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Request: 49582, **Title:** Blank request for updating form sample
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LEAD RESEARCHER

Activate user for accessing data request

Lead Researcher is also 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.

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.

Access to Data

Access to data not applicable

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STATISTICIAN RESEARCHER

Activate user for accessing data request

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.

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.

Access to Data

Access to data not applicable

ADDITIONAL RESEARCHERS

Add +

Name	Affiliation	Country	Email	Role(s)	Status Details

No Data Found

ADDITIONAL RESEARCHER - No Account

Activate user for accessing data request

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.

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.

Access to Data

Access to data not applicable

OK

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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)

Blank request for updating form sample

Lay Summary of the Research Request

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

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

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- [ ] Participant-level data meta-analysis
- [ ] Support clinical trial design
- [ ] Statistical methods
- [ ] Training/Testing
- [ ] Other

Purpose of Analysis is required.

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
- [ ] Clinical tools
- [ ] Qualification of clinical outcome tools
- [ ] Statistical tools
- [ ] Web-based tools

Other
- [ ] Other

Outcome(s) is required.

Artificial Intelligence / Machine Learning

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

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

- ( ) No
- (•) Yes

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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) *

- [ ] Machine learning models - Defined models similar in nature to standard statistical models (Lasso, Random Forests, Support Vector Regression, Decision Tree, K-Nearest Neighbors (KNN), Gradient Boosting, Kernal Machine, Boosting, Gaussian Mixture models (GMMs))
- [ ] Artificial Neural Networks (ANNs) and Similar Algorithms - ex: Artificial Neural Networks (ANNs), Convolutional Neural Networks (CNNs), Recurrent Neural Networks (RNNs), Transformer Models (non-generative)
- [ ] Generative Models / Large Language Models (LLMs) – ex: GPT, Generative Adversarial Networks (GANs), Diffusion models

Response required.

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 *

- [ ] To validate (to confirm model performance) - Data is used to confirm that a model is performing as expected
- [ ] To train (to adjust existing model algorithim parameters) – Data is used to adjust algorithms parameters
- [ ] To create a model – Data used to build a new custom model

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Response required.

Will the model form the basis of a commercial product? *

- No
- Yes

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

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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 (at least 5 months from Request creation)
04/17/2026

Estimated Analysis Completion Date (at least 12 months from Target Start date)
07/24/2027

DISSEMINATION AND PUBLICATION PLAN

Dissemination & Publication Plan

Provide references for all cited material (following APA guidelines)

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REQUESTED STUDIES Add Vivli Study

VIVLI-LISTED AND PROVISIONED STUDIES

A double-blind, randomized, stratified, placebo-controlled study of Ro 64-0796 (also known as GS4104) in children with influenza.
Study ID: WV15758 Sponsor ID: WV15758
Data Request ID: 00049582
Data Contributor: Roche IRP/Approver: Wellcome Trust
Data already on platform Remove

A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Belimumab Plus Standard of Care Versus Placebo Plus Standard of Care in...
Study ID: NCT01639339 Sponsor ID: 114054
Data Request ID: 00049582
Data Contributor: Roche IRP/Approver: Wellcome Trust
Data already on platform Remove

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

No Studies Found

EXTERNAL DATA Add External Data

No Studies Found

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GENERAL

Describe how you will analyze the requested clinical study data

Country/countries where the analysis will be conducted

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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

Request: 60728, **Title:** Assessing bleeding risk in patients with cancer-associated thrombosis
Status: Draft

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Other Information

Other Information

File Attachments

Click or drag files here to upload.

File Name	Size	Uploaded By	Uploaded Date

Upload Files Here

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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.

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Export History

Date and Time	Action	Performed By	Comments
30/9/25 2:30 pm	Initial Creation of Draft Data Request	Richard Anderson	Data Request for WV15758

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Open Chat

Communicate with Vivli staff, the Data Contributors, Independent Review Panel and the Research Team.

Send

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File Name	Uploaded By	Uploaded Date

Upload Files Here