

CHARTER OF COLLABORATION BETWEEN CANCER COOPERATIVE GROUPS (GCO) AND INDUSTRY

PREAMBLE

In biomedical research, collaboration between academic research groups (cooperative groups) and the pharmaceutical, biotechnological industries is a natural occurrence, with all parties sharing common goals: producing top-quality scientific results and developing effective, well-tolerated treatments. However, both cooperative groups and industry have to consider the potential divergences in their approaches to creating a partnership that is both effective and operates in a transparent manner. This requires the industry to respect certain principals essential to the success of cooperative groups, those which ensure both their independence and industrial confidence. Collaboration between these parties is distinctly different from a service-provider arrangement. It must therefore be formalized for each project, with terms laid out in a partnership convention. This Charter between the Cancer Cooperative Groups (*Groupes Coopérateurs en Oncologie* - GCO) and industry outlines the principals to be respected in order to establish such a partnership convention, which, once drawn up, will include the Charter as an annex.

I- Conception, analysis, and coordination of trials

All clinical trials and biological studies or ancillary statistical analyses conducted by the GCO with their industry collaborators are designed in the spirit of independence and aimed to find answers to the scientific issues under analysis. These could involve the use of a drug or not, which has been marketed or not, or is already being used or not in an indication having obtained market authorization. Such trials could equally involve research on or validation of a biomarker, of diagnostic or prognostic tools, or of concepts of epidemiology, pharmacoeconomics, quality of life, and so on.

Each study protocol is designed and written by an editorial committee constituted under the direction of the cooperative group following the usual formats and recommendations from regulatory authorities or other public bodies likely to participate in funding. This committee can interact with the representatives of one or several industry partners of the project and has the final say on the protocol to be implemented.

The design of the protocol's statistical phase is the cooperative group's responsibility, who can call upon the input of statisticians from their industry partners. All parties can be involved in establishing the methodology and statistical analysis plan. The editorial committee, which must comprise at least one statistician, is responsible for producing the final version of the statistical section.

A steering committee of the study is assigned along with written operating procedures to be respected. The cooperative group designates a Principal Investigator of the study and the members of the study's steering committee. The cooperative group is in charge of choosing the centers to participate in the study.

II- Study sponsor

As often as possible, the cooperative group is the official study sponsor, providing they are able to conform to existing regulations. They may delegate this task to a healthcare institution. The sponsor (cooperative group or healthcare institution) is responsible for conducting the trial and owns all resulting data. A partnership convention should be established outlining the respective responsibilities of the sponsor and industry partner in terms of access to and managing study data, as well as pharmacovigilance, monitoring serious adverse events (SAEs), confidentiality, data ownership, and publication.

When an industry partner is the elected sponsor, a cooperation agreement must be drawn up between the cooperative group and their representative(s) covering issues of pharmacovigilance, in addition to monitoring and interpreting SAEs. This agreement stipulates the rules for potential interruption of the study and co-ownership, freedom of analysis, and publication of the data by the cooperative group.

III- Independent Data Monitoring Committee (IDMC)

The members of the IDMC are selected by the sponsor, with the agreement of all parties, including that of the cooperative group if they are not the sponsor. The IDMC operating procedures will be outlined in the protocol or another charter. The cooperative group must verify that there are no conflicts of interest between the IDMC members and the industry partner or one of their competitors.

IV- On-site monitoring and data management

Both are conducted overseen by the sponsor, in adherence to existing regulations. The means and priorities of monitoring must be outlined by the sponsor. The cooperative group may assign the responsibility of monitoring to another company, potentially in coordination with the industry partner.

V- Ownership and use of the database

The sponsor is the sole legal owner of the database.

The partnership convention stipulates the rules of access to the results and database, where applicable, as well as confirming any co-ownership terms.

When the cooperative group is not the sponsor, the convention may stipulate that, following analysis of primary and secondary criteria, the cooperative group is the only entity authorized to use the database, possibly in the context of a consortium (for example, for subgroup analyses or meta-analyses).

The convention may outline that the industry partner, whether the sponsor or not, can conduct any analysis necessary for reporting or regulatory purposes, yet can neither publish scientific papers nor transfer the database to a third party for further scientific work, except if specifically authorized to do so by the cooperative group and the study's Principal Investigator.

VI - Duration of support

A clinical research program can comprise several successive stages (I then II, or II then III), in which case the conditions of support for each stage following the initial one must be clearly established in the very first convention.

For all studies, yet particularly adjuvant studies or those concerning the use of a new treatment or strategy, extending monitoring beyond the necessary time for obtaining results demonstrating the protocol's efficacy may prove useful for assessing long-term toxicity and/or efficacy. Given this scenario, the means, including financing, should be outlined in the convention.

VII- Analysis

When the sponsor is a cooperative group, the statistical analyses are conducted either by the cooperative group, a data processing center or an independent service provider separate from all partners, chosen by the cooperative group with the potential input of the industry partner.

When the sponsor is an industry partner, the cooperative group has access to the database and all documents concerning analyses conducted on the database data. The cooperative

group may perform a second batch of statistical tests on the principal evaluation criterion and secondary evaluation criteria identified as significant.

VIII- Publications

The obligation to publish results with no restriction features in the convention of each project. The cooperative group is responsible, via the study's steering committee, for all scientific publications and designation of authors according to their specific rules of publication. The study report must be approved by the cooperative group. Industry partners may comment upon the projects to be published over a certain period, as well as on the methods defined in the convention.

IX- Transfer of rights

The rules surrounding transferring rights to use the databases (clinical and/or biological) to an industry partner, including the financial profits thereof, are defined in the convention.

X- Conflicts of interest

Any potential conflicts of interest between members of the study's editorial and steering committees, on the one hand, and the industry partner on the other are to be declared and available for consultation. Any potential conflicts of interest with the cooperative group must also be declared.

All publications resulting from the study must feature a link to the industry partner/partners concerned, particularly when concerning funding or provision of products for the study. Each author must declare their own conflicts of interest, in accordance with existing regulations.

XI- Independence of the Principal Investigator

In the cooperative groups, the Principal Investigator of a clinical study involving a drug or drugs must not have any financial stake in the study's results, nor must his friends or family.