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ENTERPRISE DIRECTORATE-GENERAL

Single market : management & legislation for consumer goods
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**Detailed guidance on the European clinical
trials database
(EUDRACT Database)**

April 2003

This guidance has been replaced by the document

**CT 5.1 Amendment describing the Development
of EurdaCT- Lot 1 for 1 May 2004**

and

CT 5.2 EudraCT core dataset

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1 Introduction

European regulatory authorities need a database in order to provide each of them with an overview of clinical trials being conducted in the community. This database is needed to facilitate communication on these clinical trials between the authorities, to enable each to undertake better the oversight of clinical trials and investigational medicinal product development, and to provide for enhanced protection of clinical trial subjects and patients receiving investigational medicinal products.

This guidance is applicable to all clinical trials (as defined by Directive 2001/20/EC¹) for which at least one site falls within the territory of a Member State.

This document should be read in conjunction with the detailed guidance on the European Database of Suspected Unexpected Serious Adverse Reactions.

2 Scope

This detailed guidance document provides the higher-level user requirements and system definition on the European clinical trials database (Eudract). It incorporates information on the data to be included in the database, on the procedures for data entry and control, on the methods for electronic communication of the data, on the steps taken to ensure that the confidentiality of the data is strictly observed and on the methods for communicating the data between the Member States, the Agency, and the Commission.

The system specification, design, and user documentation will be developed on the basis of this document.

This database is interfaced with the Eudravigilance Clinical Trial Module (see article 17.3(a) of Directive 2001/20/EC and the Detailed guidance on the European Database of Suspected Unexpected Serious Adverse Reactions.

The Eudract database and the Eudravigilance Clinical Trial (CT) module will share common key fields including the clinical trial identification (Eudract number and sponsor protocol code number), the product identification and the sponsor identification.

3 Definitions:

The definitions of the Directive 2001/20/EC and of the implementing texts adopted in line with that directive apply.

New terms not defined in these other documents are defined here:

<i>Community Administrator:</i>	<i>Database</i>	The organisation and function within that organisation given responsibility at a Community level for managing the Eudract database.
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¹ 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

<i>Local Database Administrator:</i>	The organisation and function within that organisation given responsibility at the Member State level for interfacing with the Eudract database.
<i>Users:</i>	The users of the Eudract database are the competent authorities of the Member States, the Agency and the Commission.

4 Legal Basis

The legal basis for the Eudract database and the Eudravigilance CT Module are provided in article 11 and in article 17 of Directive 2001/20/EC.

5 User Requirements

The database is designed to be a register of all clinical trials in the Community, information on the content, commencement and termination of the clinical trials and on inspections. It is, in addition, designed to be linked with the European database of reports of suspected unexpected serious adverse reactions (SUSARs) reported during clinical trials for investigational medicinal products.

The users i.e. the competent authorities of the Member States, the Agency and the Commission require a European database of clinical trials for purposes including:

- Provision of an overview of all clinical trials in the Community
- Facilitation of communication between Member States, the Agency and the Commission on clinical trials
- Identification of ongoing, completed or terminated clinical trials, conducted at one or more sites in the Community, e.g.:
 - with a given product
 - conducted by a given sponsor
 - by patient population
 - by product type
 - by indication/disease under investigation/therapeutic area
- Generation of clinical trial statistics
- Identification of clinical trials, sponsors and the investigational medicinal products involved in order to support the interface between clinical trial information (in Eudract) and reports of suspected unexpected serious adverse reactions (in the Eudravigilance Clinical Trial Module).
- Provision of information on the GCP and clinical trial related GMP inspections that have been undertaken by the competent authorities Inspectorates e.g.:

- for a given product
 - for a given clinical trial
 - for a given sponsor
 - for specified clinical trial sites
and/or for
 - system inspections of sponsor/CRO/laboratory/clinical facilities etc.
- Notification to all competent authorities when a trial is terminated for safety reasons.

Provision of the investigator lists and lists of involved CROs, and of involved central laboratories/technical facilities. A Member State(s) may request that the sponsor supply this information electronically (in the format foreseen by the application form) and these will be entered in the database by the Member State(s) concerned.

Sponsor requirements: appropriate security and confidentiality of information, continuous, user-friendly availability, help information and user documentation.

6 Identification of the clinical trial

A unique Eudract number will identify each clinical trial.

One Eudract number is issued per protocol, irrespective of the number of clinical trial sites or member states involved.

A Eudract number will only be issued once by the system. If a number is issued but the clinical trial does not proceed that number is not available for reuse.

The Eudract number is issued to the sponsor by a central function in the system on submission of the required data to the system.

The printed form displaying the Eudract number must be included in the submission of the request for the trial to the competent authorities and ethics committees, and the Eudract number must be used on any amendments or the end of trial report. The Eudract number will also be used on suspected unexpected serious adverse reactions reports for reports from trials with sites in the Community.

Submissions to the competent authorities or ethics committees may not be accepted as valid without a valid Eudract number generated by the system, for that trial.

The sponsor's protocol code number and amendment code numbers will be included in the database.

Where an International Standard Randomised Controlled Trial Number (ISRCTN) is available for the trial, this should be entered.

7 Identification of the product

Each investigational medicinal product needs to be uniquely identifiable.

Each product will be identified in a product dictionary. The dictionary will be that of Eudravigilance, reflecting the requirements for identification of products through their development cycle, and with due regard to confidentiality of developmental products.

Where several active substances are included in one product these should be individually identified.

The product (and active substance) names need to be clearly traceable and identifiable throughout its development and use in different clinical trials, and through to post-marketing for those products, which are or become available on the market in the Community. Any new identification assigned to the product by the sponsor should be notified forthwith to the competent authority (ies) concerned as an amendment and added to the product dictionary.

Where a product that is being used in the trial has a marketing authorisation in the Community the tradename and the marketing authorisation number need to be provided, in addition to the name of the active ingredient.

Where the product is not authorised in the Community, as many of the following items of information, as are available for the substance should be provided:

- Product name
- Name of each active substance (INN or proposed INN if available)
- Other available name for each active substance (CAS, Sponsor code, a descriptive name for biological/biotechnological products etc)
- ATC code, if available
- Where the product is sourced from outside the Community, and is marketed in that 3rd country, the name of that country should be indicated.

This identification applies to both test and comparator products.

The database specification will define a link between the Eudract number and the product identification.

8 Data to be entered into the database

The purpose of the database is to provide a register of all clinical trials being conducted within the European Union, information on the content, commencement

and termination of the clinical trials and on inspections. The information entered should be complete for each trial and therefore a response to each element is mandatory (meaning that where the information is applicable for that trial it is entered, where it is not applicable then a response of “no” or “not applicable” is required). The lists of elements are given in Appendices 1 and 2. For each study the sponsor provides data required in electronic format, prior to or at the time of application to the Competent Authority(s).

Flow diagrams showing the process of sponsor registration and submission of data elements as well as validation of these and entry into the database by the competent authorities will be detailed in the specification and design documents referred to in section 1 of this detailed guidance.

The sponsor submits the data required in electronic format to a Quarantine Area, from which the competent authority enters it into the Eudract database, by electronic transfer, after a confirmation check of the data. Data may also be submitted in the form of XML messages.

The Quarantine Area is accessible to the competent authorities of the Member States, the Agency and the Commission. Each sponsor can only access their own data in the Quarantine Area. The Quarantine Area will contain a separate location in which each sponsor can prepare and draft their forms before submitting them and in which they can maintain an updated version of the data if they choose during the course of the trial and afterwards. The sponsor receives an updated file of the data submitted when it has been entered into the Eudract database by the competent authority. This permits the sponsor to maintain a current version, in their secure area.

9 Sponsor registration with the system

It is necessary that sponsors register with the system prior to using it for any purpose outlined in this guideline. This serves two key purposes:

- Security - as part of the process of protecting the system from unauthorised access
- Authentication of the submitted information – by establishing the sponsor or their representative as authentic sources of information for that company and in the context of this database.

It is foreseen that in general registration will be valid for multiple clinical trials and products.

Once complete, registration provides access to submit data to the Quarantine Area, to obtain the Eudract number for that clinical trial and provides the ability to view and to update that data in the Quarantine Area.

Each sponsor registers single or multiple users with the system. The sponsor may delegate the task of submitting information to the system, to other parties, so the sponsor may register representatives/authorised parties to act on its behalf but the sponsor retains ultimate responsibility for the data submitted.

10 Data submission and data entry procedures

10.1 Before submission of the clinical trial to the competent authority (ies)

The data required for the database, that is shown in appendix 1, is a subset of the data required by the request for authorisation submitted to the competent authority (ies). (see: 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.)

Each clinical trial needs to be clearly identified in the database before the competent authority assesses it (and before the competent authority provides written authorisation for the trial or takes the decision that there are no grounds for non-acceptance).

This is to ensure that the database is a complete database and can fulfil its objectives.

In particular it is necessary to ensure proper reporting and review of suspected unexpected serious adverse reactions (SUSARs). Unless the clinical trial is registered in the database before the trial starts, it will not be possible to ensure that the trial and the product to which each SUSAR relates are clearly identified and traceable, nor will it be possible to register amendments.

Therefore all the information required from the sponsor for the database, applicable to a given trial and available at the time of submission of the request to the competent authority, must also have been submitted, in electronic format, by the sponsor to the Quarantine Area, by that time.

The sponsor completes and submits the requested data to the Quarantine Area. The system responds by providing the unique Eudract number for that trial. The system also provides a confirmation receipt containing the Eudract number and a copy of the information submitted by the sponsor to the Quarantine Area for that trial.

This submitted data then resides in the Quarantine Area and is visible to the submitting sponsor, the competent authorities of the Member States, the Agency and the Commission. Where data in a field (s) differs between member states the sponsor repeats this operation for each member state involved, but the information common to all Member States will be automatically made available by the system, avoiding redundant repetition.

If the sponsor realises that an error, or omission has been made in data submitted, or the information has changed prior to the submission to the competent authority, the sponsor may log-on, with access only to their own submitted information, and correct this, until such time as the data is entered into Eudract from the Quarantine Area by the competent authority.

10.2 Completion of submission forms to the competent authority (ies)

The data required for the database is a subset of the data required by the request for authorisation and can therefore also be used to complete the forms submitted to the competent authority (ies) and part of those for the Ethics Committees (see: ‘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’ and guidance for application to competent authorities).

