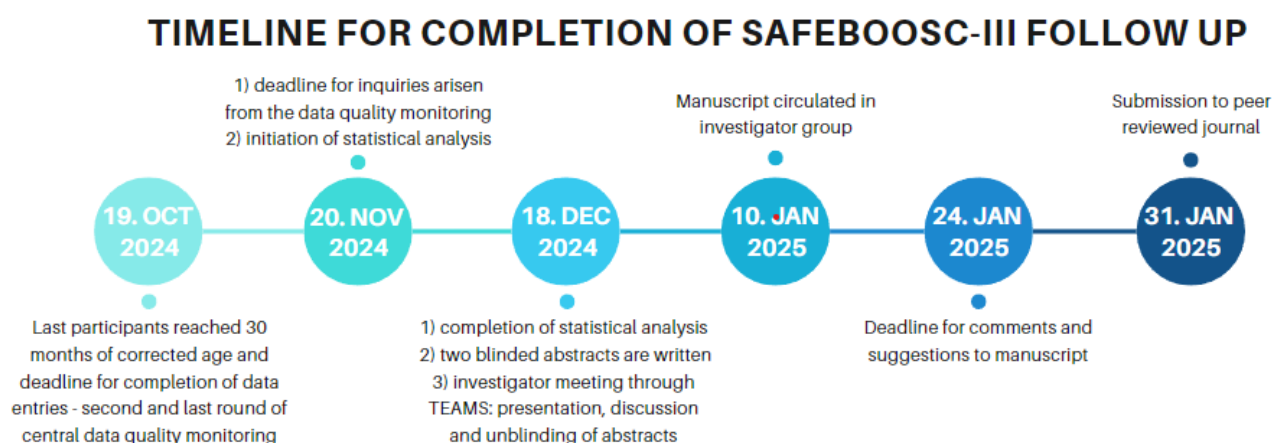


Welcome to the August 2024 issue of the SafeBoosC newsletter

SafeBoosC-III follow-up

We are in the final phase of the study and have a total of 55 sites participating. Out of these, 37 sites have completed data collection. We are working closely with the last sites to maximize data completion. In August, we completed the first round of data quality monitoring, with approximately 200 possible deviations, which has prompted direct contact with sites. We urge investigators to respond to deviations, if they have been contacted by Marie, before the 13th of September. Please see figure 1 for other important dates regarding the completion of the SafeBoosC-III follow up study.

Figure 1: Timeline for completion of the SafeBoosC-III follow up study



After subtraction of excluded and withdrawn sites, a total of 1163 participants are eligible for the follow up study and have reached two years of corrected age. In total, 836 (72%) of these participants have primary outcome data in OpenClinica. A total of 735 (63%) families have completed the parental questionnaire and 107 (9%) are lost to follow up. For the participants having reached 30 months of corrected age, 82% have enough data for the primary outcome. An overview of data completion over time can be found in figure 2 and an overview of sites with missing data can be found in table 1.

Figure 2: Overall data completion in the SafeBoosC-III follow up study.

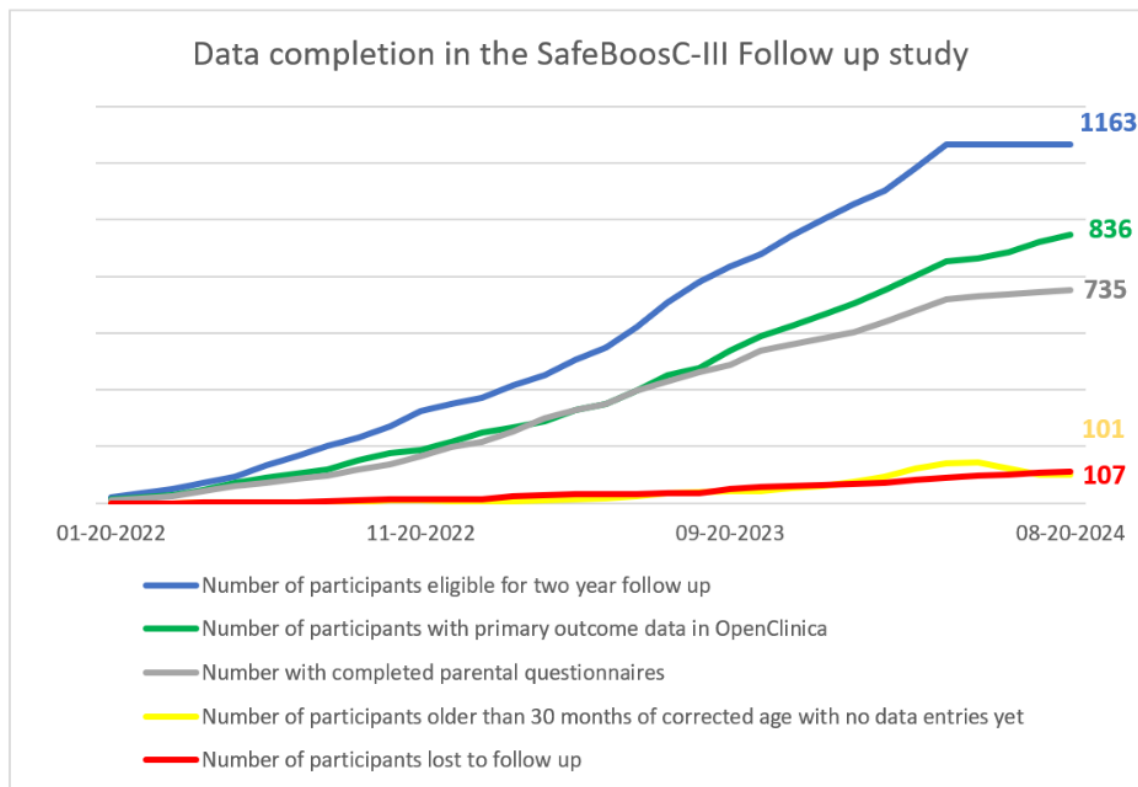


Table 1: Sites with missing data. Number of eligible participants for the two year follow up and number of completed data on 30th of August 2024. Red indicates sites that have not yet started.

Country	Site	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Belgium	Grand Hospital de Charleroi	18	17	16
Belgium	CHU Tivoli	15	4	0
Czech Republic	The Institute for the Care of Mother and Child	60	57	29
Denmark	Rigshospitalet	87	83	47
Germany	Freiburg University Hospital	16	12	5
Greece	University of Patras General Hospital	7	6	2

Country	Site	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Greece	Alexandra Univ. Hospital	15	14	13
Ireland	Rotunda Hospital Dublin	13	0	0
Ireland	NMH Holles St	11	2	4
Italy	Fondazione Policlinico Univ. A. Gemelli, Roma	12 (waiting for ethics approval)		
Norway	Oslo University Hospital	30	16	20
Poland	Szpital Uniwersytecki, Kraków	19	1	0
Poland	Specialist Hospital No. 2 in Bytom	7	3	0
Spain	Hospital Universitarie Puerta del Mar	13	12	11
Spain	Hospital Miguel Servet	1	0	0
United Kingdom	Royal Hospital for Children, Glasgow	15	12	8
United States	University of Utah, Division of Neonatology	26	23	25
United States	Loma Linda University Hospital	28	12	0

SafeBoosC-IIIv

Interest has been shown from sites across six continents. Interested sites are encouraged to reach out to trial manager Caroline (caroline.kamp@ctu.dk).

Thank you for your time,
Marie and Gorm