NCRI Cancer CTU Group

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 CTU Group has been a key contributor to the growth of clinical trial activity in cancer over the past decade, working hand in hand nationally with 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 trial within an UKCRC Registered, NCRI Cancer Group CTU, with research funding and/or drug supply 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 summarises 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 of the Chief Investigator (CI) or of the CTU (usually a university or NHS Trust) assumes the role of sponsor of the trial or both may act as co-sponsors. The sponsor (or co-sponsors) retains the legal and regulatory responsibility for the trial.

What are the CI & CTU responsibilities?

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

- trial design and protocol development;
- obtaining and maintaining institutional, regulatory and ethics approvals;
- selection and initiation of trial sites;
- monitoring;
- pharmacovigilance;
- data analysis;
- interpretation and reporting of trial results.

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

What is expected of the company?

Funding (if applicable)

Financial support for the trial via a study 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

Trial drug should be free of charge in sufficient quantities to allow completion of the trial.

If the trial is terminated early for reasons other than patient safety, the company will be expected to provide trial 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 specifically relate to trial drug and patient safety in a timely manner.

How is pharmacovigilance managed?

The sponsor retains overall responsibility for pharmacovigilance within the trial.

The CI and CTU are responsible for SAE review, DSUR development and regulatory reporting for the trial.

The CTU will:

- provide anonymised individual SAE reports to the company for safety monitoring using the CTUs template forms;
- assist in the collection of additional SAE follow up information where requests from the company are reasonable and justified;
- provide anonymised pregnancy reports for safety monitoring using the CTUs template forms;
- distribute relevant safety information received from the company to the trial sites;
- include additional safety event monitoring as is reasonably required by the company.

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 trial drug that it becomes aware of during the trial;
- advise on or respond to regulatory queries regarding the trial drug.

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 trial drug or in relation to negligence of the company's employees, subcontractors or agents.

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

How is intellectual property assigned?

Background IP is owned by the contributing party.

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

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

What are the key trial deliverables?

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

The company will be provided with 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 trial data or information that could lead to inference of trial efficacy.

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

What are the data access arrangements?

The sponsor will own the trial data.

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

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

Data will be shared if:

- provision does not undermine the scientific integrity of the trial (i.e. not prior to the reporting of the relevant trial endpoints);
- the planned use is for academic research or R&D purposes;
- the planned use is approved by an independent body appointed by the sponsor;
- the planned use is covered by the consent given by trial patients.

Data will usually be shared in an anonymised format such that the data cannot be linked by the recipient 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 for the CTU and participating sites will be expected at rates that are similar to commercial rates.

http://www.ncri.org.uk/ctu-group/