



SafeBoosC newsletter Nov 2023

Dear investigators

Welcome to the November 2023 issue of the SafeBoosC newsletter.

CogniTOT

We got external funds for a new research student to help with the CogniTOT ancillary study. She will be testing all the Danish SafeBoosC-III participants as well as term born controls by remote assessment for a validation study.

SafeBoosC-III follow-up

So far, 54 of 64 sites with eligible children are open for follow-up and 48 have entered data in OpenClinica. A total of 945 eligible infants have reached two years of corrected age. Of these, 625 (66%) infants have completed data entries in OpenClinica so far. In total, 540 (57%) participants/families have completed the parental questionnaire. For the participants having reached 30 months of corrected age, 81% have enough data for the primary outcome. We are experiencing a bit of a decline in data completions due to many sites have not started following up participants yet. The next step will be to decide if we must exclude some sites. For an overview of data completion, please see figure 1. For an overview of each sites data completion see table 1.

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

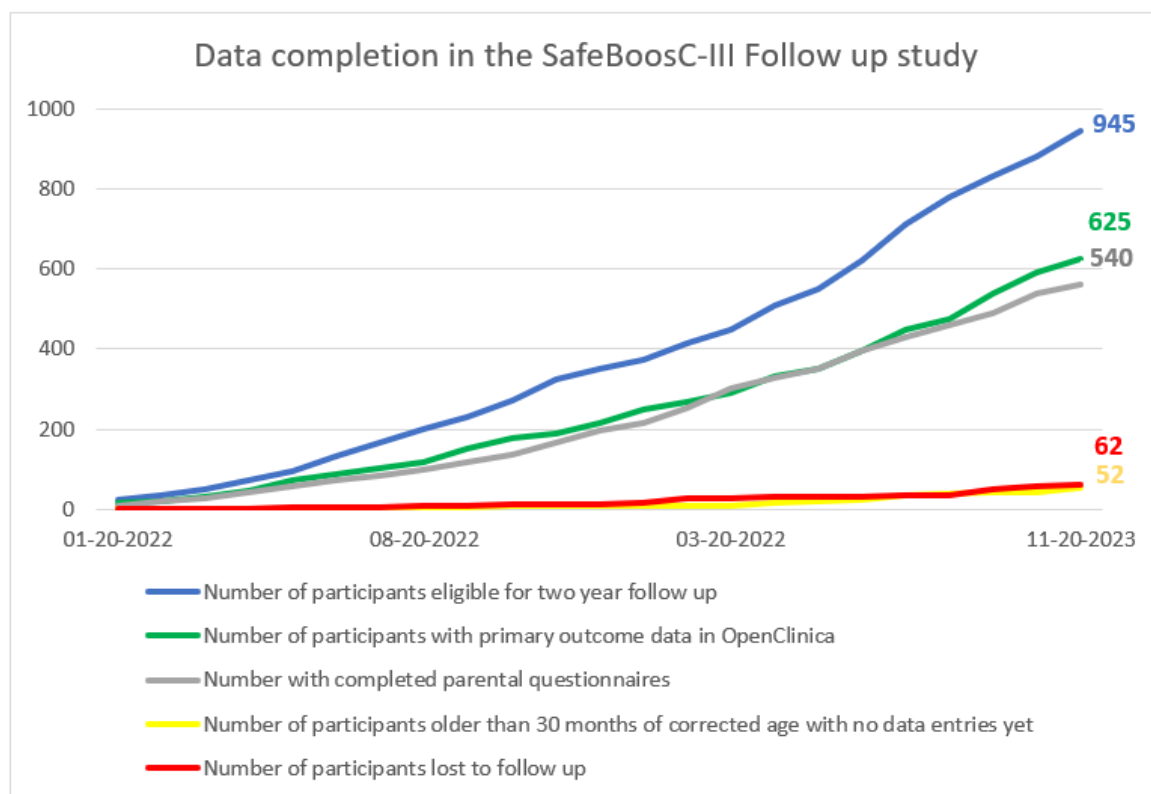




Table 1: Open sites, number of eligible participants for two year follow up and data completion for each site up until the 30th of Nov 2023. Sites highlighted in green indicate that all three tasks (ethics approval, blinding procedure approval and appointment of blinded assessor) have been completed in order to start the follow up study.

