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 public

The Paediatric Medicines Expert Advisory Group (PM EAG) of the UK Commission of Human Medicines welcomes the opportunity to comment on the Commission's proposals for information to be made public from the EU Database on Clinical Trials (EudraCT) for paediatric clinical trials in accordance with Article 41 of the Paediatric Regulation (EC 1901/2006)

The PM EAG supports the Commission's proposals as it believes as a principle that full information on paediatric trials should be made publicly available. It does have some concerns, however, that the need to classify protocols and results into sets of pre-defined data fields will have the effect of limiting the information which can be made available or its usefulness. An example is the proposal to use pre-set fields for the different age spans for children based on ICH guidelines (F.1). Whilst these age spans are useful when planning the development of a paediatric medicine, such fixed fields may prevent the extraction of useful information from the database. There are many examples where they are inappropriate, for instance, orally inhaled products for the treatment of asthma which are not generally used in children below the age of 7. In order that sufficiently useful information can be obtained from the database, it may be better that the age spans are further sub-divided (e.g. 2-5 years and 6-11 years or free text entries are allowed). This would allow identification of age-groups within the proposed age spans that had not already been studied.

Many of the terms used in the section of the proposal concerning the design of the trial (E.8) can be ambiguous in use and therefore it would be helpful to users to provide clear definitions or explanatory notes e.g. for open, single or double blind and cross-over. It may also be helpful to record whether comparisons were within patient or not.

Details of the interventions to be used in the trial should also be included in the fields to be made public.

Finally the PM EAG would welcome use of the term 'participant' rather than 'subject'

Paediatric Medicines Expert Advisory Group
Commission on Human Medicines
UK
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