SUBMISSION OF COMMENTS ON draft list of fields contained in the 'EudraCT' clinical trials database to be included in the 'EudraPharm' database on medicinal products and made public, in accordance with Article 57(2) of regulation (EC) No 726/2004.

COMMENTS FROM

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GENERAL COMMENTS

It is important to remind the following points:

- the EudraPharm database intends to give access to information on products that have been authorised (in the first step by the EMEA).

- Protocol related information: data entered in the EudraCT form is primarily intended for review by competent authorities when assessing clinical trials applications, the information is not written with the intent of sharing with public and therefore not of an easy reading. In these aspects, deletion of some sections of the EudraCT form is necessary.

Additional general comment : Some items of the EudraCT form are identified in this public consultation paper as new items because they are not included in the current version of the EudraCT form. However, the identification of the new items is not exhaustive.

- Results related information : Such information should be easily understood by the public however the elements listed in Annex I of the ICH E3 guideline have not been designed for that purpose. Therefore corresponding items should be deleted.

SPECIFIC COMMENTS on data fields contained in the 'EudraCT' clinical trials database to be included in the 'EudraPharm' database on medicinal products **Protocol-related information**		
Field number (e.g. D. 2.1.1.1)	**Comment and Rationale**	**Proposed change (if applicable)**
D. Information on each IMP D.2.1.2 Which country granted MA ?	Since the information will be made public once MA is granted, we can not see any interest for the public to know which country granted the MA.	We propose to delete the item *D.2.1.2 Which country granted MA ?* of the list of items to be made available to the public.
D. Information on each IMP D.3.9 Other available name for each active substance (CAS, sponsor code, other descriptive name, etc: provide all available)	We can not see any interest for the public and think it can be confusing for the public to know all the different "names" available for the IMP on top of the INN (if available), the commercial name (if available), and/or the product code	We propose not to disclose item D.3.9 to the public.
D. Information on each IMP Description of the IMP : - Strength - D.3.10 Concentration unit - D.3.10.2 Concentration type - D.3.10.3 Concentration (number)	These three items are confusing for the public and need to be simplified	If the field "*strength*" has to be completed in the EudraCT form, we propose to disclose only this item to the public and NOT items *D.3.10 Concentration unit, D.3.10.2 Concentration type, concentration (number).*
D. Information on each IMP Description of the IMP : D.3.11.1 Does the IMP contain an active substance of chemical origin ? D.3.11.2 Of biological/biotechnological origin ? D.3.11.3 D.3.11.4 D.3.11.5…….D.6.6	All the item concerning the type of biological/biotechnological origin of the active substance are too much complicated for the public and need to be simplified.	We propose to amend the list of items to be made available for the public and to disclose only the main information on the chemical/biological origin of the IMP, which is included in items D.3.11.1 and D.3.11.1

E. General information on the trial E.1 Medical condition or disease under investigation E.1.2 MedRA version, level, term and classification code (as many times as completed by sponsor) Define MedRA level required	We believe the term MedRA is not comprehensible by the public and can lead to confusion.	We propose to remove *the item E.1.2 MedRA version, level, term and classification code (as many times as completed by sponsor), Define MedRA level required* from the list of items to be made public
E. General information on the trial E.2 Objectives of the trial E.2.3 Is there a sub-study ? E.2.3.1 If yes, give full title, date and version of each sub-study and their related objectives	Since data from sub-studies may not have been analysed, related information should not be disclosed to the public for confidentiality reason.	We propose to remove the items *E.2.3 Is there a sub-study ?and E.2.3.1 If yes, give full title, date and version of each sub-study and their related objectives* from the list of items to be made public
E. General information on the trial E.8 Design of the trial E.8.1.5 Parallel group E.8.1.6 Cross over	We believe the terms *Parallel group* and *Cross* over group are not comprehensible by the public and can lead to confusion for the public	For comprehension purpose, we propose to remove the items *E.8.1.5 Parallel group* and *E.8.1.6 Cross over* from the list of items to be made public
E. General information on the trial E.8 Design of the trial NEW! Number of treatment arms in the trial	We can not see the interest of the disclosure to the public of the number of arms in the trial, since the information that the study is controlled will be public, as well as the name of the comparator (active or placebo)	We propose to remove the NEW item *Number of treatment arms in the trial* from the list of items to be made public
E. General information on the trial E.8 Design of the trial E.8.4.1 Number of sites anticipated in the country concerned	Since the information will be made public once MA is granted, there is no interest for the patient to know the number of sites that were anticipated in the country concerned when setting up the trial	We propose to remove the item *E.8.4.1 Number of sites anticipated in the country concerned* from the list of items to be made public
E. General information on the trial E.8 Design of the trial E.8.5.1 Number of sites anticipated in the community	There is no interest for the patient to know the number of sites that were anticipated in the community.	We propose to remove the item *E.8.5.1 Number of sites anticipated in the community* from the list of items to be made public
E. General information on the trial E.8 Design of the trial E.8.6.1 Is the trial being conducted completely outside the EEA ? Y/N E.8.6.2 If yes, specify the regions in which trial sites are planned	There is no interest for the public to know exactly, once the MA has been granted, in which third countries the trial was planned at the time of the application for authorisation in particular if the trial is already completed.	We propose to remove the item *E.8.6. If yes, specify the regions in which trial sites are planned* from the list of items to be made public
E. General information on the trial E.8 Design of the trial E.8.7 Does the trial have a data monitoring committee	The term Data Monitoring committee will not be easily understood by the public. This item should be removed from the list of items to be made public.	We propose to remove the item *E.8.7 Does the trial have a data monitoring committee* from the list of items to be made public

