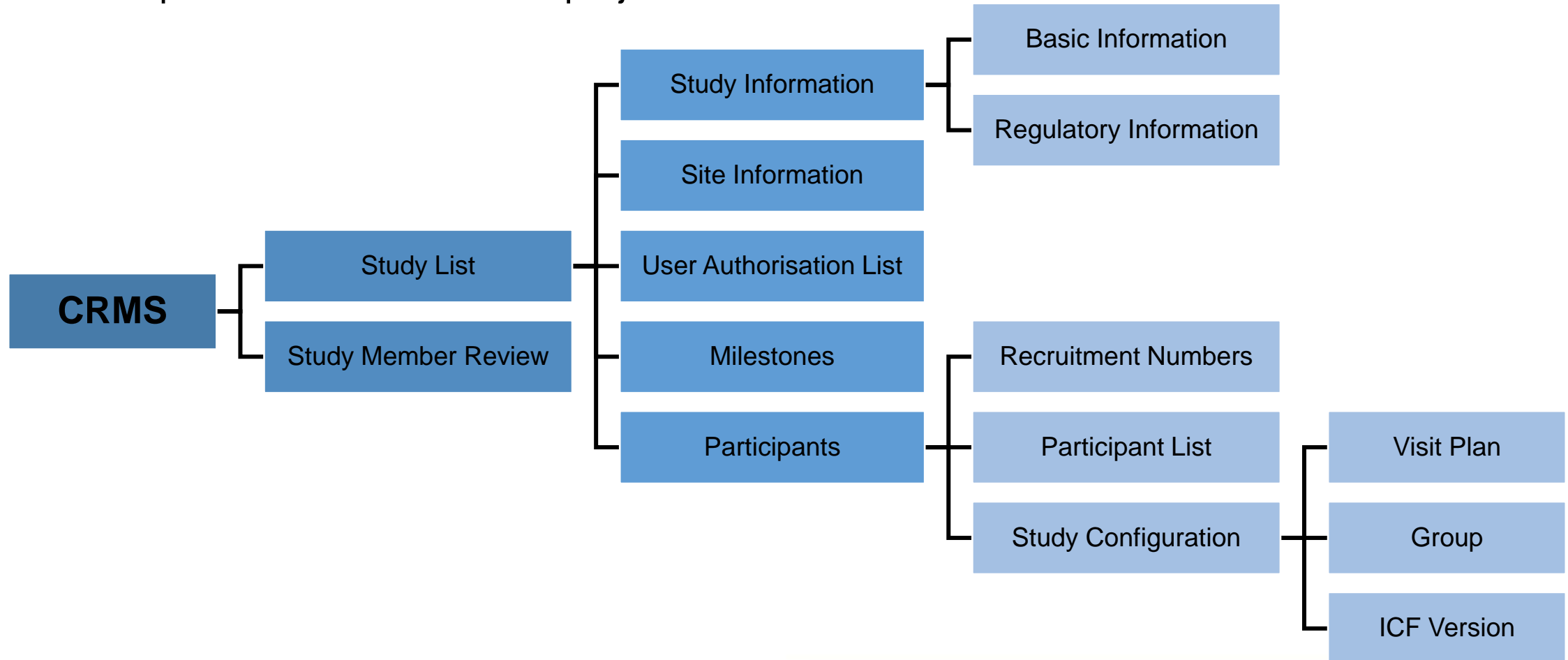


Navigating the New IT Platform:

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.



Index

- User Access Matrix – [Slide 5](#)
- CRMS Page Level – [Slide 9](#)
- CRMS Access – [Slide 11](#)
- CRMS Pages and Data Fields – [Slide 14](#)
 - Study List – [Slide 15](#)
 - Study Information - Basic Information – [Slide 18](#)
 - Study Information - Regulatory Information – [Slide 22](#)
 - Site Information – [Slide 27](#)
 - User Authorisation List – [Slide 32](#)
 - Milestones – [Slide 39](#)
 - Participants - Recruitment Numbers – [Slide 42](#)
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 - 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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- CRMS Reports – [Slide 127](#)
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- Migration of Existing Studies – [Slide 145](#)
- FAQ: Do I Add Everyone on the Delegation Log to the UAL? – [Slide 147](#)
- FAQ: I am listed on the UAL but why am I not able to view and edit the PISAF/SOC/Monitoring/Audit related forms? – [Slide 151](#)
- FAQ: Is CRMS Mandatory? – [Slide 154](#)
- Common Discrepancies Observed – [Slide 157](#)
- Summary – [Slide 161](#)



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 Research Office role** (*Please refer to the section CRMS Research Office Role – [Slide 142](#)*).
- For new investigators (i.e. PI, Site-PI, Co-I) added in the IRB **Amendment** Form, full CRMS access will be granted after IRB has provided approval. New investigators pending IRB approval will not have any access to the CRMS.

User Access Matrix

IRB Application Form

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

Legend

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

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

User Access Matrix

IRB Amendment Form

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

Legend

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

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

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 links for Help, a download icon with a red '1' badge, a bell icon, and a notification icon with a red '99+' badge. 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), CRMS (12), and FCOI (0). The CRMS card shows 'Study Member Review' with a count of 12. The FCOI card shows 'My FCOI List' with a count of 0. A 'My Notices' section on the right shows a notice for all dated 31-Jan-2024. Two callout boxes provide instructions: 'Step 1: Click to release dropdown menu.' pointing to the CRMS menu item, and 'Step 2: Click to see the list of studies available.' pointing to the Study List menu item.

ECOS Dashboard

Navigation Menu:

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

Summary Cards:

- IRB 27**
Study: 25
Endorsement: 2
- CRMS 12**
Study Member Review: 12
- 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


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

[Back to Submission List](#)

Submission Detail



2024-0205-APP1 Draft 

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.

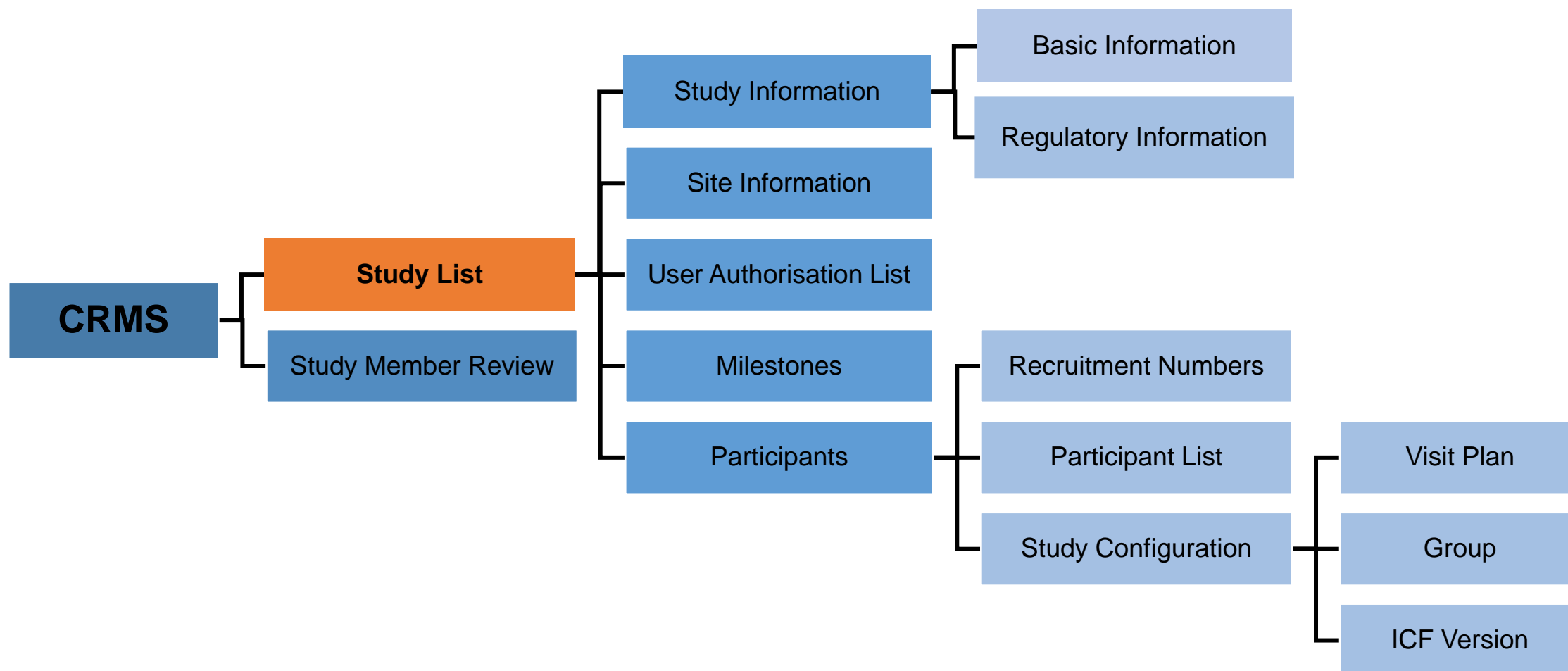
Section A: Study Title

CRMS Pages and Data Fields

CRMS Sitemap



Click [here](#) to return to Index.



Study List

- The Study List will only display the studies where a user has been added to the IRB Application/Amendment Form or User Authorisation List.
 - **Exception: CRMS Research Office administrators** *(Please refer to the section CRMS Research Office Role – [Slide 142](#)).*
- A new study will be created in CRMS once the IRB Application Form draft is saved for the first time.
- Relevant information from the IRB Application or Amendment Forms will be synced to CRMS, which are:
 - Study details (e.g. study title, study sites, etc.) to the Study List.
 - List of Investigators added to the IRB form to the User Authorisation List.
- Synchronisation points:
 - Upon saving the IRB Application Form.
 - Upon IRB approval or acknowledgement.



No information will flow from CRMS to IRB module.

Study List

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

Data Columns

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

ECOS

Homepage

IRB

Submission List

Endorsement

My Study List

CRMS

Study List

Study Member Review

FCOI

Study List

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

Detail

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	

Rows per page: 100 1-1 of 1

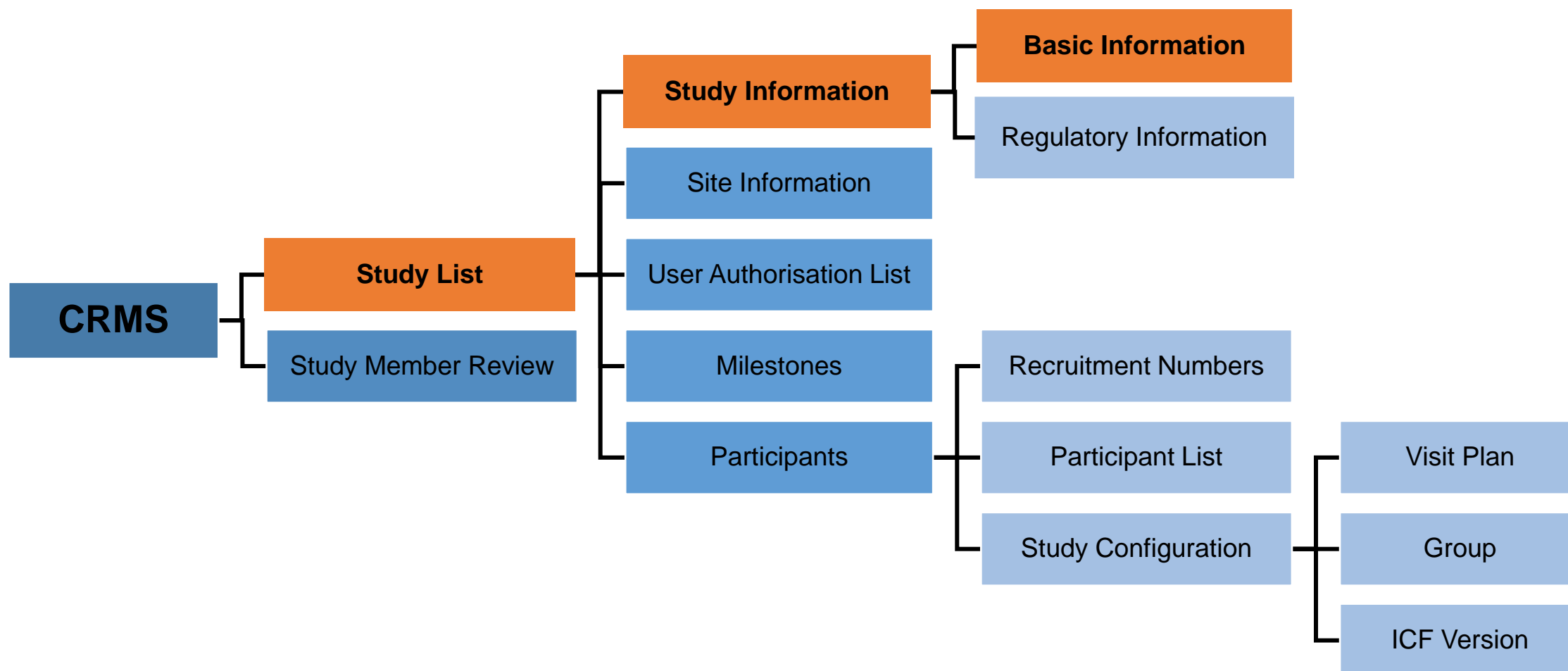
Click on the number to see the list of participating sites.

