

Danaher Corporation
Clinical Trial Conduct and Transparency Policy

Background

Clinical research in healthcare science is a key component in the foundation of evidence generation for new product development. Well-designed clinical trials in human research subjects are conducted to evaluate the efficacy and safety of medical devices. Clinical trial data are relied upon by our associates, healthcare professionals and regulators in bringing effective new products to market. Good research design, however, is not sufficient to ensure that the products we develop meet critical needs for the patients we serve. Danaher Corporation (including its subsidiaries, “Danaher”) recognizes that the utility of any product we develop lives in how a medical device is experienced across the product’s life cycle and the contribution it makes to improving the health and well-being of patient populations. As a result, Danaher is committed to the highest legal and ethical standards in clinical trial management and public disclosure of clinical trial results, including full transparency in research methods, evidence generated, the provider experience and health outcomes that inform our new product development and product improvement efforts.

Guiding Principles

Our shared purpose, “Helping Realize Life’s Potential” means that at Danaher as a science and innovation company, our people, processes, culture, and products are developed with an unwavering goal of maximizing the potential for the people we serve, including our patients, providers, employees, customers, and stakeholders. Our shared purpose is more than words. It bonds us together and aligns us to what we must do every day to deliver on these commitments.

In the conduct of clinical trials, this begins with the careful selection, training, and ongoing development of a team of research professionals committed to the highest standards in clinical trial design, management, and ethics and to a virtuous cycle of continuous quality improvement. Good research demands rigorous adherence to the ethical principles of respect for persons, beneficence, and justice.

The patient and healthcare provider sits at the nexus of everything we do in the conduct of clinical trials. Products and studies are designed around generating the right product at the right time for the right patient population as we work to realize the potential for improved patient care and better health outcomes.

Our customers are a critical source of an ongoing flow of information and data about how our medical devices are experienced in patient care settings across the product life cycle. As a result, we honor the alliances we form with them to identify, design, study and produce innovative and valuable new solutions for the populations we serve.

Relevance

As a leader in science and technology innovation, the products provided by Danaher Corporation subsidiaries contribute to the health and well-being of people around the world. Our products and services are used every day by our customers, healthcare professionals, doctors, and patients.

Danaher subsidiaries maintain an environment of innovative product development. We are committed to conducting all phases of research and development to the highest ethical standard while advancing products that serve medical needs. In support of product development and improvement, Danaher subsidiaries sponsor and support clinical trials in countries around the world to ensure a wide diversity among populations participating in research. We are committed to adhering to principles and standards that ensure clinical trials supported by Danaher subsidiaries are conducted professionally, ethically, and responsibly.

Our Position

Preclinical testing and clinical studies are important to the research and development activities required for medical device development. The data obtained provides important information that guides, directs, and informs our development activities by helping us better understand the potential risks and the benefits of our products. Clinical studies also provide critical information needed to seek and obtain clearance and authorization from government health authorities in order to bring new and improved products to the people who need them.

It is our ethical and moral duty to conduct clinical trials in accordance with the highest ethical, professional, regulatory, and

quality standards. As a result, Danaher is committed to following international requirements, guidelines, and principles on the ethical treatment and management of research participants enrolled in clinical trials. These requirements include ensuring informed consent, respect for personal and autonomous decision making, ongoing Institutional Review Board and Ethics Committee review, transparent disclosure of research results, and designing studies to the highest scientific standards to deliver credible research evidence and protect patient and user health and safety.

External Ethical Foundation:

Danaher policy requires our medical devices to adhere to all applicable statutes, regulations, and laws for the markets in which they are used. Clear guidelines for the ethical treatment of research participants for Danaher’s subsidiaries are provided by the Declaration of Helsinki and the Belmont Report’s guiding principles of respect for persons, beneficence, and justice. We are committed to adherence to the scientific quality standard for designing, conducting, recording, and reporting on clinical trials that involve the participation of human subjects as outlined in the International Conference on Harmonisation E6 Good Clinical Practice Guideline.

Clinical Trial Safety:

Our operating companies are required to have formal, documented processes for our R&D teams to evaluate and enhance the risk profile of our products at each stage (tollgate) of the development process. This process includes various, trained professionals and teams of safety, risk management and product experts that review and approve the product development plans to ensure that our products are safe and effective and benefit the people who will ultimately use them. Our product development and regulatory teams submit our development information to the relevant health authorities around the globe including product safety and clinical performance data that demonstrate the safety and efficacy of our medical devices and products. We collaborate with the regulatory authorities as they seek to ensure the benefits of our products outweigh the potential risks in order to properly label and market our products.

