

## GD026

# Data Management Software Management

The PTUC Data Management Team currently manages one major software, which is OpenClinica Enterprise Edition. This guidance covers how this software is updated and managed.

Currently there are two major versions of OpenClinica, OpenClinica 3 (OC3) and OpenClinica 4 (OC4). At the time of writing there are no active studies in OC4, however future studies will be built on this new version.

Due to how these version upgrades are managed the method of updates is handled in different ways. How OC4's updates are managed are still to be finalised as the understanding of this software is developed.

### OC3

1. When a new version is announced by OpenClinica, the Senior Clinical Trial Data Manager (SCTDM) or their deputy, will request OpenClinica support to update the test site first. (<https://papworth-test.eclinicalhosting.com/OpenClinica/>) The timing of this is on the best judgment of the SCTDM depending on the Data Team's capacity and other factors. Often this will be a few weeks after the first announcement, to allow other users to find bugs and so these can be fixed before the test site is updated.
2. The update should be documented on FRM084 OpenClinica Update Log, which can be found on S drive in <\\Resource\Papworth\shared\R&D\QA meetings\Data Management\OpenClinica>. A shortcut can also be found in <\\Resource\Papworth\shared\OpenClinica\Documentation>.
3. The Qualification Report(s) generated by OpenClinica by the update are stored on the S drive in <\\Resource\Papworth\shared\OpenClinica\Documentation> under the version number.
4. UAT is then run by the Data Team on some of the recent and largest studies. Which studies the UAT is run on, is decided by the SCTDM or their deputy, testing of different modules of OpenClinica, such as Participate should also be taken into consideration. The result is recorded on to FRM084.
5. If the UAT passed, then the SCTDM requests OpenClinica support for the live site to be updated (<https://papworth.eclinicalhosting.com/OpenClinica/>) and FRM084 is updated.
6. 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.
7. If it is decided, as it was for version 3.16, that the version was not to be upgraded on the live site, the reason should be documented on FRM084, and the test site should have the upgrade uninstalled.

### OC4

1. In theory the same process will be used for OC4 as is used in OC3, but as the live and test site are not separate as they are in OC3, this is not possible. Additionally there is no way not to install a "stack" in OC4. We are given notice of the stack install and it is installed. For

major changes, as we understand from other CTUs in the UKCRC OC User Group, there are some testing available, but we might not be able to test in the same way.

2. We will develop the process as we start to use OC4, but plan to do the following:
  - a. Before each new stack, review the expected changes.
  - b. Depending on the level of changes we will decide how many studies need UAT running, or what test we might decide to run.
  - c. FRM084 might have to be modified as well, but this will be developed as needed.