CLINICAL TRIALS

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

Background

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.

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, should be followed to ensure the credibility of clinical study data and the protection of study subjects.

Our Solutions

Intertek Health, Environmental & Regulatory Services (HERS) offers the 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;
- 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 standard operating procedures (SOPs) or to the Sponsor's SOPs; and
- Manuscript preparation and publication.

The Intertek Advantage

Intertek's scientific & regulatory consultants have been successfully delivering expert advice for over 30 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 HERS has a dedicated team of scientists that 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.

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices and over 44,000 people in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

Total Quality. Assured.

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