Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

How-To: Request Studies on Vivli

Vivli Platform Release 4.0

27 June 2026

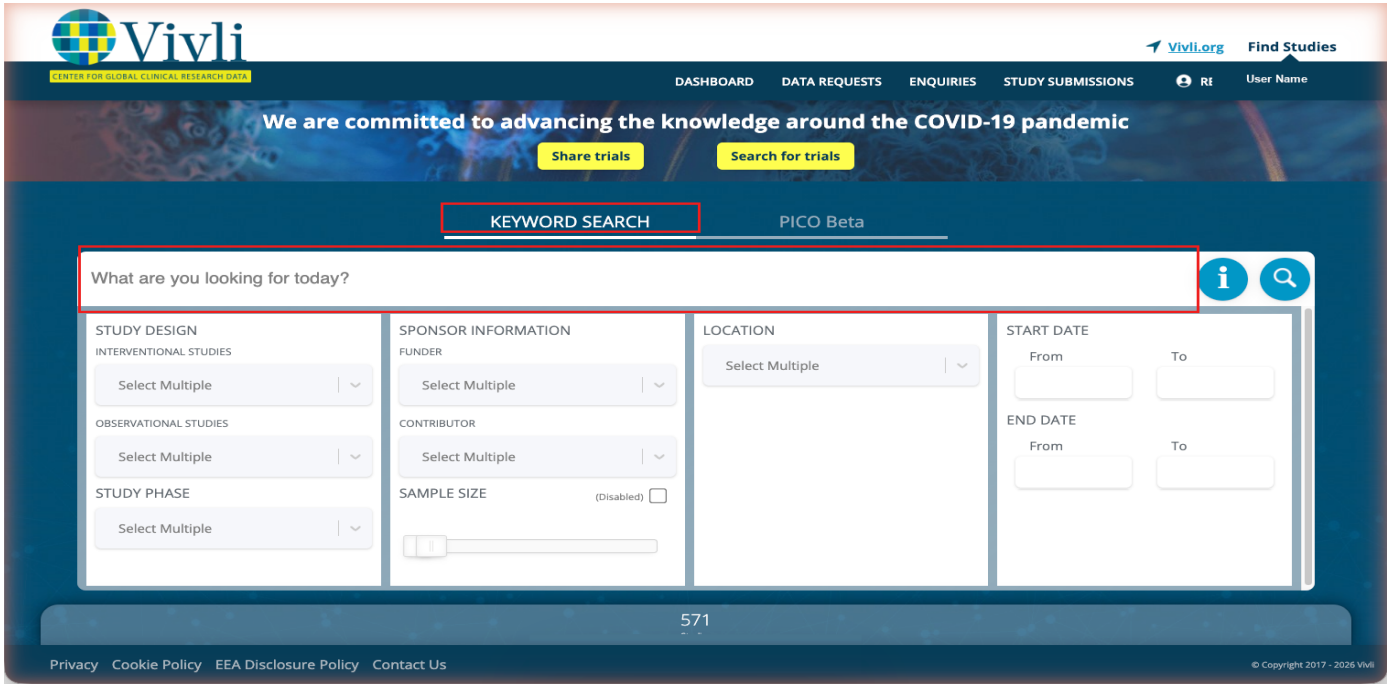
Contents

1.0 Requesting Studies on Vivli – Overview

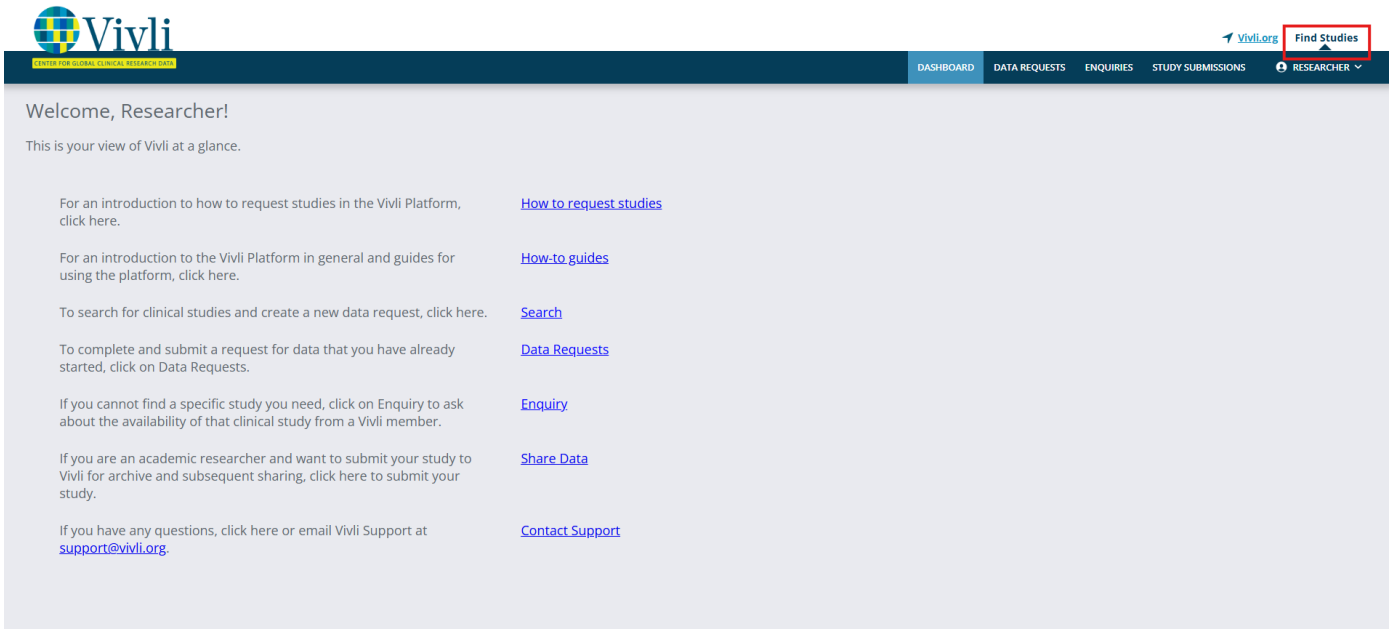
- The process starts with finding the studies you need – for assistance with the search, help is available on the Vivli site.
- Once you have completed your search, you may request the studies you would like to use for your analysis.
- To do this, you must complete a Vivli Data Request Form on the Vivli platform. You may use "Vivli Data Request Form Worksheet" to start drafting your data request form offline.
- Your data request will be submitted to all relevant Data Contributors for review, according to the Data Contributor's data-sharing policies and criteria.
    - To learn more about individual Vivli Members' data-sharing policies, please see the Vivli Members Page.
    - For an overview of the data request review process, please see the Vivli Platform Process Overviewhttps://vivli.org/about/data-request-review-process/
    - Please review the Vivli policies in brief about active requests and active enquiries before submitting a data request.

1.1 Searching for studies on the Vivli platform

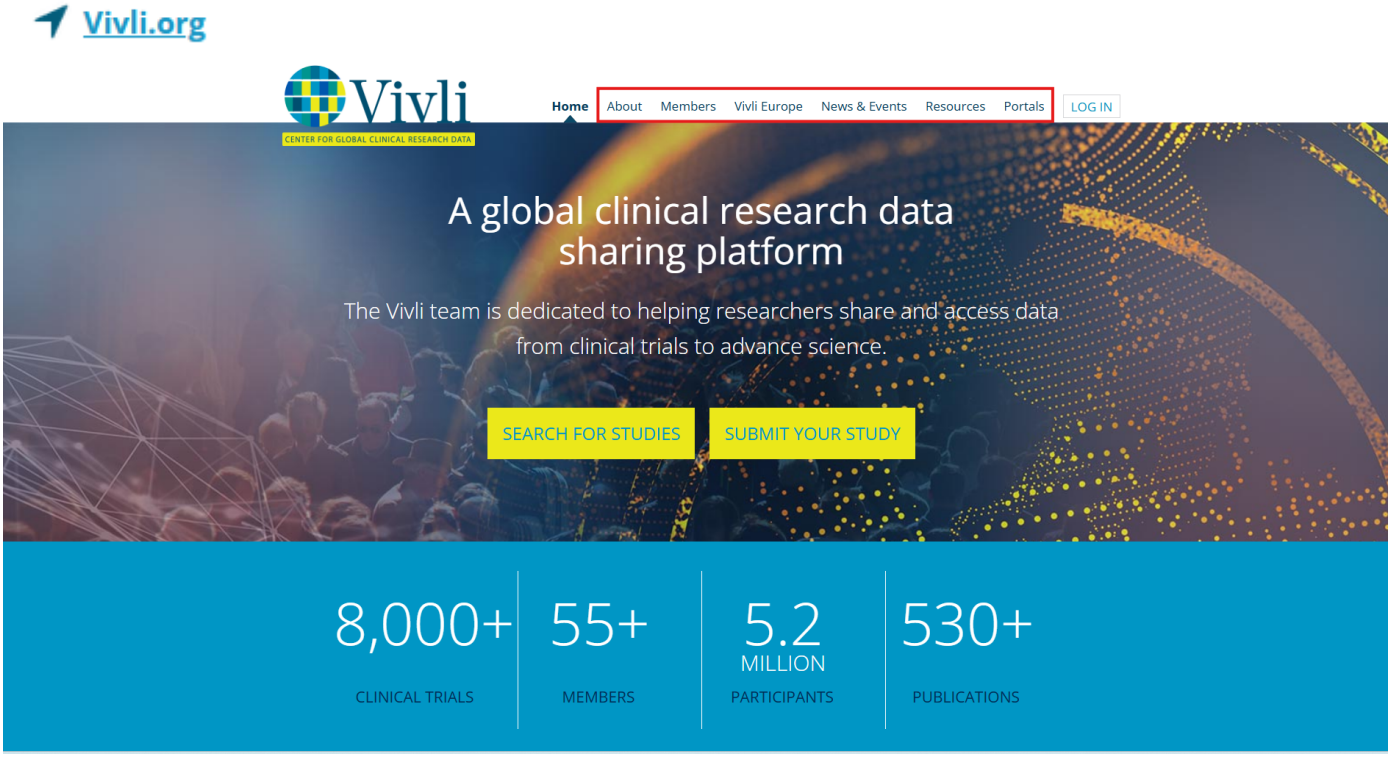
- To search for studies on the Vivli platform using the search page, *https://search.vivli.org/* enter a search term into the Keyword search bar where it says 'What are you looking for today', and/or use the drop-down filters:
    - Study Design (Interventional studies, Observational studies), Study Phase, Sponsor Information (Funder, Contributor), Sample Size, Location, Start Date, and End Date.



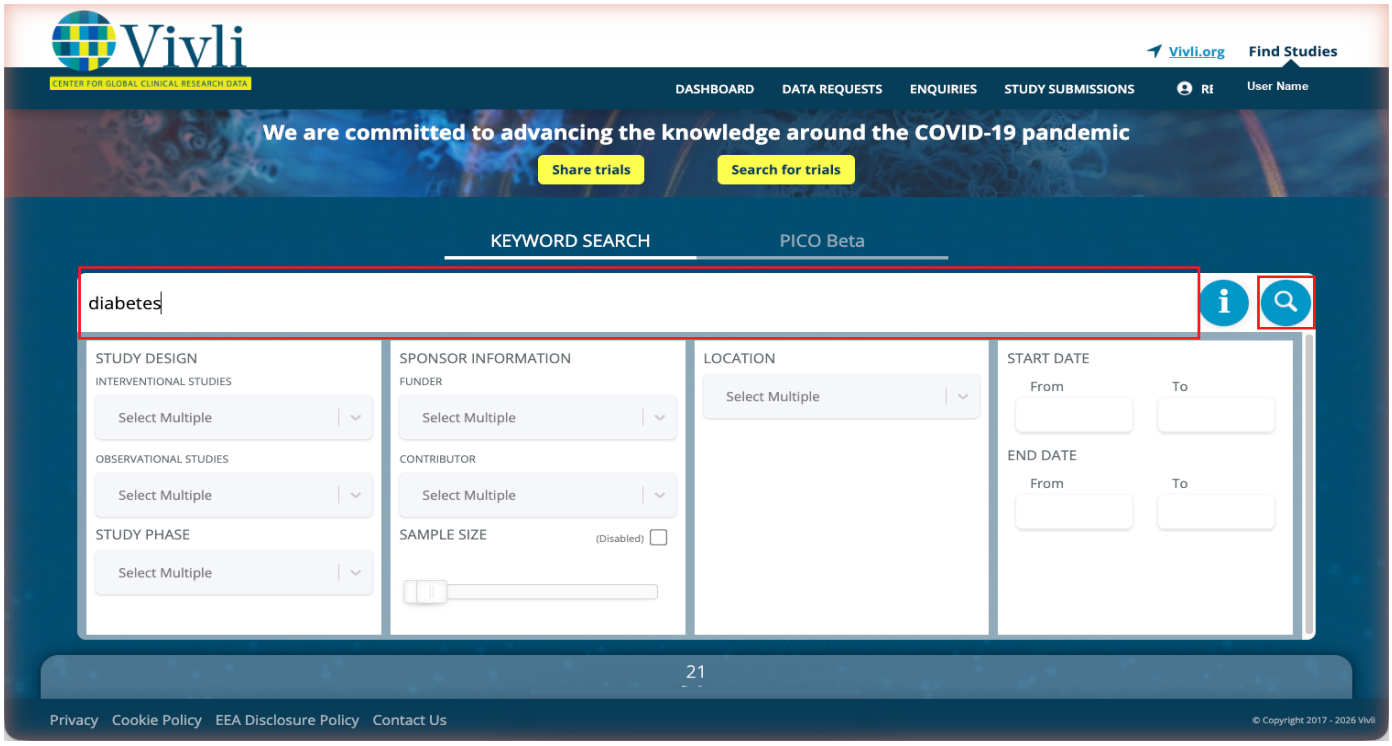
- When you are logged in, you can also click on 'Find Studies' from any screen. This will take you to the search screen above.



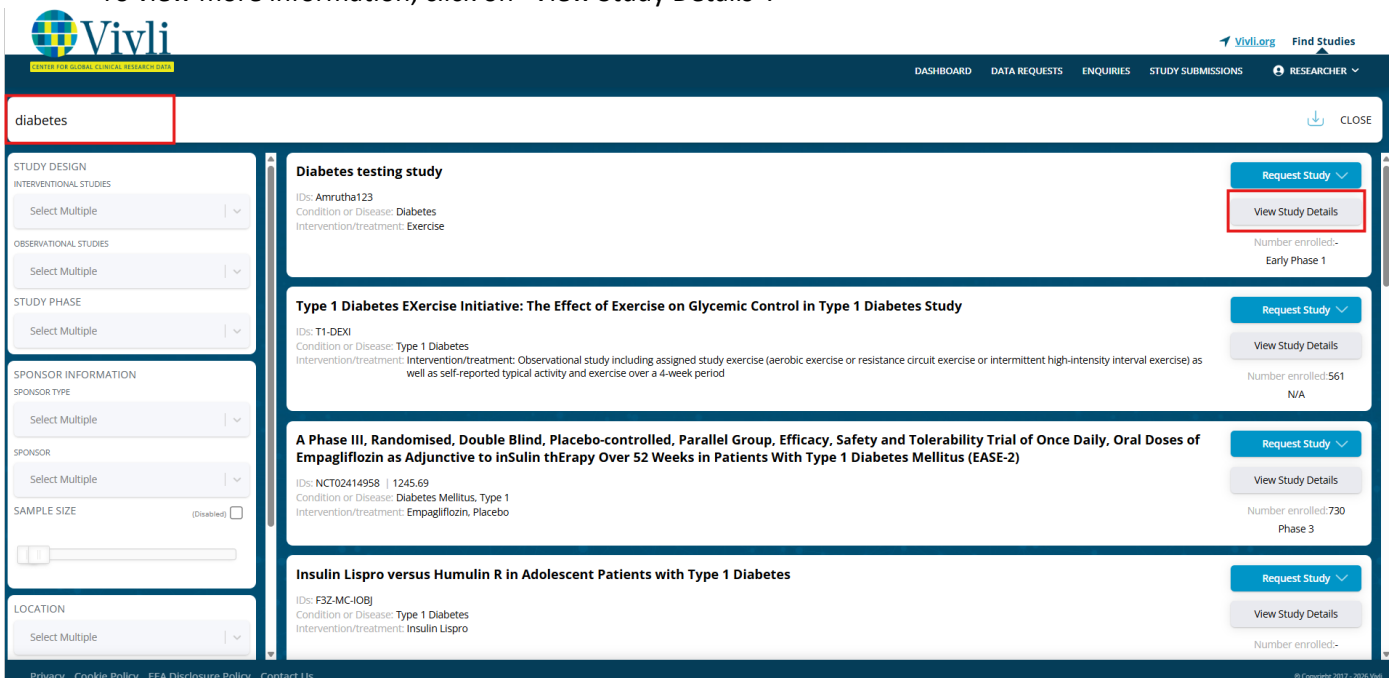
- Clicking on 'Vivli.org' in the top right corner of any screen will take you to the main Vivli website. From here you can explore the options in the top bar including the Members tab, which details our member's data sharing policies, and the Resources tab where you can find information on requesting data, sharing your own data, data use agreements, the secure research environment and more.



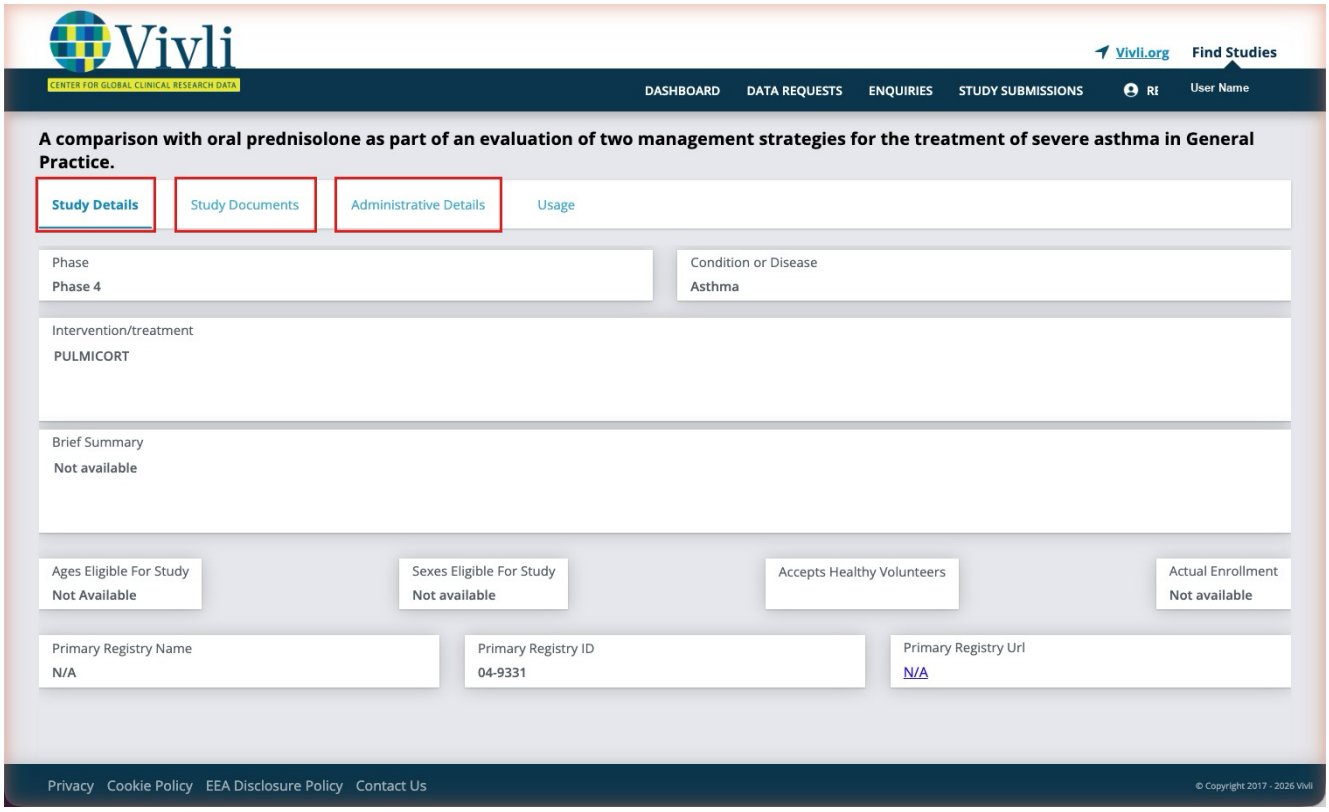
- From the Search screen, type in the keyword or study ID. The number of studies that include the search term will appear in the blue bar at the bottom of the page. If you click on the number at the bottom or the magnifying glass, it will take you to a list of studies including that term.



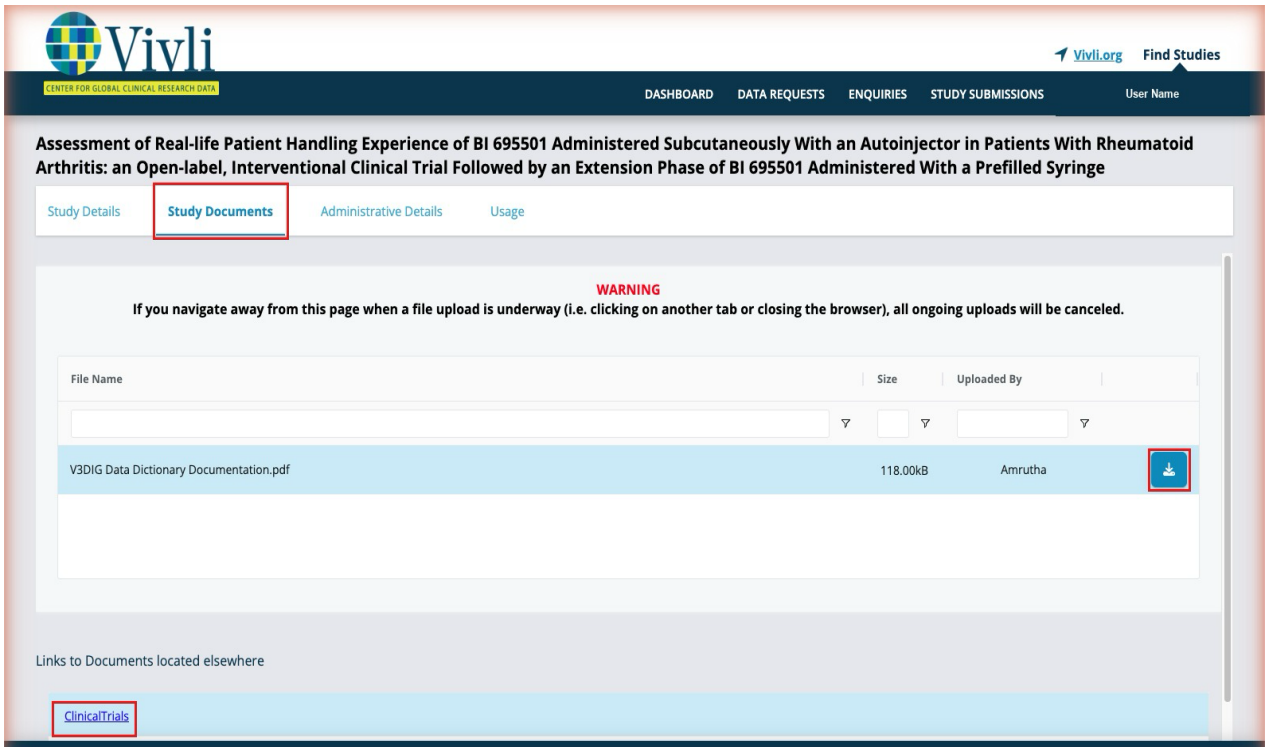
- To view more information, click on “View Study Details”.



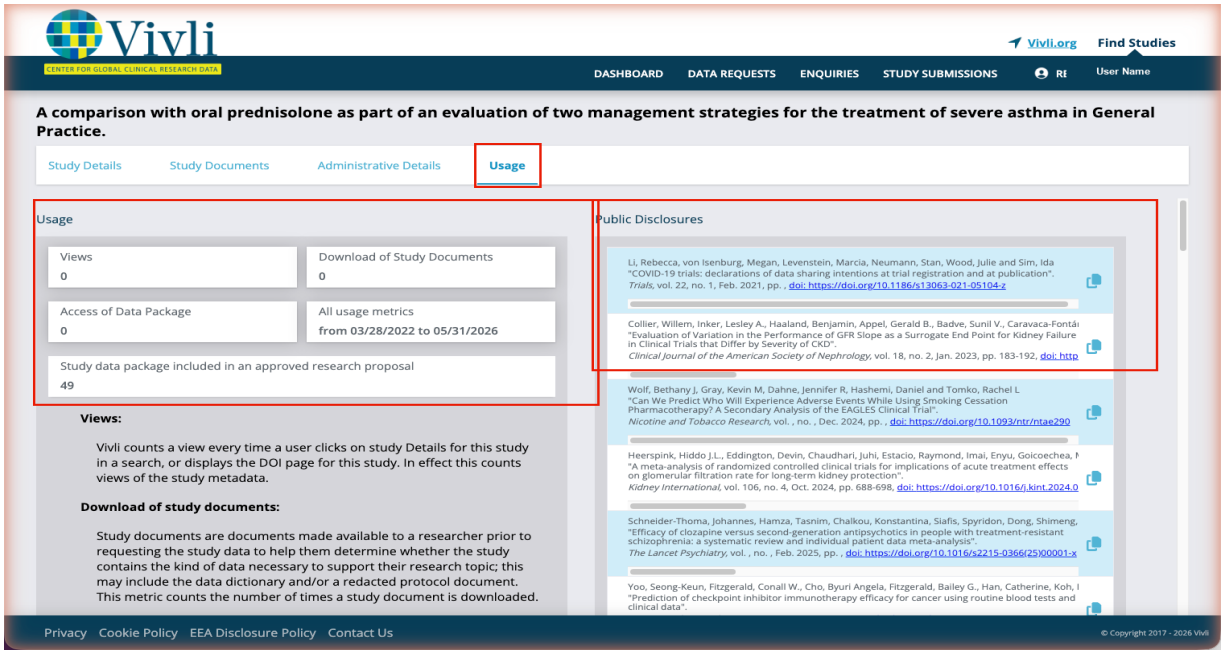
- You can find additional information about the study under the Study Details, Study Documents, and Administrative Details section



- Some members may make the supporting documents available for search. This will be available for download (once you create a Vivli user account) from the Study Documents section



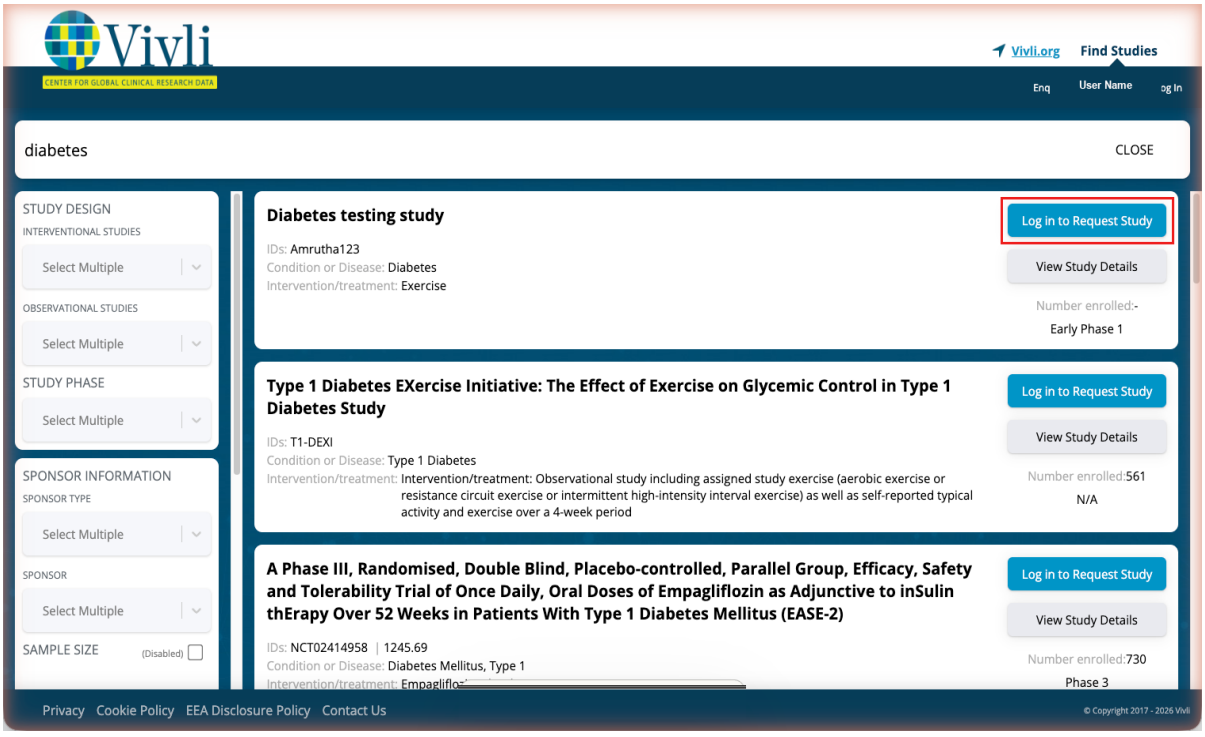
- Metrics on the usage and public disclosures involving studies (originating from Vivli data request) are available in the “Usage” section



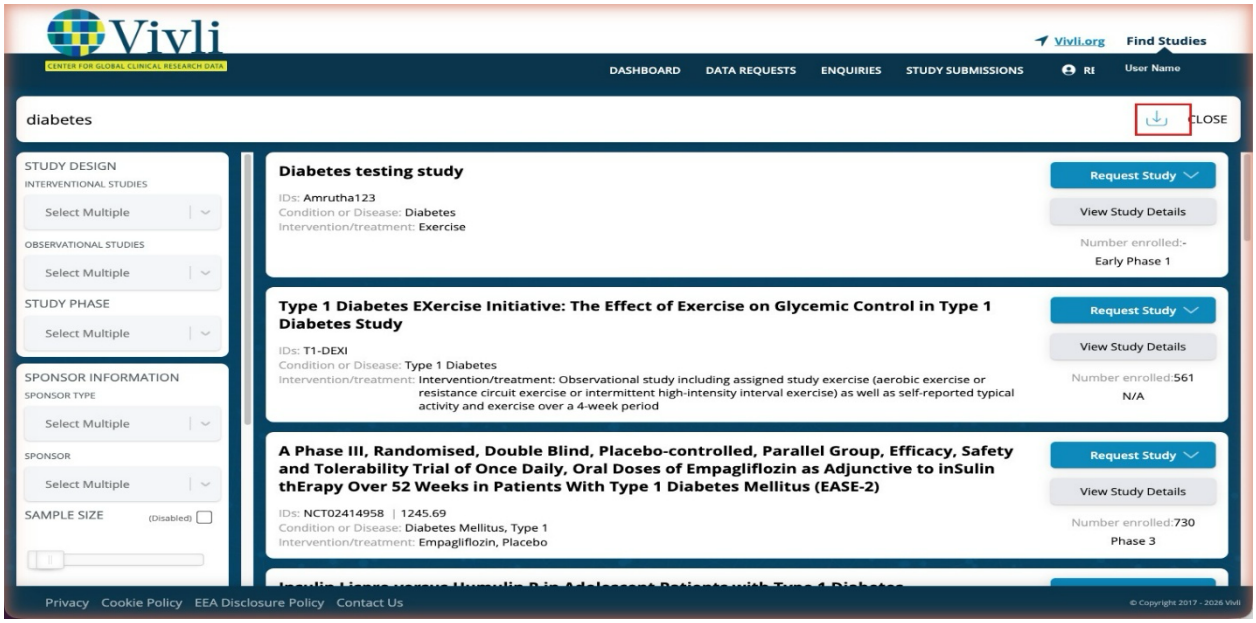
1.2 Login/Account Setup

- You must be logged in as a Vivli user to begin your data request.
- If you do not have a Vivli account, you will need to set one up before beginning a data request. To learn more about creating a Vivli account, please review our Vivli User Account Quick Start guide.

If you are not logged in, you will be prompted to do so. After you log in, you will return to the search results window:



For anyone with an Active Vivli Account, a download button is available on the search results page, to the left of the "Close" link.



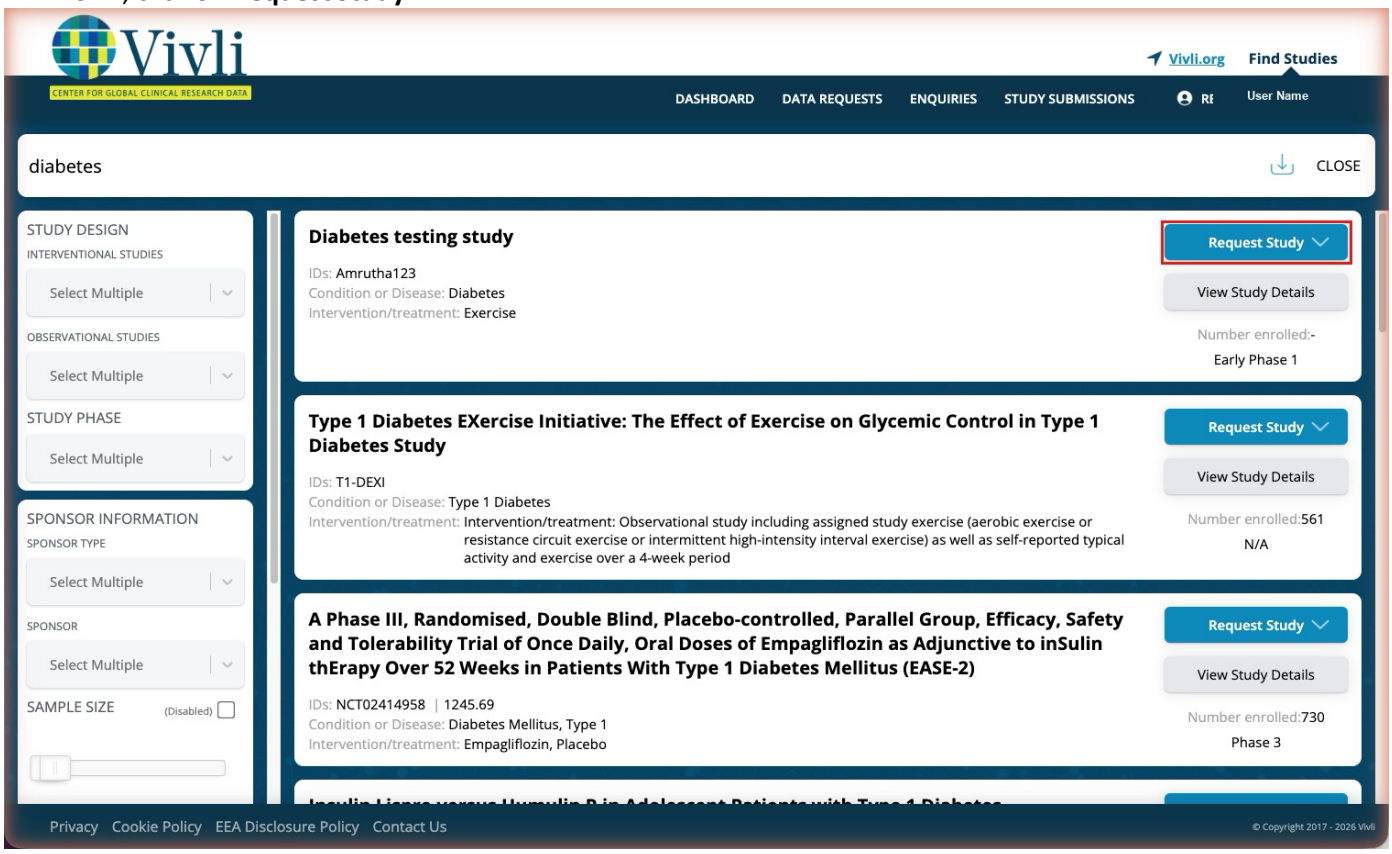
Clicking the download button will initiate a download of a CSV file containing one row for each entry in the search results, with the following columns:

- NCTID
- Sponsor Protocol Id
- Title
- Acronym
- Condition or Disease
- Intervention/Treatment
- Therapeutic Area
- Phase
- Number Enrolled
- Contributor
- Lead Sponsor Agency
- Funder
- Data Accessibility
- Data Availability
- Primary Registry URL
- URL to Request Study from Sponsor
- Other Resources for Study
- Primary DOI
- Brief Summary
- Additional Information
- Ages Eligible For Study
- Sexes Eligible For Study
- Accepts Healthy Volunteers
- Locations (of Study sites)

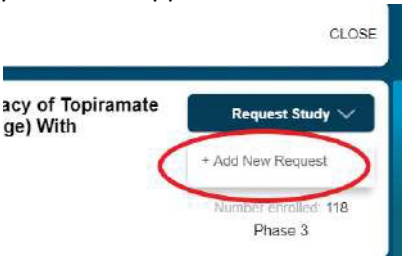
- Public Disclosures
- Vivli URL
- Study Posted Date

1.3 Add studies to your data request

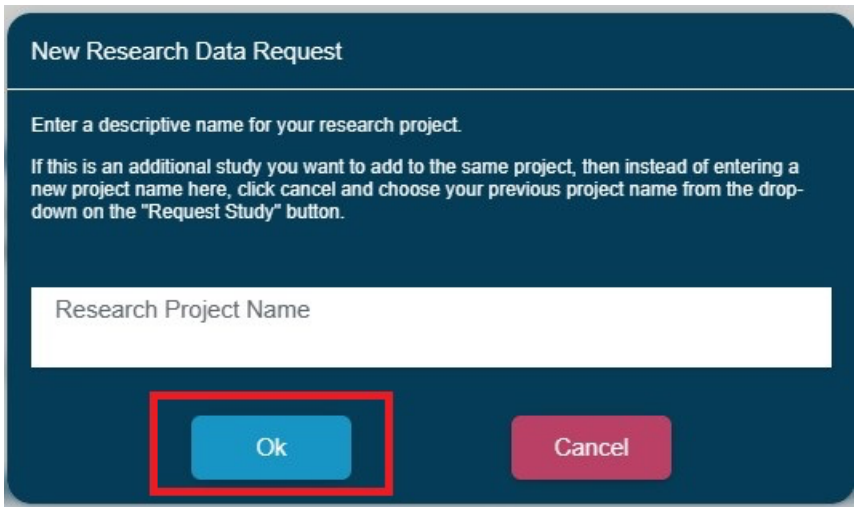
1. Starting a data request begins with the addition of studies. To add studies from a search to a Data Request Form, click on **Request Study.**



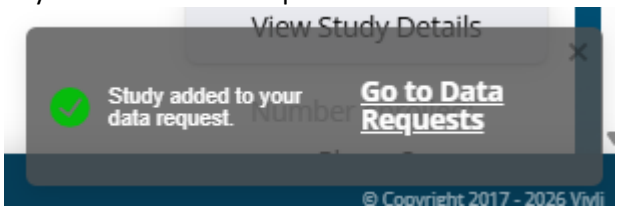
2. A dropdown will appear - click on +**Add New Request:**



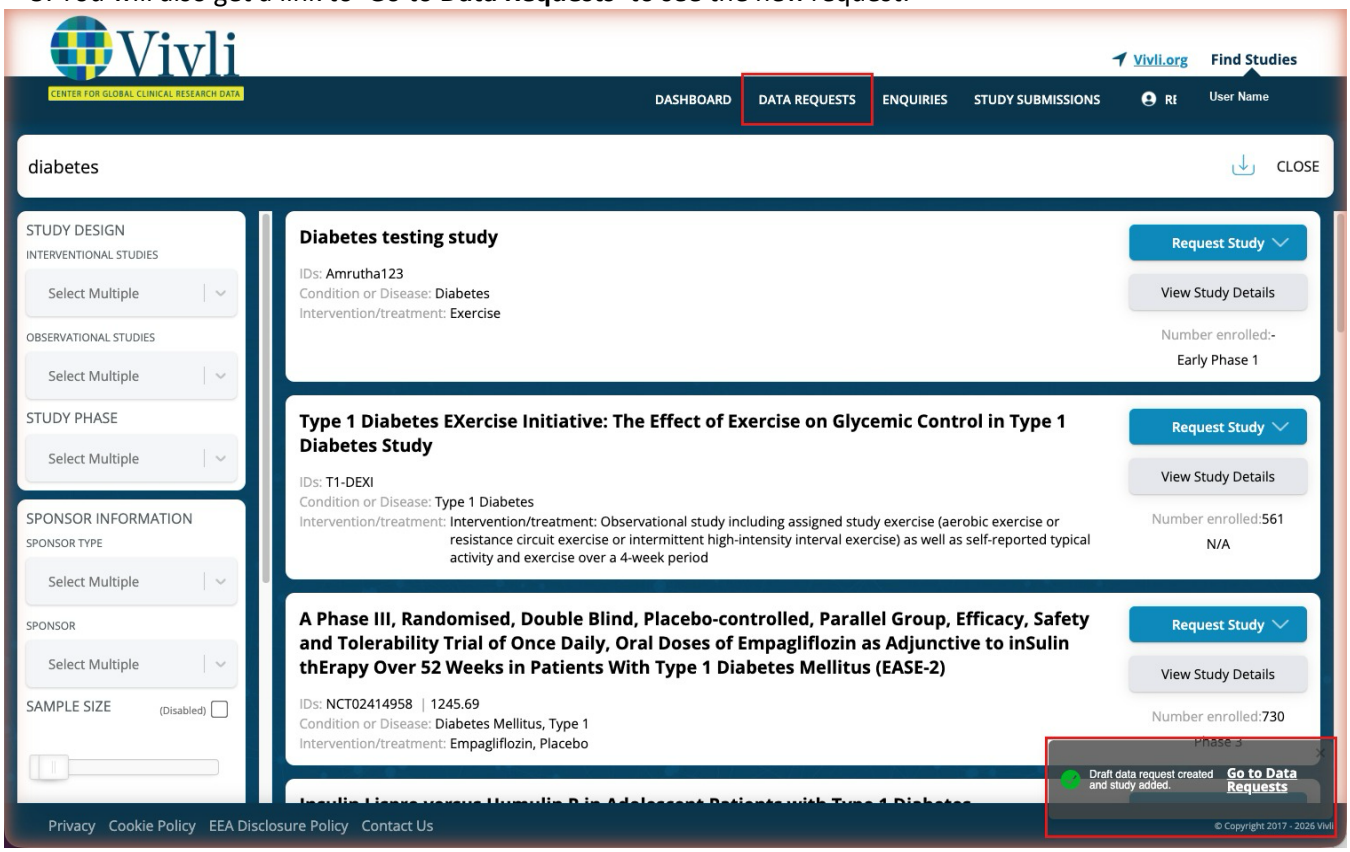
3. A dialogue box will pop up where you can provide the Research Project Name for your research project. **Note:** Your project name must match the "Title of Proposed Research" within the data request form. This can be edited before submitting the data request for review. After entering a research project name, click **Ok** to create the data request.



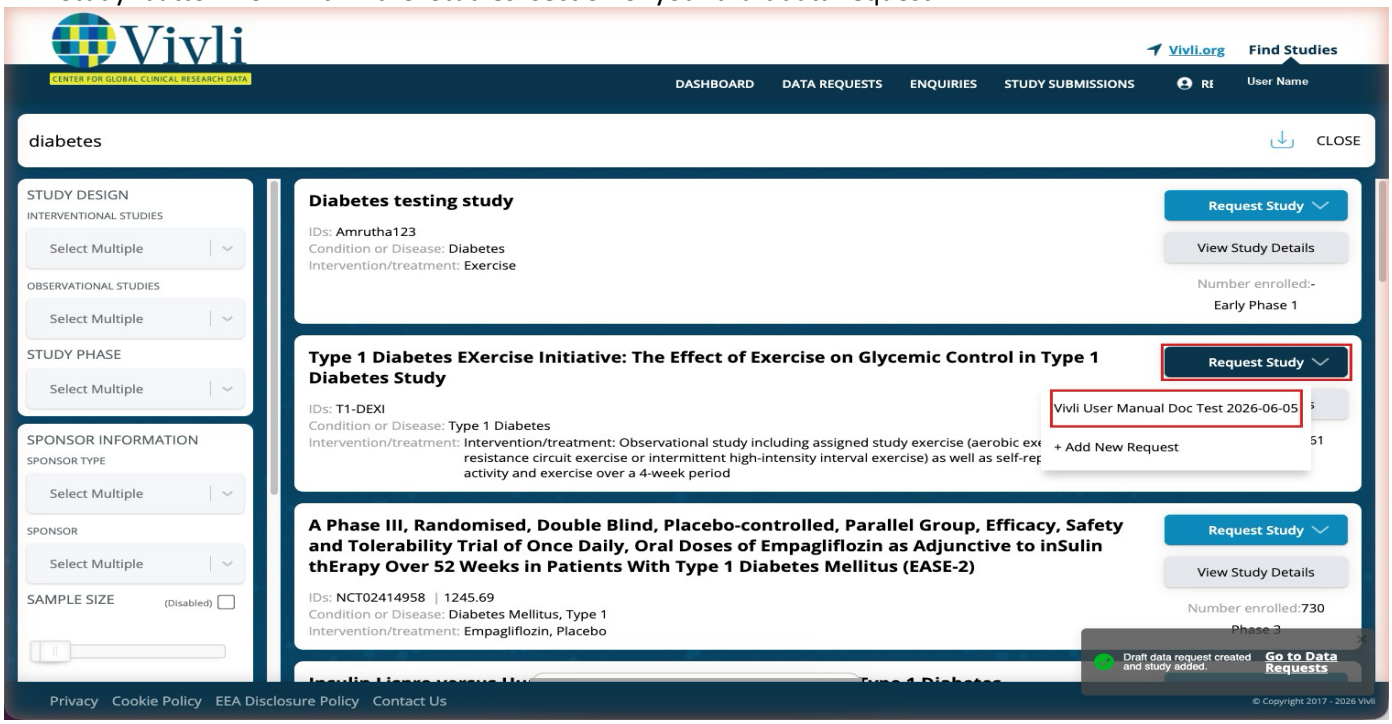
4. A pop-up will briefly appear at the bottom of the screen, indicating that you have successfully added the study to the new data request:

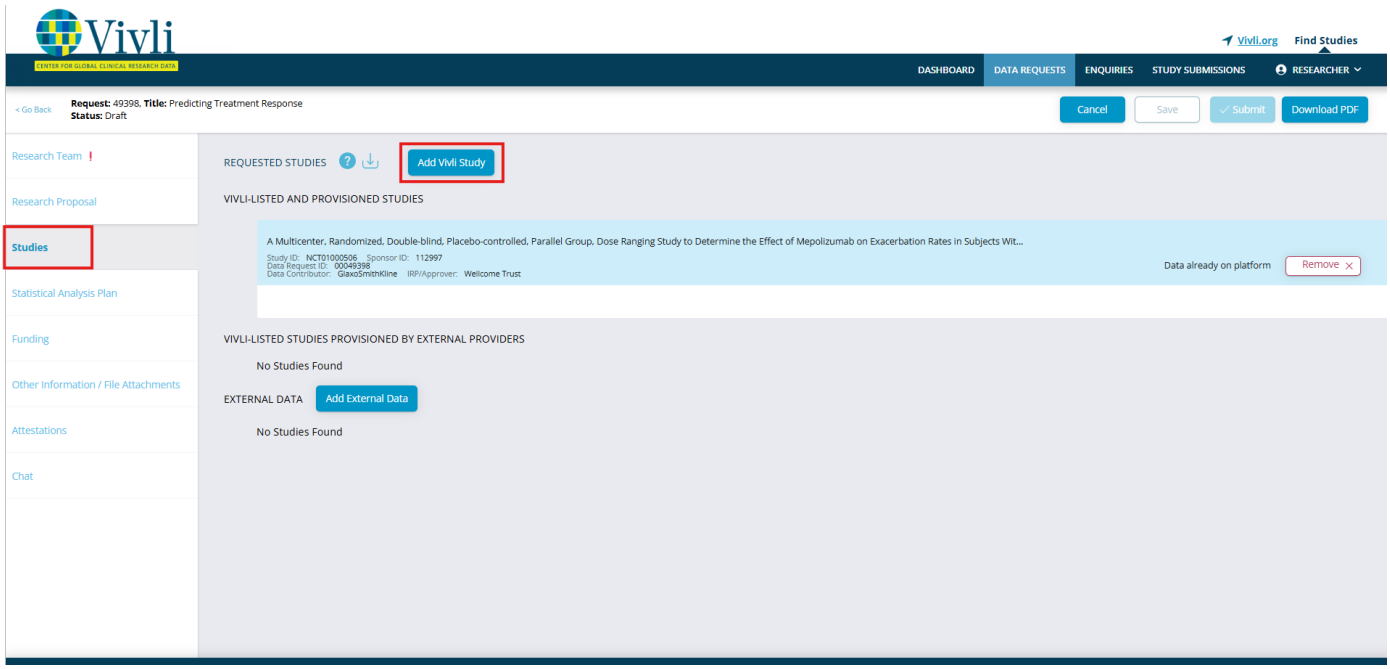


5. You will also get a link to 'Go to **Data Requests'** to see the new request:

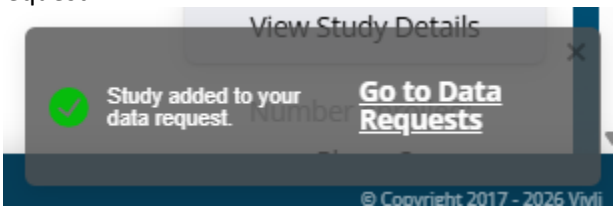


6. To add a study to an existing data request, click on **Request Study.** Then click on the existing data request's title from the dropdown. Note: If you have multiple studies to add to your research project, you can add them to the same request by repeating this step for each study you want to request, or by clicking on the 'Add Vivli Study' button from within the 'Studies' section of your draft data request .





