Research and clinical trials, what are the rights of patients?

Pilar Nicolás, PhD
Interuniversity Chair in Law and the Human Genome, University of Deusto, University of the Basque Country

The recognition of the patients' rights is developed in a clinical context. That is, in the context of protecting the health of a person. Patients have the right to be diagnosed and treated to prevent, cure or alleviate a disease. In this context it is very important for rare disease patients the implications of the transposition of the Directive on cross-border healthcare into the internal legal systems of EU Member States.

By contrast, when patients participate in research, the context varies, because the objective of the procedures is to promote the development of science. The procedures they undergo do not seek direct benefit but a collective benefit. This difference in the perspective is very important. First, while there is a right to health protection, there is no right to participate in research. The incorporation of people in a research or in a clinical trial depends on the investigator's decision according to the design of the protocol. The use drugs under experimentation or the use of drugs for not authorized applications is decided case by case and requires individualized authorizations.

The protection of the rights of the individual who participates in an research has been a concern worldwide. Consensus has been reached, especially from the second half of the twentieth century. The perspective adopted is aimed at ensuring liberty, physical integrity and privacy. It should be remembered that a new EU Regulation on clinical trials on medicinal products for human use, which applies directly in all Member States has been published in 2014. These rights are recognized and developed in this Regulation. Beside, all research must be evaluated from the ethical and legal perspective and the participation of patients in this evaluation should be promoted. Moreover, it has been recognized the interest of the subjects in the knowledge of the results of the research in which they have participated, as a kind of compensation for their selfless contribution.

Moving to other framework, it should be underlined the public health strategy, coordinated at the European level that has been designed in the field of rare diseases. Patient organizations should play a major role participating in these strategies. Different objectives are promoted, as the recognition and visibility of rare diseases; the creation of European Reference Networks to promote research; the rare diseases registries; and the use the ICT to putting patients in Contact with other patients, to sharing databases Between research groups, or patients willing to Registering to Participate in clinical research.