Developing medical device software in the NHS – a web application for calculating glomerular filtration rate

Background

Nuclear Medicine Services (NMS) across NHSGGC provide a diagnostic test to calculate glomerular filtration rate (GFR). Around 400 GFRs are performed annually, with the majority of referrals associated with pre-chemotherapy assessment or live kidney donor assessment. The test itself is a complex, multi-stage, lab-based procedure, and calculation of the result is equally complex involving around 50 data inputs.

Software to support the calculation of GFR cannot be procured as the regulatory requirements for developing such high-risk medical device software, for such a small target market, prevent it from being commercially viable. Instead, across the UK, calculations are performed by unregulated software, developed locally. With the introduction of stricter regulatory controls around software as a medical device, such unregulated software could leave health institutions open to legal challenge if it is found to compromise patient safety. Acknowledging this, NMS across NHSGGC worked together to standardise their operating procedures, and enlisted the Medical Devices Unit (MDU) to produce a regulatory-complaint application to calculate GFR.

The software application developed here, under an ISO 13485 Quality Management System, replaces several unregulated applications previously used to calculate GFR. The new application not only improves patient safety, but also improves the efficiency of the clinical service, and reduces person-hours required to carry out the test by around 30 minutes. In addition, the application facilitates more efficient data management and can be used to support clinical audit.

Design and Development Process

Below is an outline of the design and development process applied to this project. The process is iterative over the design and development lifecycle, and documentation is updated as and when required.

- Project Initiation and resource requirements
  See ticket numbers #2559, #2576 and QMS project page - https://redmine.mdu-developers.com/projects/gfr
  - Clinical need established and commercial alternatives investigated.
  - Resource estimates discussed including personnel and hardware/software requirements.
  - Roles assigned including clinical lead, project lead, technical lead, risk management team and change control board.

- Planning
  - Complete a software project plan, which includes consideration of patient data handling, ethics, development tools and technologies, dependent systems, the project team, training requirements, requirements for project specific work instructions, release types and environments, project milestones, risk assessment schedule, and a plan for maintenance and ongoing support (see P056-002-SPP).
  - Complete a landscape review, which includes a review of relevant clinical guidelines and associated literature, a review of any legacy software used previously, and a formal review of any commercially available software (see P056-005-LR).

- Requirements gathering
    - Develop a software use specification in accordance with IEC 62366 (Application of usability engineering to medical devices). Includes interviews with staff, and observation of existing processes, in order to develop a deeper understanding of the clinical need, the requirements of the different stakeholders, and where software can add the most value (see P056-003-SUS).
    - Develop detailed functional and non-functional requirements specification and review with clinical stakeholders. Once signed-off this document is translated into tasks in Jira that the development team can pick up (see P056-004-SRS, P056-004a-SRS).
    - Develop a verification and validation plan based on the agreed requirements (see P056-007-VVP).

- Risk management
    - Develop a risk management plan in accordance with ISO 14971 (Risk management for medical devices) and execute. Includes hazards analysis checklist, and definition of the roles and responsibilities of the risk management team (including clinical representation) (see P056-001-HAC, 5 x QMS-OPF-039).
    - Complete risk assessment at defined intervals and when new risks are identified and review mitigation strategy with clinical expert(s) (see 35 x QMS-OPF-012).
    - Complete a risk management report, highlighting in particular, any residual risks (see P056-006-RMR).

- System design
    - Complete high-level system design based on requirements and limitations of the clinical environment (see QMS-OPF-019 – versions attached to ticket).
    - Produce functional wireframes to represent the application interface and review at regular intervals with the clinical team (see QMS-OPF-019 – versions attached to ticket).
    - Any additional design required, e.g. database design (see QMS-OPF-019 – versions attached to ticket).
    - Translate all of the design documents into requirements that the development team can work on (see P056-004-SRS, P056-004a-SRS).
    - Review of milestones and sprint planning to prioritisation of tasks to complete these milestones (see P056-002-SPP).
    - Contact eHealth to arrange (integration) support as required.

- Verification and validation
    - Verify all requirements have been met through a combination of automated and manual testing (see P056-011-RV).
    - Optimise automated testing coverage.
    - Set up continuous integration server to prevent unverified code from being released, and ensure all release environments are managed appropriately.
    - Complete a manual testing report (see 6 x QMS-OPF-055).
    - Carry out user testing and collect feedback to identify code correctness, safety and usability issues (see 8 x QMS-OPF-007).
    - Complete a clinical evaluation and get sign off from clinical users (see P056-009-CE).
    - Carry out a system security review (see P056-012-SSR).

- Product release
    - Complete a post-market surveillance plan (see #6592).
    - Complete a release tracker, which includes confirmation that verification and validation activities have been completed (see 13 x QMS-OPF-037).
    - Complete Instructions for Use to release to end users, highlighting any (residual) risks associated with using the software (see P056-008-IFU).
    - Review the products technical file with the change control board.
    - Get authorisation from the change control board to release the product.

- Feedback and maintenance
    - Provide a communication channel for users to report bugs or requests for change.
    - Carry out post-market surveillance at agreed intervals (see 3 x QMS-OPF-029).
    - Carry out maintenance at agreed intervals or as required.
    - Complete disaster recovery exercise with eHealth.

Roles and Responsibilities

- MDU Team
    - Project Lead: planning, resourcing, risk management reporting and product manager.
    - Technical Lead: technical team management.
    - 3 x clinical scientists: all aspects of design and development, particularly algorithm development and verification.
    - 3 x software developers: all aspects of design, development and deployment
    - Other heads of section: Risk management team and CCB
    - Quality Manager: Compliance with MDU SOPs.
    - Head of Clinical Engineering: Authorisation for device deployment.
    - Audit Team: Ongoing audit of documentation for compliance with ISO 13485 and MDU SOPs.

- Clinical Stakeholders
  The following clinical stakeholders helped define requirements, provided feedback on design and development aspects, and contributed to risk assessment:
    - 3 Nuclear Medicine Heads of Service (North-East, West, South)
    - 9 Clinical Scientists
    - 10 Clinical Technologists