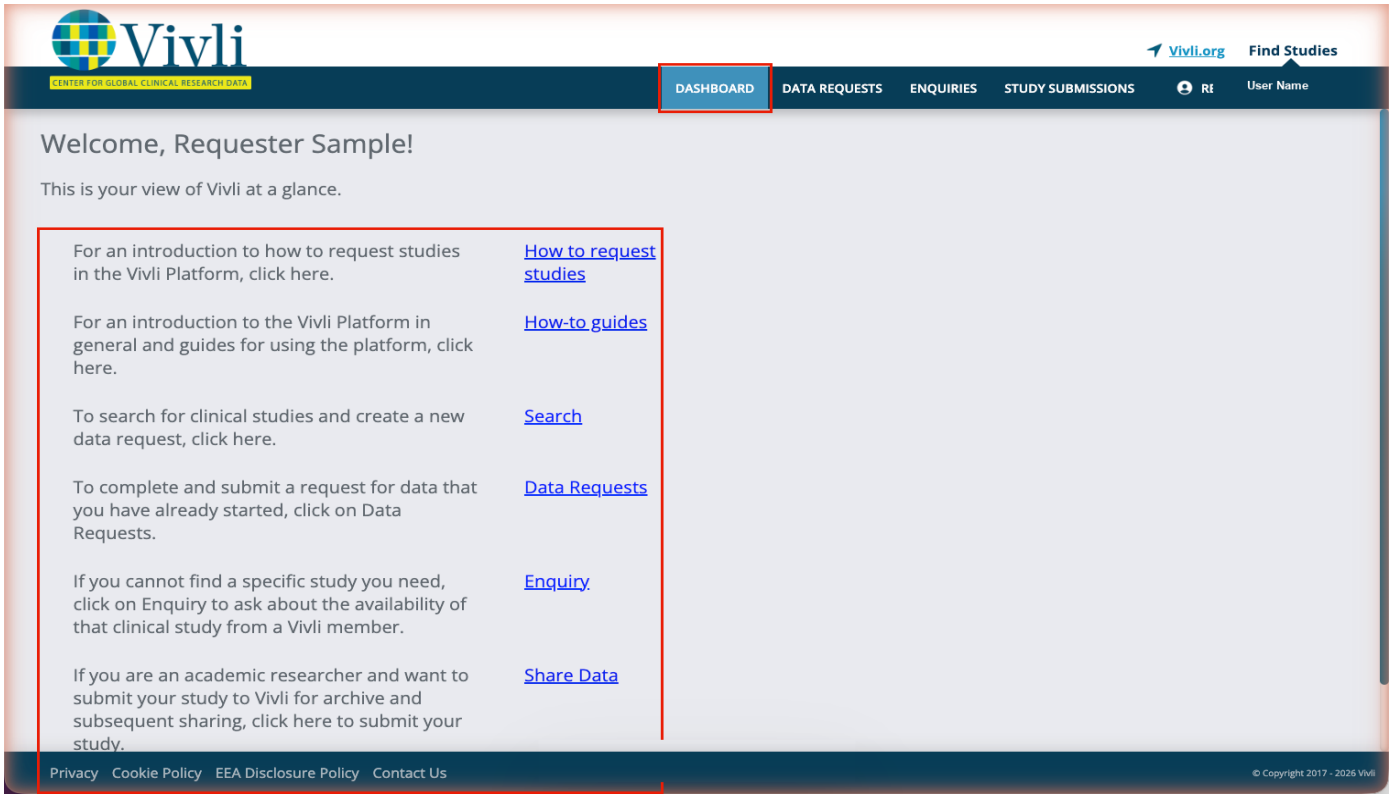
7. You will receive the same pop-up notification indicating that the study was added to your existing data request:



8. Once you have added all desired studies listed on the Vivli platform, you can complete the Data Request Form (See Section 2.0 Your Data Requests for more information).

1.4 Dashboard

Your dashboard contains your name and links to Vivli resources that may be helpful in submitting your data request.



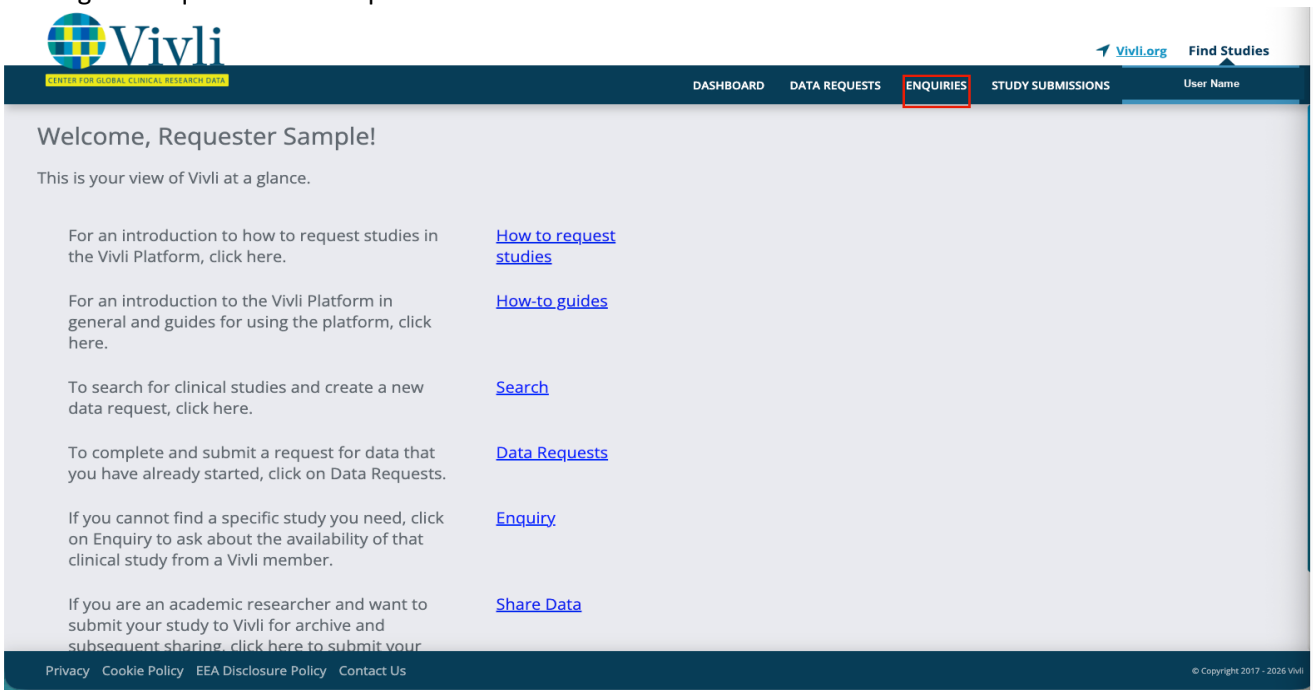
To edit your display name, please see Section 1.3 'Edit display name in profile' of the Vivli User Account Quick Start guide

2.0 Your Enquiries

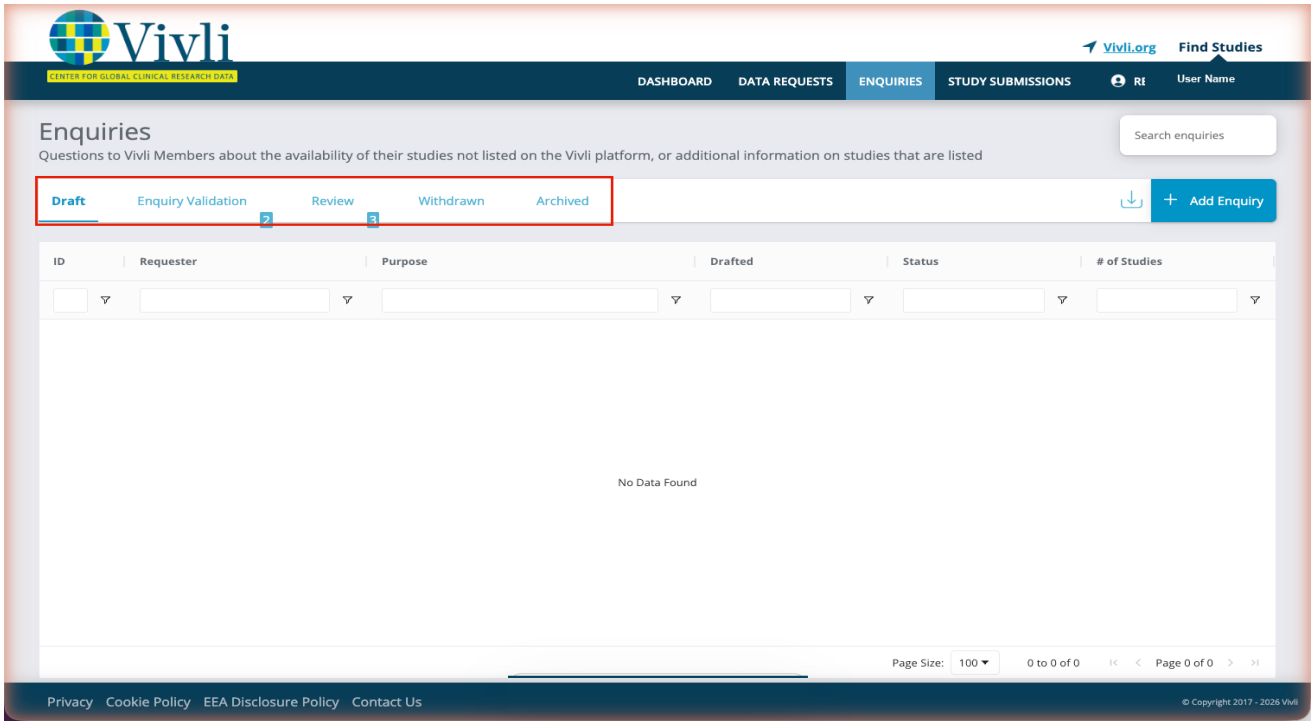
1. You can submit an enquiry using the Vivli platform https://search.vivli.org/enquiries/ regarding the availability of a Vivli Member study not listed on Vivli or for additional study information not included in a study listing.
2. The Enquiry tab allows Vivli and Data Contributors to receive, respond, and track enquiries.
3. Please fill out one Enquiry form for multiple studies that will be part of one research project, even if the studies are from multiple Vivli Members.
   i. For more information on Vivli Members, please visit the Member Page. Some Vivli Members may require that enquiries be submitted via their own portals. Enquiries will be answered at the discretion of the Member. Please note that most members do not share studies where the primary completion date has not yet been reached.
4. To create an enquiry, you must have a Vivli account. Please see Section 1.2 Login/Account Setup to create a new account
5. When submitting your enquiry, please ensure that you provide your full name as part of the submission process.

2.1 Navigation and Enquiry Overview

1. Once you have logged in to the Dashboard, you can navigate to Enquiries using the 'Enquiry' link or by clicking on 'Enquiries' in the top toolbar.

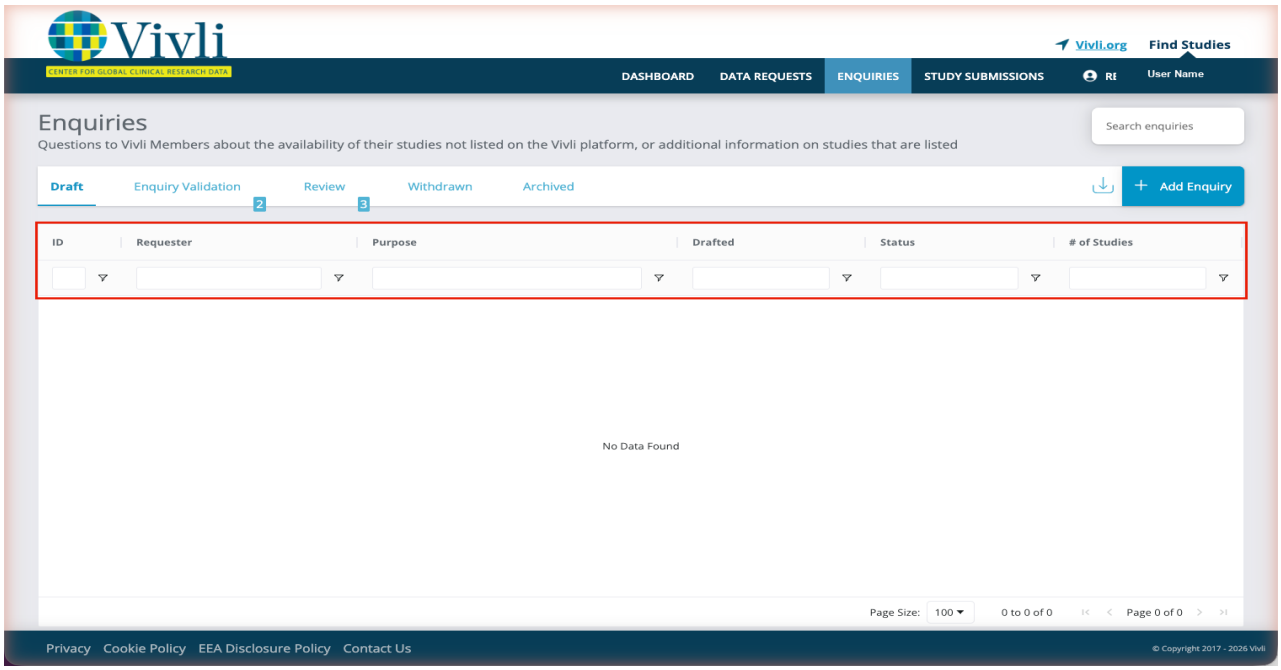


2. The Enquiries Overview displays a status bar at the top of the page which displays all the Enquiries you have submitted



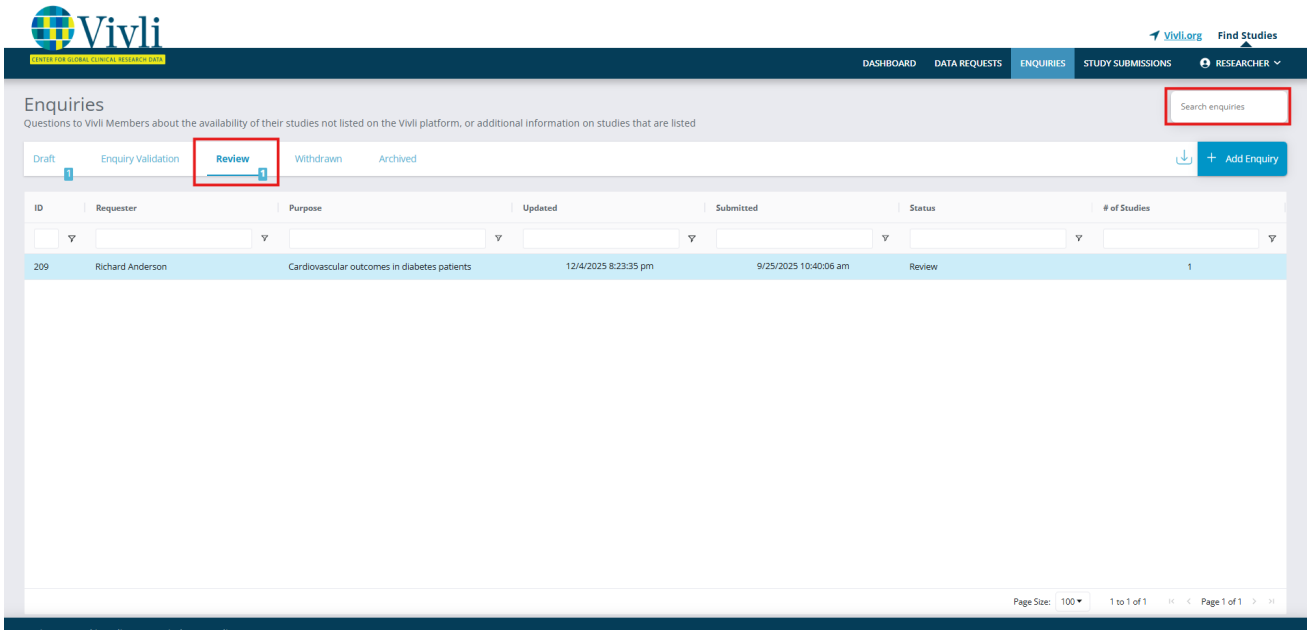
3. The status bar contains 5 sections, and you will receive email notifications for any updates:
Draft: Displays Enquiries that are being drafted but not yet submitted.
Enquiry Validation: Displays Submitted Enquiries that are in Vivli's review. The Vivli team may request additional information, return the enquiry to Draft for any revision, or may process it forward for Data Contributors' Review. You will receive an email notification for any updates.
Review: Displays Enquiries that are in review by the Data Contributors. It also includes Enquiry where decisions are made.
Withdrawn: Displays Enquiries that were withdrawn
Archived: Displays Enquiries where the final decision is made.

4. Each Enquiry recorded on the overview displays the Vivli Enquiry ID, Requester Name, Purpose of research, Date Submitted, Status of the Enquiry, and the Number of Studies in each Enquiry.



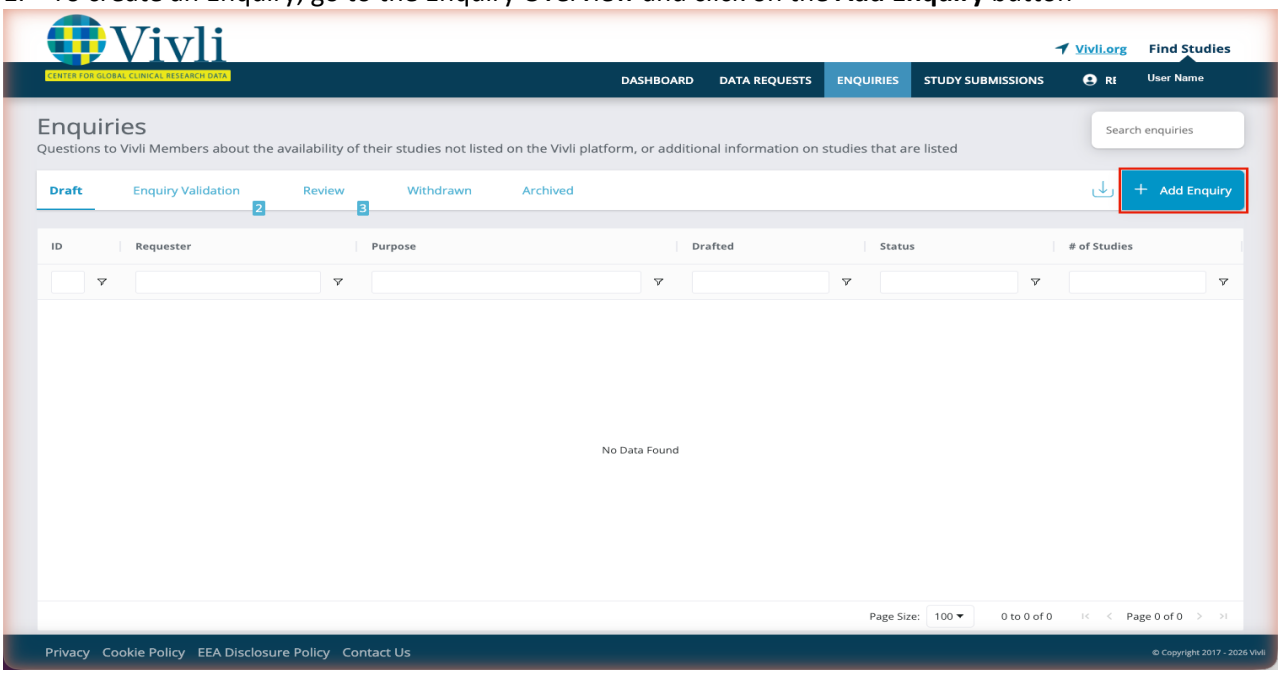
5. You can search for enquiries using one of the following fields. Search starts looking for the matching items as soon as you type the first letter, and is case-insensitive. The numbers point out the number of enquiries that match the search criteria and the status of the Enquiry:

- Enquiry ID
- Requester Name or Email
- Purpose of analysis
- NCT ID
- Sponsor ID
- Study Title
- Member Organization

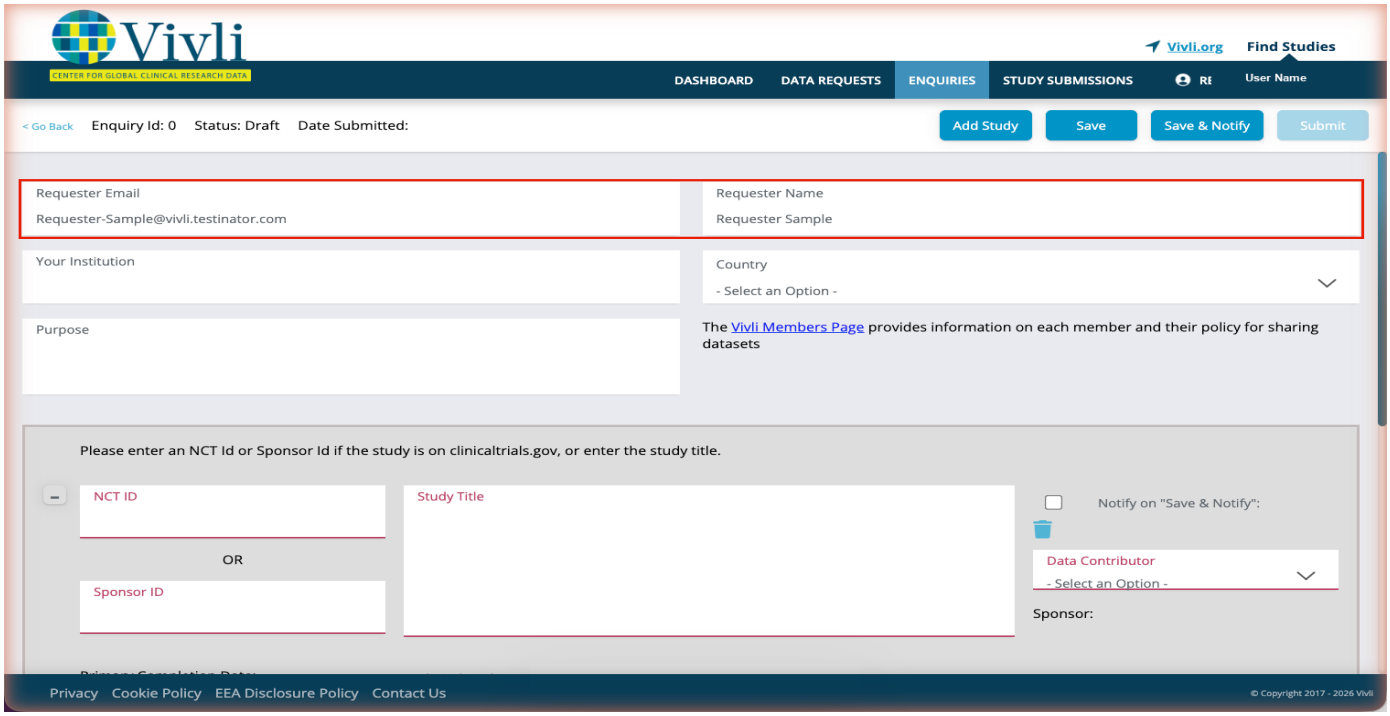


2.2 Creating an Enquiry

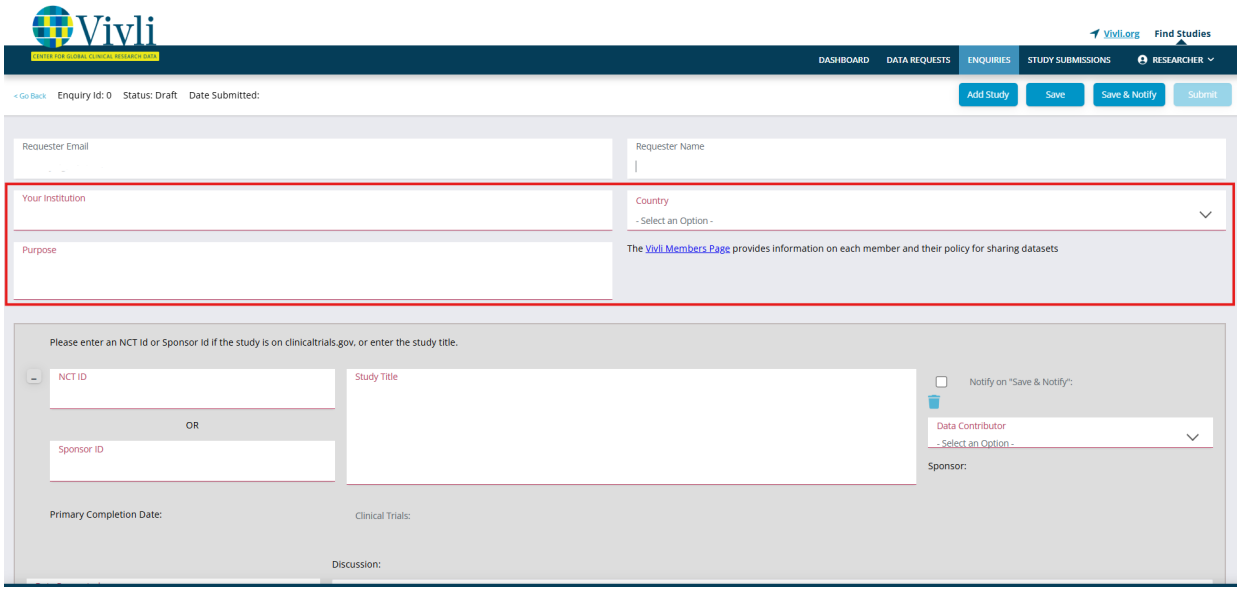
1. To create an Enquiry, go to the Enquiry Overview and click on the **Add Enquiry** button



In the Enquiry form, Requester Email and Requester Name is automatically pulled from your Vivli Account profile. If your name is incorrect, please edit the Requester Name. You may also update your profile display name. To edit your display name, please see Section 1.3 'Edit display name in profile' of the Vivli User Account Quick Start guide

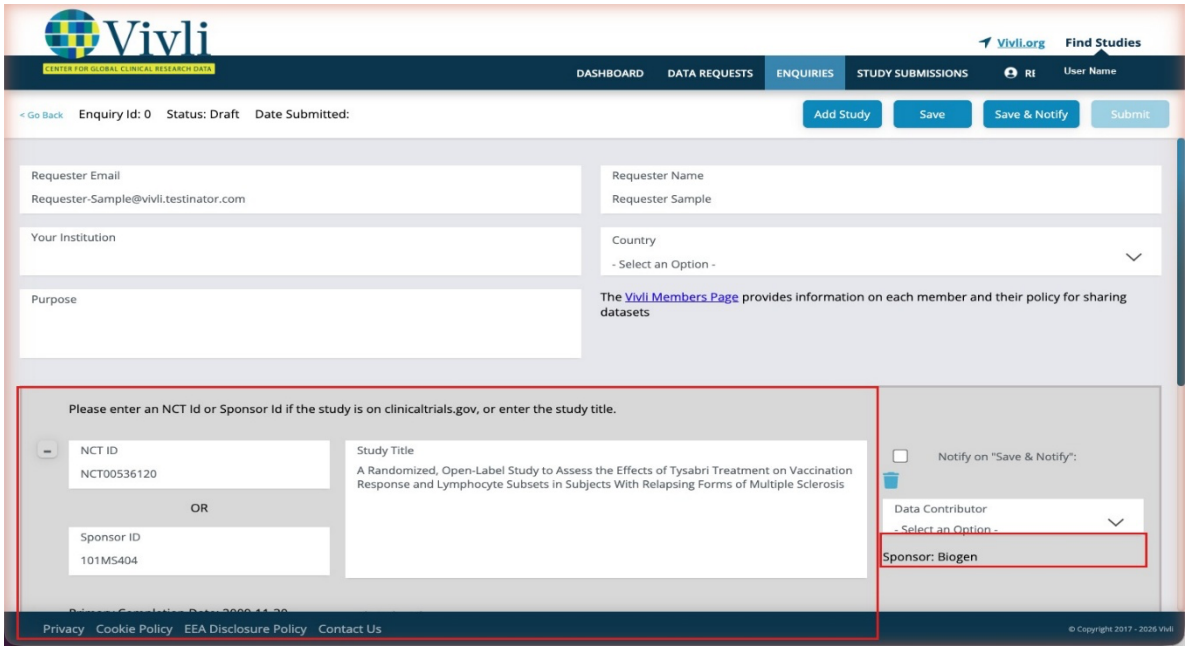


Fill in your Institution name, select your country, and provide the purpose of your research. Before proceeding further, please click the Member's page link to review the data-sharing criteria of our members. Note: If your Enquiry is related to an existing data request on Vivli, please provide the project name and/or Vivli ID in the purpose of your research to link the enquiry with your existing data request.

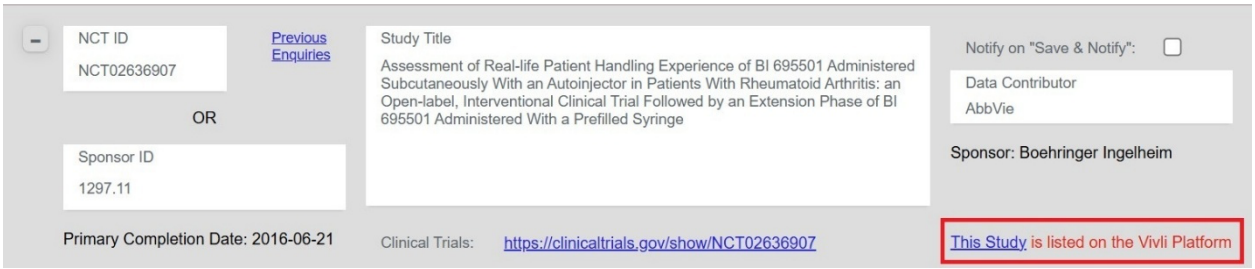


2. Type in the study information:

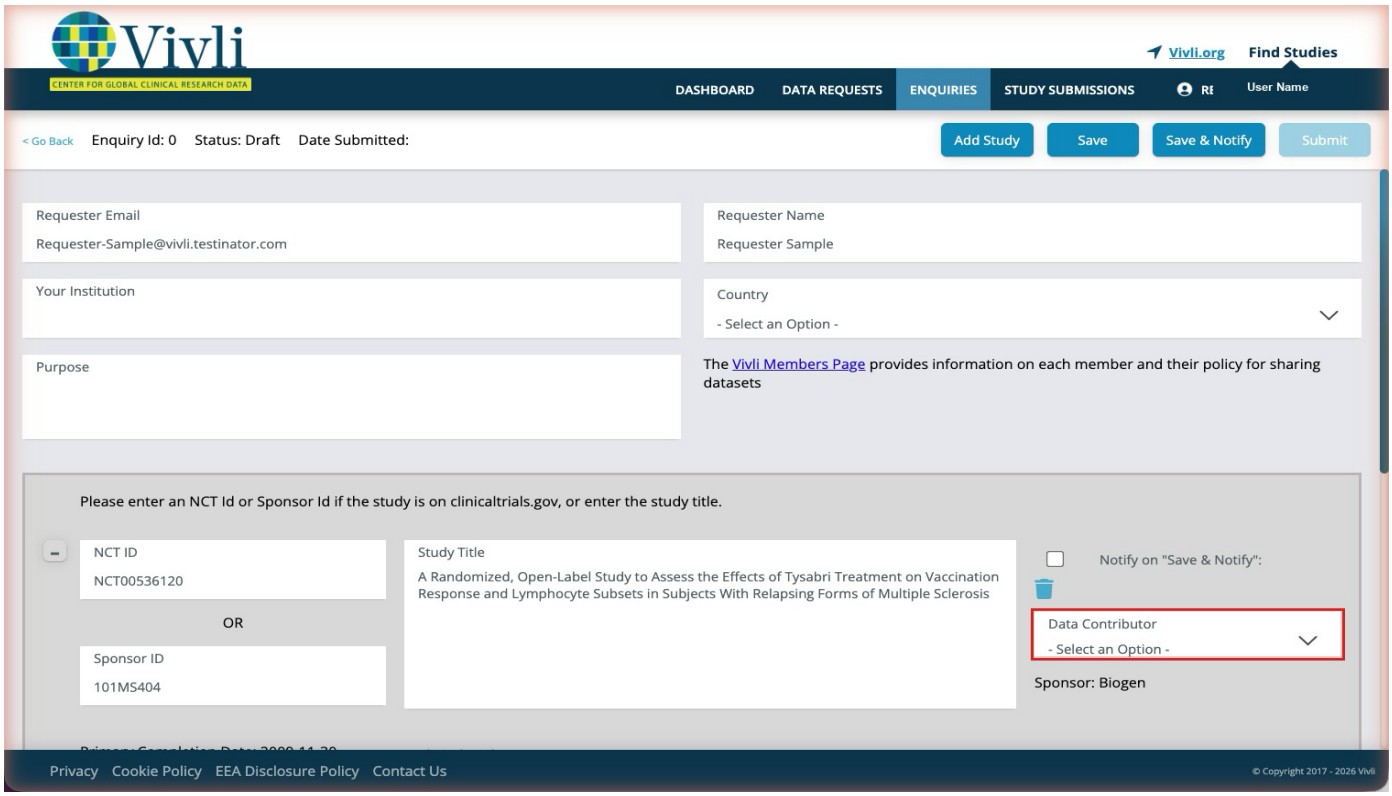
   a. If you have the NCT ID from https://clinicaltrials.gov/ website, type it in the NCT ID field. The Vivli platform will automatically populate the Sponsor ID, Study Title and Sponsor name, Primary Completion Date, and Clinical Trials.gov link from the Clinicaltrials.gov website.
   b. If you do not have the NCT ID, then please provide the Study Title and any additional information that will help the Vivli Member to identify the study. This may include but is not limited to study ID, Drug intervention/Drug Name, indication, Study Phase, primary publication, etc.



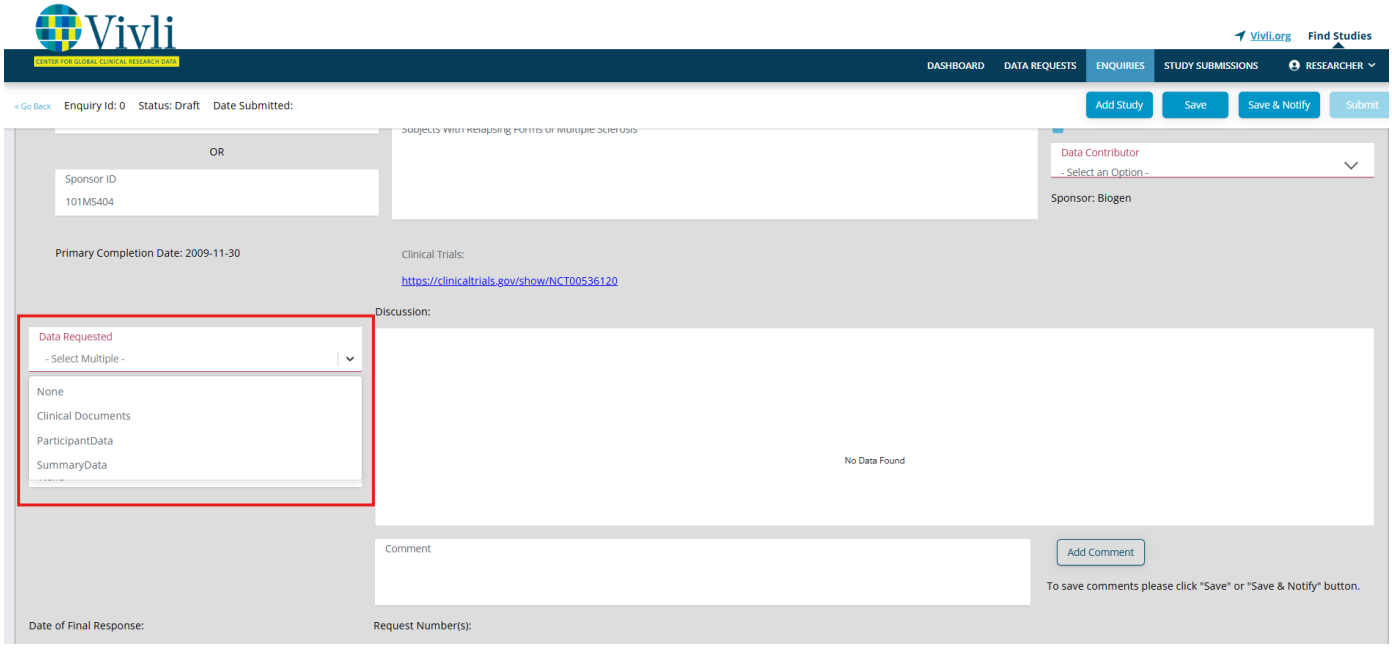
3. If a study is already listed on the Vivli platform, you will see a clickable note “This Study is listed on the Vivli Platform” which takes you to the listed study. At this point, you may stop your enquiry and go to the search page to add the study to your data request. Please see Section 1.1 Searching for studies on the Vivli platform. Do not hit the Save button. If you need to enquire about further information on the study, you can continue to proceed with the Enquiry.



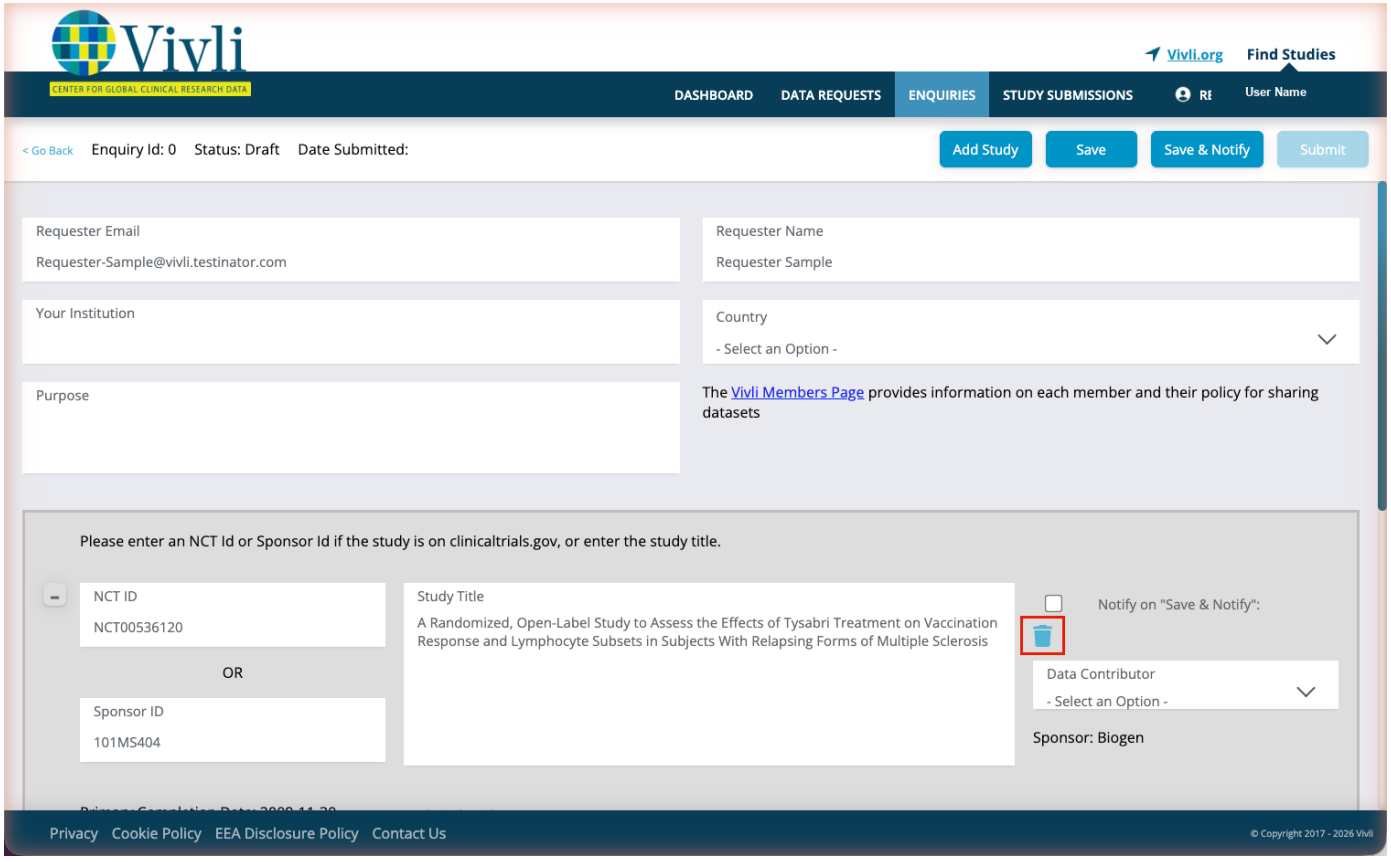
4. Select the Data Contributor from the dropdown list. If a Data Contributor is not listed in the Data Contributor dropdown, they are likely not a member of Vivli, and therefore, the study is unlikely to be shared via the Vivli platform. We recommend reaching out directly to the data contributor to learn more about their data sharing policies. Some Vivli Members may require that enquiry be submitted via their own portals and will not accept enquiries via the Vivli platform (please review their Member page https://vivli.org/members/ourmembers/).



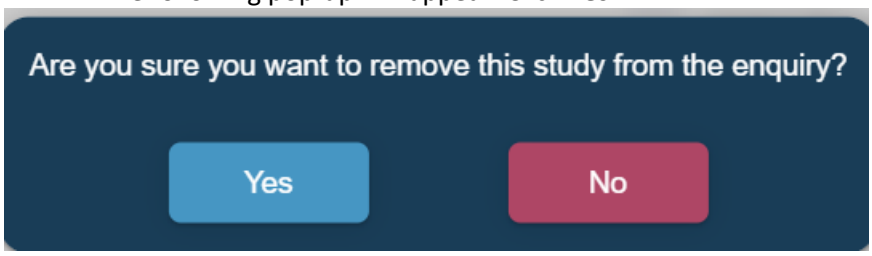
5. Select the type of data you need for your analysis. Three options available are **Clinical Documents, Participant Data, and Summary Data**. You can select one or more options.



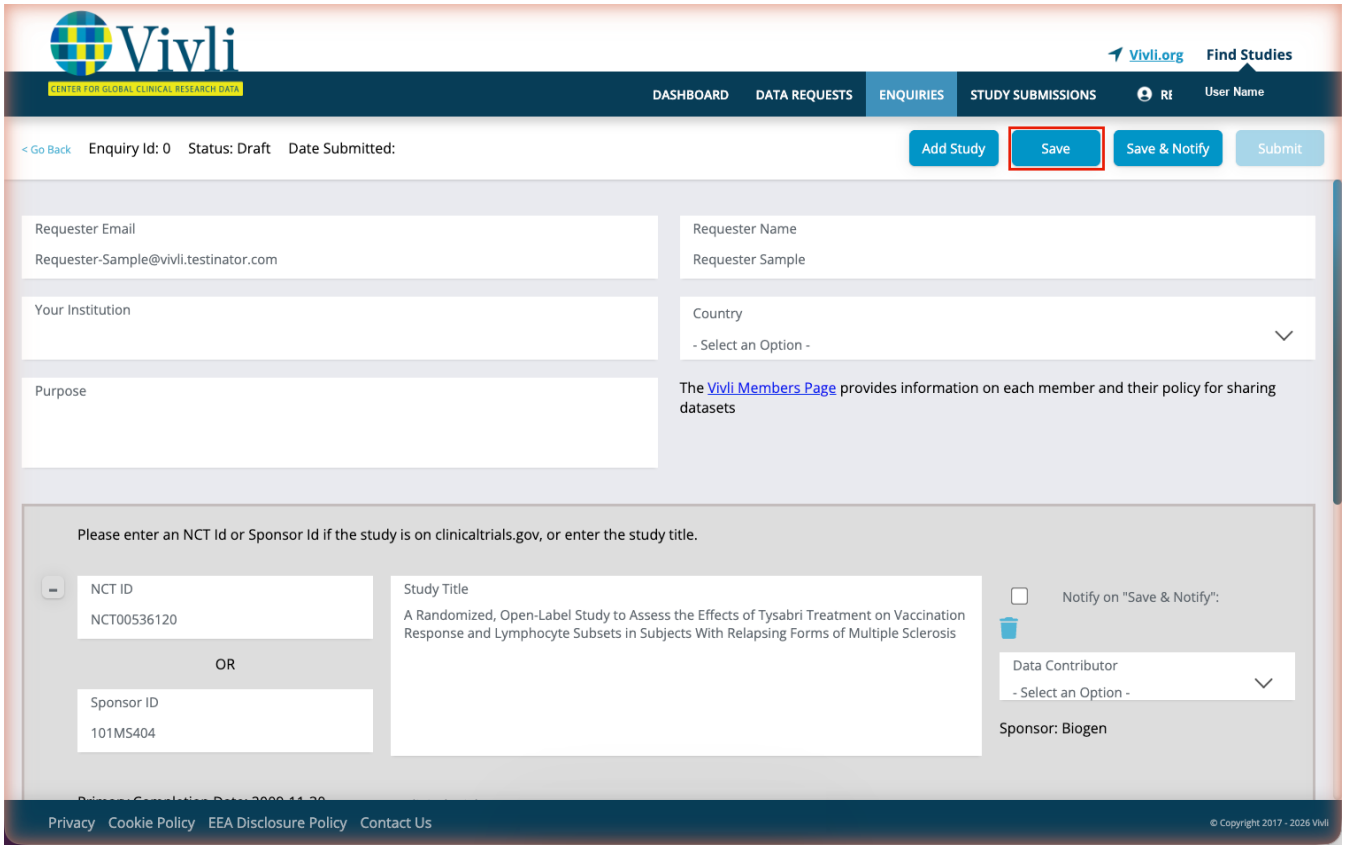
6. To delete a study, click the delete icon



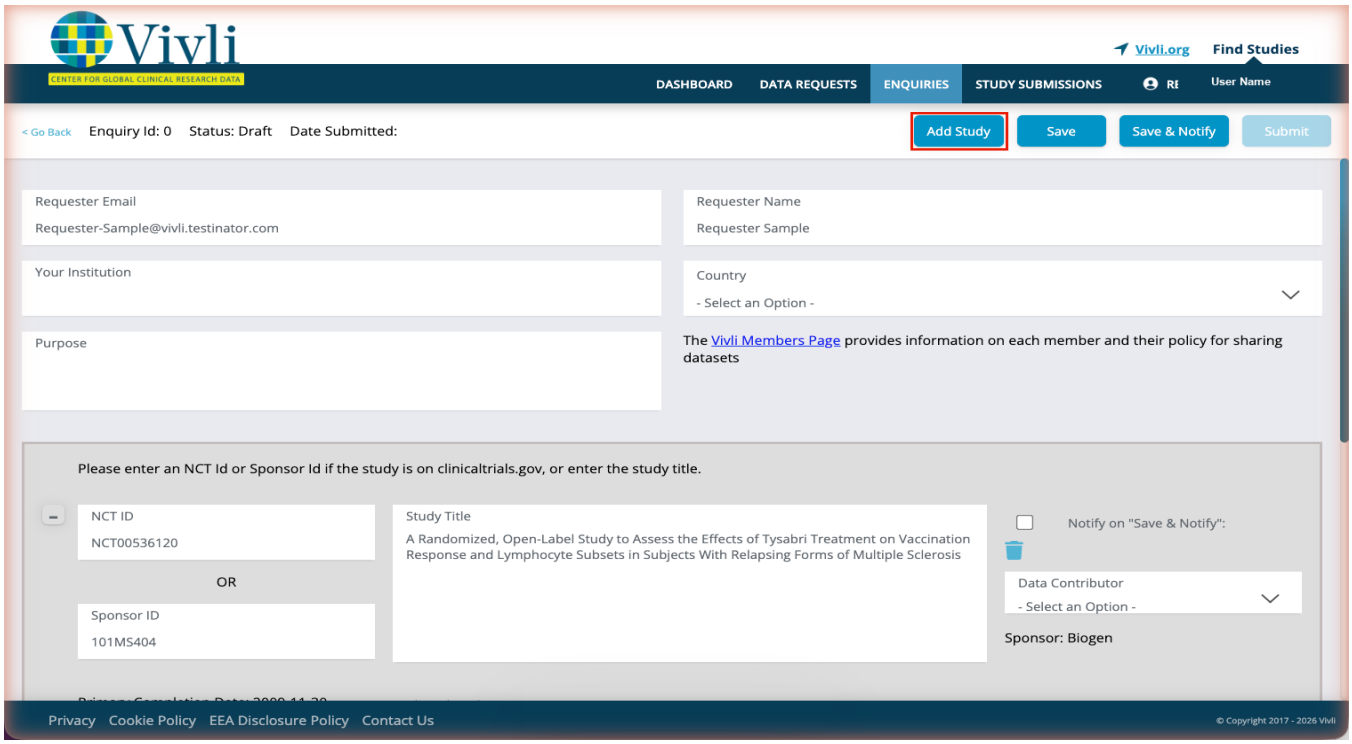
7. The following pop-up will appear. Click **Yes**



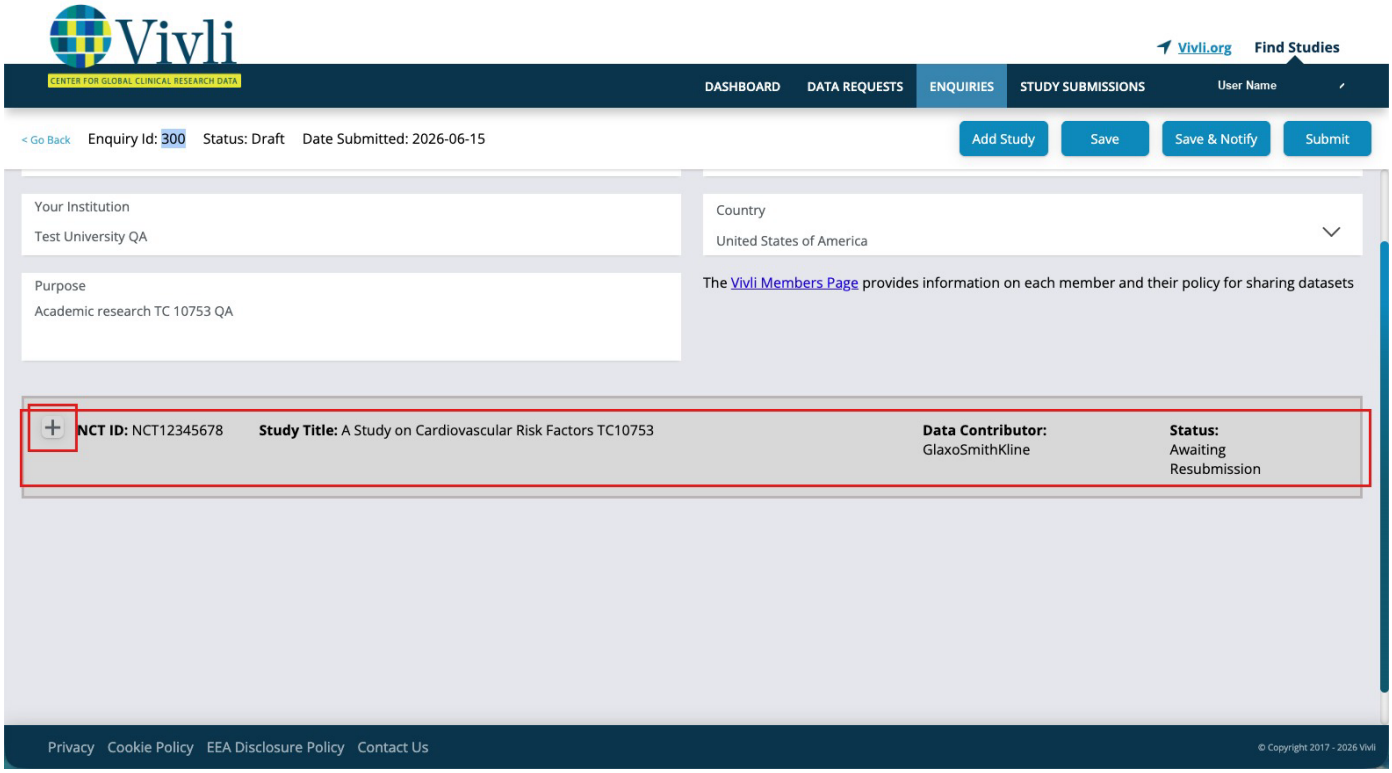
8. Click the **Save** button on the top to save your Enquiry form. Once saved, the Vivli system will assign an Enquiry ID.



