

# Clinical Trials Charter

Hiccups to think about  
Rob Camp

# 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.*
- *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

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?
- 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