<04/10/2018>

Submission of comments on

FDA Draft Guidance - Drugs for Treatment of Partial Onset Seizures: Full Extrapolation of Efficacy from Adults to Pediatric Patients 4 Years of Age and Older

Docket ID: FDA-2018-D-0178-0001

Link to original document: 2/15/2018: Drugs for Treatment of Partial Onset Seizures: Full Extrapolation of Efficacy from Adults to Pediatric Patients 4 Years of Age and Older

Comments from:

Name of organisation or individual
International Consortium for Innovation and Quality in Pharmaceutical Development (IQ Consortium)

1. General comments

General comment (if any)	Outcome (if applicable)
This new draft guidance is very welcome.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes ***(If changes to the wording are suggested, they should be highlighted using 'track changes')***	Outcome
lines 80-91	Section III-C. Clinical Pharmacology/Dosing Consideration. The guidance should give some flexibility on how supporting evidence on pediatric PK and dose selection can be generated, in addition to a dedicated pediatric PK study. There has been significant advancement in pediatric PK prediction in the past two decades. As stated in the FDA's Draft Guidance on General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biological Products (Dec 2014), "A dedicated PK study is not always required in every age group. For example, prior experience with dosing in adolescent patients has demonstrated that knowledge of adult dosing and appropriate dose scaling may be sufficient for some drugs with adequate justification. Confirmatory population PK studies may be used to supplement such a program in which a dedicated PK study is not considered essential." (lines 423-427) "When clinical PK studies in pediatric patients are not feasible, there are situations in which interpolation or extrapolation of PK data may be sufficient. PK information in certain pediatric age groups may be gained by interpolating or extrapolating from existing data in adults, data in pediatric patients in other age groups, or both." (lines 438-441) It would be preferred that the POS extrapolation guidance refers to the pediatric Clinical Pharmacology Guidance on generating pediatric PK information, and provides this flexibility based on	Please refer to the FDA's pediatric Clinical Pharmacology Guidance on generating pediatric PK information, and provide the flexibility highlighted in the "Comment and rationale" column at left.

Line number(s) of the relevant text ***(e.g. Lines 20-23)***	Comment and rationale; proposed changes ***(If changes to the wording are suggested, they should be highlighted using 'track changes')***	Outcome
	the confidence associated with a given alternative approach regarding pediatric PK prediction.	

Please add more rows if needed.