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

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)

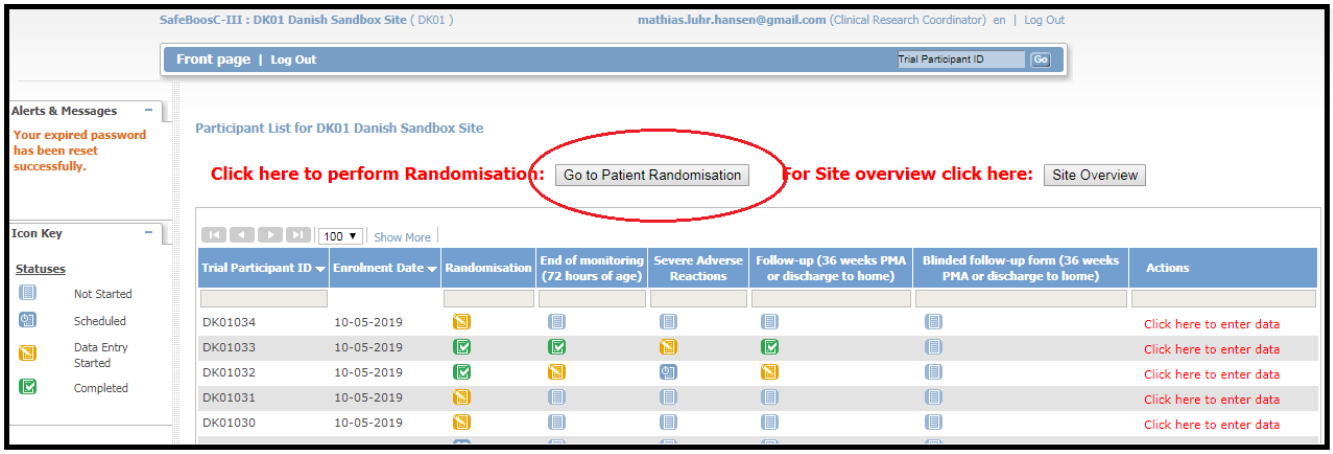


Figure 1.

2) Fill in the randomisation form (figure 2)

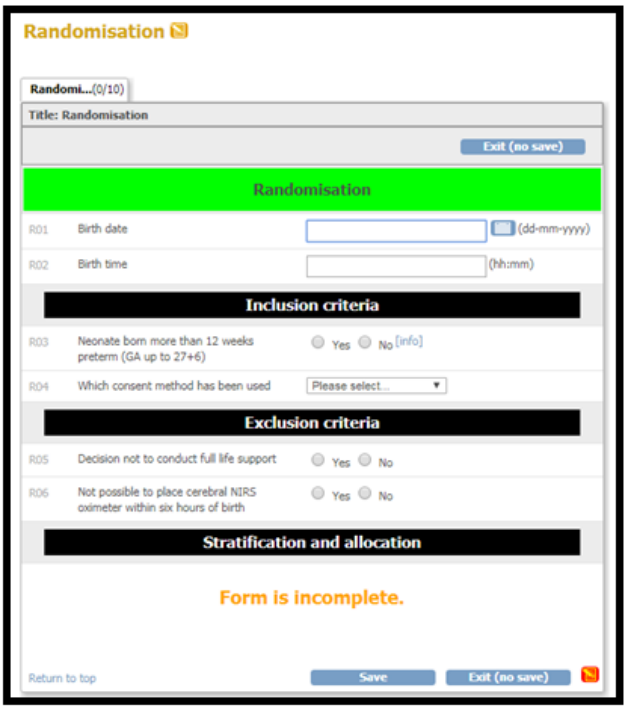


Figure 2.

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.

