

To Whom It May Concern

Please find comments regarding the Draft list of fields to be made public from EudraCT for Paediatric Clinical Trials (protocol-related information) from the Eurordis Paediatric Task Force.

**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:**

Status of Trials: whether ongoing, completed or importantly....recruiting, should be added

- 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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