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Rare Diseases Europe

Clinical Trials Charter

François Faurisson
Clinical Research Advisor, Eurordis

POs support the clinical research

76% Actions aiming at creating links between patients, researchers and physicians

57% Helping to identify patients to participate **in clinical trials**

49% Providing information and counseling for potential participants **in clinical trials**

48**%** **Defining research projects** by highlighting patients' needs and expectations

45% Collaboration **in clinical trials design**

30% Participation in scientific committees within institutions

28% Launching campaigns for the collection of biological samples from patients

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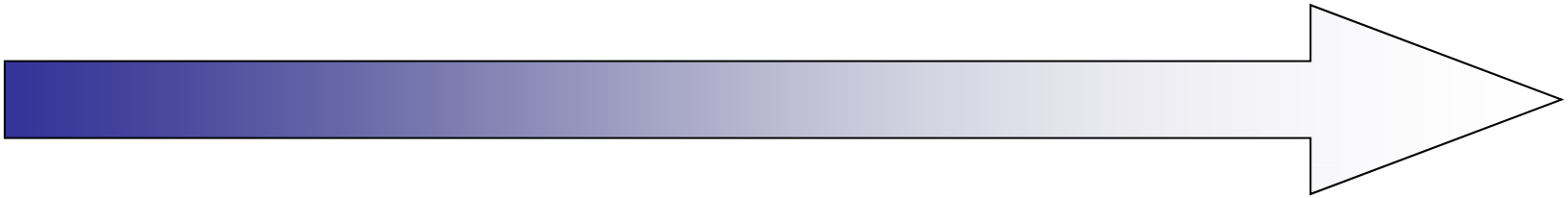
When to collaborate in clinical trials?

Protocol design — **Progress** — **Discussion of results** — **Conclusions**



Constructive Collaboration

«It is possible»

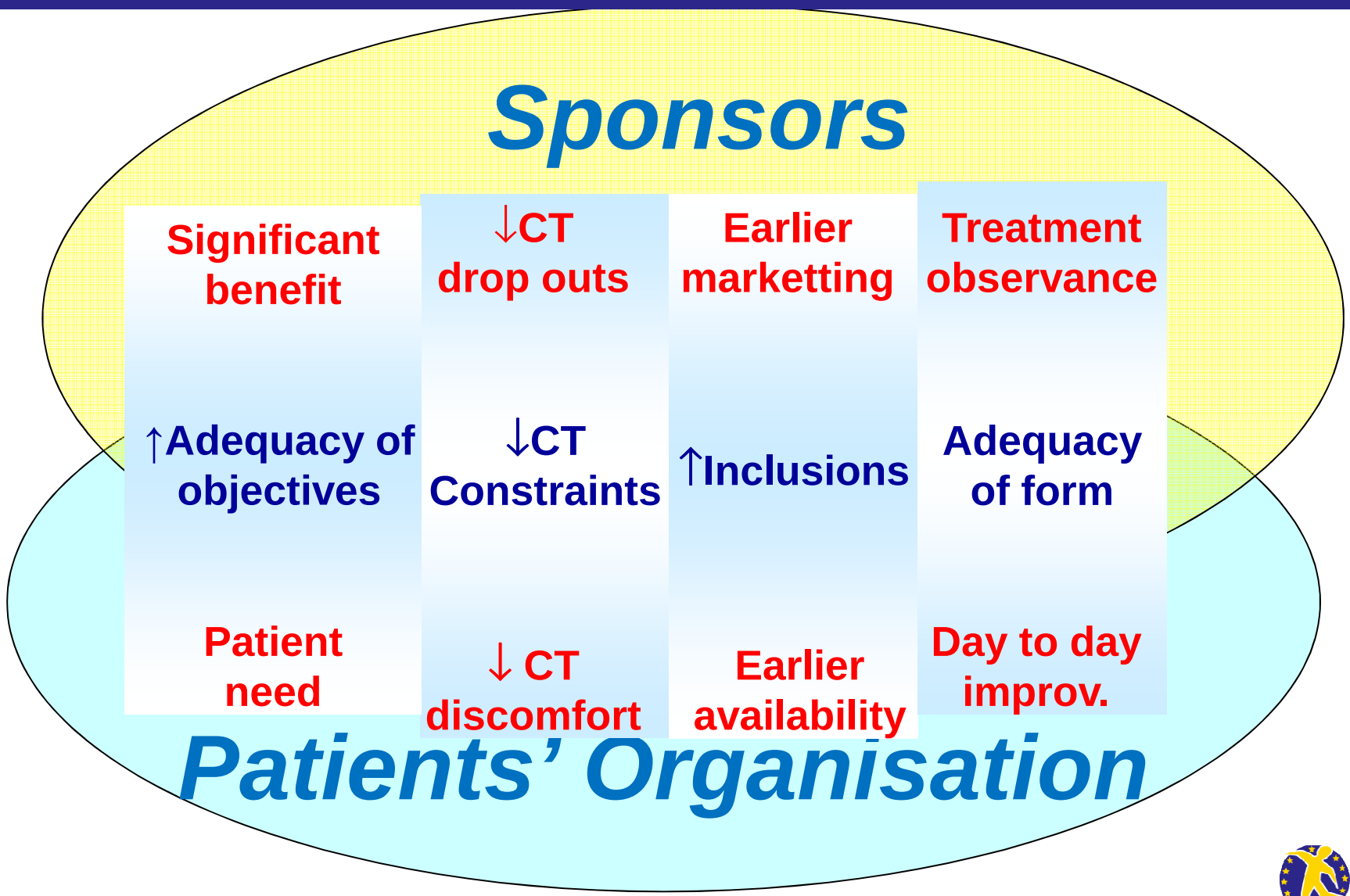
Criticism

«It would be interesting»

Censure

«Yes/No»

The sunny side of collaboration



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The dark side of collaboration

Confidentiality & Technical nature

Objectives | **Endpoints & Constraints** | **Criteria of eligibility**

Sponsors

↑**Inclusions**

Patients' Organisation

Patients ?