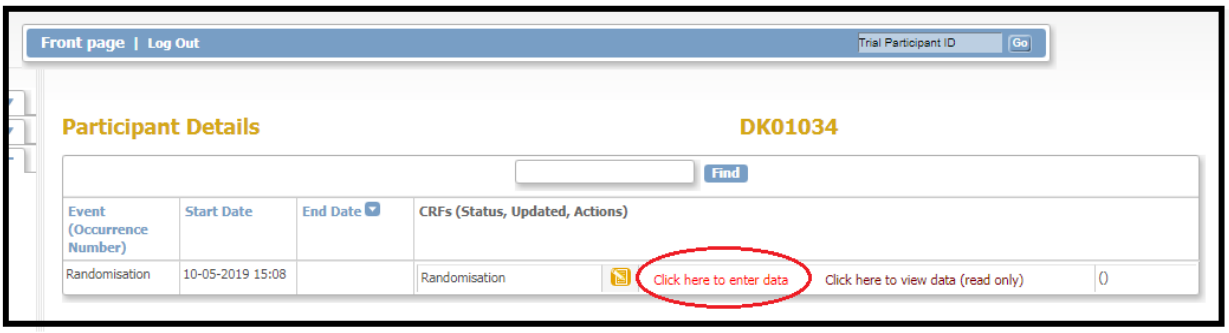


Figure 3.

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.

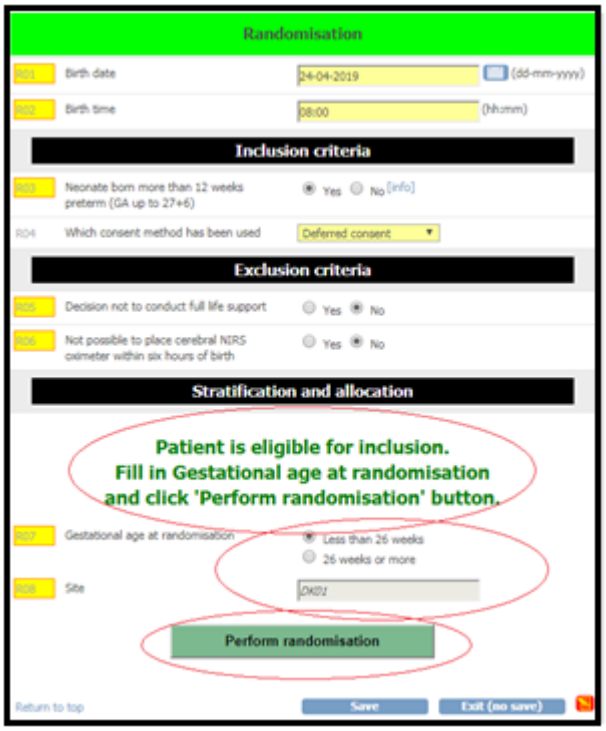


Figure 4.

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'.

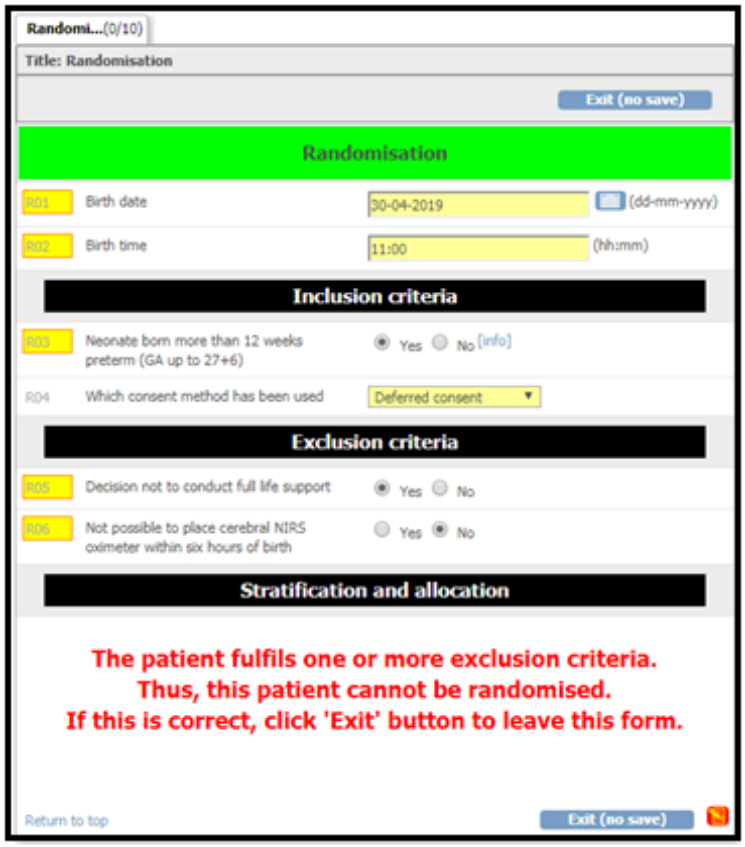


Figure 5..

