Question 9

How many (research) ethics committees are there in the country?

Austria  Hungary  Romania
Belgium  Iceland  Russia
Bulgaria  Ireland  Serbia
Croatia  Italy  Slovakia
Cyprus  Latvia  Slovenia
Czech Republic  Lithuania  Spain
Denmark  Luxemburg  Sweden
Estonia  Malta  Switzerland
Finland  Netherlands  Turkey
France  Norway  United Kingdom
Germany  Poland  
Greece  Portugal  
Austria

There are about 26 (research) ethics committees in Austria.

According to the law (Hospital Act) every hospital needs to have a (research) ethics committee that has to review applications for clinical trials. Additionally the province authorities have to establish (research) ethics committees for clinical trials in institutions outside of hospitals (outpatients). This applies to clinical trials with drugs as well as to clinical trials with medical devices and methods. However, it is possible that one Ethics Committee is the competent committee for several hospitals.

Belgium

There are currently about 215 committees. The majority are associated with hospitals and some are associated with non-hospital institutions. Until the 31st of March 2012, 38 of these research ethics committees have the full recognition.

Bulgaria

Currently there are 103 approved ethics committees that can give opinion on trials to be performed at the specific site.

Croatia

The Central Ethics Committee is responsible for clinical trials on investigational medicinal products performed in Croatia, although local ECs have been set up in universities and hospitals but they are only authorized to review local studies that do not fall under the jurisdiction of the national Central Ethics Committee.

Cyprus

There are three, but please refer to question number (2) above.

Czech Republic

There are 11 Multicentre RECs and nearly 100 Local RECs.

Denmark

Eleven.

Estonia

There are two Ethics Committees on Human Research that have equal rights to review all kinds of human studies and medical research:
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1. Research Ethics Committee of the University of Tartu.
2. Tallinn Medical Research Ethics Committee (attached to the National Health Development Institute).

**Finland**

There are 9 districts or research institute ethics committee, established by the university hospital districts.

**France**

40 CPPs.

**Germany**

Germany has a total of 53 research ethics committees for all kind of biomedical research including clinical trials with pharmaceutical drugs and medical devices, and clinical research with radiation (for the last the REC must be registered at the Bundesamt für Strahlenschutz, BfS).

**Greece**

There is one central (National Ethics Committee) and one in each hospital (Local Ethics Committee/Institutional Review Board).

**Hungary**

Only one single.

**Iceland**

Three, see Art. 3 and 4 of Reg. 286/2008.

**Ireland**

Thirteen.

**Italy**

According to the Italian Register of Ethics Committees, a section of the database of the National Monitoring Centre of Clinical Trials (OsSC), there are 264 Ethics Committees in Italy. They are continually developing after the Ministerial Decree that has given the minimum requirements for Ecs and the following transposition to Regional Laws. The number at regional level are: Valle D’Aosta (0), Piemonte (7), Lombardia (62), Trentino-AltoAdige (3), Veneto (11), Friuli-Venezia Giulia (7), Liguria (10), Emilia-Romagna (9), Toscana (13), Marche (9), Umbria (10), Lazio (34), Abruzzo (6), Campania (25), Puglia (12), Basilicata (4), Calabria (13) Sicilia (28), Sardegna (10).
Latvia

Four, other than the Central Medical Ethics Committee (CMEC). They are the Ethics Committees of the Latvian Institute of Organic Synthesis Clinical Research Unit, of the Latvian Institute of Cardiology, of the Centre for Infectious Diseases, and currently one other. There is no upper limit specified.

Lithuania

There are three EC in Lithuania responsible for the ethical review of biomedical research projects: the LBEC, the Biomedical Research Ethics Committee based in Vilnius and the Regional Biomedical Research Ethics Committee based in Kaunas.

Luxemburg

Only one, the National Research Ethics Committee (Comité National d'Ethique de Recherche, CNER).

Malta

Only one that has the power of approval (the HEC), but other advisory ethics committees are also established at the University of Malta, at the Medical School of Malta and at the Institute of Health Care.

Netherlands

Twenty-seven accredited METCs and the CCMO.

Norway

There are five regional committees in Norway, which correspond to the National Health Service organisation are: Eastern, Southern, Western, Central and Northern.

