ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK

IA-Integrating Activity

Capacities – Research Infrastructures
FP7-INFRASTRUCTURES-2011-1.1.5
ECRIN-IA

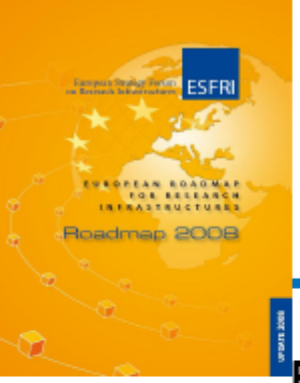
European Research Infrastructure consortium: ECRIN

Xavier Carné

www.ecrin.org

CLÍNIC BARCELONA
Hospital Universitari

SEVENTH FRAMEWORK PROGRAMME



ESFRI Roadmap Research infrastructures Biological and Medical Sciences

2006

BBMRI - Biobanks

EATRIS - Translational research facilities

ECRIN - Clinical trial platform

ELIXIR – Data repositories

Infrafrontier - Mouse archives and clinics

INSTRUCT - Structural biology facilities

EMBRC - Marine biology resources

2008

ERINHA - High-security labs

EuroBioImaging – Imaging facilities

EU-Openscreen - Chemical libraries

ANAE - Analysis and experimentation on ecosystems

2010

ISBE – Infrastructure for systems biology

MIRRI – Microbial resources

BBMRI Biobanking and Biomolecular Resources Research Infrastructure

EATRIS European Advanced Translational Research Infrastructure in Medicine

ECRIN

ELIXIR

Infrafrontier

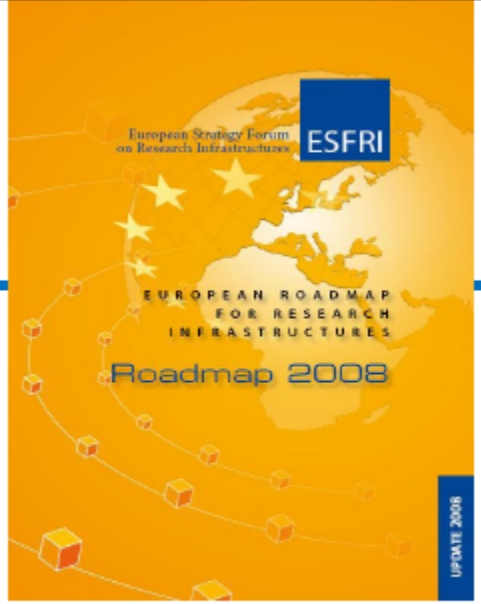
INSTRUCT

EMBRC EUROPEAN MARINE BIOLOGICAL RESOURCE CENTRE

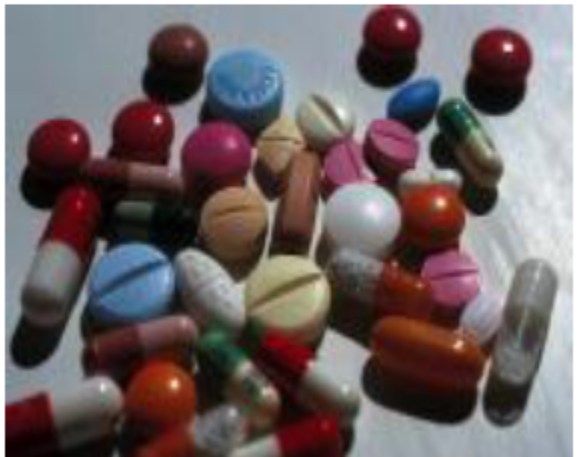
erinha

EURO-BIOIMAGING

EU-OPENSCREEN ESFRI ROADMAP 2008



A pan-European infrastructure for clinical research in any disease area



Make Europe a single area for clinical research

Pan-European, distributed infrastructure providing coordinated services to ***multinational*** clinical research in Europe:

