Navigating Ethics & Compliance Online System (ECOS) User Guide

Clinical Research Management System (CRMS) Module

(ECOS User Guide – CRMS Module , Ver 2, 21 May 24)

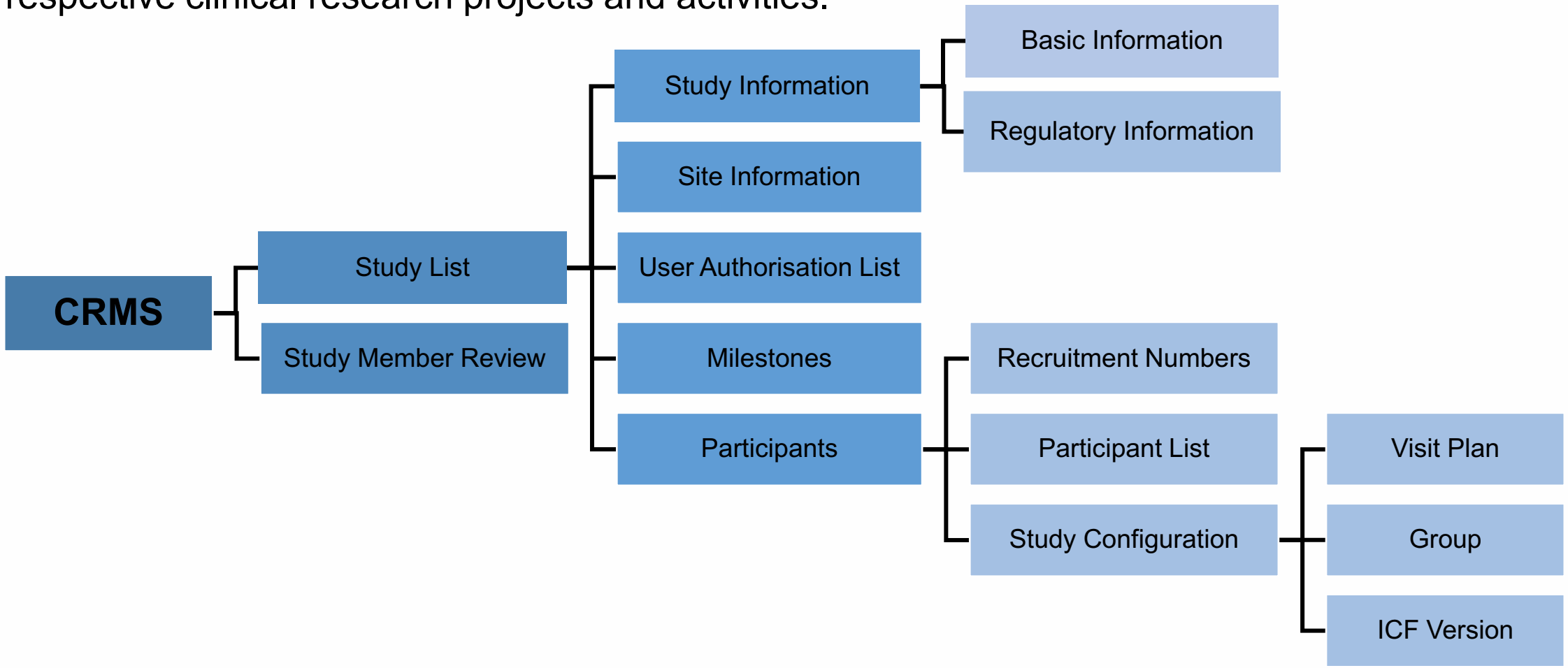
National Healthcare Group

Adding years of healthy life

Contents

Clinical Research Management System (CRMS)

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



CRMS - Overview

The use of CRMS module is optional except for these two sections.

- There are 5 main functions of CRMS:

Study Information

- Sponsor, CRO contact details
- IRB review fees billing contact details
- Regulation information (e.g. submission details)

Mandatory for **Pharmaceutical/ Industry Sponsored** study (as per **Section C1** in the IRB application form)

Site Information

- Primary & backup site coordinators
- Funding/ Grant details
- Study agreement information
- Sponsor/CRO contract
- Publications and presentations

User Authorisation List

- Study team members/ Sponsors added can draft IRB form
- 3 types of roles can be assigned (each affecting their access in CRMS): Study Sponsor, Study Administrator and Study Team Member
- PI, Site-PI and Co-I will be auto-synced from IRB App Form

Mandatory if other **non-investigator** study team members require **access to the IRB** documents and submissions

Milestones

- Project managers/Study coordinators can create & track Study Milestones (e.g. IRB approval, Study Initiation, First participant screened)

Participants

- Track recruitment numbers (by month and in total)
- Capture participants' information (e.g. Basic information, Signed ICF tracking, Visit plan)

CRMS - Overview

- CRMS module is a useful clinical research management tool at the site, study and institutional level when fully maximised.
- 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, IRB and other future modules for **Study Team Member (STM), Study Administrators (SA)** and **Study Sponsor (SS)** roles.
- Site Information, Milestones and Participants Recruitment Numbers pages contain important data fields that can be used for study management, institution's trending and reporting purposes.

User Access

- Different user roles will have different levels of access to CRMS.

- Once a user has been added in the initial IRB **Application** Form or CRMS User Authorisation List, the user will gain immediate access to a limited number of pages, i.e. limited access.

- The newly added users will then require IRB's approval or PI's endorsement in CRMS to gain full access to CRMS.

  Exception: Institutional Research Office administrators assigned with the CRMS role will have full access upon role assignment by the CRMS Module Admin (from NHG).

- PI will only be able to endorse newly added users after IRB has provided approval for the initial IRB **Application** Form .

- For new investigators (i.e. PI, Site-PI, Co-I) added in the IRB **Amendment** Forms, full CRMS access will be granted after IRB has provided approval. New investigators pending IRB approval will not have any access to the CRMS.

User Access Matrix

IRB Application Form

CRMS Sections/ Pages	Roles					
	PI/ Site-PI	Co-I	STM	SA	SS	CRMS RO
Study Information	✓	✓	✓	✓	✓	✓
User Authorisation List	✓	✓	✓	✓	✓	✓
Site Information	✓	✓	✓	✓		✓
Milestones	✓	✓	✓	✓		✓
Participants	✓	✓	✓	✓		✓
Participants – Study Configuration	✓	✓	✓	✓		
Study Member Review	✓					

Legend

✓ Access (View & Edit) granted upon the addition of user in the IRB Application 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 or endorsement 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**: Research Office administrator assigned with CRMS role.*

User Access Matrix

IRB Amendment Form

CRMS Sections/ Pages	Roles					
	PI/ Site-PI	Co-I	STM	SA	SS	CRMS RO
Study Information	✓	✓	✓	✓	✓	✓
User Authorisation List	✓	✓	✓	✓	✓	✓
Site Information	✓	✓	✓	✓		✓
Milestones	✓	✓	✓	✓		✓
Participants	✓	✓	✓	✓		✓
Participants – Study Configuration	✓	✓	✓	✓		
Study Member Review	✓					

Legend

✓ Access (View & Edit) granted upon the addition of 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 or endorsement 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**: Research Office 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

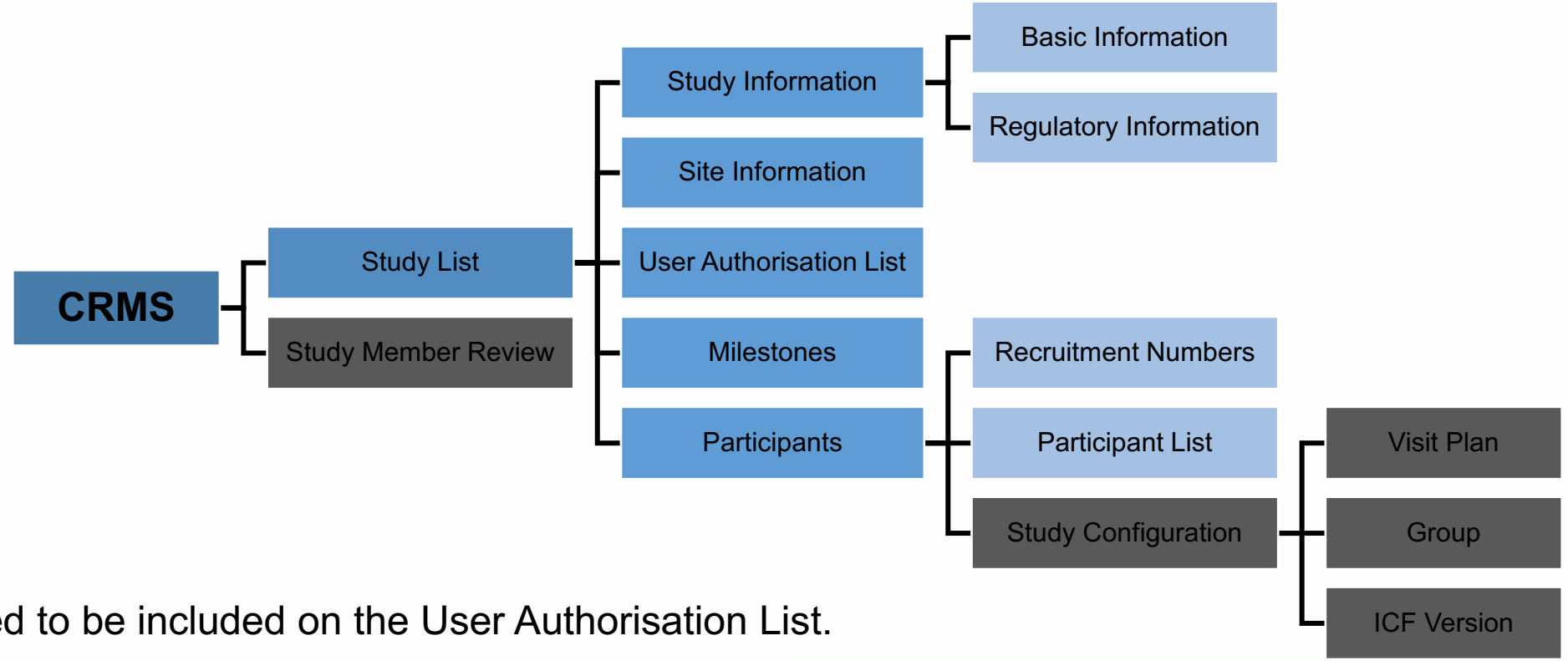
Information entered will be shared across all participating sites. E.g. data entered by 1 site will be seen by all sites. Similarly, data revision made by 1 site will also be seen by the other sites.

Site Level

Information entered are 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 Role – Research Office Administrators

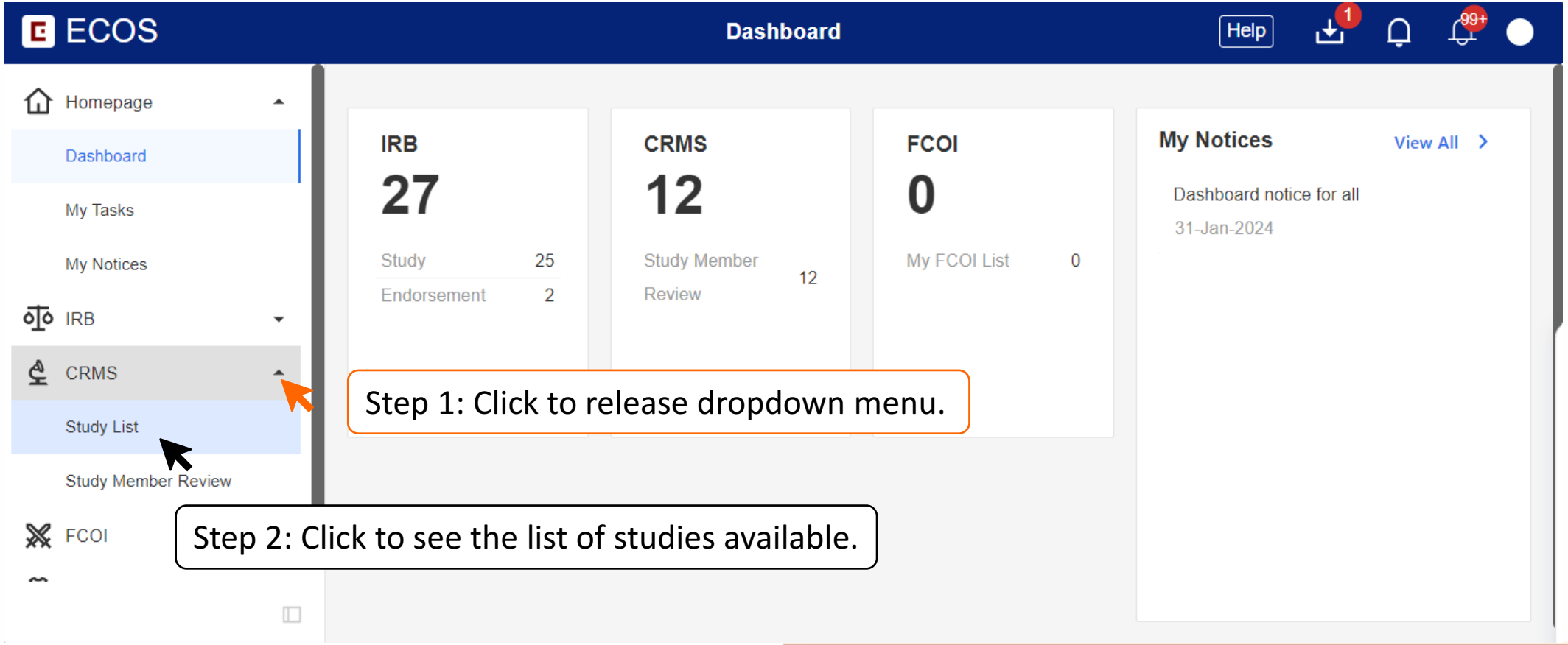
- Research Office Administrators will have View & Edit access to CRMS module.
  - Authority is Institution-specific.
  - Able to access to CRMS **Study Level** and **Site Level** pages.
  - No access to Study Member Review and Study Configuration pages.



- No need to be included on the User Authorisation List.

CRMS Access

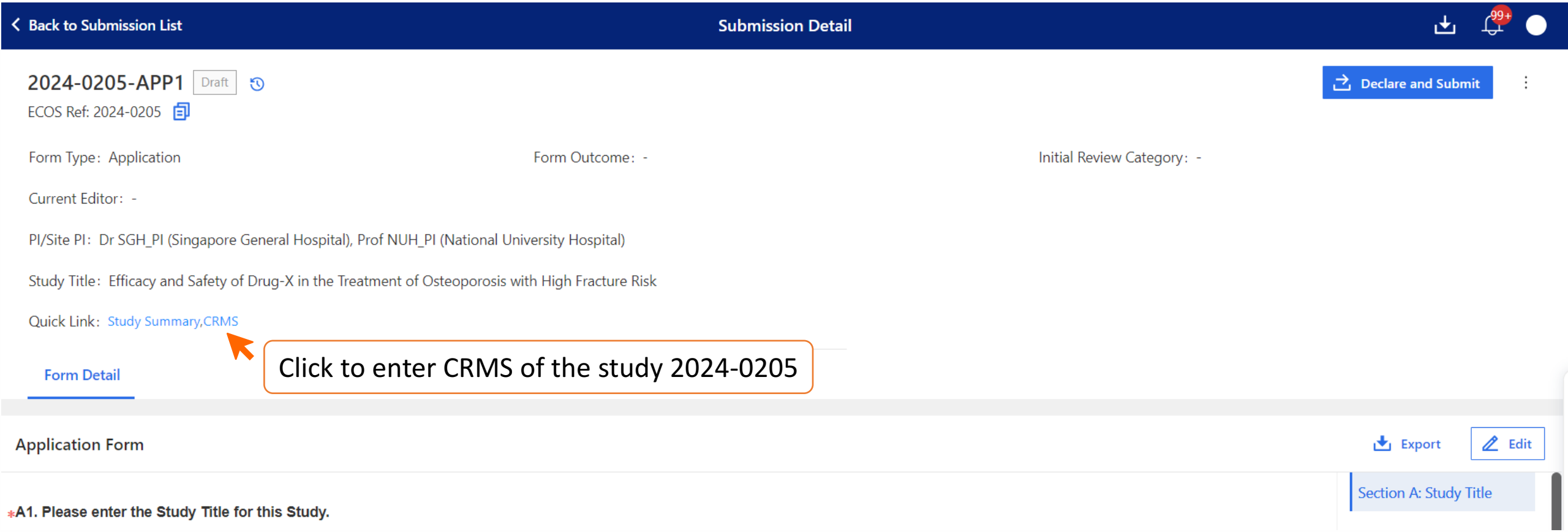
- There are 2 ways to access CRMS:
  1. Via ECOS Navigation Menu > CRMS



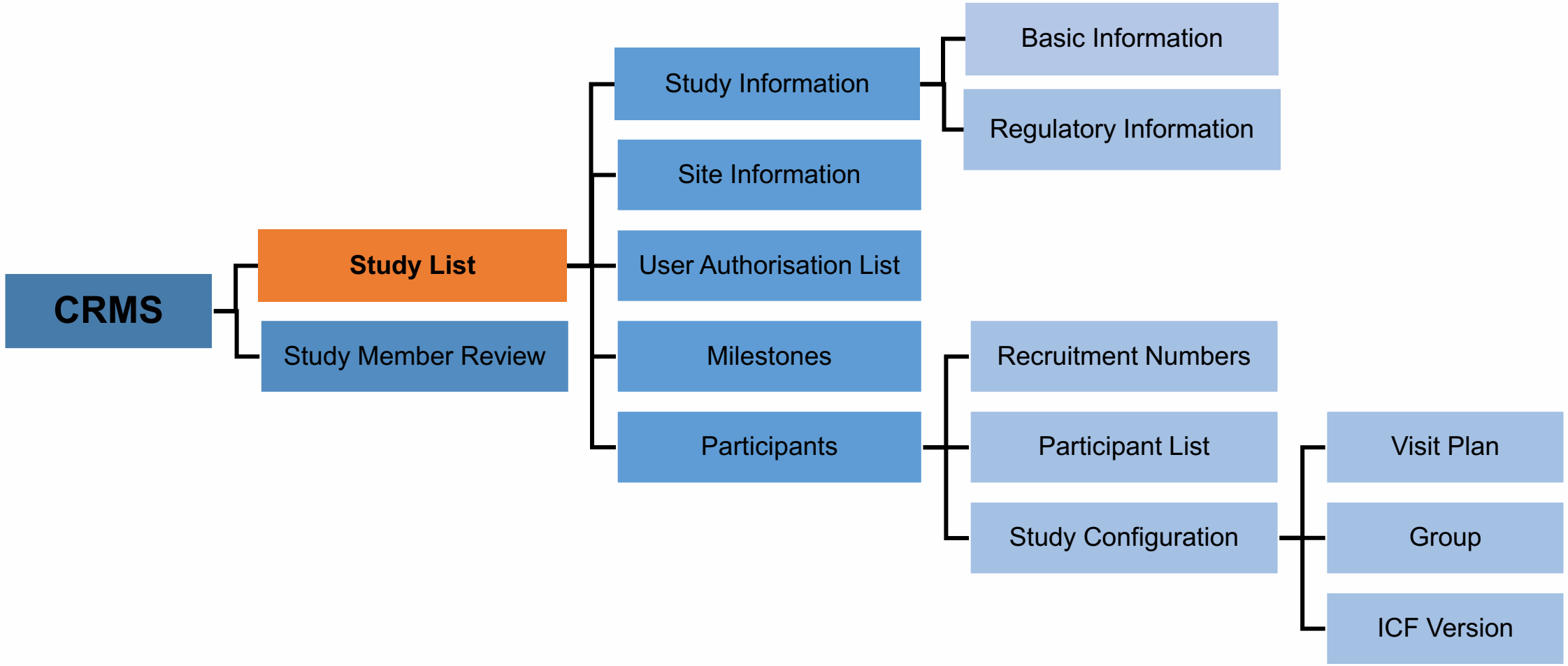
CRMS Access

This option may be made available in Q3 2024.

- There are 2 ways to access CRMS:
  2. Within the IRB Application or Amendment Form > Quick Link: CRMS



CRMS Sitemap



Study List

- The Study List will only display the studies where a user has been added into the IRB forms or User Authorisation List.
  - Exception: CRMS RO administrators will be able to see the full list of institution studies.
- 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, which are:
  - Study details (e.g. study title, study sites, etc.) to the Study List.
  - List of Investigators added in IRB form to User Authorisation List.
- Synchronisation points:
  - Upon saving the IRB Application Form.
  - Upon IRB approval or acknowledgement.

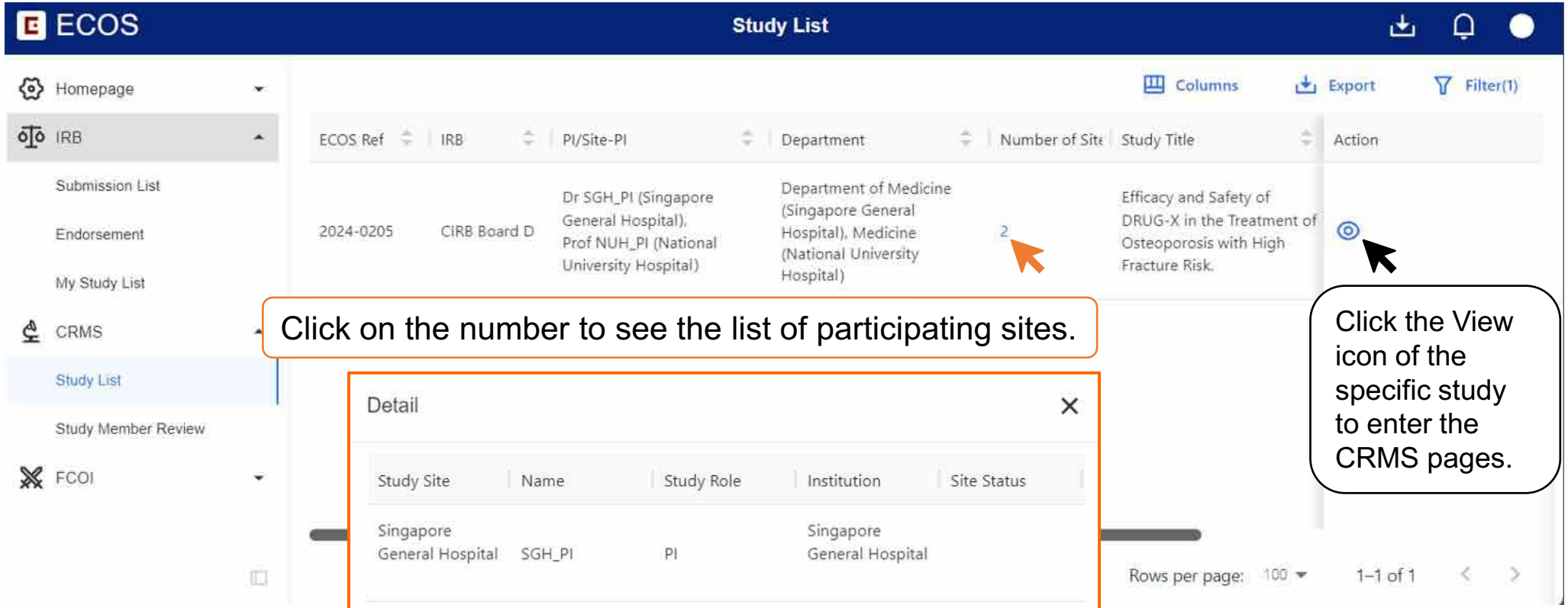
NOTE: No information will flow from CRMS to IRB module.

Study List

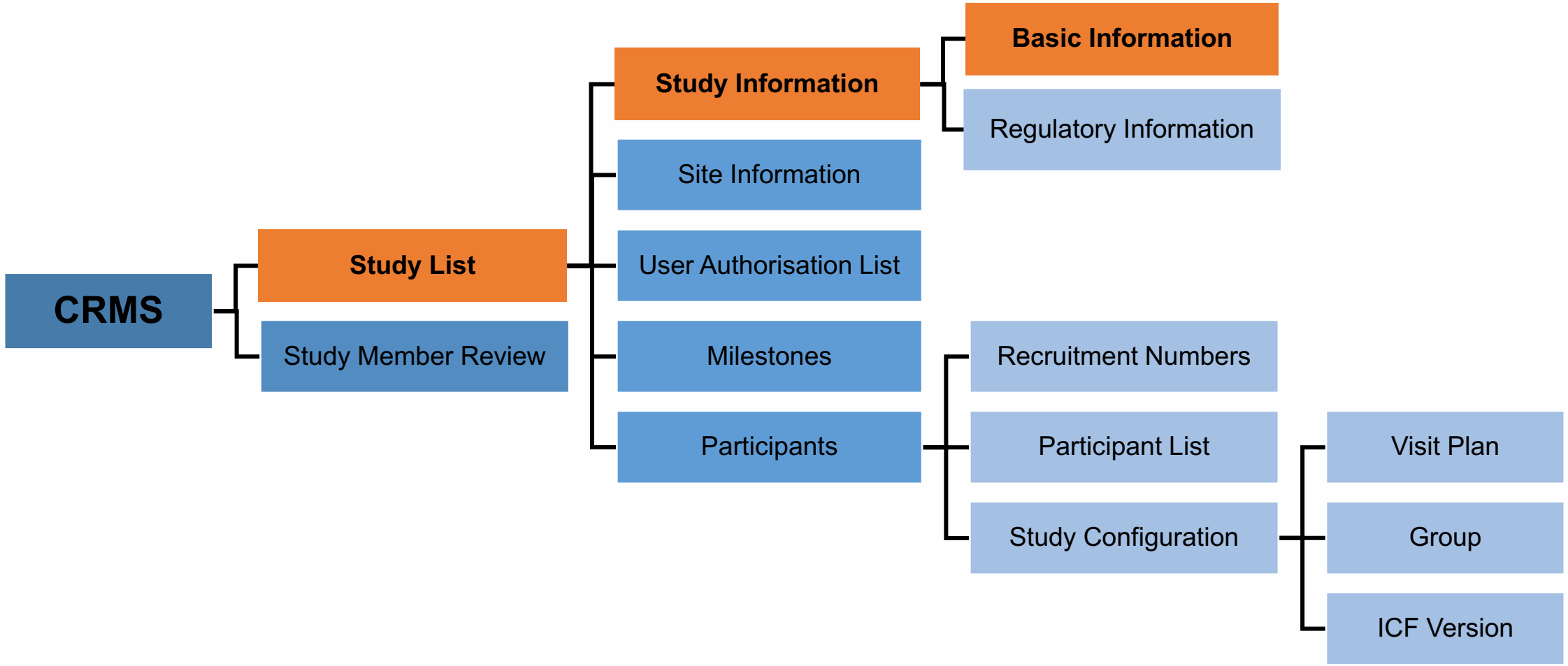
Below is an example of the Study List of a user.

Data Columns

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



CRMS Sitemap



Study Information – Basic Information

Study Level

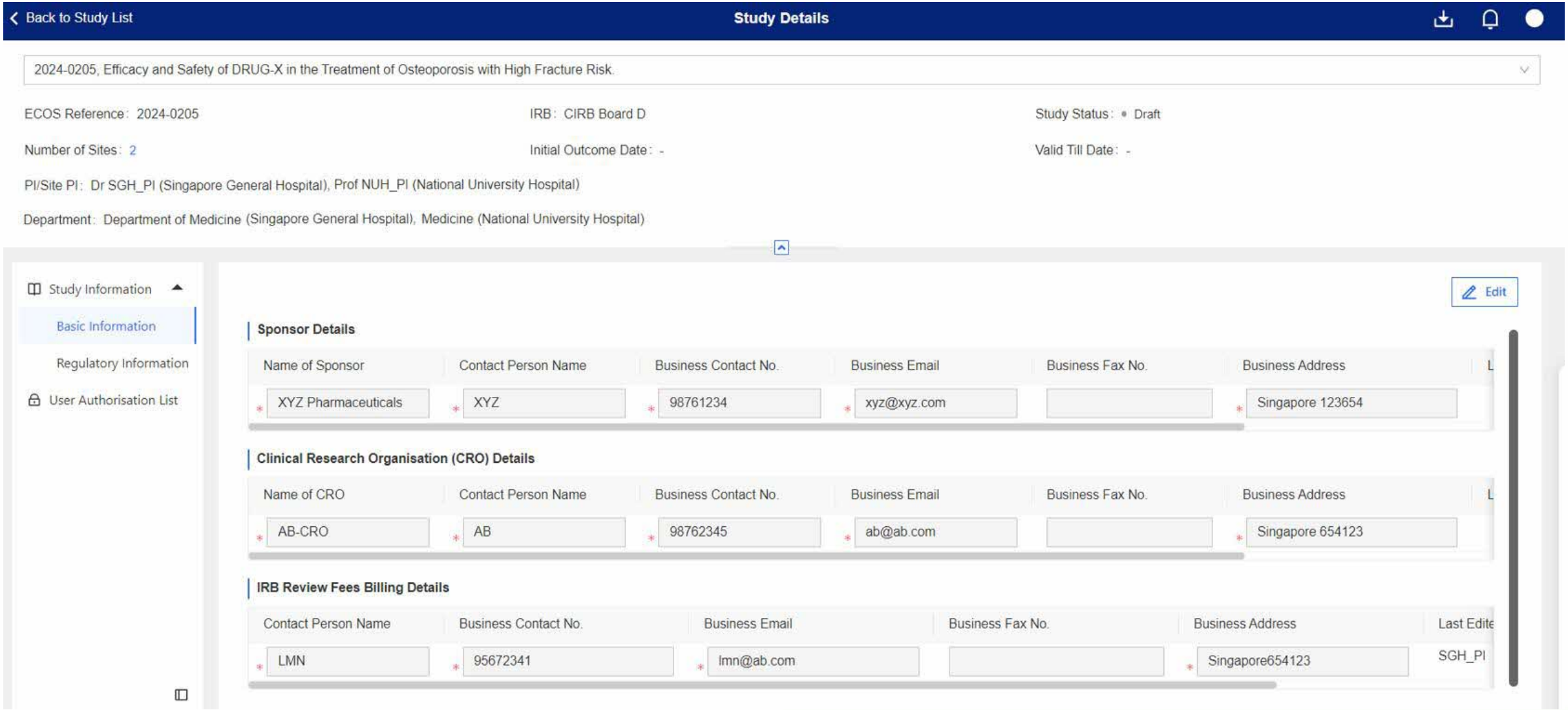
- On ECOS, **Sponsor/CRO and IRB billing details** will be entered on the Basic Information page in CRMS instead of the IRB Application/Amendment Form.

- 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.

- Subsequent changes to Sponsor/CRO and IRB billing details can be done via CRMS without submitting an IRB Amendment form.

Study Information – Basic Information

Study Level



Study Information – Basic Information

Study Level

Below are the data fields found on this page:

Sponsor Details

- Name of Sponsor
- Contact Person Name
- Business Contact No.
- Business Email
- Business Fax No.
- Business Address

Clinical Research Organisation (CRO) Details

- Name of CRO
- Contact Person Name
- Business Contact No.
- Business Email
- Business Fax No.

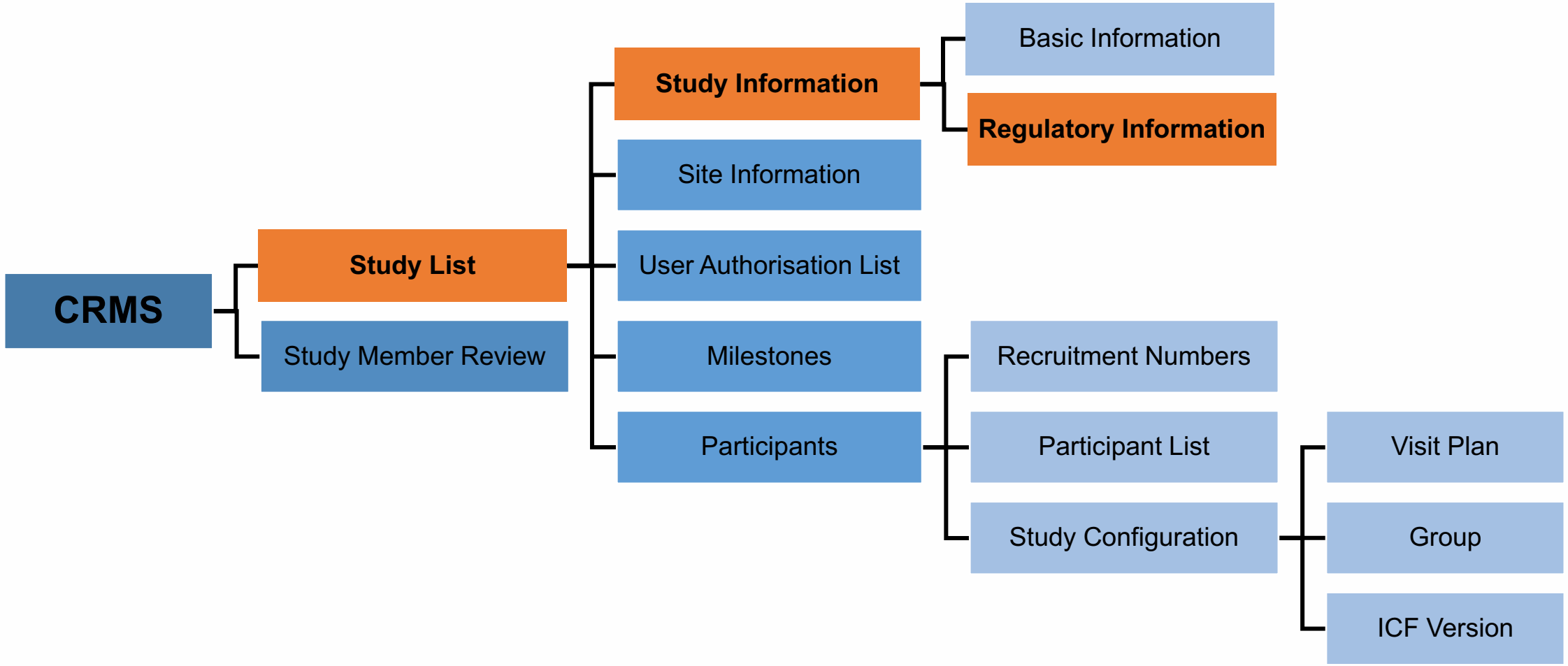
IRB Review Fees Billing Details

- Contact Person Name
- Business Contact No.
- Business Email
- Business Fax No.
- Business Address

Note:

- If a CRO is engaged for an Investigator-initiated study, CRO Details should be completed.
- 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.

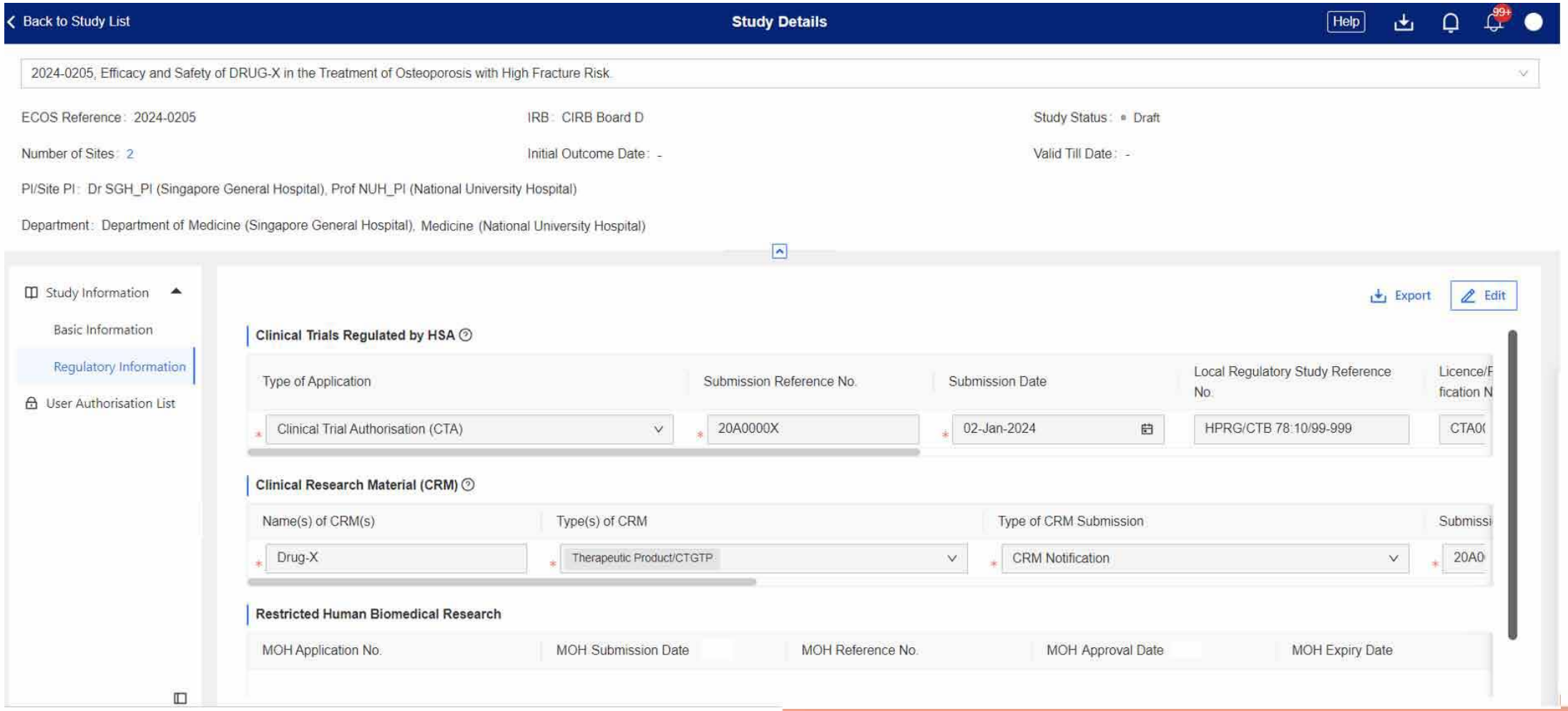
CRMS Sitemap



Study Information – Regulatory Information

Study Level

- Regulatory Information page allows user to document the HSA and/or MOH submission(s) and approval(s).



Study Information – Regulatory Information

Study Level

- Below are the data fields found on this page:

Clinical Trials Regulated by HSA

- Type of Application *(Drop-down list)*
  - Clinical Trial Certificate (CTC)
  - Clinical Trial Authorisation (CTA)
  - Clinical Trial Notification (CTN)
  - Substantial Amendments
  - Safety Report
  - Serious Breach
  - Urgent Safety Measures
  - Trial Status Report
  - Clinical Study Report Submission
  - Other Submissions

- Submission Reference No.
- Submission Date
- Local Regulatory Study Reference No.
- License/ Permit/ Certificate/ Listing/ Notification No.
- Approval/ Acceptance Date
- Remarks

ℹ A HSA application for a study involving multiple sites should be entered as one entry.

