



SafeBoosC newsletter August 2023

Dear investigators

Welcome to the August 2023 issue of the SafeBoosC newsletter.

Joint European Neonatal Society (jENS) conference in September, Rome

Mathias, Marie and Gorm will be present at the jENS conference held in Rome from the 20th to 23rd of September. If you wish to meet up with any one of us, please do not hesitate to reach out. The SafeBoosC-III results will be presented in the Thursday the 21st at 11:30 during the Parallel Session 15: *CIRCULATION 2 - Time to integrate NIRS in neonatal care?*

CogniTOT

We would like to once again invite you to participate in the ancillary study CogniTOT, having made some revision to the study which hopefully makes it more attractive to your centre to participate.

CogniTOT is a touchscreen application that can detect developmental delay in young children. It is a non-verbal, tablet-based test requiring minimal training of the assessor and has been validated in children from multilingual homes.

It has been tested in multiple cohorts, but never in a multinational setting as the SafeBoosC-III follow up study.

We have revised the study a bit to now include:

- Possibility of remote assessment meaning that if the families have a tablet, the test can be administered at home while an assessor is looking through a Zoom/Teams call.
- Possibility of assessing all children, regardless of age, meaning that if children are older than 24 months of corrected age, it is now possible to include these as well.

Up to 15 centers are participating from the SafeBoosC-III follow up study. It has posed a challenge to reach the goal sample size, as only 25 children have been assessed. We therefore hope more centers/already participating centers will want to contribute during this last phase of the study.

Please reach out to Marie if you are interested in participating.

SafeBoosC-III follow-up

So far, 48 of 60 sites with eligible children are open for follow-up and 42 have entered data in OpenClinica. A total of 780 eligible infants have reached two years of corrected age. Of these, 475 (61%) infants have completed data entries in OpenClinica so far. In total, 461 (59%) participants/families have completed the parental. For the participants having reached 30 months of corrected age, 81% have enough data for the primary outcome. 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

