Summary of organisations coordinating or facilitating Clinical Research

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ECRIN

Size: Staff 20

Budget: 2 million Euro per year

Financing: EU FP7 (formerly FP6)

Scope:

History
By connecting national networks of academic clinical research infrastructures, ECRIN was designed to bridge the fragmented organisation of European clinical research and to develop an integrated EU-wide clinical research infrastructure.

The programme started in 2004 with a diagnostic step (ECRIN-RKP, 2004-2005, funded by the FP6 Health priority) that helped identify the main bottlenecks to multinational cooperation in clinical research. This led to evidence deep and often unexpected discrepancies in national organisation and practice of clinical research. As a consequence, this pilot initiative led to define a strategy for the future development of a pan-European infrastructure for clinical research, based on the connection of national hubs providing services to multinational clinical studies and on the provision of services to investigators and sponsors in the conduct of multinational studies, as academic institutions often lack the capacity to fulfil the sponsor's responsibilities in foreign countries.

In the second step (ECRIN-TWG, 2006-2008, also funded by the FP6 Health priority), procedures and guidelines to support investigators and sponsors in multinational clinical research projects in the EU were prepared by transnational working groups and in particular:

- The description of national requirements for multinational clinical research in terms of ethical review, regulation, adverse event reporting, risk-based monitoring, and a corresponding set of guidance documents describing how to perform multinational clinical research projects and what the national requirements are, and the specific actions enabling projects to cross the borders.
- The description of existing data management tools, and the definition of requirements and specifications for ECRIN data centres.
- The description of existing resources in terms of training for clinical research, and the transposition of material developed by ECRIN into the preparation of yearly Summer Schools, designed to train European Correspondents.

Current phase
The FP7-funded ECRIN preparatory phase (2008-2011) is the third step of the ECRIN programme, funded by the FP7 Infrastructure programme as the preparatory phase of an ESFRI-roadmap project. It aims to develop a sustainable infrastructure able to support the set-up, conduct, and analysis of multinational trials in Europe.

The objective is to:

- Set up the most suitable legal form for the ECRIN infrastructure.
- Develop a business plan to ensure sustainability.
- Evaluate the organisation of the infrastructure through the conduct of pilot clinical research projects

Future:
After 2011, ECRIN will develop as a sustainable, multinational infrastructure, with an appropriate legal status and a governance involving the Ministries of member states.

ECRIN provides integrated support to multinational clinical research projects through information, consultancy, and a set of flexible services. Users of ECRIN consultancy and services are clinical research projects initiated by academic investigators or disease-oriented scientific networks, projects sponsored by public institutions, public-private partnerships, small and medium-sized enterprises (SMEs), medical devices or pharmaceutical companies.

Consultancy and practical information during the preparation of the clinical research project include:

Consultancy on protocol design and methodology
Consultancy on systematic review, meta analysis, and trial sequential analysis
Information on project registration
Information on regulatory and ethical requirements
Information on clinical trial sites and participant recruitment
Information on insurance
Information on cost evaluation and funding opportunities
Information on contracting

Information and consultancy are provided during the preparation of the study, and do not require submission to the Scientific Board. Provision of consultancy and services is coordinated by the ECRIN European Correspondent in the country hosting the principal investigator and/or the sponsor of the study.

Services provided during the conduct of the clinical research project include:

Submission to, and interaction with, competent authorities and ethics committees
Support with insurance contracting
Adverse event reporting
Monitoring
Data management
Project management
Development of central documents and trial master file
Recruitment and evaluation of trial sites
Training of study personnel
Investigational medicinal product management
Blood and tissue samples management

Services are provided during the conduct of the project. Access to the services requires submission of the protocol to the ECRIN Scientific Board Once the project is accepted, a task delegation contract defines the role and responsibilities of ECRIN in the conduct of the project. ECRIN selects projects based on scientific excellence, services are provided on a

'notfor-profit' basis and ECRIN-supported trials commit to register their protocols and publish their results.