Study Information – Regulatory Information

Study Level

- Below are the data fields found on this page:

Clinical Research Materials (CRM)

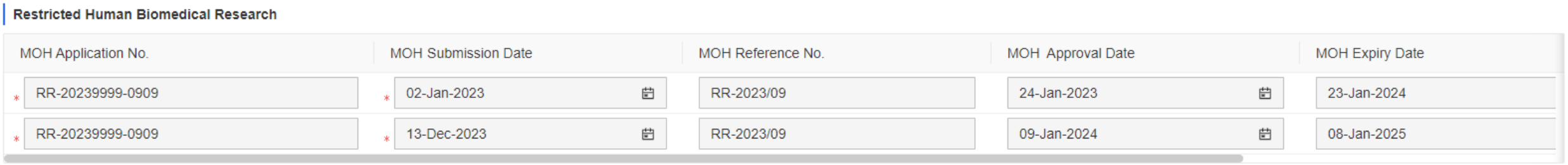
- Name(s) of CRM(s)
- Type(s) of CRM *(Multi-select)*
  - Therapeutic Product/ CTGTP
  - Medicinal Product
  - Medical Device
- Type of CRM Submission *(Drop-down list)*
  - CRM Notification
  - Product Defect and Recall Report
  - Other Submissions
- Submission Reference No.
- Submission Date
- Notification No.
- Notification Date
- Expiry Date (if applicable)
- Remarks

ℹ Each entry should match the CRM Notification sent to HSA. For CRM Notification with multiple CRMs, please include all CRMs into one entry. More than one type of CRM can be selected.

Study Information – Regulatory Information

Study Level

- Below are the data fields found on this page:



Restricted Human Biomedical Research

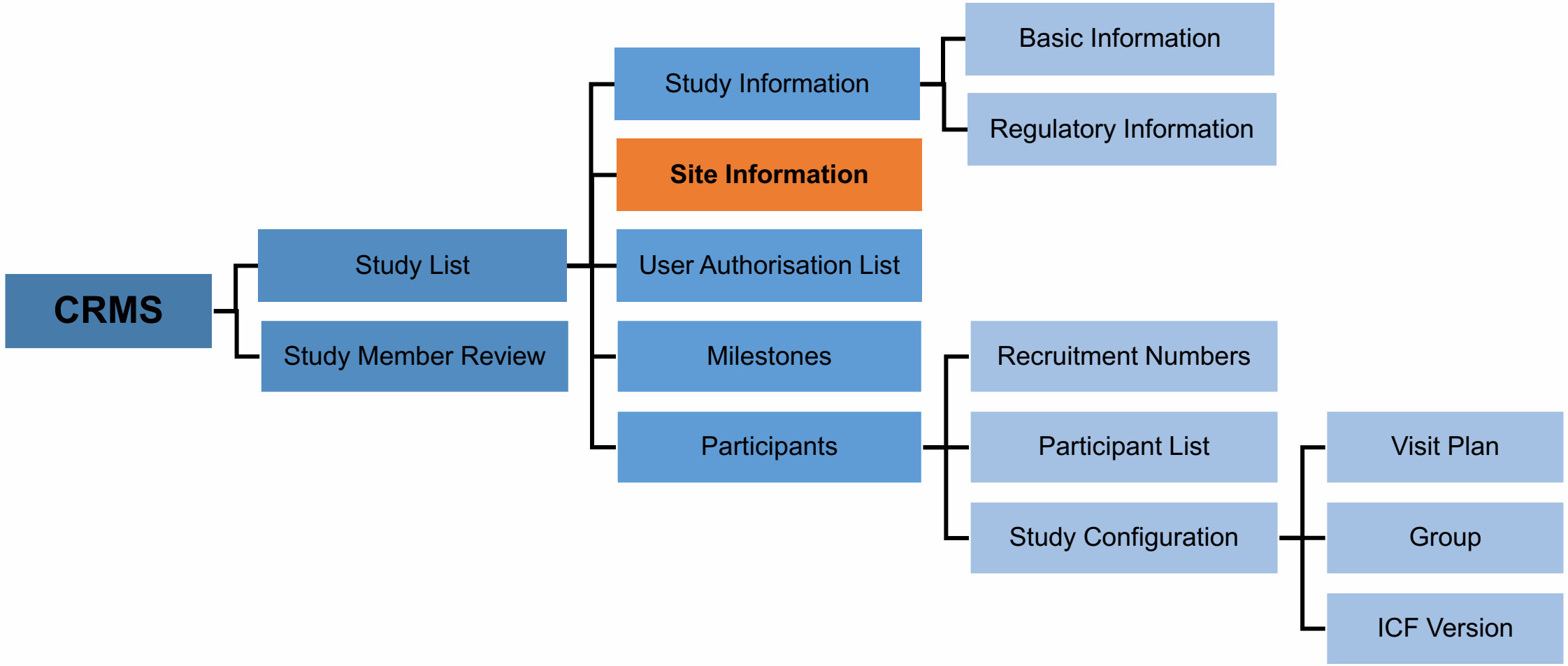
MOH Application No.	MOH Submission Date	MOH Reference No.	MOH Approval Date	MOH Expiry Date
* RR-20239999-0909	* 02-Jan-2023	RR-2023/09	24-Jan-2023	23-Jan-2024
* RR-20239999-0909	* 13-Dec-2023	RR-2023/09	09-Jan-2024	08-Jan-2025

Restricted Human Biomedical Research (rHBR)

- MOH Application No.
- MOH Submission Date
- MOH Reference No.
- MOH Approval Date
- MOH Expiry Date

ℹ The initial approval and subsequent renewal approval(s) should be entered as separate entries.

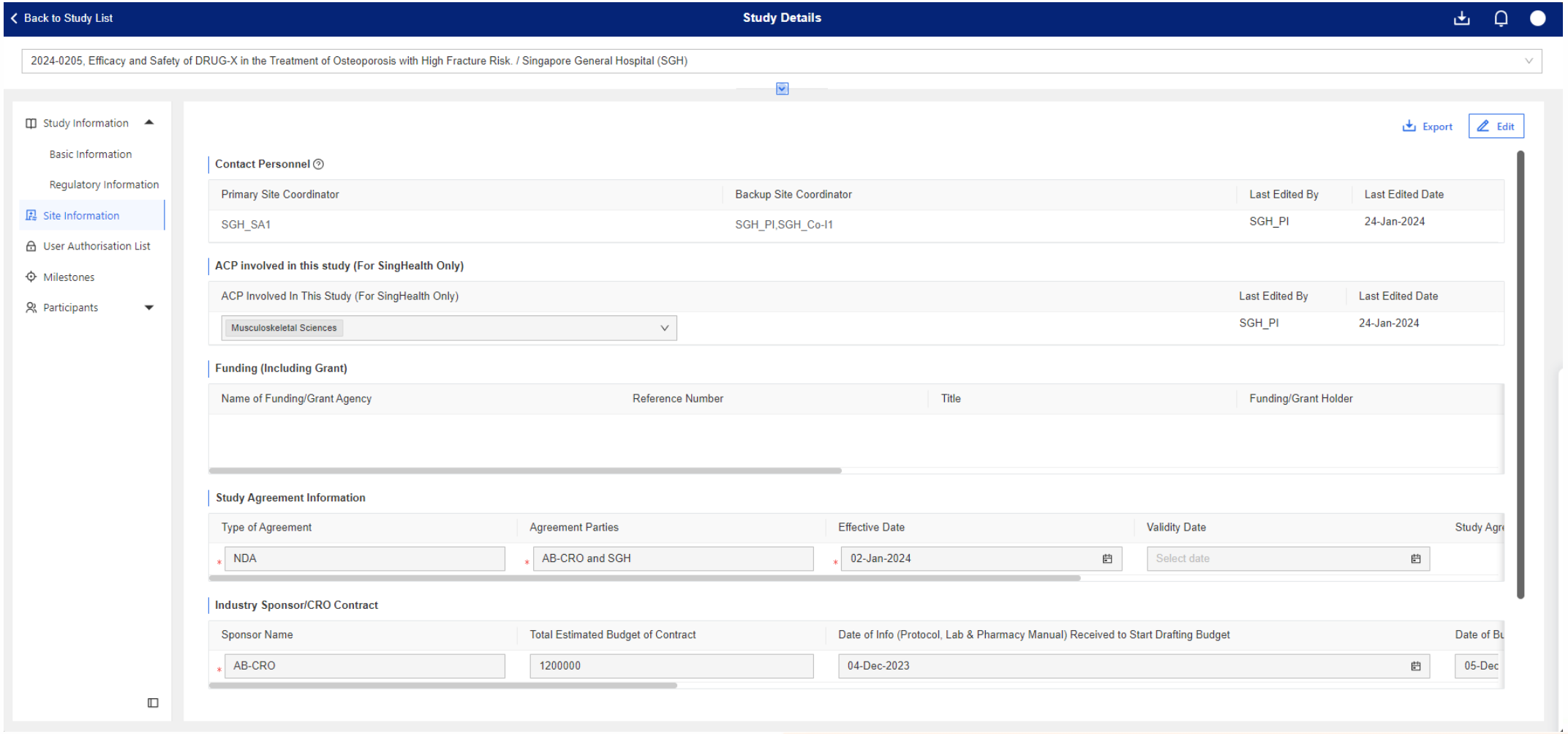
CRMS Sitemap



Site Information

Site Level

- To record and track site contact details, fundings, contracts/agreements, publications and presentations.



Site Information

Site Level

Below are the data fields found on this page:

Contact Personnel

- Primary Site Coordinator
- Backup Site Coordinator *(Multi-select)*

ℹ The Primary and Back-up Site Coordinators are the key contact personnel for the study-related matters.

Academic Clinical Programme (ACP) involved in the study *(For SingHealth only)*

(Multi-select)

- Anaesthesiology and Perioperative Sciences
- Cardiovascular Sciences
- Emergency Medicine
- Family Medicine
- Medicine
- Musculoskeletal Sciences
- Neuroscience
- Obstetrics and Gynaecology
- Oncology
- Ophthalmology and Visual Sciences
- Oral Health
- Paediatrics
- Pathology
- Radiological Sciences
- Surgery

Site Information

Site Level

Below are the data fields found on this page:

Funding (Including Grant)

- Name of Funding/ Grant Agency
- Reference No.
- Title
- Funding/Grant Holder
- Funding/Grant Amount
- Funding/Grant Duration
- Funding/Grant Award Letter *(Upload feature)* Upload

ℹ Please indicate the financial source(s) that funds the study.

- For Investigator-initiated studies, list the grant(s) and cash contribution from industry collaborators, if any.
- For Industry-sponsored studies, complete the 'Industry Sponsor/CRO Contract' section. If there are additional funding from a grant agency e.g. IAF-ICP, please provide the grant details in this section. Otherwise, please leave this section blank.

Study Agreement Information

- Type of Agreement
- Agreement Parties
- Effective Date
- Validity Date
- Study Agreement File Upload

ℹ Please indicate Non-Disclosure Agreements (NDA) and Research Collaboration Agreements (RCA) in this section.

- For Clinical Trial Agreement (CTA), please input details in the 'Industry Sponsor/CRO Contract' section.

Site Information

Site Level

Below are the data fields found on this page:

Industry Sponsor/ CRO Contract

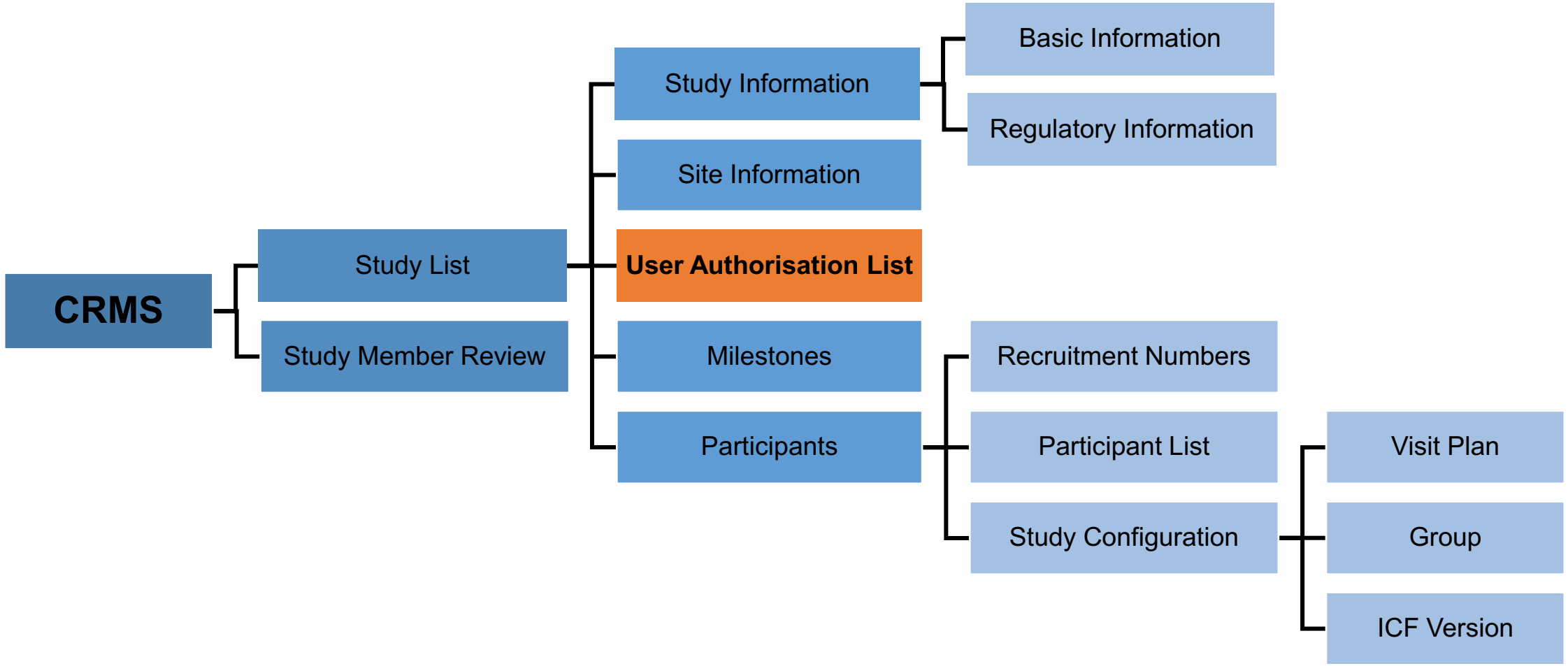
- Sponsor/CRO Name
- Total Estimated Budget of Contract
- Date of Information Received To Start Drafting Budget
- Date of Budget First Sent to Sponsor/CRO
- Date of Budget Finalisation/ Agreement
- Date of Contract Template Received From Sponsor/CRO
- Date of Contract Finalisation/ Agreement By All Parties
- Will The Sponsor/CRO Be Providing Monitoring *(Drop-down list)*
  - Yes
  - No

ℹ This section is for Industry-Sponsored studies only. Please provide details of the Clinical Trial Agreement (CTA) with an Industry Sponsor or CRO.

Publication and Presentations

- Type *(Drop-down list)*
  - Publication
  - Presentation
- Publication/ Presentation Title
- Local/ Overseas *(Drop-down list)*
  - Local
  - Overseas
- Date

CRMS Sitemap



User Authorisation List (UAL)

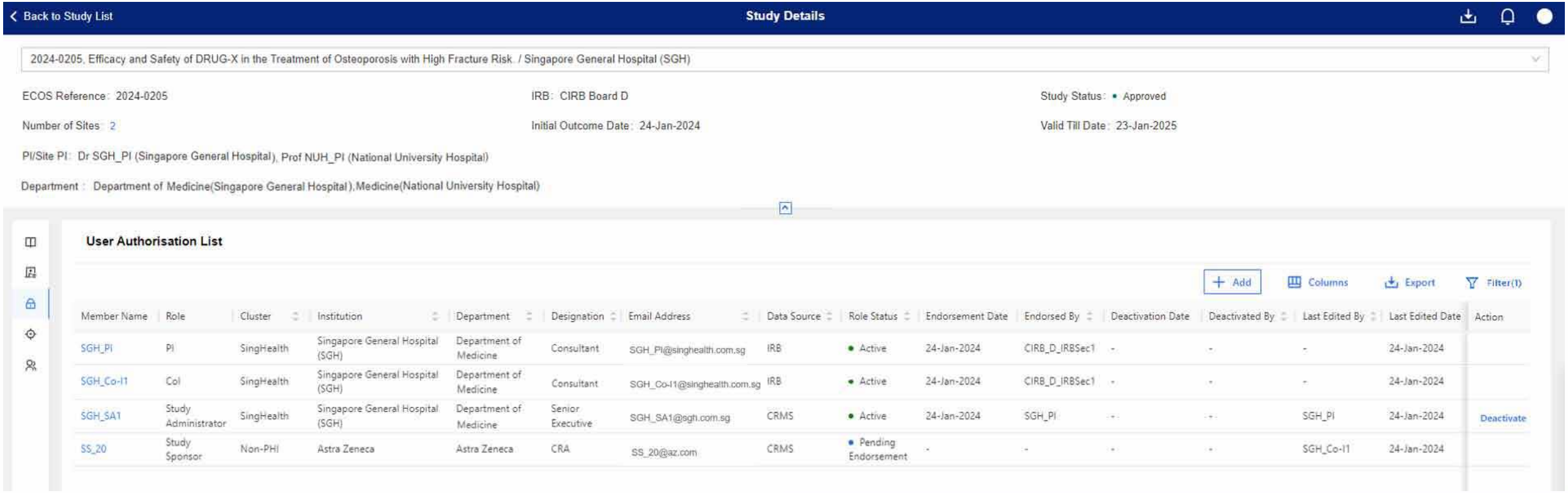
- The UAL primarily functions to manage the access of **STM**, **SA** and **SS** to the CRMS and IRB modules in ECOS.
- This is one of the harmonised processes between CIRB and DSRB where non-investigators (study team members and administrators) will no longer require IRB's approval.
- Only the PI's endorsement in CRMS is required to grant full page access to the SA/STM/SS roles. Refer to Page 56 – 63 on Study Member Review for step-by-step guide to endorse SA/ STM/ SS.
- PI will only be able to endorse newly added users after IRB has provided approval for the initial IRB Application Form .
- Refer to Page 111 – 118 on step-by-step guide to add or deactivate users in the UAL.

Access to CRMS (limited) and IRB modules, after a STM/SA/SS has been added but pending PI endorsement, will allow the new user to immediately perform data entry, submission and reporting work.

User Authorisation List (UAL)

Site Level

- PI/Site-PI, Co-I, Study Team Members (STM), Study Administrators (SA) and Study Sponsor (SS) roles will be listed here.
- Only user access to CRMS and IRB modules for STM, SA and SS roles can be managed here. User access for PI/Site-PI and Co-I will be managed via the IRB module.



User Authorisation List (UAL)

Site Level

Below are the data columns found on this page:

User Authorisation List

- Member Name
- Role
- Cluster
- Institution
- Department
- Designation
- Email Address
- Data Source
- Role Status
- Endorsement Date
- Endorsed By
- Deactivation Date
- Deactivated By
- Last Edited By
- Last Edited Date

User Authorisation List (UAL)

Site Level

Role	CRMS Access Rights	Comments
PI, Site PI & Co-I Site investigators **directly involved** in the research.	• View & edit rights. **User added in IRB Application Form** • Limited page access before IRB approval. ✓ Study Information ✓ UAL • Full page access after IRB approval. + Site Information + Milestones + Participants **User added in IRB Amendment Form** • No page access before IRB approval. • Full page access after IRB approval. ✓ Study Information ✓ UAL ✓ Site Information ✓ Milestones ✓ Participants	**Access management:** • PI, Site PI and Co-I are to be added in Section B2(a) 'Investigator List' of the IRB application or amendment form. • List of investigators will be imported from IRB to CRMS module at each synchronisation points (as applicable) with IRB indicated as the data source. • IRB approval is required to gain full CRMS access. • Further 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.

User Authorisation List (UAL)

Site Level

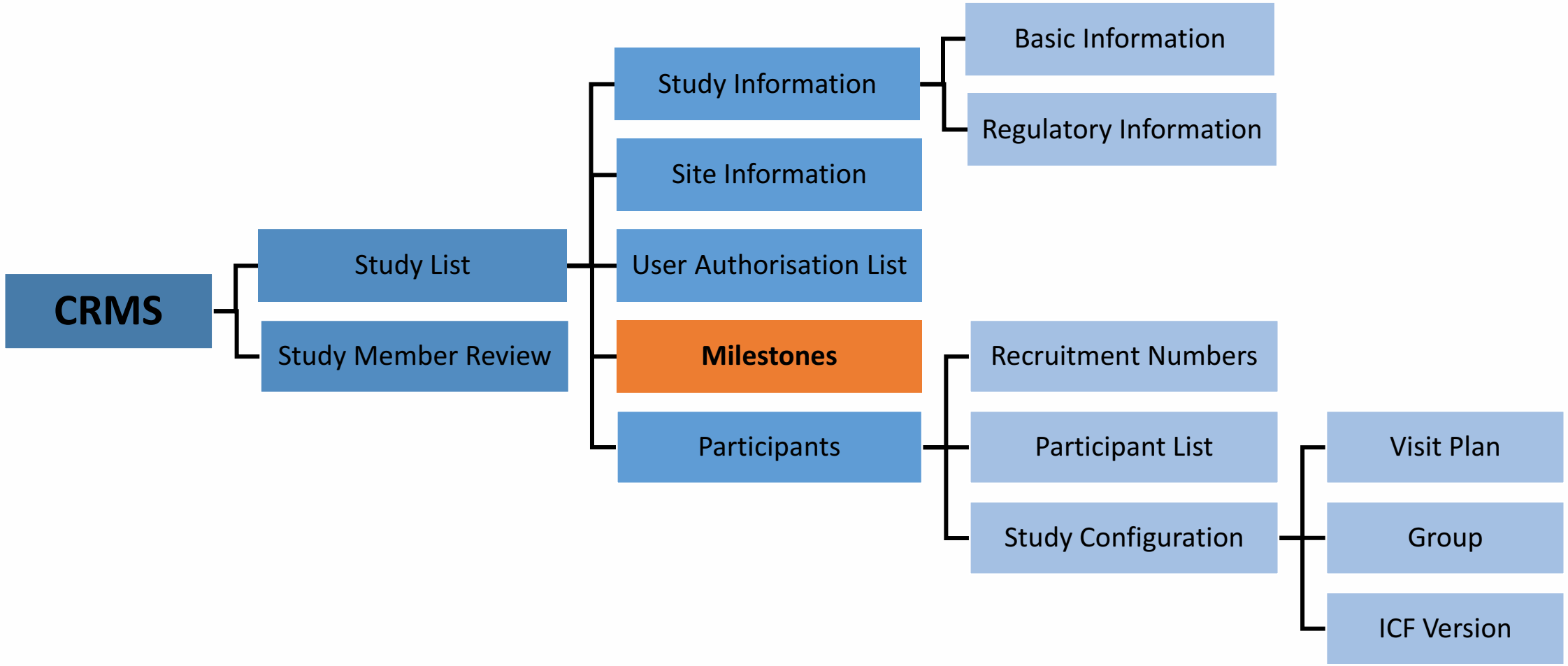
Role	CRMS Access Rights	Comments
Study Team Member (STM) Site personnel **directly involved** in the research conduct e.g. CRCs, Study Nurses, Pharmacists, etc.	• View & edit rights. • Limited page access before PI's endorsement in CRMS. ✓ Study Information ✓ UAL • Full page access after PI's endorsement in CRMS. + Site Information + Milestones + Participants	**Access management:** • STM, SA and SS are to be added via the UAL in the CRMS module, where the data source 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 into 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 access to IRB and CRMS modules to be revoked.
Study Administrator (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.		
Study Sponsor (SS) Sponsor/CRO personnel, e.g. CTAs, CRAs, CTMs etc.	• View & edit rights. • Limited page access only. ✓ Study Information ✓ UAL	

User Authorisation List (UAL)

The User Authorisation List does not replace the Site Delegation Log.

- The 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 (HBR ERC Trainings, CITI Biomed, GCP, etc.).

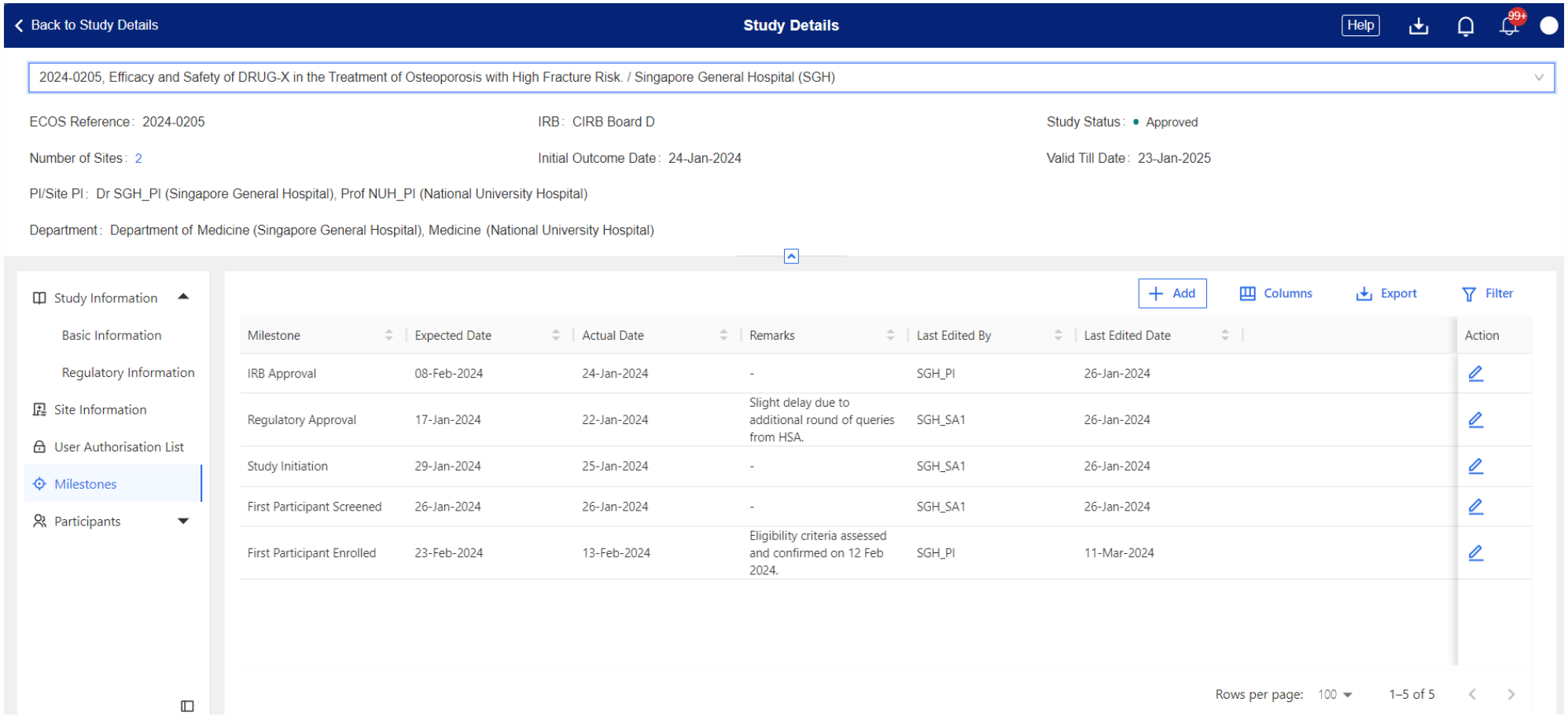
CRMS Sitemap



Milestones

Site Level

- To track significant milestones achieved in a study.
- Provides a bird's-eye view of the study progress.



Milestones

Site Level

Below are the data fields found on this page:

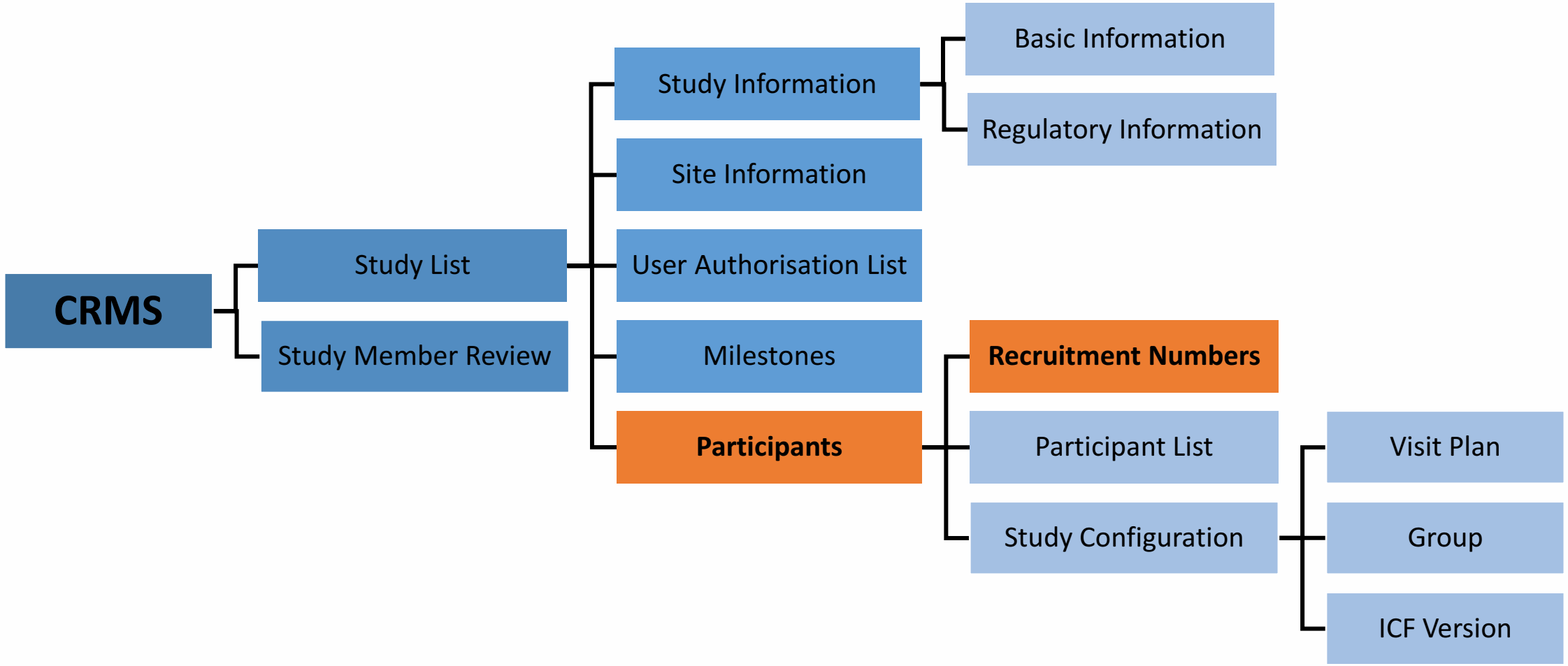
Milestones

- Milestone *(Drop-down list)*
  - IRB Approval
  - Regulatory Approval
  - Grant Approval
  - Study Initiation
  - First Participant Screened
  - First Participant Enrolled
  - Last Participant Last Visit
  - Last Participant Enrolled
  - Data Analysis
  - Study Closure
  - Other *(Free text)*
- Expected Date
- Actual Date
- Remarks

Note:

- Once an entry is created and saved, it cannot be deleted.

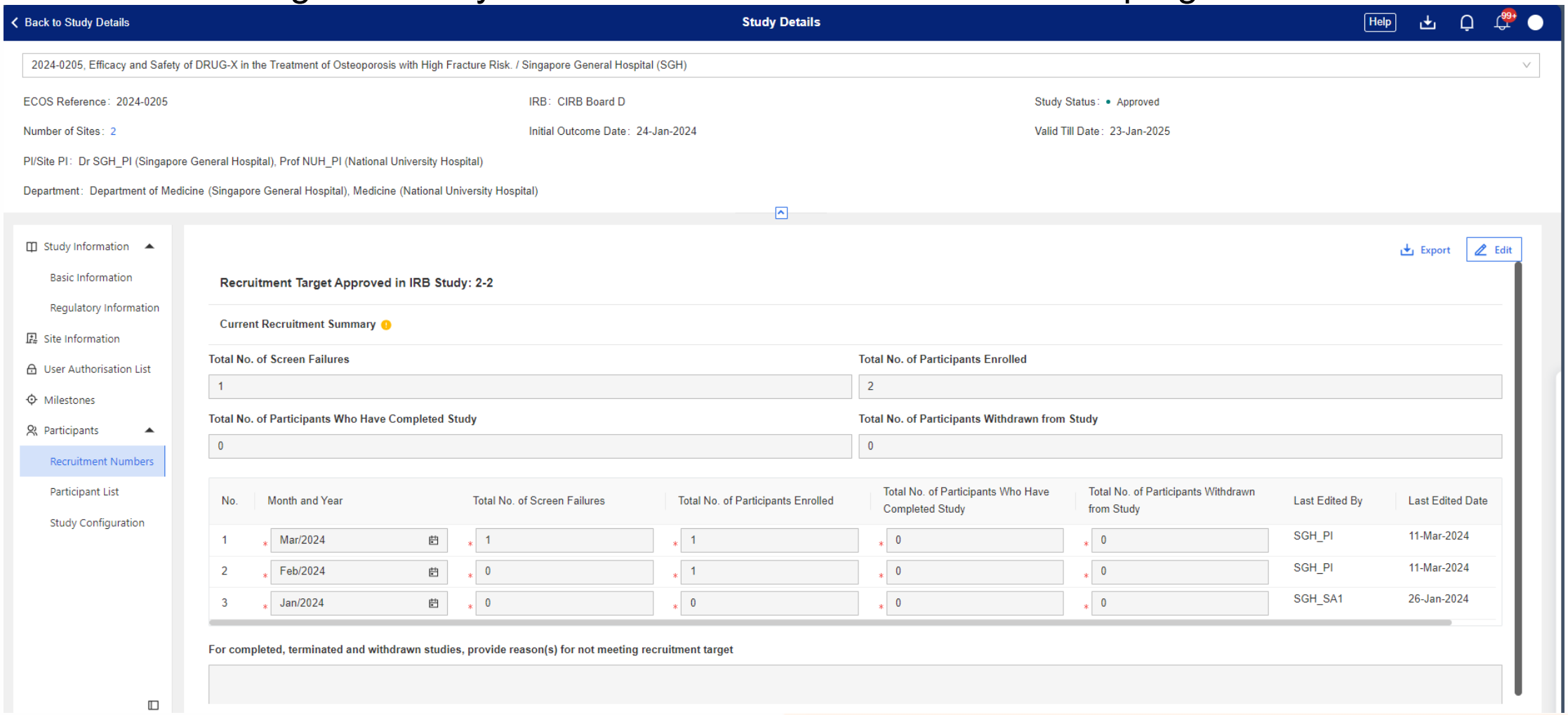
CRMS Sitemap



Participants – Recruitment Numbers

Site Level

- Allows monitoring of monthly and overall recruitment numbers and progress.



Participants – Recruitment Numbers

Site Level

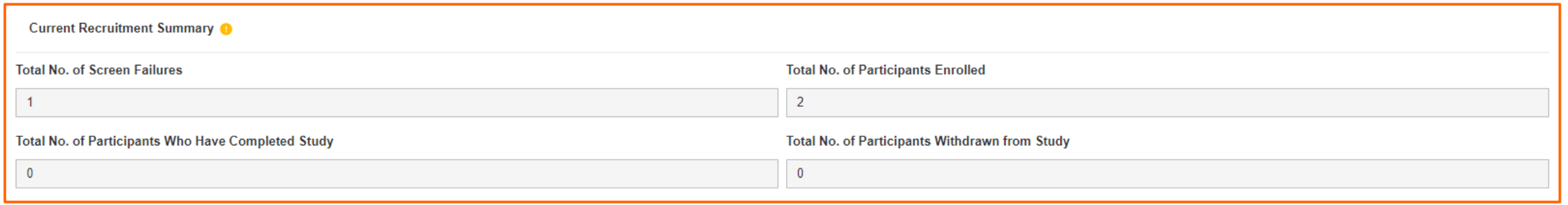
Below are the data fields found on this page:

Recruitment Numbers

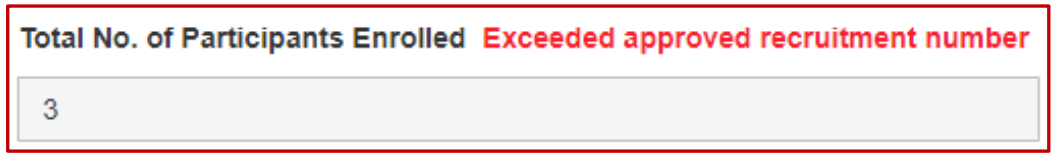
- Month and Year
- Total No. of Screen Failures
- Total No. of Participants Enrolled
- Total No. of Participants Who Have Completed Study
- Total No. of Participants Withdrawn from Study
- For completed, terminated and withdrawn studies, provide reason(s) for not meeting recruitment target *(Free text)*

Participants – Recruitment Numbers

- Definitions of Screen Failure, Participants Enrolled / Completed / Withdrawn are given in the information bubble ⓘ next to **Current Recruitment Summary**.
- Monthly numbers should be entered and overall total numbers will be auto-populated by the system.

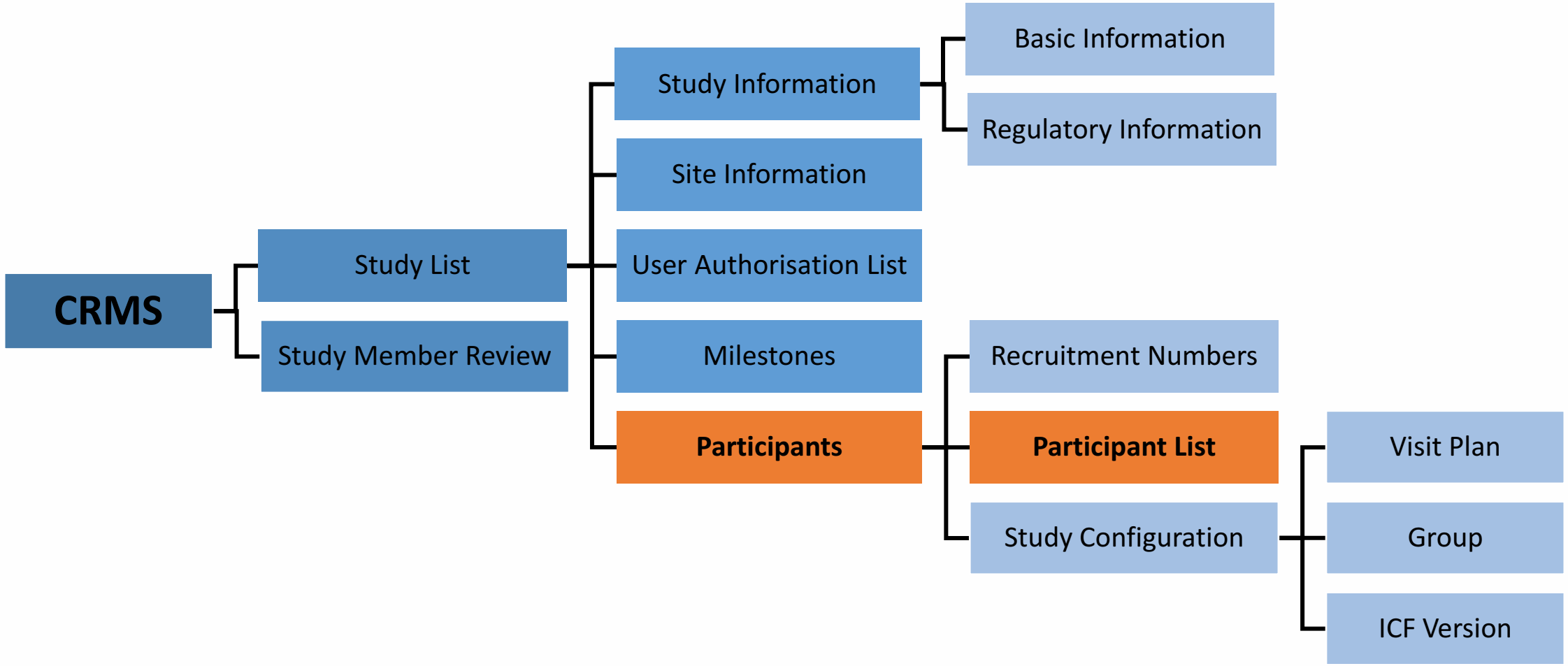


- **Recruitment Target Approved in IRB Study** will be imported from the IRB module.
- A prompt in red will appear if the **Total No. of Participants Enrolled** exceeds the approved number.



