Patients' Perspective on Clinical evidence for High-Risk Medical Devices

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Early Clinical Investigations of new high-risk medical devices – a review of European experience

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"A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE"

EPF European Patients Forum

Initial considerations

- Innovation can transform lives of patients with serious lifelong conditions
  - Innovation that matters for patients → definition of unmet medical need, quality of life, etc.
  - Not only new/innovative devices but better devices → understand how the product will benefit patients

- An effective legal/regulatory framework for clinical investigations is important to ensure that
  - The rights, safety, dignity and well-being of subjects are protected and prevail
  - New (high-risk) devices are properly tested before they are authorised for marketing and use…
  - ... while avoiding unnecessary burdens to support timely patients' access to safe and effective innovations

- Patients provide the information and ultimately manage the personal risks attached to participation in trials
  - Patients' perspective and assessment of the benefit/risk are based on lived experience and can be different from other stakeholders'

Key aspects from a patient perspective

- Meaningful Informed Consent

  Understanding of benefit-risks

- Easy access to high quality information regarding the trial and the results

  Transparency

- Meaningful involvement across all aspects of clinical investigations

  Engagement and empowerment

Meaningful Informed Consent

- EPF sees informed consent as a process, a “decision aid”, that should enable a patient to make a meaningful decision about whether or not to participate in a given study
- Today, varying quality – consent often seen as legal “tick-box” protecting researchers, not patients
- Access to quality information = linked to willingness to participate in trials

→ Documents and processes for informed consent should be co-designed with patients to ensure that informed consent is meaningful

"I'm here about the details."

High quality information

- All patients and trial subjects should have access to the same quality of information provided about CIs, regardless of where they live

- Several dimensions of information for patients:
  - What CIs are ongoing and how to enroll
  - What the CI is about
  - Results or outcomes of the trial in which the patient participated in a timely manner
    - Availability and user-friendliness of the electronic interface
  - Post-trial follow-up, CoIs, etc.

The importance of patients' involvement

…from designing research priorities to trial design and review of proposals, trial implementation and publication

- Patients' experiences and insight help understand the benefits most important to them and what risks they may or may not be willing to tolerate
- Patient involvement supports meaningful innovation
  - Enhances legitimacy, transparency and accountability
  - Leads to better, more relevant results
  - Challenges researchers' assumptions
- Need for a strong signal and guidance from regulators… and training
  - E.g. FDA guidance on Patient Engagement in the Design and Conduct of Medical Device Clinical Studies

This is true across the product's lifecycle!

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