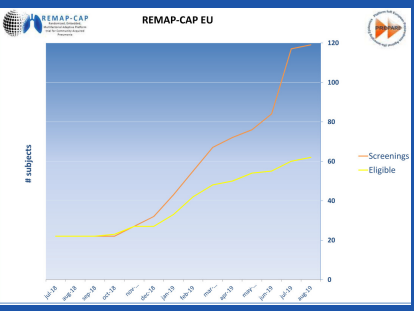
NEWS

REMAP-CAP
Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia

October 19 | NEWSLETTER ISSUE 8

Activated sites: 18
Number of randomized patients: 65

Top 4 recruiters:
1. UMC Utrecht , Utrecht
2. Hospital Universitario Reina Sofia, Cordoba
3. Centro Hospitalar do Medio Tejo, Abrantes
4. Canisius Wilhelmina Ziekenhuis, Nijmegen



Monitoring highlights
Several sites have been monitored now and we are happy with the quality of the data collected. To further improve data collection, please pay special attention to the following items:

1) Clearly document patient participations in the source documents (incl. switch because of microbiology results).

2) Please document correctly in the source data that consent has been obtained (yes/no), if patient withdrew consent (yes/no).

3) Vital status at Day 90 is the PRIMARY OUTCOME, therefore this is the most important data. Complete this form no earlier than on study day 91 and complete by study day 104.

A frequently asked questions document is also available on the landing-page of Research Online. This document will be frequently updated.

Start of new flu season

In most European countries summer has ended and the start of a new flu season is only a few weeks away. As of October, we expect the recruitment to increase and if needed, the sponsor is offering study refreshment trainings as of October 2019. Feel free to contact the sponsor team if you would like to make use of this opportunity.

STUDY HIGHLIGHTS:

- **First patients randomised in Hungary:** In May 2019 we have activated 2 sites in Hungary. These are Jose Andras County Hospital and Almasi Balogh Pal Korhaz. The first patients was included in June 2019
- **First patients randomised in the UK:** In May 2019 we activated St James's University Hospital in Leeds and Queens Medical Centre in Nottingham as the first 2 sites in the UK. The first patient was included in June 2019. Additional sites have been activated since and we currently we have 10 sites activated in the UK.
- **Approval and first initiation in Germany:** Earlier this year, we received full approval in Germany. On 28 August 2019, the first initiation within our German network took place in the Jena University Hospital in Jena. The visit was very successful and as soon as the last issues have been solved, we hope to provide the study team green light in October to start screening and including patients! Moreover, 5 additional sites are expected to be activated by the end of October.
- **Approval Belgium:** Full approval has been obtained in Belgium and we are currently in the final stages of initiating our 3 sites in Belgium. We hope to welcome CHA Marie Curie in Charleroi, AZ St. Jan in Bruges and our coordinating center in Belgium University Hospital Ghent located in Ghent soon as activated sites in the REMAP-CAP study.
- **Approval Romania:** We are very happy to announce that we succeeded to get approval in Romania and initiated the Dr. Victor Babes Clinical Hospital for Infectious and Tropical Diseases in Bucharest. We are looking forward to collaborate with the local study team.

HFNP statement

The REMAP-CAP study International Trial Steering Committee has decided to modify the operationalization of the definition of non-invasive ventilation (NIV), as used in the Eligibility Criteria, to include oxygen therapy delivered through high flow nasal prongs (HFNP) (at a flow rate of at least 30L/min). The rationale for this change is that HFNP is increasingly being used in ICU as a substitute for conventional NIV. HFNP does deliver some continuous positive airway pressure (CPAP), which we feel is sufficient to justify this change of definition.

The change is only to the operational definition of NIV in the CRF and therefore does not require a protocol amendment. A statement to explain the rationale and its implications have been provided to the sites and is also attached to this newsletter.

Are you interested to join?

If you would like to join the REMAP-CAP Study, please send an email the general e-mail address (below) The members of the Regional Coordinating Committee will provide you with the essential information and guide you through the process of becoming a member of the REMAP-CAP family.