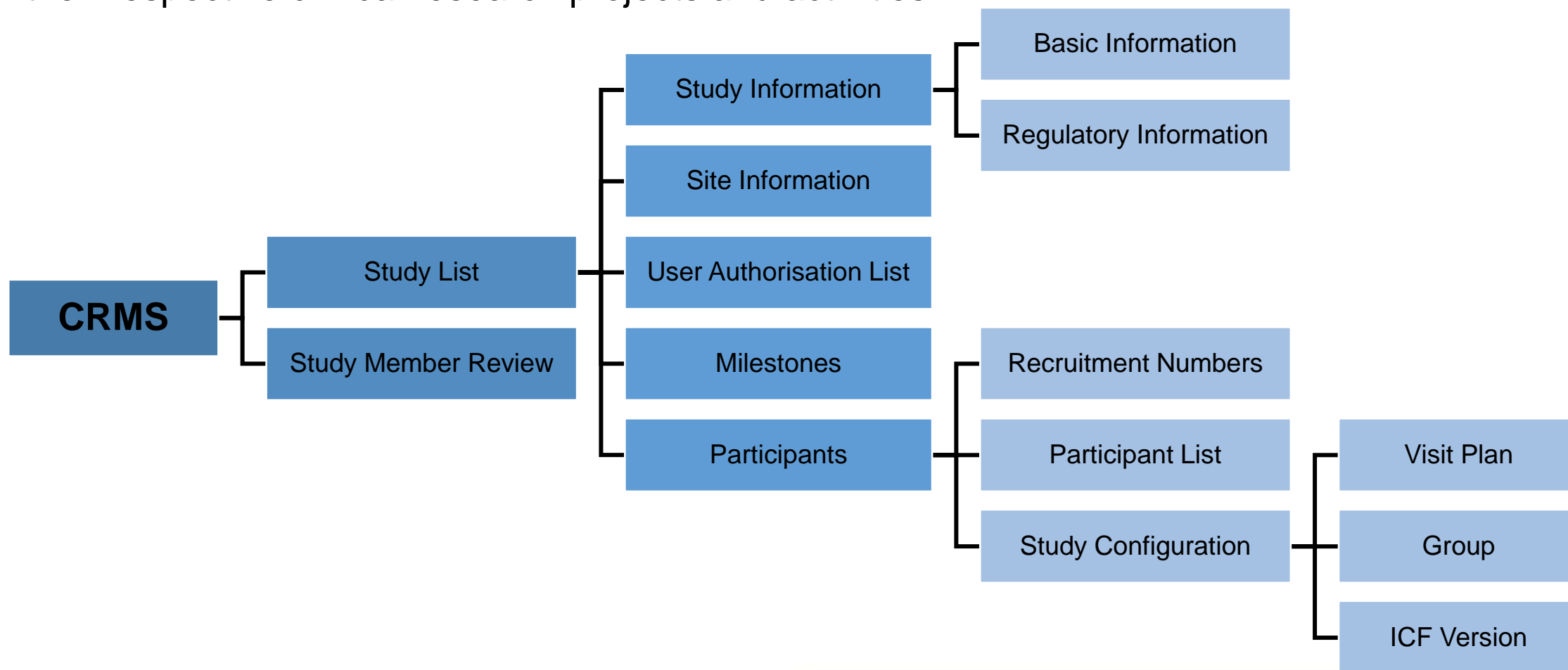


Navigating the New IT Platform:

ECOS – Clinical Research Management System (CRMS)

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.



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- User Access Matrix – [Slide 5](#)
- CRMS Page Level – [Slide 9](#)
- CRMS Access – [Slide 11](#)
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 - Study List – [Slide 15](#)
 - Study Information - Basic Information – [Slide 18](#)
 - Study Information - Regulatory Information – [Slide 22](#)
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 - Participants - Study Configuration – [Slide 52](#)
 - Study Member Review – [Slide 58](#)



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

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- In-built Logic Checks for Basic Information – [Slide 66](#)
- Addition of STM/SA/SS to the User Authorisation List by the System – [Slide 75](#)
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- Email Notifications – [Slide 124](#)
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- Migration of Existing Studies – [Slide 131](#)
- FAQ: Do I Add Everyone on the Delegation Log to the UAL? – [Slide 133](#)
- FAQ: Is CRMS Mandatory? – [Slide 137](#)



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

User Access Matrix

User Access Matrix

- Different user roles will have different levels of access to CRMS.
- Once a user has been added in the IRB **Application** Form or CRMS User Authorisation List, the user will gain immediate access to a limited number of pages, i.e. limited access.
- The newly added users will then require IRB's approval or PI's endorsement in CRMS to gain full access to CRMS.
 - **Exception:** Research Office administrators assigned with the CRMS RO role (*Please refer to the section CRMS RO Role – [Slide 129](#)*).
- For new investigators (i.e. PI, Site-PI, Co-I) added in the IRB **Amendment** Form, full CRMS access will be granted after IRB has provided approval. New investigators pending IRB approval will not have any access to the CRMS.

User Access Matrix

IRB Application Form

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

Legend

- ✓ Access (View & Edit) granted upon the addition of user on the IRB Application Form or User Authorisation List.
- ✓ Access (View & Edit) granted after IRB's approval or PI's endorsement in CRMS.
- ✓ Access (View & Edit) granted without any approval or endorsement required.

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

User Access Matrix

IRB Amendment Form

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

Legend

- ✓ Access (View & Edit) granted upon the addition of user on the User Authorisation List.
- ✓ Access (View & Edit) granted after IRB's approval or PI's endorsement in CRMS.
- ✓ Access (View & Edit) granted without any approval or endorsement required.

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

CRMS Page Level

CRMS Page Level

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

Study Level

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

Site Level

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

CRMS Access

CRMS Access

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

The screenshot shows the ECOS Dashboard interface. The top navigation bar is dark blue with the ECOS logo, the word 'Dashboard', and icons for Help, a download button with a red '1' badge, a notification bell with a red '99+' badge, and a profile icon. 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 displays three summary cards: IRB (27 total, with 25 Studies and 2 Endorsements), CRMS (12 total, with 12 Study Members and 12 Reviews), and FCOI (0 total, with 0 My FCOI List items). A 'My Notices' section on the right shows a dashboard notice for all dated 31-Jan-2024. Two callout boxes provide instructions: 'Step 1: Click to release dropdown menu.' points to the CRMS menu item, and 'Step 2: Click to see the list of studies available.' points to the Study List menu item.

ECOS Dashboard

Help 1 99+

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

IRB 27
Study 25
Endorsement 2

CRMS 12
Study Member 12
Review

FCOI 0
My FCOI List 0

My Notices View All >
Dashboard notice for all
31-Jan-2024

Step 1: Click to release dropdown menu.

Step 2: Click to see the list of studies available.

CRMS Access



This option may be 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

2024-0205-APP1

Draft

Declare and Submit

ECOS Ref: 2024-0205

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

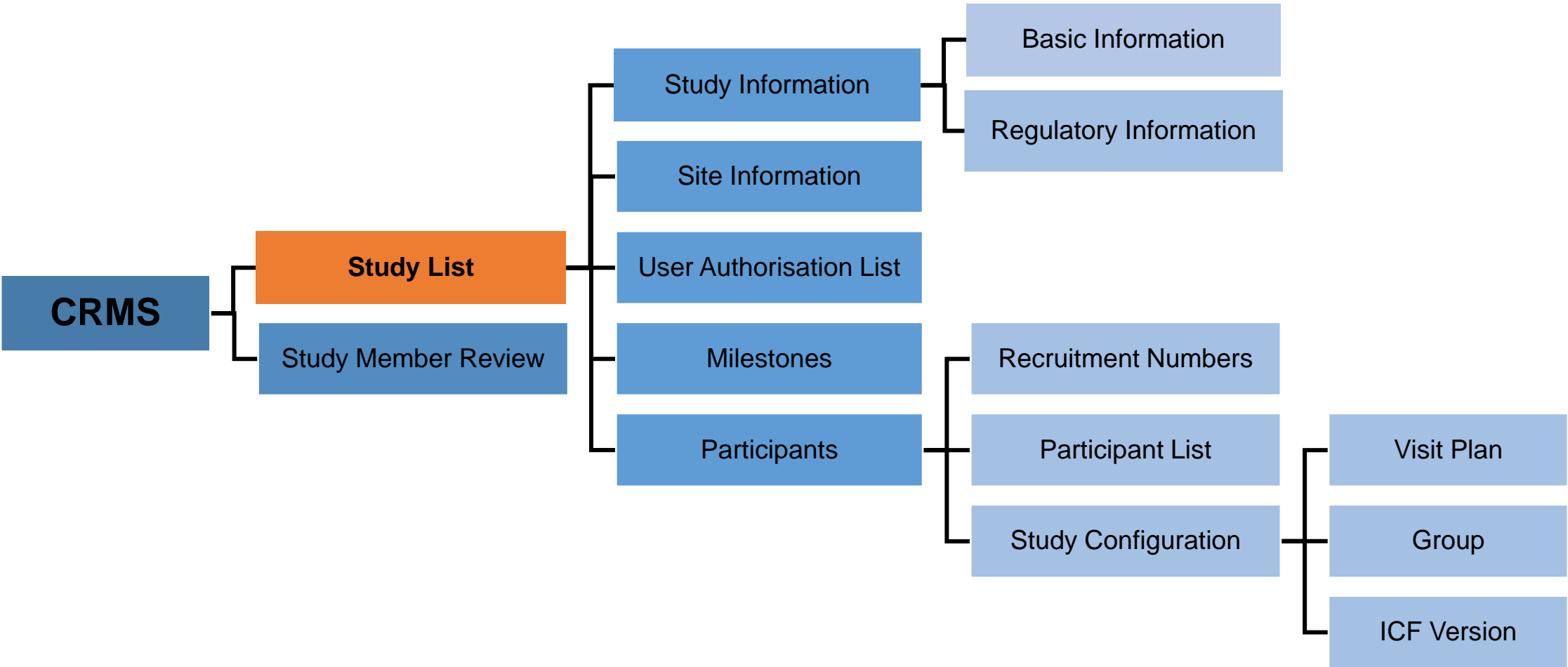
Edit

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

Section A: Study Title

CRMS Pages and Data Fields

CRMS Sitemap



Study List

- The Study List will only display the studies where a user has been added to the IRB forms or User Authorisation List.
 - **Exception: CRMS RO administrators** (*Please refer to the section CRMS RO Role – [Slide 129](#)*).
- A new study will be created in CRMS once the IRB Application Form draft is saved for the first time.
- Relevant information from the IRB Application or Amendment Forms will be synced to CRMS, which are:
 - Study details (e.g. study title, study sites, etc.) to the Study List.
 - List of Investigators added to the IRB form to the User Authorisation List.
- Synchronisation points:
 - Upon saving the IRB Application Form.
 - Upon IRB approval or acknowledgement.



