
Navigating the Ethics & Compliance Online System (ECOS)



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Overview of ECOS & General

Overview of ECOS

Minimum Training

Institutional Review Board

Clinical Research Management System

Financial Conflict Of Interest
(For NHG DSRB review studies only)

Will be available from 10 May 2024*

IRB Reports for Institutions and IRB

Compliance – Study Deviation and
Non-Compliance / Serious Adverse Event

Compliance – PI Self-Assessment Form

Quality – Monitoring & Audit

To be confirmed



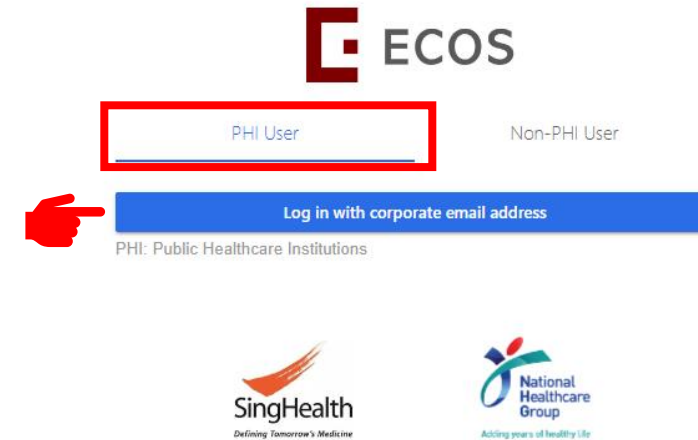
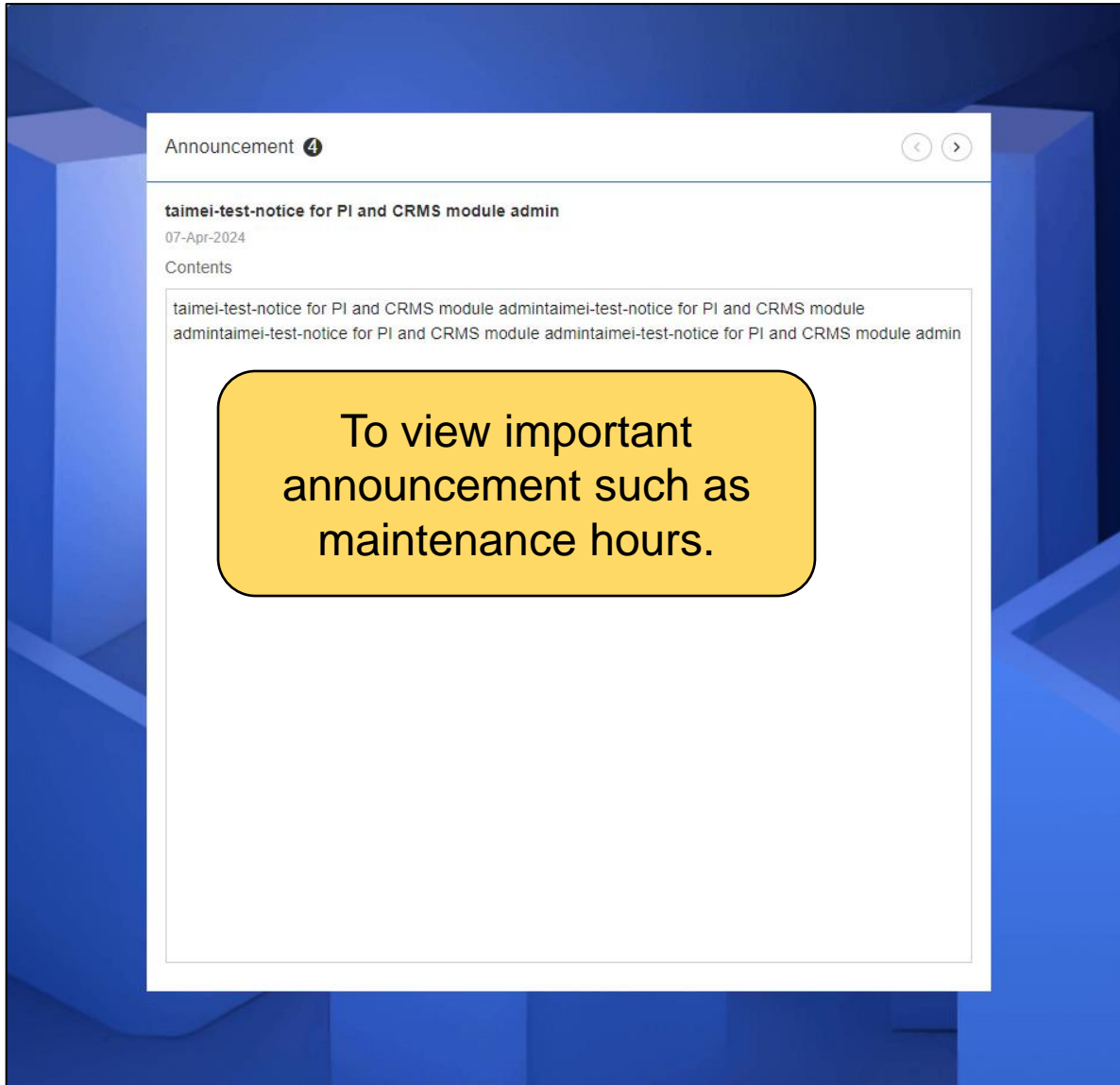
IRB Review

Submissions require Full Board Review in May, the application must reach CIRB by **17 May 2024, 5pm.**

An application is considered “Reached CIRB” only when Research Office Check, DR endorsement and IR endorsement are completed.

Full Board Meeting Dates						
	A	B	C	D	E	F
May	31 May	30 May	29 May	31 May	30 May	28 May
Jun	21 Jun	20 Jun	19 Jun	21 Jun	20 Jun	25 Jun

Account Login (For PHI Users)



ECOS account will be automatically generated for user with corporate email account (M365).

Account Login (For PHI Users)

HealthSG |

Sign in

Email, phone, or Skype

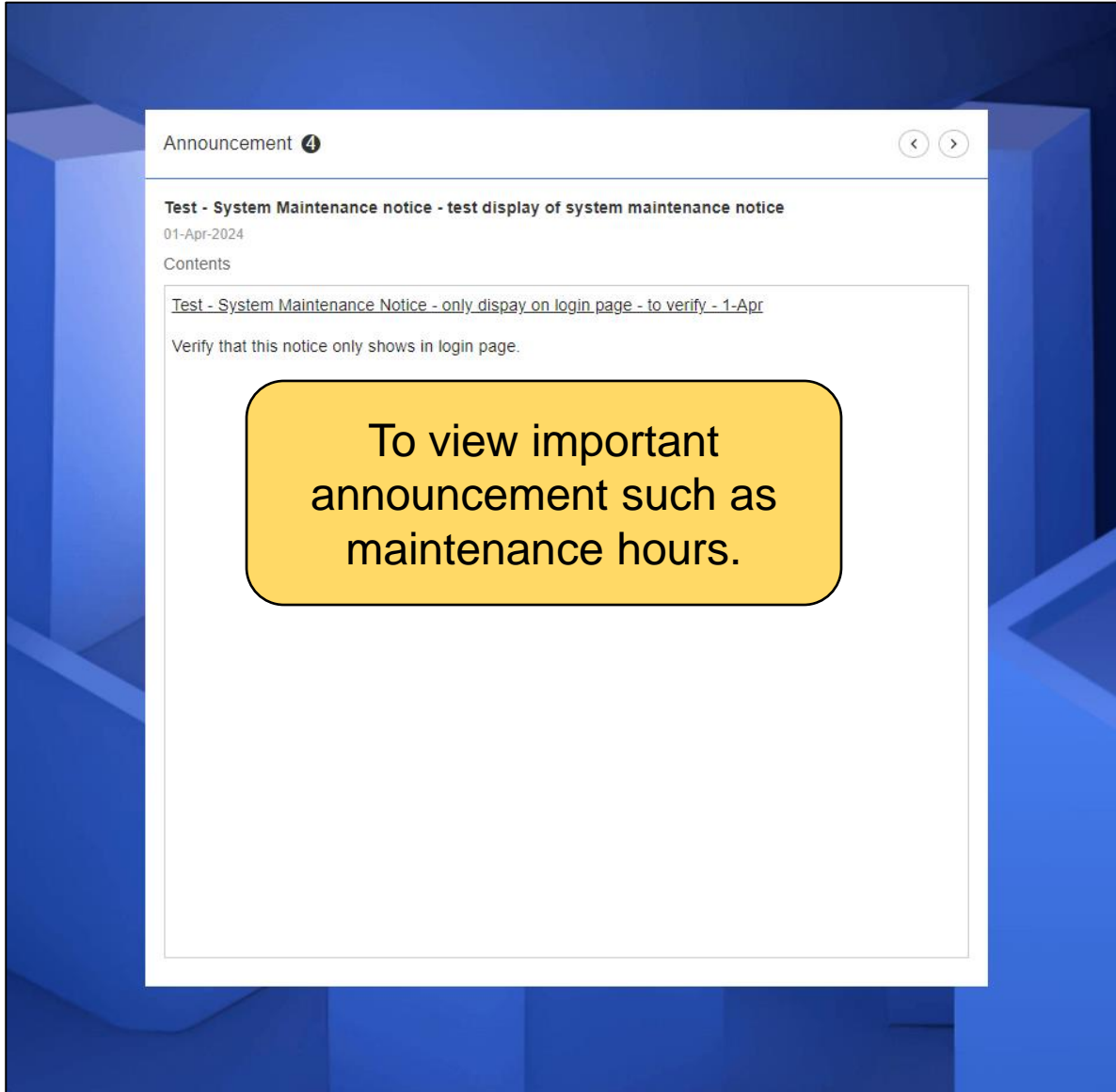
[Can't access your account?](#)

Next

Sign-in options

You will be redirected to this webpage to login to your M365 account.
Complete the login process and you will be login to ECOS.

Account Login (For non-PHI Users)



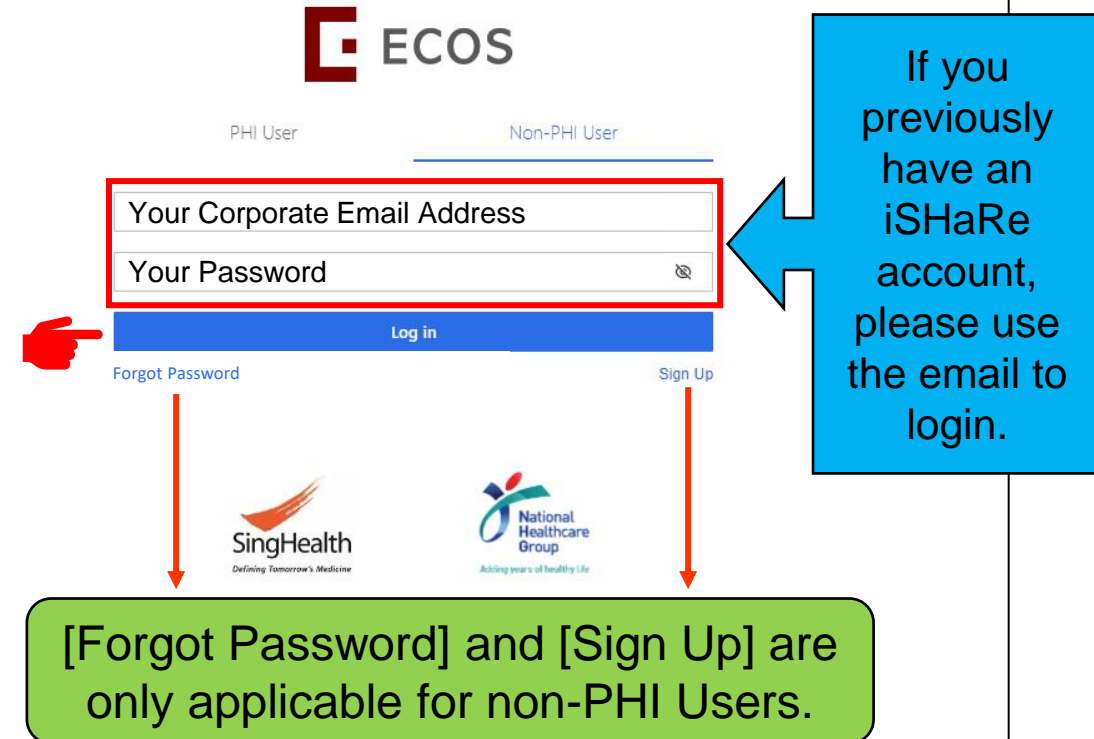
Announcement 4

Test - System Maintenance notice - test display of system maintenance notice
01-Apr-2024
Contents

[Test - System Maintenance Notice - only display on login page - to verify - 1-Apr](#)

Verify that this notice only shows in login page.

To view important announcement such as maintenance hours.



ECOS

PHI User Non-PHI User

Your Corporate Email Address

Your Password

Log in

Forgot Password Sign Up

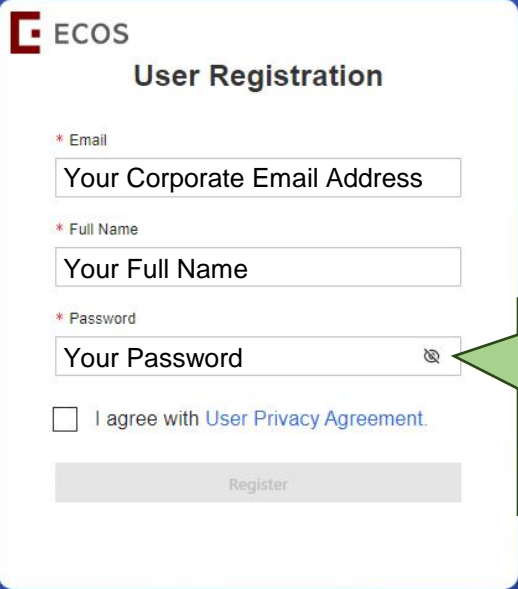
If you previously have an iSHaRe account, please use the email to login.

[Forgot Password] and [Sign Up] are only applicable for non-PHI Users.

SingHealth
Defining Tomorrow's Medicine

National Healthcare Group
Adding years of healthy life

Account Creation (For non-PHI users)



The image shows a user registration form for the ECOS system. The form is titled "User Registration" and includes the ECOS logo. It contains four input fields: "Your Corporate Email Address", "Your Full Name", "Your Password", and a checkbox for "I agree with User Privacy Agreement". A "Register" button is located at the bottom of the form. A green callout box points to the password field, listing requirements: minimum 15 characters, cannot reuse previous 5 passwords, and must contain at least 3 of 4 groups (capital letters, small letters, numbers, symbols). The background features a blue gradient with a faint illustration of a doctor and a close button in the top right corner.

ECOS
User Registration

* Email
Your Corporate Email Address

* Full Name
Your Full Name

* Password
Your Password

I agree with [User Privacy Agreement](#).

Register

- Minimum 15 characters
- Cannot reuse previous 5 passwords
- Password must have at least 3 of the 4 groups (capital letters, small letters, numbers, symbols)

Account Login (For non-PHI Users)

Announcement 4

Test - System Maintenance notice - test display of system maintenance notice
01-Apr-2024
Contents

[Test - System Maintenance Notice - only display on login page - to verify - 1-Apr](#)
Verify that this notice only shows in login page.

Verify Account [X]

To keep your account safe, please scan the QR code below to bind your account in the Authenticator APP, first.

Please enter the verification code you received in the Authenticator APP.

ECOS

PHI User Non-PHI User

Delivering Transformation • Medicine Advancing your work in healthcare

1. Please download the Microsoft Authenticator from Apple – App Store or Android – Play Store.
2. Please scan the QR code.
3. Please enter the 6-digit verification code shown in the Microsoft Authenticator app to bind your account to the app.

*After binding your account, subsequent login would only require step 3.

Account Login – Microsoft Authenticator

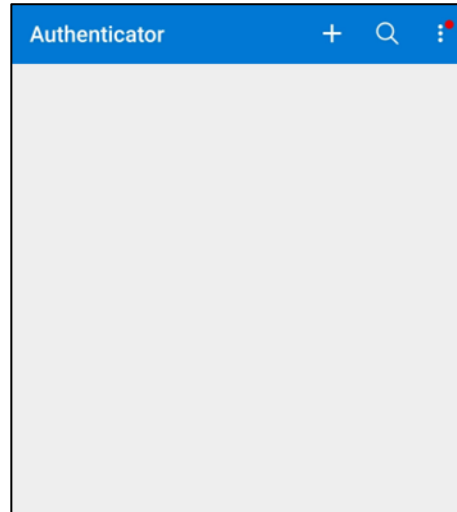
Step 1:

Download Microsoft Authenticator.



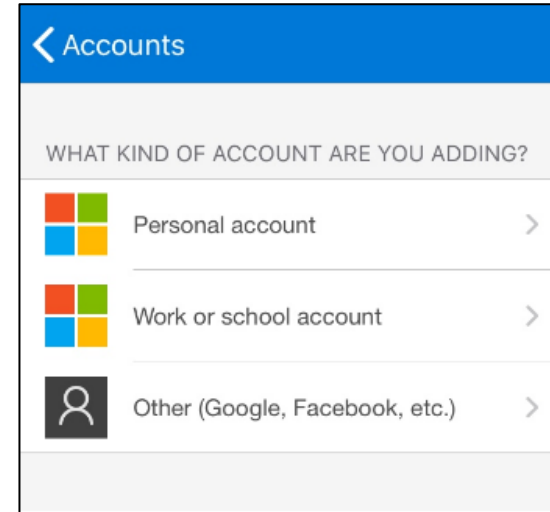
Step 2:

Click '+' to add account.



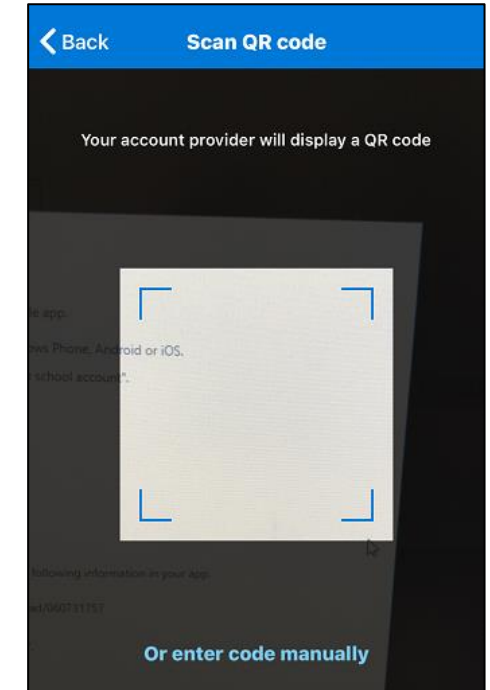
Step 3:

Select 'Other account (Google, Facebook, etc.)'



Step 4:

Scan QR code to bind your account



Account Status

- ❑ Locked Account: Locked after 5 consecutive failed logins.
 - PHI users: To unlock account, to send a request to it.helpdesk@singhealth.com.sg for SingHealth users. Other PHI users to approach their institution IT helpdesk.
 - Non-PHI users: To unlock account, to use 'Forgot Password' feature.

- ❑ Disabled Account: Disabled after 90 calendars days of user login inactivity.
 - All users: To reactivate account, send a request in <https://for.sg/ecos-support-request>.

- ❑ Forgot Password
 - For PHI users, the ECOS login password would be your corporate email address (M365) password. In the event that you have forgotten your password, please reset your password via M365 or contact your Institution's IT helpdesk.
 - For non-PHI users, you may reset your password in ECOS using 'Forgot Password' feature.

User Profile

Marilyn Lam Salutation: Ms ✕

Mandatory to indicate your salutation

Profile and Minimum Training Information | Study Information

Current Appointment Details + Add

Mandatory to provide 'Primary Appointment'

Primary/Secondary Appointment	Cluster	Institution/Organisation	Department	Designation	Action
Primary	Singapore Health Services Pte Ltd	Singapore Health Services	Centralised Institutional Review Board	Executive	✎ 🗑

Academic Qualifications + Add

Mandatory to provide at least 1 'Academic Qualifications'

Institution	Qualification	Date of Attainment	Action
Murdoch University	Bachelor's Degree	01-Apr-2016	✎ 🗑

Employment History + Add

Institution/Organisation	Department	Designation	From	To	Action
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Registration Type + Add

For medical practitioners / dental practitioners / pharmacists, please provide your registration information

Registration Council	Type of Current Registration	Date of Registration	Action
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Minimum Training Certificates ? + Add

Note: Meet the minimum training requirement to conduct:NIL

Cluster	Name of Training Certification	File Name	Training Completion Date	Expiry Date	Validity Date	Document Review Status	Comments/Rejection Reason	Action
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Accessing to User Profile

The screenshot displays the ECOS Dashboard interface. The top navigation bar includes the ECOS logo, the word "Dashboard", and utility icons for download, notifications (99+), and a user profile icon (highlighted with a red square). The left sidebar contains navigation links: Homepage, Dashboard (selected), My Tasks, My Notices, IRB, CRMS, FCOI, and Report. The main content area features three data cards: IRB (5 total, with sub-categories Study: 5 and Endorsement: 0), CRMS (2 total, with sub-category Study Member Review: 2), and FCOI (0 total, with sub-category My FCOI List: 0). A "My Notices" section shows a notification: "ECOS is officially launched". A green callout box with a white background and black text points to the user profile icon, stating: "Click to enter User Profile for updating and submission of Minimum Training Certificates."

User Profile: Minimum Training

Marilyn Lam
Salutation: Dr [↗](#)

[Profile and Minimum Training Information](#) [Study Information](#)

Minimum Training Certificates [?](#)

Note: Meet the minimum training requirement to conduct: ✓ Non-HBR, Clinical Trials, HBR + Add

Cluster	Name of Training Certification	File Name	Training Completion Date	Expiry Date	Validity Date	Document Review Status	Comments/Rejection Reason	Action
SingH...	GCP	GCP Certific...	01-Apr-2023	-	Permanent	● Completed		↗ 🕒
SingH...	HBRA Essentials	HBR CERTIFI...	01-Dec-2022	-	Permanent	● Completed		↗ 🕒
SingH...	CITI Biomed	CITI CERTIFI...	01-Nov-2021	-	Permanent	● Completed		↗ 🕒

- 1 Display the type of studies that you can conduct.
- 2 Click to add new training certification achieved.
- 3 Check Document Review Status for latest update.
Type of Document Review Status: Draft, Pending Review, Completed and Rejected
- 4 Click to edit and update the training certification.
- 5 View the history of the submission of the training certification.

User Profile: Minimum Training

- 1 Choose the type of training certification to be submitted.
- 2 Upload the training certification.
(Accepted File Format: pdf, doc)
- 3 Select Training Completion Date.
- 4 Expiry Date is not mandatory.
- 5 Click Save for more information to be included when available.
- 6 Click Submit and training certification will be reviewed by the Minimum Training Secretariat.

The screenshot shows a web form titled "Certificate Detail" with a "Close" button (marked 5) and a "Submit" button (marked 6). The form contains the following fields:

- "* Name of Training Certification" (marked 1): A dropdown menu.
- "* File Name" (marked 2): A button labeled "Upload" with an upload icon.
- "* Training Completion Date" (marked 3): A date selection field with the placeholder text "Select date" and a calendar icon.
- "Expiry Date" (marked 4): A date selection field with the placeholder text "Select date" and a calendar icon.

