PQRI Workshop:
MIDD Approaches in Pediatric Formulation Development

February 28-29, 2024

Introductory Remarks

Presented by:
Gilbert Burckart, Pharm.D., Associate Director for Pediatrics, Office of Clinical Pharmacology, Office of Translational Sciences | CDER | US FDA

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Workshop Objectives

- **The objective of this workshop is to bring together industry, regulators, and academia to develop strategies to overcome current challenges with pediatric formulation development.**
  - Day 1 will focus on in vitro and in silico approaches in support of efficient novel pediatric oral formulation development. Specifically, there will be discussion of the role of biorelevant dissolution and PBBM in pediatric formulation development such that reliable predictions of formulation performance across different age groups as well as absorption mediated drug-drug interactions can be made.
  - Day 2 will highlight current gaps in the understanding of the unique aspects of dosing solid oral formulations to pediatric patients. As such, there will be an emphasis on the need to understand the potential negative impact of dosing pediatric drugs mixed with various soft foods on product quality. Furthermore, potential application of PBBM to assess changes in product quality throughout the lifecycle of the product will be explored.
  - Each day will conclude with small group discussions ('breakout sessions') that are moderated by SMEs.
- The workshop will address the following key areas: pediatric biorelevant dissolution, formulation optimization, drug absorption in pediatric patients, food effect, and drug product quality with an emphasis on coadministration with foods as well as lifecycle management/SUPAC changes.

Agenda - Day 1

- Welcome and Introductory Remarks
- Session 1: Background and Introduction
- Session 2: Knowledge Gaps and Challenges in PBBM for Pediatric Oral Formulation Development
- Session 3: Application of PBBM to Support Pediatric Oral Formulation Development
- *Breakouts*

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Breakout Session Ground Rules

Each Session will have Key Questions to Discuss and a Note Taker to document the discussions

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Breakout Session Ground Rules

- Each break-out session is 1 hour on each day; therefore, there is limited time for discussion for each question (approx. 10 minutes per question). It is the intent of the program committee to get comments from as many attendees as possible, **so please**
  - **Be concise with your questions and comments**
  - **Allow time for other attendees in the breakout session time to voice their comments and/or questions**
  - **Respect when the facilitator announces that it is time to move to the next question**

Housekeeping I

- All Attendees are on mute.
- The Plenary Sessions are recorded.

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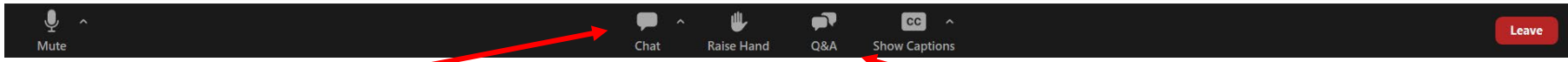

- The Chat function has been disabled for Attendees. Type your question in the Q&A box.

Housekeeping II

- Bios
  - All Speaker bios are posted on the Workshop webpage, under Workshop Materials https://pqri.org/pqri-pediatric-workshop-2024/
- Presentations
  - Post-workshop PDFS of available presentations will be posted on a password protected page: https://pqri.org/pqri-pediatric-workshop-presentations/
  - Password: PQRIPED2024!
- Recordings
  - The recordings will be posted after the Workshop has concluded. We will send out a notice to attendees with the link to view the recordings.
  - NOTE: Breakouts will be not be recorded, but summaries may be posted with the presentations following the Workshop.

Thank You

Workshop Planning Committee

- Andreas Abend, Merck, Chair – Workshop Organizing Committee
- Mary Kate Bielinski, PQRI Secretariat
- Gilbert J. Burckart, Pharm.D., US Food and Drug Administration
- Andre Dallmann, Bayer
- Dede Godstrey, PQRI Secretariat
- Wenlei Jiang, US Food and Drug Administration
- Sandra Klein, Greifswald University
- Julia Pinto, US Food and Drug Administration
- Giuseppe Randazzo, Association for Accessible Medicines (AAM)
- Karen Thompson, Merck