

# Navigating Ethics & Compliance Online System (ECOS) User Guide

## Clinical Research Management System (CRMS) Module

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



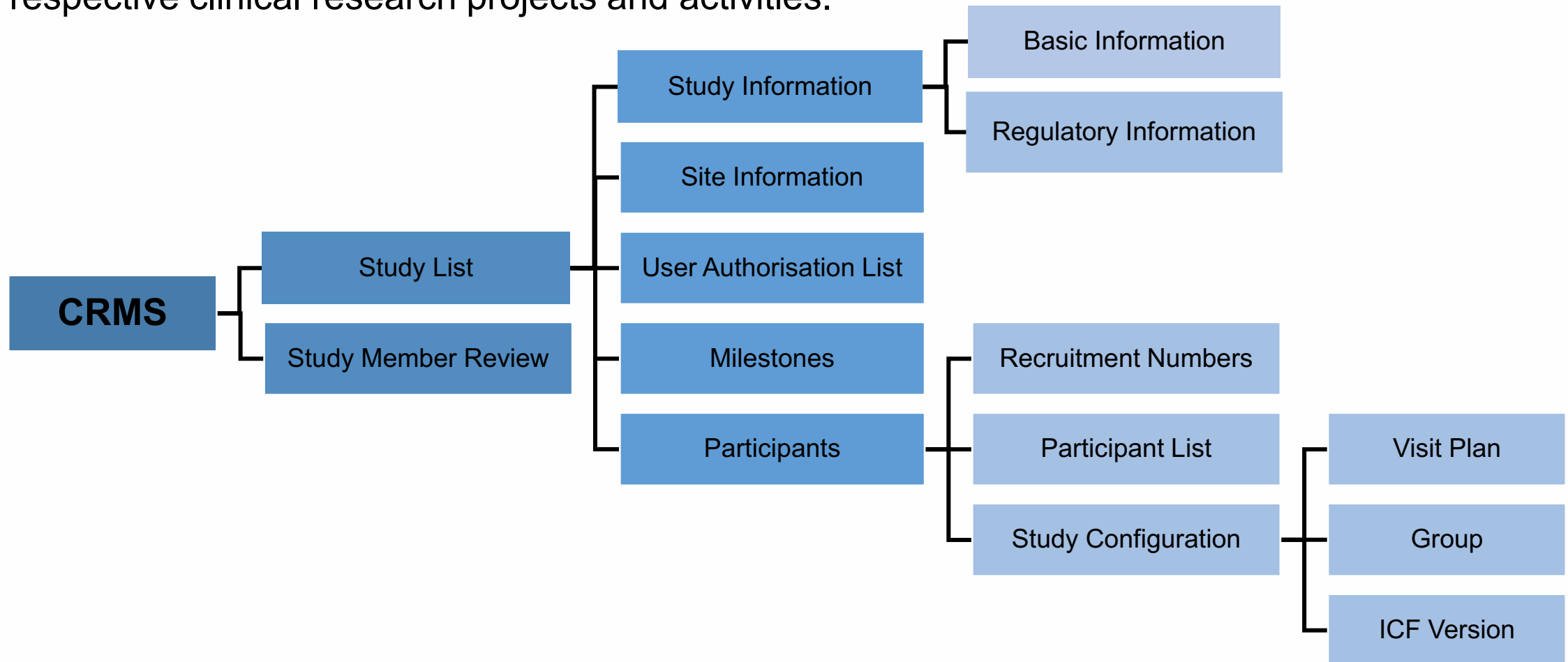
Adding years of healthy life

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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.



# 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)

## 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

## 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)

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

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

# 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

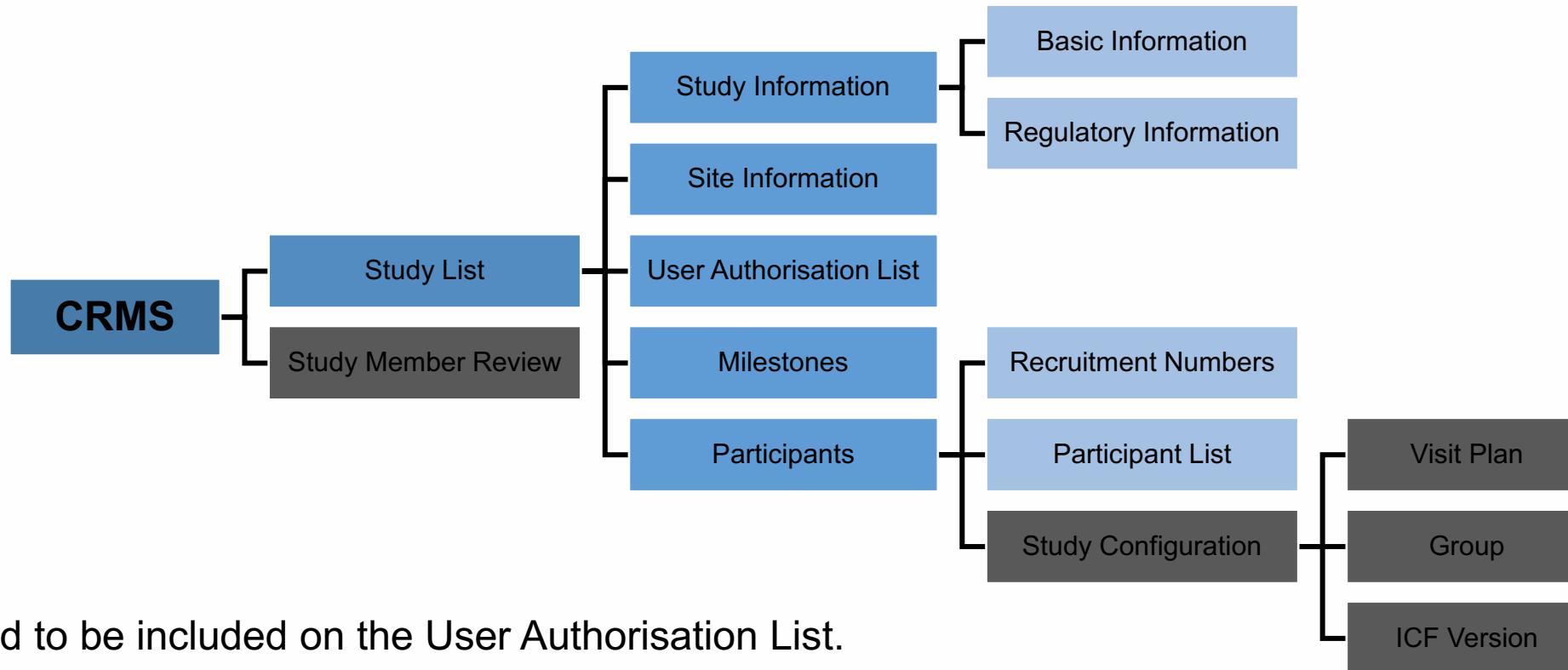
Information entered will be shared across all participating sites. E.g. data entered by 1 site will be seen by all sites. Similarly, data revision made by 1 site will also be seen by the other sites.

## 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

The screenshot displays the ECOS Dashboard interface. The top navigation bar includes the ECOS logo, the word "Dashboard", and utility icons for Help, a download icon with a "1" notification, a bell icon, and a notification icon with "99+". The left sidebar contains a navigation menu with items: Homepage, Dashboard (highlighted), My Tasks, My Notices, IRB, CRMS (highlighted), Study List (highlighted), and Study Member Review. The main content area features three summary cards: IRB (27 total, with 25 Studies and 2 Endorsements), CRMS (12 total, with 12 Study Member Reviews), and FCOI (0 total, with 0 My FCOI Lists). A "My Notices" section on the right shows a notice for all users dated 31-Jan-2024. Two callout boxes provide instructions: "Step 1: Click to release dropdown menu." points to the CRMS menu item, and "Step 2: Click to see the list of studies available." points to the Study List menu item.

# CRMS Access



*This option may be made available in Q3 2024.*

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

Navigation: < Back to Submission List | Submission Detail | Download | 99+ | Profile

Submission ID: 2024-0205-APP1 [Draft] [Refresh] | [Declare and Submit] | [More]

ECOS Ref: 2024-0205 [Copy]

Form Type: Application | Form Outcome: - | Initial Review Category: -

Current Editor: -

PI/Site PI: Dr SGH\_PI (Singapore General Hospital), Prof NUH\_PI (National University Hospital)

Study Title: Efficacy and Safety of Drug-X in the Treatment of Osteoporosis with High Fracture Risk

Quick Link: [Study Summary,CRMS](#)

**Click to enter CRMS of the study 2024-0205**

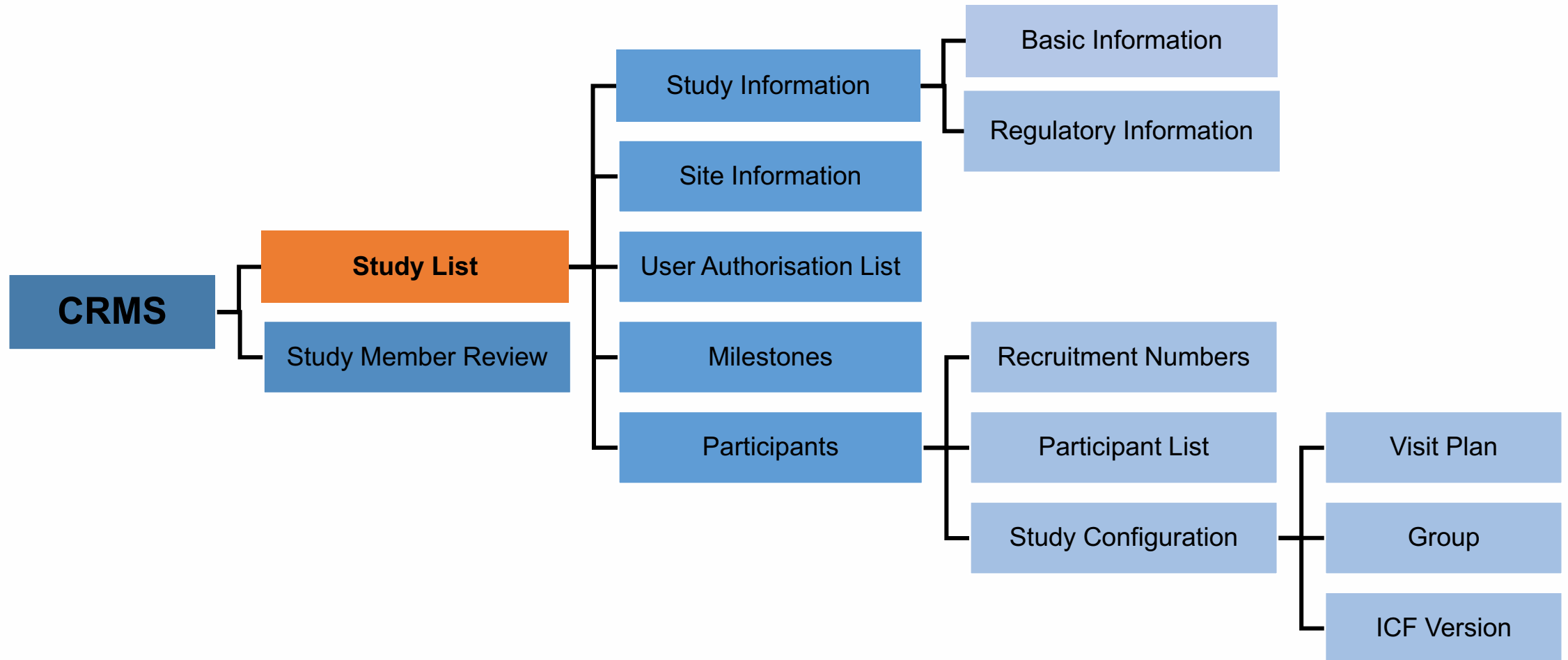
Form Detail

Application Form | [Export] | [Edit]

\*A1. Please enter the Study Title for this Study.

Section A: Study Title

# 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

The screenshot shows the ECOS Study List interface. The main table displays the following data:

ECOS Ref	IRB	PI/Site-PI	Department	Number of Sites	Study Title	Action
2024-0205	CIRB Board D	Dr SGH_PI (Singapore General Hospital), Prof NUH_PI (National University Hospital)	Department of Medicine (Singapore General Hospital), Medicine (National University Hospital)	2	Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.	

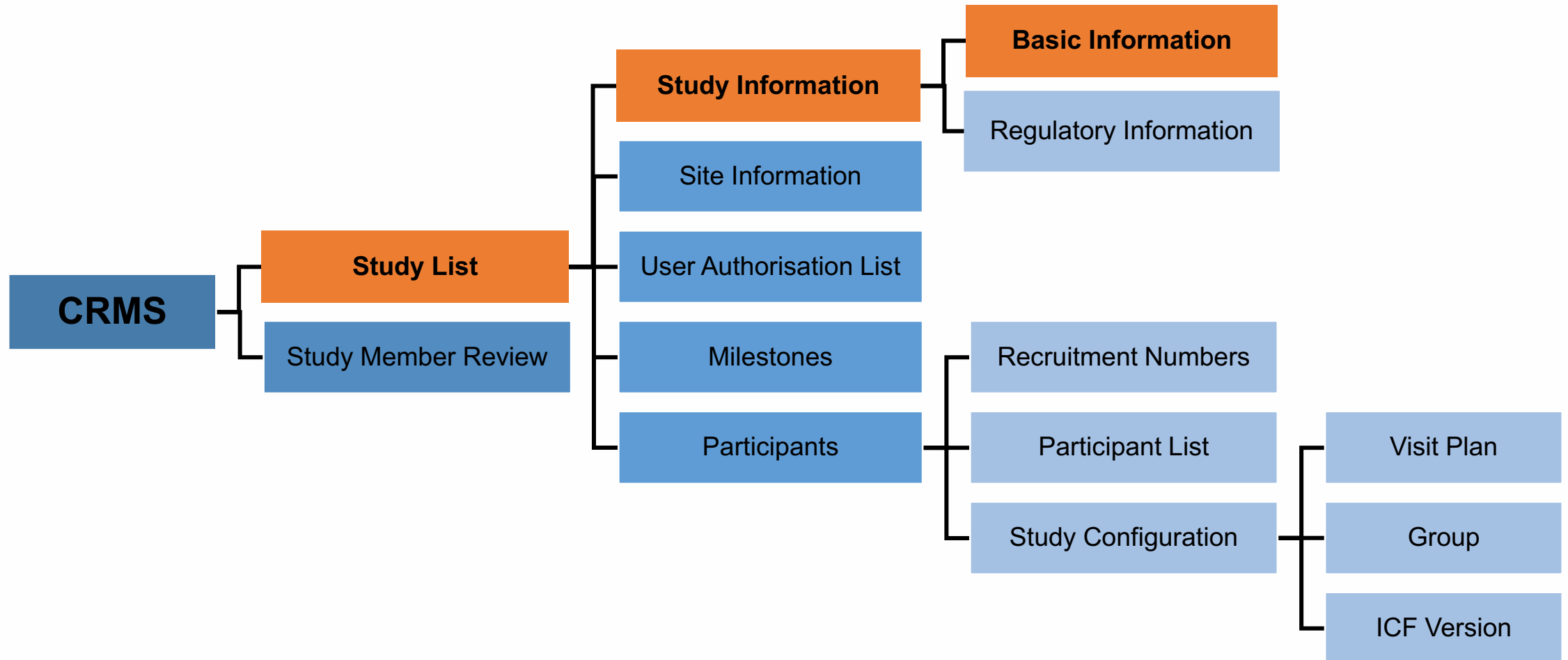
A detail popup window titled "Detail" is open, showing the following data:

Study Site	Name	Study Role	Institution	Site Status
Singapore General Hospital	SGH_PI	PI	Singapore General Hospital	
National University Hospital	NUH_PI	Site PI	National University Hospital	

Annotations in the image include:

- A callout box pointing to the "Number of Sites" column: "Click on the number to see the list of participating sites."
- A callout box pointing to the "View" icon: "Click the View icon of the specific study to enter the CRMS pages."

