

Online database for SWAT (Studies Within A Trial) and SWAR (Studies Within A Review) outlines and their data

Author of this report: Mike Clarke
Submitted: 19 June 2015

Original objectives and the deliverables

The funding requested was to employ a part-time research assistant at Queen's University Belfast to develop a repository for the SWAT (Study Within A Trial) and SWAR (Study Within A Review) outlines and data.

The original objectives were:

1. To develop an online database to store and provide easy access to short protocols for Studies Within A Trial (SWAT) and Studies Within A Review (SWAR), to facilitate the lodging of modifications to these protocols, and to store and meta-analyse the primary outcomes for SWAT and SWAR.
2. To promote and facilitate the submission of protocols and the deposit of data.

The key deliverables were

1. A functioning and sustainable, freely accessible and searchable, well-promoted database capable of storing and displaying the protocols for SWAT/SWAR, storing the data from individual SWAT/SWAR and providing cumulative meta-analyses of these.
2. The conduct and availability of SWAT/SWAR (both during and after the funding period for this award).

What was achieved

1. A template for the SWAT short protocol (now called the "outline") was agreed within the project team, informed by discussions during the first webinar for the HTMR Network's Trial Conduct Working Group on 3 March 2014. (A similar template is in place for SWAR.)
2. These templates provide the structure for the database that holds the SWAT and SWAR outlines.
3. SWAT were promoted as part of Trials Change Lives on International Clinical Trials Day 2014, with a podcast¹ and a poster.²
4. SWAT and SWAR were promoted in an invited plenary lecture at the Cochrane Canada Symposium in Ottawa in April 2014, in presentations at the Cochrane Colloquium in Hyderabad in September 2014, and during the Annual Meeting of the HTMR Network in January 2015.
5. SWAT were embedded in proposals for the new Health Research Board Clinical Trial Networks on the island of Ireland, two of which were funded:
 - a. Stroke: using Skype to improve site engagement in multi-centre trials (SWAT-10) and to monitor consent forms (SWAT-11).
 - b. Primary care: testing a web-based multimedia information resource to improve recruitment and retention of general practitioners (SWAT-14) and a video presentation of trial information for potential participants (SWAT-15).
6. An online form is available for people to submit SWAT outlines,³ which feeds into the SWAT database.
7. The outlines of 19 SWAT are available free online.⁴

¹ www.cochrane.org/podcasts/international-clinical-trials-day-2014/swats

² <http://methodologyhubs.mrc.ac.uk/files/1114/3403/0186/HUBS-trialforgepptx.pdf>

³

<http://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/SWATSWARInformation/SWATSWARApplicationForm/>

8. A preliminary bundle of these SWAT has been shared with selected Clinical Trial Units and included in the materials for the University of Oxford's MSc in Evidence Based Health Care. The assignments for the Randomised Trials and Systematic Reviews modules for this programme include the opportunity to submit a SWAT or a SWAR, respectively. One has been submitted and registered already, for the assessment of the use of projected accrual to select sites for a randomized trial (SWAT-12).
9. The findings of SWAR-2 were published in *Journal of the Royal Society of Medicine* in November 2014⁵ and the findings of SWAT-1 were published in *Trials* in May 2015.⁶
10. Progress with making the SWAT and SWAR databases available online and providing a repository for the data from these studies has been slower than hoped. This was due in part to changes to the online facilities at Queen's University Belfast and the re-design of the websites for both the Centre for Public Health and the All-Ireland HTMR (now the Northern Ireland Network for Trials Methodology Research) during 2014; and the subsequent disruption caused by the MRC's decision not to renew the funding for the Hub. However, it has been possible to secure ongoing support for publishing and hosting the SWAT and SWAR outlines on the website until at least August 2016.

Plans for the next 12 months

1. An article about the current status of the SWAT initiative will be published in the *Journal of Evidence Based Medicine* in 2015, acknowledging the funding from the HTMR Network
2. An evaluation of the implementation of SWAT and other embedded methodology research is being done as part of another project funded by the HTMR Network ("Studies within a trial and embedded trials", N64). A proposal for a workshop about this has been submitted for the International Clinical Trials Methodology Conference in Glasgow in November 2015.
3. Abstracts relating to the SWAT initiative were submitted for the International Clinical Trials Methodology Conference in Glasgow in November 2015.
4. The SWAT initiative was included as a cross cutting strand in the application for a 3-year Programme Grant to support a Northern Ireland Hub for Trials Methodology Research, which was submitted to the MRC in June 2015, for consideration by the Methodology Research Panel in November 2015 with a proposed start date of April 2016.