



Place in Site Master File #13

SUP-ICU Newsletter – January & February 2018



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

Dear Friends

Thanks to your great effort, we are now very close to be able to lock the database (estimated March 16, 2018).

Thank you very much for your support with regards to drug disposal, follow-up and validation of data.

Almost all sites have had close-out monitoring, however a few sites remain.
Please forward all close-out monitoring reports to the coordinating investigator (SM).

After closure of the database, the locked database will be forwarded to the independent and blinded statistician who will conduct the analyses according to the published detailed statistical analysis plan (<https://www.ncbi.nlm.nih.gov/pubmed/28608496>).

We expect to know the SUP-ICU trial main results in April 2018!

We will present the results confidentially to you at an investigator meeting in April/May in Copenhagen (more information will follow).

We expect to submit the main paper to a peer-reviewed journal in April/May.

Please note:

- Additional queries may emerge in the upcoming weeks – we hope you will continue to handle these swiftly
- If you encounter data aspects that need to be corrected – let us know ASAP!

Information intended for Danish trial sites only:

All Danish SUP-ICU sites have been closed and GCP-monitoring finalised.

Below you will find answers to comments in the Danish close-out monitoring reports:

- A site-specific list of all included patients and trial allocation, along with instructions on patient information, will be provided after unblinding and publication of the primary trial results
- Please remember to sign (closing date and signature) the “delegation log”
- Please archive all your trial site GCP reports in your SMF (#15)
- Please archive all extended approvals (attached in one combined file – “Extended Approvals”) (#4)
- Please archive the documentation that the relevant authority (LMST/STPS) has approved that trial allocation information do not need to be added to individual patient charts of Danish SUP-ICU participants (attached) (#16)

If you have any questions please send us an email (soeren.marker.jensen.01@regionh.dk) or contact the SUP-ICU hotline (+45 3545 7450 – daytime only).

Please archive this newsletter in your Site Master File.

Best regards

Søren, Mette, Anders and Morten