



SOLVE
ON.

Clinical Trial Data Sharing Request

Thank you for your interest in data sharing. Incyte has an established process to review research proposals from qualified external medical and scientific researchers. Please find more information below.

Information available

Researchers can request anonymized datasets (including data dictionaries, dataset specifications), study protocols, and statistical analysis plans as necessary to address the research question being proposed.

Studies in scope

Qualified researchers may request access to anonymized data from all Incyte sponsored interventional studies except Phase 1. Data sharing requests will be considered for any study for which product and indication are approved on or after Jan 1st 2020 in at least one major market (e.g., US, EU, JPN). Data requests can also be considered for products and indications in which Incyte has made a decision to discontinue development and there are no plans to submit for marketing authorization.

Timeframe

Data will be shared after the primary publication or 2 years after the study has ended for (1) market authorized products and indications, and (2) studies for which clinical development is discontinued and there are no plans to submit for marketing authorization.

Exceptions

Incyte will only share clinical data when it is feasible to anonymize the data without compromising the privacy of trial participants. This may affect small clinical trials of rare diseases or trials conducted in a very small, easily identifiable patient population, which will be reviewed on a case-by-case basis. Prematurely discontinued trials that have insufficient enrollment/exposure to warrant analysis may also not be shared. Interim data from clinical trials will generally not be shared by default, although efforts will be made to share such data in long-term follow up studies after the primary publication/within 2 years of the interim analysis completion. In rare cases, information may be restricted by Incyte in order to protect commercially confidential information (CCI) and Intellectual Property (IP) rights. In general, Incyte does not support external research questions that involve access to data for the purpose of re-evaluating safety and efficacy issues already addressed in the product labelling. Data will not be provided to applicants with significant conflicts of interest, including individuals requesting access for commercial/competitive or legal

incyte.com



**SOLVE
ON.**

purposes. Requests that pose an actual or potential conflict of interest or competitive risk may be declined at Incyte's sole discretion and without further arbitration. Incyte reserves the right to refuse to share data for any reason at any time.

Data Sharing Process

Submitting a request

Data requests are considered from qualified researchers with appropriate competencies to perform the proposed analyses. Research teams must include a biostatistician. Qualified medical/scientific researchers may submit for consideration a data sharing request containing the research objectives, Incyte product(s) and Incyte study/studies in scope, endpoints/outcomes of interest, statistical analysis plan, data requirements, and publication plan. To submit your request, please complete the [data sharing request form](#) and send the completed form and any additional attachments to datasharing@incyte.com.

Incyte will reply by email with confirmation that your request has been received. Incyte will also confirm whether all the required information has been received.

Review

Your research proposals will be reviewed by a committee of internal/external advisors who form a Data Sharing Review Panel (DSRP). For clinical trials that are subject to agreements with co-development partners, Incyte will liaise with the applicable partners regarding any data sharing requests.

Incyte will notify you of the final decision and will confirm if your request has been: approved; rejected with comments; or rejected. A request that has been "rejected with comments" may be reconsidered if it is revised and re-submitted.

Data access

Access to data is governed by the terms of a data sharing agreement. The researcher must agree to these terms and sign the agreement before Incyte will grant access to the data within the scope of the approved request.

Following the approval of a data sharing request and the signing of the agreement, Incyte will anonymize data and anonymize documents in accordance with privacy laws and regulatory guidance. The anonymized data will be provided directly to the researcher in a secure manner, and the researcher is responsible for protecting the confidentiality and integrity of the data while the research is being conducted.

Project Completion

incyte.com



SOLVE
ON.

Under the terms of the data sharing agreement, researchers can submit their findings for publication. Publications must be reviewed by Incyte as outlined in the data sharing agreement. Researchers are expected to follow the International Committee of Medical Journal Editors' recommendations for authors. Once the publication process has been completed, the researcher must return the data or confirm secure disposal.