

Clinical Trials

Clinical trials are now an essential component for foods and food constituents in order to increase support for health claims. In most jurisdictions, animal and *in vitro* studies, on their own, are insufficient for the scientific substantiation of health claims. Instead, there is a requirement for data from well-controlled human intervention studies.





Intertek can provide support for your clinical trials from start to finish, including study design, placement, management, and manuscript writing.

Your Challenge

Many factors must be considered in the design of a clinical study to ensure that the objectives of the study will be met and to ensure that the results collected will be relevant to the proposed health claim. Also, Good Clinical Practice (GCP) guidelines, which are an international ethical

and scientific quality standard for designing, conducting, recording, and reporting studies that involve human subjects, should be followed to ensure the credibility of clinical study data and the protection of study subjects.

Our Solutions

Intertek Cantox offers the regulatory and scientific expertise necessary to provide reliable advice in the area of clinical trials. Our services include:

- Preparation or review of clinical trial protocols to ensure compliance with GCP guidelines and that due consideration has been given to key factors that could affect the outcome of the study;
- Ensuring that the study outcomes meet the regulatory requirements for health claim substantiation;
- Preparation of other essential documents, including Investigator's Brochures, Informed Consent Forms, and Case Report Forms;
- Assistance with clinical study placement;
- Monitoring of clinical studies, either according to Intertek Cantox standard operating procedures (SOPs) or to the Sponsor's SOPs; and
- Manuscript preparation and publication.

Offering Expert Scientific and Regulatory Consulting Services From:

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About Intertek Cantox

Intertek Cantox has been successfully delivering regulatory and scientific consulting services for over 25 years. We realize the high cost and time commitments of clinical studies, and the influence that the study results can have on your company's marketing initiatives. Intertek Cantox's dedicated team of scientists understand the elements which characterize a methodologically robust clinical study. With our guidance, you can rest assured that your clinical study will meet the high scientific standards expected in many jurisdictions globally.

The Intertek Advantage

Intertek is a leading provider of quality and safety solutions serving a wide range of industries around the world. From auditing and inspection, to testing, quality assurance and certification, Intertek people are dedicated to adding value to customers' products and processes, supporting their success in the global marketplace. With a network of more than 1,000 laboratories and offices and over 33,000 people in more than 100 countries, Intertek helps its clients to meet end users' expectations across increasingly diverse quality, health, environmental, safety and social accountability aspects in virtually any market around the world.

To see a complete list of our services visit: www.intertek.com/food/consulting/

Additional services can be found at: www.intertek.com/cantox

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