



SPIRAL DATABASE USER GUIDE

REMAP-CAP Spiral Database User Guide Version 5.0 dated 24 November 2025

<https://remapcap.spinnakersoftware.com>

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1. CONTACT DETAILS

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2. INTRODUCTION

2.1. Purpose of this document

The REMAP-CAP trial database is redesigned, rebuilt, tested and deployed to provide updated features and functionality to accommodate the changes required for Core Protocol Version 4.0 and beyond. The redesigned electronic data capture (EDC) software is linked to the original trial database. For more information about accessing the original database refer to [section 4.1](#).

The purpose of this document is to provide instructions on the functionalities of the updated REMAP-CAP Spiral database for site staff. This user guide provides information on the following:

- Accessing the database
- Randomising patients
- Entering data into the online eCRF
- Completing the screening log
- SAE reporting
- Resolving data queries

This document is to be used in conjunctions with the following REMAP-CAP documents:

- Case Report Form (CRF) Data Completion Guidelines
- Safety Reporting Guidelines

The current version of these documents will be available on the study database in the [Resources section](#).

The database help text is linked to an online wiki version of the REMAP-CAP Data Completion Guidelines here:

<https://remap-cap.atlassian.net/wiki/x/A4AH>

For guidance on use of the original EDC system, please refer to earlier versions of this database user guide.

2.2. Global eligibility and eCRF website

The Spiral database URL is: <https://remapcap.spinnakersoftware.com>

The Spiral database is used for randomisation in all regions. It is used for further data collection by sites in:

- Australia and Kingdom of Saudi Arabia
- Canada
- New Zealand
- Europe/United Kingdom
- Colombia
- Japan
- Singapore
- CCAA regions – India, Malaysia, Nepal, and Pakistan

3. GENERAL

3.1. *Browsers*

Although the REMAP-CAP database has been developed to work efficiently on many different internet browsers (e.g. Internet Explorer, Mozilla Firefox, Google Chrome), there are some browsers that may lead the website to run in a suboptimal way.

We recommend using the following browsers:

- Mozilla Firefox
- Google Chrome
- Safari

3.2. *Spiral accounts*

3.2.1. Account types

Prior to a site starting REMAP-CAP, site users will require access to the study database to allow randomisation and data entry. Sites will be contacted by a Project Manager in order to set up access and will be asked to complete a Database Form. Accounts will be setup in accordance with this form prior to your site commencing recruitment.

All site access accounts are individual accounts. There are five different types of site access accounts for the website: Randomisation User account (replaces the Generic site account), Research Coordinator account, Investigator account, Outcome Assessor account, and eCRF Data Collector account.

1. *Randomisation User account*

- Able to access the randomisation function only
- Account is set up and managed by the Regional Project Manager
- Ideal for site staff who are not part of the core research team, for example clinicians who want to screen and randomise a patient out-of-hours
- Each Randomisation User has their own individual account.

2. *Research Coordinator account*

- Able to access all functions on the database (e.g. randomisation, data entry, data queries, SAE reporting and patient transfers)
- Each Research Coordinator will have their own individual account (username and login).

3. *Investigator account*

- Able to access some functions on the database (e.g. randomisation, data entry, data queries, SAE reporting and sign-off)
- Able to sign off Serious Adverse Event reports and eCRFs
- Intended for use by Site Principal Investigators
- Each investigator has their own individual account.

4. *Outcome Assessor*

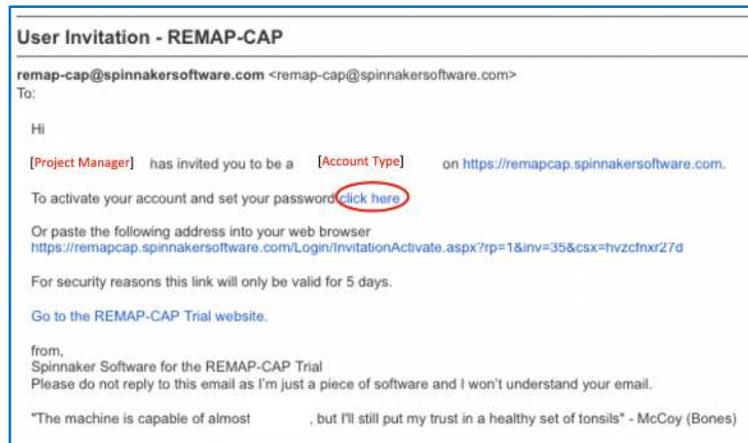
- Able to complete Day-180 follow-up for participants at sites that their account is linked to
- Used in regions or countries that have a centralised team to conduct follow-up interviews
- Not able to randomise patients or edit/modify data entered into the eCRF other than D180 form
- Each outcome assessor has their own individual account.

5. *eCRF Data Collector account*

- Able to perform all of the same functions as a Research Coordinator account, except for the ability to screen and randomise patients
- Each eCRF Data Collector has their own individual account.

3.2.2. Requesting an account

- Prior to starting REMAP-CAP, you will be asked to complete a Database Form. Accounts will be set up by your Regional Project Manager in accordance with this form.
- Subsequent requests for individual logins should be made to your Project Manager (refer to [Contact Details](#)).
- Usernames must be a valid email address.
- An email will be sent to the nominated email address containing instructions on how to activate the account and set a password (see image below).
- The user invitation will expire after 5 days. If the invitation has expired, ask your Project Manager to re-send the invitation.
- Click on the link "[click here](#)" in the email invitation, which will take you to the database. Enter your chosen password as per the [password policy](#).



3.3. Password policy

Passwords guide:

- Use a combination of at least one(1) each of upper case letter, lower case letter, number, or symbol, at least 10 characters long.
- Use a phrase, sentence or acronym at least 16 characters long. For example, choose a password by combining 5 or more random common words (e.g. correct horse battery staple home, password is = *correcthorsebatterystaplehome*).
- As long as you have not been penalised for using an obvious or repetitive phrase either of the two options above will meet the requirements.
- In both cases this is the minimum requirement but the longer and more complex your password is the stronger it will be.
- Cannot be a password that is deemed to be insecure (e.g. password, PassWord, or 123456)
- Must not contain the username (e.g. username123).

Note the list of passwords that are considered to be insecure is updated regularly, and passwords that were previously allowed may be prohibited.

Please note that passwords are case-sensitive.

Recommendations:

- Use a password manager to generate and store passwords
- Change your password regularly. It is recommended to change it every 6 months, however, it is mandatory to change it every 12 months.
- You can change your password via your *My Details* tab (blue arrow in top right of the menu bar)
- Attend Cybersecurity awareness training to learn more about how to recognise and mitigate digital threats fostering enhanced security practices to protect your data.

HINT: If you are not receiving your invitation email, check your junk (or spam) folder.

You may need to configure your email settings and add the REMAP-CAP database email address to your contact list remap-cap@spinnakersoftware.com

3.4. Logging in

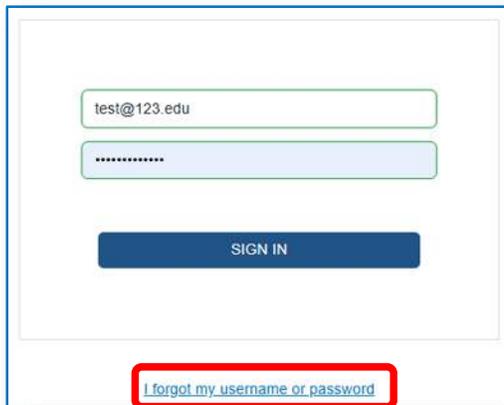
You can access the REMAP-CAP website at the following address:



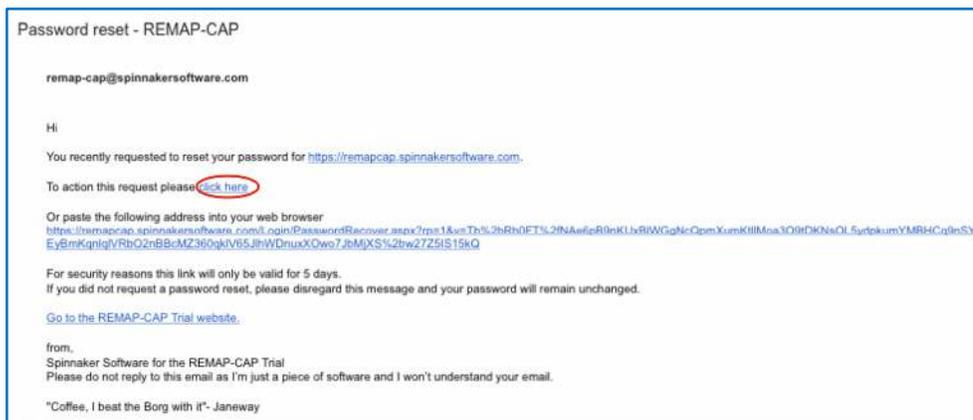
<https://remapcap.spinnakersoftware.com>

3.4.1. Forgotten username and / or password

- A user is permitted five login attempts. After five failed attempts users will be locked-out for 10 minutes.
- A user will be automatically logged out after 45 minutes of inactivity.
- Passwords are encrypted in the database and cannot be recovered.
- Individual users are responsible for their own passwords.
- If an individual user forgets their username or password (image below), click *“I forgot my username or password”* on the login page.



- By clicking on *“I forgot my username or password”*, another page will load asking you to enter the email address linked to the individual account.
- Enter your email address linked to your account and click on *“send me reset instructions”*.
- Reset instructions will be sent to your nominated email address.
- Click on the link *“click here”* in the password reset instructions which will take you to the database (image below).



- You will be directed to a new webpage, enter a new password as per the password policy (refer to [Password Policy](#)).
- The website should automatically log you in. If this does not happen automatically, re-open the REMAP-CAP database home page (<https://remapcap.spinnakersoftware.com>) and log-in using the new password you have just chosen.

3.4.2. Two-factor authentication

- Two-Factor Authentication (2FA) is an additional layer of security that helps safeguard your online accounts by requiring two forms of identification before granting access. In addition to your username and password a second form of identification, usually a unique code, is needed to verify your identity. This approach significantly strengthens the security of your account by mitigating the risk of

unauthorized access, and is being increasingly adopted by organizations and similar databases. From 1st September 2023 (UTC) it will be mandatory for all users to set up 2FA.

- We have chosen to allow users the option of utilizing any of Google Authenticator, Microsoft Authenticator, or Twilio Authy as the 2FA method for our trial database due to their reliability and ease of use.
- Follow the next steps to set up 2FA for your REMAP-CAP Trial account.

Step 1: Download a Two-Factor Authenticator app

- The following apps can be used for two-factor authentication in the REMAP-CAP database:

 Google Authenticator

 Microsoft Authenticator

 Twilio Authy

- On your smartphone or tablet, search for your preferred application (e.g., "Google Authenticator") in your device's app store, and download and install the app.
- Twilio Authy can be installed on your computer, if you are unable to use a phone or tablet.
Note: Installation of the app on your work desktop may be restricted based on your organisation's policy of using third-party applications.
- Open your authenticator application on your mobile device and follow the next set of instructions to set up your account.

Step 2: Enable 2FA in your REMAP-CAP Trial Account

- Log in to your REMAP-CAP Trial account using your usual username and password.
- The 2FA set up page will display. Throughout the 2FA set up process a link to download a [2FA quick guide](#) will be available on each page. It also outlines the steps to take if your 2FA is not functioning correctly.
- To continue with setting up your 2FA click on [Generate QR Code](#).

Two factor authentication (2FA)

Thank you for your support of the REMAP-CAP trial. To protect the privacy of our participants and their data, two-factor authentication (2FA) is now required to access this database. The following guide will assist you to set up and use 2FA.

To setup 2FA please follow these steps:

1. Install Google Authenticator, Authy, or Microsoft Authenticator on your device.
2. Once you have installed the app, click the 'generate unique QR code' button below.
3. Scan the QR code using your authenticator app.
4. Enter the code displayed on your app. Choose 'remember me on this computer' if you are using your personal or work computer. If you are using a shared computer select 'do not remember me on this device'.