ECRIN is also a partner in a portfolio of structuring projects in line with its own strategy, including :

- Assessment of the legislative framework for clinical research in Europe (the FP7 ICREL project, Impact on Clinical Research of European Legislation)
- Cross-border connection of disease-oriented research networks (the FP7 ENBREC project, European Network of Bipolar Research Expert Centres)
- Education and training projects (the IMI EMTrain project, European Medicines Research Training Network)

ECRIN organisation
ECRIN is a network of national clinical research infrastructures. The national clinical research infrastructures are composed of CTUs and CRCs able to provide information and services for clinical research in any disease area. The national infrastructures link to ECRIN through a national hub, which hosts an ECRIN European Correspondent, the national contact point for ECRIN.

The intended benefits of ECRIN
• Quality – through scientific evaluation, through high-standard service providers and through the quality assurance system
• Access – to information, experts, clinical sites, patients and service providers throughout Europe
• Cost efficiency – through speedy collaboration through national networks and 'not-for-profit' costing
• Flexibility – to meet the variety of users' expectations the provision of information and

Projects:

A number of pilot projects have been started so far.

Child Innovac
Pertussis vaccine, 48 trial participants French sponsor

6S
Hydroxyethyl starch vs crystalloid solution in severe sepsis, 800 trial participants Danish sponsor

LEAN
Effect of the GLP-1 agonist, liraglutide, on liver histology and metabolism in obese patients with NASH, 50 trial participants UK sponsor

TTM
Target temperature management 33°C versus 36°C after out-of-hospital cardiac arrest. 850 trial participants Swedish sponsor

PreCardia
Pre-clinical mutation carriers from families with dillated cardiomyopathy and ACE inhibitors, 200 trial participants French sponsor

References
www.ecrin.org (accessed on 15 Feb 2011)

Jaques Demotes *Re: Questions about ECRIN* Email To: Elin Karlberg. 2011-02-15 [2011-02-15] Personal Communication.

DCRIN (Danish Clinical Research Infrastructures Network) and DCRC (Danish Clinical Research Consortium)

Size: TBD

Budget: TBD

Financing: TBD

Scope:
Denmark (DCRIN) became the fourth member of ECRIN in 2004. DCRIN is composed of the Copenhagen Trial Unit, Centre for Clinical Intervention Research, and specialists and investigator groups from Copenhagen University Hospital, Odense University Hospital, and Aarhus University Hospital as well as the three good clinical practice (GCP) units, which are unique in Europe. DCRIN services and expertise include systematic reviews, meta-analysis, trial sequential analysis, trial design, protocol development, regulatory and ethics approval, translation, recruitment, randomisation, trial coordination, case record form design, adverse event reporting, data management, biostatistics, monitoring, and trial reporting.

The hub of the Danish network is The Copenhagen Trial Unit. Its main tasks are to conduct trials and meta-analyses, and to develop and to educate on these topics. The Copenhagen Trial Unit hosts The Cochrane Hepato-Biliary Group.

In order to further establish a strong Danish national network of clinical research and to continue Danish participation within ECRIN, the Danish Clinical Research Consortium (DCRC) is under construction. The DCRC shall become a virtual Danish clinical trial unit building upon the experiences obtained within DCRIN and ECRIN. DCRC is expected to be operative in 2013

Projects:
The Copenhagen Trial Unit presents projects on http://ctu.rh.dk/
Unclear which /how these are related to DCRIN

References

Lindschou Hansen J, Skoog M, Whitfield K, Gluud C, and the Danish Clinical Infrastructures Network (DCRIN). The establishment of a national clinical research infrastructure: the Danish Clinical Research Consortium (DCRC) - unlocking Denmark's clinical research potential. Report. Copenhagen Trial Unit, Centre for Clinical Intervention Research, 2009, p. 1-38. Available on http://ctu.rh.dk/ (accessed 22 Feb 2011)

www.ecrin.org (accessed on 15 Feb 2011)

SweCRIN

Size: ? Does not seem to have any own employees. Board consisting of 3 persons, all employed somewhere else. (to be confirmed)

Budget: ?

Financing: ?