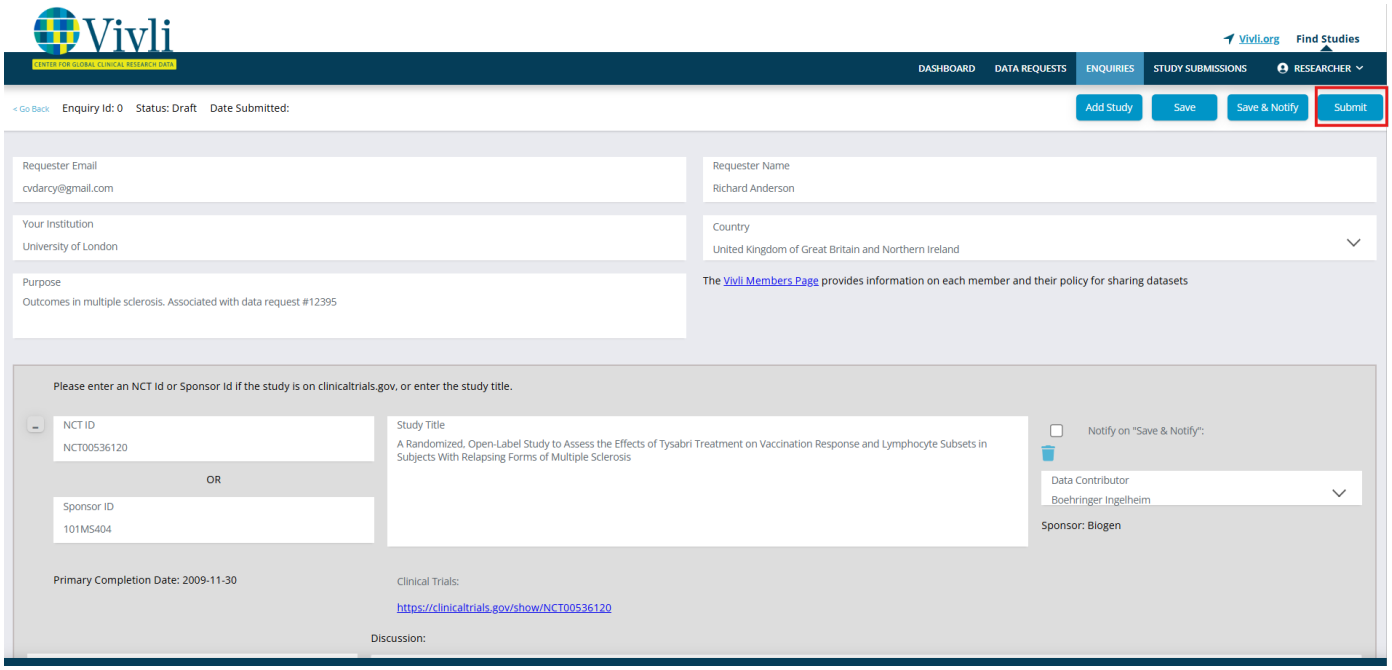
9. To add studies to the enquiry, click the **Add Study** button on the top. Please add all the studies relevant to the project in the same enquiry even if it is from different data contributors.



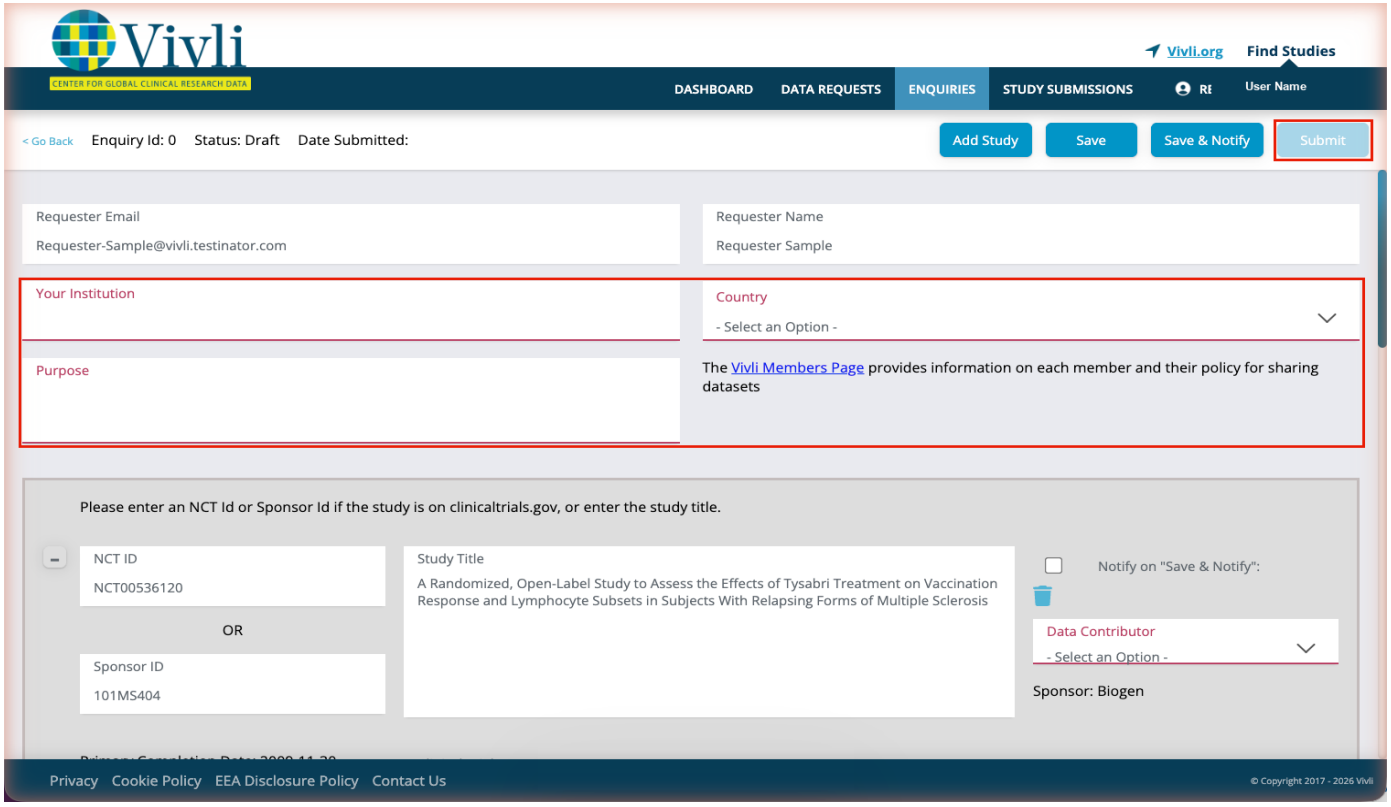
10. Scroll to the bottom to see the new study field. Use the + to expand the study field and fill out the details of the additional study



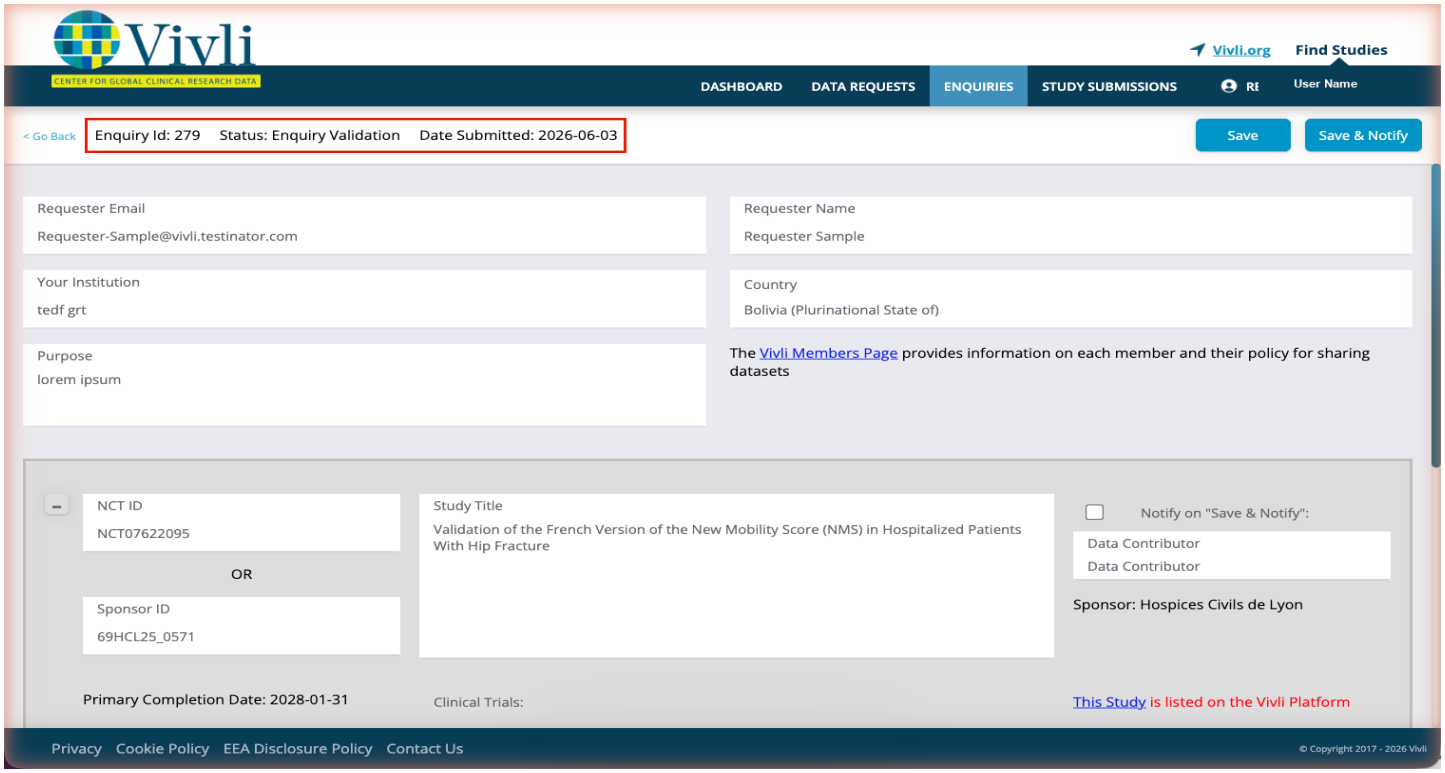
11. Once you have completed the form, click the Submit button on the top



12. If the Submit button is not enabled, look for the red text which marks incomplete fields. Please note that any field marked in red text is mandatory and must be filled out before the Submit button becomes enabled.



13. Once submitted, the enquiry moves to the Enquiry Validation stage. You can see the Enquiry ID, Enquiry Status, and the Date Submitted on the top of the request and in the Enquiry Overview screen. Please see Section 2.1 Navigation and Enquiry Dashboard

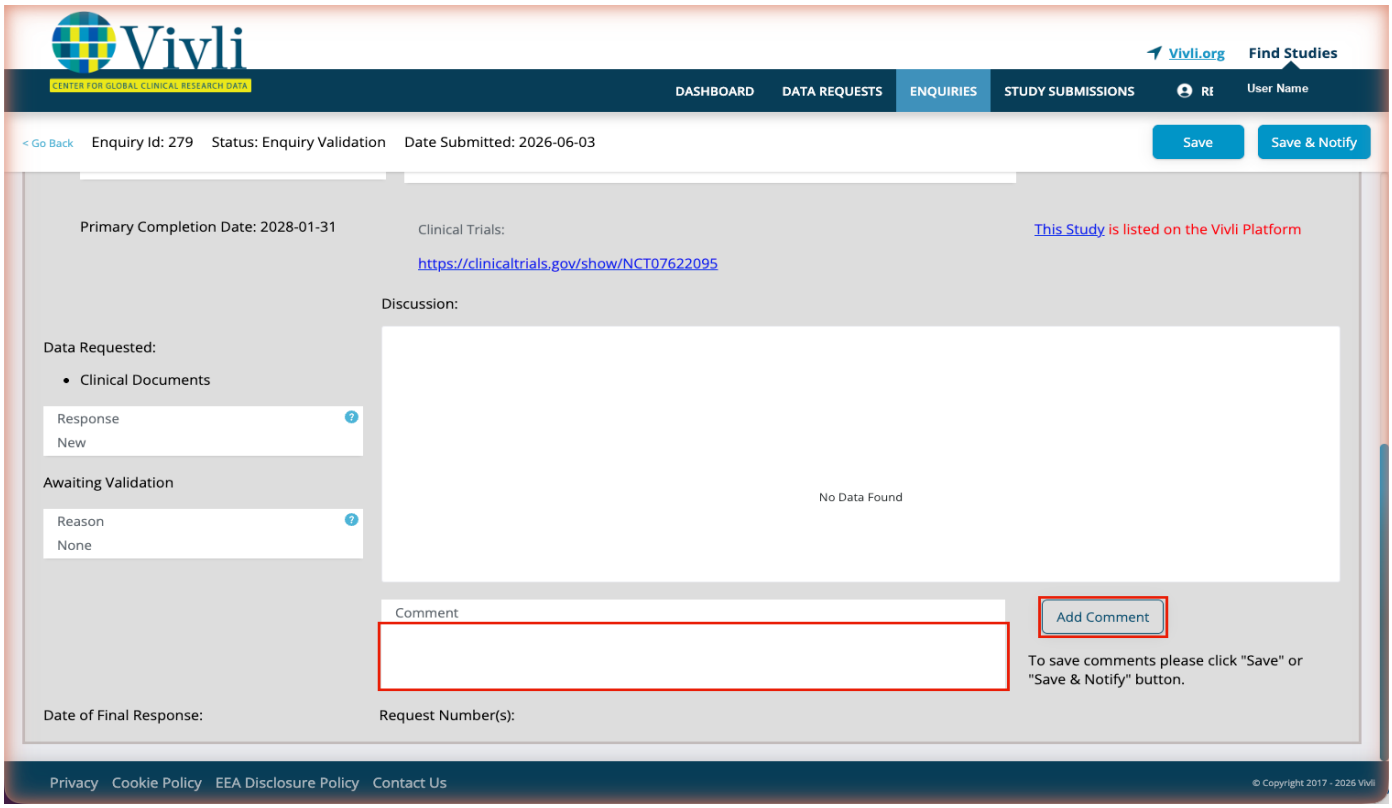


2.3 Enquiry Discussion

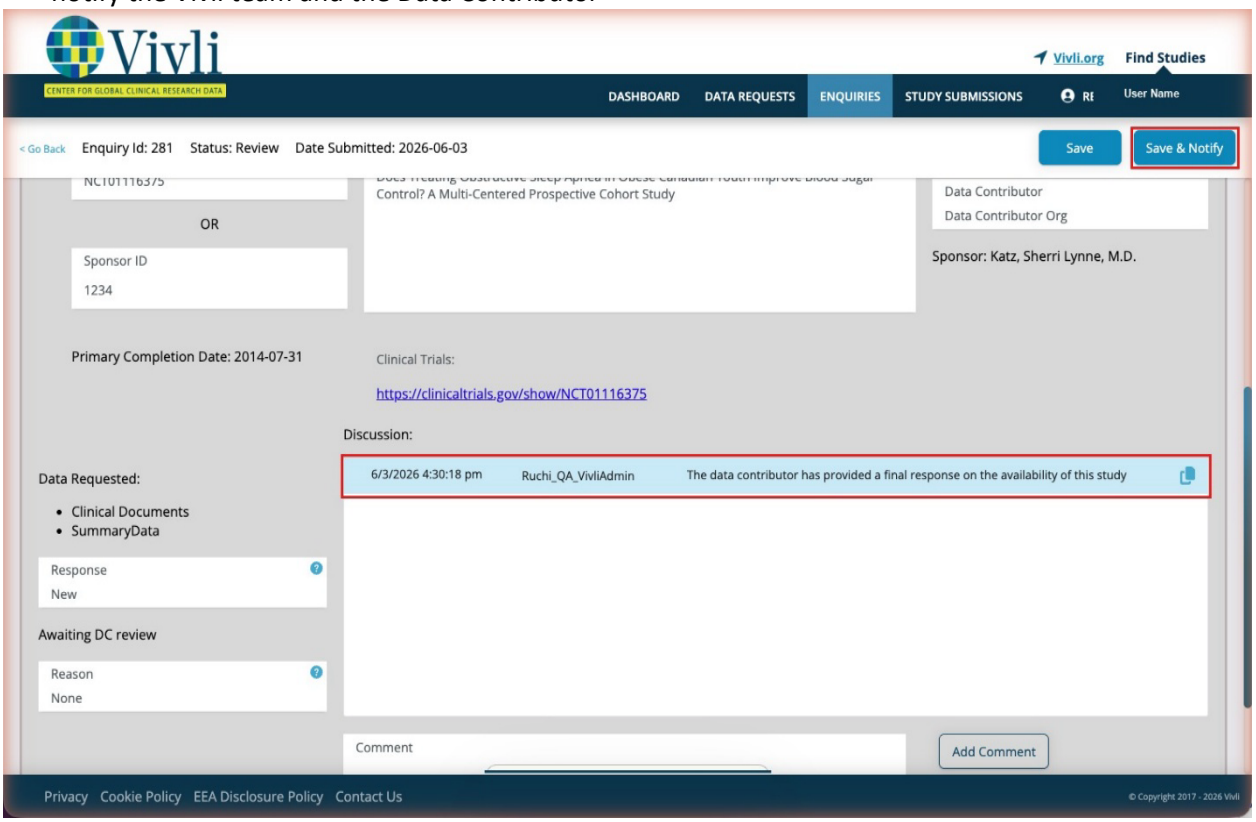
1. You may add comments in the discussion field to either provide additional information to the Data Contributors or Vivli or respond to their questions at any stage.
2. The 

button allows you to save any information you provided on the enquiry but don't notify the Data Contributor and the Vivli Admin
3. The 

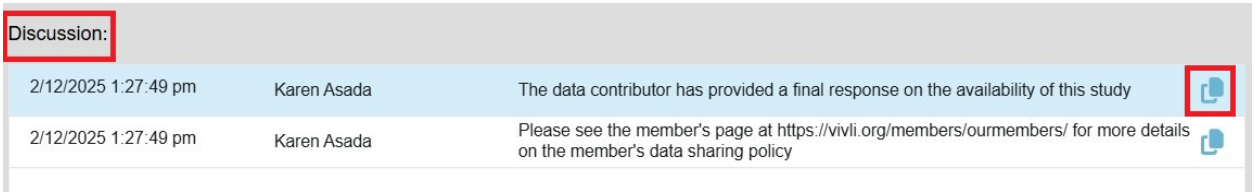
button allows you to save any information on the enquiry and notify the Data Contributor and the Vivli Admin
4. If you are responding to multiple studies in the same Enquiry, you may choose to use the **Save** button for the changes, and at the end, you can click Save & Notify.
5. Type in your comments in the comments field and click the **Add comment** button.



6. Your comments will show up in the Discussion field. Click on the **Save & Notify** Blue button on the top to notify the Vivli team and the Data Contributor



7. The copy icon next to the posted comment allows you to copy the comment and paste it.



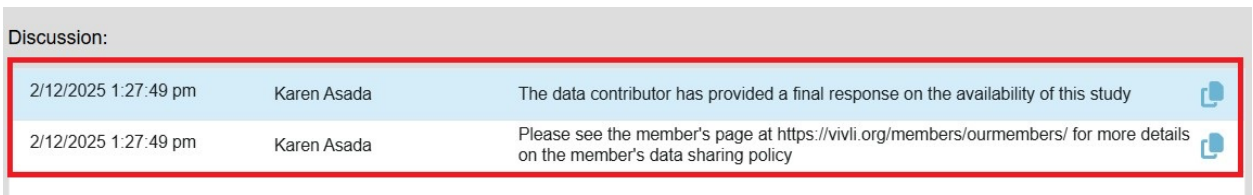
8. If the Vivli team or data contributor provides their comments, you will receive an email notification and their response will be displayed in the discussion field.

2.4 Enquiry Response

Each study will have the following fields:

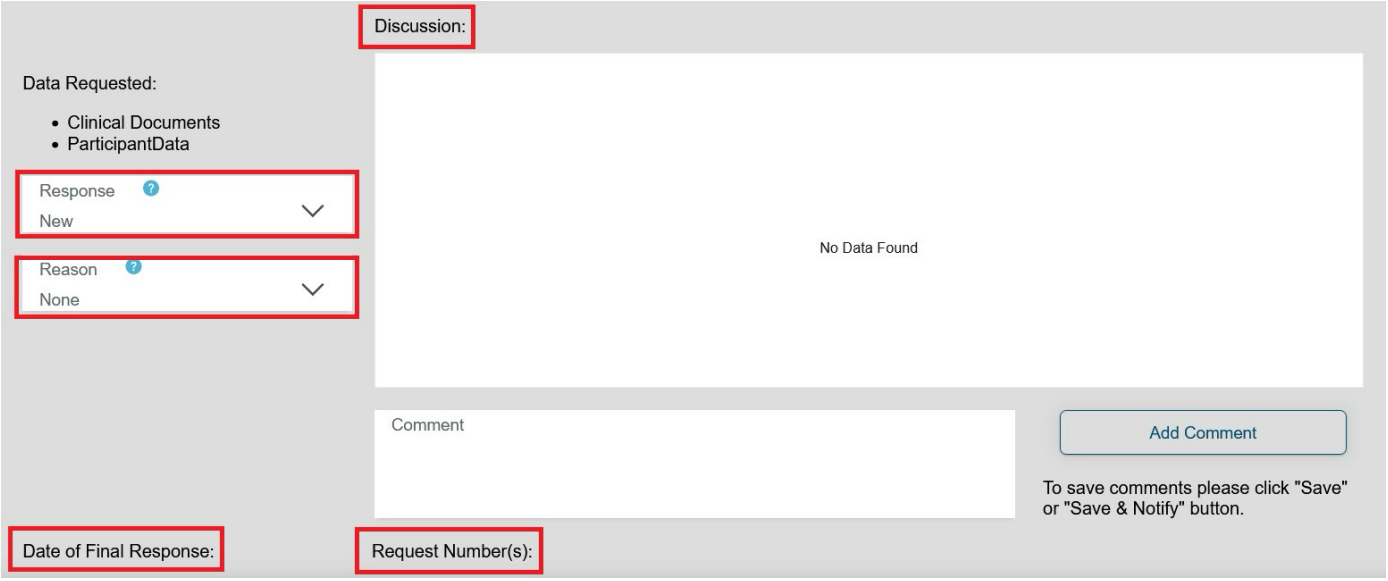
- **Responses**: This includes updates to the Enquiry discussion and decisions made by the Data Contributor:
    a. None – No responses
    b. New – Meaning no one has responded yet – this is the initial default value
    c. Response from requester – You have added information to the discussion. This is automatically set when you add a comment and click Save or Save and Notify.
        i. Response from data contributor – The Data Contributor has added information to the discussion. This is automatically set once the Data Contributor responds.
        ii. Response from Vivli – The Vivli Admin has added information to the discussion. This is automatically set when the Vivli team responds.
    d. Eligible for Request as an Unlisted Study – You can add this study to your data request. For the next steps, see Section 2.5 Adding studies to your data request
    e. Study is Listed - You can add this study to your data request. For the next steps, see Section 2.5 Adding studies to your data request
    f. Not Available – Study is not available. No Action is needed from you

- **Reason** – When the response is Not Available, the reason field provides more information. You will see an automated comment placed in the discussion saying, "Please see the member's page at https://vivli.org/members/ourmembers/ for more details on the member's data sharing policy"



    a. **Comment** – You, Vivli Admin, and Data Contributors can add a comment about the Enquiry. Once the final decision is made, you will no longer be able to add a comment to the discussion.
    b. **Discussion** – This includes all the comments provided by you, Vivli Admin, and Data Contributor for this specific study

c. **Date of Final Response** – Date when the Data Contributor makes a final decision
d. **Request Number(s)** – You can add studies from the Enquiry directly into the data request form. In such instances, the Enquiry will display the associated Data request ID once the data request is submitted on the platform. For more information See Section 2.5 Adding Studies to your data request.



2.4.1 Enquiry Study Status for Individual Studies

In addition to the overall Enquiry status, there is a Study-level Status that combines the Enquiry's status with the decision about the Study.

Here is the list of study-level statuses:

1. For studies with no decision recorded yet.

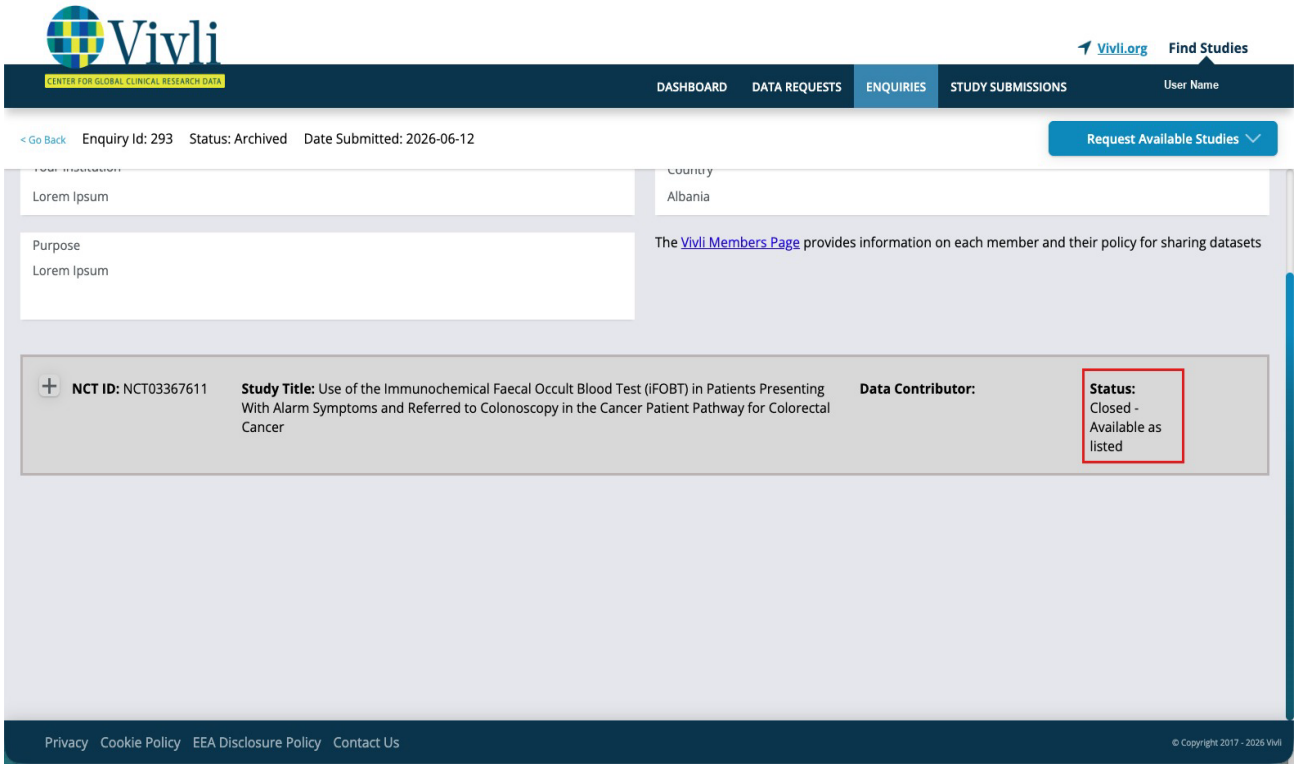
a. Awaiting Initial submission Overall Enquiry is in draft and has never been submitted
b. Awaiting Resubmission - Overall Enquiry is in draft after being sent back to draft for revision
c. Awaiting Validation (Overall Enquiry is in the Enquiry Validation state)
d. Awaiting DC review - Overall Enquiry is In review
e. Withdrawn (Overall Enquiry is in Withdrawn)
f. Archived (Overall Enquiry is in Archived)

2. For studies with decisions already recorded - e.g. response of Available or Not Available

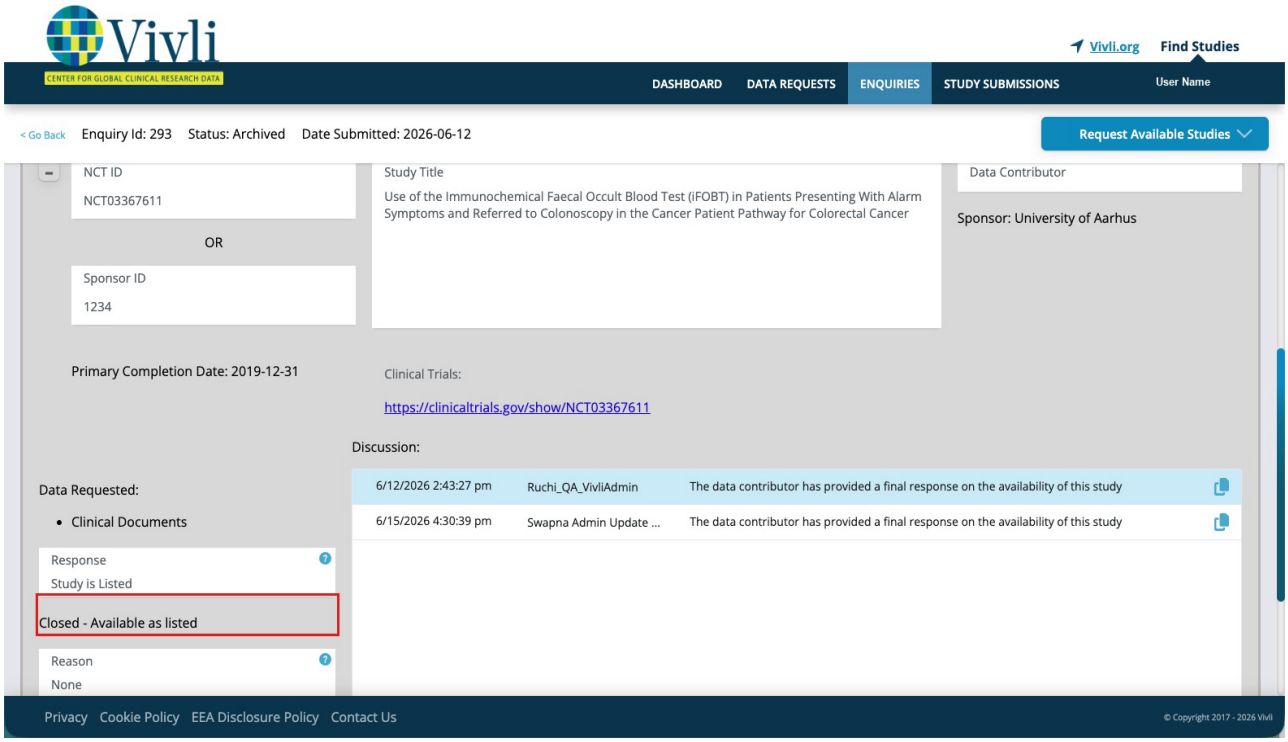
a. Closed - Available as listed (Independent of the overall Enquiry status)
b. Closed - Available as unlisted (Independent of the overall Enquiry status)
c. Closed - Not Available (Independent of the overall Enquiry status)

Study-level Status is visible in the following areas:

1. Closed Enquiry Study panel, on the right next to the Data Contributor name

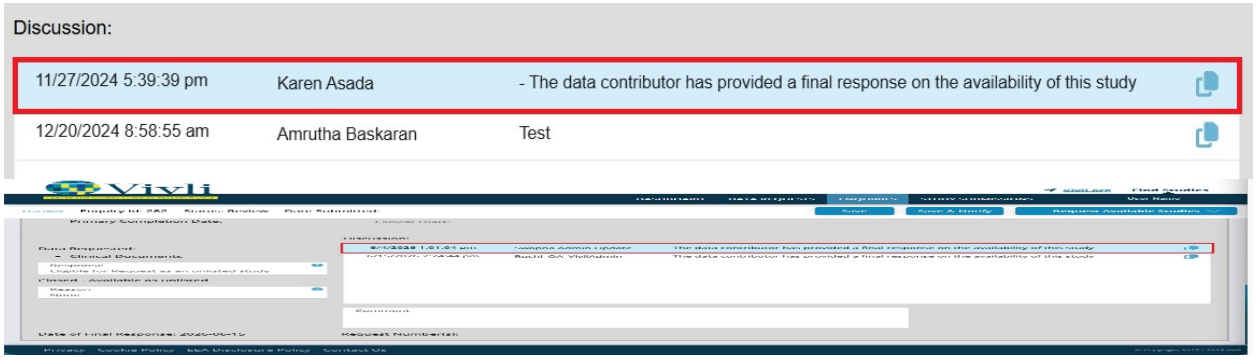


2. Open the Enquiry Study panel, on the left side below the Reason field



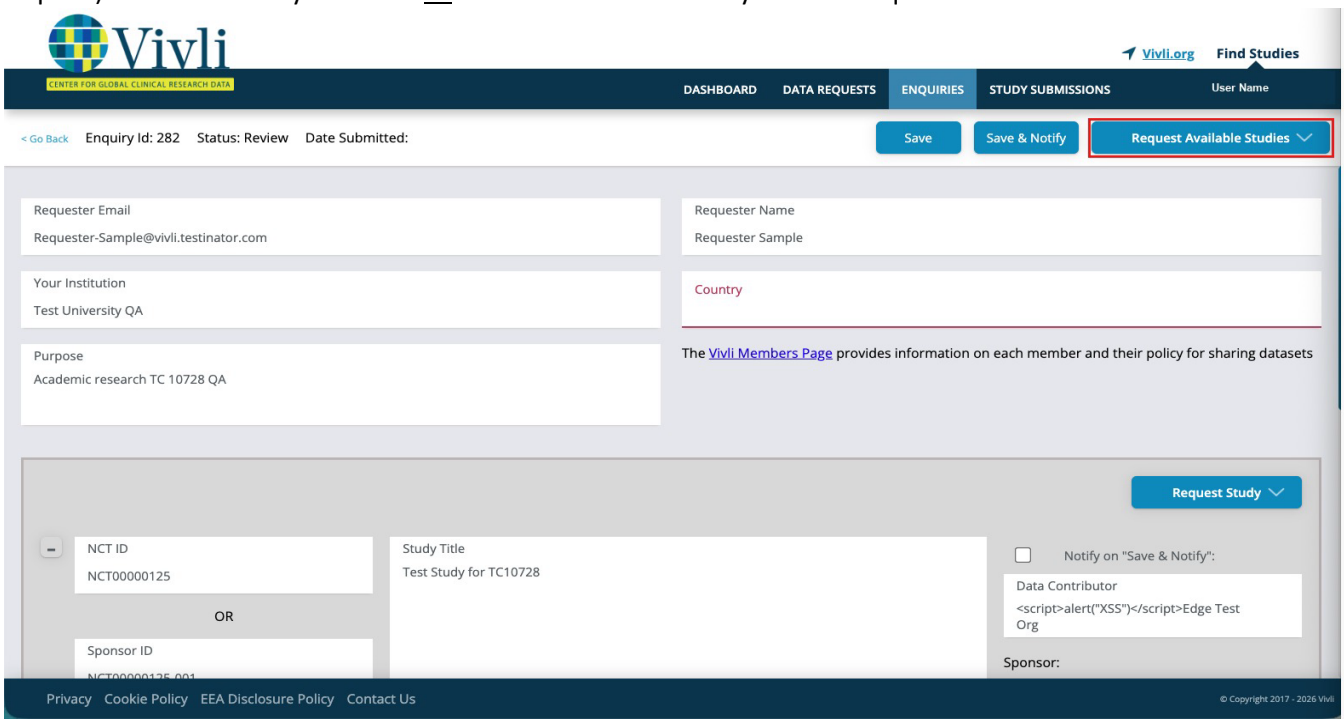
2.5 Adding studies to your data request

1. If a study is eligible for request, you will see an automated comment placed in the discussion. "The data contributor has provided a final response on the availability of this study"

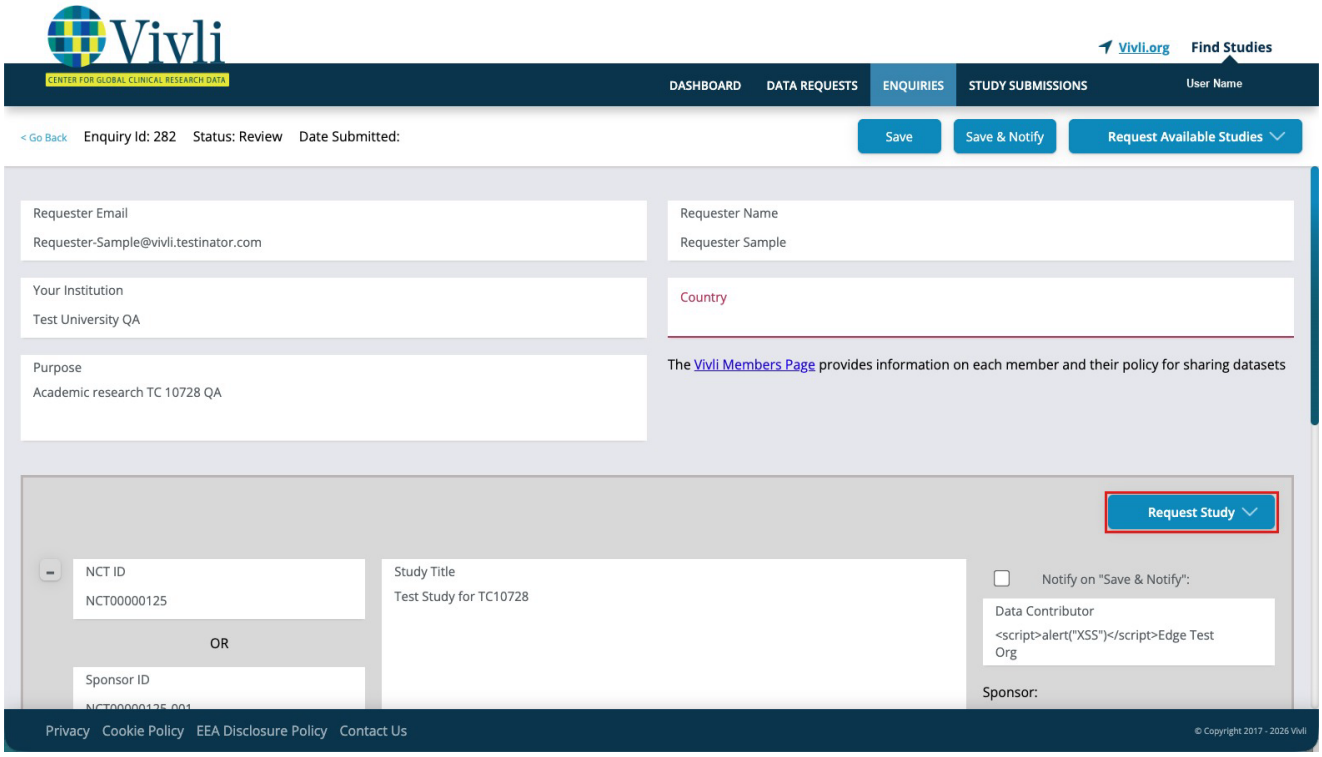


2. You can add studies from the Enquiry directly into the data request form.
   a. If the study is unlisted, you can add them immediately.
   b. If the study is listed, wait for instructions from the Vivli admin when the study is ready to be added (this might take a couple of days).

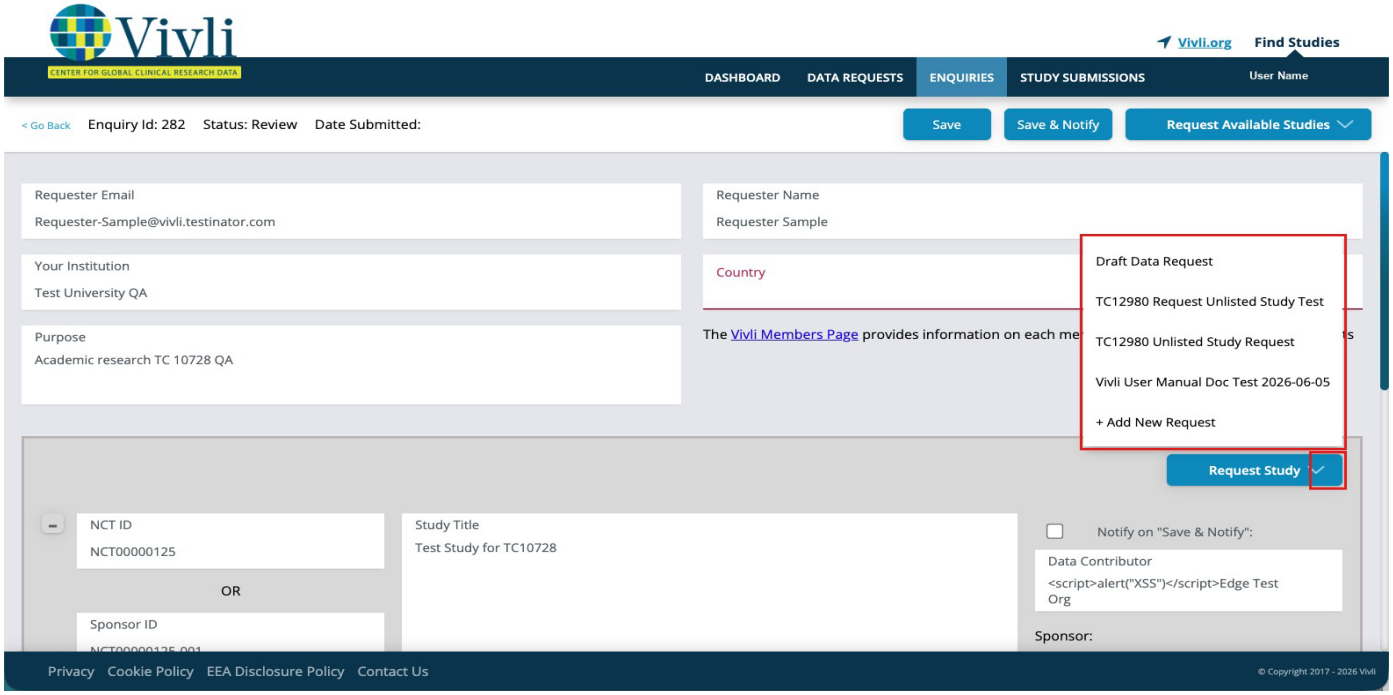
3. Open the Enquiry, click the **Request Available Studies** button, and click the down arrow next to it.
(if you have multiple studies, please wait until you receive a decision on the studies before adding them to your request). This will allow you to add <u>all</u> the available studies to your data request.



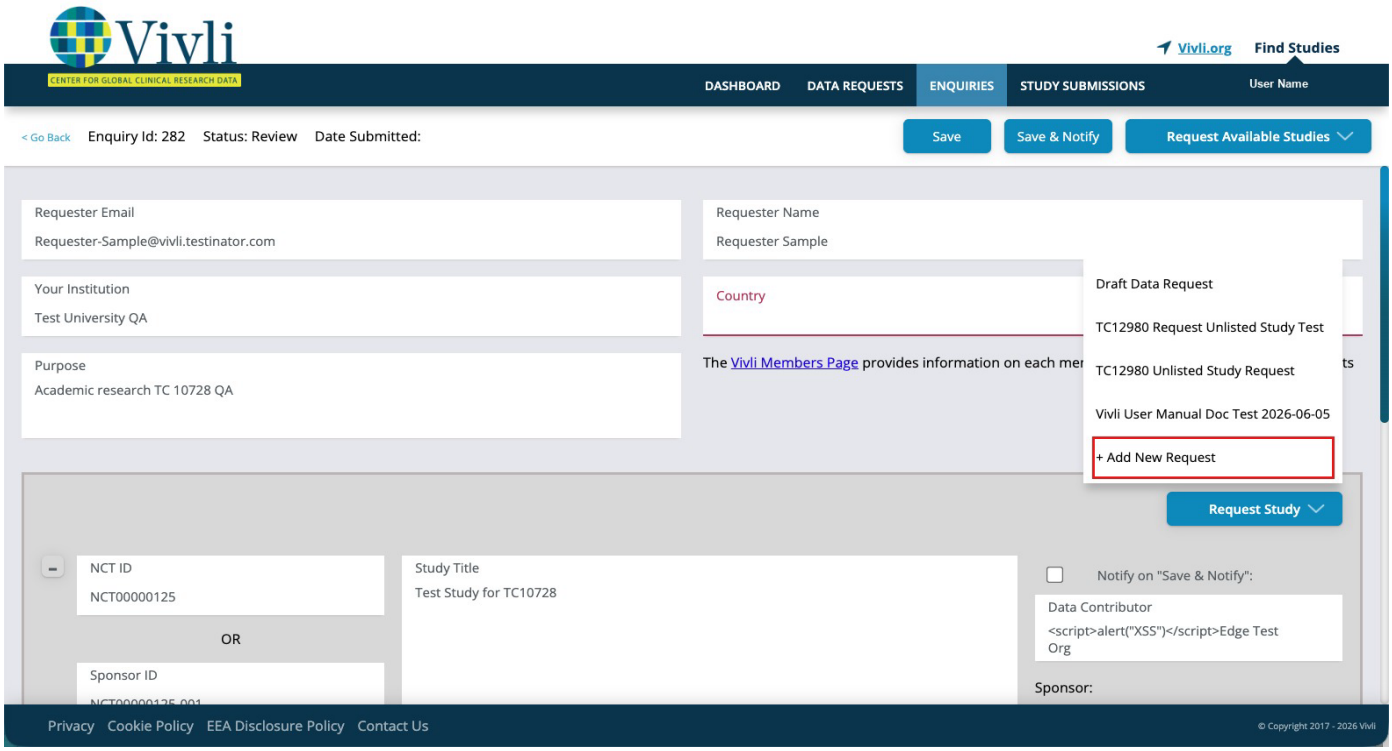
4. Alternatively, you may click the **Request Study** button under individual studies and click the down arrow next to it. Note: you have to take the below steps for <u>each study</u> in the Enquiry that is available for the data request and add it to the same data request.



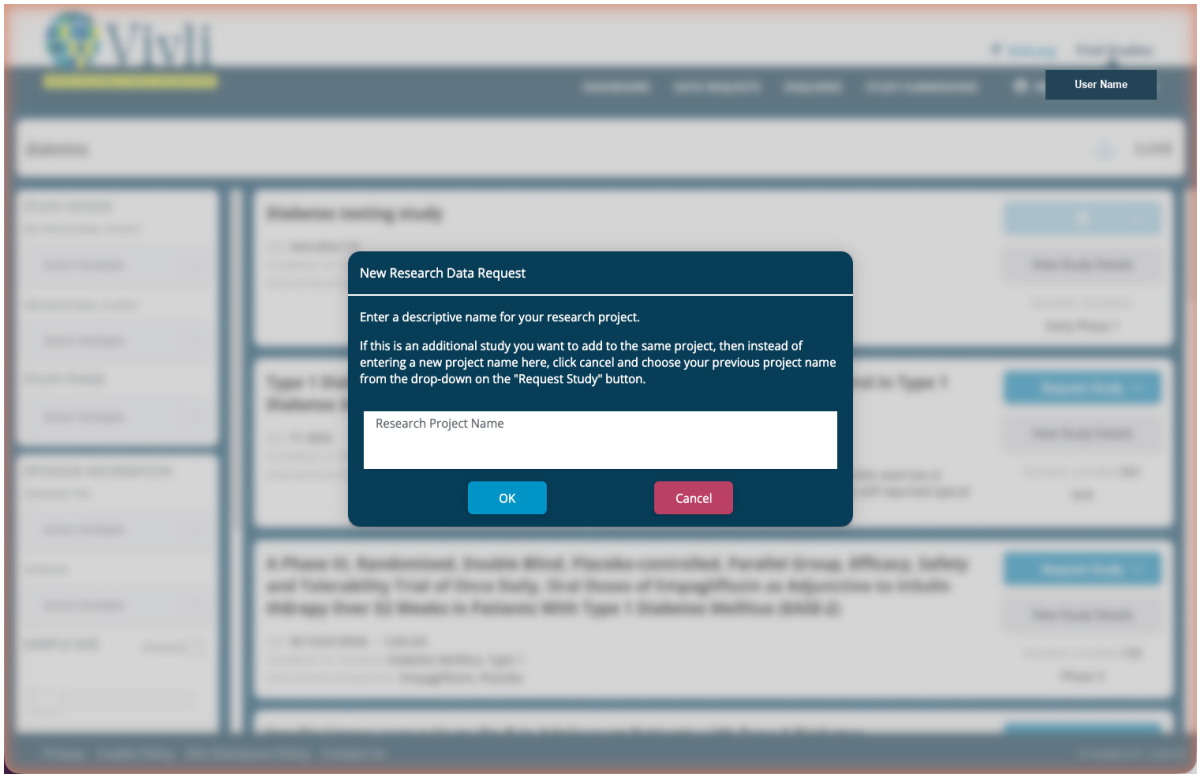
5. If you have an existing data request in drafts, you will see a list of them. Select the appropriate data request.



