A workshop and press conference on the International Clinical Trials’ Day was organised in Brussels, on Friday May 19th, 2006, hosted by the EU Commission (DG research, Health priority and Infrastructure programme) and chaired by Hervé Péro (Head of Unit, Research Infrastructures). In his opening address, Jacques Demotes (ECRIN / INSERM) presented the International Clinical Trials’ Day as a communication event initiated by the FP6-funded ECRIN\(^1\) with the support of the EU Commission and the participation of WHO, to promote open dialogue between patients, investigators, sponsors, ethics committees and competent authorities on the challenges raised by clinical research, particularly on how to improve the active involvement of patients in clinical research, the protection of participants, and the credibility and transparency of trials.

In his message, Commissioner Janez Potočnik (European Commissioner for Science and Research) highlighted the importance of patients involvement in clinical research, and the need for a strong clinical research capacity in Europe for public health, for patients and citizens in Europe and in developing countries, for the competitiveness of European academic research and the attractiveness of the EU for industrial development of innovative treatments.

Sir Iain Chalmers (The James Lind Library\(^3\)) drew a historical perspective\(^4\) of evidence-based medicine throughout the world, from the early recognition of the need for comparison by Abu Bakr Muhammad ibn Zakariyya al-Razi in the 9\(^{th}\) century, to the recent development of meta-analyses.

Tikki Pang (WHO) announced that, in order to increase public trust in clinical trials, the WHO Registry Platform\(^5\) has finalised its policies on the scope of trials to be registered, and the timing of disclosure of the 20-item Registration Data Set. The Registry Platform requires that all interventional clinical trials be registered with the 20 Data Set items prior to participant enrolment, including early uncontrolled trials involving patients and healthy volunteers. Furthermore, all 20 items should be publicly disclosed without delay at the time of registration, before the inclusion of the first participant.\(^6\)

Odile Leroy presented the role of EDCTP\(^7\) in promoting therapeutic research focused on major public health challenges through public-private partnerships in developing countries, the need to build the infrastructure for clinical trials, to develop education programs and to foster active participation of patients.

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1. European Clinical Research Infrastructures Network, [www.ecrin.org](http://www.ecrin.org)
3. [www.jameslindlibrary.org](http://www.jameslindlibrary.org)
7. European and Developing Countries Clinical Trial Partnership, [www.edctp.org](http://www.edctp.org)
Nikos Dedes (EATG) described the development over the past decade of active participation of patients in evidence-based medicine, supported by appropriate information, capacity building within patients’ organisations, and interaction with actors of drug development and healthcare providers – industry, regulators, scientific networks and international organisations. Flaminia Macchia presented the pan-European patient-driven alliance Eurordis designed to “allow patients to live longer and better”, establishing an equal-to-equal dialogue with healthcare developers and practitioners, promoting evidence-based medicine, and improving awareness on the disease. Synergistic actions based on trust include active collaboration in clinical trials based on the Eurordis charter, surveys on care needs within the patients’ groups, and a better definition of patients’ population. Ségolène Aymé presented Orphanet, a tool interfacing patients and the biomedical community through information on disease, volunteer’s files fostering recruitment in clinical trials, a trials registry, a directory of patients groups, a directory of experts and of research projects, and OrphanXchange designed to bridge the gap between basic research and clinical development.

Silvio Garattini (Istituto di Ricerche Farmacologiche Mario Negri and ECRIN) highlighted the need for institutions, infrastructures, and public funding supporting the conduct of clinical trials independently of pharmaceutical companies, and the need to reduce biases (selective publication, focus on selected adverse reactions, lack of comparisons, inadequate comparators, non-optimal doses, equivalence or non-inferiority trials) to translate clinical trials into optimal, evidence-based healthcare. Françoise Meunier presented the important contributions of multinational independent trials run by EORTC across Europe to the improvement of therapeutic strategies in cancer. For the patients’ sake, comparison of treatment strategies and combinations (drug, surgery, radiotherapy) resulted in substantial improvement in survival and on quality of life, promoting efficient strategies and avoiding unnecessary treatments to patients. This major contribution to evidence-based medicine highlights the need for integrated institutions and infrastructures for clinical trials in the EU. Masayuki Yokode (Kyoto University Hospital, Translational Research Center) presented the role of Translational Research Centres in academia-driven therapeutic innovation in Japan, their commitment to ensure a protection of patients similar to that required for industry-sponsored trials, and appealed Japan to build a comprehensive legislative framework for patients’ protection covering any type of clinical research.

