Position on Clinical Trial Data Transparency

At Johnson & Johnson Innovative Medicine (J&J IM), 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 the providers who prescribe them. As such, we support the 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, sharing of clinical study reports (CSRs) and participant-level data and Plain Language Summaries (PLS) from clinical trials, as outlined below.

Registration and disclosure of clinical trial results

J&J IM publicly discloses information about its clinical trials in external public registries, such as ClinicalTrials.gov and the EU Clinical Trials Register.

Disclosure includes:

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

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. Trials that terminate early 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 and participant-level data

We appreciate and acknowledge that trial participants (e.g., 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 to them, including patient privacy.

- Clinical Study Reports (CSRs) are formal reports that provide comprehensive descriptions of the design, methods and results of clinical trials.
- Participant-level data are those data collected on each participant at each visit or contact. Analyzable participant-level data are in databases that allow analysis by computer programs and statistical tests.
- We have an agreement with the Yale 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. For more information on this process or to make a request, please visit The YODA Project.

Making Plain Language Summaries available

J&J IM believes 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. PLSs share the clinical trial 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.

PLSs in English and local languages will be shared publicly as required by applicable law and J&J policy.

On January 1, 2019, J&J IM began writing and making PLSs available to participants through their study doctors for new Phase 2 and 3, J&J IM-sponsored interventional trials conducted with J&J IM products that had not received marketing authorization in any country. As of January 1, 2024, PLSs will be written and made available to trial participants on Trialsummaries.com for new Phase 2 – 4, J&J IM-sponsored interventional clinical trials conducted with J&J IM products regardless of marketing authorization status.

Application

This Position is relevant for Johnson & Johnson Innovative Medicine R&D activities, as detailed in our governance materials. Johnson & Johnson's ESG Policies and Positions on these and other issues are available in full here.

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