- access to ***patients*** and to ***expertise*** throughout Europe

- despite the ***fragmentation*** of health, legislative and funding systems

- ***support*** to investigators and sponsors in multinational studies

ECRIN development steps

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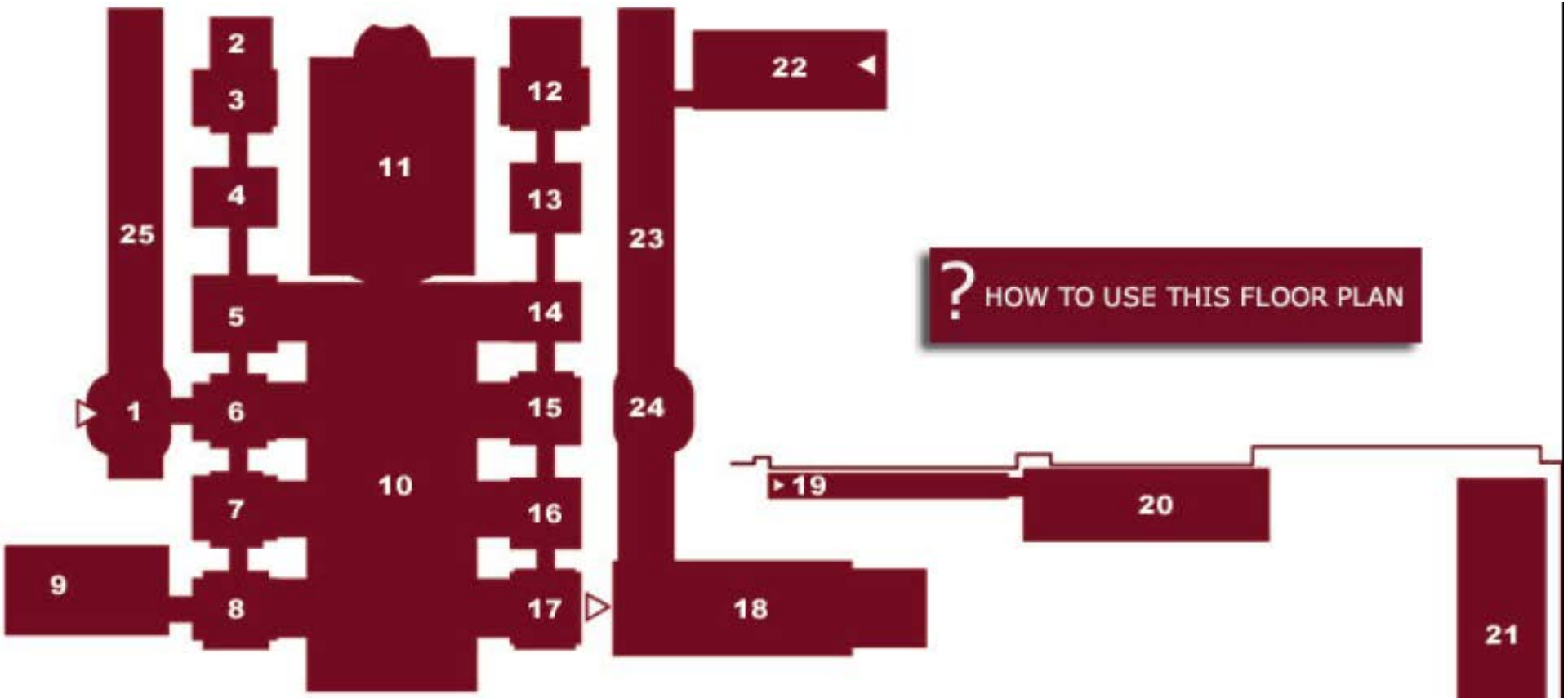
	ECRIN-RKP (2004-2005) identifying bottlenecks	
	ECRIN-TWG (2006-2008) developing know-how	
	ECRIN-PPI (2008-2011), building the infrastructure and supporting pilot multinational trials	
	ECRIN-ERIC (2013->) operating the ESFRI-roadmap infrastructure for multinational trials	
	ECRIN-Integrating Activity (2012->16) Expanding connections	


Barre des Ecrins
French Alps
alt. 4102 m
ECRIN-ERIC
OPERATIONS
ECRIN-IA
STRUCTURING
ECRIN-PPI
ECRIN-TWG
ECRIN-RKP
ECRIN

What is a distributed infrastructure ?