No information will flow from CRMS to IRB module.

Study List

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

Data Columns

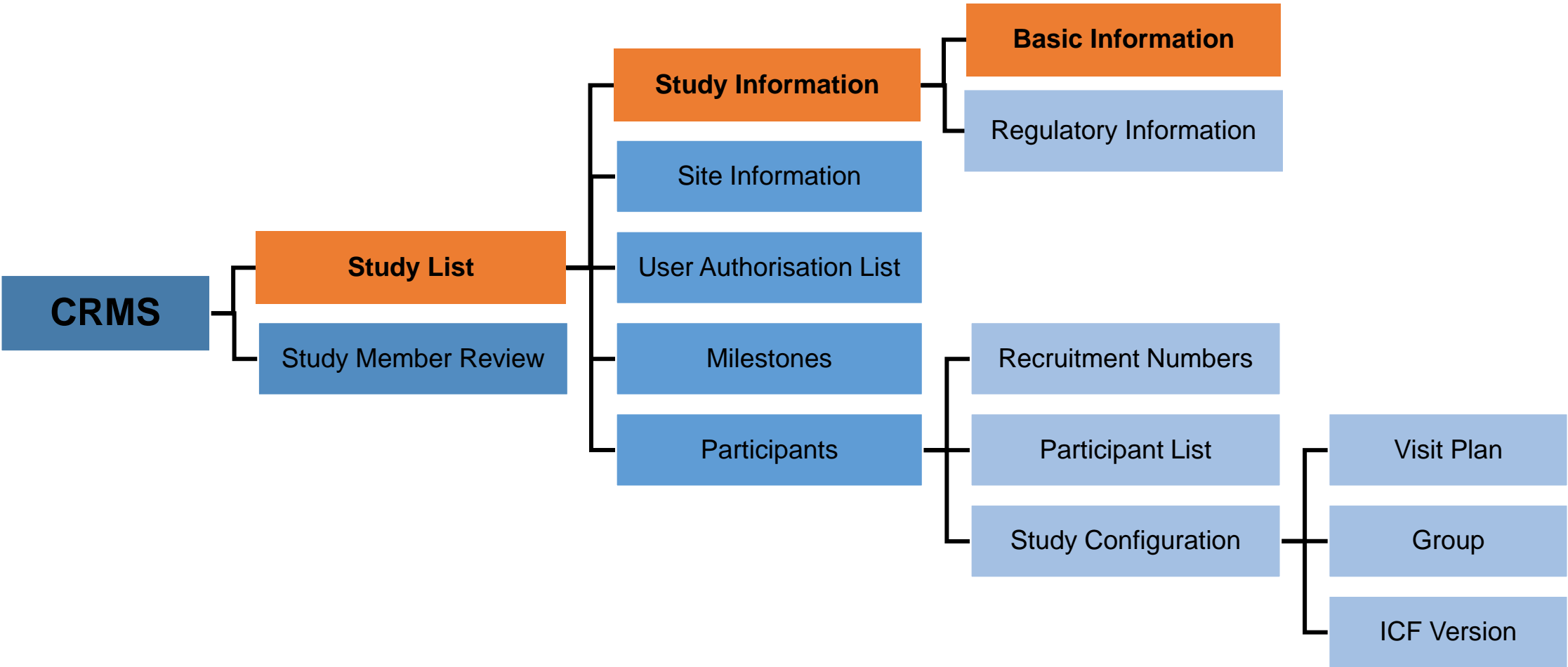
- ECOS Ref
- IRB
- PI/Site-PI
- Department
- Number of Sites
- Study Title
- Study Status
- Initial Outcome Date
- Valid Till Date

The screenshot shows the ECOS Study List interface. The left sidebar contains navigation links: Homepage, IRB (selected), Submission List, Endorsement, My Study List, CRMS, Study List (highlighted), Study Member Review, and FCOI. 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 '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 'View' 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, it shows "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 or IRB billing details can be done via CRMS without submitting an IRB Amendment form.

Study Information – Basic Information

Study Level

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	
<div>XYZ Pharmaceuticals</div>	<div>XYZ</div>	<div>98761234</div>	<div>xyz@xyz.com</div>		<div>Singapore 123654</div>	

Clinical Research Organisation (CRO) Details

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

IRB Review Fees Billing Details

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

Edit

SingHealth Version 1.0 Dated 06 May 2024

20

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.

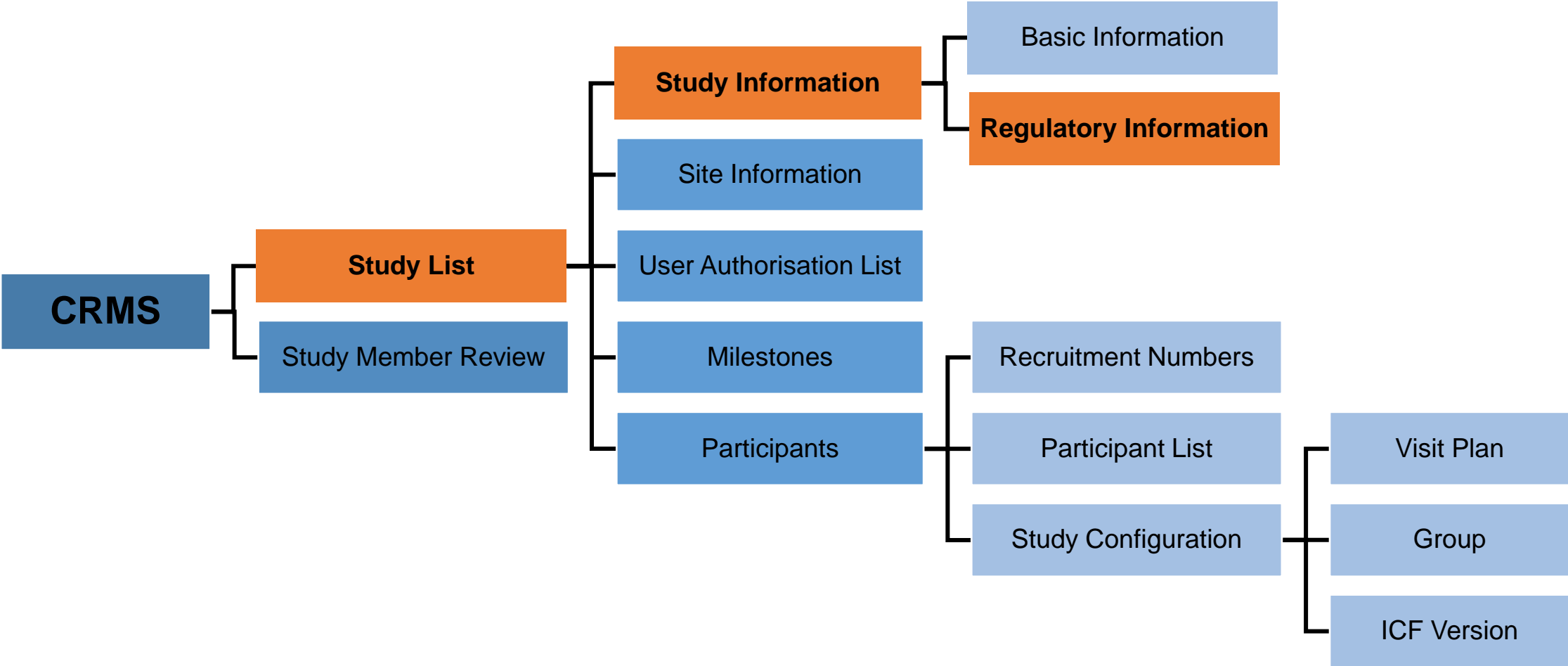
IRB Review Fees Billing Details

- 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

- Allows user to document the HSA and/or MOH submission(s) and approval(s).

< Back to Study List

Study Details

Help

99+

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

ECOS Reference: 2024-0205

IRB: CIRB Board D

Study Status: • Draft

Number of Sites: 2

Initial Outcome Date: -

Valid Till Date: -

PI/Site PI: Dr SGH_PI (Singapore General Hospital), Prof NUH_PI (National University Hospital)

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

Study Information

Basic Information

Regulatory Information

User Authorisation List

Clinical Trials Regulated by HSA

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

Clinical Research Material (CRM)

Name(s) of CRM(s)	Type(s) of CRM	Type of CRM Submission	Submissi
* Drug-X	* Therapeutic Product/CTGTP ▾	* CRM Notification ▾	* 20A0

Restricted Human Biomedical Research

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

Export

Edit

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:

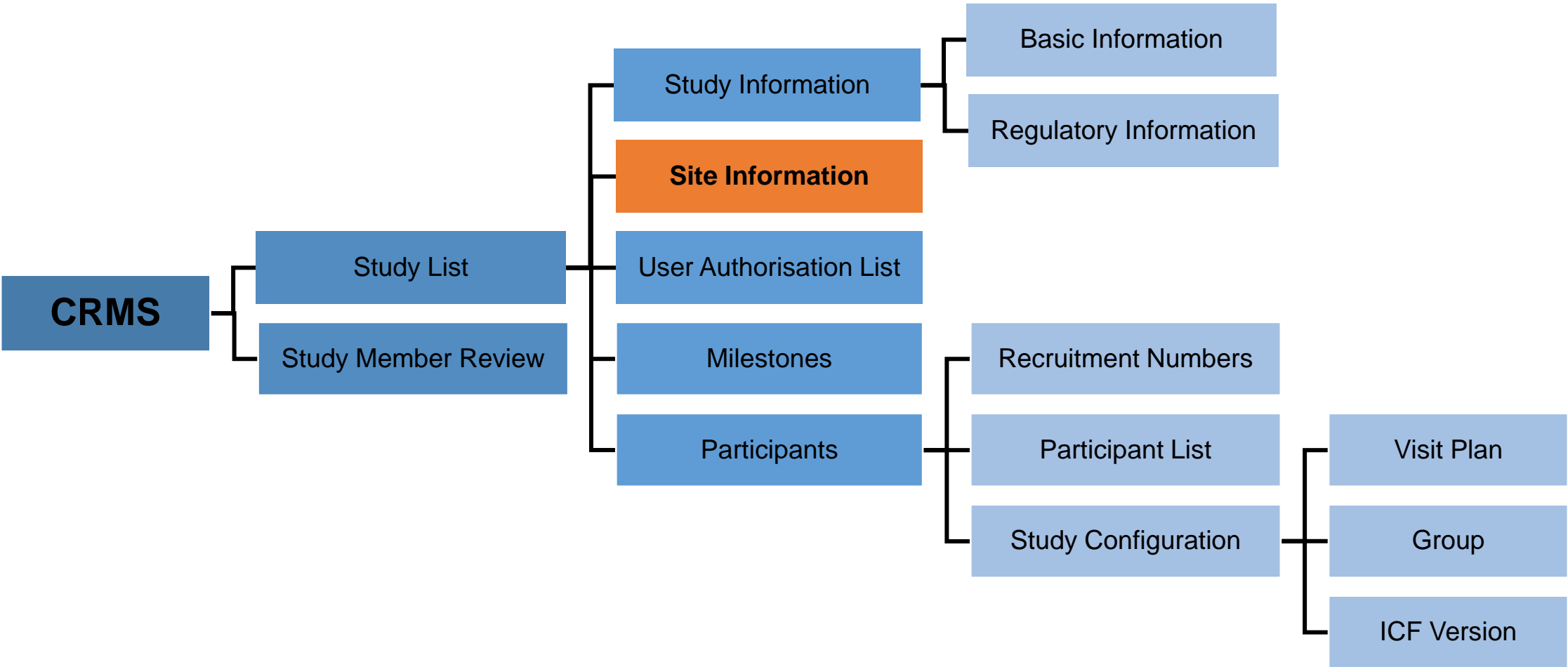
Restricted Human Biomedical Research				
MOH Application No.	MOH Submission Date	MOH Reference No.	MOH Approval Date	MOH Expiry Date
* RR-20239999-0909	* 02-Jan-2023 	RR-2023/09	24-Jan-2023 	23-Jan-2024
* RR-20239999-0909	* 13-Dec-2023 	RR-2023/09	09-Jan-2024 	08-Jan-2025

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.

Back to Study List

Study Details

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

Contact Personnel

Primary Site Coordinator	Backup Site Coordinator	Last Edited By	Last Edited Date
SGH_SA1	SGH_PI,SGH_Co-11	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
------------------------------	------------------	-------	----------------------

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

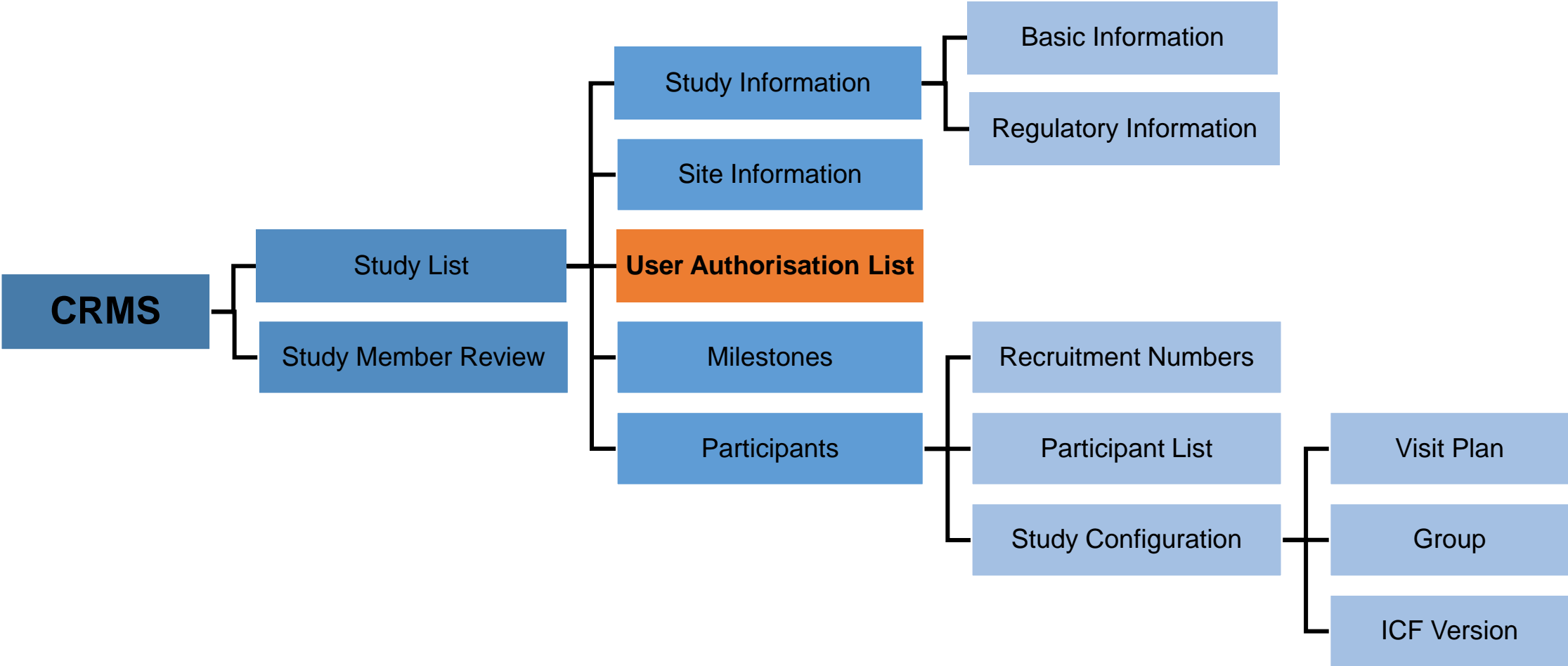
- Sponsor/CRO Name
- Total Estimated Budget of Contract
- Date of Information Received To Start Drafting Budget
- Date of Budget First Sent to Sponsor/CRO
- Date of Budget Finalisation/ Agreement
- Date of Contract Template Received From Sponsor/CRO
- Date of Contract Finalisation/ Agreement By All Parties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

Site Level

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

User Authorisation List (UAL)

Site Level

Below are the data columns found on this page:

User Authorisation List

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

User Authorisation List (UAL)

Site Level

Role	CRMS Access Rights	Comments
PI, Site PI & Co-I Site investigators directly involved in the research.	<ul style="list-style-type: none"> View & edit rights. <p>User added to IRB <u>Application</u> 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 to IRB <u>Amendment</u> 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. The list of investigators will be imported from the IRB to CRMS module at each synchronisation point (as applicable) with IRB indicated as the data source. IRB approval is required to gain full CRMS access. Further addition and deactivation will both go through the IRB module. <p>During IRB <u>Application</u> 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 <u>Amendment</u> 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
Study Team Member (STM) Site personnel <u>directly involved</u> in the research conduct e.g. CRCs, Study Nurses, Pharmacists, etc.	<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 	Access management: <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 to the UAL is not capped, but please be mindful when performing this task as every addition and deactivation will be captured on this list. Site will need to manage and keep the UAL updated, i.e. STM/SA/SS(s) no longer directly involved in the study should be deactivated for access to IRB and CRMS modules to be revoked (to protect study data confidentiality).
Study Administrator (SA) 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.		
Study Sponsor (SS) Sponsor/CRO personnel, e.g. CTAs, CRAs, CTMs etc.	<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 UAL primarily functions to manage the access of **STM**, **SA** and **SS** to the CRMS and/or IRB modules on ECOS.
- This is one of the harmonised processes between 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.



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

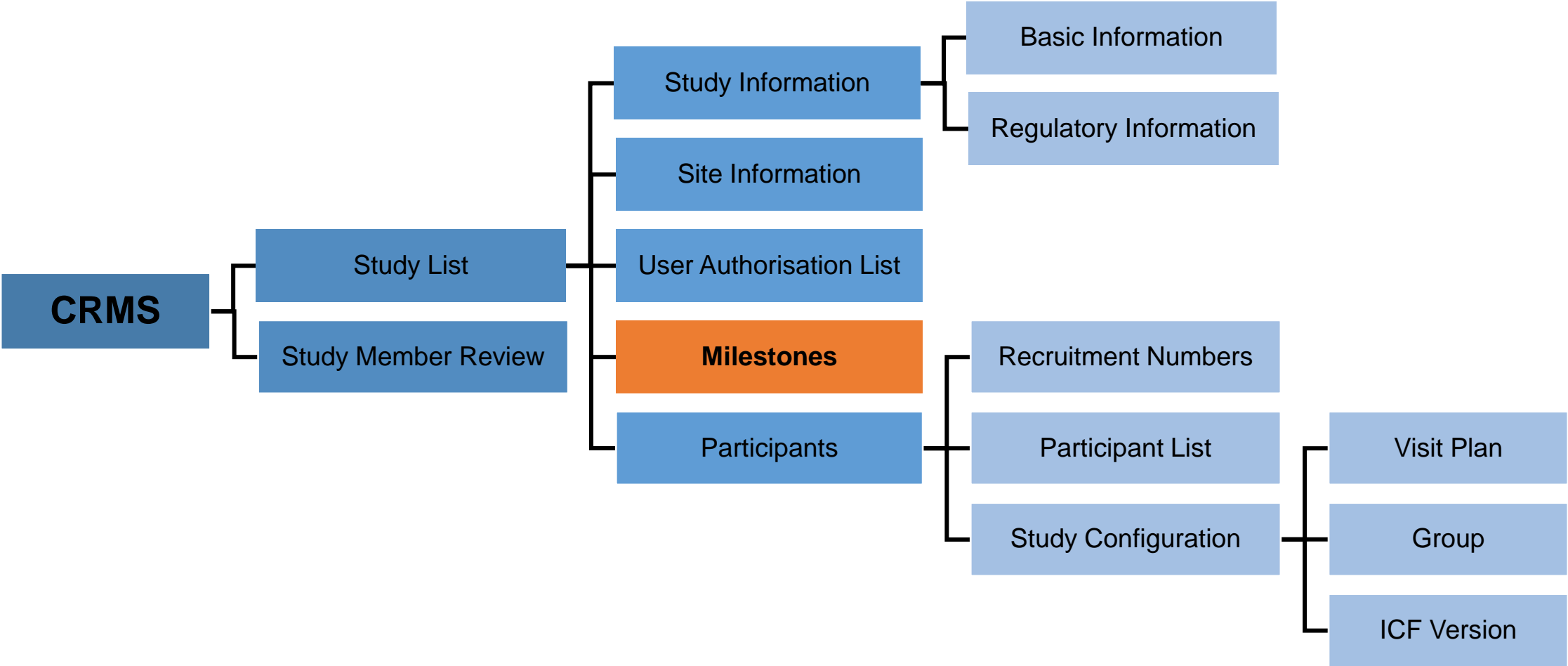
User Authorisation List (UAL)



