Pediatric Dose Selection

Co-Sponsored by the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) and U.S. Food and Drug Administration (FDA)

CERSI
University of Maryland

Online Event
Oct. 22-23, 2020

Thursday, Oct. 22, 2020

TIME	ACTIVITY
10:00 – 10:05 a.m.	**Welcome** G. Burckart (FDA)
	Introductory Talks **Moderator:** Jill Morgan (University of Maryland School of Pharmacy)
10:05 – 10:20 a.m.	**What Information Does the Pediatric Clinician Need, and How is Dosage "Drift" Over Time Handled Clinically?** J. Morgan (University of Maryland School of Pharmacy)
10:20 – 10:35 a.m.	**Review of the Adult Dose Selection EMA Workshop** E. Manolis (EMA)
10:35 – 10:50 a.m.	**Review of the Methods Used for Dose Selection in U.S. Pediatric Drug Development Programs** G. Burckart (FDA)
10:50 – 11:05 a.m.	**Drug Development Programs Where the Dose Was a Problem** Y. Wang (FDA)
	Review of Pediatric Dosing Approaches **Moderator:** Gil Burckart (FDA)
11:05 – 11:35 a.m.	**Point-Counterpoint: Traditional Approaches Versus PBPK to Predict Pediatric Doses** Two 15-minute Talks: • PBPK in Pediatric Dose Selection (Alice Ke, Certara) • PBPK for Pediatrics – Really? (Joga Gobburu, University of Maryland School of Pharmacy)

11:35 – 12:30 p.m.	**Discussion and Questions** **Moderators:** Jill Morgan (University of Maryland School of Pharmacy) and Gil Burckart (FDA)
12:30 – 1:00 p.m.	**Lunch Break**
1:00 – 1:15 p.m.	**Exposure-Matching for Pediatric Patients with Efficacy Extrapolation** H. Zhu (FDA)
1:15 – 1:30 p.m.	**Use of Exposure-Response in Pediatric Drug Development** J. Wang (FDA)
1:30 – 1:45 p.m.	**Dose Determination in Neonates** J. van den Anker (Children's National)
1:45 – 2:00 p.m.	**Biologicals Dosing in Pediatrics** B. Meibohm (University of Tennessee)
2:00 – 3:00 p.m.	**Discussion and Questions** **Moderators:** Jill Morgan (University of Maryland School of Pharmacy) and Gil Burckart (FDA)

Friday, Oct. 23, 2020

TIME	ACTIVITY
	Filling the Gap **Moderator:** Jian Wang (FDA)
10:00 – 10:15 a.m.	**Evaluation of Drug-Drug Interactions and Their Influence on Drug Dosing in the Pediatric Population** D. Gonzalez (University of North Carolina)
10:15 – 10:30 a.m.	**Renal Impairment in Pediatric Patients: How Can We Promote Best Practices in Drug Dosing?** M. Khurana (FDA)

10:30 – 10:45 a.m.	**Predictive Performance of PBPK Dose Estimates for Pediatric Trials** A. Dallmann and I. Ince (Bayer)
10:45 – 11:00 a.m.	**How Can Pharmacogenomics and Cancer Genetics Be Incorporated in Pediatric Drug Development Studies?** J. Yang (St. Jude Children's Research Hospital)
	Developing a Reasonable Approach for Pediatric Dose Selection **Moderator:** John van den Anker (Children's National)
11:00 – 11:15 a.m.	**Current and Future Pediatric Approaches** J. Barrett (Critical Path Institute)
11:15 – 11:30 a.m.	**Current and Future Pediatric Dosing Considerations from a Regulatory Viewpoint** L. Yao (FDA)
11:30 – 12:30 p.m.	**Discussion and Questions** **Moderators:** John van den Anker (Children's National) and Gil Burckart (FDA) **Speakers:** All Friday Speakers and Sander Vinks (University of Cincinnati), Dionna Green (FDA), Clinton Stewart (St. Jude Children's Research Hospital)
12:30 – 12:35 p.m.	**Wrap-Up and Adjourn** G. Burckart (FDA)