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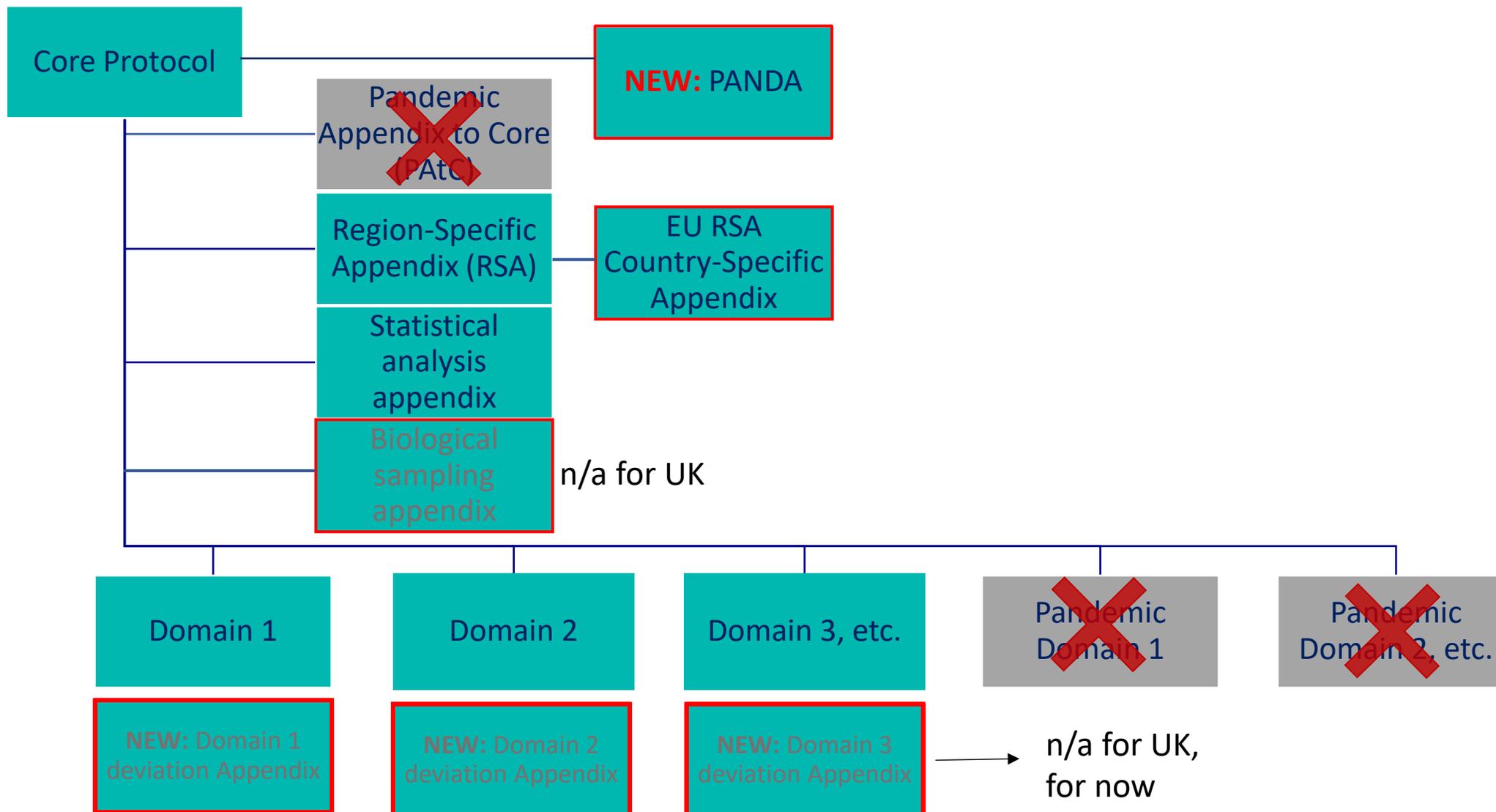
REMAP-CAP

Transition to Core Protocol V4.0

UK

VERSION 4.1
05 MAR 2026
(WITH AUDIO)

Structure of the Protocol





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REMAP-CAP

Core Protocol V4.0

Main Changes

1. Broader platform definition
2. Revised eligibility criteria
3. Revised primary outcomes and endpoints
4. Removal of Pandemic Appendix
5. Introduction of Patient, Pathogen and Disease Appendix (PANDA)
6. Clarification for transferred patients
7. Addition of PedsQL for paediatrics
8. Addition of a 'Recovering' state
9. Revised/updated statistical information

1. Broader Platform Definition

- Any reference to '(severe) community-acquired pneumonia (CAP)' / 'severe pneumonia'
→ Respiratory tract infections
- Any reference to '(admitted to) ICU' → (admitted to) hospital/hospitalized
- Removal of references to adults
- Example: aim (synopsis)
 - V3.1 – old: The primary objective of this REMAP is, for patients with severe CAP who are admitted to an ICU, to identify the effect of a range of interventions to improve outcome as defined by all-cause mortality at 90 days.
 - V4 – new: The primary objective of this **platform trial** is, for patients **hospitalized** with **respiratory tract infection**, to identify the effect of a range of interventions to improve **patient outcomes**.

2. Broader Platform Eligibility Criteria

Any hospitalised patient with a respiratory tract infection is potentially eligible for the Platform.

Simplified Inclusion criteria:

1. Aged ≥ 28 days* (*CGA for paed)s)
2. Hospitalised
3. Have an acute respiratory tract infection
 - Includes patients hospitalised with a primary reason other than respiratory tract infection
 - Includes hospital-acquired infections

(Removal of the requirement for the patient to have community-acquired pneumonia)

Exclusion criteria:

- Removal of '14 days has elapsed since hospital admission'
- Other minor wording changes

Eligibility criteria for the study are still applied at multiple levels:

- All Platform inclusion criteria met and no exclusion criteria
- Domain-specific eligibility criteria met
- Patient eligible for at least two interventions within a domain

3. Revised Primary Endpoint

Primary endpoint: **Survival and Recovery Trajectory** - a trajectory of illness and recovery to 28 days.

- All cause mortality at Day 90 post-randomisation
- Among Day-90 survivors, daily respiratory support level as defined by five-category ordinal scale:
 1. Hospitalized on extracorporeal life support (ECLS) or invasive mechanical ventilation (IMV)
 2. Hospitalized on non-invasive ventilation or high-flow oxygen*
 3. Hospitalized on low-intensity oxygen
 4. Hospitalized, no oxygen
 5. Discharged from index hospitalisation
- High-flow oxygen defined as a fractional inspired oxygen concentration of 0.4 or higher and with flow rate of at least 30 liters per minute (or at least 2 liters per minute per kilogram of bodyweight in children less than 15 kilograms).

