EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

Brussels, 03.062019
DG SANTE/B4/ES/ns

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 ITS IMPLEMENTING GUIDELINE 2009/C28/01

Version 2.0

Document history:	
Date of closure of public consultation	30 September 2008
Date of meeting of "Ad-hoc group for the development of implementing guidelines for the 'Clinical Trials Directive' 2001/20/EC":	1 December 2008
Date of publication by the Commission:	4 February 2009
Date of entry into force:	See "1. Introduction"
Supersedes:	Version 1.0
Date of submission of draft v2 "Ad-hoc group for the development of implementing guidelines for the 'Clinical Trials Directive'	May 2019
Date of publication:	June 2019
Reasons for revision:	harmonisation of the title of the fields with the "Technical Guidance On The Format Of The Data Fields Of Result-Related Information On Clinical Trials Submitted In Accordance With Article 57(2) Of Regulation (Ec) No 726/2004 And Article 41(2) Of Regulation (Ec) No 1901/2006"

Keywords: Clinical trials, EudraCT, disclosure of data fields, paediatrics

1. INTRODUCTION

The Commission, in its *Communication 2009/C28/01 on guidance 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*[1], has set out the nature of information to be entered, the information to be made available to the public, timing and corresponding responsibility in this regard.

The present guideline lists the concrete data fields to be considered in the context of paediatric clinical trials. The data to be made public will be extracted from EudraCT and made available via the European Clinical Trials Register (EU CTR).

Following publication of this guideline, the European Medicines Agency (EMA), who is in charge of administering EudraCT, 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.3.1/B.3.2	Status of sponsor – Commercial or non-commercial
B.4	Source(s) of Monetary or Material Support:
B.4.1	Name of Organisation
B.4.2	Country
B.5	Contact point[2] 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

[1] OJ C28, 4.2.2009, p. 1.

[2] 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: 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	Radiopharmaceutical medicinal product
D.3.11.6	Immunological medicinal product (such as vaccine, allergen, immune serum)
D.3.11.7	Plasma derived medicinal product
D.3.11.8	Extractive medicinal product
D.3.11.9	Recombinant medicinal product
D.3.11.10	Medicinal product containing genetically modified organisms
D.3.11.11	Herbal medicinal product
D.3.11.12	Homeopathic medicinal product
D.3.11.13	Other type of medicinal product
D.3.11.13.1	If Yes, specify:

D8	**Information on placebo**

D8	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	
E.7.1	Human pharmacology (Phase I)
E.7.1.1	First administration to humans
E.7.1.2	Bioequivalence Study
E.7.1.3	Other
E.7.1.3.1	If 'other', please specify
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	General information on the trial
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.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	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)

G[3]	Clinical trial sites/investigators in the member state or country concerned
G.4	Networks to be involved in the trial
G.4.1	Name of Organisation:

G[3]	Clinical trial sites/investigators in the member state or country concerned
G.4.3.4	Country

N	Review by the Competent authority or Ethics Committee in the country(ies) concerned
	Clinical Trial Authorised (for EEA and third countries where a clinical trial authorisation is required) Date of authorisation
	Or For third country trials if a clinical trial authorisation is not required a statement that it has been notified to the local competent authority or that this is not required as applicable Ethics committee opinion – positive or negative or pending Date of opinion
	In the case of a negative ethics committee opinion based on ethical concerns a brief statement of the reasons
	Recruitment status of the trial (not commenced, active, completed)
	End of trial status (Completed, prematurely terminated, or prohibited)
	Date of the global end of the trial
	Anticipated date of the availability of results Result-related information for paediatric trials should be submitted to the EMEA, for entry into EudraCT, no more than six months after the trial has ended, whether the trial has been completed or prematurely terminated, whichever occurs first. However, notwithstanding the above, if - the clinical trial does not fall within the scope of Article 46(1) of the Paediatric Regulation; and - it is for objective scientific reasons not possible to submit the result-related information within six months, which has been demonstrated by the submitting party, result-related information for paediatric trials may be submitted to the EMEA, for entry into EudraCT, at the latest within twelve months after the trial has ended, whether the trial has been completed or prematurely terminated, whichever occurs first.

3. INFORMATION CONCERNING PAEDIATRIC CLINICAL TRIAL RESULTS TO BE MADE PUBLIC

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