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REMAP-CAP
Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia

SPIRAL DATABASE USER GUIDE

REMAP-CAP Spiral Database User Guide Version 3.0 dated 6th September 2023

https://remapcap.spinnakersoftware.com

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1. CONTACT DETAILS

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2. INTRODUCTION

2.1. Purpose of this document

The purpose of this document is to provide instructions on the functionalities of the 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.

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

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.

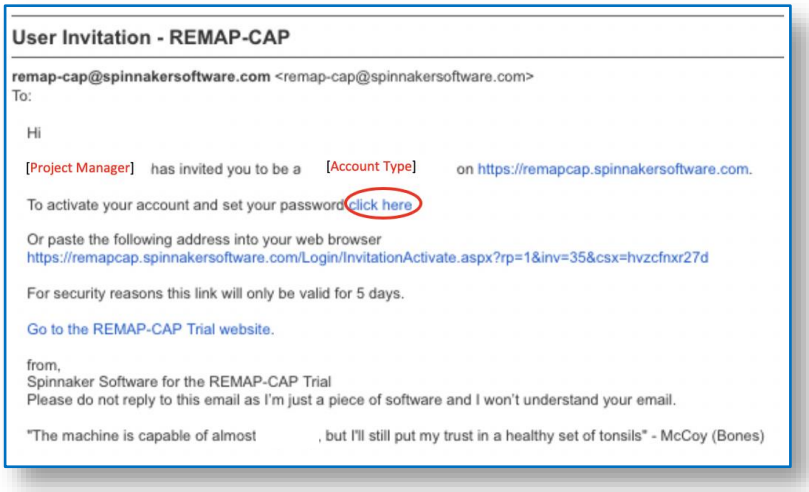
1. *Randomisation User account*
   - Able to access the randomisation function only
   - Account is set up and managed by the Regional Project Manager
   - Ideal for site staff who are not part of the core research team, for example clinicians who want to screen and randomise a patient out-of-hours
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


User Invitation - REMAP-CAP

remap-cap@spinnakersoftware.com <remap-cap@spinnakersoftware.com>
To:

Hi

[Project Manager] has invited you to be a [Account Type] on https://remapcap.spinnakersoftware.com.

To activate your account and set your password click here

Or paste the following address into your web browser
https://remapcap.spinnakersoftware.com/Login/InvitationActivate.aspx?rp=1&inv=35&csx=hvzcfnxr27d

For security reasons this link will only be valid for 5 days.

Go to the REMAP-CAP Trial website.

from,
Spinnaker Software for the REMAP-CAP Trial
Please do not reply to this email as I'm just a piece of software and I won't understand your email.

"The machine is capable of almost , but I'll still put my trust in a healthy set of tonsils" - McCoy (Bones)

3.3. Password policy

Passwords must contain:

- At least 6 characters

- 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:

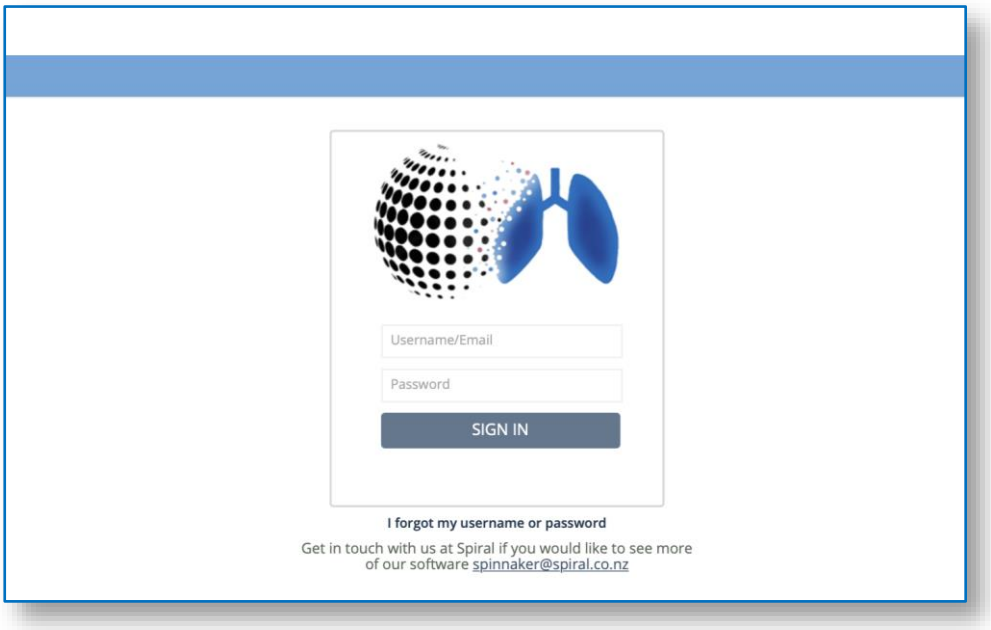
- Use a password manager to generate and store passwords
- Change your passwords regularly
- Choose a password by combining 5 or more random common words (e.g. correct horse battery staple home, password is = *correcthorsebatterystaplehome*).

⚠ **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

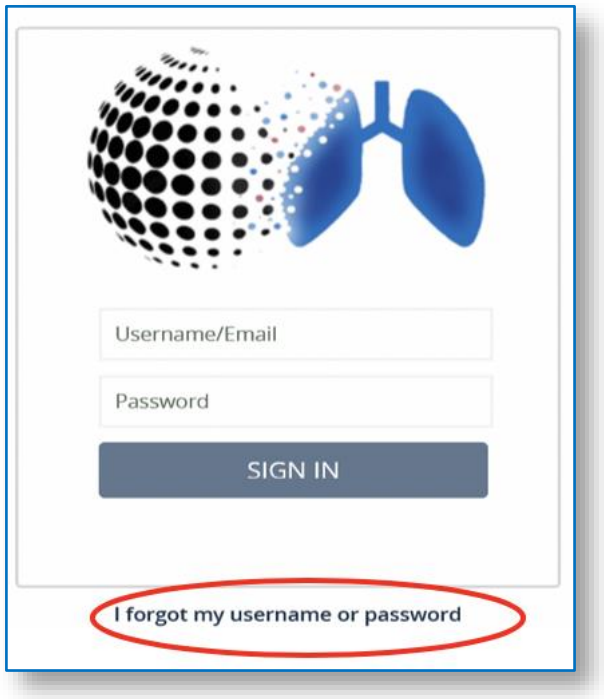
You can access the REMAP-CAP website at the following address:



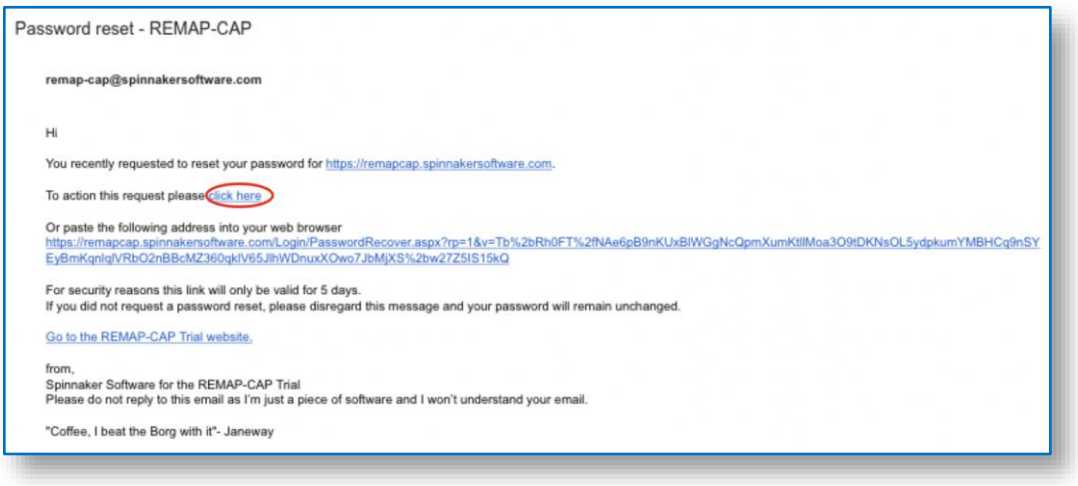
https://remapcap.spinnakersoftware.com

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.
- 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

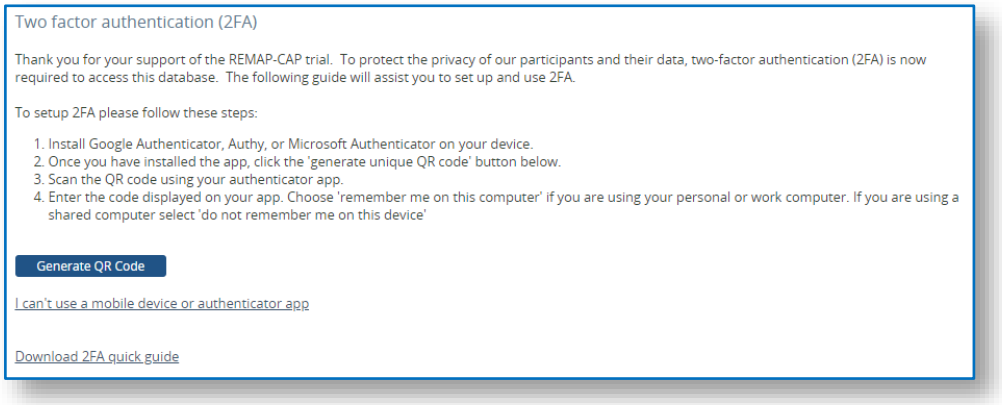
- Two-Factor Authentication (2FA) is an additional layer of security that helps safeguard your online accounts by requiring two forms of identification before granting access. In addition to your username and password a second form of identification, usually a unique code, is needed to verify your identity.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

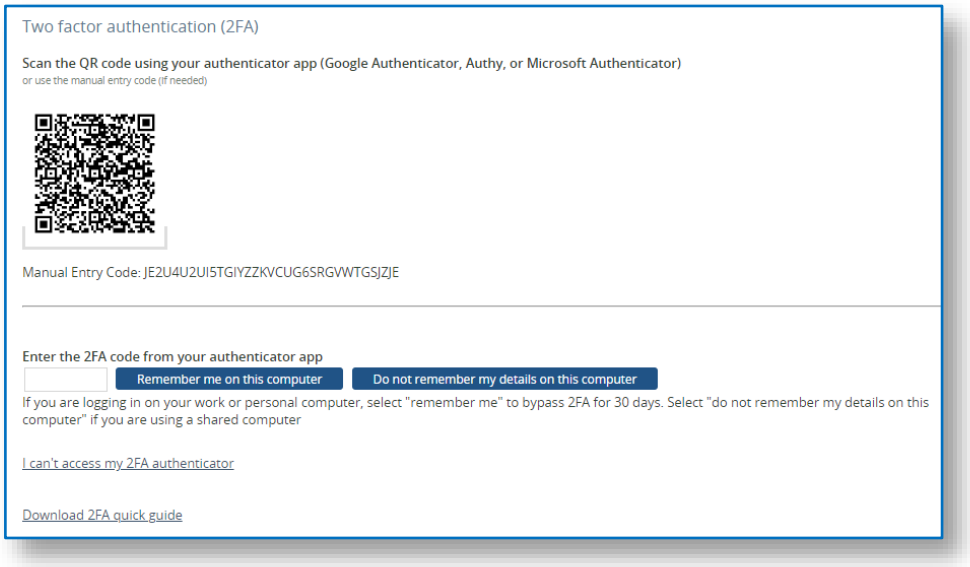
- The following apps can be used for two-factor authentication in the REMAP-CAP database:
  - Google Authenticator
  - Microsoft Authenticator
  - Twilio Authy
- On your smartphone or tablet, search for your preferred application (e.g., "Google Authenticator") in your device's app store, and download 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

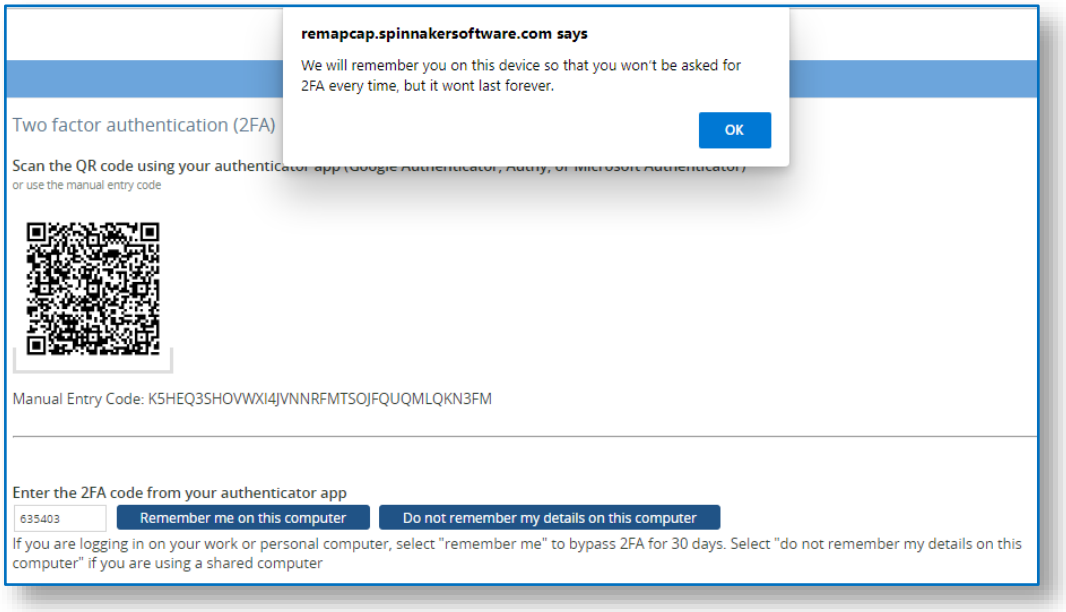
- Log in to your REMAP-CAP Trial account using your usual username and password.
- The 2FA set up page will display. Throughout the 2FA set up process a link to download a *2FA quick guide* will be available on each page. It also outlines the steps to take if your 2FA is not functioning correctly.
-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



- 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.

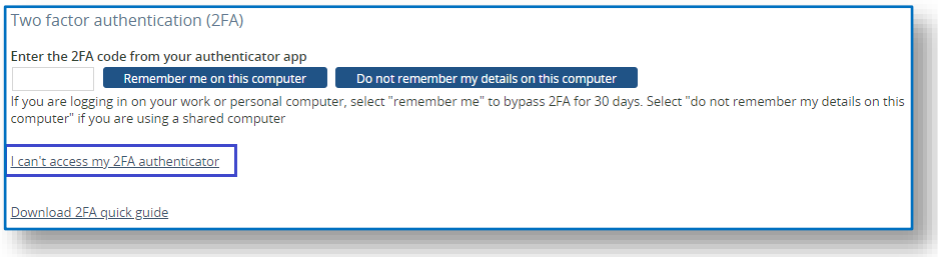


- Once you have entered the code, the REMAP-CAP Trial website will confirm successful setup.
- Your authenticator app will generate a new six-digit code every 30 seconds. When prompted for the authentication code during future login attempts, open the authenticator app and enter the most recent code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

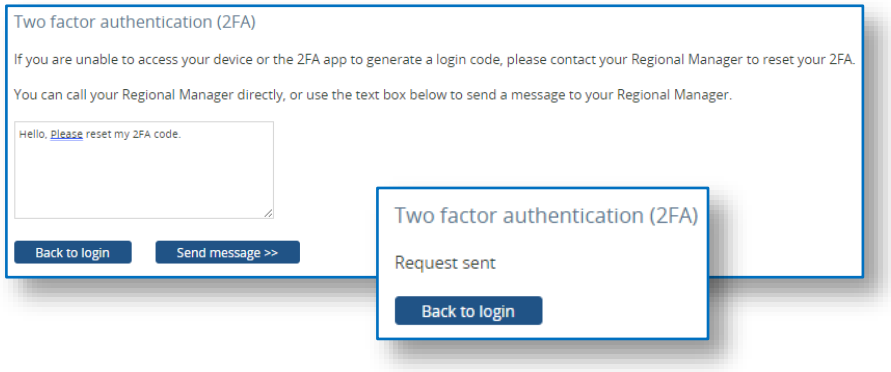
Resetting your 2FA codes

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:

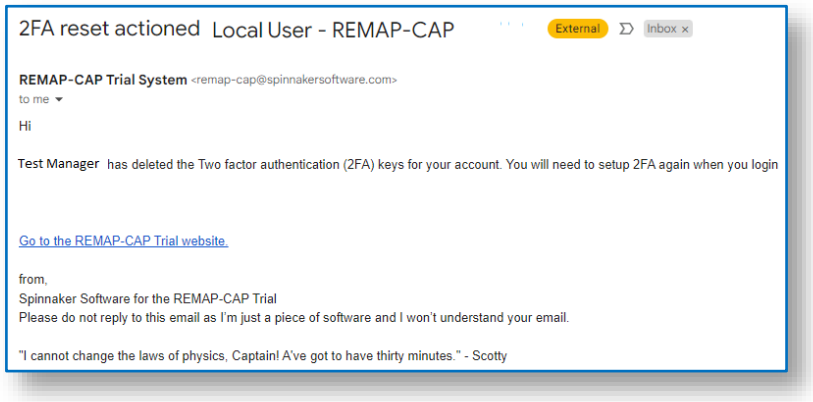
- After logging in to the REMAP-CAP Trial database, the ***Two-factor authentication (2FA)*** page will display. Click *I can't access my 2FA authenticator.*



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



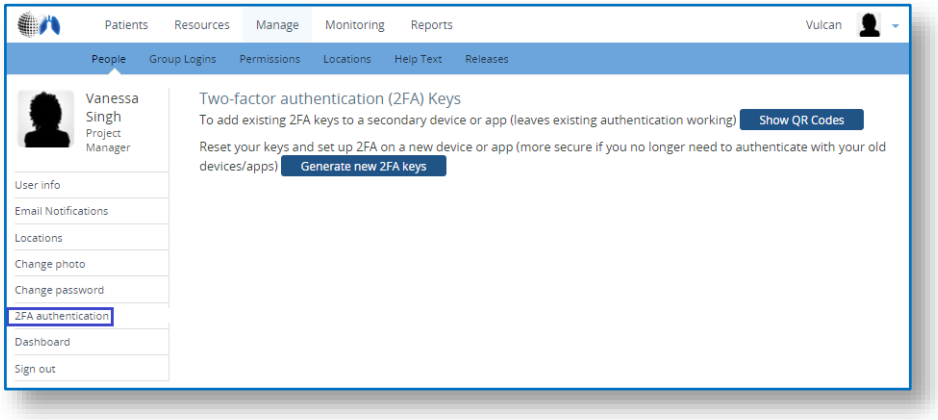
- You will receive a notification via email once your request is actioned by your regional manager.



2FA set up on a secondary device

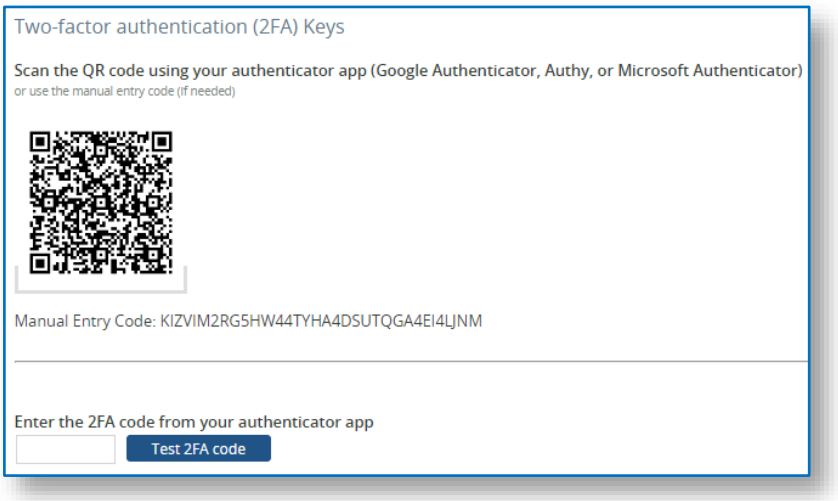
You can set up 2FA on another device. For example, on another phone or tablet.

- Go to your *My Profile* 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 ten distinctive sections:

1. Navigation bar
2. "Add patient" button
3. "Print site-specific eligibility checklist or blank CRF" function
4. Eligibility-pending patients
5. Reveal pending patients
6. Transfers pending
7. Alerts
8. List of patients recently randomised at your site
9. Graph of total enrolments at all sites
10. Open queries

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

1. Navigation bar
2. "Add patient" button
3. "Print site-specific eligibility checklist or blank CRF" function
4. Eligibility-pending patients
5. Reveal pending patients
6. Transfers pending
7. Alerts
8. List of patients recently randomised at your site
9. Graph of total enrolments at all sites.

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

1. Navigation bar
2. "Add patient" button
3. "Print site-specific eligibility or blank CRF" function
4. Eligibility-pending patients
5. Transfers pending
6. Reveal pending patients
7. Alerts
8. List of patients recently randomised at your site
9. Graph of total enrolments at all sites.
10. Open queries

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 nine distinctive sections:

1. Navigation bar
2. "Print site-specific eligibility checklist or blank CRF" function
3. Eligibility-pending patients
4. Reveal pending patients
5. Transfers pending
6. Alerts
7. List of patients recently randomised at your site
8. Graph of total enrolments at all sites
9. Open queries

4.1. Navigation bar

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

4.1.1. 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.

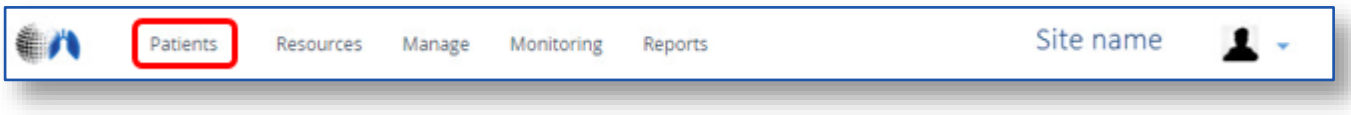
Clicking the arrow on the right of the site name will reveal a menu that will allow you to view or edit your profile, change location (if you have access to more than one location), or sign out.

4.1.2. 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.

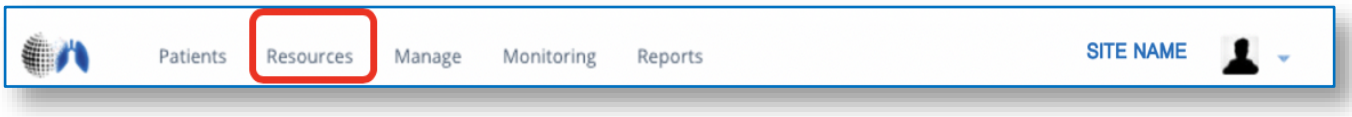
4.1.3. Patients

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 **Patients** in the navigation tab at the top of the screen (refer to Patient List).