# 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

< Back to Study List

Study Details



2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk

ECOS Reference: 2024-0205

IRB: CIRB Board D

Study Status: • Draft

Number of Sites: 2

Initial Outcome Date: -

Valid Till Date: -

PI/Site PI: Dr SGH\_PI (Singapore General Hospital), Prof NUH\_PI (National University Hospital)

Department: Department of Medicine (Singapore General Hospital), Medicine (National University Hospital)

- Study Information
- Basic Information
- Regulatory Information
- User Authorisation List

Edit

## Sponsor Details

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
* XYZ Pharmaceuticals	* XYZ	* 98761234	* xyz@xyz.com		* Singapore 123654

## Clinical Research Organisation (CRO) Details

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
* AB-CRO	* AB	* 98762345	* ab@ab.com		* Singapore 654123

## IRB Review Fees Billing Details

Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited By
* LMN	* 95672341	* lmn@ab.com		* Singapore654123	SGH_PI



# 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.

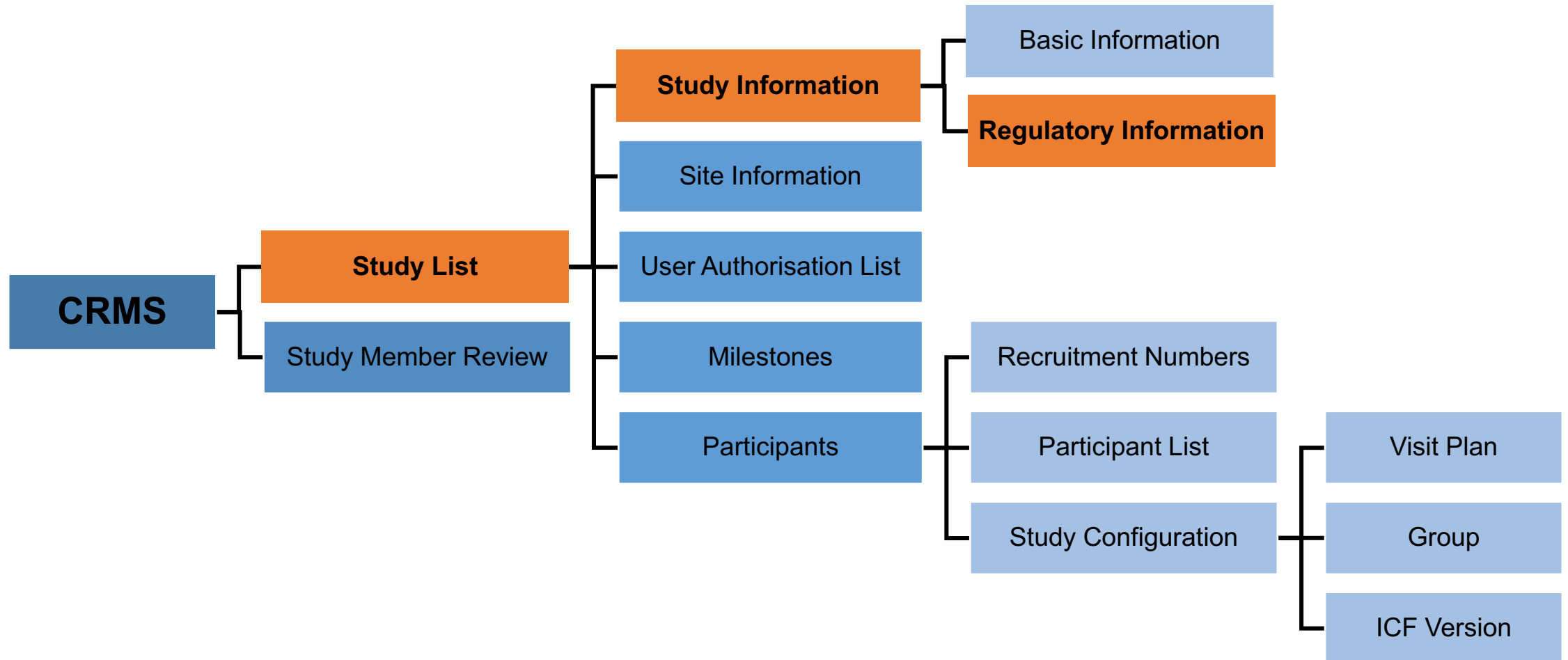
## IRB Review Fees Billing Details

- 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).

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk

ECOS Reference: 2024-0205      IRB: CIRB Board D      Study Status: Draft

Number of Sites: 2      Initial Outcome Date: -      Valid Till Date: -

PI/Site PI: Dr SGH\_PI (Singapore General Hospital), Prof NUH\_PI (National University Hospital)

Department: Department of Medicine (Singapore General Hospital), Medicine (National University Hospital)

Study Information

- Basic Information
- Regulatory Information**
- User Authorisation List

Clinical Trials Regulated by HSA

Type of Application	Submission Reference No.	Submission Date	Local Regulatory Study Reference No.	Licence/Registration No.
Clinical Trial Authorisation (CTA)	20A0000X	02-Jan-2024	HPRG/CTB 78:10/99-999	CTA00

Clinical Research Material (CRM)

Name(s) of CRM(s)	Type(s) of CRM	Type of CRM Submission	Submission No.
Drug-X	Therapeutic Product/CTGTP	CRM Notification	20A0

Restricted Human Biomedical Research

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

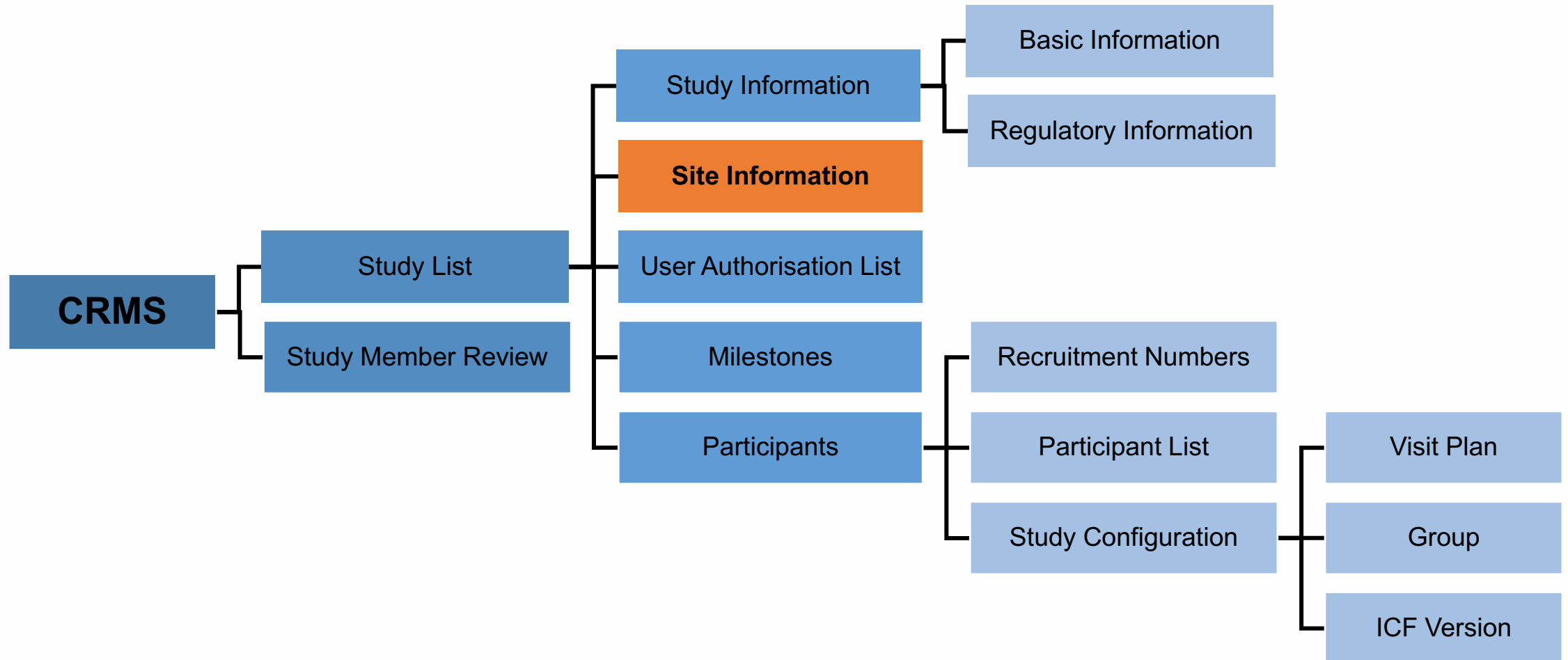
## Restricted Human Biomedical Research (rHBR)

- 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.

**Study Details**

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital (SGH)

Export Edit

**Contact Personnel**

Primary Site Coordinator	Backup Site Coordinator	Last Edited By	Last Edited Date
SGH_SA1	SGH_PI,SGH_Co-I1	SGH_PI	24-Jan-2024

**ACP involved in this study (For SingHealth Only)**

ACP Involved In This Study (For SingHealth Only)	Last Edited By	Last Edited Date
Musculoskeletal Sciences	SGH_PI	24-Jan-2024

**Funding (Including Grant)**

Name of Funding/Grant Agency	Reference Number	Title	Funding/Grant Holder
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**Study Agreement Information**

Type of Agreement	Agreement Parties	Effective Date	Validity Date	Study Agreement
* NDA	* AB-CRO and SGH	* 02-Jan-2024	Select date	

**Industry Sponsor/CRO Contract**

Sponsor Name	Total Estimated Budget of Contract	Date of Info (Protocol, Lab & Pharmacy Manual) Received to Start Drafting Budget	Date of Budget
* AB-CRO	1200000	04-Dec-2023	05-Dec-

# 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

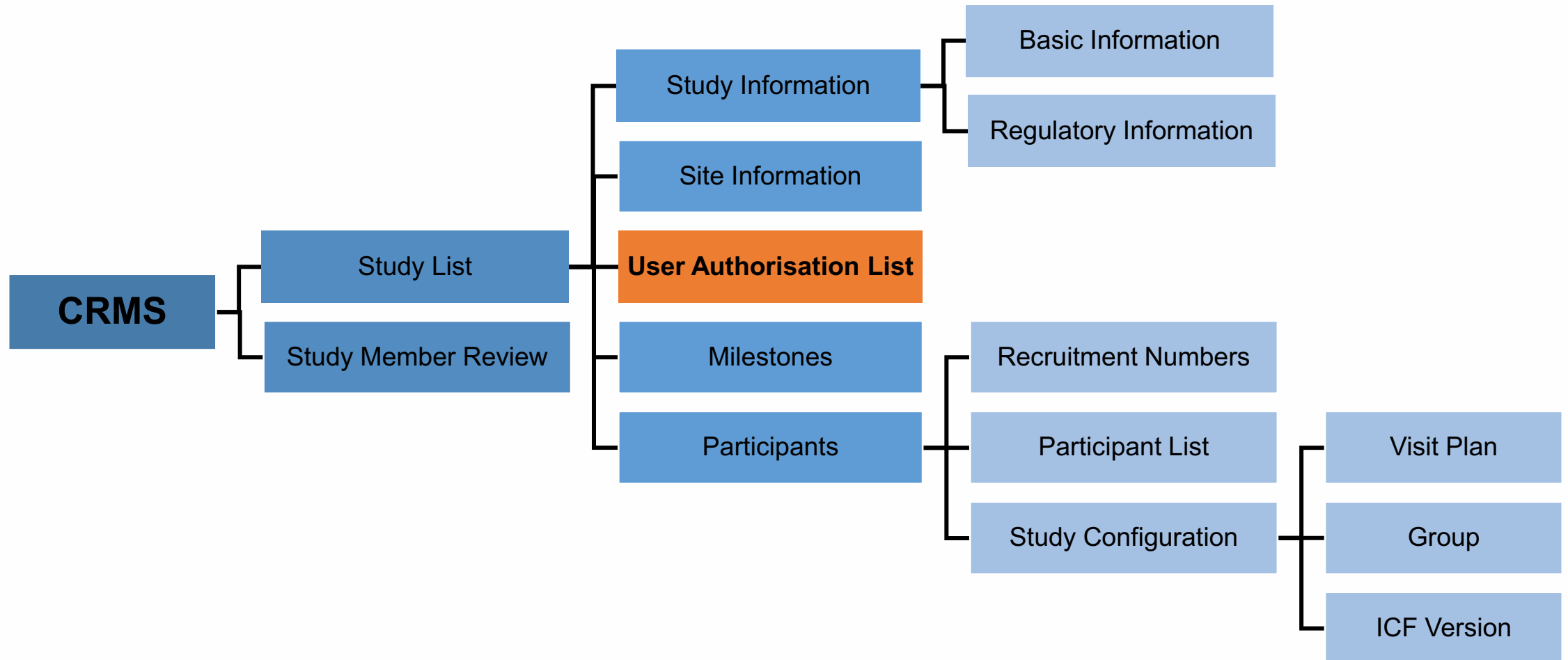
- Sponsor/CRO Name
- Total Estimated Budget of Contract
- Date of Information Received To Start Drafting Budget
- Date of Budget First Sent to Sponsor/CRO
- Date of Budget Finalisation/ Agreement
- Date of Contract Template Received From Sponsor/CRO
- Date of Contract Finalisation/ Agreement By All Parties
- 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.

