MANCHESTER 1824
The University of Manchester

**Appendix 1.**

**Sponsor Lead Pharmacist Role for CTIMPs Sponsored by The University of Manchester.**

The following list describes activities which should be overseen by the Sponsor Lead Pharmacist or delegated to a third party:

**SPONSOR OVERSIGHT**

As part of the Sponsor Oversight Committee or equivalent body, review and/ or advise on technical aspects of pharmaceutical and IMP management, including:

- CTIMP risk category assessment
- Funding applications
- Sponsor feasibility and local sites feasibility assessments
- Key trial documentation. This must include, but is not limited to: protocol, PIS, pharmacy manual, Investigator Brochure (IB), Investigational Medicinal Product Dossier (IMPD), Summary Product Characteristics (SmPC), reference safety information, contracts and technical agreements, monitoring plan, IMP risk assessment and mitigations etc.
- Pharmacy file content
- Key events such as: CT authorisation and ethical review, CT application including QP declaration, IRAS application, Substantial amendments, urgent safety measures.
- Committees/Groups such as trial management group.
- Study set up: Pharmacovigilance, IMP manufacture and assembly, QP certification, supply and release, accountability, unblinding procedure, out of hours procedure, safety plan, monitoring plan, study green light, study specific training, IMP management.
- Pharmacy green light- Review of sponsor and local documentation and process

**OVERSIGHT OF STUDY CONDUCT**

Review and/or advise on technical aspects of pharmaceutical and IMP management including:

- Suitable delegation of activities to a third party (vendor selection process, vendor audit)

- As part of the Sponsor oversight committee or equivalent body: review updates from study and monitoring activities, reports, risk management plan, protocol deviations, breaches, assurances provided about effective out of hours procedure in place when applicable
- Note the Sponsor Lead Pharmacist responsibilities will be detailed in the trial specific delegation of activities form.

**QUALITY**

Review and/or advise on technical aspects of pharmaceutical and IMP management, including:

- Gap Analysis
- Auditing and monitoring plans.
- Local SOPs to comply with GCP and needs of the specific protocols.
- GCP systems, policies and procedures for the sponsor and host sites.
- Preparation for inspection, CAPA plan
- Training
- Risk management including IMP