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

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

CRMS Sitemap



Milestones

Site Level

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

Back to Study Details

Study Details

Help

99+

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

ECOS Reference: 2024-0205

IRB: CIRB Board D

Study Status: Approved

Number of Sites: 2

Initial Outcome Date: 24-Jan-2024

Valid Till Date: 23-Jan-2025

PI/Site PI: Dr SGH_PI (Singapore General Hospital), Prof NUH_PI (National University Hospital)

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

Study Information

Basic Information

Regulatory Information

Site Information

User Authorisation List

Milestones

Participants

+ Add

Columns

Export

Filter

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:

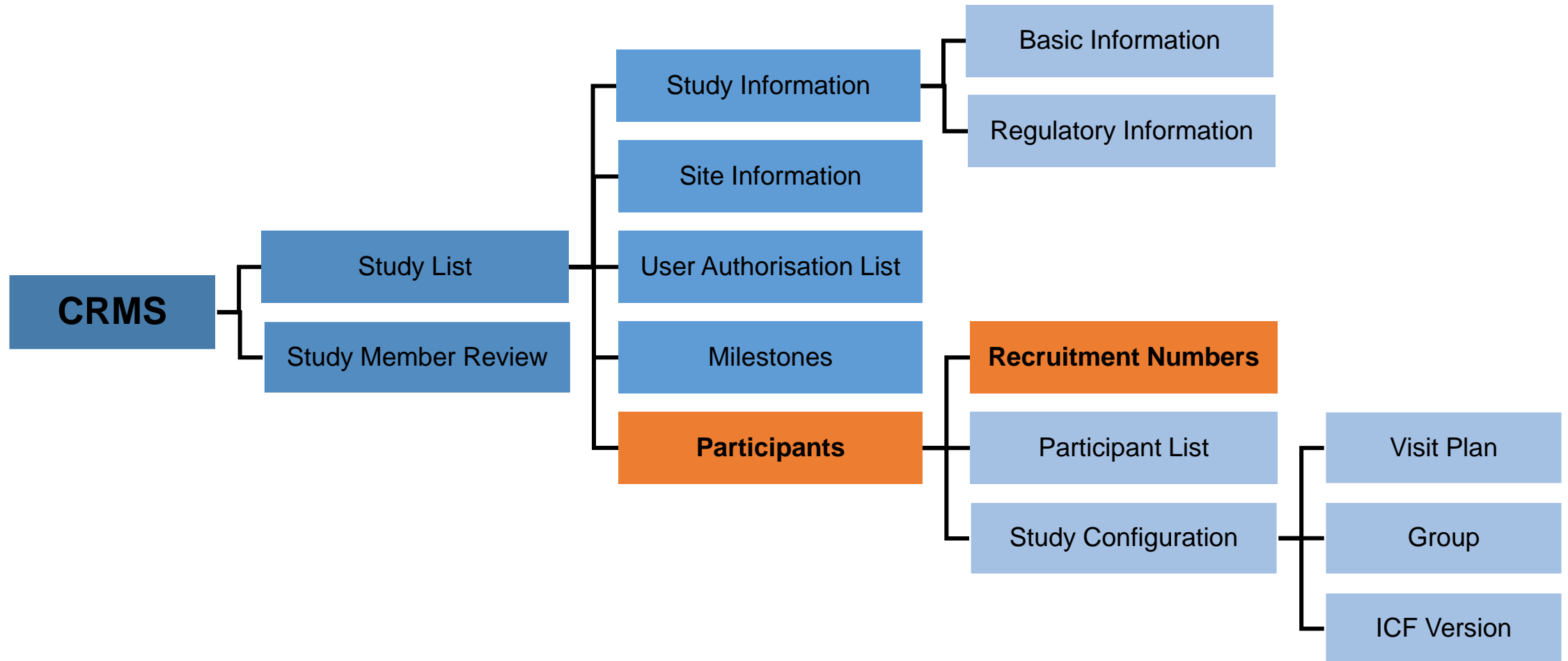
- Use the “Other” option to create unique milestones not part of the dropdown list, e.g. 50% Recruitment Target.
- Once an entry is created and saved, it cannot be deleted.



Use the Milestones page as a Project Management Tool!

Apply reverse planning and achieve your end goal in time, e.g. completion of research before the grant expiry date.

CRMS Sitemap



Participants – Recruitment Numbers

Site Level

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

Back to Study Details

Study Details

Help

Download

Notifications

99+

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

ECOS Reference: 2024-0205

IRB: CIRB Board D

Study Status: Approved

Number of Sites: 2

Initial Outcome Date: 24-Jan-2024

Valid Till Date: 23-Jan-2025

PI/Site PI: Dr SGH_PI (Singapore General Hospital), Prof NUH_PI (National University Hospital)

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

Study Information

Basic Information

Regulatory Information

Site Information

User Authorisation List

Milestones

Participants

Recruitment Numbers

Participant List

Study Configuration

Export

Edit

Recruitment Target Approved in IRB Study: 2-2

Current Recruitment Summary

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

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

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

SingHealth Version 1.0 Dated 06 May 2024

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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.

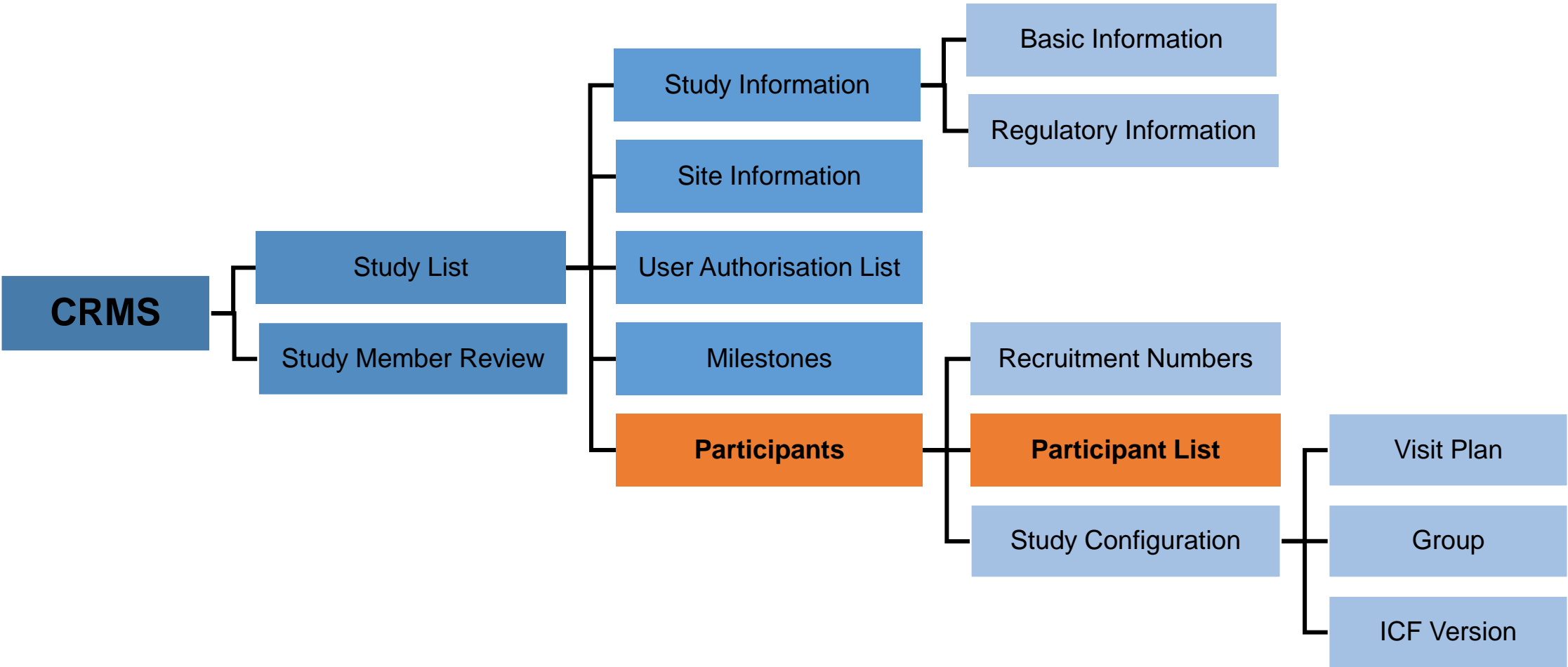
Current Recruitment Summary ⓘ

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
- **REMINDER:** PI/Site-PI should submit a Study Deviation/Non-Compliance report form to IRB should the actual recruitment number exceeds the IRB-approved figure. At the same time, please raise an IRB Amendment Form to increase the target number.

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)

Study Information

Basic Information

Regulatory Information

Site Information

User Authorisation List

Milestones

Participants

Recruitment Numbers

Participant List

Study Configuration

+ Add

Columns

Export

Filter

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

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

[< Back to Study Details](#)Participant DetailsHelp

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

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

Participants – Participant List

Site Level

Below are the data fields found on this page:

Visit Plan

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

Note:

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

[Back to Study List](#)

Participant Details

HelpDownloadNotifications99+

CRMS / Study List / Study Details / Participant Details

Please do not enter participant identifiers in CRMS.

