

SOP: manual for OpenClinica

Version	Author	Changes	Approved by
1.0	Mathias Lühr Hansen	Initial version	Janus Engstrøm Gorm Greisen

Content

- 1.0 How to log in to OpenClinica**
 - 1.1 If you forgot your password**
- 2.0 How to randomise a baby**
- 3.0 How and when to perform additional data entries**
 - 3.1 End of monitoring**
 - 3.2 Follow-up**
- 4.0 When to access the Severe Adverse Reactions (SARs) form**
- 5.0 Blinded assessment of cranial ultrasound scans and data entries**
- 6.0 What to do if you experience technical problems**

1.0 How to log in to OpenClinica

Go to <https://safeboosc.ctu.dk/OpenClinica>

Your username is the e-mail address that you provided to mathias.safeboosc@gmail.com and the password has been sent directly to you in an e-mail. When entering OpenClinica for the first time, you will be prompted to create a new password. The password must be at least 8 characters.



1.1 If you forgot your password

If you have forgotten your password, you can either use the "Forgot Password?" link from the log in page of OpenClinica. By providing your username, the system will generate a temporary random password and send it to you in an email. Alternatively, you can contact mathias.safeboosc@gmail.com to request a password reset. In this case, your password will be reset to a temporary default password. In both cases, you are requested to change the password upon log in.

2.0 How to randomise a baby

1) Click the 'Go to Patient Randomisation' button (figure 1)

SafeBoosC-III : DK01 Danish Sandbox Site (DK01) mathias.luhr.hansen@gmail.com (Clinical Research Coordinator) en | Log Out

Front page | Log Out Trial Participant ID [] Go

Alerts & Messages
Your expired password has been reset successfully.

Icon Key
Statuses
Not Started
Scheduled
Data Entry Started
Completed

Participant List for DK01 Danish Sandbox Site

Click here to perform Randomisation: **Go to Patient Randomisation** For Site overview click here: Site Overview

Trial Participant ID	Enrolment Date	Randomisation	End of monitoring (72 hours of age)	Severe Adverse Reactions	Follow-up (36 weeks PMA or discharge to home)	Blinded follow-up form (36 weeks PMA or discharge to home)	Actions
DK01034	10-05-2019						Click here to enter data
DK01033	10-05-2019						Click here to enter data
DK01032	10-05-2019						Click here to enter data
DK01031	10-05-2019						Click here to enter data
DK01030	10-05-2019						Click here to enter data

Figure 1.

2) Fill in the randomisation form (figure 2)

Randomisation

Randomi... (0/10)

Title: Randomisation

Exit (no save)

Randomisation

R01 Birth date (dd-mm-yyyy)

R02 Birth time (hh:mm)

Inclusion criteria

R03 Neonate born more than 12 weeks preterm (GA up to 27+6) ☐ Yes ☐ No [\[info\]](#)

R04 Which consent method has been used Please select...

Exclusion criteria

R05 Decision not to conduct full life support ☐ Yes ☐ No

R06 Not possible to place cerebral NIRS oximeter within six hours of birth ☐ Yes ☐ No

Stratification and allocation

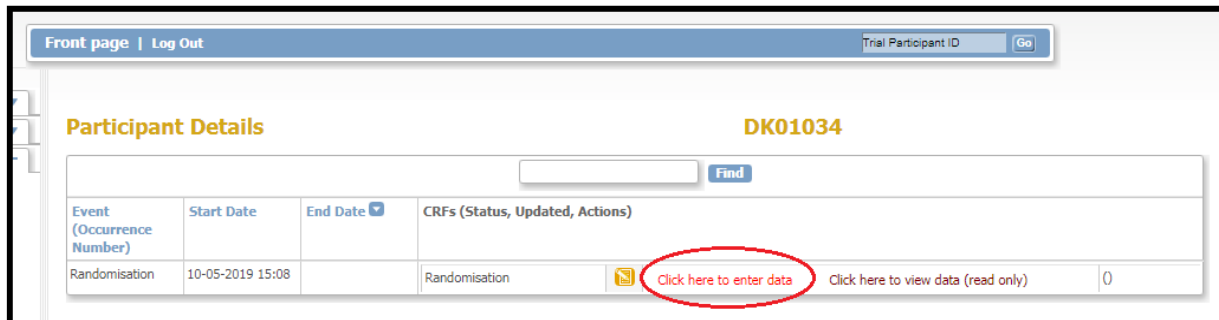
Form is incomplete.

