



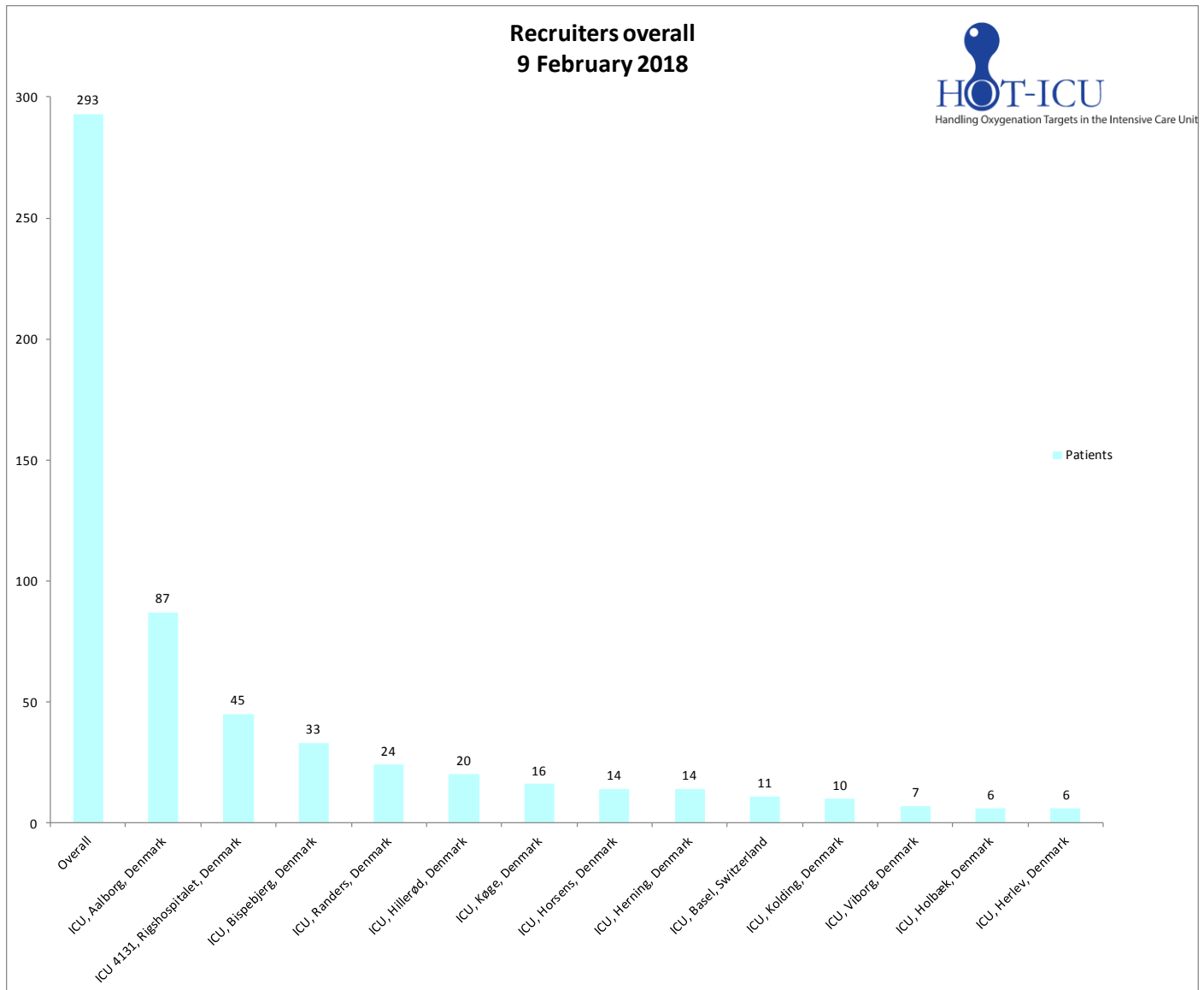
## Place in Site Master File #13f

### HOT-ICU newsletter – February 2018

Thank you very much for your great engagement in the HOT-ICU trial.

#### Status

During January 2018, the ICUs in Holbæk and in Basel has successfully joined the HOT-ICU trial. We welcome both of you.



We are actively recruiting at thirteen sites now and have randomised 293 patients in total. This means that we have passed the **10% mark** of included patients. Several national and international sites are ready to start and we are looking forward to the inclusion of their first patients.

### Top recruiters

Top five recruiters in January were

1. **Bispebjerg (12)**
2. **Hillerød (10)**
3. **Basel (8)**
4. **Aalborg (7)**
5. **Holbæk (6)**

Congratulation to Bispebjerg as the monthly top recruiter and for being the 5<sup>th</sup> overall recruiter after only two and a half month of recruitment at their site. Also congratulations to Holbæk and to Basel for finishing in top five during their first month of trial participation.

### A few things to highlight:

1. A few new options in the eCRF baseline: “estimated” check-boxes in question B19 (*GCS*), question B25 (*urinary output*) and question B30a (*habitual creatinine level*), enabling estimated registrations if there is no specific source data. A new paper-version of the eCRF for the site-master-file is available at the website: <http://www.cric.nu/hot-icu-crf-pdf-format/>
2. We experience a number of major protocol violations. Therefore, we will kindly ask you to ensure that the specific notifications of any “major protocol violations” are handled at your site
3. For Danish sites only: The information materiel “*Forsøgspersoner rettigheder i et sundhedsvidenskabeligt forskningsprojekt*” available on the website (<http://www.cric.nu/forsogspersoners-rettigheder/>) should be distributed to all patients as well as to all next of kin with the informed consent materiel

If you have any questions, do not hesitate to send an e-mail to [hot-icu@cric.nu](mailto:hot-icu@cric.nu) or to contact the HOT-ICU hotline (+45 2118 2543). Please **leave a message and your phone number if the call is not answered** and we will call you back as soon as possible.

Please archive this newsletter in your site master file.

**Best regards,**

**Bodil and Olav**