

## SafeBoosC-III newsletter November 2021

Dear investigators

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

### **Plan for completion of the SafeBoosC-III trial**

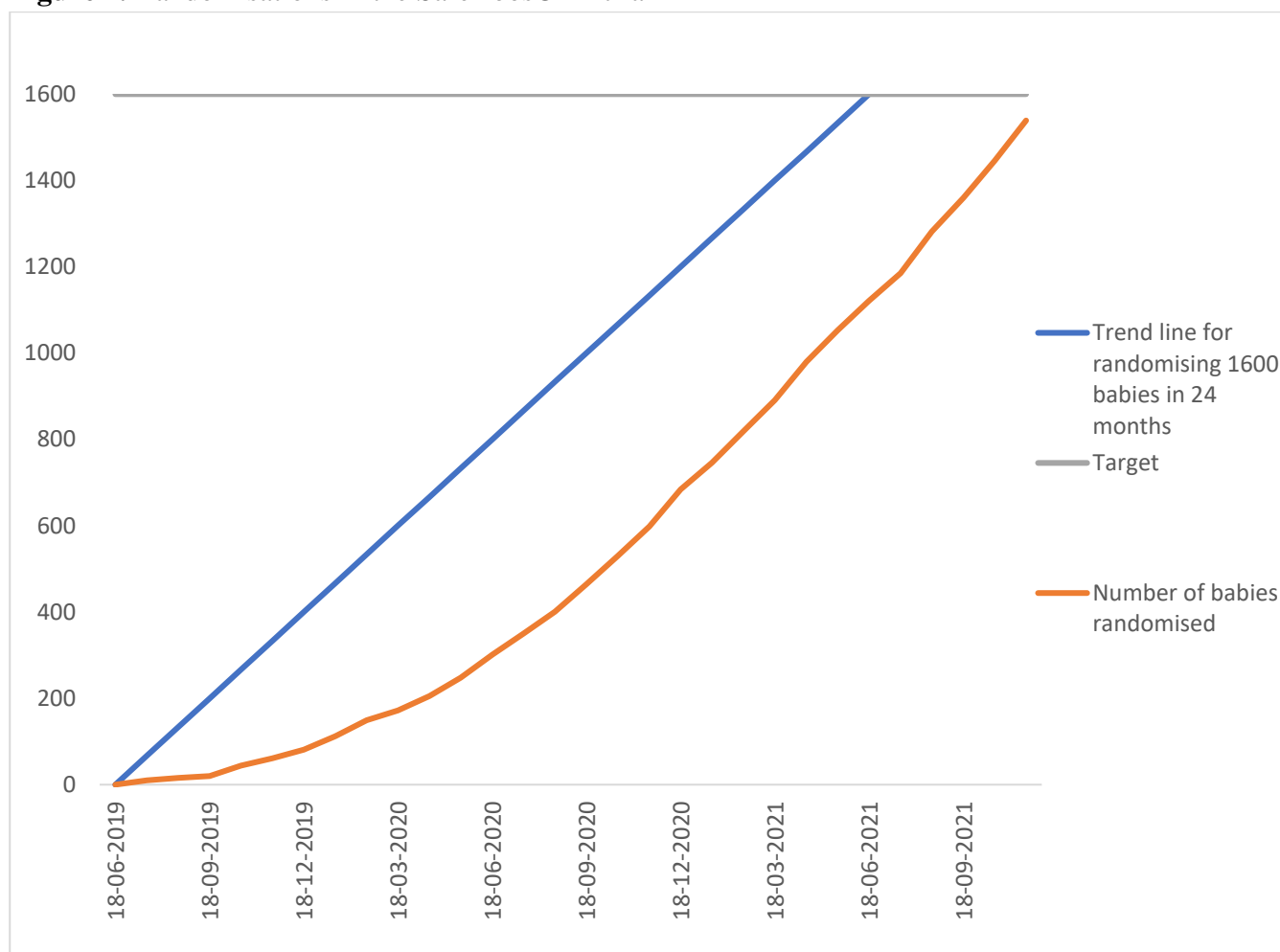
We expect to finish recruitment within the next weeks. Once recruitment is completed, we have an important job - to complete data entries, identify random and systemic errors in the entered data and complete all GCP reports. Until this is completed, the statistical analyses cannot be initiated.

To enhance the process of completing the trial, conduct the statistical analyses, write the manuscript and submit it for publication in New England Journal of Medicine, we have developed a Standard Operating Procedure (SOP). It includes an expected timeline for completion of the trial, with important deadlines and tasks for investigators (planning GCP visits, time for data entry etc).

