

SUBMISSION OF COMMENTS ON:

“Draft list of fields to be made public from EudraCT for Paediatric Clinical Trials (protocol-related information)”

“Draft list of fields on information concerning Paediatric Clinical Trial results to be made public”

PUBLIC CONSULTATION PAPER

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http://ec.europa.eu/enterprise/pharmaceuticals/index_en.htm

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GENERAL COMMENTS

None received

SPECIFIC COMMENTS on draft list of fields to be made public from EudraCT for Paediatric Clinical Trials (Protocol-related information)

| Field number (e.g. D. 2.1.1.1) | Comment and Rationale | Proposed change (if applicable) |
|---|---|--|
| | The question “ <i>Is this a specific paediatric formulation</i> ” appears to be | Remove question |

| | | |
|----------|--|--|
| D.3.4.1. | redundant Formulations used in clinical research are generally adequate for and tailored to the needs of research subjects this specific formulation is used for. This does not preclude any further development of the formulation as research conducted with the drug progresses through the usual phases. In this context, this question might not add any value. | |
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