ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK

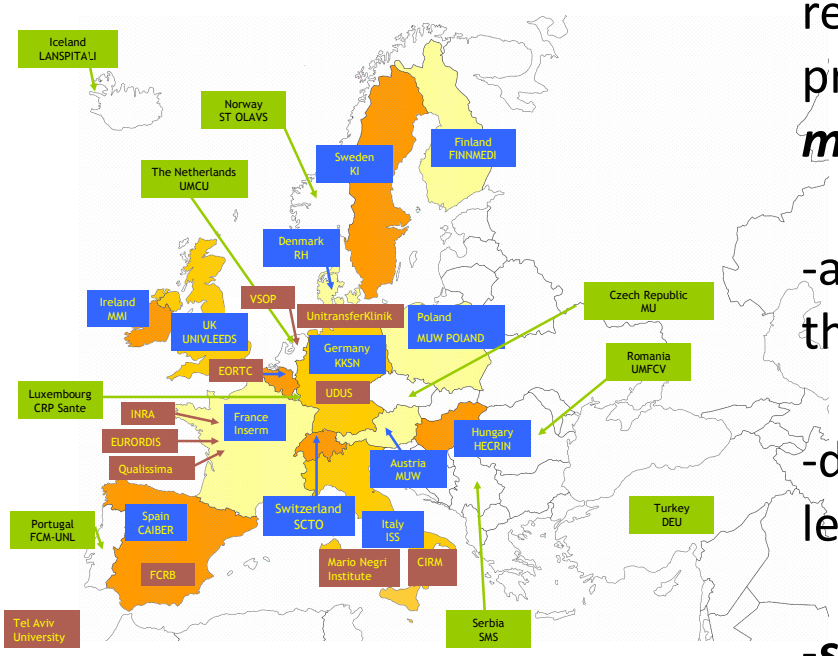
ECRIN-support to multinational clinical research

Christine Kubiak
www.ecrin.org

EURORDIS SUMMER SCHOOL FOR PATIENT ADVOCATES
IN CLINICAL TRIALS AND DRUG DEVELOPMENT – Barcelona- 17-21 June 2013

SEVENTH FRAMEWORK PROGRAMME

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



Distributed infrastructure based on existing national infrastructures composed of clinical research centres and clinical trials units and providing coordinated services to ***multinational*** clinical research in Europe:

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

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

-***support*** to investigators and sponsors

ECRIN – PPI Preparation phase 2008-2011

ESFRI (*European Strategy Forum on Research Infrastructures*) - Biological and Medical Sciences

2006

BBMRI - Biobanks

EATRIS - Translational research facilities

ECRIN - Clinical trial plateform

ELIXIR – Data repositories

Infrafrontier - Mouse archives and clinics

INSTRUCT - Structural biology facilities

2008

EMBRC - Marine biology resources

ERINHA - High-security labs

EuroBioImaging – Imaging facilities

EU-Openscreen - Chemical libraries

2010

ANAE - Analysis and experimentation on ecosystems

ISBE – Infrastructure for systems biology

MIRRI – Microbial resources

ECRIN development steps

	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	

ECRIN-ERIC

- European Research Infrastructure Consortium (ERIC) status
  - specific sustainable legal form designed to facilitate the joint establishment and operation of research infrastructures of European interest
- Mission
  - operate on a not-for profit a distributed platform for supporting multinational collaboration in clinical research (any field and any category of research), to make Europe a single area for clinical trials

