ECOS

Navigating the New IT Platform:

ECOS – Clinical Research Management System (CRMS)

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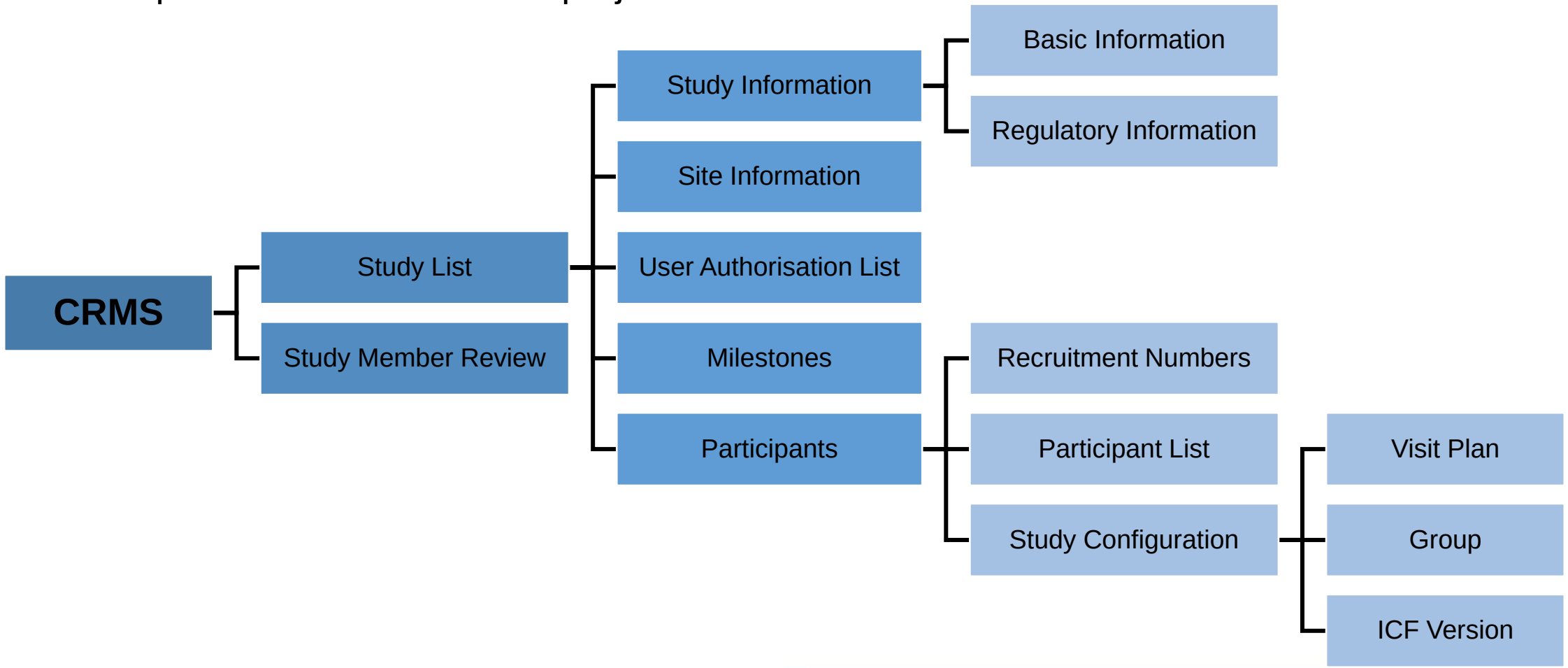
Clinical Research Management System (CRMS)

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



Index

Jump to the relevant section by clicking on the Slide Number!

Index

Jump to the relevant section by clicking on the Slide Number!

ECOS

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User Access Matrix

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User Access Matrix

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

- Once a user has been added in the 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: Research Office administrators assigned with the CRMS Research Office role *(Please refer to the section CRMS Research Office Role – Slide 142)*.

- For new investigators (i.e. PI, Site-PI, Co-I) added in the IRB **Amendment** Form, 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 on 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.*

ECOS

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CRMS Page Level

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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.

ECOS

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CRMS Access

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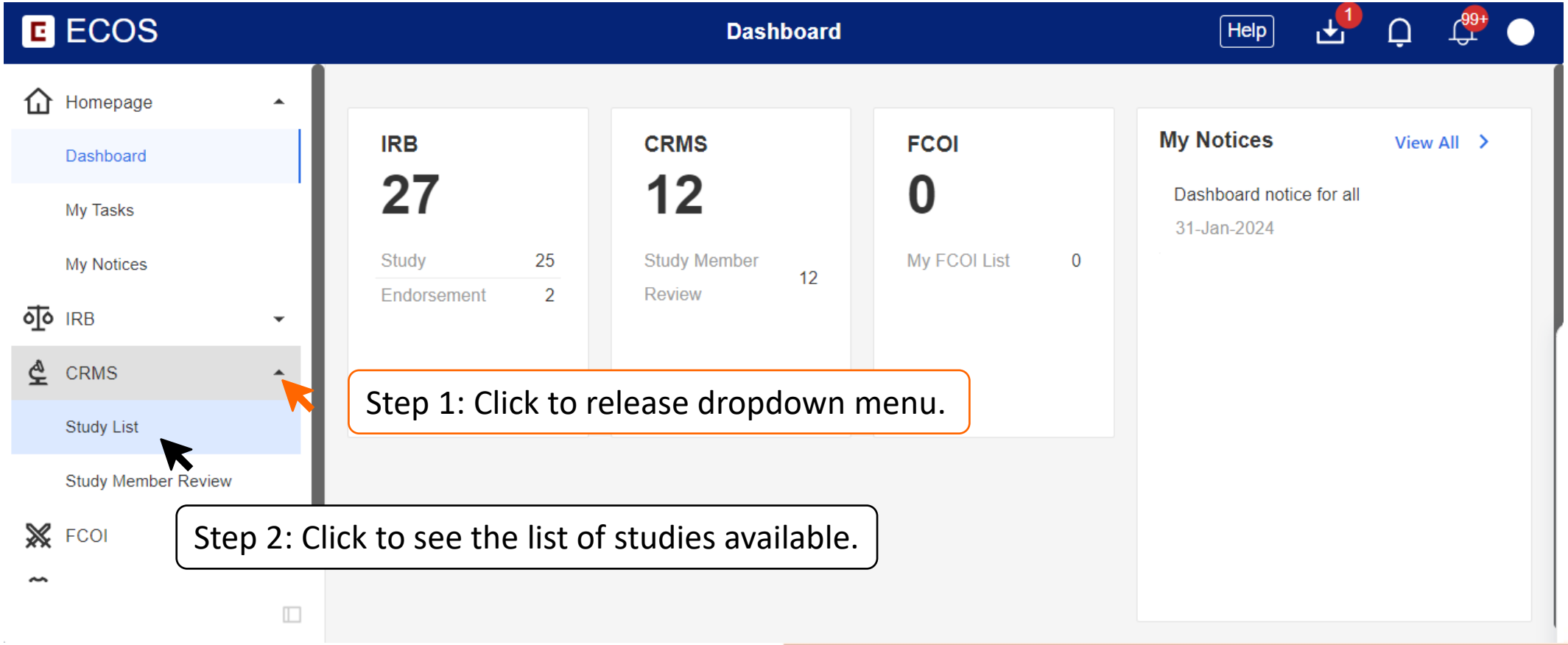
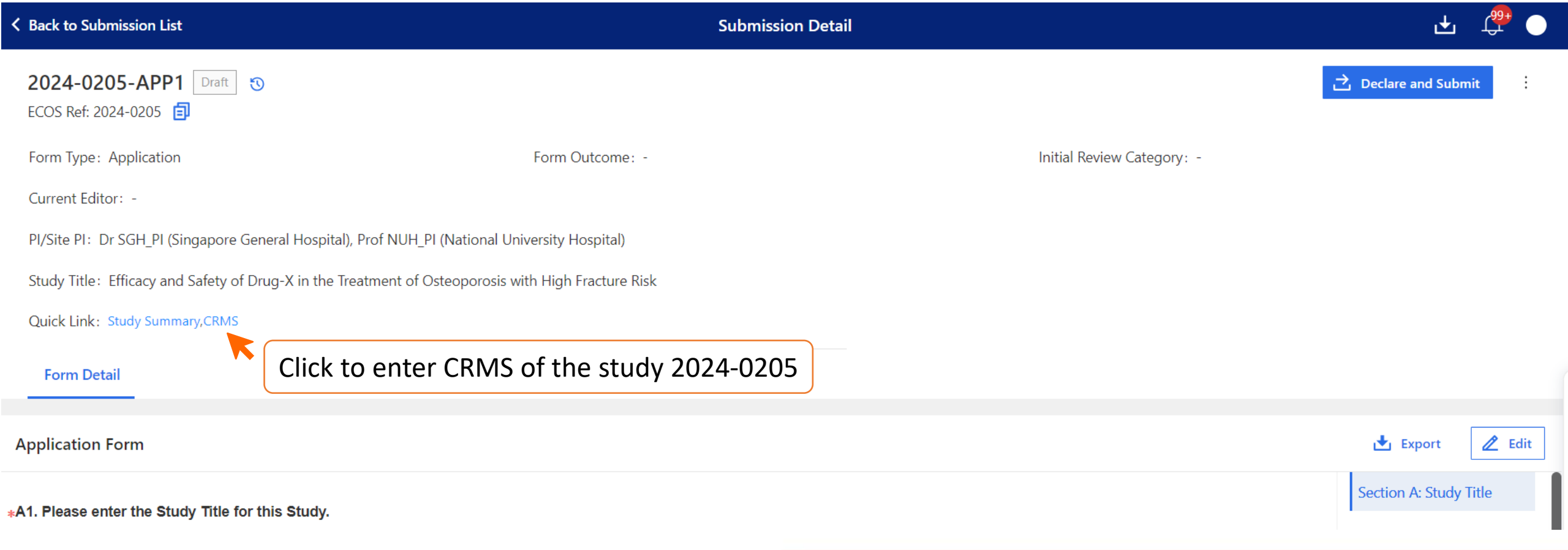
CRMS Access

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



CRMS Access

- There are 2 ways to access CRMS:
  2. Within the IRB Form (any form) > Quick Link: CRMS



ECOS

Click here to return to Index.

CRMS Pages and Data Fields

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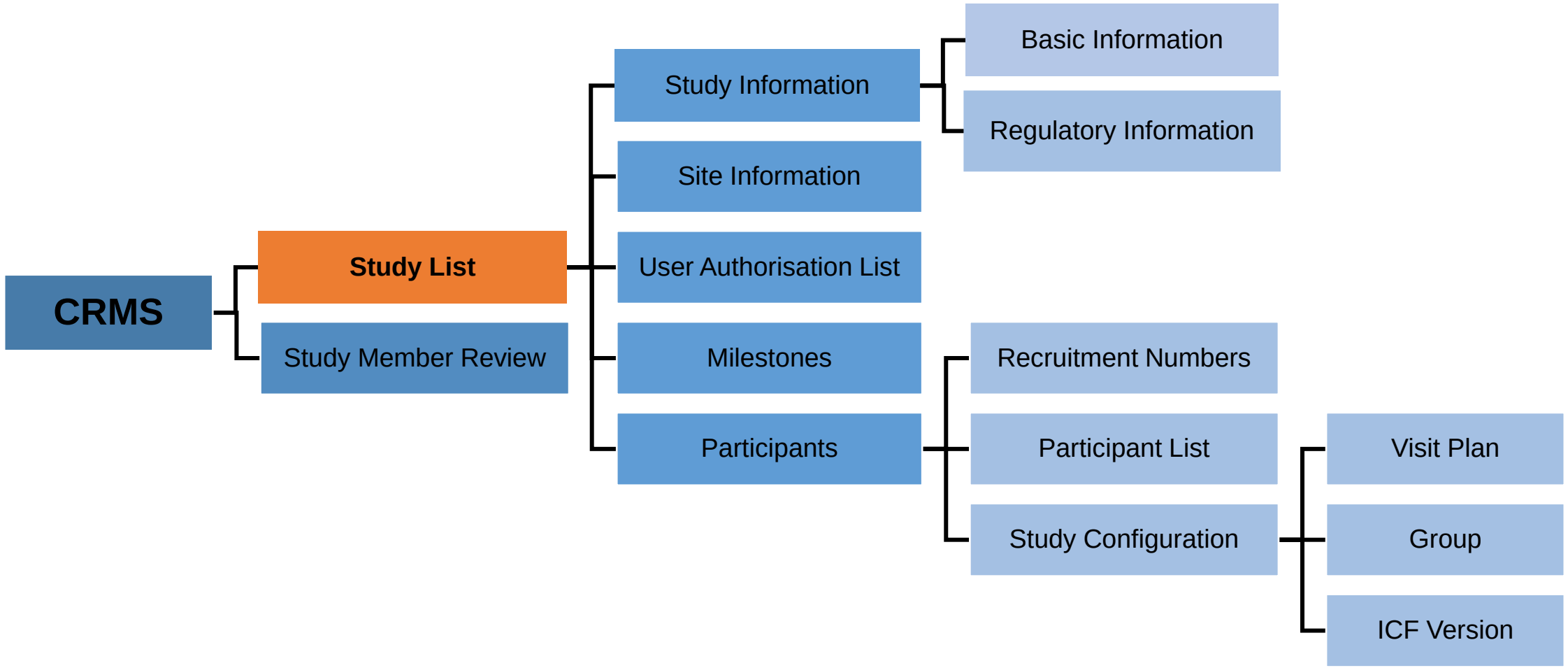
Click here to return to Index.

CRMS Sitemap



Study List

- The Study List will only display the studies where a user has been added to the IRB Application/Amendment Form or User Authorisation List.
  - Exception: CRMS Research Office administrators *(Please refer to the section CRMS Research Office Role – Slide 142)*.
- 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 to the IRB form to the User Authorisation List.
- Synchronisation points:
  - Upon saving the IRB Application Form.
  - Upon IRB approval or acknowledgement.

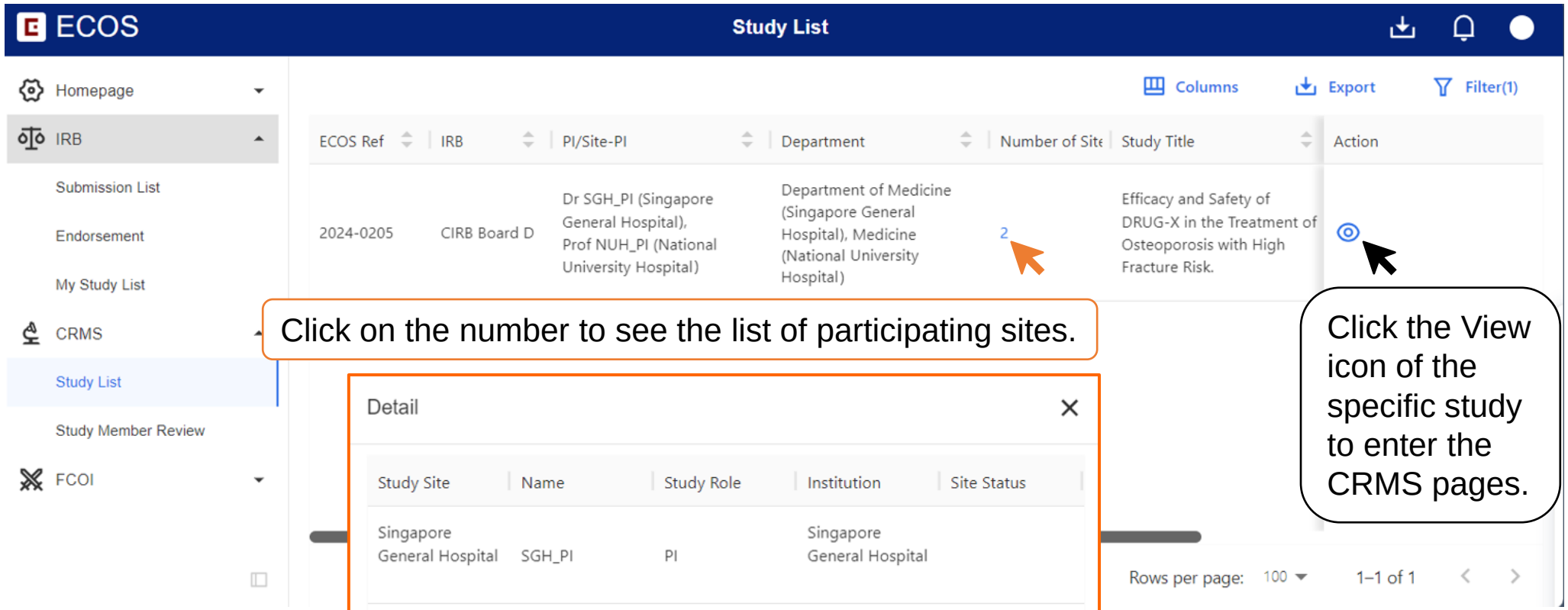
No information will flow from CRMS to IRB module.

Study List

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

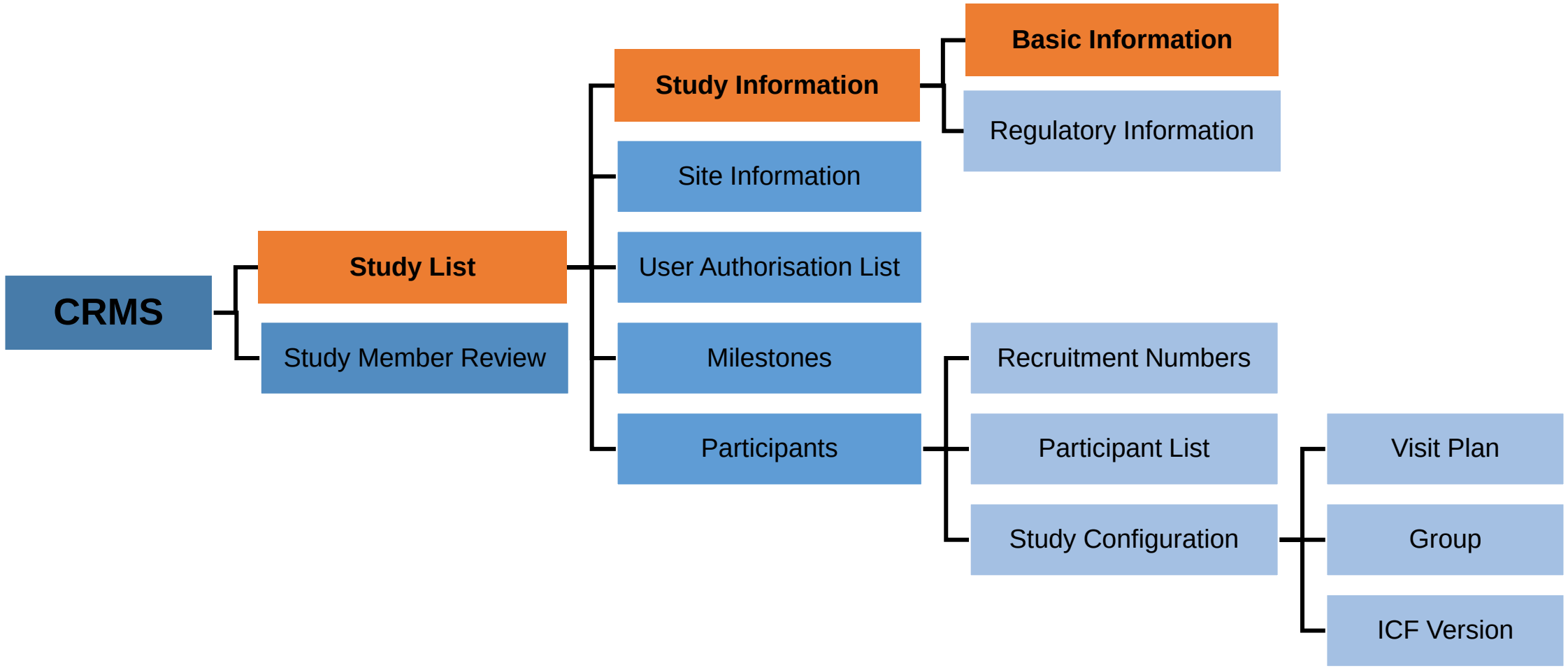
Data Columns

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



Click here to return to Index.

CRMS Sitemap



Study Information – Basic Information

Study Level

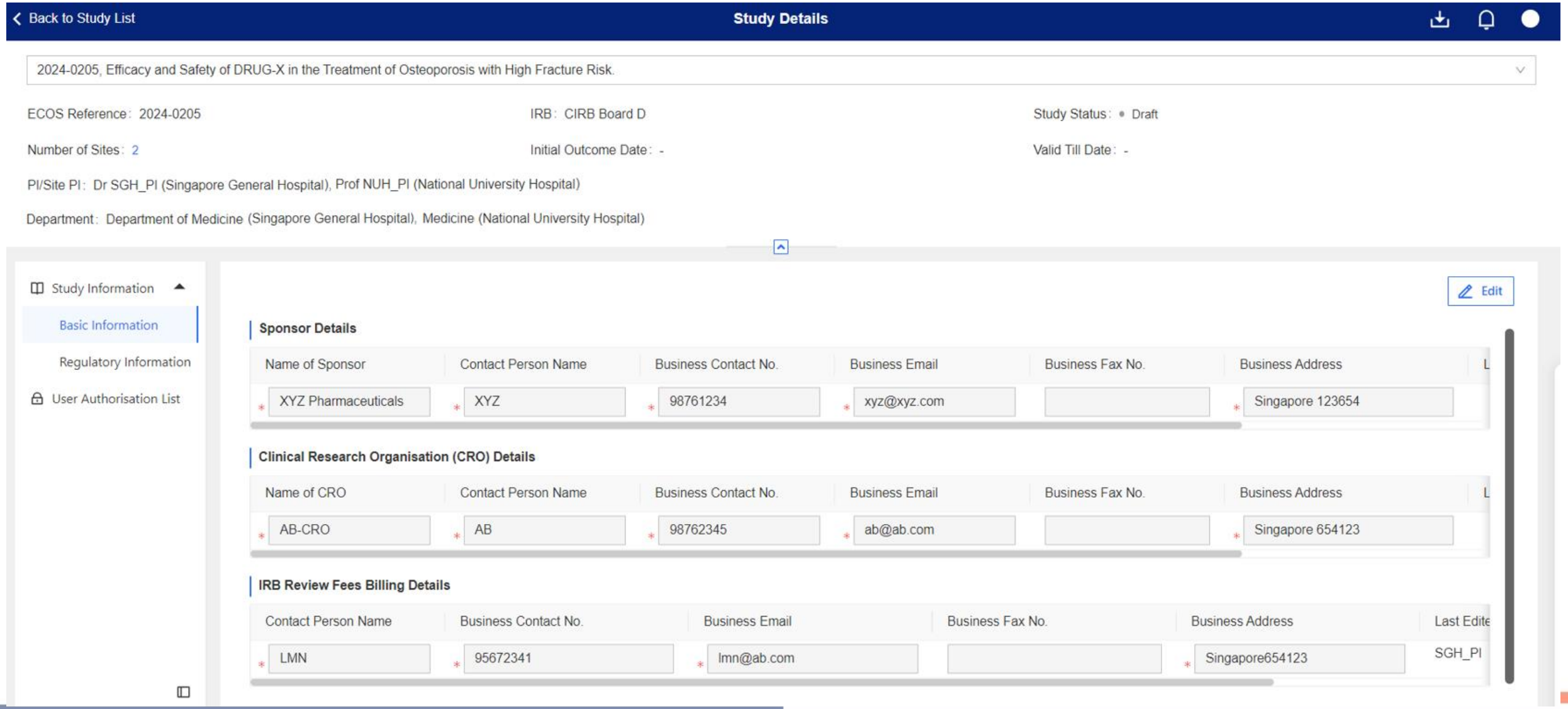
- On ECOS, **Sponsor, CRO and IRB billing details** will be entered on the **Basic Information** page in CRMS instead of the IRB Application/Amendment Form.

- 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 or 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

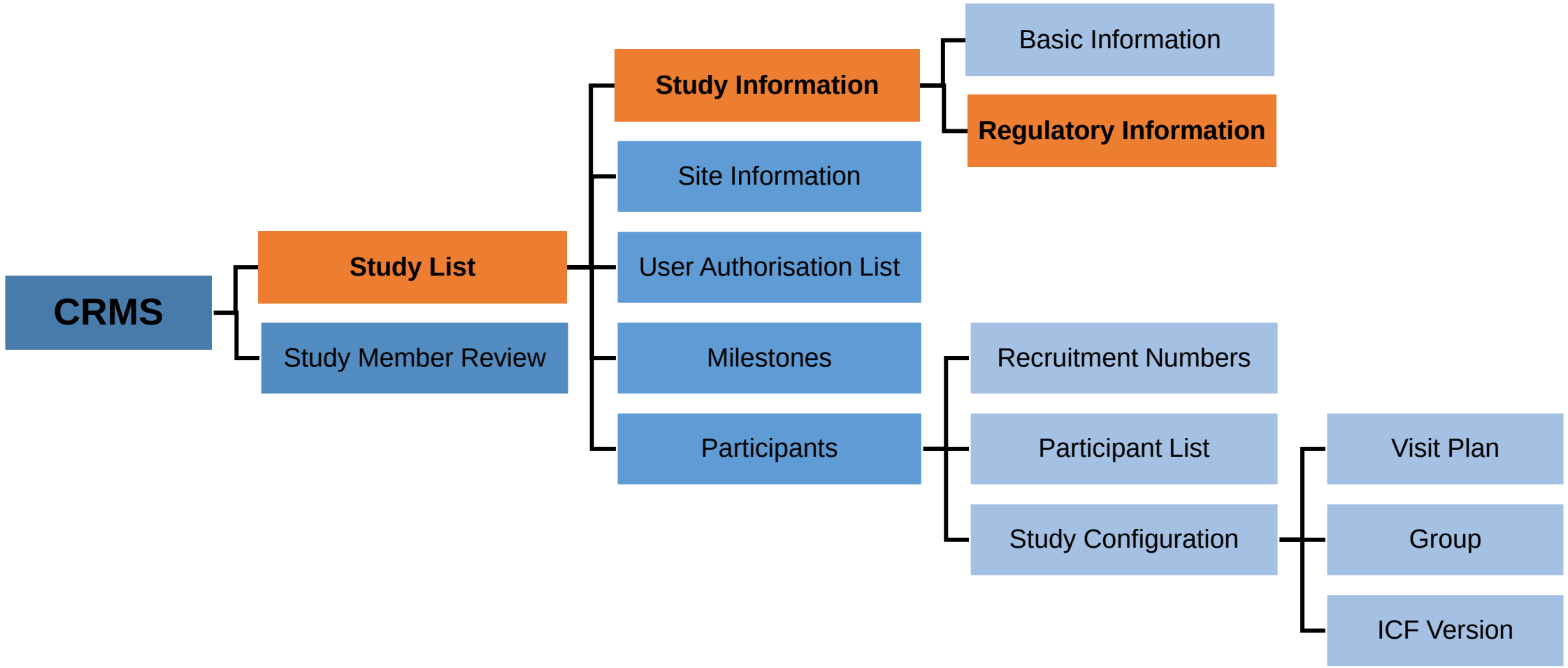
- Contact Person Name
- Business Contact No.
- Business Email
- Business Fax No.
- Business Address

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. Please include the full address including the Company Name. Sites should check with the sponsor and indicate the required information to ensure smooth invoice submission and payment processes.

Click here to return to Index.

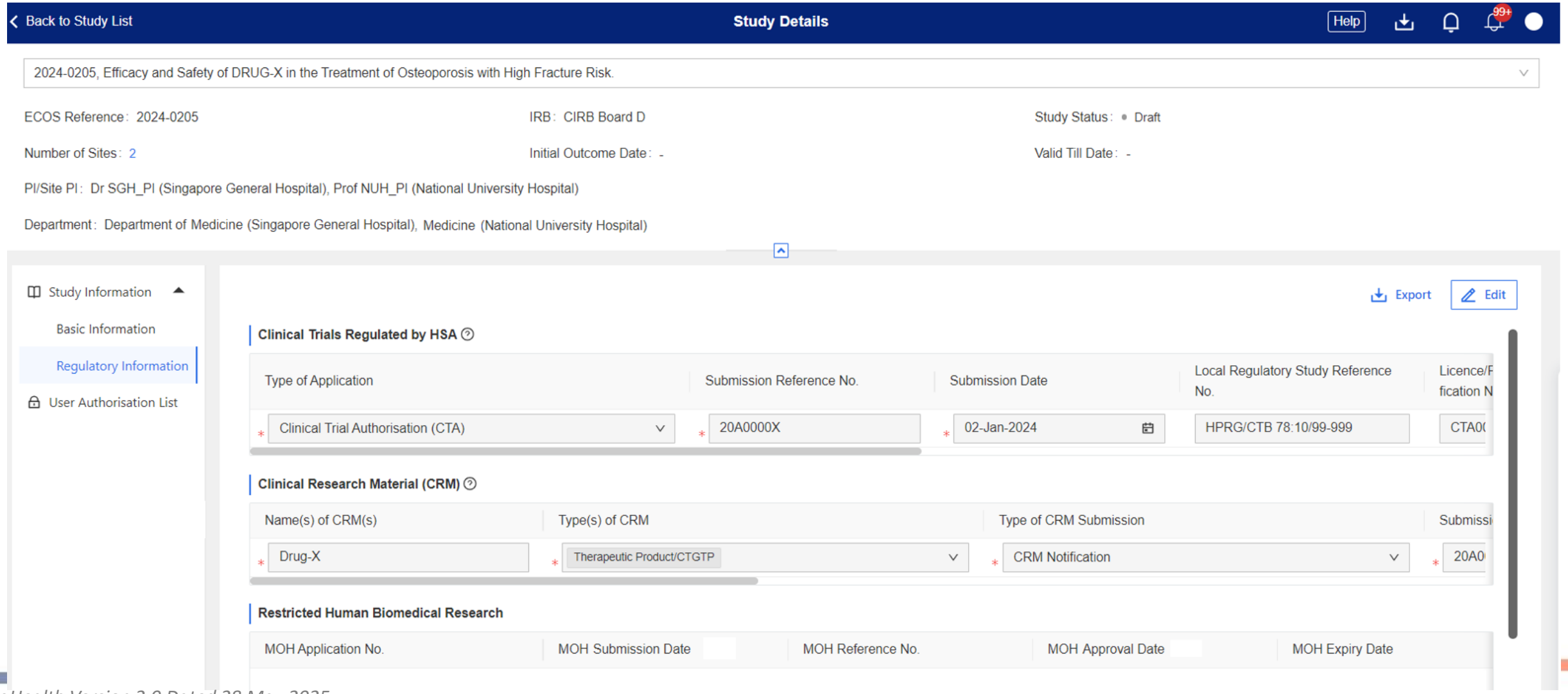
CRMS Sitemap



Study Information – Regulatory Information

Study Level

- 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)

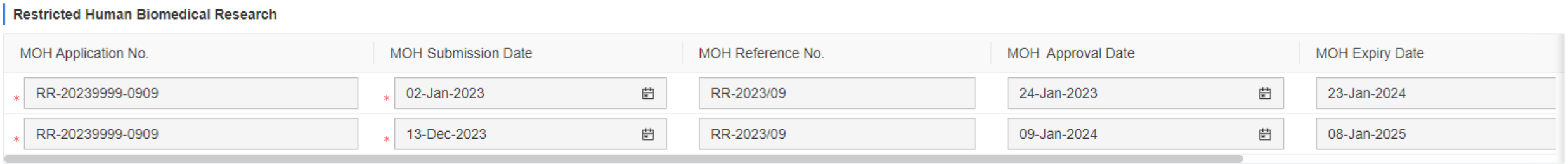
- Name(s) of CRM(s)
- Type(s) of CRM *(Multi-select)*
  - Therapeutic Product/ CTGTP
  - Medicinal Product
  - Medical Device
- Type of CRM Submission *(Drop-down list)*
  - CRM Notification
  - Product Defect and Recall Report
  - Other Submissions
- Submission Reference No.
- Submission Date
- Notification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

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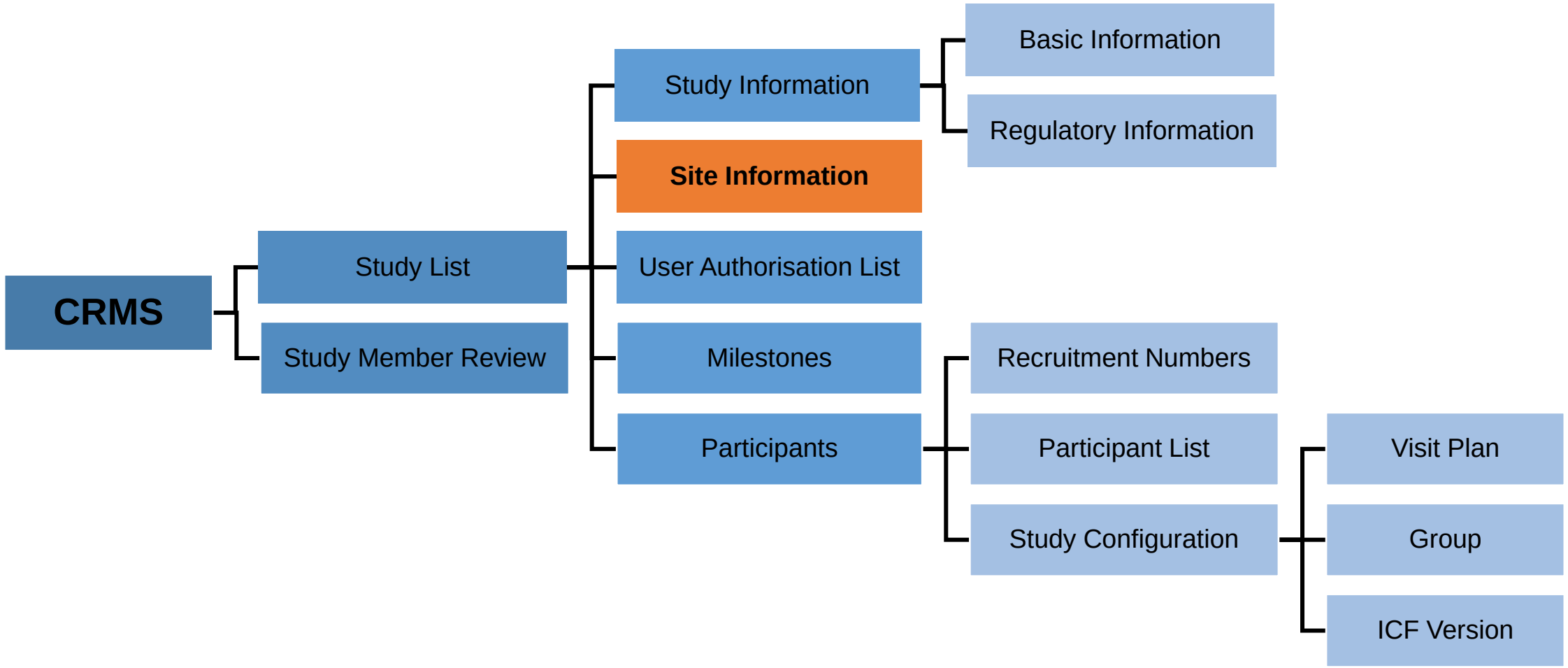
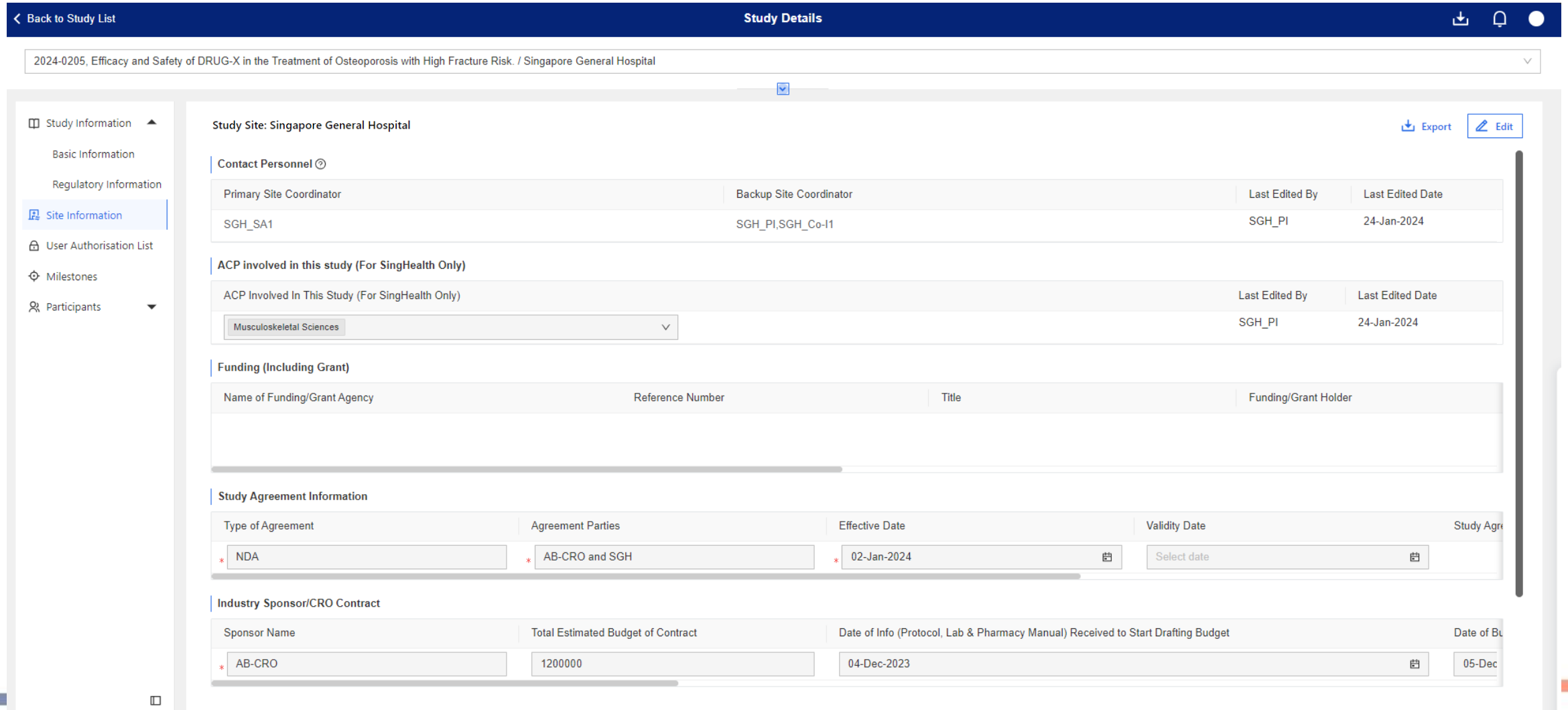
CRMS Sitemap



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 Project Agreements 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

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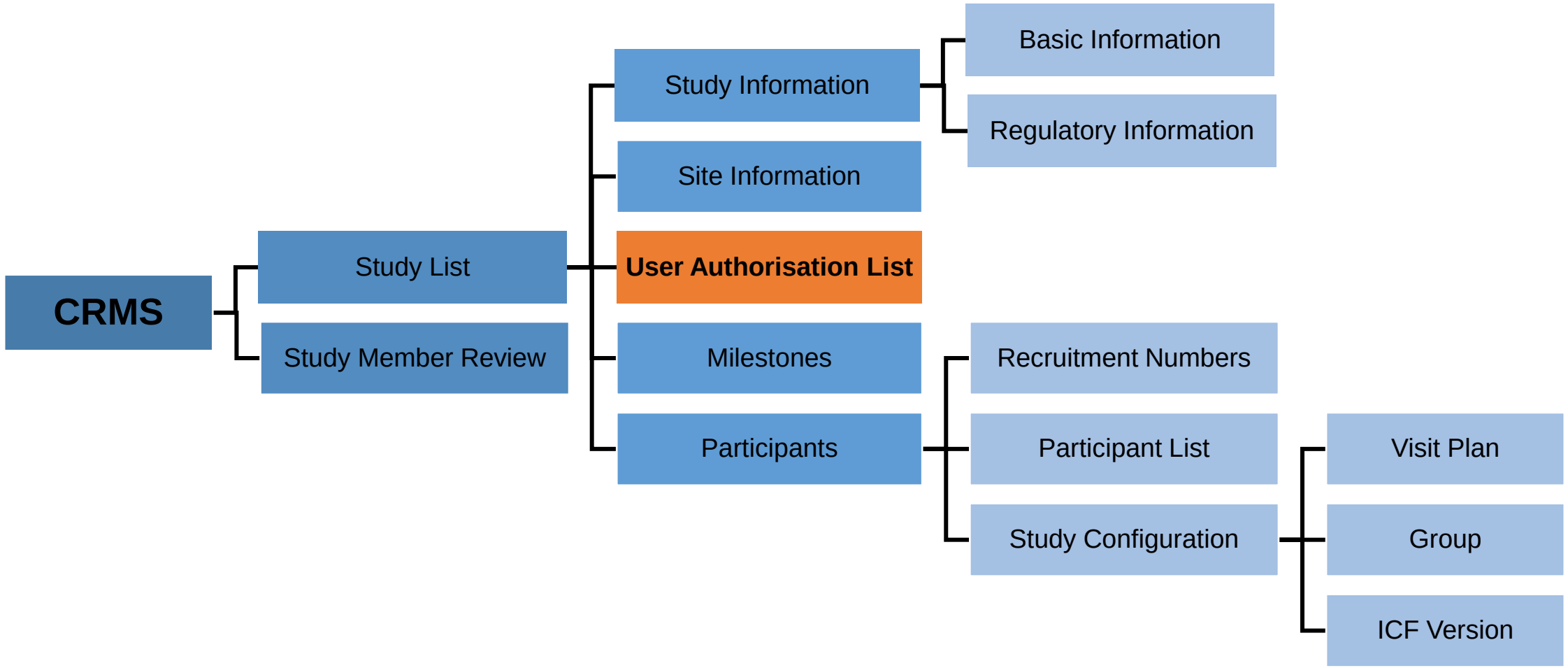
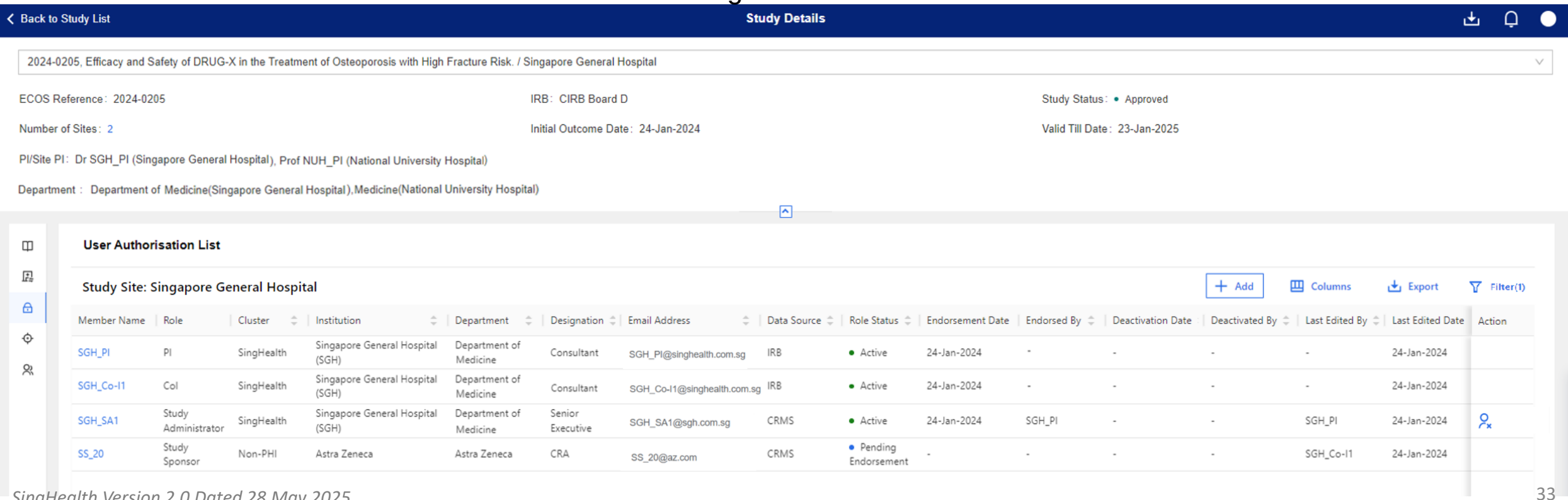
CRMS Sitemap



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.
- User access to CRMS, IRB, Compliance, Monitoring and Audit modules for STM, SA and SS roles will be managed via CRMS UAL.
- User access for PI/Site-PI and Co-I will be managed via the IRB module.



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	Action
SGH_PI	PI	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_PI@singhealth.com.sg	IRB	Active	24-Jan-2024	-	-	-	-	24-Jan-2024	
SGH_Co-I1	CoI	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_Co-I1@singhealth.com.sg	IRB	Active	24-Jan-2024	-	-	-	-	24-Jan-2024	
SGH_SA1	Study Administrator	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Senior Executive	SGH_SA1@sgh.com.sg	CRMS	Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	
SS_20	Study Sponsor	Non-PHI	Astra Zeneca	Astra Zeneca	CRA	SS_20@az.com	CRMS	Pending Endorsement	-	-	-	-	SGH_Co-I1	24-Jan-2024	

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 to IRB Application Form** • Limited page access before IRB approval. ✓ Study Information ✓ UAL • Full page access after IRB approval. + Site Information + Milestones + Participants **User added to 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. • The list of investigators will be imported from the 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. • 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, Compliance, Monitoring... • 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 for access to IRB, CRMS etc. modules to be revoked (to protect study data confidentiality).
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 UAL primarily functions to manage the access of **STM**, **SA** and **SS** to the CRMS, IRB, Compliance, Monitoring and Audit modules on 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 Slide 116 for steps to add a user to 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)

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 (HBRA, CITI Biomed, GCP, etc.).