Return to top Save Exit (no save)

Figure 2.

If you press 'Save', all entries will be saved, and you will be able to complete the randomisation later, by pressing 'click here to enter data' on the trial participant overview (figure 1) and then 'Click here to enter data' next to the randomisation form (figure 3).

Note: To be in accordance with protocol any randomisation should be completed within six hours from birth.



Front page | Log Out Trial Participant ID Go

Participant Details DK01034

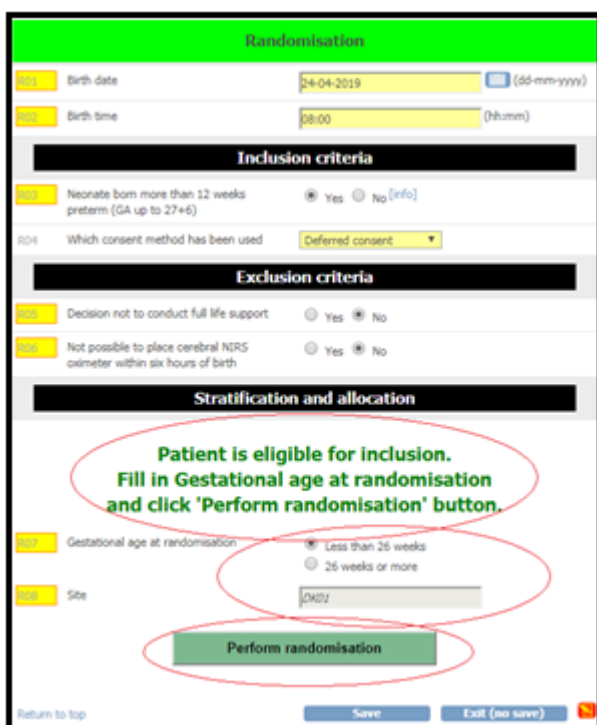
Find

Event (Occurrence Number)	Start Date	End Date	CRFs (Status, Updated, Actions)
Randomisation	10-05-2019 15:08		Randomisation Click here to enter data Click here to view data (read only) 0

Figure 3.

3) Perform randomisation

If the baby, based on your data entries, is eligible for randomisation, you will be asked to 'fill in gestational age at randomisation and click 'Perform randomisation'' (figure 4). The Site field is automatically filled and is not editable.



Randomisation

Birth date 24-04-2019 (dd-mm-yyyy)

Birth time 08:00 (hh:mm)

Inclusion criteria

Neonate born more than 12 weeks preterm (GA up to 27+6) ☒ Yes ☐ No [info]

Which consent method has been used Deferred consent

Exclusion criteria

Decision not to conduct full life support ☐ Yes ☒ No

Not possible to place cerebral NIRS oximeter within six hours of birth ☐ Yes ☒ No

Stratification and allocation

Patient is eligible for inclusion. Fill in Gestational age at randomisation and click 'Perform randomisation' button.

Gestational age at randomisation ☒ Less than 26 weeks ☐ 26 weeks or more

Site DK01

Perform randomisation

Return to top Save Exit (no save)

Figure 4.

If the baby, based on your data entries, is ineligible for randomisation, it will also be stated (figure 5). In this case, it will not be possible to click 'Submit form' or 'Save'.

The screenshot shows a web form titled 'Randomisation'. At the top, there is a tab labeled 'Randomi...(0/10)' and a button 'Exit (no save)'. Below the title bar is a green header with the word 'Randomisation'. The form contains several input fields: 'Birth date' (30-04-2019) and 'Birth time' (11:00). Below these are sections for 'Inclusion criteria' and 'Exclusion criteria'. Under 'Inclusion criteria', there is a radio button for 'Yes' selected for 'Neonate born more than 12 weeks preterm (GA up to 27+6)', and a dropdown menu for 'Which consent method has been used' set to 'Deferred consent'. Under 'Exclusion criteria', there are two radio buttons: 'Decision not to conduct full life support' (Yes selected) and 'Not possible to place cerebral NIRS oximeter within six hours of birth' (No selected). Below the exclusion criteria is a section titled 'Stratification and allocation' which contains a red message: 'The patient fulfils one or more exclusion criteria. Thus, this patient cannot be randomised. If this is correct, click 'Exit' button to leave this form.' At the bottom, there is a 'Return to top' link and another 'Exit (no save)' button.

