Question 44

If the answer to Question 42 is ‘yes’, is this register of clinical trials made available to the public?

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<th>Austria</th>
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<td>Greece</td>
<td>Portugal</td>
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</tbody>
</table>
The EFGCP Report on
The Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe
(Update: April 2012)

Austria
N/A.

Belgium
N/A.

Bulgaria
Information not available.

Croatia
N/A.

Cyprus
The Competent Authority for clinical trial registration is the Drugs’ Council.

For more information the interested person may contact the Pharmaceutical Services of the Ministry of Health of the Republic of Cyprus for more information at:
Tel: +357 22 407107
Fax: +357 22 407149
E-mail: phscentral@phs.moh.gov.cy
Website: www.moh.gov.cy/phs

Czech Republic
Yes.

Denmark
No.

Estonia
N/A.

Finland
N/A.
France


Germany

The DIMDI data base for trials with medical devices is not available to the public. The Deutsches Studienregister is public and free of charge.

Greece

N/A.

Hungary

Not at present. After the decision of the public part of EudraCT will this issue be addressed nationally?

Iceland

N/A.

Ireland

N/A.

Italy

Information not available.

Latvia

N/A.

Lithuania

N/A.

Luxemburg

N/A.
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Malta

Information not available.

Netherlands

Yes, the trial register is made available to the public.

Norway

N/A.

Poland

No, the register is not available to the public, but on the request of any interested person the chief of the competent authority (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products) may give a permission to present some data.

Additional information


Abstract

The Polish equivalents of Research Ethics Committees are Bioethics Committees (BCs). A questionnaire study has been undertaken to determine their situation. The BC is usually comprised of 13 members. Nine of these are doctors and four are non-doctors. In 2006 BCs assessed an average of 27.3 ± 31.7 (range: 0–131) projects of clinical trials and 71.1 ± 139.8 (range: 0–638) projects of other types of medical research. During one BC meeting an average of 10.3 ± 14.7 (range: 0–71) projects of medical research were assessed (2006). The amendment of Polish laws according with Directive 2001/20/EC caused a percentage increase in BCs which assessed less than 20 projects per year (16% vs. 33% or 42% in 2003 vs. 2005 or 2006 respectively, p < 0.05). The results confirm the usefulness of the current practice of creating BCs by medical universities, medical institutes and regional chambers of physicians and dentists but rationalization of the workload for individual BCs is necessary.

Keywords Research ethics committees - Bioethics committees - Clinical trials - Medical research – Polish

Portugal

N/A.
Romania

N/A.

Russia


Serbia

N/A.

Slovakia

Information not available.

Slovenia

Information not available.

Spain

N/A.

Sweden

N/A.

Switzerland

No.

Turkey

Information not available.

United Kingdom

In the case of clinical trials, with the launch of Version 8 of the EudraCT database in February 2011, all trials are now registered in the publicly accessible area of EudraCT.

In addition, sponsors may register trials on publicly available databases such as ClinicalTrials.gov and ISRCTN.
In addition, the Health Research Authority publishes a summary of the trial on its website, together with the outcome of the ethical review.

April 2012

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