Clinical Trials Charter

Hiccups to think about

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Charter focus

- Ensuring that the scientific priorities reflect the pressing needs of people living with XYZ
- Protecting the interests of research volunteers
- Representing the interests of all communities impacted by XYZ
- Advocating for as broad inclusion as appropriate into all clinical trials
- Seeking innovative solutions to facilitate inclusion of traditionally under-represented populations within studies
- Making the process of designing and conducting studies more transparent to help preempt fears of collusion

Eurordis Charter in Practice

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 will make public the list of patient organisations and sponsors having signed the Charter.*
- *This collaboration between the Sponsor and the Patient Organisation, acknowledged by the "Agreement of Understanding", will be made public to all stakeholders and included on the Eurordis website.*

Eurordis Charter in Practice

Eurordis - facilitating the application of the Charter

- *Eurordis will help the sponsor identify European POs interested in collaborating with them.*
- *Eurordis can 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 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 websites).*
- *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.*

First Agreement

- Patients need to be Federated
  - Otherwise, who signs the Agreement?
- Patients need to be involved from the beginning
- Patient education on drugs and trials
- Patient leaflet; drug leaflet; recruitment / retention

- AoU – new sites; “overselling” the product; pt info; DSMB; eligibility (inclusion/exclusion criteria)
- Analysis & dissemination
- Cross-disease patients meeting

First Agreement

- Pharma: legal, legal, legal
- CRO
- Protocol amendments
- Involving patients before the final protocol is signed
- Pharma education on non-medical aspects of trial
- Caregivers as trial “participants”

- EAP
- Future meetings to help form Federation
- Patient travel from faraway
- Medication post-trial