Conference on the Impact on Clinical Research of European Legislation – ICREL: Results & Discussion

2 December 2008
Diamant Centre, Brussels, Belgium
### Programme Committee

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Conference Rationale

The European Union Clinical Trials Directive 2001/20/EC (EU CTD) was released with the objective of harmonising the regulatory systems, of improving the protection of study participants, of optimising the use of safety information, of ensuring the quality of studies and the credibility of data. As a consequence, the Directive 2001/20/EC was adopted on April 4th, 2001 and to be implemented by all Member States on May 1, 2004 (in fact, transposition into national legislation entered into force between 2004 and 2006 in the various EU member states). Rather surprisingly, and due to the role assigned to the European Union (facilitating circulation of products and services, whereas health and ethics remain areas of national policy), this Directive was prepared by DG Enterprise and Industry, and its scope is restricted to clinical trials on medicinal products, an area of major challenge for the industry. This new EU legislation increased the responsibility of clinical trial sponsors and decreased that of the investigators; it led to shared responsibilities between ethics committees and competent authorities, and improved the patients' protection. A single sponsor in the EU, covered by liability insurance for study-related harm to study participants, has now to submit a clinical trial authorisation application to the national competent authority, and in parallel a request for a single favourable opinion to Ethics Committee(s). With the EU CTD, an EMEA-located database for study identification (EudraCT) was implemented and a section for clinical trials added to the EudraVigilance database.

Through harmonisation of the regulatory framework of clinical research, the EU CTD was expected to foster multinational collaboration, to make European clinical science more competitive and the European Union more attractive for industry-sponsored clinical trials. However, many stakeholders now have the feeling that, due to application of the same rules to all types of drug trials and divergent transposition of the Directive’s principles into pre-existing national legislations, the Directive partly missed its facilitation and harmonisation targets. In addition, the Directive is considered to impose unnecessary administrative burden and costs which is especially problematic for investigator-initiated clinical research. Therefore industry and academic stakeholders frequently claim (not exactly for the same reasons) for changes in the EU regulatory framework for clinical research.

The European Commission (DG Enterprise and Industry) and the European Medicines Agency organised a conference in October 2007 to discuss the possible changes to be brought to the Directive. Simultaneously, the DG Research funded, through the health priority of the FP7 cooperation programme, the ICREL (Impact on Clinical Research of European Legislation) project to provide metrics and thus objective arguments for the need to adapt the current legislation with the objective of making clinical research more competitive in the European Union whilst providing fair and equivalent protection to participants in every category of clinical
research. ECRIN, EORTC, the Hospital Clinic I of Barcelona and the Ethics Committee of the Medical University of Vienna are collaborating in this project coordinated by EFGCP (www.efgcp.be/ICREL).

ICREL collects:
- information on positive and negative impact factors on clinical trials with medicinal products and on other types of clinical research
- figures on the impact of the legislation on the clinical research activity of big Pharma Industry -, SME-, academia-sponsored trials
- data on the resource, cost and effectiveness implication of the CTD implementation for all stakeholders
- comparison of the success of national CTD implementation
- consolidated conclusions on the findings amongst the stakeholders

As data from individual countries, based on different methodologies, suggest that the impact of the CTD may vary from one country to another\(^i\), the collection of data throughout the European Union, with the same methodology, will certainly help further describe and interpret this impact.

ICREL's methodology includes the collection, comparison and interpretation of figures from all EU member states on all types of clinical trials on medicinal products sponsored by pharmaceutical companies, biotechnology, SMEs, and academic institutions, on other categories of clinical research, as well as on the impact on ethics committees, competent authorities, clinical research infrastructure, and on the workload, cost and funding of clinical trials. It will compare the situation before (2003) and after (2007) the implementation of Directive 2001/20/EC. Detailed data were obtained through a series of questionnaires (see www.eortc.be/ICREL) targeting the different stakeholders: commercial and non-commercial sponsors, ethics committees and competent authorities.