- **REMINDER**: PI/Site-PI should submit a Study Deviation/Non-Compliance report form to IRB should the actual recruitment number exceeds the IRB-approved figure.

CRMS Sitemap



Participants – Participant List

Site Level

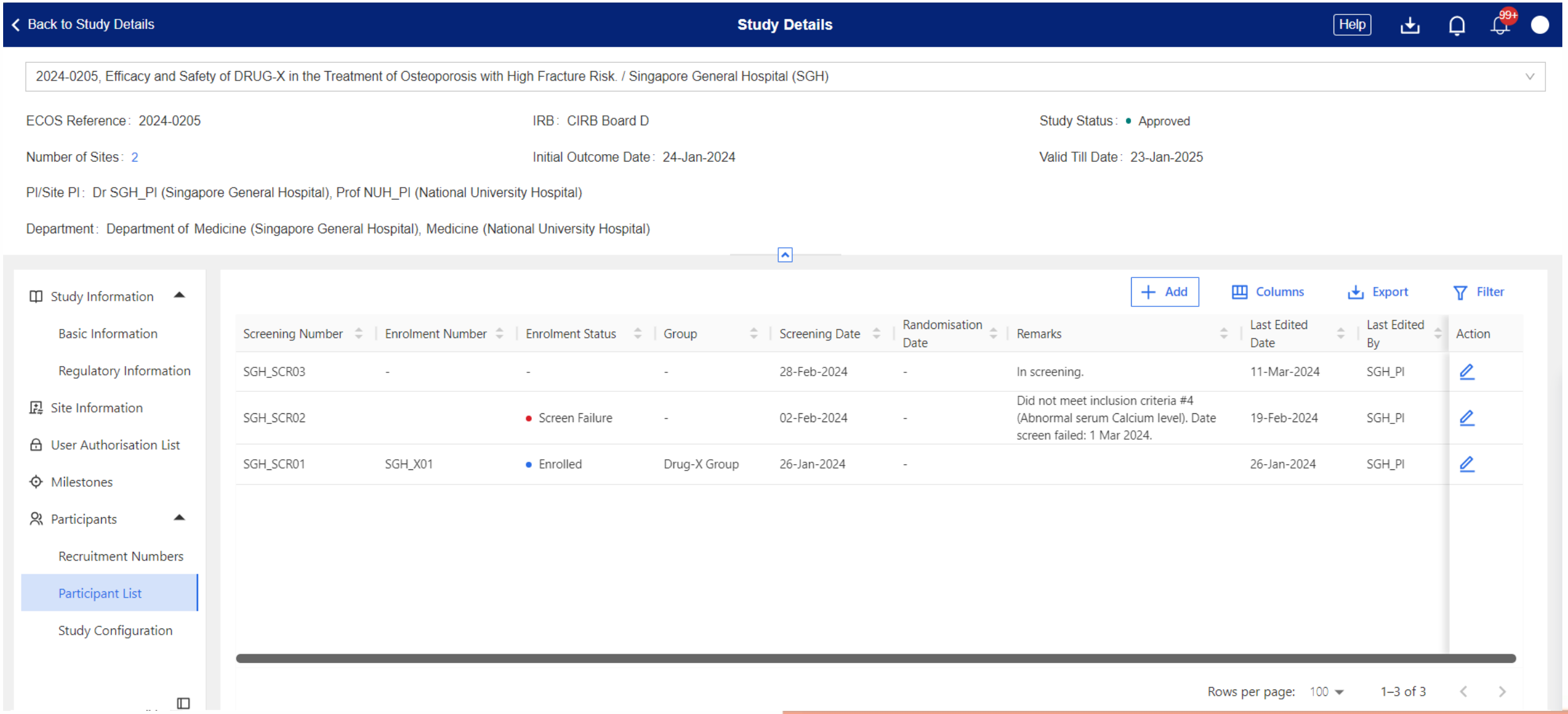
- Provides an overview of the list of participants screened, enrolled and/or randomised.

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

Please <u>DO NOT</u> enter participant identifiers in CRMS.

Participants – Participant List

Site Level



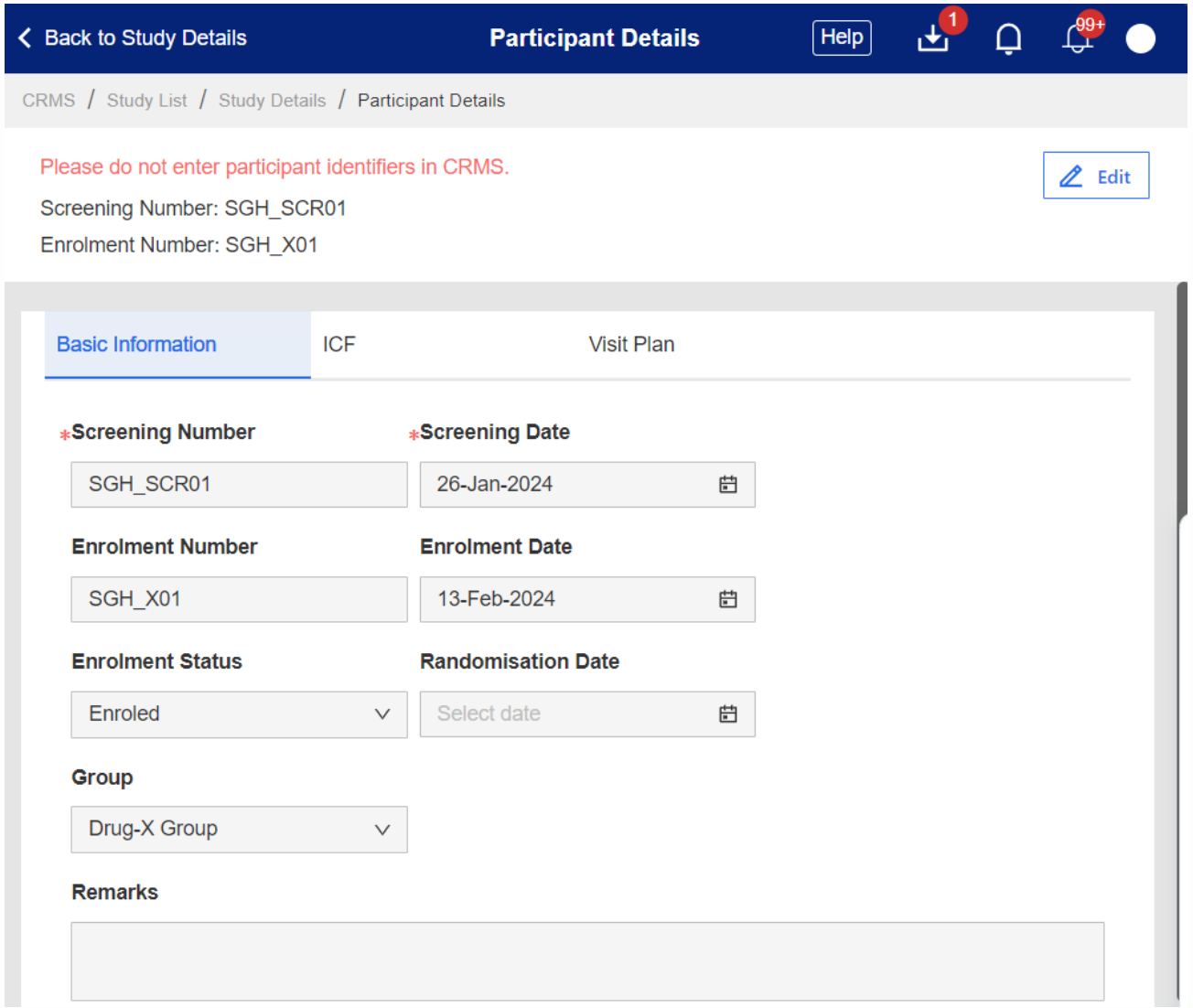
Participants – Participant List

Site Level

Below are the data fields found on this page:

Basic Information

- Screening Number
- Screening Date
- Enrolment Number
- Enrolment Date
- Enrolment Status
- Randomisation Date
- Group *(Configurable)*
- Remarks



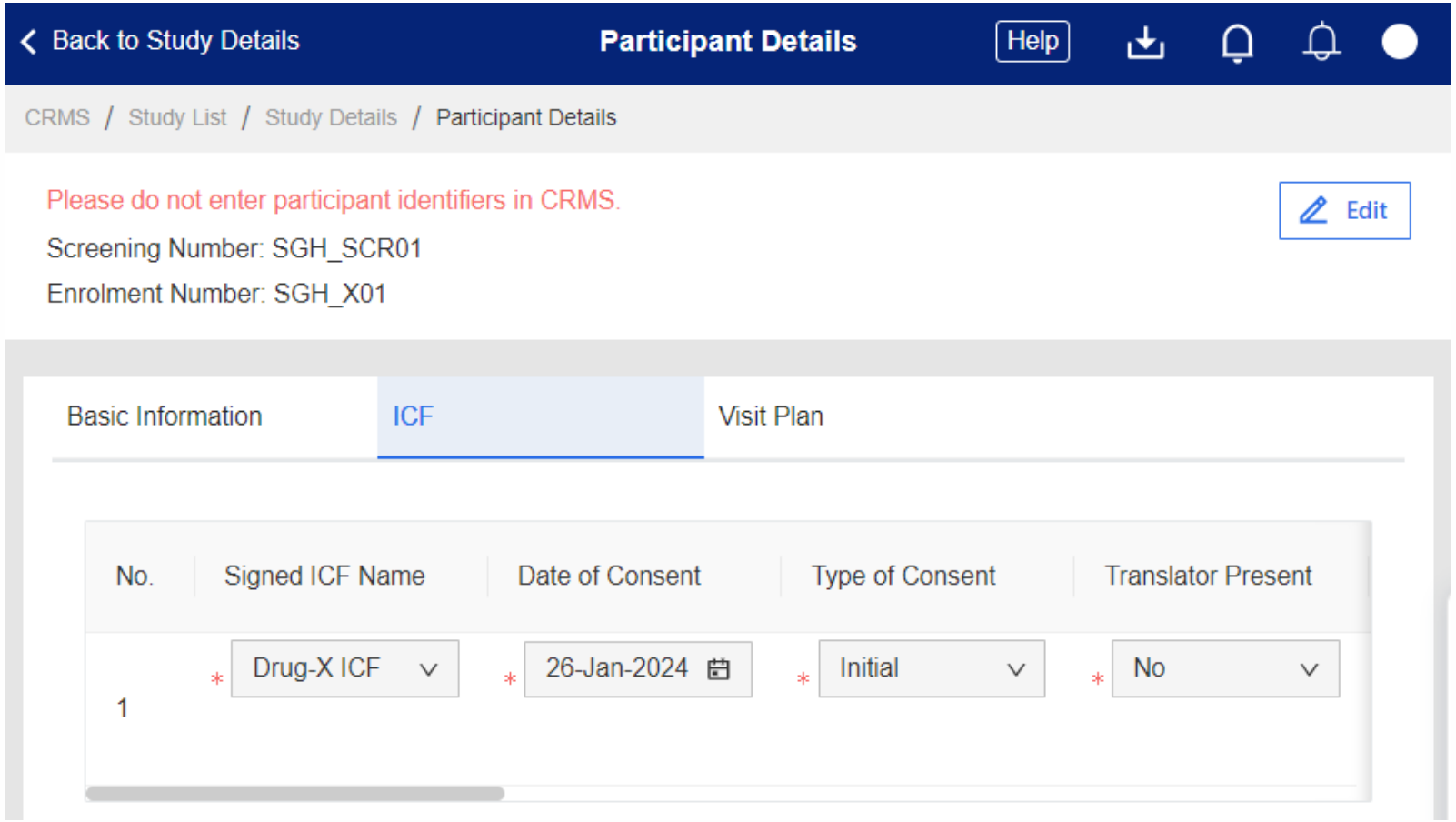
Participants – Participant List

Site Level

Below are the data fields found on this page:

ICF

- Signed ICF Name *(Configurable)*
- Date of Consent
- Type of Consent
- Translator Present
- Witness Present
- Consent to Being Re-contacted
- Consent to Future Research
- Consent to Use of Research Data for Future Research
- Consent to Donation of Biological Specimens for Future Research
- Remarks



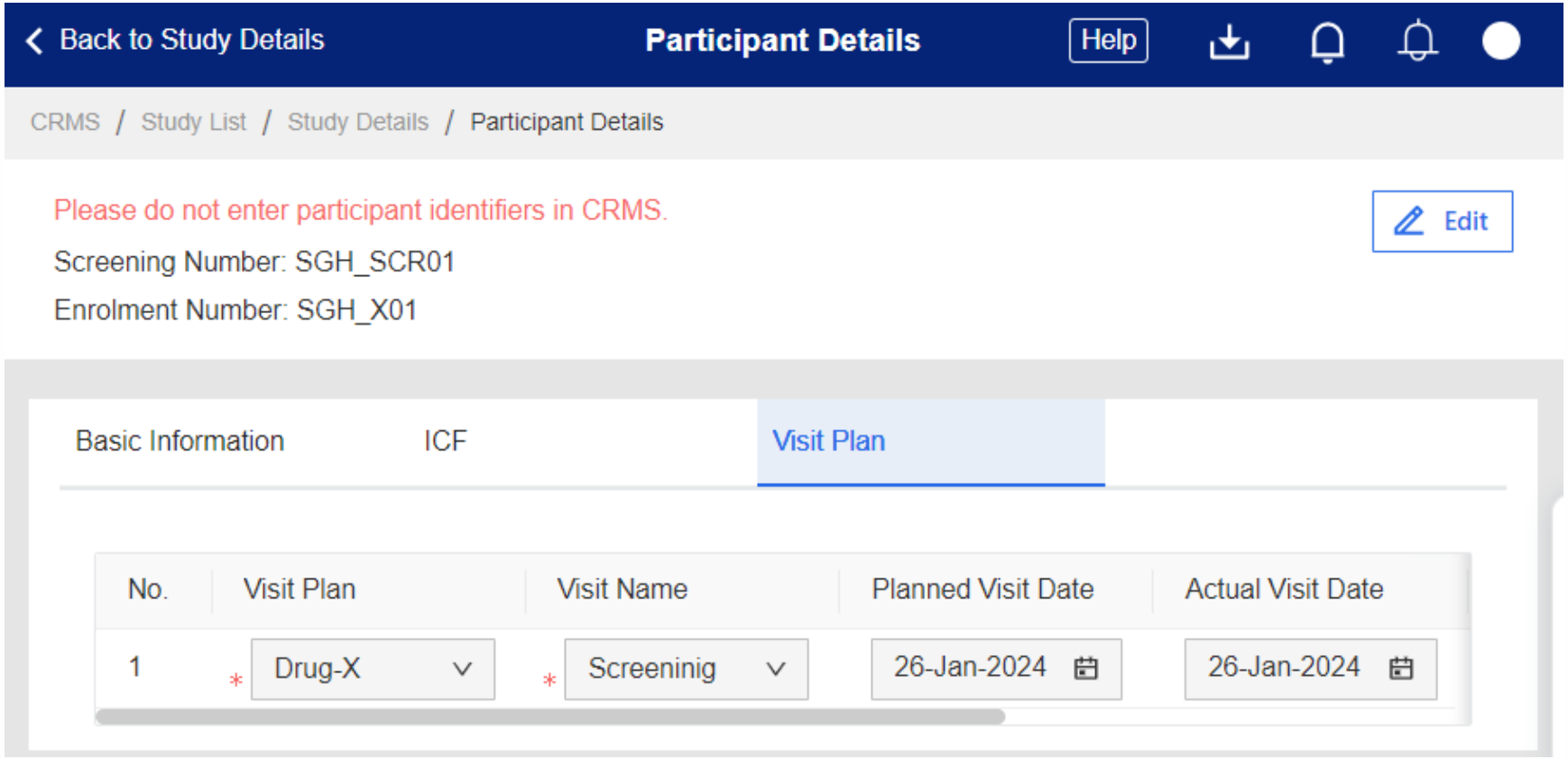
Participants – Participant List

Site Level

Below are the data fields found on this page:

Visit Plan

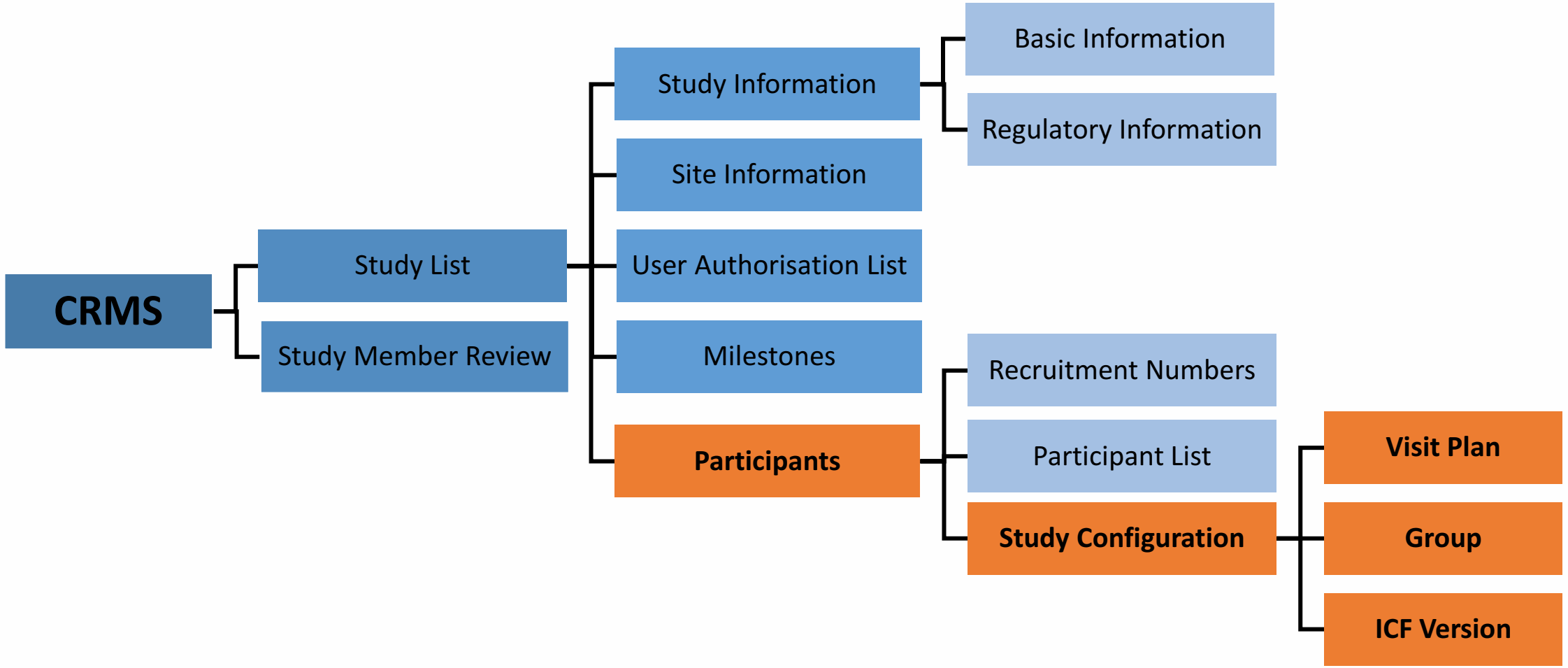
- Visit Plan *(Configurable)*
- Visit Name *(Configurable)*
- Planned Visit Date
- Actual Visit Date



Note:

- PI/Site-PI should submit a Study Deviation/Non-Compliance report form to IRB should a trial visit be missed or conducted outside the protocol-specified window period.

CRMS Sitemap



Participants – Study Configuration

Site Level

- Configuration page to configure study site-specific Visit Plan, Group and ICF Version.
- Configured details will appear as options to be selected in the Participants – Participants List page.

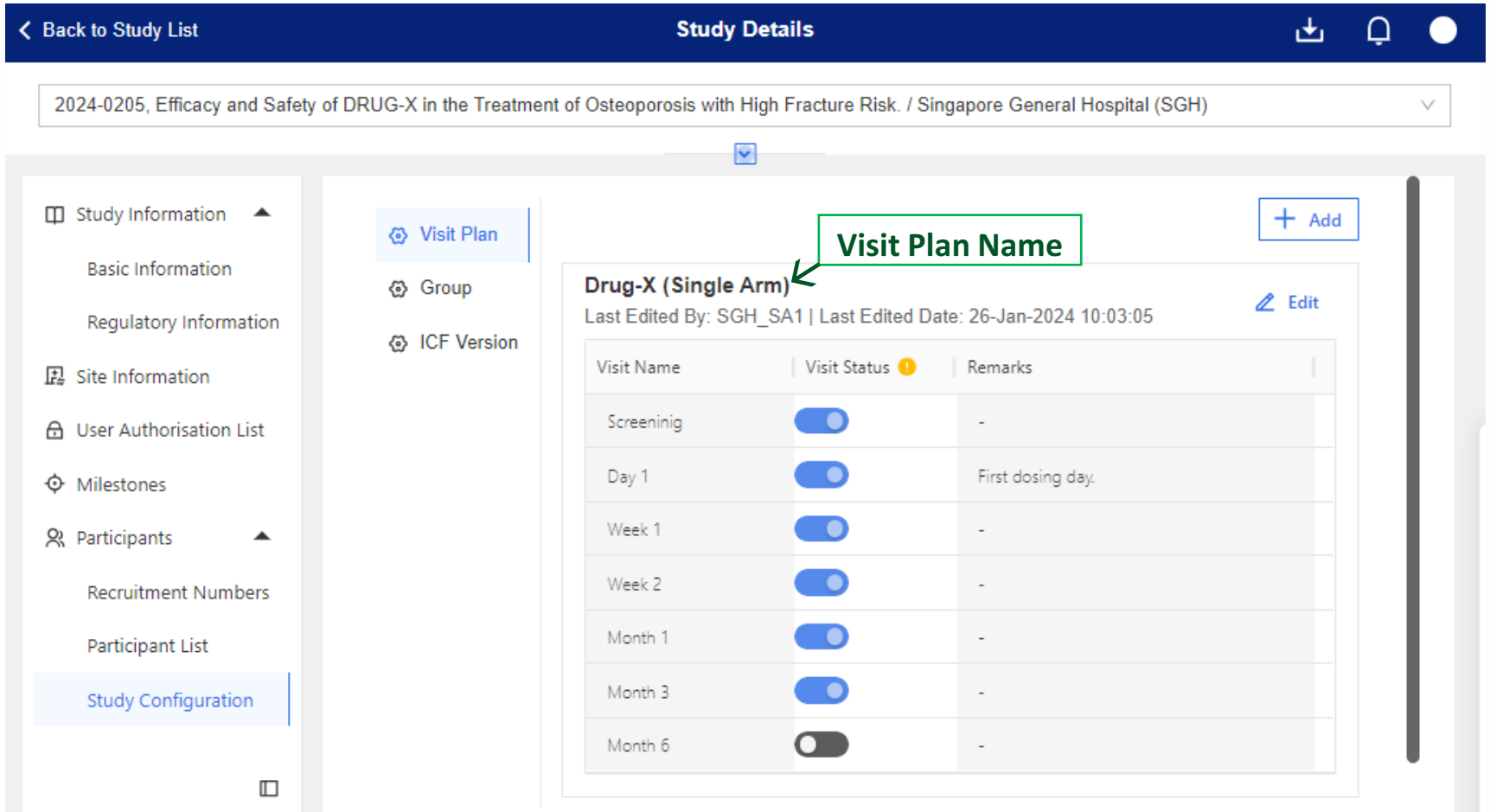
Participants – Study Configuration

Site Level

Below are the data fields found on this page:

Visit Plan

- Visit Plan Name
- Visit Name
- Visit Status
- Remarks

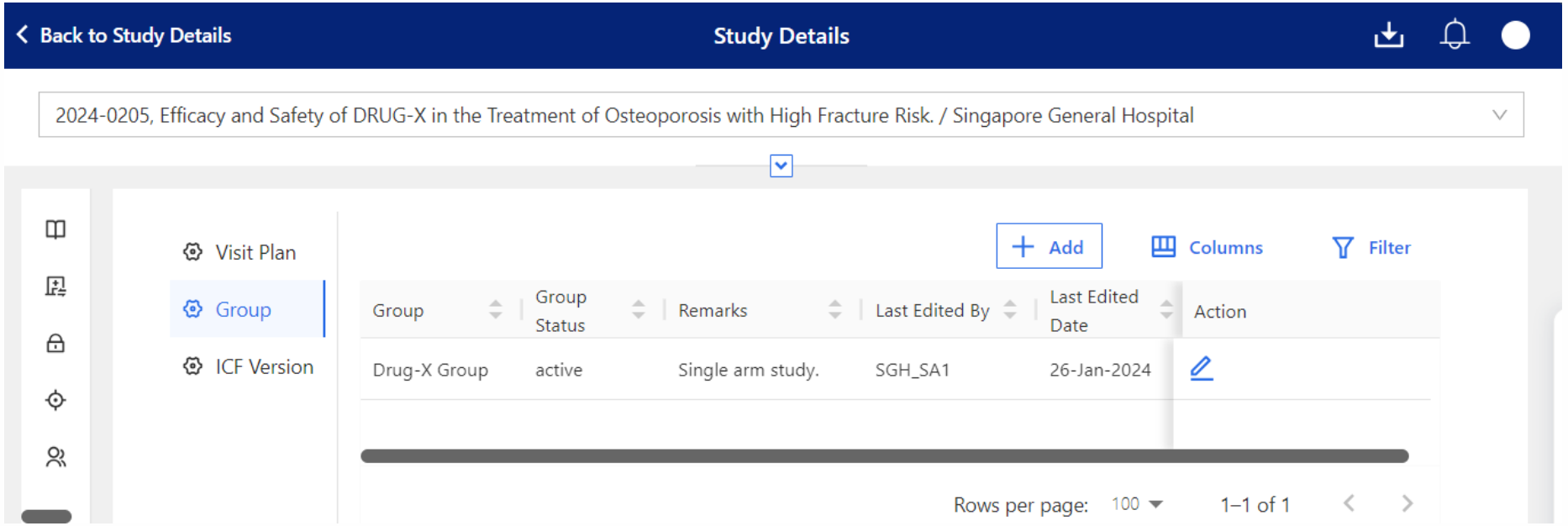


Note:

- Visit Plan Name corresponds to the study arm/group(s) planned in a research protocol, e.g. active arm vs control arm.
- Toggle the Visit Status switch to the right (*blue*) to activate a Visit Name. To inactivate, toggle it to the left (*dark grey*).
- A Visit Plan cannot be selected in the Participant Details if there are no visits (*under Visit Name column*) added to the Visit Plan, or if the visits are all inactivated under Visit Status.

Participants – Study Configuration

Site Level



Below are the data fields found on this page:

Group

- Group Name
- Group Status *(Drop-down list)*
  - Active
  - Inactive
- Remarks

Note:

o Status of Group must be “Active” for the entered row to appear on the **Participant – Participant List** page as an option to select.

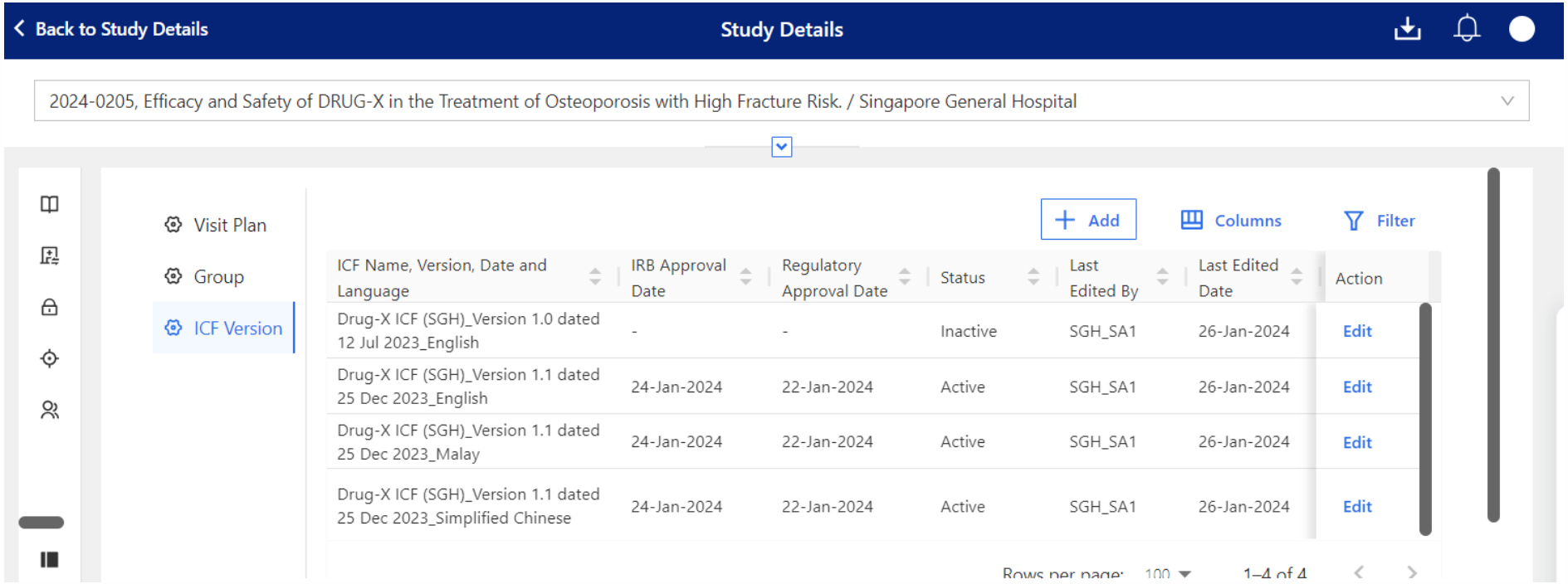
Participants – Study Configuration

Site Level

Below are the data fields found on this page:

ICF Version

- ICF Name, Version, Date and Language
- IRB Approval Date
- Regulatory Approval Date
- Status *(Drop-down list)*
  - Active
  - Inactive



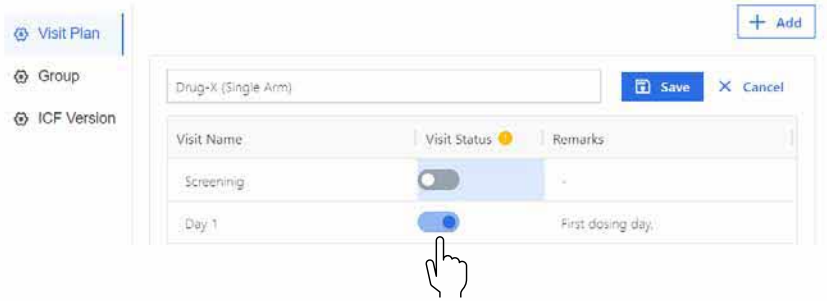
Note:

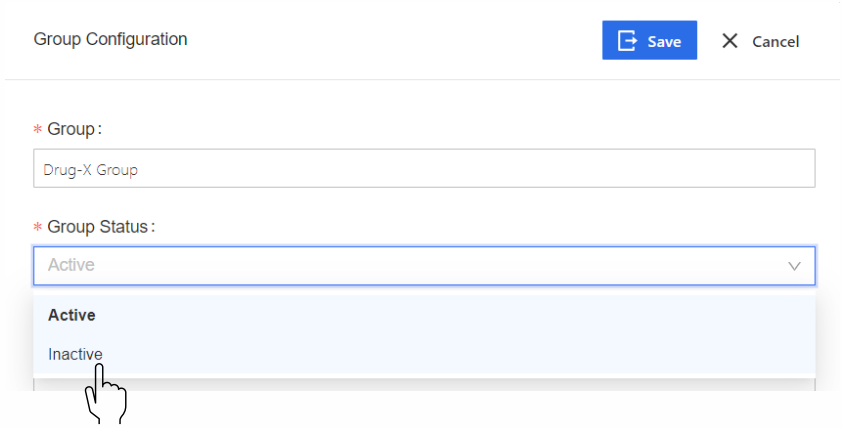
o Status of ICF must be “Active” for the entered row to appear on the **Participant – Participant List** page as an option for selection.

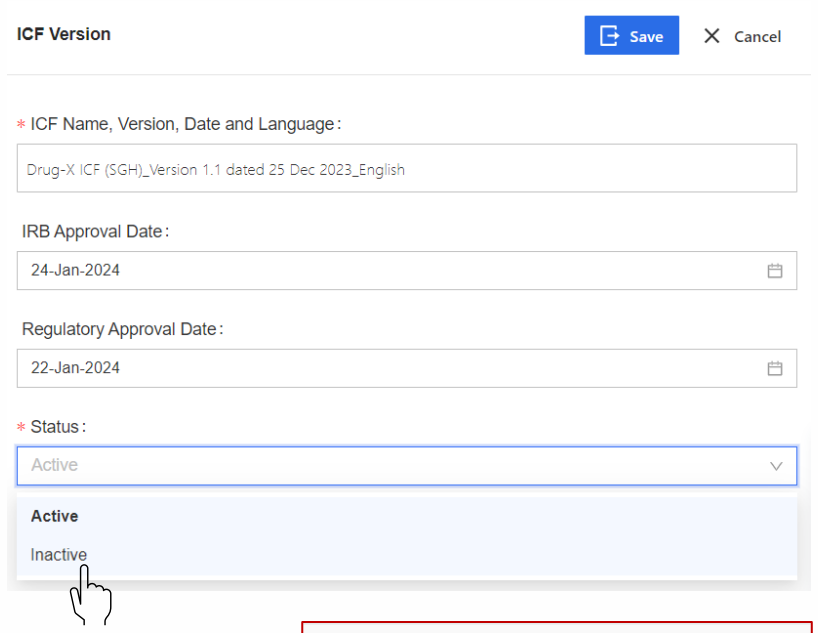
Participants – Study Configuration

Site Level

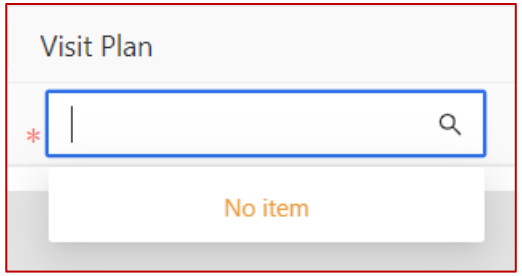
- Entries in the Study Configuration (Visit Plan, Group, ICF Version) cannot be deleted once saved.
- Users will need to use the switch toggle or drop-down list to inactivate the entry.



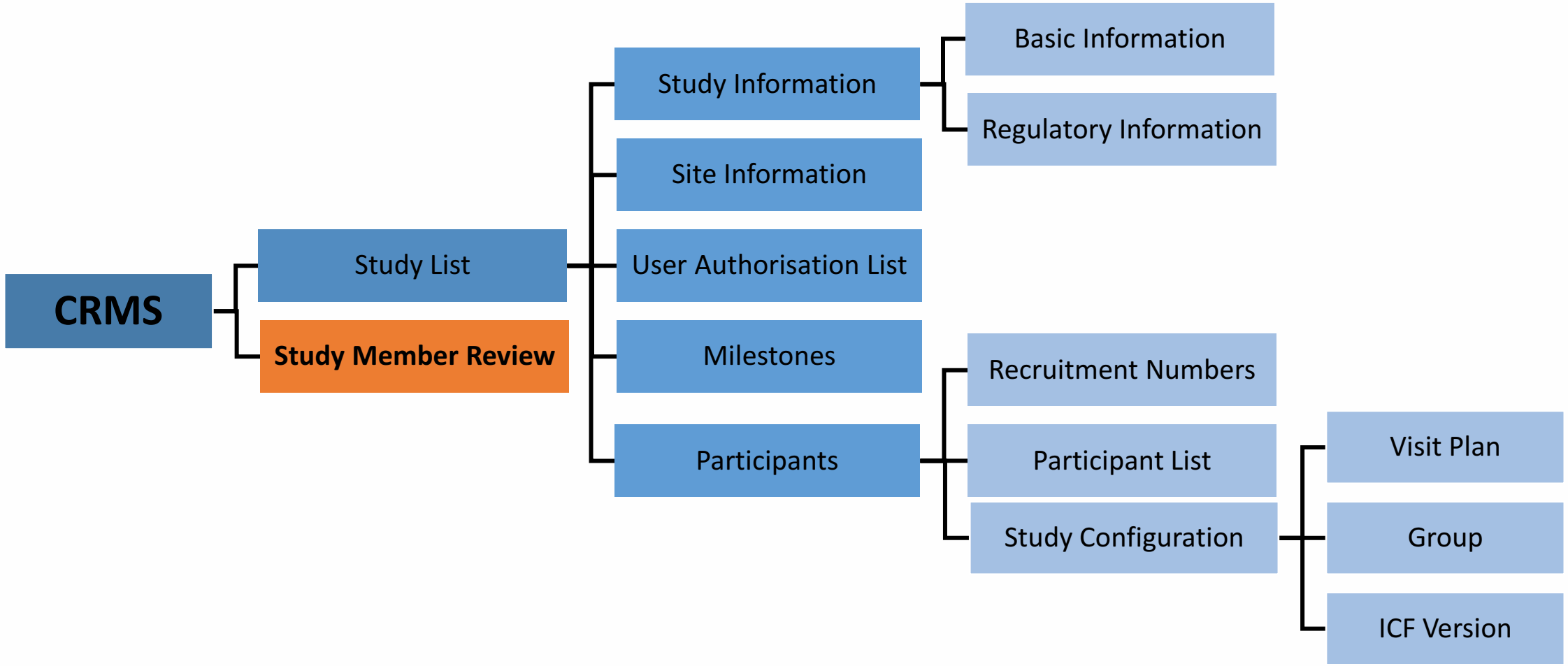




- Once inactivated, the entry will not appear as an option for selection in the drop-down list of the relevant **Participant Details** sections.



