SOP: manual for blinded data entries in OpenClinica for the SafeBoosC-III follow up study

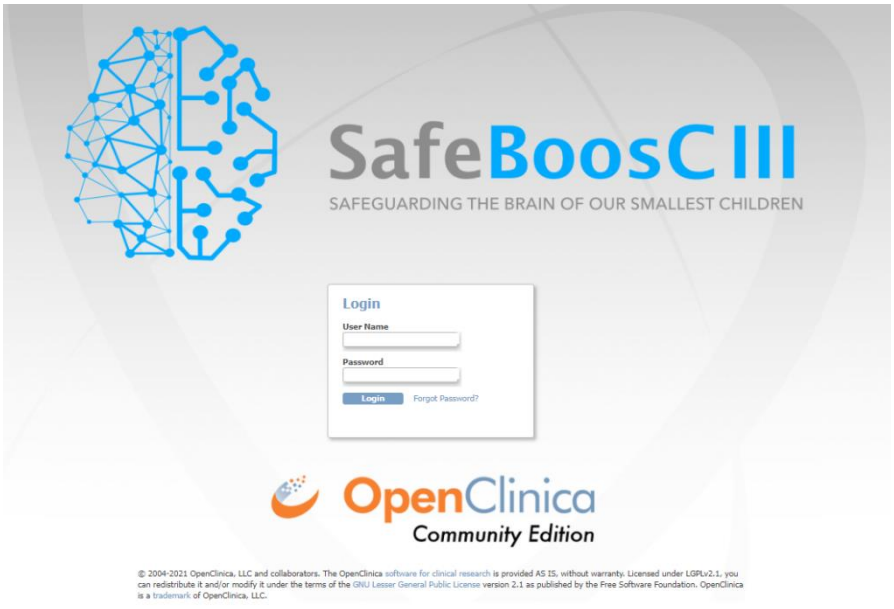
Version	Author	Changes	Approved by
1.0	Marie Isabel Skov Rasmussen	Initial version	Gorm Greisen Mathias Lühr Hansen

The purpose of this Standard Operation Procedure is to guide the blinded assessor in how to access OpenClinica and enter blinded data at two years of corrected gestational age for the SafeBoosC-III follow up study.

1.0 How to log in to OpenClinica

Go to https://safeboosc.ctu.dk/OpenClinica (the two capital letters are important)

Your username is the e-mail address that you provided to marie.isabel.skov.rasmussen@regionh.dk 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, personal password. The password must be at least 8 characters.



