



ISSUE 23 | DEC 2024

REMAP-CAP

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Dear REMAP-CAP family,

December is always a time for reflection. Looking back, I am proud of what we have achieved. We have been able to streamline our operations, that are now completely aligned with Ecrad templates and procedures. We have strengthened our collaborations through in-person meetings, and have our recruitment dashboard fully operational, as you can see in this newsletter. We currently have 7 domains open, including two for influenza, and are finalizing our report of the "7 days hydrocortisone" in CAP arm as we speak. A big achievement was our transition to CTIS, and submission of the first substantial modification. This included a major update of our Core Protocol, incorporating all the learnings of the last 10 years. Looking ahead, I hope most of all that we can continue to meet each other, connect, and strengthen, expand and improve our network. Together, we can improve the way we do research, and improve outcomes for our patients. Thank you for all your contributions, and I wish you happy holidays - enjoy time with your loved ones!

Lennie Derde

Top 3 recruiting sites since September

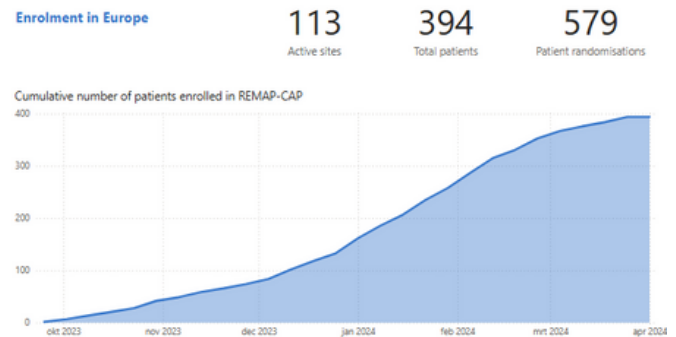
1. Milton Keynes Hospital (UK)
2. Centre Hospitalier de Dieppe (FR)
3. University Medical Centre Maribor (SI)

Recruitment

Advancing Healthcare - One Patient at a Time

With your dedication, we can reach more people, more quickly and produce results fast – giving every patient a chance to make an impact on the future of healthcare.

The flu season has started and we see recruitment picking up for EU Region countries. Below you see the recruitment graph of last winter season, and we hope to recruit even more patients this season.



Regulatory Update

We are excited to share that the first substantial modification (SM) was submitted on November 8, 2024 for countries under CTR. This includes the following new documents:

- Core Protocol V4.0
- PANDA
- Updated DSAs
- Other key documents for completing our CTIS dossier and CTR implementation (labeling, ICFs, new SmPCs, local PI updates, and a Sponsor PI change from Marc Bonten to Lennie Derde)

Over 500 documents and numerous free text fields were submitted to the authorities.

We're now in the assessment phase and aim for approval by the end of **February 2025**.

Your country manager or CRA will reach out to you to provide training on all changes and any necessary information for implementation when applicable.

Which active domain is of most interest for you?



You can participate via the QR code or click [here](#). Answers are anonymous and will be published in the next newsletter.

We are curious to see your answers.

Informed Consent (IC)

Is the IC process clearly defined for you and your research staff?

During the last few months, almost all sites have been (re-)trained on the IC process and requirements for data entry in the eCRF. Here we would like to share some tips and tricks to keep on top of your mind and stay sharp.

- Keep your country specific IC process flowchart at hand for quick reference.
- Document every discussion/ event related to ICF process **in the eCRF and source**.
- Article 35 under CTR gives the possibility to recruit patients with **delayed consent** if they are incapable of providing consent themselves. In some countries this was not possible under CTD. If this process is unclear to you, please contact your CRA or clinical trial project manager

For any questions regarding the IC procedure, please reach out to your clinical trial project manager.

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 opportunities are often free of charge.

[Subscribe](#) to the Ecraid Learning newsletter for updates on our latest initiatives.

Christmas Wish

Thank you to all participating sites and collaborators for advancing REMAP-CAP research goals & supporting an essential part of our journey! We are truly grateful for what we have been able to achieve together.

Wishing you and your teams a joyous holiday season, a prosperous and successful New Year.



For live EU region enrolment data click [here](#)

World

- 298 sites
- 14,211 unique patients
- 10,421 COVID-19 patients
- 24,586 randomisations

European region

- [114 sites](#)
- [8,143 unique patients](#)
- [6,860 COVID-19 patients](#)
- [15,093 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



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