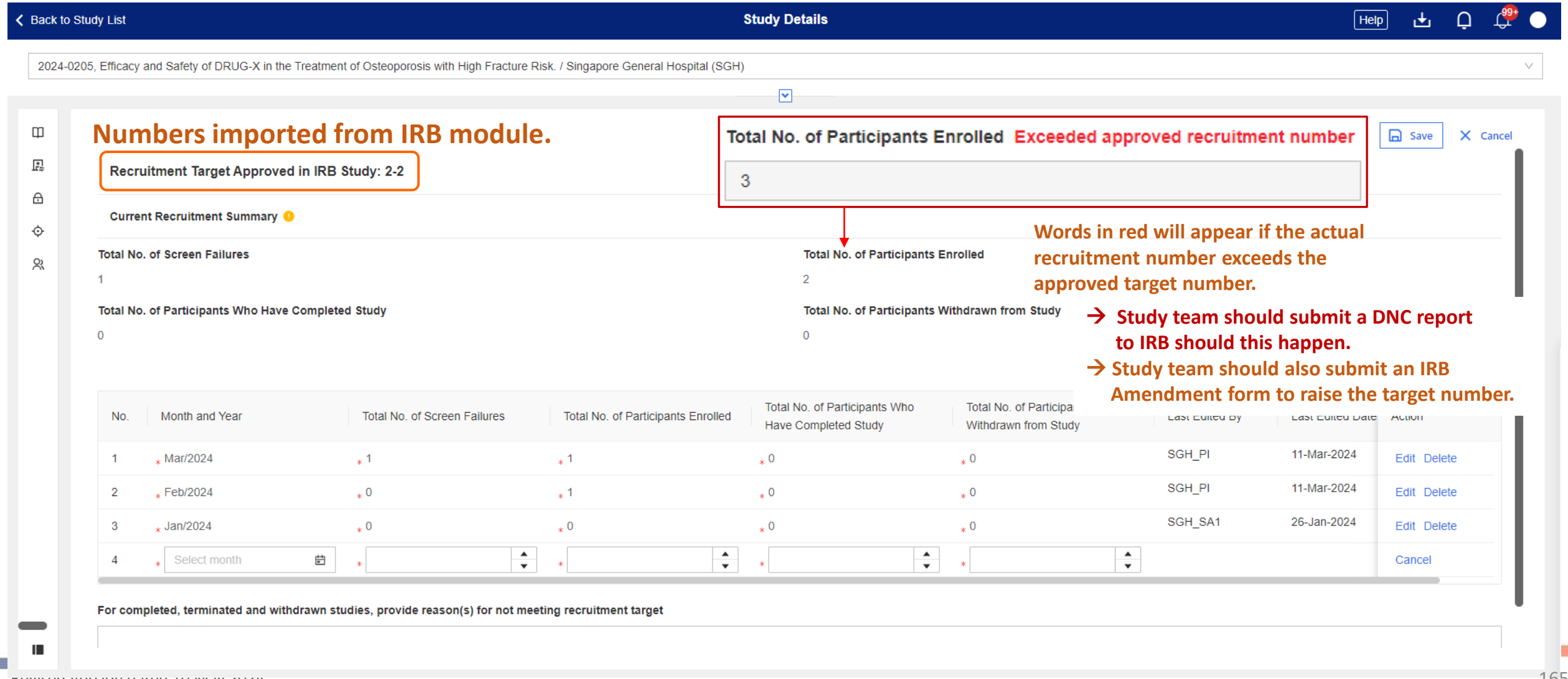
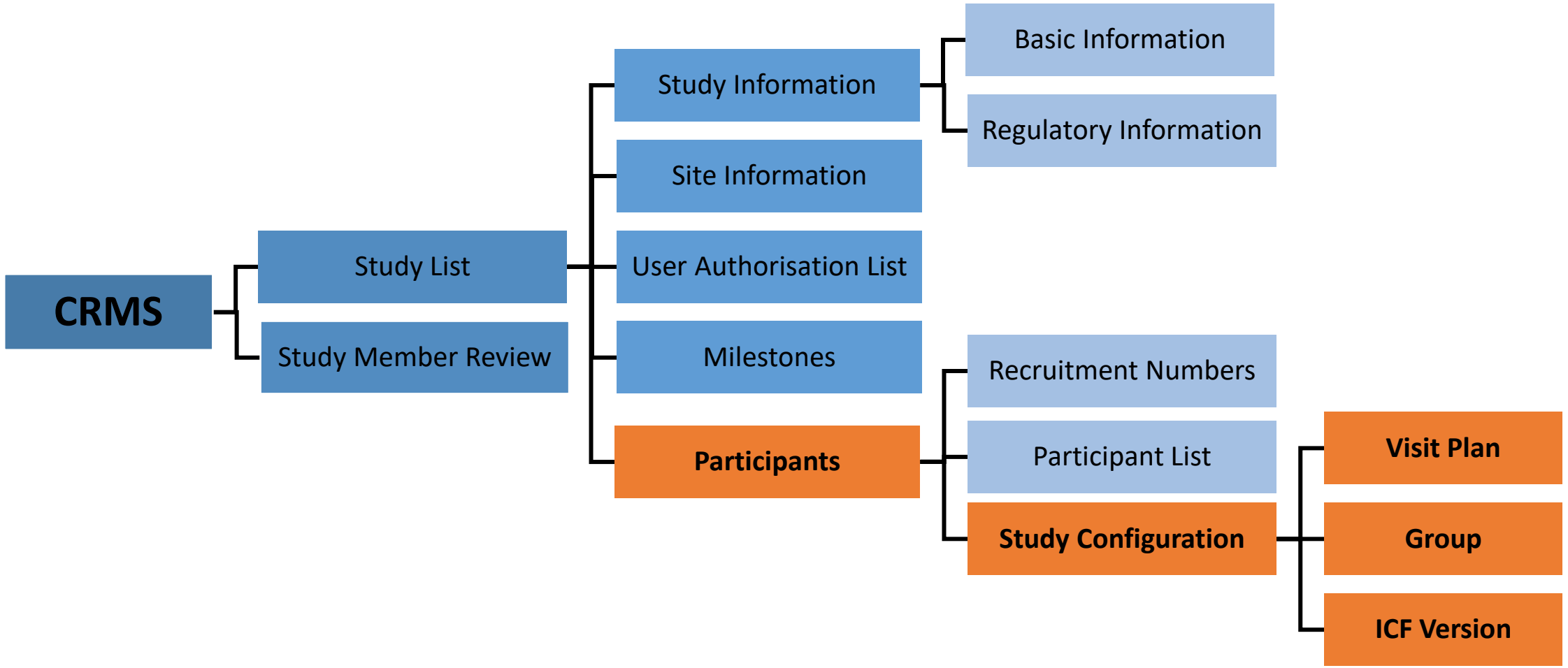


Participants – Recruitment Numbers

Site Level

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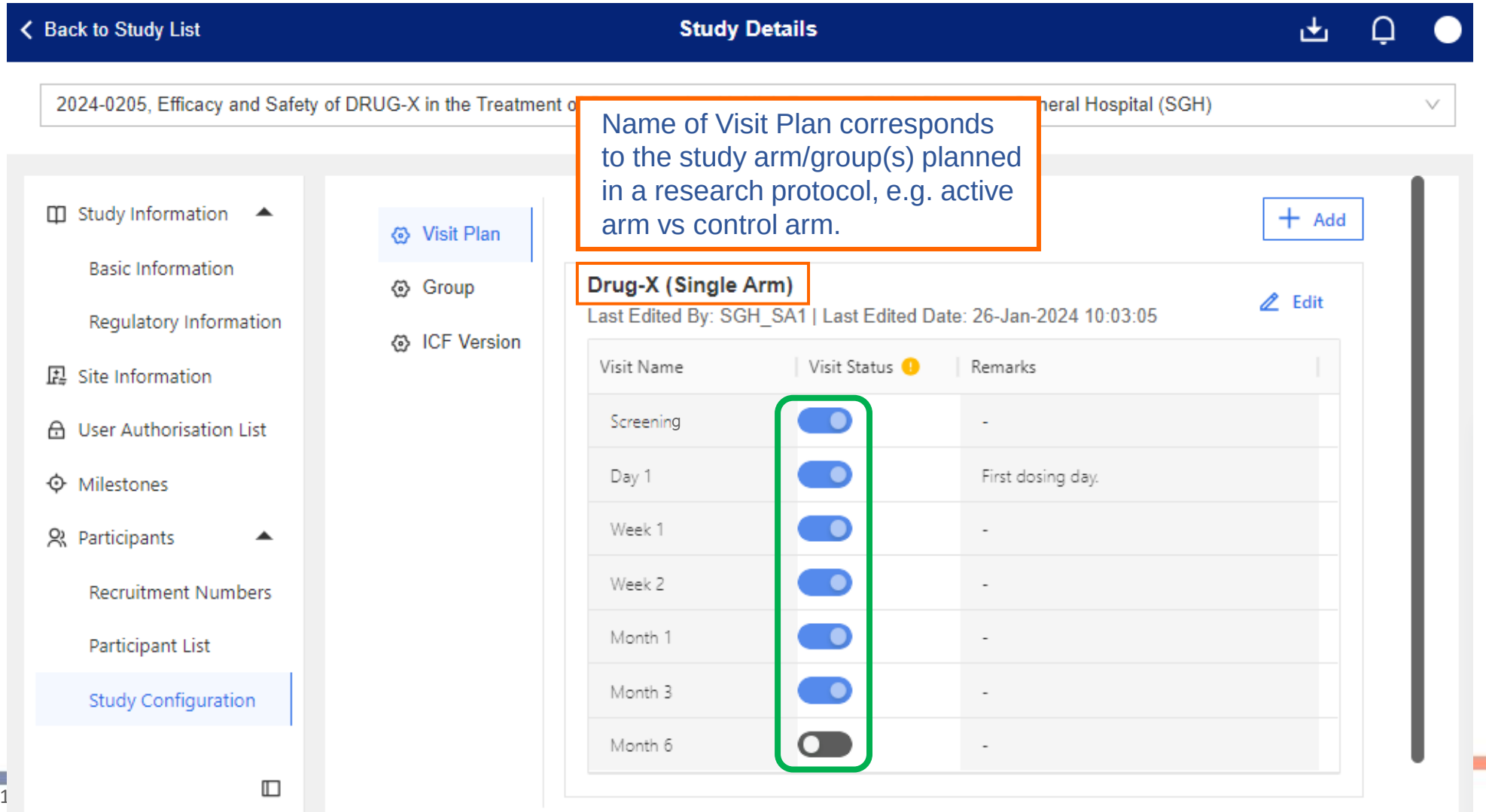
Participants – Study Configuration

Site Level

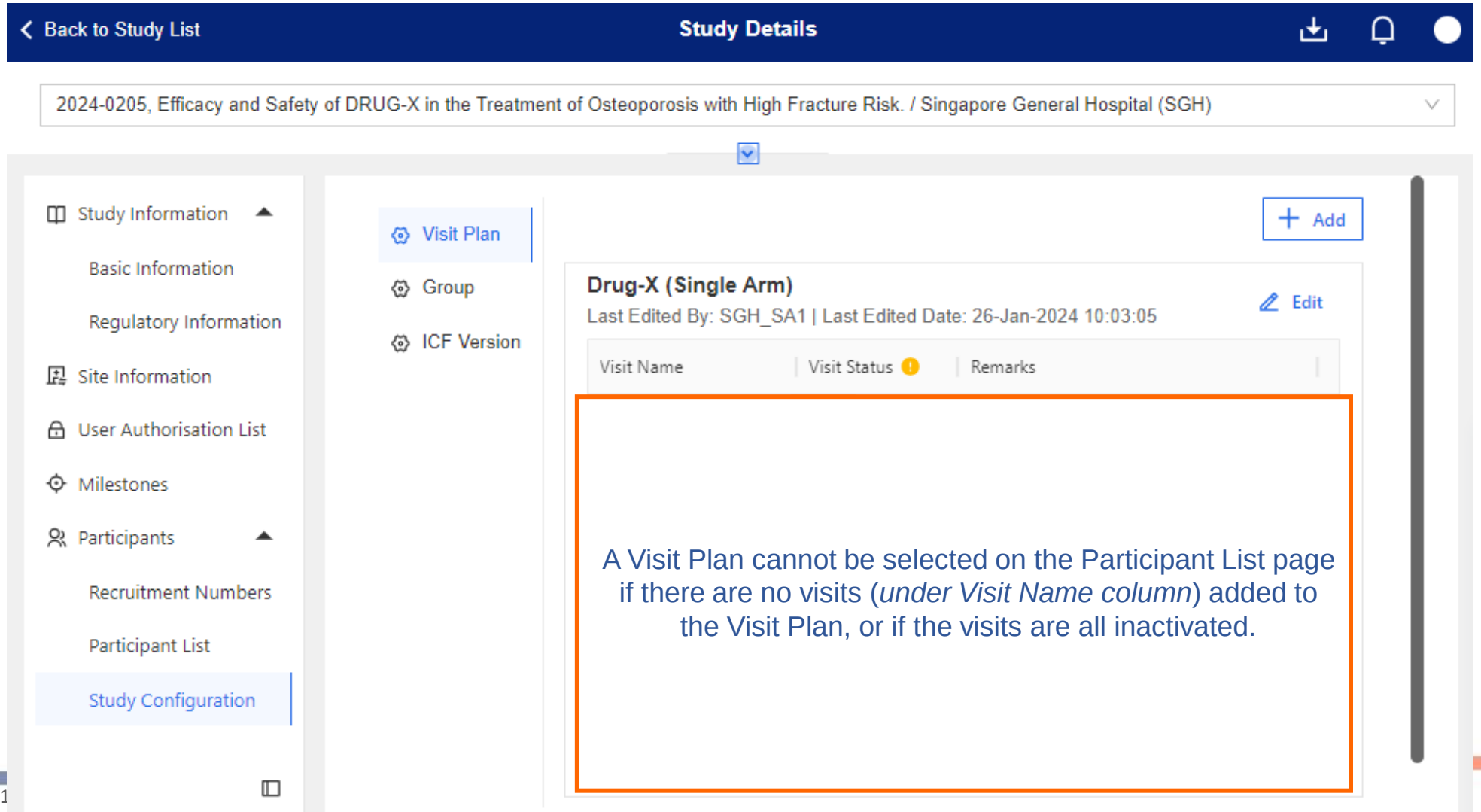
- Configured details will appear as options to be selected in the Participants – Participants List page.



