

SafeBoosC III Data completion report

22-February 2021

The data shown below is based on all registered data entries in OpenClinica on SafeBoosC III trial participants, up until 22nd of February 2021. The data has been analysed and reported according to the SafeBoosC III Central monitoring plan (see 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.

Note that completion calculations are based on babies that have reached at least 10 days of life for end-of-monitoring completion, and 40 weeks of postmenstrual age (PMA) for Follow-up and Blinded follow-up completion. n/a = not applicable, meaning that no babies at the specific site has reached 10 days of life or 40 weeks of PMA when applicable.

Site	Randomisations up until 22-February 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
AT01 Univ. Hospital Graz	12	100%	100%	100%	75%
BE01 Univ. Hospital Leuven	21	100%	100%	100%	91%
BE02 AZ St. Jain Univ. Hosp. Bruges	7	100%	0%	100%	100%

Site	Randomisations up until 22- February 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
BE03 Charleroi Univ. Hospital	5	100%	100%	100%	100%
BE04 CHU Tivoli Hospital	9	100%	100%	100%	67%
BE06 Liege Rocourt Hospital	8	100%	100%	100%	0%
CH01 University Hospital Zürich	32	100%	100%	100%	75%
CH03 University Hospital Lucern	27	89%	85%	94%	94%
CH04 University Hospital Geneva	7	100%	100%	71%	0%
CH05 Lausanne University Hospital	13	100%	20%	100%	0%
CN01 Children's Hospital, Zheijang Univ.	2	0%	0%	n/a	n/a
CN02 Children's Hospital, Fudan	35	100%	81%	75%	96%
CN04 Guangzhou Women and Children's Hospital	2	0%	0%	n/a	n/a
Total	828	97%	93%	98%	90%

Site	Randomisations up until 22- February 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
CN05 Longgang Distr. Centr. Hosp. Shenzhen	6	100%	100%	100%	100%
CN06 Xiamen Children's Hospital	2	100%	100%	0%	100%
CN07 The People's Hospital of Dehong	3	100%	100%	100%	100%
CN08 Maternal and Child Health Hosp. Guangxi	5	100%	0%	33%	33%
CZ01 The Institute for the Care of Mother and Child	44	98%	100%	100%	100%
CZ02 Motol Univ. Hospital	1	n/a	n/a	n/a	n/a
DE01 University Hospital Freiburg	6	100%	100%	100%	75%
DK01 Rigshospitalet	72	100%	100%	100%	95%
DK04 Aalborg University Hospital	6	100%	100%	100%	100%
Total	828	97%	93%	98%	90%

Site	Randomisations up until 22- February 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
DK18 Aarhus University Hospital	9	100%	100%	100%	100%
DK30 Odense University Hospital	6	67%	0%	50%	0%
ES01 La Paz University Hospital	59	100%	100%	100%	85%
ES02 Hospital Clinic de Barcelona (Maternitat)	37	100%	100%	100%	100%
ES03 University Hospital 12 de Octubre	36	100%	100%	100%	100%
ES05 Hospital de Sant Joan de Deu	24	100%	92%	100%	100%
ES06 H. U. Puerta del Mar	17	100%	100%	92%	69%
ES08 Hospital Clinico San Carlos	24	100%	100%	100%	100%
ES09 H. U. Marques de Valdecilla	14	79%	88%	100%	100%
ES10 Virgen de las Nieves	6	100%	100%	100%	100%
Total	828	97%	93%	98%	90%

Site	Randomisations up until 22- February 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
ES11 H. Univ. Juan XXIII Tarragona	11	100%	100%	100%	100%
GR01 Alexandra Hospital, Athens	12	100%	100%	100%	100%
GR02 Ippokrateion Hospital of Thessalonikki	21	100%	100%	100%	90%
GR03 Univ of Patras, General Hospital	8	100%	100%	100%	100%
GR04 Univ Hospital of Heraklion	8	100%	100%	100%	83%
IE01 Univ. College Cork	1	0%	0%	n/a	n/a
IN01 St Johns Medical College Hospital, Bangalore	3	100%	100%	100%	100%
IT01 Presidio Ospedale Sant'Anna, Turin	3	100%	100%	100%	0%
IT07 Fondazione IRCCS Milano	28	100%	100%	100%	94%
Total	828	97%	93%	98%	90%

Site	Randomisations up until 22- February 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
IT08 Ospedale del Ponte, Varese	4	100%	n/a	n/a	n/a
IT09 Fondaz. Policlinico Univ. A Gemelli	2	100%	0%	n/a	n/a
PL01 Medical Center UJASTEK Krakow	24	100%	100%	100%	88%
PL03 Specialist Hospital No. 2 Bytow	3	100%	n/a	100%	100%
PL04 Poznan Univ. of Medical Sciences	23	91%	100%	100%	88%
PL07 Warsaw Univ. Medical Sciences	4	75%	50%	0%	0%
PL08 Szpital Uniwersytecki, Krakow	4	100%	100%	n/a	n/a
TR01 Gazi University Hospital	8	100%	100%	100%	100%
TR02 Marmara University Hospital	18	100%	100%	100%	100%
TR03 Uludag University Hospital	17	94%	100%	100%	100%
Total	828	97%	93%	98%	90%

Site	Randomisations up until 22- February 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
TR04 Kanuni Sultan Hospital	11	100%	100%	100%	100%
TR05 Bilkent, Ankara City Hospital	29	93%	96%	95%	71%
TR06 Basaksehir City Hospital	1	100%	n/a	n/a	n/a
US02 Loma Linda Univresity Hospital	16	100%	100%	100%	25%
US03 University of Utah, Div. Neonatology	11	100%	100%	100%	100%
US04 UT Southwestern Medical Center	1	100%	0%	n/a	n/a
Total	828	97%	93%	98%	90%

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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.

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