

SafeBoosC

OpenClinica manual for monitors

Version 1

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This manual contains a short introduction to the features of the monitoring module in OpenClinica, along with a more elaborate use case scenario example.

This version does not include information regarding the Study Subject Matrix nor the data extraction module. These features will be explained in next version of this manual, but they are not required to perform source data verification (SDV).

Note: This manual is based on an earlier revision of the SafeBoosC database, so some discrepancies may occur when applied to the current version.

1 2 3

SafeBoosC : Denmark - Copenhagen (DK1) | Change Study/Site Monitor (Monitor) en | Log Out

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

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Welcome to SafeBoosC ©

Notes & Discrepancies Assigned to Me: 0 5

View By Event CRF View By Study Subject ID

Source Data Verification

◀ ▶ 15 Show More | The table is sorted by Event Date

Select: All Shown, None

SDV Status	Study Subject ID	Site ID	Event Name	Event Date	CRF Name / Version	SDV Requirement	CRF Status	Actions
<input type="checkbox"/>	amp	DK1	aEEG/EEG recording(1)	22-05-2012	aEEG / EEG Recording (SafeBoosC)/ v. 1	Not Required	<input checked="" type="checkbox"/>	Apply Filter Clear Filter SDV
<input type="checkbox"/>	amp	DK1	Screen, Rand, Intervention(1)	22-05-2012	Screening (SafeBoosC)/ v. 5	Not Required	<input checked="" type="checkbox"/>	SDV
<input type="checkbox"/>	amp	DK1	AE(1)	22-05-2012	Adverse Events (SafeBoosC)/ v. 4	Not Required	<input checked="" type="checkbox"/>	SDV
<input type="checkbox"/>	amp	DK1	AE(2)	22-05-2012	Adverse Events (SafeBoosC)/ v. 4	Not Required	<input checked="" type="checkbox"/>	SDV
<input type="checkbox"/>	amp	DK1	SAE(1)	22-05-2012	Serious Adverse Events (SafeBoosC)/ v. 2	Not Required	<input checked="" type="checkbox"/>	SDV
<input type="checkbox"/>	MSkoog phv testpages	DK1	AE(1)	05-06-2012	Adverse Events (SafeBoosC)/ v. 4	Not Required	<input checked="" type="checkbox"/>	SDV
<input type="checkbox"/>	amp	DK1	Screen, Rand, Intervention(1)	07-06-2012	Intervention (SafeBoosC)/ v. 6	Not Required	<input checked="" type="checkbox"/>	SDV

Results 1 - 7 of 7.

Submit Cancel

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Figure 1 Monitor home screen

After logging in to OpenClinica, the Monitor is presented with her home screen, as seen in Figure 1. Below is an explanation of the various objects on this screen.

1: The name of the Study (SafeBoosC) followed by the name of the Site (Denmark – Copenhagen) which you're currently logged onto. Both names are links and by following these links you can see information regarding the Study and the Site, i.e. associated users and their role within the Study and/or Site.

2: Use this link to change the current Study or Site, if applicable.

3: Use the Log Out link when you are done, please don't just close your browser window. This is due to security reasons.

4: The menu bar. The menus are explained below:

- **Home.** Click to show the screen in Figure 1.
- **Subject Matrix.** Click to show all subjects and all Events. From here, you can open all CRFs no matter which status they have; see (6) for further info.
- **SDV.** Shows almost the exact same window as Home, except there is just one button instead (SDV All Checked) and the Notes & Discrepancies link is not present.

- **Notes & Discrepancies.** By clicking here you are brought to a list of all discrepancy notes associated to all Study Subjects within current Site.
- **Tasks** brings up the following submenu:

Monitor and Manage Data	
Subject Matrix	Notes & Discrepancies
View Events	Study Audit Log
Source Data Verification	
Extract Data	
View Datasets	Create Dataset
Other	
Update Profile	Log Out

Figure 2 Tasks submenu

From here you can go to the Study Audit Log, View and create Datasets for extracting data and updating your profile if necessary.

