ECRIN-ERIC inauguration ceremony

The official inauguration of ECRIN-ERIC was hosted by the French Permanent Representation in Brussels on 30th January 2014. On 29th November 2013, ECRIN (European Clinical Research Infrastructure Network, www.ecrin.org) was officially awarded the status of European Research Infrastructure Consortium (*ERIC*), a legal status designed to facilitate the joint establishment and operation of research infrastructures of European interest. ECRIN-*ERIC* is a distributed infrastructure supporting multinational clinical research in Europe. ECRIN was developed and matured through the support of the European Union FP6 and FP7 programmes in a series of projects coordinated by Inserm. Germany, Spain, France, Italy and Portugal are the founding members of ECRIN-ERIC, whose management office is located in the host country (France), in Paris.

Robert-Jan Smits, Roger Genet and Jacques Demotes

The ceremony started with Robert-Jan Smits, Director General for Research and Innovation, DG RTD, European Commission, who handed over the ECRIN-ERIC plate, signifying the formal recognition of the ERIC status, and highlighted the support provided by the EU 7th Framework Programme during ECRIN development. Director-General Smits said: *'It is a great pleasure for me to hand over the official name plate confirming the ERIC legal status of ECRIN. ECRIN-ERIC will bring more coherence and efficiency to the area of clinical research which is of crucial importance for Europe. By setting common standards and harmonising procedures and protocols between clinical trials centres, the ECRIN-ERIC will further strengthen the European Research Area."*

Government representatives of the ECRIN-*ERIC* member countries (Roger Genet, Director General for Research Innovation, French Ministry of Higher Education and Research, Renate Loskill, Head of Division 'Health Research', German Federal Ministry of Education, Fabrizio Oleari, President of Istituto Superiore di Sanità, Italy, Antonio Andreu, Director General, Instituto de Salud Carlos III, Spain, and Paulo Pereira, Vice-President Fundação para a Ciência e Tecnologia, Portugal) highlighted, in the context of the national policy on health research and on research infrastructures, the importance of cooperation to foster competitiveness in clinical research and in health innovation. Silvio Garattini, Chair of ECRIN Scientific Board and Director of the Mario Negri Institute, Milan, addressed the need for multinational cooperation in independent clinical trials, then Jacques Demotes, ECRIN-*ERIC* Director General, presented an overview of ECRIN-ERIC development and activities. Finally Ruxandra Draghia-Akli, Director, Health, demographic change and wellbeing challenge, DG RTD, European Commission, discussed clinical trials in the context of the H2020 programme, and his Excellency Philippe Etienne, French Ambassador at the European Union, closed the discussion with considerations on the integration of Europe's scientific policies and capacities.

Antonio Andreu, Ruxandra Draghia-Akli, Jacques Demotes, Fabrizio Oleari, Roger Genet, Renate Loskill, Paulo Pereira, Philippe Etienne, Silvio Garattini and Christian Ohmann

ECRIN-ERIC, an infrastructure for multinational clinical research in Europe

Clinical trials represent a critical step in health innovation, as the only way to demonstrate efficacy and safety in patients. Clinical trials are also essential instruments for health systems, as comparing established treatments is the basis for optimisation of healthcare strategies and for evidence-based medical practice. Access to patients and to medical expertise are key factors in the conduct of clinical trials. ECRIN-ERIC was therefore designed to facilitate multinational trials in spite of the fragmentation and poor interoperability of national clinical trial legislation, of health systems, of competent authorities and ethics committees, of national research infrastructures, of tools and procedures, of training, of funding and of language. ECRIN-ERIC boosts the competitiveness of Europe, taking advantage of its potential patient population size and its medical expertise.

In individual countries, academic sponsors, clinical research centres or clinical trial units have the capacity to conduct national trials, but face major obstacles in the management of multinational trials. By connecting and coordinating these national centres and networks, ECRIN-ERIC makes it possible to conduct multinational trials in Europe. For this purpose, ECRIN-ERIC establishes permanent contracts with its national scientific partners. ECRIN-ERIC therefore provides, at not-for-profit cost, operational support in the conduct of multinational trials whose protocol is accepted by the ECRIN-ERIC Scientific Board, based on their scientific excellence. This support includes information and consulting before protocol finalisation then, after protocol review, operational services supporting the management of the trial in multiple countries (ethical and regulatory submissions, pharmacovigilance, monitoring, data management). ECRIN-ERIC European Correspondents, hosted in each national hub, ensure coordinated support to clinical trial operations.

Members of ECRIN-ERIC also benefit from a series of structuring activities enhancing the competitiveness of the national partners and of the European network as a whole, developing harmonised practice, tools for multinational collaboration, training, and high quality standards. For instance ECRIN-ERIC develops a certification policy to promote quality and interoperability in clinical trial management. ECRIN-ERIC also promotes harmonisation of the regulatory systems, in Europe and other world regions, shared ethical standards, transparency and optimal use of data, with the objective to stay at the forefront of methodological and technological development in clinical research.

ECRIN-ERIC thus represents a major instrument for health innovation and for the optimisation of healthcare strategies, fostering the competitiveness of European health industry, and promoting evidence-based medical practice for the benefit of healthcare systems, of healthcare professionals, and of European patients and citizens.