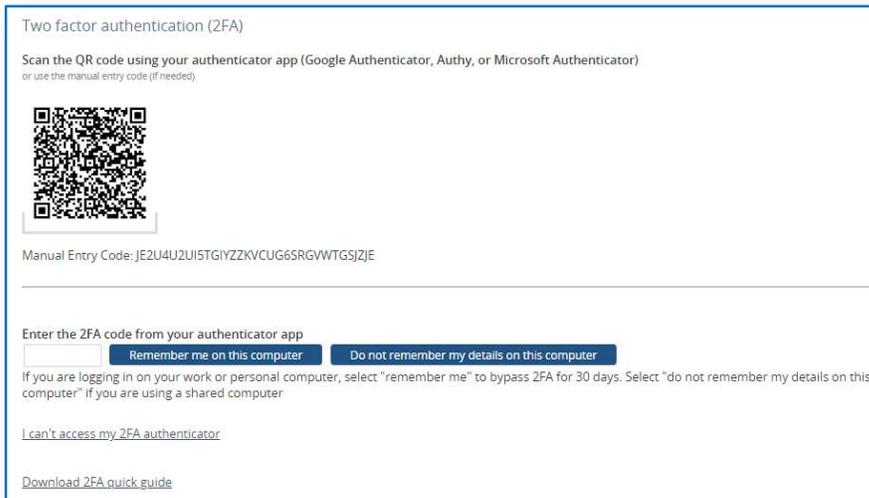
[Generate QR Code](#)

[I can't use a mobile device or authenticator app](#)

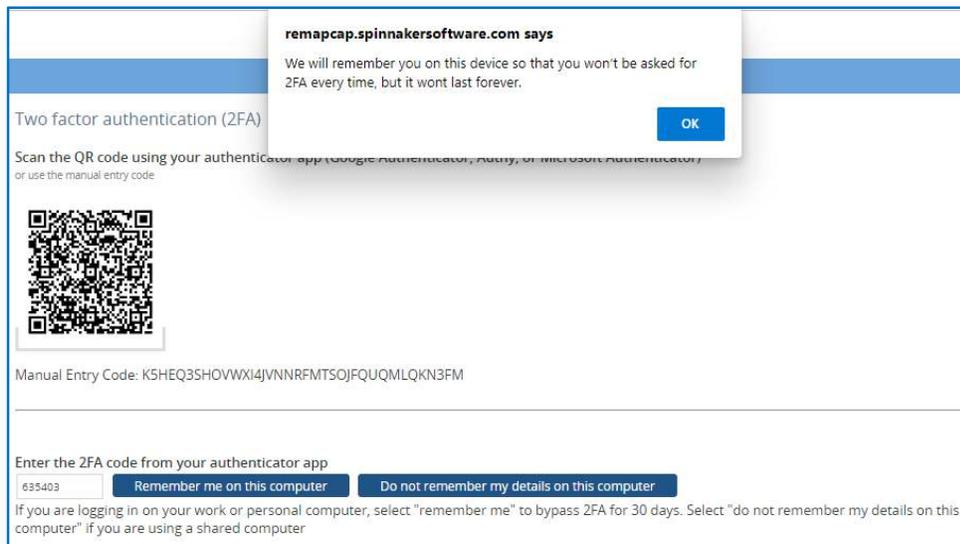
[Download 2FA quick guide](#)

- Open the Authenticator application on your mobile device.

- Follow the prompts to scan the QR code displayed on the REMAP-CAP Trial website or enter the manual entry code.



- The authenticator application will generate a unique six-digit code.
- Enter this code into the designated field on the REMAP-CAP Trial website.
- If you are logging in on a personal device, you can ask the database to remember your details and bypass 2FA for 30 days. Do not select this option when using a shared computer.

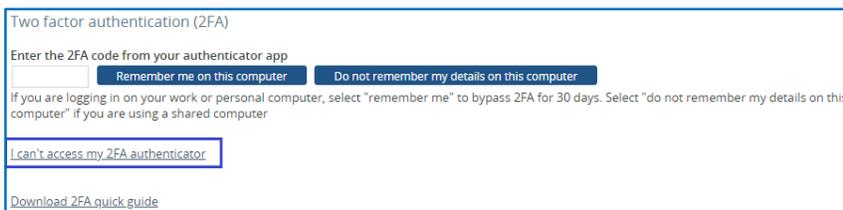


- Once you have entered the code, the REMAP-CAP Trial website will confirm successful setup.
- Your authenticator app will generate a new six-digit code every 30 seconds. When prompted for the authentication code during future login attempts, open the authenticator app and enter the most recent code displayed.

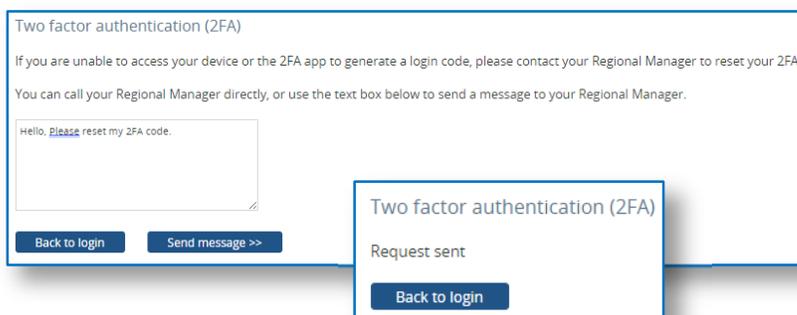
Resetting your 2FA codes

If you experience errors with your 2FA code at future login attempts you can request to clear your 2FA codes and set up your 2FA again. To do this you can call your project manager directly or send a request via the REMAP-CAP database. To send a 2FA reset request via spinnaker:

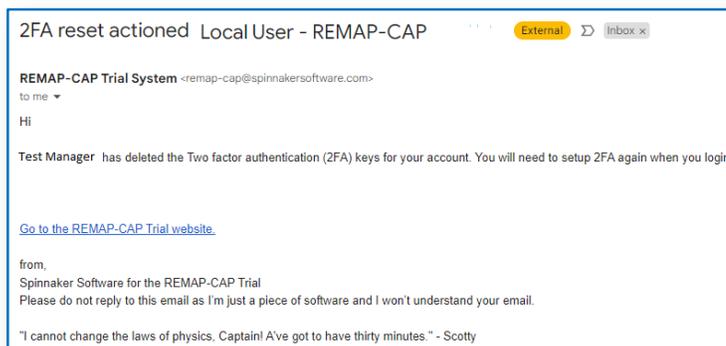
- After logging in to the REMAP-CAP Trial database, the **Two-factor authentication (2FA)** page will display. Click [I can't access my 2FA authenticator](#).



- Add an entry in the available text box and click 'Send message'. A confirmation message will display.



- You will receive a notification via email once your request is actioned by your regional manager.



2FA set up on a secondary device

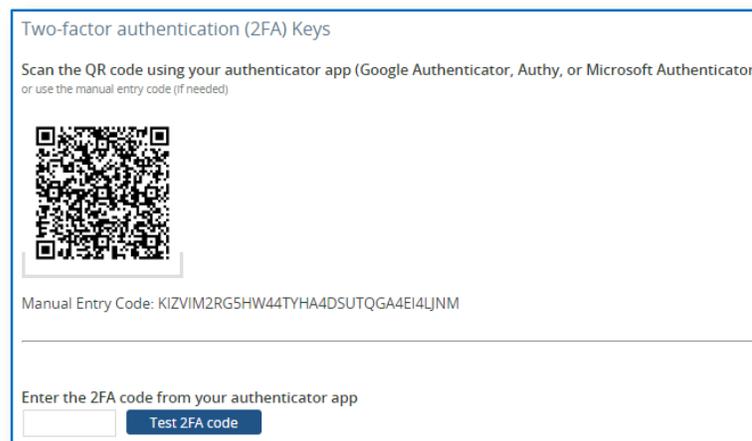
You can set up 2FA on another device. For example, on another phone or tablet.

- Go to your [My Details](#) tab (top right of the menu bar)

- Click *2FA authentication* in the left panel to display the 2FA authentication options.



- You can choose to *Show QR Codes* or *Generate new 2FA keys*.
- Select *Show QR Codes* to add existing 2FA codes to a secondary device. Users can scan and use the same QR code for each device and authenticator they have.
- Select *Generate new 2FA keys* if you would like to reset your 2FA codes. Follow the steps to scan the QR code displayed (or enter the secret key manually) and enter the new authentication code in the designated field.



- If you are unable to access your authenticator app due to a lost device, contact your regional manager. They may reset your codes and bypass 2FA for a period of time until you regain access to your device.
- If you have more than one REMAP-CAP database account, you can link your authenticator app to all relevant user accounts.
- Contact your Regional Manager if you require any assistance in managing your database accounts.

4. DASHBOARD AND NAVIGATION

Upon login, you will be presented with a *Dashboard* (also known as landing page) which provides summary information on recruitment at your site.

Different accounts will see different dashboards, depending on the website functions they have permission to access. All users can view the dashboard release notes. Pending patient transfers, reveals and eligibility display for records with a 'pending' status.

The *Research Coordinator Dashboard* can include up to **eight** distinctive sections:

1. Navigation bar
2. "New Participant" button
3. Recent screened patients
4. Domain (Reveal) pending patients
5. Pending Transfers
6. Alerts
7. List of patients recently randomised at your site
8. Graph of total enrolments at all sites

The *Investigator Dashboard* can include up to **eight** distinctive sections:

1. Navigation bar
2. "New Participant" button
3. Recent screened patients
4. Domain (Reveal) pending patients
5. Pending Transfers
6. Alerts
7. List of patients recently randomised at your site
8. Graph of total enrolments at all sites.

The *Randomisation User Site Account Dashboard* can include up to **eight** distinctive sections:

1. Navigation bar
2. "New Participant" button
3. Recent screened patients
4. Pending Transfers
5. Domain (Reveal) pending patients
6. Alerts
7. List of patients recently randomised at your site
8. Graph of total enrolments at all sites

The *Outcome Assessor Account Dashboard* includes **three** distinctive sections:

1. Navigation bar
2. Alerts
3. List of patients requiring D180 follow up at your site(s)

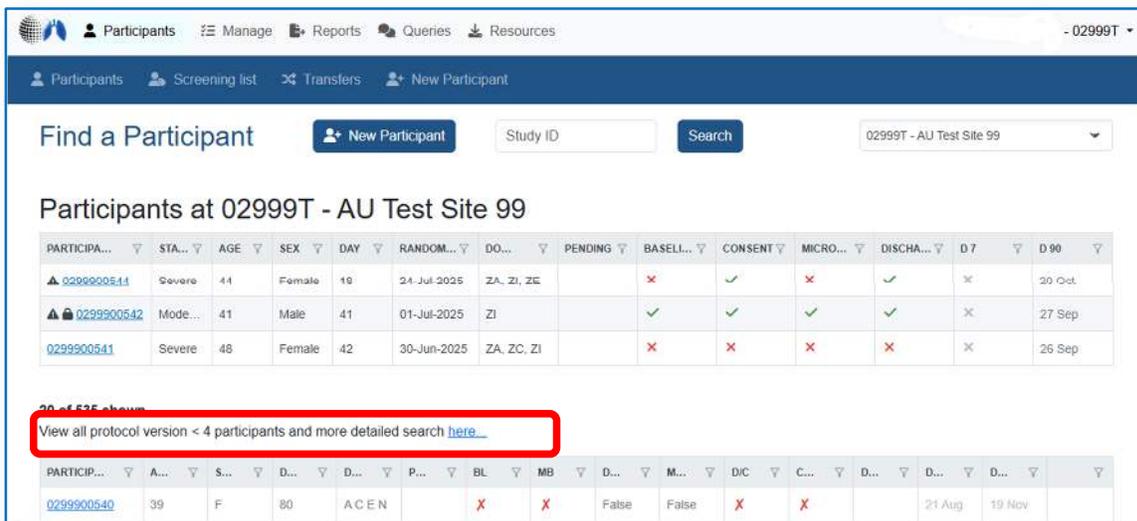
The *eCRF Data Collector Account Dashboard* can include up to **eight** distinctive sections:

1. Navigation bar
2. "Print site-specific eligibility checklist or blank CRF" function
3. Recent screened-pending patients
4. Domain (Reveal) pending patients
5. Pending Transfers
6. Alerts
7. List of patients recently randomised at your site
8. Graph of total enrolments at all sites

4.1. Navigating two database systems

You can access the original trial database via the updated database *Dashboard* (landing page) in the following ways.

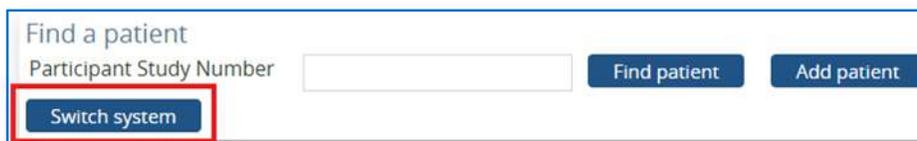
- Select **All Randomised participants** link beneath the **Recent randomisations at [Site code/name]** table.
- Select the link from **"View all protocol version < 4 participants and more detailed search [here...](#)"**



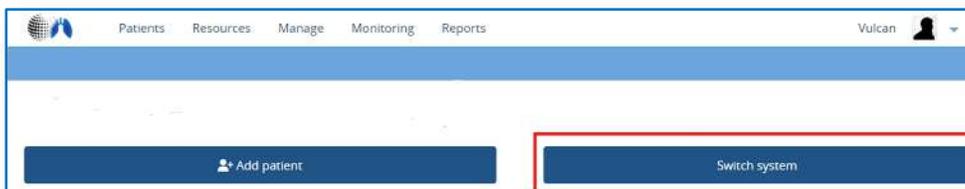
- The patient summary listing page in the original database will display.



- You can return to the updated system **Dashboard** by selecting the **‘Switch system’** button on the patient listing page.



- You can also return to the updated system **Dashboard** by selecting the **‘Switch system’** button on the patient summary page.



- If a site is still recruiting under Core Protocol Version 3 or 3.1 clicking on the **‘New Participant’** button in the new system landing page will redirect them to the original database system.

4.2. Navigation bar

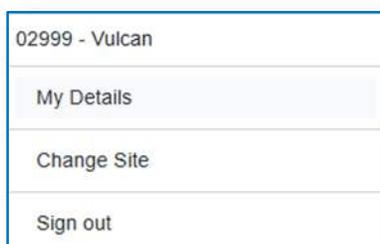


To navigate your way around the site, use the **navigation toolbar** at the top of the screen.

4.2.1. Site name

The **site name** is displayed in the top right-hand corner of the screen. Please ensure that you are logged into the correct site before assessing eligibility, entering data, or modifying site settings.

Clicking the arrow on the right of the site name will reveal a menu that will allow you to view or [edit your profile details](#), change site (if you have access to more than one site), or sign out.



4.2.2. Dashboard

The **dashboard** (or landing page) is available at any time by clicking on the REMAP-CAP logo () on the top left-hand corner of the screen.



4.2.3. Patients

Lists of patients who have been randomised at the site, who are eligibility pending, or have been transferred are available at any time by clicking on **Participants** in the navigation tab at the top of the screen (refer to [Participant List](#)).