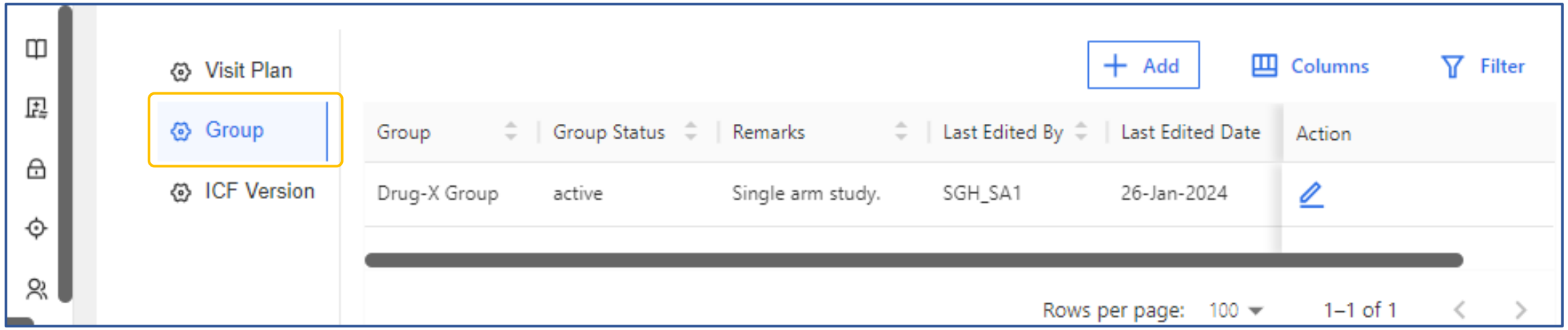
Participants – Study Configuration

Site Level

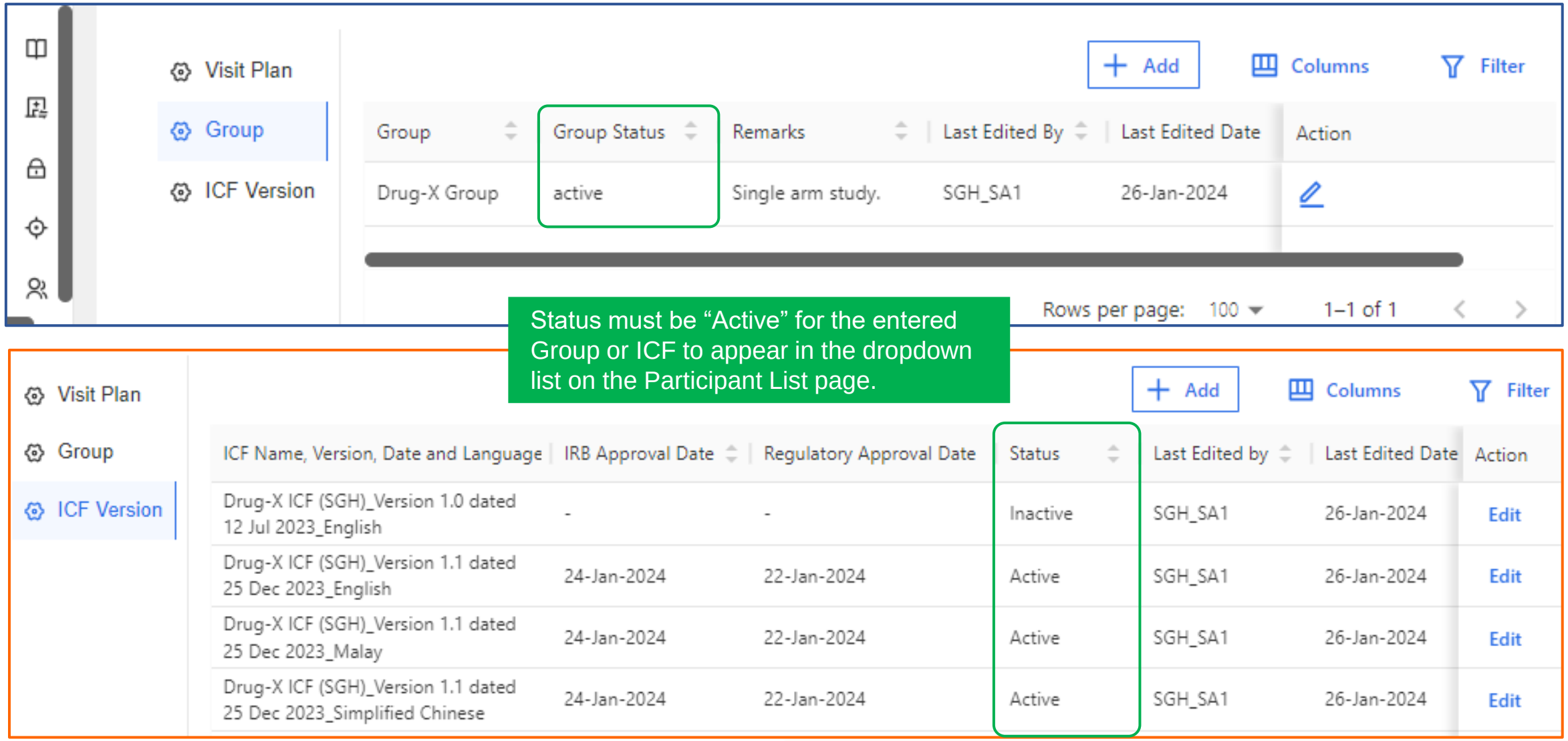
- Configured details will appear as options to be selected in the Participants – Participants List page.



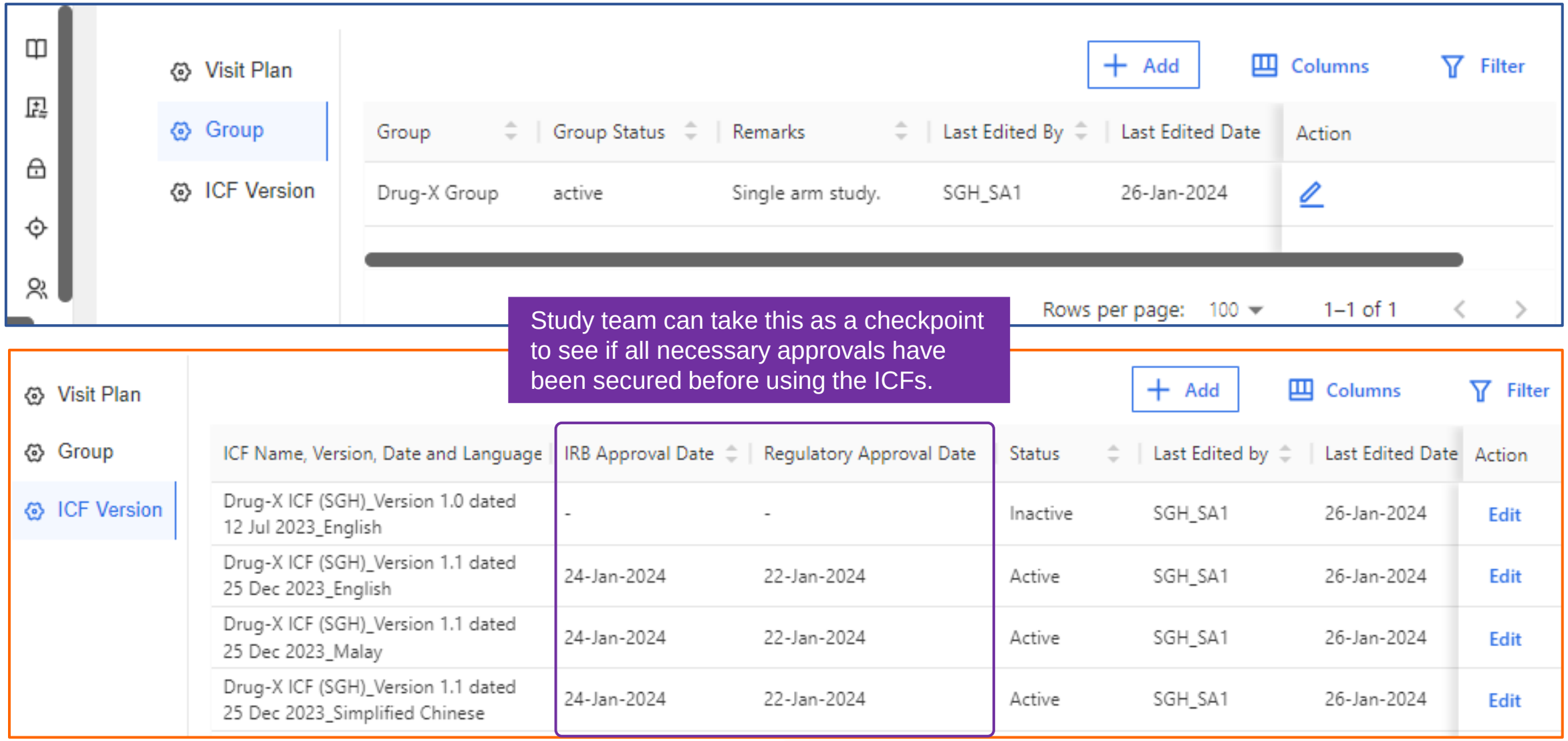
Participants – Study Configuration



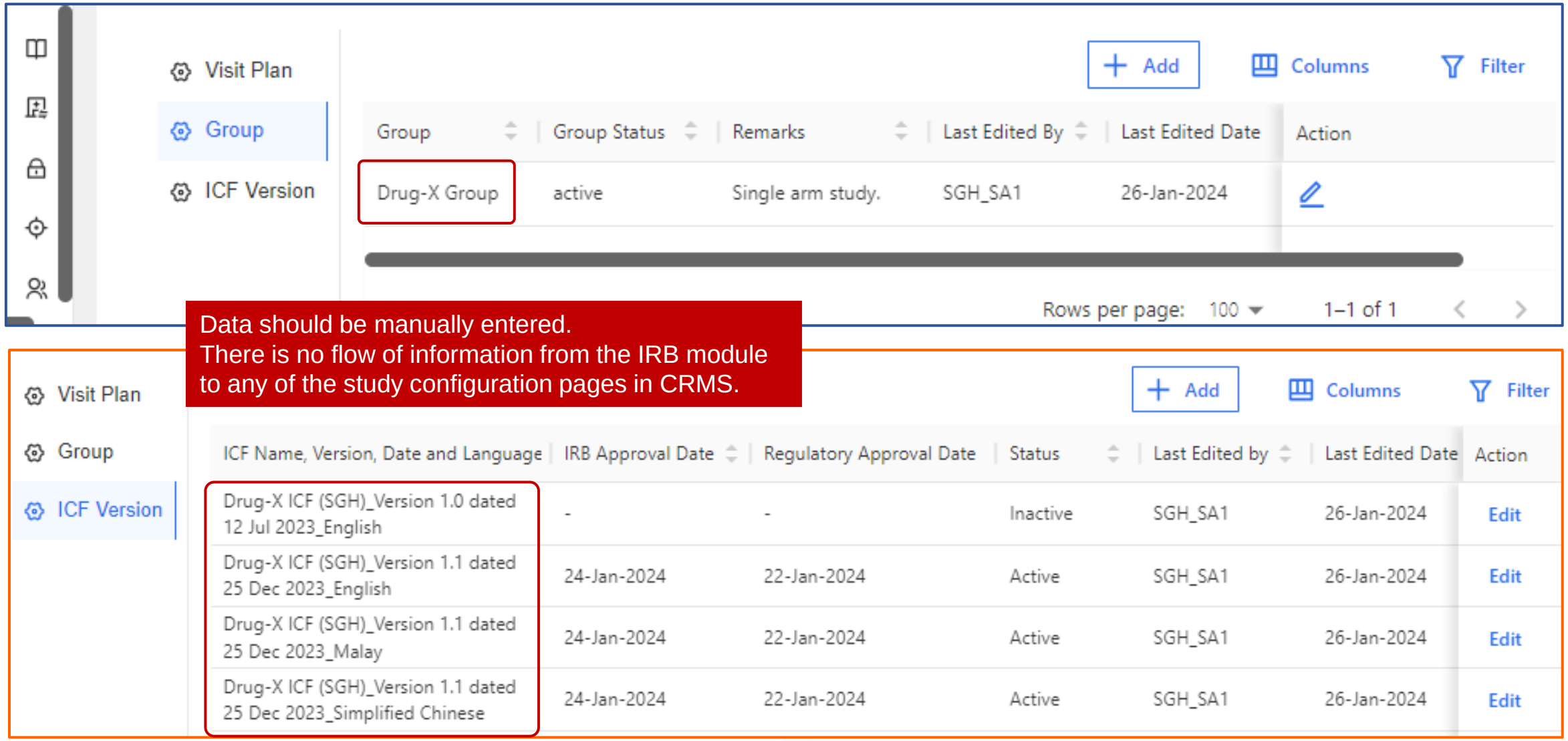
Participants – Study Configuration



Participants – Study Configuration



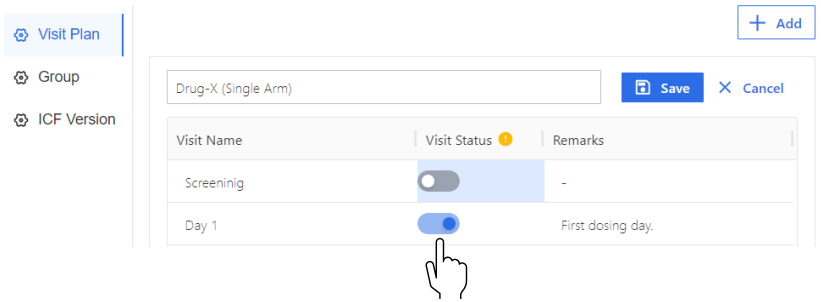
Participants – Study Configuration

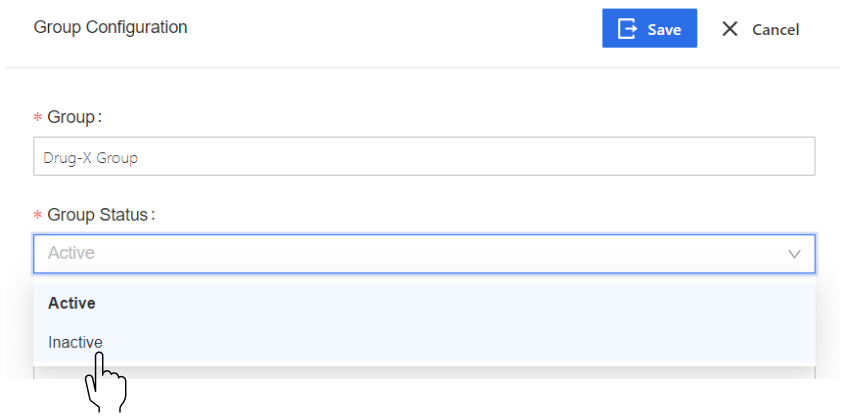


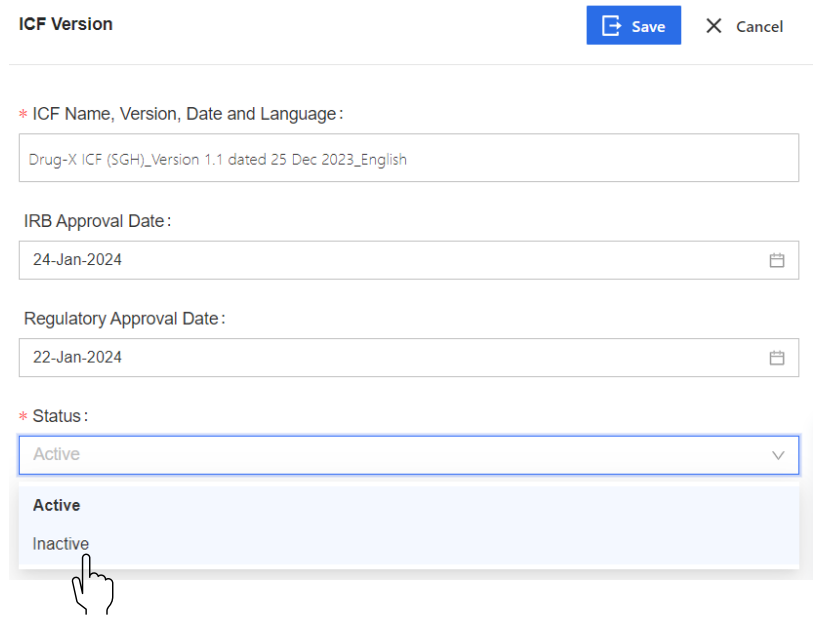
Participants – Study Configuration

NOTE:

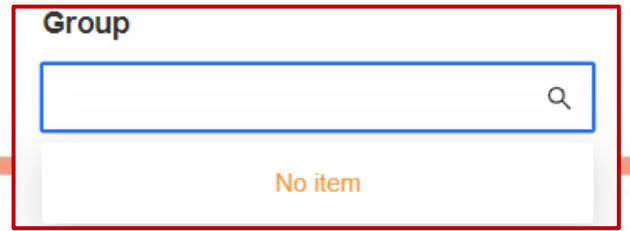
- Entries in the Study Configuration (Visit Plan, Group, ICF Version) cannot be deleted once saved.
- Users will need to use the switch toggle or drop-down list to inactivate the entry.

