

## 18.1 Study Runner

When users are entering data for testing or real world data collection, users will access OpenClinica via Study Runner. Study Runner is made up of many other paged such as the Participant Matrix, Queries Table, Data Review Tables, in addition to all Participant Details Pages and data. To access Study Runner the first step is to publish a study. Usually, studies will be published to **TEST** first . In addition to letting you use Study Runner features, publishing to **Test** generates OIDs that can be used for edit checks. To learn more about publishing to test and accessing study runner review section [5.1 Publishing Your Study](#). The following sections make up OpenClinica's Study Runner environment.

**\*This page is currently in draft form and subject to change.**

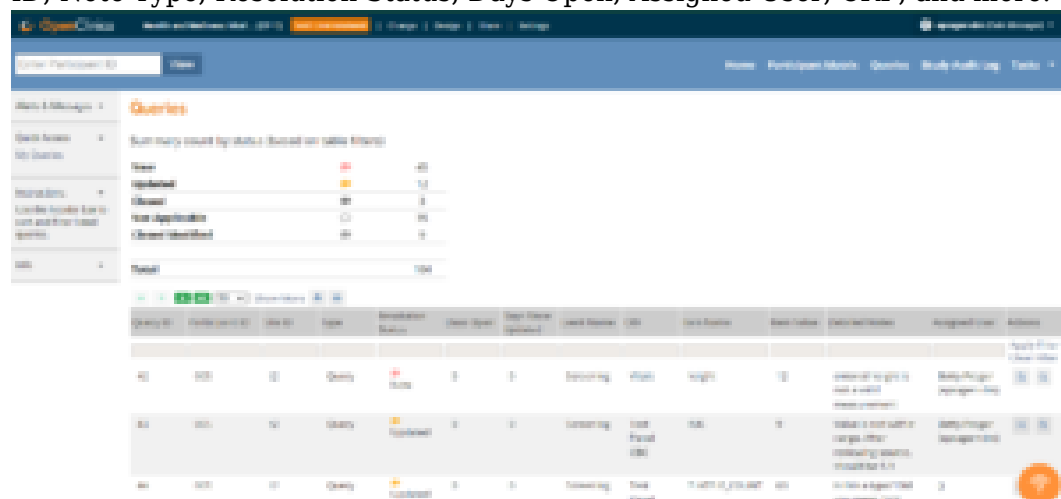
Approved for publication by Paul Bowen. Signed on 2023-12-13 1:52PM

Not valid unless obtained from the OpenClinica document management system on the day of use.

### 18.1.1 Submit Data

#### 18.1.1.1 Queries

The Queries page is the central point for reviewing all notes (queries, annotations, and reasons for change) entered within a study or site. You can sort and filter these notes by Query ID, Participant ID, Note Type, Resolution Status, Days Open, Assigned User, CRF, and more.



Query ID	Participant ID	Date	Type	Resolution Status	Days Open	Assigned User	CRF	CRF Name	CRF Version	CRF Field Name	Assigned User	Actions
40	001	12/13/2023	Query	Open	0	Paul Bowen	1	12/13/2023	1.0	12/13/2023	Paul Bowen	View Details
39	001	12/13/2023	Query	Resolved	0	Paul Bowen	1	12/13/2023	1.0	12/13/2023	Paul Bowen	View Details

The following are definitions for the 3 types of notes found in Queries page:

#### Definitions:

- **Queries** are inquiries or alerts about potential incorrect or missing data. Each query has a workflow status to ensure it is reviewed and acted on.
- **Annotations** are notes on a Form that do not contain clinical data and are usually used for keeping track of user workflow.
- **Reasons for Change** are notes added by a user when modifying data on a form that has already been marked as Complete. They explain why there was a data change.

How are queries created?

Queries can be created manually by a user when entering data within a form or automatically by the system due to a pre-configured edit check within a form.

How do I close a query?

A data manager or monitor user can close a query when updating the query note within the form.

