

Pediatric Drug Development: Use of Exposure Matching and Exposure Response for Extrapolation of Efficacy in Pediatric Product Development Final Report

January 22, 2015 University of Maryland School of Pharmacy

Number of Attendees: 437 total, 57 Industry, 17 Academia, 70 FDA, 293 Online

P.I. - Jill Morgan, UMB

Co P.I.'s-Lily Mulugeta FDA, Robert Nelson FDA, Kevin Krudys FDA, Jian Wang FDA

The program, Pediatric Drug Development: Use of Exposure Matching and Exposure Response for Extrapolation of Efficacy in Pediatric Product Development, was held on January 22, 2015 at the Food and Drug Administration (FDA) White Oak Campus from 8:30am to 4:30pm.

The workshop addressed three major objectives: (1) reviewed current practices and applications of pediatric exposure matching and pediatric exposure-response analysis from the industry and FDA perspectives; (2) defined the applications of pediatric exposure matching and pediatric exposure-response analysis in relation to extrapolation of adult efficacy; and (3) discussed recommendations for applications of pediatric exposure matching and pediatric exposure-response analysis in drug development. The workshop provided an opportunity for experts from industry, academia, and regulatory agencies to share their experience for the use of these clinical pharmacology tools in pediatric drug development.

The first half of the program was focused on pediatric extrapolation and using extrapolation as an alternate for efficacy trials. Case examples were shared and the panel allowed for a lot of discussion on determining the correct endpoint for exposure response and how similarity in exposure response can be assessed. The afternoon was focused on matching pediatric drug exposure to adult drug exposure. Again, case examples were shared and the panel allowed time for questions from the audience on this topic.

The program was advertised to the American College of Clinical Pharmacy (ACCP), American College of Clinical Pharmacology (ACCP), American Association of Colleges of Pharmacy Pediatric Special Interest Group (AACCP), Pediatric Pharmacy Advocacy Group (PPAG), FDA, American Society for Clinical Pharmacology and Therapeutic (ASCPT), and the University of Maryland School of Pharmacy. The program was a success with 437 participants which included in-person and online participants.