



EUROPEAN COMMISSION  
ENTERPRISE DIRECTORATE-GENERAL

Single market : management & legislation for consumer goods  
**Pharmaceuticals : regulatory framework and market authorisations**

Brussels,  
ENTR/CT 2

**Revision 1**

**Detailed guidance on the application format and  
documentation to be submitted in an application  
for an Ethics Committee opinion on the clinical  
trial on medicinal products for human use**

**April 2004**

## Table of contents

	Page
1. Introduction	2
2. Legal Basis	2
3. Scope	2
4. Definitions	3
5. Contacts with the Ethics Committee.	3
6. Format and content of application to the Ethics Committee	3
6.1 Before commencement of a clinical trial.	3
6.2 During the conduct of the trial.	9
6.3 After end or termination of the trial.	10
7. Appended documents	
7.1 Addresses to the competent authorities and/or where information on the Ethics Committee system in the Member States in the European Union can be obtained.	12
7.2 Information to be forwarded to the Ethics Committee in different Member States.	17
7.3 Request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities and for opinion of the Ethics Committees in the European Union.	
Module 1: EU application form,	23
Module 2, optional form exemplifying information for the Ethics Committee	
7.4 Advertising for trial subjects.	26
7.5 . Content of subject information	28

## **1. Introduction**

This detailed guidance should be read in the light of the requirements of Directive 2001/20/EC<sup>1</sup>. It is a requirement of the Directive that a clinical trial on a medicinal product for human use may not start until the appropriate Ethics Committee has issued a favourable opinion. This detailed guidance is intended to provide advice on the format and content of an application for an ethics committee opinion on a proposal to undertake such a trial and should be followed unless otherwise justified.

The Community guideline on Good Clinical Practice (CPMP/ICH/135/95)<sup>2</sup> as adopted by the Committee for Proprietary Medicinal Products and published by the Agency provides useful additional guidance on the responsibilities of the Ethics Committees and other relevant issues.

## **2. Legal Basis**

Article 8 of Directive 2001/20/EC requires the Commission, in consultation with Member States and interested parties, to draw up and publish detailed guidance on the application format and documentation to be submitted in an application for an ethics committee opinion on a clinical trial on a medicinal product for human use. This should in particular be regarding the information that is given to subjects, and on the appropriate safeguards for the protection of personal data.

The Directive also requires certain documents to be submitted to the Ethics Committee for consideration or information during the conduct of and at the termination of the trial.

This detailed guidance is intended to fulfil the obligations laid down in the Directive.

## **3. Scope**

This detailed guidance applies to the format and accompanying documentation of the application for an Ethics Committee opinion on a clinical trial on a medicinal product for human use before commencing a trial.

This detailed guidance also covers the documentation to be forwarded to the Ethics Committee during the conduct and at the termination of the trial to allow the Ethics Committee to fulfil its obligations according to the Directive and the principles of Good Clinical Practice (GCP).

---

<sup>1</sup> Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

<sup>2</sup> Notes for guidance CPMP/ICH/135/95

If substantial amendments to the protocol are requested after the start of the trial the Ethics Committee is required to give its opinion on the proposed changes. The documentation to be submitted to the Ethics Committee in such cases is also described in this guidance.

The required exchange of information between the competent authority and the Ethics Committee according to Directive 2001/20/EC is also outlined.

#### **4. Definitions**

The definitions which are provided in Directive 2001/20/EC are applicable. For additional terms used in this guideline the definitions provided in Community guideline ICH/CPMP/135/95 apply.

#### **5. Contacts with the Ethics Committee**

Member States shall adopt procedures to reach one single Ethics Committee opinion per Member State on a proposed multi-centre trial without excluding the possibility of rejecting it at specific sites. The procedures established to reach this single opinion, are outside the scope of this guideline.

The single opinion on the application for the proposed clinical trial should be reached within the timeframe stipulated in the Directive.

The Ethics Committee shall give its opinion within the scope of its responsibilities as defined in the Directive and in accordance with national regulations.

The review by the Ethics Committee may take place sequentially or in parallel with the review by the competent authority, according to the choice of the applicant.

The applicant for an Ethics Committee opinion is not defined in the Directive and can thus be either the sponsor, or the principal investigator (multi-centre trials: co-ordinating investigator) according to national provisions.

Attachment 1 to this guideline lists the addresses to the competent authorities in each Member State where further information on the national systems and procedures for the work of the Ethics Committees can be obtained.

#### **6. Format and content of application to the Ethics Committee**

##### **6.1. Before commencement of a clinical trial**

###### **6.1.1. Request for the opinion of the Ethics Committee**

Initially the submission is checked to see whether it is valid or not. This is an administrative verification of all documents that the application form indicates have been submitted. If a document has been omitted by the applicant, this must be specifically justified.

The application to the Ethics Committee is considered to be valid if it fulfils the requirements listed below. If that is the case the applicant will be informed and the review period starts. If the application is not valid the applicant will be informed of the deficiencies.

Under certain circumstances and according to national requirements an abridged application might be sufficient. For example, if an Ethics Committee already has substantial information from a previous related application from the same applicant, cross-reference can be made.

For research at a single site, the application form should be signed by the sponsor or the sponsor's legal representative and/or by the principal investigator responsible for the conduct of the trial at the site, according to regulations in each Member State. In multi-centre trials the application form should be signed by the sponsor or the sponsor's legal representative and/or by the co-ordinating investigator, who is responsible for co-ordinating the work of the principal investigators at the different sites in that Member State, according to national regulations.

When information is submitted both to the Ethics Committee and the competent authority, the Ethics Committee shall give its opinion based on the same version of the documents that have been or will be submitted to the competent authority.

### **6.1.2. Information to be supplied**

To be valid an application should contain the information listed in attachment 2 to this guideline, unless otherwise justified.

All documents should carry the trial identification (sponsor's protocol code number, date and/or version) as well as the version and/or date of the particular document (e.g. when there have only been revisions of the subject information sheet).

The information needed for the review by the Ethics Committee might vary according to the differences in responsibilities assigned to the Ethics Committees in the Member States. Attachment 2 gives information on the specific requirements in each Member State.

