Vivli

CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Vivli Data Request Form: Tips and Tricks

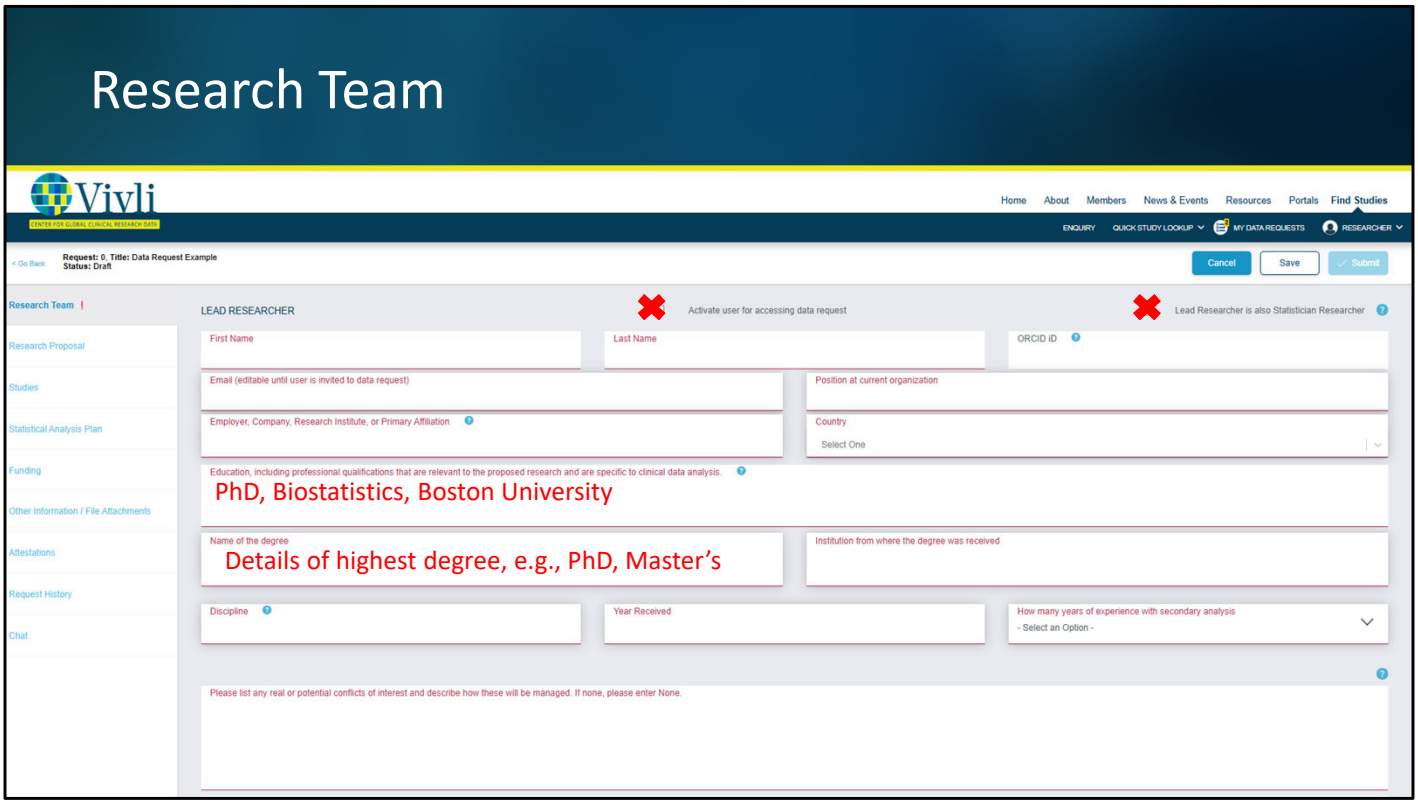
Platform Version 3.7

24 May 2025

What is the Vivli Data Request Form?

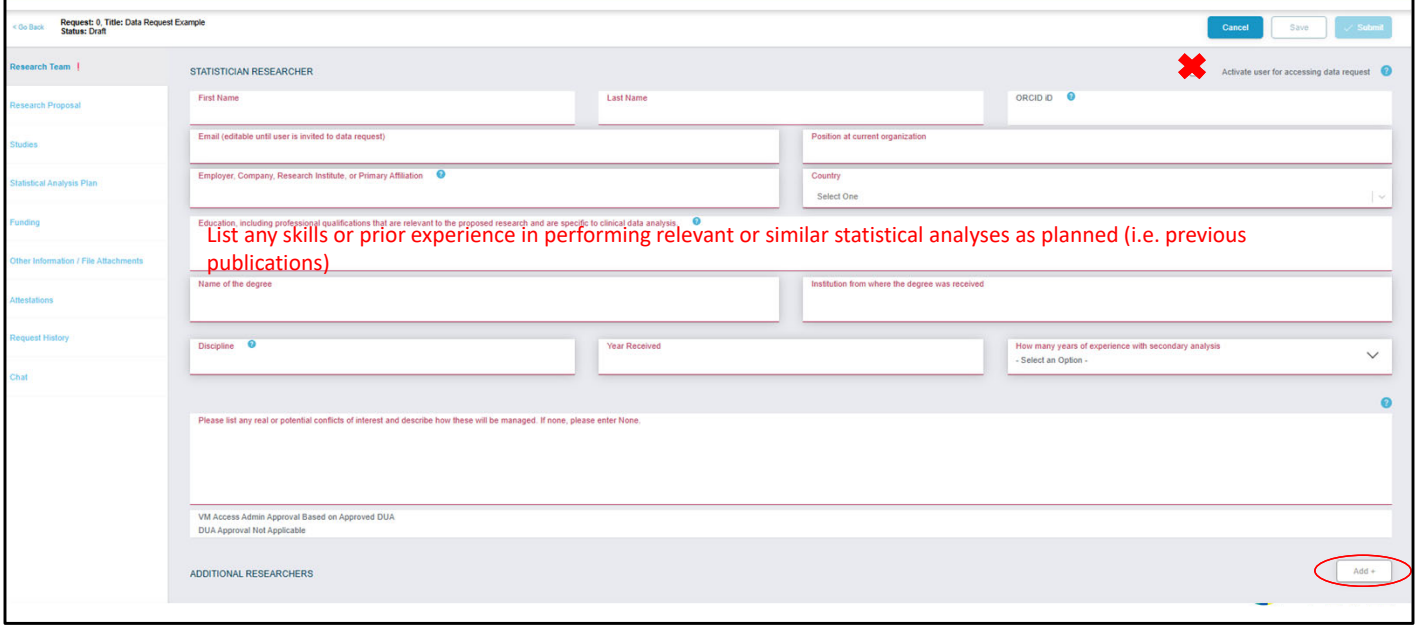
- The Vivli Data Request Form is used by data contributors and independent review panels to evaluate your proposal and make decisions on your data access for the studies requested.
- Each Vivli member describes the criteria and process for how they make decisions about the use of their completed clinical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

