NETWORKING OF EUROPEAN REC`S

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EUREC, Secretary General

First steps of EUREC

- based on 2001 EC Directive on **good clinical practice in the conduct of clinical trials on medicinal products for human use** (2001/20/EC)

Directive on Good Clinical Practice (2001/20/EC)

General aim: to ensure that the **rights**, **safety** and **well-being** of those participating in clinical trials are **protected** by

- to ensure **good clinical practice** conducting clinical trials
- to **standardize procedures** for the competent authorities
- to require inspections against internationally accepted ethical **principles** and **standards**

➔ **reliability in the safety of clinical reserach**

Directive on Good Clinical Practice (2001/20/EC)

- **'ethics committee'**: **an independent body** in a Member State, consisting of healthcare professionals and non-medical members, whose responsibility it is **to protect the rights, safety and wellbeing of human subjects involved** in a trial and **to provide public assurance of that protection,** by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent;

Directive on Good Clinical Practice (2001/20/EC)

Article 6

Ethics Committee

1. For the purposes of implementation of the clinical trials, **Member States shall take the measures necessary for establishment and operation of Ethics Committees**.

2. The Ethics Committee shall give its opinion, before a clinical trial commences, on any issue requested.

First steps of a EU Network of RECs (EUREC)

- 2001 EC Directive on good clinical practice (2001/20/EC)
- 2002/2003 studies on RECs and training programs for REC members (funded by EC)
- 2004 invitation of the EC to design a network project for RECs
- 2005 EUREC Declaration

Common results of previous studies and initatives 2003/2004

- **structure and legal basis** of RECs in EU Member States **vary greatly**
- National Associations like those in the UK, Germany or France **do not exist in all countries**. (Other Countries have centralized systems.)
- Furthermore there is a need for an **exchange of experiences** and **training opportunities** for members of RECs
- not enough reliable **information** on the work and structure of RECs
- not enough European **teaching programs** and **teaching materials** to qualify REC members
- no platform of **exchange** and **communication** among European RECs
  - **➔need for networking**

First steps of EUREC (1)

- 2001 EC Directive on good clinical practice (2001/20/EC)
- 2002/2003 studies on RECs and training programs for REC members (funded by EC)
- 2004 invitation of the EC to design an EC funded network project for RECs
- 2005 EUREC Declaration

EUREC Declaration 2005

During the **Conference on Research Ethics Committees in Europe "Facing the Future together" in Brussels (27/28 Jan 2005)** representatives from national associations of Research Ethics Committees:

EUREC as a network….

- ….that is open to representatives of national associations or bodies of RECs
- ….that provides training opportunities
- ….that establishes a platform for exchange

EUREC Declaration
Brussels, 27 January 2005

- **Creation of a European Network of Research Ethics Committees - EUREC**
- Representatives from national associations of RECs decided to work together in order to maintain and develop high quality standards in the protection of human subjects in Europe.
- They committed themselves to create a network of national networks of RECs, called EUREC, open to national associations of RECs or to national RECs.
- The purpose of the network is to facilitate exchanges of knowledge, know-how and information, to disseminate teaching material among members and to be the interlocutor of the European Commission for aspects regarding local implementation of directives.
- Another purpose will be to conduct research on research (i.e. research on characteristics of biomedical research conducted on human beings), based on the activity of RECs, in order to facilitate understanding on what is ongoing and developed.
- An interactive website (www.eurecnet.org) will be created to share information and materials.
- To facilitate the achievement of the network's basic objectives, the founders will seek support via public funding from their individual national authorities as well as from the European Commission.

- **Under the auspices of: Povl Riis (Denmark), Carlos de Sola (Council of Europe) and Claude Huriet (France)**
- Signatories: François Chapuis (France), Elmar Doppelfeld and Michael Fuchs (Germany), Jozef Glasa (Slovak Republic), Ritva Halila (Finland), Finn Kamper-Jørgensen (Denmark), Dominique Sprumont and Hermann Amstad (Switzerland), Joze Trontelj (Slovenia), subsequently joined by Peter Rehak and Ernst Singer (Austria), Rena Vrahimi-Petridou (Cyprus) and Anneke Jensma (The Netherlands).

First steps of EUREC (2)

- 2001 EC Directive on good clinical practice (2001/20/EC)
- 2002/2003 studies on RECs and training programs for REC members (funded by EC)
- 2004 invitation of the EC to design a network project for RECs
- 2005 EUREC Declaration
- **2006-2009 first EUREC project**
  - **associations of RECs and REC members started to work together in a network**
  - **a website has been set up.**

First steps of EUREC (3)

- 2001 EC Directive on good clinical practice (2001/20/EC)
- 2002/2003 studies on RECs and training programs for REC members (funded by EC)
- 2004 invitation of the EC to design a network project for RECs
- 2005 EUREC Declaration
- **2006-2009 first EUREC project**
  - **associations of RECs and REC members started to work together in a network**
  - **a website has been set up.**
- **2011-2014 EUREC integrated in EURECNET**
  - **2012 registration of EUREC as e.V. (registered association)**
  - **2012/13 common commentary of all REC representatives in EUREC on the draft proposal of the EC on a regulation on medicinal products and clinical trials**

EUREC
A new European association 2012

- **§ 1 Name, Place of business**
- (1) The name of the Association shall be "European Network of Research Ethics Committees (EUREC)". The Association shall be listed in the register of associations ("Vereinsregister"). (...)

