

Johnson & Johnson Announces Clinical Trial Data Sharing Agreement With Yale School of Medicine

NEW BRUNSWICK, N.J., Jan. 30, 2014 /PRNewswire/ -- Johnson & Johnson today announced that its subsidiary, Janssen Research and Development, LLC, has entered into a novel agreement with Yale School of Medicine's Open Data Access (YODA) Project that will extend its commitment to sharing clinical trials data to enhance public health and advance science and medicine. Under the agreement, YODA will serve as an independent body to review requests from investigators and physicians seeking access to anonymized clinical trials data from Janssen, the pharmaceutical companies of Johnson & Johnson, and make final decisions on data sharing. This is the first time any company has collaborated with a completely independent third party to review and make decisions regarding every request for clinical data.

"Sharing anonymized data from clinical trials is critical to advance public health because it furthers our understanding of diseases, expands the base of knowledge needed to develop new treatments, and generates new insights and more complete evidence to enable better healthcare decisions for patients - all while protecting patient privacy and confidentiality," said Joanne Waldstreicher, MD, Chief Medical Officer, Johnson & Johnson. "We are pleased to collaborate with YODA to ensure that each and every request for access to our pharmaceutical clinical data is reviewed objectively and independently. This represents a new standard for responsible, independent clinical data sharing."

Under the agreement, YODA will independently review and make final decisions regarding all requests for the company's clinical trial data including clinical study reports (CSRs) and de-identified patient-level data. While YODA members may reach out to Janssen researchers with questions, the final decision on data sharing will be made by YODA. Members of the YODA team at Yale School of Medicine will select and appoint an independent external panel of non-Janssen experts to help in some cases to assess requests.

In addition to Janssen's sharing of data from pharmaceutical product clinical trials through the agreement with YODA, Johnson & Johnson is also committed to the sharing of data from clinical trials of the medical device and consumer products of the Johnson & Johnson family of companies.

"Responsible sharing of clinical trial data advances science and medicine and is part of Johnson & Johnson's commitment to the doctors, nurses, patients, mothers, and fathers and all others who use our products," said Paul Stoffels, MD, Chief Scientific Officer, Johnson & Johnson & Worldwide Chairman, Pharmaceuticals. "Our agreement with YODA exemplifies the Johnson & Johnson family of companies' commitment to science, medicine and public health by creating a standardized independent, transparent and reproducible process for sharing our clinical trial data."

Janssen has also launched a new web-based mechanism to assist researchers in requesting access to data from the company's clinical trials. External researchers can make a request for clinical trial data on products from Janssen, the pharmaceutical companies of Johnson & Johnson, using the following link: www.clinicaltrialstudytransparency.com. The companies of Johnson & Johnson continue to maintain their longstanding policies for registration and publication of clinical trial data, irrespective of the outcome of the studies, and to support the overall principles of greater clinical trial data transparency. Additionally, Johnson & Johnson and Janssen support the overall PhRMA-EFPIA principles of

greater clinical trial data transparency and sharing, including registration and disclosure of clinical trial results in external registries, publication of results in peer reviewed journals, and sharing of Clinical Study Reports.

"We already have well established policies for registration and disclosure of clinical trial results in external registries as well as publication of results in peer reviewed journals, and we have historically worked with external researchers to address other types of data requests," said Bill Hait, MD, PhD, Global Head, Janssen R&D.

"We are delighted that through agreement with YODA, we will now be able to share data from our clinical trials in the form of Clinical Study Reports (CSRs) and participant level data in a systematic and objective way that advances medicine and scientific knowledge while protecting patient privacy and confidentiality," Dr. Hait added.

More information about the YODA Project can be found at <http://medicine.yale.edu/core/projects/yodap/index.aspx>.

About Janssen Research & Development, LLC

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Janssen Research & Development is part of the Janssen Pharmaceutical Companies. Please visit www.janssenrnd.com for more information.

About Johnson & Johnson

Caring for the world, one person at a time...inspires and unites the people of Johnson & Johnson. We embrace research and science -- bringing innovative ideas, products and services to advance the health and well-being of people. Our approximately 128,000 employees at more than 275 Johnson & Johnson operating companies work with partners in health care to touch the lives of over a billion people every day, throughout the world.

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