



REMAP-CAP

ecraid



IN THIS ISSUE

- New publications in JAMA and NEJM
- Domains Update
- CTR Transition
- Training - Adaptive Clinical Trial Designs
- Recruitment Update

Dear REMAP-CAP family,

At the end of 2023, we look back at our recent achievements and take a sneak preview at 2024. The simvastatin and vitamin C papers are the latest in a list of twelve publications in the last 4 years, comprising 16 conclusions from the trial. We should be proud of that achievement. For 2024, we have developed a fabulous, free, training with Ecraid and ERS, and we will focus on influenza in new domains. For the Utrecht team, the transition to CTR early 2024 is exciting and challenging, but we are ready for it. And last but not least, we are excited to plan several events for REMAP-CAP Europe in the coming year, so we can connect, share stories, and continue to shape our collaboration. On behalf of the REMAP-CAP team, Lennie Derde

Training - Adaptive Clinical Trial Designs

Adaptive clinical trial designs is a broad area of research which encompasses many different designs and implementation techniques. Ecraid and ERS organize an online training course introducing distinct types of adaptive designs and explain their advantages and limitations.

To bring the theory to life, examples of adaptive trials in respiratory infections and diseases, such as [REMAP-CAP](#) will be discussed. Participation is free

of charge and no course registration is required. **Sign-up** for important announcements about this free six-part online course running from January till November 2024. Please find more information [here](#).

Publications

We are delighted to announce that REMAP-CAP has simultaneously released results about two widely available treatments, vitamin C and simvastatin. The articles have been published in [JAMA](#) and [NEJM](#), and were presented at the annual congress of the European Society of Intensive Care Medicine (ESICM LIVES) in Milan. We are grateful to the many participants for their contribution to REMAP-CAP, and to the many collaborators and investigators for their continued support.

Simvastatin

Simvastatin was shown to have a high probability (96%) of improving outcomes (a combination of survival and length of time patients need support in an intensive care unit) when started as a treatment for critically ill patients with COVID-19, and a 92% chance of improving survival at 3 months. This equates to one life saved for every 33 patients treated with simvastatin. 2,684 critically ill patients were included at 141 hospitals across 13 countries.

Vitamin C

Vitamin C is widely available around the world and was used in some settings for the treatment of COVID-19. Through harmonising two clinical trials - REMAP-CAP and LOVIT-COVID - over 2,500 patients in 20 countries took part, including both critically ill and non-critically ill patients with COVID-19 in hospital, it was shown that high-dose vitamin C did not improve outcomes for patients. This is the largest trial examining high-dose vitamin C in COVID-19 and provides evidence that high-dose vitamin C is not beneficial and suggests a high probability that it may be harmful.



Domains Update

We are excited to announce two new domains. Firstly, three new interventions focussing on Baloxavir have been added to the Influenza Antiviral domain. Baloxavir has antiviral evidence in outpatients on time-to-symptom resolution, but no evidence of benefit in inpatients. We will investigate whether it has value by itself, or in combination with Oseltamivir, in inpatients. Secondly, the influenza immune modulation domain has been designed to test if Tocilizumab or Baricitinib are effective in confirmed flu patients in the Severe State.

A statistical trigger has been reached for the “fixed course of hydrocortison” intervention, within the Corticosteroid domain. Other interventions within this domain will continue. Next to this, the Antiplatelet and Anticoagulation domain have been closed for operational futility. We continue to evaluate optimal treatment for CAP and COVID-19 and we look forward to sharing the results of the closed domains with you, and the public, as soon as they are available.

Recruitment Update

Worldwide

- 293 sites
- 13.032 unique patients
- 10.291 COVID-19 patients
- 22.807 randomisations

European Region

- 170 sites
- 7.540 unique patients
- 6.836 COVID-19 patients
- 14.196 randomisations

Since our last issue in September 2023 we added the following new sites to the REMAP-CAP family:

- UK: Fairfield General Hospital
- UK: University College London Hospital Trust
- Belgium: CHU de Charleroi Hopital Marie Curie

CTR Transition

Our team is working hard on the upcoming CTR transition, scheduled for January 2024. The transition will occur for the following 13 countries: Belgium, Croatia, Czech Republic, Estonia, France, Germany, Ireland, Italy, Netherlands, Portugal, Romania, Slovenia and Spain. Other countries are not covered by CTR (UK, Israel, Serbia and Switzerland), or cannot be transitioned as they do not have active sites.

As ongoing amendments are not allowed during the CTR transition, they must be approved or paused for the 13 countries transitioning. Countries working on ongoing submissions are working very hard on obtaining approvals in order to prevent undesired withdrawal. We expect the transition period to take several months. After transition, all ethical assessments will be centrally submitted through CTIS (not for UK, Israel, Serbia and Switzerland).

More information and updates will follow.

If you have questions concerning the CTR transition, please contact your country manager.

Happy recruiting! The REMAP-CAP Team

May the sparkle and joy of the holidays fill your heart. The REMAP-CAP family wishes you a season filled with happiness and merry-making.