To simplify the process of application by sponsors to the competent authorities and the ethics committees, the system will facilitate the preparation of the complete paper submission forms to both. Submission forms to the competent authorities of the Member States and the submission forms to ethics committees will be available from the system, which will enable generation of these forms with the questions and headings in the official languages of the Member States. The system will automatically populate the data fields in the forms with the data submitted by the sponsor and will allow the Member State specific elements to be entered on each. These forms can then be printed and forwarded on paper to the relevant competent authority (ies) or ethics committee(s) with the required attachments (see: Detailed guidance on the application format to Ethics Committees and competent authorities). To this end these completed forms may be downloaded by the sponsor and stored electronically.

In addition the system will permit the electronic transmission of the full, completed forms to those competent authorities accepting electronic submission of the completed form.

The form design indicates those fields that appear in the database.

This principle is also applied to the Amendment and Notification of end of trial forms.

10.3 Before assessment of the clinical trial request by the competent authority (ies)

Upon receipt of the electronic data submitted by the sponsor, the competent authority will perform an administrative confirmation of the data, by comparison with the full submission form accompanying the request for the clinical trial. This confirmation is an administrative check that the fields are complete and contain information appropriate to the fields, and that the information is in accordance with that supplied on the form accompanying the full paper submission. To facilitate this process the data may be viewed in a format that is the same as that on the paper document.

The competent authority may query the submitted information and request correction or confirmation of the submitted data, or submission of missing elements in the Quarantine Area.

Failure by the sponsor to submit accurate or complete information may be a reason to consider the request submitted to conduct a clinical trial to be invalid.

The competent authority then takes the data electronically from the Quarantine Area and enters this data into the Eudract database. The competent authority performs this transfer at day 0 following validation.

For single state trials, the competent authority of the concerned Member State will do this.

For multistate trials the data is entered by the first Member State acting on the dossier, each other Member State, on receipt of the application, confirms the common data and enters the data specific to its territory, and may query it with the sponsor if they consider there is an inaccuracy or omission. If the data is specific to the Member State, any correction is made by the Member State generating the query, or by the sponsor. If the data correction/update also relates to the study conduct in Member States where the review of the dossier has already commenced the sponsor will need to make an amendment.

A copy of the transferred data and any amendments or updates made to the data submitted by the sponsor is retained accessible to the originating sponsor, in the Quarantine Area. This copy is in the form of a locked file which can be read by the sponsor and the competent authorities/agency/commission. The originating sponsor may also download or print the data from the Quarantine Area. Any further amendment or update follows the processes described in the sections below.

10.4 After validation and before authorisation/refusal of the clinical trial by the competent authority (ies)

The items relating to the initial review and authorisation of the trial are completed by the competent authority (Appendix 2, N). This information relates to the initial ethics committee opinion and authorisation by the competent authority.

Depending on whether the ethics committee opinion was known to the sponsor before the submission to the competent authority this information may have been supplied electronically by the sponsor or may need to be completed by the competent authority.

10.5 Amendment

If the information contained in the initial submission (application form, protocol or other documentation) of a clinical trial changes significantly, then this should be notified to the competent authority(s) as an amendment - see “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 declaration of the end of a clinical trial”. The sponsor completes the required information in the amendment screens of the Quarantine Area. The sponsor completes the amendment form and sends this with supporting documentation as required to the competent authority. On receipt of the forms the competent authority verifies the data as for an initial submission and then updates those fields that have changed, by entering the sponsor supplied amending information from the Quarantine Area into Eudract. This process results in an update of the locked file of sponsor

information in the Quarantine Area, thus ensuring that the sponsor has available a copy of an up to date version of the information they supplied to the competent authority(ies).

The competent authority enters information on substantial amendments to the protocol or to the request under the items in Appendix 2, N or O, as they are informed of them during the lifecycle of a trial.

Some items will be identified as only requiring update at the end of the trial with the final information.

10.6 At the end of the trial

The sponsor is required to notify the competent authority of the end of the trial, or of its early termination. This is done by the form provided in the Detailed guidance to competent authorities. The competent authority enters the data identified in Appendix 2, P, on receipt of the declaration of the end of the trial. This is done by the same process as described for amendments in section 10.5.

10.7 Availability of the Eudract number

If the sponsor requires the Eudract number for inclusion on internal documentation and other planning, it may be obtained in advance of submission of the full set of electronic information, by completion of the minimum set of parameters (essentially sponsor, protocol and test product information stated in Appendix 1 A, B and key elements of D). The remaining data required for the trial may be completed then or later but must be complete by the time of submission of the request for authorisation of the trial to the competent authority (ies).

To this end the data will remain available to the sponsor in the Quarantine Area for up to one year before a submission takes place. If no submission has been received and confirmed in that year the data are automatically deleted from the database. However this year will be automatically extended for a further 12 months on each occasion that a sponsor changes (by addition, alteration or deletion) data elements relating to the clinical trial under the given Eudract number.

10.8 Data Quality Assurance and Quality Control

It is the responsibility of the party making the data submission or entry, to ensure the accuracy and completeness of the data at the time it is first entered. The sponsor is responsible for the accuracy of data submitted to the competent authorities. The Competent Authority is responsible for the data entered into the database, based on that submitted by the sponsor.

Staff (at the sponsor and at the competent authority) responsible for data submission/confirmation/entry/review should be trained for the purpose and have

standard operating procedures available to them. Quality control and assurance systems should be in place to verify the accuracy and integrity of the data entry.

The system will include automated checks to ensure internal consistency; to check for duplicate entries; to check that valid terms are used and to validate where possible, information included. These processes will be capable of generating reports for the purposes of quality review and management of the database.

The system will be equipped with an electronic audit trail to identify the date, time and source of original entries and any changes to these, including the identity of the party making the original and any new or changed entry. The audit trail will function in such a way as to ensure that the old entries as well as the most recent version can be viewed. Where appropriate the reason for change will be recorded (standard reasons will be provided via a picklist).

Data consistency is enforced through form design and by the use of picklists, dropdown menus and dictionaries or automatically generated codes or text as appropriate and feasible. For this reason, the use of free text will be minimised. In addition the system will require a mandatory response to all sections, each section will provide the appropriate range of responses (yes, no, other, not applicable, etc.) to ensure that this is possible.

10.9 Language

In order to facilitate the implementation of the database, and to enable search and reporting functions, data will be entered in English whenever possible. Where feasible dropdown menus/picklists may be provided in the official languages. It is recognised that not all dictionaries will be available in all official languages and may initially exist only in English. Translations of dictionaries will only be used where the originators of the dictionaries make full and current versions available.

10.10 Backup

The European Database Manager will ensure appropriate and regular backup on electronic media of the system and data contents, to permit restoration in case of loss or damage to the database.

11 Links with other databases

There will be a link between this database and the Eudravigilance database.

The database(s) will be compatible with other community regulatory authority databases, in particular Eudravigilance, as far as data structure and electronic transmission and exchange standards are concerned.

It is the responsibility of member states to enable download/upload of data to/from their national databases and this database.

12 Data security and confidentiality

The security standards that apply will, as a minimum, be those set by the European Commission for the operation of secure networks for regulatory authority communication. Access to the database is restricted to the competent authorities of the Member States, the Commission and the Agency. Sponsors submit electronic information to be included in the database to a Quarantine Area but do not have access to the database itself (see section 8). The sponsor will only have access to its own data, which remains in the Quarantine Area and to reports issued to the sponsor on updates to its data.

The Eudract database will not contain individual personal information relating to clinical trial subjects/patients. Personal data should be protected in accordance with the provisions of Good Clinical Practice and Directive 95/46/EC and in keeping with other EU pharmacovigilance requirements (Volume 9 of the rules governing medicinal products in the European Union).

Member States must respect the confidentiality of information downloaded from the database to national databases in line with Directive 2001/20/EC and this detailed guidance.

13 Electronic data communication between competent authorities of the Member States, the Agency and the Commission.

Electronic communication will be enabled using the current community standards for secure communication between regulatory authorities. The precise technical specifications, including data flows, for the database(s), communications, security, data fields and electronic transmission of data will be in the specification and design documents.

14 Reporting and Search Functions

The system will be provided with a number of pre-established reporting functions.

The system will be provided with a number of search functions that will permit the location of specific information using key data items (e.g. Eudract number, sponsor protocol code number, product identification) and the generation of a range of ad hoc reports based on this function and the relations between the data items.

The system will provide a number of management reports to facilitate its use, quality control and maintenance.

15 Termination or suspension of trials

15.1 Trials terminated or suspended for safety reasons.

Eudract will send a message to the competent authorities whenever an entry is made in the database indicating that a trial has been terminated or suspended for safety reasons.

15.2 Trials terminated or suspended for other reasons.

Eudract will automatically notify all Member States where a trial is terminated or suspended in any given Member State, for the reasons outlined in article 12 of the Directive 2001/20/EC.

16 Inspections

It is a key objective of the Directive 2001/20/EC that the Member States, the Agency and the Commission are aware of inspections carried out, to determine compliance with that directive. This facilitates effective inspections relating to particular clinical trials, products or sites, within or outside the community. The Member States, the Agency and the Commission, can also be aware of inspections carried out when considering applications for marketing authorisation or for conduct of clinical trials.

The inspectorate conducting the inspection enters the data required by section 2 of appendix 2 (Q and/or R). Inspections related to particular clinical trials or reviewing data from particular clinical trials will identify those trials by their Eudract number, and by the sponsor identity and sponsor protocol code number.

The data are entered as soon as the inspection on site is carried out and the outcome when the report is finalised.

Appendix 1

Eudract Clinical Trial Database – data content

Data to be completed prior to submission of the clinical trial application to the competent authority in a Member State

NB The numbering and indents do not indicate strict hierarchical data relationships in the database.

ENTR-6421-01 Appendix 1

AAA. Free text field for each member state competent authority to enter comment.

AA. The member state to which the data apply (*This data is specific to each member state*)

A. TRIAL IDENTIFICATION

A.1 Eudract number

A.2 Full title of the trial

A.3 Sponsor's protocol code number

A.4 Name or abbreviated title of the trial where available

A.5 ISRCTN number, if available

B. IDENTIFICATION OF THE SPONSOR RESPONSIBLE FOR THE TRIAL
(*Where the trial has co-sponsors these should be identified, and the Member States in which each co-sponsor is responsible (if they are separately responsible in individual Member States)*)

B.1 Sponsor Organisation, town/city, country.

