Meeting of the European Network of Research Ethics Committees (EUREC)

September 28/29, 2015 in Vilnius

Conference Venue:

Hotel Amberton Vilnius
Amber Conference Hall
L.Stuokos-Guceviciaus 1
LT-01122 Vilnius
Tel. +370 5 210 7461
Email: vilnius@amberton.lt

Monday, 28 September 2015

15.00 h – 15.30 h	**Welcome Coffee**
15.30 h – 16.00 h	**Opening of the meeting** - Adoption of the agenda - Approval of the minutes of the EUREC meeting in Maastricht - Report of the Chairman and Secretary General
16.00 h – 17.45 h	**Report of the Royal Netherlands Academy of Arts and Sciences (www.knaw.nl) as a guidance for stakeholders involved in the evaluation, use and regulation of medical devices** (Johannes Reitsma. Introduction by Saskia de Weerd)
17.45 – 18.30 h	**REC System in Belarus** (Andrei Famenka)
19.00 h	**Common dinner**

Tuesday, 29 September 2015

10.00 h – 10.45 h	**Presentation of the European Research Council (ERC)** (Victor Alves Gomes)
10.45 h – 11.30 h	**EU Portal – proceedings** (Joerg Hasford)
11.30 h – 12.30 h	**Round table discussion on implementation of CDT Regulation for identification of common problems and best practices (-> see appendix)** (Chair: Eugenijus Gefenas)
12.30 h – 13.30 h	**Lunch Break**
13.30 h – 14.30 h	**Round table discussion on EU debates on medical devices/ in vitro diagnostic medical devices** (Chair: Saskia de Weerd)
14.30 h – 15.30 h	**General Meeting EUREC e.V.** - Cooperation with ENRIO - EUREC Statute - Any other business
15.30 h	**End of conference**

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Appendix:

Round table discussion to share Research Ethics Committees' experiences and current or possible future national practices on the following issues:

1) **The legal requirements/criteria of suitability of the investigators to conduct clinical drug trials and other types of biomedical research**

Article 49 of the REGULATION (EU) No 536/2014 on clinical drug trials says that "The investigator shall be a medical doctor as defined in national law, or a person following a profession which is recognized in the Member State concerned as qualifying for an investigator because of the necessary scientific knowledge and experience in patient care". Paragraph 65 of Annex I says that "Description of the qualification of the investigators in a current curriculum vitae and other relevant documents shall be submitted. Any previous training in the principles of good clinical practice or experience obtained from work with clinical trials and patient care shall be described". Following our long-lasting experience of scientific and ethical review of clinical trials, it seems that these requirements are too general and there is a need for more specificity. Especially, taking into account the provision of the Preamble (para 45) which says that "The individuals involved in conducting a clinical trial, in particular investigators and other healthcare professionals, should be sufficiently qualified to perform their tasks, and the facilities where a clinical trial is to be conducted should be suitable for that clinical trial. Taking into consideration the provisions of Article 49, para 65 of Annex and para 65 of the Preamble, do Member States feel the need to introduce more detailed and specific requirements for the investigators? If so, what requirements do they suggest? What requirements do they have now? (e.g. a medical license in a particular medical field relevant to the clinical trial? precise number of years of clinical practice? number of hours of GCP training? etc.).

2) **The legal requirements/criteria of suitability of clinical trial sites**

Article 50 of the REGULATION (EU) No 536/2014 on clinical drug trials says that "The facilities where the clinical trial is to be conducted shall be suitable for the conduct of the clinical trial in compliance with the requirements of this Regulation". Similar problem as with the requirements for the investigator - do Member States feel the need to introduce more detailed and specific requirements for the clinical trial sites? If so, what requirements do they suggest? What requirements do they have now? (e.g. a license to provide health care services in a particular medical field relevant for the procedures foreseen by particular clinical trial protocol? others?)

3) The national systems for damage compensation for research subjects

Article 76 of the REGULATION (EU) No 536/2014 on clinical drug trials says that "Member States shall ensure that systems for compensation for any damage suffered by a subject resulting from participation in a clinical trial conducted on their territory are in place in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk". What national systems for damage compensation do Member States have now? Is there any possibility introduced to cover clinical drug trials by the global insurance, if so, under what conditions?

4) The issues of data protection in the clinical drug trials

Article 7 of the REGULATION (EU) No 536/2014 on clinical drug trials says that national assessment of the clinical drug trial must cover the evaluation of the compliance with the Data Protection Directive 95/46/EC. Which entity (if any) does the evaluation now and how? Does the national legislation require to carry out the prior checking of the data that are planned to be used in the clinical drug trial or any other biomedical research study? If so, under what conditions? Do
Member States feel the need to change the current practices following the mentioned provision of the Article 7 of the Regulation?

The discussion on the above mentioned issues would be particularly relevant for better understanding how European countries deal with these issues now and how they plan to deal with them after the REGULATION (EU) No 536/2014 on clinical drug trials is in force as well as for identification of common problems and best practices.