



SafeBoosC newsletter April 2023

Dear investigators

Welcome to the April 2023 issue of the SafeBoosC newsletter.

SafeBoosC-III

We are happy to announce that the SafeBoosC-III trial results was published in New England Journal of Medicine on the 20th of April (<https://www.nejm.org/doi/full/10.1056/NEJMoa2207554>), and we are looking much forward to see how the results will be received and interpreted during the next months.

SafeBoosC-III follow-up

The follow up protocol manuscript has been submitted for publication. So far, 46 centers have participants that have reached two years of corrected age, and 38 centers have started data entries in OpenClinica. Data entry has been completed for a total of 330 participants and 329 families have filled out the parental questionnaire. In total, there are 398 out of 507 participants with primary outcome data, accounting for both OpenClinica data entries and parental questionnaires. We have added a new field in the parental questionnaire, where it is possible to fill in another date, if the questionnaire has been filled out previously, for example in the outpatient clinic. 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

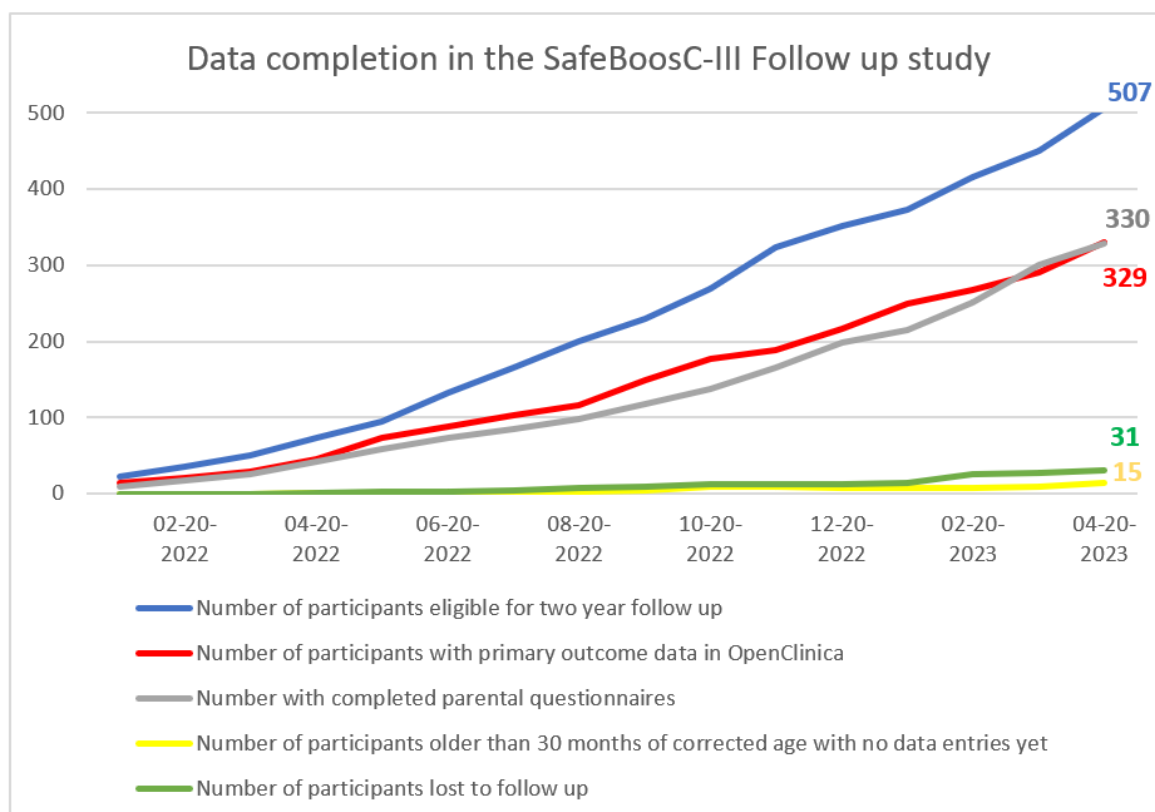




Table 1: Open centres, number of eligible participants for two year follow up and data completion for each centre up until the 30th of April 2023. Centres highlighted in green indicate that all three tasks (ethics approval, blinding procedure approval and appointment of blinded assessor) have been completed 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	7	4	3
Belgium	UZ Leuven	19	7	9
Belgium	Liege Rocourt	6	1	2
Belgium	Grand Hospital de Charleroi	5	0	4
Belgium	AZ St. Jan University Hospital Brugge	6	0	0
Belgium	CHU Tivoli	Dec 2022 (missing blinded assessor)		
Czech Republic	The Institute for the Care of Mother and Child	32	26	22
Czech Republic	Motol University Hospital	May 2023		
China	Children's Hospital of Zhejiang, Hangzhou	May 2023		
China	Children's Hospital of Fudan University, Shanghai	(unknown if they will participate due to COVID surge)		
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	(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	(unknown if they will participate due to COVID surge)		
Denmark	Rigshospitalet	50	38	27
Denmark	Odense University Hospital	5	0	1
Denmark	Aalborg University Hospital	6	1	3
Denmark	Aarhus University Hospital	8	5	6
Germany	Freiburg University Hospital	6	2	2
Greece	Ippokrateion General Hospital of Thessaloniki	13	11	6
Greece	University of Patras General Hospital	5	2	1
Greece	Alexandra Univ. Hospital	10	7	9
Greece	University Hospital of Heraklion	8	4	3
India	St Johns Medical College Hospital, Bangalore	2	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	20	18	14
Italy	Presidio Ospedaliero S. Anna, Turin	Feb 2023 (missing ethics approval)		



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	20	Clinical data not available	17
Poland	Szpital Uniwersytecki, Kraków	Mar 2023 (missing blinding procedure and assessor)		
Poland	Warsaw University of Medical Sciences	Feb 2023 (missing blinded procedure and assessor)		
Poland	Poznan University of Medical Sciences	21	Clinical data not available	17
Poland	Specialist Hospital No. 2 in Bytom	4	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	excluded		
Spain	La Paz University Hospital	46	35	37
Spain	Hospital Clinic de Barcelona	33	26	26
Spain	University Hospital 12 de Octubre	30	26	14
Spain	Hospital de Sant Joan de Deu	15	15	12
Spain	Hospital Clinico San Carlos	16	13	13
Spain	Hospital Universitarie Puerta del Mar	10	8	5



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Spain	H. Universitario Marqués de Valdecilla	9	0	1
Spain	H. U. Virgen de las Nieves, Granada	excluded		
Spain	Hospital Miguel Servet	Dec 2023		
Spain	Hospital de Cruces	June 2023		
Switzerland	Zürich University Hospital	24	11	18
Switzerland	Luzerner Kantonsspital	20	15	9
Switzerland	Geneva University Hospital	6	5	5
Switzerland	Lausanne University Hospital	8	4	4
Turkey	Gazi University Hospital	2	1	1
Turkey	Marmara University Hospital	11	10	7
Turkey	Uludag University Hospital	10	10	8
Turkey	Kanuni Sultan University Hospital	8	8	6
Turkey	Bilkent Integrated Health Care Campus	13	7	7
Turkey	Basaksehir City Hospital	1	0	0
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	10	5	4
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

The protocol manuscript is being finalised for publication. During summer, there will be a steering committee meeting where we will discuss the future of the trial.

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