Minimum Training Requirement

Your Institution's Minimum Training Secretariat will review your training certification and update the type of studies that you can conduct based on the following criteria:

		Training Certification		
		Collaborative Institutional Training Initiative (CITI) Biomedical Research Investigators and Key Personnel	Human Biomedical Research Act (HBRA) Essential	Good Clinical Practice (GCP) Certification
Type of Studies That You can Conduct	Non-HBR	✓		
	HBR	✓	✓	
	Clinical Trials	✓		✓

User Profile – Study Information

Marilyn Lam

Salutation: Ms [✎](#)

Profile and Minimum Training Information

Study Information

Study Information

[Columns](#)

[Export](#)

[Filter](#)

ECOS Ref	IRB	Site	Study Status	Initial Outcome Date	Valid Till Date	Study Classification	Study Role
2024-0193	CIRB - Board A	Singapore National Eye Centre (SNEC)	Pending Endorsement	-	-	(d) Others – The study is not regulated by Health Products Act/ Medicines Act (HSA) nor Human Biomedical Research Act (MOH)	Study Team Member
2024-0177	CIRB - Board A	Singapore National Eye Centre (SNEC)	Pending Review	-	-	(d) Others – The study is not regulated by Health Products Act/ Medicines Act (HSA) nor Human Biomedical Research Act (MOH)	PI
2024-0142	CIRB - Board A	Singapore National Eye Centre (SNEC)	Approved	16-Jan-2024	15-Jan-2025	(d) Others – The study is not regulated by Health Products Act/ Medicines Act (HSA) nor Human Biomedical Research Act (MOH)	Co-I

- View the list of studies that you are involved in.

Dashboard – At a Glance

The screenshot displays the ECOS Dashboard interface. The top navigation bar includes the ECOS logo, the title 'Dashboard', and utility icons for download, notifications (99+), and user profile. A left sidebar contains navigation links: Homepage, Dashboard (highlighted with a green box), My Tasks, My Notices, IRB, CRMS, FCOI, and Report. The main content area is divided into two sections. The first section, outlined in red, shows three columns for pending tasks: IRB (5), CRMS (2), and FCOI (0). Below these are sub-tasks: IRB Study (5) and Endorsement (0); CRMS Study Member Review (2); and FCOI My FCOI List (0). A yellow callout box states: 'Display the number of pending tasks for each modules.' The second section, also outlined in red, is titled 'My Notices' and features a 'View All >' link. It displays a single notice: '● ECOS is officially launched'. A yellow callout box states: 'Display the latest notice from ECOS'.

Module	Pending Tasks
IRB	5
CRMS	2
FCOI	0

Module	Task	Count
IRB	Study	5
	Endorsement	0
CRMS	Study Member Review	2
FCOI	My FCOI List	0

Dashboard – My Tasks

ECOS My Tasks Help

Homepage Dashboard My Tasks My Notices IRB CRMS FCOI

IRB 3 CRMS 2

Study(3) Endorsement(0)

Columns Export Filter(1)

Task Received Date	Task Status	Form Type	Form Ref	Study Title	Action
24-Jan-2024	Pending	Application	2024-0193-APP1	CG23 - For Training Purposes	
24-Jan-2024	Pending	Application	2024-0192-APP1	CG23 - To test ROC query	
29-Jan-2024					

View all pending tasks.

Dashboard – My Notices

The screenshot shows the ECOS 'My Notices' dashboard. The sidebar on the left contains navigation links: Homepage, Dashboard, My Tasks, My Notices (highlighted), IRB, CRMS, and FCOI. The main content area displays a table of notices with columns for Title and Publish Date. A single notice is listed: 'UAT - Dashboard notice for all' with a publish date of '30-Jan-2024'. A red dot next to the title indicates it has not been read. A yellow callout box with a red border contains the text 'View the list of notices sent in ECOS'. The top navigation bar includes 'My Notices', 'Help', 'Columns', 'Export', and 'Filter'.

Title	Publish Date
● UAT - Dashboard notice for all	30-Jan-2024

- The '●' shows that the notice had not been read.

System Notification

The screenshot displays the ECOS Dashboard interface. At the top left is the ECOS logo. The main header is labeled 'Dashboard'. On the right side of the header, there is a notification bell icon with a red '99+' badge, which is highlighted with a red box. Below the header is a left-hand navigation menu with options: Homepage, Dashboard (selected), My Tasks, My Notices, IRB, CRMS, FCOI, and Report. The main content area is divided into three columns: IRB (5), CRMS (2), and FCOI (0). The IRB column contains a table with 'Study' (5) and 'Endorsement' (0). The CRMS column contains 'Study Member Review' (2). The FCOI column contains 'My FCOI List' (0). On the right side, there is a 'Notification (107)' panel. It lists several notifications, each starting with 'ECOS Ref' followed by a reference number and a subject line. A green callout box with a red hand icon points to the first notification in the list. The callout box contains the text: 'Click on individual system notification to view content. (Refer to next slide)'. At the bottom of the notification panel, there are two links: 'Dismiss All Notifications' and 'Show More Notifications'.

ECOS Dashboard

Notification (107) Task

- ECOS Ref 2024-0430 – Application Rejected by DR
Dear Dr NNI_PI 1 and Mrs SNEC_Basic1,
ECOS 18 days ago
- ECOS Ref 2024-0430 – Request for DR Endorsement
Dear A/Prof SNEC_DR 1,
ECOS 18 days ago
- ECOS Ref 2024-0409 – Request for DR Endorsement
Dear Ms SKH_DR,
ECOS 18 days ago
- ECOS Ref 2024-0395 – Request for DR Endorsement
Dear Mr NNI_DR 1,
ECOS 19 days ago
- ECOS Ref 2024-0395 – Request for DR Endorsement
Dear Mr NNI_DR 1,
ECOS 19 days ago
- ECOS Ref 2024-0364 – Request for DR Endorsement
Dear A/Prof SNEC_DR 1,
ECOS 19 days ago

[Dismiss All Notifications](#) [Show More Notifications](#)

- Click on '  ' to view the list of system notifications

System Notification

The screenshot displays the ECOS Dashboard interface. The top navigation bar includes the ECOS logo, the word "Dashboard", and utility icons for download, notifications (99+), and a profile icon. The left sidebar contains navigation options: Homepage, Dashboard (selected), My Tasks, My Notices, IRB, CRMS, FCOI, and Report. The main content area features three summary cards: IRB (5 total, 5 Study, 0 Endorsement), CRMS (2 total, 2 Study Member Review), and FCOI (0 total). A red-bordered notification window is overlaid on the right, titled "ECOS Ref 2024-0395 – Request for DR Endorsement". The notification text reads: "Dear Mr NNI_DR 1, The Application requires your endorsement. Please login to ECOS to complete the DR Endorsement. ECOS Ref: 2024-0395 Study Title: CG (21 Mar 24) - Study 3 PI/Site-PI: Dr NNI_PI 1(National Neuroscience Institute (NNI)) IRB: CIRB-Board A This is a system generated notification. Please do not reply to this email. ECOS 19 days ago".

ECOS Ref 2024-0395 – Request for DR Endorsement X

Dear Mr NNI_DR 1,

The Application requires your endorsement. Please login to ECOS to complete the DR Endorsement.

ECOS Ref: 2024-0395

Study Title: CG (21 Mar 24) - Study 3

PI/Site-PI: Dr NNI_PI 1(National Neuroscience Institute (NNI))

IRB: CIRB-Board A

This is a system generated notification. Please do not reply to this email.

ECOS 19 days ago

Download Center



The screenshot shows the ECOS Dashboard with a navigation sidebar on the left and a main content area. The sidebar includes links for Homepage, Dashboard (highlighted), My Tasks, My Notices, IRB, and CRMS. The main content area features three summary cards: IRB (4), CRMS (2), and FCOI (0). A 'My Notices' section lists recent notifications. A 'Download List (1)' modal is open, showing a document titled 'Application Form_2024_2260-APP1.pdf' (547.87 KB) with 'Delete' and 'Download To Local' options. A yellow callout box at the bottom of the modal states 'Stored for 7 days only.'.

1 Click 'Refresh' if the document has not been downloaded.

2 Click 'Delete All' to delete all documents from Download Center.

3 Click 'Delete' to delete single document from Download Center.

4 Click 'Download To Local' to download document into your PC.

- Click on '  ' to view the list for documents downloaded

IRB Submission and Migrated Study

Submission Workflow

Draft New Application Form

✓ Finalise

Principal Investigator (PI)

➔ Declare and Submit

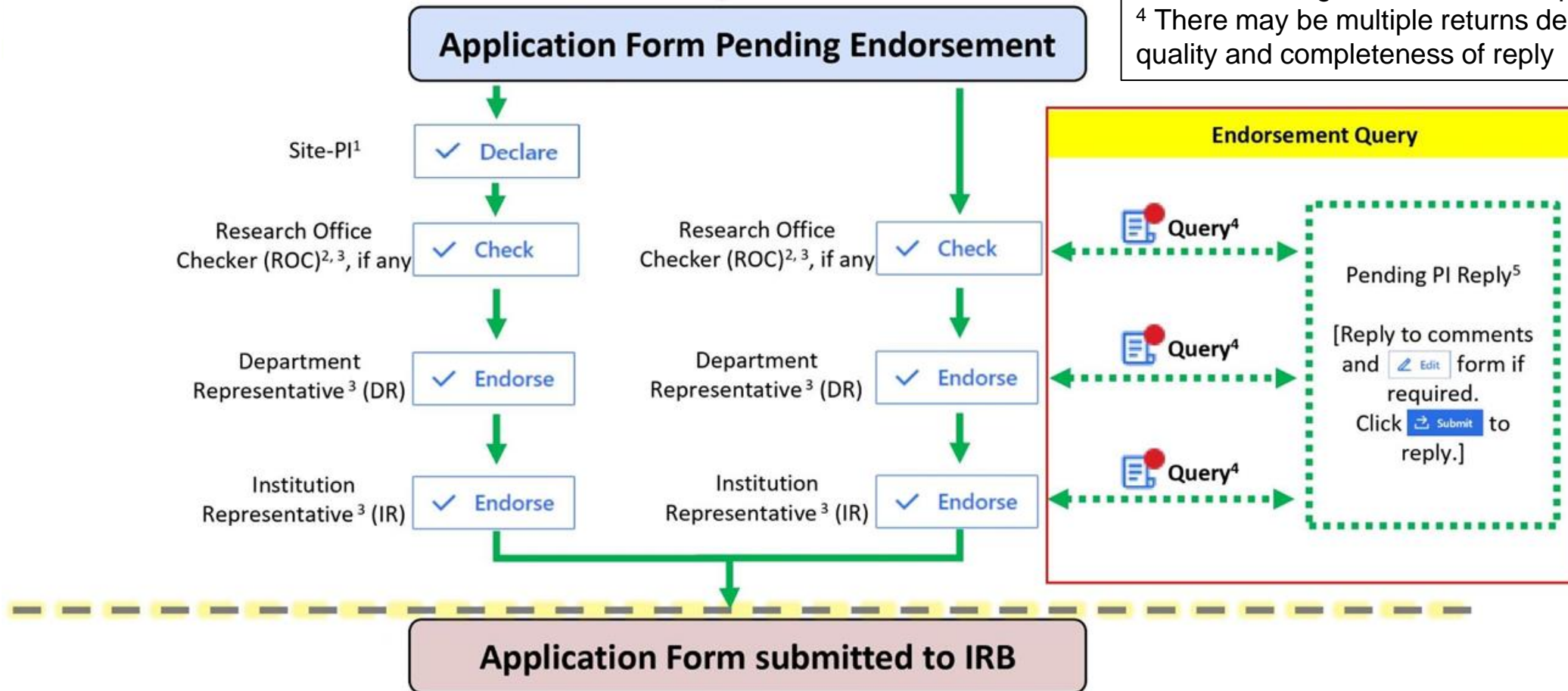
Application Form Pending Endorsement

Exact stage of endorsement is viewable by clicking on the endorser tab (**Endorsement**). Contact the respective personnel listed to follow-up on the endorsement if you have any questions.

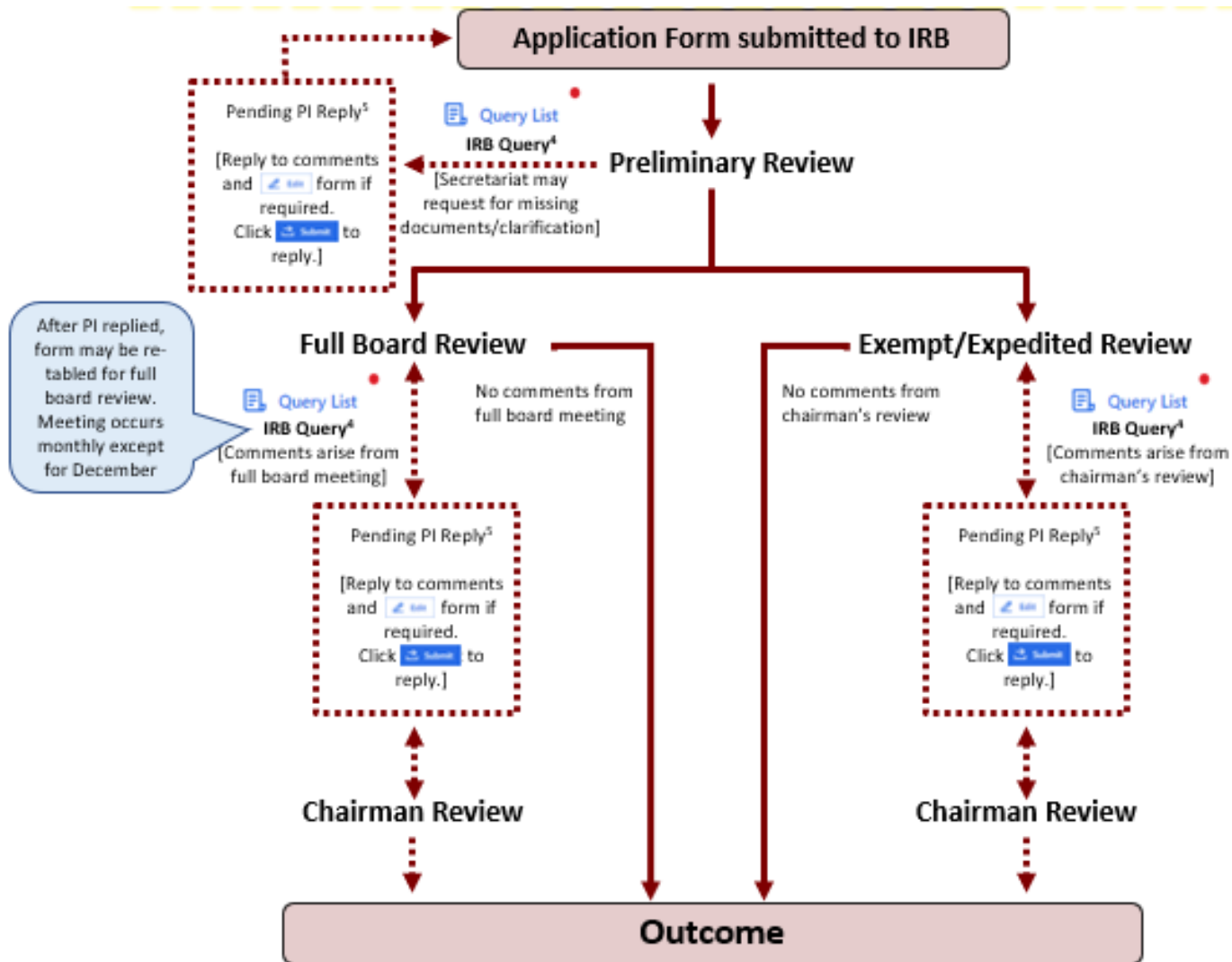
Submission Workflow

Note:

- ¹ This is only applicable for study involving multi-sites.
- ² ROC check is not applicable for all institutions
- ³ Please note that there may be queries from ROC, DR or IR during the endorsement process.
- ⁴ There may be multiple returns depending on the quality and completeness of reply



Submission Workflow



Note:
⁴ There may be multiple returns depending on the quality and completeness of reply
⁵ Re-declaration / Re-endorsement is required if there are major changes to the application form

IRB – Submission List

Submission List

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

- The '+ New Application Form' button allows the creation of a new study application.
- The '+ New Other Forms' button allows user to search for the approved study and select the different form type for submission.

ECOS Ref	IRB	Application ID	Application Type	Status	Description	Action
2024-3238	SingHealth CIRB-Board					
2024-3240	SingHealth CIRB-Board					
2024-3239	SingHealth CIRB-Board A	2024-3239-APP1	Application	Pending Endorsement	CG0415 - Study 1 (DR & IR Reminder)	
2024-3204	SingHealth CIRB-Board B	2024-3204-APP1	Application	Pending IRB Review	CG0412 - Study 1 (To test Committee Review and Triage)	
2024-3029	SingHealth CIRB-Board A	2024-3029-AMD3	Amendment	Pending Endorsement	CG02 (01 April 2024) - Retest Study (Created by new PI that had not been approved)	
2024-3203	SingHealth CIRB-Board A	2024-3203-AMD1	Amendment	Pending Endorsement	CG0411 - Notification Test (90 days) Exp: 15 Apr 24	
2024-3171	SingHealth CIRB-Board A	2024-3171-AMD1	Amendment	Pending IRB Review	CG0410 - Study 2 (Rejected once by DR)	
2024-3183	SingHealth CIRB-Board F	2024-3183-SSR3	SSR	Draft	CWL - to test on closure template	

IRB – Submission List

The screenshot displays the ECOS Submission List interface. The left sidebar contains navigation options: Homepage, IRB (with Submission List selected), Endorsement, My Study List, CRMS, FCOI, and Report. The main content area is titled 'Submission List' and includes buttons for '+ New Application Form' and '+ New Other Forms', along with 'Columns', 'Export', and 'Filter(1)' options.

ECOS Ref	IRB	Form Ref	Form Type	Form Status	Study Title	Action
2024-3238	SingHealth CIRB-Board A	2024-3238-APP1	Application	Pending PI Reply		
2024-3240	SingHealth CIRB-Board A	2024-3240-APP1	Application	Pending IRB Review		
2024-3239	SingHealth CIRB-Board A	2024-3239-APP1	Application	Pending Endorsement		
2024-3204	SingHealth CIRB-Board B	2024-3204-APP1	Application	Pending IRB Review		
2024-3029	SingHealth CIRB-Board A	2024-3029-AMD3	Amendment	Pending Endorsement	CG02 (01 Apr 2024) - Retest Study (created by new PI that had not been approved)	
2024-3203	SingHealth CIRB-Board A	2024-3203-AMD1	Amendment	Pending Endorsement	CG0411 - Notification Test (90 days) Exp: 15 Apr 24	
2024-3171	SingHealth CIRB-Board A	2024-3171-AMD1	Amendment	Pending IRB Review	CG0410 - Study 2 (Rejected once by DR)	
2024-3183	SingHealth CIRB-Board F	2024-3183-SSR3	SSR	Draft	CWL - to test on closure template	

Type of Form Status:
Draft, Pending PI Declaration, Pending Endorsement, Pending PI Reply, Pending IRB Review.

Click on ' ' to view form for further action.

Creation of New Application Form

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 on '**Close**' button to proceed with the creation of form.
- Complete **Section A: Study Title** and **B: Submission Board, Study Site, Study Investigator and Conflict of Interest** to save draft.

Creation of New Application Form

The screenshot displays a web application interface for creating a new application form. The main page is titled 'Submission Detail' and includes a 'Back to Submission List' link. A modal dialog box is open, prompting the user to 'Please select your site and role in CRMS'. The modal contains two dropdown menus: '* Site: Choose the study site that you are involved in' and '* Role: Choose your roles in CRMS'. A blue 'Save' button is located at the bottom right of the modal. The background form shows sections for 'Application Form', 'Study Site List' (with a table containing 'Singapore National Eye Centre'), and 'Investigator List' (with a table containing columns for 'Study Site', 'Name', 'Study', 'Designation', 'Department', 'Institution', 'Profile and', and 'Action').

Note: This prompt will appear the first time you saved the form, and you are not part of the Investigator List in Section B2. (a).

Features of Forms

The screenshot displays a 'Submission Detail' page for form 2024-3265-APP1. The page includes a header with a back button and notification icons. The main content area shows form metadata such as 'Form Type: Application', 'Form Outcome: -', and 'Initial Review Category: -'. A 'Quick Link: Study Summary' is highlighted with a yellow callout box. Below the details, a 'Form Detail' section is partially visible with a collapse icon. At the bottom, an 'Application Form' editing toolbar contains three buttons: 'Mandatory Check' (1), 'Save' (2), and 'Save and Exit' (3).

- 1 Click 'Mandatory Check' to ensure that all form fields are filled.
- 2 Use 'Save' frequently to ensure that all information are saved.
- 3 Use 'Save and Exit' to save and exit editing mode.

Features of Forms

2024-3260-APP1 Draft 🔄
ECOS Ref: 2024-3260 📄

[Form Detail](#)

Application Form 📄 Export ✎ Edit

Section A: Study Title

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

CG0420 - Study 4 (90 days notification)

Section A: Study Title
Section B: Submission B...
Section C: Study Fundin...
Section D: Study Type an...
Other Attachments
Declaration of Principal I...

[Declare and Submit](#)

99+

Click here to expand the study details.

Adding Study Investigator

Application Form

Study Site List + Add

Study Site	Location	Endorsement needed	Action
* Singapore National Eye Centre (SNEC)	SNEC Main Site	* Yes	Edit Delete

Investigator List + Add

Study Site	Name	Study Role	Email	Designati
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B2. (b) Study Sites (For Information Only) ?
Note: Other local/ overseas site (The sites listed here is for the IRB's information only. IRB's approval will not include any of the sites. The sites should apply for their own IRB approval if required.)*

0 characters entered

Adding Study Investigator

Add Save

* Study Site Only study site added would be available

* Name Search via full name or email address

* Study Role Select study role

Profile and Minimum Training

* Conflict of Interest Indicate if there are any conflict of interest

Complete the following questions if there are conflict of interest

* Conflict of Interest
 Yes No


B2.(a)(i) Conflict of Interest: Please tick all the applicable boxes.

- Financial interests (e.g. stocks, stock options or other ownership interests) in the assets or liabilities of any organization that may benefit from the research activity.
- Payments (e.g. salary, consultation fees, speaking fees, or honoraria) from any organisation that may benefit from the research activity.
- Intellectual property rights or proprietary interests (e.g. patents, copyrights and royalties from such rights) related to the research.
- Options or other compensation arrangements that could be affected by the outcome of the research.
- The sponsor company supporting this study offers incentives connected with research participant recruitment or completion of research study (e.g. finder's fee, recruitment bonuses etc) that will be paid to the research staff.
- Others, to specify (financial/non-financial conflict):

B2.(a)(ii) Please provide details of all of the above Conflict of Interest.

B2.(a)(iii) Please describe the plan to manage all the above Conflict of Interest. You may include the mechanism and processes in place to manage the Conflict of Interest (e.g., resignation of position, independent data analysis, data safety monitoring, blinded study, ad hoc review committee). You may also include if the Conflict of Interest will be disclosed to the participants (e.g. through the written Informed Consent Form, oral presentation etc.).

Adding Study Investigator

Application Form  Export

Investigator List

Study Site	Name	Study Role	Email	Designation
Singapore National Eye Centre (SNEC)	SNEC_Basic2	PI		Basic Us
Singapore National Eye Centre (SNEC)	SNEC_Basic1	Co-I		Basic Us
National Neuroscience Institute (NNI)	NNI_PI 1	Site PI		Senior C
National Neuroscience Institute (NNI)	NNI_PI 2	Co-I		Senior C

Minimum Training Requirement

Submission Detail

2024-3256-APP1 Draft 🕒

ECOS Ref: 2024-3256 📄

[Form Detail](#)

Application Form

✓ **Mandatory Check** ✕ Cancel 📄 Save Save and Exit

* Singapore Eye Research Institute * SERI * Yes Edit Delete

Investigator List + Add

Study Site	Name	Study Role	Designation	Department	Institution	Profile and Minimum Training	Conflict Interest	Action
Singapore Eye Research Institute	Ms SERI_PI	PI	Dr	Glaucoma	Singapore Eye Research Institute	Detail	No	Edit Delete

Section A: Study Title

Section B: Submission B...

Section C: Study Fundin...