Figure 5..

4) Recording of Participant ID

The result from the randomisation will pop-up, including a 'Participant ID':

The screenshot shows a pop-up message box with a blue header 'Randomisation complete'. Below the header, it says 'Participant ID: DK01008'. In the center, it says 'Participant randomised to: Control group' in pink text. At the bottom, there are two buttons: 'Close' and 'Print this message'.

Please record the 'Participant ID' next to the baby's Personal Identifier in the Participant Inclusion List in the Trial Master File, record the randomisation group in the baby's clinical records. When a baby has been randomised, an e-mail will be sent to the principal investigator and any other clinicians who is signed up to receive such information. This e-mail contains the baby's Participant ID and the allocation treatment group.

If you wish to find the randomisation outcome of a specific baby later on, press ‘click here to enter data’ at the relevant Participant ID at the participant list (figure 6).

Participant List for DK01 Danish Sandbox Site

Click here to perform Randomisation: [Go to Patient Randomisation](#) **For Site overview click here:** [Site Overview](#)

Trial Participant ID	Enrolment Date	Randomisation	End of monitoring (72 hours of age)	Severe Adverse Reactions	Follow-up (36 weeks PMA or discharge to home)	Blinded follow-up form (36 weeks PMA or discharge to home)	Actions
DK01034	10-05-2019	☒	☐	☐	☐	☐	Click here to enter data
DK01033	10-05-2019	☒	☒	☐	☒	☐	Click here to enter data

Figure 6.

Followed by ‘Click here to view data (read only)’. You will then be able to see the randomisation group in the bottom of the visible randomisation form (figure 7).

Participant Details **DK01034**

[Find](#)

Event (Occurrence Number)	Start Date	End Date	CRFs (Status, Updated, Actions)
Randomisation	10-05-2019 15:08	10-05-2019 18:05	Randomisation ☒ Administrative edit Click here to view data (read only) 10-05-2019 (mathias.luhr.hansen@gmail.com)
End of monitoring (72 hours of age)	10-05-2019 18:05		End of monitoring (72 hours of age) ☐ Click here to enter data Click here to view data (read only) 0
Severe Adverse Reactions	10-05-2019 18:05		Severe Adverse Reactions ☐ Click here to enter data Click here to view data (read only)
Follow-up (36 weeks PMA or discharge to home)	10-05-2019 18:05		Follow-up (36 weeks PMA or discharge to home) ☐ Click here to enter data Click here to view data (read only) 0

R06 Not possible to place cerebral NIRS oximeter within six hours of birth ☐ Yes ☒ No

Stratification and allocation

R07 Gestational age at randomisation ☒ Less than 26 weeks ☐ 26 weeks or more

R08 Site

R09 Randomisation group

R10 Randomisation date and time

Figure 7 (two images).

3.0 When and how to perform additional data entries

After randomisation, additional data entries for the baby must be done at 1) End of monitoring (72 hours of age) and 2) follow-up (36 weeks postmenstrual age or discharge home).

- 1) Choose the relevant baby for data entry by using the Participant ID and press click here to enter data (figure 6).
- 2) Press ‘Click here to enter data’ at the relevant form (figure 8)

Event (Occurrence Number)	Start Date	End Date	CRFs (Status, Updated, Actions)			
Randomisation	24-04-2019 08:27	24-04-2019 08:30	Randomisation		Administrative edit	Click here to view data (read only)
End of monitoring (72 hours of age)	24-04-2019 08:30		End of monitoring (72 hours of age)		Click here to enter data	Click here to view data (read only)
Severe Adverse Reactions	24-04-2019 08:30		Severe Adverse Reactions		Click here to enter data	Click here to view data (read only)
Follow-up (36 weeks PMA or discharge to home)	24-04-2019 08:30		Follow-up (36 weeks PMA or discharge to home)		Click here to enter data	Click here to view data (read only)

Figure 8.

