



CHARTER FOR CLINICAL TRIALS IN RARE DISEASES



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Background

Why regulate patient-sponsor interaction?

Actors involved in clinical development face highly variable situations in the field of rare diseases:

- *clinical aspects of the disease,*
- *varying skills and areas of expertise,*
- *size,*
- *experience,*
- *scientific commitment,*
- *and logistical means of both sponsors and POs*

Certain rules are required to maintain a viable relationship between the various stakeholders (sponsors, POs, patients, investigators, authorities), essential for a fruitful collaboration.

Background

Sponsors and patient organisations (POs) share common objectives:
production and sharing of high-quality knowledge on diseases and development of safe and effective treatments.

POs can collaborate with sponsors in all aspects of clinical trials:

- **Adapting the design of the study to patients' expectations, needs and realities**
- **Providing (early) information to potential participants**
- **Supporting patients during the study**
- **Taking quality of life into consideration**
- **Discussing trial results**

General Principles (I/II)

- ***Patient organisations (POs) should be informed of all aspects of the clinical protocol before collaboration.***
- ***POs should actively contribute to the documents aimed at patients - patient information document and the informed consent form.***
- ***Areas of and extent of collaboration should be enumerated in the “Agreement of Understanding”, available to all stakeholders: **patients, sponsors, investigators, ethics committees and national competent authorities.*****
- ***Financial relationships (ie, between sponsors and Pos) are transparent.***

General Principles (II/II)

- ***Study results should be published, even in case of negative outcomes, non-conclusive or otherwise abandoned clinical trials.***
- ***Data acquired during clinical trials should be made available to the scientific community, with a view to fostering scientific progress and avoiding unethical duplication of clinical trials.***
- ***The commitment of a PO in the design and/or development of a trial does not modify the role and responsibilities of the sponsor, even if the study is financially supported by the PO.***

Eurordis Charter in Practice (I/II)

A general set of principles

- ***Implementation of the Charter is based on the willingness of both sponsors and Patient Organisations***
- ***The Charter and its outcome will be reviewed after an initial trial period***
- ***Eurordis is committed to making public the list of patient organisations and sponsors having signed the Charter.***
- ***Any collaboration between the Sponsor and the Patient Organisation, according to the Charter, testified to by the “Agreement of Understanding”, will be made public to all stakeholders and included on the Eurordis website.***

Eurordis Charter in Practice (II/II)

Eurordis - facilitating the application of the Charter

- ***Eurordis will help the sponsor identify European POs interested in collaborating with them***
- ***Eurordis may also assist in the setting-up of the collaboration between sponsors and POs, without interfering in the study itself.***
- ***Eurordis develops training sessions aimed at helping PO representatives to better understand and contribute to clinical trials.***
- ***Additional documents aimed at these collaborations - glossary, specifics of agreement, “fiches de collaboration” - can be available on Eurordis website.***