Does not change data collection required by sites at follow-up

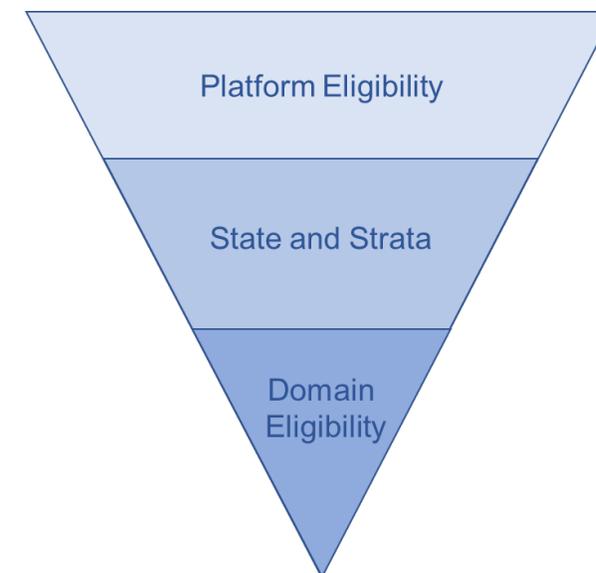
4. Removal of Pandemic Appendix to Core

Closure of pandemic strata.

Participants will no longer be classified as Pandemic Infection Suspected or Proven (“PISOP”) or Pandemic Infection Neither Suspected Nor Proven (“PINSNP”)

5. Patient, Pathogen and Disease Appendix (PANDA)

- Describes how specific patient, pathogen, disease, illness severity and additional clinical features are defined and categorized
- Does not include information about interventions
- PANDA may be amended in the context of a future pandemic, but it is intended that any amendments to the PANDA will be infrequent



Platform: Patients hospitalized with respiratory tract infection

Characteristics to constrain eligibility or stratify analysis (set for each Domain)

Patient and setting
(fixed)

Age

≥ 18 yrs
≥ 12 yrs ≤ 18 yrs
≥ 28 days ≤ 12 yrs

Immunosuppression

Present
Absent

Regional income level

High
Upper middle
Lower middle
Low

Infection
(fixed)

Acquisition

Community
Hospital
Ventilator

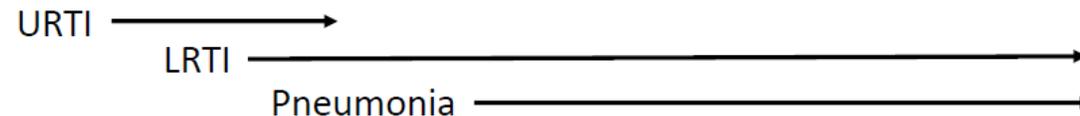
Pathogen(s)

Influenza
SARS-CoV-2
MERS-CoV
RSV
Other resp virus
Bacteria
Novel pandemic
(incl. co-infection)

Disease, severity stage & clinical features

(dynamic = 'states', category fixed at randomization)

Disease entity



Illness severity



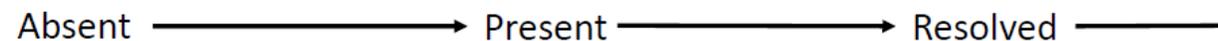
ARDS



Hypoxia



Shock



Pathogen status

Clinical assessment at eligibility

History & examination
 Non-micro lab tests
 Imaging

Confirmed
 Suspected
 - Probable (bacteria only)
 - Possible (bacteria only)
 Not suspected
 Excluded

Pathogen(s) at eligibility

Influenza
 SARS-CoV-2
 MERS-CoV
 RSV
 Other resp virus
 Bacteria
 Novel pandemic

Microbiological testing

Results available
 at eligibility

Domain eligibility
 Primary analysis strata
 RAR

Confirmed
 Suspected
 - Probable (bacteria only)
 - Possible (bacteria only)
 Not suspected
 Excluded

Final Pathogen(s)

Influenza
 SARS-CoV-2
 MERS-CoV
 RSV
 Other resp virus
 Bacteria
 Novel pandemic

Microbiological testing

(reflecting status at eligibility)

Final test results

Additional safety analyses
 Secondary analyses
 Subgroups of interest

6. Clarification for Transferred Patients

Core Protocol V4 clarifies protocol adherence for participants who are **transferred between locations**.

If a participant is transferred from a participating location to:

- a non-participating hospital
- a non-participating clinical area within a participating hospital
- a participating hospital/clinical area that is not participating in the domain/intervention to which the participant has been allocated



Continuation or discontinuation of allocated interventions becomes a **clinical decision**, rather than an intervention administered under trial protocols.

7. PedsQL at Day 180 Follow-up for Paediatrics

Paediatric quality of life questionnaire, by age group:

- <2 yrs = none/not applicable
- 2-4 yrs - completed by parent
- 5-7 yrs - completed by parent or child
- 8-12 yrs - completed by parent or child
- 13-18 yrs - completed by parent or child
(REMAP-CAP defines a paediatric up until 17yrs but they may turn 18 during follow up period)

4 x Qs on physical, emotional, social and daycare/nursery/school functioning.

8. Recovering State

Core Protocol V4 adds the **Recovering State**

The Recovering State is defined as:

- Hospitalised patients who, in the opinion of the treating clinician, are **clearly recovering** from their acute respiratory tract infection AND are **unlikely to require or receive a significant escalation in level of organ failure support** for the remainder of their hospital admission

Currently **no domains are available for patients in the Recovering State**, meaning that they cannot be randomised into the Platform

- Future domains may permit enrolment of patients in the Recovering State

9. Statistics

- Merge of two statistical models (interpandemic and pandemic), & possibly Ventilation Domain
- New trigger terminology added
 - Possible treatment effects : superiority, **efficacy**, inferiority, equivalence, **noninferiority**, **futility**, and **harm**
 - Core protocol sets default thresholds for statistical triggers
- Adaptive analyses will occur frequently, approximately proportional to the rate of recruitment
- Response Adaptive Randomization: proportions are determined by analysis of the available data informing the primary outcome measure in participants **after at least 28-days of follow-up**
 - For domains with only two available interventions, default is that RAR will not be applied
 - Allocation proportions capped at 60% for two-intervention domains, unless otherwise specified

REMAP-CAP

Domain Specific Appendices

Refer to DSAs for:

- Domain specific **eligibility criteria**
- Domain **rationale**
- **Concomitant care**
- Potential **domain-specific adverse events**
- Domain-specific **endpoints**
- Domain-specific **protocol deviations**
- **Other** domain specific information

General Domain Updates

- The broadening of Platform-level eligibility criteria mean that domain-level eligibility criteria wording has been updated to ensure continuity and correct domain constraints:
 - Removal of pandemic/non-pandemic strata in all DSAs.
 - Addition of age strata in relevant DSAs (flu domains).
 - Consistency in mention of the moderate state in steroid and antiviral DSAs.
- Although it may look like there are a lot of changes, **in practice the patients who are eligible for these domains will be the same as were eligible under previous versions.**
- In most cases there are **no changes to interventions** or their delivery.

