Position on the Conduct of Clinical Trials

Background

Clinical trials evaluate the efficacy and safety of medicines and medical devices. They are essential steps in bringing effective 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 operating companies sponsor and support clinical trials in more than 40 countries, allowing for wide diversity among populations participating in research. It is important that we adhere to clear and consistent principles and standards to enable clinical trials supported by Johnson & Johnson operating companies 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 products 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:

Adhering to external frameworks: Our operating companies are required to follow the Declaration of Helsinki and the Belmont Report, which set clear guidelines for the ethical treatment of research participants across all borders. We apply principles of Good Participatory Practice Guidelines in our HIV prevention clinical trials. Our medicines and medical devices are regulated by health authorities, 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 at the product development stage. This includes our First-in-Human Committees, which carefully review safety data, study designs and/or launch plans before our products are used in people; and our Development Committees, which review product development plans to ensure that our products address unmet needs and benefit the people who will ultimately use them.

Day-to-day safety reviews and decisions related to product safety are made by multidisciplinary safety management teams. Our business segment Medical Safety Councils, which are chaired by the business segment Chief Medical Officers, 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 required information to regulatory health authorities across the globe for products that require regulatory review, including results of clinical trials and other documentation describing the safety and efficacy profile of our products. Regulatory authorities examine these data to establish whether the benefits of a product outweigh potential risks and decide whether to approve the product for marketing.

Clinical trial audits: 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 focus on patient safety, compliance and data integrity.

Monitoring clinical trials: In accordance with industry standards, including GCPs, all our sponsored trials are being 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 research 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 worldwide operating companies, the clinical investigators must ensure that they are fully informed of the potential benefits and risks of the medicine or device. We have procedures in place to fully 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 study, they must be given relevant information about the treatment option they are considering and what it could mean for them. Study participants are informed also about available alternative therapeutic options. Patients can share this information with their families and their physicians. Clinical investigators are also required to give potential trial 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 one of our operating companies, they must sign a detailed, written "informed consent" (IC) document and are then screened and potentially enrolled in the clinical trial.

Registration and reporting: Ensuring that the medical community has access to comprehensive information about our products requires that our operating companies:

- 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 benefits of participating in the study 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 products.

Clinical trials conducted around the world by our pharmaceutical and medical device 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 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 product 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 operating companies: This work must follow the same ethical and legal standards that we adhere to internally.

Clinical trials by outside 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 investigations, outside investigators must comply with local regulations and must follow our policies. They must ensure that the safety of people who participate is respected and protected.

Application

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

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