Section D: Study Type an...

Other Attachments

Click to check if the list of investigators had completed the minimum training requirement.

Link to user profile to check their minimum training status.

- ❑ Complete: The user had fulfilled the minimum training requirement.
- ❑ Incomplete: The user had not completed the minimum training requirement to conduct the type of study (e.g. Clinical Trials, HBR, non-HBR). Therefore, the form cannot be submitted.

PI Declaration

Submission Detail

2024-0323-APP1 Draft

ECOS Ref: 2024-0323

[Form Detail](#) To view the details of the form to be submitted.

[To perform PI Declaration, click here.](#)

[Declare and Submit](#)

Application Form Export Edit

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

Guide to ECOS for RO

- Section A: Study Title
- Section B: Submission ...
- Section C: Study Fundi...
- Section D: Study Type a...
- Other Attachments
- Declaration of Principal ...

Endorsement Status

2024-0192-APP1 Pending Endorsement

ECOS Ref: 2024-0192

Form Detail

Endorsement

Click on 'Endorsement' tab for endorsement related information.


Endorsement Status

Institution	Cluster-Institution-Department	Endorsement Information	Endorser Name	Action
Singapore National Eye Centre (SNEC) Main Site	Glaucoma	1 Pending DR Endorsement	2 SNEC_DR 1	3 4

- 1 View the endorsement status.
- 2 View the name of endorser to complete the pending task.
- 3 Click to view query raised by endorsers.
- 4 View the endorsement history.

IRB – Endorsement

The screenshot shows the ECOS Endorsement page. The left sidebar contains navigation options: Homepage, IRB (expanded), Submission List, Endorsement (highlighted with a green border), My Study List, CRMS, FCOI, and Report. The main content area displays a table of IRB forms. The table has columns for Form Ref, IRB, Study Title, PI/Site-PI Name, Department, and Action. A single row is visible with the following data: Form Ref: 2024-3203-AMD1, IRB: SingHealth CIRB-Board A, Study Title: CG0411 - Notification Test (90 days) Exp: 15 Apr 24, PI/Site-PI Name: Mr NNI_PI 1(National Neuroscience Institute), Mr SNEC_Basic1(Singapore National Eye Centre), Department: Glaucoma, and Action: a target icon circled in red. A callout box with a black border and white background contains the following text:

- **Endorsement** displays the list of forms that requires Site-PI's declaration.
- Click on '  ' to view the form for further action.

Endorsement by Site-PI

2024-0036-APP1 Pending Endorsement 🕒
ECOS Ref: 2024-0036 📄

To perform site-PI Declaration, click here

✓ Declare

Form Detail ⌵ To view the details of the form to be submitted.

Site PI

Institution	Cluster-Institution-Department	Endorsement Information	Endorser Name	Action
National Neuroscience Institute Main Site	Neurology	● Pending Research Office Check	NNI_ROC1	🕒
Singapore General Hospital	Department of Renal Medicine	● Pending PI Declaration	SGH_PI	🕒

Site PI
Endorsement Status

My Tasks – Rejected by DR / IR

The dashboard shows the following task counts:

- IRB: 5
- CRMS: 2
- FCOI: 0

The 'Study (5)' tab is active, showing a table of pending tasks:

Board	Task Received Date	Task Status	Form Type	Form Ref	Study Title	Action
Board A	05-Apr-2024	Pending	Applic			
Board A	10-Apr-2024	Pending	SSR	2024-3062-SSR2	CG01 (2 Apr 2024) - For retest [To check if track change	
Board F	11-Apr-2024	Pending	SSR	2024-3183-SSR3	CWL - to test on closure template	
Board A	15-Apr-2024	Pending	Application	2024-3238-APP1	CG0415 - Study 3 (IRB Reminder)	
Board A	17-Apr-2024	Pending	Application	2024-3260-APP1	CG0417 - To test exported draft	

If there is task pending your action after submission, the action icon will have a red dot.

Endorsement – Rejected by DR / IR (Main Site)

The screenshot shows a 'Submission Detail' page for application 2024-3260-APP1. A notification at the top states: 'DR of National Neuroscience Institute has rejected the form. Reject Reason: I am rejecting to show the attendees on the buttons th...'. To the right of the notification are three buttons: 'View More' (highlighted with a red box and labeled '1'), 'Accept Rejection' (with a red 'X' icon), and 'Edit Form' (labeled '2'). Below the notification, the application details are shown: '2024-3260-APP1' with a 'Pending Endorsement' status and 'ECOS Ref: 2024-3260'. A modal dialog box is open, titled 'ECOS', with a close button (X) in the top right corner. The dialog contains the text: 'DR of National Neuroscience Institute has rejected the form. Reject Reason: I am rejecting to show the attendees on the buttons that would be available if the main site got rejected. Do you wish to accept the rejection, or edit the form for re-submission?'. A green arrow points from the 'View More' button to the dialog's close button. In the background, the 'Application Form' section is visible, showing 'Section A: Study Title' and a text input field with the value 'CG0417 - To test e...'. There are also 'Export' and 'Track Changes' buttons on the right side of the page.

- 1 As Overall PI, if you 'Accept Rejection', the entire application with all study sites will be rejected.
- 2 You may 'Edit Form' to remove the affected site or to amend the form to ensure that the rejected reason had been addressed.

****For study roles other than Overall PI, they will only be able to view the reject reason.**

Endorsement – Rejected by DR / IR (Sub-Site)

The screenshot shows a 'Submission Detail' page for application 2024-3260-APP1, which is in a 'Pending Endorsement' state. A yellow notification bar at the top states: 'Singapore National Eye Centre is rejected as a study site by the DR/IR. Rejected Reason: I am rejecting this study as I do not support t...'. To the right of this bar are three buttons: 'View More' (highlighted with a red box and a green arrow), 'Withdraw' (marked with a yellow '1'), and 'Edit Form' (marked with a yellow '2'). Below the notification, the application details are shown, including the ECOS Ref: 2024-3260. A modal dialog box is open, titled 'ECOS', with the text: '**View the reason for rejection.**'. The dialog content reads: 'Singapore National Eye Centre is rejected as a study site by the DR/IR. Rejected Reason: I am rejecting this study as I do not support the conduct of this research. You may choose to withdraw the form or proceed to edit the form. Do note that only the PI can re-submit the form. However, all study team members can edit the form.' To the right of the dialog are 'Export' and 'Track Changes' buttons. At the bottom of the page, a light blue callout box contains instructions for the 'Withdraw' and 'Edit Form' buttons.

1 Overall PI may choose to 'Withdraw' form. Please note that once a form is withdrawn, it will not be available for submission anymore. New application form will be deemed as withdrawn.

2 You may continue to 'Edit Form' to remove the affected site or to amend the form to ensure that the rejected reason had been addressed.


****For study roles other than Overall PI, the button available would be 'Edit Form'.****

IRB – My Study List

The screenshot displays the ECOS 'My Study List' interface. The left sidebar contains navigation options: Homepage, IRB (expanded), Submission List, Endorsement, My Study List (highlighted with a green box), CRMS, FCOI, and Report. The main content area shows a table of studies with the following columns: ECOS Ref, IRB, Study Status, Study Title, PI/Site-PI Name, and Action. The table contains five rows of study data. A callout box with a black border and white background is overlaid on the table, containing two bullet points. The first bullet point states that the 'My Study List' shows all studies the user is involved in. The second bullet point instructs the user to click on the 'target' icon in the Action column to view the Study Summary. The 'Action' column for the first row (2024-3069) has a red square highlighting the target icon.

ECOS Ref	IRB	Study Status	Study Title	PI/Site-PI Name	Action
2024-3069	SingHealth CIRB-Board A	Approved	UAT 2Apr - Survey across multi site	-	
2024-3046	SingHealth	Approved	KT03 (1 Apr 2024)	-	
2024-3202	SingHealth CIRB-Board A	Expired	CG0411 - Notification Test (60 days) Exp: 14 Apr 24	-	
2024-3201	SingHealth CIRB-Board B	Expired	CG0411 - Notification Test (30 days) Exp: 13 Apr 24	-	
2024-3097	SingHealth CIRB-Board A	Pending IRB Review	WM 20240404: Form D (Pilot - Single)	-	

• **My Study List** shows all the studies that the user is involved in.

• Click on '' to view the Study Summary.

Study Summary

2024-0063 Approved Click to view Study History

1

2

3

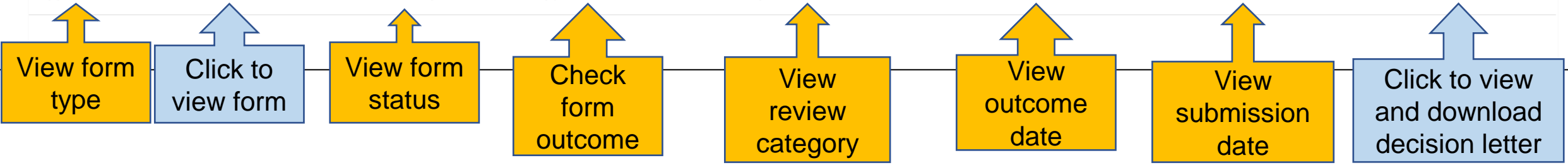
All Forms All Forms Attachments Study Letter

ALL(2) Application(1) Amendment(1)

Change tab to view specific form type.

Columns Export Filter

Form Type	Form Ref	Form Status	Form Outcome	Review Category	Outcome Date	Submission Date	Letter
Amendment	2024-0063-AMD1	● Pending Endorsement	-	-	-	12-Jan-2024	-
Application	2024-0063-APP1	● Review Completed	Approved	Expedited	12-Jan-2024	11-Jan-2024	CIRB APP Letter



1 Display all forms that had been created for the study.

2 Display the list of attachments uploaded in all forms

3 Display the study letter issued by IRB (e.g. Suspension or Termination letter)

Creation of Other Forms

The screenshot displays the ECOS Submission List interface. At the top, the 'Submission List' title is visible. The navigation bar includes a home icon, 'IRB', 'Submission', 'Endorsement', 'My Study List', 'CRMS', 'FCOI', and 'Report'. The main toolbar contains '+ New Application Form' and '+ New Other Forms' (highlighted with a green box). Below the toolbar, a table header lists columns: ECOS Ref, IRB, Form Ref, Form Type, Form Status, Study Title, PI/Site-PI Name, and Action. A modal window titled 'New Study Form' is open, showing a search field for 'ECOS Ref or Study Title' with the value 'CG'. A blue callout box points to this field with the text '1. Search for study with ECOS Ref or Study Title'. Below the search field, a search result is displayed with the following details: Study Title: CG0411 - Notification Test (60 days) Exp: 14 Apr 24; ECOS Ref: 2024-3202; PI/Site-PI Name: Mr NNI_Pi 1(National Neuroscience Institute),Mr SNEC_Basic1(Singapore National Eye Centre). Below the search result, a dropdown menu for 'Form Type' is open, showing options: Amendment Form (Amendment), Study Deviation/ Non-Compliance Report Form (DNC), Other Study Notifications Report Form (OSN), Serious Adverse Event Report Form (SAE) (highlighted), and Study Status Report Form (SSR). A blue callout box points to this dropdown with the text '2. Select Form Type to be created'. At the bottom right of the interface, the pagination shows 'Rows per page: 100' and '1-20 of 20'.

Creation of Other Forms

The screenshot displays the ECOS Submission List interface. A modal dialog titled "New Study Form" is open, allowing the user to create a new form. The dialog includes the following fields and information:


- * ECOS Ref or Study Title:** A text input field containing "CG".
- Study Title:** CG0411 - Notification Test (60 days) Exp: 14 Apr 24
- ECOS Ref:** 2024-3202
- PI/Site-PI Name:** Mr NNI_PI 1(National Neuroscience Institute),Mr SNEC_Basic1(Singapore National Eye Centre)
- * Form Type:** A dropdown menu currently showing "Amendment Form (Amendment)".

At the bottom right of the dialog, there are two buttons: "Cancel" and "Confirm". The "Confirm" button is highlighted with a red border and a yellow callout box pointing to it. The callout box contains the text: "Click 'Confirm' to create the form type selected."

The background shows a table of submissions with columns: ECOS Ref, IRB, Form Ref, Form Type, Form Status, Study Title, PI/Site-PI Name, and Action. The table contains several rows of data, including one for "2024-3143" with "SingHealth CIRB-Board A" and "Application" status.

Amendment Form

Submission Detail

ECOS Ref: - 

Form Detail

Amendment Form

Study Amendment Cover Note

***1. Describe the proposed change(s) to the research and include a rationale for each proposed change.**

***2. Will the enrolled research participants be informed of these changes?**

Yes

No

***3. Will the enrolled research participants be re-consented?**

Yes

No

4. Do the proposed amendments:

Significantly change the original objectives, innovation and scientific methodology (e.g., re-design of study methodology, change in investigational product used, etc) and/or the

Cancel Save

Study Amendment Cove...

Section A: Study Title

Section B: Submission B...

Section C: Study Fundin...

Section D: Study Type an...

Section E: Research Met...

Section F: Exemption Re...

Other Attachments

Declaration of Principal I

Navigate to the various sections to amend the form accordingly. Refer to the [IRB Guidebook: Other Forms](#) on questions that cannot be amended.

Complete the **Study Amendment Cover Note**:

- Indicate all the proposed changes to the research and include the rationale for each proposed change.
- State if enrolled study participants would be informed and re-consented.
- Check if proposed amendment would significantly affect the study aims or study participants.

Study Status Report Form (SSR)

< Back to Submission List

Submission Detail

ECOS Ref: 2024-3202

Form Detail

Study Status Report Form

NOTE:

1. For renewal of IRB approval, please submit the Study Status Report Form 90 days before study expiry.
2. For reactivation of expired study, please submit a Study Deviation /Non-Compliance Report Form if the study team had continued to carry out research activities during the lapse period before IRB approval is renewed.
3. For study closure, please submit the Study Status Report Form within 30 days after study completion.

1. I am requesting for:

Cancel Save

Study Status Report Form

Declaration of Principal I...

Select the request for submission of SSR as follows:

- Study Renewal
- Study Closure
- Study Status Update
- Study Reactivation

Study Status Report Form (SSR)

Type of SSR	Note
Study Renewal	For renewal of IRB approval. <ul style="list-style-type: none">➤ It is recommended for the form to be submitted at least 2 months (60 days) before expiry.
Study Status Update	For updating of study status such as change of study status from “Ongoing” to “Suspended”.
Study Closure	For reporting of study completion or termination. <ul style="list-style-type: none">➤ SSR should be submitted within 30 days for study completion.➤ SSR should be submitted within 7 days for study termination.
Study Reactivation	For request to re-open a research study which is previously closed or where the approval has lapsed. <ul style="list-style-type: none">➤ For reactivation of expired study, please submit a DNC form if research activities were carried out during the lapse period.

Study Deviation/ Non-Compliance Report Form (DNC)

Submission Detail

ECOS Ref: 2024-3201

Form Detail

Study Deviation/Non-Compliance Report Form

Cancel Save

Guidance

This report form should be submitted once Principal Investigator is aware of the non-compliance/ study deviation according to the reviewing IRB's requirement. All sections must be completed. Principal Investigators are obliged to suspend their research immediately pending their report to the IRB if deviations are substantial or are likely to result in greater harm or greater likelihood of harm to the research participants.

Definitions

Study Deviation: is an unplanned excursion from the study that is not implemented or intended as a systematic change.

- A study deviation could be a limited prospective exception to the protocol (e.g. agreement between sponsor and investigator to enroll a single research participant who does not meet all inclusion/exclusion criteria). Like study amendments, deviations initiated by the investigator must be reviewed and approved by the IRB and the sponsor prior to implementation unless the change is necessary to eliminate an immediate hazard to the research.
- Study deviation is also used to refer to any other, unplanned, instance(s) of non-compliance with the protocol or failures on the part of the research participant(s) to complete the study.

Non-Compliance: is a failure by an investigator or any study team member to abide by the policies and procedures of the IRB or applicable regulations governing the protection of human subject research. Some examples of non-compliance include but are not limited to:

- Failure to obtain prior approval for research
- Failure to obtain informed consent when required
- Failure to use the latest IRB approved version of the protocol or consent form
- Failure to report an adverse event report according to IRB timeline and procedure
- Performance of research at an unapproved study site
- Performing an unapproved research procedure
- Failure to adhere to the approved protocol
- Failure to submit study amendments for review and approval

Study Deviation: An unplanned excursion from the study that is not implemented or intended as a systematic change.

Non-Compliance: Failure by an investigator or any study team member to abide by the policies and procedures of the IRB or applicable regulations governing the protection of human subject research.

Serious Adverse Event Report Form (SAE)

Submission Detail

ECOS Ref: 2024-3203

Form Detail

Serious Adverse Event Report Form

Note:

1. This form is for submission of related SAE only.
2. For DSRB reviewed studies, if the related SAE is unexpected, please submit using the UPIRTSO Report Form.
3. Do not use terms such as "Refer to attached document" or similar.

Section A: Determination of SAE

*A1. Please determine if the event is related:

Related: Related means there is a reasonable possibility that the incident, experience or outcome may have been caused by the procedures involved in the study. Also includes reasonable possibility that the event occurred as a result of participation in the study.

*A2. Please classify the SAE into at least one of the following categories:

Resulted in or contributed to death

Was life-threatening

Cancel Save

Section A: Determinatio...

Section B: Basic Informat...

Section C: Investigatio...

Section D: Event Summary

Section E: Comments by ...

Section F: Investigator's ...

Serious Adverse Event Report Form (SAE)

Type of SAE	Note
Local SAE	Refer to SAE occurring in participants recruited by sites that were reviewed by IRB. If there is a specific location listed in Section B2. (a). of the application/amendment form, please specify it under Section D, question 2.
Non-local SAE (Overseas SAE)	Refers to SAE occurring in participants recruited by sites that were not reviewed by IRB. For non-local SAE, please select 'Others' and list the overseas study site in Section B1.

1. **'Initial Report'** should be selected if event is being reported for the first time. If information is incomplete at the point of initial report submission, PI should adhere to the reporting timeline and complete as much as possible.
2. **'Follow-up Report'** should be selected if there is any additional relevant information related to the initial report and to provide the Form Ref of the SAE Report that were submitted in relation to this event.

Note: If the event does not fulfil the submission criteria, you would not be able to submit the SAE.

Other Study Notification Form (OSN)

Submission Detail

ECOS Ref: 2024-3202

Form Detail

Other Study Notification

NOTE: Miscellaneous study documents that DO NOT require IRB approval may be submitted for acknowledgment using this Other Study Notifications Form.

*1. Notification type
Please select

- DSMB Report
- Annual/Interim /Periodic Safety Report
- Interim Data Analysis
- Letter from Study Sponsors
- Other Notification

*2. Please describe the contents of this notification.

OSN Form

Declaration

Cancel Save

99+

1. For submission of miscellaneous study documents for acknowledgment that DO NOT require IRB approval.
2. Safety report should be submitted via SAE (1 Event / Form)

Track Changes

Submission Detail

NOTE

New/Revised information: Green highlight

Deleted information: Purple highlight with strikethrough

Track Change

Current Version: 2024-3260-APP1 17-Apr-2024 15:30:56

Previous Version: 2024-3260-APP1 17-Apr-2024 14:10:05

Track Changes

Section E: Research Methodology (Exemption Application)




E1. What are the specific aims of this study?
~~CG11 (To test another adding site by Amendment)~~ What are the specific aims of this study?


E2. What are the hypothesis of this study? For qualitative studies, please provide the research question(s) instead.
~~CG11 (To test another adding site by Amendment)~~ What are the hypothesis of this study? For qualitative studies, please provide the research question(s) instead.


E3. Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. Please list all procedures/activities that are carried out as part of research in this study.
~~CG11 (To test another adding site by Amendment)~~ Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. Please list all procedures/activities that are carried out as part of research in this studv.


Export

Still under development, please use at your own risk.


[← Back to Submission List](#) Submission Detail   

2024-3260-APP1 Pending Endorsement  ⋮

ECOS Ref: 2024-3260 

—  —

[Form Detail](#) [Endorsement](#)

Application Form **Click to Export the form in PDF.**  [Track Changes](#)

Section A: Study Title

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

CG0417 - To test exported draft

Section A: Study Title

Section B: Submission B...

Section C: Study Fundin...

Section D: Study Type an...

Section E: Research Met...

Section F: Exemption Re...

Endorsement Query - Pending PI Reply

The screenshot shows the ECOS 'My Tasks' dashboard. The top navigation bar includes 'ECOS' and 'My Tasks' with notification icons. The left sidebar lists navigation options: Homepage, Dashboard, My Tasks (highlighted), My Notices, IRB, CRMS, FCOI, and Report. The main content area features three summary cards: IRB (4), CRMS (2), and FCOI (0). Below these is a 'Study (4)' link and an 'Endorsement (0)' label. A table displays task details with columns: Board, Task Received Date, Task Status, Form Type, Form Ref, Study Title, and Action. The first row is highlighted in green and has a red dot on its action button. The table data is as follows:

Board	Task Received Date	Task Status	Form Type	Form Ref	Study Title	Action
Board A	05-Apr-2024	Pending	Application	2024-3121-APP1	CG01 (5 Apr 24) - Ready for retest	Action (with red dot)
Board A	10-Apr-2024	Pending	SSR	2024-3062-SSR2	CG01 (2 Apr 2024) - For retest [To check if track change	Action
Board F	11-Apr-2024	Pending	SSR	2024-3183-SSR3	CWL - to test on closure template	Action

For PI, when there are endorsement query pending PI reply, the PI will receive a task in [My Tasks] and the action button would be with a red dot to symbolize that there are action required.

Endorsement Query - PI Reply

Submission Detail

2024-3121-APP1 Pending Endorsement

ECOS Ref: 2024-3121

Form Detail **Endorsement**

The red dot indicates that there are endorsement queries.

Reply Query

Endorsement Status

Institution	Department	Endorsement Information	Endorser Name	Action
National Neuroscience Institute	Main Site	Neurology (SGH Campus)	Pending PI Reply	Mrs NNI_ROC1

Click on the '📄' icon to view and address the queries sent by ROC, DR or IR.

Endorsement Query - PI Reply

← Back to My Tasks

2024-3121-APP1 Pending Endorsement

ECOS Ref: 2024-3121

Form Detail Endorsement

Endorsement Status

Institution	Department
National Neuroscience Institute Main Site	Neurology (SGH Campus)
Singapore National Eye Centre Removed	Glaucoma

Query List National Neuro... Saved at 05-Apr-2024 16:39:34

Pending Query All Query

1/1 Pending Handling

General

ABCDEF
Query Round1 Mrs NNI_ROC1 05-Apr-2024 16:39:18

* Reply Query

GHIJKLM

Input your reply here

****Note: Click the area outside to close the Query List.****

Endorsement Query - PI Reply

The screenshot shows the 'Submission Detail' page for application 2024-3121-APP1, which is in a 'Pending Endorsement' state. A green callout box points to the 'Reply Query' button, stating: 'If there is no amendment to the form, click on [Reply Query]'. An 'ECOS' dialog box is open, asking 'Are you sure to submit the following replies with the latest form?'. It lists 'National Neuroscience Institute' with '1 Query'. The query item is 'General' with two items: 'ABCDEF' and 'GHIJKLM'. The dialog has 'Cancel' and 'Confirm' buttons. A red callout box points to the 'Edit' button in the 'Track Changes' section, stating: 'Click on [Edit] to amend the form if required.'.

IMPORTANT

- All roles will have the [Reply Query] button if there are no changes to the form.
- If there are changes to the form, only Overall PI will have the [Submit] button.

