

Navigating Ethics & Compliance Online System (ECOS) User Guide

Clinical Research Management System (CRMS) Module

(ECOS User Guide – CRMS Module , Ver 1, 7 May 24)



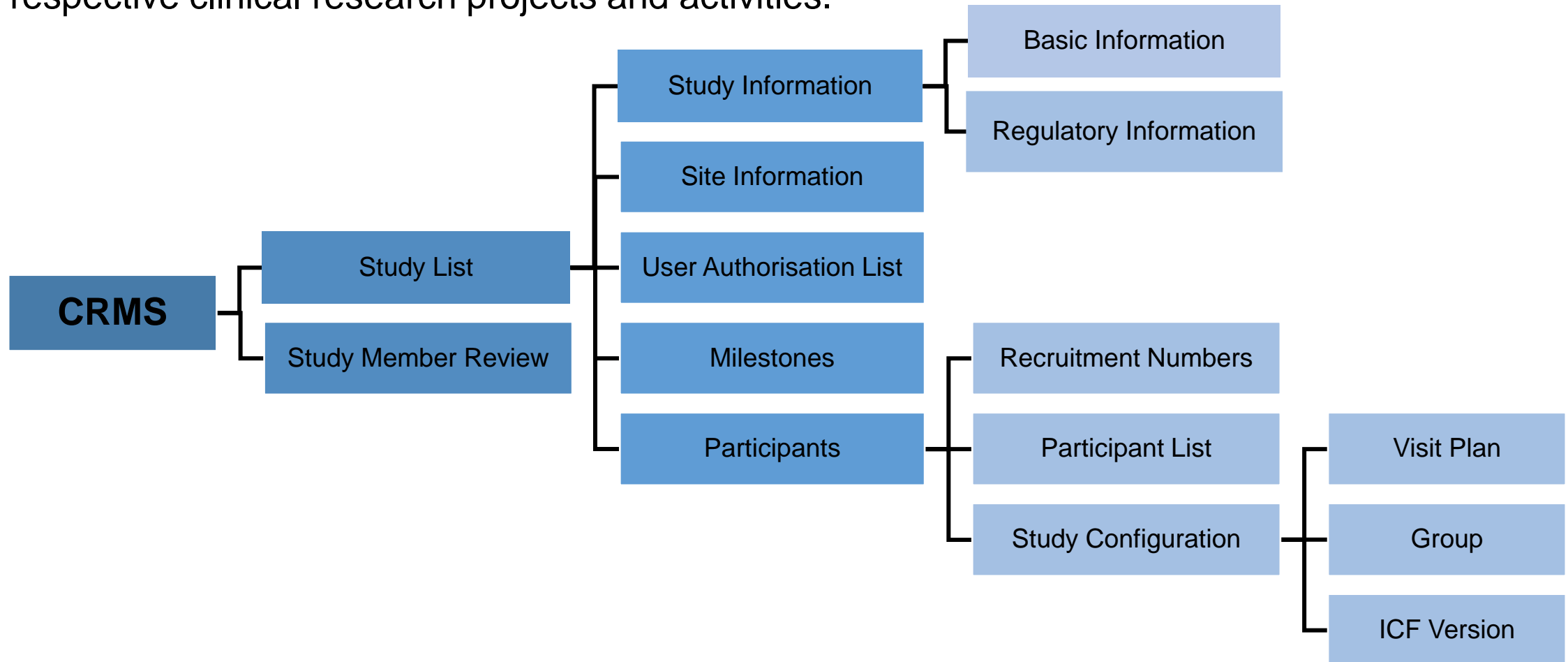
Adding years of healthy life

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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).

- 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

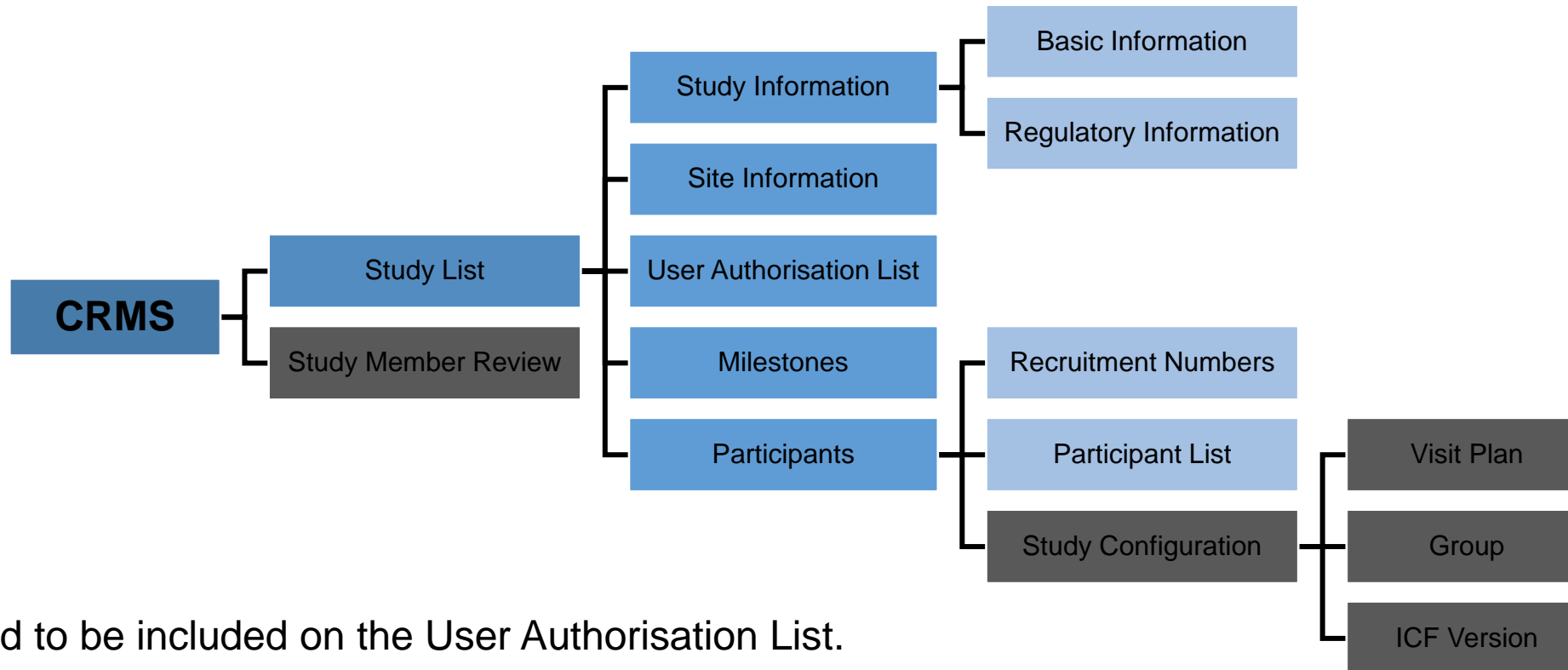
Information entered will be shared across all participating sites. E.g. data entered by 1 site will be seen by all sites. Similarly, data revision made by 1 site will also be seen by the other sites.

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." with an orange arrow pointing to the CRMS menu item, and "Step 2: Click to see the list of studies available." with a black arrow pointing 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

[Back to Submission List](#) Submission Detail Download 99+ Profile

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

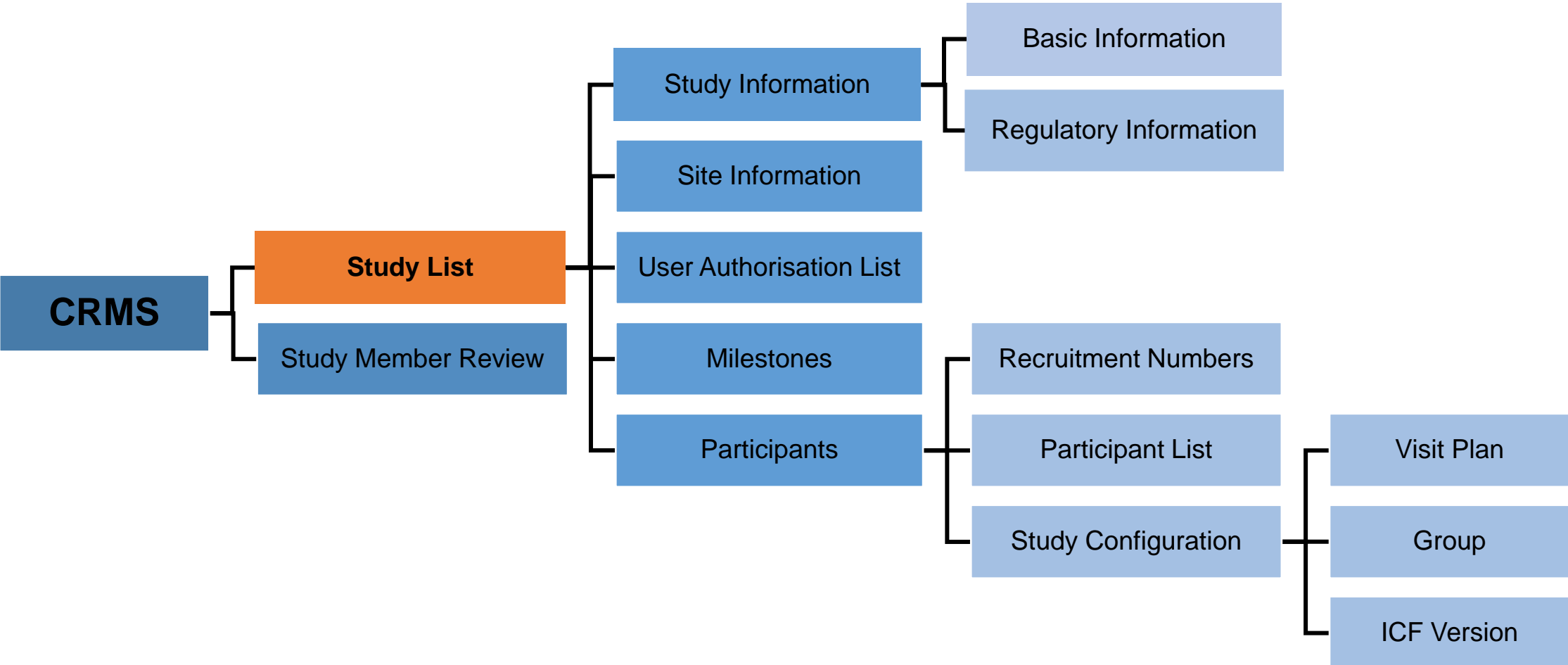
Quick Link: [Study Summary,CRMS](#)

