

Manual for using OpenClinica for SafeBoosC data entry

OpenClinica can be found at this web address: <http://safeboosc.ctu.dk/OpenClinica>

First login

After first login, you will be prompted to change your password:

Reset password

Welcome to OpenClinica, Janus Engstrøm. Your current password has been set by the system or has expired. In order to continue, you MUST change your password below.

* indicates required field.

Old Password: *

New Password: *

Confirm New Password: *

Password Challenge Question: *

Password Challenge Answer: *

Figure 1: Prompting for password change after first login

The Password Challenge Question and –answer is used for resetting your password without the intervention of an administrator.

Home Screen

After logging into OpenClinica, you will be presented with your Home Screen. For your role as Clinical Research Coordinator it will look like the following:

SafeBoosC : Denmark - Copenhagen (DK1) | Change Study/Site jengstroem (Clinical Research Coordinator) en | Log Out

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks Report Issue | Support | Study Subject ID Go

Welcome to SafeBoosC

Notes & Discrepancies Assigned to Me: 0

Subject Matrix

15 Show More | Select An Event Add New Subject

Study Subject ID	Screen, Rand, Intervention	cUS - day 1	cUS - day 4	cUS - day 7	cUS - day 14	cUS - optional	cUS - 35 days	cUS - term age	aEEG/EEG recording	Follow up	AE	SAE	Actions
DK1001SF													
DK1201													
DK1202													

Results 1 - 3 of 3.

Figure 2: The Home Screen of a Clinical Research Coordinator

The **Subject Matrix** lists the subjects currently enrolled into the database, i.e. the children eligible for participation in the SafeBoosC trial. Each subject is represented as a row. The list above currently holds 3 subjects of which one is a Screening Failure (DK1001SF). Screening Failures will occasionally be moved away from this view to prevent cluttering.

In the matrix you can see the **Events** the SafeBoosC database consists of: “Screen, Rand, Intervention”, “cUS –day XX”, “cUS – optional”, “cUS – term age”, “aEEG/EEG recording”, “Follow up”, “AE”, and “SAE”. First column holds the Study Subject ID, last column holds icons for the **Actions** available to you (as a Clinical Research Coordinator). Your only action is the View action, which brings you to a list of all the scheduled Events and the CRFs contained within. What this means will be addressed later in this manual.

An Event is a logical collection of one or more **CRFs** (questionnaires).

Each icon in the Matrix represents the status of the Events. Possible Event statuses are listed below:

-  Not started. The event has not been scheduled yet.
-  Scheduled. The event has been scheduled; data entry has not been started.
-  Data Entry Started. Data has been entered into one or more CRFs and one or more CRF has not been marked as Complete.
-  Stopped. The event has been marked as stopped. Data entry cannot continue unless the status is changed. Discrepancy notes management is possible (adding, replying, etc.).
-  Skipped. This event has been marked skipped. Data entry can be performed, but this will automatically change the status of the event to either Data Entry Started or Completed, given the completeness of the CRFs in the event.
-  Completed. The CRFs in the event has all been marked Complete.
-  Signed. The Investigator has marked the event as Signed. Data entry is possible, but this will change the status of the Event to either Data Entry Started or Completed, given the completeness of the CRFs in the event.
-  Locked. The Investigator has locked the event from further manipulation. This includes both data entry and discrepancy management.