This can be done by viewing the record as a whole or viewing only the query. If you are a Data Manager or Monitor you can find additional information about your role and queries below.

## The Summary Table

### Queries

Summary count by status (based on table filters)

1	New		45
2	Updated		12
3	Closed		3
4	Not Applicable		35
5	Closed Modified		9
6	Total		104

The summary table contains the types of query resolutions statuses and total of each resolution status shown in the Query table. These numbers reflect the breakdown of the total number of items on the current Queries table. Apply filters to the Queries table both the total number of rows and the Summary Table total will represent the filtered table view.

1: New - This status indicated that a query has been added by either a site user (e.g., a comment/annotation), data manager, or monitor, or was auto-generated by OpenClinica based on built-in edit checks. In the summary table this row represents the number of queries in the current queries table view that have the resolution status of new.

2: Updated - This status indicated that either a site user, data manager, or monitor has added information to the query. In the summary table this row represents the number of queries in the current queries table view that have the resolution status of updated.

3: Closed - This status indicated that the query is considered resolved by the data manager or monitor. In the summary table this row represents the number of queries in the current queries table view that have the resolution status of closed.

4: Not Applicable - This resolution status is given to Annotations and Reasons for Change. In the summary table this row represents the number of Annotations and/or Reason for Change shown in the current queries table view. Their resolution status is always Not Applicable and they have N/A in the Query ID column.

5: Closed Modified - This resolution status means the data was changed after the query was closed.

6: Total - The total number of New, Updated, Closed, Not Applicable, and Closed Modified Resolutions Statuses within the current queries table. In other words the total number of queries, annotations, and reason for change shown in the current queries table view.

## The Queries Table

The Queries table displays queries, annotations, and reasons for change. This table can be filtered to show only queries, only annotations, only reasons for change, and combinations of the 3 types. This

7				50	Show More		
8	Query ID	Participant ID	Site ID	Type			
9							



8: This row of the queries table shows the headers for each column. For example, the first column of this row shows the Query ID, this is a unique number that is assigned to any query when it is created. If the queries table is set to show only annotations or reasons for change this Query ID column will only contain N/A values. Other column headers are: ParticipantID, SiteID, Type, Resolution Status, Days Open, Days Since Updated, Event Name, CRF, Item Name, Item Value, Detailed Notes, Assigned User, Actions .

Examples of filters:



11: This column indicates if the query has been assigned to a user. In some cases the user is sent an email when a query is assigned to them. When there is no assigned user there will be no user name between the () parentheses.

13: Under the Actions column any row below the filter row will have 2 actions. First the "View Query Within Record" action and second the "View Query Only" action.

Icon	View	Description
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View Query Only

This option displays a mini version of the form contain only the item in question along with its queries and item history. You can add a query note, reassign the query, and you have the option of emailing the assigned user. All users with access to queries can update the query; but only Data Managers and Monitors have access to close the query. This option does not allow changing the item value.



View Query Within Record

This option displays the full form initially focused directly on the selected query. All users with access to queries can to update the query, but only Data Managers and Monitors have access to close the query. The rest of the form is also available for review. This provides reviewers with more context when reviewing specific item data issues. Note that for users with permission to edit the record, the form will be opened in edit mode allow any data value on the form to be updated.

You can click Show More at the top of the table to show more columns. The Show More text will then be replaced by Hide. If you click Hide the additional columns will be hidden from the table view and Show More will reappear.

Additional columns that will display when Show More is select are:

Date Created  
Date Updated  
Event Date  
CRF Status  
Item Type  
# of Notes

Originator - This is where you can see if a user created the query or if it was auto generated by an edit check. If it was auto generated the Originator will be System.

If you would like to learn more about Queries and how they relate to a specific user type:

[Queries and Clinical Research Coordinators \(CRC\)](#)

[Queries and Data Managers \(DMs\)](#)

[Queries and Monitors.](#)

## **18.1.2 Monitor and Manage Data**

## **18.1.3 Extract Data**

## **18.1.4 Reports**