3.1 End of monitoring (72 hours of age)

1) Fill in the End of monitoring form (figure 9)

Note that this form is automatically adapted to the allocated randomisation outcome, so slight differences exist regarding NIRS monitoring.

Endofmo...(7/17)

Title: Endofmonitoring

Exit (no save)

End of monitoring (72 hours of age)

E01 Gestational age (weeks+days) [info]

E02 Birth weight (grams)

E03 Apgar score after one minute ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☒ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

E04 Apgar score after five minutes ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☒ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

E05 Gender ☒ Male ☐ Female

NIRS monitoring (control group)

E11 If the baby had cerebral NIRS monitoring despite being in the control group, was information on cerebral oxygenation available for clinical staff? ☐ No ☐ Yes ☒ The infant did not have NIRS monitoring

Parental withdrawal

E12 Did the parents discontinue from the trial? ☐ Yes ☒ No

Treatment

E13 Did the baby receive surfactant therapy? ☒ Yes ☐ No

Return to top Submit form Save Exit (no save)

Figure 9.

2) Submit data entries

As when randomising, you can either press ‘Submit form’, ‘Save’ or Exit (no save). It is possible to edit data entries (except for data entries in the randomisation form) once you have clicked ‘Submit form’, by clicking the ‘Administrative edit’ (figure 10). All changes will be registered automatically. Be aware that it is possible to click ‘Submit form’ before 72 hours of age!

Event (Occurrence Number)	Start Date	End Date	CRFs (Status, Updated, Actions)			
Randomisation	15-04-2019 15:37	15-04-2019 15:55	Randomisation	☒	Administrative edit	Click here to view data (read only)
End of monitoring (72 hours of age)	15-04-2019 15:55		End of monitoring (72 hours of age)	☒	Administrative edit	Click here to view data (read only)
Severe Adverse Reactions	15-04-2019 15:55		Severe Adverse Reactions	☐	Click here to enter data	Click here to view data (read only)
Follow-up (36 weeks PMA or discharge to home)	15-04-2019 15:55		Follow-up (36 weeks PMA or discharge to home)	☒	Administrative edit	Click here to view data (read only)

Figure 10.

3.2 Follow-up (36 weeks postmenstrual age or discharge home)

1) Fill in the Follow-up form (figure 11)

Please be aware to only use data up until age 36+0 weeks postmenstrual age, or up until the day of discharge to home, if this has happened before the age of 36 weeks postmenstrual age.

The date where the baby is 36+0 weeks postmenstrual age will be stated in the beginning of the follow-up form (figure 11):

Follow-up form (36 weeks PMA or discharge to home)
Only data up till 19-06-2019 14:00 should be used in this form. This date is the calculated 36+0 PMA

F01 Follow-up date

F02 Did the infant suffer from any major congenital anomaly? ☐ Yes ☐ No [\[info\]](#)

F03 Did the infant receive mechanical ventilation? ☐ Yes ☐ No

F04 Did the infant receive treatment for Patent Ductus Arteriosus (medical or surgical)? ☐ Yes ☐ No

F05 What was the last registered weight of the infant before follow-up? (grams)

F06 Date of last weighing

Cranial ultrasound

F07 When has cranial ultrasound been performed? ☐ Early cUS ☐ Late cUS ☐ Both early and late cUS [\[info\]](#)

Bronchopulmonary dysplasia

F08 Did the infant need supplemental oxygen or CPAP requirements at 36 weeks postmenstrual age or discharge to home? ☐ Yes ☐ No [\[info\]](#)

Necrotising enterocolitis (NEC)

F09 Did the infant suffer from necrotising enterocolitis up until 36 weeks postmenstrual age, death or discharge to home? ☐ Yes ☐ No [\[info\]](#)

Retinopathy of prematurity (ROP)

F10 Did the infant suffer from retinopathy of prematurity stage 3 or above up until 36 weeks postmenstrual age, death or discharge to home? ☐ Yes ☐ No

Sepsis

F11 Did the infant suffer from late onset sepsis up until 36 weeks postmenstrual age, death or discharge to home? ☐ Yes ☐ No [\[info\]](#)

Death

F12 Did the infant die before discharge or 36 weeks? ☐ Yes ☐ No

[Return to top](#) [Exit \(no save\)](#) [No](#)

Figure 11.

