

VOLUME 5 | 20th Dec 2021



A CHRISTMAS HIGHLIGHTS



The REMAP-CAP team would like to extend a MASSIVE thank you to EVERYONE for their commitment to the REMAP-CAP study.

The UK has now recruited over 5,000 COVID-19 patients! Thanks to YOUR hard work, the UK now has:



143 (42%) of the 340 sites open globally

5,495 (54%) of the 10,132 patients recruited globally



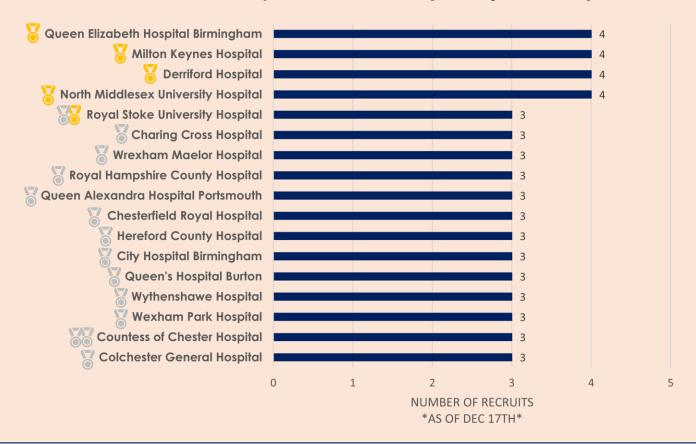


5,386 (60%) of the 8,972 COVID-19 patients recruited globally











PANDEMIC PLATFORM ACTIVE TREATMENT DOMAINS

Active on ICU only:

- ✓ Vitamin C (REMAP-CAP Ascorbic Acid IMP supplied on request)
- ✓ Simvastatin
- ✓ Anticoagulation
- ✓ ACE-2 / RAS domain (DMX-200 IMP supplied on request)
- Cysteamine (Cysteamine Bitartrate IMP supplied on request)

IT'S BACK! OUR (NEW) DOMAIN...

 Convalescent plasma will be reintroduced after Christmas for immune supressed patients only

NON-PANDEMIC PLATFORM ACTIVE TREATMENT DOMAINS

Active on ICU only:

- ✓ Antibiotics
- Macrolide Duration (only in association with the antibiotic domain)
- ✓ Corticosteroid
- ✓ Vitamin C
- Cysteamine (Cysteamine Bitartrate IMP supplied on request)



Just a quick note about Vitamin C and...

Hypoglycaemia

Definition of hypoglycaemia: Core lab [glucose] <3.8 mmol/L while in ICU

What to do if hypoglycaemia occurs:

- Standard supportive care
- Record whether the patient:
 - Was in the intervention period (defined as from the start of the first dose of vitamin C to 36 hrs after the last dose). AND
 - Treated with insulin or oral hypoalycaemic druas during the intervention period

Measuring glucose levels in patients receiving insulin/oral hypoglycaemic agents:

- During the intervention period, we suggest one of the following:
 - Core lab instrument
 - Point-of-care arterial blood gas machine with glucose measurements validated in the setting of high plasma vitamin C concentrations
 - StatStrip alucometer (Nova Biomedical)
- After the intervention period (36 hrs to 7 days after the last dose of vitamin C), we suggest:
 - 1 of the 3 validated methods
 - A standard glucometer, if the difference between its value and that measured by a validated method listed above is ≤2 mmol/L on 2 occasions ≥4 hours apart
- If a participant is discharged home <7 days after the last dose of vitamin C, we suggest the same
 approach, using the participant's glucometer, or if not available, a standard hospital glucometer

CHECKLIST TO ACTIVATE NEW DOMAINS AT YOUR SITE

- ☑ Choice page completed
- Pharmacy delivery details completed
- ☑ Self-training log for pharmacy and the research team
- ☑ IMP shipping request form completed
- ☑ Local approval for appropriate sub amendments



NB: Since patients may present acutely as medical emergencies, a 'deferred consent' model is in place in the UK so that eligible patients may be randomised prior to gaining consent.

