How-To: Request Studies on Vivli

Vivli Release 3.0

January 19, 2023

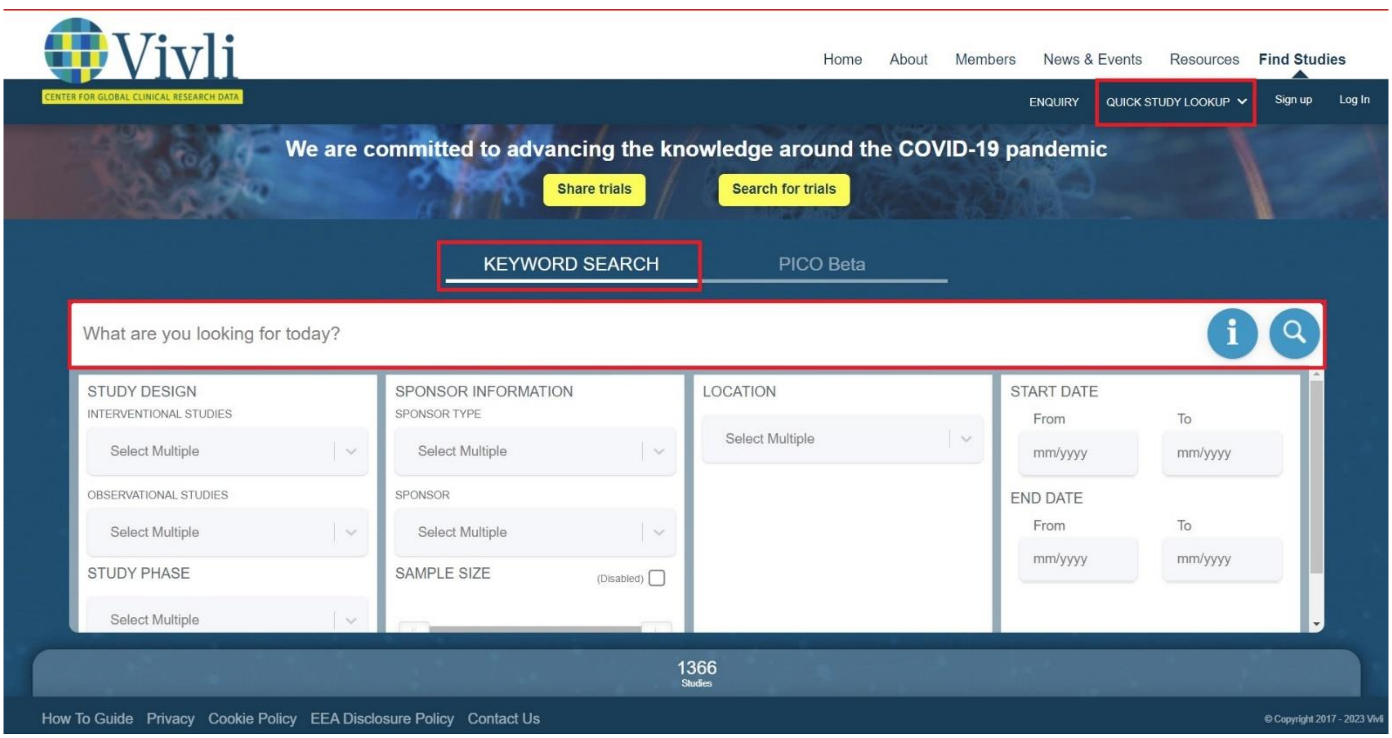
Contents

1.0 Requesting Studies on Vivli – Overview

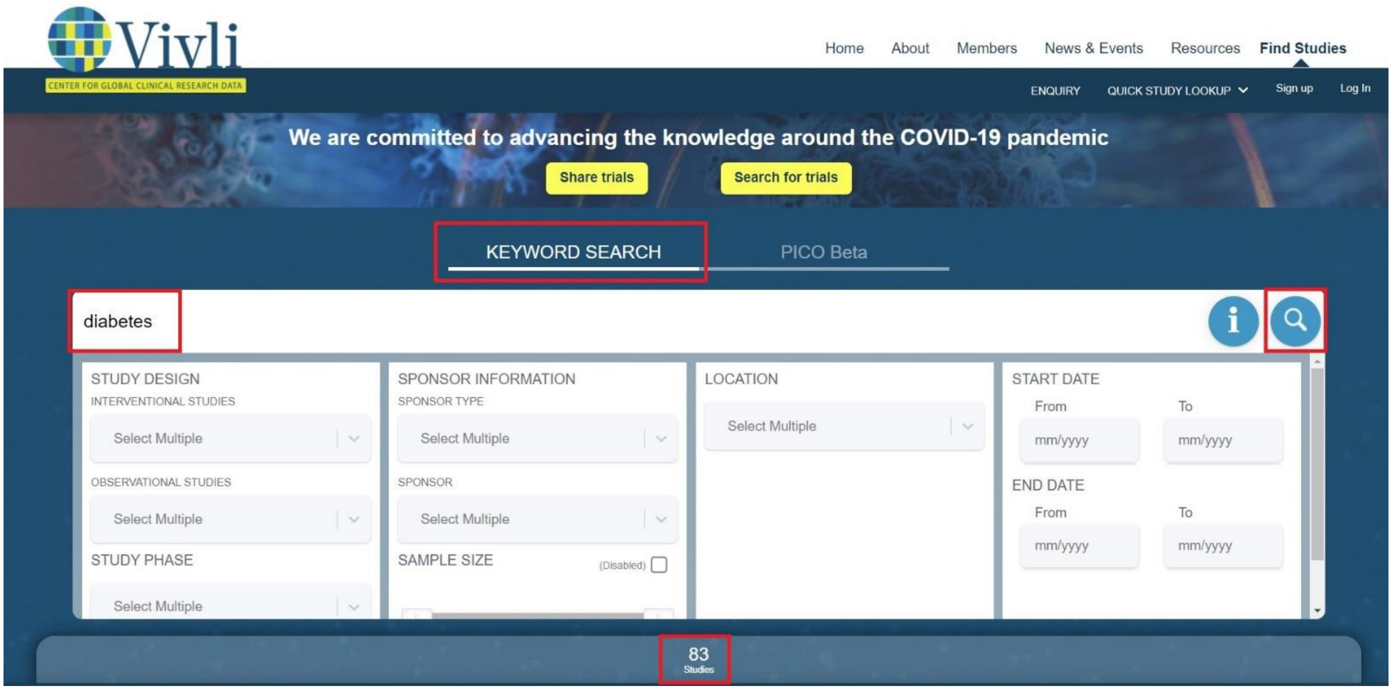
- The process starts with finding studies you need – for assistance with the search, help is available on the Vivli site.
- Once you have completed your search, you may request the data packages for the studies you would like to use for your analysis.
- To do this, the first step is to complete a Vivli 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 at a Glance.
    - Please review the Vivli policy 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 use one of the drop-down filters. You may also use the quick study lookup option to search using NCT ID or Sponsor ID.

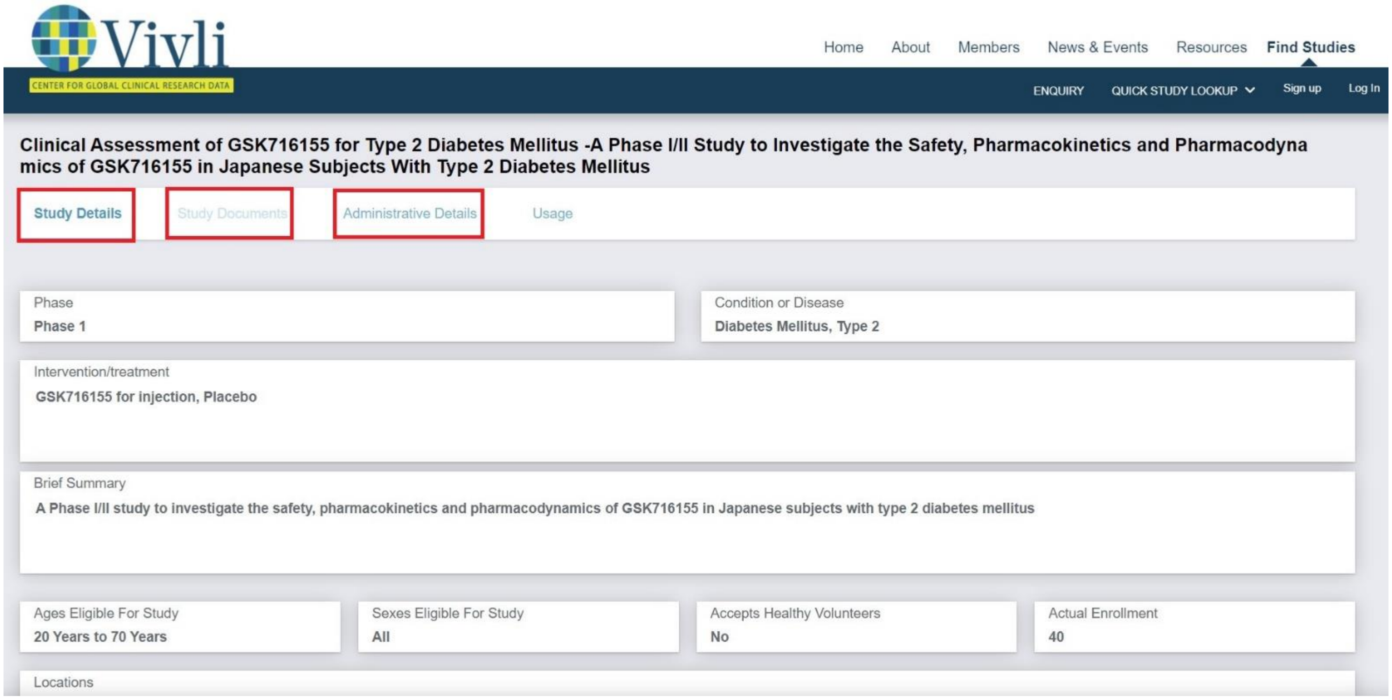


- Type in the keyword or study ID and click on the magnifying glass. The number of studies that include the search term will appear in the blue bar at the bottom of the page.