ECRIN-ERIC

MEMBER COUNTRIES

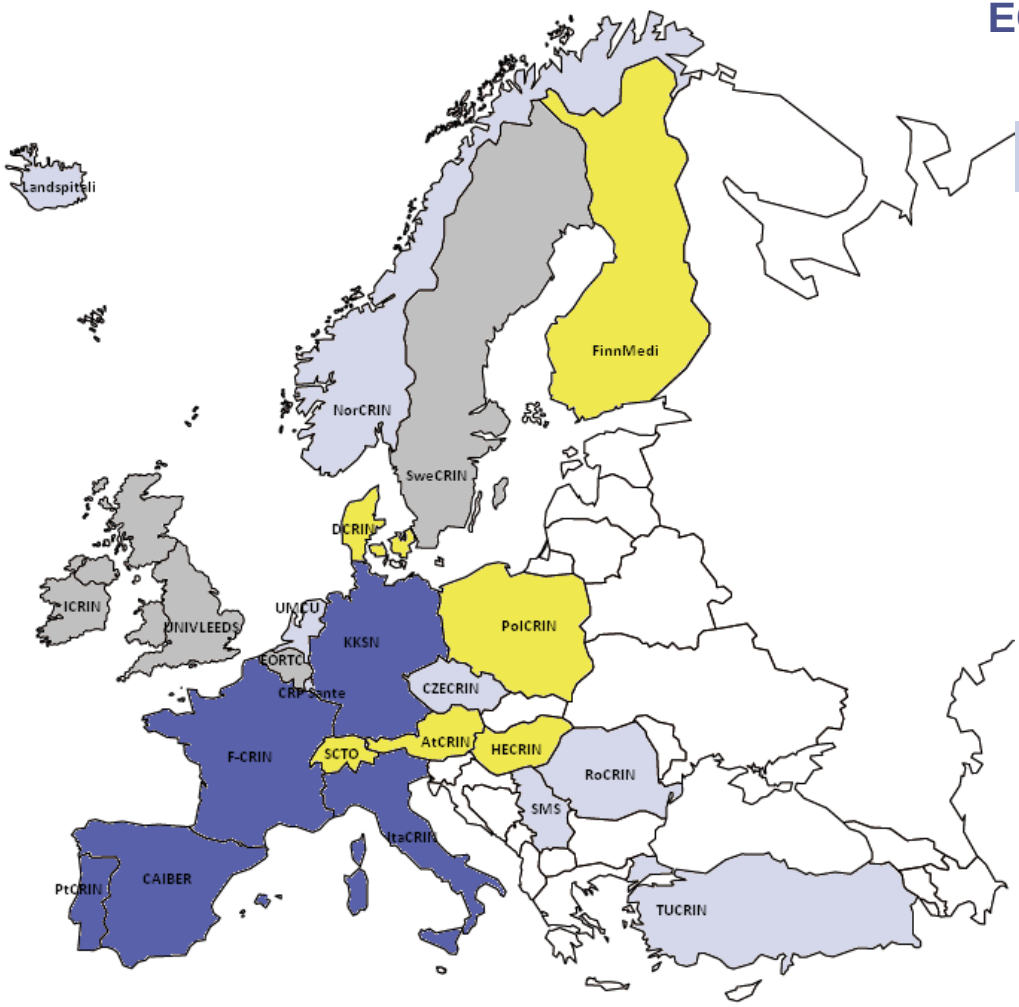
FRANCE
GERMANY
ITALY
PORTUGAL
SPAIN

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

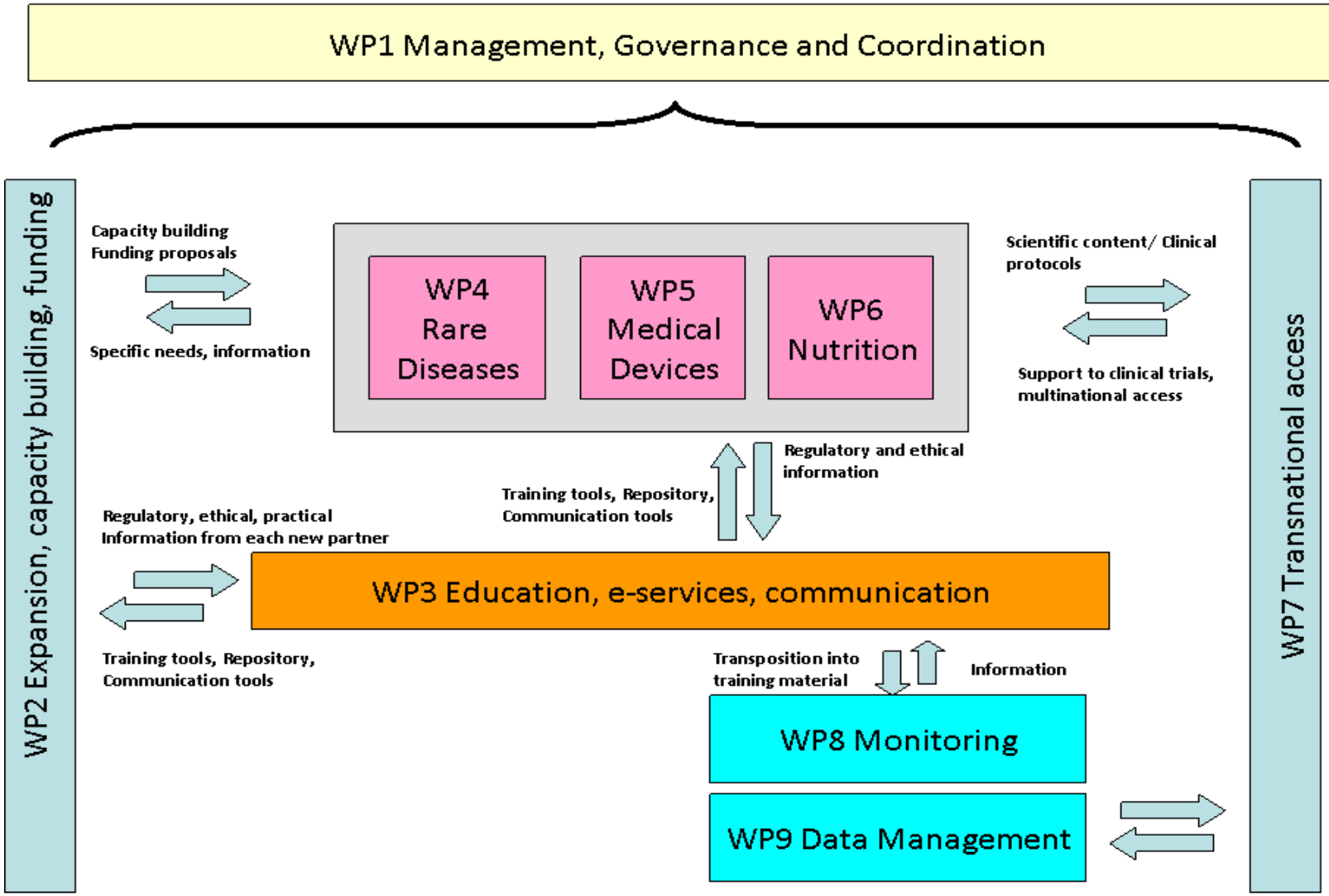
ECRIN IA:Integrating activity

- (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.

ECRIN-IA (2012-15): connecting new partners, developing new tools, structuring pan-European investigation networks



ECRIN missions/values

- Facilitate clinical research and the different types of clinical trials
- Facilitate multinational cooperation
- Promote independant clinical research
- Competitive scientific evaluation
- Promote transparency
- Promote communication
- Promote the involvement of « trained » patients and patients association in different steps of clinical research

Facilitate clinical research

- Despite efforts to harmonize the legislation on medical products in Europe, the EU Member States still have different rules for clinical research as regards the competent authority, ethical committees, monitoring, insurance, and reporting adverse events.
- ECRIN has the role to facilitate investigator-driven multinational clinical trials by making a certain number of services available. These include evaluation of the protocol by a scientific board, help in finding national networks and in providing the administrative steps to organize a trial by European national centers

Facilitate multinational cooperation

- Rapid assessment of the effects of treatments.
  - large and diverse populations
  - wider applicability of study results
  - more successful adoption in national health care systems
  - reduce inequalities in healthcare
  - promotes evidence-based medical practice
- Access to larger patient populations and to clinical expertise
  - allows study of stratified and personnalised treatment strategies
  - allows studies on rare diseases / conditions
  - allows access best appropriate medical centres

