

WRITTEN RESPONSE TO THE CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION

REVISION OF THE 'CLINICAL TRIALS DIRECTIVE' 2001/20/EC

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Introduction

The European Society of Cardiology (ESC)* welcomes the opportunity to provide comments on the European Commission (EC) concept paper on the revision of the 'Clinical Trials Directive' 2001/20/EC.

The ESC supports the EC initiative to build on the results of the 2009/10 public consultation to prepare the revision of the Clinical Trials Directive.

The ESC stresses that the development of pharmaceutical products and the improvement of medical treatment strongly rely on innovative clinical research - of which clinical trials are an essential component - in order to tackle effectively societal challenges in health. This is notably the case for cardiovascular diseases (CVD), the N°1 killer in Europe. Each year, CVD is responsible for the death of more than 2 million EU citizens in the 27 member states, killing more people than all cancers combined. CVD is estimated to cost the EU economy €192 billion a year.¹

The ESC acknowledges that, through the innovative nature of medicinal products and medical treatment, clinical research and clinical trials are key to strengthening knowledge and innovation as drivers of future growth, as highlighted in the 'Europe 2020 strategy for smart, sustainable and inclusive growth'².

The ESC hopes that its views and recommendations will prove of value for the definition of future clinical trials regulation in the EU and wishes to express its eagerness in taking part in the EC reflections.

* The European Society of Cardiology (ESC) represents over 62,000 cardiology professionals across Europe and the Mediterranean. Its mission is "to reduce the burden of cardiovascular disease in Europe". The ESC provides an array of scientific and educational activities, such as the production and continuous updating of Clinical Practice Guidelines, the organisation of educational courses and initiatives, pan-European surveys on specific disease areas. It also organises the ESC Congress, the largest medical meeting in Europe, as well as subspecialty congresses, in conjunction with its constituent bodies. The ESC edits and publishes 7 of the world's leading journals on cardiology.

¹ European Cardiovascular Disease Statistics 2008

² COM(2010) 2020, 3.3.2010

Public Consultation

1. COOPERATION IN ASSESSING AND FOLLOWING UP APPLICATIONS FOR CLINICAL TRIALS

1.1 Single submission with separate assessment

Item no.1

A single submission through an 'EU portal' administered by the European Medicines Agency is highly advisable. Such solution would simplify the administrative work notably for large-scale multi-national trials. However, the European Commission should note that most clinical trials are conducted on a small scale and local market. For these smaller studies assessment agencies within each of the member states seem to be appropriate.

Item no. 2

The ESC agrees that independent assessments by member states after submission would significantly reduce the advantages of an EU portal. It would thus be more appropriate to ensure a proper coordination at EU level of existing national Ethics Committees networks.

1.2 Single submission with subsequent central assessment

Item no. 3

The ESC agrees that a central assessment would be ineffective for the approval of many (small) clinical trials.

1.3 Single submission with a subsequent 'coordinated assessment procedure'

Item no. 4

At this stage, the ESC believes that point a) of the catalogue should include "the adequateness of the proposed sample size". It also believes that the catalogue should remain open for further development over time.

Item no. 5

Yes, only aspects under a) should be included in the scope of CAP. Items under sections b) and c) should remain within the ambit of Ethics Committees at national level. This is because the acceptability of the clinical trial in view of anticipated benefits compared to risks and inconveniences for trial subjects falls within the responsibilities of Ethics Committees. The same goes for the assessment of the intervention as compared to normal clinical practice that may differ substantially between countries.

Item no. 6

The ESC agrees that, in case of disagreements about the assessment done under the CAP, individual Member States should be allowed an 'opt out', when justified on the basis of a 'serious risk to public health or safety of the participant'. Indeed, such risks represent a local national issue and are therefore the responsibility of Ethic Committees.

Item no. 7

CAP should be optional. This will allow sponsors to seek for local appraisal notably in small scale studies which involve only one (or a few) member states.

Item no. 8

The ESC agrees that a pre-assessment leading to a classification of trials according to risk with consequent differences on the authorization procedures would be workable in practice.

2. BETTER ADAPTATION TO PRACTICAL REQUIREMENTS AND A MORE HARMONISED, RISK-ADAPTED APPROACH TO THE PROCEDURAL ASPECTS OF CLINICAL TRIALS

2.1 Limiting the scope of the Clinical Trials Directive

Item no. 9

The clinical trials directive currently is much too burdensome for non-interventional clinical trials and impairs the development of clinical treatment research. Thus, if non-interventional trials are included, the definition needs to be broadened and separate requirements for these types of trials needs to be part of the directive.

Item no. 10

The ESC agrees that harmonized and proportionate requirements for clinical trials should apply independently of the nature of the sponsor. The ESC takes the occasion to point out that the problem of performing non-interventional academic trials needs to be resolved either within or outside the directive.

2.2 More precise and risk-adapted rules for the content of the application dossier and for safety reporting

Item no. 11

The ESC agrees that this approach would help to simplify, clarify and streamline the rules for conducting clinical trials by providing a unique set of rules. However, it points out that these rules and regulations need to be adapted to different types of trials, such as non-interventional/interventional, etc.

Item no. 12

A minimal set of rules should be developed for all trials. More extensive rules and regulations should be available for interventional trials of new pharmacological or device interventions.

2.3 Clarifying the definition of 'investigational medicinal product' and establishing rules for 'auxiliary medicinal products'

Item no. 13

The ESC agrees with this appraisal. It wishes to point out that background therapy should be properly recorded and should not be considered an investigational product.

2.4 Insurance/indemnisation

Item no. 14

Optional indemnisation by member states seems to be the most attractive and feasible solution.

2.5 Single sponsor

Item no. 15

Single sponsorship seems preferable in principle. However, the cost and complexity of clinical trials is increasing as well as the number of patients required. If there are multiple sponsors it is up to these sponsors to agree who is the main sponsor (who then would become the "single sponsor").

2.6 Emergency Clinical Trials

Item no. 16

The ESC agrees that this approach would facilitate trials on emergency situations and where informed consent is not feasible. It points out that statements on clinical trials in children need to be specifically addressed in this context.

3. ENSURING COMPLIANCE WITH GOOD CLINICAL PRACTICES IN CLINICAL TRIALS PERFORMED IN THIRD COUNTRIES

Item no. 17

The ESC agrees with the need to increase transparency and safeguard the standards and ethical performance of clinical trials in low income countries. These issues probably should be further developed to guarantee the representativity of clinical trial populations both for low, middle and high income countries in order to be globally accepted.

4. FIGURES AND DATA

Item no. 18

The ESC has no additional comments.