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## **Dear REMAP-CAP family,**

While we cheer for our individual countries to win Euro 2024, as the European region of REMAP-CAP we've been very successful together. Over the last 4 years, we've included almost 5,000 patients into the trial, adding up to over 8,200 randomizations, and our collaboration as a European trials group has strengthened.

To celebrate this, we've had a very successful faceto-face meeting with the Regional Management Committee recently, where we were able to learn from each other, and create a vision to tackle the challenges we face, like funding. There, we also presented the new Data Visualization tool, that is now implemented into the <u>remapcap.eu website</u>. In this newsletter, you can read about this and other meetings, our successful transition to the European Clinical Trials Regulation system, and our preparations for the first Substantial Modification. I wish you great summer, with a well-deserved holiday!

On behalf of the REMAP-CAP team, Lennie Derde



### **Critical Care Reviews '24**

The Critical Care Reviews '24 (CCR24) conference lit up Belfast from June 12th to 14th with a packed scientific program. Highlights included three captivating talks on REMAP-CAP. The livestream is free to rewatch via the links below, but you can make a contribution to the fabulous work of Rob and his team <u>here</u>.

#### <u>REMAP-CAP Statin Trial Results - Tom Hills</u>

The trial results indicated a very high probability (96%) that simvastatin improved outcomes for critically ill patients with COVID-19.

 <u>REMAP-CAP Ivermectin Trial Results - Madiha</u> <u>Hashmi & Alistair Nichol</u>

For ICU patients with COVID-19, ivermectin was unlikely to improve the primary composite outcome of organ support-free days and hospital survival. However, it did not achieve the prespecified criteria for futility. They also highlighted the ability of the platform trial to deliver and assess interventions of interest in low-resource settings.

<u>REMAP-CAP Steroids Trial Results - Steve Webb</u>
<u>& Scott Berry</u>

For ICU patients with CAP, there was a low probability of benefit from fixed-dose hydrocortisone. The sample size is too small to draw conclusions for influenza patients.

Recruitment to the other interventions of the Corticosteroid Domain remains open, and we encourage sites to continue to participate to answer important questions that remain unanswered about the role of corticosteroids in the treatment of severe CAP.

#### **EU RMC - F2F Meeting**

On April 17th and 18th, the REMAP-CAP European Region Management Committee met face-to-face in Utrecht to foster stronger bonds and discuss challenges and opportunities. (Photo to the left)

# **Regulatory Update**

**REMAP-CAP** has successfully transitioned to the CTR and the team is preparing for the first **Substantial Modification (SM).** 

As we have learned a lot in REMAP-CAP over the last few years, the Core (or master) Protocol of the trial has undergone a major revision. We will submit the revised Core Protocol V4.0 and associated documents as part of this first SM which also serves to complete the full regulatory dossier. We aim to submit the SM in August and expect regulatory approval within 3 months.

Sites will be informed about upcoming changes to the protocol during the next months and will receive training prior to implementation. For any questions, please contact your PM or CRA.

## **IMPRINT Study - ZonMw Grant**

'Immune Modulation Platform for Influenza Treatment' (IMPRINT), has received a €2.1 million grant from ZonMw, to make vital research possible.

UMC Utrecht, will collaborate with several Dutch hospitals, the Dutch Intensive Care Association, the Dutch ICU registry stichting NICE, patient groups through FCIC/IC-CONNECT, and the Ecraid operational team on this project, that will be embedded in REMAP-CAP.

IMPRINT is a 4-year project with the aim to include 700 patients in the Influenza Immune Modulation Domain of REMAP-CAP.

Since our last issue in March 2024 we added the following new sites to the REMAP-CAP family:

- ES: Doctor Peset University Hospital
- ES: Hospital Universitario y Politécnico La Fe
- HR: University Hospital Centre Zagreb



#### **ECRAID-Base consortium**

The ECRAID-Base consortium held its third General Assembly on May 27-28 in represented Budapest. Lennie Derde REMAP-CAP. sharing the trial's latest updates and challenges. She tackled the big question: Is REMAP-CAP ready for the next pandemic? Her conclusion: it's on the right track, but there's still work to be done.

This ZonMW grant is a great example of national funding. We encourage all local teams to actively engage with their country manager regarding opportunities for similar national funding.

## **Data Visualization - PowerBI Tool**

Recently, we've changed the way we provide you with recruitment updates. Now, you can access recruitment data in almost realtime (we currently have weekly updates) via the PowerBI tool.

Recruitment data is visualized on country and domain-level. We invite you to explore the new visuals through the website and let us know any feedback or additional data requests you have.

# **Meeting Dublin September**

Mid-September, REMAP-CAP investigators will join the Federated Platform Meeting organized by INFACT, ISARIC and ICC-CTN in Dublin. Here, we aim to discuss concrete plans for collaboration between trialists at a global scale. We'll keep you posted on the results!

- 298 sites
- 13.795 unique patients
- 10.414 COVID-19 patients
  - 23.928 randomisations

118 sites

European

- <u>reagion</u> 7.962 unique patients
  - 6.852 COVID-19 patients
  - 14.822 randomisations



World

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





Let's connect

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