

ISSUE 24 | APR 2025 **REMAP-CAP**

IN THIS ISSUE

- Welcome
- Funding
- Regulatory Update
- Recruitment
- Core V4.0 Implementation Preparation

This newsletter brings a mixture of good news and challenges. We are a global trial, with a large contribution from Europe, but funding opportunities for such a large, collaborative, longterm effort are challenging. Currently, we need to pause recruitment at some sites for financial reasons, while we work hard to obtain new funding. Not an easy task, especially in the light of the current global landscape. More information is in this newsletter. On a more positive note, we have received approval for our first substantial modification in CTIS (including the updated Core Protocol), we are preparing several manuscripts, the CRF is being revised to be leaner and smarter, and we are continuously optimizing the trial and our procedures. I truly hope you remain part of our family, even if we need to pause our activities for a short while, and we can continue to investigate the optimal treatment of patients with acute respiratory infections.

Lennie Derde

Top 3 recruiting sites from January 1st

1. Milton Keynes Hospital (UK) 2. Hospital de Tortosa Verge de la Cinta (ES) 3. Ramon y Cajal University Hospital (ES)

Follow Ecraid

Besides REMAP-CAP, Ecraid manages many other international clinical studies.

Subscribe to Ecraid's newsletter for monthly updates, and follow it on LinkedIn and X.

Ecraid puts great effort in utilising its expertise and that of the collaborators for various training and educational activities. These various

Funding

After some years of exponential growth of activities during the pandemic, the current activities in REMAP-CAP have remained high, with 9 domains investigating 28 interventions active in the trial. As this activity is much higher than anticipated, our current ECRAID-Base funding will be exhausted soon, though the grant lasts until February 2026. We had previously chosen to optimize our site-to-recruitment ratio, and made the difficult decision to pause recruitment in several sites.

Now, we need to scale down even further, as there is a delay in acquiring new funding. Also, obtaining national funding that we can combine to support the European part of the trial, has proven difficult under current funding structures. Affected sites can be activated quickly when new funding is available, and/or in the event of a pandemic, with our "sleeping site" strategy.

With these modifications, we retain over 99% of recruitment.

You will be informed by the project management team about what this means for you as investigators. Any initiatives that could help fund existing networks in Europe to remain active in REMAP-CAP are welcome, of course we are continuously searching for new funds, through traditional competitive grants, charities, and pandemic preparedness initiatives.

Regulatory Update

REMAP-CAP has received approval for the first Substantial Modification (SM-01) in CTIS on 10th of March 2025. This approval applies to all EU countries.

This marks two significant milestones:

- By completing the regulatory dossier our transition from CTD to CTR is finalized.
- Core Protocol V4.0 and its appendices have been approved.

Other key elements include documentation of the acceptable informed consent processes under CTR, and approval of less extensive label requirements for most of REMAP-CAP study drugs

opportunities are often free of charge.

Subscribe to the Ecraid Learning newsletter for updates on our latest initiatives.

Recruitment

During the past flu season (2024-2025) we have increased recruitment from 414 to 434 compared to the previous flu season (2023-2024). This entails recruitments during a period from 1st of September - 30th of March



(i.e. for IMP with a market authorization).

In the coming period, active sites will receive further details on the protocol and process changes, along with necessary training to ensure a smooth transition and implementation.

We greatly appreciate your continued collaboration and commitment to REMAP-CAP. For any questions, please reach out to your PM or CRA.

Core V4.0 Implementation Preparation

Currently, the operational team is finalizing all necessary educational materials to train and activate participating sites on the new Core Protocol V4.0 and other new and updated protocol documents.

Active sites will be invited to participate in a general training that will take place after the eCRF update for Core Protocol Version 4 is released. This is expected in Q3 2025.

For live EU region enrolment data click here

- 298 sites
- 15,029 unique patients
- 10.447 COVID-19 patients
 - 25.796 randomisations
- <u>103 sites</u>

Europear

Co

- 8,461 unique patients
- 6.863 COVID-19 patients •
- reag 15.564 randomisations

Let's connect





The ECRAID-Base project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 965313





