



REMAP-CAP

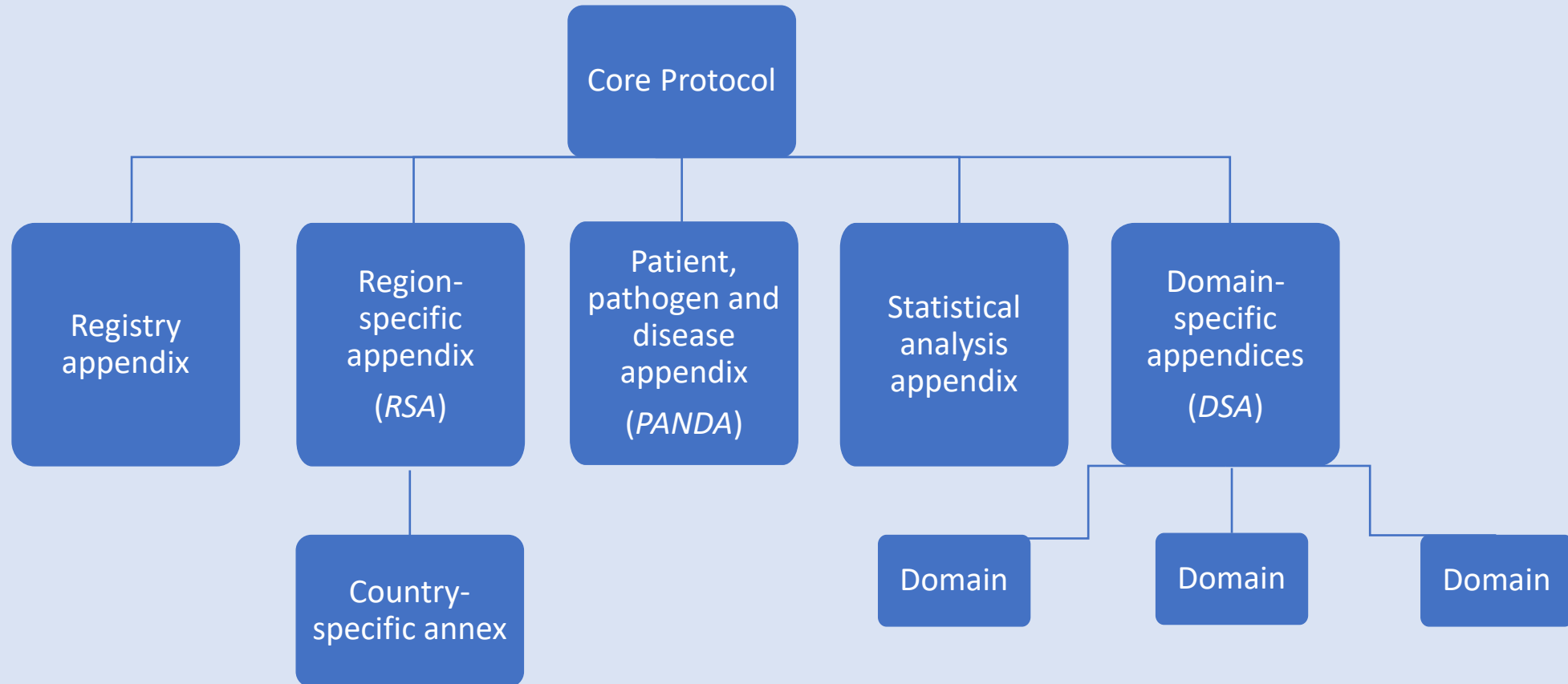
Training: Screening and Randomisation on the eCRF for Protocol V4.0

V1.0, 29-Sept-2026

+ Chief Investigator: Prof Anthony Gordon

Trial Management Team Email: ukremap-cap@icnarc.org

Trial design: modular protocol structure



Current open domains

Adults

ICU

Antibiotics
Macrolide Duration
Corticosteroid
Influenza Antiviral
Immune Modulation

Wards

Corticosteroid
Influenza Antiviral

Paeds

ICU

Corticosteroid
Influenza Antiviral
Immune Modulation

Wards

Corticosteroid
Influenza Antiviral

Screening/Randomisation Users

- + The person screening/randomising participants is required to be listed on the **delegation log** and must have completed a **training log for this screening/randomisation training**.
- + **If this is your only study duty**, the training log will ask for your **registration number** (i.e. GMC/RMC No.) to confirm you are qualified to screen/randomise - therefore a CV / GCP certificate is not required to be filed in the ISF.
- + You will be asked to complete a **dummy randomisation** on the test site of the study database following this training, before being given access to your live hospital site.
- + Participant eligibility must be **confirmed by a doctor** on the **delegation log** prior to screening/randomisation on the eCRF. This needs to be documented in the medical records.
- + The **consent process** must also have been followed prior to randomising a participant.

