



Place in Site Master File #13

SUP-ICU Newsletter – October 2017



**SUP-ICU trial inclusion completed
3350 patients**

Status

Dear friends

Inclusion in the SUP-ICU trial has been completed; the final patient was randomised October 22 in Bern, Switzerland. In less than 22 months, we managed to randomise 3350 acutely ill ICU patients to PPI or placebo. This is truly impressive, and we should all be very proud of this. Thank you very much to everybody!

We will now be entering another equally important phase of the trial, so please carefully read the rest of this newsletter.



Monthly top recruiters

Top 5 overall recruiters in September were:

1. (Rigshospitalet 4131) (28)
2. Cardiff (UK) (14)
3. Aalborg (DK) and Basel (CH) (12)
4. Aarhus NBG (DK)

Top 5 overall recruiters in October were:

1. (Rigshospitalet 4131) (16)
2. Basel (13)
3. Aalborg (DK) (12)
4. Nordsjaelland (DK) (11)
5. Aarhus NBG (DK) (10)

Congratulations to Cardiff (UK) for finishing as monthly top recruiter in September and Basel (CH) for finishing as monthly top recruiter in October.

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Weekly top recruiters

Congratulations to the weekly top recruiter:

Week 39 – Aarhus NBG (DK) and Groningen (NL)

Week 40 – Nordsjaelland (DK)

Week 41 – Aarhus NBG (DK)

Week 42 – Bern (CH)

Important information

1. **Continue to administer trial medication for already included patients until a maximum of 90-days.**
2. **Patients re-admitted to a SUP-ICU trial site within 90-days should continue to be re-admitted in the eCRF and have their trial medication resumed**
3. **Please complete data registration at the earliest, as this is a prerequisite for the final GCP visit and analysis of data**
4. **When data registration is complete we will need to validate registered data – additional information on this will follow shortly**
5. The majority of trial medication will expire end of november 2017. A minor part, however, is due one more month and will expire end of december, 2017. Boxes of trial medication will be centrally inactivated in the medication module at November 30 and December 31, respectively (you should not do anything)
6. Re-distribution of IMP will need to continue until follow-up of the last patient has been completed. We are well aware that this mandates a big effort on you to re-pack and help shipping trial medication between sites, and we are very grateful for the work you put into this
7. When follow-up has been completed, you will receive further instructions on IMP accountability and disposal

Other

- Once again, thank you very much for your huge effort in the SUP-ICU trial!

