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:

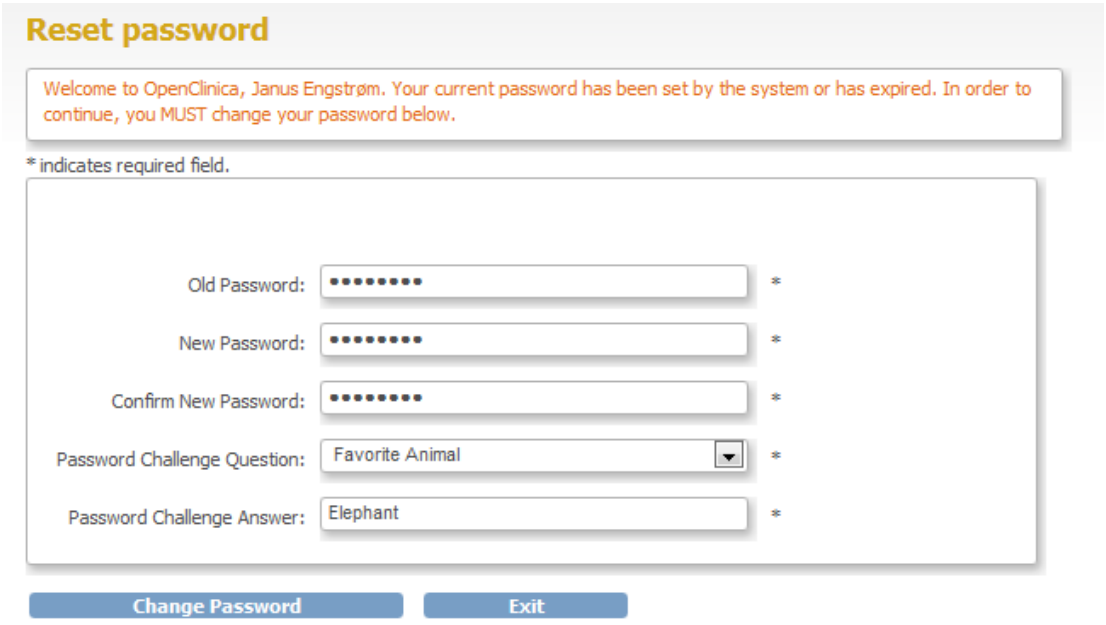

Figure 1: Prompting for password change after first login

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:

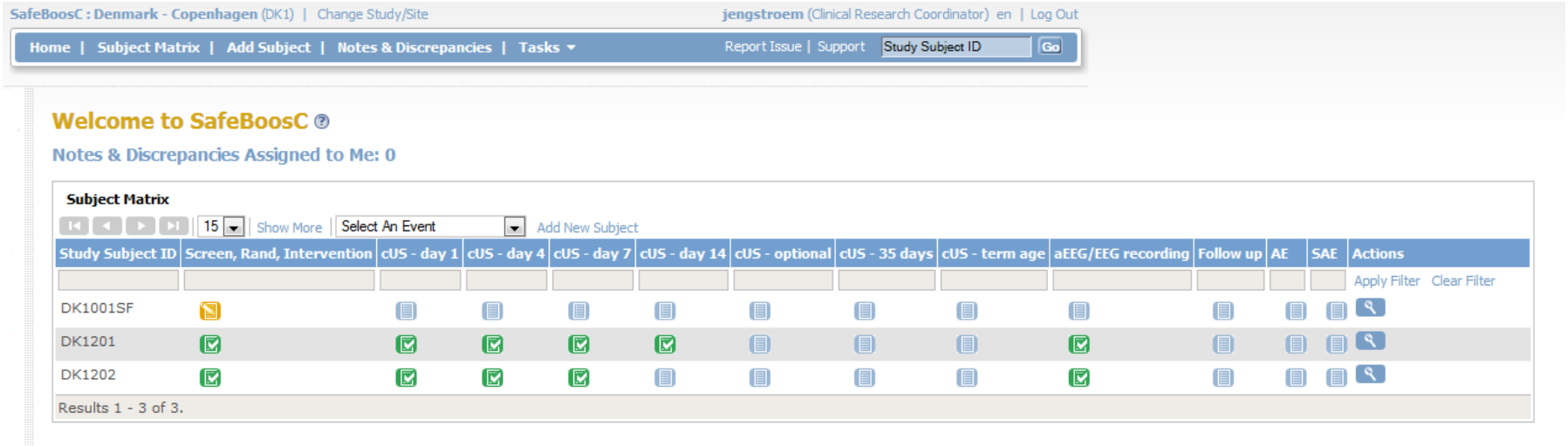

Figure 2: The Home Screen of a Clinical Research Coordinator

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.

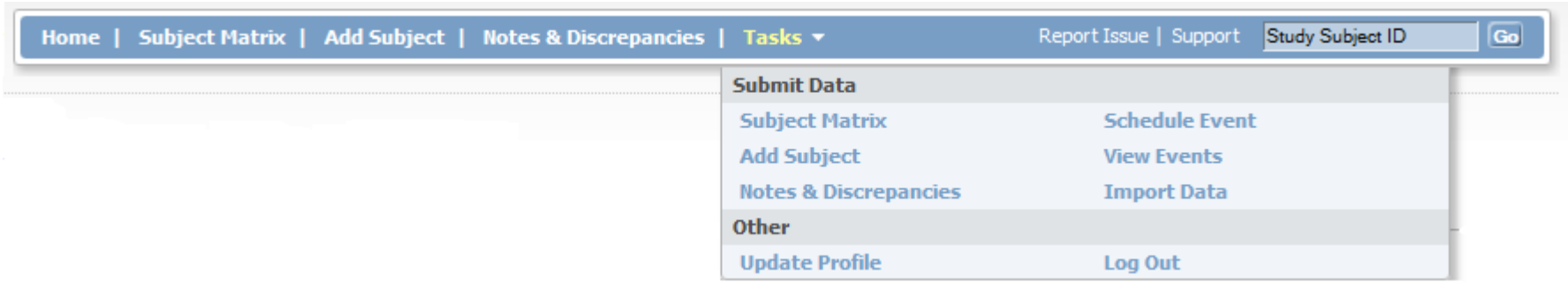

Figure 3: The menu bar for a Clinical Research Coordinator

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:

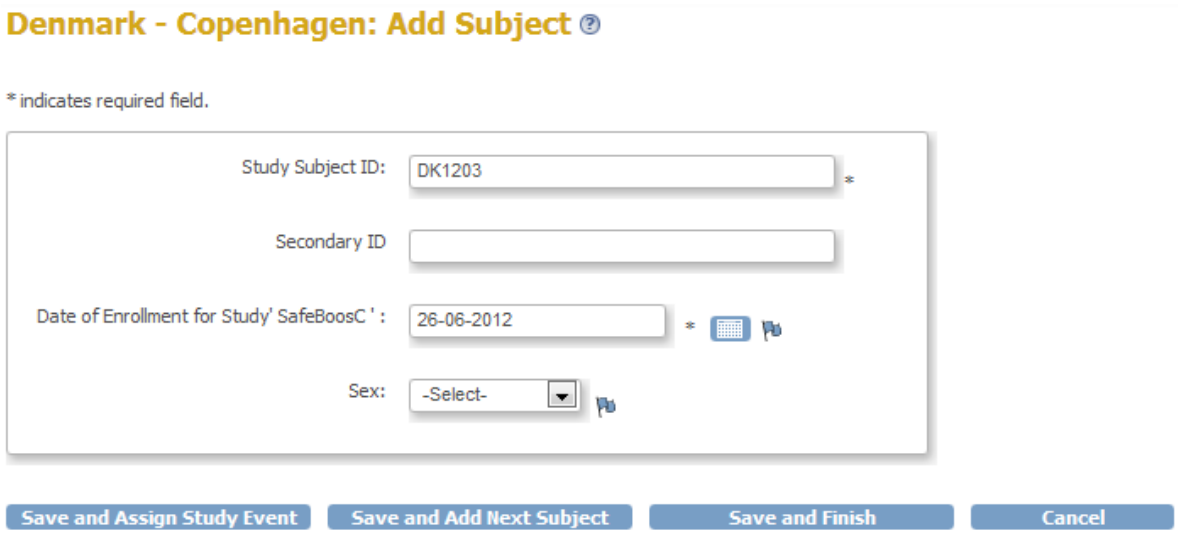

Figure 4: Adding a new Subject

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:

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).