Screening

Screening method	Screening tool	Screening documentation	Screening outcome
Screening in the eCRF (strongly encouraged)*	Automated process in the eCRF upon answering the eligibility questions	Participant is added to the eCRF	Participant will be randomised or will be a screen failure in the eCRF
Screening on paper / outside eCRF	Site-specific eligibility checklist (downloaded from the eCRF)	Complete the paper screening log in the ISF (or spreadsheet)	Participant is deemed eligible or not

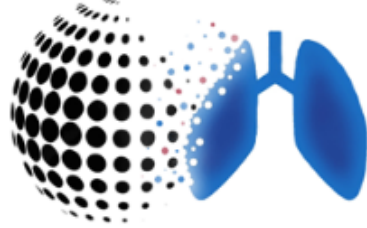
Then enter into the eCRF as well

Spinnaker (eCRF) Login

<https://remapcap.spinnakersoftware.com/Login/>

The following users have randomisation rights:

User Role	Functions
Rand user	Screening & randomisation only
Research coordinator	All functions except SAE / eCRF sign offs
Investigator	All functions including SAE / eCRF sign offs



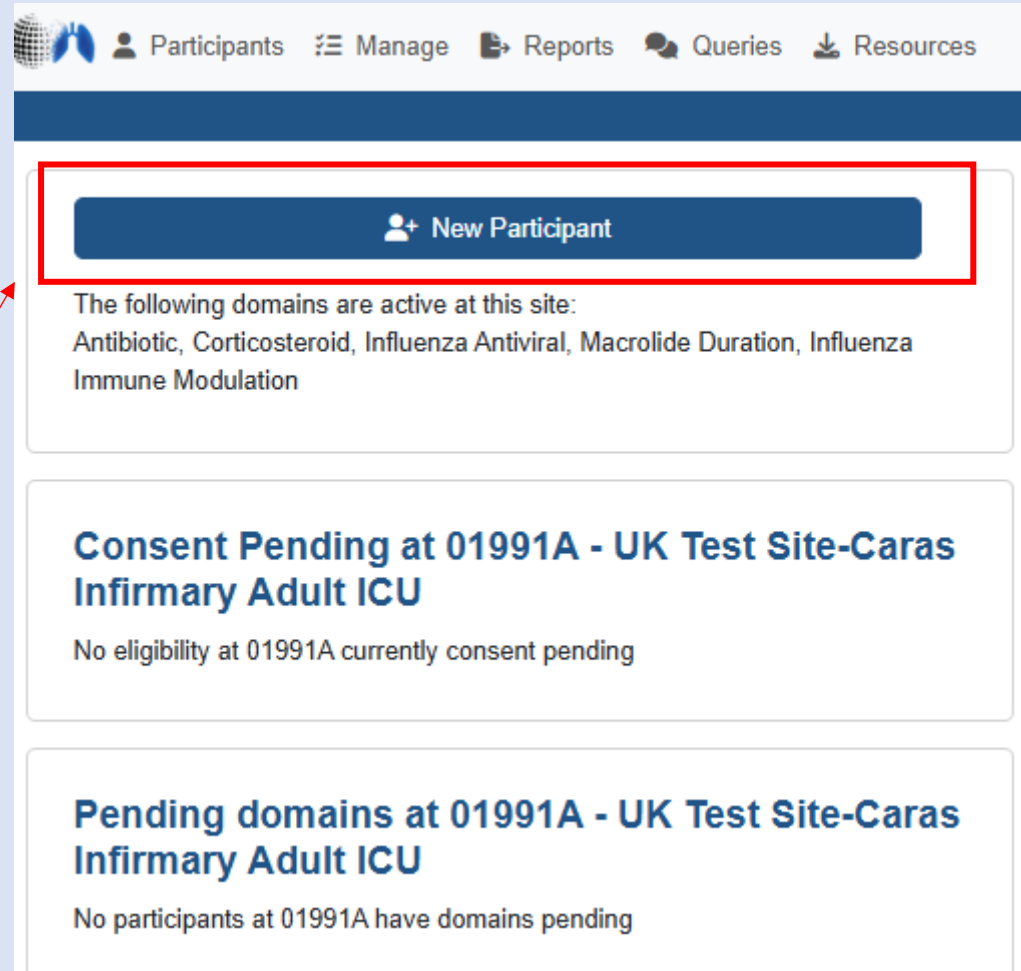
[I forgot my username or password](#)

