

Data Sharing for Research Case Study: Johnson & Johnson

Executive Summary

The [Future of Privacy Forum](#) (FPF) analyzed a diverse sample of data-sharing partnerships between companies and academic researchers and produced a series of case studies distilling our findings. We learned that there is broad consensus regarding the potential benefits of industry/academic data-sharing partnerships, including the acceleration of socially beneficial research, enhanced reproducibility of research breakthroughs, and broader access to valuable data sets. At the same time, companies and academic researchers understand and take steps to mitigate risks - particularly ethical and data protection risks. Increasingly, stakeholders are identifying risks arising from re-identification threats or data breaches while acting to mitigate those risks through the use of Data Sharing Agreements (DSAs) and Privacy Enhancing Technologies (PETs).

FPF's analysis of corporate-academic data-sharing partnerships provides practical, evidence-based recommendations for companies and researchers who want to share data in an ethical, privacy-protective way. These case studies demonstrate that corporate-academic data-sharing partnerships offer compelling benefits to companies, research, and society. Risks exist, but effective mitigation strategies can reduce the likelihood of harm to individuals, communities, and society. For many organizations, data-sharing partnerships are transitioning from being considered an experimental business activity to an expected business competency. This trend is most pronounced among established firms; it is an opportunity for researchers to access new data for scientific discovery.

Data Sharing Type

Internal, Intermediated Data Sharing

Organization and Partners

Company

Johnson & Johnson is a multinational company specializing in pharmaceuticals, medical technology, and consumer healthcare with more than 152,000 employees and reported adjusted net earnings of \$27 billion in 2022¹.

Data Intermediary

The Yale University Open Data Access (YODA) Project is a data intermediary that facilitates clinical research data sharing. The YODA Project is located in the Center for Outcomes Research and Evaluation at the Yale School of Medicine.

Partnership Considerations

Calls for Transparency

In 2013, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) jointly issued [Principles for Responsible Clinical Trial Data Sharing](#), a report that aimed to spur more researcher access to information about clinical trials. The report was written in response to [calls for greater transparency](#) from pharmaceutical companies to ensure that drugs are safe and effective for the public. Since then, qualified scientific and medical researchers can request patient-level data for medicines approved in the US and EU. As part of their effort to comply with these principles, Johnson & Johnson sought an independent organization to facilitate clinical trial data sharing with external researchers.

Johnson & Johnson and the YODA Project

¹ Johnson & Johnson. '2022 Johnson & Johnson Annual Report.' 2022.
<https://www.investor.jnj.com/asm/2022-annual-report>

The Yale Open Data Access (YODA) Project was selected as the independent review board between Johnson & Johnson and external researchers seeking anonymized clinical trial data. While there are additional mechanisms through which Johnson & Johnson shares data, the YODA Project is used for independent access requests to clinical trial data, resulting in over one hundred research publications documenting how novel research questions were answered with the analysis of data held by the YODA Project.

According to company and YODA Project representatives, Johnson & Johnson makes anonymized clinical trial data available for sharing through the YODA Project 18 months after study completion (allowing study investigators to publish first). Researchers submit research proposals to the YODA Project in order to request permission to access the data from Johnson & Johnson clinical trials. The status of the YODA Project as a separate entity from Johnson & Johnson supports the scientific integrity of the research. Because the researchers only interact with YODA Project personnel and processes, Johnson & Johnson can't restrict sharing data with researchers for any reason or improperly influence the findings of the research. All data requests are blinded to both the YODA Project and Johnson & Johnson during the request review process so that all researchers and institutions are considered on the basis of the merit and clarity of the proposal. While Johnson & Johnson requires researchers to share a copy of their manuscript with the YODA Project upon submission to a peer-reviewed journal, the company does not have the right to weigh in on the substance of the manuscript and has no decision rights in publishing. The YODA Project has supported data sharing efforts made by other companies such as Medtronic, and its funding model involves companies covering the costs of the initiative's expenses.