This work will be presented and discussed during the Conference held in Brussels on December 2\(^{nd}\), 2008. The resulting discussion and interpretation is expected to help improving Europe’s attractiveness and competitiveness for clinical research by delivering the facts for proposing pathways for improvement of the clinical trial environment in the EU, allowing to better balance a high level of patient protection, optimal use of safety information, high quality and credibility of data, with acceptable cost and workload for investigators, sponsors, ethics committees and competent authorities, for both national and multinational studies in the EU.


Agenda

07:15  Registration and Welcome Coffee

08:00  Welcome and Introduction to the Conference

Ingrid Klingmann, EFGCP, ICREL Project Coordinator, Belgium
Jacques Demotes, INSERM / ECRIN, France

Plenary Session 1

Chairpersons: Gonzalo Calvo, Hospital Clinic I Provincial Barcelona, Spain
Stefan Führing, DG Enterprise, European Commission

08:15  The European Landscape for Clinical Trials

Diane van Vyve, EORTC, Belgium

08:30  What is ICREL?

Ingrid Klingmann, EFGCP, ICREL Project Coordinator, Belgium

09:00  Need to change the legislation? Stakeholders’ views

Non-Commercial Sponsors: Françoise Meunier, EORTC, Belgium
Commercial Sponsors: Mats Ericson, EFPIA / Wyeth Research, France
Ethics Committees: Frank Wells, Cambridgeshire 4 Research Ethics Committee / EFGCP, United Kingdom
Competent Authorities: Chantal Bélorgey, AFSSAPS, France
Patients Organisations: Cees Smit, EGAN / VSOP, The Netherlands

10:15  Coffee Break

Plenary Session 2

Chairpersons: Christiane Druml, Ethics Committee of the Medical University of Vienna, Austria
Stefan Führing, DG Enterprise, European Commission

10:45  ICREL Results

Methodology
Bruno Scherrer, Biostatistician Consultant, France

Impact on competent authorities
Gonzalo Calvo, Hospital Clinic I Provincial Barcelona, Spain

Impact on ethics committees
Johannes Pleiner, Ethics Committee of the Medical University of Vienna, Austria

Impact on commercial sponsors
Ingrid Klingmann, EFGCP, ICREL Project Coordinator, Belgium

Impact on non-commercial sponsors
Denis Lacombe, EORTC, Belgium

Comprehensive view of data
Christine Kubiak, INSERM / ECRIN, France
12:00 Lunch

**Break-Out Sessions**

13:00 **Impact on Commercial Sponsors**  
Chair: Willy De Greef, EuropaBio, Belgium  
Rapporteur: Detlef Niese, Novartis, Switzerland

**Impact on Non-Commercial Sponsors and Non-Drug Trials**  
Chair: Liselotte Hoejgaard, ESF, France  
Rapporteur: Jacques Demotes, INSERM / ECRIN, France

**Impact on Competent Authorities**  
Chair: Thomas Sudhop, BfArM, Germany  
Rapporteur: Fergus Sweeney, EMEA

**Impact on Ethics Committees and Patients’ Concerns**  
Chair: Alastair Kent, GIG, United Kingdom  
Rapporteur: Christiane Druml, Ethics Committee of the Medical University of Vienna, Austria

14:00 Coffee Break

**Plenary Session 3**

14:15 Reports from break-out groups & discussion  
Chairpersons: Stefan Führing, DG Enterprise, European Commission  
Jacques Demotes, INSERM / ECRIN, France

Break-out Groups Rapporteurs &  
Ingrid Klingmann, EFGCP, ICREL Project Coordinator, Belgium  
Liselotte Hoejgaard, ESF, France  
Stefan Führing, DG Enterprise, European Commission  
Fergus Sweeney, EMEA  
Alastair Kent, GIG, United Kingdom  
Willy De Greef, EuropaBio, Belgium

15:45 Closing Remarks  
Stefan Führing, DG Enterprise, European Commission  
Ingrid Klingmann, EFGCP, ICREL Project Coordinator, Belgium

16:00 End of the meeting