The dates/deadlines in the SOP may change, depending on when we complete recruitment. The full SOP on completion of the trial by clicking here: [LINK](#). Once the deadlines have been set, we will do our utmost to respect them.

### **Status on randomisations and trial preparations**

As of the 18<sup>th</sup> of November, a total of 1539 babies have been randomised across 73 centres (fig. 1). The randomisation rate for the past month has been 3,5 per day, and we expect to complete recruitment within the next 2-3 weeks ie. the beginning of December. Once we have reached the sample size of 1600, it will no longer be possible to randomise participants in OpenClinica.

**Figure 1.** Randomisations in the SafeBoosC-III trial

In **table 1** below, you will find an overview of the randomisations in each of the 73 centres up until 18<sup>th</sup> of November 2021.

**Table 1.** Open centres, randomisations and average randomisations per month since opening for randomisation, per centre up until 18<sup>th</sup> of November 2021.

Country	Centre	Randomised since	Randomisations
<b>Austria</b>	University Hospital Graz	Jun 2020	20
<b>Belgium</b>	UZ Leuven	Jun 2020	29
<b>Belgium</b>	Liege Rocourt	Jul 2020	23
<b>Belgium</b>	Grand Hospital de Charleroi	Jul 2020	14
<b>Belgium</b>	AZ St. Jan University Hospital Brugge	Sep 2020	13
<b>Belgium</b>	CHU Tivoli	Sep 2020	19

Country	Centre	Randomised since	Randomisations
<b>Belgium</b>	Liege Citadelle Hospital	Nov 2020	0
<b>Czech Republic</b>	The Institute for the Care of Mother and Child	Sep 2019	64
<b>Czech Republic</b>	Motol University Hospital	February 2021	9
<b>China</b>	Children's Hospital of Zhejiang, Hangzhou	Jan 2020	6
<b>China</b>	Children's Hospital of Fudan University, Shanghai	Jan 2020	35
<b>China</b>	Hainan Women and Children's Medical Center	Mar 2020	5
<b>China</b>	Guangzhou Women and Children's Medical Center	Mar 2020	2
<b>China</b>	Longgang District Central Hospital of Shenzhen	May 2020	10
<b>China</b>	The People's Hospital of Dehong	May 2020	4
<b>China</b>	Guangxi Maternal and Child Healthcare Hospital, Nanning	May 2020	7
<b>China</b>	Xiamen Children's Hospital	May 2020	4
<b>Denmark</b>	Rigshospitalet	Jun 2019	103
<b>Denmark</b>	Odense University Hospital	Dec 2019	12
<b>Denmark</b>	Aalborg University Hospital	Mar 2020	19
<b>Denmark</b>	Aarhus University Hospital	May 2020	19
<b>Germany</b>	Freiburg University Hospital	June 2020	14
<b>Greece</b>	Ippokrateion General Hospital of Thessaloniki	Oct 2019	37
<b>Greece</b>	University of Patras General Hospital	Jan 2020	13
<b>Greece</b>	Alexandra Univ. Hospital	Mar 2020	14
<b>Greece</b>	University Hospital of Heraklion	Mar 2020	10
<b>India</b>	St Johns Medical College Hospital, Bangalore	Jun 2020	5
<b>Ireland</b>	University Hospital Cork	February 2021	22
<b>Ireland</b>	Rotunda Hospital Dublin	May 2021	15

