



A monitor's guide to Notes & Discrepancies

Upon logging into OpenClinica as monitor, you will see a top menu with 'Notes & Discrepancies'.



By clicking this, you will get an overview of all queries made at that site. Note that queries are site-specific.

Notes and Discrepancies

Hide summary statistics

	Query	Failed Validation Check	Reason for Change	Annotation	Total
New	--	1	--	--	1
Updated	--	--	--	--	--
Resolution Proposed	1	--	--	--	1
Closed	1	--	--	--	1
Not Applicable	--	--	--	--	--
Total	2	1	--	--	3

Trial Participant ID	Type	Resolution Status	Site ID	Days Open	Days Since Updated	Event Name	CRF	Entity Name	Entity Value	Description	Assigned User	Actions
DK01014	Query	Closed	DK01	22		Withdrawal	Withdrawal	W1_WithdrawDate	2018-02-02	W1	Janus Engstrøm (root)	Apply Filter Clear Filter
DK01042	Query	Resolution Proposed	DK01	13	3	Baseline	Baseline	BL1_Sex		Test til mig selv (monitor)	Monitor Monitor (monitor)	
DK01015	Failed Validation Check	New	DK01	0	0	Day form	Day form	D4_ComaEvening	1	Can't find screening in patients file	()	

Results 1 - 3 of 3.

The  at the right side of a query is a link to the form in which the query has been made.

Queries in the Notes & Discrepancies are site-specific. Only the monitoring unit for that site, users subscribing to Notes & Discrepancies at that site and administrators can see the queries.

How queries are used

A query is a question or a note the monitor makes during the monitoring of a form. When submitting a query you must assign the query to a user. That user will receive a notice when logging in to OpenClinica and will have to propose a resolution, before the monitor or an administrator can close the query.

Only the monitor (and administrators) can make queries. They are made by clicking the flag on the right side of the question you want to make a query to (see next page).



Delirium assessment - Morning

D3 Morning assessment (during dayshift): Was the patient in coma at morning assessment? Yes No  [info]

Delirium assessment - Evening

D4 Evening assessment (during evening shift): Was the patient in coma at evening assessment? Yes No  [info]

Clicking the flag will allow you to add a query (see below). When assigning a query to a user, you have the option to send that user an email by ticking the box. When the query is submitted, the flag will become red as seen above indicating that a new, unanswered query has been made.

Add Note

Description:*	<input type="text" value="Was the patient CAM-ICU screened?"/>
Detailed Note:	<input type="text" value="Can't find the screening in the patients file"/>
Type:*	<input type="text" value="Query"/>
Set to Status:*	<input type="text" value="New"/>
Assign to User:*	<input type="text" value="Engstrøm, Janus (root)"/>
Email Assigned User:	<input type="checkbox"/>
<input type="button" value="Submit & Close"/>	

When the user logs into OpenClinica, a message appears. This is also a link to 'Notes & Discrepancies', which could also be reached from the top menu.

Notes & Discrepancies Assigned to Me: 4

The user now has the option to propose a resolution/answer to the query by clicking the 'view'-button  (see page 1). Clicking on this will open a new window with information about the query.



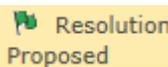
D4_ComaEvening: Notes and Discrepancies

"D4_ComaEvening" Properties:

Subject:	DK01015	Event:	Day form
Event Date:	15-02-2018	CRF:	Day form
Current Value:	1	More:	Data Dictionary Audit History

Note Details

<input type="checkbox"/> Can't find screening in patients file				Last Updated: 09-04-2018 by sed@regionsjaelland.dk	
				Assigned to: ()	
ID: 47	Type: Failed Validation Check	Current Status: New	# of Notes: 1		
Can't find screening in patients file		Status: New	09-04-2018 by sed@regionsjaelland.dk		
Are you sure this patient was screened (CAM-ICU)?					
					Propose Resolution

Proposing a resolution changes the status of the query to . If the answer to the question has been changed, this will be visible here as well (Audit history).

Audit History

Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data value updated	09-04-2018 10:49:38	sed@regionsjaelland.dk	D4_ComaEvening		1
Item data value updated	09-04-2018 14:47:31	sed@regionsjaelland.dk	D4_ComaEvening	1	0

(This item was initially entered on 16-Feb-2018.)

When a resolution has been proposed, the monitor or administrator can

- close the query ( **Closed**)
- or
- update the query ( **Updated**), which assigns the query back to the user along with a note.

In this way, monitor, administrator and the site should be able to solve discrepancies. The monitor can also use queries to keep track of odd values.