

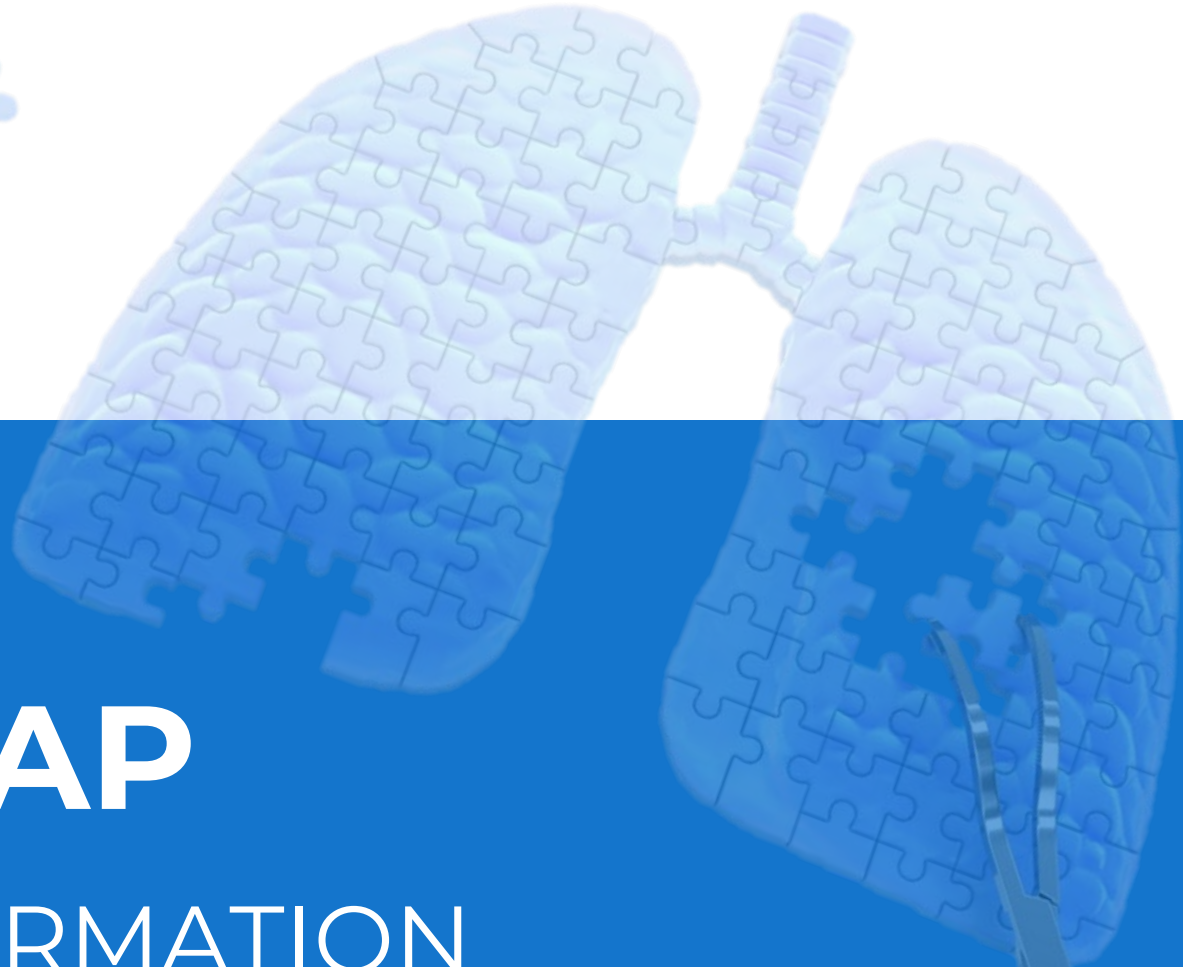
VERSION 3.0  
30-JAN-2026

# REMAP-CAP

## ECRF TRAINING (SITES)

# AGENDA

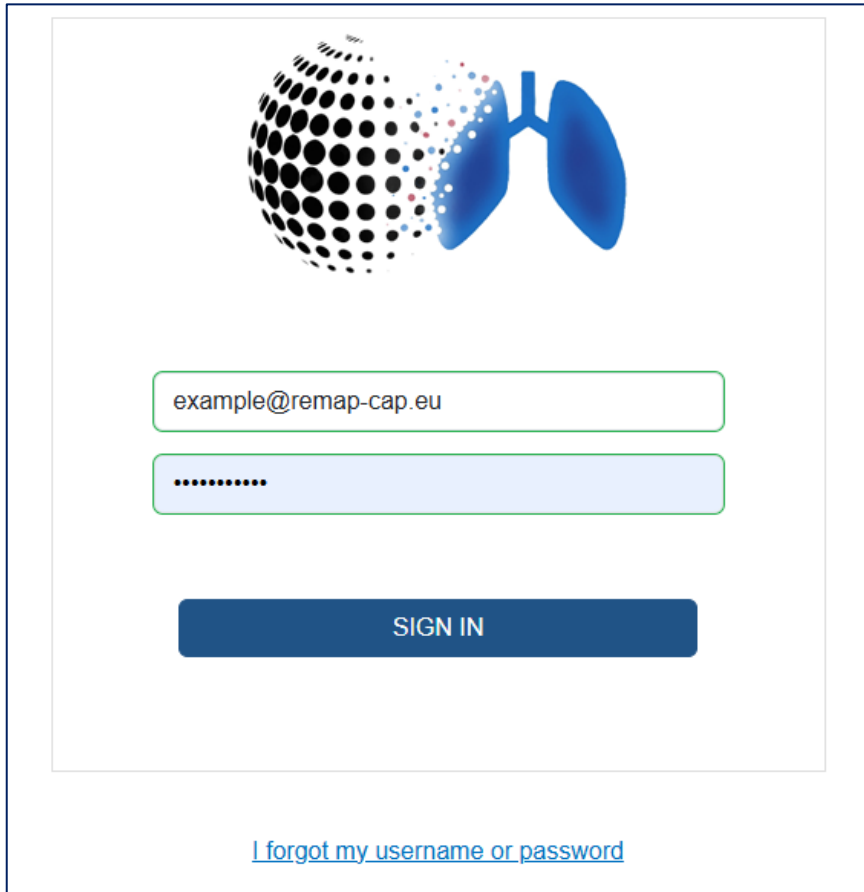
- General Information
- Navigating the Database
- Randomisation
- Specific CRFs: Informed Consent, Serious Adverse Events, Protocol Deviations
- Editing Eligibility Data
- Investigator Sign-off
- Additional tips
- Test participant Randomisation



# REMAP-CAP

## GENERAL INFORMATION

# INTRODUCTION ECRF | SPINNAKER

A screenshot of the login page for the REMAP-CAP eCRF system. At the top, there is a logo consisting of a globe and a pair of lungs. Below the logo are two input fields: the first contains the email address "example@remap-cap.eu" and the second contains a masked password ".....". A dark blue "SIGN IN" button is positioned below the password field. At the bottom of the page, there is a link that reads "I forgot my username or password".

example@remap-cap.eu

.....

SIGN IN

[I forgot my username or password](#)

- The REMAP-CAP electronic Case Report Form (eCRF) can be accessed via the following **URL**: <https://remapcap.spinnakersoftware.com>
- The following **roles** can be assigned to individual accounts, each with their own eCRF permissions:
  - Investigators
  - Research Coordinator
  - eCRF Data Collector
  - Outcome Assessor
  - Pharmacist
  - Randomisation User
- Login requires **Two-Factor Authentication** (2FA), using Google Authenticator, Microsoft Authenticator or Twilio Authy.

## INTRODUCTION ECRF | SPINNAKER

- A Spiral Database Form should be completed, to allow:
  - Set-up of site in the Spinnaker database according to domain/intervention selection.
  - Creation of personal eCRF user accounts for site staff (based on their delegated tasks). Please note that:
    - User invitations **expire after 5 days** → Sponsor / CRA should be alerted in case this happens.
    - Usernames must be an e-mail address belonging to **one individual**.
    - Subsequent account requests are arranged via Sponsor / CRA.
- Recommended browsers include Mozilla Firefox, Google Chrome and Safari.



Mozilla  
Firefox



Google  
Chrome



Safari

## SETTING UP A NEW USER ACCOUNT

- Steps for new users upon receiving invitation e-mail:
  - Click on the link in the e-mail.
  - Enter your chosen password in line with the Spinnaker Password Policy.
  - Set-up 2FA
- Your user account is initially linked to a test site environment\*.
- Your user account will be transferred to the live site environment after site greenlight and/or documented training.