Screening Number: SGH_SCR01

Enrolment Number: SGH_X01

Edit

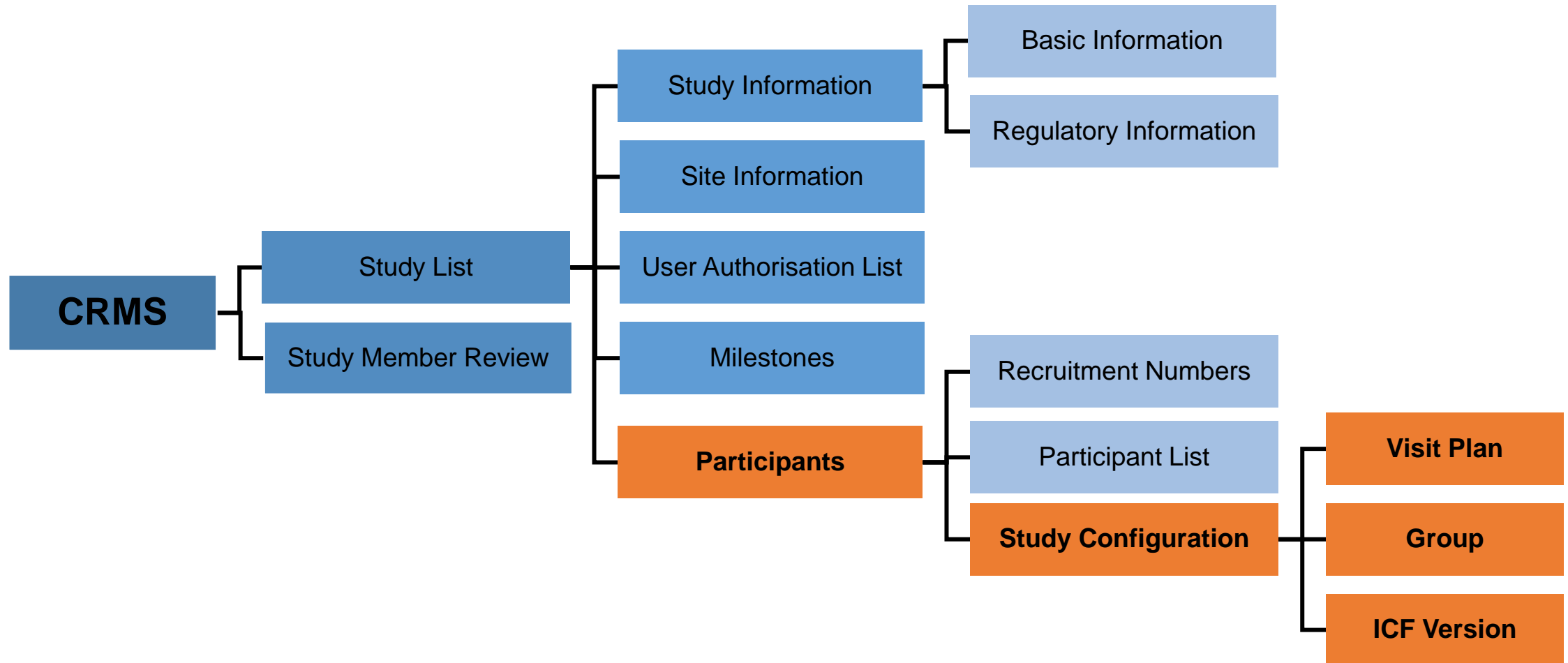
TOP TIPS

Study Team can use this to plan the participant's next visit!

Basic InformationICFVisit Plan

No.	Visit Plan	Visit Name	Planned Visit Date	Actual Visit Date	Last Edited By
1	* Drug-X (Single Arm) ▾	* Month 3 ▾	07-May-2024 📅	Select date 📅	SGH_PI
2	* Drug-X (Single Arm) ▾	* Month 1 ▾	12-Mar-2024 📅	12-Mar-2024 📅	SGH_PI
3	* Drug-X (Single Arm) ▾	* Week 2 ▾	27-Feb-2024 📅	28-Feb-2024 📅	SGH_PI
4	* Drug-X (Single Arm) ▾	* Week 1 ▾	20-Feb-2024 📅	20-Feb-2024 📅	SGH_PI
5	* Drug-X (Single Arm) ▾	* Day 1 ▾	23-Feb-2024 📅	13-Feb-2024 📅	SGH_PI
6	* Drug-X (Single Arm) ▾	* Screening ▾	26-Jan-2024 📅	26-Jan-2024 📅	SGH_PI

CRMS Sitemap



Participants – Study Configuration

Site Level

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

The screenshot shows the 'Study Details' page for the study '2024-0205, Efficacy and Safety of Drug-X in the Treatment of Osteoporosis with High Fracture Risk / Singapore General Hospital (SGH)'. The left sidebar contains a menu with 'Study Configuration' highlighted. The main content area shows 'Visit Plan', 'Group', and 'ICF Version' as configuration options. A red box with an 'IMPORTANT' banner contains the text: 'There is no flow of information from the IRB module to any of the Study Configuration pages in CRMS.'

< Back to Study Details Study Details

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

+ Add

IMPORTANT

There is no flow of information from the IRB module to any of the Study Configuration pages in CRMS.

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.

[< Back to Study List](#)Study Details



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

+ Add

Drug-X (Single Arm)

Last Edited By: SGH_SA1 | Last Edited Date: 26-Jan-2024 10:03:05

Edit

Visit Name	Visit Status	Remarks
Screening		-
Day 1		First dosing day.
Week 1		-
Week 2		-
Month 1		-
Month 3		-
Month 6		-

Visit Plan Name

Participants – Study Configuration

Site Level

The screenshot shows the 'Study Details' page for the study '2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital'. The left sidebar contains navigation options: Visit Plan, Group (selected), and ICF Version. The main area displays a table of groups with columns: Group, Group Status, Remarks, Last Edited By, Last Edited Date, and Action. One group is listed: 'Drug-X Group' with status 'active', remarks 'Single arm study.', last edited by 'SGH_SA1', and last edited date '26-Jan-2024'. The table has a '+ Add' button and 'Columns' and 'Filter' options. The bottom of the table shows '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	Edit

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

[< Back to Study Details](#)Study DetailsDownloadNotificationMenu

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

Visit Plan

Group

ICF Version

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

Rows per page: 100 1-4 of 4

Note:

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

Participants – Study Configuration

Site Level

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

The image displays three screenshots of the study configuration interface, illustrating how to inactivate entries.

Visit Plan: The 'Visit Plan' tab is selected. A table lists visits. The 'Visit Status' column has a toggle switch. A hand icon points to the toggle switch for 'Day 1', which is currently set to 'Active' (blue). The 'Remarks' column shows 'First dosing day'.

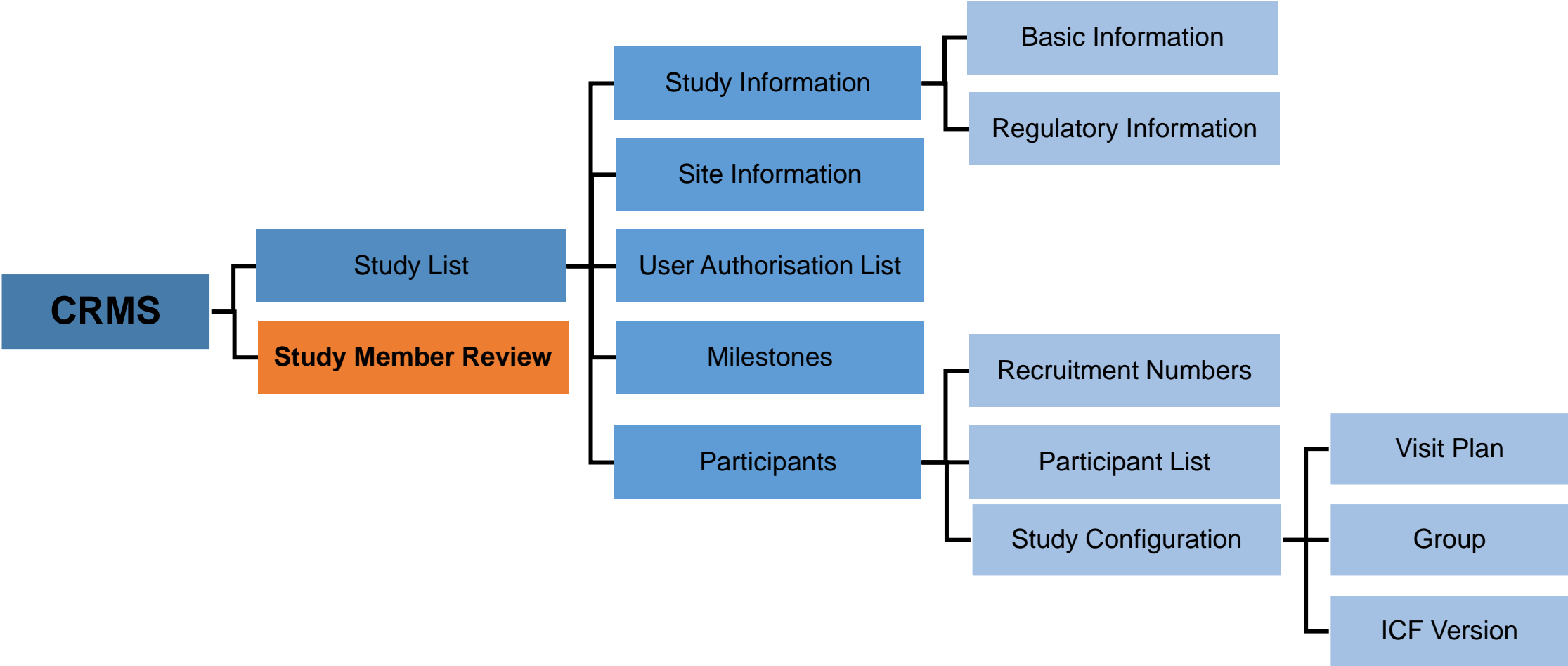
Group Configuration: The 'Group Configuration' tab is selected. The 'Group' field is 'Drug-X Group'. The 'Group Status' dropdown menu is open, showing 'Active' (selected) and 'Inactive' options. A hand icon points to the 'Inactive' option.

ICF Version: The 'ICF Version' tab is selected. The 'ICF Name, Version, Date and Language' field is 'Drug-X ICF (SGH)_Version 1.1 dated 25 Dec 2023_English'. The 'IRB Approval Date' is '24-Jan-2024'. The 'Regulatory Approval Date' is '22-Jan-2024'. The 'Status' dropdown menu is open, showing 'Active' (selected) and 'Inactive' options. A hand icon points to the 'Inactive' option.

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

The image shows a search bar for the 'Visit Plan' section. The search bar is empty, and the results area below it displays 'No item' in orange text.

CRMS Sitemap



Study Member Review

Site Level

- PI/Site-PIs can access the Study Member Review Page by 2 ways:

1. Via Dashboard > CRMS Tile > Study Member Review

The screenshot shows the ECOS Dashboard interface. On the left is a navigation sidebar with links to Homepage, Dashboard (highlighted with an orange box), My Tasks, My Notices, IRB, CRMS, FCOI, and Report. The main dashboard area features several tiles: IRB (30), CRMS (11), and FCOI (0). The CRMS tile has a sub-link 'Study Member Review 11' highlighted with a blue box and an orange arrow. A blue arrow points from a text box to the CRMS tile. On the right is a 'My Notices' section with a 'View All' link. A text box with an orange border explains that clicking the 'Study Member Review' link will bring the user to the My Task page.