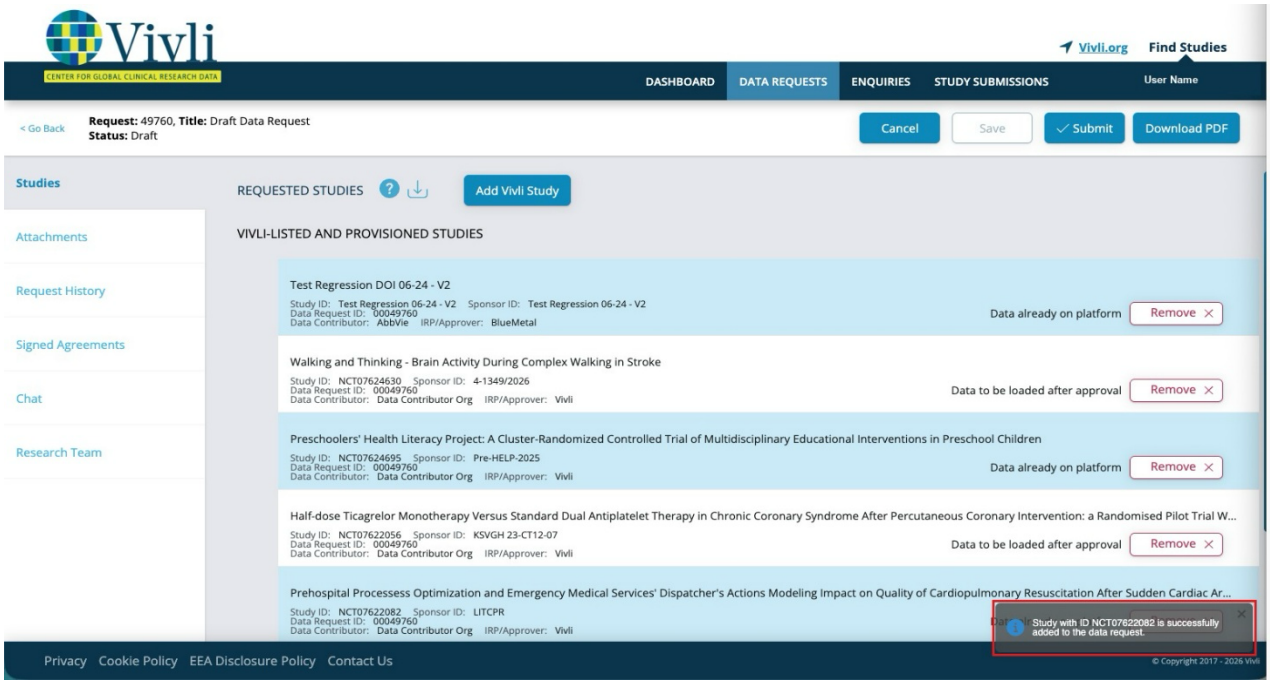
6. If you do not have an existing data request in drafts or if you want to create a new data request, select **+Add New Request**



7. You will be prompted to provide a new project name. Note: Special characters are not accepted in the Project Name

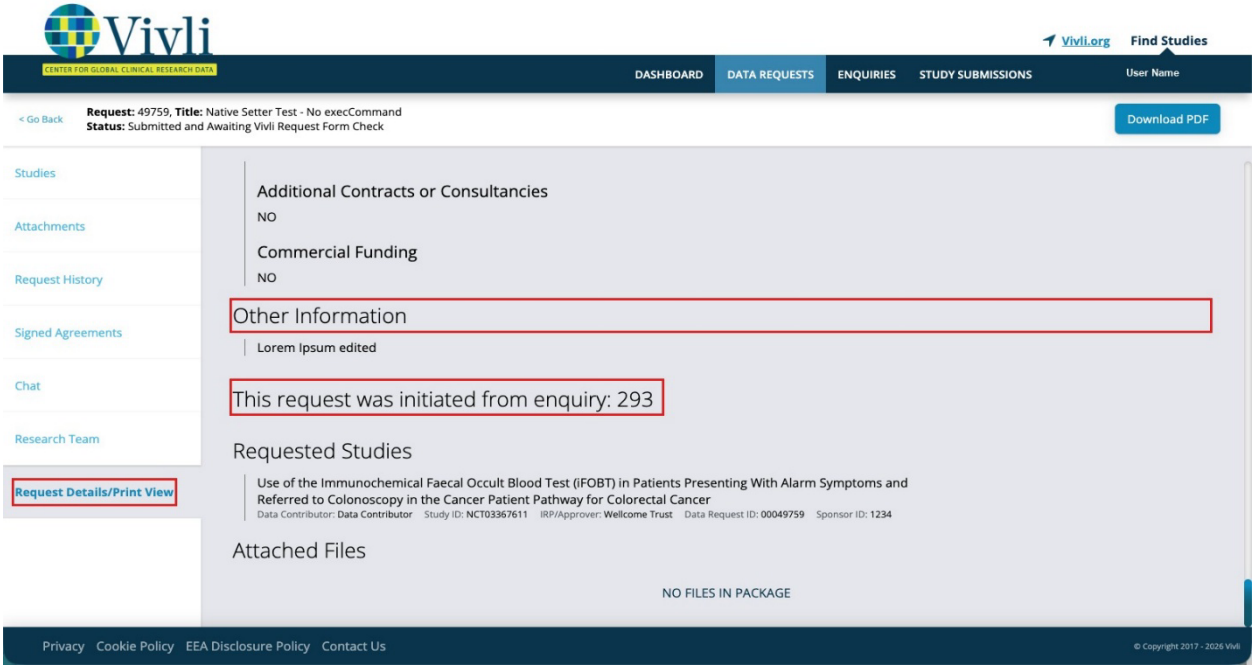


8. The following notification will appear



9. Once you have added the studies to your data request, you can fill out the remaining fields in the data request and submit the request. For more information, see Section 3.0 Your Data Requests

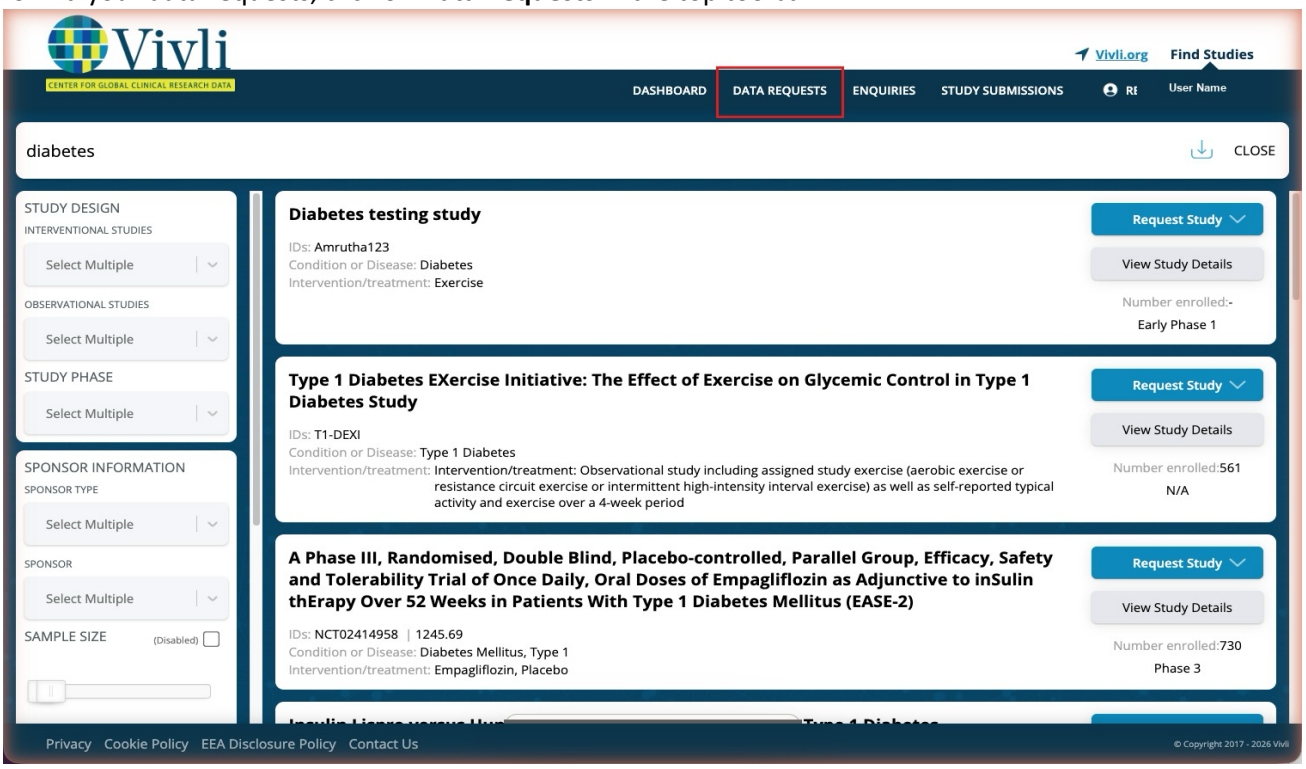
10. Once submitted, a note will also be placed in the data request form under other information stating, “This request was initiated from enquiry ID (s)”.



11. The enquiry will display the associated Data request ID once the data request is submitted on the platform

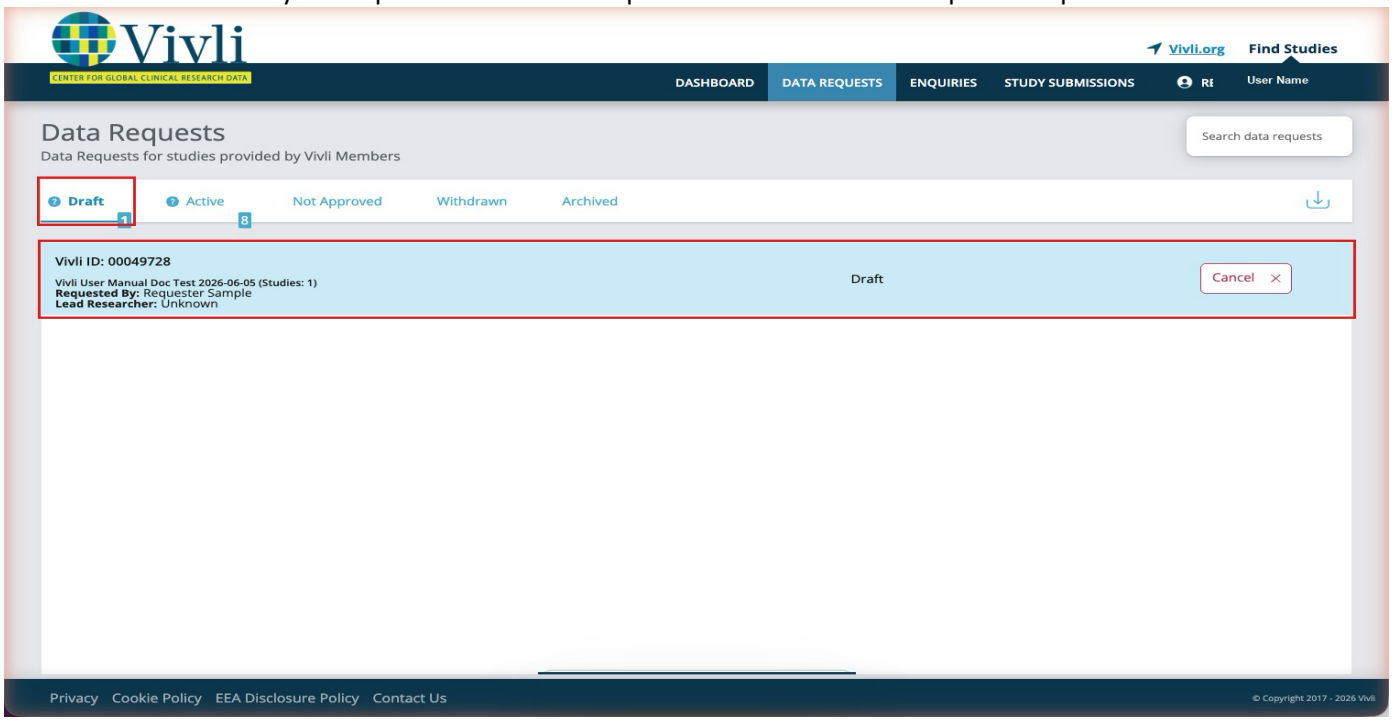
3.0 Your Data Requests

To find your data requests, click on **Data Requests** in the top toolbar:



This will take you to your data requests page, where you can navigate to complete the Vivli data request form and check the status of any previously submitted data requests.

Click on **Draft** to see any incomplete or new data requests. Click on the data request to open it:

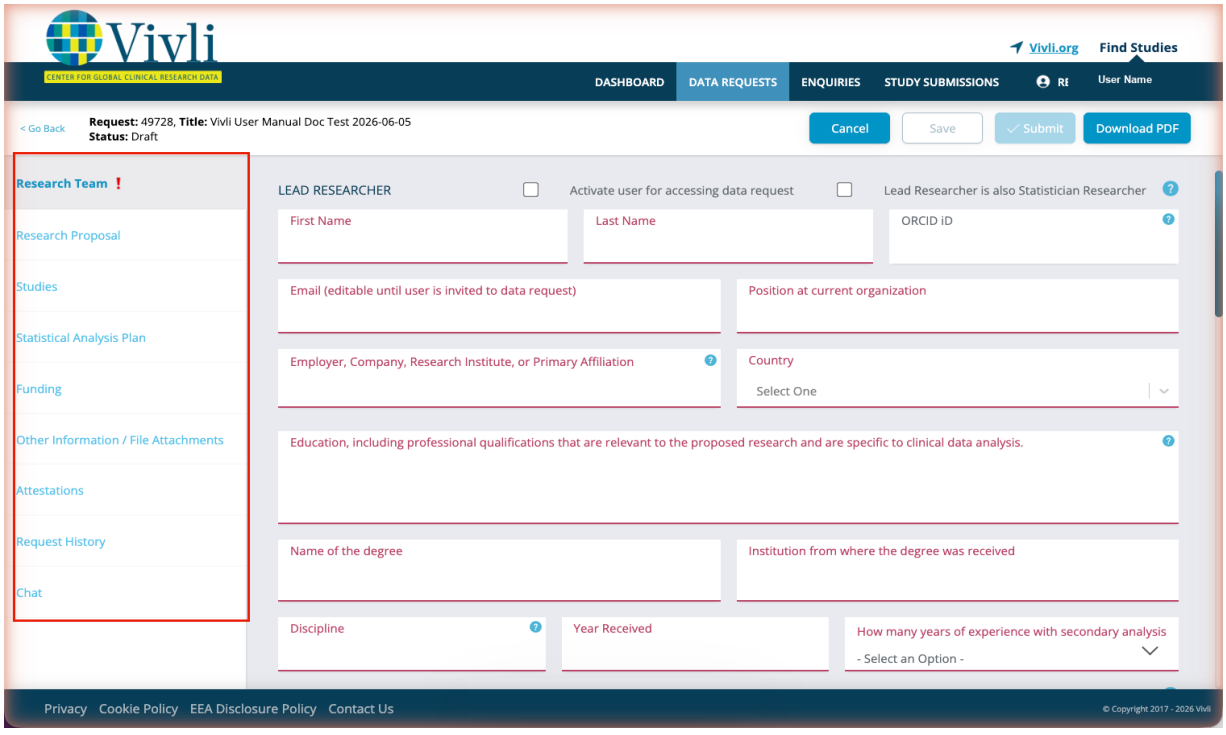


3.1 Completing a data request

To complete a data request, you must add all required information to the Data Request Form. For guidance, please see Vivli Data Request Form Worksheet. Please note that the data request must include:

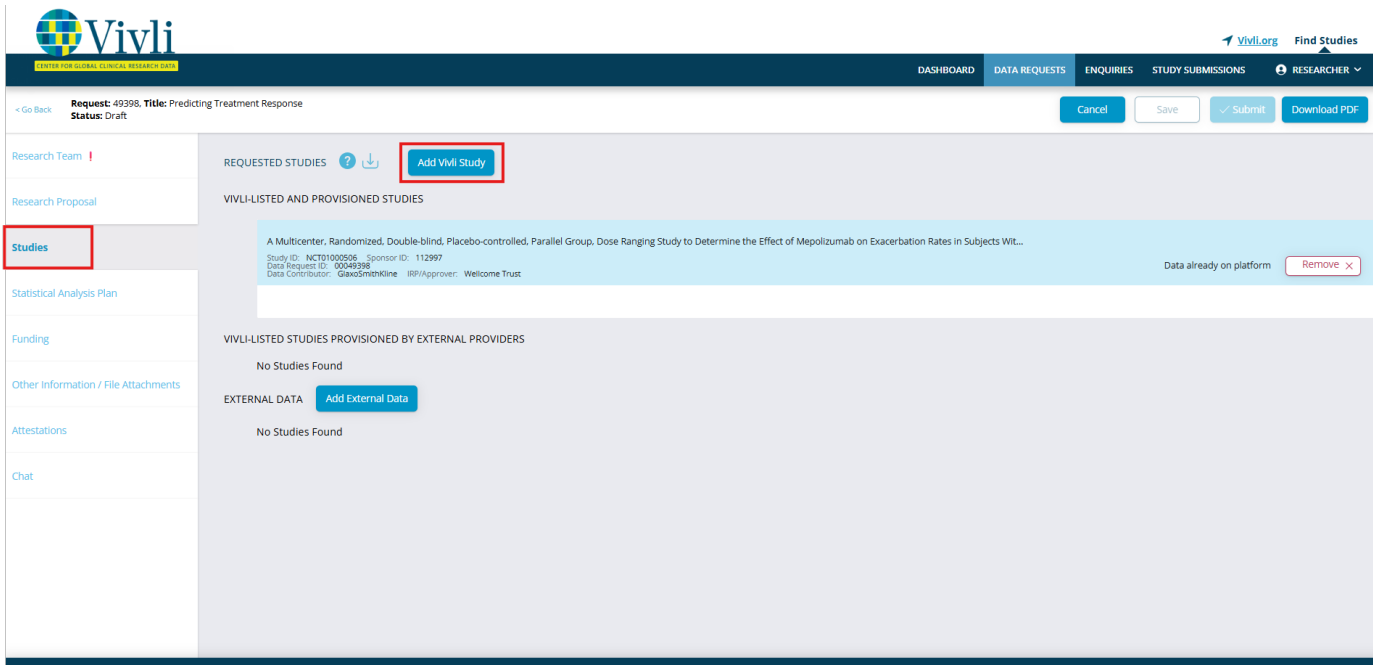
- The name, contact information, primary affiliation and position, country, qualifications, degrees, and where the degrees were obtained of all team members.
- Conflict of Interest Statement
- The title of the proposed research with a description of the study design (which should match the Project name)
- Lay summary explaining the relevance of the project to science and public health
- Brief description, main predictor variable, outcome elements, specific aims and objectives, and hypothesis to be evaluated
- Purpose of analysis and outcomes
- Project timeline, dissemination, and publication plan.
- Statistical Analysis Plan
- Information about funding
- Attestation
- All other required fields, including all data sets associated with the proposal
    - This includes studies you may request from Vivli; studies requested from other data sharing platforms; and any additional data, that you want to bring into the Vivli platform. If you will not be bringing studies into the Vivli platform but they are part of your overall research analysis plan, then please add this list of studies as an attachment.

For more information on requesting studies not listed on Vivli, please see Section 5.0 Requesting data from studies not listed on Vivli, but available for provisioning into the Secure Research Environment.

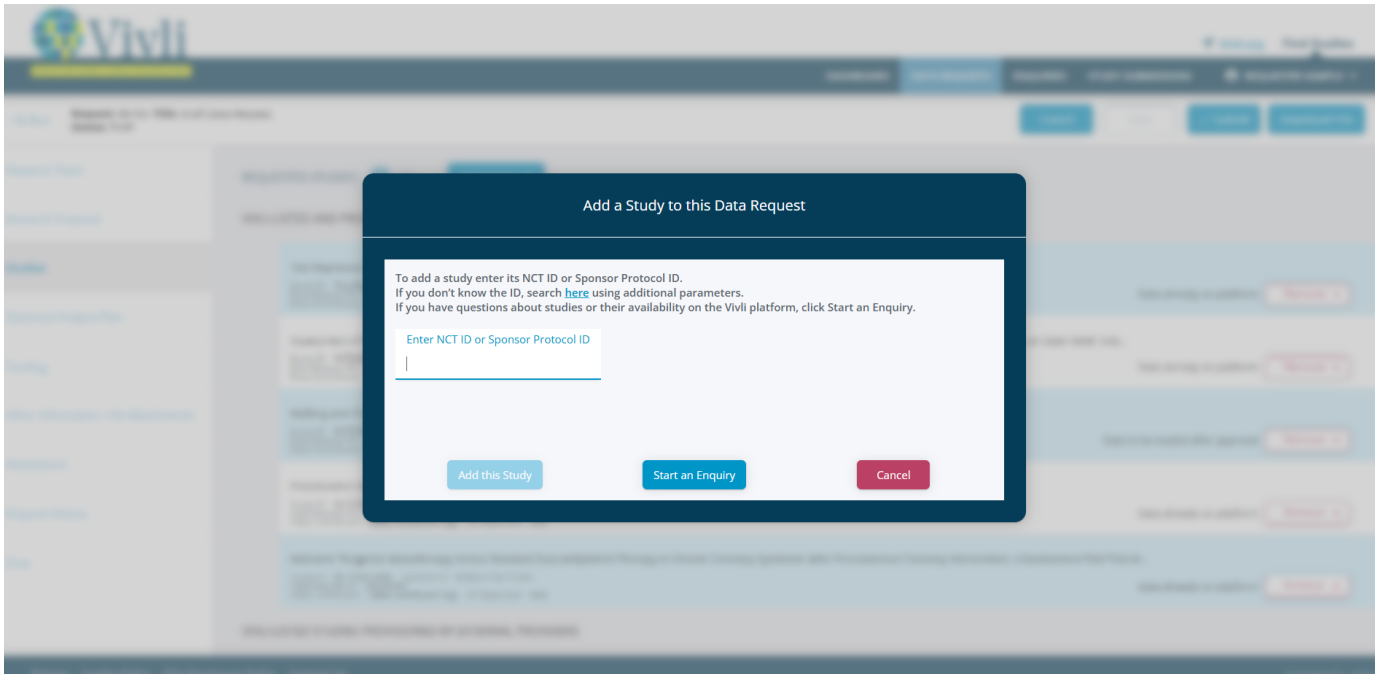


3.2.1 Adding Vivli Member Studies to your data request

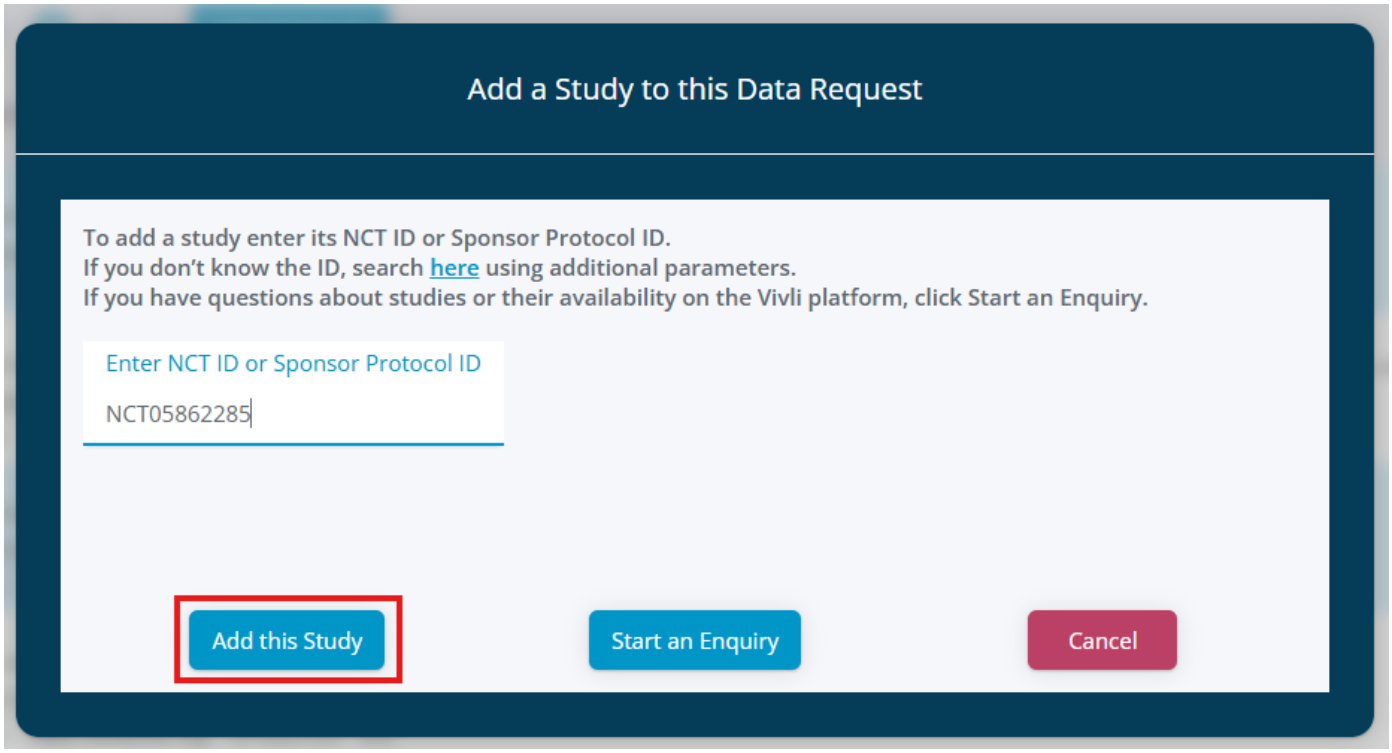
1. While the data request is in Draft status, once you have added one study to your data request using the search, as in Section 1.1 Searching for studies on the Vivli platform , you can then add further studies from the Studies tab in the data request by clicking on the 'Add Vivli Study' button



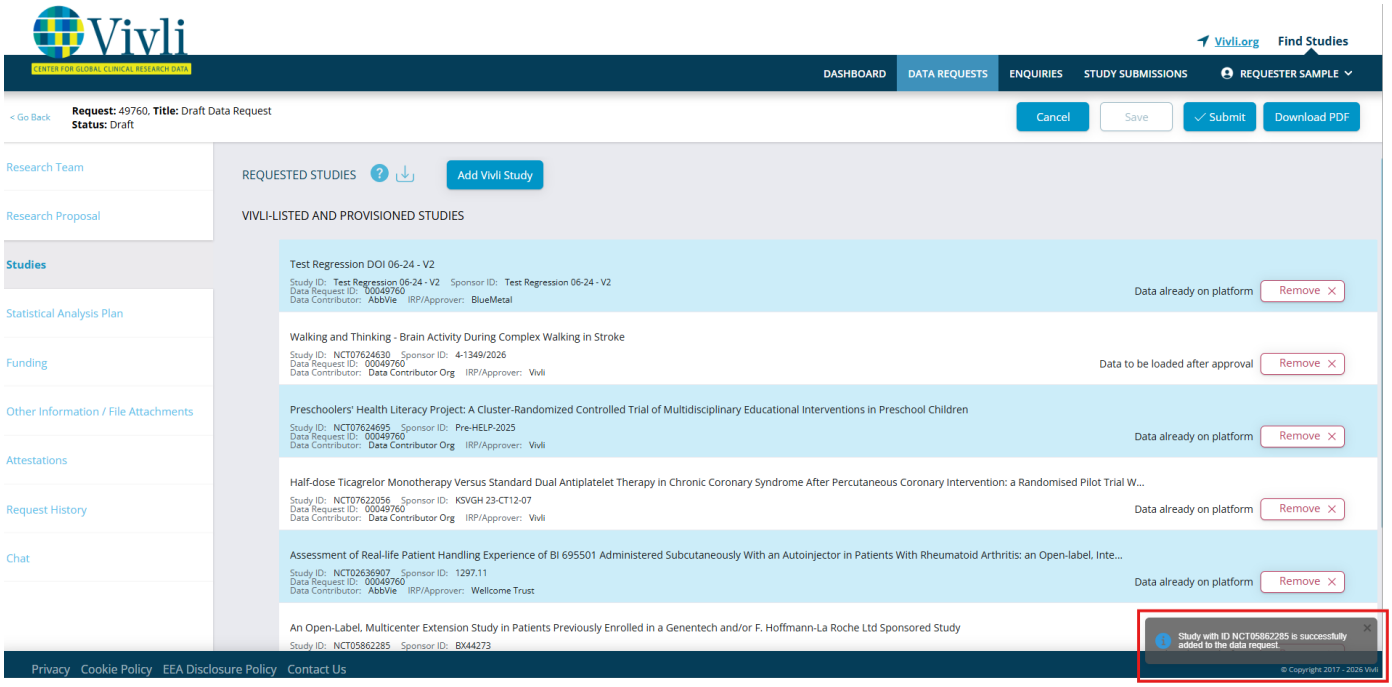
2. After clicking on this button a pop-up will appear



3. Enter the NCT ID or Sponsor Protocol ID, and click 'Add this Study'

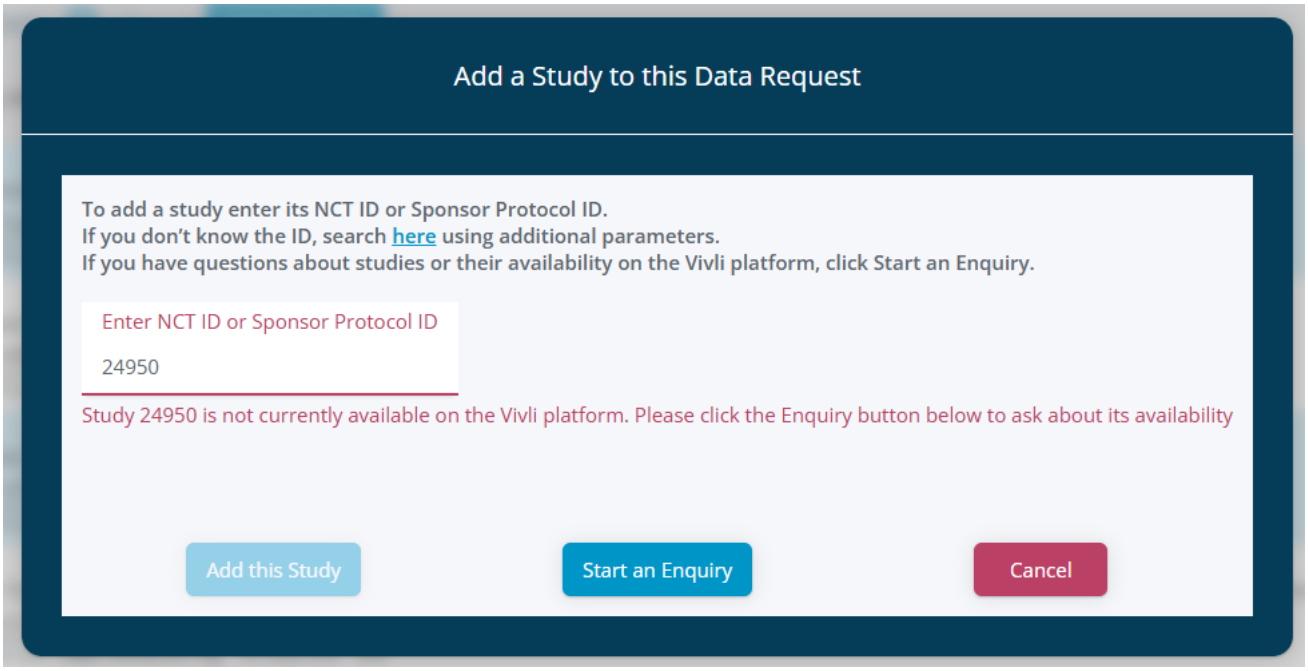


4. If the study is listed on Vivli it will be added to the Studies tab, and a message of success will be posted in the bottom corner



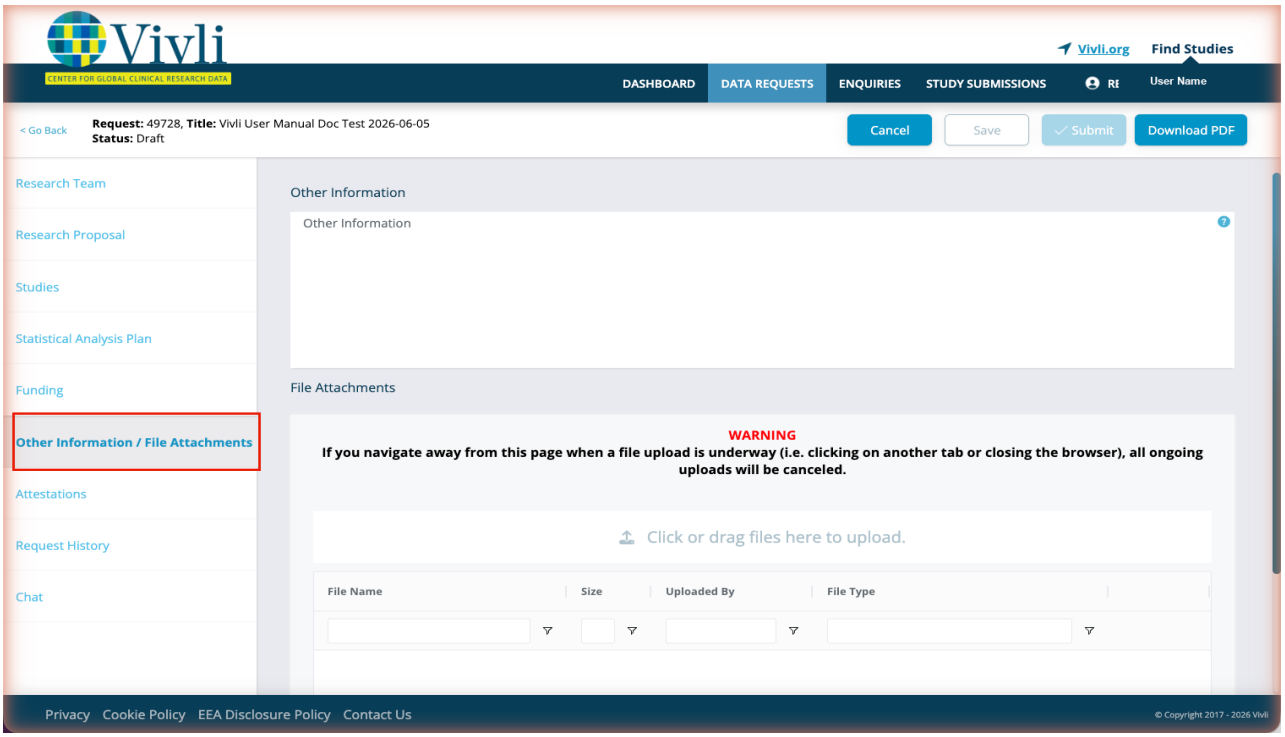
5. If the study is not listed on Vivli, a message will appear asking you to click on the Enquiry button to 'Start an

Enquiry' for the study. See section 2.2 Creating an Enquiry for how to submit an enquiry.

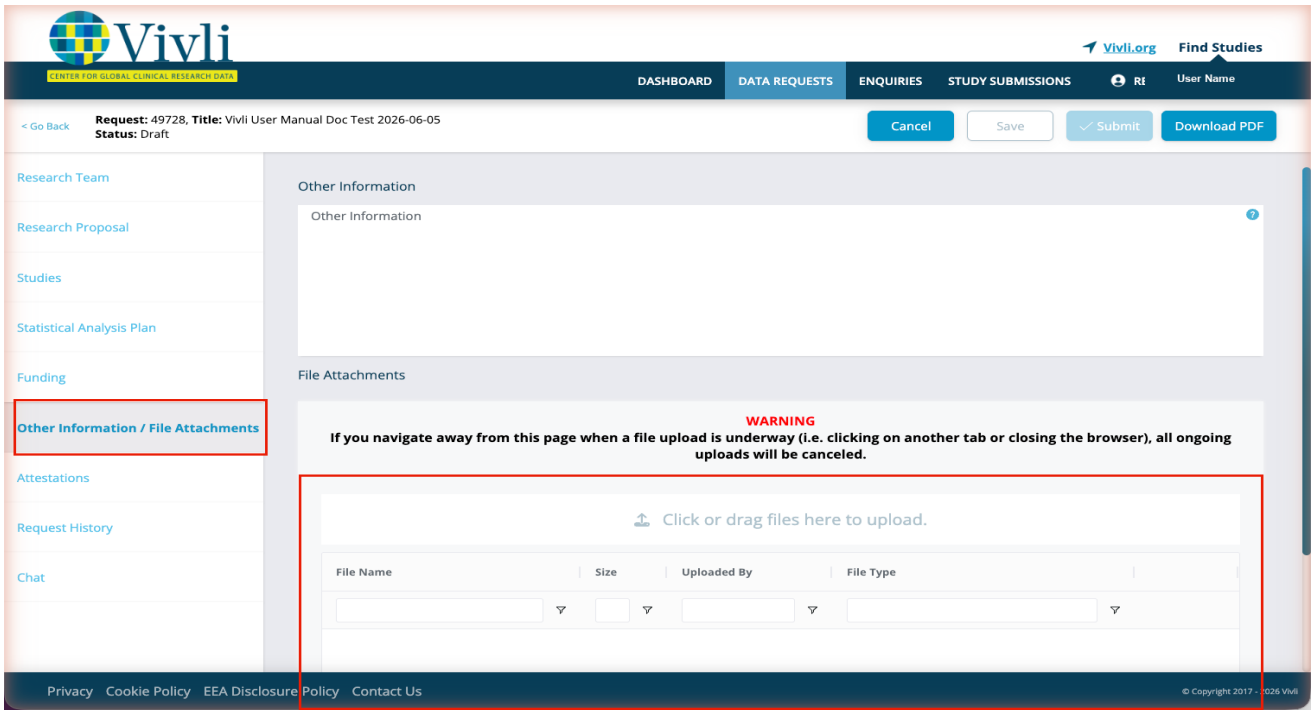


3.2.2 Adding Files or Other Information to your data request

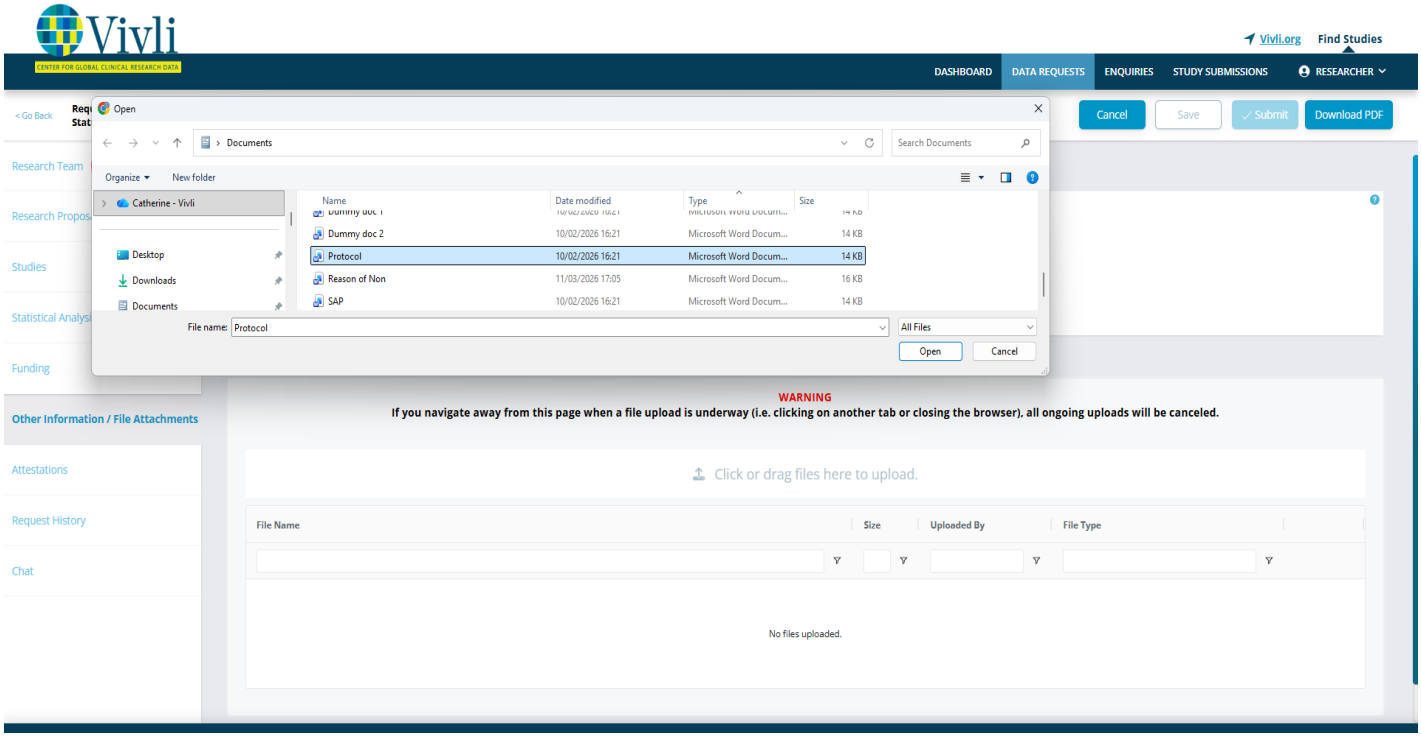
1. You can also attach files to your data request using the **Other Information/File Attachments** tab:



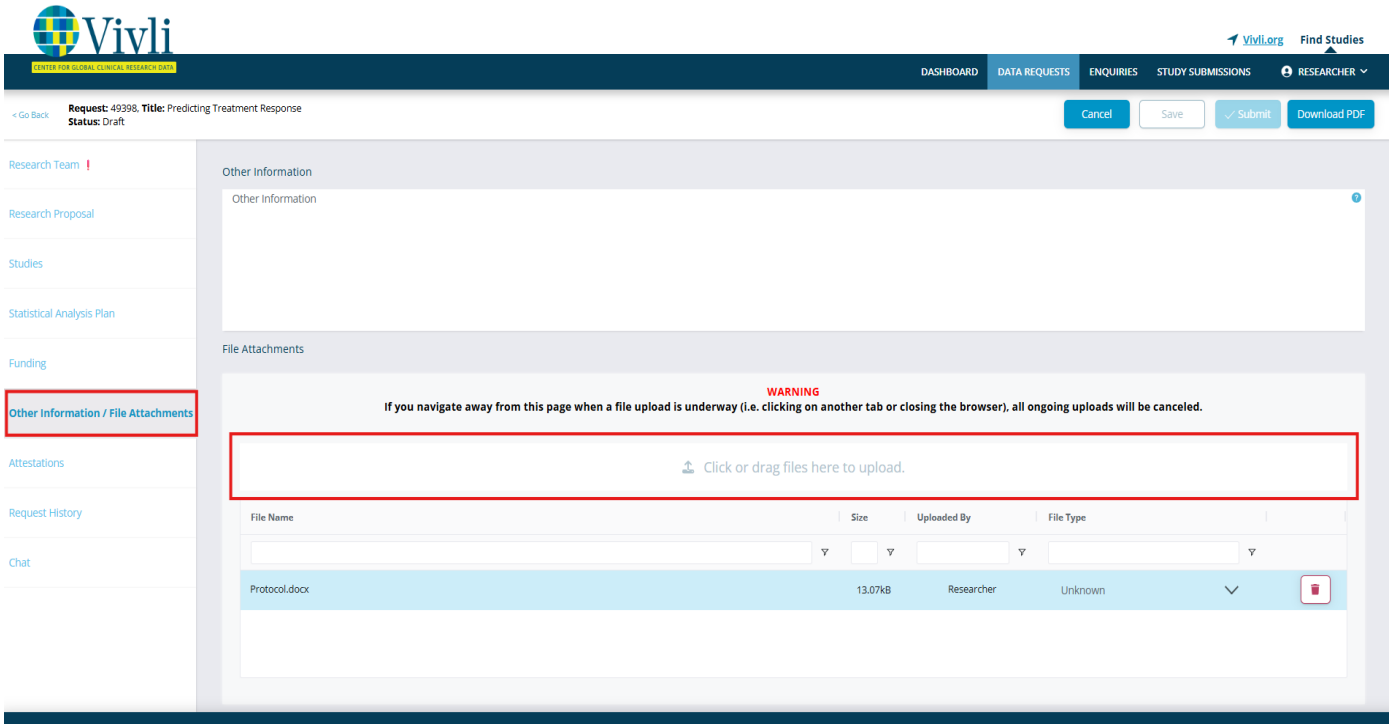
2. Go to 'Click or drag files here to upload', and click to choose a file:



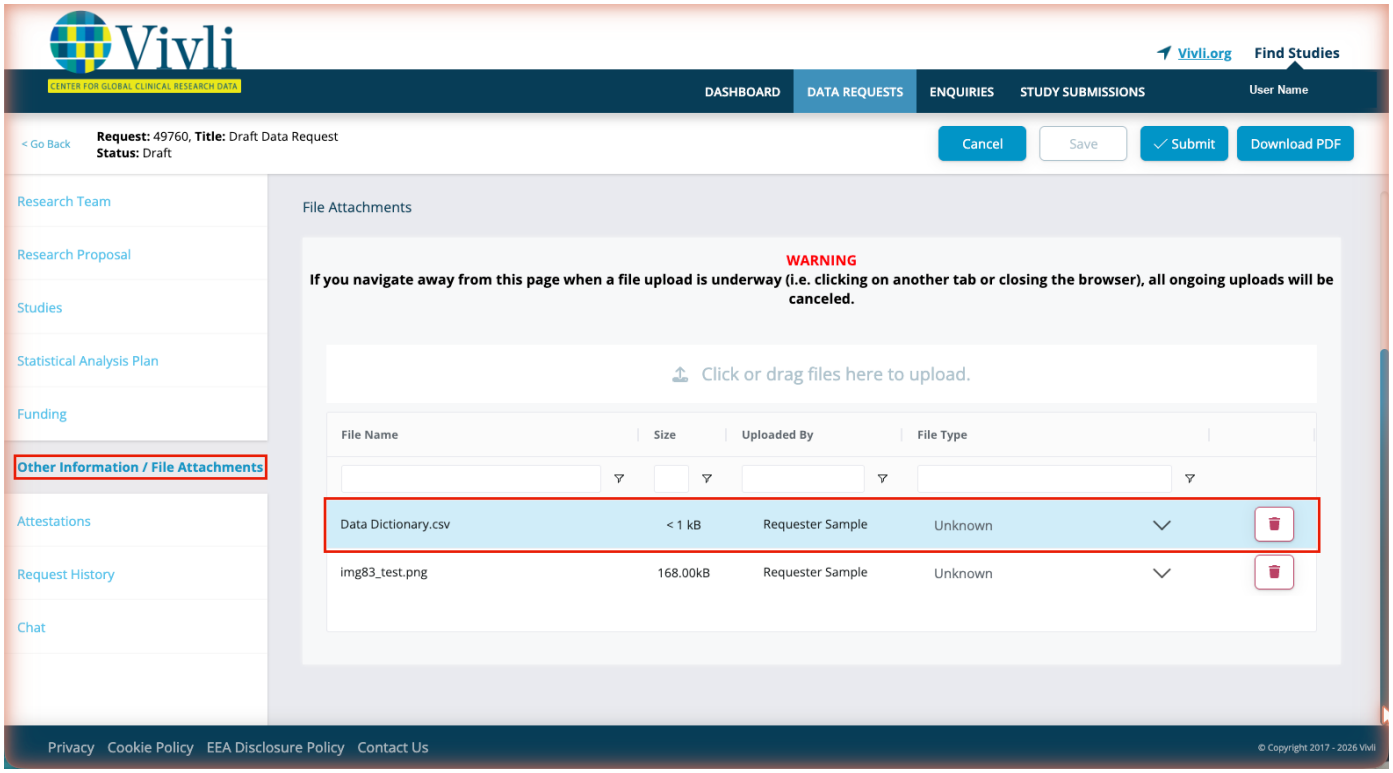
3. Then simply select the file from your computer. If you navigate away from this page when a file upload is underway (i.e. clicking on another tab or closing the browser), all ongoing uploads will be cancelled.:



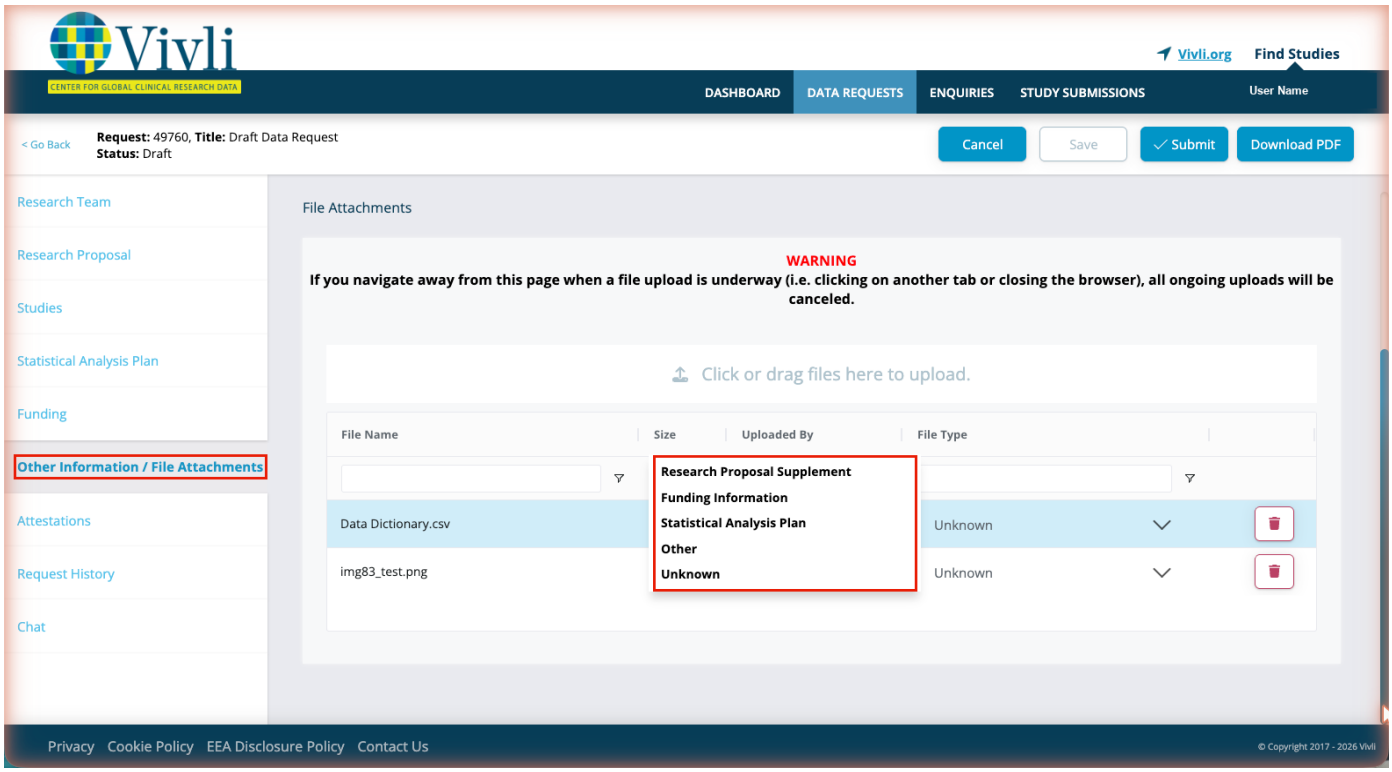
4. You can also drag and drop files into the '**Drop files here'** box:



5. Your uploaded files will appear under **Uploaded files**:

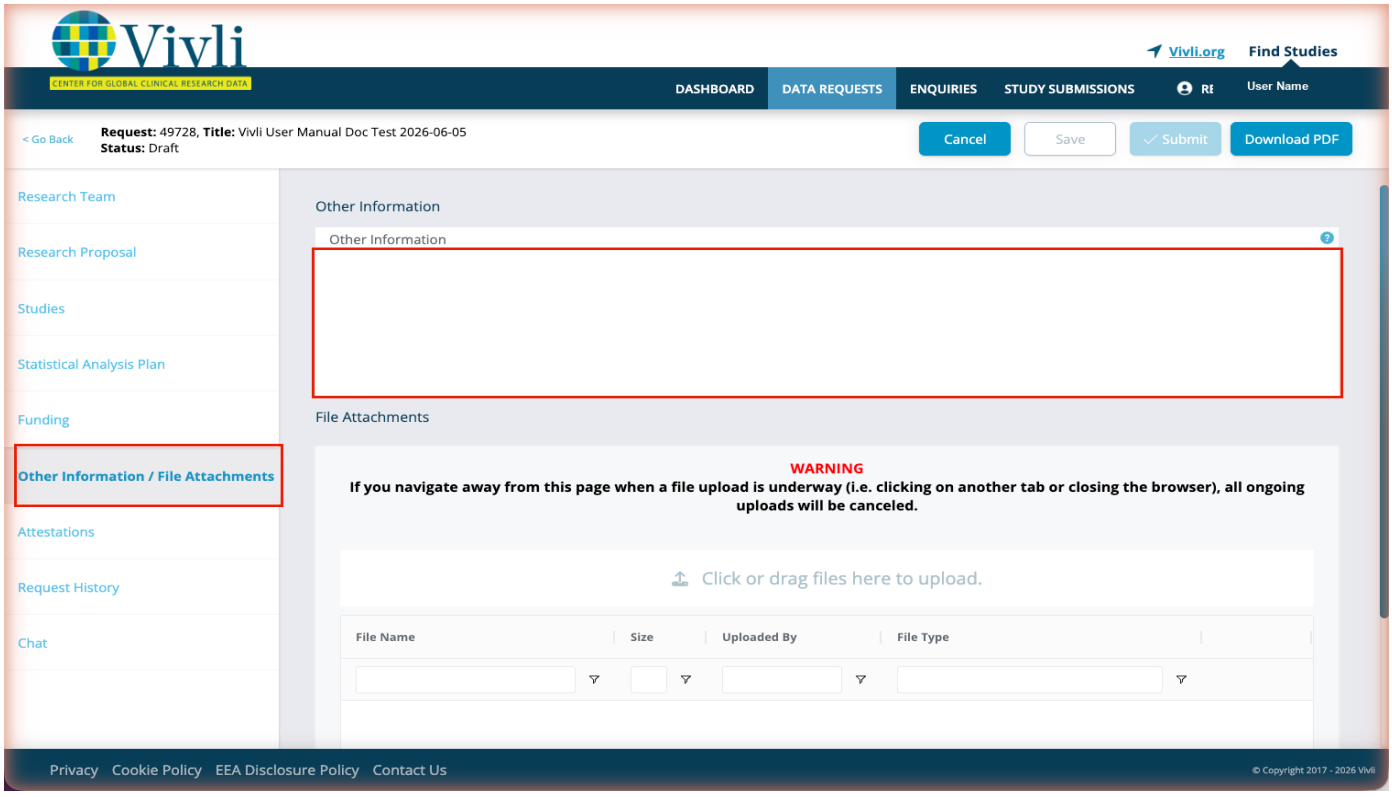


6. You can select the file type from the dropdown menu after the upload is complete:



7. To delete the file, simply click on the trash can.

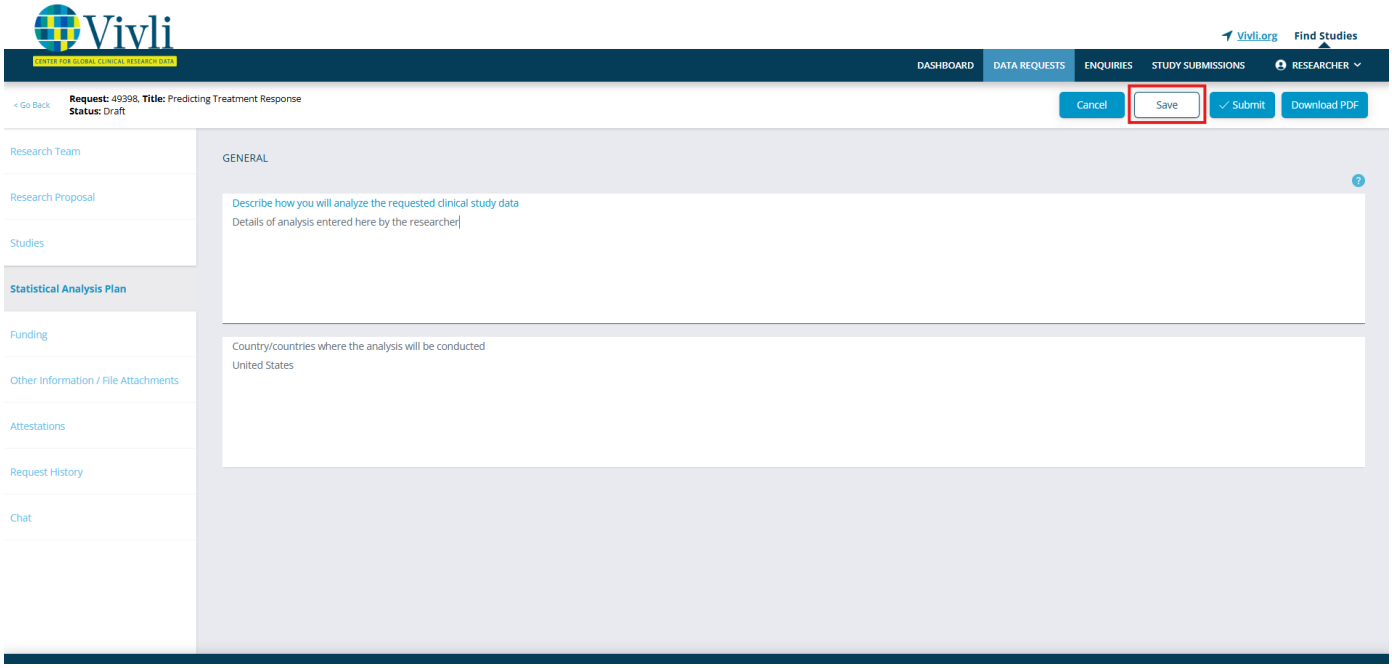
8. To enter any other information, simply type into the dialogue box:



3.3 Saving your data request

You do not have to complete the Data Request Form in a single session; you can save the Data Request Form as many times as needed prior to submission.

