To Whom It May Concern

I previously responded to the public consultation on the Draft list of fields to be made public from EudraCT for Paediatric Clinical Trials (protocol-related information) from the Eurordis Paediatric Task Force.

Once again the Eurordis Paediatric Task Force was consulted and the comments made for the previous draft list are also relevant for this one.

General Comments:
The Proposals look very good and we look forward to the time that these will be implemented.

The Lists really contain very detailed information

The essential Eurordis recommendations are well considered – info on the sites, participants flow, dates defining the periods of recruitment and follow-up etc.
however
It is not clear from the Guideline whether the key comment on publishing in all EU languages will be considered

It is disappointing to see Phase I data NOT included in the Draft List (general) .

Specific Comments:

- In **part N:** Review by the Competent authority or Ethics Committee in the country(ies) concerned
Perhaps it's important to add: protocol and annex read by parents association (Name and address).

Thank you very much.

Yours faithfully,

Maria Mavris (on behalf of the Eurordis Paediatric Task Force)

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Maria Mavris PhD
Drug Development Programme Manager
Eurordis
Plateforme Maladies Rares
102, rue Didot
75014 Paris
France
Tel.: +33 1 56 53 52 19
Fax: +33 1 56 53 52 15
More information about Eurordis at: www.eurordis.org