

SOP: Manual for data entries in OpenClinica

Version	Author(s)	Date	Changes	Approved by
1.0	Mathias Lühr Hansen Caroline Kamp Johanne Juul Petersen	14.02.25	Initial version	Steering Committee
1.1	Mathias Lühr Hansen	22.04.25	Added definition of latest time points for data entries	Caroline Kamp
1.2	Johanne Juul Petersen	17.09.25	Clarified time points for data entries	Caroline Kamp

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Introduction

This Standard Operating Procedure (SOP) provides guidance on entering data for SafeBoosC-IIIv in OpenClinica. Information on how to log in, screen, and randomise infants are provided in the ‘SOP: Screening and randomisation’ (see www.safeboosc.eu under ‘SOPs and templates’).

When to enter data in OpenClinica

In step one of SafeBoosC-IIIv, data entry must be done at two time points after randomisation:

- 1) 28 days after birth: ‘End of monitoring’ and ‘Serious Adverse Reactions (SARs)’ forms.
- 2) 90 days after randomisation: ‘90 days follow-up’ form.

Since SafeBoosc-IIIv is a pragmatic trial with limited resources and time allocated to the principal investigators, it is unrealistic to expect data entry forms to be completed at the exact time points described above. Therefore, principal investigators may postpone data entries up to ten days from the time point above, i.e., ‘End of monitoring’ and ‘SARs’ forms should be completed no later than 38 days after birth and the ‘90 days follow-up’ form no later than 100 days from randomisation.

End of monitoring: ‘End of monitoring’ form and ‘Serious Adverse Reactions’ form

Twenty-eight days after birth, an e-mail reminder to complete the ‘End of monitoring’ form will be sent. If an infant has been randomised to the cerebral oximetry group, an e-mail reminder to complete the ‘SARs’ form will also be sent.

If the infant deceased or was extubated prior to 28 days after birth, the ‘End of monitoring’ form (and ‘SARs’ form for cerebral oximetry group) may be completed at the time of death or time of extubation.

90 days after randomisation: ‘90 days follow-up’ form

90 days after randomisation, an e-mail reminder to complete the ‘90 days follow-up form’ will be sent. If the infant deceased prior to 90 days after randomisation, the form may be completed at the time of death.

How to enter data in OpenClinica

1. Go to <https://safeboosciiv.ctu.dk/OpenClinica/>. Below we will use Site DK01 test site and participant DK01_1029.

SafeBoosC-IIIiv Sandbox : DK01 test site (DK01) mathias.luehr.hansen@regionh.dk (Clinical Research Coordinator) en | Log Out

Front page | [Change Site](#) | Log Out Participant Label Go

Participant List for DK01 test site

For Screening click here: [Go to Patient Screening](#)

[Randomisations and Transfers View](#) [Remove Form Lock](#) [Site User Handling](#)

Participant Label	Name	NIN	Enrolment Date	Screening	Randomisation	Serious Adverse Reactions	End of monitoring	90 days follow-up
DK01_1030			12-01-2025					
DK01_1029			12-01-2025					
DK01_1028			10-01-2025					
DK01_1027			09-01-2025					
DK01_1026			09-01-2025					
DK01_1025			09-01-2025					
DK01_1024			09-01-2025					
DK01_1023			09-01-2025					

2. Press the relevant Participant ID.

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Participant Label	Name	NIN	Enrolment Date	Screening	Randomisation	Serious Adverse Reactions	End of monitoring	90 days follow-up
DK01_1030			12-01-2025					
DK01_1029			12-01-2025					
DK01_1028			10-01-2025					
DK01_1027			09-01-2025					
DK01_1026			09-01-2025					
DK01_1025			09-01-2025					
DK01_1024			09-01-2025					
DK01_1023			09-01-2025					

