



FDA Update, News Articles, Pharmacology

Workshops focus on long-term medication safety, pediatric big data

by from the Food and Drug Administration Office of Pediatric Therapeutics and Division of Pediatric and Maternal Health

Editor's note: This is the third in a series of articles on the Food and Drug Administration's (FDA's) Advancing the Development of Pediatric Therapeutics workshops. The first workshop on pediatric bone health was summarized in the December 2014 issue (<http://bit.ly/2EuucNt>) and the second on evaluation of neurocognitive development was summarized in July 2015 (<http://bit.ly/2E8PUct>).

The FDA continued its efforts to advance the development of pediatric therapeutics by holding public workshops that focused on successes and challenges of performing long-term safety studies and how to use "big data" to inform drug development.

During the workshop on long-term safety studies, experts discussed elements of design and implementation strategies. Industry representatives and patient/parent advocates for children with chronic conditions also participated in the discussions.

The public workshop on use of big data described pediatric big data collections and their applications, presented tools used in the latest pediatric big data research programs, and discussed ongoing challenges associated with big data use. International and multi-stakeholder perspectives were presented.

Because pediatric studies tend to enroll fewer patients than adult studies, additional information may be needed to better understand the safety and/or efficacy of drugs in children. Big data, including sources of real world evidence involving large and complex data sets, may be particularly useful in supplementing data from traditional studies. Supplementary information may include data from large observational databases, including electronic health records and registries.

Resources

- [Slides presented at the workshops](#)
- [Additional slides from the workshops](#)
- [FDA information on real world evidence](#)
- [Additional AAP News FDA Update columns](#)