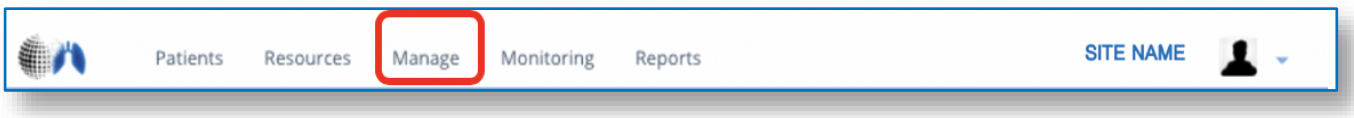
4.1.4. Resources

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



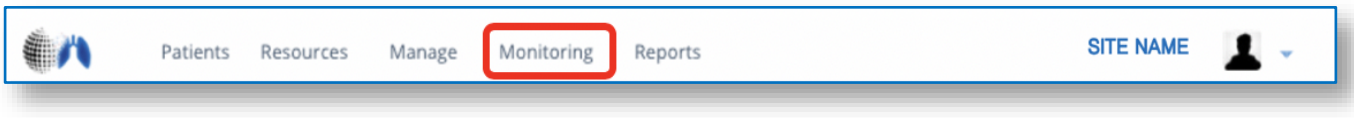
4.1.5. Manage

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).



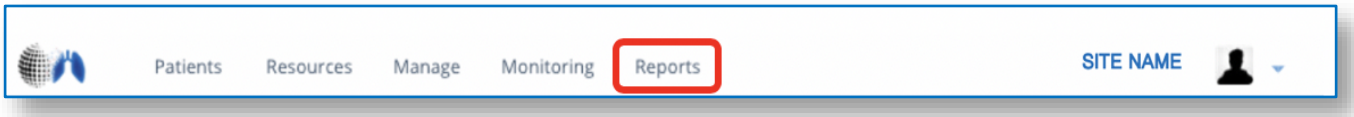
4.1.6. Monitoring

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



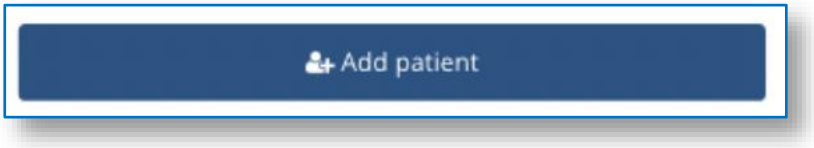
4.1.7. Reports

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).



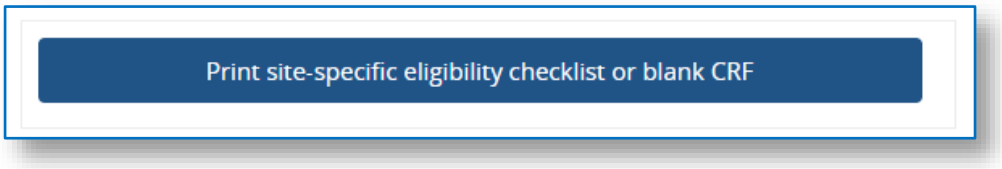
4.2. Add patient

To randomise a patient, click on the "*Add patient*" 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 account.

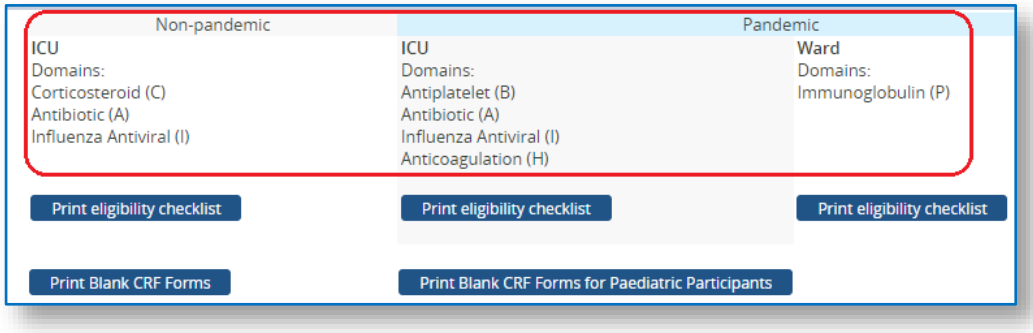


4.3. Printing a site-specific eligibility checklist or blank CRF

To print a blank CRF or eligibility checklist that is specific to the domains and interventions that are available at your site, click on the "*Print site-specific eligibility checklist or blank CRF*" button near the top of the dashboard.



Clicking this button will take you to another page which will display the domains that are active in each Stratum and State at your site.

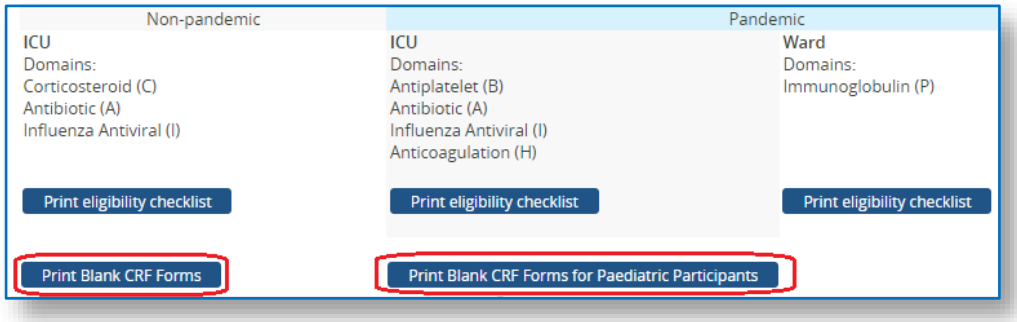


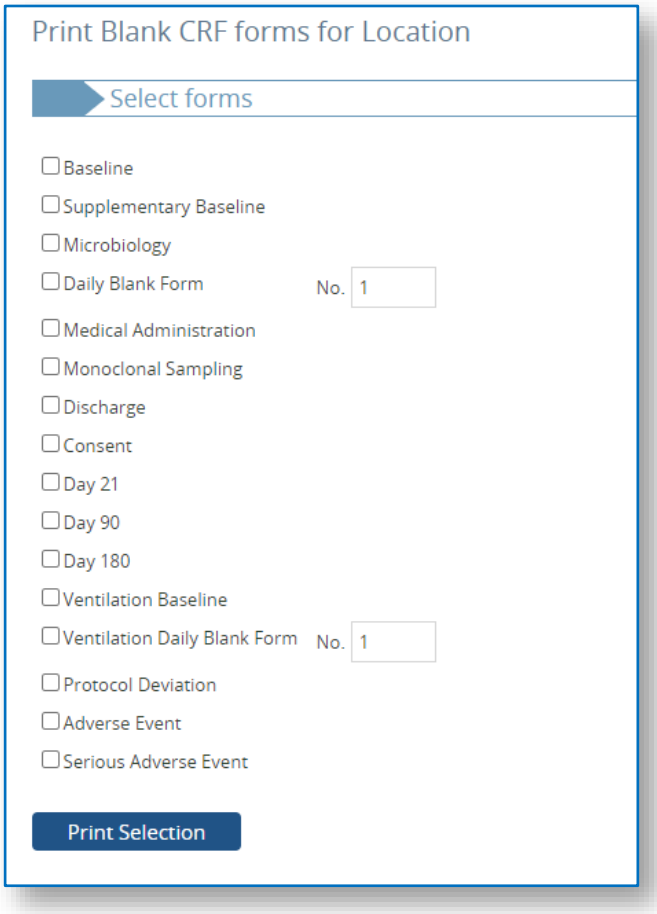
4.3.1. Print site-specific eligibility checklist

To print an eligibility checklist, click the "*Print eligibility checklist*" button under the appropriate Stratum for the patient you wish to screen for eligibility (e.g. if the patient has suspected or proven pandemic infection, click the button under the 'pandemic' column).

4.3.2. Print site-specific blank CRF

To print a blank CRF that is specific to the domains and interventions that are active at your site, click the "*Print blank CRF*" button. Clicking this button will open a new window, which will allow you to select which forms of the CRF to print. You may also see a separate button to "*Print Blank CRF Forms for Paediatric Participants*". This is only applicable if your site is enrolling paediatric participants.



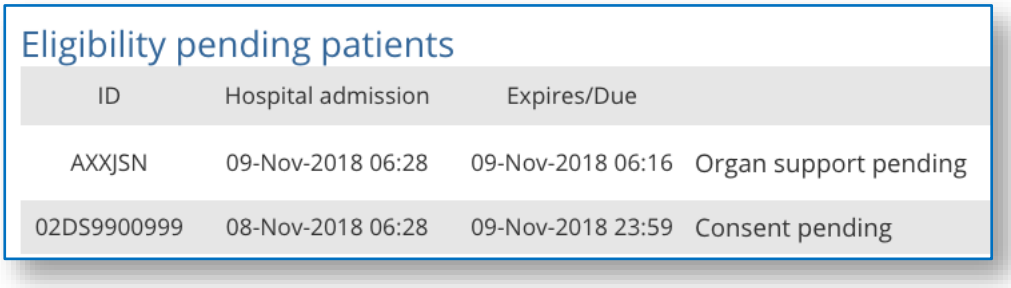


Select the forms you wish to print and click "*Print selection*".

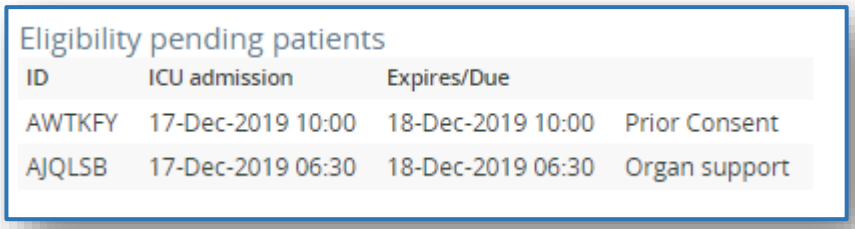
You can print a patient-specific blank daily CRF from the Patient Summary Page.

4.4. *Eligibility pending*

- If there are incomplete eligibility assessments for patients at your site ("***Eligibility pending*** patients"), these will appear on the dashboard.
- Eligibility pending patients are patients who have had an eligibility assessment commenced but this form is not yet completed. Both patients requiring confirmation of ICU organ support ("organ support pending") and patients requiring confirmation of consent prior to randomisation ("prior consent pending") are located here.

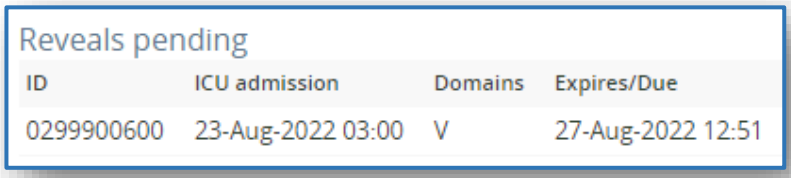


- To update eligibility on these patients, click on the *ID* and refer to Eligibility pending for more information.



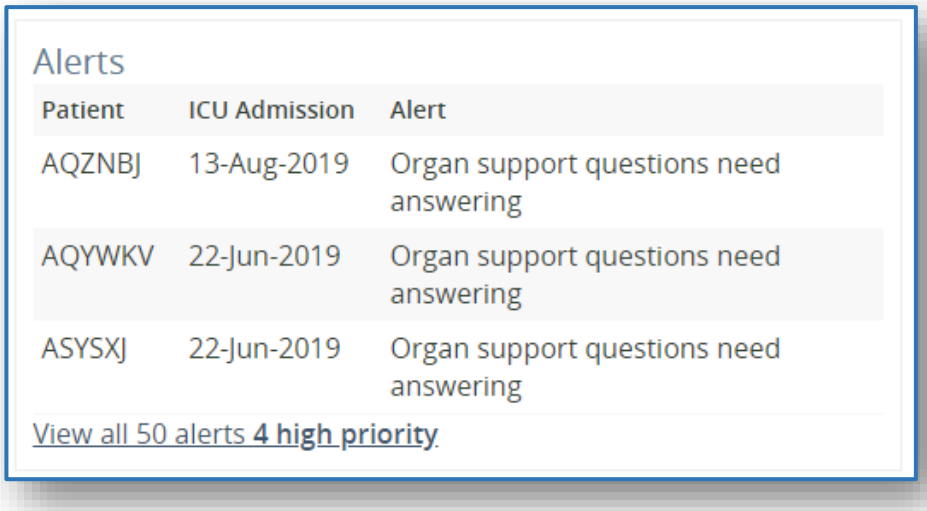
4.5. Reveal pending patients

- For some 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.



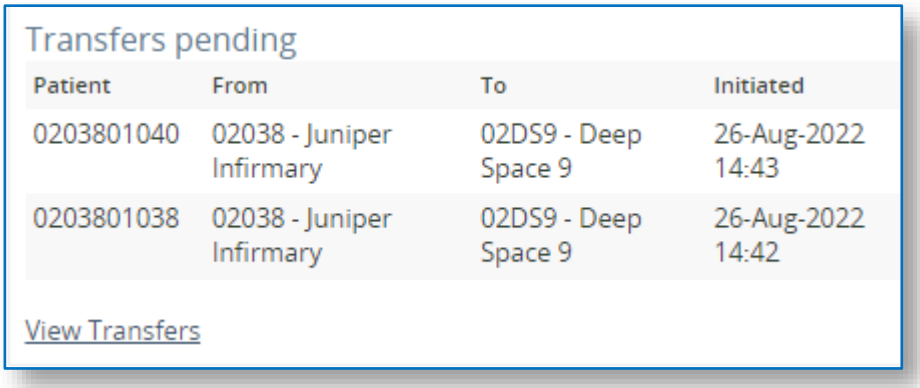
4.6. Alerts

- A list of alerts appears on the dashboard. These include any items that require action from site users. Examples of alerts include:
  - Where consent has been revoked
  - Where the eligibility CRF is incomplete
  - Where conflicting data has been entered
- Click on the *participant study number* to view the participant's CRFs, click the *Alert* description to view the relevant CRF, or click the link at the bottom of this section to view all alerts.



4.7. Transfers pending

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



- Click on the *participant study number* to navigate to that participant's patient summary page.
- Click on the "*View Transfers*" to navigate to the Transfer tab.
- To approve the patient transfer, refer to the Patient 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 patient's summary page.
- To search for a specific participant, enter their participant study number and click "***Find patient***", the Patient Summary Page for this patient will load automatically (refer to Patient Summary Page).

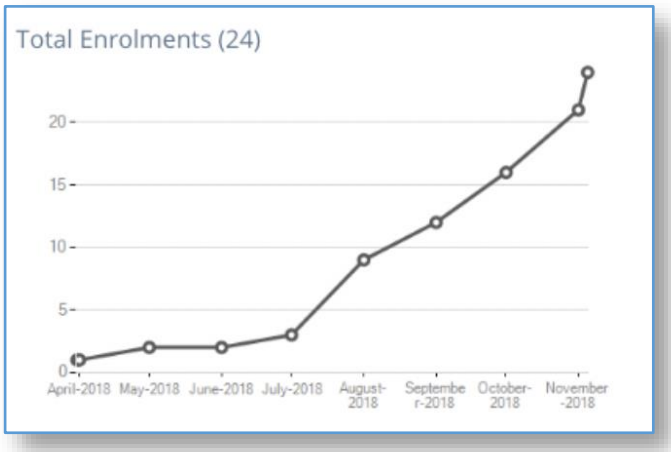
Patients randomised at Site Name

Participant Study Number Find patient

Patient	Initials	Day	Randomised
02DS900378	GHO	1	05-Nov-2018
02DS900377	GHO	2	04-Nov-2018
02DS900376	GHO	3	03-Nov-2018
02DS900375	GHO	4	02-Nov-2018
02DS900374	GHO	5	01-Nov-2018
02DS900373	GHO	6	31-Oct-2018
02DS900372	GHO	7	30-Oct-2018
02DS900371	GHO	8	29-Oct-2018
02DS900370	GHO	9	28-Oct-2018
02DS900369	GHO	10	27-Oct-2018

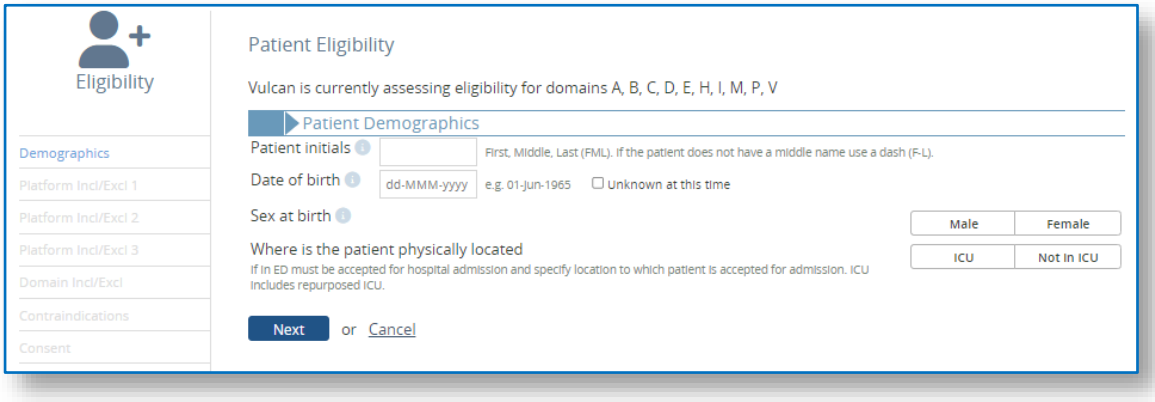
4.9. Enrolment graph

A participant recruitment graph indicates total ***REMAP-CAP recruitment*** at all sites 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, interventions, and stratum that are active at your site at the time of the eligibility assessment.
- The domain codes listed above the 'Patient Demographics' heading indicates what domains are active at your site.
- All of the questions on each page must be answered before clicking on "*Next*" to load the next page.
- The database reviews eligibility after every page (when you click "*Next*") to avoid unnecessary data entry.
- The database will inform the user if the patient is no longer eligible. At the bottom of the page click on the "*Next*" button.
- If you click on the "*Cancel*" button, the information entered in the eCRF up to this point will NOT be saved.



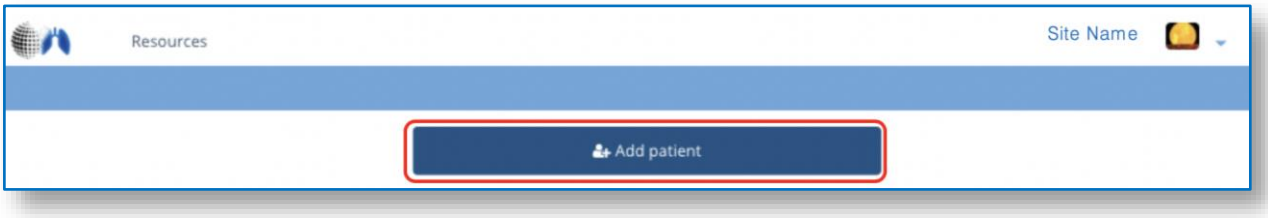
- You can go back to check previously answered questions or change answers at any time by selecting the relevant Eligibility Page on the Eligibility Page Navigation Tab.

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.

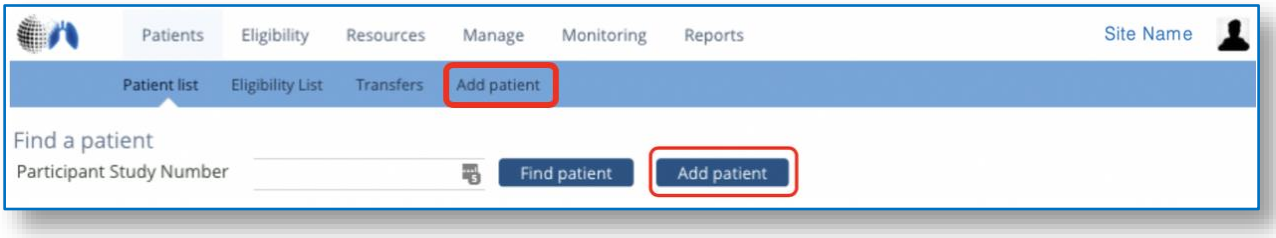
5.1. Enter a new patient

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 "*Add Patient*"



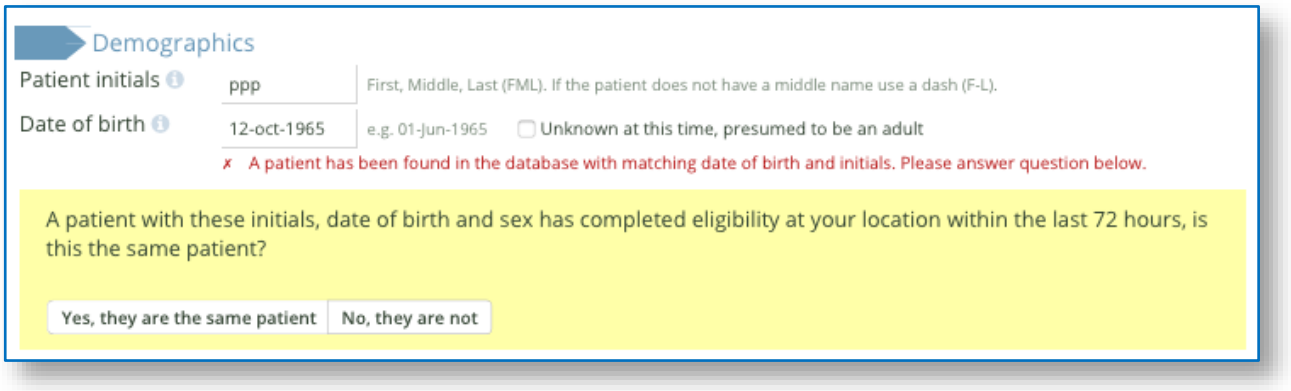
2. On the **Patients** page to randomise a patient, click on "*Add Patient*" either on the page or click on the "*Add Patient tab*".



5.2. Duplicate Patient

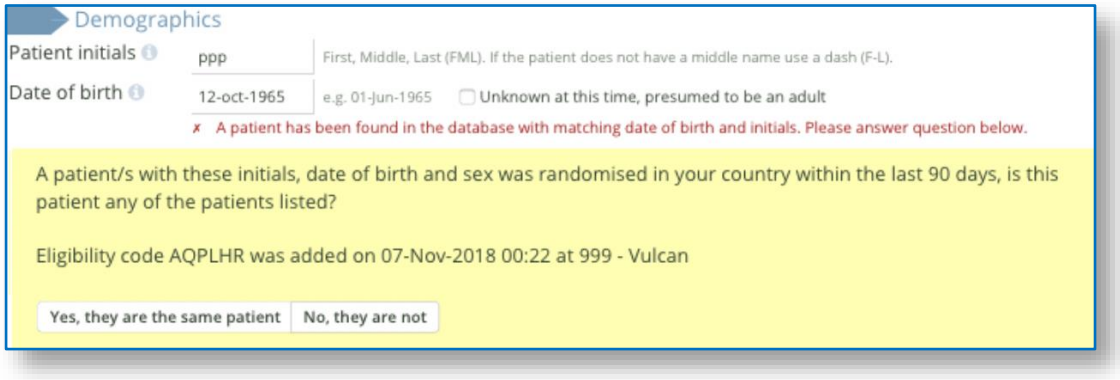
5.2.1. Duplicate patient within the last 72 hours at your site

- If you attempt to randomise a patient with the same initials, date of birth and sex at birth at your site within 72 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 72 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 within the last 90 days at any site located in your country, 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 eligibility code (NOTE: this is not the same as the participant study number)
- We recommend you contact the site listed, check the patient's medical record or ask the patient and/or a family member if the patient was admitted to the other hospital in the last 90 days.
- 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 override a duplicate patient alert.