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

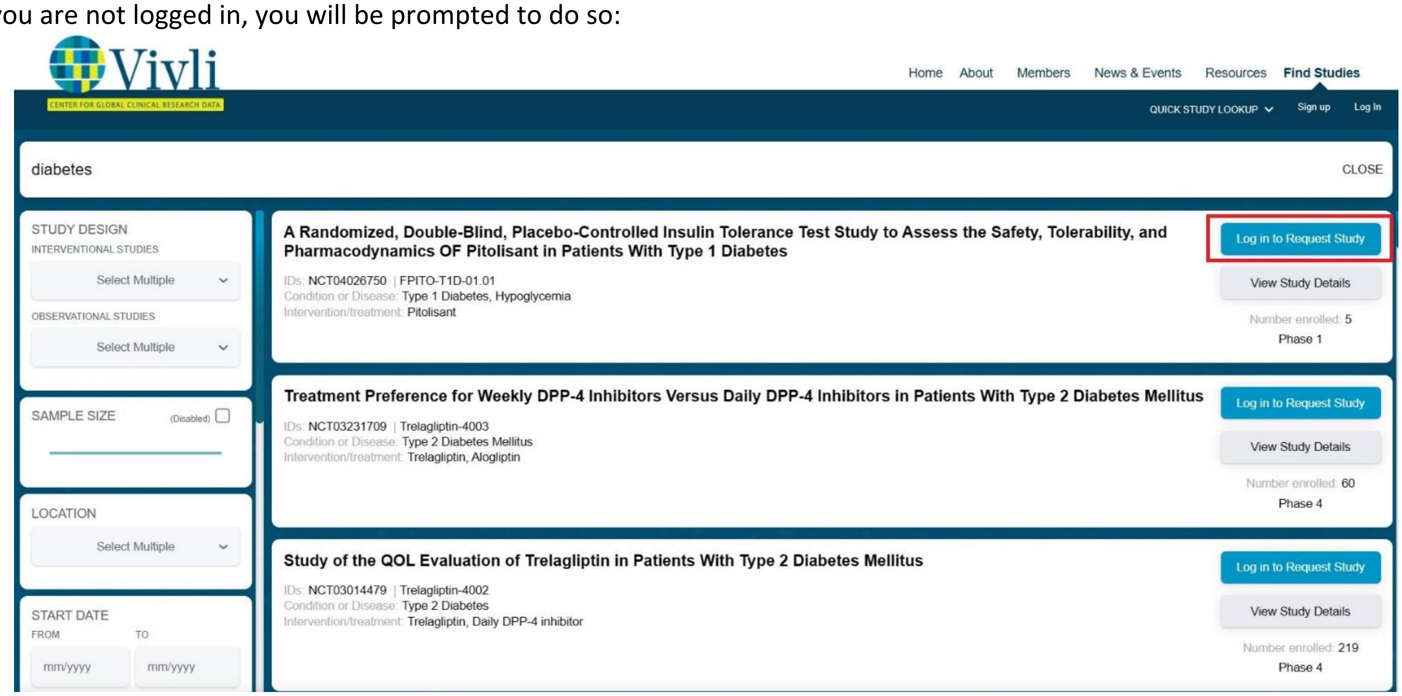
- You can find additional information about the study under Study Details, Study Documents and Administrative Details section



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](#).
  .

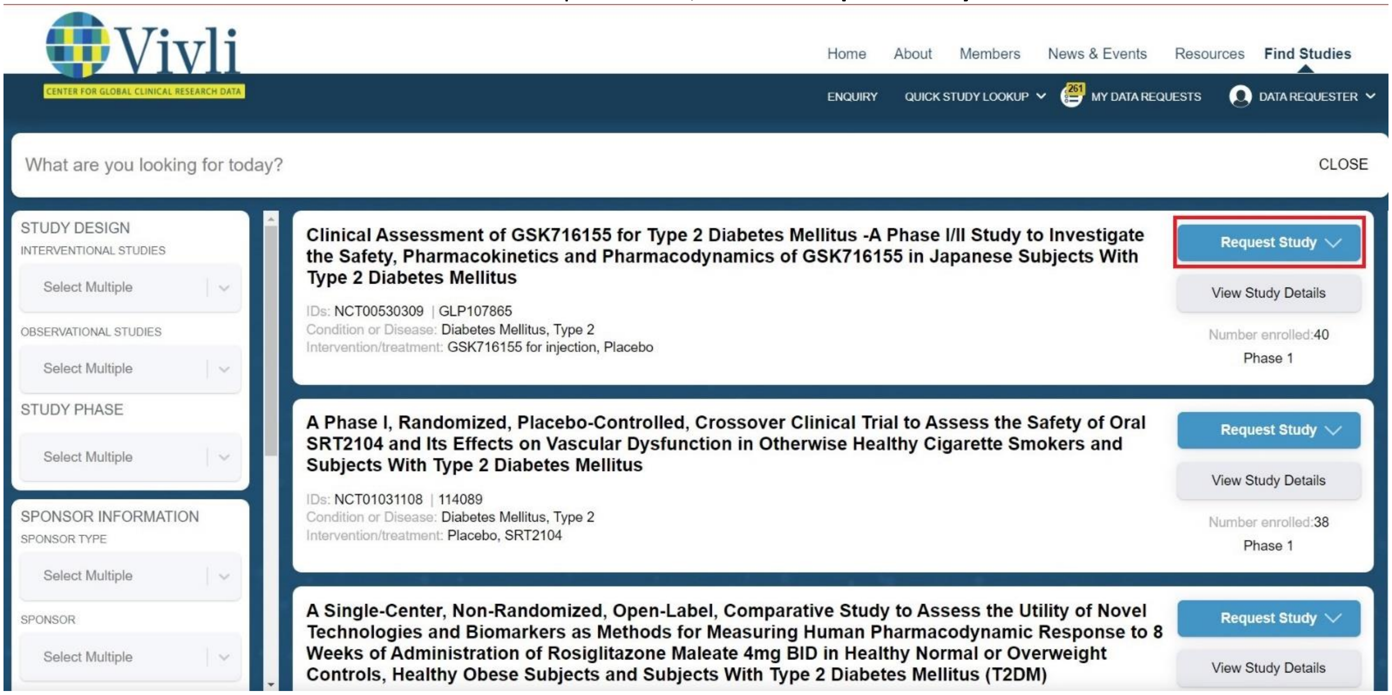
If you are not logged in, you will be prompted to do so:



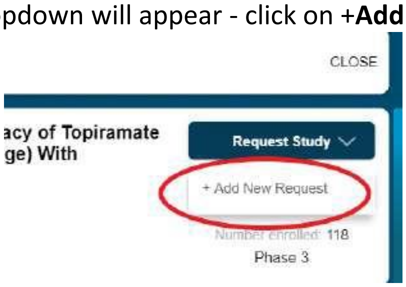
After you log in, you will return to the search results window.

1.3 Add studies to your data request

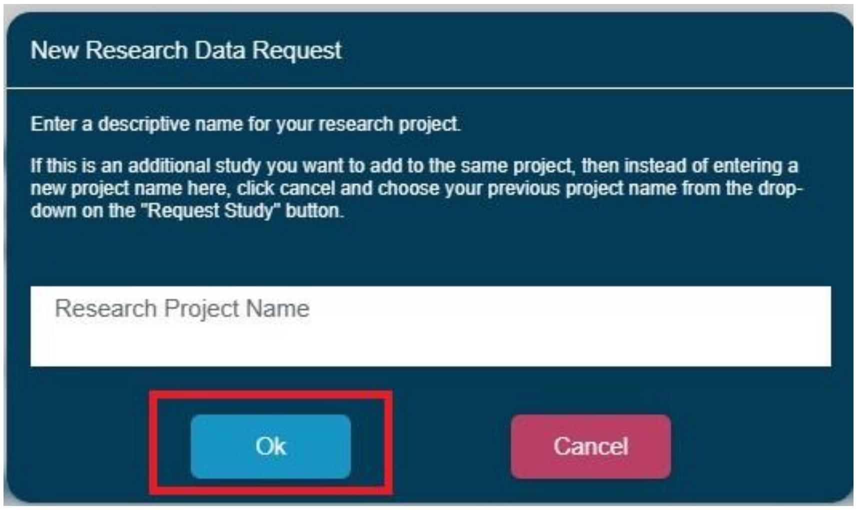
1. To add studies from a search to a Data Request Form, click on **Request Study.**



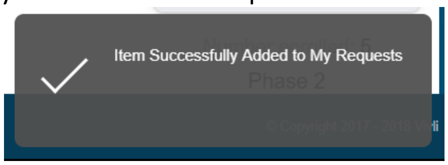
2. A dropdown will appear - click on +**Add New Request:**



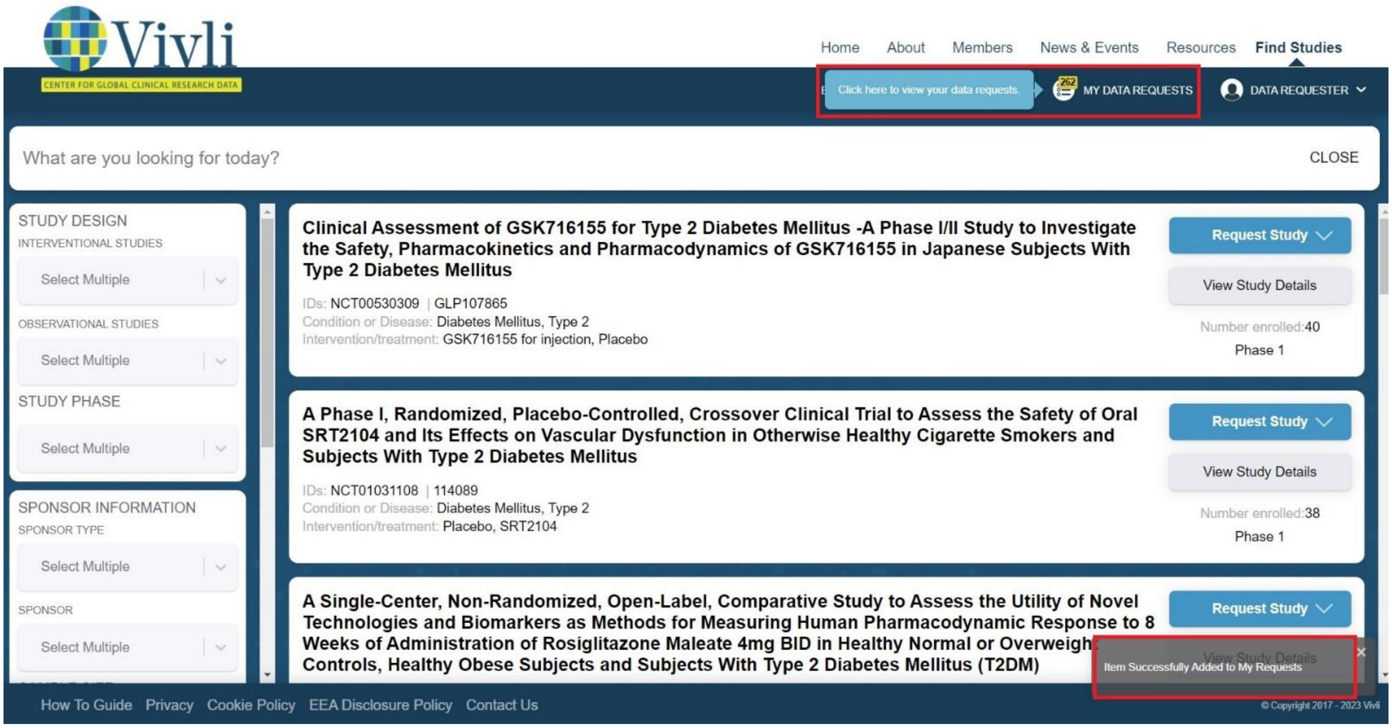
3. A dialogue box will pop up where you can provide the Project Name for your research project. **Note:** Your Project name must match the “Title of Proposed Research” within the data request form. This can be edited before submitting the data request for review. After entering a research project name,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


New Research Data Request
Enter a descriptive name for your research project.
If this is an additional study you want to add to the same project, then instead of entering a new project name here, click cancel and choose your previous project name from the drop-down on the "Request Study" button.
Research Project Name
Ok
Cancel