ECOS Dashboard

IRB 30

Study	28
Endorsement	2

CRMS 11

[Study Member Review 11](#)

FCOI 0

My FCOI List 0

My Notices [View All >](#)

- uat test-20240131
31-Jan-2024
- UAT - Dashboard notice for all
30-Jan-2024

The number on the CRMS Tile indicates the total number of users pending endorsement by PI/Site-PI.

Clicking this will bring the PI/Site-PI to the My Task page.

Study Member Review

Site Level

ECOS

My Tasks

Help

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

Help

Homepage

IRB

CRMS

Study List

Study Member Review

FCOI

Report

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	<div>Pending Endorsement</div>

Step 1: Check the box.

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

Study Member Review Access


Site Level

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




The screenshot displays the ECOS Dashboard interface. The top navigation bar is dark blue with the ECOS logo on the left and the word 'Dashboard' in the center. On the right side of the top bar are icons for a download, a notification bell with a red '99+' badge, and a user profile icon. The left sidebar contains a list of navigation items: 'Homepage', 'Dashboard' (highlighted in light blue), 'My Tasks', 'My Notices', 'IRB', 'CRMS', 'Study List', 'Study Member Review' (highlighted in light blue with an orange arrow pointing to it), and 'FCOI'. The main content area features three large white cards: 'IRB' with a large '8' and a table showing 'Study' (8) and 'Endorsement' (0); 'CRMS' with a large '3' and a table showing 'Study Member Review' (3); and 'FCOI' with a large '0' and a table showing 'My FCOI List' (0). To the right of these cards is a 'My Notices' section with a 'View All' link and a notice: 'Dashboard notice for all' dated '07-Apr-2024'. An orange callout box with a black border points to the 'Study Member Review' link in the sidebar, containing the text: 'Click to enter the Study Member Review page.'


Study Member Review Access


Site Level




Study Member Review




 Homepage


 IRB

 CRMS

Study List

Study Member Review

 FCOI

 Report

2024-3172, Study 1

2024-3170, Study 2

2024-3167, Study 3

2024-3127, Study 4

2024-3126, Study 5

2024-3125, Study 6

2024-3113, KT06 (1A App

Singapore General Hospital

Step 1: Select the study using the Study Dropdown Bar.

Step 2: Select the study site.

Study Member Review

Site Level

ECOS Study Member Review

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)

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

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

Study Member Review

Site Level

- Action: **ENDORSE**

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

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

- Action: **REJECT**

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

- Role Status, Deactivation Date, Deactivated By, Last Edited By and Last Edited Date will be updated.
- Existing limited page access to CRMS will be revoked.

In-built Logic Checks for Basic Information

In-built Logic Checks – Before IRB APP Approval

- **RECAP:**

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

- a) Sponsor Details, or
- b) Clinical Research Organisation (CRO) Details, and
- c) IRB Review Billing Details.

- The system will perform a check and prevent the submission of the IRB Application Form should the CRMS **Study Information – Basic Information** page be incomplete.
- **NOTE:** This is not applicable to studies funded by **Grant** or **Department Fund** or **No funding is required for the study to be carried out**.

IRB APP Form – Section C1

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

The screenshot shows the 'Submission Detail' page for an IRB application. The top navigation bar includes a 'Back to Submission Detail' link, the title 'Submission Detail', and icons for Help, Download, Notifications (99+), and a profile icon. Below the navigation bar, the application ID '2024-0205-APP1' is displayed with a 'Draft' status and a clock icon. The ECOS Ref: 2024-0205 is also shown. A 'Submit' button is visible on the right. The main content area is titled 'Amendment Form' and features a 'Form Detail' tab. A progress bar shows the current step. The 'Mandatory Check' button is highlighted with a blue arrow. The form content includes a section for funding source information with three radio button options: (a) Department Fund or No funding is required for this study to be carried out, (b) Grant, and (c) Pharmaceutical/ Industry Sponsored. The third option is selected. Below this is a text input field for the sponsor company name, which contains 'XYZ Pharmaceuticals'. A sidebar on the right lists the form sections: Section A: Study Title, Section B: Submission ..., Section C: Study Fundi..., Section D: Study Type a..., and Section E: Research M.

< Back to Submission Detail

Submission Detail

Help

2024-0205-APP1

Draft

ECOS Ref: 2024-0205

Submit

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

Section A: Study Title

Section B: Submission ...

Section C: Study Fundi...

Section D: Study Type a...

Section E: Research M

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.	Link
Section C: Study Funding Information	C1. Please provide information regarding the study's funding source or sponsor information.	No billing information in CRMS.	Link

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)

Study Information

Basic Information

Regulatory Information

User Authorisation List

Required sections to complete

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

SingHealth Version 1.0 Dated 06 May 2024

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Return to IRB APP Form

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

[Back to Study Summary](#)

Submission Detail

Help 99+

IRB / My Study List / Study Summary / Submission Detail

2024-0205-APP1 Draft

ECOS Ref: 2024-0205

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.

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

[Form Detail](#)

Application Form

[Track Changes](#) **Mandatory Check** [Cancel](#) [Save](#) [Save and Exit](#)

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

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

87 characters entered

Section A: Study Title

Section B: Submission ...

Section C: Study Fundi...

In-built Logic Checks – After IRB APP Approval

- After the IRB has approved the Application Form, there will be a logic check to ensure the data in the following sections are present:
 - a) Either Sponsor Details or Clinical Research Organisation (CRO) Details; **AND**
 - b) IRB Review Billing Details
- The system will trigger prompts to stop the user if there is an attempt to delete the data.
- **NOTE:** This is not applicable to studies funded by **Grant** or **Department Fund** or **No funding is required for the study to be carried out.**

At Least 1 Entry Must Be Retained

Back to Study List

Study Details

HelpDownloadNotifications99+

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

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.

Sponsor Details

Add

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited By	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 By	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 By	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.

Back to Study List

Study Details

Help

99+

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

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.

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	Last Edited	Action
-------------	---------------------	----------------------	----------------	------------------	------------------	-------------	--------

1) Data under CRO Details can be completely 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

2) However, deleting the only entry under Sponsor Details will trigger the above prompt, vice versa.

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

STM/SA/SS Initiating a New IRB Application Form

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

IRB Application Form Creation

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

The screenshot displays the ECOS Submission List interface. The left sidebar contains navigation links: Homepage, IRB (expanded), Submission List (selected), My Study List, CRMS, FCOI, and Report. The main content area is titled 'Submission List' and features two buttons: '+ New Application Form' (highlighted with an orange arrow) and '+ New Other Forms'. Below these 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. At the bottom right, there is a pagination control showing 'Rows per page: 100' and '1-3 of 3'.

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	

Important Note From The IRB Application Form

- Kindly note Point 2.

The screenshot shows the ECOS Submission List interface. A modal dialog titled 'IMPORTANT NOTE!' is displayed in the center. The dialog contains four numbered points. Point 2 is highlighted with an orange rectangle. Below the dialog, a blue 'Close' button is visible, and an orange arrow points to it with a callout box saying 'Click to proceed.'.

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.

Rows per page: 100 1-3 of 3

First Save of IRB Application Form

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

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

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...

[Cancel](#) [Save](#)

CRMS Prompt in IRB Module

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

The screenshot shows the 'Submission Detail' page in the CRMS system. A modal dialog box is open in the center, titled 'Please select your site and role in CRMS'. The dialog contains two required fields: '* Site:' and '* Role:'. The 'Site' field is a dropdown menu, and the 'Role' field is a dropdown menu with three visible options: 'Study Administrator', 'Study Sponsor', and 'Study Team Member'. A blue 'Save' button is located at the bottom right of the dialog. In the background, the 'Application Form' is visible, showing sections for 'Section B: Submission Board', 'B1. Submission IRB and Bo', and 'B1. (a) The reviewing IRB w'. There are also buttons for 'Cancel' and 'Save' on the right side of the form.

CRMS Prompt in IRB Module

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

The screenshot displays the 'Submission Detail' page in the SingHealth CRMS. A modal dialog box is centered on the screen, 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 'Application Form' section of the submission, including 'Section B: Submission Board', 'B1. Submission IRB and Board', and 'B1. (a) The reviewing IRB with Board'. The 'SingHealth CIRB' is selected for the reviewing IRB. Other sections visible include 'Section A: Study Title', 'Section C: Study Funding', 'Section D: Study Type and Aim', 'Other Attachments', and 'Declaration of Principal Investigator'.

User Added to UAL by System

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

< Back to Study Details

Study Details

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2024-3245, Study 4 / Singapore General Hospital

ECOS Reference: 2024-3245

IRB: SingHealth CIRB Board F

Study Status: • Draft

Number of Sites: 1

Initial Outcome Date: -

Valid Till Date: -

PI/Site PI: Prof SGH_PI (Singapore General Hospital)

Department: Department of Renal Medicine (Singapore General Hospital)

Study Information

Basic Information

Regulatory Information

User Authorisation List

User Authorisation List

+ Add

Columns

Export

Filter(1)

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	

Rows per page: 100 1-2 of 2

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CRMS Accessibility

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

ECOS

Study List

Download

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Homepage

IRB

CRMS

Study List

FCOI

Report

Columns

Export

Filter

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	

Rows per page: 100 1-6 of 6

IRB Accessibility

- Study Sponsor (SS_20) can also access to the IRB forms 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-Board F	2024-3101-APP1	Application	Draft	Study 1	
2024-3090	SingHealth CIRB-Board F					
2024-3016	SingHealth CIRB-Board F					

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

One Chance

- If the user clicks the ✕ button instead of **Save**, the system will not register this user to the UAL (*next slide*).

The screenshot shows a web application interface for a submission detail. At the top, there is a dark blue header with a back arrow and the text "Back to Submission List", the title "Submission Detail", and icons for download, notifications (30), and a profile. Below the header, the main content area is greyed out, showing fields for "ECOS Ref: -" with a copy icon, a dropdown menu, and a "Form Detail" section. The "Application Form" section is visible, containing "Section B: Submission Board," and "B1. Submission IRB and Bo". A modal dialog is open in the center, titled "Please select your site and role in CRMS". It has two dropdown menus: "* Site:" with "Singapore General Hospital" selected, and "* Role:" with "Study Sponsor" selected. There is a blue "Save" button at the bottom right of the modal. An orange arrow points to the "X" close button in the top right corner of the modal. In the background, there are buttons for "Cancel" and "Save" on the right side of the form.