2024-0205. Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk / Singapore General Hospital (SGH)

ECOS Reference: 2024-0205      IRB: CIRB Board D      Study Status: Approved

Number of Sites: 2      Initial Outcome Date: 24-Jan-2024      Valid Till Date: 23-Jan-2025

PI/Site PI: Dr SGH\_PI (Singapore General Hospital), Prof NUH\_PI (National University Hospital)

Department: Department of Medicine(Singapore General Hospital), Medicine(National University Hospital)

### 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	Action
SGH_PI	PI	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_PI@singhealth.com.sg	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_Co-I1	Co-I	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_Co-I1@singhealth.com.sg	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_SA1	Study Administrator	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Senior Executive	SGH_SA1@sgl.com.sg	CRMS	Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	Deactivate
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
<p>PI, Site PI &amp; Co-I</p> <p>Site investigators <u>directly involved</u> in the research.</p>	<ul style="list-style-type: none"> <li>• View &amp; edit rights.</li> </ul> <p><b>User added in IRB Application Form</b></p> <ul style="list-style-type: none"> <li>• Limited page access before IRB approval.                             <ul style="list-style-type: none"> <li>✓ Study Information</li> <li>✓ UAL</li> </ul> </li> <li>• Full page access after IRB approval.                             <ul style="list-style-type: none"> <li>+ Site Information</li> <li>+ Milestones</li> <li>+ Participants</li> </ul> </li> </ul> <p><b>User added in IRB Amendment Form</b></p> <ul style="list-style-type: none"> <li>• No page access before IRB approval.</li> <li>• Full page access after IRB approval.                             <ul style="list-style-type: none"> <li>✓ Study Information</li> <li>✓ UAL</li> <li>✓ Site Information</li> <li>✓ Milestones</li> <li>✓ Participants</li> </ul> </li> </ul>	<p><b>Access management:</b></p> <ul style="list-style-type: none"> <li>• PI, Site PI and Co-I are to be added in Section B2(a) 'Investigator List' of the IRB application or amendment form.</li> <li>• List of investigators will be imported from IRB to CRMS module at each synchronisation points (as applicable) with IRB indicated as the data source.</li> <li>• IRB approval is required to gain full CRMS access.</li> <li>• Further addition and deactivation will both go through the IRB module.</li> </ul> <p><b>During IRB Application drafting:</b></p> <ul style="list-style-type: none"> <li>➤ 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.</li> </ul> <p><b>In subsequent IRB Amendment Form(s):</b></p> <ul style="list-style-type: none"> <li>➤ New PI, Site-PI or Co-I will only appear on the CRMS UAL <b>after</b> IRB has provided approval for the Amendment Form.</li> <li>➤ Investigators to be removed will only be deactivated on the UAL <b>after</b> IRB's review.</li> </ul>

# User Authorisation List (UAL)

Site Level

Role	CRMS Access Rights	Comments
<p>Study Team Member (STM)</p> <p>Site personnel <b>directly involved</b> in the research conduct e.g. CRCs, Study Nurses, Pharmacists, etc.</p>	<ul style="list-style-type: none"> <li>• View &amp; edit rights.</li> <li>• Limited page access before PI's endorsement in CRMS.                             <ul style="list-style-type: none"> <li>✓ Study Information</li> <li>✓ UAL</li> </ul> </li> <li>• Full page access after PI's endorsement in CRMS.                             <ul style="list-style-type: none"> <li>+ Site Information</li> <li>+ Milestones</li> <li>+ Participants</li> </ul> </li> </ul>	<p><b>Access management:</b></p> <ul style="list-style-type: none"> <li>• STM, SA and SS are to be added via the UAL in the CRMS module, where the data source will indicate CRMS.</li> <li>• Any user on the UAL can add or deactivate a user.</li> <li>• New users added will require PI's endorsement in CRMS, endorsement is site-specific.</li> <li>• Addition of new user(s) by PI/Site-PI will automatically be endorsed upon submission.</li> <li>• User deactivation does not require endorsement from PI/Site-PI.</li> <li>• Once deactivated, access to CRMS and other related modules will be revoked, e.g. IRB.</li> <li>• Reactivation of the user is not allowed, i.e. a new entry needs to be added and endorsed to "reactivate" the user.</li> <li>• 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.</li> <li>• 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.</li> </ul>
<p>Study Administrator (SA)</p> <p>Site personnel <b>not directly involved</b> in the research but provides administrative support only, e.g. Executives, CRCs not involved in the conduct of research.</p>	<ul style="list-style-type: none"> <li>• View &amp; edit rights.</li> <li>• Limited page access only.                             <ul style="list-style-type: none"> <li>✓ Study Information</li> <li>✓ UAL</li> </ul> </li> </ul>	
<p>Study Sponsor (SS)</p> <p>Sponsor/CRO personnel, e.g. CTAs, CRAs, CTMs etc.</p>	<ul style="list-style-type: none"> <li>• View &amp; edit rights.</li> <li>• Limited page access only.                             <ul style="list-style-type: none"> <li>✓ Study Information</li> <li>✓ UAL</li> </ul> </li> </ul>	

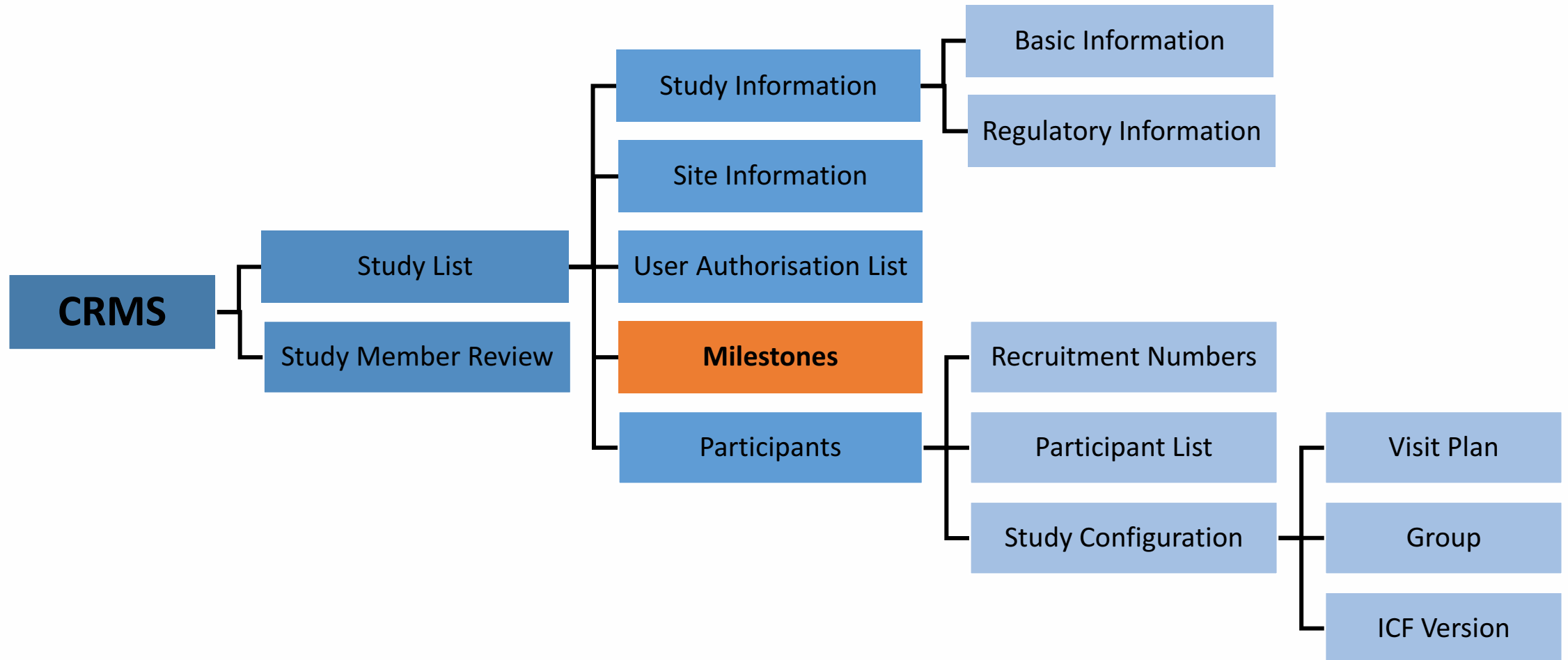
# User Authorisation List (UAL)



**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

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

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital (SGH)

ECOS Reference: 2024-0205      IRB: CIRB Board D      Study Status: ● Approved

Number of Sites: 2      Initial Outcome Date: 24-Jan-2024      Valid Till Date: 23-Jan-2025

PI/Site PI: Dr SGH\_PI (Singapore General Hospital), Prof NUH\_PI (National University Hospital)

Department: Department of Medicine (Singapore General Hospital), Medicine (National University Hospital)

Milestone	Expected Date	Actual Date	Remarks	Last Edited By	Last Edited Date	Action
IRB Approval	08-Feb-2024	24-Jan-2024	-	SGH_PI	26-Jan-2024	<a href="#">Edit</a>
Regulatory Approval	17-Jan-2024	22-Jan-2024	Slight delay due to additional round of queries from HSA.	SGH_SA1	26-Jan-2024	<a href="#">Edit</a>
Study Initiation	29-Jan-2024	25-Jan-2024	-	SGH_SA1	26-Jan-2024	<a href="#">Edit</a>
First Participant Screened	26-Jan-2024	26-Jan-2024	-	SGH_SA1	26-Jan-2024	<a href="#">Edit</a>
First Participant Enrolled	23-Feb-2024	13-Feb-2024	Eligibility criteria assessed and confirmed on 12 Feb 2024.	SGH_PI	11-Mar-2024	<a href="#">Edit</a>

Rows per page: 100    1-5 of 5

# Milestones

Site Level

Below are the data fields found on this page:

## Milestones

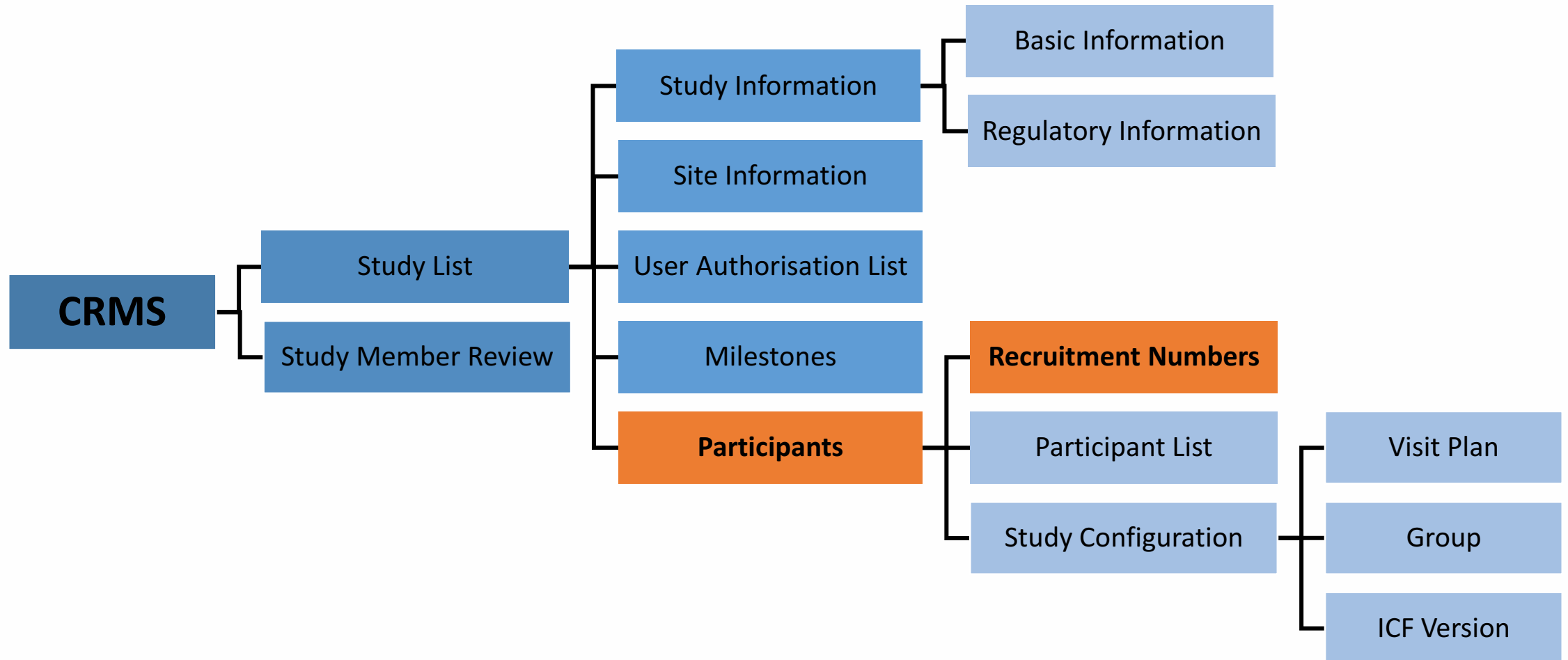
- Milestone *(Drop-down list)*
  - IRB Approval
  - Regulatory Approval
  - Grant Approval
  - Study Initiation
  - First Participant Screened
  - First Participant Enrolled
  - Last Participant Last Visit
  - Last Participant Enrolled
  - Data Analysis
  - Study Closure
  - Other *(Free text)*

- 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.

< Back to Study Details
Study Details

[Help](#)
↓
🔔
🔔<sup>99+</sup>
⊙

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital (SGH) ▼

ECOS Reference: 2024-0205      IRB: CIRB Board D      Study Status: ● Approved

Number of Sites: 2      Initial Outcome Date: 24-Jan-2024      Valid Till Date: 23-Jan-2025

PI/Site PI: Dr SGH\_PI (Singapore General Hospital), Prof NUH\_PI (National University Hospital)

Department: Department of Medicine (Singapore General Hospital), Medicine (National University Hospital)

- Study Information ▲
  - Basic Information
  - Regulatory Information
- Site Information
- User Authorisation List
- Milestones
- Participants ▲
  - Recruitment Numbers
  - Participant List
  - Study Configuration

↓ Export
✎ Edit

**Recruitment Target Approved in IRB Study: 2-2**

**Current Recruitment Summary** 🔔

<b>Total No. of Screen Failures</b>	<b>Total No. of Participants Enrolled</b>
1	2
<b>Total No. of Participants Who Have Completed Study</b>	<b>Total No. of Participants Withdrawn from Study</b>
0	0

No.	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	Last Edited By	Last Edited Date
1	* Mar/2024 <span style="float: right;">🔒</span>	* 1	* 1	* 0	* 0	SGH_PI	11-Mar-2024
2	* Feb/2024 <span style="float: right;">🔒</span>	* 0	* 1	* 0	* 0	SGH_PI	11-Mar-2024
3	* Jan/2024 <span style="float: right;">🔒</span>	* 0	* 0	* 0	* 0	SGH_SA1	26-Jan-2024

For completed, terminated and withdrawn studies, provide reason(s) for not meeting recruitment target

