Royal Papworth Hospital
NHS Foundation Trust

GD026

Software Management for OpenClinica Updates

The Data Management Team currently manages one major software, which is OpenClinica Enterprise Edition. This guidance covers the maintenance and updates of this system.

There are two major versions of OpenClinica (OC); OpenClinica 3 (OC3) and OpenClinica 4 (OC4), upgrades for OC4 are Stacks. The upgrade validation process differs between these versions, as OC deploys upgrades differently for each version.

1. OpenClinica 3 validation

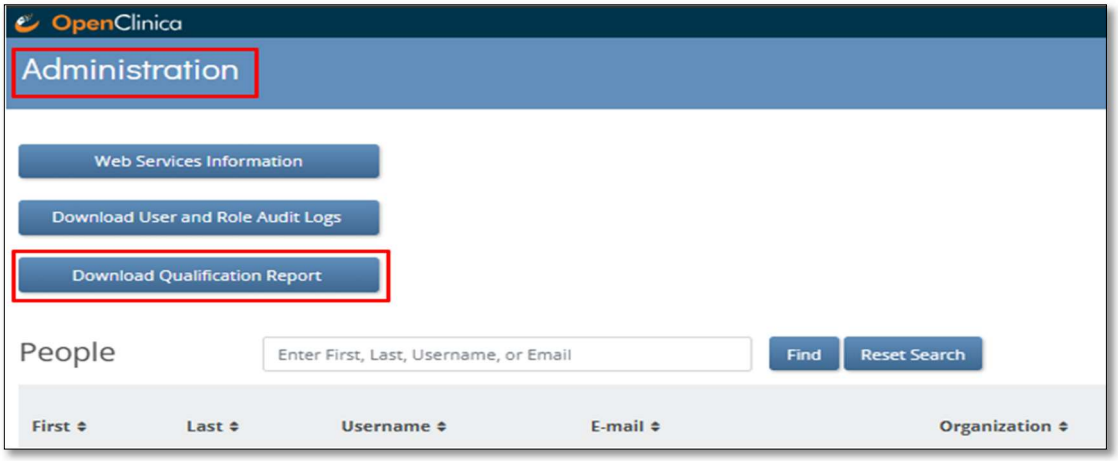
1. When a new version is announced by OpenClinica, the Senior Clinical Trial Data Manager (SCTDM) or delegated OpenClinica Superuser, responds to OpenClinica support to request update the test site first (https://papworth-test.eclinicalhosting.com/OpenClinica/). The timing of this is at the discretion of the SCTDM; this timing can allow external users to identify bugs that can be fixed before the test site is updated.
2. The update is documented on *FRM084 OpenClinica Update Log* by SCTDM, found on S:\ drive in \\Resource\Papworth\shared\R&D\QA meetings\Data Management\OpenClinica. A shortcut is found in \\Resource\Papworth\shared\OpenClinica\Documentation.
3. The Qualification Report(s) generated by OpenClinica for the update are stored on the S:\ drive in \\Resource\Papworth\shared\OpenClinica\Documentation under the upgrade version number.
4. User Acceptance Testing (UAT) is run by the Data Management Team on some of the recent and largest studies. Which studies the UAT is run on, is decided by the SCTDM (or delegate), the testing of different modules of OpenClinica, such as Participate is also to be taken into consideration. The SCTDM records the UAT on FRM084 OpenClinica Upgrade Log.
5. Other testing maybe run based on the provided Release Notes and this is decided by the SCTDM, e.g. testing of extracts in and out of DataMart, and are documented on *FRM084 OpenClinica Update Log*.
6. When UAT is considered as passed, the SCTDM or delegate requests OpenClinica support to update the live site (https://papworth.eclinicalhosting.com/OpenClinica/) and *FRM084 OpenClinica Upgrade Log* is updated with the new details.
7. The Qualification Report(s) generated by OpenClinica for the live site are stored on the S:\ drive in \\Resource\Papworth\shared\OpenClinica\Documentation under the version number.
8. If it is decided that the version is not to be upgraded on the live site, the reason is documented on FRM084 OpenClinica Upgrade Log, and a request is submitted to OpenClinica Support to uninstall the upgrade from the test site.