CRMS Sitemap

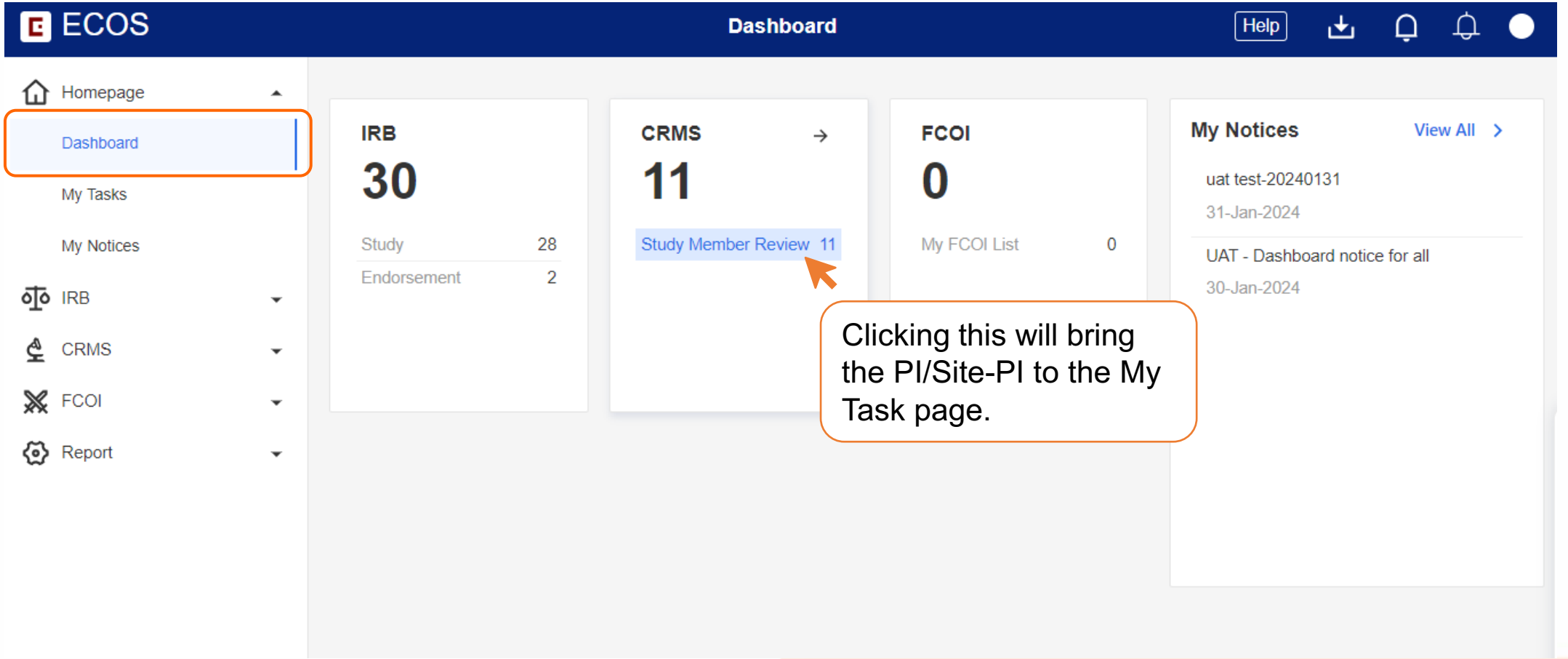


Study Member Review

Site Level

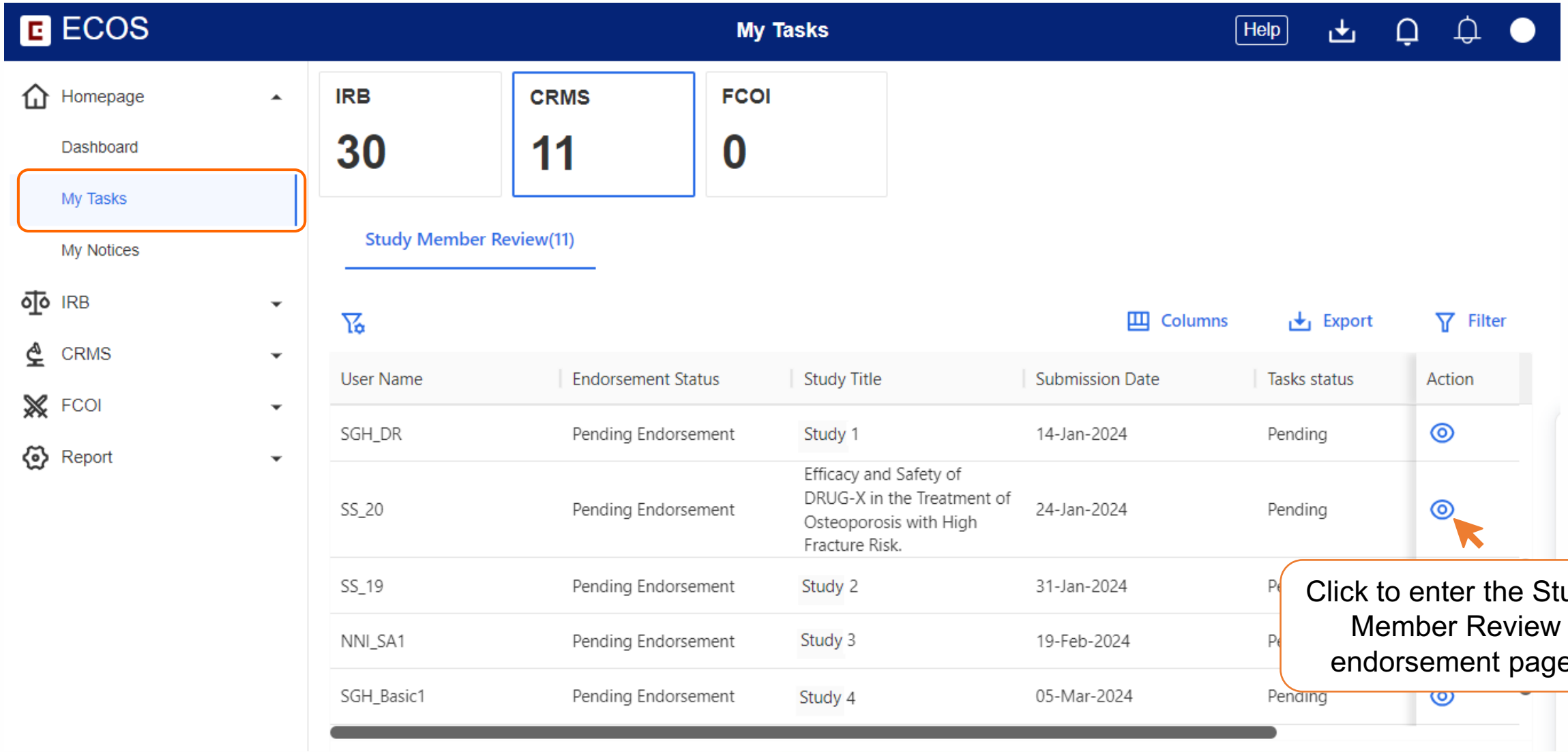
- This page is available to **PI/ Site-Pis only.** The PI/Site-PIs can access the Study Member Review Page by 2 ways:

  1. Via Dashboard > CRMS Card > Study Member Review



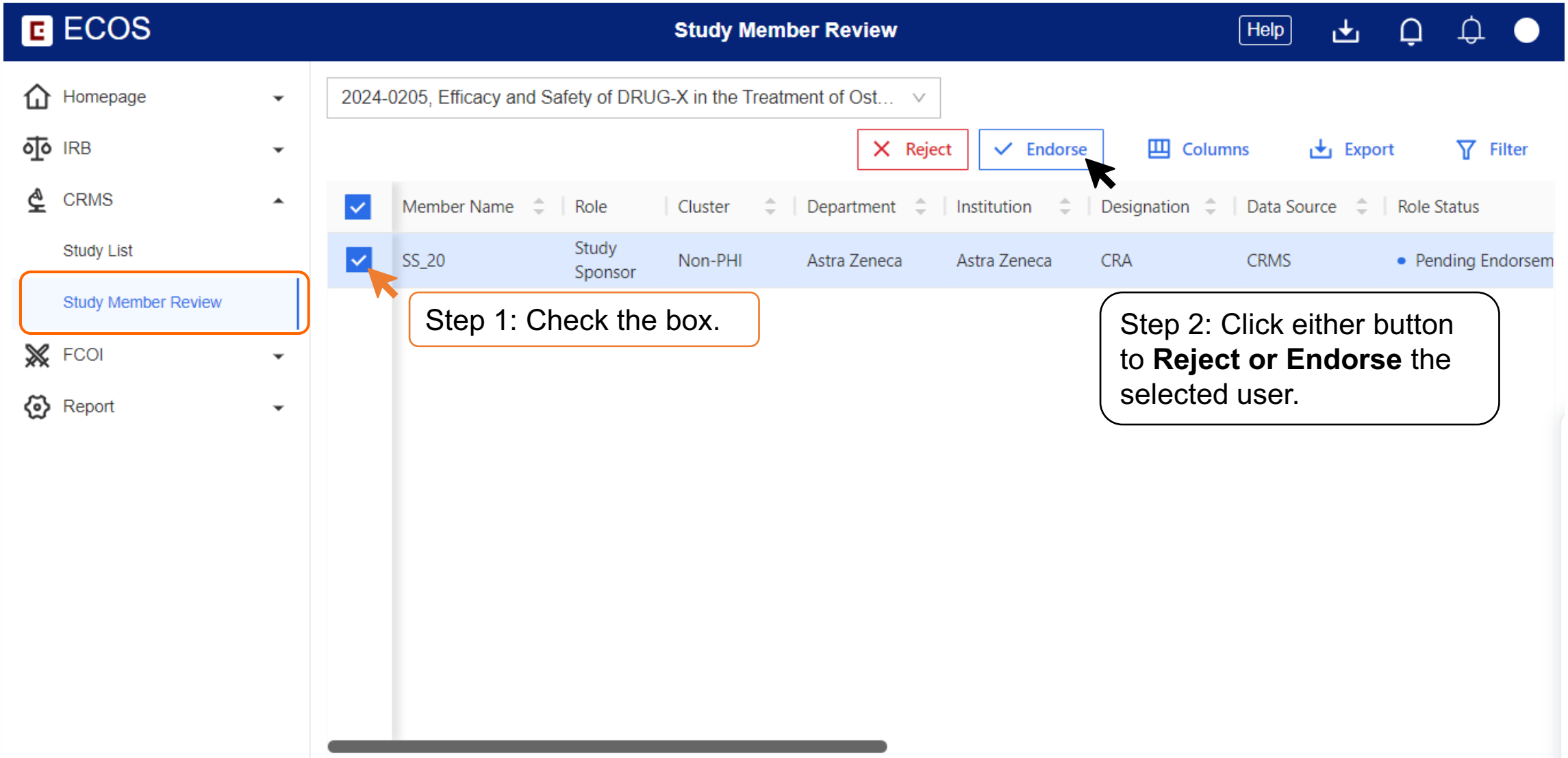
Study Member Review

Site Level



Study Member Review

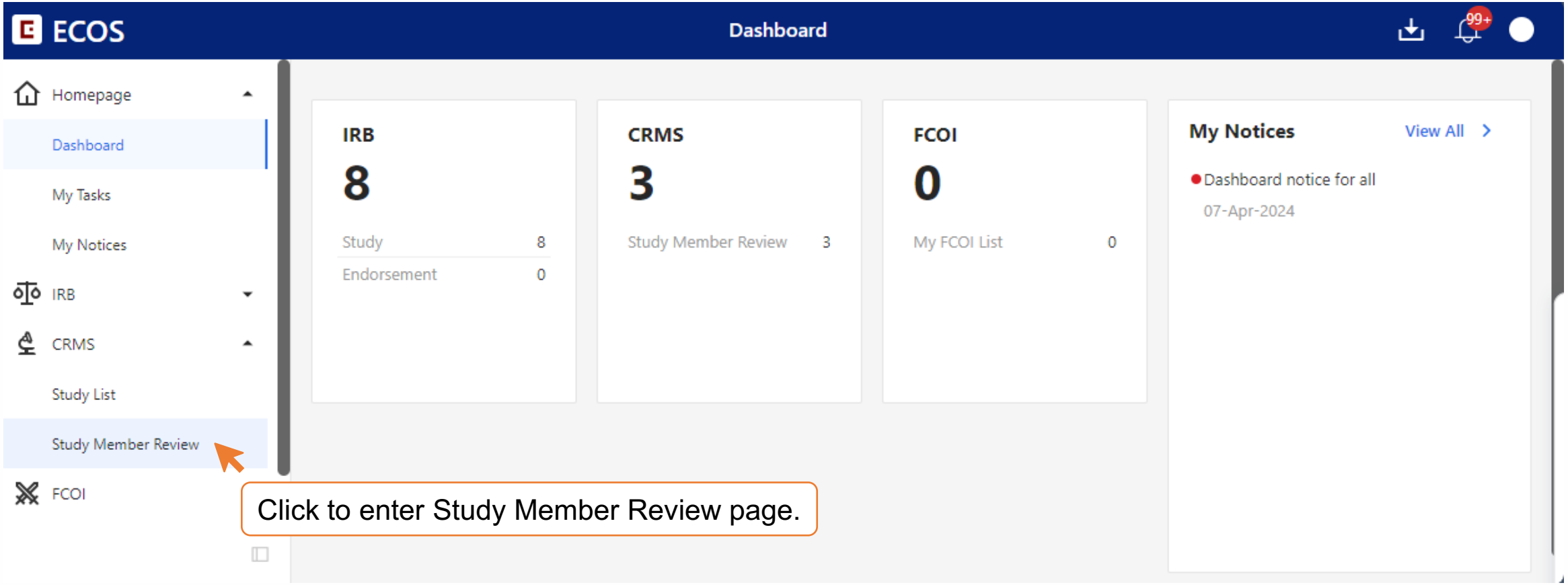
Site Level



Study Member Review Access

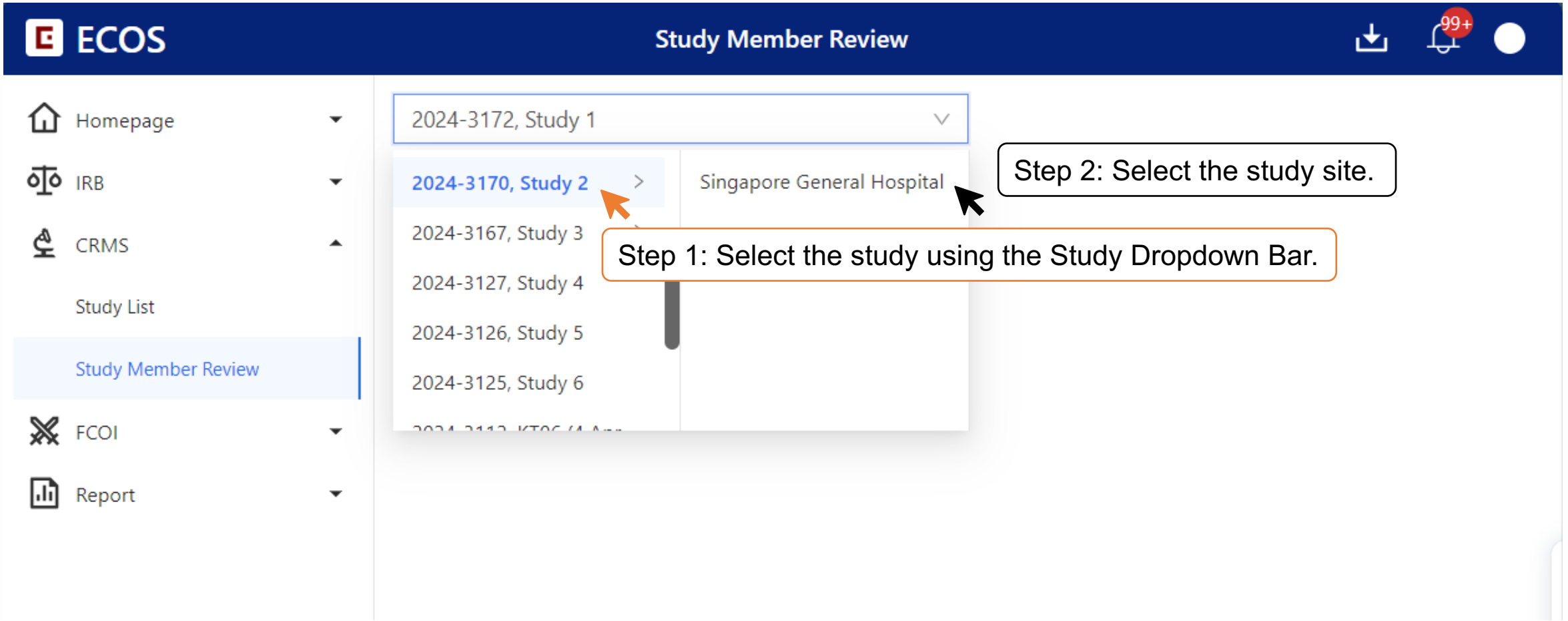
Site Level

2. Via ECOS Navigation Menu > CRMS > Study Member Review



Study Member Review Access

Site Level



Study Member Review

Site Level

- Multiple users can be selected for PI/Site-PI to endorse or reject, by selecting the checkboxes on the left.
- User Authorisation List will be automatically updated once a user is approved or rejected.

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 page 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.
  - Existing limited page access to CRMS will be revoked.

ECOS

Creating IRB application by STM/SA/SS

National Healthcare Group
Adding years of healthy life

SingHealth
Defining Tomorrow's Medicine

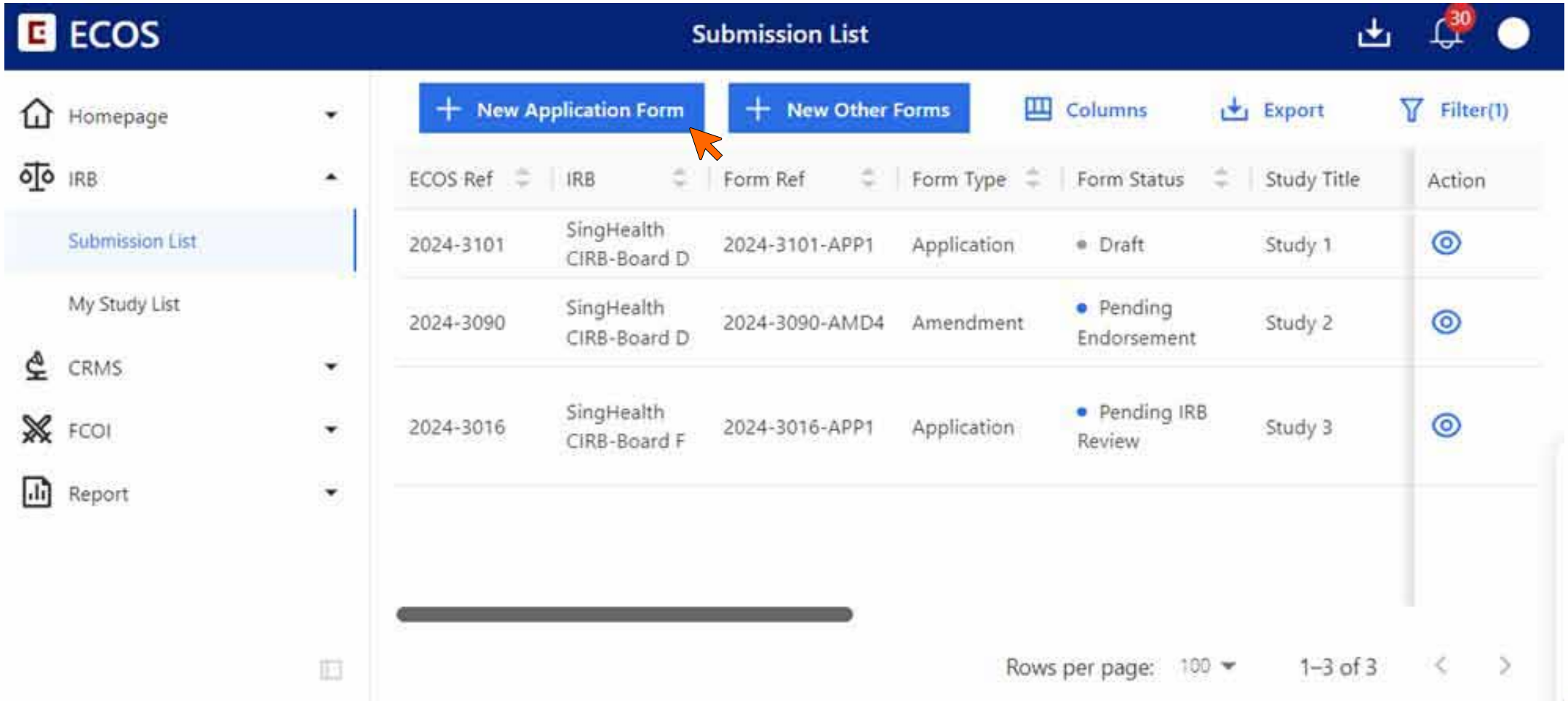
Creating New IRB Application

- All users who has access to IRB module will be able to create an IRB Application (APP) Form.
- Investigators (PI, Site-PI, Co-I) added to the IRB APP form will appear on the CRMS User Authorisation List following synchronisation between the IRB and CRMS modules.
- Investigators will be able to access CRMS pages for the study, in addition to the IRB APP Form.
- As for STM / SA / SS, since they cannot be added to the IRB APP Form, the system will prompt them to select their Study Site and Study Role when saving the form **for the first time.**
- Once completed, the STM / SA / SS will be added to the User Authorisation List in the study's CRMS. The STM / SA / SS will have access to CRMS and continue to have access to the IRB APP Form.
- The next few slide will briefly illustrate the above using a Study Sponsor (SS_20) account.

IRB APP Form Creation

Role used: Study Sponsor (SS_20)

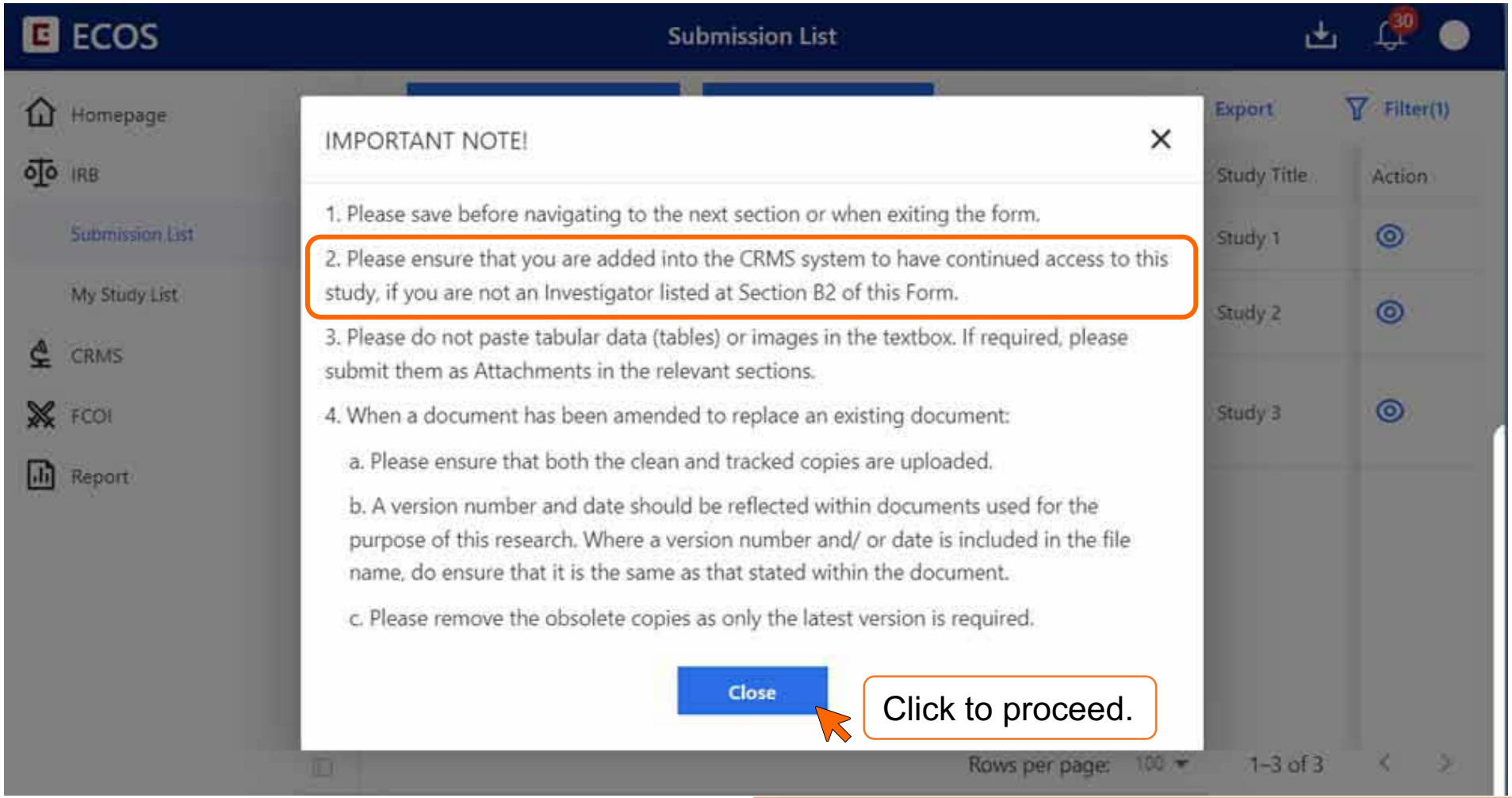
- To create a new IRB APP Form, go to **IRB** > **Submission List** and click **New Application Form**.



IRB APP Form Important Note

Role used: Study Sponsor (SS_20)

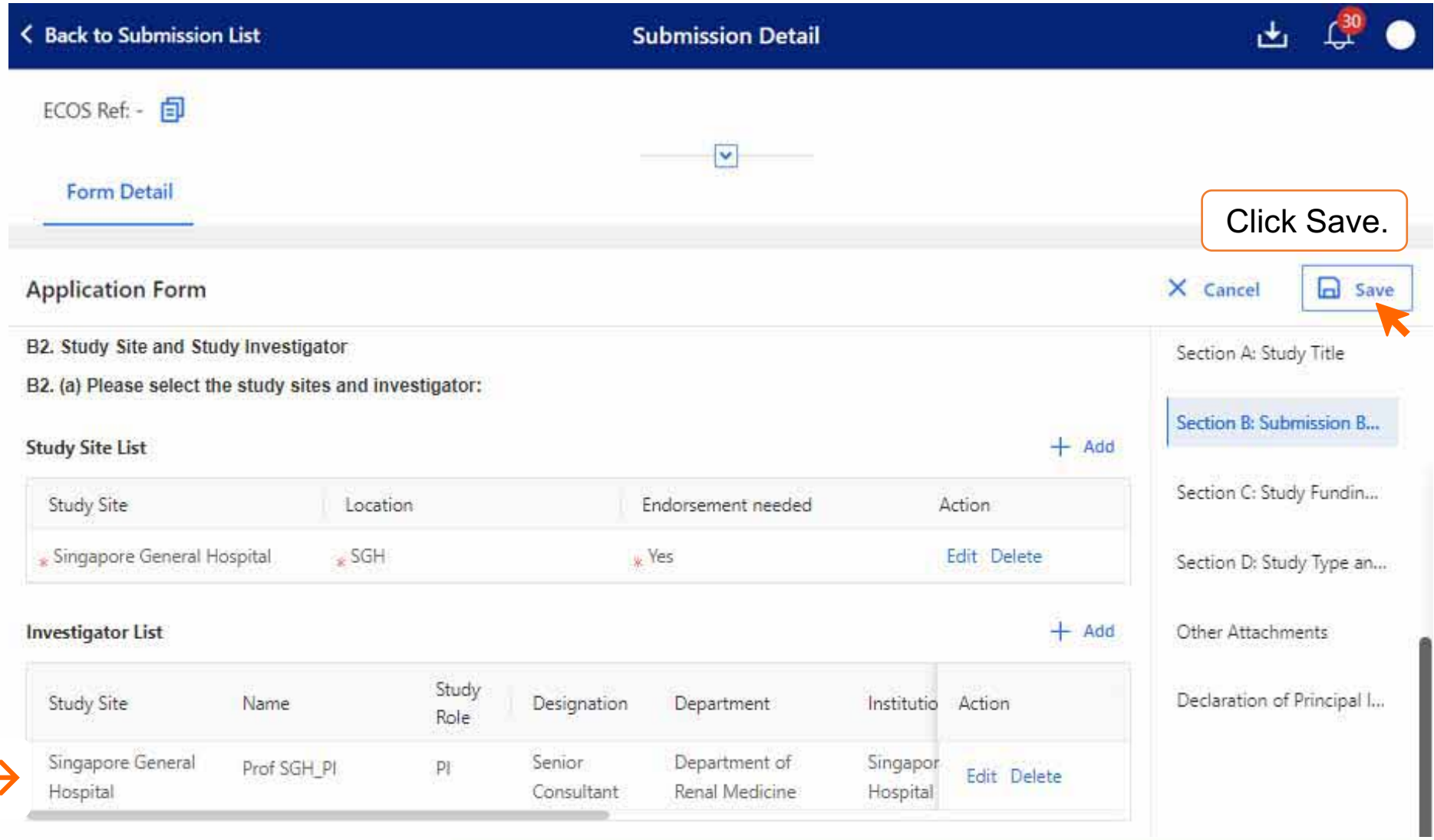
- Kindly note Point 2.



First Save of IRB APP Form

Role used: Study Sponsor (SS_20)

- At the first save of the IRB APP Form, the system will recognise that SS_20 is not part of the Investigator List in Section B2 (a).
- This will trigger a prompt (next slide).

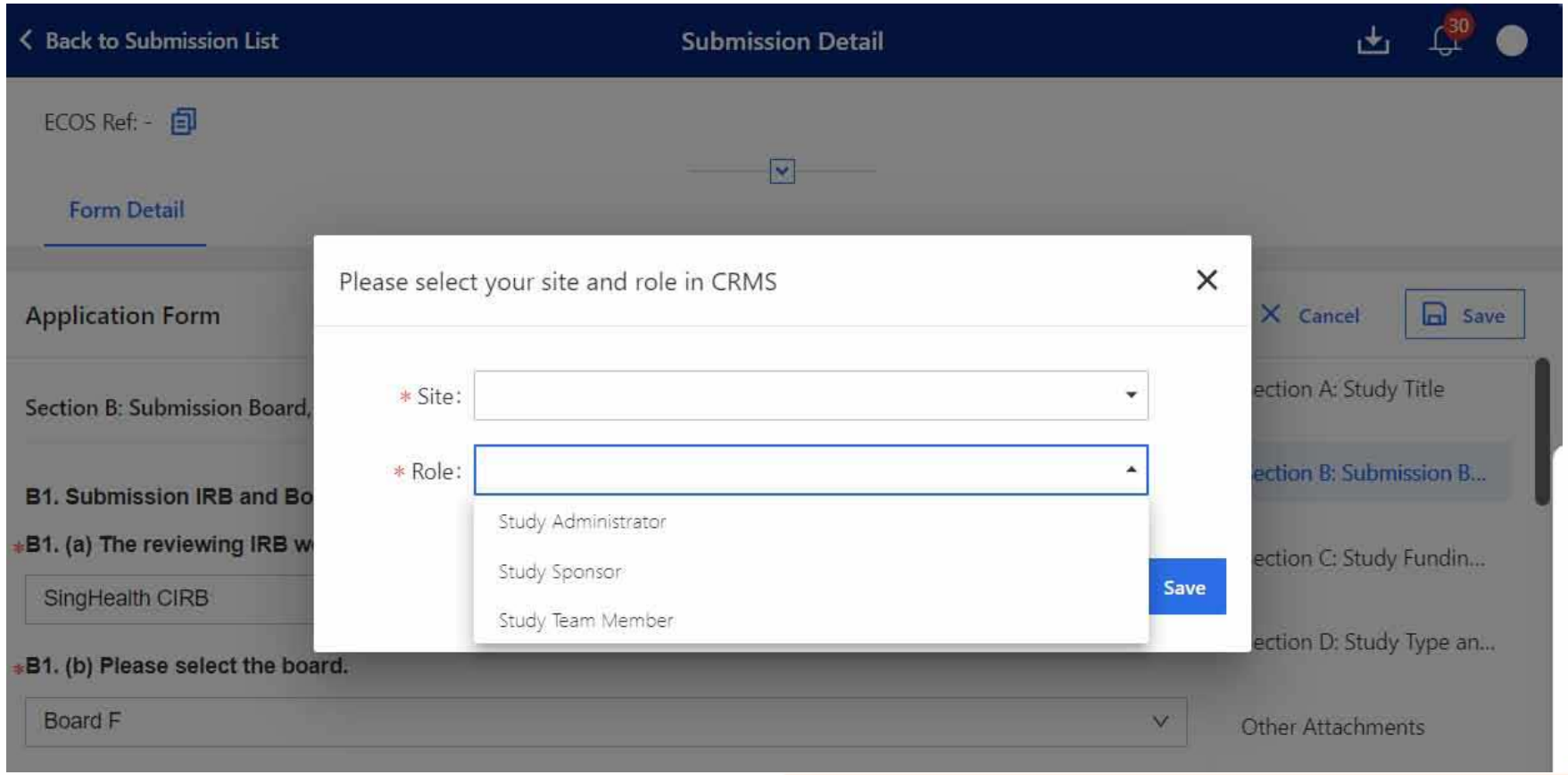


Prof SGH_PI is the only investigator at the point of first save.

CRMS Prompt in IRB Module

Role used: Study Sponsor (SS_20)

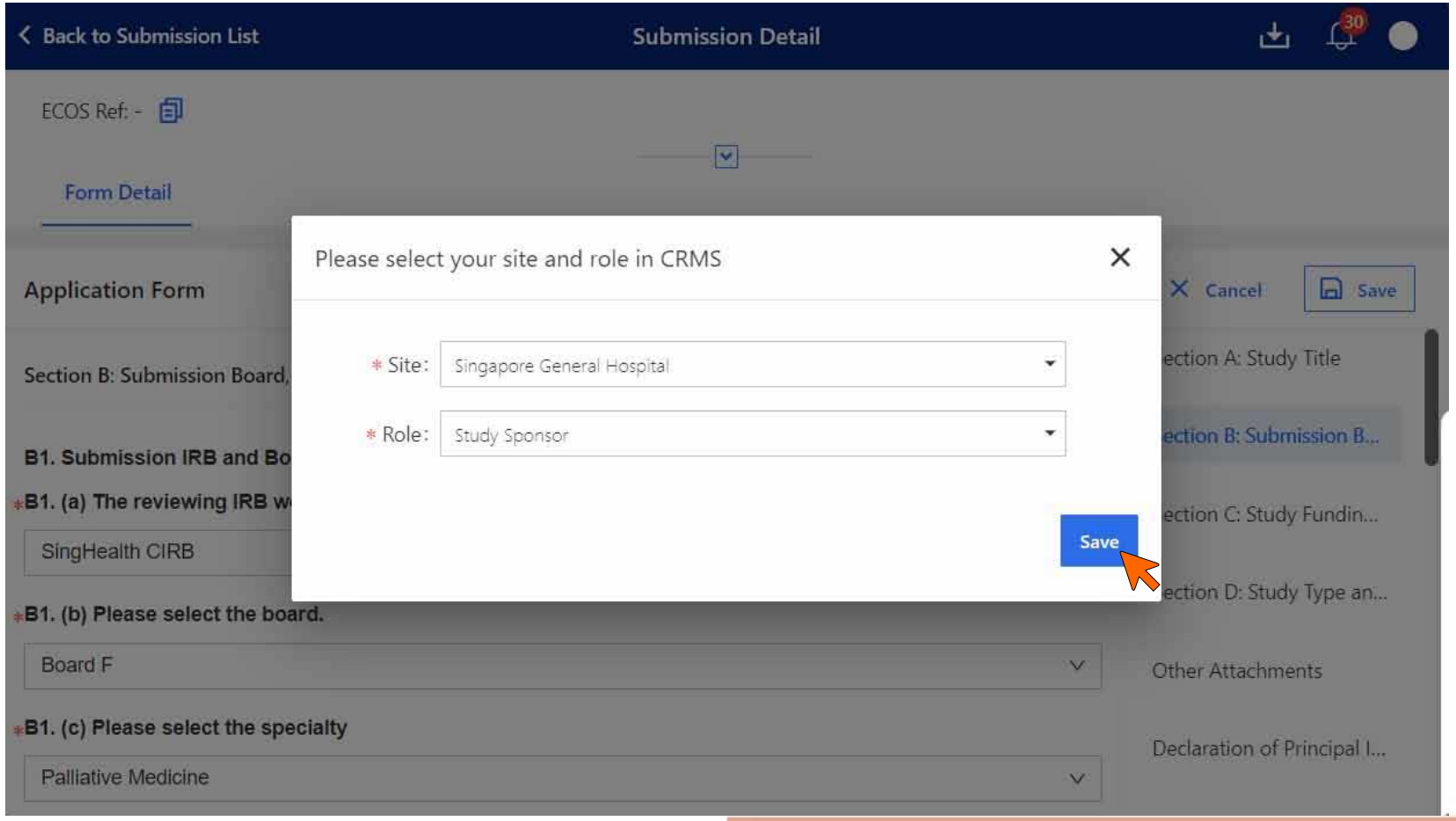
- The options for **Site** mirrors the options in Section B2 (a) Study Site List of the IRB APP Form.
- Only 3 options for **Role** available for user to select: Study Administrator, Study Sponsor or Study Team Member.



