



SafeBoosC newsletter Nov 2022

Dear investigators

Welcome to the Nov 2022 issue of the SafeBoosC newsletter.

SafeBoosC-III

The manuscript is still under review and the results are still under embargo.

SafeBoosC-III follow-up

So far, 28 centers have participants that have reached two years of corrected age, and 25 centers have started data entries in OpenClinica. Data entry has been completed for a total of 199 participants and 165 families have filled out the parental questionnaire. For an overview of data completion, please see figure 1. For an overview of each centre's data completion please see table 1.

Correction of Bayley scores

We suspected that routine follow up would be done differently across the participating centres. We now discovered that Bayley scores at two years are corrected for preterm birth at some centres but not all. Opinions on whether the Bayley scores should still be corrected as late as two years of age varies amongst experts in the field, and we do not wish to interfere with routine clinical practice. A correction, however, may increase the score by more than 1 SD (ie. over 15 points), so we need to know. Furthermore, we suspect that in some centres, raw scores have been entered into OpenClinica, rather than the composite scores. The raw scores indicate how many items the child has completed, whereas the composite score is calculated from the raw scores and the age of the child (and scaled to a mean of 100 and a SD of 15). The composite scores follow the table of five (ie. 95, 100, 105, 110, 115 etc). Sites who have put in "odd numbers" such as 58, 67, 73 etc. will be contacted directly and asked to correct these scores. The raw scores, however, can by chance also be 55, 60, 75 etc,

We therefore ask PIs/blinded assessors to do the following for all participants who have already been entered into the OpenClinica 2-year follow-up form:

1. **Enter data in a new field:** Go back into the completed forms of all participants who have had Bayley assessments done. Click "administrative edit" and complete the new field "F14d - is this score corrected for prematurity?".
2. **Make sure that it is the Bayley cognitive composite score which is entered in OpenClinica.** If not, please correct it.
3. **Hereafter click on the green button in the bottom "update record"** and the changes will be saved and the form will close.

We apologize for the extra work this may cause you and for not being completely clear from the beginning.



Figure 1: Overall data completion in the SafeBoosC-III follow up study

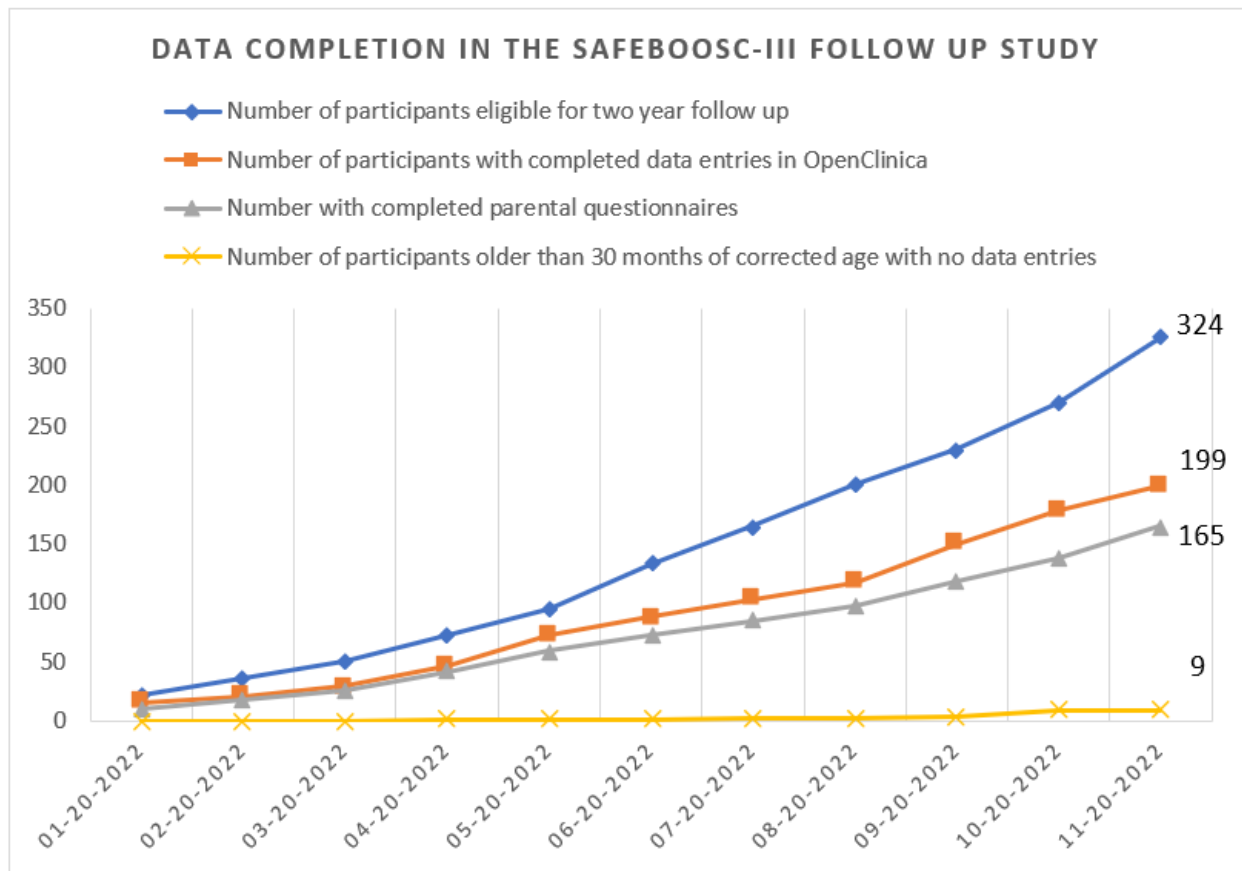


Table 1: Open centres, number of eligible participants for two year follow up and data completion for each centre up until the 28th of Nov 2022. Centres highlighted in green indicate that all three tasks (ethics approval, blinding procedure approval and appointment of blinded assessor) have been completed in order to start the follow up study.

Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Austria	University Hospital Graz	2 (Waiting for ethics)		
Belgium	UZ Leuven	7	3	5
Belgium	Liege Rocourt	Dec 2022		
Belgium	Grand Hospital de Charleroi	1	0	0
Belgium	AZ St. Jan University Hospital Brugge	Feb 2023		
Belgium	CHU Tivoli	Dec 2022		



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Czech Republic	The Institute for the Care of Mother and Child	22	19	11
Czech Republic	Motol University Hospital	May 2023		
China	Children's Hospital of Zhejiang, Hangzhou	May 2023		
China	Children's Hospital of Fudan University, Shanghai	6 (unknown if they will participate due to COVID surge)	0	0
China	Hainan Women and Children's Medical Center	Aug 2023		
China	Guangzhou Women and Children's Medical Center	No data		
China	Longgang District Central Hospital of Shenzhen	(unknown if they will participate due to COVID surge)		
China	The People's Hospital of Dehong	Dec 2022		
China	Guangxi Maternal and Child Healthcare Hospital, Nanning	(unknown if they will participate due to COVID surge)		
China	Xiamen Children's Hospital	Jan 2023		
Denmark	Rigshospitalet	42	33	18
Denmark	Odense University Hospital	2		
Denmark	Aalborg University Hospital	1 (only missing blinding procedure)		
Denmark	Aarhus University Hospital	1 (only missing blinding procedure)		
Germany	Freiburg University Hospital	Nov 2022 (missing blinding procedure and assessor)		
Greece	Ippokrateion General Hospital of Thessaloniki	10	7	3



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Greece	University of Patras General Hospital	4	2	1
Greece	Alexandra Univ. Hospital	5	0	0
Greece	University Hospital of Heraklion	4	1	1
India	St Johns Medical College Hospital, Bangalore	Dec 2022		
Ireland	University Hospital Cork	May 2023		
Ireland	Rotunda Hospital Dublin	Aug 2023		
Ireland	NMH Holles St	Aug 2023		
Ireland	Coombe Univ. Hospital	Sep 2023		
Italy	Fondazione IRCCS Cà Granda Ospedale, Milano	12	12	7
Italy	Presidio Ospedaliero S. Anna, Turin	Feb 2023		
Italy	Ospedale Fillipo del Ponte, Varese	Apr 2023		
Italy	Fondazione Policlinico Univ. A. Gemelli, Roma	May 2023		
Norway	Oslo University Hospital	July 2023		
Poland	Medical Center UJASTEK, Krakow	7	Clinical data not available	6
Poland	Szpital Uniwersytecki, Kraków	Mar 2023		
Poland	Warsaw University of Medical Sciences	Feb 2023		
Poland	Poznan University of Medical Sciences	7	Clinical data not available	6
Poland	Specialist Hospital No. 2 in Bytom	2 (missing blinded assessor)		
Poland	Wroclaw Medical University	Oct 2023		



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Poland	Jan Biziel University Hospital	Dec 2023		
Poland	Centre of Medical Postgraduate Education, Warsaw	July 2023		
Spain	H. Univ. Juan XXIII de Tarragona Hospital	5 (unknown if will participate)	0	0
Spain	La Paz University Hospital	27	16	10
Spain	Hospital Clinic de Barcelona	27	20	19
Spain	University Hospital 12 de Octubre	23	22	10
Spain	Hospital de Sant Joan de Deu	12	12	6
Spain	Hospital Clinico San Carlos	9	9	9
Spain	Hospital Universitarie Puerta del Mar	7	6	5
Spain	H. Universitario Marqués de Valdecilla	5	0	0
Spain	H. U. Virgen de las Nieves, Granada	3 (unknown if will participate)	0	0
Spain	Hospital Miguel Servet	Dec 2023		
Spain	Hospital de Cruces	June 2023		
Switzerland	Zürich University Hospital	11	4	6
Switzerland	Luzerner Kantonsspital	8	7	6
Switzerland	Geneva University Hospital	4		
Switzerland	Lausanne University Hospital	Feb 2023		
Turkey	Gazi University Hospital	1	1	1
Turkey	Marmara University Hospital	7	4	6



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Turkey	Uludag University Hospital	7	6	5
Turkey	Kanuni Sultan University Hospital	8	8	6
Turkey	Bilkent Integrated Health Care Campus	10	6	0
Turkey	Basaksehir City Hospital	Apr 2023		
United Kingdom	Royal Hospital for Children, Glasgow	June 2023		
United Kingdom	NHS Lanarkshire Hospital, Wishaw	June 2023		
United States	University of Utah, Division of Neonatology	Jan 2023		
United States	Loma Linda University Hospital	Nov 2022 (working on ethics)		
United States	UT Southwestern Medical Center, Dallas	May 2023		
United States	Washington Univ. Hospital	Sep 2023		

SafeBoosC-IIIv

On the 1st of December we unfortunately received the message that we did not get the funding from the Novo Nordisk Foundation. We will evaluate on this and soon return with a plan regarding the future of the SafeBoosC-IIIv. The protocol paper was briefly discussed at the last steering committee meeting and the work to finalize this for submission for publication continues.

Thank you for your time,
Gorm, Marie, Maria and Mathias