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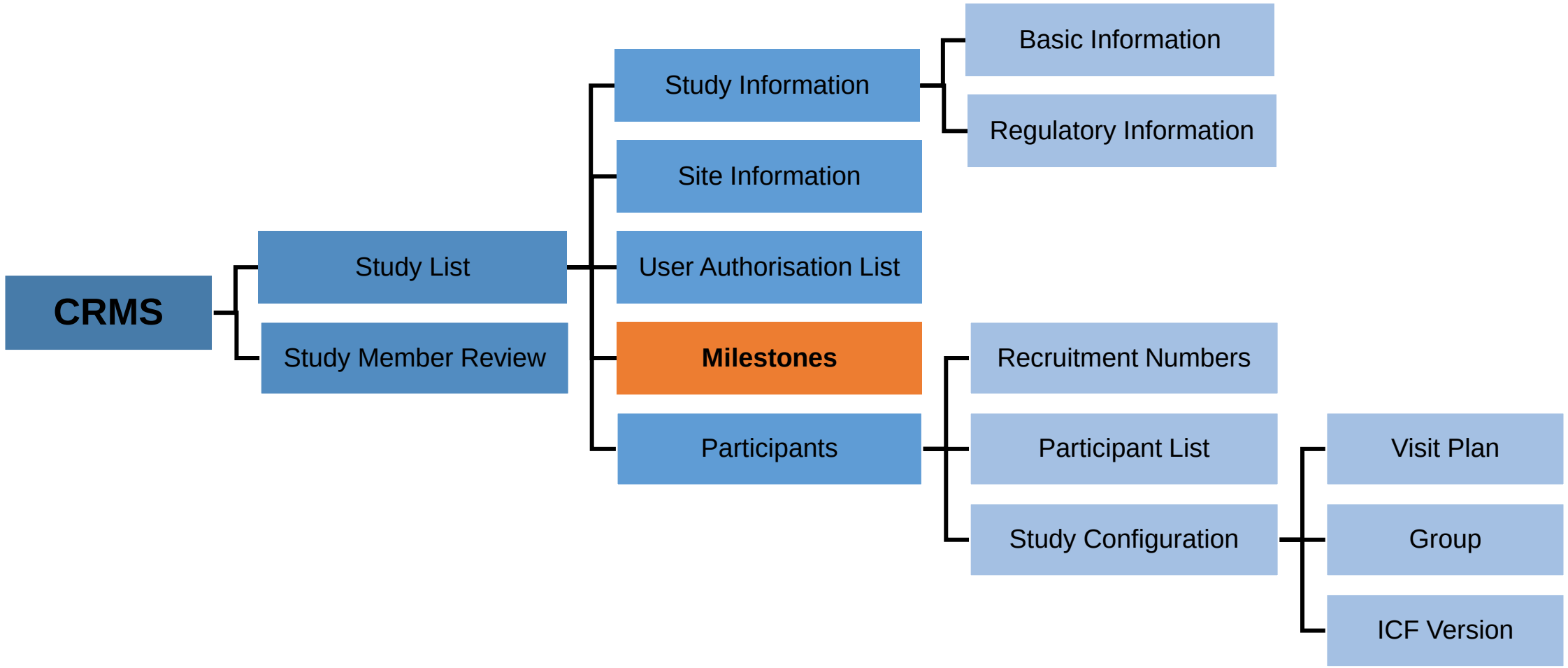
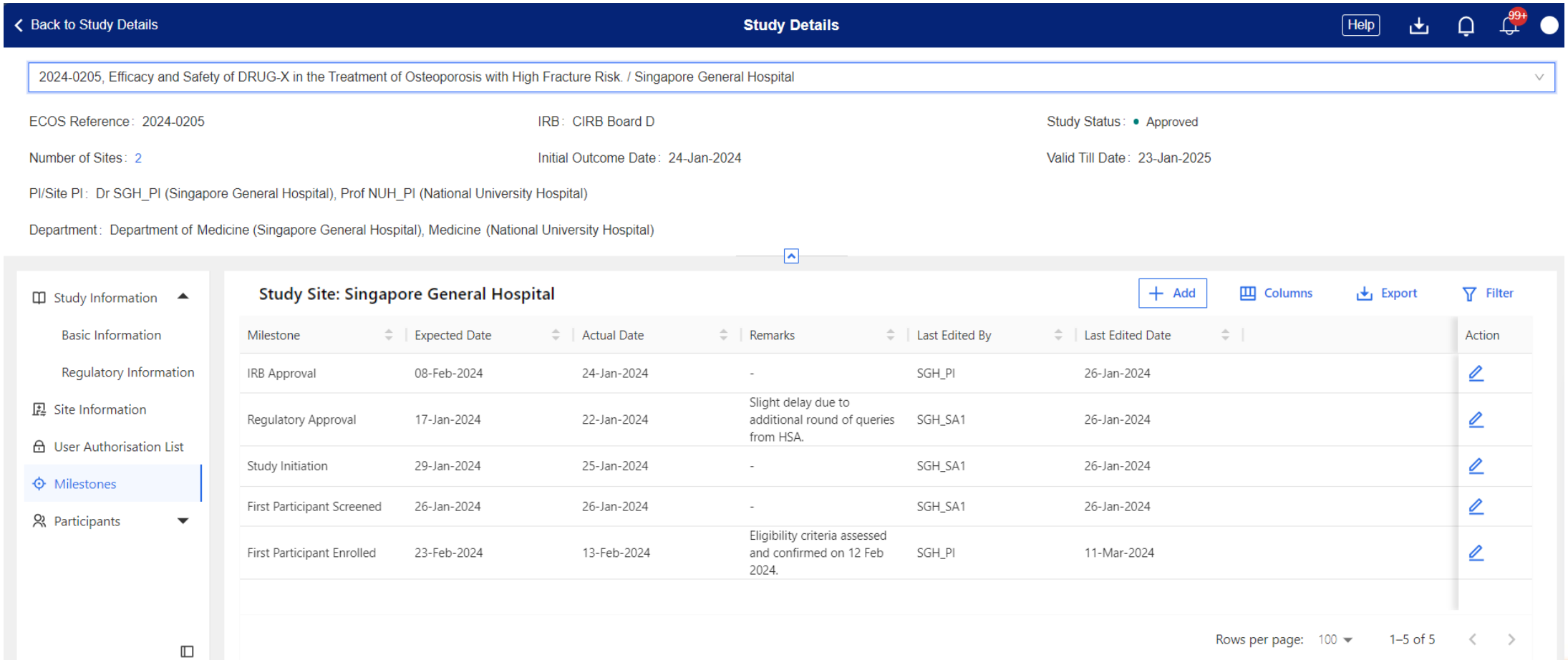
CRMS Sitemap



Milestones

Site Level

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



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

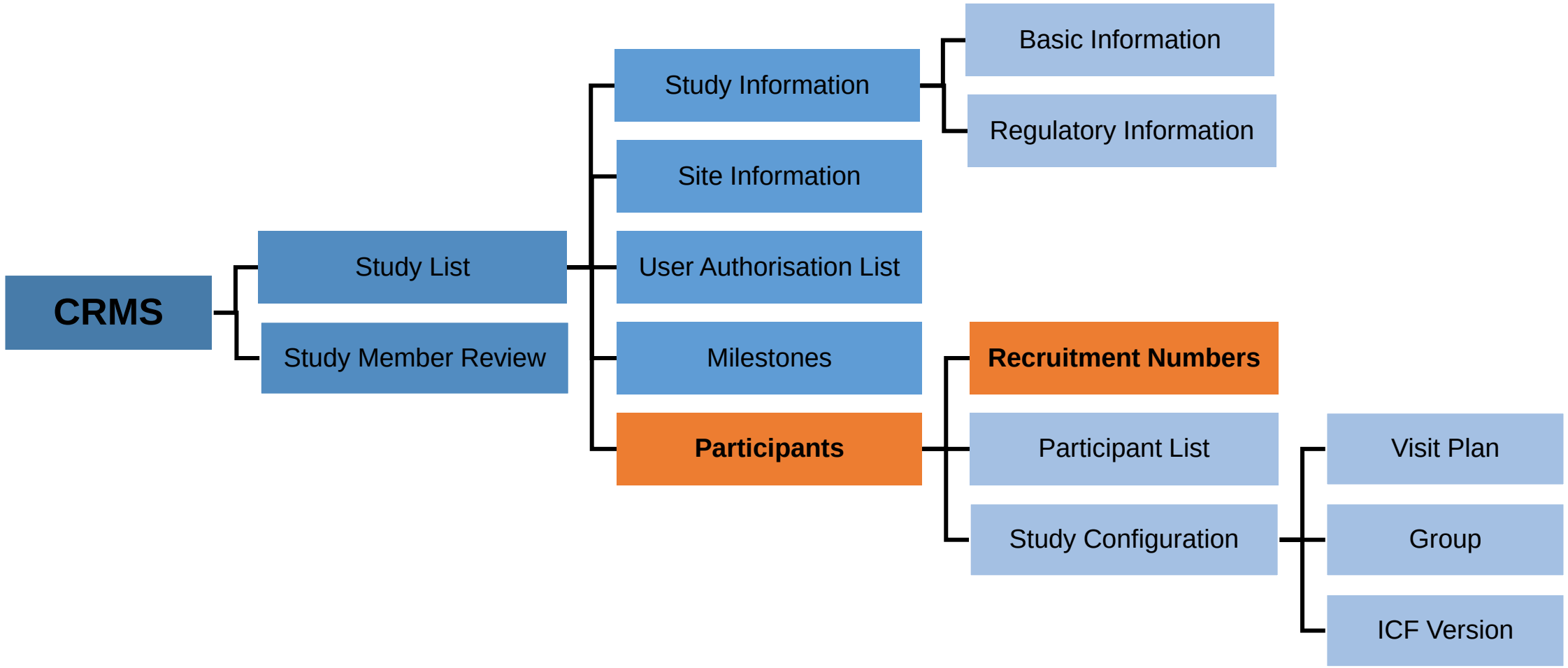
Note:

- Use the “Other” option to create unique milestones not part of the dropdown list, e.g. 50% Recruitment Target.
- Once an entry is created and saved, it cannot be deleted.

Use the Milestones page as a Project Management Tool!
Apply reverse planning and achieve your end goal in time, e.g. completion of research before the grant expiry date.

Click here to return to Index.

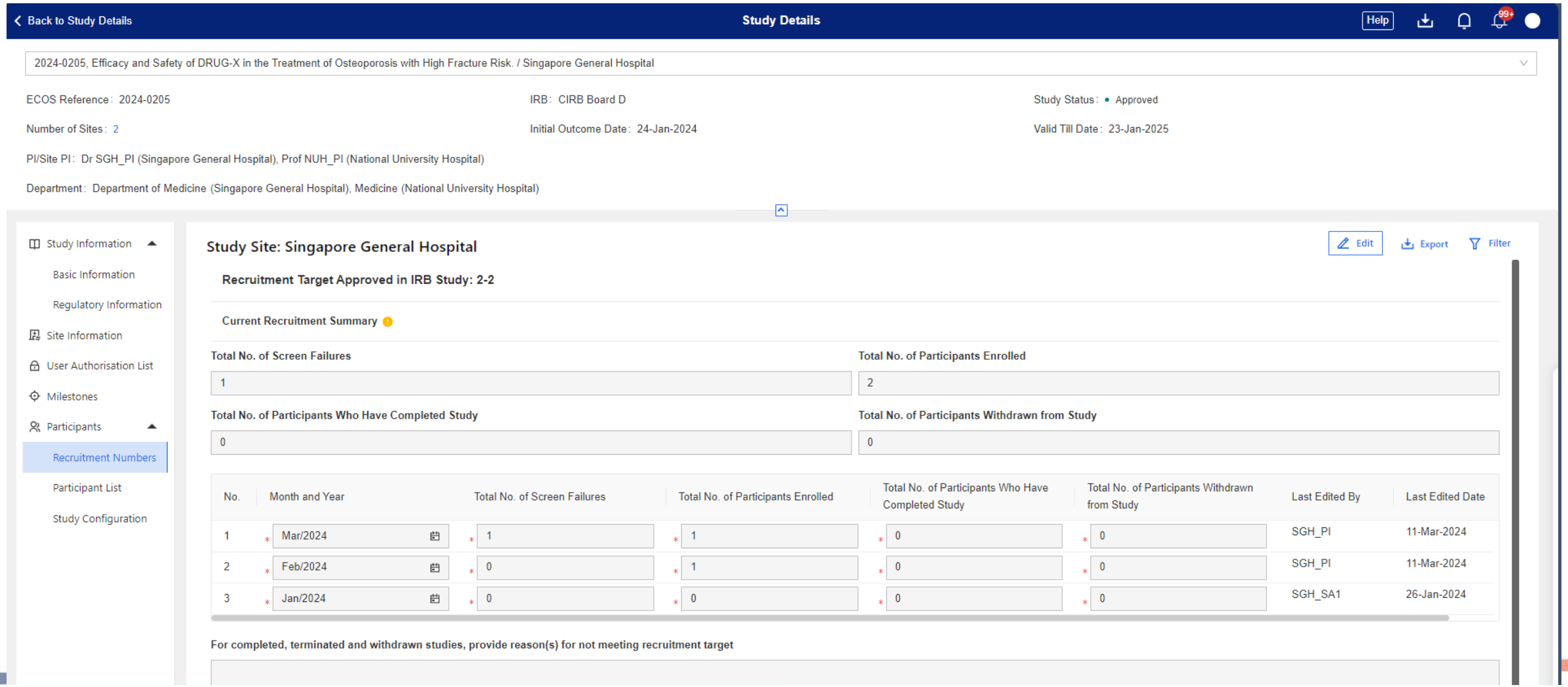
CRMS Sitemap



Participants – Recruitment Numbers

Site Level

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



Participants – Recruitment Numbers

Site Level

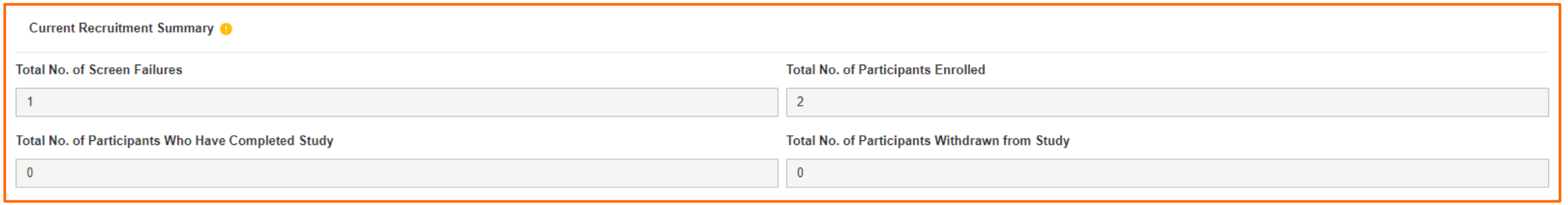
Below are the data fields found on this page:

Recruitment Numbers

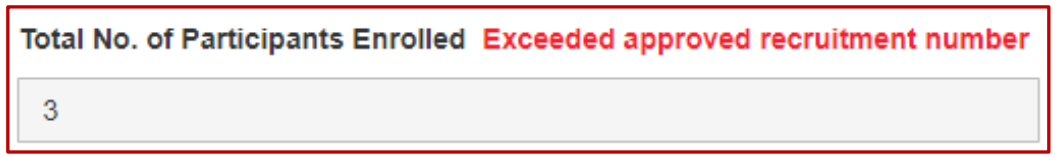
- Month and Year
- Total No. of Screen Failures
- Total No. of Participants Enrolled
- Total No. of Participants Who Have Completed Study
- Total No. of Participants Withdrawn from Study
- For completed, terminated and withdrawn studies, provide reason(s) for not meeting recruitment target *(Free text)*

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.



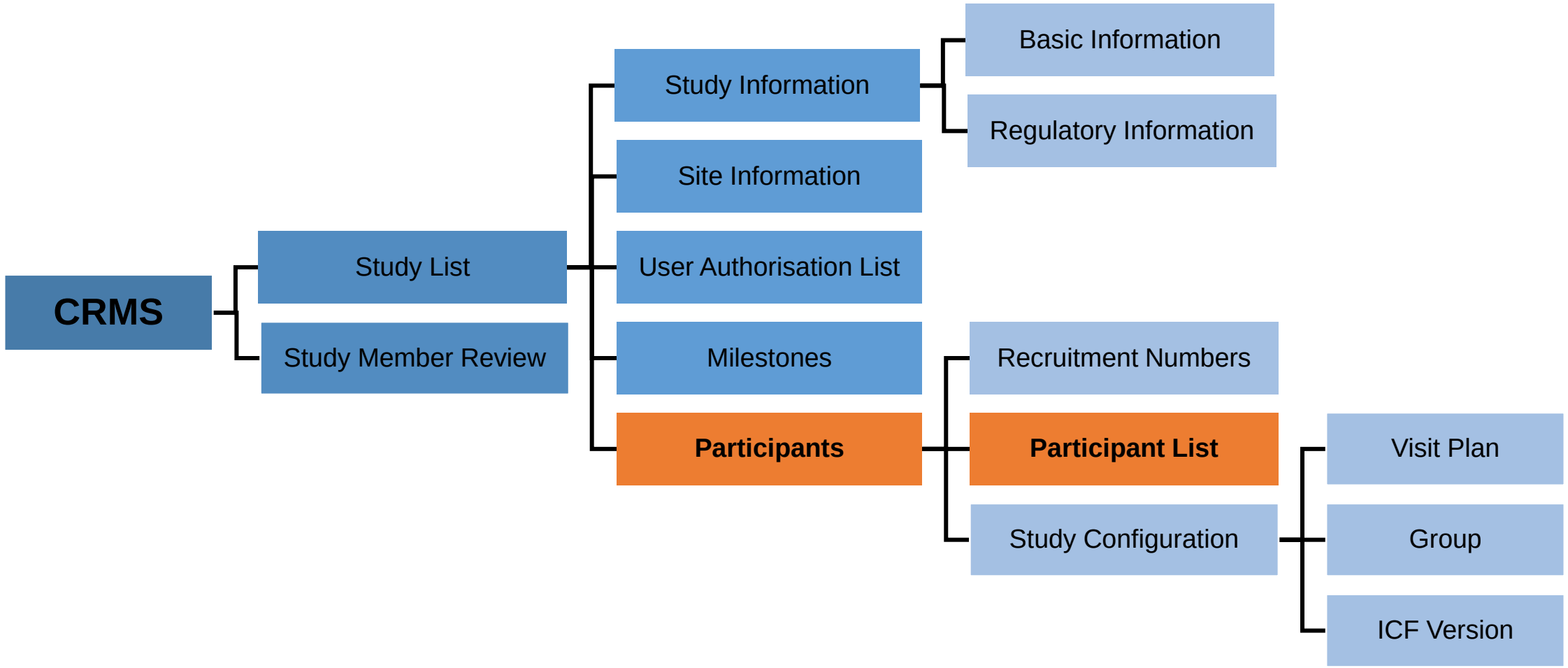
- **Recruitment Target Approved in IRB Study** will be imported from the IRB module.
- A prompt in red will appear if the **Total No. of Participants Enrolled** exceeds the approved number.



- **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. At the same time, please raise an IRB Amendment Form to increase the target number.

Click here to return to Index.

CRMS Sitemap



Participants – Participant List

Site Level

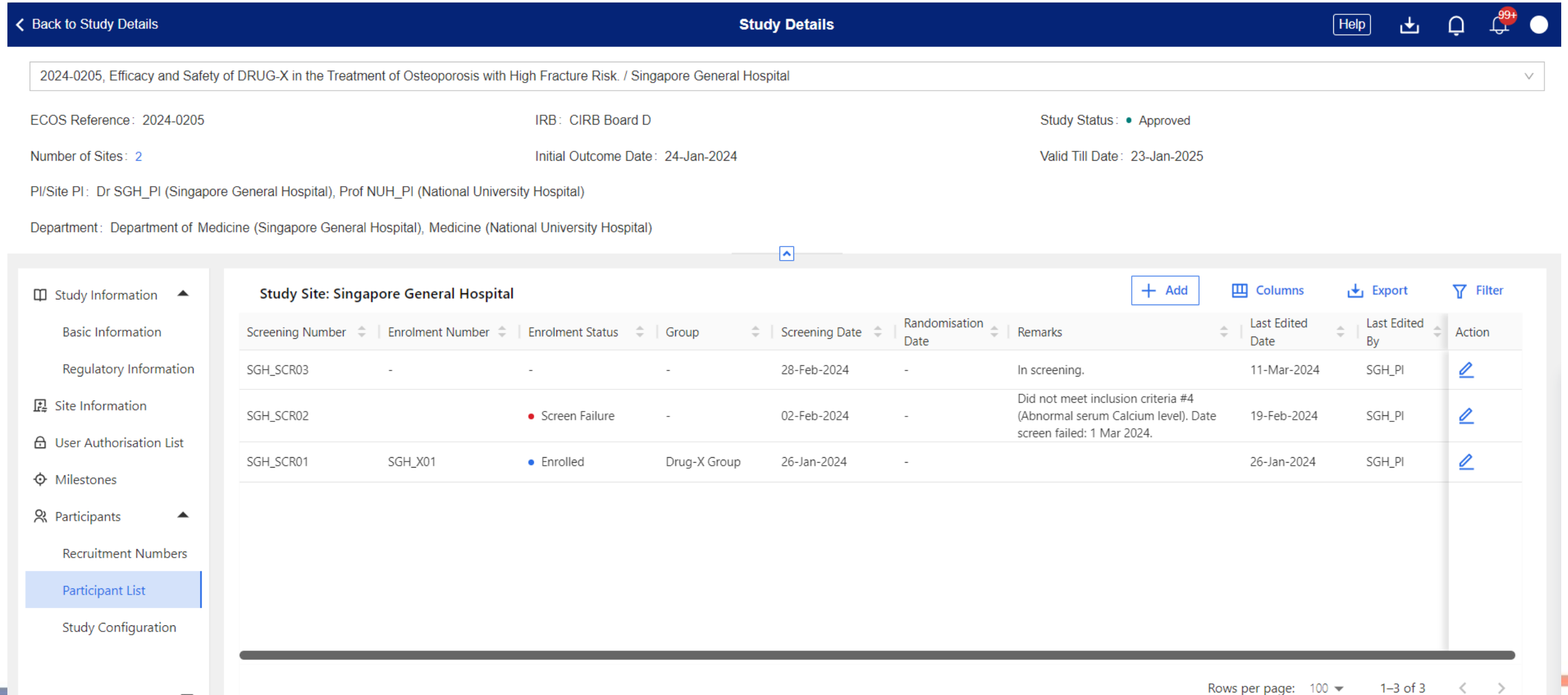
- Provides an overview of the list of participants screened, enrolled and/or randomised.

- 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



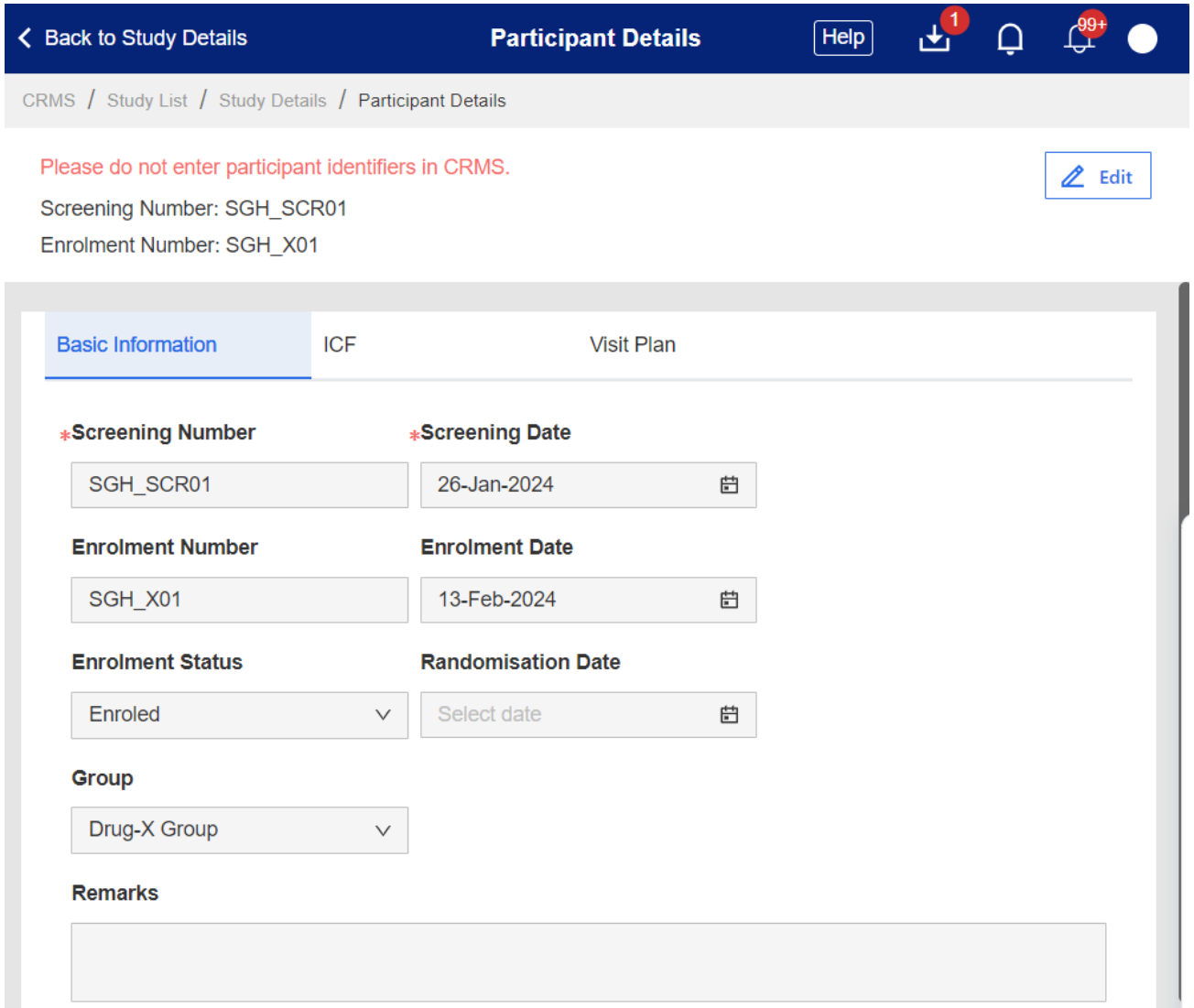
Participants – Participant List

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



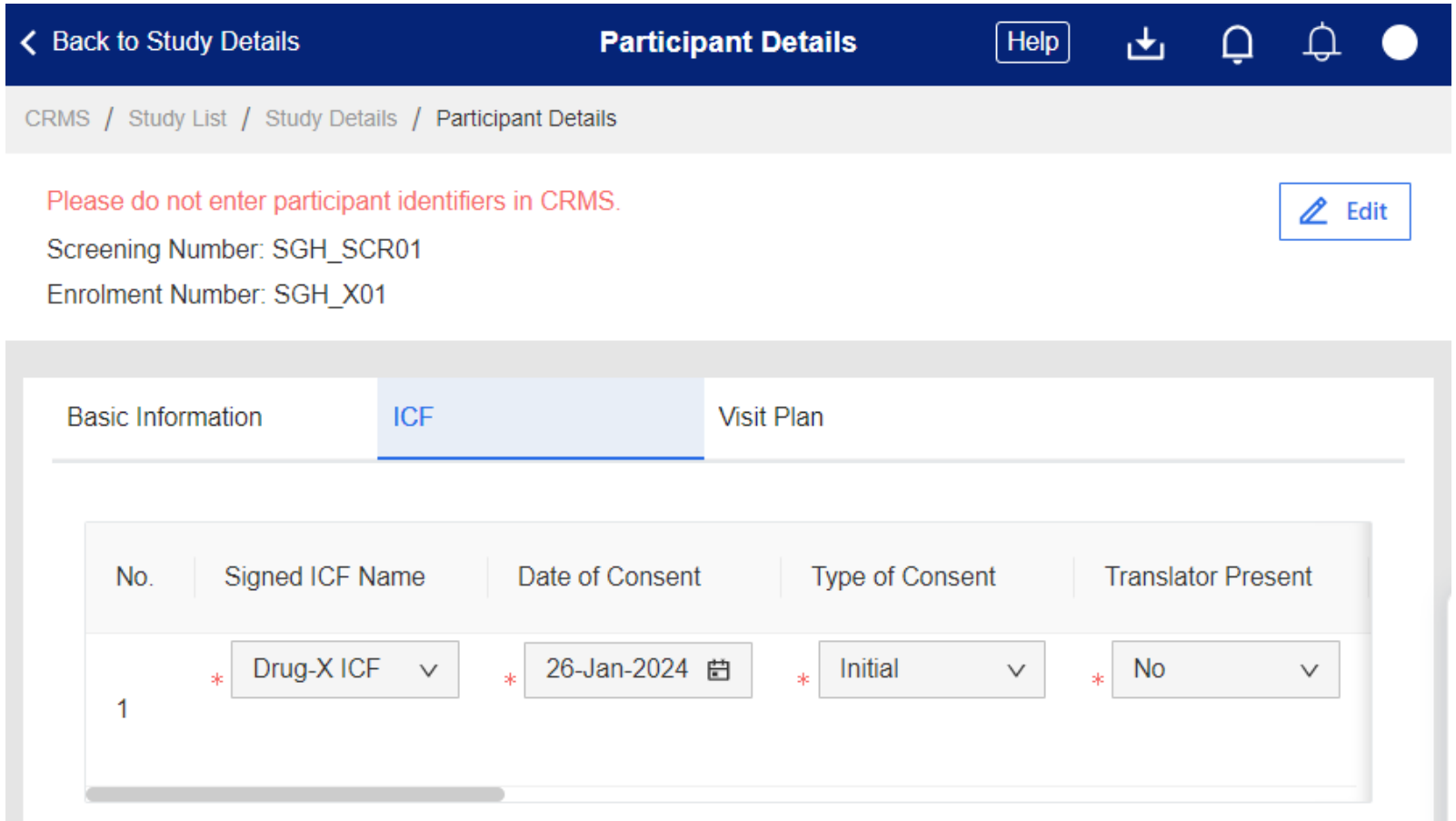
Participants – Participant List

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

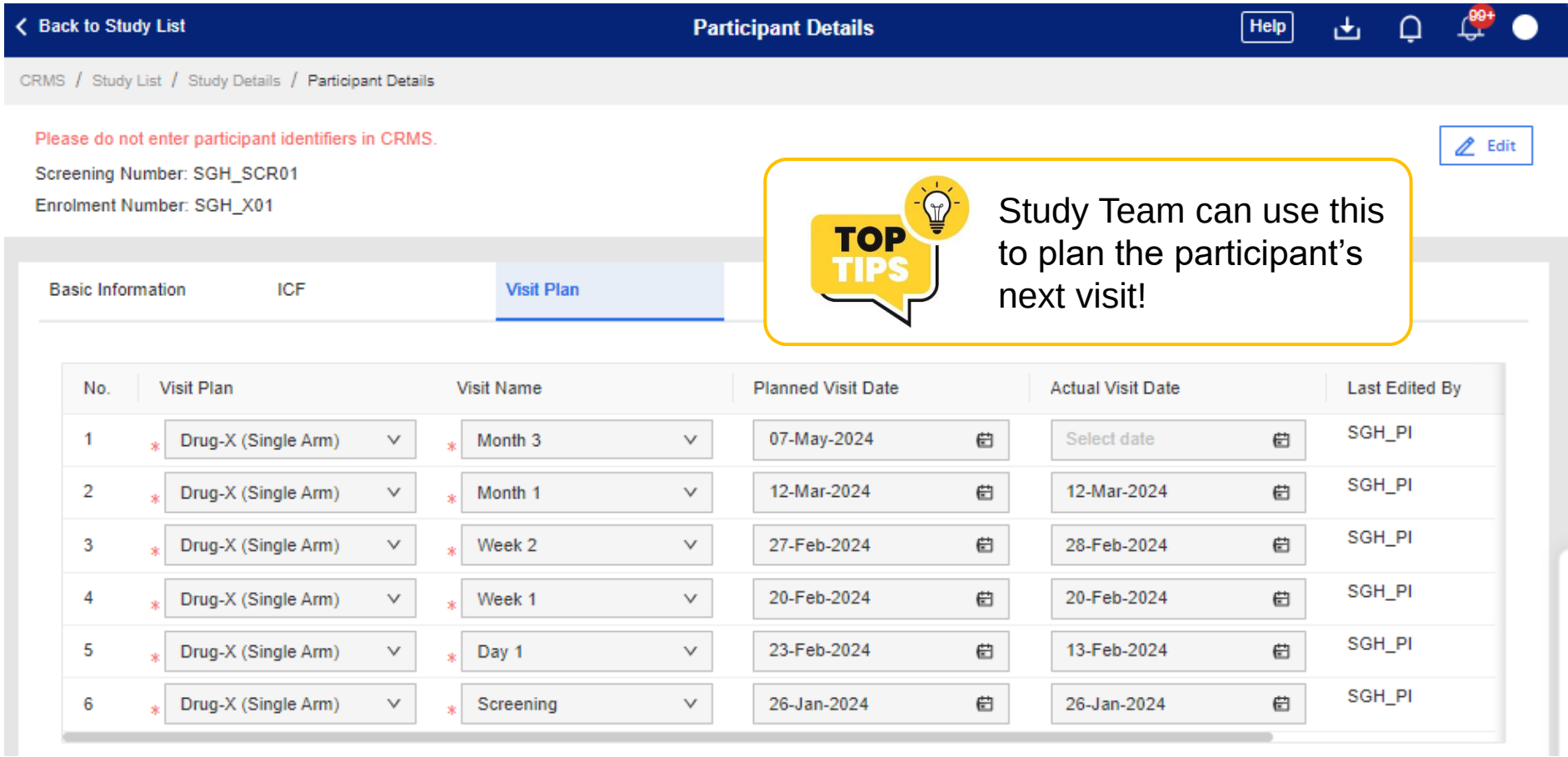
Below are the data fields found on this page:

Visit Plan

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

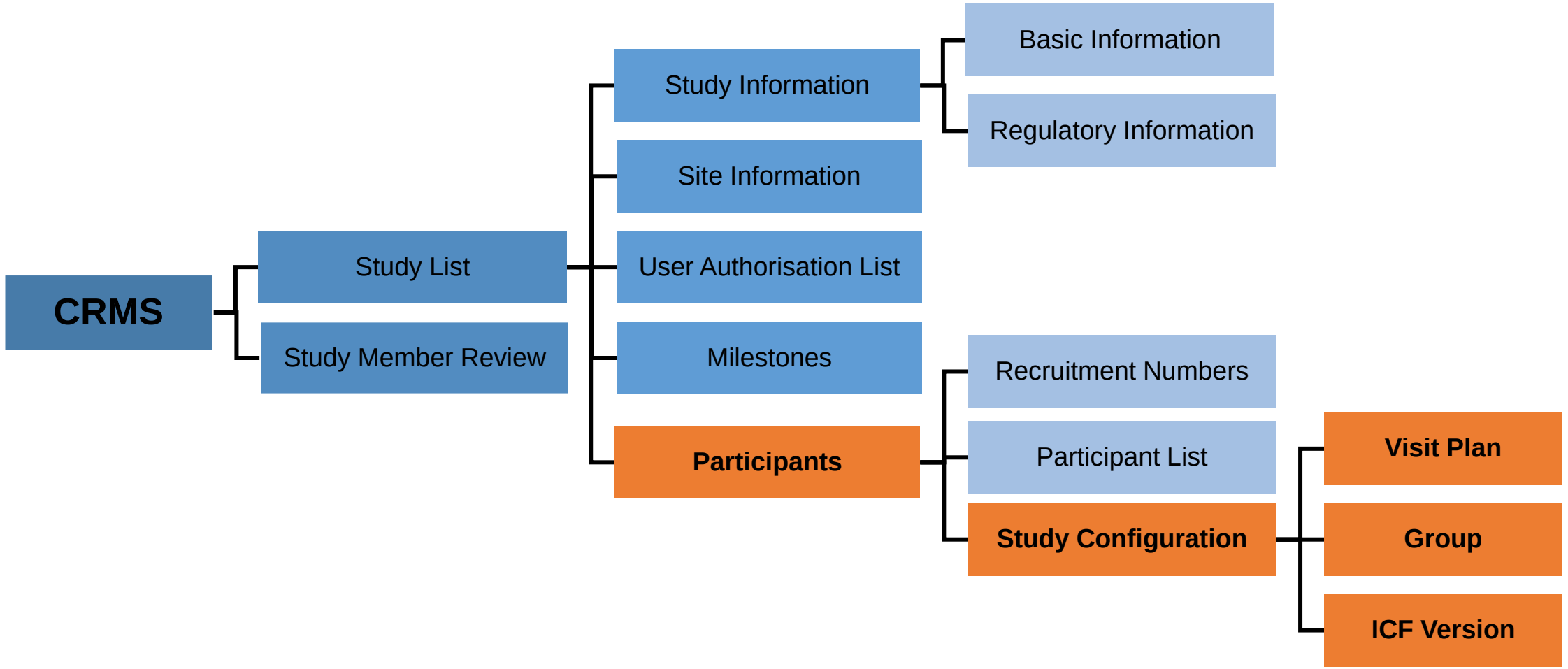
Note:

- 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.



Click here to return to Index.

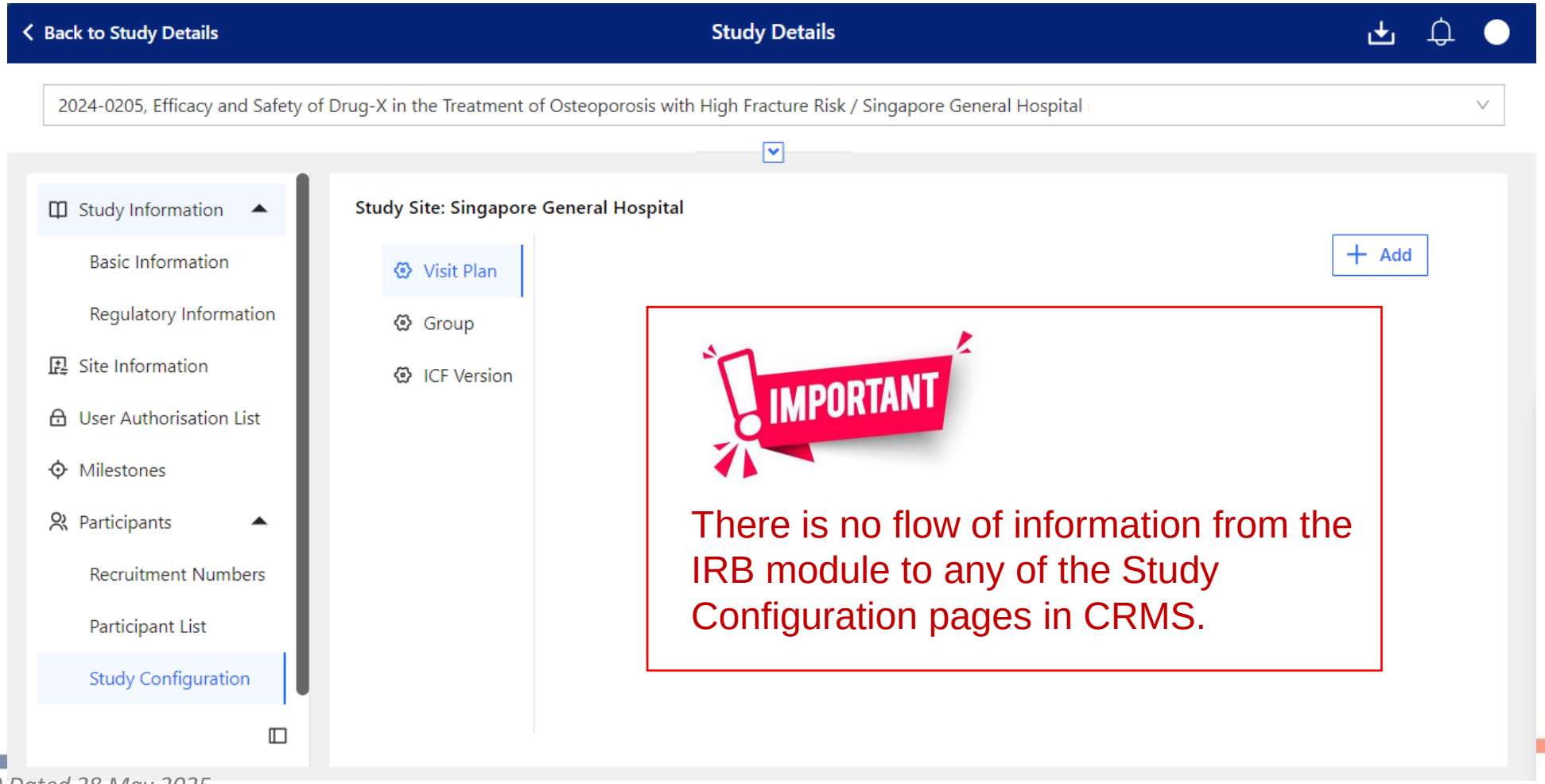
CRMS Sitemap



Participants – Study Configuration

Site Level

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



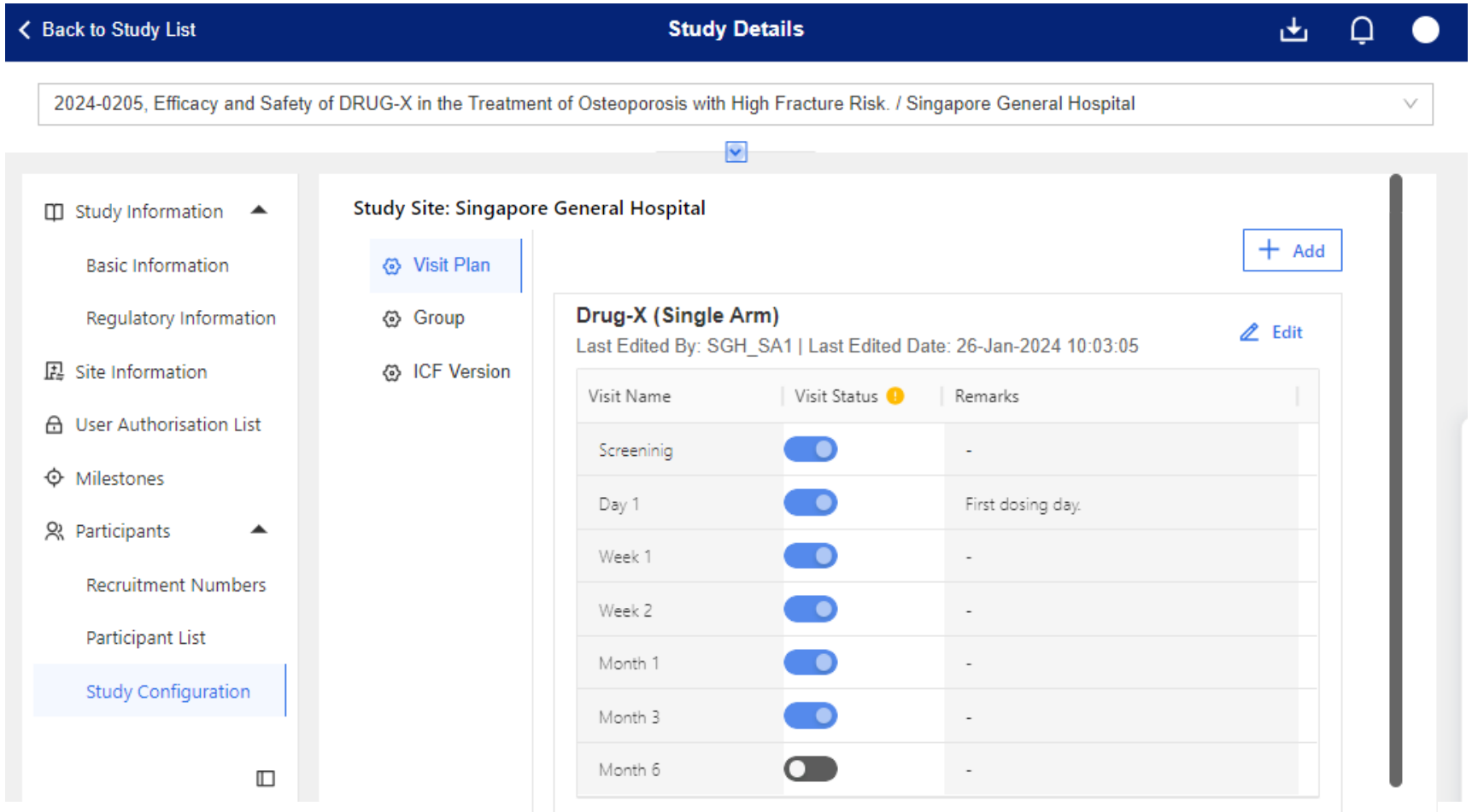
Participants – Study Configuration

Site Level

Below are the data fields found on this page:

