

Conducting Clinical Trials

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 doctors.

Johnson & Johnson operating companies sponsor and support clinical trials in more than 40 countries, allowing for wide diversity among populations participating in research. Our operating companies are required to follow the Declaration of Helsinki and the Belmont Report, which set clear guidelines for the ethical treatment of patients across all borders. We apply principles of Good Participatory Practice Guidelines in our HIV prevention clinical trials. We also implement systematic compliance and audit systems related to clinical trials. Our products regulated as pharmaceuticals or devices must adhere to all relevant statutes as well as our policies for registering and reporting clinical studies.

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

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 Harmonization.

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. They are also informed 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 companies, a detailed, written “informed consent” document is signed and the person is 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;
- Appropriately publish the results of clinical trials.

Patients and health care 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 device companies are listed on the U.S. National Institutes of Health’s (NIH) website, www.clinicaltrials.gov. 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 being considered for 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 posting requirements on www.clinicaltrials.gov.

Clinical Trials by Outside Investigators

To help advance medicine and science, we support clinical studies by outside investigators. Requests from outside investigators are carefully evaluated 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.

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