

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](#) 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](#) is executed, Vivli will publish on its website:

- Title
- Name & Affiliation of the Principal Investigator / Lead Researcher
- Funding Sources
- Conflict of Interest Statement
- Lay 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](#) and the Vivli team will find out if the requested study is available. If you have an associated data request, you must wait until the enquiry is complete to submit that data request form.

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). Ensure that the country field is filled for all the team members.

Please note that according to Vivli policy, any changes to the Lead Investigator or Lead Statistician's affiliation to a commercial entity, their conflict of interest/funding, adding studies to the request, or 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 policies 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/>



Key factors that influence the timeline:

- If Institution has an existing master DUA with Vivli or needs to execute a Master DUA
- Requesters response time to questions and feedback by data contributors
- Number of studies being requested

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.

Field	Details & Notes	Response to be entered into the online form
Tab: Research Team		
<i>Lead Researcher</i> First and Last Name	Please provide the full name.	
<i>Lead Researcher</i> Position at current organization	Please provide the current position/job role at your institution	
<i>Lead Researcher</i> Email		
<i>Lead Researcher</i> <i>ORCID ID # - optional</i>	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 your professional activities ensuring that your work is recognized.	
<i>Lead Researcher Affiliation</i> Employer, Company, Research Institution or Primary Affiliation	Please list only one organization (full name) under which you will carry out the research and which will sign the Data Use Agreement. Search for your institution using the dropdown menu and select the appropriate institution. If your institution is not in the list, then manually enter the full name of the institution.	
<i>Lead Researcher Country</i>	From the dropdown, select the country where the Lead Researcher is located	
<i>Lead Researcher</i> <i>Qualifications</i> Education, degree, professional qualifications, and memberships that are	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 the degree was granted, and citations or DOIs for relevant publications	

<p>relevant to the proposed research. *Character limit is 1000 characters</p>		
<p>Name of the degree</p>	<p>Enter information about your highest/most relevant degree, e.g. PhD, Master's</p>	
<p>Institution from where the degree was received</p>		
<p>Discipline</p>	<p>The subject in which the degree was obtained</p>	
<p>Year Received</p>	<p>(If the degree is in progress, enter the current year and make a note in the Education box above)</p>	
<p>How many years of experience with secondary analysis?</p>	<p>Select from the drop-down list</p>	
<p>Lead Researcher Conflicts Any real or potential conflicts of interest, including how they will be managed.</p>	<p>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:</p> <ul style="list-style-type: none"> • Research grants from governments or government agencies 	

	<ul style="list-style-type: none"> • 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). <p>Applicants from for-profit companies should detail their inherent conflicts of interest from their employment.</p> <p>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.</p> <p>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.</p> <p>If none, please enter "None."</p>	
<p>Statistician Researcher First and Last Name</p>	<p>Complete this section if the statistician is different from the lead researcher; if they are the same person, check the "Lead Researcher is also a Statistician Researcher" box at the top of the form, and review the Statistician Qualifications field below and ensure all criteria are met and reflected in this field.</p>	

<p>Statistician Researcher Position at current organization</p>		
<p>Statistician Researcher Email</p>		
<p>Statistician Researcher ORCID ID # - optional</p>		
<p>Statistician Researcher Affiliation Employer, Company, Research Institution or Primary Affiliation</p>	<p>Please list only one organization (full name) under which you will carry out the research and which will sign the Data Use Agreement. Search for your institution using dropdown menu and select the appropriate institution. If your institution is not in the list, then manually enter the full name of the institution.</p>	
<p>Statistician Researcher Country</p>	<p>From the dropdown, select the country where the Lead Researcher is located</p>	
<p>Statistician Researcher Qualifications Education, degree, professional qualifications, and memberships that are relevant to the proposed research.</p>	<p>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.</p> <p>If the designated statistician does not have a higher degree in mathematics, statistics, epidemiology or biostatistics but has conducted a meta-analysis, please include the statement that he/she acted as the statistician on peer-reviewed publications, and include the relevant citations or DOIs. You can also add their CV in the attachments tab.</p>	
<p>Name of the degree</p>	<p>Enter information about your highest/most relevant degree, e.g. PhD, Master's</p>	
<p>Institution from where the degree was received</p>		

