

## Agreeing current good practice for clinical trial data access and sharing – R39

Lead applicant: Dr Catrin Tudur Smith, North West Hub

Co-applicants: Dr Matt Sydes, Professor Paula Williamson, Professor Mike Clarke, Professor Jane Armitage, Professor Richard Riley, Professor Gordon Murray, Dr Jan Boegerts, Dr Gill Booth (maternity leave taken during the project), Dr Kerry Woolfall  
Research Associate employed by the grant: Carolyn Hopkins

### Original objectives:

- a) Determine current practice across the UK registered Clinical Trials Units (CTUs) regarding data access and sharing policies for clinical trials.
- b) Review existing clinical trial data access and sharing policies and identify good practice guidelines.
- c) Develop recommendations for clinical trial data sharing agreements, with particular relevance to the network of UK registered Clinical Trials Units.

### What we have achieved:

Each of the objectives has been achieved, albeit at varying stages of development. In particular, we have

- a) Completed an online survey of 45 UKCRC registered CTUs. Results from this survey have been submitted to the Journal of Clinical Epidemiology (Clinical trial data sharing and access from publicly-funded Clinical Trials Units' perspectives: an opinion survey Carolyn Hopkins, Matthew Sydes, Gordon Murray, Kerry Woolfall, Mike Clarke, Paula Williamson, Catrin Tudur Smith) and have informed the development of a good practice principles guidance document for CTUs.
- b) We have reviewed the literature and undertaken an extensive internet search to identify existing policy documents and examples of data sharing agreements. This work has informed the development of a good practice principles guidance document for CTUs.
- c) We have hosted a one day expert committee meeting to generate feedback on the draft guidance document for CTUs. Attendees at the meeting were as follows:

<i>Catrin Tudur Smith</i>	<i>Liverpool Clinical Trials Research Centre</i>
<i>Carolyn Hopkins</i>	<i>Liverpool Clinical Trials Research Centre</i>
<i>Matt Sydes</i>	<i>MRC Clinical Trials Unit</i>
<i>Gordon Murray</i>	<i>University of Edinburgh</i>
<i>Kerry Woolfall</i>	<i>University of Liverpool</i>
<i>Sally Hollis</i>	<i>AstraZeneca</i>
<i>Rob Frost</i>	<i>GlaxoSmithKline</i>
<i>Jamie Garner</i>	<i>Keele Primary Care Musculoskeletal Trials Unit</i>
<i>Sue Bell</i>	<i>Leeds Clinical Trials Research Unit</i>
<i>Claire Daffern</i>	<i>Warwick Clinical Trials Unit</i>
<i>Peter Varnai</i>	<i>The Wellcome Trust/Technopolis</i>
<i>Maike Renter</i>	<i>The Wellcome Trust/Technopolis</i>
<i>Will Greenacre</i>	<i>The Wellcome Trust</i>
<i>Lesley Stewart</i>	<i>University of York</i>
<i>Nazir Lone</i>	<i>University of Edinburgh</i>
<i>Liz Tremain</i>	<i>National Institute of Health Research</i>

- d) We have developed a guidance document (Good Practice Principles for Sharing Individual Participant Data from Publicly Funded Clinical Trials. Tudur Smith C, Hopkins C, Sydes M, Woolfall K, Clarke M, Murray G, Williamson P. 2015). A consultation process is currently ongoing to gather feedback from the UKCRC registered CTUs.
- e) We have invited the following organisations to 'endorse' the document: Wellcome Trust, MRC, Cancer Research UK, Arthritis Research UK, UKCRC registered CTU executive committee, NIHR.
- f) We have received a positive response to an initial request for the guidance document to be integrated in some way into the clinicatrials toolkit.
- g) We have received invitations to present on the topic of data sharing.

### **Changes to the original application:**

We originally planned to conduct a Delphi survey to identify good practice principles for data sharing agreements. After careful consideration we felt that a Delphi survey would not be the best approach. Instead, we developed a guidance document incorporating the good practice principles that had been identified from the literature and requested expert committee (incorporating representatives from commercial clinical trial organisations and publicly funded clinical trial organisations) feedback. The document was revised accordingly and sent to the UKCRC CTUs for comments and feedback, which has so far been mostly very positive.

### **Next steps:**

- a) We are currently writing a publication to summarise good practice principles and signpost the guidance document.
- b) We plan to conduct another survey in 12 months time to identify whether the guidance has helped CTUs and whether improvements are needed.

### Publication status April 2015

1. Clinical trial data sharing and access from publicly-funded Clinical Trials Units' perspectives: an opinion survey Carolyn Hopkins, Matthew Sydes, Gordon Murray , Kerry Woolfall, Mike Clarke, Paula Williamson, Catrin Tudur Smith

[Submitted](#)

2. Good Practice Principles for Sharing Individual Participant Data from Publicly Funded Clinical Trials. Tudur Smith C, Hopkins C, Sydes M, Woolfall K, Clarke M, Murray G, Williamson P. **2015**

[Document for internal circulation](#)