CRMS Prompt in IRB Module

Role used: Study Sponsor (SS_20)

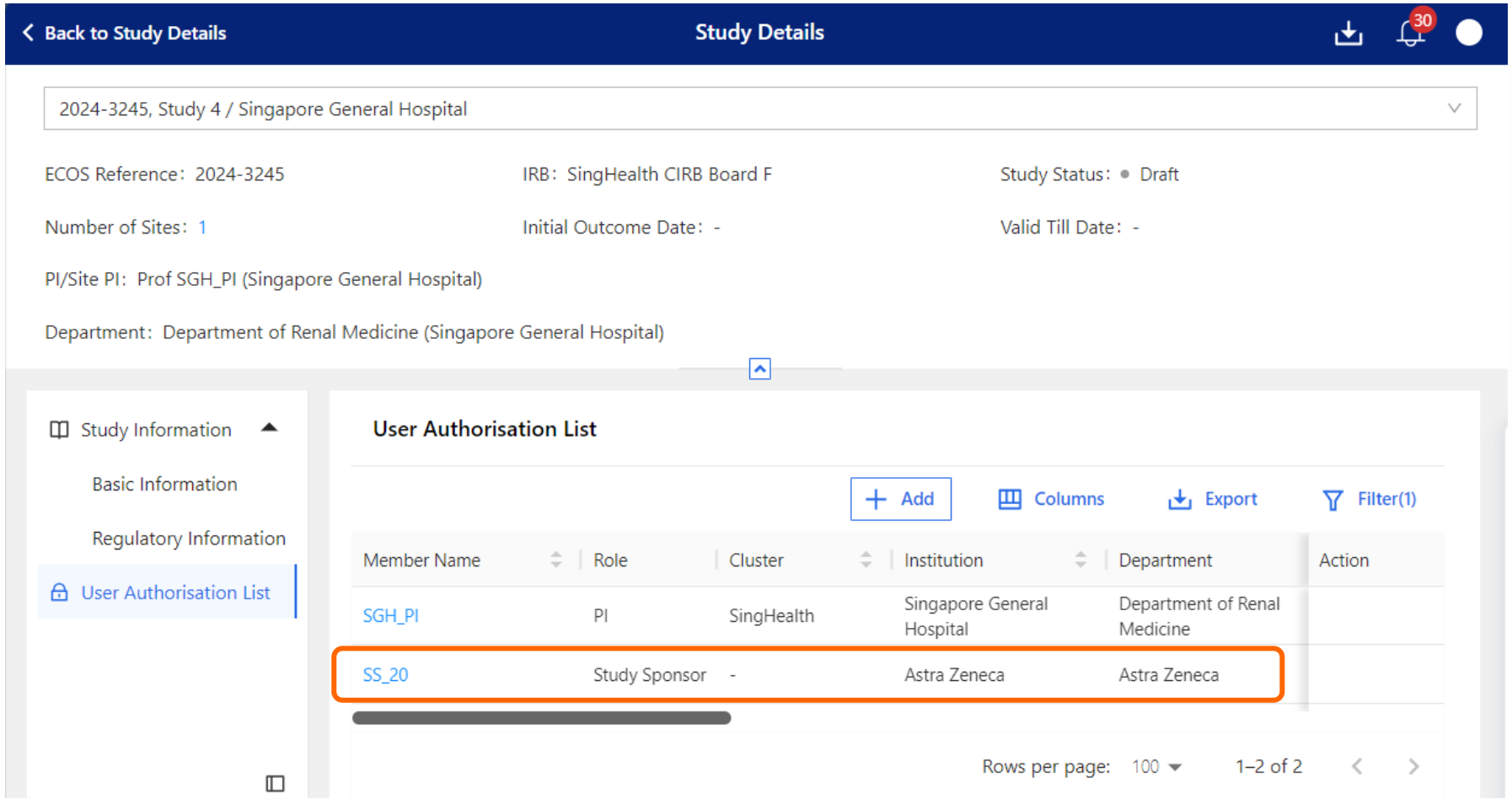
- Select the correct **Site** and **Role**, then click **Save**.
- The system will register this and add SS_20 to the CRMS User Authorisation List (next slide).



User Added to UAL by System

Role used: Study Sponsor (SS_20)

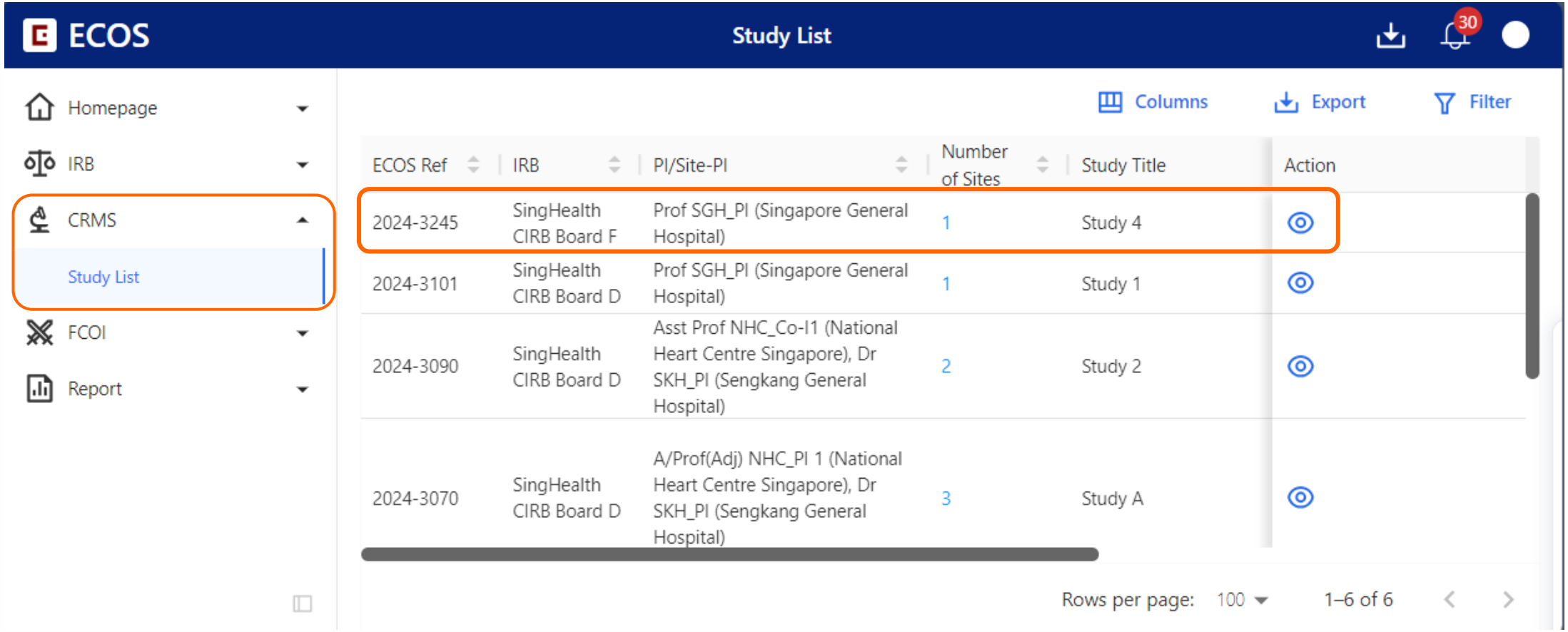
- SS_20 added to the User Authorisation List.



CRMS Accessiility

Role used: Study Sponsor (SS_20)

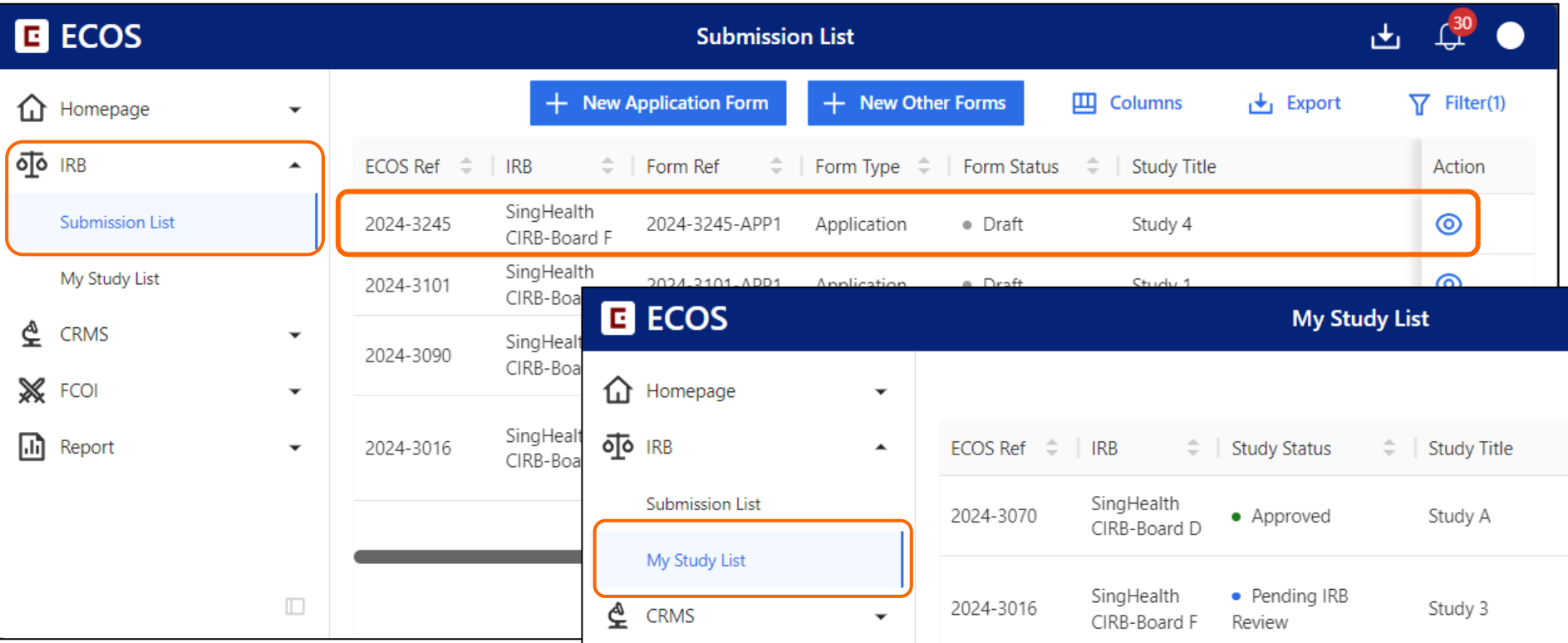
- SS_20 can now access to the study 2024-3245 in CRMS modules.

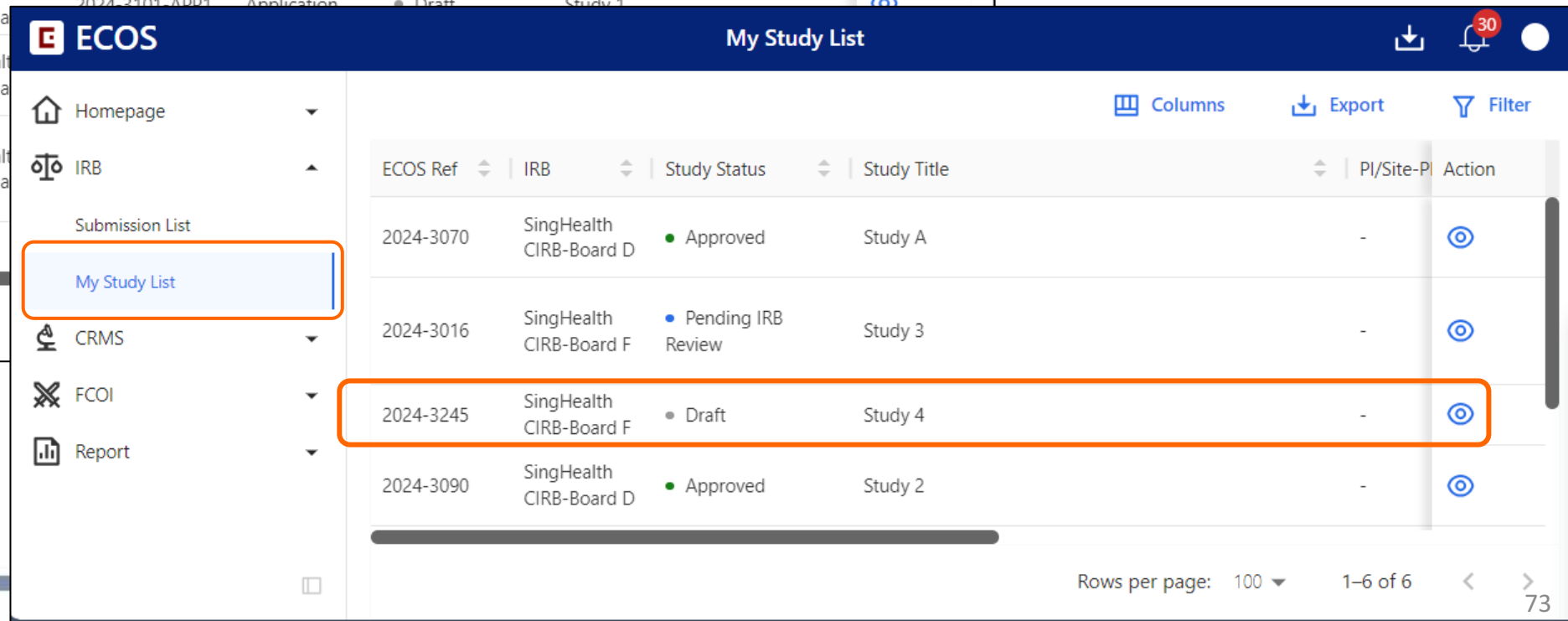


IRB Accessibility

Role used: Study Sponsor (SS_20)

- SS_20 can also access to the IRB APP Form in the IRB module.





ECOS

Mandatory Fields for Pharmaceutical/ Industry-sponsored studies

National Healthcare Group
Adding years of healthy life

SingHealth
Defining Tomorrow's Medicine

In-built Logic Checks – Before IRB APP Approval

- **RECAP:**

For Pharmaceutical/ Industry-sponsored studies, the following details must be provided for the IRB Application Form to be submitted successfully.

a) Sponsor Details, **or**

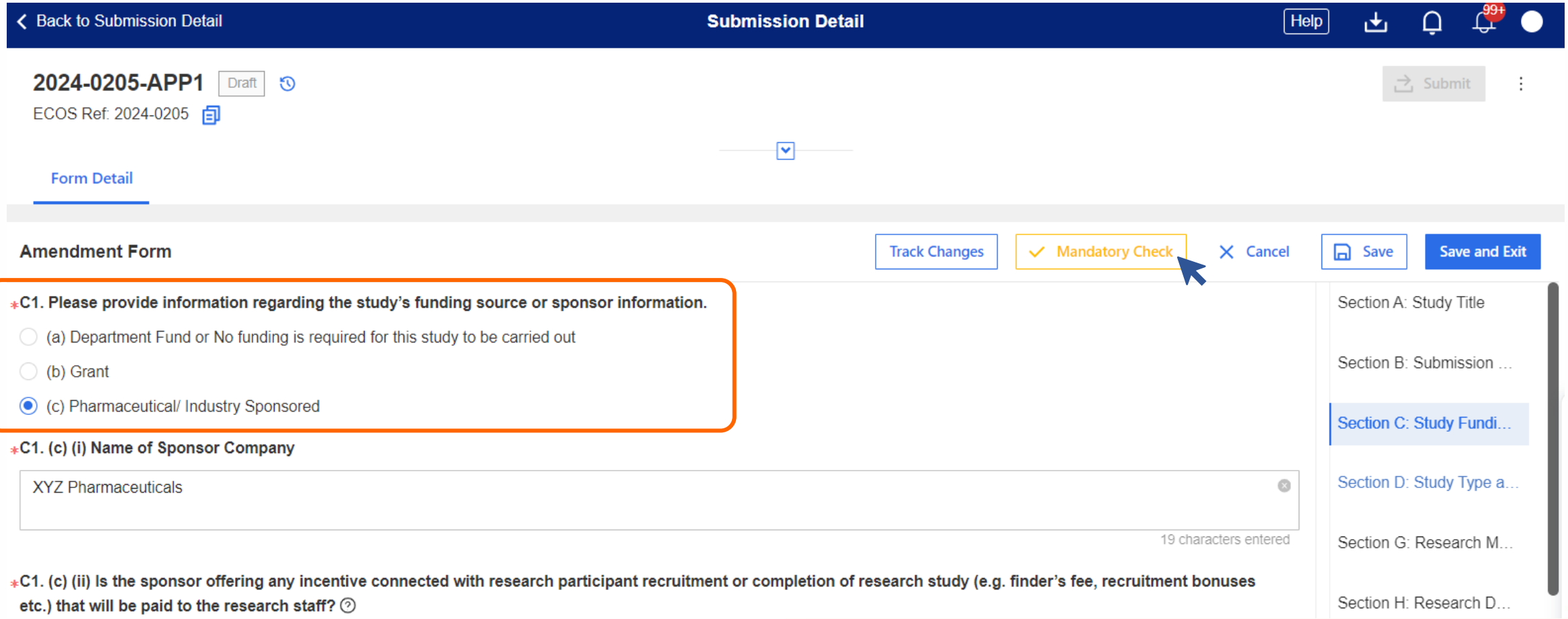
b) Clinical Research Organisation (CRO) Details, **and**

c) IRB Review Billing Details.

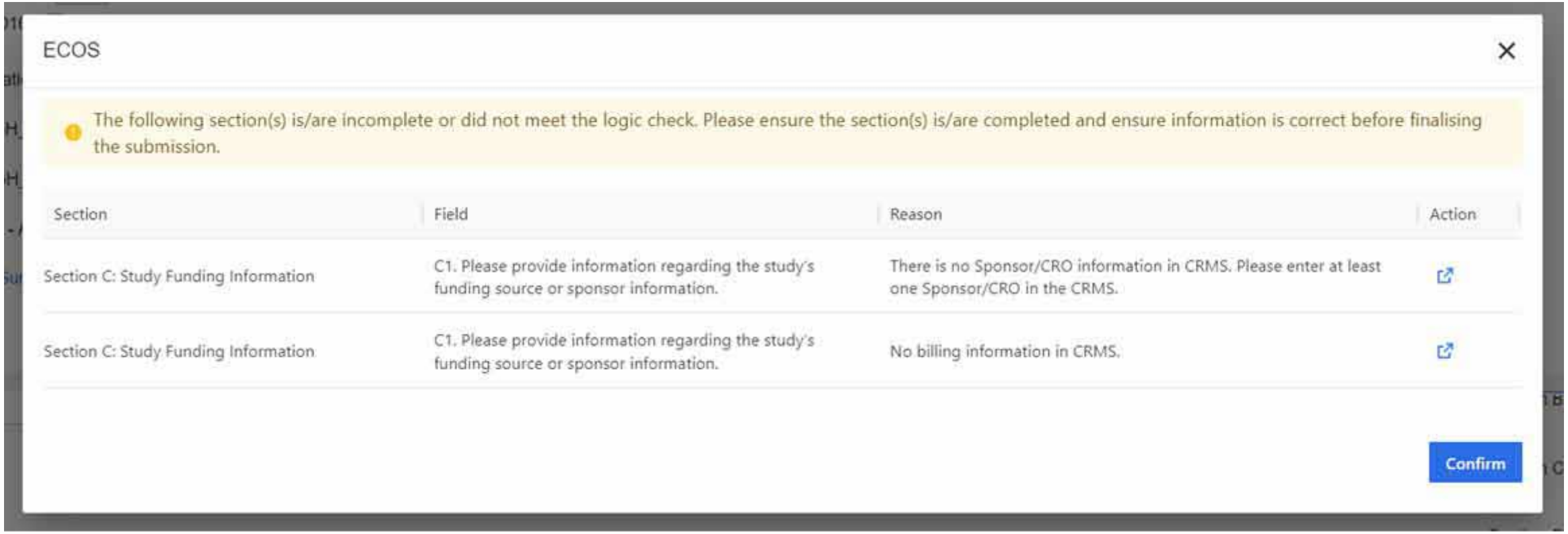
- The system will check and prevent the submission of IRB Application Form should the CRMS 'Study Information – Basic Information' page be incomplete.

IRB APP Form – Section C1

- Under Section C1 of the IRB Application Form, if the **Pharmaceutical/ Industry Sponsored** option was selected, upon clicking the **Mandatory Check** button, user will be prompted with a message *(next slide).*



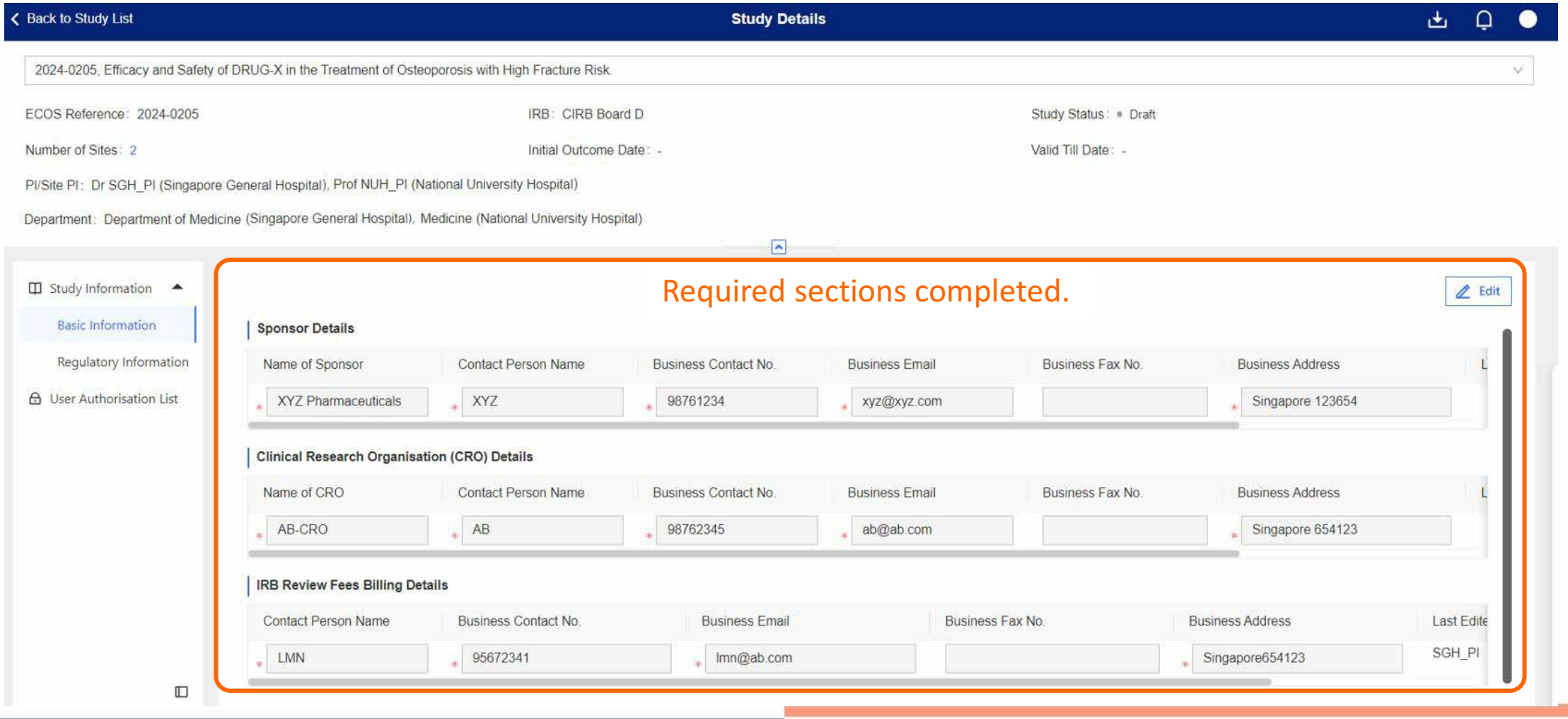
Mandatory Check Prompt From IRB APP Form



- User will need to go into CRMS > Study Information – Basic Information page to complete the necessary sections.

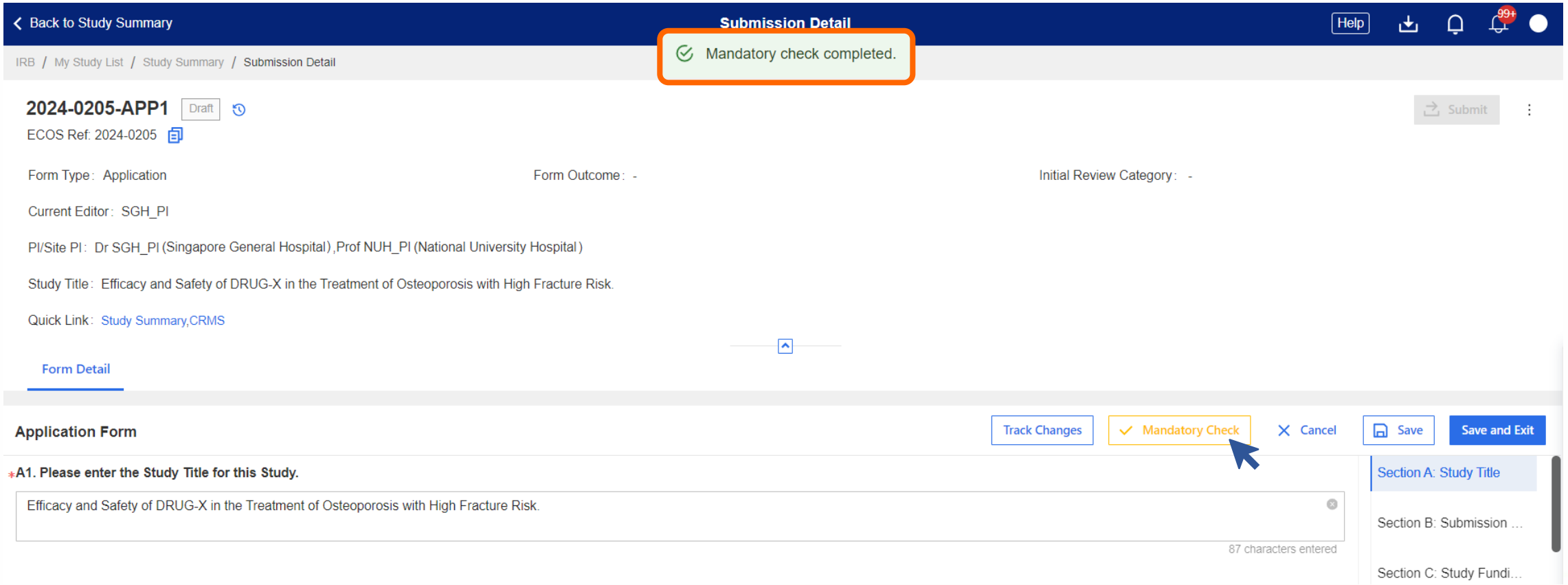
Complete Sponsor/CRO and IRB Details in CRMS

- Once completed, user will need to return to the IRB Application Form to finalise it for PI's declaration.



Return to IRB APP Form

- Click on **Mandatory Check** again, the system will inform the user that there are no outstanding tasks preventing the submission of IRB Application Form.
- User can proceed to **Save and Exit** the form, then **Finalise** or **Submit** the form.



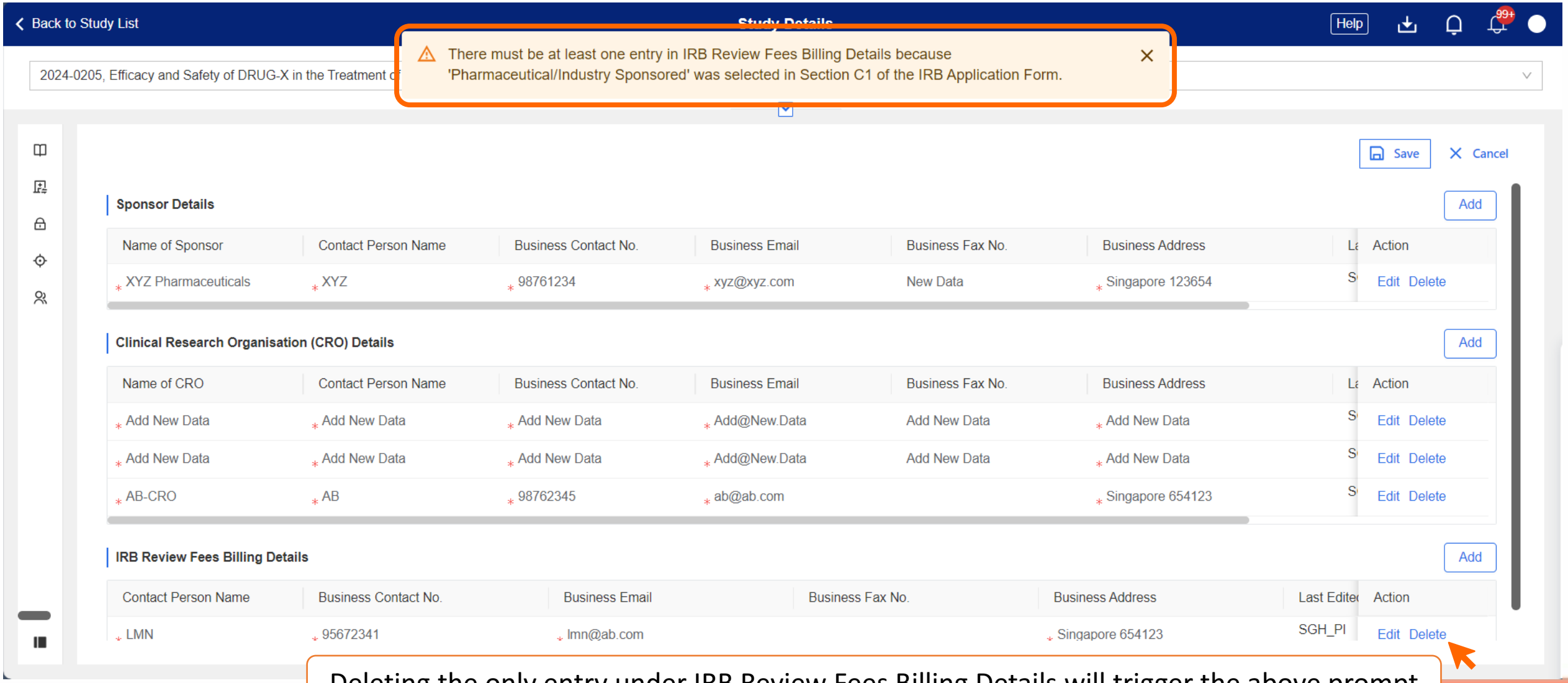
In-built Logic Checks – After IRB APP Approval

- After IRB has approved the Application Form, there will be a logic check to ensure the data in the following sections are present:
  a) Either Sponsor Details **or** Clinical Research Organisation (CRO) Details; AND
  b) IRB Review Billing Details

- The system will trigger prompts to stop the user if there is an attempt to delete the data.

- This does not affect studies funded by other sources.

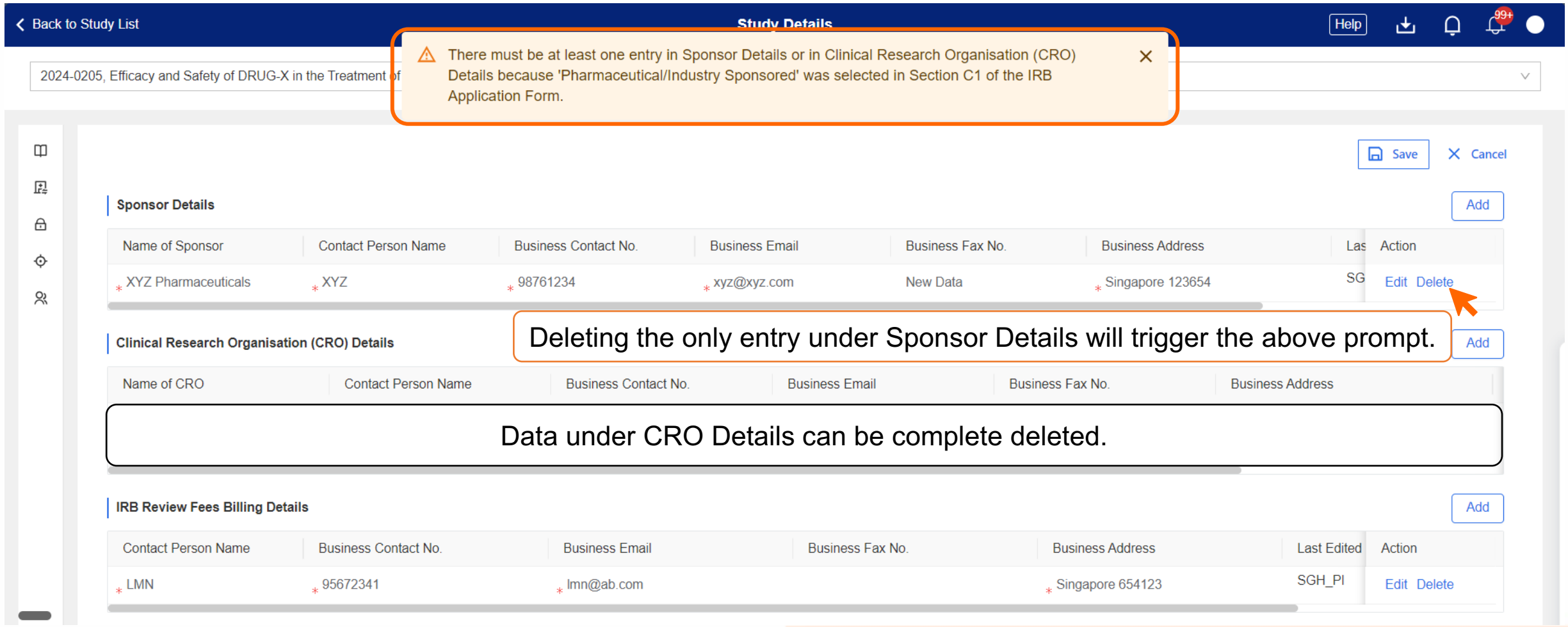
At Least 1 Entry Must Be Retained



Deleting the only entry under IRB Review Fees Billing Details will trigger the above prompt.

Applicable To Both Sponsor/CRO and IRB Details

- The system will allow the complete deletion of 1 section but not both.



ECOS

CRMS General Page Functions

National Healthcare Group
Adding years of healthy life

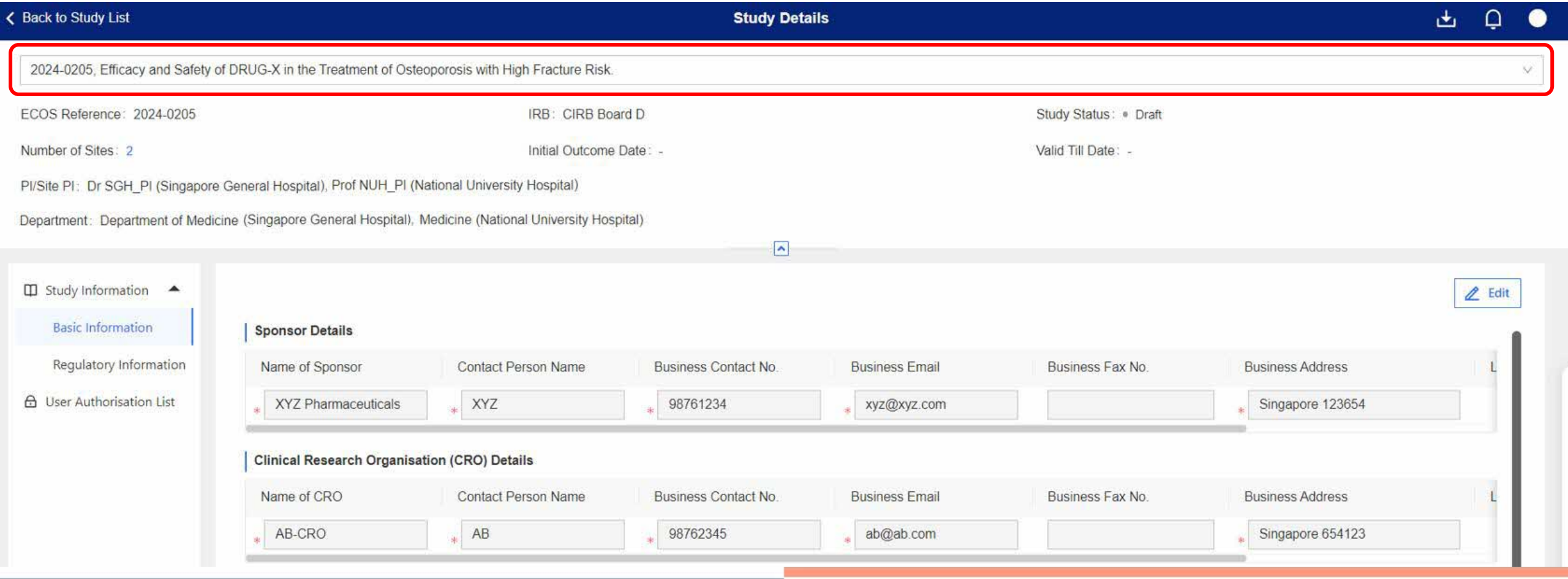
SingHealth
Defining Tomorrow's Medicine

CRMS General Page Functions

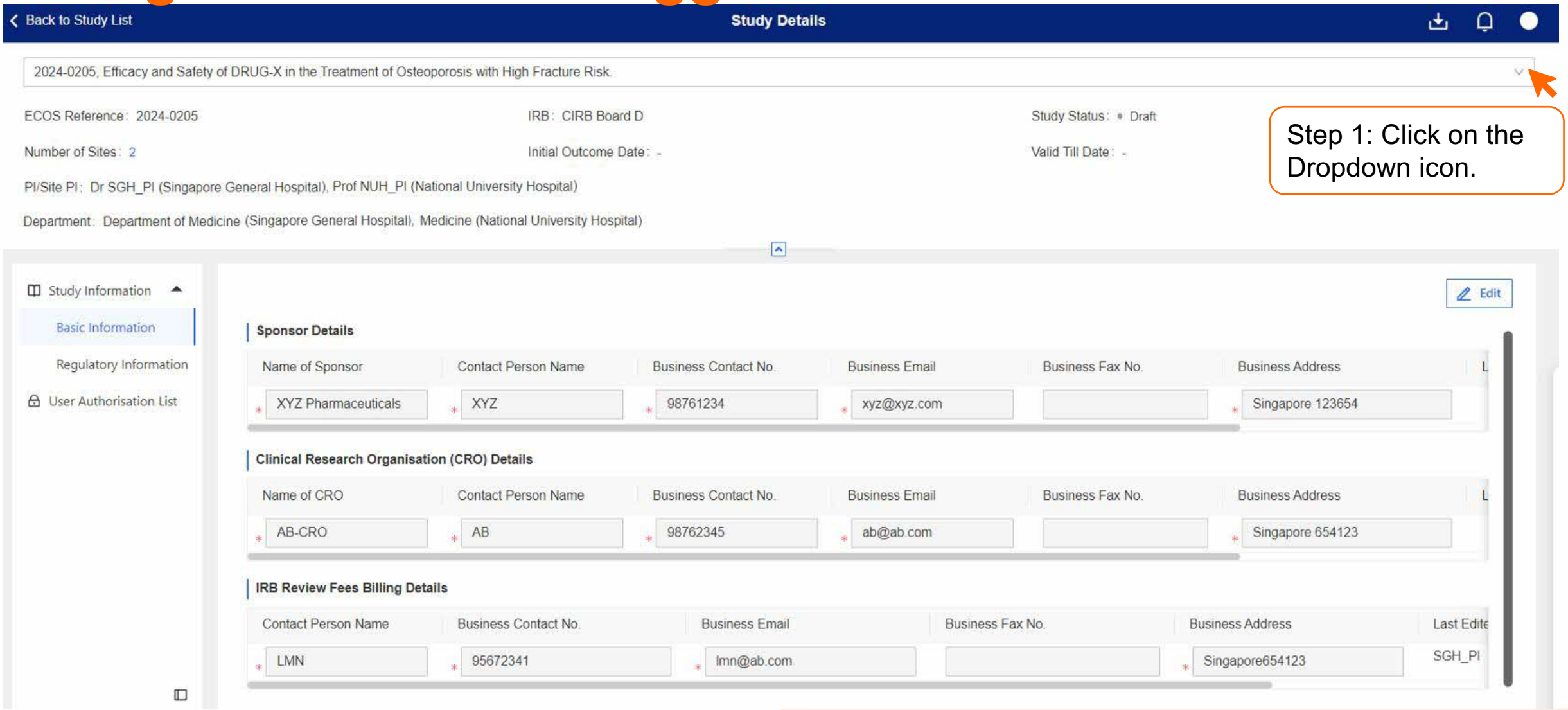
- Every CRMS webpage has the similar page functions.
- The next few slides demonstrate how the page functions work, it applies to all pages that has the exact function.
- The available functions are: -
  - ✓ Toggle between different studies
  - ✓ Collapse the Study Details panel and CRMS Side Navigation Bar
  - ✓ Expand the Study Details panel and CRMS Side Navigation Bar
  - ✓ Edit data
    - Add data
    - Delete data
    - Save data
    - Cancel edit
  - ✓ Filter/search for data in lists
  - ✓ Select columns to display in the lists
  - ✓ Export
  - ✓ Add user in User Authorisation List
  - ✓ Deactivate user in User Authorisation List

Page Functions – Toggle between different studies

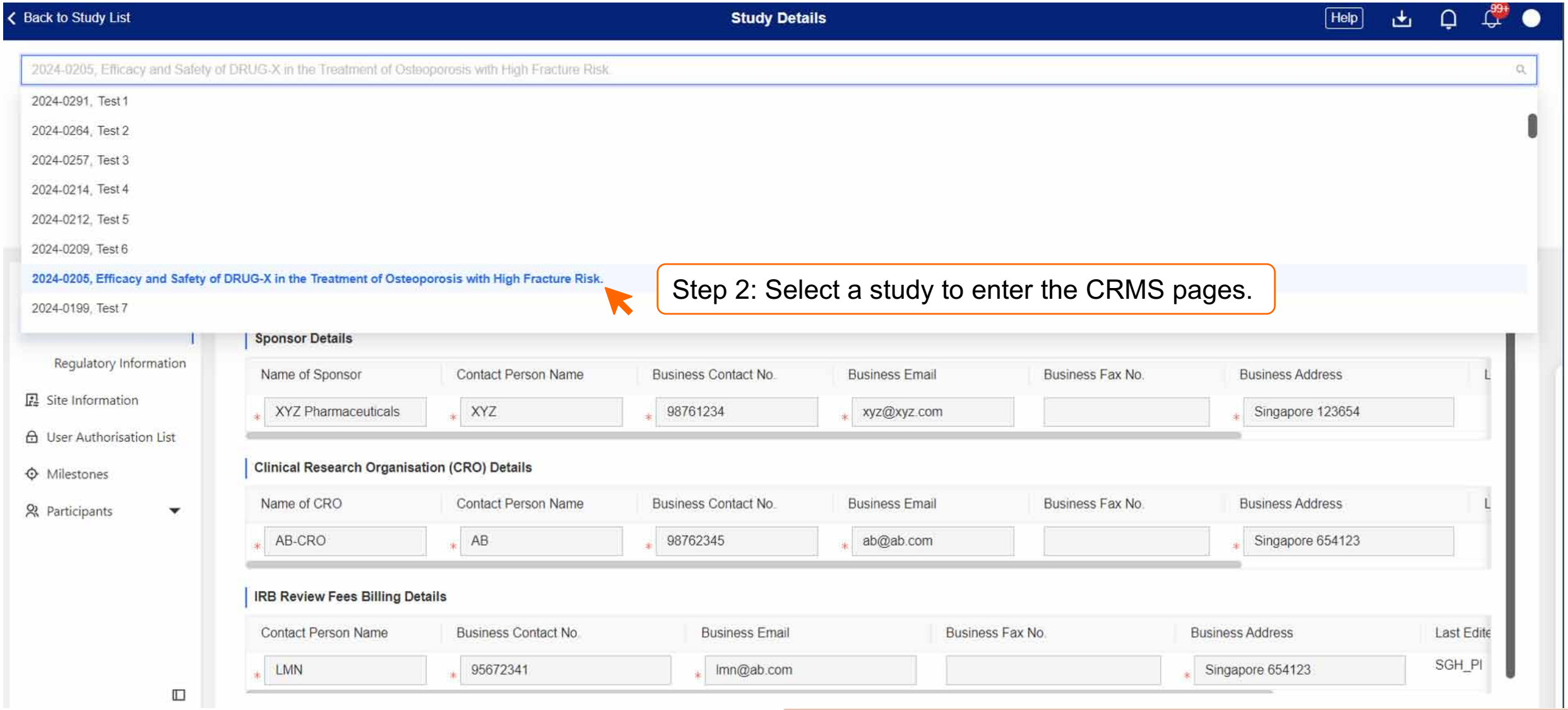
- Red box highlights the Study Dropdown Bar.
- User can toggle to another study using this bar.