5.2.3. Override duplicate patient

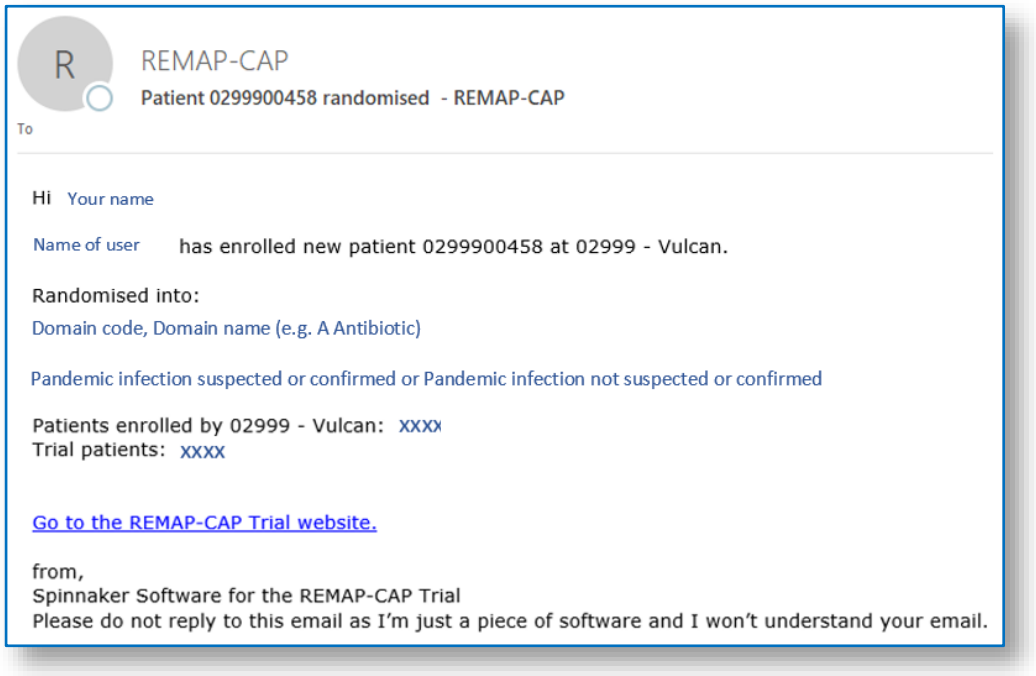
- A Research Coordinator account must be used to override duplicate patient alerts.
- Select "*Add Patient*" on the Dashboard or Patients page.
- Enter the patient demographics.

- 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, they are the same patient*".
    - If the patient has **not** been enrolled in the study before, select "*No, they are not*"

  Continue answering the eligibility assessment questions.

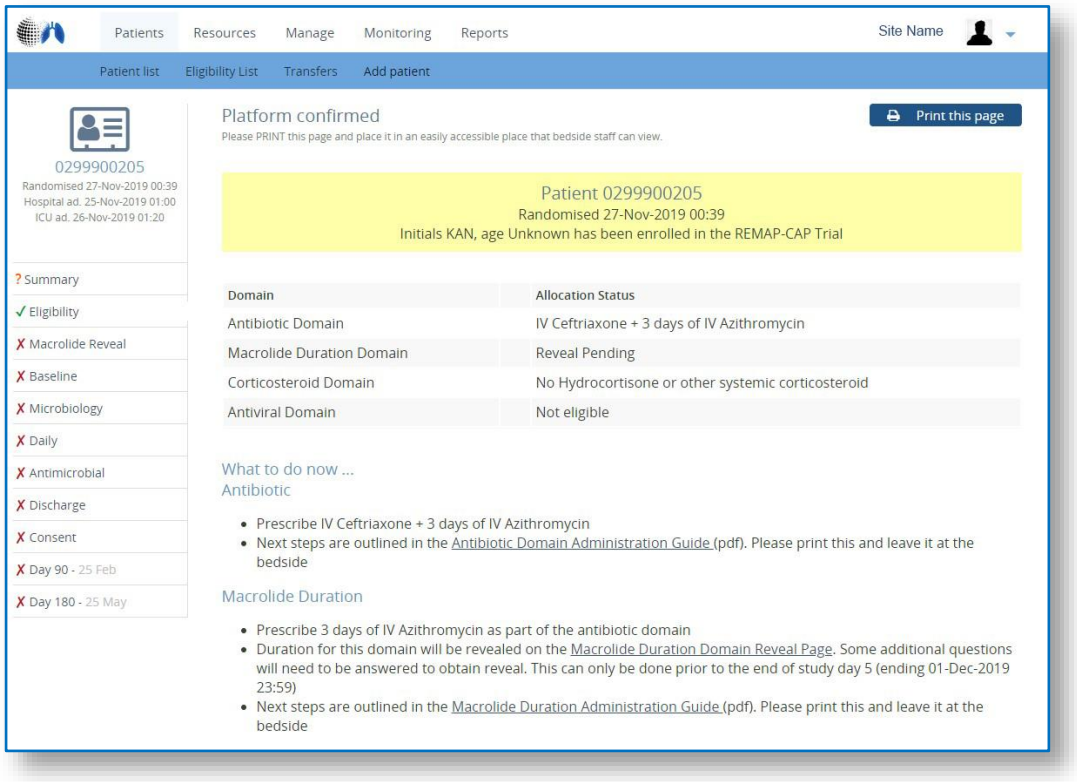
5.2.4. Randomisation email

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).

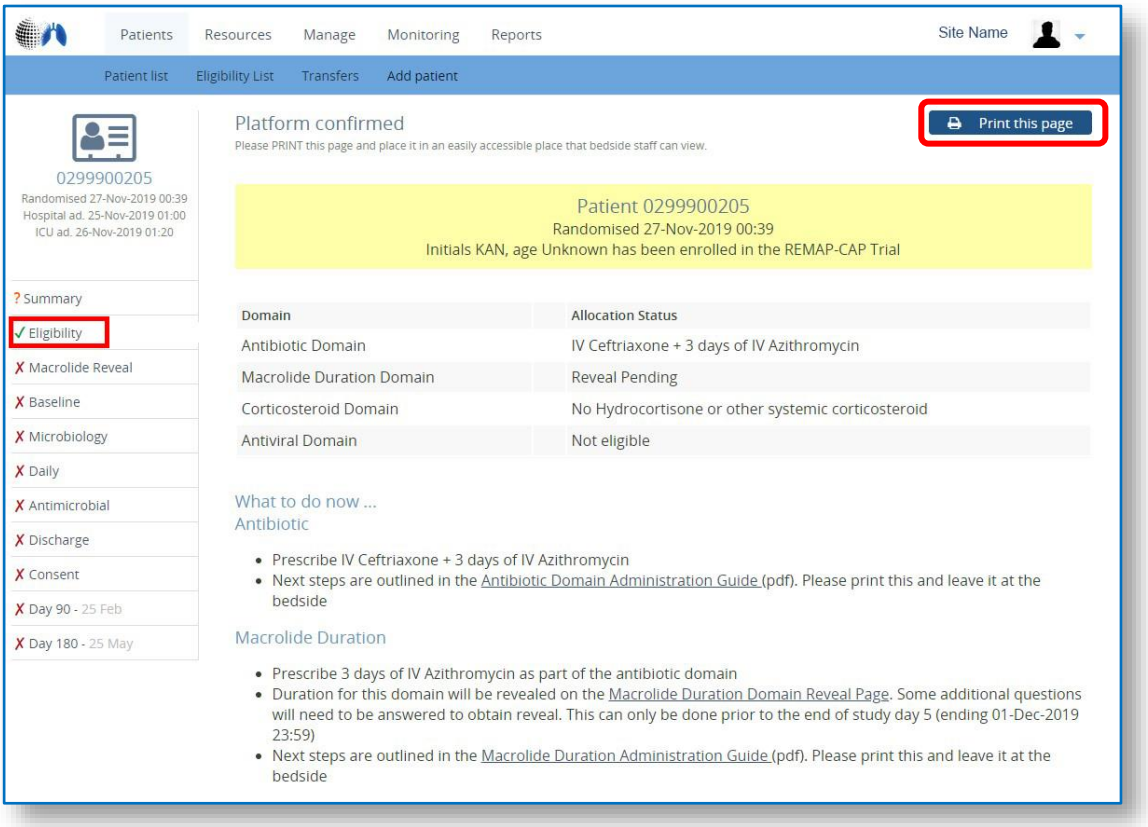


5.3. Randomisation Allocation

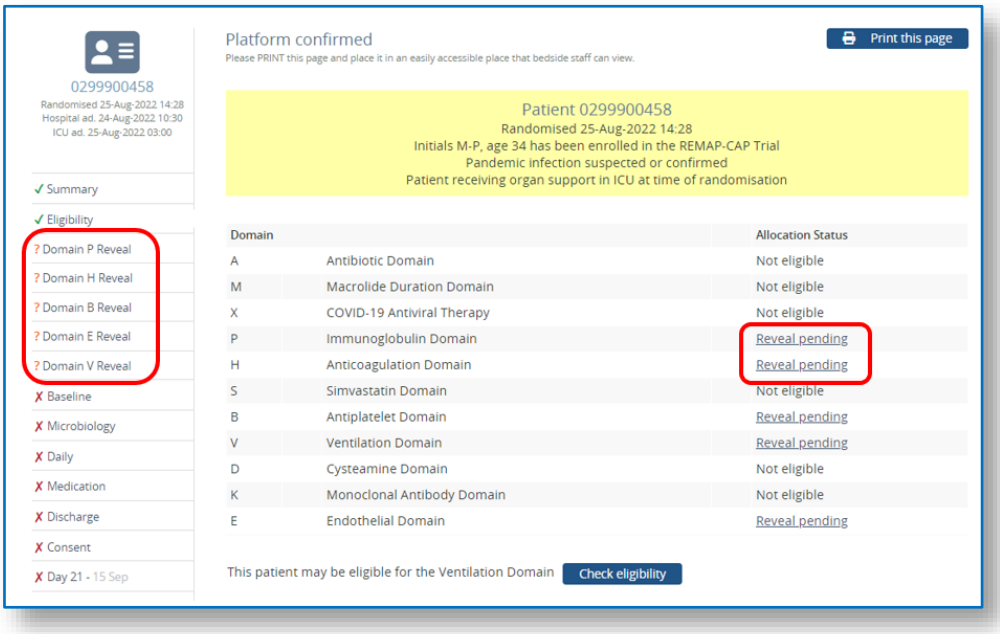
- Once all of the eligibility questions have been answered and the patient's eligibility is confirmed, you will be taken to a new page confirming that the patient has been randomised and outlining which domain interventions that patient has been allocated to.
- A randomisation confirmation email will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



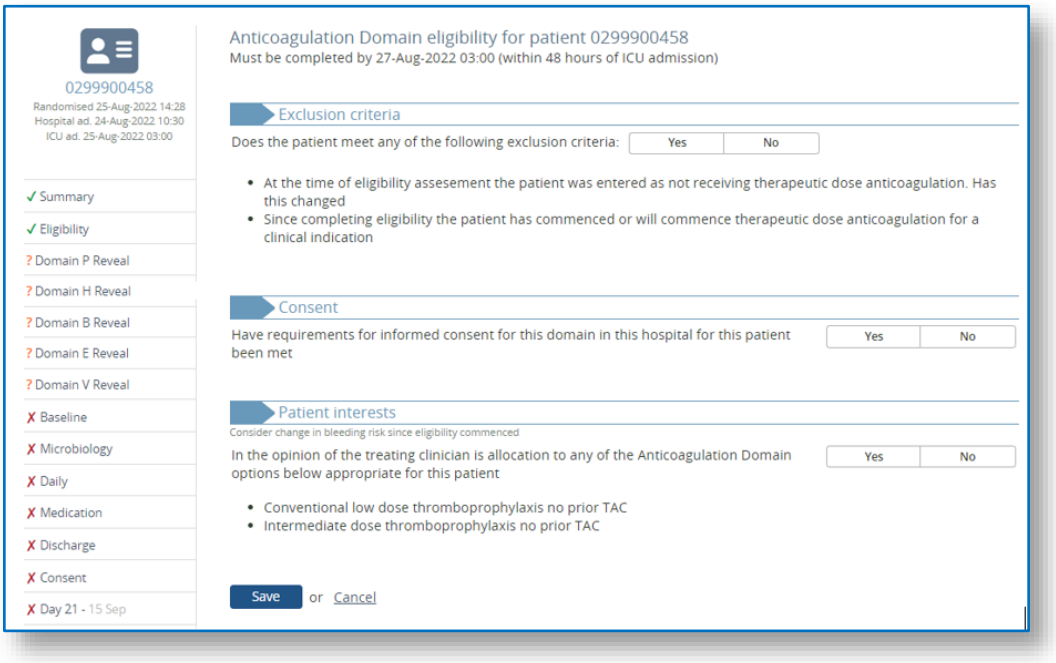
- Please print the randomization page for the patients' medical records, a "*Print this page*" button is located at the top of the page.



- 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 "*Patient 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 Reveal*", and provide links to Reveal forms for each domain.



- 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.

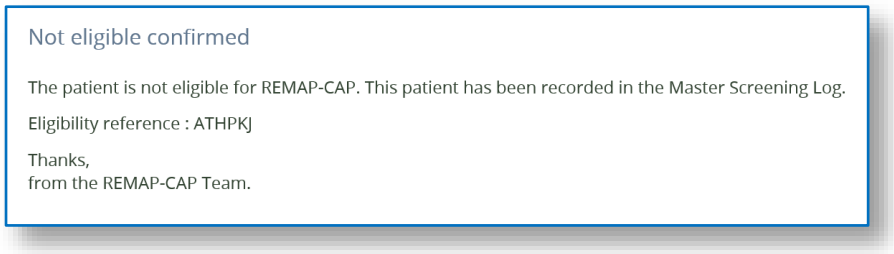


- For domain-specific pending reveal information refer to the REMAP-CAP Data Completion Guidelines.

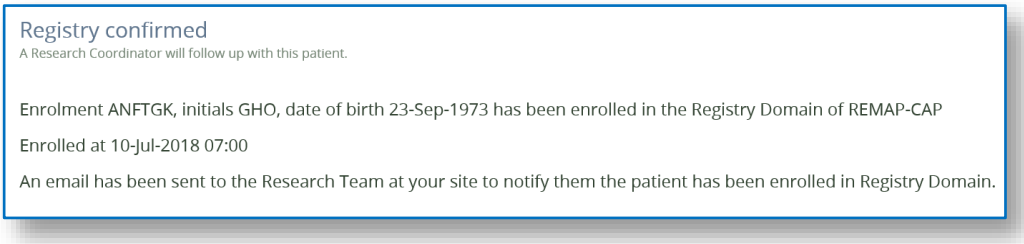
5.4. Eligibility Outcomes

There are four **Eligibility Outcomes**:

1. ***Not Eligible***: This patient does not meet platform eligibility criteria and are added to the list of patients who were screened and not eligible.

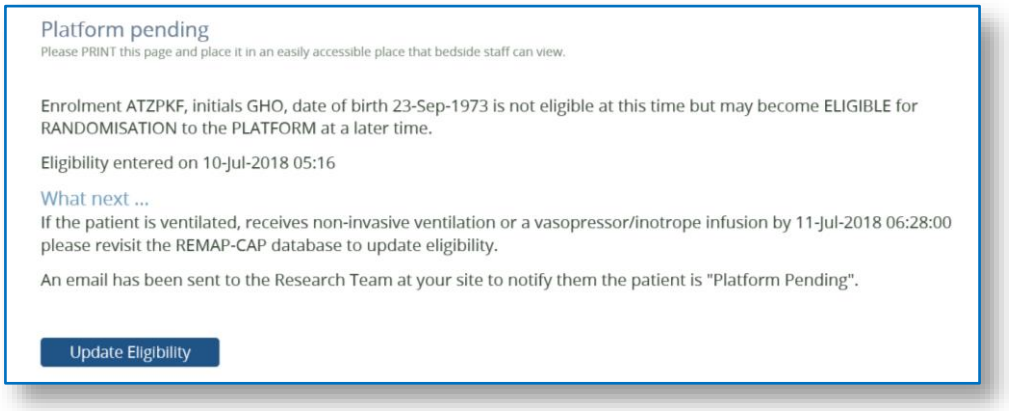


2. ***Registry confirmed:*** This patient does meet platform eligibility criteria but is not eligible for randomisation. This may occur when a patient is eligible for the platform, but is not eligible for randomisation to any available domains.



3. ***Eligibility 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).



- The two eligibility pending categories are:

  3.1. *Organ Support Pending*: The patient is not receiving qualifying organ failure support, and requires this before they are eligible for the platform. Note that ICU organ failure support is not required for eligibility for the Moderate State of the Pandemic Infection Suspected or Proven (PISOP) strata. The eCRF can be updated when/if organ support is required.

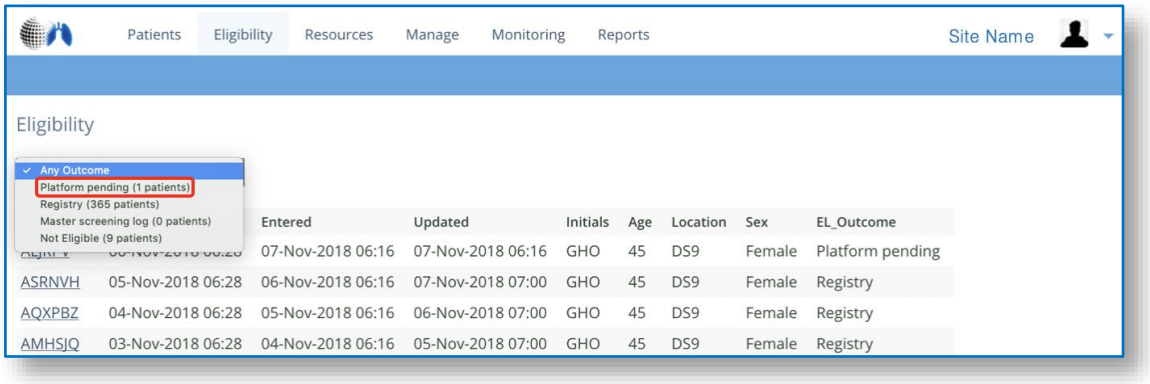
  3.2. *Consent Pending*: The patient was indicated as capable of providing informed consent prior to randomisation, or prospective consent from the patient or their representative is required prior to randomisation. The eCRF can be updated once a consent discussion has occurred, whether consent has been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

4. ***Platform Confirmed*** (Randomised or Enrolled): This patient has been randomised and has received an allocation to one or more domains.

   4.1. ***Registry Pending:*** This patient has been randomised and has received an allocation in a domain, however further information is required before their allocation can be revealed.

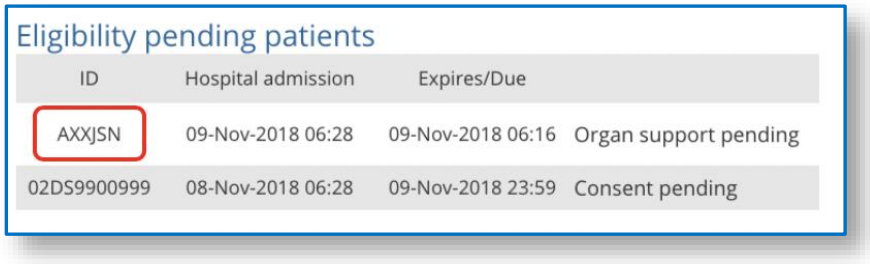
5.5. Eligibility pending patients

- To view patients that are currently in the "Eligibility pending" patient list, go to the Eligibility Pending section of the Dashboard page.
- The list of Eligibility pending patients is also located on the *Eligibility List Tab* of the *Patients* page.
    - Select "*Platform pending*" from the dropdown list to display only the current Eligibility pending patients.

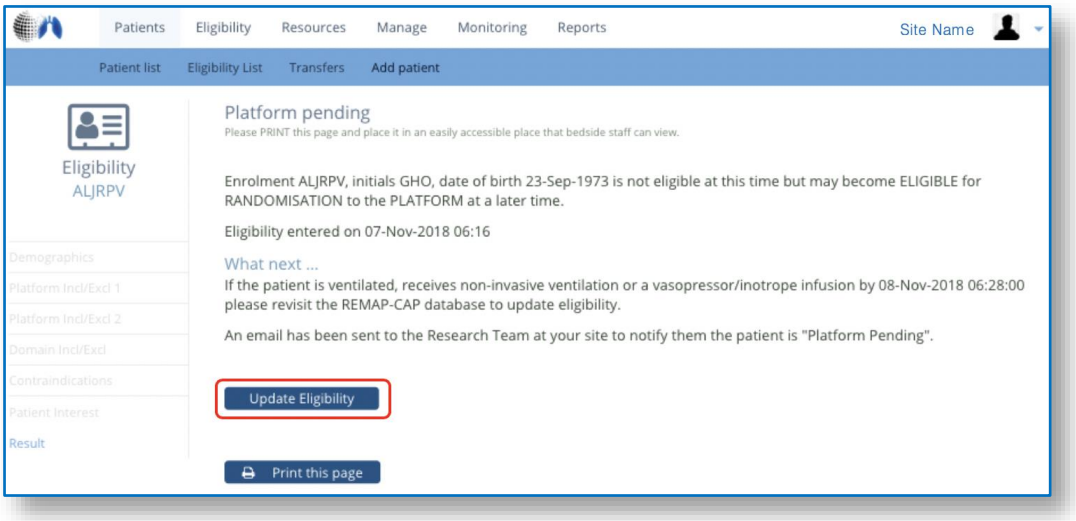


5.5.1. Update eligibility assessment for Eligibility pending patients

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

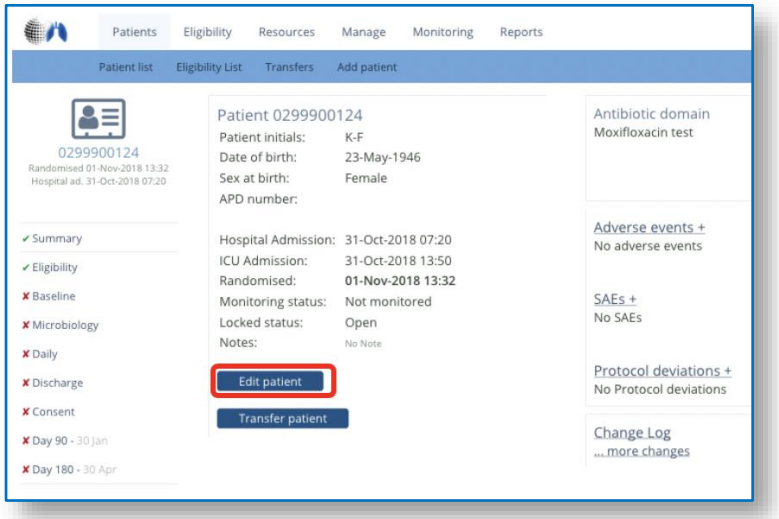


- A new page will load, providing a summary of why the patient was not randomised previously.
- To update the patient's eligibility assessment check click "*Update Eligibility*".
- The system will open to the last saved page of the eCRF before they were assigned to the eligibility pending category.