Poland

There are 52 Regional Bioethics Committees and one Appeal Bioethics Committee in the Ministry of Health*.

The 52 Regional Committees comprise:

- 12 appointed by the Medical Universities.
- 17 appointed by the Medical or Scientific Institutes.

*Source: Czarkowski M, Różanowski K. Polish Research Ethics Committees in the European Union system of assessing medical experiments. Sci Eng Ethics. 2009 Jun;15(2):201-12 (See 41A below) for an abstract of this article).
• 23 appointed by the Regional Chambers of Physicians and Dentists. They are all recognised for the review of all clinical trials with IMPs.

**Portugal**

There is only one (the CEIC) that is responsible for assessing CTIMP applications, though it may delegate to a research ethics committee established by a local health institution. By law all health care institutions must have an institutional ethics committee that have also the responsibility for the evaluation of all clinical research with human beings except in what concerns clinical trials with human medicines.

**Romania**

To receive the approval to begin a clinical trial, it is mandatory to obtain the favourable opinion of NECCT. The other local EC’s have only consultative tasks.

**Russia**

One central committee, the Council on Ethics of Ministry of Health and Social Development and a lot of local research ethics committees (in Hospitals, Universities and etc). The exact number is not listed.

**Serbia**

Hospitals/clinics have their own LEC that reviews CT applications. There are approximately 30 LECs in Serbia.

**Slovakia**

There are 8 regional ethics committees, and about 60 “local” ethics committees. According to the law each inpatient health care facility in Slovakia should have an ethics committee, which is expected to assess applications for the ethical review of clinical trial protocols to be conducted at that facility. If chosen by the sponsor, that committee may give “the single opinion” for a multi-site clinical trial.

The addresses and other contact details of all regional and all functioning “local” ethics committees can be found in the list given at the web page of the Ministry of Health of the Slovak Republic – web link to the document:

http://www.health.gov.sk/redsys/rsi.nsf/0/1F79D6C7C9726858C12574C7004104A7?OpenDocument&ID=&TYPE=U&LANGUAGE=S&LENGTH=S or at the web page of S IDC:
Slovenia

One, the NMEC. Local (research) ethics committees have been set up at university and regional hospitals but they are only authorised to review local studies that do not present any serious risk to the participants. They are also invited to give a preliminary review of the protocols of all studies to be carried out at the local level, and to monitor their progress after they had been approved by the NMEC.

Spain

There are one hundred and thirty six EC. They are periodically updated in the previously mentioned annex 4 of “Aclaraciones…”.

Sweden

There are six independent Regional Boards for Research Ethics Review, each chaired by a judge, as well as a Central (National) Board for research ethics review. The regional boards are situated in Gothenburg, Linköping, Lund, Umeå, Uppsala and at the Karolinska Institute in Stockholm. Most boards have one committee reviewing both medical and non-medical research; however, Gothenburg has two separate committees: one for reviewing medical research and one for non-medical research. And Stockholm (the Karolinska) has five committees, four reviewing medical research and one reviewing non medical research. The national (central) EC (for appeal) is located in Stockholm.

Switzerland

Twelve with full responsibilities, recognised by the Cantonal authorities. Several act for two or more cantons. However in three cantons (Geneva, Vaud and Zurich) the cantonal RECs are subdivided in sub-commissions, but without the competence to finally approve a protocol. A complete and updated list of Swiss EC’s is maintained at http://swissethics.; http://www.swissethics.ch.

Turkey

N/A

United Kingdom

In April 2012 there were 104 Research Ethics Committees in the UK (England 828, Scotland 11, Wales 8, and Northern Ireland 3).

Not all RECs are recognised to review CTIMPs and some RECs can be both Type 1 (recognised to review phase 1 trials in healthy volunteers for the whole of the UK) and Type 3 (recognised to review trials in patients for the whole of the UK).

Of the total of 104 RECs, there are:
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- 27 Type 1 recognised committees.
- 62 Type 3 recognised committees.

In addition many universities also have research ethics committees for studies which do not involve patients (more details from the Association of Research Ethics Committees at http://www.arec.org.uk/). These RECs are not part of the UK Health Departments’ Research Ethics Service and are not included in the above figures.

April 2012
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