3. In 'Participant Details' press 'Click here to enter data' for the relevant Case Report Form.

Participant Details**ID: DK01_1029****NIN:****Name:**

				Find
Event name	Start Date	End Date	Case Report Forms	
Screening	12-01-2025 21:09		Screening	☒ Click here for Administrative Edit Click here to view data (read o
Randomisation	12-01-2025 21:10	12-01-2025 21:11	Randomisation	☒ Click here for Administrative Edit Click here to view data (read o
Serious Adverse Reactions	12-01-2025 21:11		Serious Adverse Reactions	☐ Click here to enter data Click here to view data (read only)
End of monitoring	09-02-2025 21:11		End of monitoring	☐ Click here to enter data Click here to view data (read only)
90 days follow-up	12-04-2025 21:11		90 days follow-up	☐ Click here to enter data Click here to view data (read only)

End of monitoring data entries

1. Press 'Click here to enter data' in the 'End of monitoring' form. Small differences in this form exist depending on group allocation. For infants randomised to the cerebral oximetry group, additional questions related to cerebral oximetry monitoring are included:

End of Monitoring		
Support: mail, phone: +45 2032 4108		
E01	Gestational age	28+5 (weeks+days) [info]
E02	Birth weight	1000 (grams)
E03	Singleton or multiple birth?	☒ Singleton

Cerebral oximetry (experimental) group		
E09	Did the newborn undergo cerebral oximetry monitoring during the index (first) episode of mechanical ventilation?	☒ Yes ☐ No
E10	Was cerebral oximetry monitoring discontinued for more than 12 hours straight?	☐ Yes ☒ No
E11	Time from tracheal intubation and start of mechanical ventilation to cerebral oximetry monitoring	7 (hours) [info]
E12	Days from birth to cerebral oximetry monitoring was started	2 (days)
E13	Days of cerebral oximetry monitoring during the first (index) episode of mechanical ventilation	2 (days)
E14	Did clinical staff change the medical management due to cerebral hypoxia?	☒ Yes ☐ No
E14a	Tick one or more interventions:	☒ Volume expansion ☒ Initiation of, or change in vasopressor/inotrope infusion rate ☐ Treatment of PDA ☐ Red blood cell transfusion ☐ FiO2 adjustment ☐ Change in ventilator settings ☐ Other
E15	Reason for termination of cerebral oximetry monitoring	☒ Cardio-pulmonary function has been stabilised ☐ Extubation ☐ Infant exceeded 28 days from birth ☐ Infant deceased ☐ Other
E15a	Was the infant still undergoing invasive mechanical ventilation when cerebral oximetry monitoring was terminated?	☐ Yes ☒ No
E16	Which oximeter device did you use to monitor the infant	☐ INVOS ☐ NIRO ☐ Fore-Sight ☒ Other

2. Once you have filled out all relevant data entries, you will be able to either 'Submit form' or 'Save'. If you press 'Save' instead of 'Submit form', your data entries will be saved, but you will need to complete and submit the form later. If you press 'Submit form', your data entries will be registered, and you will return to the Participant Details page.

Treatment

E19

Did the baby receive surfactant therapy at any time until end of monitoring?

☒ Yes
☐ No

E20

Did the baby receive cardiovascular support at any time until end of monitoring?

☒ Yes
☐ No

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Submit form

Save

Exit (no save)

📄

3. 'Click here to enter data' by the 'End of monitoring' form now appears with a green 'tick' mark and the text 'Click here for Administrative Edit'. If you click on the administrative edit button, you may edit the registered date entries. All changes will automatically be registered.

Participant Details

ID: DK01_1029

NIN:

Name:

Event name	Start Date	End Date	Case Report Forms	
Screening	12-01-2025 21:09		Screening	☒ Click here for Administrative Edit Click here to view data (read o
Randomisation	12-01-2025 21:10	12-01-2025 21:11	Randomisation	☒ Click here for Administrative Edit Click here to view data (read o
Serious Adverse Reactions	12-01-2025 21:11		Serious Adverse Reactions	Click here to enter data Click here to view data (read only)
End of monitoring	09-02-2025 21:11		End of monitoring	☒ Click here for Administrative Edit Click here to view data (read o
90 days follow-up	12-04-2025 21:11		90 days follow-up	Click here to enter data Click here to view data (read only)

Serious Adverse Reactions (SARs) data entries

For all infants randomised to the cerebral oximetry group, a 'SARs' form is available (see above).