Missed Opportunity

- This user will lose access to the IRB Application Form the moment the **Save and Exit** button on the IRB form is clicked.

Solution:

Enlist help from

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

to manually add the user to the CRMS UAL.

2024-3245, Study 4 / Singapore General Hospital

ECOS Reference: 2024-3245

IRB: SingHealth CIRB Board F

Study Status: ● Draft

Number of Sites: 1

Initial Outcome Date: -

Valid Till Date: -

PI/Site PI: Prof SGH_PI (Singapore General Hospital)

Department: Department of Renal Medicine (Singapore General Hospital)

Study Information

Basic Information

Regulatory Information

User Authorisation List

User Authorisation List

+ Add

Columns

Export

Filter(1)

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	

Rows per page: 100 1-2 of 2

Page Functions

Page Functions

- This section will demonstrate how the page functions work, it applies to all pages that have the functions available.
- The available functions are: -
 - Study Dropdown Bar to toggle between different studies – [Slide 89](#)
 - Collapse the Study Details panel and CRMS Side Navigation Bar – [Slide 94](#)
 - Expand the Study Details panel and CRMS Side Navigation Bar – [Slide 95](#)
 - Edit data – [Slide 96](#)
 - Add data – [Slide 98](#)
 - Delete data – [Slide 100](#)
 - Save data – [Slide 101](#)
 - Cancel – [Slide 104](#)
 - Filter to display specific data – [Slide 107](#)
 - Columns to narrow specific data columns to be displayed – [Slide 110](#)
 - Export – [Slide 113](#)
 - Add user to the User Authorisation List – [Slide 115](#)
 - Endorse or Reject user via the Study Member Review – [Slide 121](#)
 - Deactivate user on the User Authorisation List – [Slide 122](#)

Page Functions – Study Dropdown Bar

- 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

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 – Study Dropdown Bar

Back to Study List

Study Details

Download

Alert

Profile

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	Last Edited By
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 By
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

Step 1: Click on the Dropdown icon.

Page Functions – Study Dropdown Bar

[Back to Study List](#)

Study Details

Help

99+

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

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	L

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	L

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

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

Page Functions – Study Dropdown Bar

[< Back to Study List](#)

Study Details

Help

Download

Notifications

99+

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	L
* 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	L
* 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

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

Page Functions – Study Dropdown Bar

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

Back to Study List

Study Details

Help

4

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

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

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.

Study Information

Basic Information

Regulatory Information

Site Information

User Authorisation List

Milestones

Participants

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	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-I1	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.

[< 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





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

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Page Functions – Expand

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

[Back to Study List](#)

Study Details

Help

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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 E
* 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.

[Back to Study List](#)

Study Details

Help

99+

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

Edit

Sponsor Details

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

Page Functions – Edit Data

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

[Back to Study List](#)

Study Details

HelpDownloadNotifications99+

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

Save

Cancel

Add

Sponsor Details

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.**

Add

Sponsor Details

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.

Back to Study List

Study Details

Help

99+

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

Save

Cancel

Add

Clinical Research Organisation (CRO) Details

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

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

Add

Clinical Research Organisation (CRO) Details

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

System In-built Requirements

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

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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	Location	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		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.

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

IRB Review Fees Billing Details

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

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

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

Sponsor Details

Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Action
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Do you want to proceed?

Cancel Confirm

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

11th Version 1.0 Dated 06 May 2024

Page Functions – Save Data

- Page view after Save.

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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
---------------------	----------------------	----------------	------------------	------------------	---------

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

SingHealth Version 1.0 Dated 06 May 2024

Page Functions – Cancel

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

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

Save

Cancel

Add

Sponsor Details

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.

Add

Sponsor Details

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 the demonstration.

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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 deletions. 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.

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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, the User Authorisation List is pre-set to display only roles that are **Active**, **Pending IRB Approval** or **Pending Endorsement**.
-  indicates that there is one (1) filter applied.

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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(1)

Member Name	Role	Cluster	Institution	Department	Designation	Email Address	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date	Action
SGH_PI	PI	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_PI@singhealth.com.sg	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_Co-I1	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_SA1	Study Administrator	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Senior Executive	SGH_SA1@sg.h.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 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 'Study Details' page for '2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk. / Singapore General Hospital'. The 'User Authorisation List' is displayed with columns: Member Name, Role, Cluster, Institution, and Department. Two users are listed: SGH_PI1 (PI) and SGH_Co-11 (Col), both from SingHealth and Singapore General Hospital, Department of Medicine.

The 'Filter' modal is open, showing the following filters:

- Role Status:** Active x, Pending IRB Approval x, Pending Endorsement x. (Annotation: Step 2: Delete the 3 labels pre-set.)
- Endorsement Date:** Start Date → End Date
- Endorsed By:** [Text Input]
- Deactivation Date:** Start Date → End Date [Calendar Icon]
- Deactivated By:** [Text Input]
- Buttons:** Reset, Search. (Annotation: Step 3: Click Search.)

Page Functions – Filter

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

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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	

Page Functions – Columns

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

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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.

Column Selected 15

Search

☐ Select All

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

Clear Cancel Save

Step 2: Uncheck the boxes of 4 columns:

- Cluster
- Department
- Designation
- Email Address

Step 3: Click Save.

User Authorisation List

Member Name	Role	Cluster	Institution
SGH_PI1	PI	SingHealth	Singapore General Hospital
SGH_Co-I1	Col	SingHealth	Singapore General Hospital

Page Functions – Columns

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

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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-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	

Rows per page: 100 1-5 of 5

Column

Selected 11

☐ Select All

☒ Member Name

☒ Role

☐ Cluster

☒ Institution

☐ Department

☐ Designation

☐ Email Address

☒ Data Source

☒ Role Status

Clear

Cancel

Save

Page Functions – Export



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

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

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

User Authorisation List

+ AddColumnsExportFilter

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_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	

Rows per page: 1001-5 of 5

Page Functions – Export



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

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

ECOS Reference: 2024-0205										
Unique Identifier: 2024-0205-Singapore General Hospital										
Study Title: Efficacy and Safety of DRUG-X in the Treatment of Osteoporosis with High Fracture Risk.										
PI/Site-PI: Dr SGH_PI (Singapore General Hospital), Prof NUH_PI (National University Hospital)										
Study Status: Approved										
Initial Outcome Date: 24-Jan-2024										
Valid Till Date: 23-Jan-2025										
Downloaded By: SGH_PI										
Downloaded Date and Time: 23-Feb-2024 17:54:46										
Member Name	Role	Institution	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date
SGH_PI	PI	Singapore General Hospital	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1				24-Jan-2024
SGH_Co-I1	CoI	Singapore General Hospital	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1				24-Jan-2024
SGH_STM11	Study Team Member	Singapore General Hospital	CRMS	Inactive			24-Jan-2024	SGH_PI	SGH_PI	24-Jan-2024
SGH_SA1	Study Administrator	Singapore General Hospital	CRMS	Active	24-Jan-2024	SGH_PI			SGH_PI	24-Jan-2024
SS_20	Study Sponsor	Astra Zeneca	CRMS	Pending Endorsement					SGH_Co-I1	24-Jan-2024

Expected view of the exported User Authorisation List.

Page Functions – Add User

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

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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: 1001-4 of 4

Step 1: Click Add.

Page Functions – Add User



Fuzzy search is not allowed.

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User Authorisation List

Member Name	Role	Institution	Data Source	Role Status	Endorsement Date
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024
SGH_Co-I1	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	-

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

Add

Submit Cancel

Step 3: Click the Search icon.

* Member Name/Email :

SGH_STM22



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

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

* Role :

Please select

Total Rows: 1

Page Functions – Add User

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

User Authorisation List

Member Name	Role	Institution	Data Source	Role Status	Endorsement Date
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024
SGH_Co-I1	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

Step 6: Click Submit.

* 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 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.

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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.

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

User Authorisation List

+ AddColumnsExportFilter(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	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 the PI/Site-PI has reviewed and endorsed the newly added user. New information will be recorded in the relevant columns.

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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: 1001-6 of 6

Page Functions – Endorse or Reject User

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

The screenshot displays the ECOS Study Member Review interface. The top navigation bar includes the ECOS logo, the title 'Study Member Review', and utility icons for Help, download, notifications, and a profile menu. A left sidebar contains navigation links: Homepage, IRB, CRMS, Study List, Study Member Review (highlighted), FCOI, and Report. The main content area features a search bar with the text '2024-0205, Efficacy and Safety of DRUG-X in the Treatment of Ost...'. Below the search bar are two prominent action buttons: 'Reject' (with a red X icon) and 'Endorse' (with a blue checkmark icon). To the right of these buttons are links for 'Columns', 'Export', and 'Filter'. A table lists study members with columns: Member Name, Role, Cluster, Department, Institution, Designation, Data Source, and Role Status. The first row is highlighted in blue and contains the following data: a checked selection box, 'SS_20', 'Study Sponsor', 'Non-PHI', 'Astra Zeneca', 'Astra Zeneca', 'CRA', 'CRMS', and 'Pending Endorsement'. An orange arrow points to the selection box, and a black arrow points to the 'Endorse' button. Two callout boxes provide instructions: 'Step 1: Check the box.' and 'Step 2: Click either button to Reject or Endorse the selected user.'

	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

Page Functions – Deactivate User

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

[Back to Study List](#)

Study Details

Help

2

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_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	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-I1	24-Jan-2024	

Click Deactivate.

Page Functions – Deactivate User

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

[Back to Study List](#)

Study Details

Help

2

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-I1	Col	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
Study Team		Singapore General									

Email Notifications

Email Notifications



Email notifications will be soft-launched in May.

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

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

CRMS Reports



This option may be available in Q3 2024.

CRMS Reports

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

ECOS

CRMS Institution Report

Help

Regulatory Information (CRM)

Regulatory Information (rHBR)

SAE Reports for CT Insurance

Publications Listing

Grant Listing

Recruitment Report

Enrolment and Reporting Status

Studies Listing

Study Milestones

Regulatory Information (Clinical Tri...

