

SHORT COMMUNICATION

Launch of a European paediatric clinical trials register

Clinical trials have a fundamental role in promoting an evidence based use of drugs in children. However, it is often difficult to identify the few paediatric studies carried out and to thus implement the knowledge derived from them. Furthermore, studies that are stopped prematurely or that have insignificant or negative results often remain unpublished, leading to duplication of effort by researchers, waste of resources, and concealment of potentially significant risks.

An international register of completed and ongoing clinical trials in children represents a step towards improving the well-documented lack of suitable trials necessary for generating data on safety and efficacy of paediatric drug therapies.

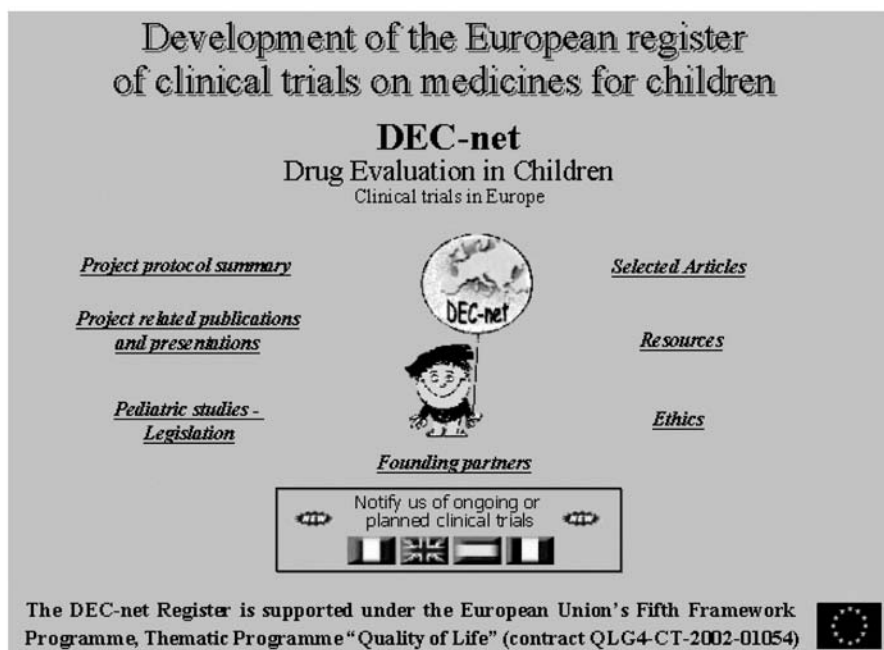
Furthermore, despite the remarkable efforts made to create numerous, diverse databases addressing the needs of the biomedical research community in the past few years, none have involved a register dedicated to children. Such a register represents a useful resource for planning new studies, promoting communication and collaboration among researchers, facilitating patient access and recruitment into trials, preventing trial duplication and inappropriate funding, and identifying the therapeutic needs of children that remain neglected. It will also allow for active monitoring of new or evolved knowledge of drug therapies.

The European Community decided to support the development of a European register of clinical trials in children as part of its Fifth Framework Programme, Thematic Programme "Quality of Life" (contract QL4-CT-2002-01054), in 2002, following through with the commitment shown in the "Better Medicines for Children" consultation document. The project, entitled The European register of clinical trials on medicines for children – Drug Evaluation in Children

(DEC-net), is co-ordinated by the Laboratory of Mother and Child Health of the "Mario Negri" Institute for Pharmacological Research in Milan and currently involves members from four countries: France, Italy, Spain, and the United Kingdom. It is unique in that it is the first population oriented clinical trial register.

The DEC-net register was activated on July 1st 2004 and can be accessed through the website www.dec-net.org. The register is freely available to anyone interested in accessing information on paediatric drug therapy clinical trials. The trial information is displayed in two different formats, a simple one intended for the public/parents and a more advanced one intended for health professionals, although users are free to choose between views. The information displayed in the simple view is: protocol title, current trial status, disease, gender, age range, purpose, main investigator contact details, and centres (if multicentre) or countries (if multinational) involved. The advanced view also displays the following information: ISRCTN, EudraCT number, local protocol number, experimental drug, trial phase, type of study (safety/toxicity, therapeutic efficacy, pharmacokinetics, etc.), and inclusion and exclusion criteria. Some of the information is also provided in the original language (Italian, Spanish, or French).

With this letter, the members of the DEC-net project would like to kindly ask the collaboration of ethical committees, hospitals, international organisations, paediatrician associations, regulatory authorities, scientific societies, and the pharmaceutical industry in sharing paediatric drug therapy clinical trial information. In addition to this direct request for collaboration, the members have provided a form, accessible on the DEC-net website's homepage, allowing anyone wishing to collaborate to notify them of ongoing trials.



www.dec-net.org

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