Click the View icon of the specific study to enter the CRMS pages.

CRMS Sitemap



Click [here](#) to return to Index.



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	
<input type="text" value="XYZ Pharmaceuticals"/>	<input type="text" value="XYZ"/>	<input type="text" value="98761234"/>	<input type="text" value="xyz@xyz.com"/>	<input type="text"/>	<input type="text" value="Singapore 123654"/>	<input type="text" value="L"/>

Clinical Research Organisation (CRO) Details

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

IRB Review Fees Billing Details

Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited By
<input type="text" value="LMN"/>	<input type="text" value="95672341"/>	<input type="text" value="lmn@ab.com"/>	<input type="text"/>	<input type="text" value="Singapore654123"/>	<input type="text" value="SGH_PI"/>

Edit

SingHealth Version 2.0 Dated 28 May 2025

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Study Information – Basic Information

Study Level

Below are the data fields found on this page:

Sponsor Details

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

Clinical Research Organisation (CRO) Details

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

IRB Review Fees Billing Details

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

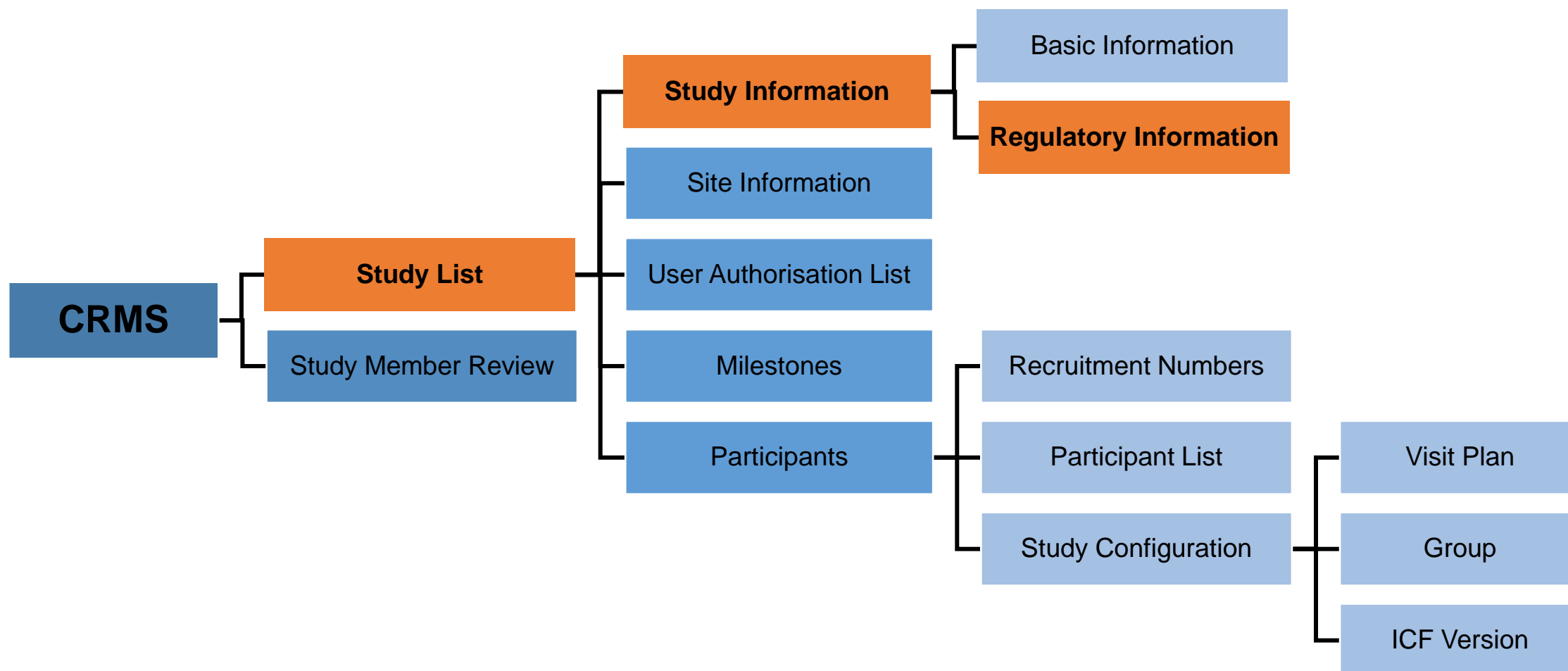
Note:

- If a CRO is engaged for an Investigator-initiated study, CRO Details should be completed.
- Business Address under IRB Review Billing Details will be reflected on the invoice. Please include the full address including the Company Name. Sites should check with the sponsor and indicate the required information to ensure smooth invoice submission and payment processes.

CRMS Sitemap



Click [here](#) to return to Index.



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

Export

Edit

Clinical Trials Regulated by HSA

Type of Application	Submission Reference No.	Submission Date	Local Regulatory Study Reference No.	Licence/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
---------------------	---------------------	-------------------	-------------------	-----------------

SingHealth Version 2.0 Dated 28 May 2025

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Study Information – Regulatory Information Study Level

Below are the data fields found on this page:

Clinical Trials Regulated by HSA

- Type of Application *(Drop-down list)*
 - Clinical Trial Certificate (CTC)
 - Clinical Trial Authorisation (CTA)
 - Clinical Trial Notification (CTN)
 - Substantial Amendments
 - Safety Report
 - Serious Breach
 - Urgent Safety Measures
 - Trial Status Report
 - Clinical Study Report Submission
 - Other Submissions
- Submission Reference No.
- Submission Date
- Local Regulatory Study Reference No.
- License/ Permit/ Certificate/ Listing/ Notification No.
- Approval/ Acceptance Date
- Remarks

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

Study Information – Regulatory Information Study Level

Below are the data fields found on this page:





Clinical Research Materials (CRM)

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

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

Study Information – Regulatory Information Study Level

Below are the data fields found on this page:

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

Restricted Human Biomedical Research (rHBR)

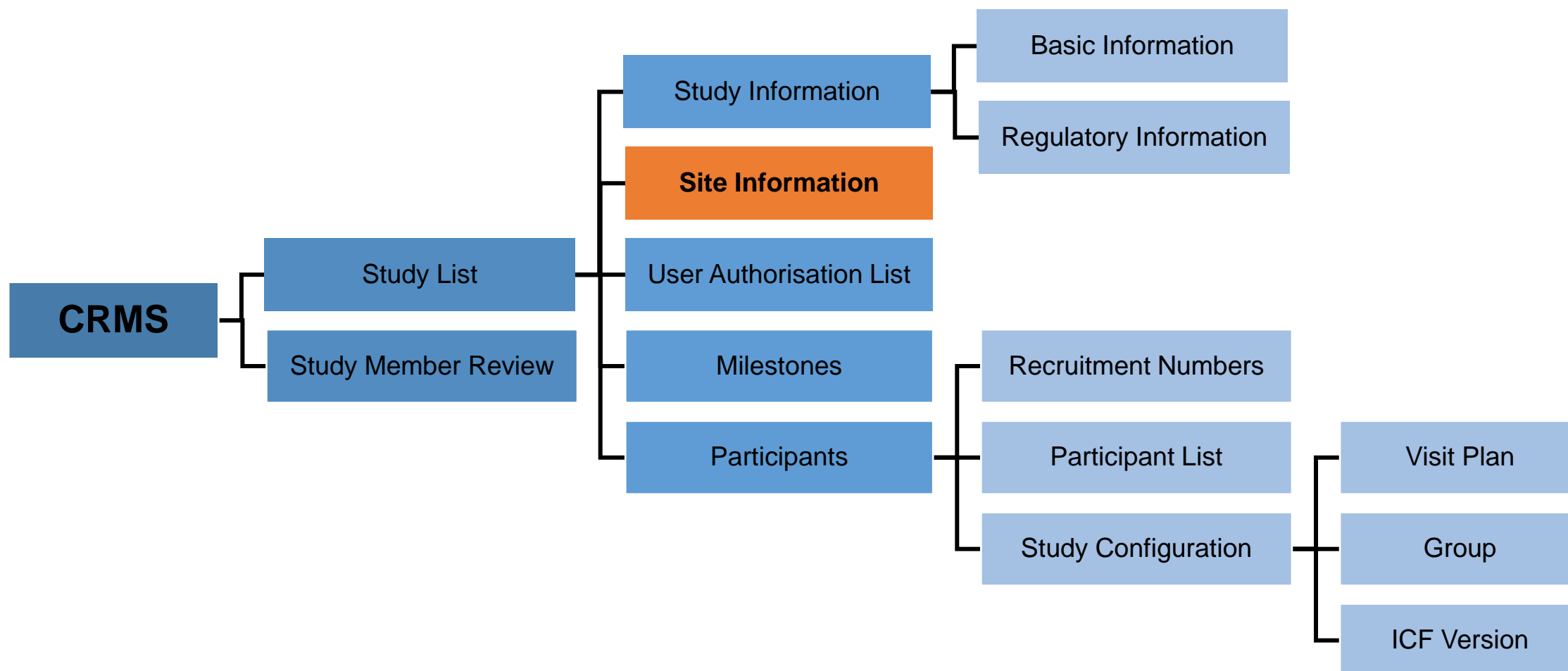
- MOH Application No.
- MOH Submission Date
- MOH Reference No.
- MOH Approval Date
- MOH Expiry Date

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

CRMS Sitemap



Click [here](#) to return to Index.



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

Study Information

Basic Information

Regulatory Information

Site Information

User Authorisation List

Milestones

Participants

Study Site: Singapore General Hospital

Export

Edit

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 Project Agreements and Research Collaboration Agreements (RCA) in this section.
- For Clinical Trial Agreement (CTA), please input details in the 'Industry Sponsor/CRO Contract' section.

Site Information

Site Level

Below are the data fields found on this page:

Industry Sponsor/ CRO Contract

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

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

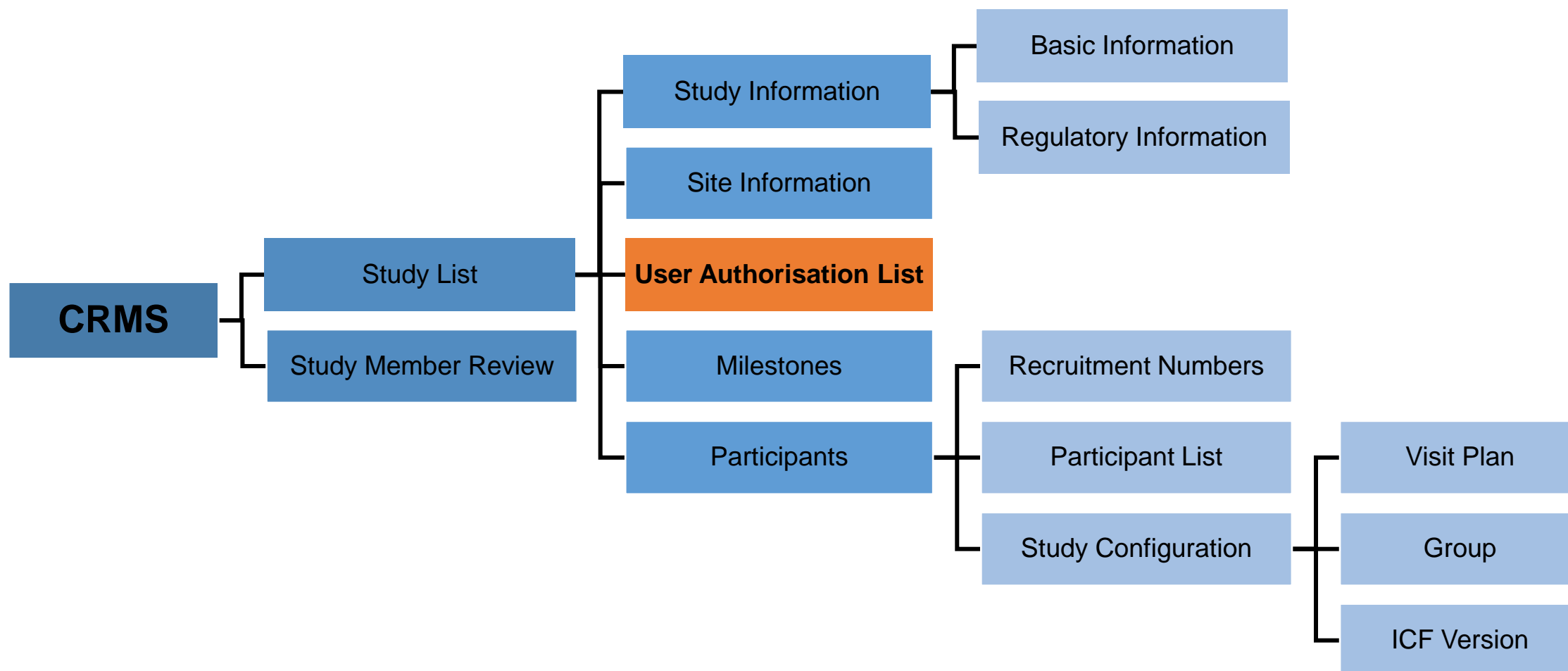
Publication and Presentations

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

CRMS Sitemap



Click [here](#) to return to Index.