Scope:

The Swedish partner of ECRIN is SweCRIN (Swedish Clinical Research Infrastructure Network) that is coordinated via the Karolinska Trial Alliance. SweCRIN consists of 23 clinical trial centres and units, spread across the country. Each member locally supports investigators, sponsored by public funds or industry, through conducting and coordinating clinical trials as well as providing advice and training.

The purpose of SweCRIN is to improve the quality and efficiency of clinical trials in Sweden.

The network collects, distributes and increases competence in clinical research through meetings and working groups. Further, it stimulates the dialogue with authorities, implements new regulations, and facilitates the cooperation between research units, hospitals, and county councils.

Projects:
SweCRIN has in collaboration with other organisations (Föreningen för klinisk prövning, LIF) and the Medical Products Agency developed generic templates (in English) of study documents that can be used in clinical trials (replacing sponsor specific forms).

References

www.ecrin.org (accessed on 15 Feb 2011)

www.swecrin.se (accessed on 15 Feb 2011)

FinnMedi Research Ltd

Size: 11 employees (to be confirmed)

Budget: ?

Financing:
Pirkanmaa Hospital District 33,3 %,City of Tampere 27,8 %, Tampere University Foundation 16,7 %, Industrial Research Fund at Tampere University of Technology 11,1 %, Finnish Red Cross 11,1 %

Scope:
The Finnish participant in ECRIN is Finn-Medi Research Ltd, a biotechnology and healthcare technology development company located in Tampere Finland. The company offers tailored expert services for research and technology commercialization, and is also in charge of coordinating development programmes and developing a joint operating model for the Finn-Medi network in the Tampere region.

Finn-Medi Research Ltd is a partner in the Finnish national clinical research network of university hospitals. The network has recently started a nationally funded project called FinnTrials to develop a common practice in conducting clinical research in hospitals in Finland and in utilizing investigator networks to effectively initiate industry sponsored trials. The network is also an active partner in ECRIN activities.

FinnMedi is an internationally operating company providing services related to business development and clinical research in the Life Sciences sector. Customers have an access to the leading scientific know-how, experienced researchers, university hospitals, life science companies, public and venture capital funding.

Customers are

- research institutions, researchers and other business or product idea owners in the Life Science sector,
- early stage and growth companies in the Life Sciences sector,
- research and development focused pharmaceutical and medical device companies and
- life science developers from the public sector.

Projects:

ECRIN

FinPedMed

FinnMedi is a part of the Finnish Investigators Network for Pediatric Medicines trough Finpedmed project. Finpedmed is a Finnish Investigators Network for Pediatric Medicines in joint collaboration with Finland's five university hospitals and their pediatric clinics.

Finpedmed operates on a non-profit basis, aims to improve both academic and sponsored pediatric clinical trials for the benefit of children's health, supports investigators and sponsors

in multinational studies and facilitates the recruitment of experts and investigators to work as specialists in trials supported by industry or other funding

Finpedmed establish itself as a nationally and internationally reliable and state-of-the-art paediatric trial unit and increase co-operation and influence in the EU. During 2011 Finpedmed will join European network of paediatric research, EnprEMA, established by the European Medicines Agency (EMA). This network will comprise of both national and European networks as well as investigators and research units that have special expertise in paediatric clinical trials

FinnTrials

FinnTrials is a Tekes Pharma funded project of the five Finnish university hospitals coordinated by FinnMedi

- FinnTrials develops a national operational model and processes for clinical research
- Creates and improves systems in investigator networks
- Harmonizes varied operation systems and
- Clarifies different kinds of budgeting principles

FinnTrials enables clinical studies to get initiated faster and more fluently in Finnish University Hospitals.

Coordinating the Receptor project

Receptor's purpose is to develop operational models for international marketing and investment acquisition for bio- and life-science sector expertise. Additionally, Receptor aims to attract customers, partners and foreign investors through the marketing and sales of life science expertise to foreign companies.