Domain	Moderate State	Severe State	Paediatric (≥28 days)	Adolescent (≥12 years)	Adult (≥18 years)
Antibiotic Domain	x	✓	x	x	✓
Macrolide Duration Domain	x	✓	x	x	✓
Corticosteroid Domain	✓	✓	✓	✓	✓
Influenza Antiviral Domain	✓	✓	✓	✓	✓
Immunoglobulin Domain	✓	✓	x	✓ (≥16 years)	✓
Mechanical Ventilation Domain	x	✓ - n/a UK	x	x	✓ - n/a UK
Endothelial Domain	x	✓ - n/a UK	x	x	✓ - n/a UK
Influenza Immune Modulation Domain	x	✓	✓ (≥2 years)	✓	✓

Domain Eligibility Changes

Steroid eligibility

- CAP is removed from platform incl. criteria, but added to steroid domain incl. criteria for severely ill patients
- Patients must have a lower resp. tract infection (platform is open to lower and upper)
- Confirmed SARS-CoV-2 infection is an exclusion
- Hospital-acquired respiratory tract infection is an exclusion except for flu

Antiviral eligibility – no changes

Immune modulation eligibility

Removed from platform exclusion and added to domain exclusion:

- More than 48 hours has elapsed since commencement of sustained organ failure support



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REMAP-CAP

eCRF for Core Protocol V4.0

eCRF Changes

The REMAP-CAP case report form (CRF) has undergone a thorough review and substantial update. These changes are intended to:

- Reflect changes to Core Protocol V4
- Reduce burden of data collection by removing unnecessary fields / finding more efficient ways of capturing necessary data; and
- Future-proof for any future public health emergencies

Eligibility Form Changes

The eligibility assessment was updated to:

- Reflect the reduced Platform eligibility criteria
- Reflect modifications to domain-specific eligibility criteria
- Manage the complexity of simultaneously assessing eligibility for multiple domains and interventions

Used to be ±20 platform eligibility questions on 3 pages



5 platform eligibility questions on 1 page



Platform inclusion/exclusion 1

Platform inclusion/exclusion 2 - ICU admission time window

Platform inclusion/exclusion 3 - Organ support time-window

Is the patient receiving a continuous vasopressor and/or inotrope infusion (I) At the time of completing this form

Is the patient receiving high-flow oxygen delivered via nasal prongs or cannula High-flow oxygen delivered by nasal prongs with FIO2.40% or higher and at a flow rate of at least 30 L

Is the patient receiving non-invasive ventilation (NIV) NIV includes positive inspiratory or expiratory pressure or both via a mask, helmet, or similar device

Is the patient receiving invasive mechanical ventilation Any form of positive pressure ventilation via an orotracheal, nasotracheal or tracheostomy tube

Is influenza infection suspected by the treating clinician or confirmed by microbe testing As part of the current illness

What is the date of the first onset of clinical features of this acute illness Symptoms may include coughing, sore throat, headache, nasal discharge/nasal congestion, feeling feverish or having chills, aches or pains of the muscles or joints, and fatigue

Does the patient have clinically suspected or proven active pandemic influenza Clinically suspected means pandemic influenza is considered likely. Active means that the patient has symptoms attributed to pandemic influenza. Answer "no" for in-patients with incidental SARS-CoV-2 infection

Is death deemed imminent and inevitable during the next 24 hours AND either the patient or their substitute decision maker or attending physician is not committed to active treatment A clinical treatment or intensity of treatment that would otherwise be indicated is being withheld

Next or Cancel



Eligibility
ALVSHN

Demographics

Platform Incl/Excl 1

Platform Incl/Excl 2

Platform Incl/Excl 3

Domain Incl/Excl

Contraindications

Consent

Patient Interest

Result *Old system*



AJTJWP

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

New system

Platform Eligibility

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

Is death deemed imminent and inevitable during the next 24 hours ⓘ ⓘ 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 ⓘ ⓘ 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 ⓘ ⓘ Yes No

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

Fewer questions necessary to assess Platform eligibility

New pages added for "PANDA", to continue eligibility assessment based on...

Pathogen

What is the likelihood that bacterial respiratory tract infection is contributing to this acute illness ? 🕒 ➡ Not suspected

At this time

What is the likelihood that the following viral pathogens are contributing to this acute illness ? 🕒 ➡

At this time. Excluding positive tests which are not considered to represent active infection (e.g. recovered recent SARS-CoV-2)

Influenza virus ? 🕒 ➡ Suspected but n...

SARS-CoV-2 infection ? 🕒 ➡ Not suspected

Respiratory Syncytial Virus (RSV) infection ? 🕒 ➡ Suspected but n...