2) Submit data entries

As when randomising, you can either press 'Submit form', 'Save' or Exit (no save). It is possible to edit data entries (except for data entries in the randomisation form) once you have clicked 'Submit form', by clicking the 'Administrative edit' (figure 10). All changes will be registered automatically.

4.0 When to access the Severe Adverse Reactions (SARs) form

SARs are relevant for babies in the experimental group only, as SARs define prespecified reactions related to the intervention. Only reactions occurring within the first 72 hours of life should be recorded in the SAR form.

1) Press 'Click here to enter data' at the Severe Adverse Reactions' form (figure 8)

2) Fill out the SARs form (figure 12)

Severe Adverse Reactions

SAR (0/4)

Title: SAR

Exit (no save)

Severe Adverse Reactions

Reactions related to NIRS monitoring up till: 13-05-2019 16:00

(1) Date of severe adverse reaction (SAR)	(2) SAR specification	(2a) Specification of mismanagement	(3) Comment
10-05-2019	Severe skin damage = 0		

Add

Return to top

Save Exit (no save)

Figure 12.

When entering the form, you are initially able to report only one SAR. However, if you press 'Add' in the left side, a new bar will be available for SARs reporting.

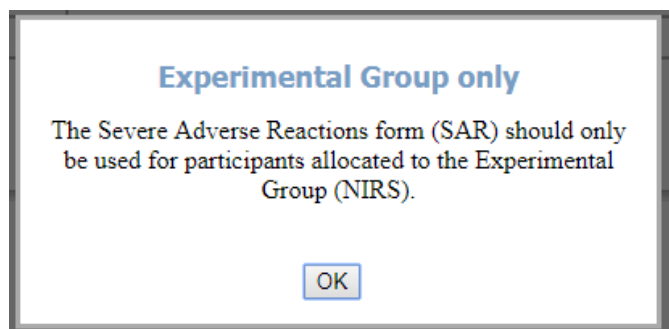
Be aware that 'Specification of mismanagement' should only be registered if you choose a SAR related to clinical mismanagement. The 'Comment' fields are optional.

3) Save the form

As you can register SARs as they occur, this form cannot be submitted. Pressing 'Save' is adequate in any situation for this form (figure 12).

What happens if I try to enter the SARs form for a baby in the control group?

If you do this, you will be met with the following message:



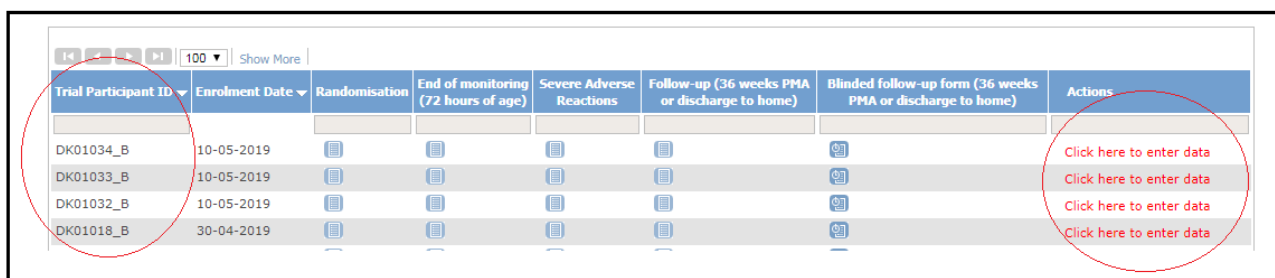
5.0 Blinded assessment of cranial ultrasound scans and data entries

Important: OpenClinica works with a site for non-blinded data entry and a corresponding site for blinded data. The blinded assessor should only access forms regarding the blinded assessment, but for technical reasons, columns for both blinded assessor and non-blinded clinicians are shown on the participant overview on both sites, but the possibility to view and enter data are mutual exclusive.

