The EFGCP Report on
The Procedure for the Ethical Review of Protocols for
Clinical Research Projects in Europe and Beyond

Question 35

How does the REC ensure reception of the Annual Safety Report and the Summary of the Final Report of a research project that it has approved?

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Austria

No processes yet in place.

Belgium

This is not defined.

Bulgaria

Submission of final report and annual progress report is an official requirement to the investigator. These requirements are additionally outlined in the text of the approval decision.

Croatia

It is the responsibility of the sponsor to ensure that Annual Safety Reports (ASRs) and the Summary of the Final Report are submitted. These are required by law. The Central EC discusses the ASR and the Final Report at the official, regular meetings and that is confirmed in writing. According to the By-law 29/05 on the monitoring of adverse drug and medical devices reactions and adverse events, if the report of a serious AE is not expedited, the responsible person may be fined with an assigned penalty of EUR 4000-7000.

Cyprus

Submission of an annual safety report is not compulsory. Information about the progress of a study is obtained via the standard forms of CNBC available at its website (Form EEBK 05 Follow up, Form EEBK 06 Completion of a study, Form EEBK 07 Program Interruption etc).

Czech Republic

According to our law the sponsor has to send the ASR to the MREC and to the LREC if asked. Summary of Final Report is not yet asked for.

Denmark

According to the law a regional committee may follow the course of a project and request that the final research report or publication be sent to the committee. The committee will therefore send a request.

It is also laid-down in the law that once a year during the entire research period the sponsor or the investigator shall to the committee submit a list of all serious adverse reactions and all serious events encountered during the period and shall provide information about the safety of the trial subjects.
Estonia

It is required by law and demanded if it is not submitted.

Finland

They note them as they are received.

France

Not yet defined.

Germany

It is not the duty of RECs to ensure reception, rather it is the duty of the sponsor to ensure provision of these documents to RECs (according to GCP Decree § 13).

Greece

A protocol number is given upon submission as a receipt.

Hungary

It is required by law.

Iceland

Researchers are reminded to send reports when final approval is given, and prompted for such reports in they are not sent in.

Ireland

It is the responsibility of the sponsor to ensure that annual safety reports are submitted. The ethics committee administrator will issue reminders if annual progress reports or annual safety reports are not submitted and a reminder letter 12 months after the declaration of the end of the trial if the summary final report has not been received.

Italy

Not yet defined.
Latvia

Submission of the Reports to the EC and SAM is required by legislation.

Lithuania

According to the Decree No. 435 of the Ministry of Health on the Procedure for Issuing Favourable Opinion to Conduct Clinical Trial on Medicinal Product, Approval for Clinical Trial on Medicinal Product, Conducting and Controlling Clinical Trials it is the responsibility of the sponsor to ensure that annual safety reports are submitted. For further information please refer to the website of the LBEC: http://bioetika.sam.lt/index.php?428692189.

Luxemburg

Through a regular monitoring performed by the CNER secretariat.

Malta

The HEC was only established in March 2005. However, each clinical trial is tracked.

Netherlands

The internet portal ToetsingOnline (ReviewOnline) described briefly (see Question 34 above) will automatically generate e-mail alerts for investigators/sponsors and METCs. One of the alerts concerns a message to the investigator/sponsor that they are requested to submit their annual safety reports. Upon receipt, the investigator/sponsor will receive a message that the annual report has arrived.

Norway

There is no system to ensure reception or follow up of missing reports.

Additional information:

The Act of 30 June 2006 No 56 on ethics and integrity in research.

Section 1: Purpose of the Act

This Act seeks to ensure that research carried out by public and private institutions is conducted in accordance with recognised ethical standards.

Section 2: Autonomy

Committees and commissions appointed pursuant to this Act shall be state bodies that are autonomous in professional matters.
Section 3: National research ethics committees

National research ethics committees that collectively cover all disciplines shall be established. These committees shall serve as advisory bodies on research ethics. The Ministry will establish such committees, determine the committees’ fields of responsibility and appoint members.

The committees shall have expertise in relevant research disciplines, ethics and law. They shall also have lay members.

Section 4: Regional committees for medical and health research ethics

Regional committees for medical and health research ethics shall be established. The Ministry will establish such committees, determine the committee’s fields of responsibility and appoint members. Members shall be appointed on the basis of proposals from relevant bodies. The committees shall have expertise in relevant research disciplines, ethics and law. They shall also have lay members.

Research projects in Norway that involve experiments on human subjects shall be submitted to the committee for approval. Research projects conducted outside Norway shall be submitted to the committee for approval if the research is being carried out by a researcher employed by a Norwegian employer or if a substantial portion of the funding comes from Norway.

