

Project R27

Applicant: Borislava Mihaylova, MRC Clinical Trial Service Unit Hub, University of Oxford.

Project title: R27“Methods for extrapolation from clinical trials data to inform economic evaluation” workshop funding

Co-Applicants: Alastair Gray, MRC Clinical Trial Service Unit Hub, University of Oxford; Nicky Welton, ConDuCT II Hub, University of Bristol; Linda Sharples and Chris Jackson, MRC Biostatistics Unit, Cambridge

Project duration: Initial duration 1 October 2012 to 30 September 2013; non-cost extended to 30 September 2014

Final project report October 2014

Summary/list of the original objectives:

1. To organise a workshop for about 50 participants
 - a. a series of presentations, plus discussions; and
 - b. a meeting of a smaller working group of around 15 key people working in this area
2. To develop a core working group
 - a. to finalise manuscripts from the workshop,
 - b. to develop a position paper on appropriate strategies to follow with respect to extrapolation in clinical trials for the purpose of economic analyses, and
 - c. to identify fruitful collaborations for future grant applications.
3. To develop 2 small focussed working groups to develop identified research needs into substantial research proposals capable of attracting grant funding in the following areas: 3.1) Evidence synthesis and extrapolation, and 3.2) Extrapolation of continuous outcomes, through
 - a. 2 half-day meetings to discuss the larger grant application areas identified: aim for a London Location
 - b. 2 smaller meeting to discuss progress on grant application drafting: to be held at a collaborator's location

What was actually achieved?

1. The workshop “Methods for extrapolation from clinical trials data to inform economic evaluation” took place on 22 January 2013 in St Anne’s College, University of Oxford (see Appendix 1 for Workshop Programme). It was attended by 46 participants with 11 representatives from the clinical trials hubs among the attendees.
 - a. The series of presentations were well received by the attendees.
 - b. A thematic discussion among the core invitees’ group took place following the presentation part of the workshop and research themes of interest for further development were identified.
2. A core working group was established
 - a. Some of the presentations presented at the workshop have been submitted for publication or published (developed independently from the HTMR workshop funding grant):
 - i. (submitted) Parametric survival models with time updated covariates in development of disease models for extrapolation from RCT data (Iryna Schlackow, Boby Mihaylova, University of Oxford)
 - ii. (submitted) Using external (registry) data to extrapolate from RCT data (Patricia Guyot, University of Bristol)
 - iii. Benaglia T, Jackson CH, Sharples LD. Survival extrapolation in the presence of cause specific hazards. Stat Med. 2014 Feb

28;34(5):796-811.

<http://onlinelibrary.wiley.com/doi/10.1002/sim.6375/abstract>

- b. No position paper was developed
- c. Two areas of common research interest were identified for potential collaborative research targets: (1) Evidence synthesis and extrapolation, and (2) Extrapolation of continuous outcomes; not developed into research proposals.
- 3. Discussions between the applicants were held over the phone and during HTMR annual meeting in Edinburgh; limited development of project ideas has taken place: datasets to support the work; likely promising approaches to investigate; further collaborators. A PhD proposal with contribution from all applicants (BM/AG DPhil supervisors; LS/CJ/NW as methodological advisers) secured DPhil Studentship funding from elsewhere with a student working on it at the University of Oxford from October 2014.
 - a. Not held
 - b. Not held

The next steps for the project

- 1. The project has allowed for wider discussions and possible collaborations on methodological developments in on-going/new PhD projects.
- 2. Project applicants share common research interests with the HTMR Working Group on "Evidence Synthesis"; currently most of the applicants are members of this working group. The identified areas of research interest and in need of further guidance are also areas of interest for this wider working group.

List of other associated researchers:

Prof Alan Brennan	School of Health and Related Research (ScHARR), University of Sheffield
Miss Patricia Guyot	University of Bristol
Dr. Martin Hoyle	PenTAG, University of Exeter
Mr Nicholas Latimer	University of Sheffield
Mr Ronan Mahon	Centre for Health Economics, University of York
Prof Andrea Manca	Centre for Health Economics, University of York
Prof Stephen Palmer	University of York
Dr Iryna Schlackow	Health Economics Research Centre, University of Oxford
Dr John Stevens	University of Sheffield