## Division of Responsibilities

The aim of this document is to outline the duties undertaken in a clinical trial. It summarises the responsibilities that may need to be assigned and allows you to start thinking about who will be responsible for these specific duties, by country and organisation. Any future contract negotiation will also be built around this information. Ultimately this information could be included in a contract and sign off by relevant participating organisations.

This list is only a snapshot of high level activities. The full list can be found here <http://researchsupport.admin.ox.ac.uk/ctrg/resources>. It would be expected that the complete and final full list would be signed by the Chief Investigator, Clinical Trials Unit and Sponsor.

N.B Top level categories should not be changed. Subdivision can be changed or added to in order to meet specific trial requirements but these changes must be highlighted in red. When assigning a responsible one of the following should be added to every cell;

* ‘A’ - ‘for trial’ if the organisation is taking on that particular responsibility for the whole trial,
* ‘B’ - ‘country specific’ if the organisation is only taking on that responsibility in their particular country,
* ‘C’ - ‘no responsibility’ if that organisation is not taking on that responsibility. Note for each duty there should be at least one organisation assigned unless the responsibility is not relevant for the trial and then N/A should be used.

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|  | Activities (listed in study conduct order) | | Name of Organisation | | | |
| **Number** | **Top level** | **Subdivision** | **<insert name of organisation>** | **<insert name of organisation>** | **<insert name of organisation>** | **<insert name of organisation>** |
| 1 | Funding |  |  |  |  |  |
| 1.1 |  | Develop and secure the budget |  |  |  |  |
| 1.2 |  | Budget management and report to funder |  |  |  |  |
| 2 | Trial design |  |  |  |  |  |
| 2.1 |  | Scientific rationale, clinical relevance, clinical feasibility, schedule of tests/events and recruitment strategy |  |  |  |  |
| 2.2 |  | Statistical advice |  |  |  |  |
| 3 | Protocol |  |  |  |  |  |
| 3.1 |  | Obtain EudraCT number and relevant registration |  |  |  |  |
| 3.2 |  | Protocol and supporting document preparation |  |  |  |  |
| 3.3 |  | Protocol and supporting document review (including internal department review) and sign off |  |  |  |  |
| 4 | Risk Assessment |  |  |  |  |  |
| 4.1 |  | Develop, review and update risk assessment and monitoring plan |  |  |  |  |
| 5 | Sponsorship and Insurance |  |  |  |  |  |
| 5.1 |  | Confirm Sponsorship and Arrange insurance and / or indemnity |  |  |  |  |
| 6 | Trial Master File |  |  |  |  |  |
| 6.1 |  | Prepare and maintain Trial Master File (TMF) |  |  |  |  |
| 7 | Service and Supply |  |  |  |  |  |
| 7.1 |  | Identify appropriate providers / suppliers |  |  |  |  |
| 7.6 |  | Identify, negotiate and sign off appropriate contracts |  |  |  |  |
| 8 | Site Selection and Management |  |  |  |  |  |
| 8.1 |  | Identify, select and recruit sites / centre / hubs / investigators |  |  |  |  |
| 8.2 |  | Provide information to sites including Investigator Site File (ISF) |  |  |  |  |
| 8.3 |  | Activate authorised sites and oversee performance of sites |  |  |  |  |
| 9 | Site Conduct |  |  |  |  |  |
| 9.1 |  | Obtain authorisation from local regulatory bodies (e.g. host organisation) |  |  |  |  |
| 9.2 |  | Ensure adequate facilities, resources and support are available to conduct the study |  |  |  |  |
| 10 | Ethics Approval |  |  |  |  |  |
| 10.1 |  | Prepare, review, sign off and submit submission bundle |  |  |  |  |
| 11 | Competent Authority Approval |  |  |  |  |  |
| 11.1 |  | Prepare, review, sign off and submit submission bundle |  |  |  |  |
| 12 | Other Approvals |  |  |  |  |  |