Research Team



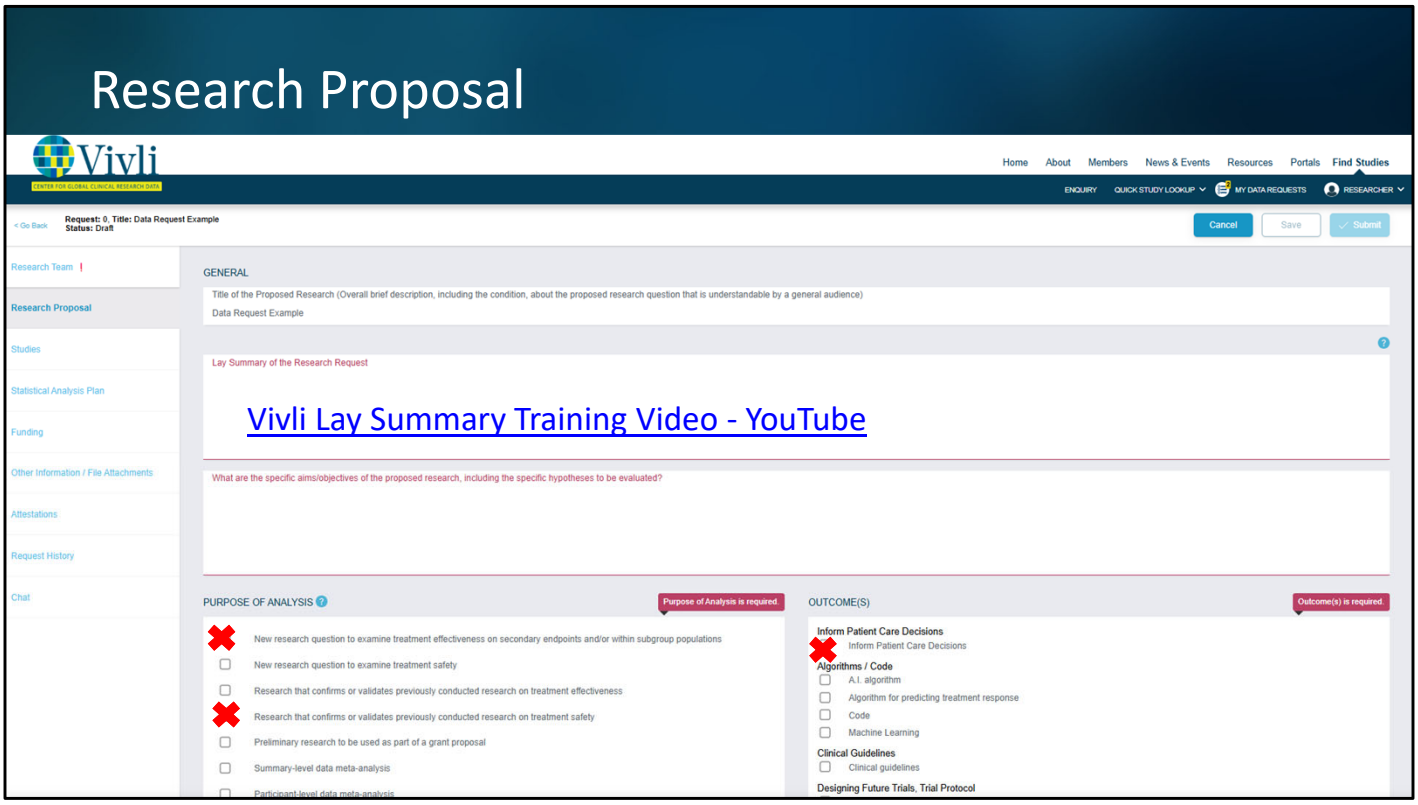
1) If the Lead Researcher and Statistician Researcher are the same individual, fill in the details under Lead Researcher and then click the "Lead Researcher is also Statistician Researcher" box.
2) For team members who will need to be able to access the data request on Vivli, click the "Activate use 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.

