



AIM

ASSOCIATION INTERNATIONALE DE LA MUTUALITE

AIM response to Public Consultation Paper

“Draft list of fields to be made public from EudraCT for Paediatric Clinical Trials”

1 October 2008

AIM would like to submit following comments regarding the above mentioned public consultation paper:

AIM requests to add following items:

- Fields for names of all investigators
- Fields for all study centres
- Field for publication: full name of reference, if not published how to access the final study report.

On **page 8** of the European Commission consultation paper AIM has following concerns:

- As general comment we wonder if it would not be clearer to decide which information should remain confidential; all other information should be made public.
- AIM would also like to highlight the need of the possibility of access to the original data (data on file).
- As regards adverse events, we propose the following:
Adverse events: **all** adverse events or side effects in each intervention group.

About the Association Internationale de la Mutualité (AIM)

The ‘Association Internationale de la Mutualité’ (International Association of Mutual benefit societies) brings together 43 national federations of autonomous health insurance and social protection bodies in 28 countries. All these organizations are operating according to the principles of solidarity and not-for-profit orientation.

In Europe, they provide coverage against sickness and other social welfare risks to more than 150 million people, either by participating directly in the management of compulsory health insurance, by providing voluntary health insurance or by delivering directly health care and social services through own facilities.

AIM's goal is to defend and promote, at international and European level, the social values and basic principles shared by its members: access to health care as a fundamental right, solidarity and non-exclusion as essential means to ensure this access to quality health care for all, irrespective of health status or financial capacity to pay; and non profit orientation as guiding principles for health insurance based upon the needs of citizens.

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