B.2 Legal representative of the sponsor in the Community, Person/organisation, town/city, country.

B.3 Status of the sponsor: commercial or non commercial

B.4 Lead/co-sponsor per Member State *repeat as needed*

C. APPLICANT IDENTIFICATION (*This data is specific to each member state*)

C.1 Sponsor or legal representative of the sponsor or Person or organisation authorised by the sponsor to make the application

C.2 Person/organisation, town/city, country.

D. INVESTIGATIONAL MEDICINAL PRODUCT

INFORMATION ON INVESTIGATIONAL MEDICINAL PRODUCT (S) BEING USED IN THE TRIAL: MEDICINAL PRODUCT BEING TESTED OR USED AS A COMPARATOR – repeat for each product being tested and where necessary should be entered specifically for each Member State (D.1.1 and D.1.2)

D.0 IMP being tested/IMP used as comparator – insert a sequential number (1 to n) for each product described.

D.1.1 Has the IMP a MA in the MS? Tradename, MAH, MA number

D.1.2 Has the IMP a MA in another MS from which it is sourced for this trial?
Trade name, MAH, MA number

- D.1.3 If no to 2 has the IMP a MA in the 3rd country from which it is sourced for this trial? country
- D.1.4 Has the test IMP been previously authorised in a clinical trial conducted by the sponsor in the Community?
- D.1.5 Has the investigational medicinal product been designated in this indication as an orphan product in the Community?
- D.1.6 If yes to D.1.5 give the orphan product designation number?

D.2 DESCRIPTION OF THE IMP

- D.2.1 Product name and product code where applicable:
- D.2.2 Name of each active substance (INN or proposed INN if available)
- D.2.3 Other available name for each active substance (CAS, sponsor code (including previous code(s), other descriptive name etc)
- D.2.4 ATC code if officially registered:
- D.2.5 Sponsor generated ATC code for this indication, if applicable
- D.2.6 Pharmaceutical form (standard terms)
- D.2.7 Route of administration (standard terms)
- D.2.8 Strength (all strengths to be used)
- D.2.9 Does the IMP contain an active substance:
 - D.2.9.1 of chemical origin?
 - D.2.9.2 of biological/biotechnological origin?
- D.2.10 Is this:
 - D.2.10.1 a cell therapy medicinal product?
 - D.2.10.2 a gene therapy medicinal product?
 - D.2.10.3 a radiopharmaceutical medicinal product?
 - D.2.10.4 an immunological medicinal product (such as vaccine, allergen, immune serum)?
 - D.2.10.5 a herbal medicinal product?
 - D.2.10.6 a homeopathic medicinal product?
 - D.2.10.7 a medicinal product containing GMO(s)?
 - D.2.10.8 another medicinal product? - specify
- D.2.11 If D.2.9.2 if yes indicate:
 - D.2.11.1 is the substance extractive, recombinant, vaccine, GMO, plasma derived and/or other (specify)?
- D.2.12 If D.2.10.1 if yes indicate the following
 - D.2.12.1 origin of the cells – autologous, allogeneic or xenogeneic
 - D.2.12.2 species of origin for xenogeneic cells
 - D.2.12.3 Type of cells: stem cells, differentiated cells (specify type), other (specify)
- D.2.13 If D.2.10.2 if yes indicate:
 - D.2.13.1 Gene(s) of interest
 - D.2.13.2 In vivo or ex vivo gene therapy
 - D.2.13.3 Type of gene therapy product:
 - D.2.13.3.1 Nucleic acid and if yes specify if naked or complexed
 - D.2.13.3.2 Viral vector and if yes specify the type
 - D.2.13.3.3 Other (specify)
 - D.2.13.4 If Genetically modified cells:

D.2.13.4.1 Origin of the cells – autologous, allogeneic or xenogeneic

D.2.13.4.2 Species of origin for xenogeneic cells

D.2.13.4.3 Type of cells

E. INFORMATION ON PLACEBO (repeat as necessary)

E.1 Is it placebo for test IMP or comparator IMP or both/all?

E.2 Pharmaceutical form

E.3 Route of administration

E.4 Is it otherwise identical to the IMP?

E.5 Is it otherwise identical to the comparator?

E.6 If not E.4 or E.5 specify major ingredients:

F. AUTHORISED SITE RESPONSIBLE IN THE COMMUNITY FOR THE RELEASE OF THE INVESTIGATIONAL MEDICINAL PRODUCT IN THE COMMUNITY (repeat as necessary)

F.1 Who is responsible in the Community for the release of the finished IMP?

F.1.1 Manufacturer or importer

F.1.2 Organisation, town/city, Country

F.1.3 Identify the products released at this site

G. GENERAL INFORMATION ON THE TRIAL

G.1 Medical condition or disease under investigation

G.1.1 Specify the medical condition (free text)

G.1.2 ICD10 classification

G.1.3 MedDRA classification code

G.1.4 Is it a rare disease?

G.2 Objective of the trial

G.2.1 Main objective of the trial

G.2.2 Secondary objectives (repeat as necessary)

G.2.3 Principal inclusion criteria (repeat as necessary)

G.2.4 Principal exclusion criteria (repeat as necessary)

G.2.5 Primary endpoints (repeat as necessary)

G.3. Scope of the trial

G.3.1 Indicate all which apply: diagnostic, prophylactic, therapeutic, safety, efficacy, pharmacokinetic, pharmacodynamic, bioequivalence, dose response, pharmacogenomic, pharmacoeconomic, others (specify)

G.4.1 Trial type and phase:

G.4.1.1 Human pharmacology (phase I)

G.4.1.2 Therapeutic exploratory (Phase II)

G.4.1.3 Therapeutic confirmatory (Phase III)

G.4.1.4 Therapeutic use (Phase IV)

G.4.1.5 Bioequivalence study

G.4.1.6 Other (specify)

G.5 Design of trial:

- G.5.1 Randomised
- G.5.2 Controlled
 - G.5.2.1 Open
 - G.5.2.2 Single blind
 - G.5.2.3 Double blind
 - G.5.2.4 Parallel group
 - G.5.2.5 Cross-over
 - G.5.2.6 Other (specify)
- G.6 Specify comparator:
 - G.6.1 (An)Other medicinal product(s)
 - G.6.2 Placebo
 - G.6.3 Other (specify)
- G.7 Sites:
 - G.7.1 Single site
 - G.7.2 Multiple sites, single state
 - G.7.3 Multiple states
 - G.7.4 Includes third country sites
- G.8 Dosing and duration of dosing and trial with test product
 - G.8.1 Maximum duration of treatment of a subject according to the protocol
 - G.8.2 Maximum dose allowed (specify: per day or total)
- G.9 Definition of the end of the trial and justification, in the case where it is not the last visit of the last subject undergoing the trial
- G.10 Initial estimation of the duration of the trial in the Community (in weeks/months/years)

H. POPULATION OF TRIAL SUBJECTS

- H.1 Age span
 - H.1.1 In Utero
 - H.1.2 Preterm newborn infants (up to gestational age ≤ 37 weeks)
 - H.1.3 Newborn (0-27 days)
 - H.1.4 Infant and toddler (28 days - 23 months)
 - H.1.5 Children (2-11 years)
 - H.1.6 Adolescent (12-17 years)
 - H.1.7 Adult (18-65 years)
 - H.1.8 Elderly (> 65 years)
- H.2 Gender
 - H.2.1 Male
 - H.2.2 Female
- H.3 Population of trial subjects
 - H.3.1 Healthy volunteers
 - H.3.2 Patients
 - H.3.3 Women of child-bearing potential
 - H.3.4 Pregnant women
 - H.3.5 Nursing Women
 - H.3.6 Emergency situation
 - H.3.7 Subjects incapable of giving consent personally (specify)
 - H.3.8 Other (specify)
- H.4 Planned number of subjects to be included:

- H.4.1 In the Community
- H.4.2 In the whole trial

I. PROPOSED CLINICAL TRIAL SITES IN THE MEMBER STATE CONCERNED BY THIS REQUEST

INVESTIGATORS

- I.1.1 Principal investigator (for single centre trials)
 - I.1.2.1 Person, department, institution, town/city, country.
- I.1.2 Coordinating investigator (for multicentre trials)
 - I.1.1.1 Person, department, institution, town/city, country

(The following data is optional but to be completed on request of a Member State, specifically for that member state)

- I.2.1 Other principal investigators (for multicentre trials, repeat as necessary)
 - I.2.1.1 Person, department, institution, town/city, post code, country.

CENTRAL TECHNICAL FACILITIES, CROs etc.

(This data is specific to each member state, or may be the same for several/all member states; the facilities may be within or outside the community) (Where it is different for each Member State it is entered at the optional request of each Member state concerned)

- I.3.1 Central technical facilities to be used in the conduct of the trial (laboratory or other technical facility, repeat as necessary)
 - I.3.1.1 Department, institution/organisation, town/city, post code, country.
 - I.3.1.2 Duties subcontracted (picklist)
 - I.3.1.3 Providing services to the following Member States (picklist)

- I.4.1 Trial monitoring facilities, has the sponsor transferred any or all the sponsor's trial related duties and functions to another organisation or third party (repeat as necessary)?
 - I.4.1.1 Department, organisation/institution, town/city, post code, country.
 - I.4.1.2 Duties/functions subcontracted (picklist)
 - I.4.1.3 Providing services to the following Member States (picklist)

J. ETHICS COMMITTEE IN THE MEMBER STATE CONCERNED BY THIS REQUEST *(This data is specific to each member state)*

- J.1 Name of the committee/or not yet identified
- J.2 Town/city, country
- J.3 Opinion
 - J.3.1 To be requested, pending, given
 - J.3.2 Given opinion:
 - J.3.2.1 Date of opinion
 - J.3.2.2 Favourable or non-favourable

K. NOT APPLICABLE

L. NOT APPLICABLE

M. ORIGINATOR OF THE DATA PROVIDED ELECTRONICALLY

M.1 Sponsor electronic data completed by:

M1.1 Organisation

M.1.2 Address

M.1.3 Eudract registration identity

M.1.4 Confirmation that the data are accurate

Appendix 2

EUDRACT Clinical Trial Database – data content

Data to be completed at the time of initiation or after the initiation of the clinical trial and up to and after its completion

List of data to be entered after the initial submission to the competent authority. This data needs to be entered separately for each Member State

NB The numbering and indents do not indicate strict hierarchical data relationships in the database.

