EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

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PROCEDURE FOR STANDARDISATION OF GCP INSPECTION ENTRIES IN EUDRACT

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Applies to: EMEA, EU/EEA Inspectorates	
Summary of scope: This procedure describes the procedure on the entry of certain inspection data in EudraCT by the responsible competent authority of the Member States	
Keywords: GCP Inspection, EudraCT	**Restricted**
Supersedes: N/A	

1. PURPOSE OF THIS GUIDELINE

According to Article 11(1) of Directive 2001/20 relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use[1], Member States in whose territory the clinical trial takes place shall enter in a European database, accessible only to the competent authorities of the Member States, the Agency and the Commission:

(a) extracts from the request for authorisation referred to in Article 9(2);

(b) any amendments made to the request, as provided for in Article 9(3);

(c) any amendments made to the protocol, as provided for in point a of Article 10;

(d) the favourable opinion of the Ethics Committee;

(e) the declaration of the end of the clinical trial; and

(f) a reference to the inspections carried out on conformity with good clinical practice.

With regard to point (f), some experience has been gained with the use of EudraCT for recording of GCP inspections and this has given rise to a number of questions and a request for a common agreement on the entry of certain data.

2. RESPONSIBILITIES

It is the responsibility of each Inspectorate to ensure that a reference to the inspections carried out on conformity with good clinical practice is entered in EudraCT and therefore this procedure/guideline is adhered to within their own Inspectorate.

3. DEFINITIONS AND ACRONMYS

For the purpose of this guideline, the definitions apply as set out in:

- Directive 2001/20/EC;
- The Detailed guidance on the European clinical trials database[2]; and
- with regard to definitions such as “lead inspector”, “reporting inspector” the guidelines “Procedure for coordinating GCP inspections requested by the EMEA” (INS/GCP/1)[3].

The following acronyms are used in this guideline:

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1 OJ L121, 1.5.2001, p. 1.

2 http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-10/13_cp_and_guidance_eudract_april_04.pdf

3 http://www.emea.europa.eu/Inspections/docs/gcp/INS-GCP-1.pdf

- EudraCT: European clinical trial database
- GCP: Good Clinical Practice
- EU/EEA: Europe/European Economic Area
- BE/BA: Bioequivalence/Bioavailability
- ECG: electrocardiogram
- SUSAR: Suspected, Unexpected Serious Adverse Event
- e-CRF: electronic Case Report Form
- IVRS: Interactive Voice Response System

4. DESCRIPTION OF PROCEDURE/REQUIREMENTS, INCLUDING RESPONSIBILITIES

4.1. Inspections to be entered in EudraCT:

All GCP inspections conducted by the EU/EEA inspectorates after the implementation of the Directive 2001/20/EC should be entered in EudraCT. This includes GCP inspections conducted by the competent authority within its Member State and inspections conducted by that authority in a third country.

4.2. EU/EEA Inspector responsible for the inspections entries in EudraCT

The lead inspectorate which has the responsibility for an inspection is responsible for the entries in the EudraCT GCP inspection section, relating to that inspection. Where more than one Member State is involved in a third country inspection, the lead inspectorate, for that site, should record that inspection in EudraCT. Where the inspection is in the EEA the inspectorate of the Member State in which the site is located is responsible for that entry.

Where there are several inspections grouped together and there is a reporting inspector, the lead inspector of each of the individual inspections should record in EudraCT the inspection for which it is lead inspectorate.

4.3. Organization of the GCP inspection records in EudraCT

There is one record for each inspection in EudraCT, which relates to one site. An inspection record can only be entered and edited by one competent authority, which should be that of the lead inspectorate.

Within the database each inspection record has a separate sequential number. It is a simple numeric sequence and each new inspection record receives the next available number in increasing order. This number is not currently visible but a future enhancement of EudraCT will be requested to make it visible.

Each inspection record has a field “Inspection reference number” – this is a free text field in which the national “Inspection reference number” and where applicable the EMEA reference for CHMP requested inspections, can be entered.

