PUBLIC CONSULTATION PAPER
Version: 15 July 2008

Deadline for consultation: 15 October 2008

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

Please note, that we have only listed the variables we find necessary to comment on.

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Table of comments		
No.	Variable	Comment
A	**Trial Identification**	
A.6	Additional international study identifiers (e.g. WHO, clinicaltrials.gov, ISRCTN, US NCT Number)	Too much time and effort required to keep this information up-to-date throughout the trial.
A.8	Is the trial part of a Paediatric Investigation Plan? Y/N	Questionable public interest. For the authorities, this information is already accessible through EudraCT clinical trials database.
A.9	EMEA Decision number of Paediatric Investigation Plan	No public interest. For the authorities, this information is already accessible through EudraCT clinical trials database
B	**Identification of the sponsor**	
B.5	Contact Point designated by the sponsor for further information on the trial	The items listed are not identical with the information in B.1 in Annex 1, Application Form. Where do you get this information from, if not from Annex 1, Application Form? Please harmonise.
D	**Information on each Investigational Medicinal Product (IMP)**	
D.2.1.2	Which country granted the MA?	We consider this to be confidential information with no public interest. Additionally, to answer this question is difficult, once there are different MA's in different countries.
D.2.5	Has the IMP been designated in the indication as an orphan drug in the Community?	No public interest.

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D.2.5.1	If 'Yes', give the orphan drug designation number	No public interest.
Description of the IMP		General comment: We consider the entire information listed from variables no. D.3.11.1 to variable no. D.6.1 to be *confidential.* Where should the motivation of a pharmaceutical company come from, to develop a new medicinal product, if everybody has easily access to this information? We do question the public interest in this information as this is company know-how. In addition, this information is not easily understood by lay people (autologous, allogeneic, xenogeniec cells, for instance). Additional comments for certain variables contained in this section are listed below together with the variable and it's no.
D.3.11.4	Is it a Gene therapy medical product?	Wording is inconsistent. Annex 1, Application Form, uses "medicinal", please harmonise.
D.3.11.6	Is it an Immunological medicinal product (such as vaccine, allergen, immune serum)?	Spelling.
D.3.11.8	Is it another extractive medicinal product?	Spelling. Is there a particular definition for *other extractive medicinal product?* The distinction between D.3.11.8 and D.3.11.12 with the specification "extractive" (D.4.1.1) remains unclear. Is this the same? Then the redundant variables should be eliminated from the list and (if applicable) from Annex 1, Application Form.
D.3.11.9	Is it a Herbal medicinal product?	Regulatory information, might not be available for IMP's without MA, unless the classification 'herbal' is based on other information (i. e. origin of raw materials, production process).
D.3.11.10	Is it a Homeopathic medicinal product?	Regulatory information, might not be available for IMP's without MA, unless the classification 'herbal' is based on other information (i. e. origin of raw materials, production process).
D.3.11.12	Other type of medicinal product?	See comment on D.3.11.8.

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No.	Variable	Comment
D.4.1.1	Type of Product: Extractive	See comment on D.3.11.8.
D	**Information on each Investigational Medicinal Product (IMP)**	General comment: We consider the entire information listed from variables no. D.6.2. to variable no. D.6.6 to be *confidential.* Again, where should the motivation of a pharmaceutical company come from, to develop a new medicinal product, if everybody has easily access to this information? We question the public interest in this information as this is company know-how.
E	**General information on the trial**	
E.1.3	Is any of the conditions being studied a rare disease?	No public interest.
E.2.3	Is there a sub-study?	Is there a definition for the term 'sub-study'?
E.5	End point(s):	Confidential information; development of the study design requires effort, time and know-how – we consider this to be intellectual property of the company, hence this should be confidential until publication in a medical paper or at least until results of the trial are available (i.e. 12 months after completion).
E5.1	Primary End Point (repeat as necessary)	See comment above (E.5).
E.5.1.1	Timepoint(s) of evaluation of this endpoint	See comment above (E.5). In addition, there is no public interest in this information. Information is irrelevant in order to avoid duplication of efforts (i.e. replication of trials with the same objective/IMP/collective of patients).
E.5.2	Secondary End Point (repeat as necessary)	See comment above (E.5).
E.8	**Design of the trial**	
E.8.6	Does this trial involve countries outside the EEA? Y/N	No public interest. We wonder about how many lay people are familiar with the abbreviation EEA and know what countries/regions are covered by the EEA.
E.8.6.1	Is the trial being conducted completely outside of the EEA? Y/N	

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E.8.6.2	If yes, specify the regions in which trial sites are planned:	
E.8.7	Does the trial have a data monitoring committee? Y/N	No public interest.
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.4	PLANNED NUMBER OF SUBJECTS TO BE INCLUDED	
F.4.1	In the Member State	No public interest.
F.4.2	For a multinational trial	
F.4.2.1	In the Community (EEA)	
F.5	Plans for the treatment or care after a subject has ended his/her participation in the trial, if it is different from expected normal treatment of that condition, please specify (free text):	No public interest.
N	**Review by the Competent authority or Ethics Committee in the country(ies) concerned**	
There are no variable numbers given in the draft.	Clinical Trial Authorised (for EEA countries) Date of authorisation	No public interest, the competent authority will have this information already.
	Ethics committee opinion – positive, or pending Date of opinion	No public interest, the competent authority/ethics committee will have this information already.
	Recruitment status of the trial (not commenced, active, ended)	Where does this information come from? Who will up-date this? As a pharmaceutical company, we have

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	End of trial status (ended)	already sufficient bureaucratic regulations to fulfil (Pharma is already one of the most regulated industries!), hence the competent authorities should up-date this or the information should be omitted.
	Date of the global end of the trial	
	Anticipated date of the availability of results (no more than end of trial date plus 12 months)	There could be a public interest in this information.
Clinical trial results information		
		General comment on this section: If all of this information is made public, then everybody will have access to it. The status of a published summary on clinical trials results would then be authorised (by the competent authority) and comparable to abstracts published in PubMed, for instance. Can we consider this to be an online-publication then, which can be cited?
Administrative information	Is the trial part of a Paediatric Investigation Plan? (Y/N)	No public interest.