Research Team



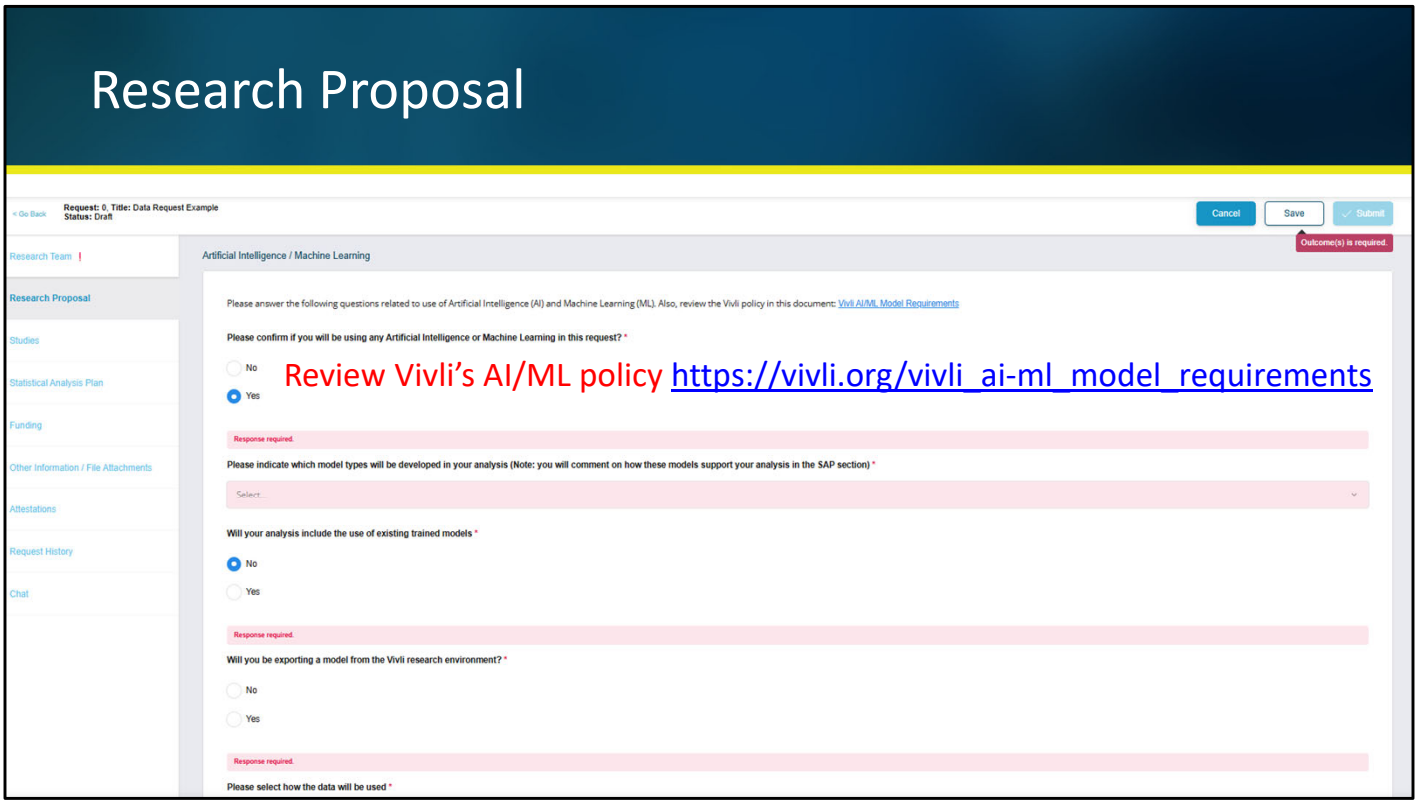
1) For the Name of the degree, institution from where the degree was received, discipline and Year Received, enter the details of your highest or most relevant degree, e.g., PhD or Master's. For the statistician this should ideally be in a statistical discipline.
2) If your statistician does not have 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