Endorsement Query - PI Reply with Amendment to Form

The screenshot displays a web application interface for submission details. At the top, there is a navigation bar with a back arrow and the text "Back to My Tasks", and a title "Submission Detail" with download, notification, and user icons. Below the navigation bar, the submission ID "2024-3121-APP1" is shown with a "Pending Endorsement" status and a refresh icon. A green callout box points to a "Submit" button with an external link icon, stating: "This button will only appear for PI if there is changes to form." Below this, a modal window titled "ECOS" is open, containing a confirmation message: "Please confirm to submit. If applicable, the form will be routed for the necessary checks and endorsements." Under the "Query" section, a checkbox for "National Neuroscience Institute" is checked, and a "1 Query" indicator is visible. The query details show "Query Item: General" with two items: "ABCDEF" and "GHIJKLM". At the bottom of the modal are "Cancel" and "Submit" buttons. In the background, the "Application Form" section is partially visible, showing a "Form Detail" tab and a list of sections: "Section A: Study Title", "Section B: Submission B...", "Section C: Study Fundin...", and "Section D: Study Type an...". A yellow callout box with the word "IMPORTANT" in red text is positioned above a blue callout box containing two bullet points.

IMPORTANT

- For all other roles, there will be no buttons available if there is changes to form.
- Please inform your PI when the form is ready for submission.

IRB Query - Pending PI Reply

The screenshot shows the ECOS 'My Tasks' dashboard. The top navigation bar includes the ECOS logo, 'My Tasks' title, and notification icons (2 and 97). The left sidebar contains navigation options: Homepage, Dashboard, My Tasks (highlighted), My Notices, IRB, CRMS, FCOI, and Report. The main content area displays three summary cards: IRB (3), CRMS (0), and FCOI (0). Below these is a filter for 'Study (3)' and 'Endorsement (0)'. A table lists tasks with columns: Board, Task Received Date, Task Status, Form Type, Form Ref, Study Title, and Action. The last row, representing a pending IRB query, is highlighted with a green border and has a red dot on its action button.

Board	Task Received Date	Task Status	Form Type	Form Ref	Study Title	Action
Board A	10-Apr-2024	Pending	SSR	2024-3062-SSR2	CG01 (2 Apr 2024) - For retest [To check if track change	
Board A	10-Apr-2024	Pending	Application	2024-3181-APP1	WM 20240410: WM01 Phase 1 [CIRB APP Letter - Multi-	
Board A	15-Apr-2024	Pending	Application	2024-3238-APP1	CG0415 - Study 3 (IRB Reminder)	

For PI, when there are IRB query pending PI reply, the PI will receive a task in [My Tasks] and the action button would be with a red dot to symbolize that there are action required.

IRB Query – PI Reply

Submission Detail

2024-3238-APP1 Pending PI Reply

ECOS Ref: 2024-3238

Form Detail Endorsement

Application Form

Section A: Study Title

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

CG0415 - Study 3 (IRB Reminder)

Export Track Changes Edit

Section A: Study Title

Section B: Submission B...


Section C: Study Fundin...


Section D: Study Type an...


The red dot symbolized that there is IRB queries pending reply.

Click on [Edit] to amend the form if required.

IRB Query – PI Reply

[← Back to My Tasks](#) Sub Query List  Saved at 18-Apr-2024 07:40:26

2024-3238-APP1 Pending PI Reply 

ECOS Ref: 2024-3238 


[Form Detail](#) [Endorsement](#)


Application Form

Section A: Study Title

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

CG0415 - Study 3 (IRB Reminder)

General 

 Please check the aims of the study in Section E1
Query Round2 Ms CIRB_A_IRBSec1 18-Apr-2024 07:40:26

*** Reply Query**

Please enter

Input your reply here

****Note: Click the area outside to close the Query List.****

IRB Query – PI Reply

The screenshot shows the 'Submission Detail' page for application 2024-3238-APP1. The status is 'Pending PI Reply'. A callout box states: 'Red dot disappears when queries have been addressed.' This callout points to a red dot on the 'Query List' button. A green arrow points from the 'Submit' button to a modal dialog box.

Form Data

Application Form

Section A: Study

*A1. Please enter

CG0415 - Study

ECOS

Are you sure to submit the following replies with the latest form?

Query

Query Item: General

Please check the aims of the study in Section E1

Replying

Cancel Submit

Section E: Research Met...

IMPORTANT

- Only the Overall PI will have the [Submit] button.
- Please inform your PI when the queries had been addressed and is ready for submission.

Withdrawal of Form – Pending Endorsement

2024-3238-APP1 Pending PI Reply

ECOS Ref: 2024-3238

Submit

Withdraw

Withdrawal

The form is currently pending endorsement, please confirm that you wish to withdraw the form.

Cancel Confirm

Section A: Study Title

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

Section B: Submission B...

Section C: Study Fundin...

Section D: Study Type an...

IMPORTANT

- The withdrawal feature is only available to Overall PI.
- Form will be automatically withdrawn if the form had not been submitted to the IRB before.

Withdrawal of Form – Pending IRB Review

Back to My Tasks Submission Detail

2024-3238-APP1 Pending PI Reply

ECOS Ref: 2024-3238

Form Detail Endorsement

Application Form

Section A: Study Title

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

Withdrawal

The form is pending IRB review, please confirm that you wish to withdraw the form. If yes, please state your reason(s) for withdrawing the form. Note: If your intent is to edit the submitted form, please contact the IRB Secretariat instead of submitting a withdrawal request.

* Withdraw Reason:

Please state your reason(s) for withdrawing the form.

Cancel Confirm

Submit Withdraw

Export Track Changes Edit

Section A: Study Title

Section B: Submission B...

Section C: Study Fundin...

Section D: Study Type an...

Other Attachments

IMPORTANT

- The withdrawal feature is only available to Overall PI.

Withdrawal of Form – Pending IRB Review

The screenshot displays the 'Submission Detail' page for application 2024-3240-APP1. The 'Form History' section on the right lists two events: 1. 'SingHealth CIRB Secretariat accepted withdrawn.' (18-Apr-2024 08:57:52) and 2. 'Request for withdrawal of Application sent.' (18-Apr-2024 08:53:49) with the reason 'To test withdrawal'. The 'Application Form' section on the left shows 'Section A: Study Title' with a field for 'A1. Please enter' containing 'CG0415 - Stud'. A callout box points to a clock icon in the 'Review Completed' status, stating 'Click on '🕒' to view the Form History.' Another callout box explains the form history entries: '1 Shows that Secretariat has accepted the withdrawal request. If Secretariat rejected the withdrawal request, a rejection reason will be provided. Refer to next slide.' and '2 Shows that the PI has requested for withdrawal of form with the reason provided.'

Form History

Event	User	Timestamp
1 SingHealth CIRB Secretariat accepted withdrawn.	Ms CIRB_A_IRBSec1	18-Apr-2024 08:57:52
2 Request for withdrawal of Application sent.	Mr SNEC_Basic1	18-Apr-2024 08:53:49

Application Form

Section A: Study Title

*A1. Please enter
CG0415 - Stud

Callout 1: Shows that Secretariat has accepted the withdrawal request. If Secretariat rejected the withdrawal request, a rejection reason will be provided. Refer to next slide.

Callout 2: Shows that the PI has requested for withdrawal of form with the reason provided.

Withdrawal of Form – Pending IRB Review

The screenshot displays a web interface for submission details. At the top left, there is a navigation link '< Back to Submission List'. The main header is 'Submission Detail'. On the left side, the submission ID '2024-3285-APP1' is shown with a 'PI Replied' status and a circular refresh icon. A callout box points to this icon with the text 'Click on '🔄' to view the Form History.' Below this, the 'Form Outcome' is listed as '-'. The main content area shows 'Application Form' details, including 'Section A: Study Title' with the value 'CG0420 - Study 6 (Red dot/ Orange dot testing)'. On the right side, a 'Form History' panel is visible, containing a list of events. A yellow callout box with the number '1' highlights the top entry: 'SingHealth CIRB Secretariat rejected withdrawn. Ms CIRB_A_IRBSec1 20-Apr-2024 15:47:57'. A green box below this entry contains the text: 'Please note that your request for withdrawal had been rejected. Thank you.'

< Back to Submission List

Submission Detail

2024-3285-APP1 PI Replied 🔄

ECOS Ref: 2024-3285

Form Outcome: -

Initial Review C

Click on '🔄' to view the Form History.

Form History

1

⊗ SingHealth CIRB Secretariat rejected withdrawn.
Ms CIRB_A_IRBSec1 20-Apr-2024 15:47:57

Please note that your request for withdrawal had been rejected. Thank you.

↩ Request for withdrawal of Application sent.
Mr NNI_PI 1 20-Apr-2024 15:46:51

I would like to request for withdrawal of this application form

📄 IRB query was replied.
Mr NNI_PI 1 | View Query 20-Apr-2024 13:21:19

✅ Application was submitted.
Mr NNI_PI 1 20-Apr-2024 13:21:18

📄 Application was edited.
Mr NNI_PI 1 20-Apr-2024 13:21:18

📄 Application was edited.
Mr NNI_PI 1 20-Apr-2024 13:21:10

📄 Query was sent.
Ms CIRB_A_IRBSec1 | View Query 20-Apr-2024 12:46:43

Application Form

Section A: Study Title

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

CG0420 - Study 6 (Red dot/ Orange dot testing)

1 Shows that Secretariat has rejected the withdrawal request with a reason for rejection provided.



Application/ Amendment Form will be Routed for Re-Endorsement

- Section B2: Addition of study sites (Endorsement for additional sites only)
- Section B2: Change/ Addition of PI/ Site-PI (Endorsement for additional sites only)
- Section D2: Change of study classification to ‘Clinical Trial’
- Section D3: Inclusion of Vulnerable Participants
- Section H4: Change to Placebo Controlled Trial
- IRB may unlock the Application/Amendment Form if there are major changes made besides the scenario described above.

Account – Migrated Users (iSHaRe)

- PI, Site-PI and Co-I from existing ongoing studies in iSHaRe would be migrated to ECOS.
 - Only iSHaRe profile with valid email address will be migrated.
- Study Team Members and Protocol Administrator will not be migrated to ECOS. You may add them in the Clinical Research Management System (CRMS) module.

Migrated Study

The screenshot shows the ECOS 'My Study List' interface. The left sidebar contains navigation options: Homepage, IRB (with sub-items Submission List and Endorsement), My Study List (highlighted with an orange box), CRMS, FCOI, and Report. The main content area displays a table of study records. The table has columns for ECOS Ref, IRB, Study Status, Study Title, PI/Site-PI Name, and Action. All studies listed have a status of 'Approved'.

ECOS Ref	IRB	Study Status	Study Title	PI/Site-PI Name	Action
2024-3069	SingHealth CIRB-Board A	Approved	Study Title	PI/Site-PI Name	🎯
2024-3046	SingHealth CIRB-Board B	Approved	Study Title	PI/Site-PI Name	🎯
2024-3171	SingHealth CIRB-Board A	Approved	Study Title	PI/Site-PI Name	🎯
2024-3203	SingHealth CIRB-Board A	Approved	Study Title	PI/Site-PI Name	🎯
2024-3202	SingHealth CIRB-Board A	Approved	Study Title	PI/Site-PI Name	🎯
2024-3201	SingHealth CIRB-Board B	Approved	Study Title	PI/Site-PI Name	🎯
2024-3097	SingHealth CIRB-Board A	Approved	Study Title	PI/Site-PI Name	🎯

Instructions:

- To view your migrated study, proceed to [My Study List].
- Your ECOS Ref would be the same as your CIRB Ref.

Migrated Study

2024-2187 Approved Refresh

Valid Till Date: 21-Feb-2025

Initial Review Category: Full Board

PI/Site-PI Name: The PI/Site-PI Name of Your Study (e.g. Dr Marilyn Lam (Singapore General Hospital))

Study Title: Your Study Title

- All Forms**
- All Forms Attachments
- Study Letter
- Data migration for other roles

ALL(1) Application(1) Columns Export Filter

Form Type	Form Ref	Form Status	Form Outcome	Review Category	Outcome Date
Application	2024-2187-APP1	● Review Completed	Approved	Full Board	14-Mar-2024

The latest approved or acknowledged Application Form or Amendment Form in iSHaRe.


Migrated Study

2024-2187 Approved 



Valid Till Date: 21-Feb-2025 Initial Review Category: Full Board





PI/Site-PI Name: The PI/Site-PI Name of Your Study (e.g. Dr Marilyn Lam (Singapore General Hospital))

Study Title: Your Study Title

All Forms All Forms Attachments Study Letter Data migration for other roles 

▪ [All Forms Attachments] consists of the documents submitted with the latest approved/acknowledged application or amendment form.

 Columns  Filter

No.	Form Ref	Form Type	Form Status	Form Section	Document Name	Action
1	2024-2187-APP1	Application	● Review Completed	Section G: Research Methodology	Document	
2	2024-2187-APP1	Application	● Review Completed	Section G: Research Methodology	Document	
3	2024-2187-APP1	Application	● Review Completed	Section G: Research Methodology	Document	
4	2024-2187-APP1	Application	● Review Completed	Section G: Research Methodology	Document	

Migrated Study

2016-3130 Ongoing Refresh

- All Forms
- All Forms Attachments
- Study Letter
- Migrated Documents**

Filter

- 2016-3130 CIRB C Approved
 - 2016-3130 AMD1 Approved 20180518
 - 2016-3130 AMD10 Approved 20210717
 - 2016-3130 AMD11 Approved 20220502
 - 2016-3130 AMD12 Approved 20240217
 - 2016-3130 AMD2 Approved 20181102
 - 2016-3130 AMD3 Approved

NO.	Document Type	Document Name	Action
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▪ [Migrated Documents] consists of documents in iSHaRe that had been all converted to PDF format.



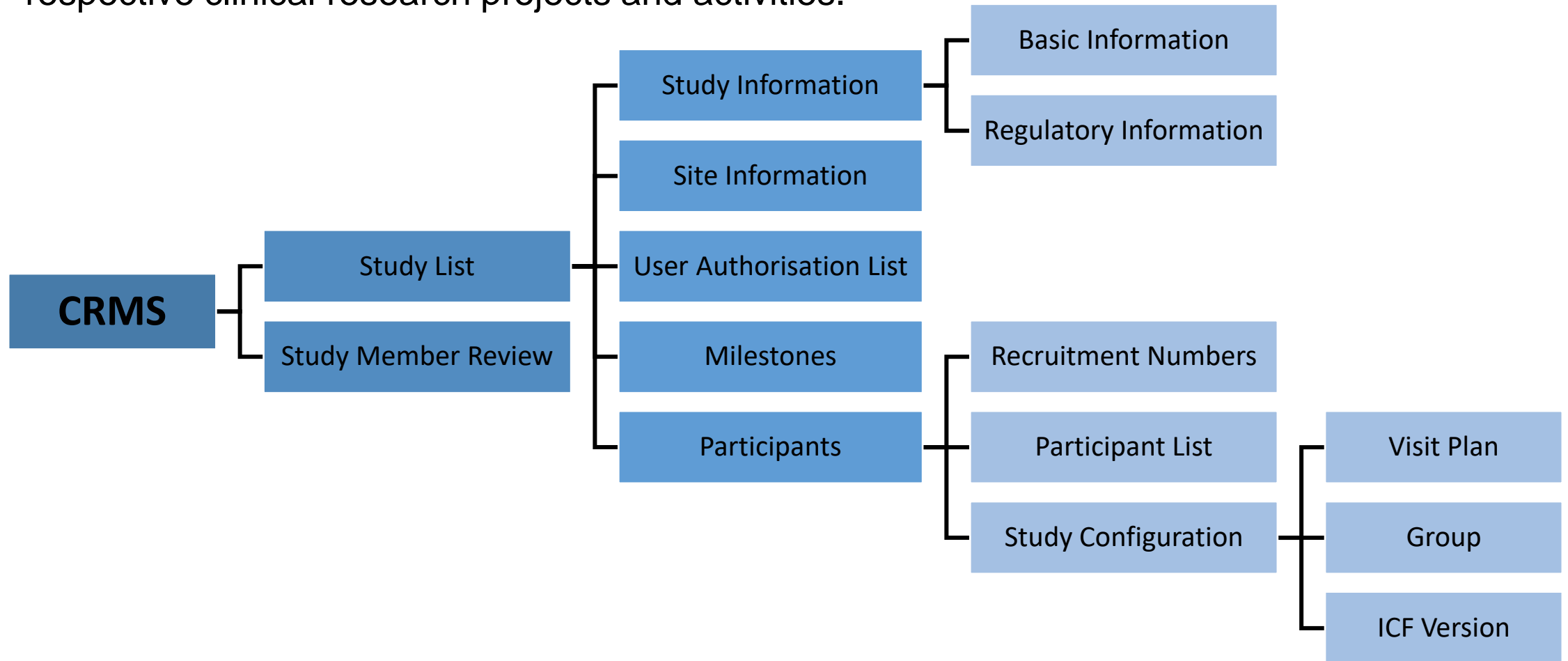
Data Migration Studies Timeline (Updated)

- All on-going IRB approved studies will be migrated to ECOS by **31 May 2024** and any action such as creation of forms for your migrated studies should start from **1 June 2024** onwards.
 - If there are any reporting of DNC, SAE, ORE or Study Closure before 1 June 2024, please refer to [CIRB Updates 1 Feb 2024](#), items 2 and 3.
 - CIRB will cease to accept submissions via email from 1 June 2024. All submissions should be via ECOS for on-going IRB approved studies.
- For studies with Valid Till Date between 1 Aug 2024 and 31 Aug 2024. Please target to submit the Renewal in ECOS **by 21 Jun 2024, 5pm or earlier** to avoid lapse of renewal.

Clinical Research Management System (CRMS)

Clinical Research Management System (CRMS)

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



User Access Matrix

IRB APPLICATION Form Stage

Access Level	CRMS Sections	Type of Access		Roles					
				PI/ Site-PI	Co-I	STM	SA	SS	CRMS RO
Study Level	Study Information	Full Access	Limited Access	✓	✓	✓	✓	✓	✓
	User Authorisation List			✓	✓	✓	✓	✓	✓
Site Level	Site Information		✓	✓	✓	✓		✓	
	Milestones		✓	✓	✓	✓		✓	
	Participants		✓	✓	✓	✓		✓	
	Participants – Study Configuration		✓	✓	✓	✓			
	Study Member Review		✓						

Legend

- ✓ Access (View & Edit) granted upon the addition of a user in the IRB 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 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: RO administrator assigned with CRMS role.

User Access Matrix

IRB AMENDMENT Form Stage

Page Level	CRMS Sections	Type of Access		Roles					
				PI/ Site-PI	Co-I	STM	SA	SS	CRMS RO
Study Level	Study Information	Full Access	Limited Access	✓	✓	✓	✓	✓	✓
	User Authorisation List			✓	✓	✓	✓	✓	✓
Site Level	Site Information		✓	✓	✓	✓		✓	
	Milestones		✓	✓	✓	✓		✓	
	Participants		✓	✓	✓	✓		✓	
	Participants – Study Configuration		✓	✓	✓	✓			
	Study Member Review		✓						

Legend

- ✓ Access (View & Edit) granted upon the addition of a 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 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: RO administrator assigned with CRMS role.

CRMS Page Level

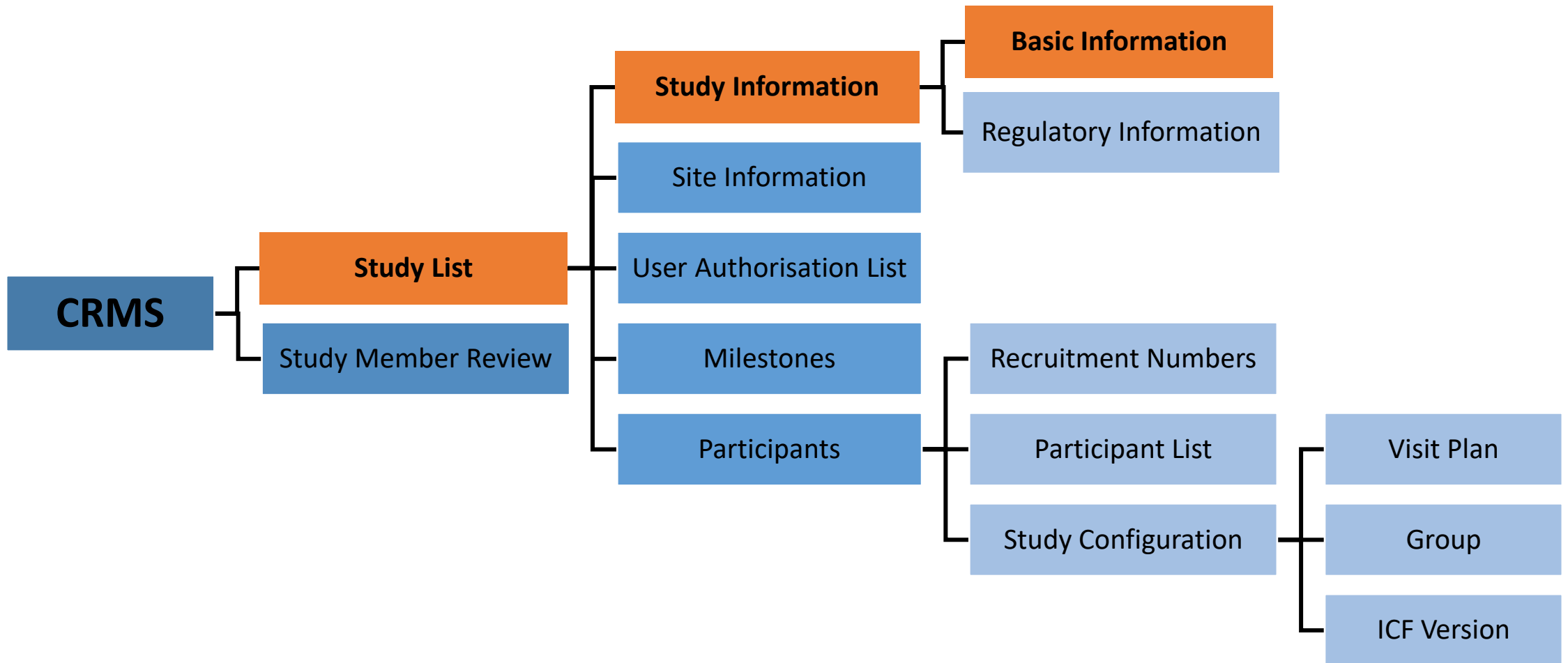
Page Level	CRMS Sections/ Pages	
Study Level	Study Information	Basic Information
		Regulatory Information
Site Level	Site Information	
	User Authorisation List	
	Milestones	
	Participants	Recruitment Numbers
		Participant List
Study Configuration		

Study Level

Information entered will be shared across all participating sites. E.g. data entered by 1 site will be seen by all sites. Similarly, data 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

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

The screenshot displays the ECOS Dashboard interface. The top navigation bar includes the ECOS logo, the word "Dashboard", and utility icons for Help, a download icon with a red notification bubble containing the number "1", a bell icon, and a notification icon with a red bubble containing "99+".

The left-hand navigation menu is expanded, showing the following items: Homepage, Dashboard (highlighted), My Tasks, My Notices, IRB, CRMS (highlighted), and FCOI. The CRMS menu item is further expanded to show "Study List" (highlighted with a blue circle and a mouse cursor) and "Study Member Review". A red circle with the number "1" is placed over the CRMS menu item, and a red circle with the number "2" is placed over the "Study List" sub-item.

The main dashboard area contains four data cards:

- IRB**: 27. Sub-items: Study (25), Endorsement (2).
- CRMS**: 12. Sub-items: Study Member (12), Review.
- FCOI**: 0. Sub-item: My FCOI List (0).
- My Notices**: Dashboard notice for all (31-Jan-2024). Includes a "View All" link.