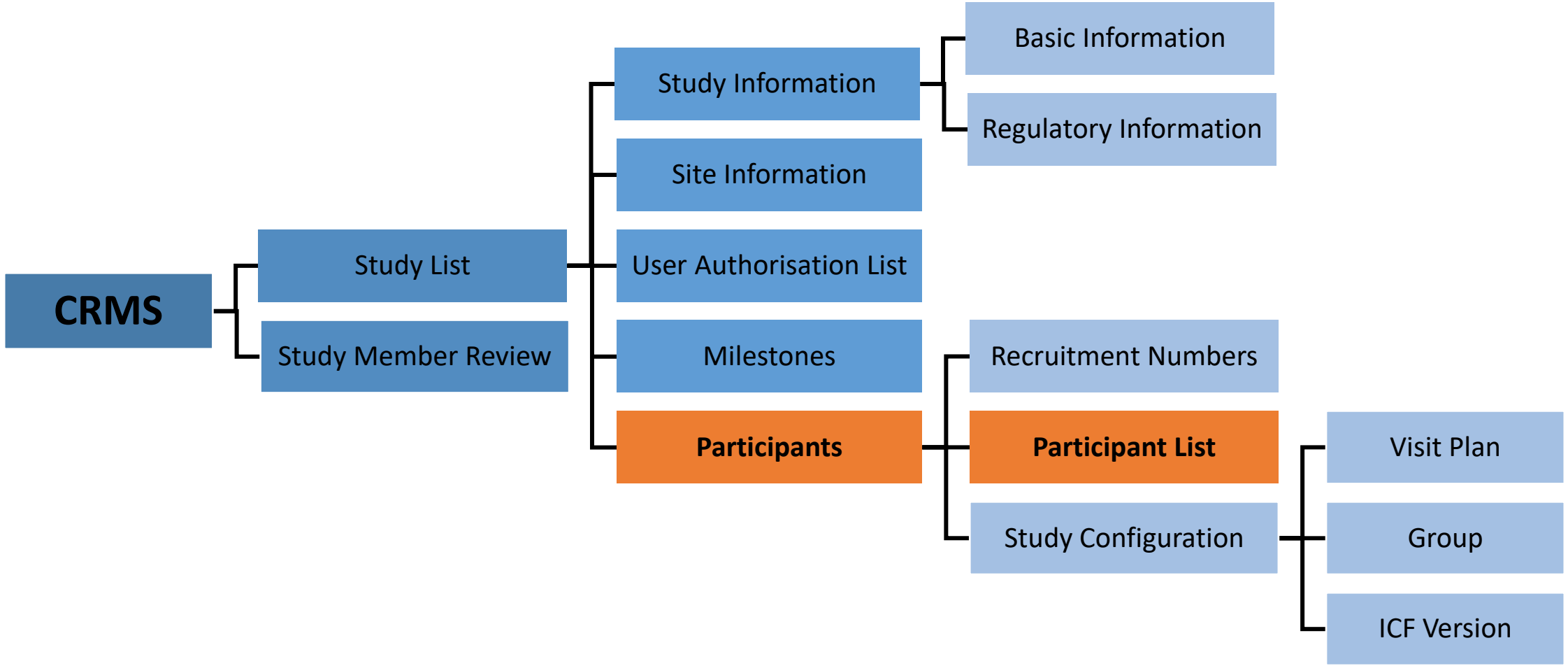






- Once inactivated, the entry will not appear as an option for selection in the drop-down list of the relevant Participant Details sections.

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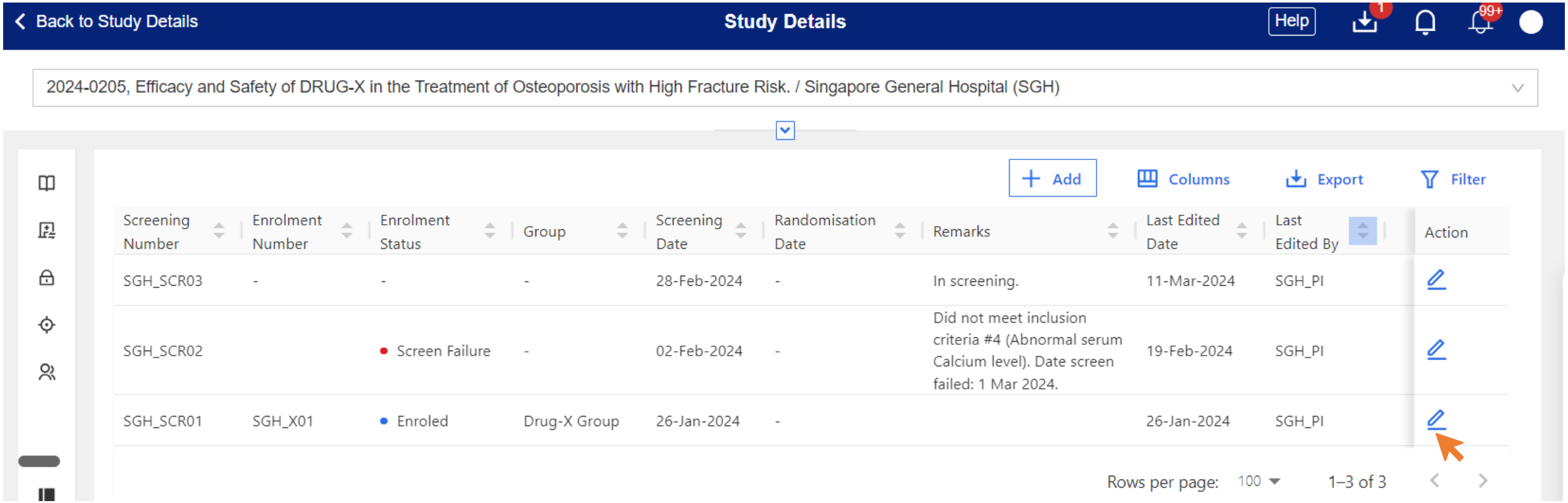
Participants – Participant List

Site Level

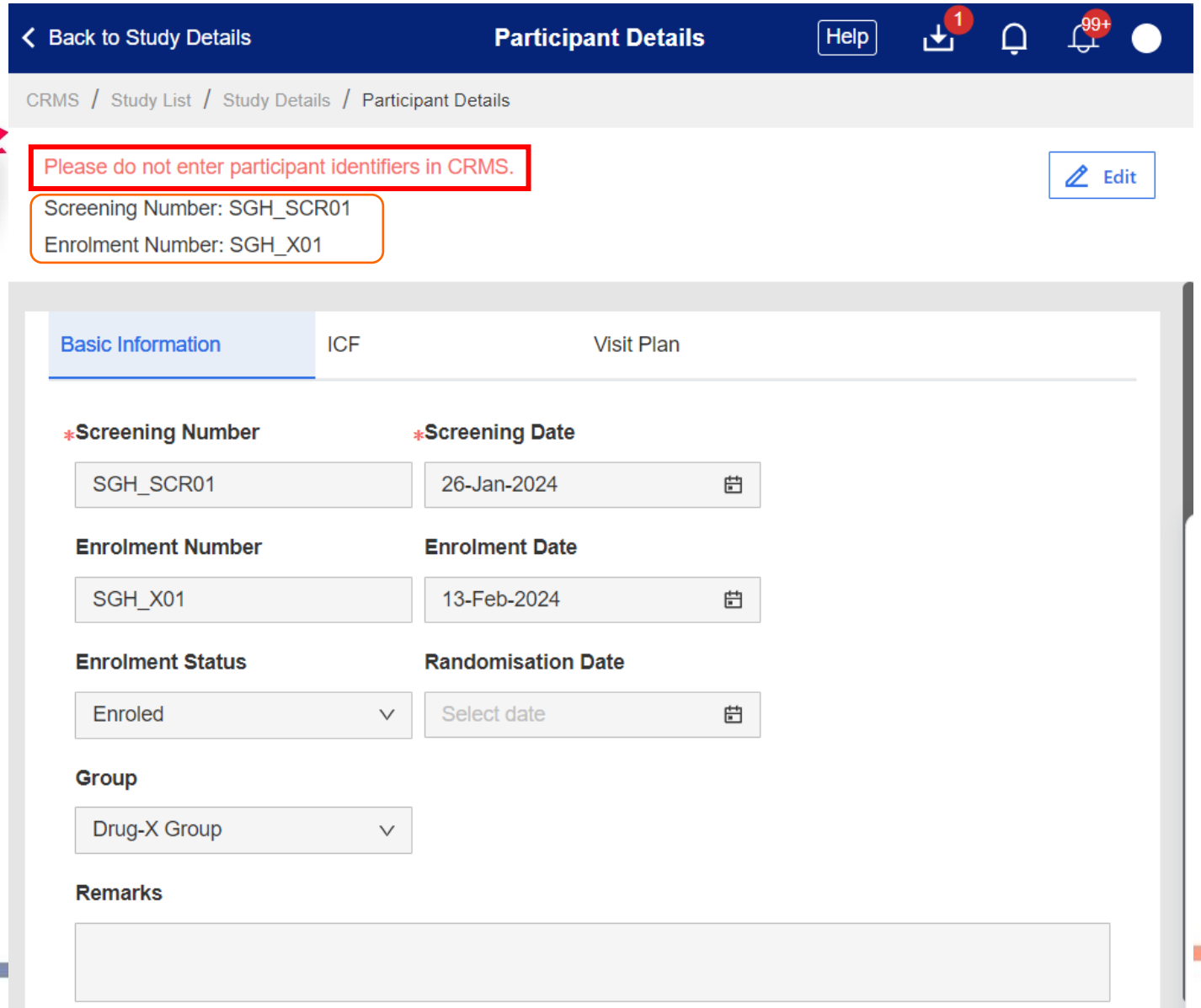


- Consists of 3 sub-pages to allow the recording of: -
  1. Basic Information
  2. ICF Details
  3. Visit Plan

