FDA Finalizes Guidance on Extrapolating Data for Pediatric Medical Devices

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A little more than a year after introducing the draft version, the US Food and Drug Administration (FDA) on Monday finalized guidance on how and when it may be appropriate to leverage existing clinical data to support pediatric medical device indications and labeling.

The guidance, which, like the draft from May 2015, reveals FDA's concerns with the paucity of scientific evidence substantiating medical device submissions for pediatric indications, outlines ways in which companies can extrapolate data so devices can be used for such younger populations.

"For the purposes of this document, 'extrapolation' refers to the leveraging process whereby an indication for use of a device in a new pediatric patient population can be supported by existing clinical data from a studied patient population," FDA says. "That is, when existing data are relevant to a pediatric indication and determined to be valid scientific evidence, it may be scientifically appropriate to attempt to extrapolate such data to a pediatric use in support of demonstrating a reasonable assurance of effectiveness or probable benefit and, occasionally, safety."

And also like the draft, the finalized guidance focuses on four objectives:

- To increase the availability of safe and effective pediatric devices by providing a road map for leveraging relevant clinical data "for use in demonstrating a reasonable assurance of safety and effectiveness in PMAs [premarket applications] and de novo requests, as well as for use in supporting approvals of HDEs [humanitarian device exemptions]"
- To explain the circumstances of when it may be appropriate to leverage this data to support pediatric device indications and labeling
- To outline the approach FDA uses to determine whether extrapolation is appropriate, and to what extent the data can be leveraged
- And to describe statistical methodology that can be used to leverage the data in a way that increases precision for pediatric inferences.

Draft to Final

The comments on the draft version, according to FDA, sought clarification of the scope of the guidance and FDA updated it to include de novo requests. Comments also sought further information on the extent of extrapolation that may be feasible across various pediatric sub populations, and the concept of "borrowing strength" from existing adult data.

Accordingly, FDA says it has provided additional explanation on the concepts of extrapolation of data across pediatric sub populations and "borrowing strength" (an entire section of the guidance is dedicated to the term).

- See more at: http://www.raps.org/Regulatory-Focus/News/2016/06/20/25167/FDA-Finalizes-Guidance-on-Extrapolating-Data-for-Pediatric-Medical-Devices/#sthash.RwMUIEJx.dpuf