# Overview

The Vivli Data Request Form is used by data contributors and independent review panels to evaluate your proposal and make data access decisions. Each [Vivli member](https://vivli.org/members/ourmembers/) describes the criteria and process for making decisions about using their completed clinical trial data. To ensure a timely review of the proposal, your request form should be as detailed and complete as possible.

If your request is approved, specific information about the request will be posted on the Vivli website so the Vivli team will request that you spell out acronyms in the first instance. If your request is approved and a [Data Use Agreement](https://vivli.org/resources/vivli-data-use-agreement/) is executed, Vivli will publish on its website:

* Project Name
* Name & Affiliation of the Principal Investigator / Lead Researcher
* Funding Sources
* Conflict of Interest Statement
* Narrative Summary of your Research Proposal
* List of requested studies

After your publication is published, Vivli will publish the following information related to your data request:

* Statistical Analysis Plan
* Publication Citation

If you have questions about a study that is not available in the search on the Vivli platform from one of our members , please use the [enquiry form](https://vivli.org/members/enquiries-about-studies-not-listed-on-the-vivli-platform/) and the Vivli team will find out if the requested study is available.

Additional information and videos on how to request studies and get started are available here: <https://vivli.org/resources/resources/>

When you have completed the form and are ready to move your data request forward, you must click the “Submit” button on the top right. If the Submit button is not enabled, that indicates that you haven't filled out all of the required fields.

The button will be dark blue if you can submit  or light blue if it isn’t enabled.  If it is not enabled, look in each of the tabs on the left for a field outlined in red which indicates that a required field needs to be completed. Be sure to review the Research Proposal tab, Statistical Analysis Plan tab, Attestations (you need to check a checkbox), and the Research Team tab (you need to specify both a Lead Researcher and a Statistician. Please fill out all the details of the additional researcher(s), if applicable).

Please note that according to Vivli policy, any changes to the Lead Investigator, Lead Statistician, their conflict of interest, adding and removal of studies in the request, changes to the Statistical Analysis Plan will require that Data contributors have the opportunity to re-review your data request and have it go through their entire approval process. This allows the reviewers of a request to know which data sets will be combined into the same analysis environment.  This entire process could take an additional 2-5 months. Hence, please finalize your plans ahead of time to avoid any delays later.

Please review the Vivli policy in brief about active requests and active enquiries before submitting a data request: <https://vivli.org/resources/resources/>

For additional guidance on completing your data request form, please see our videos in the resources section: https://vivli.org/resources/resources/



**You will need the following information to complete your Vivli Data Request Form on the platform. Optional fields are italicized. Use this worksheet to collate all the necessary information with the help of your research team. If you have any questions, please submit them to the Vivli team via email** **support@vivli.org****.**

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| --- | --- | --- |
| **Field** | **Details & Notes** | **Response to be entered into the online form** |
| **Tab: Research Team** |
| Project Name | Ensure that the Project name matches the Title of the proposed research (The project name appears on the top of the data request). It should be an overall description of the research that is understandable by a general audience |  |
| Lead ResearcherFirst and Last Name | Please provide the full name.  |   |
| Lead Researcher Position | Please provide the current position/job role at your institution |   |
| Lead Researcher Email |  |  |
| Lead Researcher*ORCID ID # - optional* | ORCID ID # is a persistent digital identifier that distinguishes you from every other researcher, and, through integration in key research workflows such as manuscript and grant submission, supports automated linkages between you and yourprofessional activities ensuring that your work is recognized. |  |
| Lead Researcher AffiliationEmployer, Company, Research Institution or Primary Affiliation | If you have more than one affiliation, please indicate the institution under which you will carry out the research and which will sign the Data Use Agreement. Please include the city, state, and country of your Employer Institution. |  |
| Lead Researcher Country | From the dropdown, select the country where the Lead Researcher is located |  |
| Lead Researcher QualificationsEducation, degree, professional qualifications, and memberships that are relevant to the proposed research. | Please make sure to include all educational and professional criteria relevant to the proposed research, for the Lead Researcher. Please include the degree, discipline, and the institutions from where degree was granted. |  |
| Lead Researcher ConflictsAny real or potential conflicts of interest, including how they will be managed. | For each member of the research team, please provide information on financial relationships that could be perceived to influence the planning, conduct or interpretation of the proposed research. This should not be limited to financial relationships with the study sponsors involved in this initiative and other pharmaceutical or biotechnology companies within the last three years. This may include but is not limited to:* Research grants from governments or government agencies
* other grants or donations
* funding from employers through employment contracts
* other contracts, consultancies, honoraria and payments that will be used for the proposed research.
* Board memberships
* Patents (planned, pending or issued)
* Royalties - Stocks or shares (including options).

