

Tasks for Trial Manager

This is not an exhaustive list and will vary from trial to trial and centre to centre.

Pre-trial

- Protocol development
- Application and submission to ethics and regulatory authority (as required by country/countries in which trial is to be conducted)
- Clinical trial agreements with sites
- R&D approvals
- Site set up
- Set up of governance groups DSMC and TSC, TMG
- TMF set up
- Insurance/indemnity
- Training
- Patient/public involvement

During trial

- Data chasing, data cleaning
- Monitoring visits
- Organisation, running and documentaion of Investigator meetings T&S
- Organisation, running and documentaion of TSC meetings:T&S
- CTA and ammdement fees
- DMC meetings:T&S
- Conference fees + travel + subsistence (opt)
- Site payments made
- Contact with the sites
- Reports to ethics/MHRA and funders (Annual, DSUR, recruitment uploads)

Provision of equipment to sites:

- Tubes, cryoboxes, labels - per patient
- Arranging shippment /courier of samples
- Liasion with the Biobank and lab for specimen movement and assay timelines
- QA
- Maintainance of TMF
- Reimbursment for PPI members time
- Patient/public involvement
- Patient payments

End of trial

- Archiving TMF and samples
- Open access publication
- Creation of writing group
- Coordination of publication