[Form Detail](#) Click to enter CRMS of the study 2024-0205

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

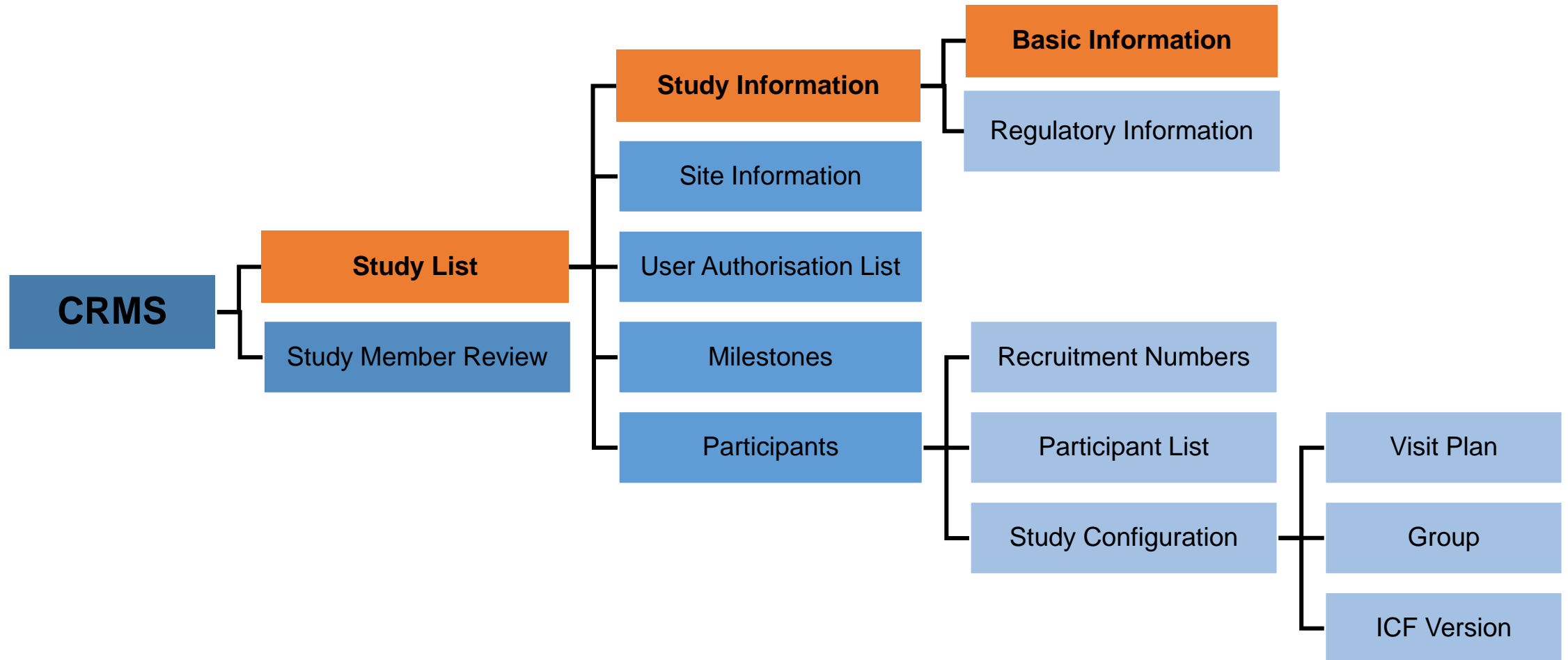
- ECOS Ref
- IRB
- PI/Site-PI
- Department
- Number of Sites
- Study Title
- Study Status
- Initial Outcome Date
- Valid Till Date

The screenshot shows the ECOS Study List interface. The main table displays study information with columns: ECOS Ref, IRB, PI/Site-PI, Department, Number of Sites, Study Title, and Action. A callout box points to the number '2' in the 'Number of Sites' column, stating: "Click on the number to see the list of participating sites." Another callout box points to the eye icon in the 'Action' column, stating: "Click the View icon of the specific study to enter the CRMS pages." A 'Detail' modal window is open, showing a table of participating sites:

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	

At the bottom right of the interface, there are controls for "Rows per page: 100" and "1-1 of 1".

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	Last Edited
* 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	Last Edited
* 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		* 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.

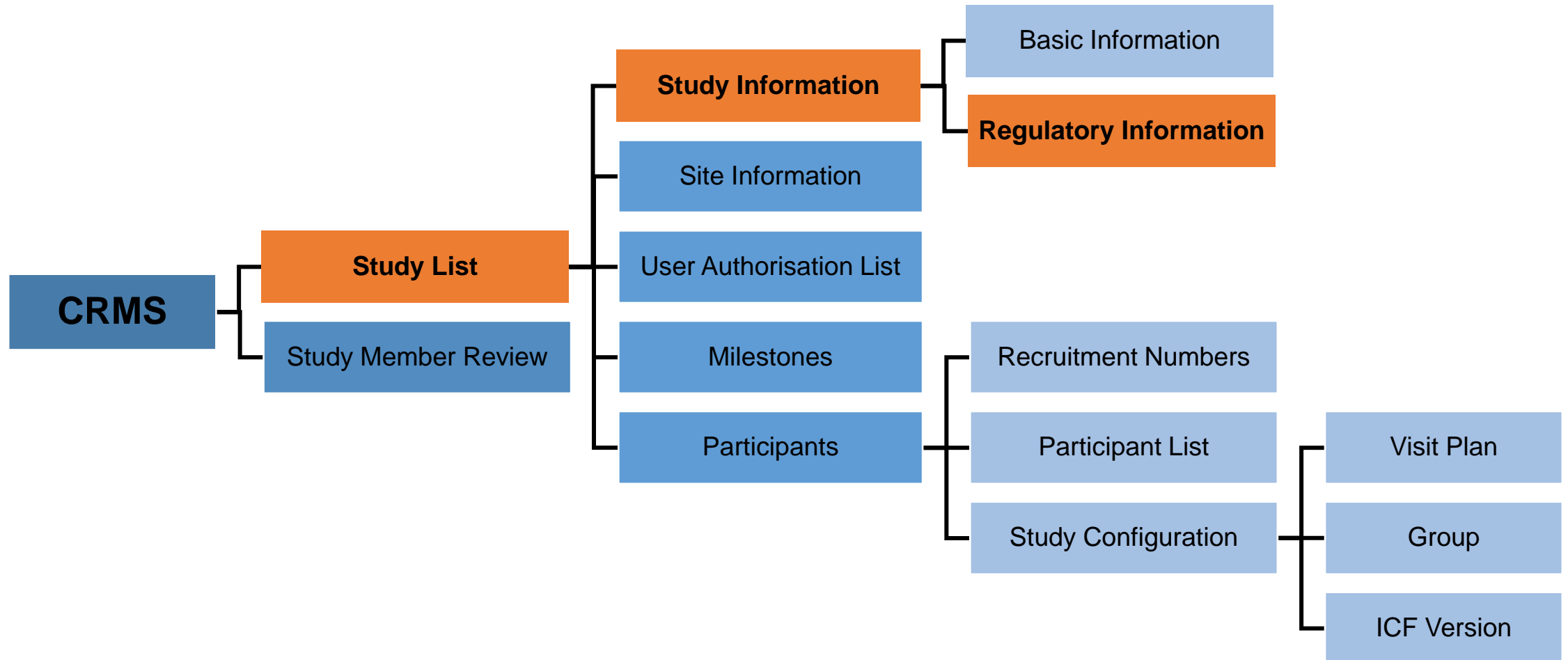
IRB Review Fees Billing Details

- 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).