List of Chapels

The chapel of the Langue of Castille, Leon and Portugal
The chapel of the Langue of Provence
The chapel of the Langue of Aragon
The chapel of the Langue of Auvergne
The chapel of Our Lady of Philermos
The chapel of the Langue of Italy
The chapel of the Langue of Germany
The chapel of the Langue of France
The chapel of the Anglo-Bavarian Langue

ECRIN-IA (2012-15)

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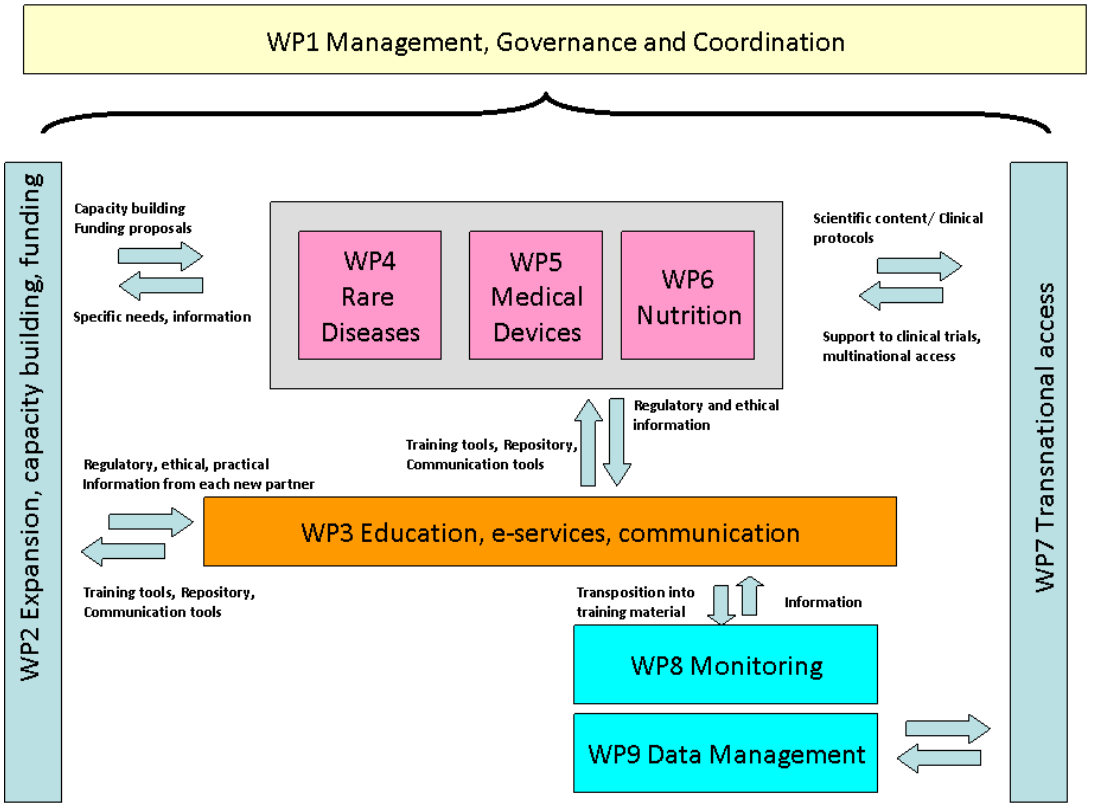

(i) *Networking activities,* to foster a culture of co-operation between research infrastructures and scientific communities and help developing a more efficient and attractive European Research Area;

(ii) *Trans-national access and/or service activities,* to support scientific communities in their access to the identified research infrastructures;

(iii) *Joint research activities*, to improve, in quality and/or quantity, the services provided by the infrastructures.

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How does ECRIN support multinational trials ?