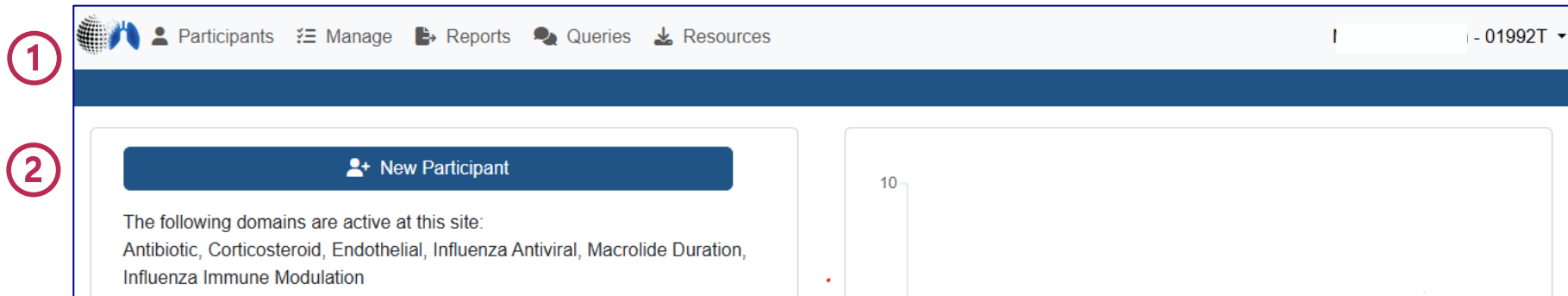
\* For all site staff entering data in the eCRF, randomization of a test-participant needs to be performed before getting access to the site live-environment.

# REMAP-CAP

NAVIGATING THE DATABASE

# DASHBOARD (I)

- 1. Navigation toolbar:** select to view dashboard, view enrolled / screened participants, view user accounts, export data reports, follow-up on monitoring queries, access resources, switch sites, update user account information and to setup eCRF e-mail notifications.
- 2. New Participant:** select to screen / randomise a new participant.



1

2

Participants Manage Reports Queries Resources | - 01992T

+ New Participant

The following domains are active at this site:  
Antibiotic, Corticosteroid, Endothelial, Influenza Antiviral, Macrolide Duration,  
Influenza Immune Modulation

# DASHBOARD (II)

- 3. Switch system:** select to go to the old database system. Note that this is only applicable to sites who were active before core protocol V4.0 to view the eCRF for participants enrolled under core protocol <V4.0.
- 4. Enrolment Graph:** shows participant recruitment over time at your site.

**3**

+ New Participant

The following domains are active at this site:  
 Antibiotic, Corticosteroid, Endothelial, Influenza Antiviral, Macrolide Duration, Influenza Immune Modulation

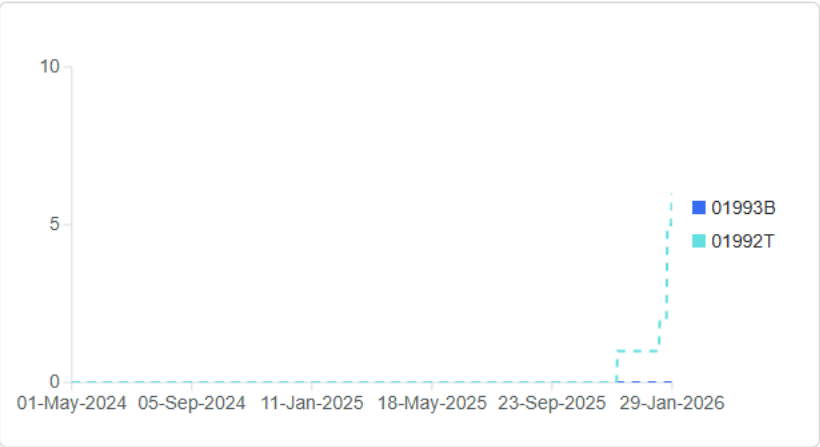
Switch system

**Pending transfers at 01992T - Germany Test Site- Eriador Infirmiry Adult ICU**

ID	PARTICIPANT	TYPE	FROM	TO
<a href="#">8</a>	<a href="#">0199200059</a>	Physical	01992T	01992T

[Transfer List](#)

**4**



Legend: 01993B (blue), 01992T (teal)

## DASHBOARD (III)

- 5. Pending transfers:** shows participant transfers to other sites, pending approval of the receiving site.
- 6. Consent Pending:** shows participants for which eligibility is pending informed consent. Once obtained, click on the hyperlink to complete the Eligibility eCRF.
- 7. Pending domains:** shows participants for which additional information is required for intervention allocation. Once obtained, click on the hyperlink to complete the Eligibility eCRF.

5

### Pending transfers at 01992T - Germany Test Site- Eriador Infirmary Adult ICU

ID	PARTICIPANT	TYPE	FROM	TO
<a href="#">8</a>	<a href="#">0199200059</a>	Physical	01992T	01992T

[Transfer List](#)

6

### Consent Pending at 01992T - Germany Test Site- Eriador Infirmary Adult ICU

No eligibility at 01992T currently consent pending

7

### Pending domains at 01992T - Germany Test Site- Eriador Infirmary Adult ICU

No participants at 01992T have domains pending

# DASHBOARD (IV)

- 8. **Recent randomisations:** shows the most recent randomised participants.
- 9. **Recent screenings:** shows the most recent screened participants. Note that participants with a blank “Outcome” column require additional data entry in their Eligibility eCRF to complete eligibility assessment

8

## Recent randomisations at 01992T - Germany Test Site-Eriador Infirmary Adult ICU

PARTICIPANT	RANDOMISED	DOMAINS	PENDING
<a href="#">0199200061</a>	<a href="#">28-Jan-2026</a>	<a href="#">ZL_ZN</a>	
<a href="#">0199200060</a>	<a href="#">23-Jan-2026</a>	<a href="#">ZN</a>	
<a href="#">0199200059</a>	<a href="#">23-Jan-2026</a>	<a href="#">ZN</a>	
<a href="#">0199200058</a>	<a href="#">23-Jan-2026</a>	<a href="#">ZN</a>	
<a href="#">0199200057</a>	<a href="#">15-Jan-2026</a>	<a href="#">ZA_ZC</a>	
<a href="#">0199200056</a>	<a href="#">01-Dec-2025</a>	<a href="#">ZC</a>	
<a href="#">0199200055</a>	<a href="#">04-Feb-2025</a>		
<a href="#">0199200054</a>	<a href="#">17-Apr-2024</a>		
<a href="#">0199200053</a>	<a href="#">17-Apr-2024</a>		
<a href="#">0199200052</a>	<a href="#">14-Apr-2024</a>		

[All randomised participants](#)

9

## Recent screenings at 01992T - Germany Test Site-Eriador Infirmary Adult ICU

ELIGIBILITY	AGE	OUTCOME
<a href="#">IZTLZL</a>	<a href="#">30</a>	<a href="#">Not Randomised</a>
<a href="#">IRMYXS</a>	<a href="#">30</a>	<a href="#">Timeout 48hr</a>
<a href="#">AKGYFY</a>	<a href="#">30</a>	<a href="#">Timeout 48hr</a>
<a href="#">UNRXVZ</a>	<a href="#">30</a>	<a href="#">Timeout 48hr</a>
<a href="#">AFXYNK</a>	<a href="#">53</a>	
<a href="#">AHZTVY</a>	<a href="#">76</a>	
<a href="#">AMKQWD</a>	<a href="#">78</a>	
<a href="#">ATHWYN</a>	<a href="#">68</a>	
<a href="#">APYDBL</a>	<a href="#">77</a>	
<a href="#">ASZYGW</a>	<a href="#">72</a>	

[Screening list](#)

# PARTICIPANTS SECTION (I)



Participants Manage Reports Queries Resources RohanTestIRC - 01992T

Participants Screening list New Participant

Find a Participant New Participant Study ID Search 01992T - Germany Test Site-Eriador In...

### Participants at 01992T - Germany Test Site-Eriador Infirmary Adult ICU

PARTICIPA...	STA...	AGE	SEX	DAY	RANDOM...	DO...	PENDING	BASELI...	CONSE...	MICRO...	DAILY	DISCHA...	D 90
<a href="#">0199200056</a>	Severe	77	Female	45	01-Dec-2025	ZC		✓	✓	✓	?	✗	28 Feb

20 of 55 shown  
View all protocol version < 4 participants and more detailed search [here...](#)

PARTICIP...	A...	S...	D...	D...	P...	BL	MB	D...	M...	D	D 21	D 90	D 180
<a href="#">0199200055</a>	35	F	345	AC		✗	✗	False	False	✗	✗	05 May	03 Aug

