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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public health and Risk assessment
Pharmaceuticals

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IMPLEMENTING TECHNICAL GUIDANCE - LIST OF FIELDS FOR RESULT-RELATED INFORMATION TO BE SUBMITTED TO THE 'EUDRACT' CLINICAL TRIALS DATABASE, AND TO BE MADE PUBLIC, IN ACCORDANCE WITH ARTICLE 57(2) OF REGULATION (EC) NO 726/2004 AND ARTICLE 41 OF REGULATION (EC) NO 1901/2006 AND THEIR IMPLEMENTING GUIDELINES 2008/C168/02 AND 2009/C28/01

DRAFT – SUBMITTED FOR PUBLIC CONSULTATION

At present, no result-related data is uploaded in EudraCT. This draft document (including the draft Annex which is published as a separate document) sets out the details as to how result-related information should be uploaded in EudraCT in the future and how this information is made public.

This draft document (including its Annex) is submitted for public consultation. Contributions are invited from all stakeholders related to clinical trials. Stakeholders who are not established within the European Union are equally invited to comment.

Contributions should be sent by e-mail to sanco-pharmaceuticals@ec.europa.eu on 30 September 2010 at the latest.

Contributions will be made publicly available on the 'Pharmaceuticals' website of the Commission once the consultation period is over. If you do not wish your contribution to be made public please indicate this clearly and specifically in the submitted documentation. In this case, only an indication of the contributor will be disclosed.

All contributions will be carefully analysed by the Commission. The final version of the detailed guidance is going to build on this consultation.

Apart from this initiative, please note that the information which is presently available in EudraCT (ie protocol-related information) is going to be made publicly accessible, in accordance with the applicable guidelines published in EudraLex, Volume, 10 Chapter V[1], in September 2010.

[1] http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/index_en.htm

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1. BACKGROUND AND PURPOSE

This technical guidance sets out the details regarding the submission of result-related information referred to in:

- Section 4.3. of Guideline 2010/C82/01 on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and declaration of the end of the trial (hereinafter 'detailed guidance CT-1');[2]

- Guideline 2008/C168/02 on the data fields contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC to be included in the database on medicinal products provided for in Article 57 of Regulation (EC) No 726/2004;[3] and

- Guideline 2009/C28/01 on the information concerning paediatric clinical trials to be entered into the EU Database on Clinical Trials (EudraCT) and on the information to be made public by the European Medicines Agency (EMEA), in accordance with Article 41 of Regulation (EC) No 1901/2006.[4]

This technical guidance is complementary to the two other implementing technical guidances on the *List of fields to be made public from EudraCT for Paediatric Clinical Trials in accordance with Article 41 of Regulation (EC) No 1901/2006* and the *List of fields contained in the 'EudraCT' clinical trials database to be made public, in accordance with Article 57(2) of Regulation (EC) No 726/2004*.[5]

2. MODALITIES OF SUBMISSION AND PROCESSING OF RESULT-RELATED DATA FIELDS

Submission

The result-related data are submitted to the European Medicines Agency ("the Agency"). This may be done by directly entering data using a web interface provided by the Agency, by uploading a XML file via the web interface or using a gateway technology. The data are submitted to a secure module of EudraCT.

The data should be provided in accordance with the XML schema and XML standard for these data established and published by the Agency. Guidance on completion of the data will also be provided.

The data are submitted by the sponsor, PIP addressee, Marketing Authorisation Holder, or their agent, as applicable. To this end the party responsible for submitting the data will have a secure user account to enable the upload and/or editing of these data in the system.[6] That party will have access only to their own data. This access will enable the

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2 OJ C82, 30.3.2010, p. 1.

3 OJ C168, 3.7.2008, p. 3.

4 OJ C28, 4.2.2009, p. 1.

5 http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/index_en.htm

6 In a future version of EudraCT, the possibility of user upload may serve also for updating certain fields not directly related to results, such as contact points for further information or enrolment status.

submission and maintenance of the data in a secure part of the system. The further processing and making public of these data will be controlled by the Agency.

Processing

In the secure part of the system, an automated and/or manual technical validation may take place. The data are then entered into the EudraCT database, and information on clinical trials to be made public in accordance with the guidance set out under (1) are selected by the applicable business rules and made public in the EU Clinical Trials Register. They will be linked to the protocol related data, where the latter are available in EudraCT.

It is not possible for the public to access the secure module. The submission of result-related data does not overwrite existing protocol-related data that are stored in EudraCT.

Timing

Result-related data should be submitted to the Agency within the timeframes set out in the Regulation (EC) No 1901/2006 and the guidelines referred to under (1), i.e. (relating to paediatric clinical trials) within 6 months[7] and otherwise within 1 year of the end of the clinical trial.[8]

The result-related data to be made public will be accessible in the EU Clinical Trials Register within 5 working days from the submission of a valid data set.

