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
- Research and Development (R&D) approvals
- Site set up
- Set up of governance groups – Data and Safety Monitoring Committee (DSMC), Trial Steering Committee (TSC), Trial Management Group (TMG)
- Trial Management File (TMF) set up
- Insurance/indemnity
- Training
- Patient/public involvement

During trial

- Data chasing, data cleaning
- Monitoring visits
- Organisation, running and documentation of Investigator meetings
- Organisation, running and documentation of Trial Steering Committee (TSC) meetings
- Clinical Trial Agreement (CTA) and amendment fees
- Data Monitoring Committee (DMC) meetings
- Conference fees + travel + subsistence (optional)
- Site payments made
- Contact with the sites
- Reports to ethics, regulatory bodies and funders (for example safety update reports, recruitment uploads)

Payments and provision of equipment to sites:

- Tubes, cryoboxes, labels - per patient
- Arranging shipment / delivery of samples
- Liaison with biobank and laboratory for specimen movement and assay timelines
- Quality Assurance (QA)
- Maintenance of TMF
- Reimbursement for Patient and Public Involvement (PPI) members' time
- PPI
- Patient payments

End of trial

- Archiving TMF and samples
- Open access publication

- Creation of writing group
- Coordination of publication