User Authorisation List (UAL)

Site Level

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

[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

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

Study Site: Singapore General Hospital

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

User Authorisation List (UAL)

Site Level

Below are the data columns found on this page:

User Authorisation List

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

User Authorisation List (UAL)

Site Level

Role	CRMS Access Rights	Comments
PI, Site-PI & Co-I Site investigators directly involved in the research.	<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, Compliance, Monitoring... Reactivation of the user is not allowed, i.e. a new entry needs to be added and endorsed to "reactivate" the user. Number of users that can be added to the UAL is not capped, but please be mindful when performing this task as every addition and deactivation will be captured on this list. Site will need to manage and keep the UAL updated, i.e. STM/SA/SS(s) no longer directly involved in the study should be deactivated for access to IRB, CRMS etc. modules to be revoked (to protect study data confidentiality).
Study Administrator (SA) Site personnel <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, IRB, Compliance, Monitoring and Audit modules on ECOS.
- This is one of the harmonised processes between CIRB and DSRB where non-investigators (study team members and administrators) will no longer require IRB's approval.
- Only the PI's endorsement in CRMS is required to grant full page access to the SA/STM/SS roles.
- Refer to [Slide 116](#) for steps to add a user to the UAL.



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

User Authorisation List (UAL)



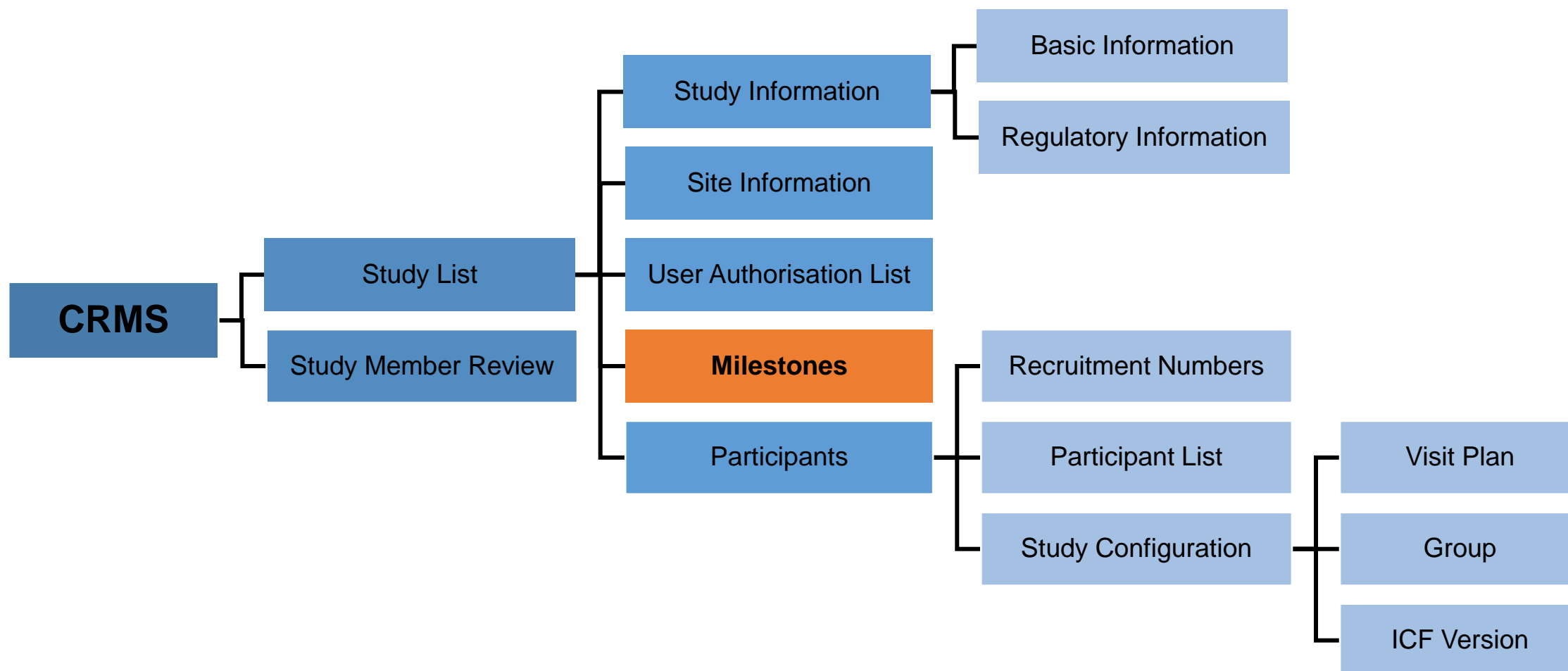
The User Authorisation List does not replace the Site Delegation Log.

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

CRMS Sitemap



Click [here](#) to return to Index.



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

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

Study Site: Singapore General Hospital

+ 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.



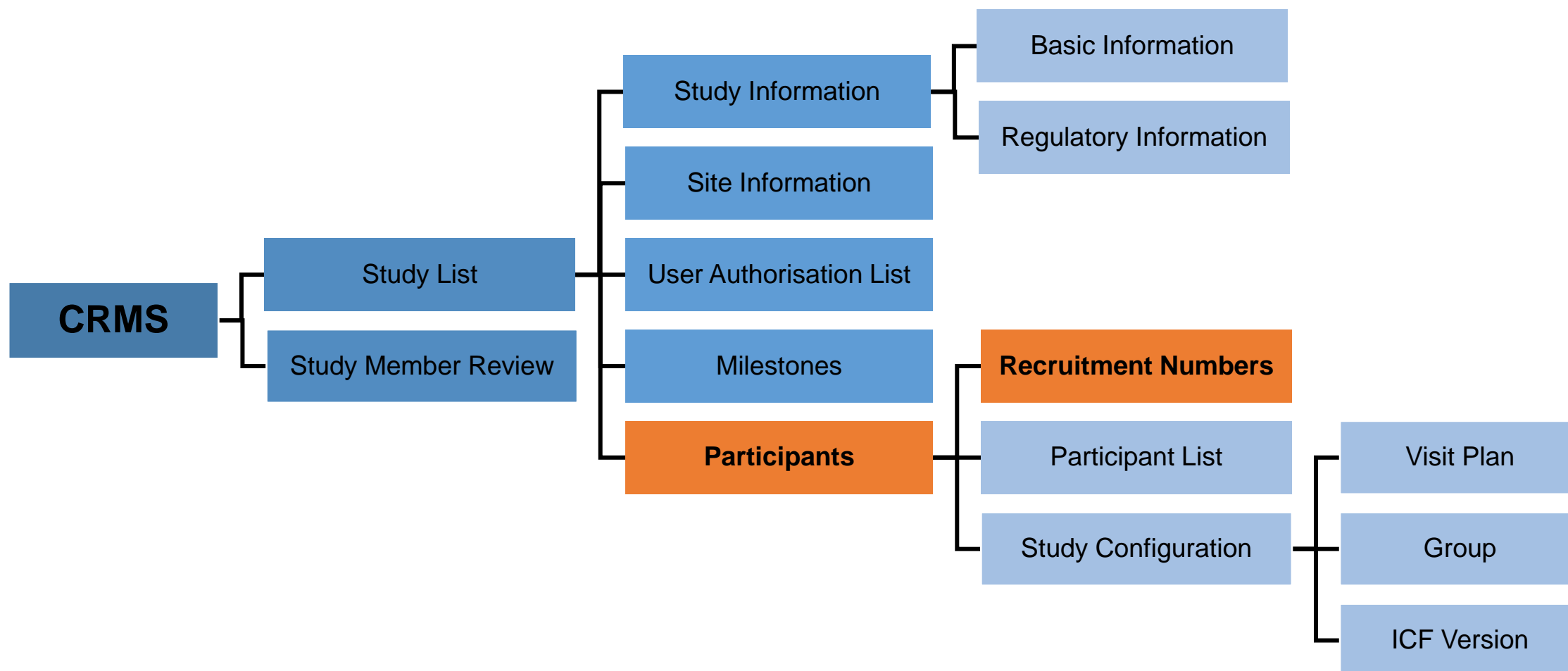
Use the Milestones page as a Project Management Tool!

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

CRMS Sitemap



Click [here](#) to return to Index.



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

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

Study Site: Singapore General Hospital

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

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"/>

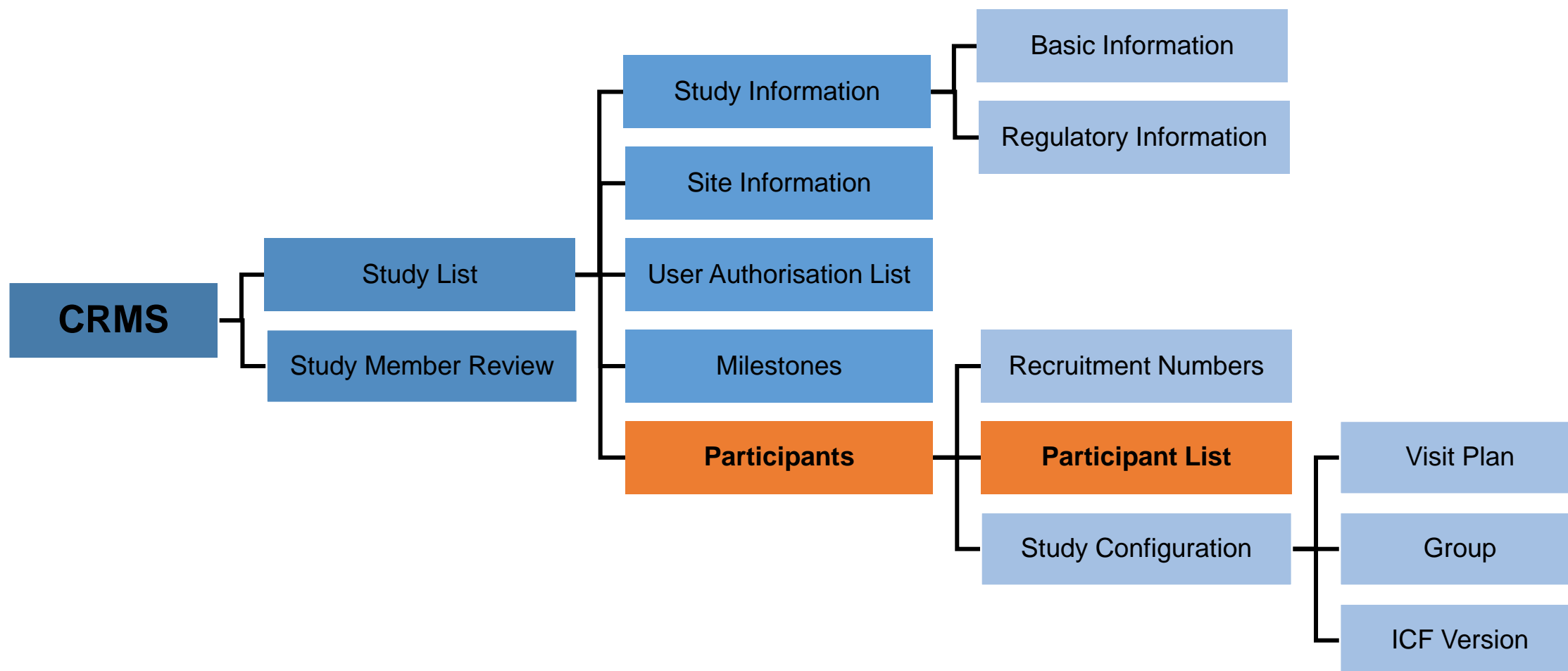
- **Recruitment Target Approved in IRB Study** will be imported from the IRB module.
- A prompt in red will appear if the **Total No. of Participants Enrolled** exceeds the approved number.

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



Click [here](#) to return to Index.