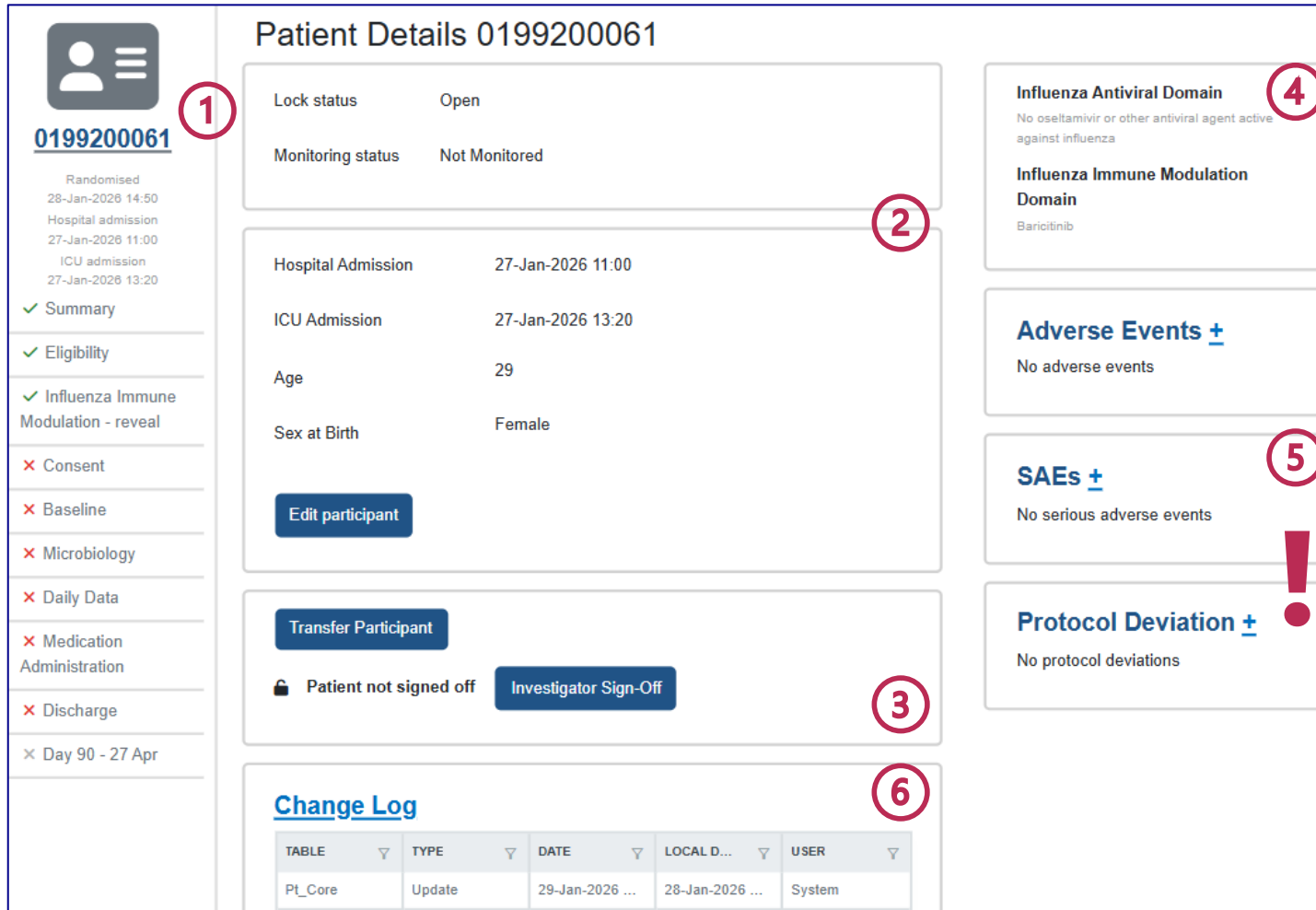
E-mail notifications will be sent.

Only applicable to sites who were active before core protocol V4.0.

E-mail notifications will be sent.

Select participant study number to see details & complete eCRF.

# PARTICIPANTS SECTION (II)



**1** Participant eCRF Navigation Pane

**2** Patient Details Summary

**3** Transfer Participant & Investigator Sign-Off

**4** Randomisation allocation

**5** Event reporting: Serious Adverse Events (SAEs) and/or Protocol Deviations (PDs)

**6** Change Log

**0199200061**

Randomised  
28-Jan-2026 14:50  
Hospital admission  
27-Jan-2026 11:00  
ICU admission  
27-Jan-2026 13:20

✓ Summary  
✓ Eligibility  
✓ Influenza Immune Modulation - reveal  
✗ Consent  
✗ Baseline  
✗ Microbiology  
✗ Daily Data  
✗ Medication Administration  
✗ Discharge  
✗ Day 90 - 27 Apr

**Patient Details 0199200061**

Lock status: Open  
Monitoring status: Not Monitored

Hospital Admission: 27-Jan-2026 11:00  
ICU Admission: 27-Jan-2026 13:20  
Age: 29  
Sex at Birth: Female

Edit participant

Transfer Participant

🔒 Patient not signed off Investigator Sign-Off

**Influenza Antiviral Domain**  
No oseltamivir or other antiviral agent active against influenza

**Influenza Immune Modulation Domain**  
Baricitinib

**Adverse Events ±**  
No adverse events

**SAEs ±**  
No serious adverse events

**Protocol Deviation ±**  
No protocol deviations


**Change Log**

TABLE	TYPE	DATE	LOCAL D...	USER
Pt_Core	Update	29-Jan-2026 ...	28-Jan-2026 ...	System

- Participant eCRF Navigation Pane:** select an eCRF tab or icon (tick or cross) to open the corresponding eCRF page.
- Participant details:** shows participant summary, monitoring and lock status.
- Transfer Participant & Investigator Sign-Off**
- Randomisation allocation**
- Event reporting:** select to add Serious Adverse Events (SAEs) and/or Protocol Deviations (PDs).
- Change Log**

# PARTICIPANTS SECTION (III)





### 0199200056

Randomised  
01-Dec-2025 16:40  
Hospital admission  
30-Nov-2025 15:00  
ICU admission  
01-Dec-2025 09:00

⚠

- ✓ Summary
- ✓ Eligibility
- ✓ Consent
- ✓ Baseline
- ✓ Microbiology
- ? Daily Data
- ✓ Medication Administration
- ✗ Discharge
- ✗ Day 90 - 28 Feb

#### Patient Details 0199200056

⚠ Based on this participant's allocated intervention for administration, prohibited medications (Triamcinolone) have been administered. Please ensure this is correct or complete a Protocol Deviation form.

Lock status: Open

Monitoring status: Not Monitored

Hospital Admission: 30-Nov-2025 15:00


ICU Admission: 01-Dec-2025 09:00

Age: 77

Sex at Birth: Female

**Edit participant**

**Transfer Participant**



### 0199200056

Randomised  
01-Dec-2025 16:40  
Hospital admission  
30-Nov-2025 15:00  
ICU admission  
01-Dec-2025 09:00

⚠

- ✓ Summary
- ✓ Eligibility
- ✓ Consent
- ✓ Baseline
- ✓ Microbiology
- ? Daily Data
- ✓ Medication Administration
- ✗ Discharge
- ✗ Day 90 - 28 Feb

#### Patient Details 0199200056

⚠ Based on this participant's allocated intervention for administration, prohibited medications (Triamcinolone) have been administered. Please ensure this is correct or complete a Protocol Deviation form.

Lock status: Open

Monitoring status: Not Monitored

Hospital Admission: 30-Nov-2025 15:00 24 hr clock

ICU Admission: 01-Dec-2025 09:00 24 hr clock

Age: 77

Sex at Birth:  Male  Female

**Update** **Cancel**

**Transfer Participant**



# PARTICIPANTS SECTION (IV)



Participants Manage Reports Queries Resources RohanTestRC - 01992T

Participants **Screening list** New Participant

### Screening List

Eligibility Code Search 01992T - Germany Test Site-Eriador Infirmary Adult ICU

#### Screenings at 01992T - Germany Test Site-Eriador Infirmary Adult ICU

PARTICIPANT CODE	REGISTRY OR STUDY ID	AGE AT ENTRY	SEX AT BIRTH	ENTERED DATE	UPDATED DATE	OUTCOME OF ELIGIBILITY	REASON FOR OUTCOME
<a href="#">IRMYXS</a>		30	Male	12-Jan-2026 12:38	12-Jan-2026 12:46	Timeout 48hr	Timeout 48hr
<a href="#">AKGYFY</a>							Timeout 48hr
<a href="#">UNRXVZ</a>							Timeout 48hr
<a href="#">AJTJWP</a>							

#### Result - IRMYXS - Timeout 48hr

Reasons:  
Timeout 48hr

#### Domain and intervention eligibility

The participant is ineligible for the trial for the reason stated above but the information below shows which domains and interventions they were eligible for

This patient was eligible for the following domains at 01992T - Germany Test Site-Eriador Infirmary Adult ICU  
Antibiotic, Influenza Antiviral, Macrolide Duration, Influenza Immune Modulation  
Ineligible for 2 domains

[Show details](#)

# QUERIES SECTION

Participants Manage Reports **Queries** Resources

## Queries

01992T - Germany Test Site    Open or Resolved

PATI...	SUBJECT
<a href="#">01992000...</a>	<a href="#">Eligibility &gt; Illness Severity State &gt; Is the patient c</a>

### Query for participant 0199200060

Patient: [0199200060](#)    Site: 01992T - Germany Test Site- Eriador Infirmary Adult ICU    Raised by:    Status: Open

Variable Queried: [Eligibility](#) > Illness Severity State > Is the patient currently receiving oxygen support : Invasive mechanical ventilation

**Query description**  
Test query.

**Action request**  
Test action request.

**Status Open**    [Update status](#)

**Replies**    [Add reply](#)

Click on hyperlink to open the query details and to resolve / update the query.



