Application of "Big Data" to Pediatric Safety Studies – September 18-19 , 2017 DoubleTree by Hilton Hotel Washington DC – 8727 Colesville Rd., Silver Spring, MD 20910		
Day 1		
8: 30 AM	Welcome & Introduction	Ann McMahon, Office of Pediatric Therapeutics, FDA
8:35 AM	Therapeutics in children: great progress, now let's fill in the gaps	Robert Califf, Former Commissioner of FDA
9:05 AM	Regulatory context- "Big Data" and pediatrics at the Food and Drug Administration	Mona Khurana, Division of Pediatric and Maternal Health, FDA
9:35 AM	Reflections on the findings and conclusions of the European Medicines Agency (EMA) Workshop on " Big Data" and healthcare	Alison Cave, EMA
10:05 AM	BREAK	
Panel 1: How "Big Data" can be created and used for solving public health problems in healthcare		
10:20 AM	How can we use medical records to create "Big Data" for analysis of safety signals?	Mark Hoffman, Mercy Children's Hospital
10:50 AM	Data-driven healthcare: visual analytics for exploration and prediction of clinical data	Adam Perer, IBM
11:20 AM	"Big Data " in analysis of streaming physiologic data: implications for health care	Rishikesan Kameleswaran, University of Tennessee
11:50 PM	LUNCH	
12:50 PM	Large-scale analysis to transform the evidence generation process: lessons from the Observational Health Data Sciences and Informatics (OHDSI) collaborative	Patrick Ryan, Johnson and Johnson
1:20 PM	Medical product safety surveillance research in multi-site settings	Jeff Brown, Harvard Medical School and Harvard Pilgrim Health Care Institute
1:50 PM	Panel 1 Discussion with additional discussants Joshua Denny/Vanderbilt University, Michael Blum/FDA, Carolyn McCloskey/FDA	Ann McMahon (moderator)
3:00 PM	BREAK	
Panel 2: International perspectives on "Big Data" in health care		
3:15 PM	European perspectives on the use of "Big Data" in health care research	Mark Turner, University of Liverpool and European Network of Paediatric Research at the EMA
3:45 PM	Pharmaceutical and Medical Devices Agency's (PMDA) plans for use of "Big Data" in healthcare	Shohko Sekine, PMDA, Japan Michiyo Sakiyama, PMDA, Japan
4:15 PM	Panel 2 Discussion with additional discussants, Alison Cave/EMA, Miriam Sturkenboom/ Utrecht University	Ann McMahon, FDA
Day 2		
8:30 AM	Introduction to 2nd Day	Ann McMahon, FDA

Panel 3: Opportunities and risks in using “Big Data” for pediatrics		
8:35 AM	“Big Data” to generate biomarkers for pediatric precision medicine: use and misuse	Isaac Kohane, Harvard Medical School
9:15 AM	Responsible and transparent use of “Big Data ” to advance pediatric research	Finale Doshi-Velez, School of Engineering and Applied Sciences, Harvard University
9:45 AM	Panel 3 Discussion	Isaac Kohane (moderator)
10:30 AM	BREAK	
Panel 4: Creating knowledge for clinical and regulatory decision making from “Big Data” in pediatrics		
10:45 AM	The need for “Big Data” in pediatrics	Miriam Sturkenboom, Utrecht University Medical Center, Netherlands
11:25 AM	Prevention of adverse drug reactions (ADRs) in childhood by identifying predictive genomic markers for specific ADRs: Use of “Big Data”	Bruce Carleton, University of British Columbia
11:35 AM	Panel 4 Discussion	M. Sturkenboom (moderator)
12:20 PM	LUNCH	
Panel 5: Pediatric pharmacoepidemiologic considerations in use and analysis of “Big Data”		
1:30 PM	Developmental and environmental considerations in analysis of “Big Data” in pediatrics	Jennifer Goldman, Children’s Mercy Hospital
2:00 PM	Consideration of factors occurring between pediatric exposures and outcomes that could confound signals derived from “Big Data”	Allen Mitchell, Boston University
2:40 PM	Panel 5 Discussion with additional discussant Stephen Spielberg/ Former FDA Deputy Commissioner for Medical Products & Tobacco	Allen Mitchell (moderator)
3:25 PM	BREAK	
3:40 PM	Summary of workshop	William Cooper , Vanderbilt University
5:00 PM	Farewell	Ann McMahon, FDA

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