Independent clinical research

- Required to support health authorities, develop healthcare policies and define clinical guidelines for healthcare professionals *"what is the best treatment option for this patient / disease ?"* rather than *"is this particular product effective and safe?"*
- Highly positive return on investment for society in terms of
  - decrease in the burden of disease
  - increased harmonisation across countries of a common nomenclature for diagnosis and more uniform therapy
  - improvements in clinical practice
  - best possible knowledge of the effectiveness of treatments (optimized healthcare strategies)
  - cost containment in healthcare systems

Scientific evaluation

- Independant scientific board
- Based on criteria and recommendations
- Rules of transparency

Acceptance criteria

1 - Multicentre trial run in at least two European countries.

2 - Rules for transparency:

- Commitment to register the trial in a public register before inclusion of the first participant, for example on www.clinicaltrials.gov.
- Commitment to publish results irrespective of findings.
- Commitment to make raw anonymised data sets available to the scientific community upon legitimate request to the sponsor or principal investigator once the trial is completed.
- Declaration of conflicts of interest.

3 - Rationale based on up-to-date systematic reviews of clinical data or, where not possible, of preclinical data on the experimental intervention and comparator.

4 - Clinical relevance and/or marked impact on public health.

5 - Suitable overall trial design appropriate to the clinical question, including for example:

- Selection of an appropriate and justified experimental intervention and comparator.
- Adequate sample size with supporting calculation.
- Relevant patient population (inclusion and exclusion criteria), setting, and duration of treatment and follow up.
- Outcome measures for efficacy and safety with clinically meaningful benefit for the patient.

Recommendations

1 - Randomised superiority design is preferable for efficacy assessment, rather than non-inferiority.

2 - Use of the best available comparator.

3 - Primary outcome measure most suitable for patient and public health's interests.

4 - Sample size calculation based on the primary outcome measure, and power calculation for other important outcome measures.

5 - Adequate recording of adverse events.

6 - Adequate strategies to reduce or control possible biases, for example central randomisation; blinding of all parties (at least assessors, statisticians); intention-to-treat analysis for efficacy in superiority trial; blinded conclusions drawn before breaking the allocation code; and interpretation of, and decision to publish results, independent of funding source.

7 - Description of potential risks and how to handle them, including involvement of and charter for independent data monitoring and safety committee.

8 - Description of governance structure of the project including responsibility for coordination, data analysis, and independent monitoring.

9 - Description of indications of feasibility, for example: committed clinical sites; expected participant recruitment to meet sample size; resources and funding available; and logistics of delivering the intervention(s).

10 - Involvement of pertinent patient organisation (if available) in the protocol design.