# 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

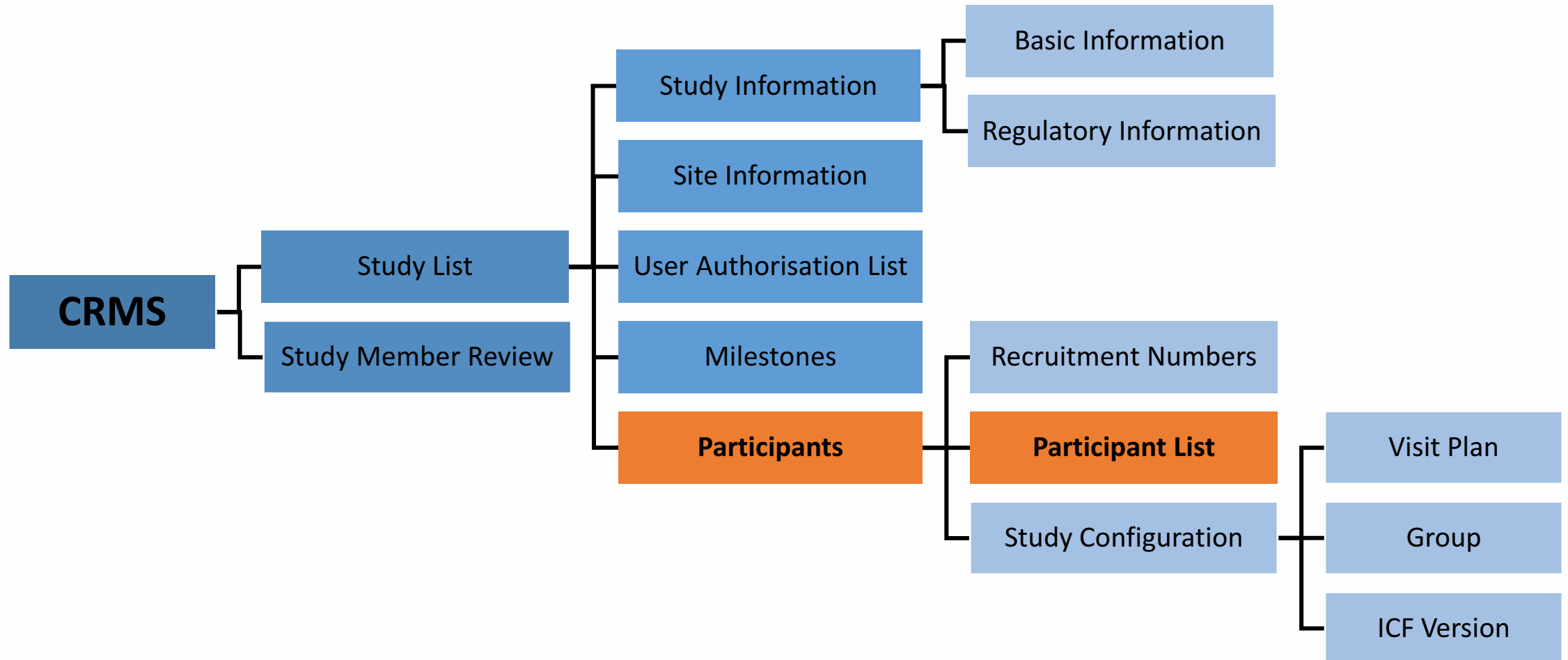
- Definitions of Screen Failure, Participants Enrolled / Completed / Withdrawn are given in the information bubble ⓘ next to **Current Recruitment Summary**.
- Monthly numbers should be entered and overall total numbers will be auto-populated by the system.

Current Recruitment Summary ⓘ	
Total No. of Screen Failures	Total No. of Participants Enrolled
<input type="text" value="1"/>	<input type="text" value="2"/>
Total No. of Participants Who Have Completed Study	Total No. of Participants Withdrawn from Study
<input type="text" value="0"/>	<input type="text" value="0"/>

- **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.

Total No. of Participants Enrolled <b>Exceeded approved recruitment number</b>
<input type="text" value="3"/>
- **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 DO NOT enter participant identifiers in CRMS.

# Participants – Participant List

Site Level

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital (SGH)

ECOS Reference: 2024-0205 IRB: CIRB Board D Study Status: Approved  
Number of Sites: 2 Initial Outcome Date: 24-Jan-2024 Valid Till Date: 23-Jan-2025  
PI/Site PI: Dr SGH\_PI (Singapore General Hospital), Prof NUH\_PI (National University Hospital)  
Department: Department of Medicine (Singapore General Hospital), Medicine (National University Hospital)

Screening Number	Enrolment Number	Enrolment Status	Group	Screening Date	Randomisation Date	Remarks	Last Edited Date	Last Edited By	Action
SGH_SCR03	-	-	-	28-Feb-2024	-	In screening.	11-Mar-2024	SGH_PI	<a href="#">Edit</a>
SGH_SCR02	-	Screen Failure	-	02-Feb-2024	-	Did not meet inclusion criteria #4 (Abnormal serum Calcium level). Date screen failed: 1 Mar 2024.	19-Feb-2024	SGH_PI	<a href="#">Edit</a>
SGH_SCR01	SGH_X01	Enrolled	Drug-X Group	26-Jan-2024	-		26-Jan-2024	SGH_PI	<a href="#">Edit</a>

# 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

[Back to Study Details](#) **Participant Details** [Help](#) 1 99+

CRMS / Study List / Study Details / Participant Details

Please do not enter participant identifiers in CRMS. [Edit](#)

Screening Number: SGH\_SCR01  
Enrolment Number: SGH\_X01

**Basic Information** ICF Visit Plan

\*Screening Number: SGH\_SCR01 \*Screening Date: 26-Jan-2024

Enrolment Number: SGH\_X01 Enrolment Date: 13-Feb-2024

Enrolment Status: Enroled Randomisation Date: Select date

Group: Drug-X Group

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

The screenshot displays the 'Participant Details' page in the CRMS system. The breadcrumb trail is 'CRMS / Study List / Study Details / Participant Details'. A warning message states: 'Please do not enter participant identifiers in CRMS.' Below this, the 'Screening Number: SGH\_SCR01' and 'Enrolment Number: SGH\_X01' are shown. An 'Edit' button is present. The main content area has three tabs: 'Basic Information', 'ICF' (selected), and 'Visit Plan'. The 'ICF' tab contains a table with the following data:

No.	Signed ICF Name	Date of Consent	Type of Consent	Translator Present
1	* Drug-X ICF	* 26-Jan-2024	* Initial	* No



# 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

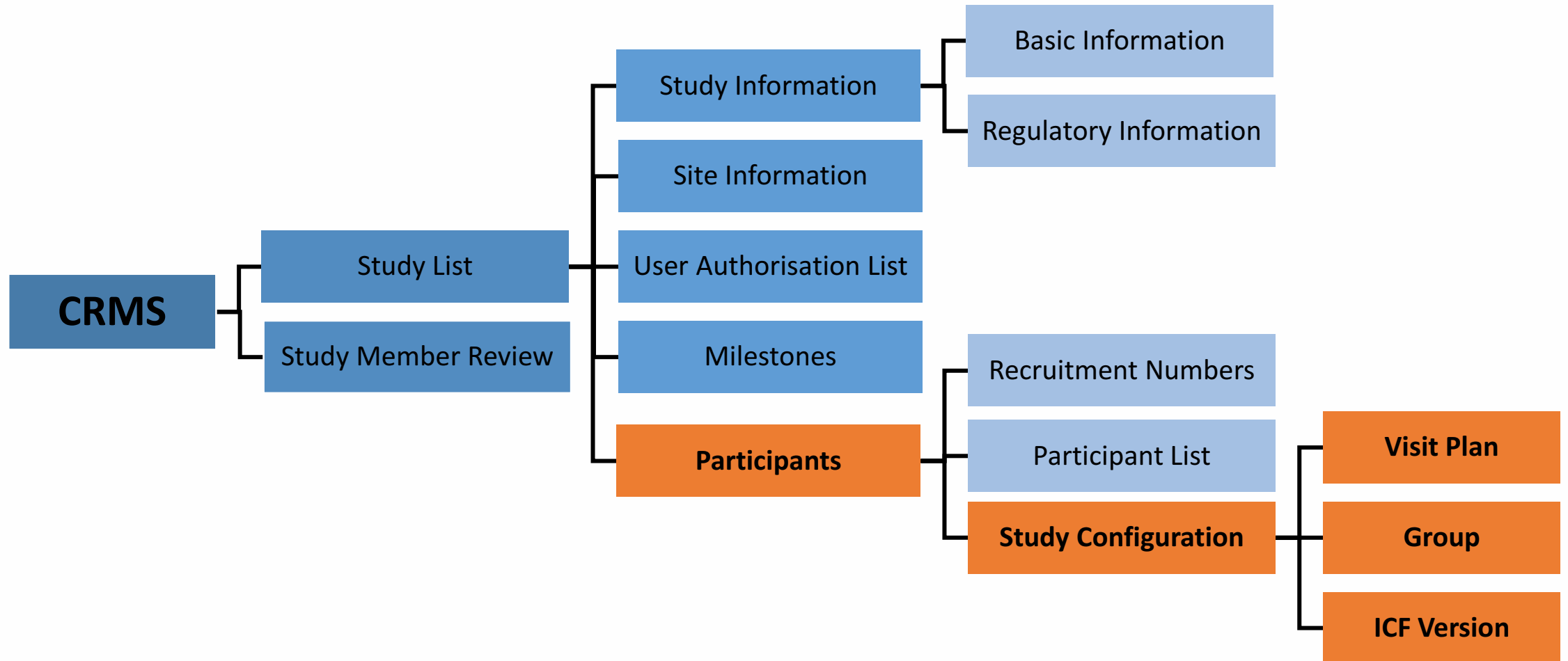
### Note:

- 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.

The screenshot shows the 'Participant Details' page in CRMS. The breadcrumb trail is 'CRMS / Study List / Study Details / Participant Details'. A warning message states: 'Please do not enter participant identifiers in CRMS.' Below this, the 'Screening Number: SGH\_SCR01' and 'Enrolment Number: SGH\_X01' are displayed. An 'Edit' button is visible. The 'Visit Plan' tab is active, showing a table with the following data:

No.	Visit Plan	Visit Name	Planned Visit Date	Actual Visit Date
1	* Drug-X	* Screeninig	26-Jan-2024	26-Jan-2024

# 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.

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital (SGH)

Study Information

- Basic Information
- Regulatory Information

Site Information

- User Authorisation List
- Milestones

Participants

- Recruitment Numbers
- Participant List

Study Configuration

Visit Plan

- Group
- ICF Version

Drug-X (Single Arm)

Last Edited By: SGH\_SA1 | Last Edited Date: 26-Jan-2024 10:03:05

Visit Name	Visit Status	Remarks
Screening	<input checked="" type="checkbox"/>	-
Day 1	<input checked="" type="checkbox"/>	First dosing day.
Week 1	<input checked="" type="checkbox"/>	-
Week 2	<input checked="" type="checkbox"/>	-
Month 1	<input checked="" type="checkbox"/>	-
Month 3	<input checked="" type="checkbox"/>	-
Month 6	<input type="checkbox"/>	-

# Participants – Study Configuration

Site Level

The screenshot shows a web application interface for study configuration. At the top, there is a dark blue header with a back arrow and the text "Back to Study Details", the title "Study Details", and icons for download, notification, and a profile. Below the header is a search bar containing the text "2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital". The main content area features a sidebar on the left with icons for Visit Plan, Group (selected), and ICF Version. The central part of the interface is a table with columns: Group, Group Status, Remarks, Last Edited By, Last Edited Date, and Action. A single row is visible with the following data: Drug-X Group, active, Single arm study., SGH\_SA1, 26-Jan-2024, and an edit icon. Above the table are buttons for "+ Add", "Columns", and "Filter". At the bottom right of the table area, it says "Rows per page: 100" and "1-1 of 1".

Group	Group Status	Remarks	Last Edited By	Last Edited Date	Action
Drug-X Group	active	Single arm study.	SGH_SA1	26-Jan-2024	

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

ICF Name, Version, Date and Language	IRB Approval Date	Regulatory Approval Date	Status	Last Edited By	Last Edited Date	Action
Drug-X ICF (SGH)_Version 1.0 dated 12 Jul 2023_English	-	-	Inactive	SGH_SA1	26-Jan-2024	<a href="#">Edit</a>
Drug-X ICF (SGH)_Version 1.1 dated 25 Dec 2023_English	24-Jan-2024	22-Jan-2024	Active	SGH_SA1	26-Jan-2024	<a href="#">Edit</a>
Drug-X ICF (SGH)_Version 1.1 dated 25 Dec 2023_Malay	24-Jan-2024	22-Jan-2024	Active	SGH_SA1	26-Jan-2024	<a href="#">Edit</a>
Drug-X ICF (SGH)_Version 1.1 dated 25 Dec 2023_Simplified Chinese	24-Jan-2024	22-Jan-2024	Active	SGH_SA1	26-Jan-2024	<a href="#">Edit</a>

### Note:

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

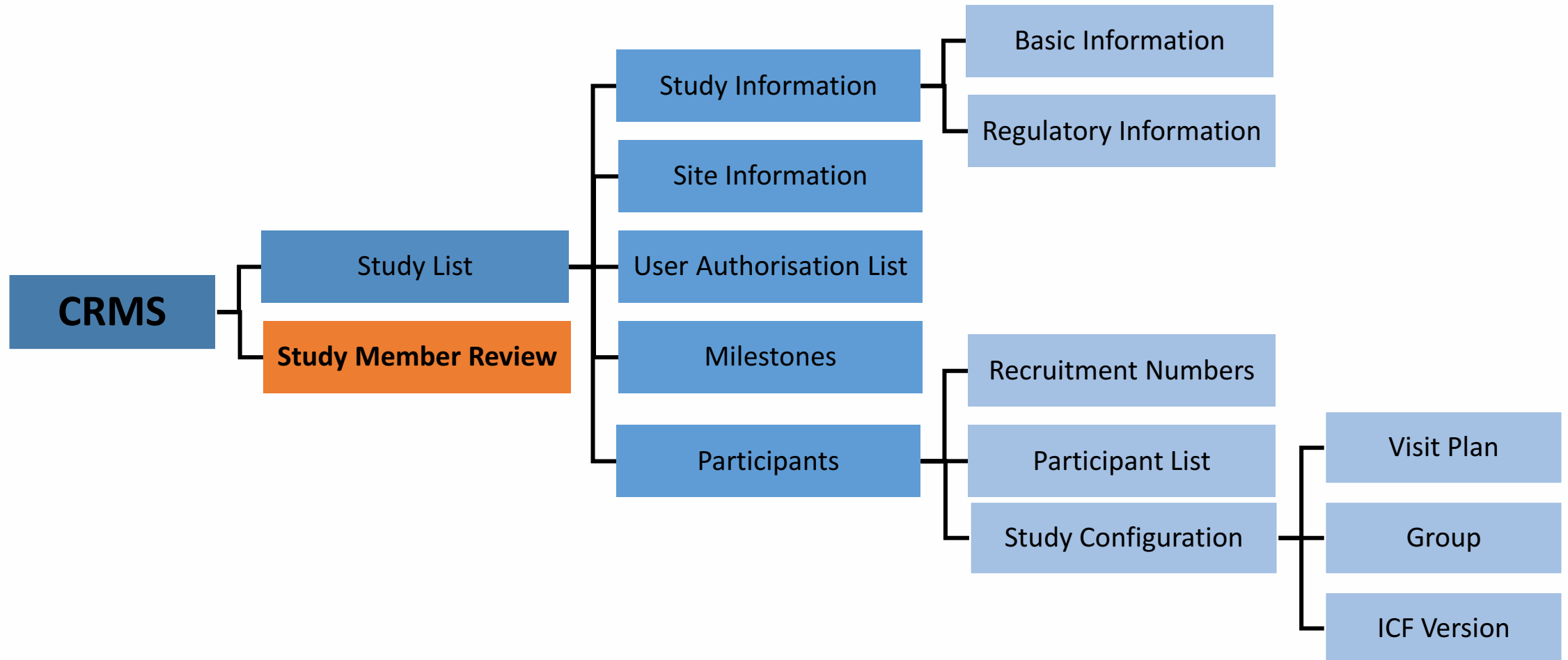
# Participants – Study Configuration

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

The screenshot shows the ECOS Dashboard interface. The top navigation bar includes the ECOS logo, the word 'Dashboard', and utility icons for Help, download, notifications, and a profile icon. A left-hand navigation menu is visible, with 'Dashboard' highlighted in a blue box. The main dashboard area contains several cards: 'IRB' with a count of 30 and sub-items 'Study' (28) and 'Endorsement' (2); 'CRMS' with a count of 11 and a link to 'Study Member Review' (11) highlighted in a blue box with an orange arrow pointing to it; 'FCOI' with a count of 0 and a sub-item 'My FCOI List' (0); and 'My Notices' with a 'View All' link and a list of notices including 'uat test-20240131' and 'UAT - Dashboard notice for all'. A callout box with an orange border and arrow points to the 'Study Member Review' link, containing the text: 'Clicking this will bring the PI/Site-PI to the My Task page.'