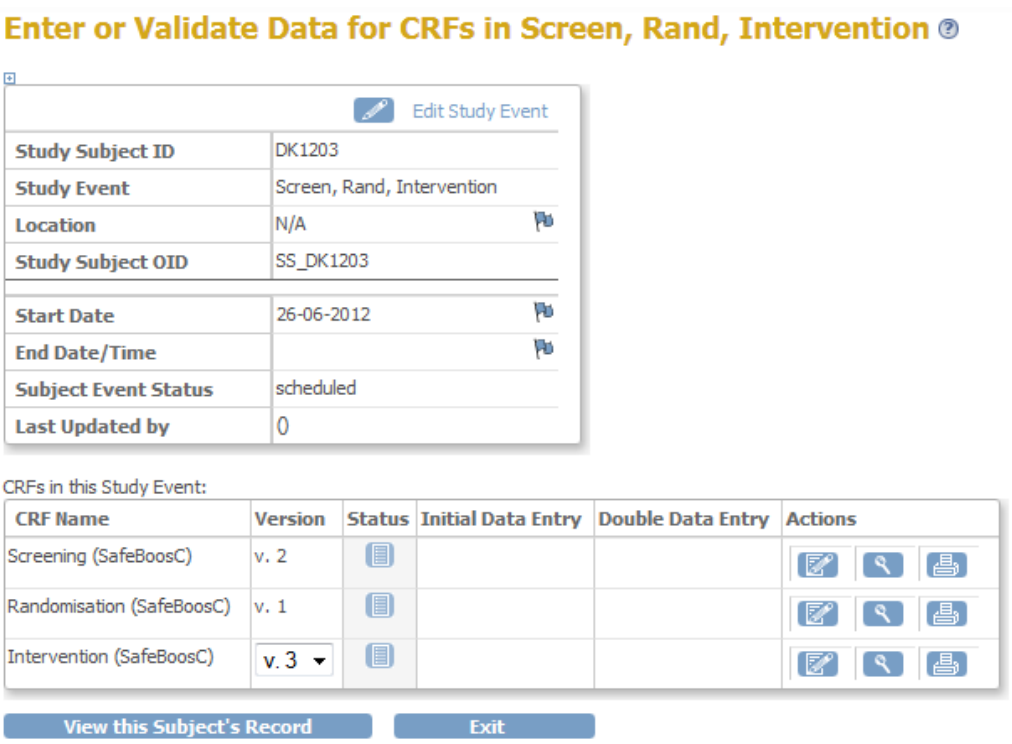

Figure 6: Overview of the CRFs within a particular Event

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

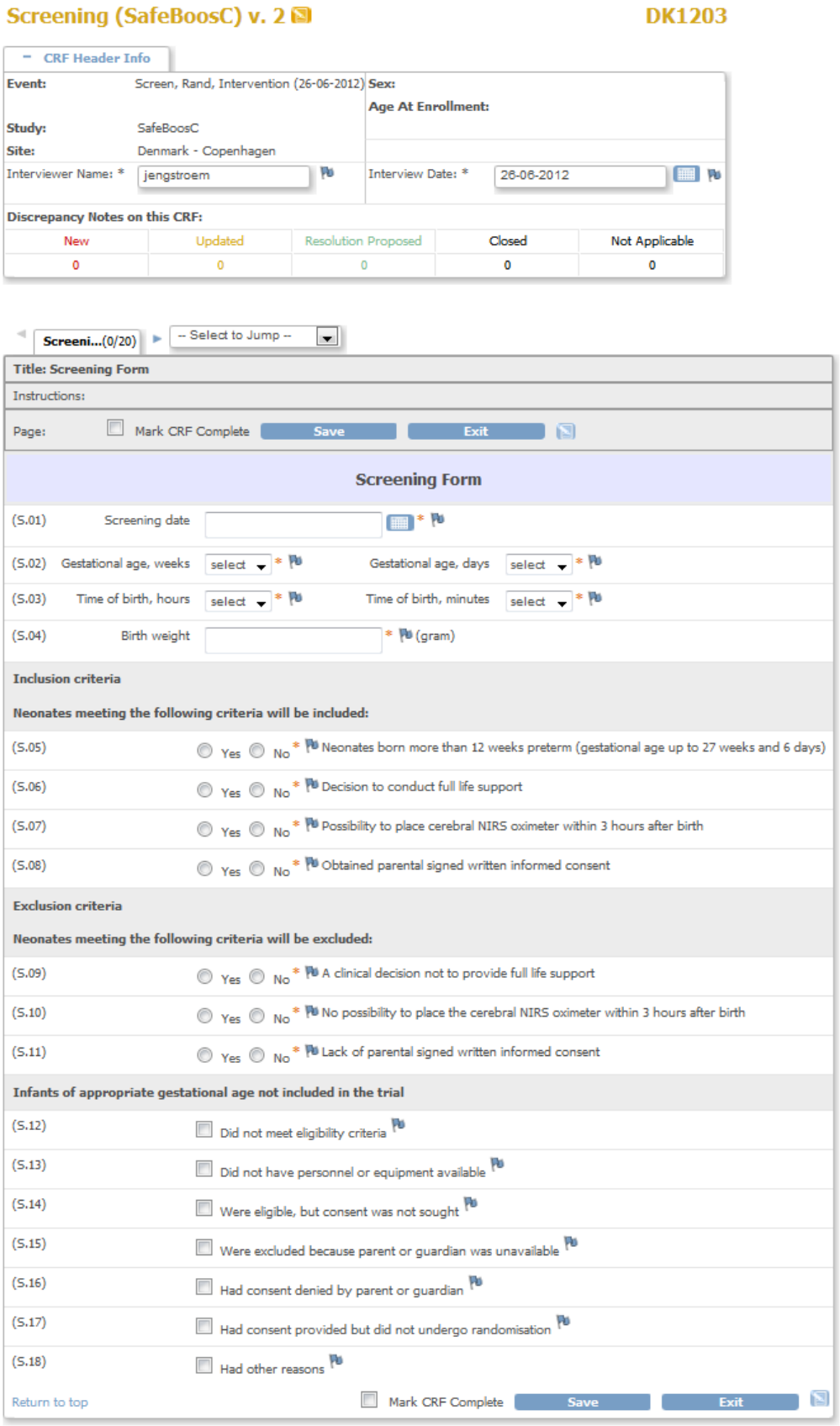

Figure 7: Entering data into the CRF named "Screening"

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:

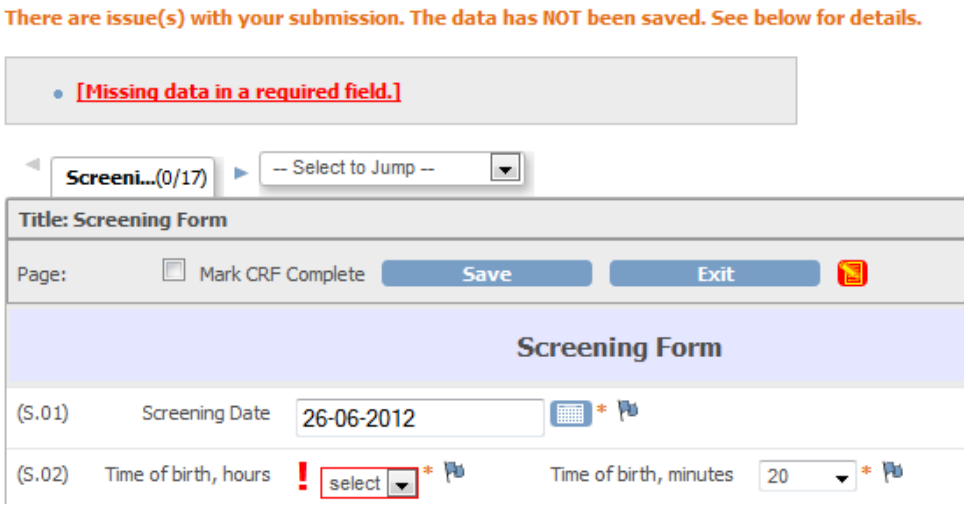

Figure 8: Time of birth, hours has missing data

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:

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:

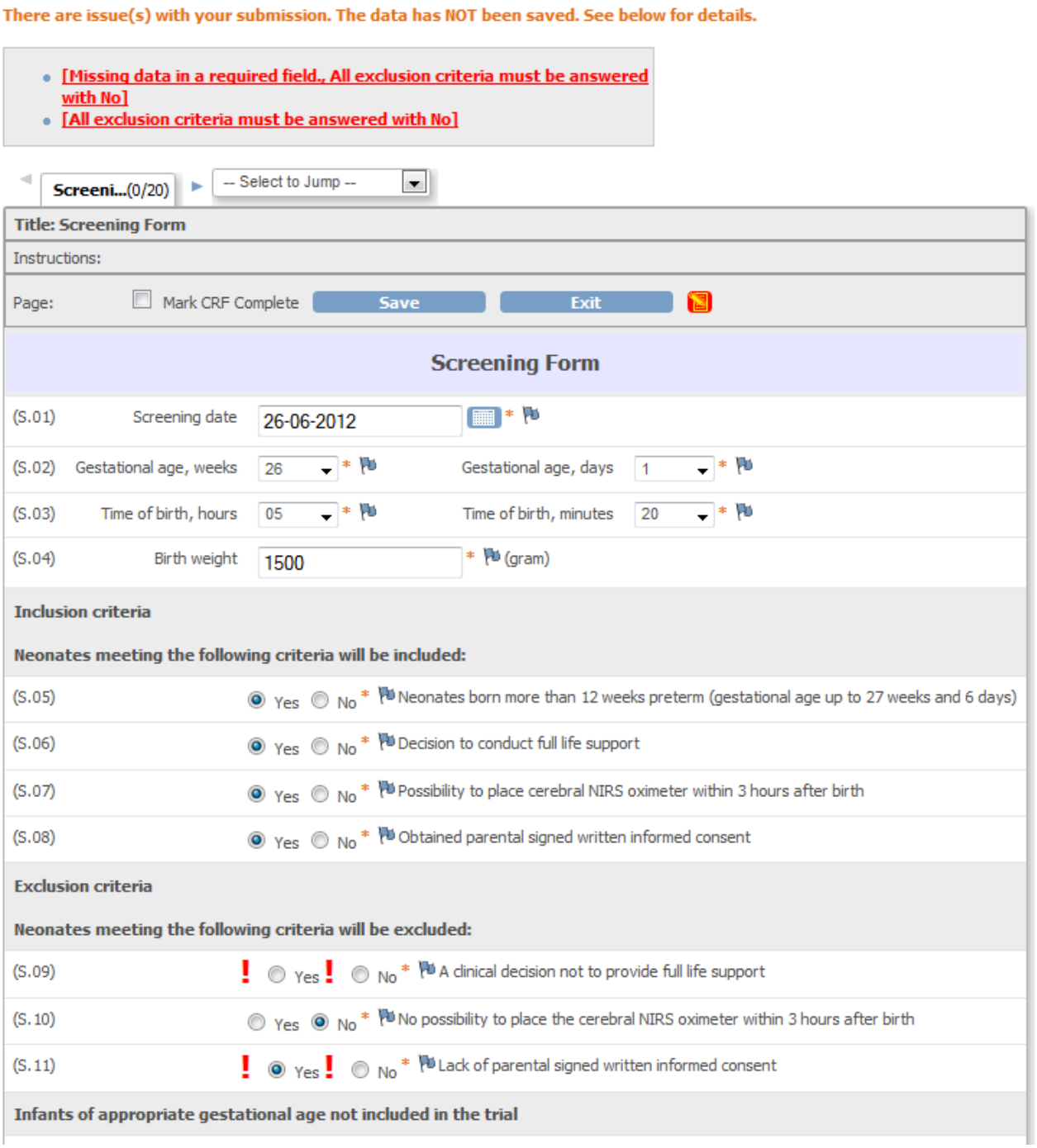

Figure 10: Failed validation; missing data (S.09) and a 'Yes' answer to an exclusion criterion (S.11)

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:

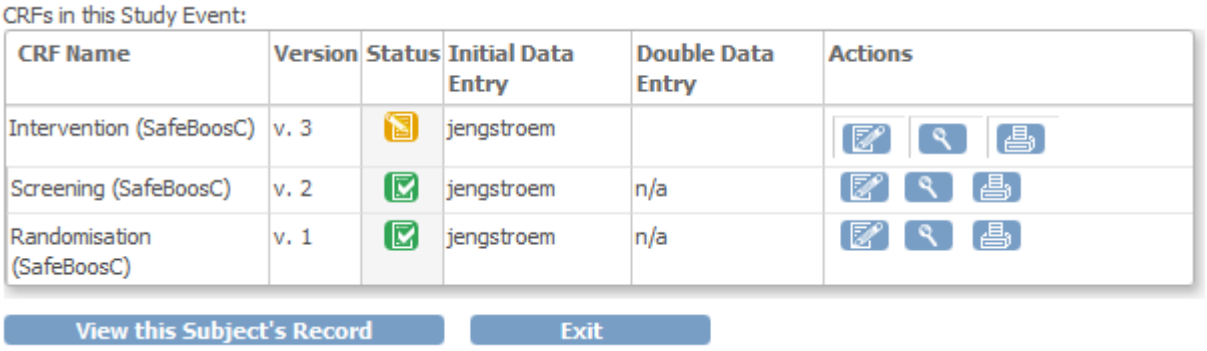

Figure 11: Two CRFs are completed and one is still uncompleted.

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:

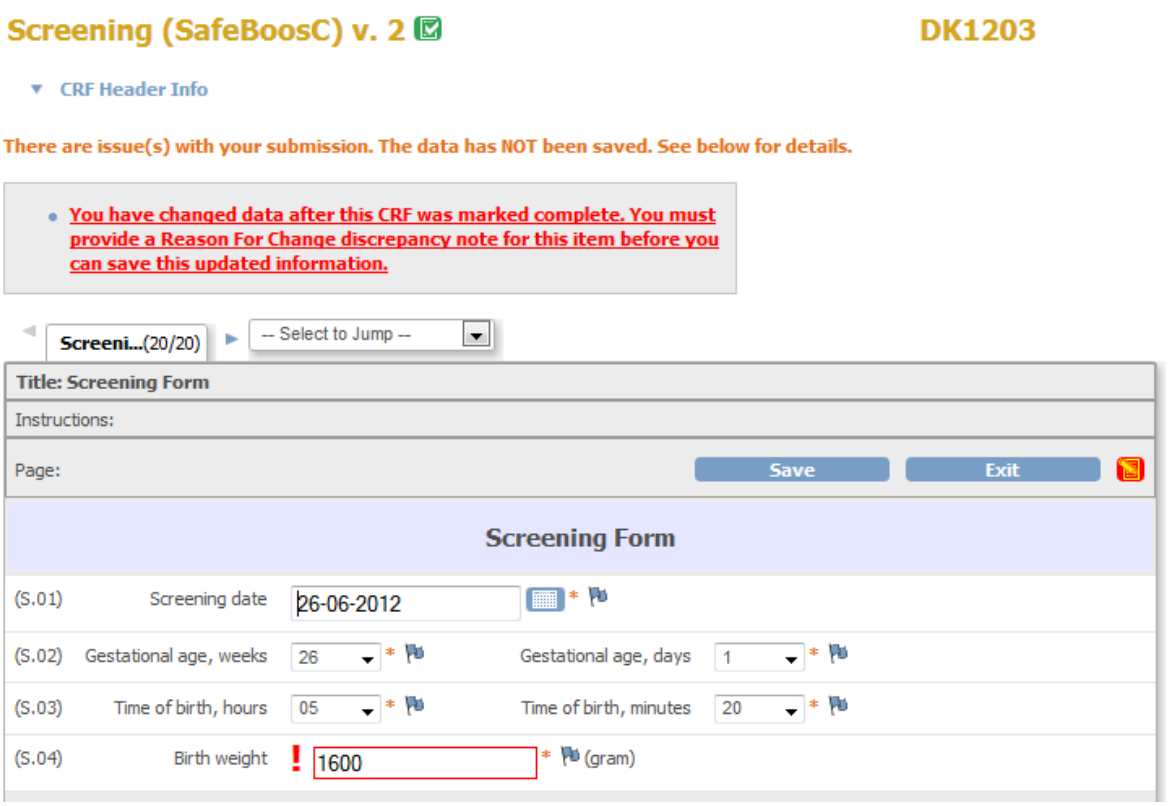

Figure 12: Changing data on a completed CRF requires a Reason for Change.

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:

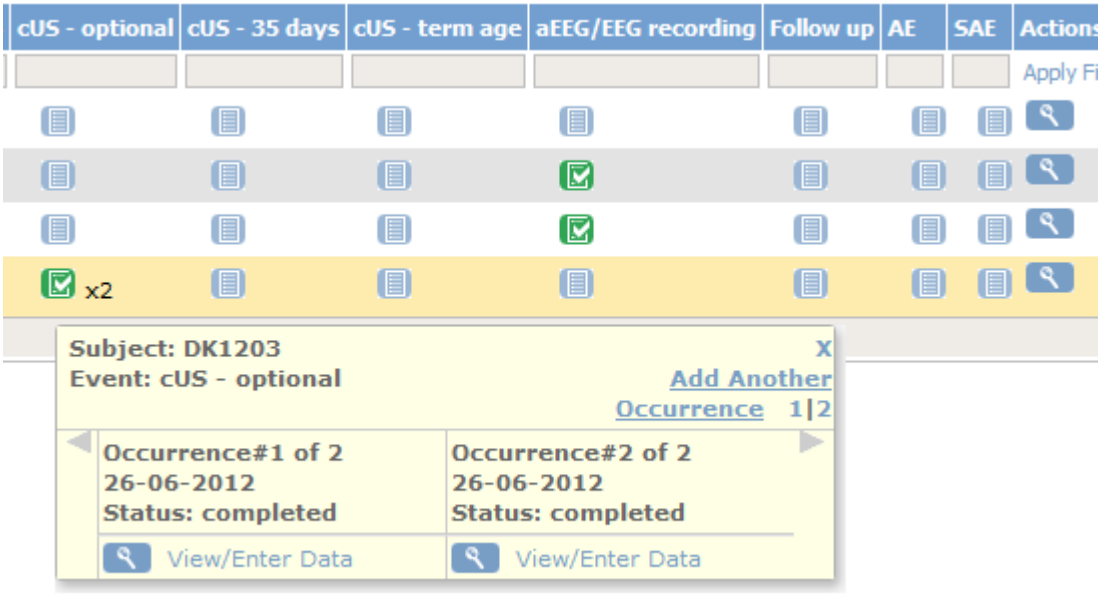

Figure 14: "c-US optional" is a Repeating event and has been scheduled twice already

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