Visit Plan

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

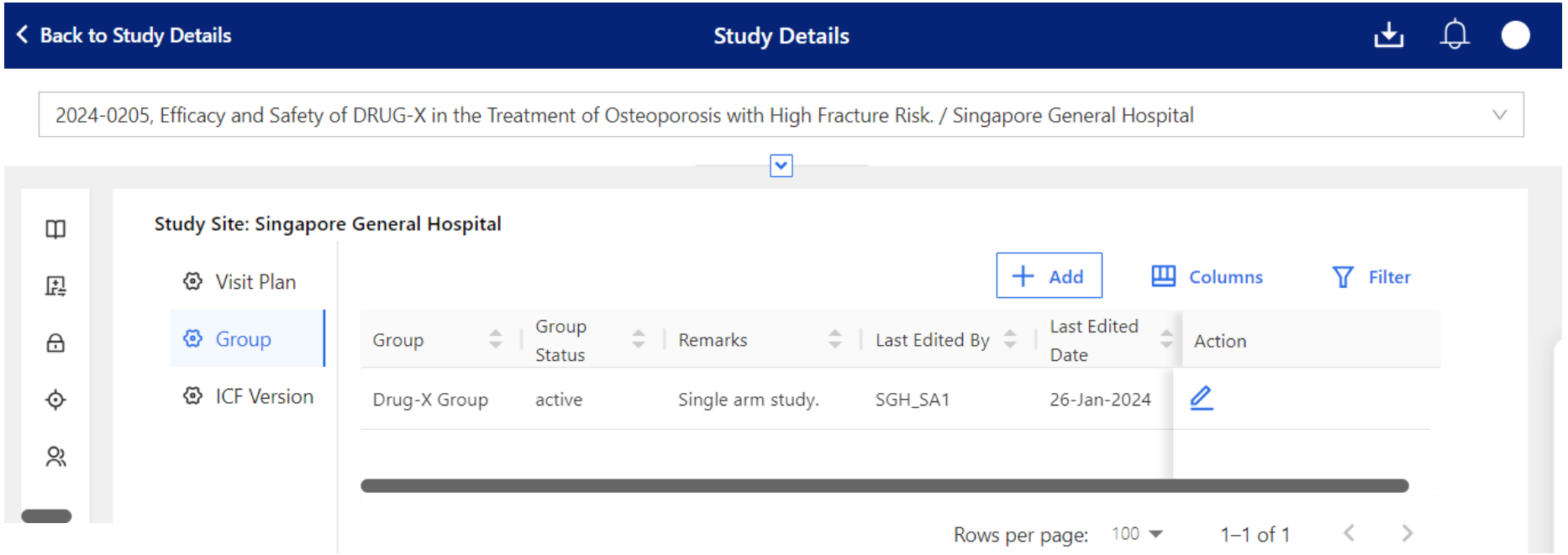


Note:

- 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:

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

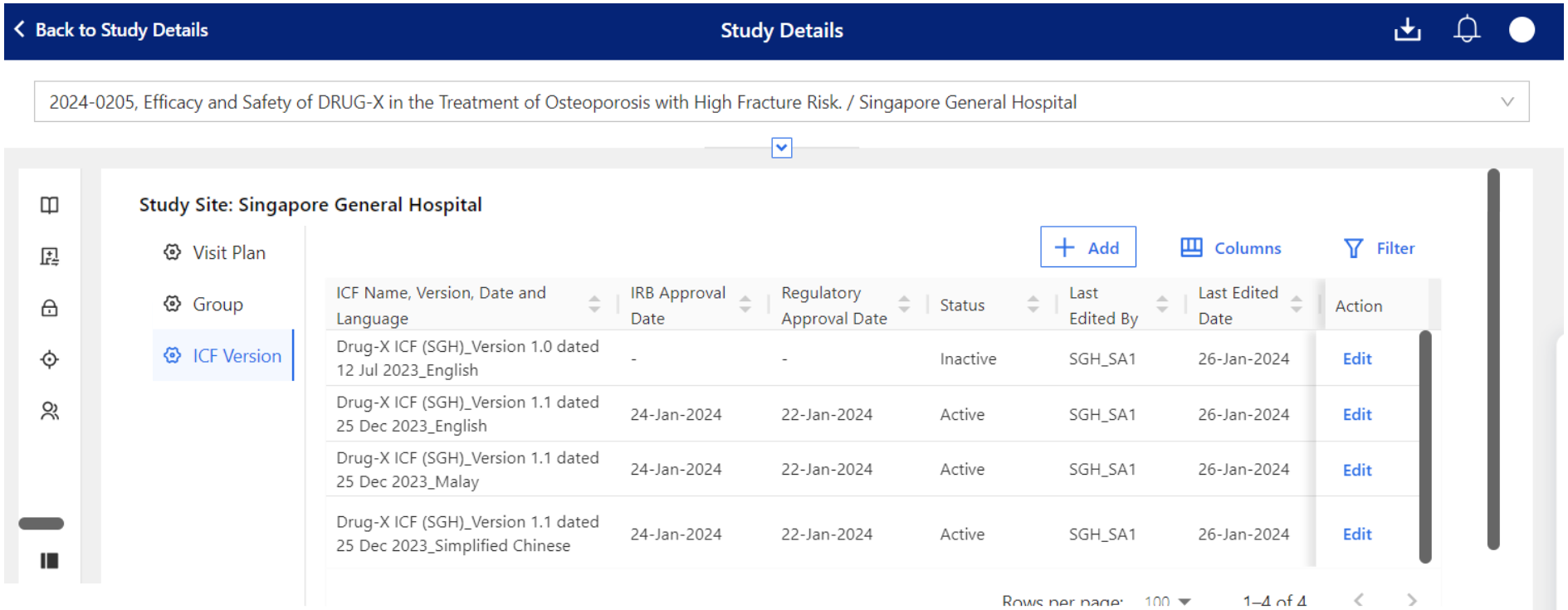
Participants – Study Configuration

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



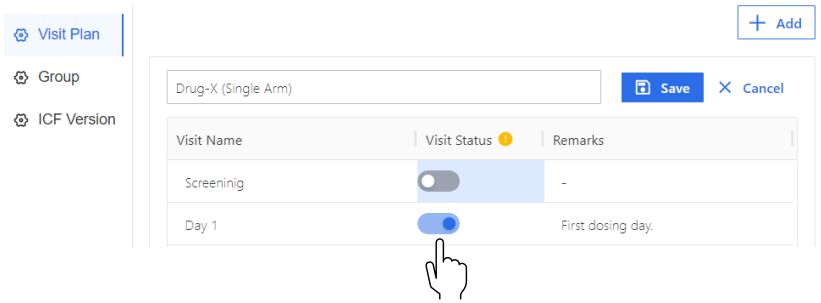
Note:

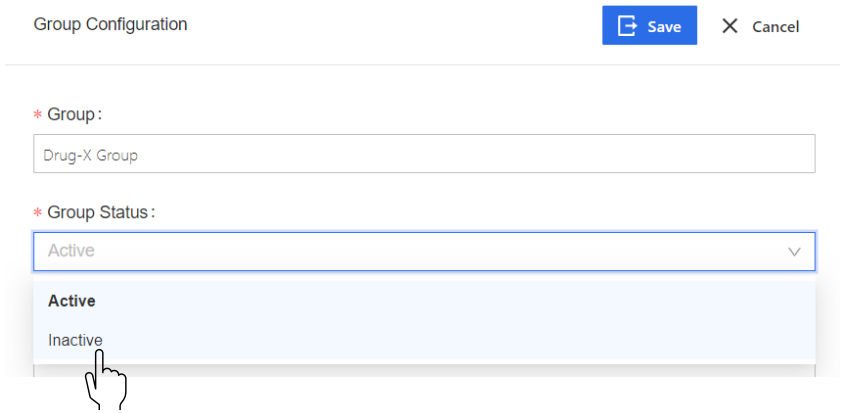
- Status of ICF must be “Active” for the entered row to appear on the **Participant – Participant List** page as an option to select.
- Study team can take this as a checkpoint to see if all necessary approvals have been secured before using the ICFs.

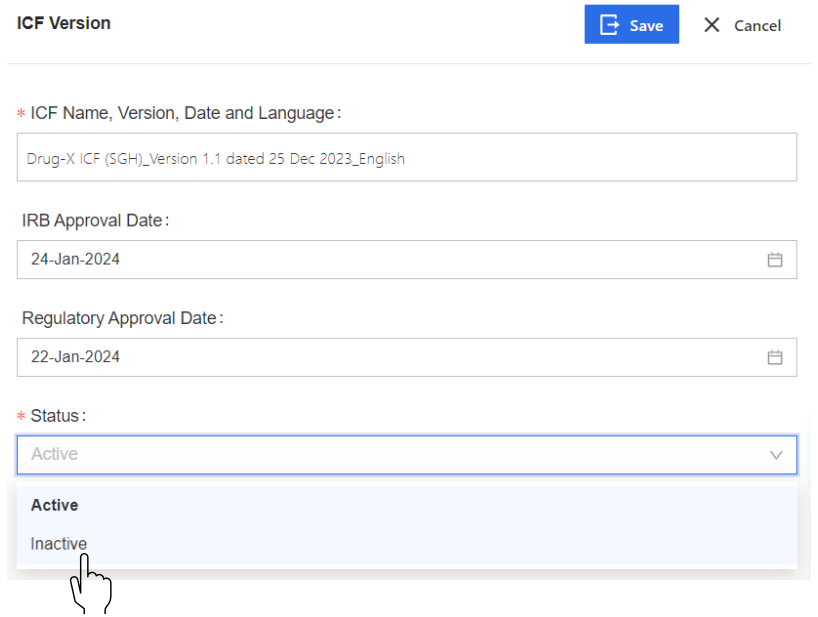
Participants – Study Configuration

Site Level

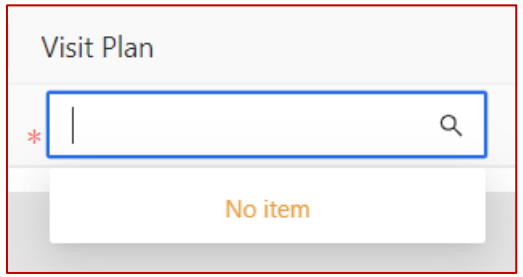
- Entries in the Study Configuration (Visit Plan, Group, ICF Version) cannot be deleted once saved.
- Users will need to use the switch toggle or drop-down list to inactivate the entry.





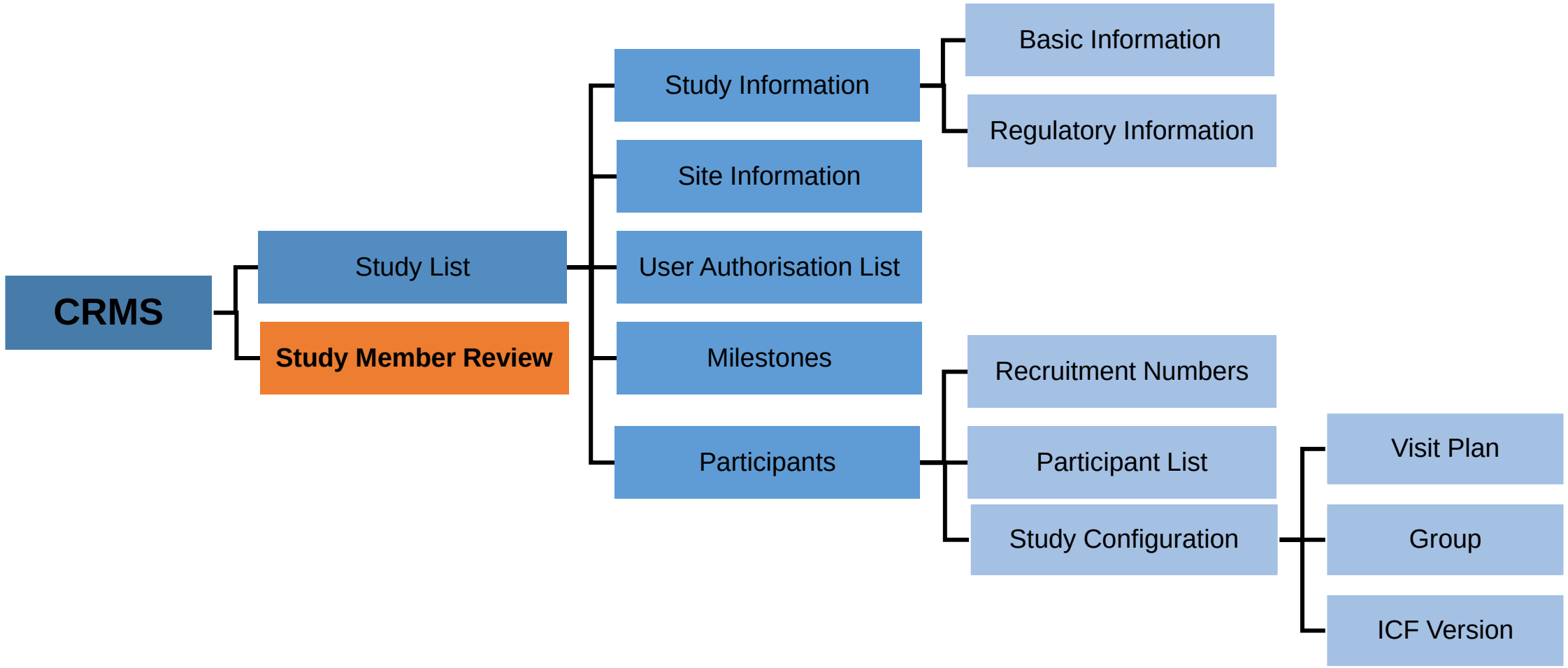


- Once inactivated, the entry will not appear as an option in the drop-down list of the relevant **Participant List** sections.



Click here to return to Index.

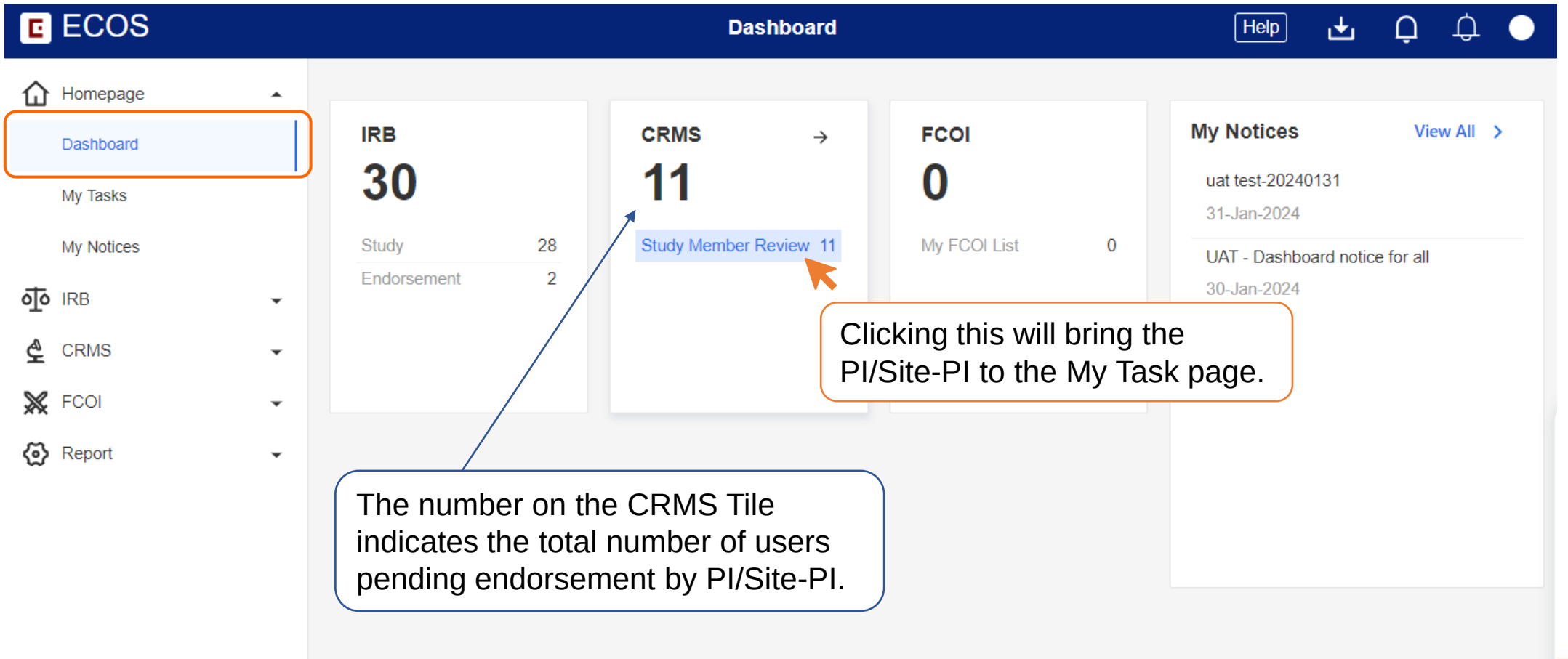
CRMS Sitemap



Study Member Review

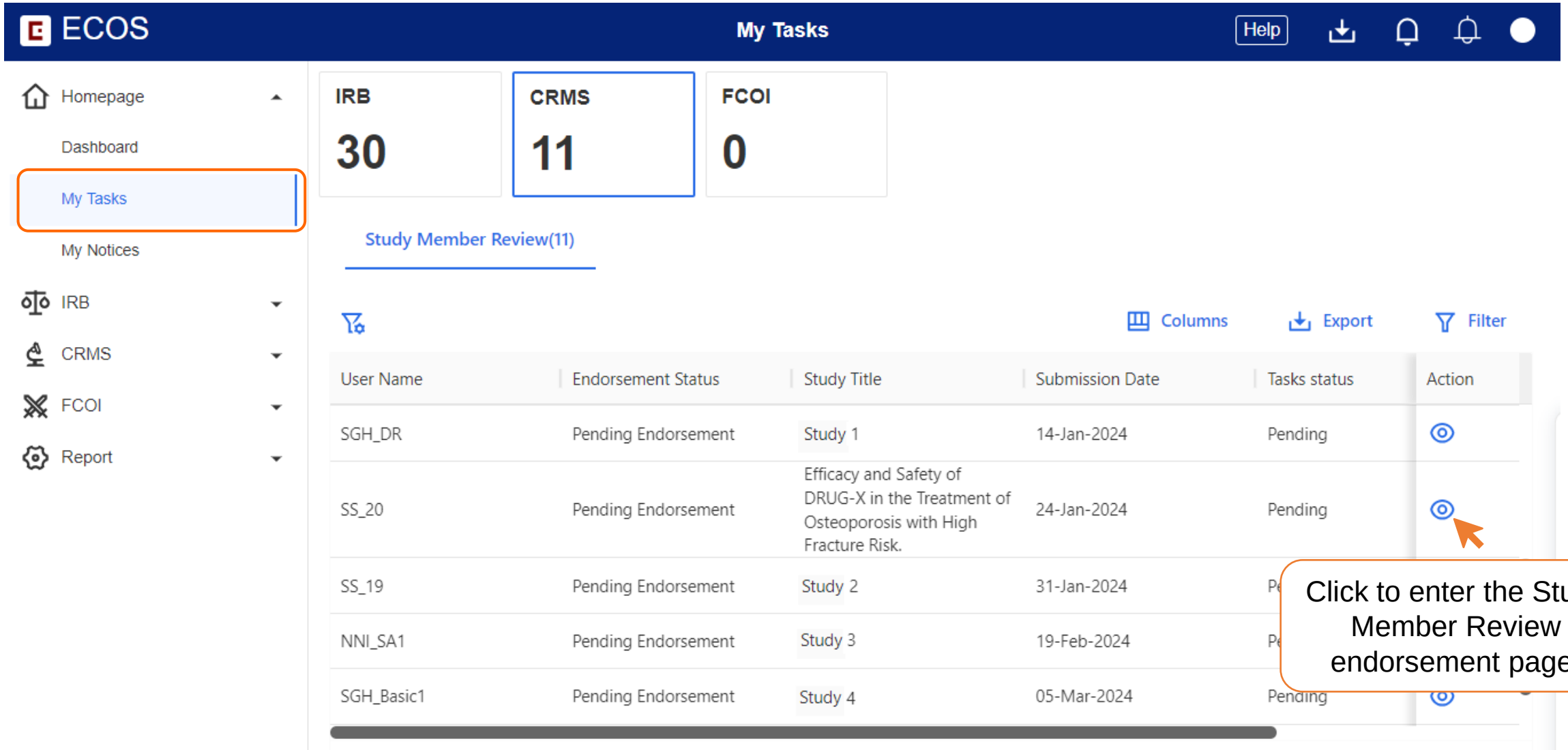
Site Level

- PI/Site-PIs can access the Study Member Review Page by 2 ways:
  1. Via Dashboard > CRMS Tile > Study Member Review



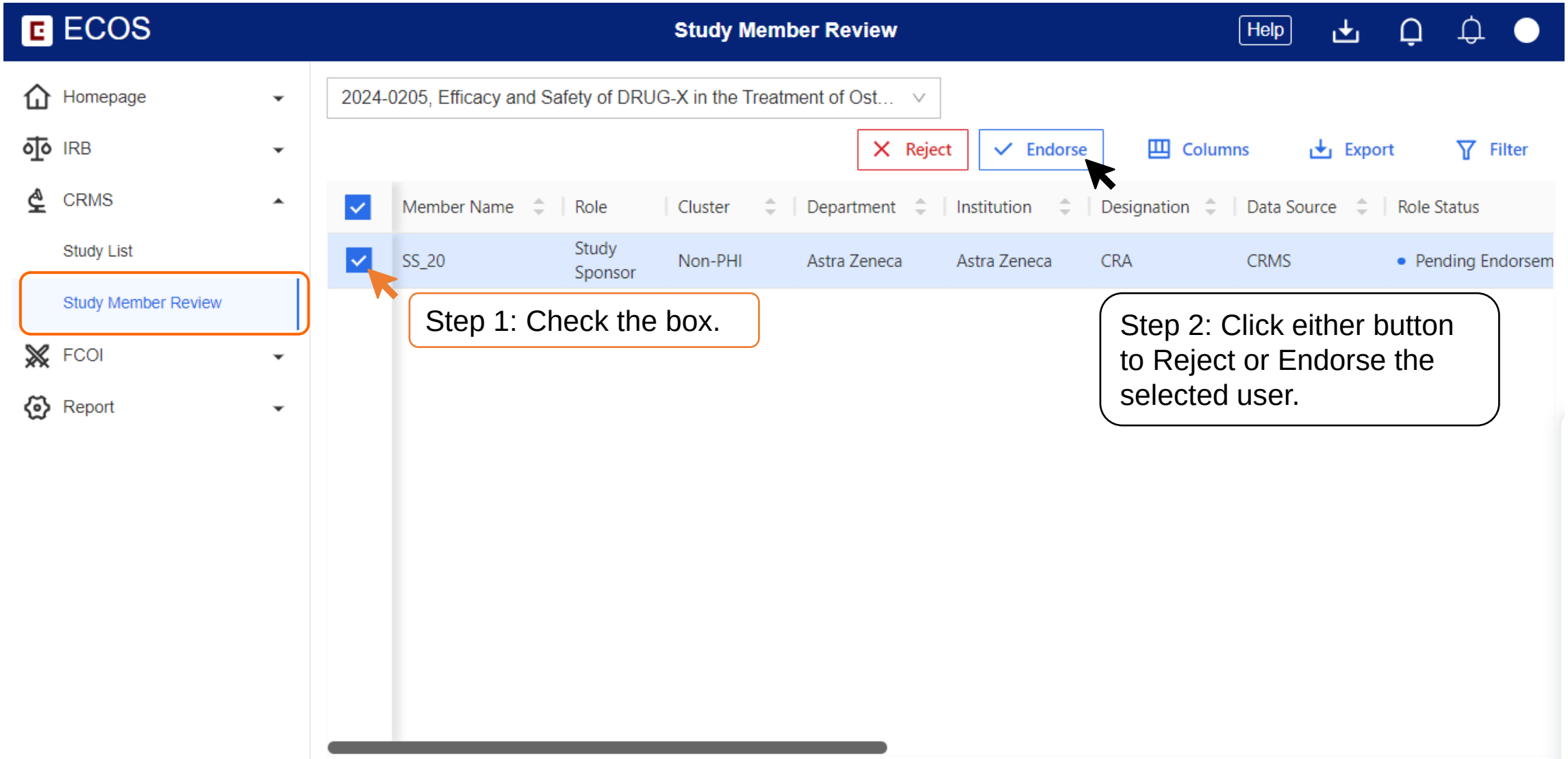
Study Member Review

Site Level



Study Member Review

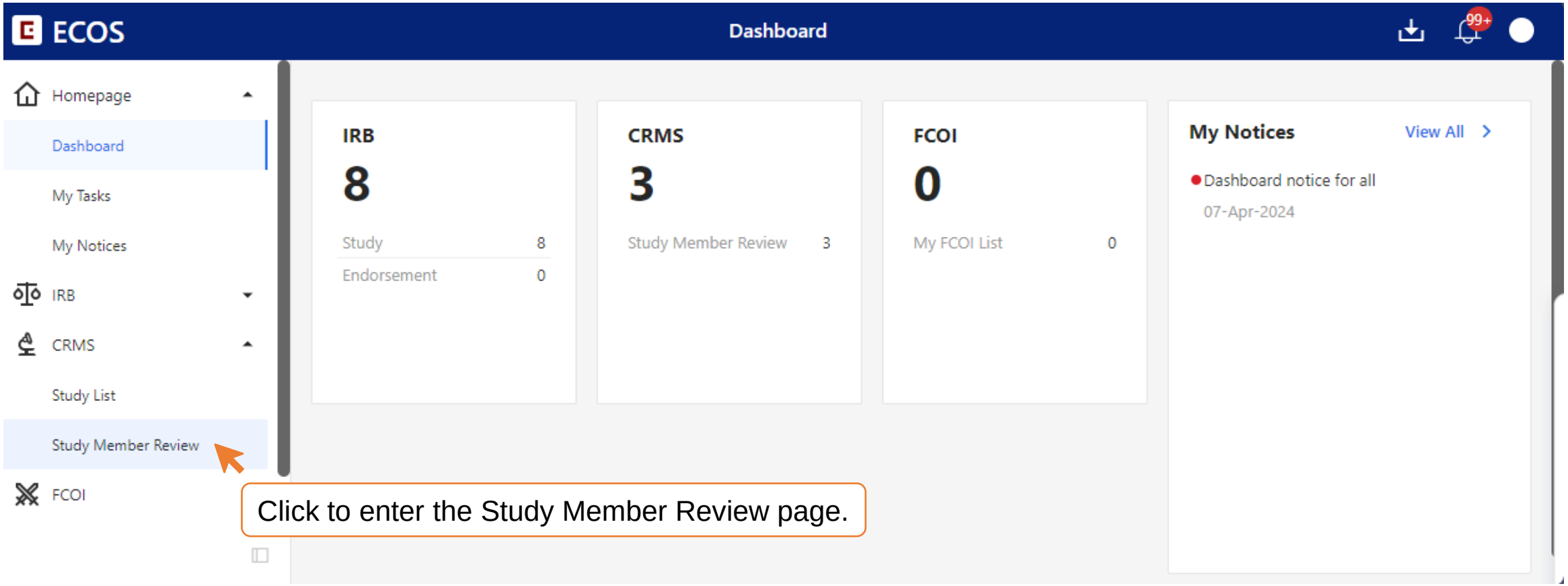
Site Level



Study Member Review Access

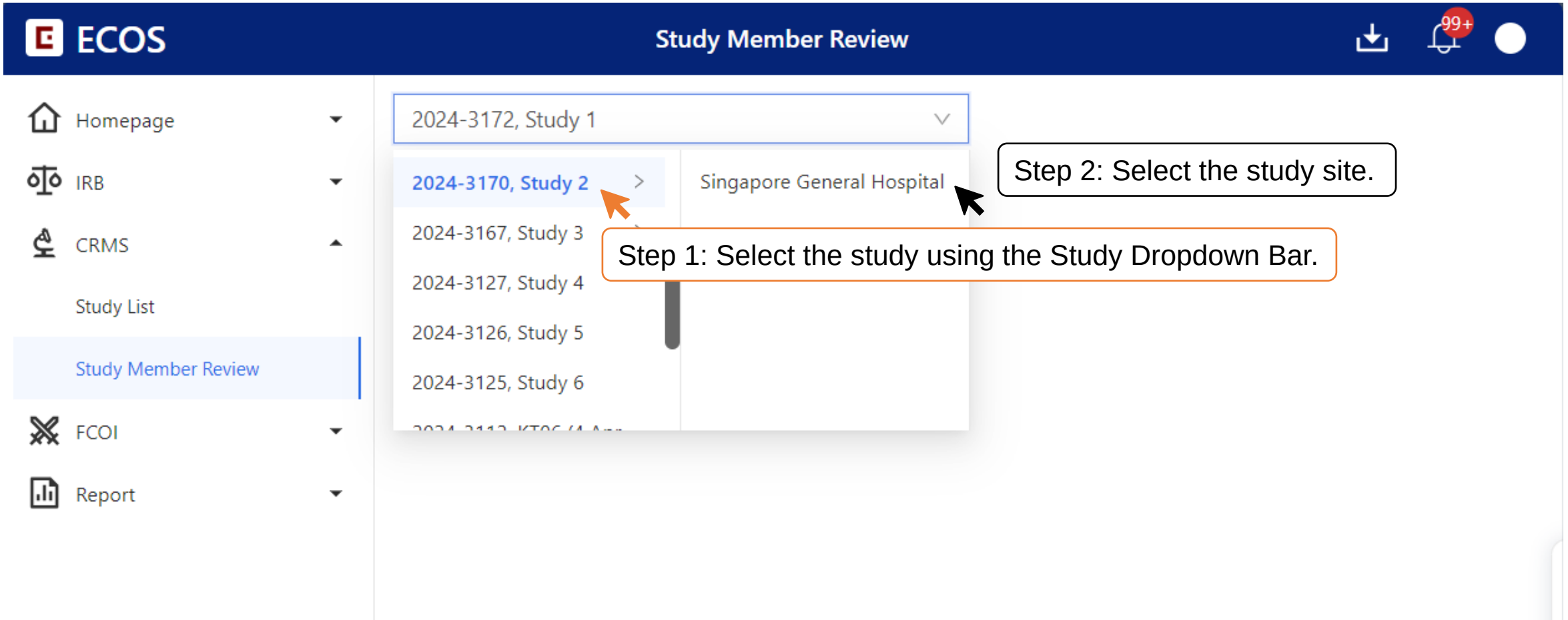
Site Level

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



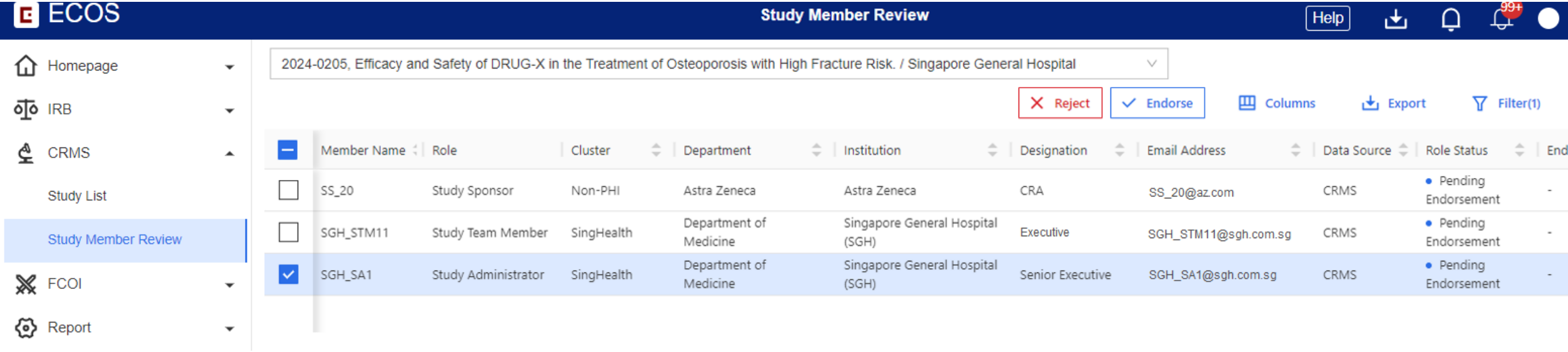
Study Member Review Access

Site Level



Study Member Review

Site Level



- Endorsement page is exclusive to PI/Site-PI.
- PI/Site-PI can start performing the user endorsement once he/she has been added to the IRB Application Form, i.e. while pending IRB's approval.
- New PI/Site-PI added to a study through an IRB Amendment Form can only perform the review/endorsement after he/she has been approved by the IRB.
- Multiple users can be selected by the PI/Site-PI to endorse or reject.
- User Authorisation List will be updated accordingly based on the action taken.

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

Click here to return to Index.

In-built Logic Checks for Basic Information

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**

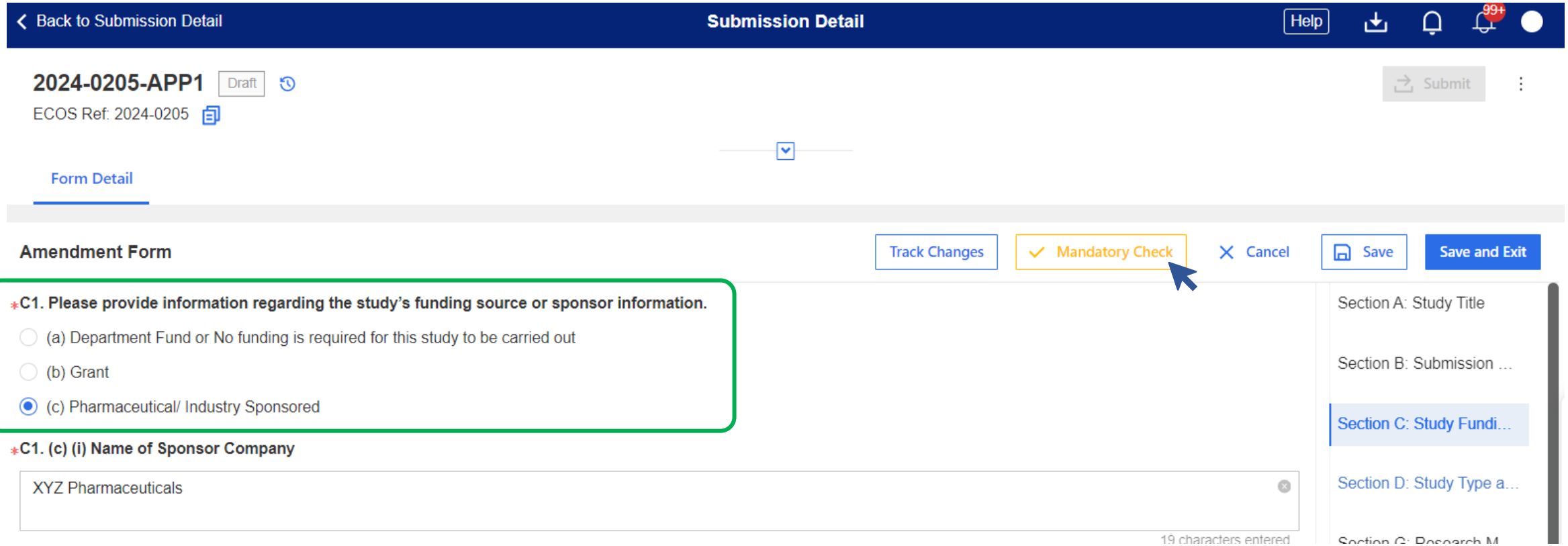
c) IRB Review Billing Details.

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

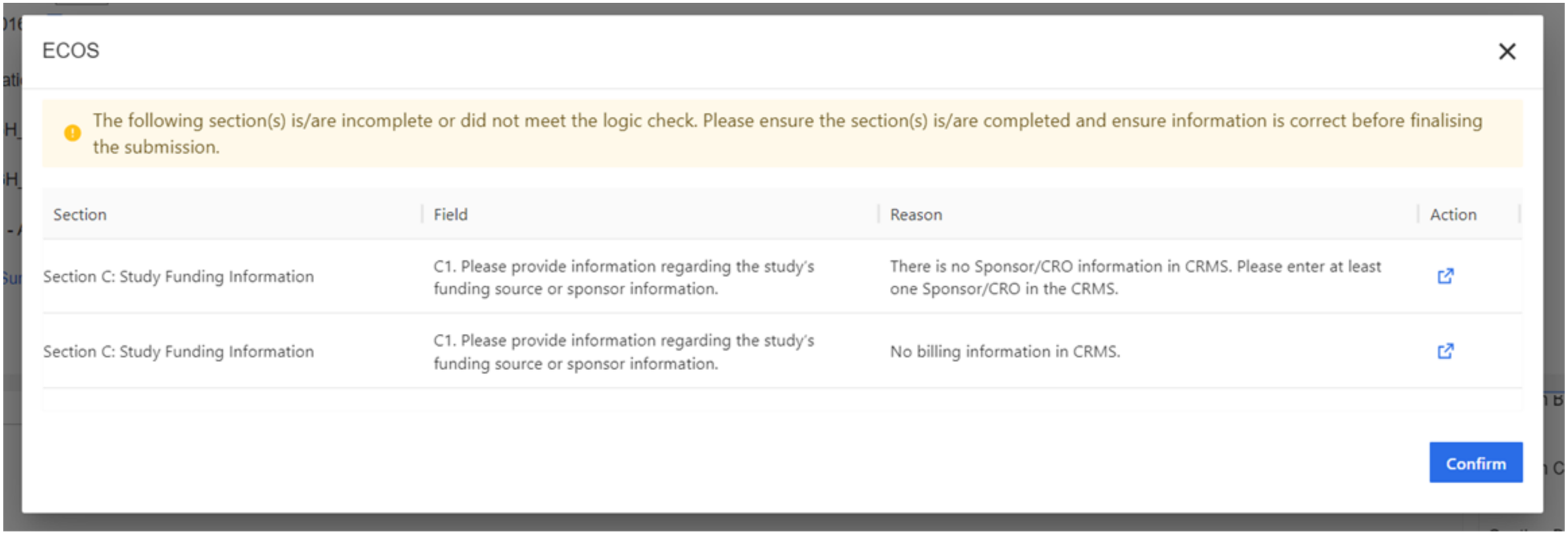
- **NOTE:** This is not applicable to studies funded by **Grant** or **Department Fund or No funding is required for the study to be carried out**.

IRB APP Form – Section C1

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



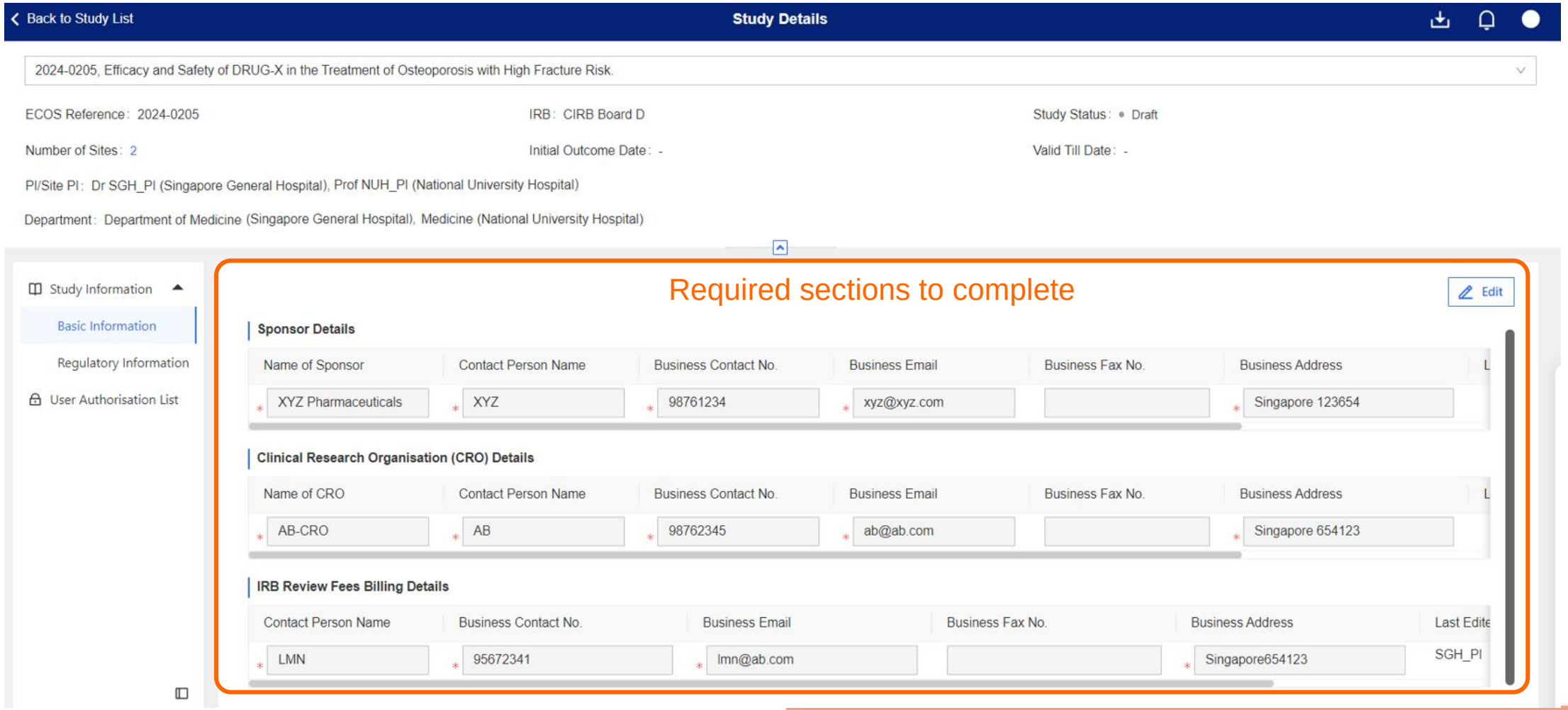
Mandatory Check Prompt From IRB APP Form



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

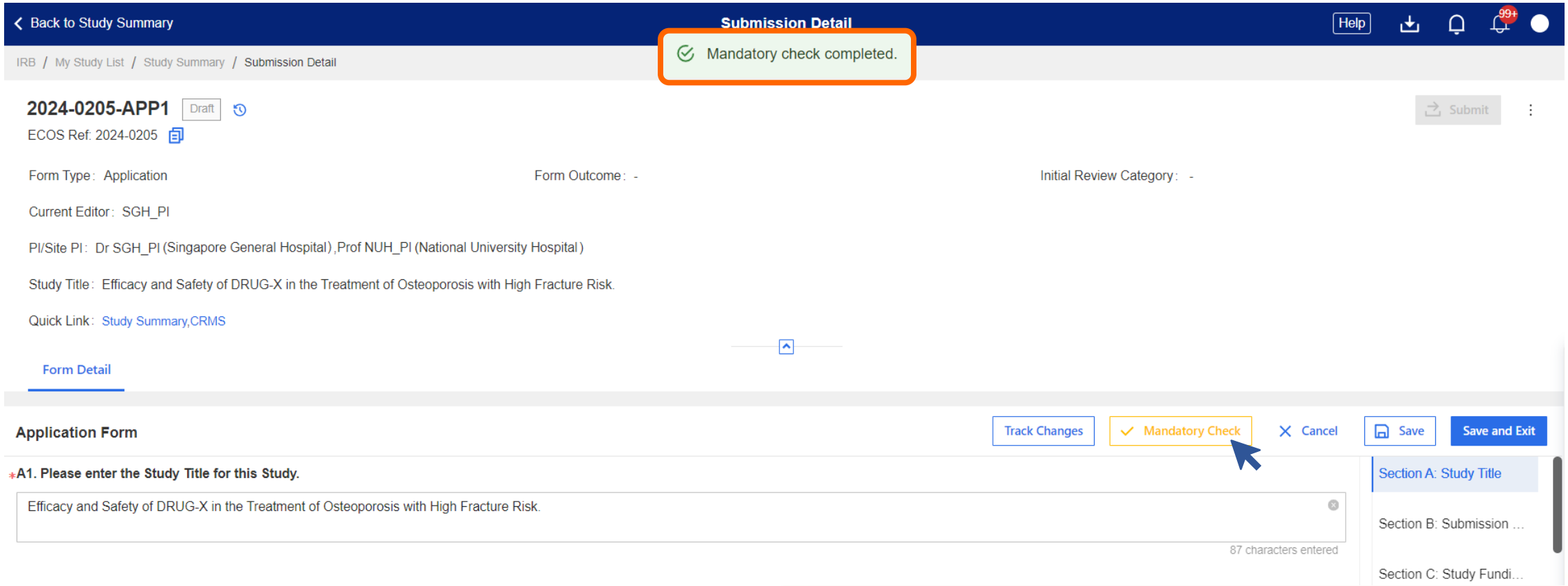
Complete Sponsor/CRO and IRB Details in CRMS

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



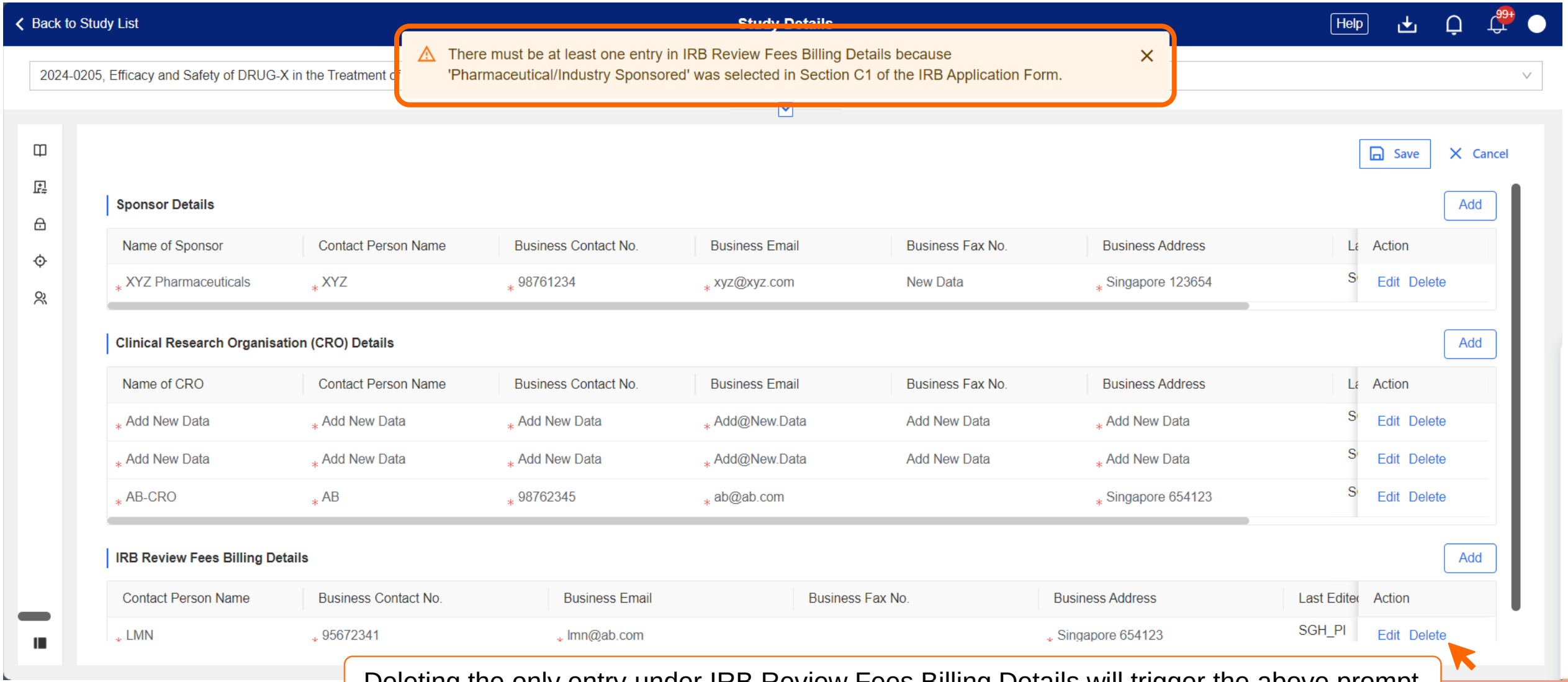
In-built Logic Checks – After IRB APP Approval

- After the 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.