Please also include any other (e.g. non-financial) real or potential conflicts of interest that could be perceived to influence the planning, conduct or interpretation of the proposed research. For example, potential biases based on pre-existing personal views, academic or commercial competition, personal relationships or institutional affiliations. For each conflict, please summarize how real or potential conflicts of interest related to the funding of the proposed research, other financial relationships or other real or potential conflicts of interest will be managed. For example, through disclosure of interests when the research is presented and published. If none, please enter “None.” |  |
| Statistician Researcher First and Last Name | Complete this section if the statistician is different from the lead researcher; if the same, check the box **Lead Researcher is also a Statistician Researcher.**  |  |
| Statistician Researcher Position |  |  |
| Statistician Researcher Email |  |  |
| Statistician Researcher*ORCID ID # - optional* |  |  |
| Statistician Researcher AffiliationEmployer, Company, Research Institution or Primary Affiliation | If you have more than one affiliation, please indicate the institution under which you will carry out the research and which will sign the Data Use Agreement. Please include the city, state, and country of your Employer Institution.  |  |
| Statistician Researcher Country | From the dropdown, select the country where the Lead Researcher is located |  |
| Statistician Researcher Qualifications Education, degree, professional qualifications, and memberships that are relevant to the proposed research. | Please include the degree, discipline, and the institutions from where the degree was granted and any professional criteria or publications relevant to the proposed research where the statistician conducted the statistical analysis.If the designated statistician does not have a degree in statistics or biostatistics but has conducted a meta-analysis, please include the statement that he/she acted as the statistician on peer-reviewed publications. Also, please include their publications where they acted as a statistician (or CV) in the attachments tab. |  |
| Statistician Researcher ConflictsAny real or potential conflicts of interest, including how they will be managed. | See note above, Lead Researcher Conflicts.  |  |
| Additional Researchers | Same criteria as lead and statistician researchers - click on the box marked **Add+** to add additional research team members. Make sure to fill out all required fields for each team member. Include all the Research team members who will be assisting with the research.Note: If any of the team member comes from an institution other than the Lead researcher’s institution and if the research team member will be accessing the data in the Vivli secure research environment, they will also need to sign a DUA.  |  |
| **Tab: Research Proposal** |
| **General**Title | Ensure that the Title of the proposed research matches the Project name. It should be an overall description of the research that is understandable by a general audience.**Note, this title will be published on the Vivli website if the request is approved.** |  |
| Narrative Summary explaining the relevance of the project to science and public health | Please provide an English-language lay - summary of the proposed research that is suitable for a general or lay audience, clarifies the design, and explains the relevance of the research project to science and public health, covering the following topics:The project background including the condition studied;The necessity of the research;How many patients/members of the public are potentially affected; How the research will add to medical science or patient care;How the research will be conducted;What design and methods you have you chosen and why (in brief); Provide references to prior work on the topic, if applicable. In the first instance, please spell out and explain all acronyms used. For additional guidance on writing your narrative summary, please see our video here: https://www.youtube.com/watch?v=KVIgV4lugDg**Note, this summary will be published on the Vivli website if the request is approved.**  |  |
| Specific aims/objectives of the research, including thespecific hypotheses to be evaluated. | Provide a description of the specific aims of the project. Please specify what specific hypotheses will be evaluated.  |  |
| **Purpose of Analysis** | Choose from the available categories – select all that apply:* New research question to examine treatment effectiveness on secondary endpoints and/or within subgroup populations
* New research question to examine treatment safety
* Research that confirms or validates previously conducted research on treatment effectiveness
* Research that confirms or validates previously conducted research on treatment safety
* Preliminary research to be used as part of a grant proposal
* Summary-level data meta-analysis
* Participant-level data meta-analysis
* Support clinical trial design
* Statistical methods
* Training/testing
* Other

If you only need summary-level data or documents related to the study, please specify that here. For those performing research that confirms or validates previously conducted research on treatment safety, if MedDRA coding is interpreted, research teams are required to have **at least one member** who is trained in MedDRA. And where safety events are coded from verbatim terms, research teams are required to have **at least two members** who are trained in MedDRA. Please provide the information in the Other Information tab and upload evidence of this MedDRA training as an attachment.If MedDRA coding will not be interpreted, please provide this confirmation in the “Other Information” tab.  |  |
| **Outcome(s)** | Choose from the available categories – select all that apply:Algorithms / Code* A.I. algorithm
* Algorithm for predicting treatment response
* Code
* Machine Learning

Clinical Guidelines* Clinical guidelines

Designing Future Trials, Trial Protocol* Clinical trial design
* Clinical trial patient selection/recruitment
* Optimization of clinical trial parameters

Funding Application / Grants* Funding application/grants
* NIH grant

Tools* Patient-care decision aid/clinical tools
* Qualification of clinical outcome tools
* Statistical tools
* Web-based tools

Other* Other
 |  |
| **Study Design**Brief Description | Please provide a full description of the study design, for example: * case-control
* cohort
* cross-sectional
* historical controlled
* hybrid designs
* meta-analysis
* pooled analysis.

