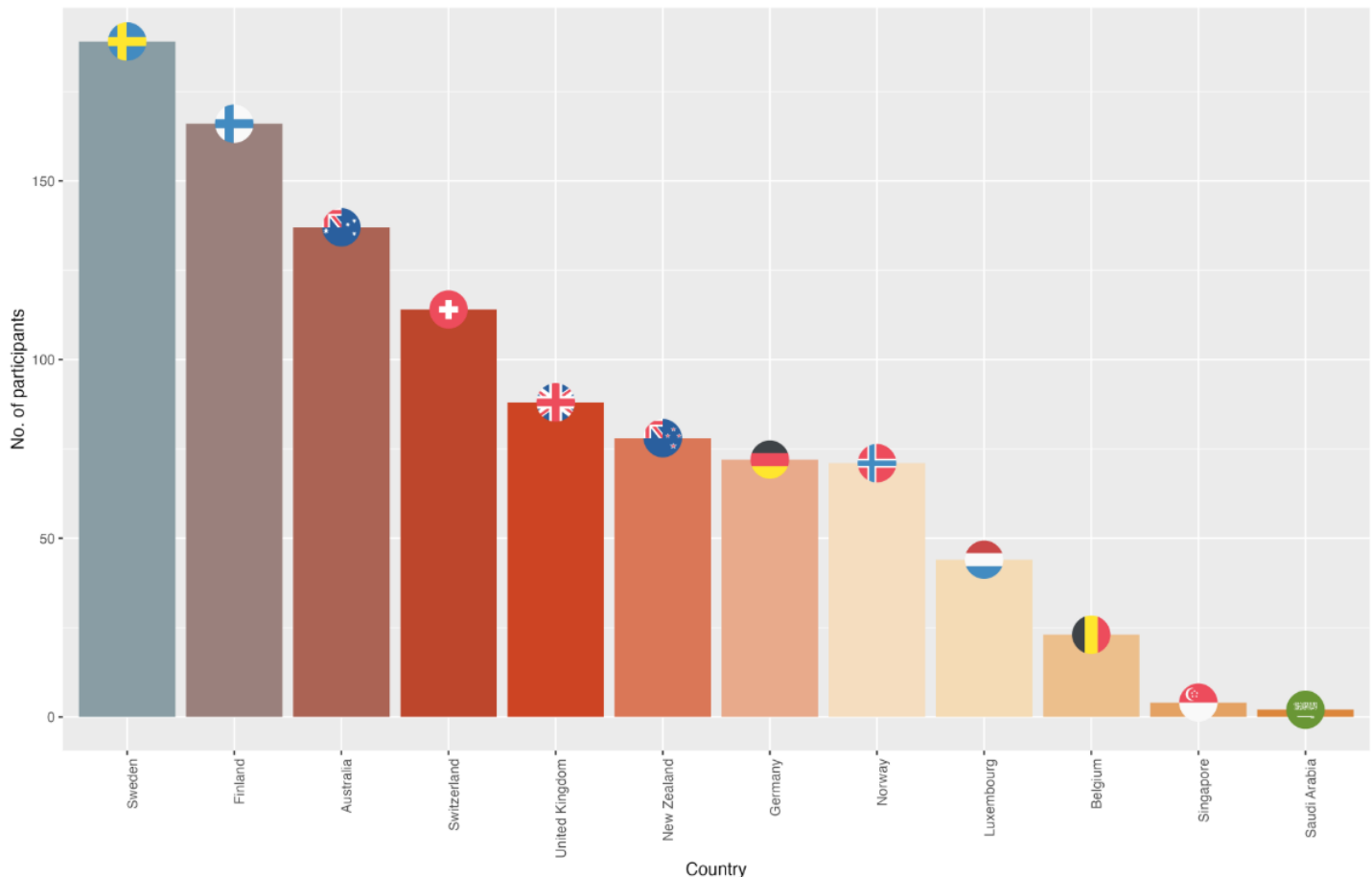




Dear all,

With a great team effort, we enrolled participant 1000 last night! Almost 1/3 done! We encourage every site to keep the momentum and a sharp lookout for every eligible candidate. Recently we received the long-awaited report from the Data Safety Monitoring Committee chaired by Prof Paul Mouncey at ICNARC, London, UK. The DSMC report can be accessed via the [stepcare.org website](https://stepcare.org). The overall message was that STEPCARE trial shall *continue as planned*. There is adequate separation for all interventions, the data is complete, and the recruitment is steady. The next interim will be when 1250 participants have passed 30-day follow-up, which likely will be in February/March 2025. So, we need to keep our data accurate and continue to complete the eCRFs in the same exemplary fashion as we have done so far. Big congratulations to everyone for being part of this important voyage!