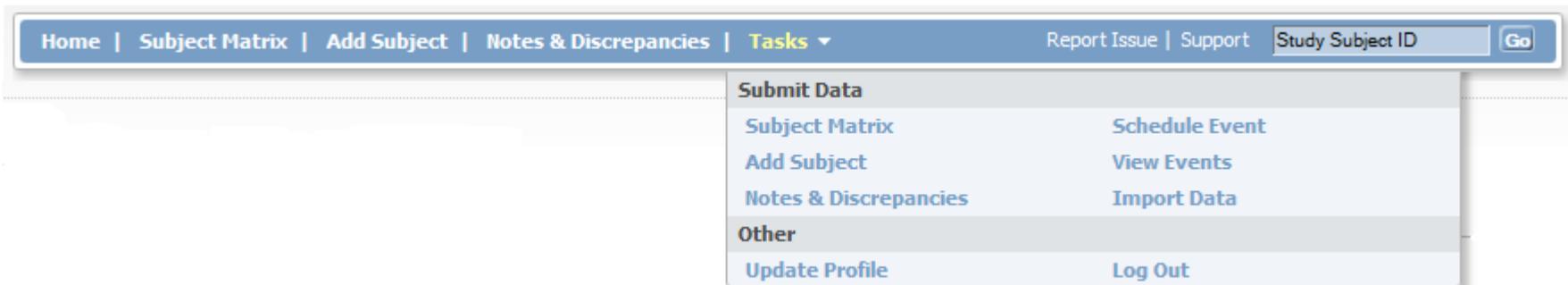


Figure 3: The menu bar for a Clinical Research Coordinator

The **menu bar** is used to handle the basic tasks as a Clinical Research Coordinator. The figure above shows the menu bar with the Tasks list expanded. Below are most of the tasks described:

- Home: Takes you to your Home screen.

- Subject Matrix: Takes you to the Subject Matrix. Only difference between Home and Subject Matrix is the line “Notes and Discrepancies Assigned to me: XX”.
- Add Subject: Click here to add a new subject.
- Notes & Discrepancies: Takes you to an overview of the notes and discrepancies addressed to you.
- Tasks > View Events: Changes the view of study data, focusing on events. This view provides functionality to filtering study events associated with the subjects of your site. You can filter by Study Event Definition, status of the events and dates.
- Tasks > Update Profile: Update information about yourself such as name, email address and institutional affiliation. You can also change your password.

To add a new Subject to the Study, click the “Add Subject” in the menu bar:

Denmark - Copenhagen: Add Subject

* indicates required field.

Study Subject ID: *

Secondary ID:

Date of Enrollment for Study' SafeBoosC' : *  

Sex: 

Save and Assign Study Event
Save and Add Next Subject
Save and Finish
Cancel

Figure 4: Adding a new Subject

Type in a Study Subject ID (as found in the provided Subject List documents for your site). You do not have to provide information regarding Secondary ID or Sex, nor change the Date of Enrollment. This information is not used in SafeBoosC. Sex is collected within a CRF instead.

When done, click Save and Assign Study Event:

Schedule Study Event for DK1203 ?

* indicates required field.

Study Subject ID: **DK1203**

Study Event Definition: *

Start Date/Time: : (DD-MM-YYYY HH:MM) *

End Date/Time: : (DD-MM-YYYY HH:MM)

Leave this field blank if the end date/time is not applicable.

- Schedule Another Event: (optional)

Figure 5: Scheduling an Event

In the drop down list, select the Event for which you would like to begin data entry and click **Proceed to Enter Data**. To schedule an Event for an existing Subject, go to the Subject Matrix, **left click to the icon for the Event** and click "Schedule" on the popup menu. This will take you to the same screen as above (Figure 5).

After clicking Proceed to Enter Data, a screen like to one below is shown (depending on the Event selected). In this example, the Event consists of 3 CRFs: Screening, Randomisation, and Intervention. In the Actions column you click the **magnifying glass** to show a read-only version of the CRF (you are able to enter data into the fields of the CRF, but no Save button is shown).

Enter or Validate Data for CRFs in Screen, Rand, Intervention ?

Edit Study Event	
Study Subject ID	DK1203
Study Event	Screen, Rand, Intervention
Location	N/A
Study Subject OID	SS_DK1203
Start Date	26-06-2012
End Date/Time	
Subject Event Status	scheduled
Last Updated by	0

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
Screening (SafeBoosC)	v. 2				
Randomisation (SafeBoosC)	v. 1				
Intervention (SafeBoosC)	v. 3				

[View this Subject's Record](#)

[Exit](#)

Figure 6: Overview of the CRFs within a particular Event

Click the **pencil / notepad** icon to begin data entry:

CRF Header Info

Event: Screen, Rand, Intervention (26-06-2012)	Sex:
Study: SafeBoosC	Age At Enrollment:
Site: Denmark - Copenhagen	
Interviewer Name: * jengstroem	Interview Date: * 26-06-2012