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Confidentiality vs Autonomy

Participation of patients, involvement of Patients' Organisations, are based on the trust in the sponsor and the investigator.

No room for hidden topics.

Documents dedicated to patients, aimed to obtain an informed consent

Comprehensive information → **Content of the information brochure**

Access to the whole protocol

Understandable information → **POs reviewing of the Form**

Autonomy

Technical nature vs POs legitimacy

Endpoints and Constraints

Which, how many exams, tests, appointments

Are they acceptable ?

Obtain evidence-based conclusions

Avoid excessive harm

Non Maleficence

Prevent

Missing data

Drop-outs from the study

?

Criteria of eligibility

Which patients will participate to the study

Are they representative of the patients population ?

Compassionate Use access ?

Conclude

Represent the whole population

Distributive Justice

Prevent

Unconclusive studies

Neglected patients

Charter : Objectives

In-depth collaboration : shared, reciprocal benefits (a larger sunny side)

Transparent collaboration , i.e. avoiding:

" Don't worry the trial has been developed with your PO"

Definition of the scope of the collaboration, available for all stakeholders, first for the possible participants

Clearly distinguish the respective roles and responsibilities of the sponsor and the PO.

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Charter : Two Parts

General principles

The PO accesses all the content of the protocol

Contribution to the document aimed at patients

Transparency:

Area of collaboration : AoU

Financial relationships

Availability of the results

Ad hoc document: AoU

(Agreement of Understanding)

What is included in or excluded from the collaboration

Respective commitments

Possible confidentiality agreements

Agreement of Understanding : nature

Agreement of Understanding between [PO] patients' organisation and [Sponsor] sponsor[a], regarding the collaboration for

"Title of the study".

Introduction[b]

To refine objectives, improve the quality of results and comfort of participants, as well as to accelerate the clinical research process, Sponsor [Sp] and [PO] have decided to engage in transparent collaboration for *"Title of the study".* In accordance with the "*Eurordis Charter for Collaboration between Sponsors and Patient Organisations for Clinical Trials in Rare Diseases"*, the scope and conditions of this collaboration are described in this Agreement of Understanding (AoU).

This AoU is a non-confidential and non-legally binding document, aimed to guarantee transparency in the collaboration between [Sp] and [PO]. It is available from both the sponsor and the PO, including on their websites and on the EURORDIS website.

The AoU has to be attached to any documents mentioning this collaboration (fund-raising, submission to ethics committee, information leaflet for participants,...).

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Agreement of Understanding : what is included in / excluded from the collaboration

A/ Initiators of the research project[b]

• This project [Pj] was submitted by the Sponsor [Sp] to the Patients' Organisation [PO]

or

• [Pj] was suggested by [PO] to [Sp]

or

• [Pj] results from collaboration between [PO] and [Sp]

B/ Protocol design

Discussion between [PO] and [Sp] covers[b]

-The title of the study, the study design, including the type of possible control, the objectives, endpoints and constraints for participants, the number of planned participants and feasibility, the inclusion/exclusion criteria, the evaluation criteria.

Discussion between [PO] and [Sp] does not cover[b]

-The title of the study, the study design, including the type of possible control, the objectives, endpoints and constraints for participants, the number of planned participants and feasibility, the inclusion/exclusion criteria, the evaluation criteria.

or

The protocol design is excluded from the collaboration

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Agreement of Understanding :
what is included in / excluded from the collaboration

C/ Implementation of the research study

- The collaboration between [PO] and [Sp] covers[b]

The study announcement, writing patient information documents, writing the Informed Consent form, the choice of trial sites, the setting up of a Data Monitoring Committee, including (or not) a [PO] representative[d].

-The collaboration between [PO] and [Sp] does not cover[b]

The study announcement, writing of patient information documents, writing the Informed Consent form, the choice of trial sites, the setting up of a Data Monitoring Committee.

or

The implementation of the research study is excluded from the collaboration

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Agreement of Understanding :
what is included in/excluded from the collaboration

E/ Analysis and Dissemination of results

- The collaboration between [PO] and [Sp] covers[b]

The analysis of results, the evaluation of possible benefits, including those based on secondary endpoints and Quality of Life criteria, writing scientific papers, dissemination of results to the patient community, dissemination of results to the general public, the date(s) of dissemination of results to the different target audiences.

-The collaboration between [PO] and [Sp] does not cover[b]

The analysis of results, the evaluation of possible benefits, including those based on secondary endpoints and Quality of Life criteria, writing scientific papers, dissemination of results to the patient community, dissemination of results to the general public, the date(s) of dissemination of results to the different target audiences.

or

The analysis and the dissemination of results are excluded from the collaboration

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