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REMAP-CAP

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Dear REMAP-CAP family,

As summer slowly comes to an end, we are anticipating increased trial recruitment and activities. We are preparing our first Substantial Modification in CTIS, as you will read in this newsletter. We have 7 domains open, with a special focus on influenza. Please let us know if you're interested in participating, so we can answer important questions for patients this season! We are expecting publication of the Corticosteroid Domain results in the next weeks, that we will inform you of separately. Challenges remain regarding funding and the longer-term sustainability of the trial in Europe, that we are working on with the members of the EU Regional Management Committee in the background.

On behalf of the REMAP-CAP team,
Lennie Derde

eCRF: Sign off

With this we would like to remind the investigators to continuously sign off the Case Report Forms (eCRFs) to confirm correctness and completeness of data. Patient data can be signed off on form-level or patient-level. We recommend that data is signed off no later than 20 days after a patient's trial completion. Interim sign off after completion of Day 21 or Day 90 is endorsed by the Sponsor. Please reach out to your local monitor in case of questions related to the sign off process.

Safety Reporting Updates

In April 2024, the SAE CRF in Spinnaker was updated to improve ease of use and facilitate safety event assessment. Key changes included:

- An auto-population feature for follow-up and final SAE reports.
- More response options for certain questions.
- Rephrasing of several questions for clarity and better understanding.

For instance, the question "Is this event a SUSAR?" was revised to "Is the event expected in the context of available reference safety information for the allocated intervention in the domain?" The new version of this form is only applicable for patients enrolled after April 2024. Updated CRF completion guidelines and educational material have been shared with sites, and can be found here.

This is a kind reminder to submit follow-up/final SAE report when new information becomes available and ensure that SAE reports are signed off by the PI or delegated investigator.

Please be informed that the REMAP-CAP safety phone will no longer be in use. Reference to the phone number will be removed with the next revision of documents where it is listed. If you need to discuss safety or eCRF related issues, please contact your local monitor or EU.remapcap@umcutrecht.nl

For eCRF related questions or issues outside office hours which need to be addressed immediately, please contact info@remapcap.org

Top 3 recruiting sites

Since previous newsletter

- Milton Keynes Hospital (UK)
- Centre Hospitalier de Dieppe (FR)
- University Medical Centre Maribor (SI)

Regulatory Update

We are pleased to inform you that Dr. Lennie Derde will be the new overarching principal investigator of the REMAP-CAP trial. She will take over this role from Prof. Dr. Marc Bonten. This change will be incorporated in all documentation in preparation for the upcoming substantial modification.

We'd like to bring to your attention that the submission of the first Substantial Modification (SM) in CTIS, which includes the revised Core Protocol V4.0, is taking a bit longer than anticipated. While we initially planned to submit in August, we kindly ask for your patience as we finalize the details.
We will keep you updated on our progress and will ensure that all sites will be informed and trained on the upcoming protocol changes before implementation. If you have any questions, please don't hesitate to contact your PM or CRA. We greatly appreciate your understanding and continued support.

Meeting Dublin September

REMAP-CAP investigators and project managers attended the Federated Platform Trials technical workshop in Dublin organized by the Irish Critical Care Clinical Trials Network, ISARIC and InFACT. The focus was on principles needed to enable critical care platform trials to collaborate and federate effectively. Strategy sessions were held for three major platform trials, REMAP-CAP, PRACTICAL and PANTHER.

Adaptive Clinical Trials Training

Adaptive trial designs offer a flexible alternative to traditional clinical trials, allowing for real-time adjustments based on emerging research. Also REMAP-CAP significantly enhances the speed and efficiency of clinical research. A free modular training series is now available, providing insights from leading experts on the various types, benefits, and challenges of adaptive trial designs, featuring Lennie Derde and Marc Bonten. This series is ideal for anyone interested in advancing clinical research in infectious diseases. Please click **here** for more information.

2024 postgrad course on clinical research methods - Belgrade

The third edition of Ecraid and ESCMID's postgraduate course, 'Better methods for clinical studies in infectious diseases and microbiology,' will be held in October in Belgrade. Young researchers in clinical microbiology and infectious diseases are invited to join experienced lecturers for practical discussions. This **three-day event** begins on 22 October 2024, marking the first time it will be hosted in Eastern Europe. Register by 04 October 2024 to secure your spot!

For live EU region enrolment data click **here**

World

- 298 sites
- 14,106 unique patients
- 10.418 COVID-19 patients
- 23.433 randomisations

European region

- 113 sites
- 8,032 unique patients
- 6.855 COVID-19 patients
- 14.933 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

UMC Utrecht ecraid ecraid Base