# RESOURCES SECTION

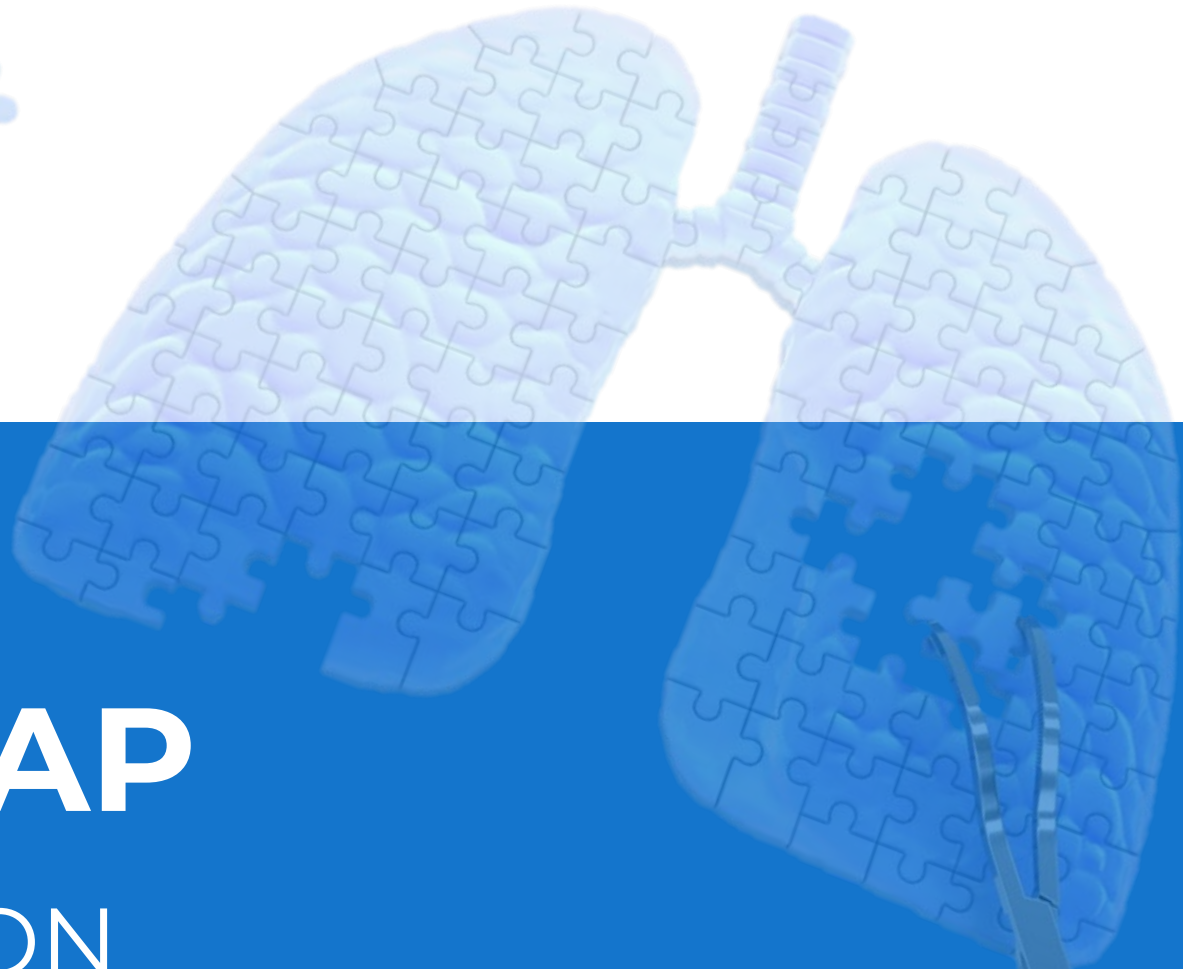


Participants Manage Reports Queries Resources

## Resources REMAP-CAP

- ▶ 10CRF (2)
- ▶ 20Manuals (1)
- ▶ 30Protocol documents (0)
- ▶ 40Forms and Logs (0)
- ▶ 50Study Tools (0)
- ▶ 60Co-enrolment (0)
- ▶ 70Newsletters (0)
- ▶ 80Training (1)
- ▶ 90Other (0)
- ▶ 95AdministrationGuides (10)

In case you need eCRF guidance, the Spiral database guide and/or eCRF data completion guidelines can also be found in this section.



# REMAP-CAP

## RANDOMISATION

## INTRODUCTION ECRF | SPINNAKER

- Spinnaker's eligibility assessment tool is dynamic → reviews eligibility after every page (when you click "Next"), which prevents unnecessary data entry.
- The database will inform you if the participant is no longer eligible.
- Eligibility criteria defined at multiple levels:
  - Platform criteria
  - Domain criteria
  - Intervention criteria
- Data entry in the Eligibility eCRF takes about 10 minutes.



# ADDING A NEW PARTICIPANT



The screenshot shows the 'Participants' section of the REMAP-CAP interface. The navigation bar includes 'Participants', 'Screening list', and 'New Participant'. Below the navigation bar, there is a 'Find a Participant' section with a 'New Participant' button circled in red. To the right of this button is a 'Study ID' input field and a 'Search' button. Below this is a table titled 'Participants at 01992T - Germany Test Site-Eriador Infirmary Adult ICU'.

PARTICIPA...	STA...	AGE	SEX	DAY	RANDOM...	DO...	PENDING	BASELI...	CONSENT	MICRO...	DAILY	DISCHA...	D 90
▲ 0199200056	Severe	77	Female	45	01-Dec-2025	ZC		✓	✓	✓	?	×	28 Feb


Via the "New Participant" button on the Participants section of the Navigation toolbar...

There are two ways to access the Eligibility eCRF and add a new participant

The screenshot shows the dashboard of the REMAP-CAP interface. The navigation bar includes 'Participants', 'Manage', 'Reports', 'Queries', and 'Resources'. Below the navigation bar, there is a large blue button with a person icon and the text 'New Participant', which is circled in red.

... or via the "New Participant" button on your dashboard / landing page.

# ELIGIBILITY CRF (I)



**IZTLZL**

- ✓ Demographics
- ➔ Platform Eligibility
- ✗ State
- ✗ PANDA
- ✗ Domain Eligibility
- ✗ Intervention Eligibility
- ✗ Consent
- ✗ Best Interests

## Platform Eligibility IZTLZL

▶ Platform Eligibility

Does the patient have acute infection of the respiratory tract i ⌚ Yes No

Is death deemed imminent and inevitable during the next 24 hours i ⌚ Yes No  
The senior treating clinician believes there is no reasonable possibility of the patient surviving the next 24h

Is the patient, their substitute decision maker, or their primary treating clinician committed to some active treatment i ⌚ Yes No  
This criterion seeks to exclude those patients where supportive comfort measures are being provided. Patients who are planned for active ward management with a clear aim to improve survival, even if intensive care unit level support is not being offered, should still be included

Is the patient expected to be discharged from this hospital admission today or tomorrow i ⌚ Yes No

Has the patient been enrolled into this Platform before i ⌚ Yes No

Save

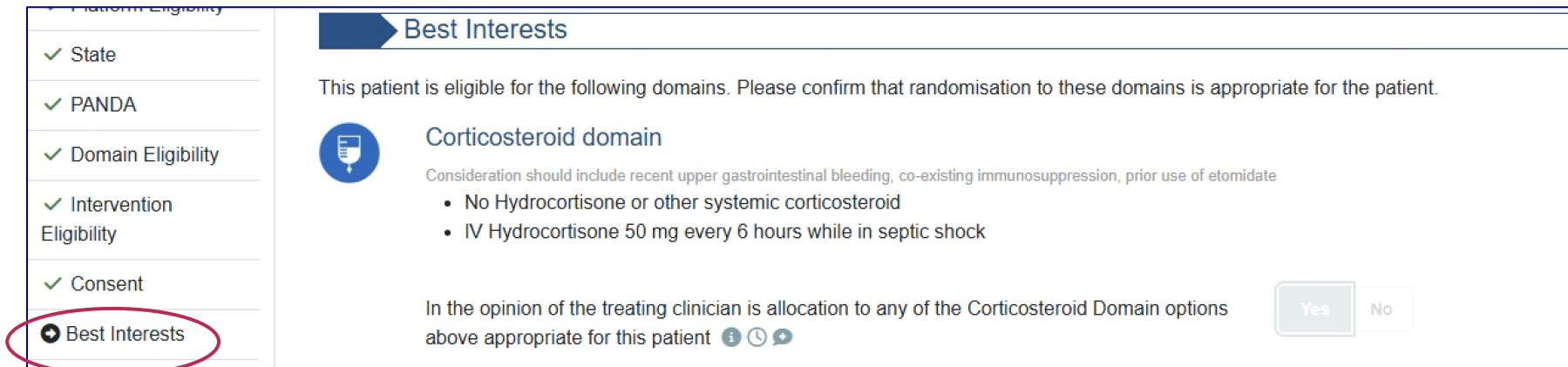
Eligibility eCRF  
Navigation Pane

- All questions must be answered before clicking on “Next”.
- If you click stop midway in a form, the information entered in the Form will not be saved.
- You can go back to check or change previously answered questions at any time by selecting the relevant tab on the Eligibility eCRF Navigation Pane.



## ELIGIBILITY CRF (III)

- Best interests of participant → final step before randomization.
- Decision if domain participation is appropriate by a clinician → EMERGENCY BRAKE



The screenshot displays the 'Platform Eligibility' section of the CRF. On the left, a list of steps is shown with checkmarks: State, PANDA, Domain Eligibility, Intervention Eligibility, Consent, and Best Interests. The 'Best Interests' step is circled in red. The main content area is titled 'Best Interests' and contains the following text:

This patient is eligible for the following domains. Please confirm that randomisation to these domains is appropriate for the patient.

