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HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems and Products
Medicinal products – quality, safety and efficacy

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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 AND ITS IMPLEMENTING GUIDELINE 2008/C168/02[1]
VERSION 2.0

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[1] OJ C 168, 3.7.2008, p. 3.

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11.
E-mail: entr-pharmaceuticals@ec.europa.eu

1. INTRODUCTION

The Commission, in its *Communication regarding the guideline 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 726/2007*[2], has set out the scope, the elements and guidance on implementation of making information contained in EudraCT publicly available.

The present guideline lists the concrete data fields of the clinical trials database EudraCT to be made publicly available. The data to be made public will be extracted from EudraCT and made available via the European Clinical Trials Register (EU CTR), together with the EudraPharm database a source of information concerning human medicines authorised in the European Union (EU) and the European Economic Area. The interface of the EU CTR will be accessible via the EudraPharm website and the EudraCT clinical trials public information website.

Following publication of this guideline, the European Medicines Agency (EMA) has developed new business rules to enable the information to be made publicly available in the EU CTR.

2. PROTOCOL-RELATED INFORMATION

A	**Trial identification**
A.1	Country in which the submission is being made:
A.2	EudraCT number
A.3	Full title of the trial:
A.3.1	Title of the trial for lay people, in easily understood, i.e. 'non-technical' language:
A.3.2	Name or abbreviated title of the trial where available:
A.4	Sponsor's protocol code number
A.5	Additional international study identifiers (e.g. WHO, ISRCTN, US NCT Number), if available
A.7	Is the trial part of a Paediatric Investigation Plan? Y/N
A.8	EMEA Decision number of Paediatric Investigation Plan
B	**Identification of the sponsor**
B.1.1	Name of organisation:
B.1.3.4	Country
B.4	Source(s) of Monetary or Material Support:
B.4.1	Name of Organisation
B.4.2	Country
B.5	Contact point[3] designated by the sponsor for further information on the trial B.5.1 Name of organisation: B.5.2 Functional name of contact point (e.g. "Clinical Trial Information Desk"): B.5.3 Address: B.5.3.1 Street address B.5.3.2 Town/city B.5.3.3 Post code

[2] OJ C 168, 3.7.2008, p. 3.

[3] The contact point should give functional information rather than details of one "person", in order to avoid the need for update and maintenance of these contact details.

	B.5.3.4 Country B.5.4 Telephone number: B.5.5 Fax number: B.5.6 E-mail: (use a functional e-mail address rather than a personal one)

D	**Information on each Investigational Medicinal Product (IMP)**
D.1	IMP Identification
D.1.2	IMP being tested Y/N
D.1.3	IMP used as a comparator Y/N
D.2.1	Has this IMP to be used in the trial a marketing authorisation?:
D.2.1.1.1	Trade name
D.2.1.1.2	Name of MA holder
D.2.1.2	Which country granted the MA?
D.2.5	Has the IMP been designated in the indication as an orphan drug in the Community?
D.2.5.1	If 'Yes', give the orphan drug designation number
	Description of the IMP
D.3.1	Product name, where applicable
D.3.2	Product code, where applicable
D.3.4	Pharmaceutical form (use standard terms)
D.3.4.1	Is this a specific paediatric formulation?
D.3.7	Route of administration (use standard terms) (more than one can be selected)
D.3.8	Name of each active substance (INN or proposed INN if available)
D.3.9	Other available name for each active substance (provide all available): D.3.9.1 CAS number D.3.9.2 Current sponsor code D.3.9.3 Other descriptive name D.3.9.4 EV Substance Code
D.3.10	Strength (specify all strengths to be used)
D.3.10.1	Concentration unit
D.3.10.2	Concentration type (“exact number”, “range”, “more than” or “up to”)
D.3.10.3	Concentration (number)
D.3.11.1	Does the IMP contain an active substance of chemical origin
D.3.11.2	Of biological/ biotechnological origin (other than an Advanced Therapy IMP (ATIMP)
D.3.11.3	Advanced Therapy IMP (ATIMP)
D.3.11.3.1	Somatic Cell therapy medicinal product
D.3.11.3.2	Gene therapy medicinal product
D.3.11.3.3	Tissue Engineered Product
D.3.11.3.4	Combined Advanced Therapy Medicinal Product
D.3.11.3.5	Has the Committee on Advanced Therapies issued a classification for this product
D.3.11.3.6	If yes please provide that classification and its reference number
D.3.11.4	Product that includes a device, other than a combined ATIMP
D.3.11.5	Is it a Radiopharmaceutical medicinal product?
D.3.11.6	Is it an Immunological medicinal product (such as vaccine, allergen, immune serum)?
D.3.11.7	Is it a Plasma derived medicinal product?
D.3.11.8	Is it another extractive medicinal product?
D.3.11.9	Recombinant medicinal product
D.3.11.10	Medicinal product containing genetically modified organisms
D.3.11.11	Is it a Herbal medicinal product?
D.3.11.12	Is it a Homeopathic medicinal product?
D.3.11.13	Other type of medicinal product?
D.3.11.13.1	If Yes, specify:

D.8	Information on placebo
D.8.1	Is a placebo used in the trial?
D.8.3	Pharmaceutical form
D.8.4	Route of administration