- **NOTE:** This is not applicable to studies funded by **Grant** or **Department Fund or No funding is required for the study to be carried out**.

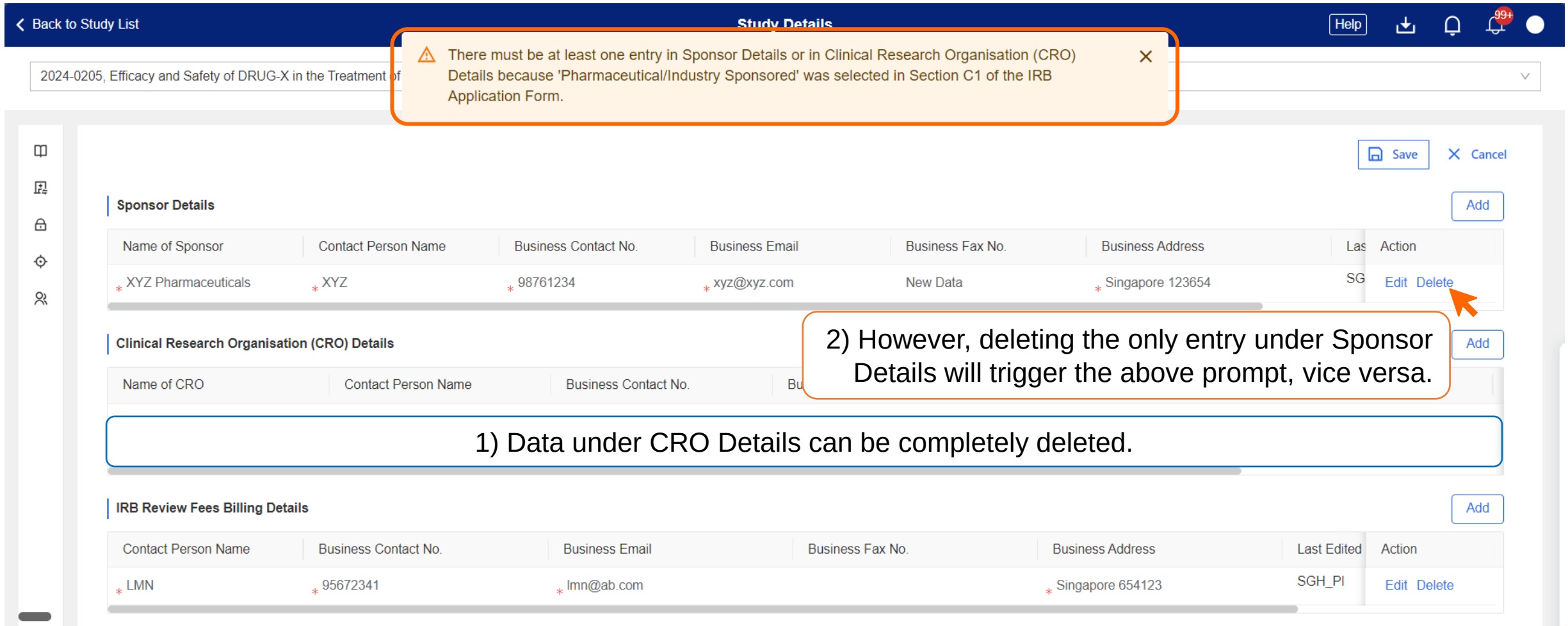
At Least 1 Entry Must Be Retained



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

Click here to return to Index.

Addition of STM/SA/SS to the UAL by System

National Healthcare Group
Adding years of healthy life

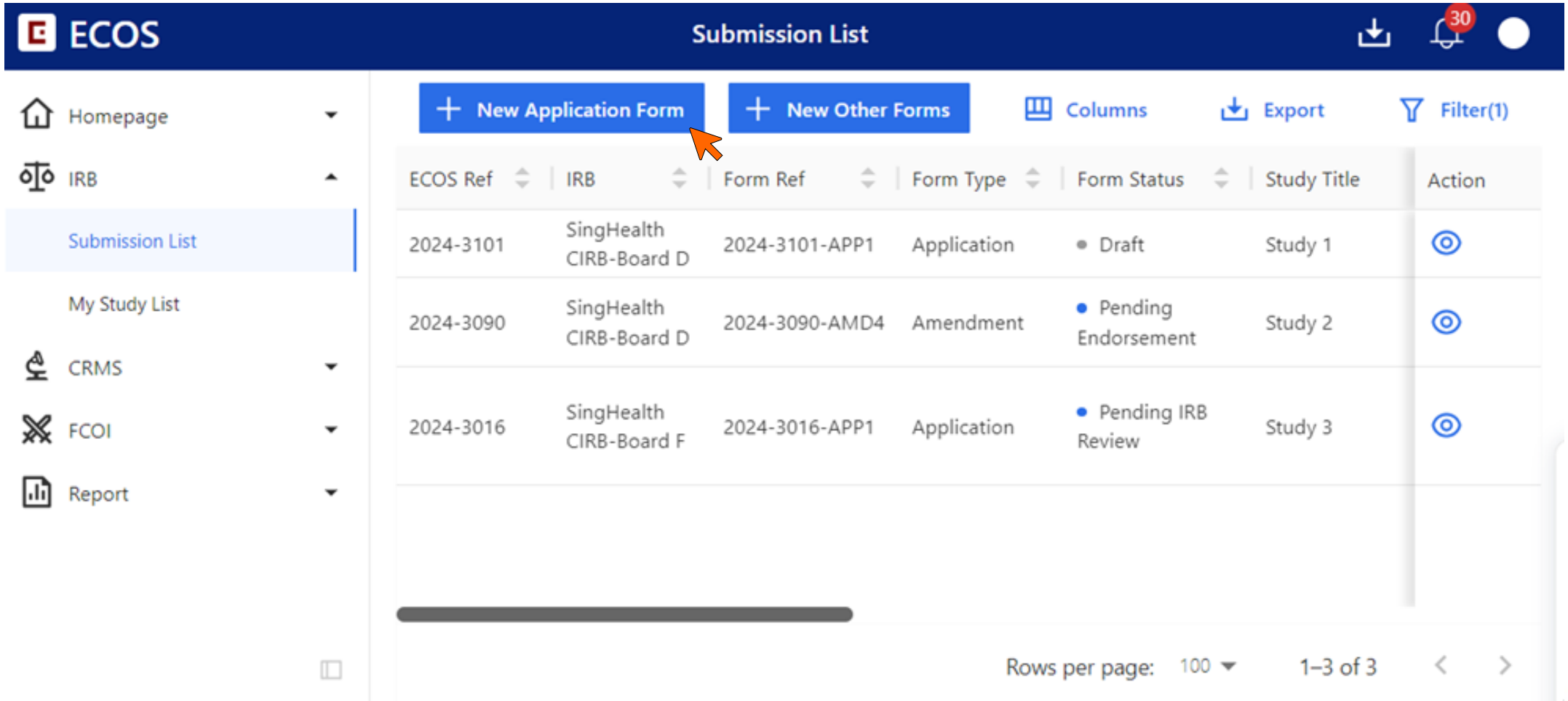
SingHealth
Defining Tomorrow's Medicine

STM/SA/SS Initiating a New IRB Application Form

- Users who have access to the IRB module will be able to create an IRB Application Form.
- Investigators (PI, Site-PI, Co-I) added to the IRB Application 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 Application Form.
- As for STM/SA/SS, since they cannot be added to the IRB Application 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 of the study. The STM/SA/SS will have access to CRMS and continue to have access to the IRB Application Form.
- The next few slides will briefly illustrate the above using a Study Sponsor (SS_20) account.

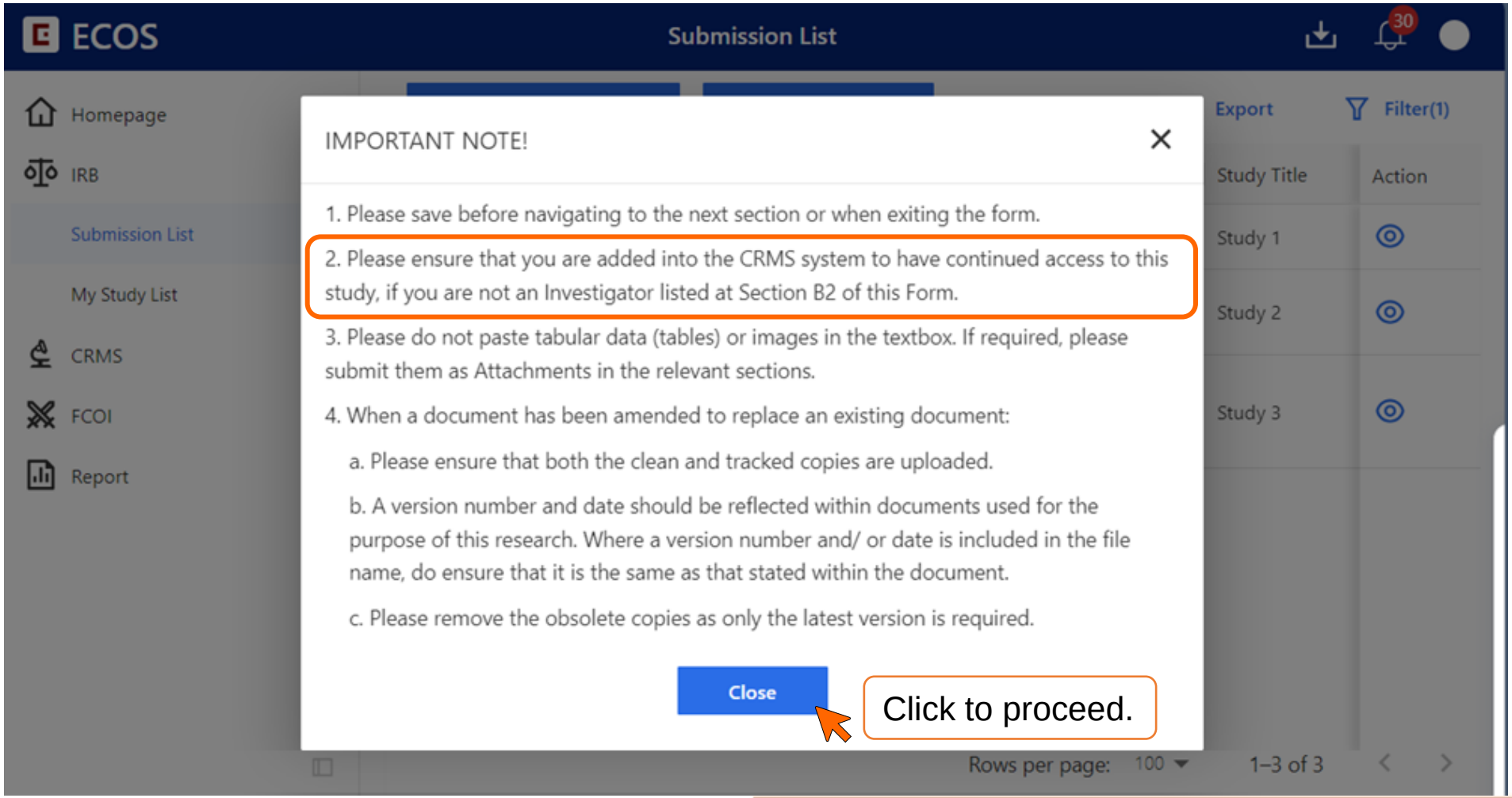
IRB Application Form Creation

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



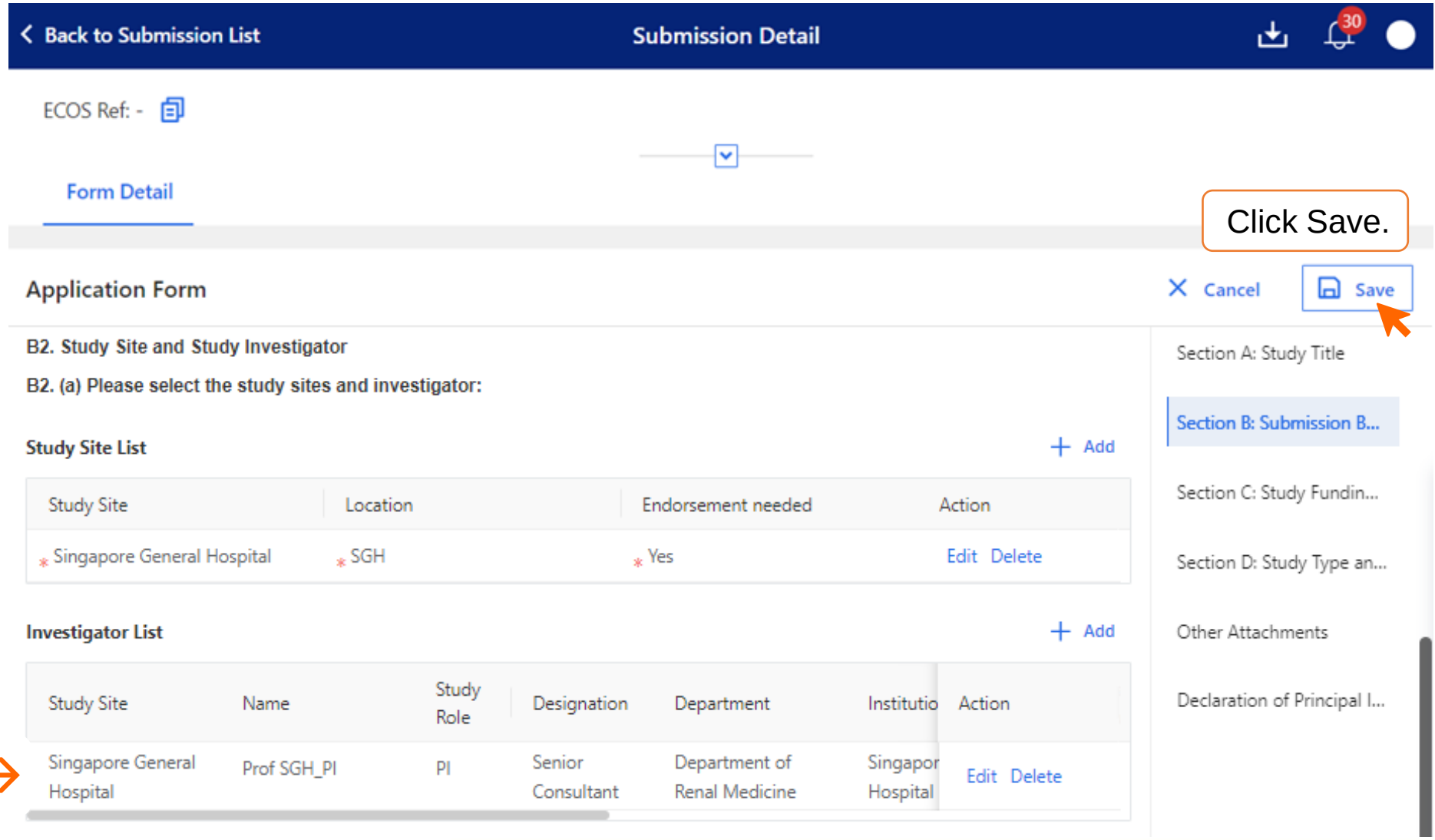
Important Note From The IRB Application Form

- Kindly note Point 2.



First Save of IRB Application Form

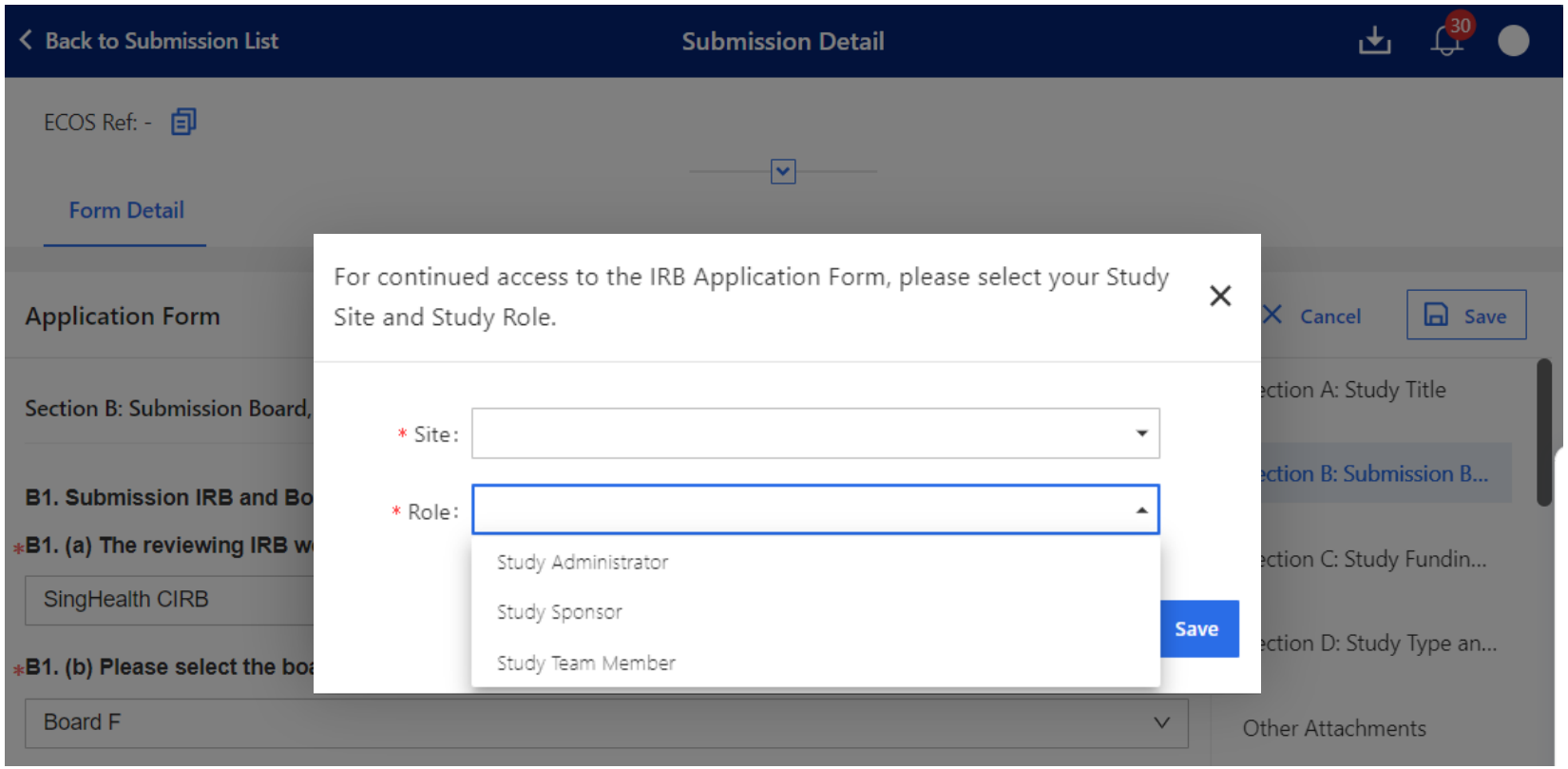
- At the first save of the IRB Application Form, the system will recognise that Study Sponsor (SS_20) is not part of the Investigator List in Section B2 (a).
- This will trigger a prompt *(next slide)*.



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

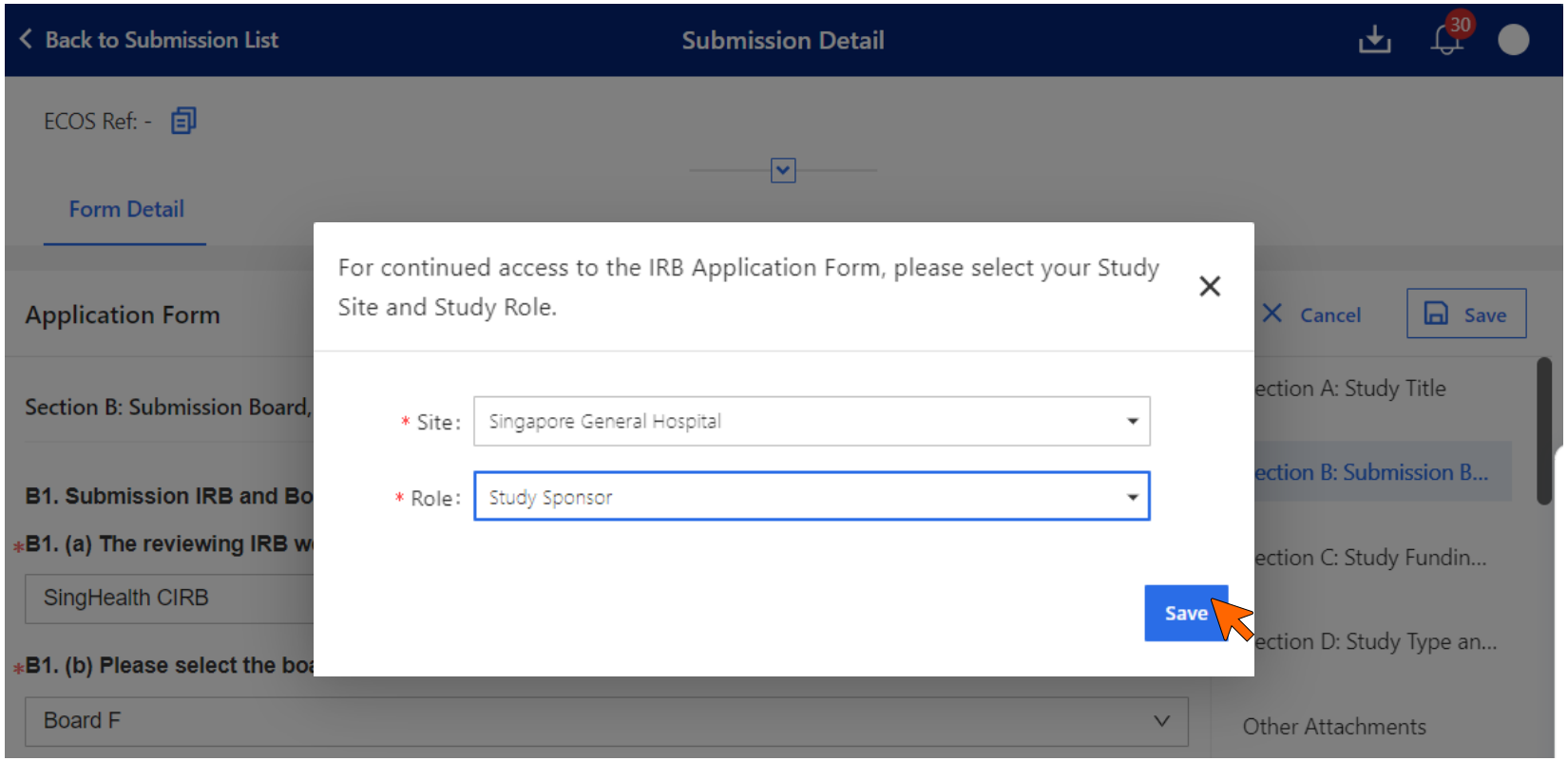
CRMS Prompt in IRB Module

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



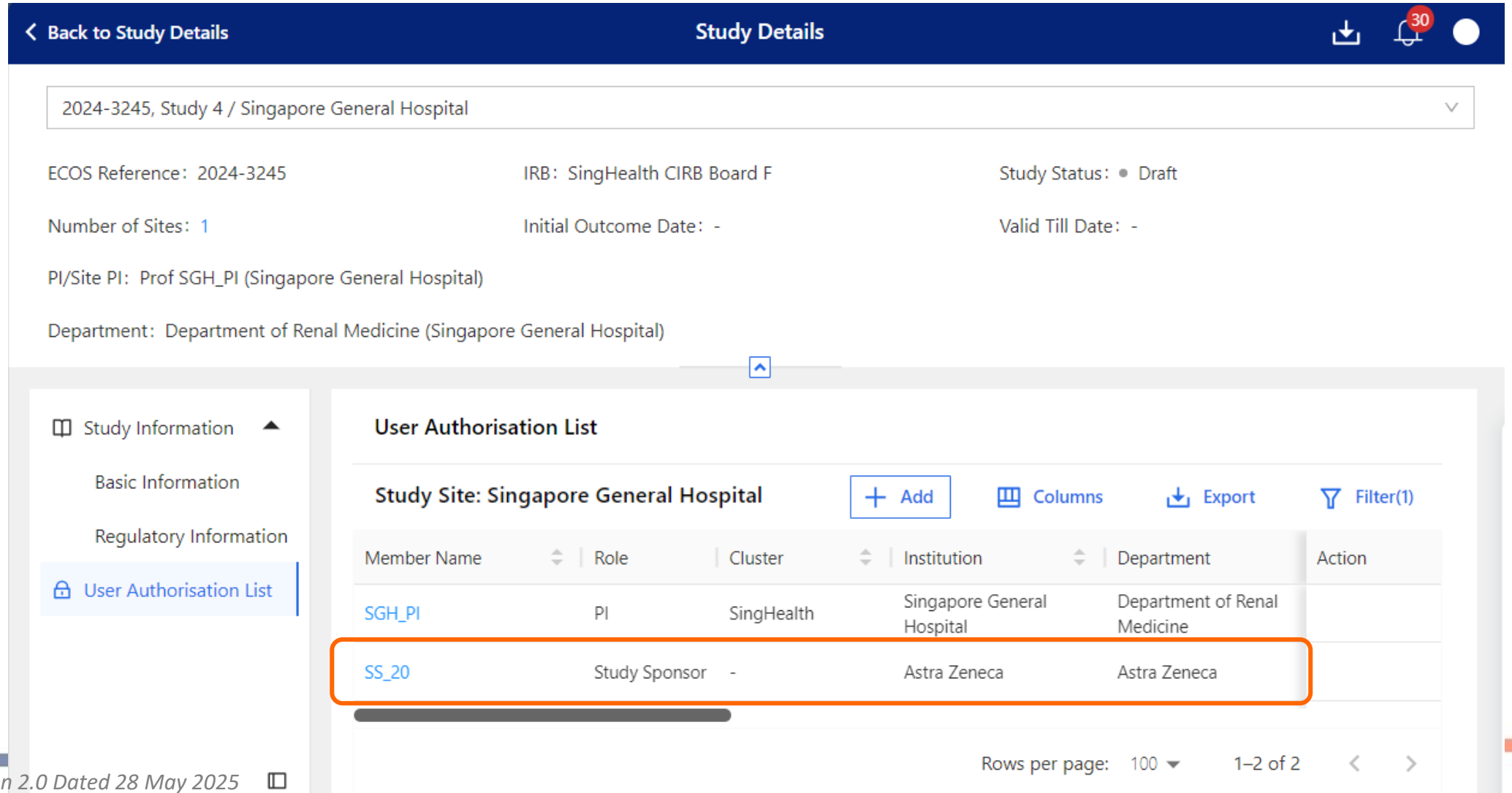
CRMS Prompt in IRB Module

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



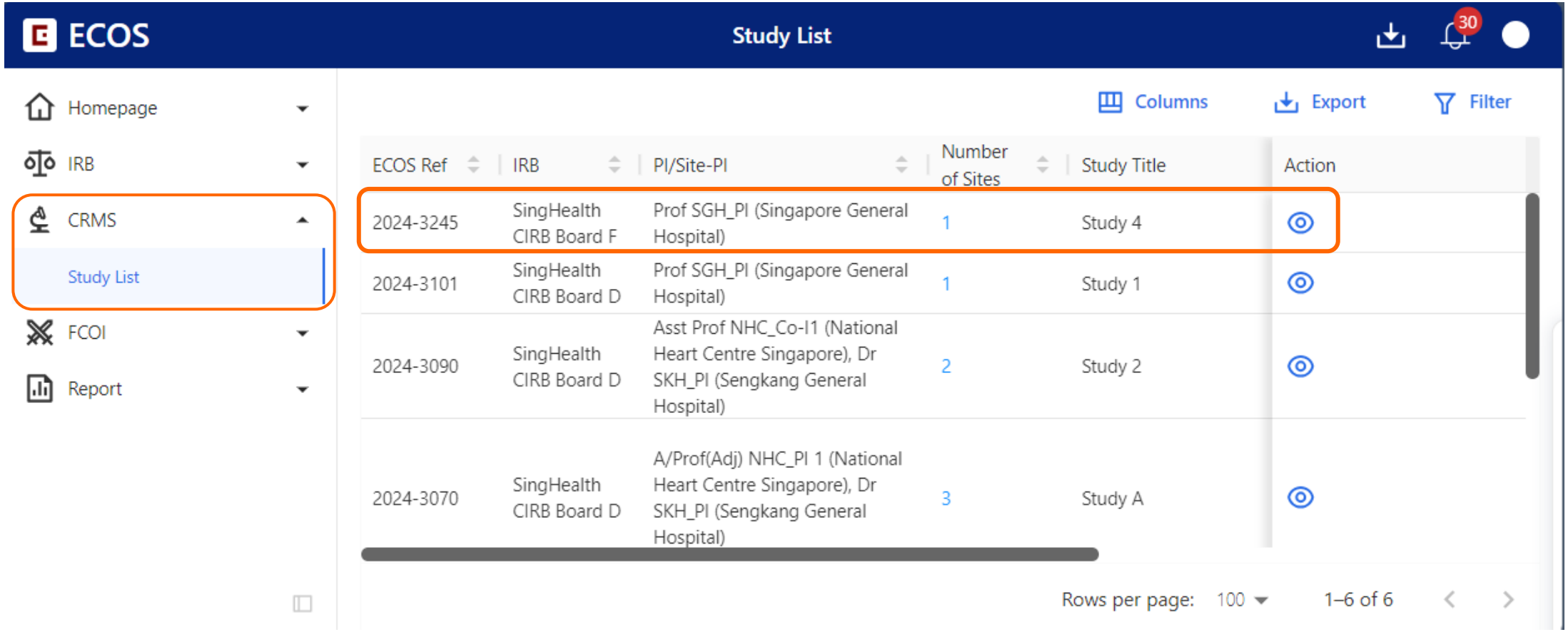
User Added to UAL by System

- Study Sponsor (SS_20) added to the User Authorisation List.



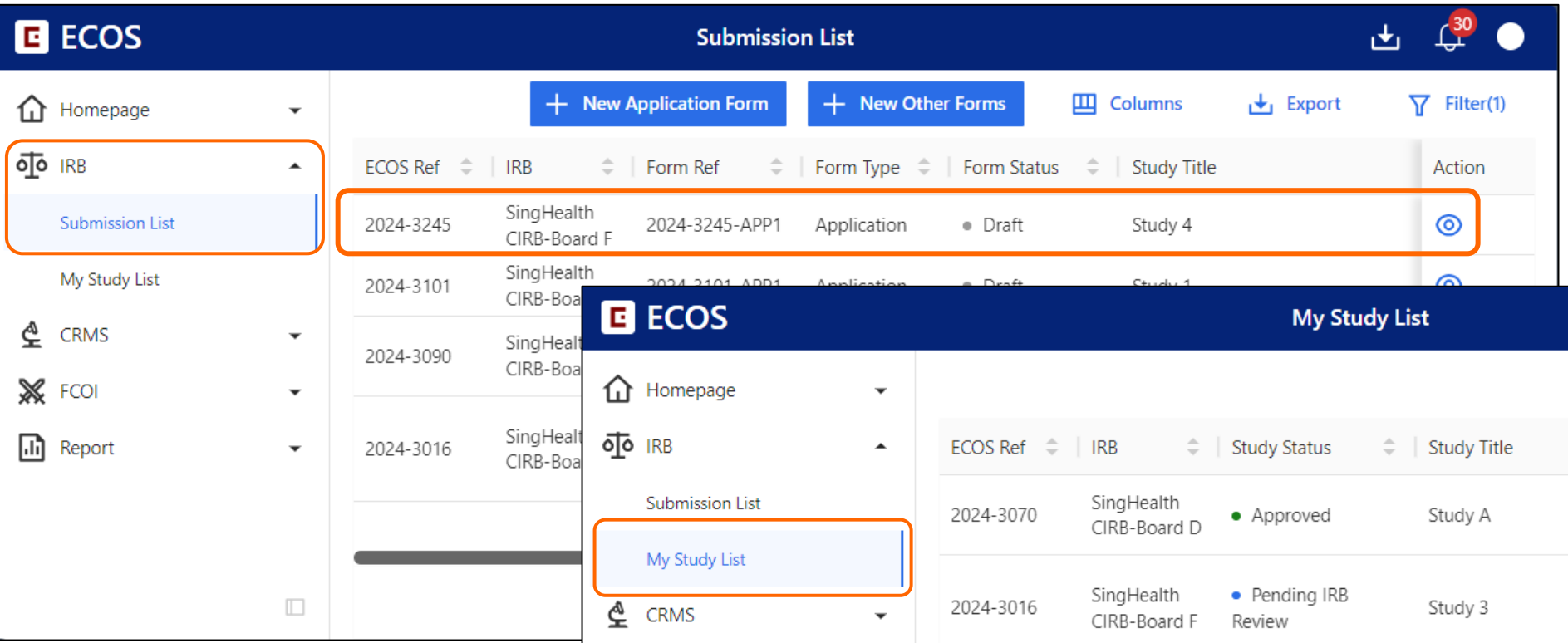
CRMS Accessibility

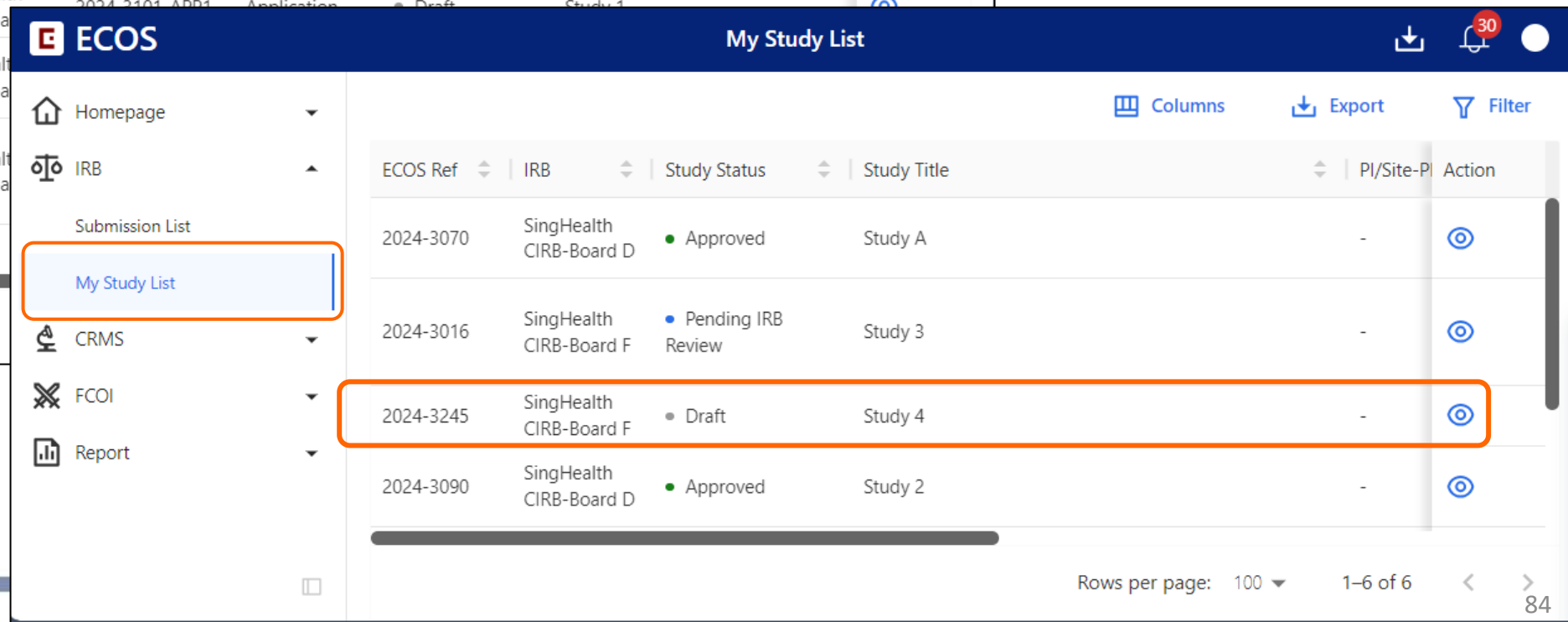
- Study Sponsor (SS_20) can now access to the study 2024-3245 in the CRMS module.



IRB Accessibility

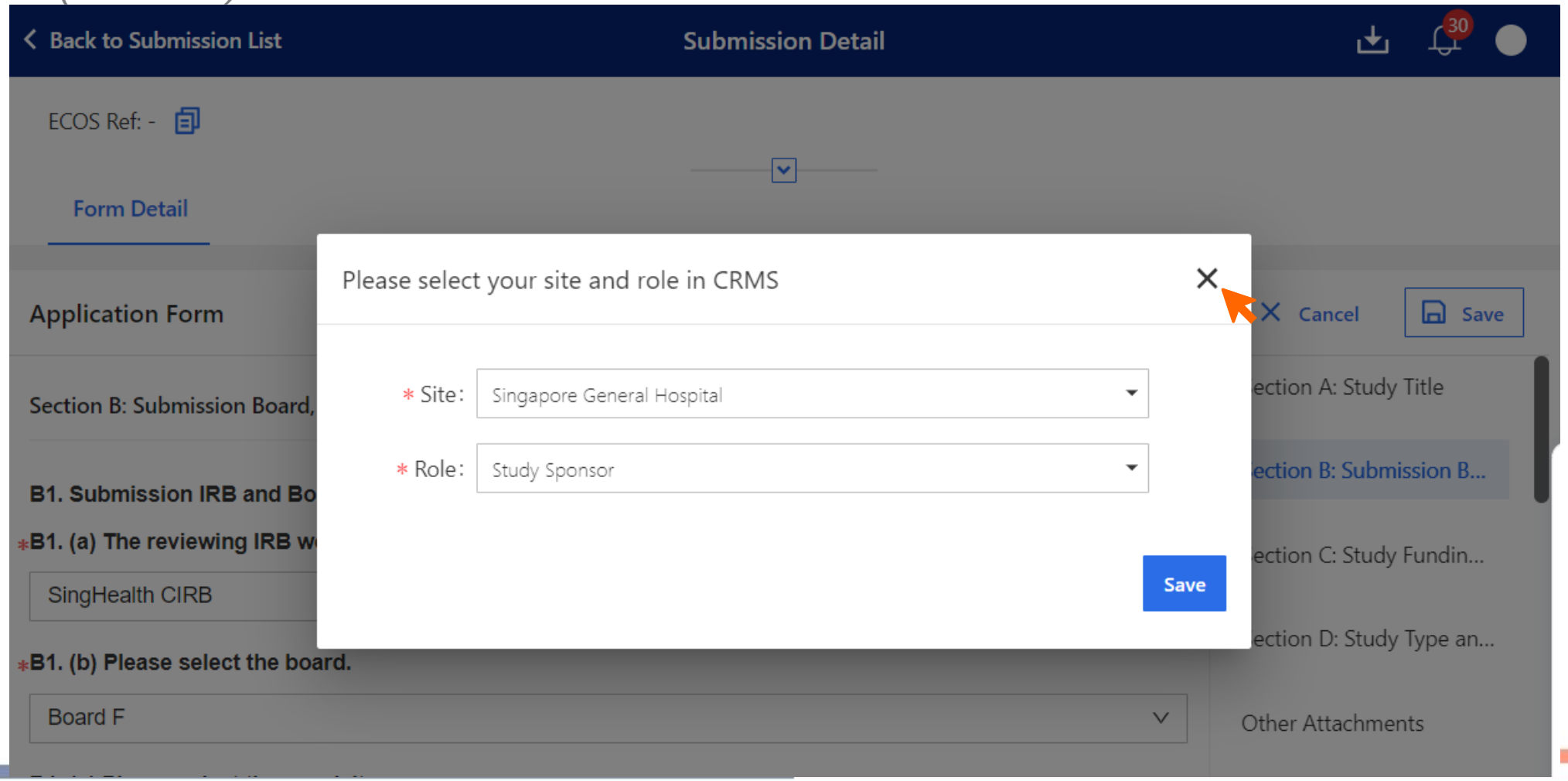
- Study Sponsor (SS_20) can also access to the IRB forms in the IRB module.





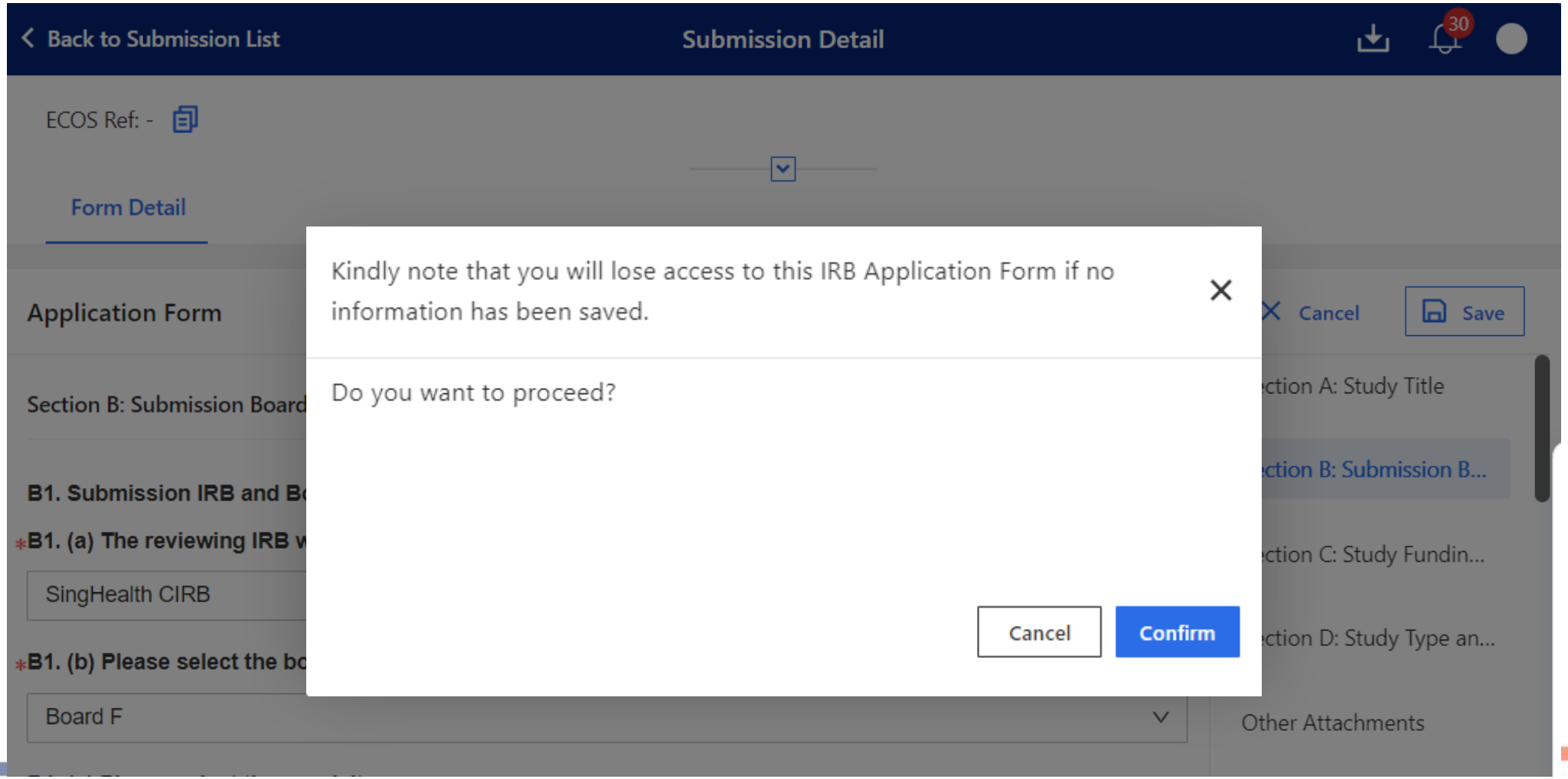
System Prompt

- If the user clicks the ✕ button instead of **Save**, a system prompt will appear for the user to confirm his/her action *(next slide)*.