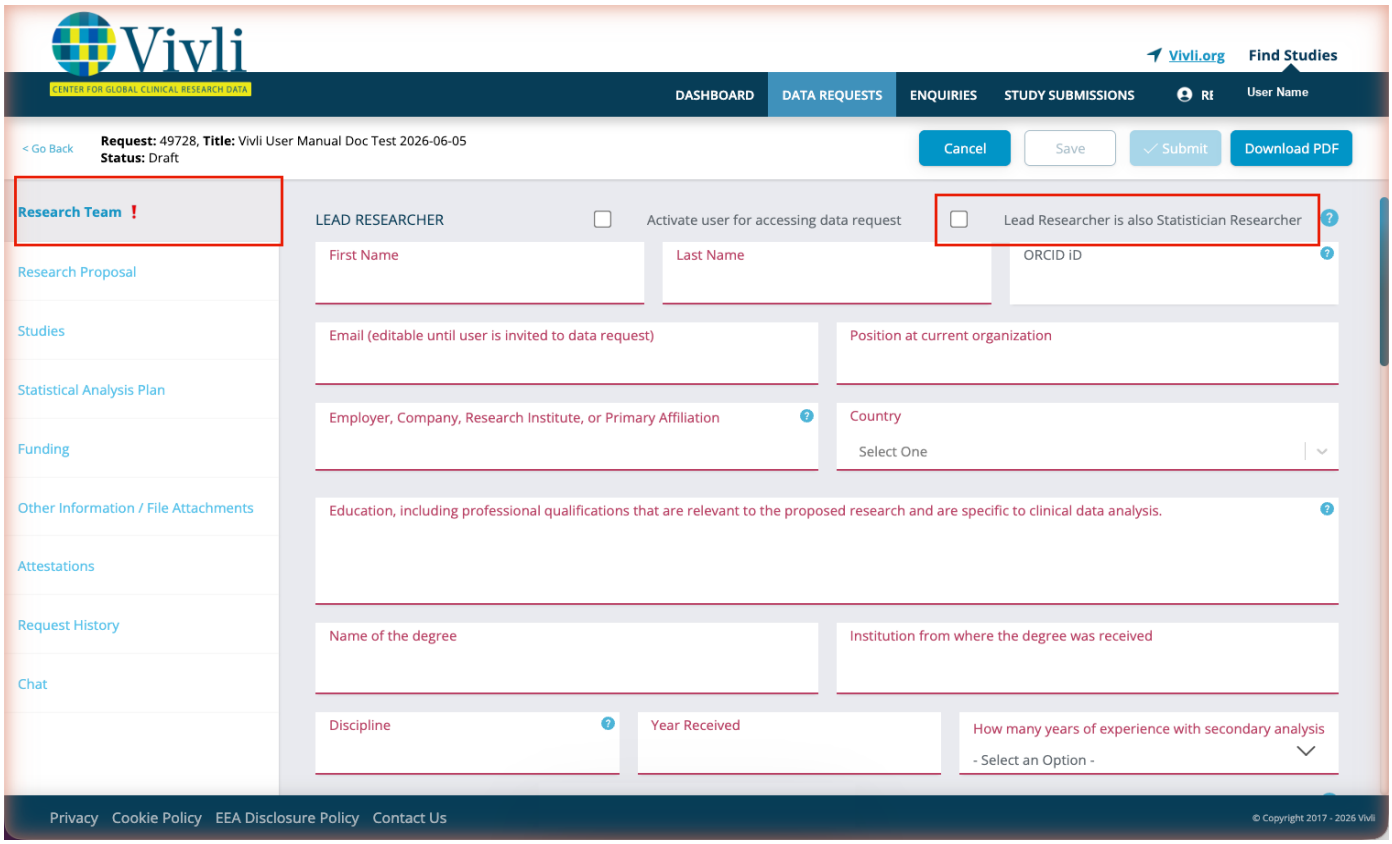
To save a Data Request Form, click on **Save** in the top right corner of the screen:



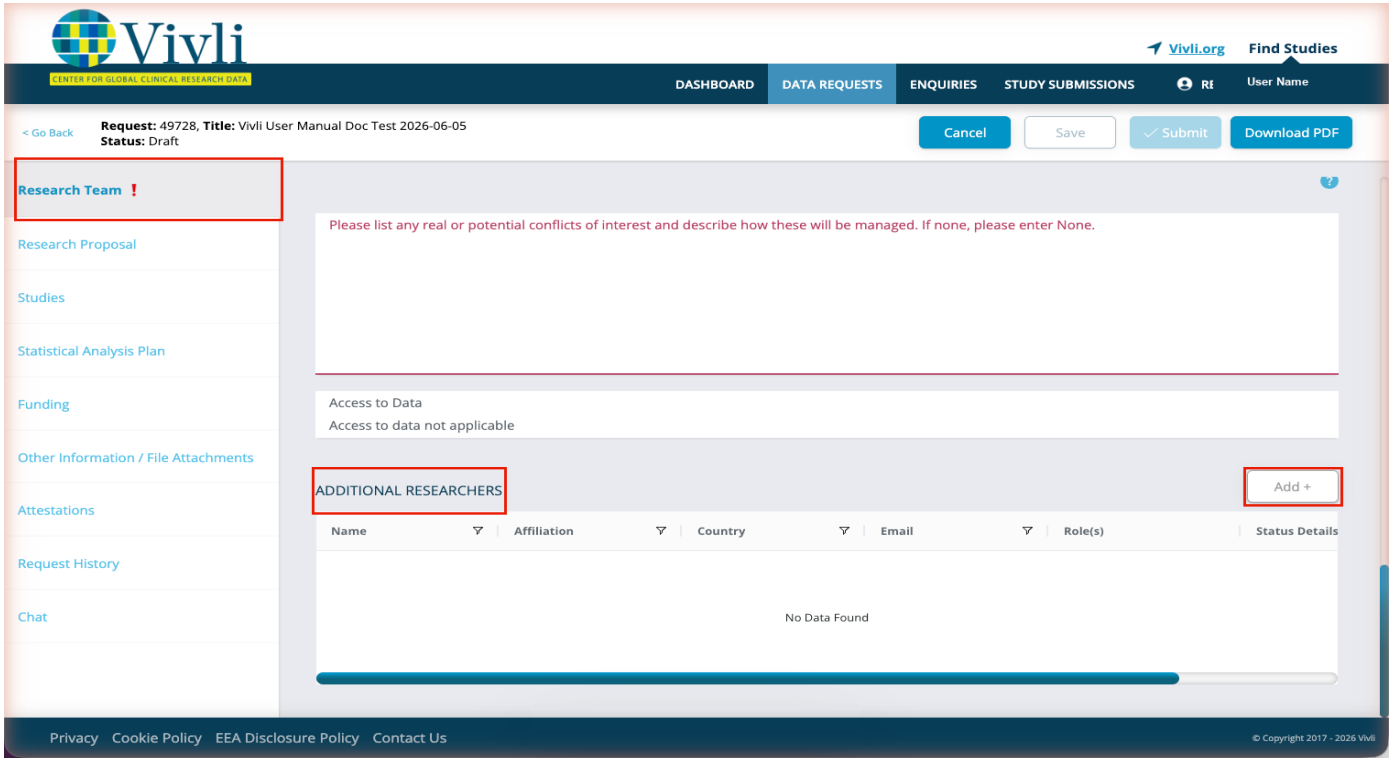
3.4 Adding Research Team Members

1. When the request is in the **"Drafts"** stage**,** additional research team members may be added to a Data Request by the research team directly following the steps below.
2. Individuals activated for a data request will be able to view and edit the Data Request Form.
3. If the Data Use Agreement (DUA) covers the individual, they will have access to the Secure Research Environment.
    - If your team member is from a different institution than the Lead Researcher and would like to access the data, they will need to have a separate DUA in place from their institution before accessing the data.
4. These permissions can also be changed before starting the secure research environment and while the secure research environment is running.
5. If the Lead Researcher is also a Statistician Researcher, select the checkbox as shown below.

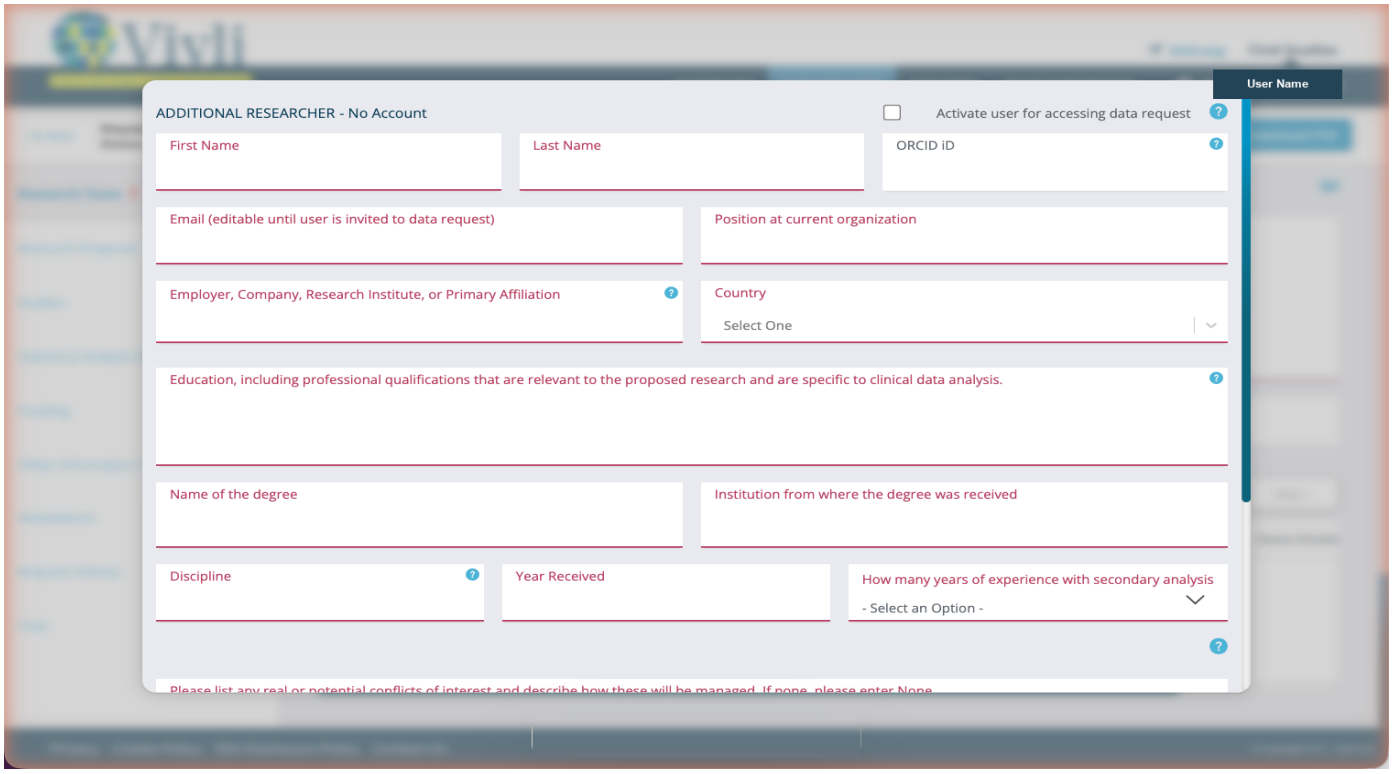
Note: you are unable to add two Research team members with the same email address.



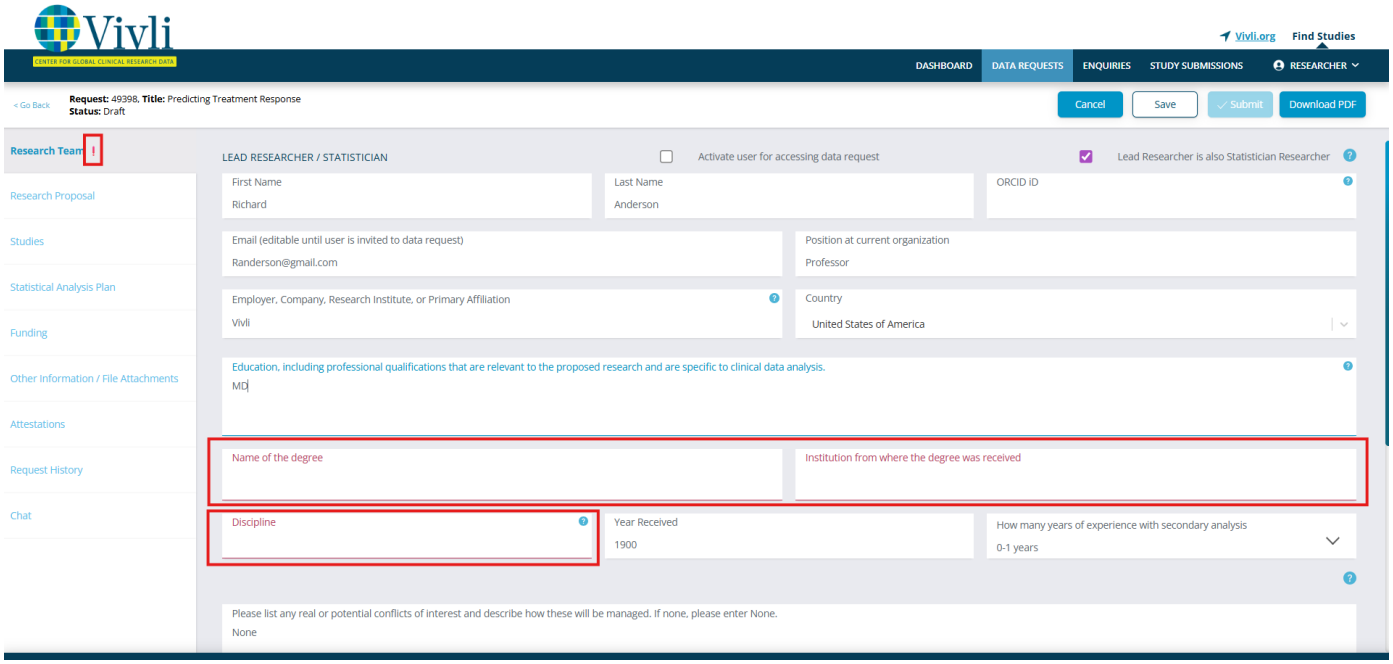
6. To add additional team members, scroll down to add additional team members - click on **Add+** in the lower right corner, opposite **ADDITIONAL RESEARCHERS**:



7. The following dialogue box will appear:



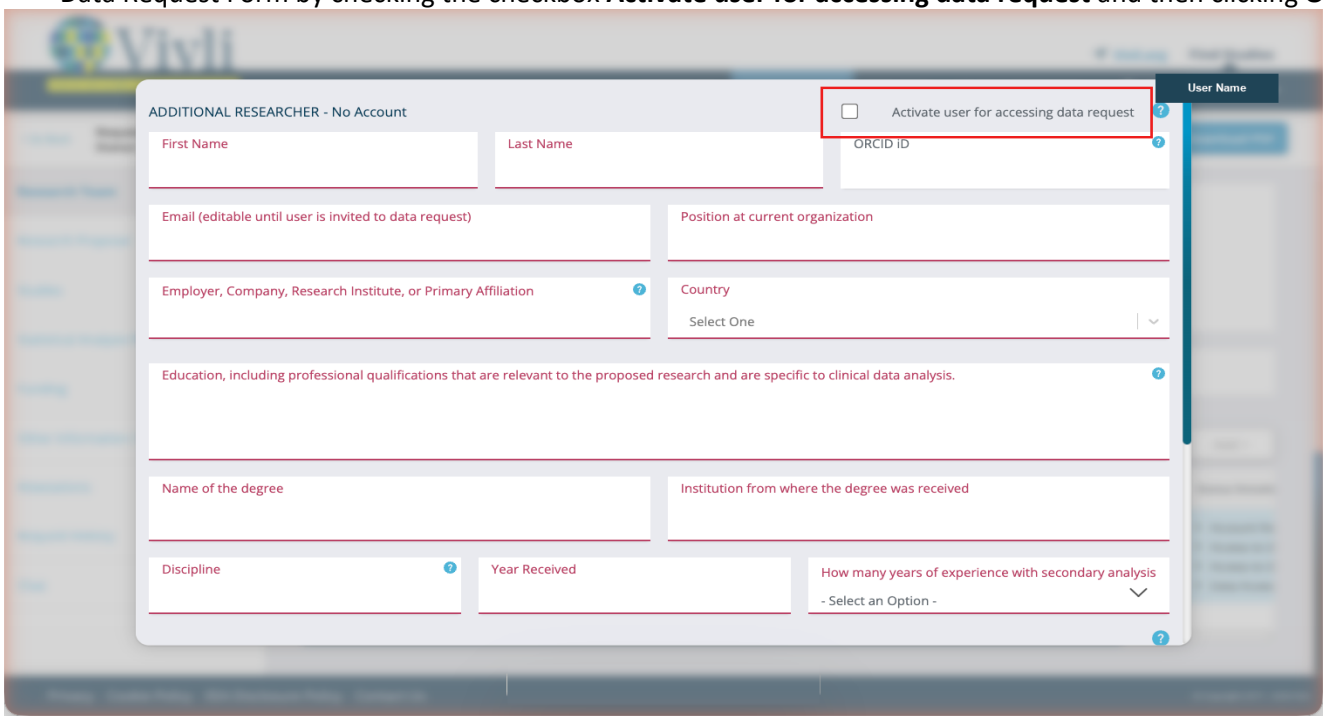
8. Note that if there is missing information in a required field in the Research Team section, the field will be outlined in red and a red exclamation mark will appear in the “Research Team tab” on the left side. Once the required field is input, the exclamation mark will disappear.



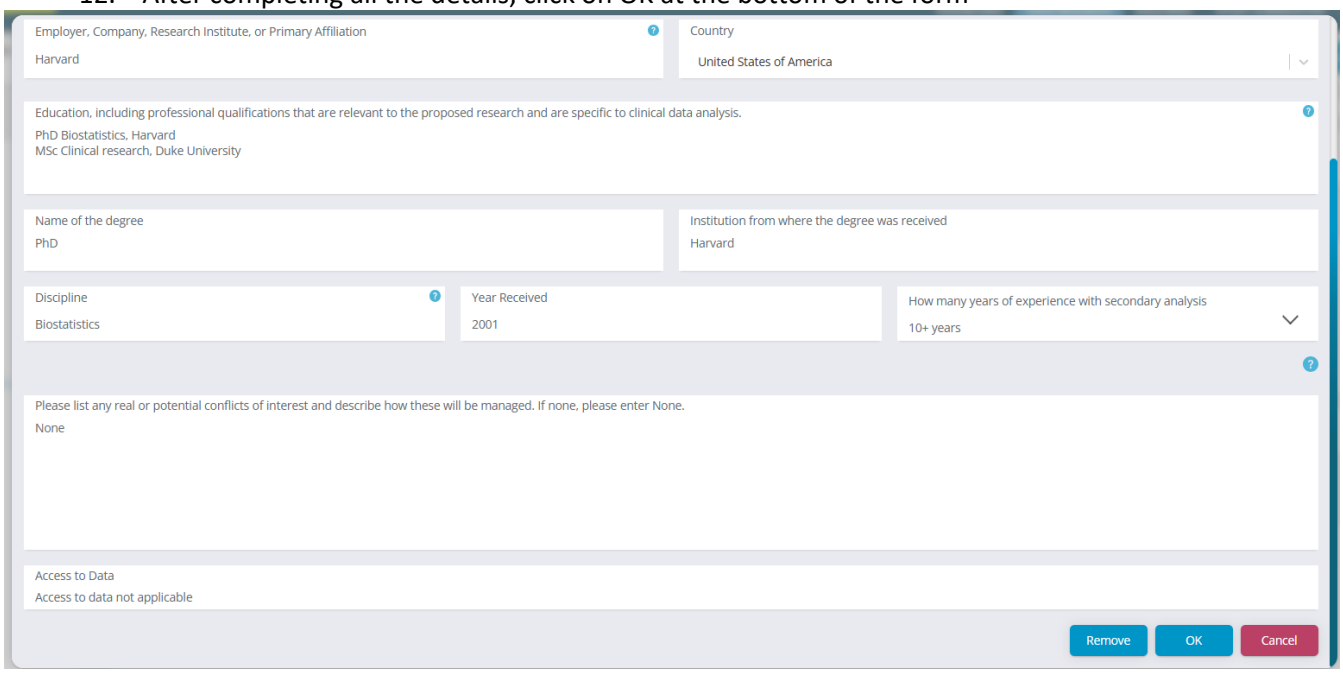
9. Complete all fields, and click 

10. Please ask the research team member to "sign up" for a Vivli account. They can follow Section 1.1 of the Vivli User Account Quick Start guide

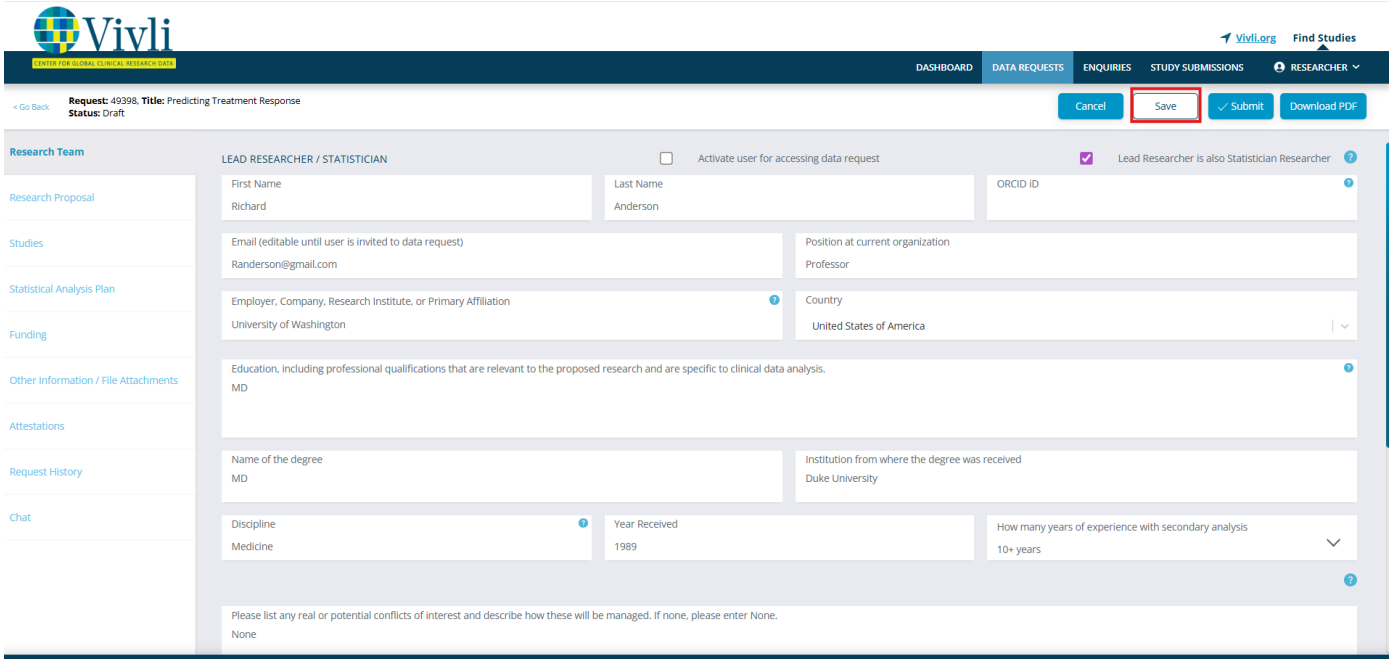
11. Once the Research team members have created their Vivli account, you can activate them for accessing the Data Request Form by checking the checkbox **Activate user for accessing data request** and then clicking **OK:**



12. After completing all the details, click on OK at the bottom of the form



13. Then, on the main data request form, click **Save**. The team member will then be added to the data request.



14. If you would like to make changes to the Research team members including the Lead Researcher or Lead Statistician **during the review process, or after the data request is approved,** please reach out to the Vivli team via platform chat or support@vivli.org.
15. Please provide the following information when requesting to add an additional research team member:

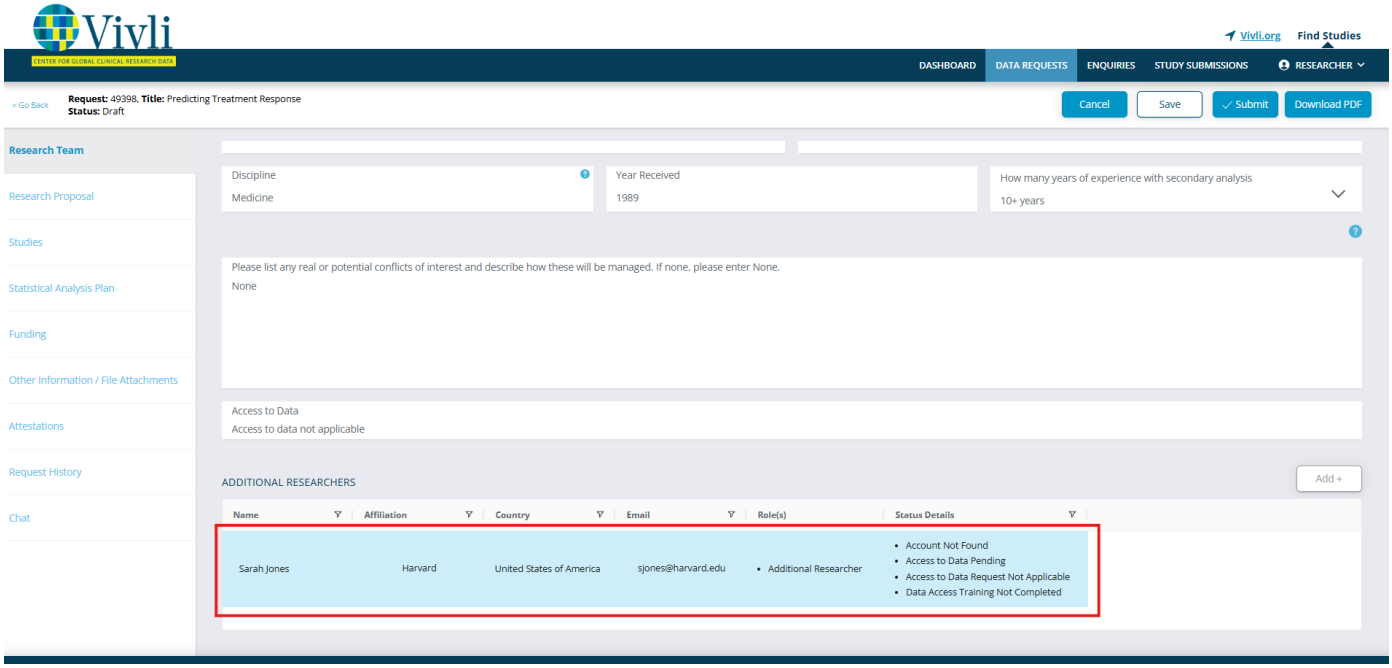
- First Name
- Last Name
- Email
- Position at employer/institution
- ORCiD (if available)
- Employer/company/institution name
- Country location
- Education (include qualifications, disciplines and institutions where they were obtained, and publications relevant to this analysis):
- Conflict of interest statement and plan for mitigation
- Name of highest or most relevant degree
- Institution from where the degree was received
- Discipline of the degree
- Year Received
- Number of years of experience with secondary analysis
  - *Note: If your team member is from a different institution we will need to ensure that they have a DUA in place from their institution before accessing the data*
  - *Before the new team member can be granted access to the data they must complete the data access training at https://vivli.org/VivliDataAccessTraining. Once this has been completed, please send a message via chat and we will move forward with granting access.*

16. Please note that according to Vivli policy, the following changes are considered a major revision and will require that Data Contributors have the opportunity to re-review your data request and have it go through their entire approval process:
    - The Lead Researcher or Lead Statistician's affiliation, if the new affiliation is a commercial entity
    - Funding
    - Conflict of interest
    - Adding studies from a data contributor not originally in the request,
    - bringing in external data not declared in the original proposal
    - Aims/objectives or Statistical Analysis Plan

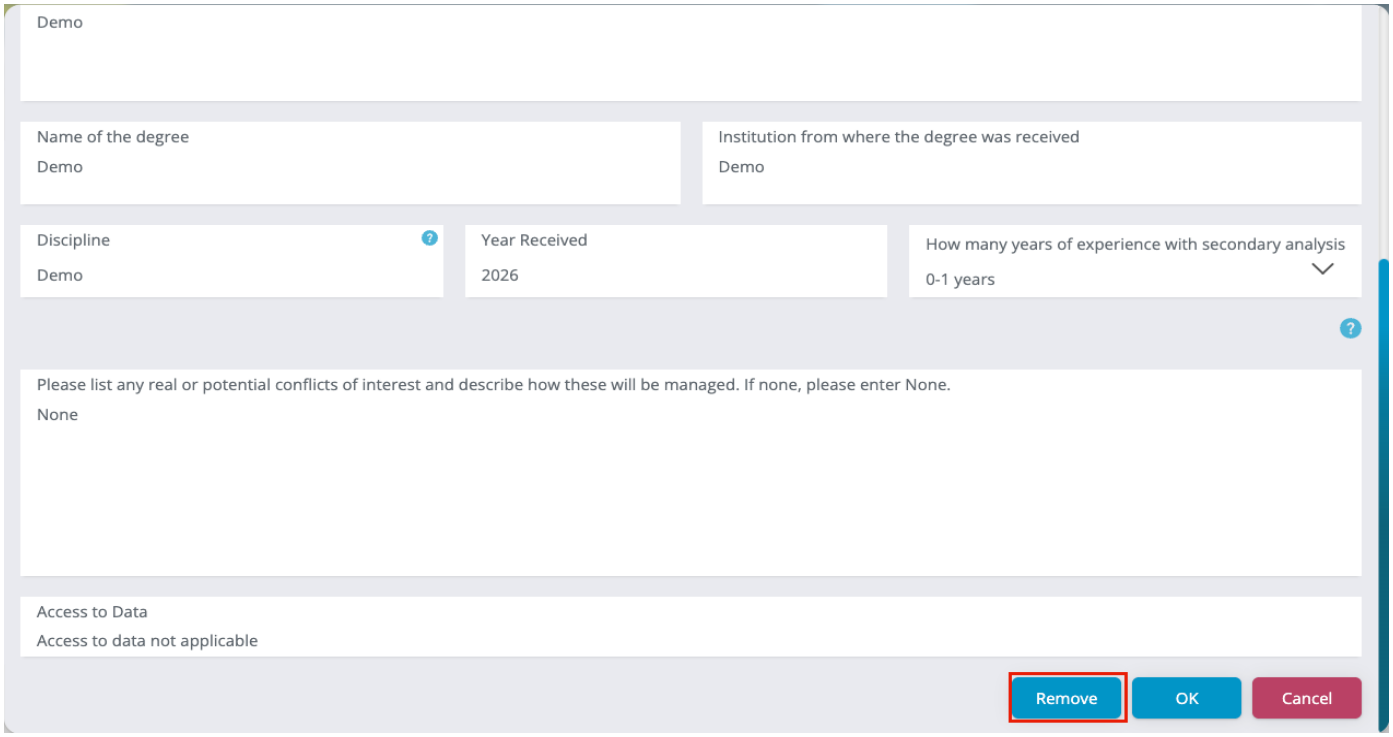
3.5 Deleting research team members

Follow these steps to remove a team member from your data request form while it is still in **draft**:

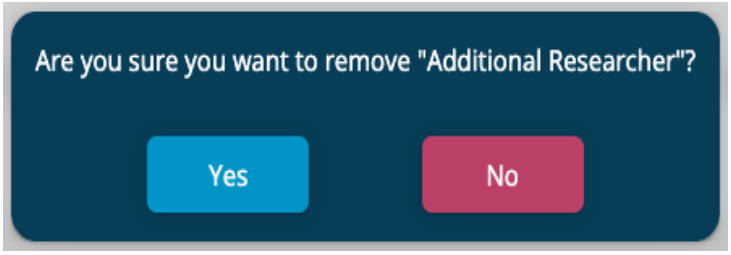
1. Open your draft data request and Click on the **Research Team** tab:
2. Under **ADDITIONAL RESEARCHERS,** click anywhere in the blue box with the researcher's details to enter the record



3. Scroll to the bottom of the record and click on the ‘Remove’ button



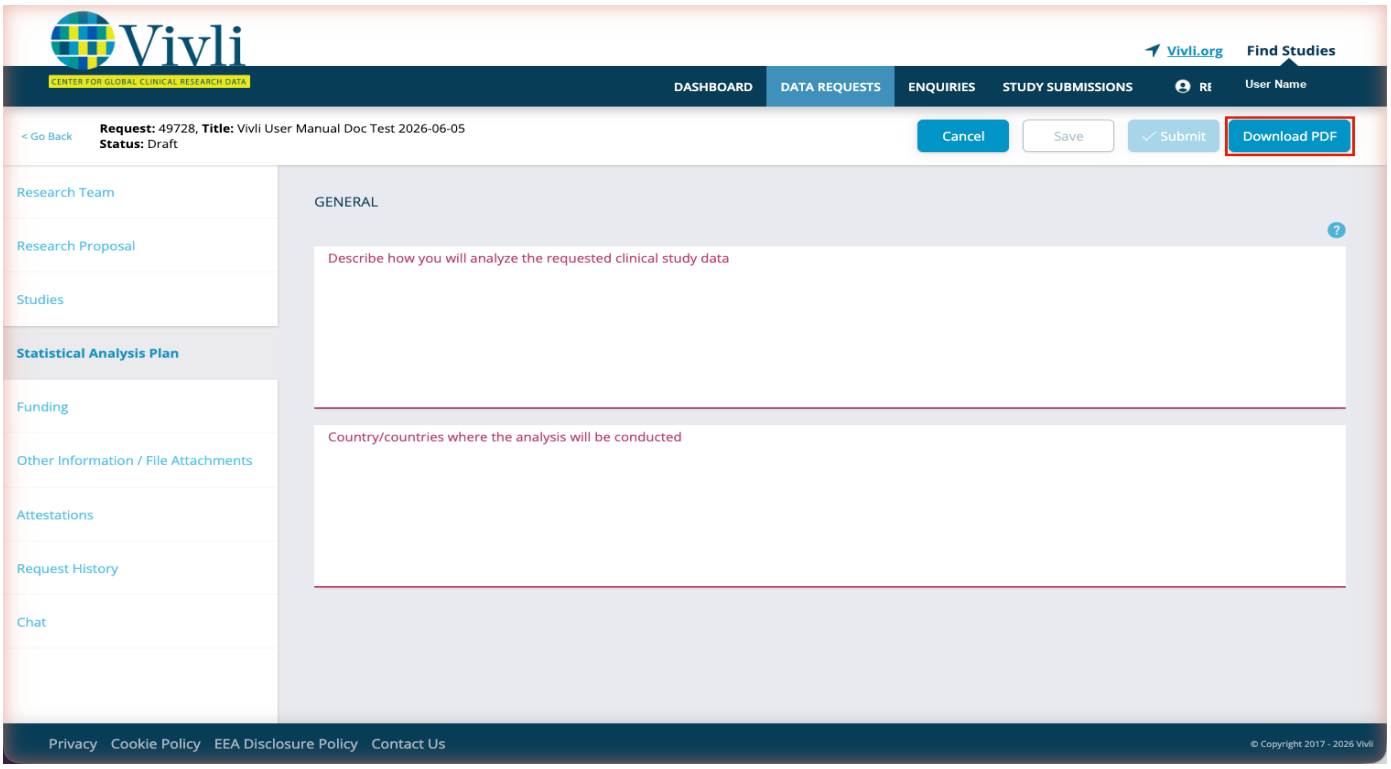
4. The following pop-up will appear:



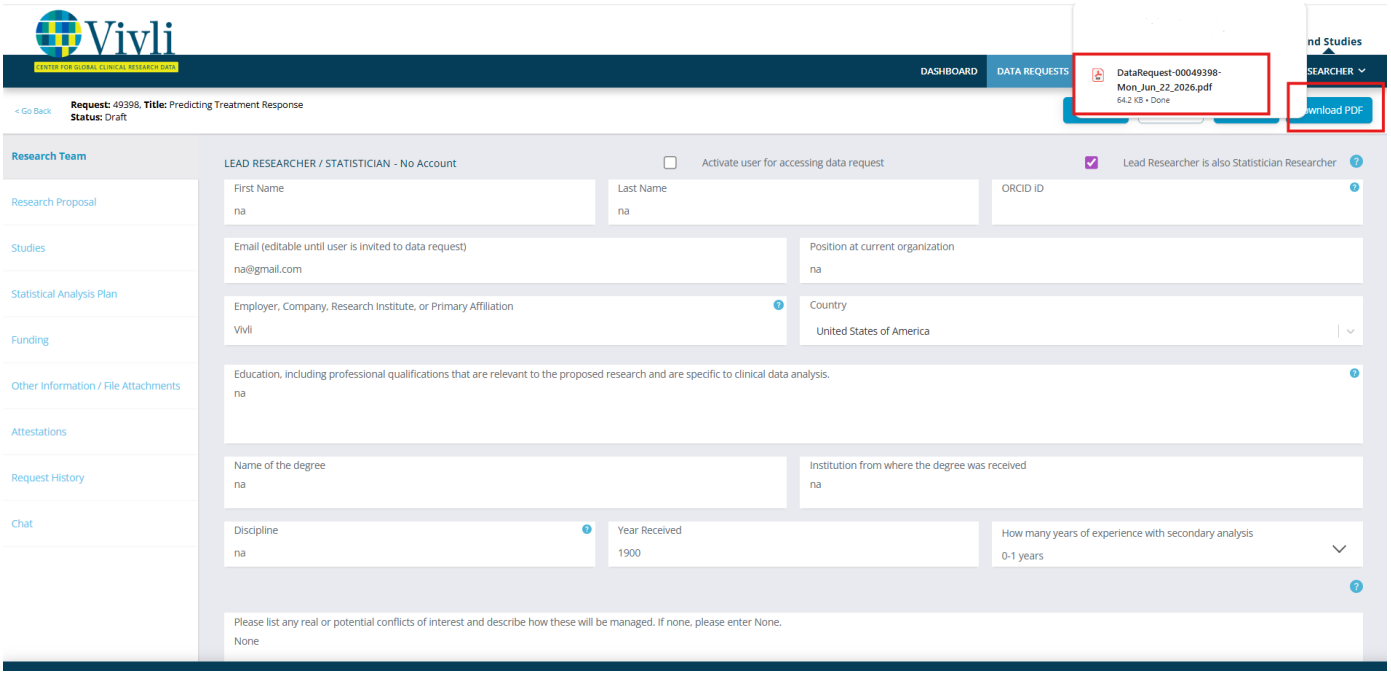
5. Click on **Yes** to remove the team member.
6. Click Save at the top of the form for the removal to be retained.

Saving a PDF version of your Data Request

To save a copy of your data request at any time while you are editing it, you can click on the ‘Download PDF’ button in the top right of your screen.



This will download a copy to your browser where you can view it or save it elsewhere.



4.0 Requesting Vivli-listed studies provisioned by external providers

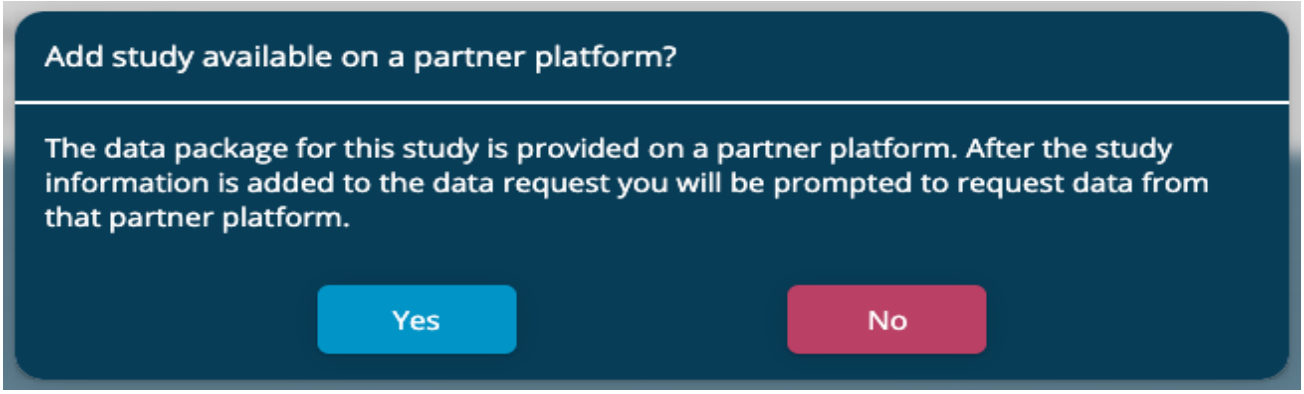
4.1 Overview

- Some studies are listed and searchable on both the Vivli platform as well as on other platforms that are Partner Platforms with Vivli.
- In addition to completing the Vivli request form, you will need to request such studies directly through the Partner Platform.
- After the relevant Data Contributor(s) have approved your request, you will sign a Data Use Agreement (DUA). The Data Contributor will then provision the data from their platform into the secure research environment.

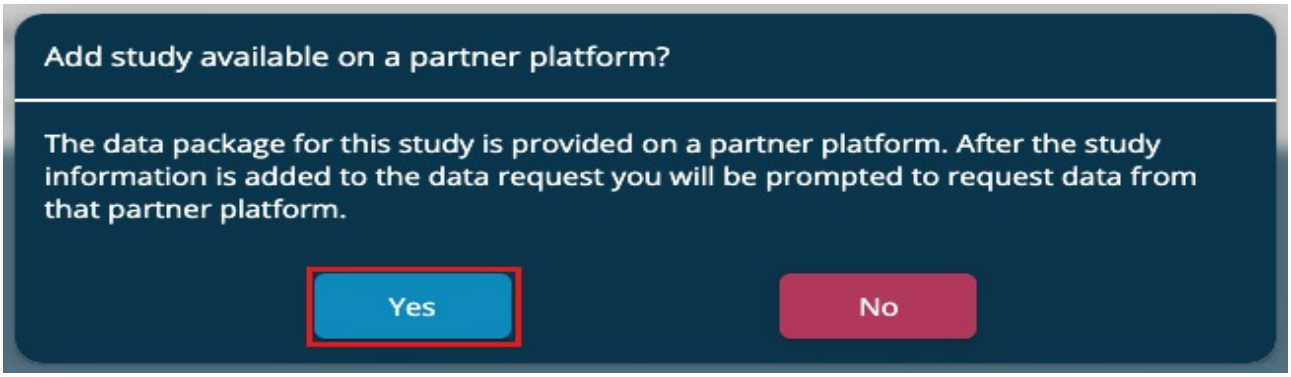
4.2 Requesting studies provisioned by external providers

1. If the study you are searching for is on the Vivli Platform but provisioned by an external provider, it will appear on the Studies page when you search for studies as described in Section 1.1, *Searching for studies on the Vivli platform*.

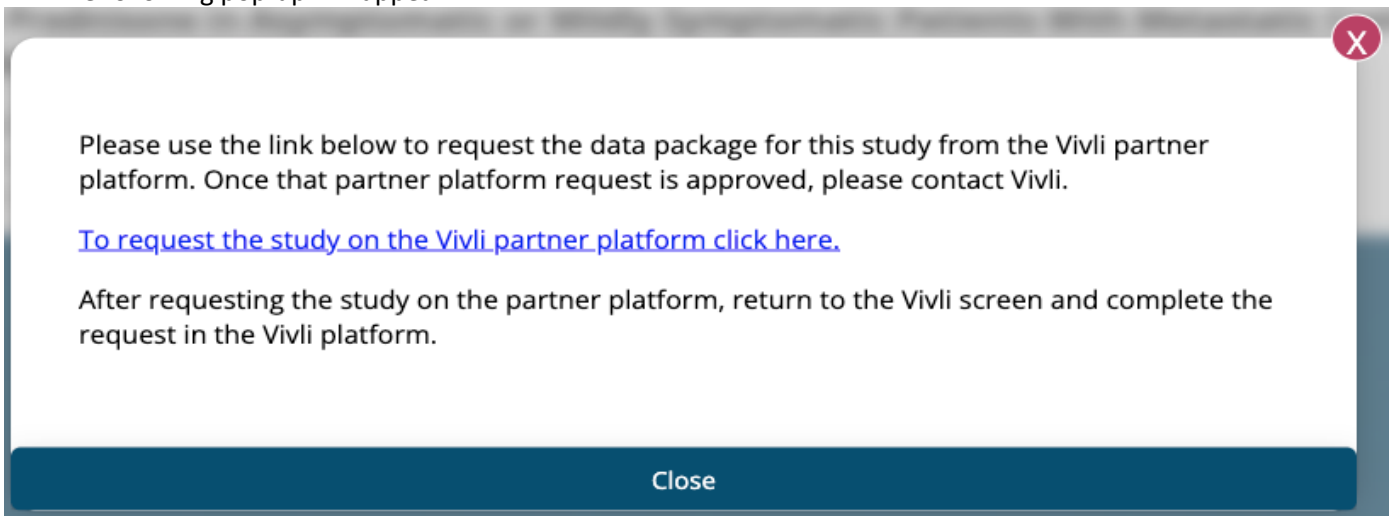
2. When attempting to add a study in this category to a Data Request Form, the following pop-up will appear:



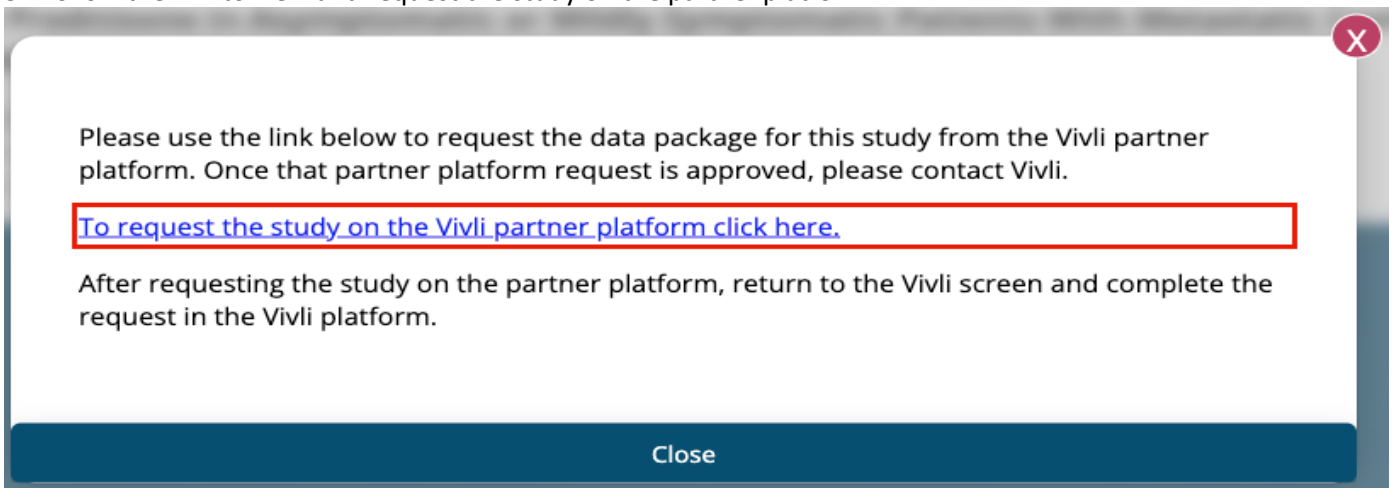
3. Click on **Yes** to add the study to the Data Request Form:



4. The following pop-up will appear:

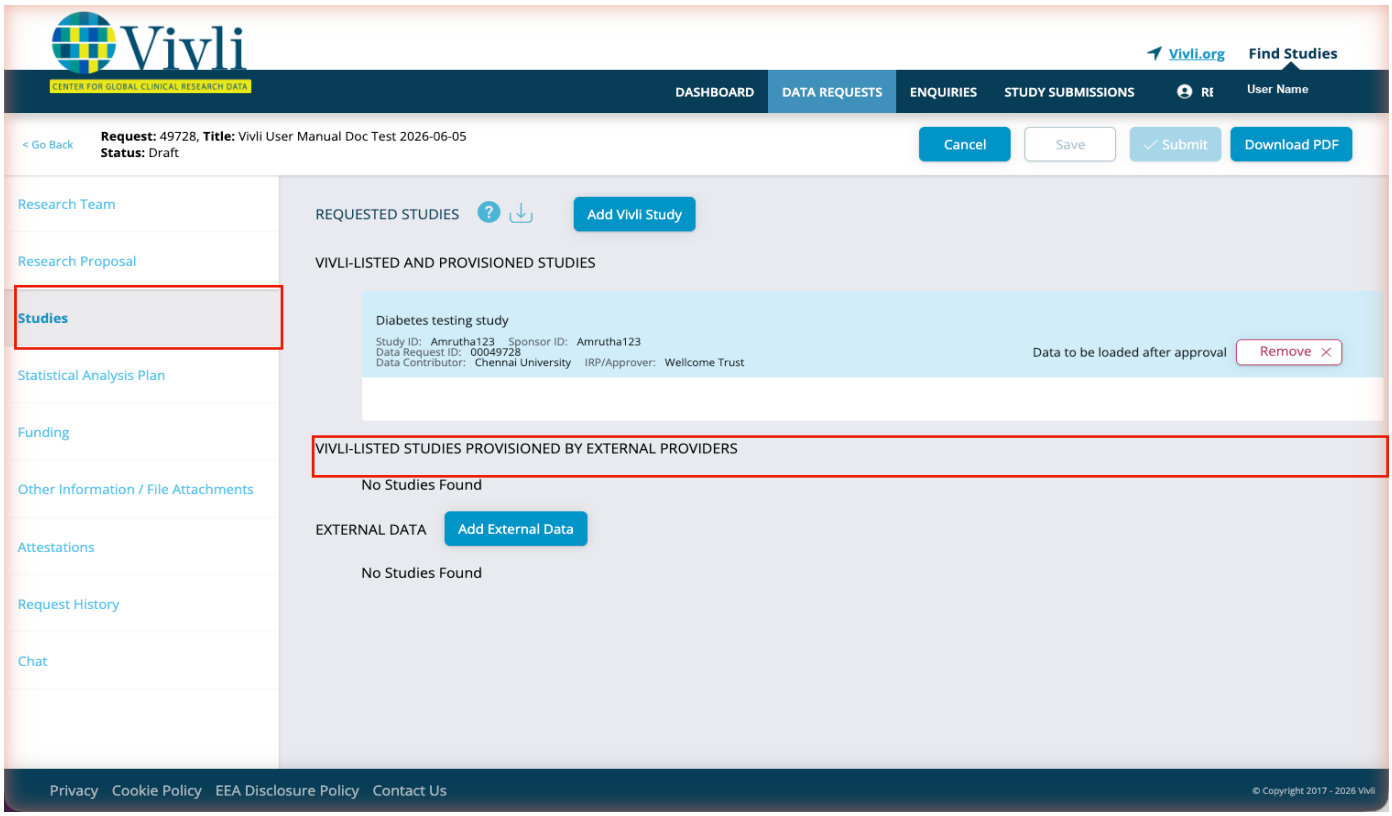


5. Follow the link to view and request the study on the partner platform:



Note: this link will open up the partner platform website in another browser tab.