CRMS Access

Study List									
ECOS Ref	IRB	PI/Site-PI	Department	Number of Sites	Study Title	Study Status	Action		
2024-3177	SingHealth CIRB Board D	Prof SGH_PI (Singapore General Hospital), Dr NNI_PI 2 (National Neuroscience Institute), A/Prof NUH_PI (National University Hospital)	Department of Renal Medicine (Singapore General Hospital), Neurology (TTSH Campus) (National Neuroscience Institute), Division of Nephrology (National University Hospital)	3	Study 1	Approved			
2024-3172	SingHealth CIRB Board D	Prof SGH_PI (Singapore General Hospital), Prof BVH_PI (Bright Vision Hospital)	Department of Renal Medicine (Singapore General Hospital), Medical (Bright Vision Hospital)	2	Study 2	Ongoing			
2024-3101	SingHealth CIRB Board D	Prof SGH_PI (Singapore General Hospital)	Department of Renal Medicine (Singapore General Hospital)	1	Study 3	Draft			
2024-3092	SingHealth CIRB Board D	Dr SKH_PI1 (Sengkang General Hospital), Prof SGH_PI (Singapore General Hospital)	Department of Internal Medicine (Sengkang General Hospital), Department of Renal Medicine (Singapore General Hospital)	2	Study 4	Approved			
2024-3066	SingHealth CIRB Board D	Prof SGH_PI (Singapore General Hospital), Prof NHC_PI 2 (National Heart Centre Singapore), Dr KKH_Co-I 2 (KK Women's and Children's Hospital)	Department of Renal Medicine (Singapore General Hospital), Department of Cardiology (National Heart Centre Singapore), Family Medicine Service (KK Women's and Children's Hospital)	3	Study 5	Approved			

CRMS Access



This option may be available in Q3 2024.

- There are 2 ways to access CRMS.

2. IRB Application or Amendment Form: Dashboard > IRB > My Study List > APP or AMD Form > Quick Link: CRMS

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

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

ECOS Ref: 2024-0205 [Icon]

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

Section A: Study Title

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

Study List

- Study List will only display the studies where a user has been added to the IRB forms or User Authorisation List.
- 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.
 - Study details (*next slide*).
 - List of Investigators added in IRB form to User Authorisation List.
- Synchronisation points: -
 - Upon saving of IRB **Application** Form.
 - Upon IRB approval or acknowledgement.

The screenshot shows the ECOS Study List interface. The left sidebar contains navigation options: Homepage, IRB, CRMS, Study List (highlighted), Study Member Review, and FCOI. The main area displays a table with columns: ECOS Ref, IRB, PI/Site-PI, Department, and Action. The table contains four rows of study data.

ECOS Ref	IRB	PI/Site-PI	Department	Action
2024-0205	CIRB Board D	Dr SGH_PI (Singapore General Hospital (SGH)), Prof NUH_PI (National University Hospital (NUH))	Department of Department of Renal Medicine(Singapore General Hospital (SGH)),Paediatrics(National University Hospital (NUH))	🔍
2024-0199	CIRB Board C	Dr NNI_PI 1 (National Neuroscience Institute (NNI)), Dr SGH_PI (Singapore General Hospital (SGH))	Department of Neurology (SGH Campus)(National Neuroscience Institute (NNI)),Department of Renal Medicine(Singapore General Hospital (SGH))	🔍
2024-0197	CIRB Board D	Dr NCC_BU (National Cancer Centre (NCC)), Asst Prof SGH_PI1 (Singapore General Hospital (SGH))	Department of Division of Medical Oncology(National Cancer Centre (NCC)),Department of Renal Medicine(Singapore General Hospital (SGH))	🔍
2024-0168	CIRB Board D	Dr NCC_Co-11 (National Cancer Centre (NCC)), Dr CGH_Site-PI1 (Changi)	Department of Division of Radiation Oncology(National Cancer Centre (NCC)),Accident & Emergency/Chanai Gene	🔍

Rows per page: 100 1-63 of 63

Study List

Study Details

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

The screenshot shows the ECOS Study List interface. The main table displays study information, and a 'Detail' modal is open for the first study. The table has columns for ECOS Ref, IRB, PI/Site-PI, Department, Number of Sites, Study Title, and Action. The 'Detail' modal shows a table of study sites with columns for Study Site, Name, Study Role, Institution, and Site Status.

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.	

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	

Study Information – Basic Information

Study Level

[Back to Study List](#)

Study Details



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

ECOS Reference: 2024-0205

IRB: CIRB Board D

Study Status: • Draft

Number of Sites: 2

Initial Outcome Date: -

Valid Till Date: -

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

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



Study Information

Basic Information

Regulatory Information

User Authorisation List

Edit

Sponsor Details

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

Clinical Research Organisation (CRO) Details

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

IRB Review Fees Billing Details

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

Page Function – Study Dropdown Bar

Study Details

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

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

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

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

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

Study Information

- Basic Information
- Regulatory Information
- User Authorisation List

[Edit](#)

Sponsor Details

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

Clinical Research Organisation (CRO) Details

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

IRB Review Fees Billing Details

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

Page Function – Study Dropdown Bar

Study Details

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

2024-0291, Test 1

2024-0264, Test 2

2024-0257, Test 3

2024-0214, Test 4

2024-0212, Test 5

2024-0209, Test 6

2024-0199, Test 7

NOTE: User can use the Study Dropdown Bar to toggle to other studies.

Regulatory Information

Site Information

User Authorisation List

Milestones

Participants

Sponsor Details

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

Clinical Research Organisation (CRO) Details

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

IRB Review Fees Billing Details

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

Page Function – Collapse/Expand

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

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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Page Functions – Edit, Add, Delete, Save Data

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

[Edit](#)

Sponsor Details

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

Clinical Research Organisation (CRO) Details

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

IRB Review Fees Billing Details

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

Expand

Page Functions – Edit, Add, Delete, Save Data

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

Save Cancel

Sponsor Details

Add

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

Clinical Research Organisation (CRO) Details

Add

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

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		* Singapore654123	SGH_PI	Edit Delete

Page Functions – Edit, Add, Delete, Save Data

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

Study Details Help Download Notifications 99+

Sponsor Details Save Cancel 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	Cancel

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
* AB-CRO	* AB	* 98762345	* ab@ab.com		* Singapore 654123	S	Edit Delete
* Add New Data	* Add New Data	* Add New Data	* Add New Data	ⓘ	Add New Data	* Add New Data	Cancel
* Add New Data	* Add New Data ⓘ	* Add New Data	* Add New Data ⓘ	Add New Data	* Add New Data		Cancel

ⓘ This is a mandatory field. Please fill in response.

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

Page Functions – Edit, Add, Delete, Save Data

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

Study Details

Help [Download] [Notifications] [99+]

Do you want to proceed?

Cancel Confirm

Save Cancel

Add

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		Cancel
* Add New Data	* Add New Data	* Add New Data	* Add@New.Data	Add New Data	* Add New Data		Cancel

IRB Review Fees Billing Details

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

Page Functions – Edit, Add, Delete, Save Data

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

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

Save Cancel Add

Sponsor Details

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

IRB Review Fees Billing Details

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

Record Tracking

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

Study Details

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

Sponsor Details

Name of Sponsor	Contact Person Name	Business Fax No.	Business Address	Last Edited By	Last Edited Date
XYZ Pharmaceuticals	XYZ	New Data	Singapore 123654	SGH_PI	14-Mar-2024

Clinical Research Organisation (CRO) Details

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

IRB Review Fees Billing Details

Contact Person Name	Business Contact No.	Business Fax No.	Business Address	Last Edited By	Last Edited Date
---------------------	----------------------	------------------	------------------	----------------	------------------

Study Information – Basic Information

- On ECOS, Sponsor, CRO and IRB billing details will be entered on the **CRMS – Basic Information** page instead of the IRB Application Form.
- Subsequent changes to Sponsor/CRO and IRB billing details can be done via CRMS without submitting an IRB Amendment form.

NOTE:

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

Study Information – Basic Information

- 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.

IRB Application Form – Section C1

2024-0205-APP1 Draft Refresh

ECOS Ref: 2024-0205 Copy

Submit More

[Form Detail](#)



Amendment Form

Track Changes Mandatory Check Cancel Save Save and Exit

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

- (a) Department Fund or No funding is required for this study to be carried out
- (b) Grant
- (c) Pharmaceutical/ Industry Sponsored

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

XYZ Pharmaceuticals

19 characters entered

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

- Yes
- No

- Section A: Study Title
- Section B: Submission ...
- Section C: Study Fundi...**
- Section D: Study Type a...
- Section G: Research M...
- Section H: Research D...
- Section T: Research Da...

Mandatory Check Prompt From IRB APP Form

ECOS



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

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

Confirm

Complete Sponsor/CRO and IRB Details in CRMS

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 completed. [Edit](#)

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

Clinical Research Organisation (CRO) Details					
Name of CRO	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
AB-CRO	AB	98762345	ab@ab.com		Singapore 654123

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

Return to IRB APP Form

[Back to Study Summary](#)

Submission Detail

Help



99+



[IRB](#) / [My Study List](#) / [Study Summary](#) / [Submission Detail](#)

✓ Mandatory check completed.

2024-0205-APP1 Draft

[Submit](#)

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...

Section D: Study Type a...

After IRB APP Form Approval

Study Details

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

Help [Download] [Notifications] [99+]

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

Save Cancel

Sponsor Details

Add

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

Clinical Research Organisation (CRO) Details

Add

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

IRB Review Fees Billing Details

Add

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

Applicable To Both Sponsor/CRO and IRB Details

Study Details

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

Help [Download] [Notifications] [99+]

2

3

1

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

Save Cancel Add

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	SGH_PI	Edit Delete

Add

Clinical Research Organisation (CRO) Details

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

Add

IRB Review Fees Billing Details

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

Add

Original Data Reverted

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 Edited
* LMN	* 95672341	* lmn@ab.com		* Singapore 654123	SGH_

Page Functions – Cancel

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

Study Details

Help [Download] [Notifications] [99+]

Save Cancel

Sponsor Details

Add

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

Clinical Research Organisation (CRO) Details

Add

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

IRB Review Fees Billing Details

Add

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



Page Functions – Cancel

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

Study Details

Help [Download] [Notifications] [99+]

Save Cancel

Sponsor Details

Add

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

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

Page Functions – Cancel

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

Study Details

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

[Save] [Cancel]

Sponsor Details

[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

Data Reverted

Page Functions – Cancel

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

Save Cancel Add

Sponsor Details

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

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	SGH_PI	Edit Delete

IRB Review Fees Billing Details

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

Original Data Reverted

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

Edit

Sponsor Details

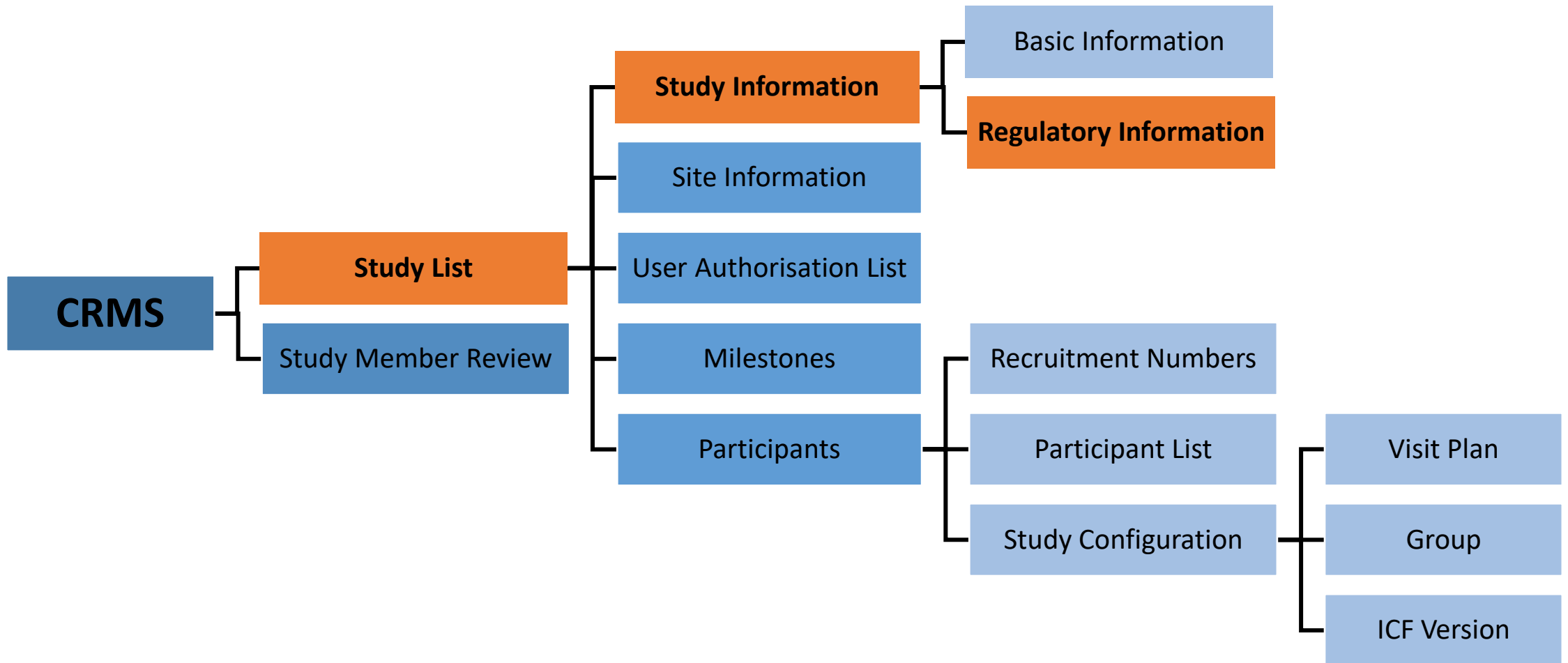
Name of Sponsor	Contact Person Name	Business Contact No.	Business Email	Business Fax No.	Business Address
* XYZ Pharmaceuticals	* XYZ	* 98761234	* xyz@xyz.com	New Data	* Singapore 123654

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_



Study Information – Regulatory Information

Study Level

Study Details

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

Study Information

- Basic Information
- Regulatory Information
- User Authorisation List

Clinical Trials Regulated by HSA

Type of Application

* Clinical Trial Authorisation (CTA)

Clinical Research Material (CRM)

Name(s) of CRM(s)	Type(s) of CRM
* Drug-X	* Therapeutic Product/CTGTP

Restricted Human Biomedical Research

MOH Application No.	MOH Initial Submission Date	Submission Date

Local Regulatory Study Reference No. Licence/P No.

HPRG/CTB 78:10/99-999 CTA00

Submission Date

MOH Expiry Date

Export Edit

Type of Application

- Clinical Trial Certificate (CTC)
- Clinical Trial Authorisation (CTA)
- Clinical Trial Notification (CTN)
- Substantial Amendments
- * Safety Report
- Serious Breach
- Urgent Safety Measures
- R Trial Status Report

Study Information – Regulatory Information

Study Level

Study Details

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

Study Information

- Basic Information
- Regulatory Information
- User Authorisation List

Clinical Trials Regulated by HSA

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

Clinical Research Material (CRM)

Name(s) of CRM(s)	Type(s) of CRM
* Drug-X	* Therapeutic Product/CTGTP

Restricted Human Biomedical Research

MOH Application No.	MOH Initial Submission Date	MOH Reference No.	Submission Date
---------------------	-----------------------------	-------------------	-----------------

Type(s) of CRM

- Therapeutic Product/CTGTP x Medical Device x
- Therapeutic Product/CTGTP ✓
- Medicinal Product
- Medical Device ✓

Study Information – Regulatory Information

Study Level

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

Study Details

Study Information

- Basic Information
- Regulatory Information
- User Authorisation List

Clinical Trials Regulated by HSA

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

Type of Application: Clinical Trial Authorisation (CTA) | Submission Reference No.: 20A0000X | Submission Date: 02-Jan-2024

Clinical Research Material (CRM)

Name(s) of CRM(s): Drug-X | Type(s) of CRM: Therapeutic Product/CTGTP | Type of CRM Submission: CRM Notification

Restricted Human Biomedical Research

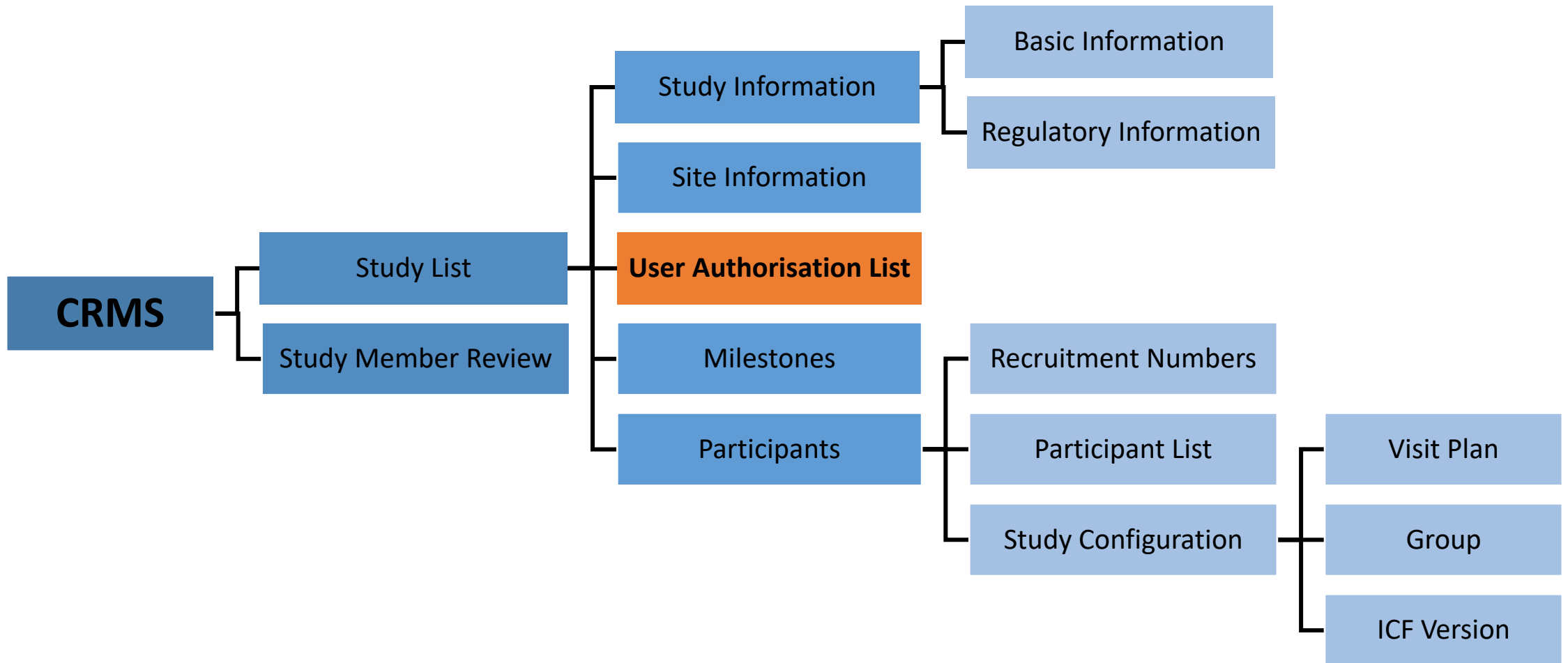
MOH Application No. | MOH Initial Submission Date | MOH Reference No. | MOH Initial Approval Date

Submission Date | Approval Date

Export | Edit

Calendar: Mar 2024

Su	Mo	Tu	We	Th	Fr	Sa
25	26	27	28	29	1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31	1	2	3	4	5	6



User Authorisation List (UAL)

Site Level

- User access management to CRMS and/or IRB modules on ECOS.
- PI/Site-PI, Co-I, Study Team Members, Study Administrators and Study Sponsor roles will be listed.
- But the UAL access management is for STM, SA and SS roles only.

Study Details

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

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

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

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

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

User Authorisation List

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

Member Name	Role	Cluster	Institution	Department	Designation	Email Address	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date	Action
SGH_PI	PI	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_PI@singhealth.com.sg	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_Co-I1	CoI	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_Co-I1@singhealth.com.sg	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_SA1	Study Administrator	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Senior Executive	SGH_SA1@sgh.com.sg	CRMS	● Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	Deactivate
SS_20	Study Sponsor	Non-PHI	Astra Zeneca	Astra Zeneca	CRA	SS_20@az.com	CRMS	● Pending Endorsement	-	-	-	-	SGH_Co-I1	24-Jan-2024	

User Authorisation List (UAL)

Site Level

- User access management to CRMS and/or IRB modules on ECOS.
- PI/Site-PI, Co-I, Study Team Members, Study Administrators and Study Sponsor roles will be listed.
- But the UAL access management is for STM, SA and SS roles only.

Study Details

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

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

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

PI/Site PI: Dr SGH_PI (Singapore General Hospital) Department: Department of Medicine(Singapore General Hospital)

User Authorisation List

Member Name	Role	Institution	Data Source
SGH_PI	PI	Singapore General Hospital (SGH)	IRB
SGH_Co-I1	Col	Singapore General Hospital (SGH)	IRB
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	CRMS
SS_20	Study Sponsor	Astra Zeneca	CRMS

Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date	Action
Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	Deactivate
-	-	-	-	SGH_Co-I1	24-Jan-2024	

User Authorisation List (UAL)

Role	Definition	Comments
PI	Site investigators directly involved in the research.	<p>Access management: IRB module > IRB APP or AMD Form > Section B2(a) Investigator List</p> <ul style="list-style-type: none"> The list of investigators will be imported from 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. Addition and deactivation will both go through the IRB module. <p>During IRB Application drafting:</p> <ul style="list-style-type: none"> The addition or removal of any PI, Site-PI or Co-I in the draft IRB Application Form will be reflected on the CRMS UAL each time the IRB Application Form is saved. <p>In subsequent IRB Amendment Form(s):</p> <ul style="list-style-type: none"> New PI, Site-PI or Co-I will only appear on the CRMS UAL after IRB has provided approval for the Amendment Form. Investigators to be removed will only be deactivated on the UAL after IRB's review.
Site PI		
Co-I		

User Authorisation List (UAL)

Role	Definition	Comments
Study Team Member (STM) & Study Administrator (SA)	<p>STM: Site personnel <u>directly involved</u> in the research e.g. CRCs, Study Nurses, Pharmacists etc.</p> <p>SA: Site personnel <u>not directly</u> involved in the research but provides administrative support only, e.g. Executives, CRCs not involved in the conduct of research.</p>	<p>Access management: CRMS module > UAL</p> <ul style="list-style-type: none"> • Data source on UAL 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.
Study Sponsor (SS)	Sponsor/CRO personnel, e.g. Clinical Trial Assistants, Clinical Research Associates, Clinical Trial Managers etc.	<ul style="list-style-type: none"> • 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 in the list for IRB and CRMS accesses to be revoked.

Page Functions – Filter

NOTE:

- The UAL is pre-set to display only roles that are Active, Pending IRB Approval or Pending Endorsement.
- To view all Active, Pending and Inactive roles, remove the default filter configured.

Study Details

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

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

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

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

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

User Authorisation List

Member Name	Role	Cluster	Institution	Department	Designation	Email Address	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date	Action
SGH_PI	PI	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_PI@singhealth.com.sg	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_Co-I1	Col	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_Co-I1@singhealth.com.sg	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_SA1	Study Administrator	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Senior Executive	SGH_SA1@sgh.com.sg	CRMS	Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	Deactivate
SS_20	Study Sponsor	Non-PHI	Astra Zeneca	Astra Zeneca	CRA	SS_20@az.com	CRMS	Pending Endorsement	-	-	-	-	SGH_Co-I1	24-Jan-2024	

Page Functions – Filter

NOTE:

- The UAL is pre-set to display only roles that are Active, Pending IRB Approval or Pending Endorsement.
- To view all Active, Pending and Inactive roles, remove the default filter configured.

