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

BfArM (Clinical Trials Unit) would like to **comment on the public consulation paper**
(Version: 15 July 2008 - Deadline for consultation: 15 October 2008)

Protocol related information:

1. Section F.1 - Age Span :

   It is appreciated to include the approximate number of subjects per age span.

2. Section N - Review by the Competent Authority or Ethics Committee in the country(ies) concerned:

   It seems of considerable importance to add informations in case of non-authorisation of a clinical trial.
   If a favourable opinion has been refused - either by the Competent Authority or the Ethics Committee – a brief statement of the reasons should be added.

   If a clinical trial has been prematurely terminated, prohibited or suspended a brief statement of the reasons should be added.

   Furthermore it could be of importance to make public if a clinical trial information has been put on hold.

   The anticpated date of availabilty of results should be no more than the end of trial date plus six months.
   This may be seen in accordance with article 46 of the Regulation EC 1901/2006 where defined authorisation holder-sponsored studies „which involve the use in the paediatric population of a medicinal product covered by a marketing authorisation…shall be submitted to the competent authority *within six months* of completion of the studies concerned.
   On the other hand Article 41 of the Regulation EC 1901/2006 goes even further as „details of the results of all the trials“…(all clinical trials referred to in Articles 1 and 2 of Directive 2001/20/EC and those clinical trials carried out in third countries which are contained in an agreed paediatric investigation plan)… shall be submitted *without delay.*