4.2.4. Resources

All available resources are available by clicking on **Resources** in the navigation tab at the top of the screen (refer to [Resources](#)).



4.2.5. Manage

To view and manage all of the account(s) linked to your site, and the interventions that are available at your site, click on **Manage** in the navigation tab at the top of the screen (refer to [Manage](#)).



4.2.6. Monitoring

To view a list of data queries for participants at your site, click on **Queries** in the navigation tab at the top of the screen (refer to [Queries](#)).



4.2.7. Reports

To view a list of the reports and data extracts available for you to download, click on **Reports** in the navigation tab at the top of the screen (refer to [Reports](#)).

Site Name ▾

4.3. Add patient

To randomise a patient, click on the “[New Participant](#)” button on the top of the dashboard to start the eligibility process. This function is only available to Randomisation User accounts, Research Coordinators, and Investigators. It is not available to users with an Outcome Assessor or eCRF Data Collector role.



4.4. Eligibility/Screening pending

- If there are incomplete eligibility assessments for patients at your site (“[Eligibility pending](#) patients”), these will appear on the dashboard under Recent screenings

ELIGIBILITY	AGE	OUTCOME
IPCJPH	43	
OBWBVF	45	Consent pending
UPSXNK	36	Registry
ADRBKV	15	Registry

- Eligibility pending patients are patients who have had an eligibility assessment commenced but this form is not yet completed. Incomplete forms are denoted by a blank **Outcome** column. Patients requiring confirmation of consent prior to randomisation (Consent = Not yet) are also located here.
- To update eligibility on these patients, click on the *ID* and refer to Screening List pending for more information.

Screening List 02999 - Vulcan ▾

PARTICIPANT CODE	A...	OUTCOME OF ELIGIBILITY	REASON FOR OUTCOME
IPCJPH	43		
OBWBVF	45		
UPSXNK	36	Registry	No eligible domains
AWMZMV	59	Randomised	

4.5. Pending domains

- For all domains, after a participant is randomised additional information may be required before the participant’s allocation (i.e. the intervention that the participant is assigned in that domain) can be revealed.
- A list of patients who have been randomised to a given domain, but have not had their allocation status revealed, appears on the dashboard. Refer to [Reveal pending](#) for more information.

Pending domains at 02999 - Vulcan

PARTICIPANT	PENDING	RANDOMISED
0299900073	ZV_ZI	15-Jul-2025
0299900072	ZV	15-Jul-2025

4.6. Consent pending

- A list of patients with eligibility consent pending (Consent = Not yet) appears on the dashboard prior to randomisation.

Consent Pending at 02999 - Vulcan

ELIGIBILITY	AGE	ENTERED	SAVED
QBWBVF	45	17-Jul-2025 20:42	17-Jul-2025 20:44
AYVMDV	17	20-Nov-2024 22:01	20-Nov-2024 22:04

[Screening list](#)

- Click on the *Eligibility ID* or any other hyperlinked line in the record to open the relevant Eligibility form to complete the consent question.

4.7. Pending Transfers

- Participants may be transferred between participating sites.
- A list of transfers that have not yet been accepted by the receiving site is provided on the dashboard.

Pending transfers at 02999 - Vulcan

ID	PARTICIPANT	TYPE	FROM	TO
2	0299900070	Physical	02993A	02999

[Transfer List](#)

- Click on the *participant study number* to navigate to that participant’s summary page.
- Click on the “ID” to view the [Transfer request page](#) and approve the transfer.
- To approve the transfer, refer to the [Participant Transfers](#).

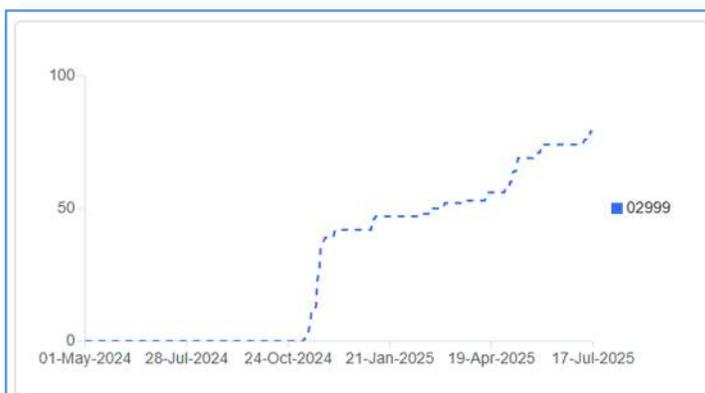
4.8. Randomised patient list

- A list of participants randomised at your site is located on the dashboard.
- Click on a *participant study number* to open that participant’s summary page.

PARTICIPANT	RANDOMISED
0299900073	15-Jul-2025
0299900072	15-Jul-2025
0299900071	15-Jul-2025

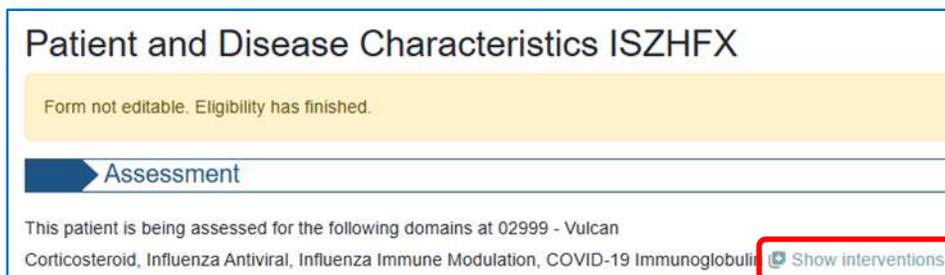
4.9. Enrolment graph

A participant recruitment graph indicates total *REMAP-CAP recruitment* at your site utilising the Spiral database.



5. RANDOMISATION

- Randomisation Users, Research Coordinators, and Investigators are able to screen and randomise patients. Outcome assessor and eCRF Data Collector accounts are not able to use the eligibility module.
- There are a number of eligibility questions to be completed. The eligibility module is dynamic, and the questions that you are asked to answer will depend on the domains and interventions that are active at your site at the time of the eligibility assessment.
- The domains listed at the top of page during the eligibility assessment indicates the domains active at your site and for which the patient is assessed.
- The eligibility form consists of the following pages: [Demographics](#), [Platform Eligibility](#), [State](#), [PANDA](#) (Pathogens and patient disease & characteristics), [Domain Eligibility](#), [Intervention Eligibility](#), [Consent](#) and [Best Interests](#).
- All of the questions on each page must be answered before clicking on “[Save](#)” to load the next page.
- The database reviews eligibility after every page (when you click “[Save](#)”) to avoid unnecessary data entry. The database will inform the user if the patient is no longer eligible for the platform, a domain or intervention as you work through the form.
- The updated database has a new [Assessment](#) section at the top of the PANDA page which lists the domains and interventions for which the patient is being assessed. Click on “[Show interventions](#)” to expand the list.



Assessment

This patient is being assessed for the following interventions at 02999 - Vulcan

Corticosteroid
No Hydrocortisone or other systemic corticosteroid
IV Hydrocortisone 50 mg every 6 hours while in septic shock
Dexamethasone 6mg daily for 10 days

Influenza Antiviral
No oseltamivir or other antiviral agent active against influenza
5 days of Oseltamivir
10 days of Oseltamivir
Baloxavir on Days 1 and 4
5 days of Oseltamivir + Baloxavir on days 1 and 4
10 days of Oseltamivir + Baloxavir on days 1 and 4

Influenza Immune Modulation
Tocilizumab
Baricitinib

COVID-19 Immunoglobulin
No immunoglobulin against COVID-19
High titre convalescent plasma

- At the bottom of the page click on the "Save" button. If you click abandon the page before you click on the "Save" button, any information entered up to this point will not be saved.

Patient age ⁱ years
Enter estimated age, if exact age is unknown

Sex at birth ⁱ

Date and time of hospital admission ⁱ 24 hr clock

Date and time of ICU admission 24 hr clock

- You can go back to check previously answered questions or change answers at any time by selecting the relevant Eligibility Page on the left navigation pane.

Illness Severity State IPCJPH

Is the patient currently receiving oxygen support ⁱ

FiO2 > 0.21

No

Low intensity oxygen therapy
FiO2 of at least 21% delivered at a flow rate of less than 30L/min OR FiO2 less than 40% delivered at any flow rate

High flow oxygen
High-Flow oxygen delivered by nasal prongs with FiO2 40% or higher and at a flow rate of at least 30 L/min (or at least 2 L/min/kg in children less than 15 kilograms)

Non-invasive ventilation (NIV)
NIV includes positive inspiratory or expiratory pressure or both via a mask, helmet, or similar device

Invasive mechanical ventilation
Any form of positive pressure ventilation via an endotracheal, nasotracheal or tracheostomy tube

Is the patient currently receiving a continuous vasopressor and/or inotrope infusion ⁱ

At the time of completing this form

Is the patient now clearly recovering from their acute infection ⁱ

IPCJPH

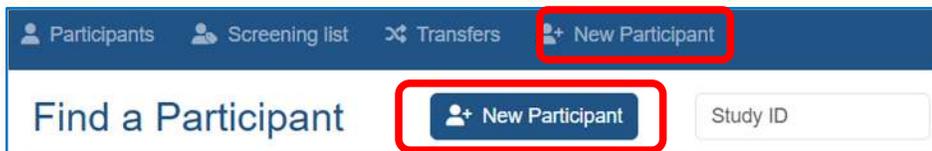
- Demographics
- Platform Eligibility
- State
- PANDA
- Domain Eligibility
- Intervention Eligibility
- Consent
- Best Interests
- Raw Data

HINT: click on the information button () at the end of each question to view the question definition. If you have viewed the definition and you are still unsure, contact your Project Manager to discuss the item.

5.1. Enter a new patient

There are two places where you can easily access the eligibility CRF for a new patient.

1. On the **Dashboard** to randomise a patient, click on *“New Participant”*
2. On the **Participants** page to randomise a patient, click on *“New Participant”* either on the page or on the blue bar.



5.2. Duplicate Patient

5.2.1. Duplicate patient within the last 72 hours at your site

- If you attempt to randomise a patient with the same age, sex at birth and hospital admission date and time at your site within 96 hours, an **ALERT** will appear.
- Please check that the patient you are trying to randomise has not already been enrolled in REMAP-CAP before continuing.
 - If the patient has been enrolled in the study, select *“Yes, they are the same patient”*.
 - If the patient has not been enrolled in the study before, select *“No, they are not”*.
- Only a Research Coordinator account can enter two patients with the same initials, DOB, and sex at birth within 96 hours.

5.2.2. Duplicate patient within the last 90 days at any site in your country

- If you attempt to randomise a patient with the same initials, date of birth and sex at birth of another record within the last 90 days at your site, an **ALERT** will appear.



- In the alert you will be told:
 - The name of the site where the previous patient was randomised
 - The date they were randomised
 - The participant study number
- Please check that the patient you are trying to randomise has not already been enrolled in REMAP-CAP before continuing.
 - If the patient has been enrolled in the study, select “Yes”
 - If the patient has not been enrolled in the study before, select “No”.

Only a Research Coordinator account can override a duplicate patient alert.

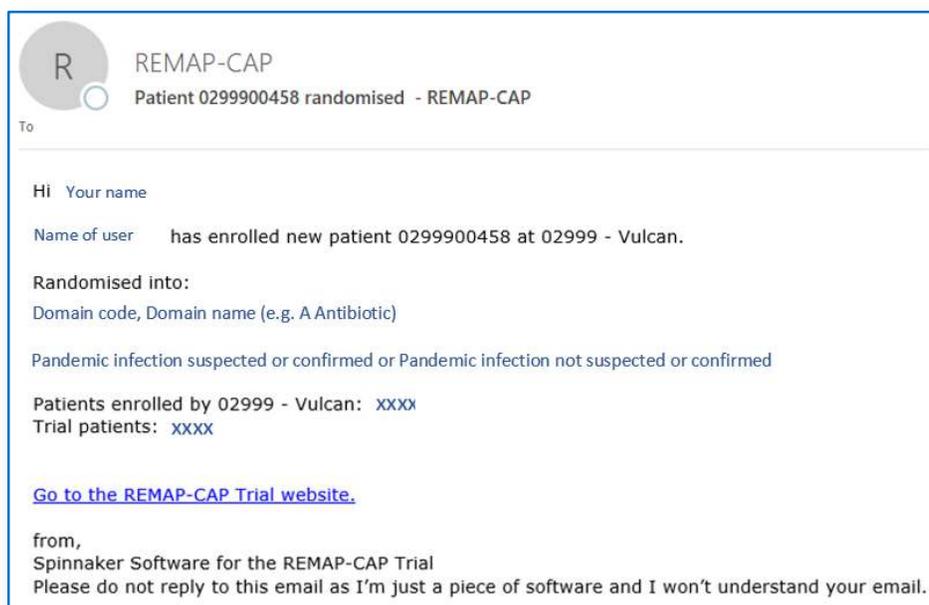
5.2.3. Override duplicate patient

- A Research Coordinator account must be used to override duplicate patient alerts.
- Select “*New Participant*” on the Dashboard or Participant page.
- Enter the patient demographics.
- If duplicate randomisation alert appears, please check that the patient you are trying to randomise has not already been enrolled in REMAP-CAP before continuing.
 - If the patient has been enrolled in the study select “Yes”.
 - If the patient has **not** been enrolled in the study before, select “No”

Continue answering the eligibility assessment questions.