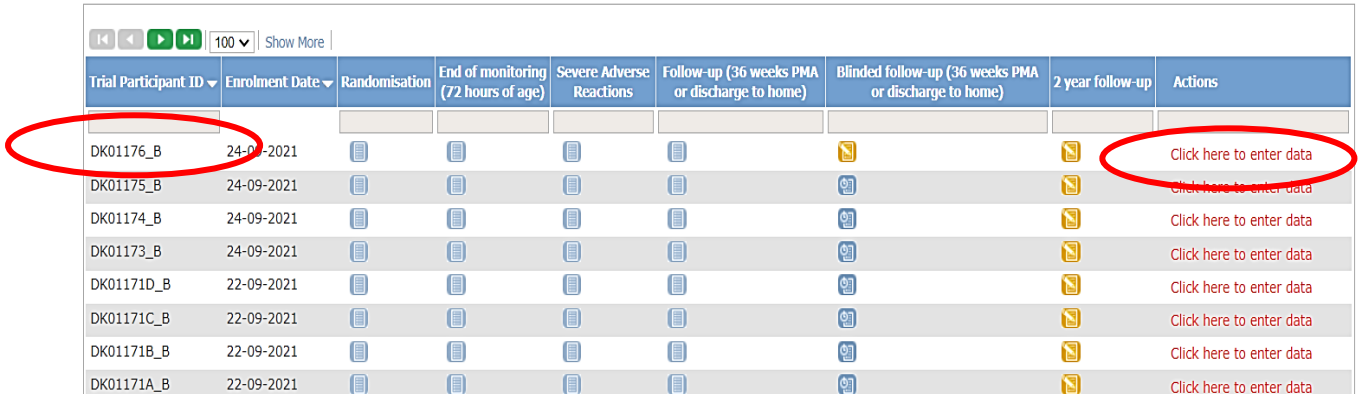
1.1 If you forgot your password

If you have forgotten your password, you can use the "Forgot Password?" link from the log in page of OpenClinica. By providing your username (e-mail address), the system will generate a temporary random password and send it to you in an email. Alternatively, you can contact marie.isabel.skov.rasmussen@regionh.dk 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 temporary password during the next log in.

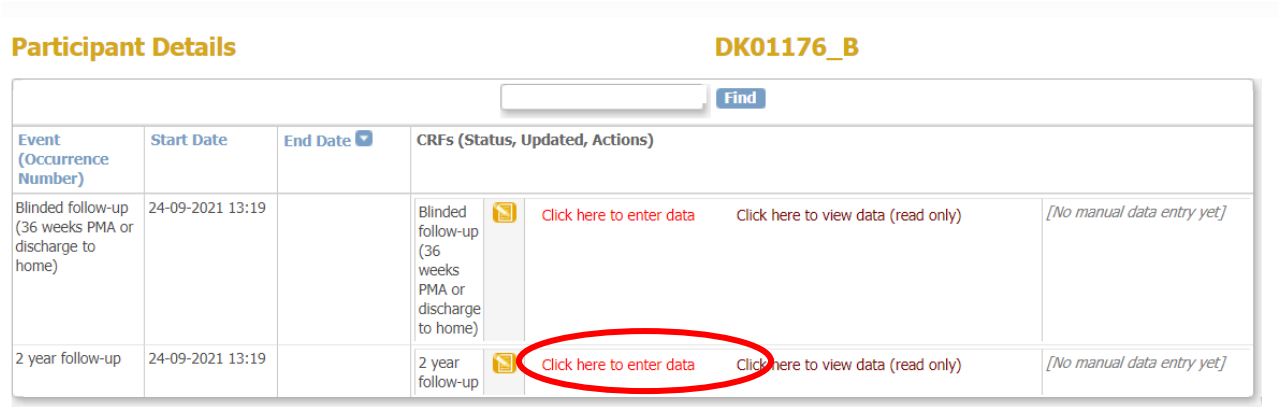
2.0 Blinded assessment of two year follow up data in OpenClinica

The Principal Investigator and/or the blinded assessor will be informed by e-mail, when a participant has reached 24 months of corrected age, including the relevant trial participant ID. To complete the data entries, the blinded assessor must follow the next steps:

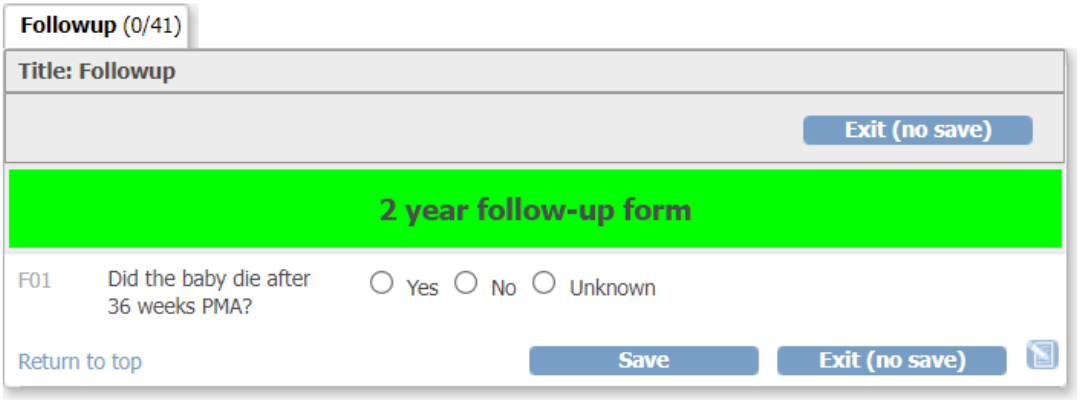
1) Choose the relevant participant for data entry by using the Trial Participant ID and press 'click here to enter data.



