



SafeBoosC newsletter Dec 2022

Dear investigators

Welcome to the Dec 2022 issue of the SafeBoosC newsletter.

SafeBoosC-III

The results of the SafeBoosC-III trial were presented at the Hot Topics conference in Washington DC, USA in December. The manuscript is still under review and the results are still under embargo.

SafeBoosC-III follow-up

So far, 41 centers have participants that have reached two years of corrected age, and 31 centers have started data entries in OpenClinica. Data entry has been completed for a total of 217 participants and 198 families have filled out the parental questionnaire. Two centers in Poland do not have routine follow up of trial participants but are instead rigorously focusing on collecting parental questionnaires. This is a pragmatic solution to still collect data for the co-primary outcome moderate-to-severe neurodevelopmental disability, without losing power. For an overview of data completion, please see figure 1. For an overview of each centre's data completion see table 1.

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

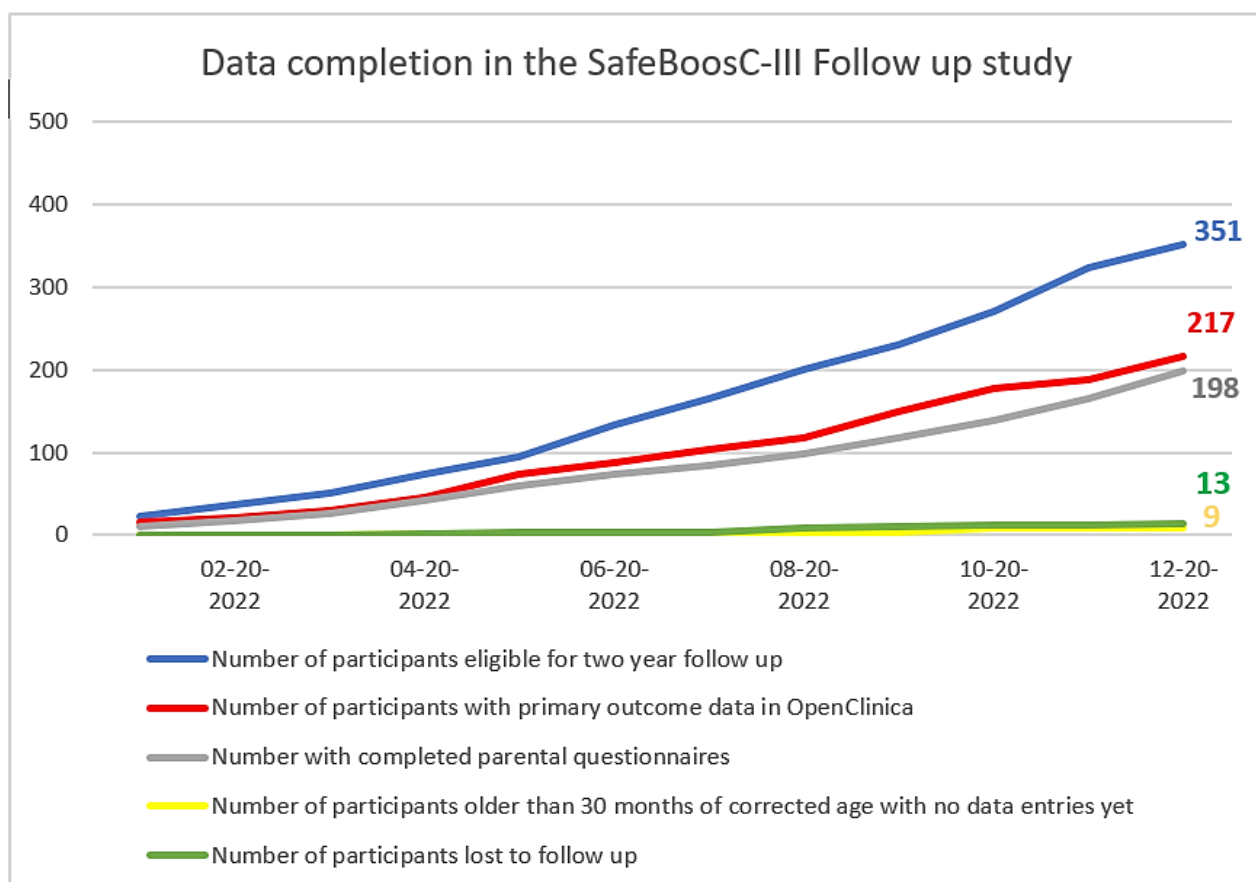




Table 1: Open centres, number of eligible participants for two year follow up and data completion for each centre up until the 30th of Dec 2022. Centres highlighted in green indicate that all three tasks (ethics approval, blinding procedure approval and appointment of blinded assessor) have been completed 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	0	0
Belgium	UZ Leuven	9	6	6
Belgium	Liege Rocourt	1		
Belgium	Grand Hospital de Charleroi	1	0	0
Belgium	AZ St. Jan University Hospital Brugge	Feb 2023		
Belgium	CHU Tivoli	Dec 2022 (missing blinded assessor)		
Czech Republic	The Institute for the Care of Mother and Child	26	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	1 (unknown if they will participate due to COVID surge)		
China	The People's Hospital of Dehong	1 (unknown if they will participate due to COVID surge)		



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
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	46	33	18
Denmark	Odense University Hospital	2	0	1
Denmark	Aalborg University Hospital	2	1	0
Denmark	Aarhus University Hospital	2	0	0
Germany	Freiburg University Hospital	Nov 2022 (missing blinding procedure and assessor)		
Greece	Ippokrateion General Hospital of Thessaloniki	10	7	3
Greece	University of Patras General Hospital	4	2	1
Greece	Alexandra Univ. Hospital	7	1	0
Greece	University Hospital of Heraklion	4	3	2
India	St Johns Medical College Hospital, Bangalore	1	1	1
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	11	11	6
Italy	Presidio Ospedaliero S. Anna, Turin	Feb 2023		



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
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	9	Clinical data not available	7
Poland	Specialist Hospital No. 2 in Bytom	2	0	0
Poland	Wroclaw Medical University	Oct 2023		
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	33	21	19
Spain	Hospital Clinic de Barcelona	27	21	21
Spain	University Hospital 12 de Octubre	25	23	11
Spain	Hospital de Sant Joan de Deu	13	12	6
Spain	Hospital Clinico San Carlos	11	10	10
Spain	Hospital Universitarie Puerta del Mar	7	6	5



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
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	15	4	7
Switzerland	Luzerner Kantonsspital	11	10	7
Switzerland	Geneva University Hospital	4	0	2
Switzerland	Lausanne University Hospital	Feb 2023		
Turkey	Gazi University Hospital	1	1	1
Turkey	Marmara University Hospital	8	5	6
Turkey	Uludag University Hospital	8	6	5
Turkey	Kanuni Sultan University Hospital	8	8	6
Turkey	Bilkent Integrated Health Care Campus	12	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. Maria is now on maternity leave and we will evaluate on the future of the SafeBoosC-IIIv trial in the near future. The work with the protocol paper continues.

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