Royal Papworth Hospital NHS Foundation Trust

GD053

Discrepancy Notes and Queries for Data Management

OpenClinica Discrepancy Notes and Queries provide a means for users to document, communicate, and manage issues about data to facilitate verification of the accuracy and completeness of the data. This guidance document provides guidance for any study team member with an OpenClinica Data Manager role, for data entry user please see guidance in the GD011 Generic OpenClinica User Guide.

Whilst the process for managing discrepancy notes and queries for OpenClinica 3 and OpenClinica 4 is the same, there are differences between the two databases. OpenClinica 3 refers to 'Notes and Discrepancies' and uses the flag symbol, OpenClinica 4 uses the term 'Queries' and uses a speech bubble instead of a flag – see appendices A through to D.

Important Note: it is important to note Study Data Managers can close manual queries they have raised. However, they should not close any other note or query unless this responsibility is delegated to them by QA via email communication (email to be retained for audit purposes), file note or in the Data Management Plan (DMP). If there is any doubt regarding the Study Data Manager closing a query, confirm the appropriate action with the Data Manager Lead or the Study Monitor.

Using Discrepancy Notes / Queries when data cleaning

Used by the Study Data Manager or Monitor to verify the data entered into an eCRF, e.g. to query a blood test date that differs from the visit date.

1a. Raising a discrepancy note in OC3:

I. To raise a discrepancy 'query' note click the flag next to the date of blood test field:
   a. **Description Field** – enter a brief description of the query e.g. 'Query date'.
   b. **Detailed Note** – if required, enter a more detailed description of the query e.g. 'Please check the date entered as it differs from the visit, please amend if necessary'.
   c. **Type** – select the Query option from the drop-down menu.
   d. **Set to Status** – select the 'New' option from the drop-down menu**.**
   e. **Assign to User** – select the appropriate user from the drop-down menu (this will usually be the user who entered the data; however, you should work from an up-to-date list of study location staff, and the query can be assigned to an individual in the drop-down field.
   f. **Email Assigned User** – tick this option if you require an email to be sent to the user to notify them that a query note has been assigned to them.

1b. Raising a discrepancy note in OC4:

I. To raise a discrepancy 'query' note query click the bubble next to the date of blood test field:
   a. Press + New next to Queries.
   b. In the box prefilled "Add a new query" enter a detailed description of the query e.g. 'Please check the date entered as it differs from the visit, please amend if necessary'.
   c. **Assign to** – select the appropriate user from the drop-down menu. This will usually be the user who entered the data; however, you should work from an up-to-date list of

study location staff, and the query can be assigned to an individual in the drop-down field. NOTE: Although an individual is selected other site staff with the appropriate role may also respond to discrepancies.

d. **Email?** – tick this option if you require an email to be sent to the user to notify them that a query note has been assigned to them.
e. To submit click on **'Add Query' the screen closes with the query assigned to the selected user and if selected an email is also sent.**

NB: Whilst raising a query can only be to an individual, it is not only that individual that can view or respond to the query. Any member of staff at that location can view all discrepancy queries for that location by navigating to the Notes & Discrepancies page of OC3 or the Queries page in OC4. Any member of staff at that location is able to respond to a discrepancy note or query.

1. Resolving answered queries:

OpenClinica 3 and OpenClinica 4 share the same process with the exception that OpenClinica 3 users can return the query with the status of 'updated' or 'resolution proposed'; OpenClinica 4 users will use the status of 'updated'.

I. When answered, the query is directed back to the individual who raised the query. If the information provided or the alteration made to the data is considered adequate, then the query note can be closed (see section 2. Closing discrepancy notes) by the query raiser. NOTE: Although the discrepancy is returned to the raiser other Data Managers with the appropriate Study Permissions can take any of the actions in the preceding bullet points.
II. Should further clarification be required, the query note can be returned to the user asking for more information / re-query the data / advise that the data has not been edited. This can be done by clicking on **Update Note** and following steps in point II above.
III. Discrepancy notes raised should generally be assigned to the user who initially entered that data. However, in certain cases for example when an individual is unavailable then the query can be assigned to another individual as per the location's delegation log. Please see Appendix E for examples on writing a note.
IV. Ensure that the Study Data Review document has been updated to reflect an open discrepancy note.

2. Closing a discrepancy note

I. Remember to check that you have been delegated the task of closing discrepancy notes. If the query has been raised by a Study Data Manager, then usually another Study Data Manager can close the query.
II. Read the response provided in the **Description** or **Detailed Note**. If it is stated that the data has been corrected, check the **Audit History** to see the change and check that the change made is appropriate.
III. To close a note, follow these steps:
    a. **Description** – provide a reason for closing the note e.g. 'data amended, note closed'.
    b. **Detailed Note** – if required further detail can be added in this field.
    c. **Set to Status** – select Closed from the drop-down menu, for OC4 press Close This Query.
    d. **Assign to User** – it is not necessary to change this field.
    e. **Email Assigned User** – it is not necessary select this option.

IV. Update the Study Data Review document to show this query has been resolved and closed.

3. Reviewing annotations:

The Study Data Manager reviews the data entered for patterns of issues such as missing data and out of range data especially where annotations are present confirming entries. Any issues found are discussed with the Data Manager Lead and could lead to design changes within the database.

Downloading the annotations gives the Study Data Manager and/or the Monitor a clearer indication of any recurring issues that a study location may be having.

I. For all CTIMP and device studies the Study Data Manager should download the annotations from OpenClinica using either:
   a. Using the facility available on the **notes & discrepancies/queries** page and then filtering the **type** column by **annotation** and downloading the results as csv file. The csv file can be saved in the relevant section of the eTMF and reviewed by the Study Data Manager by filtering the columns to show the relevant data.
   b. Insight can be used for OpenClinica 4 studies to download the annotations to facilitate the reviews.

