

SafeBoosC-III newsletter September 2021

Dear investigators

Welcome to the September 2021 issue of the SafeBoosC-III newsletter.

Reminder on new authorship criteria

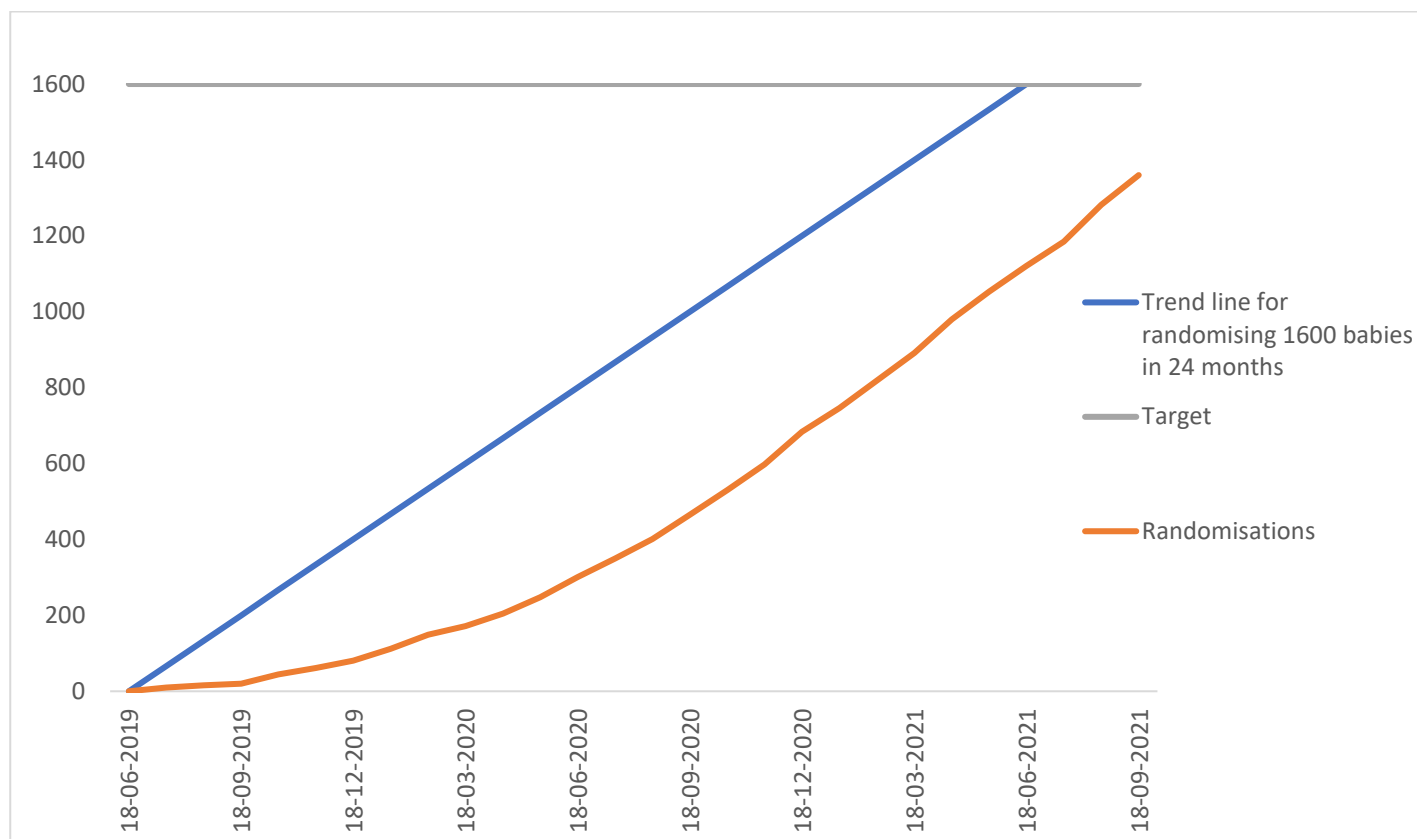
Once again, we would like to remind you of the new co-author requirements, which was approved by the steering group at 26th of July:

- 1) All investigators that have randomised at least one baby will obtain co-authorship. We hereby acknowledge the effort in getting the trial up-and-running, which is quite an effort, and the contribution of one or more babies to the trial.
- 2) Investigators who randomise more than 30 babies, will be allowed to include one additional investigator from their centre as co-author on the main publication – on the condition that he or she has contributed substantially to the conduct of the trial.
- 3) Investigators who randomise more than 60 babies will be allowed to include two additional investigators from the centre as co-authors on the main publication – on the condition that they have contributed substantially to the conduct of the trial.