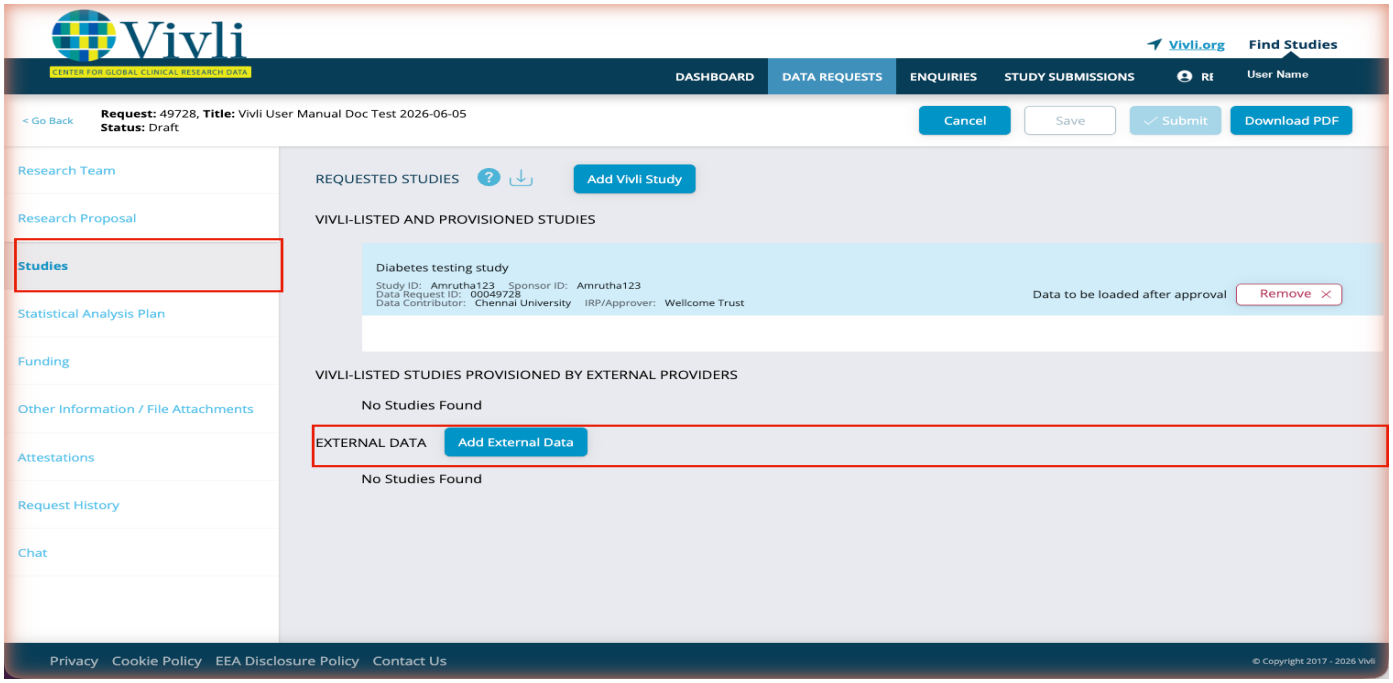
6. Complete and submit the request on the partner platform, as well as the Vivli Data Request Form.
7. When you review the studies tab on your Data Request Form, the study will be categorized as **VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS:**



8. After all the Data Contributors associated with the request have approved it and you have signed a Data Use Agreement, all the data package(s) will be provisioned directly into the secure research environment. Note: In some cases you will be advised to obtain the downloaded data from the external partner, and Vivli will help you upload it to your secure research environment if you wish.

5.0 Requesting Vivli member data from studies not listed on Vivli

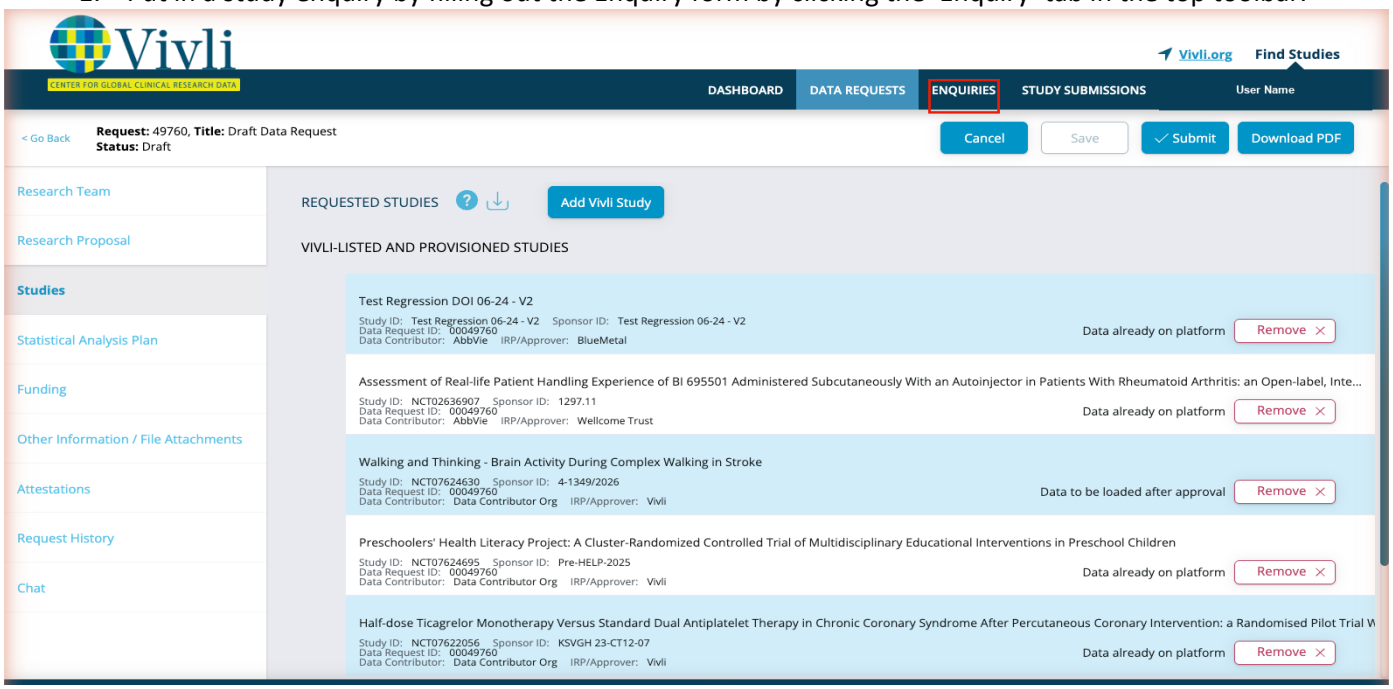
Data not listed on Vivli can be included in a data request if you have submitted an enquiry and the data contributor has agreed that the researcher can add an unlisted study to their data request. Such studies will be designated on your Vivli Data Request Form as **EXTERNAL DATA**.



5.1 Process Overview

To request data from Vivli Member studies that are not listed on Vivli, complete the following steps:

1. Put in a study enquiry by filling out the Enquiry form by clicking the 'Enquiry' tab in the top toolbar.



2. If the enquiry is approved and the study is available for sharing, complete the Vivli Data Request Form for all studies to be analyzed on Vivli and add in the study.
3. After all Data Contributors have approved your request, all the data packages will be provisioned into your secure research environment.

Note: *Do not submit* a data request before all enquiries have been resolved as this will cause delays.

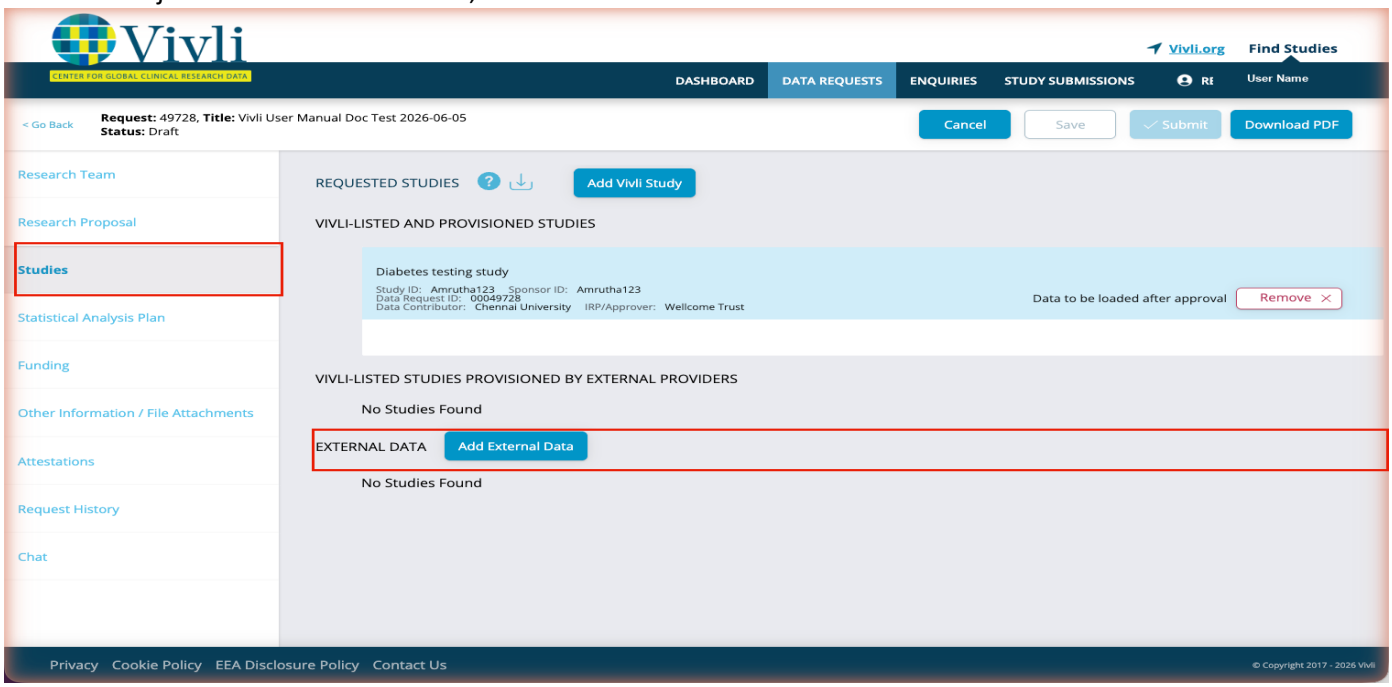
6.0 Requesting to add other data or software, models, tools or scripts (provided by you) to use in the Vivli Secure Research Environment

6.1 Adding your own data

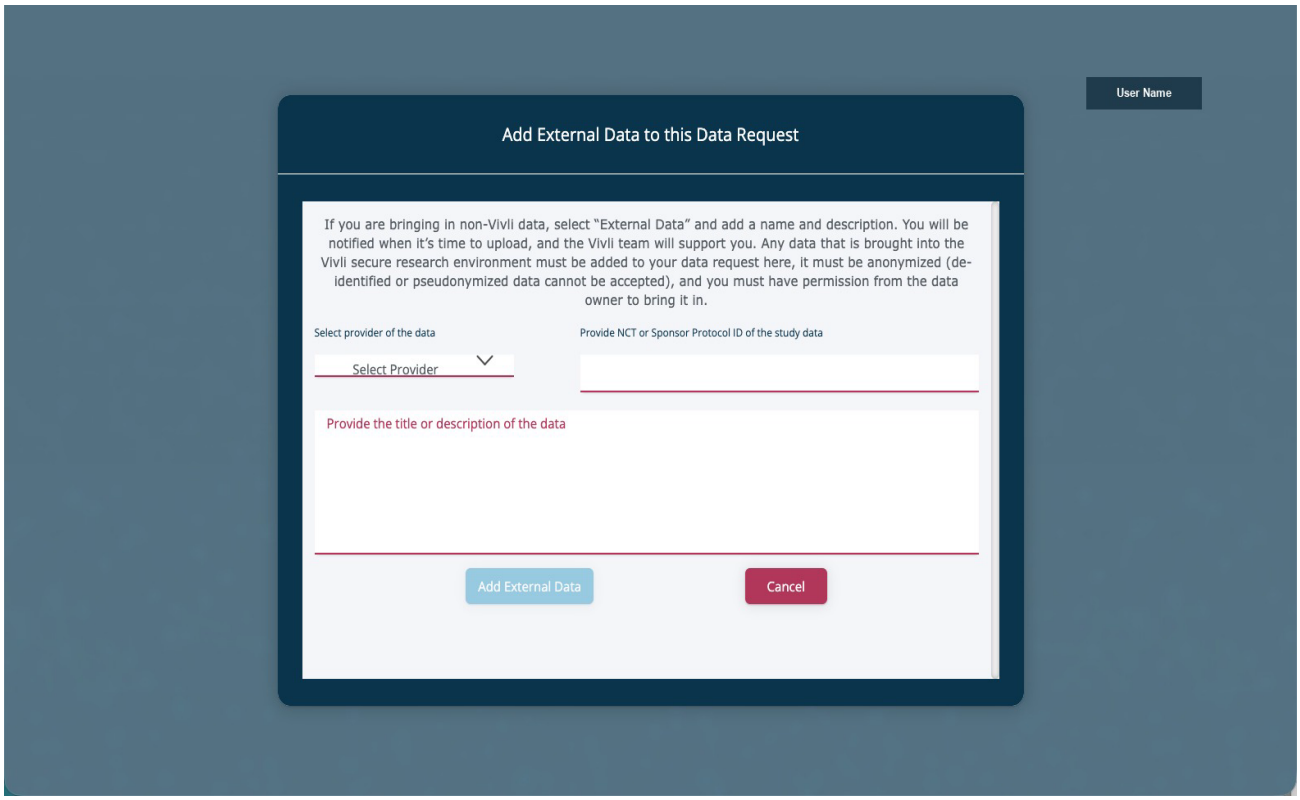
1. If you have access to a study that is included in your project but is not listed on the Vivli platform, you will need to add this to your data request.

2. To add the study to a Vivli Data Request Form, first open data requests by clicking on **Data Requests** in the top toolbar, and navigate to the data request:

3. Next, open the data request to add the external study. Then, scroll down and click on **Add External Data** adjacent to **EXTERNAL DATA**, at the bottom of the screen:



4. The following dialogue box will appear as a pop-up:



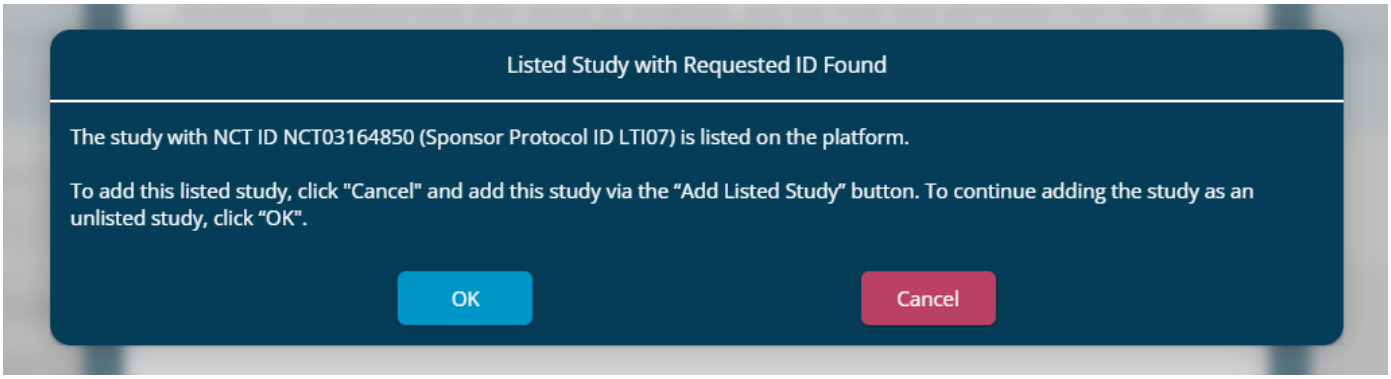
5. Complete all fields, selecting 'I WILL BRING MY OWN' from a dropdown 'Select provider of the data' menu, at the NCT (or sponsor ID if there isn't an NCT ID), and in the description box provide the study title and the name of the data owner (or if it is publicly available data).

Note: Before bringing any data into the Vivli Secure Research Environment, you will need to confirm that a) the data are anonymized (de-identified or pseudonymized data cannot be accepted) b) that you have permission from the data owner to bring the data in, or that it is publicly available.

6. and then click **Add External Data.**

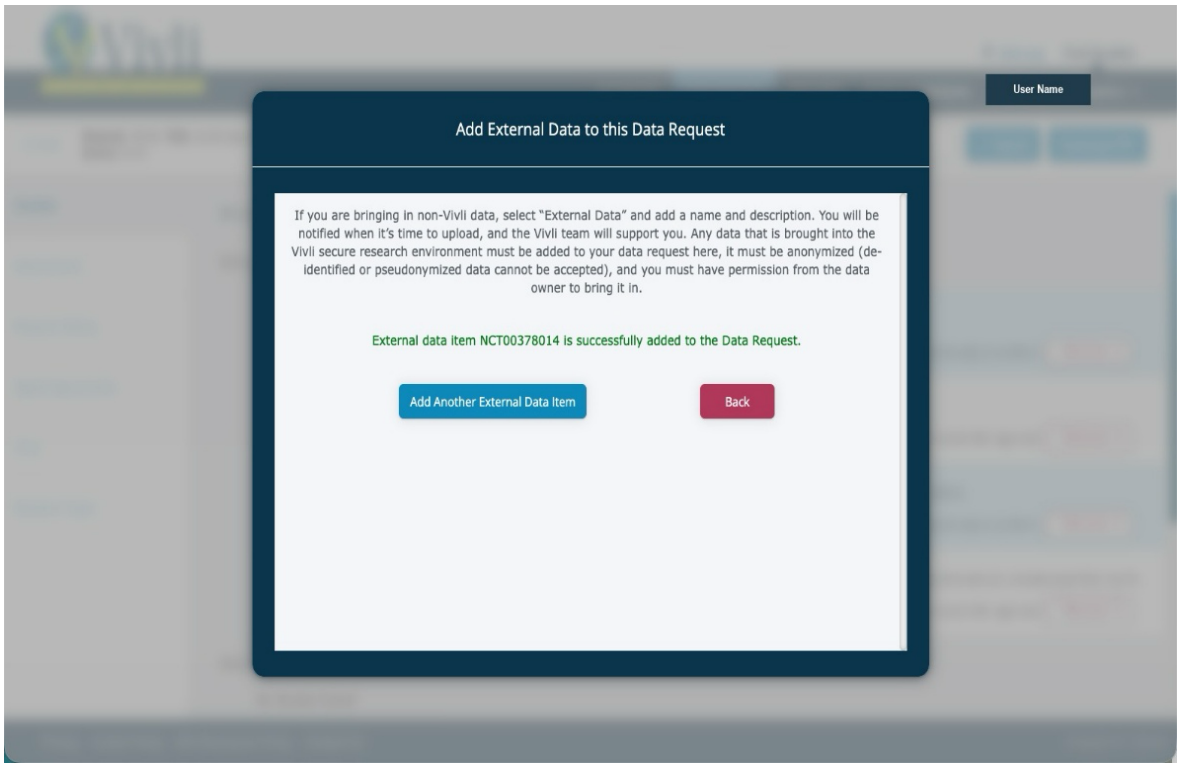
Note: Please add only one study in the dialogue box. If you wish to add additional studies, please complete this process, and repeat it for the additional studies.

7. If the study ID that you have entered matches a the ID of a study already listed on Vivli, the following pop-up will appear:

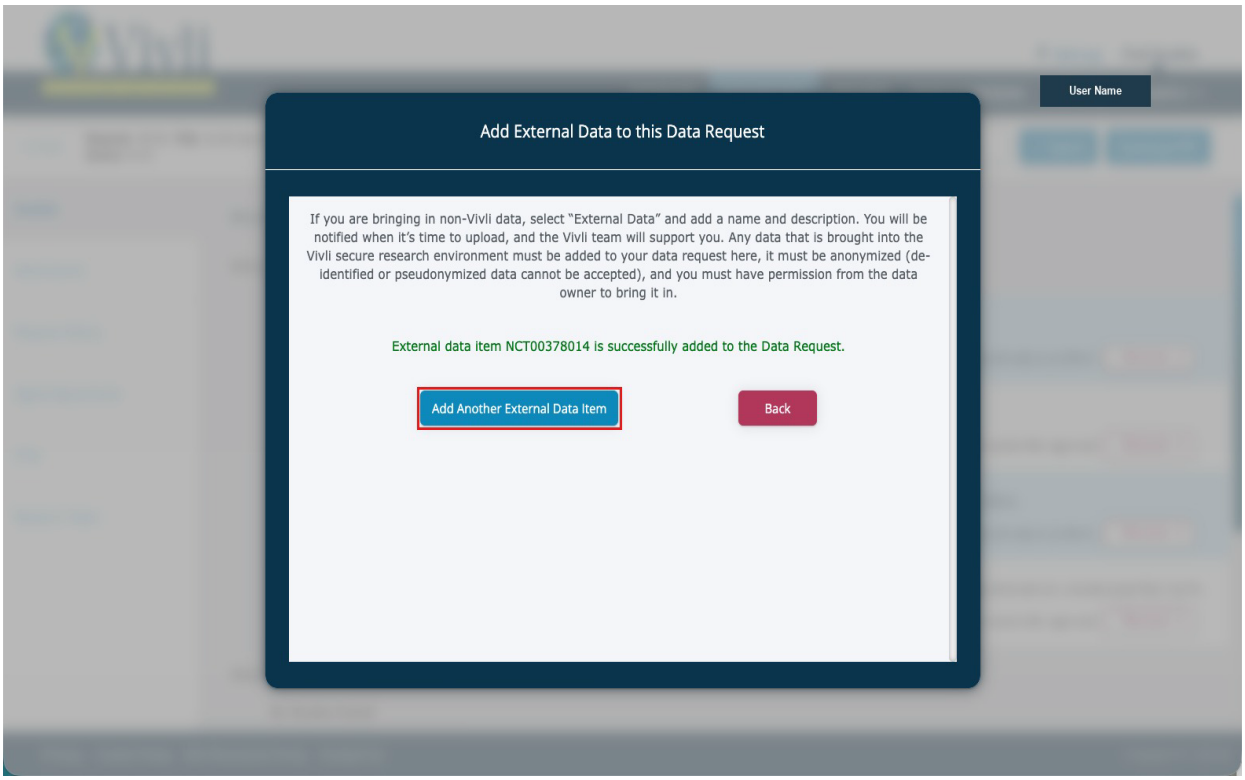


8. You can then choose to either add the listed study (click 'Cancel') or continue to add the study as unlisted (click 'OK').

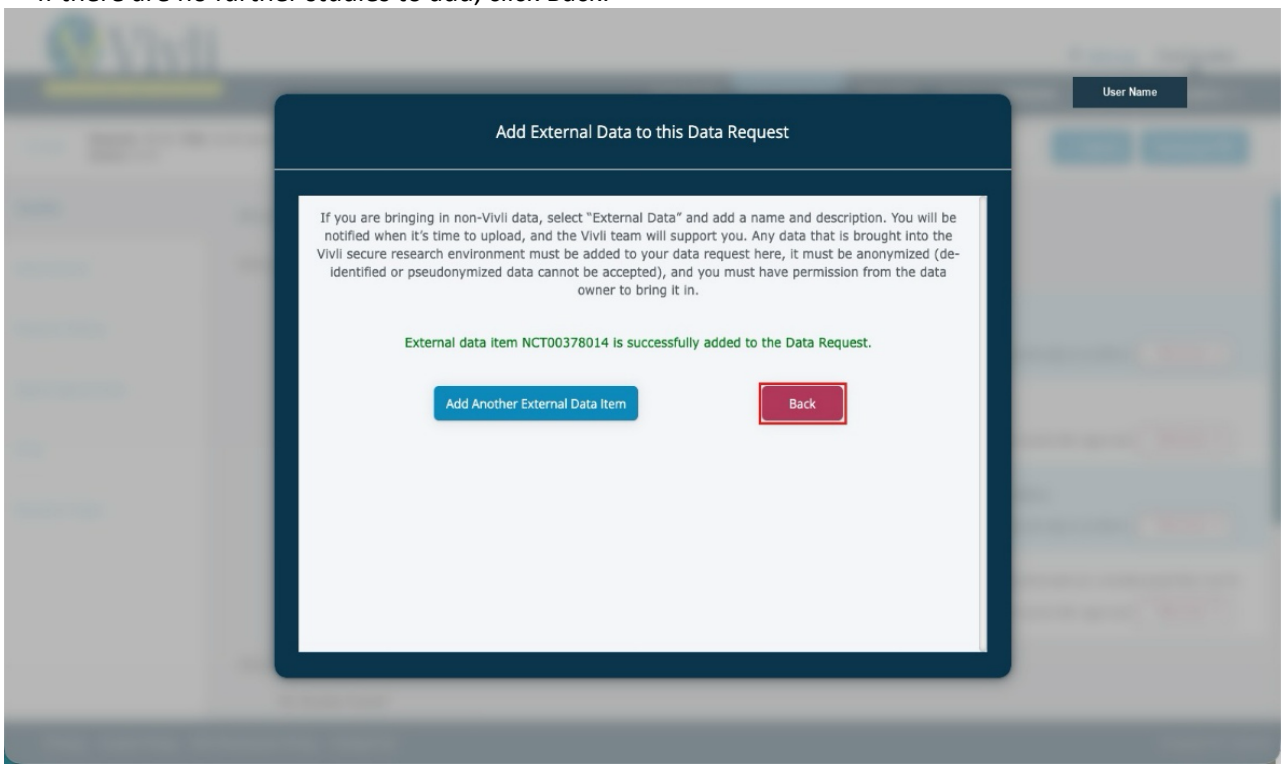
9. If the Study ID that you have entered does not match a study already listed as available on Vivli, the following notification will appear:



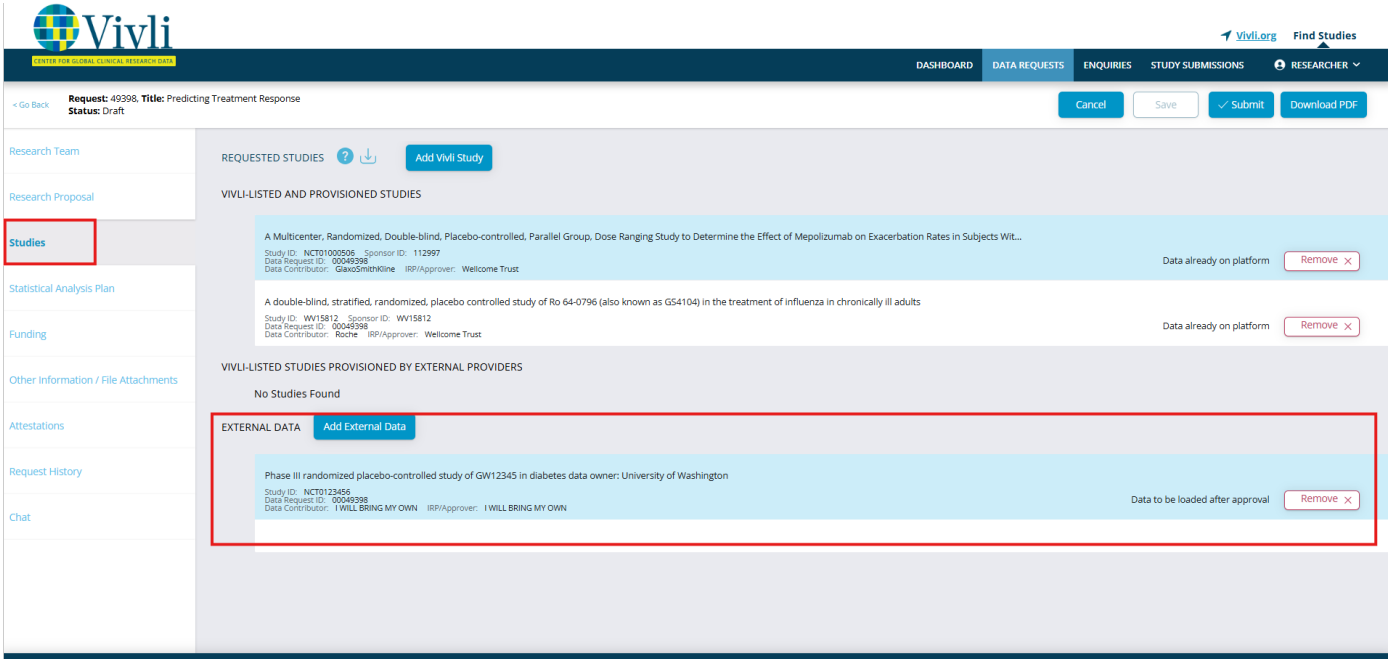
10. You may add additional studies to your data request by clicking on **Add Another External Data Item:**



11. If there are no further studies to add, click Back:



12. The studies will appear in the study list



13. After your request is approved and you have access to the Secure Research Environment, you can send your external data files to Vivli by email at support@vivli.org

    Note: Data should NEVER be uploaded to the chat.

6.2 Adding scripts, software or models for use in the Secure Research Environment

The Vivli secure research environment is a cloud-based remote workspace. The Vivli secure research environment allows research teams to access data and conduct analyses in a shared workspace that is equipped with analytical tools and may be flexibly configured. Download a complete list of Software and R packages available in the secure research environment.

If your research plan includes using a model which includes any data, it must be recorded in the data request as in section 6.1 Adding your own data

If you plan to use specific software, please note, we can support software that is not pre-installed on the system as long as:

1. You describe your intent to use that software as part of the request for data, so that the sponsors and review panels are able to consider that as part of the request
2. The software installs into the Research Environment and runs locally (specifically: network restrictions prevent web-based applications). The Research Environment runs Windows Server 2022
3. You own and can provide a license that we can install on your behalf, if needed.
4. 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. In general, we've found most software teams can tell us the network demands of the licensing, so when you determine what you'd like to use, let us know and we can investigate.

When you have access to the secure research environment, if you need to upload scripts or software, email them directly to support@vivli.org , including your data request ID, and we will upload them into your research environment.

7.0 Submitting your data request

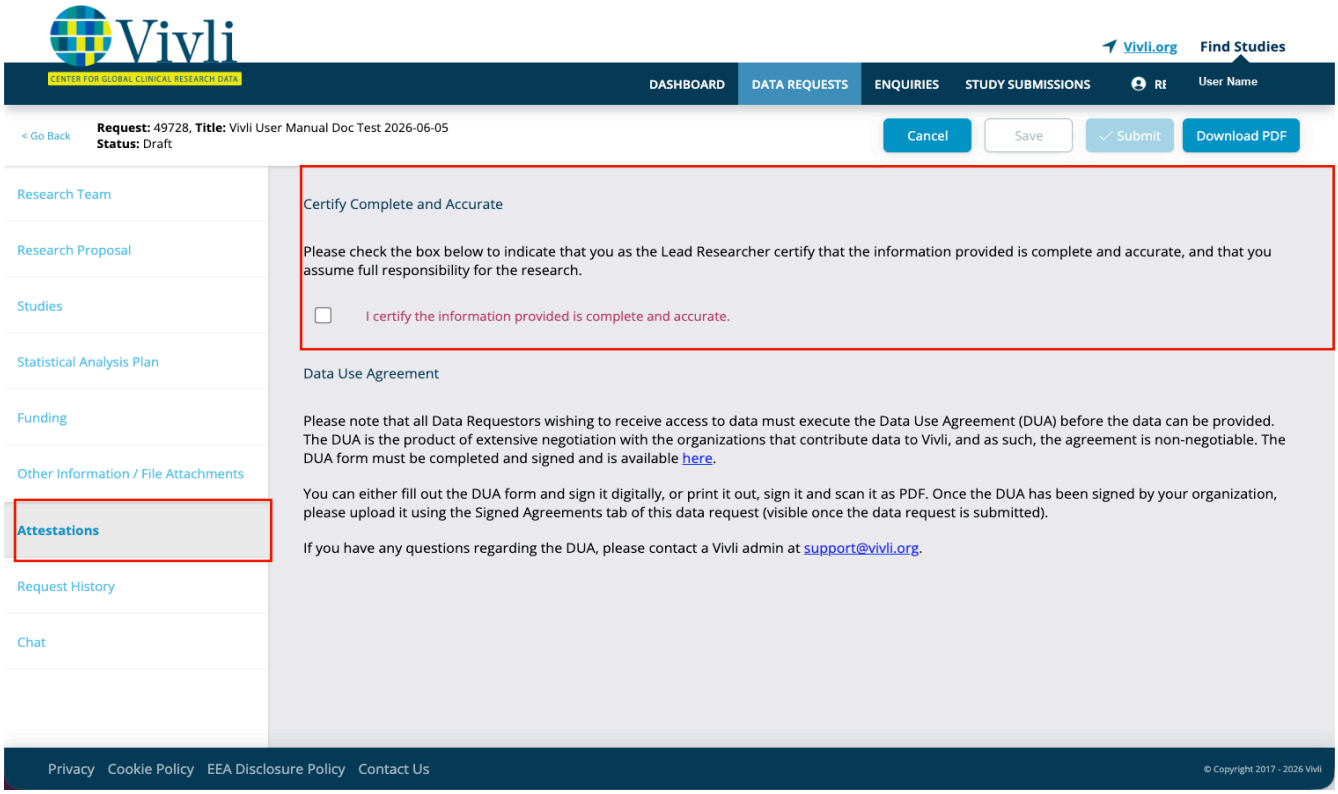
- Once the Data Request Form is complete, you may submit it for review.
- Do not submit a form before it is complete, as you will be unable to make changes once it has been submitted.
- Please make sure that you have added all the desired studies to your data request as adding it later will lead to additional delays. If you have ongoing enquiries for studies involved in this project, please wait until all the enquiries are closed before submitting the data request.

- Please note that according to Vivli policy, any changes to the Lead Researcher, Lead Statistician, their conflict of interest, adding and removal of studies in the request, 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.

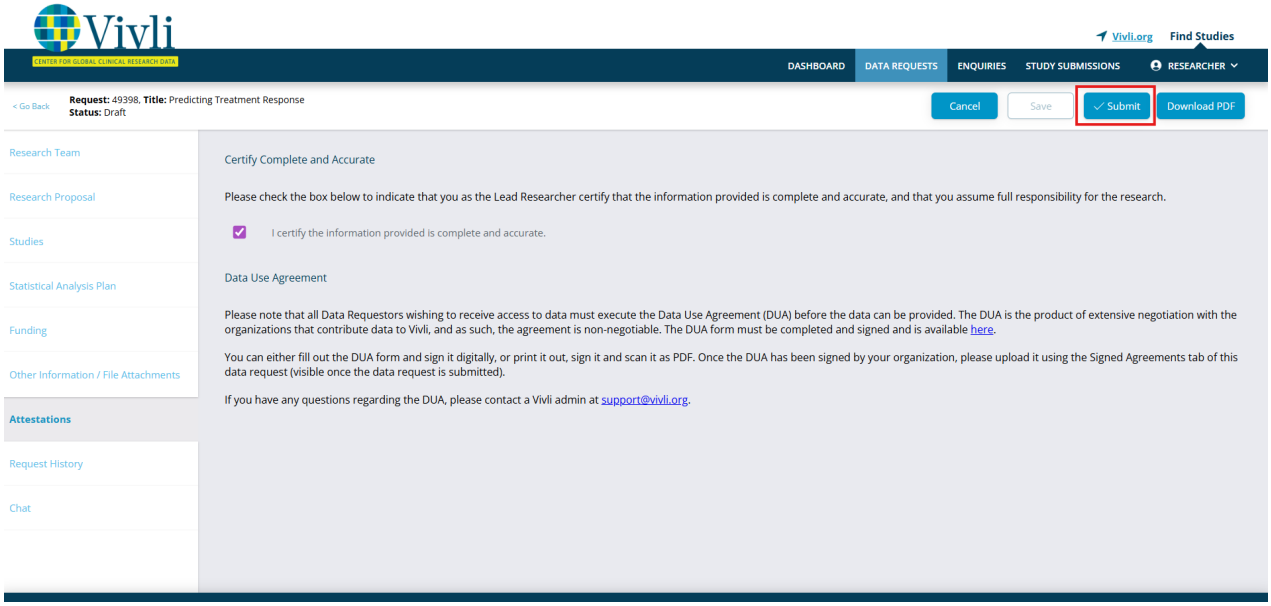
Key factors that influence the timeline:

- 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

- Before submitting a Data Request Form, the Lead Researcher must attest that all the information provided is accurate and complete:



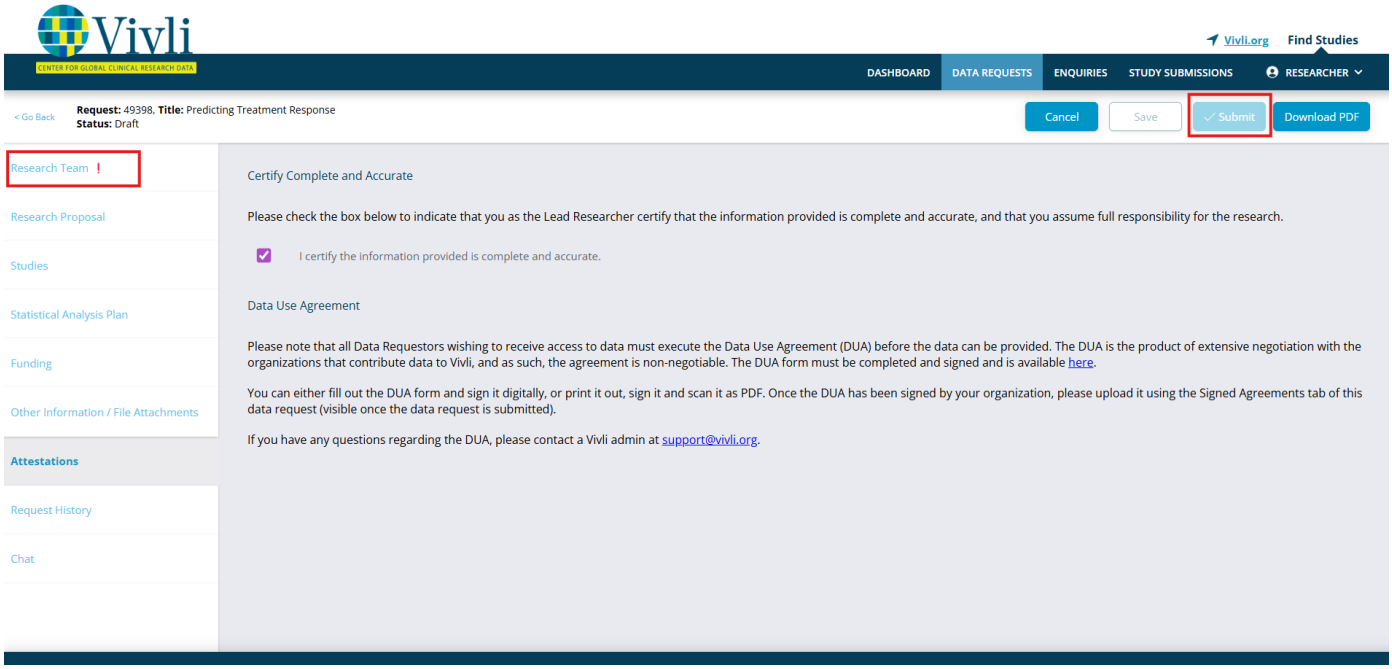
- To submit a Data Request Form, simply click the blue box marked **Submit** in the top right corner of the screen:



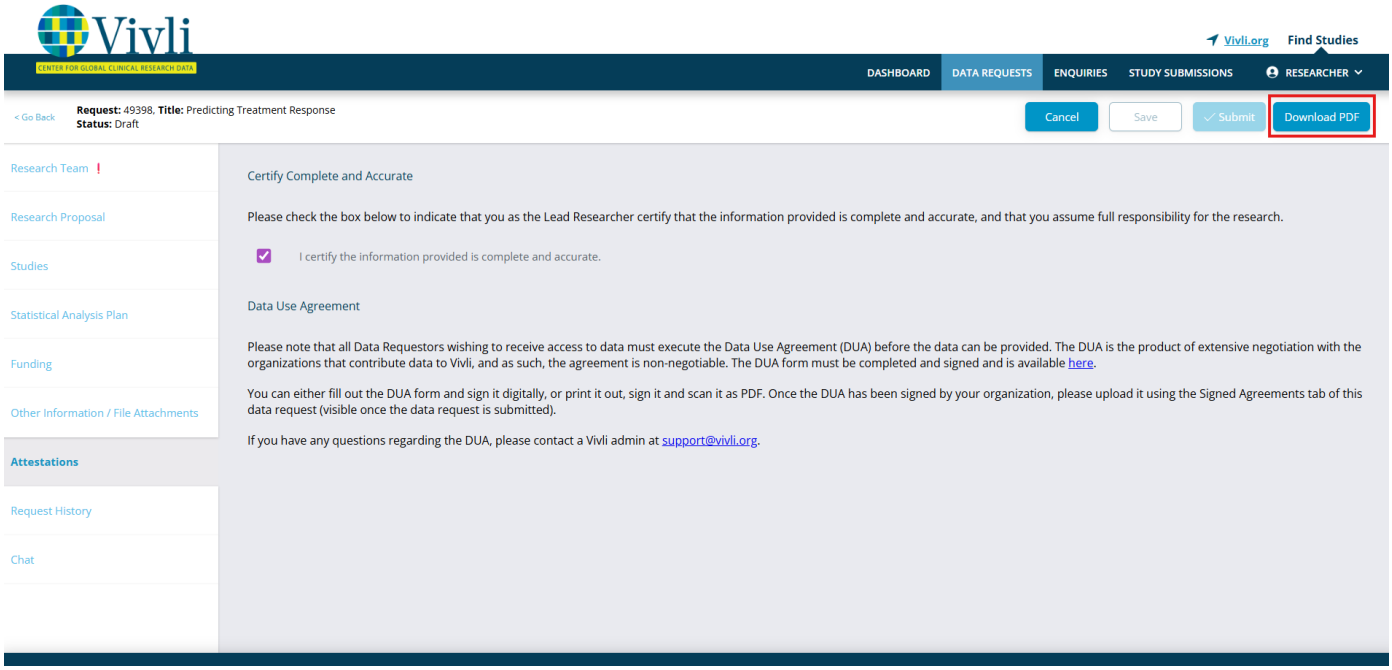
- If the Submit button is still light blue 

and does not respond to a click, you have a required field that is not completed. You can look in each of the tabs on the left for a field with red text 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. If there is missing information in the Research Team field, a red exclamation mark (!) will appear in the Research Team tab on the left.

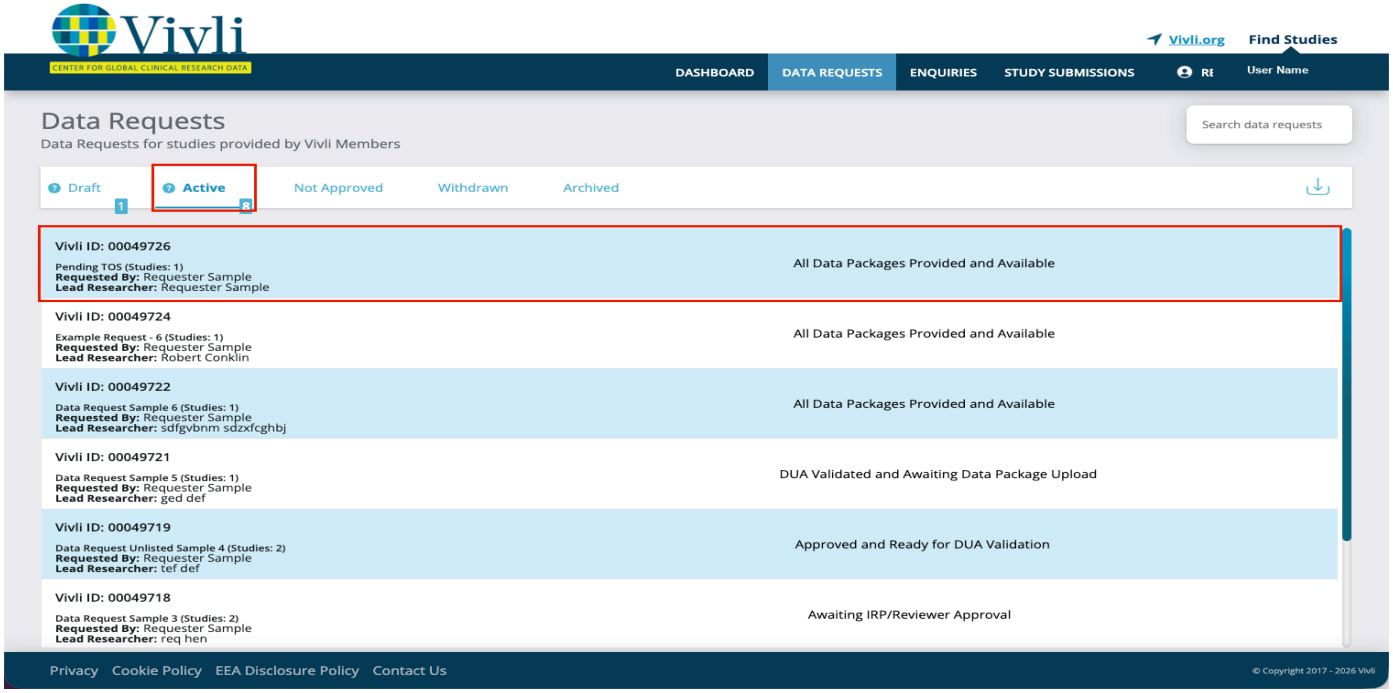


You can obtain a PDF copy of your data request application by clicking on the 'Download PDF' button in the top right corner. This will download a copy of the data request to your browser which you can then view or save elsewhere.