➢ **Information and consultancy during the preparation of the trial**

- Information on regulatory and ethical requirements
- Information on sites and participant recruitment
- Information on clinical trials units
- Information on insurance
- Information on cost and funding opportunities
- Information on contracting
- Adaptation to local context

Full protocol

Scientific evaluation

Logistical assessment

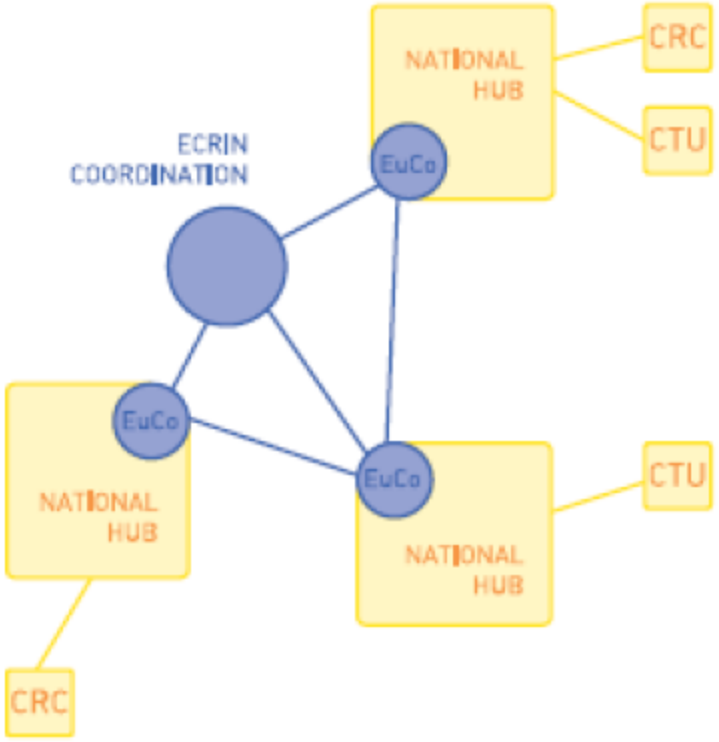
Contract with sponsor

➢ **Services during the conduct of the trial**

- Interaction with competent authorities and ethics committees
- Support with insurance contracting
- Adverse event reporting
- Monitoring
- Data management
- Investigational medicinal product management
- etc.

Network of European Correspondents

- Single contact point
- Hosted in national hubs
- Local relay in ECRIN activities
  - structuring
    - developing common tools and know-how
  - operations
    - providing information and consulting
    - coordinating the support and services



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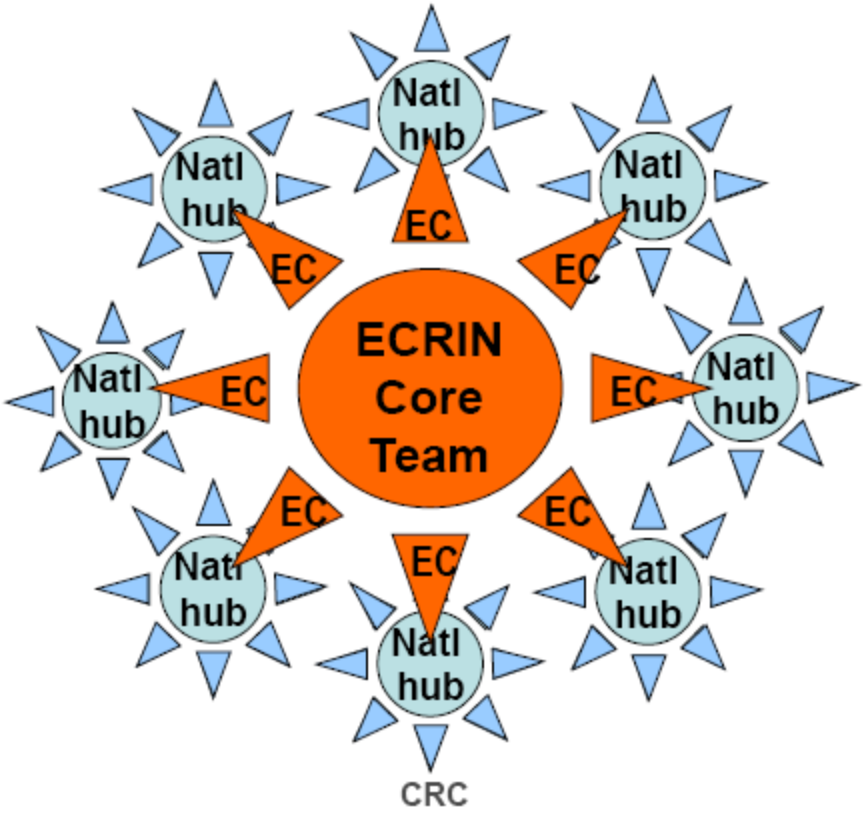
ECRIN-ERIC objective/ mission

