



SafeBoosC newsletter June 2023

Dear investigators

Welcome to the June 2023 issue of the SafeBoosC newsletter.

SafeBoosC-IIIv

Janus Jacobsen, CTU has submitted an application for the SafeBoosC-IIIv trial to the Independent Fund Denmark.

SafeBoosC-III follow-up

So far, 45 of 53 sites with eligible children are open for follow-up and 38 have entered data in OpenClinica. A total of 625 infants have reached two years of corrected age. Of these, 396 (63%) infants have completed data entries in OpenClinica so far. In total, 397 (63%) participants/families have completed the parental questionnaires and 477 (76%) 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

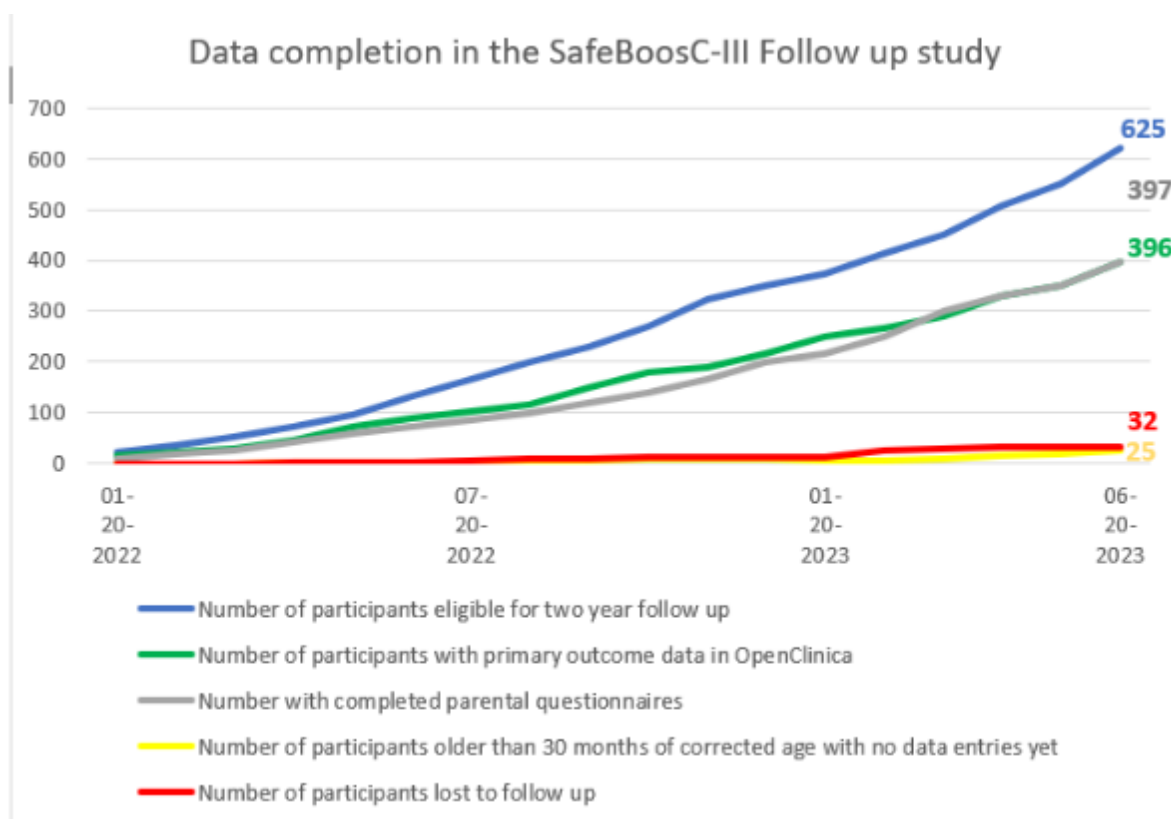


Table 1: Open centres, number of eligible participants for two year follow up and data completion for each centre up until the 30th of June 2023. Centres highlighted in green indicate that all three tasks (ethics approval, blinding procedure approval and appointment of blinded assessor) have been completed 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	9	6	5
Belgium	UZ Leuven	23	21	17
Belgium	Liege Rocourt	10	1	2
Belgium	Grand Hospital de Charleroi	6	4	4
Belgium	AZ St. Jan University Hospital Brugge	6	4	6
Belgium	CHU Tivoli	Dec 2022 (missing blinded assessor)		
Czech Republic	The Institute for the Care of Mother and Child	41	32	23
Czech Republic	Motol University Hospital	May 2023 (missing all three prep tasks)		
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)		



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Denmark	Rigshospitalet	63	49	30
Denmark	Odense University Hospital	6	3	1
Denmark	Aalborg University Hospital	7	1	4
Denmark	Aarhus University Hospital	9	6	7
Germany	Freiburg University Hospital	7	5	2
Greece	Ippokrateion General Hospital of Thessaloniki	16	13	6
Greece	University of Patras General Hospital	5	2	1
Greece	Alexandra Univ. Hospital	12	9	9
Greece	University Hospital of Heraklion	8	6	6
India	St Johns Medical College Hospital, Bangalore	2	1	1
Ireland	University Hospital Cork	May 2023 (missing all three prep tasks)		
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	23	20	18
Italy	Presidio Ospedaliero S. Anna, Turin	3	0	0
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		



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Poland	Medical Center UJASTEK, Krakow	23	Clinical data not available	18
Poland	Szpital Uniwersytecki, Kraków	Mar 2023 (missing blinding procedure and assessor)		
Poland	Warsaw University of Medical Sciences	5	5	5
Poland	Poznan University of Medical Sciences	23	Clinical data not available	18
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	50	41	43
Spain	Hospital Clinic de Barcelona	33	30	28
Spain	University Hospital 12 de Octubre	33	26	14
Spain	Hospital de Sant Joan de Deu	16	15	12
Spain	Hospital Clinico San Carlos	18	18	18
Spain	Hospital Universitaria Puerta del Mar	10	10	7
Spain	H. Universitario Marqués de Valdecilla	10	0	1
Spain	H. U. Virgen de las Nieves, Granada	excluded		
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 (missing all three prep tasks)		
Switzerland	Zürich University Hospital	30	15	22
Switzerland	Luzerner Kantonsspital	24	15	14
Switzerland	Geneva University Hospital	6	6	5
Switzerland	Lausanne University Hospital	12	12	12
Turkey	Gazi University Hospital	5	2	2
Turkey	Marmara University Hospital	16	10	7
Turkey	Uludag University Hospital	11	11	8
Turkey	Kanuni Sultan University Hospital	8	8	6
Turkey	Bilkent Integrated Health Care Campus	15	7	7
Turkey	Basaksehir City Hospital	2	1	1
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	11	5	6
United States	Loma Linda University Hospital	16	0	0
United States	UT Southwestern Medical Center, Dallas	1	0	0
United States	Washington Univ. Hospital	Sep 2023		

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