Communication

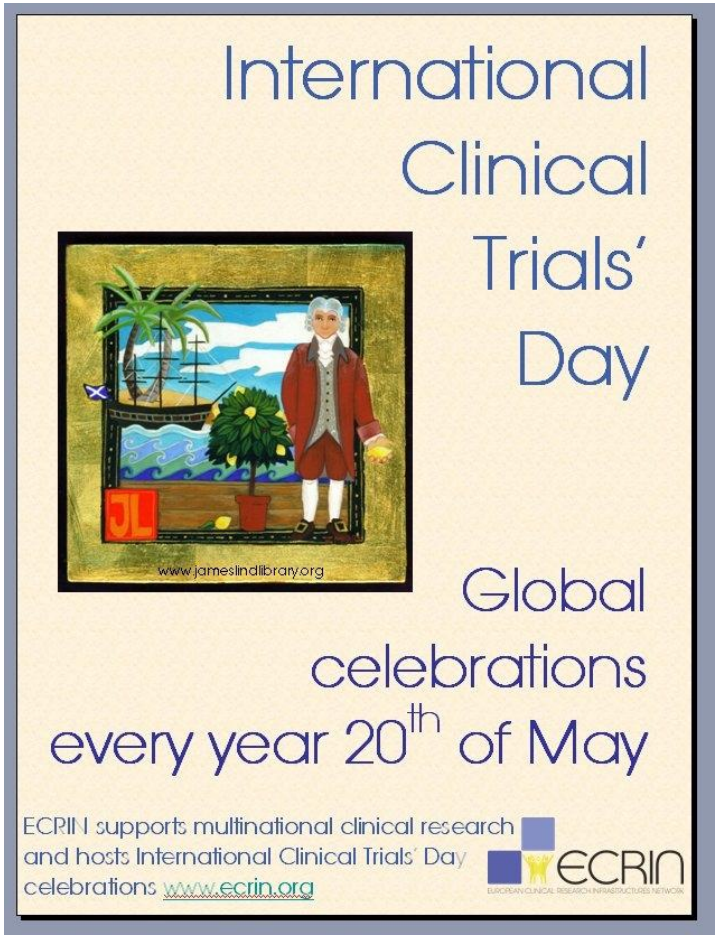
International Clinical Trials' Day

- since 2005 ECRIN hosts ICTD in one European capital
- Promote public awareness of the challenges raised by clinical research
- Stimulate debates between representatives of European patients associations, clinical scientists, scientific agencies, sponsors, ethics committees, competent authorities, medical journal editors, citizens

2013 in Warsaw, Poland (17 May)

2014 in Brussels, Belgium?

- **National and local events**



The **objective of the ECRAN project** is to develop tools to communicate key messages to citizens, patients, patients organizations and society - first target - healthcare professionals, researchers, policymakers – second target - **about independent, multinational clinical research**.

The key messages of the project are:

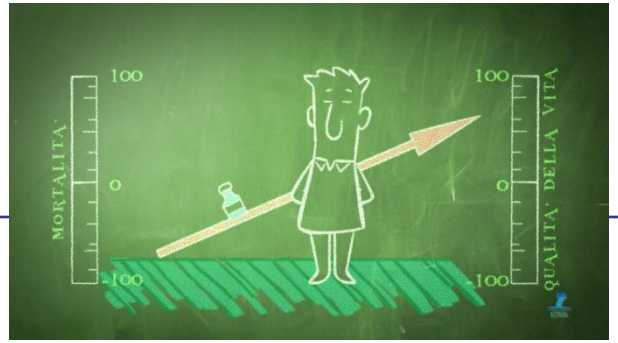
- importance of **public understanding** of the need for, and basic principles of clinical trials, fostering active involvement of citizens/pts in trials and of their representatives in trial design

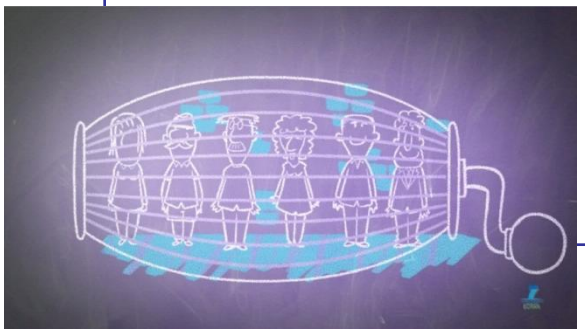
- need for **independent clinical trials** driven by healthcare needs, to optimise treatment strategies through comparison of benefits and harms of multiple therapeutic options, supporting evidence-based clinical practice and reduction in healthcare inequalities

- need for **transparency and optimal use of data** to allow their use in analysis and meta-analysis, but also to prevent bias in presenting and analysing results

- need for **multinational cooperation**, taking advantage of Europe's population size and diversity

These key messages will be addressed using communication tools such as: **animated** film on clinical trials, **website** (www.ecranproject.eu), online **database** of open educational resources, **interactive** online package including a serious game, podcasts and videos, **Testing Treatments** interactive sibling websites, **collaborative work** with journalists, and an **international event**