- **§ 2 Purpose**
- (1) The purpose of the Association shall be to **promote co-operation** between national Networks of Research Ethics Committees in Europe; and **harmonisation** of multidisciplinary ethical reviews to improve the protection of human subjects in all aspects of medical and health-related research involving human subjects, human material or data.
- (2) The Association shall undertake such activities that facilitate these purposes, for example **developing and maintaining a website, discussing and harmonising best practice, supporting training, and holding regular meetings of the membership.** For this purpose the Association shall collaborate with the EUREC Secretariat and make use of its office. The office shall be located in Bonn.

EUREC: a vision

- structuring an independent network of RECs in Europe that is able to exchange information on a regular basis and **gives RECs a voice in Europe**

- **Cooperation** with relevant groups like Competent Authorities, academics and researchers, other networks

challenges

- **difficulties to identify country representatives** who have a national mandate
  - therefore EUREC encourage national RECs to found national networks **(after 2012 associations in Poland, Spain have been founded)**

- **as reaction on a lack of communication and information** between RECs in EU member states
  - EUREC started with a series of workshops and a web-based communication system

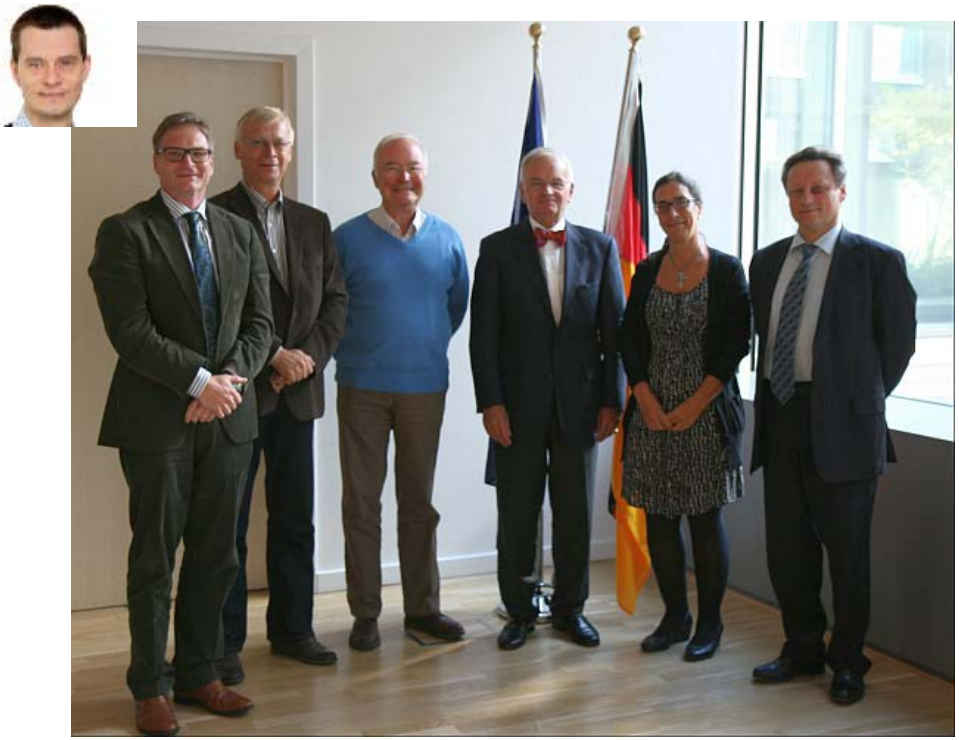
- **meeting the challenges of the EU Regulation**

➔ Biomedical Research itself will improve if those who evaluate such research have **a strong platform of exchange**

EUREC: recent activities

- cooperation with specific acitivities like the Human Brain Project (HBP) (multi centra, using biobanks…)
- cooperation with EMA to implement EU-Regulation and to set up the EU portal (expert group/stakeholder group)
- establishing a new network ENERI as European Network of Research Ethics and Reserach Integrity (in cooperation with ENRIO and ALLEA)
- cooperation with SATORI (Stakeholders Acting Together On the ethical impact assessment of Research and Innovation) to analyse the recent ethical review systems and to harmonise ethical assessments

EUREC Board 2015



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- Chair of EUREC Board

Elmar Doppelfeld

- Coordinator/ Secretary General

Dirk Lanzerath

- Coordination Assistance

Dorothee Güth

www.eurecnet.org