Participants – Participant List

Configurable

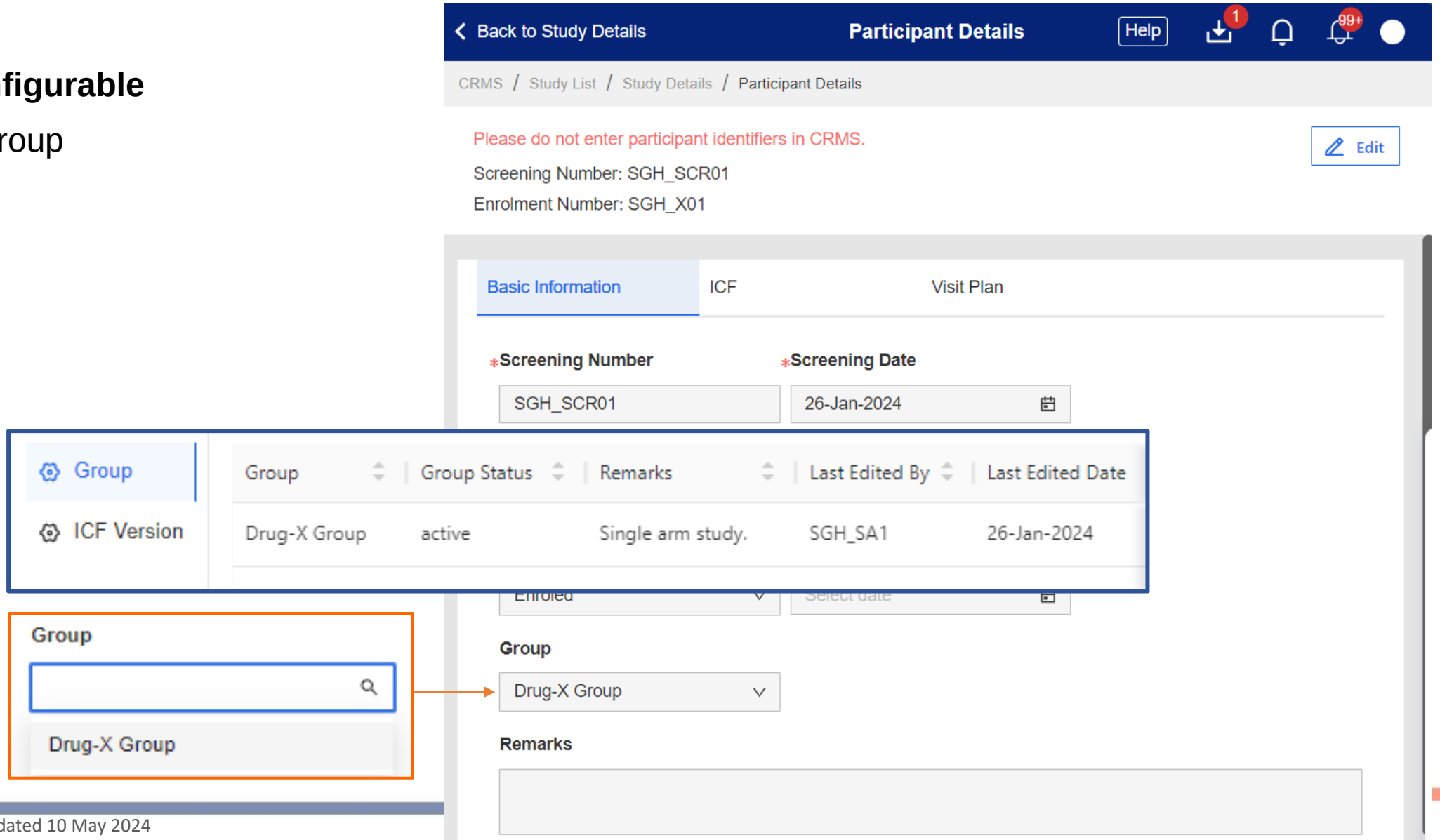
- Group



Participants – Participant List

Configurable

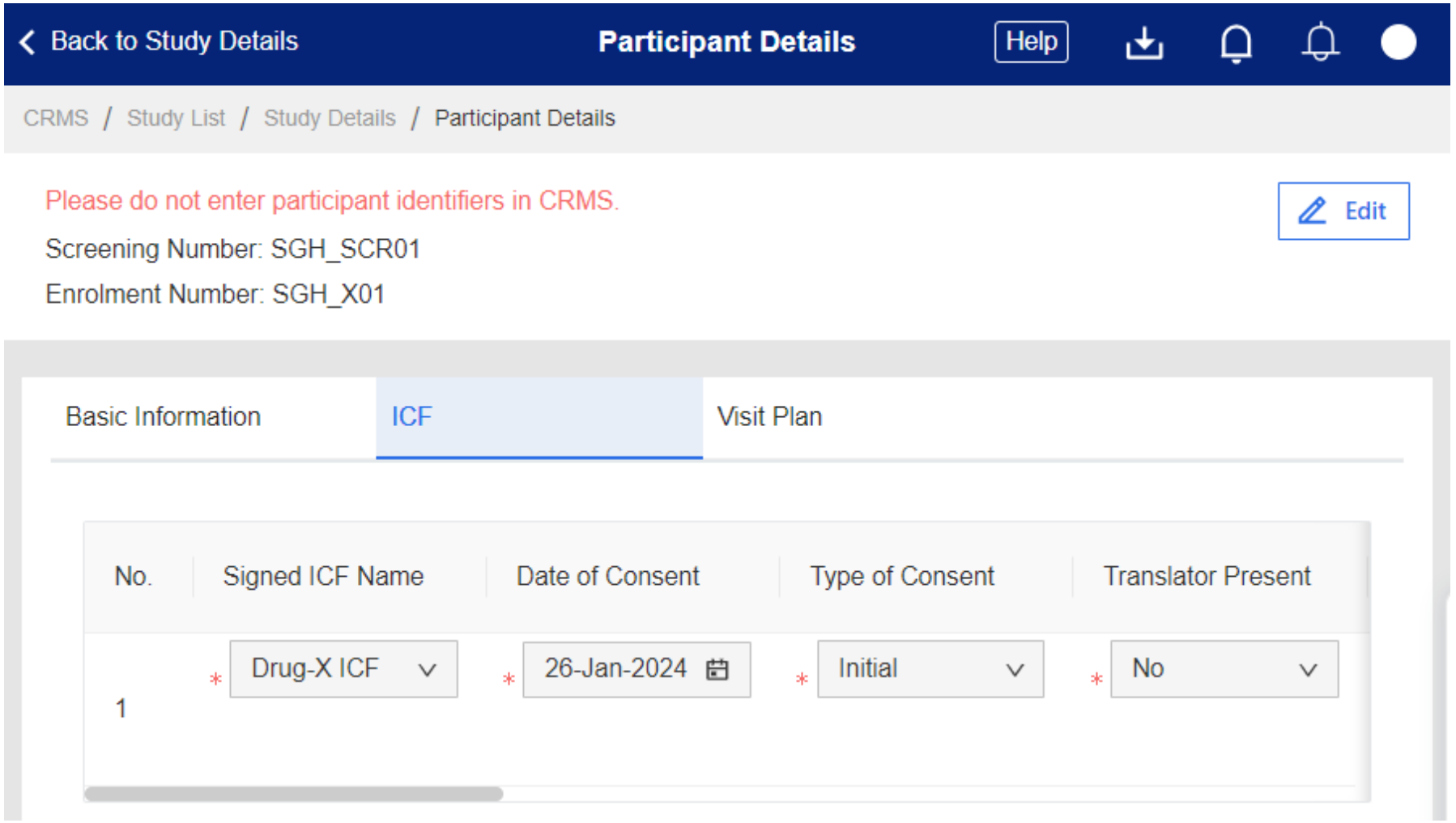
- Group



Participants – Participant List

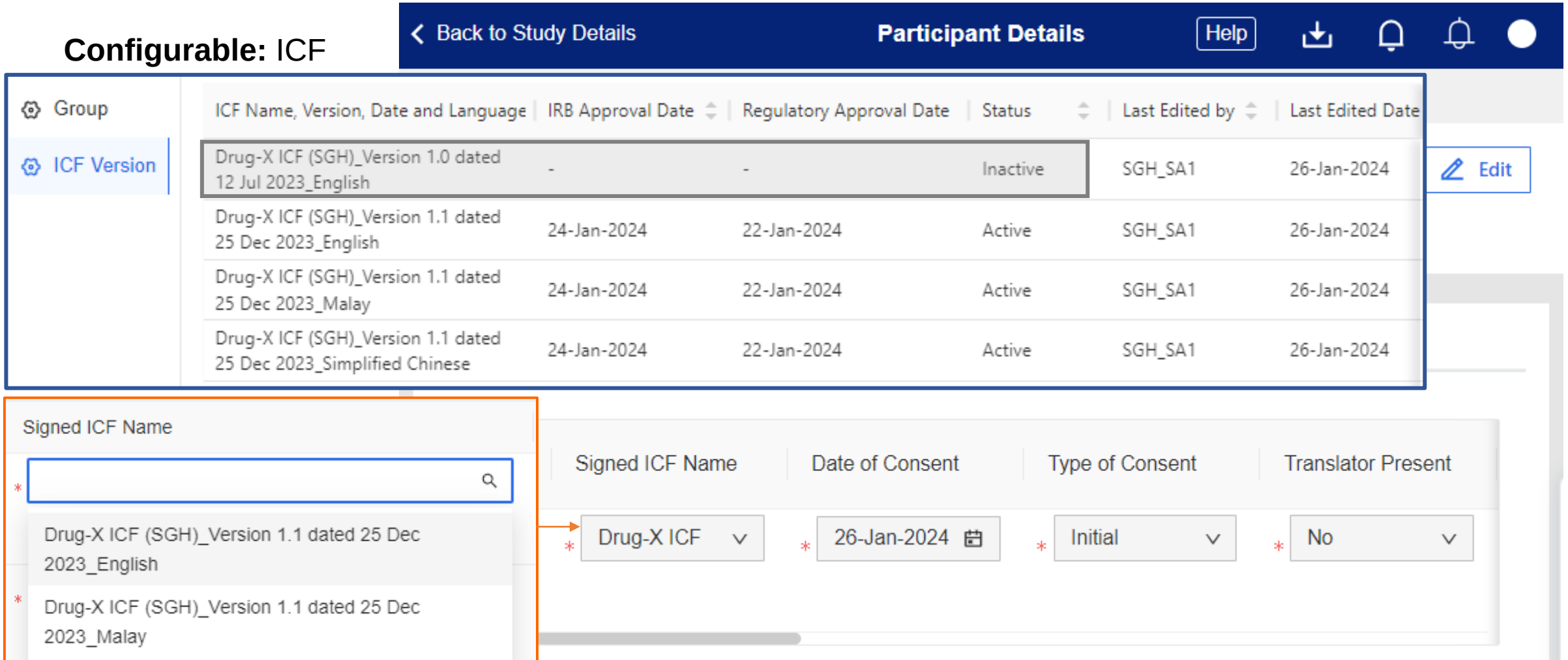
Configurable

- ICF

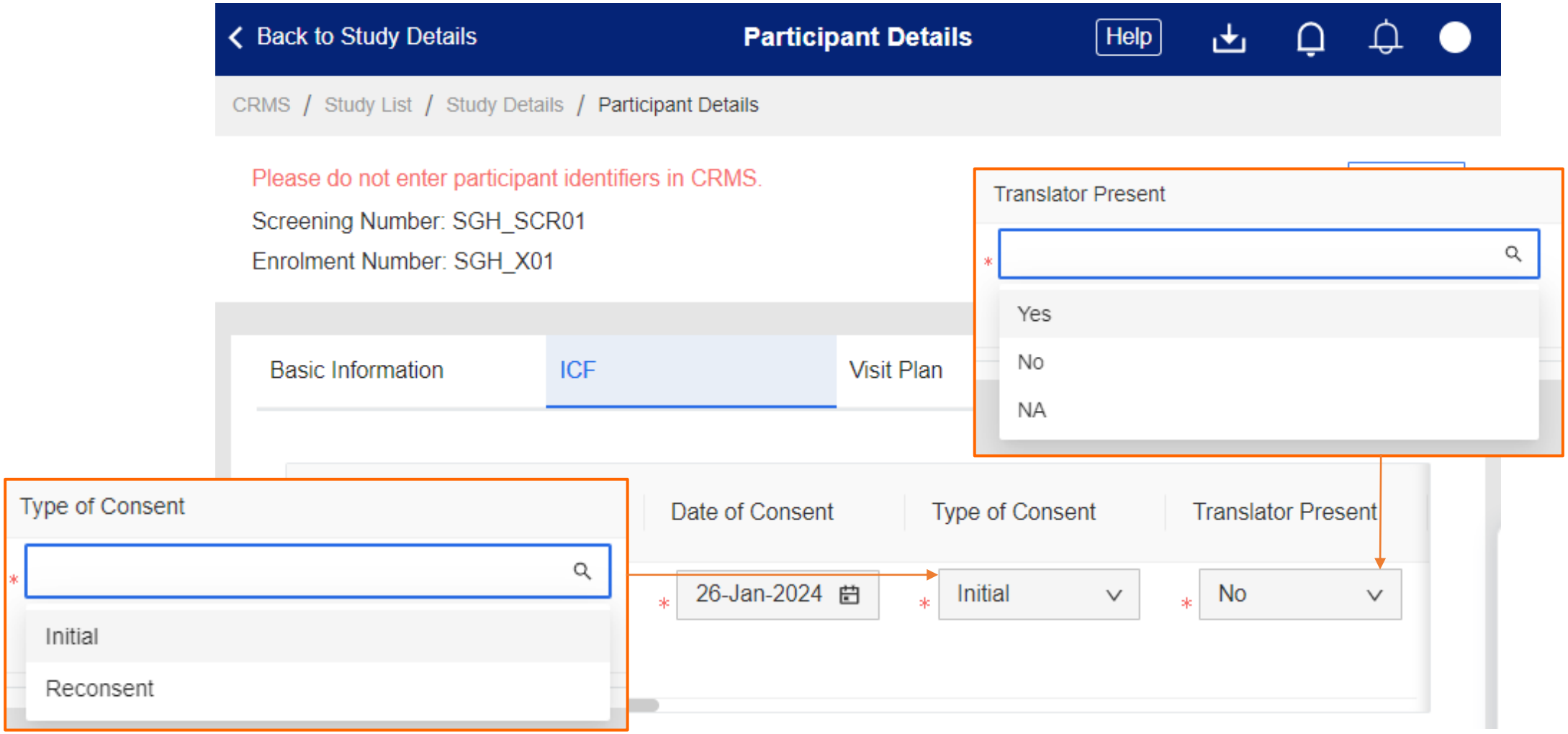


Participants – Participant List

Configurable: ICF



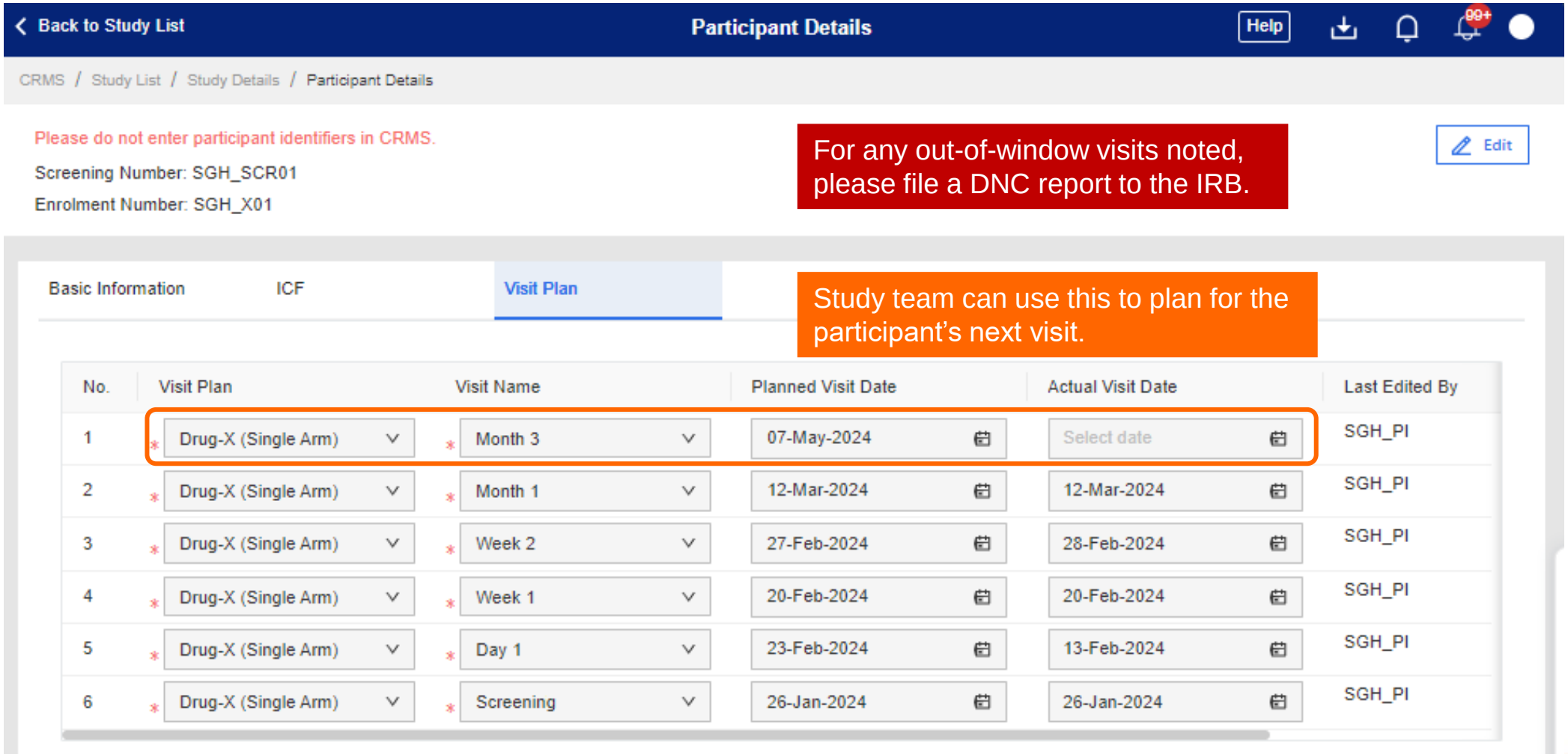
Participants – Participant List



Participants – Participant List

Configurable

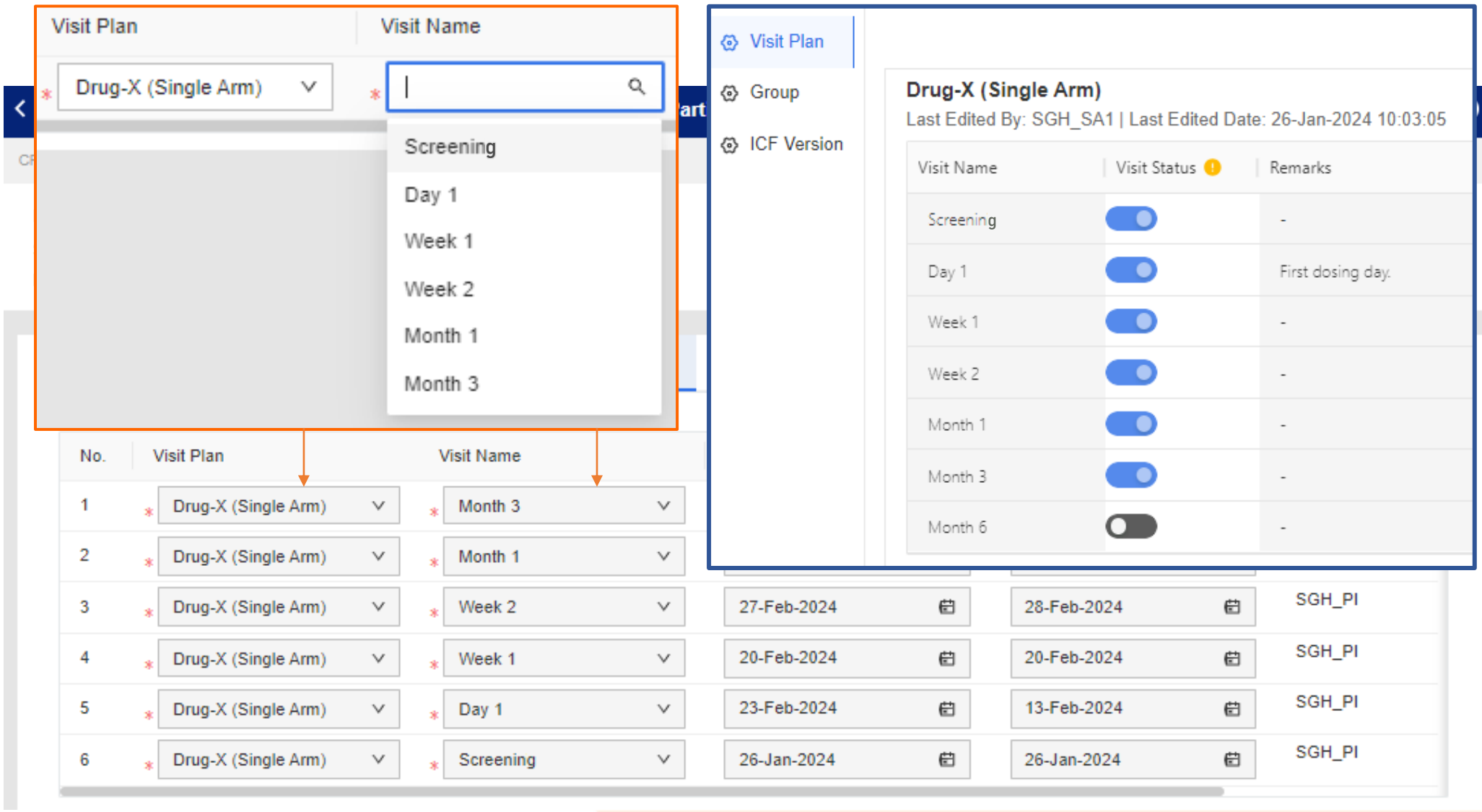
- Visit Plan
- Visit Name

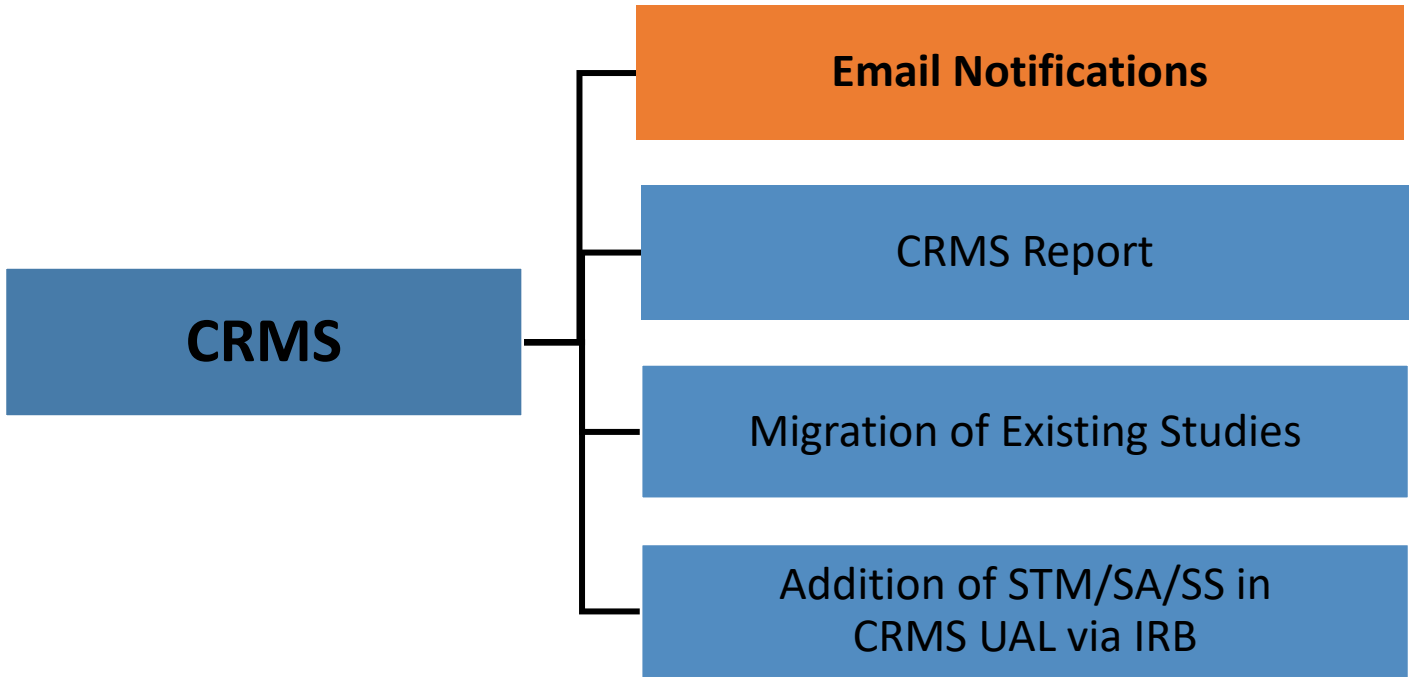


Participants – Participant List

Configurable

- Visit Plan
- Visit Name




CRMS
Email Notifications
CRMS Report
Migration of Existing Studies
Addition of STM/SA/SS in CRMS UAL via IRB

Email Notifications

Email notifications will be soft-launched in May.

- System-generated notification emails will be sent to the relevant users at specific trigger points.

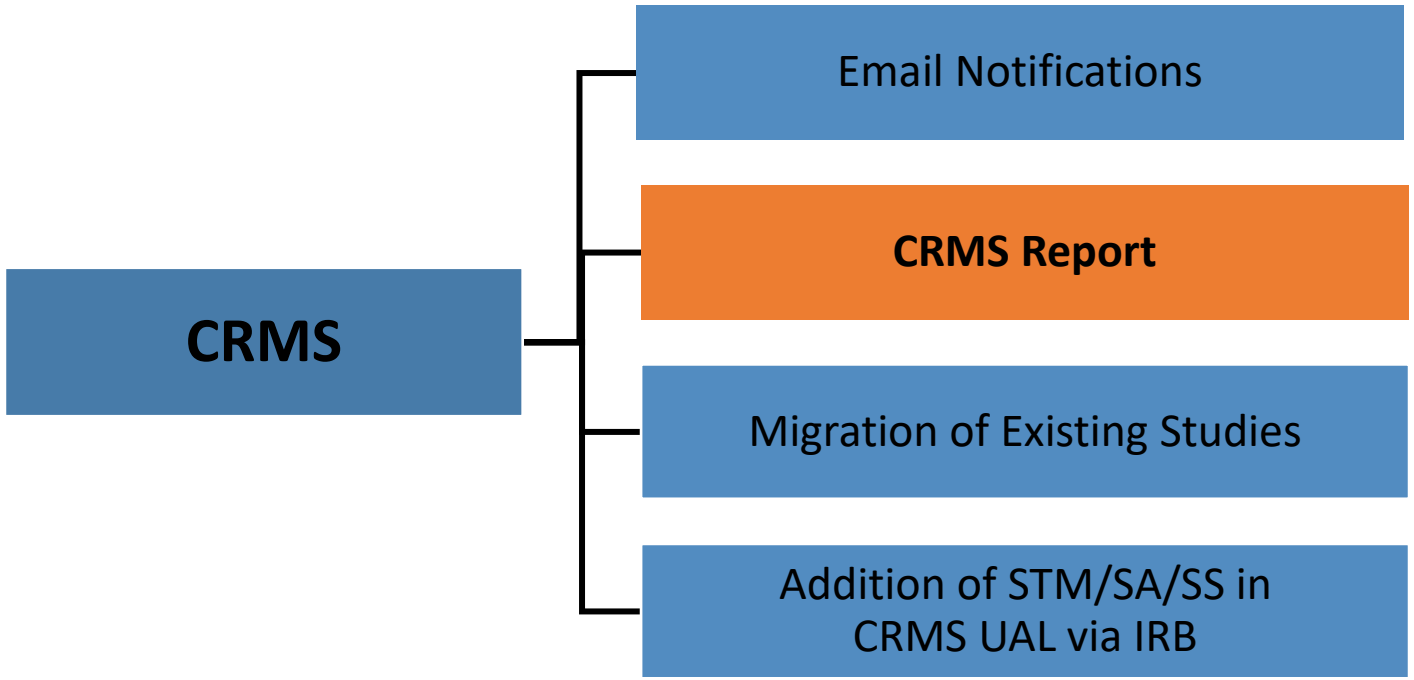
Notification Email Subject	Trigger Points	To List	Cc List
CRMS is Now Available	Study creation in CRMS module, i.e. upon first save of IRB Application form.	PI and Site-PI(s)	Co-I(s)
New User(s) Pending PI Endorsement	Daily reminders to PI/Site-PI when there is minimally 1 new SA/STM/SS pending endorsement in CRMS.	PI or Site-PI(s)	-
Successfully Added as User in CRMS	Endorsement of a new SA/STM/SS by PI/Site-PI in CRMS.	New user endorsed by PI/Site-PI	-
User Deactivated in CRMS	Deactivation of an approved SA/STM/SS in the User Authorisation List.	Deactivated user	PI/Site-PI(s)
Successfully Added as Primary Site Coordinator	Once a STM/SA is saved as the Primary Site Coordinator on the Site Information page.	Primary Site Coordinator user	PI/Site-PI(s)
Successfully Added as Backup Site Coordinator	Once a STM/SA is saved as the Backup Site Coordinator on the Site Information page.	Backup Site Coordinator user	PI/Site-PI(s)

Email Notifications

Email notifications will be soft-launched in May.

Notification Email Subject	Trigger Points	To List	Cc List
CRMS is Now Available	Study creation in CRMS module, i.e. upon first save of IRB Application form.	PI and Site-PI(s)	Co-I(s)

- Referring to the trigger point, if you have a multi-site study with 3 sites to be added to the IRB form, however you have only selected 1 site and 1 overall PI in Section B2 when you first hit the “Save” button, the overall PI will be the only person to receive this email notification.
- Investigators added later from the same site or new sites will not receive this email notification after the trigger point has passed.