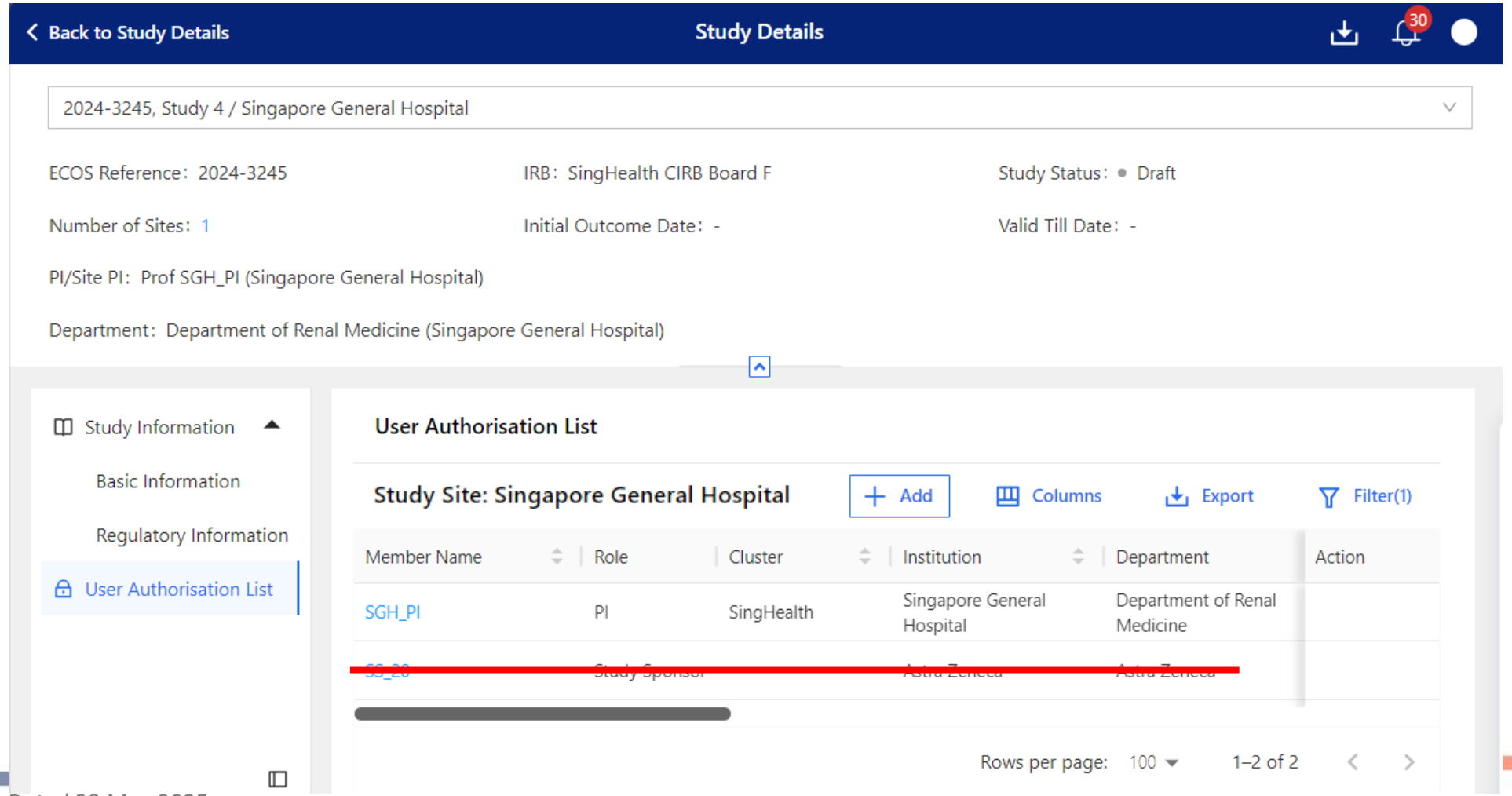
System Prompt

- The user can click **Cancel** and return to the previous screen, or click **Confirm** to proceed.



System Prompt

- Once the **Confirm** button is clicked, the user will not be added to User Authorisation List and will lose access to the IRB Application Form the moment the **Save and Exit** button on the IRB form is clicked.



ECOS

Click here to return to Index.

Page Functions

National Healthcare Group
Adding years of healthy life

SingHealth
Defining Tomorrow's Medicine

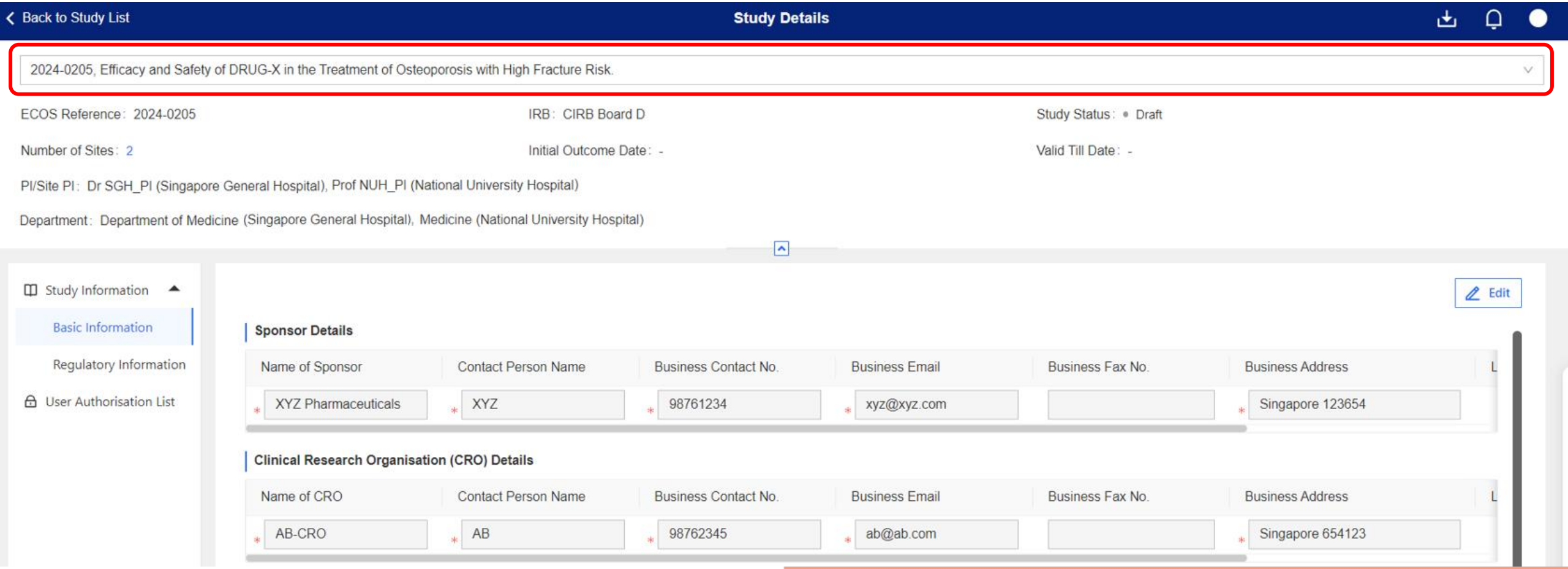
Page Functions

- This section will demonstrate how the page functions work, it applies to all pages that have the functions available.
- The available functions are: -
  - Study Dropdown Bar to toggle between different studies – Slide 90
  - Collapse the Study Details panel and CRMS Side Navigation Bar – Slide 95
  - Expand the Study Details panel and CRMS Side Navigation Bar – Slide 96
  - Edit data – Slide 97
  - Add data – Slide 99
  - Delete data – Slide 101
  - Save data – Slide 102
  - Cancel – Slide 105
  - Filter to display specific data – Slide 108
  - Columns to narrow specific data columns to be displayed – Slide 111
  - Export – Slide 114
  - Add user to the User Authorisation List – Slide 116
  - Endorse or Reject user via the Study Member Review – Slide 122
  - Deactivate user on the User Authorisation List – Slide 123

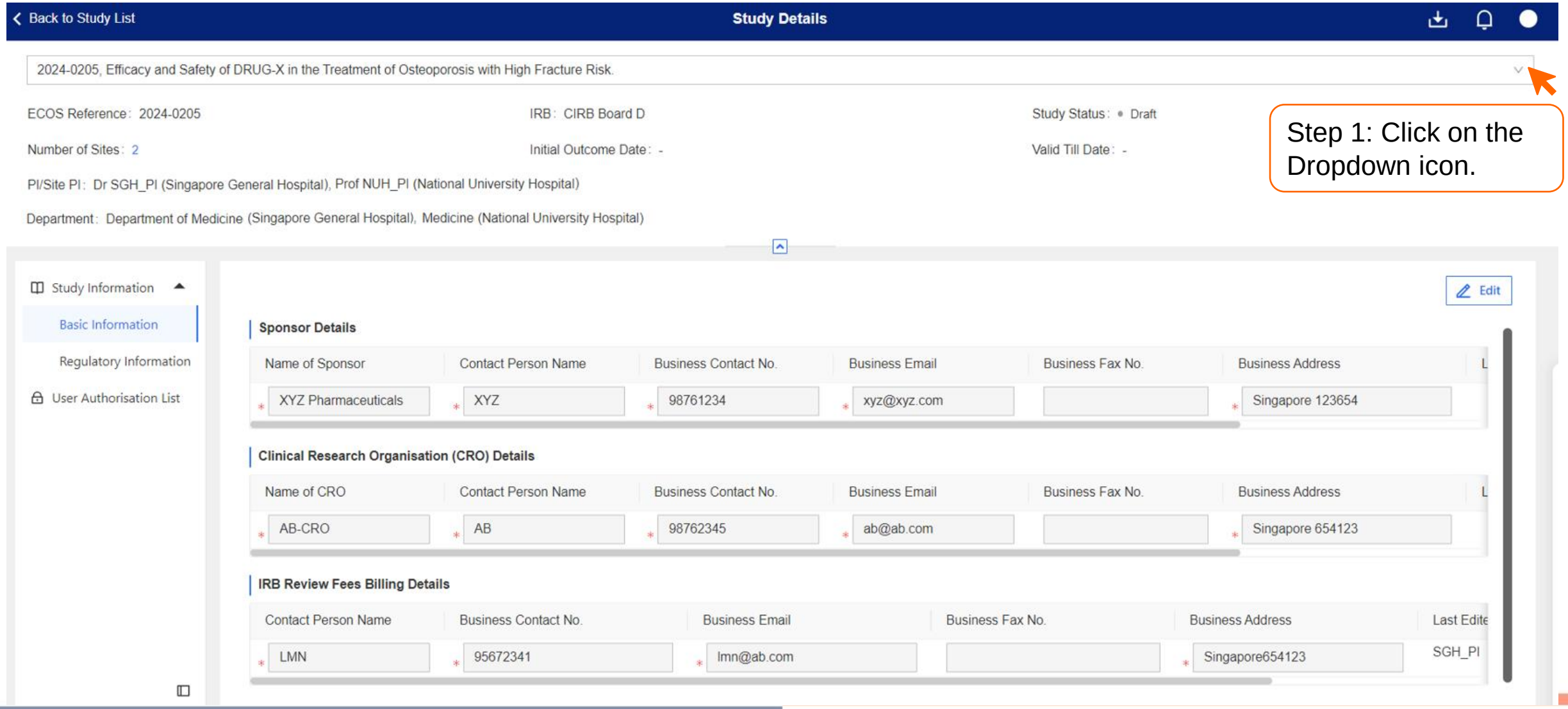
Click here to return to Page Functions index.

Page Functions – Study Dropdown Bar

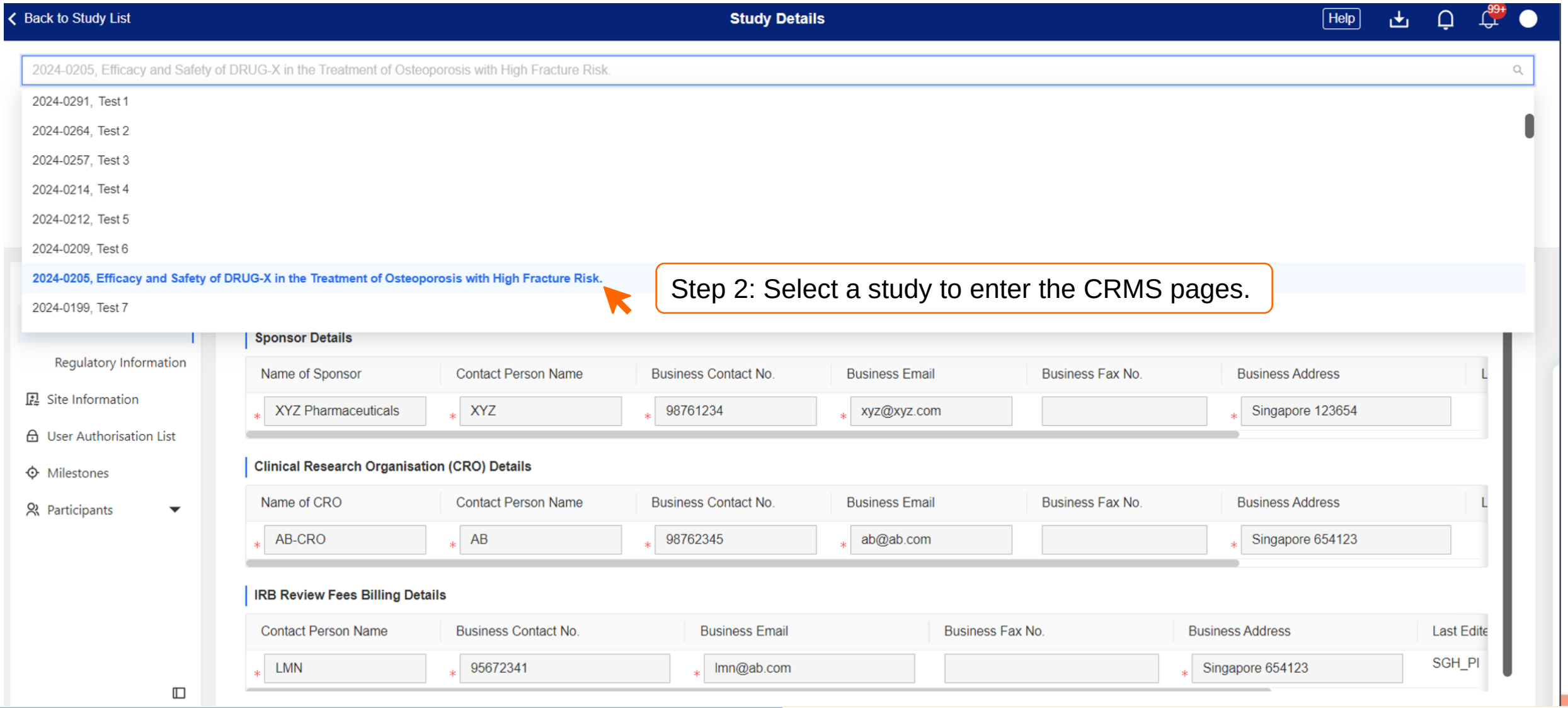
- Red box highlights the Study Dropdown Bar.
- User can toggle to another study using this bar.



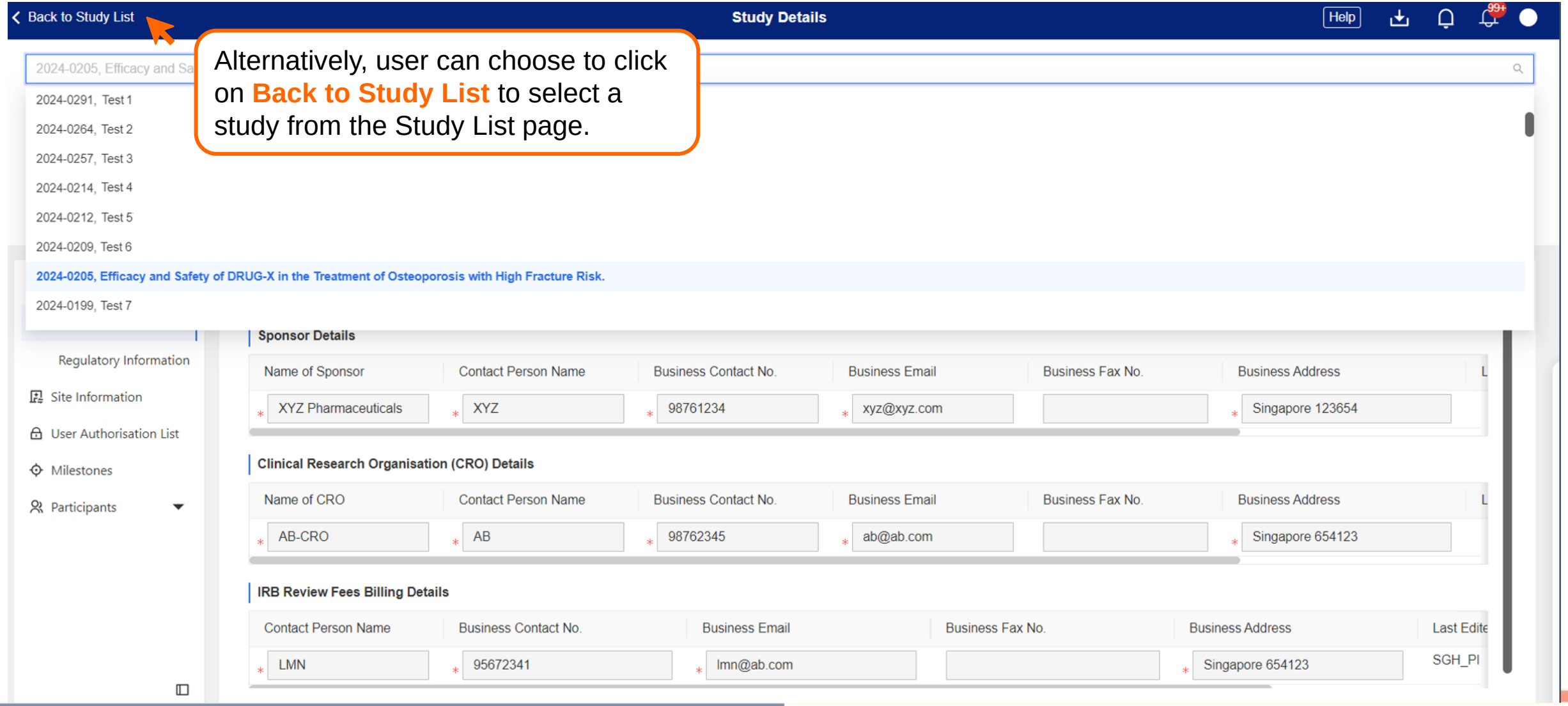
Page Functions – Study Dropdown Bar



Page Functions – Study Dropdown Bar

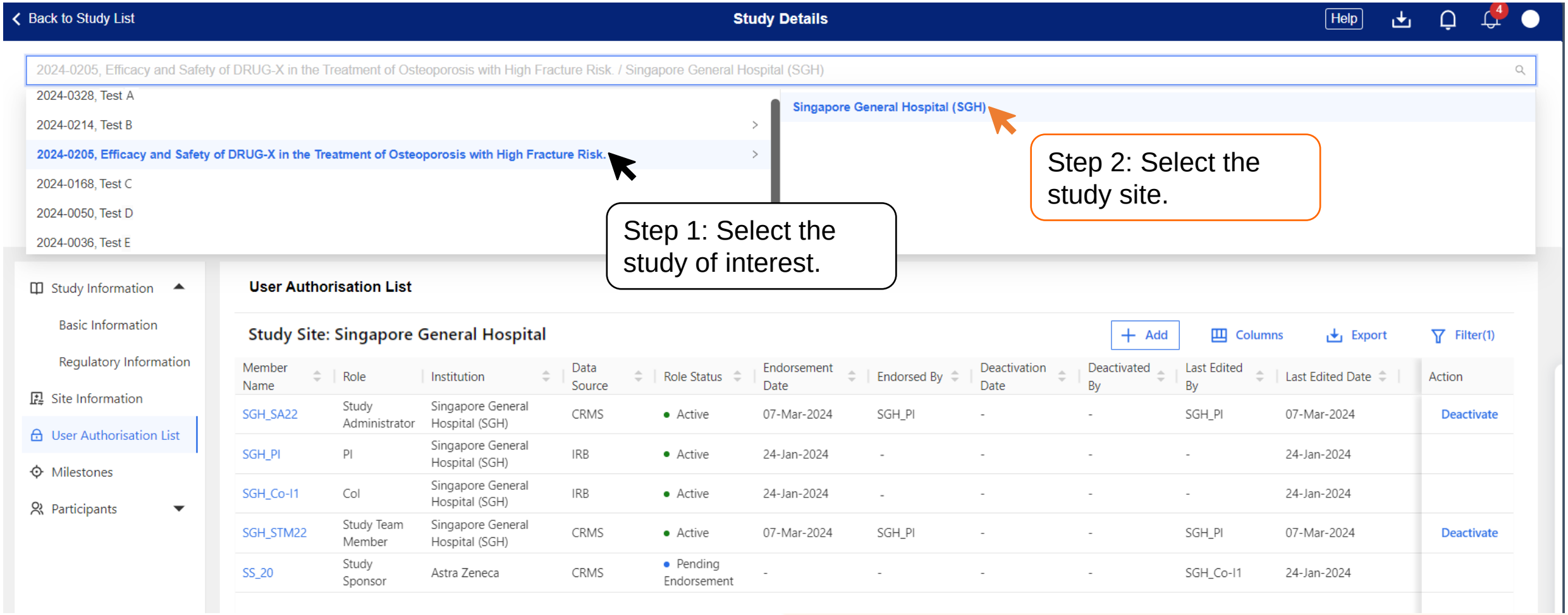


Page Functions – Study Dropdown Bar



Page Functions – Study Dropdown Bar

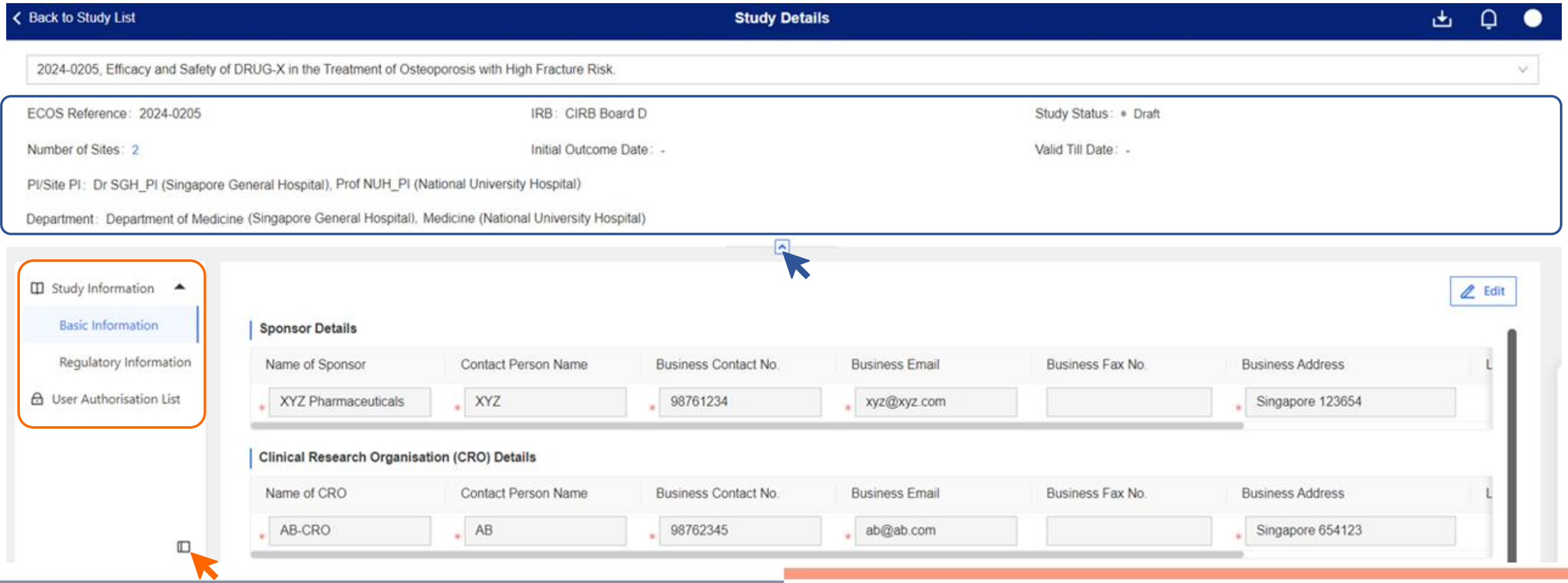
- For Site Level pages, user will need to additionally select the study site before toggling to another study.



Click here to return to Page Functions index.

Page Function – Collapse

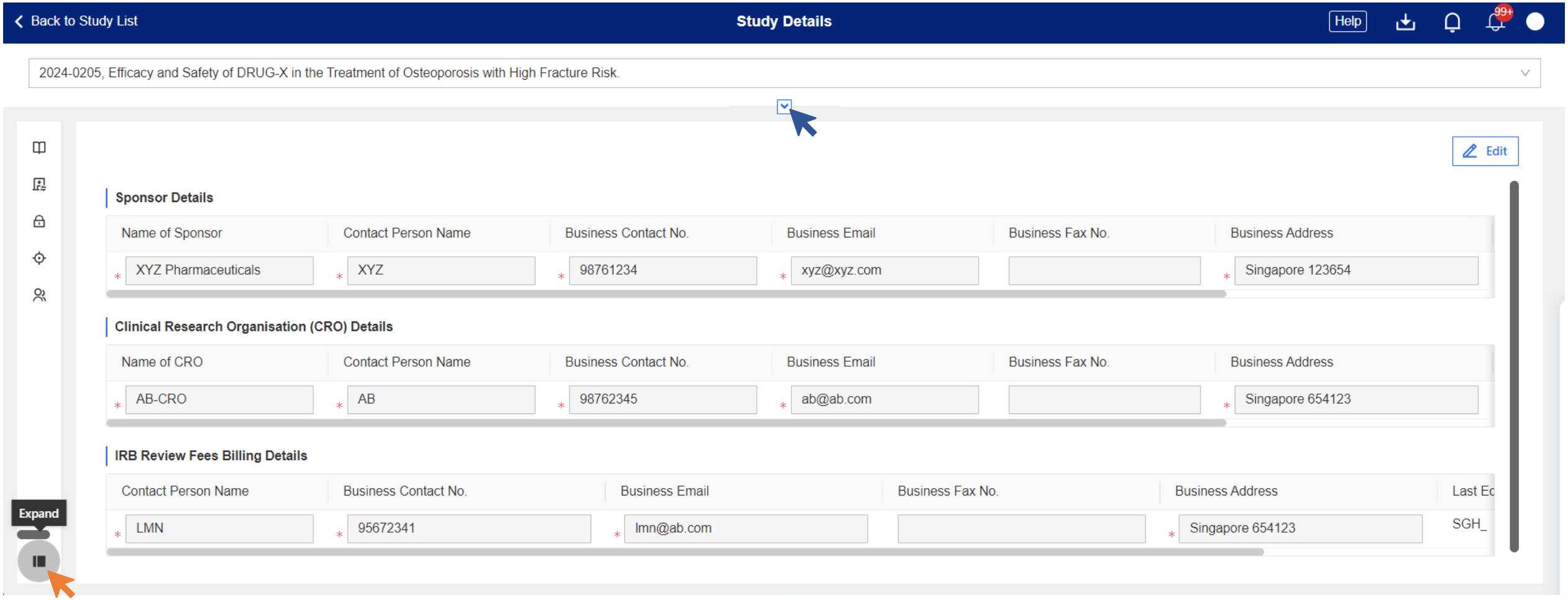
- Study Details panel on top and the CRMS Side Navigation Bar on the left are expanded by default.
- To collapse either sections, click on the **Up arrow** on top or the **Panel icon** at the bottom left, respectively.



Click here to return to Page Functions index.

Page Functions – Expand

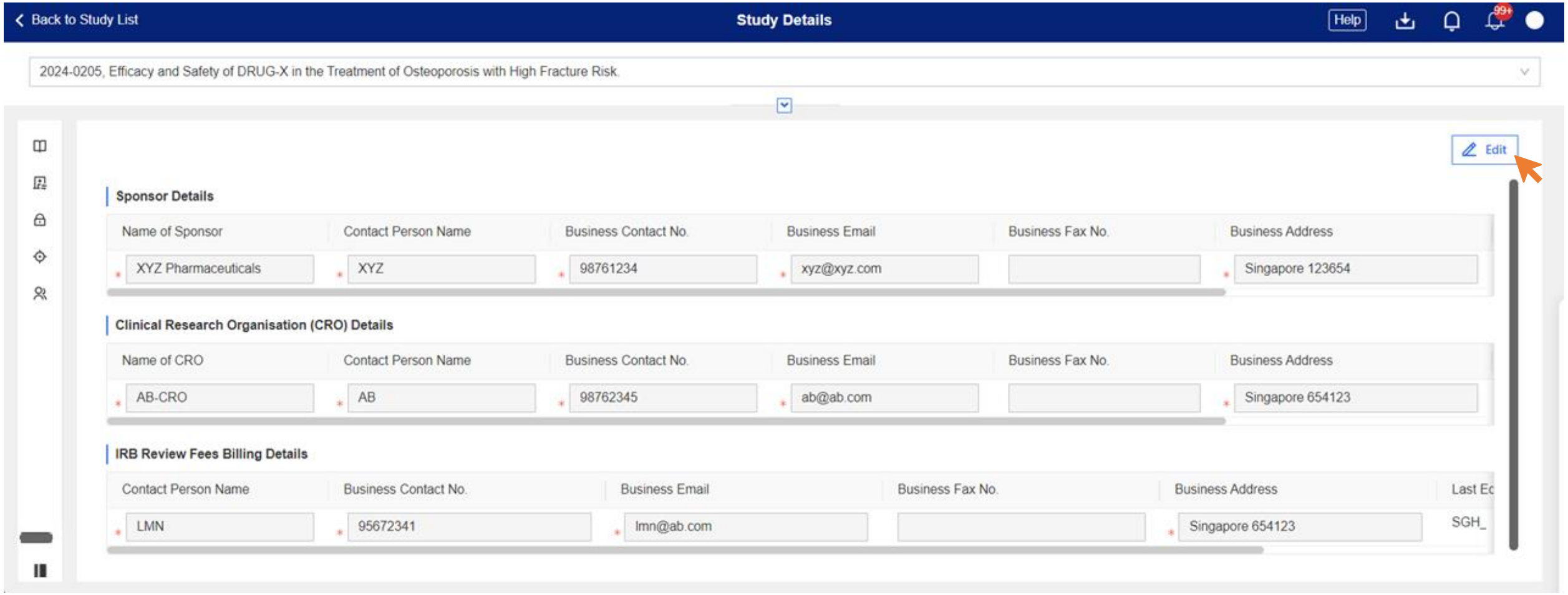
- Likewise, to expand either sections, click on the **Down arrow** or the **Panel icon,** respectively.



Click here to return to Page Functions index.

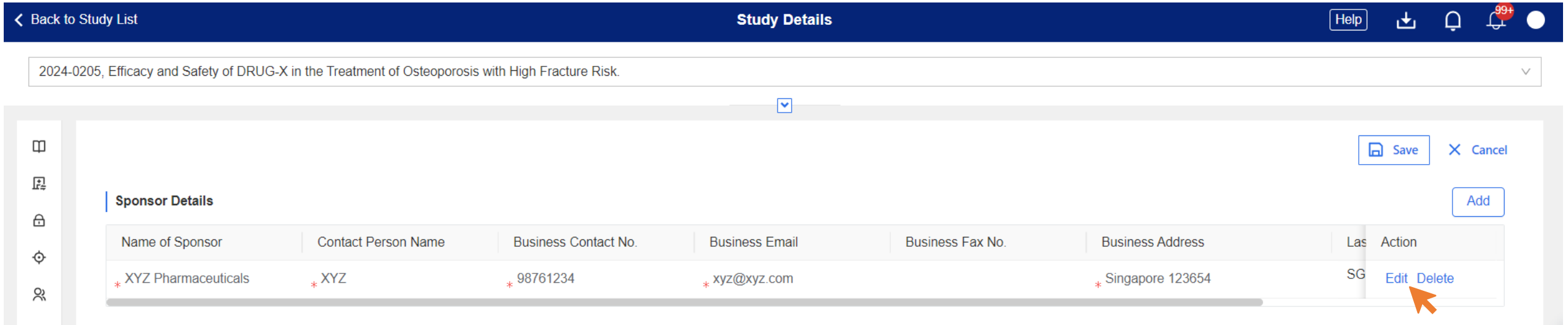
Page Functions – Edit Data

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

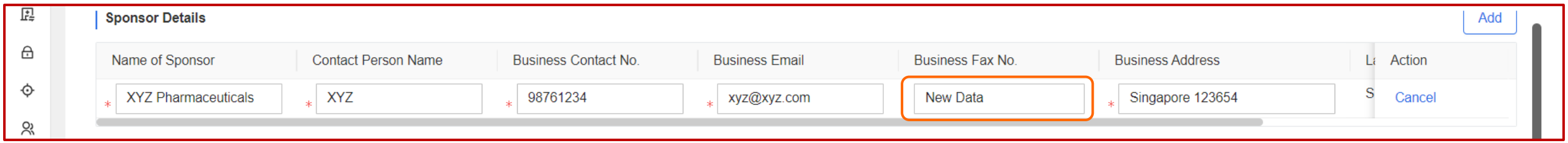


Page Functions – Edit Data

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



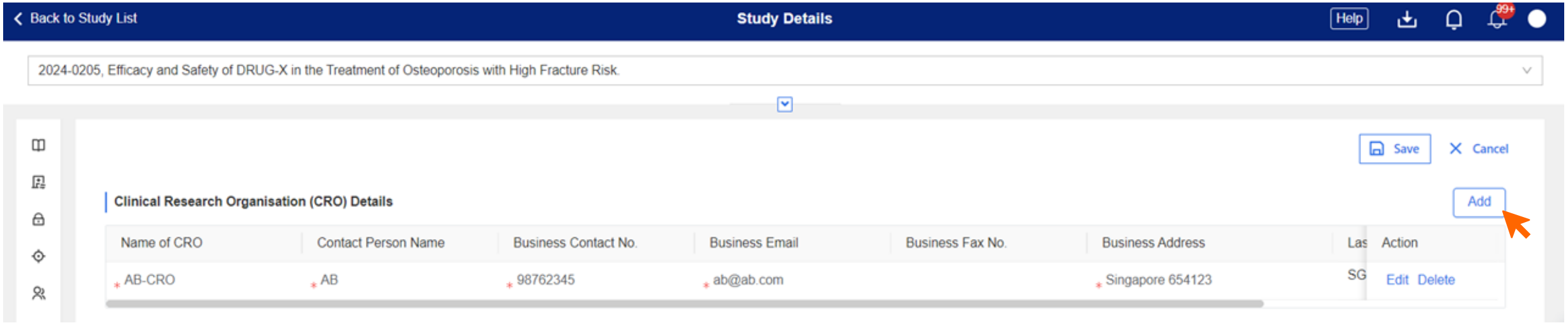
- The selected row will be unlocked for edits to be done. In this case, we have added “New Data” under **Business Fax No**.



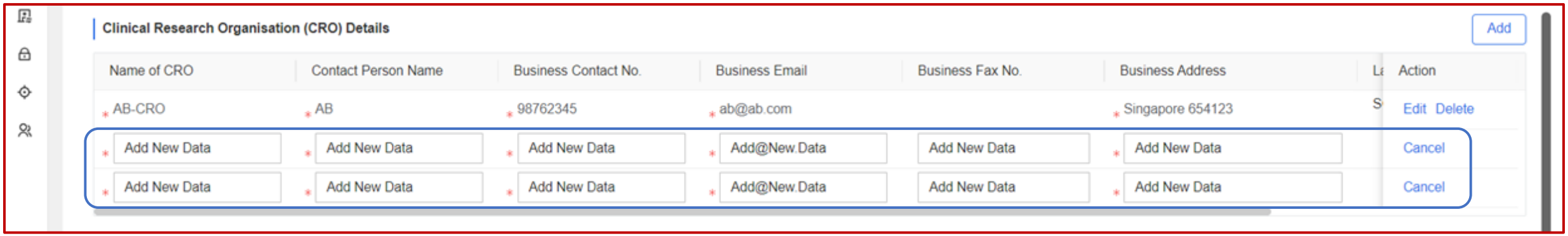
Click here to return to Page Functions index.

Page Functions – Add Data

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

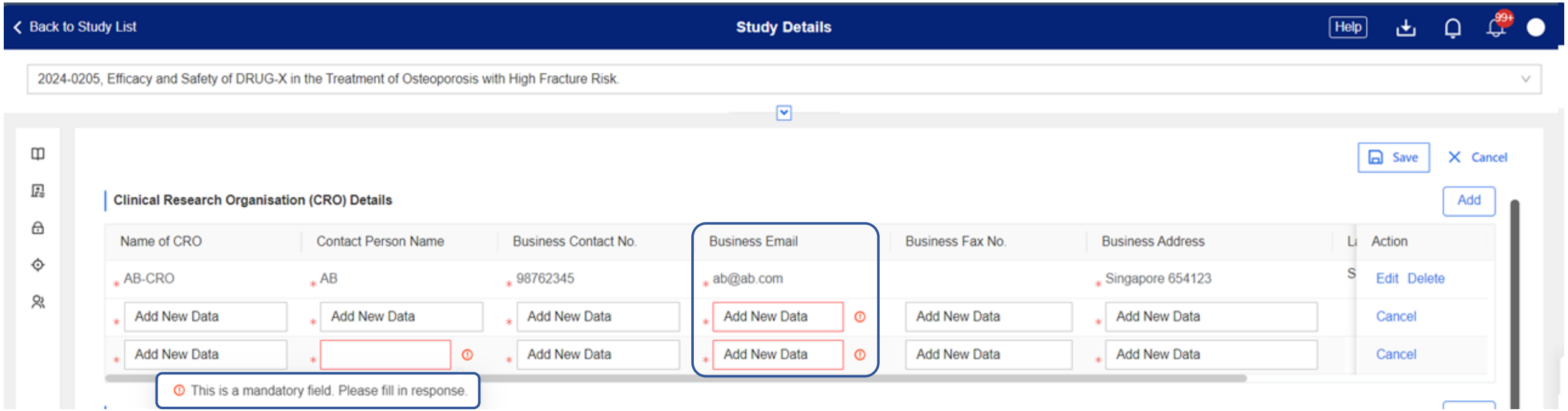


- **2 new blank rows** will be created for data entry. In this case, we entered them as “Add New Data”.



System In-built Requirements

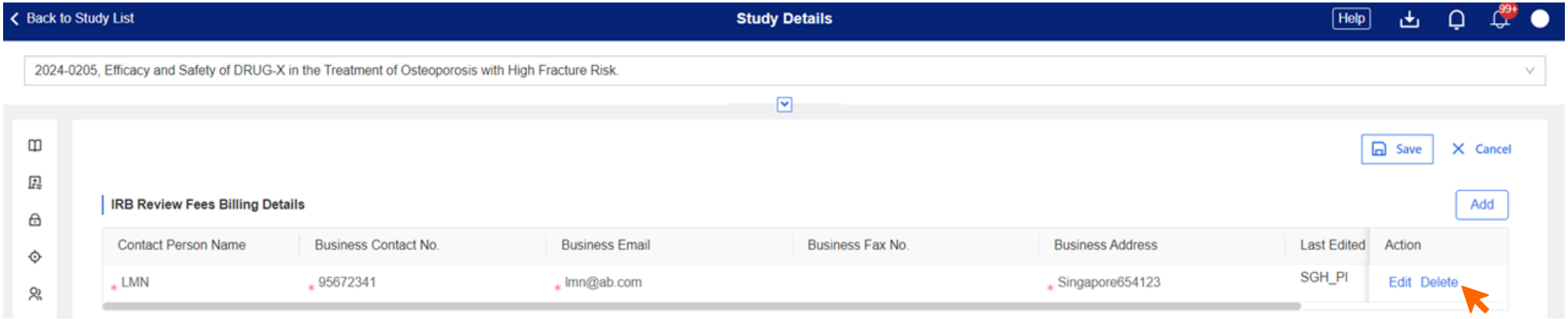
- Mandatory fields are indicated by asterisks. If this is not completed, the system will trigger an error prompt. At the same time, the data field will be outlined in red.
- Data fields that require email address input are configured to accept proper email address format. If this is completed incorrectly,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



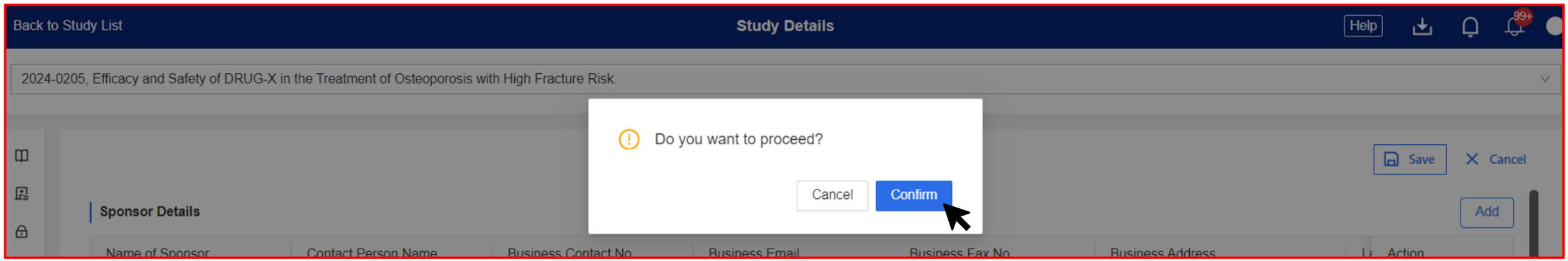
Click here to return to Page Functions index.

Page Functions – Delete Data

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



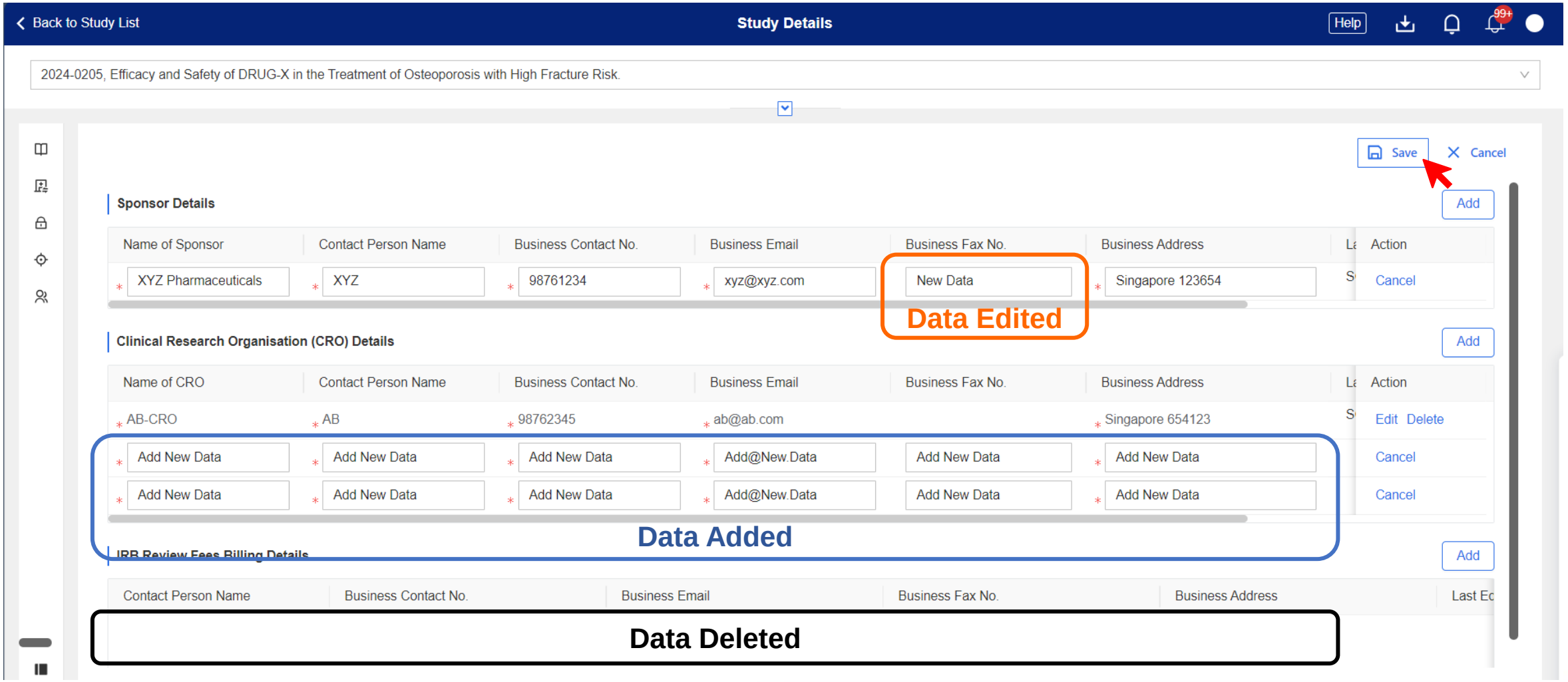
- The system will generate a prompt to confirm deletion. Click **Confirm** to proceed.



Click here to return to Page Functions index.