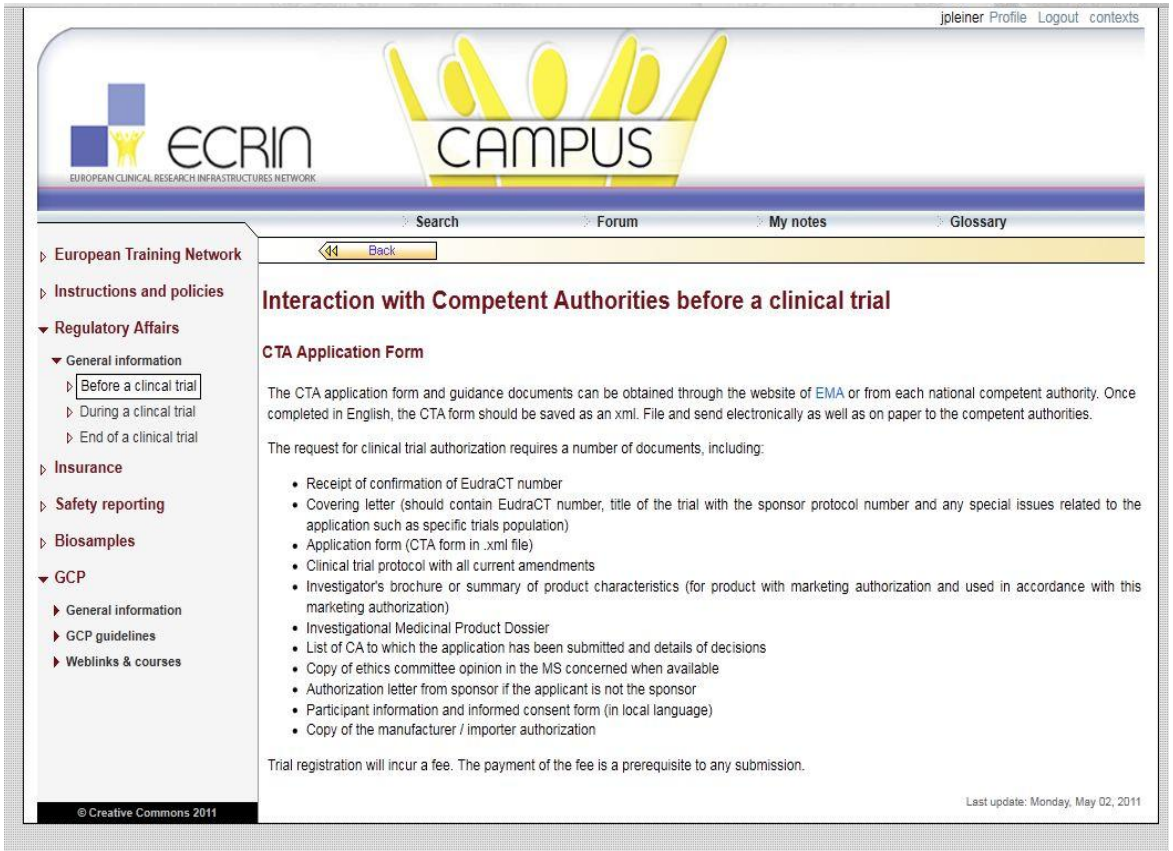




The ECRAN Consortium: IRCCS-Mario Negri Institute, Cochrane Consumer Network, Copenhagen University Hospital Copenhagen Trial Unit, European AIDS Treatment Group, German Network of clinical research centres, INSERM, Oxford University, University of Freiburg, Zadig

Tools to support multinational clinical research/training

- Training of European correspondents
  - requirements for multinational clinical trials
- Training of patients associations
- ECRIN Campus (repository /knowledge)
  - regulation for the different types of clinical studies and per country
  - ECRIN procedures and interactive flow-charts



Involvement of patients

- Representation in ethics committees
- Outcome measures design
- Scientific evaluation (participation in the evaluation of ECRIN IA competitive call to provide transnational access to the infrastructure)
- Scientific board criteria
- Revision of the directive and discussion at global level: risk based approach (collect patients' feedback on acceptability of the risk) and « OECD GSF 'Working Group to Facilitate International Cooperation in Non-Commercial Clinical Trials »
- Training
- ECRIN Advisory Board

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Thank you