

# Regulatory and Industry: Break-Out 2 - QUESTIONS

## 1. Globalization & Harmonization Beyond US and EU

- a) If you develop pediatric products for *global* markets, what regulatory guidance do you follow?
- b) Any examples where following US/EU guidance was insufficient to get approval in a given country? What were the consequences?

## 2. Patient-Centric Design for the Formulation Scientist – The Right Product for the Patient?

- a) How can formulation scientists most effectively interact with patients, parents, caregivers?
- b) Are liquid formulations still relevant considering the trend to solids/multi-particulates? Preferences for single-use vs multi-dose products?
- c) How to address formulation development for neonates? What are the preferred dosage forms?
- d) Are we moving towards individualized pediatric medicines, e.g. produced locally by 3D printing?
- e) Is extemporaneous drug preparation a good approach for pediatrics?
- f) Are there new dosage forms/delivery concepts that pediatric patients could benefit from and we should be aware of?

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## **3. Emergence of New Partners Developing Pediatric Products**

- a) Philanthropic organizations are getting into pediatric product development. Are you aware of this, do you have examples to share?
- b) In what ways can industry and regulatory agencies collaborate with those new partners?

## **4. Big Data, Artificial Intelligence & Machine Learning for Pediatrics**

- a) Will this change how pediatric products are being developed and prescribed/given to patients?
- b) Is this the right time for us to develop an AI strategy?

# Regulatory and Industry: Break-Out 2 - READING

## Globalization:

- WHO pre-qualification process: <https://extranet.who.int/prequal/information/manufacturers>
- WHO: Paediatric Development Tool Kit (anti-HIV), Module 5: Acceptability: [https://globalhealthtrainingcentre.tghn.org/site\\_media/media/medialibrary/2018/07/WHO\\_Research\\_Toolkit\\_Module\\_5.pdf](https://globalhealthtrainingcentre.tghn.org/site_media/media/medialibrary/2018/07/WHO_Research_Toolkit_Module_5.pdf)

## New Partners:

- Bill & Melinda Gates Medical Research Institute: focus on access and affordability (CMC): [www.gatesmri.org](http://www.gatesmri.org)
- TB Alliance (tuberculosis): [www.tballiance.org](http://www.tballiance.org)
- Schistosomiasis: Pediatric Praziquantel Consortium [www.pediatricpraziquantelconsortium.org](http://www.pediatricpraziquantelconsortium.org)

## Artificial Intelligence:

- Looking for input from workshop attendees!