5.2.4. Randomisation email

If a patient is randomised to a REMAP-CAP domain or entered into Eligibility pending, an automated email will be sent to site research staff (refer to [Email Notifications](#)).



5.3. Randomisation Allocation

- Once all of the eligibility questions have been answered and the patient’s eligibility is confirmed, you will be taken to a new page confirming that the patient has been randomised and outlining which domain interventions that patient has been allocated to.
- A randomisation confirmation email will automatically be sent to all site research staff upon successful randomization.

Platform confirmed 0299900072 Print this page

Participant 0299900072
 Randomised 15-Jul-2025 20:39
 Age 25 has been enrolled in the REMAP-CAP Trial

Domain	Allocation Status
ZA Antibiotic Domain	IV Amoxicillin-clavulanate + Macrolide
ZP COVID-19 Immunoglobulin Domain	High titre convalescent plasma
ZV Mechanical Ventilation Domain	Reveal pending by 19-Jul-2025 20:39 (within 96 hours of randomisation)

What to do now ...

Antibiotic

- IV Amoxicillin-clavulanate + Macrolide
- You indicated you suspected MRSA, please prescribe an antibiotic to provide MRSA cover

COVID-19 Immunoglobulin

- Prescribe High titre convalescent plasma

Mechanical Ventilation

- Intervention for this domain will be revealed on the [Mechanical Ventilation Reveal Page](#). Some additional questions will need to be answered to obtain reveal. This can only be done within 96 hours of randomisation (19-Jul-2025 20:39)

An email has been sent to the Research Team at your site to notify them the patient has been enrolled.
 If any allocated intervention is not able to be administered please contact the Research Coordinator

- Please print the randomization page for the patients’ medical records, a “*Print this page*” button is located at the top of the page.

Platform confirmed 0299900072

Participant 0299900072
 Randomised 15-Jul-2025 20:39
 Age 25 has been enrolled in the REMAP-CAP Trial

Domain	Allocation Status
ZA Antibiotic Domain	IV Amoxicillin-clavulanate + Macrolide
ZP COVID-19 Immunoglobulin Domain	High titre convalescent plasma
ZV Mechanical Ventilation Domain	Reveal pending by 19-Jul-2025 20:39 (within 96 hours of randomisation)

What to do now ...

Antibiotic

- IV Amoxicillin-clavulanate + Macrolide
- You indicated you suspected MRSA, please prescribe an antibiotic to provide MRSA cover

COVID-19 Immunoglobulin

- Prescribe High titre convalescent plasma

Mechanical Ventilation

- Intervention for this domain will be revealed on the [Mechanical Ventilation Reveal Page](#). Some additional questions will need to be answered to obtain reveal. This can only be done within 96 hours of randomisation (19-Jul-2025 20:39)

An email has been sent to the Research Team at your site to notify them the patient has been enrolled.
 If any allocated intervention is not able to be administered please contact the Research Coordinator

- Administration guides for each domain that the participant is randomised to are available for download by clicking on the hyperlink under each relevant domain. These administration guides are also available for download under the [Resources tab](#).
 - As these administration guides may be updated over time, it is recommended that they are downloaded at the time that the participant is randomized to ensure that the current version is utilized.
 - Administration guides are intended to provide a brief reference guide to the delivery of allocated interventions, and should not substitute entirely for a thorough knowledge of the study protocol. If you have any questions about the delivery of allocated interventions please contact your Project Manager.
- If you have closed the page, you can view this page by clicking on the Participant’s Study Number to open the *“Pt Summary Page”* and then by clicking on *“Eligibility”* in the CRF tab.
- For some domains, additional information may be required before the participant’s allocation can be revealed.
 - The *“Eligibility”* outcome page will indicate which domains are *“Pending domain”* reveal, and provide links to Reveal forms for each domain.

Patient Details 0299900072

Lock status: Open

Monitoring status: Not Monitored

[Transfer Participant](#)

Change Log

TABLE	TYPE	DATE	USER
Pt_Elig_Reveals	Insert	15-Jul-2025 22:38	
Pt_Core	Insert	15-Jul-2025 22:38	
Pt_Elig_Core	Update	15-Jul-2025 22:38	
Pt_Elig_Core	Update	15-Jul-2025 22:38	
Pt_Elig_Core	Update	15-Jul-2025 22:38	

[More changes](#)

Left Sidebar:

- 0299900072
- Randomised 15-Jul-2025 20:39
- Hospital admission 15-Jul-2025 05:00
- ICU admission 15-Jul-2025 09:00
- Summary
- Eligibility**
- Mechanical Ventilation - reveal
- Consent
- Baseline
- Microbiology
- Daily Data
- Medication Administration
- Discharge
- Day 90 - 11 Oct

- Domain-specific Reveal forms are also accessible via the [eCRF Navigation tab](#).
- Click on the ‘Reveal pending’ link or the domain-specific reveal form in the left pane to navigate to the additional criteria page and complete the eligibility form.

Patient Details 0299900072

Lock status: Open

Monitoring status: Not Monitored

[Transfer Participant](#)

Change Log

TABLE	TYPE	DATE	USER
Pt_Elig_Reveals	Insert	15-Jul-2025 22:38	
Pt_Core	Insert	15-Jul-2025 22:38	
Pt_Elig_Core	Update	15-Jul-2025 22:38	
Pt_Elig_Core	Update	15-Jul-2025 22:38	
Pt_Elig_Core	Update	15-Jul-2025 22:38	

[More changes](#)

Left Sidebar:

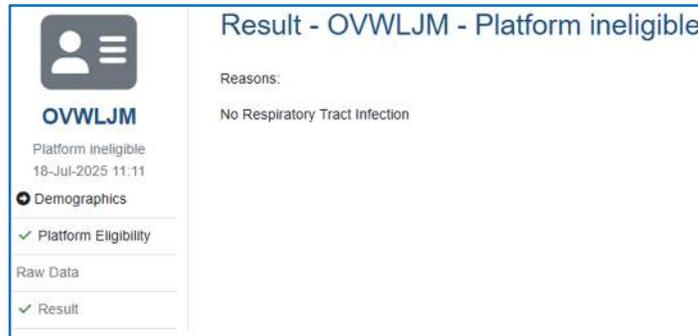
- 0299900072
- Randomised 15-Jul-2025 20:39
- Hospital admission 15-Jul-2025 05:00
- ICU admission 15-Jul-2025 09:00
- Summary
- Eligibility
- Mechanical Ventilation - reveal**
- Consent
- Baseline
- Microbiology
- Daily Data
- Medication Administration
- Discharge
- Day 90 - 11 Oct

- For domain-specific pending reveal information refer to the REMAP-CAP Data Completion Guidelines.

5.4. Eligibility Outcomes

There are various **Eligibility Outcomes**:

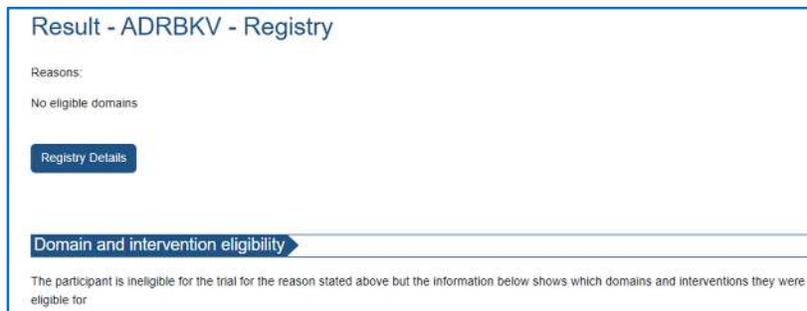
1. **Randomised:** This patient meets platform and domain eligibility criteria for at least one domain and are the list of patients who were successfully randomised on the participant listing summary page.
2. **Platform Ineligible:** This patient does not meet platform eligibility criteria and are added to the list of patients who were screened and not eligible.



3. **Not Randomised:** This patient does not meet state or domain eligibility criteria and are added to the list of patients who were screened and not eligible.



4. **Registry:** This patient does meet platform eligibility criteria but is not eligible for randomisation. This may occur when a patient is eligible for the platform, but is not eligible for randomisation to any available domains.



5. **Eligibility/Screening pending:** This patient has not yet met all the platform eligibility criteria, however, there is still time for the patient to meet these eligibility criteria. On the outcome page, the reason why the patient has been placed in the eligibility pending criteria will be listed, including the date and time the patient's

eligibility assessment must be updated before the study time-windows close (refer to [Eligibility pending patients](#)).

5.1. Consent Pending: The patient was indicated as capable of providing informed consent prior to randomisation, or prospective consent from the patient or their representative is required prior to randomisation. The eCRF can be updated once a consent discussion has occurred, whether consent has been provided or declined (refer to updating eligibility CRF).

5.5. Screening pending patients

- To view patients that are currently pending eligibility completion, go to the Recent screenings section of the Dashboard page.
- The list of Eligibility pending (Outcome = blank) patients is also located on the [Screening List Tab](#) of the [Participants](#) page.

PARTICIPANT CODE	A...	OUTCOME OF ELIGIBILITY	REASON FOR OUTCOME
IPCJPH	43		

5.5.1. Update eligibility assessment for Eligibility pending patients

- To update eligibility on these patients, click on the patient’s *ID* on either the Dashboard or Screening list page.

PARTICIPANT CODE	A...	OUTCOME OF ELIGIBILITY	REASON FOR OUTCOME
IPCJPH	43		

- The system will open to the first page of the Eligibility eCRF.

5.6. Accessing eligibility data post randomisation

You can access a participant’s eligibility data after randomisation has occurred.

- Select the [Summary](#) page in the left navigation pane and click on the “[Eligibility](#)” link.

- The 'Result' page will display and the left navigation pane will display the eligibility assessment pages. Clicking on the "Pt Summary" page will display the CRFs required for the participant.

Domain	Allocation Status
ZA Antibiotic Domain	IV Piperacillin-tazobactam + Macrolide
ZM Macrolide Duration Domain	Extended course IV Azithromycin (14 days)
ZC Corticosteroid Domain	Dexamethasone 6mg daily for 10 days
ZI Influenza Antiviral Domain	5 days of Oseltamivir
ZV Mechanical Ventilation Domain	Not revealed
ZN Influenza Immune Modulation Domain	Not revealed

What to do now ...

Antibiotic

- IV Piperacillin-tazobactam + Macrolide
- You indicated you suspected MRSA, please prescribe an antibiotic to provide MRSA cover

5.7. Updating incorrect information entered at eligibility

- Information entered during the eligibility assessment can be updated after a patient is randomised.
- Demographic data, Hospital admission date & time and ICU admission date & time can be edited via the Patient [Summary](#) page, by selecting "Edit Patient".

Patient Details 0299900545

Lock status	Open	✎
Monitoring status	Not Monitored	✎

ICU Admission	18-Aug-2025 06:00
Hospital Admission	17-Aug-2025 17:00

APD number

[Edit participant](#)

6. PATIENTS

6.1. Patient list

This list includes the patient details, the date they were randomised and an overview of eCRF progress.

6.1.1. eCRF overview key definitions

<i>Symbol</i>	<i>Definition</i>
	Indicates that a CRF is no longer needed (no data entry required).
	Indicates that a CRF is complete.
	Indicates when a CRF is partially complete.
	Indicates that a CRF has not been started.
6 Apr	Future due dates appear in light grey
6 Nov	Past due dates appear in black.
 0299900115	Yellow highlighted PSN indicate a query that requires attention (e.g. consent revoked or cross-validation query).
	Patient transfer pending confirmation by receiving site.
	Patient transferred, the patient's eCRF is not at your site (data entry closed).
	Patient transferred, the patient's eCRF is at your site (open for data entry).
 0299900109	A lock next to a yellow highlighted PSN indicates that the patients file is locked (e.g. consent has been revoked or patient's file is closed after data cleaning).
	Indicates that the participant has declined consent for participation and that data use conditions apply.
	Indicates that the participant or their representative has declined consent for participation in one or more domains, but has consented to participate in one or more other domains.
	Indicates that the participant record is locked after being signed off by the site investigator.
	Indicates a paediatric participant.



Indicates that the participant has a reported Serious Adverse Event.

6.1.2. Navigation

- To open a specific patient’s **Summary** page click on the patient’s *Participant Study Number*. Alternatively, you can enter their PSN in the search box provided and click **Search**.
- To open a specific **CRF** click on the tick, cross or question mark relevant under the CRF you want to open for that patient.
- *Follow-up* due dates are displayed in the overview (final two columns)

D 7	D 90
02 Jun	23 Aug

D 7	D 90
×	11 Oct
×	11 Oct

- If the follow-up is not relevant (e.g. deceased patients or patients with withdrawn consent), the date will be replaced by a light grey cross (X).

HINT: To open a patient’s eCRF, from the patient’s Patient Summary Page you can use the eCRF navigation tab on the left-hand side of the window to open a specific eCRF.

- The patient listing defaults to displaying Participant Study Number in descending order. You can re-order the list by clicking on a column name. For example, if you click on the ‘Participant’ column, it will sort the list in ascending order by age. You can also apply filters to each column by clicking on the funnel icon in the column heading

Find a Participant

New Participant Search

Site name ▼

PARTICIPA... ▼	STA... ▼	AGE ▼	SEX ▼	DAY ▼	RANDOM... ▼	DO... ▼	PENDING ▼	BASEL... ▼	CONSENT ▼	MICRO... ▼	DISCHA... ▼	D 7 ▼	D 90 ▼
0299900073	Severe	59	Male	6	15-Jul-2025	ZC	ZV	×	×	×	×	×	11 Oct

Filter

Contains ▼

And ▼

Equals ▼

Clear Apply

6.2. Screening list

The **Screening List** under the *Patients* tab will load a list of patients who have been entered into eligibility who have either been randomised, not randomised or whose eligibility assessment is incomplete.