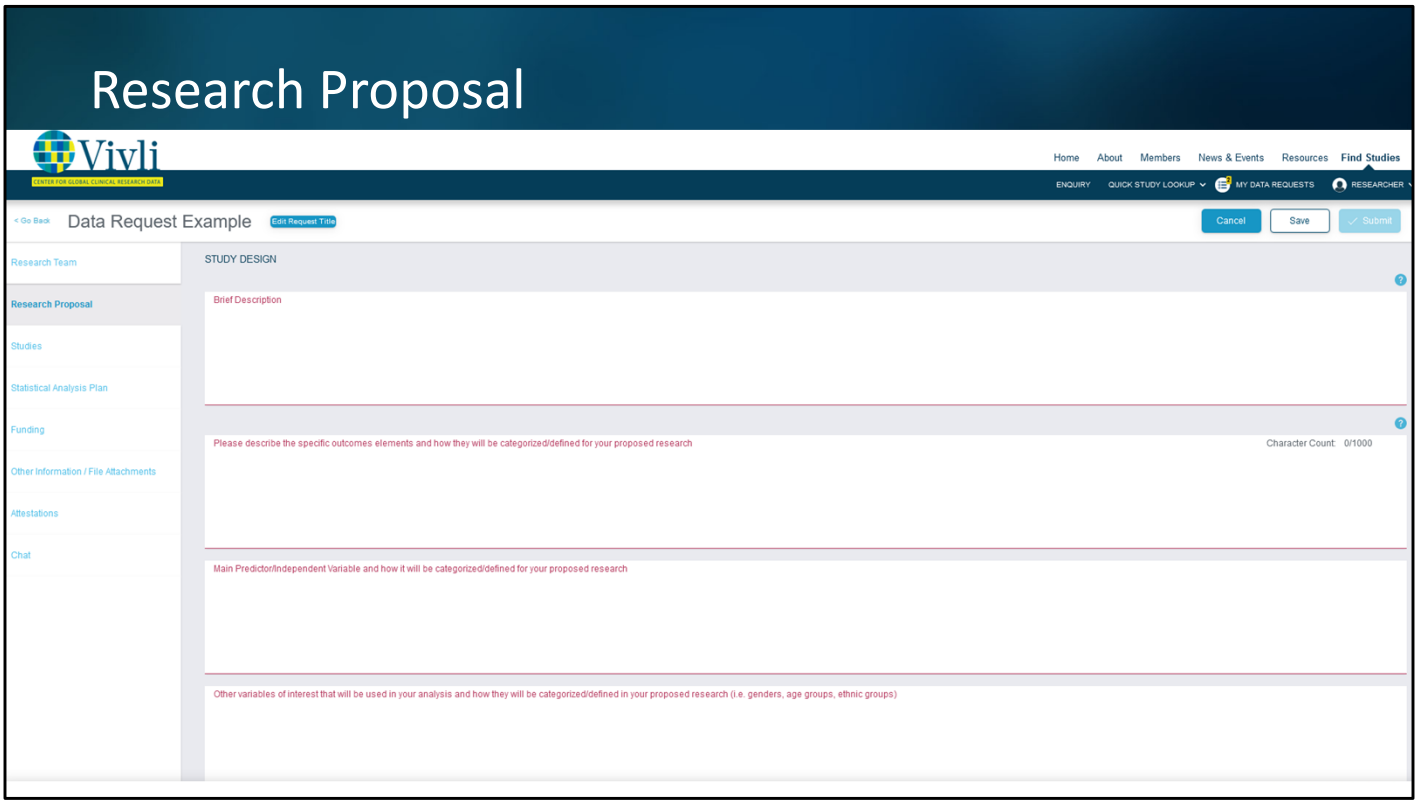
1) To update the name of your project on your dashboard, edit the Title of Proposed Research
2) In the Research Proposal section, you will fill out all relevant details of your proposal, including the title, narrative summary, aims and hypotheses. Please use the full form of any abbreviations in their 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.

Research Proposal



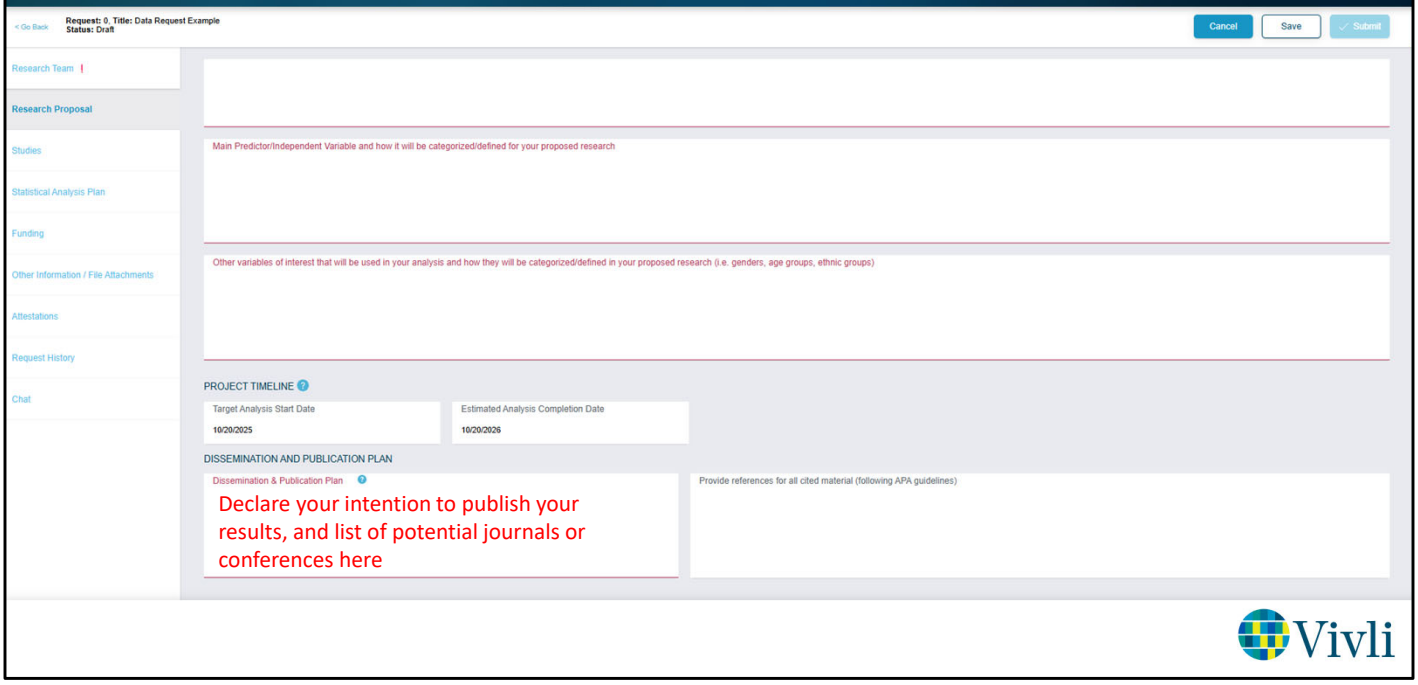
If your research will involve the use of artificial intelligence or machine learning, in the Artificial intelligence / Machine learning section answer the first question 'Yes' and complete all the questions that will then appear. Please review Vivli's policy for use of AI/ML here to ensure that your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

Research Proposal



The second half of the Research Proposal tab contains the Study Design section. All required fields are outlined in red. As a reminder, be sure to use the full form of any acronyms or abbreviations in their first use.