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

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

User Authorisation List

Member Name	Role	Cluster	Institution	Department	Designation	Email Address	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deacti
SGH_PI	PI	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_PI@singhealth.com.sg	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-
SGH_Co-I1	Col	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_Co-I1@singhealth.com.sg	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-
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	-	-
SS_20	Study Sponsor	Non-PHI	Astra Zeneca	Astra Zeneca	CRA	SS_20@az.com	CRMS	Pending Endorsement	-	-	-	-

Filter

Role Status: Active x Pending IRB Approval x Pending Endorsement x

Endorsement Date: Start Date → End Date

Endorsed By:

Deactivation Date: Start Date → End Date

Deactivated By:

Reset Search

2

3

Page Functions – Columns

- With the filter removed, the UAL additionally displays SGH_STM11 (Role Status: Inactive).
- Use the Columns function to narrow the information to be displayed.

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

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

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

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

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

User Authorisation List

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

Member Name	Role	Cluster	Institution	Department	Designation	Email Address	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Edited Date	Action
SGH_PI	PI	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_PI@singhealth.com.sg	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_Co-11	Col	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_Co-11@singhealth.com.sg	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_STM11	Study Team Member	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Executive	SGH_STM11@sgh.com.sg	CRMS	● Inactive	-	-	24-Jan-2024	SGH_PI	SGH_PI	24-Jan-2024	
SGH_SA1	Study Administrator	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Senior Executive	SGH_SA1@sgh.com.sg	CRMS	● Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	Deactivate
SS_20	Study Sponsor	Non-PHI	Astra Zeneca	Astra Zeneca	CRA	SS_20@az.com	CRMS	● Pending Endorsement	-	-	-	-	SGH_Co-11	24-Jan-2024	



Page Functions – Columns

- With the filter removed, the UAL additionally displays SGH_STM11 (Role Status: Inactive).
- Use the Columns function to narrow the information to be displayed.

Study Details

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

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

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

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

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

User Authorisation List

Member Name	Role	Cluster	Institution	Department	Designation	Email Address	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date
SGH_PI	PI	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_PI@singhealth.com.sg	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-
SGH_Co-I1	Col	SingHealth	Singapore General Hospital (SGH)	Department of Medicine	Consultant	SGH_Co-I1@singhealth.com.sg	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-
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_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	-
SS_20	Study Sponsor	Non-PHI	Astra Zeneca	Astra Zeneca	CRA	SS_20@az.com	CRMS	Pending Endorsement	-	-	-

Column

Selected 15

Search

Select All

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

Clear Cancel Save

Page Functions – Export

- The 4 data columns unchecked will not be displayed.

Study Details Help

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

User Authorisation List

+ Add Columns Export Filter

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

Rows per page: 100 1-5 of 5

Column Selected 11

Search

Select All

Member Name

Role

Cluster

Institution

Department

Designation

Email Address

Data Source

Role Status

Clear Cancel Save

Page Functions – Export

- Click on the Export button to print the UAL in Excel or PDF.

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

User Authorisation List

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

Rows per page: 100 1-5 of 5

Page Functions – Export



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

- The Export function will generate the UAL with the specific Columns and Filter selected (if any).
- Use can choose to export in Excel or PDF version.
 - Excel offers better flexibility to modify the column and row width/heights before saving as PDF.
- Steps to export are the same across all pages that can be exported.

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

Expected view of the exported UAL.

Page Functions – Add

Study Details

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

User Authorisation List

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

Rows per page: 100 1-4 of 4

Navigation: < >

Buttons: + Add, Columns, Export, Filter(1)

Annotation: 1 (circled) with arrow pointing to the + Add button

Page Functions – Add



Fuzzy search is not allowed.

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

Member Name	Role	Institution	Data Source	Role Status	Endorsement Date
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024
SGH_Co-11	Col	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	CRMS	Active	24-Jan-2024
SS_20	Study Sponsor	Astra Zeneca	CRMS	Pending Endorsement	-

Add Submit Cancel

* Member Name/Email: **Enter full name or email address**

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

Total Rows: 1

* Role:

Page Functions – Add

Study Details

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

User Authorisation List

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

7

* 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

5

6

Page Functions – Add User

Role used: **PI or Site-PI**

← Back to Study List Study Details Help 1 99+

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

User Authorisation List

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

Member Name	Role	Institution	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date	Action
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_Co-I1	CoI	Singapore General Hospital (SGH)	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	CRMS	● Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	Deactivate
SGH_STM22	Study Team Member	Singapore General Hospital (SGH)	CRMS	● Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	Deactivate
SS_20	Study Sponsor	Astra Zeneca	CRMS	● Pending Endorsement	-	-	-	-	SGH_Co-11	24-Jan-2024	

RECAP: The addition of new user(s) by PI/Site-PI will automatically be endorsed upon submission.

Rows per page: 100 1–5 of 5

Page Functions – Add User

Role used: CRMS RO administrator

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

User Authorisation List

+ Add Columns Export Filter(1)

Member Name	Role	Institution	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date	Action
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_Co-I1	CoI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	CRMS	Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	Deactivate
SGH_STM22	Study Team Member	Singapore General Hospital (SGH)	CRMS	Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	Deactivate
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	

RECAP: PI endorsement is required, endorsement is site-specific.

Rows per page: 100 1-6 of 6

Page Functions – Add User

Updated page after PI or Site-PI's Endorsement in CRMS

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

User Authorisation List

+ Add Columns Export Filter(1)

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

NOTE: Logic applies to all roles except for PI/Site-PI.

Rows per page: 100 1-6 of 6

Page Functions – Deactivate User

Role used: Study Administrator

< 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 (SGH)



User Authorisation List

+ Add

Columns

Export

Filter

Member Name	Role	Institution	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date	Action
SGH_SA22	Study Administrator	Singapore General Hospital (SGH)	CRMS	● Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	Deactivate
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_Co-I1	Col	Singapore General Hospital (SGH)	IRB	● Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_STM11	Study Team Member	Singapore General Hospital (SGH)	CRMS	● Inactive	-	-	24-Jan-2024	SGH_PI	SGH_PI	24-Jan-2024	
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	CRMS	● Active	24-Jan-2024	SGH_PI	-	-	SGH_PI	24-Jan-2024	Deactivate
SGH_STM22	Study Team Member	Singapore General Hospital (SGH)	CRMS	● Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	Deactivate
SS_20	Study Sponsor	Astra Zeneca	CRMS	● Pending Endorsement	-	-	-	-	SGH_Co-I1	24-Jan-2024	

Page Functions – Deactivate User

Role used: Study Administrator

← Back to Study List Study Details Help Download Notifications Profile

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

User Authorisation List

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

Member Name	Role	Institution	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date	Action
SGH_SA1	Study Administrator	Singapore General Hospital (SGH)	CRMS	Inactive	24-Jan-2024	SGH_PI	14-Mar-2024	SGH_SA22	SGH_SA22	14-Mar-2024	
SGH_SA22	Study Administrator	Singapore General Hospital (SGH)	CRMS	Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024	Deactivate
SGH_PI	PI	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_Co-11	Col	Singapore General Hospital (SGH)	IRB	Active	24-Jan-2024	CIRB_D_IRBSec1	-	-	-	24-Jan-2024	
SGH_STM11	Study Team Member	Singapore General Hospital (SGH)	CRMS	Inactive	-	-	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	Deactivate
SS_20	Study Sponsor	Astra Zeneca	CRMS	Pending Endorsement	-	-	-	-	SGH_Co-11	24-Jan-2024	

Page Functions – Study Dropdown Bar

Study Details

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

Singapore General Hospital (SGH)

NOTE: Users can use the Study Dropdown Bar to toggle to another study's UAL. The same logic applies to other Site Level pages.

Study Information

- Basic Information
- Regulatory Information
- Site Information
 - User Authorisation List
- Milestones
- Participants

User Authorisation List

+ Add Columns Export Filter(1)

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

Rows per page: 100 1-5 of 5

User Authorisation List (UAL)

- The UAL primarily functions to manage the access of **STM**, **SA** and **SS** to the CRMS and/or IRB modules on ECOS.
- This is one of the harmonised processes between SingHealth and NHG where non-investigator(s) will no longer require IRB's approval.



Limited access to Study Information and UAL on CRMS, once a STM/SA/SS has been added, would allow the new user to gain immediate access to IRB and CRMS modules for data entry, submission and reporting work.

- Only the PI's Endorsement in CRMS is required to fully activate the STM/SA/SS roles.

User Authorisation List (UAL)



The User Authorisation List does not replace a site delegation log.

- 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).

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



Does the user require access to
IRB or CRMS modules?



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

- Draft IRB Forms?
- Draft DNC, OSN, SAE, SSR etc?
- Need access to the IRB documents, e.g. protocol, ICFs and IRB approval letters?
- Entering data into CRMS pages?
- Back-up users?

Site Delegation Log

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

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

UAL can also contain
sponsors or any other users
outside the delegation log.

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

CRMS UAL

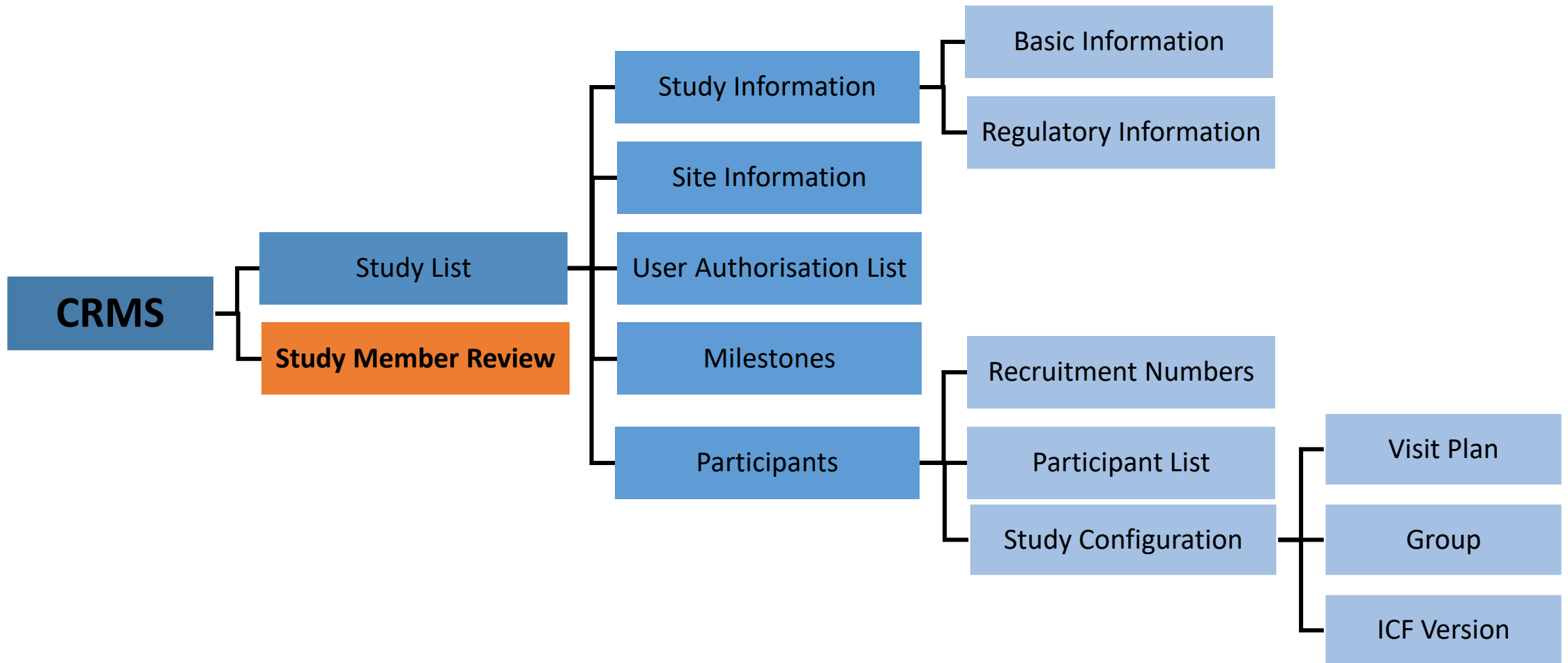
ECOS

User Authorisation List

Member Name

Role

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








Study Member Review





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

The screenshot displays the ECOS Dashboard interface. The top navigation bar includes the ECOS logo, the word "Dashboard", and utility icons for Help, download, notifications, and a profile icon. The left sidebar contains a navigation menu with "Dashboard" highlighted in a blue box and an orange border. Below it are "My Tasks", "My Notices", and a dropdown menu with "IRB", "CRMS", "FCOI", and "Report". The main content area features three data cards: "IRB" with a count of 30 (subdivided into Study: 28 and Endorsement: 2), "CRMS" with a count of 11 and a "Study Member Review 11" link highlighted in blue with an orange arrow, and "FCOI" with a count of 0. A "My Notices" section on the right lists two notices: "uat test-20240131" dated 31-Jan-2024 and "UAT - Dashboard notice for all" dated 30-Jan-2024.

Study Member Review

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	

Rows per page: 100 1-11 of 11  

Study Member Review

ECOS Study Member Review

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

Reject Endorse Columns Export Filter

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

1

2

Rows per page: 100 1-1 of 1

Study Member Review Access

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

The screenshot displays the ECOS Dashboard interface. The top navigation bar is dark blue with the ECOS logo on the left, the word "Dashboard" in the center, and a notification bell icon with "99+" on the right. The left-hand navigation menu is light blue and includes: "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 features three summary cards: "IRB" with a large "8" and a table showing "Study" (8) and "Endorsement" (0); "CRMS" with a large "3" and a table showing "Study Member Review" (3); and "FCOI" with a large "0" and a table showing "My FCOI List" (0). A "My Notices" section on the right shows a notification: "Dashboard notice for all" dated "07-Apr-2024" with a "View All" link.

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

Study Member Review Access

The screenshot displays the ECOS interface for 'Study Member Review'. The top navigation bar includes the ECOS logo, the page title 'Study Member Review', and utility icons for download, notifications (99+), and a profile icon. A left-hand navigation menu lists various sections: Homepage, IRB, CRMS, Study List, Study Member Review (highlighted), FCOI, and Report. The main content area features a dropdown menu currently open, showing a list of study entries. The selected entry is '2024-3170, Study 2', which is highlighted in blue. An orange arrow labeled '1' points to this entry. To the right of the dropdown, the text 'Singapore General Hospital' is visible, with an orange arrow labeled '2' pointing to it. Other entries in the dropdown include '2024-3172, Study 1', '2024-3167, Study 3', '2024-3127, Study 4', '2024-3126, Study 5', and '2024-3125, Study 6'.

Study Member Review

Site Level

ECOS Study Member Review

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

Reject Endorse Columns Export Filter(1)

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

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

Study Member Review

Site Level

- Action: **ENDORSE**

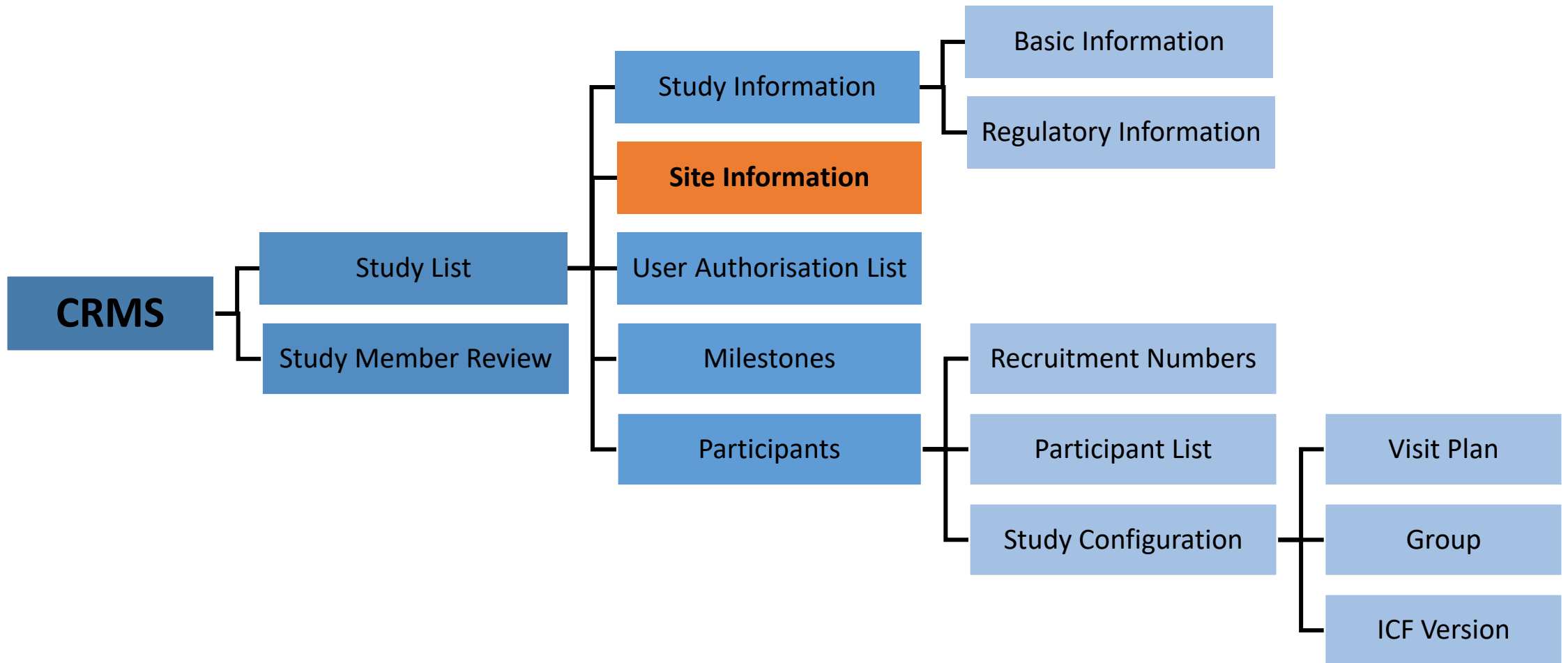
Member Name	Role	Institution	Data Source	Role Status	Endorsement Date	Endorsed By	Deactivation Date	Deactivated By	Last Edited By	Last Edited Date
SGH_STM22	Study Team Member	Singapore General Hospital (SGH)	CRMS	● Active	07-Mar-2024	SGH_PI	-	-	SGH_PI	07-Mar-2024

- Role Status, Endorsement Date, Endorsed By, Last Edited By and Last Edited Date will be updated.
- Full 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.
- Limited access to CRMS will be revoked.



Site Information

Site Level

[Back to Study List](#)

Study Details



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

Study Information

Basic Information

Regulatory Information

Site Information

User Authorisation List

Milestones

Participants

Export Edit

Contact Personnel

Primary Site Coordinator

SGH_SA1

Funding/Grant Duration

01-Jan-2024 → 31-Dec-2024

Funding/Grant Award Letter

Upload

Last Edited By Last Edited Date

SGH_PI 24-Jan-2024

ACP Involved in this study (For SingHealth)

ACP Involved In This Study (For SingHealth)

Musculoskeletal Sciences

Nov 2024 Dec 2024

Su	Mo	Tu	We	Th	Fr	Sa	Su	Mo	Tu	We	Th	Fr	Sa
27	28	29	30	31	1	2	1	2	3	4	5	6	7
3	4	5	6	7	8	9	8	9	10	11	12	13	14
10	11	12	13	14	15	16	15	16	17	18	19	20	21
17	18	19	20	21	22	23	22	23	24	25	26	27	28
24	25	26	27	28	29	30	29	30	31	1	2	3	4
1	2	3	4	5	6	7	5	6	7	8	9	10	11

Last Edited By Last Edited Date

SGH_PI 24-Jan-2024

Funding (Including Grant)

Name of Funding/Grant Agency

Funding/Grant Holder

Study Agreement Information

Type of Agreement

* NDA

Date Study Agreement

date

Industry Sponsor/CRO Contract

Sponsor Name

* AB-CRO

Total Estimated Budget of Contract

1200000

Date of Info (Protocol, Lab & Pharmacy Manual) Received to Start Drafting Budget

04-Dec-2023

Date of Budget

05-Dec

Publications and Presentations

Type

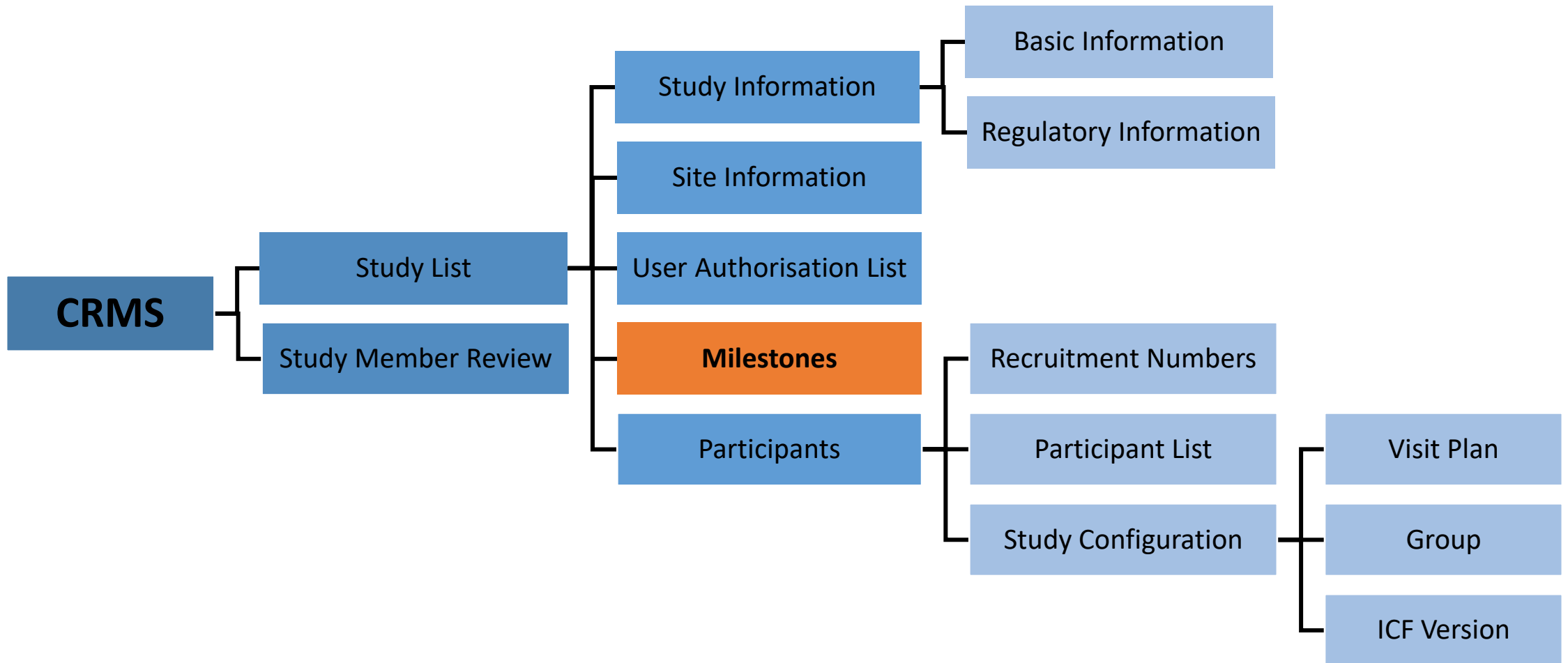
Publication/Presentation Title

Local/Overseas

Date

Last Edited By

Last Edited Date



Milestones

Site Level

If you have a unique milestone not part of the dropdown list..