Clinical Features and Syndromes

What was the date of onset of clinical features of this acute respiratory infection ? 🕒 ➡ Asymptomatic Unknown

🕒 ➡

Symptoms may include coughing, sore throat, headache, nasal discharge/nasal congestion, feeling feverish or having chills, aches or pains of the muscles or joints, and fatigue

Does the patient have a known condition, or have they received treatment, resulting in immune suppression ? 🕒 ➡ Yes No

Underlying immunodeficiency, or receipt of immunosuppressant therapy prior to this hospitalisation

What is the patient's PaO2 ? 🕒 ➡ mmHg kPa Not available

What was the corresponding FIO2 ? 🕒 ➡

What was the corresponding PEEP ? 🕒 ➡ Patient receiving APRV

Does the patient have bilateral opacities on chest imaging that are not fully explained by effusions, lobar or lung collapse, nodules, cardiac failure, or fluid overload ? 🕒 ➡ Yes No

In the opinion of the treating clinician, based on most recently obtained images during this acute illness

Is the patient's respiratory tract infection the primary contributor for their requirement for this organ support ? 🕒 ➡ Yes No

Not primarily attributable to acute heart failure, fluid overload, or pulmonary embolism (PE)

Patient and Disease Characteristics

Where was the respiratory tract infection acquired ? 🕒 ➡

Community-acquired
Acute infection acquired outside of the hospital and manifesting v
hospital admission

Hospital-acquired
Acute infection not incubating at the time of hospital admission an
more than 48h after hospital admission

Does the infection involve the lower respiratory tract ? 🕒 ➡ Yes No

Infection of the airways below the level of the larynx (including tracheitis, bronchitis, bronchiolitis and pneumonia)

Is pneumonia present ? 🕒 ➡ Present Absent

Pneumonia is defined as radiological evidence of new onset infiltrate consistent with infection

New system

Clearer output for users regarding which domains a participant is being assessed for on the “*Domain Eligibility*” page...





AJTJWP

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

Best Interests AJTJWP

➔ Assessment

Age group: Adult
Illness Severity State: Severe
This patient is still eligible for the following interventions at 01992T - Germany Test Site-Eriador Infirmary Adult ICU

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

➔ Ineligible domains and interventions

Ineligible for

Antibiotic
[PANDA](#) Pathogen bacterial not suspected

Macrolide
[PANDA](#) Antibiotic domain not eligible

Influenza-Antiviral
[DomainElig](#) This Hospital Oseltamivir

New system



AJTJWP

- ✓ Demographics
- ✓ Platform Eligibility
- ✓ State
- ✓ PANDA
- ➔ Domain Eligibility

Domain Eligibility AJTJWP

➔ Assessment

This patient is being assessed for the following interventions at 01992T

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

Influenza Antiviral
No oseltamivir or other antiviral agent active against influenza
5 days of Oseltamivir
10 days of Oseltamivir

New system



... and why participants are ineligible for certain domains on the “*Best Interests*” page.

Re-assessment of Eligibility

Patients who have been randomised in the Moderate State may be eligible to be randomised again to additional domains if they progress to the Severe State.

However, patients cannot be randomised in the Moderate State **AFTER** the Severe State.

To reassess a participant's eligibility for domains in the Severe State, navigate to the **patient summary page**.



0299900542

Randomised
01-Jul-2025 15:14
Hospital admission
30-Jun-2025 11:00
ICU admission
01-Jul-2025 07:00

✓ Summary

✓ Eligibility

✗ Re-Assess for severe

Patient Details 0299900542

Lock status Open



Monitoring status Not Monitored



Transfer Participant

Change Log

TABLE	TYPE	DATE	USER
-------	------	------	------

Re-assess this patient for additional domains of REMAP-CAP. Patient must be receiving organ failure support

Influenza Antiviral Domain

5 days of Oseltamivir

Adverse Events ±

No adverse events

Consent Form Changes

- Qs re patient capacity and PerLR/ProLR made clearer to avoid accidental randomisations
- For paediatrics, 'proxy' consent should be selected if the parent is providing consent
Can indicate why written consent wasn't obtained from child participant i.e. did not have capacity (if too young/can't fully understand) or enter your own free text if preferred under 'another reason' option
- 'Best interest' statement added for emergency enrolment of patients without any consent in place i.e. Patient has no capacity, PerLR/ProLR is not available, and timeframe is running out.

Reminder: ALL consent discussions mentioned in source notes must be entered on eCRF even if there is no outcome/no decision made!

Baseline Form Changes

- Some questions in the Baseline Form have been made domain-specific.
- Some questions in the Baseline Form have been removed.
- Illness Severity Scores are now calculated automatically by the database for ICU patients, based on data entered in the Baseline Form.



Illness Severity Scores	
APACHE II	
APS points <small>APACHE II acute physiology score</small>	
Age points	6
Chronic health points	0
APACHE II score	
<hr/>	
CURB-65	
CURB-65 score	2
<hr/>	
SOFA	
SOFA score	7
<hr/>	
<input type="button" value="Save Baseline"/>	Cancel

New system

Daily Data Form Changes

- Focus on organ support.
- Study days are now defined by **calendar days** instead of ICU chart days.
- **Yes/No** questions about organ support received on each study day



Daily data for 0199300560 - day 1
3.8 hours from 01-Dec-2025 20:13 till 01-Dec-2025 24:00
Discharge from ICU 01-Dec-2025 23:59

Patient in ICU during this day Yes No

2.0 Daily treatments

Airway
HIGHEST level of airway support only

Hours of invasive mechanical ventilation hours
0-24

FiO₂ associated with lowest P/F ratio
e.g.0.21. If no ABG was taken enter the highest FiO₂

Corresponding PaO₂ mmHg kPa Not recorded

Corresponding PEEP cmH₂O Not recorded Patient receiving APRV
Must correspond with FiO₂ and PaO₂
If no ABG was taken enter the highest PEEP.

Corresponding SpO₂ Not recorded
Must correspond with FiO₂ and PEEP

cardiovascular SOFA score

placement Therapy

oreal gas exchange

or

Old system

Daily Organ Support 0199200056

DAY	DATE	LOCATION	HIGHEST LEVEL OF OXYGEN THERAPY RECEIVED	VASOPRESSORS / INOTROPE	RRT	
1	01-Dec-2025	ICU	High flow nasal pro...	No	No	<input checked="" type="checkbox"/> <input type="button" value="X"/>

Form is un-locked

New system

Medication Form Changes

- Focus on daily administration of allocated intervention, instead of details of each prescribed course.



Medication administration for patient 0199300560

Enter all medications administered between arrival at the randomising hospital and study day 14. Include medications administered prior to randomisation (e.g. antibiotics/antivirals given in the emergency department or a ward). Include courses commenced after ICU discharge but before day 14. Ensure all randomised interventions are recorded e.g. Antiplatelet Domain, Clopidogrel intervention administration.

[Print Form](#) [Mark all as complete](#)

Antibiotic administration

[Add an antibiotic administration](#)

All antibiotics for this patient have been entered

Antiviral administration

[Add an antiviral administration](#)

All antivirals for this patient have been entered

New system

Antibiotic administration 0199300560

Antibiotic [Show antibiotic list](#)

Date & time first dose administered : : 24 Hour clock
Date & time of first dose administered

Prescribed route of administration
Enteral includes but is not limited to oral and nasogastric

Prescribed dose

Prescribed daily frequency

Date last dose administered
Including if given after ICU discharge. Censored at hospital discharge

[Add Antibiotic](#) or [Cancel](#)

Old system

- Non-study medications of interest will be collected in a simplified “Yes / No” format. 
- Data collection will be domain-specific.