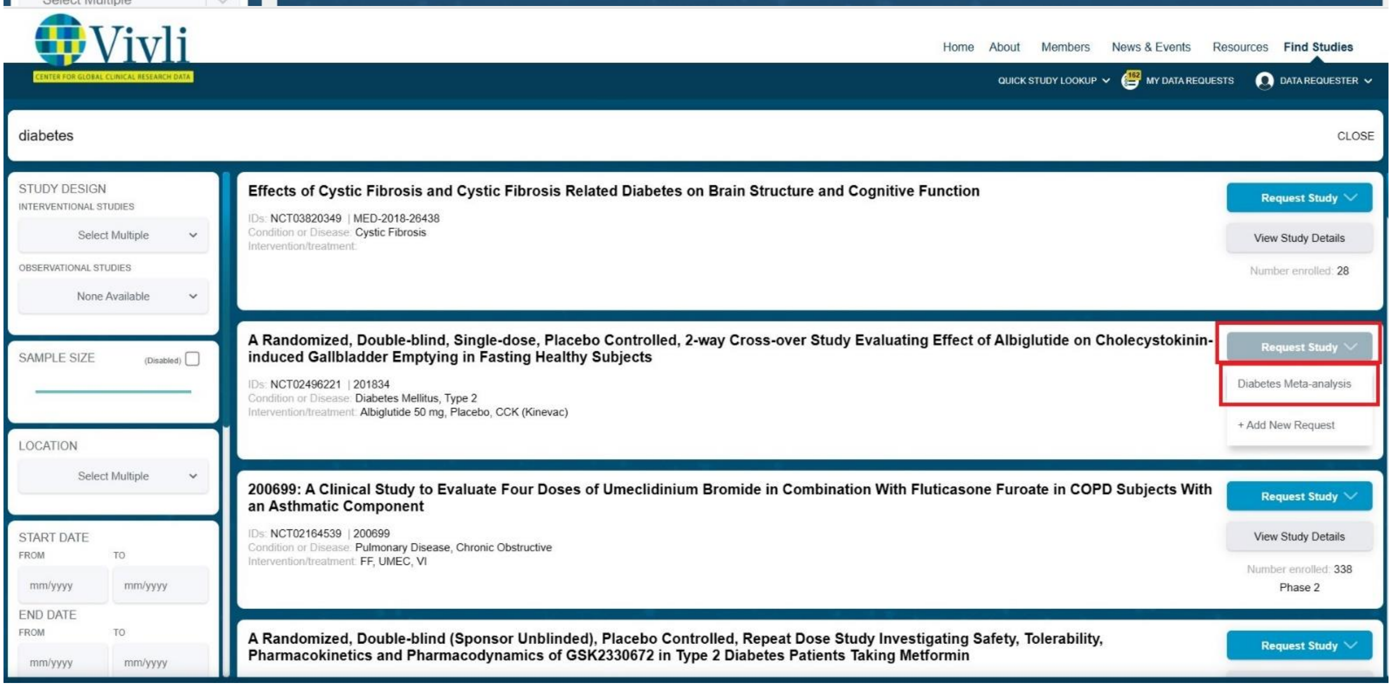
4. A pop-up will briefly appear at the bottom of the screen, indicating that you have successfully added the study to the new data request:



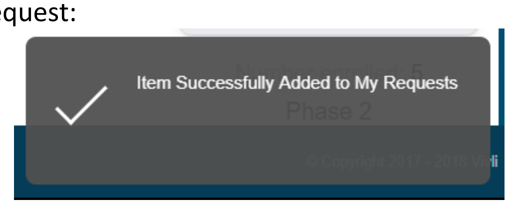
5. You will also get a notification that you may review **My Data Requests** to see the new request:



6. To add an additional 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, add them to the same request by repeating this step for each study you want to request.



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



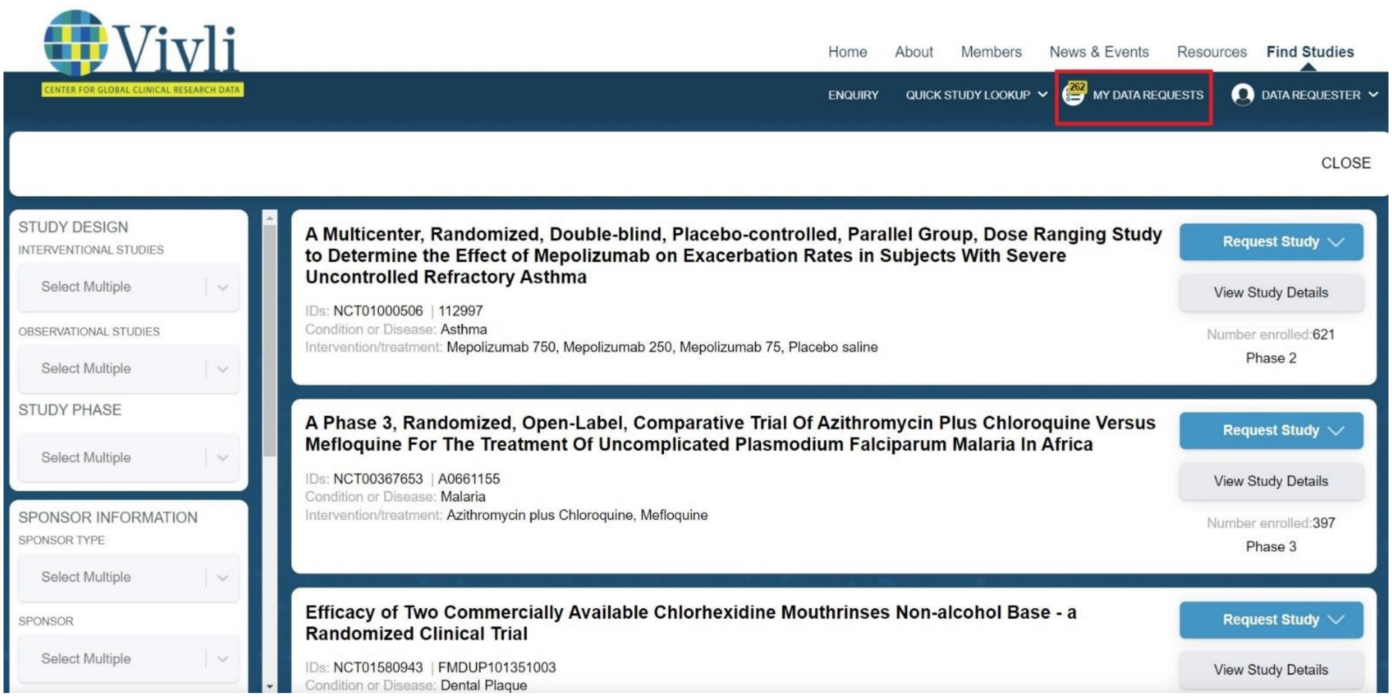
9. Once you have added all desired studies listed on the Vivli platform, you can complete the Data Request Form (See 2.0 Your Data Requests for more information).

1.4 Active Platform Accounts

1. As part of Vivli's security policy, for accounts to remain active on the platform, users must log in every six months.
2. If you have not logged in for more than six months, the Vivli team will email you asking that you log in to your account. The Vivli team cannot accept notifications via email to keep these accounts active. It will require you to log in every six months.
3. If this is not done within 10 business days, the account will be de-activated. If you want your account re-activated, you can email us at support@vivli.org and, we can re-activate your account at any time.

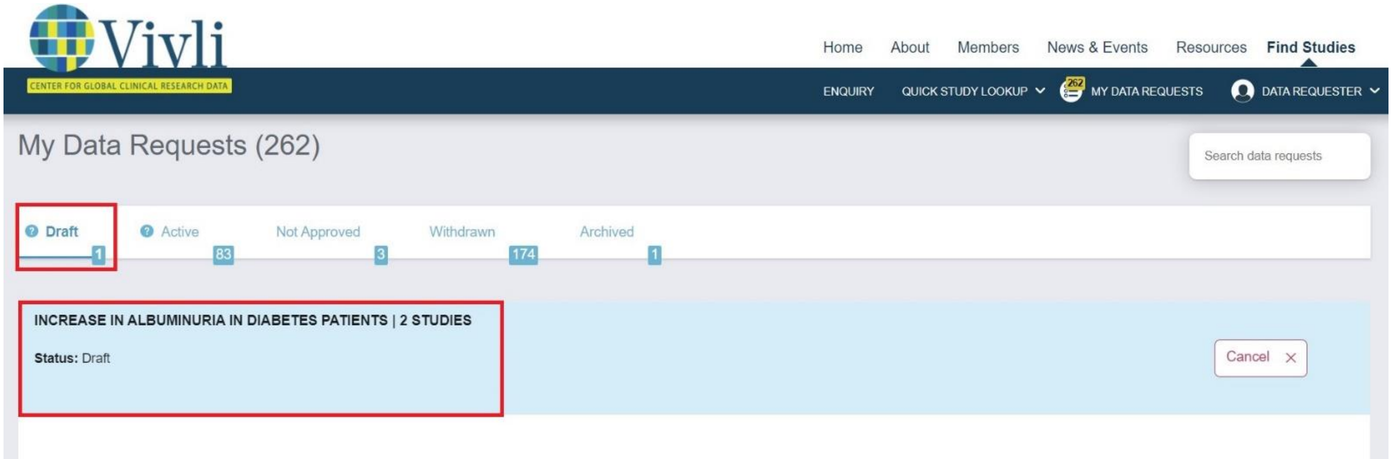
2.0 Your Data Requests

To find your data requests, click on **My Data Requests** in the top right corner of the screen:



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. For guidance on how to fill out the data request, please see Vivli [Data Request Form worksheet](#).

Click on **Draft** to see any incomplete or new data requests:

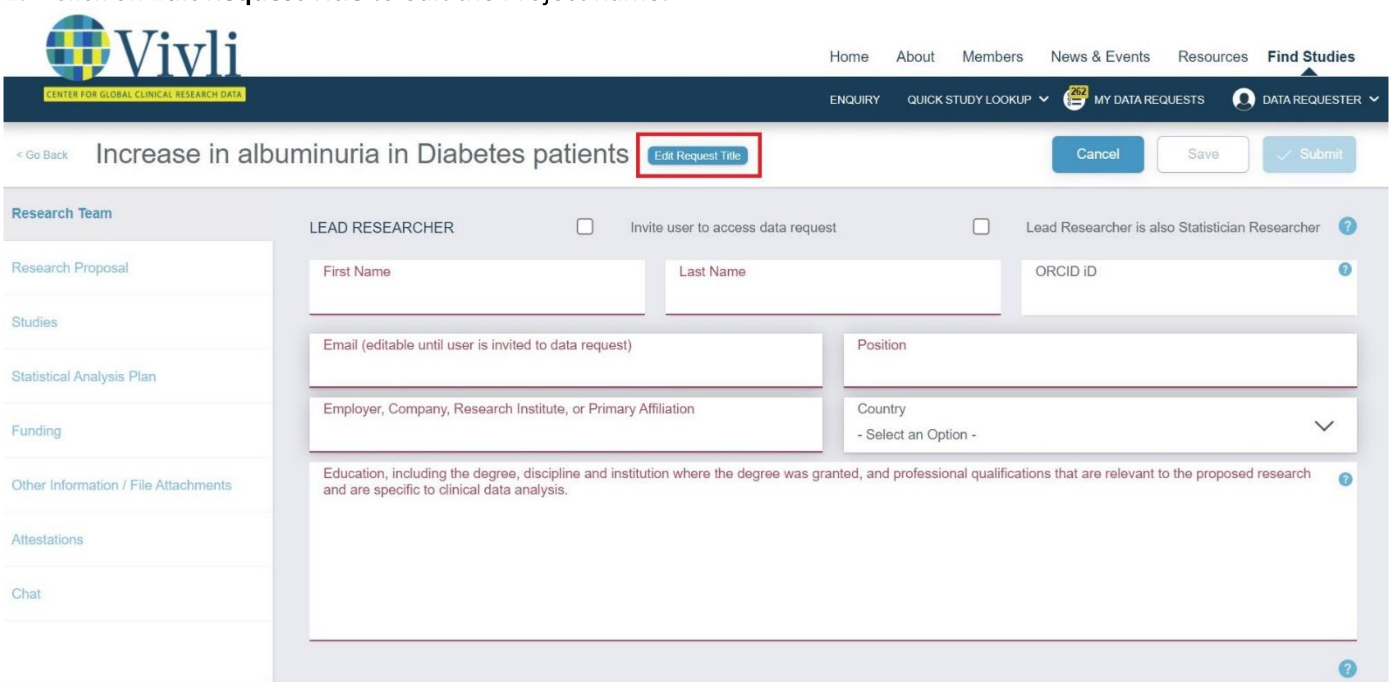


Click on the data request to open it.