Discipline		
Year Received		
How many years of experience with secondary analysis?	Select from the drop-down list	
Statistician Researcher Conflicts Any 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 members 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		
Title of the Proposed Research	The title should be an overall description of the research that is understandable by a non-scientific audience. Note, this title will be published on the Vivli website if the request is approved.	
Lay Summary explaining the relevance of the project to	Please provide an English-language summary of the proposed research in <500 words, that is suitable for a non-	

<p>science and public health</p>	<p>scientific or lay audience. Aim for a reading age of 12.</p> <p>Please include information regarding:</p> <ul style="list-style-type: none"> --The project background, e.g. a brief description of the disease/condition in lay terms and how many members of the public are potentially affected --Explain in lay terms any necessary technical or field-specific language --Necessity of the research (i.e. how the research will add to medical science or patient care) --How the research will be conducted; (i.e. briefly describe what design and methods you have chosen and why) --Provide full form of all abbreviations in their first instance --For additional guidance on writing your lay summary, please see our video here: https://youtu.be/lmTfVsU-sC4 <p>Note, this summary will be published on the Vivli website if the request is approved.</p>	
<p>Specific aims/objectives of the research, including the specific hypotheses to be evaluated.</p>	<p>Provide a description of the specific aims of the project. Please specify what specific hypotheses will be evaluated. If your research doesn't have a statistical hypothesis, state the question(s) your research aims to answer.</p>	
<p>Purpose of Analysis</p>	<p>Choose from the available categories - select all that apply. If you only need summary-level (not participant-level) data or documents, please specify that here and in your study design description below:</p> <ul style="list-style-type: none"> • 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 	

	<ul style="list-style-type: none"> • 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 <p>If you only need summary-level data or documents related to the study, please specify that here.</p> <p>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.</p> <p>Please provide the information in the Other Information tab and upload evidence of this MedDRA training as an attachment.</p> <p>If MedDRA coding will not be interpreted, please provide this confirmation in the “Other Information” tab.</p> <p>We can accept the MedDRA Coding Basics training as evidence.</p> <p>This link will take you to the Training and Materials page, click on 'Coding' and the trainings will be displayed by Language. https://www.meddra.org/training-materials</p>	
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<p>Outcome(s)</p>	<p>Choose from the available categories – select all that apply:</p> <p>Inform Patient Care Decisions</p> <ul style="list-style-type: none"> • Inform Patient Care Decisions <p>Algorithms / Code</p> <ul style="list-style-type: none"> • A.I. algorithm • Algorithm for predicting treatment response • Code • Machine Learning <p>Clinical Guidelines</p> <ul style="list-style-type: none"> • Clinical guidelines <p>Designing Future Trials, Trial Protocol</p> <ul style="list-style-type: none"> • Clinical trial design • Clinical trial patient selection/recruitment • Optimization of clinical trial parameters <p>Funding Application / Grants</p> <ul style="list-style-type: none"> • Funding application/grants • NIH grant <p>Tools</p> <ul style="list-style-type: none"> • Clinical tools • Qualification of clinical outcome tools • Statistical tools • Web-based tools <p>Other</p> <ul style="list-style-type: none"> • Other 	
<p>Artificial Intelligence / Machine Learning</p>	<p>Please confirm if you will be using any Artificial Intelligence or Machine Learning in this request?</p> <p>Please provide a description of how AI/ML methods will be used in your analysis including the type of models to be developed, if models are trained on external data, and model export intentions.</p>	

	<p>Please review the Vivli AI/ML framework guideline here and utilize the following criteria carefully before proceeding with your submission</p>	
<p>Study Design Brief Description</p>	<p>Please provide a full description of the study design, for example:</p> <ul style="list-style-type: none"> • case-control • cohort • cross-sectional • historical controlled • hybrid designs • meta-analysis • pooled analysis. <p>Please also provide a description of the study population or populations for the proposed research, for example:</p> <ul style="list-style-type: none"> • 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. <p>Please clarify how the data you have requested will help you answer the hypothesis you have proposed.</p> <p>If you will be using any data that has not been requested through Vivli for your analysis, please provide details of the data, including the NCT ID, study title and sponsor name, and how it will be used in the analysis. If this list is more than 3 studies, please upload it as an Excel spreadsheet and include this as an additional attachment with your request.</p>	