Only SARs occurred during cerebral oximetry monitoring should be registered in this form.

1. Press 'Click here to enter data' in the 'SARs' form. Remember to write a short description of the SAR and consequences for the infant and the treatment.
2. Press 'Add' if you wish to add additional SARs.

Serious Adverse Reactions			
Support: mail, phone: +45 2032 4108			
Date of severe adverse reaction (SAR)	SAR specification	Short description of SAR required for central monitoring and trial report	
	☐ Severe skin damage ☐ Critical displacement of endotracheal tube threatening the life of the baby ☐ Critical displacement of endovascular line threatening the life of the baby ☐ Mismanagement while trying to improve respiratory status ☐ Mismanagement while trying to improve cardiovascular status ☐ Clinical mismanagement while trying to improve oxygen transport		X
Add			
☐ No SARs were registered up until end of monitoring			

3. If end of monitoring has not yet been reached, press 'Save'. You will then exit the form and may add additional SARs and/or submit the form later. When end of monitoring has been reached, press 'Submit form'. If no SARs occurred, tick the box 'No SARs were registered up until end of monitoring' and submit the form.

Serious Adverse Reactions Support: mail, phone: +45 2032 4108		
Date of severe adverse reaction (SAR)	SAR specification	Comment
13-01-2025	☒ Severe skin damage ☐ Critical displacement of endotracheal tube threatening the life of the baby ☐ Critical displacement of endovascular line threatening the life of the baby ☐ Mismanagement while trying to improve respiratory status ☐ Mismanagement while trying to improve cardiovascular status ☐ Clinical mismanagement while trying to improve oxygen transport	Requiring termination of cerebral oximetry monitoring and treatment of severe pressure mark.
13-01-2025	☐ Severe skin damage ☒ Critical displacement of endotracheal tube threatening the life of the baby ☐ Critical displacement of endovascular line threatening the life of the baby ☐ Mismanagement while trying to improve respiratory status ☐ Mismanagement while trying to improve cardiovascular status ☐ Clinical mismanagement while trying to improve oxygen transport	While repositioning the cerebral oximetry sensor, the ETT was displaced.
Add		
☐ No SARs were registered up until end of monitoring		
Return to top Submit form Save Exit (no save)		

90 days follow-up data entries

1. Press 'Click here to enter data' in the '90 days follow-up' form. When completing primary outcome data entries, use data from the primary outcome log. For more details on primary outcome assessment and data entry, see 'SOP: Assessment of the primary outcome' (www.safeboosc.eu under 'SOPs and templates').
2. The process of saving, submitting, and editing data entries is identical to the process described under 'End of monitoring data entries':

Data to be reported at 90 days after randomisation		
Support: mail, phone: +45 2032 4108		
F01	Did the infant die within 90 days of randomisation?	☐ Yes ☒ No
F02	Follow-up date	14-05-2025 Calendar
<i>Calculated</i> You have registered that the child did not die within 90 days from randomisation. Therefore, the follow-up date is 14-05-2025, which is 90 days from randomisation. Answers below must be based on data up until the follow-up date		
F03	Did the infant suffer from any major malformation or congenital disease?	☐ Yes ☒ No
F04	Beyond the first episode of invasive mechanical ventilation, was the neonate reintubated and mechanically ventilated?	☐ Yes ☒ No
F05	Did the neonate receive treatment for patent ductus arteriosus (medical or surgical)?	☐ Yes ☒ No
F06	What was the last registered weight of the infant before follow-up?	500 (grams)
F07	Date of last weighing	13-02-2025 Calendar
Primary outcome		
F08	Hospital-free days within 90 days of randomisation based on review of health care records	0 (days) [info]
F09	Additional days in hospital (not reported in clinical records) based on parental information	0 (days) [info]
F10	Total number of hospital-free days based on clinical records and parental information	0 (days) [info]
Secondary and exploratory outcomes		