#### **6.1.2.1. The application form**

The application should state the EudraCT number obtained for that clinical trial. The procedure for allocating this number is described in the Commission guideline<sup>3</sup>.

The application form to the Ethics Committee might be composed of two modules. One should be common for all Member States and one according to the national requirements in the concerned Member State. An example of the application form to be used in the application to the Ethics Committee is given in section 7.3 of this guideline.

The module common for all Member States should be identical to the application form that has to be used in the submission to the competent authority (see the Commission guideline<sup>4</sup>). This common module contains information on the administration of the trial, identifying the sponsor or legal representative of the sponsor and the principal investigator or the co-

---

3 Detailed guidance on the European clinical trials database (EUDRACT Database)

4 Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities in the European Union, notification of substantial amendments and the declaration of the end of a clinical trial

ordinating investigator for multi-centre trials. There will also be information on the investigational medicinal products.

For multi-centre trials a list should be given of the principal investigators and the sites that plan to participate in the conduct of the trial. Some basic information on the design of the proposed trial should also be given to allow an easy overview of the trial design and an evaluation of the expertise needed for the review.

The second module that is proposed to be used and specific for each Member State could then contain headings that might be helpful for the ethical review by the Ethics Committee. The aim of the example given in section 7.3 of this guideline is to provide guidance on how trial and site specific information might be presented. The list of items addressed is not complete and should be modified according to the responsibilities assigned to the Ethics Committee in the Member State. It is thus not mandatory to use this second module in the application to the Ethics Committee. It is only included in section 7.3 to present one possible way to present the ethical issues and describe the trial in lay language.

#### **6.1.2.2. Information on the investigational medicinal product**

The application form contains the information required to identify the investigational medicinal product(s), the pharmaceutical form(s) and strength(s), dose(s) route(s) of administration and treatment period(s).

Information on the investigational medicinal product(s) is provided in the Investigator's Brochure (IB). The Investigator's Brochure should reflect all the clinical and non-clinical data on the investigational medicinal product(s) which is relevant for the trial and provide evidence that supports the rationale for the proposed clinical trial and the safe use of the product(s) in the trial.

If the investigational medicinal product has a marketing authorisation in any Member State in the Community and the product is to be used as authorised, the Investigator's Brochure could be substituted by the authorised Summary of Products Characteristics (SmPC).

In some Member States the Ethics Committee is responsible for the review of the more extensive quality aspects and pre-clinical documentation included in the Investigational Medicinal Product Dossier (IMPD). The information that should be included in the IMPD is described in the Commission guideline<sup>4</sup>. Attachment 2 shows which Member States require the IMPD to be included in the submission to the Ethics Committee.

#### **6.1.2.3. The clinical trial protocol**

The trial protocol should be identified by: the full title, the sponsor's protocol code number, version and date, and, if available, also by name or abbreviated title. It should be dated and signed by the sponsor and the principal investigator at the site (for multi-centre trials: the co-ordinating investigator).

The protocol should contain the information outlined in the Commission guideline<sup>4</sup> and listed in the Community guideline CPMP/ICH/135/95<sup>5</sup>.

The end of the trial should preferably be defined in the protocol. If this is not the last visit of the last subject undergoing the trial in the Member State, the reason should be given.

---

<sup>5</sup> Guideline on Good Clinical Practice in the conduct of clinical trials on medicinal products for human use.

There should also be a description of the plan for the provision of any additional care of the subjects once their participation in the trial has ended, where it differs from what is normally expected according to the subject's medical condition.

In addition to the full protocol, a summary of the protocol in the national language should be submitted when required according to national provisions.

A justification for the selection of trial subjects, especially when including subjects who are incapable to giving informed consent, should be given.

Some arrangements specific for the Member State or site might be described in separate documents. For example, the financial agreements between the sponsor and principal investigator or site, the publication policy and the investigators' access to the data might be in an agreement separate from the protocol. Copies of these agreements should be included in the application.

#### **6.1.2.4. Recruitment arrangements**

The procedures for enrolment of subjects should be described in detail in the trial protocol or in a separate document if it varies between sites. This description as well as the reasons for selection of the subject group is of special importance in studies where subjects are included who are not able to give their informed consent.

When recruitment of subjects is planned to be by advertisement, copies of the material to be used should be appended, including any printed materials, recordings or videotapes. The procedures proposed for handling the responses to the advertisement(s) should be outlined. This includes the planned arrangements for information and/or advice to the respondents found not to be suitable for inclusion in the trial. Further guidance and information on issues that might be relevant to consider depending on the type of trial and advertisement are given in Appendix 1.

#### **6.1.2.5. Subject information and the informed consent procedure**

All information to be provided to the subjects (and/or, where appropriate, the parent(s)/legal representative) before their decision to participate or abstain from participation should be submitted together with the form for written informed consent.

The information should be based on the elements set out in the Community guideline CPMP/ICH/135/95. There should also be a description of the arrangements for taking care of the subjects after their participation in the trial has ended, where there is additional care necessary because of the subjects' participation in the trial and where it differs from that normally expected according to the medical condition.

The information sheets given to the subject and/or the parent(s)/legal representative should be kept short, clear, relevant, and understandable to a lay person. They should be in a language the subject knows.

In cases where minors or incapacitated subjects are to be included, two sets of information sheets might be needed according to national regulations. In addition to the information given to the subject's parent(s) or legal representative, the subject should be given information

according to his/her capacity to understand. This information should include, where appropriate, a statement that the subject's decision not to participate or to withdraw from a trial will be respected, even if consent is given by the parent/ legal representative.

The measures taken to safeguard the subject's privacy and the protection of personal data should be described as is required according to Directive 95/46/EEC<sup>6</sup>. There should be information on how the identity of the subject, biological material obtained from the subject, and any recorded data will be coded, stored and protected. Information should be given about the person(s) who will have access to the code list, where the list will be kept and for how long, and who will be responsible for keeping it. The information should address the right of the subject to ask for updated information on what data are recorded, to require corrections of errors, and to know who will be responsible for keeping the data and who will have access to them in keeping with Directive 95/46/EEC.

