

# REMAP-CAP



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## RECRUITMENT UPDATE

As of 11 April 2022, REMAP-CAP is active in **359** sites in **21** countries worldwide and a total of **11,122** unique patients have been included, of which **9,772** are COVID-19 patients. These patients contributed to a total of **19,744** randomisations in the different domains.

### Europe:

- **216** Activate Sites
- **6,961** Patient Inclusions
- **6,664** COVID-19 Patients
- **13,264** Randomisations

## EU Inspections

During the course of 2021 and 2022, several ICH GCP site inspections, and one sponsor inspection took place. The focus was on overall ICH GCP compliance of the study on-site and from a sponsor point of view. The inspection reports have brought to light several points for improvement. During the pandemic, the focus has necessarily been on expanding the trial and delivering results. We view these comments as an opportunity to improve our trial as the pandemic slows down. The UMCU is working together with sites and other global partners to address these.

## Dear REMAP-CAP investigators,

This pandemic is not over yet. However, two years later, we start to look forward, to a future where COVID-19 may become an endemic disease. We want REMAP-CAP to be a part of the future, and aim to contribute to improve not just outcomes for patients, but also to deliver a more efficient and high quality research.

At recent Brussels ISICEM conference, these aims came together. It was great to meet members of the global [#remapcapfamily](#) in person. Charlotte Bradbury presented the results of the Antiplatelet Domain with a competitive publication in JAMA ([doi:10.1001/jama.2022.2910](https://doi.org/10.1001/jama.2022.2910)).

I presented on the future of research in pandemics, stressing the need for global collaboration (including addressing inequalities), platform trial designs, and new approaches to research like we have established in Ecrad. You can read about our contributions to ISICEM and more in this newsletter, enjoy reading!



Charlotte Bradbury presenting at the ISICEM conference

'The place of antiplatelet agents in COVID-19'  
[Click here to watch the presentation at ISICEM22](#)  
 (LD 33:45 - 53:45 and CB 53:50 - 1:14:10)

On behalf of the REMAP-CAP team,  
 Lennie Derde  
 Global Chair of the International Trial Steering Committee  
 European Coordinating Investigator

## A Big Welcome

Since our last issue we added the following three sites to the [#remapcapfamily](#)

- Istituto Mediterraneo per I Trapianti e Terapie ad Alta Specializzazione (Italy)
- University Medical Centre Maribor (Slovenia)
- Hospital de Tortosa Verge de la Cinta (Spain)

## PLATFORM CONCLUSION:

### ACE2RAS Domain

On February 24th 2022, the REMAP-CAP Data Safety Monitoring Board recommended to stop enrolment of critically ill COVID-19 patients into the ACE2RAS domain. This recommendation was implemented by the International Trial Steering Committee. Although no safety concerns were raised for non-critically ill COVID-19 patients by the DSMB, the ITSC temporarily paused enrolment of noncritically ill patients into this domain to allow review of additional data prior to potentially resuming enrolment. More updates to follow soon.

Read the ITSC letter to REMAP-CAP sites [here](#).

### WE4YOU

The WE4YOU webinar continues every first Wednesday of the month at 16:00 CEST.

During the March 2022 session, Prof. Djillali Annane from [Hopital Raymond Pointcaré](#) presented an upcoming domain "High Steroids" for Covid-19 patients. You can already sign up for this domain, details will follow when the domain is ready for activation.

Click [here](#) to watch WE4YOU videos.

## NEW PUBLICATION: Antiplatelet

REMAP-CAP Antiplatelet domain showed that among critically ill patients with COVID-19, treatment with an antiplatelet agent, compared with no antiplatelet agent, had a low likelihood of providing improvement in the number of organ support-free days within 21 days. However, when looking at survival on its own we saw that both aspirin and clopidogrel may improve survival. We are unsure why this is, but it may be that these drugs are helpful for some patients, but not all. We will re-open the domain for critically ill patients, focussing on longer-term survival and making sure that the drugs are not given to patients we know need full doses of other anti-coagulants. If you want to contribute to answering this question, please let us know by contacting us: [eu.remapcap@umcutrecht.nl](mailto:eu.remapcap@umcutrecht.nl)

Read or download full article [here](#).

## Media Campaign

Follow us on [LinkedIn](#), [Instagram](#), and [Twitter](#). If you have ideas or would like to support our efforts, contact us: [eu.remapcap@umcutrecht.nl](mailto:eu.remapcap@umcutrecht.nl)

## UCD Research Impact Award

The REMAP-CAP global family congratulates Professor Alistair Nichol, Kathy Brickell, Kate Ainscough and the Irish Critical Care Clinical Trials Network with the great achievement of winning the UCD Research Impact Award!

Click [here](#) for the article and [interview](#) with Prof. Alistair Nichol.

## On-site Monitoring

Project managers Albertine and Janine visited Italy and met with country coordinating PI Prof. Maurizio Cecconi of Humanitas Research Hospital, PI Prof. Giovanni Landoni of Ospedale San Raffaele, and Sara Paina and Nadia Moffa at the Italian CRO Mediolanum Cardio Research. "It was great to have the opportunity to meet site staff and see and discuss how REMAP-CAP is executed in Italy. We were really impressed by the very kind people we met and the quality of their work. We look forward to visiting other sites in the future, together with the dedicated Italian monitoring team." - Albertine



Monitoring in The Netherlands



Co-monitoring in France

Project managers Maaïke and Clementina visited the ICU at the UMCU. "Being in the field and talking face-to-face with one of our investigators at UMCU (Jelle Haitsma) just made the process go faster. Nothing beats seeing where the ground work for the trial takes place." - Clementina

Project managers Sara and Sarah visited Hospital Raymond Pointcaré Garches along with Assistance Publique - Hôpitaux de Paris (APHP) staff. "It was a very succesful monitoring visit in which we saw the professionalism of the clinical staff at the site and the CRA. Inclusion rates are high at this site, it was great to see how the trial is embedded in the daily work." - Sara & Sarah