



SafeBoosC newsletter Oct 2023

Dear investigators

Welcome to the October 2023 issue of the SafeBoosC newsletter.

Publications

Both the protocol for the SafeBoosC-III follow up study (<https://doi.org/10.1186/s13063-023-07653-x>) and the SafeBoosC-IIIv trial (<https://doi.org/10.1186/s13063-023-07699-x>) have been published in the journal Trials.

SafeBoosC-III follow-up

So far, 53 of 64 sites with eligible children are open for follow-up and 48 have entered data in OpenClinica. A total of 880 eligible infants have reached two years of corrected age. Of these, 590 (67%) infants have completed data entries in OpenClinica so far. In total, 532 (60%) participants/families have completed the parental questionnaire. For the participants having reached 30 months of corrected age, 82% have enough data for the primary outcome. We have established contact with the Chinese departments and will soon decide which sites will be able to participate. The UK sites will soon be able to start follow up after having ethics and sponsor challenges. One Italian site has dropped out. 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

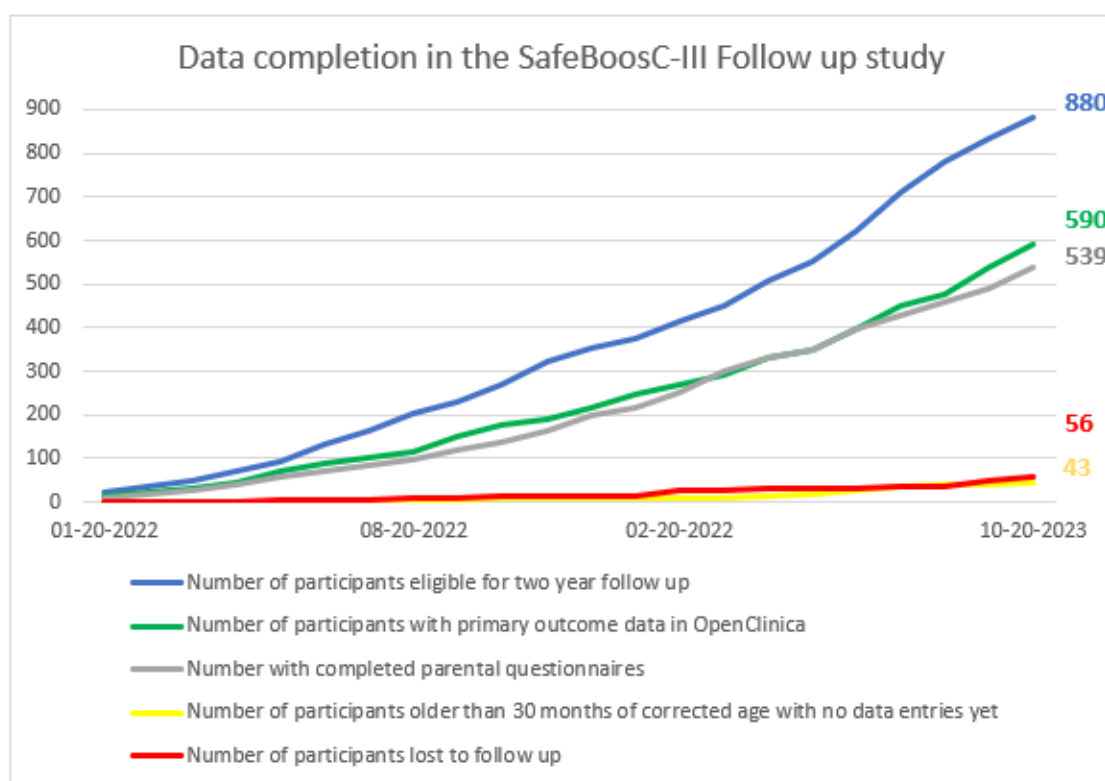




Table 1: Open centres, number of eligible participants for two year follow up and data completion for each centre up until the 30th of Oct 2023. Centres highlighted in green indicate that all three tasks (ethics approval, blinding procedure approval and appointment of blinded assessor) have been completed 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	11	10	5
Belgium	UZ Leuven	24	23	18
Belgium	Liege Rocourt	17	12	8
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	48	35	23
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	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)		



Country	Centre	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	69	60	35
Denmark	Odense University Hospital	6	3	3
Denmark	Aalborg University Hospital	14	6	6
Denmark	Aarhus University Hospital	14	11	9
Germany	Freiburg University Hospital	13	5	4
Greece	Ippokrateion General Hospital of Thessaloniki	20	19	7
Greece	University of Patras General Hospital	6	5	2
Greece	Alexandra Univ. Hospital	13	12	10
Greece	University Hospital of Heraklion	8	6	6
India	St Johns Medical College Hospital, Bangalore	3	2	2
Ireland	University Hospital Cork	9 (missing all three prep tasks)		
Ireland	Rotunda Hospital Dublin	2 (missing all three prep tasks)		
Ireland	NMH Holles St	1	1	0
Ireland	Coombe Univ. Hospital	Sep 2023		
Italy	Fondazione IRCCS Cà Granda Ospedale, Milano	28	26	24
Italy	Presidio Ospedaliero S. Anna, Turin	4	1	1



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Italy	Ospedale Fillipo del Ponte, Varese	4 (missing all three prep tasks)		
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	28	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	26	Clinical data not available	24
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	2 (missing all three prep tasks)		
Spain	H. Univ. Juan XXIII de Tarragona Hospital	excluded		
Spain	La Paz University Hospital	56	50	45
Spain	Hospital Clinic de Barcelona	41	37	28
Spain	University Hospital 12 de Octubre	46	36	14
Spain	Hospital de Sant Joan de Deu	18	15	14
Spain	Hospital Clinico San Carlos	22	22	20
Spain	Hospital Universitarie Puerta del Mar	11	10	9



Country	Centre	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	22	25
Switzerland	Luzerner Kantonsspital	28	24	17
Switzerland	Geneva University Hospital	8	6	6
Switzerland	Lausanne University Hospital	14	13	12
Turkey	Gazi University Hospital	5	3	3
Turkey	Marmara University Hospital	22	14	14
Turkey	Uludag University Hospital	14	14	11
Turkey	Kanuni Sultan University Hospital	8	8	6
Turkey	Bilkent Integrated Health Care Campus	18	11	8
Turkey	Basaksehir City Hospital	10	10	5
United Kingdom	Royal Hospital for Children, Glasgow	8 (missing all three prep tasks)		
United Kingdom	NHS Lanarkshire Hospital, Wishaw	3 (missing all three prep tasks)		
United States	University of Utah, Division of Neonatology	15	9	9
United States	Loma Linda University Hospital	21	7	0
United States	UT Southwestern Medical Center, Dallas	3	1	0



Country	Centre	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
United States	Washington Univ. Hospital	2	2	1

Thank you for your time,

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