

Pediatric Formulation Development

Opportunities from an Industry Perspective

M-CERSI Workshop

Challenges and Strategies to Facilitate Formulation Development of Pediatric Drug Products

June 8th and 9th, 2016

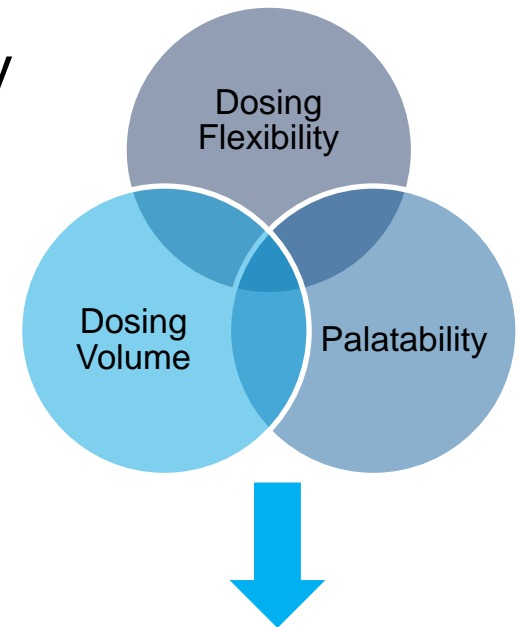
College Park, MD

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The Drug Product Challenge

One size does NOT (usually) fit all

- ◆ Safety
 - Stability, Excipients, Dosing Accuracy
- ◆ Performance
 - Efficacy and In-Vivo Performance
- ◆ Functionality in Use
 - Dosing and Administration Flexibility
- ◆ Acceptability
 - Palatability and Swallowability
- ◆ Add your challenge here....
 - And share this afternoon



Tradeoffs and Compromise

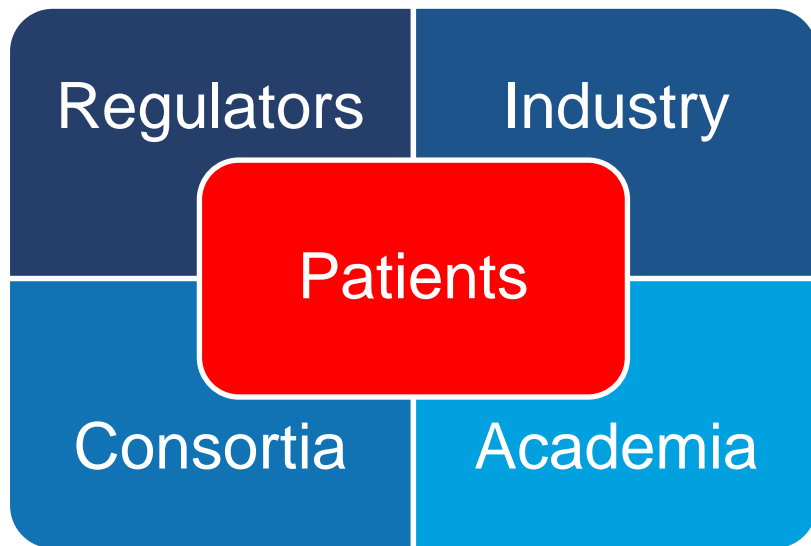
Industry's Reality

- ◆ Pharmaceutical Companies cannot (and do not want to) address these challenges independently
 - Variability in experience in developing for pediatrics
 - Access to the proper capabilities
 - Business constraints
 - Uncertain and evolving expectations and criteria
- ◆ These realities slow the progress we are making



The GOAL - Make the most progress*FASTEST*.....for Children

Cooperation + Collaboration = Synergy



- ◆ Common Tools
- ◆ Greater Confidence
- ◆ Faster Development
- ◆ Better Products
- ◆ Greater Consistency
- ◆ Improved Outcomes

- ◆ Increased Alignment
- ◆ Clarified Expectations
- ◆ Continuous Improvement

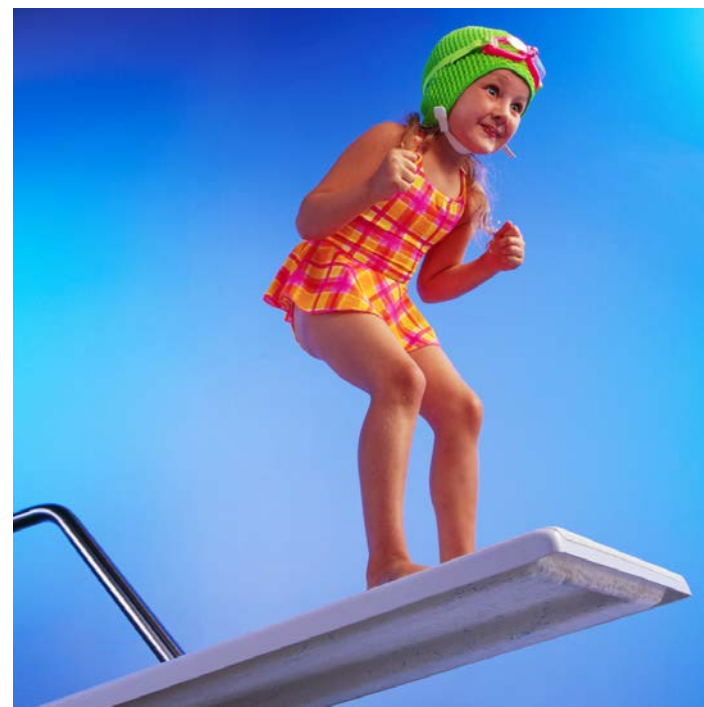
Reaching the Goal

- ◆ Industry and Pre-Competitive Collaborations
 - Shared Learning, Best Practices, Common Approaches
- ◆ Regulatory Agencies are Key Influencers
 - Risk Based Strategic Approaches
 - “Defining” Criteria
- ◆ Academia and Basic Research
 - Laying the Foundation
- ◆ Creating a shared vision for the future
 - Building relationships and trust while respecting our individual responsibilities and objectives
- ◆ Inclusion to create “Critical Mass”

A Springboard to Action

- ◆ Your active engagement in the workshop will enable creation of a shared vision
- ◆ Creating a roadmap to enable development of better pediatric formulations
- ◆ Tangible next steps in areas of greatest opportunity

The Patient is the Focal Point





Thank You!

Coming together is a Beginning

Keeping together is Progress

Working together is Success

Henry Ford