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

Export Edit

Clinical Trials Regulated by HSA

Type of Application	Submission Reference No.	Submission Date	Local Regulatory Study Reference No.	Licence/F fication N
* Clinical Trial Authorisation (CTA) v	* 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	Submissi
* Drug-X	* Therapeutic Product/CTGTP v	* CRM Notification v	* 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

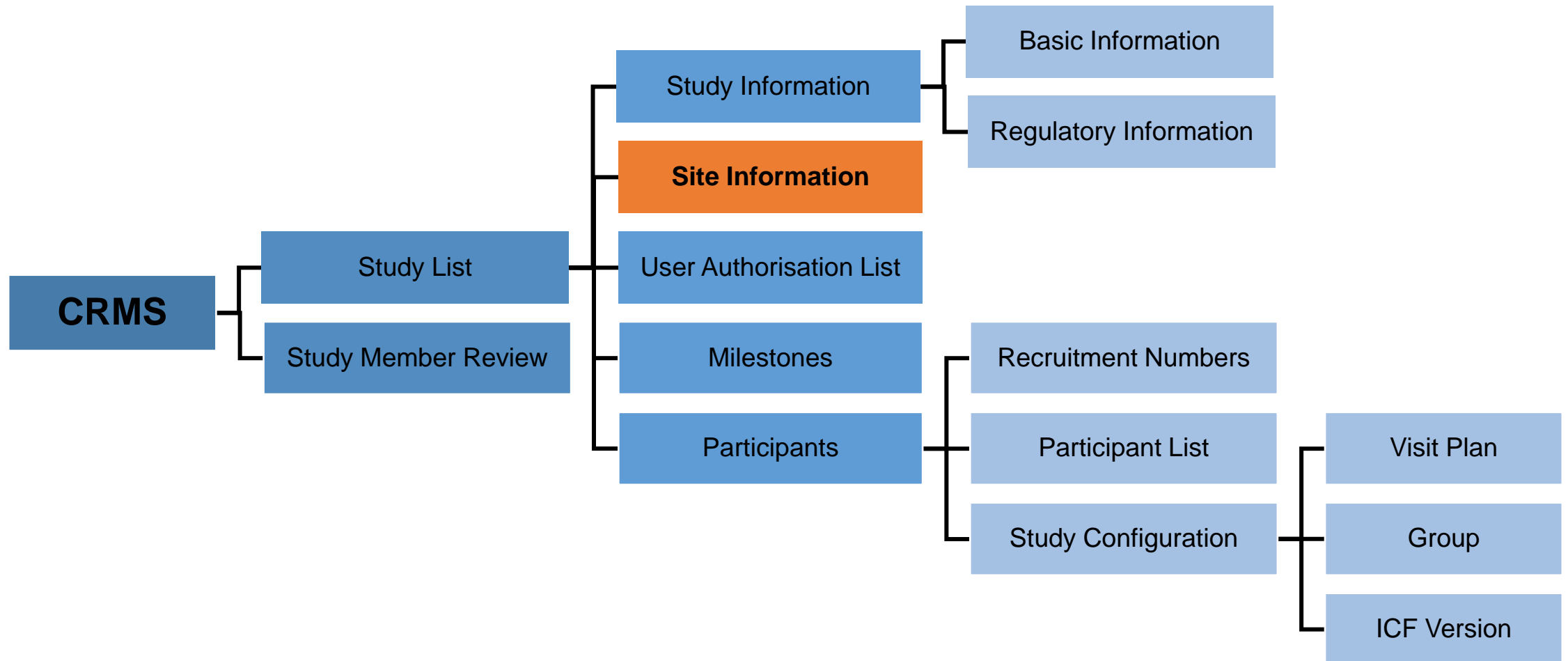
MOH Application No.	MOH Submission Date	MOH Reference No.	MOH Approval Date	MOH Expiry Date
* RR-20239999-0909	* 02-Jan-2023 	RR-2023/09	24-Jan-2023 	23-Jan-2024
* RR-20239999-0909	* 13-Dec-2023 	RR-2023/09	09-Jan-2024 	08-Jan-2025

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

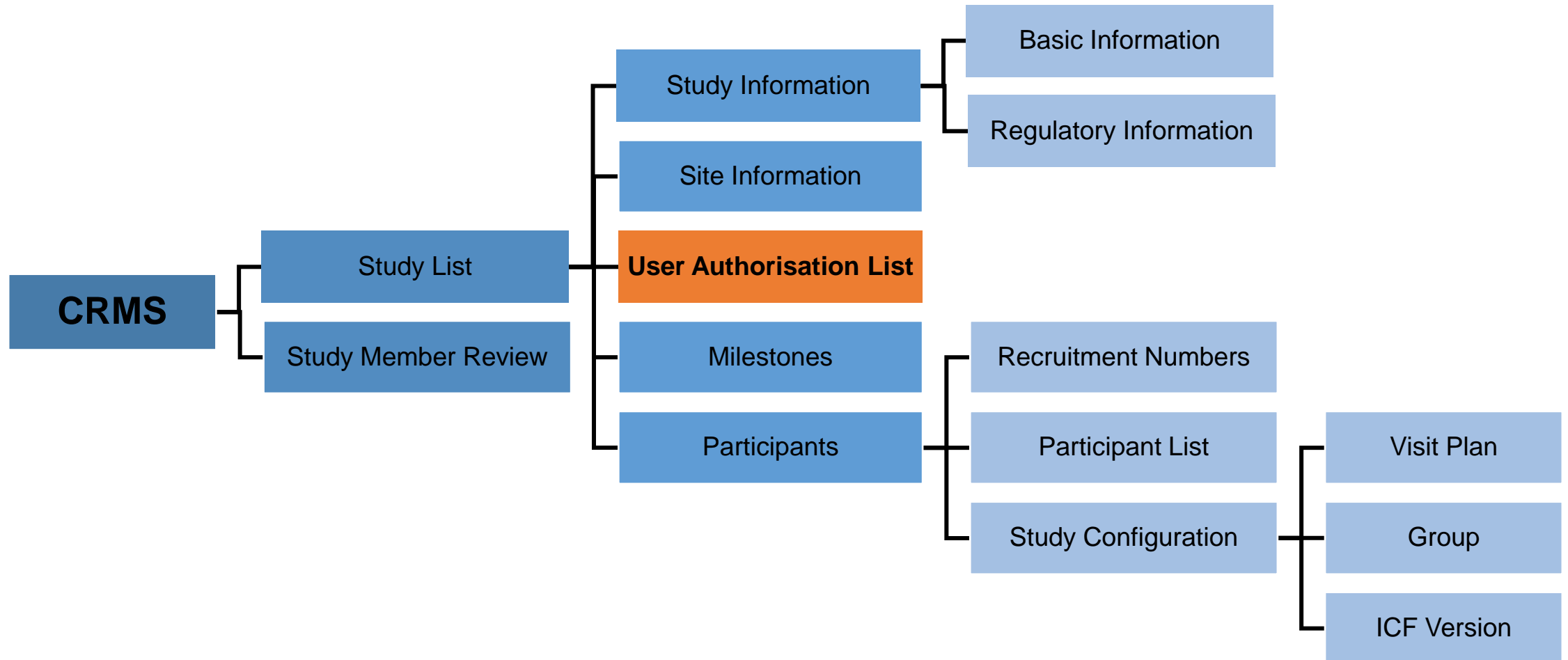
- Sponsor/CRO Name
- Total Estimated Budget of Contract
- Date of Information Received To Start Drafting Budget
- Date of Budget First Sent to Sponsor/CRO
- Date of Budget Finalisation/ Agreement
- Date of Contract Template Received From Sponsor/CRO
- Date of Contract Finalisation/ Agreement By All Parties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

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

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@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	

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 & Co-I</p> <p>Site investigators <u>directly involved</u> in the research.</p>	<ul style="list-style-type: none"> • View & edit rights. <p>User added in IRB Application Form</p> <ul style="list-style-type: none"> • Limited page access before IRB approval. <ul style="list-style-type: none"> ✓ Study Information ✓ UAL • Full page access after IRB approval. <ul style="list-style-type: none"> + Site Information + Milestones + Participants <p>User added in IRB Amendment Form</p> <ul style="list-style-type: none"> • No page access before IRB approval. • Full page access after IRB approval. <ul style="list-style-type: none"> ✓ Study Information ✓ UAL ✓ Site Information ✓ Milestones ✓ Participants 	<p>Access management:</p> <ul style="list-style-type: none"> • PI, Site PI and Co-I are to be added in Section B2(a) 'Investigator List' of the IRB application or amendment form. • List of investigators will be imported from IRB to CRMS module at each synchronisation points (as applicable) with IRB indicated as the data source. • IRB approval is required to gain full CRMS access. • Further addition and deactivation will both go through the IRB module. <p>During IRB Application drafting:</p> <ul style="list-style-type: none"> ➤ 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. <p>In subsequent IRB Amendment Form(s):</p> <ul style="list-style-type: none"> ➤ New PI, Site-PI or Co-I will only appear on the CRMS UAL after IRB has provided approval for the Amendment Form. ➤ Investigators to be removed will only be deactivated on the UAL after IRB's review.

