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| **Project Management Delegation log – Study Title**  Protocol Number: Ethics reference: \_\_\_\_\_\_\_\_\_  ISRCTN Study ID\_\_\_\_\_\_\_\_\_ EudraCT\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |  |
| NB: Where more than one individual is jointly responsible for a task add additional lines under the task and enter dates for everyone | **Name** | **Role in Study** | **Start Date** | **Stop Date** |
| **Study set-up** |  |  |  |  |
| 1. Project team meeting organisation |  |  |  |  |
| 2. Project team meeting minute taking |  |  |  |  |
| 3. Sponsor file – preparation and upkeep |  |  |  |  |
| 4. Protocol design |  |  |  |  |
| 5. Grant application completion |  |  |  |  |
| 6. Grant application submission |  |  |  |  |
| 7. Submission of ethics, HRA and R&D applications |  |  |  |  |
| 8. Submission of MHRA application |  |  |  |  |
| 9. Risk assessment |  |  |  |  |
| 10. Represent PTUC at collaborators meetings |  |  |  |  |
| 11. Design of CRFs / liaison with Data Management team and database build |  |  |  |  |
| 12. Data Management Plan |  |  |  |  |
| 13. Validation and licence agreements for data collection instruments and applications (electronic data transfer plan) |  |  |  |  |
| 14. Non-compliance reporting process and review for trend analysis |  |  |  |  |
| 15. Statistical advice |  |  |  |  |
| 16. Randomisation strategy (including back-up randomisation system and emergency code break procedure) |  |  |  |  |
| 17. Safety Plan (including RSI (defining expected AEs), AE collection, assessment and reporting, ongoing safety updates, safety signal detection and reconciliation of safety and clinical database) |  |  |  |  |
| 18. Completion of Statistical Plan |  |  |  |  |
| 19. Contracting with the funding body |  |  |  |  |
| 20. Collaborators Agreements (as applicable) |  |  |  |  |
| 21. Vendor selection and oversight |  |  |  |  |
| 22. Contracts with sub-contractors/vendors |  |  |  |  |
| 23. Audit planning and inspection readiness |  |  |  |  |
| 24. PPI contact |  |  |  |  |
| 25. Trial Supply Management (including manufacture, packaging, labelling, QP release and distribution) |  |  |  |  |
| 26. Completion of study green light checks |  |  |  |  |
| 27. Completion of Monitoring Plan |  |  |  |  |
| 28. Completion of Sponsor responsibilities delegation log (as necessary) |  |  |  |  |
| 29. Completion of Project management delegation log |  |  |  |  |
| 30. Completion and regular update of the Trust Asset register |  |  |  |  |
| 31. Site Feasibility and Selection Process |  |  |  |  |
| **Study Management** |  |  |  |  |
| 32. Overall responsibility for setting up studies at each site |  |  |  |  |
| 33. Carrying out site initiation visits at each site |  |  |  |  |
| 34. Preparation of site files |  |  |  |  |
| 35. Completion and filing of all SIV documentation |  |  |  |  |
| 36. Maintain contact with other sites |  |  |  |  |
| 37. Contract negotiation with study sites |  |  |  |  |
| 38. Completion and submission of any necessary financial reporting |  |  |  |  |
| 39. Regular invoicing (sending invoice requests and invoice review and approval) |  |  |  |  |
| 40. TSC meeting organisation |  |  |  |  |
| 41. Preparation of DMC meeting reports |  |  |  |  |
| 42. DMC meeting organisation |  |  |  |  |
| 43. Organisation and documentation of all project team meetings (as necessary) |  |  |  |  |
| 44. Submission of annual reports to Ethics, MHRA and other regulatory requirements |  |  |  |  |
| 45. Completing and submitting reports to funding bodies |  |  |  |  |
| 46. Periodic review of SmPC / IB |  |  |  |  |
| 47. Completion and Submission of DSUR |  |  |  |  |
| 48. Completing and Submitting of amendments to REC / MHRA |  |  |  |  |
| 49. Periodic updates of ClinicalTrials.gov and other databases as required. |  |  |  |  |
| 50. NIHR portfolio and Edge accrual data uploads |  |  |  |  |
| 51. Training all new starters (at all sites) in the protocol |  |  |  |  |
| 52. Maintain regular contact with and notify PTUC and sponsor of progress, problems and any unexpected event or development |  |  |  |  |
| 53. Overview of adverse events; assessment of seriousness and onward reporting as appropriate |  |  |  |  |
| 54. Report any breaches of trial protocol or GCP |  |  |  |  |
| 55. Overview of breaches reported; assessment of seriousness and onward reporting as appropriate |  |  |  |  |
| 56. Periodic review of risk assessments |  |  |  |  |
| 57. Maintenance of Sponsor level (green) EDGE profile |  |  |  |  |
| **Study Completion** |  |  |  |  |
| 58. Ensure all outstanding monitoring data queries resolved at each site |  |  |  |  |
| 59. Carry out study close-out visits at each site |  |  |  |  |
| 60. IMP accountability and destruction |  |  |  |  |
| 61. Data Analysis |  |  |  |  |
| 62. Complete end of study reports for ethics / MHRA |  |  |  |  |
| 63. Archiving of study documents |  |  |  |  |
| 64. Drafting publication / study report |  |  |  |  |
| 65. Closure of study at sites |  |  |  |  |
| 66. Inform Governance team of study closure and update Sponsor level (green) EDGE profile |  |  |  |  |

PI: ……………………………….. Date: ………………………. CPM: ……………………………. Date: ……………………….