PARTICIPANT CODE	Eligibility Code	A...	OUTCOME OF ELIGIBILITY	REASON FOR OUTCOME
ABSMPH	Eligibility code	36	Timeout 48hr	Timeout 48hr
ABYVRD		0	Platform ineligible	Infant under 1 month
ABZRHY		33	Timeout 48hr	Timeout 48hr
ACVKBP		12	Randomised	

- Click on the “*Eligibility Code*” to load more information about the eligibility record.
 - The eligibility code is the mix of alphabet letters next to each eligibility record.
- You can filter the list of patients by the different **Eligibility Outcomes**.
- Select the dropdown menu and choose the eligibility outcome you are interested in. An incomplete record will have a blank value in the ‘*Reason*’ column.

OUTCOME OF ELIGIBILITY	REASON FOR OUTCOME
Timeout 48hr	Any
Platform ineligible	Blank
Timeout 48hr	Consent pending
Randomised	Not Randomised
Not Randomised	Platform ineligible
Randomised	Randomised
Registry	Re-assessment failed
Not Randomised	Registry
Randomised	Timeout 48hr

- A summary of the different eligibility outcomes is provided in [Eligibility Outcome](#).
- To update or review the current status of **an incomplete screening record**, click on the “*Eligibility code*” to open up the record and update the patient record.

6.3. Transfers

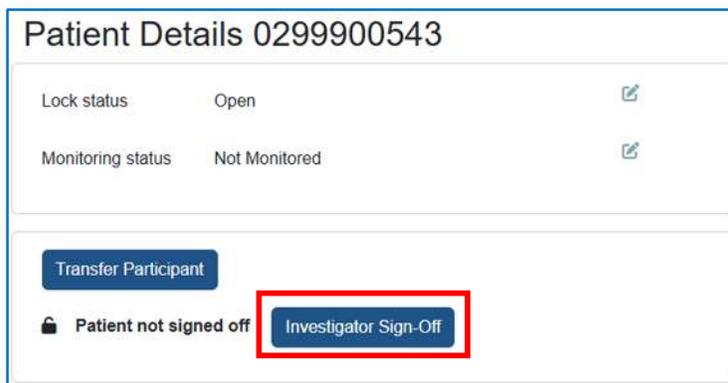
Transfers under the Patients tab displays a summary of all patients transferred to or from your site. For more information refer to [Patient Transfers](#).

6.4. Investigator sign-off of the CRF

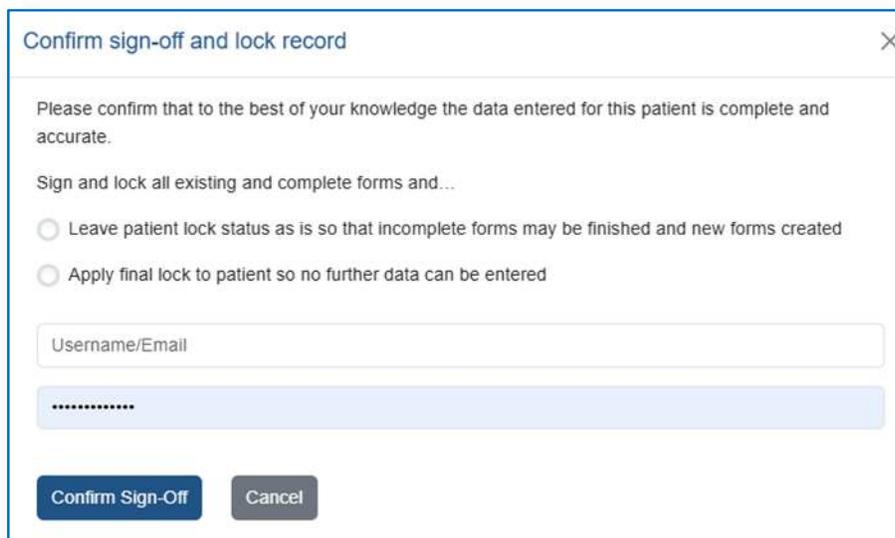
6.4.1. Patient level sign-off

Site Investigators can sign off the eCRF as complete and accurate. Sign-off can occur at either the patient or form level. eCRFs can only be signed off if the form is complete (green tick).

- At a patient level, select the **Investigator sign off** button on the patient **Summary** page to sign off multiple forms simultaneously.



- Two options will display.



- **Option 1:** 'Leave patient lock status as is so that incomplete forms may be finished and new forms created.' Use this option if you'd like to sign off and lock multiple forms with completed data (green tick) while awaiting data to be entered for other forms. For example, if all in-hospital data is entered but follow up forms are not yet due.

Patient Details 0299900073

Lock status: Open

Monitoring status: Not Monitored

ICU Admission: 15-Jul-2025 07:00

Hospital Admission: 14-Jul-2025 11:00

APD number

Transfer Participant

⚡ Patient has been signed off

Change Log

TABLE	TYPE	DATE	USER
Pt Discharge	Insert	11-Aug-2025 14:33	Rafi User local

- Completed forms (with green tick) are locked. Incomplete forms remain open.
- **Option 2:** 'Apply final lock to patient so no further data can be entered.' Use this option if all data has been entered for all required forms.
- **Confirm sign-off and lock record:** To complete the CRF sign-off process, the you (i.e., Investigator) will need re-enter your database username and password, and confirm sign-off.

Confirm sign-off and lock record

Remember unsaved changes will be lost so please save first if necessary

Username/Email

Password

Confirm Sign-Off Cancel

- Once sign-off is complete, an appropriate message will display on the summary page.
- The Investigator sign off icon (🔒) will display on the patient listing summary page.

PARTICIPA...	STA...	AGE	SEX	DAY	RANDOM...	DO...	PENDING	BASELI...	CONSENT	MICRO...	DISCHA...	D 7	D 90
🔒 0299900073	Severe	59	Male	27	15-Jul-2025	ZC		✗	✓	✗	✓	✗	11 Oct

6.4.2. Form level sign-off

- At form level, the 'Investigator Sign-off' button displays at the bottom of the form upon partial or complete entry of the form.
- Select the **Investigator Sign-off** button and re-confirm your password.

WHY WRITTEN CONSENT WAS NOT OBTAINED	DATA USE WITHOUT WRITTEN CONSEN	
Patient deceased	No	

Form is Locked

- 'Form is locked' message displays along with an 'Unlock this form' button allowing Investigators to unlock the form if required.
- The lock icon () displays at the top of the form and in the left navigation pane.
- Daily data forms must be individually signed off/locked.
- All sections on the Medication administration form must be completed (green tick) to display the 'Sign off and lock this form' button.
- Investigators and project managers can [Remove \[Investigator\] sign off](#) via the [Patient Summary](#) or on the individual CRF page.

Patient Details 0299900072

Lock status	Final Lock	
Monitoring status	Not Monitored	

ICU Admission: 15-Jul-2025 09:00
Hospital Admission: 15-Jul-2025 05:00
APD number

[Edit participant](#)

[Transfer Participant](#)

Patient has been signed off
But this form has not been: Microbiology [Remove Sign-Off](#)

- Re-confirm your username and password to complete the removal of sign-off process.

✕

Confirm remove sign-off

Note this does not affect patient lock status. Please update lock status appropriately after sign off removal.

Username/Email

Password

Remove Sign-Off
Cancel

- Note:** Removing INV sign-off does not impact the lock status of the form. If further changes are required the CRF must be unlocked by your Project Manager or Investigator by updating the 'Lock status' from *'Final lock'* to *'Open'* on the patient summary page.

Daily Organ Support 0299900072

Form not editable. This form has been signed off and locked.

DAY	DATE	LOCATION	HIGHEST LEVEL OF OXYGEN THERAPY RECEIVED	VASOPRESSORS / INOTROPE	RRT
1 ✓	15-Jul-2025	ICU <small>ⓘ ⌚ 🗨</small>	High flow nasal pro... <small>ⓘ ⌚ 🗨</small>	No <small>ⓘ ⌚ 🗨</small>	No <small>ⓘ ⌚ 🗨</small>
2 ✓	16-Jul-2025	ICU <small>ⓘ ⌚ 🗨</small>	High flow nasal pro... <small>ⓘ ⌚ 🗨</small>	No <small>ⓘ ⌚ 🗨</small>	No <small>ⓘ ⌚ 🗨</small>
3 ✓	17-Jul-2025	ICU <small>ⓘ ⌚ 🗨</small>	High flow nasal pro... <small>ⓘ ⌚ 🗨</small>	No <small>ⓘ ⌚ 🗨</small>	No <small>ⓘ ⌚ 🗨</small>
4 ✓	18-Jul-2025	ICU <small>ⓘ ⌚ 🗨</small>	Low-intensity oxygen <small>ⓘ ⌚ 🗨</small>	No <small>ⓘ ⌚ 🗨</small>	No <small>ⓘ ⌚ 🗨</small>
5 ✓	19-Jul-2025	ICU <small>ⓘ ⌚ 🗨</small>	Low-intensity oxygen <small>ⓘ ⌚ 🗨</small>	No <small>ⓘ ⌚ 🗨</small>	No <small>ⓘ ⌚ 🗨</small>

🔒 **Form is Locked**
Remove Sign-Off

6.5. **Add Patient**

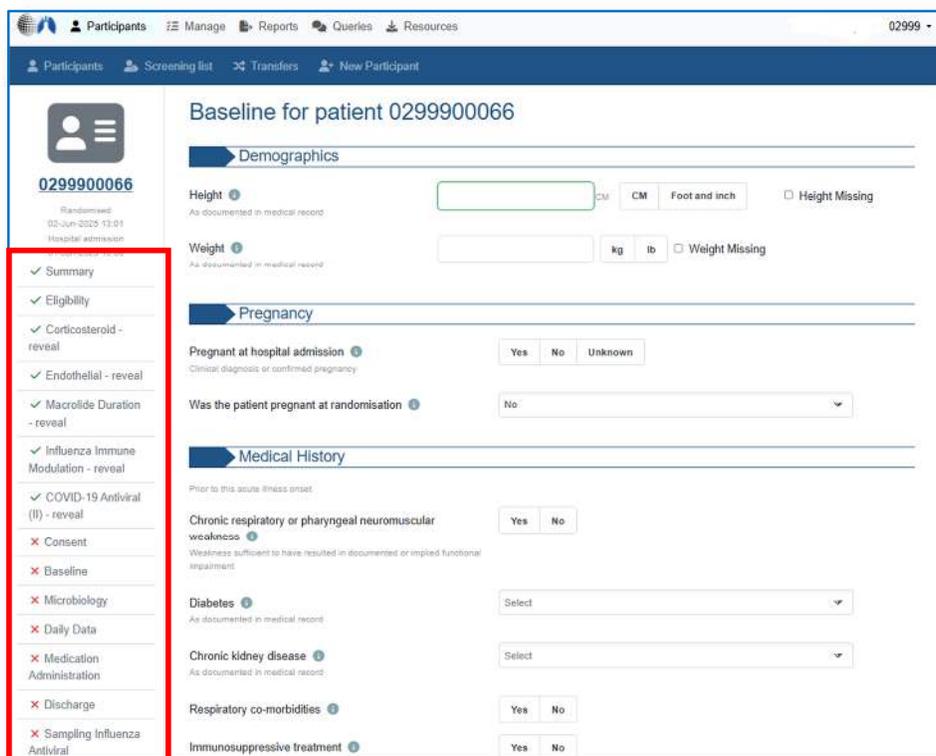


If you click on the “*Add Patient tab*”, you will be taken to the first page of the Eligibility assessment.

7. CASE REPORT FORMS

7.1. General

- Most questions in the eCRF have an information button (). Select this button to open the question’s definition linked to the [wiki version](#) of the REMAP-CAP Data Completion Guidelines.
- For more information refer to the REMAP-CAP Data Completion Guidelines, or contact your project manager.
- The eCRFs are dynamic. Questions on some pages load according to answers previously provided. Certain questions may also be displayed or hidden depending on the interventions, domains, or States that the participant is randomised to.
- The date format is DD-MMM-YYYY. A date selector is available on all date fields except for the date of birth on the eligibility assessment.
- Missing data are indicated by checking “*Not Recorded*” or “*Not Applicable*”, as relevant. Never leave a field blank. This will ensure data queries are not raised unnecessarily.



- The eCRF navigation tab is displayed in the same place on all eCRFs.

7.2. Forms

7.2.1. How to open a patient’s eCRF

- Select the patient’s *Participant study number* on either the **Dashboard** or **Participant List** tabs.

PARTICIPA...	STA...	AGE	SEX	DAY	RANDOM...	DO...	PENDING	BASEL...	CONSENT	MICRO...	DISCHA...	D 7	D 90
0299900076	Severe	24	Female	14	28-Jul-2025	ZA, ZC, ZI		x	x	x	x	x	24 Oct
0299900075	Severe	36	Male	17	25-Jul-2025	ZA, ZC, ZI, ZN, ZV		x x	x	x	x	x	21 Oct

- Alternatively enter the patient’s Participant Study Number in the search bar and click on “*Search*”.