User Authorisation List (UAL)

Site Level

Role	CRMS Access Rights	Comments
<p>Study Team Member (STM)</p> <p>Site personnel <u>directly involved</u> in the research conduct e.g. CRCs, Study Nurses, Pharmacists, etc.</p>	<ul style="list-style-type: none"> • View & edit rights. • Limited page access before PI's endorsement in CRMS. <ul style="list-style-type: none"> ✓ Study Information ✓ UAL • Full page access after PI's endorsement in CRMS. <ul style="list-style-type: none"> + Site Information + Milestones + Participants 	<p>Access management:</p> <ul style="list-style-type: none"> • STM, SA and SS are to be added via the UAL in the CRMS module, where the data source will indicate CRMS. • Any user on the UAL can add or deactivate a user. • New users added will require PI's endorsement in CRMS, endorsement is site-specific. • Addition of new user(s) by PI/Site-PI will automatically be endorsed upon submission. • User deactivation does not require endorsement from PI/Site-PI. • Once deactivated, access to CRMS and other related modules will be revoked, e.g. IRB. • Reactivation of the user is not allowed, i.e. a new entry needs to be added and endorsed to "reactivate" the user. • Number of users that can be added into the UAL is not capped, but please be mindful when performing this task as every addition and deactivation will be captured on this list. • Site will need to manage and keep the UAL updated, i.e. STM/SA/SS(s) no longer directly involved in the study should be deactivated in the list for access to IRB and CRMS modules to be revoked.
<p>Study Administrator (SA)</p> <p>Site personnel <u>not directly involved</u> 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"> • View & edit rights. • Limited page access only. <ul style="list-style-type: none"> ✓ Study Information ✓ UAL 	
<p>Study Sponsor (SS)</p> <p>Sponsor/CRO personnel, e.g. CTAs, CRAs, CTMs etc.</p>	<ul style="list-style-type: none"> • View & edit rights. • Limited page access only. <ul style="list-style-type: none"> ✓ Study Information ✓ UAL 	

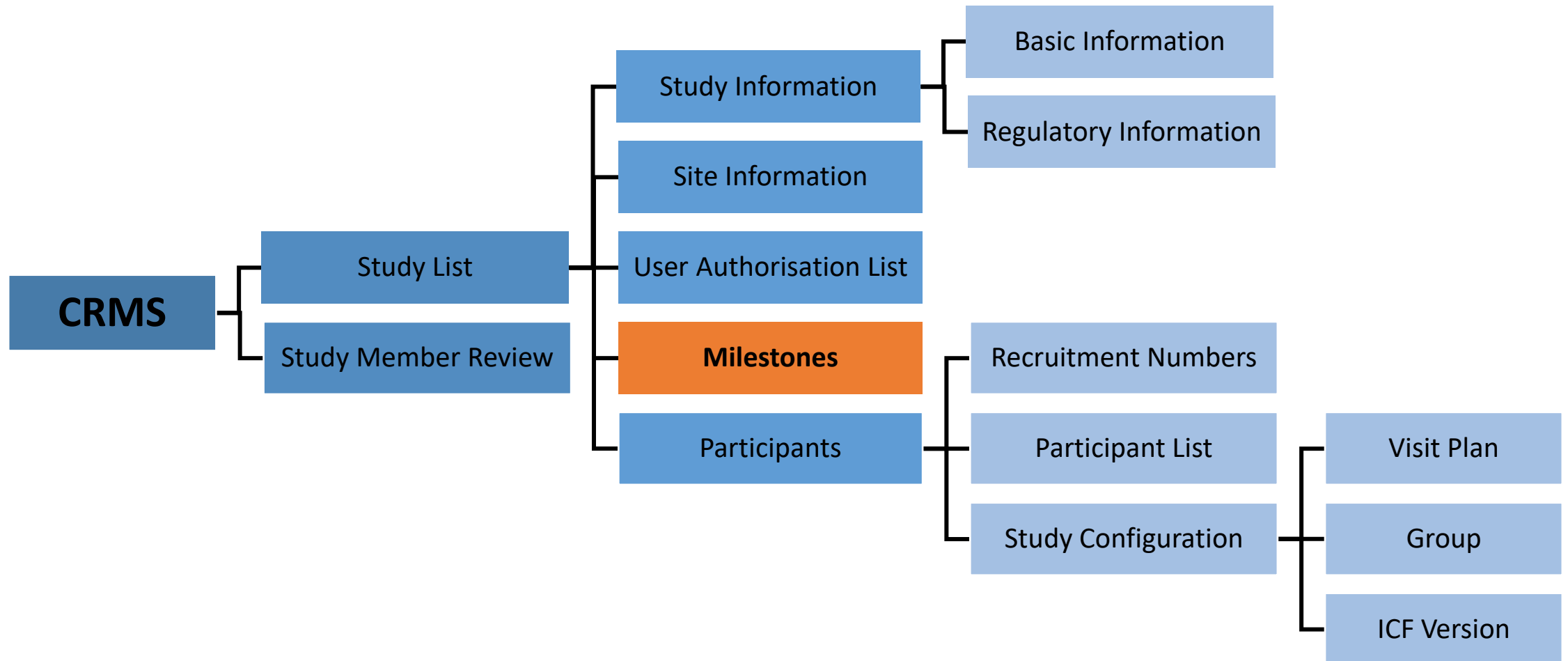
User Authorisation List (UAL)



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

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

CRMS Sitemap



Milestones

- 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	✎
Regulatory Approval	17-Jan-2024	22-Jan-2024	Slight delay due to additional round of queries from HSA.	SGH_SA1	26-Jan-2024	✎
Study Initiation	29-Jan-2024	25-Jan-2024	-	SGH_SA1	26-Jan-2024	✎
First Participant Screened	26-Jan-2024	26-Jan-2024	-	SGH_SA1	26-Jan-2024	✎
First Participant Enrolled	23-Feb-2024	13-Feb-2024	Eligibility criteria assessed and confirmed on 12 Feb 2024.	SGH_PI	11-Mar-2024	✎

Rows per page: 100 1-5 of 5

Milestones

Site Level

Below are the data fields found on this page:

Milestones

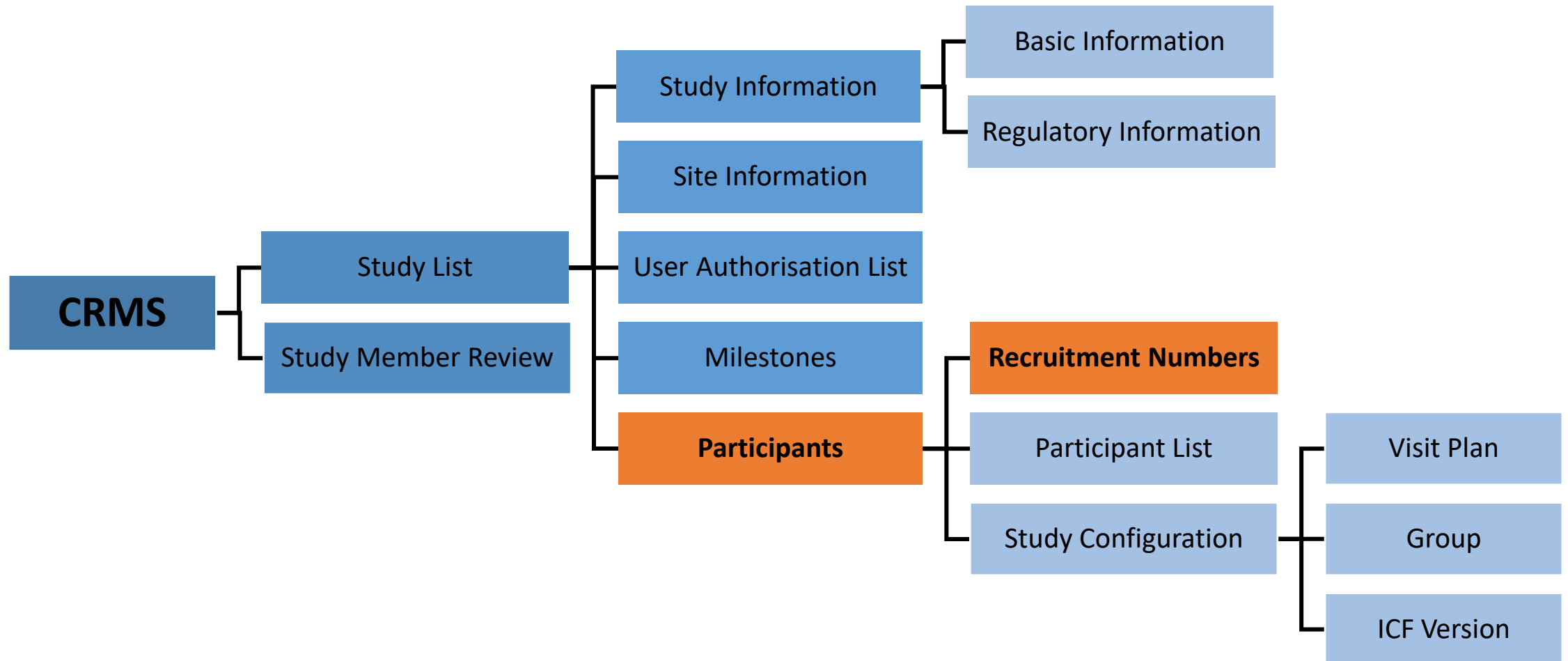
- Milestone *(Drop-down list)*
 - IRB Approval
 - Regulatory Approval
 - Grant Approval
 - Study Initiation
 - First Participant Screened
 - First Participant Enrolled
 - Last Participant Last Visit
 - Last Participant Enrolled
 - Data Analysis
 - Study Closure
 - Other *(Free text)*

- 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.

The screenshot shows the 'Study Details' page for a study titled '2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital (SGH)'. The page includes a navigation bar with 'Back to Study Details', 'Study Details', 'Help', and notification icons. The study information section displays details such as 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, Prof NUH_PI), and Department (Department of Medicine at both SGH and NUH).

The main content area is titled 'Recruitment Target Approved in IRB Study: 2-2' and features a 'Current Recruitment Summary' section with four summary cards:

- Total No. of Screen Failures: 1
- Total No. of Participants Enrolled: 2
- Total No. of Participants Who Have Completed Study: 0
- Total No. of Participants Withdrawn from Study: 0

Below the summary is a table with columns: 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, and Last Edited Date.