PANDEMIC PLATFORM ELIGIBILITY CRITERIA

Inclusion

- ✓ Patient is 18 years or over
- ✓ COVID-19 is suspected by the treating clinician or has been confirmed by microbiological testing
- Microbiological testing for SARS-CoV-2 infection of the upper or lower respiratory tract

Exclusion

- Death deemed to be imminent or inevitable during the next 24 hrs AND one or more of the patient, substitute decision maker or attending physician are not committed to full active treatment
- Admission to hospital over 14 days ago with acute COVID illness
- Expected to be discharged from hospital today or tomorrow
- Previous participation in this REMAP within the last 90 days















NON-PANDEMIC PLATFORM ELIGIBILITY CRITERIA

Inclusion

- ✓ Patient is 18 years or over
- ✓ Admitted to ICU for acute severe CAP within 48 hrs of hospital admission:
 - Has symptoms or signs or both that are consistent with lower respiratory tract infection (for example, acute onset of dyspnoea, cough, pleuritic chest pain)
 - Has radiological evidence of new onset infiltrate of infective origin (in patients with pre-existing radiological changes, evidence of new infiltrate)
- ✓ Up to 48 hrs after ICU admission, patient is receiving organ support with one or more of:
 - Non-invasive or invasive ventilatory support
 - Infusion of vasopressor or inotropes or both

Exclusion

- * Healthcare-associated pneumonia:
 - Prior to this illness, is known to have been an inpatient in any healthcare facility within the last 30 days
 - Resident of a nursing home or longterm care facility
- Death is deemed to be imminent or inevitable during the next 24 hrs AND one or more of the patient, substitute decision maker or attending physician are not committed to full active treatment
- Previous participation in this REMAP within the last 90 days





COVID-19

Randomised, Embedded, Multi-factorial, Adaptive Platform for Community-Acquired Pneumonia

MILESTONES 2021

JANUARY 07 2021

Immune Modulation Pre-Print Publications

JANUARY 23 2021

Therapeutic Anticoagulation showed superiority for hospitalised patients not requiring organ support

FEBRUARY 25 2021

<u>Immune Modulation paper</u> published online.

JUNE 20 2021

REMAP-CAP VIT C stock made available

AUGUST 10 2021

REMAP-CAP DMX-200 stock made available

SEPTEMBER 29 2021

REMAP-CAP wins Critical Care Team of the year at the BMJ awards

OCTOBER 05 2021

Cysteamine domain made available in the UK

DECEMBER 06 2021

1st patient randomised to Cysteamine

JANUARY 11 2021

Convalescent plasma reaches futility trigger

FEBRUARY 08 2021

Multiplatform RCT Anticoagulation results published online

APRIL 10 2021

Tocilizumab and Sarilumab reach a prespecified trigger for equivalence

JULY 6 2021

WHO include tocilizumab & sarilumab in COVID-19 treatment guideline

AUGUST 26 2021

Anticoagulation manuscripts published back-to-back online for <u>critically ill</u> and <u>non-critically ill</u>

OCTOBER 04 2021

Immunoglobulin paper published

OCTOBER 11 2021

1st patient randomised to DMX-200 Intervention

♣ REMINDERS **♣**

- Please note the following when requesting access:
 - o **Spiral:** Used to screen, randomise, and enter data for patients
 - o MACRO: Used for 6-month follow-up and data linkage
- Please remember that the platform inclusion and exclusion criteria differ for pandemic and non-pandemic domains (page 4)

WE4YOU Webinars

- Next webinar: Wednesday 12th January 2022 at 15:00 GMT
- Please click the link below to join the first webinar of 2022:
 https://us02web.zoom.us/j/82888442003?pwd=TEtwTC91RVBPUGkrNGNQQ3Y5R2c5QT09
 Webinar ID: 828 8844 2003. Passcode: 632964
- Recordings of previous webinars, including the last one on Vitamin C, can be accessed here: https://bit.ly/we4youwebinar

Co-Enrolment

Co-enrolment agreements are in place for the following studies:

ACCORD, ADAPT-Sepsis, ARCADIA, ARREST, ASICS, BALANCE, BLING III, CEEG SE STUDY, COVRAS, COVSurf, COVEMERALD, EFFORT, EMPRESS, GenOMICC, INHALE, INNATE, INNATE IMMUNITY IN CRITICAL ILLNESS, INTENT, ISARIC, LUCID, MATIS, PASS, Patch, Plasmalyte 148® vs Saline study, PROMEDIC, PRONTO, REACTOR, REALIST, RECOVERY, SUDDICU, START-AKI, STOP-COVID, STRESS-L, SUDDICU, TEAM-ICU, VACIRIS, VITAMINS Trial, XARELTO









Despite the most difficult of circumstances, YOU have helped achieve SO MUCH this year, with UK sites leading the way for REMAP-CAP around the world. The evidence you are generating is already improving care for patients with COVID-19.

Thank you so much.

We would love to hear from you so please stay in touch via our social media outlets.

We look forward to the time when we can celebrate your success together.

Until then, we wish you a MERRY CHRISTMAS and a HAPPY NEW YEAR!

