

# **Pediatric Master Protocols Final Report**

University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI)  
Science Exchange and Conference Grants

The program, Pediatric Master Protocols, was held on September 23, 2016 at the Food and Drug Administration (FDA) White Oak Campus from 8:30am to 4:30pm. The workshop addressed three major objectives: (1) discuss the regulatory, industry and study site concerns with pediatric master protocols, (2) discuss the design considerations for pediatric master protocols, and (3) discuss examples from pediatric therapeutic areas where master protocols could be used. The workshop provided an opportunity for experts from industry, academia, and regulatory agencies to share their experience for the use of these protocols in pediatric drug development.

The morning presentations focused on the benefits of using pediatric master protocols and some of the challenges in designing studies for children. Also, information on combining protocols for the FDA and the European Union (EU) were discussed. Next, Dr. Dionna Green, FDA, shared information on trial designs that work based on previous protocols submitted to the FDA. The need for biostatistics assistance early in the design of the protocols was presented as well as building and working with consortia. The afternoon presentations were focused on specific areas that have been successful using master protocols including oncology, analgesics, infectious diseases, and in vitro diagnostic tests. Panels were available for questions in both the morning and afternoon and lead to great discussion with participants in attendance in-person and online. 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), the FDA, the Federal Register, and the University of Maryland School of Pharmacy. The program was a success with 499 participants which included 109 in-person and 390 online participants.

A majority of the budget was spent on travel reimbursement for speakers and lunch for the speakers and planning committee members. The planning committee included: Dr. Jill Morgan, Ann Anonsen, and Dr. Jim Polli from the University of Maryland CERSI; Dr. Gil Burkhart from FDA, Center for Drug Evaluation and Research (CDER); Drs. York Tomita, and Rebekah Zinn, Audrey Thomas, Donna Blum-Kemelor, Shari Solomon, and Amal Manseur from FDA, Office of the Chief Scientist, Office of Regulatory Science and Innovation (ORSI); Drs. Vasum Peiris and Anand Pathak from FDA, Center for Devices and Radiological Health (CDRH); Drs. Maura O'Leary and Barbara Buch from FDA, Center for Biologics Evaluation and Research (CBER); Leslie Wheelock, Eileen Parish, and Marcy Wexler, FDA, Office of Scientific Professional Development (OSPD); and Drs. Jean Temeck and Dianne Murphy from FDA, Office of the Commissioner (OC).