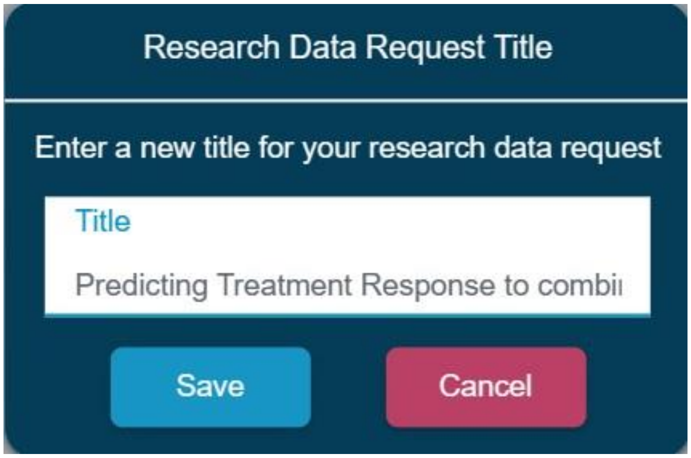
2.1 Editing a data request

You may edit the Project name of your data request as it will appear on the Data Request Form and Vivli Dashboard. The Project name of your data request should be the same as the “Title of Proposed Research” as it appears on the Data Request Form.

1. Click on **Edit Request Title** to edit the Project name**:**



2. The following dialogue box will pop up. Add a new title and then click **Ok**:

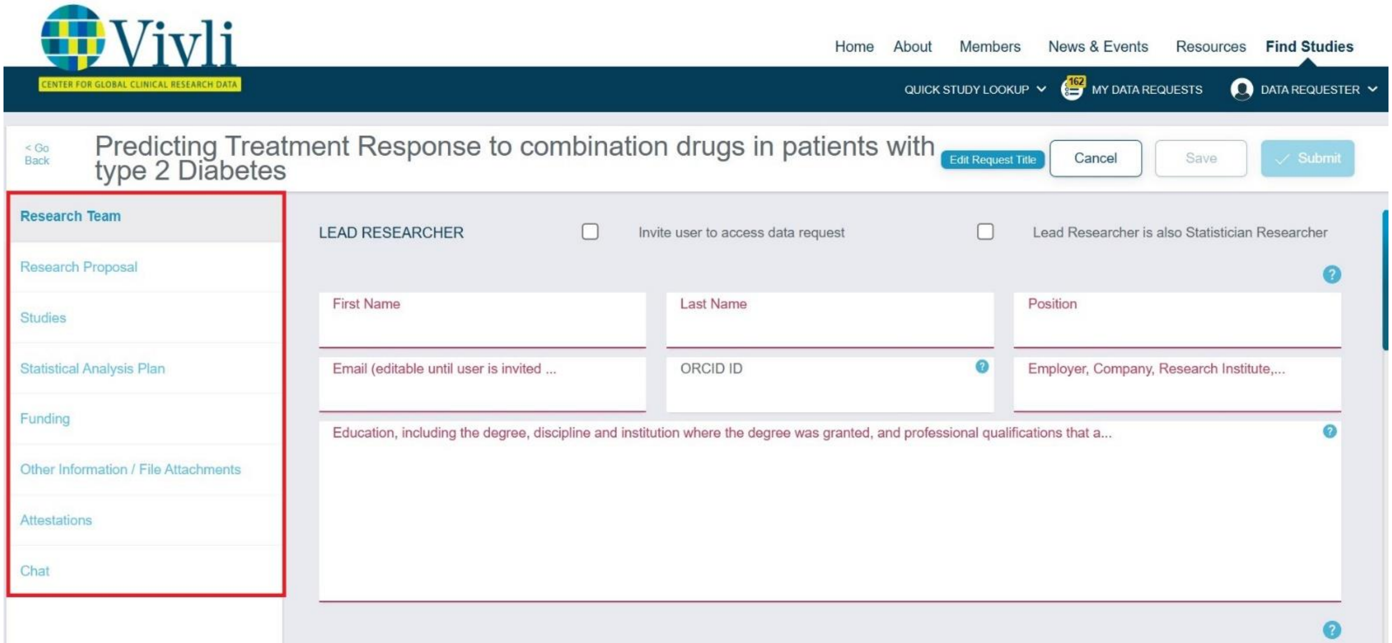


2.2 Completing a data request

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:

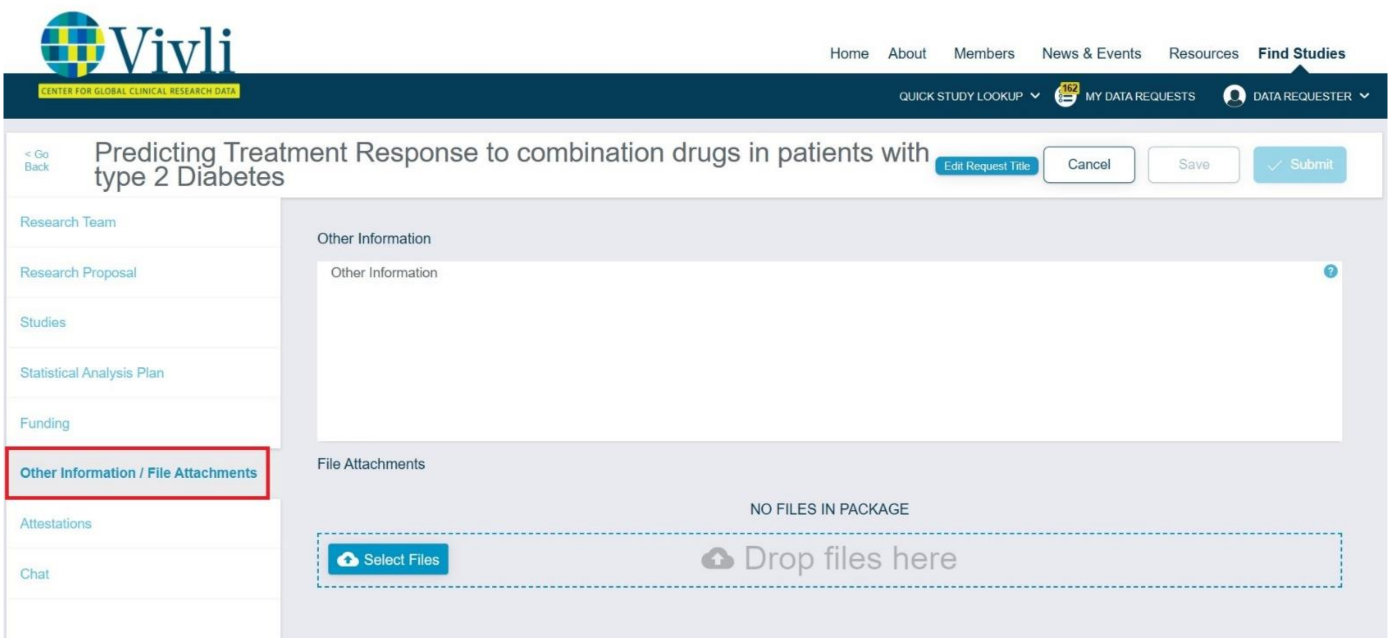
- The name, contact information, primary affiliation, country, qualifications, degrees and where the degrees were obtained of the all team members.
- Conflict of Interest Statement
- The title of the proposed research with a description of the study design (which should match the Project name)
- Narrative summary explaining the relevance of the project to science and public health
- Brief description, Main outcomes of interest, specific aims and objectives and hypothesis to be evaluated
-
- 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 or Portals; and any additional data, tools, and scripts 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 4.0, Requesting data from studies not listed on Vivli, but available for provisioning into the Secure Research Environment.