Appeals against decisions made by the committees may be lodged with the National Committee for Medical and Health Research Ethics. The decision of the National Committee is final and may not be further appealed.

Section 5: The National Commission for the Investigation of Scientific Misconduct

A national commission for the investigation of scientific misconduct shall be established. The commission shall give a statement as to whether scientific misconduct has occurred in research conducted in Norway. The commission shall also give a statement on research conducted outside Norway if the research has been carried out by a researcher employed by a Norwegian employer or if a substantial portion of the funding comes from Norway.

Scientific misconduct is defined as falsification, fabrication, plagiarism and other serious breaches of good scientific practice that have been committed wilfully or through gross negligence when planning, carrying out or reporting on research.

The members of the commission shall be appointed by the Ministry. The commission chair shall have judicial experience. The composition of the commission shall ensure that the commission has the necessary expertise in the field of research and research ethics.

The commission may in individual cases decide that the documents relating to a case shall not be made public until a final statement has been given.
The Ministry is the administrative appeals body for appeals regarding the administrative procedures of the commission. Appeals regarding the content of the statement shall be dealt with by a specially appointed commission. A special commission shall be appointed for each appeal and shall comprise members with the necessary professional or technical, research ethics and legal expertise. The decision of the special commission is final.

Section 6 Regulations

The Ministry may make supplementary regulations regarding the appointment and administrative procedures of committees and commissions pursuant to this Act.

Section 7 Commencement

This Act shall enter into force from the date decided by the King.

Poland

Order of the Minister of Health concerning detailed requirements of Good Clinical Practice and last amendments of the Pharmaceutical Act regulates these requirements.

Portugal

These are required by law and by the European guidance.

Romania

The NECCT receives the Annual Safety Reports. It does not receive the final reports.

Russia

It is a requirement of the research ethics committee that these reports are submitted.

Serbia

In accordance with local regulations. Four centres with websites are at:

www.klinicki-centar.rs (website of Clinical centre of Serbia)
www.kcv.rs (website of Clinical centre of Vojvodina)
www.kcnis.co.rs (website of Clinical centre of Nis)
www.kc-kg.co.rs (website of Clinical centre of Kragujevac)

Slovakia

ECs appear passive in this regard. The obligation to provide these reports, however, is provided for by law and lays responsibility for providing these reports on the sponsor. They should, therefore, be sent to the EC in a timely manner.
The ability of ECs to process/consider these documents, however, is questionable.

The website for the Slovak Ministry of Health is at http://www.health.gov.sk.

For applications for drug clinical trials authorizations to the State Institute for Drug Control (SIDC) for phase I – III drug CTs, and for notifications of CTs for phase IV drug CTs, the Note for Guidance No. 7/2008 of SIDC for applicants for the authorization of drug clinical trials is relevant – the web link to the document:

http://www.sukl.sk/buxus/docs/Klinicke_skusanie_liekov/Pokyny/Metodicky_pokyn_klin_skus_revizia_2_1_2009.pdf

The term “ethics committee” is defined in general terms (for any biomedical research) in the Law No. 576/2004 Coll. on health care.

Some additional specifications for drug CTs – according to the principles and requirements of Good Clinical Practice – are provided for in the relevant paragraphs of the Law No. 140/1998 Coll. on drugs and medical devices (as later amended) and the Ministry’s of Health Regulation No. 239/2004 Coll. on clinical investigations and good clinical practice.

Registration or even accreditation of ECs is foreseen in Slovakia, which would allow for quality assurance of their establishment, composition (competence) and work. This is to be provided for by the ministerial regulation on ECs, which is pending.

**Slovenia**

The NMEC has no means or power to ensure reception of these documents. However, it is felt that the policy of sponsors, following international regulations and recommendations regarding monitoring of studies, should suffice.

**Spain**

This is not yet known.

**Sweden**

They do not. They file any reports that are sent to them.

**Switzerland**

Control by the secretary of the REC.

**Turkey**

ECs follow-up the studies according to timelines. The first annual report should be
submitted one year after the approval date of MoH and then yearly submission should be done until the end of study. After all the study patients have completed the study in all sites in Turkey, then the Final Report should be submitted.

The responsibility to ensure regular submission of the reports to the relevant general directorate rests with the sponsor.

**United Kingdom**

It is the responsibility of the sponsor to ensure that the ASR/DSUR is submitted. If it comes to light that the sponsor has failed to submit the report, the REC Co-ordinator will report the matter to the committee and will issue a reminder to the sponsor. The MHRA inspectors may also be notified.

REC Co-ordinators will also issue reminders if annual progress reports are not submitted.

The REC Co-ordinator will issue a reminder letter 12 months after the declaration of the end of the trial if the summary final report has not been received.

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