4) Recording of Participant ID

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

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).

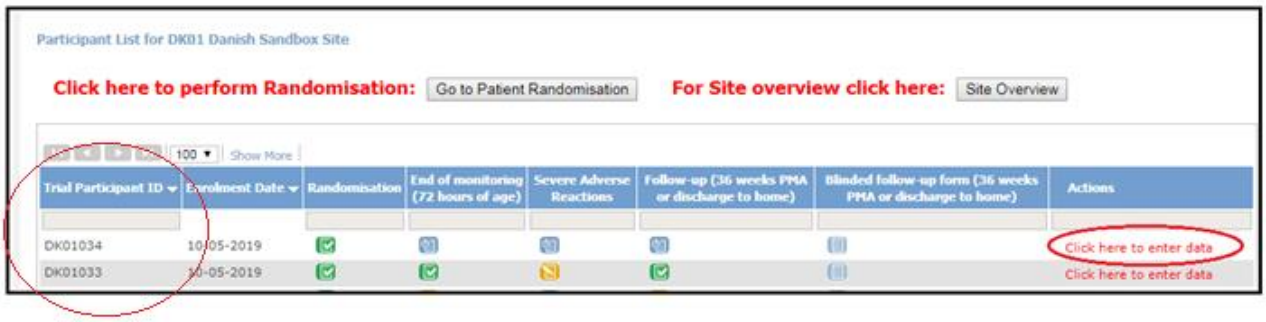
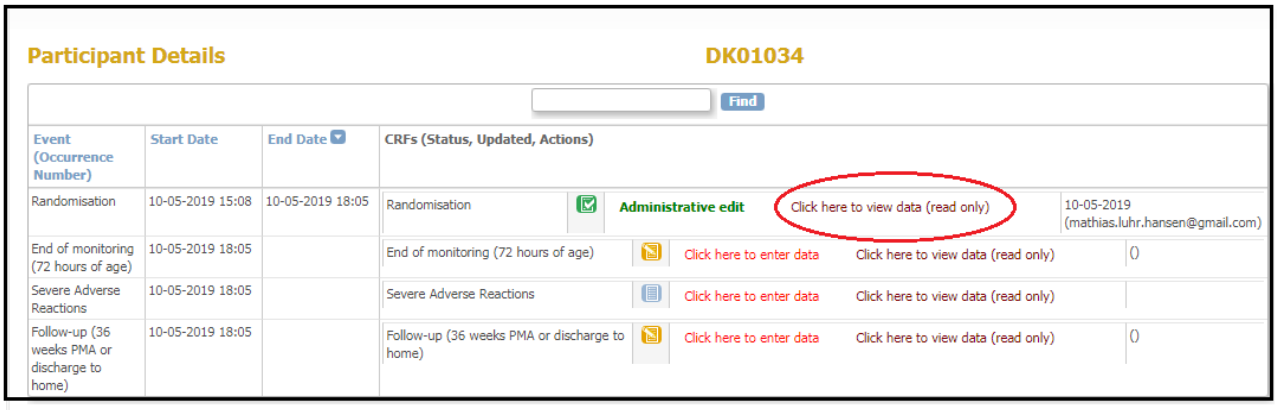


Figure 6.

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).



