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

Content

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.

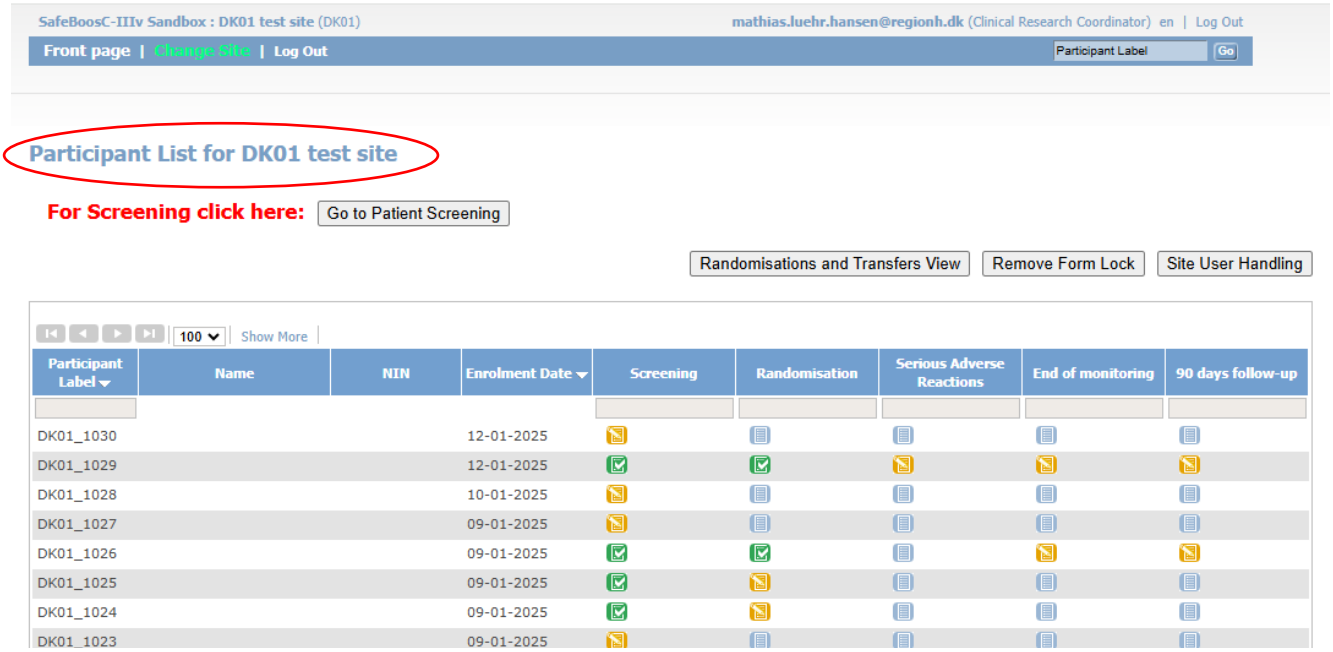
If the infant deceased or was extubated prior to 28 days after birth, the 'End of monitoring' form (and 'SARs' form for cerebral oximetry group) may be completed at the time of death or time of extubation.