E	General information on the trial
E.1 MEDICAL CONDITION OR DISEASE UNDER INVESTIGATION	
E.1.1	Specify the medical condition(s) to be investigated (free text)
E.1.1.1	Medical condition in easily understood,, i.e. 'non-technical' language
E.1.1.2	Therapeutic area
E.1.2	MedDRA version, level, term and classification code (as many times as completed by sponsor) Define MedDRA level required
E.1.3	Is any of the conditions being studied a rare disease?
E.2 Objective of the trial	
E.2.1	Main objective
E.2.2	Secondary objective
E.2.3.	Is there a sub-study?
E.2.3.1	If yes give the full title, date and version of each sub-study and their related objectives
E.3	Principal inclusion criteria (list the most important)
E.4	Principal exclusion criteria (list the most important)
E.5	End point(s):
E.5.1	Primary End Point (repeat as necessary)
E.5.1.1	Timepoint(s) of evaluation of this endpoint
E.5.2	Secondary End Point (repeat as necessary)
E.5.2.1	Timepoint(s) of evaluation of this endpoint
E.6 Scope of the trial	
E.6.1	Diagnosis
E.6.2	Prophylaxis
E.6.3	Therapy
E.6.4	Safety
E.6.5	Efficacy
E.6.6	Pharmacokinetic
E.6.7	Pharmacodynamic
E.6.8	Bioequivalence
E.6.9	Dose response
E.6.10	Pharmacogenetic
E.6.11	Pharmacogenomic
E.6.12	Pharmacoeconomic
E.6.13	Others
E.6.13.1	If other, specify:
E.7 Trial type and phase (Phase I clinical trials are not made public)	
E.7.2	Therapeutic Exploratory (Phase II)
E.7.3	Therapeutic Confirmatory (Phase III)
E.7.4	Therapeutic Use (Phase IV)
E.8 Design of the trial	
E.8.1	Controlled, if yes, specify
E.8.1.1	Randomised
E.8.1.2	Open
E.8.1.3	Single Blind
E.8.1.4	Double Blind
E.8.1.5	Parallel Group
E.8.1.6	Cross-over
E.8.1.7	Other
E.8.1.7.1	If yes, specify:
E.8.2	If controlled, specify the comparator:

E	General information on the trial
E.8.2.1	Other medicinal product(s):
E.8.2.2	Placebo
E.8.2.3	Other
E.8.2.3.1	If yes, specify:
E.8.2.4	Number of arms in the trial
E.8.3	Single site in the Country concerned
E.8.4	Multiple sites in the Country concerned
E.8.4.1	Number of sites anticipated in the country concerned
E.8.5	Multiple countries
E.8.5.1	Number of sites anticipated in the EEA
E.8.6	Does this trial involve countries outside the EEA? Y/N
E.8.6.1	Is the trial being conducted completely outside of the EEA? Y/N
E.8.6.2	If yes, specify the regions in which trial sites are planned:
E.8.7	Does the trial have an independent data monitoring committee? Y/N
E.8.8	Definition of the end of trial and justification in the case where it is not the last visit of the last subject undergoing the trial:
E.8.9	Initial estimate of the duration of the trial (years, months and days):
E.8.9.1	In the MS concerned:
E.8.9.2	In all countries concerned by the trial:

F	**Planned population of trial subjects**
F.1 Age range	
F.1.1	Less than 18 years: Y/N
NEW	If the trial population includes subjects < 18 years:
NEW	Approximate number of subjects for this age range:
F.1.1.1	In Utero
NEW	Approximate number of subjects for this age range:
F.1.1.2	Preterm newborn infants (gestational age <37 weeks)
NEW	Approximate number of subjects for this age range:
F.1.1.3	Term newborn infants (0-27 days)
NEW	Approximate number of subjects for this age range:
F.1.1.4	Infant and toddler (28days-23months)
NEW	Approximate number of subjects for this age range:
F.1.1.5	Children (2-11years)
NEW	Approximate number of subjects for this age range:
F.1.1.6	Adolescents (12-17 years)
NEW	Approximate number of subjects for this age range:
F.1.2	Adult (18-64 years)
NEW	Approximate number of subjects for this age range:
F.1.3	Elderly (≥65 years)
NEW	Approximate number of subjects for this age range:
F.2 GENDER	
F.2.1	Female
F.2.2	Male
F.3 GROUP OF TRIAL SUBJECTS	
F.3.1	Healthy volunteers
F.3.2	Patients
F.3.3	Specific vulnerable populations
F.3.3.1	Women of child-bearing potential not using contraception
F.3.3.2	Women of child-bearing potential using contraception
F.3.3.3	Pregnant women
F.3.3.4	Nursing women
F.3.3.5	Emergency situation
F.3.3.6	Subjects incapable of giving consent personally
F.3.3.6.1	If yes specify:
F.3.3.7	Others
F.3.3.7.1	If others specify:
F.4 PLANNED NUMBER OF SUBJECTS TO BE INCLUDED	
F.4.1	In the Member State
F.4.2.	For a multinational trial:
F.4.2.1	In the Community (EEA)
F.4.2.2	In the whole trial
F.5	Plans for the treatment or care after a subject has ended his/her participation in the trial, if it is different from the expected normal treatment of that condition, please specify (free text)

N	**Review by the Competent authority or Ethics Committee in the country(ies) concerned**
	Clinical Trial Authorised (for EEA countries) Date of authorisation
	Ethics committee opinion – positive, or pending Date of opinion
	Recruitment status of the trial (not commenced, active, ended)
	End of trial status (ended)
	Date of the global end of the trial

N	Review by the Competent authority or Ethics Committee in the country(ies) concerned
	Anticipated date of the availability of results (no more than the end of trial date plus twelve months)

3. CLINICAL TRIAL RESULTS INFORMATION

The publication of clinical trial results, both positive and negative, are visible in the European Clinical Trials Register (EU CTR) two weeks after the posting date.

Details of the data fields of results-related information on clinical trials can be found in the "Technical guideline on the format of the data fields of results-related information on clinical trials".

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2013_01_22_tg_en.pdf