The subject should be informed of the possibility to withdraw consent without giving any reason and to require that all previously retained identifiable samples will be destroyed to prevent future analyses, according to national provisions. The information should include a statement that the consequence of the subject's withdrawal of consent will be that no new information will be collected from the subject and added to existing data or a database.

Information should be provided on a contact point where additional information can be obtained about the trial and the right of the trial subjects and whom to contact in the event of trial related injury, according to the system in the Member State.

The form to be used to verify that information has been given and that the trial subject has consented (the informed consent form) should contain at least three elements.

- Consent to participate in the trial;
- Consent to make confidential personal information available (direct access) for quality control and quality assurance by relevant personnel from the sponsor, a nominated research organisation on behalf of the sponsor, and inspection by the competent authorities/institutions assigned this task in the Member State or, if applicable, the Ethics Committee;
- Consent to archive coded information, and for its transmission outside the Community if applicable.

In trials with minors or incapacitated subjects the procedures to obtain assent/consent from the minor or incapacitated subject, where appropriate, as well as from the parent(s) or legal representative should be described.

In cases where a minor or an incapacitated adult, who is capable of forming an opinion and assessing this information, explicitly wishes to refuse to participate or to be withdrawn from the clinical trial at any time, this will have to be considered by the investigator, or where appropriate, the principal investigator. The plan for taking care of such a situation should be outlined.

---

<sup>6</sup> Directive 95/46/EC of the European parliament and of the council of 24 October 1995



When a procedure with witnessed consent is to be used, the procedure for the selection of witness and the procedure to be used for providing information and obtaining consent should be stated. The notion of legal representative refers back to national legislation.

In case of temporarily incapacitated patients the procedure for obtaining the consent of the legal representative should be described. The procedure should be outlined that will be used to obtain/ confirm consent if/when the patient regains the capacity to consent and the information to be given the patient in that case. The detailed rules adopted by the Member States to protect individuals who are not capable of giving their consent should also be followed.

Appendix 2 provides more guidance and gives examples of items that might be addressed in the subject information leaflet depending on the type of trial.

#### **6.1.2.6. Suitability of the investigator and quality of the facilities**

The qualification of the principal investigator should be described in current curriculum vitae and/or other relevant documents. Any previous training in the principles of GCP or experience obtained from work with clinical trials and patient care should be described. Any conditions, such as economic interests, that might be suspected to influence the impartiality of the investigator should be presented

The Ethics Committee should give an opinion on the quality of the facilities (including the availability of adequate resources, personnel and laboratory facilities). The evaluation of the quality of the facilities might for example be based on a written statement by the head of the clinic/institution at the trial site or by some other responsible person, according to the system in the Member State.

The Ethics Committee should consider the suitability of the principal investigator and the quality of the facilities of each site in the Member State concerned in a multi-centre trial.

#### **6.1.2.7. Insurance and indemnity**

The provisions for indemnity or compensation in case of injury or death of a trial subject should be described to the Ethics Committee. Also the insurance or indemnity arrangements to cover the liability of the sponsor and investigator, should be stated.

The review of these provisions might alternatively be undertaken by the competent authority according to national provisions.

#### **6.1.2.8. Financial arrangements**

This includes information on financial transactions and compensation to subjects and investigator/site.

It might be the responsibility of either the Ethics Committee or the competent authority to review the arrangements for rewarding or compensating investigator(s) / sites and trial subjects as well as the relevant aspects of any agreement between the sponsor and the site according to national provisions.

### **6.1.2.9. Proposed other sites and/or countries involved**

For multi-centre trials a list should be provided on the planned locations of the sites, the name and position of the principal investigators and the number of subjects to be included in the Member State. Brief information should be given on any plans to include sites in other Member States or 3<sup>rd</sup> countries.

When additional sites are recruited in a multi-centre trial after the Ethics Committee has given its favourable opinion on the trial the Ethics Committee should review and give an opinion on the qualification of the new principal investigator(s), provisions for insurance, the quality of the facilities and according to national provisions on the indemnity and financial agreements. The application form for substantial amendments that is common for competent authority and Ethics Committee should be used, see also below in section 6.2.1.

## **6.2. During the conduct of the trial**

Directive 2001/20/EC describes the information arising during the conduct of a trial that must be submitted to the Ethics Committee for review or information.

This includes new events relating to the conduct of the trial or the development of the investigational medicinal product where that event is likely to affect the safety of the subjects, reports of adverse reactions and when the trial is halted or terminated early by the sponsor. If the competent authority suspends or prohibits a clinical trial the Ethics Committee should be informed. The procedures should be followed as outlined in other Commission guidelines<sup>4 7 8</sup>.

In addition, the Ethics Committee may request the investigator and/or sponsor to submit any other information necessary to fulfil the requirement of continuing review of the trial according to the Community guideline on Good Clinical Practice (CPMP/ICH/135/95).

### **6.2.1. Amendments**

The sponsor is obliged by Directive 2001/20/EC to inform the Ethics Committee about substantial amendments to the protocol and to submit all relevant documents in support of such amendments. The procedures described in the Commission guideline<sup>4</sup> section 4.2.2 should be followed.

The sponsor may not implement such amendments without a favourable opinion of the Ethics Committee, unless the changes consist of urgent safety measures to protect the trial subjects. In case of urgent measures are taken, the sponsor should as soon as possible inform the Ethics Committee of the new event, the measures taken and any plan for further action. This should be done at the same time as the competent authority is informed as described in the Commission guideline<sup>4</sup>

Criteria for considering an amendment as substantial, the format and content of the application to make such an amendment are given in the above mentioned guidance. An

---

7 Detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use

8 Detailed guidance on the European database of Suspected Unexpected Serious Adverse Reactions (Eudravigilance-Clinical Trial Module)

<sup>4</sup> see footnote 4

<sup>4</sup> see footnote 4

application of amendments identified as substantial should be submitted at the same time to both the Ethics Committee and the competent authority.

The application form, that should be used, is common to both the Ethics Committee and the competent authority. The EudraCT number of the trial should be on the application form.

