Pediatric Dose Selection

Workshop sponsored by US FDA and Un. of Maryland CERSI

Thursday, October 22, 2020

10:00-10:05 Welcome (G. Burckart)

Introductory talks – Moderator: Jill Morgan

10:05-10:20 AM What information does the pediatric clinician need, and how is dosage "drift" over time handled clinically? (J. Morgan, Un. Maryland)

10:20-10:35 AM Review of the adult dose selection EMA workshop (E. Manolis, EMA)

10:35-10:50 AM Review of the methods used for dose selection in US Pediatric drug development programs (G. Burckart, FDA)

10:50-11:05 AM Drug Development programs where the dose was a problem (Yaning Wang, FDA)

Review of pediatric dosing approaches Moderator: G. Burckart

11:05 – 11:35 AM 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, Un. of Maryland)

11:35 AM – 12:30 PM **Discussion & Questions** (Moderators Jill Morgan , Gil Burckart)

Panel of Thursday morning speakers

12:30 – 1:00 PM Lunch Break

1:00 – 1:15 PM Exposure-matching for pediatric patients with efficacy extrapolation (Hao Zhu, FDA)

1:15-1:30 PM Use of exposure-response in pediatric drug development (Jian Wang, FDA)

1:30 - 1:45 PM Dose determination in neonates (John van den Anker, Children's National)

1:45 – 2:00 PM Biologicals dosing in pediatrics (Bernd Meibohm, Un. of Tennessee)

2:00 – 3:00 PM **Discussion and Questions** (Moderators Jill Morgan , Gil Burckart)

Panel of Thursday afternoon speakers

FRIDAY, October 23, 2020

Filling the gap – Moderator: Jian Wang

10:00 – 10:15 AM Evaluation of Drug-Drug Interactions and Their Influence on Drug Dosing in the Pediatric Population (D. Gonzalez, Un. North Carolina)

10:15 – 10:30 AM Renal impairment in pediatric patients: how can we promote best practices in drug dosing? (Mona Khurana, MD, FDA)

10:30 – 10:45 AM - Predictive performance of PBPK dose estimates for pediatric trials (Andre Dallmann, Ibrahim Ince, Bayer)

10:45 – 11:00 AM How can pharmacogenomics and cancer genetics be incorporated in pediatric drug development studies? (Jun Yang, St. Jude Children's Research Hospital)

Developing a reasonable approach for pediatric dose selection: Moderator: John van den Anker

11:00 – 11:15 AM Current and future pediatric approaches – (Jeff Barrett, Critical Path Institute)

11:15 – 11:30 AM Current and future pediatric dosing considerations from a regulatory viewpoint – (Lynne Yao, FDA)

11:30 AM – 12:30 PM **Discussion and Questions**

– Moderators: J. van den Anker / J. Wang

Panelists: Friday speakers PLUS: Sander Vinks (Un. of Cincinnati), Dionna Green (FDA), Clinton Stewart (St. Jude Children's Research Hospital)

12:30 – 12:35 PM Wrap up and Adjourn (Gil Burckart)