Please also provide a description of the study population or populations for the proposed research, for example: * the study arms from the requested clinical studies;
* intent-to-treat or per-protocol populations;
* the inclusion and exclusion criteria for any cohort or subgroup analysis.

Please clarify how the data you have requested will help you answer the hypothesis you have proposed.  |  |
| Specific Outcomes Elements and how they will be categorized/defined for your study | Please describe the specific outcomes elements and how they will be categorized/defined for your study, including:* Domain (e.g., anxiety)
* Specific measurement (e.g., Hamilton Anxiety Rating Scale)
* Specific Metric (e.g., change from baseline)
* Method of Aggregation (e.g., mean)
* Time-point(s) (e.g., 3 and 6 months).

Please describe the endpoints of the requested studies that will be analyzed. **Note,** that some data contributors require that research proposals must relate to the intervention or disease that was the subject of the original clinical studies to ensure the use of the data aligns with the informed consent provided by clinical study participants. For information about the requirements of members, please review their [Members Page.](https://vivli.org/members/ourmembers/)  |  |
| Main Predictor / Independent Variable and how it will be categorized/ defined for your study |  |  |
| *Other Variables of Interest – optional* |  |  |
| **Project Timeline**Target Analysis Start Date | Provide an estimation of key milestone dates for the proposed research, including the anticipated project start date and analysis completion date. This refers to the timeline of your work on the Vivli platform only, so make sure the dates you enter reflect this expectation and are a future date. The data request review and data use agreement process can take between 2-5 months. The length of the review process depends on the number of factors such as the number of Data Contributors involved in a data request, the number of studies involved, and how long it takes the requester to respond to comments.Please note: if your data request is approved, the Data Use Agreement allows for data access for a 12-month period, with the possibility of extension in 6-month intervals. |  |
| Estimated Analysis Completion Date | Please note that it can be very easy to overlook the estimated completion date when filling the form. We anticipate that working through the approval process, signing the DUA and uploading the data may take between 2-5 months. Please use this timeline as a guideline to adjust your Target Analysis Start Date and Estimated Analysis Completion Date, if necessary. |  |
| **Dissemination & Publication Plan**Dissemination & Publication Plan | Provide a description of anticipated products and target audience, including an expectation for study manuscripts and potentially suitable journals for submission of the completed research project. Include how the findings will be interpreted and communicated to the public (publication plan). You may provide a structured abstract for the proposed work. As per the Data Use Agreement, there is an expectation that the dissemination plan includes a definitive statement to publish and disseminate your findings to contribute to furthering scientific knowledge. Please include a statement declarative of your intention to publish your research findings (e.g. ”We plan to submit our research findings to peer-reviewed journals targeted at X scientific community such as \_\_\_\_\_\_\_.”). |  |
| *References for all cited material – optional* | Use [APA format](https://www.apastyle.org/index) |  |
| **Tab: Studies** |
| Vivli Listed and Provisioned Studies | * Studies from Vivli Members added to your Data Request Form via searching on the Vivli platform.
* Please specify all the studies you intend to use and remove any studies that you decided not to use.
* If you have prepared a list of studies, feel free to attach that to the request under the attachment section to allow us to cross-check the selection of studies.
* If you are interested in a study from a Vivli member that is not listed on the Vivli platform, please use the enquiry form [here](https://vivli.org/members/enquiries-about-studies-not-listed-on-the-vivli-platform/) to check with the Data Contributors whether the study meets their Data Sharing criteria.
 |  |
| Vivli Listed Studies Provisioned by External Providers | This space is for studies added to your data request, listed on Vivli, that require a parallel request on a Vivli partner platform. When you are adding studies to your data request from the search function, Vivli will automatically add studies in that category here and you will be redirected to the partner platform to fill out the parallel request. You will need to sign their Data Use Agreement to access their data. If you have any questions about this process, you can submit them using the platform chat, or via email to support@vivli.org.  |  |
| Studies, Data, or Tools not available on Vivli | **For studies or data:** include the Data Provider, an identifier for the data (NCTID / Sponsor Protocol ID or tool name), and title or description. Add one study at a time and repeat this process until all are included.**Please note:** * Requests to upload external data must be clearly stated in the Data Request Form when you submit it. If you add studies during the data request review process, your request will require **re-review**.
* Such requests should include the description of the additional data, the origin of the data, scientific validity, and how the external data adds value to the research purpose.
* You should also attest to having permission to use the data in the Vivli research environment. For example, that the data is from a study conducted by you, is publicly available data that can be used for secondary analysis, and/or adequate permission has been obtained.