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

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)

<div>Study Information</div> <div>Basic Information</div> <div>Regulatory Information</div> <div>Site Information</div> <div>User Authorisation List</div> <div>Milestones</div> <div>Participants</div> <div>Recruitment Numbers</div> <div>Participant List</div> <div>Study Configuration</div>	Study Site: Singapore General Hospital										<div>+ Add</div>	<div>Columns</div>	<div>Export</div>	<div>Filter</div>
	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](#)    

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 InformationICFVisit Plan

*Screening Number

SGH_SCR01

Enrolment Number

SGH_X01

Enrolment Status

Enroled

Group

Drug-X Group

*Screening Date

26-Jan-2024

Enrolment Date

13-Feb-2024

Randomisation Date

Select date

Remarks

SingHealth Version 2.0 Dated 28 May 2025

49

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 DetailsHelpDownloadNotificationProfile

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

Help

99+

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 Information

ICF

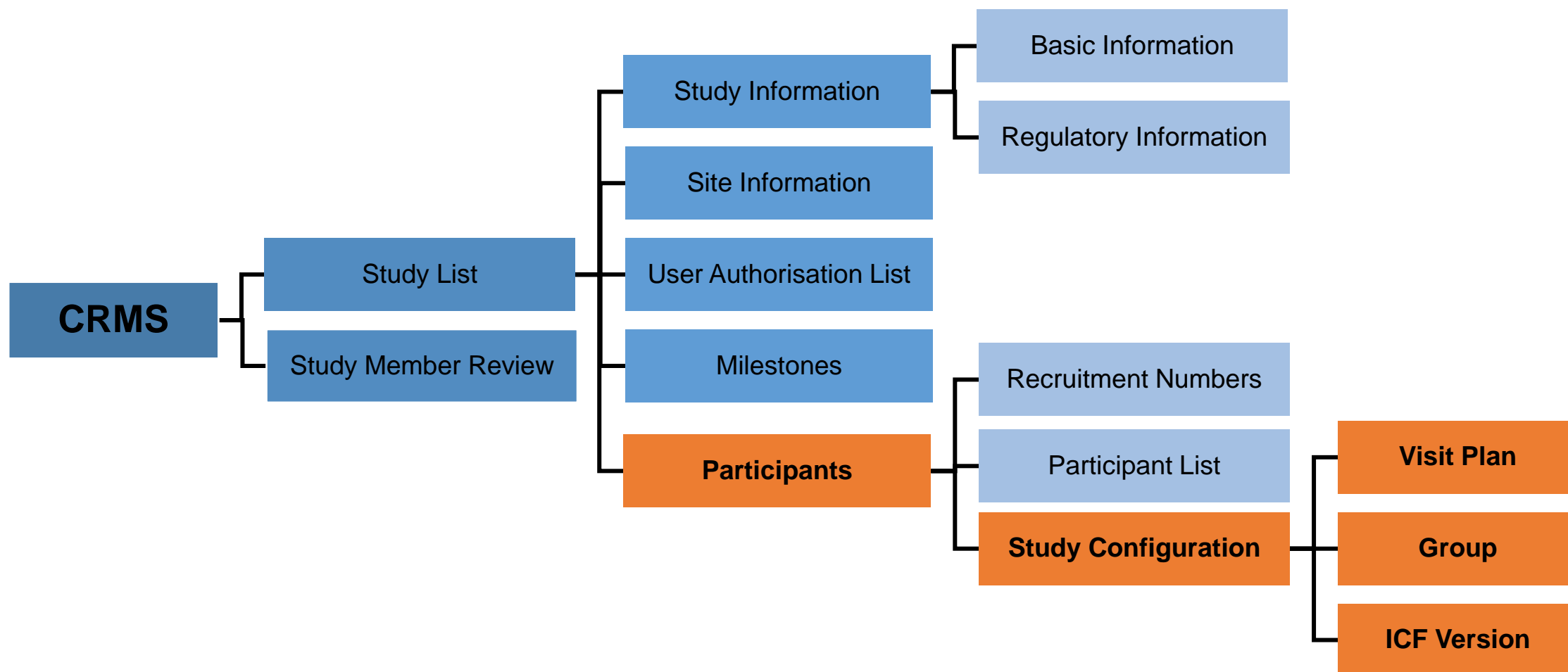
Visit Plan

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



Click [here](#) to return to Index.



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'. The left sidebar contains a menu with 'Study Configuration' selected. The main content area is titled 'Study Site: Singapore General Hospital' and lists 'Visit Plan', 'Group', and 'ICF Version' as configuration options. A red box with a banner icon and the word 'IMPORTANT' contains the text: '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

Study Information

Basic Information

Regulatory Information

Site Information

User Authorisation List

Milestones

Participants

Recruitment Numbers

Participant List

Study Configuration

Study Site: Singapore General Hospital

Visit Plan

Group

ICF Version

+ Add

Edit

Drug-X (Single Arm)

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

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

Participants – Study Configuration

Site Level

Study Details

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

Study Site: Singapore General Hospital

Visit Plan

Group

ICF Version

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

Rows per page: 100 1-1 of 1

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

Study Site: Singapore General Hospital

Visit Plan

Group

ICF Version

+ Add

Columns

Filter

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

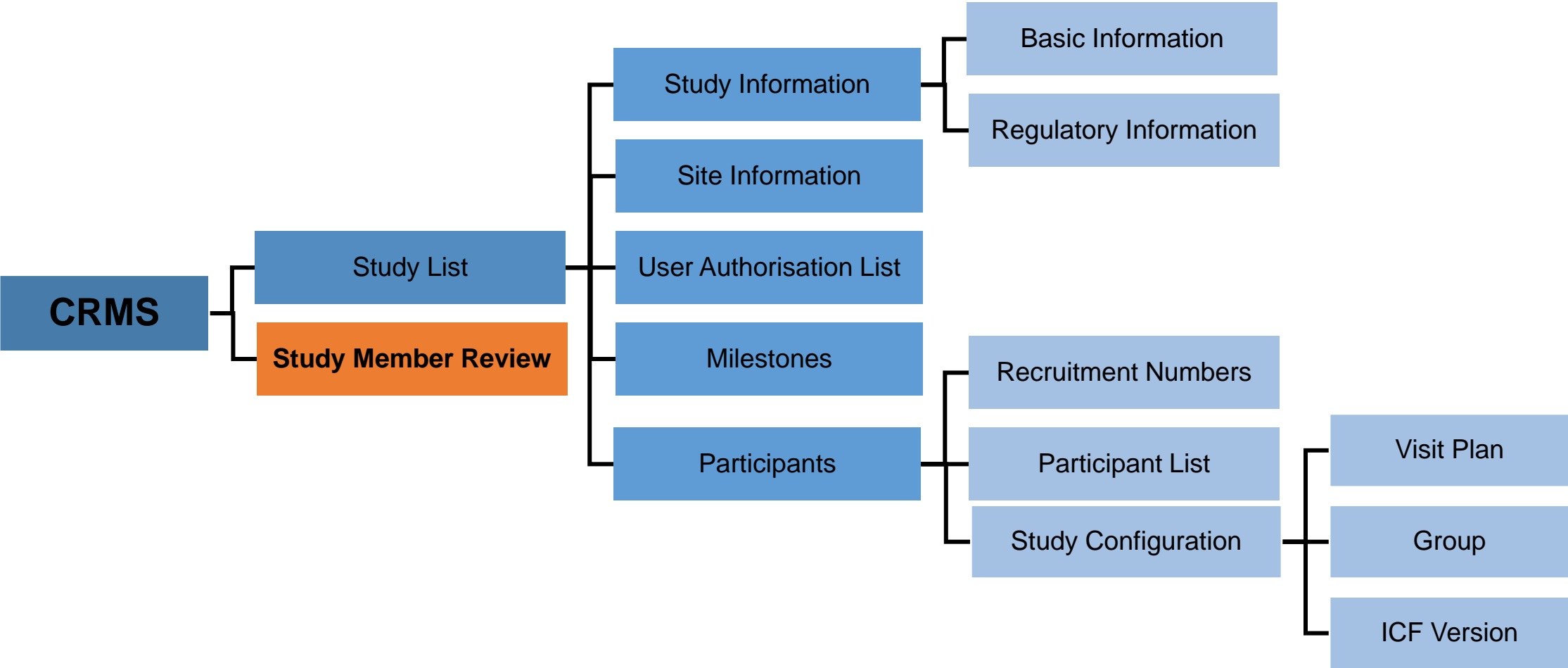
Below the screenshots, a red box highlights a search bar in the 'Visit Plan' section. The search bar contains a red asterisk and a magnifying glass icon. Below the search bar, the text 'No item' is displayed.

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

CRMS Sitemap



Click [here](#) to return to Index.



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 displays the ECOS Dashboard interface. On the left, a navigation sidebar includes links for Homepage, Dashboard (highlighted with an orange box), My Tasks, My Notices, IRB, CRMS, FCOI, and Report. The main dashboard area features three large tiles: IRB (30), CRMS (11), and FCOI (0). The CRMS tile contains a link labeled 'Study Member Review 11', which is pointed to by an orange arrow. A blue arrow points from a text box to the CRMS tile. To the right, there is a 'My Notices' section with a 'View All' link and a list of notices. 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	Pending Endorsement

Step 1: Check the box.

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

Study Member Review Access

Site Level


- 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. On the left, a navigation menu lists various options: Homepage, Dashboard (highlighted), My Tasks, My Notices, IRB, CRMS, Study List, Study Member Review (highlighted with an orange arrow), and FCOI. The main content area shows three summary cards: IRB with a count of 8 (Study: 8, Endorsement: 0), CRMS with a count of 3 (Study Member Review: 3), and FCOI with a count of 0 (My FCOI List: 0). A 'My Notices' section on the right shows a notice for all dated 07-Apr-2024. An orange callout box with an arrow pointing to the 'Study Member Review' menu item contains the text: 'Click to enter the Study Member Review page.'




Category	Count
IRB	8
CRMS	3
FCOI	0


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

Homepage

IRB

CRMS

Study List

Study Member Review

FCOI

Report

Study Member Review

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

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

Study Member Review

Site Level

- Action: **ENDORSE**

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

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

- Action: **REJECT**

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

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

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*).

[Back to Submission Detail](#) **Submission Detail** [Help](#) [Download](#) [Notifications](#) [99+](#)

2024-0205-APP1 [Draft](#) [Refresh](#)

ECOS Ref: 2024-0205 [Print](#)

[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

The screenshot shows a modal window titled "ECOS" with a close button (X) in the top right corner. A yellow banner at the top contains a warning icon and the text: "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." Below this is a table with four columns: "Section", "Field", "Reason", and "Action". The table lists two identical rows for "Section C: Study Funding Information". The first row's reason is "There is no Sponsor/CRO information in CRMS. Please enter at least one Sponsor/CRO in the CRMS." and the second row's reason is "No billing information in CRMS." Both rows have a blue square icon with a white arrow pointing outwards in the "Action" column. A blue "Confirm" button is located at the bottom right of the modal.

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

Confirm

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

Complete Sponsor/CRO and IRB Details in CRMS

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

Back to Study List

Study Details

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

ECOS Reference: 2024-0205

IRB: CIRB Board D

Study Status: • Draft

Number of Sites: 2

Initial Outcome Date: -

Valid Till Date: -

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

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

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

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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

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

Help

99+

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	Action
* XYZ Pharmaceuticals	* XYZ	* 98761234	* xyz@xyz.com	New Data	* Singapore 123654	S	Edit Delete

Clinical Research Organisation (CRO) Details

Add

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

IRB Review Fees Billing Details

Add

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

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

Applicable To Both Sponsor/CRO and IRB Details

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

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.