# Study Member Review

Site Level

ECOS My Tasks Help [Download] [Notifications] [Profile]

Homepage Dashboard My Tasks My Notices IRB CRMS FCOI Report

IRB 30 CRMS 11 FCOI 0

Study Member Review(11)

Columns Export Filter

User Name	Endorsement Status	Study Title	Submission Date	Tasks status	Action
SGH_DR	Pending Endorsement	Study 1	14-Jan-2024	Pending	
SS_20	Pending Endorsement	Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.	24-Jan-2024	Pending	
SS_19	Pending Endorsement	Study 2	31-Jan-2024	Pending	
NNI_SA1	Pending Endorsement	Study 3	19-Feb-2024	Pending	
SGH_Basic1	Pending Endorsement	Study 4	05-Mar-2024	Pending	

Click to enter the Study Member Review endorsement page.

# Study Member Review

Site Level

ECOS Study Member Review

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Ost...

Reject Endorse Columns Export Filter

<input checked="" type="checkbox"/>	Member Name	Role	Cluster	Department	Institution	Designation	Data Source	Role Status
<input checked="" type="checkbox"/>	SS_20	Study Sponsor	Non-PHI	Astra Zeneca	Astra Zeneca	CRA	CRMS	• Pending Endorsement

Step 1: Check the box.

Step 2: Click either button to **Reject** or **Endorse** the selected user.

# Study Member Review Access

Site Level

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

The screenshot shows the ECOS Dashboard interface. The top navigation bar is dark blue with the ECOS logo on the left, the word "Dashboard" in the center, and a notification bell icon with "99+" on the right. The left-hand navigation menu is light blue and contains the following items: "Homepage", "Dashboard" (highlighted), "My Tasks", "My Notices", "IRB", "CRMS" (highlighted), "Study List", "Study Member Review" (highlighted with an orange arrow), and "FCOI". The main content area features three data cards: "IRB" with a large "8" and a sub-table showing "Study" (8) and "Endorsement" (0); "CRMS" with a large "3" and a sub-table showing "Study Member Review" (3); and "FCOI" with a large "0" and a sub-table showing "My FCOI List" (0). To the right is a "My Notices" section with a "View All" link and a notice: "Dashboard notice for all" dated "07-Apr-2024". An orange callout box at the bottom points to the "Study Member Review" menu item with the text "Click to enter Study Member Review page."

Category	Count
IRB	8
Study	8
Endorsement	0
CRMS	3
Study Member Review	3
FCOI	0
My FCOI List	0

# Study Member Review Access

Site Level

The screenshot shows the ECOS interface for 'Study Member Review'. On the left is a navigation menu with items: Homepage, IRB, CRMS, Study List, Study Member Review (highlighted), FCOI, and Report. The main content area features a dropdown menu for selecting a study. The current selection is '2024-3172, Study 1'. An orange arrow points to the second option, '2024-3170, Study 2', with a callout box that reads 'Step 1: Select the study using the Study Dropdown Bar.' To the right of the dropdown, the text 'Singapore General Hospital' is displayed, with a black arrow pointing to it and a callout box that reads 'Step 2: Select the study site.' The top right of the interface includes a download icon, a notification bell with '99+', and a profile icon.

# Study Member Review

Site Level

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital (SGH)

<input type="checkbox"/>	Member Name	Role	Cluster	Department	Institution	Designation	Email Address	Data Source	Role Status
<input type="checkbox"/>	SS_20	Study Sponsor	Non-PHI	Astra Zeneca	Astra Zeneca	CRA	SS_20@az.com	CRMS	• Pending Endorsement
<input type="checkbox"/>	SGH_STM11	Study Team Member	SingHealth	Department of Medicine	Singapore General Hospital (SGH)	Executive	SGH_STM11@sgh.com.sg	CRMS	• Pending Endorsement
<input checked="" type="checkbox"/>	SGH_SA1	Study Administrator	SingHealth	Department of Medicine	Singapore General Hospital (SGH)	Senior Executive	SGH_SA1@sgh.com.sg	CRMS	• Pending Endorsement

Check the boxes to select the users

- 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.

---

# Creating IRB application by STM/SA/SS

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# 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**.

The screenshot displays the ECOS Submission List interface. The left sidebar contains navigation options: Homepage, IRB (expanded), Submission List (selected), My Study List, CRMS, FCOI, and Report. The main content area is titled 'Submission List' and features two prominent blue buttons: '+ New Application Form' and '+ New Other Forms'. An orange arrow points to the '+ New Application Form' button. Below the buttons is a table with columns: ECOS Ref, IRB, Form Ref, Form Type, Form Status, Study Title, and Action. The table contains three rows of data:

ECOS Ref	IRB	Form Ref	Form Type	Form Status	Study Title	Action
2024-3101	SingHealth CIRB-Board D	2024-3101-APP1	Application	• Draft	Study 1	🎯
2024-3090	SingHealth CIRB-Board D	2024-3090-AMD4	Amendment	• Pending Endorsement	Study 2	🎯
2024-3016	SingHealth CIRB-Board F	2024-3016-APP1	Application	• Pending IRB Review	Study 3	🎯

At the bottom right, there is a pagination control showing 'Rows per page: 100' and '1-3 of 3'.

# IRB APP Form Important Note

Role used: Study Sponsor (SS\_20)

- Kindly note Point 2.

The screenshot shows the ECOS Submission List interface. A modal window titled "IMPORTANT NOTE!" is displayed in the center. The modal contains four numbered instructions. The second instruction is highlighted with an orange box. Below the modal, a blue "Close" button is visible, with an orange arrow pointing to it and a callout box containing the text "Click to proceed." The background interface shows a sidebar with navigation options like "Homepage", "IRB", "Submission List", "My Study List", "CRMS", "FCOI", and "Report". The main content area shows a table with columns "Study Title" and "Action", listing "Study 1", "Study 2", and "Study 3". The top right corner of the interface has a notification bell icon with a "30" badge and a download icon. The bottom right corner shows "Rows per page: 100" and "1-3 of 3".

ECOS Submission List

IMPORTANT NOTE!

1. Please save before navigating to the next section or when exiting the form.
2. Please ensure that you are added into the CRMS system to have continued access to this study, if you are not an Investigator listed at Section B2 of this Form.
3. Please do not paste tabular data (tables) or images in the textbox. If required, please submit them as Attachments in the relevant sections.
4. When a document has been amended to replace an existing document:
  - a. Please ensure that both the clean and tracked copies are uploaded.
  - b. A version number and date should be reflected within documents used for the purpose of this research. Where a version number and/ or date is included in the file name, do ensure that it is the same as that stated within the document.
  - c. Please remove the obsolete copies as only the latest version is required.

Close

Click to proceed.

Export Filter(1)

Study Title	Action
Study 1	
Study 2	
Study 3	

Rows per page: 100 1-3 of 3

# 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).

Back to Submission List Submission Detail

ECOS Ref: - [icon]

Form Detail

Application Form

B2. Study Site and Study Investigator

B2. (a) Please select the study sites and investigator:

Study Site List + Add

Study Site	Location	Endorsement needed	Action
* Singapore General Hospital	* SGH	* Yes	Edit Delete

Investigator List + Add

Study Site	Name	Study Role	Designation	Department	Institutio	Action
Singapore General Hospital	Prof SGH_PI	PI	Senior Consultant	Department of Renal Medicine	Singapor Hospital	Edit Delete

Section A: Study Title

Section B: Submission B...

Section C: Study Fundin...

Section D: Study Type an...

Other Attachments

Declaration of Principal I...

Cancel Save

Click Save.

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.

The screenshot shows the 'Submission Detail' page in the CRMS system. A modal dialog titled 'Please select your site and role in CRMS' is open in the foreground. The dialog contains two required fields: '\* Site:' and '\* Role:'. The 'Role:' dropdown menu is open, showing three options: 'Study Administrator', 'Study Sponsor', and 'Study Team Member'. A blue 'Save' button is located at the bottom right of the dialog. In the background, the 'Form Detail' section of the submission is visible, including fields for 'Application Form', 'Section B: Submission Board', and 'B1. Submission IRB and Board'. The 'B1. (a) The reviewing IRB website' field contains 'SingHealth CIRB', and the 'B1. (b) Please select the board.' field contains 'Board F'. The top navigation bar includes a 'Back to Submission List' link and a 'Submission Detail' title. A notification bell icon with the number '30' is visible in the top right corner.

# 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).

The screenshot shows the 'Submission Detail' page in the CRMS system. A modal dialog is open, prompting the user to select their site and role. The dialog contains two dropdown menus: 'Site' (selected as 'Singapore General Hospital') and 'Role' (selected as 'Study Sponsor'). A blue 'Save' button is highlighted with an orange arrow. The background form shows various sections, including 'Application Form', 'Section B: Submission Board', and 'B1. Submission IRB and Board'. The 'B1. (a) The reviewing IRB with' section has 'SingHealth CIRB' selected. The 'B1. (b) Please select the board.' section has 'Board F' selected. The 'B1. (c) Please select the specialty' section has 'Palliative Medicine' selected. The background form also includes sections for 'Section A: Study Title', 'Section B: Submission B...', 'Section C: Study Fundin...', 'Section D: Study Type an...', 'Other Attachments', and 'Declaration of Principal I...'. The top navigation bar includes a 'Back to Submission List' link and a 'Submission Detail' title. The top right corner shows a download icon, a notification bell with '30', and a profile icon.

# User Added to UAL by System

Role used: Study Sponsor (SS\_20)

- SS\_20 added to the User Authorisation List.

The screenshot displays the 'Study Details' page for study 2024-3245. The 'User Authorisation List' is visible, showing two entries. The entry for 'SS\_20' is highlighted with an orange box, indicating it was added by the system. The entry for 'SGH\_PI' is also visible.

Member Name	Role	Cluster	Institution	Department	Action
SGH_PI	PI	SingHealth	Singapore General Hospital	Department of Renal Medicine	
SS_20	Study Sponsor	-	Astra Zeneca	Astra Zeneca	

# CRMS Accessiility

Role used: **Study Sponsor (SS\_20)**

- SS\_20 can now access to the study 2024-3245 in CRMS modules.

The screenshot displays the ECOS Study List interface. The left sidebar contains navigation options: Homepage, IRB, CRMS (highlighted), FCOI, and Report. The 'Study List' sub-menu under CRMS is selected. The main content area shows a table with the following data:

ECOS Ref	IRB	PI/Site-PI	Number of Sites	Study Title	Action
2024-3245	SingHealth CIRB Board F	Prof SGH_PI (Singapore General Hospital)	1	Study 4	
2024-3101	SingHealth CIRB Board D	Prof SGH_PI (Singapore General Hospital)	1	Study 1	
2024-3090	SingHealth CIRB Board D	Asst Prof NHC_Co-I1 (National Heart Centre Singapore), Dr SKH_PI (Sengkang General Hospital)	2	Study 2	
2024-3070	SingHealth CIRB Board D	A/Prof(Adj) NHC_PI 1 (National Heart Centre Singapore), Dr SKH_PI (Sengkang General Hospital)	3	Study A	

At the bottom of the table, there is a pagination control showing 'Rows per page: 100' and '1-6 of 6'.



# IRB Accessibility

Role used: **Study Sponsor (SS\_20)**

- SS\_20 can also access to the IRB APP Form in the IRB module.

**ECOS Submission List**

Navigation: + New Application Form, + New Other Forms, Columns, Export, Filter(1)

ECOS Ref	IRB	Form Ref	Form Type	Form Status	Study Title	Action
2024-3245	SingHealth CIRB-Board F	2024-3245-APP1	Application	Draft	Study 4	
2024-3101	SingHealth CIRB-Boa	2024-3101-APP1	Application	Draft	Study 1	
2024-3090	SingHealth CIRB-Boa					
2024-3016	SingHealth CIRB-Boa					

**ECOS My Study List**

Navigation: Columns, Export, Filter

ECOS Ref	IRB	Study Status	Study Title	PI/Site-PI	Action
2024-3070	SingHealth CIRB-Board D	Approved	Study A	-	
2024-3016	SingHealth CIRB-Board F	Pending IRB Review	Study 3	-	
2024-3245	SingHealth CIRB-Board F	Draft	Study 4	-	
2024-3090	SingHealth CIRB-Board D	Approved	Study 2	-	

Rows per page: 100 | 1-6 of 6

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# Mandatory Fields for Pharmaceutical/ Industry- sponsored studies

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# 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*).

The screenshot shows the 'Submission Detail' page for application 2024-0205-APP1. The 'Form Detail' section is active, and the 'Amendment Form' is displayed. The 'Mandatory Check' button is highlighted with a blue arrow. The form includes a dropdown menu, a 'Track Changes' button, a 'Mandatory Check' button, a 'Cancel' button, a 'Save' button, and a 'Save and Exit' button. The form content includes a required field for funding source information, with options (a) Department Fund or No funding, (b) Grant, and (c) Pharmaceutical/ Industry Sponsored. The 'Pharmaceutical/ Industry Sponsored' option is selected. Below this is a required field for the sponsor company name, with 'XYZ Pharmaceuticals' entered. A character count shows '19 characters entered'. At the bottom, there is a required question about incentives for research staff.

Back to Submission Detail Submission Detail Help 99+

2024-0205-APP1 Draft Submit

ECOS Ref: 2024-0205

Form Detail

Amendment Form Track Changes Mandatory Check Cancel Save Save and Exit

\*C1. Please provide information regarding the study's funding source or sponsor information.

(a) Department Fund or No funding is required for this study to be carried out

(b) Grant

(c) Pharmaceutical/ Industry Sponsored

\*C1. (c) (i) Name of Sponsor Company

XYZ Pharmaceuticals 19 characters entered

\*C1. (c) (ii) Is the sponsor offering any incentive connected with research participant recruitment or completion of research study (e.g. finder's fee, recruitment bonuses etc.) that will be paid to the research staff? ?

Section A: Study Title

Section B: Submission ...

Section C: Study Fundi...

Section D: Study Type a...

Section G: Research M...

Section H: Research D...