**For tools or scripts:** You may also use this field to provide the details of any additional scripts and tools that you plan to bring into the secure research environment. Make sure you list all additional tools packages (Like R packages) you are planning to use in your analysis. Please note that if you want to bring in additional licensed software, it’s your responsibility to ensure that you have the necessary licenses. The secure research environment includes several tools for analysis. Please see the Vivli Secure Research Environment page [here](https://vivli.org/resources/vivli-secure-research-environment/) for the full list of tools available as part of the Vivli Research Environment.  |  |
| **Tab: Statistical Analysis Plan (SAP)** |
| GeneralDescription of how you will analyze the requested clinical study data.  | Consider providing well-defined baselines and SAP details that consider as many variables as possible. Describe how you will analyze the requested clinical study data, including: The reasoning behind/criteria used for selecting a specific study (ie. search criteria)* If your proposed research involves studies from other sources or platforms, please provide a table of all the studies that you are requesting from Vivli platform and other platforms along with their study ID and Title and Data Contributor name. In the table, please add a column “Data requested from” and for studies on Vivli platform, write Vivli and for other studies, please include their respective platform. This will help the members who are reviewing your data request to understand all the studies you are planning to analyze. Attach this table in the Attachments tab.

Also, please propose a brief plan on how you will combine the results from different platforms.Include a discussion of descriptive, bivariate and multivariable analysesAny other planned advanced analyses (such as propensity score methods, Kaplan-Meier or Cox modeling approaches, non-parametric testing). Effect measure of interest (e.g. for inferential studies: risk or rate ratio, risk or rate difference, absolute difference; for descriptive studies: rate with confidence intervals)Methods to control for bias (e.g. restriction, matching, stratification, covariate adjustment)Assumptions and any planned adjustments for covariates or meta-regression or modeling of covariatesThe statistical approach (e.g. Bayesian or frequentist (classical), fixed or random effects)Meta-analysis approach where applicable (e.g. random-effects meta-analysis, stratified meta-analysis) Statistical tests and methods (e.g. Fisher’s exact test, Kaplan-Meier curves, log-rank test to compare groups, multiplicity adjustments)Power to detect an effect, or the precision of the effect estimate given the sample size availableStatistical power calculations and levels of significance Model fit tests, sensitivity or heterogeneity analyses (e.g. Chi-Squared Test, I squared statistic) Analysis of subgroups (e.g. by age, disease status, ethnicity, socioeconomic status, presence or absence or co-morbidities);Different types of intervention (e.g. drug dose)Handling of missing dataSpecial note regarding outcome assessments in the Statistical Analysis Plan (SAP) – your SAP should cover the following questions: What is the approach for handling missing values? Will missing data be either excluded or imputed?What outcome elements would be assessed? How will differences in outcome measures used across studies be handled? How will the differences in study designs be handled? Will the analysis distinguish between different phases? How will differences in patient enrollment criteria be addressed? If the data request includes more than one study and if you are planning to conduct a metaanalysis, describe how the independence of the studies will be maintained, (i.e. not just combining them all together and analyzing as a single data set)? A pooled analysis, which combines data from multiple treating them as if they were from a single study,  ignores differences in study design, patient characteristics, and other factors is inappropriate unless the studies and populations are identical. Please describe how your analysis or analytical models will take account of these differences among studies.In the first instance, please spell out and explain all acronyms used. Vivli may request that you revise your request and spell out acronyms, before moving your request forward. **Note, this Statistical analysis plan will be published on the Vivli website once the publication is published.** |  |
| Country or countries where the analysis will be conducted – optional | Please include the country from where you will be performing this analysis. |  |
| **Tab: Funding** |
| General | Answer yes/no to the four questions regarding the funding of the research proposal. If yes, please provide additional details. |  |
| **Tab: Other Information / File Attachments** |
| Other Information | This tab allows an opportunity to provide any other information that might be relevant to the research study, either entered on the form or as an uploaded attachment.  |  |
| File Attachments | You may attach any relevant files *-* this may include references, a list of studies, a published proposal, or other supporting documentation. |  |
| **Tab: Attestations** |
| Certify Complete and Accurate | You cannot submit your data request until you have checked the attestation checkbox. |  |