If the changes are in information that either the Ethics Committee or the competent authority has the sole responsibility to review according to their nationally assigned duties, the application form provides information on the planned changes to the party that will not receive the documentation. Examples might be changes in an advertisement for subjects to participate in the trial only considered by the ethics committee or in the investigational product quality data in the IMPD only considered by the competent authority.

The substantial amendment should be identifiable (sponsor's amendment code number, version, date) and be signed by the sponsor or the legal representative of the sponsor and/or the principal investigator in single-centre trials or co-ordinating investigator in multi-centre trials according to national regulations.

The reasons for the amendment should be stated and all updated documents should be submitted, including any new version of the Investigator's Brochure (and/or Summary of Products Characteristics) and a new risk benefit analysis, if applicable. Only relevant new documents should be resubmitted and clear references should be made to ones already submitted. It might be sufficient to submit only separate pages with the changes and if so both old and new text should be indicated.

Changes to the protocol might lead to a modification of the subject information sheet and any new subject information should be appended. If there is a need to obtain new consent from the subjects, the procedure should be described. Possible consequences for the evaluation of the results for the subjects already included and for the usefulness of data recorded and stored should be discussed.

The non-substantial amendments should be handled as outlined in the Commission guideline<sup>4</sup>. Documentation of the changes should be kept at the sponsor and at the site and be made available on request and for inspection.

### **6.2.2. Safety measures and adverse events**

The sponsor shall ensure that all relevant information about serious adverse reactions and new events likely to affect the safety of the subjects are reported to the Ethics Committee in accordance with the obligations outlined in the Commission guideline<sup>7</sup>.

### **6.3. After end or termination of the trial.**

At the end of the trial in the Member State, as defined in the protocol, the sponsor should notify the Ethics Committees within 90 days in accordance with Directive 2001/20/EC.

In case of an early termination of the trial or temporary halt by the sponsor the Ethics Committee should be notified within 15 days, and a detailed written explanation of the reasons for the termination/halt should be given.

---

<sup>4</sup> see footnote 4

<sup>7</sup> Detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use

The same procedures should be followed as outlined in the Commission guideline<sup>4</sup>. The notification form to be used is common for the Ethics Committee and the competent authority.

At the end of the trial (on all sites in a multi-centre trial) the sponsor should provide the Ethics Committee with a summary of the clinical trial report. To be responsible for his/her part in the report writing, the investigator should have access to the recorded and reported data to ensure accuracy, completeness and timeliness. This report should be the same as the one forwarded to the competent authority according to the Commission guideline<sup>4</sup>.

If after the termination of a trial the risk/ benefit analyses have changed, the new evaluation should be provided in case it will have an impact on the planned follow up of the subjects who have participated in the trial. If so, the actions needed to protect the subjects should be described.

---

<sup>4</sup> see footnote 4

<sup>4</sup> see footnote 4

## 7. Appended documents

### 7.1 Addresses to the competent authorities and/or where information on the Ethics Committee system in the Member States in the European Union can be obtained

#### DENMARK

The Danish Medicines Agency  
Clinical Trials, Inspection and Enforcement Division  
Axel Heides Gade 1,  
DK- 2300 Kobenhavn S  
Denmark  
e-mail: [dkma@dkma.dk](mailto:dkma@dkma.dk)

Ethics Committee information:  
e-mail: [cvk-sekretariatet@forsk.dk](mailto:cvk-sekretariatet@forsk.dk)  
home page: [www.forsk.dk/cvk/](http://www.forsk.dk/cvk/)

#### FINLAND

Clinical trials Enforcement & Inspection  
National Agency for Medicines  
PO Box 55  
FIN-00301 Helsinki  
Finland  
Tel: + 358 9 473341  
Fax: + 358 9 47334 323  
Homepage [www.nam.fi](http://www.nam.fi)

Ethics Committee information:  
The National Advisory Board on Health Care Ethics (ETENE)  
The Sub-Committee on Medical Research Ethics (TUKIJA)  
Ministry of Social Affairs and Health  
PO. Box 33  
(Kirkkokatu 14, Helsinki)  
00023 Government  
Tel : + 358 9 16001 (switch board)  
Fax : 358 9 160 74312  
e-mail: [etene@stm.fi](mailto:etene@stm.fi)  
WWW <http://www.etene.org>

#### FRANCE

Direction Générale de la Santé  
Sous direction des Politiques de santé et stratégies, SDIC  
8, avenue de Ségur,  
753 50 Paris 07 SP  
Tel: 01 40 56 60 00  
Fax: 01 40 56 67 69

- GERMANY** Permanent Working Group of German Ethics Committees  
Ottostrasse 12  
D-50859 Köln  
Tel +49-(0)2234-7011-570  
Fax +49-(0)2234-7011-140  
e-mail: [doppelfeld@aerzteblatt.de](mailto:doppelfeld@aerzteblatt.de)  
home page: [www.ak-me-ethik-komm.de](http://www.ak-me-ethik-komm.de)
- ITALY** Clinical Trials Office  
Medicines and Medical Devices General Direction  
Ministry of Health  
Piazzale dell'Industria, 20  
00144 Rome  
Italy  
E-mail: [sperimentazione.clinica@sanita.it](mailto:sperimentazione.clinica@sanita.it)  
Home page:  
[http://oss-sper-clin.sanita.it/consultazione\\_ce\\_pub.htm](http://oss-sper-clin.sanita.it/consultazione_ce_pub.htm)
- LUXEMBOURG** CNER  
CRP-Sante  
B.P. 2021  
L- 1020 Luxembourg
- NETHERLANDS** Ethics Committee information:  
Central Committee on Research  
Involving Human Subjects (CCMO)  
PO Box 16302  
7500 BH The Hague  
The Netherlands  
Tel: + 31 70 3406700  
Fax: + 31 70 3406737  
e-mail: [ccmo@ccmo.nl](mailto:ccmo@ccmo.nl)  
homepage: [www.ccmo.nl](http://www.ccmo.nl)
- PORTUGAL** Instituto Nacional da Farmacia e do Medicamento (INFARMED)  
Departamento de Ensaios Clinicos  
Parque da Saude de Lisboa  
Avenida do Brasil, 53, 1749-004 Lisboa  
Tel: +35121 7987100  
Fax: +35121 7987316  
Website: [www.infarmed.pt](http://www.infarmed.pt)

