



TARGETING IMMUNITY

Challenges and opportunities

To address the increased demand for evidence-based immune health products and supplements, brands in the natural healthcare space need to maintain consumer trust through a combination of regulatory compliance, transparency, and scientifically substantiated solutions. Also, and to accelerate innovation in this field, companies must understand the role ingredients have in supporting immune health.

Bringing together a unique combination of clinical and regulatory expertise in natural health and with a future-oriented mindset, our team is ready to deliver tailor-made innovative solutions to maximize the value of your immune health benefits solution.

OUR SERVICES INCLUDE

Regulatory compliance

- Competent and customized support at any stage of the product development from the initial idea to launch
- Regulatory evaluation of concepts, products, and claims
- Country-specific assessment of the marketability as a food ingredient with regards to the demarcation criteria between food, drug, and medical device
- Label check for each target market
- Support in preparing the required documentation for different product categories
- Advice on possibilities for data protection
- Maximize claims strategy to build on consumer awareness and knowledge (i.e. marketing claims, generic claims, pending botanical claims, health and nutrition claims)
- Strategic innovation support from scientific analyses for early-stage development to



Clinical Research

- From small consumer acceptance studies to multinational, multi-site double-blind RCTs, including digital and decentralized solutions
- Assessment and evaluation of study design, protocols, and reports
- Planning of clinical studies to substantiate intended claims
- A broad network of accredited laboratories offering relevant markers analyses

The immunity ingredient space ranges from key vitamins and minerals to botanicals, probiotics, fermented foods, and to pre-biotics. The increasing evidence around the microbiome and its role in immune health is also a key aspect. Consumers are increasingly aware of the importance of microbiome health not only for digestion but also for several health outcomes, including immune system support. Hence, supporting the immune system can be done in a lot of ways.

We have profound know-how and experience with clinical studies with natural products (including food and medical devices) in the area of immune health, such as botanicals, probiotics, fibers, or vitamins. This experience includes various study designs ranging from short-term studies investigating effects on markers of immune function up to classical large-scale "common cold" RCTs evaluating incidence/severity of infections.

In order to boost product innovation, a&r provides services and expertise in market analysis, product development, regulations, and claim substantiation by state-of-the-art clinical research.

CONTACT US

DR. ANNEGRET NIELSEN

Senior Consultant
anielsen@a-r.com



**analyze & realize
GmbH**

Weißenseerweg 111
10369 Berlin – Germany

www.a-r.com