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	1	1	0	0	SGH_PI	11-Mar-2024
2	Feb/2024	0	1	0	0	SGH_PI	11-Mar-2024
3	Jan/2024	0	0	0	0	SGH_SA1	26-Jan-2024

At the bottom, there is a text input field for '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

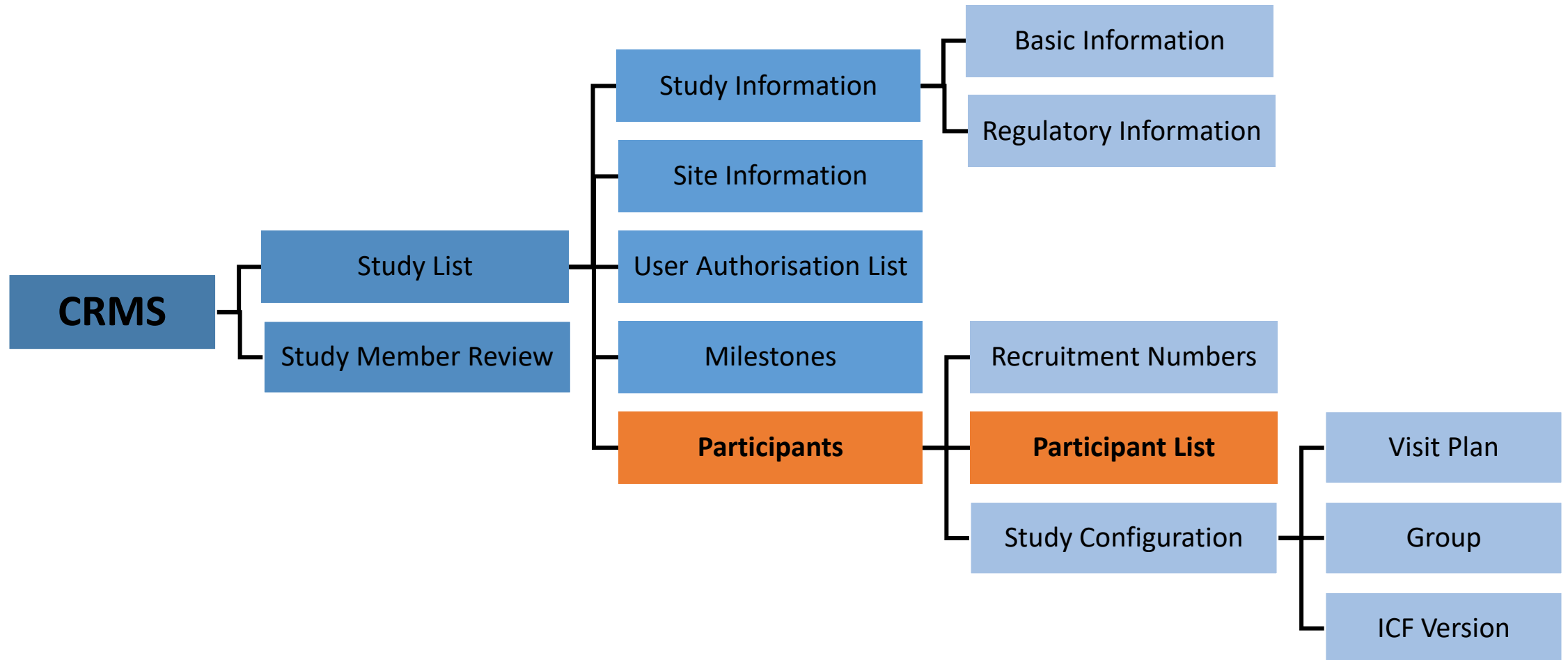
- Definitions of Screen Failure, Participants Enrolled / Completed / Withdrawn are given in the information bubble ⓘ next to **Current Recruitment Summary**.
- Monthly numbers should be entered and overall total numbers will be auto-populated by the system.

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 Exceeded approved recruitment number
<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	Edit
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	Edit
SGH_SCR01	SGH_X01	● Enrolled	Drug-X Group	26-Jan-2024	-		26-Jan-2024	SGH_PI	Edit

Rows per page: 100 1-3 of 3

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 shows the 'Participant Details' page in the CRMS system. The page has a dark blue header with a 'Back to Study Details' link, the title 'Participant Details', and icons for Help, download, notifications, and a profile. Below the header is a breadcrumb trail: 'CRMS / Study List / Study Details / Participant Details'. A red warning message states: 'Please do not enter participant identifiers in CRMS.' To the right of this message is an 'Edit' button. Below the warning, the 'Screening Number: SGH_SCR01' and 'Enrolment Number: SGH_X01' are displayed. The main content area has three tabs: 'Basic Information', 'ICF' (which is selected), and 'Visit Plan'. Under the 'ICF' tab, there is a table with the following columns: 'No.', 'Signed ICF Name', 'Date of Consent', 'Type of Consent', and 'Translator Present'. The table contains one row with the following data: '1', '* Drug-X ICF', '* 26-Jan-2024', '* Initial', and '* No'. Each data cell in the table has a red asterisk to its left and a dropdown arrow to its right.

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

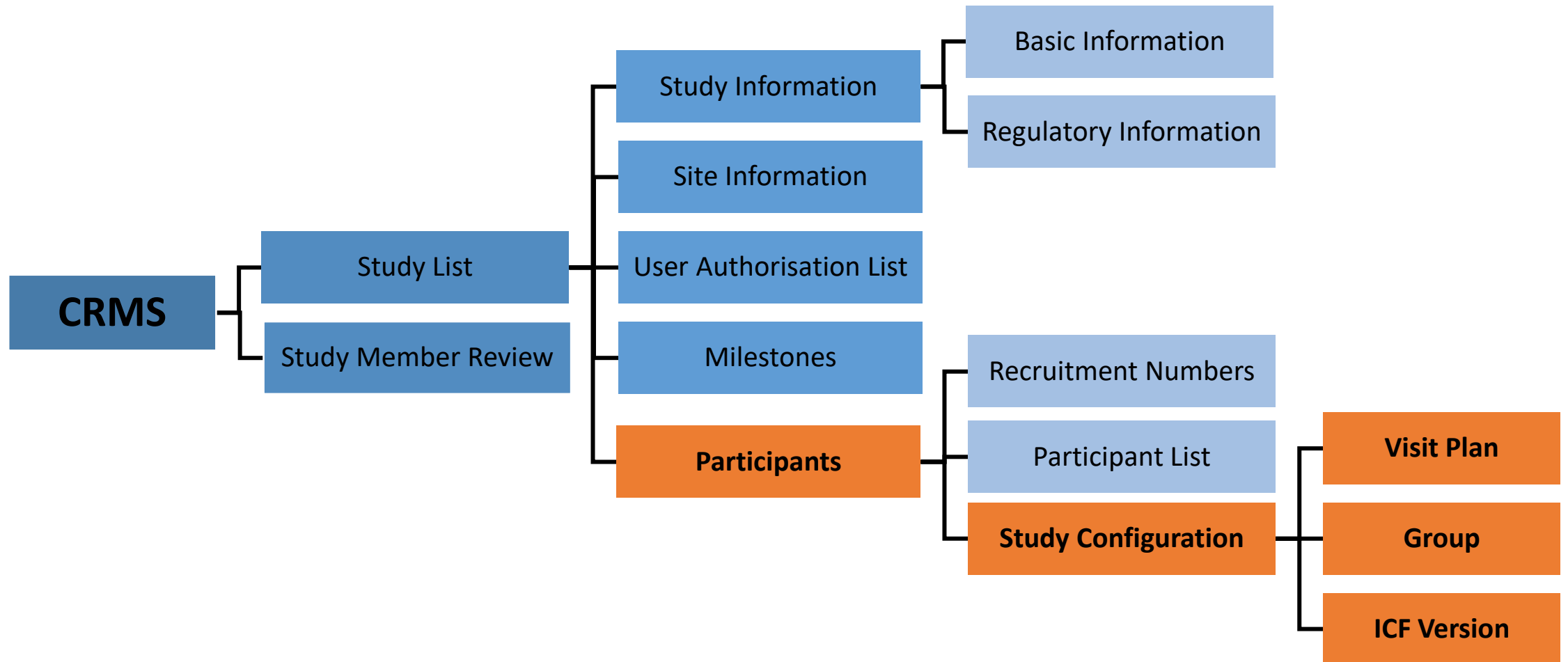
The screenshot shows the 'Participant Details' page in the CRMS system. At the top, there is a navigation bar with a back arrow and 'Back to Study Details', the title 'Participant Details', and icons for Help, download, notifications, and a profile menu. Below the navigation bar is a breadcrumb trail: 'CRMS / Study List / Study Details / Participant Details'. A red warning message states: 'Please do not enter participant identifiers in CRMS.' To the right of this message is an 'Edit' button. Below the warning, the 'Screening Number: SGH_SCR01' and 'Enrolment Number: SGH_X01' are displayed. The main content area has three tabs: 'Basic Information', 'ICF', and 'Visit Plan' (which is selected). Under the 'Visit Plan' tab, there is 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

Note:

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

CRMS Sitemap



Participants – Study Configuration

Site Level

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

Participants – Study Configuration

Site Level

Below are the data fields found on this page:

Visit Plan

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

Note:

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

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	Edit
Drug-X ICF (SGH)_Version 1.1 dated 25 Dec 2023_English	24-Jan-2024	22-Jan-2024	Active	SGH_SA1	26-Jan-2024	Edit
Drug-X ICF (SGH)_Version 1.1 dated 25 Dec 2023_Malay	24-Jan-2024	22-Jan-2024	Active	SGH_SA1	26-Jan-2024	Edit
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	Edit

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.