7.2.2. Patient summary page

The *Summary* page includes several distinct sections:



0299900076

Randomised
28-Jul-2025 12:59
Hospital admission
27-Jul-2025 08:00
ICU admission
28-Jul-2025 05:00

- ✓ Summary
- ✓ Eligibility
- ✓ Macrolide Duration
- reveal
- ✓ Mechanical
Ventilation - reveal
- ✗ Consent
- ✗ Baseline
- ✗ Microbiology
- ✗ Daily Data
- ✗ Medication
Administration
- ✗ Discharge
- ✗ Sampling Influenza
Antiviral
- ✗ Day 90 - 24 Oct

Patient Details 0299900076

Lock status: Open

Monitoring status: Not Monitored

ICU Admission: 28-Jul-2025 05:00

Hospital Admission: 27-Jul-2025 08:00

APD number

[Edit participant](#)

[Transfer Participant](#)

🔒 Patient not signed off
[Investigator Sign-Off](#)

Change Log

TABLE	TYPE	DATE	USER
Pt_MedDaily	Insert	06-Aug-2025 12:07	Cameron Green
Pt_Elig_Reveals	Insert	28-Jul-2025 14:58	Vanessa S
Pt_Elig_Reveals	Insert	28-Jul-2025 14:58	Vanessa S
Pt_Core	Insert	28-Jul-2025 14:58	Vanessa S
Pt_Elig_Core	Update	28-Jul-2025 14:58	Vanessa S

[More changes](#)

Antibiotic Domain
IV Amoxicillin-clavulanate + Macrolide

Corticosteroid Domain
No Hydrocortisone or other systemic corticosteroid

Influenza Antiviral Domain
5 days of Oseltamivir

Adverse Events +
No adverse events

SAEs +
No serious adverse events

Protocol Deviation +
No protocol deviations

- Participant key date summary:

Above the eCRF navigation tab is a summary of key dates for the participant.



0299900423

Randomised 02-Dec-2021 10:03
Re-assessed at 03-Dec-2021 10:09
Hospital ad. 30-Nov-2021 11:30
ICU ad. 01-Dec-2021 12:00
Deceased 15-Dec-2021 12:30

The summary includes:

- Participant study number
- Date and time of randomisation (and re-randomisation, if applicable)
- Date and time of hospital admission
- Date and time of ICU admission
- Date and time of death (if applicable)
- **eCRF Navigation tab:** The participant's eCRF pages are listed on the left-hand side.
 - Only pages required for the participant will be displayed. Some forms may be greyed-out if they are no longer required.
 - Clicking the eCRF name or icon (tick or cross) will open the corresponding eCRF form
- **Patient Details:** The middle section is a summary of the patient's details and the link to edit these details (if required) or transfer the patient to another site. You can also add a note for other people reviewing the patient's eCRF (e.g. you may list the dates of patient follow-up attempts or explain why the day 90 eCRF data entry is late). Please note no one will be notified via email if a note is entered. We recommend you check this section of the patient's summary page regularly.
 - To transfer a participant record to another participating REMAP-CAP site, use the '**Transfer participant**' button and refer to section 9 [Participant transfers](#) for further guidance.
 - To print a participant-specific CRF, click on "print CRF". This will take you to another page that allows you to select which forms you wish to print. Only questions that are required to be answered for that participant will appear in the CRF, based on their State, Stratum, and domain allocations.
 - Site Investigators have the ability to sign off the eCRF as complete and accurate. Once the eCRF has been completed and has been checked for accuracy, click the "investigator sign off" button and confirm that the data entered are complete and accurate.
Investigator sign-off locks the eCRF at either a form level or a patient level, and the sign-off must be removed by a Project Manager if any further changes are required to the participant's data after it has been signed off by the Investigator. It can then be signed off again by the investigator once the necessary changes are made. This function may not be implemented in all regions.
- **Randomisation allocation:** Displayed at the top right are the Domains the patient is participating in, and the intervention the patient has been randomised to.
- **Event reporting:** On the bottom right-hand side are links to adverse event, serious adverse event, and protocol deviation eCRFs.
- **Change log:** The change log allows users to see all changes that have been made to the participant's eCRF, as well as the date and time of the change and the username of the person who made the change. Click on the "details" link beside a given entry to see the details of that change, or click "...more changes" to see a complete list of changes that have been made.

7.2.3. Baseline

- The Baseline form is designed to be completed before any other eCRF as the baseline eCRF data impacts questions that are shown or hidden on other eCRF pages.

- Hospital admission date and time that was collected on the Eligibility assessment form and can be edited on the Participant summary page. If the two dates and time do not match, an error message will be displayed asking for confirmation that the date & time entered is correct.
- After you have confirmed that the date and time updated in the Participant summary page is correct, this will overwrite the date and time entered in error during the eligibility assessment.
- Note that participants who have received an allocation in the Moderate State and have later received an allocation in the Severe State will have two Baseline CRFs, corresponding to each randomisation.

7.2.3.1. *APACHE II APS CALCULATOR and other Illness Severity Scoring*

- The **APACHE-II acute physiology score (APS)**, **CURB-65**, **SOFA** and **pSOFA** scores are calculated by the system based on the select questions raw values required for these scores entered on the Baseline eCRF.

Illness Severity Scores	
APACHE II	
APS points ⓘ ⌚ ⚙️	12
APACHE II acute physiology score	
Age points ⓘ ⌚ ⚙️	0
Chronic health points ⓘ ⌚ ⚙️	5
APACHE II score ⓘ ⌚ ⚙️	17
CURB-65	
CURB-65 score ⓘ ⌚ ⚙️	1
SOFA	
SOFA score ⓘ ⌚ ⚙️	6

7.2.4. Ventilation Domain baseline

- The Ventilation Baseline CRF is only required for participants enrolled in the Mechanical Ventilation Domain and will not appear on the eCRF navigation tab for participants who have not been randomised to this domain.

7.2.5. Microbiology

- The microbiology eCRF is dynamic and is designed to stop asking questions as soon as the causative organism(s) have been identified.
- If a patient is immunocompromised, the **‘Immunocompromised patients’** section of the microbiology eCRF will be displayed and must be answered.
- Two questions on the Baseline eCRF must be entered prior to opening the Microbiology eCRF.
 - If the two questions are not answered, the microbiology eCRF is locked and the following error message will be displayed:

Immunosuppressive questions on the [Baseline form](#) must be answered before any entry on Microbiology

- The two Baseline eCRF questions are in Section 4.0 Past medical history:

Immunosuppressive treatment ⓘ Therapy that has suppressed resistance to infection	Yes	No
Immunosuppressive disease ⓘ Disease that has suppressed resistance to infection	Yes	No

- The questions on this eCRF have different time-windows regarding specimen collection timeframes, please check the grey text and / or Data Completion Guidelines for each question before answering.

Other upper or lower respiratory tract PCR detected organisms
On specimens collected during this acute respiratory illness, up until 72 hours after completion of the eligibility assessment
Check all that apply
<input type="checkbox"/> Chlamydomphila pneumoniae ⓘ
<input type="checkbox"/> Legionella spp. ⓘ
<input type="checkbox"/> Mycoplasma pneumoniae ⓘ
<input type="checkbox"/> Other (non-SARS-CoV-2) coronavirus ⓘ
<input type="checkbox"/> Adenovirus ⓘ
<input type="checkbox"/> Not tested or none of the above are positive ⓘ

- To make answering this eCRF easier, the database automatically calculates the time-window for each patient based on the date and time of hospital admission.

7.2.6. Daily organ support

- The Daily CRF is completed every day the patient is admitted to hospital to Study Day 28 post-randomisation.
- The Daily form shows a summary of entered daily data for that patient.

Daily Organ Support 0299900072

DAY	DATE	LOCATION	HIGHEST LEVEL OF OXYGEN THERAPY RECEIVED	VASOPRESSORS / INOTROPE	RRT	MECHANICAL VENTILATION DOMAIN DATA	
1 ✓	15-Jul-2025	ICU	High flow nasal pro...	No	No		 
2 ✓	16-Jul-2025	ICU	High flow nasal pro...	No	No		 
3 ✓	17-Jul-2025	ICU	High flow nasal pro...	No	No		 
4 ✓	18-Jul-2025	ICU	Low-intensity oxygen	No	No		 
5 ✓	19-Jul-2025	ICU	Low-intensity oxygen	No	No		 

- To edit a specific Daily eCRF click on the pen icon for that study day.

DAY	DATE	LOCATION	HIGHEST LEVEL OF OXYGEN THERAPY RECEIVED	VASOPRESSORS / INOTROPE	RRT	MECHANICAL VENTILATION DOMAIN DATA	
1 ✓	15-Jul-2025	ICU	High flow nasal pro...	No	No		 

- There are validations between the Daily eCRF and Discharge eCRF.
 - If the data entered into the Discharge eCRF indicates a patient is discharged from hospital prior to study day 28, the Daily eCRF for each study up to discharge date will automatically appear.

7.2.7. Ventilation Domain daily data

- For participants enrolled in the Mechanical Ventilation Domain additional daily data are required. The Daily CRF is dynamic and will only show these sections if they are required for the participant.

7.2.8. Medication Administration

- Administration of medications that are relevant to the participant are recorded in the Medication Administration form.
- Medications that may be collected include allocated interventions, as well as pre-determined important concomitant medications administered prior to the index hospital admission or during the treatment period, that may interact with allocated interventions or potentially impact on the outcome of the participant.
- The Medication Administration form has a number of sections, broadly grouped by type of medication (e.g. antibiotic medications, antiviral medications, corticosteroids, etc.).
- A daily administration section is available for each intervention therapy the participant is allocated. Intervention therapies administered to the participant should be captured for each study day up to max of 14 days during the treatment period. For example, if the patient is enrolled in the “Amoxicillin with clavulanic acid” intervention therapy in the Antibiotic Domain, enter total daily dose of this agent for each study day.

- To enter an allocated intervention medication, click on the pencil icon within the relevant section to enter the total daily dose of that medication.

Medication for participant 0299900072

▶ Prehospital Medications

Bamlanivimab / etesevimab Yes No Other monoclonal therapy directed against SARS-CoV-2 Yes No

Ronapreve (casirivimab / imdevimab) Yes No Sotrovimab Yes No

▶ Antibiotic Administration

All Antibiotics for this participant have been entered.
 Yes No

▶ Amoxicillin with clavulanic acid daily administration

	DAY	DATE	AGENT	ROUTE	DOSE	UNITS
	1	15-Jul-2025	Amoxicillin with clavulanic acid	IV bolus	85	mg
	2	16-Jul-2025	Amoxicillin with clavulanic acid	IV bolus	50	mg
<input checked="" type="checkbox"/>	3	17-Jul-2025	Amoxicillin with clavulanic acid	Select ▼ IV bolus IV extended infusion IV continuous infusion Oral/enteral		S...▼
	4	18-Jul-2025				
	5	19-Jul-2025				

- Answer all Yes/No questions for non-intervention therapies.
- The Antibiotics Domain includes an additional section to ***"Add other Antibiotics of interest"***. Click on the button to display drag and drop lanes for 'Administered' versus 'Not administered' medications. Drag any medications listed in the 'Not administered' lane to the 'Administered' lane if the patient was administered any of the agents listed and click ***'Save'***. Please refer to the Data Completion Guidelines for guidance as to how to complete each section.

Other Antibiotics of interest

Administered

None

Add other Antibiotics of interest

Other Antibiotics of interest Save Cancel

Drag and drop between lanes

Administered

Ampicillin

Cefotaxime

Not administered

Amikacin

Amoxicillin

Aztreonam

Benzathine benzylpenicillin

Benzylpenicillin

- Once each section is complete, change ***"All ... for this patient have been entered"*** to Yes. This may include where all daily doses of that type of medication have been entered, or to indicate that no medications of that type were administered and therefore the section is complete.

<https://remapcap.spinnakersoftware.com>

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Antibiotic Administration

All Antibiotics for this participant have been entered.

Yes No

7.2.9. Discharge

- The Discharge eCRF is dynamic and sections will be displayed or hidden depending on the participant’s Domain allocation.
- Readmissions or transfers between hospitals and clinical areas during the patient’s index acute hospitalisation can be captured in the ‘Change of Location During Index Acute Hospitalisation’ table at the top of the form. **Note:** This is separate from the **Transfer** feature uses a different mechanism.

Discharge for patient 0299900895

Change of Location During Index Acute Hospitalisation

(1)

Transfer to 1

Location

Date and time of transfer : : 24 hr clock Unknown

2

3

- If the participant is not transferred during their acute index hospitalisation click on the ‘**Remove transfer**’ button to remove the table.
- If the participant is transferred multiple times during their index hospitalisation add each transfer using the ‘**Add another transfer**’ feature.
- The Discharge eCRF and Daily eCRF are validated against each other, refer to the [Daily eCRF](#) for more information.

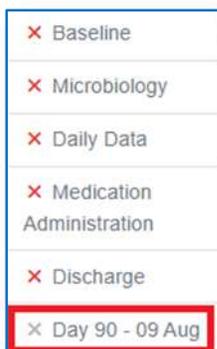
7.2.10. Consent

- Enter the details of any consent discussion that is conducted with the participant or their family, proxy, or other legal representative. There is no limit to the number of agreement events that can be entered in the eCRF for a participant.
- If the participant or proxy revokes consent, the other eCRF pages will be locked in accordance with what they agreed to and what they did not agree to.
- Consent revoked types:
 - *Data already collected cannot be used:* the patient’s entire eCRF will be locked, indicated by a lock next to the PSN (). A yellow error message will be displayed on the top of the patient summary page.

- *Data can be collected until hospital discharge*: the patient’s day 90 & 180 eCRF will be locked. A yellow error message will be displayed on the top of the patient summary page.
- *Vital status can be collected at day 90 & 180*: the patient’s day 180 eCRF section 1 (vital status) will be displayed, the follow-up questionnaires will be hidden preventing data entry. A yellow error message will be displayed on the top of the patient summary page.