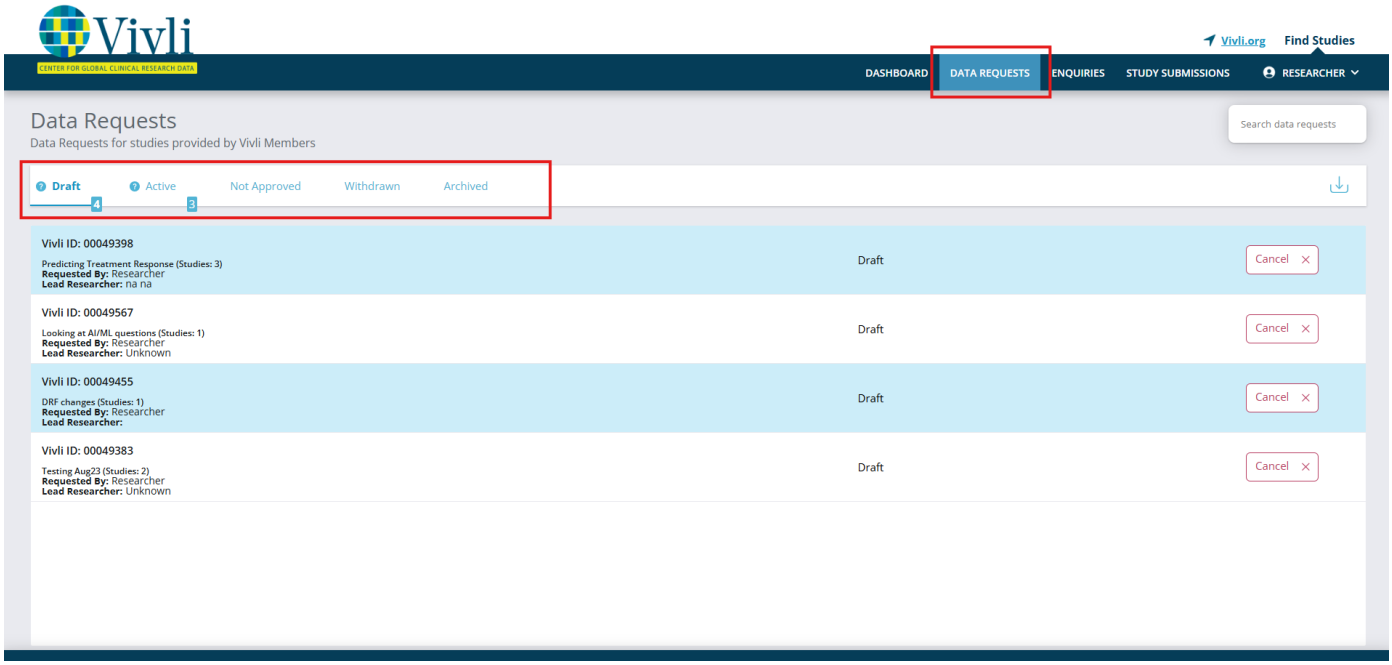
7.1 Data Request Status

Once you click submit, the data request will now appear under **Active** in your data request status bar:



The status bar contains 5 sections:

Draft: Displays data requests that are being drafted but not yet submitted and hence don't have a Vivli ID.
Active: Displays data requests that are in progress. This includes requests in the Vivli form check stage, requests that were sent back to drafts, requests in the Data Contributor Review stage, IRP review stage, DUA validation stage, awaiting data package upload stage, requests where some or all of the data packages have been uploaded. It also displays requests that are currently in the analysis stage, awaiting results review and awaiting publication review.
Not Approved: Displays data requests that are not approved. It also temporarily displays requests where revisions were requested until the Vivli Admin moves the requests to draft.
Withdrawn: Displays data requests that were withdrawn.
Archived: Displays data requests that were completed including those with publication or summary of results



Your data request will go through the following steps:

1. Vivli Form Check
2. Data Contributor Review
3. IRP review
4. DUA validation
5. Data package upload
6. Analysis of data in the secure research environment
7. Export of results from the secure research environment
8. Your submission of public disclosure for a 30-day review
9. Data Progress Report
10. Public disclosures published in a journal or learned forum
11. Secure Research Environment closure
12. Request Archival

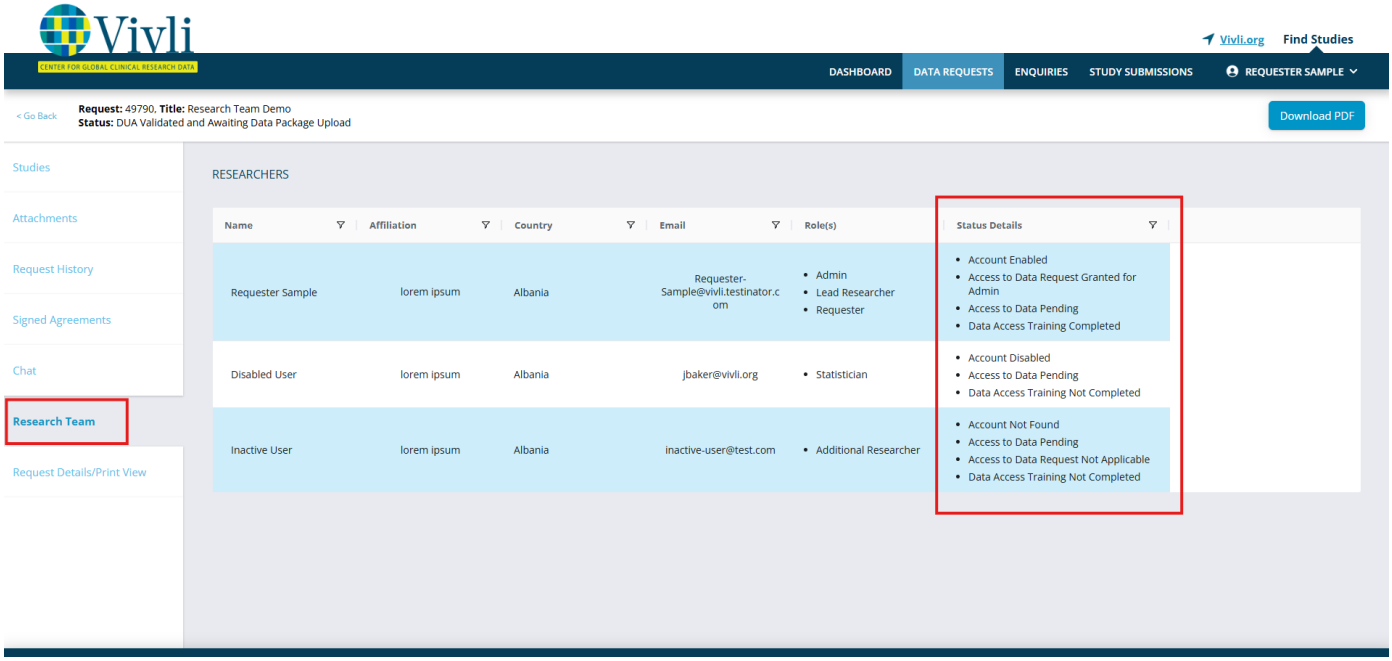
7.2 Research team account status

Once your data request is submitted you can see additional details about the status of the Research teams' accounts in the Research Team tab.

- Account not found – A research team member doesn't have a Vivli account. Once they sign up for an account, you can activate the user for data access. Please see Section 3.4 Adding Research Team Members.
- Account Enabled – They have an active account on Vivli
- Account Disabled – They haven't logged into the Vivli platform for more than 180 days so their account is disabled and they can no longer access the data request, please see Section 1.4 Active Platform Accounts
- Access to Data Request Granted for Admin – This team member is the data request admin and has access to the request and will receive messages from the Chat
- Access to Data Request Granted – Team member has access to see the data request and will receive messages from the Chat
- Access to Data Request Pending – Team member does not have access to the data request and will not

receive Chat messages

- Access to Data Request Denied – Team member does not have access to the data request and will not receive Chat messages
- Access to Data Request Not Applicable – Team member doesn't have a Vivli account.
- Access to Data Granted – Team member has access to the data
- Access to Data Pending – Team member does not have access to the data
- Access to Data Denied – Team member had access to the data, but it has been removed
- Data Access Training Not Completed – Team member has not take the data access training
- Data Access Training Completed – Team member has taken data access training and Vivli team has confirmed the training and updated the account



8.0 Modifying or revising your data request

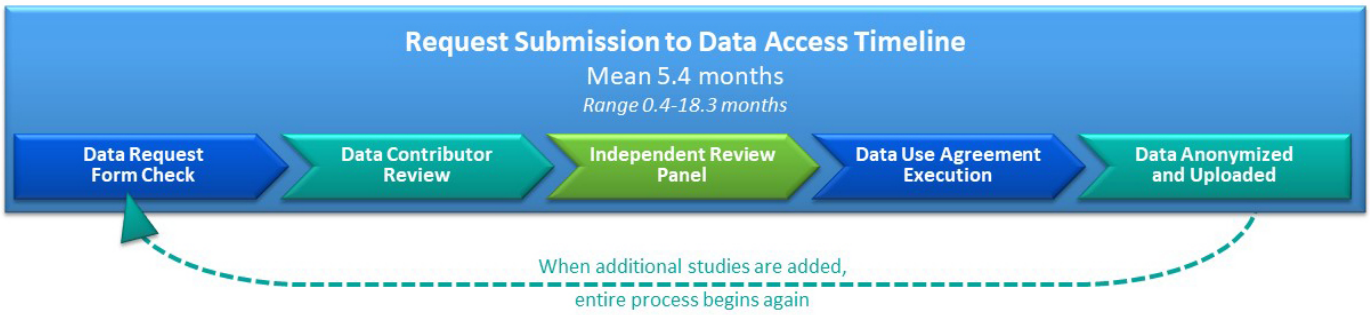
8.1 Overview

- If necessary, you may modify your data request. Please review the Vivli policies in brief about active requests and active enquiries before submitting a data request.
- You can make as many changes as needed before submitting your data request.
- If the research team associated with a data request changes, you must update the request or you can reach out to the Vivli team via open chat while your data request is being reviewed. For minor changes, the Vivli team can make changes on your behalf.

PLEASE NOTE: According to Vivli policy, any changes to the Lead Researcher's affiliation (to a commercial entity), Lead Statistician's affiliation (to a commercial entity), their conflict of interest, , 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.

Changes to a Lead Researcher or Statistician's affiliation (to an academic institution), adding or removing studies, and personnel changes are considered minor changes.



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

8.2 Modification after submission

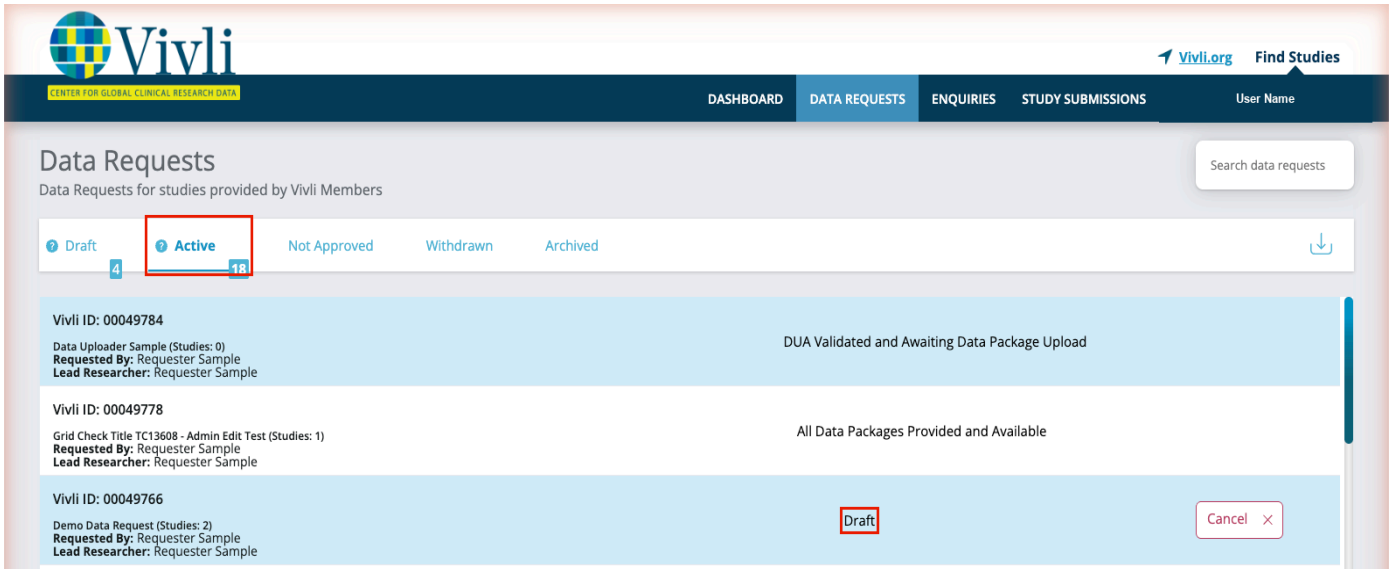
To modify your data request after you have submitted it, please contact Vivli via open chat on the platform.

8.3 Requested revisions to your data request

- At times, the Data Contributor, Independent Review Panel (IRP), or Vivli may request that you make changes to your data request.
- If this is the case, you will be notified in the Chat andvia email.
- The specific changes requested will be placed in the Chat window.
- If you fail to make the requested changes, the data request will be withdrawn after 3 months.

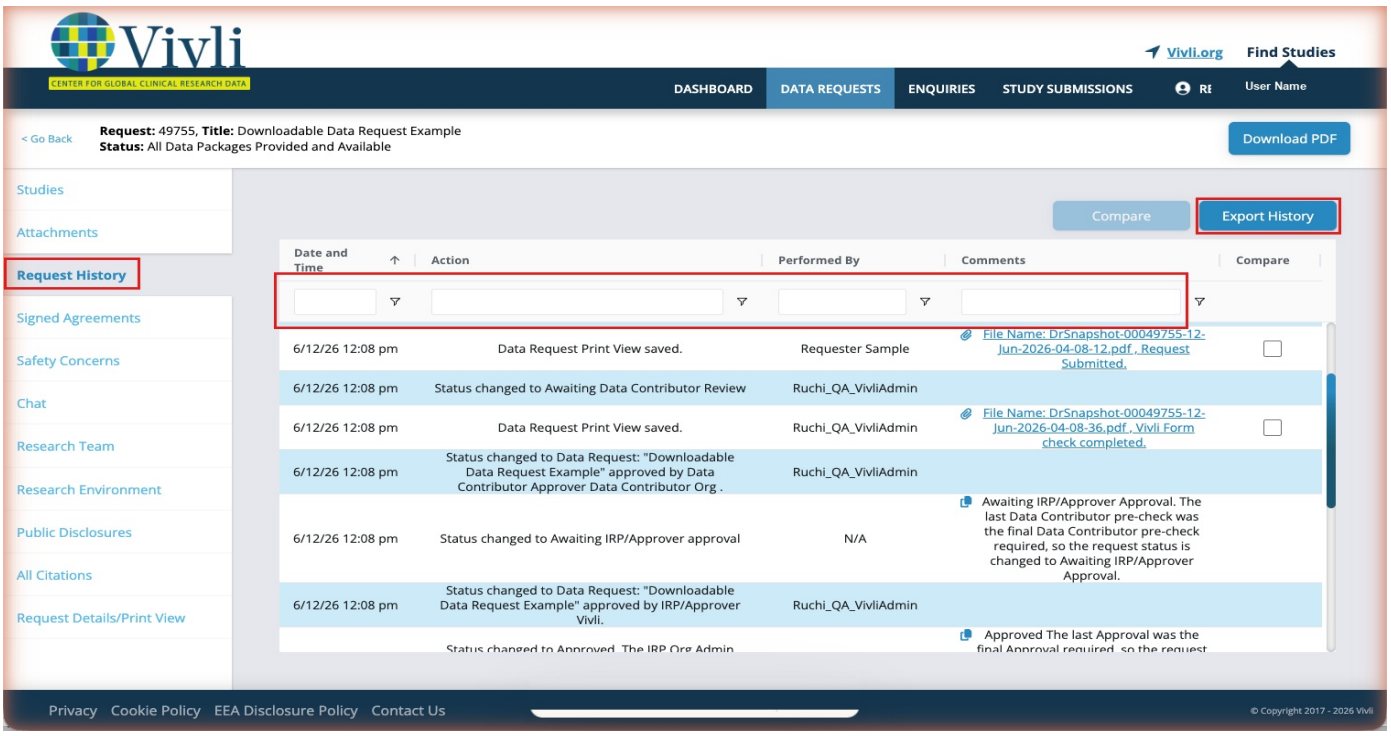
8.3.1 Steps for revising request

1. If any party requests revisions to the Data Request Form, the Vivli Admin will return your data request to 'Draft', but you will find it in the **Active** data request tab:



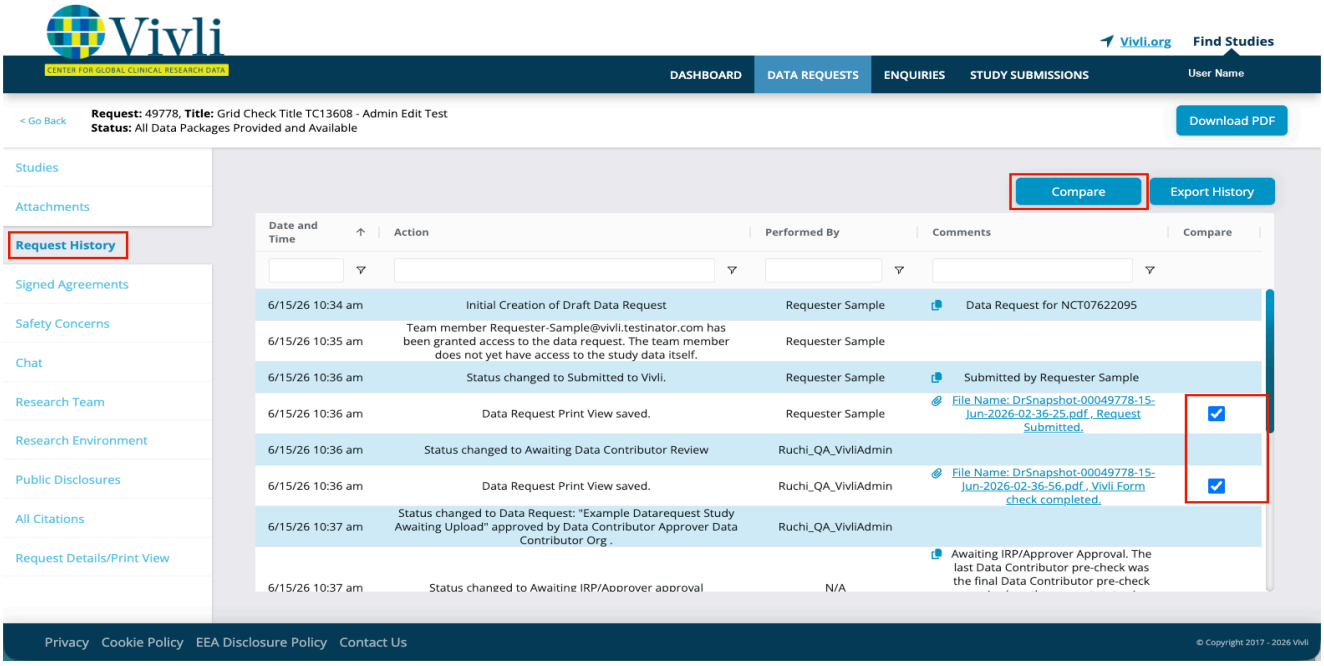
2. Open the data request and click on the **Request History** tab

On the Request History tab, you can review, filter and export the request history including any comments related to your data request. You can also review the chat associated with your request for any additional comments or use the chat to ask for any clarifications about the revision request.



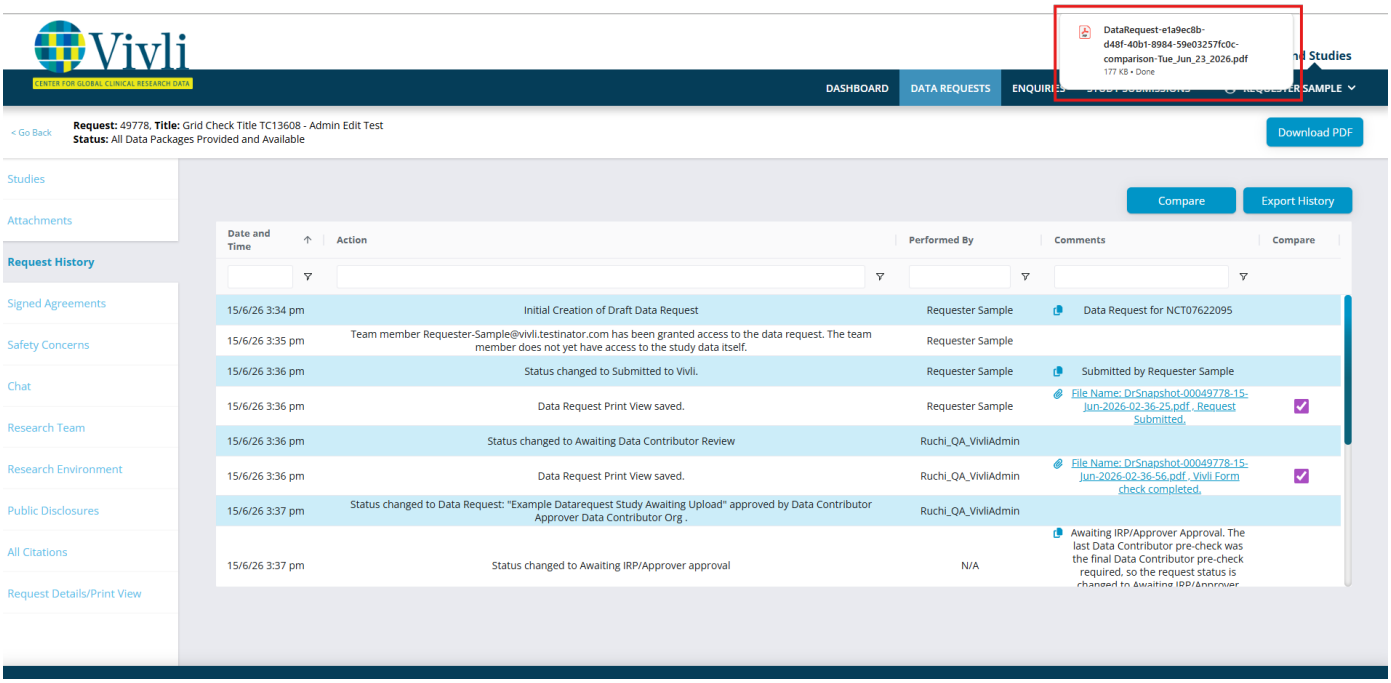
The request history also contains the PDF version of the request for each time the request is submitted, passes Vivli form checks and is processed for data contributor review. You can compare the PDF versions within this tab and save a copy of the PDF.

To compare two PDF versions of the request, check the checkbox next to the request version that you would like to compare, and then click the “Compare” blue button on the top right.



A compare PDF will be downloaded, which will show the two documents with differences highlighted

Note: The two-page view can differ from browser to browser.
For PDF compare, to open 2 page view:
In Acrobat: click on menu in the title bar - in the drop down click on View -> Page Display -> 2 Page View
In Chrome, or Firefox: Click on the three dots on the upper right, and choose Two Page View
drop down to choose between 1 page and 2 pages.
Safari - Right click and select "two page continuous”



Green highlighted sections indicates text that has been inserted:

Education Institution

University of California, San Francisco

Discipline

Psychiatry

Year Received

2000

Years of Secondary Analysis

5-10

Conflicts of Interest and Plan for Management

In placebo controlled randomized clinical trials of new therapeutics for moderate to severe psoriasis patients, some patients assigned to the placebo arm experience clinical improvement in their psoriasis signs. The basis for this observed improvement is not clear. Possible explanations include: random fluctuations in disease severity, increased attention to skin care instigated by study personnel translating into more diligent application of emollients by the subject, or the subject experiencing the psychological benefit of inaccurately believing that he or she is receiving effective experimental therapy (i.e., the true "placebo" effect).

Research Team

Lead Investigator

Amrutha Baskaran

datarequester.vivli@gmail.com
Professor at the great wonderful university of America
Boston University
Country: American Samoa

Education or Qualifications

In placebo controlled randomized clinical trials of new therapeutics for moderate to severe psoriasis patients, some patients assigned to the placebo arm experience clinical improvement in their psoriasis signs. The basis for this observed improvement is not clear. Possible explanations include: random fluctuations in disease severity, increased attention to skin care instigated by study personnel translating into more diligent application

Name of the degree

PhD in Psychology

Education Institution

University of California, San Francisco

Red highlighted sections indicate text that has been deleted:

Aims/Objectives and Hypotheses

In placebo controlled randomized clinical trials of new therapeutics for moderate to severe psoriasis patients, some patients assigned to the placebo arm experience clinical improvement in their psoriasis signs. The basis for this observed improvement is not clear. Possible explanations include: random fluctuations in disease severity, increased attention to skin care instigated by study personnel translating into more diligent application of emollients by the subject, or the subject experiencing the psychological benefit of inaccurately believing that he or she is receiving effective experimental therapy (i.e., the true "placebo" effect). In addition to these explanations, it is also possible that seasonal fluctuations in ambient UV exposure may account for some of the response observed among placebo patients. The purpose of the proposed research is to investigate if and to what extent fluctuations in ambient UV exposure could be causing improvements in psoriasis among patients being treated with placebo.

There is evidence from the dermatologic literature for seasonal variation in psoriasis severity: Pascoe and Kimball (2015) collected psoriasis PGA (Physician's Global Assessment) scores from psoriasis patients in a large New England-based healthcare system, analyzed the data for seasonal variations, and noted that a higher percentage of psoriasis patients were clear or almost clear in the summer than in the winter, with statistically significant variation in the

Aims/Objectives and Hypotheses

In placebo controlled randomized clinical trials of new therapeutics for moderate to severe psoriasis patients, some patients assigned to the placebo arm experience clinical improvement in their psoriasis signs. The basis for this observed improvement is not clear. Possible explanations include: random fluctuations in disease severity, increased attention to skin care instigated by study personnel translating into more diligent application of emollients by the subject, or the subject experiencing the psychological benefit of inaccurately believing that he or she is receiving effective experimental therapy (i.e., the true "placebo" effect). In addition to these explanations, it is also possible that seasonal fluctuations in ambient UV exposure may account for some of the response observed among placebo patients. The purpose of the proposed research is to investigate if and to what extent fluctuations in ambient UV exposure could be causing improvements in psoriasis among patients being treated with placebo.

Purpose of Analysis

New research question to examine treatment safety
Research that confirms or validates previously conducted research on treatment safety

---

percentage of patients who were clear or almost clear across the different seasons. This outcome is biologically plausible, because UV (ultraviolet) light exposure is greater in the summer than in the winter, with the difference in exposure more marked at higher latitudes, and because UV exposure is known to ameliorate psoriasis. However, the results from Pascoe and Kimball may be confounded by the concomitant treatments that the psoriasis patients were receiving at their office visits. To eliminate the effect of this confounding, analysis of controlled clinical trial data would be valuable.

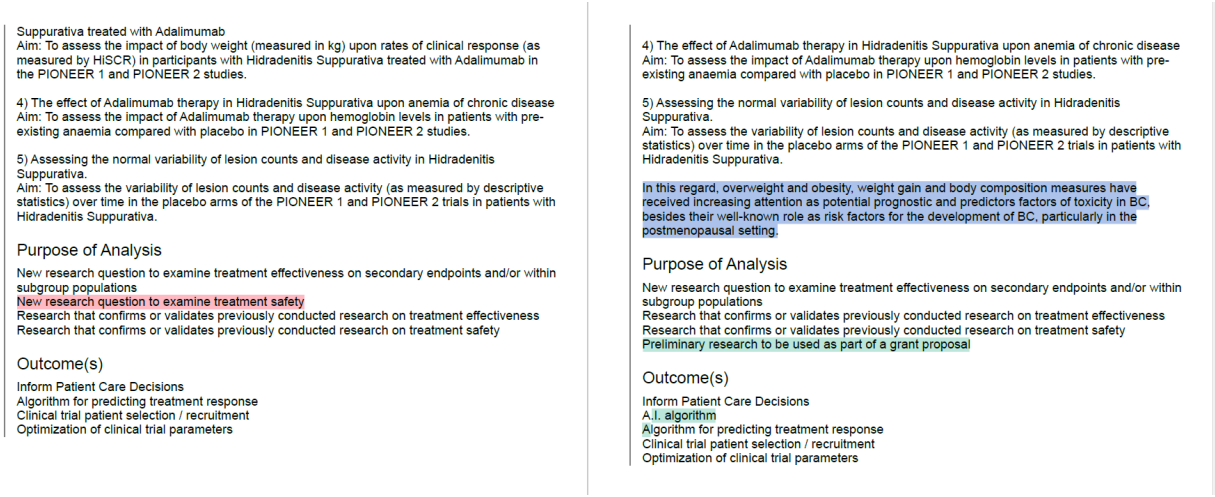
Purpose of Analysis

New research question to examine treatment safety
Research that confirms or validates previously conducted research on treatment safety

Outcome(s)

Inform Patient Care Decisions
Algorithm for predicting treatment response
Clinical trial patient selection / recruitment
Funding application / grants

Blue/purple highlighted sections indicate text has been moved from one section to another



Suppurativa treated with Adalimumab
Aim: To assess the impact of body weight (measured in kg) upon rates of clinical response (as measured by HiSCR) in participants with Hidradenitis Suppurativa treated with Adalimumab in the PIONEER 1 and PIONEER 2 studies.

4) The effect of Adalimumab therapy in Hidradenitis Suppurativa upon anemia of chronic disease
Aim: To assess the impact of Adalimumab therapy upon hemoglobin levels in patients with pre-existing anaemia compared with placebo in PIONEER 1 and PIONEER 2 studies.

5) Assessing the normal variability of lesion counts and disease activity in Hidradenitis Suppurativa.
Aim: To assess the variability of lesion counts and disease activity (as measured by descriptive statistics) over time in the placebo arms of the PIONEER 1 and PIONEER 2 trials in patients with Hidradenitis Suppurativa.

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

Outcome(s)

Inform Patient Care Decisions
Algorithm for predicting treatment response
Clinical trial patient selection / recruitment
Optimization of clinical trial parameters

4) The effect of Adalimumab therapy in Hidradenitis Suppurativa upon anemia of chronic disease
Aim: To assess the impact of Adalimumab therapy upon hemoglobin levels in patients with pre-existing anaemia compared with placebo in PIONEER 1 and PIONEER 2 studies.

5) Assessing the normal variability of lesion counts and disease activity in Hidradenitis Suppurativa.
Aim: To assess the variability of lesion counts and disease activity (as measured by descriptive statistics) over time in the placebo arms of the PIONEER 1 and PIONEER 2 trials in patients with Hidradenitis Suppurativa.

In this regard, overweight and obesity, weight gain and body composition measures have received increasing attention as potential prognostic and predictors factors of toxicity in BC, besides their well-known role as risk factors for the development of BC, particularly in the postmenopausal setting.

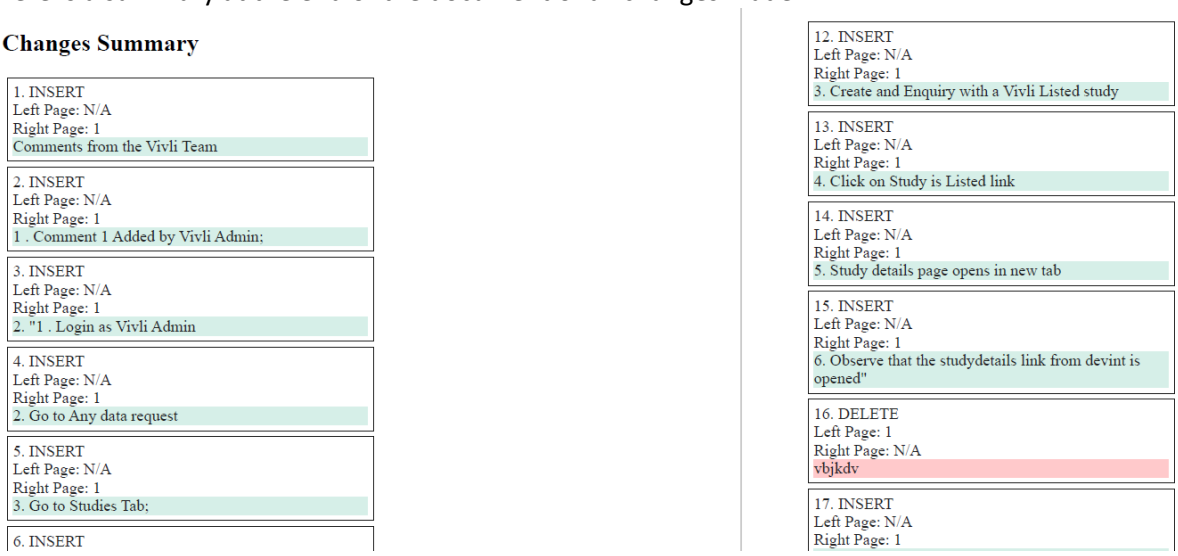
Purpose of Analysis

New research question to examine treatment effectiveness on secondary endpoints and/or within subgroup populations
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)

Inform Patient Care Decisions
A.I. algorithm
Algorithm for predicting treatment response
Clinical trial patient selection / recruitment
Optimization of clinical trial parameters

There is a summary at the end of the document of all changes made:



Changes Summary

1. INSERT
Left Page: N/A
Right Page: 1
Comments from the Vivli Team

2. INSERT
Left Page: N/A
Right Page: 1
1 . Comment 1 Added by Vivli Admin;

3. INSERT
Left Page: N/A
Right Page: 1
2. "1 . Login as Vivli Admin

4. INSERT
Left Page: N/A
Right Page: 1
2. Go to Any data request

5. INSERT
Left Page: N/A
Right Page: 1
3. Go to Studies Tab;

6. INSERT

12. INSERT
Left Page: N/A
Right Page: 1
3. Create and Enquiry with a Vivli Listed study

13. INSERT
Left Page: N/A
Right Page: 1
4. Click on Study is Listed link

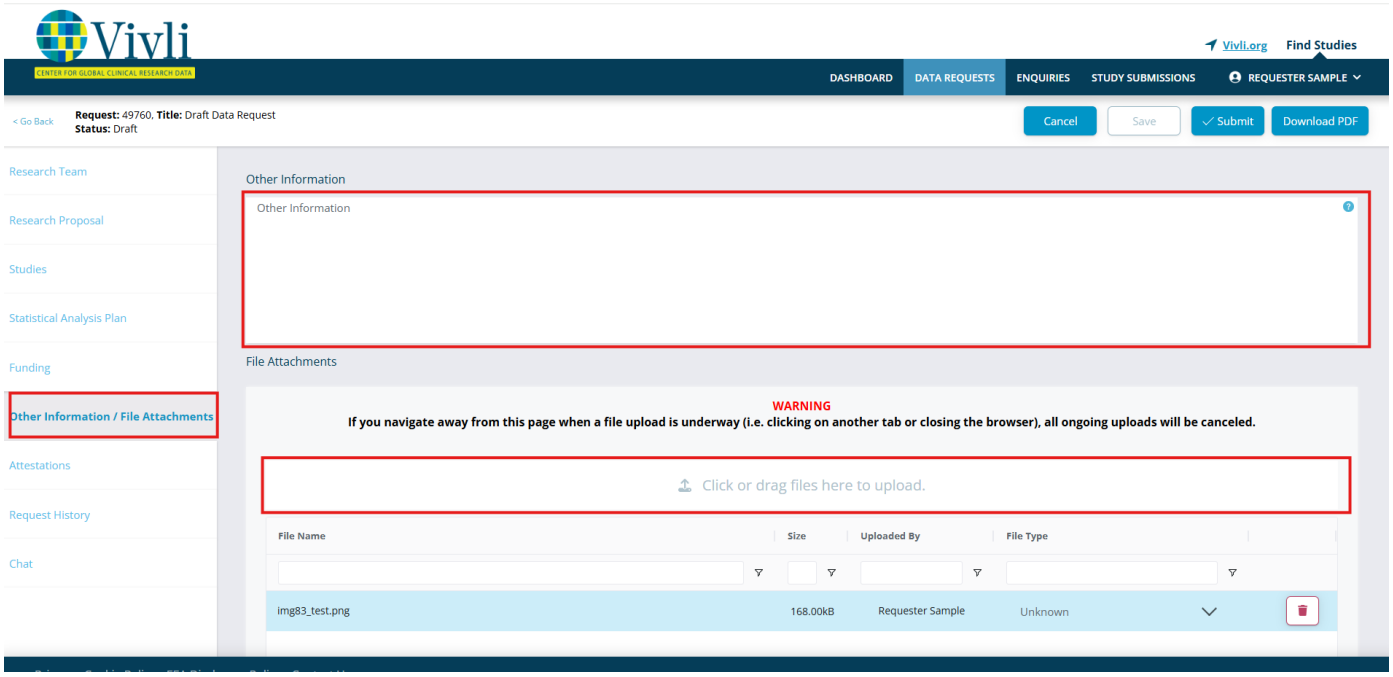
14. INSERT
Left Page: N/A
Right Page: 1
5. Study details page opens in new tab

15. INSERT
Left Page: N/A
Right Page: 1
6. Observe that the studydetails link from devint is opened"

16. DELETE
Left Page: 1
Right Page: N/A
vbjkdv

17. INSERT
Left Page: N/A
Right Page: 1

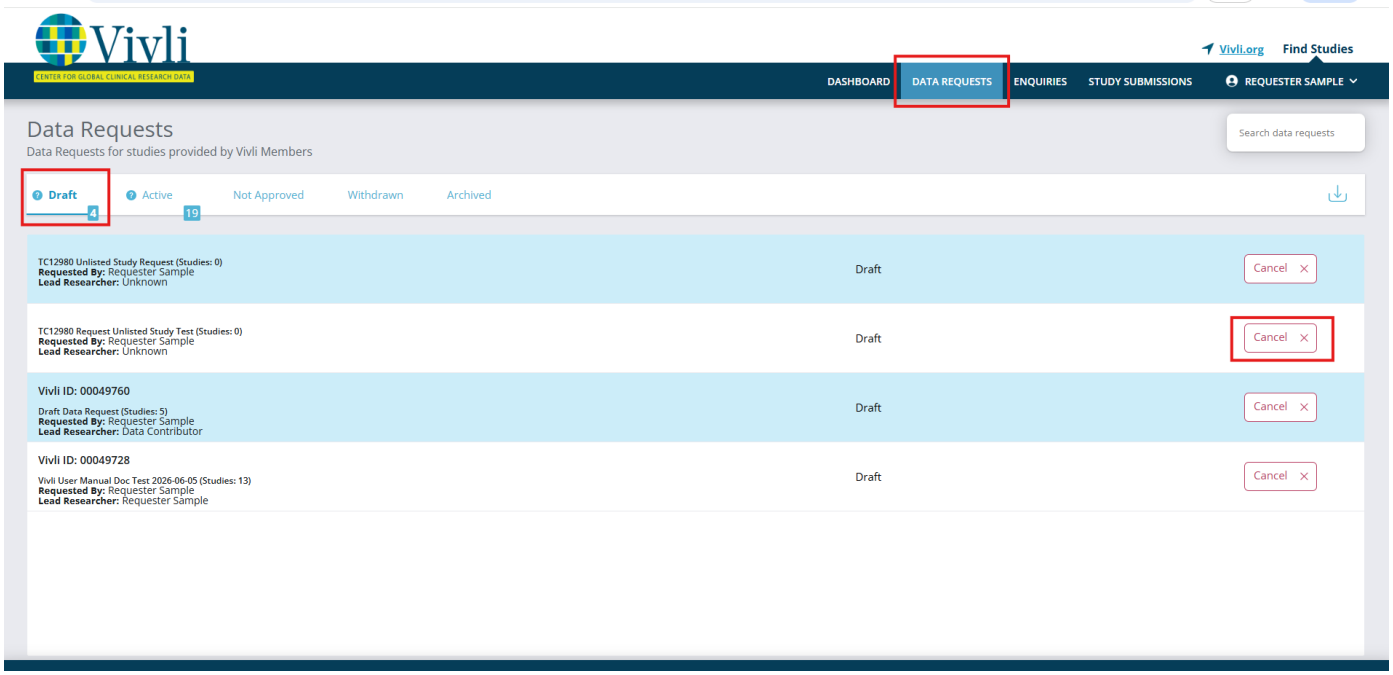
3. Once comments are reviewed in the history or in the chat, you may revise and resubmit the Data Request Form.
4. Use the **Other Information / File Attachments** tab to add any additional comments about the revision that don't belong in other fields, or to add any documents:



For more information on attaching files, see [3.2.1 Adding Files or Other Information to your data request]

8.4 Deleting Draft Data Requests

You may cancel your draft data request at any time. Navigate to the Data Requests Drafts tab and click on 'Cancel' next to the relevant request.



8.5 Withdrawal process for submitted data request

If you decide to withdraw your request once it is submitted, you can reach out to the Vivli team via open chat or through support@vivli.org and provide your reasons for withdrawal.

A Data Request will be considered to be non-responsive when it has met the following criteria:

- When the request has been submitted and returned to Drafts for revision (and)
- Has not been revised, resubmitted, or progressed to the next stage of review (and)
- No response has been received from the Research Team to Vivli Admin for 3 months following check-ins via chat.

After 3 months, the request is considered abandoned and moved to the withdrawn status. You may contact Vivli at support@vivli.org anytime to move the request back from withdrawn to drafts.

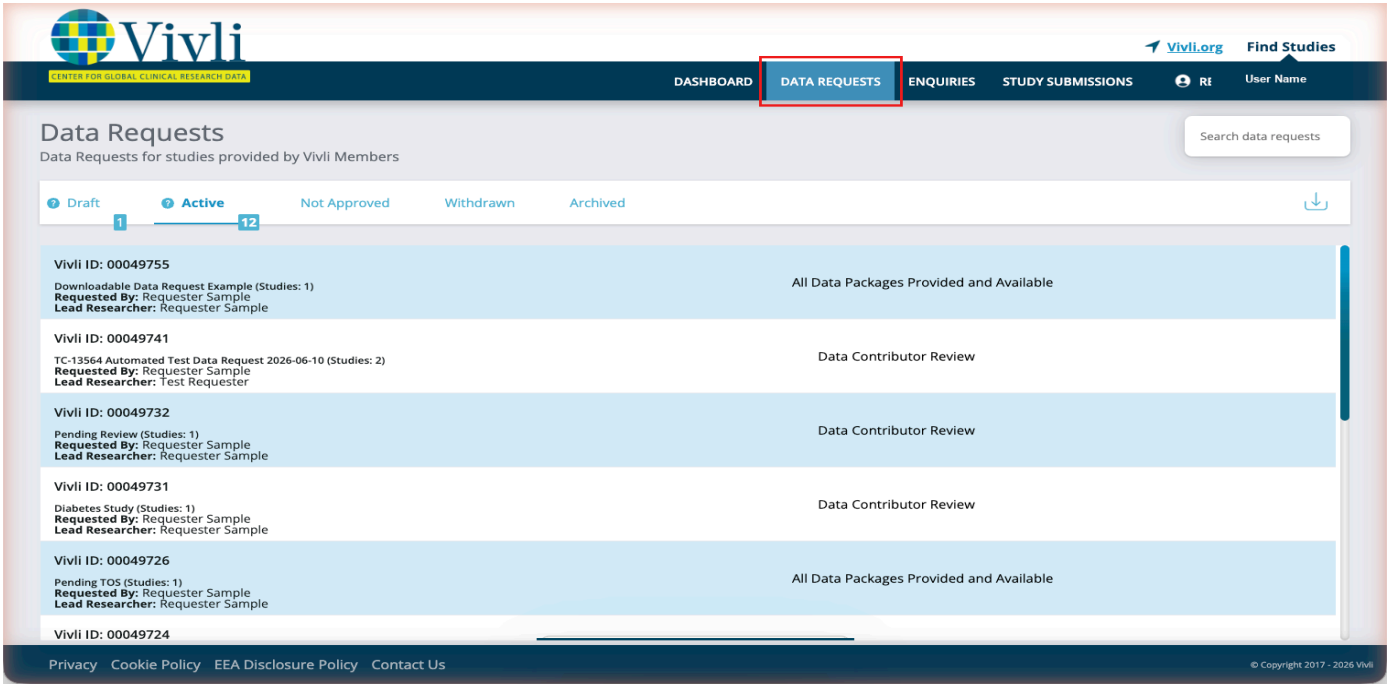
Communications

9.1 Open Chat

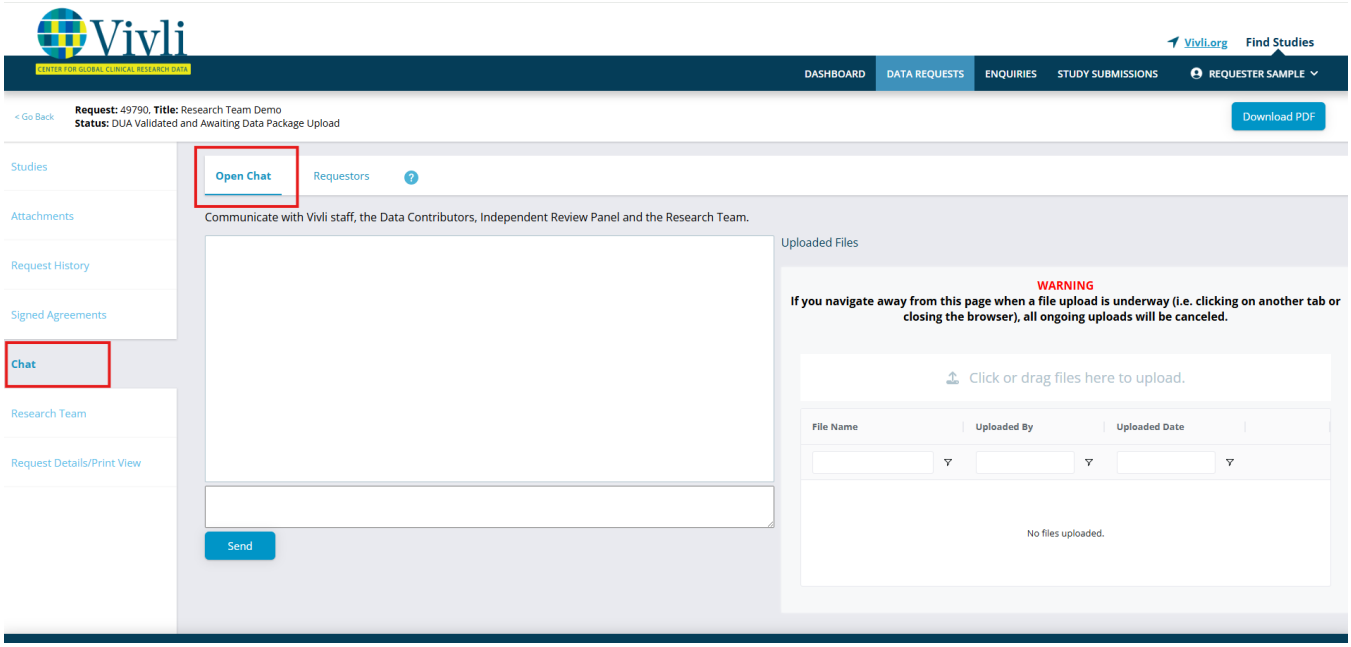
- You can use the open chat within the data request to communicate with the Vivli team, and the data contributors or review entities associated with your data request.
- Please note that messages in open chat are visible to all persons attached to a data request.
- When any other party enters a message in chat, you will receive an email notification.

9.2 Steps for creating a chat message

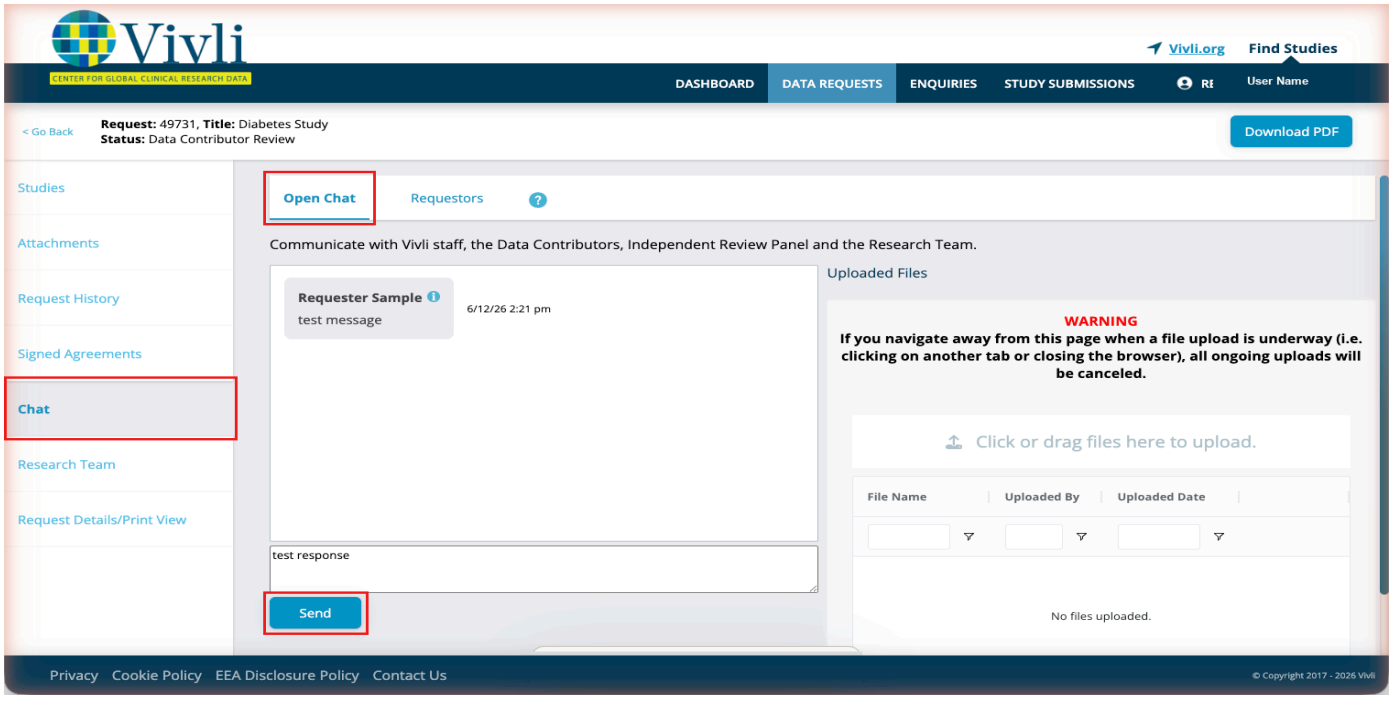
1. Log on to the platform and go to **Data Requests** from the top toolbar or click on 'Data Requests' on the Dashboard:



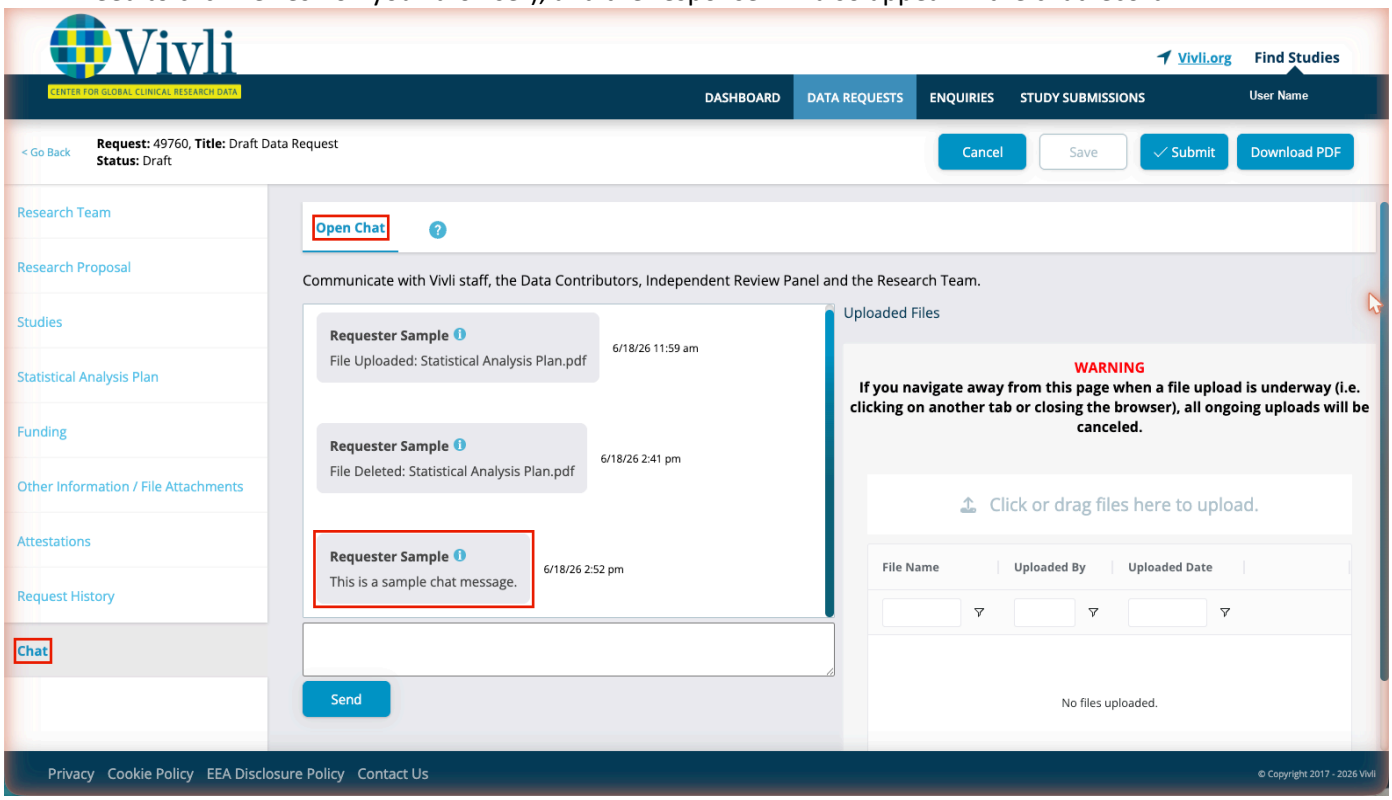
2. Open a data request and click on the **Chat** tab on the left-hand side of the screen and go to **Open chat.** Messages entered here are received by research team members who have access to the data request, the Vivli team, and all Data Contributors after the request has reached the Data Contributor Review stage.
3. Requestors chat can be used to communicate within your research team with those members who have access to the data request – no one else will receive these messages including the Vivli Team. If there is no one else on the team with access to the data request, the Requestors chat will not be present.