Medication for participant 0199200056

Corticosteroid Administration

All Corticosteroids for this participant have been entered.
Yes No

Corticosteroid non-assigned medication administration

Betamethasone	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Dexamethasone	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Hydrocortisone	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Methylprednisolone	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Prednisolone	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Prednisone	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Triamcinolone	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		

 Form is un-locked

New system

Discharge Form Changes

- Modified to more clearly capture participant movement during the acute hospital admission, including between hospitals in case of transfers.
- Cause of death will be collected for paediatric participants who die in hospital.

Discharge for patient 0199200056 *New system*

Change of Location During Index Acute Hospitalisation

(2)

Transfer to Ward/Non-ICU

Location Non-participating hospital

Date and time of transfer 30-Nov-2025 17 : 20 24 hr clock Unknown Remove transfer

(3)

Transfer to Ward/Non-ICU

Location 01992 - Germany Test Site - Eriador Infirmary

Date and time of transfer 01-Dec-2025 06 : 00 24 hr clock Unknown Remove transfer

Discharge patient 0199300560 *Old system*

1.0 ICU discharge

ICU discharge dd-MMM-yyyy : 24 Hour clock

Status Select ▼

Date and time of last organ support in ICU dd-MMM-yyyy : Never received

2.0 Add ICU admission

Add ICU admission Yes No

ICU Admission 1 dd-MMM-yyyy : ICU Discharge dd-MMM-yyyy :

Did the patient receive organ support during this ICU admission Yes No

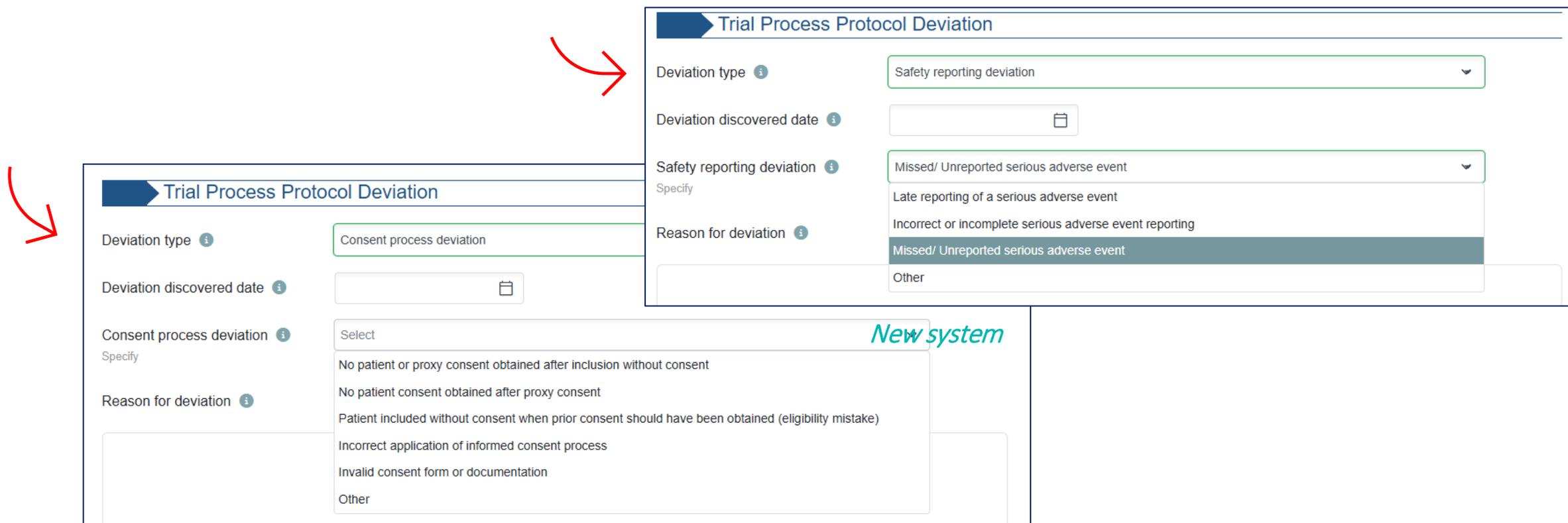
ICU Admission 2 dd-MMM-yyyy : ICU Discharge dd-MMM-yyyy :

Did the patient receive organ support during this ICU admission Yes No

[Add another readmission](#)

Protocol Deviation Form Changes

- The Protocol Deviation Form now allows entries that relate to trial processes, including safety reporting and consent processes.



Left Screenshot: Consent process deviation

Trial Process Protocol Deviation

Deviation type ⓘ Consent process deviation

Deviation discovered date ⓘ

Consent process deviation ⓘ
Specify

Reason for deviation ⓘ

Select

- No patient or proxy consent obtained after inclusion without consent
- No patient consent obtained after proxy consent
- Patient included without consent when prior consent should have been obtained (eligibility mistake)
- Incorrect application of informed consent process
- Invalid consent form or documentation
- Other

New system

Right Screenshot: Safety reporting deviation

Trial Process Protocol Deviation

Deviation type ⓘ Safety reporting deviation

Deviation discovered date ⓘ

Safety reporting deviation ⓘ
Specify

Reason for deviation ⓘ

- Missed/ Unreported serious adverse event
- Late reporting of a serious adverse event
- Incorrect or incomplete serious adverse event reporting
- Missed/ Unreported serious adverse event
- Other

D90 & D180 Follow Up

- Survival status will continue to be collected at D90 and D180
- Questionnaires will continue to be collected at D180:

Adults D180	Paediatrics D180
EQ-5D-5L	EQ-5D-Y
WHODAS	PedsQL SF15 - New

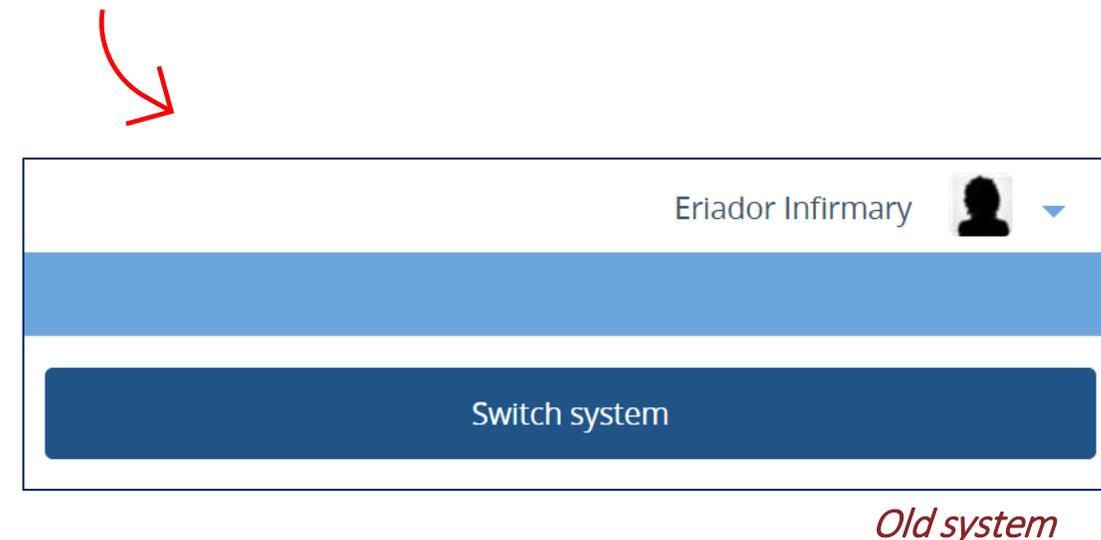
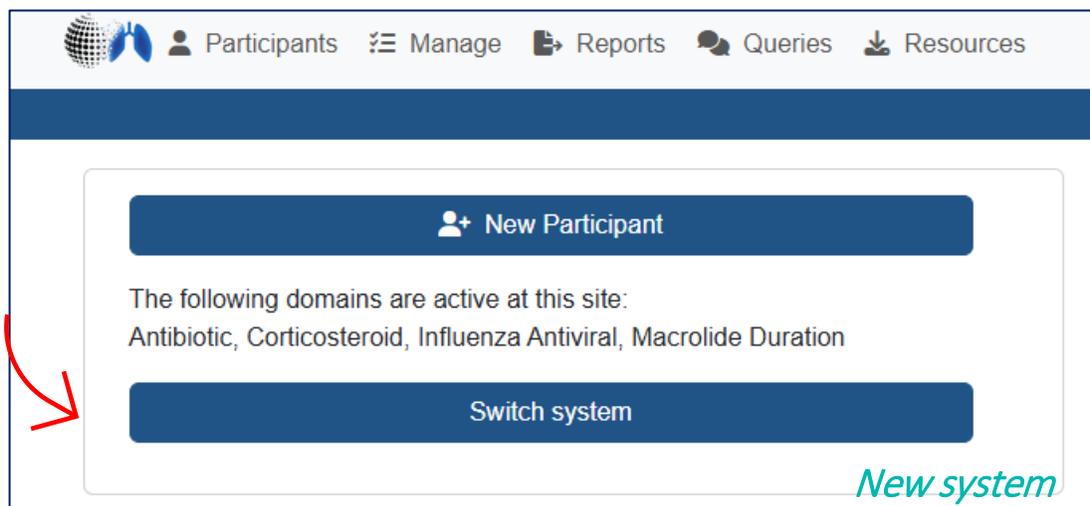
New Form: Pregnancy Outcome

- Pregnancy status at hospital discharge if part of Immune Modulation domain
- If no longer pregnant at hospital discharge, complete from medical records
- If pregnant at hospital discharge, follow up at d180 unless info is available earlier from medical records
- If still pregnant at d180, complete additional follow up approx. 6 weeks after delivery due date

Qs include neonatal outcome, date, birth weight, sex, NICU admission info, neonatal status 1 month post birth, anomalies at delivery.

Old vs. New Database

- Once your site is activated for Core Protocol V4.0, your eCRF accounts will be linked to the new database system.
- You can access the entered eCRF data under **both** database systems by selecting the “**Switch System**” button on your landing page.



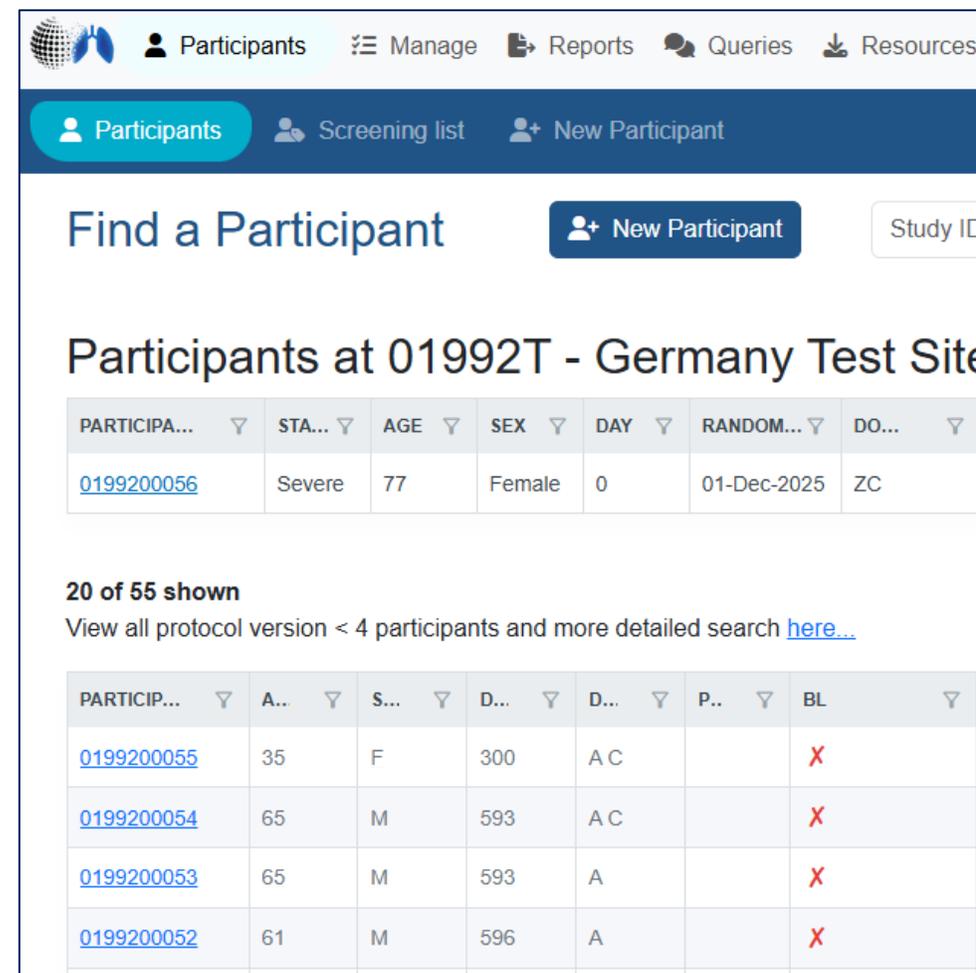
Only **new patients** recruited under Core Protocol V4.0 are saved in the **new database** system.