Language

The result related data are largely numerical, or based on value list definitions, using pre-defined options or dictionaries, thus allowing for several language versions, subject to the availability of translations of these lists or dictionaries. Free text data will be made available in the language in which it is submitted and the system will permit the entry of more than one language (from the official languages of the EU) version of each free text field.

Follow-up submission

The result-related data of a given trial may be locked so that no new submission for that trial is accepted by the system, after a period, to be established, but usually one year after the first submission of phase 1 or 2 trial results and 2 years after first submission of phase 3 or 4 trial results. The sponsor may still request to have the record unlocked for additional submission or correction or to have the data locked earlier.

Each version of result-related data will be stored and submission of new versions will not result in deletion of previously submitted versions, thus providing a record of changes. By default, the current version will be presented for public access, but previous versions may be reviewed by public users.

Provisions for results of clinical trials which have ended in the past

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[7] Point 2.2.2. of Guideline 2009/C28/01.

[8] Section 4.3. of the Detailed guidance CT-1.

An alternative submission process will be made available for clinical trials within the scope of Directive 2001/20/EC or within the scope of Article 41(2) of Regulation (EC) No 1901/2006, and which have ended more than 6 or 12 months (as applicable according to the required deadline for submission for the trial type in question) prior to the coming into operation of the systems set out in the present guidance.

For these trials the submission of result related data to the Agency for the purpose of EudraCT publication may be done as a PDF file, for example of an authorised copy of a medical journal article, or in the format of a synopsis in accordance with the ICH Topic E 3 guidance. To this end, a reduced set of fields will be established in EudraCT to identify the trials involved, to facilitate searching and to allow attachment of the PDF file containing the results.

Non-compliance, factual inaccuracy

Member States should verify that for clinical trials authorised by them the result-related data are submitted to the Agency.

In general, all corrections to published information will be made by the party submitting that information.

If GCP inspections reveal that there are serious doubts about the accuracy or reliability of the result-related data, the Agency will be informed immediately.

The Agency will retain the possibility of removing information from the public view, and/or adding a notice to the public record where necessary for reasons of factual accuracy or compliance with regulatory requirements.

3. STRUCTURE AND FORMAT OF THE RESULT-RELATED DATA TO BE SUBMITTED

The structure of the data to be collected is tabulated in Annex 1.

Certain fields of the protocol related data (e.g. E.6. Scope of the trial) will be used to present the context of the trial facilitating the presentation of the results related data fields. On the occasion of submitting results related data these fields may be updated by means of the web interface or alternatively via submission of an updated XML-file with protocol related data.

In general a comment field will be made available linked to data fields other than free text fields. The comment field is intended to allow for inclusion of information supplementing the fixed field contents. The structure of the collected data accommodates the large majority of clinical trials; however, the comment field may be used if data fields do not adequately accommodate the required information.

Note to the reader for the purpose of this public consultation:

For ease of reading, Annex 1 is published separately from this document.
As far as is practical EudraCT and ClinicalTrials.gov use common lists of pre-defined values and dictionaries, taking into account international standards in development.

For the purpose of this public consultation, the data elements of EudraCT are mapped to those of ClinicalTrials.gov. Explanation is given for those fields where differences exist.

Coherence with other public databases, both in the EU and internationally is an important objective. To ensure that sponsors do not have to provide different versions of results-related information to EudraCT and other international clinical trial results registers, it is important to develop consistent data elements. International standardisation of the data elements is being addressed through a number of initiatives at the level of ICH and HL7.

In developing the structure for results related data semantic interoperability should be established between the data elements required by different registers and databases.

The Agency continues to consult with the ClinicalTrials.gov staff at the US National Institutes of Health (NIH) to ensure that a common set of data elements can be used for reporting results to both EudraCT and ClinicalTrials.gov. The aim is to develop a commonly acceptable data standard for provision of results-related data, whilst allowing for some region-specific information requirements. The results related data set for EudraCT will take into account internationally agreed data standards that become available.

4. PRESENTATION OF THE RESULT-RELATED DATA FIELDS TO THE PUBLIC

The fields that are collected for the result-related data are made public through the EU Clinical Trials Register web site in accordance with the guidance set out under (1), ie excluding phase I trials not included in an agreed Paediatric Investigation Plan. The results-related information will be linked to the protocol-related information for each trial.

In addition to being readable in situ on the web, the data will be retrievable in an XML file. The data will also be made available in a printable format.

The web interface is going to provide tools to facilitate the searching, reading and browsing of the public information on clinical trials and their results.

[end]