



## **European Commission Proposal for a Regulation on Clinical Trials – 2012/0192**

### **Position of the European Heart Network**

*December 2012*

#### **About the European Heart Network and cardiovascular diseases**

The European Heart Network (EHN) is a Brussels-based alliance of heart foundations and likeminded non-governmental organisations throughout Europe with members in 26 countries. The EHN plays a leading role in the prevention and reduction of cardiovascular diseases, in particular heart disease and stroke, through advocacy, networking, education and patient support, so that they are no longer a major cause of premature death and disability throughout Europe.

#### **Proposal for a Regulation on Clinical Trials**

EHN welcomes the European Commission's proposal for a Regulation on Clinical Trials. The proposal largely addresses the weaknesses of the current Clinical Trials Directive whilst maintaining high standards of quality and safety for medicinal products and protecting the safety and rights of the patients.

Cardiovascular diseases represent the major cause of mortality in Europe<sup>1</sup> and millions of people live with these diseases. The results of large randomised clinical trials have allowed the introduction of medicinal products that help prevent and control cardiovascular diseases leading to a significant increase in survival rates, reduction of disability for patients suffering from cardiovascular diseases and improvement of quality of life.

Innovation in and facilitation of clinical research is in the interest both of patients and society. Getting the regulation right is, therefore, of the utmost importance.

#### **Alleviating administrative burden**

##### *Single Submission Process*

The option for sponsors to send the application dossier to the Member State concerned via a single submission process administered by the European Commission, as laid down by Article 5 of the draft Regulation, represents an important step in overcoming the duplication of effort, administrative burden, time delays and costs often associated with the current process. This will speed up the application procedure and eventually be of benefit to the patients, as the medicines will arrive sooner on the market.

Therefore, EHN welcomes the proposal by the Commission to establish an EU portal for the submission of clinical trials applications.

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Nichols M, Townsend N, Luengo-Fernandez R, Leal J, Scarborough P, Rayner M (2012). European Cardiovascular Disease Statistics 2012. European Heart Network, Brussels, European Society of Cardiology, Sophia Antipolis.

### *Risk-based approach*

The provisions included in Article 2.3 on low-intervention clinical trials are an important step to adopting a risk-based approach in clinical trials legislation. EHN supports this new provision as it adequately corresponds to the different levels of risk to subjects' safety.

### **Participation of Patients and Patients' Organisations**

The participation of patients in the different phases of a clinical trial (from design to post-marketing surveillance) is important as it enables the development of more efficient trials that address issues expressed by those living with the condition. Patients' involvement will ensure better outcomes and improve processes, e.g. help recruit and retain patients.

Consequently, EHN supports the mechanism provided by Article 9 of the draft Regulation to involve patients in the panel involved in the assessment of the clinical trial.

### **Informed consent and protection of the vulnerable patient**

Chapter V of the proposal addresses the protection of patients and informed consent, including consent by incapacitated patients and in emergency situations.

EHN approves the procedure proposed by Article 30 of the draft Regulation for the informed consent of incapacitated subjects, following very strict conditions, amongst which the obtainment of informed consent of a legal representative. This provision is particularly important as after an acute cardiovascular event, a patient might not be in full capacity to give his/her consent.

EHN also welcomes the provisions proposed by Article 32 regarding the very specific case of emergency trials. As underlined by Recital 23, for the cases of emergency situations where a patient has suffered a sudden life-threatening medical condition due to multiple traumas, strokes or heart attacks necessitating immediate medical intervention, the intervention within an already approved clinical trial may be pertinent.

Finally, EHN supports the provisions stated by Article 28 on the possibility for a subject to withdraw from the clinical trial at any time by revoking his/her informed consent.

### **Gender Equity and Diversity of EU Population**

Though Recital 4 of the draft Regulation makes reference to specific patient populations, EHN wonders that no specific article in the draft Regulation, for example in the general provisions and principles (Chapter I), refers to the need for clinical trials to respond to patient populations' specificities. EHN believes that clinical trials should reflect the diversity of the population and, report on differences in efficacy and/or safety for specific patient populations.

According to research<sup>2</sup> published by the EHN, gender differences in the clinical presentation of cardiovascular diseases have been demonstrated. The research shows that women have largely been under-represented in cardiovascular research resulting in safety and efficacy of several drugs being evaluated predominantly in male populations. Furthermore, it has been demonstrated that some therapeutic options are not equally effective and safe in men and women.

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<sup>2</sup> Red Alert for Women's Hearts Women and Cardiovascular Research in Europe, European Heart Health Strategy, EuroHeart Project, Marco Stramba-Badiale, <http://ehnheart.org/projects/euroheart/publications-wp-5-wp-6/publication/117.html>; Women and research on cardiovascular diseases in Europe: a report from the European Heart Health Strategy (EuroHeart) project, Marco Stramba-Badiale, European Heart Journal (2010) 31, 1677–1685, doi:10.1093/eurheartj/ehq094; Red alert for women's heart: the urgent need for more research and knowledge on cardiovascular disease in women, Maas et al, European Heart Journal (2011) 32, 1362–1368, doi:10.1093/eurheartj/ehr048.

EHN recommends including in Chapter I of the proposal an article setting out the principle of population diversity, including notably gender balance.

### **Final remarks**

EHN broadly supports the proposal for a Regulation on Clinical Trials. We acknowledge the efforts of the European Commission to provide a better-functioning framework for developing and testing treatments, for the benefit of patients across Europe, while maintaining the high standards of patient safety and well-being. However, we regret the lack of legal provisions on the importance of gender balance in clinical research and recommend that the legal text includes a principle on representativeness of patient populations.