   This should be completed prior to any interim analysis and depending on volume of recruitment at a minimum of six months.

4. Reviewing data validation fails:

I. During the process of data cleaning the Study Data Manager should review the **failed validation checks** (OC3) or query notes with prefix **automatic query** (OC4).
II. These checks are raised automatically by OpenClinica when out of range data is added to a data field or if a programmed condition is not met. These failed checks show as new open queries that require action to close them.
III. Failed validation checks/Automatic system queries can be reviewed by the Study Data Manager but only closed by the Monitor.
IV. In some instances, the Monitor may delegate the task of closing the failed validation checks to the Study Data Manager; these delegations should be documented and for CTIMPs should be file noted.
V. Reviewing the failed validation checks will highlight particular data fields that have a high number of failed checks and therefore a review of this field may be required. Any fields with a high number of failed checks should be raised with the Data Manager Lead to review the data range tolerances or highlight a training requirement at the location.
VI. Failed validation checks in OC3 can be overridden by data entry if, after clicking on save and reading the warning, the user creates an annotation note over the option of a failed validation check. The subsequent failed validation check will be of the status n/a. In OC4 the user is advised of the presence of checks and may update the value before proceeding or click PROCEED which generates a query.

5. **Reasons for change:**

A data entry user may be required to change the data entered or add missing data to eCRFs when the eCRF has been marked as complete, this action will create a reason for change note. The Study Data

Manager may close a reason for change note if data has been added where no data was previously. If data is being changed, then the reason for change discrepancy note must be reviewed and closed by the monitor. OC4 does not require these to be closed, as their status is Not Applicable, similar to annotations.

Reminder: it is not the Study Data Manager's role to close discrepancy notes without the agreement of the Monitor. For CTIMP studies this should be file noted, for non-CTIMP studies, the monitor email detailing the agreement should be filed in the Data Management section of the eTMF.

Appendix A
OpenClinica 3 types of notes and discrepancies

Type	Description
Failed validation check	For data that does not comply with programmed data validation rules. Auto created by OpenClinica, the status of this note will be **new**. The note requires further review to determine if the data is acceptable.
Query	Manually generated, mostly used to ask a question about data entered.
Reason for change	Notes added by a user when modifying data on a form that has already been marked as complete.
Annotation	To make comments or provide information about the data that cannot be adequately represented in the CRF, annotation notes will auto fill to a status of not applicable.

Appendix B
OpenClinica 3 statuses of notes and discrepancies

Status	Icon	Description
New		The initial status for a query or failed validation check discrepancy note.
Updated		Used when responding to a discrepancy note, but the response requires further follow up or additional information.
Resolution Proposed		When a user addresses a discrepancy note by fixing or responding to a data problem or by explaining why the existing data is correct and sets the status to resolution proposed. A monitor or study data manager (depending on who created the note) then reviews the proposed resolution and updates the status.
Closed		The final status for a failed validation check or query that has been answered. The status of closed cannot be altered.
Not Applicable		This status is for reason for change and annotations as no further action is required. The not applicable status cannot be used for failed validation check or query notes.

Appendix C
OpenClinica 4 types of queries

Type	Description
Queries (manual)	Manually generated, mostly used to ask a question about data entered.
Queries (automatic)	Differentiated from the manual queries by the prefix "Automatic query for: ". When data does not comply with programmed data validation rules. Auto

	created by OpenClinica on entry, the status of this query will be new. The query requires site location to review the data to determine if the data is acceptable.
Reason for change Δ	Notes added by a user when modifying data on a form that has already been marked as complete.
Annotation ⓘ	To make comments or provide information about the data that cannot be adequately represented in the CRF, annotation notes will auto-fill to a status of not applicable.

Appendix D
OpenClinica 4 statues of queries

Status	Icon	Description
New		The initial status for a query or failed validation check discrepancy note.
Updated		Used when responding to a discrepancy note, but the response requires further follow up or additional information.
Closed		The final status for a failed validation check or query that has been answered. The status of closed cannot be altered.
Not Applicable		This status is for reason for change and annotations as no further action is required. The not applicable status cannot be used for failed validation check or query notes.
Closed Modified		This means the data was changed after the query was closed, or the field/item was removed during a design change and query was auto closed.

Appendix E
Further guidance for authoring a query note

1. Queries raised to study locations to clarify data entered should be clear, concise, polite and not lead the recipient to an answer. A generic example is provided below:
   Please check the data entered. If necessary, please amend the data and save the changes made.
2. If a data query is based on another data field being incorrect, it is important to not assume which data entry is incorrect. For example, if the start time in row 5 is earlier than the stop time in row 4, do not assume start time in row 5 is incorrect as the entry error could be the stop time in row 4.
   Do not lead the user to an answer, the query should be worded as:
   Please check the times in rows 4 and 5 as the time periods overlap one another.
3. If data is missing or partially complete, query should clarify whether data will be expected to be entered and if not then why. Example: Can I clarify whether this value is available and if so, can this be entered now please. Or if data was not recorded or unavailable can this please be mentioned clearly via an annotation.
4. When raising queries involving multiple data points, ensure that they are queried separately to reduce the likelihood of some of the data points not being addressed by end user. For instance, instead of raising one query to say can date and time be checked for this follow up visit as well as the next two follow up visits – three separate queries should be raised for each follow up visit to highlight the data that needs to be addressed in that follow up.

Referenced Documents	
GD011	OpenClinica 3 Generic User Guide