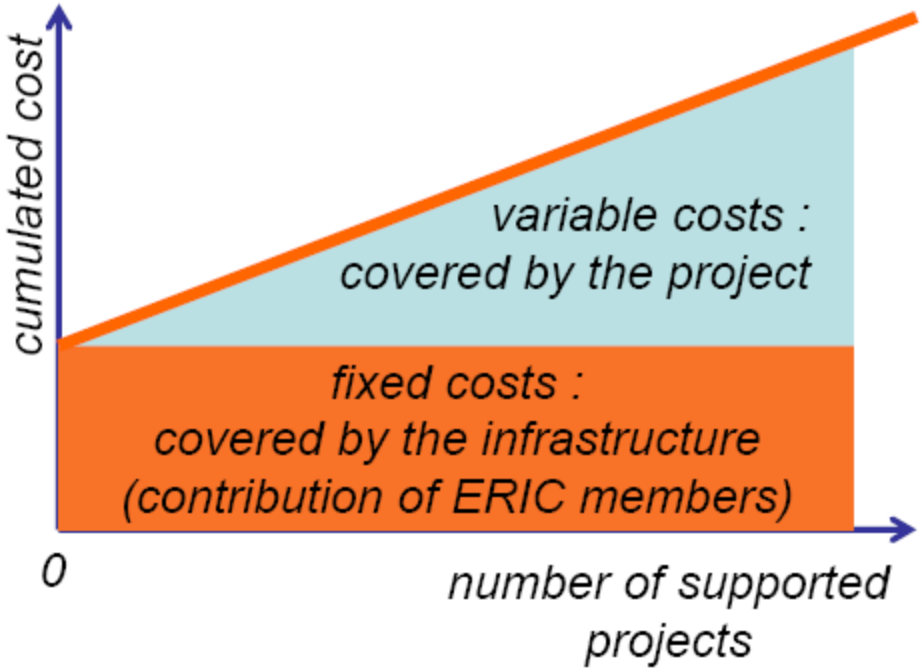
- ECRIN-ERIC is designed to provide a sustainable not-for-profit distributed platform for the support to pan-European clinical research projects in any medical field and for any category of research
  - operate the infrastructure
  - provides consultation, advices and services through a network of academic organisations specialized in clinical research

ECRIN-ERIC business model

For non-economic activities
- plus limited economic activities (max 10-20%)