**Corticosteroid domain**

Consideration should include recent upper gastrointestinal bleeding, co-existing immunosuppression, prior use of etomidate

- No Hydrocortisone or other systemic corticosteroid
- IV Hydrocortisone 50 mg every 6 hours while in septic shock

In the opinion of the treating clinician is allocation to any of the Corticosteroid Domain options above appropriate for this patient


Yes No

## ELIGIBILITY OUTCOMES

- “*Randomised*” → participant meets platform and domain eligibility criteria for at least one domain.
- “*Platform Ineligible*” → participant does not meet platform eligibility criteria.
- “*Not Randomised/Registry*” → participant meets platform eligibility criteria but does not meet state or domain eligibility criteria.
- “*Eligibility/Screening pending*” → participant has not yet met all the platform eligibility criteria, but there is still time for these to be met.
  - “*Consent Pending*” → participant (or their representative) has not yet provided informed consent, but there is still time for this to be obtained.
- E-mail notifications are sent to all user accounts linked to the site, confirming the eligibility assessment outcome.


# RANDOMISATION RESULTS

1. **Participant credentials**
2. **Randomisation results:** shows allocation status of participant per domain.
3. **Next steps:** shows how to proceed with participant (reference to administration guide where needed).
4. **Print option:** select to [print the randomisation results for in your Investigator Site File \(ISF\)](#).



**IZWNTP**  
Randomised  
15-Jan-2026 16:19  
**0199200057**

- ✓ Pt Summary
- ✓ Demographics
- ✓ Platform Eligibility
- ✓ State
- ✓ PANDA
- ✓ Domain Eligibility
- ✓ Intervention Eligibility
- ✓ Consent
- ✓ Best Interests
- ✓ Result

Platform confirmed 0199200057 4  Print this page

**1** Participant 0199200057

Randomised 15-Jan-2026 16:19  
Age 22 has been enrolled in the REMAP-CAP Trial

	Domain	Allocation Status
<b>2</b>	<b>ZA</b> Antibiotic Domain	IV Ceftriaxone + Macrolide
	<b>ZM</b> Macrolide Duration Domain	Reveal pending by 20-Jan-2026 23:59 (end of day 5)
	<b>ZC</b> Corticosteroid Domain	No Hydrocortisone or other systemic corticosteroid
	<b>ZI</b> Influenza Antiviral Domain	Reveal pending by 17-Jan-2026 16:19 (within 48 hours of randomisation)
	<b>ZE</b> Endothelial Domain	Reveal pending by 17-Jan-2026 16:19 (within 48 hours of randomisation)
	<b>ZN</b> Influenza Immune Modulation Domain	Reveal pending by 17-Jan-2026 16:19 (within 48 hours of randomisation) Intervention for this domain will be revealed on the Reveal Page. Some additional questions will need to be answered to reveal allocation. A positive microbiological test for influenza is required to reveal allocation in this domain. Please ensure that results of microbiological testing for influenza are available before revealing allocation

**3** What to do now ...


**Antibiotic**

- IV Ceftriaxone + 3 days of Macrolide
- Next steps are outlined in the [Antibiotic Domain \(ZA\) Administration Guide](#) (pdf). Please print this and leave it at the bedside

# DOMAIN REVEAL PENDING



Some domains require extra info before allocation can be revealed.



**0199200057**

Randomised  
15-Jan-2026 16:19  
Hospital admission  
15-Jan-2026 15:00  
ICU admission  
15-Jan-2026 15:00

✓ Summary

✓ Eligibility

- ? Endothelial - reveal
- ? Influenza Antiviral - reveal
- ? Macrolide Duration - reveal
- ? Influenza Immune Modulation - reveal

## Patient Details 0199200057

Lock status	Open
Monitoring status	Not Monitored

Hospital Admission	15-Jan-2026 15:00
ICU Admission	15-Jan-2026 15:00
Age	22
Sex at Birth	Male

[Edit participant](#)

[Transfer Participant](#)

**Antibiotic Domain**  
IV Ceftriaxone + Macrolide

**Macrolide Duration Domain**  
Reveal pending by 20-Jan-2026 23:59 (end of day 5)

**Corticosteroid Domain**  
No Hydrocortisone or other systemic corticosteroid

**Influenza Antiviral Domain**  
Reveal pending by 17-Jan-2026 16:19 (within 48 hours of randomisation)

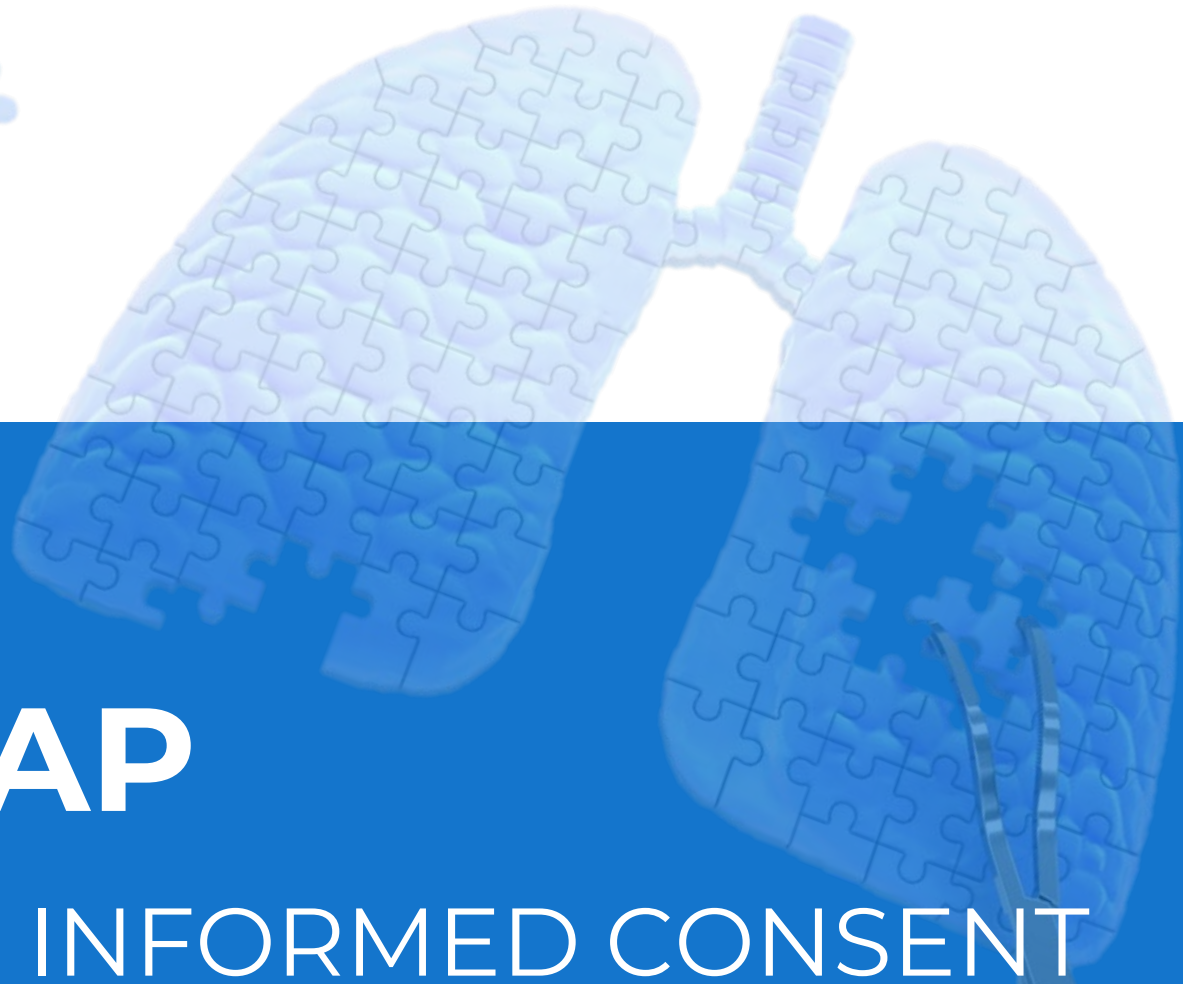
**Endothelial Domain**  
Reveal pending by 17-Jan-2026 16:19 (within 48 hours of randomisation)

**Influenza Immune Modulation Domain**  
Reveal pending by 17-Jan-2026 16:19 (within 48 hours of randomisation)



The Participant's Summary Page will indicate which domains are pending reveal





# REMAP-CAP

SPECIFIC CRFS: INFORMED CONSENT

## CONSENT ECRF

- Every consent event must be entered in the eCRF, also if obtained at a later stage.
- Select the Consent eCRF tab of the Participant eCRF Navigation to add consent events, including (but not limited to):
  - Consent approval (by participant or proxy);
  - Consent revokal (by participant of proxy);
  - Consent discussion without clear outcome;
  - Consent in verbal form / via phone.
- If participant or proxy revokes consent, the Participant eCRF will be locked in accordance with indicated (participant/proxy) preferences and country regulations.