The aim of the project is to market and sale life science expertise to the foreign companies. The challenge of these development activities has been to identify and define commercially interesting expertise and products, to market and sell specialized skills and to start up national cooperation projects. The sales and contacts made have remained on the general level of national bio-sector marketing. The Receptor project is a response to this need. The project focuses on demand-led substance marketing and connects top-companies with research expertise to promote their specialized skills, as well as Finland in general. These competence entities are devoted to determining customer needs and acquiring market information. Competence entities consist of researchers or research groups from universities and research institutions and the companies operating within the same field. These communities become broader marketable entities than the individual quarters from which they are created. The objective is to create entities which provide concrete business opportunities for international companies.
Receptor is the joint venture of the National HealthBio and Well-being clusters for expertise.

References

www.ecrin.org (accessed on 15 Feb 2011)

www.finnmedi.com (accessed on 15 Feb 2011)

UKCRC (UK Clinical Research Collaboration)

Size: 1 employee, had up to 10 before

Budget:
£700.000 in 2009/2010 but decreased to £54.000 in 2010/2011, change associated with expenses to be covered by Department of Health.

Financing: The UKCRC is now solely funded by the Department of Health, England. Previously all the Partners contributed to its running and workstreams.

Scope: The scope is wide and includes commercial/academic/political and funders.

The UK Clinical Research Collaboration brings together the National Health Service, research funders, industry, regulatory bodies, Royal Colleges, patient groups and academia in a UK-wide environment that facilitates and promotes high quality clinical research for the benefit of patients.

The UK Clinical Research Collaboration (UKCRC) Partners' goal is to establish the UK as a world leader in clinical research.
The UKCRC provides a forum that enables all Partners to work together to transform the clinical research environment in the UK.

The forum promotes a strategic approach to the identification of opportunities and obstacles to clinical research and their resolution. In so doing the UKCRC aims to benefit the public and patients by improving national health and increasing national wealth

Projects:

Infrastructure in the NHS

The UK Clinical Research Network: one of the strategic aims of the UKCRC, is designed to support the conduct of high quality clinical trials and other well designed studies. Ultimate goal is to improve patient care by improving the speed and coordination of high quality clinical research in the UK. Building infrastructure is about embedding dedicated staff in the health service to deliver clinical research, backed up by streamlined systems and research management processes.

Major investment in Experimental Medicine – a coordinated initiative supported by UKCRC Partners and Stakeholders:

- Support for Research: grants focusing on the early testing of novel treatments or interventions in human participants (£15 million investment)

- Experimental Cancer Medicine Centres £35 million funding for the establishment of 17 Experimental Cancer Medicine Centres.

- Clinical Research Infrastructure Initiative - £84 million of new funding to provide significant new investment for clinical research infrastructure e.g. clinical research facilities, enabling technologies, capacity for early medicinal chemistry and pharmaceutical support.

- UKCRC Experimental Medicine Resources website: a new, definitive online resource on UK experimental medicine research was launched in January 2008 This is the first central information repository on the UK's capability and expertise in experimental medicine and early phase trials and contains up-to-date information on over 40 major UK experimental medicine facilities.

Developing an expert research workforce

- Integrated Academic training pathway - provides a clear and flexible pathway through which junior **doctors and dentists** can combine research and education with a clinical career. Based on recommendations in the report of the joint Academic Careers Subcommittee of Modernising Medical Careers and the UKCRC: *Medically and dentally qualified academic staff: Recommendations for training the researchers and educators of the future*.

- UKCRC Subcommittee for **Nurses in Clinical Research** (Workforce), chaired by Professor Janet Finch, conducted work to identify barriers and make recommendations for training and careers for nurses in clinical research. Their findings were published in a report '*Developing the Best Research Professionals - Qualified graduate nurses: recommendations for preparing and supporting clinical academic nurses of the future*' in August 2007, and recommendations made around capacity, capability and education and training.

