



## “I’m Eating” Study

During February of 2017 Focus Pointe Global (FPG) partnered with Northwestern University Feinberg School of Medicine to facilitate a research study to determine how 5 to 12 month old infants would tolerate a nutritional supplement that introduced a proprietary blend of proteins from common allergenic foods into their diet.

Participants kept an online diary and completed an online questionnaire at the end of both 28-day usage periods.

Titled “I’m Eating,” research partners also included the Institute for Public Health and Medicine, and the Center for Healthcare Studies.

**FPG recruited 700 infants/parents in four weeks, leveraging its national panel of research participants.**

### Focus Pointe Global project facilitation included:

- Designed all study documents and worked with the IRB for study and document approval
- Designed and executed a retention program to keep participants engaged in the process
- Executed the project online, reducing the burden of travel time for parents
- Mailed the test product to participants’ homes
- Managed participation (daily diary and end of period online questionnaires) and compliance, including distribution of stipends
- Collected in-home bio-specimens (blood samples) from babies through a mobile Phlebotomy service provider
- Managed \$1 million+ budget

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### Phase 2 is currently underway

After the successful completion of the study, FPG was asked to extend the research for a longer-term understanding of the impact of future outcomes of children’s allergies. When asked if they wished to continue to participate for an additional period of time (one year), 85% of the parents accepted the offer, agreeing to continue using the supplement

for 12 months. FPG ships the product to participants each month. Participants no longer complete daily diaries but do monthly surveys covering any potential adverse event experiences and monthly product usage questions. We continue to have zero adverse events requiring pediatrician follow-up related to the supplement.

*This study was conducted by Northwestern University Feinberg School of Medicine and Focus Pointe Global*

Northwestern University Feinberg School of Medicine and Focus Pointe Global

## “I’m Eating” Study

*The safety and tolerability of a proprietary blend of proteins from common allergenic foods was investigated in a randomized, blinded, placebo-controlled nationwide study in more than 700 healthy infants.*



### Research Objectives

- Evaluate the safety and acceptability of a blend of 16 commonly allergenic proteins (peanut, soy, almond, cashew, hazelnut, pecan, pistachio, walnut, wheat, oat, milk, egg, cod, shrimp, salmon, sesame), combined with 400IU of Vitamin D into a food supplement powder
- Show that the food supplement is well tolerated by infants, particularly in a real-life, at-home setting
- Learn what aspects of the food supplement are more or less attractive to infants and parents/caregivers

### Methods

- Population: Over 700 healthy, full-term infants, 5-12 months of age at enrollment, without self-reported severe eczema, food allergy, or hospitalization
- Sample: Recruited from a national, web-enabled research panel (Focus Pointe Global)
- Protocol: 28-day placebo period for all subjects followed by a 28-day randomized to food supplement or placebo period by:
  - ▶ Adding one packet (approx. 1 tbsp.) of the placebo or food supplement powder to a feeding once daily
  - ▶ Observing their infant for 2 hours after the feeding
  - ▶ Recording any allergic type reaction, including anaphylaxis, occurring within 2 hours after ingestion in an online daily diary
  - ▶ Recording any other symptoms (e.g., vomiting, diarrhea).

### Top-Level Results

- Of the 8,803 food supplement ingestions, no infant had any allergic reaction within 2 hours of ingestion of the food supplement, and no infant received any medical care or received any prescribed medication for any reaction.
- Of the 8,803 food supplement and 24,899 placebo ingestions, 0.84% and 1.66%, respectively, resulted in a reported symptom (e.g., cough, diarrhea).
- There was no statistical difference between the proportion of children with reported symptoms or reactions in the food supplement versus placebo group.

### Conclusions

- This study strongly suggests that the food supplement is safe and feasible for infants 5-12 months of age.
- Future studies are underway to assess the effect of the food supplement on immunologic responses to the allergenic proteins and on the longer-term incidence of food allergy.