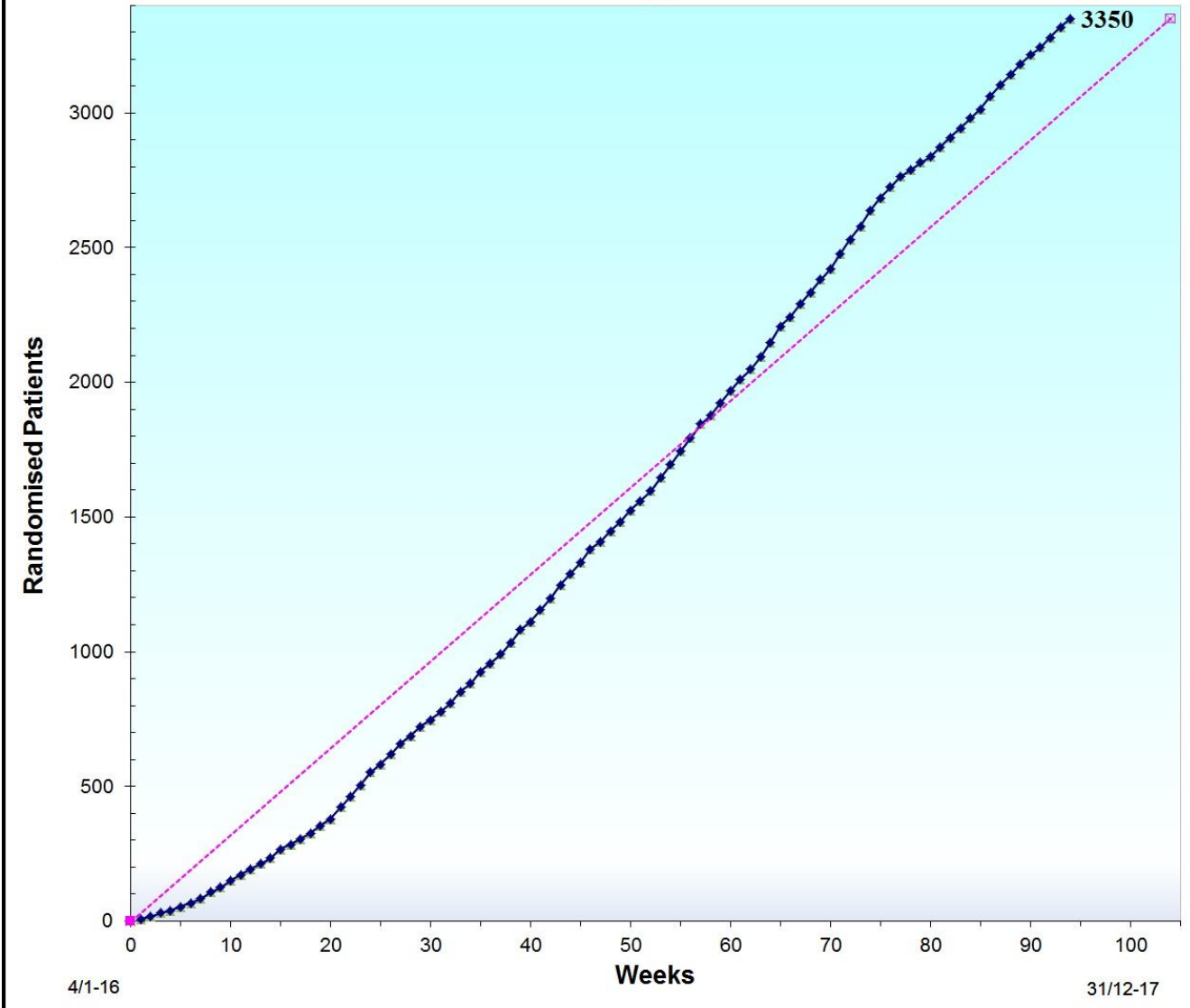
SUP-ICU hotline

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.

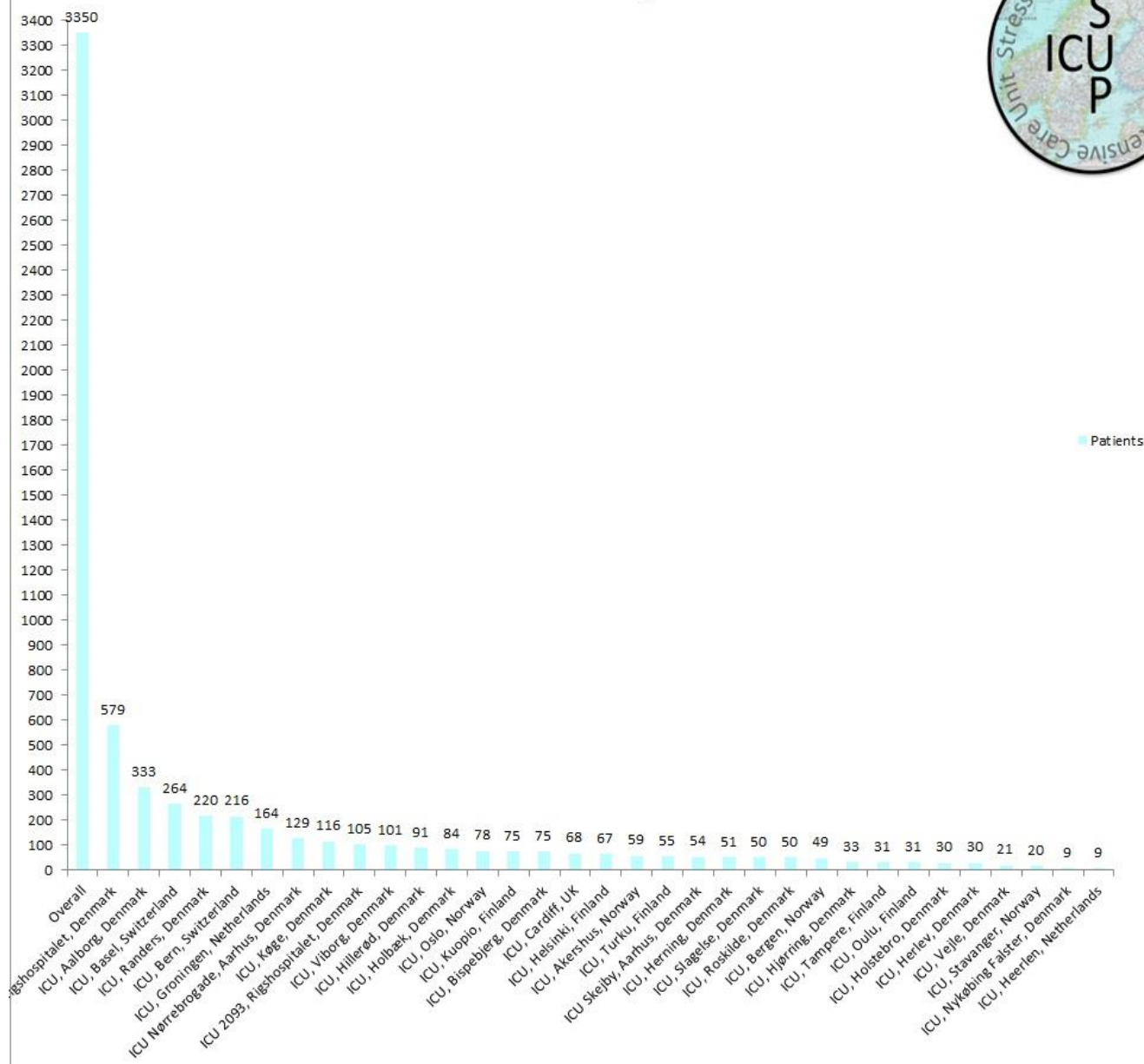
Please continue your great work during the follow-up period!



Actual Goal Actual Goal



**Recruiters overall
October 22, 2017**



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Best regards

Søren, Anders, Carl and Morten