



Welcome to the Feb 2024 issue of the SafeBoosC newsletter.

SafeBoosC-IIIv

Copenhagen Trial Unit has received a grant to cover the central costs for SafeBoosC-IIIv. The proposed primary outcome is hospital free days within 90 days from randomisation. In total, 1610 participants must be randomised. The hope is to start randomisation at the end of 2024. Please reach out to us if you are interested in participating.

SafeBoosC-III follow-up

So far, 53 of 59 sites with eligible children are open for follow-up and 46 have entered data in OpenClinica. In total, 6 sites who have eligible children have not yet started the follow up and 11 sites have been excluded/withdrawn. A total of 1102 eligible infants have reached two years of corrected age. Of these, 753 (68%) infants have completed data entries in OpenClinica so far. As we are reaching the end of the study, we highly encourage data to be completed as soon as possible. In total, 640 (58%) 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. 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

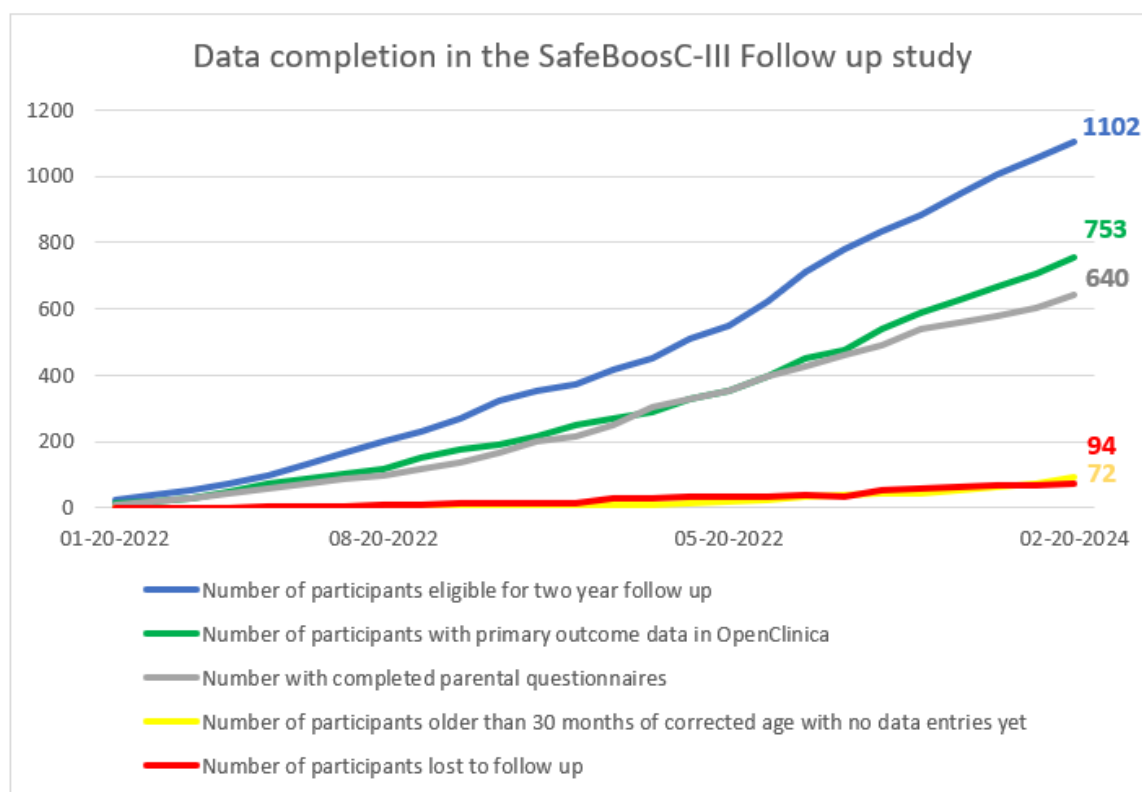


Table 1: Open sites, number of eligible participants for two year follow up and data completion for each site up until the 29th of Feb 2024. Sites highlighted in green indicate that all three tasks (ethics approval, blinding procedure approval and appointment of blinded assessor) have been completed 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	14	12	7
Belgium	UZ Leuven	29	28	21
Belgium	Liege Rocourt	20	16	10
Belgium	Grand Hospital de Charleroi	17	5	6
Belgium	AZ St. Jan University Hospital Brugge	10	10	8
Belgium	CHU Tivoli	15	4	0
Czech Republic	The Institute for the Care of Mother and Child	59	42	26
Czech Republic	Motol University Hospital	8	3	7
China	Children's Hospital of Zhejiang, Hangzhou	Excluded		
China	Children's Hospital of Fudan University, Shanghai	Excluded		
China	Hainan Women and Children's Medical Center	Excluded		
China	Guangzhou Women and Children's Medical Center	No data		
China	Longgang District Central Hospital of Shenzhen	Excluded		
China	The People's Hospital of Dehong	Withdrawn		
China	Guangxi Maternal and Child Healthcare Hospital, Nanning	Excluded		
China	Xiamen Children's Hospital	Excluded		
Denmark	Rigshospitalet	84	74	41



Country	Site	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Denmark	Odense University Hospital	8	3	3
Denmark	Aalborg University Hospital	16	11	10
Denmark	Aarhus University Hospital	19	12	10
Germany	Freiburg University Hospital	15	5	5
Greece	Ippokrateion General Hospital of Thessaloniki	20	20	8
Greece	University of Patras General Hospital	6	6	2
Greece	Alexandra Univ. Hospital	14	12	11