# Mandatory Check Prompt From IRB APP Form

ECOS

The following section(s) is/are incomplete or did not meet the logic check. Please ensure the section(s) is/are completed and ensure information is correct before finalising the submission.

Section	Field	Reason	Action
Section C: Study Funding Information	C1. Please provide information regarding the study's funding source or sponsor information.	There is no Sponsor/CRO information in CRMS. Please enter at least one Sponsor/CRO in the CRMS.	
Section C: Study Funding Information	C1. Please provide information regarding the study's funding source or sponsor information.	No billing information in CRMS.	

Confirm

- 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.

[Back to Study List](#) Study Details 📄 🔔 ⊙

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk

ECOS Reference: 2024-0205      IRB: CIRB Board D      Study Status: • Draft

Number of Sites: 2      Initial Outcome Date: -      Valid Till Date: -

PI/Site PI: Dr SGH\_PI (Singapore General Hospital), Prof NUH\_PI (National University Hospital)

Department: Department of Medicine (Singapore General Hospital), Medicine (National University Hospital)

**Required sections completed.** [Edit](#)

**Sponsor Details**

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
XYZ Pharmaceuticals	XYZ	98761234	xyz@xyz.com		Singapore 123654

**Clinical Research Organisation (CRO) Details**

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
AB-CRO	AB	98762345	ab@ab.com		Singapore 654123

**IRB Review Fees Billing Details**

Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited By
LMN	95672341	lmn@ab.com		Singapore654123	SGH_PI

# 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.

The screenshot displays the 'Submission Detail' page for application 2024-0205-APP1. At the top, a navigation bar includes a back arrow, the text 'Back to Study Summary', the title 'Submission Detail', and utility icons for Help, download, notifications (99+), and a profile icon. Below the navigation bar, a breadcrumb trail reads 'IRB / My Study List / Study Summary / Submission Detail'. A green notification box with a checkmark icon and the text 'Mandatory check completed.' is highlighted with an orange border. The main content area shows application details: '2024-0205-APP1' with a 'Draft' status and a refresh icon; 'ECOS Ref: 2024-0205' with a document icon; 'Form Type: Application', 'Form Outcome: -', and 'Initial Review Category: -'; 'Current Editor: SGH\_PI'; 'PI/Site PI: Dr SGH\_PI (Singapore General Hospital), Prof NUH\_PI (National University Hospital)'; 'Study Title: Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.'; and 'Quick Link: Study Summary,CRMS'. A 'Submit' button is visible in the top right. Below the details, a 'Form Detail' section is active, showing the 'Application Form' with a 'Track Changes' button, a highlighted 'Mandatory Check' button (indicated by a blue arrow), a 'Cancel' button, a 'Save' button, and a 'Save and Exit' button. The form content includes a required field '\*A1. Please enter the Study Title for this Study.' with the text 'Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.' and a character count of '87 characters entered'. A sidebar on the right lists sections: 'Section A: Study Title', 'Section B: Submission ...', and 'Section C: Study Fundi...'. A blue arrow points to the 'Mandatory Check' button.

# 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

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of

Study Details

Help Download Notifications 99+

⚠ There must be at least one entry in IRB Review Fees Billing Details because 'Pharmaceutical/Industry Sponsored' was selected in Section C1 of the IRB Application Form.

Save Cancel

### Sponsor Details

Add

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited	Action
* XYZ Pharmaceuticals	* XYZ	* 98761234	* xyz@xyz.com	New Data	* Singapore 123654	S	Edit Delete

### Clinical Research Organisation (CRO) Details

Add

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited	Action
* Add New Data	* Add New Data	* Add New Data	* Add@New.Data	Add New Data	* Add New Data	S	Edit Delete
* Add New Data	* Add New Data	* Add New Data	* Add@New.Data	Add New Data	* Add New Data	S	Edit Delete
* AB-CRO	* AB	* 98762345	* ab@ab.com		* Singapore 654123	S	Edit Delete

### IRB Review Fees Billing Details

Add

Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited	Action
* LMN	* 95672341	* lmn@ab.com		* Singapore 654123	SGH_PI	Edit Delete

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.

The screenshot displays a web application interface for 'Study Details'. At the top, there is a navigation bar with a back button, the title 'Study Details', and utility icons for help, download, notifications, and a user profile. Below the navigation bar, a search bar contains the text '2024-0205, Efficacy and Safety of DRUG-X in the Treatment of...'. A prominent warning message is shown in a yellow box with a red border: 'There must be at least one entry in Sponsor Details or in Clinical Research Organisation (CRO) Details because 'Pharmaceutical/Industry Sponsored' was selected in Section C1 of the IRB Application Form.' The main content area is divided into three sections: 'Sponsor Details', 'Clinical Research Organisation (CRO) Details', and 'IRB Review Fees Billing Details'. Each section has an 'Add' button. The 'Sponsor Details' section contains a table with one entry for 'XYZ Pharmaceuticals'. The 'CRO Details' section is currently empty. The 'IRB Review Fees Billing Details' section contains one entry for 'LMN'. A callout box with an orange border points to the 'Delete' button in the 'Sponsor Details' table, containing the text: 'Deleting the only entry under Sponsor Details will trigger the above prompt.' A larger white callout box with a black border at the bottom of the 'CRO Details' section states: 'Data under CRO Details can be complete deleted.'

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of

Study Details

Help Download Notifications 99+

⚠️ There must be at least one entry in Sponsor Details or in Clinical Research Organisation (CRO) Details because 'Pharmaceutical/Industry Sponsored' was selected in Section C1 of the IRB Application Form.

Save Cancel

Sponsor Details Add

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited	Action
* XYZ Pharmaceuticals	* XYZ	* 98761234	* xyz@xyz.com	New Data	* Singapore 123654	SG	Edit Delete

Clinical Research Organisation (CRO) Details Add

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

Data under CRO Details can be complete deleted.

IRB Review Fees Billing Details Add

Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited	Action
* LMN	* 95672341	* lmn@ab.com		* Singapore 654123	SGH_PI	Edit Delete

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# CRMS General Page Functions

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# 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.

← Back to Study List Study Details 📄 🔔 ⦿

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. ▼

ECOS Reference: 2024-0205 IRB: CIRB Board D Study Status: • Draft

Number of Sites: 2 Initial Outcome Date: - Valid Till Date: -

PI/Site PI: Dr SGH\_PI (Singapore General Hospital), Prof NUH\_PI (National University Hospital)

Department: Department of Medicine (Singapore General Hospital), Medicine (National University Hospital)

Study Information ▲

Basic Information

Regulatory Information

User Authorisation List

[Edit](#)

### Sponsor Details

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
<input type="text" value="XYZ Pharmaceuticals"/>	<input type="text" value="XYZ"/>	<input type="text" value="98761234"/>	<input type="text" value="xyz@xyz.com"/>	<input type="text"/>	<input type="text" value="Singapore 123654"/>

### Clinical Research Organisation (CRO) Details

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
<input type="text" value="AB-CRO"/>	<input type="text" value="AB"/>	<input type="text" value="98762345"/>	<input type="text" value="ab@ab.com"/>	<input type="text"/>	<input type="text" value="Singapore 654123"/>

# Page Functions – Toggle between different studies

< Back to Study List

Study Details



2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.

ECOS Reference: 2024-0205

IRB: CIRB Board D

Study Status: • Draft

Number of Sites: 2

Initial Outcome Date: -

Valid Till Date: -

PI/Site PI: Dr SGH\_PI (Singapore General Hospital), Prof NUH\_PI (National University Hospital)

Department: Department of Medicine (Singapore General Hospital), Medicine (National University Hospital)

Step 1: Click on the Dropdown icon.

Study Information

Basic Information

Regulatory Information

User Authorisation List

Edit

## Sponsor Details

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
* XYZ Pharmaceuticals	* XYZ	* 98761234	* xyz@xyz.com		* Singapore 123654

## Clinical Research Organisation (CRO) Details

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
* AB-CRO	* AB	* 98762345	* ab@ab.com		* Singapore 654123

## IRB Review Fees Billing Details

Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited By
* LMN	* 95672341	* lmn@ab.com		* Singapore654123	SGH_PI

# Page Functions – Toggle between different studies

← Back to Study List Study Details Help Download Notifications 99+

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk

2024-0291, Test 1

2024-0264, Test 2

2024-0257, Test 3

2024-0214, Test 4

2024-0212, Test 5

2024-0209, Test 6

**2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.**

2024-0199, Test 7

Step 2: Select a study to enter the CRMS pages.

**Sponsor Details**

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
XYZ Pharmaceuticals	XYZ	98761234	xyz@xyz.com		Singapore 123654

**Clinical Research Organisation (CRO) Details**

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
AB-CRO	AB	98762345	ab@ab.com		Singapore 654123

**IRB Review Fees Billing Details**

Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited
LMN	95672341	lmn@ab.com		Singapore 654123	SGH_PI

Regulatory Information

Site Information

User Authorisation List

Milestones

Participants

# Page Functions – Toggle between different studies

Alternatively, user can choose to click on **Back to Study List** to select a study from the Study List page.

**Study Details**

[Back to Study List](#)

2024-0205, Efficacy and Sa  
2024-0291, Test 1  
2024-0264, Test 2  
2024-0257, Test 3  
2024-0214, Test 4  
2024-0212, Test 5  
2024-0209, Test 6  
**2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.**  
2024-0199, Test 7

Regulatory Information  
Site Information  
User Authorisation List  
Milestones  
Participants

**Sponsor Details**

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
<input type="text" value="XYZ Pharmaceuticals"/>	<input type="text" value="XYZ"/>	<input type="text" value="98761234"/>	<input type="text" value="xyz@xyz.com"/>	<input type="text"/>	<input type="text" value="Singapore 123654"/>

**Clinical Research Organisation (CRO) Details**

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
<input type="text" value="AB-CRO"/>	<input type="text" value="AB"/>	<input type="text" value="98762345"/>	<input type="text" value="ab@ab.com"/>	<input type="text"/>	<input type="text" value="Singapore 654123"/>

**IRB Review Fees Billing Details**

Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited
<input type="text" value="LMN"/>	<input type="text" value="95672341"/>	<input type="text" value="lmn@ab.com"/>	<input type="text"/>	<input type="text" value="Singapore 654123"/>	SGH_PI



# Page Functions – Toggle between different studies

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

The screenshot shows a web application interface for study details. The top navigation bar includes a 'Back to Study List' link, the title 'Study Details', and utility icons for Help, download, notifications, and a profile menu. Below the navigation bar is a search bar containing the text '2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk / Singapore General Hospital (SGH)'. A list of studies is displayed below the search bar, with the selected study highlighted. A callout box labeled 'Step 1: Select the study of interest.' points to the selected study. Another callout box labeled 'Step 2: Select the study site.' points to the 'Singapore General Hospital (SGH)' site name. Below the study list is a 'User Authorisation List' table with columns for Member Name, Role, Institution, Data Source, Role Status, Endorsement Date, Endorsed By, Deactivation Date, Deactivated By, Last Edited By, Last Edited Date, and Action. The table contains five rows of user authorizations, with the first and fourth rows having a 'Deactivate' button in the Action column.

**Step 1: Select the study of interest.**

**Step 2: Select the study site.**

Member Name	Role	Institution	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date	Action
SGH_SA22	Study Administrator	Singapore General Hospital (SGH)	CRMS	Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	Deactivate
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_Co-11	Col	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_STM22	Study Team Member	Singapore General Hospital (SGH)	CRMS	Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	Deactivate
SS_20	Study Sponsor	Astra Zeneca	CRMS	Pending Endorsement	-	-	-	-	SGH_Co-11	24-Jan-2024	

# 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.

**Study Details**

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk

ECOS Reference: 2024-0205      IRB: CIRB Board D      Study Status: \* Draft

Number of Sites: 2      Initial Outcome Date: -      Valid Till Date: -

PI/Site PI: Dr SGH\_PI (Singapore General Hospital), Prof NUH\_PI (National University Hospital)

Department: Department of Medicine (Singapore General Hospital), Medicine (National University Hospital)

**Study Information** (Collapsible Panel)

- Basic Information
- Regulatory Information
- User Authorisation List

**Sponsor Details**

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
XYZ Pharmaceuticals	XYZ	98761234	xyz@xyz.com		Singapore 123654

**Clinical Research Organisation (CRO) Details**

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
AB-CRO	AB	98762345	ab@ab.com		Singapore 654123

# Page Functions – Expand

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

The screenshot displays a web application interface for "Study Details". At the top, there is a navigation bar with a "Back to Study List" link, the title "Study Details", and utility icons for Help, download, notifications (99+), and a profile icon. Below the navigation bar, the study title "2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk" is shown in a dropdown menu. The main content area features three expandable sections: "Sponsor Details", "Clinical Research Organisation (CRO) Details", and "IRB Review Fees Billing Details". Each section contains a table of fields with input boxes and asterisks indicating required fields. An "Edit" button is located in the top right corner of the main content area. On the left side, there is a sidebar with icons for home, search, lock, refresh, and user profile. At the bottom left, there is an "Expand" button with a panel icon and a red arrow pointing to it. A blue arrow points to a small down arrow icon above the "Sponsor Details" section.

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk

**Sponsor Details**

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
* XYZ Pharmaceuticals	* XYZ	* 98761234	* xyz@xyz.com		* Singapore 123654

**Clinical Research Organisation (CRO) Details**

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
* AB-CRO	* AB	* 98762345	* ab@ab.com		* Singapore 654123

**IRB Review Fees Billing Details**

Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Ec
* LMN	* 95672341	* lmn@ab.com		* Singapore 654123	SGH_

Expand

# Page Functions – Edit Data

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

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk

[Edit](#)

### Sponsor Details

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
XYZ Pharmaceuticals	XYZ	98761234	xyz@xyz.com		Singapore 123654

### Clinical Research Organisation (CRO) Details

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
AB-CRO	AB	98762345	ab@ab.com		Singapore 654123

### IRB Review Fees Billing Details

Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Ec
LMN	95672341	lmn@ab.com		Singapore 654123	SGH_

# 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.

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.

Save Cancel

Sponsor Details Add

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last	Action
* XYZ Pharmaceuticals	* XYZ	* 98761234	* xyz@xyz.com		* Singapore 123654	SG	Edit Delete

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

Sponsor Details Add

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last	Action
* XYZ Pharmaceuticals	* XYZ	* 98761234	* xyz@xyz.com	New Data	* Singapore 123654	S	Cancel

# Page Functions – Add Data

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

The screenshot shows the 'Study Details' page for study 2024-0205. The 'Clinical Research Organisation (CRO) Details' table has one row with the following data:

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last	Action
AB-CRO	AB	98762345	ab@ab.com		Singapore 654123	SG	Edit Delete

An 'Add' button is highlighted with a red arrow, indicating the next step in the process.

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

The screenshot shows the 'Clinical Research Organisation (CRO) Details' table after clicking the 'Add' button. Two new blank rows have been added, each containing the text 'Add New Data' in the input fields. The 'Action' column for these rows shows 'Cancel'.