7.2.11. Day 90

- The day 90 eCRF will only be editable on study day 91, this is to ensure that follow-ups are not conducted earlier than they are due.
- The Day 90 eCRF is validated against the other eCRFs. If the patient died during the hospital admission, the Day 90 eCRF will be locked and no data can be entered.



7.2.12. Day 180

- The Day-180 eCRF will only be editable on study day 181, this is to ensure that follow-ups are not conducted earlier than they are due.
- The Day-180 eCRF is validated against the other eCRFs. If the patient is recorded as deceased in any of the other eCRFs, the Day-180 eCRF will be locked and no data can be entered.
- *Use the relevant validated instruments provided in the long-term follow-up pack to conduct follow-up interviews.*
- Some sections of the Day-180 eCRF is dynamic, based on information entered in the **Consent eCRF**, please enter all consent agreements in the eCRF before conducting the follow-up interview.

8. REPORTING AEs, SAEs and PDs

8.1. Reporting an Adverse Event

- To report an adverse event (AE), open the patient’s summary page (see [How to open a patient’s eCRF](#)) and click on “*Adverse events +*” on the right of the page.

Patient Details 0299900073

Lock status	Open	
Monitoring status	Not Monitored	

ICU Admission: 15-Jul-2025 07:00
Hospital Admission: 14-Jul-2025 11:00
APD number:
[Edit participant](#)

[Transfer Participant](#)

Corticosteroid Domain
Dexamethasone 6mg daily for 10 days

Adverse Events +
No adverse events

SAEs +
No serious adverse events

Protocol Deviation +
No protocol deviations

- Complete the AE eCRF, only the domains the patient was randomised to will be displayed. Refer to the Case Report Form Data Completion Guidelines for more information on reporting AEs.

Adverse event for patient 0299900073

Adverse Event Description

Adverse Event diagnosis:

Adverse Event diagnosis detail:

Adverse Event description:

Adverse Event severity:

Adverse Event onset date:

Which domain is the event related to, or reportable for
Check all that apply

Corticosteroid

General participation

- You can enter more than one AE for each patient if they have experienced more than one AE. Do not complete multiple reports for the same AE.

8.2. Reporting a Serious Adverse Event

8.2.1. Report

- To report a SAE, open the patient’s summary page (see [How to open a patient’s eCRF](#)) and click on “SAEs+” on the right of the page.

Patient Details 0299900073

Lock status	Open	✎
Monitoring status	Not Monitored	✎

ICU Admission: 15-Jul-2025 07:00
Hospital Admission: 14 Jul 2026 11:00
APD number

[Edit participant](#)

[Transfer Participant](#)

Corticosteroid Domain
Dexamethasone 8mg daily for 10 days

Adverse Events ±
No adverse events

SAEs ±
No serious adverse events

Protocol Deviation ±
No protocol deviations

- You can complete more than one SAE for each patient if necessary.
- Please complete a SAE report as soon as it becomes known to site research staff, you do not have to wait until all the information is known about the SAE in order to complete a SAE report. If not all information about the event is available at the time of completing the report, an “*Initial report*” can be completed.

SAE for patient 0299900073

➔ Serious Adverse Event

Report type: **Initial report**

SAE no. for this patient: 1

Follow-up report number: 1

SAE ID: [input field]

SAE Diagnosis: [Select]

SAE Diagnosis Detail: [Select]

Event severity: [Select]

SAE description: [text area]

Onset date: [calendar icon]

Which domain is the event related to: Corticosteroid

- If further information becomes available about a SAE after an initial report has been submitted, create a new report and select “*Add Follow up report*” or “*Add Final report*” under the **History** section.

REPORT TYPE	DATE	ACTION TAKEN	OUTCOME	ENTERED BY	INVESTIGATOR SIGN ...
Initial report	16-Jul-2025	No action taken	Unresolved	User_local	

Add follow up report Add final report

- Once the follow up or final report form is launched, the SAE Diagnosis, SAE Diagnosis Detail, Event severity and SAE description field values are pre-filled from the “Initial report” of the corresponding event. The data in these fields can be changed, and remaining data can be entered based on up-to-date information about the SAE.

SAE for patient 0299900073

Serious Adverse Event

Report type	Follow-up report
SAE no. for this patient	1
Follow-up report number	1
SAE ID	
SAE Diagnosis	Bleeding
SAE Diagnosis Detail	Eye haemorrhage
Event severity	Grade 3: Severe or medically significant but not life threatening
SAE description	SAE bleeding event

Onset date: 16-Jul-2025

Which domain is the event related to

Corticosteroid

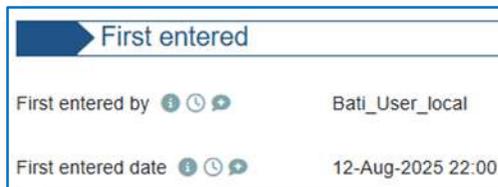
General participation

Not related to participation in any domain

- Only the domains the patient was randomised to will be displayed. Refer to the Case Report Form Data Completion Guidelines for more information on reporting SAEs.
- Once a SAE has been submitted by a member of the research team, the site Principal Investigator (PI) will need to log into the database to check the SAE report and sign off on it. The SAE report can be edited by a member of the research team prior to sign-off by the PI.
- For every SAE report, a confirmation email will be sent to the Project Manager, the site PI and the other site research coordinator/s to notify users that the submission of the SAE report has been successful. File the SAE confirmation email.

8.2.2. Site Principal Investigator sign-off

- The site PI will be notified via email if a SAE is reported.
- The site PI will need to log into the database using their Investigator account. Ensure only Investigators with appropriate delegation (as per the site signature and delegation log) sign off SAEs.
- The site PI can edit the SAE report or sign off on the existing SAE report.
- The report will be displayed with the information already entered. The name of the person who entered the SAE report is included in Section 4, if you have any questions about the SAE and SAE report please speak to this person.



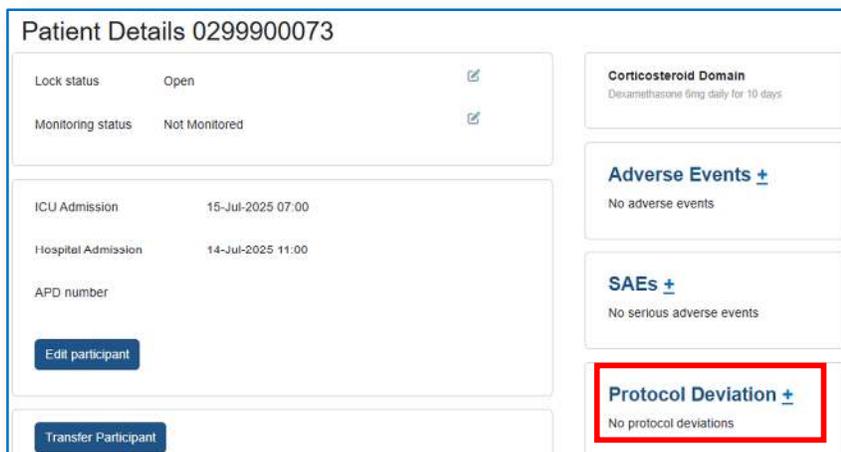
- To sign off on the SAE, click on "Sign off on SAE" at the bottom of the SAE report.



- Once a SAE has been signed off by the site PI, a confirmation email will be sent to the relevant Project Manager, the site PI and the other site Research Coordinator/s. File the SAE sign off confirmation email.

8.3. Reporting a protocol deviation

- To report a protocol deviation, open the patient’s summary page and click on “*Protocol deviations +*” on the right of the page.



- Protocol deviations resulting in SAEs must be reported as both a protocol deviation and a SAE, and the Project Manager must be notified.
- Only the domains the patient was randomised to will be displayed. Refer to the REMAP-CAP Data Completion Guidelines for more information on reporting PDs.
- You can complete more than one protocol deviation for each patient if necessary. Only complete one report per deviation that occurs.
- Each protocol deviation should be recorded separately in the database.
 - For example, a patient does not meet age criteria at the time of enrolment, and the REMAP-CAP allocated antibiotic was stopped due to an error. These are two separate deviations and must be reported on two deviation reports.

9. PATIENT TRANSFERS

9.1. General

- A **Research Coordinator, Investigator or account** is required to transfer a patient to another REMAP-CAP participating site in your country.
- If a participant’s eCRF needs to be transferred and no one with a Research Coordinator or Investigator account is available, please contact the Project Manager who will be able to transfer the patient’s eCRF on your behalf.
- There are two types of patient transfers:
 - *Physical Transfer*: When a patient physically leaves one ICU and is transferred to an ICU at another REMAP-CAP participating hospital.
 - *Data only transfer*: When the patient does not physically leave the ICU hospital, but the patient’s eCRF is transferred to the other ICU participating site for data entry purposes. A *data only transfer* can occur only after a physical transfer is completed.
- For guidance on patient transfers refer to the REMAP-CAP Data Completion Guidelines.

9.2. Transfer on the patient list

- Patient transfers are highlighted on the patient list and eCRF overview by a “T” to the left of the participant study number.

T	0299900072	Severe	25	Female	28	15-Jul-2025
T	0299900071	Severe	32	Male	28	15-Jul-2025
T	0299900070	Severe	54	Male	33	10-Jul-2025

- The colour of the T indicates the status of the transfer (refer to [eCRF overview key definitions](#)).

9.3. Transfer a patient’s eCRF

- We recommend you print the REMAP-CAP randomisation allocation page and add it to the patient’s transfer documents, including contact details for the research team your site.
- To transfer a patient on the patient **Summary** page, click on the “*Transfer Participant*” button.

Patient Details: 0299900074

Lock status: Open

Monitoring status: Not Monitored

ICU Admission: 25-Jul-2025 07:00

Hospital Admission: 24-Jul-2025 14:30

APD number:

[Edit participant](#)

[Transfer Participant](#)

- A summary of all the eCRF transfers for a participant will be displayed on the patient summary page.

ID	TYPE	FROM	TO	APPROVED
2	Physical	02993A	02999	12-Aug-2025
1	Physical	02999	02993A	17-Jul-2025

- A new page will load with a few questions:
 - *Transfer patient to:* select the receiving hospital from the dropdown list.
 - If the receiving hospital is not listed, contact your project manager.
 - *Transfer type:* Indicate if the transfer is a physical transfer (i.e. the patient physically moves between hospitals) or if it is for data entry purposes only (i.e. transfer of eCRF to enable data entry).
 - *Date of physical transfer:* If it was a physical transfer, enter the date & time the patient physically left your ICU.

Transfer participant 0299900070

Transfer participant to:

Transfer type:

Date of physical transfer:

- The receiving site will be notified about the transfer by email and on the Dashboard page. Please contact the receiving site to discuss the REMAP-CAP participant and hand over any relevant information about their participation in REMAP-CAP and their allocated interventions.
- The receiving site needs to **approve** the transfer and enter the date and time the patient arrived at their site.
- This process can be repeated if another physical transfer occurs (e.g. if the patient returns to the initial participating hospital).
- You can also transfer the patient between sites for data entry purposes.
 - Select *“data only transfer”* from the dropdown menu under Transfer Type.
- You cannot enter data in the eCRF when the other site has the patient’s eCRF.
 - On the Patient List, this is also indicated by a red **T** on the left of the Participant Study Number.

9.4. Approve the patient's eCRF transfer

- The receiving site must approve the patient's eCRF transfer before the patients file is displayed.
- To accept a patient transfer, click on the *Patient Study Number (PSN)* in the Pending Transfer table on the [Dashboard](#) or select "[Transfer List](#)" to navigate to the [Transfers](#) page and select the PSN of interest.
- If it is a physical patient transfer, enter the date and time the patient physically arrived in your ICU before clicking on "[Approve Transfer](#)".

Transfer request for participant 0299900070 (Transfer ID 5)

Transfer patient from	02999 - Vulcan
Transfer patient to	02997 - Jupiter
Initiated by	Vanessa S
Initiate Date	12-Aug-2025 23:10
Transfer type	Physical
Physical Arrival Date	13-Jul-2025 14:00
Physical Transfer Date	13-Jul-2025 13:00
Arrival time in ICU	<input style="width: 100%;" type="text" value="13-Jul-2025 14:00"/> ✕ 📅 📌

[Approve Transfer](#)
[Cancel Transfer](#)
[Transfer List](#)

9.5. Requesting the patient's eCRF from another site

- If you need to enter data in the patient eCRF and the patient's eCRF is at the other site, you can request the patients eCRF by:
 - Opening the "[Patient Transfer tab](#)", find the patient in the list of transfers, identify the person at the other site (under "[Initiated](#)" or "[Approved](#)").
 - Send this person an email requesting they transfer the patient's eCRF to your site for Data only.
 - If you have any questions or don't hear back from the other site, contact your project manager.

Transfers Complete											
ID	PARTICIPA...	TYPE	FROM	TO	INITIAT...	INITIAT...	APPRO...	APPRO...	TRANS...	ARIVED	
2	0299900070	Physical	02993A	02999	17-Jul-2025	Vanessa S	12-Aug-2025	Vanessa S	17-Jul-2025	17-Jul-2025	

9.6. Transfer summary page

[Transfers](#) under the Patients tab displays a summary of all patients transferred to or from your site.