2) Press 'Click here to enter data' at the 2 year follow-up form



3) Fill in the blinded 2 year follow-up form. When accessing the form, it will look as the image below with only one data point to enter. However, the form will expand as you fill out the data entries. Please complete the data entries as close to the date where the participant reaches two years of corrected age, with routine data from the participants health care record.



If you press NO to "did the baby die after 36 weeks PMA" and YES to the following questions "Are there relevant health care records, such as formal assessments of vision, hearing, psychomotor, neurodevelopment, from corrected age 18-30 months available", the follow-up form will be extended as below (see next page for example):

2 year follow-up form

F01 Did the baby die after 36 weeks PMA? ○ Yes ◉ No ○ Unknown

F02 Are there relevant health care records, such as formal assessments vison, hearing, psychomotor, neurodevelopment, from corrected age 18-30 months available? ◉ Yes ○ No

If the child had a medical assessment between 18-30 months of age, please fill out as much data as possible

F04	Weight	12	(kg) F04a	Date of measure	06-10-2021	☐ Not Available
F05	Height	85	(cm) F05a	Date of measure	06-10-2021	☐ Not Available
F06	Head circumference	50	(cm) F06a	Date of measure	06-10-2021	☐ Not Available

F07 Has the child been diagnosed with cerebral palsy? ○ Yes ◉ No ○ Unknown [info]

F08 Has the child been diagnosed with a visual impairment? ◉ Yes ○ No ○ Unknown [info]

F09 Has the child been diagnosed with a hearing impairment? ○ Yes ◉ No ○ Unknown [info]

F10 Was retinopathy of prematurity grade 3 or more diagnosed after 36 weeks postmenstrual age? ○ Yes ◉ No ○ Unknown

F11 Was the baby treated for retinopathy of prematurity, any grade, after 36 weeks of postmenstrual age? ○ Yes ◉ No ○ Unknown

F12 Has the child been diagnosed with any chronic health problems? ○ Yes ◉ No ○ Unknown [info]

F13 Has the child received any daily medication for the last two months? ○ Yes ◉ No ○ Unknown [info]

F14 Has the child been assessed with a Bayley-III? ◉ Yes ○ No ○ Unknown

F14a Cognitive subscore 50

F14b Date of test 06-10-2021

F15 Has the child been assessed with another standardised neurodevelopmental test? ○ Yes ◉ No ○ Unknown *If multiple tests have been performed, please register the name and score of the latest assessment*

The information above is based on assessments from (check one or more) and last date of assessment

F17 ☐ Neuropediatrician

F18 ☑ Pediatrician/neonatologist F18a Date of last assessment 06-10-2021

F19 ☐ Other specialised or subspecialised physician (ophthalmologist etc)

F20 ☐ Physiotherapist

F21 ☐ Psychologist

Return to top Submit form Save Exit (no save)

When the data entries have been completed, you can either press ‘Submit form’, ‘Save’ or Exit (no save). It is possible to edit data entries once you have clicked ‘Submit form’, by clicking the ‘Administrative edit’. All changes will be registered automatically.

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

The SafeBoosC-III follow up set-up in OpenClinica is hosted by Copenhagen Trial Unit. However, all problems and questions should be addressed to the Study Manager Marie Rasmussen (marie.isabel.skov.rasmussen@gmail.com), which then will contact Copenhagen Trial Unit, if relevant.