Discrepancy Notes on this CRF:

New	Updated	Resolution Proposed	Closed	Not Applicable
0	0	0	0	0

Screening... (0/20) -- Select to Jump --

Title: Screening Form

Instructions:

Page: Mark CRF Complete

Screening Form

(S.01) Screening date *

(S.02) Gestational age, weeks * Gestational age, days *

(S.03) Time of birth, hours * Time of birth, minutes *

(S.04) Birth weight * (gram)

Inclusion criteria

Neonates meeting the following criteria will be included:

(S.05) Yes No * Neonates born more than 12 weeks preterm (gestational age up to 27 weeks and 6 days)

(S.06) Yes No * Decision to conduct full life support

(S.07) Yes No * Possibility to place cerebral NIRS oximeter within 3 hours after birth

(S.08) Yes No * Obtained parental signed written informed consent

Exclusion criteria

Neonates meeting the following criteria will be excluded:

(S.09) Yes No * A clinical decision not to provide full life support

(S.10) Yes No * No possibility to place the cerebral NIRS oximeter within 3 hours after birth

(S.11) Yes No * Lack of parental signed written informed consent

Infants of appropriate gestational age not included in the trial

(S.12) Did not meet eligibility criteria

(S.13) Did not have personnel or equipment available

(S.14) Were eligible, but consent was not sought

(S.15) Were excluded because parent or guardian was unavailable

(S.16) Had consent denied by parent or guardian

(S.17) Had consent provided but did not undergo randomisation

(S.18) Had other reasons

[Return to top](#) Mark CRF Complete

Figure 7: Entering data into the CRF named "Screening"

The Screening date is a **Date field**. Either use the **Calendar icon** to select a date, or type the date manually. Use the format dd-mm-yyyy (i.e. 26-06-2012).

The orange star indicates the field being a **Required field**. You need to provide data for this field before OpenClinica will save the CRF data. If you do not enter data for one of the required fields and you click Save, the following will be shown:

There are issue(s) with your submission. The data has NOT been saved. See below for details.

The screenshot shows a notification box at the top with a red star icon and the text "[Missing data in a required field.]". Below this is a navigation bar with "Screeni...(0/17)" and a "-- Select to Jump --" dropdown. The main form area is titled "Screening Form" and includes a "Page:" section with a "Mark CRF Complete" checkbox, "Save" and "Exit" buttons, and a red star icon. The form fields are: (S.01) Screening Date: 26-06-2012; (S.02) Time of birth, hours: a dropdown menu with "select" and a red star icon; Time of birth, minutes: 20. The "select" dropdown is highlighted with a red box.

Figure 8: Time of birth, hours has missing data

You need to select the hours of birth before being able to save data. If you for some reason do not have this information, you can click the flag next to the field and provide a reason for why you do not have this data:

SF2_TimeOfBirthHours: Add Discrepancy Note

The screenshot shows the "SF2_TimeOfBirthHours" Properties section with the following details: Subject: test2, Event: Screen, Rand, Intervention, Event Date: 26-06-2012, CRF: Screening (SafeBoosC) v. 5, Current Value: , More: Data Dictionary. Below this is the "Add Note" form with the following fields: Description: Enter a reason here. This goes to the Audit Log.; Detailed Note: [Missing data in a required field.]; Type: Failed Validation Check; Set to Status: New. A "Submit" button is at the bottom.

Figure 9: Stating a reason for missing data.

After this, you will be able to save the CRF.

Some fields of the CRFs have validation routines attached. See below for an example:

There are issue(s) with your submission. The data has NOT been saved. See below for details.

