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Trial Forge: a systematic approach to organising, sharing and extending trial methodology research

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Original objectives and the deliverables

The funding requested was to support a workshop, jointly with the University of Aberdeen. The original objectives of the workshop were:

1. To reach agreement of the key stages of the trial pathway, that is, the points on the path from trial idea to implementation of results into practice.
2. To develop the outline of an MRC Methodology Panel proposal to develop the pathway into the basis of a major, global resource for trialists, researchers and others that collates and organises existing trial methodology evidence, supplements it with case studies and operational experience from trialists and, importantly, both highlights evidence gaps and provides a means of supporting collaborative work to fill those gaps.

The original three deliverables were:

1. A trial pathway (i.e. the points on the path from trial idea to implementation of results).
2. A statement paper.
3. Outline of an MRC Methodology Panel proposal.

What was achieved

1. The workshop was held in Edinburgh on 10 July 2014. The 38 participants were invited based on their experience in methodology and trial design, trial management, statistics, data management, clinical care, commissioning and publishing research, public and patient involvement and providing trial support through trials units. Participants reached agreement on the key stages of the trial pathway, which is now shown on the Trial Forge website (http://www.trialforge.org/trial-forge-workshop.html). While there is continued discussion as to whether *all* of the key stages are contained within this pathway, there was agreement on where it should start and end. Participants agreed that the pathway should start with choosing the right research question and end at dissemination of trial results.
2. A statement paper describing the background to the workshop, summarising the discussion and suggesting how Trial Forge to might work was submitted to the journal *Trials* on 18 January 2015 and was published on 5 June 2015.[1]
3. The last section of the workshop discussed how Trial Forge might work, how did we interface with other initiatives, how to prioritise activity and how to demonstrate impact. This discussion has continued beyond the workshop, influenced in particular by a discussion with David Crosby, the MRC Methodology Research Programme manager. Our shared view was that an MRC methodology panel proposal would be premature and that a staged process would be more likely to be successful, with smaller projects that act as demonstrators for the Trial Forge approach, which can then be used to support a larger funding proposal. It was also recognised that there would be a need to coordinate Trial Forge; in other words it is unlikely that the collaborative work expected in Trial Forge will happen without coordination.

[1] Treweek S, Altman DG, Bower P, Campbell M, Chalmers I, Cotton S, Craig P, Crosby D, Davidson P, Devane D, Duley L, Dunn J, Elbourne D, Farrell B, Gamble C, Gillies K, Hood K, Lang T, Littleford R, Loudon K, McDonald A, McPherson G, Nelson A, Norrie J, Ramsay C, Sandercock P, Shanahan DR, Summerskill W, Sydes M, Williamson P, Clarke M. Making randomised trials more efficient: report of the first meeting to discuss the Trial Forge platform. Trials 2015;16:261.

Plans for the next 12 months

To address this staged approach a number of initiatives have been set in motion for the next 12 months including:

- Obtaining funding for the first Trial Forge PhD student. The student has been offered the PhD award, will be based in Aberdeen and start on 1 July 2015.
- Entering a Trial Forge PhD as part of competitive Institute of Applied Health Science, University of Aberdeen, round of PhD awards. One award is on offer, which will be given to the best combination of student and project.
- Submission of a grant proposal to the Carnegie Trust for an interdisciplinary project involving two Scottish Trials Units and a Business School that aims to apply business methods to trial launch planning and the development of recruitment and retention strategies. The latter were identified as methodology research priorities in a recent survey of the directors of Clinical Trial Units (CTU).
- Developing a two-year implementation plan for Trial Forge, which outlines concrete activities to achieve the aims discussed at the workshop.
- Identification of site selection and data collection as two demonstrator projects. Initial work on both is currently underway in Aberdeen involving trial managers and a visiting student, and with the Nottingham CTU. Using an update of the Cochrane recruitment review as a testbed for new approaches to presenting the results of reviews (to improve the choice of research question in primary research) and in supplying materials to support the conduct of studies to fill important methodological gaps (e.g. by developing SWAT linked directly to Cochrane reviews). Some of these methods may also be tried out in the Cochrane Incontinence Review Group, of which Shaun Treweek is now a co-editor.
- A collaborative patient and public involvement (PPI) project led by the University of Oxford and linked to Trial Forge is addressing a current gap in evidence with regards to the use of PPI for recruitment in surgical trials.
- Collaboration with other initiatives, including the Cochrane Transform project, CTUs, the Lancet Research Waste group and the US Clinical Trials Transformation Initiative.
- Exploration of large-scale funding options in the US. There are very few options for methodology research in the European Horizon 2020 program but there may be opportunities to tap into North American funding.
- Presentations and webinars on Trial Forge are planned, including an invited session on Trial Forge at the US Society of Clinical Trials conference in May 2015.