Florence FAQ's

Introduction

During the 2023 MHRA inspection UHS received a finding and some advice regarding working electronically for clinical trials. It was decided in line with the Department of health steer towards going paper-light and creating a more sustainable way of working that UHS would find a solution for the management and storage of Trial Master Files (TMF) and Investigator Site Files (ISF).

After a great deal of work reviewing and evaluating several available solutions it was decided that the Florence Healthcare solution was the best fit for UHS requirements. It also has a number of other features which have made it a more attractive and cost effective solution.

Going forward, the plan is to have all new studies set up and managed through Florence and to replace QPulse with functionality within Florence.

The Florence steering group have put together this set of FAQs to alleviate any concerns and to ensure information is accurate and centrally located. These questions will be updated as further information becomes available and more questions arise.

1) **Who is on the steering group/project management group.**

Currently the steering group consists of 4 people who have undergone in depth training with the Florence implementation team and passed the super user examination. The members are of different seniority in the R&D office and have different functions:
Laura Purandare – Deputy Director of R&D, *Chair of the steering group and liaison with senior management.*
Mikayala King – R&D Governance, QA and Sponsorship Manager, *Governance lead.*
Sharon Davies-Dear – R&D Deputy QA Manager, *Operations lead.*
Luke Atwill – R&D QA Officer, *Florence project manager.*

A number of other people are helping with the build, validation and roll-out:

Marie Nelson - R&D Head of Nursing and Health Professions
Liliana Goncalves cordeiro – Head of Clinical Trials Pharmacy
Kim Lee – Senior QA Lead for the CRF – *lead for the transfer from QPulse to Florence.*
Sue Wellstead - Clinical Research Specialist in Education and QA
Hope Howard – Senior QA lead for ATIMPs
Gemma Scott – R&D QA Officer
Richard Munday - Commercial Business Development Manager
Angela Darekar - Head of MRI Physics and UHS Lead for Imaging Research
Gavin Babbage - Translational Scientist Laboratory Manager

Once through the initial phase of roll out the steering group will involve further senior members of staff from across the infrastructure.

2) Will it replace Edge?

No, Florence will not replace EDGE. The functions and purpose of the two systems are different therefore EDGE will still be used as a communication tool, monitoring recruitment, set up management, finances and reporting.

3) Will workflows on Edge move to Florence?

No, the term workflow when applied to Florence has a different meaning to what is recognisable as a workflow in Edge; therefore, these will remain on Edge.

4) Are we moving existing studies?

Existing studies will remain in their current format. Florence will be rolled out for new studies only.

5) Will it replace QPulse?

Yes, Florence will replace QPulse and your SOPs will be transferred over. You will be required to sign your SOP acknowledgement in the Florence system. The contract for QPulse will come to an end in March 2025.

6) Will there be training?

Yes, there will be training, on roll out of the software which will be on a study by study basis. The team delivering that study will be given training, additionally they will have support for roughly 2 weeks where someone will be with them during the day so that all questions can be answered, and support given. This will start with a UHS Sponsored study and will gradually move outwards. Once fully rolled out there will be champions, similar to Edge. There is also a support email that has been set up, in case of any questions and concerns florenceadmin@uhs.nhs.uk

Training on the use of Florence to replace QPulse will be separate to the study training and will be rolled out to larger groups, team by team.

7) When can we get access?

The building and roll out of Florence is a huge undertaking and takes time to ensure we get it right first time. We are therefore not rushing the roll out and are ironing out glitches as we move forward. The first study is currently being put into Florence and the associated study and support teams have been given access and are undergoing training. The full roll out of Florence for new studies will take some time and we are anticipating this will not be fully complete until the end of 2025. However, everyone who needs to have access to view and acknowledge SOPs etc will have access to that function before the end of March 2025.

8) What is happening at the moment?

We have just completed the first UAT development stage of the software, and this code has been built by the central Florence team. The system has to be built section by section and we have been following Florence's implementation plan and the timescales set by Florence.

We have just started building the first study into the system and have given access to the study team and associated support staff. Training is underway and further studies are being prepared to go into the system.

The filing structure for the SOPs and other controlled documents are being built in the 'live' version of Florence prior to the SOPs etc being transferred from QPulse.

