Solutions to Drug Development Challenges Workshop: Utilizing Quantitative Approaches, Data Sharing, and Novel Biomarkers

Title	Presenter	Presentation Link
Introduction	Dr. John-Michael Sauer (C-Path)	
Keynote Address	Dr. Joseph Scheeren (C-Path)	
Welcoming Remarks	Dr. Janet Woodcock (US FDA)	
Session 2: Benefits of DDT progression to regulatory acceptance	**Moderators: Dr. Inish O'Doherty (C-Path) and Dr. Ameeta Parekh (US FDA)**	
2.1 A perspective on the history and evolution of drug development tools at FDA	Dr. Ameeta Parekh (US FDA)	
2.2 Overview of Fit-for-Purpose Initiative	Dr. Sharonjit Sagoo (US FDA)	
2.3 Overview of Biomarker Qualification Program	Dr. Katherine Hollinger (US FDA)	
2.4 Broad perspective on how the paths impact industry	Dr. James Mayne (PhRMA)	
Session 3: Approaches to regulatory acceptance of drug development tools	**Moderators: Dr. John-Michael Sauer (C-Path) and Dr. Katherine Hollinger (US FDA)**	
Examples of drug development tool regulatory acceptance covering the unmet need, solution, process, impact, and next steps		
3.1 Quantitative solutions for drug development	Dr. Klaus Romero (C-Path)	
3.2 Kidney Safety Project Composite Measure of drug-induced kidney injury biomarkers	Dr. Gary Friedman (Pfizer)	
3.3 Total kidney volume as a prognostic biomarker / reasonably likely surrogate endpoint for use in clinical trials for Polycystic Kidney disease	Dr. Vijay Modur (Sanofi)	
Presentations on approaches to regulatory acceptance of current projects		
3.4 Islet autoantibodies as susceptibility/risk biomarkers for T1D diagnosis in at risk subjects	Dr. Joe Hedrick (Janssen)	

3.5 Novel biomarkers for Crohn's disease drug development programs	Dr. Jiri Aubrecht (Takeda)	
3.6 Developing and validating an *in silico* model for proarrhythmia risk assessment under the CiPA Initiative	Dr. Zhihua Li (US FDA)	
Keynote Address	Dr. Peter Stein (US FDA)	
Session 4. Addressing Drug Development Gaps through Data Sharing: Converting Data into Knowledge	**Moderators: Dr. Klaus Romero (C-Path) and Ms. Amanda Borens (C-Path)**	
4.1 Introduction and notes on data sharing and acquisition	Dr. Klaus Romero (C-Path)	
4.2 Data-driven models for drug development	Dr. Jackson Burton (C-Path)	
4.3 Bridging the gap	Ms. Amanda Borens (C-Path)	
4.4 NIH Strategic Data Initiative	Dr. Ken Wilkins (NIDDK)	
4.5 CREATE: Children's REgistry for the Advancement of ThErapeutics	Dr. Eric Zuckerman (Pediatric IBD Foundation)	
4.6 C-Path Biomarker Data Repository	Dr. Jennifer Burkey (C-Path)	