



Yale University Open Data Access (YODA) Project



REQUESTS FOR DATA ACCESS OUTSIDE SECURE DATA SHARING PLATFORM

All clinical trial data being made available by Johnson & Johnson and Janssen Pharmaceuticals, Inc. through the YODA Project will be made available on a secure, online data sharing platform accessed via a password-protected personalized account. Released data will include all data relevant to the Research Proposal that are available, including collected participant-level data sets (appropriately de-identified as per current regional standards to protect patient privacy), data set specifications, protocols with any amendments, and reporting and analysis plans.

There are certain circumstances that may require access to clinical trial data outside of the secure platform. However, given the sensitivity of patient data, including the importance of protecting privacy and risk of re-identification, as well as the greater risk for unauthorized data dissemination and analysis, access outside of the secure platform requires clear justification. If you are requesting access to clinical trial data outside of the secure platform, please provide the additional information regarding your research proposal requested below, so that the YODA Project may adequately assess the need for data access outside of the secure platform. Please attach additional sheets if necessary.

Rationale for Data Source

Provide strong rationale for why the requested data can uniquely be used to address the proposed project aims, and reasons why other clinical research data are not available or cannot be used.

(Continued on page 2)



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Justification for Access

Provide clear justification for access outside the secure data sharing platform, including reasons why the platform may not permit the proposed analyses, such as the need for proprietary software that cannot be placed in the secure data sharing platform or to pool data from other sources that cannot access the secure data sharing platform. If describing proprietary software, please be specific in regards to the name of the software and reason(s) why it is needed for the proposed analyses. If describing data from other sources, please be specific in regards to the type(s) of data and reason(s) why the data cannot be uploaded to the secure data sharing platform.

Security

Describe the protections in place to ensure data security outside of the platform, including technological and related procedural safeguards. Please note: the YODA Project requires that data be stored on a HIPAA-compliant server with security passwords. Any breach of data must be immediately reported to the YODA Project.