Multidisciplinary Workshop

Research Ethics Committees and Ethical Review in Europe

19th January 2010
Barcelona, Spain

Organised by ECRIN

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK

on behalf of the "Road Map Initiative for Clinical Research in Europe"

Excellence in science
EBMT
European Group for Blood and Marrow Transplantation

EF GCP

EORTC
European Organisation for Research and Treatment of Cancer
AISBL International Non-Profit Association under Belgian law IVZW

CLINT: facilitating international prospective clinical trials in stem cell transplantation

ICREL

ELN European LeukemiaNet

Workshop Rationale

Research ethics committees (REC) play a central role in the legislation on clinical research. Although the Directive 2001/20/EC gave provisions for a better harmonisation of their practice between member states, including the single opinion per member state, inconsistent provisions and divergent implementation in the member states resulted in a suboptimal situation, especially for investigators and sponsors in multinational studies, and under some circumstances in unnecessary burden for research ethics committees.

In the perspective of proposed changes to the EU legislation on clinical research, there will be a need for in-depth discussion on how best to adapt the roles, responsibilities and missions of the ethics committees as well as an optimised ethical review process, especially in multi-national trials. The concept of a one-stop-shop application to competent authorities for clinical trials authorisation raises a major question: what are the respective roles of the competent authorities and the ethics committees in the various aspects of clinical trial supervision (assessment of the product, of the risk/benefit ratio, of the protocol's science and methodology aspects, and of the informed consent process). This also requires a common definition for the mission of RECs in all countries. Such harmonisation in the role and mission of ethics committees would probably require the development of training for EC members, of a quality assurance system, and raises the question of the need for an accreditation process. Harmonisation would be facilitated by an efficient networking of ethics committees. What could be the role of existing pan-European networks, or of DG SANCO in this process?
Would it be possible to submit a common electronic submission dossier for all the RECs across the member states (and as far as possible the same for RECs and competent authorities)? And would it be possible to coordinate the assessment of a given multi-national protocol by multiple ethics committees across the borders, as the CTFG proposes in the Voluntary Harmonisation Process for the assessment by competent authorities or by a qualified (accredited?) single ethics committee in collaboration with national RECs?

On the other hand the risk-based approach to clinical trial regulation raises specific questions to RECs: should the RECs adopt risk-based procedures, with an expedited review for low-risk studies? Would it be the role of the RECs to validate the risk level for a given protocol, therefore defining the regulatory context for this study, including the need for insurance, safety reporting, submission to competent authority, level of monitoring, etc? And should the ethics committee be insured for possible misevaluation of the risk level?

The current legislation also raises specific questions regarding the responsibilities of research ethics committees, including involvement in safety reporting (replacing SUSAR reporting by an access to EudraVigilance data?), the waiver of consent in incapacitated patients and its possible withdrawal, or the issue of ethical supervision of clinical trails with investigation centres in third countries. Another issue – if we consider the possibility for an extension of the EU legislation to all categories of clinical research - is the role of ethics committees in clinical studies other than clinical trials on medicinal products.

This workshop will give the opportunity to discuss these questions. A roundtable discussion will allow all the relevant stakeholders to discuss the acceptability and the feasibility of the solutions proposed.

The ultimate goal is to produce ground for recommendations, acceptable for all stakeholders, which will be discussed and released during the final Stakeholder Conference in Brussels on 17th March 2010. These recommendations will be submitted to the European Commission for initiation of the necessary legal steps to create a more efficient legislative framework for clinical research in the European Union, preserving participants' protection and data quality but improving the scientific competitiveness of Europe in clinical research and fostering its attractiveness for clinical trials.

Programme Committee

Xavier Carné, Hospital Clinic I Provincial Barcelona, ECRIN, Spain
Jacques Demotes, INSERM, ECRIN, France
Christiane Druml, Ethics Committee Medical University of Vienna
Ingrid Klingmann, EFGCP, Pharmaplex, Belgium
Christine Kubiak, INSERM, ECRIN, France
Nuria Sanz, Hospital Clinic I Provincial Barcelona, ECRIN , Spain
Lea Stankovski, INSERM, ECRIN, France

Workshop Language

The language of the Workshop will be English. No translation will be provided.

Venue

Room "Farreras Valentí"
Hospital Clinic Barcelona
C/Villarroel nº 170.
08036 Barcelona, Spain

Programme

9h00	**Welcome and Introduction** *Xavier Carné, Hospital Clinic I Provincial Barcelona, Spain*
9h10	**Ethics Committees interdependencies – Is there a need for centralised review at EU-level for multinational clinical trials?** *Christiane Druml, Ethics Committee Medical University of Vienna, Austria* *Rokus De Zeeuw, BEBO, Assen, The Netherlands*
9h35	**Ethics Committees and Competent Authorities: Avoiding duplication of evaluation. Is a single submission dossier feasible for multicentre trials?** *Chantal Bélorgey, AFSSAPS, France* *Xavier Carné, Hospital Clinic I Provincial Barcelona, Spain*
10h00	**Improving Ethics Committees practice: Need for transparency, coordination, harmonisation, training, quality assurance and accreditation of Ethics Committees** *Janet Wisely, NRES, UK*
10h15	**Impact of risk-based regulation on Ethics Committees and who should assess the risk of IMP- and non-IMP- trials?** *Xavier Carné, Hospital Clinic I Provincial Barcelona, Spain*
10h30	**Adverse events reporting: What should be notified to Ethics Committees?** *Petra Knupfer, Ethics Committee of Ärztekammer Baden-Württemberg, Germany*
10h45	**Coffee break**
11h15	**Panel Discussion: How could a future system for European ethical review look like?** *Chairpersons: Christiane Druml, Ethics Committee Medical University of Vienna, Austria* *Xavier Carné, Hospital Clinic I Provincial Barcelona, Spain* *Previous Speakers* *Pascal Gil, EORTC* *Barry Arnold, AstraZeneca* *Jan Geissler, ECPC, Germany*
13h00	**Lunch**
14h00	**Clinical trials and temporarily incapacitated patients** *François Lemaire, Hôpital Henri-Mondor, Créteil, France* *Elmar Doppelfeld, Permanent Working Party of German Research Ethics Committees, Germany*
14h45	**ECs and clinical trials performed in developing countries** *Clara Menendez, CRESIB, Spain*
15h30	**Coffee break**
15h50	**Open Forum Discussion: Which changes to the European ethics review system should be proposed to the European Commission?** *Chairpersons: Jane Apperley, Imperial College London, EBMT, UK* *Ingrid Klingmann, EFGCP, Belgium*
17h30	**End of Workshop**