Supplementary Terms of Reference

Monitoring Task & Finish Group

Remit of the proposed working group

To enable monitoring to be discussed between CTUs, to galvanise the defining of monitoring good practice and to do any work needed to be able to define good practice and/or refine processes and systems in the conduct of monitoring. To further liaise with external organisations on monitoring issues and matters and to develop and share best practice in monitoring across the UKCRC Registered CTU Network.

Aim

To help every UKCRC registered CTU implement, or develop a plan for implementation of, good practices for monitoring of clinical trials.

Members

Member	Organisation
Sharon Love (Chair)	MRC CTU at UCL
Andrea Corkhill (Deputy Chair)	Southampton CTU
Carrie Bayliss	Cambridge Clinical Trials Unit
Emma Armstrong	Leeds Clinical Trials Research Unit
Jo Grumett	Warwick CTU
Krista Wills	CR UK & UCL Cancer Trials Centre
Patricia Rafferty	NI CTU
Barbara Temesi	Manchester CTU
Melanie Boulter	Nottingham CTU
Lisa Fox	The Institute of Cancer Research CTSU
IS Group Chair	Sharon Kean – Glasgow Clinical Trials Unit
QA Group Chair	Patricia Henley – LSHTM Clinical Trials Unit
Statistics Group Chair	Catherine Hewitt – York Trials Unit
Trial Management Group Chair	TBC

Proposed activity

The working group would meet approximately 3 times a year by teleconference and communicate in between via e-mail. The proposed activities would be:

- Develop a scoping workshop to identify clear deliverables and outputs in year 1
- Clarify and confirm the below proposed outputs or define others
    - Report to the CTUs the combined MHRA inspection monitoring data from all units inspected since 1 January 2018 and engage with the MHRA to discuss monitoring at the year 2 meeting
    - Ascertain and publish the benefits of the two models of monitoring used in the registered CTU (either using defined monitors or monitoring being part of the trial manager's role)
    - Assess the validity and reliability of the published triggers using the monitoring data from several CTU to assess if these triggers should be used by all CTU
    - Creation of monitoring templates and guidance on how to monitor for differing risks
    - Identification, collection, creation of training materials to assist CTUs with in house monitoring training. (e.g. monitoring handbook, fictitious medical notes for monitoring, SDV and drug accountability)
    - Establishing a forum for CTUs to share experiences and questions on monitoring related issues.

Support required from the CTU Network

The main support required is to pay for teleconferences, pay for the year 1 workshop (room and refreshments) and to provide administrative support to organise meetings (including any workshop/conference meeting across the Network) and liaise with CTUs. The Task & Finish Group is allocated an annual budget of £1500 to cover these costs.

Governance

The Group will run for an initial period of 18 months to galvanise ideas and begin delivery. The Executive will then review and identify the longer-term governance structure required for monitoring across the Network.