Due 31 Aug 2016

Submission of comments on 'Consultation document – Ethical considerations for clinical trials on medicinal products conducted with minors'

Comments from:

Regeneron Pharmaceuticals, Inc.

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Regeneron is a fully-integrated, biopharmaceutical company that produces and develops biological drugs, including recombinant fusion proteins and monoclonal antibodies, for the treatment of a broad array of diseases and conditions, particularly for the treatment of serious medical conditions.

Our research is conducted on a global level and includes clinical development in EU Member States.

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)*
	Regeneron appreciates the opportunity to provide feedback on the Consultation document on "Ethical considerations for clinical trials on medicinal products conducted with minors." Our comments are focused on providing specific feedback on the Commission's proposed topics, on risk categorisation of study procedures (Annex 3), and general feedback on clinical trials in minors in emergency situations.	

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)*
Annex 3: Examples for levels of risks and burdens		***Q2: Which insights may lead to changes in categorisations (in particular those indicated in yellow)?*** It is important to note that several of the procedures in Category 2 and Category 3 are very much dependent on the indication under clinical trial evaluation. In particular, in indications such as oncology and life-threatening rare diseases, patients already undergo routine procedures (such as MRI, CT, or PET scan) as part of standard care, and these procedures as part of the clinical trial do not necessarily add incremental risk to participants. As such, we recommend the following revisions in categorisations (in particular those indicated in yellow) **Proposed change in categorisation table**: • Asterisk (*) be added to 'MRI Scan' (Category 2) and Spinal CSF tap (Category 2) to indicate that evaluation of these procedures may depend on the context of its use in the trial • PET scanning be moved to Category 2, with addition of * to indicate that evaluation may depend on the context of its use in the trial. Particularly in oncology trials, where PET scanning is part of routine care, this would not be appropriate for the Category 3 grouping. **In addition, we request clarification on two of the Category 3 procedures listed in the table:** • Please clarify whether "systemic analgesia" is in reference to	

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		opioid analgesics, and whether this applies to all analgesics, or there are specific ones of concern. • Please clarify "Hypoglycaemia test" – We interpret this as 'Insulin-induced hypoglycaemia test' and thus different from oral glucose tolerance test (Category 1).	
Section 6.6 Consent, assent, and agreement in emergency situations Lines 553-560		***F1: General feedback on clinical trials in minors in emergency situations (within the meaning of Article 35 of the Clinical Trials Regulation)*** As currently stated in this paragraph, it is unclear which "particular situations…should be considered according to national law." We request that guidance be provided to delineate these particular situations from emergency situations that fall under Article 35 of the Clinical Trials Regulation.	

Please add more rows if needed.