90 days after randomisation: '90 days follow-up' form

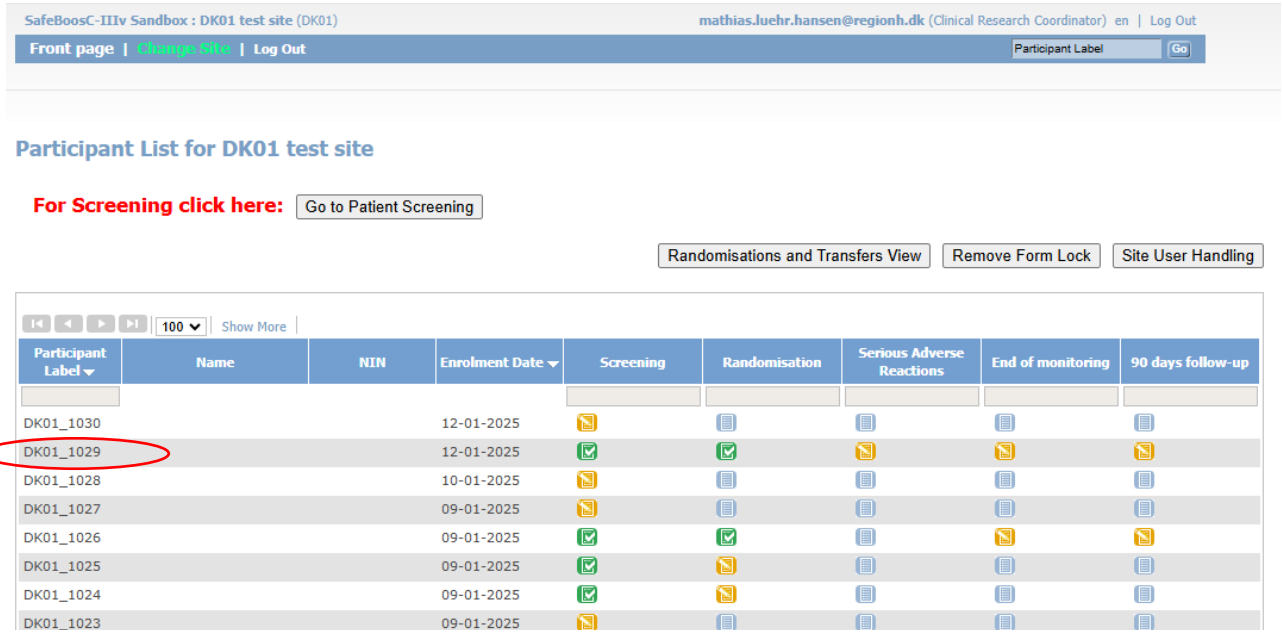
90 days after randomisation, an e-mail reminder to complete the '90 days follow-up form' will be sent. If the infant deceased prior to 90 days after randomisation, the form may be completed at the time time of death.

How to enter data in OpenClinica

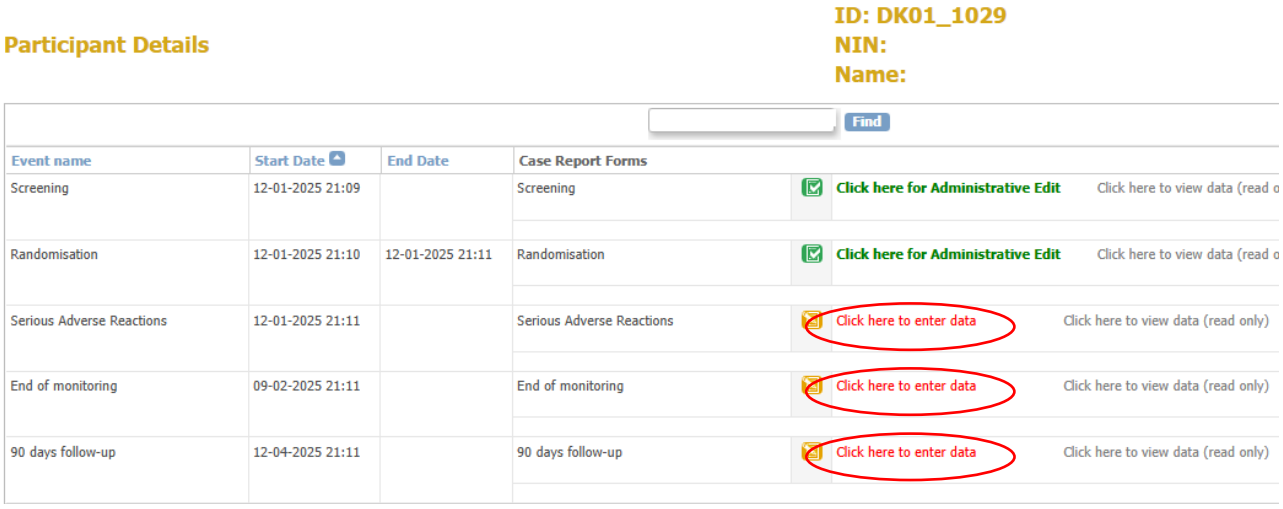
1. Go to https://safeboosciiiv.ctu.dk/OpenClinica/. Below we will use Site DK01 test site and participant DK01_1029.