Participant Transfers

02999 - Vulcan

Transfers Pending

ID	PARTICIPANT	TYPE	FROM	TO	INITIATED	INITIATED BY
5	0299900070	Physical	02999	02997	12-Aug-2025	Vanessa S
4	0299900072	Physical	02999	02996	12-Aug-2025	Vanessa S

Transfers Complete

ID	PARTICIPANT	TYPE	FROM	TO	INITIATED	INITIATED BY	APPROVED	APPROVED BY	TRANSFERRED	ARRIVED
2	0299900070	Physical	02993A	02999	17-Jul-2025	Vanessa S	12-Aug-2025	Vanessa S	17-Jul-2025	17-Jul-2025
3	0299900071	Physical	02999	02993A	12-Aug-2025	Vanessa S	12-Aug-2025	Vanessa S	18-Jul-2025	18-Aug-2025
1	0299900070	Physical	02999	02993A	17-Jul-2025	Vanessa S	17-Jul-2025	Vanessa S	17-Jul-2025	17-Jul-2025

This includes physical transfers, where the patient is transferred between participating sites, and data-only transfers, where only the participant’s CRF is transferred to another site for completion.

- Patient transfers that are currently pending (e.g. the receiving site hasn’t approved the transfer) are indicated at the top of the page.
- Click on “*Details*” to view the patient transfer request and to approve the transfer.

10. REGISTRY

- In some regions patients who meet Platform eligibility criteria but are not eligible for any domains will be entered into a patient registry.
- A list of all the patients that have entered the registry domain at your site is located under the **Screening List** tab in the *Participants tab*.
- Registry patients will have a **'Registry'** status listed under Outcome column.
- To search for a specific patient, enter the patient's eligibility 6-character alpha code (e.g. AJTGJH) and click **"Search"**.
- To open a registry participant's details, click on a the *Participant eligibility code* to navigate to their result page and select **'Registry Details'**.

The screenshot shows a patient result page for 'AGKVJB' in the 'Registry'. On the left, there is a sidebar with a profile icon and a list of tabs: 'Registry' (selected), 'Demographics', 'Platform Eligibility', 'State', and 'Result'. The main content area is titled 'Result - AGKVJB - Registry' and shows 'Reasons:' with the text 'State age combo not active at site'. A blue button labeled 'Registry Details' is positioned below the reasons.

The screenshot shows the 'Registry Details R-AGKVJB' page. It displays the following information:

Age	31
Sex	Female
Age group	Adult
State	Moderate
Enrolled	13-May-2025 20:54

11. RESOURCES

11.1. *Resources tab*

- All available study resources are provided in the Resources tab of the database.
- Resources include:
 - Protocol documents
 - Case Report Forms
 - Data Completion Guidelines
 - Database User Guide
 - FAQs
 - Co-enrolment guide
 - Study tools
 - Newsletters
- For site specific study tools, speak to Research Coordinators at your site.

12.MANAGE

12.1. User List

- The User List tab lists all of the users at your site.
- It also lists the different user groups (e.g. Research Coordinator or Investigator).
- A filter is provided at the top of the page to allow you to filter the list by “Active Users” and deactivated accounts, termed “Locked out”.

12.2. Interventions

If a study intervention is not available at your site (e.g. the medication is out of stock, or there is a drug shortage), a **Research Coordinator** account can indicate this on the database to prevent randomisation to this intervention until it is available.

- From the **Dashboard**, click on the ‘Manage’ in the navigation tab.
- Click on “Interventions” in the tab below the navigation bar.
- Only the domains and interventions your site is participating in will be displayed. From the list provided in the dropdown list next to the relevant intervention, select “Unavailable”.
- The rest of your research team will be notified via email of this change to the database.
- If your site needs to permanently stop participating in a domain and/or a domain intervention, or if you

INTERVENTION		ADULT <small>PRESENTS 18 YEARS AND OLDER</small>
ZA01 - IV Ceftriaxone + Macrolide		Available
ZA02 - IV Moxifloxacin	IV Moxifloxacin	Available
ZA03 - IV Piperacillin-tazobactam + Macrolide		Available
ZA04 - IV Amoxicillin-clavulanate + Macrolide		Available

would like to open new domains or interventions, email your Project Manager.

12.3. Releases

- The Releases tab will give you information regarding the various changes to the database as the database has been improved or changed.
- We recommend you check this tab occasionally to keep up to date with the changes to the system.
- If you are experiencing a problem with the database or have recommendations on how to make the database more user friendly, please send your feedback to your project manager.

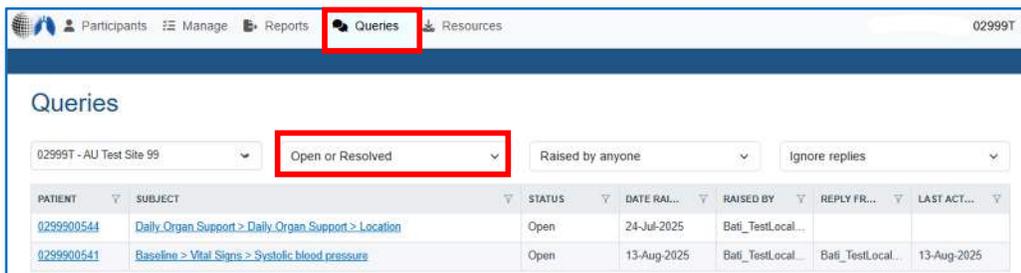
13. MONITORING QUERIES

13.1. Data queries

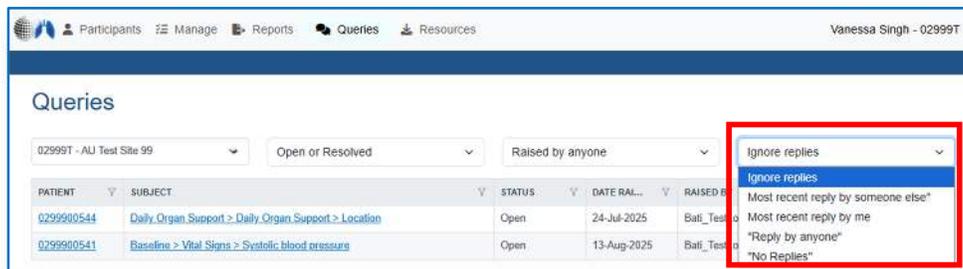
- New data queries are indicated on the dashboard.
- To open the full list of data queries for your site open the Monitoring tab. You can do this by selecting the “Queries tab” on the **Navigation tab** (refer to [Monitoring](#)).

13.2. Data query list

- The Queries tab lists all of the data queries for review.
- The list of Data queries can be sorted by two groups:
 - **Data query status:**
 - Open
 - Resolved
 - Closed
 - Any status



- **Data query replies:**
 - Ignore replies
 - Most recent reply by someone else
 - Most recent reply by me
 - Reply by anyone, etc..



13.2.1. Data query page

- Click on the Participant Study Number to open the patient summary page.
- Click on the “*Variable*” to open the full data query.

PATIENT	SUBJECT	STATUS	DATE RAIS...	RAISED BY	REPLY FR...	LAST ACT...
0299900541	Baseline > Vital Signs > Respiratory rate	Open	13-Aug-2025	Vanessa Singh		

- In the full data query, the name of the person who raised the query will be indicated at the top of the screen.
- Under “*Query*”, a summary of the query will be provided.

Query for participant 0299900541

Site : 02999T - AU Test Site 99 Raised by: 124 Status: Open

Variable Queried: Baseline > Vital Signs > Respiratory rate : 26

Query description
RR value in EMR is 29.

Action request
Please update RR value

Status Open

Replies
Add comment

- Under “*Action request*”, a request made by the person who raised the query regarding how to proceed.

Query for participant 0299900541

Site : 02999T - AU Test Site 99 Raised by: 124 Status: Open

Variable Queried: Baseline > Vital Signs > Respiratory rate : 26

Query description
RR value in EMR is 29.

Action request
Please update RR value

Status Open

Replies
Add comment

- If you have any questions or response to the Action request, click “*Add comment*”. We recommend that you reply indicating that you have updated a variable or if the variable is correct.
- Go to the CRF for the “*Variable queried*” to update the data entered if required.

13.3. Error messages

- Validations are applied to many fields in the database.
- These validations are triggered after data are entered in the eCRF or when the eCRF is saved.
- There are **five types of data validations**:
 - **Not allowed**: the value isn't allowed to be saved. If the value is correct contact your project manager.

- **Amber Validation**: the value is considered abnormal but possible, check the value you entered, if it is correct, confirm the value by ticking the box.

- **Protocol deviation**: the information entered is a protocol deviation, if this occurs please complete the protocol deviation eCRF.

- **eCRF not complete**: if a mandatory question in the eCRF is not entered, the eCRF page will not save. A blue message will be displayed at the top of the form.

- **eCRF form inconsistencies**: if data entered in two different forms do not match (e.g. date of death entered in the SAE eCRF and Discharge eCRF don't match), a yellow error will be displayed on the patient summary page and the patient list.

14.REPORTS

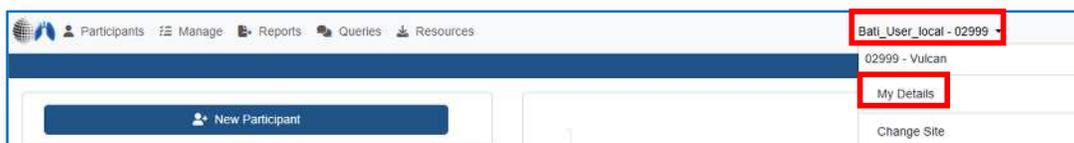
14.1. Reports tab

- Reports are available at a site level to help the site to maintain data quality.

- There are **two types** of reports available:
 - **Query Reports:** displayed in a web browser, or can be downloaded by clicking “export results” once the report has loaded in your browser
 - **Direct Data Exports:** downloaded as a CSV or Excel file
- To access reports or exports that have been downloaded, use the “**My Downloads**” tab. This will display a list of reports or exports that have been generated for download, as well as the date it was last generated and the size of the file.

15.ACCOUNT PROFILE

- Individual accounts (e.g. Research Coordinator and Investigator) can update their passwords and manage their account settings via the Profile.
- From the dashboard page, navigate to the top right-hand corner where you will see your site name, click on the icon and select “*My Details*” from the dropdown menu.



- An individual can edit the following settings:
 - User information
 - Email notifications
 - Change photo
 - Change password
- If you have access to more than one location (e.g. for Research Coordinators that work in more than one hospital), you will be able to change your location via this menu.



15.1.1. User information

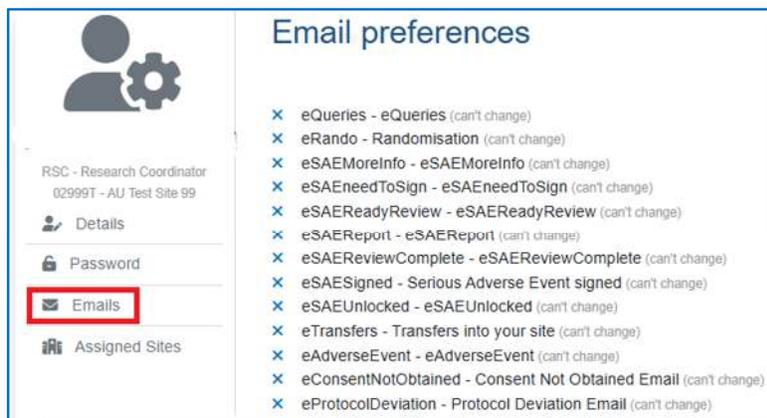
- When you select “*My Details*” the User Info page will automatically load.
- On the User Info page, you can edit:
 - Full name
 - Email address (username)
 - Export format (whether exports are downloaded as CSV or Excel files)

- Users cannot edit their own:
 - Account Location
 - User Group (account type)



15.1.2. Email notifications

- Users may receive a variety of automated notification emails from the database.
- Click on “*Email*” tab to load the email notification settings associated with your account type.
- When your account is created, you will be setup to receive all available email notifications.



Individual emails

Email notifications are sent to appropriate user groups when:

- Patient randomised – a patient is successfully randomised.
- Patient queries and replies – a query is raised or responded to.
- SAE reported /SAE needs signing / SAE has been signed off – an SAE is reported/needs signing or when an SAE has been signed off.
- Consent Revoked – a patient consent is revoked via the consent CRF.
- AE or PD added – an AE or PD is added via the summary page.
- Transfers – a patient transfer is submitted via the summary page.

Email reminders

Pending domains

- A patient randomised to a domain and allocation status has not been [revealed](#).

Temporarily unavailable intervention

- If an intervention is not available at your site temporarily, please indicate this on the study database. Randomisation to this option will be turned off.
- If an intervention is indicated as temporarily unavailable, a reminder will be sent daily reminding sites to check the intervention's availability and to update the database.

Weekly email

Day 90 and Day 180 Follow-up

- Follow-ups due this week
- Follow-ups not yet entered on the database

15.1.3. Change password

An individual account can change their password at any time from the Profile page by clicking on "[Password](#)".

A new page will load requesting a new password and for you to confirm the password. The password policy applies to all passwords (refer to [Password Policy](#)).

16.TROUBLESHOOTING

1. It says my username is wrong, I am SURE that it is right. Why can't I login?

Try [resetting your password](#) or contact your research coordinator and/or project manager.

2. I got the hospital admission time wrong and randomised my patient. How do I fix it?

Enter the correct hospital admission time in the [Patient Summary page](#). If the patient wasn't eligible for randomisation complete a [Platform Protocol Deviation eCRF](#).

3. I finished the form, but it is not ticked green. What's going on?

You have queries outstanding or you have missed a data point. Please go back and check points on the form. On rare occasions, this is a database glitch due to recent updates.

4. I have checked the data completion guidelines, but I still do not know how to answer a question. What can I do?

Discuss the question with another member of your research team or your project manager.

5. How do I check which domains & interventions my patient is randomised to?

Refer to [Randomisation allocation](#) in this document.