**SPAIN**

Spanish Medicines Agency  
Paseo del Prado, 18 – 20  
28071 Madrid  
Spain

**SWEDEN**

Clinical Trial Unit  
Medical Products Agency  
PO Box 26  
S- 751 03 Uppsala  
Sweden  
Tel : + 46 18 174600  
Fax: + 46 18 54 85 66  
e-mail: [clintrials@mpa.se](mailto:clintrials@mpa.se)  
homepage: [www.mpa.se](http://www.mpa.se)

Ethics Committee information:  
Scientific Research Council  
S- 103 78 Stockholm  
Sweden  
Tel : + 46 8 546 44 000  
Fax: + 46 8 546 44 210  
Homepage: [www.vr.se](http://www.vr.se)

**UNITED KINGDOM**

Central Office for Research Ethics Committees (COREC)  
50 Eastbourne Terrace  
London W2 3 QR  
UK  
Tel: + 44 20 7725 3431  
Fax: + 44 20 7725 3465  
COREC website: [www.corec.org.uk](http://www.corec.org.uk)

**7.1 Addresses to the competent authorities and/or where information on the Ethics Committee system in the new Member States in the European Union can be obtained**

<b>Cyprus</b>	CYPRUS NATIONAL BIOETHICS COMMITTEE 1 Apellis st. 1403, Lefkosia, Cyprus Tel. No.: 00357 22 889100 or 103 Fax. No.: 00357 22 665080 E-mail: <a href="mailto:roc-law@cytanet.com.cy">roc-law@cytanet.com.cy</a>
<b>Czech Republic</b>	State Institute for Drug Control – Branch of Clinical Trials and Pharmacovigilance Šrobárova 48 100 41 Praha 10 Phone: +420 272 185 817 Fax: +420 272 185 816 E-mail: <a href="mailto:klin.sekret@sukl.cz">klin.sekret@sukl.cz</a> <a href="http://www.sukl.cz">http://www.sukl.cz</a>
<b>Estonia</b>	Ethics Review Committee on Human Research of the University of Tartu 19 Ravila Street 51014 Tartu Estonia Tel +372 7 374 350 Faks +372 7 374 352  Tallinn Medical Research Ethics Committee Hiiu 42 11619 Tallinn Estonia Tel: +372 6 514 381 Faks: +372 6 706 814
<b>Hungary</b>	National Institute of Pharmacy, 1051 Budapest Zrínyi u. 3.
<b>Latvia</b>	Ministry of Health, Department of Pharmacy, 25 Baznīcas Street, Riga, LV-1010, phone: 371- 7021608, fax: 371-7021691, e-mail address: <a href="mailto:Sandra.Linde@vm.gov.lv">Sandra.Linde@vm.gov.lv</a>



**Lithuania**

Lithuanian Bioethics Committee  
Vilniaus str. 33,  
LT-01119 Vilnius,  
Lithuania  
[www.sam.lt/bioetika](http://www.sam.lt/bioetika)

**Malta****Poland****Slovakia****Slovenia**

Clinical centre, Centre for Pharmacovigilance  
Zaloska 7, 1000 Ljubljana  
Agency for Medicinal Products,  
Kersnikova 2, 1000 Ljubljana, Slovenia

**EFTA****Norway**

Norwegian Medicines Agency  
Sven Oftedalsvei 6  
NO-0950 OSLO  
NORWAY  
Telephone: (+47) 22 89 77 00  
Telefax: (+47) 22 89 77 99  
Internet: [www.noma.no](http://www.noma.no)  
E-mail: [post@noma.no](mailto:post@noma.no)

The National Committees for Research Ethics  
Street address: Prinsensgate 18  
Postal address: P.O. Box 522, Sentrum,  
N-0105 Oslo, Norway  
Phone: +47 23 31 83 00 Fax: +47 23 31 83 01  
Internet: <http://www.etikkom.no>  
e-mail: [post@etikkom.no](mailto:post@etikkom.no)

## 7.2 Information to be forwarded to the Ethics Committee in different Member States

### INFORMATION FOR ETHICS COMMITTEES

INFORMATION REQUIRED FOR ETHICS COMMITTEES	AT	BE	DK	FI	FR	DE	EL	IT	IE	LU	NL	PT	ES	SE	UK
<b>MS SPECIFIC INFORMATION</b>															
Covering letter	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Application form	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
Clinical trial protocol	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Investigator's brochure	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
List of Competent Authorities to which the application has been submitted and details of decisions, if available	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
<b>Subject related</b>															
Informed consent form	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Subject information leaflet	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Arrangements for recruitment of subjects	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b>Protocol related</b>															
Summary of the protocol in the national language	No	Yes		Yes	Yes	Yes		Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
Outline of all active trials with the same IMP	No	A	No	No	No	No	Yes	Yes	Yes	No	Yes	No	No	No	No
Peer review of the scientific value of the trial, when available, not compulsory	Yes	No	No	No	Yes	No	Yes	No	Yes	No	Yes	Yes	No	No	Yes
Ethical assessment made by the principal/coordinating investigator, if not given in the application form	No	No	Yes	Yes	Yes	No		No	No	No	Yes	No	Yes	Yes	Yes
<b>IMP related</b>															
Investigational Medicinal Product Dossier (IMPD)	No	No	No	No	No	No	Yes	No	No	No	Yes	No	No	No	No
Simplified IMPD for known products. See table 1 in application to competent authorities	No	No	No	No	No	No	Yes	No	No	No	Yes	No	No	No	No
Summary of Product Characteristics (SmPC) (for products with marketing authorisation in the Community)		No		No	No	No		Yes	Yes	Yes	Yes	No	Yes	Yes	No
If IMP manufactured in E.U.:															
– copy of the manufacturer authorization referred to in Art. 13.1. of the Directive stating the scope of this authorization		No		No	No	No		Yes	No	No	Yes	No	No	No	No

