11 Glossary

Audit Log: System feature that maintains a historical record of key actions related to a Study Subject that have run on the OpenClinica database (this is part of 21 CFR Part 11 compliance).

CRF (Case Report Form): A form that collects and contains Study Event information for a Study Subject. CRFs are defined using Excel spreadsheets and are presented in a web interface that is easy to complete. See also Defined CRF.

Dataset Definition: Criteria (metadata) specified to create a dataset.

Dataset: A collection of data and metadata from records such as CRFs, Study Events, etc. that matches a dataset definition and is exported to a file whose format can be selected, for use in other applications.

Defined CRF: An Excel spreadsheet composed of Sections, Item Groups, and Items that you create for use in OpenClinica. A defined CRF can have multiple versions. You assign it to one or more Study Events in one or more Studies.

Delete: A delete action  completely removes the information from the OpenClinica system. Deleted information cannot be restored, although the audit log tracks the deletion action. Nearly all information in OpenClinica is removed rather than deleted because removed information can be restored.

Discrepancy Notes: Means of communicating about CRF Items whose value, condition, level of detail, etc. are not as expected.

Enrollment: Adding a Subject to a Study. The OpenClinica Enrollment Date is when the Subject is added to an OpenClinica Study.

Event: See Study Event.

Group: See either Item Group, or Subject Group in Subject Group Class.

Item: Also known as a data Item. A single question in a CRF. Items have metadata attached to them. Each Item has an OID attached to it. Items can have multiple Edit Checks attached to them through either metadata or Rules.

Item Group: A grouping of Items in a CRF. Item Groups can be repeating (for example, recording multiple Adverse Events on one form) or non-repeating.

Installation Qualification (IQ): Evidence that the system installed successfully per design without incident.

Job: In OpenClinica, you can schedule **Export Data Jobs** and **Import Data Jobs** to run automatically at a specified frequency.

Module: A group of related features in OpenClinica, such as the Submit Data module. Access to a module is based on a user's Role and Type.

Null Values: The string that represents null values for an Event Definition, for example "N/A" for Not Applicable. The string is considered to be a reserved word for the CRF.

OID (Object Identifier): System-generated unique identifiers that OpenClinica uses to directly reference key entities in a Study. OIDs are essential for importing data, creating Rules, and using data exported from OpenClinica to certain formats.

Operational Qualification (OQ): Evidence that the system operates as expected per functional requirements and business processes, and that it does so accurately and consistently.

Performance Qualification (PQ): Evidence that the system operates as expected in the user environment. This is performed by the end-user and is sometimes referred to as User Acceptance Testing (UAT).

Person ID: The unique identifier for a Subject that references the Subject across all Studies in the OpenClinica system. It can be required or optional, depending on the way the Study is set up.

Remove: A remove action  makes the information unavailable in the OpenClinica system. You can restore information that has been removed to make it available again. Most information in OpenClinica is removed so that it can be restored, although in some cases, information can be deleted. See also the glossary description for Delete.

Roles: Categories for users in OpenClinica that determine the tasks available to them in the system.

Rules: Customized methods used to trigger actions on records such as the automatic generation of a Discrepancy Note, email, etc. Rules are stored in XML files. They can be built directly in an XML file and uploaded to OpenClinica, or built in OpenClinica using the Rule Designer feature.

Secondary ID: An optional identifier given to a Subject. It is often a legacy identifier like a patient record number that is used to link the Subject to another system or workflow, for example.

Sites: Locations where the Study is taking place, although they do not have to be physical locations. You can work with OpenClinica at the Site level, which limits the view of the Study to a specified Site.

Study: In OpenClinica, a clinical trial or clinical research project, including all the metadata and data for it.

Study Event: A visit or encounter in the Study where data is captured or created. A Study Event packages one or more case report forms (CRFs). Also referred to as an Event.

Study Event Definition: Information that describes a type of Study Event, and includes specifying the CRFs to be used for it.

Study Level: A view of the Study that aggregates information and data for all Sites in the Study.

Study Subject: A person added to a Study in OpenClnica. Also referred to as a Subject.

Subject Group Class: An optional feature used to categorize Subjects in a Study. Often, Subject Group Classes are used for different treatment options.

Study Subject ID: A unique identifier generated either manually or by the system when adding a Subject to a Study.

Subject: In OpenClinica, a person who participates in Studies.

Subject Case Book: All CRFs for all Events for a Study Subject.

User: Person using the OpenClinica software. A user can have one or more Roles in one or more Studies or Sites. For some automated processes, the user can be an automated system.

Functional approval by Laura Keita. Signed on 2016-01-11 5:57AM

Approved for publication by Ben Baumann. Signed on 2016-01-11 9:10AM