An effective legal framework for clinical trials is important to ensure that new therapies are properly tested before they are authorised for marketing and use. As a point of principle, all patients should have easy access to the same high quality of information about clinical trials, regardless of where in the EU they happen to live. However, this is not yet the case.

**WHAT IS A CLINICAL TRIAL?**

A clinical trial is a biomedical research study in which participants are assigned according to a pre-defined plan (protocol) to receive a health-related intervention, such as a medicine or procedure, in order to evaluate its effects on health outcomes, usually compared to another (or sometimes no) treatment*. Clinical trials are used to generate data on the safety and efficacy of the intervention.

**WHY DOES IT MATTER FOR PATIENTS?**

1. An effective legal framework for clinical trials is important to ensure that new therapies are properly tested before they are authorised for marketing and use.

2. Patients have an obvious and central role in clinical trials: they provide the information and ultimately manage the personal risks attached to participation in trials. Patients therefore have a moral right to be involved in the way clinical trials are developed, managed and evaluated.

3. As a point of principle, all patients should have easy access to the same high quality of information about clinical trials, regardless of where in the EU they happen to live. However, this is not yet the case.

**WHAT ROLE DOES THE EU PLAY?**

EU rules specify the requirements for the conduct of clinical trials in the EU. These are laid out in the Clinical Trials Regulation. The Regulation was adopted in 2014 but is still in a transition phase and will be applied from 2019. The rules for conducting clinical trials also include various guidelines adopted by the European Commission and international bodies, such as guidelines on Good Clinical Practice, and international conventions in the area of ethics and biomedicine.

* For more information about clinical trials and different types of trials, see the EUPATI Toolbox: https://www.eupati.eu
WHERE CAN I FIND MORE INFORMATION?

EPF has recently published position statements on informed consent (2016) and the communication of lay summaries of clinical trial results (2015). For more information on EPF’s other work on clinical trials, please visit our website: