



Conticanet

***Report on the EORTC-CONTICANET-ICREL-ECRIN Workshop “Biomedical Research in Europe: Which Challenges and Solutions for Academic Sponsors?”
May 21st, 2008, Brussels, Belgium.***

Colette Lukan¹, Diane van Vyve¹, Stephane Lejeune¹, Françoise Meunier¹, Ingrid Klingmann², Jacques Demotes-Mainard³, Peter Hohenberger⁴

¹ The European Organisation for Research and Treatment of Cancer

² European Forum for Good Clinical Practice

³ Institut National de La Santé et de la Recherche Médicale

⁴ University Hospital Mannheim, University of Heidelberg

Current European legislation on biomedical research appears to adversely affect pan-European clinical research activities. The impact of the EU Clinical Trials Directive 2001/20/EC has been widely debated since coming into force in May of 2004. Ongoing translational research activities and the growing use of human biological materials have exposed additional critical legislative gaps at the European level. The Directive aims to protect the rights and well-being of human subjects enrolled in clinical trials, increase European clinical research competitiveness, harmonise regulatory procedures, and ensure Good Clinical Practices by means of a common legal framework. Member States, however, have interpreted, transposed and implemented the Directive in different ways. The core principles of the Directive on subject protection and general procedural rules are identical at the European level but differ in practice, a result of the various transpositions of those principles into national legislation – true harmonisation has yet to be achieved. European researchers must overcome these national discrepancies in order to carry out multi-national clinical trials. This costs time, money and precious resources and has failed to increase trial subject protection and to ensure equal access to innovative research for all European citizens. Both the academic research community and the pharmaceutical industry agree

that amendments to the current legislation or new legislation are urgently required if Europe is to remain competitive and patients are to benefit from the latest cutting-edge medical research.

More than sixty decision-makers including leaders of academic research organisations, top clinical researchers, legal experts and representative from the European Commission, took part in the one day workshop, “*Biomedical Research in Europe: Which Challenges and Solutions for Academic Sponsors*” held at the EORTC Headquarters, in Brussels on May 21, 2008. The EORTC along with three EU-funded consortiums, the Connective Tissue Cancer Network (CONTICANET), the European Clinical Research Infrastructures Network (ECRIN) and the Impact on Clinical Research of European Legislation (ICREL) organised this event with financial support from the European Commission 6th Research Framework Programme CONTICANET project. All four organisations are working towards a common goal – improving current EU legislation for clinical trials.

Academic Research under Threat from the Clinical Trials Directive

A panel of distinguished experts co-chaired the workshop and presented the position of their respective organisations concerning the EU Directive. Professor Françoise Meunier, Director General of the EORTC [\[1\]](#) opened the meeting by highlighting the key challenges faced by pan-European research organisations today in the conduct of academic multi-national clinical trials. She outlined the task for all in attendance; namely, to work in partnership to find concrete solutions to the issues, to develop a new model of funding for academic research and to convince policymakers that European academic clinical research is essential and not simply a luxury. Professor Meunier deeply regretted the absence of representation on behalf of the DG Enterprise, the source of the Directive. Despite a drop in the number of new cancer clinical trials conducted by the EORTC since inception of the Clinical Trials Directive, the associated rising costs and administrative burden, she remains enthusiastic and positive, commenting that, “it’s an exciting

time to be working in the field of oncology with over six hundred pharmaceutical molecules now in development. The EORTC's mission is not only to conduct high-quality translational and clinical cancer research but to conduct clinical trials that best serve the needs of future cancer patients." Oncology clinical studies demand high levels of scientific expertise as well as large patient numbers and therefore need to be pan-European. Harmonisation of the regulations is therefore of primary importance.

