

Dear Madam/Sir

Comparing with the public consultation paper on "Draft list of fields contained in the 'EudraCT' clinical trials database to be included in the 'EudraPharm' database on medicinal products and made public, in accordance with Article 57(2) of Regulation (EC) No 726/2004", the list of fields to be made public for Paediatric Clinical Trials includes a number of additional fields (B.3.1/B.3.2, all of E.7.1, all of G).

In section N, the "Ethics committee opinion – positive or negative or pending. Date of opinion" should presumably be in a separate row in the table.

Finally, in the list of fields concerning Trial results, on "Objective(s) of the trial", this paper mentions IMP and age group whereas the paper on fields from 'EudraCT' to be included in 'EudraPharm' mentions IMP and "indication". Presumably both papers should recommend indicating all three aspects.

Kind regards,

Claus Bo Jørgensen

Academic Employee

Licensing Division – Legal & International Services

Danish Medicines Agency

clbj@dkma.dk

T (dir.) +45 44 88 93 63

Axel Heides Gade 1

DK-2300 København S

T +45 44 88 95 95

F +45 44 88 95 99

dkma@dkma.dk

www.dkma.dk