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/EC[1]) 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.

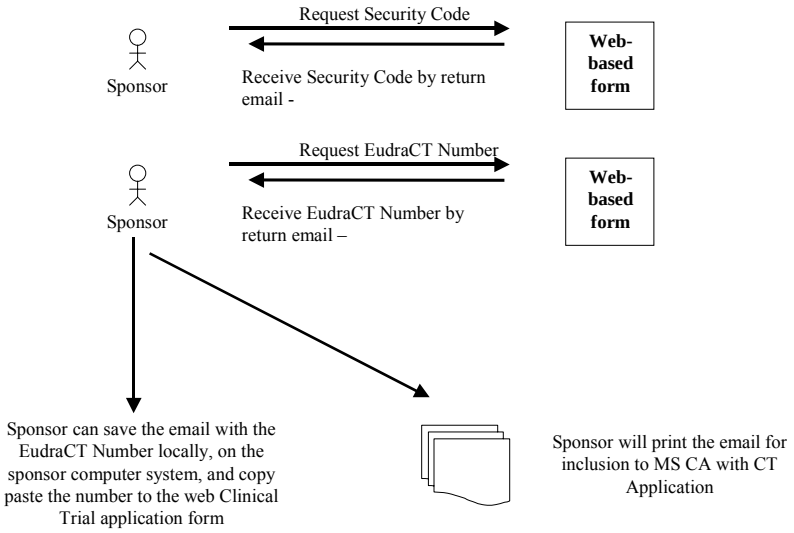
The EudraCT number has the format YYYY-NNNNNN-CC, where:

- 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

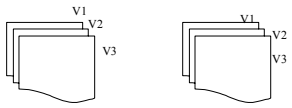


EudraCT Database Structure
Member State and Multistate

EudraCT number

YYYY-NNNNNN-CC

MS 1 **MS 2 etc**



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)

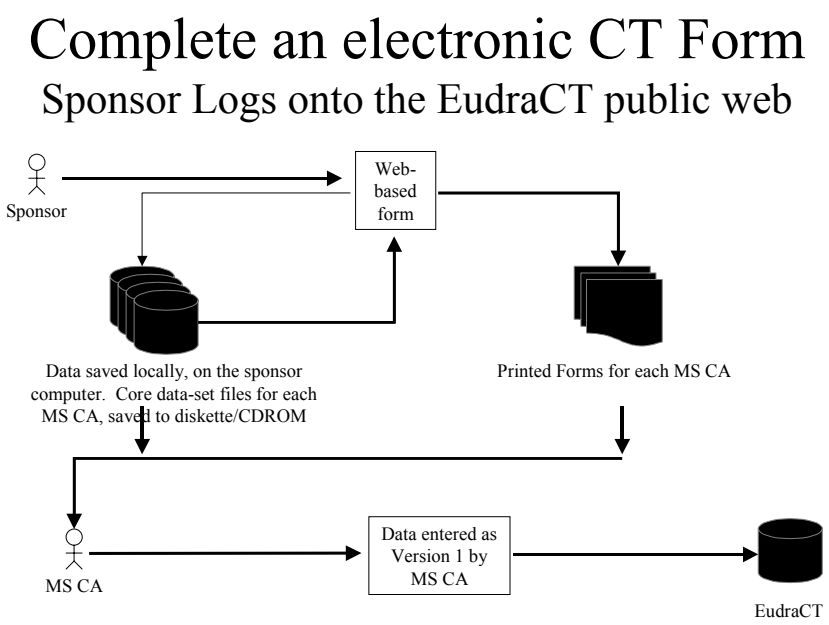
The data required for the database, which is shown in appendix 1, is a subset of the data required by the request for authorisation submitted to the competent authority (ies). (see: Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent 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)



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.

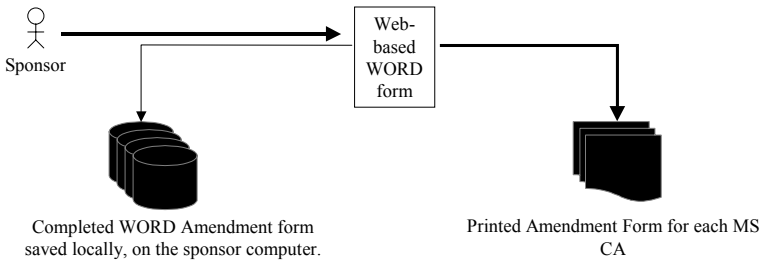
10.4 Recording of authorisation/refusal of the clinical trial by the competent authority (ies)

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.

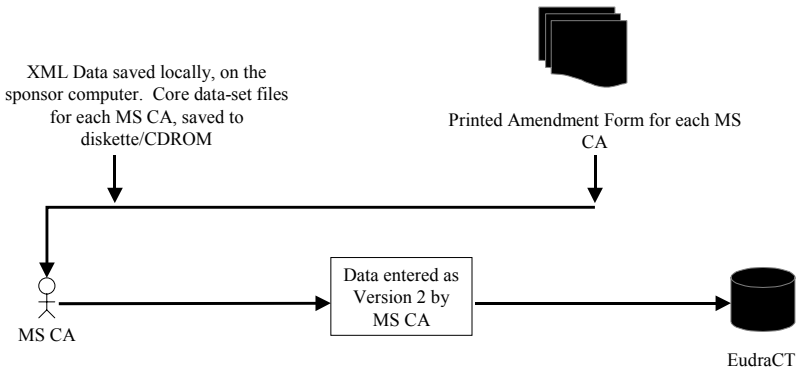
10.5 Amendment

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