Collaboration with industry is essential for granting patient access to new drugs but the independence of researchers must be safeguarded. Professor Meunier called for more structural and long term funding of academic EU clinical researchers as the only means of guaranteeing scientific research independence and keeping crucial expertise in Europe. A new model of clinical trials is needed for the 21st century that involves all stakeholders including patients, academic researchers, industry, funding bodies and policymakers. Professor Meunier closed her presentation by highlighting three concrete proposals to improve the future of European research, (1) PhD programs should be encouraged and supported, (2) healthcare professionals, namely physicians, clinicians, data managers and nurses should be trained in clinical research and (3) regulations should be revised and harmonised.

Professor Peter Hohenberger spoke on behalf of CONTICANET [\[2\]](#). This Network of Excellence launched in 2006 and funded by the 6th Framework Programme of the European Commission, is dedicated to research on the diagnosis and management of connective tissue tumors. It also seeks to promote a better understanding of these rare tumors, and to harmonise and optimise their treatment on a European level. CONTICANET is generating a critical mass of key stakeholders in order to overcome the current difficulties in terms of lack of data, data fragmentation, and mobility of researchers, heterogeneity of methodologies and legislation and is working to harmonise research projects. In its efforts, the Network has identified various barriers

to clinical research resulting from current European legislation. Despite a harmonisation directive on clinical trials, biomedical research on human tissues remains insufficiently regulated. National regulations differ on informed consent for tissue sampling, tissue exchange transfer rights, industry collaboration and financial implications, drug availability, off-label drug usage, reimbursement and non-commercial sponsored studies; as well as the conduct of multi-national clinical trials where the interests of industry are currently favoured over those of patients and researchers. CONTICANET is actively addressing these and other issues in partnership with like-minded research groups by meeting with Health Authorities, detailing specific problems of legislation and ethics faced by European networks of excellence and proposing strategies and an action list to improve harmonisation.

Dr. Ingrid Klingmann presented the ICREL project financed by the European 7th Framework Programme and coordinated by EFGCP in collaboration with ECRIN, EORTC, the Hospital Clinic i Provincial of Barcelona and the Ethics Committee of the Medical University of Vienna. [3] ICREL aims to measure and analyse the direct and indirect impact of the Clinical Trials Directive and related legislations in the EU on all categories of clinical research and the different stakeholders including commercial and non-commercial sponsors, Ethics Committees and Competent Authorities. This work will aid in determining the most relevant pathways for improvement of the Directive. Dr. Klingmann pointed out that the new Directive has increased the complexity and administrative work required to conduct clinical trials, introduced new legal requirements not easy to fulfil in the academic environment, and resulted in higher costs for sponsors to perform and supervise clinical trials. Other stakeholders such as Ethics Committees and Regulatory Authorities have also experienced expensive and burdensome new challenges. Dr. Klingmann believes that, “the objectives of the Directive are sound and justify increased efforts by all stakeholders. However, in its current form, the Directive not only fails to encourage European clinical research but also to better protect study participants.” In response to multiple

complaints, the DG Research awarded the current ICREL one-year project that entails analysing available data and collecting metrics on the impact of the Directive by conducting a pan-European survey of all major stakeholders. ICREL will discuss their fact-based results at a workshop in Brussels on December 2, 2008 and prepare a list of recommendations for changes to the current Clinical Trials Directive for public discussion.

Professor Jacques Demotes-Mainard coordinates the ECRIN projects, funded by the 6th and 7th Frameworks. ECRIN aims to facilitate multi-national European clinical research through the integration of EU research capacity and public funding, the harmonisation of tools, training and practice; by improving quality, credibility and transparency; and the harmonisation of legislative systems. This is achieved by providing support to investigators and sponsors of multi-national trials as well as supporting interaction with Ethics Committees and Competent Authorities. [\[4\]](#) According to Professor Demotes-Mainard, the first challenge to clinical research in Europe is access to patients. The European Union should take advantage of its population size of over 500 million to increase its competitiveness through multi-national trials, especially in rare diseases. The second problem is fragmentation of funding and the need for an integrated approach to clinical research funding. A third issue is the availability of infrastructures. Not all countries have established clinical research and trial centres, disease-oriented networks or national coordination. The first step in the ECRIN process, accomplished between 2004 and 2005, helped identify bottlenecks in multi-national cooperation. Step two (2006-2008) saw trans-national working groups define procedures and guidelines for multi-national studies in the EU. The third step (2008-2011) consists of building a European infrastructure for clinical trials and biotherapy to provide high-quality services in a “one-stop shop” for multi-national clinical research. Improvement in the legislative framework for the conduct of clinical research is required as a critical element and ECRIN is collaborating with others towards revising the EU Clinical Trials Directive.

