Project N78: Development of user-friendly web-based software for conducting Bayesian Phase I dose-escalation studies

Original outputs

1. Stand-alone web-based software and an accompanying repository of training material that can be used by clinical trialists to simulate, design, and conduct Bayesian model-based dose-escalation trials.

   Achieved: The software (MoDEsT – Model-based Dose Escalation Trials) has been produced, tested and made available on a dedicated website:
   modest.lancaster.ac.uk

   The website also contains help pages to support the use of the software.

2. A series of software demonstrations will be delivered at relevant clinical meetings to disseminate the software. For example, we are in discussions with the ECMC Junior Investigator Network Group about holding a workshop on Bayesian adaptive dose-finding methods, at which the software could be showcased.

   Achieved: The software has been presented at different meetings. Specifically it was presented during a short course on dose-finding at the 2017 SCT-ICTMC conference, a poster talk has been given the 2017 NCRI conference. Additionally it has been presented as part of a guest session on the MRes Experimental Cancer Medicine in Manchester. A further presentation of the software will be given in Feb 2018 at the NIHR early phase statistics meeting.

3. R packages comprising the software in part 1) will be submitted to CRAN. These packages may be used and adapted by expert biostatisticians to design their own studies and communicate results to clinical collaborators. This software will be free to use and will represent a lasting long-term output from the project.

   Achieved: The software is also freely available on CRAN: https://cran.r-project.org/web/packages/modest/index.html

4. A paper describing the web-based software will be prepared and submitted to a journal such as Trials (or Clinical Trials) read by a mixture of clinicians and statisticians engaged in clinical research.

   Achieved: A draft paper has been produced and has been submitted for publication.

5. In consultation with the HTMR Network, the co-applicants will explore avenues for securing additional funding from the public sector and/or industry to build upon the proposed software to incorporate additional methods for Bayesian model-based dose-escalation trials. Potential sources of public sector funding include the Medical Research Council's Methodology Research Programme. The applicants will consult the HTMR Network ahead of time on any proposed strategies for securing additional funding.

   Achieved: Initial discussions of the co-applicants have taken place but no clear strategy has yet been agreed.

   Next steps: To agree a strategy and consult HTMR network.