

Thank you

abbvie

Lilly



Bristol-Myers Squibb

Pediatric Formulation Development: Challenges of Today and Strategies for Tomorrow



CERSI
University of Maryland

Meeting Objectives

- Identify/discuss key barriers that inhibit development of pediatric formulations
 - Via a combination lectures and group discussion
- Gather up your opinions on key barriers
- Put results together for publication
- Develop a strategy for addressing these key barriers
 - Ideally using the combined resources of academics, industry and regulatory bodies
- Network
- Share ideas and meet with colleagues

Four Key Tracks

- Formulation:
 - Formulation Breakout 1: Excipients
 - Formulation Breakout 2: Acceptability
 - Formulation Breakout 3: Devices
- Analytical
 - Analytical Breakout 1: Mini-tablets
 - Analytical Breakout 2: Dosing Vehicles
- Clinical
 - Clinical Breakout 1: Pharmacokinetics
 - Clinical Breakout 2: Study Design
 - Clinical Breakout 3: Biostudies to Support Formulation
- Regulatory and industry feedback
 - Regulatory-Industry Breakout 1: Regulatory Lessons Learned
 - Regulatory-Industry breakout 2: Future Landscape

Formulation Breakout Session

June 18th, 2019

Participant Name	
Group #	

Topic:
Thoughts & Ideas:

Topic:
Thoughts & Ideas:

Topic:
Thoughts & Ideas:

Breakout Session Schedule

Formulations Breakout Sessions

Time	Group 1 & 2 Room N306	Group 3 & 4 Room N310	Group 5 & 6 Room N314
9:45 a.m. - 10:30 a.m	Breakout 1: Excipients	Breakout 3: Devices	Breakout 2: Acceptability
10:45 a.m. - 11:30 a.m	Breakout 2: Acceptability	Break Out 1: Excipients	Breakout 3: Devices
11:30 a.m. - 12:15 p.m	Breakout 3: Devices	Breakout 2: Acceptability	Breakout 1: Excipients

Meeting highlights

- 12:15 photo after breakout session
- 12:20 Lunch in Atrium
- Posters session
- 5:45 Reception in Atrium right after handing in your breakout form

Acknowledgments

- IQ Pediatric Consortium
- Ann Anonsen
- CERSI support from the FDA
- Speakers and moderators



Recent application: Topical Drug Development– Evolution of Science and Regulatory Policy

July 29-30, 2019

Pharmacy Hall in Baltimore

www.pharmacy.umaryland.edu/topical