

Enhancing global public health through data transparency

JOHNSON & JOHNSON SETS A NEW STANDARD FOR RESPONSIBLE DATA SHARING

As the world's most comprehensive and broadly based healthcare company, we believe that responsible sharing of clinical trial data can advance science and medicine knowledge, and improve public health. The first and very important step in data transparency is to ensure disclosure of the conduct of clinical trials as well as a summary of findings once the trial is completed. Johnson & Johnson has long-standing policies to publicly disclose information about its clinical trials in external public registries, such as clinicaltrials.gov. We support the use of registries as the primary source of this information, which effectively forms a catalogue of clinical trials that can be used for further research.

At the beginning of 2014, we extended our commitments by announcing a unique agreement with the Yale Open Data Access (YODA) Project to provide increased access to our pharmaceutical clinical trial data. At the beginning of 2015, we extended this commitment to include medical device clinical trial data. Through the agreement, we commit to sharing clinical trial data, including participant level data with YODA, from our portfolio of products with qualified researchers, physicians and investigators through the YODA Project.

Working with the YODA Project, Johnson & Johnson has set a new standard for collaborating with an independent organization to share clinical trial data, while emphasizing the following principles:

- Safeguarding the privacy of patients
- Respecting the integrity of national regulatory systems
- Maintaining incentives for investment in biomedical research

WHY THE YODA PROJECT?

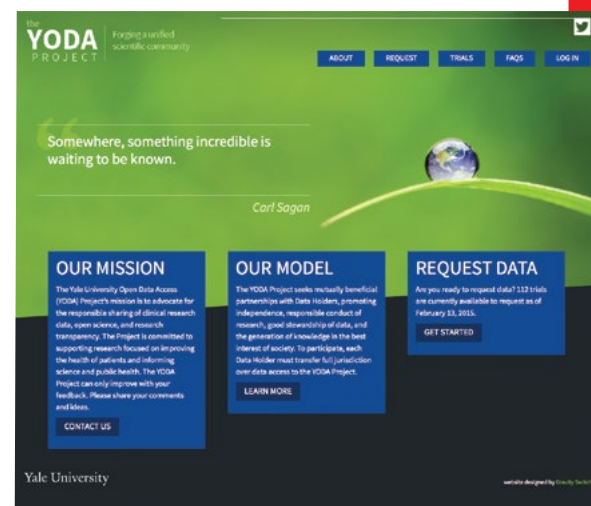
The YODA Project serves as an independent body, comprised of pharmaceutical and medical device experts. It reviews and makes final decisions regarding all requests from outside researchers who are not engaged in a research collaboration with Johnson & Johnson and would like to independently access Johnson & Johnson clinical trial data, including clinical study reports (CSRs) and de-identified participant level data.

Johnson & Johnson chose to make its clinical trial data available through the YODA Project because of Yale's previously demonstrated position and leadership in research and data transparency across both pharmaceutical and medical device products.

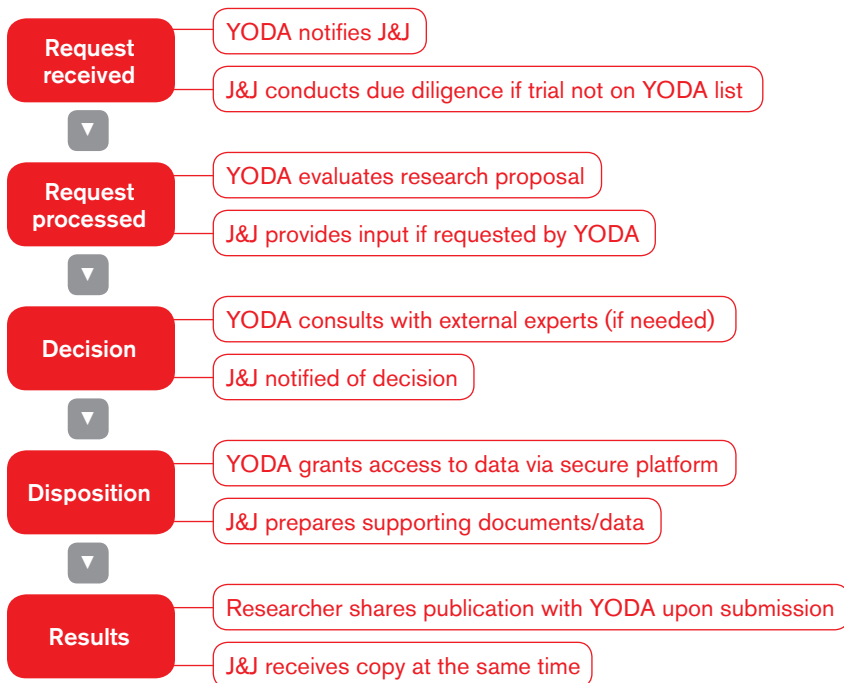
Johnson & Johnson is the first integrated healthcare company to work through an independent third party to review **all** requests and approve access to clinical data across its portfolio of products.

INDUSTRY'S COMMITMENT TO SHARING DATA

In July 2013, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) endorsed the Principles for Responsible Clinical Trial Data Sharing, which enhance the commitment of biopharmaceutical companies to increase transparency of clinical trial data for researchers, patients and the public. Johnson & Johnson has fully committed to these principles.



HOW THE YODA PROJECT WORKS



THE FUTURE OF DATA TRANSPARENCY

The potential for greater data transparency to improve public health is easy to imagine. We hope that all sponsors of clinical trials — government-funded, academic, small / large industry, biotech — will share their data so research can move faster, so we can increase the knowledge needed to develop new treatments, and that, together, we can advance the science that is the foundation of medical care.

HELPFUL RESOURCES

Visit the websites below for more information:

- **The YODA Project:**
<http://yoda.yale.edu>
For metrics and information about requests:
<http://yoda.yale.edu/summary-data-inquiries-and-requests>
- **U.S. Public Registry and Results Database:**
<https://clinicaltrials.gov/>
- **EU Clinical Trial Register:**
<https://www.clinicaltrialsregister.eu>
- **Institute of Medicine Report - Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk:**
<http://www.iom.edu/Reports/2015/Sharing-Clinical-Trial-Data.aspx>
- **PhRMA/EFPIA Principles for Responsible Sharing of Clinical Trial Data:**
PhRMA Press Release:
<http://www.phrma.org/press-release/EFPIA-and-phrma-release-joint-principles-for-responsible-clinical-trial-data-sharing-to-benefit-patients>
EFPIA Principles:
<http://transparency.efpia.eu/uploads/Modules/Documents/data-sharing-prin-final.pdf>

FOR MORE INFORMATION

Contact the Johnson & Johnson internal data sharing coordinator at: JnJDataSharingCoordinator@its.jnj.com