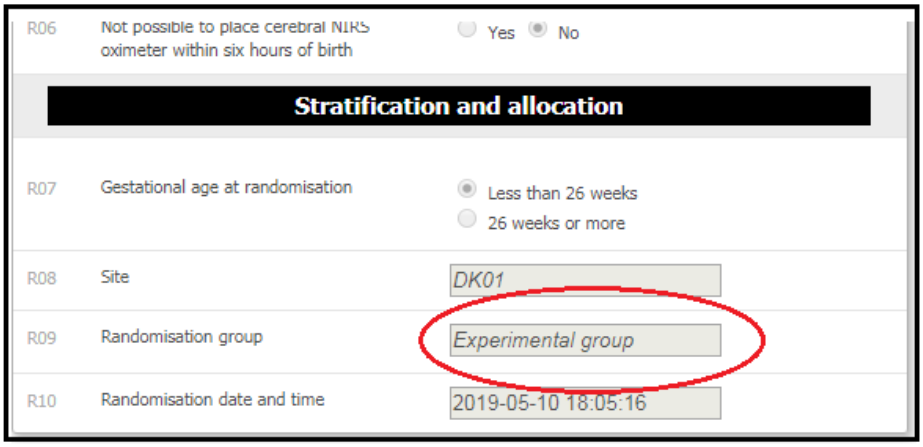


Figure 7 (two images).

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)**

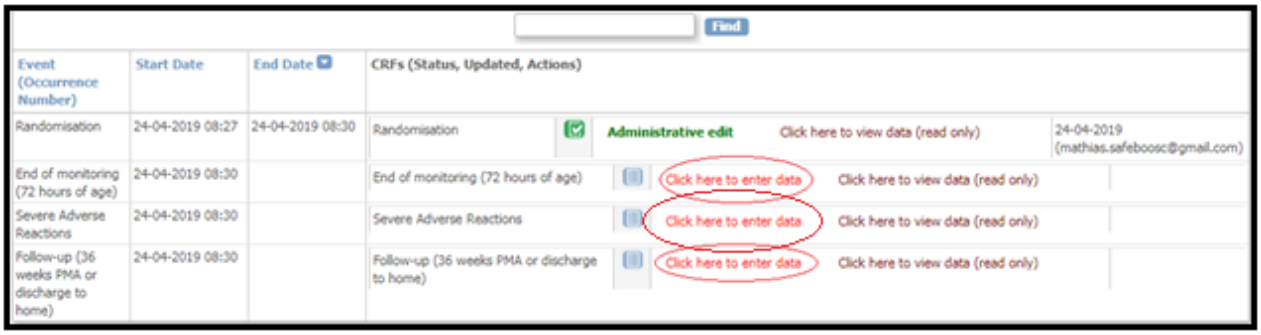


Figure 8.

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.

