Project Title: Consolidating guidelines for the prevention, detection and appraisal of reporting biases in clinical trials.

Applicants: Dr Jamie Kirkham (NW Hub, Lead), Professor Paula Williamson (NW Hub), Professor Jonathan Sterne (ConDuCT Hub), Professor Julian Higgins (ConDuCT Hub), Professor Mike Clarke (All-Ireland Hub), Professor Doug Altman (University of Oxford), Dr Kerry Dwan (NW Hub), Professor Carrol Gamble (NW Hub).

1. To demonstrate and disseminate the importance of pre-specifying analysis and reporting strategies during the **planning and design of a clinical trial**, for the purposes of minimizing bias when the findings are reported.

To help collate the available evidence, we updated a 2008 systematic review which looked at the empirical evidence of outcome reporting bias. This review has now been updated and published in PloS ONE.

(http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0066844)

A second new review was also completed, to include studies that have investigated other aspects of selective reporting in trials, mainly selective reporting of analyses. This review has been completed. Comments have been received on a draft manuscript from co-investigators with a plan to submit for publication (November 2013). A copy of the article will be sent to the Hub Network on publication.

This second review was also presented as an oral presentation at the Peer Review Congress in Chicago (2013) [http://www.peerreviewcongress.org/2013/Final-Program.pdf], as a poster presentation at the Cochrane Colloquium in Quebec City (2013) [http://colloquium.cochrane.org/sites/colloquium.cochrane.org/files/uploads/content/CochraneQuebecBooklet_12-Sept-2013.pdf] and is to be presented as an oral presentation at the 2nd UK Clinical Trials Methodology Conference, Edinburgh (2013).

2. To provide guidance and resources to support the appropriate **reporting of a clinical trial** with respect to outcomes, outcome measures, subgroups and analyses.

On July 2nd 2013, the group hosted a stakeholder meeting at the University of Liverpool to discuss the results to the systematic reviews in 1). The purpose of the meeting was to highlight all the problems and to map out any further guidance that could be offered to trialists in order to prevent the problem of selective reporting. Attendees included [Elaine O' Connell (University of Bristol), Kerry Avery (University of Bristol), Isabelle Boutron (University Paris Descartes), Joerg Meerpohl (University Medical Center Freiburg), Julian Higgins (University of Bristol), Doug Altman (University of Oxford), John Ioannidis (Stanford University), Mike Clarke (Queen's University Belfast), Paula Williamson (University of Liverpool), Erik von Elm (University of Lausanne), Carrol Gamble (University of Liverpool), Jonathan Sterne (University of Bristol), An-Wen Chan (University of Toronto)] experts in the field of selective reporting, many of which were primary investigators for the empirical studies included within the two reviews. We also discussed current reporting guidelines such as CONSORT and ICH. The focus of the discussion was around the idea of statistical analysis plans (SAPs), and that there was little in the way of guidance of what should be included in a SAP. The availability of a SAP (which may or not be part of a trial protocol) would promote transparency between planned analyses and the analyses that was actually carried out Future work is planned

between a number of co-investigators on this project to identify items that should be included in a SAP. As part of this current work, an article is planned to summarise the discussions from the stakeholder meeting. This document is in preparation. A copy of the article will be sent to the Hub Network on publication.

3. To facilitate interpretation of a clinical trial report by those wishing to learn from its findings in a **health care or policy context**, with respect to the potential for biased reporting of outcomes, outcome measures, subgroups and analyses.

This objective will be achieved from the output in 2).

4. To inform the development of methods for assessing risk of reporting bias in the context of a **systematic review of clinical trials**, with respect to outcomes, outcome measures, subgroups and analyses.

The lead applicant (Dr Jamie Kirkham) was invited as a contributor to the selective reporting working group as part of the development of the new version of the Cochrane Risk of Bias tool. During a number of face-to-face meetings and teleconference discussions, examples of the types of selective reporting were discussed which were translated into signalling questions. The first version of the new tool has currently been finalised with plans to pilot and refine the new tool in the near future. Plans to launch the new tool, including the writing of guidelines, handbook chapters and training are planned for 2014. It is anticipated that the publications from this project and a number of examples identified will be included in this documentation.