Dr. Markus Hartmann rounded off the first workshop session presenting the results of his impact analyses of the Directive on academic research. He highlighted the discrepancies and gaps in legislation at the Member State level concerning multi-national multi-modality, surgery and radiotherapy clinical trials—typically the clinical research conducted by non-commercial academic and independent research groups, and where the legal and administrative burdens fall. Drug authorisation statistics pre- and post-implementation from six large EU countries indicate a marked drop in non-commercial academic cancer clinical research within the EU post-implementation.

Drs. Denis Lacombe, Jacques Demotes-Mainard and Carole Moquin-Patthey presented specific examples of how the Clinical Trials Directive influences academic cancer research and proposed strategies for overcoming these challenges. The EORTC, which develops, conducts and coordinates high quality translational and clinical cancer research on a pan-European level has been particularly hard hit by the Directive's failure to bring real harmonisation. This academic organisation conducts clinical trials involving new drugs but more importantly, large-scale multi-national trials that evaluate innovative and more effective therapeutic strategies using approved drugs, radiotherapy and/or surgery. The latter type of study may fall under the Directive in some Member States if classified as an interventional trial and in all, if it involves the use of an investigational medicinal product as interpreted by each Member State's legislation. The EORTC is required to meet and adhere to the legislation of each country participating in a multi-national clinical trial. The complexity of this exercise and lack of EU harmonisation are illustrated by the multi-national EORTC "*TEACH*" observational study designed to evaluate the risk of thrombo-embolism in patients receiving chemotherapy. Three EU countries considered this academic trial to fall under the EU Directive, four did not and two countries approved the study without comment—different interpretations of the Directive for the same study. The study was cancelled due to inextricable regulatory issues.

According to Dr. Lacombe, metrics collected by the EORTC over the past decade indicate that the number of newly activated EORTC cancer clinical trials and the number of patients treated have declined precipitously in the post-implementation period. Simultaneously, trial insurance costs have skyrocketed, the overall EORTC budget has increased six fold and the number of EORTC Headquarters staff required to handle the additional administrative burden resulting from the Directive has tripled [5]. The nature of EORTC clinical trials has also changed with fewer academic trials and more industry-sponsored studies. The increasing cost of clinical trials impairs the autonomy and independence of academic clinical research and favours industry. The number of pure academic trials has decreased significantly. The Directive may also result in Europe becoming less rather than more competitive, as exemplified by one EORTC transatlantic US-European study designed to further evaluate important genetic findings from an earlier EORTC brain tumor study. The US research centres, all subject to a common central approval process, were able to initiate patient recruitment twelve months earlier and recruit fifty times more patients into the study compared to their European counterparts. The EORTC continues to collect hard data to support its case for changing the current Clinical Trials Directive.

