<13/04/2016>

Submission of comments on '<ICH E11 (R1) guideline on clinical investigation of medicinal products in the pediatric population>' (EMA/CHMP/ICH/2711/1999)

Comments from:

Name of organisation or individual
TEDDY European Network of Excellence for Paediatric Clinical Research

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	The relevance of this addendum to update and complement the original document is acknowledged, because of scientific, technological, ethical and regulatory advancements. Specific guidance documents focused on each mentioned aspects are also relevant and should be read in conjunction with the proposed addendum.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
Lines 91-92		Comment: DISSENT- A definition for DISSENT is missing in the glossary. Proposed change (if any): To add dissent definition in the glossary: Dissent means the expression of the minor's will not to participate	
Paragraph 4 "Age classification and pediatric subgroups, including neonates", lines 139-140		It must be better highlighting that the inclusion of paediatric subpopulations in adult studies or adult subpopulation in paediatric studies is not the rule, but an exception and has to be properly justified (e.g. in the case of rare diseases). The reasoning should take into account also study features (different from condition and treatment), e.g. endpoints and procedures.	
Paragraph 5.1 "Approaches to optimize pediatric drug development" – Use of existing knowledge		Comment: the use of existing knowledge for paediatric drug development may also refer to off-label use. This is particularly useful in case of old medicines, that have been not duly studied in paediatrics, but with a large use in an off-label manner.	
Paragraph 7.3 "Paediatric formulations" – palatability and acceptability		Comment: a reference to the need to address patients' compliance when planning the development of new paediatric formulations can be added in the paragraph	