

Dear Niklas

22 August 2025

Re: STEPCARE trial, Data Safety Monitoring Board

I write as Chair of the STEPCARE Data Safety Monitoring Board (DSMB). The DSMB met on 28 July 2025 and 13 August 2025 (open session with the trial team), to review progress from the trial alongside the results from the second interim analysis. In attendance, including myself, was Professor Kathy Rowan, Professor David Harrison, Professor Tim Walsh and Professor Joyce Yeung.

Across the two meetings we reviewed the progress of the trial, the completeness of the data, the delivery of the interventions, interim analysis results (from the first 1200 patients recruited) including safety data. There was no additional external evidence to review. As a DSMB, we would like to congratulate the trial team with the progress of the trial.

For the second interim analysis we reviewed: potential interactions between the trials; 6-month mortality (or hospital discharge); functional outcome at 30 days; and serious adverse events. I can confirm that the DSMB recommendation is for STEPCARE to **continue without any changes**.

We would expect the third interim analysis at 2000 patients to be the final of the three interim analyses.

Congratulations again from the DSMB for your fantastic progress made already in the trial. I would be happy either to discuss the above and/or to provide any further information, if useful.

Yours Sincerely



Paul Mouncey
Co-Director, ICNARC