<b>INFORMATION REQUIRED FOR ETHICS COMMITTEES</b>	<b>AT</b>	<b>BE</b>	<b>DK</b>	<b>FI</b>	<b>FR</b>	<b>DE</b>	<b>EL</b>	<b>IT</b>	<b>IE</b>	<b>LU</b>	<b>NL</b>	<b>PT</b>	<b>ES</b>	<b>SE</b>	<b>UK</b>
If IMP not manufactured in E.U.:															
– Declaration of the QP that the manufacturing site works in compliance with GMP at least equivalent to EU GMP		No		No	No	No		Yes	No	No	Yes	No	No	No	No
– Copy of the importer authorization as referred to in Art. 13.1. of the Directive		No		No	No	No		Yes	No	No	Yes	No	No	No	No
Certificate of analysis for test product in exceptional cases:															
– where impurities are not justified by the specification or when unexpected impurities (not covered by specification) are detected		No	Yes	No	No	No		No	No	No	Yes	No	No	No	No
–															
Viral safety studies	Yes	A	Yes	No	No	No		No	No	No	Yes	No	No	No	No
Examples of the label in the national language	No	No	Yes	No	No	Yes		Yes	No	No	Yes	No	No	No	No
Applicable authorizations to cover trials or products with special characteristics (if available) e.g. <u>GMOs, radiopharmaceuticals</u>	No	No	Yes	No	No	No		Yes	No	No	Yes	No	No	No	No
TSE Certificate when applicable		No		No	No	No		Yes	No	No	Yes	No	No	No	No
Declaration of GMP status of active biological substance		No		No	No	No		No	No	No	Yes	No	No	No	No
<b>Facilities &amp; staff related</b>															
Facilities for the trial	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
CV of the coordinating investigator in the MS concerned (for multicentre trials)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
CV of each investigator responsible for the conduct of the trial in a site in the MS concerned (principal investigator)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Information on supporting staff in each site					Yes										
<b>Finance related</b>															
Provision for indemnity or compensation in the event of injury or death attributable to the clinical trial	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Any insurance or indemnity to cover the liability of the investigator and sponsor	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Compensation to subjects				Yes	Yes			Yes	Yes		Yes			Yes	

<b>INFORMATION REQUIRED FOR ETHICS COMMITTEES</b>	<b>AT</b>	<b>BE</b>	<b>DK</b>	<b>FI</b>	<b>FR</b>	<b>DE</b>	<b>EL</b>	<b>IT</b>	<b>IE</b>	<b>LU</b>	<b>NL</b>	<b>PT</b>	<b>ES</b>	<b>SE</b>	<b>UK</b>
Compensation to investigators	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Agreement between the sponsor and the trial site	Yes	Yes	No		Yes	Yes	Yes	Yes	Yes	Yes	A	Yes	Yes	Yes	Yes
Agreement between the investigators and the trial sites		Yes			No	Yes		Yes	Yes		A		No	No	
Certificate of agreement between sponsor and investigator when not in the protocol	No	Yes	No	No	No	No	Yes	Yes	Yes		A		Yes	No	No

**MEMBER STATES' ADDITIONAL EXPLANATION**

**The symbol # means that the issue is being discussed in the MS.**

The letter A preceding information below refer to letter under the MS column in the table above and provide additional explanation about the information to be provided.

**Belgium:**

A. Yes, but the protocol or the investigator's brochure can include this information. There is no need for a separate document.

**Netherlands**

A. Available on request

**7.2 Information to be forwarded to the Ethics Committee in different new Member States**  
**INFORMATION FOR ETHICS COMMITTEES**

<b>INFORMATION REQUIRED FOR ETHICS COMMITTEES</b>	<b>CY</b>	<b>CZ</b>	<b>EE</b>	<b>HU</b>	<b>LV</b>	<b>LT</b>	<b>MT</b>	<b>PL</b>	<b>SK</b>	<b>SI</b>		<b>NO</b>	<b>IS</b>
<b>MS SPECIFIC INFORMATION</b>													
Receipt of confirmation of the EUDRACT number TBD ! This is not necessary !!		Yes			No	Yes						Yes	
Covering letter	Yes	Yes	Yes	Yes	Yes	Yes				Yes		Yes	
Application form	Yes	Yes	Yes	Yes	Yes	Yes						Yes	
Clinical trial protocol	Yes	Yes	Yes	Yes	Yes	Yes				Yes		Yes	
Investigator's brochure	Yes	Yes	Yes	Yes	Yes	Yes				Yes		Yes	
List of Competent Authorities to which the application has been submitted and details of decisions, if available	No	Yes	Yes	No	No	Yes				Yes			
<b>Subject related</b>													
Informed consent form	Yes	Yes	Yes	Yes	Yes	Yes				Yes		Yes	
Subject information leaflet	Yes	Yes	Yes	Yes	Yes	Yes				Yes		Yes	
Arrangements for recruitment of subjects	Yes	Yes	Yes	Yes	Yes	Yes				Yes		Yes	
<b>Protocol related</b>													
Summary of the protocol in the national language	Yes	Yes	Yes	No	No	Yes				Yes		No	
Outline of all active trials with the same IMP	No	No	No	Yes	No	No						Yes	
Peer review of the scientific value of the trial, when available, not compulsory	No	No	No	Yes	No	Yes				Yes		Yes	
Ethical assessment made by the principal/coordinating investigator, if not given in the application form	Yes	No	Yes	No	No	Yes				Yes		Yes	
<b>IMP related</b>													
Investigational Medicinal Product Dossier (IMPD)	No	No	No		No	No							
Simplified IMPD for known products. See table 1 in application to competent authorities	No	No	No	No	No	No				Yes		No	
Summary of Product Characteristics (SmPC) (for products with marketing authorisation in the Community)	No	No	Yes	No	No	Yes				Yes			
If IMP manufactured in E.U.:													
– copy of the manufacturer authorization referred to in Art. 13.1. of the Directive stating the scope of this authorization	No	No	No	No	No	Yes				No		No	