2. Press the relevant Participant ID.

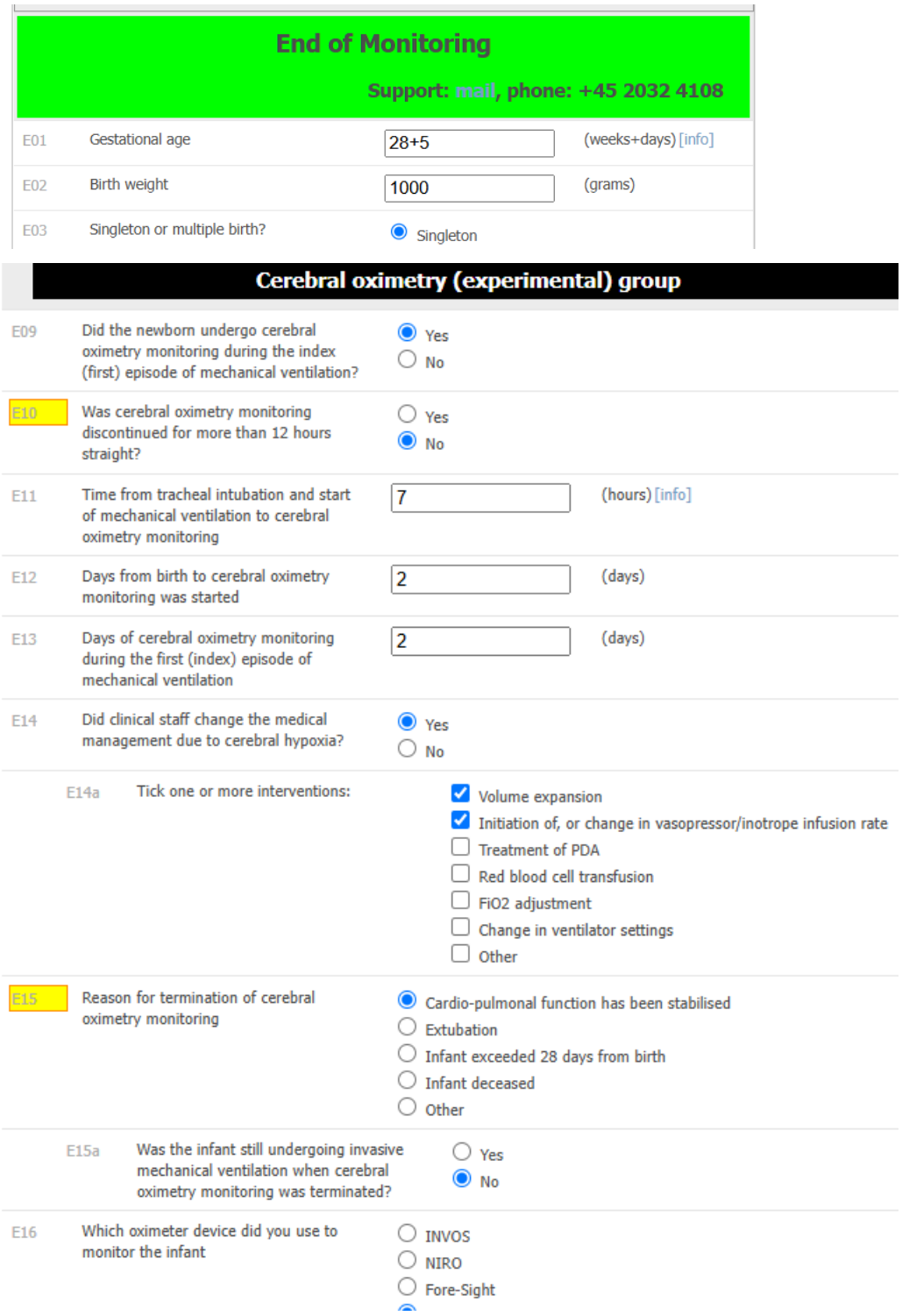


3. In ‘Participant Details’ press ‘Click here to enter data’ for the relevant Case Report Form.

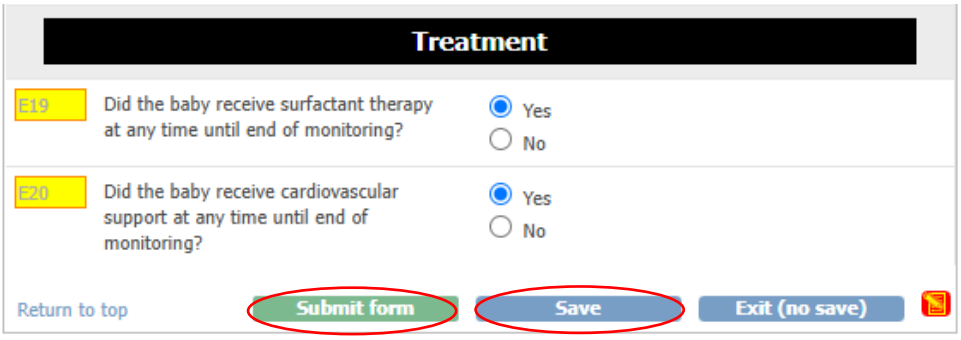


End of monitoring data entries

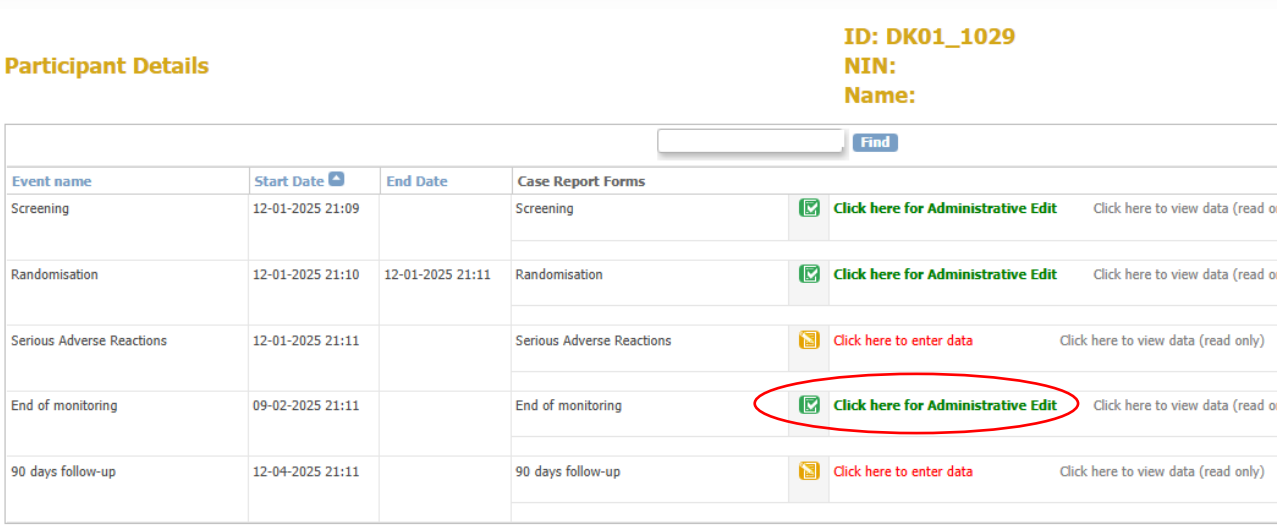
1. Press 'Click here to enter data' in the 'End of monitoring' form. Small differences in this form exist depending on group allocation. For infants randomised to the cerebral oximetry