Royal Papworth Hospital
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GD010

Data Repository User Training

Training – Part 2 (8) of Schedule 1 to SI 2004/1031 requires that '*Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his or her respective task(s).'* The GCP guide also includes *'role-specific training relevant to the post holder's duties and clinical trial role(s) and responsibility'* as one of the training requirements.

This guidance document outlines how users are trained to use the electronic data capturing (EDC) systems managed by the PTUC Data Management team, mainly OpenClinica 3 and OpenClinica 4. Any additional EDC systems adopted will follow the same training process, as applicable. Training documentation would be recorded as per R&D SOP002 Training Records for Research Active Staff.

1. PTUC Staff

	OpenClinica 3 (OC3)	**OpenClinica 4 (OC4)**
Training	• All PTUC Staff that will have access to OC3 should have training by a member of the data team or assigned personnel. These training sessions can be performed upon request or per study need, and preferably in small groups of 5 or less. • The training should cover all the tasks the users are expected to do. • PTUC staff will also have access to the generic user guide for OpenClinica (GD011) for reference purposes. • The users may have access to a training or test environment to actually use the system for themselves, before moving on to the live site, or as specified in the study Data Management Plan (DMP) (FRM046).	• PTUC staff who require access to OC4 can complete self-paced online training via the OpenClinica Learning Management System (LMS) (See Appendix 1 below). • The LMS training will cover most of the tasks the users are expected to do, and the permission levels they will have on OC4. Thus, although the training is self-paced, it is important to complete it before access is being granted. • Alternatively, any PTUC staff who are already familiar with OC3, may not require LMS training, but can be trained by a member of the data team or assigned personnel. These training sessions can be performed upon request or per study need, and preferably in small groups of 5 or less. The training should cover all the tasks the users are expected to do. • PTUC staff will also have access to the generic user guide for OpenClinica (GD011) for reference purposes. On FRM056 (Data Repository Training Record), the trainer will be asked to confirm if the relevant entry guide was provided to the user. • The users may have access to a training or test environment to use the system before being given access to a live site or as specified in the study Data Management Plan (DMP) (FRM046).
Training Documentation	• The training record (FRM056 Data Repository Training Record) should be completed for each individual by the trainer and stored in the eForms. This can be updated if their role changes and new tasks are added. • On FRM056, the trainer will be asked to confirm if the relevant entry guide was provided to the PTUC staff.	• The training record (FRM056 Data Repository Training Record) should be completed for each individual by the trainer and stored in the eForms. This can be updated if their role changes and new tasks are added. • On FRM056, the trainer will be asked to confirm if the relevant entry guide was provided to the PTUC staff. • Where applicable, the LMS certificate of completion, should be provided to the assigned personnel (cc'ing papworth.openclinica@nhs.net) as a pdf file for uploading to FRM056.

2. Royal Papworth Staff

	OpenClinica 3 (OC3)	OpenClinica 4 (OC4)
Training	• All Papworth staff that will have access to OC3 should undergo a user training, usually with a member of the data team, or assigned personnel. These training sessions should ideally be in small groups of 5 or less. • OC3 training for Papworth staff can also occur during site initiation visit (SIV), depending on the agreement with the study team. • Any training option selected should cover all the tasks the users are expected to do. • Also, the data entry guideline outlined in the study's DMP (FRM046) will be provided to the user, as a reference material for day-to-day tasks. • Before accessing the live site, users are typically given access to a training or test environment to familiarise with the system. However, where the required activities for users in the test site have been outlined in the study's Data Management Plan (see SOP078, GD016, and FRM046 for further details), users are expected to follow them accordingly.	• Depending on the option agreed by the study team, Papworth staff requiring access to OC4 can either be; i. Signed up to complete the LMS training. ii. Scheduled for a training session with a member of the data team or assigned personnel. iii. Trained on OC4 during site initiation visit (SIV). • Any Papworth staff who is already familiar with OC3, may not require LMS training, but can be trained by a member of the data team or assigned personnel. These training sessions can be performed upon request or per study need, and preferably in small groups of 5 or less. • However, whatever training option is selected, should cover all the tasks the users are expected to do. • Also, the data entry guideline outlined in the study's DMP (FRM046) will be provided to the user, as a reference material for day-to-day tasks. • Before accessing the live site, users are typically given access to a training or test environment to familiarise with the system. However, where the required activities for users in the test site have been outlined in the study's Data Management Plan (see SOP078, GD016, and FRM046 for further details), users are expected to follow them accordingly.
Training Documentation	• The training record (FRM056) should be completed for each individual by the trainer and stored in the eForms. This can be updated if their role changes and new tasks are added. • For Papworth staff, there will also be a question in FRM056 asking the trainer to confirm if the relevant entry guide has been provided to the user.	• The training record (FRM056) should be completed for each individual by the trainer and stored in the eForms. This can be updated if their role changes and new tasks are added. • Where applicable, the LMS certificate should be provided to the assigned personnel (cc'ing papworth.openclinica@nhs.net) as a pdf file for uploading to FRM056. • For Papworth staff, there will also be a question in FRM056 asking the trainer to confirm if the relevant entry guide has been provided to the user.

