NCRI
National Cancer Research Institute

NCRI Cancer Group CTUs

Principles for Collaboration with Pharmaceutical Company Partners

Collaboration between the academic clinical research community and pharmaceutical company partners is a key aspect of UK clinical cancer research. Clinical trials units (CTUs), working in partnership with clinical investigators, play a pivotal role in delivering UK research, from the design and delivery of trials, to analysis and publication of results. The collective academic expertise of the UKCRC Registered, NCRI Cancer Group CTUs has been a key contributor to the growth of clinical trial activity in cancer over the past decade, working hand in hand with national clinicians and scientists, clinical networks, NCRI Clinical Studies Groups and the pharmaceutical industry to deliver NCRI portfolio trials.

Many successful UK cancer studies have been developed as Investigator Initiated Research (IIRs) with a non-commercial sponsor (usually university or NHS Trust), management of the study within an UKCRC Registered, NCRI Cancer Group CTU, with drug and research funding obtained from a partner pharmaceutical company.

In order to facilitate successful academic/ pharmaceutical company partnerships a consistent approach to collaboration is required across the CTU network.

This document describes how academia and pharmaceutical company partners can collaborate effectively to deliver the cancer research portfolio and defines standard terms of collaboration.

Who assumes the role of sponsor?

The host institution (HI) of the Chief Investigator (CI) or CTU (usually a university or NHS Trust) assumes the role of sponsor or the HI's may co-sponsor the study. The sponsor retains the legal and regulatory responsibility for the study.

What are the responsibilities of the CI & CTU?

The CI and CTU are responsible for study development, initiation, conduct and analysis including:

- study design and protocol development;
- obtaining and maintaining institutional, regulatory and ethics approvals;
- site selection and initiation;
- monitoring and pharmacovigilance;
- data analysis, interpretation and reporting.

Study conduct is according the principles of Good Clinical Practice as defined in UK law and all laws and statutes applicable to the performance of the clinical study.

What is expected of the company?

Funding

Financial support for the study via an unrestricted educational grant.

Payment milestones linked to the agreed schedule of costs for set up, recruitment and analysis. Milestones solely linked to recruitment rate will not be accepted.

Where the contract is terminated early, costs to cover work already committed or carried out by the CI/CTU should be covered.

Drug Supply & Distribution

Study drug should be free of charge in sufficient quantities to allow completion of the study.

If the study is terminated early for reasons other than patient safety, the company will be expected to provide study drug to allow patients on treatment to finish treatment according to the protocol.

It is preferable that the packaging and distribution is carried out by the company, or a 3rd party vendor subcontracted to the company.

If the sponsor is required to sub-contract with a 3rd party vendor, this will be expected to be treated as a pass through cost.

Who is responsible for the protocol?

The sponsor will retain overall responsibility for and final decision on the content of the protocol.

The company will be expected to review the protocol and any amendments that relate to study drug and patient safety.

How will pharmacovigilance be managed?

The sponsor retains overall responsibility for pharmacovigilance within the study.

The CI and CTU are responsible for SAE review and regulatory reporting.

The CTU will provide anonymised individual SAEs to the company for safety monitoring using the CTUs template form.

The CTU will assist in the collection of additional follow up information where requests from the company are reasonable and justified.

The company will be expected to maintain the IB/SmPC and notify the CI/CTU of any updates or additional safety information relevant to the study drug that it becomes aware of during the study. The CTU will distribute relevant information to the research sites.

What indemnification will be required?

The company will be expected to indemnify the sponsor against personal injury claims made in relation to manufacture / supply of study drug.

The sponsor will indemnify the company against claims made for personal injury or death in relation to administration of the study drug or any other intervention in accordance with the study protocol or any other declaration concerning the treatment of a patient on the study, except where the claims were caused or contributed to by the company, subcontractor or their respective employees.

How is intellectual property assigned?

Background IP is owned by the contributing party.

Foreground IP includes study data and results and is owned by the sponsor.

Foreground IP relating to the study drug is owned by the company.

What are the key study deliverables ?

The CI/CTU will publish the results of the study in a peer reviewed scientific journal.

The company will be provided the opportunity to review, comment on and postpone publications and abstracts in order to protect intellectual property rights for a reasonable period of time.

The CTU will provide progress reports to the company at mutually agreed intervals. The reports will be limited to recruitment data and will not contain any information that could lead to inference of study efficacy.

The primary deliverable will be the final study report which will be according to the CTU standard template.

What are the data access arrangements ?

The sponsor will own the study data.

Data sharing is encouraged but the sponsor has a responsibility to ensure sharing is complaint with consents, data protection regulations and non-commercial intent of the trial.

Requests for access to study data should be made to the sponsor and use should be restricted to the approved purpose.

Data will be shared if:

- it does not undermine the scientific integrity of the study (ie not prior to the reporting of the relevant study endpoints);
- is for academic research or R&D purposes;
- has been approved by an independent body appointed by the sponsor;
- is covered by the consent given by study patients.

Data will usually be shared in an anonymised format such that the data cannot be linked back to patient records at participating sites.

If the data are to be used for commercial purposes in support of licensing or similar, cost recovery will be expected at rates that are similar to commercial rates.

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http://www.ncri.org.uk/accelerating-cancer-research/ctu/