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The Drug Product Pediatric Working Group

The Drug Product Pediatric Working Group's vision is to become a catalyst for advancing science and technologies for the purpose of designing and developing age-appropriate pediatric formulations across the globe. Our mission is to bring together leading pharmaceutical companies and their partners and suppliers, academic researchers, and regulatory bodies to collaboratively advance pediatric formulation development and regulatory harmonization globally.

CONTRIBUTED BY:

Robert Ternik (Eli Lilly)

COLLABORATORS:

Lorraine Buckley (Eli Lilly)

Trupti Dixit (Takeda)

Beth Galella (BMS)

Julia Gao (BMS)

Rob Ju (AbbVie)

Melissa Keeney (Eli Lilly)

Carrie Page (Eli Lilly)

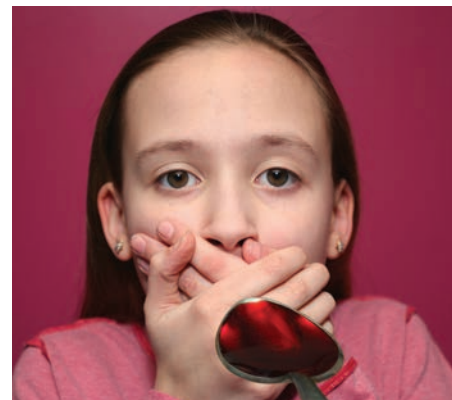
David Tan (AbbVie)

Karen Thompson (Merck)

Advancing Global Collaboration in Pediatric Formulation Development

THE CHALLENGE

The use of pharmaceuticals for treatment of pediatric patients is ubiquitous in clinical practice. In many instances, clinicians, pharmacists, and parents treat children with dose forms and products designed for and tested in adults. This practice can lead to incorrect dosing, poor acceptance, and therapeutic failure or adverse events. Enhanced awareness of these issues, pediatric patients' needs, and evolving regulatory expectations has generated a focus on development of age-appropriate pediatric drug products for clinical and commercial use. Understanding the best product presentations for a diverse pediatric population as well as how to administer these products and assess their acceptability are areas of key importance and rapid innovation for regulators, academics, and the pharmaceutical industry.



OBJECTIVES & APPROACH

The Drug Product Pediatric Working Group was created to address the above challenges and catalyze advancement of science and technologies for age-appropriate formulation development. Recognizing the importance of cross-sector collaboration to facilitate progress, the Working Group sought to establish a shared framework for academics, industry professionals, and regulators to share knowledge, foster consensus on key topics, and advance best practices. One of the key tactics the Working Group used to build and strengthen this framework was a scientific workshop, "Challenges and Strategies to Facilitate Formulation Development of Pediatric Drug Products." Organized with the University of Maryland's Center for Excellence in Regulatory Science and Innovation (M-CERSI) and the U.S. Food and Drug Administration (FDA) as well as the European Pediatric Formulation Initiative (EuPFI), this workshop sought to catalyze cross-sector dialogue on pediatric drug product development challenges, promote an aligned approach to address these challenges, and build relationships to enable future collaboration.

RESULTS

"Challenges and Strategies to Facilitate Formulation Development of Pediatric Drug Products" created a unique opportunity for experts to identify and address critical challenges in pediatric drug product development. The June 2016 workshop reached over 85 leading academic, regulatory, and industry scientists from the US and Europe, who jointly examined a range of topics related to pediatric formulations.¹ Workshop discussions generated consensus on several topics that will provide a foundation for future work, including the need for:

- Improved swallowability and palatability definitions, methodologies and assessment criteria, foundational data-sharing, and investigation of risk mitigation strategies;
- Cross-industry partnerships focused on excipients, greater data-sharing around excipients, and use of strategic risk-based approaches for excipients; and
- Increased use of physiologically based pharmacokinetic (PBPK) modeling for food effects, publication of clinical data on food effects, and creation of standardized protocols for assessing risk when using food as a co-administration vehicle.

Key points of discussion and conclusions from the workshop were captured in three post-workshop peer-reviewed journal articles on palatability and swallowability, excipients, and food effects. (Intl J Pharmaceutics 2018, 2, 530-535; Intl J Pharmaceutics 2018, 2, 563-569; Intl J Pharmaceutics 2018, 2, 570-581).

IMPACT

Through this workshop, the Drug Product Pediatric Working Group catalyzed cross-sector dialogue and laid the foundation for future collaboration on pediatric drug development challenges. This workshop and its related publications – prepared with regulatory representatives and academics – demonstrated IQ's ability to work effectively with key external stakeholders, and led to ongoing collaboration between the FDA and IQ. Since the workshop, several FDA representatives have become standing members of the Working Group. In October 2017 and May 2018, Working Group members participated in additional meetings with FDA scientists to share progress and further align on future priorities. It is hoped that this collaboration will continue far into the future. This workshop has also provided an example for multi-sector collaboration on other topics. The workshop has been recognized as a highly effective approach for coordinating multi-stakeholder engagement on pharmaceutical development topics, and this approach has since been replicated by other working groups.

1. Workshop sessions included: Overview of Pediatric Formulations and Key Considerations; Age-Appropriate Formulations – Swallowability; Age-Appropriate Formulations – Palatability; Use of Excipients in Pediatric Formulations - Safety Considerations; Understanding of Food Effect for Pediatric Formulations Co-Administered with Food; and Biopharmaceutical Considerations.