5: The Notes & Discrepancies Assigned to Me is a link which brings you to an overview of the notes and discrepancy notes associated to all Study Subjects within current Site, filtered by the recipient being you. If any discrepancies are specifically assigned to you and their status is not “Resolved”, they will increase the count after the link. In this screen shot there are none (0).

6: The CRF table shows the CRFs ready to be monitored. A CRF has to be marked as “Complete” before it is eligible to be shown in this table. Uncompleted CRFs can be monitored too; they are just not shown in this table. The most important columns are explained below:

- **CRF Status:** By clicking the , a popup window opens containing this CRF. In this popup window you can perform Source Data Verification. When SDV is done, close the popup window and click the SDV button in the **Actions** column.
Note: If you accidentally click the SDV button for the incorrect CRF, just click the  icon in the SDV Status column. This will reset the SDV status for that CRF.
- **SDV Status:** If you have monitored several CRFs at once, you can opt to check the SDV Status boxes for these CRFs and then press the “Submit” button.
Note: The buttons shown here can change into a single “SDV All Checked” button. The functionality of these buttons is the same.
- **Study Subject ID:** The unique subject identifier within the OpenClinica installation for SafeBoosC.
- **CRF Name / Version:** The name (and version) of the CRF this table row represents.
- **Event Name:** A CRF can be present in several Events; hence the name of the Event is shown here.
Note: The AE(1) and AE(2) are two different instances of the same Event. This is possible because this Event is repeating; two AE (Adverse Event) Events are registered for study subject “amp”. Even though an Event is not repeating, a serial number is shown anyways. The serial will always be (1), though.
- **The grey areas below the Column names** are filters; only rows matching the chosen filter are shown.