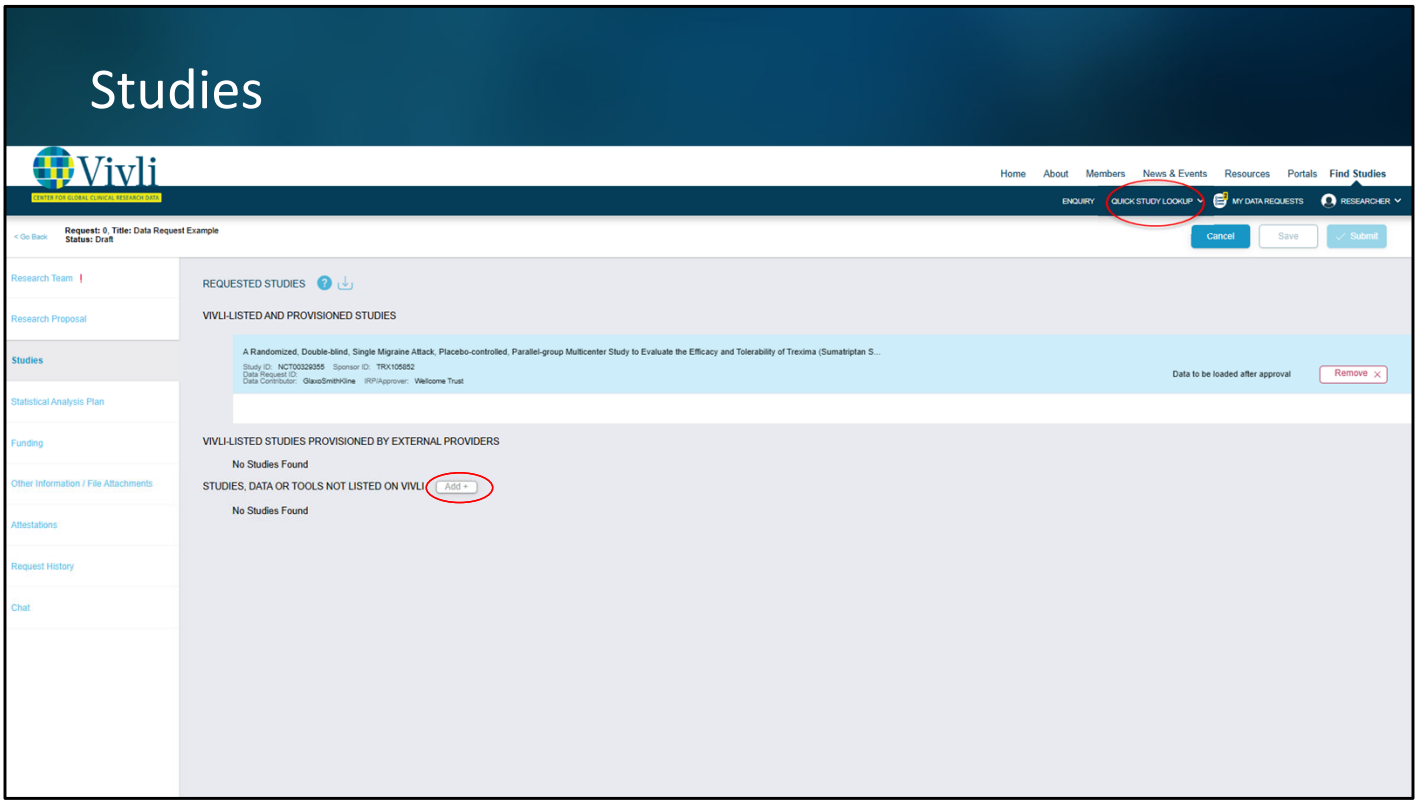
Research Proposal



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.