A detailed description can be found in the standard operation procedure 'Updated co-author requirements', on safeboosc.eu: <https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Sider/sops.aspx>

Status on randomisations and trial preparations

As of the 18th of September, a total of 1360 babies have been randomised across 72 centres (fig. 1). The average randomisation rate across the last six months is 2.53 randomised babies per day. If we continue in a similar pace, we will complete recruitment before the end of 2021.

Figure 1. Randomisations in the SafeBoosC-III trial

In **table 1** below, you will find an overview of the randomisations in each of the 72 centres up until 18th of September 2021. You will also find an overview of the average number of randomisations since opening for randomisation, per centre.

Table 1. Open centres, randomisations and average randomisations per month since opening for randomisation, per centre up until 18th of September 2021.

Country	Centre	Randomised since	Randomisations	Average randomisations per month since opening for randomisations
Austria	University Hospital Graz	Jun 2020	17	1.1
Belgium	UZ Leuven	Jun 2020	27	1.8
Belgium	Liege Rocourt	Jul 2020	20	1.4
Belgium	Grand Hospital de Charleroi	Jul 2020	11	0.8
Belgium	AZ St. Jan University Hospital Brugge	Sep 2020	13	1.1
Belgium	CHU Tivoli	Sep 2020	15	1.3

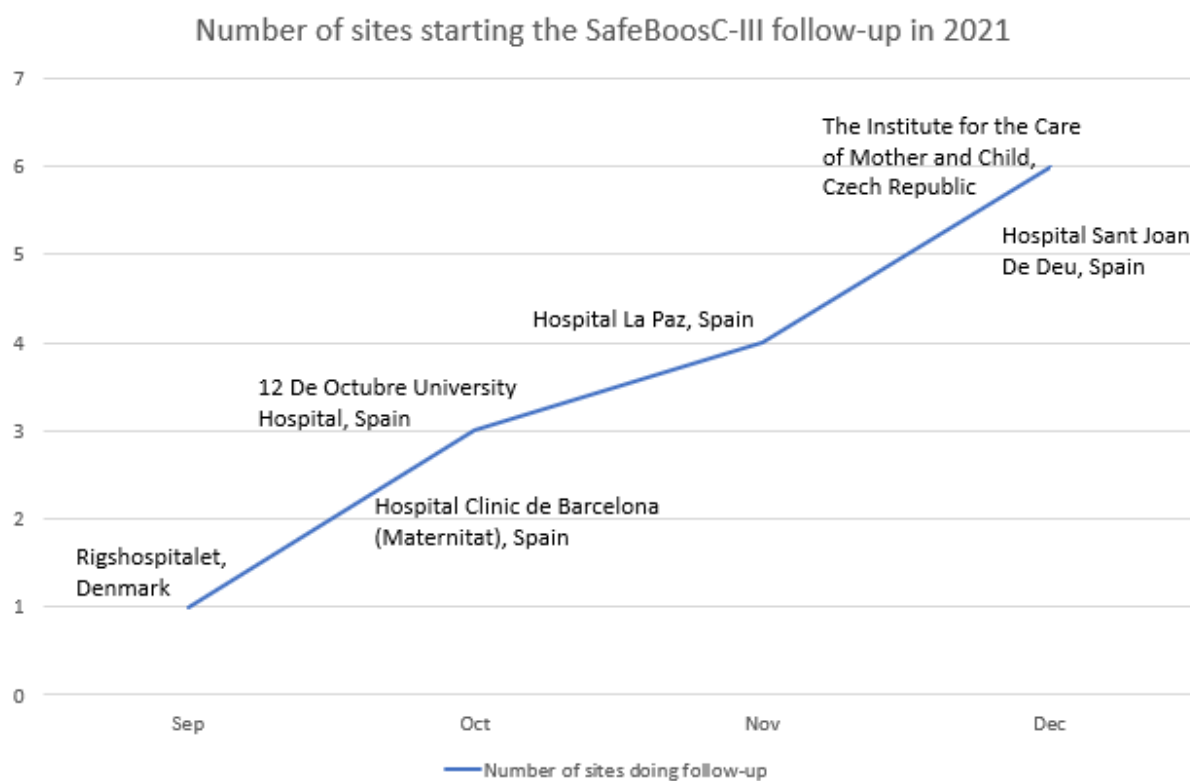
Country	Centre	Randomised since	Randomisations	Average randomisations per month since opening for randomisations
Belgium	Liege Citadelle Hospital	Nov 2020	0	0
Czech Republic	The Institute for the Care of Mother and Child	Sep 2019	61	2.5
Czech Republic	Motol University Hospital	February 2021	7	1.0
China	Children's Hospital of Zhejiang, Hangzhou	Jan 2020	4	0.2
China	Children's Hospital of Fudan University, Shanghai	Jan 2020	35	1.8
China	Hainan Women and Children's Medical Center	Mar 2020	3	0.2
China	Guangzhou Women and Children's Medical Center	Mar 2020	2	0.1
China	Longgang District Central Hospital of Shenzhen	May 2020	9	0.6
China	The People's Hospital of Dehong	May 2020	3	0.2
China	Guangxi Maternal and Child Healthcare Hospital, Nanning	May 2020	7	0.4
China	Xiamen Children's Hospital	May 2020	4	0.3