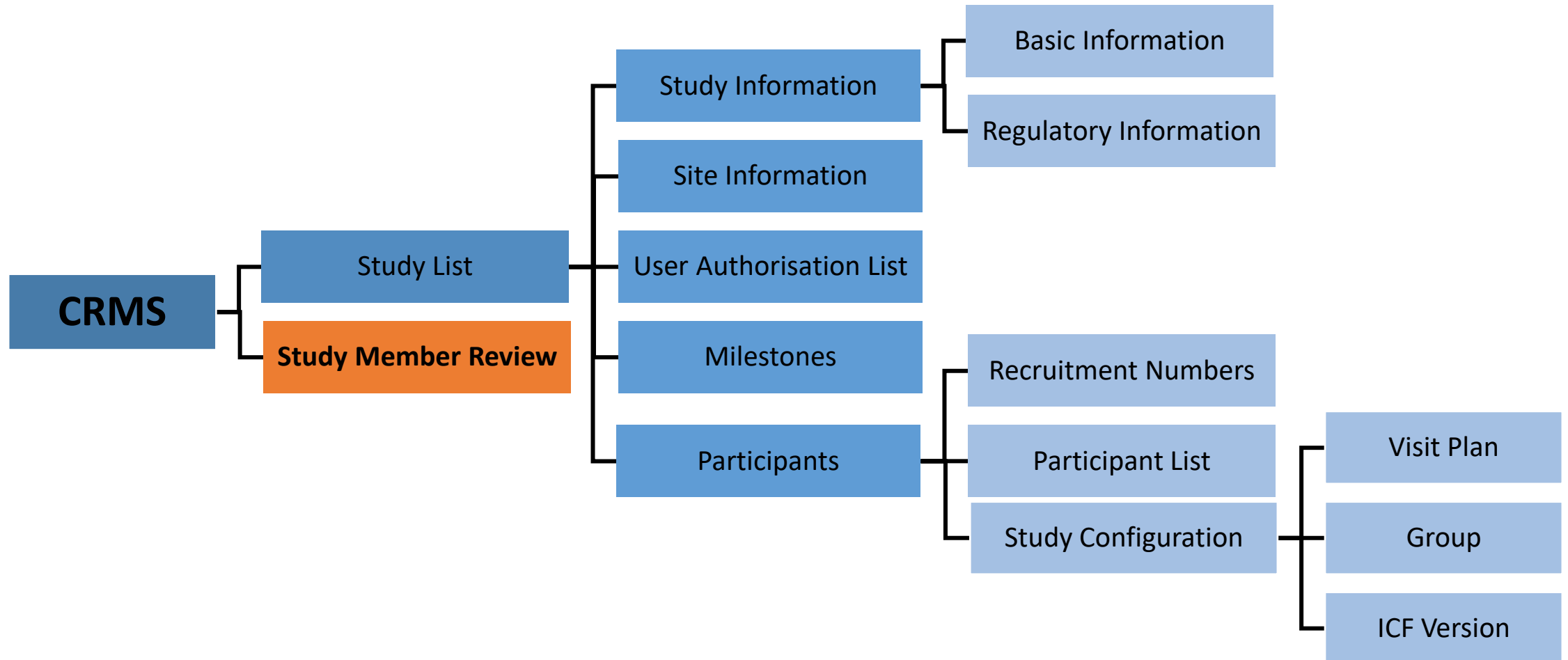
The image displays three screenshots illustrating the inactivation process for different study configuration elements:

- Visit Plan:** A table with columns 'Visit Name', 'Visit Status', and 'Remarks'. The 'Screening' row has a toggle switch turned off, and the 'Day 1' row has a toggle switch turned on. A hand icon points to the 'Day 1' toggle.
- Group Configuration:** A form with a 'Group' field containing 'Drug-X Group' and a 'Group Status' dropdown menu. The dropdown is open, showing 'Active' and 'Inactive' options. A hand icon points to the 'Inactive' option.
- ICF Version:** A form with fields for 'ICF Name, Version, Date and Language', 'IRB Approval Date', and 'Regulatory Approval Date'. The 'Status' dropdown menu is open, showing 'Active' and 'Inactive' options. A hand icon points to the 'Inactive' option.

Below the screenshots, a fourth screenshot shows a search box for 'Visit Plan' with the text 'No item' displayed below it, indicating that the inactivated entry is no longer available for selection.

- 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 displays 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 menu. The left sidebar contains navigation options: Homepage, Dashboard (highlighted with an orange box), My Tasks, My Notices, IRB, CRMS, FCOI, and Report. The main dashboard area features several cards: IRB (30), CRMS (11), and FCOI (0). The CRMS card has a sub-link for 'Study Member Review 11' which is highlighted with an orange arrow. A callout box points to this link with the text: 'Clicking this will bring the PI/Site-PI to the My Task page.' The FCOI card shows 'My FCOI List' with a count of 0. The 'My Notices' section on the right lists two notices: 'uat test-20240131' dated 31-Jan-2024 and 'UAT - Dashboard notice for all' dated 30-Jan-2024.

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.

Homepage IRB CRMS Study List Study Member Review FCOI Report

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 includes the ECOS logo, the word "Dashboard", and utility icons for download, notifications (99+), and user profile. The left-hand navigation menu lists: Homepage, Dashboard (highlighted), My Tasks, My Notices, IRB, CRMS, Study List, Study Member Review (highlighted with an orange arrow), and FCOI. The main dashboard area contains three data cards: IRB (8 total, with 8 Study and 0 Endorsement), CRMS (3 total, with 3 Study Member Review), and FCOI (0 total, with 0 My FCOI List). A "My Notices" section on the right shows a notification for "Dashboard notice for all" dated 07-Apr-2024, with a "View All" link.

ECOS Dashboard

Navigation Menu:

- Homepage
- Dashboard
- My Tasks
- My Notices
- IRB
- CRMS
- Study List
- Study Member Review
- FCOI

Dashboard Data:

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

My Notices: Dashboard notice for all (07-Apr-2024)

Click to enter Study Member Review page.

Study Member Review Access

Site Level

The screenshot displays the ECOS Study Member Review interface. 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 'Study Member Review' header and a dropdown menu. The dropdown menu is open, showing a list of studies: '2024-3172, Study 1', '2024-3170, Study 2' (highlighted), '2024-3167, Study 3', '2024-3127, Study 4', '2024-3126, Study 5', and '2024-3125, Study 6'. To the right of the dropdown, the text 'Singapore General Hospital' is visible. Two callout boxes provide instructions: 'Step 1: Select the study using the Study Dropdown Bar.' with an arrow pointing to the highlighted study, and 'Step 2: Select the study site.' with an arrow pointing to the site name. 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)

Reject Endorse Columns Export Filter(1)

<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

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 top navigation bar includes the ECOS logo, the title 'Submission List', and utility icons for download, notifications (30), and a profile icon. The left sidebar contains navigation options: Homepage, IRB (expanded), Submission List (selected), My Study List, CRMS, FCOI, and Report. The main content area 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' with navigation arrows.

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. A blue "Close" button is at the bottom of the modal, with an orange arrow pointing to it and a callout box that says "Click to proceed." The background shows a table with columns "Study Title" and "Action", listing "Study 1", "Study 2", and "Study 3". The interface also includes a sidebar with navigation options like "Homepage", "IRB", "Submission List", "My Study List", "CRMS", "FCOI", and "Report".

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).

Submission Detail

ECOS Ref: -

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	Institution	Action
Singapore General Hospital	Prof SGH_PI	PI	Senior Consultant	Department of Renal Medicine	Singapore 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...

Click Save.

Cancel 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 IRB module. A modal dialog titled 'Please select your site and role in CRMS' is open, prompting the user to select a site and a role. The dialog contains two dropdown menus: '* Site:' and '* Role:'. The '* Role:' dropdown is currently open, showing three options: 'Study Administrator', 'Study Sponsor', and 'Study Team Member'. A blue 'Save' button is visible at the bottom right of the dialog. The background shows the 'Application Form' section with various fields like 'Section B: Submission Board', 'B1. Submission IRB and Board', and 'Section A: Study Title'.

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 a web application interface for 'Submission Detail'. A modal dialog box is open in the center, titled 'Please select your site and role in CRMS'. The dialog contains two dropdown menus: '* Site:' with 'Singapore General Hospital' selected, and '* Role:' with 'Study Sponsor' selected. A blue 'Save' button is located at the bottom right of the dialog, with an orange arrow pointing to it. The background shows the 'Form Detail' section of the application, including 'Application Form', 'Section B: Submission Board', and 'B1. Submission IRB and Board'. The 'B1. (a)' section has 'SingHealth CIRB' selected, 'B1. (b)' has 'Board F' selected, and 'B1. (c)' has 'Palliative Medicine' selected. The top navigation bar includes 'Back to Submission List', 'Submission Detail', and a notification bell icon with '30'.

User Added to UAL by System

Role used: Study Sponsor (SS_20)

- SS_20 added to the User Authorisation List.

The screenshot shows the 'Study Details' page for study 2024-3245. The 'User Authorisation List' is displayed with the following data:

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	

The SS_20 entry is highlighted with an orange box. The page also shows a sidebar with 'User Authorisation List' selected and a top navigation bar with 'Back to Study Details' and 'Study Details'.

