

A public consultation paper on paediatric clinical trial disclosure: European Union (EU) and European Economic Area (EEA)

Clinical trial disclosure, i.e. release of information regarding clinical trials to the public (Internet), is now a topic of mandatory interest for those performing paediatric clinical trials in the European Union (EU) and the European Economic Area (EEA). It is planned that all clinical trials that include children (0 to 18 years) will be disclosed (independent of the clinical development phase, or whether the investigational product used in the trial is still in development or already registered or marketed). Affected trials include those that are performed in the EU/EEA countries (and elsewhere, if the trial is part of the sponsor's Paediatric Investigation Plan). At present, information submitted to the EU database on Clinical Trials (EudraCT) by the sponsor as part of the Clinical Trial Application (CTA), is available only to the respective national drug regulatory authorities in the EU and EEA member states—not to the general public. It is this aspect of information accessibility that is about to change. The European Commission (EC) has recently issued a draft document stating the information segments of the *study protocol* and *study results* that are proposed to go public.

A public consultation was conducted (February to April 2008) on a draft Guidance concerning information on paediatric clinical trials to be entered into the EudraCT and the information to be made public by the European Medicines Agency (EMA), in accordance with article 41 of Regulation No. (EC) 1901/2006 (Regulation on Medicinal Products for Paediatric Use). The Directive currently includes clinical trials with at least one site in the EU (27 member states) and additionally countries of the EEA (Iceland, Liechtenstein, Norway). The Directorate-General for Enterprise and Industry (DG ENTR) has prepared an extensive list of EudraCT data fields and information that should be made publicly available on trial *protocols* and *results* for clinical trials involving paediatric patients.

The information fields are part of a public consultation paper that is available at:

http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008_07/consultation_draft_field-2008-07-16.pdf.

Comments should be e-mailed by 15th October 2008 to the DG ENTR:

entr-pharmaceuticals@ec.europa.eu.

It is being proposed that EudraCT will release the information to the public through the EudraPharm database. This would occur for the *study protocol* at the time of trial authorisation and for the *results* within a relatively short time after trial completion (e.g. 6 months), and be made publicly available as soon as submitted.

The proposed information released by EudraCT in the EudraPharm public database includes:

- for **study protocols**: trial identification (protocol number), EudraCT number, other international identifier number, title (full technical wording and lay language), identification of the sponsor (name and country, contact details), information on each investigational product, population endpoints, sites (even those outside of the EEA), recruiting status, ethics committee opinion (positive, negative, pending—with a statement of reasons, if the opinion was negative).
- for **study results**: contents and format likely to be similar to ICH E3 summary requirements and the Consort statement, primary and secondary outcome measures, statistical methods, number of participants in each group, flow of patients through the trial (flow-chart), early termination information, information on all important adverse events in each intervention group, interpretation of results by sponsor/by competent authority.

This is the first coordinated effort by the EC (through EMA) to provide information to the public on clinical studies performed in the EU and EEA. The initial focus is on paediatric clinical trials. However, it is expected that clinical studies with adults will be covered by similar requirements in the not too distant future. These EMA activities are similar to those implemented in the USA through the new federal law FDAAA 801 (enacted September 2008), which was summarized recently in *TWS* [1].

Reference:

1. Thomas KB, Tesch C. Clinical trial disclosure—focusing on results *The Write Stuff* 2008; 17:70-73.

Kathy B. Thomas
Meersburg, Germany
kathy-b.thomas@t-online.de

Claudia Tesch
Konstanz, Germany
claudia.tesch@nycomed.com

Michael Braun
Radolfzell, Germany
michael.braun@exalon.com