Section 1 Dates and associated information on the initiation, amendment and end of the trial.

N. REVIEW OF INITIAL APPLICATION

- N.1 Member State Concerned
- N.2 National clinical trial number (at option of each national competent authority)
- N.3 Amendment to the request prior to authorisation/no notification of non-acceptance
 - N.3.1 Amendment code number
 - N.3.2 Date of Amendment
- N.4 ETHICS COMMITTEE IN THE MEMBER STATE CONCERNED BY THIS REQUEST (if not already entered under J) and repeat with opinion on amendment in N.3 if required due to sequence of applications to ethics committee and competent authority
 - N.4.1 Name of the committee
 - N.4.2 town/city, country
 - N.4.3 Opinion
 - N.4.3.1 Date of opinion
 - N.4.3.2 Favourable or non-favourable
- N.5 Competent Authority concerned:
 - N.5.1 Name, town/city, country
 - N.5.2 Clinical Trial authorised/refused
 - N.5.3 Date of authorisation or refusal

O. AMENDMENTS TO THE PROTOCOL OR THE REQUEST

- O.1 Substantial amendment to the protocol:
 - O.1.1 Amendment code number
 - O.1.2 Date of Amendment
- O.2 Ethics committee opinion on Substantial protocol amendment
 - O.2.1 Date of opinion concerning the amendment
 - O.2.2 Favourable or non-favourable
- O.3 Competent authority authorisation of Substantial protocol amendment
 - O.3.1 Protocol Amendment authorised/refused
 - O.3.2 Date of authorisation or refusal
- O.4 Substantial amendment to request:
 - O.4.1 Amendment code number
 - O.4.2 Date of Amendment
- O.5 Competent authority authorisation of Substantial amendment to request
 - O.5.1 Amendment to request authorised/refused
 - O.5.2 Date of authorisation or refusal
- O.6 Ethics committee opinion on Substantial amendment to request
 - O.6.1 Date of opinion
 - O.6.2 Favourable or non-favourable

P. DECLARATION OF THE END OF THE CLINICAL TRIAL

P.1 Date of the end of the trial

P.2 Is it the completion of the trial

P.2.1 In the member state?

P.2.2 Is it the end of the complete trial in all Member States concerned by the trial?

P.3 Is it a premature ending of the trial? Yes/No

Is it a temporary halt of the trial? Yes/No

In either case:

Specify reason(s)

P.3.1 Safety

P.3.2 Lack of Efficacy

P.3.3 Not commenced

P.3.4 Other - specify

P.4 Briefly describe the justification in case of a premature ending of the trial

P.5 Anticipated date of final clinical study report:

P.6 Date of receipt of the final clinical study report by the competent authority (if applicable)

Section 2 Inspections – to be completed by the Member State Inspectorate

Q. INSPECTION OF CLINICAL TRIAL SITES

- Q.1 Inspection reference number
- Q.2 Was the inspection:
 - Q.2.1 Trial specific –
 - Q.2.1.1 Eudract number (repeat as needed for several trials)
 - Q.2.1.2 Sponsor protocol code number in case of third country inspection of protocols without a Eudract number
 - Q.2.2 System / facility inspection (not clinical trial specific)
 - Q.2.2.1 Specify system / facility
- Q.3 Type of site
- Q.4 First and last date of on-site inspection
- Q.5 Inspecting authority (lead inspectorate)
- Q.6 Name and address of site
- Q.7 Was the inspection triggered?
- Q.8 Inspection outcome

R. INSPECTION OF INVESTIGATIONAL MEDICINAL PRODUCT MANUFACTURER/IMPORTER

- R.1 Inspection reference number
- R.2 First and last date of inspection
- R.3 Inspecting authority (lead inspectorate)
- R.4 Site inspections – name and address of site
- R.5 Type of site manufacturer, importer, manufacturer/importer
- R.6 Was the inspection part of the site authorisation process?
 - R.6.1 Initial inspection
 - R.6.2 Recontrol
- R.7 Was the inspection part of the control of a particular product(s)?
 - R.7.1 Specify product(s)
- R.8 Was the inspection part of the control of a particular trial(s)?
 - R.8.1 Specify the Eudract number(s) or if there is no Eudract number specify the sponsor protocol code number(s)
- R.9 Was the inspection triggered?
- R.10 Inspection outcome



EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

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

Brussels,
ENTR/CT 5.1

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

**Amendment describing Deployment of
EudraCT – Lot 1 for 1 May 2004**

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1 Introduction

European regulatory authorities need a database in order to provide each of them with an overview of clinical trials being conducted in the community. .
This guidance is applicable to all clinical trials (as defined by Directive 2001/20/EC¹) for which at least one site falls within the territory of a Member State.

The Detailed Guidance published in April 2003, foresaw that the EudraCT system described would be deployed as one system with all its features for 1 May 2004. Having taken into account constraints on the production of such a system in that time frame the Telematics Steering Committee (TSC) at its meeting in Verona, July 2003 decided that the EudraCT system should be developed in two lots as follows:

- Development of a first version of the database of information on clinical trials (EudraCT), in compliance with the requirements of Directive 2001/20/EC: **2004**
- Extension and upgrading of the first version of the database EudraCT, in compliance with the requirements of the detailed guidance, modified if necessary: **2005**

The Telematics Steering Committee represents the Commission, the Member States and the Agency and is the high level decision making body for implementation of European Telematics systems for the Regulatory Authorities of medicinal products.

This document is an Annex to the original Detailed guidance on the European clinical trials database (EudraCT) (April 2003). It has been drawn up in order to describe the implementation of the TSC decision set out above.

This Annex should be read in conjunction with the Detailed guidance on the European clinical trials database (EudraCT) (April 2003), to which it is an annex and the Detailed guidance on the European Database of Suspected Unexpected Serious Adverse Reactions.

A simple overview of Lot 1 is provided in diagrams in sections:

2 Scope

This Annex describes the version of EudraCT to be deployed as Lot 1 on for 1 May 2004. As such it highlights the similarities and differences from the detailed guidance published in April 2003. Therefore this annex and the detailed guidance document together provide the higher-level user requirements and system definition on the European clinical trials database (EudraCT) for Lot 1 and 2.

¹ 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

3 Definitions:

The definitions of the Directive 2001/20/EC and of the implementing texts adopted in line with that directive, including this annex, apply.

4 Legal Basis

The legal basis for the EudraCT database is provided in article 11 of Directive 2001/20/EC. The deployment of Lot 1 is designed to meet minimum requirements of the Directive.

5 User Requirements

Section 5 of the Detailed guidance on the European clinical trials database (EudraCT) (April 2003) applies.

The link to Eudravigilance Clinical Trial Module is anticipated as part of Lot 2 of the deployment.

6 Identification of the clinical trial

Section 6 of the Detailed guidance on the European clinical trials database (EudraCT) (April 2003) applies. The EudraCT number is made available via a public web interface, on the provision of minimal information concerning the clinical trial (essentially the sponsor's protocol code number, the identity of the requestor (the person requesting the EudraCT number on behalf of the sponsor) of the EudraCT number, and the email address to which the system should return the EudraCT number. The requestor should first obtain a security code from the system and then using this the EudraCT number. The process is automated and requires input only from the requestor and the EudraCT database server, which issues the number via email.

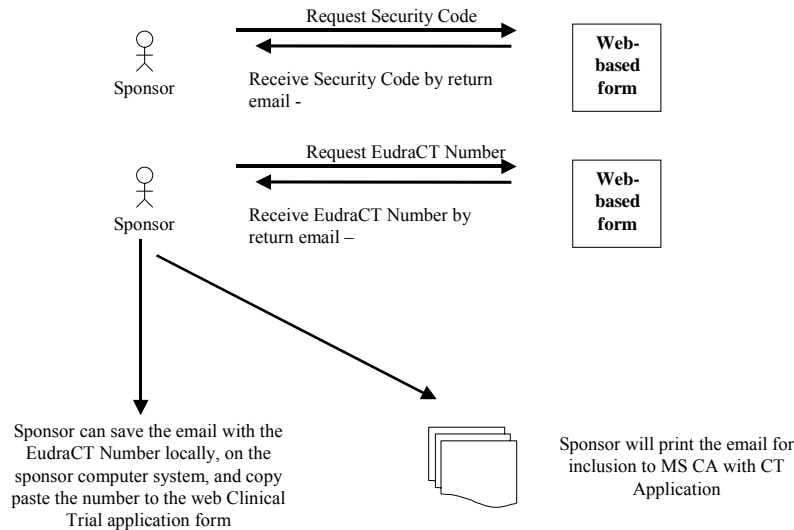
The EudraCT number has the format YYYY-NNNNNN-CC, where:

- YYYY is the year in which the number is issued.
- NNNNNN is a six digit sequential number
- CC is a check digit

The sponsor's protocol code number is also used throughout as a trial identifier, the record is not case sensitive, will not recognise spaces as characters, should be unique (at least within the sponsor organisation) for that trial, and should not change during the trial.

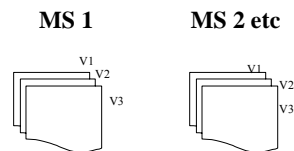
To Get a EudraCT Number

Log on to the public web site of EudraCT



EudraCT Database Structure Member State and Multistate

EudraCT number
YYYY-NNNNNN-CC



V1 = original application

V2 = substantial amendment 1 affecting EudraCT data set

V3 = substantial amendment 2 affecting EudraCT data set

7 Identification of the product

Each investigational medicinal product (IMP) needs to be uniquely identifiable.

The link to the Eudravigilance product dictionary will be established as part of Lot 2. The fields describing the IMP(s) for a trial in EudraCT and those in Eudravigilance Clinical Trial Module (EVCTM) are harmonised at the time of deployment of Lot 1 but an interface cannot be established at this point. The principles set out in the

Detailed guidance section 7 serves as the basis for the data included now in EudraCT and foreseen in the EVCTM product dictionary and its future interface with EudraCT. Reference is made to section 7 of the Detailed guidance on the European clinical trials database (EudraCT)(April 2003).

For situations where it is not possible to identify the IMPs in advance of the start of the clinical trial the Clinical Trial Authorisation Application form and procedure foresee exceptions, to this explicit and unambiguous identification of the IMP, where in specific circumstances products may be identified only by the active substance, or even by the ATC group. The products are required to be on the market in the Member State concerned. These are set out in the 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, in section 4.1.6.2.2 Marketed products and in section D.1.b of the Application form, in annex to the same Detailed guidance.

