



SafeBoosC newsletter July 2022

Dear investigators

Welcome to the July 2022 issue of the SafeBoosC newsletter.

SafeBoosC-III

In June, the SafeBoosC-III manuscript was submitted to The New England Journal of Medicine and we are still awaiting a decision regarding a potential revision. Information on a potential revision progress will be sent separately to co-authors of the manuscript.

SafeBoosC-III Follow-up

Seventeen centres have participants that have reached two years of corrected age, and fifteen centres have started completing data entries in OpenClinica. A total of 103 participants have been followed up and 85 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

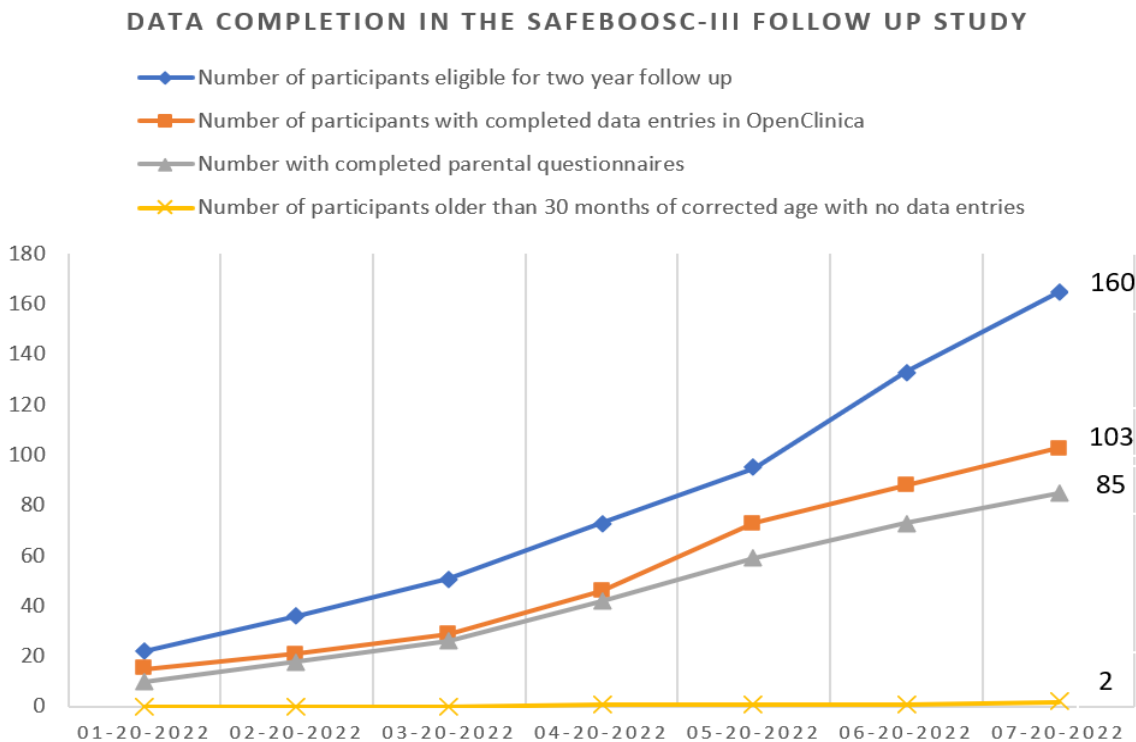


Figure 2: Open centres, number of eligible participants for two year follow up and data completion for each centre up until the 1st of August 2022. Centres highlighted in green indicate that all three tasks (ethics approval, blinding procedure approval and appointment of blinded assessor) have been completed 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	11	11	6
Czech Republic	Motol University Hospital	May 2023		
China	Children's Hospital of Zhejiang, Hangzhou	May 2023		
China	Children's Hospital of Fudan University, Shanghai	1	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 Healthcare Hospital, Nanning	Nov 2022		
China	Xiamen Children's Hospital	Jan 2023		
Denmark	Rigshospitalet	31	18	14
Denmark	Odense University Hospital	Aug 2022		



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Denmark	Aalborg University Hospital	Oct 2022		
Denmark	Aarhus University Hospital	Oct 2022		
Germany	Freiburg University Hospital	Nov 2022		
Greece	Ippokrateion General Hospital of Thessaloniki	4	4	2
Greece	University of Patras General Hospital	1	0	0
Greece	Alexandra Univ. Hospital	July 2022		
Greece	University Hospital of Heraklion	Sep 2022		
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	7	6	3
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	3	0	0
Poland	Szpital Uniwersytecki, Kraków	Mar 2023		



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Poland	Warsaw University of Medical Sciences	Feb 2023		
Poland	Poznan University of Medical Sciences	4	0	2
Poland	Specialist Hospital No. 2 in Bytow	Sep 2022		
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	1	0	0
Spain	La Paz University Hospital	19	15	9
Spain	Hospital Clinic de Barcelona	16	10	10
Spain	University Hospital 12 de Octubre	19	18	9
Spain	Hospital de Sant Joan de Deu	8	6	2
Spain	Hospital Clinico San Carlos	6	3	5
Spain	Hospital Universitarie Puerta del Mar	5	4	3
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		
Spain	Hospital de Cruces	June 2023		
Switzerland	Zürich University Hospital	6	0	0
Switzerland	Luzerner Kantonsspital	4	4	1



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Switzerland	Geneva University Hospital	Sep 2022		
Switzerland	Lausanne University Hospital	Feb 2023		
Turkey	Gazi University Hospital	1	1	1
Turkey	Marmara University Hospital	5	1	1
Turkey	Uludag University Hospital	Aug 2022		
Turkey	Kanuni Sultan University Hospital	5	0	
Turkey	Bilkent Integrated Health Care Campus	3	0	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		
United States	UT Southwestern Medical Center, Dallas	May 2023		
United States	Washington Univ. Hospital	Sep 2023		

CogniTOT ancillary study

So far, 10 centres across eight countries will participate in the ancillary study which we have planned together with Professor Deirdre Murray from Cork, Ireland. This ancillary study will test a touchscreen application called CogniTOT to detect developmental delay in young children. It is a non-verbal, tablet-based test requiring minimal training of the assessor

The study requires one person (or more) from your center to be trained in one online session with the study psychologist. Training cost for each site are 200 euro +VAT per session (non-profit). Liltoda will provide the software and support free of charge. Please let Marie know if your center is interested in participating.



SafeBoosC-IIIv

We received approval of the trial protocol from the Danish Ethics Committee 8th of July. We are working on the design article, which we plan to submit in the fall.

Unfortunately, we received a rejection from the Innovation Foundation. We will submit a new application for the Novo Nordisk Foundation mid-August with a decision in December. If funding is granted, we hope to start the trial in the beginning of 2023.

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