Streamlining the UK regulatory and governance environment

- Restructuring Health Service R&D Permissions

- Streamlining information requirements for permissions & approvals (the Integrated Research Application System (IRAS)

- Consistent approach to advice provision

- Research Passport for Honorary Contracts

- Suite of model agreements

- Early engagement with regulatory change

Coordinating Research Funding

UK Health Research Analysis - an analysis of the directly funded UK research portfolios of the 11 largest government and charity funders of health related research, published in 2006. Subsequent analysis of 29 medium and smaller UK health research charities followed in 2007

Major joint initiatives to fund five new UKCRC Centres of Excellence for Public Health Research (**£20 million joint investment**) and Consortium and Strategy Development Grants for Translational Infection Research (£16.5 million joint investment).

References

Sarah Qureshi *Re: Questions about UKCRC* Email To: Elin Karlberg. 2011-02-23 [2011-02-23] Personal Communication.

www.ukcrc.org (accessed 15 Feb 2011)

NCBIO
(The Nordic Committee on Bioethics)

Size:
The Nordic Committee on Bioethics has two members from each Nordic country. Members are appointed for three years at a time by the Nordic Council of Ministers from the nominations of the Nordic countries.
1 secretary employed

Budget:
<200.000 Euros /year

Financing:
The Committee's work is funded by the Nordic Council of Ministers.

Scope:
The mission of the Nordic Committee on Bioethics is to foster co-operation between the Nordic countries by bringing together representatives from different backgrounds to discuss and analyse issues in bioethics in order to achieve greater awareness, promote common understanding and improve policy in this area. The Nordic Committee on Bioethics was founded in 1989 to promote Nordic cooperation and exchange of information between scientists, parliamentarians, opinion leaders and public officials in the area of bioethics. In the increasing international variety of approaches taken to address bioethical questions, it is important to have a committee that reflects the Nordic dimension in responding to ethical issues raised by biosciences and biotechnology. The Committee's tasks are:

- to identify ethical problems arising from genetic engineering and other biotechnology research, development and modification of microorganisms, plants, animals and humans.
- to promote Nordic collaboration among researchers, opinion formers and parliamentarians on bioethical issues by cooperating with national research institutions, authorities and ethics committees, and by the same token creating opportunities for the exchange of information.
- to contribute to a joint Nordic debate on bioethical questions by disseminating material that can be used in constructive discussions of bioethics issues.
- to monitor biotechnological developments in the Nordic region and internationally.
- to keep abreast of Nordic and international debate on ethical questions issuing from biotechnology research, development and application.
- to follow legislative developments within the sphere of biotechnology in the Nordic countries.

Projects:

- The Committee arranges workshops, hearings, conferences, symposia and public talks/lectures in order to contribute to the exchange of information between researchers, parliamentarians and opinion leaders on current issues in bioethics.
- The Committee publishes reports and other publications to promote Nordic and international debate on issues of bioethics.

- The Committee holds regular in-house meetings.
- The Committee can co-opt experts for a particular activity.
- Work is ongoing to develop common Nordic web based Teaching Materials in Bioethics

References

ncbio.org (accessed on 15 Feb 2011)

ScanBalt

Size: 1

Budget: Variable, depending on EU project activity

Financing: Fees and EU-funding, initiated in 2002 with Nordic funding

Scope:
ScanBalt is the organisation for the Baltic Sea or Nordic-Baltic Region's Life science and Health Economy community, named ScanBalt BioRegion.

ScanBalt is a not-for-profit member association which serves as a service provider for the members and promotes ScanBalt BioRegion as a globally competitive Green Valley and Health Region.

The regional/national networks and clusters together with public authorities, industries and hospitals constitute the basis for ScanBalt. ScanBalt is a mediating, coordinating and communicating umbrella and/or platform aimed to:

- promote projects, business and research
- promote visibility and branding
- promote policy issues, regional innovation and cluster development

Projects: EU FP 6 (3), EU FP 7 (1), BSR 2001-2006 (1), BSR 2007-2013 (1), BSR Flagship (1), South Baltic (1), NIC (3), NordForsk pilot (3)

References

Peter Frank *Re: Questions about ScanBalt* Email To: Elin Karlberg. 2011-02-16 [2011-02-23] Personal Communication.

www.scanbalt.org (accessed 15 Feb 2011)

NRC (Nordic University Hospital Research Conference)

Size:
The steering committee consists of the Leader of the Strategic Research Programme Haukeland University Hospital, professor Jan Olofsson, and the managing director of the coordinating organisation; Arne Godal, Innovest AS.

