



SafeBoosC newsletter September 2022

Dear investigators

Welcome to the Sep 2022 issue of the SafeBoosC newsletter.

EAPS conference in Barcelona

Gorm, Maria and Marie will be attending the EAPS conference in Barcelona from Friday the 7th of October to Tuesday the 11th of October. Gorm will present the results of the primary outcome for the SafeBoosC-III trial for the first time in public at 13:30 on Sunday the 9th of October in the Short Oral Session: Late Breaking, Hall 113. Maria will present the study “Alternative consent methods used in the SafeBoosC-III trial” at 16:00 on Saturday the 8th of October in the Interdisciplinary Session 01, Hall 117. If any of you wish to meet and talk about the SafeBoosC-III follow up study or the SafeBoosC-IIIv trial, please let us know. We look forward to seeing some of you there!

SafeBoosC-III follow-up

So far, 28 centers have participants that have reached two years of corrected age, and 24 centers have started completing data entries in OpenClinica. A total of 150 participants have completed follow up forms in OpenClinica and 118 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 figure 2.

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

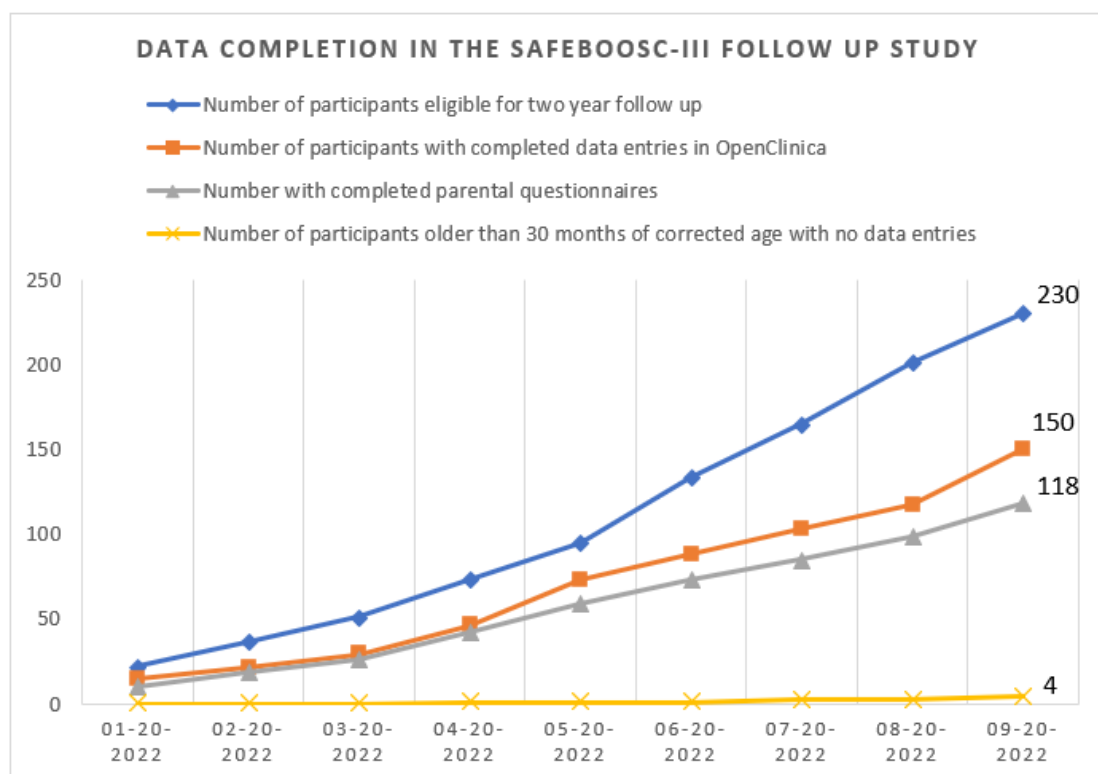




Figure 2: Open centres, number of eligible participants for two year follow up and data completion for each centre up until the 27th of Sep 2022. Centres highlighted in green indicate that all three tasks (ethics approval, blinding procedure approval and appointment of blinded assessor) have been completed 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	Nov 2022		
Belgium	UZ Leuven	Oct 2022		
Belgium	Liege Rocourt	Dec 2022		
Belgium	Grand Hospital de Charleroi	Nov 2022		
Belgium	AZ St. Jan University Hospital Brugge	Feb 2023		
Belgium	CHU Tivoli	Sep 2022		
Czech Republic	The Institute for the Care of Mother and Child	18	15	10
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	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	Nov 2022		
China	The People's Hospital of Dehong	Dec 2022		
China	Guangxi Maternal and Child	Nov 2022		



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
	Healthcare Hospital, Nanning			
China	Xiamen Children's Hospital	Jan 2023		
Denmark	Rigshospitalet	37	25	15
Denmark	Odense University Hospital	2		
Denmark	Aalborg University Hospital	Oct 2022		
Denmark	Aarhus University Hospital	Oct 2022		
Germany	Freiburg University Hospital	Nov 2022		
Greece	Ippokrateion General Hospital of Thessaloniki	7	4	3
Greece	University of Patras General Hospital	1	0	0
Greece	Alexandra Univ. Hospital	3	0	0
Greece	University Hospital of Heraklion	2	0	0
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	11	11	4
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		



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Norway	Oslo University Hospital	July 2023		
Poland	Medical Center UJASTEK, Krakow	6	Clinical data not available	3
Poland	Szpital Uniwersytecki, Kraków	Mar 2023		
Poland	Warsaw University of Medical Sciences	Feb 2023		
Poland	Poznan University of Medical Sciences	5	Clinical data not available	3
Poland	Specialist Hospital No. 2 in Bytom	2		
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	0	0
Spain	La Paz University Hospital	22	16	10
Spain	Hospital Clinic de Barcelona	20	17	17
Spain	University Hospital 12 de Octubre	21	18	10
Spain	Hospital de Sant Joan de Deu	8	8	3
Spain	Hospital Clinico San Carlos	8	6	8
Spain	Hospital Universitaria Puerta del Mar	7	4	5
Spain	H. Universitario Marqués de Valdecilla	1	0	0
Spain	H. U. Virgen de las Nieves, Granada	3	0	0
Spain	Hospital Miguel Servet	Dec 2023		



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Spain	Hospital de Cruces	June 2023		
Switzerland	Zürich University Hospital	8	4	4
Switzerland	Luzerner Kantonsspital	7	7	2
Switzerland	Geneva University Hospital	2		
Switzerland	Lausanne University Hospital	Feb 2023		
Turkey	Gazi University Hospital	1	1	1
Turkey	Marmara University Hospital	6	1	3
Turkey	Uludag University Hospital	3	3	0
Turkey	Kanuni Sultan University Hospital	8	8	6
Turkey	Bilkent Integrated Health Care Campus	5	1	4
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		
United States	UT Southwestern Medical Center, Dallas	May 2023		
United States	Washington Univ. Hospital	Sep 2023		



SafeBoosC-IIIv

We have applied to the Novo Nordisk Foundation to cover central costs of the trial and expect a decision in December 2022. We are working on the design article. The next step will be signing contracts with participating departments. If anyone is interested in joining the trial, please contact maria.linander.vestager@regionh.dk

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