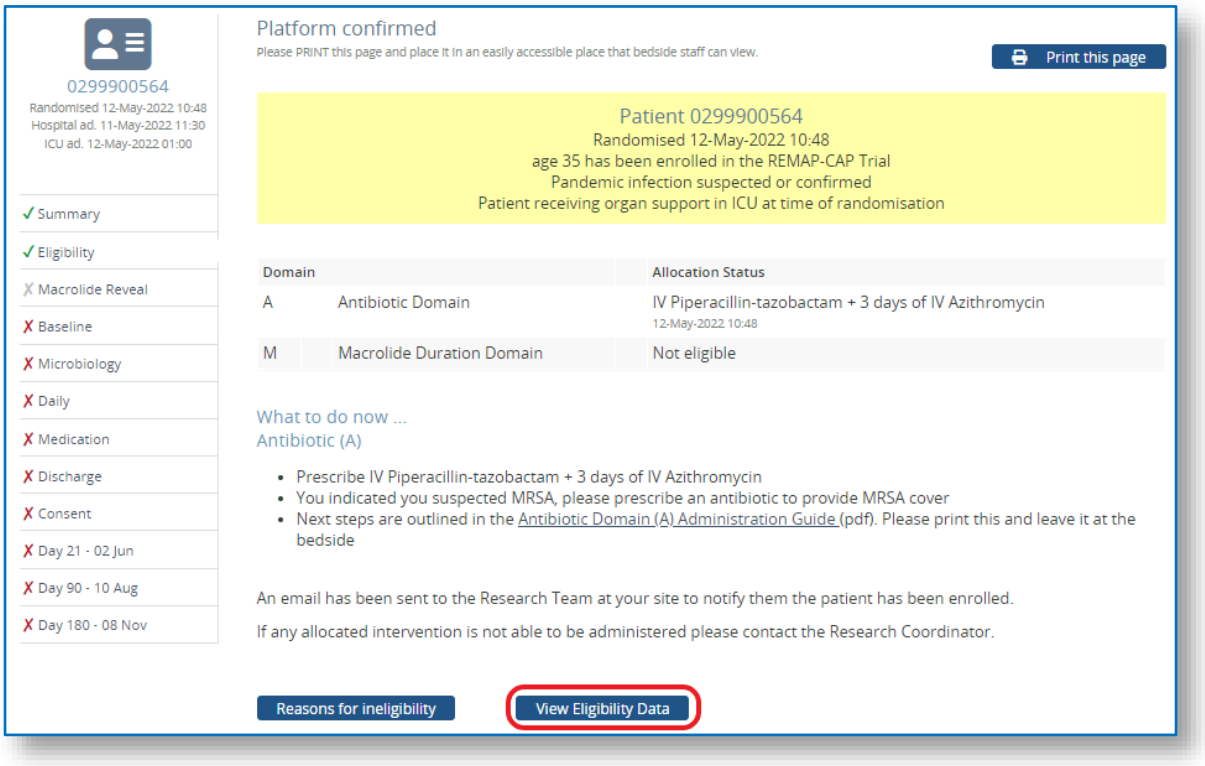
5.6. Updating incorrect information entered at eligibility

- Information entered during the eligibility assessment can be updated after a patient is randomised.
- Patient initials, date of birth, sex at birth and ICU admission date & time can be edited via the **Patient Summary Page**, by selecting "*Edit Patient*".

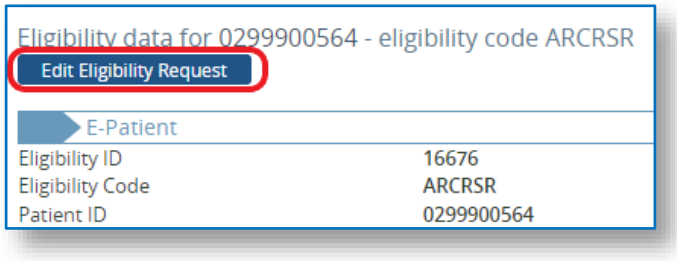


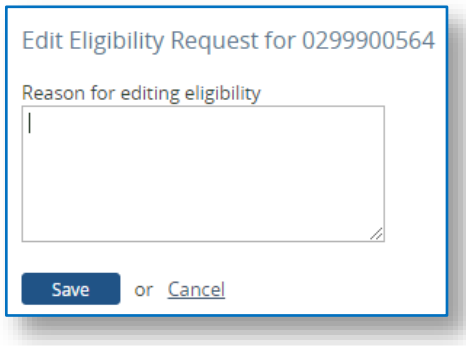
⚠ **HINT:** Hospital admission date & time cannot be updated on the Patient Summary Page. This is because it is a question on the Baseline eCRF. If the date entered on the Baseline CRF doesn't match the Eligibility eCRF, you will be asked to confirm the date that is entered. Once confirmed, the new date entered into the Baseline form will overwrite the date and time entered into the Eligibility assessment.

- Other eligibility data can be updated by selecting **View Eligibility Data** on the eligibility result page.

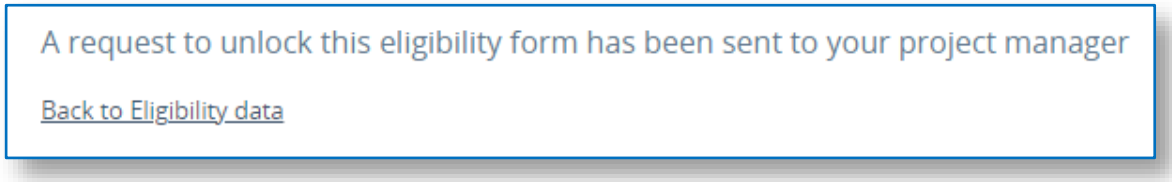


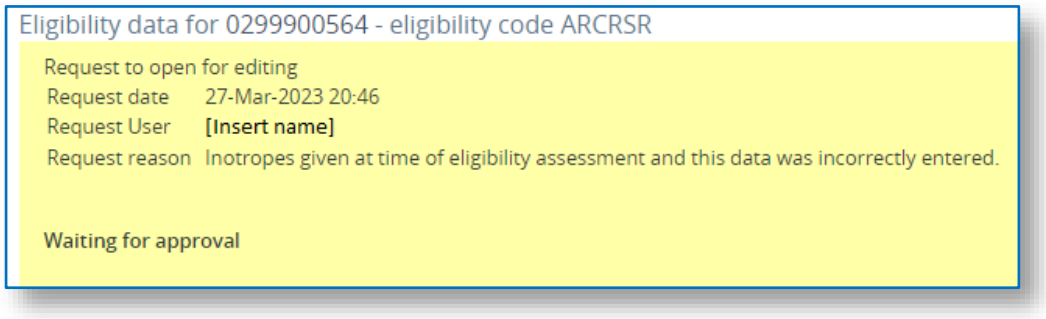
- Select "*Edit Eligibility Request*", enter a reason for updating eligibility and click 'Save'.



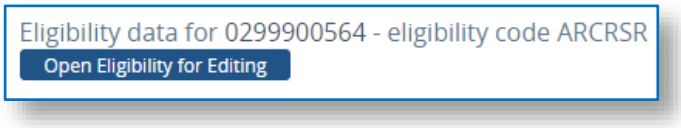


- A request will be emailed to your local project manager to unlock the form. Select "*Back to Eligibility data*" to return to the *View Eligibility Data* page. A yellow alert message will display the request details.



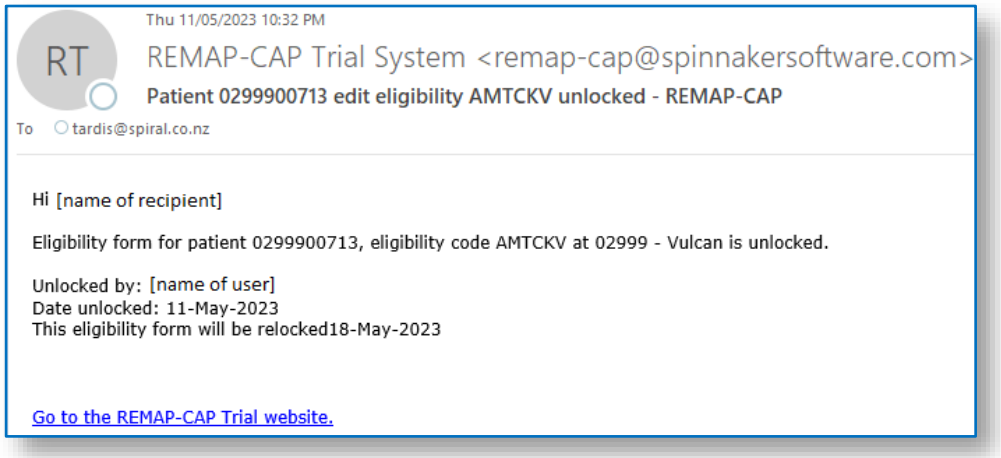


- If the edit eligibility request is declined, the yellow alert text will no longer display and the eligibility form will display an *Open Eligibility for Editing* button.

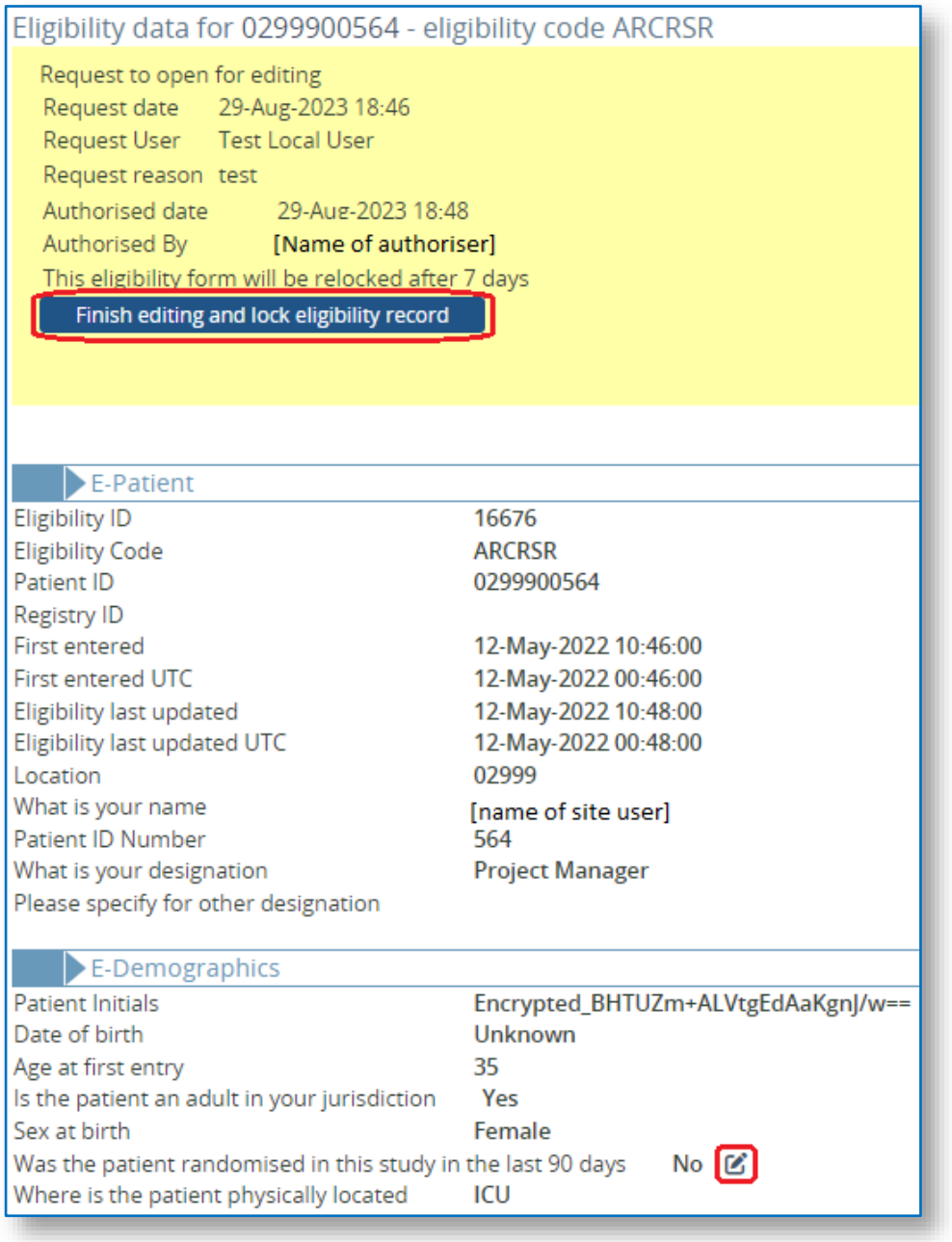


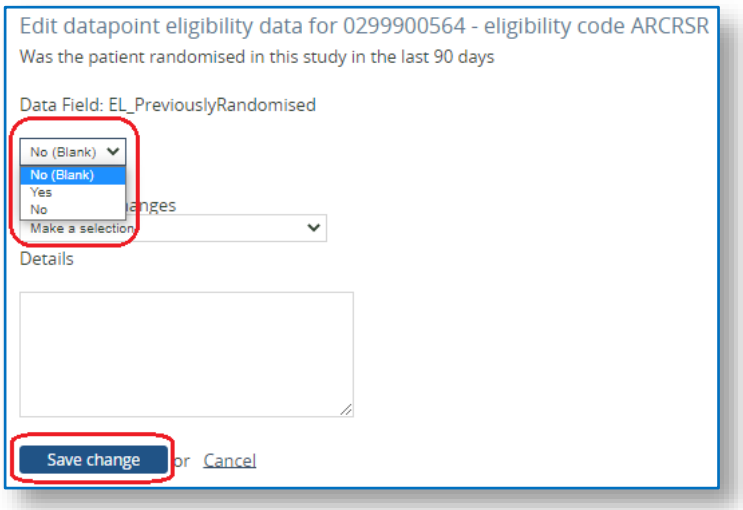
HINT: An edit eligibility request may require further discussion with your Site Investigator and/or local Project Manager before it is processed. If you are unsure an eligibility record should be updated after randomisation, contact your local Project Manager.

- If the edit eligibility request is approved, you will receive an email notification stating the form is unlocked, including an auto lock date if it is not locked by the site.



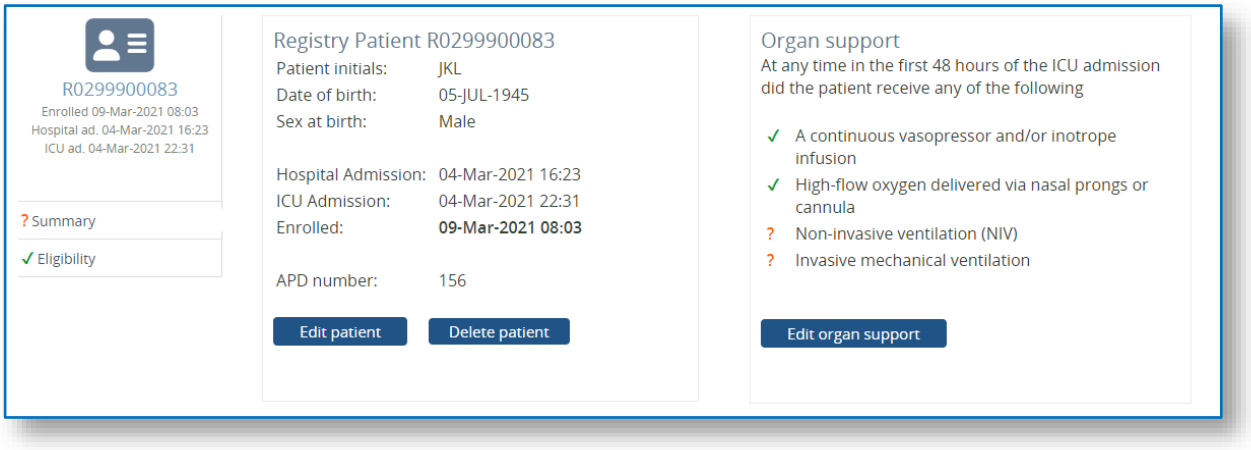
- Return to the *View Eligibility Data* page to start editing your data. To edit a question, click the pencil icon located to the right of the current value, edit the data value and click 'Save change'.
- More than one field can be updated, however, only one field at a time can be edited.
- Once you have updated your data, click **"***Finish editing and lock eligibility record***"** to relock the form.
- The form will automatically relock after 7 days (from the date it was unlocked) if it is not locked by the site.


Eligibility data for 0299900564 - eligibility code ARCRSR
Request to open for editing
Request date 29-Aug-2023 18:46
Request User Test Local User
Request reason test
Authorised date 29-Aug-2023 18:48
Authorised By [Name of authoriser]
This eligibility form will be relocked after 7 days
Finish editing and lock eligibility record
E-Patient
Eligibility ID 16676
Eligibility Code ARCRSR
Patient ID 0299900564
Registry ID
First entered 12-May-2022 10:46:00
First entered UTC 12-May-2022 00:46:00
Eligibility last updated 12-May-2022 10:48:00
Eligibility last updated UTC 12-May-2022 00:48:00
Location 02999
What is your name [name of site user]
Patient ID Number 564
What is your designation Project Manager
Please specify for other designation
E-Demographics
Patient Initials Encrypted_BHTUZm+ALVtgEdAaKgnJ/w==
Date of birth Unknown
Age at first entry 35
Is the patient an adult in your jurisdiction Yes
Sex at birth Female
Was the patient randomised in this study in the last 90 days No
Where is the patient physically located ICU


Edit datapoint eligibility data for 0299900564 - eligibility code ARCRSR
Was the patient randomised in this study in the last 90 days
Data Field: EL_PreviouslyRandomised
No (Blank)
No (Blank)
Yes
No
Make a selection
Details
Save change
or Cancel

5.6.1. Update information for Registry patients

- For patients in the Registry, initials, date of birth, sex at birth and ICU admission date & time can be edited via the **Patient Summary Page**, by selecting "*Edit Patient*".



- Information regarding ICU-level organ support received by Registry patients within the first 48 hours of their ICU admission can be added by navigating to the Patient Summary Page and clicking "edit organ support"

6. PATIENTS

6.1. Patient list

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

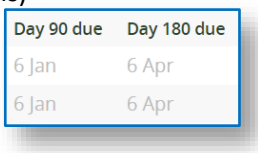
6.1.1. eCRF overview key definitions

Symbol	*Definition*
X	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).
T	Patient transfer pending confirmation by receiving site.
T	Patient transferred, the patient's eCRF is not at your site (data entry closed).
T	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).
S	A "S" next to a participant's PSN indicates that this participant has received an allocation in the Severe state of the Pandemic Infection Suspected or Proven (PISOP) stratum. Please note that it is possible for a participant to receive allocations in both the Moderate and the Severe state.
M	A "M" next to a participant's PSN indicates that this participant has received an allocation in the Moderate state of the Pandemic Infection Suspected or Proven (PISOP) stratum. Please note that it is possible for a participant to receive allocations in both the Moderate and the Severe state.

	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.

6.1.2. Navigation

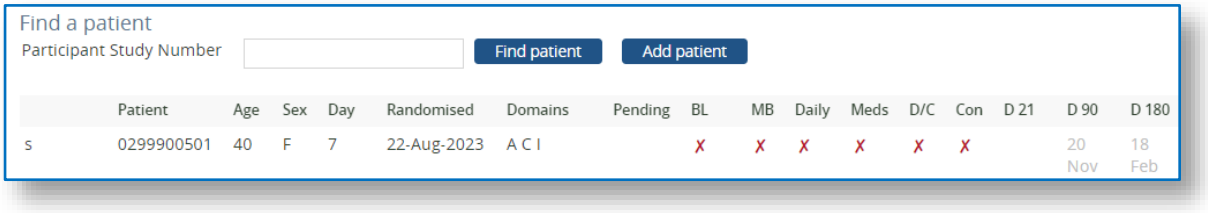
- To open a specific patient's **Patient Summary Page** click on the patient's *Participant Study Number.* Alternatively, you can enter their PSN in the search box provided and click **Find patient'.**
- To open a specific **CRF** click on the tick, cross or question mark relevant under the CRF you want to open for that patient.
- *Follow-up* due dates are displayed in the overview (final two columns)
- If the dates are light grey the follow-up is not yet due.
- If the dates are black the follow-up is due.



- 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 (✗).

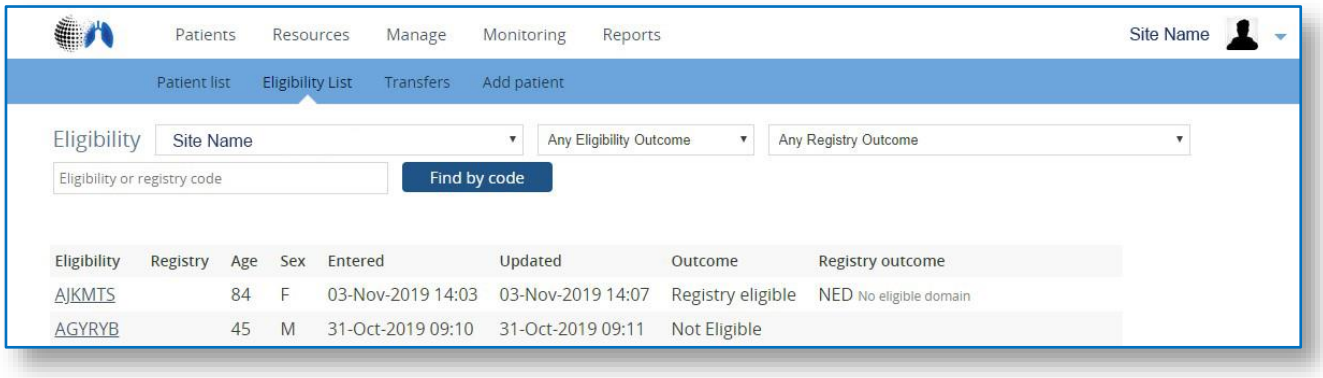
> **HINT:** To open a patient's eCRF, from the patient's Patient Summary Page you can use the eCRF navigation tab on the left-hand side of the window to open a specific eCRF.

- The patient listing defaults to displaying Participant Study Number in descending order.
  You can also re-order the list by clicking on a column name (except *Domains* and *Pending* columns).
  For example, if you click on the 'Age' column, it will sort the list in ascending order by age.

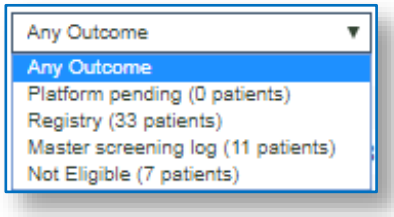


6.2. Eligibility list

The **Eligibility List** under the *Patients* tab will load a list of patients who have been entered into eligibility who have not been randomised, this includes both not eligible and registry eligible patients.