- Nonetheless, all investigators will receive an email notification from the IRB module notifying that they have been added as an investigator in the study.


CRMS
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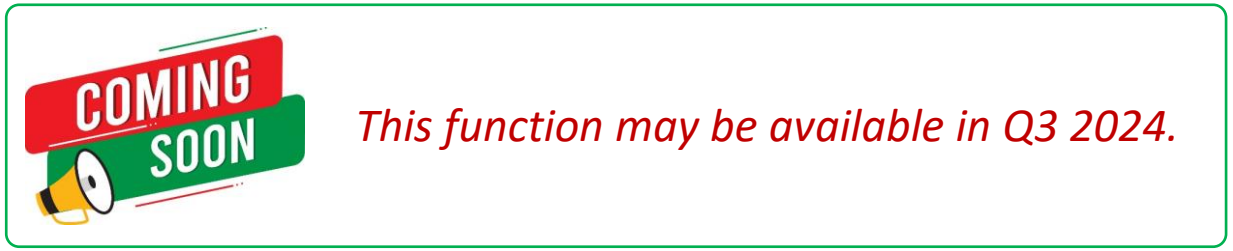
CRMS Reports



This function may be available in Q3 2024.

- Reports can be generated from CRMS to fulfil any periodic or KPI reporting at the institution level.
- CRMS Report section can only be accessed by selected roles.

ECOS

CRMS Institution Report

Help

Regulatory Information (CRM)
Regulatory Information (rHBR)
SAE Reports for CT Insurance
Publications Listing
Grant Listing
Recruitment Report
Enrolment and Reporting Status
Studies Listing
Study Milestones
Regulatory Information (Clinical Tri...
Contracts Tracking Listing
Study Agreement

Columns Export Filter(1)

Unique identifier	Study Title	Study PI or Site-PI Name	Study Role	Milestone	Expected Date	Actual Date	Remarks
2024-0205-Singapore General Hospital (SGH)	Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.	SGH_PI	PI	IRB Approval	08-Feb-2024	24-Jan-2024	-
2024-0205-Singapore General Hospital (SGH)	Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.	SGH_PI	PI	Regulatory Approval	17-Jan-2024	22-Jan-2024	Slight delay due to additional round of queries from HSA.
2024-0205-Singapore General Hospital (SGH)	Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.	SGH_PI	PI	Study Initiation	29-Jan-2024	25-Jan-2024	-
2024-0205-Singapore General Hospital (SGH)	Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.	SGH_PI	PI	First Participant Screened	26-Jan-2024	26-Jan-2024	-
2024-0205-Singapore General Hospital (SGH)	Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.	SGH_PI	PI	First Participant Enrolled	23-Feb-2024	13-Feb-2024	Eligibility criteria assessed and confirmed on 12 Feb 2024.

NOTE: This is a very simplified version of the report generated from a single study.

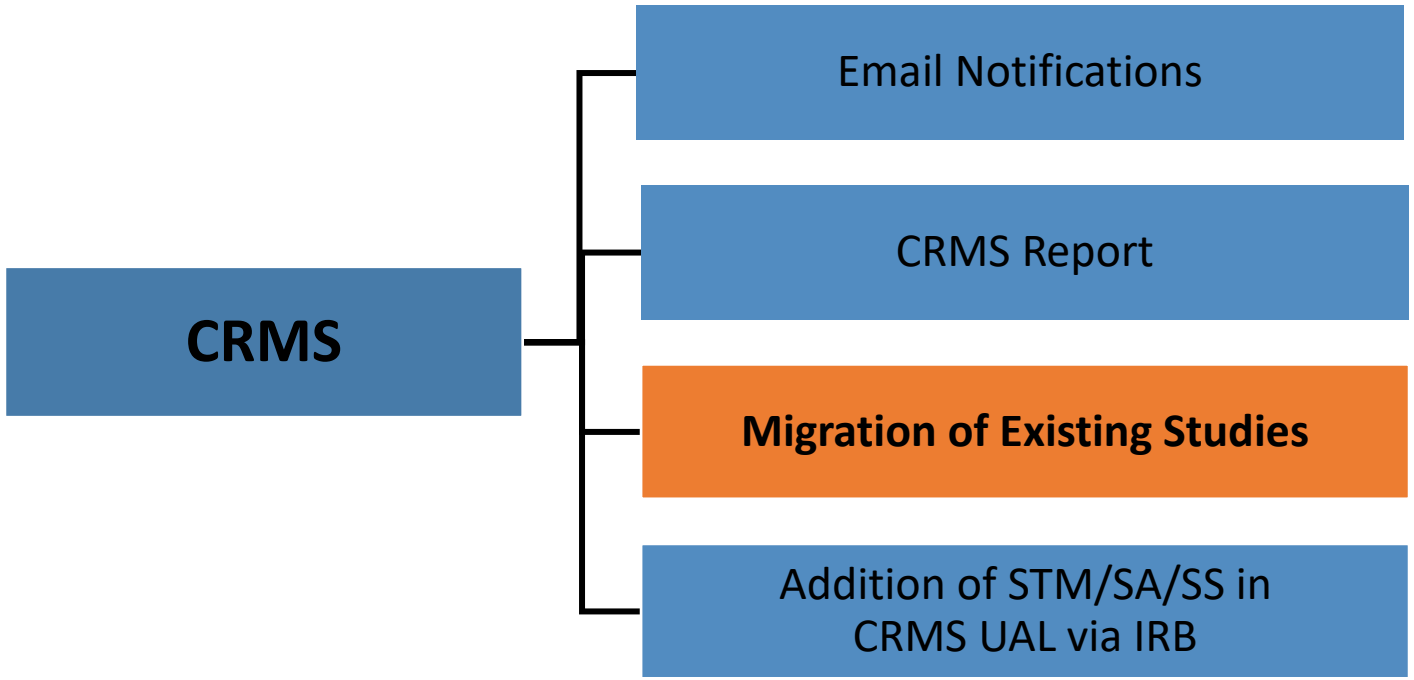
Rows per page: 100 1–5 of 5

CRMS Reports

This function may be available in Q3 2024.

- 12 types of reports:
  - Recruitment Number
  - Enrolment and Reporting Status
  - Study Milestones
  - Regulatory Information (Clinical Trials Regulated by HSA)
  - Regulatory Information (CRM)
  - Regulatory Information (rHBR)
  - Publication Listing
  - SAE Reports for CT Insurance
  - Studies Listing
  - Grant Listing
  - Contracts Tracking Listing
  - Study Agreement Listing
- CRMS Reports can be exported.

TIP: Use the Column function to narrow data selection.