8 Data to be entered into the database

The EudraCT database will contain, in Lot 1 all the data fields listed in Appendix to this annex, changes from the Detailed Guidance of April 2004 are underlined.

The minimum fields to be completed (to the extent they apply to a given trial and the data is available) are set out in a separate document “EudraCT Core Data Set”, to be published by the Commission.

8.1 Aims of Lot 1

The Quarantine area and the related registration of sponsors foreseen in the April 2003 Detailed Guidance do not form part of Lot 1.

In Lot 1 there is a public web form, which provides the following functionality:

- A sponsor completes the application form to the Member State Competent Authority (or module 1 of the Ethics Committee application form). This is done using the web utility on-line, as is editing of previously saved data.
- The data is saved locally on the sponsor’s computer system, as a complete data set or as a core data set (XML file). No data can be saved over the web but only locally in the sponsor’s computer system. A form can be completed in several work sessions provided the XML file is saved locally, during work and before logging off each session.
- The complete data set can be used to generate a .pdf rendition of the completed application form to the competent authority or module 1 of the application form to the Ethics Committee, which can be saved locally on the sponsor’s computer system.

- Locally saved XML files can be uploaded for completion of the form over more than one on-line working period. The same function can be used to permit editing, by the sponsor, of a locally saved data set, for use in application to another Member State, or modification for use in closely related clinical trial. This minimises redundant data entry.

Member States may request an XML file of the Core Data Set or the complete data set from the Sponsor.

9 Sponsor registration with the system

Since the quarantine area is not part of Lot 1 and no data is saved by the Sponsor onto any central database, but locally on the sponsor's computer system, there is no requirement for sponsor registration. The sponsor portal to the application form and its functionality is via a public site.

10 Data submission and data entry procedures

10.1 Before submission of the clinical trial to the competent authority (ies)

The data required for the database, which is shown in appendix 1, is a subset of the data required by the request for authorisation submitted to the competent authority (ies). (see: 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.)

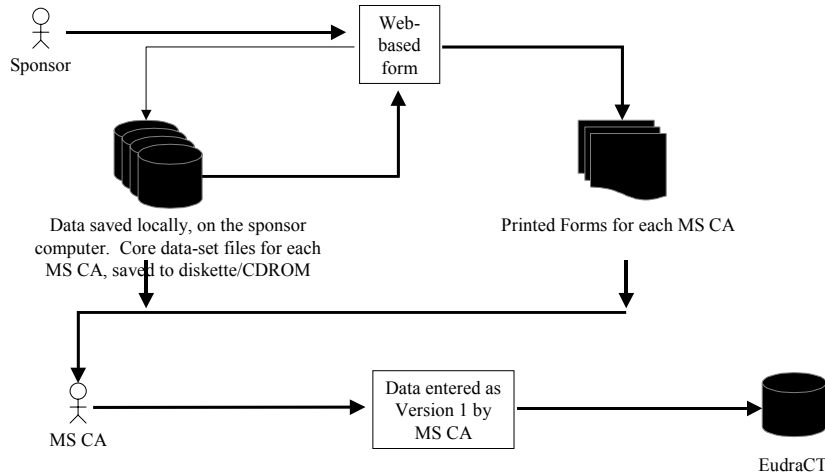
Each clinical trial needs to be clearly identified in the database preferably at the start of the assessment period (and at the latest before the competent authority provides written authorisation for the trial or takes the decision that there are no grounds for non-acceptance).

This is to ensure that the database is a complete database and can fulfil its objectives, in supporting communication between authorities, review of SUSARs, inspections and the ongoing recording of amendments and end of trial notifications.

All the information required from the sponsor for the database, applicable to a given trial and available at the time of submission of the request to the competent authority, must also have been submitted, in electronic format (XML file generated from the clinical trial application form on the public website of EudraCT), by the sponsor to the Competent Authority, by that time.

10.2 Completion of submission forms to the competent authority (ies)

Complete an electronic CT Form Sponsor Logs onto the EudraCT public web



The sponsor (or their delegate)

- logs on to the public EudraCT website
- completes the Clinical Trial Application form
- saves the XML file of the application form data to his local computer system
- saves the core data set XML file to his local computer system
- saves the .pdf rendition of the application form to his local computer system
- prints and signs the application form
- saves the corresponding full or core data set (as requested by the MS CA) XML file to a disk
- sends the package containing the signed application form, XML file on disc and all required supporting documentation for the Clinical Trial Application (protocol IPD etc) to the Competent Authority
- for multistate trials this is repeated for each competent authority, with modification of Member State specific information in the XML file and .pdf form to the situation in each new Member State.

In the same way the web system can be used to generate and print the Module 1 of the application to the Ethics committee, reusing the same XML file.

10.3 Before assessment of the clinical trial request by the competent authority (ies)

The Member State Competent Authority (MS CA):

- Receives and opens the application package
- Loads the XML file onto the secure EudraCT database (Edit area)
- Checks the information on screen to that on the signed paper application form

- Enters the data from the XML file to the EudraCT database, thus creating the record for that trial for that Member State
- If the MS CA recognizes an error, in the initial application, the sponsor will be asked to revise the XML file and the signed request form and return it to the MS CA.
- If the MS CA alters data in the submitted XML the MS CA will return a copy of the revised XML to the sponsor

For multistate trials this process is repeated by each MS CA and thus for one EudraCT number there is an associated record per Member State, in EudraCT.

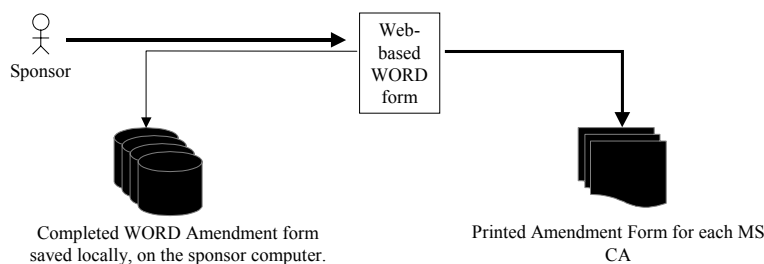
10.4 Recording of authorisation/refusal of the clinical trial by the competent authority (ies)

The items relating to the initial review and authorisation of the trial are completed by the competent authority (Appendix 2, N). This information relates to the initial ethics committee opinion and authorisation by the competent authority.

Depending on whether the ethics committee opinion was known to the sponsor before the submission to the competent authority this information may have been supplied electronically by the sponsor or may need to be completed by the competent authority.

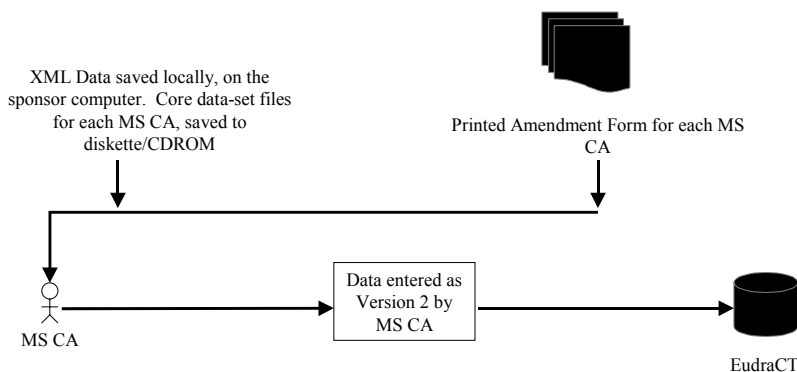
10.5 Amendment

Making a substantial Amendment



Sponsor determines if the amendment changes information in the original application form then if so
 The Sponsor retrieves the original XML file and updates the information in line with the amendment and resaves
 The XML and sends it on a CD/floppy to the MS CA with the paper amendment forma and supporting documentation.

Amendment Part 2 – applicable where it affects the EudraCT data set



The request for substantial amendment form is available on the EudraCT public website as an active Word template.

The sponsor:

- completes the form, saves it locally on his computer system
- prints and signs the application form

If the substantial amendment alters data in the XML dataset initially submitted to the MS CA, the sponsor (or their delegate)

- logs on to the public EudraCT website
- uploads the full XML file of the initial Clinical Trial Application form data
- revises those items changed by the amendment
- saves the revised XML file of the application form data and core data set to his local computer system
- prints out the revised Clinical Trial Application form (from this revised XML), and highlight on the paper those items modified
- sends the package containing the signed request for substantial amendment form, revised XML file on disc, highlighted changes on a copy of the revised Clinical Trial Application form and all required supporting documentation for the substantial amendment to the Competent Authority
- for multistate trials this is repeated for each competent authority, with modification of Member State specific information in the XML file and amendment form to the situation in each new Member State.

The Member State Competent Authority (MS CA):

- Receives and opens the substantial amendment application package, then:

Either

- Accesses the EudraCT record for that trial
- Edits that record in line with the highlighted changes on the printout of the Clinical Trial Application form
- Enters the revised record into the EudraCT database
- Sends a copy of the revised XML data to the sponsor

Or

- Loads the revised XML file onto the secure EudraCT database (Edit area)
- Checks the information on screen to that on the signed paper substantial amendment application form
- Enters the data from the XML file to the EudraCT database, thus creating a revised record for that trial for that Member State. This revised record is a complete set of the originally submitted data, incorporating the amendment changes, and held as a new version

For multistate trials this process is repeated by each MS CA and thus for one EudraCT number there is an associated record per Member State, in EudraCT, for each amendment.

The competent authority enters information on substantial amendments to the protocol or to the request under the items in Appendix 2, N or O, as they are informed of them during the lifecycle of a trial. Where there is no change to the original application data recorded in EudraCT only the fields in Appendix 2, N or O are required to be completed and no new version of the XML file is required.

Some items may be identified as only requiring update at the end of the trial with the final information.

10.6 At the end of the trial

The sponsor is required to notify the competent authority of the end of the trial, or of its early termination. This is done by the form provided in the Detailed guidance to competent authorities. The competent authority enters the data identified in Appendix 2, P, on receipt of the declaration of the end of the trial. This is done by the same process as described for amendments in section 10.5.

The Notification of End of Trial form is available on the EudraCT public website as an active Word template.

The sponsor:

- completes the form, saves it locally on his computer system
- prints and signs the form
- submits the form to the MS CA

Temporary halts or suspensions:

If the suspension is such that it is lifted by submission of new information/data, confirmation of an action, or a changed protocol by the sponsor this will take the form of a substantial amendment.

