Position on the Conduct of Clinical Trials

Background

Clinical trials, sometimes referred to as studies, are conducted to evaluate the efficacy and safety of medicines and medical devices. They are essential to bring new medicines and treatments to patients and their healthcare providers.

Relevance

As the largest and most diverse healthcare company in the world, reaching billions of people each day with our medicines and medical devices, Johnson & Johnson is a leader in healthcare research and development (R&D). Johnson & Johnson sponsors and support clinical trials around the world, allowing for research participants who are representative of the populations impacted by the conditions these new medicines and devices are designed to treat. We recognize the importance of adhering to clear and consistent principles and standards to enable clinical trials supported by Johnson & Johnson to be conducted professionally, ethically, and responsibly.

Guiding Principles

As stated in Our Credo: “We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality.” This serves as a constant guide to our decision-making and reinforces that improving healthcare for the people we serve—patients and customers—must come first as we seek to break new ground with advances in science and technology.

Our Ethical Code for the Conduct of Research and Development provides more specific standards of conduct and behavior for physicians, clinical research scientists and others who are responsible for R&D.

Our Position

Preclinical testing, clinical studies, and observational data play an important role in the R&D of our medicines and medical devices. The data from these sources provide important insights and information that help us understand the potential risks and benefits of investigational products. These studies also provide critical information needed to seek and obtain approval from government health authorities in order to bring new medicines and medical devices to the people who need them. In addition to having an ethical code that guides our R&D activities, our processes follow guidelines on the ethical treatment of trial participants, which include details of our extensive process around ensuring informed consent and protecting their health and safety.

We aim to conduct clinical trials in accordance with the highest ethical, professional, and quality standards. Our approach includes:

External Frameworks: Johnson & Johnson recognizes the importance of external frameworks such as the Declaration of Helsinki and the Belmont Report and works to integrate these principles into our clinical trial planning. In addition, J&J at the request of external coalitions, may contribute to updates of such frameworks in response to evolving patient needs. Our medicines and medical devices are regulated by health authorities globally, and we must adhere to relevant statutes, regulations, and laws.

Clinical trial safety: We have formal processes involving committees of experts who perform governance reviews and provide input on how R&D teams should evaluate and enhance the safety profile of our medicines and medical devices at the development stage. This includes our First-in-Human Committees, which carefully review safety data, study designs and/or launch plans before our investigational medicines and medical devices are used in people; and our Development Committees, which review development plans to ensure our medicines and medical devices w address unmet needs and provide potential benefit to the people who will ultimately use them.

Day-to-day safety reviews and decisions related to safety are made by multidisciplinary safety management teams. Our Medical Safety Councils, which are chaired by the Chief Medical Officer, manage more complex safety assessments and decisions. The Johnson & Johnson Medical Safety Council, chaired by the Johnson & Johnson Chief Medical Officer, advises as needed and sets standards and policies related to medical safety.

Our R&D groups submit to regulatory health authorities across the globe information about our medicines and medical devices that require regulatory review, including results of clinical trials and other documentation describing the safety and efficacy profiles. Regulatory authorities examine these data to establish whether the benefits outweigh the known and potential risks and decide whether to approve medicines or medical devices for use.

Clinical trial safety: We implement systematic compliance and audit systems related to clinical trials. This includes a risk-based annual program of audits conducted globally by a highly specialized and qualified internal audit team. We conduct audits based on Good Clinical Practices (GCPs) with a focus on patient safety, compliance, and data integrity.

Monitoring clinical trials: In accordance with industry standards, including GCPs, all Johnson & Johnson sponsored trials are monitored to ensure the protocol is being adhered to and to safeguard our participants in the studies.

Participating in a clinical trial: Clinical trials rely upon human volunteers. Participants in clinical trials may gain access to new treatments before they are widely available and can help others by contributing to medical research. Before anyone can enroll and participate in a clinical trial sponsored by one of our Jonson & Johnson, the clinical investigators must ensure that the potential study participants are fully informed of the possible benefits and risks of the medicine or medical device. We have procedures in place to inform participants of potential benefits and risks, to protect the confidentiality of their private information, and to protect vulnerable populations. We abide by the guidelines for Good Clinical Practice of the International Conference on Harmonisation. Also, information provided to clinical trial participants is reviewed first by external institutional review boards (IRBs)/ independent ethics committees (IECs).

To ensure that study participants know what to expect and can make an informed decision about whether to participate in a clinical trial they must be given relevant information about the treatment option they are considering and what it could mean for them. Study participants are also informed about potential alternative therapeutic options and can share this information with their families and their physicians. Clinical investigators are also required to give potential study participants time to discuss and consider whether to participate in a specific clinical trial.

If a person decides to participate in a clinical trial sponsored by Johnson & Johnson , they must sign a detailed, written "informed consent" (IC) document and are then evaluated to see if they meet the eligibility requirements before potentially being enrolled in the clinical trial.

Post-trial access

Johnson & Johnson recognizes that participants in clinical trials may not have access to the investigational product once the trial has ended. While steps are being taken to make the product available—such as seeking marketing authorization or reimbursement where applicable, we consider providing continued access to our investigational medicines when the following criteria are met:

- There is an unmet medical need;
- Participant has completed clinical trial requirements;
- Participant is benefitting from the investigational medicine;
- Participant may suffer medical harm if transitioned off the investigational medicine;
- Reasonable clinical alternatives are not available where the participant resides;
- Post-trial access is addressed in our clinical trial protocols for the investigators and in the informed consent for participants.

Registration and reporting: Ensuring that the medical community has access to comprehensive information about our medicines and medical devices requires that clinical trials sponsored by Johnson & Johnson:

- Publicly announce or register clinical trials in accordance with journal and legal requirements; • Disclose timelines for conducting and completing these studies;
- Provide information about the potential risks as well as the potential benefits of participating in the clinical trial with those who are considering study participation; and
- Appropriately publish the results of clinical trials.

Patients and healthcare providers can benefit from knowing about clinical trials that are open for enrollment. We recognize that providing this information is part of our obligation to all who may use our medicines and medical devices.

Clinical trials conducted around the world by our pharmaceutical and medical device companies are listed on the U.S. National Institutes of Health's website (www.clinicaltrials.gov), the European Union Clinical Trials Information System (CTIS) website, 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 publishing data that are scientifically or medically important, and to abiding by established codes of ethics, presenting truthful, complete, and accurate information. We consider factors such as whether the findings suggest a new effect, lack of effect, potential benefit or harm to patients or specific sub-populations, or an alteration of the overall benefit/risk profile of a medicine or medical device in determining whether new information merits publication. Our companies publish research findings in peer-reviewed journals, present at scientific meetings, and comply with registry posting requirements. See also our Position on Clinical Trial Data Transparency.

Clinical work performed by companies on behalf of Johnson & Johnson: This work must follow the same ethical and legal standards that we adhere to internally.

Clinical trials by external investigators: To help advance medicine and science, we support clinical studies by outside investigators, and we carefully evaluate requests for their potential value. In conducting clinical trials, outside investigators must comply with local regulations. They must ensure that the safety of people who participate is respected and protected.

Application

This Position is applicable for all medicine and medical device R&D activities of the Johnson & Johnson Family of Companies, as detailed in our governance materials.

Last updated: April 2026