Previously enrolled participants under Core Protocol V3.1 remain in the old database system.



No reconsent is needed for patients recruited under Core V3.1 (no changes in protocol).



The screenshot shows the 'Participants' section of the REMAP-CAP web application. The top navigation bar includes 'Participants', 'Manage', 'Reports', 'Queries', and 'Resources'. Below this, there are tabs for 'Participants', 'Screening list', and 'New Participant'. The main heading is 'Find a Participant' with a 'New Participant' button and a 'Study ID' input field. The title of the data view is 'Participants at 01992T - Germany Test Site'. A table displays participant information with columns: PARTICIPA..., STA..., AGE, SEX, DAY, RANDOM..., and DO... The first row shows participant ID 0199200056, Severe status, age 77, Female sex, day 0, randomization date 01-Dec-2025, and DO... ZC. Below the table, it indicates '20 of 55 shown' and provides a link to 'View all protocol version < 4 participants and more detailed search here...'. A second table shows a list of participants with columns: PARTICIP..., A..., S..., D..., D..., P..., and BL. The first four rows show IDs 0199200055, 0199200054, 0199200053, and 0199200052, with corresponding age, sex, and D... values, and a red 'X' in the BL column.

PARTICIP...	STA...	AGE	SEX	DAY	RANDOM...	DO...
0199200056	Severe	77	Female	0	01-Dec-2025	ZC

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

PARTICIP...	A...	S...	D...	D...	P...	BL
0199200055	35	F	300	A C		X
0199200054	65	M	593	A C		X
0199200053	65	M	593	A		X
0199200052	61	M	596	A		X

New system

Email Notifications

Updated format for randomisation email notifications:

- **Site code** in email body will include a letter denoting site type (adult ICU/ward or paed ICU/ward) i.e. A, B, C, D or T for test site

01061B St Mary's Hospital Ward

01061C St Mary's Hospital
Paediatrics ICU

01061D St Mary's Hospital
Paediatrics Ward

- **2-character domain codes** will replace the previous single letter domain code
- **Illness Severity State** (“moderate” or “severe”) will replace previous text of “Pandemic infection not suspected or confirmed” and “Pandemic infection suspected or confirmed”

Hi Vanessa Singh,

Vanessa Singh has enrolled new participant 0299900558 at 02999T - AU Test Site 99

Randomised into:

XA Tropical Antibiotic

ZC Corticosteroid

ZI Influenza Antiviral (Reveal pending)

ZM Macrolide Duration (Reveal pending)

ZN Influenza Immune Modulation (Reveal pending)

State: Severe

Participants enrolled by 02999T - AU Test Site 99: 14

Trial participants: 0

[Go to the REMAP-CAP online platform.](#)

from,

Spinnaker Software for the REMAP-CAP Study

Please do not reply to this email as I'm just a piece of software and I won't understand your email.

REMAP-CAP

IMP Procedures

IMP Procedures

Baloxavir & Tocilizumab are provided by Roche from clinical trial stock and is supplied with clinical trial labelling.

All other IMP are from hospital stock.

For IMP from external suppliers (Roche):

- Training on ordering, temperature and storage monitoring, drug accountability and destruction is provided prior to activation of domains. Study templates also provided.

For IMP from hospital stock: Site's routine procedures to be followed for drug accountability, temperature monitoring and destruction

- As long as information is clearly captured and accountability can be monitored from drug charts/medical notes



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REMAP-CAP

Safety

Safety Reporting

Safety event definitions were updated in the protocol.

Reminder: Only protocol defined SAEs need to be reported

- 1. SAEs deemed to be possibly, probably or definitely related to study treatment / participation.
- 2. Pre-specified SAEs listed in the DSAs

Reminder: It is expected that site investigators make an initial (documented) assessment on event severity, relatedness and expectedness:

- An SAE is considered 'expected' if the nature and severity of the event is consistent with the current approved version of the reference safety information (SmPCs).
- Expectedness should be assessed "from the perspective of previously observed, not on the basis of what might be anticipated from the pharmacological properties of a medicinal product" (ICH E2A, 1994).



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REMAP-CAP

Informed Consent

Informed Consent

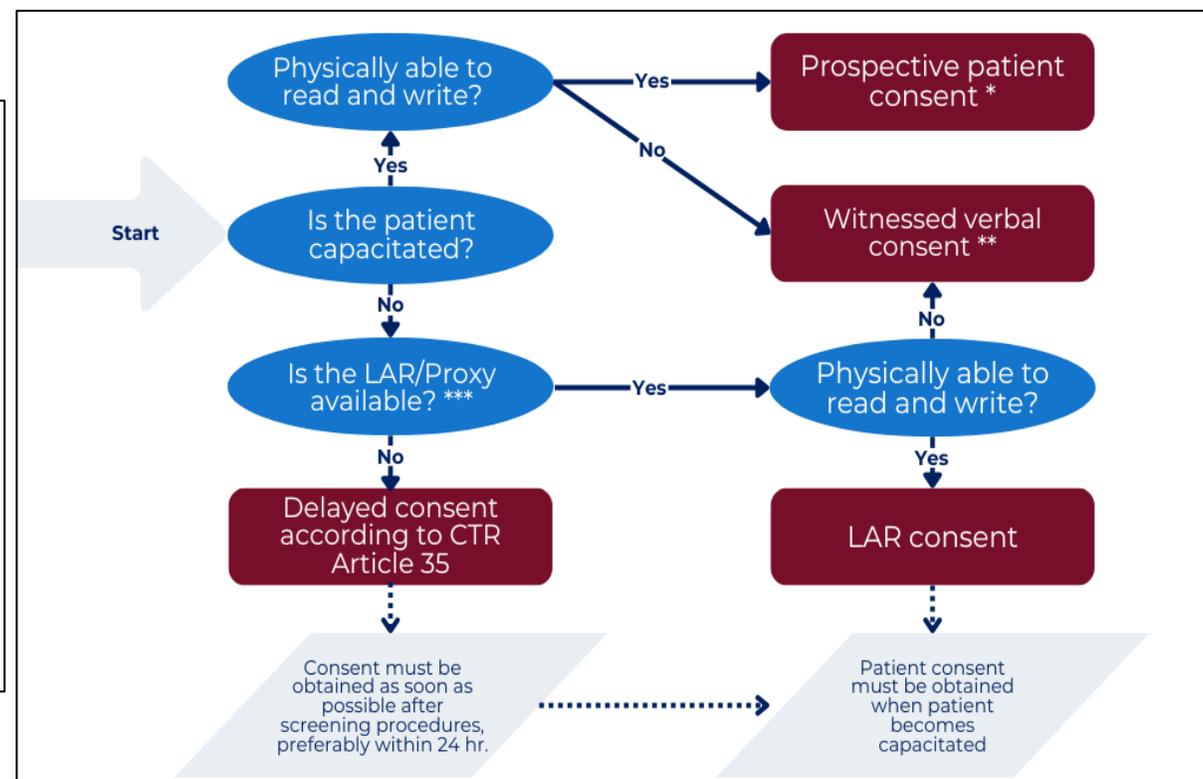
- Obtaining Informed Consent in an emergency setting is now described in the **EU RSA V4** for all countries and aligned with CTR requirements.
- **EU RSA: UK Country Annex** lists approved consent types and procedures, as described in refresher training session.

