

Clinical Trial Data Transparency Statement

At Janssen, the Pharmaceutical Companies of 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 pharmaceutical products and providers who prescribe them. As such, we support overall principles of greater clinical trial data transparency, including registration and disclosure of clinical trial results in external registries, publication of results in peer-reviewed journals, and sharing of Clinical Study Reports (CSRs) and participant level data (PLD) from clinical trials, as outlined below.

Registration and Disclosure of Clinical Trial Results

Janssen policies for clinical trial registration and results disclosure for company-sponsored trials include, but may not be limited to, the following elements:

- Registration of clinical trials ongoing at or started after 1 July 2005,
- Company-sponsored interventional phase 1-4 trials involving patients,
- Disclosure of medically important results for trials in patients with marketed products completed after October 2002, and
- Registration prior to first patient receiving an intervention is required.

The Janssen policy covers registration or results disclosure requirements in any region where our trials are conducted. At Janssen, we are committed to ensuring adherence to our policies and have processes in place for self-monitoring.

Publication of Clinical Trials Results in Peer-Reviewed Journals

We seek to publish, in peer-reviewed journals, results from all company-sponsored pharmaceutical Phase 2 through 4 clinical trials and Phase 1 trials in patients. Studies that terminate early (prior to 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 medically or scientifically important pharmaceutical research 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 are fully engaged with experts and stakeholders, both internally and externally, across academia, government and industry, to develop a unified approach and best practices for sharing clinical study data, including development of standards to protect patient privacy and intellectual property, and to ensure maintenance of scientific integrity, while creating greater transparency to advance medical knowledge and science.

To provide access to our clinical trial data, we have entered into an agreement with the Yale Open Data Access (YODA) Project to serve as the Independent Review Panel (IRP) that will evaluate and make decisions regarding the approval or denial of all requests from researchers for CSRs and participant level data. Proposed research should be for the purposes of conducting scientific or medical research and have the objective of increasing generalizable knowledge and improving public health.

- As part of our process, we abide by agreements we have made with our co-development partners which may not permit us to grant all requests.
- We also have an obligation to protect intellectual property rights and confidential company information.

We also appreciate and acknowledge that study participants, investigators and sites who agree to participate in our clinical trials are critical partners in advancing medical knowledge. As such, we are dedicated to protecting the commitments we have made with them, including participant privacy.

- We provide access to participant level data via a secure platform that permits analysis within the platform but does not permit downloading of data
- We require researchers to sign data use agreements in which they commit to maintain the confidentiality of the data and to not attempt to re-identify trial participants or use data for anything other than the stated research purpose
- We de-identify participant level data before sharing



For more information on this process or to make a request for a CSR or participant level data, please visit the YODA Project portal at <http://yoda.yale.edu>.

Key definitions:

- **CSRs** are detailed study reports that provide comprehensive details on design and results of clinical trials.
- **Participant level data** are those data collected on each study subject at each visit or study contact.
- **Analyzable participant level data** are in databases that allow analysis by computer programs and statistical tests.