**0199200057**

Randomised  
15-Jan-2026 16:19  
Hospital admission  
15-Jan-2026 15:00  
ICU admission  
15-Jan-2026 15:00

✓ Summary

✓ Eligibility

? Endothelial - reveal

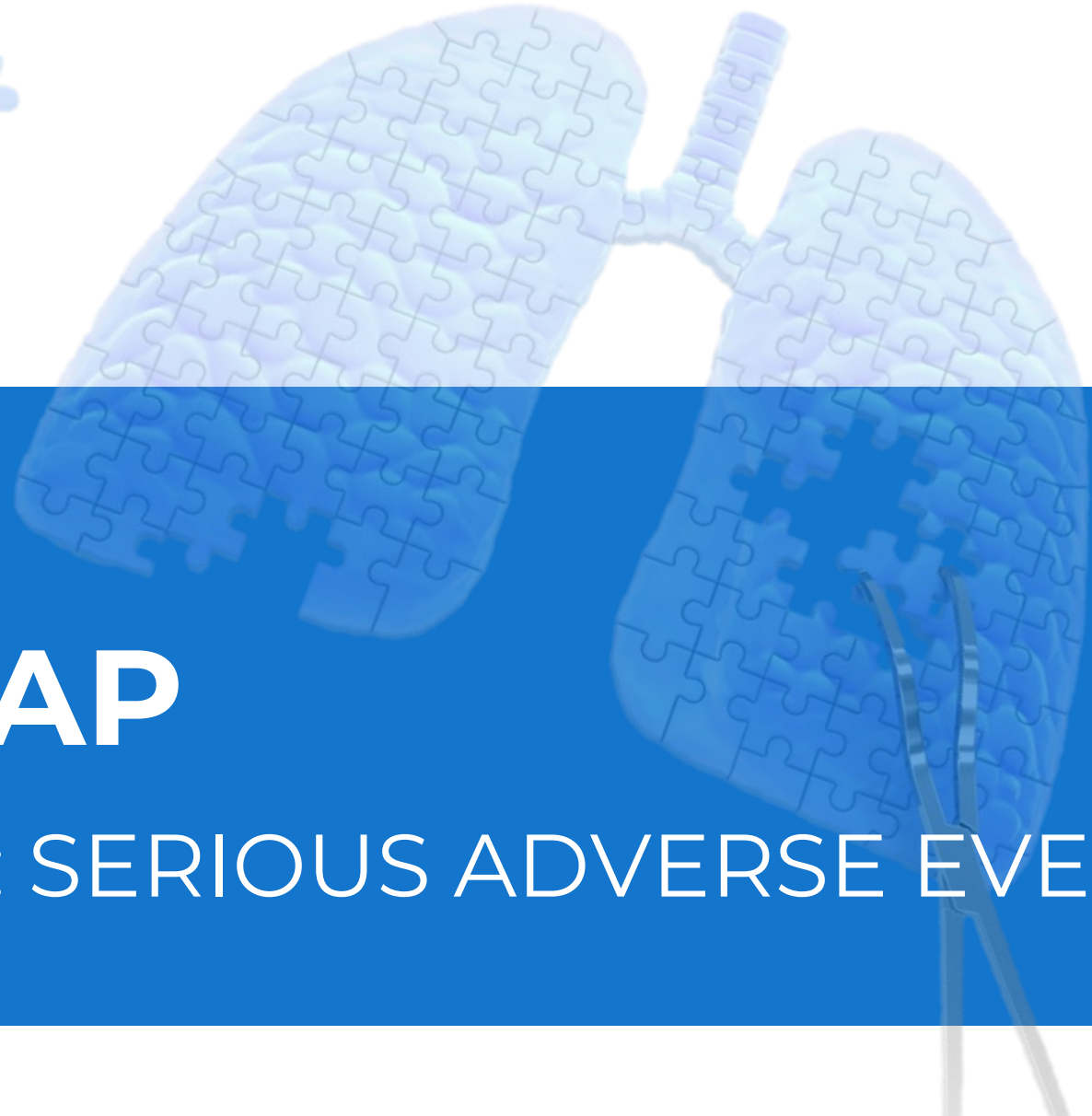
? Influenza Antiviral -  
reveal

? Macrolide Duration  
- reveal

? Influenza Immune  
Modulation - reveal

✗ Consent

✗ Baseline



# REMAP-CAP

SPECIFIC CRFS: SERIOUS ADVERSE EVENTS

# SAE ECRF

- Every SAE meeting the REMAP-CAP safety reporting criteria, need to be entered in the eCRF.
- Complete an initial SAE report within 24 hours of becoming aware of the event → Sponsor receives an automatic e-mail notification and may follow-up to request additional information.
- If more info about the event becomes available, complete a follow-up report linked to the initial SAE report
- Once Sponsor Assessor has approved the information provided for this SAE, a final SAE report can be completed.
- The site’s Principal Investigator (PI) needs to sign off on every SAE.

L.D...	USER
n-2026 1...	RohanTestRC
n-2026 1...	RohanTestRC
n-2026 1...	RohanTestRC
n-2026 1...	RohanTestRC
n-2026 1...	RohanTestRC

**Adverse Events ±**  
No adverse events

**SAEs ±**  
No serious adverse events

**Protocol Deviation ±**  
No protocol deviations

# REMAP-CAP

SPECIFIC CRFS: PROTOCOL DEVIATIONS

## PD ECRF

- Every PD discovered on patient-level should be reported in the eCRF, separately.
- eCRF requires you to categorize the PD with pre-defined options, distinguishing between trial-related / platform-specific or domain-specific deviations.
- For PDs that do not fit a pre-defined category → select platform deviation and “OTHER”. Describe the PD in the free text box.

L.D...	USER
n-2026 1...	RohanTestRC
n-2026 1...	RohanTestRC
n-2026 1...	RohanTestRC
n-2026 1...	RohanTestRC
n-2026 1...	RohanTestRC

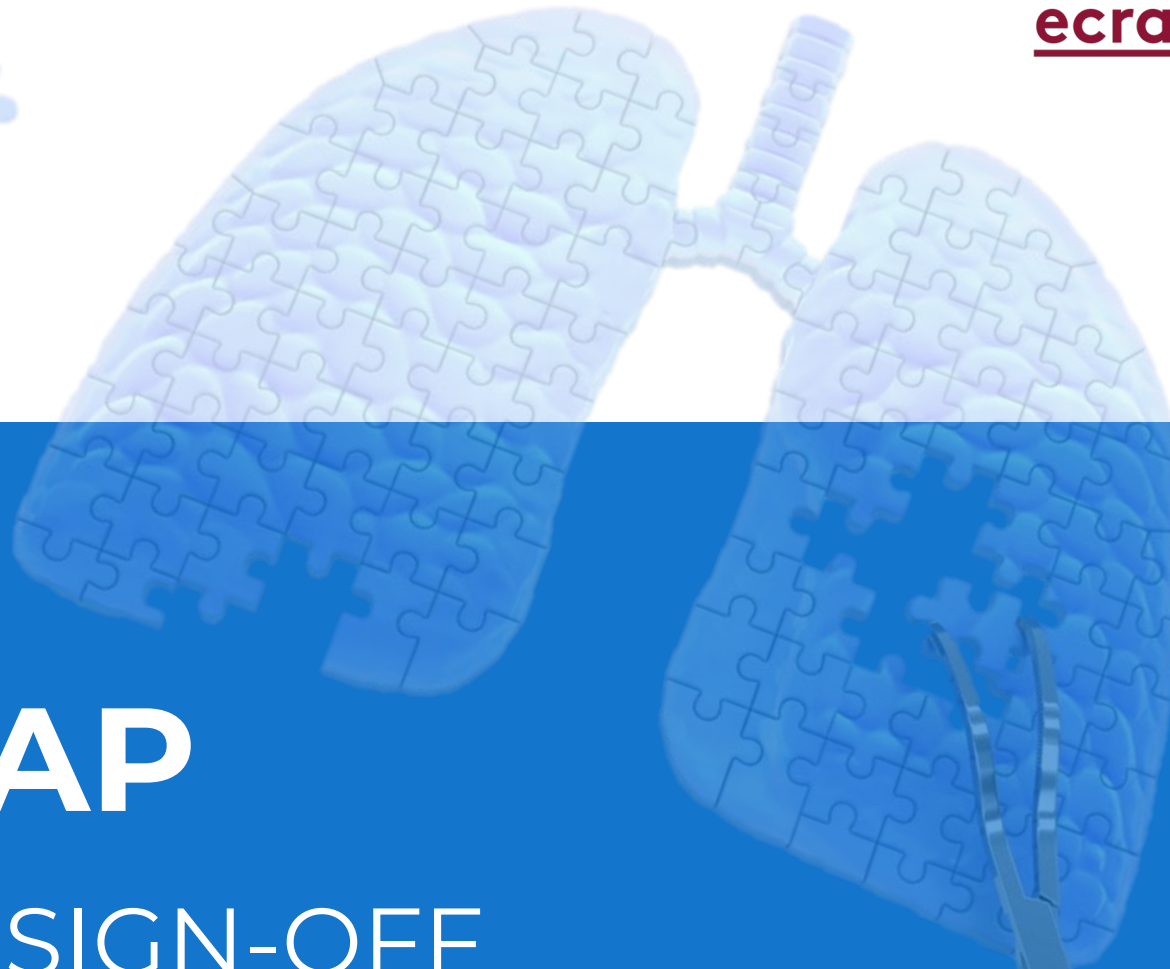
**Adverse Events ±**  
No adverse events

**SAEs ±**  
No serious adverse events

**Protocol Deviation ±**  
No protocol deviations



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# REMAP-CAP

INVESTIGATOR SIGN-OFF


## INVESTIGATOR SIGN-OFF

- Investigator sign-off of the eCRF is needed to confirm completeness and accuracy of data.
- PI or delegated sub-investigator are requested to sign-off eCRFs in regular intervals, at minimum:
  - within 20 days of completion of D180, or
  - prior to data lock requests by Sponsor.
- Two levels of sign-off possible:
  - Form-level sign-off
    - Signs off a specific Form as complete and accurate.
    - All Forms can be signed off, including SAE and PD forms.
  - Participant-level sign-off
    - Signs off the whole Participant eCRF as complete and accurate.