CRMS
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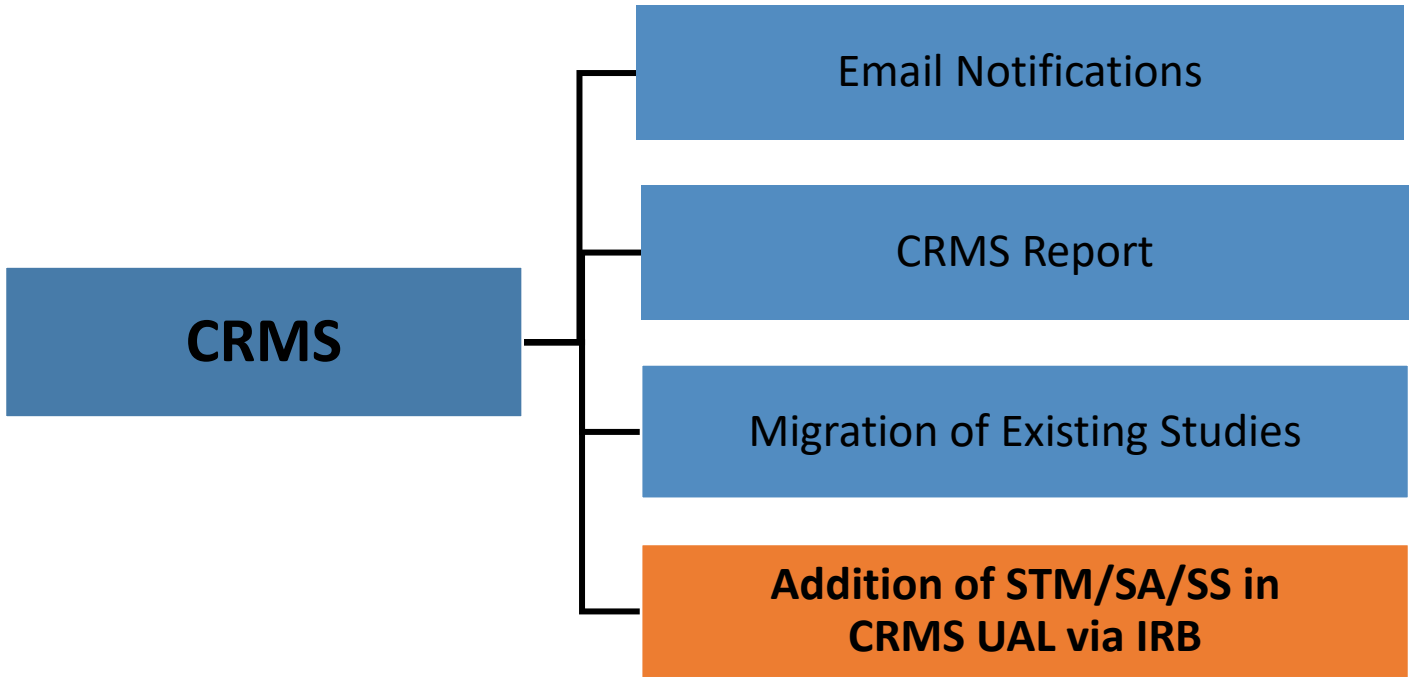
Migration of Existing Studies

- **Study Information – Basic Information**
  - Sponsor, CRO and payment data from Study Funding Information in the existing iSHaRe CIRB forms will be migrated to the CRMS Study Information page on ECOS.
  - Any new changes after the migration should be promptly updated by the site team via CRMS.

- **User Authorisation List**
  - PI, Site-PI and Co-I in the existing iSHaRe CIRB form will be migrated to the CRMS UAL.
  - Protocol Administrators and Study Team Members will not be migrated.
  - **Migrated PI, Site-PI, Co-I or CRMS RO administrator that has access to CRMS will need to manually add the STM, SA and/or SS into the UAL should they require access to CRMS and/or IRB modules. This is for migrated studies only.**

RECAP: Once a STM/SA/SS is added to the UAL, he/she will gain limited access to CRMS. This user can then add the other STM/SA/SS as needed to the CRMS UAL.


CRMS
Email Notifications
CRMS Report
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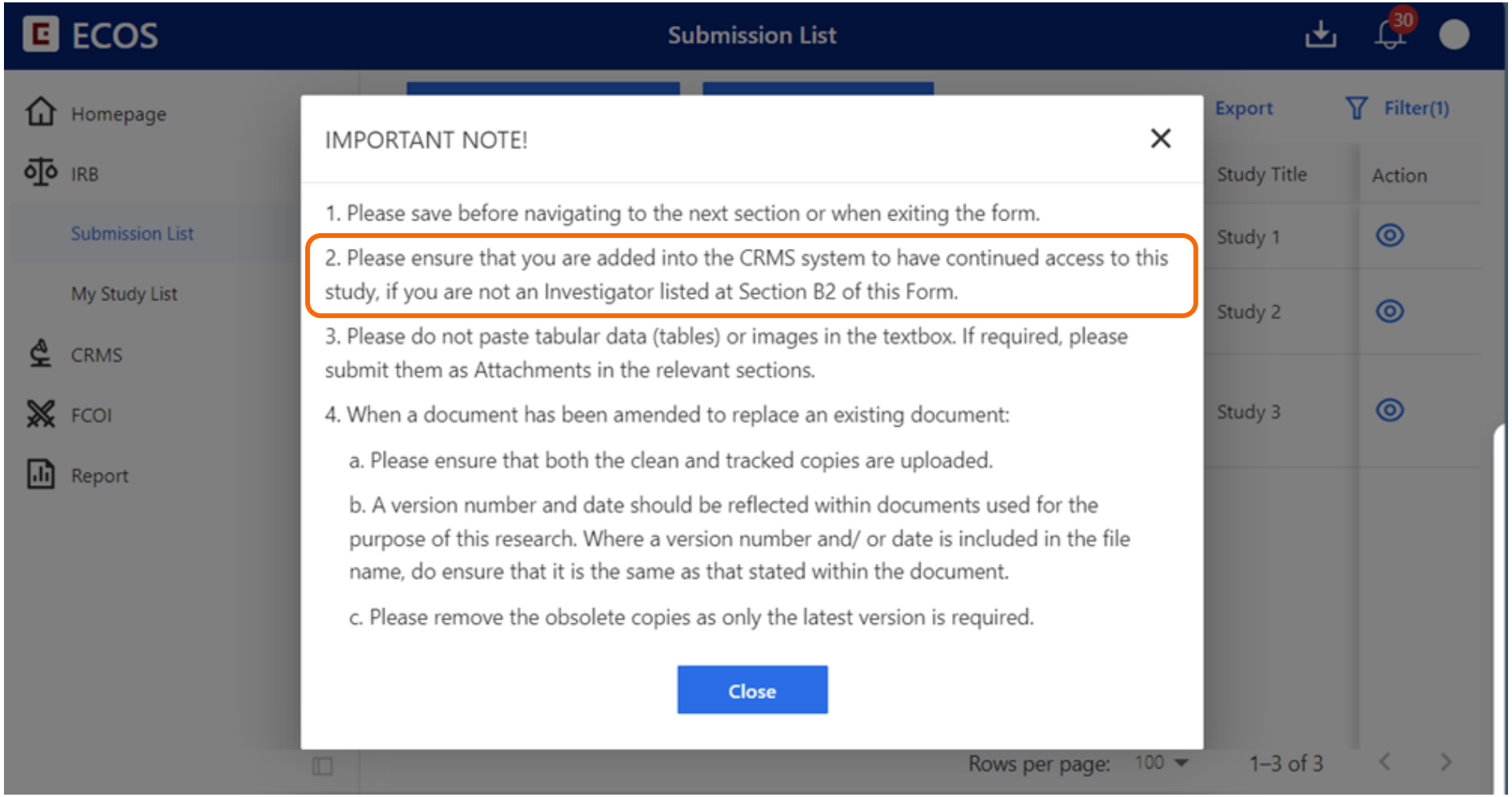
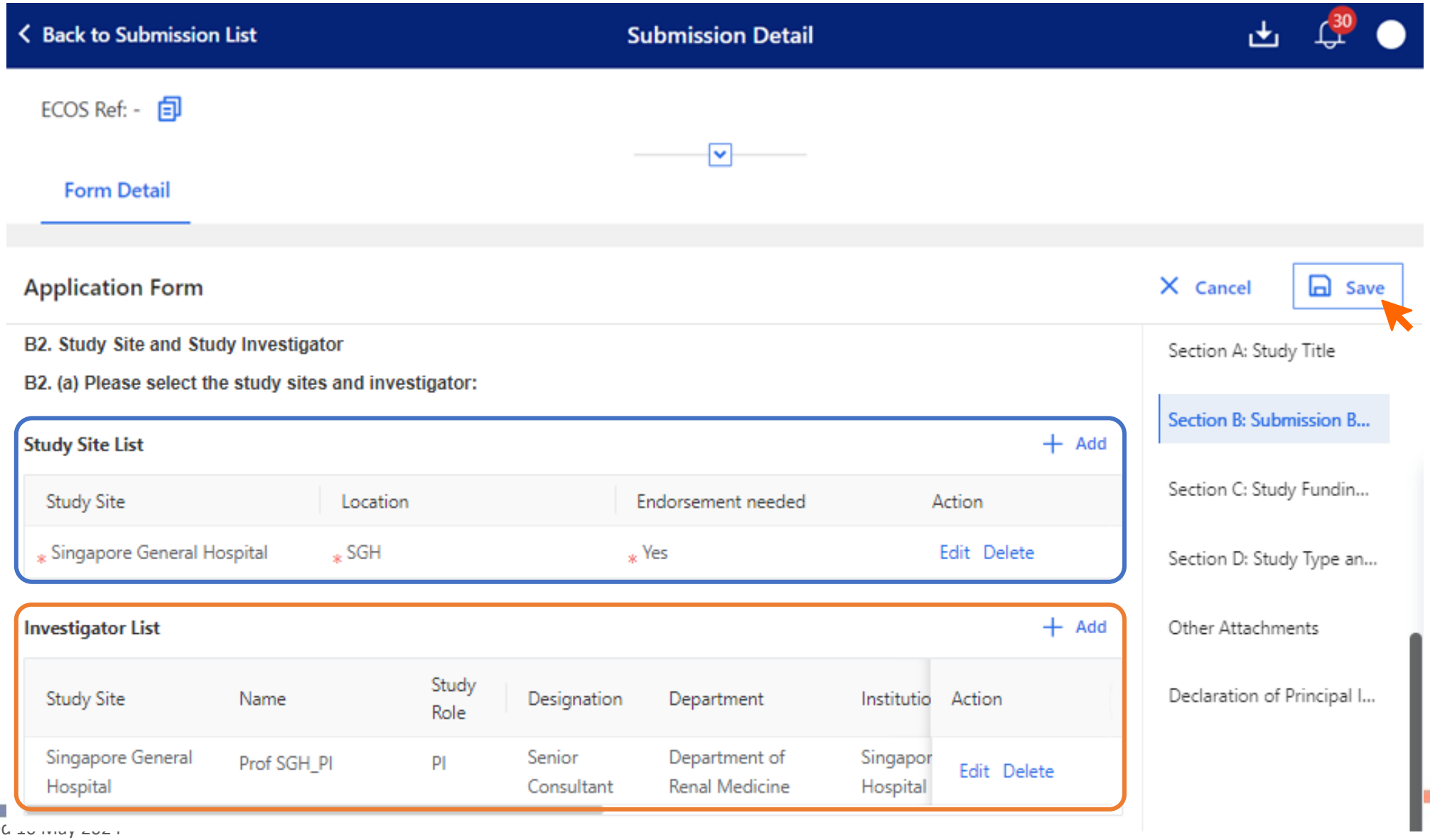
Important Note – IRB APP Form

Role used: Study Sponsor (SS_20)