Spinnaker (eCRF) Login

Please ensure the correct **hospital name** appears when you are logged in to the eCRF (Spinnaker database) and that it does not appear with the **test site**

Please ensure you are in the correct area i.e. **Adult ICU or Adult Ward / Paed ICU or Paed Ward** (click in top right hand corner to change)

Click here to add participant



The screenshot shows the Spinnaker (eCRF) interface. At the top, there is a navigation bar with icons and labels for 'Participants', 'Manage', 'Reports', 'Queries', and 'Resources'. Below this, a red box highlights a button labeled 'New Participant' with a person icon. A red arrow points from the text 'Click here to add participant' to this button. Below the button, there are three sections:

- The following domains are active at this site:**
Antibiotic, Corticosteroid, Influenza Antiviral, Macrolide Duration, Influenza Immune Modulation
- Consent Pending at 01991A - UK Test Site-Caras Infirmary Adult ICU**
No eligibility at 01991A currently consent pending
- Pending domains at 01991A - UK Test Site-Caras Infirmary Adult ICU**
No participants at 01991A have domains pending

eCRF: Platform Eligibility

5 platform eligibility questions on 1 page:

 AJTJWP ✓ Demographics ➔ Platform Eligibility ✗ State ✗ PANDA ✗ Domain Eligibility ✗ Intervention Eligibility ✗ Consent ✗ Best Interests	Platform Eligibility AJTJWP ➔ Platform Eligibility Does the patient have acute infection of the respiratory tract ⓘ ⌚ YesNo 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 YesNo 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 YesNo Is the patient expected to be discharged from this hospital admission today or tomorrow ⓘ ⌚ YesNo Has the patient been enrolled into this Platform before ⓘ ⌚ YesNo
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eCRF: PANDA Eligibility Qs

Pathogen

What is the likelihood that bacterial respiratory tract infection is contributing to this acute illness i 🕒 🗨

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 i 🕒 🗨

Suspected but n... ▾

SARS-CoV-2 infection i 🕒 🗨

Not suspected ▾

Respiratory Syncytial Virus (RSV) infection i 🕒 🗨

Suspected but n... ▾

Patient and Disease Characteristics

Where was the respiratory tract infection acquired i 🕒 🗨

☒ Community-acquired

Acute infection acquired outside of the hospital and more than 48h after hospital admission

☐ Hospital-acquired

Acute infection not incubating at the time of hospital admission or more than 48h after hospital admission

Does the infection involve the lower respiratory tract i 🕒 🗨

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

Yes

No

Is pneumonia present i 🕒 🗨

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

Present

Absent

Clinical Features and Syndromes

What was the date of onset of clinical features of this acute respiratory infection i 🕒 🗨

☐ 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 i 🕒 🗨

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

Yes

No

What is the patient's PaO2 i 🕒 🗨

13.00

mmHg kPa

☐ Not available

What was the corresponding FiO2 i 🕒 🗨

0.88

What was the corresponding PEEP i 🕒 🗨

43

☐ 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 i 🕒 🗨

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

Yes

No

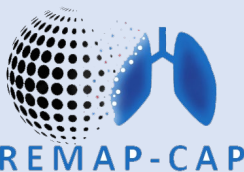
Is the patient's respiratory tract infection the primary contributor for their requirement for this organ support i 🕒 🗨

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

Yes

No

+ domain specific eligibility Qs



REMAP-CAP

eCRF: Eligibility Outcome

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

Clear output about which domains a participant is being assessed for on the “*Domain Eligibility*” page

 AJTJWP	Best Interests AJTJWP
✓ Demographics ✓ Platform Eligibility ✓ State ✓ PANDA ✓ Domain Eligibility ✓ Intervention Eligibility ✓ Consent ➔ Best Interests	Assessment Age group: Adult Illness Severity State: Severe This patient is still eligible for the following interventions at 01992T 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

The “*Best Interests*” page shows why participants are ineligible for certain domains

Randomisation Allocation

- Treat participants according to protocol and randomisation result
- Study participation and randomisation results must be documented in (electronic) patient medical notes
- The randomisation page must be printed and filed in the ISF

Baloxavir & Tocilizumab are provided by Roche and is supplied to sites with clinical trial labelling

- request from Clinical Trial Pharmacy
- some stock may or may not be kept on ICU / ward

All other IMP are from hospital stock

- follow routine procedures for requesting from hospital Pharmacy if not in stock on ICU / ward

IMPs to be administered as per **REMAP-CAP administration guides** for each domain.