# FORM-LEVEL SIGN-OFF

- The "Sign off and lock this form" button is shown for every completed Form.

Baseline patient 0299900468

 Form is unlocked **Sign off and lock this form**


This form has been marked as complete by your project manager

**1.0** Hospital and ICU Admission source

Hospital admission source ⓘ  
Usual residence immediately prior to this hospital admission

Hospital admission date & time ⓘ  
Date & time the patient first presented from the community for this hospital admission e.g. ED presentation

Baseline patient 0299900468

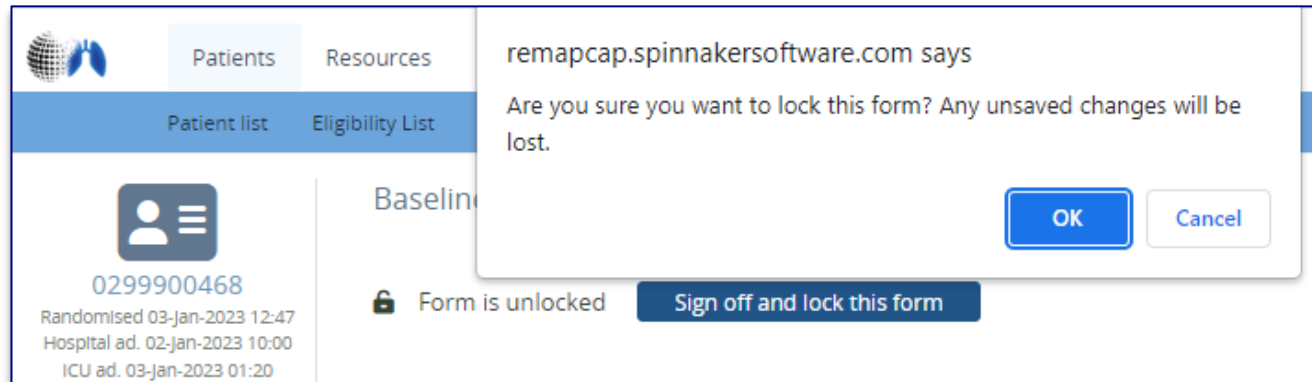

 Form is locked **Unlock this form**

This form has been marked as complete by your project manager

**1.0** Hospital and ICU Admission source

Hospital admission source ⓘ  
Usual residence immediately prior to this hospital admission

Hospital admission date & time ⓘ  
Date & time the patient first presented from the community for this hospital admission e.g. ED presentation




remapcap.spinnakersoftware.com says

Are you sure you want to lock this form? Any unsaved changes will be lost.

**OK** **Cancel**

Patients Resources  
Patient list Eligibility List


Baselin

 Form is unlocked **Sign off and lock this form**

0299900468  
Randomised 03-Jan-2023 12:47  
Hospital ad. 02-Jan-2023 10:00  
ICU ad. 03-Jan-2023 01:20



# PARTICIPANT-LEVEL SIGN-OFF



**Patient Details 0199200061**

Lock status: Open

Monitoring status: Not Monitored

Hospital Admission: 27-Jan-2026 11:00

ICU Admission: 27-Jan-2026 13:20

Age: 29

Sex at Birth: Female

[Edit participant](#)

[Transfer Participant](#)

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

**0199200061**

Randomised: 28-Jan-2026 14:50

Hospital admission: 27-Jan-2026 11:00

ICU admission: 27-Jan-2026 13:20

- Summary
- Eligibility
- Influenza Immune Modulation - reveal
- Consent
- Baseline
- Microbiology
- Daily Data
- Medication Administration
- Discharge

- Two possible options for participant-level sign-off:
  - “Leave participant lock status as is so that incomplete forms may be finished and new forms entered.” (e.g. if follow-up is still due)
  - “Apply final lock to participant so that no further data can be entered.” (e.g. if no further data entry is required).
- Lock status will appear on the participant summary page and change log.

Investigator sign-off 0299900457

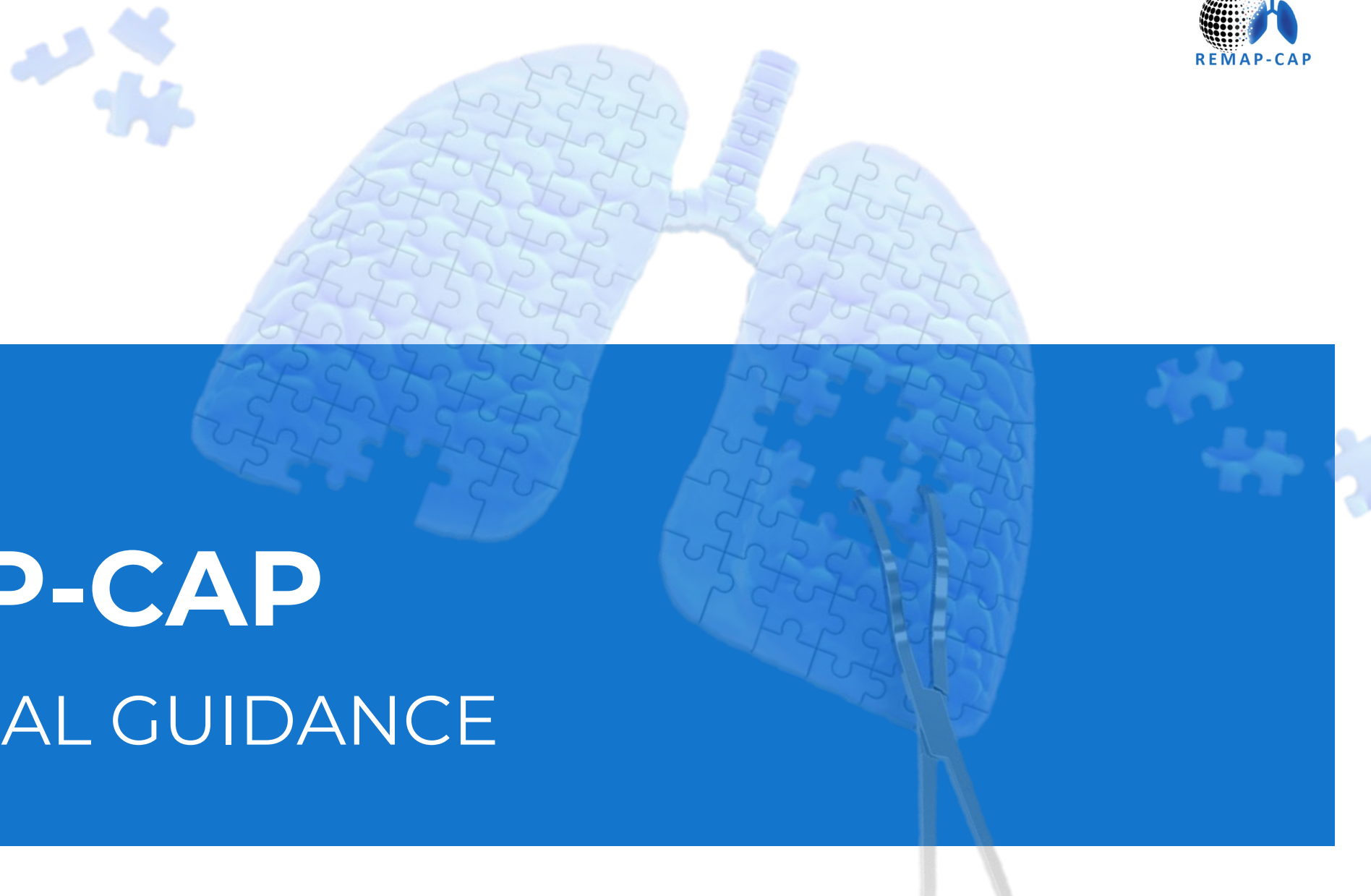
Please confirm that to the best of your knowledge the data entered for this patient is accurate and complete.

Sign and lock all existing and complete forms and...

- Leave patient lock status as is so that incomplete forms may be finished and new forms entered.
- Apply final lock to patient so that no further data can be entered.