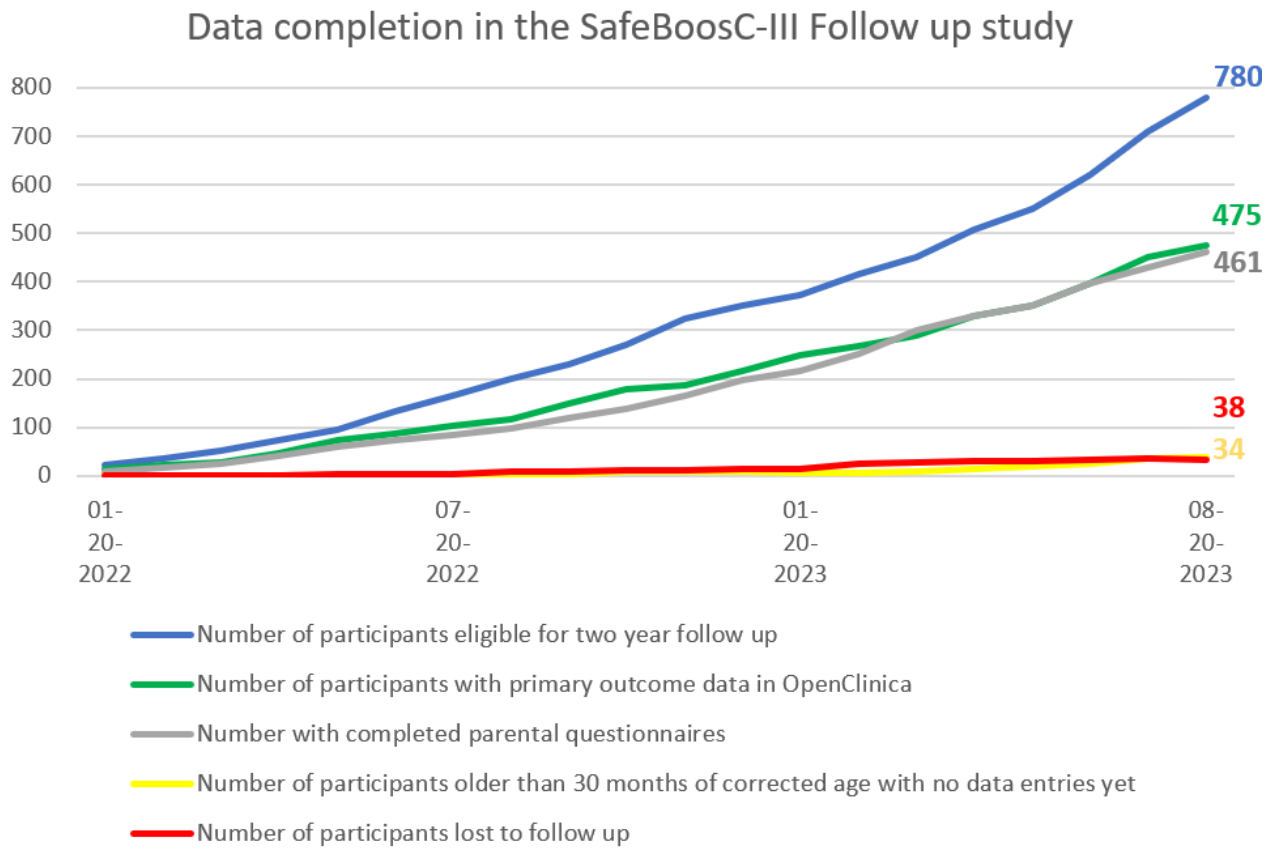


Table 1: Open centres, number of eligible participants for two year follow up and data completion for each centre up until the 26th of July 2023. Centres highlighted in green indicate that all three tasks (ethics approval, blinding procedure approval and appointment of blinded assessor) have been completed 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	10	6	5
Belgium	UZ Leuven	23	23	18
Belgium	Liege Rocourt	15	9	7
Belgium	Grand Hospital de Charleroi	6	5	5
Belgium	AZ St. Jan University Hospital Brugge	8	6	6
Belgium	CHU Tivoli	Dec 2022 (missing blinded assessor)		



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	46	35	23
Czech Republic	Motol University Hospital	May 2023 (missing ethics approval)		
China	Children's Hospital of Zhejiang, Hangzhou	(unknown if they will participate due to COVID surge)		
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)		
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	64	49	33
Denmark	Odense University Hospital	6	3	1
Denmark	Aalborg University Hospital	12	1	6
Denmark	Aarhus University Hospital	11	11	7
Germany	Freiburg University Hospital	9	5	3



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Greece	Ippokrateion General Hospital of Thessaloniki	18	13	6
Greece	University of Patras General Hospital	5	5	2
Greece	Alexandra Univ. Hospital	12	10	10
Greece	University Hospital of Heraklion	8	6	6
India	St Johns Medical College Hospital, Bangalore	2	2	2
Ireland	University Hospital Cork	May 2023 (missing all three prep tasks)		
Ireland	Rotunda Hospital Dublin	Aug 2023		
Ireland	NMH Holles St	1	0	0
Ireland	Coombe Univ. Hospital	Sep 2023		
Italy	Fondazione IRCCS Cà Granda Ospedale, Milano	24	23	20
Italy	Presidio Ospedaliero S. Anna, Turin	3	1	1
Italy	Ospedale Fillipo del Ponte, Varese	Apr 2023 (missing all three prep tasks)		
Italy	Fondazione Policlinico Univ. A. Gemelli, Roma	May 2023 (missing all three prep tasks)		
Norway	Oslo University Hospital	July 2023		
Poland	Medical Center UJASTEK, Krakow	28	Clinical data not available	19
Poland	Szpital Uniwersytecki, Kraków	Mar 2023 (missing blinding procedure and assessor)		
Poland	Warsaw University of Medical Sciences	8	8	8
Poland	Poznan University of Medical Sciences	25	Clinical data not available	23



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Poland	Specialist Hospital No. 2 in Bytom	6	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	54	48	43
Spain	Hospital Clinic de Barcelona	40	33	28
Spain	University Hospital 12 de Octubre	41	26	14
Spain	Hospital de Sant Joan de Deu	17	15	14
Spain	Hospital Clinico San Carlos	20	18	18
Spain	Hospital Universitarie Puerta del Mar	11	10	7
Spain	H. Universitario Marqués de Valdecilla	11	0	6
Spain	H. U. Virgen de las Nieves, Granada	excluded		
Spain	Hospital Miguel Servet	Dec 2023		
Spain	Hospital de Cruces	June 2023 (missing all three prep tasks)		
Switzerland	Zürich University Hospital	33	17	23
Switzerland	Luzerner Kantonsspital	25	15	14
Switzerland	Geneva University Hospital	6	6	5
Switzerland	Lausanne University Hospital	14	12	12



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Turkey	Gazi University Hospital	5	3	3
Turkey	Marmara University Hospital	21	14	14
Turkey	Uludag University Hospital	13	13	10
Turkey	Kanuni Sultan University Hospital	8	8	6
Turkey	Bilkent Integrated Health Care Campus	17	11	7
Turkey	Basaksehir City Hospital	9	9	5
United Kingdom	Royal Hospital for Children, Glasgow	June 2023 (missing all three prep tasks)		
United Kingdom	NHS Lanarkshire Hospital, Wishaw	June 2023 (missing all three prep tasks)		
United States	University of Utah, Division of Neonatology	13	7	8
United States	Loma Linda University Hospital	19	2	0
United States	UT Southwestern Medical Center, Dallas	2	1	0
United States	Washington Univ. Hospital	Sep 2023		

Thank you for your time,

Marie, Maria, Mathias and Gorm