* **Prospective patient consent** is the default consent type.

** **In case of verbal/telephone consent**, the witness should be impartial (not involved in the trial). Alternative methods for consent include watching a video, or summary IS.

*** **Order of Legal Representative priority:**

1. Legal rep appointed by court (adults/children) or parent (children)
2. Personal Legal Rep (adults)
3. Professional Leg Rep (adult/children)





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ICH-GCP

ICH-GCP E6 R3

Effective date for Revision 3 was 23rd July 2025 in the EU.

Mandatory in the UK as of 28th April 2026.

Please file your (updated) GCP certificates in the ISF and share with Trial Management team for TMF filing, **by end of April 2026!**



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Practical Information

What's Next?

Expected from sites:

- Attend Core Protocol V4 Transition training / self-train via slides
- Provide (self-) training logs for:
 - Core protocol v4 transition training
 - Protocol v4 and associated documents
 - Updated DSAs
- Complete Protocol Signature Page and Choice Pages
- Complete Spiral Database Form
- All the above to be filed in ISF



Provided to sites by us:

- Self-training logs with all mandatory documents/slide decks listed for self-training
- Updated eCRF guides and associated eCRF documents
- Protocol documents and PIS/CFs (already sent as part of Am43 and on the study website under **Protocol v4 training module**)

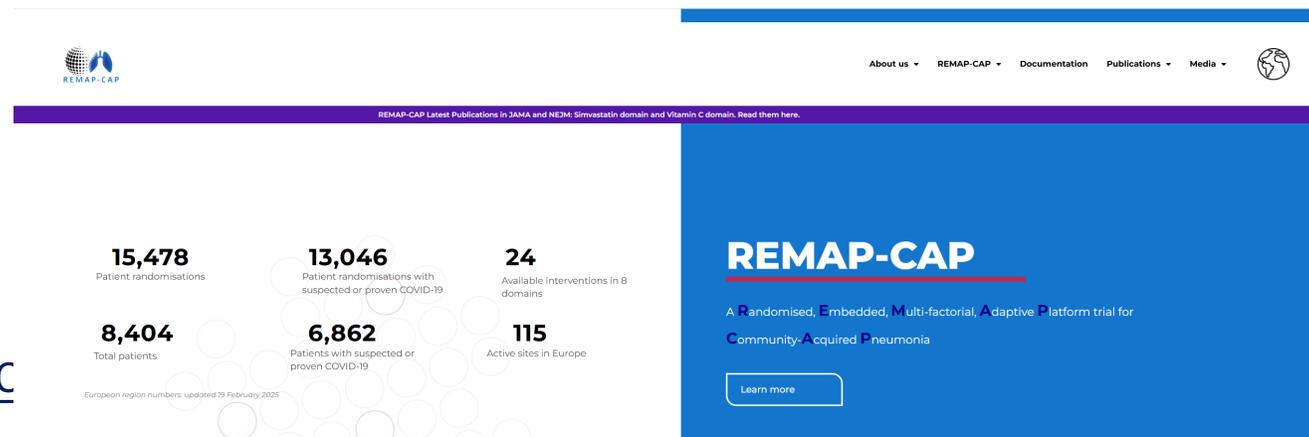
Site staff should be trained on Core V4 and provide all documents before conducting any Core V4 trial-related tasks!!!

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AoB

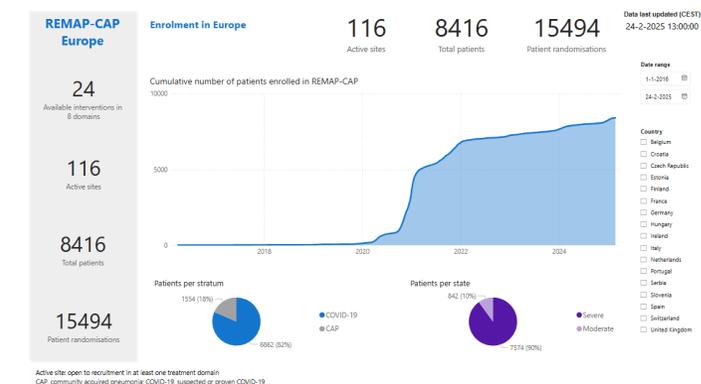
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Enrolment data

Here you can find live enrolment data for REMAP-CAP Europe. The graphs below are being fed information directly from the trial's enrolment database and are updated weekly*. They are interactive, thus allowing you to specify the parameters of the data you are interested in.



Contacts

General e-mail address (always in cc):

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Our team:

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Janis Best-Lane - Senior Trial manager

Lucy Stronach - Trial Coordinator/Monitor

Millie Parke - Trial Coordinator/Monitor

Ashley Alexander - Trial Admin/Monitor

Lindsay Jack - Trial Monitor

Tina Reetun - Trial Monitor

For urgent situations outside office hours if UK team cannot be reached

info@remapcap.org

THANK YOU!