Your innovation experts in natural health products

INNOVATION IN INFANT NUTRITION

Meeting the challenges for clinical research on a vulnerable age group

No doubt that breastmilk is the best nutrition for infants because it is perfectly adapted to meet the specific and dynamic needs of the growing human organism, which is why health authorities worldwide recommend exclusive breastfeeding for 4-6 months.

If breast feeding is not possible, infant formulas may be the exclusive nutrition for this vulnerable age group. Therefore, the composition and information requirements of infant and follow-on formulas are highly regulated. In addition, ingredients and food additives can only be used for the manufacture of infant formulas if they are authorized for this age group.

Manufacturers of infant nutrition are committed to improving their formulas and to mimicking the composition of breastmilk as much as technically possible, e.g. by adding human milk oligosaccharides, specific milk proteins, or non-bovine dairy alternatives. Innovations in the manufacture of infant and follow-on formulas require that the suitability and safety of the new formula for infants is demonstrated, when necessary, by appropriate studies.

A clinical evaluation provides a comprehensive assessment of all safety and tolerability data related to the product as well as to comparable and equivalent products.

If literature data is not sufficient, we will support you with generating product-specific clinical data. Our Clinical Research team has extensive experience in clinical trials for infant nutrition.

Supported by our regulatory consulting team, we will be your reliable and committed partner, supporting you on your way to successfully bring the innovative infant nutrition food products to the market.

OUR SERVICES INCLUDE

- Planning, concept development, coordination, and performance of infant formula studies in collaboration with a carefully selected and experienced investigator network.
- Writing of study reports and publications
- Notification of the formula to national authorities
- Planning and compilation of applications for the pre-market authorization for novel food ingredients or food additives

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AT A&R, WE HAVE CONDUCTED SEVERAL GROWTH AND TOLERANCE STUDIES

- With more than 300 newborns (0 to 14 days after birth old) per study including complex microbiota (sub)-studies
- In different EU countries.
- Thanks to the the carefully selected and experienced investigator network that we collaborate with, including hospitals and a pediatric network, we were able to manage timely recruitment (recruitment period: 6-12 months)
- We developed a sophisticated logistics tool to manage the challenges of investigational product logistics, ensuring a smooth supply for all involved parties.
- Our regulatory team has developed a deep understanding of infant nutrition regulations (FDA, EFSA) and can facilitate a smooth market access.

CHALLENGES OF CLINICAL STUDIES WITH INFANTS

- Growth and tolerance studies are usually performed with subjects not older than 14 days at enrollment. A large sample size is necessary to compensate for the expected high drop-out rates, which can be caused e.g. by violation of study requirements with respect to the test formula or breast feeding, and the very tight visit windows during the whole study period. Compliance to a clinical study protocol in a clinical study is very challenging for young mothers caring for a newborn.
- Having to supply investigational product for a study duration of 4-6 months means storing large amounts of investigational product at the study sites. As storage space usually is limited, this requires highly sophisticated logistics.

In Europe, a&r is your partner of choice for infant nutrition with regulatory expertise and experience in multisite, multinational growth and tolerance studies.

CONTACT US

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