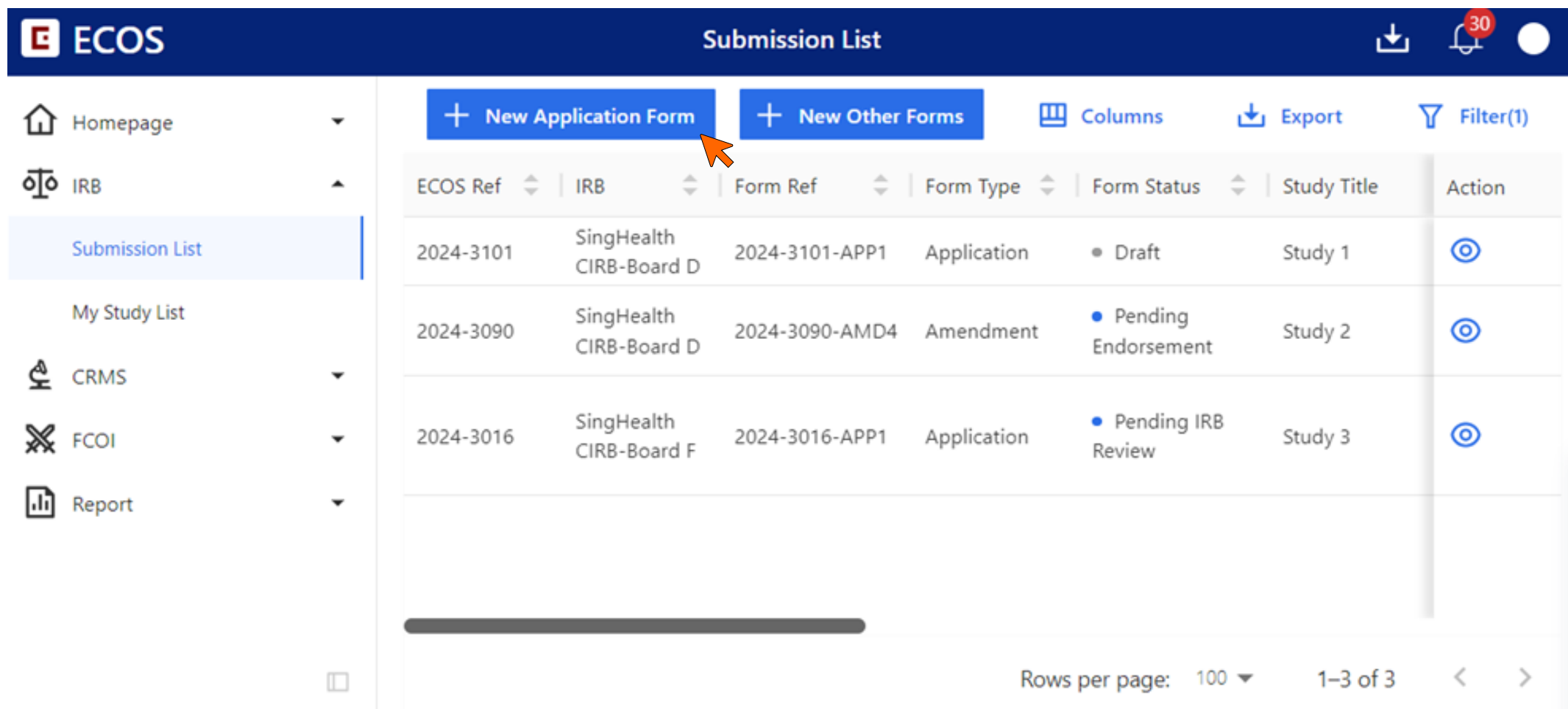
Addition of STM/SA/SS to the UAL by System

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 slides will briefly illustrate the above using a Study Sponsor (SS_20) account.

IRB Application Form Creation

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



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 prominent blue buttons: '+ New Application Form' and '+ New Other Forms'. An orange arrow points to the '+ New Application Form' button. 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 that says '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: - [icon]

Form Detail

Application Form

B2. Study Site and Study Investigator

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

Study Site List + Add

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

Investigator List + Add

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

Section A: Study Title

Section B: Submission B...

Section C: Study Fundin...

Section D: Study Type an...

Other Attachments

Declaration of Principal I...

Click Save.

Cancel Save

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 displays the 'Submission Detail' page in the CRMS IRB Module. A modal dialog box is open, prompting the user to select their Study Site and Study Role for continued access to the IRB Application Form. The dialog contains two dropdown menus: '* Site:' and '* Role:'. The '* Role:' dropdown is currently open, showing three options: 'Study Administrator', 'Study Sponsor', and 'Study Team Member'. A 'Save' button is visible in the bottom right corner of the dialog. The background shows the 'Application Form' section, including 'Section B: Submission Board' and 'B1. Submission IRB and Board'. The top navigation bar includes a 'Back to Submission List' link and a 'Submission Detail' title. The top right corner shows a download icon, a notification bell with a red '30' badge, and a user profile icon.

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 of the CRMS IRB Application Form. A modal dialog is open, prompting the user to select their Study Site and Study Role for continued access. The modal contains two dropdown menus: '* Site:' with 'Singapore General Hospital' selected, and '* Role:' with 'Study Sponsor' selected. A blue 'Save' button is visible at the bottom right of the modal, with an orange arrow pointing to it. The background shows the 'Form Detail' section of the application form, including 'Section B: Submission Board', 'B1. Submission IRB and Board', and 'B1. (a) The reviewing IRB will...'. The 'Save' button in the background is also visible, with a red '30' notification badge.

User Added to UAL by System

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

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

Study Site: Singapore General Hospital

+ 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.

The screenshot displays the ECOS Study List interface. On the left sidebar, the 'CRMS' module is highlighted with an orange box, and its sub-item 'Study List' is also highlighted. The main content area shows a table of studies. The first row of the table, corresponding to study 2024-3245, is highlighted with an orange box. The table has columns for ECOS Ref, IRB, PI/Site-PI, Number of Sites, Study Title, and Action. The Action column for the first row contains a target icon. The bottom of the interface shows pagination controls indicating 'Rows per page: 100' and '1-6 of 6'.

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

IRB Accessibility

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

ECOS Submission List

Navigation: Homepage, IRB, Submission List, My Study List, CRMS, FCOI, Report

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

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

ECOS My Study List

Navigation: Homepage, IRB, Submission List, My Study List, CRMS, FCOI, Report

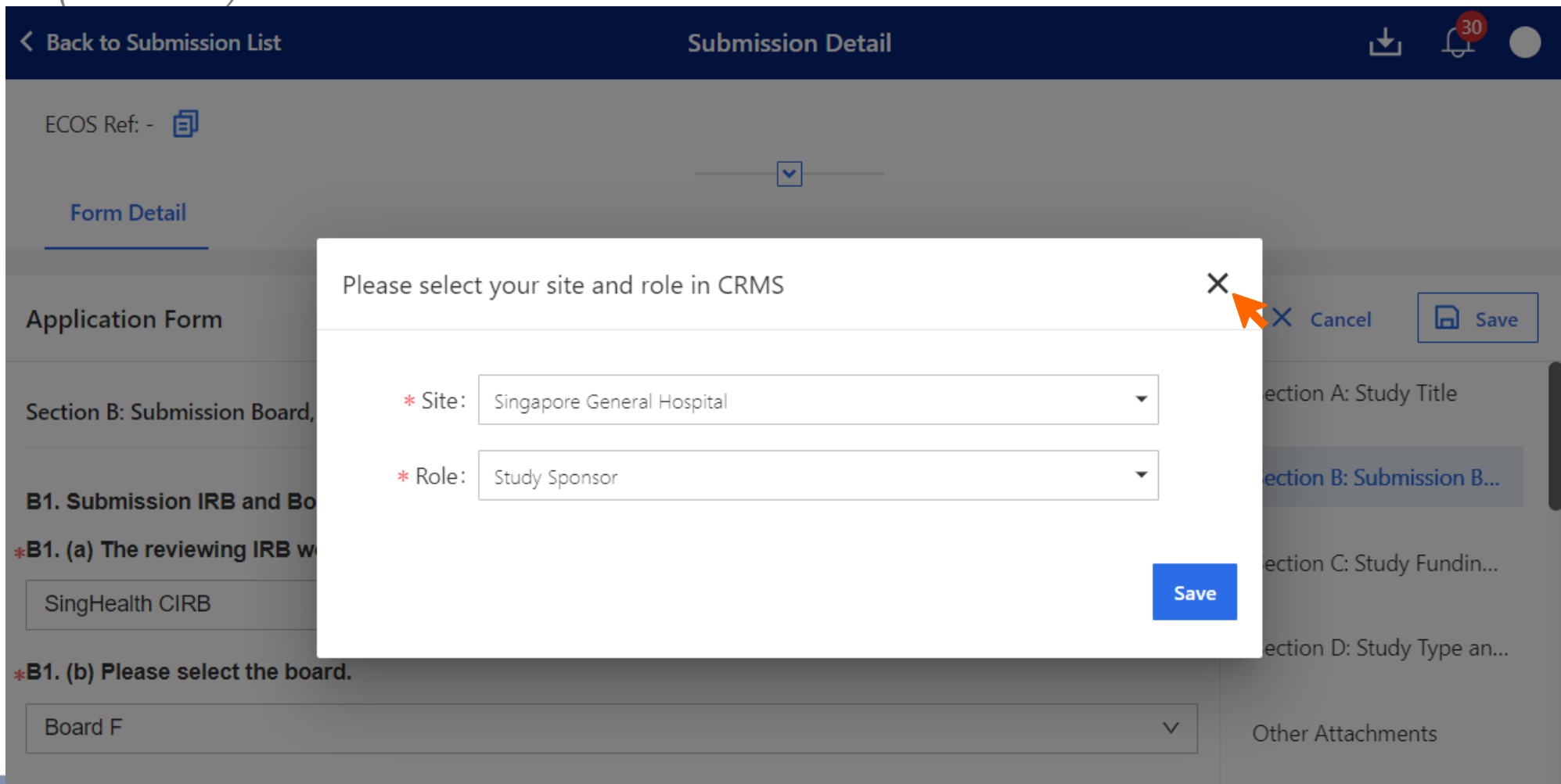
Buttons: Columns, Export, Filter

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

System Prompt

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



The screenshot shows a web application interface for a submission detail. The background is a form titled "Submission Detail" with a dark blue header. The form contains sections for "Form Detail", "Application Form", and "Section B: Submission Board". A modal dialog box is overlaid on the form, titled "Please select your site and role in CRMS". The dialog has a close button (✕) in the top right corner, which is highlighted by an orange arrow. The dialog contains two dropdown menus: "Site:" with "Singapore General Hospital" selected, and "Role:" with "Study Sponsor" selected. There is a "Save" button at the bottom right of the dialog. The background form has a "Cancel" button and a "Save" button on the right side. The background form also has a "Back to Submission List" link in the top left corner. The background form has a "SingHealth CIRB" button and a "Board F" dropdown menu. The background form has a "Section A: Study Title" and "Section B: Submission B..." and "Section C: Study Fundin..." and "Section D: Study Type an..." and "Other Attachments" section.

System Prompt

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

The screenshot shows a web application interface for 'Submission Detail'. At the top, there is a dark blue header with a back arrow and 'Back to Submission List' on the left, and 'Submission Detail' in the center. On the right of the header are icons for download, a notification bell with a red '30' badge, and a profile circle. Below the header, the main content area is greyed out. It includes an 'ECOS Ref: -' with a document icon, a dropdown menu, and a 'Form Detail' section. The 'Application Form' section is visible, showing 'Section B: Submission Board' and 'B1. Submission IRB and Board'. Under 'B1', there are two items: '*B1. (a) The reviewing IRB v' with a text input containing 'SingHealth CIRB', and '*B1. (b) Please select the bo' with a dropdown menu showing 'Board F'. A white confirmation dialog box is centered over the form. It has a close 'X' button in the top right corner. The text inside the dialog reads: 'Kindly note that you will lose access to this IRB Application Form if no information has been saved.' followed by 'Do you want to proceed?'. At the bottom of the dialog are two buttons: 'Cancel' and 'Confirm'.

System Prompt

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

Back to Study Details

Study Details

Download

30

Profile

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

Study Site: Singapore General Hospital

Add

Columns

Export

Filter(1)

Member Name	Role	Cluster	Institution	Department	Action
SGH_PI	PI	SingHealth	Singapore General Hospital	Department of Renal Medicine	
SG_20	Study Sponsor		Astra Zeneca	Astra Zeneca	

Rows per page: 1001-2 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 90](#)
 - Collapse the Study Details panel and CRMS Side Navigation Bar – [Slide 95](#)
 - Expand the Study Details panel and CRMS Side Navigation Bar – [Slide 96](#)
 - Edit data – [Slide 97](#)
 - Add data – [Slide 99](#)
 - Delete data – [Slide 101](#)
 - Save data – [Slide 102](#)
 - Cancel – [Slide 105](#)
 - Filter to display specific data – [Slide 108](#)
 - Columns to narrow specific data columns to be displayed – [Slide 111](#)
 - Export – [Slide 114](#)
 - Add user to the User Authorisation List – [Slide 116](#)
 - Endorse or Reject user via the Study Member Review – [Slide 122](#)
 - Deactivate user on the User Authorisation List – [Slide 123](#)



Click [here](#) to return to Page Functions index.

Page Functions – Study Dropdown Bar

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

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



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	
<input type="text" value="XYZ Pharmaceuticals"/>	<input type="text" value="XYZ"/>	<input type="text" value="98761234"/>	<input type="text" value="xyz@xyz.com"/>	<input type="text"/>	<input type="text" value="Singapore 123654"/>	<input type="text" value="L"/>

Clinical Research Organisation (CRO) Details

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

IRB Review Fees Billing Details

Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Last Edited By
<input type="text" value="LMN"/>	<input type="text" value="95672341"/>	<input type="text" value="lmn@ab.com"/>	<input type="text"/>	<input type="text" value="Singapore654123"/>	<input type="text" value="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

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	
* XYZ Pharmaceuticals	* XYZ	* 98761234	* xyz@xyz.com		* Singapore 123654	

Clinical Research Organisation (CRO) Details

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

IRB Review Fees Billing Details

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

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.

