



Vivli

CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Vivli Data Request Form: Tips and Tricks

Platform Version 3.7
24 May 2025

What is the Vivli Data Request Form?

- The Vivli Data Request Form is used by data contributors and independent review panels to evaluate your proposal and make decisions on your data access for the studies requested.
- Each Vivli member describes the criteria and process for how they make decisions about the use of their completed clinical trial data.
- To ensure a timely review of the proposal, your data request form should be as detailed and complete as possible.

CONFIDENTIAL - Not for distribution



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LEAD RESEARCHER

✖

Activate user for accessing data request

✖

Lead Researcher is also Statistician Researcher

First Name

Last Name

Email (editable until user is invited to data request)

Employer, Company, Research Institute, or Primary Affiliation

Education, including professional qualifications that are relevant to the proposed research and are specific to clinical data analysis

PhD, Biostatistics, Boston University

Name of the degree

Details of highest degree, e.g., PhD, Master's

Discipline

Year Received

Please list any real or potential conflicts of interest and describe how these will be managed. If none, please enter None.

ORCID ID

Position at current organization

Country

Select One

Institution from where the degree was received

How many years of experience with secondary analysis

Select an Option

- 1) If the Lead Researcher and Statistician Researcher are the same individual, fill in the details under Lead Researcher and then click the “Lead Researcher is also Statistician Researcher” box.
- 2) For team members who will need to be able to access the data request on Vivli, click the “Activate use for accessing data request” box.
- 3) For the Employer/Affiliation field, use the dropdown menu to select the institution under which you will be conducting the research, and who will sign the DUA – if you cannot find your institution, add it in as free text
- 4) In the Education field, you should list your degrees, disciplines and the institutions from which the degrees were received.
- 5) For the Name of the degree, institution from where the degree was received, discipline and Year Received, enter the details of your highest or most relevant degree, e.g., PhD or Master’s. For the statistician this should ideally be in a statistical discipline.

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STATISTICIAN RESEARCHER

First Name Last Name ORCID ID

Email (editable until user is invited to data request) Position at current organization

Employer, Company, Research Institute, or Primary Affiliation Country

Select One

Education, including professional qualifications that are relevant to the proposed research and are specific to clinical data analysis

List any skills or prior experience in performing relevant or similar statistical analyses as planned (i.e. previous publications)

Name of the degree Institution from where the degree was received

Discipline Year Received How many years of experience with secondary analysis

Select an Option

Please list any real or potential conflicts of interest and describe how these will be managed. If none, please enter None.


VM Access Admin Approval Based on Approved DUA
DUA Approval Not Applicable

ADDITIONAL RESEARCHERS

Add +

- 1) For the Name of the degree, institution from where the degree was received, discipline and Year Received, enter the details of your highest or most relevant degree, e.g., PhD or Master's. For the statistician this should ideally be in a statistical discipline.
- 2) If your statistician does not have an advanced degree in Statistics, Epidemiology, or Biostatistics, please list any prior experience in performing relevant or similar statistical analyses as planned. You may provide a list of prior publications in the education field where the person acted as a Statistician, or using the Attachments tab.
- 3) Please use the Add button in the bottom right corner to list any additional researchers that will be working on your project.

Research Proposal



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GENERAL

Title of the Proposed Research (Overall brief description, including the condition, about the proposed research question that is understandable by a general audience)

Data Request Example

Lay Summary of the Research Request

[Vivli Lay Summary Training Video - YouTube](#)

What are the specific aims/objectives of the proposed research, including the specific hypotheses to be evaluated?

PURPOSE OF ANALYSIS

Purpose of Analysis is required

☒ 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

OUTCOME(S)

Outcome(s) is required

☒ Inform Patient Care Decisions
 ☐ Inform Patient Care Decisions
 ☒ Algorithms / Code
 ☐ A.I. algorithm
 ☐ Algorithm for predicting treatment response
 ☐ Code
 ☐ Machine Learning
 ☐ Clinical Guidelines
 ☐ Clinical guidelines
 ☐ Designing Future Trials, Trial Protocol

- 1) To update the name of your project on your dashboard, edit the Title of Proposed Research
- 2) In the Research Proposal section, you will fill out all relevant details of your proposal, including the title, narrative summary, aims and hypotheses. Please use the full form of any abbreviations in their first use.
- 3) If you need assistance with your lay summary, please view our lay Summary Video.
- 4) For your Purpose of Analysis, please select all boxes that apply. If you are interested in treatment safety, you will need to provide MedDRA training documentation for at least one member of your research team via the attachments tab.

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Outcome(s) is required.

