

## SafeBoosC III Central monitoring report

20-January 2020

The data shown below is based on all registered data entries in OpenClinica on SafeBoosC III trial participants, up until 20<sup>th</sup> of January 2020. The data has been analysed and reported according to the SafeBoosC III Central monitoring plan (see [www.safeboosc.eu](http://www.safeboosc.eu) under “Good Clinical Practice”).

Direct link to the Central monitoring plan: <https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/central-monitoring-plan.pdf>

### Completion of data entries

Below you will find an overview of data entries across all centres where at least one randomised baby has reached 10 days of life.

Site	Randomisations up until 20-jan	End-of-monitoring (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
CH01 University Hospital Zürich	2	100%	n/a	n/a
CZ01 The Institute for the Care of Mother and Child	11	100%	100%	14%
DK01 Rigshospitalet	31	97%	100%	100%
ES01 La Paz University Hospital	15	100%	100%	71%
Total	107	94%	100%	79%

Note that this table only includes randomised babies that have reached at least 10 days of life, and that completion percentages for Follow-up and Blinded follow-up modules is based only on babies that have reached 40 weeks of postmenstrual age (PMA). n/a = not applicable, meaning that no babies at the specific site has reached 40 weeks of PMA.

Site	Randomisations up until 20-jan	End-of-monitoring (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
ES02 Hospital Clinic de Barcelona (Maternitat)	11	100%	100%	100%
ES03 University Hospital 12 de Octubre	20	100%	100%	100%
ES05 Hospital de Sant Joan de Deu	6	100%	100%	100%
ES06 H. U. Puerta del Mar	1	0%	n/a	n/a
ES08 C. H. Universitario de Santiago	4	100%	n/a	n/a
ES09 H. U. Marques de Valdecilla	2	100%	n/a	n/a
GR02 Ippokrateion Hospital of Thessalonikki	4	0%	n/a	n/a
Total	107	94%	100%	79%

Note that this table only includes randomised babies that have reached at least 10 days of life, and that completion percentages for Follow-up and Blinded follow-up modules is based only on babies that have reached 40 weeks of postmenstrual age (PMA). n/a = not applicable, meaning that no babies at the specific site has reached 40 weeks of PMA.

Investigators who do not have 100% completion of data entries across all three modules will be contacted by e-mail and asked to enter the missing data into OpenClinica.

### Ensuring correct data entries

Analysis to find systematic deviations in data entries will be initiated once 100 randomised babies have reached 40 weeks of postmenstrual age. This will at the 6<sup>th</sup> of April 2020.

Gorm Greisen and Mathias Lühr Hansen