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

Study Site: Singapore General Hospital

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	-	-	-	-	24-Jan-2024	
SGH_Co-I1	Col	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	-	-	-	-	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	



Click [here](#) to return to Page Functions index.

Page Function – Collapse

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

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



Click [here](#) to return to Page Functions index.

Page Functions – Expand

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

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

Expand

Sponsor Details

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

Clinical Research Organisation (CRO) Details

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

IRB Review Fees Billing Details

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

Edit

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Click [here](#) to return to Page Functions index.

Page Functions – Edit Data

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

[< Back to Study List](#)Study DetailsHelpDownloadNotifications99+

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

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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		Singapore 123654

Clinical Research Organisation (CRO) Details

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

IRB Review Fees Billing Details

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

Page Functions – Edit Data

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

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Study Details

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

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SaveCancel

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.**

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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

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

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

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System In-built Requirements

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

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Study Details

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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.



Click [here](#) to return to Page Functions index.

Page Functions – Delete Data

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

Back to Study List Study Details Help [Download] [Bell] [99+] [Profile]

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

IRB Review Fees Billing Details [Save] [Cancel] [Add]

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.

Back to Study List Study Details Help [Download] [Bell] [99+] [Profile]

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

Sponsor Details [Save] [Cancel] [Add]

⚠ Do you want to proceed?

Cancel Confirm

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



Click [here](#) to return to Page Functions index.

Page Functions – Save Data

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

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Study Details

Help

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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

Last Edited

Action

* XYZ Pharmaceuticals

* XYZ

* 98761234

* xyz@xyz.com

New Data

* Singapore 123654

S

Cancel

Clinical Research Organisation (CRO) Details

Name of CRO

Contact Person Name

Business Contact No.

Business Email

Business Fax No.

Business Address

Last Edited

Action

* AB-CRO

* AB

* 98762345

* ab@ab.com

* Singapore 654123

S

Edit

Delete

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

* Add New Data

Add New Data

IRB Review Fees Billing Details

Contact Person Name

Business Contact No.

Business Email

Business Fax No.

Business Address

Last Edited

Save

Cancel

Add

Add

Add

Add

Data Edited

Data Added

Data Deleted

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Page Functions – Save Data

- Page view after Save.

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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	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 E

Record Tracking

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

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Study Details

Help

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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
* 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 6

IRB Review Fees Billing Details

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

Business Fax No.

Business Address

Last Edited By

Last Edited Date

New Data

* Singapore 123654

SGH_PI

14-Mar-2024

Business Fax No.

Business Address

Last Edited By

Last Edited Date

Add New Data

* Add New Data

SGH_PI

14-Mar-2024

Add New Data

* Add New Data

SGH_PI

14-Mar-2024

* Singapore 654123

SGH_PI

23-Jan-2024

s Fax No.

Business Address

Last Edited By

Last Edited Date

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Click [here](#) to return to Page Functions index.

Page Functions – Cancel

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

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Study Details

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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 delete 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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Study Details

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

Clinical Research Organisation (CRO) Details

Save

Cancel

Add

Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address	Location	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	Last Updated	Action
* AB-CRO	* AB	* 98762345	* ab@ab.com		* Singapore 654123	SG	<div>EditDelete</div>

Page Functions – Cancel

- Deletion of 2 rows canceled.

[← Back to Study List](#)

Study Details

Help

99+

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

Edit

Sponsor Details

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

Clinical Research Organisation (CRO) Details

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


IRB Review Fees Billing Details

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



Click [here](#) to return to Page Functions index.

Page Functions – Filter

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

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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

ECOS Reference : 2024-0205

Number of Sites : 2

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)

IRB : CIRB Board D

Initial Outcome Date : 24-Jan-2024

Study Status : Approved

Valid Till Date : 23-Jan-2025

User Authorisation List

Study Site: Singapore General Hospital

+ 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	-	-	-	-	24-Jan-2024	
SGH_Co-I1	CoI	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_Co-I1@singhealth.com.sg	IRB	Active	24-Jan-2024	-	-	-	-	24-Jan-2024	
SGH_SA1	Study Administrator	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Senior Executive	SGH_SA1@sgh.com.sg	CRMS	Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	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 sections:

- Role Status:** Active X, Pending IRB Approval X, Pending Endorsement X, Not Approved X, Not Human Subjects Research X. An arrow points to the 'X' icon to delete these filters.
- Endorsement Date:** Start Date → End Date
- Endorsed By:** [Text input field]
- Deactivation Date:** Start Date → End Date [Calendar icon]
- Deactivated By:** [Text input field]
- Buttons:** Reset, Search. An arrow points to the Search button.

Step 2: Delete the pre-set labels.

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

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

Study Site: Singapore General Hospital

+ 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	-	-	-	-	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	-	-	-	-	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	User
SS_20	Study Sponsor	Non-PHI	Astra Zeneca	Astra Zeneca	CRA	SS_20@az.com	CRMS	Pending Endorsement	-	-	-	-	SGH_Co-I1	24-Jan-2024	



Click [here](#) to return to Page Functions index.

Page Functions – Columns

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

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

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

Study Site: Singapore General Hospital

+ 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	-	-	-	-	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	-	-	-	-	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	
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.

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Page Functions – Columns

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

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 for 'Study Site: Singapore General Hospital'. The list contains two entries: 'SGH_PI1' (PI) and 'SGH_Co-I1' (Col), both associated with 'SingHealth' and 'Singapore General Hospital'.

The 'Column' modal is open, showing a list of columns with checkboxes. The columns are: Member Name, Role, Cluster, Institution, Department, Designation, Email Address, Data Source, and Role Status. The checkboxes for 'Cluster', 'Department', 'Designation', and 'Email Address' are unchecked, as indicated by the orange callout box. The 'Save' button is highlighted by another callout box.

Step 2: Uncheck the boxes:

- Cluster
- Department
- Designation
- Email Address

Step 3: Click Save.

Page Functions – Columns

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

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Study Details

Help

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

User Authorisation List

Study Site: Singapore General Hospital

+ 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	-	-	-	-	24-Jan-2024	
SGH_Co-I1	CoI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	-	-	-	-	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	
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

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Click [here](#) to return to Page Functions index.

Page Functions – Export

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

[Back to Study List](#)

Study Details

Help

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

User Authorisation List

Study Site: Singapore General Hospital

+ 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	-	-	-	-	24-Jan-2024	
SGH_Co-I1	Col	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	-	-	-	-	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	
SS_20	Study Sponsor	Astra Zeneca	CRMS	Pending Endorsement	-	-	-	-	SGH_Co-I1	24-Jan-2024	

Rows per page: 100 1-5 of 5

Page Functions – Export

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

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



Click [here](#) to return to Page Functions index.

Page Functions – Add User

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

[< 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. Singapore General Hospital

User Authorisation List

Study Site: Singapore General Hospital

Step 1: Check that you are on the correct Study Site's UAL.

Step 2: Click Add.

+ 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	-	-	-	-	24-Jan-2024	
SGH_Co-I1	CoI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	-	-	-	-	24-Jan-2024	
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	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	

Rows per page: 1001-4 of 4

Page Functions – Add User



Fuzzy search is not allowed.

[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

User Authorisation List

Study Site: Singapore General Hospital

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

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

Add

[Submit](#) [Cancel](#)

Step 4: 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 5: 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

< 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

User Authorisation List

Study Site: Singapore General Hospital

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 7: 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 6: 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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Study Details

Help

1

99+

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

User Authorisation List

Study Site: Singapore General Hospital

+ 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	-	-	-	-	24-Jan-2024	
SGH_Co-I1	CoI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	-	-	-	-	24-Jan-2024	
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	CRMS	Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	
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	

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.

[Back to Study List](#)

Study Details

HelpDownloadNotifications

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

User Authorisation List

Study Site: Singapore General Hospital

+ 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	-	-	-	-	24-Jan-2024	
SGH_Co-I1	Col	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	-	-	-	-	24-Jan-2024	
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	CRMS	Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	
SGH_STM22	Study Team Member	Singapore General Hospital (SGH)	CRMS	Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	
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.

Back to Study List

Study Details

Help

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99+

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

User Authorisation List

Study Site: Singapore General Hospital

+ 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	
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	● Active	24-Jan-2024	-	-	-	-	24-Jan-2024	
SGH_Co-I1	CoI	Singapore General Hospital (SGH)	IRB	● Active	24-Jan-2024	-	-	-	-	24-Jan-2024	
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	CRMS	● Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	
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	

Rows per page: 100 1-6 of 6



Click [here](#) to return to Page Functions index.

Page Functions – Endorse or Reject User

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

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 icon. 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 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



Click [here](#) to return to Page Functions index.

Page Functions – Deactivate User

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

Back to Study List

Study Details

Help

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

User Authorisation List

Study Site: Singapore General Hospital

+ 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	
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	-	-	-	-	24-Jan-2024	
SGH_Co-I1	Col	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	-	-	-	-	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	
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 the Deactivate icon.

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

User Authorisation List

Study Site: Singapore General Hospital

+ 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	
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	-	-	-	-	24-Jan-2024	
SGH_Co-I1	Col	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	-	-	-	-	24-Jan-2024	
Study Team		Singapore General									

Email Notifications

Email Notifications

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

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

CRMS Reports

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.

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)

- **14 types of reports:**
 - Recruitment Number
 - Enrolment and Reporting Status
 - Study Milestones
 - Regulatory Information (Clinical Trials Regulated by HSA)
 - Regulatory Information (CRM)
 - Regulatory Information (rHBR)
 - Publication Listing
 - SAE Reports for CT Insurance
 - Studies Listing
 - Grant Listing
 - Contracts Tracking Listing
 - Study Agreement Listing
 - List of Studies Managed by the Respective Primary/Backup Site Coordinator
 - Recruitment Numbers and Recruitment Summary
- Access to the different CRMS Reports is tied to a user's role.
 - CRMS RO administrator has access to all CRMS Reports.
 - PI, Site-PI, Co-I, STM, SA can only access 2 reports, i.e. List of Studies Managed by the Respective Primary/Backup Site Coordinator and Recruitment Numbers and Recruitment Summary.

CRMS Report Access

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

The screenshot displays the ECOS CRMS Institution Report interface. The left sidebar contains a navigation menu with the following items: Homepage, IRB, CRMS, FCOI, SDB, Report, CRMS Office, and CRMS Institution Report. The 'Report' item is highlighted with an orange box, and 'CRMS Institution Report' is selected. The main area shows a table header with columns: S/N, CY, FY, Unique Identifier, ECOS Ref, Study Status, and Site Status. A blue arrow points to the 'Filter' button in the top right corner of the table area. The table content is currently empty, displaying the message: 'Please use "Filter" to search data first.'

Data Generation

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

The screenshot shows the ECOS (Electronic Clinical Outcome System) interface for generating data. The main header is "CRMS Institution Report". On the left, a sidebar menu lists various options, with "CRMS Institution Report" selected. The main content area displays a table with columns: S/N, CY, FY, Unique Identifier, and ECOS Ref. A message in the center of the table reads: "Please use 'Filter' to search data first." On the right, a "Filter" panel is open, showing input fields for "FY:", "Unique Identifier:", "ECOS Ref:", "Study Status:", "Site Status:", and "Study PI/Site-PI Name:". At the bottom of the filter panel, there are buttons for "Save Filter" (with a star icon), "Reset", and "Search". An orange arrow points to the "Search" button.

ECOS

CRMS Institution Report

Filter My Saved Filter X

Homepage

IRB

CRMS

FCOI

SDB

Report

CRMS Office

CRMS Institution Report

Regulatory Information (CRM)

Regulatory Information (rHBR)

SAE Reports for CT Insurance

Publications Listing

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Recruitment Number

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Regulatory Information (Clinical Tri...

Contracts Tracking Listing

S/N CY FY Unique Identifier ECOS Ref

Please use "Filter" to search data first.

FY:

Unique Identifier:

ECOS Ref:

Study Status:

Site Status:

Study PI/Site-PI Name:

Rows

Save Filter

Reset

Search

Export Function

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

The screenshot displays the ECOS CRMS Institution Report interface. The left sidebar contains a navigation menu with options: Homepage, IRB, CRMS, FCOI, SDB, Report, CRMS Office, and CRMS Institution Report (selected). The main content area shows a table of data with columns: S/N, CY, FY, Unique Identifier, ECOS Ref, Study Status, and Site Status. The table contains four rows of data, all with a status of 'Approved'. An orange arrow points to the 'Export' button in the top right corner of the table area. The bottom right corner shows 'Rows per page: 100' and '1-5 of 5'.

