SOP: completion of SafeBoosC-III and submission of manuscript

Version	Author(s)	Date	Changes	Approved by
1.0	Mathias Lühr Hansen	06.09.21	Initial version	Trial Steering Committee
2.0	Marie Isabel Rasmussen	16.12.21	Dates updated based on last randomisations	Mathias Lühr Hansen, Gorm Greisen

1.0 Rationale

SafeBoosC-III is the first sufficiently powered randomised clinical trial to evaluate the clinical effects of cerebral oximetry monitoring in extremely preterm infants. The trial is designed to generate 'real world evidence', i.e. of pragmatic trial design and with global recruitment from more than 70 neonatal intensive care units across 18 countries. Therefore, the trial results may have an immediate effect on clinical practice of extremely preterm infants.

Evidence that is likely to alter clinical practice should be available to peers and the public as soon as possible, but without compromising the quality. To enhance the quality of the trial results, it is important that all possible data entries are completed, that random and systematic errors identified during central data monitoring are handled (and if possible, corrected), and that GCP reports are completed. Until this work is done, statistical analyses cannot be initiated, and the results cannot be made available to the public.

To enhance the process of completing the trial and submitting the manuscript for publication without compromising the quality, we have developed this standard operation procedure (SOP). The aim is to create a simple overview of expected important deadlines and tasks for investigators, so that they can make the necessary preparations in time (e.g. pre-plan the GCP monitoring visits and the periods with extra trial-related workload). The timelines on the next pages provide an overview of the final steps from completion of recruitment and until submission for publication (see figure 1 and 2).

Recruitment was completed on the 16th of December 2021, and therefore the most important deadlines/dates for principal investigators during the spring will be:

1) Deadline for completion of data entries – ***1st of April 20222***
2) Deadline for completion of the last GCP report – ***5th of April 2022***
3) Deadline for completion of inquiries arisen from the last data quality monitoring report – ***15th of April 2022***

A full overview of the completion process, including deadlines, can be found on the next pages.

2.0 Expected timeline for completion of SafeBoosC-III and submission of the manuscript

Figure 1. Expected timeline for completion of SafeBoosC-III from December 2021 to April 2022

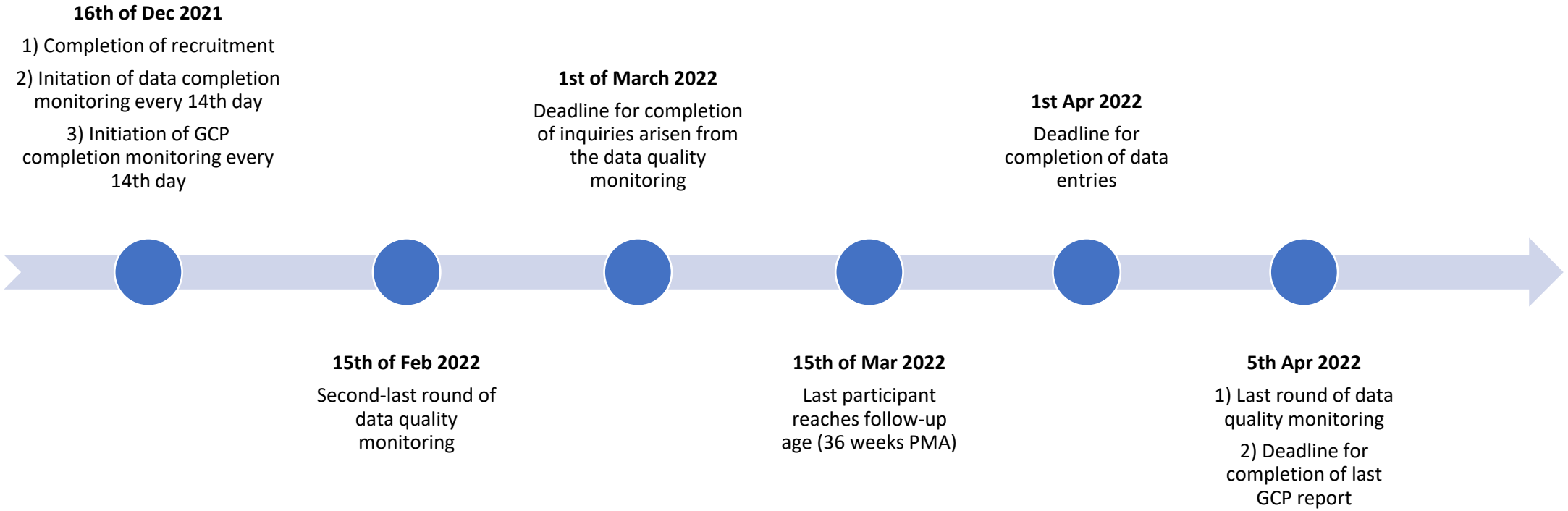

Figure 2. Expected timeline for completion of SafeBoosC-III and submission of manuscript from April to June 2022