ACTIONS Trial Management Group Meeting Minutes

Date: 14-June-2011

Location: 21 Upper Wimpole Street, London, W1G 6NA

Attendees: Thomas.R.Barnes, Verity Leeson, Helen Killaspy, Carol Paton, Fenella Lemonsky, Suzanne Law & Kavi Gakhal.

Agenda:

1. **Terms of reference:**

   - Professor T.R. Barnes, Chief Investigator, presented the roles and responsibilities of the ACTIONS Trial Management Group. The study group itself is consisted of the Chief Investigator, statistician, trial manager, research assistants, and data manager.
   - The specific responsibilities outlined included recruitment of participating centres; design of study documentation; data collection & management; data entry and cleaning; data analysis; collection of adverse event data; collection of protocol deviation data; organising and servicing the Data Monitoring and Ethics Committee (ISDMEC); organising and servicing the Trial Steering Committee (TSC); organising regular TMG meetings, and to retain copies of the minutes for future reference.
   - The ideology presented behind the Trial Management Group is to monitor all aspects of the conduct and progress of the trial, ensure the protocol is adhered to, and to take appropriate action to safeguard participants.
   - Emphasis was put on the Trial Management Group to consider and act on the recommendations of the TSC & Data Monitoring and Ethics Committee (DMC).
   - It was proposed for the development of an ACTIONS Trial Website, which will allow approved users to access study specific information such as: SOPs, CRFs, meeting minutes, and training updates.

2. **Research Governance:**

   - It was stated the ACTIONS Trial has CTA and Ethical approval.
   - Verity Leeson, Trial Manager, outlined the amendments to the protocol since original approval, both previously submitted and currently being prepared. These involve: addition of trial sites, change in trial site Principle Investigator, amendments to the cognitive measure scales & the addition of the participant carer questionnaire.
   - It was outlined the Citalopram supplier, Catalent, have stated they will have irregularities in the pill count in their bottles by ±1 pill. Thus it was suggested to still attain the compliance scale, however, cannot be considered as a true

method of adherence. This will be presented as part of the current substantial amendment.

- It was outlined the ACTIONS trial has gained 10 month extension as agreed with the funders, HTA.

3. Progress:

- It was confirmed the IMP, Citalopram, would be ready by the beginning of July.
- It was stated the electronic database, INFORM, would be possibly ready in July. Professor T.R. Barnes confirmed that if there is a delay in the construction of the electronic database, it is feasible to proceed with paper source data capturing and transcribe at a later point once INFORM is fully functional.
- It was outlined that there are 16 approved sites, of which 7 are funded and the rest are volunteering via the Mental Health Research Network (MHRN).
- It was established that both Nottingham and London sites had hosted ACTIONS study specific training days including on: SOPs and rating scales by Professor T.R. Barnes & Verity Leeson.
- Professor T.R. Barnes issued a proposal of developing online video training sessions that allows access to all approved investigators and researchers at ACTIONS study trial sites.
- Verity Leeson outlined current technical issues with the Bristol Randomised Control Trial's telephone randomisation service, which currently has no certain date for resolution. Thus it was agreed that within the SOP: Assessment and Follow-up, randomisation would be revised to include only the web based randomisation format, however, once the telephone based service is fully functional it would be re-inserted into the SOP with an updated version number.

4. Review of Study Documents

- It was agreed to develop a summary of responsibilities for those consultants that are on the prescribing IMP delegation log.
- It was confirmed the patient information leaflet had been completed.
- It was outlined the importance of attaining all CVs of all consultants working on the ACTIONS study in compliance with MHRA regulations. However, it was agreed that contacting the consultant's human resources department and confirming that they have a copy of the CV was allowed, subject to a file note being added in the Investigator Site File of the location of the CV.
- It was agreed to develop a single document of possible A/Es associated with Citalopram, to be issued to all study sites.
- It was agreed for the development of a flow chart to outline participant time lines, assessments, and responsibilities through screening to study end.

- It was outlined that the term “Non-Professional Carer” should be incorporated into the SOP for “carer assessment”.
- Helen Killaspy outlined to include OPCRIT within the Assessment and follow-up SOP.
- Carol Paton outlined to amend section 5.4 in SOP for Assessments and follow-up procedures that quotes on certain occasions where “study medication may be posted to the participant”. In such instances the study site local SOP, which should be approved by the ACTIONS Trial Manager, should be adhered to.
- It was emphasized that the researcher should prompt the participant if he or she still has the participant information card and if lost should be given a replacement immediately.

5. **Next TMG Meeting:** 15-July-2011, 10:00am-13:00pm. Meeting room to be confirmed.