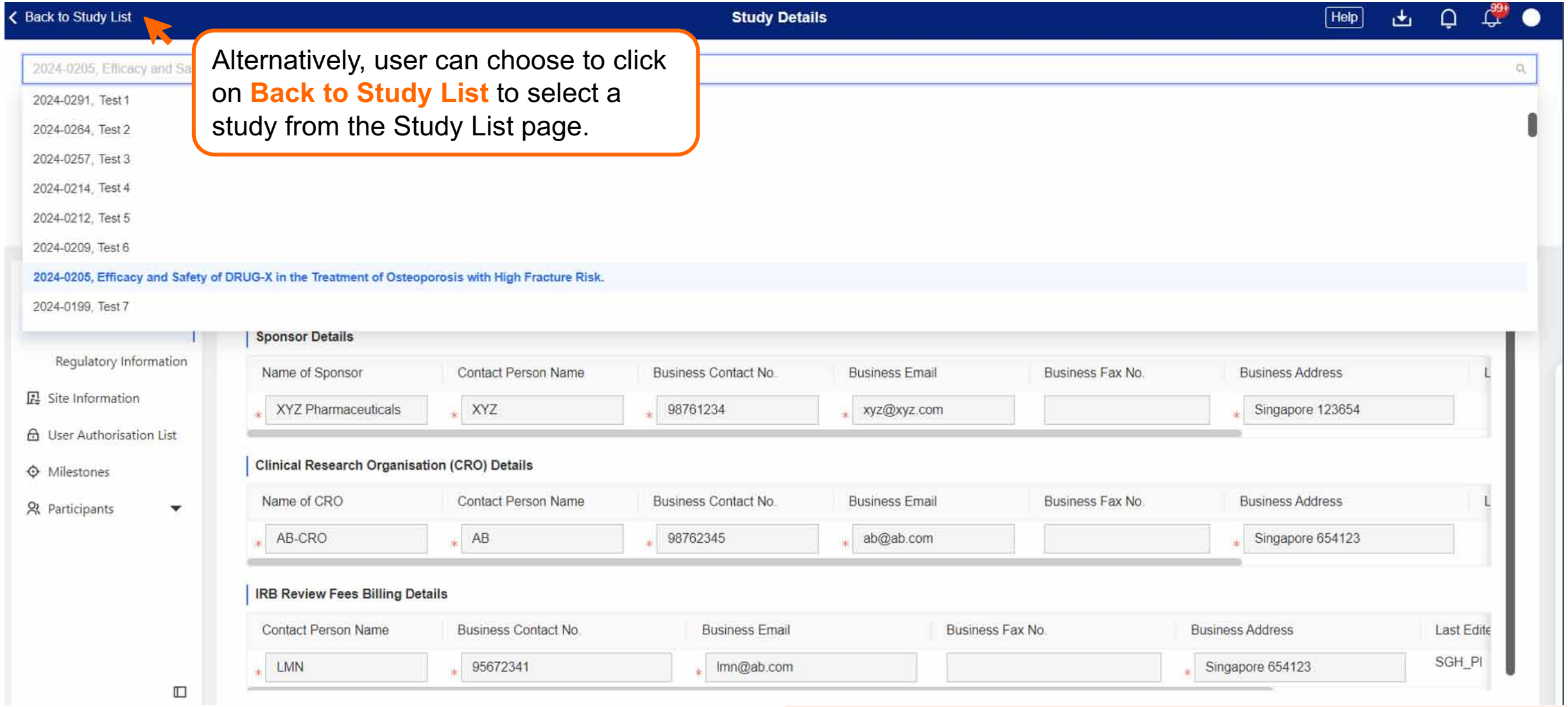
Page Functions – Toggle between different studies



Page Functions – Toggle between different studies

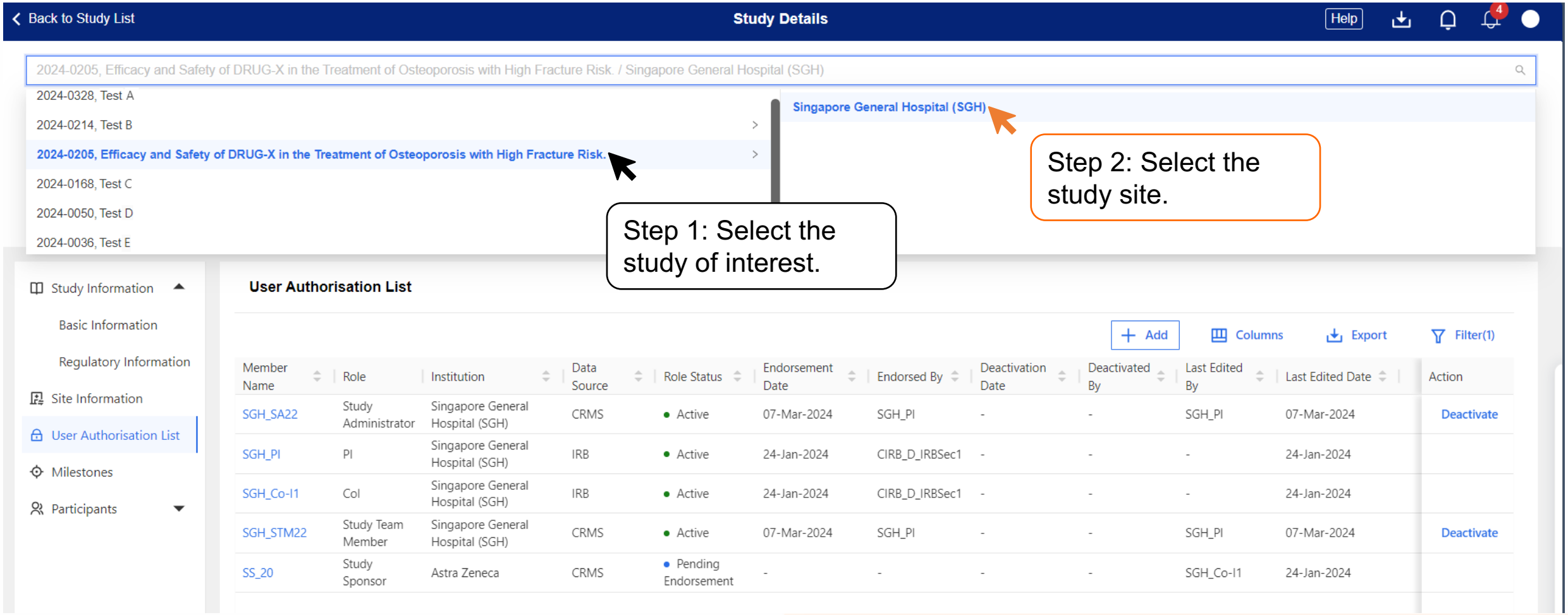


Page Functions – Toggle between different studies



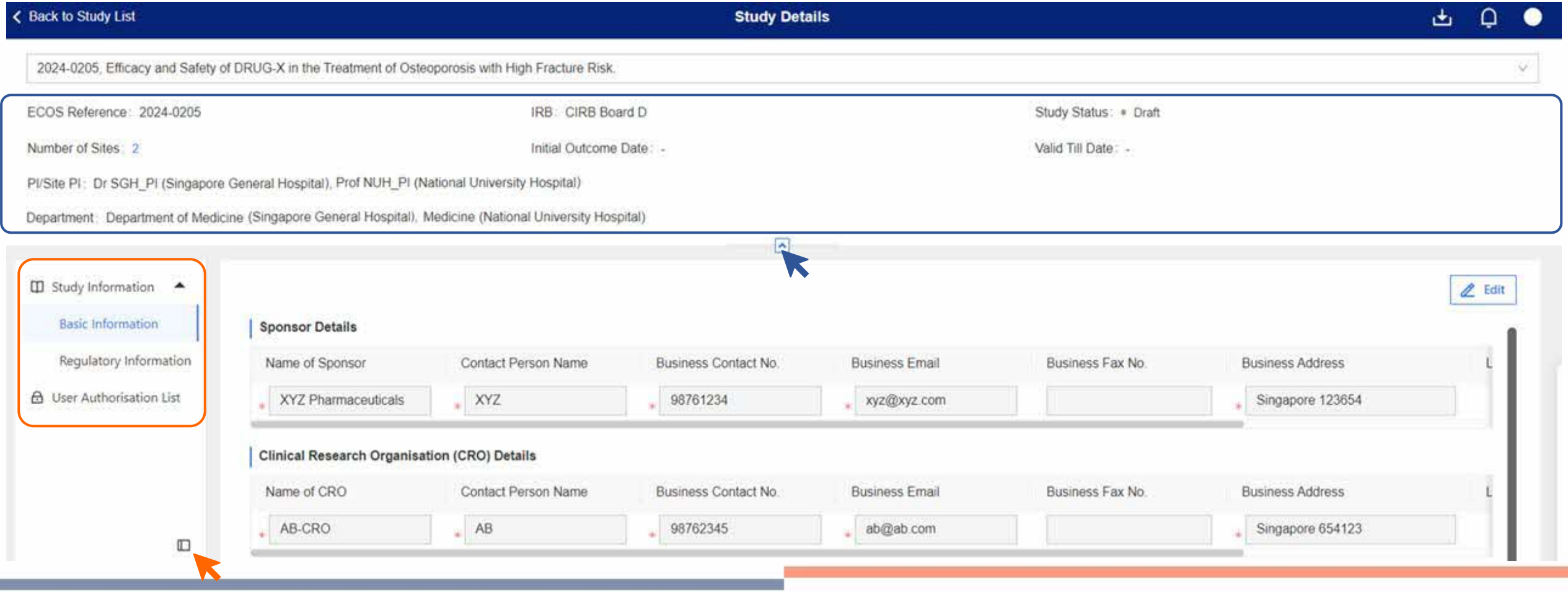
Page Functions – Toggle between different studies

- For Site Level pages, user will need to additionally select the study site before toggling to another study.



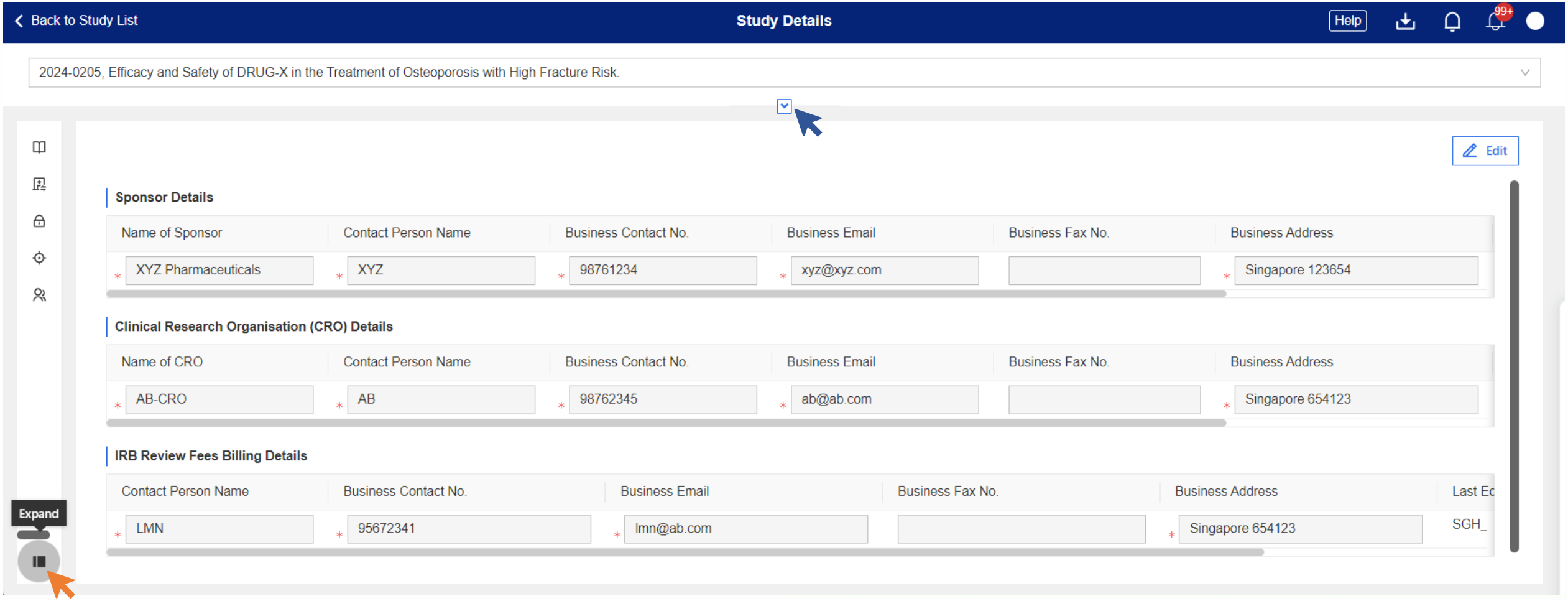
Page Function – Collapse

- Study Details panel on top and the CRMS Side Navigation Bar on the left are expanded by default.
- To collapse either sections, click on the **Up arrow** on top or the **Panel icon** at the bottom left, respectively.



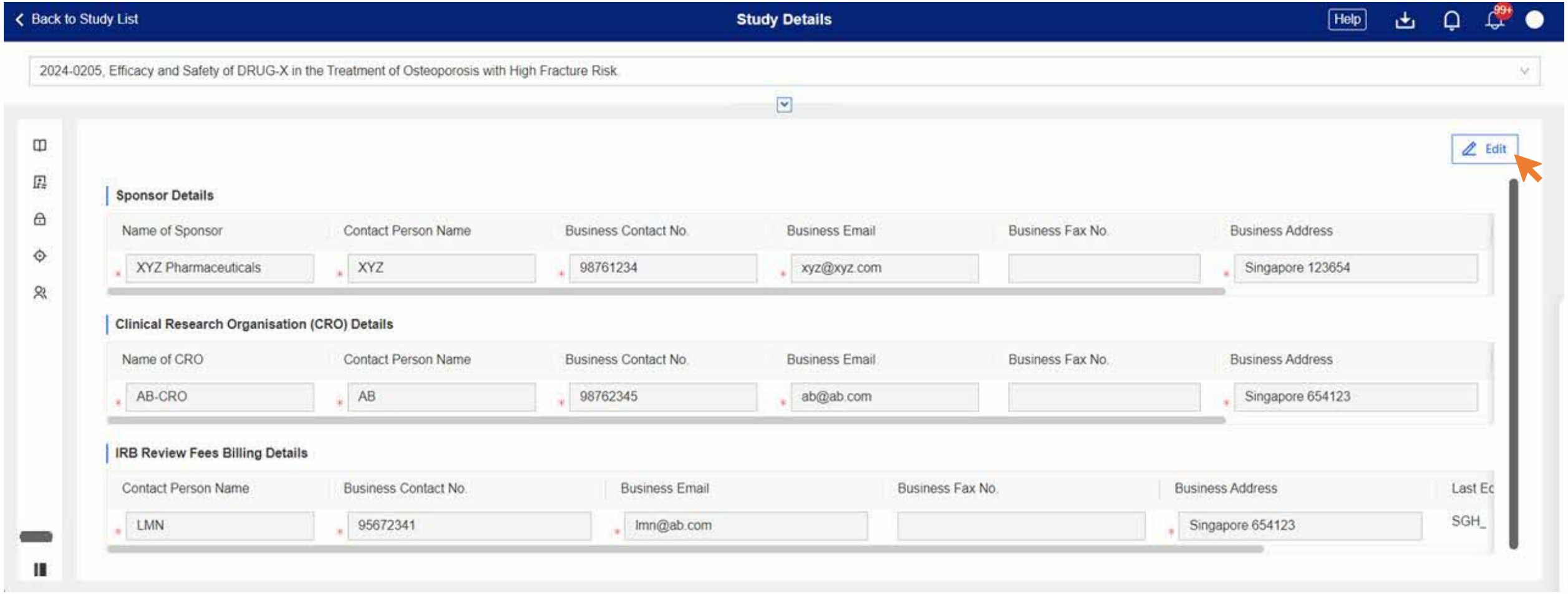
Page Functions – Expand

- Likewise, to expand either sections, click on the **Down arrow** or the **Panel icon,** respectively.



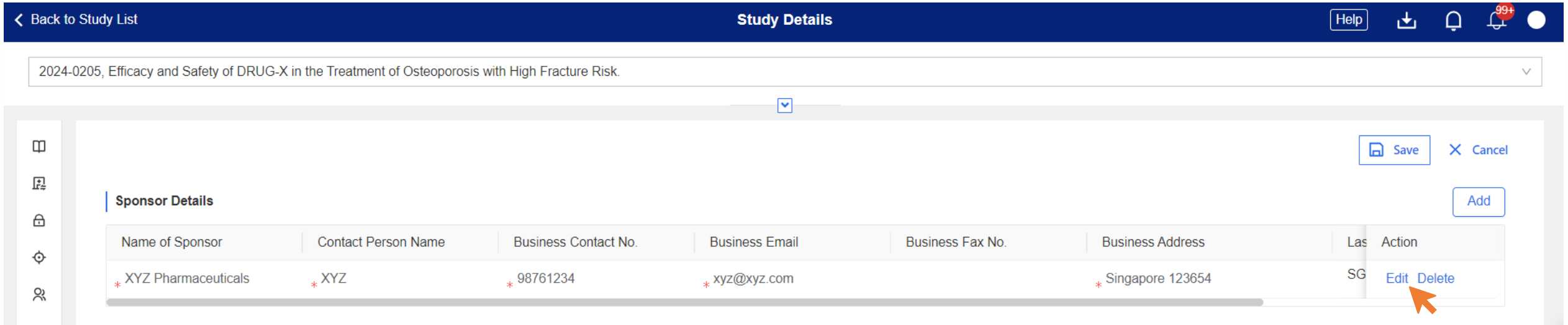
Page Functions – Edit Data

- Click **Edit** to edit the page and to reveal more page functions.

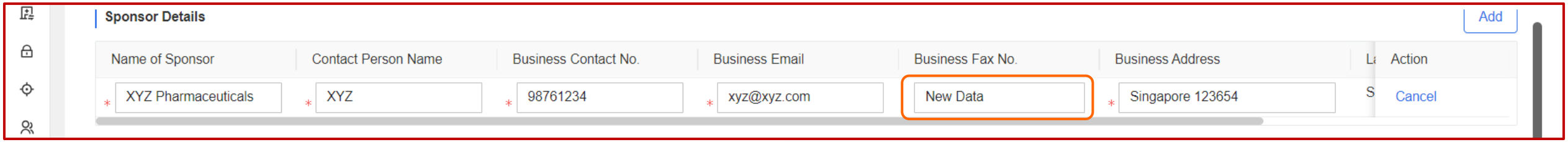


Page Functions – Edit Data

- Other page functions such as Save, Cancel, Add, Edit and Delete will appear.
- To edit any existing data, click **Edit** for the corresponding row.

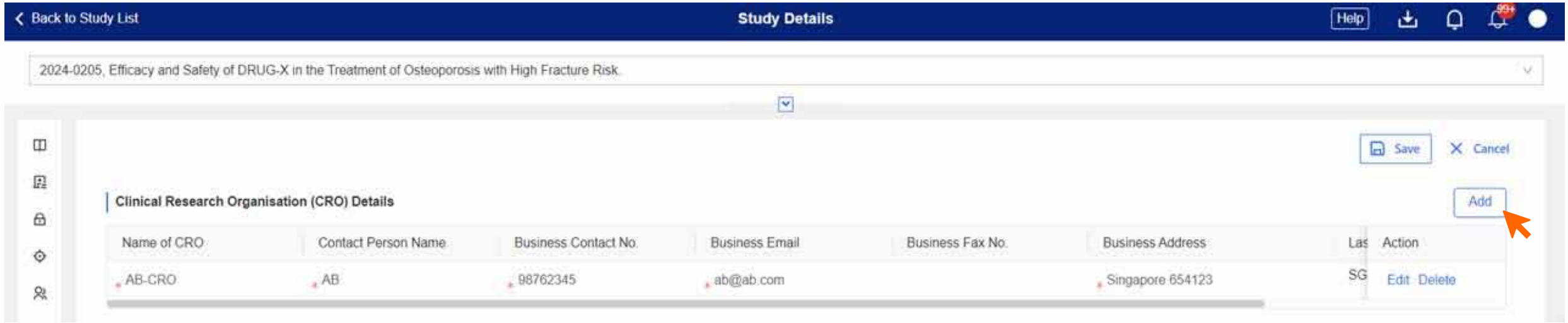


- The selected row will be unlocked for edits to be done. In this case, we have added “New Data” under **Business Fax No**.

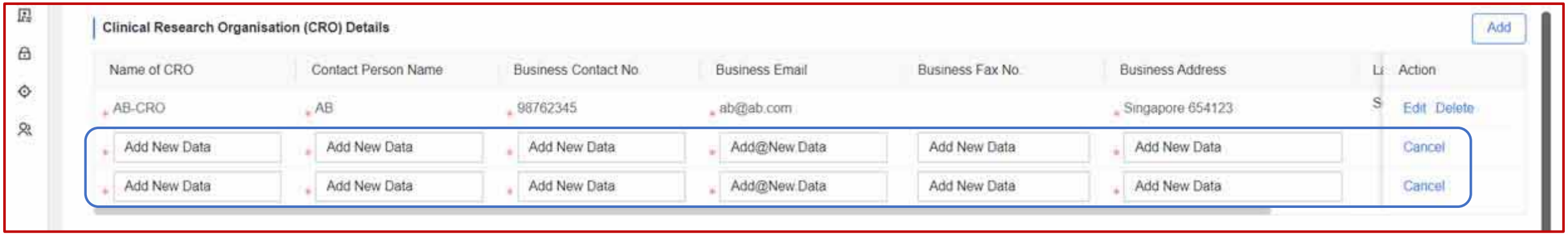


Page Functions – Add Data

- To add another row, click **Add**. If you need to add 2 rows, click **Add** twice.

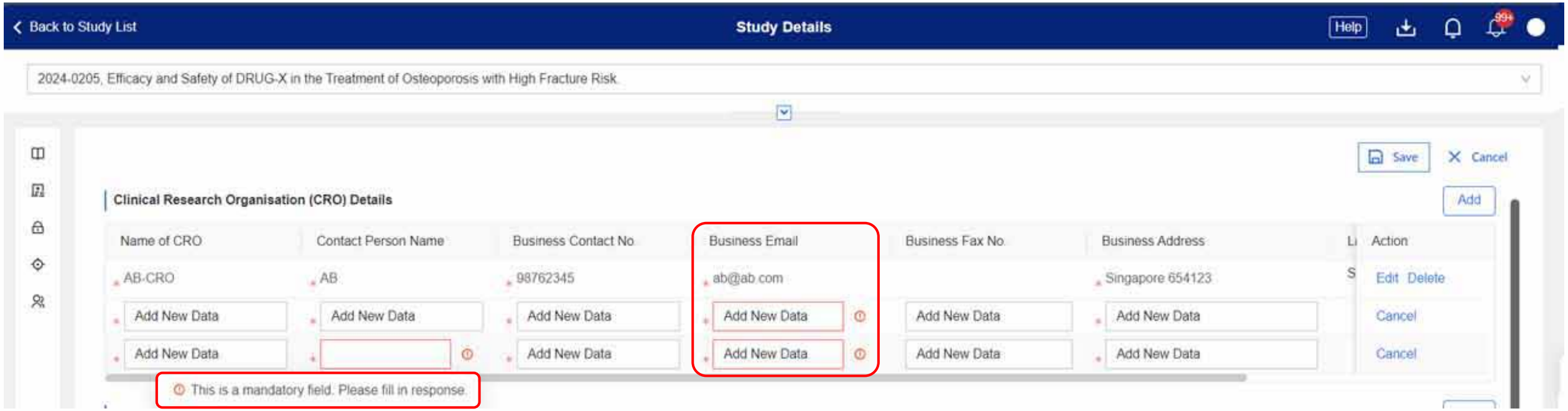


- **2 new blank rows** will be created for data entry. In this case, we entered them as “Add New Data”.



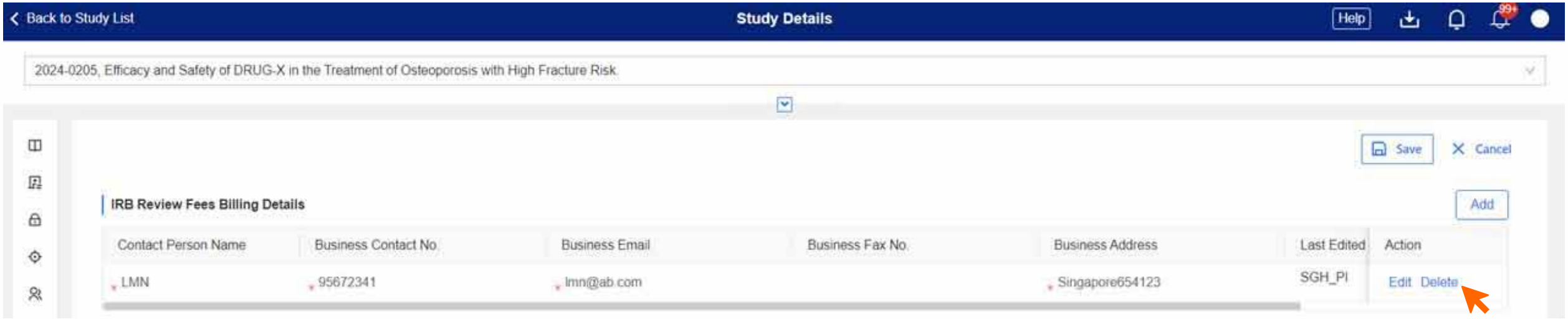
System In-built Requirements

- Mandatory fields are indicated by asterisks. If this is not completed, the system will trigger an error prompt. At the same time, the data field will be highlighted in a red outline.
- Data fields that requires email address input are configured to accept proper email address format. If this is completed incorrectly, the system will also prompt the user to enter an appropriate email address, e.g. xx@xx.com.

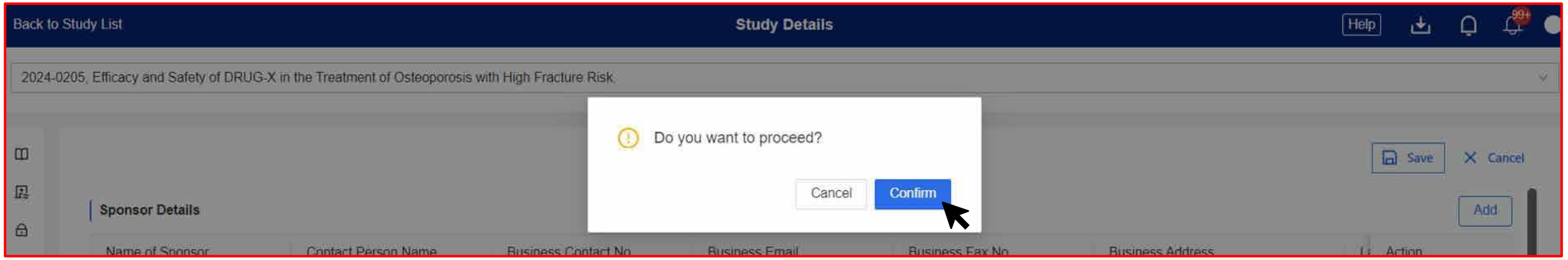


Page Functions – Delete Data

- To delete a row, click **Delete**. Multiples rows can be deleted as needed.

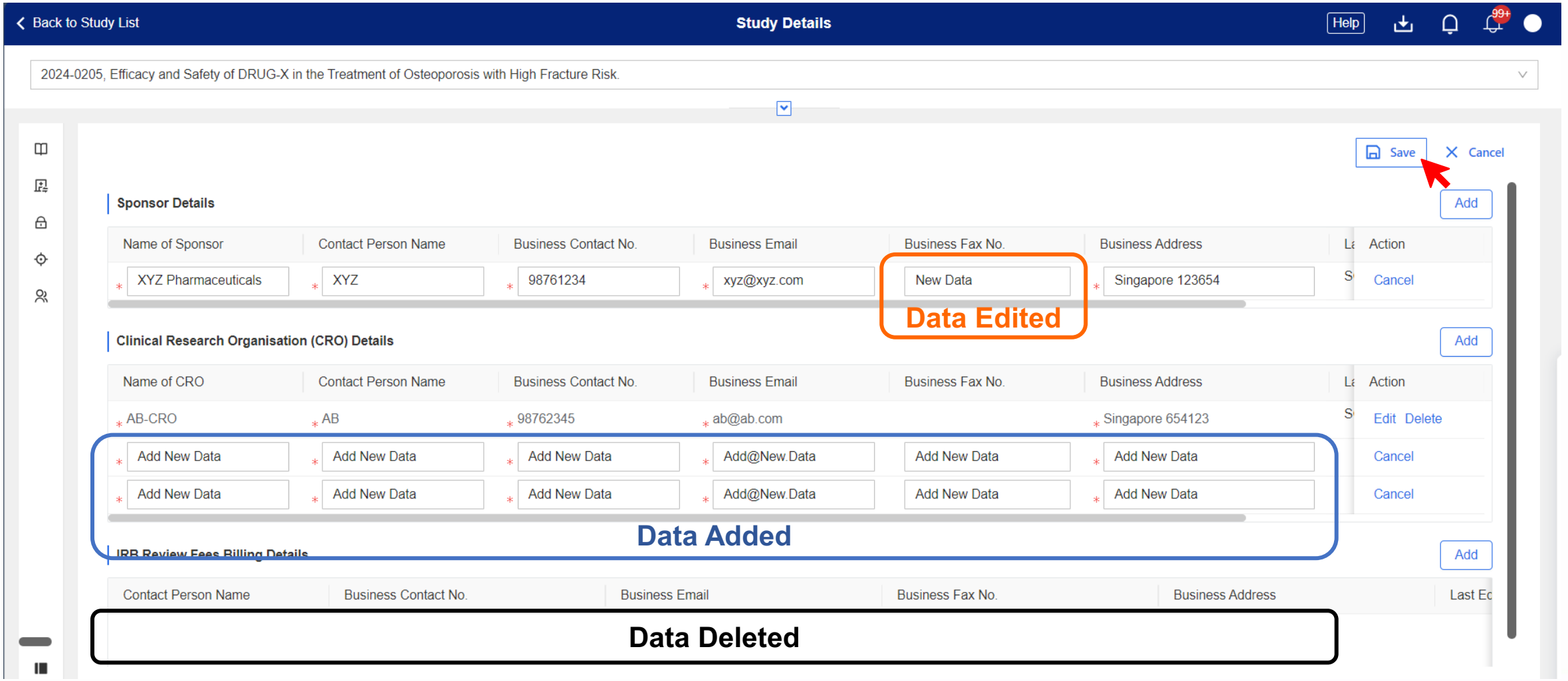


- The system will generate a prompt to confirm deletion. Click **Confirm** to proceed.



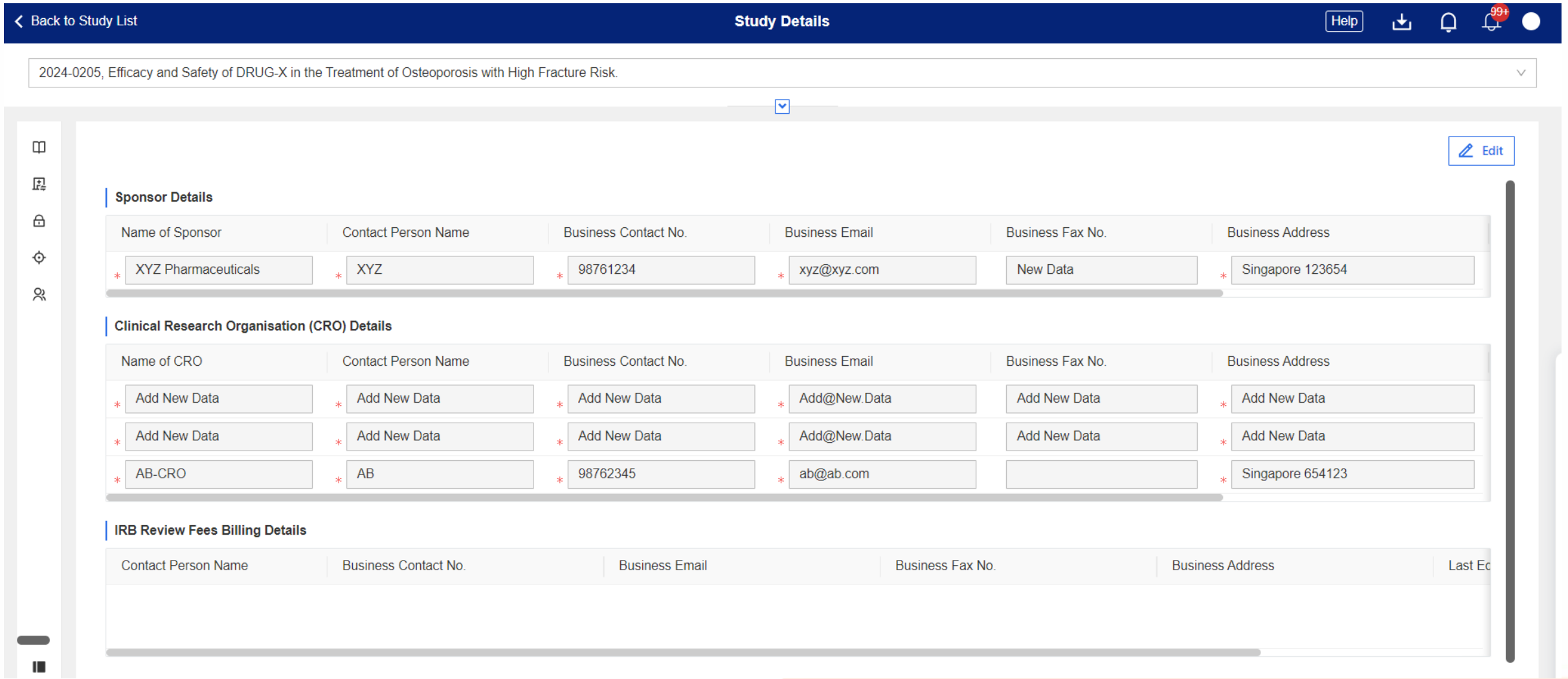
Page Functions – Save Data

- Click **Save** to save all changes made.