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. On the left, a navigation menu includes 'Homepage', 'IRB', 'CRMS', 'FCOI', and 'Report'. The 'CRMS' menu item is highlighted with an orange box, and its sub-item 'Study List' is selected. The main area shows a table of studies with columns for 'ECOS Ref', 'IRB', 'PI/Site-PI', 'Number of Sites', 'Study Title', and 'Action'. The first row, corresponding to study 2024-3245, is highlighted with an orange box. The table also includes a 'Rows per page' dropdown set to 100 and a pagination indicator showing '1-6 of 6'.

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	

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

Mandatory Fields for Pharmaceutical/ Industry- sponsored studies

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*).

← Back to Submission Detail Submission Detail Help [Download] [Notifications] 99+ [Profile]

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 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 print icon, 'Form Type: Application', 'Form Outcome: -', '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 'Form Detail' section is visible below. At the bottom, the 'Application Form' section contains a 'Track Changes' button, a highlighted 'Mandatory Check' button with a blue arrow pointing to it, a 'Cancel' button, a 'Save' button, and a 'Save and Exit' button. A text input field contains the study title 'Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.' with 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...'. The page footer shows the number '79'.

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 (Help, download, notification, and a '99+' badge). 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.' Another callout box with a black border is positioned below the 'CRO Details' section, containing the text: 'Data under CRO Details can be complete deleted.'

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

Study Details

Help Download Notification 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

CRMS General Page Functions

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
* 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 – Toggle between different studies

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

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

Edit

Page Functions – Toggle between different studies

Study Details

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.

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
* 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		* Singapore 654123	SGH_PI

Page Functions – Toggle between different studies

← Back to Study List

Study Details

Help

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
* 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

Page Functions – Toggle between different studies

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

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

2024-0328, Test A

2024-0214, Test B

2024-0168, Test C

2024-0050, Test D

2024-0036, Test E

Step 1: Select the study of interest.

Step 2: Select the study site.

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_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.

The screenshot displays the 'Study Details' page. At the top, a dark blue header contains a back arrow and 'Back to Study List' on the left, 'Study Details' in the center, and download, notification, and user icons on the right. Below the header is a search bar with the text '2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk'. A summary box contains the following information: 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), and Department: Department of Medicine (Singapore General Hospital), Medicine (National University Hospital). The main content area is divided into two sections: 'Sponsor Details' and 'Clinical Research Organisation (CRO) Details'. Each section has a table with columns for Name, Contact Person Name, Business Contact No., Business Email, Business Fax No., and Business Address. The 'Sponsor Details' table has one row with values: XYZ Pharmaceuticals, XYZ, 98761234, xyz@xyz.com, and Singapore 123654. The 'CRO Details' table has one row with values: AB-CRO, AB, 98762345, ab@ab.com, and Singapore 654123. An 'Edit' button is located in the top right of the main content area. On the left side, a 'Study Information' sidebar is visible, with 'Basic Information' selected. An orange box highlights this sidebar. At the bottom left of the sidebar, a small square icon is highlighted with an orange arrow. At the top center of the main content area, a small square icon with an up arrow is highlighted with a blue arrow.

< Back to Study List Study Details [Download] [Notification] [User]

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

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

[Edit]

Page Functions – Expand

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

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		* 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 an orange arrow. The table also includes 'Save' and 'Cancel' buttons at the top right.

- 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 'Add' twice. The table now has three rows:

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

The two new rows are highlighted with a blue border. The 'Add' button is still visible at the top right.

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**.

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

Study Details

Help

Save Cancel

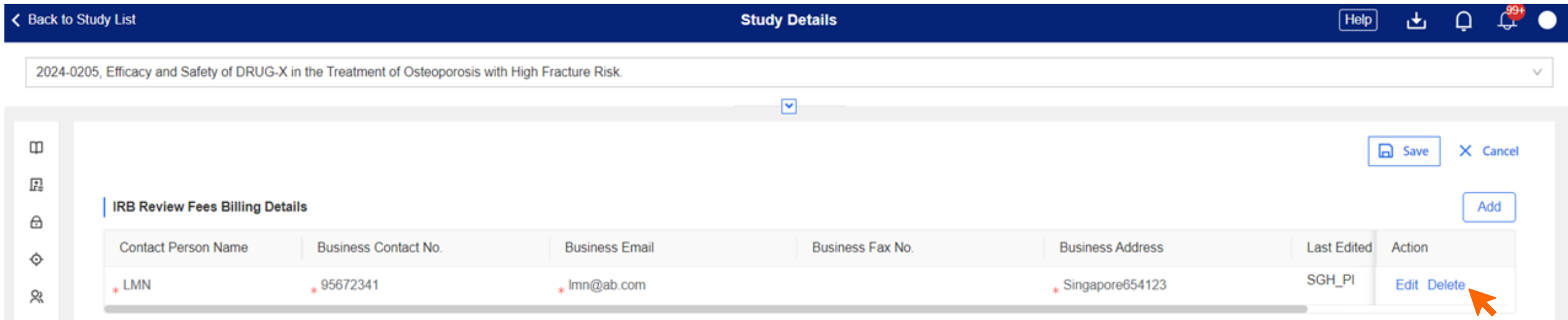
Clinical Research Organisation (CRO) Details

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Li	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	* <input type="text"/>	* 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.

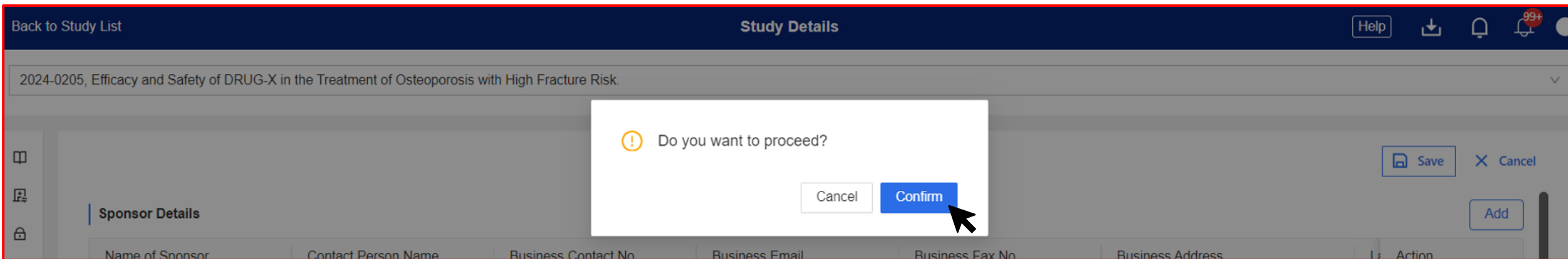


The screenshot shows the 'Study Details' page for study 2024-0205. The 'IRB Review Fees Billing Details' section contains a table with the following data:

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 first row. The 'Save' and 'Cancel' buttons are visible in the top right corner of the table area.

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



The screenshot shows the same 'Study Details' page, but 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. The background is dimmed, and the 'Sponsor Details' section is visible below the dialog box.

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.

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

Study Details Help Download Notifications 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
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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.

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

Study Details

Help

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	Last Edited By	Last Edited Date
Add New Data	Add New Data	Add New Data	Add@New.Data	Add New Data	Add New Data	SGH_PI	14-Mar-2024
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 6		

IRB Review Fees Billing Details

Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited By	Last Edited Date
Add New Data	Add New Data	Add New Data	Add New Data	Add New Data	SGH_PI	14-Mar-2024
Add New Data	Add New Data	Add New Data	Add New Data	Add New Data	SGH_PI	14-Mar-2024
				Singapore 654123	SGH_PI	23-Jan-2024

Business Fax No. Business Address Last Edited By Last Edited Date

New Data * Singapore 123654 SGH_PI 14-Mar-2024

Business Fax No. Business Address Last Edited By Last Edited Date

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

s Fax No. Business Address Last Edited By Last Edited Date

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**.

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	Li	Action
* XYZ Pharmaceuticals	* XYZ	* 98761234	* xyz@xyz.com	Data Deleted	* Singapore 123654	S	Cancel

- The deleted action reversed, original data reverted.