2. OpenClinica4 validation

The validation process for OC4 differs from OC3 due to the more frequent Stack releases. OpenClinica Superusers receive notifications from OpenClinica support about upcoming upgrades. Major upgrades (changing to a whole version number e.g. v18.1.2 to v19.0) come with longer notice than minor upgrades (e.g. v18.1.1 to v18.1.2).
Note: Stack releases are deployed into the system without user approval making it important for the Superusers to validate upgrades to identify system bugs and address any issues that could impact data security and compliance.

2a. Major upgrades

1. For major upgrades an SCTDM or delegate OC4 Superuser reviews the release notes, to understand the upcoming changes and potential impact on OC4 studies. OpenClinica often offers webinars in advance of major upgrades, in addition to release notes, the SCTDM should attend or review these as part of their assessment.
2. After the upgrade release, the Superuser uploads eCRFs from a range of studies to the *Preview staging environment* (also called Sandbox) to validate the upgraded features. At this stage any system bugs and other OC4 related issues are identified and if found reported in an OpenClinica support ticket.
3. It is advised to monitor the OpenClinica support platform for system bugs reported by other users. This step helps the data team to proactively protect the study data on OC4 and where applicable, keep relevant study team members informed.
4. Testing upgrades on OC4 modules, which are not used by PTUC, for example eConsent and Randomize, may be impossible. However, reviewing user feedback and related release notes informs potential future use.
5. Not all updates in the release notes can be tested directly as some might be related to PTUC studies but not be applicable now. For example, (**OC-21950**) in stack 19.3, fixed a display issue where the Publish History table on the Share Page did not correctly render the page number being viewed above page 99. To test this new update, only PTUC studies with over 100 pages of revision history could have been used, however, none of the studies had up to 100 pages at the point of testing.
6. On release of the update, where the SCTDM deems it necessary, User Acceptance Testing (UAT) is run by the Data Management Team on a sample of active and large studies in the *Test environment*. The studies for UAT is decided by the SCTDM or delegate, testing of different modules of OpenClinica such as Participate is also be taken into consideration.
7. UAT for OC4 validation may be achieved using Selenium, if required, as an automated data entry utility.
8. Any study specific or data team related issues identified during UAT (for example, the overriding of a customised user role due to an upgrade in user permissions levels, an upgrade to cross-form instances), are the responsibility of the Data Management Team to resolve. Where applicable, the Data Management Team collaborates with the Study Team to discuss solutions.
9. Any system bugs and overall performance issues identified are reported in an OpenClinica support ticket.
10. The update and UAT outcomes are documented on *FRM084 OpenClinica Update Log*, which is found on S drive in \\Resource\Papworth\shared\R&D\QA meetings\Data Management\OpenClinica. A shortcut is also be found in \\Resource\Papworth\shared\OpenClinica\Documentation.
11. The Qualification Report(s) generated by OpenClinica by the update are downloaded (see screenshot below) and stored on the S\: drive in \\Resource\Papworth\shared\OpenClinica\Documentation under the version number.



12. All upgrade certification and validation documents are stored in the S\: drive in \\Resource\Papworth\shared\OpenClinica\Documentation .

2b. Minor Upgrades

1. For minor upgrades, the assigned Superuser conducts a risk-based assessment of the upcoming release, and its potential impact on existing studies in OC4. Dependent on the notification times it is not always possible to check prior to the release.
2. For the risk assessment, the upgrades are reviewed on the OpenClinica support platform, where videos and screenshots of the user's complaint are stored to understand issue, or on eCRFs in the *Preview staging environment*.
3. The SCTDM or delegate makes the final decision on whether a minor upgrade is tested, based on discussions with the Superuser who conducted the risk assessment.
4. If the minor upgrades are of no impact, e.g. a minor update on an OC4 module that is not used by PTUC, then testing cannot be done, and this will be documented in FRM084 or changes to support icons or additional footnote text.
5. If the minor upgrades are considered low impact, testing such upgrades may be scheduled for the next approved UAT session.
6. For the remaining steps, refer to steps 5 to 10 and 12 of the major upgrade validation.

See appendix A for OC4 validation flowchart.