Randomisation Errors

- If you happen to **unintentionally randomise** an ineligible patient by making a mistake while answering the eligibility Qs, please let us know ASAP by emailing UKREMAP-CAP@icnarc.org
- We will then ask the database team to move the entry to the screen failures list
- If you **unintentionally enter an eligible patient as a screen failure** by answering one of the eligibility Qs incorrectly, please let us know ASAP by emailing UKREMAP-CAP@icnarc.org
- You can re-screen them as a new patient and answer 'No' when the system asks if you are entering the same patient (this will bypass the check)

Re-assessment of Eligibility

Participants 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 participant's **summary page**.

Re-assessment of Eligibility



Participants



Manage



Reports



Queries



Resources

Vanessa Singh - 02999T ▾

Participants

Screening list

Transfers

New Participant



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 statusOpen

Monitoring statusNot Monitored

Transfer Participant

Change Log

TABLE	TYPE	DATE	USER
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2

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

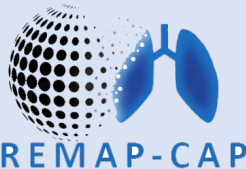
Influenza Antiviral Domain

5 days of Oseltamivir

Adverse Events ±

No adverse events

1



Help / Guidance

- eCRF Spiral Database User Guide – for general functions, symbols etc.
- eCRF Data Completion Guidelines – for completing each eCRF page
- 2FA Quick Guide – to reset multi factor authentication
- ‘Forgot my password’ function
- Hover mouse over ‘i’ next to data entry field for information

Good Clinical Practice (GCP) R3

- International, ethical and scientific quality standard to which all research involving human participants is conducted
- Comprises of **11 core principles** as per latest GCP R3. It applies to all clinical investigations that could affect safety and well-being of human participants, providing international assurance that:
 - Data and reported results of clinical investigations are credible and accurate
 - Rights, safety and confidentiality of participants in clinical research are respected and protected
- You are encouraged to obtain GCP certification, such as that available through NIHR:
<https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm>

11 Principles of Good Clinical Practice (GCP)

- 1.Ethical Conduct:** Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with GCP and applicable regulatory requirement(s). Clinical trials should be designed and conducted in ways that ensure the rights, safety and well-being of participants.
- 2.Informed Consent:** Clinical trial participation should be voluntary and based on a consent process that ensures participants (or their legally acceptable representatives, where applicable) are well-informed.
- 3.Independent Review (IRB/IEC):** Clinical trials should be subject to an independent review by an IRB/IEC.
- 4.Scientific Soundness:** Clinical trials should be scientifically sound for their intended purpose and based on adequate and current scientific knowledge and approaches.
- 5.Qualified Individuals:** Clinical trials should be designed and conducted by qualified individuals.
- 6.Quality by Design:** Quality should be built into the scientific and operational design and conduct of clinical trials.
- 7.Proportionality of risks (NEW):** Clinical trial processes, measures and approaches should be implemented in a way that is proportionate to the risks to participants and to the importance of the data collected and that avoids unnecessary burden on participants and investigators.
- 8.Clear Protocol:** Clinical trials should be described in a clear, concise, scientifically sound and operationally feasible protocol.
- 9.Reliable results:** Clinical trials should generate reliable results.
- 10.Roles and responsibilities (NEW):** Roles and responsibilities in clinical trials should be clear and documented appropriately.
- 11.IMP / GMP:** Investigational products used in a clinical trial should be manufactured in accordance with applicable Good Manufacturing Practice (GMP) standards and be managed in accordance with the product specifications and the trial protocol

GCP: Data Governance

- Ensure appropriate management of **data integrity, traceability and security**, allowing accurate reporting, verification and interpretation of clinical trial-related information
 - Ensure **source data** records are accurate, complete and contemporaneous
 - Facilitate timely and accurate **data entry** into eCRFs
 - Implement appropriate measures to **protect privacy and confidentiality** of personal information of trial participants per regulatory requirements on personal data protection
 - Ensure **record retention** as per regulatory requirements and sponsor agreements

GCP: Computerised Systems

- Only appropriate qualified individuals are allowed access, and that this access is secure and traceable
- Notify the Trial Management Team when access permissions need to be changed or revoked from an individual
- Always use your own account (not of a colleague)
- Use your hospital email address (not a private email address) when requesting/creating an account