



FOOD CLINICAL RESEARCH SERVICES

Within the current regulatory framework it is important to demonstrate clinically relevant effects of your products and ingredients.

“Substantiating these health benefits is at the heart of what we do.”

It will help you to stay ahead of competition and to select the right ingredients at an earlier stage.

Food Clinical Research Services:

With nearly 70 years of history in food research, we bring you the expert resources to help you in plan, design and conduct your food clinical trials. We have developed a systematic approach to bridge the gap between preclinical in vitro assays and clinical trials in humans. This results in a faster and more effective selection process of the right ingredient. Our approach: optimize design to maximize outcomes.

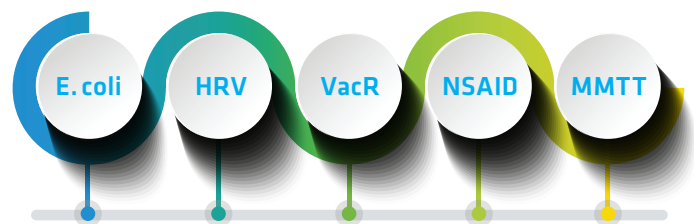


- Scientific and regulatory consultancy: building a convincing health benefit dossier
- In vitro models related to clinical outcomes: in vitro elucidation of the mode of action linked to in vivo biomarker assessment
- Unique human challenge models capabilities: early human data for data driven decisions
- Efficient project management and trial execution: single point of contact approach
- Data analysis and interpretation: statistical analysis and scientific report writing

HUMAN CHALLENGE MODELS: DATA DRIVEN DECISIONS

To make decisions on your most promising ingredient, to determine the best way-forward in the development of your product or to demonstrate health benefits, we use human challenge models.

The models



The benefits

- Early human data on resistance to infection, immune response, gut barrier and metabolic health
- Stress resilience is a more sensitive marker of health than steady state markers
- Fewer subjects and shorter timelines
- Aligned with EFSA requirements for scientific substantiation of gut and immune health benefits
- High correlation between clinical outcome parameters, subject symptom scores and e.g. markers of infection

Clinical trial	# subjects since 2012 (incl. planned)	Client base (EU/NA/Asia)
E.coli challenge (<i>E.coli</i>)	398	EU (7), NA (2)
Rhinovirus challenge (HRV)	200	EU (2), NA (1)
Cholera vaccination (VacR)	200	EU (2), Asia (1)
Immune response, inflammation (with MMTT*)	70	EU (2)
Digestion, absorption	38	EU (3)
Gut comfort	120	NA (1)
Using Intellicap®	10	EU (1)

* MMTT = Mixed Meal Tolerance Test

**INNOVATING
TOGETHER**

FOR MORE INFORMATION:

Meet our experts in bacteria, proteins and processing on www.nizo.com/our-team. Or call +31 318 659 511 or mail to info@nizo.com

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