<b>INFORMATION REQUIRED FOR ETHICS COMMITTEES</b>	<b>CY</b>	<b>CZ</b>	<b>EE</b>	<b>HU</b>	<b>LV</b>	<b>LT</b>	<b>MT</b>	<b>PL</b>	<b>SK</b>	<b>SI</b>		<b>NO</b>	<b>IS</b>
If IMP not manufactured in E.U.:													
– Declaration of the QP that the manufacturing site works in compliance with GMP at least equivalent to EU GMP	Yes	No	No	No	No	No				No		No	
– Copy of the importer authorization as referred to in Art. 13.1. of the Directive	Yes	No	No	No	No	No				No		No	
Certificate of analysis for test product in exceptional cases:													
– where impurities are not justified by the specification or when unexpected impurities (not covered by specification) are detected	No	No	No	No	No	No				No		No	
–													
Viral safety studies	No	No	No	No	No	No				No		No	
Examples of the label in the national language	No	No	No	No	No	Yes*				No		No	
Applicable authorizations to cover trials or products with special characteristics (if available) e.g. <u>GMOs, radiopharmaceuticals</u>	No	No	No	No	No	Yes				No		No	
TSE Certificate when applicable	<u>No</u>	No	No	No	No	No				No		No	
Declaration of GMP status of active biological substance	<u>No</u>	No	<u>No</u>	<u>No</u>	No	No				No		No	
<b>Facilities &amp; staff related</b>													
Facilities for the trial	Yes	Yes	Yes	Yes	Yes	Yes				Yes		No	
CV of the coordinating investigator in the MS concerned (for multicentre trials)	Yes	Yes	Yes	Yes	No	Yes				Yes		Yes	
CV of each investigator responsible for the conduct of the trial in a site in the MS concerned (principal investigator)	Yes	Yes	Yes	Yes	Yes	Yes				Yes		Yes	
<b>Finance related</b>													
Provision for indemnity or compensation in the event of injury or death attributable to the clinical trial	Yes	Yes	Yes	Yes	Yes	Yes				Yes		Yes	
Any insurance or indemnity to cover the liability of the investigator and sponsor	Yes	Yes	Yes	Yes	Yes	Yes				Yes		Yes	
Compensation to subjects	Yes	Yes	Yes	Yes	Yes	Yes				Yes		Yes	

<b>INFORMATION REQUIRED FOR ETHICS COMMITTEES</b>	<b>CY</b>	<b>CZ</b>	<b>EE</b>	<b>HU</b>	<b>LV</b>	<b>LT</b>	<b>MT</b>	<b>PL</b>	<b>SK</b>	<b>SI</b>		<b>NO</b>	<b>IS</b>
Compensation to investigators	Yes	Yes	Yes	Yes	No	Yes				No		Yes	
Agreement between the sponsor and the trial site	Yes	Yes	No	Yes	No	Yes				Yes		Yes	
Agreement between the investigators and the trial sites	Yes	Yes	No	Yes	No	Yes				No		Yes	
Certificate of agreement between sponsor and investigator when not in the protocol	Yes	Yes	No	No	No	Yes				No		Yes	

**MEMBER STATES' ADDITIONAL EXPLANATION**

**Lithuania:** \*For authorized products in Lithuania, for other –according to Directive 2001/20/EC

### **7.3. Request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities and for opinion of the Ethics Committees in the European Union.**

#### **Module 1**

This first module of the application form to be used to the Ethics Committee is the same as the form used in the submission to the competent authority.

To be found in ‘Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial’ Annex 1.

#### **Module 2**

The second module presented below, is intended to provide detailed information on the planned trial and also on aspect that might be specific for the Member State in case of multi-centre trials. The headings provided below is intended to give guidance on aspects that might be addressed when relevant. It is not intended to be a complete listing of all elements necessary for the Ethics Committee to consider during its work, but to indicate some and give examples that might have to be considered by the Ethics Committee in some Member States.

1. EudraCT trial number Ethics Committee trial ID
2. Title of the project ( This should be understandable for laypersons )
3. Summary of the project. (justification and relevance)
4. Results of pre-clinical tests or reasons for not doing pre-clinical tests
5. Primary hypothesis in this trial (if relevant, also secondary hypotheses)
Research ethical considerations (Identify and state any possible problems that might occur. Present possible gain in knowledge to be obtained in the trial and its importance, possible risks for injuries or distress for the participants. Present your own evaluation of the risk-benefit ratio).
Reason for including persons from vulnerable groups, i.e. minors, temporarily or permanently incapacitated subjects.



8. Description of the recruitment procedure (all material to be used should be appended )
Procedure at the site to provide information and obtain consent from the subjects, or parents or legal representatives if applicable (who will give the information and when, need for legal representatives, witness etc).
10. Investigational procedures and any deviations necessary from the routine treatment
Risk assessment, foreseeable risks of treatment and procedures to be used (incl. pain, discomfort, violation of integrity and means to avoid and/or take care of unforeseen / unwanted events)
12. Previous experience of the conduct of similar research procedures at this site.
13. Any foreseeable benefit for included subjects
14. Relation between subject and investigator (patient-physician, student – teacher etc)
15. Procedures of the site to check if the subject participates simultaneously in other research or if a required period has elapsed since previous participation in research (of special importance when healthy subjects are included in pharmacology trials).
16. Requirements and methods for recording health control for healthy subjects (i.e. hospital files or other national requirements)
17. Methods for searching, recording and reporting adverse effects (describe when, by whom and how, i.e. open questions and/or according to lists)
18. Procedures used to protect the privacy of recorded data, source documents and samples (if applicable).
19. Plan for treatment or care after the subject has ended the participation in the trial (who will be responsible and where)
20. Statistical consideration and reasons for the number of subjects to be included in the trial.

21. Amount and procedure for remuneration or compensation of subjects (description of amount paid, during the participation in the trial and for what, i.e. travel cost, loss of earning, pain and discomfort etc) .
22. Rules for stopping or prematurely ending the trial at the site(s) in this Member State or as a whole
23. Agreement on investigator's access to data, publication policy etc. (if not available in the protocol)
24. Sources of funding (if not available in the protocol) and information on financial or other interests of the investigator(s).