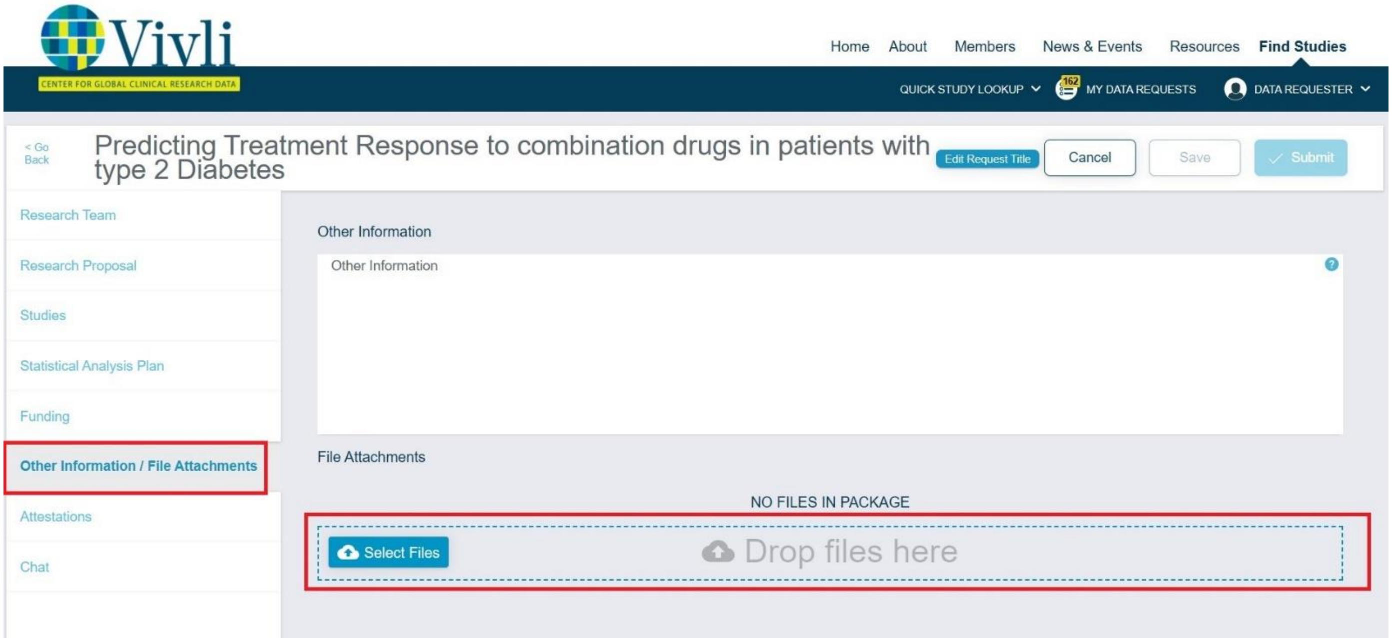


2.2.1 Adding Files or Other Information to your data request

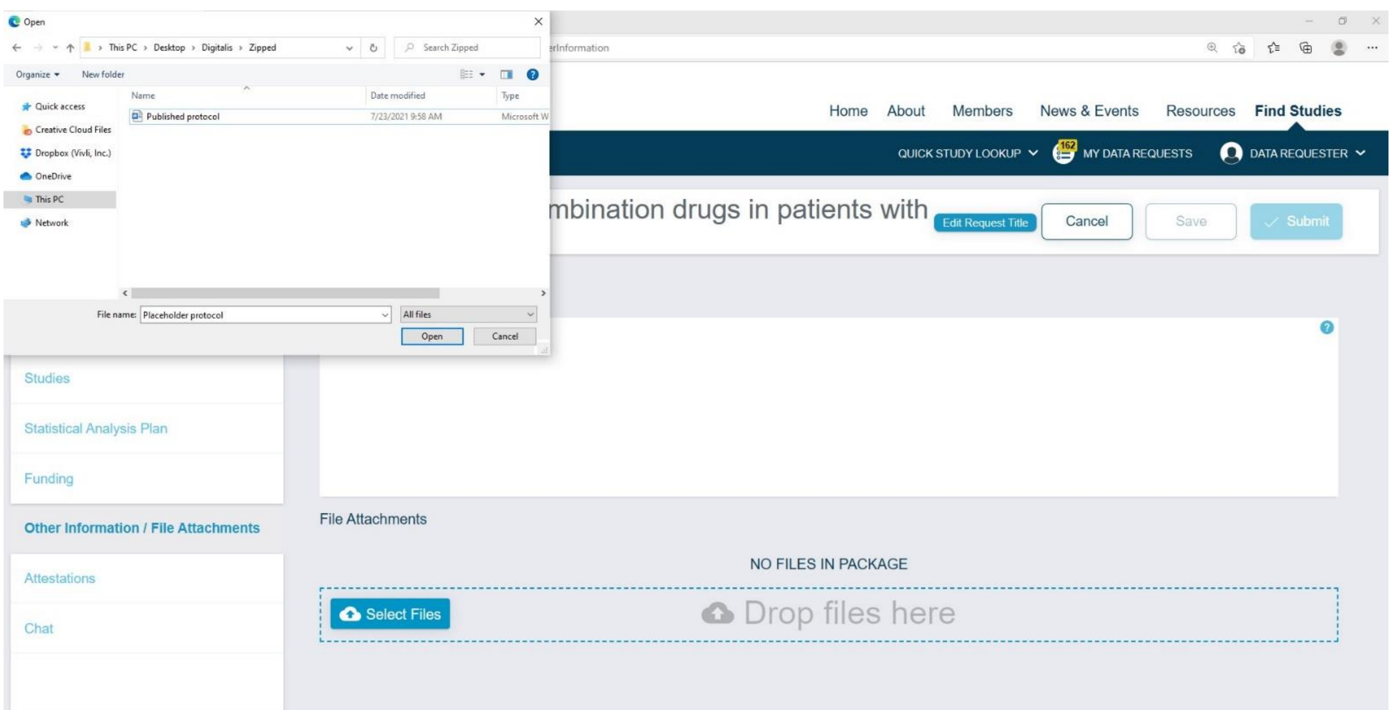
You may also attach files to your data request using the **Other Information/File Attachments** tab:



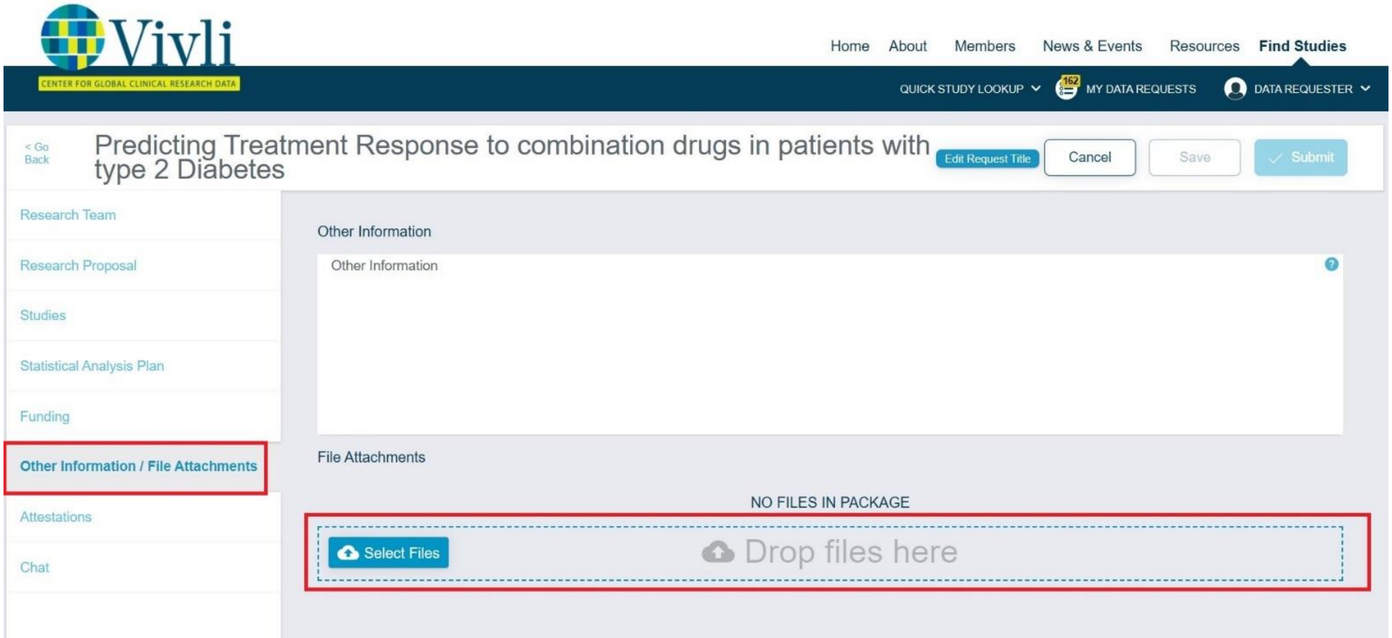
1. Click on **Select Files** to choose a file:



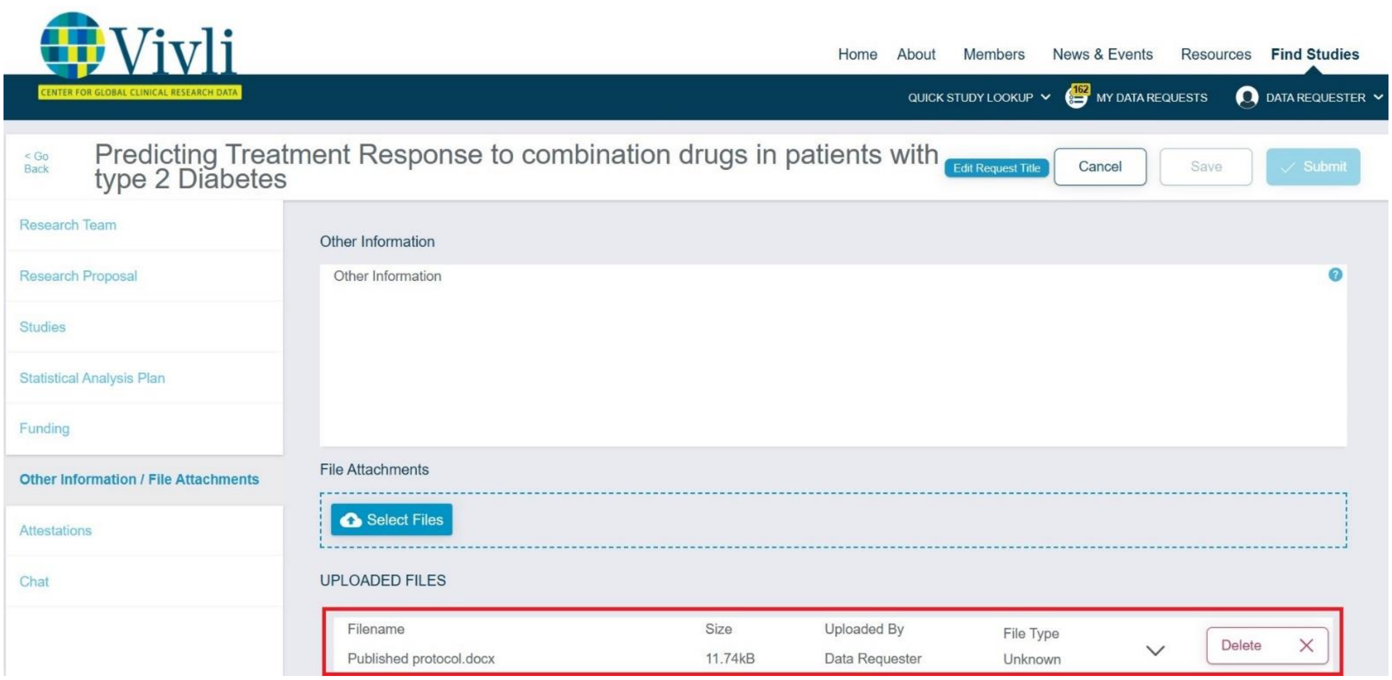
2. Then simply select the file from your computer:



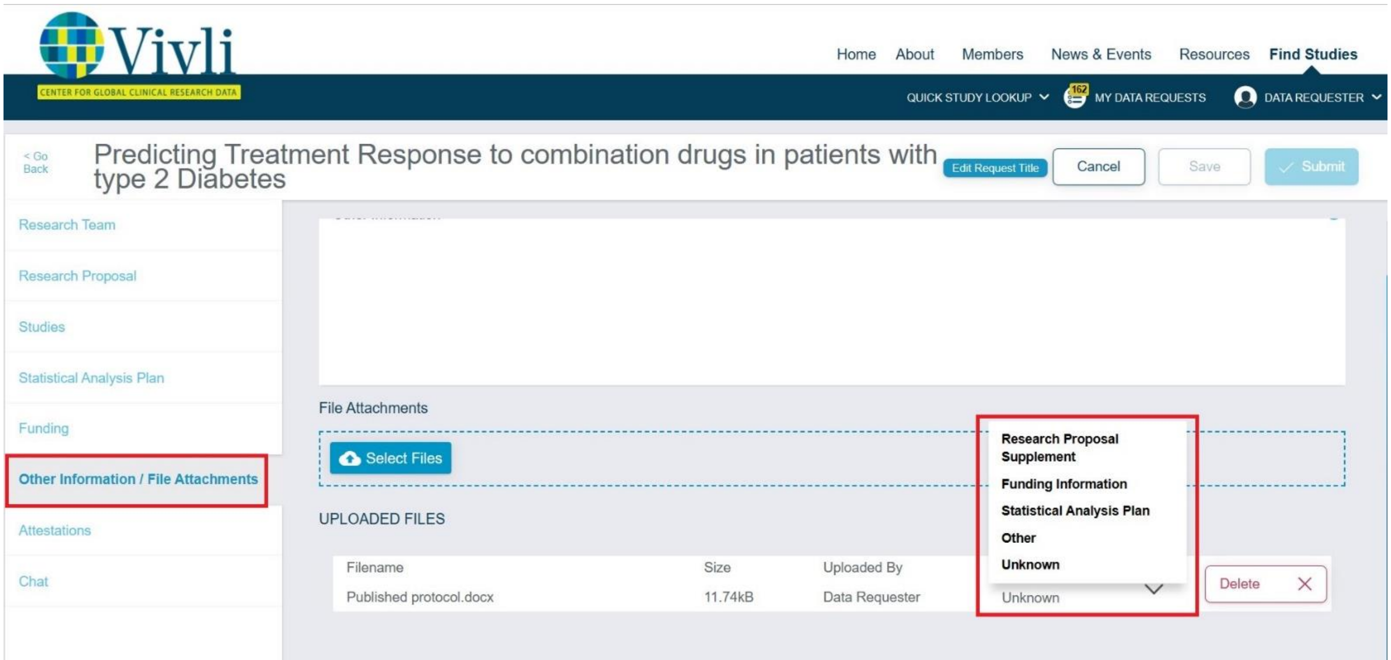
3. You may also drag and drop files into the '**Drop files here'** box:



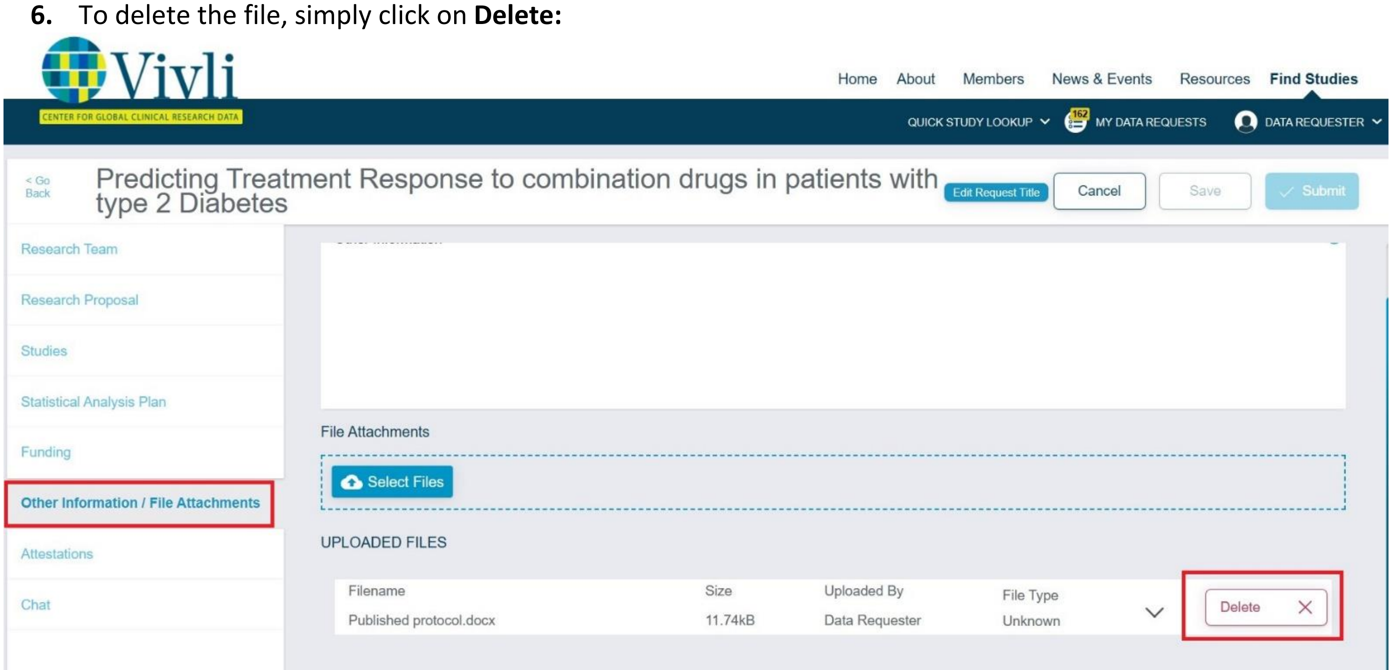
4. Your uploaded files will appear under **Uploaded files**:



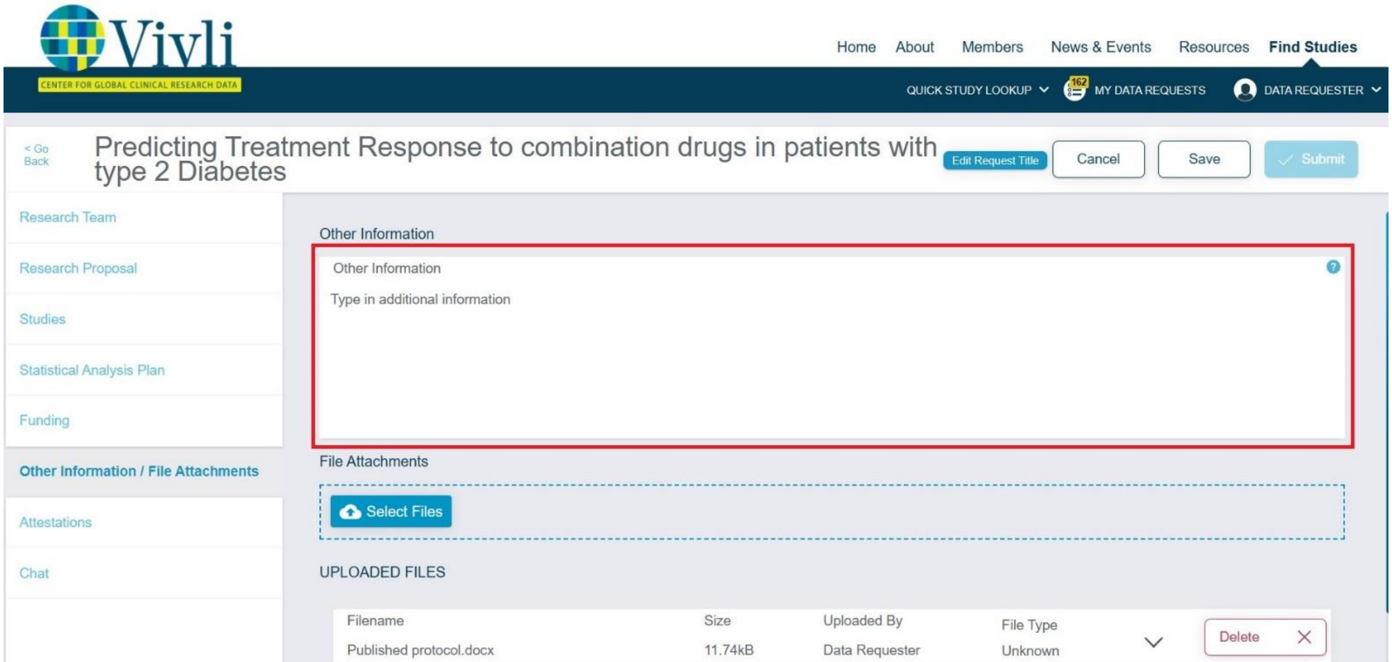
5. You can select the file type from the dropdown menu after upload is complete:



6. To delete the file, simply click on **Delete:**



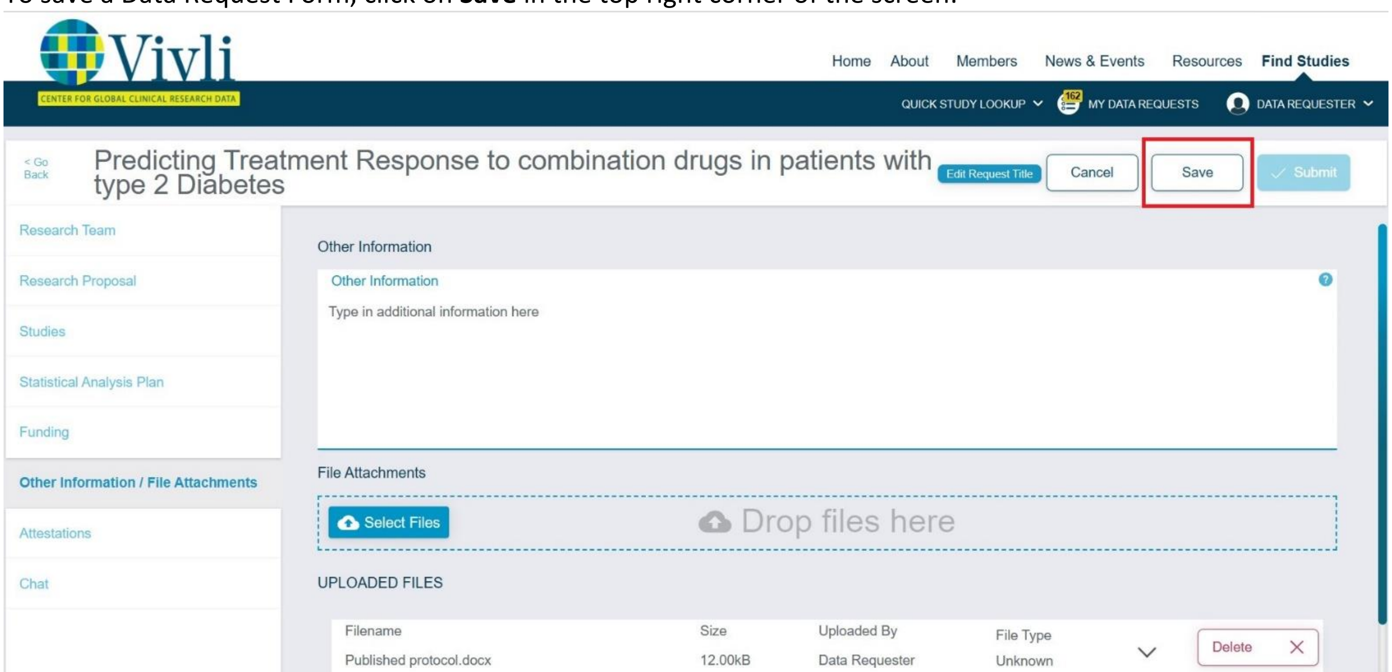
7. To enter any other information, simply type into the dialogue box:



2.3 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.