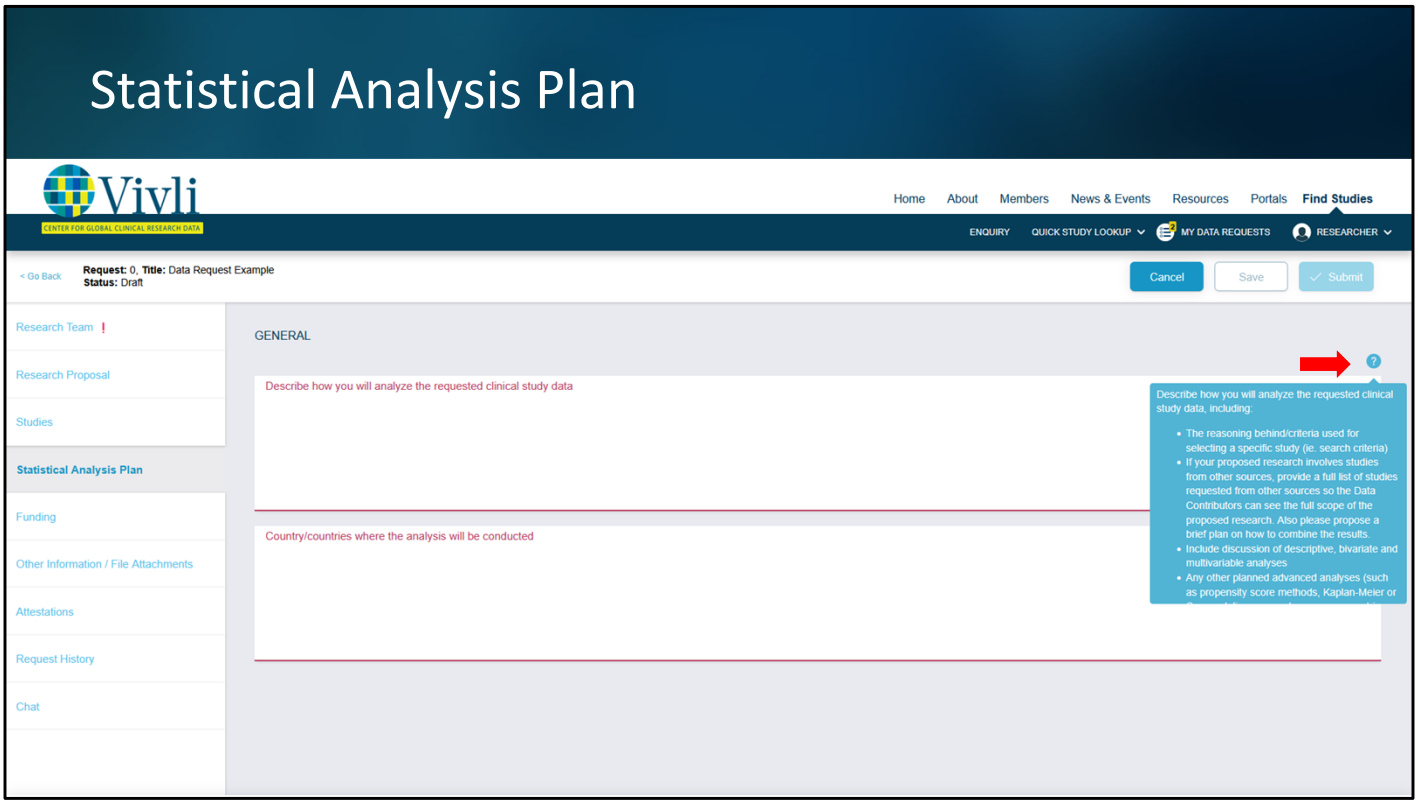
2) As per the Data Use Agreement, there is an expectation that the dissemination plan includes a definitive statement to publish and disseminate your findings to contribute to furthering scientific knowledge . Your dissemination and publication plan should include possible journals or conferences you plan to submit your research findings and should make the appropriate statements declarative of your intention to publish your research findings.

Studies



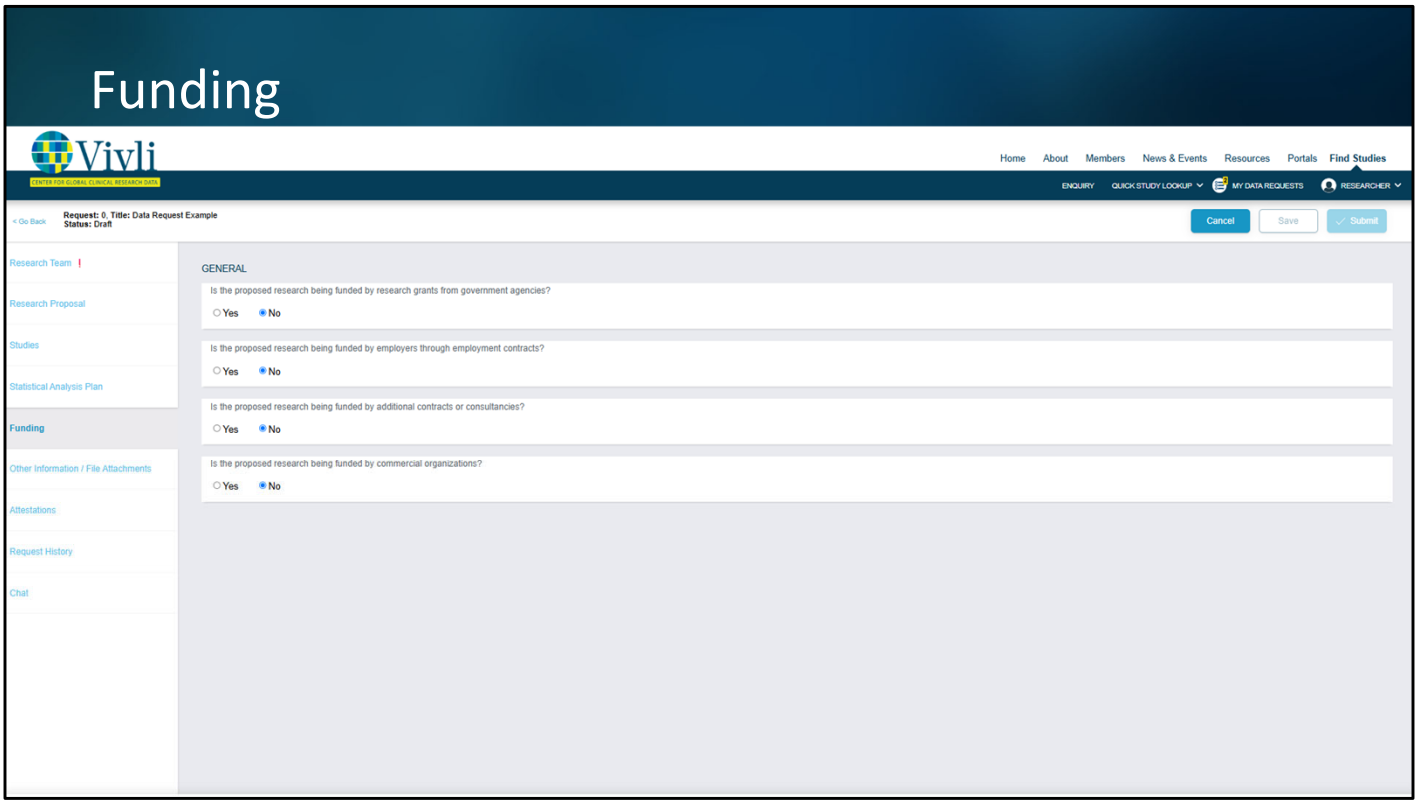
1. To add additional studies to your request while the request is in drafts, please use “Quick study lookup” option and type in the study ID. This is for studies already listed on the platform.
2. The Vivli platform has the flexibility for you to bring in data for studies that are outside of Vivli as 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