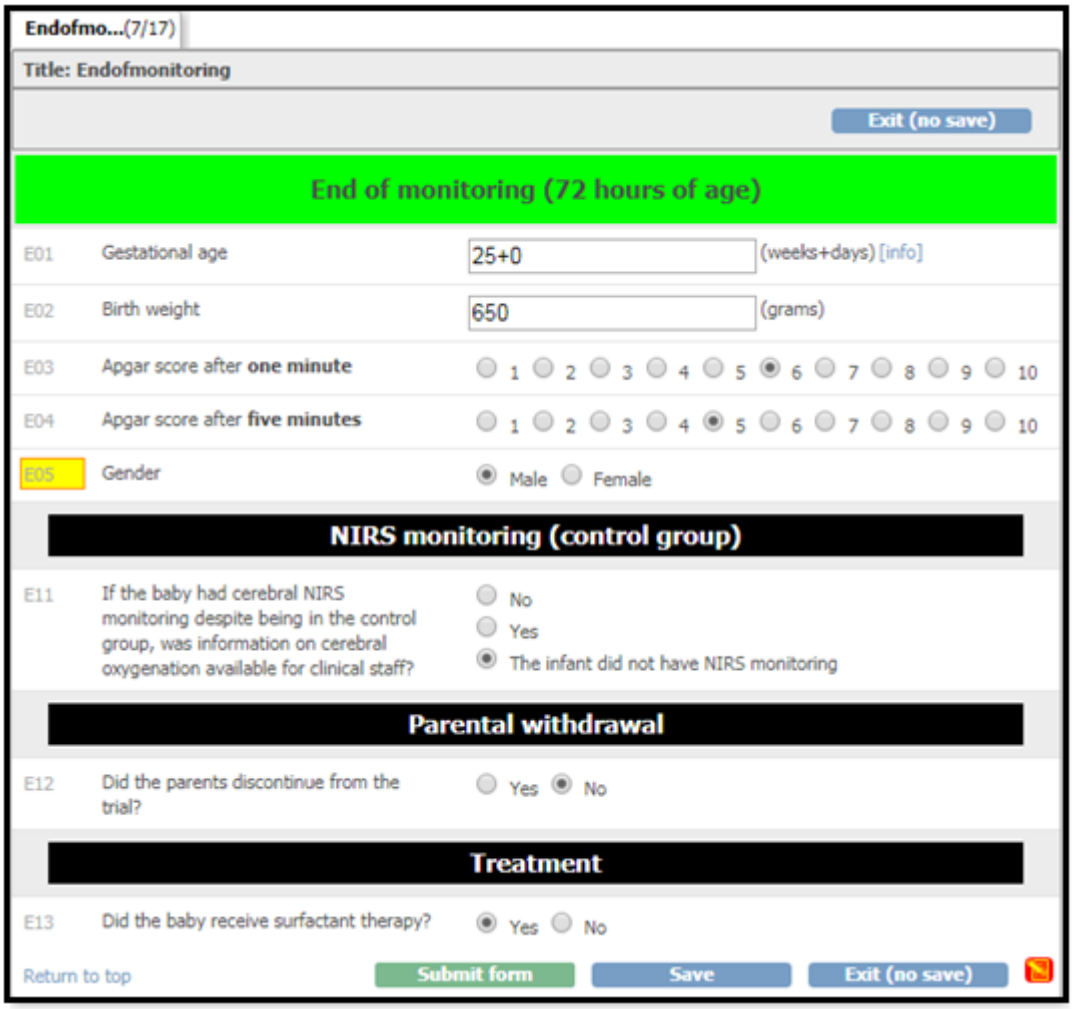


Figure 9.

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!

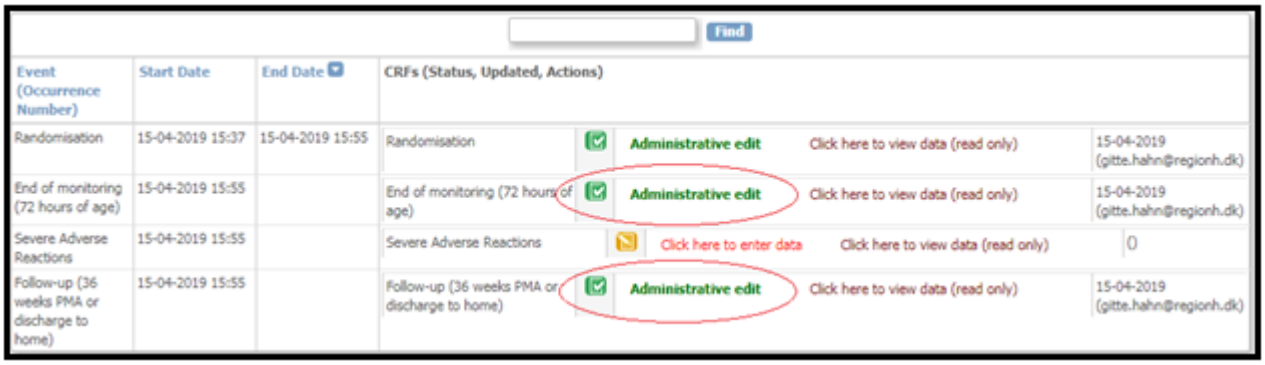


Figure 10.