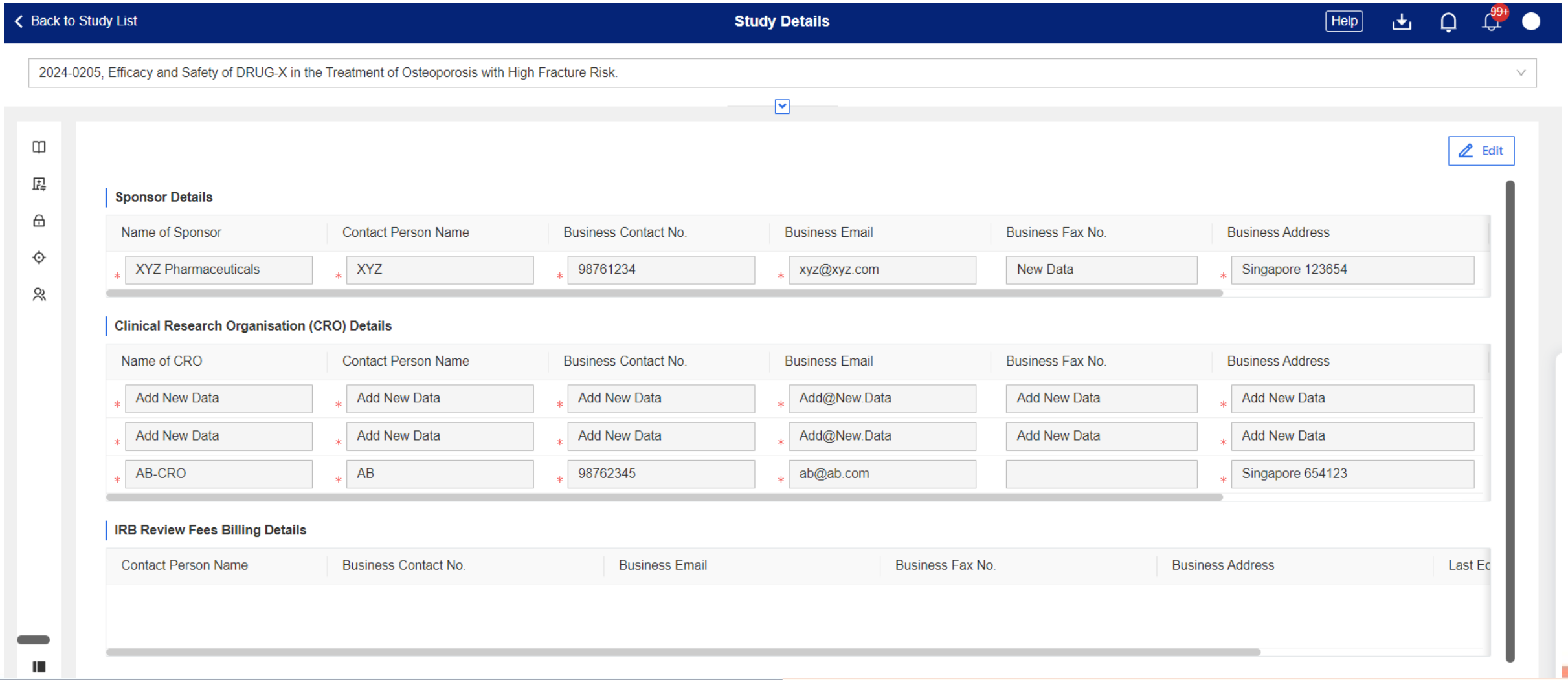
Page Functions – Save Data

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



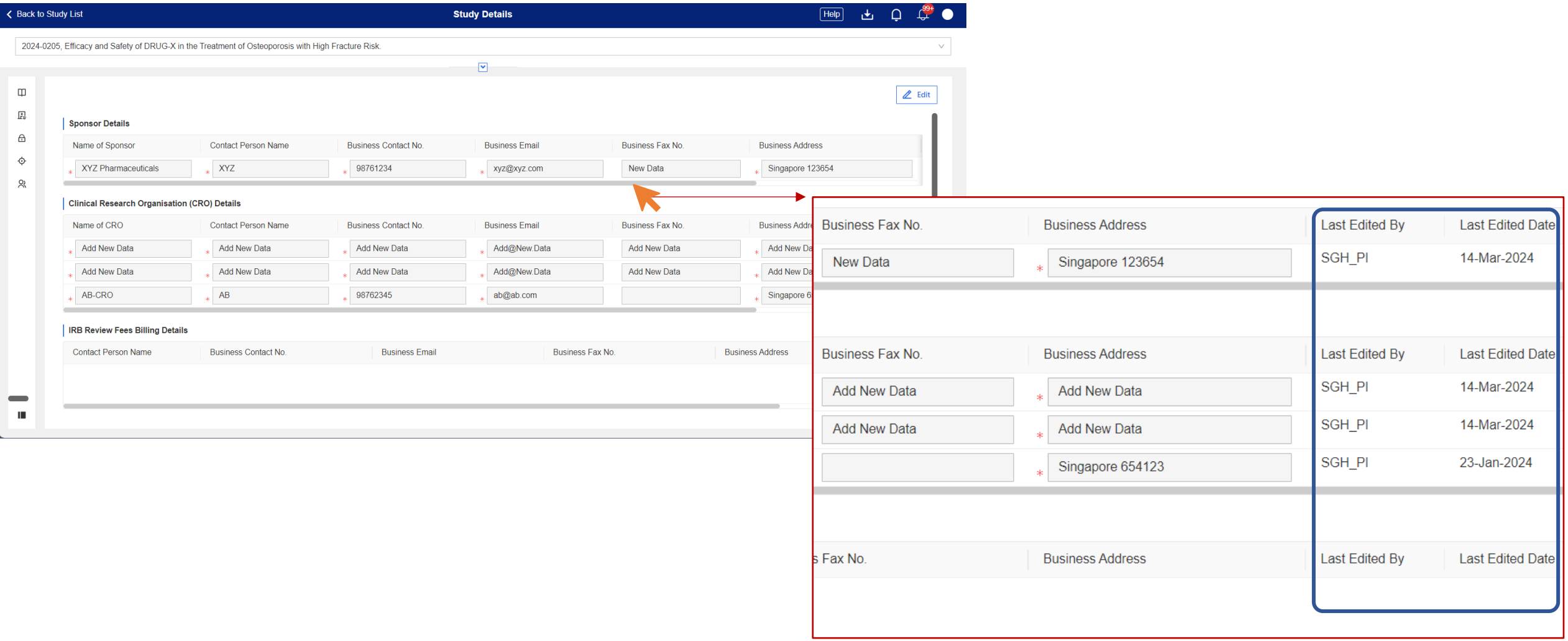
Page Functions – Save Data

- Page view after Save.



Record Tracking

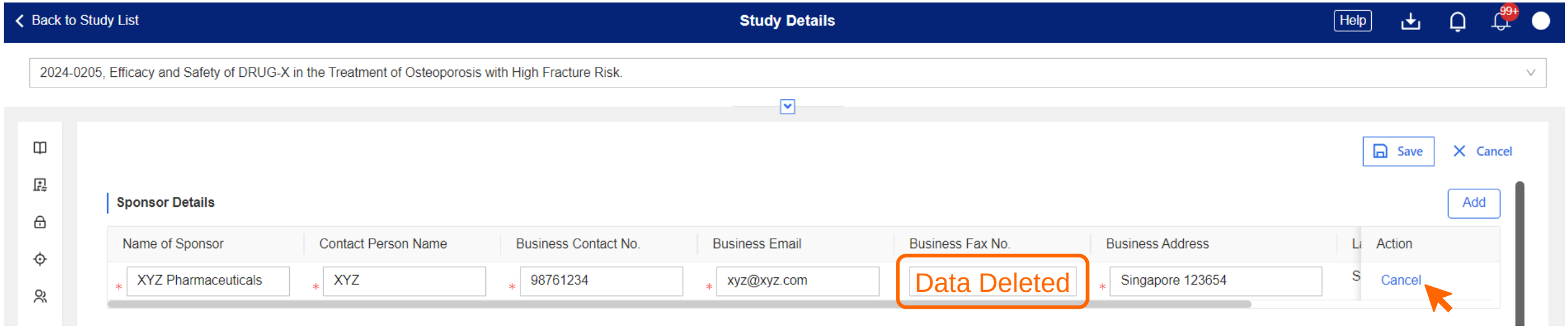
- Drag the **scroll bar** of each section to the right to see the **Last Edited By** and **Last Edited Date** columns.



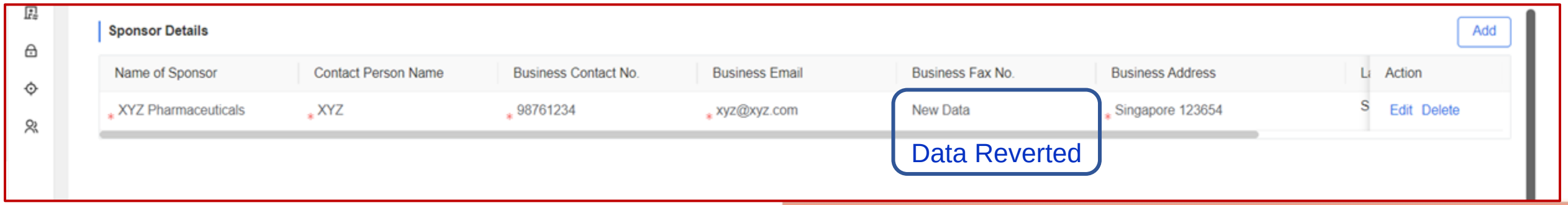
Click here to return to Page Functions index.

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**.

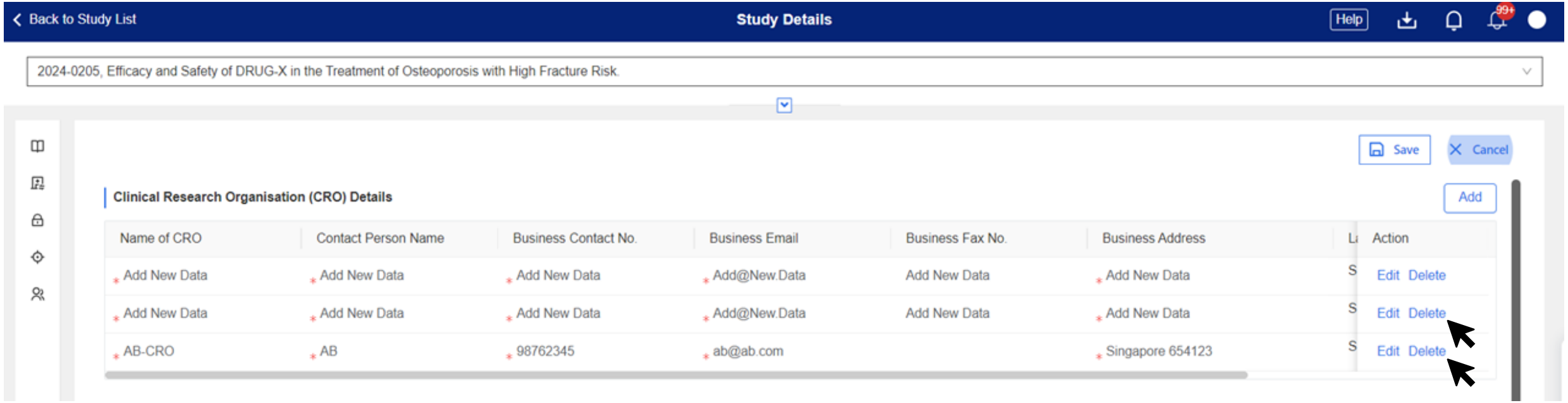


- The delete action reversed, original data reverted.

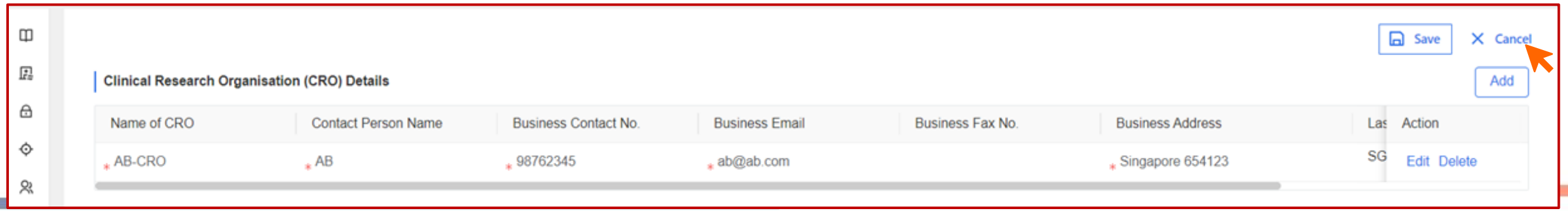


Page Functions – Cancel

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

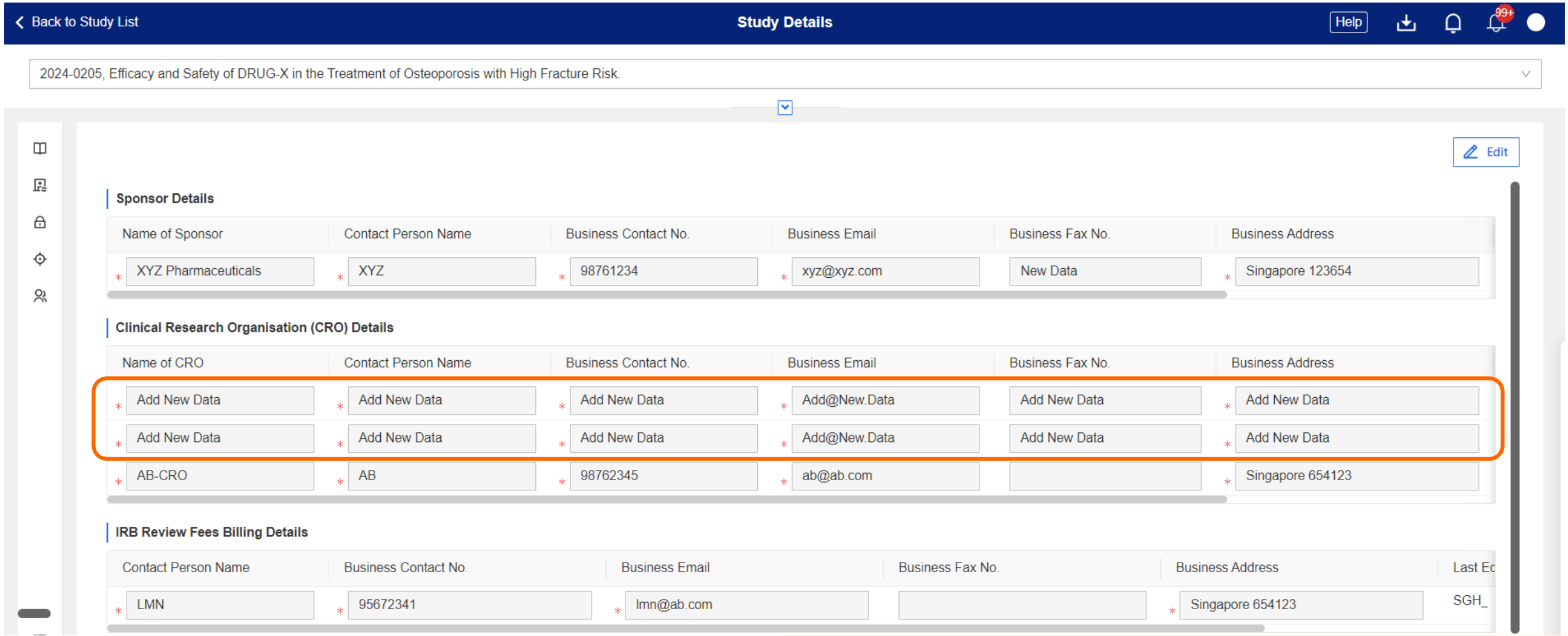


- Page view after user confirms the deletions. Click **Cancel** to reverse the deletion.



Page Functions – Cancel

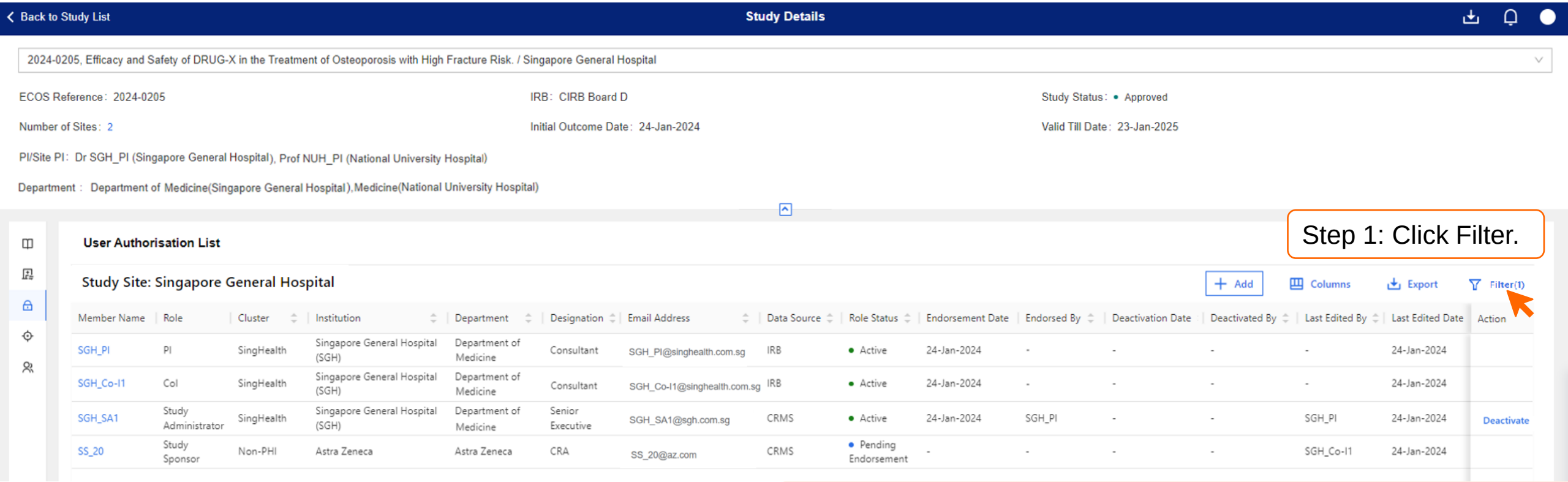
- Deletion of 2 rows canceled.



Click here to return to Page Functions index.

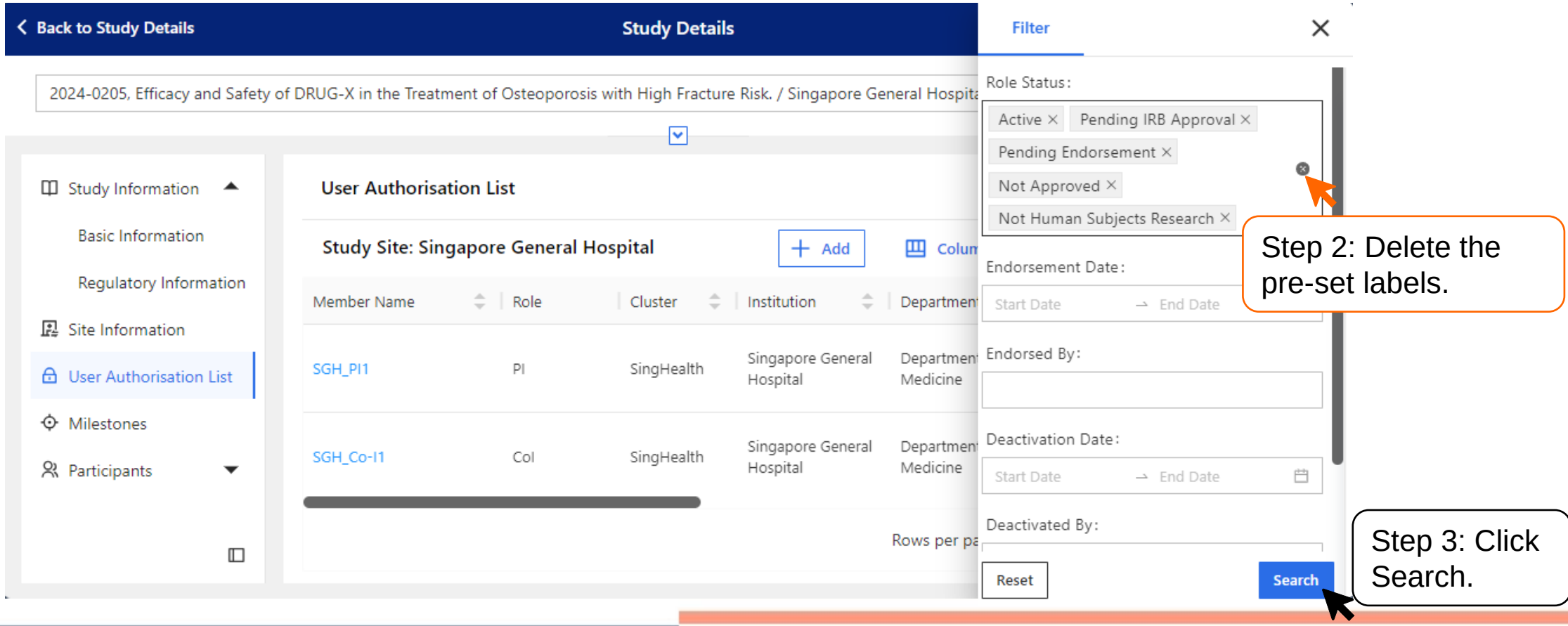
Page Functions – Filter

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



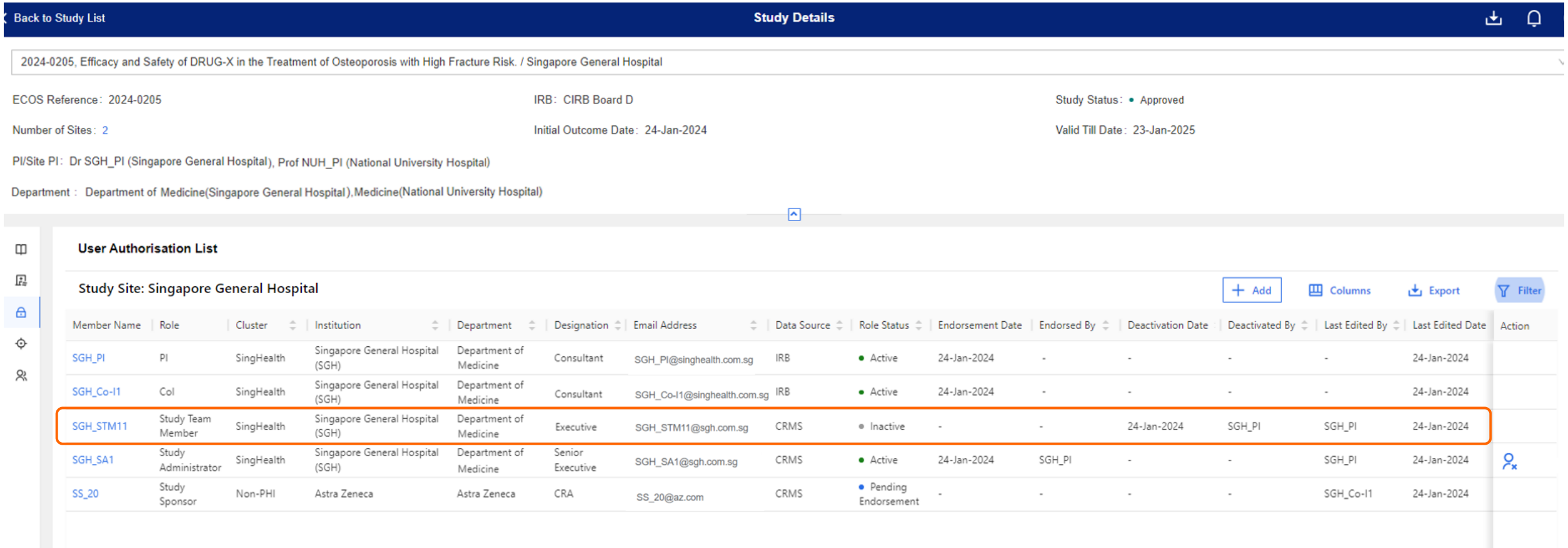
Page Functions – Filter

- 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

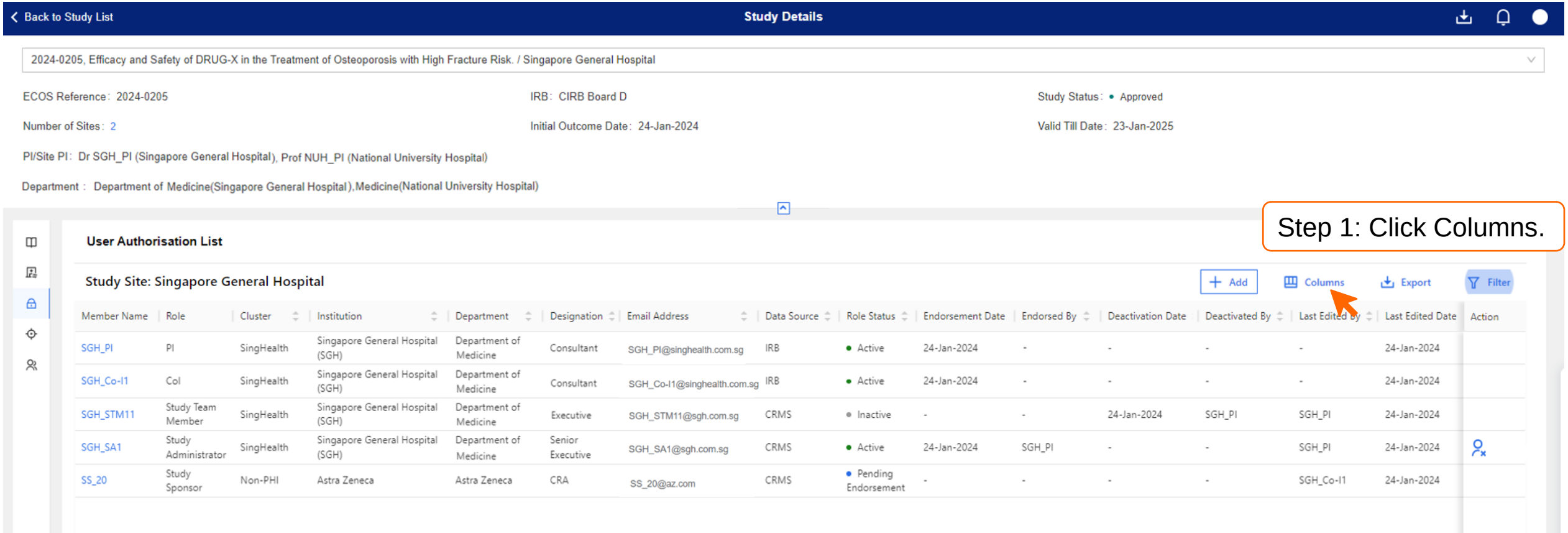
- With the filter removed, the User Authorisation List now displays all users, including **Inactive** ones.



Click here to return to Page Functions index.

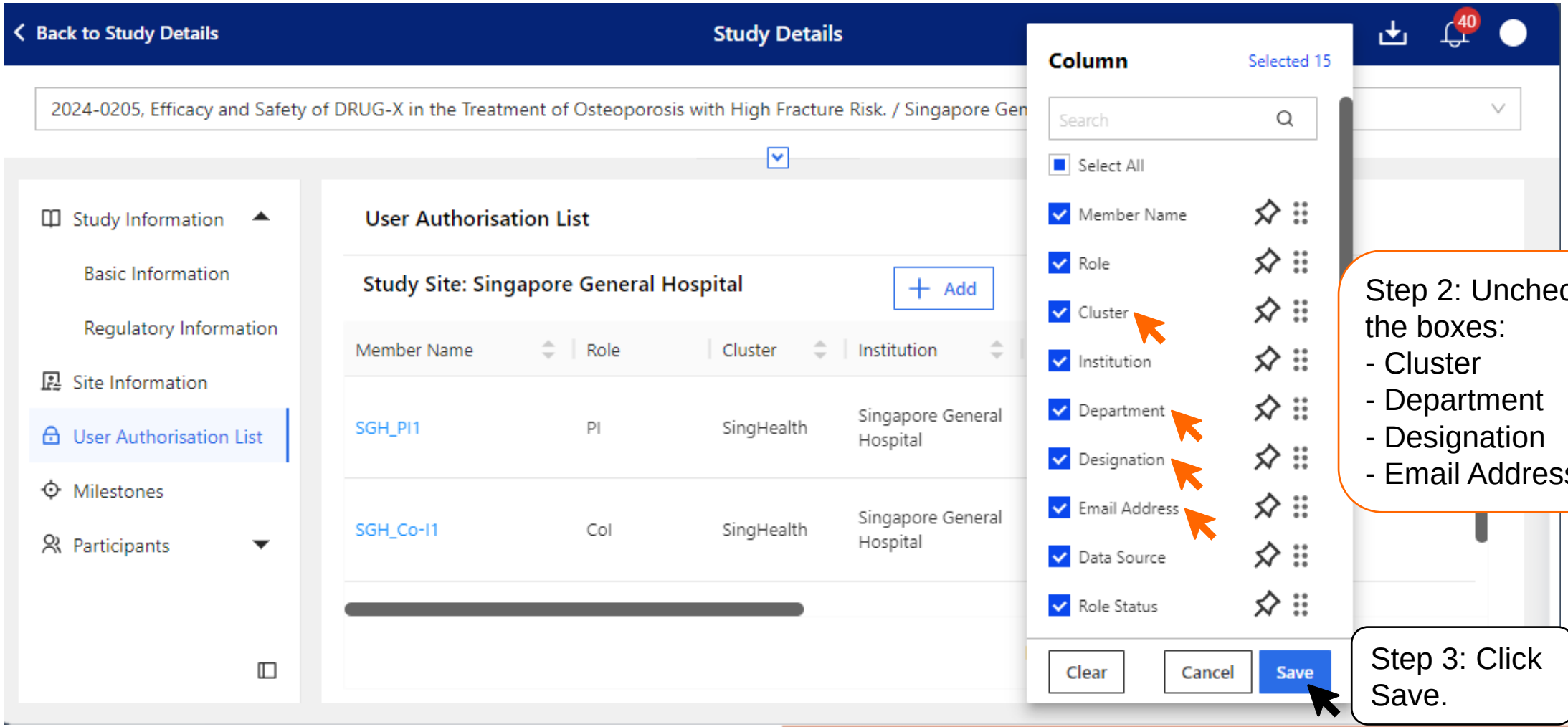
Page Functions – Columns

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



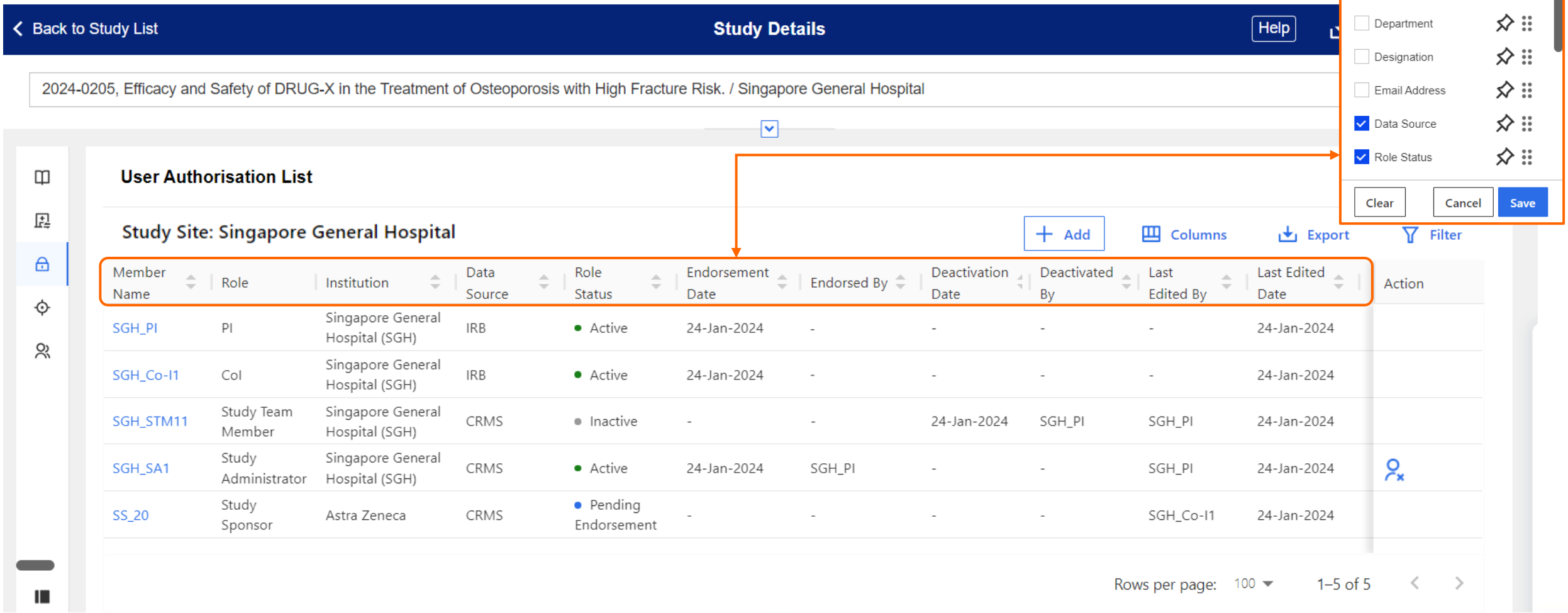
Page Functions – Columns

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



Page Functions – Columns

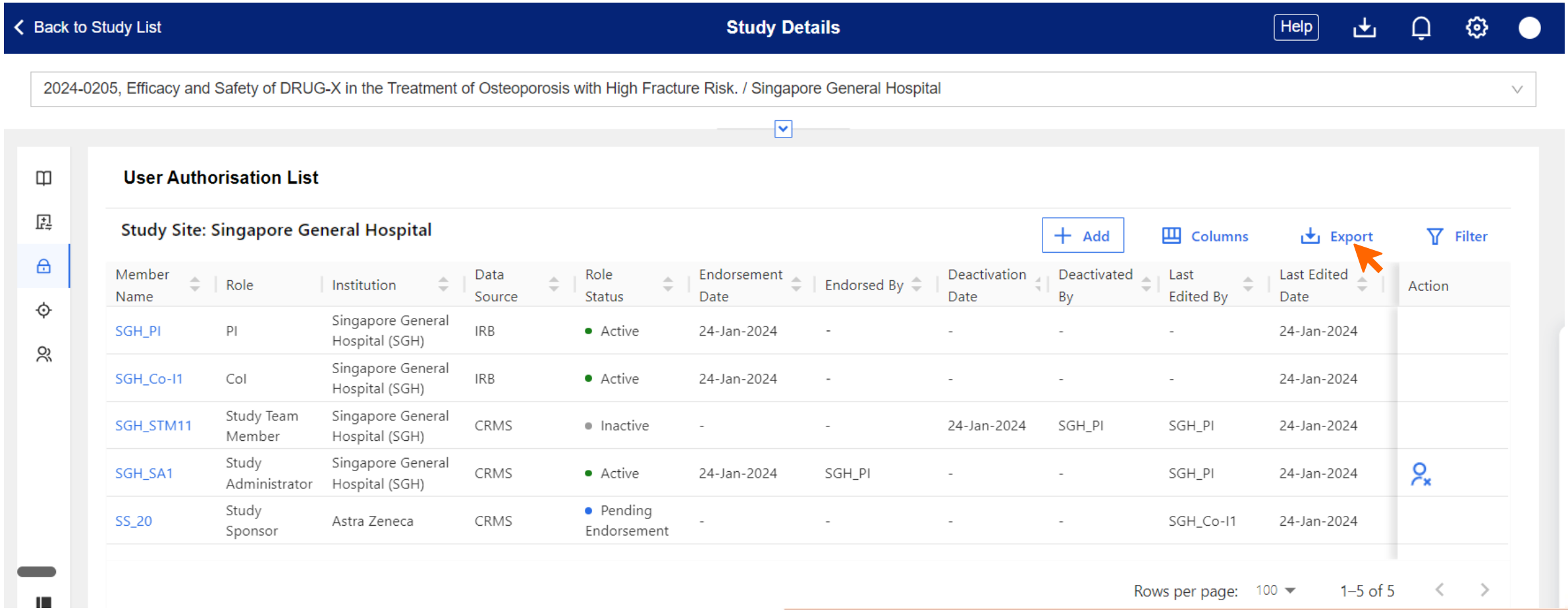
- The User Authorisation List will not display the data columns that were unchecked.



Click here to return to Page Functions index.

Page Functions – Export

- 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 or printing.



Page Functions – Export

- 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.**

CRMS User Authorisation List

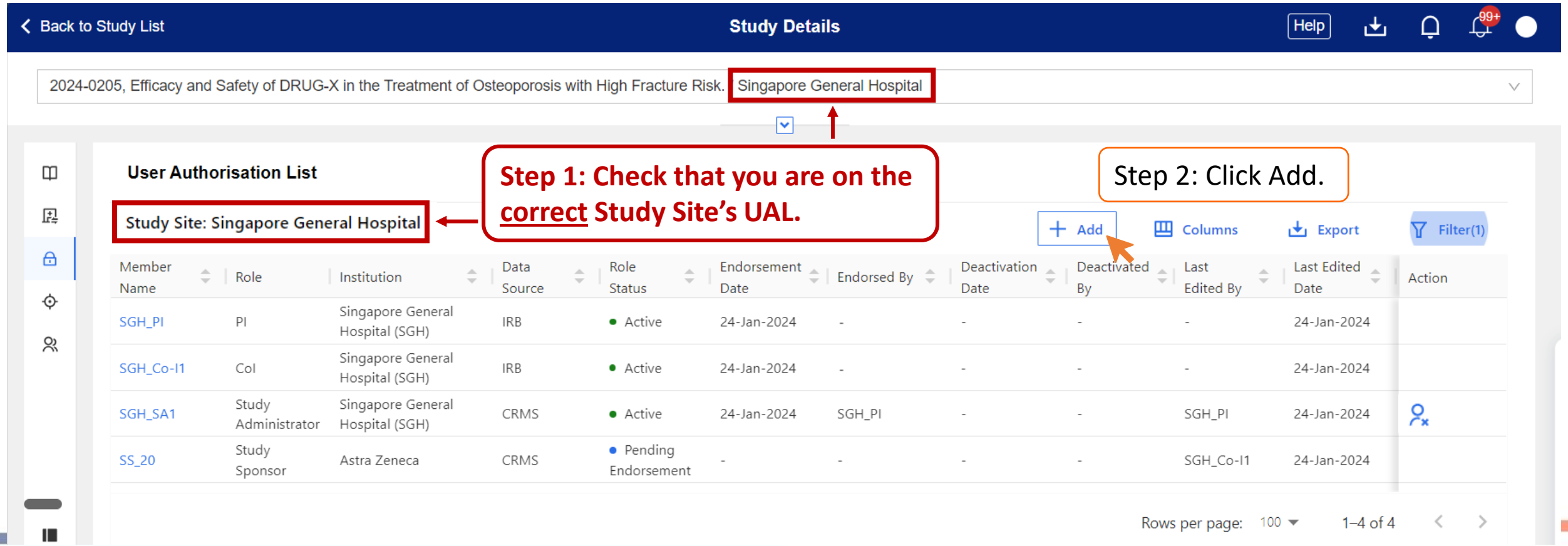
ECOS Reference: 2024-0205
Unique Identifier: 2024-0205-Singapore General Hospital
Study Title: Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.
PI/Site-PI:Dr SGH_PI (Singapore General Hospital), Prof NUH_PI (National University Hospital)
Study Status: Approved
Initial 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	-	-	-	-	24-Jan-2024
SGH_Co-I1	Co-I	Singapore General Hospital	IRB	Active	24-Jan-2024	-	-	-	-	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

Click here to return to Page Functions index.

Page Functions – Add User

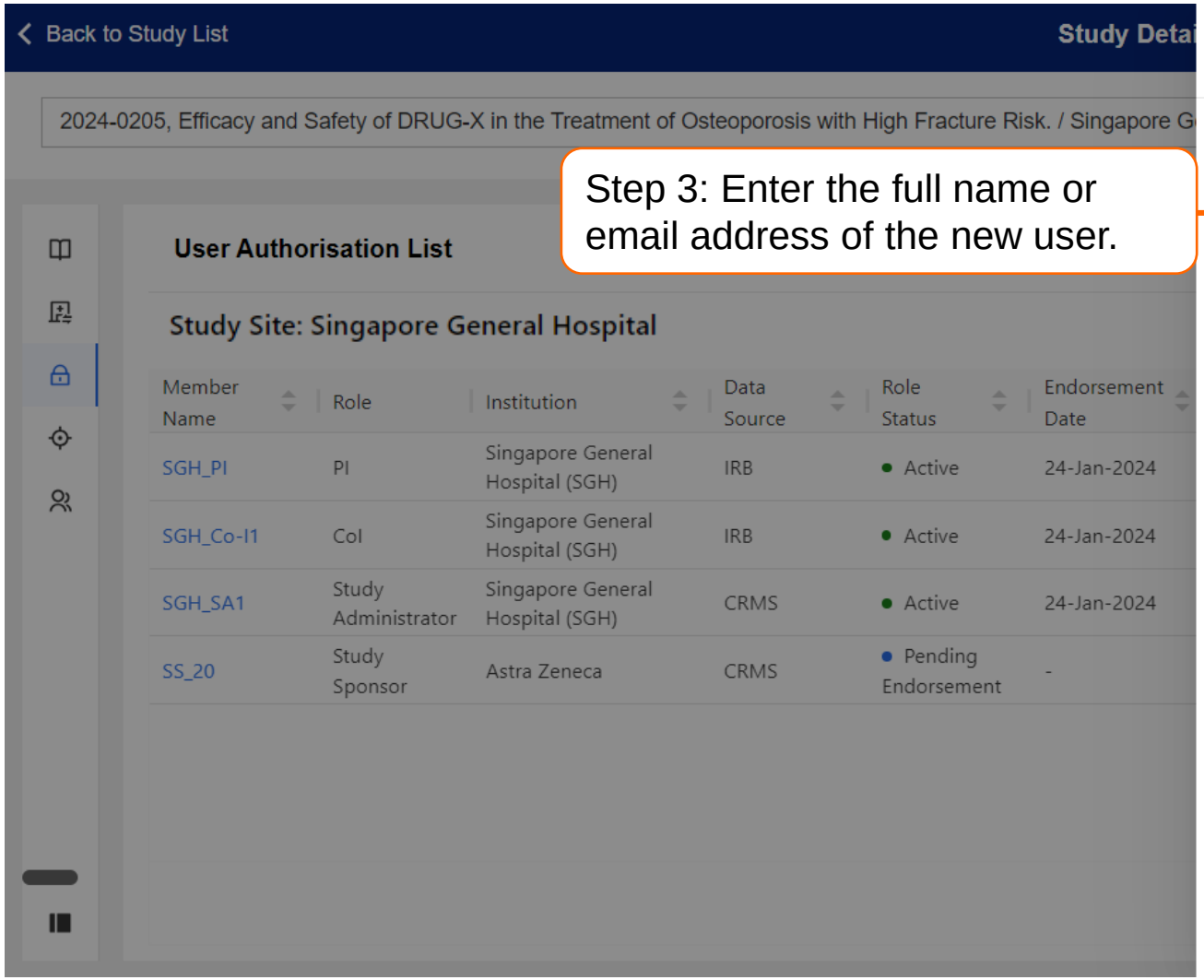
- Any user that has access to the CRMS User Authorisation List (UAL) will be able to add a new user.
- Prior to adding a new user, please check that the **Study Site** is the correct site for the new user to be added.
- If you do not see your study site, please approach your PI/Site-PI or Co-I to add you to your site's UAL.