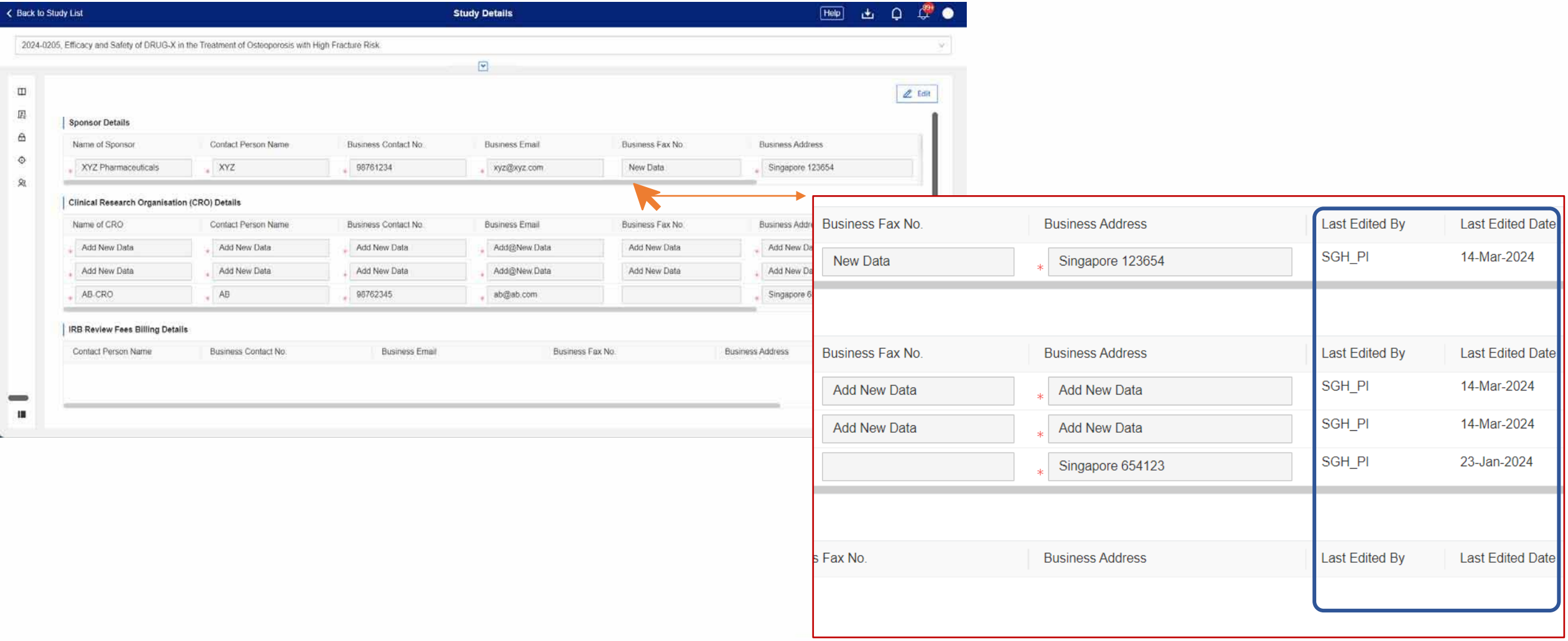
Page Functions – Save Data

- Page view after Save.



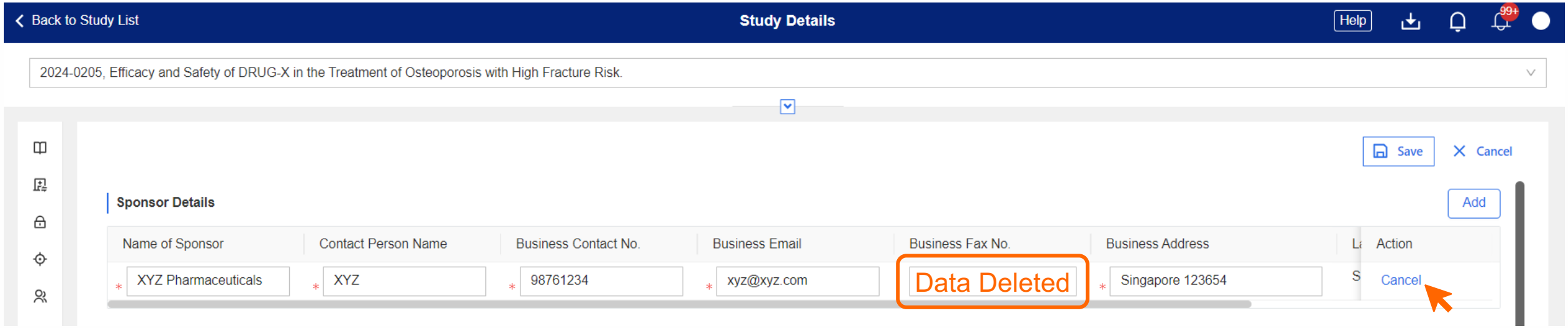
Page Functions – Save Data

- Drag the **scroll bar** of each section to the right to see the **Last Edited By** and **Last Edited Date** columns.

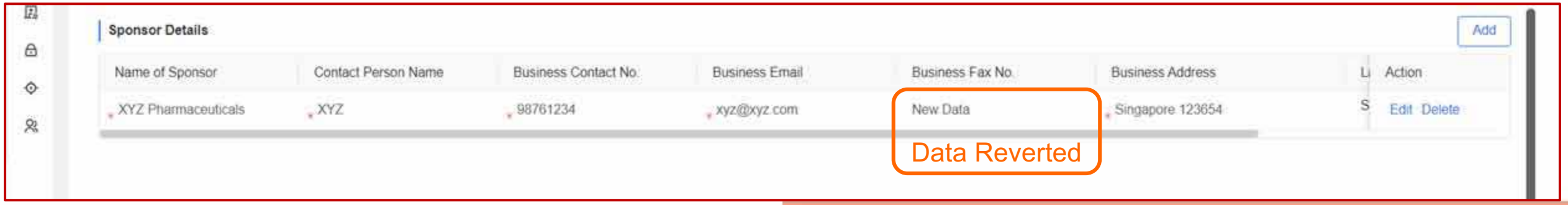


Page Functions – Cancel

- To cancel any changes done, click **Cancel**. In this case, data in the Business Fax No. has been deleted. To reverse the deletion, click **Cancel**.

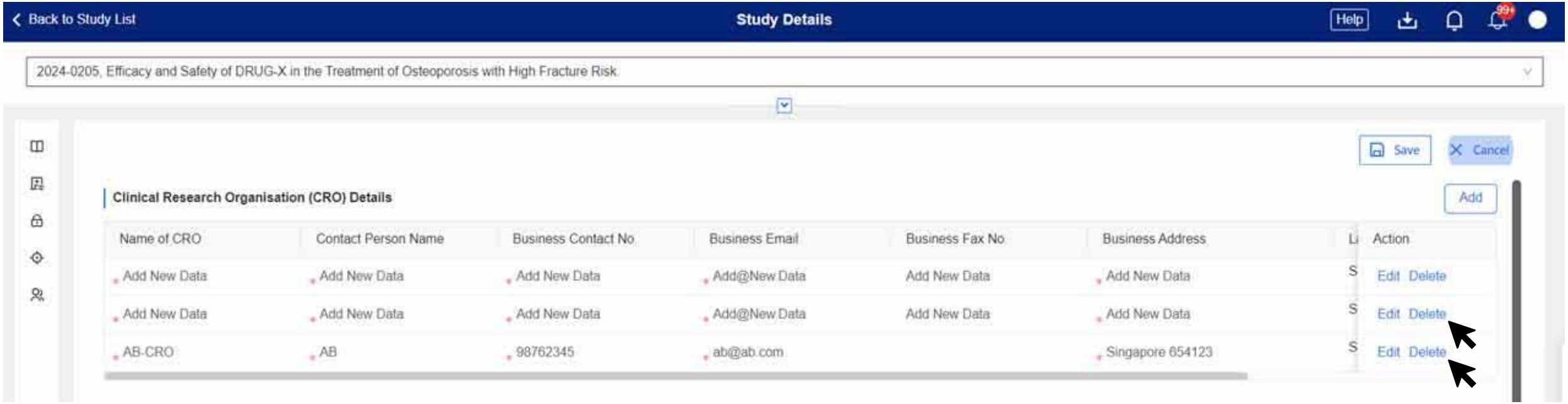


- The deleted action reversed, original data reverted.

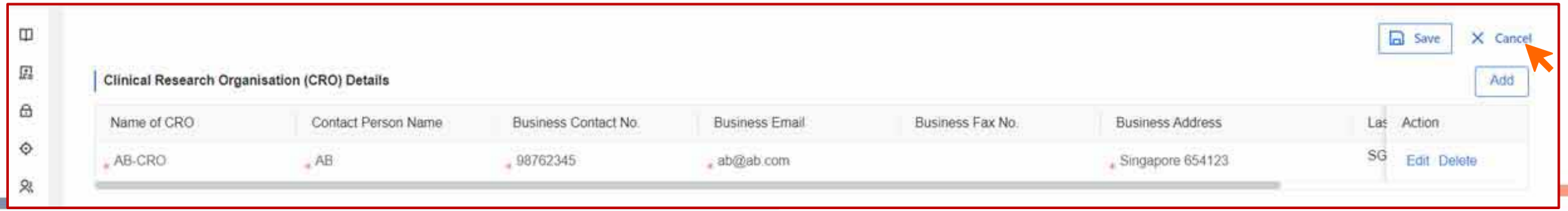


Page Functions – Cancel

- Deleted rows can also be reversed. In this case, 2 rows will be deleted for demonstration.

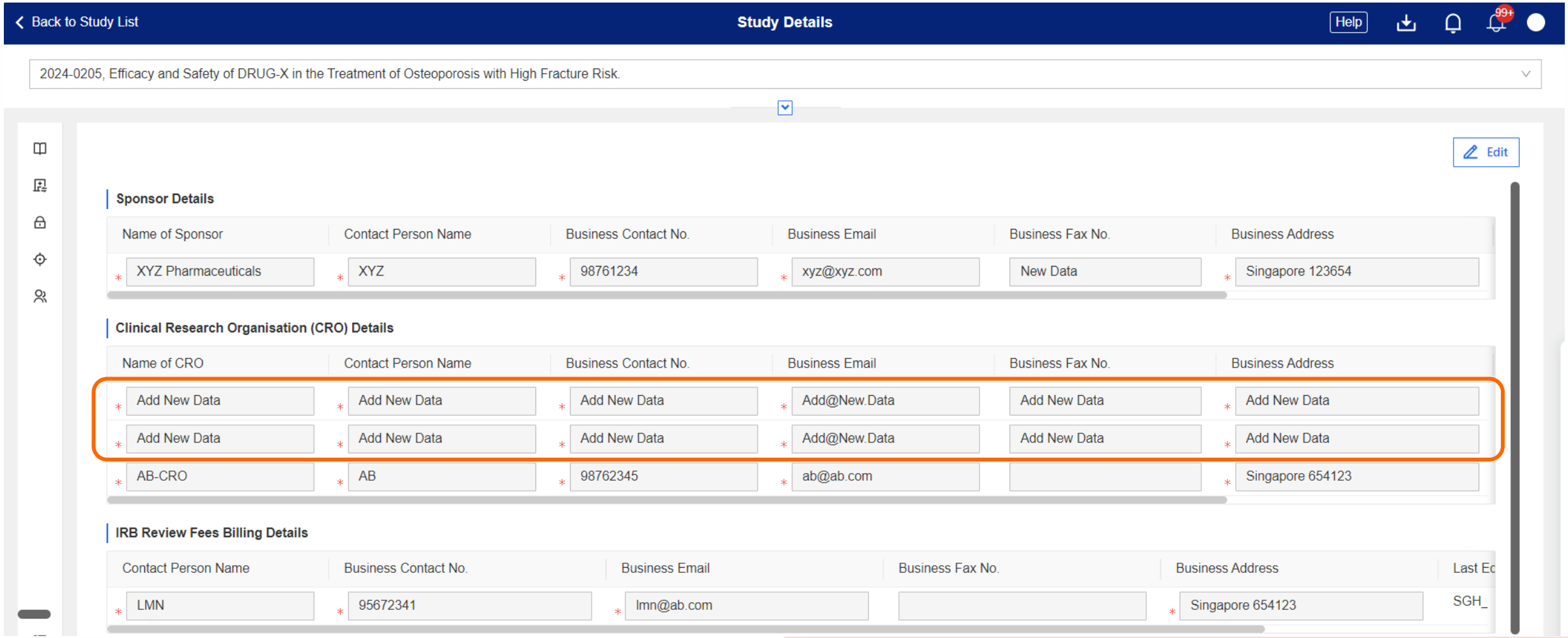


- Page view after user confirms the deletion. Click **Cancel** to reverse the deletion.



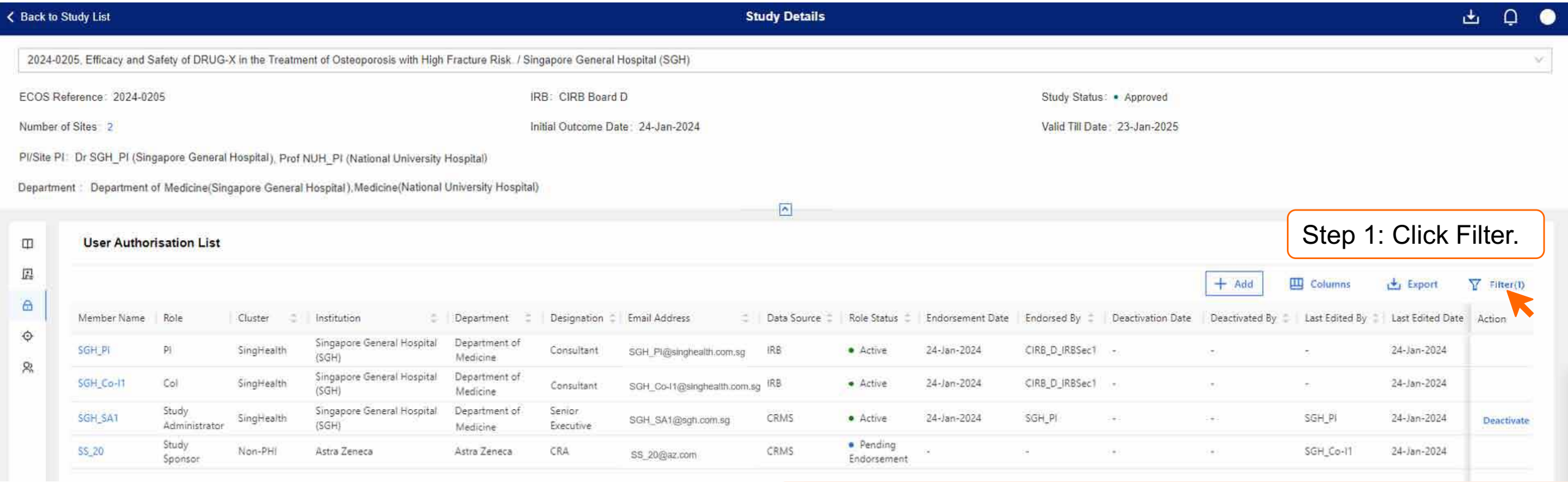
Page Functions – Cancel

- Deletion of 2 rows canceled.



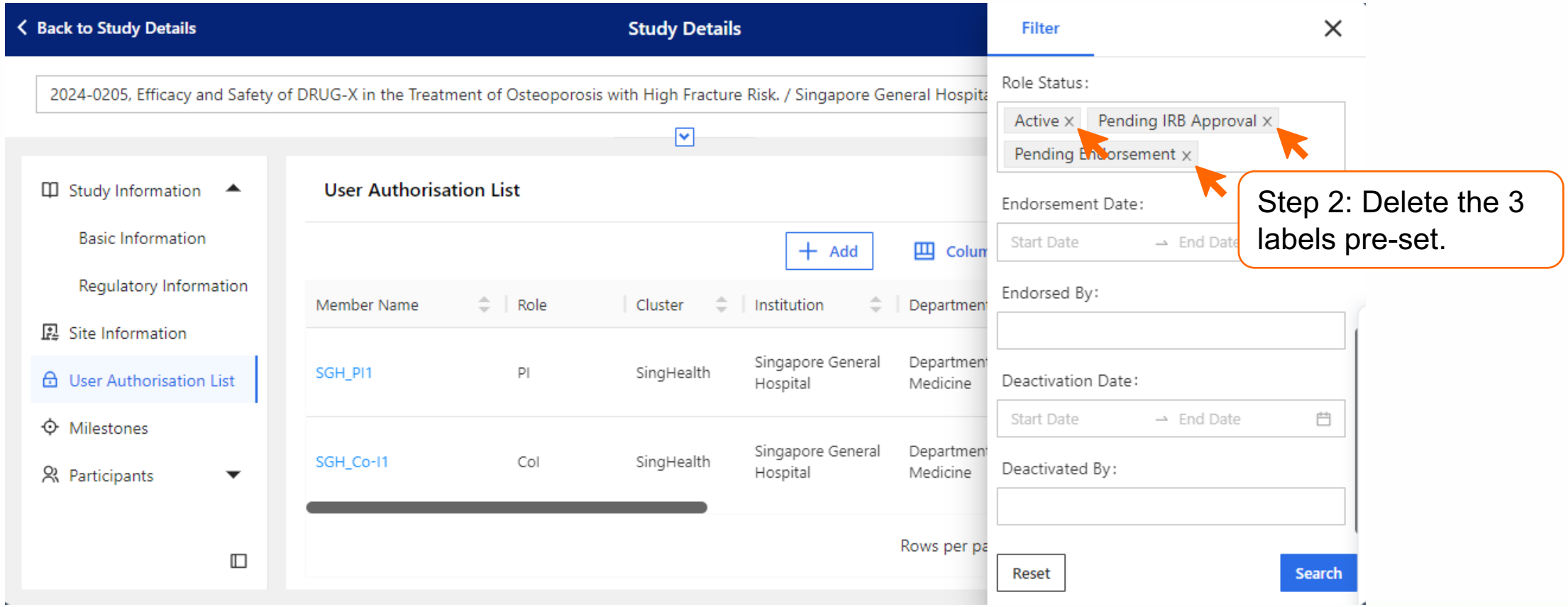
Page Functions – Filter

- In certain CRMS pages, users can use the Filter function to display specific information only.
- For example, in the User Authorisation List, it is pre-set to display only roles that are **Active**, **Pending IRB Approval** or **Pending Endorsement**.
- Filter(1) indicates that there is one (1) filter applied.



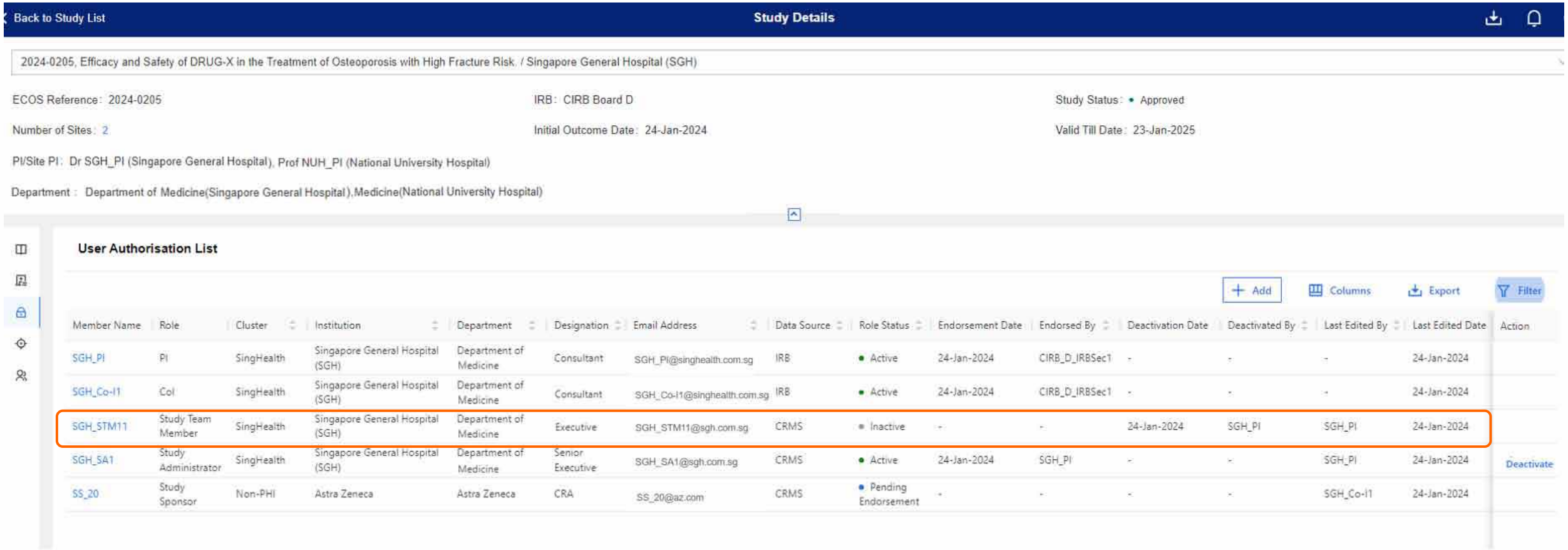
Page Functions – Filter

- Users with role status 'Active' and 'Pending' are displayed by default. To see users with any role status, **remove** the default filters.
- Alternatively, user can choose to add on the “Inactive” label under Role Status.



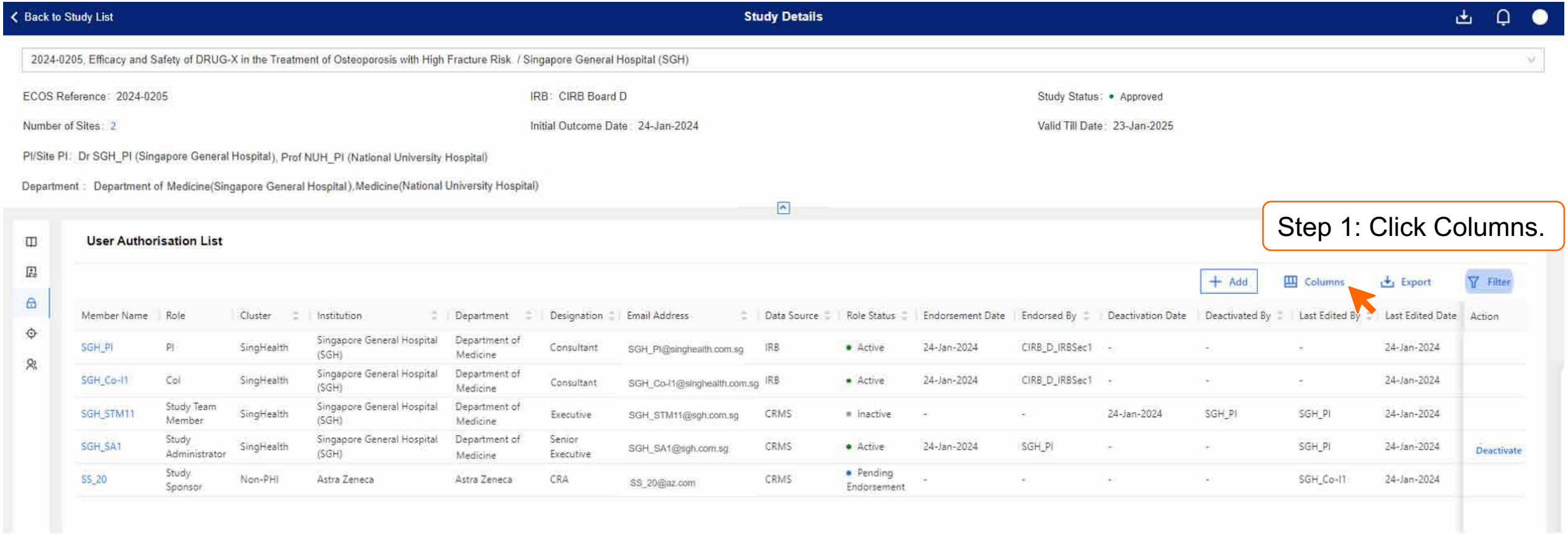
Page Functions – Filter

- With the filter removed, the User Authorisation List now displays all users, including **Inactive** ones.



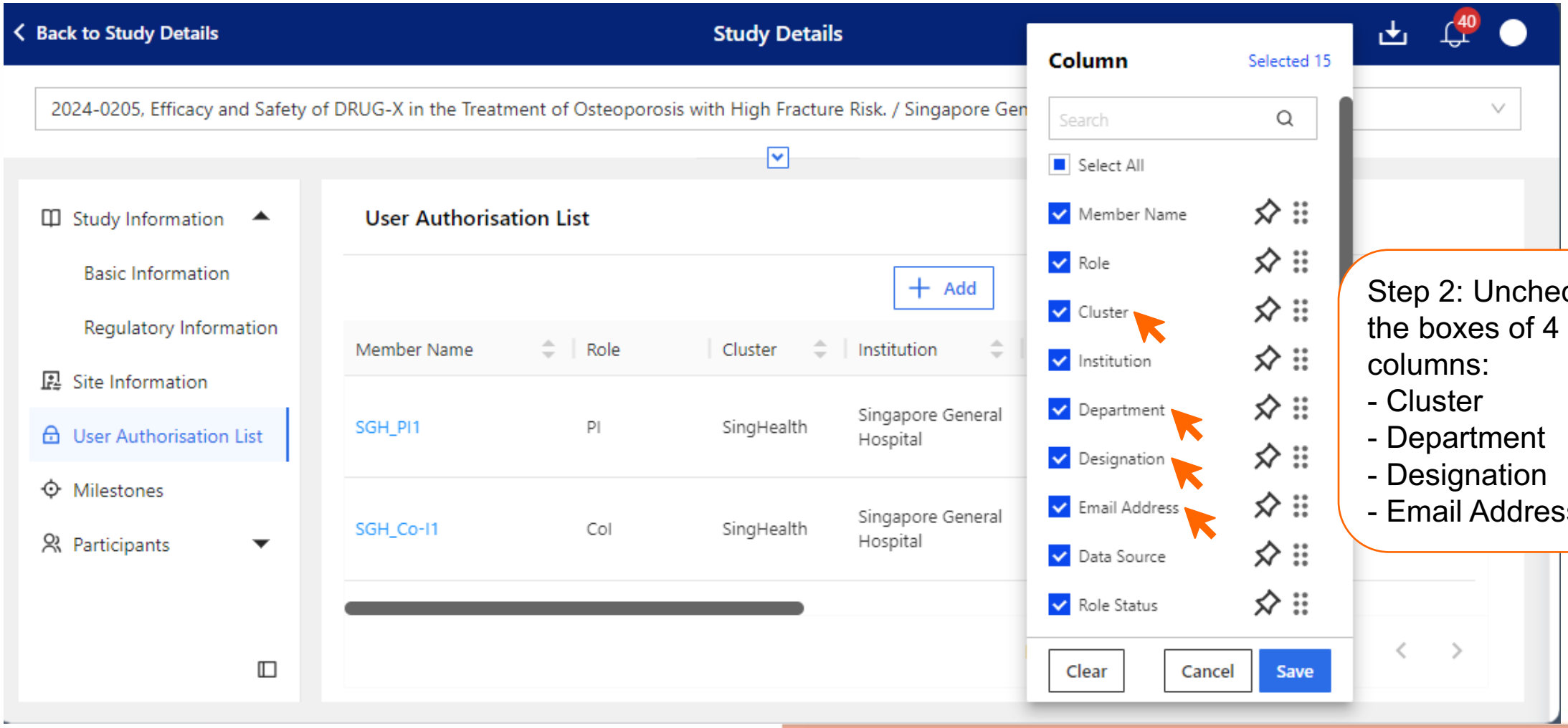
Page Functions – Columns

- Use the Columns function to narrow the information to be displayed.
- The User Authorisation List will be used as an example.



Page Functions – Columns

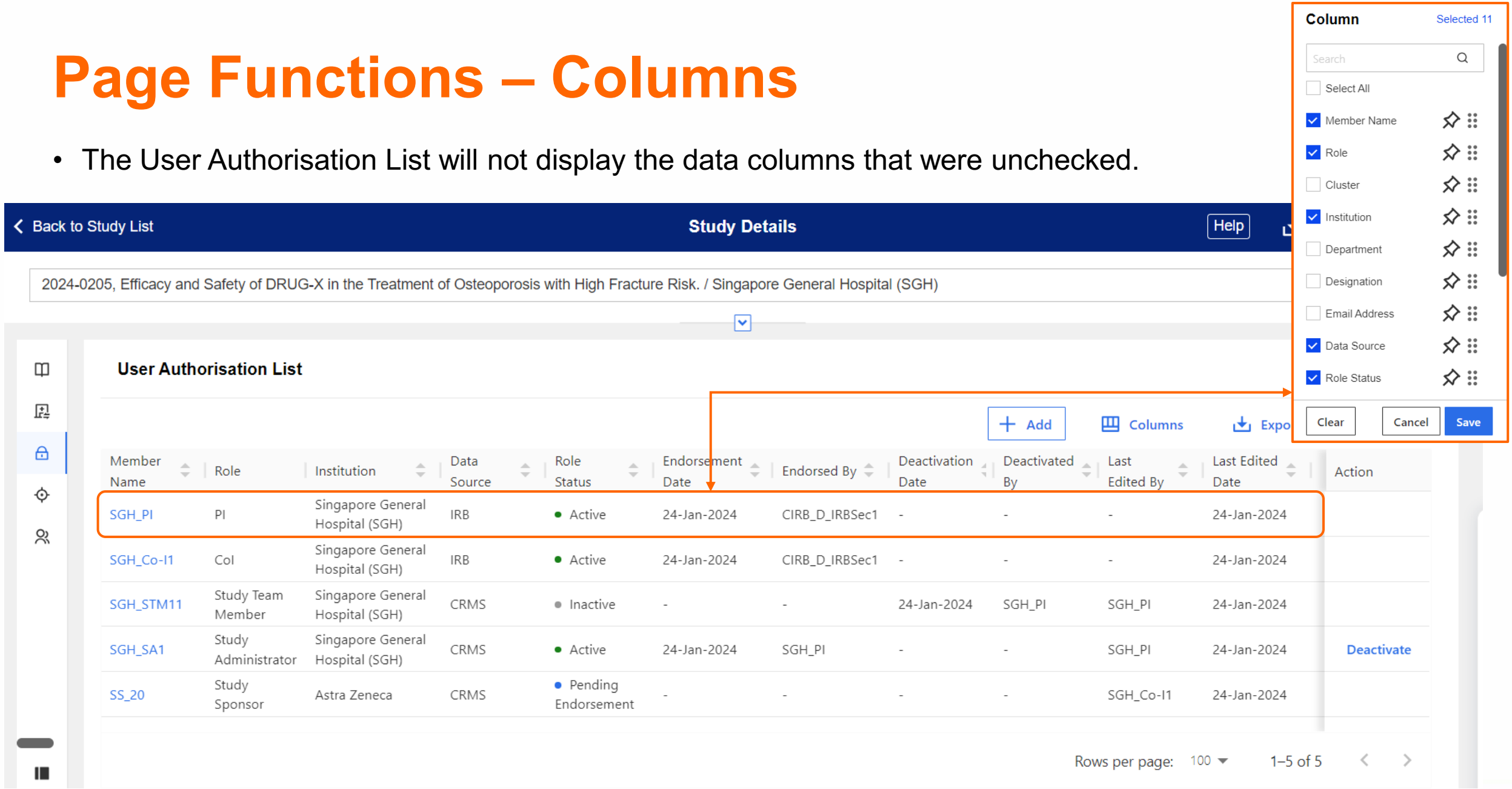
- By default, all boxes will be checked to display all data columns.



Step 2: Uncheck the boxes of 4 columns:
- Cluster
- Department
- Designation
- Email Address

Page Functions – Columns

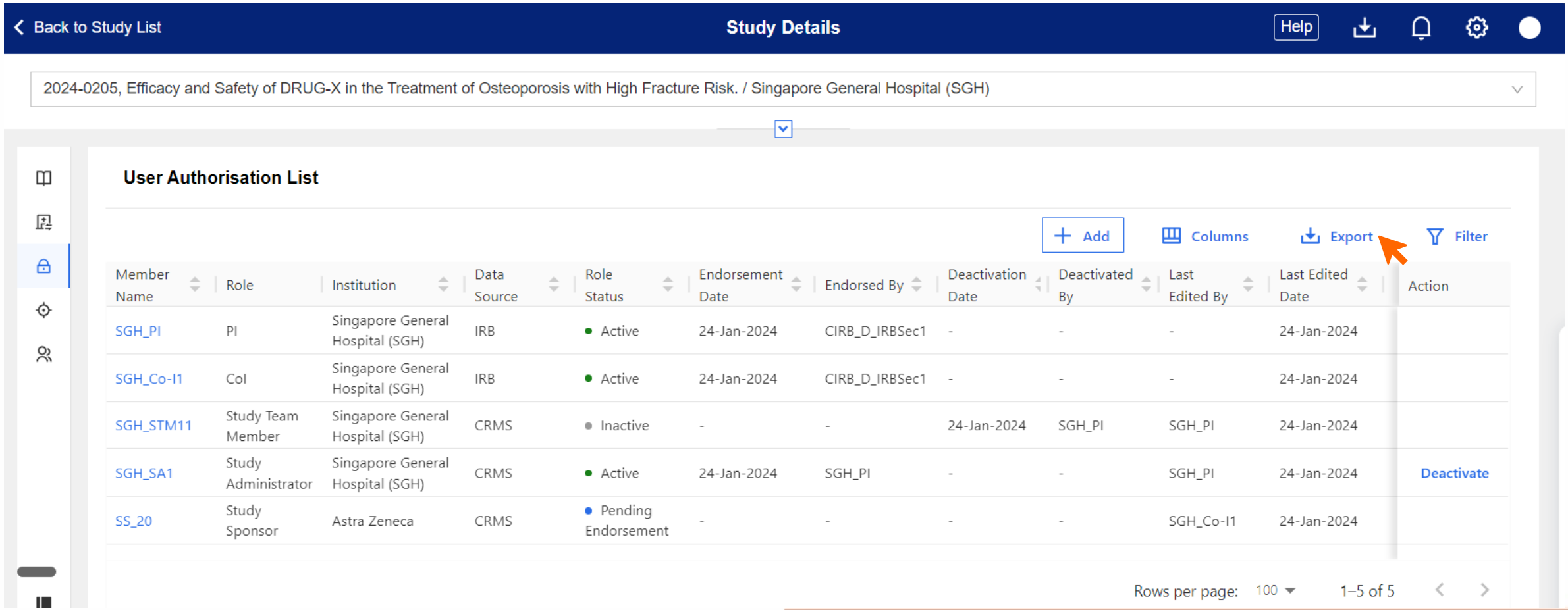
- The User Authorisation List will not display the data columns that were unchecked.



Page Functions – Export

Export function will be soft-launched in May go-live.

- Click the **Export** button to download the User Authorisation List in Excel or PDF.
- Excel offers better flexibility to modify the column and row width/heights before saving as PDF.



Page Functions – Export

Export function will be soft-launched in May go-live.

- The Export function will generate the User Authorisation List with the specific Columns and Filter selected (if any).
- Steps to export are the same across all pages that can be exported.

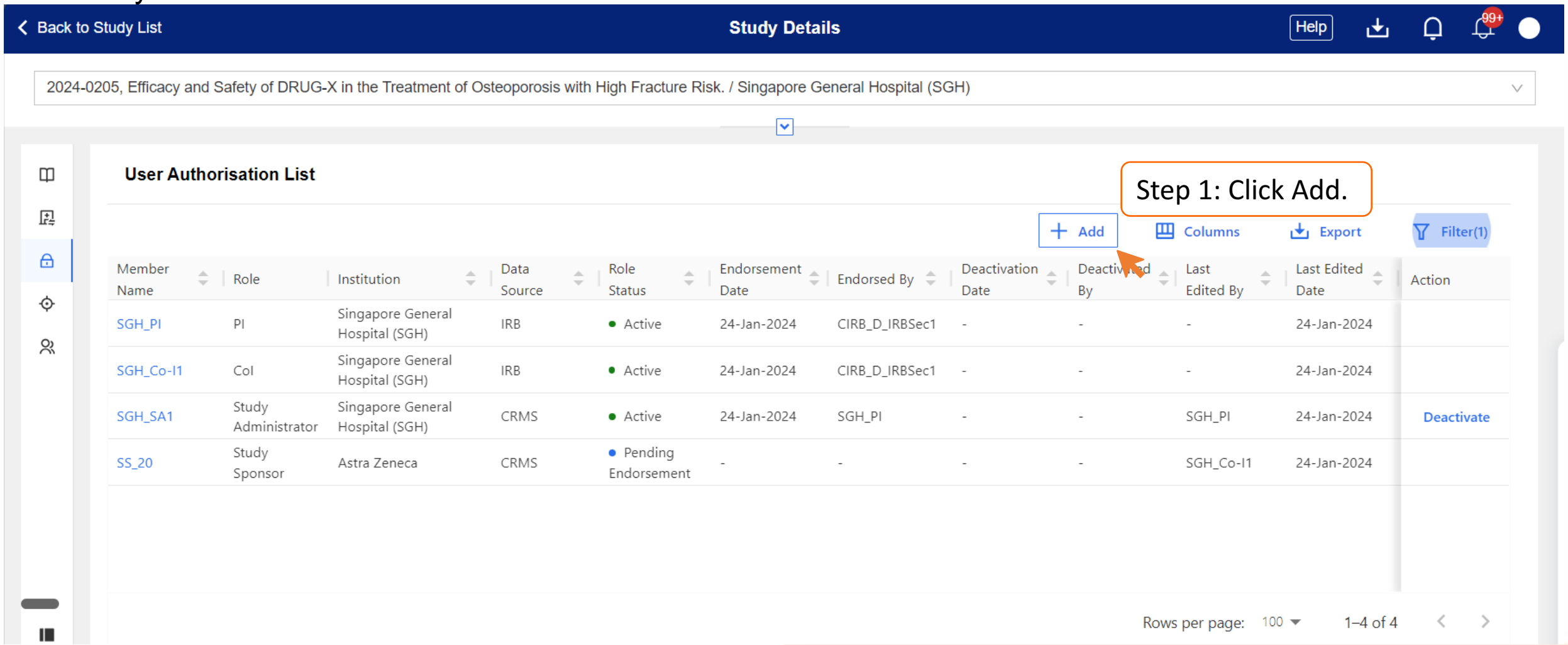
ECOS Reference: 2024-0205
Unique Identifier: 2024-0205-Singapore General Hospital
Study Title: Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.
PI/Site-PI: Dr SGH_PI (Singapore General Hospital), Prof NUH_PI (National University Hospital)
Study Status: Approved
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

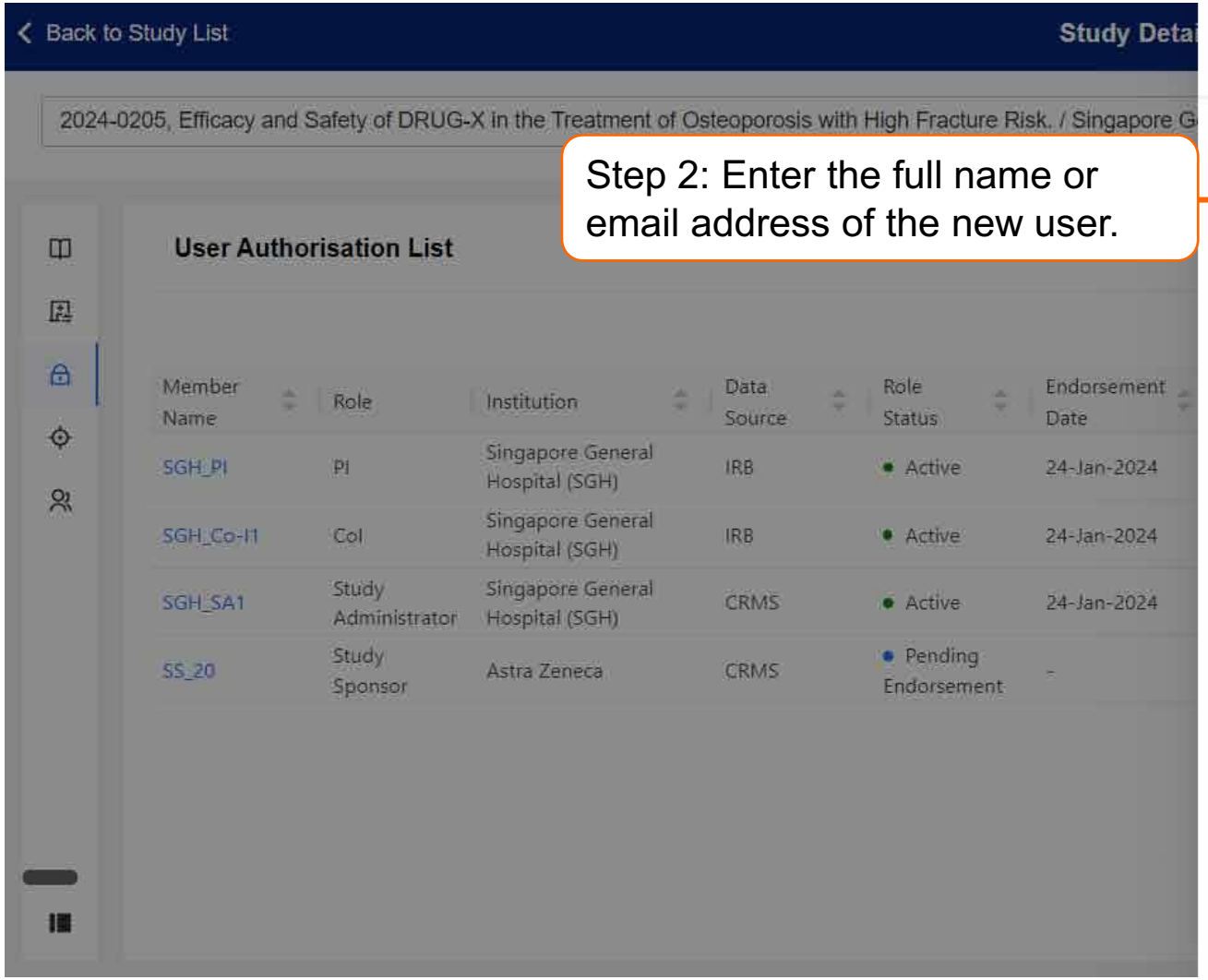
Expected view of the exported User Authorisation List.