<p>Specific Outcomes Elements and how they will be categorized/defined for your study</p>	<p>Please describe the specific outcomes elements and how they will be categorized/defined for your study, including:</p> <ul style="list-style-type: none"> • 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). <p>Please describe the endpoints of the requested studies that will be analyzed.</p>	
<p>Main Predictor / Independent Variable and how it will be categorized/defined for your study/specify if genomic or imaging data is included in this request</p>	<p>Note, if you are requesting genomic or imaging data please review the Data Contributors Members Page to ensure that this type of data is shared before submitting your data request.</p>	
<p><i>Other Variables of Interest – optional</i></p>		
<p>Project Timeline Target Analysis Start Date</p>	<p>Pre-filled date set at data request creation date +5 months.</p> <p>The Average timeline from request submission to data access is 5 months (see graphic above). All data requests proceed through a data request review.</p> <ul style="list-style-type: none"> • Step 1: Vivli Administrator form check — Ensure all required fields of the data request form are completed and that a qualified statistician is part of the team. • Step 2: Data Contributor Review — Check 	

	<p>feasibility of fulfilling request.</p> <ul style="list-style-type: none"> • Step 3: Independent Review Panel or Scientific Committee — Reviews based upon the merits of the research proposal. • Depending on the studies being requested for reuse, not all three steps will be completed. Please see a member's page for the specific review process their studies or alternatively the metadata about a specific study. • Once the data request review is completed, the Data Use Agreement will be executed and the data, if not already stored in the Vivli platform, will be anonymized and uploaded for the researcher to access the data package. <p>The length of the review process depends on a 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.</p> <p>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.</p>	
<p>Estimated Analysis Completion Date</p>	<p>Pre-filled, data request creation date +12 months, as the Data Use Agreement allows for data access for a 12-month period.</p>	
<p>Dissemination & Publication Plan</p>	<p>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.</p>	

	<p>Please provide the full form of all abbreviations such as conference and journal names.</p> <p>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 _____.").</p>	
<p><i>References for all cited material – optional</i></p>	<p>Use APA format</p>	
<p>Tab: Studies</p>		
<p>Vivli Listed and Provisioned Studies</p>	<ul style="list-style-type: none"> • 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 to check with the Data Contributors whether the study meets their Data Sharing criteria. Please refrain from submitting your Data request until your enquiry is complete. 	
<p>Vivli Listed Studies Provisioned by External Providers</p>	<p>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</p>	

	<p>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.</p>	
<p>External Data</p>	<p>For studies or data that you want to bring into the Vivli secure research environment to analyze with the Vivli Listed Studies: 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.</p> <p>Please note:</p> <ul style="list-style-type: none"> • 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. • Only anonymized data can be uploaded to the Vivli research environment <p>For tools or scripts: We can support software that is not pre-installed on the system as long as:</p>	

	<ol style="list-style-type: none"> 1. The software installs into the Research Environment and runs locally (specifically: network restrictions prevent web-based applications). The Research Environment runs Windows Server 2022 2. You own and can provide a license that we can install on your behalf, if needed. <p>The software validates that license *only* at the time of installation. If the software validates the license over the internet every time the software is started, the network restrictions prevent the software from running. The secure research environment includes several tools for analysis. Please see the Vivli Secure Research Environment page for the full list of tools available as part of the Vivli Research Environment.</p>	
<p>Tab: Statistical Analysis Plan (SAP)</p>		
<p>General Description of how you will analyze the requested clinical study data.</p>	<p>Consider providing well-defined baselines and SAP details that consider as many variables as possible.</p> <p>Describe how you will analyze the requested clinical study data, including:</p> <ul style="list-style-type: none"> • The reasoning behind/criteria used for selecting a specific study (i.e. 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 the 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 	

	<p>reviewing your data request to understand all the studies you are planning to analyze. Attach this table in the Attachments tab.</p> <p>Also, please propose a brief plan on how you will combine the results from different platforms.</p> <ul style="list-style-type: none"> • Include a discussion of descriptive, bivariate and multivariable analyses • Any 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 covariates • The 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 available • Statistical power calculations and levels of significance • Model fit tests, sensitivity or heterogeneity analyses (e.g. Chi-Squared Test, I-squared statistic) 	
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- 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 data

Special 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 you are using AI or ML models, explain how these models will be used in your analysis

If the data request includes more than one study and if you are planning to conduct a meta-analysis, 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.

	<p>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.</p> <p>Note, this Statistical analysis plan will be published on the Vivli website once the publication is published.</p>	
Country or countries where the analysis will be conducted – optional	Please include the country(ies) 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 reference 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.	