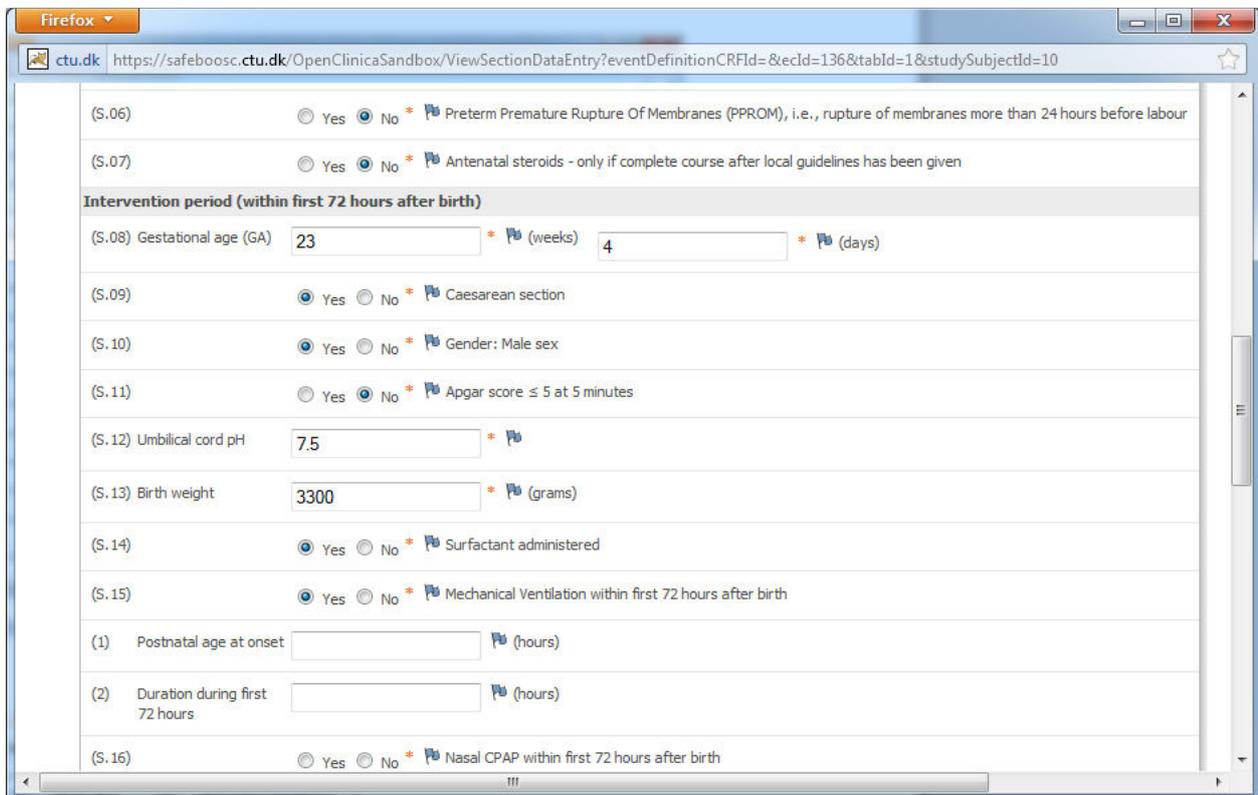
Example use

You would like to monitor the Intervention CRF for “amp”, so you click the  on row number 7. This brings up a window as seen in Figure 3. Please note, that the window is resized and scrolled a bit for practical purposes for this demonstration.

The registration of the birth weight catches your attention. 3300 grams for a baby with a gestational age of less than 24 weeks seems off, so you would like to make a query about this. You click the blue flag  next to the birth weight, which brings up the Discrepancy interface, see Figure 4.

You have to give the discrepancy note a Description and state its Type and Status; these are all required values, indicated by the yellow stars. Per default, a new discrepancy note has status “New” and type “Query”. As a monitor you only have the “Query” type available, but other types exist for other roles in OpenClinica. Too, the recipient of this Query is automatically set to the person having begun data entry.

After filling in the blanks, you click Submit & Close and continue the monitoring process. When you are done with this CRF, you close the popup window. You decide that the monitoring process is not over for this CRF, so you don’t click the SDV button. Instead, you just move on to another CRF.



The screenshot shows a Firefox browser window displaying a CRF form. The URL in the address bar is <https://safeboosc.ctu.dk/OpenClinicaSandbox/ViewSectionDataEntry?eventDefinitionCRFId=&ecId=136&tabId=1&studySubjectId=10>. The form contains several sections and fields:

- (S.06) Yes No *  Preterm Premature Rupture Of Membranes (PPROM), i.e., rupture of membranes more than 24 hours before labour
- (S.07) Yes No *  Antenatal steroids - only if complete course after local guidelines has been given
- Intervention period (within first 72 hours after birth)**
- (S.08) Gestational age (GA) *  (weeks) *  (days)
- (S.09) Yes No *  Caesarean section
- (S.10) Yes No *  Gender: Male sex
- (S.11) Yes No *  Apgar score ≤ 5 at 5 minutes
- (S.12) Umbilical cord pH * 
- (S.13) Birth weight *  (grams)
- (S.14) Yes No *  Surfactant administered
- (S.15) Yes No *  Mechanical Ventilation within first 72 hours after birth
- (1) Postnatal age at onset  (hours)
- (2) Duration during first 72 hours  (hours)
- (S.16) Yes No *  Nasal CPAP within first 72 hours after birth

Figure 3 CRF popup

IF13_BirthWeight: Add Discrepancy Note

"IF13_BirthWeight" Properties:

Subject: **amp** Event: **Screen, Rand, Intervention**
 Event Date: **08-05-2012** CRF: **Intervention (SafeBoosC)**
 Current Value: **3300** More: [Data Dictionary](#)

Add Note

Description:*

Detailed Note:

Type:*

Set to Status:*

Assign to User:

Email Assigned User:

Submit & Close

Figure 4 Discrepancy interface

You choose to investigate a bit into the discrepancy notes too, so you click the “Notes & Discrepancies” link on the menu bar, see Figure 5. Now you can see your newly created Query and another discrepancy note. The last note is something about an incorrect date that you’d like to investigate, so you click either the 🔍 to show the discrepancy note or 📄 to show both the CRF and the discrepancy note.

