Job Description

1. **Job Details**

   Job title: Trial Co-ordinator / Manager
   School/Support Department: School of Molecular & Clinical Medicine
   Unit (if applicable): Division of Clinical Neurosciences
   Line manager: Trial Chief Investigator

2. **Job Purpose**

   Plan, co-ordinate and manage the clinical trial from inception to completion.

3. **Main Responsibilities**

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1. Manage and co-ordinate the project and project team effectively to ensure the successful completion of the trial.
2. Communicate effectively internally, externally and internationally with collaborators, colleagues and health professionals in order to develop, motivate and maintain a world-wide collaborative group.
3. Promote and market the trial, in order to reach the goals outlined in the protocol. Design strategies and monitor effectiveness of these.
4. Supervise trial team and be involved in their recruitment and training.
5. Ensure compliance with regulations (e.g. ethics, data protection and GCP) by designing, producing and regularly updating trial materials including the protocol, SOPs and data collection forms.
6. Contributing to grant applications and financial reports for funding bodies and University, thereafter, working within and monitoring the budget.
7. Publish scientific papers based on trial findings and surveys.
8. Represent trial at relevant meetings, e.g. Steering Committee, Collaborator meetings, scientific conferences and site visits.

4. **Planning and Organising**

   - Respond daily to queries from team, collaborators and other health professionals on all aspects of the trial.
   - Self-generate tasks in order to achieve pre-specified goals.
   - Plan schedule of work in conjunction with Management Group on a yearly basis.

5. **Problem Solving**

   - Persuade collaborators to enlist support without any financial reward.
   - Relate legislation and guidelines (e.g. ICH GCP) intended for commercial medicinal trials to non commercial and non medicinal trials.

6. **Decision Making**
- Alone, or in consultation with Trial team, involved in all decision making processes including how funds are spent and how to implement regulations for data processing.
- Prioritising work carried out by data management team (data processors, computer programmers and trial secretary).
- Where decisions will have a major impact on the trial or where clinical/specific (e.g. statistical) guidance is required other members of the trial team consulted.

7. **Key Contacts/Relationships**
   Internal - Chief Investigator, fellow trial co-ordinators, university support departments, trial management group and data management team.

   External - Collaborators, funders, health departments, organisations relating to clinical trials (e.g. COREC).

   Providing and seeking advice / information, e.g.

   - Finance office in order to prepare funding applications/ justifications and yearly reports.
   - Effecting any necessary changes to the trial (e.g. implementing changes to the protocol in terms of gaining the necessary approval via MREC, funding via the funder and/or Department of Health).

8. **Knowledge, Skills and Experience Needed for the Job**
   - Demonstrable trial management experience of co-ordinating large multi-centre randomised controlled trials in a non commercial environment.
   - A relevant qualification.
   - Ability to work independently and to drive the project forward.
   - Ability to keep up to date with relevant guidelines and regulations.
   - Ability to monitor and analyse complex information to effect improvements to trial.

9. **Dimensions**
   - Trial manager for 6 members of staff.
   - Administering grant budget of £1m+.
   - Mentoring staff and highlighting training requirements.
   - Customers – External - 50+ international collaborative centres thus dealing with hundreds of collaborators worldwide.
   - Customers – Internal – Trial Unit staff, including clinicians, computer programmers, statistician, technical staff and support staff.

10. **Job Context and any other relevant information**
    Promoting and ensuring the success of the trial in light of changing opinion and policy, both scientifically and politically.