- **[Missing data in a required field., All exclusion criteria must be answered with No]**
- **[All exclusion criteria must be answered with No]**

Screeni...(0/20) -- Select to Jump --

Title: Screening Form

Instructions:

Page: Mark CRF Complete

Screening Form

(S.01)	Screening date	26-06-2012	*
(S.02)	Gestational age, weeks	26	*
	Gestational age, days	1	*
(S.03)	Time of birth, hours	05	*
	Time of birth, minutes	20	*
(S.04)	Birth weight	1500	* (gram)

Inclusion criteria

Neonates meeting the following criteria will be included:

(S.05)	<input checked="" type="radio"/> Yes <input type="radio"/> No	* Neonates born more than 12 weeks preterm (gestational age up to 27 weeks and 6 days)
(S.06)	<input checked="" type="radio"/> Yes <input type="radio"/> No	* Decision to conduct full life support
(S.07)	<input checked="" type="radio"/> Yes <input type="radio"/> No	* Possibility to place cerebral NIRS oximeter within 3 hours after birth
(S.08)	<input checked="" type="radio"/> Yes <input type="radio"/> No	* Obtained parental signed written informed consent

Exclusion criteria

Neonates meeting the following criteria will be excluded:

(S.09)	! <input type="radio"/> Yes ! <input type="radio"/> No	* A clinical decision not to provide full life support
(S.10)	<input type="radio"/> Yes <input checked="" type="radio"/> No	* No possibility to place the cerebral NIRS oximeter within 3 hours after birth
(S.11)	! <input checked="" type="radio"/> Yes ! <input type="radio"/> No	* Lack of parental signed written informed consent

Infants of appropriate gestational age not included in the trial

Figure 10: Failed validation; missing data (S.09) and a 'Yes' answer to an exclusion criterion (S.11)

Either change the entered data or use the flags to force OpenClinica to accept your data.

You can choose to save the CRF and come back at a later time to finish data entry. If you choose this, you do not check the **Mark CRF Complete** checkbox. If data entry is complete, you check the checkbox and click OK on the question popup.

After the CRF is saved (either data entry completed or not), you will be taken back to the Event overview. Now the status of the Event has changed accordingly:

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
Intervention (SafeBoosC)	v. 3		jengstroem		
Screening (SafeBoosC)	v. 2		jengstroem	n/a	
Randomisation (SafeBoosC)	v. 1		jengstroem	n/a	

Figure 11: Two CRFs are completed and one is still uncompleted.

To continue data entry on the Intervention CRF, simply click the pencil / notepad icon.

You can also change data for already completed CRFs. When saving a completed CRF on which you have changed data, you will be asked to enter a Reason for Change:

Screening (SafeBoosC) v. 2

DK1203

▼ CRF Header Info

There are issue(s) with your submission. The data has NOT been saved. See below for details.

- You have changed data after this CRF was marked complete. You must provide a Reason For Change discrepancy note for this item before you can save this updated information.

Screeni...(20/20) | -- Select to Jump --

Title: Screening Form

Instructions:

Page:

Screening Form

(S.01) Screening date: *

(S.02) Gestational age, weeks: * Gestational age, days: *

(S.03) Time of birth, hours: * Time of birth, minutes: *

(S.04) Birth weight: ! * (gram)

Figure 12: Changing data on a completed CRF requires a Reason for Change.

Use the flag to add the Reason for Change.

To enter an Event for an **Event which is already scheduled** (and perhaps data entry already has started), go to the Subject Matrix and click the icon for the Event in question:



Figure 13: From the Subject Matrix the Event “Screen, Rand, Intervention” has been clicked after it being scheduled

Click the View/Enter Data to go the Event overview.

The “cUS – optional” Event is defined as begin a **Repeating Event**. This means that it can be scheduled multiple times:

cUS - optional	cUS - 35 days	cUS - term age	aEEG/EEG recording	Follow up	AE	SAE	Actions
							Apply Filter
			<input checked="" type="checkbox"/>				
			<input checked="" type="checkbox"/>				
<input checked="" type="checkbox"/> x2							

Subject: DK1203 X
 Event: cUS - optional [Add Another Occurrence 1/2](#)

Occurrence#1 of 2 26-06-2012 Status: completed View/Enter Data	Occurrence#2 of 2 26-06-2012 Status: completed View/Enter Data
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Figure 14: “c-US optional” is a Repeating event and has been scheduled twice already

Click the **Add Another Occurrence** to schedule yet another instance of the Event.