Professor Demote-Mainard outlined potential solutions and recommendations for the future as proposed by major European research groups and discussed during a conference organised by the European Commission and EMEA in October 2007. Certain aspects of the Directive do work well (partial harmonisation, EudraCT, EudraVigilance, single Ethics Committee opinion, increased quality and GCP compliance). However, harmonisation remains incomplete, interpretation of the Directive is divergent among Member States and the scope of the Directive is indiscriminately all-inclusive failing to recognize the different types and risks of clinical trials. Submissions to Competent Authorities for multinational trials would benefit from integration and centralisation. Ethics Committees' review process needs more standardisation and their

organisation requires accreditation and quality assessment. The joint responsibilities of multiple sponsorship demands further definition. Academic institutions would benefit from supportive measures including access to data from trials not yet submitted for marketing authorisation purposes, waivers on fees to Competent Authorities as well as for the purchase of investigational medicinal products, public health system insurance coverage, technical support in the reporting of Suspected Unexpected Serious Adverse Reactions (SUSARs), development of a research infrastructure and increased funding. The use of data from trials run by academic institutions should be allowed for marketing authorisation purposes.

Although aspects of the Directive could be remedied, the optimal new legal framework would be a single and comprehensive legislation. This legislation would cover all clinical “research” and protect participating patients according to trial risk associated with the study and not to the commercial or non-commercial objective of the trial, be assessed by one single Competent Authority and accredited Ethics Committees based on clear guidance on their roles and harmonised interactions. This legislation would promote trust, transparency and the best use of data through open registration, reporting and data repositories.

Dr. Carole Moquin-Patthey spoke on the future strategy for medical research in Europe and investigator-driven clinical trials on behalf of the European Science Foundation-European Medical Research Council (ESF-EMRC). The mission of the EMRC is to promote innovative medical research and its clinical application towards improved health; provide authoritative strategic advice for policymaking, research management, ethics and better health services; serve as a consensus voice for all research organisations; disseminate knowledge; and promote the socioeconomic value of medical research to the public and policymakers. In this regard, the ESF-EMRC has produced a white paper aimed at strengthening and improving European medical research for creating new knowledge, better practice of medicine and improved human health

and welfare. These are achievable through peer-reviewed funding of research based on excellence, collaboration via the EMRC, revision of the EU Directive to facilitate research, equal opportunities for research and the doubling of public funding of medical research in Europe to a minimum level of 0.25 % of GDP within the next ten years.

Specific to investigator-driven clinical trials, a Forward Look, launched in mid-2007, will provide recommendations on ways to improve coordination of the various national and European initiatives and strengthen investigator-driven clinical trials from an international perspective. Through a series of strategic workshops, European experts have recently addressed: (1) categories and design of clinical trials; (2) regulatory and legal issues, intellectual property rights and data sharing; (3) management and logistics; (4) education, training, career and authorship; and (5) funding and partnership models for investigator-driven trials in cancer, central nervous system, cardiovascular and infectious diseases, inflammatory and metabolic disorders. The workshop findings are currently undergoing a review and consensus process. In a final conference participants will further refine and agree on a set of recommendations for dissemination to major interest groups.

Several topics were addressed during the morning session general discussion. Workshop delegates questioned whether the role of Ethics Committees includes the review of study protocol methodology. The answer is not clear-cut. Ethics Committees must balance the risks and benefits of any research proposal for the patient. Poor or weak study methodology may prohibit a patient benefiting from a study, receiving adequate treatment or wasting their participation due to non-interpretable results. The quality of judgements made by Ethics Committees was also questioned and a proposal was put forward to develop accreditation via peer-review committees and a training process for Ethics Committee members.

Delegates agreed that partnership with industry is crucial for obtaining access to innovative drugs but guidelines for collaboration need to be established. The entire academic community that conducts non-registration drug clinical trials should agree on a minimum set of criteria for working in collaboration with industry. The EORTC has proposed rules also applicable to other disease areas, the main tenants being that (1) the study design and methodology should be controlled by the academic researchers and (2) the database and subsequent analyses should be performed by the academic researchers. National and European academic clinical research funding should be improved. European research is fragmented as a result of the available funds being allocated mainly on a national level. It is estimated that 93% of available research funding in Europe is in the hands of Member States and spent mainly at the national level. Only the remaining 7% of funding is made available for international research such as through the EU Research Framework Programmes.