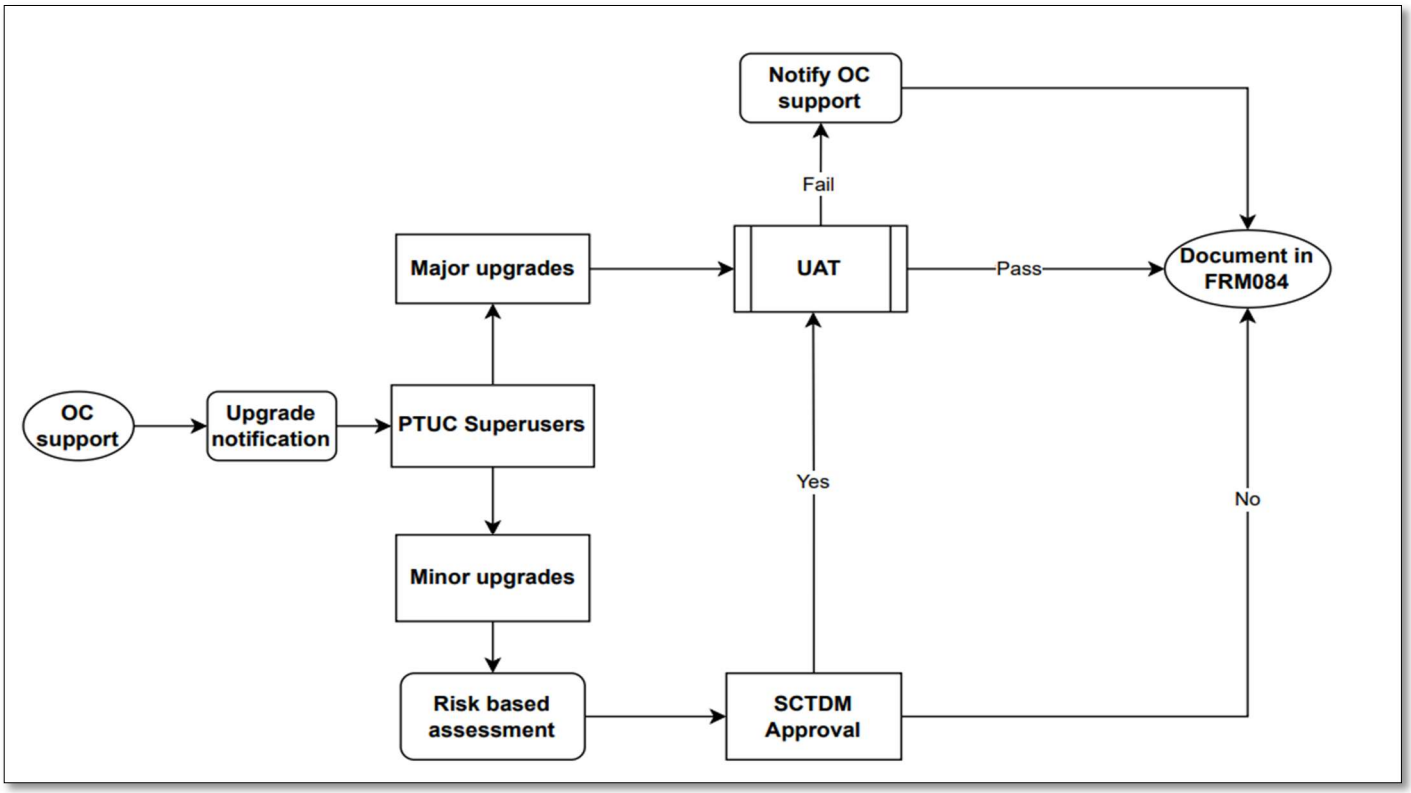
Note: Internal validation of the OpenClinica systems is not limited to testing formal patch releases. Validation also occurs during day-to-day use, where any technical issues or user requests are promptly reported to the Data Management Team for investigation. Where necessary, a Superuser escalates to OpenClinica Support and tracks through the support issue tracker until resolved. Early identification and reporting of issues are essential for maintaining data integrity and ensuring ongoing system compliance.

For further guidance on computerised systems validation, refer to *GD014 Clinical Data Management Validation*.

OpenClinica Support can be found at https://www.openclinica.com/openclinica-support/.

Appendix A

Flow chart of OC4 Validation process.



Referenced Documents
FRM084 - OpenClinica Upgrade log
GD014 - Clinical Data Management Validation