- 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.
- A summary of the different eligibility outcomes is provided in Eligibility Outcome.

To update or review the current status of **Eligibility Pending Patient**, click on the "*Eligibility code*" to open up the record and update the patient record.

6.3. Transfers

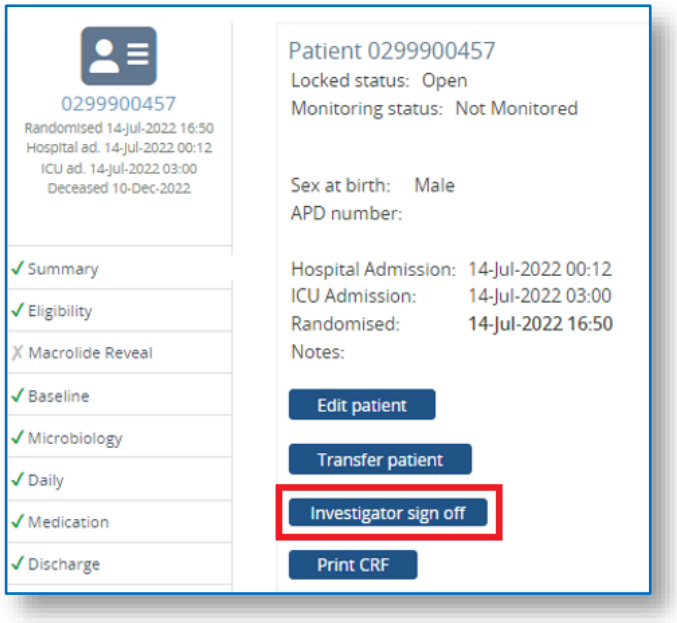
Transfers under the Patients tab displays a summary of all patients transferred to or from your site. For more information refer to Patient Transfers.

6.4. Investigator sign-off of the CRF

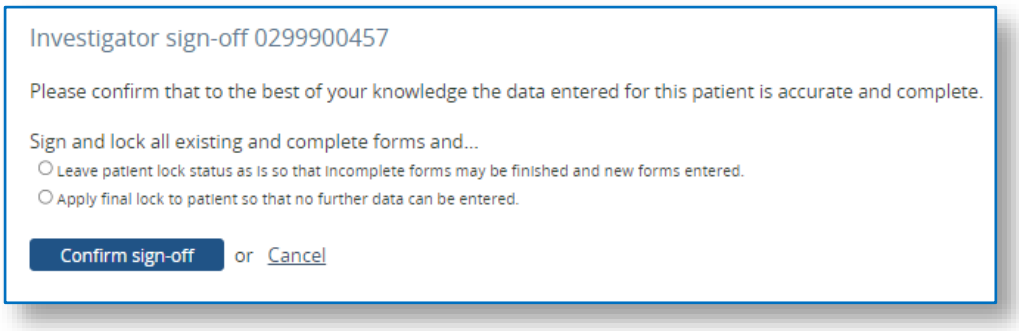
6.4.1. Patient level sign-off

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).

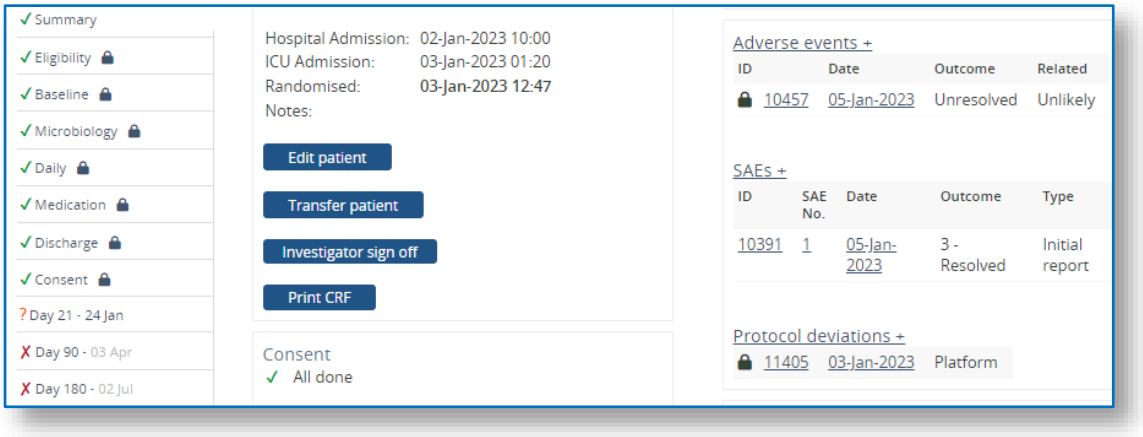
- At a patient level, select the **Investigator sign off** button on the Patient Summary page to sign off multiple forms simultaneously.



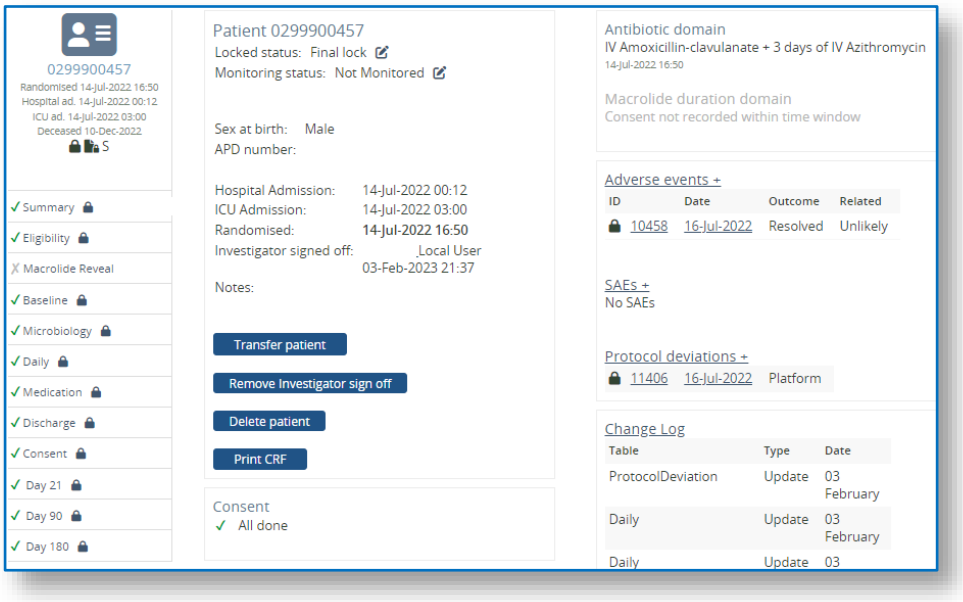
- Two options will display.



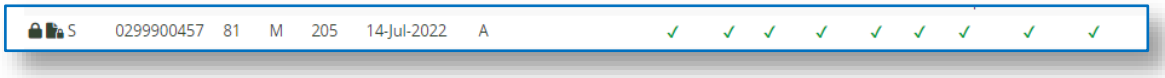
- ***Option 1:*** 'Leave patient lock status as is so that incomplete forms may be finished and new forms entered.' Use this option if you'd like to sign off and lock multiple forms with completed data (green tick) while awaiting data to be entered for other forms. For example, if all in-hospital data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



- ***Option 2***: 'Apply final lock to patient so that no further data can be entered.' Use this option if all data has been entered for all required forms.
- All forms are locked, including any entered Adverse events and Protocol deviation forms.

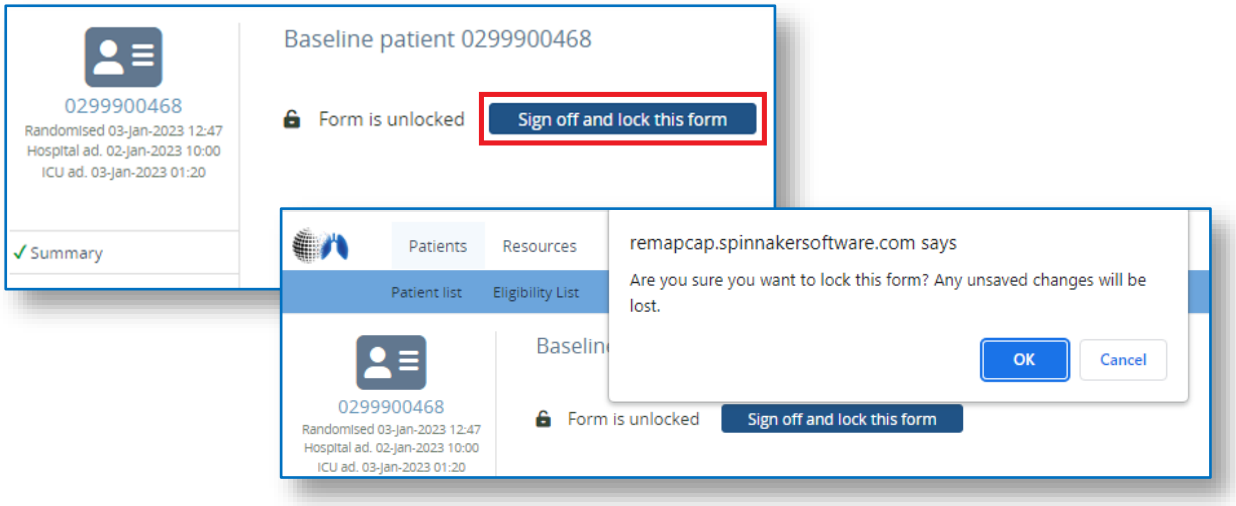


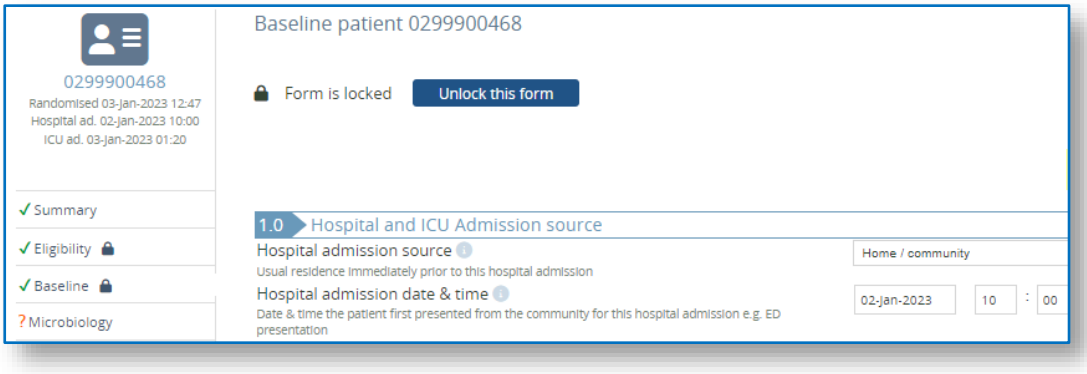
- The Investigator sign off icon ( ) will display on the patient listing summary page.



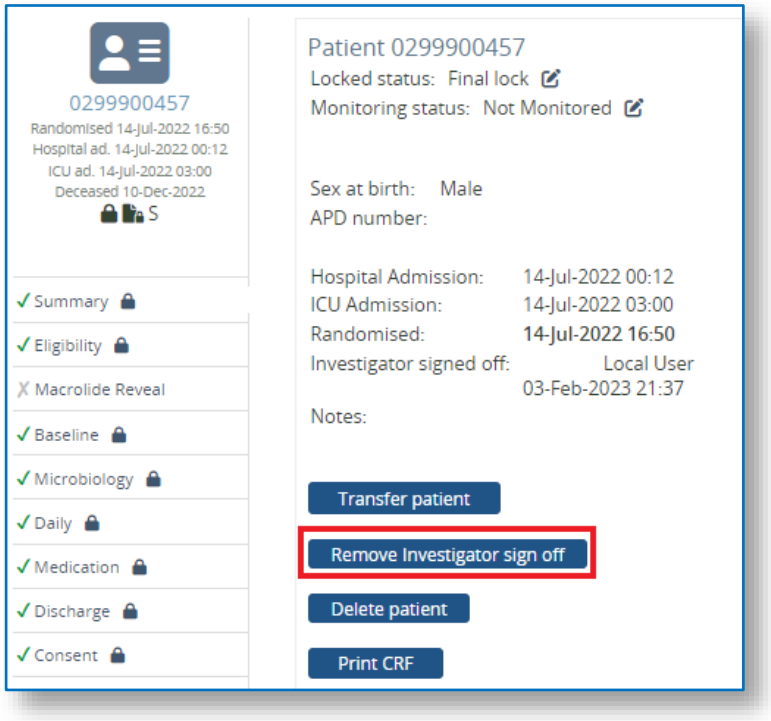
6.4.2. Form level sign-off

- At form level, the 'Sign off and lock this form' button displays when the form has a green tick (completed status).
- Select the **Sign off and lock this form** button at the top of the eCRF and Click 'OK' to confirm.

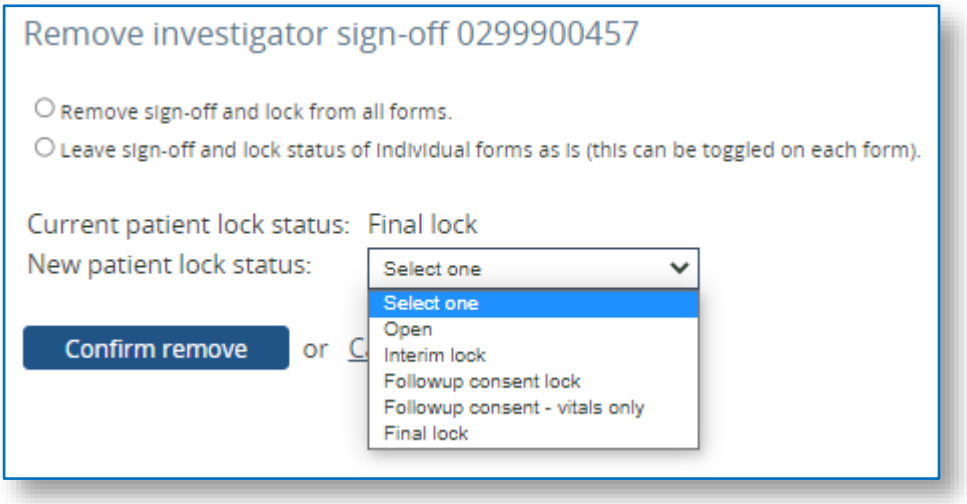




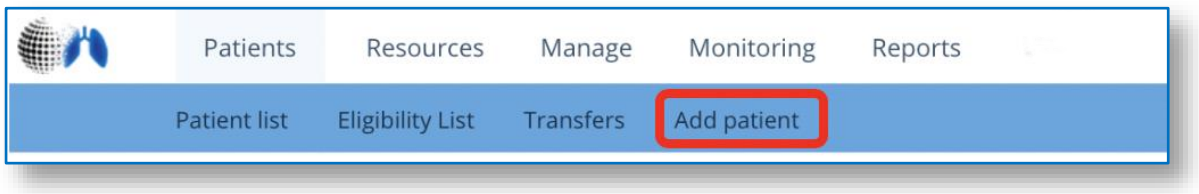
- 'Form is locked' message displays along with an 'Unlock this form' button allowing Investigators to unlock the form if required.
- The lock icon (🔒) displays at the top of the form and in the left navigation pane.
- Daily data forms must be individually signed off/locked.
- All sections on the Medication 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 page.



- Choose the appropriate removal sign-off option, select 'Open' from the drop-down menu and click 'Confirm remove'.



6.5. Add Patient

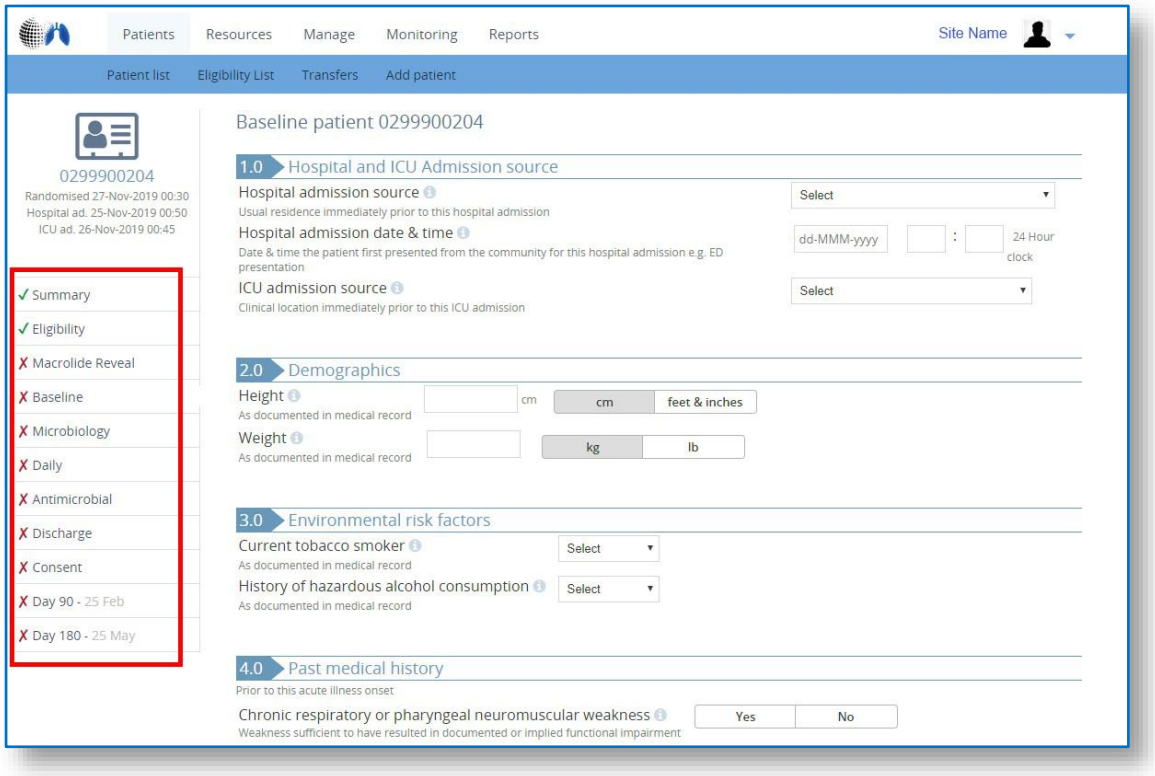


If you click on the "*Add Patient tab*", you will be taken to the first page of the Eligibility assessment.

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. 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, States, or Stratum 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.

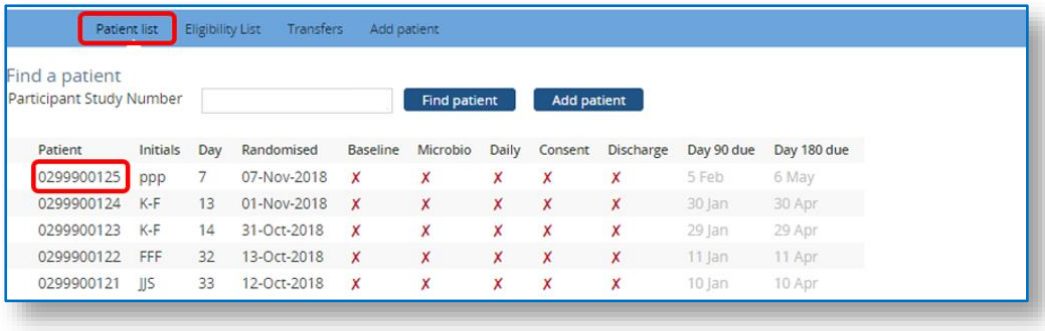


- The eCRF navigation tab is displayed in the same place on all eCRFs.

7.2. Forms

7.2.1. How to open a patient's eCRF

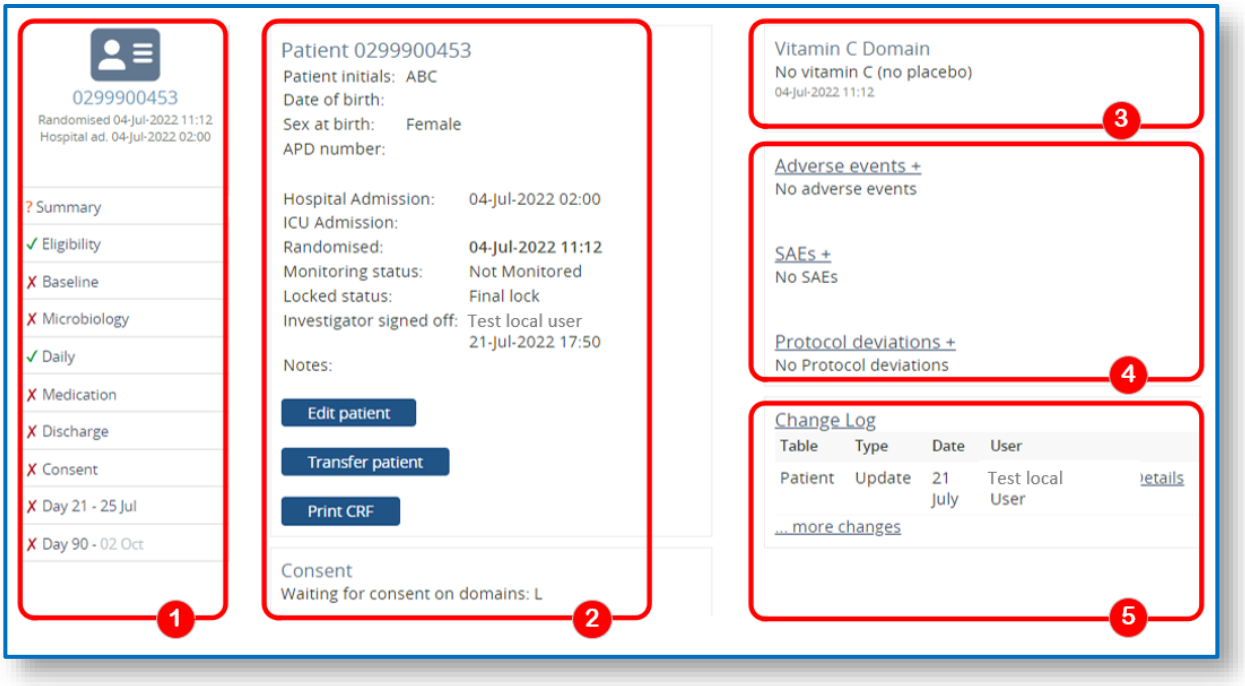
- Select the patient's *Participant study number* on either the **Dashboard** or **Patient List** tabs.



- Alternatively enter the patient's Participant Study Number in the search bar and click on "*Find patient*".

7.2.2. Patient summary page

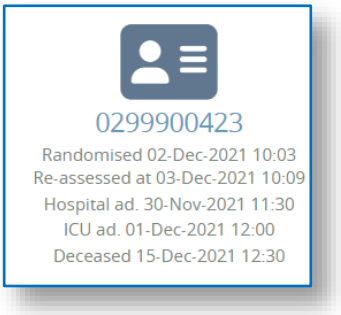
The *Patient Summary Page* includes Five distinct sections:



- Participant key date summary:

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

  These key dates are displayed on every summary page for that participant.



