Why is sharing clinical trial data important to Johnson & Johnson?

Clinical trial data sharing has the potential to advance the science that is the foundation of medical care. We believe that responsible sharing of clinical trial data can ultimately improve public health.

How does Johnson & Johnson's access to clinical trial data system work?

At the beginning of 2014, we announced an 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. The YODA Project serves as an independent body, comprised of pharmaceutical and medical device experts. It reviews research proposals and makes final decisions regarding all requests from outside researchers who are not engaged in a research collaboration with Johnson & Johnson operating companies and would like to independently access clinical trial data of Johnson & Johnson operating companies, including clinical study reports (CSRs) and de-identified participant level data.

HOW THE YODA PROJECT WORKS

Request received
- YODA notifies J&J
- J&J conducts due diligence if trial not on YODA list

Request processed
- YODA evaluates research proposal
- J&J provides input if requested by YODA

Decision
- YODA consults with external experts (if needed)
- J&J notified of decision

Disposition
- YODA grants access to data via secure platform
- J&J prepares supporting documents/data

Results
- Researcher shares publication with YODA upon submission
- J&J receives copy at the same time

How many requests has your company received? Where have they come from? What has been the result?

Metrics and details regarding research proposals received through the YODA Project are made public on the YODA Project portal (http://yoda.yale.edu). As of April 30, 2015, we had received 13 full research proposals, 12 of which were approved for release by the YODA Project; one proposal is under review. The requests, thus far, have come from a range of academic researchers.

Once the data have been shared what will happen next?

Once a research proposal has been approved by the YODA Project and the researcher has signed a data use agreement, the researchers are granted access to de-identified data and supporting documentation via a secure platform in which they conduct their analyses. Upon completion of their work, researchers export their results and are then expected to share their work in an appropriate publication or forum. The results and final publication will also be made public on the YODA Project portal.

What do you hope will be the outcome from developing the data sharing system?

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.