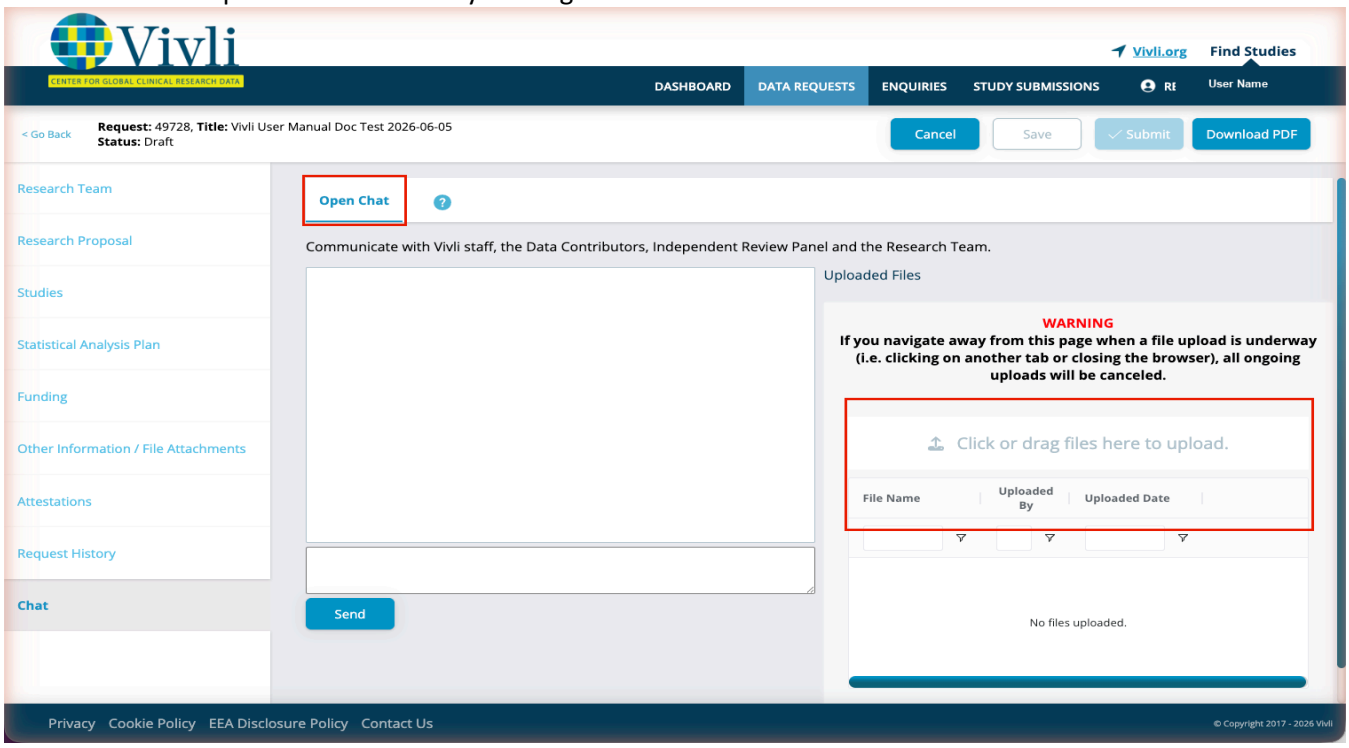
4. Enter your message in the chat message box and click **Send:**



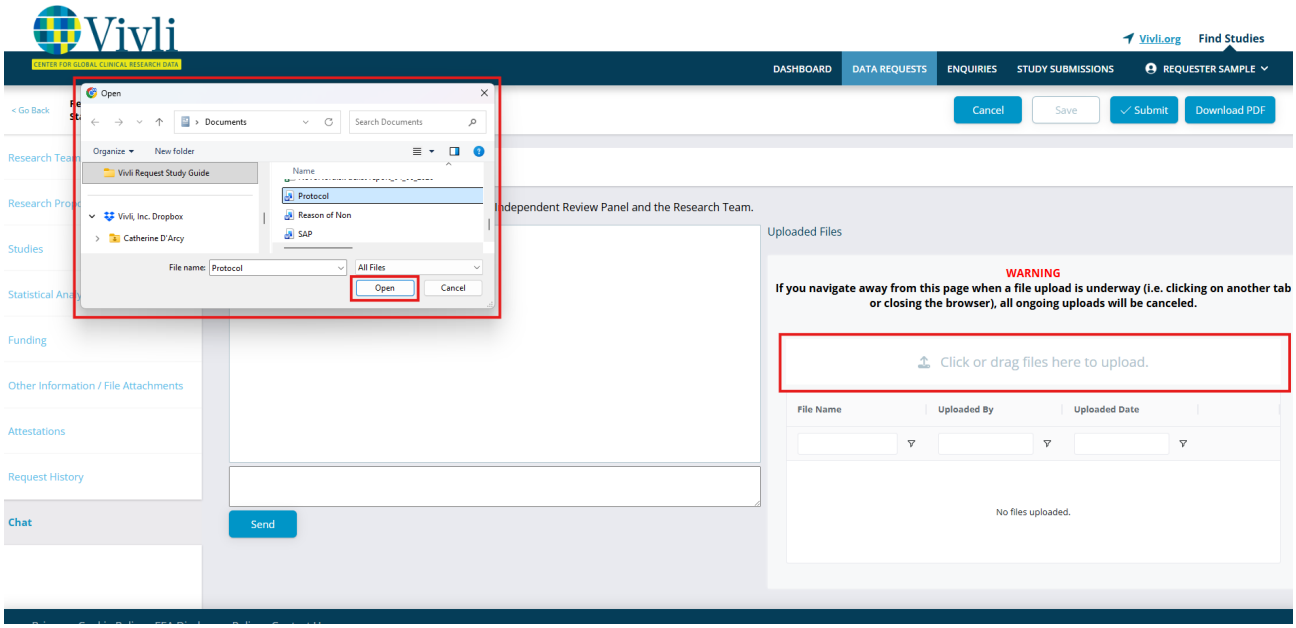
5. The message will now appear in the Chat record for all users (to see your just-entered chat message, you may need to click Refresh on your browser), and the response will also appear in the chat record:



6. You can also upload files via chat by clicking on **Select Files:**

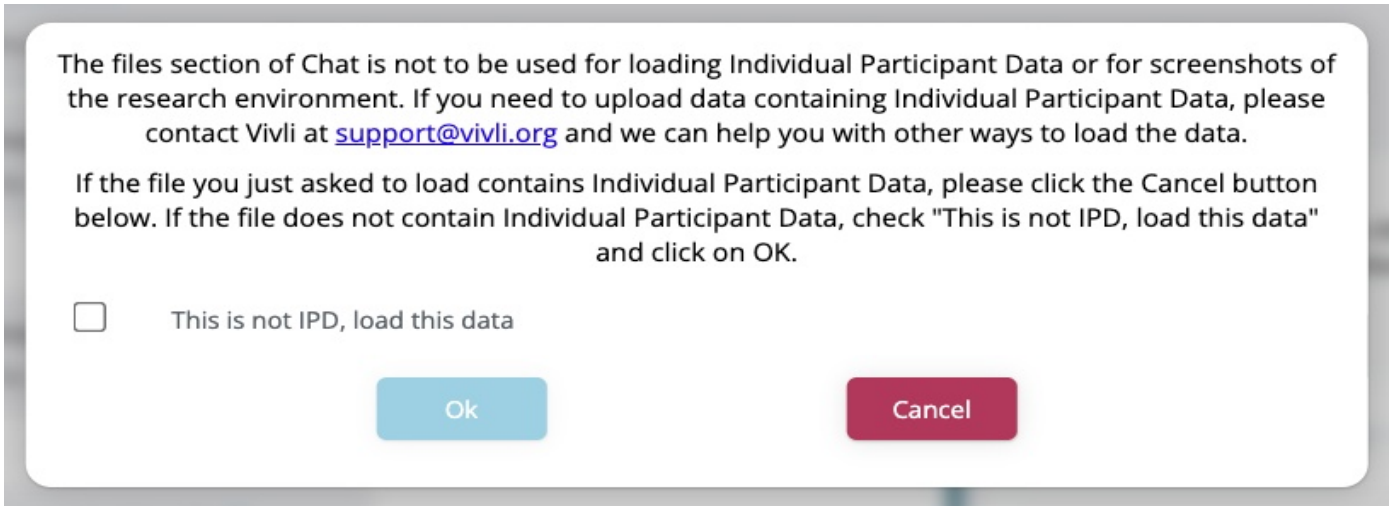


7. Select the file you wish to upload from your computer:

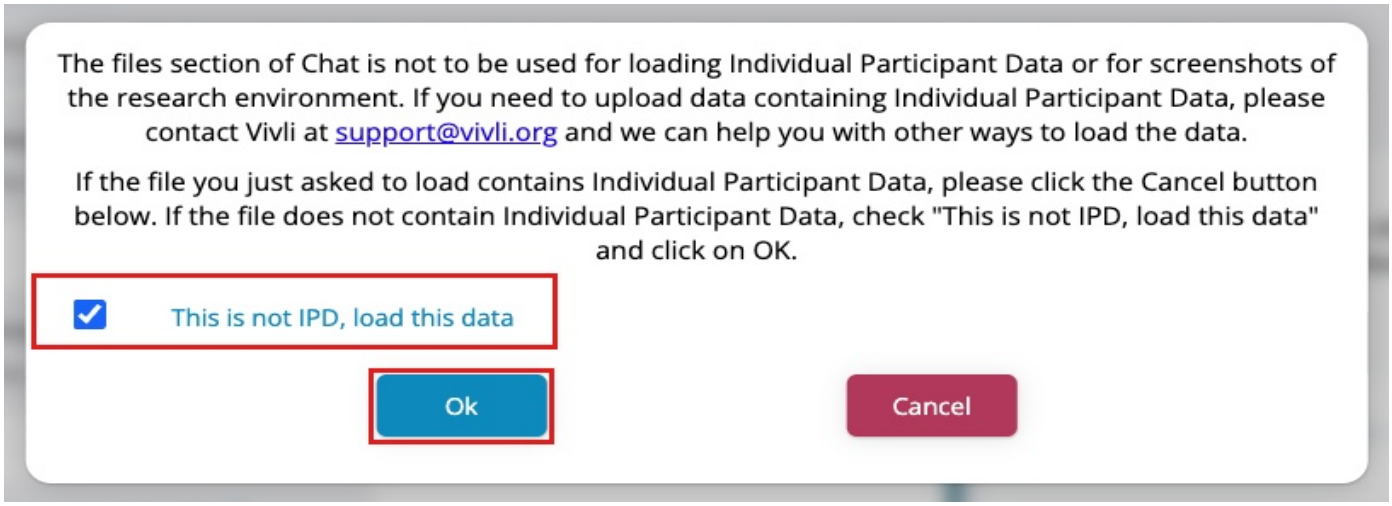


8. **Note**: Individual participant data (IPD) **should NOT** be uploaded in this section

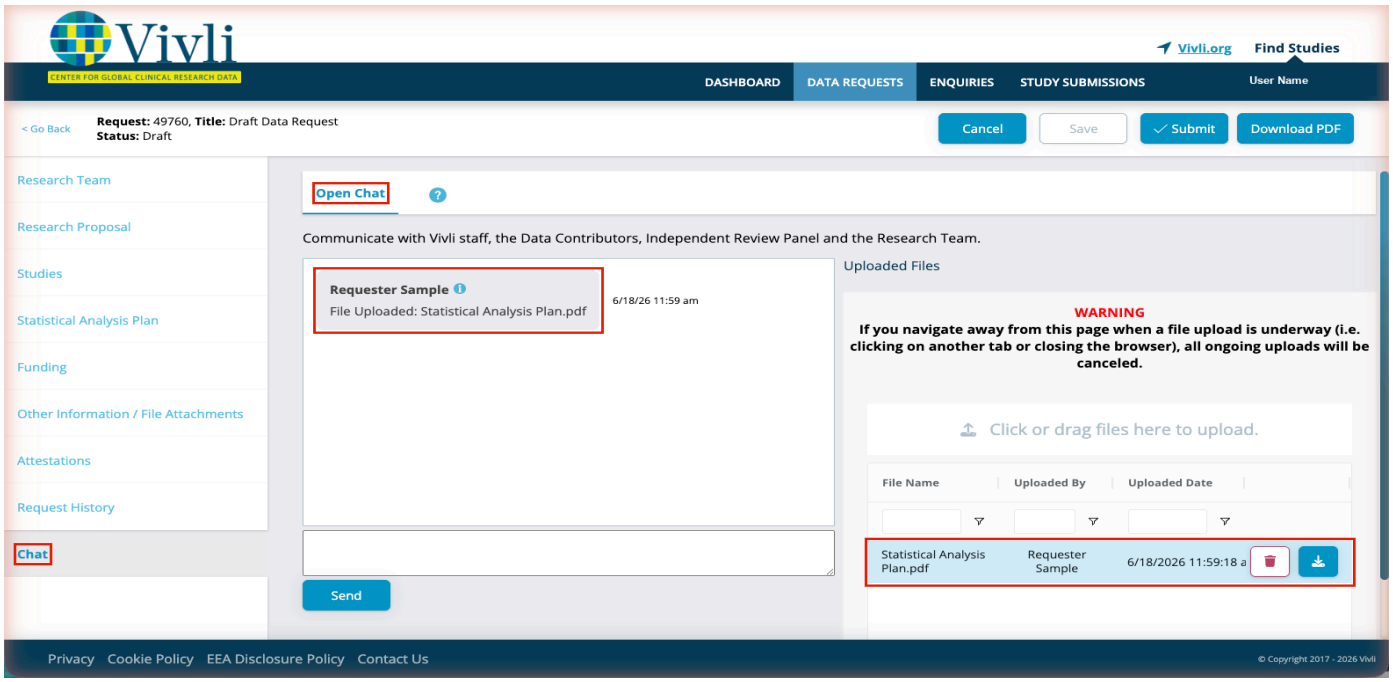
9. The following window may appear to confirm that IPD files are not uploaded in this section



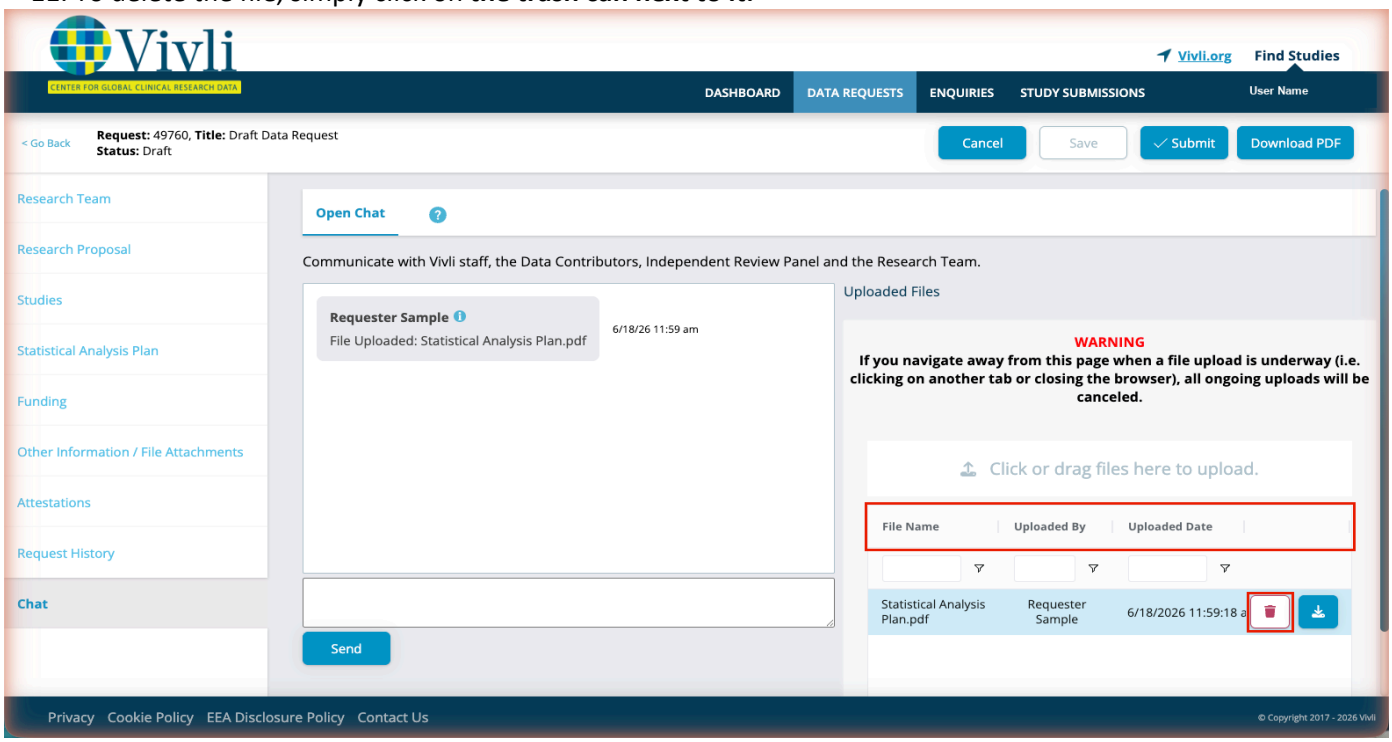
9. Check the checkbox to confirm that the files are not IPD and then click OK.



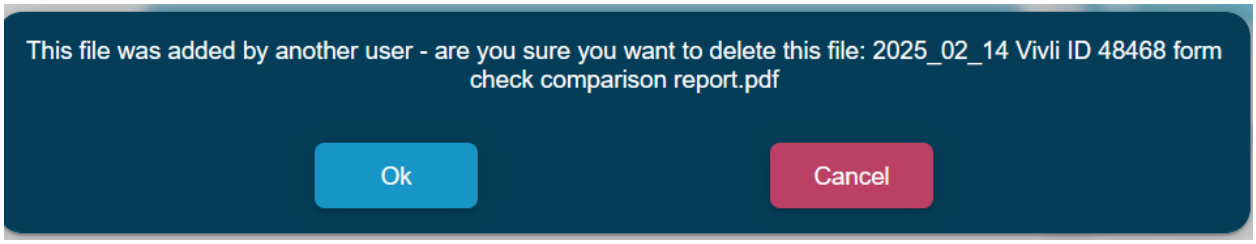
10. The uploaded file will appear in the file list on the right, and in the chat history. **If you navigate away from a page on which an upload is underway, that will cancel the upload automatically:**



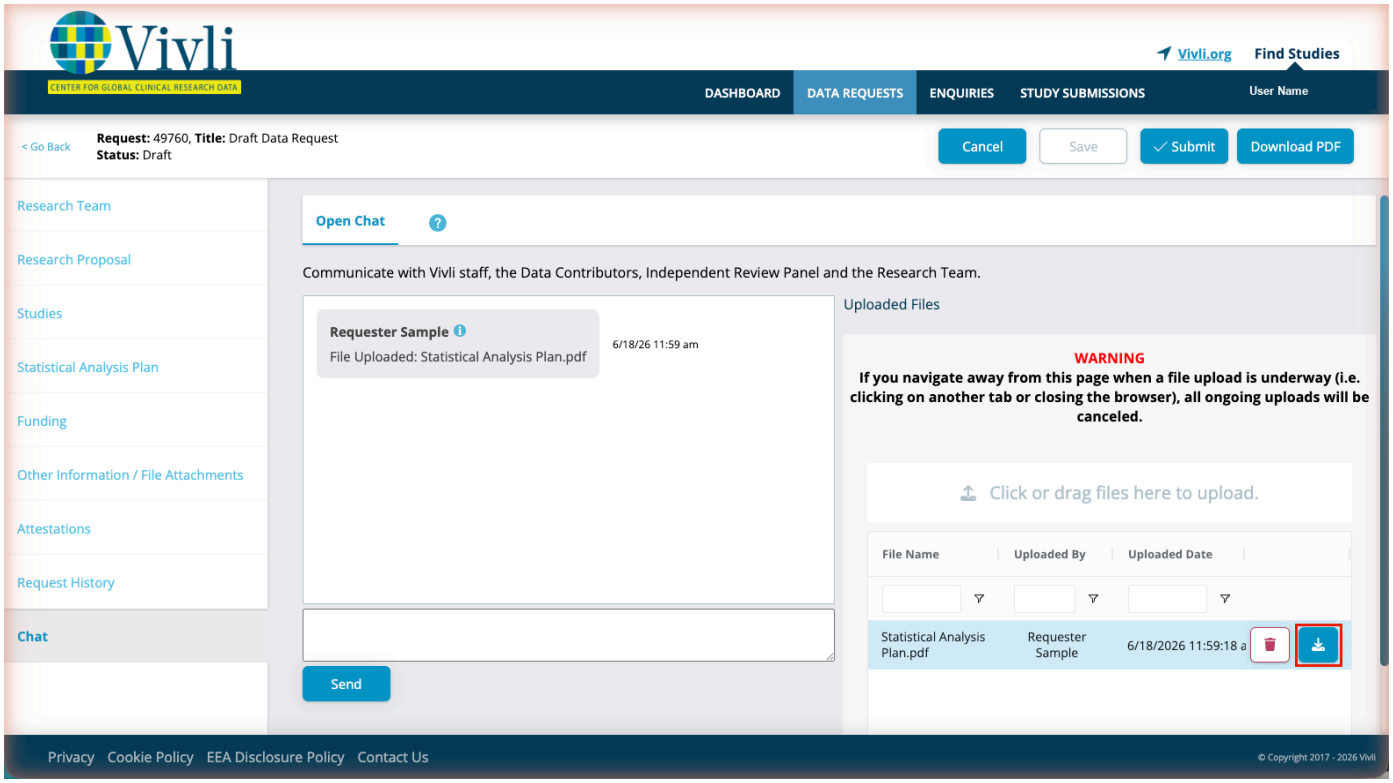
11. To delete the file, simply click on **the trash can next to it:**



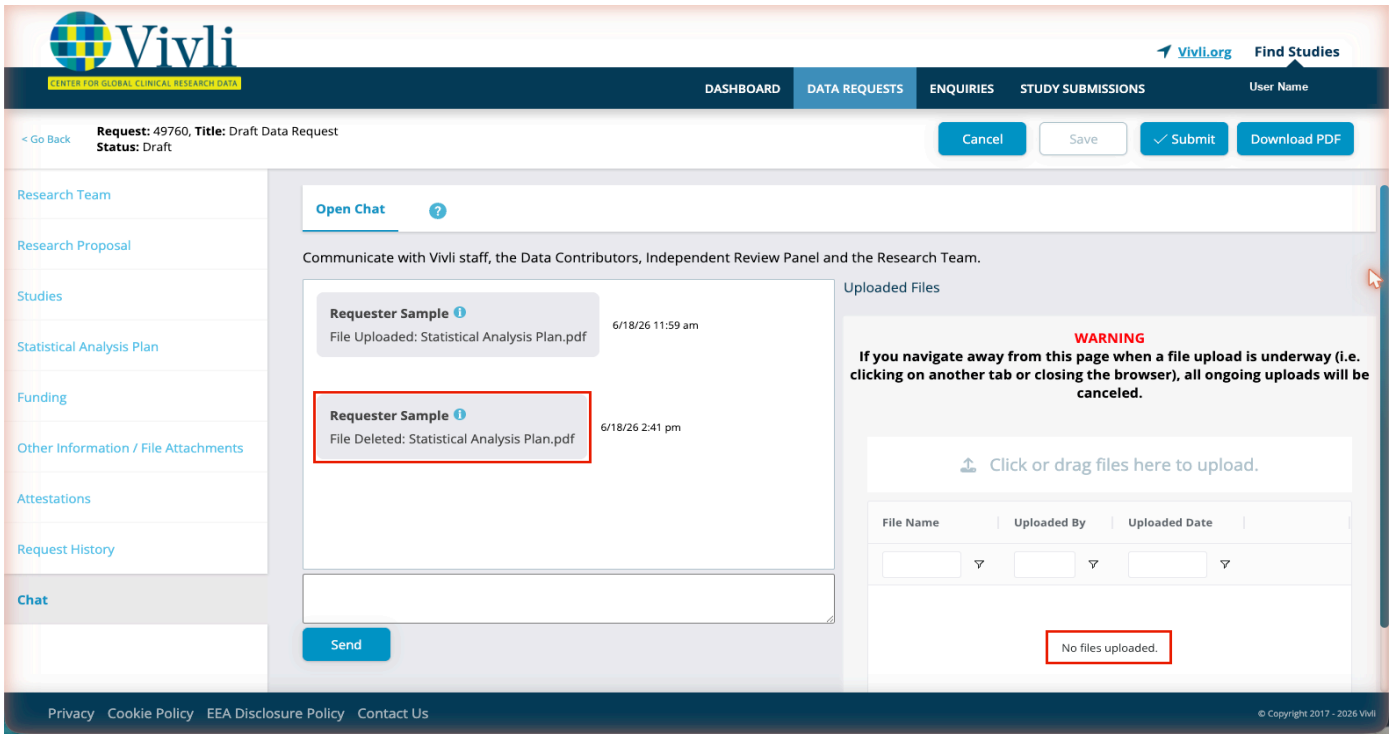
12.You will see a confirmation box asking you to confirm if you intended to delete the file "This file was added by another user - are you sure you want to delete this file: <filename>". Click Ok if you want to proceed to delete the file or Click Cancel if you do not want to proceed.



13. You may also download chat files by clicking on the **Download arrow:**



14. The deletion of the file will appear in the chat history:



15. Chats are posted when you click “Send” which permits you to write and read distinct paragraphs
16. Chat messages automatically scroll to the most recent post.

17. In chat, files are sorted by date, newest on top, and the hover text displays the filename, date uploaded, and person who uploaded it.
18. Posted chat messages are visible immediately.

9.3 Emails from Platform

You will receive a number of automated emails from the Vivli platform relating to your data request

Email	When sent	Purpose
Status Change, data Request passed Vivli form check	When your data request passes the Vivli form check for completeness	Notify you when the review process has commenced. The email lists the next steps in the data request review process
Status Change, data Request - Revision requested or Request not approved	When your data request changes status to Revision or Not approved. If you have requested studies from multiple contributors, you will receive a notification after all the Data Contributors have recorded their decision.	Notify you of any changes in the status to your data requests.
Request Final Approval	When your data request is approved, by a delegated approver/IRP. If you have requested studies from multiple contributors, you will receive a notification after final approval.	Notify you of final approval.
DUA Approved	When the Vivli Admin has validated the DUA associated with the data request.	Notify you of the executed DUA.
Data Uploaded	When requested Study Data Package from the Data Contributor has been uploaded. If you have multiple studies, you will receive individual emails when each data package is uploaded. You will also receive an email when all data packages are loaded.	Notify you of the data upload status to plan your analysis.
Secure Research Environment was provisioned.	When you start the secure research environment.	Notify you when the Secure Research Environment is ready to be used for analysis.
Request for results export	When your request to export results is approved or/not approved.	Notify the status of the results export.
Data Request Archived	When the data request is Archived, the project is considered closed.	Notify that the lead researcher and research team have met the DUA obligations for public disclosure/summary of results and

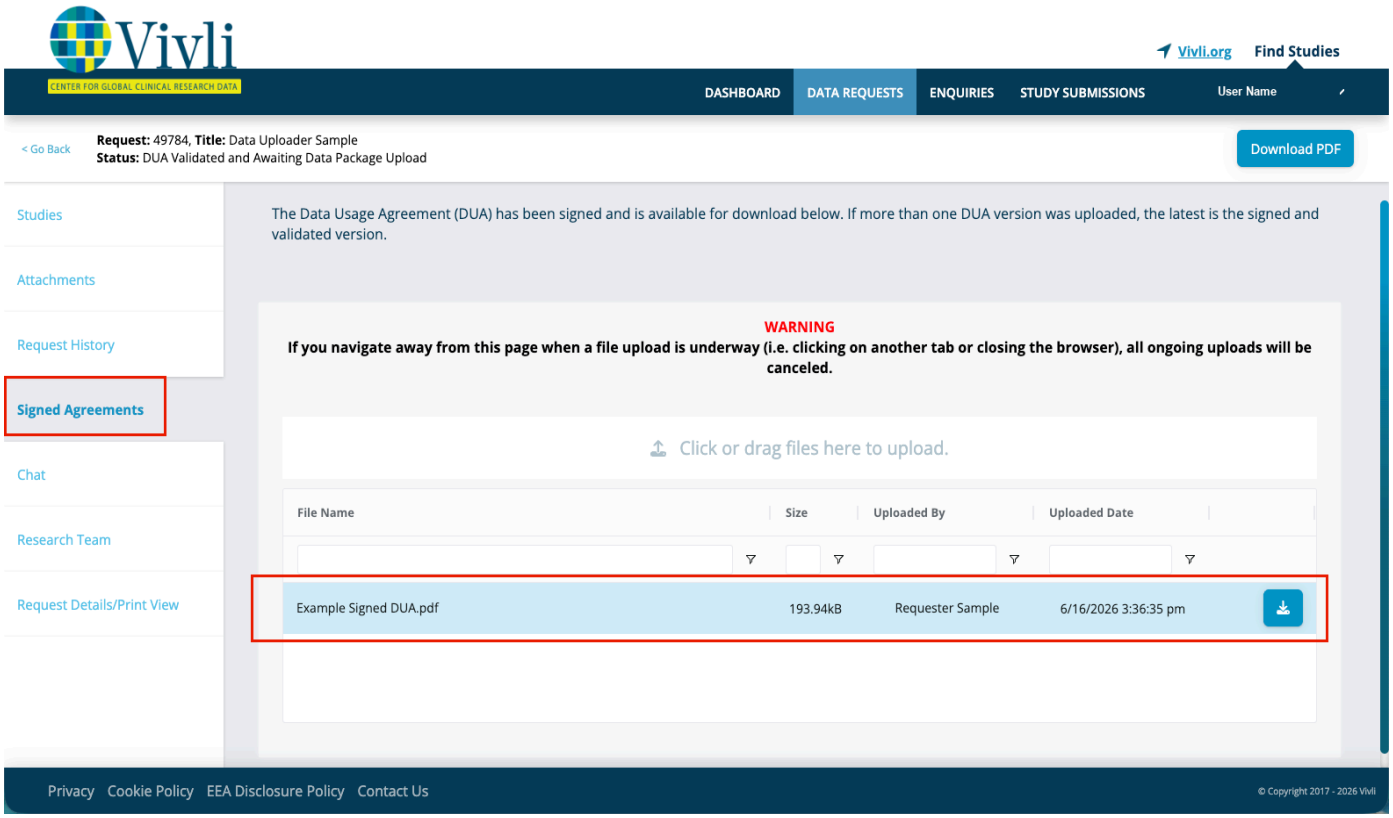
		the data request is now archived.
Chat	When anyone associated with a data request enters a message in chat. This includes chat messages from Open chat and Requester chat	Facilitate communication and the data request workflow
Enquiry	When anyone associated with a data request enters a comment or makes a decision	Facilitate communication and the Enquiry workflow.
Public Disclosure submitted	When a disclosure is submitted, an email is sent to notify the team that the 30-day review period has begun.	Notify the research team that the disclosure was received and the 30-day review period has begun
Public Disclosure re-set to "Drafts"	When a public disclosure is re-set to the "Drafts" stage.	Notify the research team that the public disclosure has been re-set to drafts by the Vivli team so that the researcher can modify the form
Public Disclosure 30-day review complete	When a disclosure reaches the end of the review stage (once all data contributors have completed review or the 30-day period is complete) .	Notify the research team that the 30-day review is complete and the publication may be submitted to a learned forum.

Note: Only users with active Vivli accounts and who are activated in the data request will receive automated emails. See 3.4, Adding Research Team Members, for instructions on adding research team members to a data request and activating members for a data request.

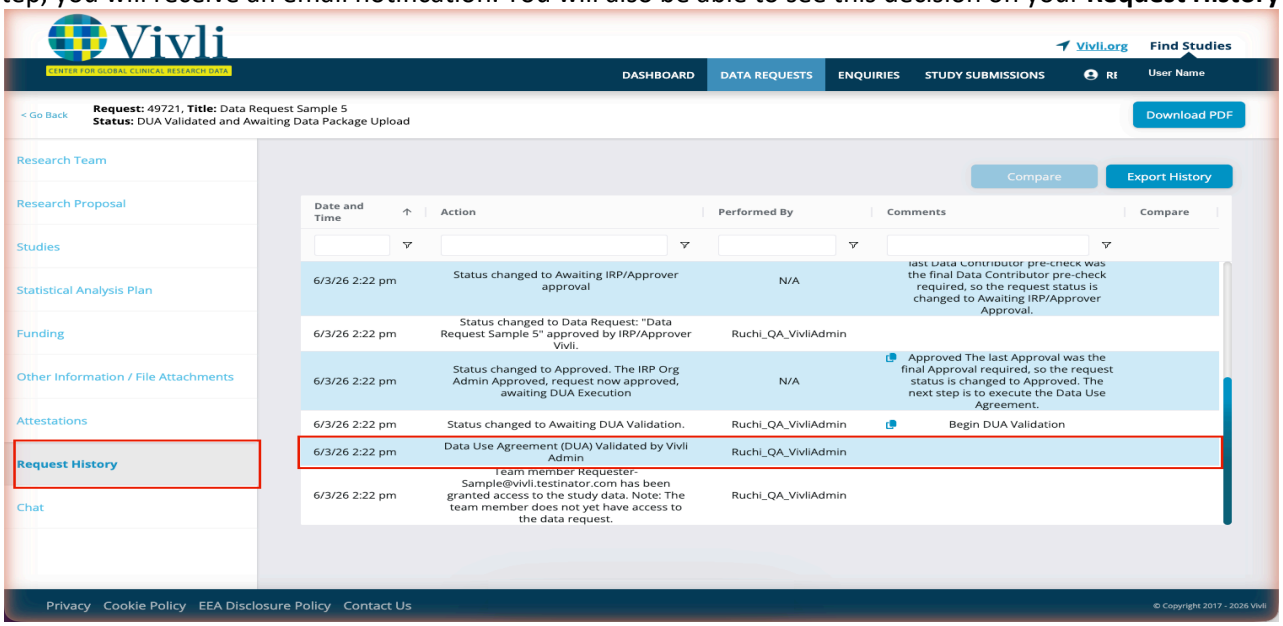
10.0 Data Use Agreement

All Data Requestors must execute the Data Use Agreement before receiving the data. The Data Use Agreement is the product of extensive negotiation with the organizations that contribute data to Vivli, and as such, the agreement is non-negotiable. If you have any questions about the Data Use Agreement, contact support@vivli.org.

1. Review the Data Use Agreement template.
2. After your request is submitted and once Vivli checks the data request form is complete, Vivli will send you the Data Use Agreement via DocuSign for your signature and, if needed, that of an institutional official at your organization.
3. Once your data request is approved, Vivli will execute this document and load it into the platform under the signed agreements tab.



4. Once your Data Use Agreement has been executed, Vivli will record that decision on the platform. For that step, you will receive an email notification. You will also be able to see this decision on your **Request History**

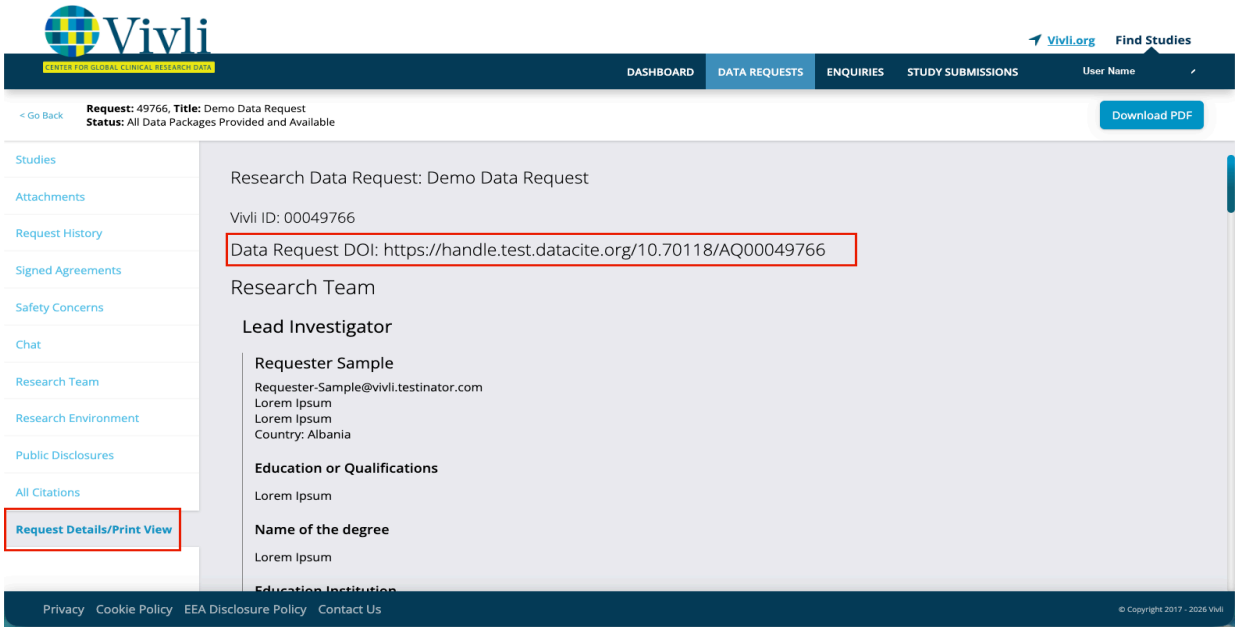


5. If your request is approved, specific information about the request will be posted on the Vivli website so the Vivli team will request that you spell out acronyms in the first instance. If your request is approved and a Data Use Agreement is executed, Vivli will publish the following fields on its website, and generate a DOI for the data request:
   - Project Name

- Name & Affiliation of the Lead Researcher
- Funding Sources
- Conflict of Interest Statement
- Lay Summary of your Research Proposal
- List of requested studies

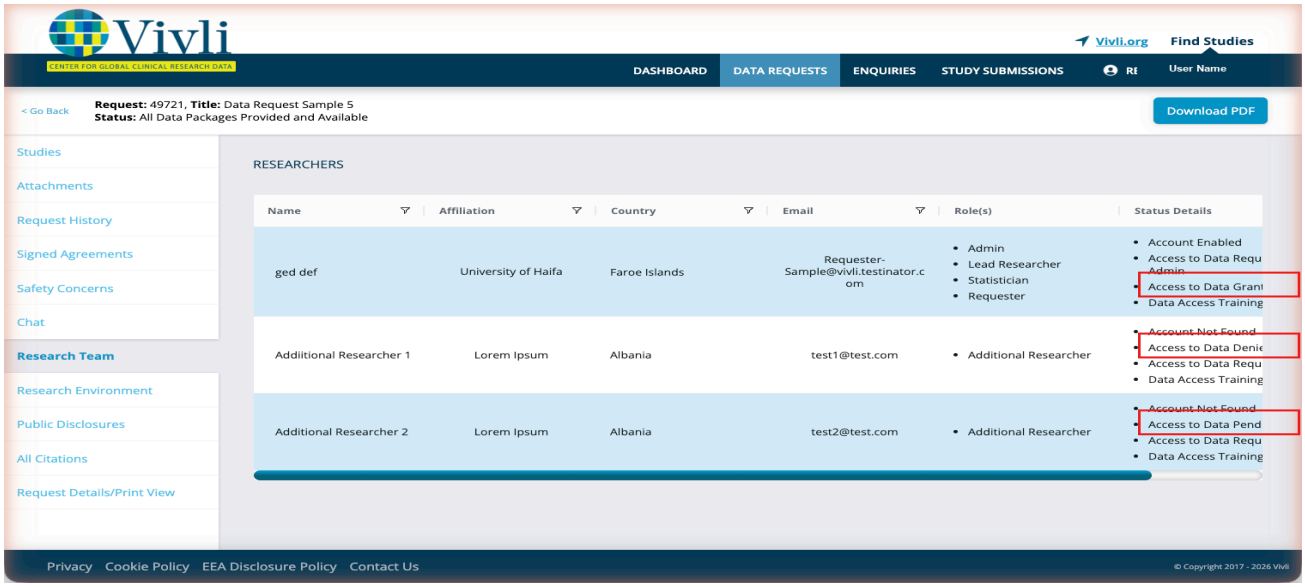
After your publication is published, Vivli will publish the following information related to your data request:

- Statistical Analysis Plan
- Publication Citation



6. Once your request passes the DUA validation stage, the Vivli team will set the DUA approval for each team member. You can see additional details about the status of the Research teams' DUA approval in the Research Team tab.

- Access to Data Pending – A research team member doesn't have DUA approval to proceed with analysis, or they haven't completed data access training. When a new team member is added, you can see this status. Vivli Admin will review the DUA and provide further information on the next steps.
- Access to Data Granted – A research team member has a valid DUA and has completed data access training so can proceed with analysis. They can access the data.
- Access to Data Denied – A research team member doesn't have DUA approval to proceed with analysis, or hasn't completed data access training. This could be due to failure to return the Data Progress report annually or non-payment of secure research environment payment or failure to meet some other DUA obligations. The Vivli Admin will keep you informed.



11.0 Data Package Upload

The Data Contributors will anonymize the data and upload the data into the platform. You will be notified via email when each data package is uploaded and when all data packages are uploaded.

12.0 Secure Research Environment and Results Export

The Vivli secure research environment is a cloud-based remote workspace. The Vivli secure research environment allows research teams to access data and conduct analyses in a shared workspace that is equipped with analytical tools and may be flexibly configured. Further guidance will be provided when you reach this stage.

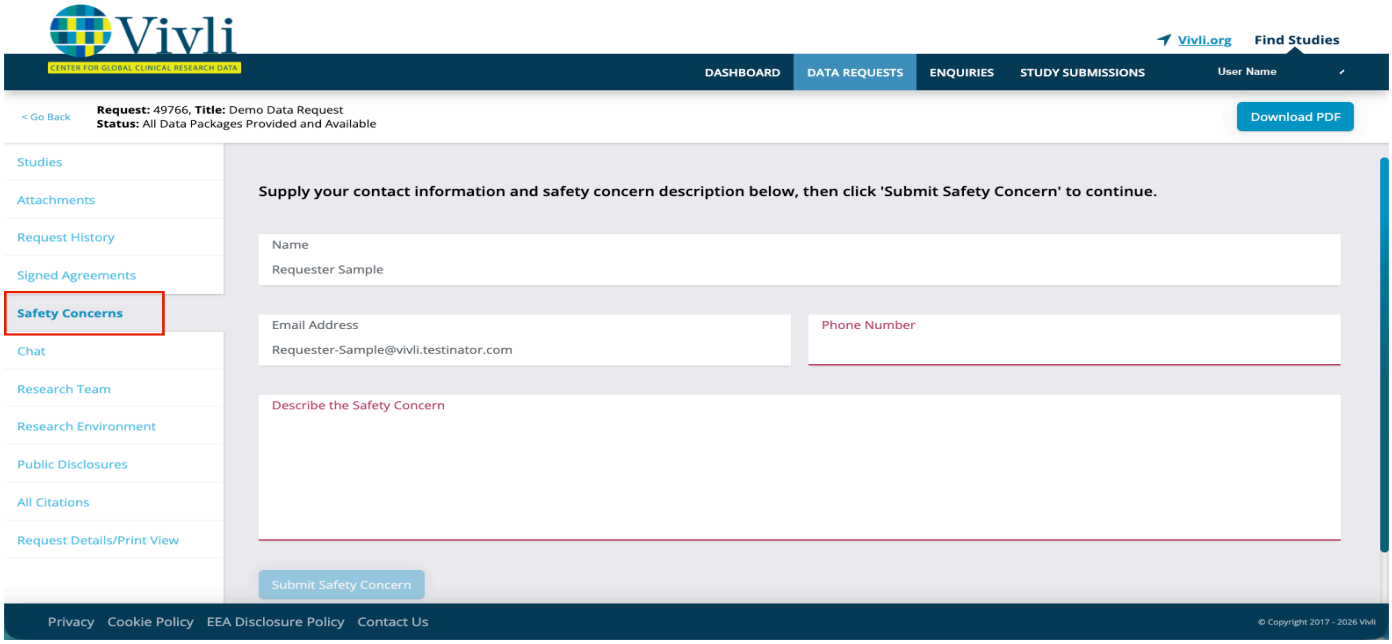
The software available in the secure research environment is updated on a regular basis and a comprehensive listing of the software and R packages is available in the Vivli Secure Research Environment. The full list is on the Vivli website, https://vivli.org/resources/resources/

You may request to export intermediate or final results from the secure research environment. You can use these results to write your publication. Vivli will send you detailed instructions during the analysis stage.

13.0 Safety Concerns

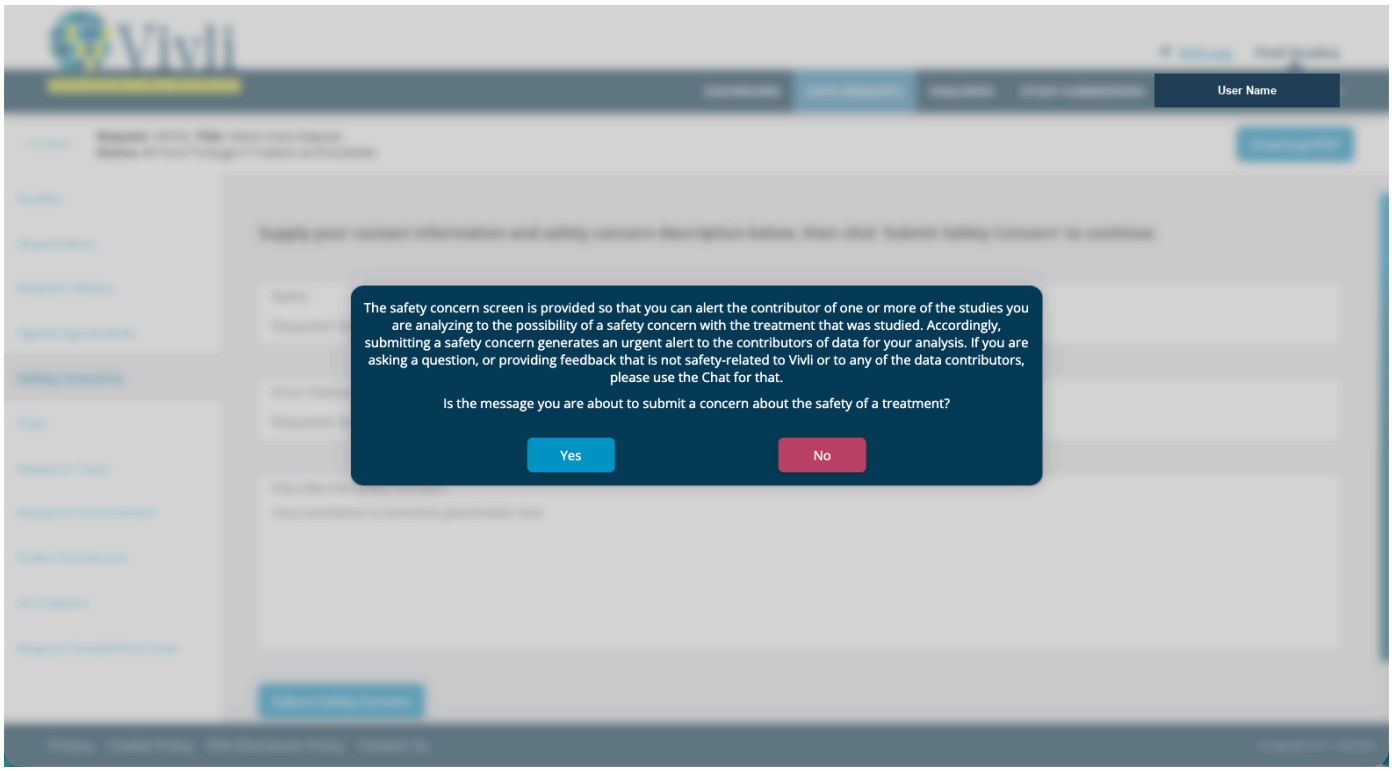
The safety concern tab is available so that you can alert the contributor of one or more of the studies you are analyzing to the possibility of a safety concern with the treatment that was studied. Accordingly, submitting a safety concern generates an urgent alert to the contributors of data for your analysis.

To submit a safety concern, select the “Safety Concerns” tab on the left-hand side of your data request dashboard and complete required fields.



Before pressing “Submit”, a message will appear to confirm that the message you are about to submit is a concern about the safety of a treatment.

- Press “Yes” if you wish to submit the safety concern or press “No” to return to the previous screen.



If you are asking a question, or providing feedback that is not safety-related to Vivli or to any of the data contributors, please use Open Chat for communication. Please see Section 9.1 Open Chat for more information.

14.0 Data Progress Report

The Data Use Agreement allows for 1 year for accessing the data from the date it was executed by Vivli. Vivli will send a Data Progress Report 90 days before the DUA is about to expire. If you would like to apply for an extension to the DUA, you have to complete the Data Progress Report sent by Vivli and send the signed form back to us before the expiration date of your access to the data requested in your research proposal. According to Vivli policy, DUA extensions are given in 1-year intervals.

Please note that this is not the extension of your no-charge period of the Secure Research Environment which may have a different end date based on when it was started. Vivli will reach out to you separately via email on that. For more information, please see the Vivli secure research environment webpage.

15.0 Public Disclosures & Publications & Summary of results

The Data Use Agreement requires Data Requestors to provide to Vivli, at least 30 days prior to journal submission, the submitted copy of any publication, which Vivli will make available to all Data Contributors for review. Please upload the abstract, poster, presentation, manuscript, etc. via the platform in the "Public Disclosures" tab. Please complete all required fields within the "Public Disclosures" tab and inform Vivli whether you are planning any additional public disclosures for this request via the platform open chat. Vivli will send periodic follow-ups on the public disclosures via the request open chat.

You must add the following language to your acknowledgment section:
This [publication or presentation, as applicable] is based on research using data from data contributors *Data Contributor(s) Name* that has been made available through Vivli, Inc. Vivli has not contributed to or approved, and is not in any way responsible for, the contents of this publication.

As per the Vivli DUA, during this period, the data contributors may provide you with non-binding comments regarding the scientific content. They may also possibly request the deletion of any confidential information (confidential information as defined in the signed DUA). When a public disclosure based on the results obtained from the data request is published, the research team must inform Vivli. The publication citation and the Statistical Analysis Plan (SAP) will be made available on the Vivli website.

If you do not have any publishable results, then you must send the summary of results to the Vivli team the "Public Disclosures" tab. The summary of the results will be sent to Data Contributors for a 30-day review. For a summary of results, once the 30-day review is complete, the Statistical Analysis Plan (SAP) and the summary of results will be posted on the Vivli website and the data request will be archived on the Vivli platform

16.0 Secure Research Environment Closure & Request Archival

Once all the publications are published and the analysis is complete, the Vivli team will reach out to you about the long-term storage of the analyzed data. The secure research environment will then be de-provisioned and we will move the data request to the Archived section of the data request.