Human Tissue Research and Biobanking—Is Regulation Necessary?

The afternoon session focused on the legal and ethical aspects of biomedical research on human biological materials. Hildrun Sunseth, Head of EU Policy for the European Cancer Patient Coalition (ECPC) offered insights from the patient perspective. This coalition, launched in 2003, represents 26 EU countries and over 250 full-member organisations. The coalition's main concerns regarding the storage of human bio-specimens or biobanking include the protection of personal information and privacy rights and the use and misuse of tissue samples and data. Patients recognize the potential benefits of biomedical research. Tissue donation must remain a voluntary and informed decision, provide anonymity through the use pseudonyms linking tissue data and donor, provide feedback, and benefit sharing. Consent forms must be explicit rather than implicit as they are today No one can predict the nature of medical research

as science advances and patients need to be aware that tissue donated today may be used for research in the future.

Patients require protection against exploitation when tissues and/or data are transferred, employment and insurance discrimination and stigmatisation when negative hereditary factors are identified. A regulatory framework is needed that governs biobanking but that does not hinder or block research. The Data Protection Directive already exists yet legal and ethical common guiding principles, uniform quality standards, ethical oversight and EU legislation are lacking. The ECPC motto “Nothing About Us, Without Us!” indicates the willingness of patients to move into the future together with researchers but also underscores their importance and power as policy influencers. The Head of ECPC EU Policy commented that, “patients want to work with cancer research organisations to ensure that the balance is correct between patient rights and research interests but the general public is still fearful of bio-banking.” Broad public support, realistic and balanced perceptions as well as transparency will help address people’s fears and concerns. Steps towards achieving this include (1) registering all cancer trials, (2) lobbying for change—open EudraCT, (3) systematically involving patients in the design of trials and on Ethics Committees, (4) publishing both positive and negative research results, (5) amending the EU Clinical Trials Directive, and (6) keeping clinical cancer research in Europe. Hildrun Sunseth was emphatic in her support of European research stating that, “It is crucial to keep clinical cancer research in Europe as it provides patients with options and access to new treatments. Most patients cannot travel to the US for such treatments.”

Three legal experts presented on the ethical and governance issues surrounding human biological tissue research and biobanking, addressing aspects concerning the definition and scope of tissue biobanking, implications for the individual and population at large, current international governance and the best direction forward for Europe. Evert-Ben van Veen believes

that the mere definition of tissue banking is problematic, currently spanning the research use of ‘leftover’ tissue in pathology labs to population-based biobanks. Tissue research and data go hand-in-hand and the type of data associated with tissue (i.e. full or coded anonymity, directly or indirectly identifiable) will determine the legal rules for use of such data. Researchers are interested in identifying population patterns that emerge from the study of biological materials, not the individual per se. The sharing or flow of tissue and/or data between biobanks requires privacy enhancing technology-coding techniques, which allow for donor anonymity yet remain uniquely discernible. [6] Good research governance is the way forward, striking a fair balance between the interests of all stakeholders. It should encompass strict privacy protection, transparent basic principles for research projects, methods for disseminating research results, conflict of interest policies, and intellectual property rights while at the same time allowing for sufficient flexibility. Researchers together with patient organisations should develop this type of research governance and not look to governments. This will avoid repeating the experience encountered with the Clinical Trials Directive. Harmonisation if any should be ‘soft’.

Elisabeth Rynning presented the controversies surrounding access to human biobank materials. There is a lack of agreement on the definition of what constitutes a biobank—is it a collection of human tissue, organs or cells? Is this collection always associated with data? What constitutes a genetic database or a tissue database? Researchers and biobank administrators face the challenge of defining the relevant requirements for biobanking. Policymakers must decide what rules are needed. International activities and cooperation are essential but international legislation is lacking. Many guidelines exist but each country is pursuing its own route. The goals and interests underlying biobanking governance must be balanced, facilitate the justifiable use of human tissue and provide protection of individual privacy and respect for human dignity. Policymakers are struggling to understand whether today’s regulations cover the use of human

biobank materials, if consistency and harmonisation exist between internal and domestic regulations and whether these comply with external/international requirements.