Clinical trial and new product development safety is also required to be evaluated and continuously monitored by a multidisciplinary team of health care professionals and clinical scientists. Company medical officers are required to be engaged in new product development and monitoring throughout the product life cycle beginning with developing the overarching evidence generation strategy, to protocol design consultation, to research adverse event analysis, and in evaluating customer feedback on product safety and performance post launch. In addition, when indicated, a team of independent medical experts may be assembled to create clinical trial data and outcomes adjudication committees, ensuring thorough medical analysis of research results.

Clinical Trial Auditing and Monitoring:

Our operating companies are required to utilize highly trained professionals to perform clinical quality system audits related to our clinical trials in accordance with Good Clinical Practices (GCPs). These audits are part of a broad clinical compliance function focused on patient safety, regulatory and ethics compliance, adherence to company quality system requirements, protocol and process compliance, and data integrity. All sponsored clinical trials are required to be monitored on an ongoing and repeated basis to ensure study integrity and the ongoing suitability and adequacy of clinical site performance. In addition, monitoring is required to be conducted to identify issues in study execution that may require additional training or design modification of the clinical trial protocol.

Participation in Clinical Trials:

Danaher’s subsidiaries rely on human volunteers for our clinical trials. By participating in our trials, participants may gain access to new products and treatments before they are widely available and thus contributing to further medical research. Specialized and trained clinical investigators are used in all clinical studies by all our operating companies to help ensure every participant is fully informed of the potential benefits and risks of the medical device before participating. Our procedures are required to be designed to:

- protect the confidentiality of participants’ private health and personal information,
- protect vulnerable populations,
- ensure study participants know what to expect and are able to make an informed decision about study participation,
- ensure study participants are provided with relevant information about the treatment or diagnostic option they are considering, and about available alternative therapeutic options, and
- ensure participants have time to discuss and consider whether to participate in the trial.

Danaher policy requires strict adherence to the guidelines for Good Clinical Practice of the International Conference on Harmonisation and seeks to ensure all information provided to clinical trial participants is first reviewed by an external

institutional review boards (IRBs)/independent ethics committees (IECs). Patients can share this information with their families and their physicians. A detailed, written informed consent (IC) must be signed by all participants before they are processed, screened, and enrolled in a clinical trial.

Registration and Reporting:

All Danaher subsidiaries are required to ensure that the medical community has access to comprehensive information about our products. Patients and healthcare providers can benefit from knowing about clinical trials that are open for enrollment and it is part of our obligation to those who may use our products.

We inform patients and healthcare providers participating in clinical research activities through various means including:

- registering or publicly announcing clinical trials in accordance with journal, institutional, IRB and/or other legal requirements
- clearly describing the clinical trial planned, including purpose, procedures, and goals
- disclosing the name and contact information of the sponsor of the clinical trial and any compensation or costs associated with research participation
- disclosing research methods and requirements for study participants including research related activities, time commitments, and any sponsor-specific study requirements and expectations
- disclosing the expected timeline for conducting and completing the planned clinical studies
- providing information to trial participants and researchers about the potential risks and benefits associated with participating in a study
- disclosing any alternative diagnostic or treatment options that may be available outside of the clinical trial
- ensuring that the potential research participant understands that enrollment in the clinical trial is voluntary
- appropriately publishing the results of clinical trials.

Clinical trials conducted around the world by our operating companies are listed on the U.S. National Institutes of Health's website (www.clinicaltrials.gov), the European Union Drug Regulating Authorities Clinical Trials (EudraCT) Database, and country-specific and regional registries across the globe, as required. This includes studies that are ongoing as well as those that have been completed as of the posting requirement cut-off. Clinical trials are listed on the website by disease or condition, location, and sponsor. Information on who can participate and how to get information about enrollment is also provided.

We are committed to abiding by established codes of ethics, presenting truthful, complete, and accurate information.

Companies Performing Clinical Work on behalf of Danaher

All work performed on behalf of Danaher by other companies is required to follow the same ethical and legal standards that Danaher and our subsidiaries are required to adhere to. This includes clinical trials conducted by outside investigators which must adhere to our requirements as well as all applicable national and local regulation to ensure the safety of all participants.

Transparency

Danaher endorses transparency of clinical trial results in order to advance medical science for the benefit of all in the execution of our shared purpose to help realize life's potential. This includes various public disclosure activities that could include:

- registration of planned and ongoing research trial activities
- disclosure of clinical trial purpose, goals, and results
- publication of clinical trials results in peer-reviewed journals and/or at scientific or medical conferences

Providing Plain Language Summaries

Danaher believes those who participated in our clinical trials have the option to access information about the study findings in which they contributed. A Plain Language Summary (PLS) presents the key results of a clinical trial in a non-technical manner the general reader can understand. A PLS summarizes the study outcomes and helps participants understand more about the research they have contributed to in English and the local language as required by local law.