Notes and Discrepancies

[Hide summary statistics](#)

	Query	Failed Validation Check	Reason for Change	Annotation	Total
New	1	--	--	--	1
Updated	--	--	--	--	--
Resolution Proposed	--	--	--	--	--
Closed	--	--	--	--	--
Not Applicable	--	--	1	--	1
Total	1	--	1	--	2

Study Subject ID	Type	Resolution Status	Site ID	Days Open	Days Since Updated	Event Name	CRF	Entity Name	Entity Value	Description	Assigned User	Actions
amp	Query	New	DK1	0	0	Screen, Rand, Intervention	Intervention (SafeBoosC)	IF13_BirthWeight	3300	Weight seems too high, please review	Cora Dina (Coordinator)	🔍 📄
amp	Reason for Change	Not Applicable	DK1			aEEG/EEG recording	aEEG / EEG Recording (SafeBoosC)	AER1_RecordingDate	16-05-2012	Incorrect date	()	🔍 📄

Results 1 - 2 of 2.

Figure 5 Discrepancy note list

OpenClinica- View Discrepancy Note - Mozilla Firefox

ctu.dk https://safeboosc.ctu.dk/OpenClinicaSandbox/ViewDiscrepancyNote?name=itemData&id=1460&writeToDB=1&monitor=1&strRes!

AER1_RecordingDate: Notes and Discrepancies

Exit Window

"AER1_RecordingDate" Properties:

Subject: **amp** Event: **aEEG/EEG recording**
 Event Date: **22-05-2012** CRF: **aEEG / EEG Recording (SafeBoosC)**
 Current Value: **16-05-2012** More: [Data Dictionary](#)
[Audit History](#)

Note Details

Incorrect date Last updated: **07-06-2012 by Coordinator**
 Assigned to: ()

ID: 109	Type: Reason for Change	Current Status: Not Applicable	# of Notes: 1
Incorrect date		Status: Not Applicable	07-06-2012 by Coordinator
Typing error			

[Begin New Thread](#)

Audit History

Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data value updated	22-05-2012 20:57:27	amplomgaard	AER1_RecordingDate		17-05-2012
Item data value updated	07-06-2012 22:26:18	Coordinator	AER1_RecordingDate	17-05-2012	16-05-2012

(This item was initially entered on 22-May-2012.)

Figure 6 Discrepancy note with audit history

The discrepancy note is shown in Figure 6 and here you can see the full history of the evolvement of the item data for the Recording Date field on CRF aEEG/EEG Recording in the Event of the same name for the study subject "amp".

Should you opt to intervene, you would press the "Begin new Thread" link, but let's say you chose not to.

Next day, Cora Dina logs into OpenClinica. She's the one you selected as recipient for your newly created discrepancy note. She too has a "Notes & Discrepancies Assigned to Me" link, and now there's a (1) after the link, indicating one unresolved entry exists for Cora.

At your next logon, you too have a (1) after the "Notes & Discrepancies Assigned to Me" link, so you click the link and investigate the discrepancy note using the  button. Now you see that the item data has changed to 1300 grams and that the discrepancy note has evolved: Cora has made a reply and chosen to change the status of the note to "Resolution proposed", see Figure 7.

Note Details

<input type="checkbox"/> Weight seems too high, please review		Last updated: 07-06-2012 by Monitor Assigned to: Mona Torres (Monitor)	
ID: 111	Type: Query	Current Status: Resolution Proposed	# of Notes: 2
Weight seems too high, please review	Status: New	07-06-2012 by Monitor Assigned to: Cora Dina (Coordinator)	
Misread birth datasheet.	Status: Resolution Proposed	07-06-2012 by Coordinator Assigned to: Mona Torres (Monitor)	
Data has been changed.			
		<input type="button" value="Update Note"/>	<input type="button" value="Close Note"/>

[Begin New Thread](#)

Audit History

Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data value updated	07-06-2012 23:46:37	Coordinator	IF13_BirthWeight	3300	1300
Item data value updated	07-06-2012 21:59:36	Coordinator	IF13_BirthWeight		3300

(This item was initially entered on 07-Jun-2012.)

Figure 7 Discrepancy note with audit history and query thread

You are satisfied with the new data, so you click the "Close Note" button, fill in the form and click the "Submit & Exit" button afterwards.