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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

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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 Web.

Following publication of this guideline, the European Medicines Agency (EMEA), who is in charge of administering EudraCT, is going to take the necessary steps to revise the programming of EudraCT. The launch of the revised version of EudraCT is going to be announced *inter alia* via the Commission-website "Clinical trials – major developments".[2]

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

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

[2] http://ec.europa.eu/enterprise/pharmaceuticals/clinicaltrials/clinicaltrials_key.htm

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 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

[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.

D	Information on each Investigational Medicinal Product (IMP)
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
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	General information on the trial
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.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[4]	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[4]	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

At present, EudraCT does not contain results-related information on clinical trials. Publication of clinical trial results, both positive and negative, will take place as the information actually becomes available in EudraCT. Work to standardise reporting is ongoing and guidelines on the nature of the data collection process, structure of the collected data and structure of the public data will be included in this document and, if necessary, in additional technical documents.

TOPIC	DESCRIPTION to include:
Administrative information	Protocol number EudraCT number Trial report number Date of trial report Is the trial part of a Paediatric Investigation Plan? (Y/N)
Trial design	**Principle trial design** (*e.g.*, randomized, open, single-blinded etc)
Background for conducting the trial	**Scientific background and explanation of rationale for the trial** Explanation on the rationale for the trial, e.g. lack of available information.
Participants of the trial	**Eligibility criteria for participants** In/exclusion criteria to allow assessment of generalisability of the trial results **Settings and locations where the data were collected** Information on the sites/institutions, geographic regions of recruitment to assess external validity of the trial
Interventions	Precise **details of the interventions** intended for each group and how and when they were actually administered. Includes statement of precise dose, treatment duration, control interventions, additional treatment for each arm of the trial.
Objective(s) of the trial	Specific **objectives of the trial** Questions that the trial was designed to answer, e.g. efficacy and safety of XY in children 0-24 months
Outcome measures	**Clearly defined primary and important secondary outcome measures** Precise description of outcome measures and time points of assessment
Randomisation implementation	Information on the generation of the allocation sequence, participants enrolment and assignment to treatment groups to allow assessment of potential bias
Blinding	**Information on blinding** E.g. double-blinded, single-blinded
Statistical methods	**Statistical methods** used to compare groups for primary outcome(s). Any methods for additional analyses, such as subgroup analyses and adjusted analyses.
Participant flow	Flow of participants through each stage (diagram, if appropriate) For each group the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and

	analyzed for the primary outcome should be stated. This should include the **number of participants in each group** included in each analysis and whether the analysis was by "intention-to-treat" or "per protocol". Protocol deviations from the study as planned, together with reasons should be stated.
Recruitment	Dates defining the **periods of recruitment** and follow-up. To allow assessment of the trial in a historical context
Baseline data	Baseline **demographic and clinical characteristics** of each group.
Trial interruption	Was the **trial interrupted**? State reasons for interruption, e.g. recruitment difficulties, protocol amendments etc.
Outcomes and estimation	For each primary and secondary outcome, a **summary of results** for each group, and the **estimated effect size** and its precision (*e.g.*, 95% confidence interval).
Ancillary analysis	Any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory should be stated to address multiplicity
Adverse events	All **important adverse events** or side effects in each intervention group.
Trial termination	Study **terminated prematurely** Y/N State reason for premature termination
Discussion and interpretation of study results	**Interpretation of trial results**: - by sponsor (if available) - by competent authority (if available)