### Recruitment by Country



## IMPORTANT UPDATES

### CRF

There continues to be a number of changes and updates to the eCRF. We are constantly working to improving the eCRF. The main updates to the eCRF since the last newsletter in September 2024 are:

- **Summary form:** Site users (generic accounts) can now see the randomization allocation summary page for patients.
- **Hourly observation form:** hour 10 was inadvertently not included in the eCRF therefore this has been added- we apologize in advance if this creates more work for those entering data. 'Not done' box has been added non-core temperature data field and pH, N/A box added to PEEP & tidal volume data fields. Data limits/ranges have been amended for temperature, heart rate and creatinine.
- **Intervention form:** Data limit/range fields have been amended for Paracetamol dosage.
- **Neuroprognostication form;** if cEEG is removed before 24hrs and cEEG reactivity is not assessed a N/A button has been added.
- **6-month form:** Location settings added so only sites participating in the 6 mth extended follow up sub study will see the extended data fields for the 6 months form. Question "on sick leave" added in occupational status question and life satisfaction question added.
- Reports are now able to be downloaded from "Report" tab.
- A large number of bugs fixed to be able to save data on all forms addressed.

There will be one more eCRF sprint released before Christmas this will include, the ROSC data field to be editable, correct bugs and error messages that pop up for some of the Neuroprognostication questions, field logic checks applied to discharge and vital status page e.g if a patient passes away in ICU this information that is entered in discharge form will transfer over to vital status page.

### REMOTE MONITORING

We will soon schedule 30 min to 1 h meetings with each and every site in the trial to go through the logs, recruitment, intervention performance etc. to try to understand if there is anything that needs attention. We will divide this task upon a few members of the management group. Please look out for invitations.

### SUB - STUDIES

We are working on facilitating all sub-studies. Instructions on how to submit sub-studies are on [www.stepcare.org](http://www.stepcare.org). After submission, we aim to handle these within the management group as quickly as possible.

