



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2018-01-12

Submission of comments on 'Reflection paper on the use of extrapolation in the development of medicines for paediatrics' (EMA/199678/2016)

Comments from:

Name of organisation or individual

European Federation of Statisticians in the Pharmaceutical Industry (EFSPI)

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).



1. General comments

Stakeholder number	General comment (if any)	Outcome (if applicable)
<i>(To be completed by the Agency)</i>		<i>(To be completed by the Agency)</i>

2. Specific comments on text

Line number(s) of the relevant text <i>(e.g. Lines 20-23)</i>	Stakeholder number <i>(To be completed by the Agency)</i>	Comment and rationale; proposed changes <i>(If changes to the wording are suggested, they should be highlighted using 'track changes')</i>	Outcome <i>(To be completed by the Agency)</i>
Line 200		<p>Comment: This seems to be an incomplete sentence.</p> <p>Proposed change (if any):</p>	
Lines 392-396		<p>Comment: It is unclear what is meant by “adequately powered” here? Adequately powered so that the study shows a statistically significant result or adequately powered so that the study meets a pre-defined success criteria, eg [Prob (treatment difference)>x]>y%? Doesn't the latter make more sense when there are feasibility constraints around sample size? And also what is an adequate power (90%, 80%, ...)? Of course the success criteria should not be artificial in order to line up with a certain sample size. However, the success criteria that could be met with a feasible sample size should be discussed with regulators to reach agreement on (i) the definition of the success criteria and (ii) the probability of meeting this success criteria.</p> <p>Proposed change (if any):</p>	
Line 401		<p>Comment: When referring to “information” (1st word) does this mean treatment difference and if so should this be more explicit?</p> <p>Proposed change (if any):</p>	

Please add more rows if needed.