If the suspension is imposed and lifted by decision of the Competent Authority and/or Ethics Committee without the sponsor submitting an amendment then the option in section P- End of the trial “Is there another reason? Specify” will be used, to identify if the suspension was performed by the sponsor or at the request of the Competent

Authority and if the suspension has been lifted by the Competent Authority/Ethics Committee in the absence of an amendment being submitted by the sponsor.

10.7 Availability of the EudraCT number

The EudraCT number must be obtained in advance of the first application to a Competent authority or to an Ethics committee for that clinical trial in any Member State. The process is described in section 6.

10.8 Data Quality Assurance and Quality Control

Section 10.8 of the Detailed guidance on the European clinical trials database (EudraCT) (April 2003) applies, with the following constraints.

- In Lot 1 automated checks and data validation will be present as a limited range of functions, expansion of which is anticipated for Lot 2.
- The member state checks the data on the XML file received against that on the application form.
- In Lot 1 due to the public nature of the Website, (and its design using a thin client architecture), the MedDRA dictionary cannot be made available over the Web to the sponsor completing the form. The sponsor should obtain the code, for the indication being studied (see in section G of the form), from the MedDRA dictionary available to them (once they are a licensed user) and copy this code to the field provided. The MS CA may access the MedDRA dictionary through their usual access point, as a licensed user of the system.
- In Lot 1 the development of the Eudravigilance Medicinal Product Dictionary and the EudraCT database in parallel, has not permitted time prior to 1 May 2004 to create a dynamic link between the dictionary and the database. This is anticipated for Lot 2. However, in Lot 1 data fields in EudraCT and in the Eudravigilance Medicinal Product Dictionary have been mapped, to ensure future compatibility.

10.9 Language

In order to facilitate the implementation of the database, and to enable search and reporting functions, data will be entered in English whenever possible.

In lot 1 entry screens, printed forms and drop down lists or dictionaries may only be available in English. Member States competent authorities, have agreed to accept application forms (to the competent authority) in English where a sponsor wishes to apply in English or finds this more practical (e.g. in multistate trials).

10.10 Backup

The European Database Manager will ensure appropriate and regular backup on electronic media of the system and data contents, to permit restoration in case of loss or damage to the database.

11 Links with other databases

The link between EudraCT and the Eudravigilance database and its dictionary is anticipated for Lot 2 of the development of EudraCT.

The database(s) will be compatible with other community regulatory authority databases, in particular Eudravigilance, as far as data structure and electronic transmission and exchange standards are concerned.

It is the responsibility of member states to enable download/upload of data to/from their national databases and this database.

12 Data security and confidentiality

Section 12 of the Detailed guidance on the European clinical trials database (EudraCT) (April 2003) applies, except for references to the Quarantine area, which does not form part of Lot 1.

13 Electronic data communication between competent authorities of the Member States, the Agency and the Commission.

Section 13 of the Detailed guidance on the European clinical trials database (EudraCT) (April 2003) applies.

14 Reporting and Search Functions

A minimum set of search and reporting functions will be made available, for the Member State, EMEA and Commission users, with Lot 1. These will include some preset and some ad hoc search capabilities.

15 Termination or suspension of trials

15.1 Trials terminated or suspended for safety reasons.

EudraCT will highlight that a trial has been suspended in a Member State for safety reasons.

15.2 Trials terminated or suspended for other reasons.

EudraCT will highlight when a trial has been terminated in a Member State for reasons specified

16 Inspections

Section 16 of the Detailed guidance on the European clinical trials database (EudraCT) (April 2003) applies. Inspectorates may indicate that an inspection is anticipated, completed (on-site) or cancelled.

Appendix 1

EudraCT Clinical Trial Database – data content

Data to be completed prior to submission of the clinical trial application to the competent authority in a Member State (Refer to separate document detailing the core data set to be maintained for all clinical trials).

NB The numbering and indents do not indicate strict hierarchical data relationships in the database.

ENTR-6421-01 Appendix 1

AAA. Free text field for each member state competent authority to enter comment.

AA. The member state to which the data apply (*This data is specific to each member state*)

AA.1 The Member State Competent authority

A. TRIAL IDENTIFICATION

A.1 EudraCT number

A.2 Full title of the trial

A.3 Sponsor's protocol code number

A.4 Name or abbreviated title of the trial where available

A.5 ISRCTN number, if available

B. IDENTIFICATION OF THE SPONSOR RESPONSIBLE FOR THE TRIAL

B.1 Sponsor Organisation, town/city, country.

B.2 Legal representative of the sponsor in the Community, Person/organisation, town/city, country.

B.3 Status of the sponsor: commercial or non commercial

C. APPLICANT IDENTIFICATION (*This data is specific to each member state*)

C.1 Sponsor or legal representative of the sponsor or Person or organisation authorised by the sponsor to make the application

C.2 Person/organisation, town/city, country.

D. INVESTIGATIONAL MEDICINAL PRODUCT

INFORMATION ON INVESTIGATIONAL MEDICINAL PRODUCT (S) BEING USED IN THE TRIAL: MEDICINAL PRODUCT BEING TESTED OR USED AS A COMPARATOR – repeat for each product being tested and where necessary should be entered specifically for each Member State (D.1.1 and D.1.2)

D.0 IMP being tested/IMP used as comparator – insert a sequential number (1 to n) for each product described.

D.1.1 Has the IMP a MA in the MS? Tradename, MAH, MA number

D.1.2 Has the IMP a MA in another MS from which it is sourced for this trial?

Member State, Trade name, MAH, MA number

D.1.3 If no to D.1.2 has the IMP a MA in the 3rd country from which it is sourced for this trial? Country

D.1.b Situations where the IMP to be used in the CT has a MA in the MS concerned but the protocol allows that any brand of the IMP with a MA in that MS be administered to the trial subjects, but it is not possible to clearly identify the IMP(s) in advance of the trial start:

D.1.b.1 In the protocol treatment is defined only by active substance Y/N

D.1.b.2 In the protocol treatment regimens allow different combinations of marketed products used according to local clinical practice at some or all investigator sites in the MS Y/N

D.1.b.3 The products to be administered are defined as belonging to an ATC group Y/N

D.1.b.4 Other - please specify

D.1.4 Has the test IMP been previously authorised in a clinical trial conducted by the sponsor in the Community?

D.1.5 Has the investigational medicinal product been designated in this indication as an orphan product in the Community?

D.1.6 If yes to D.1.5 give the orphan product designation number?

D.2 DESCRIPTION OF THE IMP

D.2.1 Product name

D.2.1.2 product code where applicable

D.2.2 Name of each active substance (INN or proposed INN if available)

D.2.3 Other available name for each active substance (CAS, sponsor code (including previous code(s), other descriptive name etc)

D.2.4 ATC code if officially registered:

D.2.6 Pharmaceutical form (standard terms)

D.2.7 Route of administration (standard terms)

D.2.8 Concentration (all concentrations (presentations) to be used)
Concentration (number), Concentration Unit, Concentration type

D.2.9 Does the IMP contain an active substance:

D.2.9.1 of chemical origin?

D.2.9.2 of biological/biotechnological origin?

D.2.10 Is this:

D.2.10.1 a cell therapy medicinal product?

D.2.10.2 a gene therapy medicinal product?

D.2.10.3 a radiopharmaceutical medicinal product?

D.2.10.4 an immunological medicinal product (such as vaccine, allergen, immune serum)?

D.2.10.5 a herbal medicinal product?

D.2.10.6 a homeopathic medicinal product?

D.2.10.7 a medicinal product containing GMO(s)?

D.2.10.8 another medicinal product? - specify

D.2.11 If D.2.9.2 if yes indicate:

D.2.11.1 is the substance extractive, recombinant, vaccine, GMO, plasma derived and/or other (specify)?

D.2.12 If D.2.10.1 if yes indicate the following

D.2.12.1 origin of the cells – autologous, allogeneic or xenogeneic

- D.2.12.2 species of origin for xenogeneic cells
- D.2.12.3 Type of cells: stem cells, differentiated cells (specify type), other (specify)
- D.2.13 If D.2.10.2 if yes indicate:
 - D.2.13.1 Gene(s) of interest
 - D.2.13.2 In vivo or ex vivo gene therapy
 - D.2.13.3 Type of gene therapy product:
 - D.2.13.3.1 Nucleic acid and if yes specify if naked or complexed
 - D.2.13.3.2 Viral vector and if yes specify the type
 - D.2.13.3.3 Other (specify)
 - D.2.13.4 If Genetically modified cells:
 - D.2.13.4.1 Origin of the cells – autologous, allogeneic or xenogeneic
 - D.2.13.4.2 Species of origin for xenogeneic cells
 - D.2.13.4.3 Type of cells

E. INFORMATION ON PLACEBO (repeat as necessary)

- E.1 Which IMP is it a placebo for? Specify sequence number(s) from D.0
- E.2 Pharmaceutical form
- E.3 Route of administration
- E.4 Is it otherwise identical to the IMP?
- E.5 Is it otherwise identical to the comparator?
- E.6 If not E.4 or E.5 specify major ingredients:

F. AUTHORISED SITE RESPONSIBLE IN THE COMMUNITY FOR THE RELEASE OF THE INVESTIGATIONAL MEDICINAL PRODUCT IN THE COMMUNITY (repeat as necessary)

- F.1 Who is responsible in the Community for the release of the finished IMP?
 - F.1.1 Manufacturer or importer
 - F.1.2 Organisation, town/city, Country
 - F.1.3 Identify the products released at this site by sequence number from D.0 or E

G. GENERAL INFORMATION ON THE TRIAL

- G.1 Medical condition or disease under investigation
 - G.1.1 Specify the medical condition (free text)
 - G.1.2 ICD10 classification (if available)
 - G.1.3 MedDRA classification code
 - G.1.4 Is it a rare disease?
- G.2 Objective of the trial
 - G.2.1 Main objective of the trial
 - G.2.2 Secondary objectives
 - G.2.3 Principal inclusion criteria
 - G.2.4 Principal exclusion criteria