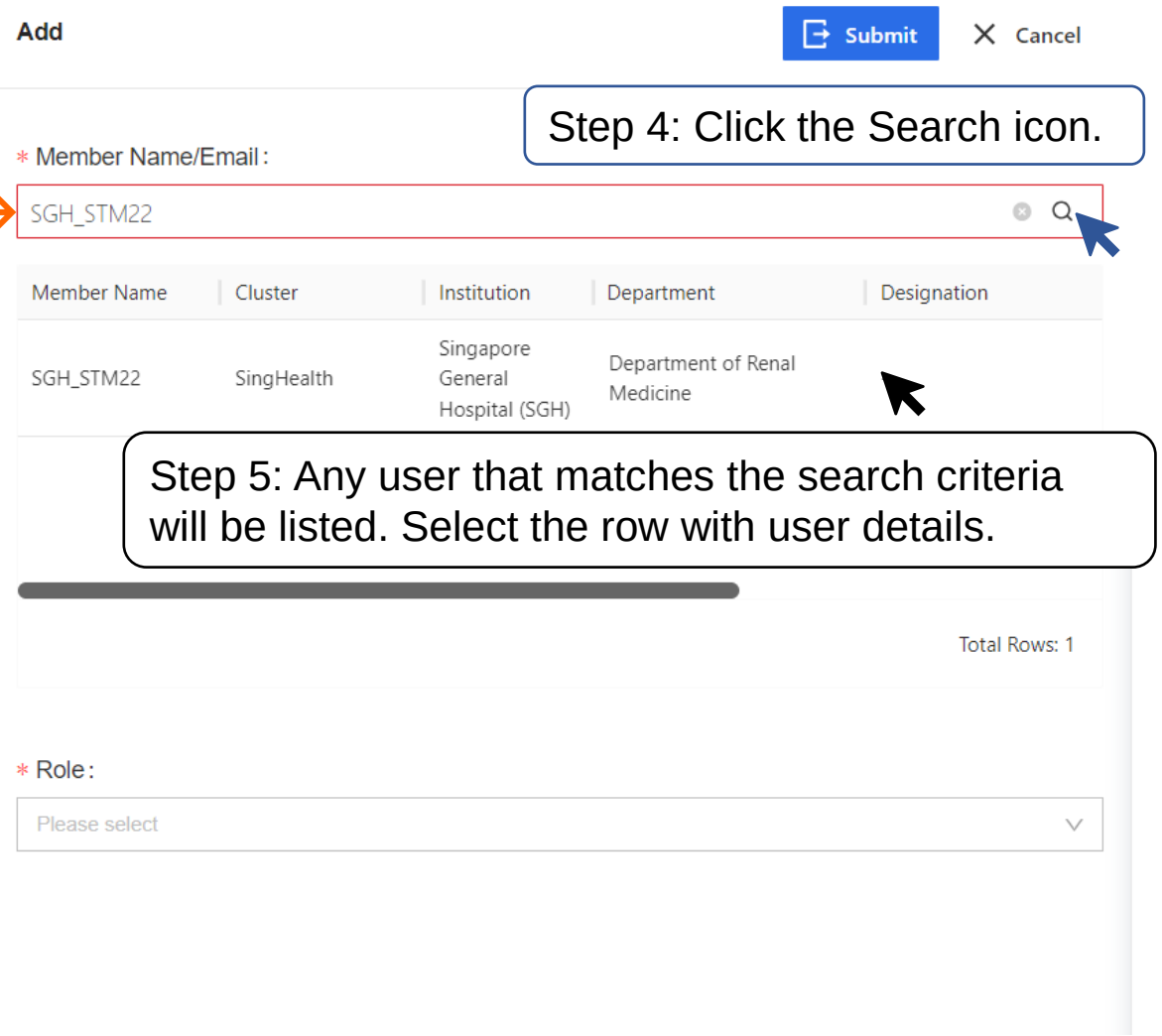
Page Functions – Add User

IMPORTANT

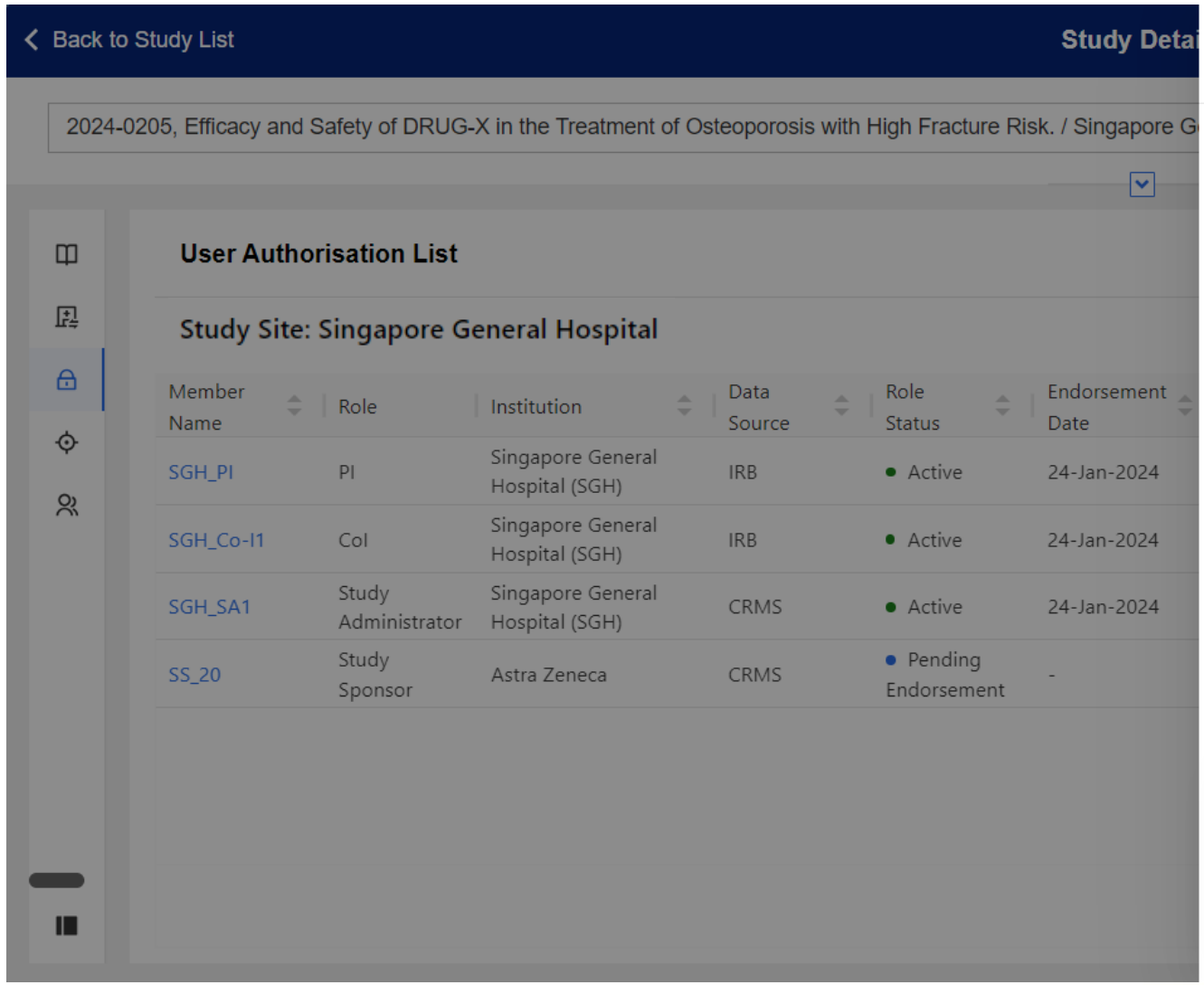
Fuzzy search is not allowed.

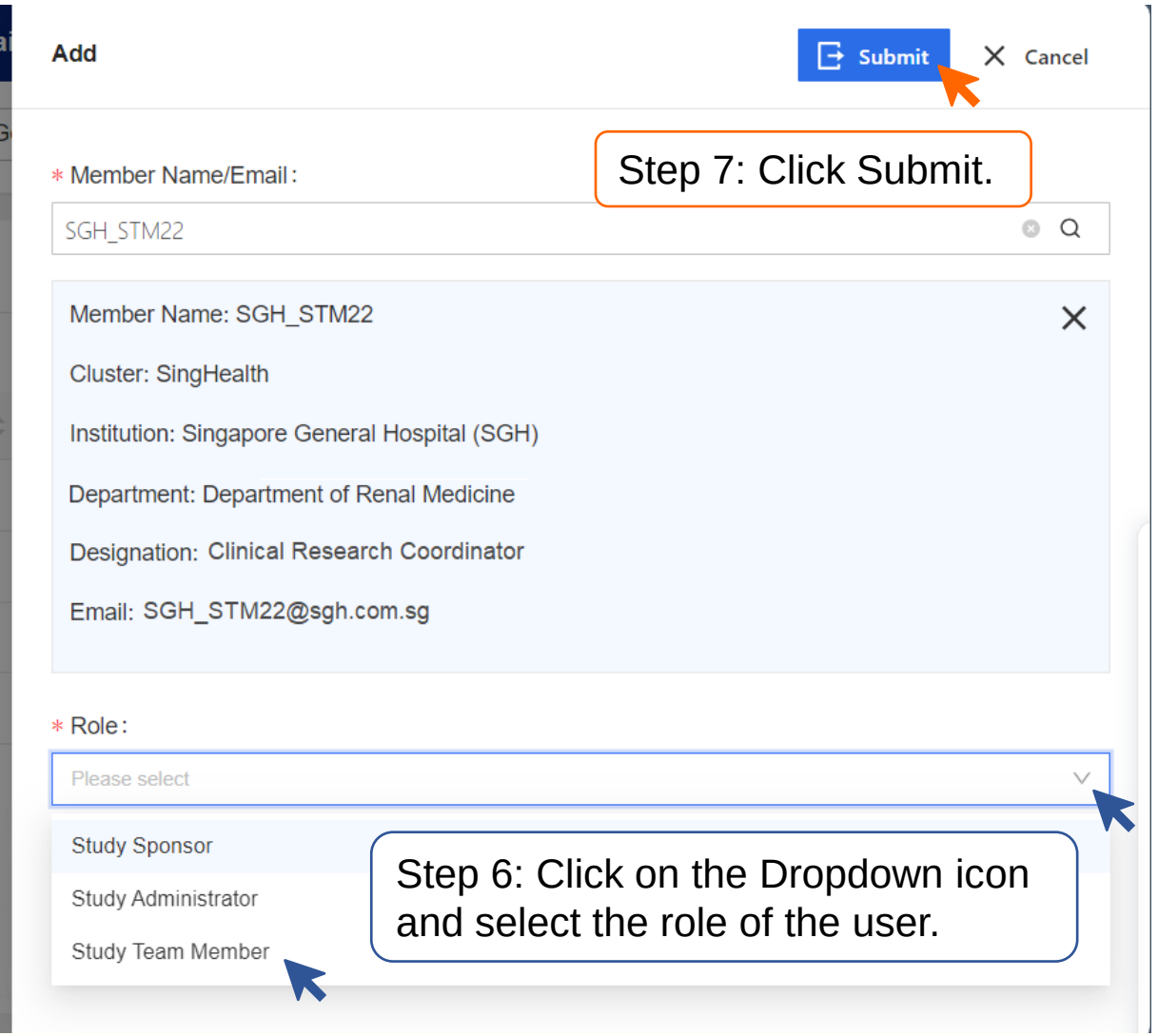


Step 3: Enter the full name or email address of the new user.



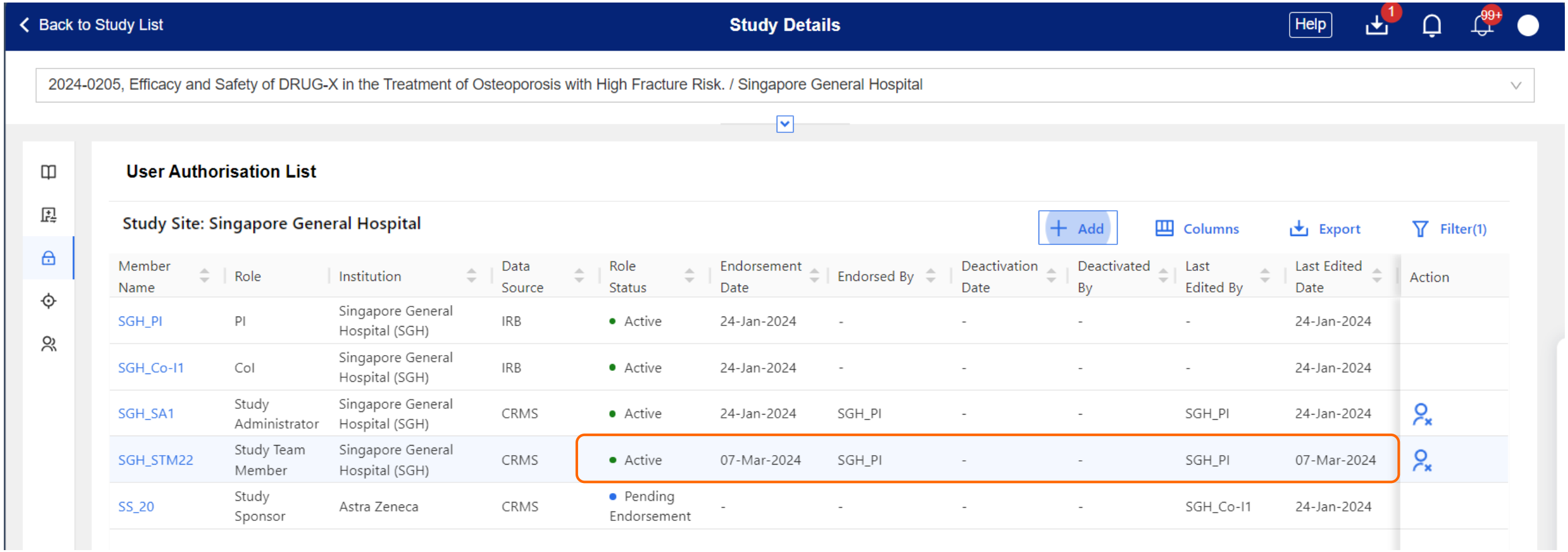
Page Functions – Add User





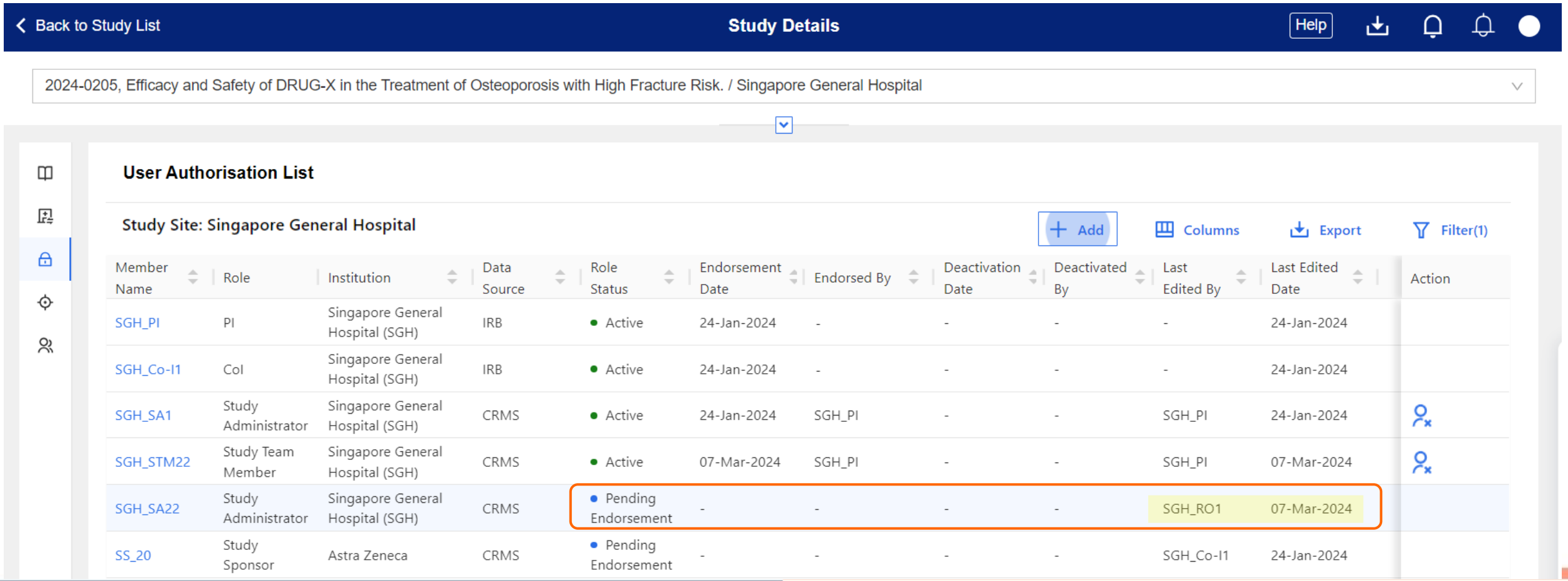
Page Functions – Add User

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



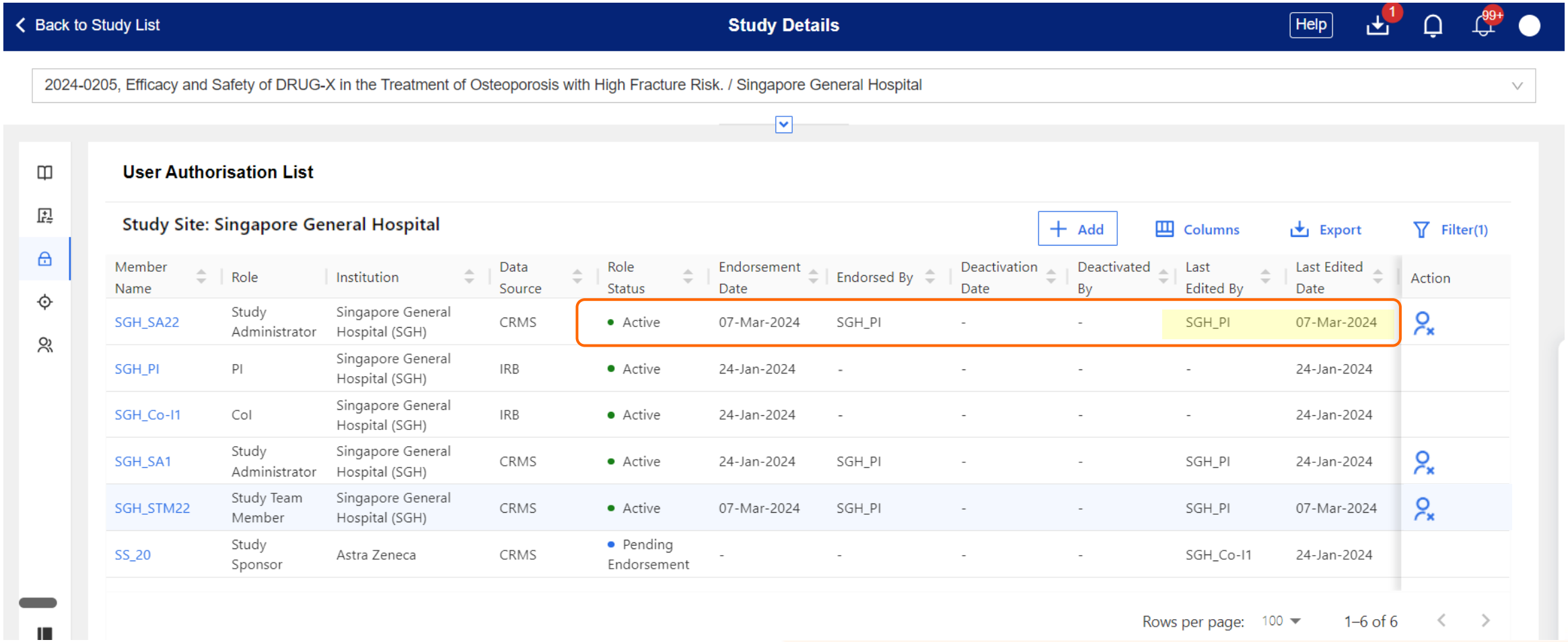
Page Functions – Add User

- 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

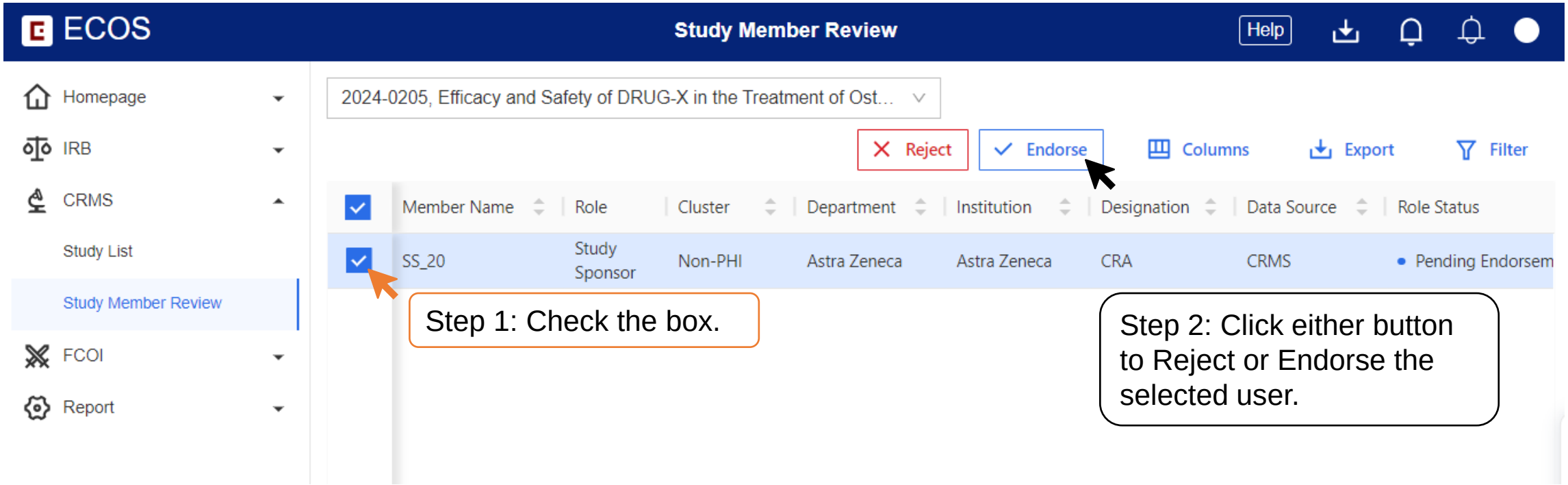
- Below is the updated page view after the PI/Site-PI has reviewed and endorsed the newly added user. New information will be recorded in the relevant columns.



Click here to return to Page Functions index.

Page Functions – Endorse or Reject User

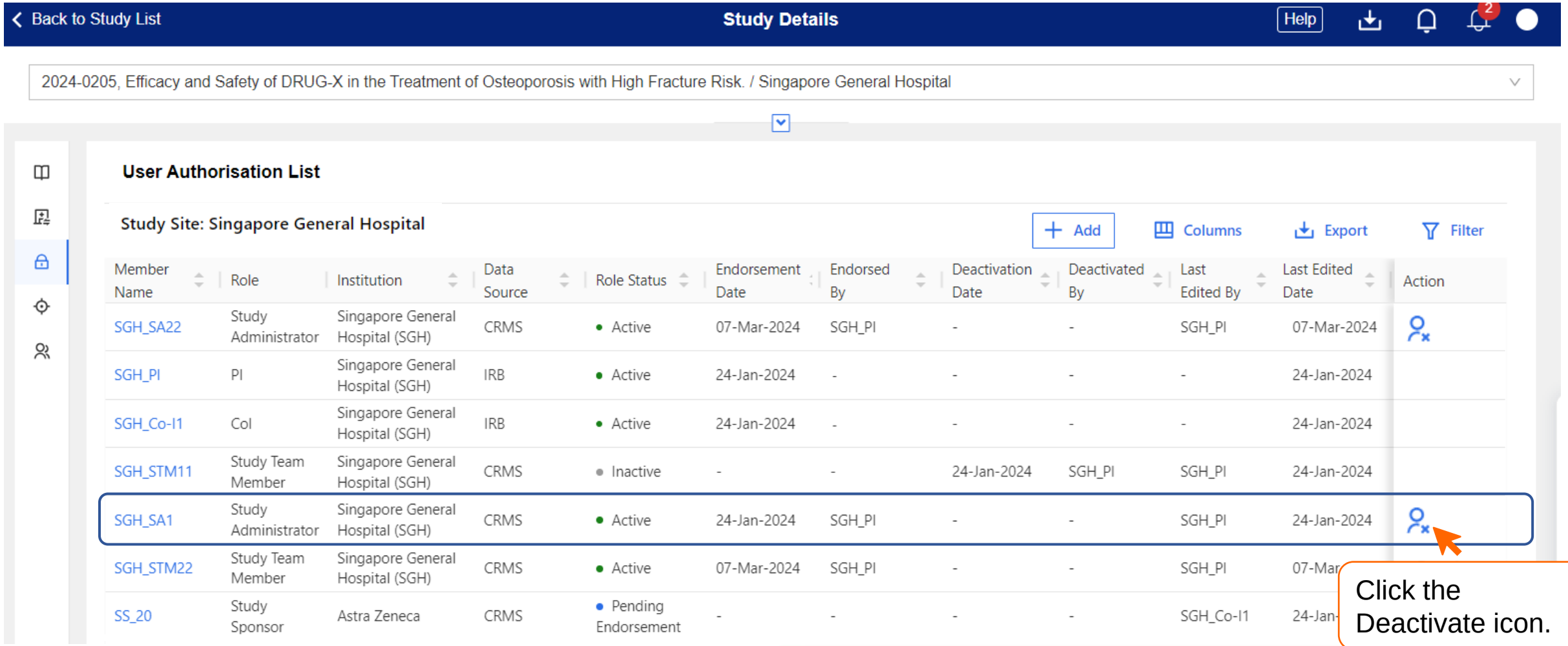
- PI/Site-PI can endorse or reject a user via the Study Member Review page.
- Visit the Study Member Review section (Slide 58) for the steps to access the Study Member Review page.



Click here to return to Page Functions index.

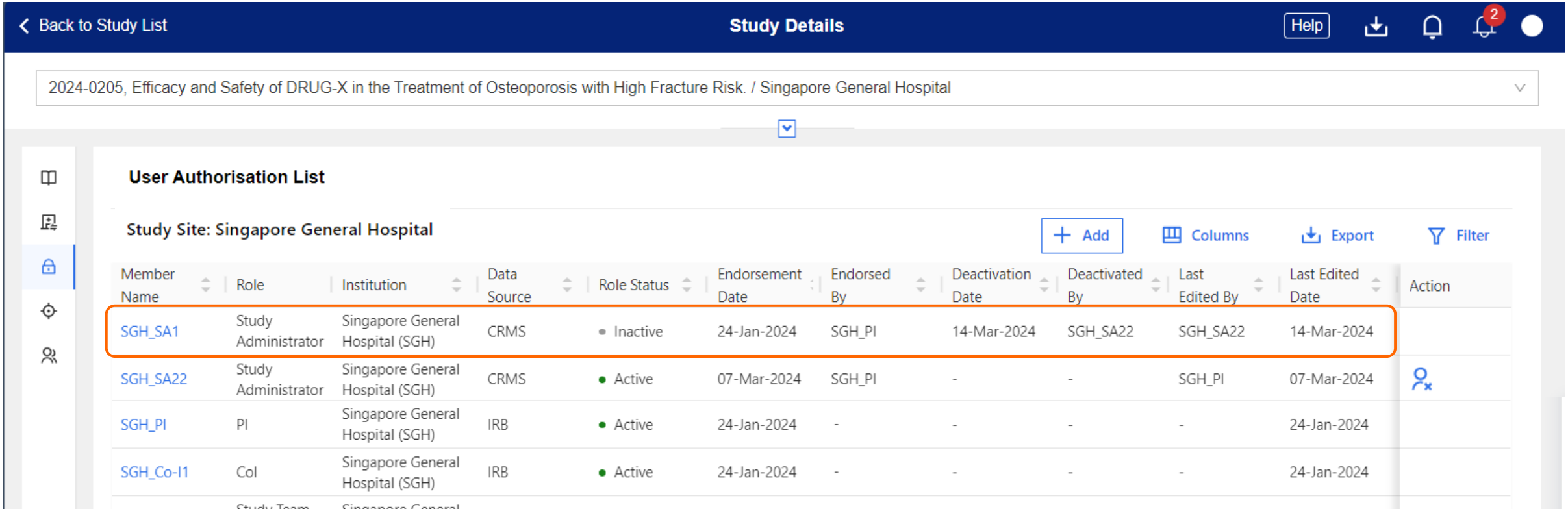
Page Functions – Deactivate User

- 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 and will take effect immediately.
- In this example, SGH_SA22 has deactivated SGH_SA1.



ECOS

Click here to return to Index.

Email Notifications

National Healthcare Group
Adding years of healthy life

SingHealth
Defining Tomorrow's Medicine

Email Notifications

- 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 STM/SA/SS pending endorsement in CRMS.	PI or Site-PI(s) *Site-specific*	-
Successfully Added as User in CRMS	Endorsement of a new STM/SA/SS by PI/Site-PI in CRMS.	New user endorsed by PI/Site-PI	-
User Deactivated in CRMS	Deactivation of an approved STM/SA/SS in the User Authorisation List.	Deactivated STM/SA/SS	PI or Site-PI(s) *Site-specific*
Successfully Added as Primary Site Coordinator	Once a user is saved as the Primary Site Coordinator on the Site Information page.	Primary Site Coordinator user	PI or Site-PI(s) *Site-specific*
Successfully Added as Backup Site Coordinator	Once a user is saved as the Backup Site Coordinator on the Site Information page.	Backup Site Coordinator user	PI or Site-PI(s) *Site-specific*

ECOS

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CRMS Reports

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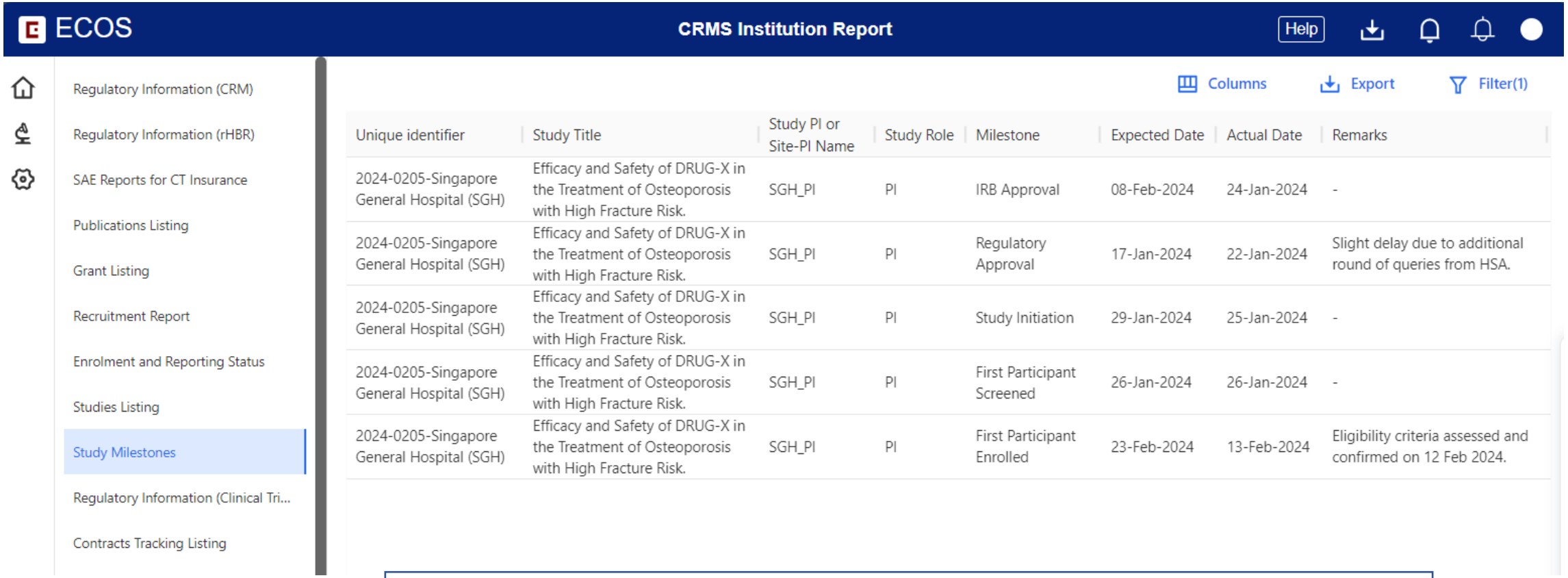
CRMS Reports

- 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.



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.

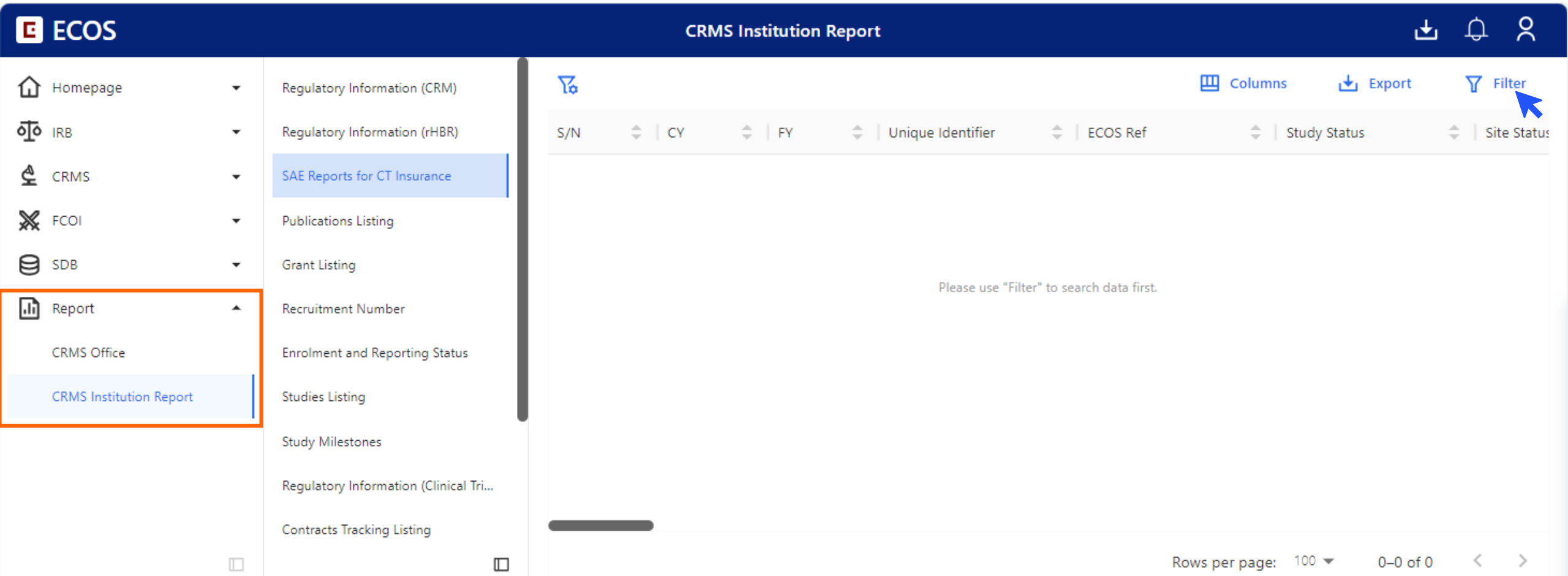
CRMS Reports (SingHealth)

- **14 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
  - List of Studies Managed by the Respective Primary/Backup Site Coordinator
  - Recruitment Numbers and Recruitment Summary

- Access to the different CRMS Reports is tied to a user's role.
  - ➢ CRMS RO administrator has access to all CRMS Reports.
  - ➢ PI, Site-PI, Co-I, STM, SA can only access 2 reports, i.e. List of Studies Managed by the Respective Primary/Backup Site Coordinator and Recruitment Numbers and Recruitment Summary.

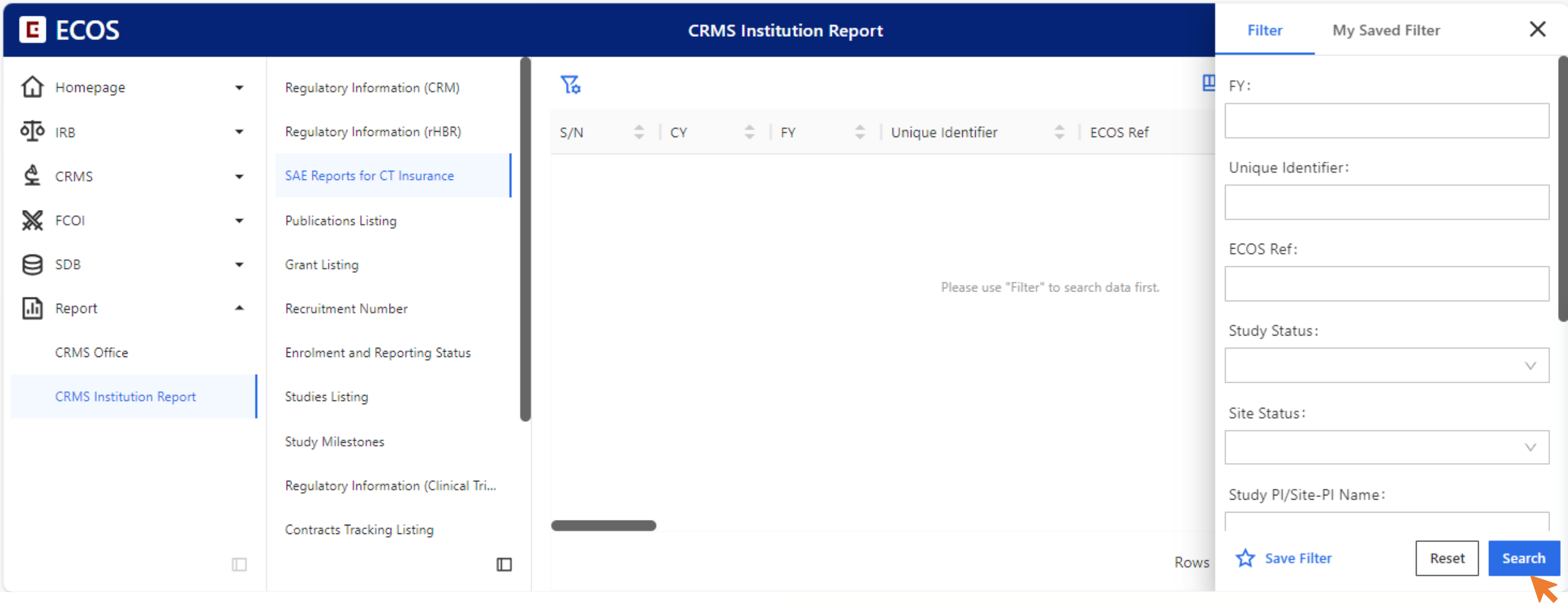
CRMS Report Access

- Access the CRMS Reports via the ECOS Navigation Menu > Reports > **CRMS Institution Report**.
- Using **SAE Reports for CT Insurance** report as an example, click **Filter**…



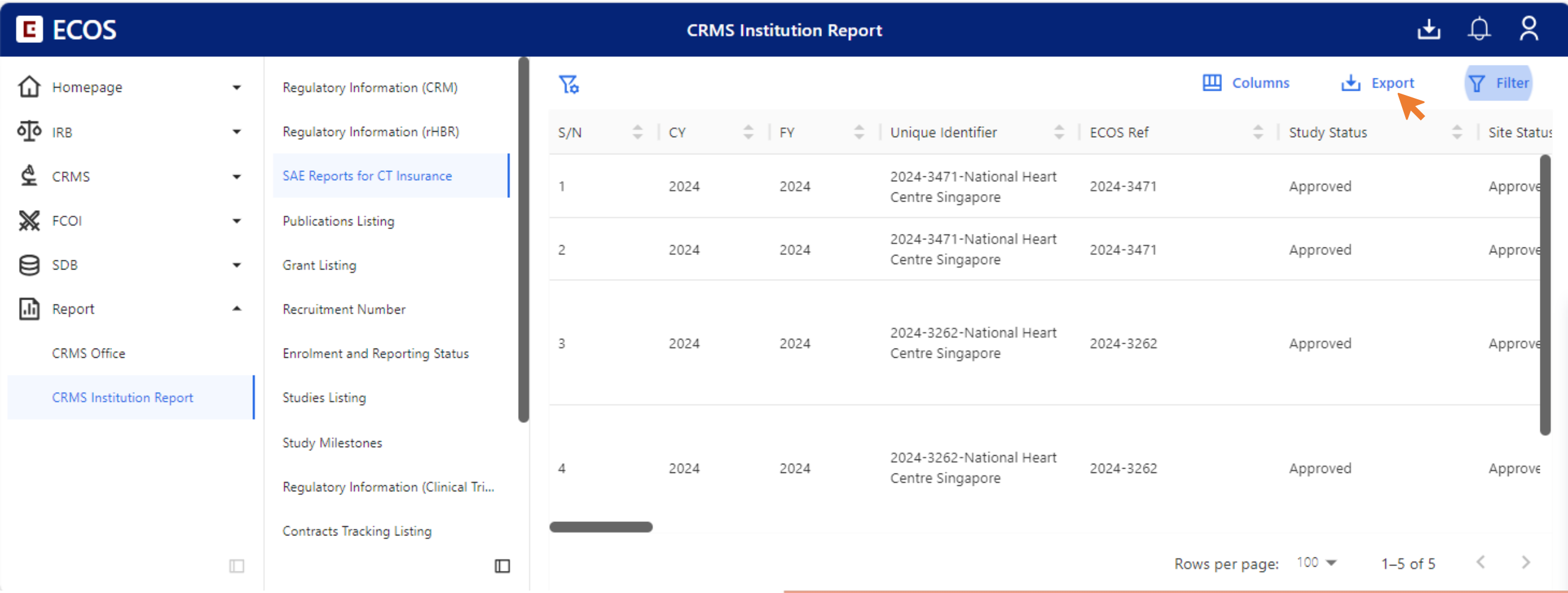
Data Generation

- … then click **Search** to generate data.



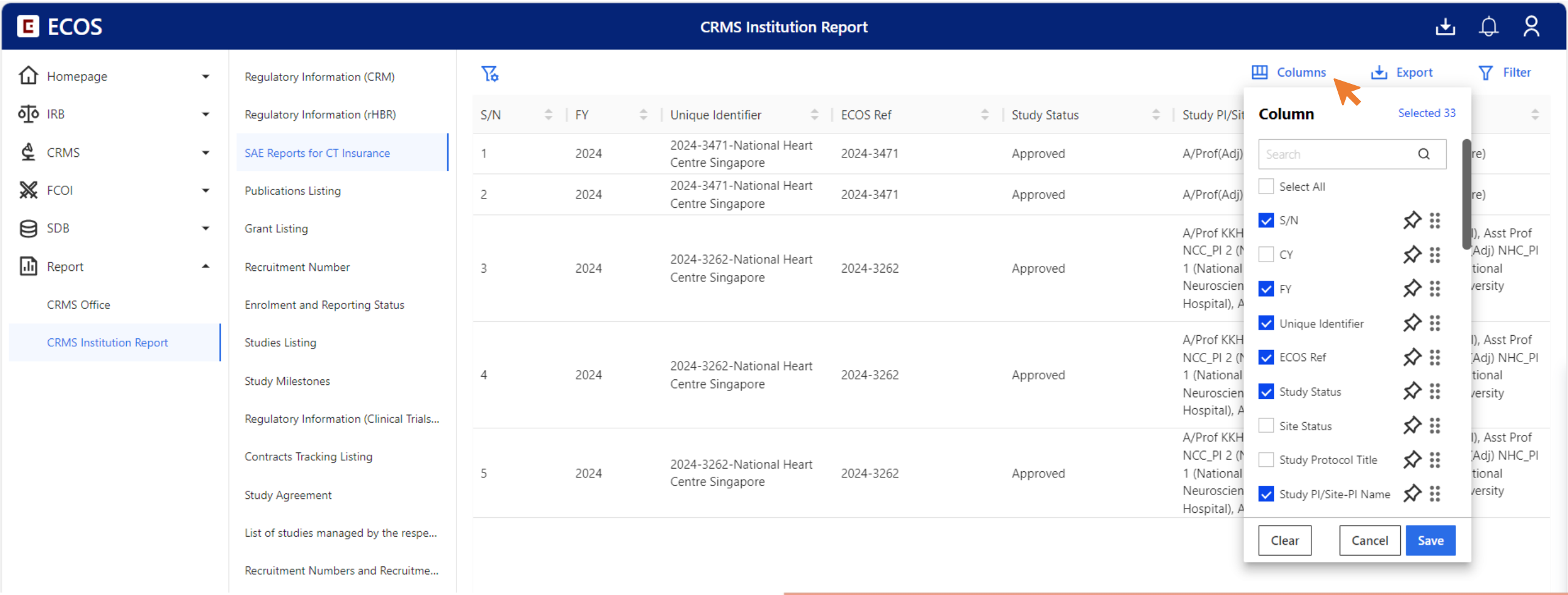
Export Function

- Without any filters applied, all available data will be generated and displayed on the report.
- Click **Export** to download the report in Excel format.

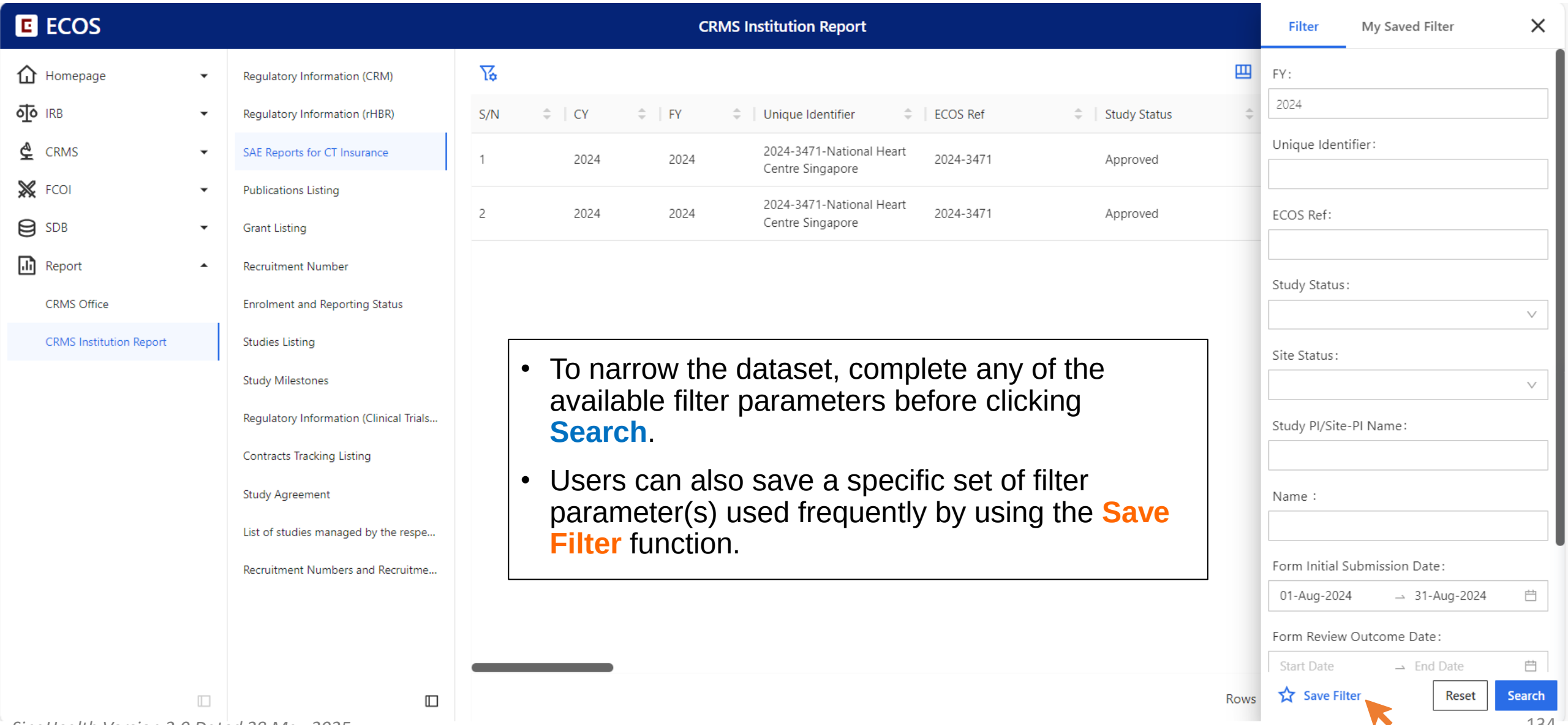


Columns Function

- Use the **Columns** function to reduce the data columns displayed. This allows the user to focus on specific few data columns of interest. Alternatively, the entire report can be exported and manipulated in Excel.

