MOCK-TEAM WORKSHOP: EXTRAPOLATION IN PEDIATRIC TYPE 2 DIABETES

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What we heard…

- Extrapolation of adult efficacy data to inform the effectiveness of a product in pediatric patients:
  - multi-disciplinary exercise
  - requires understanding of disease pathophysiology of disease in adults and children and potential differences in response

- Available knowledge around similarities and differences between childhood and adult type 2 diabetes was discussed.
- Barriers to study execution in this population including the small number of available study participants, study design elements, limited research sites, and a large number of trials competing for patients were discussed.
- Innovative strategies including Bayesian methodologies, multi-agent protocols, leveraging RWD, use of QSP, alternative biomarkers etc. were explored.
- The need for better research and infrastructure capabilities as well as harmonization of requirements between regulatory agencies were mentioned.

- Further collaboration between industry, academia, advocacy groups, and regulators was suggested to enable more efficient drug development in youth with type 2 diabetes.

Acknowledgment

- Facilitator: Larry Lesko
- Panelists: Lynne Yao, Philip Zeitler, Jan Marquard, Jeffrey Barrett, Margaret Gamalo-Siebers, Lisa Yanoff, Cecile Ollivier and Janina Karres
- Members of the IQ consortium pediatric working group: Sebastian Haertter, Amy Cheung and Christina Bucci-Rechtweg, Dionna Green
- FDA Commissioner's fellow: Ramy Abdelrahman
- ASCPT meeting planning committee

Thank you!