E. General information on the trial E.8 Design of the trial 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 E.8.9.1 In the MS concerned E.8.9.2 In all countries concerned	Since the information will be made public once MA is granted, there's no interest for the patient to know the duration of the study in the MS concerned AND the duration of the study in all countries concerned by the trial	We propose to remove the item *E.8.9.1 In the MS concerned* from the list of items to be made public
F. Planned population of trial subjects F.1Age span F.1.1 Less than 18 years If the trial population includes subjects < 18 years: Approximate number of subjects for this age span ….. F.1.3 Elderly (>65 years)	We consider it is of high interest for the public to know which paediatric age groups are being investigated, however we think there's no interest to disclose the number of subjects being investigated for each age span.	We propose to remove all the new items *Approximate number of subjects for this age span* from item F.1.1. to F.1.3.
F. Planned population of trial subjects F.4 Planned number of subjects to be included F.4.1 In the member state F.4.2 For a multinational study F.4.2.1 In the community (EEA) F.4.2.2 In the whole trial	We think the only item of interest concerns the planned number of patients in the whole trial	We propose to remove the items *F.4.1 and F.4.2.*1 from the list of items to be made public.
F. Planned population of trial subjects 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	According to footnote 25 of the EudraCT form, this information, if provided in the protocol, does not need to be completed in the EudraCT form.	We propose to remove the item 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* from the list of items to be made public.
N Review by the competent authority or ethics committee in the country (ies) concerned	The release to the public of protocol-related information should take place only after validation of data in EudraCT has been completed, i.e when the sponsor has obtained both competent authority (CA) approval and positive ethics committee (EC) opinion in at least one country involved in the trial. For this reason, only dates of the authorisations in the country which has been granted the first CA approval and EC positive opinion. Negative ethics committee are not to be disclosed to the public since the MA Holder may appeal.	We propose to amend this section as following : Date of first authorisation of the study by the CA : Date of first positive opinion of one ethics committee : Recruitment status of the trial (not commenced, active, completed) End of trial status (completed, prematurely terminated, prohibited or suspended)

	In addition, we do not think that the date of submission of the results to the CA is of high interest for the patient since the results related information will only be made public after the assessment by one competent authority. Therefore we do not wish to disclose publicly the anticipated date of availability (to CA) of the results.	

SPECIFIC COMMENTS on Clinical Trial results information to be made public		
Topic name	**Comment and Rationale**	**Proposed change (if applicable)**
	It should be reminded that the EudraPharm database intends to give access to information on products that have been authorised. Results of studies not included in the MAA dossier should be made available within one year after trial completion (Joint Position, 2005). If the trial results are published, the database should include a citation to journal article or a summary such as in ICH E3. Interpretation results should be given by the sponsor and not by competent authorities. Trials performed once the MA has been granted are most of the time performed for an extension of indication which is applied in some cases far from the completion of the trial.	**Administrative information** Protocol number EudraCT number Trial report number Date of this report Is the trial part of a Paediatric Investigation Plan **Trial design** Principle trial design (e.g, randomized, open, single blinded etc) **Background for the conducting of 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** **Main** 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. **Objectives of the trial** Specific objectives of the trial Questions that the trial was designed to answer, e.g efficacy of XY in "indication" **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 method for additional analyses, such as subgroup analyses and adjusted analyses. **Participant flow** Flow of participants trough 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 estimations**~~ ***To be replaced by:*** **Efficacy and safety results** 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** ~~**(except if available)**~~ ~~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 on each intervention group. ~~**Trial termination**~~ ~~Study terminated prematurely Y/N~~ ~~State reason for premature termination.~~ **Discussion and interpretation of the results** By the sponsor ~~By competent authority (if available)~~