[Confirm sign-off](#) or [Cancel](#)







# REMAP-CAP

## ADDITIONAL GUIDANCE

# FREQUENTLY REOCCURRING ICONS



	eCRF completion not / no longer required		Transfer confirmed, participant eCRF not located at your site
	eCRF completed		Transfer confirmed, participant eCRF located at your site
	eCRF partially completed		eCRF is locked due to revoked consent or post-data cleaning
	eCRF not started yet		Consent declined for all domains
	Future due date (grey font)		Consent declined for some domains
	Past due date (black font)		eCRF locked after investigator sign-off
	Query pending resolution (yellow-highlighted)		Paediatric participant
	Transfer pending confirmation from receiving site		SAE was reported for this participant

## QUESTION DEFINITIONS



Does the patient have acute infection of the respiratory tract  



Is death deemed imminent and inevitable during the next 24 hours  

The senior treating clinician believes there is no reasonable possibility of the patient surviving the next 24h

Is the patient, their substitute decision maker, or their primary treating clinician committed to some active treatment  

This criterion seeks to exclude those patients where supportive comfort measures are being provided. Patients who are planned for active ward management with a clear aim to improve survival, even if intensive care unit level support is not being offered, should still be included

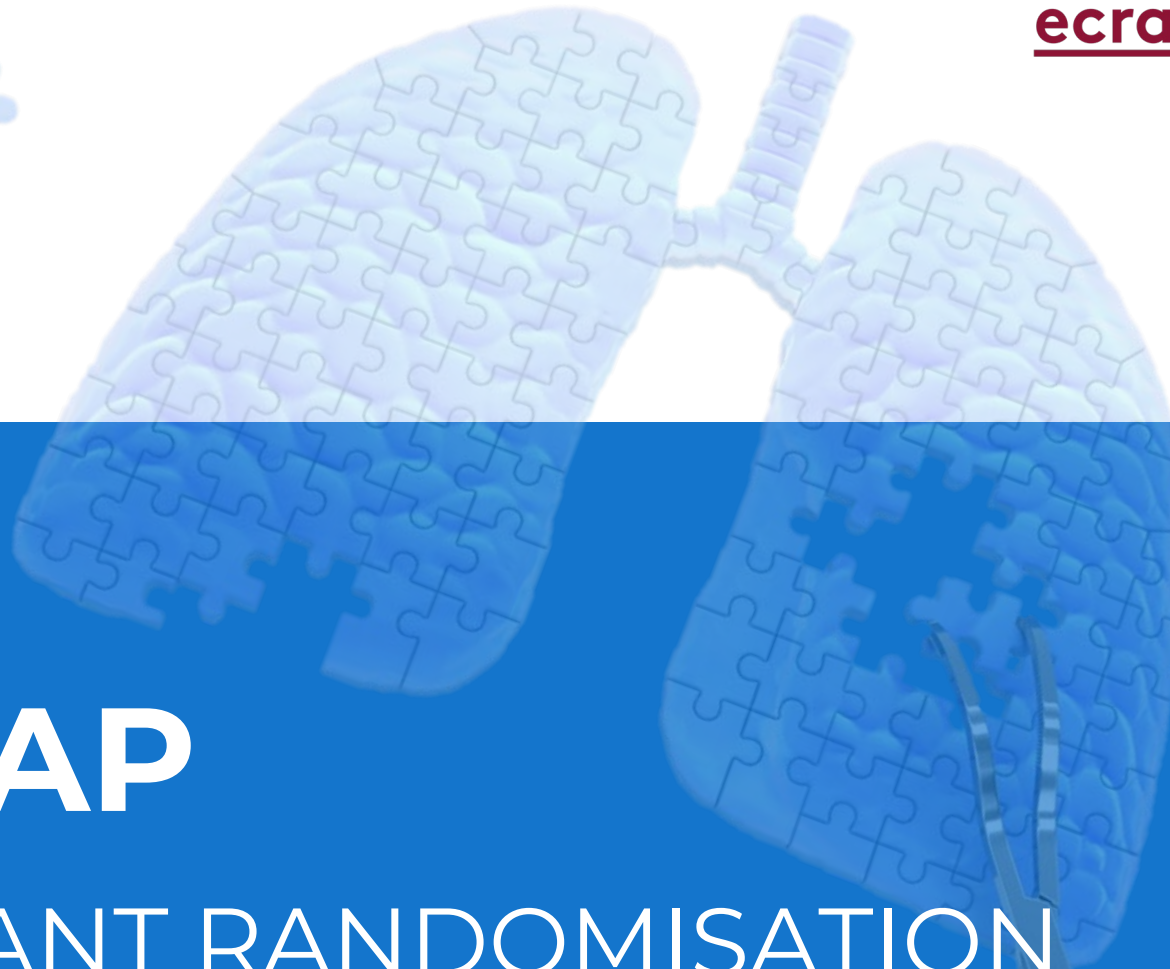
Is the patient expected to be discharged from this hospital admission today or tomorrow  

Has the patient been enrolled into this Platform before  

An information icon is available at the end of each question, selecting it will provide you with the detailed explanation of the question.



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# REMAP-CAP

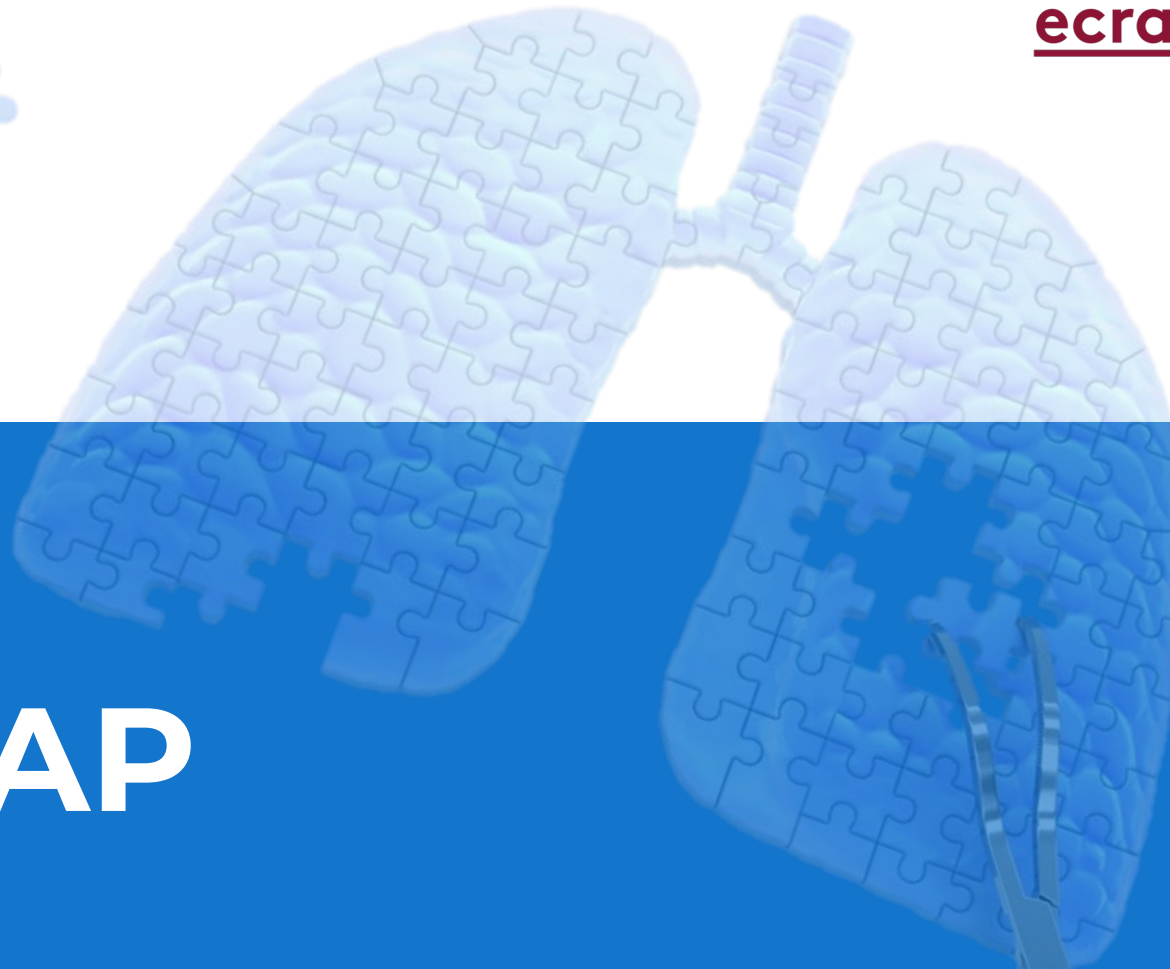
TEST PARTICIPANT RANDOMISATION

## TEST PARTICIPANT RANDOMISATION

- Go to: <https://remapcap.spinnakersoftware.com>
- Each new user has to randomise a test participant in the test environment (Eriador Infirmary) with their user account, before getting access to the live site.
- Please do NOT do the following within the TEST environment:
  - Report SAEs or SUSARs
  - Transfer a participant to a different location
  - randomise a real participant □ the data cannot be transferred to the live site



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# REMAP-CAP

## THANK YOU!

#REMAPCAPFAMILY