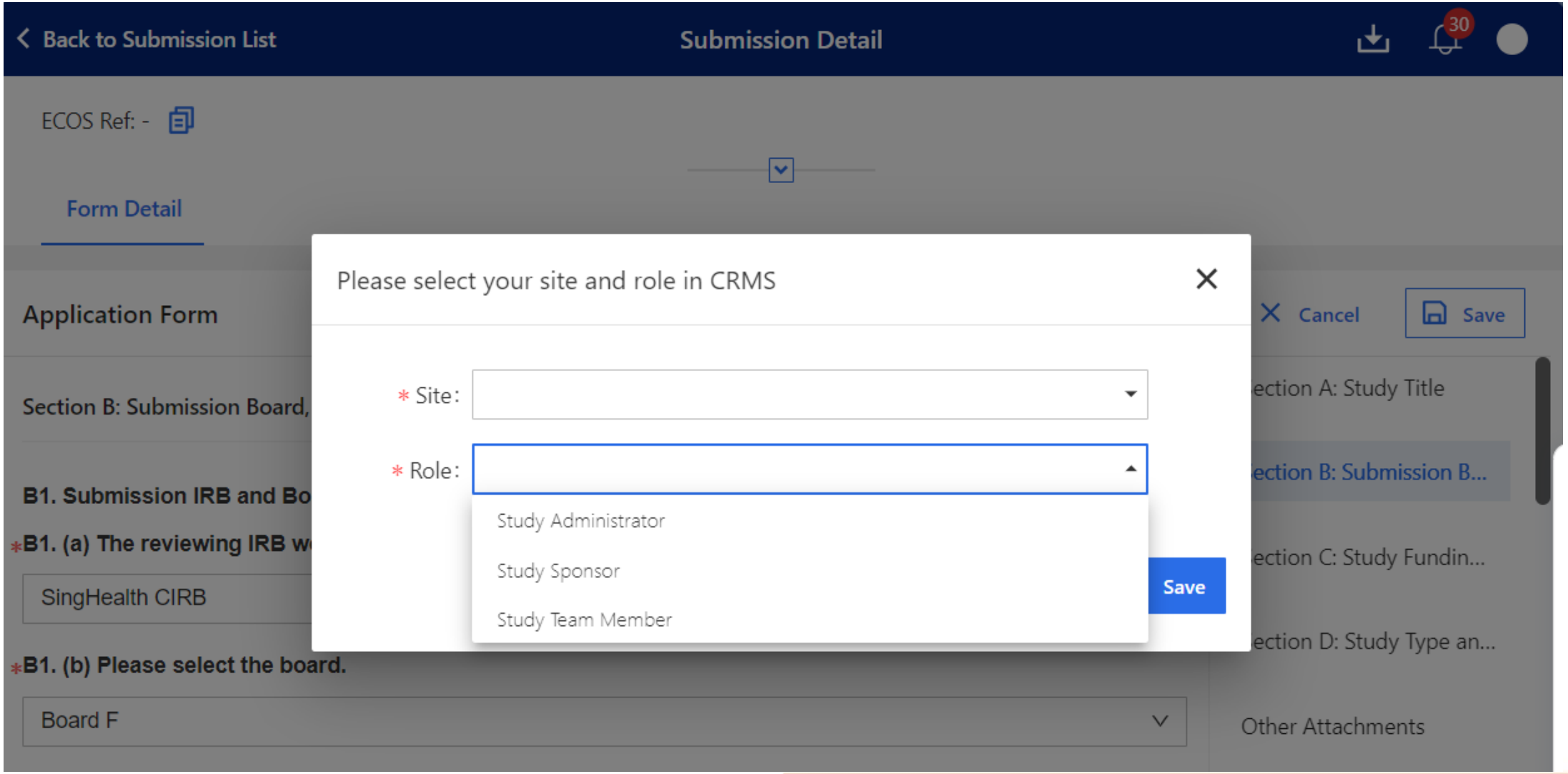
System Recognition Function

Role used: Study Sponsor



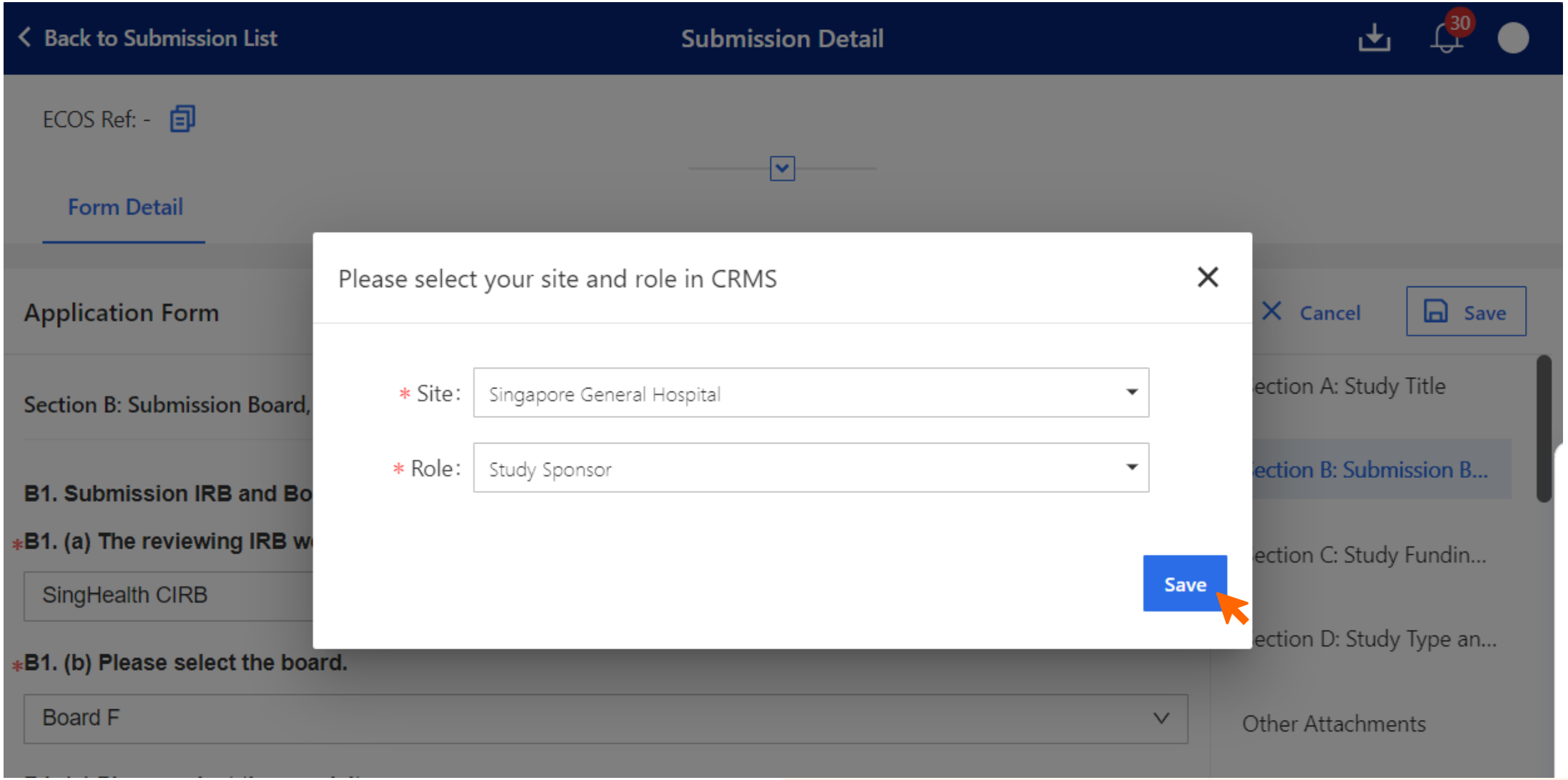
CRMS Prompt in IRB Module

Role used: Study Sponsor



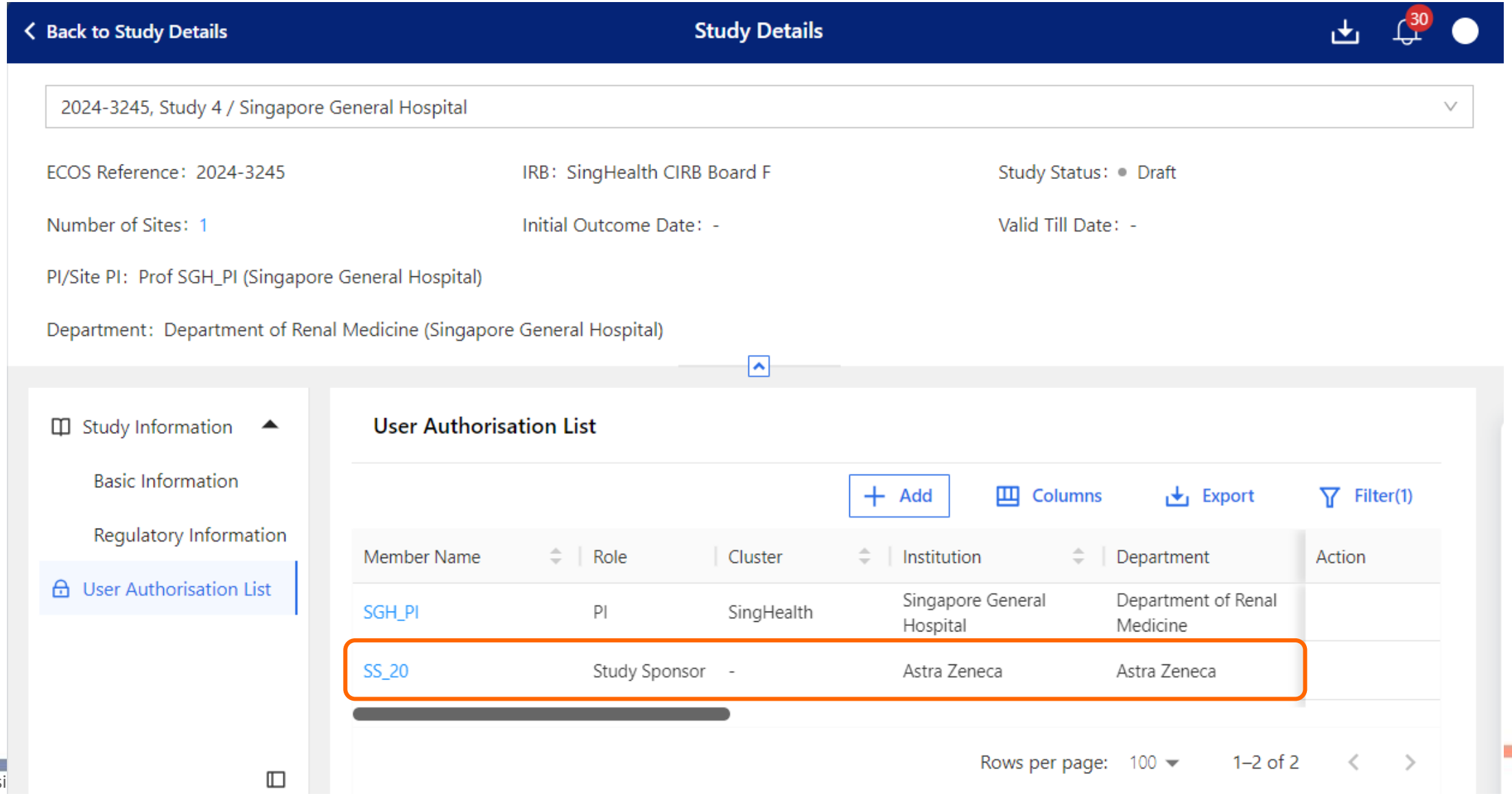
CRMS Prompt in IRB Module

Role used: Study Sponsor



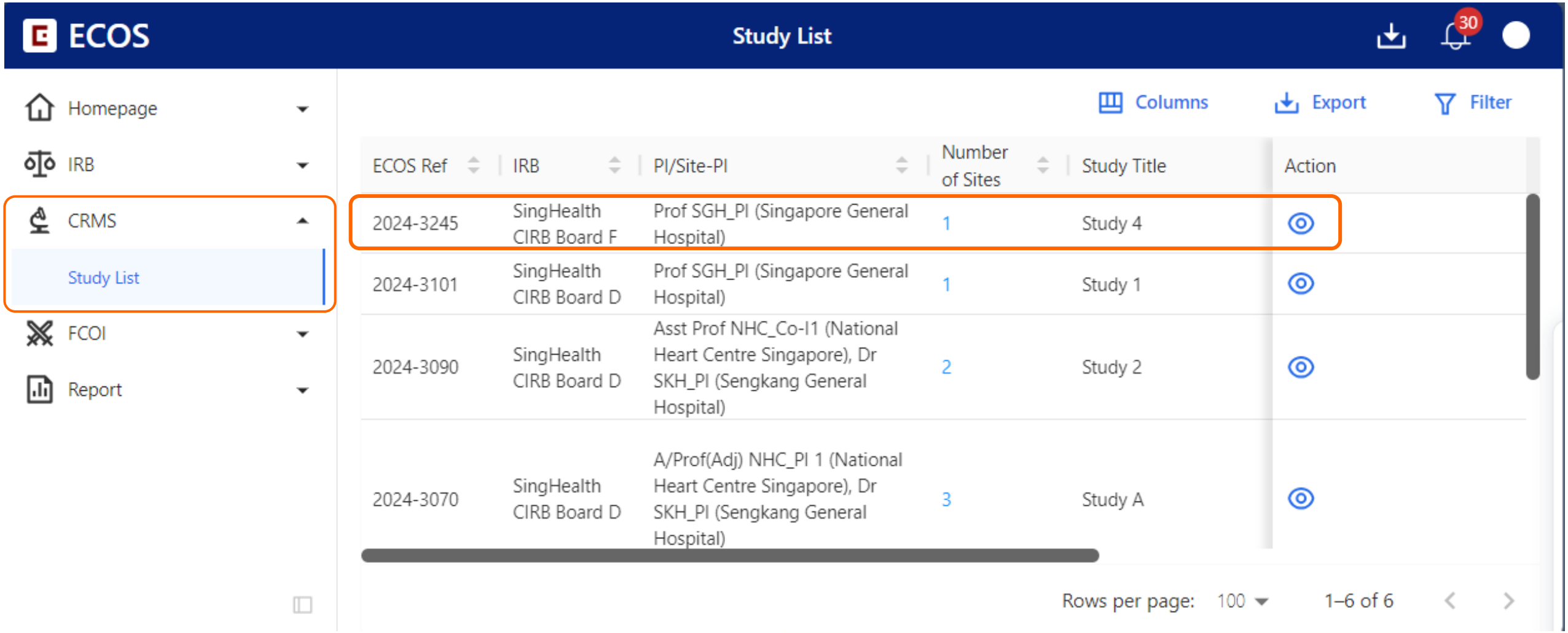
Addition of STM/SA/SS by System

Role used: Study Sponsor



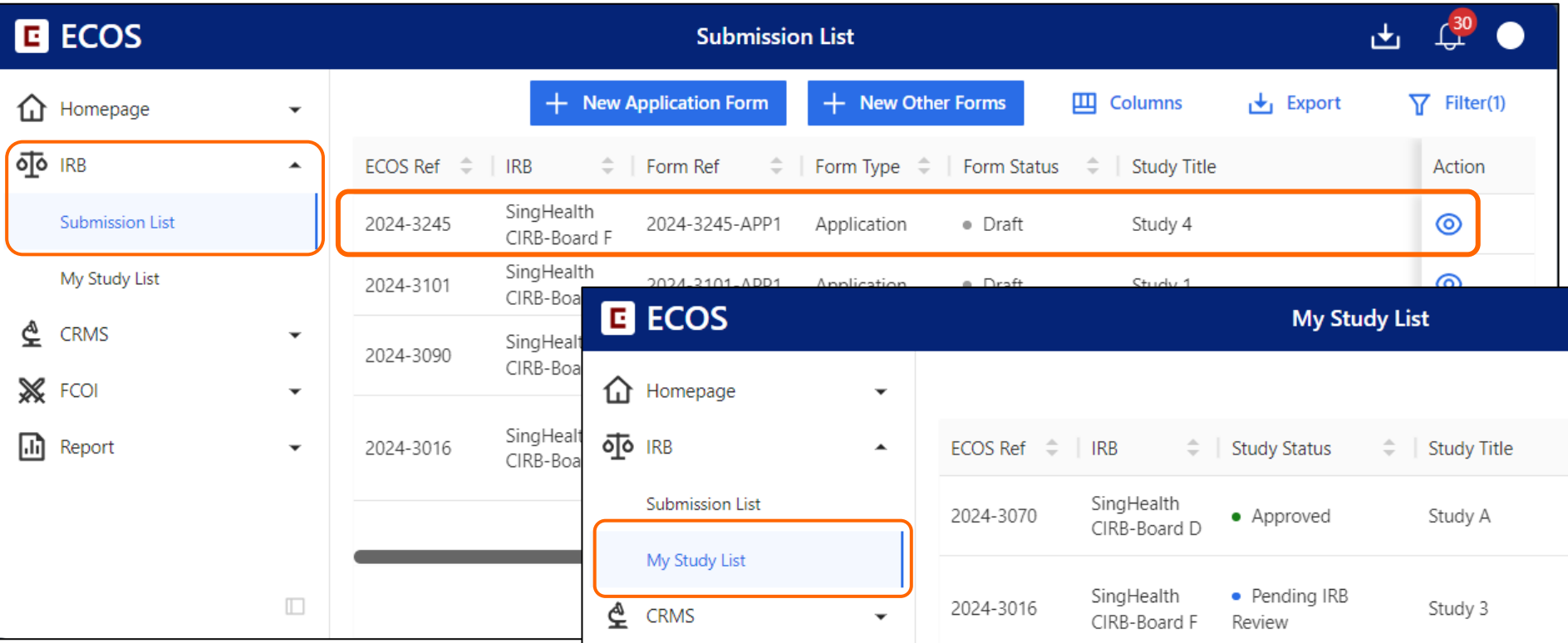
CRMS Accessibility

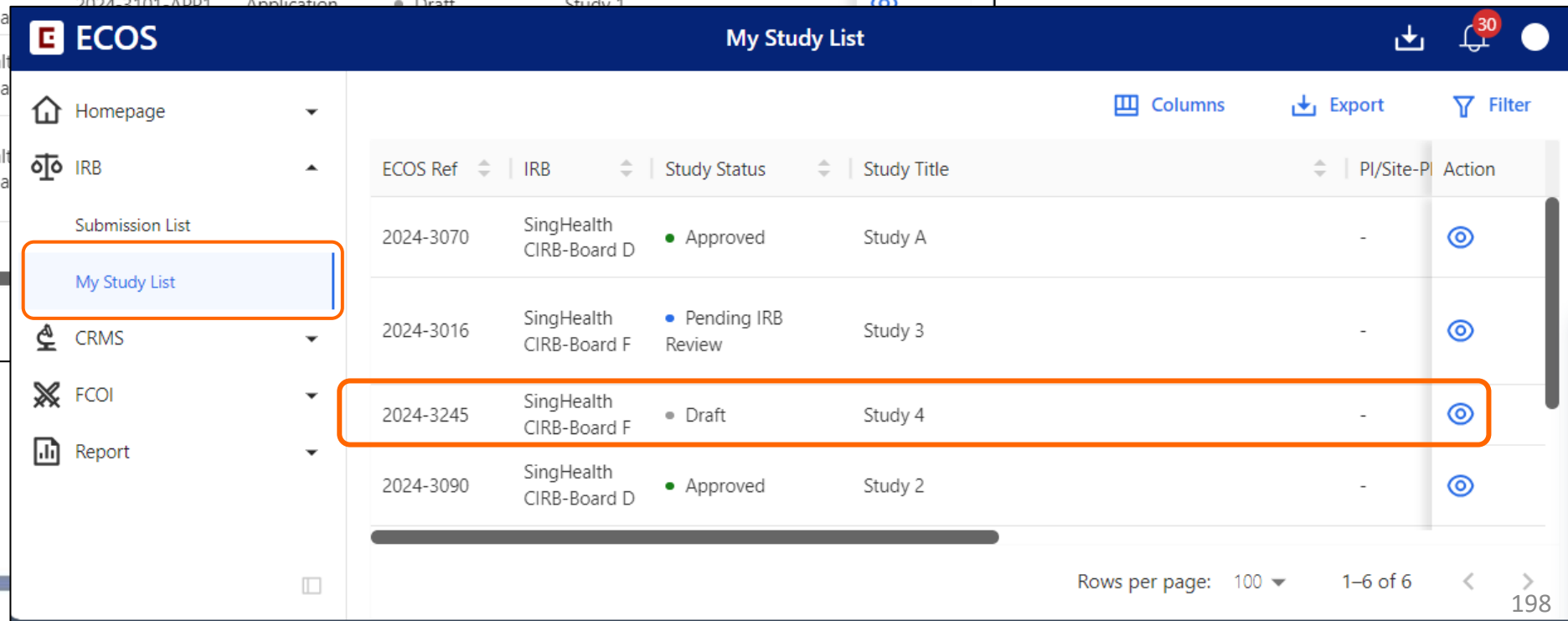
Role used: Study Sponsor



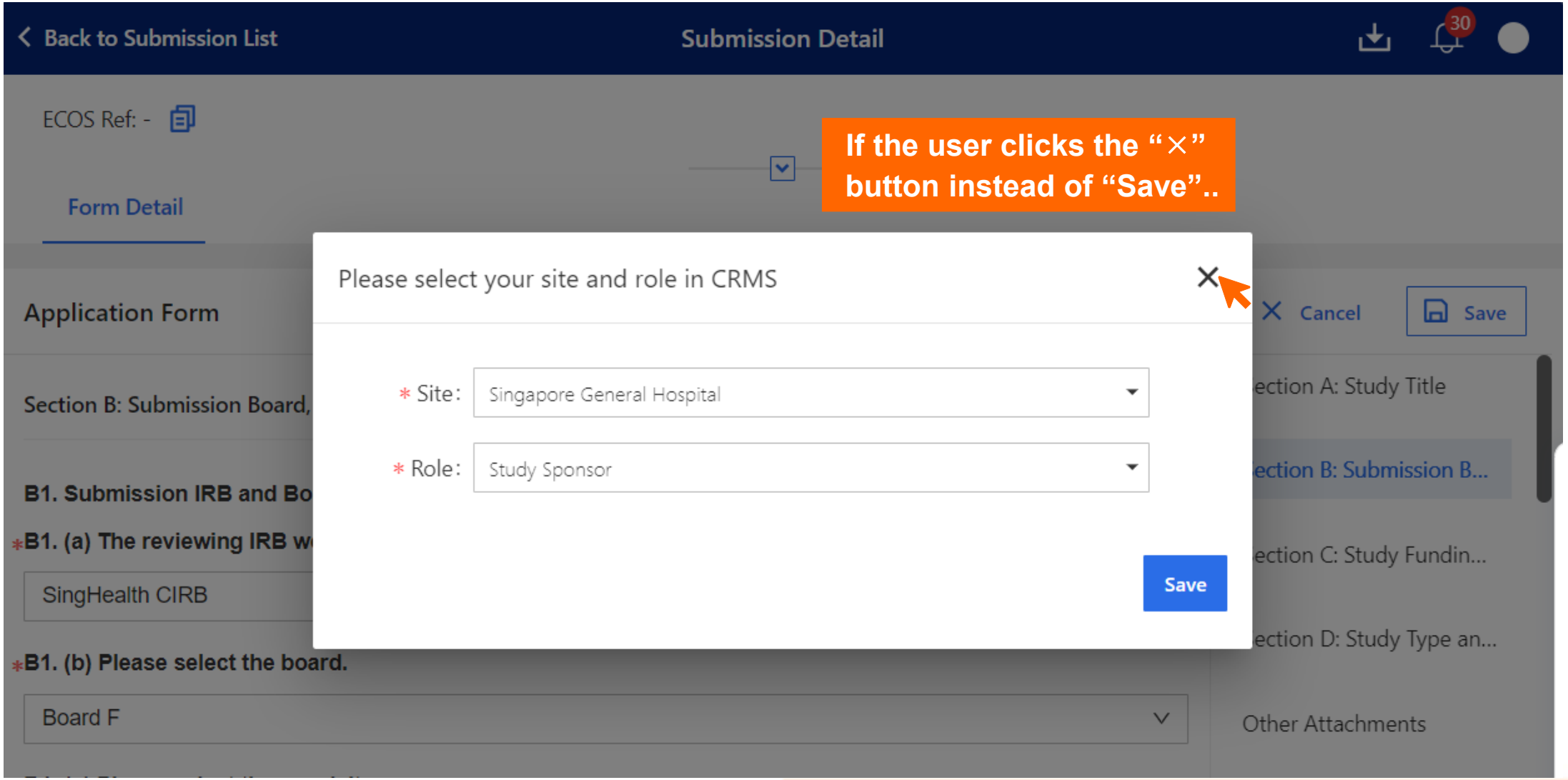
IRB Accessibility

Role used: Study Sponsor





One Chance


Back to Submission List
Submission Detail
30
ECOS Ref: -
Form Detail
If the user clicks the "×" button instead of "Save"..
Application Form
Cancel
Save
Section B: Submission Board,
B1. Submission IRB and Bo
*B1. (a) The reviewing IRB w
SingHealth CIRB
*B1. (b) Please select the board.
Board F
Please select your site and role in CRMS
* Site: Singapore General Hospital
* Role: Study Sponsor
Save
ection A: Study Title
ection B: Submission B...
ection C: Study Fundin...
ection D: Study Type an...
Other Attachments

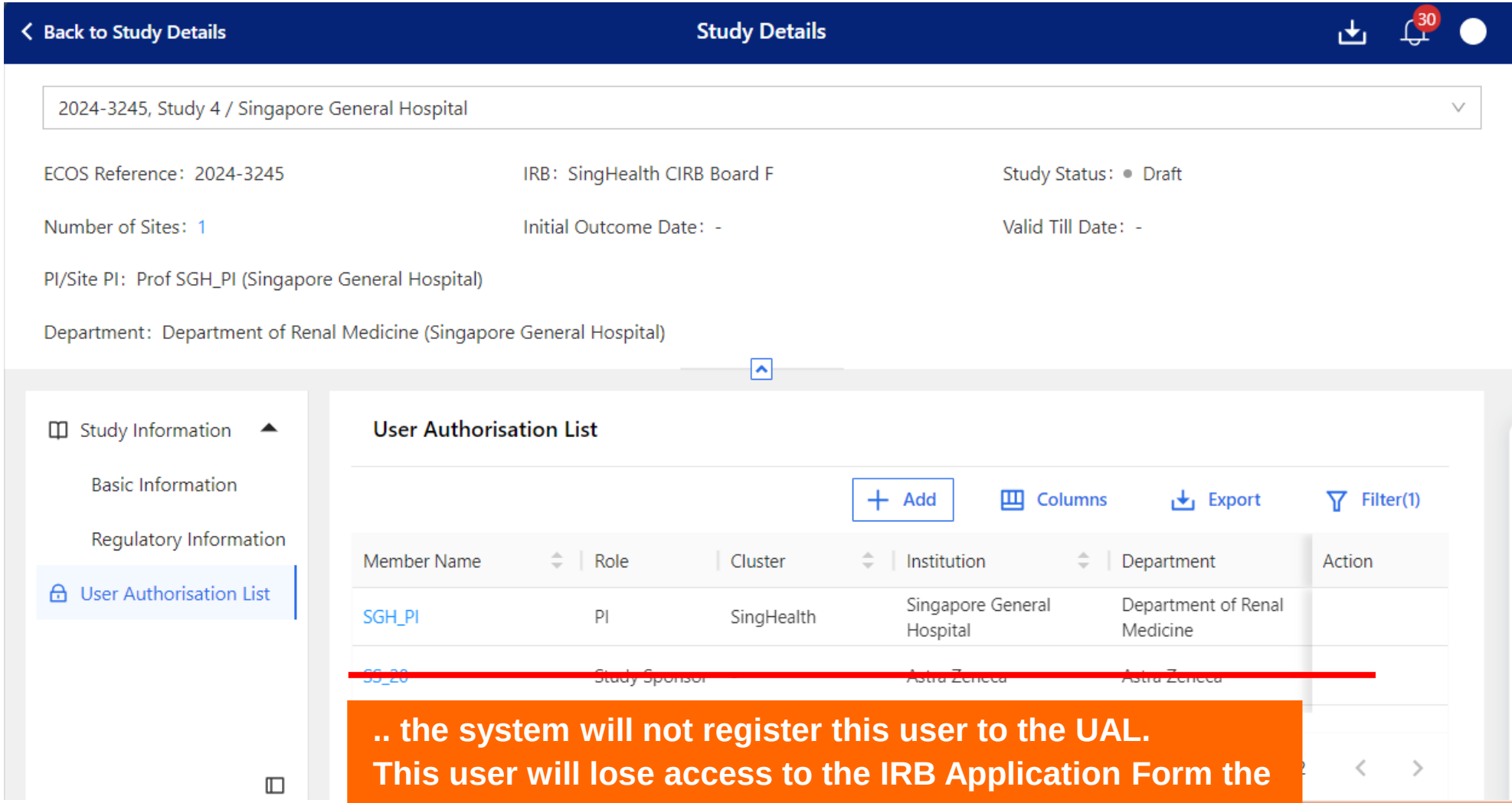
Missed Opportunity

Solution:

Enlist help from

- PI/Site-PI/Co-I **or**
- CRMS RO administrator

to manually add the user to the CRMS UAL.



.. the system will not register this user to the UAL. This user will lose access to the IRB Application Form the moment the "Save and Exit" button is clicked.

Is CRMS mandatory?

- **Mandatory:**
  1. Milestones
  2. Participant – Recruitment Numbers*
  3. Site Information*

- **Conditional**:**
  1. User Authorisation List (Access requirement by STM/SA/SS)
  2. Study Member Review (If STM/SA/SS added)
  3. Study Information – Basic Information (Pharmaceutical/ Industry sponsored studies or if CRO is engaged for Investigator-initiated studies)
  4. Study Information – Regulatory Information*

- **Optional** but highly encouraged:**
  1. Participants – Participant List, Study Configuration

NOTE:

* SingHealth CTCC will release more information.

** Each institution's Research Office may impose different requirements on each CRMS page.

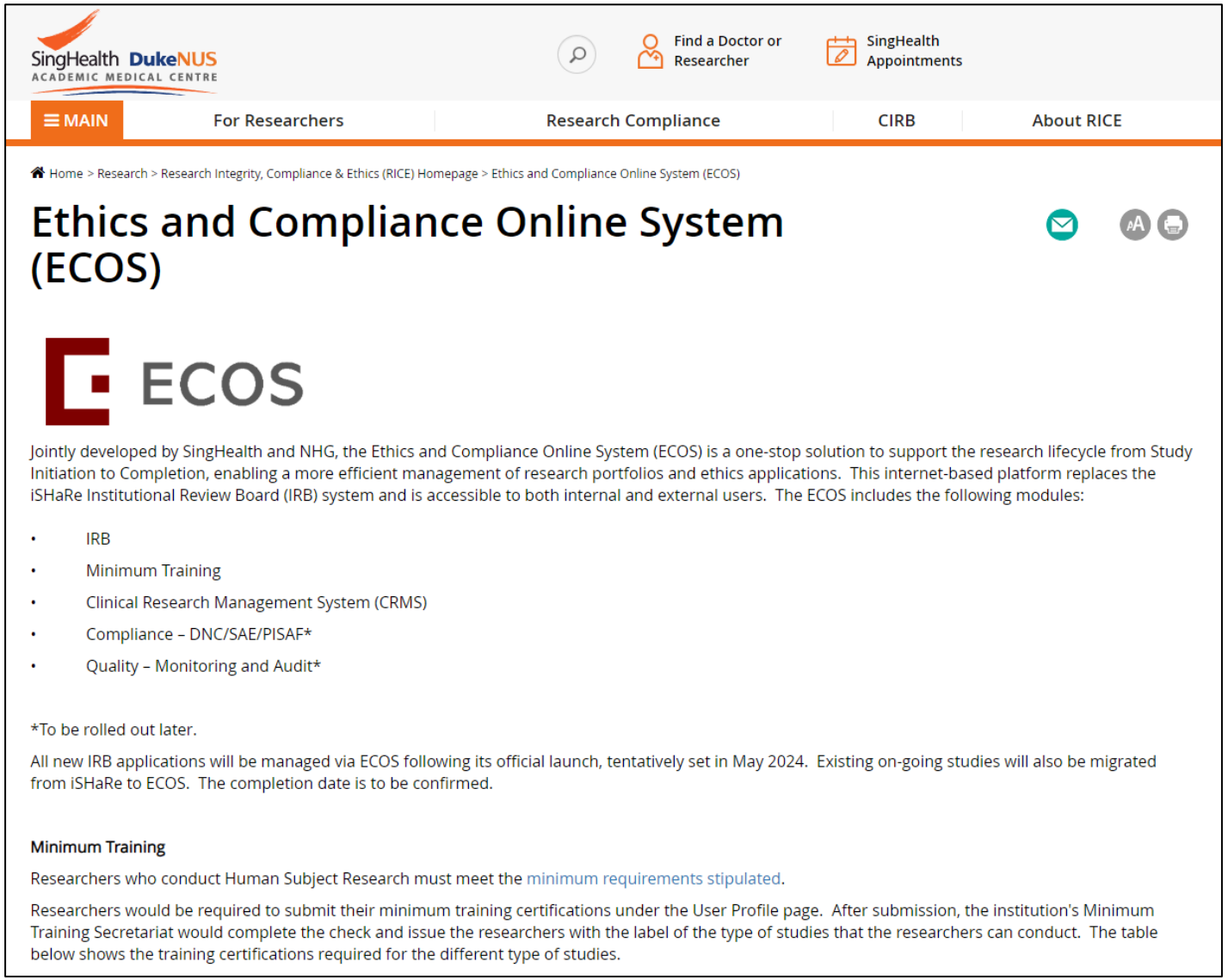
Summary

- Study Information page must be completed for Pharmaceutical/ Industry Sponsored studies to facilitate submission of IRB Application Form.
- User Authorisation List (UAL) controls user access to CRMS and/or IRB modules for STM, SA and SS roles.
