

POSTER PRESENTATION

Open Access

Exploring the role and functionality of trial steering committees

Nicola Harman^{1*}, Elizabeth Conroy¹, Steff Lewis², Gordon Murray⁷, John Norrie⁴, Matthew Sydes³, Athene Lane⁵, Doug Altman⁹, Colin Baigent⁶, Judith Bliss¹², Marion Campbell¹⁰, Diana Elbourne⁸, Stephen Evans⁸, Peter Sandercock¹¹, Carrol Gamble¹

From 3rd International Clinical Trials Methodology Conference
Glasgow, UK. 16-17 November 2015

Background

Independent oversight of clinical trials, recommended by Good Clinical Practice, is typically provided by an independent advisory Data Monitoring Committee (DMC) and an independent executive committee, to whom the DMC make recommendations. The detailed role and functionality of this executive committee, known as the Trial Steering Committee (TSC) have not been studied since proposed by the MRC.

Methods

An expert panel was convened comprising statisticians, clinicians and trial methodologists with prior TSC membership experience. Twelve questions about the role and functionality of the TSC were discussed by the panel at two full-day meetings. Each meeting was transcribed in full and discussions summarised.

Results

The expert panel reached agreement on the role of the TSC, who they worked for, membership and the definition of independence, and the experience and training needed. The management of ethical issues, difficult/complex situations and issues the TSC should not ask the DMC to make recommendations upon were more difficult to discuss without specific examples. Additional topics discussed, not identified by the DAMOCLES study but pertinent to the role of the TSC, included: indemnity; life-span of the TSC and role of the sponsor.

Conclusions

Expert panel discussion and subsequent recommendations will contribute to revision and update of the MRC

TSC terms of reference. Uncertainty still remains in some areas due to the absence of published real-life examples. A repository for case studies would be useful. Public contribution to trial oversight was not discussed and warrants further consideration.

Authors' details

¹North West Hub for Trials Methodology Research, Liverpool, UK. ²Edinburgh MRC Hub for Trials Methodology Research, Edinburgh, UK. ³MRC Clinical Trials Unit at UCL, London, UK. ⁴Centre for Healthcare Randomised Trials (CHaRT), Aberdeen, UK. ⁵Bristol Randomised Trials Collaboration Trials Unit, Bristol, UK. ⁶Clinical Trial Service Unit & Epidemiological Studies Unit, Oxford, UK. ⁷Usher Institute of Population Health Sciences and Informatics, Edinburgh, UK. ⁸Department of Medical Statistics, London School of Hygiene and Tropical Medicine, London, UK. ⁹Centre for Statistics in Medicine, University of Oxford, Oxford, UK. ¹⁰Health Services Research Unit, University of Aberdeen, Aberdeen, UK. ¹¹School of Clinical Sciences, University of Edinburgh, Edinburgh, UK. ¹²Institute of Cancer Research, Clinical Trials & Statistics Unit, London, UK.

Published: 16 November 2015

doi:10.1186/1745-6215-16-S2-P189

Cite this article as: Harman *et al.*: Exploring the role and functionality of trial steering committees. *Trials* 2015 **16**(Suppl 2):P189.

¹North West Hub for Trials Methodology Research, Liverpool, UK
Full list of author information is available at the end of the article