Contracts Tracking Listing

Columns

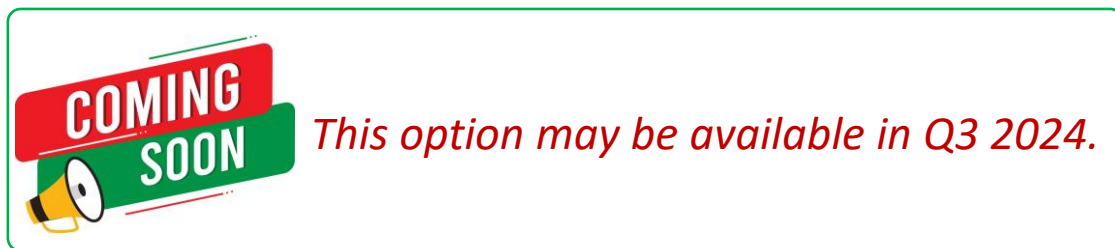
Export

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 (SingHealth)



- **12 types of reports:**

- Recruitment Number
- Enrolment and Reporting Status
- Study Milestones
- Regulatory Information (Clinical Trials Regulated by HSA)
- Regulatory Information (CRM)
- Regulatory Information (rHBR)
- Publication Listing
- SAE Reports for CT Insurance
- Studies Listing
- Grant Listing
- Contracts Tracking Listing
- Study Agreement Listing



**Use the Columns
function to narrow
data selection.**

- Steps to export is the same as the one demonstrated using the User Authorisation List.

CRMS RO Role

CRMS RO Role

- Research Office administrators assigned with the CRMS RO role will have full View & Edit access to the CRMS module upon role assignment.
 - New users requiring this CRMS RO role should contact their respective institution Research Office.
- Access authority is institution-specific.
 - Under Study List, the CRMS RO administrators will be able to see the full list of institution studies.

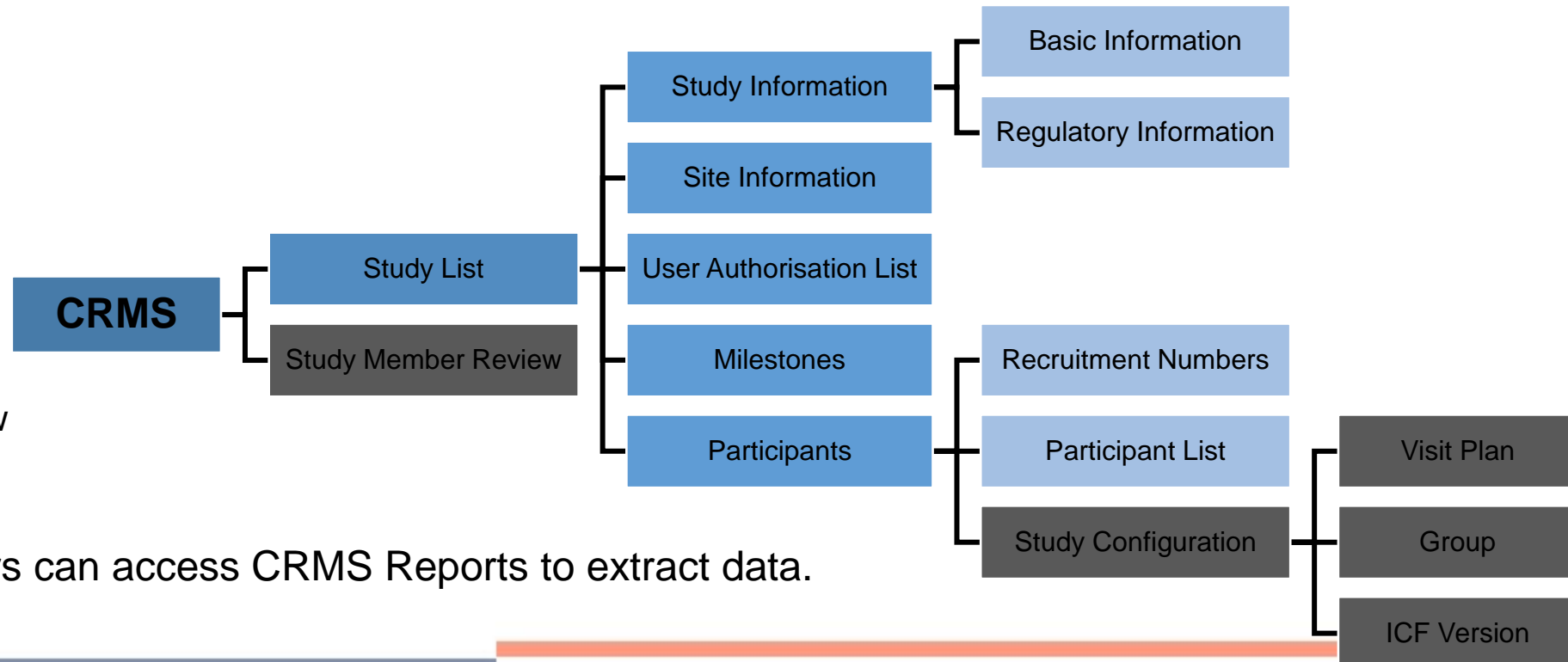
- Page level access: -

✓ **Study Level**

✓ **Site Level**

- No page access to: -

- × Study Member Review
- × Study Configuration



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

Migration of Existing Studies

Migration of Existing Studies (SingHealth)

- **Study Information – Basic Information**

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

- **User Authorisation List**

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

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

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

Site Delegation Log

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

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

CRMS UAL

 ECOS

User Authorisation List

Member Name

Role



Correct question to ask:
Does the user require access
to IRB and/or CRMS modules?

Q: Does the user require access to IRB and/or CRMS modules?

- Additional helpful questions to ask:

Is the user required to...

- Draft IRB Forms?
- Draft DNC, OSN, SAE, SSR etc.?
- Have access to the IRB documents, e.g. protocol, ICFs and IRB approval letters?
- Enter data into the CRMS pages?
- Function as a back-up?

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

Site Delegation Log

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

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

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

If access is required, proceed
to add the user to the UAL.

CRMS UAL

ECOS

User Authorisation List

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

FAQ: Is CRMS Mandatory?

Is CRMS Mandatory?

- **Mandatory for ALL SingHealth studies:**

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

- **Conditional** if it meets the requirement:**

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

- **Optional** but highly encouraged:**

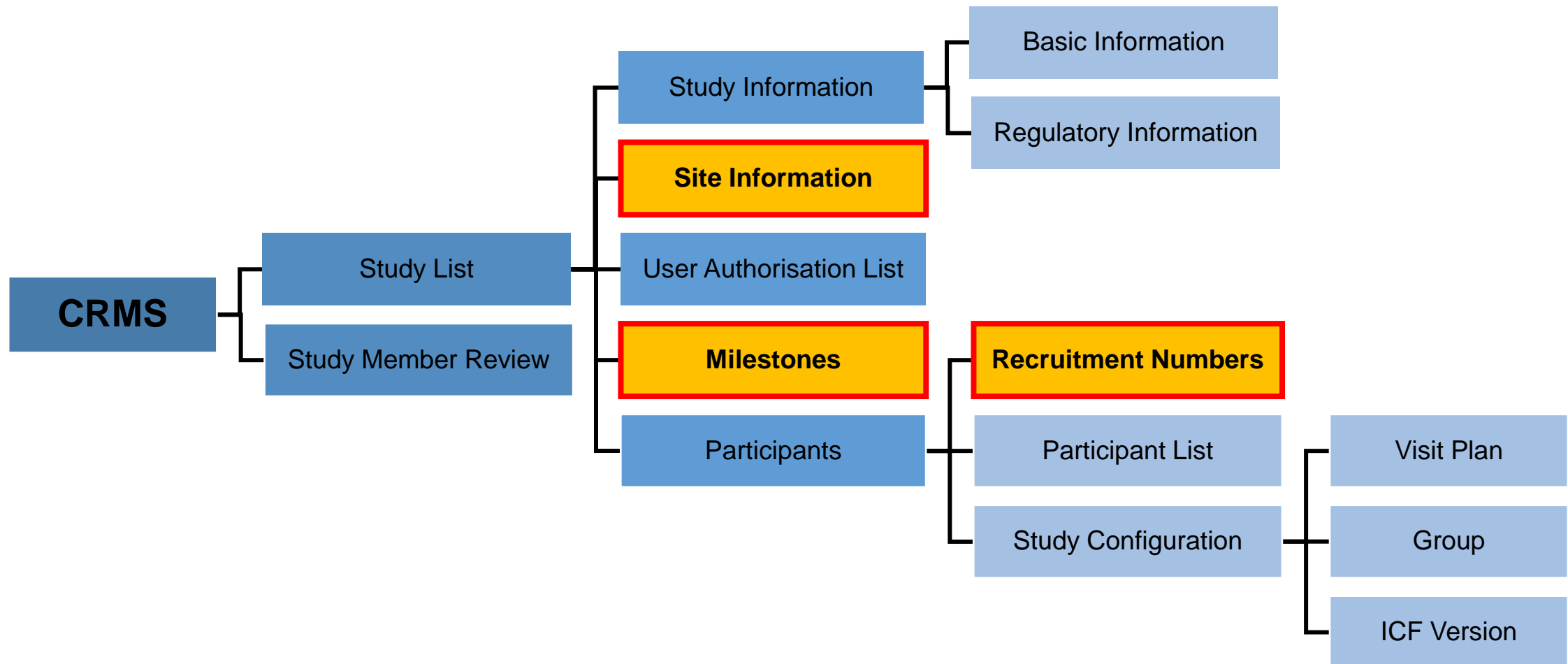
1. Participants – Participant List
2. Participants – Study Configuration (Visit Plan, Group, ICF Version)

NOTE:

* SingHealth CTCC will release more information.

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

Mandatory Pages



Summary

Key Takeaways

- Basic Information page must be completed for Pharmaceutical/ Industry Sponsored studies to facilitate submission of IRB Application Form.
- User Authorisation List (UAL) controls user access to CRMS and/or IRB modules for Study Team Member (STM), Study Administrators (SA) and Study Sponsor (SS) roles.
- **For the migrated studies, the addition of STM/SA/SS users to CRMS UAL will need to be manually done by PI/Site-PI or CRMS RO administrators.**
- PI/Site-PI should perform the endorsement in CRMS via the Study Member Review page (as needed).
- **! The User Authorisation List does not replace a delegation log.**
- Regulatory Information, Site Information, Milestones and Participants pages contain important data fields that can be extracted for institutions' trending and reporting purposes.
- Data fields from the CTCC Bi-Annual Data Collection Excel Worksheet has also been incorporated into the CRMS. The entered information will be pulled from the system for reporting to the National Clinical Trials Insurance, national bodies for tracking of grant funding KPIs and study deliverables such as site start-up and recruitment rates.

Key Takeaways

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