Research Team | Artificial Intelligence / Machine Learning

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Please answer the following questions related to use of Artificial Intelligence (AI) and Machine Learning (ML). Also, review the Vivli policy in this document: [Vivli AI/ML Model Requirements](https://vivli.org/vivli_ai-ml_model_requirements)

Please confirm if you will be using any Artificial Intelligence or Machine Learning in this request? *

☐ No **Review Vivli's AI/ML policy https://vivli.org/vivli_ai-ml_model_requirements**

☒ Yes

Response required.

Please indicate which model types will be developed in your analysis (Note: you will comment on how these models support your analysis in the SAP section) *

Select...

Will your analysis include the use of existing trained models? *

☒ No

☐ Yes

Response required.

Will you be exporting a model from the Vivli research environment? *

☐ No


☐ Yes

Response required.

Please select how the data will be used *

If your research will involve the use of artificial intelligence or machine learning, in the Artificial intelligence / Machine learning section answer the first question 'Yes' and complete all the questions that will then appear. Please review Vivli's policy for use of AI/ML here to ensure that your request complies with the requirements: https://vivli.org/vivli_ai-ml_model_requirements

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STUDY DESIGN

Brief Description

Please describe the specific outcomes elements and how they will be categorized/defined for your proposed research

Main Predictor/Independent Variable and how it will be categorized/defined for your proposed research

Other variables of interest that will be used in your analysis and how they will be categorized/defined in your proposed research (i.e. genders, age groups, ethnic groups)

Character Count: 0/1000

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Main Predictor/Independent Variable and how it will be categorized/defined for your proposed research

Other variables of interest that will be used in your analysis and how they will be categorized/defined in your proposed research (i.e. genders, age groups, ethnic groups)

PROJECT TIMELINE

Target Analysis Start Date
10/29/2025


Estimated Analysis Completion Date
10/29/2025

DISSEMINATION AND PUBLICATION PLAN

Dissemination & Publication Plan

Declare your intention to publish your results, and list of potential journals or conferences here

Provide references for all cited material (following APA guidelines)



- 1) The Project Timeline is pre-filled and non-editable. The Target Analysis Start Date is +5 months from data request creation date, because on Vivli it takes an average of 5.4 months for a data request to move through from submission to data access. The Estimated Analysis Completion Date is +12 months from the creation date.
- 2) 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 . Your dissemination and publication plan should include possible journals or conferences you plan to submit your research findings and should make the appropriate statements declarative of your intention to publish your research findings.

Studies

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REQUESTED STUDIES

VIVLI-LISTED AND PROVISIONED STUDIES

A Randomized, Double-blind, Single Migraine Attack, Placebo-controlled, Parallel-group Multicenter Study to Evaluate the Efficacy and Tolerability of Trexima (Sumatriptan S...

Study ID: NCT00326255 Sponsor ID: TRX105852
Data Request ID: OlavoSmithKline IRP Approver: Wellcome Trust

Data to be loaded after approval [Remove](#)

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

No Studies Found

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI [Add](#)

No Studies Found

1. To add additional studies to your request while the request is in drafts, please use “Quick study lookup” option and type in the study ID. This is for studies already listed on the platform.
2. The Vivli platform has the flexibility for you to bring in data for studies that are outside of Vivli as long as you have the appropriate permissions to bring that study data into the Vivli platform and you specify that in your request. Please use the “Studies, Data or Tools Not Listed on Vivli” section to add information about the data you want to bring into the platform and confirm that the data you will bringing is anonymized data as Vivli can only accept anonymized data in the Research Environment.
3. You may also use this field to add in the information about the tools and scripts that you want to use in the secure research environment.

Statistical Analysis Plan

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GENERAL

Describe how you will analyze the requested clinical study data


Country/countries where the analysis will be conducted

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, provide a full list of studies requested from other sources so the Data Contributors can see the full scope of the proposed research. Also please propose a brief plan on how to combine the results.
- Include discussion of descriptive, bivariate and multivariable analyses
- Any other planned advanced analyses (such as propensity score methods, Kaplan-Meier or ...)

1. For the Statistical Analysis Plan, please describe how the analysis will be performed. The data request form contains help text for further guidance.
2. In the next field, include the country or countries where the analysis will be conducted.

Funding



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Is the proposed research being funded by research grants from government agencies?
☐ Yes ☒ No

Is the proposed research being funded by employers through employment contracts?
☐ Yes ☒ No


Is the proposed research being funded by additional contracts or consultancies?
☐ Yes ☒ No

Is the proposed research being funded by commercial organizations?
☐ Yes ☒ No

Answer yes or no to the four questions regarding the funding of the research proposal. If you respond yes to any of the questions, please provide further information, such as grant IDs or other funding identifiers.

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Other Information / Attachments



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Other Information

File Attachments


NO FILES IN PACKAGE

Select Files

Drop files here

Use the “Other Information / File Attachments” tab to provide any additional information not covered in your Research Proposal. **This may include references or other supporting documentation.** You may drag and drop files into the file attachments section

Attestation



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Certify Complete and Accurate

Please check the box below to indicate that you as the Lead Researcher certify that the information provided is complete and accurate, and that you assume full responsibility for the research.