S/N	CY	FY	Unique Identifier	ECOS Ref	Study Status	Site Status
1	2024	2024	2024-3471-National Heart Centre Singapore	2024-3471	Approved	Approved
2	2024	2024	2024-3471-National Heart Centre Singapore	2024-3471	Approved	Approved
3	2024	2024	2024-3262-National Heart Centre Singapore	2024-3262	Approved	Approved
4	2024	2024	2024-3262-National Heart Centre Singapore	2024-3262	Approved	Approved

Columns Function

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

ECOS

CRMS Institution Report

Download

Notification

User

Homepage

IRB

CRMS

FCOI

SDB

Report

CRMS Office

CRMS Institution Report

Regulatory Information (CRM)

Regulatory Information (rHBR)

SAE Reports for CT Insurance

Publications Listing

Grant Listing

Recruitment Number

Enrolment and Reporting Status

Studies Listing

Study Milestones

Regulatory Information (Clinical Trials...

Contracts Tracking Listing

Study Agreement

List of studies managed by the respe...

Recruitment Numbers and Recruitme...

Columns

Export

Filter

Column

Selected 33

Search

Q

Select All

S/N

CY

FY

Unique Identifier

ECOS Ref

Study Status

Site Status

Study Protocol Title

Study PI/Site-PI Name

Clear

Cancel

Save

S/N	FY	Unique Identifier	ECOS Ref	Study Status	Study PI/Site-PI Name
1	2024	2024-3471-National Heart Centre Singapore	2024-3471	Approved	A/Prof(Adj)
2	2024	2024-3471-National Heart Centre Singapore	2024-3471	Approved	A/Prof(Adj)
3	2024	2024-3262-National Heart Centre Singapore	2024-3262	Approved	A/Prof KKH NCC_PI 2 (N 1 (National Neuroscien Hospital), A
4	2024	2024-3262-National Heart Centre Singapore	2024-3262	Approved	A/Prof KKH NCC_PI 2 (N 1 (National Neuroscien Hospital), A
5	2024	2024-3262-National Heart Centre Singapore	2024-3262	Approved	A/Prof KKH NCC_PI 2 (N 1 (National Neuroscien Hospital), A

Filter Function

ECOS

CRMS Institution Report

Filter

My Saved Filter

X

Homepage

IRB

CRMS

FCOI

SDB

Report

CRMS Office

CRMS Institution Report

Regulatory Information (CRM)

Regulatory Information (rHBR)

SAE Reports for CT Insurance

Publications Listing

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Recruitment Number

Enrolment and Reporting Status

Studies Listing

Study Milestones

Regulatory Information (Clinical Trials...

Contracts Tracking Listing

Study Agreement

List of studies managed by the respe...

Recruitment Numbers and Recruitme...

S/N

CY

FY

Unique Identifier

ECOS Ref

Study Status

1	2024	2024	2024-3471-National Heart Centre Singapore	2024-3471	Approved
2	2024	2024	2024-3471-National Heart Centre Singapore	2024-3471	Approved

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

Rows

12

FY:

2024

Unique Identifier:

ECOS Ref:

Study Status:

Site Status:

Study PI/Site-PI Name:

Name :

Form Initial Submission Date:

01-Aug-2024 → 31-Aug-2024

Form Review Outcome Date:

Start Date → End Date

Save Filter

Reset

Search

My Saved Filter Function

ECOS

CRMS Institution Report

Homepage

IRB

CRMS

FCOI

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Regulatory Information (rHBR)

SAE Reports for CT Insurance

Publications Listing

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Study Agreement

List of studies managed by the respe...

Recruitment Numbers and Recruitme...

CRMS Institution Report

S/N

CY

FY

Unique Identifier

ECOS Ref

Study Status

1

2024

2024

2024-3471-National Heart Centre Singapore

2024-3471

Approved

2

2024

2024

2024-3471-National Heart Centre Singapore

2024-3471

Approved

Filter

My Saved Filter

FY:

2024

Unique Identifier:

ECOS Ref:

Study Status:

Site Status:

Study PI/Site-PI Name:

Name :

Form Initial Submission Date:

FY 2024, Month Aug

2024

Cancel

Confirm

Start Date

End Date

Save Filter

Reset


Search

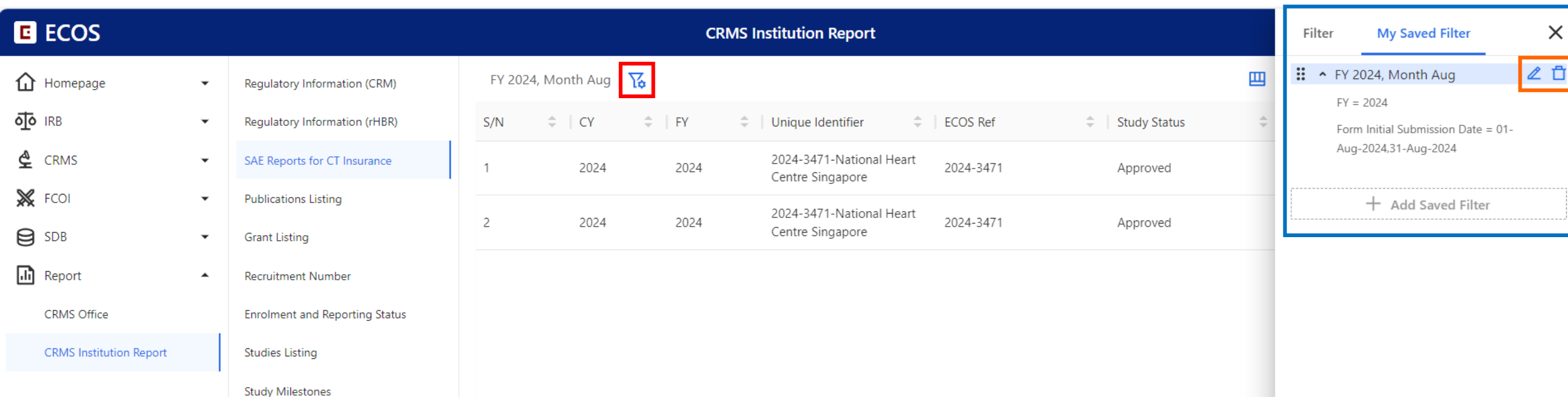
• Name the filter parameter(s) to be saved, then click **Confirm**.

SingHealth Version 2.0 Dated 28 May 2025

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My Saved Filter Function

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



The screenshot displays the ECOS CRMS Institution Report interface. On the left is a navigation menu with options like Homepage, IRB, CRMS, FCOI, SDB, Report, and CRMS Office. The main content area is titled 'CRMS Institution Report' and shows a table of data for 'FY 2024, Month Aug'. A red box highlights the 'My Saved Filter' icon in the top right corner of the report area. On the right side, a 'Filter' panel is open, showing the 'My Saved Filter' tab. This panel lists the saved filter 'FY 2024, Month Aug' with its parameters: 'FY = 2024' and 'Form Initial Submission Date = 01-Aug-2024,31-Aug-2024'. There are edit and delete icons for this filter, and a button to 'Add Saved Filter'.

S/N	CY	FY	Unique Identifier	ECOS Ref	Study Status
1	2024	2024	2024-3471-National Heart Centre Singapore	2024-3471	Approved
2	2024	2024	2024-3471-National Heart Centre Singapore	2024-3471	Approved

My Saved Filter Function

ECOS

Homepage

IRB

CRMS

FCOI

SDB

Report

CRMS Office

CRMS Institution Report

Regulatory Information (CRM)

Regulatory Information (rHBR)

SAE Reports for CT Insurance

Publications Listing

Grant Listing

Recruitment Number

Enrolment and Reporting Status

Studies Listing

Study Milestones

Regulatory Information (Clinical Trials...

Contracts Tracking Listing

Study Agreement

List of studies managed by the respe...

Recruitment Numbers and Recruitme...

CRMS Institution Report

FY 2024, Month Aug

S/N	CY	FY	Unique Identifier	ECOS Ref	Study Status
1	2024	2024	2024-3471-National Heart Centre Singapore	2024-3471	Approved
2	2024	2024	2024-3471-National Heart Centre Singapore	2024-3471	Approved

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

Filter

My Saved Filter

FY 2024, Month Aug

FY:

2024

Unique Identifier:

ECOS Ref:

Study Status:

Site Status:

Study PI/Site-PI Name:

Name :

Form Initial Submission Date:

01-Aug-2024 → 31-Aug-2024

My Saved Filter Function

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

The screenshot displays the ECOS CRMS Institution Report interface. On the left is a navigation menu with options: Homepage, IRB, CRMS, FCOI, SDB, Report, CRMS Office, and CRMS Institution Report (selected). The main content area shows a report titled 'CRMS Institution Report' with a filter tab 'FY 2024, Month Aug' highlighted. A tooltip for this filter shows 'FY = 2024' and 'Form Initial Submission Date = 01-Aug-2024,31-Aug-2024'. The report table has columns: Unique Identifier, ECOS Ref, Study Status, and Site Status. Two rows of data are visible, both for '2024-3471-National Heart Centre Singapore' with 'Approved' status.

Unique Identifier	ECOS Ref	Study Status	Site Status
2024-3471-National Heart Centre Singapore	2024-3471	Approved	Approved
2024-3471-National Heart Centre Singapore	2024-3471	Approved	Approved

My Saved Filter Function

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

ECOS

Homepage

IRB

CRMS

FCOI

SDB

Report

CRMS Office

CRMS Institution Report

Regulatory Information (CRM)

Regulatory Information (rHBR)

SAE Reports for CT Insurance

Publications Listing

Grant Listing

Recruitment Number

Enrolment and Reporting Status

Studies Listing

Study Milestones

Regulatory Information (Clinical Trials...

Contracts Tracking Listing

Study Agreement

CRMS Institution Report

FY 2024, Month AugFY2024, Month Jul

S/N	CY	FY	Unique Identifier	ECOS Ref	Study Status
1	2024	2024	2024-3262-National Heart Centre Singapore	2024-3262	Approved
2	2024	2024	2024-3262-National Heart Centre Singapore	2024-3262	Approved
3	2024	2024	2024-3262-National Heart Centre Singapore	2024-3262	Approved

FilterMy Saved Filter

FY 2024, Month Aug

FY2024, Month Jul

Add Saved Filter

Exported Report View

SAE Reports for CT Insurance								
Downloaded By: Ms NHC_RO14								
Downloaded Date and Time: 07-May-2025 15:30:38								
Data is accurate as of: 07-May-2025 00:00:00								
S/N	CY	FY	Unique Identifier	ECOS Ref	Study Status	Site Status	Study Protocol Title	Study PI/Site-PI Name
1	2024	2024	2024-3471-National Heart Centre Singapore	2024-3471	Approved	Approved	AAA	A/Prof(Adj) NHC_PI 1 (National Heart Centre Singapore)
2	2024	2024	2024-3471-National Heart Centre Singapore	2024-3471	Approved	Approved	BBB	A/Prof(Adj) NHC_PI 1 (National Heart Centre Singapore)

REMINDER:

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

Filters Applied

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

SAE Reports for CT Insurance			
Downloaded By: Ms NHC_RO14			
Downloaded Date and Time: 07-May-2025 15:30:38			
<u>Data Filter(s) Applied</u>			
FY: 2024			
Unique Identifier:			
ECOS Ref:			
Study Status:			
Site Status:			
Study PI/Site-PI Name:			
Name :			
Form Initial Submission Date: 01-Aug-2024 ~ 31-Aug-2024			
Form Review Outcome Date:			
Form Review Outcome:			
Onset Date:			
Study Site:			