Greece	University Hospital of Heraklion	7	7	6
India	St Johns Medical College Hospital, Bangalore	4	4	3
Ireland	University Hospital Cork	15	5	0
Ireland	Rotunda Hospital Dublin	14 (missing all three prep tasks)		
Ireland	NMH Holles St	10	2	0
Ireland	Coombe Univ. Hospital	10	0	
Italy	Fondazione IRCCS Cà Granda Ospedale, Milano	34	30	28
Italy	Presidio Ospedaliero S. Anna, Turin	8	1	1
Italy	Ospedale Fillipo del Ponte, Varese	withdrawn		
Italy	Fondazione Policlinico Univ. A. Gemelli, Roma	8 (missing all three prep tasks)		
Norway	Oslo University Hospital	28	0	7
Poland	Medical Center UJASTEK, Krakow	31	Clinical data not available	24



Country	Site	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Poland	Szpital Uniwersytecki, Kraków	19	1	0
Poland	Warsaw University of Medical Sciences	9	9	9
Poland	Poznan University of Medical Sciences	29	Clinical data not available	24
Poland	Specialist Hospital No. 2 in Bytom	7	0	0
Poland	Wroclaw Medical University	3 (missing blinding procedure and assessor)		
Poland	Jan Biziel University Hospital	1 (missing blinding procedure and assessor)		
Poland	Centre of Medical Postgraduate Education, Warsaw	2 (missing blinding procedure and assessor)		
Spain	H. Univ. Juan XXIII de Tarragona Hospital	excluded		
Spain	La Paz University Hospital	59	52	48
Spain	Hospital Clinic de Barcelona	50	45	34
Spain	University Hospital 12 de Octubre	60	52	30
Spain	Hospital de Sant Joan de Deu	24	19	14
Spain	Hospital Clinico San Carlos	27	25	22
Spain	Hospital Universitarie Puerta del Mar	13	12	11
Spain	H. Universitario Marqués de Valdecilla	13	11	8
Spain	H. U. Virgen de las Nieves, Granada	excluded		
Spain	Hospital Miguel Servet	1 (missing all three prep tasks)		
Spain	Hospital de Cruces	3 (missing all three prep tasks)		



Country	Site	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Switzerland	Zürich University Hospital	33	30	25
Switzerland	Luzerner Kantonsspital	37	33	17
Switzerland	Geneva University Hospital	9	9	7
Switzerland	Lausanne University Hospital	19	16	16
Turkey	Gazi University Hospital	7	6	6
Turkey	Marmara University Hospital	23	21	17
Turkey	Uludag University Hospital	25	21	20
Turkey	Kanuni Sultan University Hospital	8	8	6
Turkey	Bilkent Integrated Health Care Campus	19	11	8
Turkey	Basaksehir City Hospital	12	12	5
United Kingdom	Royal Hospital for Children, Glasgow	15	0	0
United Kingdom	NHS Lanarkshire Hospital, Wishaw	8	0	0
United States	University of Utah, Division of Neonatology	26	19	18
United States	Loma Linda University Hospital	28	7	0
United States	UT Southwestern Medical Center, Dallas	3	1	0
United States	Washington Univ. Hospital	12	12	10

Thank you for your time,

Marie and Gorm