- G.2.5 Primary endpoints
- G.3. Scope of the trial
 - G.3.1 Indicate all which apply: diagnostic, prophylactic, therapeutic, safety, efficacy, pharmacokinetic, pharmacodynamic, bioequivalence, dose response, pharmacogenomic, pharmacoeconomic, others (specify)
 - G.4.1 Trial type and phase:
 - G.4.1.1 Human pharmacology (phase I)
 - G.4.1.2 Therapeutic exploratory (Phase II)
 - G.4.1.3 Therapeutic confirmatory (Phase III)
 - G.4.1.4 Therapeutic use (Phase IV)
 - G.4.1.1.1 Is it a first administration to humans?
 - G.4.1.5 Bioequivalence study
 - G.4.1.6 Other (specify)
- G.5 Design of trial:
 - G.5.1 Randomised
 - G.5.2 Controlled
 - G.5.2.1 Open
 - G.5.2.2 Single blind
 - G.5.2.3 Double blind
 - G.5.2.4 Parallel group
 - G.5.2.5 Cross-over
 - G.5.2.6 Other (specify)
- G.6 Specify comparator:
 - G.6.1 (An)Other medicinal product(s)
 - G.6.2 Placebo
 - G.6.3 Other (specify)
- G.7 Sites:
 - G.7.1 Single site
 - G.7.2 Multiple sites, single state
 - G.7.3 Multiple states
 - G.7.4 Includes third country sites
- G.8 Dosing and duration of dosing and trial with test product
 - G.8.1 Maximum duration of treatment of a subject according to the protocol
 - G.8.2 Maximum dose allowed (specify: per day or total)
- G.9 Definition of the end of the trial and justification, in the case where it is not the last visit of the last subject undergoing the trial
- G.10 Initial estimation of the duration of the trial in the Community (in weeks/months/years)

H. POPULATION OF TRIAL SUBJECTS

- H.1 Age span
 - H.1.0 Less than 18 years (if yes specify):
 - H.1.1 In Utero
 - H.1.2 Preterm newborn infants (up to gestational age ≤ 37 weeks)
 - H.1.3 Newborn (0-27 days)
 - H.1.4 Infant and toddler (28 days - 23 months)
 - H.1.5 Children (2-11 years)

- H.1.6 Adolescent (12-17 years)
- H.1.7 Adult (18-65 years)
- H.1.8 Elderly (> 65 years)
- H.2 Gender
 - H.2.1 Male
 - H.2.2 Female
- H.3 Population of trial subjects
 - H.3.1 Healthy volunteers
 - H.3.2 Patients
 - H.3.3 Women of child-bearing potential
 - H.3.4 Pregnant women
 - H.3.5 Nursing Women
 - H.3.6 Emergency situation – if yes specify
 - H.3.7 Subjects incapable of giving consent personally (if yes specify)
 - H.3.8 Other (if yes specify)
- H.4 Planned number of subjects to be included:
 - H.4.1 In the Community
 - H.4.2 In the whole clinical trial

I. PROPOSED CLINICAL TRIAL SITES IN THE MEMBER STATE CONCERNED BY THIS REQUEST

INVESTIGATORS

- I.1.1 Principal investigator (for single centre trials)
 - I.1.2.1 Person, department, institution, town/city, country.
- I.1.2 Coordinating investigator (for multicentre trials)
 - I.1.1.1 Person, department, institution, town/city, country

(The following data is optional but to be completed on request of a Member State, specifically for that member state)

- I.2.1 Other principal investigators (for multicentre trials, repeat as necessary)
 - I.2.1.1 Person, department, institution, town/city, post code, country.

CENTRAL TECHNICAL FACILITIES, CROs etc.

(This data is specific to each member state, or may be the same for several/all member states; the facilities may be within or outside the community) (Where it is different for each Member State it is entered at the optional request of each Member state concerned)

- I.3.1 Central technical facilities to be used in the conduct of the trial (laboratory or other technical facility, repeat as necessary)
 - I.3.1.1 Department, institution/organisation, town/city, post code, country.
 - I.3.1.2 Duties subcontracted (picklist)

- I.4.1 Trial monitoring facilities, has the sponsor transferred any major or all the sponsor's trial related duties and functions to another organisation or third party (repeat as necessary)?

- I.4.1.1 Department, organisation/institution, town/city, post code, country.
- I.4.1.2 Duties/functions subcontracted (picklist)
- I.4.1.3 Providing services to the following Member States (picklist)

J. ETHICS COMMITTEE IN THE MEMBER STATE CONCERNED BY THIS REQUEST (*This data is specific to each member state*)

- J.1 Name of the committee/or not yet identified
- J.2 Town/city, country
- J.3 Opinion
 - J.3.1 To be requested, pending, given
 - J.3.2 Given opinion:
 - J.3.2.1 Date of opinion
 - J.3.2.2 Favourable or non-favourable

K. NOT APPLICABLE

L. NOT APPLICABLE

Appendix 2

EUDRACT Clinical Trial Database – data content

Data to be completed at the time of initiation or after the initiation of the clinical trial and up to and after its completion

List of data to be entered after the initial submission to the competent authority. This data needs to be entered separately for each Member State

NB The numbering and indents do not indicate strict hierarchical data relationships in the database.

Section 1 Dates and associated information on the initiation, amendment and end of the trial.

N. REVIEW OF INITIAL APPLICATION

N.1 Member State Concerned

N.1.1 Date of start of the procedure in the Member State

N.2 National clinical trial number (at option of each national competent authority)

N.3 Amendment to the request prior to authorisation/no notification of non-acceptance

N.3.1 Sponsor's protocol amendment code number

N.3.2 Date of Amendment

N.3.3 Sponsor's protocol amendment code number

N.3.4 Date of Amendment

N.4 ETHICS COMMITTEE IN THE MEMBER STATE CONCERNED BY THIS REQUEST (if not already entered under J) and repeat with opinion on amendment in N.3 if required due to sequence of applications to ethics committee and competent authority

N.4.1 Name of the committee

N.4.2 town/city, country

N.4.3 Opinion

N.4.3.1 Date of opinion

N.4.3.2 Favourable or non-favourable

N.5 Competent Authority concerned:

N.5.1 Name, town/city, country

N.5.2 Clinical Trial authorised/refused

N.5.3 Date of authorisation or refusal

O. AMENDMENTS TO THE PROTOCOL OR THE REQUEST

O.1 Substantial amendment to the protocol:

O.1.1 Amendment code number

O.1.2 Date of Amendment

O.2 Ethics committee opinion on Substantial protocol amendment

O.2.1 Date of opinion concerning the amendment

O.2.2 Favourable or non-favourable

O.3 Competent authority authorisation of Substantial protocol amendment

O.3.1 Protocol Amendment authorised/refused

O.3.2 Date of authorisation or refusal

O.4 Substantial amendment to request:

O.4.1 Amendment code number

O.4.2 Date of Amendment

O.5 Competent authority authorisation of Substantial amendment to request

O.5.1 Amendment to request authorised/refused

O.5.2 Date of authorisation or refusal

O.6 Ethics committee opinion on Substantial amendment to request

O.6.1 Date of opinion

O.6.2 Favourable or non-favourable

P. DECLARATION OF THE END OF THE CLINICAL TRIAL

P.1 Date of the end of the trial

P.2 Is it the completion of the trial

P.2.1 In this member state?

P.2.2 Is it the end of the complete trial in all countries concerned by the trial?

P.3 Is it a premature ending of the trial? Yes/No

Is it a temporary halt of the trial? Yes/No

In either case:

Specify reason(s)

P.3.1 Safety

P.3.2 Lack of Efficacy

P.3.3 The trial has not commenced

P.3.4 Other - specify

P.4 Briefly describe the justification in case of a premature ending of the trial

P.5 Anticipated date of final clinical study report:

P.6 Date of receipt of the final clinical study report by the competent authority (if applicable)

Section 2 Inspections – to be completed by the Member State Inspectorate

Q. INSPECTION OF CLINICAL TRIAL SITES

- Q.1 Inspection reference number
- Q.2 Was the inspection:
 - Q.2.1 Trial specific –
 - Q.2.1.1 EudraCT number and / or sponsor protocol code number (repeat as needed for several trials)
 - Q.2.1.2 Sponsor protocol code number in case of third country inspection of protocols without a EudraCT number
 - Q.2.2 System / facility inspection (not clinical trial specific)
 - Q.2.2.1 Specify system / facility
- Q.3 Type of site
 - Q.3.1 Free text for inspectorate to make note if needed, on inspection
 - Q.3.2 Anticipated date of inspection and status (pending, completed on site, cancelled)
- Q.4 First and last date of on-site inspection (actual completed dates)
- Q.5 Inspecting authority (lead inspectorate)
- Q.6 Name and address of site
- Q.7 Was the inspection triggered?
- Q.8 Inspection outcome

R. INSPECTION OF INVESTIGATIONAL MEDICINAL PRODUCT MANUFACTURER/IMPORTER

- R.1 Inspection reference number
 - R.1.1 Free text for inspectorate to make note if needed, on inspection
 - R.1.2 Anticipated date of inspection and status (pending, completed on site, cancelled)
- R.2 First and last date of inspection (actual completed dates)
- R.3 Inspecting authority (lead inspectorate)
- R.4 Site inspections – name and address of site
- R.5 Type of site manufacturer, importer, manufacturer/importer
- R.6 Was the inspection part of the site authorisation process?
 - R.6.1 Initial inspection
 - R.6.2 Re-inspection
- R.7 Was the inspection part of the control of a particular product(s)?
 - R.7.1 Specify product(s)
- R.8 Was the inspection part of the control of a particular trial(s)?
 - R.8.1 Specify the EudraCT number(s) and / or the sponsor protocol code number(s)
- R.9 Was the inspection triggered?
- R.10 Inspection outcome



EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

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

Brussels,
ENTR/CT 5.2

Final

**Annex to CT 5.1 describing Deployment of
EudraCT
– Lot 1 for 1 May 2004**

Core dataset

This dataset is the minimum core dataset to be maintained by all CAs, and to be made mandatory in the future for the request form filled in by the sponsors through EudraCT web (for those data that come from the application form) in order to:

- Fulfill a minimum legal compliance with the Directive 2001/20/EC article 11
- Fulfill the agreed requirements of the CAs on a basic initial communication of clinical trial information at the European database level

These represent the data that will be entered for new trials commencing as of 1 May 2004 (this means new applications for clinical trials as of 1 May 2004)

Not all of the data will apply to each trial and if some fields are completed others will, as a consequence, not be necessary. A set of data entry conventions will be needed to address this e.g. if INN entered then proposed INN or sponsor's protocol code number are not required unless they are widely used in the trial documentation.

