**Supplemental Digital Content (SDC) for Puccio et al.**

**SDC 2.** Additional information on statistical analyses

**Anthropometric results** were summarized using descriptive statistics by visit, sex, and formula group. Each outcome was analyzed using a mixed-effect model repeated measures (MMRM) model including baseline anthropometric assessments as a covariate and sex, center, visit, treatment, sex x visit, and sex x treatment as fixed effects. Results were presented as LS means and the difference between LS means, with associated 2-sided 95% confidence intervals (CIs) and *P*-values for each post-baseline visit.

Results for **digestive tolerance** (flatulence, spitting-up, vomiting) and **behavioral patterns** (restless and irritable, colic, night awakenings) were categorized by frequency as occurring “never,” “sometimes” and “often” in the 3 days prior to each visit; results were summarized using frequency counts and percentages by visit and formula group. The Cochran-Mantel-Haenszel test (CMH) test was used to evaluate the linear associations between the digestive tolerance and behavioral pattern outcomes and type of formula in the full study population and in subgroups by type of delivery.

**Stool consistency** was measured using the 7-point Bristol scale reflecting the 3 days prior to each visit. The CMH test was used to evaluate the linear association between formula and stool consistency. Stool consistency was also analyzed using a two-sample independent student’s t-test by visit and delivery method. **Number of stools per 24 hours** were recorded in the 3 days prior to each visit; the negative binomial generalized linear model was used to evaluate the total number of stools at each visit with treatment, sex and delivery method as predictors. The exponent of beta parameter, corresponding two-sided 95% CIs, and *P*-values were reported.

**Morbidity outcomes** (reported AEs, AE clusters, and reported concomitant medications) were analyzed using the Fisher’s exact test and reported as odds ratios with 95% CIs and *P*-values; analyses were done in the full study population and in subgroups by type of delivery.