Royal Papworth Hospital
NHS Foundation Trust

GD023

eForms system for study documents

The eForms (electronic forms) system is an electronic system that contains forms outlined for use within the R&D SOPs, including data management forms. It allows users to access the forms from multiple locations and removes the need for staff to be at the same location to obtain signatures.

The eForms system uses OpenClinica to store forms, this provides a robust audit trail for each field, showing who signed/initialed the form and when. We are accepting this audit trail as an e-signature.

Within OpenClinica, eForms is set up as a study, the individual studies are set-up as sites. Then within that site there is one subject which is the study's eForm. By storing eForms on OpenClinica as sites, access is limited to those individuals with the appropriate approval. At study set up the data manager lead, with consultation from the study team, will complete 'eForm Usage' (see section 2 Data Forms) documenting which eForms will be used for the study (this should be updated throughout the study if usage changes). Access will also be issued to the appropriate members of staff by the Data Management Team.

Currently these forms are both on the Live and Test sites of OpenClinica3. This is due to the original design only being accessed by the sponsor site at Papworth however this has been expanded to the Live site to allow multisite access. The eForms that are sponsor based are still on the Test site. Eventually all the eForms will be moved to the Live site on OpenClinica4.

The eForms are divided into three sections: Study Forms, Data Forms and Data Management Plan (DMP). Each section is listed below with the forms that are relevant to that section.

1. Study Forms

FRM name	Use	Responsibility for completing
FRM038 Protocol Non-Compliance	To record each instance of non- compliance to the study's protocol	Clinical Project Manager (CPM) Trial Manager Site Research Staff*
Sponsor non-compliance categories*(this is a sub-section of FRM038)	Allows each study to have study specific protocol non-compliance categories, beyond the generic ones	Clinical Project Manager (CPM) Trial Manager
FRM042 Project Management Delegation Log	To record the responsibility of tasks relating to the study set up	Clinical Project Manager
TPL007 File Note	When an event, decision or situation requires explanation and there is no other study documents designed to record this	Clinical Project Manager Trial Manager Site Research Staff*

*This is only on the Live site version of eForms.

2. Data Forms**

FRM name	Use	Responsibility for completing
eform Usage	To record which eForms will be used for a study	Clinical Project Manager Trial Manager Data Manager Lead Study Data Manager
FRM037 Design Changes	To record database design changes post study going live	Data Manager Lead Study Data Manager Lead Clinical Project Manager
FRM039 Data Changes	To record changes to subject data, that cannot be done by data entry staff	Study Data Manager
FRM051 Registration Form	To record registration details of the study	Clinical Project Manager Trial Manager
FRM052 Database Access	To record when access to the study has been provided to a new or existing user	Study Data Manager Trial Manager (only the first half of the form)
FRM055 eSAE CRF Design Checklist	To ensure required actions have been completed	Clinical Project Manager Data Manager Lead
FRM057 Database Issues Log	To record any issues that may impact the statistical review of the study	Study Data Manager
FRM071 Importing Data into OpenClinica	To record instances where data is imported into OpenClinica	Data Manager Lead Study Data Manager

3. DMP**

FRM name	Use	Responsibility for completing
FRM046 DMP Prior to build start	To record the roles and study details	Data Manager Lead
FRM046 DMP Prior to going live	To record roles, access, guidelines, validations, audit, timelines, security, version control and blinding	Data Manager Lead
FRM046 DMP Prior to locking	To record the PI sign off, database lock and SAE reconciliation	Data Manager Lead

It is important to note which member of the study team is responsible for completing each of the forms and that this responsibility is maintained throughout the study.

**These are only on the Test site version of eForms.

End of Study

At the end of a study all eForms should be marked complete in the period after database lock and while the study is prepared for archiving.

For CTIMPs these should be printed and filed in the Sponsor File, for non-CTIMPs these should be downloaded from the database and filed in the electronic Sponsor File. In some cases (e.g., Protocol Non-Compliance Forms), monthly reports may already be filed and in this case the individual download of each eForm is not necessary.

All forms will have a designated place in the Sponsor File Index (FRM021), except eForm Usage and FRM057 Database Issues Log: these should be filed at the top level of the Data Management section of the Sponsor File, or as advised by the Clinical Project Manager.