European Medicines Agency
Communications and Networking

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Subject: Comments from the EMEA following the Public Consultation period for:
1) Clinical Trial Application Form and
2) The two guidance documents relating to the "making public" of the clinical trial protocol and the results information

1) Implementation of the Advanced Therapies Regulation: public consultation on the Revised Clinical Trial Application Form as regards advanced therapy investigational medicinal products

The EudraCT Project Team has taken this opportunity, at the end of the public consultation period, to provide proposals on the "Implementation of the Advanced Therapies Regulation: public consultation on the Revised Clinical Trial Application Form as regards advanced therapy investigational medicinal products" document.

Our proposals are documented in the attached WORD file ref: Consultation paper-NR-2008-07-22.

These proposals are made in an effort to:

- **Standardise** the input of information in the Clinical Trial Application (CTA) Form e.g. name and address information
- **Rationalise** the information collected in the CTA Form e.g. D4 and D3 sections of the form
- **Harmonise** the information with other Eudra Application e.g. overlap with Eudra GMP
- **Support and facilitate** the harmonisation and ongoing initiatives with regard to the collection and recording of Active Substances and product information in line with the cross project proposal with the EudraVigilance project.

As a consequence of our proposals (Fergus Sweeney has provided input and guidance), we anticipating that the technical implementation will involve the mapping of data fields currently stored in the EudraCT Database.

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2) a) Public consultation on the data fields of the clinical trials database (EudraCT) and the information on trial results for paediatric clinical trials to be made publicly available, and
b) Public consultation on the data fields of the clinical trials database (EudraCT) and the information on trial results for paediatric clinical trials to be made publicly available

With regard to the other two documents which have been and are now ending their public consultation period, the EMEA note this and look forward to the feedback from this outcome. These documents are:

- 23/07/2008 - Public consultation on the data fields contained in the 'EudraCT' clinical trials database to be included in the 'Eudra Pharm' database on medicinal products and made public.
- 27/06/2008 - Public consultation on the data fields of the clinical trials database (EudraCT) and the information on trial results for paediatric clinical trials to be made publicly available.

Since the information as described in these documents is destined for the **PUBLIC** domain and will be implemented in EudraCT, wherever possible, a single set of data fields for both of the above mentioned guidelines should be harmonised to provide the recipient with a cohesive and standard view of the information.

In addition, the level of detailed information made public should be sustainable for the maintainer i.e... the Sponsor or Member State and understandable for the consumers of the information - the public. The public should be able to easily consume and understand the necessary information.

Secondly, the implementation of "making public" the information will take place in two distinct phases:

- The Protocol Information – this information is already established for the EEA trials in EudraCT. The functionality will be developed and the software finalised.

- The Result Information – As yet, this information does not exist in EudraCT and will require time to develop the software to collect this information in a structured and harmonised way. It is important that any new development of software involved in providing this functionality takes into account initiatives which are currently ongoing at a European and international level in the realm of "result gathering and making public".

Finally, thank you for giving us this opportunity to provide input.

Please contact me if I can be of any further assistance.

Yours faithfully

Signature on File

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