



CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Vivli Data Request Form: Tips and Tricks

September 2023

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.

Research Team



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Research Team

LEAD RESEARCHER



Invite user to access data request



Lead Researcher is also Statistician Researcher [?](#)

Research Proposal

First Name

Last Name

ORCID ID [?](#)

Studies

Email...

Position

Statistical Analysis Plan

Employer, Company, Research Institute...

Country

- Select an Option -

Funding

Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. [?](#)

Character Count: 0/1000

Other Information / File Attachments

PhD, Biostatistics, Boston University

Attestations

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

Chat

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

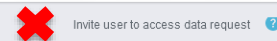


Research Team



Research Team

STATISTICIAN RESEARCHER



First Name Last Name ORCID ID

Email Position

Employer, Company, Research Institute... Country

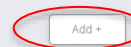
Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. Character Count: 0/1000

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

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



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)

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 is required.

PURPOSE OF ANALYSIS

- 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

Outcome(s) is required.

OUTCOME(S)

Algorithms / Code

- A.I. algorithm
- Algorithm for predicting treatment response
- Code
- Machine Learning

Clinical Guidelines

- Clinical guidelines

Decision Support Tools, Trial Protocol

Research Proposal



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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

Character Count: 0/1000

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)

Research Proposal



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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

08/15/2023

Estimated Analysis Completion Date

08/16/2023

DISSEMINATION AND PUBLICATION PLAN

Dissemination & Publication Plan [?](#)

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

Provide references for all cited material (following APA guidelines)

Estimated timeline for request approval: 2-5 months

Studies



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REQUESTED STUDIES [?](#) [↓](#)

VIVLI-LISTED AND PROVISIONED STUDIES

A Multicenter, Open-Label Conversion of Valproate Monotherapy to Lamotrigine Monotherapy in Patients With Epilepsy

Study ID: NCT00043914 Sponsor ID: LAM40013
Data Request ID:
Data Contributor: GlaxoSmithKline 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

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 (i.e. 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 Cox)

Funding



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GENERAL

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

Other Information / Attachments



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Other Information

Other Information [+](#)

File Attachments

NO FILES IN PACKAGE

[Select Files](#)

[Drop files here](#)

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



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Open Chat ?

Communicate with stakeholders involved in this data request.

Insert questions here or email support@vivli.org

Send

NO FILES IN PACKAGE

Select Files

Drop files here