Budget: ?
but Conference fees are paid by participants.

Financing:
The Nordic University Hospital Research Conference is independent of the pharmaceutical industry. Sponsors are: Innovest AS , Bergen Teknologioverføring AS , Nordea Bank Norge ASA, avd. Bergen , HolbergFondene

Scope:
Annual conferences are arranged (since 2006) for a network of professionals at University Hospitals in the Nordic countries. An arena where researchers and administrators can meet, share their experiences and learn from the best. NRC aims to challenge, stimulate and inspire researchers and administrators at University Hospitals throughout the Nordic countries in order to increase the rate of success in medical research.

Projects:
Annual conferences since 2006

References

nrcnetwork.org (accessed 15 Feb 2011)

ESF (European Science Foundation)

Size:
Staff: equivalent to 170 full time in 2009 including COST Office , 78 member organisations

Budget:
58M€in 2009 including COST 30M€ (contracted by EU)

Financing:
ESF's funding is provided by its member organisations. ESF is an independent non-governmental organisation. Some of its programmes receive part support from the European Commission under the Framework Programmes

Scope:
ESF is not a funding agency. It can best be described as a networking organisation for its member organisations, who themselves are often funding agencies. The research community benefits from the ESF through its various instruments and activities, designed to bring European researchers together to network and share their knowledge for the benefit of European Research.

ESF have built up a high degree of expertise since the foundation in 1970-ies, in the management of international networking and research and in the formulation of international research strategy. The Strategic Plan outlines the vision of becoming a leading European research policy generator. ESF has a range of ways of doing this, through the scientific committees, the research activities, and through special instruments such as the policy flagship of ESF Forward Looks. ESF covers all areas in all disciplines: natural, medical and engineering sciences, social sciences and humanities.

Projects: Many.

Note:
This organisation is about to be merged with EUROHORCs (European Heads of Research Councils), as they have overlapping memberships. The idea behind merging the two organisations is to create a united voice for science in Europe that would be a powerful driving force to lead the future of the European Research Area. This combined organisation would focus on influencing policy that impacts research and science, and improving how research is managed and organised in Europe. The overarching objective is to increase the global competitiveness of Europe. This would need a strong emphasis on strategic activities, and less focus on managing collaborative research instruments, such as scientific conferences, EUROCORES and Research Networking Programmes (RNPs).

References

www.esf.org (accessed on 15 Feb 2011)

NSG (Nasjonal Samarbeidsgruppe for forskning innen medicin og helsefag)

Size:
Consists of representatives from each of the member organisations, leadership and secretariat currently managed by the NTNU (Norwegian University of Science and Technology)

Budget:
?

Financing:
?

Scope:

This national (Norwegian) collaboration party for medical and health science research is a strategic advisory organisation, with members from universities, regional healthcare providers, the Norwegian Directorate of Health, the Norwegian Institute of Public Health, the Norwegian Research Council, and other organisations. It was founded in 2005 to secure dialogue and coordination of research on a national level. Their scope is to

- Provide advice on research in a national perspective with focus on coordination of research strategies and development of collaborative relationships.
- Contribute to a national sharing of workload within the research field.
- Provide advice in relation to introduction of new medical technologies and expensive equipment relevant to research.
- Contribute to coordination in: establishment and use of biobanks and health registries, research based innovation and commercialization, ethical practices and standards in the field of research, modes to measure and report utilization of resources.

They also aim to function as an advocate for medical and health science research in public debate, contributing to legitimacy of research and positive attitudes towards research, for example in relation to discussions on research ethics.

Projects: ?

References
http://www.helseforsk.no/ (accessed 23 Feb 2011)

http://www.helse-sorost.no/fagfolk/forskning/nsg/Sider/side.aspx (accessed 23 Feb 2011)