Infrastructure -> fixed costs
Project -> variable costs





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ECRIN-ERIC

MEMBER COUNTRIES

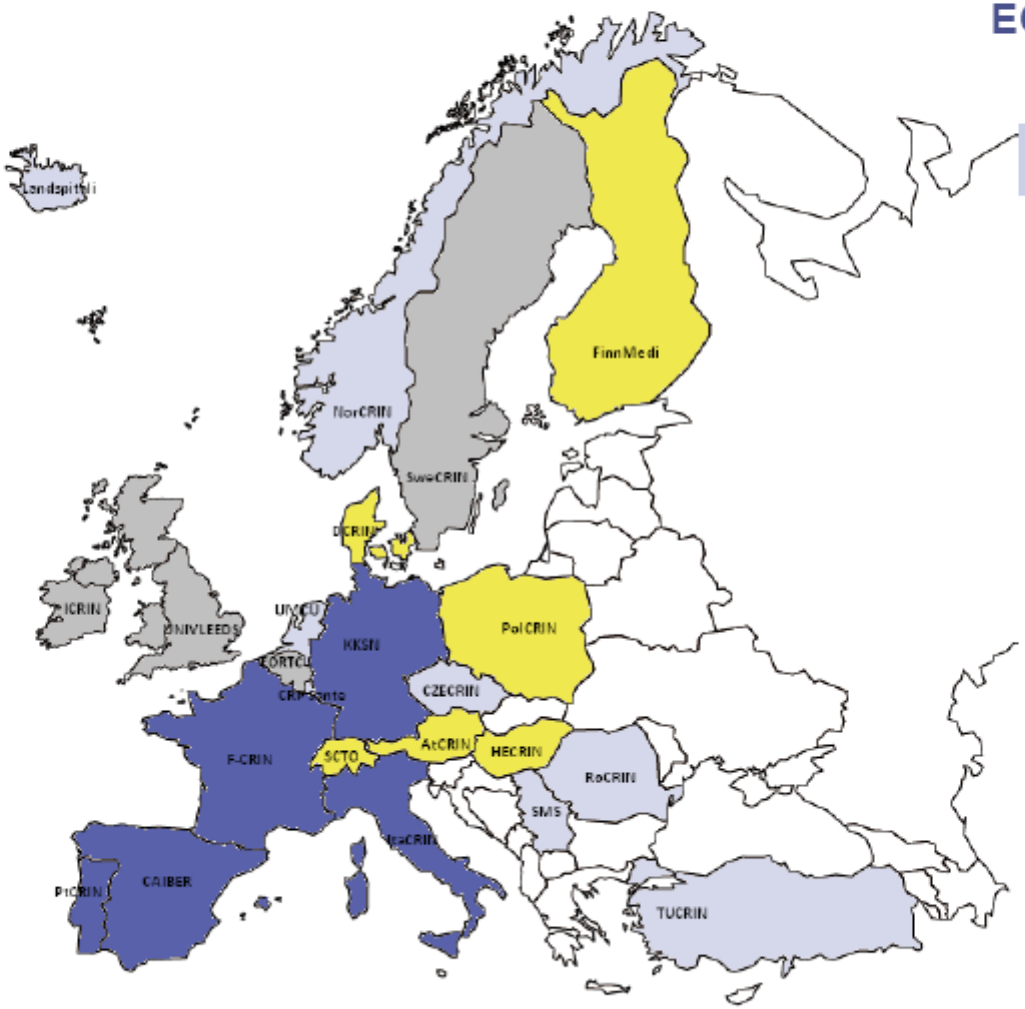
FRANCE
GERMANY
ITALY
PORTUGAL
SPAIN

SCIENTIFIC PARTNERS NON MEMBERS

Austria - MUW (for AtCRIN)
Denmark - RH (for DCRIN)
Finland- Finn-Medi
Hungary - HECRIN
Poland - MUW PL (for PolCRIN)
Switzerland – SCTO

AFFILIATE PARTNERS

EU - EORTC
Ireland - MMI (for ICRIN)
Sweden - KI (for SweCRIN)
UK - UNIVLEEDS



ECRIN-IA PROJECT PARTNERS

NEW COUNTRIES

Czech Republic - MU
Iceland - Landspitali
Luxemburg - CRP Santé
Norway - ST OLAVS
Romania - UMFCV
Serbia - SMS
The Netherlands - UMCU
Turkey - DEU

INSTITUTIONS

CIRM- Italy
ESPEN - Belgium
Eurordis- France
FCRB- Spain
INRA- France
IRFMN- Italy
Qualissima- France
UDUS- Germany
UniTransferKlinik- Germany
VSOP- The Netherlands

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3-Scope of work	12-Effectiveness-duration-termination
4- ECRIN-ERIC Services policies	13-Inalienability
5-Confidentiality	14-Force majeure
6-Intellectual property rights	15-General provisions
7-Use of name	16-Applicable law- Language
8-Financial arrangements	17-Disputes
9- Partners as beneficiaries of ECRIN-ERIC services	18-Appendices

Description of the services / tasks	Cost unit used (hour/day/flat rate/ etc...)	Cost - Mean value (min-max if differences between individual centres within the national network)	Comment
Regulatory Submission			
Initial submission Initial submission to central CA Preparation /compilation documents to obtain Authority Clinical Trial Initial notification to the local authorities			
Management of initial submission to lead and / or local EC for Initial Ethics Committee Approval: - Preparation of the country specific part of dossier (in addition of the Master Documents provided by the sponsor) - Compilation documents			