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):

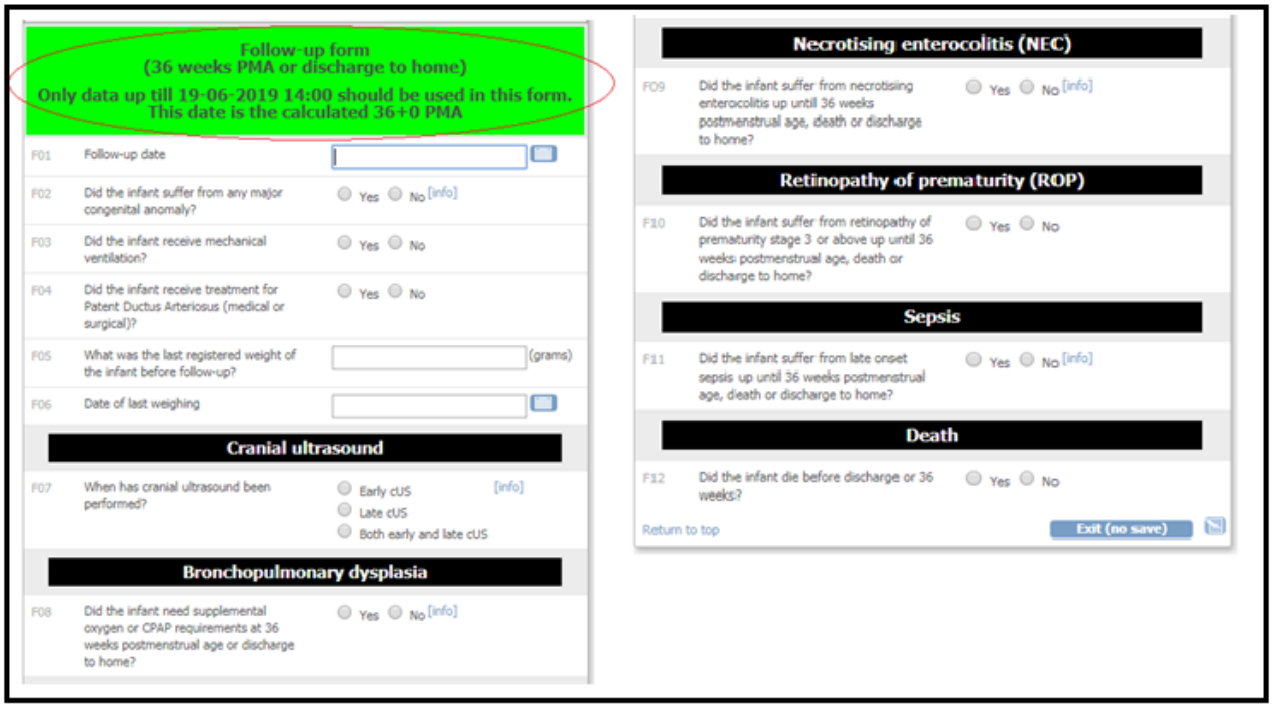


Figure 11.

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)