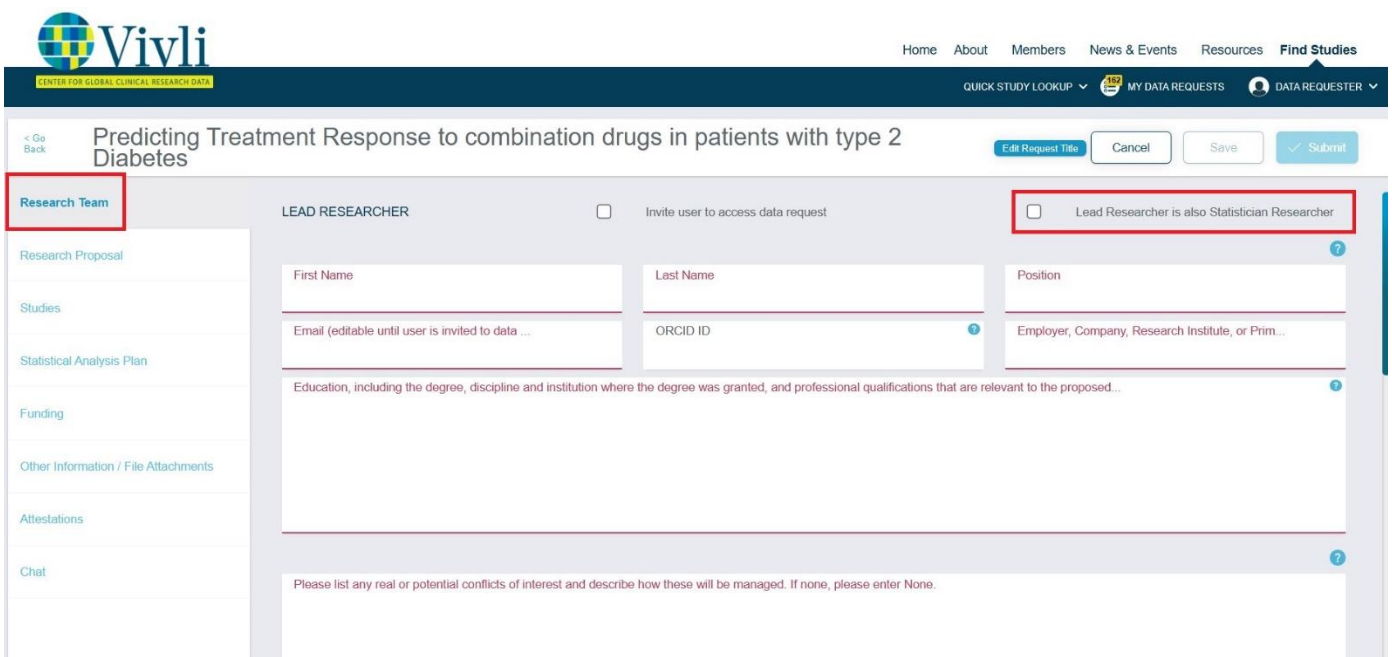
To save a Data Request Form, click on **Save** in the top right corner of the screen:



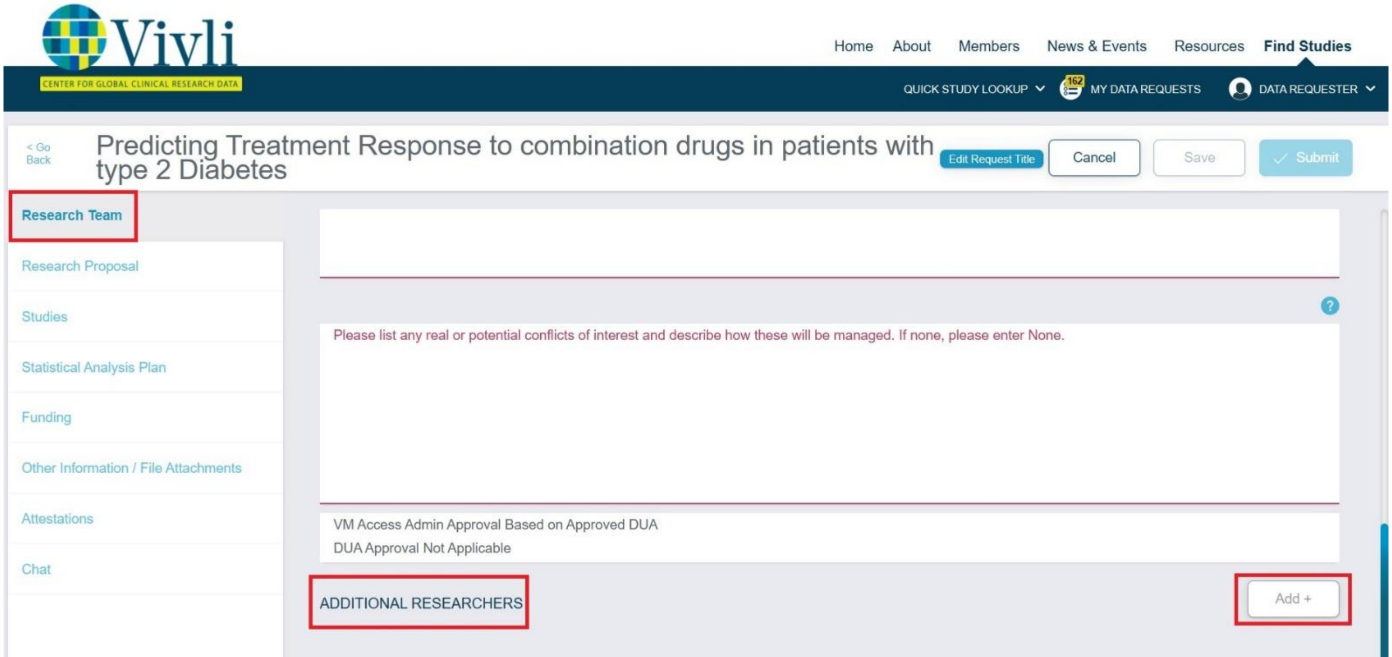
2.4 Adding Research Team Members

- Individuals added to a data request will be able to view and edit the Data Request Form
- Individuals added to a request and if the Data Use Agreement (DUA) covers the individual, they will have access to the Secure Research Environment
- These permissions can also be changed before starting the research environment and while the research environment is running.
- If you would like to make changes to the Research team members including the Lead Investigator or Lead Statistician during the review process, please reach out to the Vivli team via platform chat. Please note that according to Vivli policy, any changes to the Lead Investigator, 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.
- If your team member is from a different institution than the Lead Investigator and they would like to access the data, they will need have a DUA in place from their institution before accessing the data.
- Here are the steps to add a new research team member:
  1. Please ask the research team member to "sign up" for a Vivli account. They can follow Section 2.0 of the Vivli User Account Quick Start guide
  2. Please add the research team member to your data request but don't check the checkbox "Invite user to access data request" yet and just save it.
  3. Once the research team member signs up for an account, then you can check the checkbox "Invite user to access data request".
  4. Your team member will get an email notification and can follow the instructions in the email and select "Existing Account" and login using their username and password. Please see Section 2.1 of the Vivli User Account Quick Start guide

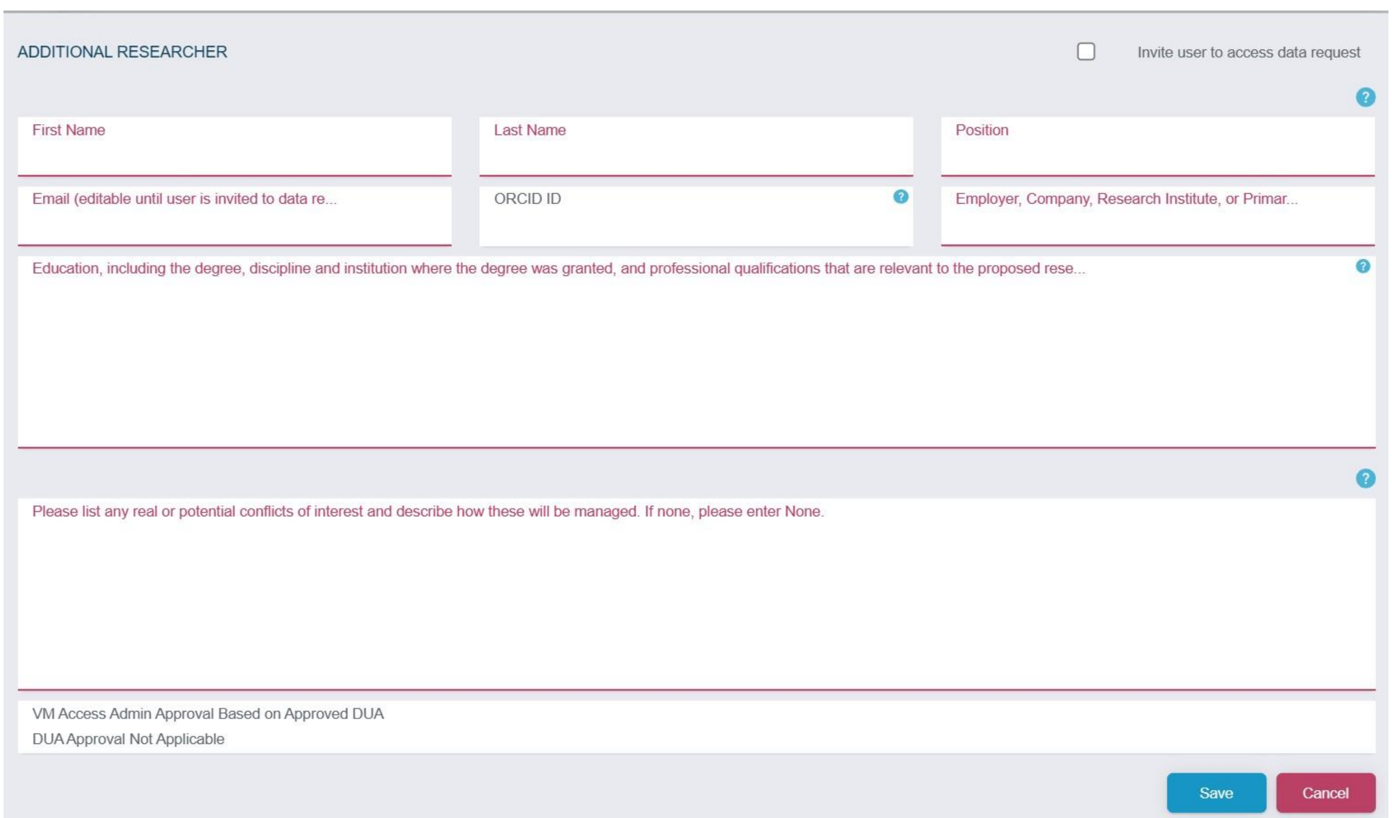
1. If the Lead Investigator is also Statistician Researcher, select the checkbox as shown below