The summary includes:

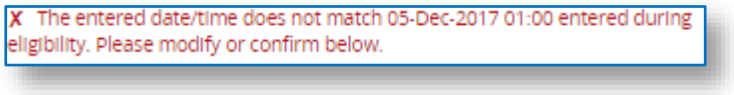
- Participant study number
- Date and time of randomisation (and re-randomisation, if applicable)
- Date and time of hospital admission
- Date and time of ICU admission
- Date and time of death (if applicable)

- 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 patient' button and refer to section 9 Patient 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

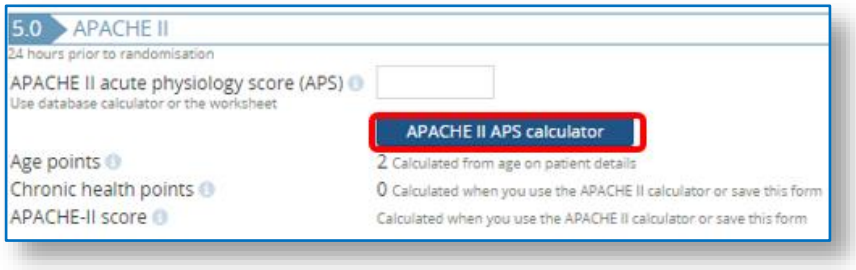
- The Baseline form is designed to be completed before any other eCRF as the baseline eCRF data impacts questions that are shown or hidden on other eCRF pages.
- Hospital admission date and time that was collected on the Eligibility assessment form is asked again on the Baseline eCRF. If the two dates and time do not match, an error message will be displayed asking for confirmation that the date & time entered in the Baseline eCRF is correct.



- After you have confirmed that the date and time entered into the Baseline form 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

- An APACHE-II acute physiology score (APS) calculator is available on the Baseline eCRF.



- The eCRF calculator is an automated tool for calculating APACHE-II score, which is designed to mirror the paper APACHE-II worksheet provided in the REMAP-CAP study tools.
- If the eCRF APACHE-II calculator is used, it will automatically fill the Baseline eCRF APACHE-II APS points. If a manual worksheet is used, you may enter the calculated APACHE-II score without using the online calculator.
- The remaining APACHE-II points are automatically calculated based on the information entered in other parts of the Baseline eCRF.

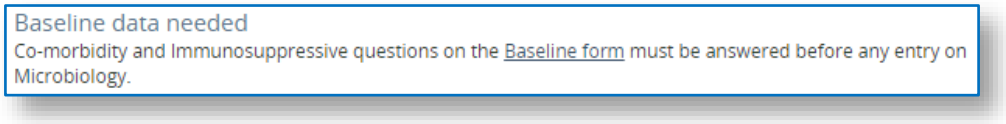
7.2.4. Ventilation Domain baseline

- 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.

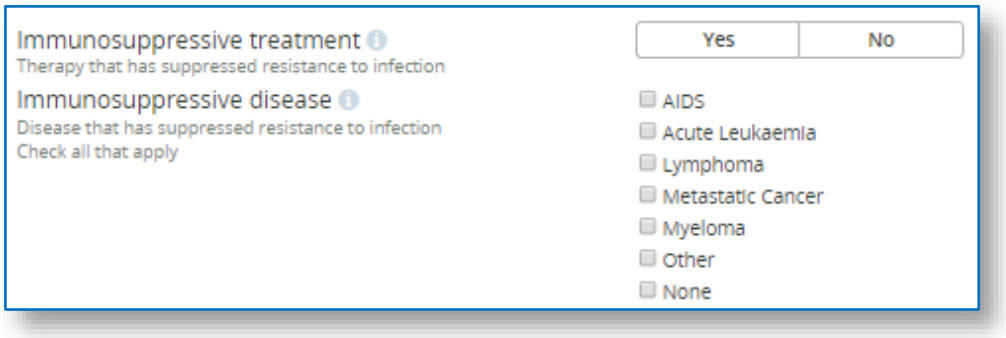
7.2.5. Microbiology

- 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, Section 2 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:

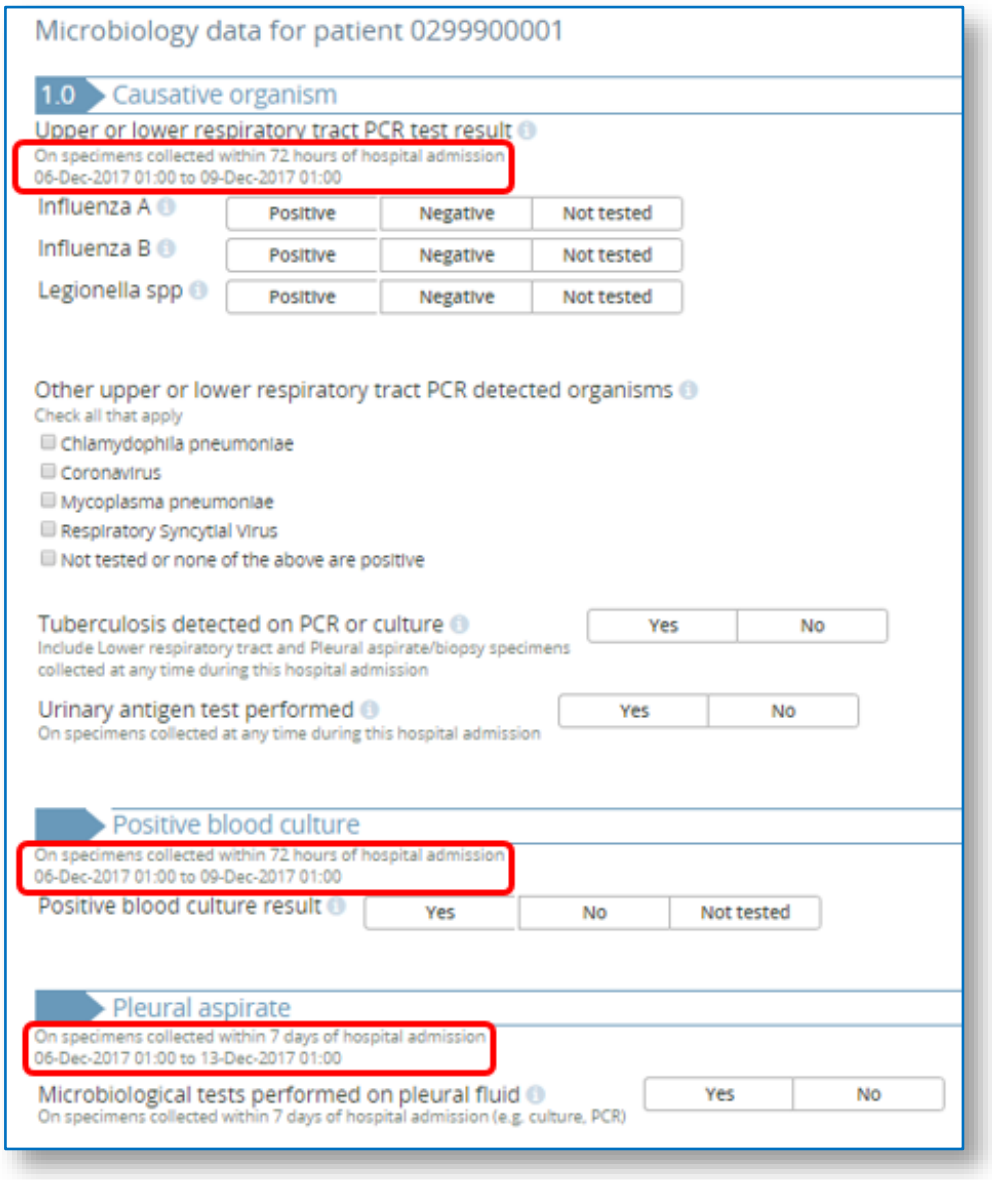


    - The two Baseline eCRF questions are in Section 4.0 Past medical history:



- 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.

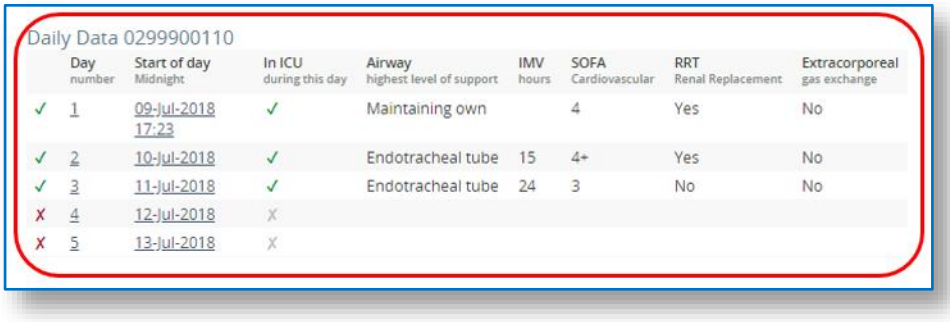
- To make answering this eCRF easier, the database automatically calculates the time-window for each patient based on the date and time of hospital admission.



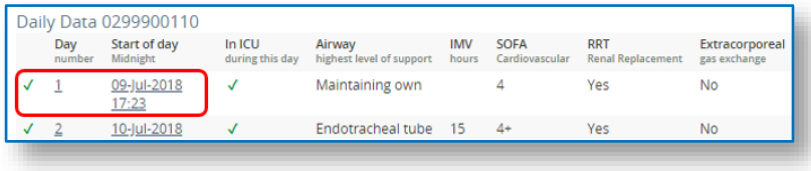
7.2.6. Daily data

- The Daily CRF is completed every day the patient is admitted to a physical or repurposed ICU to Study Day 28 post-randomisation.

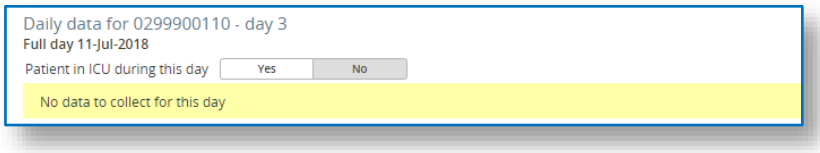
- The Daily form shows a summary of entered daily data for that patient.



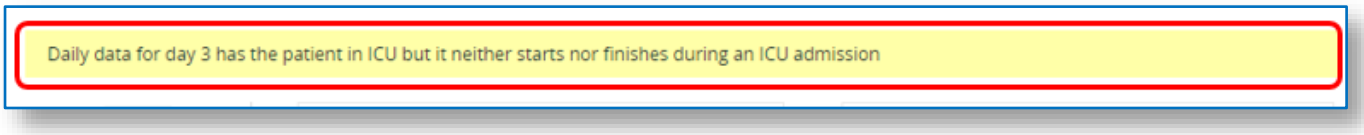
- To open a specific Daily eCRF click on the tick, study day or date for that study day.



- There are validations between the Daily eCRF and Sections 1 and 2 of the Discharge eCRF.
  - If the data entered into the Discharge eCRF indicate a patient is in ICU on a given study day, a Daily eCRF for that study day will automatically appear.
  - If the data entered into the Discharge eCRF indicate a patient is not in ICU at any time on that study day, the corresponding Daily eCRFs will automatically be hidden. If you try to enter data, an error message will appear.



  - If you want to override this function, answer Patient in ICU during this day with "*Yes*" and immediately update the Discharge eCRF Section 1 or 2 as appropriate.
  - If there is an inconsistency between the Discharge and Daily eCRF, an error message will display on the two eCRFs and on the Patient Summary Page.



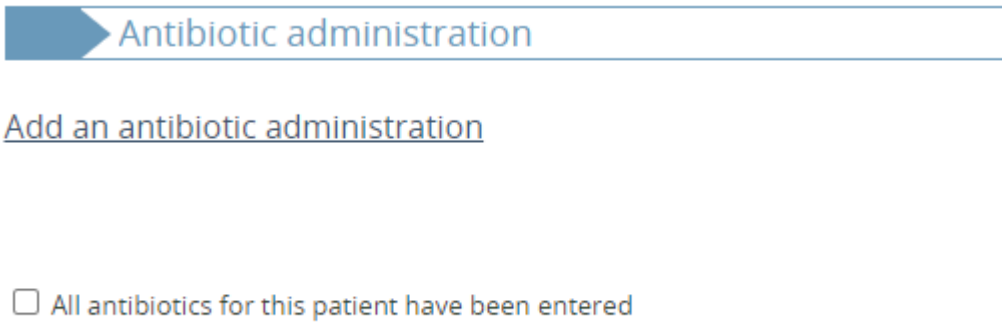
7.2.7. Ventilation Domain daily data

- 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 important concomitant medications 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.). To enter a medication, click on the link within the relevant section to add a course of that medication.



- This will take you to a separate page where you will be asked to enter the details of a course of that type of medication that was administered. Please refer to the Data Completion Guidelines for guidance as to how to complete each section.
- Once each section is complete, click "all … for this patient have been entered". This may include where all courses 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.

7.2.9. Discharge

- The Discharge eCRF is dynamic and sections will be displayed or hidden depending on the participant's domain allocation, State, and Stratum.
- 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.

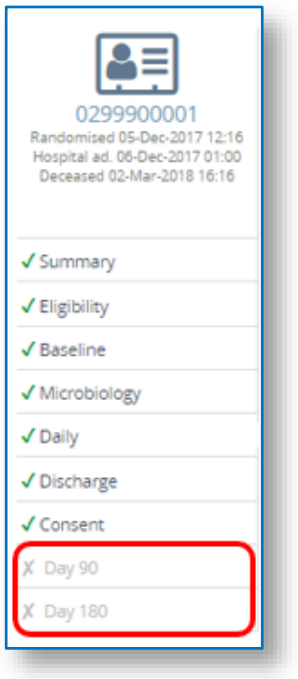
- *Vital status can be collected at day 90 & 180*: the patient's day 180 eCRF section 1 (vital status) will be displayed, the follow-up questionnaires will be hidden preventing data entry. A yellow error message will be displayed on the top of the patient summary page.

7.2.11. Day 21

- The Day 21 eCRF is only required for patients with proven or suspected pandemic infection.
- The Day 21 eCRF will be editable after Study Day 22, to ensure that the relevant information is available to site personnel.
- The Day 21 eCRF is validated against the Daily and Discharge forms.

7.2.12. 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.



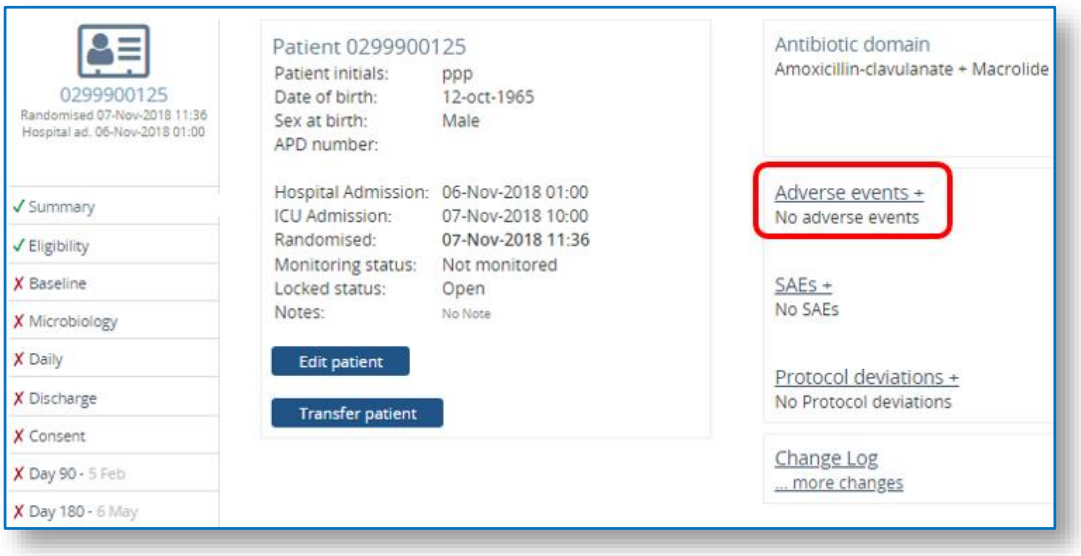
7.2.13. Day 180

- 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.*
- Section 5 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.

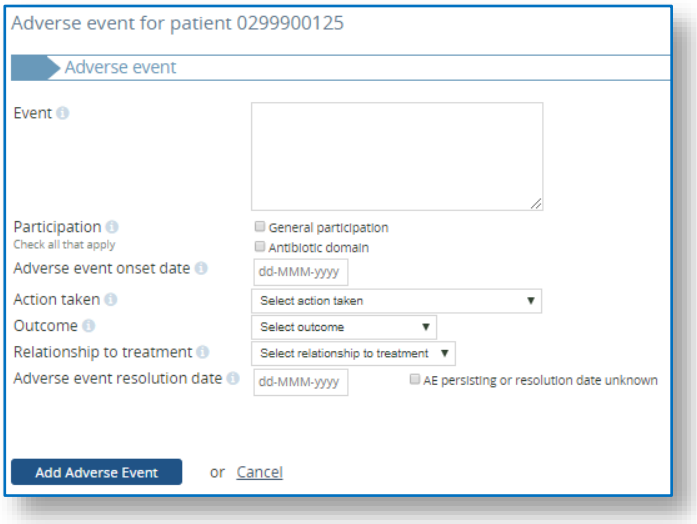
8. REPORTING AEs, SAEs and PDs

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.



- 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.

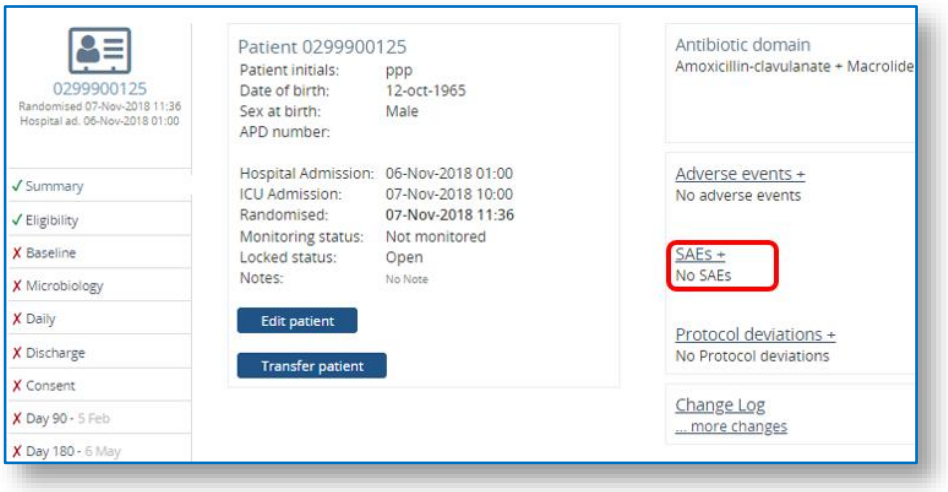


- You can enter more than one AE for each patient if they have experienced more than one AE. Do not complete multiple reports for the same AE.
- Adverse events that are fatal, life-threatening, require hospitalization or prolongation of treatment, result in (or may result) in disability that is long-lasting and significant, or result in a birth defect or congenital anomaly must be reported as a Serious Adverse Events (SAE), and your Project Manager must be notified.

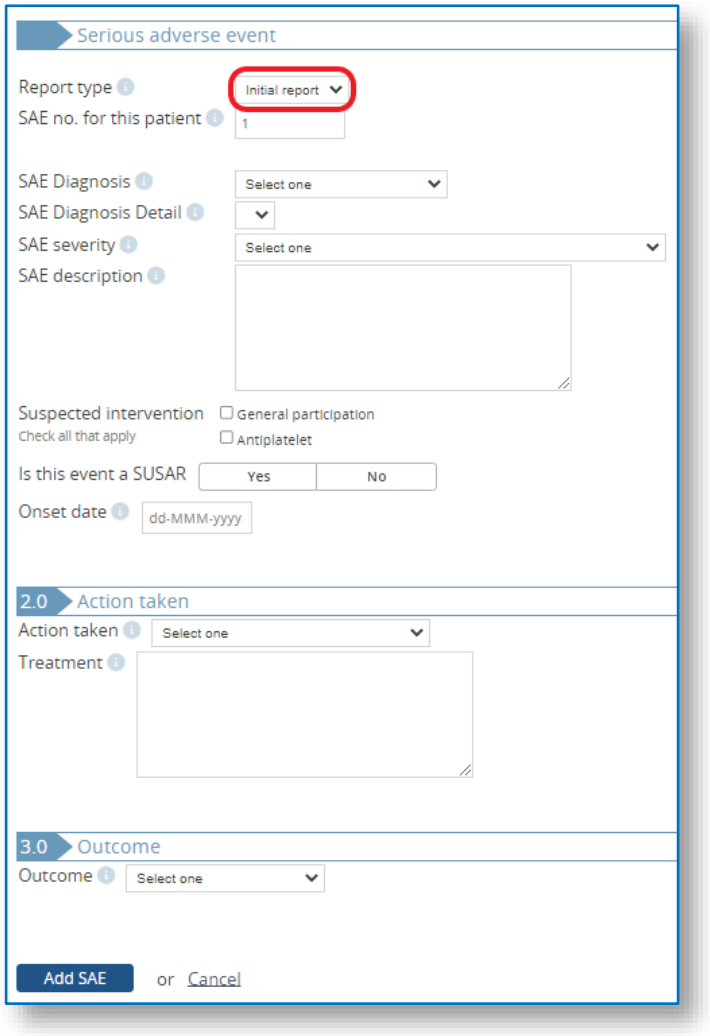
8.2. Reporting a Serious Adverse Event

8.2.1. Report

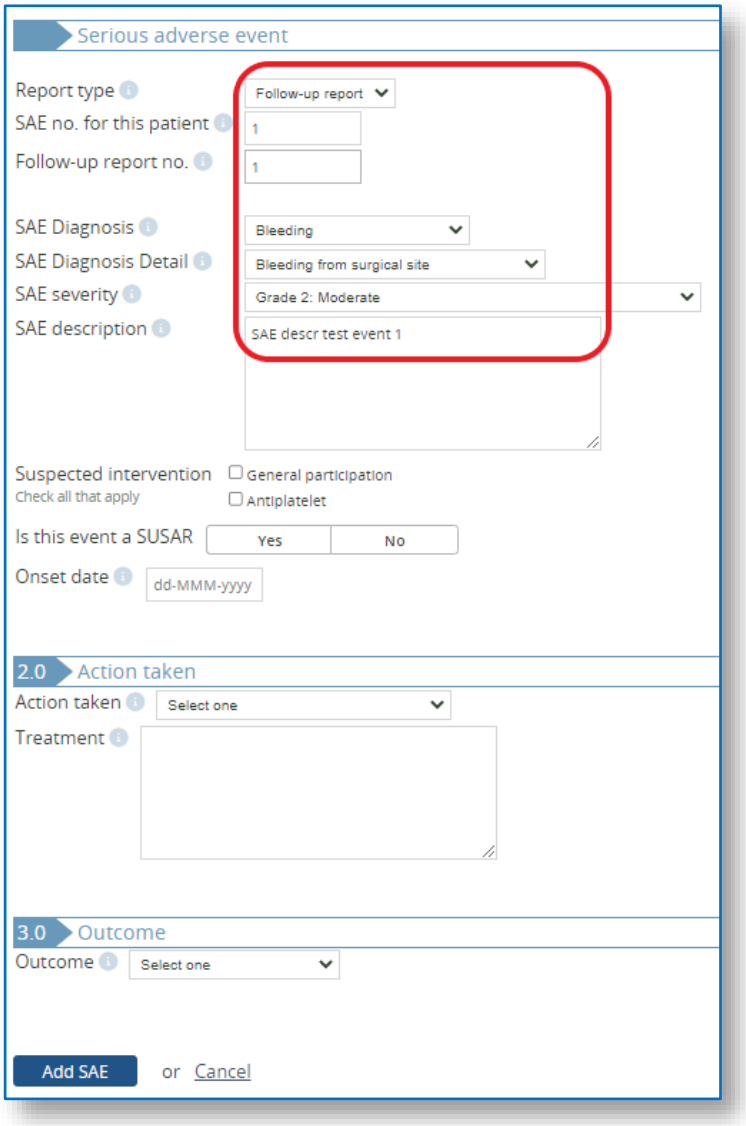
- To report a SAE, open the patient's summary page (see How to open a patient's eCRF) and click on "*SAEs +*" on the right of the page.