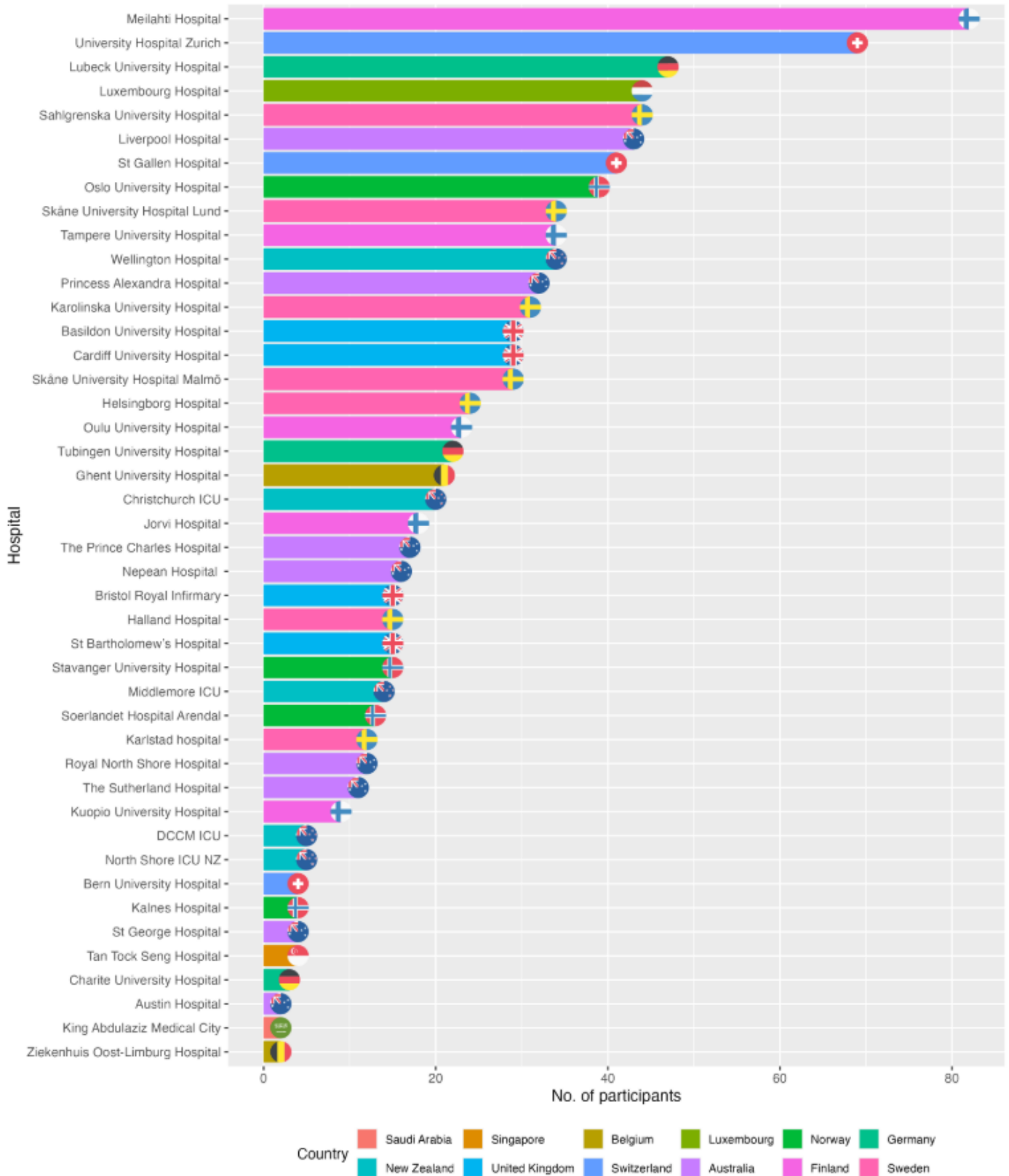
### PROTOCOL MANUSCRIPTS

We have been working on four protocol papers, one for each intervention and one for the statistical analysis. We are very close to sending these out to all authors and aim for submission the peer reviewed journal Acta Anaesthesiologica Scandinavica before Christmas.

### STEP CARE INVESTIGATOR MEETING 2025

An investigator meeting in Helsinki, Finland is being planned to be held on June 16th and 17. The overall meeting will be very similar to the Helsingborg meeting held in 2024. You may need to arrive on Sunday night at the latest in order to be on site in time for the meeting start. Regarding hotel and flight bookings please contact Jenny at [jenny@mkon.se](mailto:jenny@mkon.se) subject heading "STEP CARE Helsinki". Given limited funding we can sponsor the meeting (travel and hotel) for one person per site, unless other agreements have been made.

## Recruitment by Site



We would like to welcome new sites and take the opportunity to thank all of the sites for their hard work and dedication towards STEPCARE. Keep up the amazing work!

Once again, thank you for joining STEPCARE. We hope that a few more sites will be active before Christmas, and then a continuous and gradual increase during the first quarter of 2025. The ambition is that all sites will be up and running before the end of the European summer. We will then have chance to finish the largest cardiac arrest ICU trial ever in mid-2026.

All the best and happy festive season.

The STEPCARE trial management committee.



For more information [stepcare.org](http://stepcare.org)

**The STEPCARE (Sedation, Temperature and Pressure after Cardiac Arrest and RESuscitation) trial**

- We are happy to announce the milestone of reaching 900 inclusions!**  
15 November, 2024
- First randomization at North Shore Hospital, Auckland!**  
4 November, 2024
- A historic first inclusion at King Abdulaziz Hospital, Saudi Arabia. Congratulations!**  
30 October, 2024