Beat Widler (EFPIA) pointed to the interdisciplinary nature of drug development, and the need for a two-way dialogue between patients and the industry. Particularly, input from patients in the development of new therapeutic agents includes the preparation of informed consent forms, the protocol design and review, the quality of life assessment, and the selection of relevant outcome measures. Carole Moquin-Pattey presented the role of ESF-EMRC in fostering innovative medical research and its clinical application towards improved human health in a patient-centred process, serving as a voice of its Member Organisations and the European scientific community, disseminating knowledge and promoting the socio-economic value of medical research to the general public and the decision makers. Among other instruments, two Science Policy Briefings (2001 on controlled clinical trials, 2006 on pan-European clinical trials) address the challenges of clinical research in the EU.

Patients protection and quality of clinical trials was discussed by Jean-Pierre Tassignon (EFGCP), promoting the dialogue and training on GCP and ethics to build a robust regulatory and ethics framework in the perspective of the globalisation of clinical trials and of the increasing activity in eastern European countries. Beyond ethical review and the diversity of research ethics committees in charge of protecting participants in clinical trials in the EU, Christiane Druml (Ethics Committee of the Medical University of Vienna and VISEAR) reviewed the main

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8 European AIDS Treatment Group, www.eatg.org
9 European Organisation for Rare Disorders, www.eurordis.org
10 www.orpha.net
11 www.orphanexchange.org
12 www.marionegri.it
14 www.kuhp.kyoto-u.ac.jp/~trc/e_index.htm
15 European Federation of Pharmaceutical Industries Associations, www.efpia.org
16 European Science Foundation – European Medical Research Council, www.esf.org/emrc
17 European Forum for Good Clinical Practice, www.efgcp.be
challenge to academic clinical research in Europe, namely the public sponsor’s tasks, the insurance, the temporarily incapacitated patient, adverse event reporting, and clinical trials registration.

Transparency in clinical trials was further developed by Steff Lewis, emphasising the role of The Cochrane Collaboration\(^1\) in optimising the use of clinical data through meta-analyses and systematic reviews, their role in avoiding unnecessary trials, and the CONSORT\(^2\) recommendation to include systematic reviews in the discussion of clinical trial reports. On behalf of ICMJE,\(^3\) Torben Schroeder reported the role of medical journal editors in improving transparency, unbiased reporting, and in preventing fraud and misconduct. As publication bias may result in harmful outcomes for public health, and in deceiving altruistic persons who volunteered to participate in clinical research, the ICMJE statements on clinical trial registration in September 2004\(^4\) and June 2005\(^5\) were major steps in the ongoing process towards more transparency, defining which trials should be registered, what information, and where (regrettting the secrecy of the EUDRACT database). An-Wen Chan further developed the WHO policies in terms of clinical trial registration\(^6\), initiated in May 2005 by WHO General Director Dr Lee, based on ethical obligations, on the need to avoid unnecessary duplication of trials, to reduce selective reporting, and to track study results. By January 2007 the Clinical Trial Registration Platform will be based on an official and standardised, global and independent network of existing registries, providing a unique clinical trial registration number, an internet search portal, and will define the future policies particularly in terms of publication of results\(^7\) and compliance mechanisms. Christian Gluud (Copenhagen Trial Unit, Rigshospitalet, and ECRIN) drew perspectives regarding transparency in clinical trials\(^8\), requesting open registration and unbiased reporting of clinical trials and similar legislations in all countries enforcing registration and public access to data, and recommending patients to participate in registered trials with a commitment to communicate the study outcome. The future looks bright for clinical research, if collaboration between the public, industry, and academia could result in more trials being conducted.

As a conclusion, Jacques Demotes insisted on the need for education and communication programs to invite patients and citizens to discuss the organisation, legislation, and conduct of clinical research, as patients and citizens benefit from health innovation, but also support its costs and - this is unique in scientific activity - run personal risk while they act as participants in research. The science and society dialogue on clinical research should therefore be based on trust.

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\(^{1}\) [www.cochrane.org](http://www.cochrane.org)

\(^{2}\) [www.consort-statement.org](http://www.consort-statement.org)

\(^{3}\) International Committee of Medical Journal Editors, [www.icmje.org](http://www.icmje.org)