- **For migrated studies, the addition of STM/SA/SS users to CRMS UAL will need to be manually done by PI/Site-PI, Co-I or CRMS RO administrators.**
- PI/Site-PI should perform the endorsement via the CRMS Study Member Review page (as needed).

! The User Authorisation List does not replace a site delegation log.

- Site Information, Milestones and Participants Recruitment Numbers pages contain important data fields that can be extracted for institutions' trending and reporting purposes.
- In conclusion, the CRMS module has great potential to be a useful clinical research management tool from the site to cluster level when fully maximised. We strongly encourage researchers/clinicians to take full advantage of this module and update the pages frequently.

Find out more information about ECOS...



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MAIN | For Researchers | Research Compliance | CIRB | About RICE

Home > Research > Research Integrity, Compliance & Ethics (RICE) Homepage > Ethics and Compliance Online System (ECOS)

Ethics and Compliance Online System (ECOS)

ECOS

Jointly developed by SingHealth and NHG, the Ethics and Compliance Online System (ECOS) is a one-stop solution to support the research lifecycle from Study Initiation to Completion, enabling a more efficient management of research portfolios and ethics applications. This internet-based platform replaces the iSHaRe Institutional Review Board (IRB) system and is accessible to both internal and external users. The ECOS includes the following modules:

- IRB
- Minimum Training
- Clinical Research Management System (CRMS)
- Compliance – DNC/SAE/PISAF*
- Quality – Monitoring and Audit*

*To be rolled out later.

All new IRB applications will be managed via ECOS following its official launch, tentatively set in May 2024. Existing on-going studies will also be migrated from iSHaRe to ECOS. The completion date is to be confirmed.

Minimum Training

Researchers who conduct Human Subject Research must meet the minimum requirements stipulated.

Researchers would be required to submit their minimum training certifications under the User Profile page. After submission, the institution's Minimum Training Secretariat would complete the check and issue the researchers with the label of the type of studies that the researchers can conduct. The table below shows the training certifications required for the different type of studies.