The assessment of cranial ultrasound scans and data entries on brain injuries must be done by a blinded person, i.e. a person unaware of the baby's group allocation. The blinded assessor will be informed by e-mail (if he/she have signed up to receive notifications), when the baby is 36 weeks of postmenstrual age, including the participant ID for the relevant baby.

The following information is relevant for the blinded assessor only.

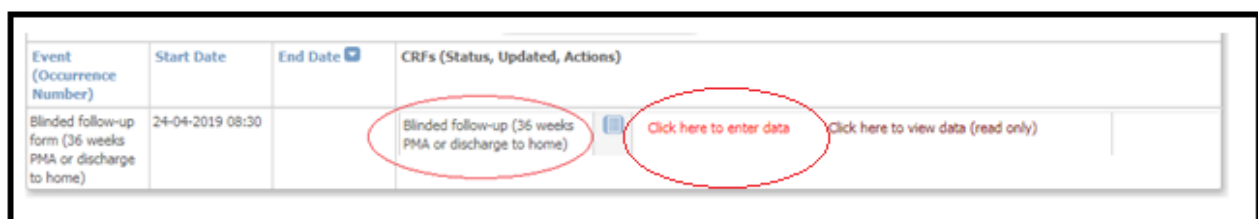
- 1) Choose the relevant baby by using the participant ID from the e-mail and press 'click here to enter data' (figure 13)



Trial Participant ID	Enrolment Date	Randomisation	End of monitoring (72 hours of age)	Severe Adverse Reactions	Follow-up (36 weeks PMA or discharge to home)	Blinded follow-up form (36 weeks PMA or discharge to home)	Actions
DK01034_B	10-05-2019						Click here to enter data
DK01033_B	10-05-2019						Click here to enter data
DK01032_B	10-05-2019						Click here to enter data
DK01018_B	30-04-2019						Click here to enter data

Figure 13.

Only the 'Blinded follow-up form' is available to the blinded assessor (figure 14)



Event (Occurrence Number)	Start Date	End Date	CRFs (Status, Updated, Actions)
Blinded follow-up form (36 weeks PMA or discharge to home)	24-04-2019 08:30		Blinded follow-up (36 weeks PMA or discharge to home) Click here to enter data Click here to view data (read only)

Figure 14

- 2) Press 'click here to enter data' at the blinded follow-up form (figure 14)

3) Fill in the blinded follow-up form and submit data entries (figure 15)

Blinded... (0/5)

Title: BlindedFollowup

Exit (no save)

**Blinded follow-up form
(36 weeks PMA or discharge to home)**

BP01 Did the infant suffer from Intraventricular haemorrhage up until 36 weeks postmenstrual age, death or discharge to home? ☒ Yes ☐ No [info]

BP02 Did the infant suffer from cystic periventricular leukomalacia up until 36 weeks postmenstrual age, death or discharge to home? ☐ Yes ☒ No

BP03 Did the infant suffer from Intraventricular haemorrhage grade 3 or 4 up until 36 weeks postmenstrual age, death or discharge to home? ☐ Yes ☒ No

BP04 Did the infant suffer from cerebellar haemorrhage up until 36 weeks postmenstrual age or discharge to home? ☐ Yes ☒ No

BP05 Did the infant suffer from cerebral atrophy up until 36 weeks postmenstrual age or discharge to home? ☐ Yes ☒ No

Return to top Submit form Save Exit (no save)

Figure 15

You can either press 'Submit form', 'Save' or Exit (no save). It is possible to edit data entries (except for data entries in the randomisation form) once you have clicked 'Submit form', by clicking the 'Administrative edit'. All changes will be registered automatically.

6.0 What to do if you experience technical problems or have questions

OpenClinica is provided to SafeBoosC-III trial by Copenhagen Trial Unit, but it is important that any problem and question is addressed to the Trial Manager which then will contact the service provider, if relevant. The Coordinating Investigator can be contacted at +45 27 14 214 44 or mathias.safeboosc@gmail.com, depending on the urgency.