	On site Monitoring		
Pre-study visit for site adequacy			
Study initiation visit - Organizing, performance and reporting a site initiation visit - Training the site on the implementation of sponsor's SOPs and study specific procedures and documents - Collecting and checking regulatory documents		-	
Investigator site file setting up, printing, shipment and checking of the investigator site file			
Regular Study monitoring visit - Organizing, performance and reporting of a monitoring visit			
Site close-out - Organizing, performance and reporting of a site close-out			
Communications (communication with the sponsor, with the trial sites)			
Setting up/ checking of **country trial master file**			

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PART 3: MONITORING

Expression of interest in providing services	
Is your institution capable and interested in providing local onsite monitoring within the ECRIN infrastructure?	☐ Yes ☐ Yes, under condition that ☐ No
Which type of activities can your institution provide?	General activities of monitoring ☐ **Setting up and checking Investigator file** *(mandatory)* ☐ Setting up and checking of Trial Master File ☐ Attending the CRA training and / or familiarisation with the study ☐ Pre study visit / checking site adequacy ☐ **Initiation visit** *(mandatory)* ☐ **Regular on site visit** *(mandatory)* ☐ **Pharmacy visit** *(mandatory)* ☐ **Contact to the trial site** *(mandatory)* ☐ **Close out visit** *(mandatory)* Activities of lead monitoring ☐ **Pre study visit / checking site adequacy** *(mandatory)* ☐ Writing the monitoring manual / plan ☐ Organisation of CRA training ☐ Review of reports by the lead monitor / project manager ☐ Communication between sponsor and ECRIN partner ☐ Activities of remote monitoring : please specify: ☐ Other, please specify:
Where are you able to monitor	☐ In my area, please specify: ☐ In my country ☐ Across Europe
Comments	

Quality management system	
Does your institution have written and up-to-date Standard Operating Procedures (SOPs) or equivalent policies / guidelines / controlled documents for local monitoring?	☐ Yes *(mandatory)* ☐ No, describe your action plan in the comments section (below)o
If yes, which items are covered:	☐ Pre-study visit / adequacy of study site / trial centre, including preparation and report (*mandatory for tasks of lead monitoring*) ☐ Initiation visit, including preparation / training log and report *(mandatory)* ☐ Regular monitoring visit on site , including preparation and report *(mandatory)* ☐ Close-out visit , including preparation and report *(mandatory)* ☐ Template for the report of accountability and destruction of IMP / device *(mandatory)* ☐ Query management ☐ Writing monitoring manual / plan ☐ Centralised monitoring ☐ Training of monitors (including GCP, SOPs and national / international regulations) ☐ Others, please specify:
Comments	

Quality assurance requirements

The ECRIN Scientific partners should have implemented local QA system including SOPs especially for the study tasks they want to take over within an ECRIN project.
Respecting the fact that different ECRIN partners have implemented individual QM systems as part of their business concept, ECRIN-ERIC will not aim at harmonizing the systems, however, define on a general level, the principal rules that need to be addressed in the QM system implemented by each ECRIN partner.

To document the compliance with the standards developed (last version) and that are considered as minimum to guaranty high quality standard services, the scientific partner will have to complete the self assessment sheet.
Regular updates will be required and audits (cross partners or internal audits/ external audits) will be performed according to the ECRIN-ERIC audit plan.

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Clinical trials supported

Trial	Phase	Number of Countries	Number of patients	Status
Scandinavian Starch for Severe Sepsis/Septic Shock Trial	III	5	804	Completed
TTM-trial (Target Temperature Management after Cardiac Arrest)	III	12	850	Recruiting
Phase I intranasal genetically modified *B. pertussis*	I	2	48	Completed
PRE clinical mutation CARriers from families with DIlated cardiomyopathy and ACE inhibitors	III	7 (7 sites)	200	Recruiting
Efficacy and safety of anti-Pseudomonas (IgY) in cystic fibrosis	III	5 (18 sites)	180	Recruiting
Fluconazole versus Micafungin in neonates with Candidiasis	II/III	5	100	Preparation phase

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Trial	Phase	Number of countries	Number of patients	Status
Transfusion Requirements In Septic Shock trial	III	5 (23 sites)	1000	recruiting
Safeguarding the Brain of Our Smallest Children	II	12	100	Recruiting (1 country) approval in 3 countries)
Ivermectin (different doses) for the treatment of Strongyloidiasis	III	5 (11 sites)	400	Not yet recruiting
Efficacy of FOLFOX alone, FOLFOX plus bevacizumab and FOLFOX plus panitumumab as perioperative treatment in patients with resectable liver metastases from wild type KRAS colorectal cancer	II	10	360	Not yet recruiting