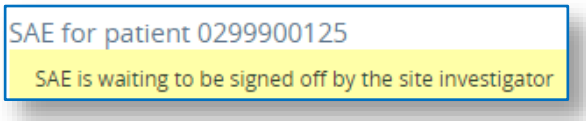
- You can complete more than one SAE for each patient if necessary.
- Please complete a SAE report as soon as it becomes known to site research staff, you do not have to wait until all the information is known about the SAE in order to complete a SAE report. If not all information about the event is available at the time of completing the report, indicate this by selecting "*Initial report*" under **Report Type**.



- If further information becomes available about a SAE after an initial report has been submitted, create a new report and select "*Follow up report*" or "*Final report*" under **Report Type**
- Selecting "*Follow up report*" or "*Final report*" will allow you to enter the SAE event number for the participant. If the participant has had more than one SAE, please ensure that this number correctly identifies which initial report the subsequent follow up or final report relates to.
- Once the SAE event number is selected for the "*Follow up report*" or "*Final report*", the SAE Diagnosis, SAE Diagnosis Detail, SAE 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.



- 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.
- A yellow highlighted message will be displayed on the patient's file until the site PI signs off the SAE.

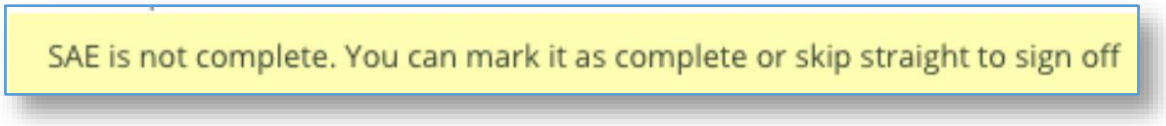


- For every SAE report, a confirmation email will be sent to the Project Manager, the site PI and the other site research coordinator/s to notify users that the submission of the SAE report has been successful. File the SAE confirmation email.

8.2.2. Site Principal Investigator sign-off

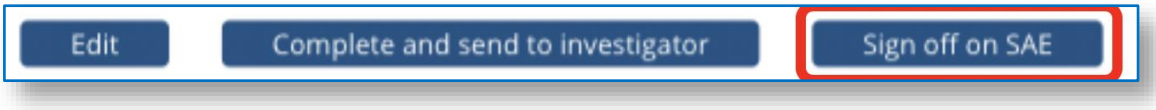
- The site PI will be notified via email if a SAE is reported.

- 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 will be notified of the SAE on the landing page and on the patient's summary page.



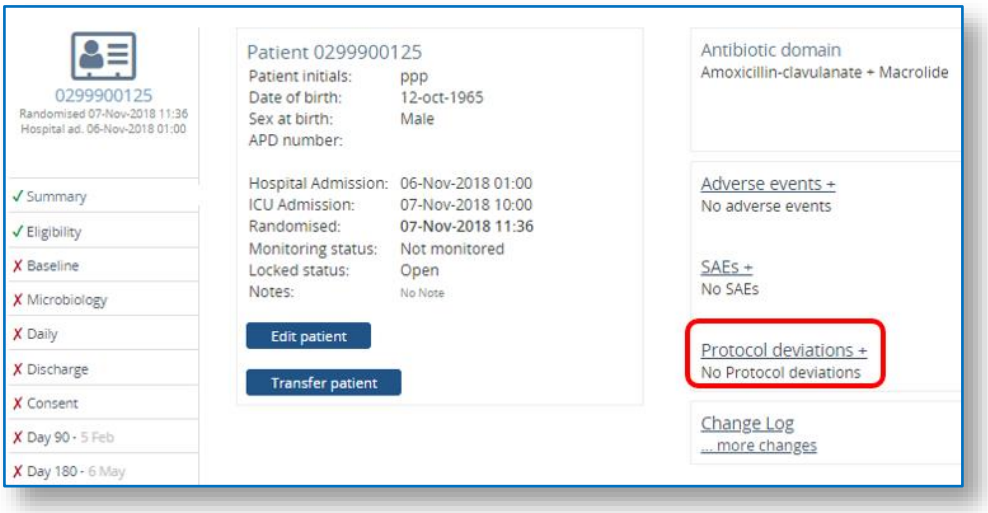
- The site PI can edit the SAE report or sign off on the existing SAE report.
- The report will be displayed with the information already entered. The name of the person who entered the SAE report is included in Section 4, if you have any questions about the SAE and SAE report please speak to this person.

- 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 is underage 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.

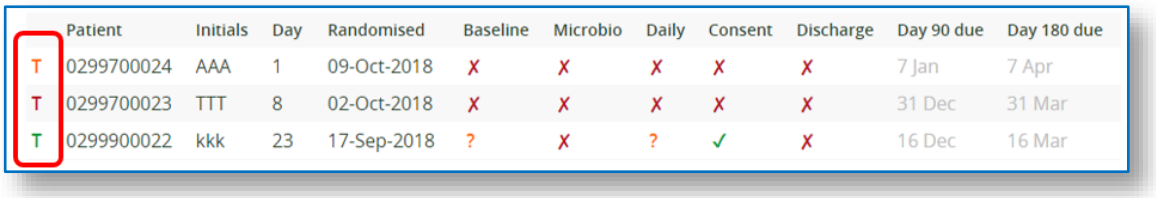
9. PATIENT TRANSFERS

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.

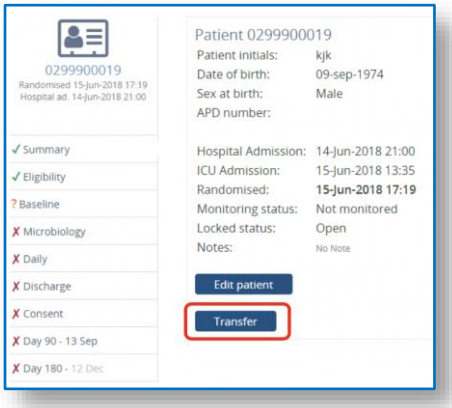


	Patient	Initials	Day	Randomised	Baseline	Microbio	Daily	Consent	Discharge	Day 90 due	Day 180 due
T	0299700024	AAA	1	09-Oct-2018	✗	✗	✗	✗	✗	7 Jan	7 Apr
T	0299700023	TTT	8	02-Oct-2018	✗	✗	✗	✗	✗	31 Dec	31 Mar
T	0299900022	kkk	23	17-Sep-2018	?	✗	?	✓	✗	16 Dec	16 Mar

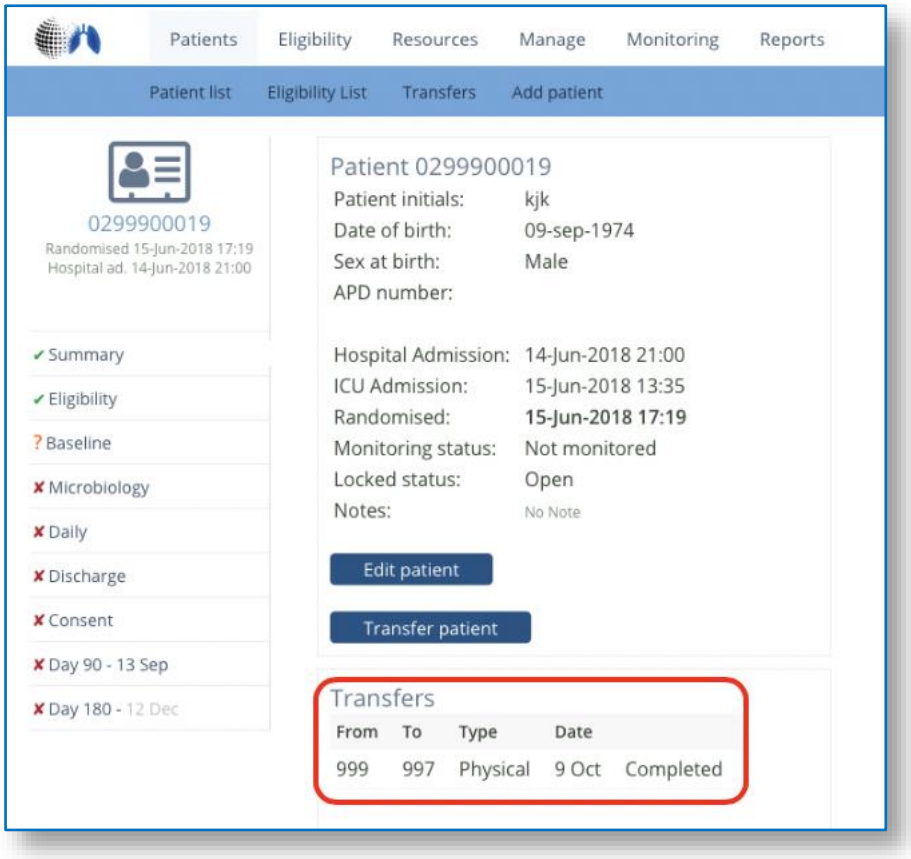
- The colour of the T indicates the status of the transfer (refer to eCRF overview key definitions).

9.3. Transfer a patient's eCRF

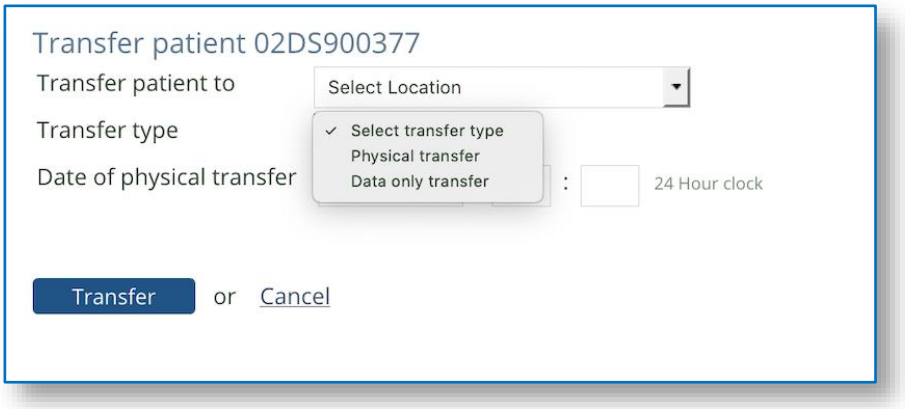
- We recommend you print the REMAP-CAP randomisation allocation page and add it to the patient's transfer documents, including contact details for the research team your site.
- To transfer a patient on the **Patient Summary Page,** click on the "*Transfer*" button.



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

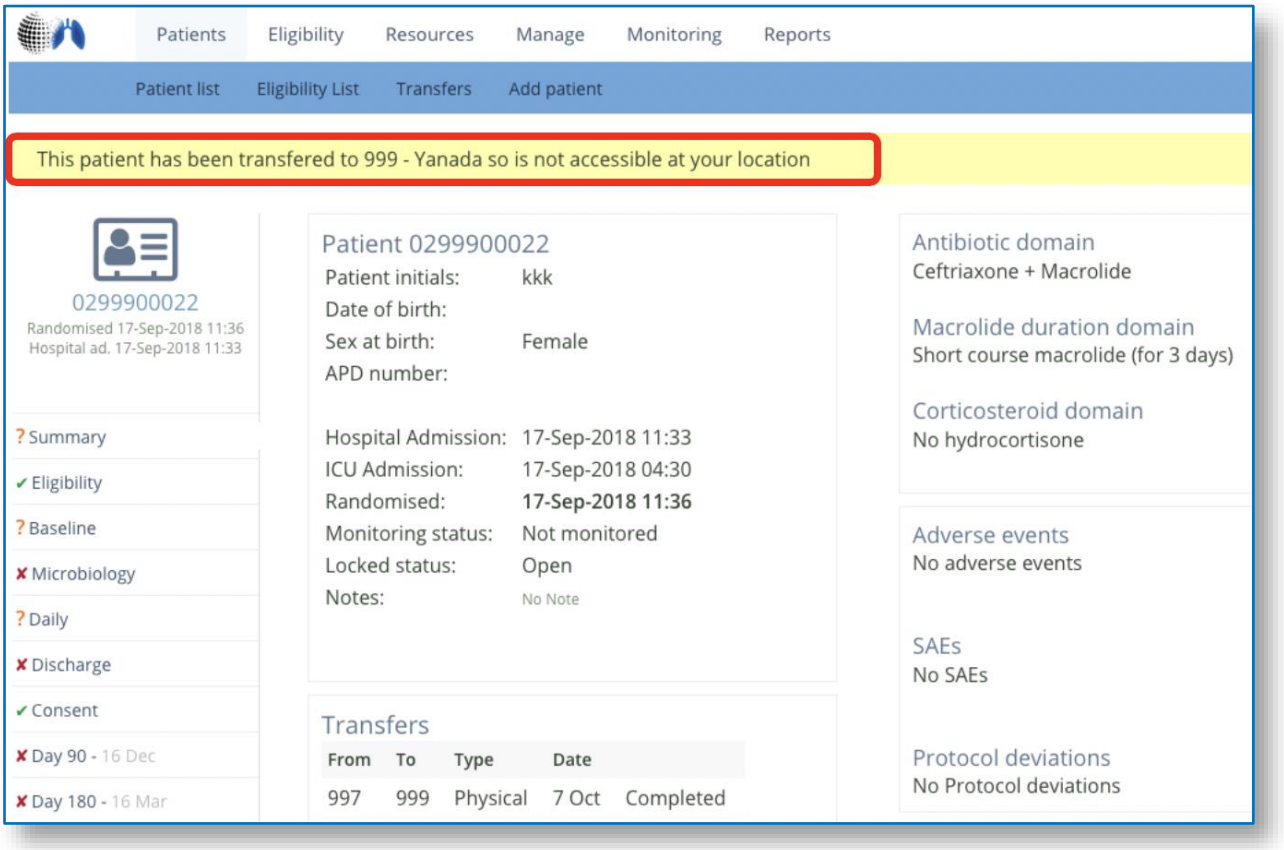


- A new page will load with a few questions:
  - *Transfer patient to:* select the receiving hospital from the dropdown list.
    - If the receiving hospital is not listed, contact your project manager.
  - *Transfer type:* Indicate if the transfer is a physical transfer (i.e. the patient physically 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.



- 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.

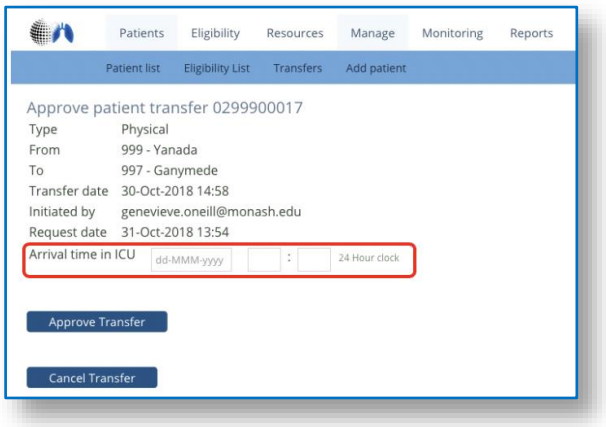
- The receiving site needs to **approve** the transfer and enter the date and time the patient arrived at their site.
- This process can be repeated if another physical transfer occurs (e.g. if the patient returns to the initial participating hospital).
- You can also transfer the patient between sites for data entry purposes.
    - Select "*data only transfer*" from the dropdown menu under Transfer Type.
- If the patient's eCRF is at the other site, a yellow error message will be displayed at the top of the patient summary page. 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.

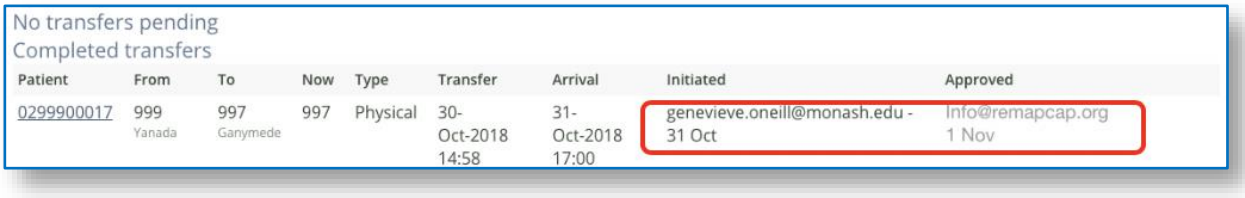
9.4. Approve the patient's eCRF transfer

- 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 Transfer notification on the **Dashboard** or select the "*Transfer tab*" in the **navigation bar**.
- If it is a physical patient transfer, enter the date and time the patient physically arrived in your ICU before clicking on "*Approve Transfer*".



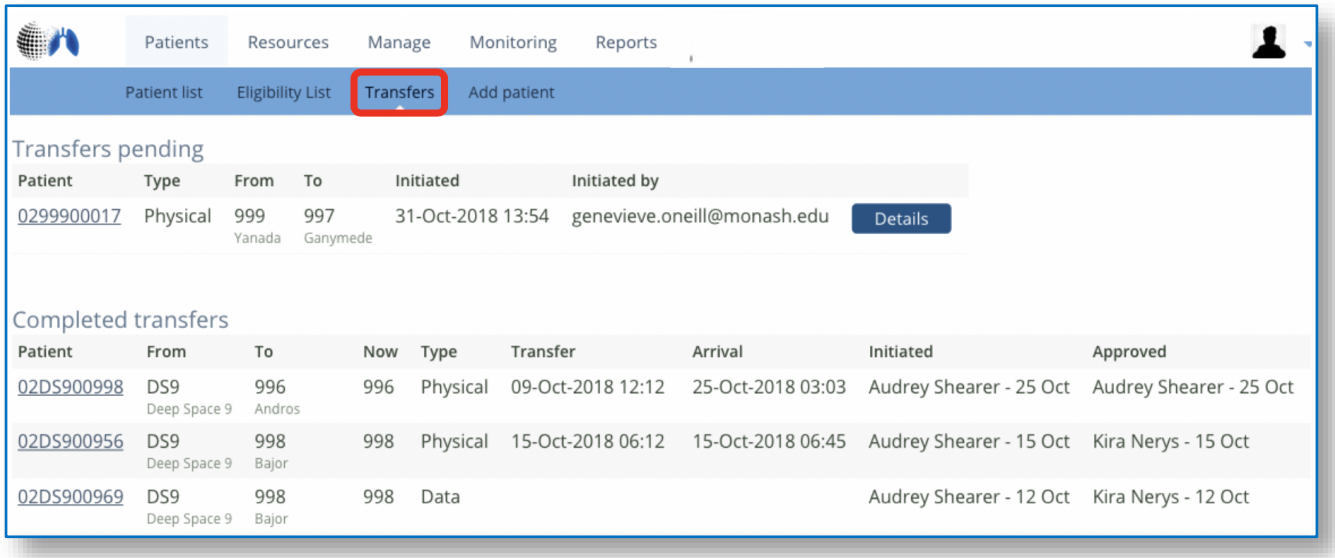
9.5. Requesting the patient's eCRF from another site

- 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.

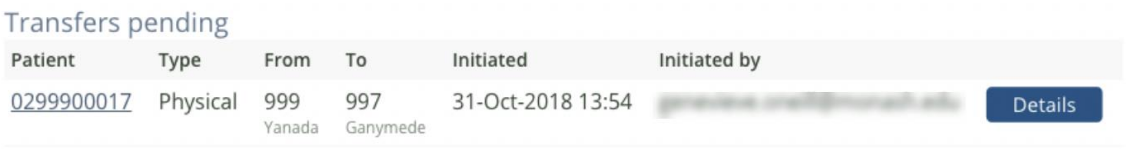


9.6. Transfer summary page

Transfers under the Patients tab displays a summary of all patients transferred to or from your site.



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.

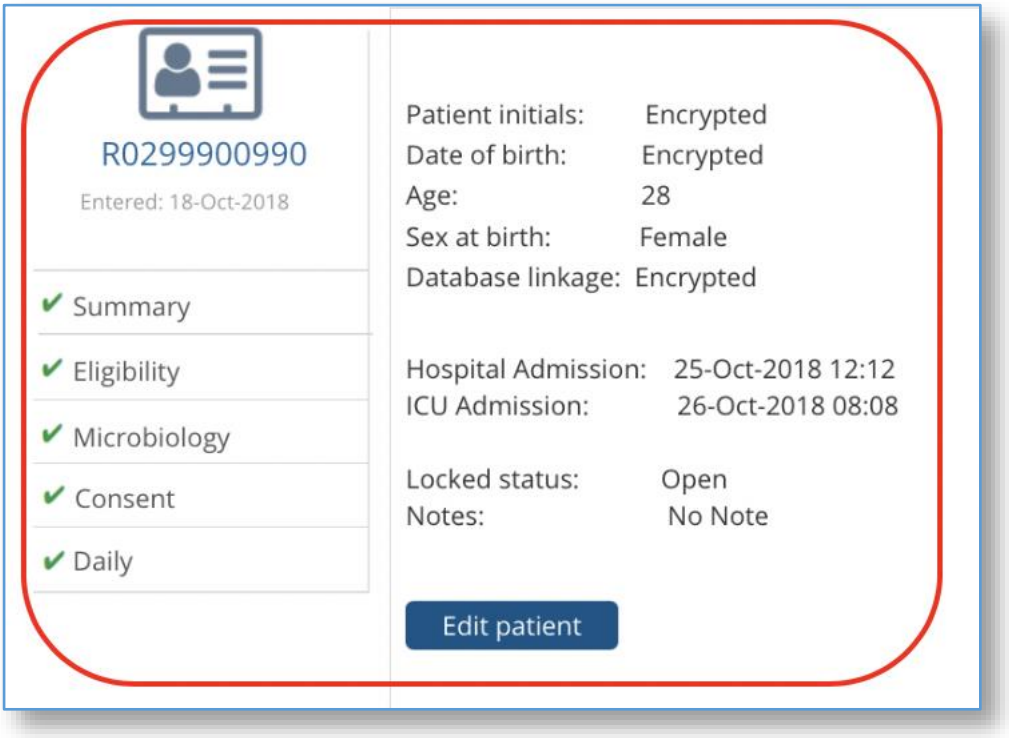


- Patient transfers that are currently pending (e.g. the receiving site hasn't approved the transfer) are indicated at the top of the page.
- Click on "*Details*" to view the patient transfer request and to approve the transfer.