group, additional questions related to cerebral oximetry monitoring are included:



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.



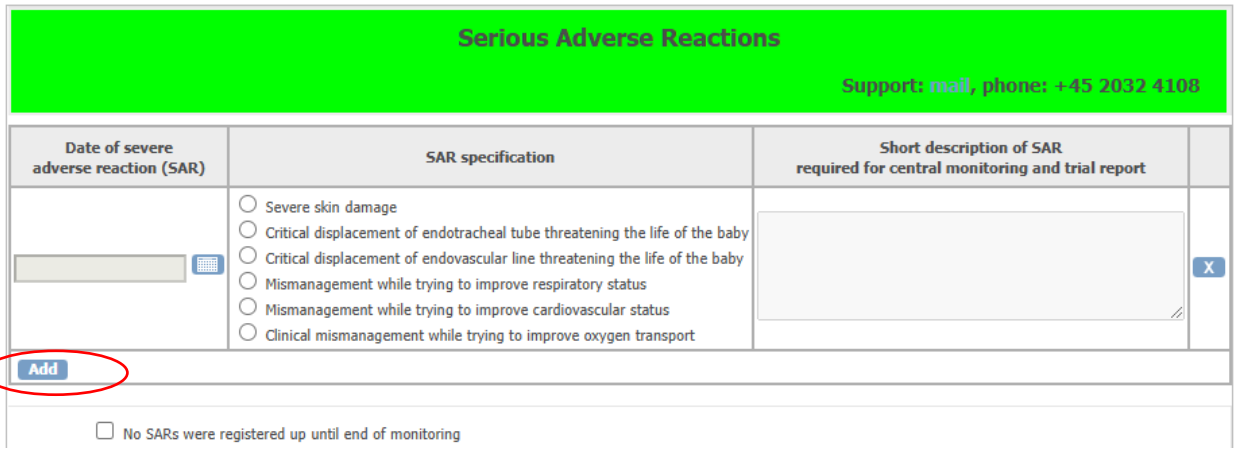
3. ‘Click here to enter data’ by the ‘End of monitoring’ form now appears with a green ‘tick’ mark and the text ‘Click here for Administrative Edit’. If you click on the administrative edit button, you may edit the registered date entries. All changes will automatically be registered.