Blood samples were once considered waste products. Today these samples represent human beings with personal information and a public resource of potential knowledge that should not be wasted. Samples are full of data, ordinary but most importantly genetic information that can affect individuals and families for many generations. UNESCO claims that genetic data are special and need different treatment. The regulatory issues are multiple. Should biological material be considered a product, an intervention on a body or simply data? When does the tissue stop being a human being and become a research product, data or only information?

What forms of regulation are required—local rules, guidelines, international laws, declarations, conventions? Who is better suited to decide the rules that govern the use of biological materials, donors and researchers or politicians and lawyers?

In the realm of international public law, the Council of Europe recognizes the 1950 Convention on Human Rights and Fundamental Freedoms, the 1997 Convention on Human Rights and Biomedicine with its 2004 Additional Protocol on scientific research (not ratified by all countries) as well as the formally non-binding Recommendation (2006) 4 on research on biological materials of human origin. UNESCO and the WHO have non-binding documents that address biobanking issues but the UNESCO Declaration on the Human Genome and Human Rights (1997) and the Declaration on Human Genetic Data (2003) are still relevant. At the EU level, relevant directives already exist for personal data protection, legal protection of biotechnical inventions, implementation of GCP as part of the Clinical Trials Directive, the setting of standards of quality and safety for human tissues and cells as well as regulation on advance medicinal products. The fundamental principle of non-commercialisation or ‘no

financial gain from parts of the human body' is paramount and biobank materials must not be sold. Issues requiring further attention include payment and compensation, benefit sharing and determining when a sample is no longer deemed a 'part of the human body'.

The scope of EU competency in the field of research is questionable. Is "soft coordination" based on guidelines, recommendations, funding restrictions and European Group ethics and opinions the preferred way to govern human biological materials? Clear definition of the key concepts, analysis of guiding principles and review of the complex systems of relevant national law, public international and EU law will help in determining the most appropriate level, form and content of potential regulation. Biobank research must remain open to continuous debate, show consideration of potentially sensitive ethical and legal issues, especially concerning international cooperation, genetic analyses, and research on minors and incapacitated minors while keeping abreast of developing policies and new laws.

Emmanuelle Rial-Sebbag discussed the Council of Europe and the legal instruments adopted for research on biological materials of human origin, Recommendation REC (2006) 4 of the committee of Ministers to Member States on research on biological materials of human origin. [\[7\]](#) This intergovernmental organisation, comprised of 47 countries, aims to protect human rights, democracy and the rule of the law. It encourages the use of biological materials in research for scientific progress but this in practice must be balanced with the protection of human beings based on the Convention on Human Rights and Biomedicine (Oviedo 1997), the Additional Protocol to this convention concerning biomedical research (2005) and Recommendation 4 on stored biological materials for future research (2006). Binding (national laws, treaties, EU law) and non-binding (international rules, professional guidelines and ethics) instruments contribute to the legal framework applied to biobanks and the associated data.

Within the scope of the Recommendation (2006) 4, ‘data’ are defined as identifiable biological materials (coded and linked anonymised materials) and non-identifiable or all other biological material not traceable back to the individual. ‘Samples’ are biological material directly obtained for research, residual biological materials and biological materials removed after death. There is no specific definition for the term ‘collection’ but may be inferred in REC 4 from references to formal procedures. For the Council of Europe, informed “consent” is an operational ‘principal’ in relation to human dignity whereas the OECD considers “consent” a process or procedure required to carry out some activity. Informed consent for ‘first use in research’ details any unforeseen potential further uses including commercial use of research results, data or biological materials. Informed consent for ‘re-use in research’ provides specific procedures for using human biological materials for other purposes.