Denmark	Rigshospitalet	Jun 2019	96	3.6
Denmark	Odense University Hospital	Dec 2019	11	0.5
Denmark	Aalborg University Hospital	Mar 2020	19	1.1
Denmark	Aarhus University Hospital	May 2020	18	1.0
Germany	Freiburg University Hospital	June 2020	13	0.9
Greece	Ippokrateion General Hospital of Thessaloniki	Oct 2019	32	1.4
Greece	University of Patras General Hospital	Jan 2020	12	0.6
Greece	Alexandra Univ. Hospital	Mar 2020	14	0.8
Greece	University Hospital of Heraklion	Mar 2020	8	0.4
India	St Johns Medical College Hospital, Bangalore	Jun 2020	5	0.3
Ireland	University Hospital Cork	February 2021	20	2.9
Ireland	Rotunda Hospital Dublin	May 2021	7	1.8
Ireland	NMH Holles St	May 2021	7	1.8
Ireland	Coombe Univ. Hospital	May 2021	10	2.5

Country	Centre	Randomised since	Randomisations	Average randomisations per month since opening for randomisations
Italy	Fondazione IRCCS Cà Granda Ospedale, Milano	Nov 2019	40	1.8
Italy	Presidio Ospedaliero S. Anna, Turin	Aug 2020	9	0.7
Italy	Ospedale Fillipo del Ponte, Varese	Oct 2020	5	0.5
Italy	Fondazione Policlinico Univ. A. Gemelli, Roma	Dec 2020	13	1.4
Norway	Oslo University Hospital	March 2021	24	4
Poland	Medical Center UJASTEK, Krakow	Jan 2020	35	1.8
Poland	Szpital Uniwersytecki, Kraków	Oct 2020	16	1.5
Poland	Warsaw University of Medical Sciences	Oct 2020	9	0.8
Poland	Poznan University of Medical Sciences	Mar 2020	32	1.8
Poland	Specialist Hospital No. 2 in Bytow	Feb 2020	6	0.3
Poland	Wroclaw Medical University	Apr 2020	1	<0.1
Poland	Jan Biziel University Hospital	Sep 2020	0	0.0
Poland	Centre of Medical Postgraduate Education, Warsaw	May 2021	4	1.0
Spain	H. Univ. Juan XXIII de Tarragona Hospital	Feb 2020	15	0.9
Spain	La Paz University Hospital	Jul 2019	72	2.8
Spain	Hospital Clinic de Barcelona	Jul 2019	50	1.9
Spain	University Hospital 12 de Octubre	Jul 2019	62	2.4
Spain	Hospital de Sant Joan de Deu	Oct 2019	31	1.3
Spain	Hospital Clinico San Carlos	Sep 2019	33	1.4
Spain	Hospital Universitarie Puerta del Mar	Oct 2019	20	0.9
Spain	H. Universitario Marqués de Valdecilla	Dec 2019	20	1.0
Spain	H. U. Virgen de las Nieves, Granada	Jan 2020	13	0.7
Spain	C. U. Universitario de Santiago	Jan 2020	0	0
Spain	Hospital Miguel Servet	Apr 2020	1	<0.1