3. External Site Staff

	OpenClinica 3 (OC3)	OpenClinica 4 (OC4)
Training	• Staff at sites, are usually trained at site initiation visits (SIV) by the study team, or a user training can be organised by assigned personnel, usually a member of the data team. • This training should cover all the tasks they will be expected to do. • The data entry guideline outlined in the study's DMP will also be provided to the user, as a reference material for day-to-day tasks. • Before accessing the live site, users are typically given access to a training or test environment to familiarise with the system. However, where the required activities for users in the test site have been outlined in the study's Data Management Plan (see SOP078, GD016, and FRM046 for further details), users are expected to follow them accordingly.	• For external site staff who will have access to OpenClinica 4 (OC4), it is important that the study team includes OC4 user training during Site Initiation Visit (SIV). The assigned personnel, usually a member of the data team, can organise a training session. • If deemed necessary, the LMS training option for OC4 may also be offered to site. However, if this training has been previously done, then the site can provide the certificate for upload to FRM056, if not already uploaded. • However, any selected user training should cover all the tasks the users are expected to do. • The data entry guideline outlined in the study's DMP will also be provided to the user, as a reference material for day-to-day tasks. • Before accessing the live site, users are typically given access to a training or test environment to familiarise with the system. Where the required activities for users in the test site have been outlined in the study's Data Management Plan (see SOP078, GD016, and FRM046 for further details), users are expected to follow them accordingly.
Training Documentation	• This training will be recorded in study's FRM056 in the eForms or any training documentation used for the study (usually, the signed paper version of FRM056). • For external site staff, there will also be a question in FRM056 asking the trainer to confirm if the relevant entry guide has been provided to the user.	• If DM training sessions or training at SIV was used, then the training will be recorded in study's FRM056 in the eForms or any training documentation used for the study (usually, the signed paper version of FRM056). • Where applicable, the LMS certificate should be provided to the assigned personnel (cc'ing papworth.openclinica@nhs.net) as a pdf file for uploading to FRM056. • For external site staff, there will also be a question in FRM056 asking the trainer to confirm if the relevant entry guide has been provided to the user.

Investigator's Training

It is recognised that different investigators (Chief investigators or Principal investigators) will have different user training needs, based on their; technical background, assigned study tasks, and level of involvement in the study. Thus, whether for OC3 or OC4, it remains the Data Manager's responsibility to offer the most appropriate training option to the investigator before granting access to OpenClinica.

For example, a PI who has previously completed PI signoffs for previous studies may only need a simple instructional guide via email for the current study, rather than a full DM training on PI signatures, unless requested.

Appendix 1

OpenClinica Learning Management System (LMS)

- The LMS is a free online documentation site, owned and managed by OpenClinica, where OC users can sign up to read about the basic information and functionalities of OC3 or OC4.
- To access the LMS, a request should be submitted through an OpenClinica supported user, usually a member of the PTUC DM team, who will raise a ticket with OpenClinica to create an account for the user.
- Once the account is set up, the user will receive an invitation via their registered email. The email will include their username and a link to set up their password and login page.
- For users with the LMS account, you can access the LMS via the OpenClinica Documentation and Training Site (https://docs.openclinica.com/).
- Also, on the LMS website, there is a *self-paced training course on OC4*, that users can complete to learn how to use OC4.
- After completing the LMS OC4 training, a certificate of completion is automatically generated, carrying the trainee's name and training module completed.
- The training courses on OC4 LMS are role specific. As of the writing of this guidance document, there are five role profiles that a user can be trained for;
    i. Study/Site viewer,
    ii. Clinical Research Coordinator (CRC),
    iii. Investigator,
    iv. Data Manager,
    v. Monitor.
- Each user is expected to complete the training that corresponds to the role they will be assigned in OC4. All training modules will generate individual certificates, however, only the certificate for the relevant training should be filed in FRM056 (see table below). For example, a user that will be granted the Study Viewer role does not need to complete the Data Manager training but should first complete the Site Viewer training instead.
- In some cases, the Investigator may not be assigned the LMS training, depending on the training needs and level of involvement of the Investigator (see Investigator's training section above). A different user role aside the Investigator role, may be granted to the investigator to perform day-to-day study activities, up until the time of database lock where signoff will occur.
- For OC3 and OC4, when the need arises for an investigator to perform sign-off tasks, depending on the agreed training option, a member of the data team can organise a training with the investigator, covering all the processes required for sign-off, before giving Investigator role. This training should be recorded in FRM056, accordingly.
- Where the investigator has had prior training on the database for previous studies, or is an experienced OC user, then, an instructional guide or email, covering PI sign-off steps can be provided as reference.

OC4 User role	**Study or Site level**	**Recommended LMS training and certificate**
Data Manager	Study	Data Manager
Site Data Manager	Site	This role type will not be used for any study.
Data Entry Person	Study	Clinical Research Coordinator (CRC)
Clinical Research Coordinator (CRC)	Site	Clinical Research Coordinator (CRC)
Investigator	Site	Based on study needs, either of the trainings can be done; **a. During the study** - Investigator (LMS) - Clinical Research Coordinator (CRC) (LMS) - Generic instructional guide **b. At PI sign-off** - Sign off training with DM - Investigator (LMS) - Generic instructional guide
Monitor	Both	Monitor
Viewer	Both	Site/Study viewer
Data Specialist	Study	This role type will not be used for any study.

Referenced Documents
SOP002 Training Records for Research Active Staff
FRM056 Data Repository Training Record
SOP078 Data Management Plan
GD016 Data Management Plan
FRM046 Data Management Plan
GD011 OpenClinica 3 Generic User Guide