Country	Centre	Randomised since	Randomisations
<b>Ireland</b>	NMH Holles St	May 2021	17
<b>Ireland</b>	Coombe Univ. Hospital	May 2021	17
<b>Italy</b>	Fondazione IRCCS Cà Granda Ospedale, Milano	Nov 2019	41
<b>Italy</b>	Presidio Ospedaliero S. Anna, Turin	Aug 2020	11
<b>Italy</b>	Ospedale Fillipo del Ponte, Varese	Oct 2020	11
<b>Italy</b>	Fondazione Policlinico Univ. A. Gemelli, Roma	Dec 2020	15
<b>Norway</b>	Oslo University Hospital	March 2021	31
<b>Poland</b>	Medical Center UJASTEK, Krakow	Jan 2020	37
<b>Poland</b>	Szpital Uniwersytecki, Kraków	Oct 2020	19
<b>Poland</b>	Warsaw University of Medical Sciences	Oct 2020	9
<b>Poland</b>	Poznan University of Medical Sciences	Mar 2020	34
<b>Poland</b>	Specialist Hospital No. 2 in Bytow	Feb 2020	6
<b>Poland</b>	Wroclaw Medical University	Apr 2020	1
<b>Poland</b>	Jan Biziel University Hospital	Sep 2020	3
<b>Poland</b>	Centre of Medical Postgraduate Education, Warsaw	May 2021	4
<b>Spain</b>	H. Univ. Juan XXIII de Tarragona Hospital	Feb 2020	18
<b>Spain</b>	La Paz University Hospital	Jul 2019	76
<b>Spain</b>	Hospital Clinic de Barcelona	Jul 2019	58
<b>Spain</b>	University Hospital 12 de Octubre	Jul 2019	70
<b>Spain</b>	Hospital de Sant Joan de Deu	Oct 2019	32
<b>Spain</b>	Hospital Clinico San Carlos	Sep 2019	36
<b>Spain</b>	Hospital Universitarie Puerta del Mar	Oct 2019	21
<b>Spain</b>	H. Universitario Marqués de Valdecilla	Dec 2019	21

Country	Centre	Randomised since	Randomisations
<b>Spain</b>	H. U. Virgen de las Nieves, Granada	Jan 2020	14
<b>Spain</b>	C. H. Universitario de Santiago	Jan 2020	0
<b>Spain</b>	Hospital Miguel Servet	Apr 2020	1
<b>Spain</b>	Hospital de Cruces	Jan 2021	4
<b>Switzerland</b>	Zürich University Hospital	Dec 2019	37
<b>Switzerland</b>	Luzerner Kantonsspital	Jan 2020	44
<b>Switzerland</b>	Geneva University Hospital	May 2020	11
<b>Switzerland</b>	Lausanne University Hospital	Sep 2020	20
<b>Turkey</b>	Gazi University Hospital	Jan 2020	17
<b>Turkey</b>	Marmara University Hospital	Jan 2020	33
<b>Turkey</b>	Uludag University Hospital	Jan 2020	44
<b>Turkey</b>	Kanuni Sultan University Hospital	Jan 2020	11
<b>Turkey</b>	Bilkent Integrated Health Care Campus	Jan 2020	37
<b>Turkey</b>	Basaksehir City Hospital	Jan 2021	12
<b>United Kingdom</b>	Royal Hospital for Children, Glasgow	Feb 2021	19
<b>United Kingdom</b>	NHS Lanarkshire Hospital, Wishaw	March 2021	10
<b>United States</b>	University of Utah, Division of Neonatology	Jun 2020	28
<b>United States</b>	Loma Linda University Hospital	Sep 2020	37
<b>United States</b>	UT Southwestern Medical Center, Dallas	Oct 2020	6
<b>United States</b>	Washington Univ. Hospital	June 2021	14
<b>United States</b>	University of Virginia	October 2021	0
<b>Total</b>			1539

### **The SafeBoosC-III two-year follow-up study**

Four centers across Spain and Denmark have participants who have reached two years of corrected age, and all these centers have started data entries in OpenClinica. A total of six participants have been followed up. The parental questionnaire is also being filled out by families. The start of the follow up study has been smooth and so far without any major difficulties. Investigators report that the two year follow up data entries are intuitive and clear and easy to fill out when assessing patient records.

### **SafeBoosC-IIIv**

The protocol has been admitted for ethics approval in Denmark and now the design paper will be drafted. We will receive the decision from the Novo Nordisk foundation in December regarding the grant for SafeBoosC-IIIv. If the funding is granted, we plan on starting quickly hereafter and are hopeful to randomise the first patient in late spring/early summer.

### **Data completion monitoring report**

You will find the central monitoring report on data completion from November by clicking here [LINK](#)

For the end-of monitoring forms, serious adverse reactions forms (SAR) and 36 weeks follow-up forms, completion of data entries is rather stable (+/-1% changes in the previous months).

Completion of the blinded follow-up form has increased to 92% (+3%), but it is unfortunately still lower than for the other data forms and lower than the 'less than five percent' missing data, which we aim for. Once recruitment is completed, we will start doing data completion monitoring every 14<sup>th</sup> day.

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

### **Minutes from the 15th steering committee meeting**

The latest steering committee meeting was held online through Zoom on the 10<sup>th</sup> of November. Please find the minutes, as well as minutes from all previous meetings, by clicking here [LINK](#).

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