Country	Centre	Randomised since	Randomisations	Average randomisations per month since opening for randomisations
Spain	Hospital de Cruces	Jan 2021	4	0.5
Switzerland	Zürich University Hospital	Dec 2019	37	N/A (withdrew in May 2021)
Switzerland	Luzerner Kantonsspital	Jan 2020	40	2.0
Switzerland	Geneva University Hospital	May 2020	11	0.7
Switzerland	Lausanne University Hospital	Sep 2020	16	1.3
Turkey	Gazi University Hospital	Jan 2020	14	0.7
Turkey	Marmara University Hospital	Jan 2020	29	1.5
Turkey	Uludag University Hospital	Jan 2020	37	1.9
Turkey	Kanuni Sultan University Hospital	Jan 2020	11	N/A (withdrew in December 2020)
Turkey	Bilkent Integrated Health Care Campus	Jan 2020	37	1.9
Turkey	Basaksehir City Hospital	Jan 2021	10	0.5
United Kingdom	Royal Hospital for Children, Glasgow	Feb 2021	14	2.0
United Kingdom	NHS Lanarkshire Hospital, Wishaw	March 2021	7	1.2
United States	University of Utah, Division of Neonatology	Jun 2020	21	1.4
United States	Loma Linda University Hospital	Sep 2020	30	2.5
United States	UT Southwestern Medical Center, Dallas	Oct 2020	6	0.5
United States	Washington Univ. Hospital	June 2021	8	2.7
Total			1360	

The SafeBoosC-III two-year follow-up study

The first child randomised in the trial will reach two years of corrected age this September from Copenhagen. Five more centers will start following up participants this fall, and the first three Spanish centers have ethical approval (fig. 2).



We would like to remind you that all ‘follow-up study preparation tasks’ must be completed before commencement of the study. Marie will contact all of you 3-6 months before your first participant turns two years of corrected age and remind you of this. For more details on the tasks to complete before commencement of the SafeBoosC-III follow-up study, see the following SOP:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/departments-of-neonatology/research/safeboosc/Documents/sop-tasks-for-pls-before-start-of-follow-up.pdf>

SafeBoosC-IIIv

Before the latest steering committee meeting (20th of September), a draft protocol for the SafeBoosC-IIIv trial was circulated to the members. Based on this draft, it was decided during the meeting, that the work with finalising the protocol can continue. The next steps will be to finalise the protocol, obtain ethics approval in Denmark and draft the design paper. Once the protocol is finalised, it will be circulated to principal investigators and uploaded to safeboosc.eu.

Additionally, we are still waiting for a decision on the funding application to the Novo Nordisk Foundation. Reply is expected in December.

If any of you are interested in hearing more about the trial up front, please do not hesitate to contact the trial manager Maria Vestager (maria.vestager.jensen.03@regionh.dk).

Data completion monitoring report

In the link below you will find the central monitoring report on data completion from September 2021.

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/data-completion-report-17-Sep-2021.pdf>

For the serious adverse reactions (SAR) and 36 weeks follow-up forms, completion of data entries has increased from last month, to 97% (+3%) and 99% (+1%) respectively. As for the end of monitoring form, data completion is unchanged (98%). These completion rates are very impressive.

Unfortunately, completion of the blinded follow-up form has decreased for the second month in a row, to 88% (-1%). As in the preceding months, it is a smaller group of centres that accounts for the majority of the incomplete blinded-follow-up forms.

Investigators with missing data entries have been contacted and urged to complete data entries.

Minutes from the 14th steering committee meeting

The latest steering committee meeting was held online through Zoom on the 20th of September. Please find the minutes, as well as minutes from all previous meetings, in the link below:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/safeboosc-steering-committee-meeting-sep-2021.pdf>

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