CRMS Research Office Role

CRMS RO Role

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

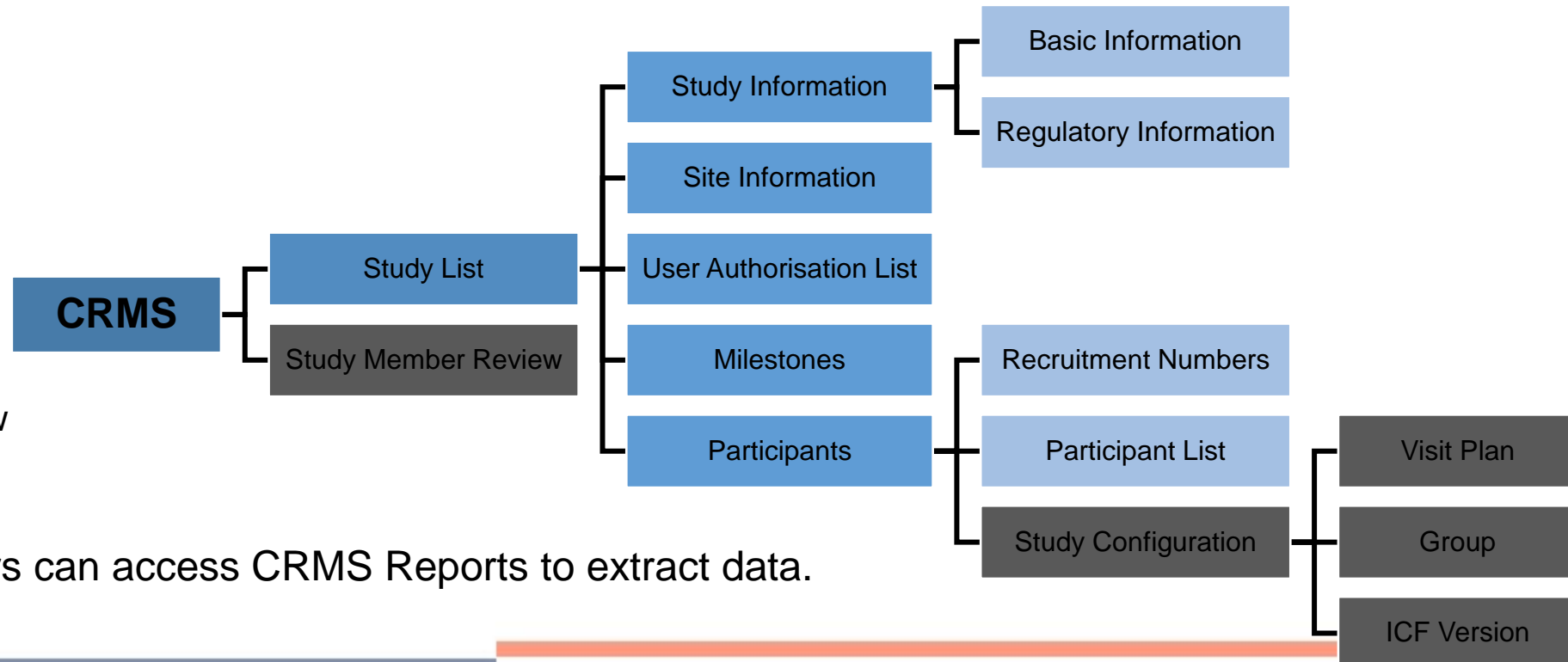
- Page level access: -

✓ **Study Level**

✓ **Site Level**

- No page access to: -

- × Study Member Review
- × Study Configuration



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

Access to IRB Institution Study List

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

ECOS Institution Study List													Columns		Export		Filter	
ECOS Ref IRB Study Status Study Title PI/Site-PI Name Initial Review Category Outcome Date Valid Till Date Study Funding Involved Inst Action																		
2024-3267													SingHealth CIRB-Board D		Approved		Compliance DNC/SAE UAT 1 – Multi-Cluster, Multi-Site Restricted HBR	
A/Prof(Adj) NHC_PI 1 (National Heart Centre Singapore), A/Prof KKH_PI 1 (KK Women's and Children's Hospital), Asst Prof NCC_PI 2 (National Cancer Centre Singapore), Mr NNI_PI 1 (National Neuroscience Institute), A/Prof NUH_PI (National University Hospital), Asst Prof TTSH_PI (Tan Tock Seng Hospital)													Expedited		08-Jul-2024		07-Jul-2025	
(b) Grant													KK Women's Medicine Se Singapore-C Oncology, Ni Department Institute-Ne University H Hospital-Op					
2024-3265													SingHealth CIRB-Board D		Approved		Compliance DNC/SAE UAT 1 – Multi-Cluster, Multi-Site Other Study	
Mr NNI_PI 1 (National Neuroscience Institute), A/Prof KKH_PI 1 (KK Women's and Children's Hospital), Asst Prof NCC_PI 2 (National Cancer Centre Singapore), A/Prof(Adj) NHC_PI 1 (National Heart Centre Singapore), A/Prof NUH_PI (National University Hospital), Asst Prof TTSH_PI (Tan Tock Seng Hospital)													Expedited		08-Jul-2024		07-Jul-2025	
(b) Grant													KK Women's Medicine Se Singapore-C Oncology, Ni Department Institute-Ne University H Hospital-Op					
2024-3262													SingHealth CIRB-Board D		Approved		Compliance DNC/SAE UAT 1 – Multi-Cluster, Multi-Site HBR	
A/Prof KKH_PI 1 (KK Women's and Children's Hospital), Asst Prof NCC_PI 2 (National Cancer Centre Singapore), A/Prof(Adj) NHC_PI 1 (National Heart Centre Singapore), Mr NNI_PI 1 (National Neuroscience Institute), A/Prof NUH_PI (National University Hospital), Asst Prof TTSH_PI (Tan Tock Seng Hospital)													Expedited		08-Jul-2024		07-Jul-2025	
(b) Grant													KK Women's Medicine Se Singapore-C Oncology, Ni Department Institute-Ne University H Hospital-Op					
2024-3201													SingHealth CIRB-Board C		Approved		BH Sprint 2 Re-test Multi-site - selecting sites to test patience - extremely slow typing is the way to go but no one asked for this test	
Prof NHC_PI 2 (National Heart Centre Singapore), Asst Prof TTSH_PI (Tan Tock Seng Hospital), A/Prof CGH_PI11													Full Board		01-Jul-2024		30-Jun-2025	
(a) Department Fund or No funding is required for this study to be carried out													Changi Gene Emergency, Department					
													Rows per page: 100		1-12 of 12			

Migration of Existing Studies

Migration of Existing Studies (SingHealth)

- **Study Information – Basic Information**

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

- **User Authorisation List**

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

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

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 ECOS access to IRB, CRMS, Compliance, Monitoring and/or Audit modules?

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

- Additional helpful questions to ask:

Is the user required to...

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

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

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

Site Delegation Log

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

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

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

CRMS UAL

ECOS

User Authorisation List

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

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

Access Roles to Other Modules



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

Modules	Pages/Forms	Access Roles
Compliance	Site Task List for <ul style="list-style-type: none"> - DNC - SAE - PISAF 	<ul style="list-style-type: none"> • Approved PI/Site-PI and Co-I • Active STM
Monitoring	Plan Review for <ul style="list-style-type: none"> - Monitoring Plan 	<ul style="list-style-type: none"> • Approved PI/Site-PI
	Study Monitoring Information for <ul style="list-style-type: none"> - Plan Visit - Confirmation Letter - Monitoring Report - Issue List - Follow-up Letter 	<ul style="list-style-type: none"> • Approved PI/Site-PI and Co-I • Active STM
	My Issue	Any of the below selected as the Responsible Person: <ul style="list-style-type: none"> • Approved PI/Site-PI or Co-I • Active STM
Audit	Study Audit Information for <ul style="list-style-type: none"> - Plan Audit - Site Audit (Audit Report and Audit Report Observation) 	<ul style="list-style-type: none"> • Approved PI/Site-PI and Co-I • Active STM

Key Points

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

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

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

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*

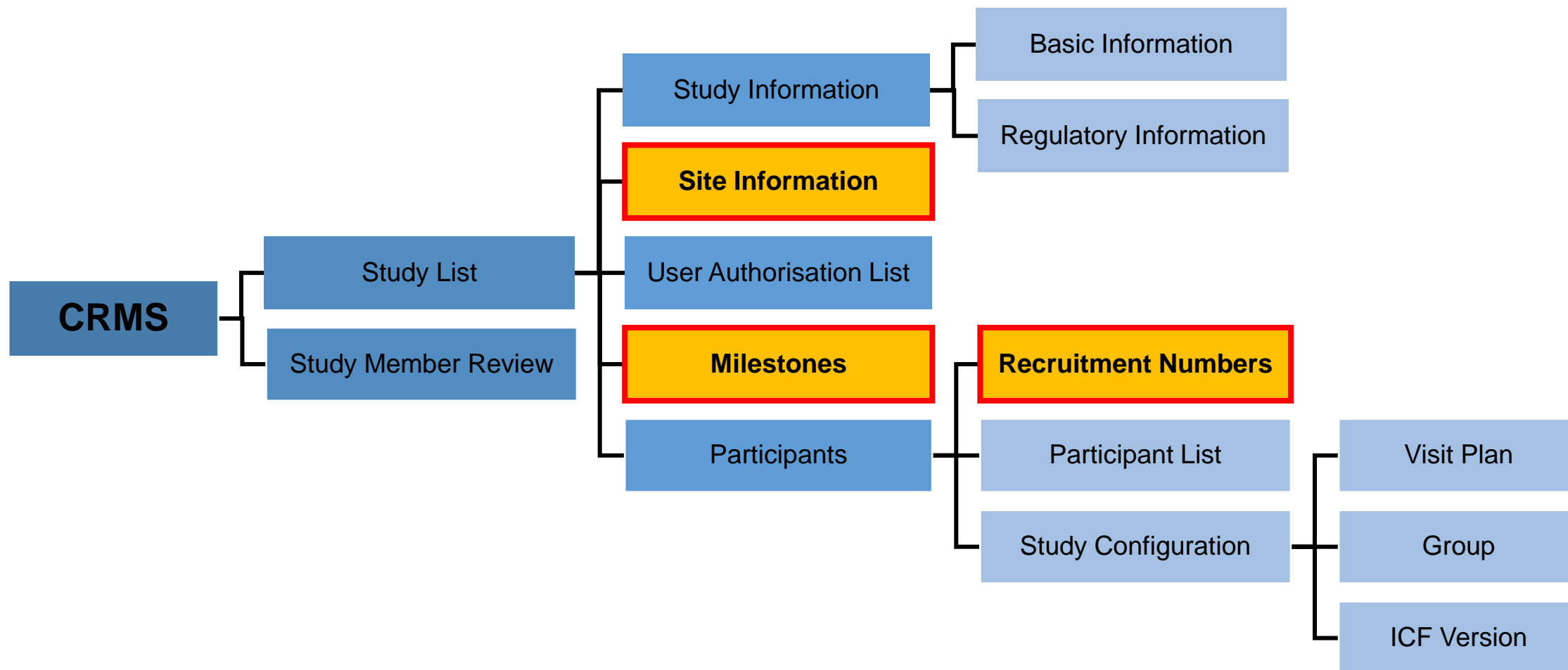
- **Optional** but highly encouraged:**

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

NOTE:

- * Refer to the guide by SingHealth CTCC for more information.
- ** Each institution's Research Office may impose different requirements on each CRMS page.

Mandatory Pages



Common Discrepancies Observed

Observation #1: Improper Role Assigned

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

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Regulatory Information

Site Information

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Milestones

Participants

User Authorisation List

Study Site: Study Site A

+ Add

Columns

Export

Filter(1)

Member Name	Role	Cluster	Institution	Department	Designation	Email Address	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Action
	Study Team Member	Singapore Health Services Pte Ltd			Senior Clinical Research Coordinator		CRMS	Active	26-Jul-2024		-	
	Study Administrator	External			Associate Director, Country Clinical Operations		CRMS	Active	26-Jul-2024		-	
	Study Administrator	External			Site Activation Specialist		CRMS	Active	26-Jul-2024		-	
	Study Administrator	External			Clinical Research Associate		CRMS	Active	26-Jul-2024		-	
	Study Administrator	External			Site Activation Specialist II		CRMS	Active	16-Jul-2024		-	
	PI	Singapore Health Services Pte Ltd			Consultant		IRB	Active	15-Jun-2024		-	
	Col	Singapore Health Services Pte Ltd			Associate consultant		IRB	Active	15-Jun-2024		-	
	Study Team	Singapore Health			Clinical Research		CRMS	Active	26-Jul-2024		-	

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

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

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ECOS Ref, Study Protocol Title / SingHealth Study Site B

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Basic Information

Regulatory Information

Site Information

User Authorisation List

Milestones

Participants

User Authorisation List

Study Site: SingHealth Study Site B

+ Add

Columns

Export

Filter(1)

Member Name	Role	Cluster	Institution	Department	Designation	Email Address	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Action
	Col	Singapore Health Services Pte Ltd			Consultant		IRB	Pending IRB Approval	-	-	-	
	Col	Singapore Health Services Pte Ltd			Senior Consultant		IRB	Pending IRB Approval	-	-	-	
	PI	Singapore Health Services Pte Ltd			Senior Consultant		IRB	Pending IRB Approval	-	-	-	
	Study Sponsor	External			Site Activation Specialist		CRMS	Pending Endorsement	-	-	-	
	Study Team Member	National University Health System			Clinical Research Coordinator		CRMS	Pending Endorsement	-	-	-	
	Study Team Member	Singapore Health Services Pte Ltd			Clinical Research Coordinator		CRMS	Pending Endorsement	-	-	-	
	Study Team Member	National University Health System			Clinical Research Coordinator		CRMS	Pending Endorsement	-	-	-	

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Potential Downstream Impacts

- **Data privacy issues.**

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

- **Disrupts data accuracy in the CRMS Report section.**

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

Summary

Key Takeaways

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

Key Takeaways

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