Country	Site	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Austria	University Hospital Graz	12	10	6
Belgium	UZ Leuven	25	24	18
Belgium	Liege Rocourt	18	16	9
Belgium	Grand Hospital de Charleroi	7	5	6
Belgium	AZ St. Jan University Hospital Brugge	9	9	8
Belgium	CHU Tivoli	11 (missing blinded assessor)		
Czech Republic	The Institute for the Care of Mother and Child	54	37	24
Czech Republic	Motol University Hospital	3 (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	(unknown if they will participate due to COVID surge)		
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	Site	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	75	60	37
Denmark	Odense University Hospital	7	3	3
Denmark	Aalborg University Hospital	15	7	7
Denmark	Aarhus University Hospital	14	12	9
Germany	Freiburg University Hospital	13	5	5
Greece	Ippokrateion General Hospital of Thessaloniki	20	19	8
Greece	University of Patras General Hospital	6	6	2
Greece	Alexandra Univ. Hospital	13	12	11
Greece	University Hospital of Heraklion	8	7	6
India	St Johns Medical College Hospital, Bangalore	4	4	3
Ireland	University Hospital Cork	9 (missing all three prep tasks)		
Ireland	Rotunda Hospital Dublin	2 (missing all three prep tasks)		
Ireland	NMH Holles St	2	1	0
Ireland	Coombe Univ. Hospital	3 (missing all three prep tasks)		
Italy	Fondazione IRCCS Cà Granda Ospedale, Milano	30	28	24
Italy	Presidio Ospedaliero S. Anna, Turin	6	1	1



Country	Site	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Italy	Ospedale Fillipo del Ponte, Varese	withdrawn		
Italy	Fondazione Policlinico Univ. A. Gemelli, Roma	3 (missing all three prep tasks)		
Norway	Oslo University Hospital	7 (missing all three prep tasks)		
Poland	Medical Center UJASTEK, Krakow	29	Clinical data not available	24
Poland	Szpital Uniwersytecki, Kraków	5 (missing blinding procedure and assessor)		
Poland	Warsaw University of Medical Sciences	9	9	9
Poland	Poznan University of Medical Sciences	27	Clinical data not available	24
Poland	Specialist Hospital No. 2 in Bytom	6	0	0
Poland	Wroclaw Medical University	3 (missing blinding procedure and assessor)		
Poland	Jan Biziel University Hospital	Dec 2023		
Poland	Centre of Medical Postgraduate Education, Warsaw	2 (missing all three prep tasks)		
Spain	H. Univ. Juan XXIII de Tarragona Hospital	excluded		
Spain	La Paz University Hospital	58	50	45
Spain	Hospital Clinic de Barcelona	43	37	28
Spain	University Hospital 12 de Octubre	50	45	18
Spain	Hospital de Sant Joan de Deu	21	16	14
Spain	Hospital Clinico San Carlos	23	22	20
Spain	Hospital Universitarie Puerta del Mar	12	10	9



Country	Site	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Spain	H. Universitario Marqués de Valdecilla	11	11	8
Spain	H. U. Virgen de las Nieves, Granada	excluded		
Spain	Hospital Miguel Servet	Dec 2023		
Spain	Hospital de Cruces	2 (missing all three prep tasks)		
Switzerland	Zürich University Hospital	33	21	25
Switzerland	Luzerner Kantonsspital	32	28	17
Switzerland	Geneva University Hospital	9	9	7
Switzerland	Lausanne University Hospital	14	13	12
Turkey	Gazi University Hospital	6	5	3
Turkey	Marmara University Hospital	22	14	14
Turkey	Uludag University Hospital	17	17	14
Turkey	Kanuni Sultan University Hospital	8	8	6
Turkey	Bilkent Integrated Health Care Campus	18	11	8
Turkey	Basaksehir City Hospital	10	9	5
United Kingdom	Royal Hospital for Children, Glasgow	12	0	0
United Kingdom	NHS Lanarkshire Hospital, Wishaw	3 (missing all three prep tasks)		
United States	University of Utah, Division of Neonatology	19	11	12
United States	Loma Linda University Hospital	22	7	0
United States	UT Southwestern Medical Center, Dallas	3	1	0



Country	Site	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
United States	Washington Univ. Hospital	3	3	1

Thank you for your time,

Marie, Mathias and Gorm