Dear Madam/Sir

Please find below my comments on the above-mentioned public consultation.
While the proposed list of fields as a whole looks very reasonable, I do not see the need for the proposed differences between the requirements for paediatric clinical trials and for clinical trials in general:

Comparing with the public consultation paper on ”Draft list of fields to be made public from EudraCT for Paediatric Clinical Trials”, the list of fields contained in the 'EudraCT' clinical trials database to be included in the 'EudraPharm' database omits a number of fields (B.3.1/B.3.2, all of E.7.1, all of G).

In addition, in section N, the ”End of trial status” does not include any indication of the way in which the trial was ended – the consultation paper on Paediatric Clinical Trials distinguishes between ”Completed, prematurely terminated, prohibited or suspended”, which seems very relevant for all Clinical Trials.

Finally, in the list of fields concerning Trial results, on ”Objective(s) of the trial”, this paper mentions IMP and ”indication” whereas the paper on Paediatric Clinical Trials mentions IMP and age group. Presumably both papers should recommend indicating all three aspects.

Kind regards,

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