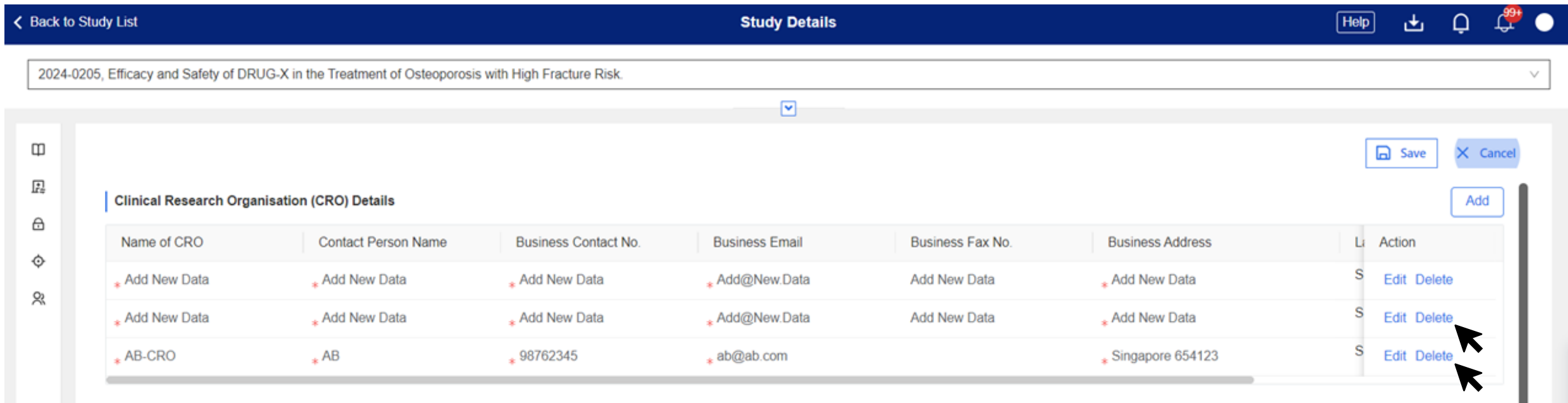
Sponsor Details Add

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

Data Reverted

Page Functions – Cancel

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



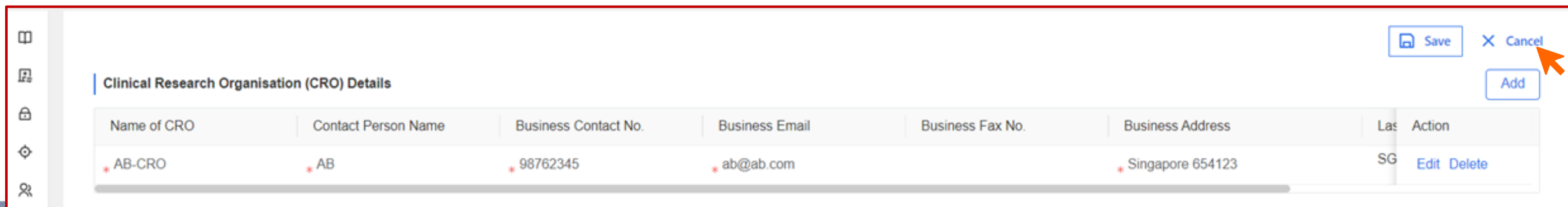
2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk

Save Cancel Add

Clinical Research Organisation (CRO) Details

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

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



Save Cancel Add

Clinical Research Organisation (CRO) Details

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

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

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
* 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-11	Col	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_Co-11@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@sg.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-11	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. A 'Filter' dialog box 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 background shows a table with columns: Member Name, Role, Cluster, Institution, and Department. Two rows are visible: SGH_PI1 (PI) and SGH_Co-11 (Col).

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.

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-11	Col	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_Co-11@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-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	Col	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: Member Name, Role, Cluster, and Institution. The table contains two rows of data:

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

A 'Column' selection modal is open, showing a list of columns with checkboxes. The modal title is 'Column' and it indicates 'Selected 15'. The columns listed are:

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

Four orange arrows point to the 'Cluster', 'Department', 'Designation', and 'Email Address' checkboxes, indicating they are to be unchecked. A callout box on the right contains the following text:

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	Deactivate
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.

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	Deactivate
SS_20	Study Sponsor	Astra Zeneca	CRMS	● Pending Endorsement	-	-	-	-	SGH_Co-I1	24-Jan-2024	

Rows per page: 100 1-4 of 4

Step 1: Click Add.

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-11	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 :

 Search

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

Total Rows: 1

* Role :

Step 3: Click the Search icon.

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

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-11	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.

← Back to Study List Study Details Help 1 99+

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	Deactivate
SGH_STM22	Study Team Member	Singapore General Hospital (SGH)	CRMS	● Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	Deactivate
SS_20	Study Sponsor	Astra Zeneca	CRMS	● Pending Endorsement	-	-	-	-	SGH_Co-I1	24-Jan-2024	

Page Functions – 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

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	Col	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
SGH_STM22	Study Team Member	Singapore General Hospital (SGH)	CRMS	● Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	Deactivate
SGH_SA22	Study Administrator	Singapore General Hospital (SGH)	CRMS	● Pending Endorsement	-	-	-	-	SGH_RO1	07-Mar-2024	
SS_20	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
SGH_SA22	Study Administrator	Singapore General Hospital (SGH)	CRMS	● Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	Deactivate
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_Co-I1	CoI	Singapore General Hospital (SGH)	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	CRMS	● Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	Deactivate
SGH_STM22	Study Team Member	Singapore General Hospital (SGH)	CRMS	● Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	Deactivate
SS_20	Study Sponsor	Astra Zeneca	CRMS	● Pending Endorsement	-	-	-	-	SGH_Co-I1	24-Jan-2024	

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
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_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
SGH_STM22	Study Team Member	Singapore General Hospital (SGH)	CRMS	● Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	
SS_20	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)

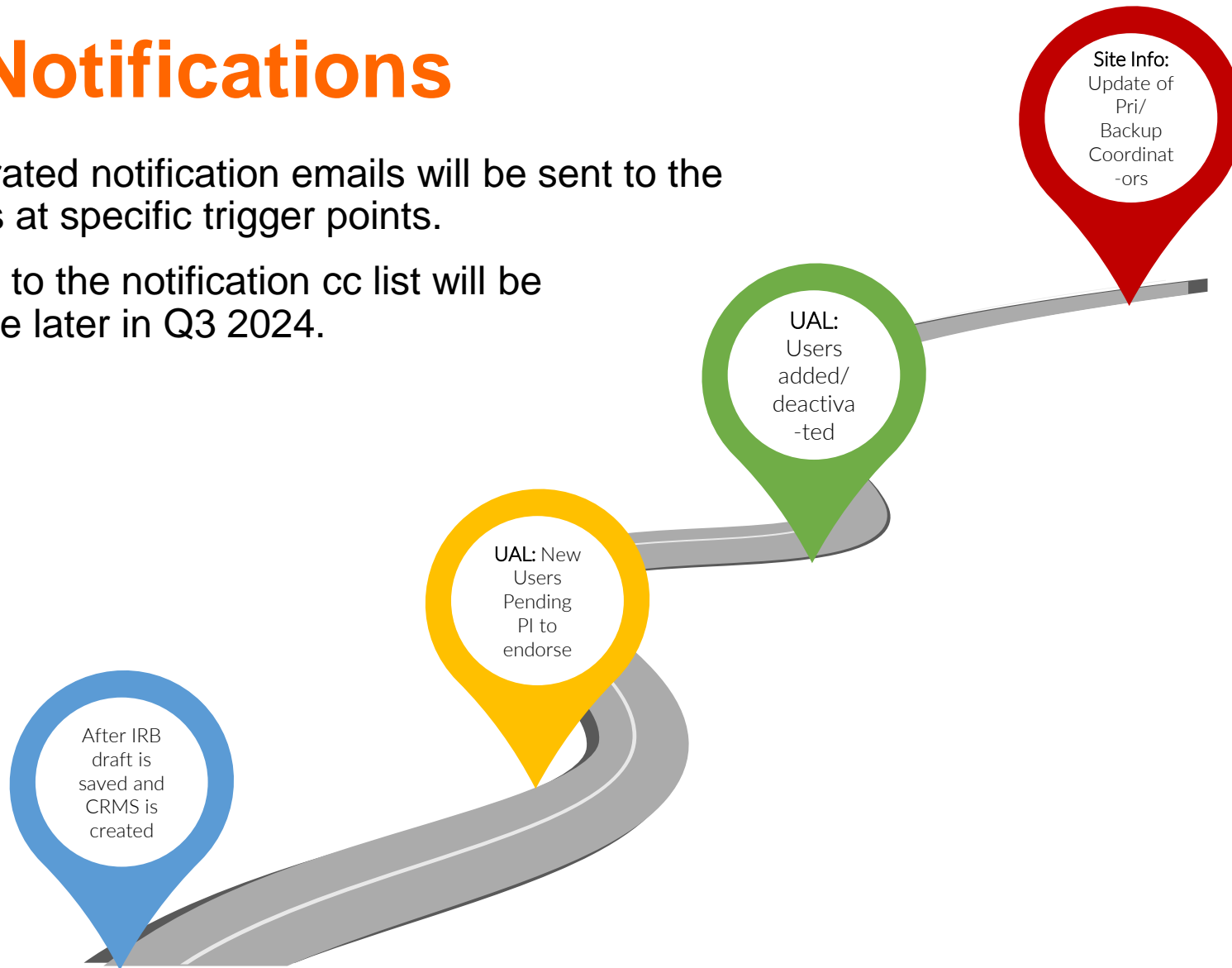
User Authorisation List

[+ 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	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	

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.





This option may be available in Q3 2024.

CRMS Report

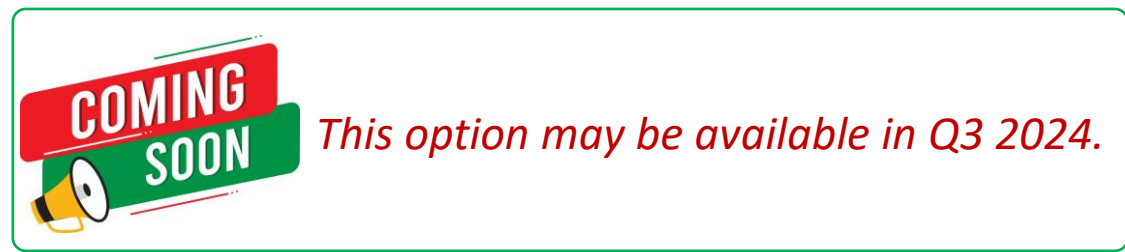
- Reports can be generated from CRMS to fulfil any periodic or KPI reporting at the institution level.
- Reports generated will include all data except for new data entered on the day itself.
- CRMS Report section can only be accessed by selected roles.

ECOS CRMS Institution Report Help Download Notifications Filter(1)

Columns Export Filter(1)

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

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



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.