☒ I certify the information provided is complete and accurate.

Data Use Agreement

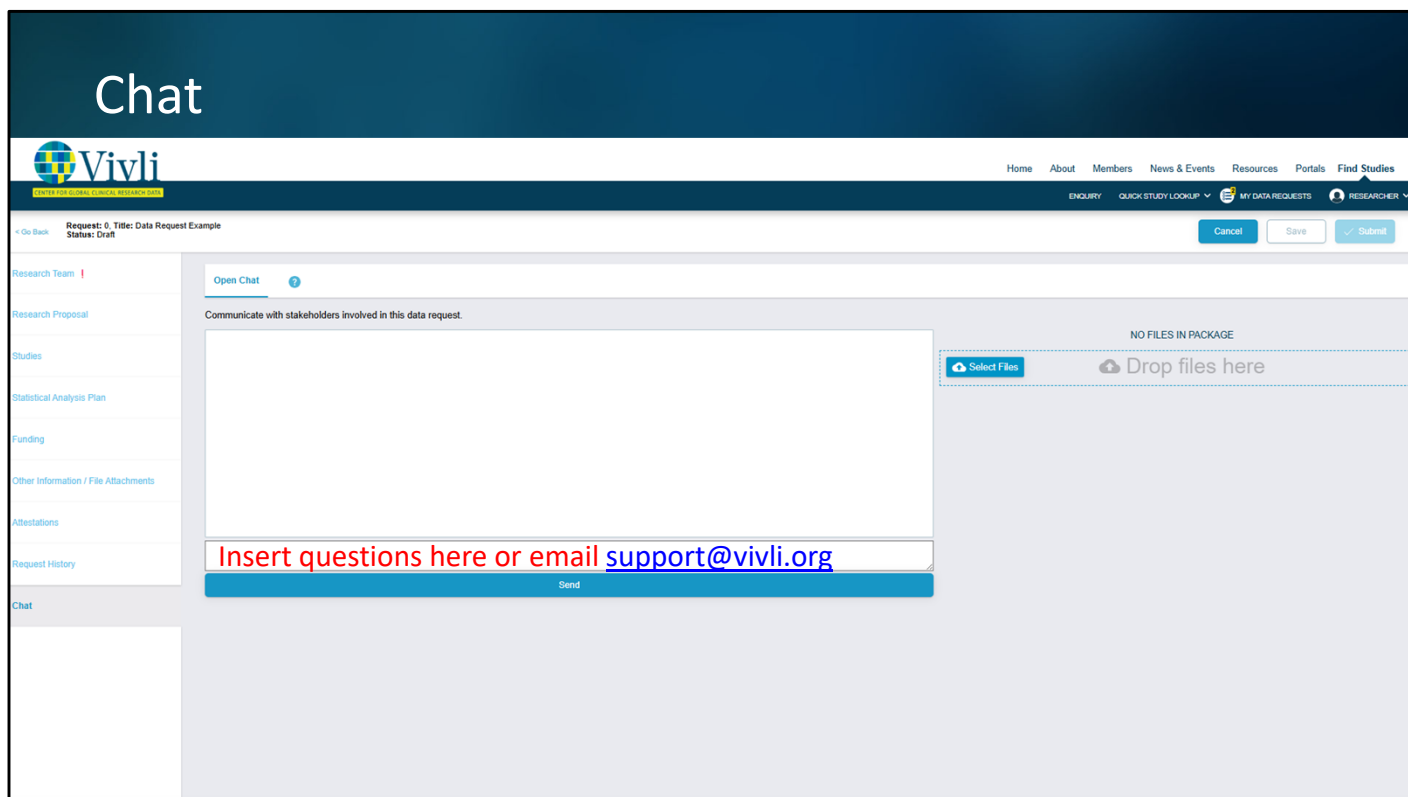
Please note that all Data Requestors wishing to receive access to data must execute the Data Use Agreement (DUA) before the data can be provided. The DUA is the product of extensive negotiation with the organizations that contribute data to Vivli, and as such, the agreement is non-negotiable. The DUA form must be completed and signed and is available [here](#).

You can either fill out the DUA form and sign it digitally, or print it out, sign it and scan it as PDF. Once the DUA has been signed by your organization, please upload it using the Signed Agreements tab of this data request (visible once the data request is submitted).

If you have any questions regarding the DUA, please contact a Vivli admin at support@vivli.org.

If the Submit button 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

- 1) On the Attestation tab, click to certify that the information you have provided is complete and accurate.
- 2) Once all required fields are complete, the blue button in the corner is enabled and you may submit your request for review.



If you have any questions for the Vivli team, use the chat feature or email support@vivli.org