Core data set

Field ID	Field	Comments
AA	The member to which the data apply	
AA.1	The member state competent authority to which the data apply	
A	TRIAL IDENTIFICATION	
A.1	Eudract number	
A.2	Full title of the trial	
A.3	Sponsor's protocol code number	
B.	IDENTIFICATION OF THE SPONSOR RESPONSIBLE FOR THE TRIAL	<i>(repeat as needed)</i>
B.1	Sponsor Organisation, town/city, country.	
B.2	Legal representative of the sponsor in the Community, Person/organisation, town/city, country.	
B.3	Status of the sponsor: commercial or non commercial	
D	INVESTIGATIONAL MEDICINAL PRODUCT	INFORMATION ON EACH INVESTIGATIONAL MEDICINAL PRODUCT (S) BEING USED IN THE TRIAL EXCEPT FOR PLACEBOS (to be used either as test, comparator or both):-
D.0	IMP sequential number (1 to n) for each product described.	(automatically generated by database)
D.1.1	Has the IMP a MA in the MS? Tradename,	
D.1.2	If no to D.1.1, Has the IMP a MA in another MS from which it is sourced for this trial? Trade name, Member State	
D.1.3	If no to D.1.1 and D.1.2 has the IMP a MA in the 3 rd country from which it is sourced for this trial? Country	
D.1.b	Situations where the IMP to be used in the CT has a MA in the MS concerned but the protocol allows that any brand of the IMP with a MA in that MS be administered to the trial subjects, but it is not possible to clearly identify the IMP(s) in advance of the trial start:	
D.1.b.1	In the protocol treatment is defined only by active substance Y/N	
D.1.b.2	In the protocol treatment regimens allow different combinations of marketed products used according to local clinical practice at some or all investigator sites in the MS Y/N	
D.1.b.3	The products to be administered are defined as belonging to an ATC group Y/N	
D.1.b.4	Other - please specify	
D1.5	Has the IMP been designated in this indication as an orphan product in the Community?	This information on orphan status should be entered when known to the

		sponsor and especially where it is the sponsor or the sponsor's parent organisation that has the designation, but it should not be considered mandatory since for many IMPs the sponsor may not know the answer.
D.1.6	If yes to 1.5 give the Orphan Product Designation Number?	See above
D.2	DESCRIPTION OF THE IMP	
D.2.1	If no to D.1.1, D.1.2 and D.1.3, Product name and product code where applicable	
D.2.2	Name of each active substance (INN or proposed INN if available)	
D.2.3	Other available name for each active substance (CAS, sponsor code, other descriptive name etc)	
D.2.4	ATC code if officially registered	Only if the product is used within the terms of the MA in the MS concerned and may be used to define a class/group of therapy and using the applicable levels of the official ATC code to the most detailed level applicable
D.2.6	Pharmaceutical form	(standard terms)
D.2.7	Route of administration	(standard terms)
D.2.8	Concentration (all strengths to be used)	=concentration (terms as per Eudravigilance) – to be entered where the specific strengths being used are clearly known – incorporates concentration type, concentration number, and concentration unit
D.2.9	Does the IMP contain an active substance:	
D.2.9.1	of chemical origin?	
D.2.9.2	of biological/biotechnological origin?	
D.2.10:	Is this	
D.2.10.1	a cell therapy medicinal product?	
D.2.10.2	a gene therapy product?	
D.2.10.3	a radiopharmaceutical product?	
D.2.10.4	an immunological product (such as vaccine, allergen, immune serum)?	
D.2.10.5	a herbal medicinal product?	
D.2.10.6	a homeopathic medicinal product?	
D.2.10.7	a medicinal product containing GMO(s)?	
D.2.10.8	another medicinal product? - specify	
E.1	Is placebo used	yes/No
F.	AUTHORISED SITE RESPONSIBLE IN THE COMMUNITY FOR THE RELEASE OF THE INVESTIGATIONAL MEDICINAL PRODUCT IN THE COMMUNITY (REPEAT AS NECESSARY)	
F.1	Who is responsible in the Community for the release of the finished IMP?	
F.1.1	Manufacturer or importer or both (tick box)	

F.1.2	Organisation, town/city, Country	
F.1.3	Identify the products released at this site	
G.	GENERAL INFORMATION ON THE TRIAL	
G.1	Medical condition or disease under investigation	
G.1.1	Specify the medical condition	(free text)
G.1.2	ICD code	If known to sponsor ICD or MedDRA may be used but MedDRA is requested where available to sponsor
G.1.3	MedDRA classification code	If known to sponsor
G.1.4	is it a rare disease?	In the opinion of the sponsor.
G.3.	Scope of the trial	(all yes/no check boxes)
G.3.1	Indicate all which apply: diagnostic, prophylaxis, therapeutic, safety, efficacy, pharmacokinetic, pharmacodynamic, bioequivalence, dose response, pharmacogenomic, pharmacoeconomic, others (specify)	(tick boxes)
G.4.1	Trial type and phase:	
G.4.1.1	Human pharmacology (phase I)	
G.4.1.2	Therapeutic exploratory (Phase II)	
G.4.1.3	Therapeutic confirmatory (Phase III)	
G.4.1.4	Therapeutic use (Phase IV)	
G.4.1.1.1	Is it a first administration to humans?	
G.4.1.5	Bioequivalence study	
G.4.1.6	Other (specify)	
G.5	Design of trial:	(yes / no check boxes)
G.5.1	Randomised	
G.5.2	Controlled	
H.	POPULATION OF TRIAL SUBJECTS	(All Yes/No check boxes)
H.1	Age span	
	Are any patients under 18 included:	Y/N if Y specify:
H.1.1	In Utero	
H.1.2	Preterm newborn infants (up to gestational age ≤ 37 weeks)	
H.1.3	Newborn (0-27 days)	
H.1.4	Infant and toddler (28 days - 23 months)	
H.1.5	Children (2-11 years)	
H.1.6	Adolescent (12-17 years)	
H.1.7	Adult (18-65 years)	
H.1.8	Elderly (> 65 years)	
H.2	Gender	
H.2.1	Male	
H.2.2	Female	
H.3	Population of trial subjects	
H.3.1	Healthy volunteers	
H.3.2	Patients	

H.3.3	Women of child-bearing potential	
H.3.4	Pregnant women	
H.3.5	Nursing Women	
H.3.6	emergency situation– if yes specify	
H.3.7	Subjects incapable of giving consent personally (specify)	
H.3.8	Other (specify)	
H.4	Planned number of subjects to be included:	
H.4.1	In the Community	
J.	ETHICS COMMITTEE IN THE MEMBER STATE CONCERNED BY THIS REQUEST	<i>(This data is specific to each member state)</i>
J.3	Opinion	
J.3.2	Given opinion:	
J.3.2.1	Date of opinion	
J.3.2.2	Favourable or non-favourable	
N.	INITIAL APPLICATION	
N.0	Member State Concerned	(automatically derived by database for MS CA userid)
N.2	Amendment to the request prior to authorisation/no notification of non-acceptance	
N.2.1	Amendment code number	
N.2.2	Date of Amendment	
N.3	ETHICS COMMITTEE IN THE MEMBER STATE CONCERNED BY THIS REQUEST	
N.3.3	Opinion	
N.3.3.1	Date of opinion	
N.3.3.2	Favourable or non-favourable	
N.4	Competent Authority concerned:	
N.4.1	Name, town/city, country (automatically derived by database for MS CA userid)	
N.4.2	Clinical Trial authorised/refused	
N.4.3	Date of authorisation or refusal	
O.	AMENDMENTS TO THE PROTOCOL OR THE REQUEST	
O.1	Substantial amendment to the protocol:	
O.1.1	Amendment code number	
O.1.2	Date of Amendment	
O.2 t	Ethics committee opinion on Substantial protocol amendment	
O.2.1	Date of opinion concerning the amendment	
O.2.2	Favourable or non-favourable	
O.3	Competent authority authorisation of Substantial protocol amendment	
O.3.1	Protocol Amendment authorised/refused	
O.3.2	Date of authorisation or refusal	
O.4	Substantial amendment to request:	
O.4.1	Amendment code number	
O.4.2	Date of Amendment	
O.5	Competent authority authorisation of Substantial amendment to request	
O.5.1	Amendment to request authorised/refused	

O.5.2	Date of authorisation or refusal	
O.6	Ethics committee opinion on Substantial amendment to request	
O.6.1	Date of opinion	
O.6.2	Favourable or non-favourable	
P.	DECLARATION OF THE END OF THE CLINICAL TRIAL	
P.1	Date of the end of the trial	
P.2	Is it the completion of the trial	
P.2.1	In the member state?	
P.3	Is the trial terminating early?	Yes/No Specify reason(s)
P.3.1	Safety	
P.3.2	Lack of Efficacy	
P.3.3	Not commenced	
P.3.4	Suspended	
P.3.5	Other	
P.4	Is it a temporary halt?	
P.5	Decision of CA on temporary halt?	
Q.	INSPECTION OF CLINICAL TRIAL SITES	
Q.0	Inspection reference number	
Q.1:	Was the inspection?	
Q.1.1	Trial specific –	
Q.1.1.1	Eudract number (repeat as needed for several trials)	
Q.1.1.2	Sponsor protocol code number in case of third country inspection of protocols without a Eudract number	
Q.1.2	System or facility inspection (not clinical trial specific)	
Q.1.2.1	Specify system or facility	
Q.2	Type of site (drop down list)	
Q.3	date of on-site inspection	
Q.4	Inspecting authority (lead inspectorate)	
Q.5	Name and address of site	
Q.7	Inspection outcome (drop down list)	
R.	INSPECTION OF INVESTIGATIONAL MEDICINAL PRODUCT MANUFACTURER/IMPORTER	
R.0	Inspection reference number	
R.1	date of inspection	
R.2	Inspecting authority (lead inspectorate)	
R.3	Site inspections – name and address of site	
R.4	Type of site manufacturer, importer, manufacturer/importer	
R.5	Was the inspection part of the site authorisation process;	
R.5.1	Initial authorisation inspection	
R.5.2	Re-inspection	
R.6	Was the inspection part of the control of a particular product(s)?	
R.6.1	Specify product(s)	
R.7	Was the inspection part of the control of a	

	particular trial(s)?	
R.7.1	Specify the Eudract number(s) or if there is no Eudract number specify the sponsor protocol code number(s)	
R.9	Inspection outcome (drop down list)	