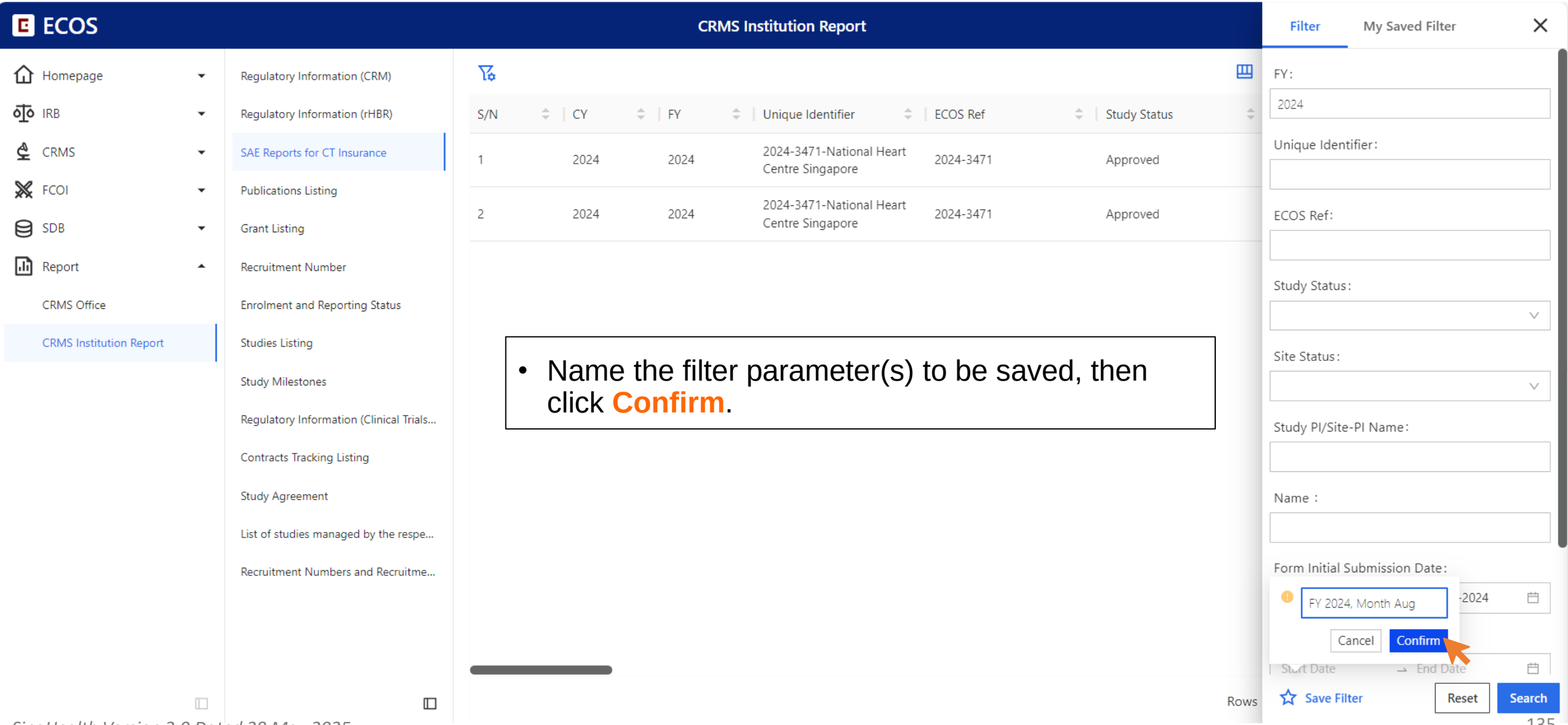


Filter Function



- To narrow the dataset, complete any of the available filter parameters before clicking **Search**.
- Users can also save a specific set of filter parameter(s) used frequently by using the **Save Filter** function.

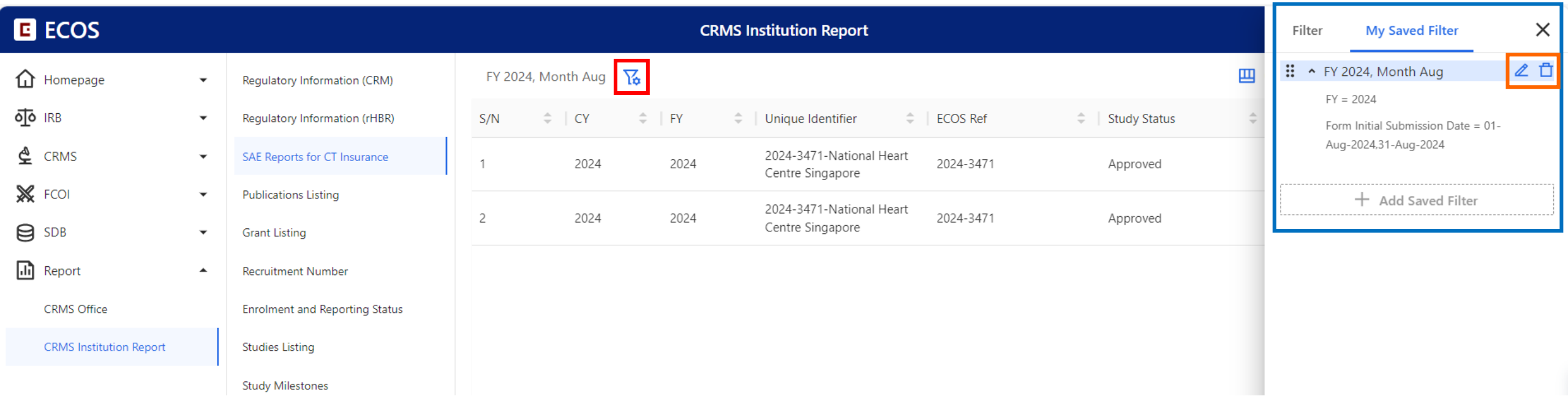
My Saved Filter Function



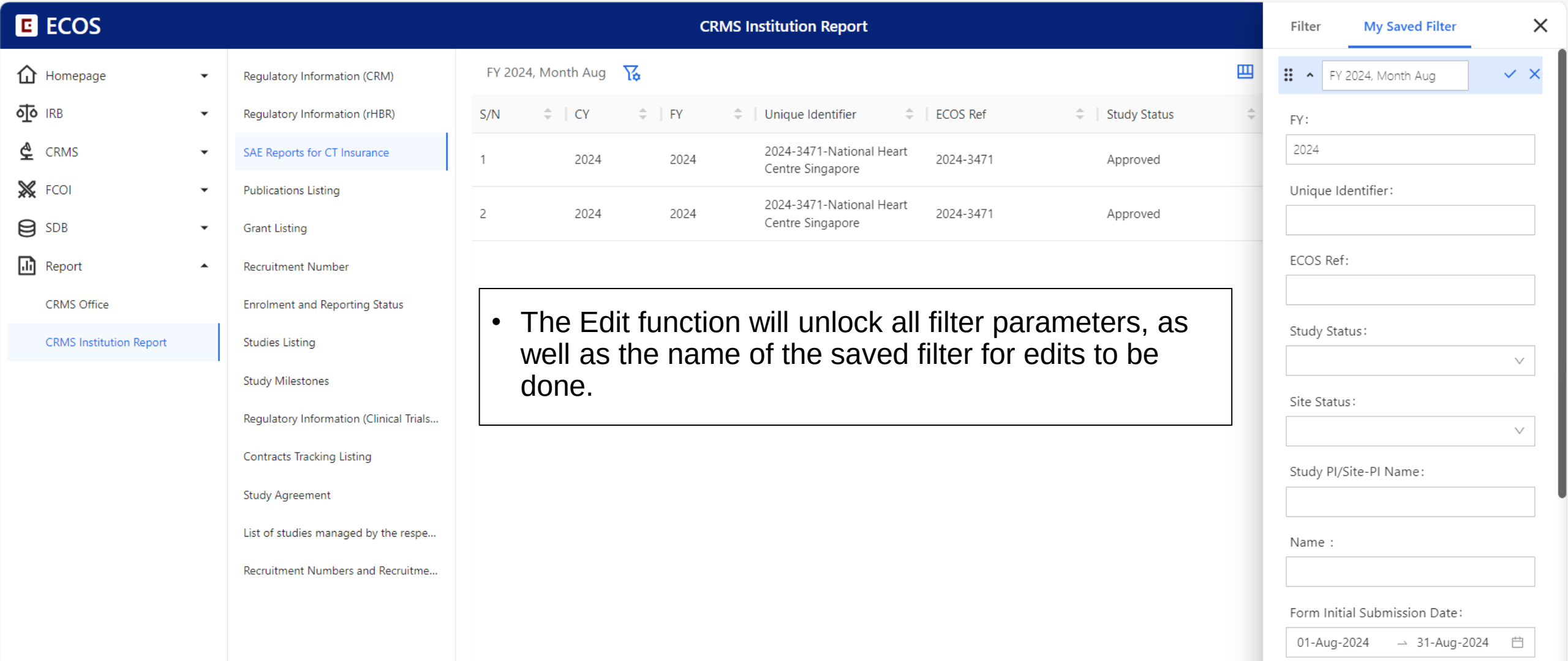
- Name the filter parameter(s) to be saved, then click **Confirm**.

My Saved Filter Function

- The saved filter can be easily located in the **My Saved Filter** tab on the Filter panel.
- Alternatively, the user can click on the **My Saved Filter icon** on top of the Report page, which would open the same **My Saved Filter** panel.
- From the **My Saved Filter** panel, user can see the exact filter parameter(s) saved.
- Existing saved filters can also be **Edited** or **Deleted**.



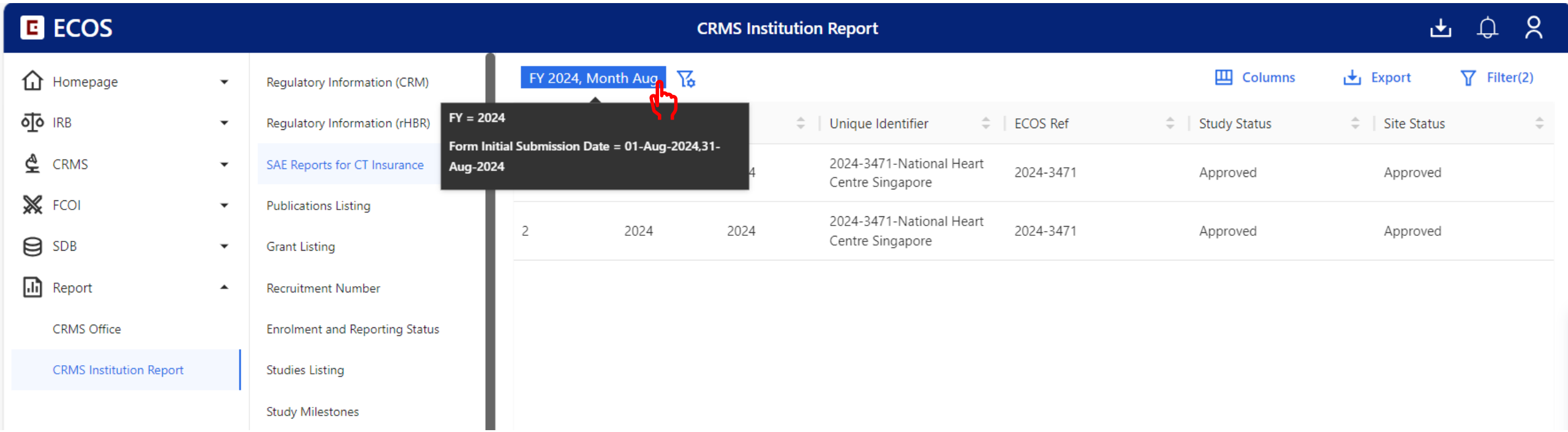
My Saved Filter Function



- The Edit function will unlock all filter parameters, as well as the name of the saved filter for edits to be done.

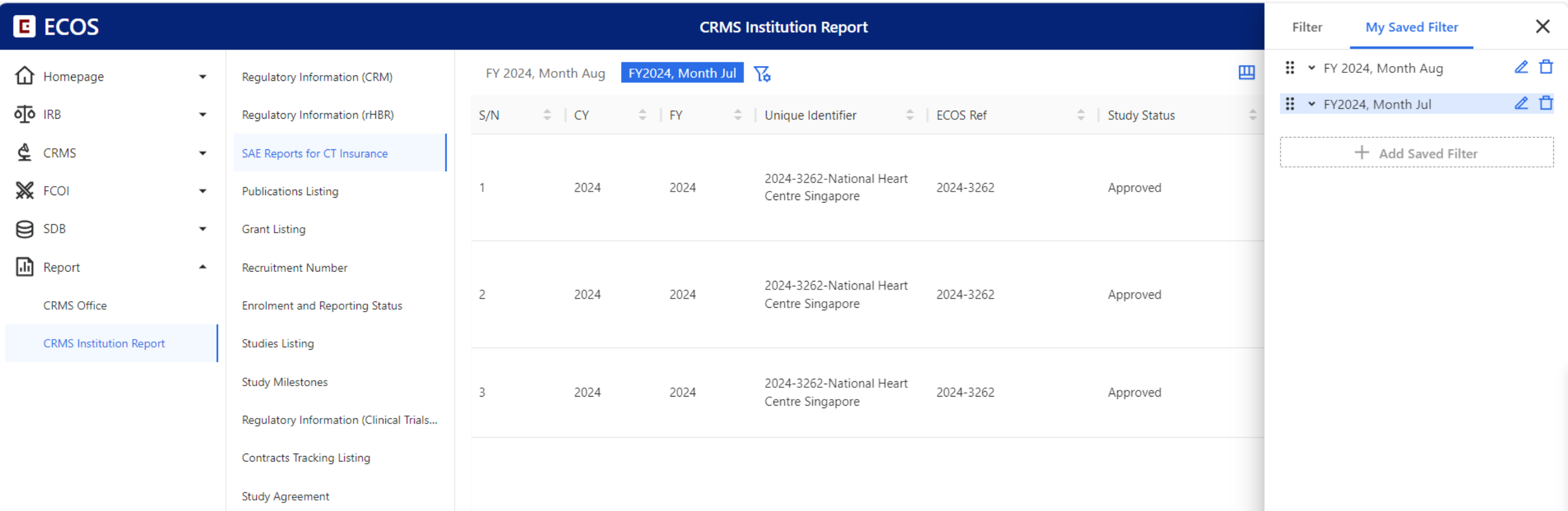
My Saved Filter Function

- A new tab will be created on top of the Report page for each filter parameter(s) saved.
- To generate a dataset using the saved filter, user can simply click on the saved filter tab.
- User can hover over the saved filter to have a quick glance at the filter parameters applied.



My Saved Filter Function

- More than 1 filter parameter(s) can be saved.



Exported Report View

SAE Reports for CT Insurance

Downloaded By: Ms NHC_RO14

Downloaded Date and Time: 07-May-2025 15:30:38

Data is accurate as of: 07-May-2025 00:00:00

S/N	CY	FY	Unique Identifier	ECOS Ref	Study Status	Site Status	Study Protocol Title	Study PI/Site-PI Name
1	2024	2024	2024-3471-National Heart Centre Singapore	2024-3471	Approved	Approved	AAA	A/Prof(Adj) NHC_PI 1 (National Heart Centre Singapore)
2	2024	2024	2024-3471-National Heart Centre Singapore	2024-3471	Approved	Approved	BBB	A/Prof(Adj) NHC_PI 1 (National Heart Centre Singapore)

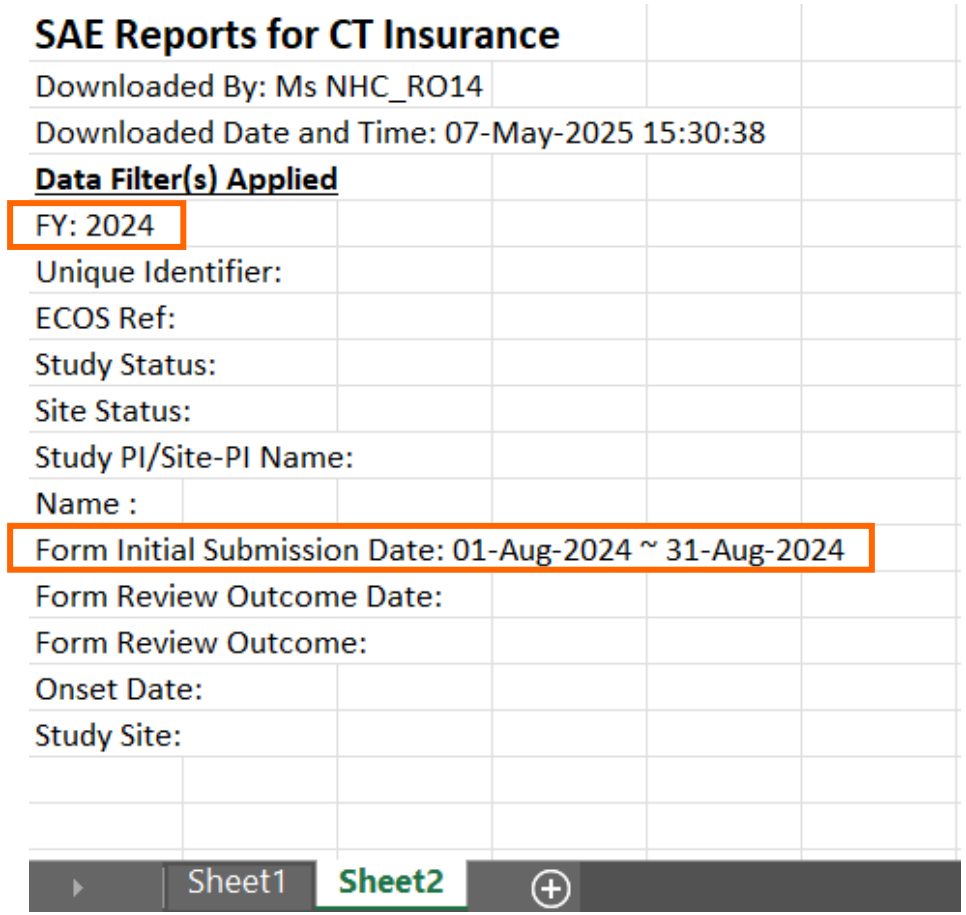
Sheet1 Sheet2

REMINDER:

1. Reports generated will include all data from the previous day. New data entered in ECOS on the day itself will not be included in the generated report.
2. If there are specific Columns and Filter applied (if any) prior to export, the report will be generated as per the Columns and Filters applied.

Filters Applied

- Any filters applied when generating reports can be identified on Sheet 2 of the exported Excel Report.



ECOS

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CRMS Research Office Role

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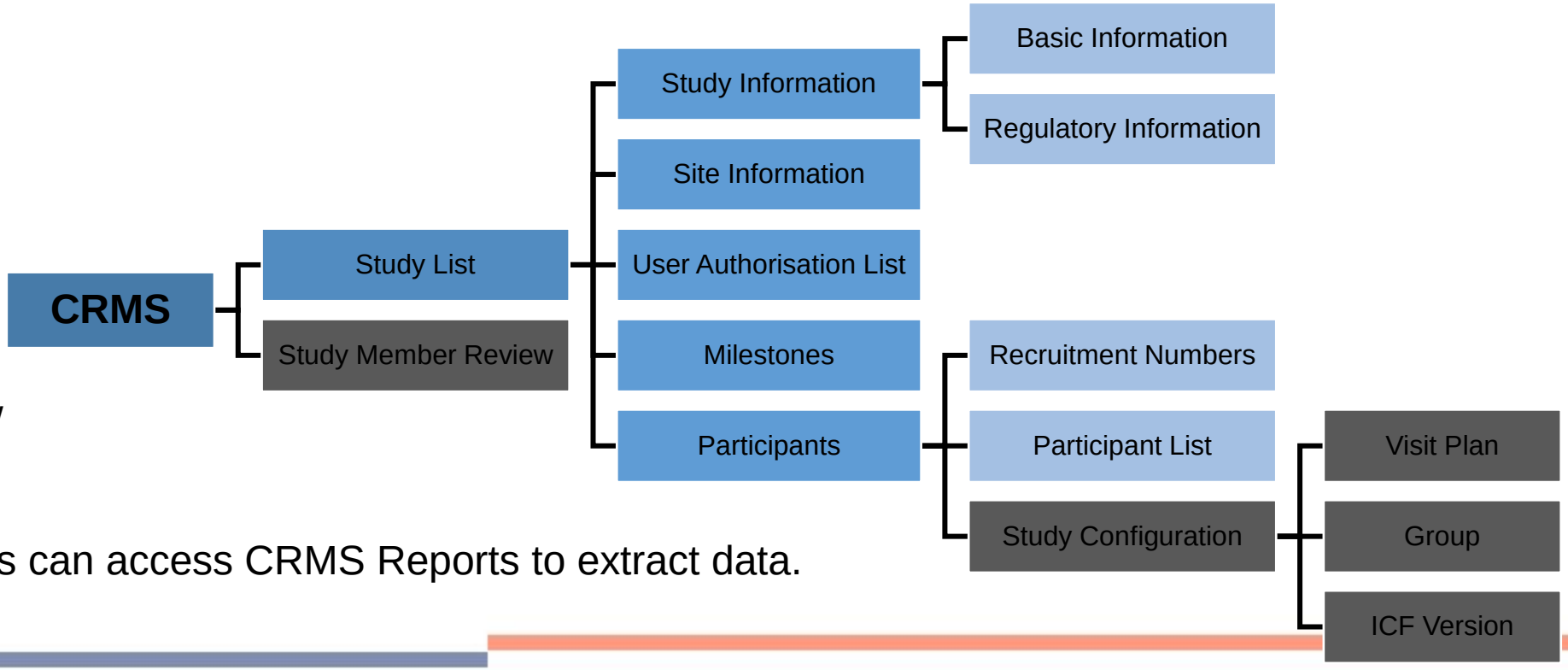
CRMS RO Role

- Research Office (RO) administrators assigned with the CRMS RO role will have full View & Edit access to the CRMS module upon role assignment.
  - New users requiring this CRMS RO role should contact their respective institution RO.

- Access authority is institution-specific.
  - Under Study List, the CRMS RO administrators will be able to see the full list of institution studies.

- Page level access: -
  - ✓ **Study Level**
  - ✓ **Site Level**

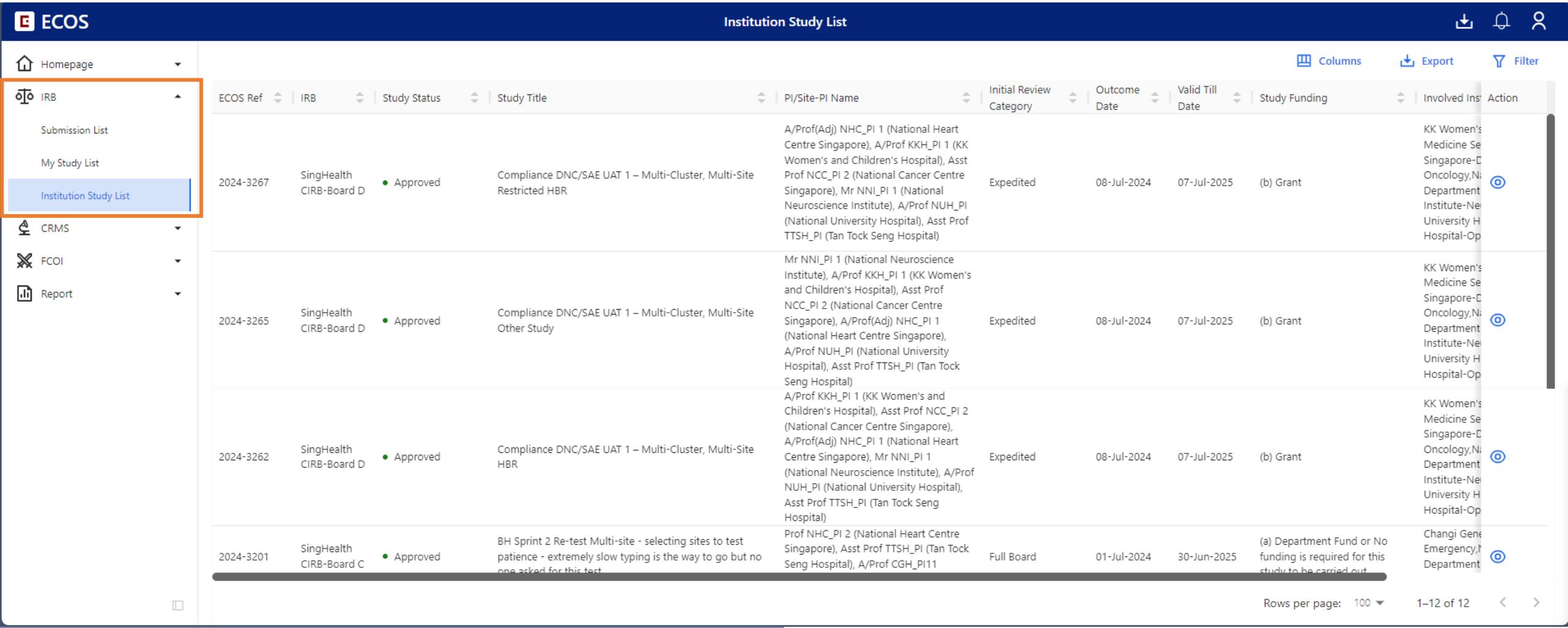
- No page access to: -
  - × Study Member Review
  - × Study Configuration



- CRMS RO administrators can access CRMS Reports to extract data.

Access to IRB Institution Study List

- CRMS RO administrators also have full access to the **Institution Study List** in the IRB module.



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Migration of Existing Studies

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Migration of Existing Studies (SingHealth)

- **Study Information – Basic Information**
  - Sponsor, CRO and payment data from Study Funding Information in the iSHaRe CIRB forms have been migrated to 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 users in the iSHaRe CIRB form have also been migrated to the CRMS UAL page.
  - Protocol Administrators and Study Team Members were not 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 the study on ECOS. 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.

ECOS

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FAQ: Do I add everyone on the Delegation Log to the User Authorisation List?

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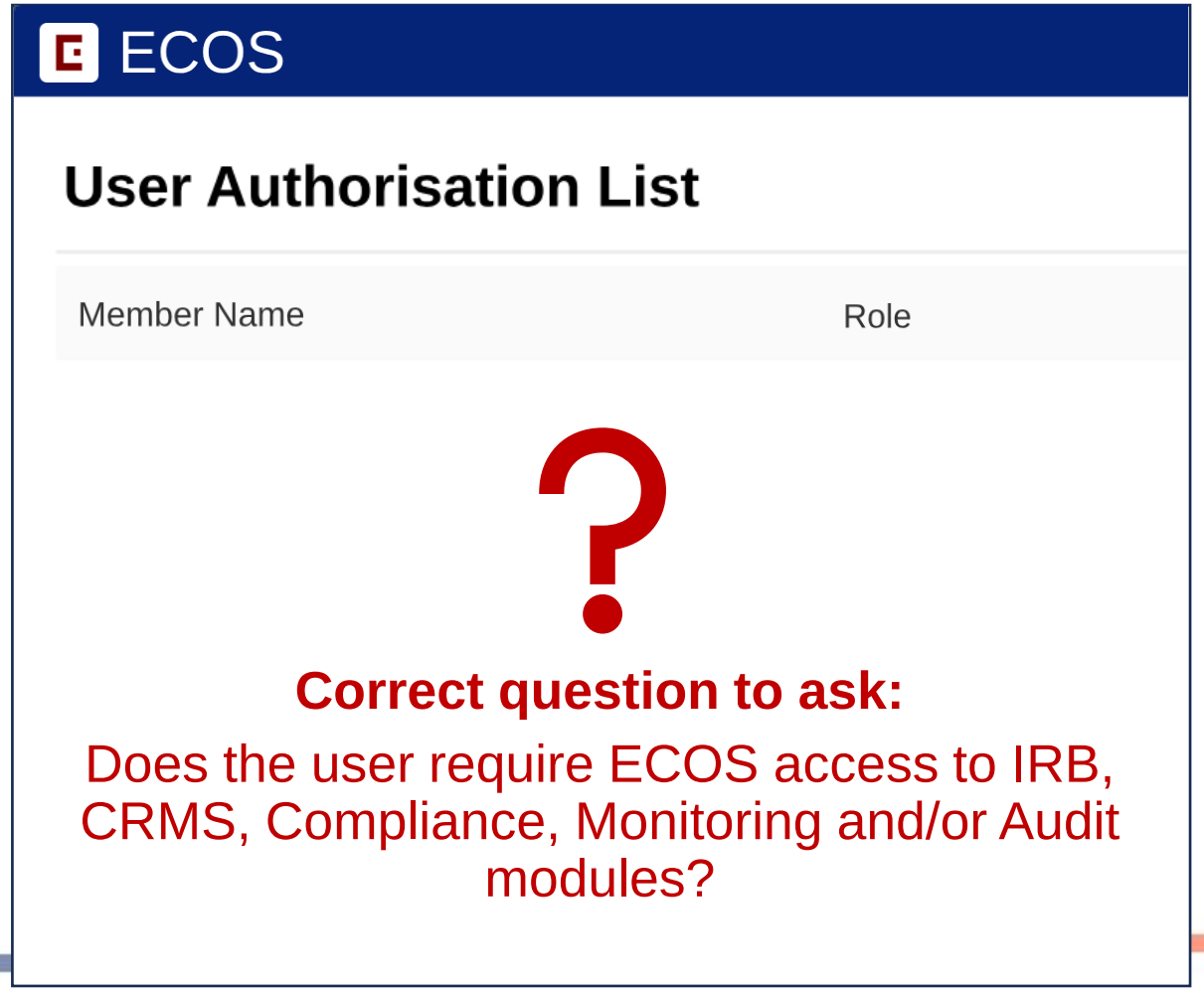
Do I add everyone on the delegation log to the UAL?

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



Correct question to ask:

Does the user require ECOS access to IRB, CRMS, Compliance, Monitoring and/or Audit modules?

Q: Does the user require access to IRB, CRMS etc. modules?

- Additional helpful questions to ask:

Is the user required to…

- Draft IRB APP/AMD, DNC, OSN, SAE, SSR etc. forms?
- Have access to the IRB documents, e.g. protocol, ICFs and IRB approval letters?
- Enter data into the CRMS pages?
- Function as a back-up?
- Complete PISAF, SOC and/or tiered SOC forms?
- Facilitate Monitoring or Audit visits and/or complete CAPA plan(s)?

- If the answer to any of the questions above is yes, proceed to add the user to the User Authorisation List (UAL).
- **The next slide will illustrate the following:-**
  - PI, Site-PI(s) and Co-I(s) added to the IRB form will automatically be added to the UAL when synchronisation happens between the IRB and CRMS module.
  - Primary CRC is expected to have study access to IRB, CRMS, Compliance, Monitoring and Audit modules for data entry, reporting and submission work, hence he/she should be added to the UAL.
  - It is a good practice to always provide study access to at least 1 back-up CRC.
  - Study Nurses and Pharmacists are usually not significantly involved in the administrative portion of clinical research, access to IRB, CRMS and the other modules is generally not required. However, if they do require if for any appropriate reason, please add them to the UAL.

If access is required, proceed to add the user 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, CRMS etc. access, add him/her to the UAL. If not, ok to omit.

UAL can also contain sponsors or any other users outside the delegation log, e.g. department Executive helping with CRMS data entry.

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

ECOS

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FAQ: I am listed on the UAL but why am I not able to view and edit the PISAF/SOC/Monitoring/Audit related forms?

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Access Roles to Other Modules

SA does not have a role here. Only STM has access role.

Modules	Pages/Forms	Access Roles
Compliance	Site Task List for - DNC - SAE - PISAF	• Approved PI/Site-PI and Co-I • Active STM
Monitoring	Plan Review for - Monitoring Plan	• Approved PI/Site-PI
	Study Monitoring Information for - Plan Visit - Confirmation Letter - Monitoring Report - Issue List - Follow-up Letter	• Approved PI/Site-PI and Co-I • Active STM
	My Issue	Any of the below selected as the Responsible Person: • Approved PI/Site-PI or Co-I • Active STM
Audit	Study Audit Information for - Plan Audit - Site Audit (Audit Report and Audit Report Observation)	• Approved PI/Site-PI and Co-I • Active STM

Key Points

- Only approved investigator(s) and/or active STM(s) have access to the Compliance, Monitoring and Audit modules.
- PI/Site-PI, Co-I or STM that are pending approval/endorsement do not have access to the modules.
- **SA and SS do not have any role in Compliance, Monitoring and Audit module. ie. SA listed on the UAL cannot view/edit/complete the PISAF form.**
- The role in CRMS should be assigned correctly. The roles of a SA and STM are different.

Role	Definition
Study Team Member (STM)	Site personnel **directly involved** in the research conduct e.g. CRCs, Study Nurses, Pharmacists, etc.
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.

- For detailed information about the other modules, kindly refer to the module-specific training materials uploaded to the RICE ECOS website.

ECOS

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FAQ: Is CRMS Mandatory?

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Is CRMS Mandatory?

- **Mandatory for ALL SingHealth studies:**
  1. Milestones
  2. Participant – Recruitment Numbers*
  3. Site Information*

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

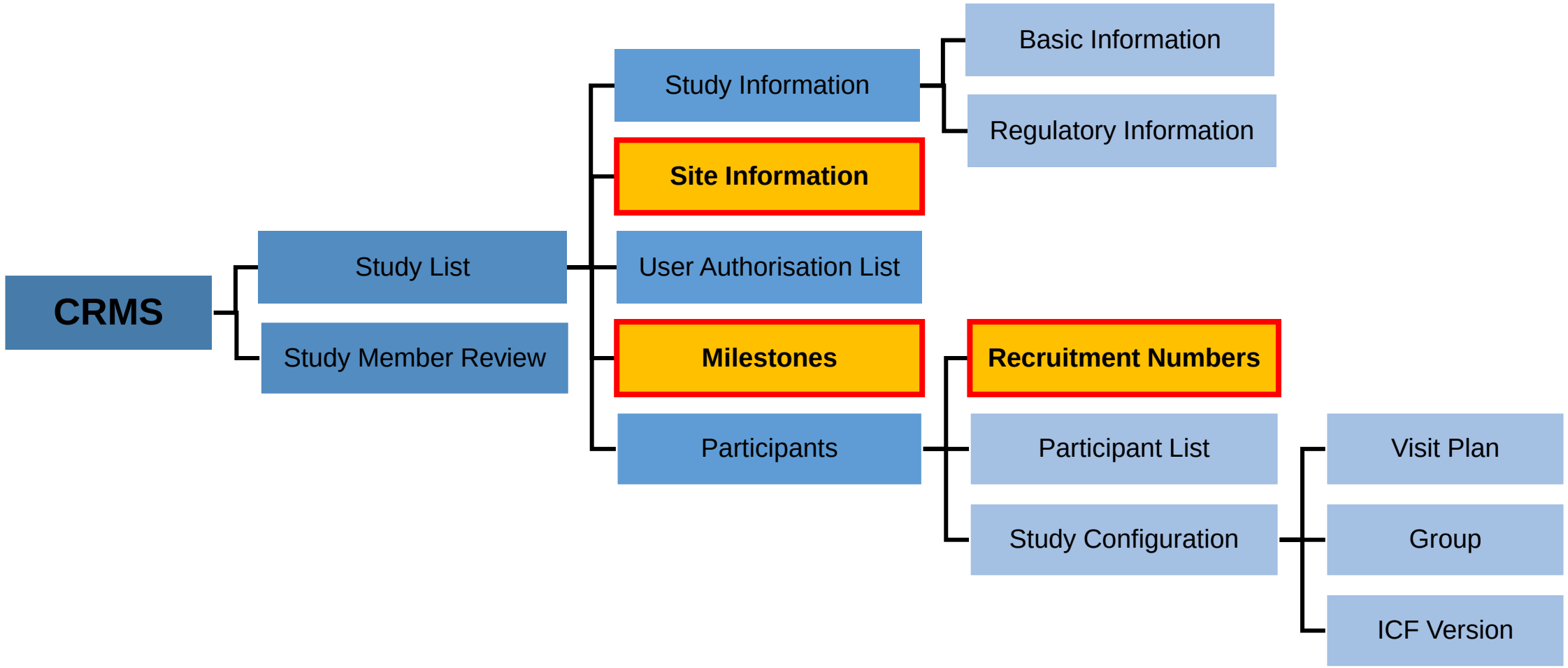
- **Optional** but highly encouraged:**
  1. Participants – Participant List
  2. Participants – Study Configuration (Visit Plan, Group, ICF Version)

NOTE:

* Refer to the guide by SingHealth CTCC for more information.

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

Mandatory Pages



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Common Discrepancies Observed

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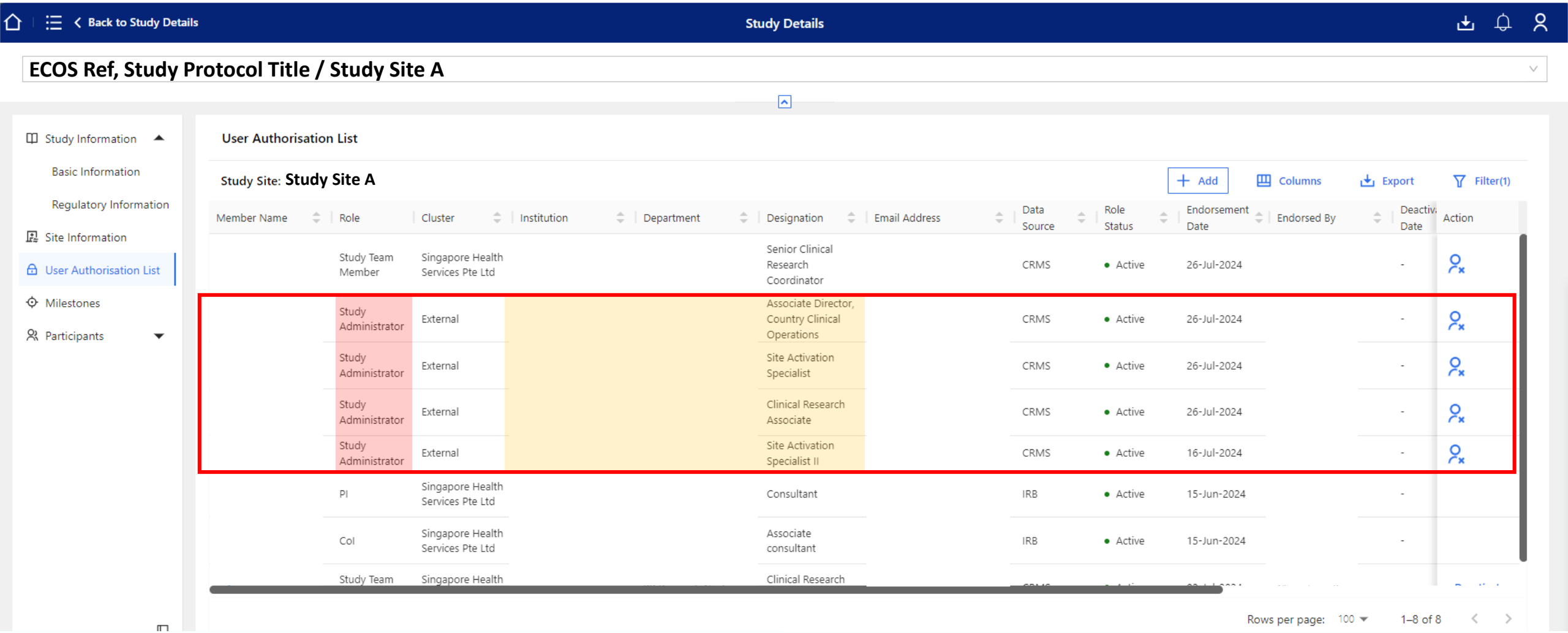
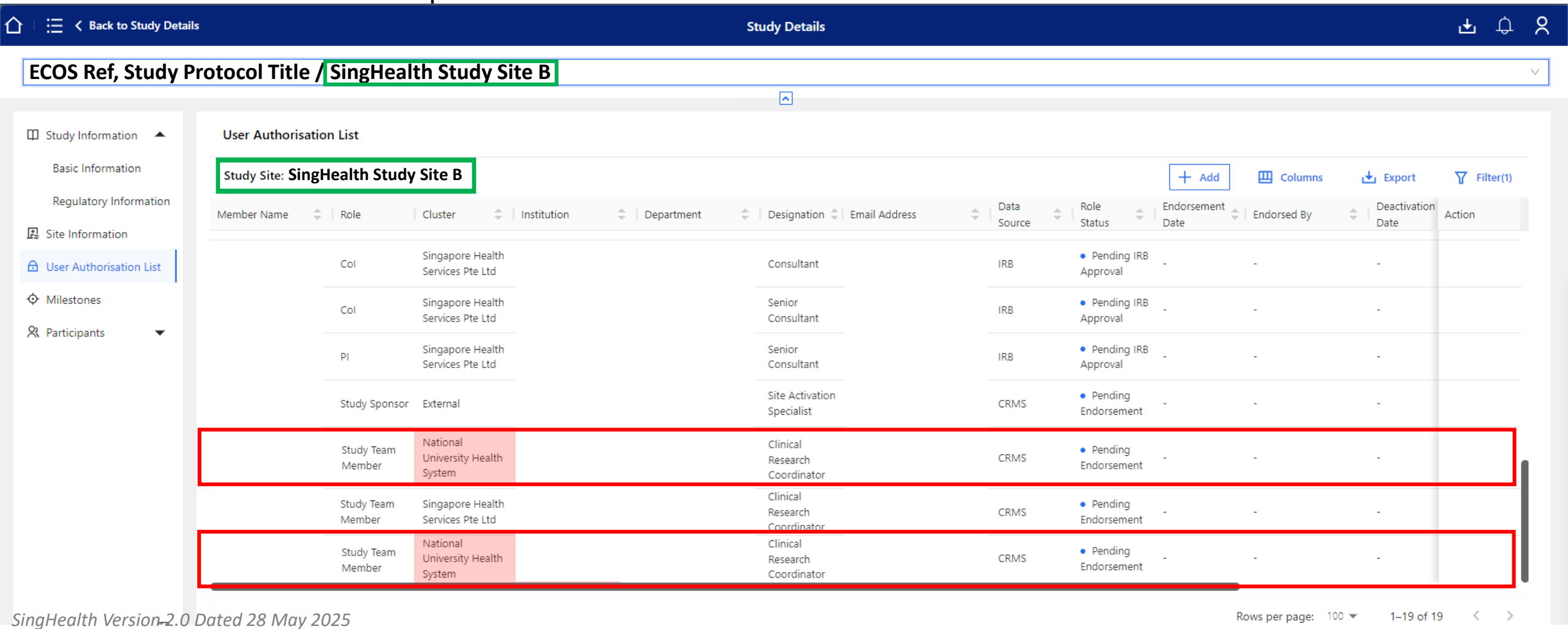
Observation #1: Improper Role Assigned

- Sponsor personnel from pharmaceutical companies or CRO such as CRA, Site Activation Specialist etc. should be assigned the Study Sponsor role, not Study Administrator or Study Team Member.



Observation #2: Non-SingHealth personnel added as SA/STM for SingHealth sites

- **<u>The UAL is site-specific</u>**. STM should be added to their respective institution study site. If a staff member external to the institution has been added as a SA/STM for your study site, this will enable that person to view and edit the site-specific information.



Potential Downstream Impacts

- **Data privacy issues.**
  - Assigning STM or SA roles to Sponsor personnel will grant them access to CRMS pages where they are not authorised to access.
  - Likewise, external personnel from another institution (e.g. Study Site B) will gain unauthorised access to the CRMS pages of the institution (e.g. Study Site A). Information entered in CRMS (e.g. recruitment, grant, agreement etc. data) for Study Site A will be visible to the external personnel from Study Site B.

- **Disrupts data accuracy in the CRMS Report section.**
  - If a STM/SA from Study Site B enters incorrect data into the CRMS pages of the Study Site A, when the RO of Study Site A extracts the institution data, it will contain incorrect information meant for Study Site B.

ECOS

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Summary

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Key Takeaways

- Basic Information page must be completed for Pharmaceutical/ Industry Sponsored studies to facilitate submission of the IRB Application Form.
- User Authorisation List (UAL) controls user access to CRMS, IRB, Compliance, Monitoring and Audit modules for Study Team Member (STM), Study Administrators (SA) and Study Sponsor (SS) roles.
- **For the migrated studies, the addition of STM/SA/SS users to 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.

- Regulatory Information, Site Information, Milestones and Participants pages contain important data fields that can be extracted for institutions' trending and reporting purposes.
- Data fields from the CTCC Bi-Annual Data Collection Excel Worksheet has also been incorporated into the CRMS. The entered information will be pulled from the system for reporting to the National Clinical Trials Insurance, national bodies for tracking of grant funding KPIs and study deliverables such as site start-up and recruitment rates.

Key Takeaways

- In conclusion, the CRMS module has great potential to be a useful clinical research management tool from site to cluster level when fully maximised.
- It is expected to improve the current work processes and productivity, enhance communication, improve project planning and execution, allowing more efficient use of time and existing resources.
- Researchers and clinicians are strongly encouraged to take full advantage of this module and update the pages frequently.