Page Functions – Add User

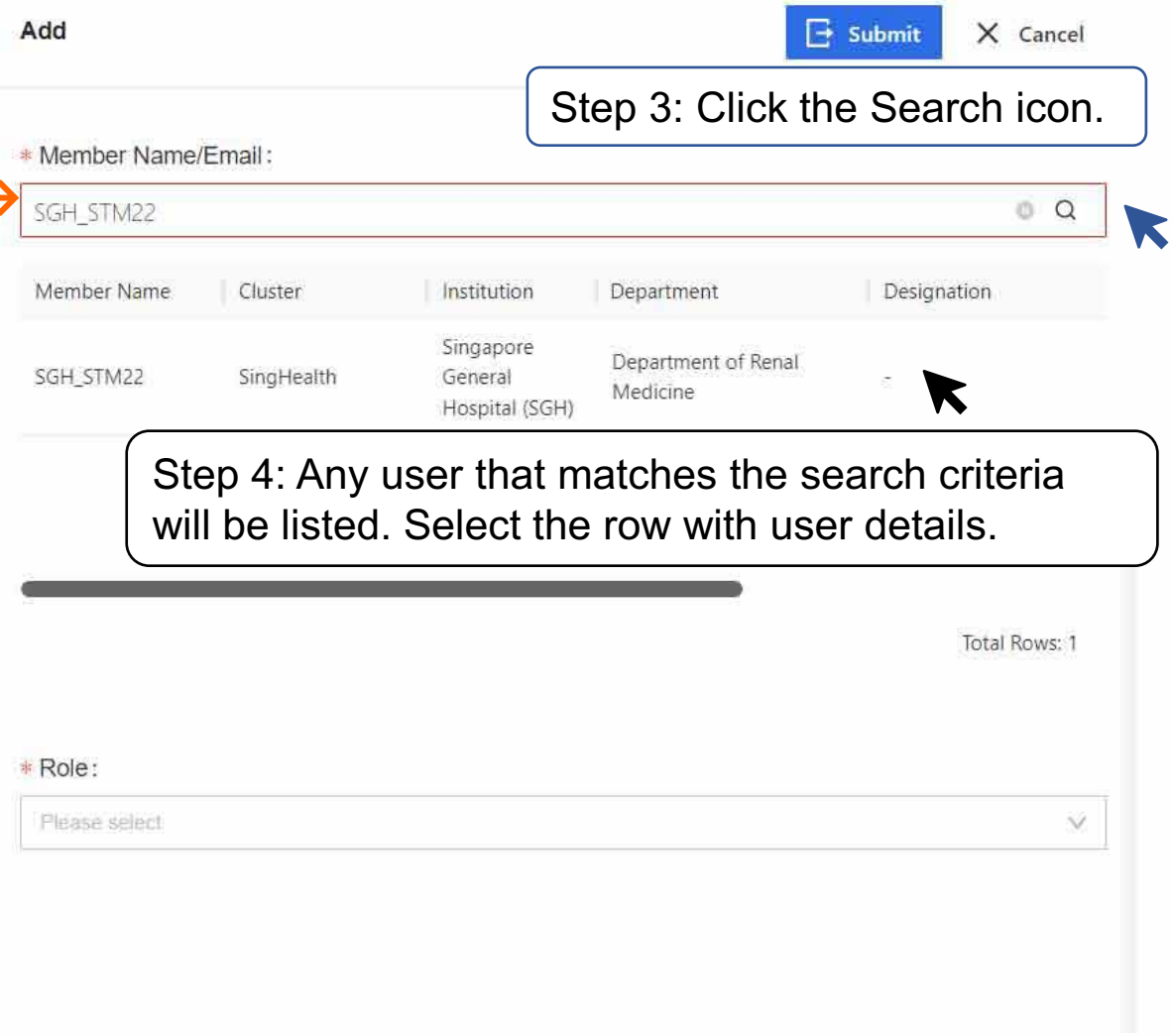
- Any user that has access to the CRMS User Authorisation List will be able to add a new user.



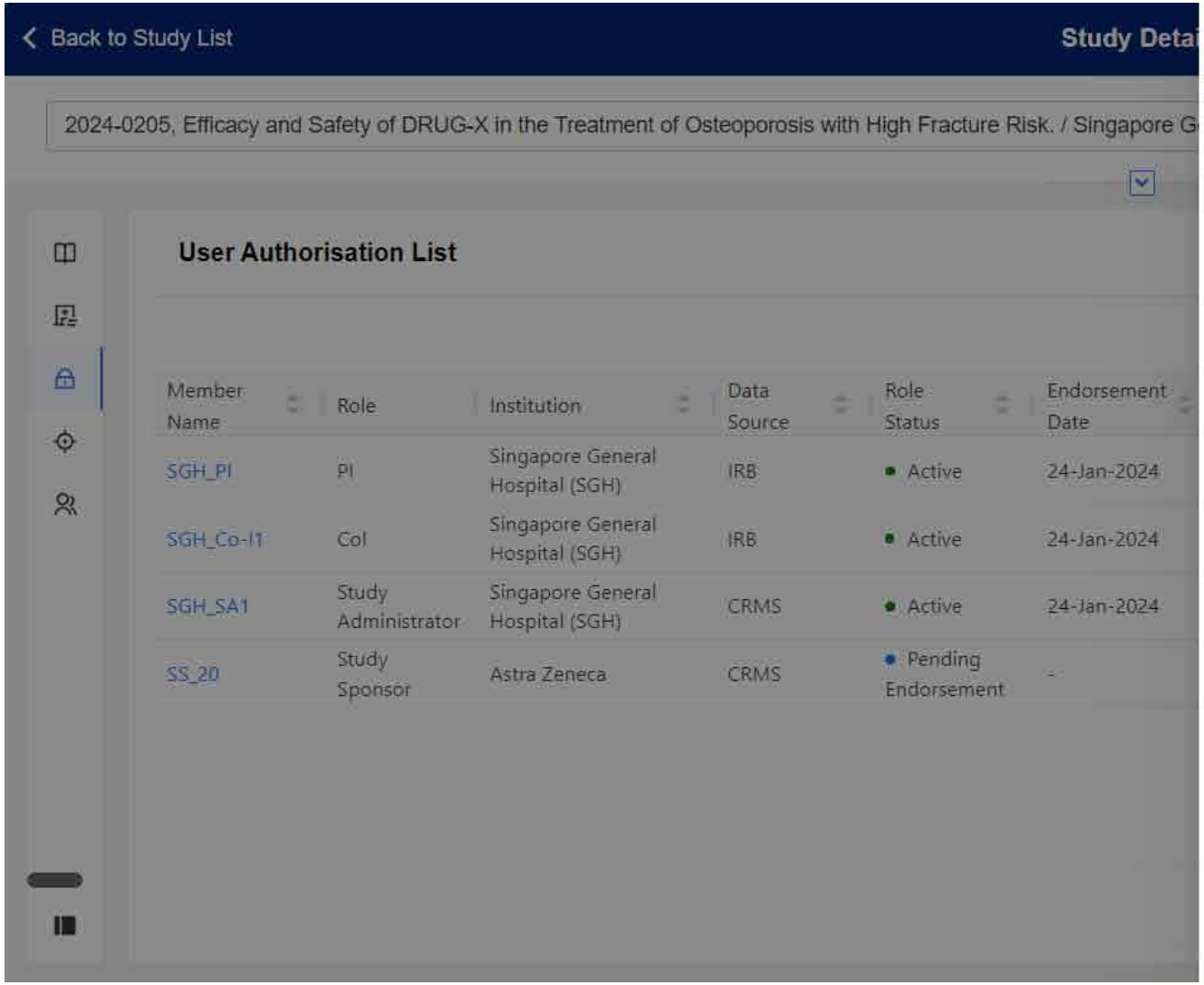
Page Functions – Add User

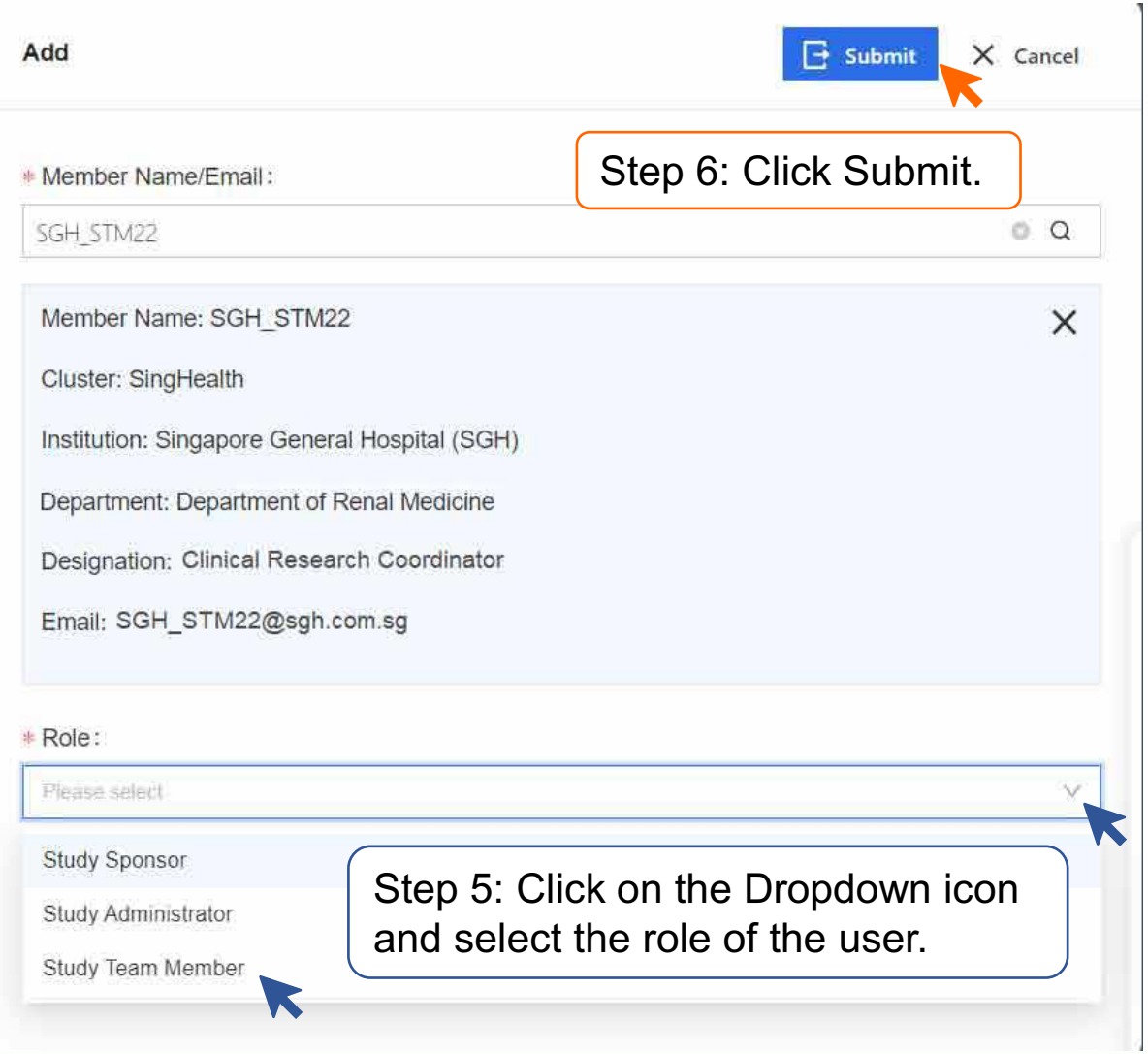


Step 2: Enter the full name or email address of the new user.



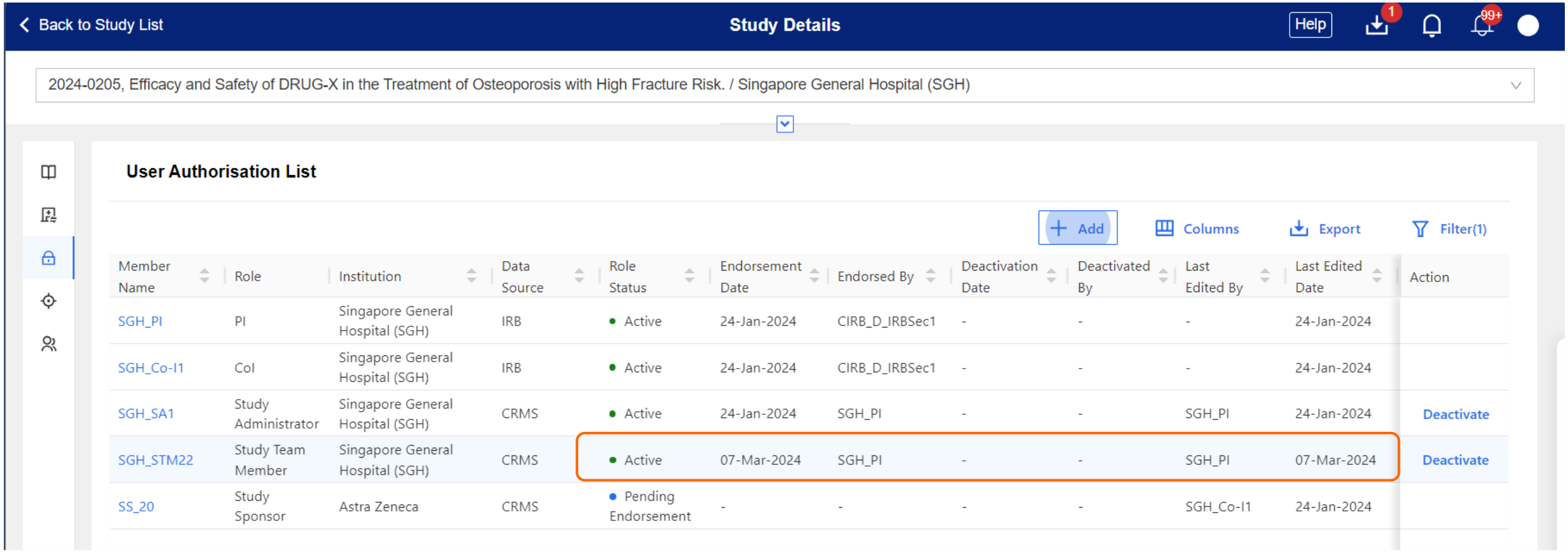
Page Functions – Add User





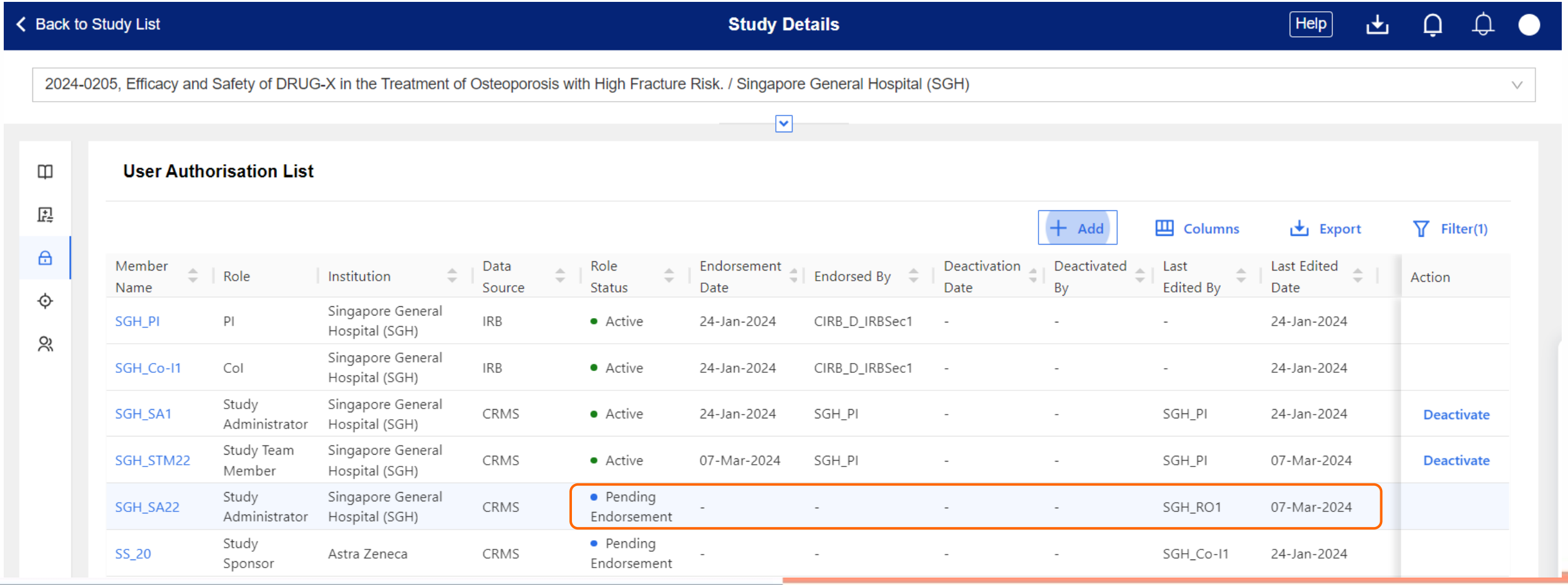
Page Functions – Add User

- If the addition of user was performed by a PI/Site-PI (SGH_PI in this example), the endorsement is immediate.



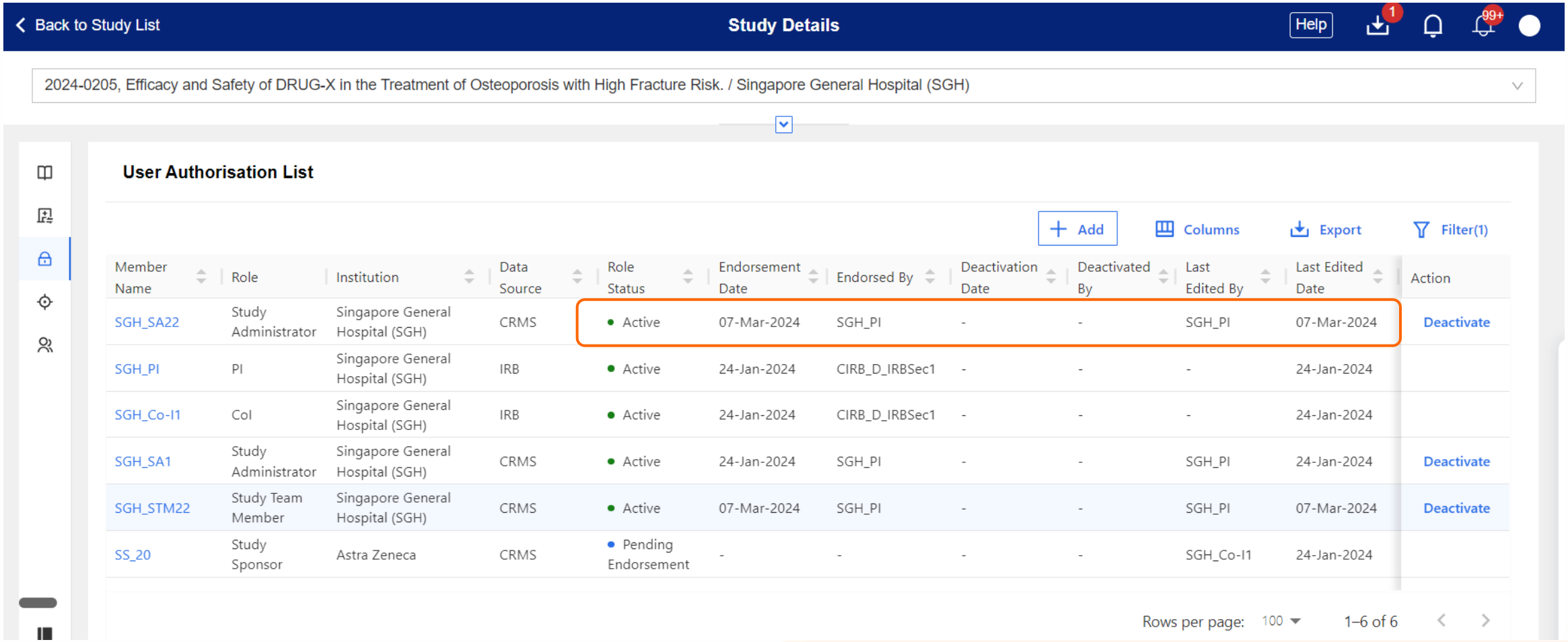
Page Functions – Add User

- If the addition of user was performed by any other role (SGH_RO1 in this example), PI/Site-PI's endorsement in CRMS is required.
- System will route the pending task to PI/Site-PI for completion. Endorsement Is site-specific.



Page Functions – Add User

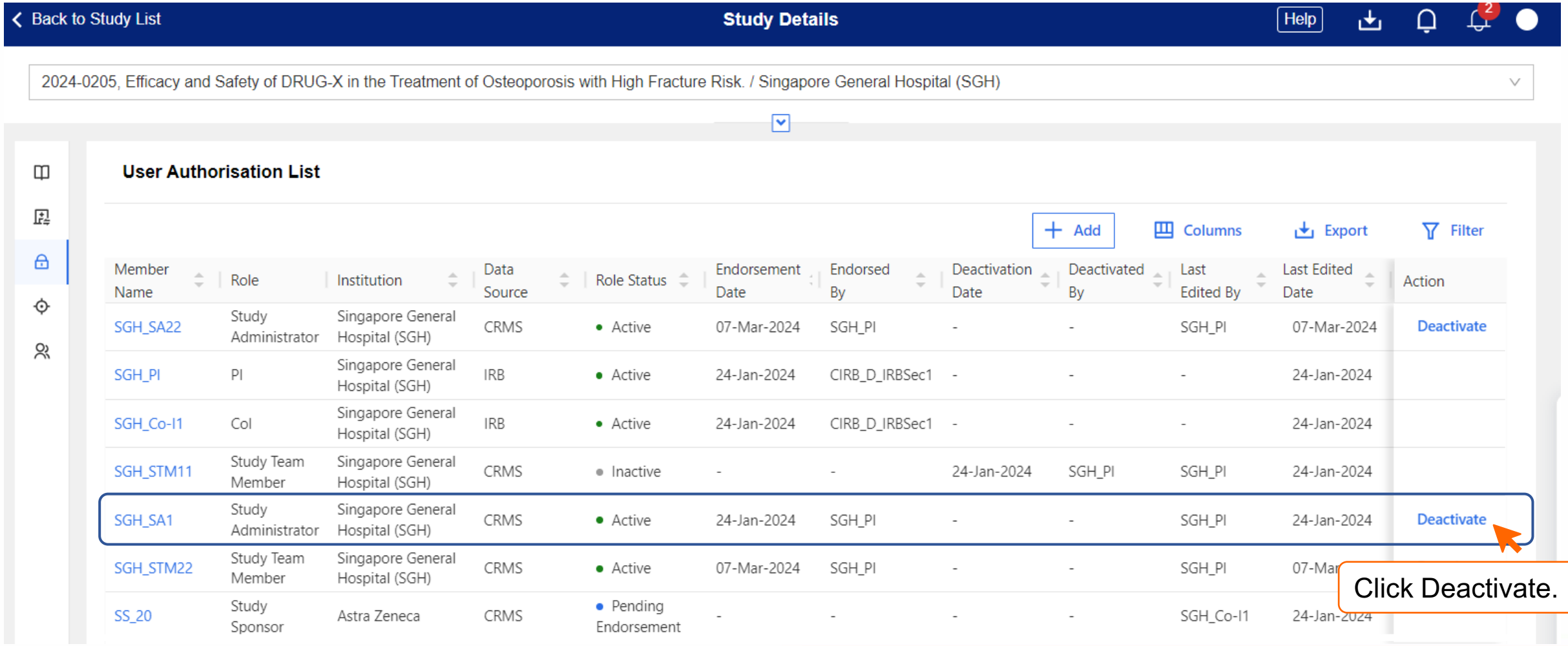
- Below is the updated page view after PI/Site-PI has reviewed and endorsed the newly added user. New information will be recorded in the relevant columns.



Page Functions – Deactivate User

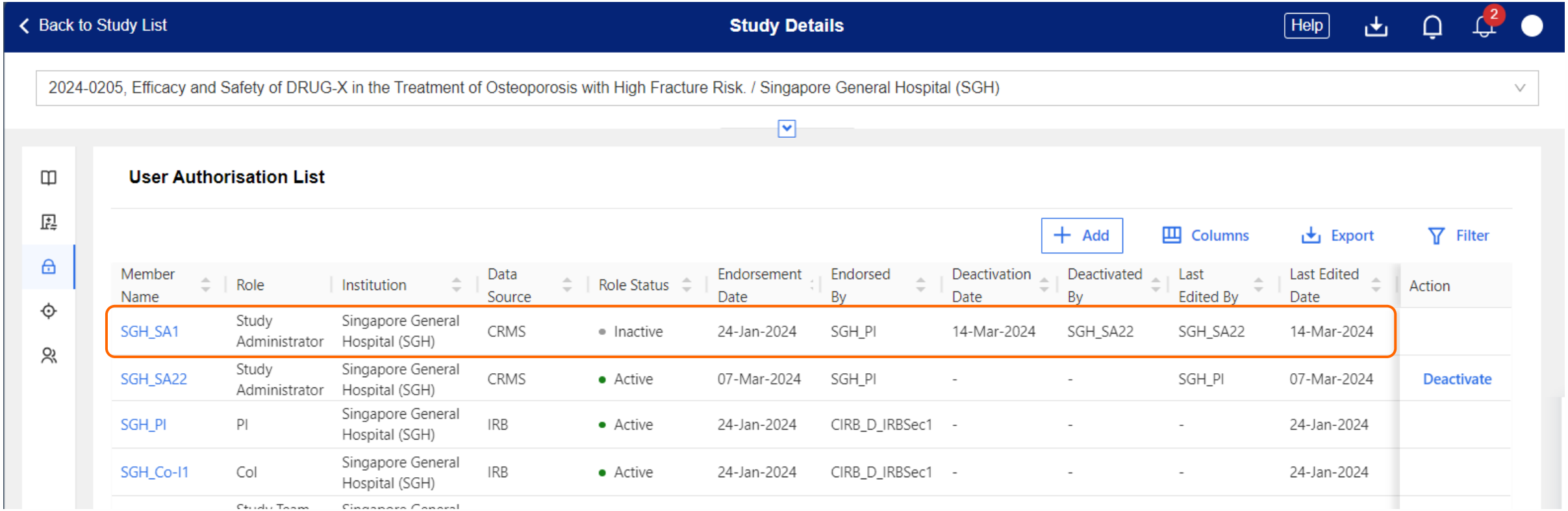
Role used: Study Administrator (SGH_SA22)

- User deactivation can also be done by any user who has access to the CRMS User Authorisation List.



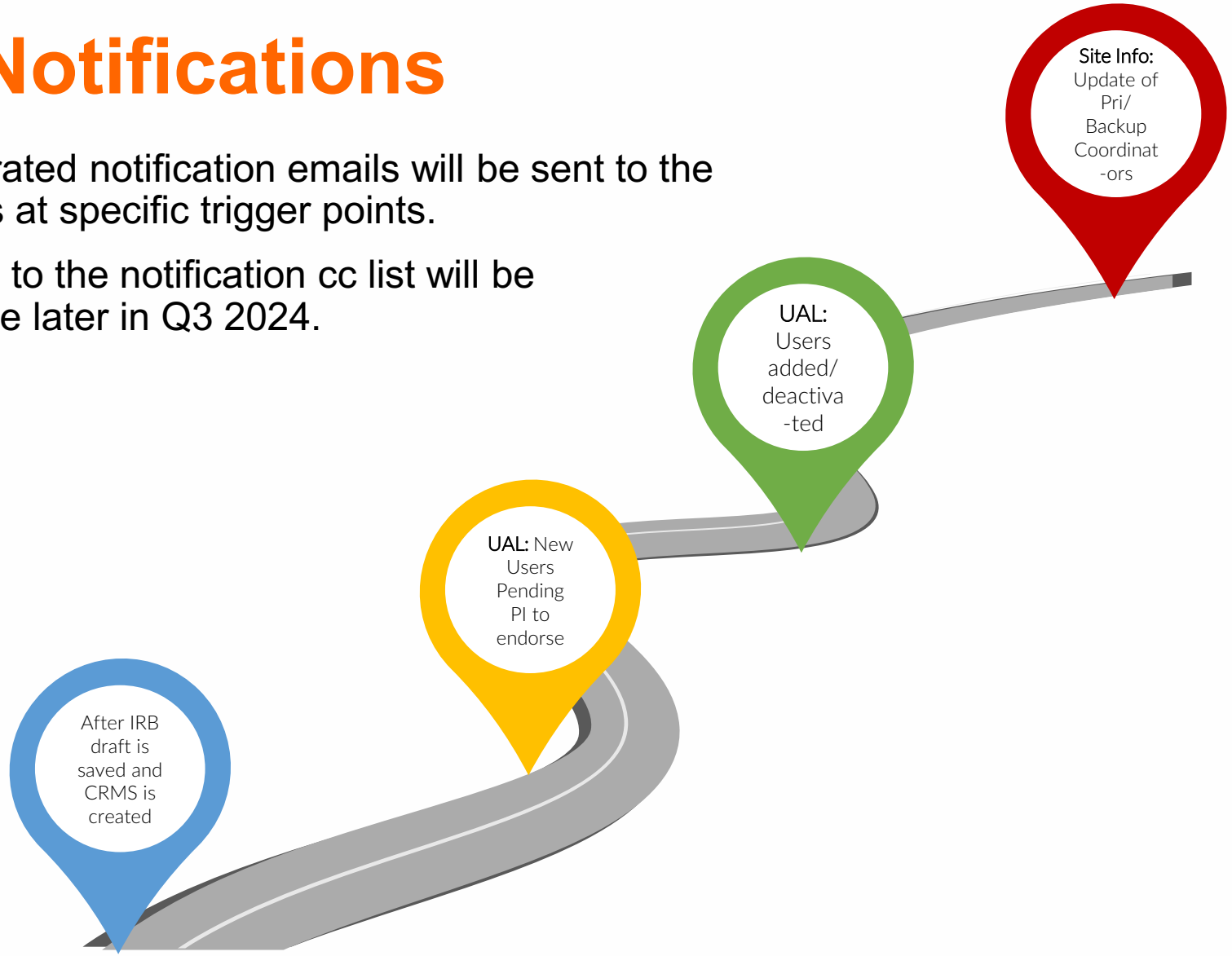
Page Functions – Deactivate User

- User deactivation does not require PI/Site-PI's endorsement in CRMS, it will take effect immediately. In this example, SGH_SA22 has deactivated SGH_SA1."



Email Notifications

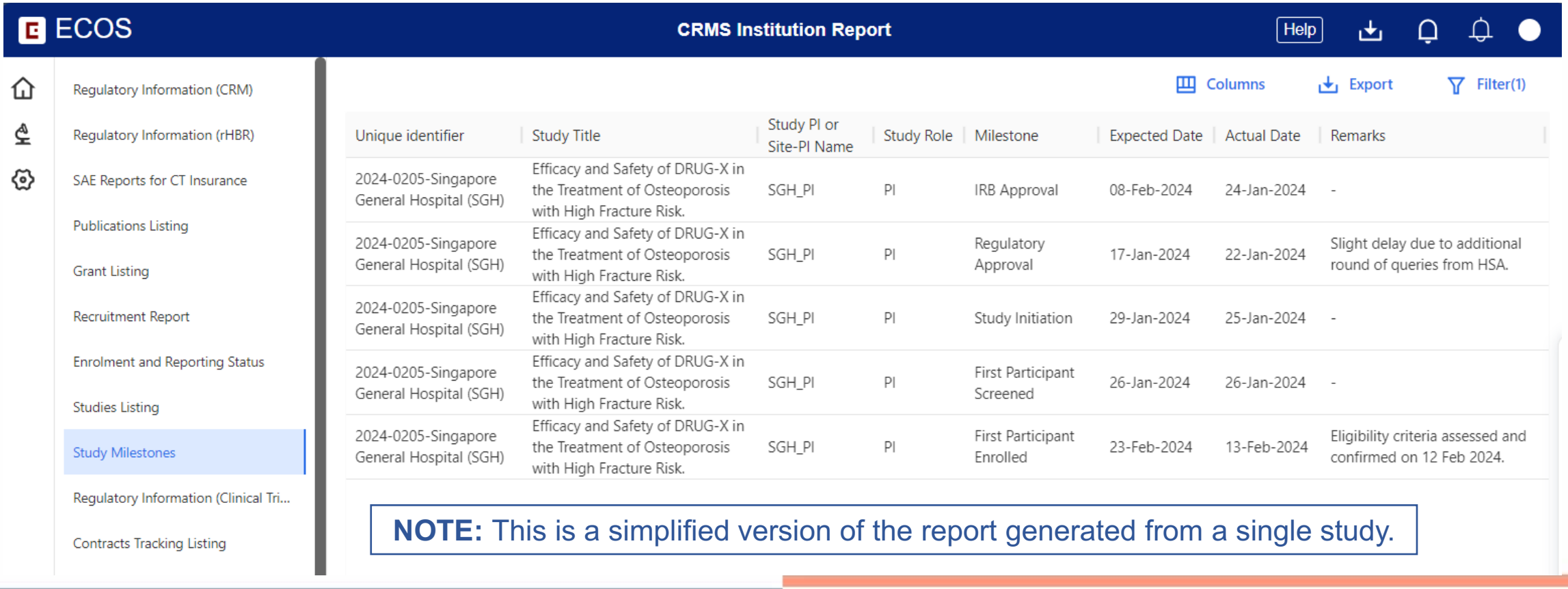
- System-generated notification emails will be sent to the relevant users at specific trigger points.
- Enhancement to the notification cc list will be made available later in Q3 2024.



CRMS Report

This option may be available in Q3 2024.

- Reports can be generated from CRMS to fulfil any periodic or KPI reporting at the institution level.
- Reports generated will include all data except for new data entered on the day itself.
- CRMS Report section can only be accessed by selected roles.



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 simplified version of the report generated from a single study.

CRMS Reports (NHG)

This option may be available in Q3 2024.

- Types of reports:
  - Clinical Trials within the Institution
  - Studies with CRM (Medical Device)
  - Studies managed by the respective Primary Site Coordinator/ Backup Site Coordinator
  - Turn-around Time (TAT) report for budget
  - Recruitment Numbers
  - Basic Participant Information
  - Participant ICF Information
  - Participant Visit Plan
  - Participant-Visit Configuration
  - Participant-ICF Configuration
  - Site-Funding and Grant Information
  - Site-Agreement Information
  - Site-Contract Information
  - Site-Milestone Information
- Steps to export is the same as the one demonstrated using the User Authorisation List.

TIP: Use the Columns function to narrow data selection.

Migration of Existing Studies (NHG)

- **User Authorisation List**:
  - When a study is migrated to ECOS, the **PI, Site-PI and Co-I** will be auto populated into the CRMS User Authorisation List.
  - For "**Study Administrators**" in current ROAM IRB application form, it will not be auto populated in CRMS. PI, Site-PI or Co-I will need to add **Study Sponsor, Study Administrator and Study Team Members** after study migration.

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 IRB modules for Study Team Member (STM), Study Administrators (SA) and Study Sponsor (SS) roles.
- **For the migrated studies, the addition of SA/STM/SS users into CRMS UAL will need to be manually done by PI/Site-PI or CRMS RO administrators.**
- PI/Site-PI should perform the endorsement in CRMS via the Study Member Review page (as needed).

! The User Authorisation List does not replace a 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 at the site, study and institutional level when fully maximised. Research Office from all institutions should strongly encourage their researchers/clinicians to take full advantage of this module and update the pages frequently.