Study Details

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

Study Information

- Basic Information
- Regulatory Information
- Site Information
- User Authorisation List
- Milestones**
- Participants

Milestone	Expected Date	Actual Date	Remarks	By	Last Edited Date	Action
Regulatory Approval	17-Jan-2024	22-Jan-2024	Slight delay due to additional round of queries from HSA.	SGH_SA1	26-Jan-2024	
IRB Approval	08-Feb-2024	24-Jan-2024	-	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_PI	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

Study Details

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

Study Information

- Basic Information
- Regulatory Information
- Site Information
- User Authorisation List
- Milestones**
- Participants

Milestone	Expected Date	Actual Date	Remi
Regulatory Approval	17-Jan-2024	22-Jan-2024	Sligh queri
IRB Approval	08-Feb-2024	24-Jan-2024	-
Study Initiation	29-Jan-2024	25-Jan-2024	-
First Participant Screened	26-Jan-2024	26-Jan-2024	-
First Participant Enrolled	23-Feb-2024	13-Feb-2024	Eligit confi

Milestone

Submit Cancel

* Milestone:

Please select

- Study Initiation
- First Participant Screened
- First Participant Enrolled
- Last Participant Last Visit
- Last Participant Enrolled
- Data Analysis
- Study Closure
- Other

2

Milestones

Site Level

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

- Study Information
- Basic Information
- Regulatory Information
- Site Information
- User Authorisation List
- Milestones**
- Participants

Milestone	Expected Date	Actual Date	Remi
Regulatory Approval	17-Jan-2024	22-Jan-2024	Sligh quer
IRB Approval	08-Feb-2024	24-Jan-2024	-
Study Initiation	29-Jan-2024	25-Jan-2024	-
First Participant Screened	26-Jan-2024	26-Jan-2024	-
First Participant Enrolled	23-Feb-2024	13-Feb-2024	Eligit confi

Milestone Submit Cancel

* Milestone: Other

50% Recruitment Target

Expected Date: 31-Mar-2024

Actual Date: Select date

Remarks:

Milestones

Site Level

< 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 (SGH)



Study Information

Basic Information

Regulatory Information

Site Information

User Authorisation List

Milestones

Participants

+ Add

Columns

Export

Filter

Milestone	Expected Date	Actual Date	Remarks	Last Edited By	Last Edited Date	Action
Regulatory Approval	17-Jan-2024	22-Jan-2024	Slight delay due to additional round of queries from HSA.	SGH_SA1	26-Jan-2024	
IRB Approval	08-Feb-2024	24-Jan-2024	-	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_PI	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	
50% Recruitment Target	31-Mar-2024	-	-	SGH_PI	18-Mar-2024	

Rows per page: 100

1-6 of 6



Project Management Tool – Reverse Planning

Study Details

2024-3261, Test Study 1 / National Neuroscience Institute

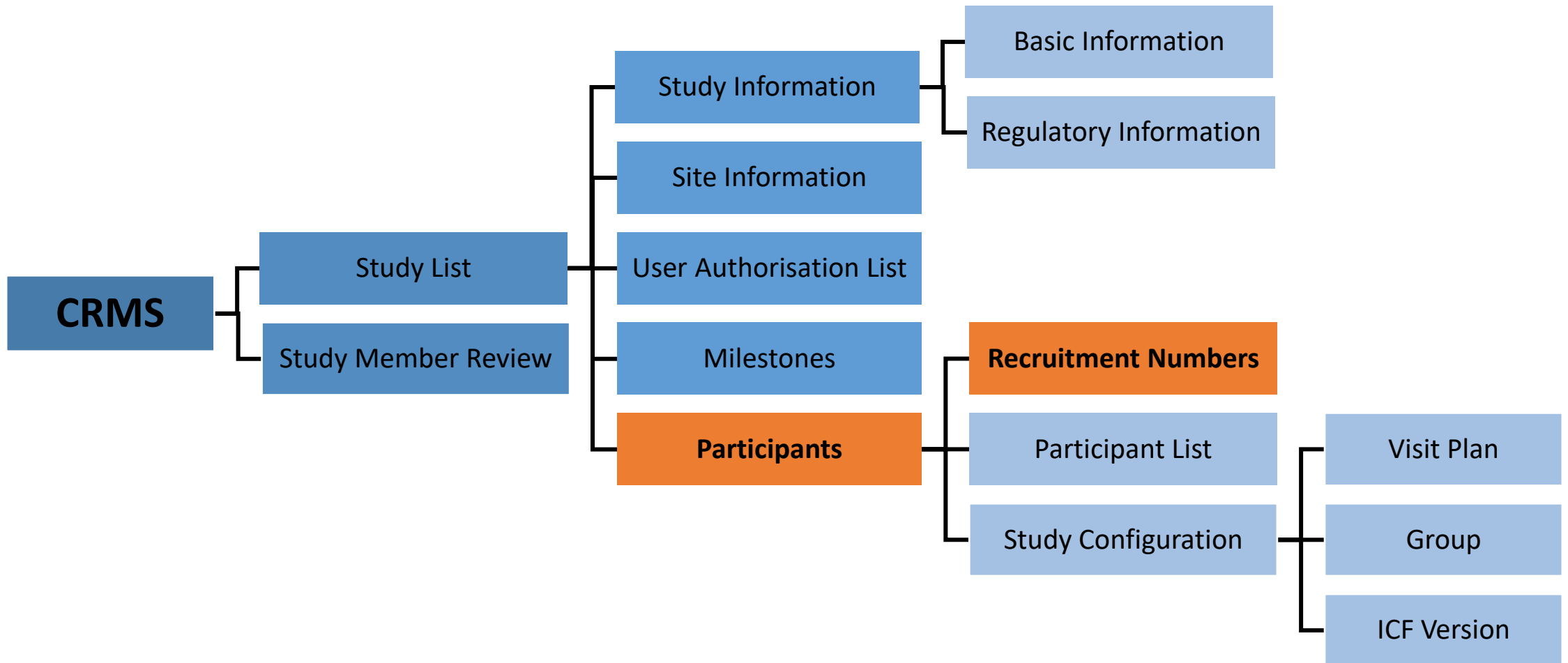
Study Information

- Basic Information
- Regulatory Information
- Site Information
- User Authorisation List
- Milestones**
- Participants

+ Add Columns Export Filter

Milestone	Expected Date	Actual Date	Remarks	Last Edited By	Last Edited Date	Action
Grant Approval	-	01-Jan-2024	-	SHS_MA3	22-Apr-2024	Edit
IRB Approval	25-Oct-2023	25-Nov-2023	HBRA study, non-restricted.	SHS_MA3	22-Apr-2024	Edit
Study Initiation	29-Apr-2024	-	KIV prepare slides using SingHealth SIV template.	SHS_MA3	22-Apr-2024	Edit
First Participant Screened	30-Apr-2024	-	-	SHS_MA3	22-Apr-2024	Edit
First Participant Enrolled	01-May-2024	-	-	SHS_MA3	22-Apr-2024	Edit
Last Participant Enrolled	01-Apr-2025	-	-	SHS_MA3	22-Apr-2024	Edit
NMRC Interim Report	31-May-2025	-	-	SHS_MA3	22-Apr-2024	Edit
NMRC Grant Expiry	31-Dec-2025	-	-	SHS_MA3	22-Apr-2024	Edit
NMRC Full Report	31-Dec-2025	-	-	SHS_MA3	22-Apr-2024	Edit

Rows per page: 100 1-9 of 9



Participants – Recruitment Numbers

Site Level

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

- Home
- Study
- Lock
- Refresh
- Search

Save Cancel

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

Add

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	Action
1	* Mar/2024	* 1	* 1	* 0	* 0	SGH_PI	11-Mar-2024	Edit Delete
2	* Feb/2024	* 0	* 1	* 0	* 0	SGH_PI	11-Mar-2024	Edit Delete
3	* Jan/2024	* 0	* 0	* 0	* 0	SGH_SA1	26-Jan-2024	Edit Delete
4	* <input type="text" value="Select month"/>	* <input type="text"/>	* <input type="text"/>	* <input type="text"/>	* <input type="text"/>			Cancel

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

Participants – Recruitment Numbers

Site Level

Study Details

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

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.	Enrolled	Total No. of Participants Who Have Completed Study	Total No. of Participants Withdrawn from Study	Last Edited By	Last Edited Date	Action
1	* Mar/2024	* 1		* 0	* 0	SGH_PI	11-Mar-2024	Edit Delete
2	* Feb/2024	* 0		* 0	* 0	SGH_PI	11-Mar-2024	Edit Delete
3	* Jan/2024	* 0		* 0	* 0	SGH_SA1	26-Jan-2024	Edit Delete
4	* Select month	*		*	*			Cancel

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

2024

Jan Feb Mar

Apr May Jun

Jul Aug Sep

Oct Nov Dec

Participants – Recruitment Numbers

Site Level

Study Details

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

Recruitment Target Approved in IRB Study: 2-2

Current Recruitment Summary

Total No. of Screen Failures: 1

Total No. of Participants Who Have Completed Study: 0

No.	Month and Year
1	* Mar/2024
2	* Feb/2024
3	* Jan/2024
4	* <input type="text" value="Select month"/>

For completed, terminated and withdrawn study

Note

Total No. of Screen Failure: Total number of participants who have signed an informed consent form; or who gave verbal consent on a study conducted under a waiver of documentation of consent but do not qualify for research participation after screening.

Total No. of Participants Enrolled: Total number of participants who have signed an informed consent form; or who gave verbal consent on a study conducted under a waiver of documentation of consent, minus total number of screen failures.

Total No. of Participants Who Have Completed Study: Total number of participants who have completed all interventions and follow-up.

Total No. of Participants Withdrawn from Study: Total number of participants who consented to participate in research, but later discontinued their participation in research at any point for various reasons (e.g. serious adverse events). This does not include screen failures.

Participants from Study	Last Edited By	Last Edited Date	Action
	SGH_PI	11-Mar-2024	Edit Delete
	SGH_PI	11-Mar-2024	Edit Delete
	SGH_SA1	26-Jan-2024	Edit Delete
			Cancel

Participants – Recruitment Numbers

Site Level

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

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

Numbers will be auto-populated by system.

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	Action
1	* Mar/2024	* 1	* 1	* 0	* 0	SGH_PI	11-Mar-2024	Edit Delete
2	* Feb/2024	* 0	* 1	* 0	* 0	SGH_PI	11-Mar-2024	Edit Delete
3	* Jan/2024	* 0	* 0	* 0	* 0	SGH_SA1	26-Jan-2024	Edit Delete
4	* <input type="text" value="Select month"/>	* <input type="text"/>	* <input type="text"/>	* <input type="text"/>	* <input type="text"/>			Cancel

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

Participants – Recruitment Numbers

Site Level

Study Details

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

Numbers imported from IRB module.

Recruitment Target Approved in IRB Study: 2-2

Current Recruitment Summary

Total No. of Screen Failures	1	Total No. of Participants Enrolled	3
Total No. of Participants Who Have Completed Study	0	Total No. of Participants Withdrawn from Study	0

Total No. of Participants Enrolled Exceeded approved recruitment number

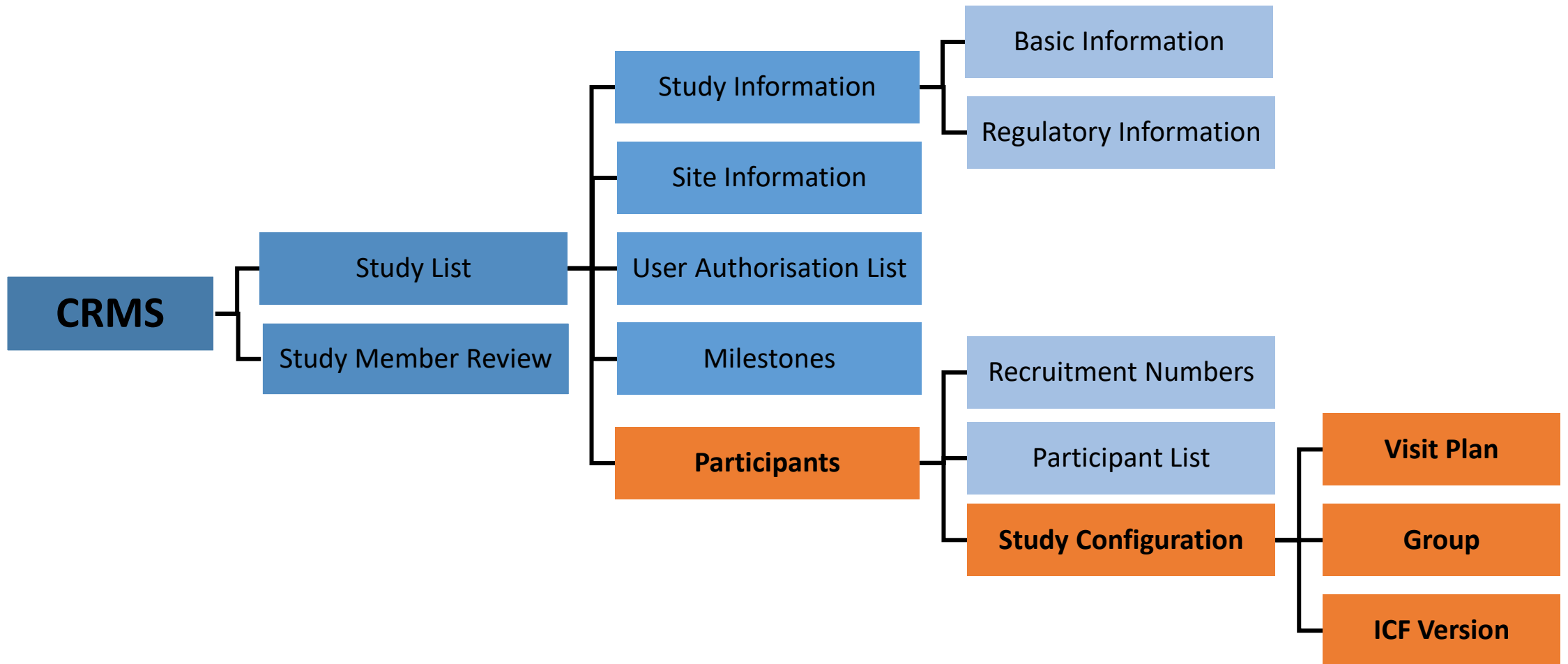
3

Words in red will appear if the actual recruitment number exceeds the approved target number.

- Study team should submit a DNC report to IRB should this happen.
- Study team should also submit an IRB Amendment form to raise the target number.

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	Actions
1	* Mar/2024	* 1	* 1	* 0	* 0	SGH_PI	11-Mar-2024	Edit Delete
2	* Feb/2024	* 0	* 1	* 0	* 0	SGH_PI	11-Mar-2024	Edit Delete
3	* Jan/2024	* 0	* 0	* 0	* 0	SGH_SA1	26-Jan-2024	Edit Delete
4	* Select month	*	*	*	*			Cancel

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



Participants – Study Configuration

Site Level

- Configured details will appear as options to be selected in the Participants – Participants List page.

2024-0205, Efficacy and Safety of DRUG-X in the Treatment of ... General Hospital (SGH)

Study Details

Back to Study List

Study Information

Basic Information

Regulatory Information

Site Information

User Authorisation List

Milestones

Participants

Recruitment Numbers

Participant List

Study Configuration

Visit Plan

Group

ICF Version

+ Add

Drug-X (Single Arm)

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

Edit

Visit Name	Visit Status	Remarks
Screening	<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"/>	-

Name of Visit Plan corresponds to the study arm/group(s) planned in a research protocol, e.g. active arm vs control arm.

Participants – Study Configuration

Site Level

- Configured details will appear as options to be selected in the Participants – Participants List page.

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

Study Information ▲
Basic Information
Regulatory Information

Site Information
User Authorisation List
Milestones

Participants ▲
Recruitment Numbers
Participant List
Study Configuration

Visit Plan
Group
ICF Version

Drug-X (Single Arm)
Last Edited By: SGH_SA1 | Last Edited Date: 26-Jan-2024 10:03:05

Visit Name	Visit Status	Remarks
A Visit Plan cannot be selected on the Participant List page if there are no visits (<i>under Visit Name column</i>) added to the Visit Plan, or if the visits are all inactivated.		

Participants – Study Configuration

[Visit Plan](#)
[Group](#)
[ICF Version](#)

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

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

[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

Participants – Study Configuration

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

Status must be “Active” for the entered Group or ICF to appear in the dropdown list on the Participant List page.

Visit Plan

Group

ICF Version

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

Participants – Study Configuration

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

Rows per page: 100 1-1 of 1

Study team can take this as a checkpoint to see if all necessary approvals have been secured before using the ICFs.

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

Study team can take this as a checkpoint to see if all necessary approvals have been secured before using the ICFs.

Participants – Study Configuration

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

Data should be manually entered.
There is no flow of information from the IRB module to any of the study configuration pages in CRMS.

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

Participants – Study Configuration

NOTE:

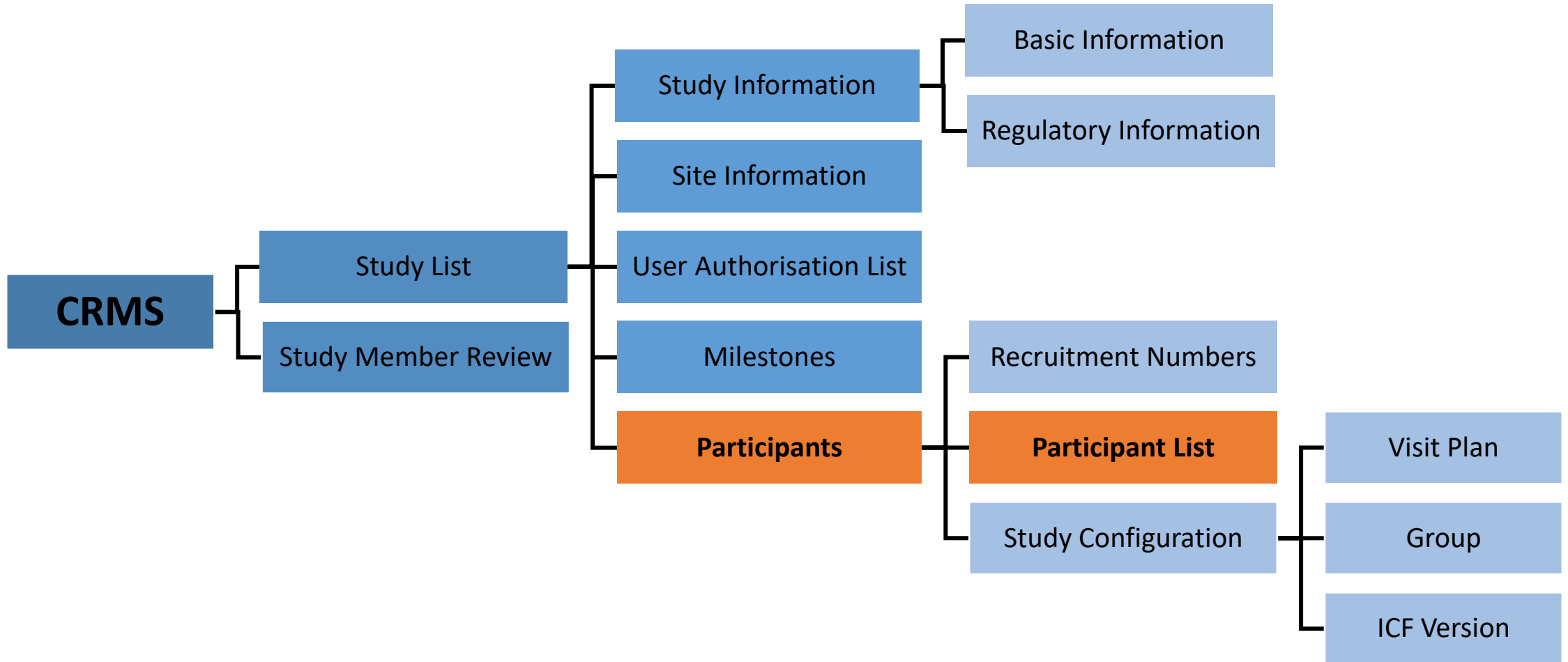
- Entries in the Study Configuration (Visit Plan, Group, ICF Version) cannot be deleted once saved.
- Users will need to use the switch toggle or drop-down list to inactivate the entry.

The image displays three screenshots from a study configuration interface, illustrating how to inactivate entries:

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

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

A screenshot of a search dropdown menu titled 'Group'. The search input field is empty, and the dropdown list below it displays 'No item' in orange text, indicating that no results were found.






Participants – Participant List

Site Level

Study Details

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

+ Add Columns Export Filter

Screening Number	Enrolment Number	Enrolment Status	Group	Screening Date	Randomisation Date	Remarks	Last Edited Date	Last Edited By	Action
SGH_SCR03	-	-	-	28-Feb-2024	-	In screening.	11-Mar-2024	SGH_PI	
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	
SGH_SCR01	SGH_X01	● Enroled	Drug-X Group	26-Jan-2024	-		26-Jan-2024	SGH_PI	

Rows per page: 100 1-3 of 3

- Consists of 3 sub-pages to allow the recording of:
 1. Basic Information
 2. ICF Details
 3. Visit Plan

Participants – Participant List

Configurable

- Group



[← 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 Information ICF Visit Plan

*Screening Number	*Screening Date
<input type="text" value="SGH_SCR01"/>	<input type="text" value="26-Jan-2024"/>
Enrolment Number	Enrolment Date
<input type="text" value="SGH_X01"/>	<input type="text" value="13-Feb-2024"/>
Enrolment Status	Randomisation Date
<input type="text" value="Enroled"/>	<input type="text" value="Select date"/>
Group	
<input type="text" value="Drug-X Group"/>	
Remarks	
<input type="text"/>	

Participants – Participant List

Configurable

- Group

CRMS / Study List / Study Details / Participant Details

Participant Details

Help

1

99+

Please do not enter participant identifiers in CRMS.

Edit

Screening Number: SGH_SCR01

Enrolment Number: SGH_X01

Basic Information

ICF

Visit Plan

*Screening Number

*Screening Date

SGH_SCR01

26-Jan-2024

Group

ICF Version

Group

Group Status

Remarks

Last Edited By

Last Edited Date

Drug-X Group

active

Single arm study.

SGH_SA1

26-Jan-2024

Group

Drug-X Group

Enrolled

Select date

Group





Drug-X Group

Remarks

Participants – Participant List

Configurable

- ICF

[← 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 Information **ICF** Visit Plan

No.	Signed ICF Name	Date of Consent	Type of Consent	Translator Present
1	* Drug-X ICF <input type="text"/>	* 26-Jan-2024 <input type="text"/>	* Initial <input type="text"/>	* No <input type="text"/>

Participants – Participant List

Configurable: ICF

[← Back to Study Details](#)

Participant Details

Help



Group	ICF Name, Version, Date and Language	IRB Approval Date	Regulatory Approval Date	Status	Last Edited by	Last Edited Date	
ICF Version	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	
	Drug-X ICF (SGH)_Version 1.1 dated 25 Dec 2023_Malay	24-Jan-2024	22-Jan-2024	Active	SGH_SA1	26-Jan-2024	
	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	

Signed ICF Name

Signed ICF Name

Date of Consent

Type of Consent

Translator Present

* Drug-X ICF (SGH)_Version 1.1 dated 25 Dec 2023_English

* Drug-X ICF (SGH)_Version 1.1 dated 25 Dec 2023_Malay

* Drug-X ICF (SGH)_Version 1.1 dated 25 Dec 2023_Simplified Chinese





* Drug-X ICF

* 26-Jan-2024

* Initial

* No

Participants – Participant List




[← Back to Study Details](#) **Participant Details** [Help](#)    

CRMS / Study List / Study Details / Participant Details

Please do not enter participant identifiers in CRMS.

Screening Number: SGH_SCR01
Enrolment Number: SGH_X01

Basic Information | **ICF** | Visit Plan

Date of Consent	Type of Consent	Translator Present
<input type="text" value="26-Jan-2024"/> 	<input type="text" value="Initial"/> 	<input type="text" value="No"/> 

Type of Consent dropdown options: Initial, Reconsent

Translator Present dropdown options: Yes, No, NA

Participants – Participant List

Configurable

- Visit Plan
- Visit Name

CRMS / Study List / Study Details / Participant Details

Please do not enter participant identifiers in CRMS.

Screening Number: SGH_SCR01
Enrolment Number: SGH_X01

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

Participant Details [Edit]

Basic Information ICF **Visit Plan**

Study team can use this to plan for the participant's next visit.

