Information about regulatory systems in European countries

ESO Trials Network Committee

1 Introduction

Investigators of multi-national trials need information about rules and regulations for clinical trials in the different countries.

2 Ethics Committees

2.1 European Network of Research Ethics Committees (EURECNET) (http://www.eurecnet.org)

EURECNET is a network that brings together national Research Ethics Committees (REC) associations, networks or comparable initiatives on the European level. One of the aims is to "gather information on RECs in Europe to build a basis for mutual exchange". The EURECNET website includes a database of:

- RECs systems in European countries
- Legislation for RECs in these countries
- Literature relevant for the REC systems in these countries

2.2 European Forum for Good Clinical Practice (EFGCP) (http://www.efgcp.be)

EFGCP is a non-profit organisation established by and for individuals with a professional involvement in the conduct of biomedical research, with the support of the European Commission. EFGCP is a leading European think tank for discussion, research, and critical evaluation in the development of European health research. Its purpose is to promote good clinical practice and encourage the practice of common, high-quality standards in all stages of biomedical research throughout Europe. The website give:

- An overview of the procedures of RECs in the European countries.
- Links to related national and international organisations and institutions
- Information about EFGCP Annual Conferences and other meeting

3 Competent Authorities

Heads of Medicines Agencies (HMA) (http://www.hma.eu)
The HMA is a network of the Heads of the national competent authorities whose organisations are responsible for the regulation of medicinal products for human and veterinary use in the European Economic Area. It contains:

- a directory of the competent authorities in all European countries.

4 Regulatory systems in general

4.1 EU Legislation (Eudralex) (http://ec.europa.eu/health/documents/eudralex/index_en.htm)

Eudralex is the EU legislation for medicinal products for human use. The legislation is supported by regulatory and scientific guidelines for medicinal products, guidelines for good manufacturing practices, guidelines for pharmacovigilance, and guidelines for clinical trials.

4.2 European Clinical Research Infrastructures Network (ECRIN) (http://www.ecrin.org)

ECRIN is a not-for-profit infrastructure supporting multinational clinical research projects in Europe. ECRIN provides information, consulting and services to investigators and sponsors in the preparation and in the conduct of multinational clinical studies, for any category of clinical research and in any disease area. For example, ECRIN is partner of the EuroHyp project on stroke treatment. Support to projects is provided by the distributed infrastructure connecting national ECRIN partners (networks of Clinical Research Centers or Clinical Trials Units).

ECRIN is now developing a repository for clinical research, the ECRIN Campus. The website will encompass features such as:

- Public access to the information collected by ECRIN on clinical research in Europe:
- Practical information on and requirements for a submission of a clinical trial application to competent authorities and ethics committees
- General information on competent/regulatory authorities and ethics committees (composition, organisation, rules, fees, requirements)
- Definition and information for different types of studies or different type of population
- Information about the regulations for data inspectorates and insurance arrangements in the different countries.
- The Campus will be launched by the end of the year following final validation by the ECRIN European correspondents and regulatory experts. The ESO Trials Network Committee will be asked to act as a peer reviewer for ECRIN Campus. (See http://www.ecrin.org/index.php?id=29.)

ESO may choose to become an ECRIN-ERIC Scientific Partner, which will give full access to ECRIN Campus. If ESO prefers to be an Affiliate Partner, we will have access only to ECRIN Compass, which is a "light" version.

4.3 TREAT-NMD Neuromuscular Network (www.treat-nmd.eu/regulatoryaffairs)

This database was made by the Clinical Trials Unit Freiburg as project partner of the TREAT-NMD Neuromuscular Network. The aim was to provide a valuable source of advice to people who are involved in the planning of mono- or multi-centre clinical trials within different European countries.

As a result of the cooperation between TREAT-NMD and ECRIN, country-specific information has been updated, and new sections for additional countries have been included. Currently, the database contains regulatory clinical trial information for 14 European countries as well as relevant European and international regulations and guidelines. For the future it is planned to make the information available via the ECRIN webpage.