NAME AND SIGNATURE OF APPLICANT - CO-ORDINATING INVESTIGATOR/PRINCIPAL INVESTIGATOR (and/or sponsor, if applicable)	
I hereby confirm that the information given in this application is correct and that I am of the opinion that it will be possible to conduct the trial in accordance with the protocol, national regulations and principles of Good Clinical Practice.	
Name : Surname : Address :	
Position: :	
Date :	Signature:

## 7.4 Advertising for trial subjects

This appendix is intended to provide guidance on items that might be relevant to consider when advertising for subjects who will be asked to participate in a clinical trial. The items listed do not comprise a complete list and should be modified according to the type of trial and national recommendations.

All advertisements for trial subjects should be included in the submission for approval by the Ethics Committee. The review by the Ethics Committee might also include the procedures to take care of subjects responding to the advertisement.

The advertisement might contain information on the following points:

1. The research nature of the project
2. The scope of the trial
3. Which type/group of subjects might be included
4. The investigator clinically/scientifically responsible for the trial, if possible or if required by local regulations.
5. The person, name, address, organisation, to contact for information
6. That the subject responding will be registered
7. The procedure to contact the interested subjects
8. Any compensation for expenses
- 9- That a response on the part of a potential subject only signifies interest to obtain further information

Information concerning the procedures to handle the answers to the advertisement might contain information on the qualifications of the person who will be responsible for the first contact with the subjects, i.e. might be a nurse. This is especially important when patients are replying to an advertisement. In addition, resources/procedures should be in place to provide information to and take care of patients not suitable for inclusion in the planned trial. Lack of suitability might be obvious at the first contact or after screening of the subjects who responded. There might be a description of how the patient will be given advice or help to contact a relevant institution/clinic not related to the planned trial.

All information to be provided to the respondent should be submitted to the Ethics Committee for approval. If there is a screening procedure to evaluate the suitability of the respondent two sets of information sheets might be used. One set could provide information on the procedure and the reasons for screening. It should be explained what the consequences might be in case of a certain outcome of the screening. For example if a biopsy shows pathological changes the patient will be asked if he/she is willing to participate in a trial and a brief overview of the trial be given. The second more extensive information could provide the detailed information on the trial and should follow the usual requirements.

Potential subjects should be informed that personal information might be recorded and will be protected according to national requirements. The procedure for giving the participating subject compensation or rewards and the amount(s) should be outlined. The applicant should

also describe the procedure for informing the subject on how he/she may be eliminated from the register.

## **7.5. Content of subject information**

This appendix is intended to provide further guidance on items that might be of relevance for the subject information leaflet. It is not intended to provide a complete list of items which should be included, but to give some examples of items that might have to be considered if relevant to the particular trial.

### **7.5.1. Subject information, general aspects.**

The information sheet should state clearly the justification for the trial, its relevance and objective and should contain at least all the items listed in the relevant section of the Community guideline on Good Clinical Practice (CPMP/ICH/135/95).

In addition written information should be provided on:

- 1.1 the contact point from which further information may be obtained relating to the trial and in case of injury, according to national requirements.
- 1.2 the names and addresses of the investigator, study nurse etc who are responsible for taking care of the included subjects.
- 1.3 any planned procedures for follow up after the end of the trial (for example for trials involving gene transfer medicinal products) and/or plans for additional care that might be needed due to findings during follow up.
- 1.4 any financial or other ties to the sponsor as well as institutional affiliations of the investigator as well as the name and address of sponsor /sources of funding
- 1.5 the Ethics Committee positive opinion.
- 1.6 the subject's rights to privacy and the means have taken to ensure protection of personal data.  
This might include information on:
  - procedures for coding,
  - the arrangement with code-keys: the name of the person responsible for keeping the key and who will have access
  - in the case of retention of subject samples and information,
    - to whom the data and samples are accessible
    - the location and duration of retention
    - name of the person who will be responsible for keeping the samples and the results
    - procedure for handling any retained identifiable samples
    - plans to anonymise or destroy samples after analysis
- 1.7 the subject's right to obtain updated information about what data is recorded as well as the right to require corrections of errors

- 1.8 the right of the subject (or parent or legal representative) to withdraw consent to participate in the trial
- 1.9 the fact that in the event of the withdrawal of consent to participate in the trial, no new data will be added to the database and that, according to national provisions, the subject (or parent, guardian or legal representative) may require all previously retained identifiable samples to be destroyed to prevent further analysis.
1. 10 the right of the subject (parent or legal representative) to be informed of any plans for new analyses on retained identifiable material that were not foreseen when the subject consented to participate in the study. The investigator might have to ask for new consent and the subject has the right to refuse further analyses, according to national rules.

### **7.5.2. Information in Pharmacogenetic trials**

In clinical trials where genetic testing is included, this should be clearly explained to the subject. The information should give the background and purpose of the genetic tests, the planned analyses and whether the samples will be kept to make future analyses possible in conjunction with the planned project. When applicable, the information on the genetic part of the trial might be separate from the information on the other part. Information should be provided on the possibility for the subject to abstain from the genetic testing but still be able to participate in the non-genetic part of the trial, according to national recommendations. Further information on pharmacogenetic trials can be obtained from the position paper from the Committee for proprietary medicinal Products<sup>10</sup>.

### **7.5.3. Trial specific and general explanatory information to subjects.**

It might sometimes be useful to divide the information to be provided in two parts. One part should contain the information necessary for the subject to decide whether or not to participate in the planned trial. It could focus on the information specific for the planned trial and only contain information related to general issues and systems such as protection of privacy, insurance etc. as is relevant to the trial in question.

The second part should contain general information common to trials in the Member State. It might address and explain in more detail the national systems for the protection of the rights, welfare and safety of the subjects. The reasons for quality control and quality assurance and the need for Source Data Verification (SDV) as well as measures to protect the confidentiality of personal information, systems for labelling, analysing and publishing data and availability of insurance/indemnity systems could be explained. This general second part, once approved by the Ethics Committee, could be used where appropriate in similar trials in that Member State.

*CT-12-EN rev5 mars04*

---

<sup>10</sup> Position paper on terminology in pharmacogenetics, EMEA/CPMP/3070/01