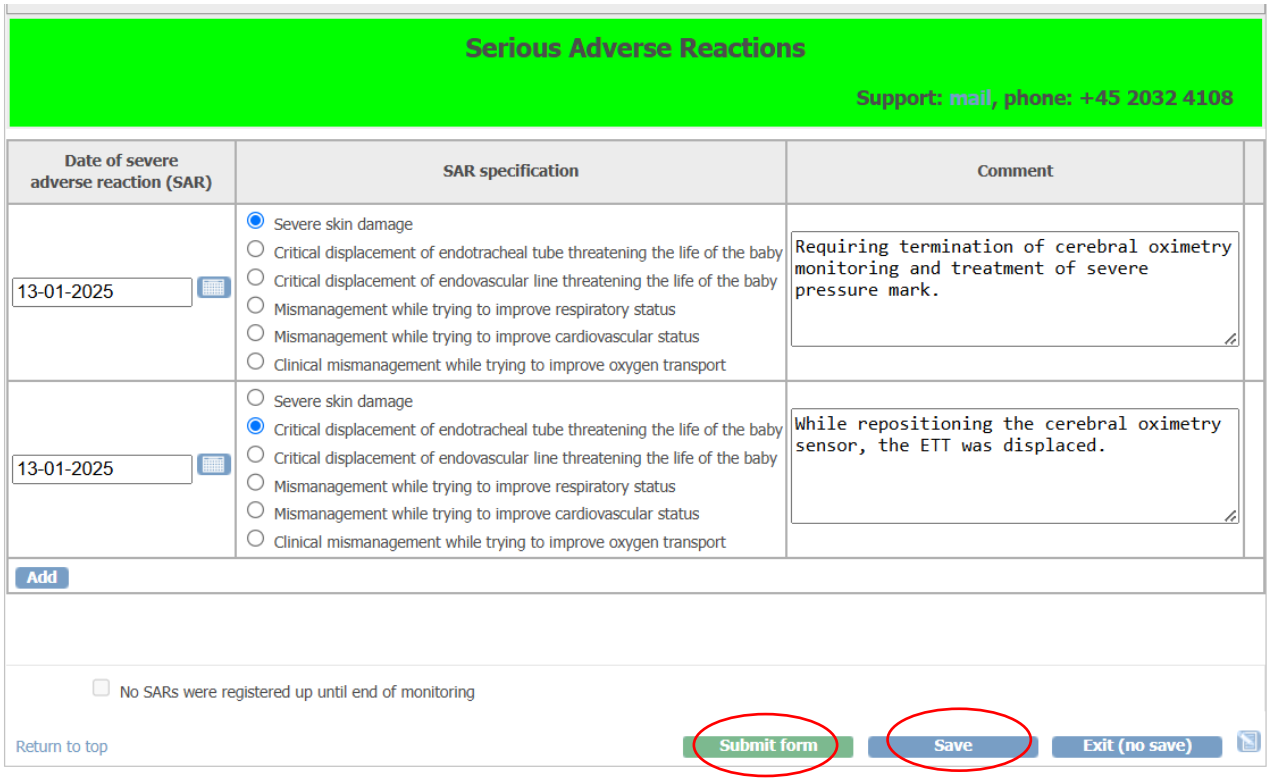
Serious Adverse Reactions (SARs) data entries

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.



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':