SafeBoosC III Data completion report

14-October 2021

The data shown below is based on all registered data entries in OpenClinica on SafeBoosC III trial participants, up until 14th of October 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 14-October 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	**18**	**100%**	**100%**	**100%**	**100%**
BE01 Univ. Hospital Leuven	**28**	**100%**	**100%**	**96%**	**96%**
BE02 AZ St. Jain Univ. Hosp. Bruges	**13**	**92%**	**100%**	**90%**	**80%**

Site	Randomisations up until 14-October 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	12	58%	33%	100%	86%
BE04 CHU Tivoli Hospital	18	87%	86%	100%	100%
BE06 Liege Rocourt Hospital	22	90%	100%	100%	47%
CH01 University Hospital Zürich	37	100%	100%	100%	69%
CH03 University Hospital Lucern	41	97%	85%	100%	90%
CH04 University Hospital Geneva	11	100%	100%	89%	0%
CH05 Lausanne University Hospital	20	100%	89%	100%	0%
CN01 Children's Hospital, Zheijang Univ.	6	100%	100%	100%	75%
CN02 Children's Hospital, Fudan	35	100%	100%	100%	100%
Total	1431	98%	96%	98%	89%

Site	Randomisations up until 14-October 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
CN03 Hainan Women and Children's Medical Center	5	100%	100%	100%	100%
CN04 Guangzhou Women and Children's Hospital	2	0%	0%	n/a	n/a
CN05 Longgang Distr. Centr. Hosp. Shenzen	10	100%	100%	100%	100%
CN06 Xiamen Children's Hospital	4	100%	100%	100%	100%
CN07 The People's Hospital of Dehong	3	100%	100%	100%	33%
CN08 Maternal and Child Health Hosp. Quangxi	7	100%	100%	100%	57%
CZ01 The Institute for the Care of Mother and Child	63	100%	100%	100%	98%
CZ02 Motol Univ. Hospital	8	88%	100%	100%	100%
DE01 University Hospital Freiburg	13	100%	100%	100%	100%
Total	1431	98%	96%	98%	89%

Site	Randomisations up until 14-October 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
DK01 Rigshospitalet	97	100%	100%	99%	99%
DK04 Aalborg University Hospital	19	100%	100%	100%	100%
DK18 Aarhus University Hospital	19	100%	100%	100%	63%
DK30 Odense University Hospital	12	91%	0%	89%	56%
ES01 La Paz University Hospital	74	100%	100%	99%	96%
ES02 Hospital Clinic de Barcelona (Maternitat)	54	100%	100%	100%	100%
ES03 University Hospital 12 de Octubre	64	100%	100%	98%	98%
ES05 Hospital de Sant Joan de Deu	32	100%	93%	100%	100%
ES06 H. U. Puerta del Mar	20	100%	100%	100%	93%
ES08 Hospital Clinico San Carlos	35	100%	100%	100%	100%
Total	1431	98%	96%	98%	89%

Site	Randomisations up until 14-October 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
ES09 H. U. Marques de Valdecilla	21	100%	100%	88%	65%
ES10 Virgen de las Nieves	14	100%	100%	100%	100%
ES11 H. Univ. Juan XXIII Tarragona	17	69%	89%	100%	100%
ES12 Hospital Miguel Servet	1	0%	n/a	n/a	n/a
ES13 Hospital de Cruces	4	100%	50%	50%	100%
GR01 Alexandra Hospital, Athens	14	100%	100%	100%	100%
GR02 Ippokrateion Hospital of Thessalonikki	34	100%	100%	100%	97%
GR03 Univ of Patras, General Hospital	12	100%	100%	100%	100%
GR04 Univ Hospital of Heraklion	8	100%	100%	100%	100%
IE01 Univ. College Cork	20	100%	100%	94%	100%
Total	1431	98%	96%	98%	89%

Site	Randomisations up until 14-October 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
IE02 Rotunda Hospital Dublin	8	100%	100%	100%	0%
IE03 Coombe Univ. Hospital	14	93%	71%	100%	0%
IE04 NMH Holles St	11	90%	80%	100%	0%
IN01 St Johns Medical College Hospital, Bangalore	5	100%	100%	100%	100%
IT01 Presidio Ospedale Sant'Anna, Turin	10	90%	83%	100%	100%
IT07 Fondazione IRCCS Milano	41	100%	100%	100%	97%
IT08 Ospedale del Ponte, Varese	7	100%	100%	100%	100%
IT09 Fondaz. Policlinico Univ. A Gemelli	14	100%	100%	100%	100%
NY10 Oslo University Hospital	25	100%	73%	63%	64%
Total	1431	98%	96%	98%	89%

Site	Randomisations up until 14-October 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
PL01 Medical Center UJASTEK Krakow	37	100%	100%	100%	100%
PL02 Wroclaw Medical University	1	100%	n/a	n/a	n/a
PL03 Specialist Hospital No. 2 Bytow	6	100%	100%	100%	100%
PL04 Poznan Univ. of Medical Sciences	33	100%	100%	100%	100%
PL06 Jan Biziel University Hospital	3	0%	50%	n/a	n/a
PL07 Warsaw Univ. Medical Sciences	9	100%	100%	89%	44%
PL08 Szpital Uniwersytecki, Krakow	17	94%	100%	100%	82%
PL12 Centre of Medical Postgraduate Education, Warsaw	4	25%	100%	50%	50%
TR01 Gazi University Hospital	15	93%	88%	100%	100%
Total	1431	98%	96%	98%	89%

Site	Randomisations up until 14-October 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
TR02 Marmara University Hospital	31	100%	100%	100%	100%
TR03 Uludag University Hospital	42	100%	100%	100%	100%
TR04 Kanuni Sultan Hospital	11	100%	100%	100%	100%
TR05 Bilkent, Ankara City Hospital	37	94%	100%	100%	91%
TR06 Basaksehir City Hospital	10	100%	100%	100%	100%
UK08 Royal Hospital for Children, Glasgow	14	100%	100%	100%	67%
UK09 NHS Lanarkshire Hospital	7	100%	100%	100%	75%
US02 Loma Linda Univresity Hospital	33	100%	100%	100%	93%
US03 University of Utah, Div. Neonatology	24	100%	100%	100%	100%
US04 UT Southwestern Medical Center	6	100%	100%	67%	50%
Total	1431	98%	96%	98%	89%

Site	Randomisations up until 14-October 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
US05 Washington Univ. Hospital	**10**	**100%**	**100%**	**67%**	**0%**
Total	**1431**	**98%**	**96%**	**98%**	**89%**

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.

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.

Copenhagen Trial Unit, Gorm Greisen and Mathias Lühr Hansen