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last	Action
AB-CRO	AB	98762345	ab@ab.com		Singapore 654123	S	Edit Delete
Add New Data	Add New Data	Add New Data	Add@New Data	Add New Data	Add New Data		Cancel
Add New Data	Add New Data	Add New Data	Add@New Data	Add New Data	Add New Data		Cancel

# 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**.

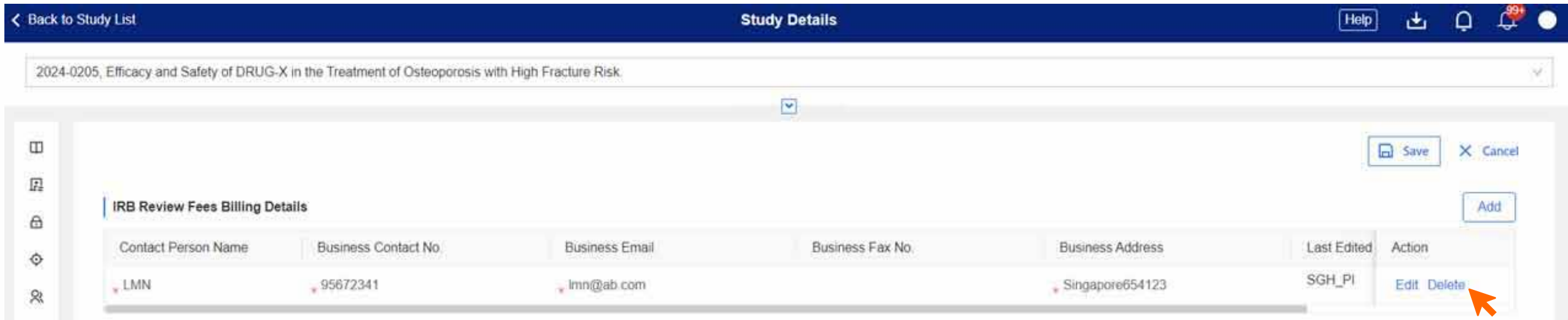
The screenshot shows a web application interface for 'Study Details'. The main content area is titled 'Clinical Research Organisation (CRO) Details' and contains a table with the following columns: Name of CRO, Contact Person Name, Business Contact No, Business Email, Business Fax No, Business Address, and Action. The table has two rows of data. The 'Business Email' field in the first row is highlighted with a red border. Below the table, there is a red-bordered box containing the text: 'This is a mandatory field. Please fill in response.' The interface also includes a navigation bar at the top with 'Back to Study List', 'Study Details', 'Help', and a notification icon. The top right corner has 'Save' and 'Cancel' buttons. The bottom right corner has 'Add', 'Edit', and 'Delete' buttons.

Name of CRO	Contact Person Name	Business Contact No	Business Email	Business Fax No	Business Address	Action
AB-CRO	AB	98762345	ab@ab.com		Singapore 654123	Edit Delete
Add New Data	Add New Data	Add New Data	Add New Data	Add New Data	Add New Data	Cancel
Add New Data		Add New Data	Add New Data	Add New Data	Add New Data	Cancel

This is a mandatory field. Please fill in response.

# Page Functions – Delete Data

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

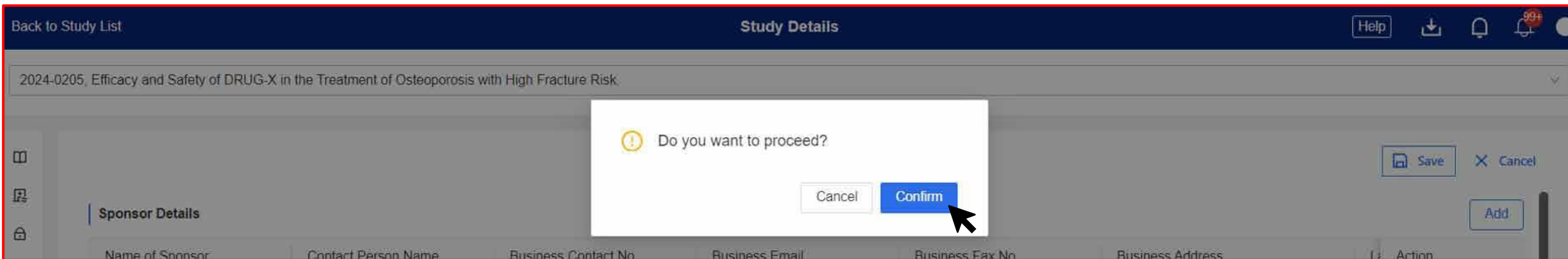


The screenshot shows the 'Study Details' page for study 2024-0205. The 'IRB Review Fees Billing Details' section contains a table with the following data:

Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited	Action
LMN	95672341	lmn@ab.com		Singapore654123	SGH_PI	Edit Delete

An orange arrow points to the 'Delete' button in the 'Action' column of the table row.

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



The screenshot shows the 'Study Details' page with a confirmation dialog box overlaid. The dialog box contains the text 'Do you want to proceed?' and two buttons: 'Cancel' and 'Confirm'. A black arrow points to the 'Confirm' button.



# Page Functions – Save Data

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

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.

Study Details

Help [Download] [Notifications] [99+] [Profile]

Save Cancel

### Sponsor Details

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited	Action
* XYZ Pharmaceuticals	* XYZ	* 98761234	* xyz@xyz.com	New Data	* Singapore 123654		Cancel

### Clinical Research Organisation (CRO) Details

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited	Action
* AB-CRO	* AB	* 98762345	* ab@ab.com		* Singapore 654123		Edit Delete
* Add New Data	* Add New Data	* Add New Data	* Add@New.Data	Add New Data	* Add New Data		Cancel
* Add New Data	* Add New Data	* Add New Data	* Add@New.Data	Add New Data	* Add New Data		Cancel

### IRB Review Fees Billing Details

Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited
Data Deleted					

**Data Edited**

**Data Added**

# Page Functions – Save Data

- Page view after Save.

[← Back to Study List](#) Study Details [Help](#) 99+

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk

[Edit](#)

### Sponsor Details

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
* XYZ Pharmaceuticals	* XYZ	* 98761234	* xyz@xyz.com	New Data	* Singapore 123654

### Clinical Research Organisation (CRO) Details

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
* Add New Data	* Add New Data	* Add New Data	* Add@New.Data	Add New Data	* Add New Data
* Add New Data	* Add New Data	* Add New Data	* Add@New.Data	Add New Data	* Add New Data
* AB-CRO	* AB	* 98762345	* ab@ab.com		* Singapore 654123

### IRB Review Fees Billing Details

Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Ec

# 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.

The screenshot displays the 'Study Details' page for the study '2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk'. The interface is divided into three main sections: 'Sponsor Details', 'Clinical Research Organisation (CRO) Details', and 'IRB Review Fees Billing Details'. Each section contains a table of data with columns for 'Name of [Sponsor/CRO]', 'Contact Person Name', 'Business Contact No.', 'Business Email', 'Business Fax No.', and 'Business Address'. The 'Sponsor Details' section shows data for 'XYZ Pharmaceuticals'. The 'Clinical Research Organisation (CRO) Details' section shows multiple entries, including 'AB-CRO'. The 'IRB Review Fees Billing Details' section shows a table with columns for 'Contact Person Name', 'Business Contact No.', 'Business Email', 'Business Fax No.', and 'Business Address'. A red box highlights a zoomed-in view of the 'Business Fax No.' and 'Business Address' fields, along with 'Last Edited By' and 'Last Edited Date' columns. An orange arrow points from the scroll bar in the 'Sponsor Details' section to the zoomed-in view.

Business Fax No.	Business Address	Last Edited By	Last Edited Date
New Data	* Singapore 123654	SGH_PI	14-Mar-2024
Add New Data	* Add New Data	SGH_PI	14-Mar-2024
Add New Data	* Add New Data	SGH_PI	14-Mar-2024
	* Singapore 654123	SGH_PI	23-Jan-2024

# 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 screenshot shows the 'Study Details' page for '2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk'. The 'Sponsor Details' section contains a table with the following data:

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Li	Action
XYZ Pharmaceuticals	XYZ	98761234	xyz@xyz.com	Data Deleted	Singapore 123654	S	Cancel

The 'Data Deleted' text in the Business Fax No. column and the 'Cancel' button in the Action column are highlighted with orange boxes. A red arrow points to the 'Cancel' button. The interface includes a 'Save' button and a 'Cancel' button at the top right of the table area.

- The deleted action reversed, original data reverted.

The screenshot shows the 'Study Details' page after the 'Data Deleted' action is reversed. The 'Sponsor Details' section contains a table with the following data:

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Li	Action
XYZ Pharmaceuticals	XYZ	98761234	xyz@xyz.com	New Data	Singapore 123654	S	Edit Delete

The 'New Data' text in the Business Fax No. column is highlighted with an orange box. The 'Data Reverted' text is written below the table. The interface includes an 'Add' button at the top right of the table area.

# Page Functions – Cancel

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

The screenshot shows the 'Study Details' page for study '2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk'. The 'Clinical Research Organisation (CRO) Details' table is displayed with the following data:

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Li	Action
Add New Data	Add New Data	Add New Data	Add@New Data	Add New Data	Add New Data	S	Edit Delete
Add New Data	Add New Data	Add New Data	Add@New Data	Add New Data	Add New Data	S	Edit Delete
AB-CRO	AB	98762345	ab@ab.com		Singapore 654123	S	Edit Delete

The 'Cancel' button is highlighted with a red arrow, indicating the next step to reverse the deletion.

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

The screenshot shows the 'Study Details' page after the deletion of two rows. The 'Clinical Research Organisation (CRO) Details' table now contains only one row:

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Las	Action
AB-CRO	AB	98762345	ab@ab.com		Singapore 654123	SG	Edit Delete

The 'Cancel' button is highlighted with a red arrow, indicating the next step to reverse the deletion.

# Page Functions – Cancel

- Deletion of 2 rows canceled.

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.

Study Details

Help

99+

Edit

### Sponsor Details

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
* XYZ Pharmaceuticals	* XYZ	* 98761234	* xyz@xyz.com	New Data	* Singapore 123654

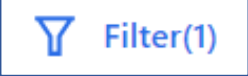
### Clinical Research Organisation (CRO) Details

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
* Add New Data	* Add New Data	* Add New Data	* Add@New.Data	Add New Data	* Add New Data
* Add New Data	* Add New Data	* Add New Data	* Add@New.Data	Add New Data	* Add New Data
* AB-CRO	* AB	* 98762345	* ab@ab.com		* Singapore 654123

### IRB Review Fees Billing Details

Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Ec
* LMN	* 95672341	* lmn@ab.com		* Singapore 654123	SGH_L

# 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**.
-  indicates that there is one (1) filter applied.

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk / Singapore General Hospital (SGH)

ECOS Reference: 2024-0205      IRB: CIRB Board D      Study Status: Approved

Number of Sites: 2      Initial Outcome Date: 24-Jan-2024      Valid Till Date: 23-Jan-2025

PI/Site PI: Dr SGH\_PI (Singapore General Hospital), Prof NUH\_PI (National University Hospital)

Department: Department of Medicine(Singapore General Hospital), Medicine(National University Hospital)

### User Authorisation List

[+ Add](#) [Columns](#) [Export](#) [Filter\(1\)](#)

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	CIRB_D_IRBSec1	-	-	-	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	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_SA1	Study Administrator	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Senior Executive	SGH_SA1@sgl.com.sg	CRMS	Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	<a href="#">Deactivate</a>
SS_20	Study Sponsor	Non-PHI	Astra Zeneca	Astra Zeneca	CRA	SS_20@az.com	CRMS	Pending Endorsement	-	-	-	-	SGH_Co-I1	24-Jan-2024	

Step 1: Click Filter.

# 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.

The screenshot shows the 'User Authorisation List' page for a study. The 'Filter' dialog is open, showing the 'Role Status' section with three pre-set filters: 'Active', 'Pending IRB Approval', and 'Pending Endorsement'. An orange callout box with the text 'Step 2: Delete the 3 labels pre-set.' points to these filters. The 'Endorsement Date' and 'Deactivation Date' sections also show date range filters. The 'Reset' and 'Search' buttons are visible at the bottom of the dialog.

Member Name	Role	Cluster	Institution	Department
SGH_PI1	PI	SingHealth	Singapore General Hospital	Department of Medicine
SGH_Co-11	Col	SingHealth	Singapore General Hospital	Department of Medicine



# Page Functions – Filter

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

Back to Study List Study Details Download Alert

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital (SGH)

ECOS Reference: 2024-0205      IRB: CIRB Board D      Study Status: ● Approved

Number of Sites: 2      Initial Outcome Date: 24-Jan-2024      Valid Till Date: 23-Jan-2025

PI/Site PI: Dr SGH\_PI (Singapore General Hospital), Prof NUH\_PI (National University Hospital)

Department: Department of Medicine(Singapore General Hospital), Medicine(National University Hospital)

### User Authorisation List

[+ Add](#)   [Columns](#)   [Export](#)   [Filter](#)

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	<span style="color: green;">●</span> Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_Co-11	Col	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_Co-11@singhealth.com.sg	IRB	<span style="color: green;">●</span> Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_STM11	Study Team Member	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Executive	SGH_STM11@sgh.com.sg	CRMS	<span style="color: grey;">●</span> Inactive	-	-	24-Jan-2024	SGH_PI	SGH_PI	24-Jan-2024	
SGH_SA1	Study Administrator	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Senior Executive	SGH_SA1@sgh.com.sg	CRMS	<span style="color: green;">●</span> Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	<a href="#">Deactivate</a>
SS_20	Study Sponsor	Non-PHI	Astra Zeneca	Astra Zeneca	CRA	SS_20@az.com	CRMS	<span style="color: blue;">●</span> Pending Endorsement	-	-	-	-	SGH_Co-11	24-Jan-2024	

# Page Functions – Columns

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

Study Details

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk / Singapore General Hospital (SGH)

ECOS Reference: 2024-0205      IRB: CIRB Board D      Study Status: Approved

Number of Sites: 2      Initial Outcome Date: 24-Jan-2024      Valid Till Date: 23-Jan-2025

PI/Site PI: Dr SGH\_PI (Singapore General Hospital), Prof NUH\_PI (National University Hospital)

Department: Department of Medicine(Singapore General Hospital), Medicine(National University Hospital)

### User Authorisation List

+ Add   Columns   Export   Filter

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	CIRB_D_IRBSec1	-	-	-	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	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_STM11	Study Team Member	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Executive	SGH_STM11@sgh.com.sg	CRMS	Inactive	-	-	24-Jan-2024	SGH_PI	SGH_PI	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	Deactivate
SS_20	Study Sponsor	Non-PHI	Astra Zeneca	Astra Zeneca	CRA	SS_20@az.com	CRMS	Pending Endorsement	-	-	-	-	SGH_Co-I1	24-Jan-2024	

Step 1: Click Columns.

# Page Functions – Columns

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

The screenshot shows a web application interface for 'Study Details'. The main content area displays a 'User Authorisation List' table with columns for Member Name, Role, Cluster, and Institution. A modal window titled 'Column' is open, showing a list of columns with checkboxes. The 'Cluster', 'Department', 'Designation', and 'Email Address' columns are highlighted with orange arrows, indicating they are to be unchecked. A callout box on the right provides instructions for Step 2.

