

Advancing Pediatric Pharmacovigilance – September 14, 2018
 Great Room, Building 31, US FDA, 10903 New Hampshire Ave., Silver Spring, MD 20993

Introductory Comments

8:00 AM	Opening Remarks	Janet Woodcock, Director, Center for Drug Evaluation and Research (CDER), United States Food and Drug Administration (FDA)
8:10 AM	Background of ADEPT Workshops	Ken Quinto, Office of Pediatric Therapeutics, FDA
8:20 AM	Overview of pediatric pharmacovigilance; Mission of Today's Workshop	Ethan D. Hausman, Division of Pediatric and Maternal Health (DPMH), CDER, FDA

Panel 1: Pediatric Pharmacovigilance and Current Data Sources

8:30 AM	Pediatric pharmacovigilance at FDA	Cindy Kortepeter, Director, Division of Pharmacovigilance I, CDER, FDA Steven Bird, Division of Epidemiology I, CDER, FDA
9:10 AM	The Use of Sentinel in Pediatric Safety	Jeffrey Brown, Harvard Medical School and Harvard Pilgrim Health Care Institute
9:40 AM	Drug Safety Research in Canada: Canadian Network for Observational Drug Effect Studies	Robert Platt, McGill University
10:10 AM	BREAK	
10:20 AM	Opportunities and Challenges in Using Observational Health Data for Pediatric Pharmacovigilance	Patrick Ryan Janssen Research and Development
10:50 AM	Panel 1 Discussion	Moderator, Ethan D. Hausman
11:30 AM	LUNCH	

Panel 2: Future Directions

12:30 PM	RAPID: A Real-Time FDA System for Pediatric Case Reporting and Evaluation	Henry "Skip" Francis, Office of Translational Science, CDER, FDA
1:00 PM	Mobile Technology, Social Media, and Paediatric Signal Detection	Phil Tregunno, MHRA
1:30 PM	PEDSnet: A National Pediatric Learning Health System	Christopher B Forrest, Children's Hospital of Philadelphia

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2:00 PM	Use of Artificial Intelligence to Interpret Safety Reports Submitted to FDA	Scott Proestel, Senior Medical Officer, Biomedical Informatics and Regulatory Review Science, Office of New Drugs, CDER, FDA
2:30 PM	Using Machine Learning/Cognitive/AI Approaches to Identify Individual Case Safety Reports in Social-Digital Media	Sujan Perera, Watson Health, IBM
3:00 PM	BREAK	
3:10 PM	The Benefits of Linked Data Sets for Research	Ranjit Kher, Watson Health, IBM
3:40 PM	Lessons from Health Security Intelligence as Applied to Pediatric Pharmacovigilance	James M Wilson V, Director, Nevada Medical Intelligence Center at the University of Nevada-Reno
4:10 PM	Panel 2 Discussion	Moderator, Scott Proestel
4:55 PM	Closing Remarks	John J. Alexander, Deputy Director, DPMH, CDER, FDA