

# Position on Clinical Trial Data Transparency

## Background

Our scientists, patients, healthcare professionals and regulators rely on clinical trials to evaluate the efficacy and safety of new medicines, vaccines and medical devices. Increasingly, transparency is demanded relating to the clinical trial process, data and outcomes in order to assist research and development (R&D) of new or improved healthcare solutions and accelerate the approval of new medicines. Similarly, transparency assists healthcare professionals in making the best decisions for their patients. Beyond the ethical considerations supporting public disclosure, transparency of clinical trial data is also a legal requirement in certain countries, including the United States through the Food and Drug Administration.

## Relevance

Johnson & Johnson is a pioneer in the R&D of new products, pharmaceuticals and medical devices that contribute to the health and well-being of people around the world. Our desire to bring innovative, life-changing products and services to patients, doctors and customers requires thoughtful consideration of new science and research programs that are grounded in the core values Johnson & Johnson has represented for decades as well as in ethical research standards. We strive to maintain an environment of innovative product development, conducting all phases of R&D to the highest ethical standard while advancing pipelines that serve medical needs.

## 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 the needs and well-being of 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 medical aspects of R&D.

We also respect and uphold the principles developed by the pharmaceutical industry: [PhRMA Principles for Responsible Clinical Trial Data Sharing](#) and the [International Federation of Pharmaceutical Manufacturers & Associations Principles for Responsible Clinical Trial Data Sharing](#).

## Our Position

At Johnson & Johnson, we believe transparency of clinical trial data advances science and medicine and is in the best interest of the patients who use our products and the providers who prescribe them. We support the overall principles of greater clinical trial data transparency and aim to advance medical science for the benefit of all through our public disclosures. This is reflected in our approach described below.

**Registration and disclosure of clinical trial results:** Janssen publicly discloses information about clinical trials in external public registries, such as [ClinicalTrials.gov](https://www.clinicaltrials.gov) and the EU Clinical Trials Register. Our disclosure includes:

- Registering pharmaceutical clinical trials conducted in patients (Phase 1b through Phase 4) on external registries in accordance with specified requirements;
- Disclosing clinical trial results of investigational studies in accordance with specific format and timeframe of local laws and regulations; and
- Upon receiving regulatory approval, disclosing clinical trial results summaries of investigational studies in patients in accordance with our internal policy.

**Publication of clinical trials results in peer-reviewed journals:** We seek to publish in peer-reviewed journals the results from all Company-sponsored pharmaceutical Phase 2 through Phase 4 clinical trials and Phase 1 trials in patients. Studies that terminate early (prior to the pre-specified study end date) are included in our commitment to publish, provided they yield scientifically or medically important results.

We also seek to publish pharmaceutical research of scientific or medical importance from discontinued clinical research programs, prospective observational studies (including registries), analyses from subscribed databases, and health economics and outcomes research programs.

**Sharing of clinical study reports (CSRs) and participant-level data:** We appreciate and acknowledge that study participants (patients, investigators and sites) who agree to participate in our clinical trials are critical partners in advancing medical knowledge. We are dedicated to protecting the commitments we have made with them, including patient privacy.

- CSRs are formal reports that provide comprehensive description of the design, methods and results of clinical trials.
- Participant-level data are those data collected on each study participant at each visit or study contact. Analyzable participant-level data are in databases that allow analysis by computer programs and statistical tests.
- We have an agreement with the [Yale School of Medicine's Open Data Access \(YODA\) Project](#) to serve as the independent review panel for evaluation of requests for CSRs and participant-level data from investigators and physicians for scientific research that will advance medical knowledge and public health. The YODA agreement exemplifies Janssen's continued commitment to science, medicine and public health by creating a standardized independent, transparent and reproducible process for sharing our clinical trial data. For details regarding availability of data and timing for sharing, please visit [this page](#) on the YODA Project website.

**Making Plain Language Summaries available:** As partners in research, we believe the people who participated in our clinical trials should have the option to access information about the study findings to which they contributed. A Plain Language Summary (PLS), is a summary of the key results of a clinical trial, written in a non-technical manner that is understandable to the general reader. These summaries share the study outcomes, acknowledge the important contribution of the people who participated in the trial, and help

participants understand more about the research they have contributed to. We aim to publicly share PLS in English and in local languages, as required by local law, for Janssen-sponsored interventional trials in accordance with local regulatory requirements.

Where not required by law, PLS are made available to study participants for Phase 2 and Phase 3 interventional studies. These studies, initiated in 2019, are conducted with drug products that have not received marketing authorization in any country.

## **Application**

This Position is relevant for all pharmaceutical, medical devices and consumer health R&D activities of the Johnson & Johnson Family of Companies, as detailed in our [governance materials](#). See also [Janssen Clinical Trial Data Transparency](#).

*Last Updated: June 2020*