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Hydroxyethyl Starch 130/0.4 versus Ringer's Acetate in Severe Sepsis

Anders Perner, M.D., Ph.D., Nicolai Haase, M.D.,
Anne B. Guttormsen, M.D., Ph.D., Jyrki Tenhunen, M.D., Ph.D.,
Gudmundur Klemenzson, M.D., Anders Åneman, M.D., Ph.D.,
Kristian R. Madsen, M.D., Morten H. Møller, M.D., Ph.D., Jeanie M. Elkjær, M.D.,
Lone M. Poulsen, M.D., Asger Bendtsen, M.D., M.P.H., Robert Winding, M.D.,
Morten Steensen, M.D., Pawel Berezowicz, M.D., Ph.D., Peter Søe-Jensen, M.D.,
Morten Bestle, M.D., Ph.D., Kristian Strand, M.D., Ph.D., Jørgen Wiis, M.D.,
Jonathan O. White, M.D., Klaus J. Thornberg, M.D., Lars Quist, M.D.,
Jonas Nielsen, M.D., Ph.D., Lasse H. Andersen, M.D., Lars B. Holst, M.D.,
Katrin Thormar, M.D., Anne-Lene Kjældgaard, M.D., Maria L. Fabritius, M.D.,
Frederik Mondrup, M.D., Frank C. Pott, M.D., D.M.Sci., Thea P. Møller, M.D.,
Per Winkel, M.D., D.M.Sci., and Jørn Wetterslev, M.D., Ph.D.,
for the 6S Trial Group and the Scandinavian Critical Care Trials Group*

ABSTRACT

BACKGROUND

Hydroxyethyl starch (HES) 130/0.4 is widely used for fluid resuscitation in intensive care units (ICUs), but its safety and efficacy have not been established in patients with severe sepsis.

The authors' affi
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Integrating clinical research in Europe

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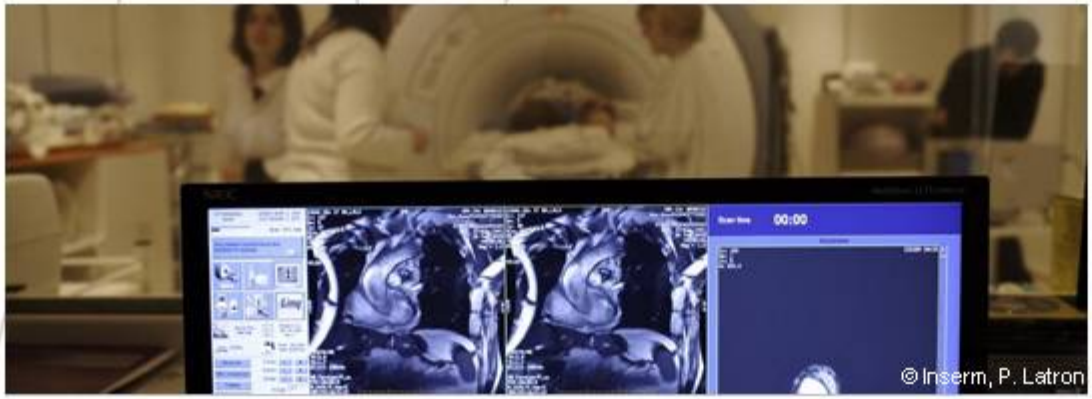

Welcome to the European Clinical Research Infrastructures Network

The European Clinical Research Infrastructures Network (ECRIN) is a sustainable, not-for-profit infrastructure supporting multinational clinical research projects in Europe.

Latest News

Proposal for an EU Regulation on Clinical Trials

A joint statement from non-commercial and commercial organisations

We welc...
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The celebration of the 2012 International Clinical Trials Day in Spain

May 22-25, 2012

The celebration of the 2012 International Clinical Trials ...
read more

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Muchas gracias

Nos vemos en

Mayo de 2014