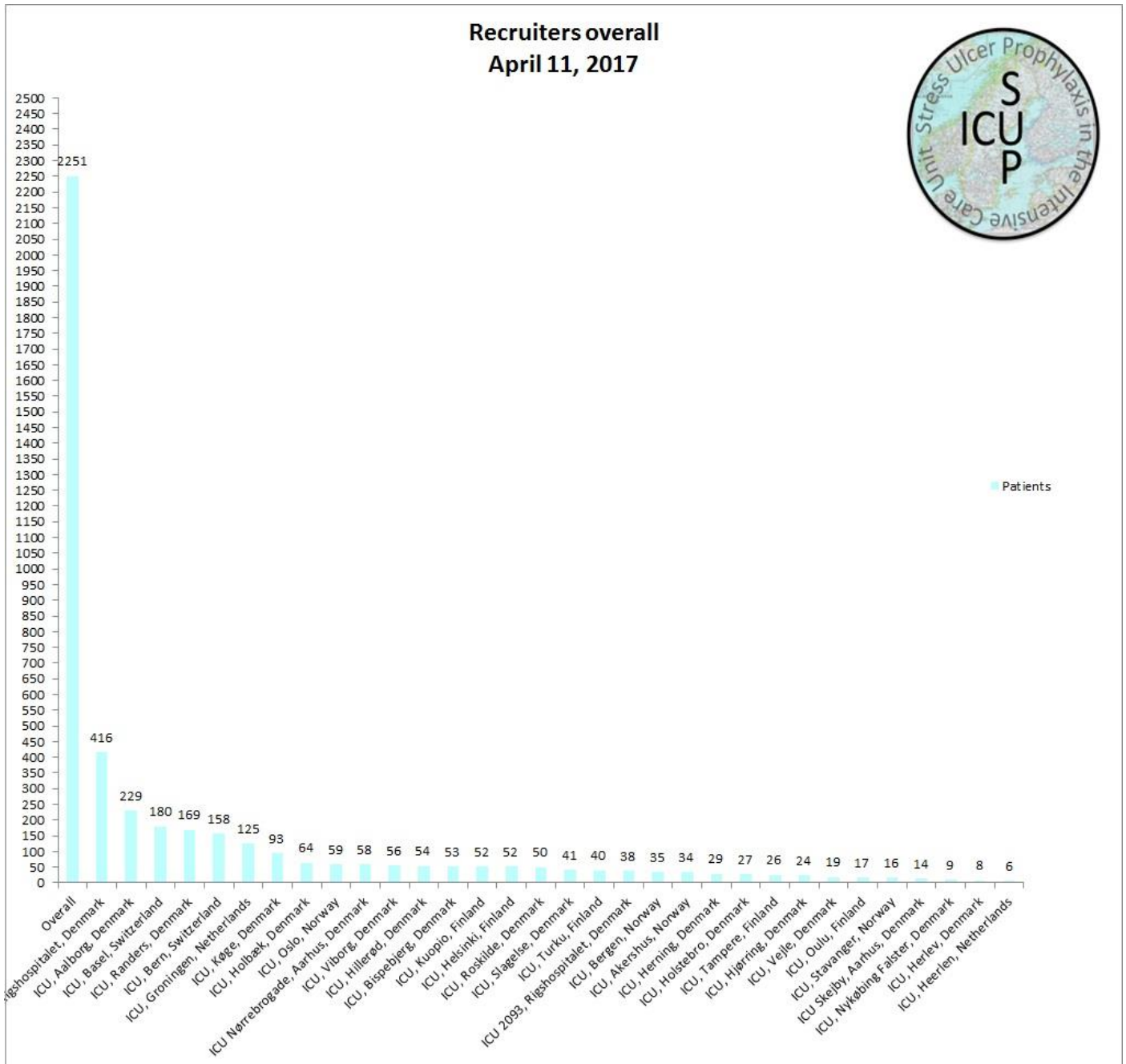




Place in Site Master File #13

SUP-ICU newsletter – April 2017



Thank you for your great commitment to the SUP-ICU trial.



Status

Since the previous newsletter more than 212 patients have been randomised, and we have now randomised 2243 patients (66%). Thirty-two sites in five countries are active.

You can follow the inclusion and the number of active trial sites at www.sup-icu.com (press F5 to refresh the page and get the updated status).

New sites

Cardiff, Wales are expected to begin inclusion at the earliest - a warm welcome in SUP-ICU.

Top recruiters

Top 5 overall recruiters in March were:

1. Basel (24)
2. (Rigshospitalet 4131) (23)
3. Aalborg (21)
4. Randers (17)
5. Århus NBG (12)

Congratulations to Basel for finishing as monthly top recruiter in February – 24 patients included in Basel in one month - very impressive! Aalborg and Randers continue to randomise patients at a steady state.

Future active sites

Additional UK sites are expected to join SUP-ICU. Italian sites are awaiting the final national approvals.

Important information

- **IMPORTANT: The trial medication will expire end of november 2017, why we need to randomise the last patient before September 1, 2017. We have tried hard to come up with other solutions, but this is unfortunately not possible. Consequently, we need to complete the SUP-ICU trial in less than 5 months = 20 weeks. This means, that we need to include at least 55 patients each week! Please continue to systematically screen patients for inclusion, as a big combined effort is needed to finish the trial in time. Weekly inclusion rate emails will be introduced. Please keep the spirit high – you are all doing a tremendous and impressive effort!**
- **IMPORTANT: Please complete all data registration of patients randomised in the trial until january 20th 2017, including 90-day follow-up to prepare for the first interim analysis of 1675 randomised patients (50%). Deadline for complete data registration, including 90-day follow-up, of these patients are april 20th 2017.**
- Please check the status of previously completed 'follow-up'-forms - We have fixed an error in the eCRF and some forms may have returned to 'uncompleted'/'yellow'.
- A lot of 'unobtainable'-values are still registered in baseline forms. Please take measures to obtain these values if possible. Local principal investigators will from now on receive automatic email notifications in these cases

Other

- In March the inclusion rate has increased to more than 200/month – great job!
- Thank you very much for your commitment; please keep up the great work – less than 35% to go!

SUP-ICU hotline

If you have any questions please send us an email (soeren.marker.jensen.01@regionh.dk) or contact the SUP-ICU hotline 24/7 (+45 3545 7450). If no one answers the phone, please **leave a message and your phone number** and we will call you back as soon as possible.

Please archive this newsletter in your Site Master File.

Best regards

Søren, Anders, Carl and Morten