

Investigational medicinal product (IMPs) used in clinical trials need to be of consistent quality. Inappropriate products can raise efficacy and safety concerns, raising doubts on the validity of trial data. Moreover, IMP related decisions made during early stages of the research pathway can have a significant impact on the study design, regulatory requirements, deliverability of the study, as well as the total cost of research. As IMP related activities are often costly, necessitating months of advance planning, it is imperative that specialist inputs are sought from the very start of the study planning process.

PRE-AWARD: Free advisory service (also available to non-CTIMP trials involving the use of medicinal products)

- The KCTU-affiliated pharmacy group provides IMP advisory services to investigators within King's Health Partners at the grant application stage of their study.
- Investigators can request support by submitting a completed KCTU support request form (via www.ctu.co.uk). Please note that this support can be requested even where no additional KCTU services are required.
- The support request will be processed and the investigator will be offered up to two free 1 hour meetings with a clinical trials pharmacist to discuss the plan for IMP management. Depending on the complexity of the planned study, additional meetings are considered on a case-by case basis.
- Post-award input will only be provided on a funded basis – see collaboration section below.

POST-AWARD: Funded collaboration

KCTU-affiliated pharmacy collaborations offer expertise to support investigators in planning and managing IMP related activities throughout the research life cycle.

Standard collaboration – bronze level (mandatory for all KHP-partner sponsored studies involving administration of medicines and/or placebos)

- UK-based studies where IMP are licensed in UK and used without modification
 - Pharmacy review of IMP labels
 - IMP section of protocol
 - Pharmacy review of manufacturer technical agreements
 - Pharmacy review of MHRA applications (if needed)
 - £750 to be included in all grant applications
- Please seek a bespoke quote for:
 - International studies
 - Trials of IMP not licensed in the UK
 - Trials of IMP used in a modified form

Advanced collaboration – silver level (optional)

This level of service provides all the benefits of 'bronze' collaboration, but additionally:

- Pharmacy acts as the key point of contact between the Chief Investigator and the IMP/placebo manufacturers (including GSTT manufacturing unit) to ensure:
 - Quantities for purchase or donation are accurate
 - IMP management plan is developed
 - Projections of number of manufacturing runs needed, and implications, are considered
 - Implications of stability testing programmes (if appropriated) are considered
 - Effective liaison with Qualified Person and MHRA where appropriate
- Trial manager will receive advice from a qualified trials pharmacist throughout the trial to:
 - Ensure emergency code break mechanisms implemented
 - Ensure mechanisms for maintaining stock levels at recruiting sites are implemented
 - Advise on the preparation of a pharmacy file template for use across all study sites
 - Advise on the preparation of a study specific prescription
 - Advise on temperature deviations at study sites
 - Advise on IMP reconciliation during and at end of trial
- Silver level support starts at confirmation of funding award and ends when IMP reconciliation is complete.
- Typically costs will be 0.1-0.2wte pharmacist throughout the grant, but occasionally more in complex trials.
- A quote will be provided by the relevant pharmacist after detailed discussion about your project.

Advanced collaboration – gold level (optional)

This service may be offered in addition to, or independently of, the silver level of service.

- Pharmacy will ensure IMP stock levels are maintained at recruiting sites throughout the entire life-cycle of the trial, titrated against recruitment and withdrawals, though regular unblinded review of IMP levels, assuming:
 - Trial manager will liaise with sites to provide pharmacist with updated information on recruitment and withdrawals
 - This service should be considered where the trial manager is blind to treatment allocation, the trial is multicentre and it is important to ensure there is a continuous supply of active and placebo stock to sites
- Typically, 0.05-0.1wte pharmacist per project over the full duration of the grant, but occasionally more in complex trials.
- A quote will be provided by the relevant pharmacist after detailed discussion about your project.

Additional costs not included in the above:

- Costs associated with the purchase of drug, placebo manufacturing, packaging, labelling, storage and distribution activities, IMP inventory IT systems, emergency code break facilities, IMP dispensing at recruiting sites and drug destruction must be costed separately