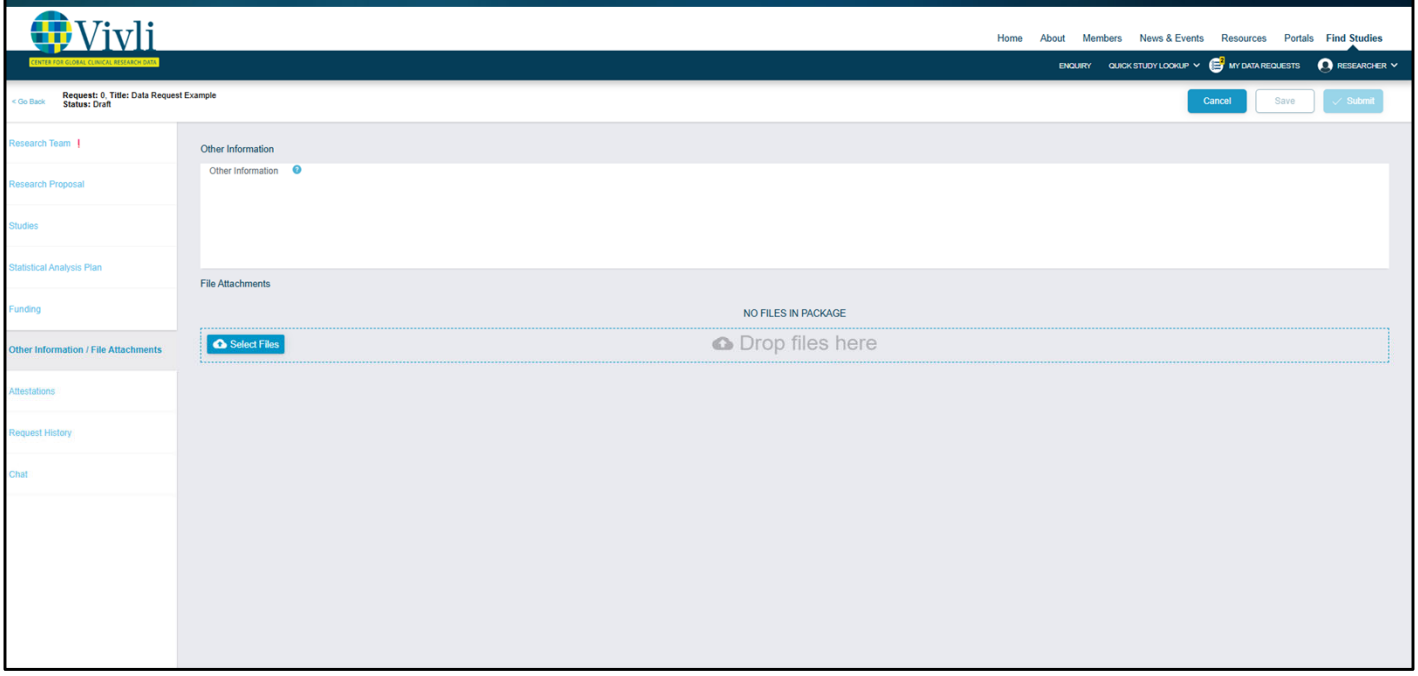
1. For the Statistical Analysis Plan, please describe how the analysis will be performed. The data request form contains help text for further guidance.
2. In the next field, include the country or countries where the analysis will be conducted.