The YODA Project Data Sharing

YODA Project representatives communicated that they developed several methods that safeguard patient privacy, increase the likelihood of ethical use, and increase transparency about what data researchers can request. First, the YODA Project has standard and detailed [Data Use Agreements](#) that are publicly posted for researchers to

see at any time. Second, the YODA Project provides a [policies and procedures](#) document that describes the full scope of data sharing so that the data requestors know what to expect at every stage, including data availability, requirements, internal and external review processes, due diligence assessments, data use agreements, and data distribution. Third, a significant feature of the YODA Project is that clinical trial data sets that research sponsors have agreed to share are publicly listed, and the interface and study metadata support both searching and browsing functions. Fourth, if a researcher doesn't see a known clinical trial data set they had hoped to find, they can [submit a request to the YODA Project to determine whether the data can be made available](#). Fifth, the YODA Project maintains a list of clinical trials they can't share with the public for reasons such as the trial being incomplete, regulatory approval being pending, or the trial being older and the data hasn't been digitized. Lastly, the YODA Project provides a [dashboard](#) with metrics about their data sharing. The YODA Project staff works with researchers to clarify and strengthen proposals where needed.

YODA Project representatives added that data provided to the YODA Project for sharing are not transferred directly to researchers after a request is approved. Instead, they are made available through a secure analysis environment and accessed through a VPN. Company representatives said that Johnson & Johnson incurs a considerable expense to support the associated infrastructure. After accessing and analyzing the data, researchers can download their analyses but not the data themselves, and researchers must agree to several privacy-protective measures to avoid reidentifying patients who participated in the clinical trials. An illustration of the kind of research this partnership produces can be found in the [systematic review](#) prepared for the World Health Organization by [Dr. Lawrence Mbuagbaw](#), an associate professor at McMaster University. Dr. Mbuagbaw used data held in part by the YODA Project to review the [evidence and efficacy of bedaquiline](#) for treating multidrug-resistant tuberculosis, ultimately informing global policy guidance on the treatment.

Clinical Data Preparation

Johnson & Johnson reported that it has an internal group that prepares data, performs assessments of quantitative risk for anonymization, and leads in the development of anonymization techniques at the company. Once a Data Use Agreement is fully executed between the YODA Project and the approved researcher's institution, researchers access data through an independent secure platform, where they can work on the data with embedded analytical tools, and then export the analysis. They also have the option to securely upload their own data to the platform in order to combine data sources.

Johnson & Johnson says their approach is to try and increase the utility of the clinical data as much as possible without compromising patient privacy. However, they recognized the need for a framework to identify potential risks and effective mitigation strategies that don't compromise the data's utility once its sensitivity reaches a certain threshold. Johnson & Johnson's Head of Clinical Data Standards & Transparency, Stephen Bamford, co-authored a paper titled '[Sharing Anonymized and Functionally Effective \(SAFE\) Data Standard for Safely Sharing Rich Clinical Trial Data](#)' where he and his co-authors explored a process to grade data depending on its utility on a scale from 0-5 depending on the amount of anonymization needed to suit a research method.

When preparing clinical data for sharing, Johnson & Johnson stated they use a variety of privacy techniques, such as minimization, key-coding, pseudonymization, anonymization, and clinical data synthesis, which creates a synthetic model to generate artificial but realistic study data. These different techniques allow Johnson & Johnson to produce different versions of data for different studies depending on the requirements. While pseudonymized or key-coded data is never let outside Johnson & Johnson's secure environment, there are some circumstances where anonymized or pseudonymized data can be shared, including through approved YODA Project researcher proposals.

Risks and Benefits

Risks

Johnson & Johnson representatives acknowledge that there are risks associated with data sharing depending on how that sharing is stewarded, including risks to individuals' privacy, to the obligations the company made in the informed consent process, and to the reputation of the company. However, the company believes that the benefits of data sharing significantly outweigh the risks, noting that none of the worst-case scenarios that were predicted in early discussions of data sharing have come to pass, in part because of the policies and processes that have been put in place by Johnson & Johnson.

Benefits

Company representatives believe that sharing existing data has enabled researchers to answer many novel research questions without exposing patients to the inherent risks of clinical trials. Johnson & Johnson also engages in less sensitive data sharing for research when appropriate. For example, the company recently contributed data to an antimicrobial resistance surveillance data register hosted on the Vivli platform. The data shared were from past clinical trials where participants from diverse geographical regions submitted sputum to be tested against pathogens. The project required minor data minimization due to the nature of how data were collected during the study and are hoped to yield meaningful public benefits

Partnership Information

Johnson & Johnson: <https://www.jnj.com/>

YODA Project: <https://yoda.yale.edu/>

To learn more about data-sharing partnerships, read [The Playbook: Data Sharing for Research](#) or join the [Ethics and Data in Research Working Group](#) for updates on legislative developments and monthly calls with experts. This project is supported by the Alfred P. Sloan Foundation, a not-for-profit grantmaking institution whose mission is to enhance the welfare of all through the advancement of scientific knowledge.