⚠ **HINT**: The email address of the person who requested the patient transfer will be under "*Initiated by*". If you have any questions about the transfer, we recommend you email this person.

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 **Eligibility List tab** in the *Patients tab*.
- Registry patients will have a Registry study number starting with R and be listed under registry.
- To search for a specific patient, enter the patient's registry study number and click "***Find by code".***
- To open a Registry **patient summary page**, click on a specific patient's "*Registry study number*".
- The Registry patient summary page is very similar to the randomised patient summary page, with eCRF navigation on the left-hand side of the screen and the ability to edit the patient's details.



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

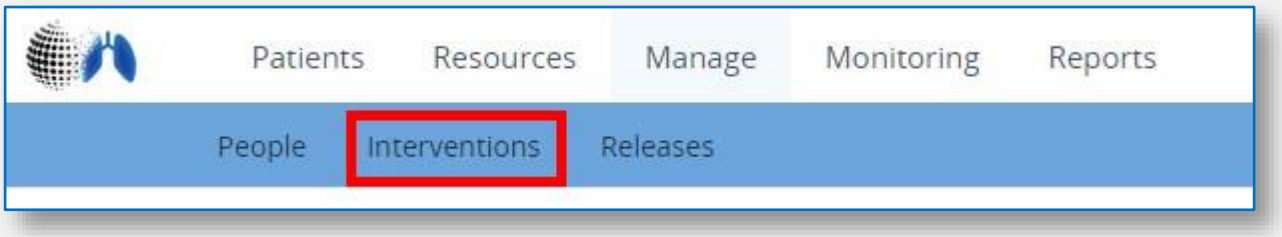
12.1. People

- The People 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*".

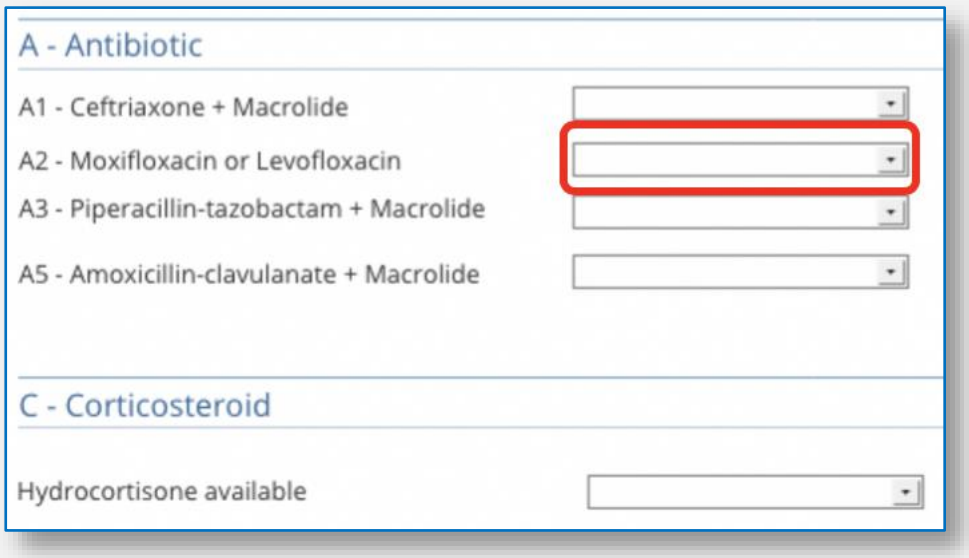
12.2. Interventions

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

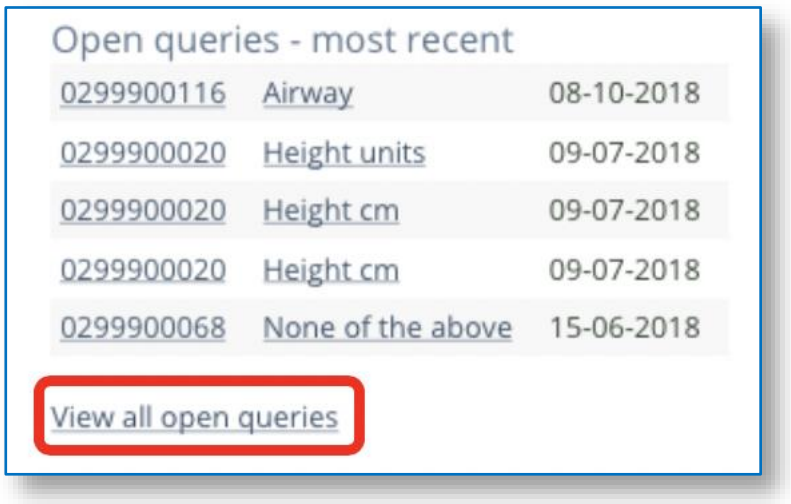
12.3. Releases

- 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

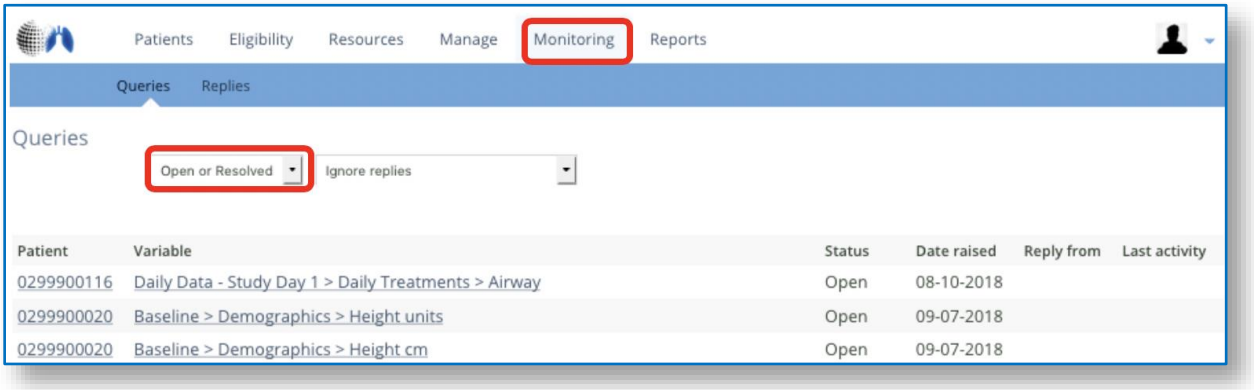
13.1. Data queries

- 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 either:
  - Selecting the "*Monitoring tab*" on the **Navigation tab** (refer to Monitoring).
  - Selecting "*Open all data queries*" in the Data Query section of the **Dashboard**.

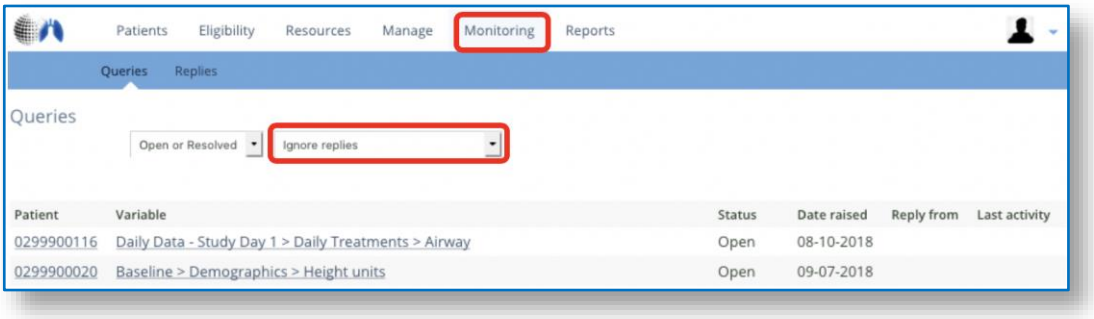


13.2. Data query list

- The Monitoring 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

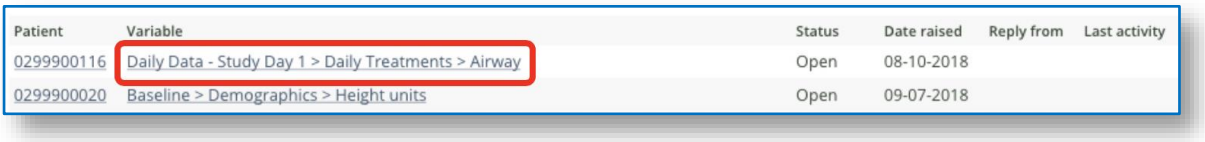


- **Data query replies:**
  - Ignore replies
  - Most recent reply by someone else
  - Most recent reply by me
  - Reply by anyone

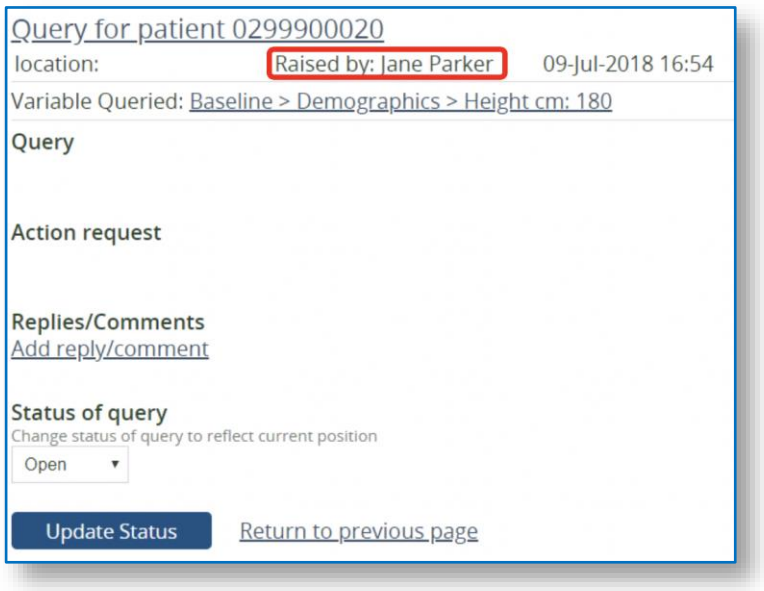


13.2.1. Data query page

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



- 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.

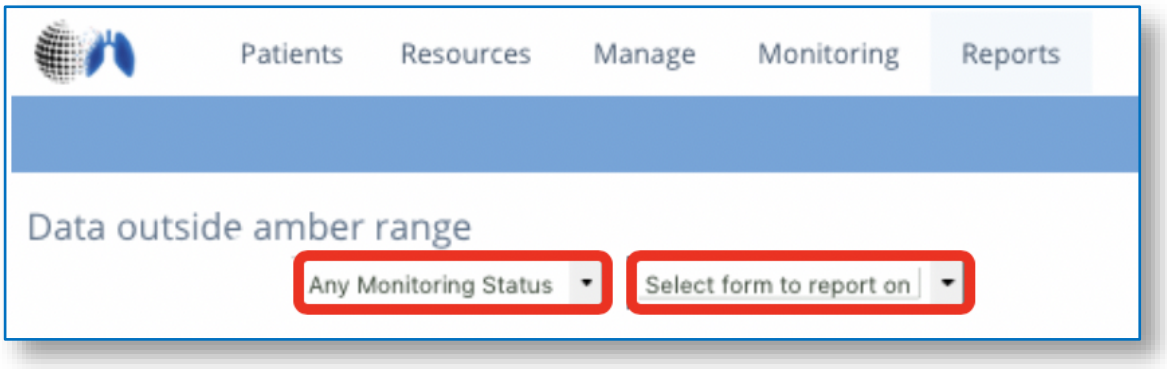
- Under "*Action request*", a request made by the person who raised the query regarding how to proceed.

- If you have any questions or response to the Action request, click "*Add reply/comment*". We recommend that you reply indicating that you have updated a variable or if the variable is correct.

- From the query page, click on the "*Variable queried*" to open up CRF page to update the data entered if required.

13.2.2. Data outside normal ranges query report

- A report of queries for data that are outside normal ranges can be viewed under the "**Reports tab**".
- This report returns all entered values that are outside pre-determined limits. All values on this report have been confirmed as correct when entering data on the CRF (see section 16.3 amber validations).
- Select the **Report** titled "*Data outside normal ranges*".

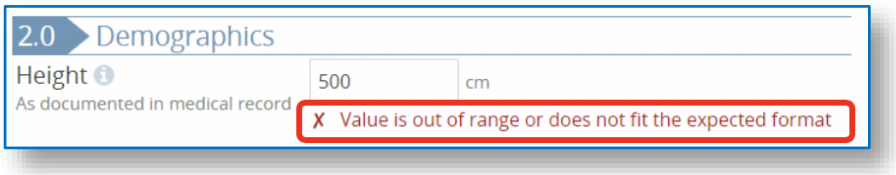


- Using the two dropdown categories to display a list of patients with data outside normal ranges.
- The two categories are:
  - **Monitoring status**: select monitored or unmonitored status
  - **Select form to report on**: select the relevant eCRF from the list provided.

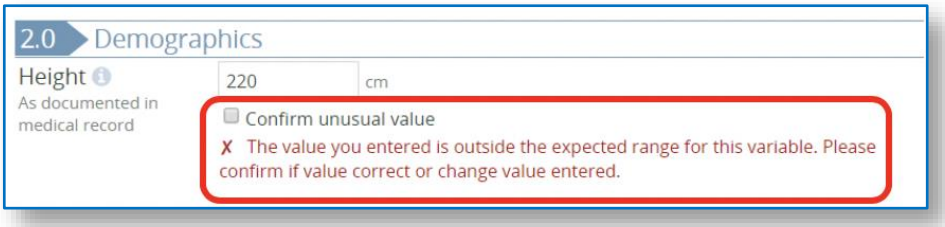
13.3. Error messages

- 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**:

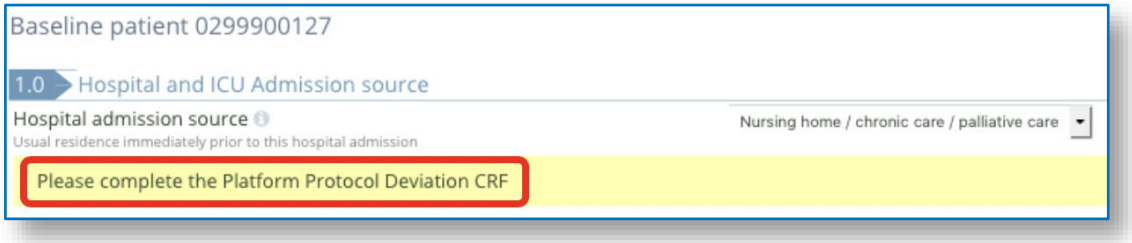
- **Not allowed**: the value isn't allowed to be saved. If the value is correct contact your project manager.



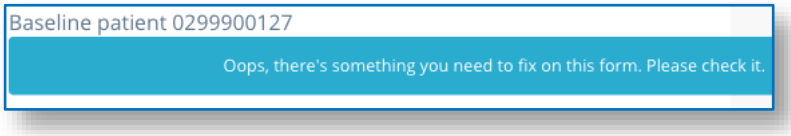
- **Amber Validation**: the value is considered abnormal but possible, check the value you entered, if it is correct, confirm the value by ticking the box.



- **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.

Daily data for day 7 has the patient in ICU but it neither starts nor finishes during an ICU admission

On the Patient List the patient's Participant Study Number is highlighted in yellow.

Patient	Initials	Day	Randomised	Baseline	Microbio	Daily	Consent	Discharge	Day 90 due	Day 180 due
0299900118	F-L	2	08-Oct-2018	✗	✗	✗	✗	✗	6 Jan	6 Apr
0299900117	FML	2	08-Oct-2018	✗	✗	✗	✗	✗	6 Jan	6 Apr
0299900116	KLJ	37	03-Sep-2018	✓	✓	?	✓	✓	✗	✗
0299900115	HBH	63	08-Aug-2018	?	✗	?	✗	?	6 Nov	4 Feb
0299900114	TEE	63	08-Aug-2018	✗	✗	✗	✗	✗	6 Nov	4 Feb

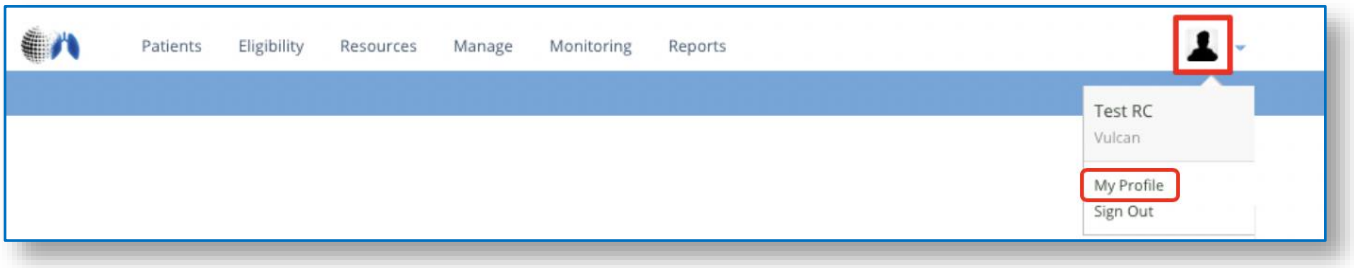
14.REPORTS

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:
    - **Data Query Reports**: displayed in a web browser, or can be downloaded by clicking “export results” once the report has loaded in your browser
    - **Data Exports**: downloaded as a CSV or Excel file
- To access reports or exports that have been downloaded, use the **“My Reports”** 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

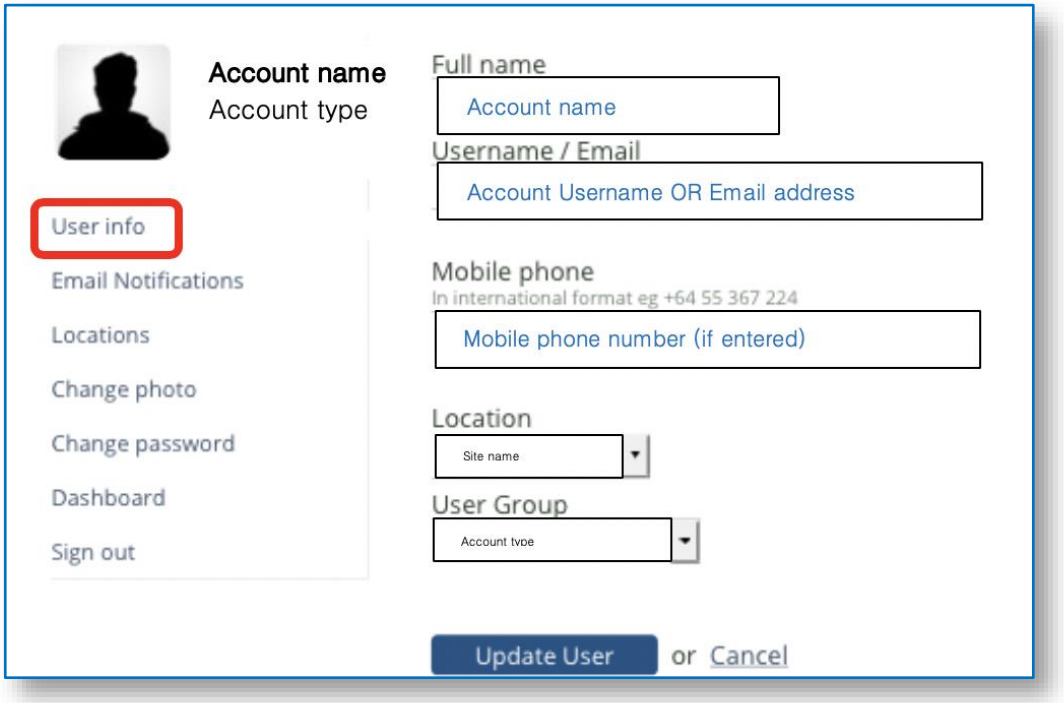
- Individual accounts (e.g. Research Coordinator and Investigator) can update their passwords and manage their account settings via the Profile.
- From the dashboard page, navigate to the top right-hand corner where you will see your site name, click on the icon and select "*My Profile*" from the dropdown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

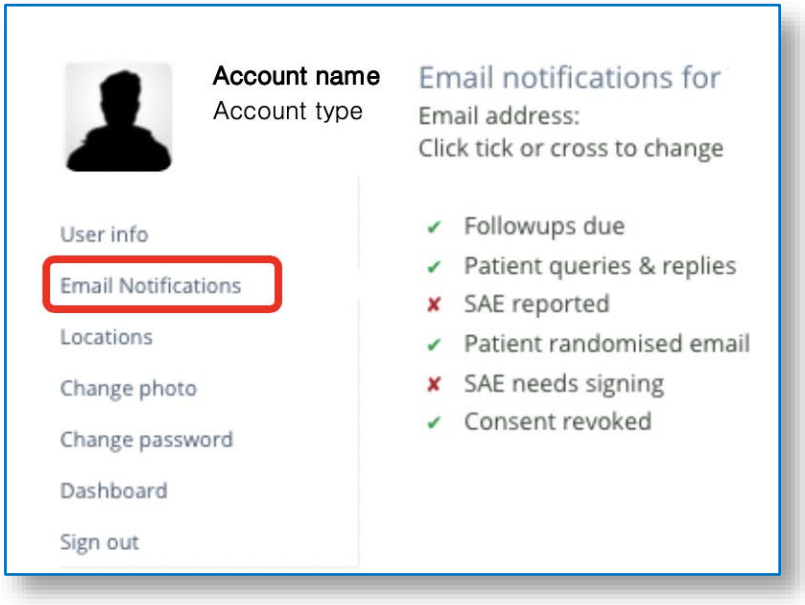
15.1.1. User information

- When you select "*My Profile*" the User Info page will automatically load.
- On the User Info page, you can edit:
  - Account name
  - Account username or email address
  - Mobile phone number (including all international calling codes)
  - Export format (whether exports are downloaded as CSV or Excel files)
- Users cannot edit their own:
  - Account Location
  - User Group (aka account type)



15.1.2. Email notifications

- Users may receive a variety of automated notification emails from the database.
- Click on "*Email Notifications*" 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.
- To change your settings, click on the cross (✘) or tick (✔) to turn the notification on or off.



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.
- Treatment availability change – treatment intervention is made available.
- 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

Eligibility pending

- Any patient who is 'Eligibility pending' are in the following categories:
    - Platform Pending – the patient does not have the required level of organ support but the time-window for randomisation is still open.
    - Consent Pending - the patient has been indicated as capable of providing informed consent to participate in REMAP-CAP (prior to randomisation) and consent is still pending and the time-window for randomisation is still open.

Reveal pending

- 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 21, 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 "*Change 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 Baseline eCRF. 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. **The calculation of chart-days is wrong in our database. What can I do?**
   Collect data as requested on the paper CRF and contact your project manager to fix the database.

5. **My ICU Chart start time is changing (e.g. changing from 08:00 to midnight). What can I do?**
   Contact your project manager who can change this for you.

6. **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.

7. **How do I check which domains & interventions my patient is randomised to?**
   Refer to Randomisation allocation in this document.