4.4. Table of the fields in the EudraCT clinical trial site inspection details record: Data Entry Convention

(NB: The asterisk "*" to the left of the Field column denotes that a search can be made involving this field in the search criteria

EudraCT – Clinical Trial Site Inspection Details – Data entry conventions				
Field	Type	Length	Comment	Data Entry Convention
Inspectorate			Not entered but taken by the system as the Inspection organisation of the user from the user's security record	The lead inspector enters the record of an inspection
Member State carrying out the inspection	Alphanumeric	50	ISO 3166 country description for the MS to which the inspection is recorded. This information is not entered here, but is taken from the security record of the user recording the information.	
*Inspection reference number	Alphanumeric	50		National reference number using a consistent standard format followed by a space and then where applicable the EMEA reference for a centralised procedure inspection
Inspection Comments	Alphanumeric	4000		Protocol title(s)/protocol number/sponsor/ monitor.
*Inspection status	Alphanumeric	50	Drop-down list with three values 0 - Cancelled 1 - Carried out 2 - Planned	Complete once record is created and update as appropriate, so that others can find e.g. planned inspections. Cancelled is needed as the record cannot be deleted
*Planned date of	Numeric	8	Date format yyyy-mm-dd	Enter as soon as an inspection is planned, so that

onsite inspection				others can see something is planned, a provisional date could be used, and updated if needed, especially for inspections of potential community interest
*First date of the inspection	Numeric	8	Date format yyyy-mm-dd	Enter once it is carried out
*Last date of inspection	Numeric	8	Date format yyyy-mm-dd	Enter once it is carried out
*Hospital	Alphanumeric	1(Y/N)	Yes / No radio button	Check whether trial or system inspection
*Out patient Clinic / GP site	Alphanumeric	1(Y/N)	Yes / No radio button	Check whether trial or system inspection
*Phase 1	Alphanumeric	1(Y/N)	Yes / No radio button	Check whether trial or system inspection
*Phase 1 BE/BA	Alphanumeric	1(Y/N)	Yes / No radio button	Check whether trial or system inspection
*Analytical laboratory - BE/ BA	Alphanumeric	1(Y/N)	Yes / No radio button	Check whether trial or system inspection
*Clinical Pathology	Alphanumeric	1(Y/N)	Yes / No radio button	Check whether trial or system inspection
*Technical Facility (ECG, X-ray etc. analysis)	Alphanumeric	1(Y/N)	Yes / No radio button	Check whether trial or system inspection
*Data management, analysis and	Alphanumeric	1(Y/N)	Yes / No radio button	Check whether trial or system inspection

reporting				
*Monitoring	Alphanumeric	1(Y/N)	Yes / No radio button	Check whether trial or system inspection
*SUSAR Reporting / product safety	Alphanumeric	1(Y/N)	Yes / No radio button	Check whether trial or system inspection
*e-CRF, patient diary, IVRS	Alphanumeric	1(Y/N)	Yes / No radio button	Check whether trial or system inspection
*Other	Alphanumeric	1(Y/N)	Yes / No radio button	Check whether trial or system inspection
*Other - specify	Alphanumeric	1(Y/N)	Yes / No radio button	Check whether trial or system inspection
*Was the inspection triggered?	Alphanumeric	1(Y/N)	Yes / No radio button	
*What was the inspection outcome?	Alphanumeric	50	Select the outcome form a dropdown list of three possibilities 0 - One or more critical findings 1 - No critical findings, One or more major findings 2 - No critical findings, no major findings	
The EudraCT numbers and Sponsor Protocol Code Numbers may repeat and also the product trade name and product name				
Enter EudraCT numbers for trial	Alphanumeric	14	Repeating field	Enter all applicable for this inspection, both those with and those without EudraCT numbers. Related

specific inspections				protocol and EudraCT number are entered on one screen per pair.
Eudra Sponsor Protocol Code Numbers for 3rd country inspections or where no EudraCT number exists	Alphanumeric	35	Repeating field Case insensitive. No spaces. Stored twice – once as lower case and no spaces for speed of search and check on duplicates, once as entered. As ICH E2B A.2.3.2 Sponsor Study Number.	Enter all applicable for this inspection, both those with and those without EudraCT numbers. Related protocol and EudraCT number are entered on one screen per pair.
Specify the products (Tradename)	Alphanumeric	250		Enter all applicable for this inspection Related tradename and product name are entered on one screen per pair. In the absence of a tradename the commonly used name for the product (e.g. INN or other descriptive name of the active substance is used)
Specify the products (Product name)	Alphanumeric	250		Enter all applicable for this inspection Related tradename and product name are entered on one screen per pair. In the absence of a tradename the commonly used name for the product (e.g. INN or other descriptive name of the active substance is used)