**Column** Selected 15

Search

Select All

- Member Name
- Role
- Cluster
- Institution
- Department
- Designation
- Email Address
- Data Source
- Role Status

Clear Cancel Save

**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.

Study Details

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital (SGH)

### User Authorisation List

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

Columns panel (Selected 11):

- Member Name
- Role
- Cluster
- Institution
- Department
- Designation
- Email Address
- Data Source
- Role Status

Buttons: Clear, Cancel, Save

Rows per page: 100 | 1-5 of 5

# 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.

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital (SGH)

### User Authorisation List

[+ Add](#) [Columns](#) [Export](#) [Filter](#)

Member Name	Role	Institution	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date	Action
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_Co-11	Col	Singapore General Hospital (SGH)	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_STM11	Study Team Member	Singapore General Hospital (SGH)	CRMS	● Inactive	-	-	24-Jan-2024	SGH_PI	SGH_PI	24-Jan-2024	
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	CRMS	● Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	<a href="#">Deactivate</a>
SS_20	Study Sponsor	Astra Zeneca	CRMS	● Pending Endorsement	-	-	-	-	SGH_Co-11	24-Jan-2024	

Rows per page: 100 1-5 of 5

# 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	Col	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.

The screenshot displays the 'Study Details' page for '2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital (SGH)'. The main content area is titled 'User Authorisation List' and contains a table with the following data:

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

At the top right of the table, there are three buttons: '+ Add', 'Columns', and 'Export'. A red callout box labeled 'Step 1: Click Add.' points to the '+ Add' button. The interface also includes a 'Filter(1)' button and a pagination bar at the bottom right showing 'Rows per page: 100' and '1-4 of 4'.

# Page Functions – Add User

Study Details

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore G

### User Authorisation List

Member Name	Role	Institution	Data Source	Role Status	Endorsement Date
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024
SGH_Co-I1	Col	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	CRMS	Active	24-Jan-2024
SS_20	Study Sponsor	Astra Zeneca	CRMS	Pending Endorsement	-

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

Add Submit Cancel

\* Member Name/Email :

 Q

Step 3: Click the Search icon.

Member Name	Cluster	Institution	Department	Designation
SGH_STM22	SingHealth	Singapore General Hospital (SGH)	Department of Renal Medicine	-

Step 4: Any user that matches the search criteria will be listed. Select the row with user details.

\* Role :



# Page Functions – Add User

Study Details

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore G

### User Authorisation List

Member Name	Role	Institution	Data Source	Role Status	Endorsement Date
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024
SGH_Co-IT	CoI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	CRMS	Active	24-Jan-2024
SS_20	Study Sponsor	Astra Zeneca	CRMS	Pending Endorsement	-

Add

Submit Cancel

\* Member Name/Email :

SGH\_STM22

Member Name: SGH\_STM22

Cluster: SingHealth

Institution: Singapore General Hospital (SGH)

Department: Department of Renal Medicine

Designation: Clinical Research Coordinator

Email: SGH\_STM22@sgh.com.sg

\* Role :

Please select

Study Sponsor

Study Administrator

Study Team Member

Step 6: Click Submit.

Step 5: Click on the Dropdown icon and select the role of the 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.

Study Details

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital (SGH)

### User Authorisation List

[+ Add](#) [Columns](#) [Export](#) [Filter\(1\)](#)

Member Name	Role	Institution	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date	Action
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_Co-I1	CoI	Singapore General Hospital (SGH)	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	CRMS	● Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	<a href="#">Deactivate</a>
SGH_STM22	Study Team Member	Singapore General Hospital (SGH)	CRMS	● Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	<a href="#">Deactivate</a>
SS_20	Study Sponsor	Astra Zeneca	CRMS	● Pending Endorsement	-	-	-	-	SGH_Co-I1	24-Jan-2024	

# 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.

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital (SGH)

### User Authorisation List

[+ Add](#) [Columns](#) [Export](#) [Filter\(1\)](#)

Member Name	Role	Institution	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date	Action
<a href="#">SGH_PI</a>	PI	Singapore General Hospital (SGH)	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
<a href="#">SGH_Co-I1</a>	Col	Singapore General Hospital (SGH)	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
<a href="#">SGH_SA1</a>	Study Administrator	Singapore General Hospital (SGH)	CRMS	● Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	<a href="#">Deactivate</a>
<a href="#">SGH_STM22</a>	Study Team Member	Singapore General Hospital (SGH)	CRMS	● Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	<a href="#">Deactivate</a>
<a href="#">SGH_SA22</a>	Study Administrator	Singapore General Hospital (SGH)	CRMS	● Pending Endorsement	-	-	-	-	SGH_RO1	07-Mar-2024	
<a href="#">SS_20</a>	Study Sponsor	Astra Zeneca	CRMS	● Pending Endorsement	-	-	-	-	SGH_Co-I1	24-Jan-2024	

# 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.

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital (SGH)

### User Authorisation List

[+ Add](#) [Columns](#) [Export](#) [Filter\(1\)](#)

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

Rows per page: 100 1-6 of 6

# 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.

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital (SGH)

### User Authorisation List

Member Name	Role	Institution	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date	Action
<a href="#">SGH_SA22</a>	Study Administrator	Singapore General Hospital (SGH)	CRMS	● Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	<a href="#">Deactivate</a>
<a href="#">SGH_PI</a>	PI	Singapore General Hospital (SGH)	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
<a href="#">SGH_Co-11</a>	Col	Singapore General Hospital (SGH)	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
<a href="#">SGH_STM11</a>	Study Team Member	Singapore General Hospital (SGH)	CRMS	● Inactive	-	-	24-Jan-2024	SGH_PI	SGH_PI	24-Jan-2024	
<a href="#">SGH_SA1</a>	Study Administrator	Singapore General Hospital (SGH)	CRMS	● Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	<a href="#">Deactivate</a>
<a href="#">SGH_STM22</a>	Study Team Member	Singapore General Hospital (SGH)	CRMS	● Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	
<a href="#">SS_20</a>	Study Sponsor	Astra Zeneca	CRMS	● Pending Endorsement	-	-	-	-	SGH_Co-11	24-Jan-2024	

Click Deactivate.

# 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."

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital (SGH)

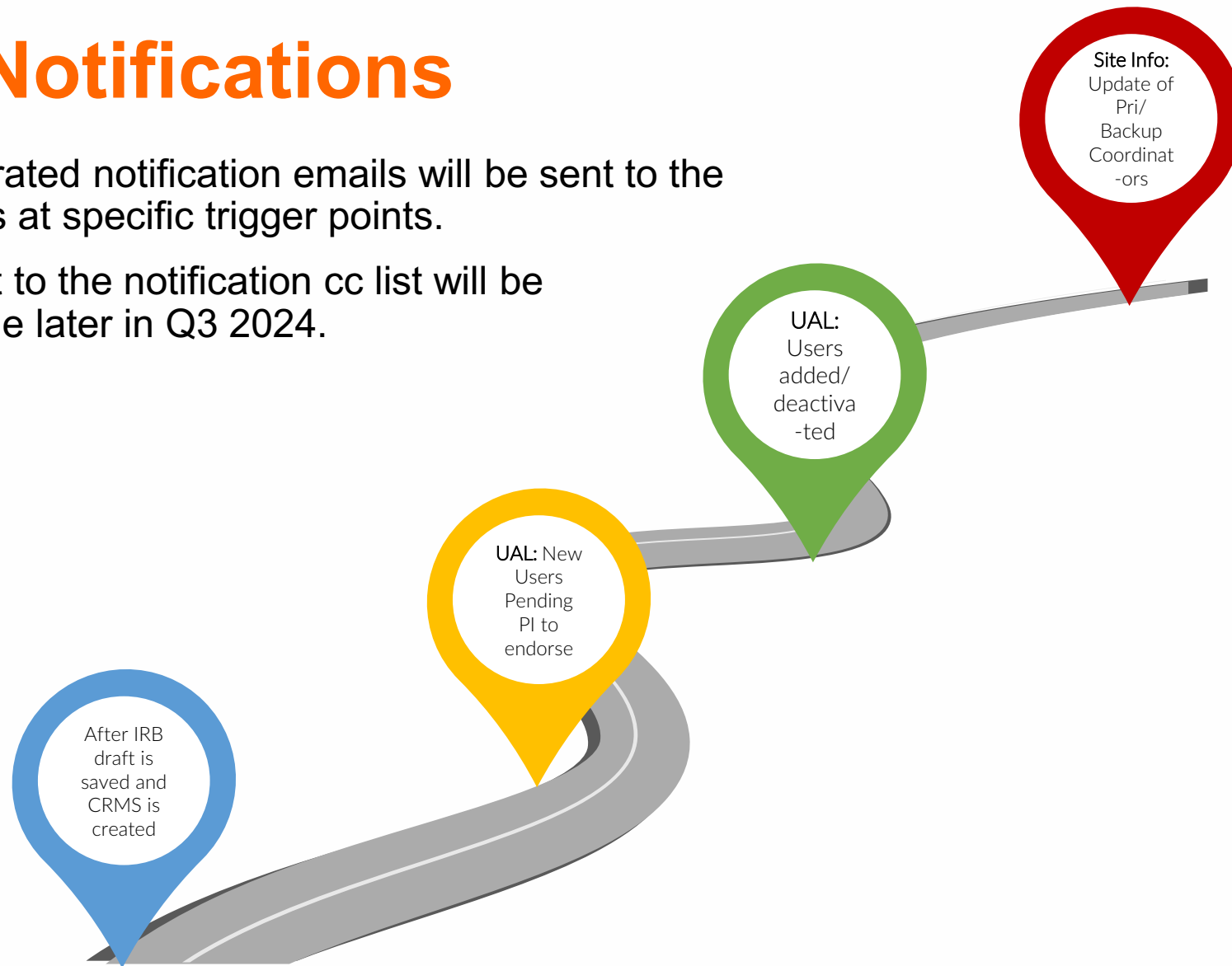
### User Authorisation List

[+ Add](#) [Columns](#) [Export](#) [Filter](#)


Member Name	Role	Institution	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date	Action
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	CRMS	Inactive	24-Jan-2024	SGH_PI	14-Mar-2024	SGH_SA22	SGH_SA22	14-Mar-2024	
SGH_SA22	Study Administrator	Singapore General Hospital (SGH)	CRMS	Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	<a href="#">Deactivate</a>
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_Co-11	Col	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	

# 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.

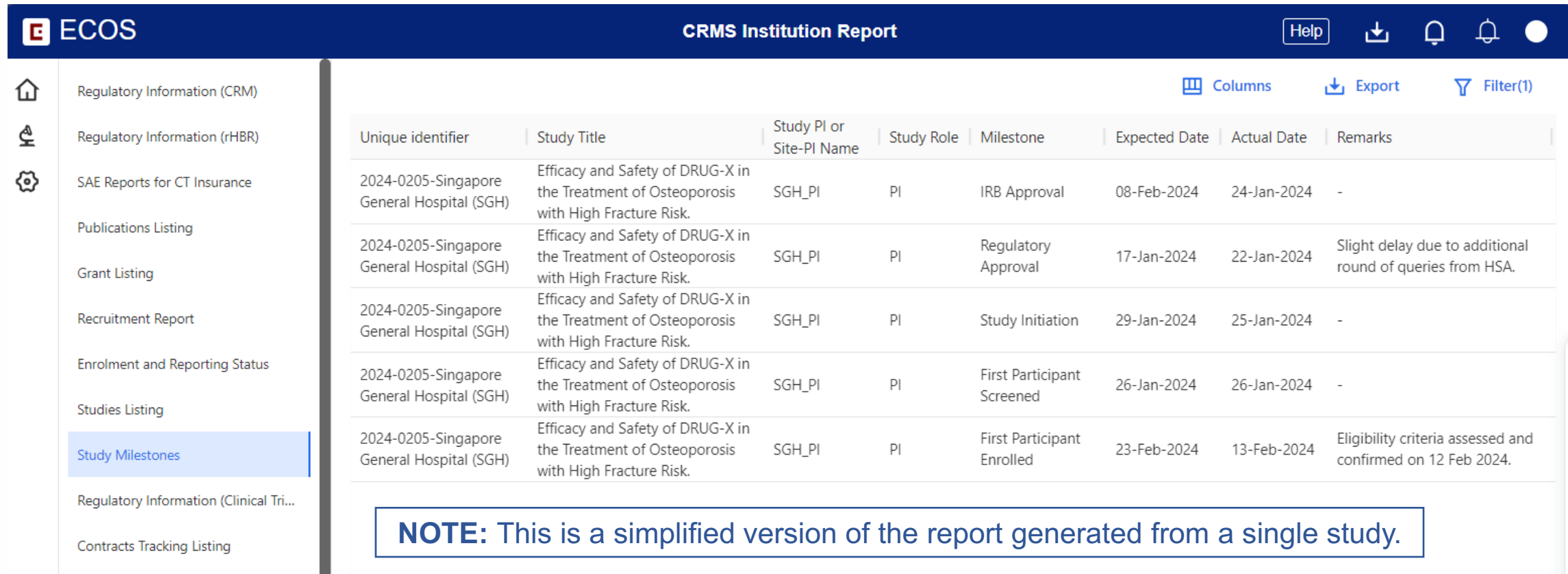


# CRMS Report



*This option may be available in Q3 2024.*

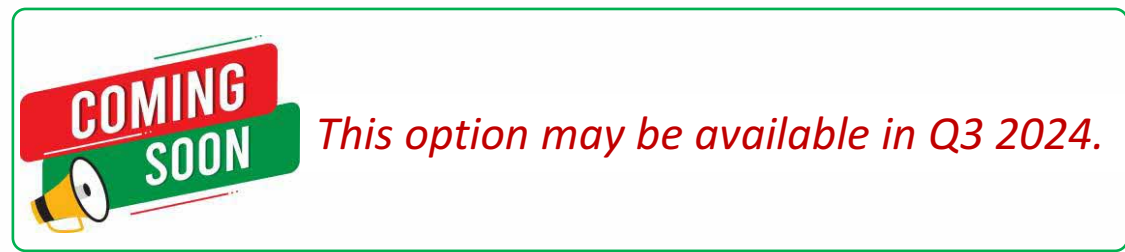
- Reports can be generated from CRMS to fulfil any periodic or KPI reporting at the institution level.
- Reports generated will include all data except for new data entered on the day itself.
- CRMS Report section can only be accessed by selected roles.



The screenshot shows the ECOS interface for the CRMS Institution Report. The left sidebar contains a navigation menu with items like Regulatory Information (CRM), SAE Reports for CT Insurance, Publications Listing, Grant Listing, Recruitment Report, Enrolment and Reporting Status, Studies Listing, Study Milestones (highlighted), Regulatory Information (Clinical Tri...), and Contracts Tracking Listing. The main content area displays a table with columns: Unique identifier, Study Title, Study PI or Site-PI Name, Study Role, Milestone, Expected Date, Actual Date, and Remarks. The table contains five rows of data for a study at Singapore General Hospital (SGH) with the title 'Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk'. The milestones shown are IRB Approval, Regulatory Approval, Study Initiation, First Participant Screened, and First Participant Enrolled. A note at the bottom states: 'NOTE: This is a simplified version of the report generated from a single study.'

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.





# CRMS Reports (NHG)

- 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.