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

Participants – Participant List

Configurable

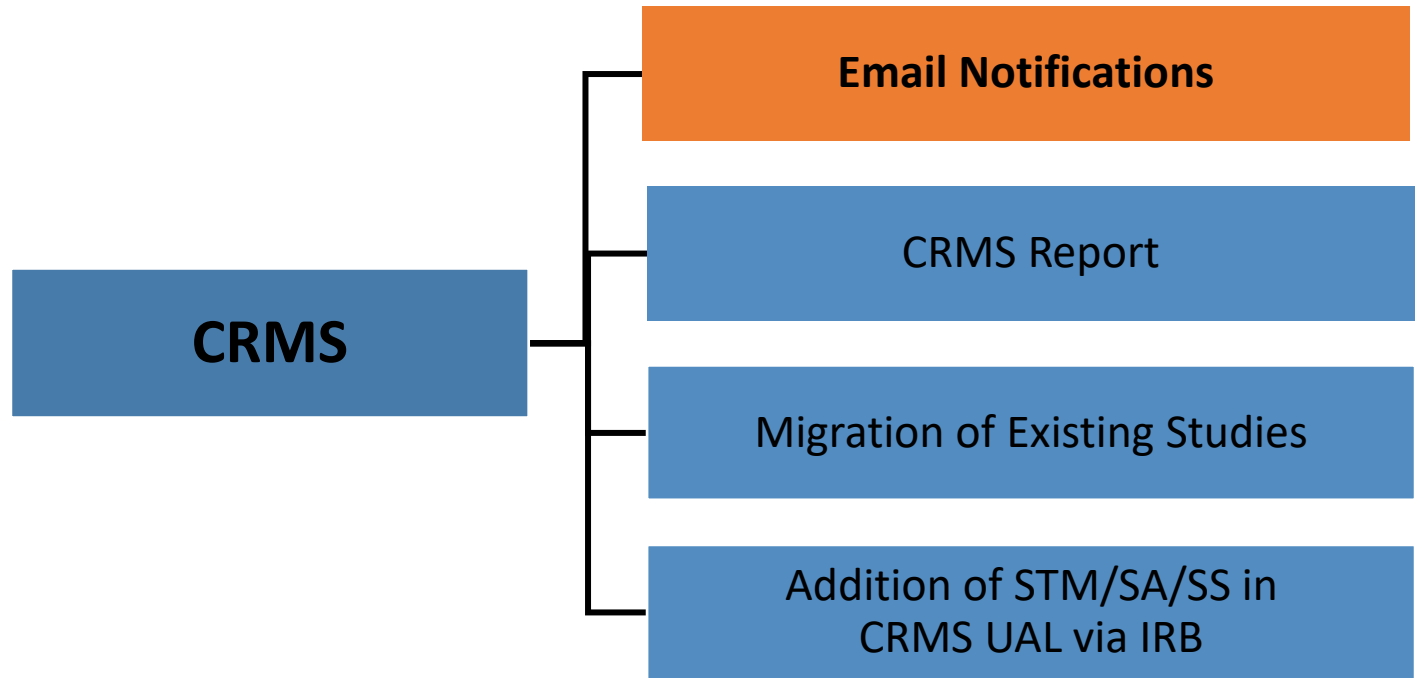
- Visit Plan
- Visit Name

The screenshot displays a software interface for managing clinical trial visits. It is divided into several sections:

- Configuration Panel (Top):**
 - Visit Plan:** A dropdown menu currently set to "Drug-X (Single Arm)".
 - Visit Name:** A search box with a dropdown menu open, listing options: Screening, Day 1, Week 1, Week 2, Month 1, and Month 3.
- Summary Panel (Right):**
 - Drug-X (Single Arm):** Last Edited By: SGH_SA1 | Last Edited Date: 26-Jan-2024 10:03:05
 - Table:** A table with columns for Visit Name, Visit Status (toggle), and Remarks.

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"/>	-
- Participant List Table (Bottom):**

No.	Visit Plan	Visit Name				
1	* Drug-X (Single Arm)	* Month 3				
2	* Drug-X (Single Arm)	* Month 1				
3	* Drug-X (Single Arm)	* Week 2	27-Feb-2024		28-Feb-2024	
4	* Drug-X (Single Arm)	* Week 1	20-Feb-2024		20-Feb-2024	
5	* Drug-X (Single Arm)	* Day 1	23-Feb-2024		13-Feb-2024	
6	* Drug-X (Single Arm)	* Screening	26-Jan-2024		26-Jan-2024	



Email Notifications



Email notifications will be soft-launched in May.

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

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

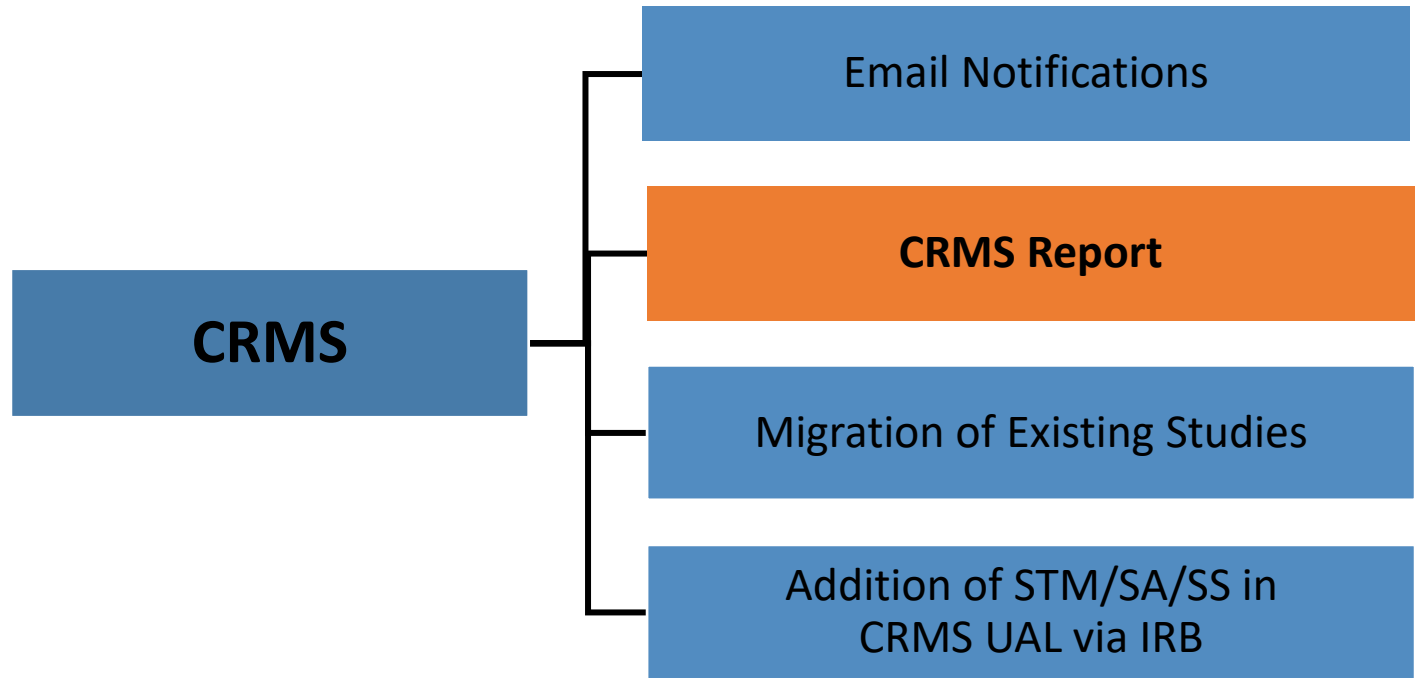
Email Notifications



Email notifications will be soft-launched in May.

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)

- Referring to the trigger point, if you have a multi-site study with 3 sites to be added to the IRB form, however you have only selected 1 site and 1 overall PI in Section B2 when you first hit the “Save” button, the overall PI will be the only person to receive this email notification.
- Investigators added later from the same site or new sites will not receive this email notification after the trigger point has passed.
- Nonetheless, all investigators will receive an email notification from the IRB module notifying that they have been added as an investigator in the study.



CRMS Reports



This function may be available in Q3 2024.

- Reports can be generated from CRMS to fulfil any periodic or KPI reporting at the institution level.
- CRMS Report section can only be accessed by selected roles.

ECOS CRMS Institution Report Help Download Notifications Columns Export Filter(1)

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
Study Agreement

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 very simplified version of the report generated from a single study.

Rows per page: 100 1-5 of 5

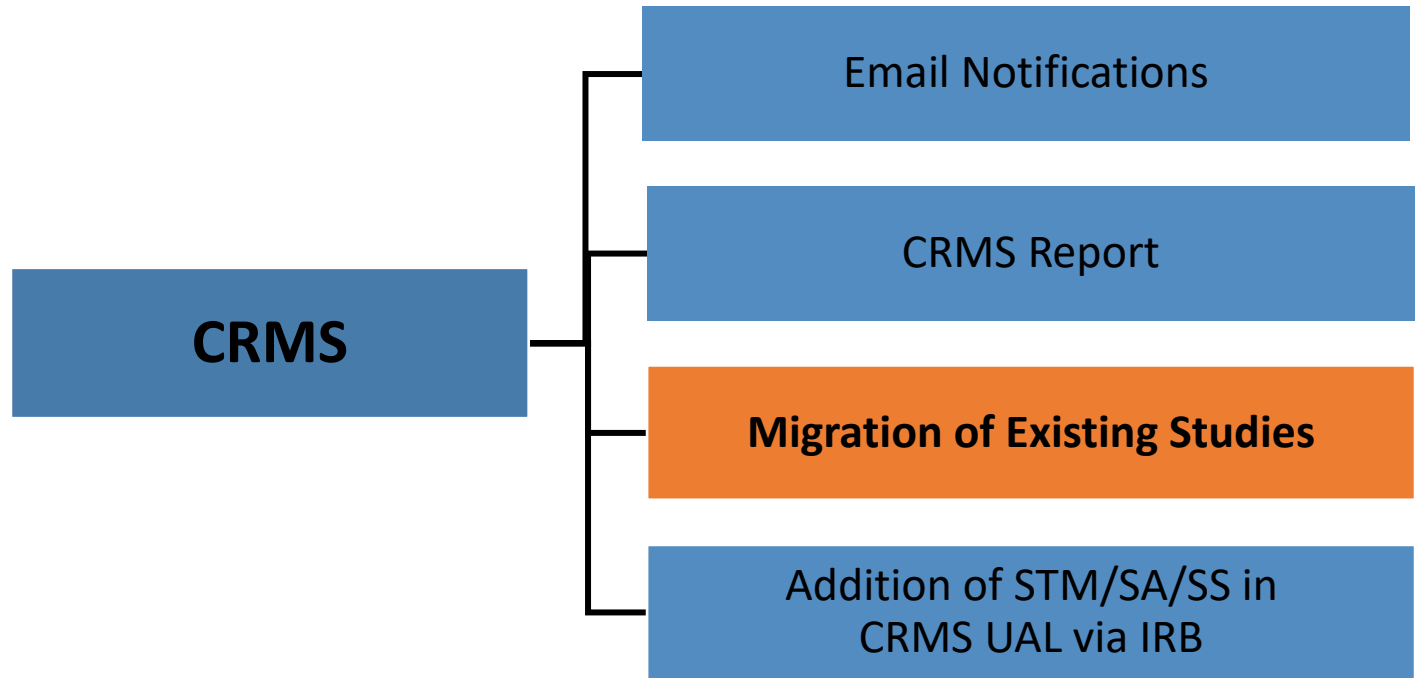
CRMS Reports



This function may be available in Q3 2024.

- 12 types of reports:
 - Recruitment Number
 - Enrolment and Reporting Status
 - Study Milestones
 - Regulatory Information (Clinical Trials Regulated by HSA)
 - Regulatory Information (CRM)
 - Regulatory Information (rHBR)
 - Publication Listing
 - SAE Reports for CT Insurance
 - Studies Listing
 - Grant Listing
 - Contracts Tracking Listing
 - Study Agreement Listing
- CRMS Reports can be exported.

TIP: Use the Column function to narrow data selection.



Migration of Existing Studies

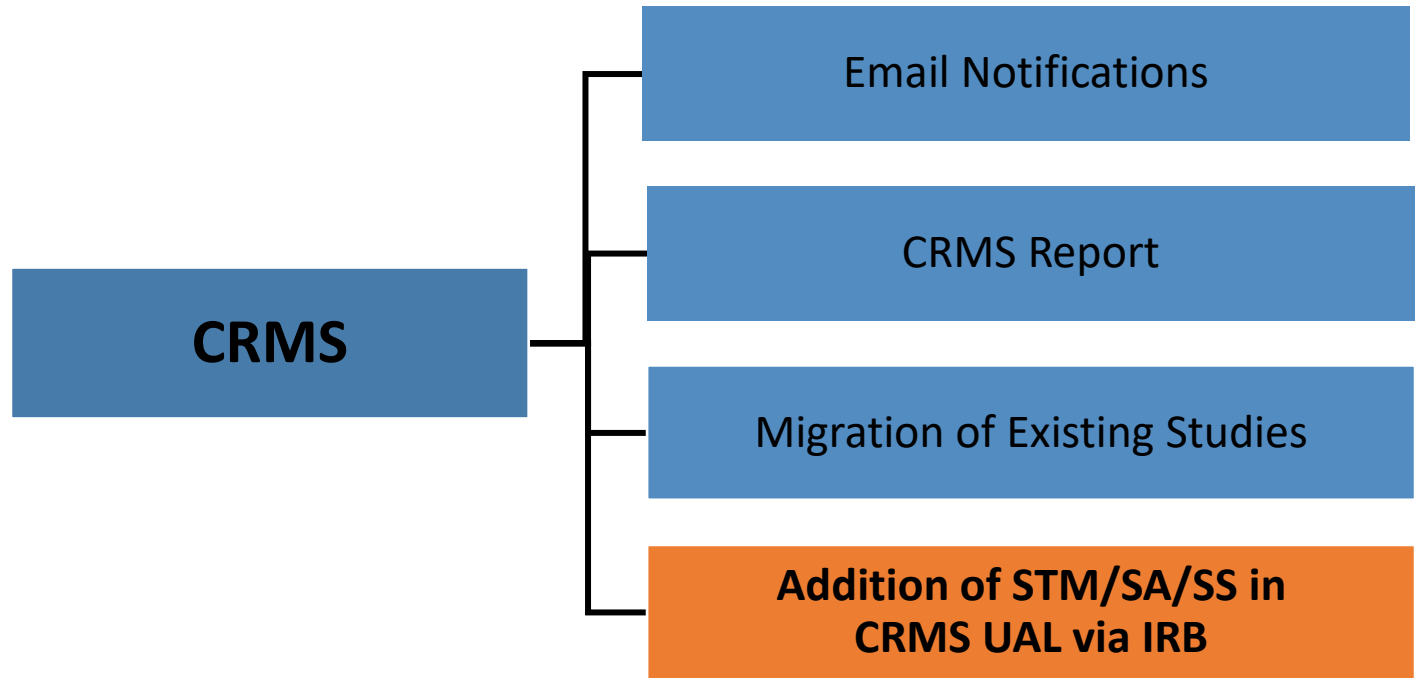
- **Study Information – Basic Information**

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

- **User Authorisation List**

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

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



Important Note – IRB APP Form

Role used: Study Sponsor (SS_20)

The screenshot shows the ECOS Submission List interface. A modal window titled "IMPORTANT NOTE!" is centered on the screen. The modal contains four numbered instructions. The second instruction is highlighted with an orange border. The background interface shows a sidebar with navigation options: Homepage, IRB, Submission List (selected), My Study List, CRMS, FCOI, and Report. The main content area displays a table with columns for "Study Title" and "Action", listing "Study 1", "Study 2", and "Study 3". At the bottom of the interface, there are controls for "Rows per page" (set to 100) and "1-3 of 3" items.

ECOS Submission List

Export Filter(1)

Study Title Action

Study 1

Study 2

Study 3

Rows per page: 100 1-3 of 3




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

System Recognition Function

Role used: Study Sponsor

[← Back to Submission List](#) **Submission Detail**   

ECOS Ref: - 

[Form Detail](#)

Application Form Cancel Save

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...

CRMS Prompt in IRB Module

Role used: Study Sponsor

The screenshot shows the 'Submission Detail' page in the IRB Module. The page has a dark blue header with a back arrow and the text '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 icon. Below the header, there is a section for 'ECOS Ref: -' with a document icon. A 'Form Detail' section is highlighted with a blue underline. The main content area is titled 'Application Form' and contains several sections: 'Section B: Submission Board', 'B1. Submission IRB and Board', '*B1. (a) The reviewing IRB will be the IRB that is reviewing the application.' with a dropdown menu showing 'SingHealth CIRB', and '*B1. (b) Please select the board.' with a dropdown menu showing 'Board F'. A modal dialog box is overlaid on the page, titled 'Please select your site and role in CRMS'. It contains two required fields: '* Site:' and '* Role:'. The 'Role:' dropdown is open, showing three options: 'Study Administrator', 'Study Sponsor', and 'Study Team Member'. A blue 'Save' button is located at the bottom right of the modal. In the background, there are buttons for 'Cancel' and 'Save' on the right side of the page.

CRMS Prompt in IRB Module

Role used: Study Sponsor

The screenshot shows the 'Submission Detail' page in the IRB Module. A modal dialog box is open, prompting the user to select their site and role in CRMS. The dialog contains two dropdown menus: 'Site' (selected as 'Singapore General Hospital') and 'Role' (selected as 'Study Sponsor'). A blue 'Save' button is highlighted with an orange arrow. The background page shows the 'Form Detail' section with various fields and a 'Save' button.

Back to Submission List Submission Detail

ECOS Ref: -

Form Detail

Application Form

Section B: Submission Board,

B1. Submission IRB and Bo

*B1. (a) The reviewing IRB w

SingHealth CIRB

*B1. (b) Please select the board.

Board F

Please select your site and role in CRMS

* Site: Singapore General Hospital

* Role: Study Sponsor

Save

Cancel Save

Section A: Study Title

Section B: Submission B...

Section C: Study Fundin...

Section D: Study Type an...

Other Attachments

Addition of STM/SA/SS by System

Role used: Study Sponsor

Study Details

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)

User Authorisation List

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

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

Rows per page: 100 1-2 of 2

CRMS Accessibility

Role used: Study Sponsor

The screenshot displays the ECOS Study List interface. On the left, a navigation menu includes 'Homepage', 'IRB', 'CRMS', 'FCOI', and 'Report'. The 'CRMS' menu item is highlighted with an orange box, and its sub-item 'Study List' is selected. The main content area shows a table of studies with columns for ECOS Ref, IRB, PI/Site-PI, Number of Sites, Study Title, and Action. The row for ECOS Ref 2024-3245 is highlighted with an orange box. At the bottom right, there are controls for 'Rows per page' (set to 100) and pagination (1-6 of 6).

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

IRB Accessibility

Role used: Study Sponsor

ECOS Submission List

Home + 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					

IRB Submission List

CRMS FCOI Report

ECOS My Study List

Home 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	-	

IRB My Study List

CRMS FCOI Report

Rows per page: 100 1-6 of 6

One Chance

Submission Detail

ECOS Ref: -

Form Detail

Application Form

Section B: Submission Board,

B1. Submission IRB and Bo

*B1. (a) The reviewing IRB w

SingHealth CIRB

*B1. (b) Please select the board.

Board F

Other Attachments

Please select your site and role in CRMS

* Site: Singapore General Hospital

* Role: Study Sponsor

Save

Cancel Save

Section A: Study Title

Section B: Submission B...

Section C: Study Fundin...

Section D: Study Type an...

If the user clicks the "X" button instead of "Save"..

Missed Opportunity

Solution:

Enlist help from

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

to manually add the user to the CRMS UAL.

2024-3245, Study 4 / Singapore General Hospital

ECOS Reference: 2024-3245 IRB: SingHealth CIRB Board F Study Status: • Draft

Number of Sites: 1 Initial Outcome Date: - Valid Till Date: -

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

Department: Department of Renal Medicine (Singapore General Hospital)

User Authorisation List

+ Add Columns Export Filter(1)

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

.. the system will not register this user to the UAL.
This user will lose access to the IRB Application Form the moment the “Save and Exit” button is clicked.

Is CRMS mandatory?

- **Mandatory:**

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

- **Conditional**:**

1. User Authorisation List (Access requirement by STM/SA/SS)
2. Study Member Review (If STM/SA/SS added)
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, Study Configuration

NOTE:

* SingHealth CTCC will release more information.

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



Summary

- Study Information page must be completed for Pharmaceutical/ Industry Sponsored studies to facilitate submission of IRB Application Form.
- User Authorisation List (UAL) controls user access to CRMS and/or IRB modules for STM, SA and SS roles.
- **For migrated studies, the addition of STM/SA/SS users to CRMS UAL will need to be manually done by PI/Site-PI, Co-I or CRMS RO administrators.**
- PI/Site-PI should perform the endorsement via the CRMS Study Member Review page (as needed).
- **! The User Authorisation List does not replace a site delegation log.**
- Site Information, Milestones and Participants Recruitment Numbers pages contain important data fields that can be extracted for institutions' trending and reporting purposes.
- In conclusion, the CRMS module has great potential to be a useful clinical research management tool from the site to cluster level when fully maximised. We strongly encourage researchers/clinicians to take full advantage of this module and update the pages frequently.

Find out more information about ECOS...



The screenshot shows the SingHealth DukeNUS Academic Medical Centre website. The header includes the logo and navigation links for 'Find a Doctor or Researcher' and 'SingHealth Appointments'. A secondary navigation bar contains 'MAIN', 'For Researchers', 'Research Compliance', 'CIRB', and 'About RICE'. The main content area features a breadcrumb trail: 'Home > Research > Research Integrity, Compliance & Ethics (RICE) Homepage > Ethics and Compliance Online System (ECOS)'. The title 'Ethics and Compliance Online System (ECOS)' is prominently displayed with icons for email, accessibility, and print. Below the title is the ECOS logo, a stylized 'E' in a square. The text describes ECOS as a one-stop solution for the research lifecycle, replacing the iSHaRe IRB system. A bulleted list of modules includes IRB, Minimum Training, Clinical Research Management System (CRMS), Compliance - DNC/SAE/PISAF*, and Quality - Monitoring and Audit*. A note states that IRB applications will be managed via ECOS starting in May 2024. A section titled 'Minimum Training' explains that researchers must meet minimum requirements and submit certifications under the User Profile page.




SingHealth DukeNUS
ACADEMIC MEDICAL CENTRE

Find a Doctor or Researcher SingHealth Appointments

MAIN For Researchers Research Compliance CIRB About RICE

Home > Research > Research Integrity, Compliance & Ethics (RICE) Homepage > Ethics and Compliance Online System (ECOS)

Ethics and Compliance Online System (ECOS)



ECOS

Jointly developed by SingHealth and NHG, the Ethics and Compliance Online System (ECOS) is a one-stop solution to support the research lifecycle from Study Initiation to Completion, enabling a more efficient management of research portfolios and ethics applications. This internet-based platform replaces the iSHaRe Institutional Review Board (IRB) system and is accessible to both internal and external users. The ECOS includes the following modules:

- IRB
- Minimum Training
- Clinical Research Management System (CRMS)
- Compliance - DNC/SAE/PISAF*
- Quality - Monitoring and Audit*

*To be rolled out later.

All new IRB applications will be managed via ECOS following its official launch, tentatively set in May 2024. Existing on-going studies will also be migrated from iSHaRe to ECOS. The completion date is to be confirmed.

Minimum Training

Researchers who conduct Human Subject Research must meet the [minimum requirements stipulated](#).

Researchers would be required to submit their minimum training certifications under the User Profile page. After submission, the institution's Minimum Training Secretariat would complete the check and issue the researchers with the label of the type of studies that the researchers can conduct. The table below shows the training certifications required for the different type of studies.