The second stage of development is due to commence in January 2025 and will again follow the timescales set by the central Florence team.

9) Will the system be validated?

Yes, the system is fully validated. The installation and software aspects of the system are centrally validated by the central Florence team and we have all of the associated documentation to demonstrate this. We have also been working on validating the system so that it performs as expected in the live system and have completed this prior to roll out. Validation will be ongoing as more functionality comes into use.

10) Who will validate this?

The Florence project manager (Luke Atwill) is leading on the validation of the system with assistance from the QA team, UHS digital and the central Florence Team. Volunteers have also been called on to validate different aspects of the system and document their findings.

11) Who is the asset owner and responsible for the system?

The Research and Development Governance, Quality Assurance and Sponsorship manager is responsible for oversight of the entire system and is the registered asset owner.

12) How will it be managed?

The current steering group will be expanded to ensure input from all appropriate parties. There is also a national Florence group being established in order to share best practice with other users within the UK. The day-to-day management of the software will be managed by the QA and Sponsorship teams in the first instance and then by a team of appropriately trained champions.

13) What access will I get?

Florence has been built to have specific roles and responsibilities that can be applied to users dependant on their role in the study. You may have more than one role in a study or different roles on different studies and this will be customised study by study.

If you have studies, either commercial or non-commercial, that are already using Florence, you will be able to see this in your account. Your roles in these trials will not be affected. Unlike Edge it is one log in for the system rather than organisation specific and you can be assigned to different teams dependant on the access you need and your role.

14) Will this replace the sharedrive?

The sharedrive should not be used for any documents that should be in your site file. All documents that should be in your site file should either be kept as paper or in a validated eISF system supplied by the sponsor. EDGE and the sharedrive are not suitable for this purpose.

15) Will Florence replace my paper ISF or TMF?

Florence will only be for new studies in which case yes it would replace the paper ISF and TMF. However, if your study is already running in a paper format, this will continue and will not be replicated or reproduced in Florence.

16) What about archiving?

Florence has an inbuilt archive facility which will preserve electronic data and will store for the regulated amount of time. This will not replace the paper archiving for existing studies but will be used for all studies that are in Florence.

17) Does Florence meet the regulatory requirements?

Yes, Florence is compliant. Florence's Compliance Team has reviewed regulations set forth by the Medicines and Healthcare products Regulatory Agency (MHRA) and confirmed that the use of electronic systems such as Florence is compliant with United Kingdom (UK) requirements.

Florence complies with numerous regulations within the UK, which directly facilitate the use of Florence across various areas, including electronic document management, electronic signatures, remote monitoring, and remote source data verification.

- MHRA Good Clinical Practice Guide
- "GxP" Data Integrity Guidance
- UK MHRA TMF Q&A
- Guidance on Access to Electronic Health Records by Sponsor representatives in clinical trials
- Joint statement on seeking consent by electronic methods

Florence is compliant with The Data Protection Act 2018, and utilizes General Data Protection Regulation (GDPR) as the foundational basis for global privacy. Florence additionally adheres to the Caldicott Principles and is active under the UK Extension to the EU-U.S. Data Privacy Framework to provide adequate data protection.

Florence has completed the Digital Technology Assessment Criteria (DTAC) to ensure the Site Enablement Platform meets the assessment criteria.

Additionally, Florence has completed a Data Security and Protection Toolkit self-assessment to demonstrate we are practicing good data security and that personal information is handled correctly.

18) Will external monitors be able to access Florence?

Yes, external monitors will be able to access Florence via unique log ins and with specific roles limiting what actions they are able to complete. Monitors are also able to raise queries within the system and these can be answered in the system too.

19) Does Florence have other features we can use?

Yes, Florence has a number of features that are being explored including upload of documents via an ePrinter and email, document redaction and eSignatures, and these will be rolled out in due course.

20) Will there be any demonstration prior to full roll out?

The Florence system is being built from scratch using the tools and advice supplied by the central Florence team. Since Florence originated in the USA, a lot of work has to be done to adapt it to the UK and then to how NHS organisations work. This work is ongoing and therefore as soon as we are ready to show the system we will be running some demonstration days prior to full roll out.