Patients Involvement in Clinical Studies

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Clinical Studies from Patient Perspective

• Individual patient is **not aware** about EU health policy, nor EC initiatives: (1) Patient-Partner; (2) Value+; (3) Predict; (4) Respect
• Websites of clinical trials are **not patient - friendly**
• Enrolment procedures are **complex** and often not explained
• Proposal for revised CT directive **lacks vision** and does not assess needs of patient as a priority
• Dr. Richard Pazdur, director of the cancer drug office at the Food and Drug Administration, said in a recent interview that the new wave of drugs in development — especially for intractable cancers like melanoma — might require individual evaluation.

• “This is an unprecedented situation that will, hopefully, be increasingly common, and it may require a regulatory flexibility and an open public discussion,” he said.
Convict on a death row is waiting to hear a death warrant.

The court has ruled that a death by lethal injection, shooting or hanging is far too mild for the crimes committed and therefore condemns you to apply for clinical trials in European Union.
Types of Patient Involvement

- Research subject
- Driving Force
- Information provider
- Advisor
- Reviewer
- Co-researcher

Source: Patient-Partner FP7 Project (2010)
Involving Patients in Decision Making

Contributes to:

- Managing stakeholder **expectations**
  → hope vs hype
- Enhanced **accuracy** of measuring outcomes that will be used for economic evaluation
  → quality of life
  → return to normal life
  → impact on carers
  → well-being rather than health
- Increased accuracy of economic modelling done by industry
  → assuring that direct and **indirect costs** are included
  → involving patients at the stage the issue is converted into economic model
- Enhanced quality of patient involvement during EMA / HTA review
  → **patient reported outcomes**
  → additional value for patients
  → revealing additional evidence
Patients Vision for Revised CT Directive

• Randomized trials to be accessible to all patients concerned, without introducing multi-layer limitations
• Temporary registration to become available in late stage clinical trials for rare cancer treatments
• Complementary or alternative methods to be monitored besides the existing clinical trials
• Registries to be linked with tissue banks
• Facilitated access to off-label and early use of drugs
On the Bright Side

- Rituximab trial for Chronic Fatigue Syndrome succeeded with **3 patients** in a study
- **patientslikeme**™ will be adopted for Europe
- Patients number in Ethical Review Committees is **doubling** on a yearly basis

Help us
to
Help you
to
Help ourselves
Thank You

Nothing about us – without us!

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