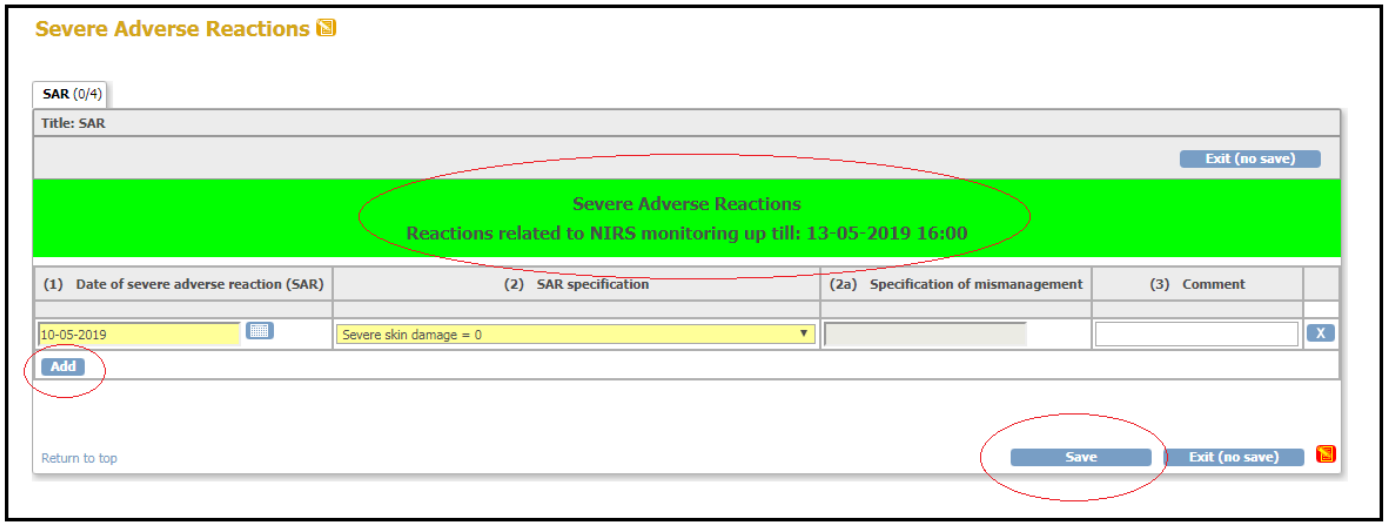


Figure 12.

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.

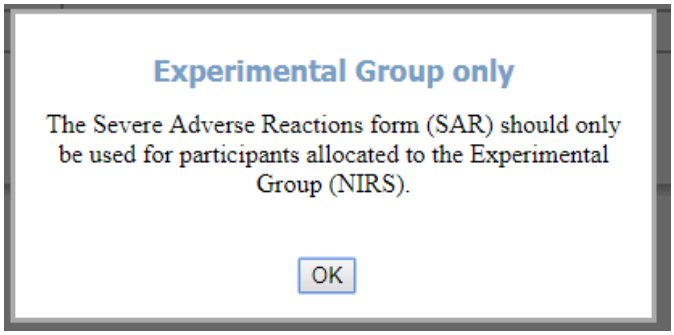
Be aware that 'Specification of mismanagement' should only be registered if you choose a SAR related to clinical mismanagement. The 'Comment' fields are optional.

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)**

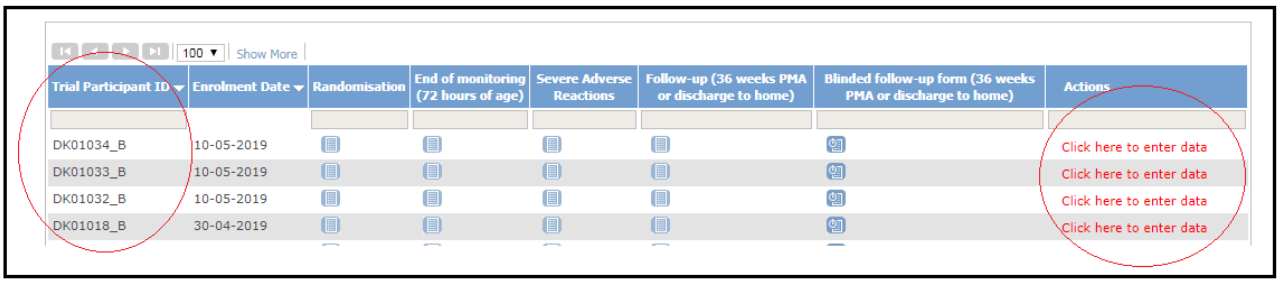


Figure 13.

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

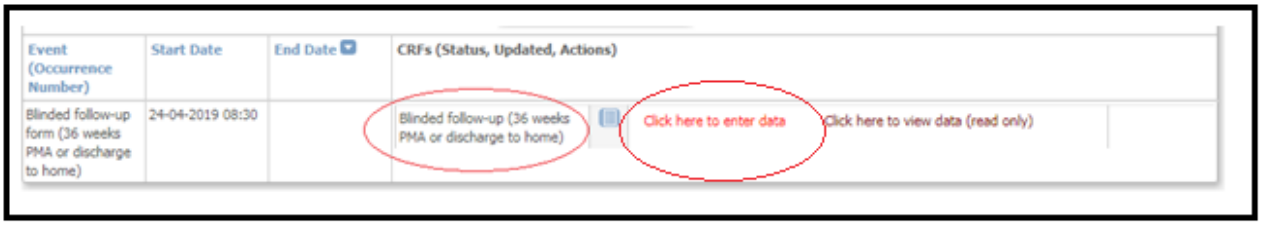


Figure 14

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)

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.