Advances in the Science to Assess Quality Factors for Infant Formulas in United States

July 9-10, 2024

The National Academies' Keck Center

Washington, DC

The goal of this workshop is to gather information on current global perspectives on the rationale for use of protein quality assessment measures, the applicability of animal model research and challenges of assessing protein quality using infant growth in clinical studies for the purpose of approving new infant formulas for market.

Objectives:

- Provide a critical review of the state of the science on current methods for assessment of protein quality and their use/limitations as measures of protein quality of infant formula.
- Explore the approaches considered by other countries in establishing regulations for protein quality in infant formula.
- Obtain a global perspective of the variation in requirements for the conduct of clinical trials in infants for the purpose of regulatory approval locally/internationally and the challenges experienced.

Tuesday, July 9, 2024

Open Session

8:45 am	**Welcome and Chair's Statement** *Stephanie Atkinson, Committee Chair*
	Session 1: Models for Assessment of Protein Quality in Infant Formula *Moderated by: Rajavel Elango*
9:00	**Critical Analysis of PER Method to Assess Protein Quality in Infant Formula** *Robert Burns, PhD, Indiana University Bloomington*
9:20	**PDCAAS and DIAAS as an Assessment of Amino Acid Score and Use of Human Milk Pattern as a Reference** *Paul Moughan, PhD, Massey University, New Zealand*
9:40	**Q&A**
10:00	**Models of Ileal Digestion and Amino Acid Composition of Breast Milk in Protein Quality Studies** *Daniel Tomé, PhD, International Milk Genomics Consortium, Paris, France*
10:30	**Q&A**
10:45	**Break**

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11:00	**Session 2: Global Perspectives on Guidance for Measures and Regulation of Protein Quality in Infant Formula – Panel Discussion** *Moderated by: John C. Wallingford*
11:00	**Perspectives from the European Union** *Brian Kineman, Regulatory Affairs, Dannone*
	Perspectives from Multinational Corporations *Robert DiGregorio, DO, Harmony Baby Nutrition*
	Perspectives from the United States *Russell Merritt, MD, PhD, Division of Gastroenterology, Hepatology and Nutrition, University of Southern California, Los Angeles*
11:30	**Questions and Discussion**
12:00 pm	**Adjourn Open Session**

Closed Session

1:00 pm	**Start Closed Session**
4:30 pm	**Adjourn Closed Session**

Wednesday, July 10, 2024

Open Session

8:30 am	**Welcome and Chair's Statement** *Stephanie Atkinson, Committee Chair*
Session 3:	**Challenges in the Conduct and Interpretation of Clinical Trials for Regulatory Approval for a New Infant Formula** *Moderated by: Steven Abrams*
8:40	**Body Composition as a Measure of Quality of Growth in Infants** *Shane Norris, PhD, MASSAf, FAAS, University of Southampton, UK*
9:00	**Challenges in Conduct of Clinical Trials Assessing Quality Factors for Infant Formula: Methods, Cost and Options** *Michael B Montalto, PhD, Principal, Montalto Consulting Services in Health Sciences*
9:20	**Optimizing Clinical Trial Design for Studies in Infants** *Deborah O'Connor, PhD, Department of Nutritional Sciences, University of Toronto*
9:40	**Q&A**
10:10	**Closing Remarks** *Stephanie Atkinson, Committee Chair*
10:30	**Adjourn Open Session**

Closed Session

11:00	**Start Closed Session**
1:00 pm	**Adjourn Meeting**