Funding



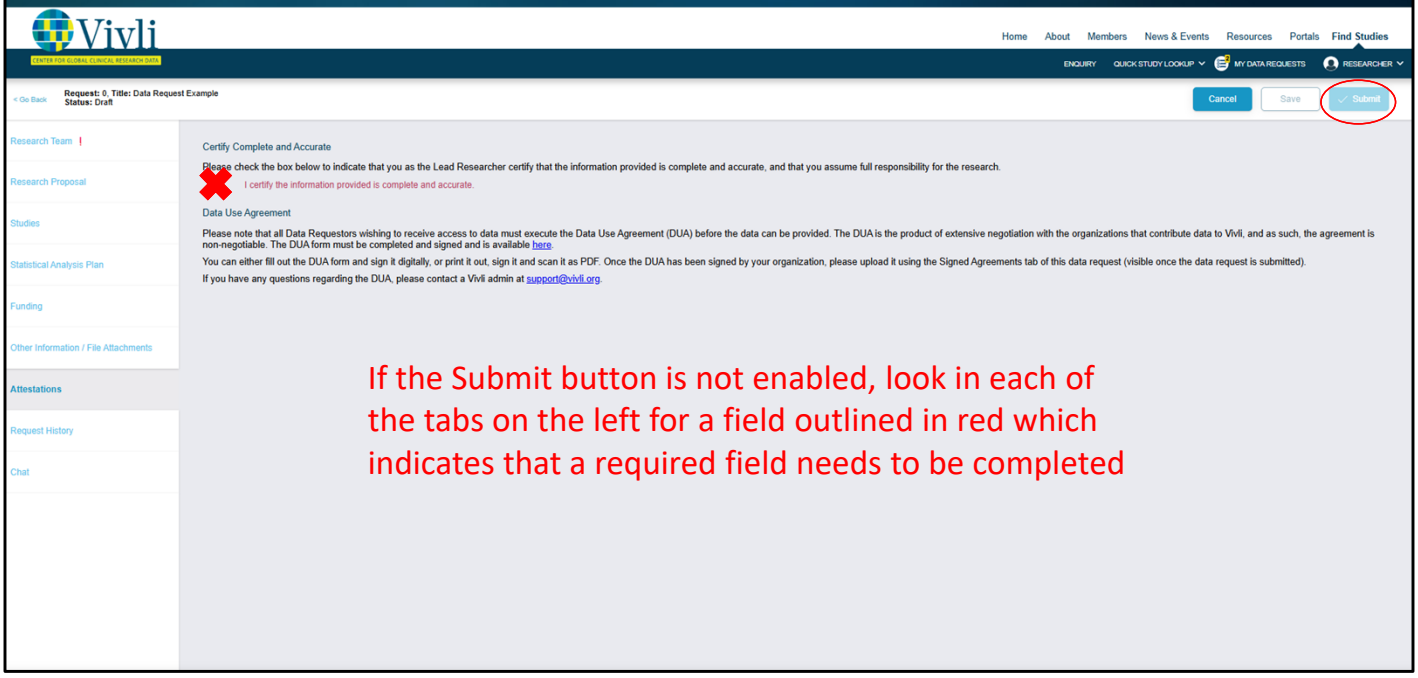
Answer yes or no to the four questions regarding the funding of the research proposal. If you respond yes to any of the questions, please provide further information, such as grant IDs or other funding identifiers.

Other Information / Attachments



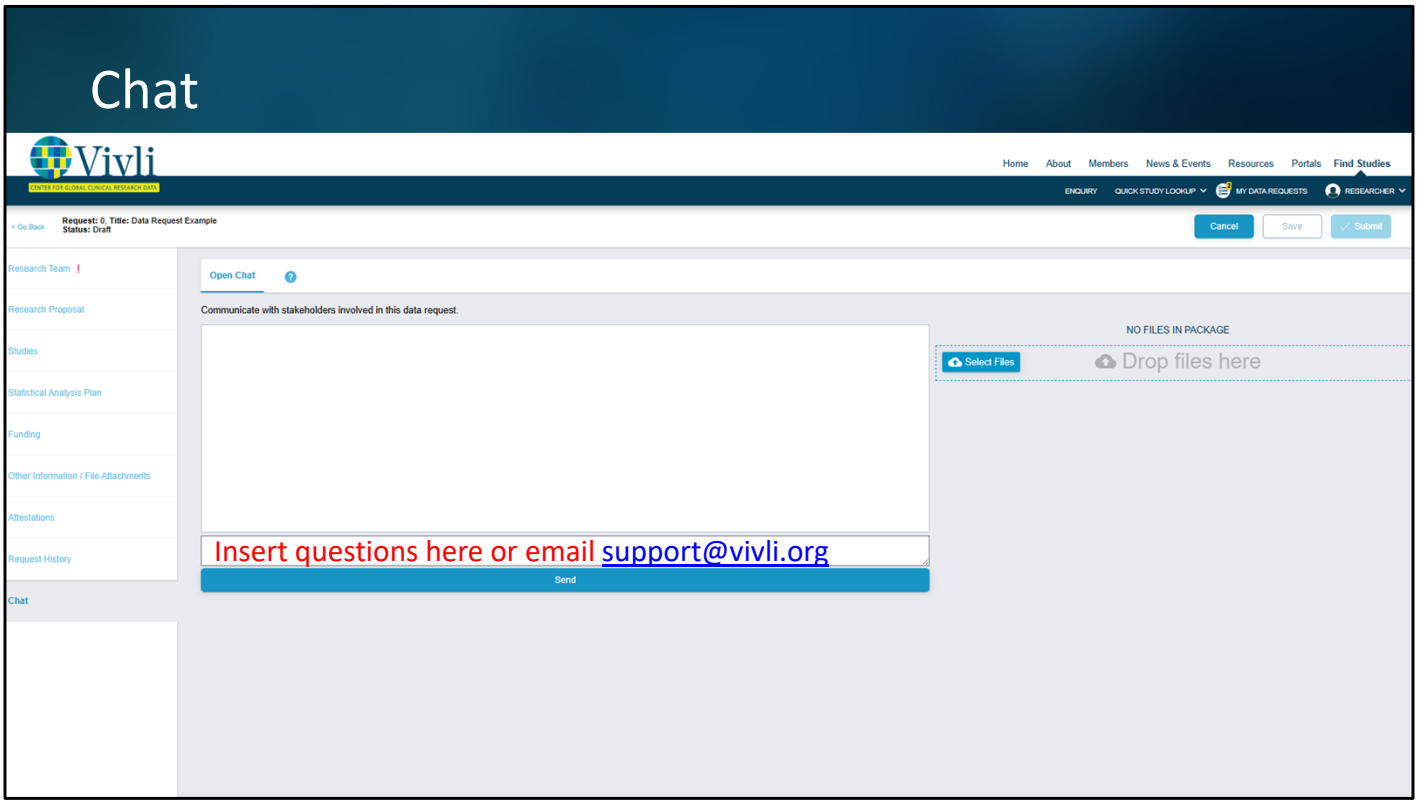
Use the “Other Information / File Attachments” tab to provide any additional information not covered in your Research Proposal. This may include references or other supporting documentation. You may drag and drop files into the file attachments section

Attestation



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.

Chat



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