Article 17 of REC 4 (2006) defines “population biobank” as a collection of biological material with the following characteristics: (1) the collection has a population basis; (2) it is established, or has been converted, to supply biological materials or data derived there from for multiple future research projects; (3) it contains biological materials and associated personal data, which may include or be linked to genealogical, medical and lifestyle data and which may be regularly updated; (4) it receives and supplies materials in an organised manner. ‘Collections’ are not synonymous with ‘population biobanks’, depending on the level of organisation and standardised procedures. Likewise, obtaining biological materials does not translate into their use in research projects and consent given for tissue removal is not synonymous with consent to conduct research on the biological material.

Regarding international regulation, the speaker agreed that if this is deemed necessary then the correct avenue must be envisaged and any regulation must be realistic, consensual, anchored

to practice and above all applicable. The principle of “mutual recognition” may represent a viable option. If a human tissue sample is used for research in one country, then its use should be permitted in a second or third country. Any legal framework should not prevent the export of human tissue samples. A point to be stressed is the fact that the patient has given his/her Informed Consent. When questioned as to whether the existing legal texts are responding to any major biobanking past issue, the experts comment that current legislation is purely anticipatory as no major biobanking precedent exists that would justify such legal enforcement.

Workshop Conclusions for Moving the Ship Forward

Workshop delegates agreed that their needs as academic researchers would be best served if all groups speak with one voice when the Clinical Trials Directive is re-opened for discussion. By coming to the table with a prepared common level of consensus, the discussion can start at a much higher level thereby increasing the likelihood of addressing all issues. To this end, each of the four workshop co-organisers agreed to identify and prepare their position on 3-4 key issues for the next round of meetings. The outcomes of the EMEA October 2007 conference prepared by Professor J. Demotes (ECRIN) on behalf of non-commercial sponsors, the ESF Forward Look and ICREL findings will be forthcoming in 2008 and will serve to prepare a list of changes to the Clinical Trials Directive to be submitted to regulatory authorities. Final words on the task ahead came in the closing comments from the EORTC Director General, Francoise Meunier when she encouraged delegates to “take up the magic wand and rewrite the Directive as we want it to be—a risk-driven translational research-based directive.”

Faculty

Pr. Jacques Demotes-Mainard (INSERM, FR)

Dr. Markus Hartmann (European Consulting & Contracting in Oncology, DE)

Pr. Peter Hohenberger (University Hospital Mannheim, DE)

Dr. Ingrid Klingmann (EFGCP, BE)
Dr. Denis Lacombe (EORTC, BE)
Pr. Françoise Meunier (EORTC, BE)
Dr. Carole Moquin-Patthey (ESF-EMRC, FR)
Emmanuelle Rial-Sebbag (INSERM, FR)
Pr. Elisabeth Rynning (Uppsala University, SE)
Hildrun Sundseth (ECPC, BE)
E.- B. van Veen (MedLawConsult, NL)

References

- 1 European Organisation for Research and Treatment of Cancer Website: www.eortc.be
- 2 The Connective Tissue Cancer Network Website: www.conticanet.eu/html/
- 3 “Impact on Clinical Research of European Legislation” (ICREL) www.efgcp.be/ICREL
- 4 European Clinical Research Infrastructures Network (ECRIN) Website: www.ecrin.org
- 5 van Vyve D. Meunier F. Facing the Challenges of the European Clinical Trials Directive: The EORTC Perspective. *European Oncological Disease* 2008. Issue 1 [In print]
- 6 van Veen EB . Obstacles to European research projects with data and tissue: Solutions and further challenges. *Eur J Cancer*. 2008 Apr 24. [Epub ahead of print]
- 7 COUNCIL OF EUROPE Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin. *Adopted by the Committee of Ministers on 15 March 2006 at the 958th meeting of the Ministers' Deputies*. Available online at: <https://wcd.coe.int/ViewDoc.jsp?id=977859>