| 12.1 |  | Obtain relevant national host organisation approval e.g. HRA |  |  |  |  |
| 12.2 |  | Obtain local agreement for trial conduct |  |  |  |  |
| 13 | Trial Management |  |  |  |  |  |
| 13.1 |  | Coordinate Investigator meetings |  |  |  |  |
| 13.2 |  | Ensure third parties compliance to appropriate regulations and other requirements |  |  |  |  |
| 14 | CRF/eCRF design |  |  |  |  |  |
| 14.1 |  | Design, prepare, review, test, validate and sign off CRF |  |  |  |  |
| 15 | Database design |  |  |  |  |  |
| 15.1 |  | Design, build, test and validate database |  |  |  |  |
| 16 | Data Management |  |  |  |  |  |
| 16.1 |  | Oversee or prepare data management plan (DMP) |  |  |  |  |
| 16.2 |  | Data coding, entry and checks and ultimately database lock |  |  |  |  |
| 17 | Code breaking |  |  |  |  |  |
| 17.1 |  | Define and provide emergency code breaking procedures (if applicable) |  |  |  |  |
| 18 | IMP management |  |  |  |  |  |
| 18.1 |  | Source IMP in line with relevant procurement rules, ensure labelling and QP release |  |  |  |  |
| 18.2 |  | Ensure distribution and retention of IMP documentation (e.g. certificate of analysis, IMP packaging sample etc.) |  |  |  |  |
| 18.3 |  | Ensure appropriate destruction of IMP and maintain detailed records |  |  |  |  |
| 19 | Device management |  |  |  |  |  |
| 19.1 |  | Ensure that investigational medical devices are not used for any purpose other than the conduct of the study, unless specific permission is given |  |  |  |  |
| 19.2 |  | Ensure detailed records are maintained regarding movement from delivery to return / destruction |  |  |  |  |
| 20 | Sampling handling |  |  |  |  |  |
| 20.1 |  | Oversee, prepare and maintain lab / sample handling manual |  |  |  |  |
| 20.2 |  | Transfer of appropriate analysis results to study database |  |  |  |  |
| 20.3 |  | Organise appropriate retention or disposal of samples on completion of study |  |  |  |  |
| 21 | Monitoring |  |  |  |  |  |
| 21.1 |  | Conduct and document monitoring according to monitoring plan |  |  |  |  |
| 22 | Audit and Inspection |  |  |  |  |  |
| 22.1 |  | Plan and conduct audits appropriate to trial |  |  |  |  |
| 22.2 |  | Facilitate audits and inspections |  |  |  |  |
| 23 | Safety Reporting |  |  |  |  |  |
| 23.1 |  | Define reportable events in protocol |  |  |  |  |
| 23.2 |  | Ensure RSI definition, provision and revision |  |  |  |  |
| 23.3 |  | Arrange appropriate systems and data collection documentation related to safety |  |  |  |  |
| 23.4 |  | Prepare, submit and distribute annual safety reports (e.g. DSUR) |  |  |  |  |
| 24 | Serious Breach |  |  |  |  |  |
| 24.1 |  | Report potential serious breaches to Sponsor |  |  |  |  |
| 24.2 |  | Report serious breach to CA |  |  |  |  |
| 25 | Complaint |  |  |  |  |  |
| 25.1 |  | Receipt and investigation of compliant |  |  |  |  |
| 26 | Amendments |  |  |  |  |  |
| 26.1 |  | Identify, communicate and implement urgent safety measures |  |  |  |  |
| 26.2 |  | Prepare, review, sign off and submit amendment submission bundle |  |  |  |  |
| 27 | Committee Management |  |  |  |  |  |
| 27.2 |  | Coordinate and report appropriate Trial / Project Management Group, Steering and Data Monitoring Committees |  |  |  |  |
| 28 | Statistical analysis |  |  |  |  |  |
| 28.1 |  | Develop statistical analysis plan and conduct statistical analysis (interim and final) |  |  |  |  |
| 28.2 |  | Prepare, review and sign off trial report |  |  |  |  |
| 29 | Publication |  |  |  |  |  |
| 29.1 |  | Prepare, review and submit publication |  |  |  |  |
| 30 | Close out |  |  |  |  |  |
| 30.1 |  | End of trial or early termination communication (including end of study report) to CA, ethics, Sponsor, host organisation as applicable |  |  |  |  |
| 30.2 |  | Reconcile trial finances and terminate service agreements |  |  |  |  |
| 31 | Archiving |  |  |  |  |  |
| 31.1 |  | Archive by Named Archivist |  |  |  |  |