ECRIN aims at connecting national networks of clinical research infrastructures in Europe in order

1 – to develop harmonisation and compatibility of procedures, tools and practice, and to improve quality in clinical research,
2 – to act as a support to sponsors (academic or industry) in the conduct of multinational studies in Europe,
3 – and to promote the connection of specialty- or disease-specific networks, that will use ECRIN for carrying-out their transnational projects, and will provide ECRIN with multinational cohorts and registries of patients, fostering enrolment.

ECRIN is a network of clinical research infrastructures, co-ordinated by INSERM, currently covering six European countries (Denmark, France, Germany, Italy, Spain, Sweden) and Canada, with the EFGCP providing a focus on ethics and Good Clinical Practice across the network. ECRIN plans to extend to other EU member states, and therefore stimulates the set-up of national networks. Connecting ECRIN requires a network of clinical research infrastructures (clinical research centres, clinical trial units) able to support clinical studies in any medical field, reaching critical mass in their country, and willing to participate in the shared harmonisation and quality process. Contacts have been made in numerous EU countries. In some countries where clinical research is organised through specialty- or disease-specific networks, connection to ECRIN could be achieved through a national coordination of topic-specific networks.

ECRIN started in 2004 with a FP6 EU funding (SSA, priority 1), through a ‘reciprocal knowledge programme’ (ECRIN-RKP)*, a diagnostic step aiming at identifying bottlenecks to clinical research according to a ten-item frame:

1 – Centres, networks and partners in their structuring
2 – Partners of projects : sponsors, funding
3 – Ethics and informed consent
4 – Legislation, regulation, insurance
5 – Adverse event reporting, drug dispensing
6 – Methodology, data management, monitoring

www.ecrin.org

Coordination : Jacques Demotes-Mainard, CIC INSERM-CHU de Bordeaux

CHU Haut-Lévèque, Avenue de Magellan, 33604 PESSAC, France

Tel +33 55765 6170, fax +33 55765 6168, demotes@bordeaux.inserm.fr
7 – Quality assurance, standard operating procedures, and audits
8 – Communication with participants, investigators and sponsors
9 – Transparency and clinical trial registries
10 – Education and careers

In each participating country, these ten items were covered during a workshop in September-October 2004, leading to reports on the national state-of-the-art (downloadable from www.ecrin.org). A comparative workshop was organised in Brussels (December 16-17th, 2004), and the resulting comparative analyses were presented and discussed during the ECRIN Meeting ‘Towards an integration of clinical research infrastructures in Europe’ in Brussels, on February 14-15th (130 invited attendees, programme and comparative analyses downloadable from www.ecrin.org).

In addition, this meeting allowed to start transnational working groups, and helped define the content of the next ECRIN application submitted to the FP6 Infrastructure call on March 3rd, 2005 (Co-ordination action, ECRIN-CA). Based on bottlenecks identified in the first (ECRIN-RKP) project, ECRIN-CA will develop:

1 – transnational working groups allowing to build-up the foundations of a harmonised, high quality network, focusing on:
   a – ethics, regulation and adverse event reporting
   b – methodology, data management and monitoring
   c – quality assurance, standard operating procedures and audits

2 – a communication strategy targeting participants and patients’ associations, academic and industry sponsors, and investigators. A major challenge will consist of providing specialised networks with support for transnational connection and for the set-up of transnational patients registries and cohorts, facilitating their enrolment in clinical studies.

3 – a consulting and services activity facilitating the role of sponsors in European studies. Services will include interaction with ethics committees and with competent authorities, data management and data monitoring, adverse event reporting, drug dispensing and management of biological samples.

This programme (and other activities, eg. education) is part of a strategic partnership with other industry or academic actors involved in clinical research, and in preclinical drug development. ECRIN participates in the preparation of the Technology Platform project ‘Innovative Medicines for Europe’, under development in the perspective of the 7th Framework Programme, steered by the European Commission and the EFPIA. ECRIN will contribute in this project by making clinical studies easier, faster, safer and of higher quality in Europe, thus stimulating the competitiveness of academic research as well as the capacity of the industry to develop new drugs faster. ECRIN will also contribute by helping specialised networks to connect across the borders.

ECRIN therefore meets the expectations of the European Union and the European pharmaceutical industry through a bottom-up harmonisation processes and an improved quality, through a network of audited infrastructures able to conduct common project complying with Good Clinical Practice.

ECRIN meets the expectations of investigators and academic sponsors (whose task is made more difficult with the implementation of the 2001/20/EC Directive on clinical trials). ECRIN aims at facilitating multinational clinical studies in Europe, as well as collaborations with the North-american continent with the help of the Canadian participant. This concerns translational research on the mechanism of disease, or biotechnology projects where public-private partnership is usual.

ECRIN finally meets the expectations of European citizens, addressing public health challenges : ECRIN will facilitate the conduct of clinical studies not covered by industry investment : strategy studies, surgery trials, pediatric drug evaluation, studies on rare diseases or orphan drugs.

Jacques Demotes, April 6th, 2005


www.ecrin.org

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CHU Haut-Lévêque, Avenue de Magellan, 33604 PESSAC, France
Tel +33 55765 6170, fax +33 55765 6168, demotes@bordeaux.insERM.fr