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ECRIN-RKP
FP6, SSA, Priority I, Contract 511963

FINAL REPORT
May 12th, 2005

ECRIN started on May 13th, 2004 with a FP6 EU funding (SSA, priority 1), through a 'reciprocal knowledge programme' (ECRIN-RKP, see A1), 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
7 – Quality assurance, standard operating procedures, and audits
8 – Communication with participants, investigators and sponsors
9 – Transparency and clinical trial registries
10 – Education and carreers

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 (A2 to A7, downloadable from www.ecrin.org). A comparative workshop was organised in Brussels (A8, December 16-17th, 2004), and the resulting comparative analyses (A9) 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 (A10) and comparative analyses downloadable from www.ecrin.org) (see A11, meeting report).

In addition, this SSA allowed to define the content of the next ECRIN application submitted to the FP6 Infrastructure call on March 3rd, 2005 (Co-ordination action, ECRIN-CA, A12), and to participate in the preparation of the FP7 Technology Platform 'Innovative Medicines for Europe' (Barcelona workshop, A16). ECRIN also participated in the debate on transparency in clinical trials (A14), and will co-ordinate a communication event on clinical research, targeting EU citizens and patients associations, on May 20th (A15).

Content of the annexes :

A1 : ECRIN RKP contract
A2 to A7 : national reports (Denmark A2, France A3, Germany A4, Italy A5, Spain A6, Sweden A7)
A8 : programme comparative meeting
A9 : comparative analyses
A10 : programme closure meeting
A11 : meeting report 'Towards an integration of clinical research infrastructures in Europe)
A12 : ECRIN-CA, application to the FP6 'Infrastructure' call prepared during the ECRIN-RKP programme, under evaluation since March 2005.
A13-A14 : Articles (Lancet on ECRIN, A13, BMJ on study registers, A14)
A15 : Press release on the International Clinical Trials day (May 20th)
A 16 : Preliminary report of the Barcelona Workshop 'How to establish a European Technology Platform for innovative medicines'

Workpackages

WP1 : website development : website activated on December 2004 (www.ecrin.org)

WP2 *:* comparative workshop : December 16-17th (A8), 2004, prepared by 6 national workshops and national reports (A2-7)

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WP3 : draft comparative analysis : February 2005 (A9)

WP4 : closure meeting : February 14-15th, 2005 (A10, A11)

WP5 : Final Report : May 2005

Deliverables

Deliverable 1 :
Working documents for comparative analysis : reports on the national workshops, available on December 04, uploaded on the website on March 05 (A2-7)

Deliverable 2 :
Draft comparative analysis : available on February 05, final document uploaded on the website on March 05 (A9)

Deliverable 3 :
Closure meeting : February 05 (A10-11)

Deliverable 4 :
Final report : May 05

Deliverable 5 :
Papers : from January 05 (A3, A13-A14)

Dissemination

Website (www.ecrin.org)
Activated on December 2004
Documents downloadable from http://www.ecrin.org/ecrin_files/download.php?level=1 since March 2005 :
- 6 national reports (Denmark, France, Germany, Italy, Spain, Sweden)
- Comparative analyses
- Programmes of the comparative and closure meetings
- Information on the International Clinical Trials day

Articles
- Demotes-Mainard J, Ohmann C : European Clinical Research Infrastructures Network : Promoting harmonisation and quality in European clinical research. Lancet, 2005, 365:107-8.
- Krleza-Jeric K, Chan AW, Dickersin K, Sim I, Grimshaw J, Gluud C : Principles for an international registration of protocol information and results from human trials of health related intervention : Ottawa statement (part 1). BMJ, 2005, 330 :956-8.
- Demotes-Mainard J, Chêne G, Libersa C, Pignon JP : Clinical research infrastructures and networks in France : report on the french ECRIN workshop. Thérapie, 60 :183-199, 2005.
- Demotes-Mainard J et al. European Clinical Research Infrastructures Network *Meeting report :* 'Towards an integration of clinical research infrastructures in Europe', Brussels, Feb 14-15th, 2005. Int J Pharm Med, in press, 2005.

Conferences - Workshops
- Demotes-Mainard J.: Involvement of ECRIN in education programmes. OCTAVE Meeting, Lausanne, 2 september 2004.
- Gluud C. Meeting on international clinical trials registration. The Ottawa Statement (Part 1). The Canadian Institutes of Health Research. Ottawa, Canada. October 4, 2004.
- Demotes-Mainard J.: Clinical Research: Do new medicines need new approaches. European technology platform stakeholders meeting on Innovative Medicines for Europe, EU Commission, Brussels, October 5-6th, 2004.
- Demotes-Mainard J.: The ECRIN project. Committee for Orphan Medicinal Products, EMEA, London, October 7th, 2004.
- Gluud C. WHO ‚New York Statement' Meeting on General Consensus of Stakeholders. The Rockefeller Foundation, New York, USA. October 28-29, 2004.
- Demotes-Mainard J.: Expectations of academic research in Europe. Plenary lecture, 17th DIA Meeting 'Medicines in Changing Times', Lisbon, March 7th, 2005
- Demotes-Mainard J.: Le projet ECRIN. Perspectives pour des plateformes d'essais cliniques intégrées aux projets de recherche internationaux, INSERM-Transfert, Paris, 21 Mars 2005.
- Demotes-Mainard J.: Networks of clinical research infrastructures in Europe. Ophtalmic pan-European Clinical Trials and the impact of EU Directive (2001/20/EC). European vision institute, Royal Society of Medicine, London, 18 April 2005.

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- Demotes-Mainard J.: The contribution of national and European networks : ECRIN. Meeting on national and European pediatric networks. Brussels, European Commission, 19 april 2005.
- Demotes-Mainard J.: How to best expoit existing assets and resources in the European Union ? Chair breakout session B3, Workshop on how to establish a technology Platform for Innovative Medicines. Barcelona, 21-22 April 2005.
- Gluud C. The WHO technical consultation on clinical trial registration standards meeting. WHO Headquarters, Geneva, Switzerland. April 25-27, 2005.
- Demotes-Mainard J.: The development of a European GCP framework for academic clinical trials. Meeting 'Examining the value and impact of the EU clinical trial Directive: One year into the new European GCP reality'. Brussels, May 10-11, 2005.
- Gluud C. International efforts to get trials registered. 26th Annual Meeting of the Society for Clinical Trials. Plenary Session II: Forum on Making/Influencing Public Policy. Portland, Oregon, USA. May 23-25, 2005.
- Gluud C. Ottawa Group: Developing operationalisation of trial registration principles. The Ottawa Statement (Part 2). 26th Annual Meeting of the Society for Clinical Trials, Portland, Oregon, USA. May 23, 2005.
- Demotes-Mainard J : ECRIN as a support to Virgil clinical studies programme. Virgil Meeting, Lyon, June 6-8th, 2005.