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

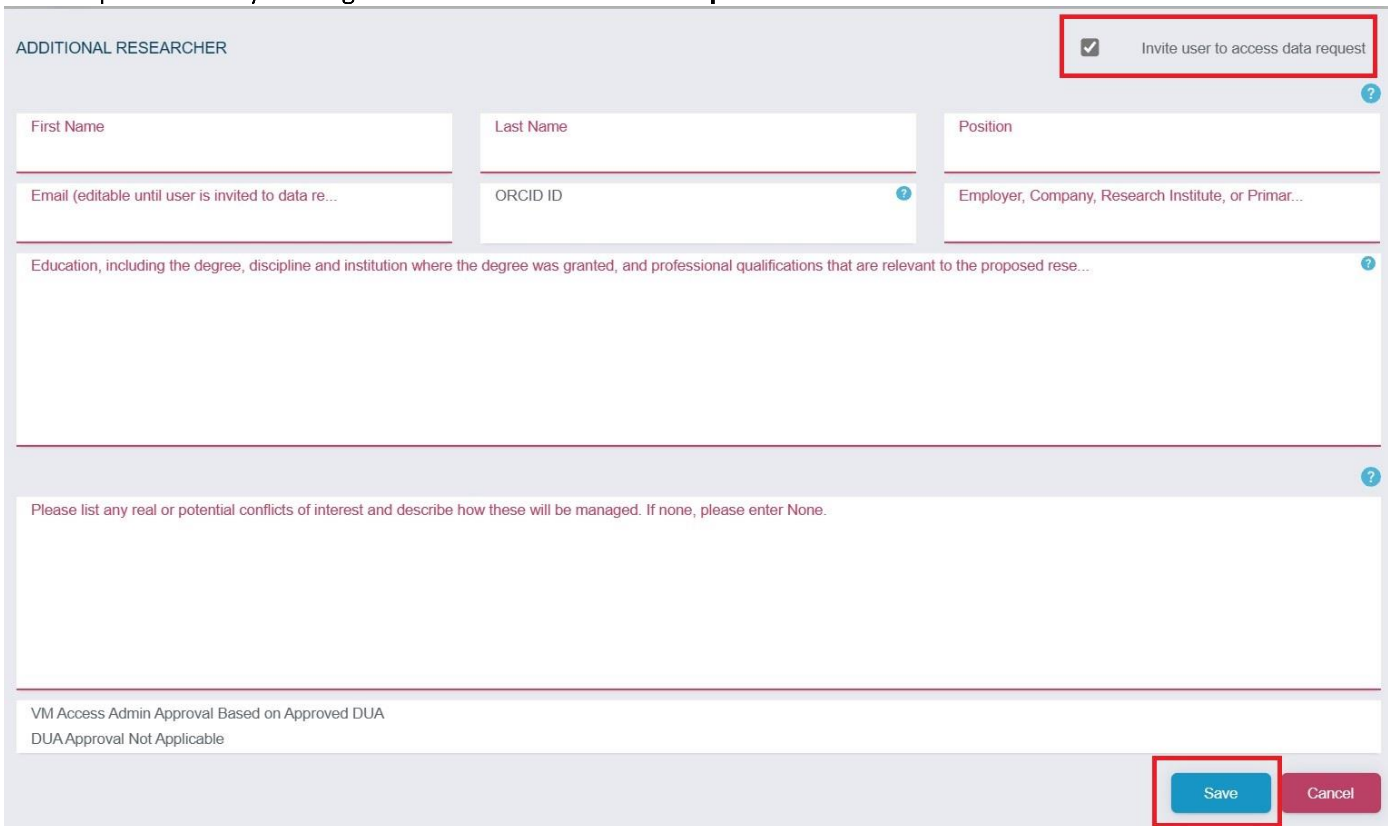


3. The following dialogue box will appear:



4. Complete all fields, and click 

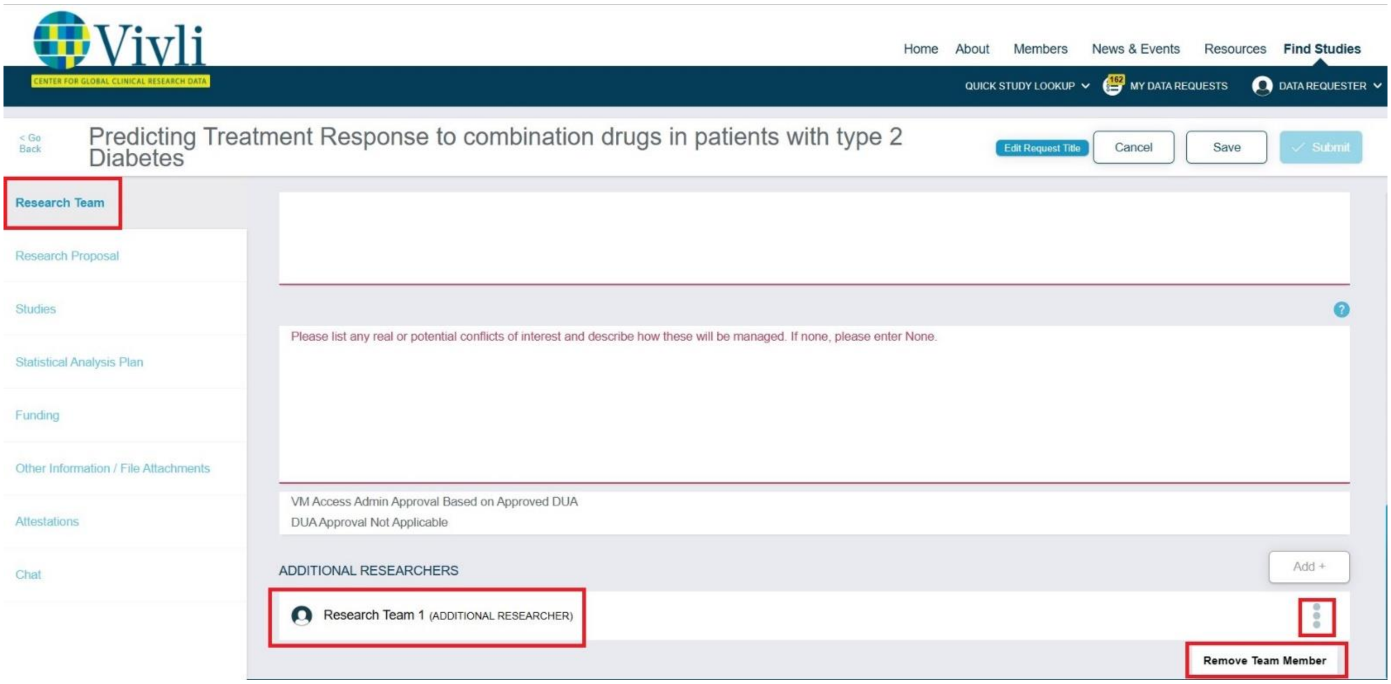
5. Once the Research team members have created their Vivli account, you can invite them to access the Data Request Form by clicking **Invite user to access data request** and then click **Save:**



2.5 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 on the three vertical dots in the lower right-hand corner and select **Remove Team member**:

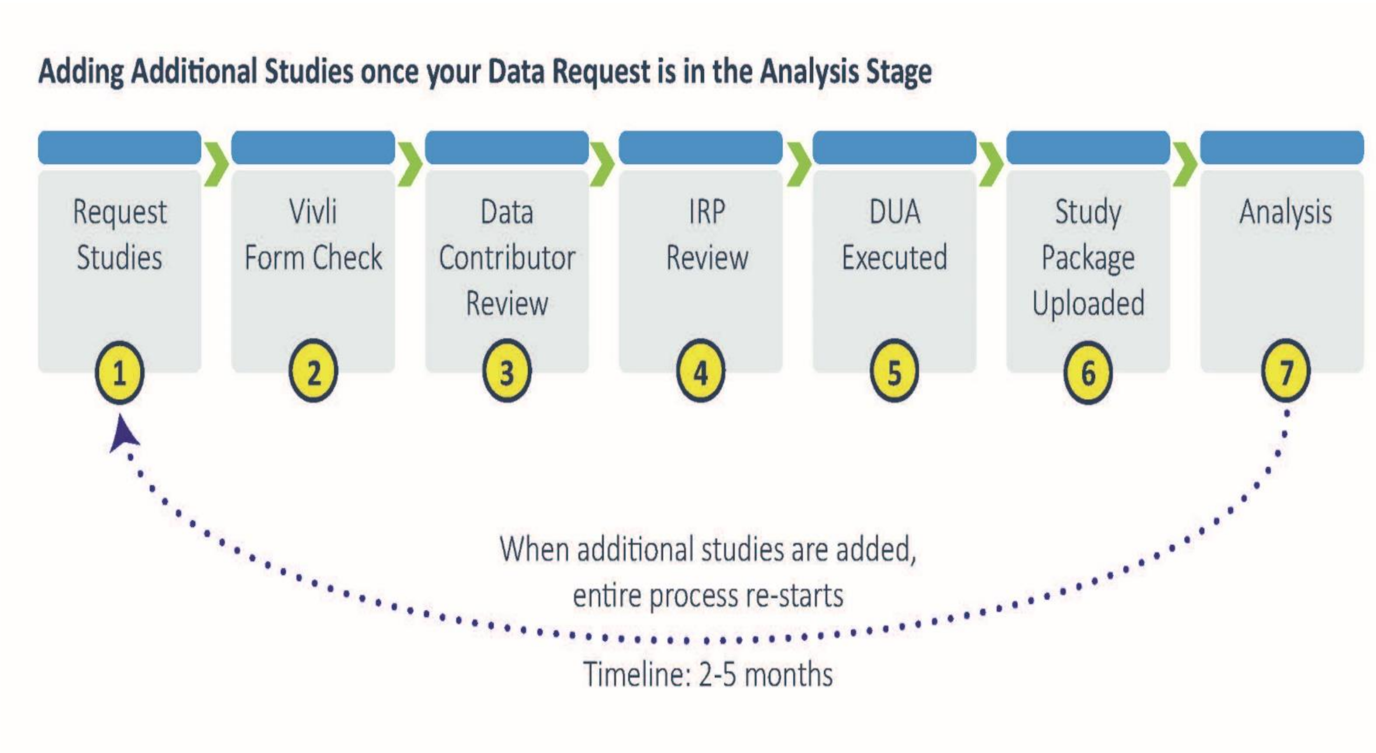


3. The following pop-up will appear:

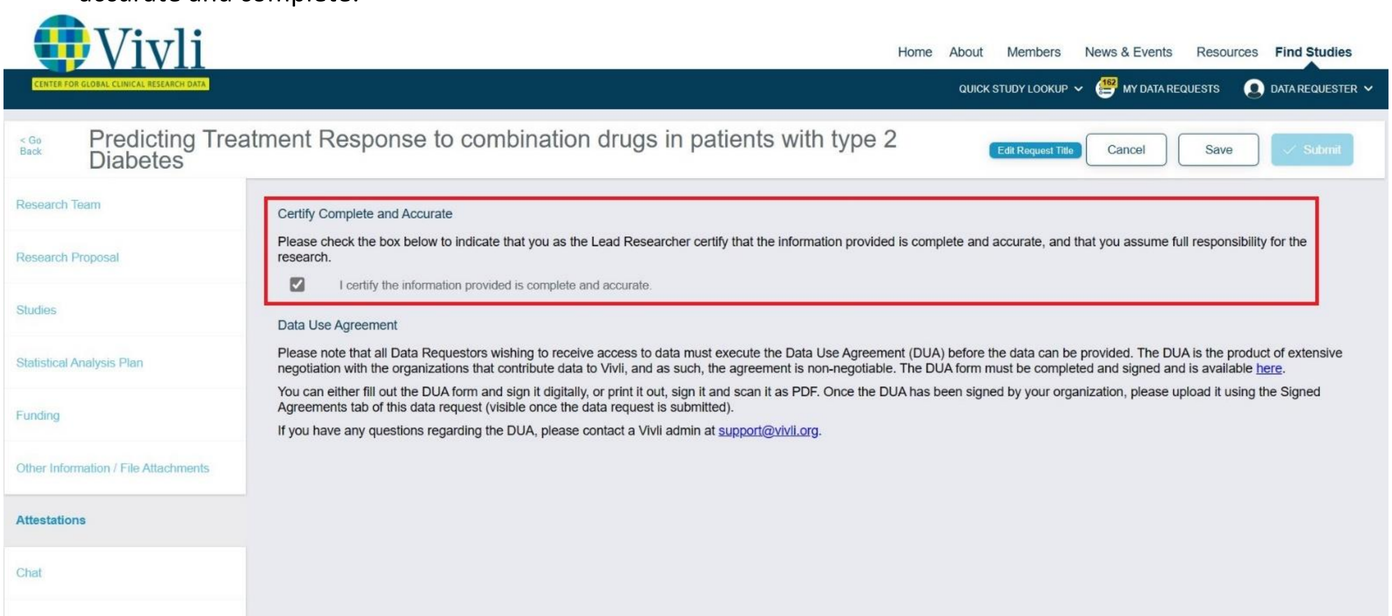
4. Click on **Ok** to remove the team member.

2.6 Submitting your data request

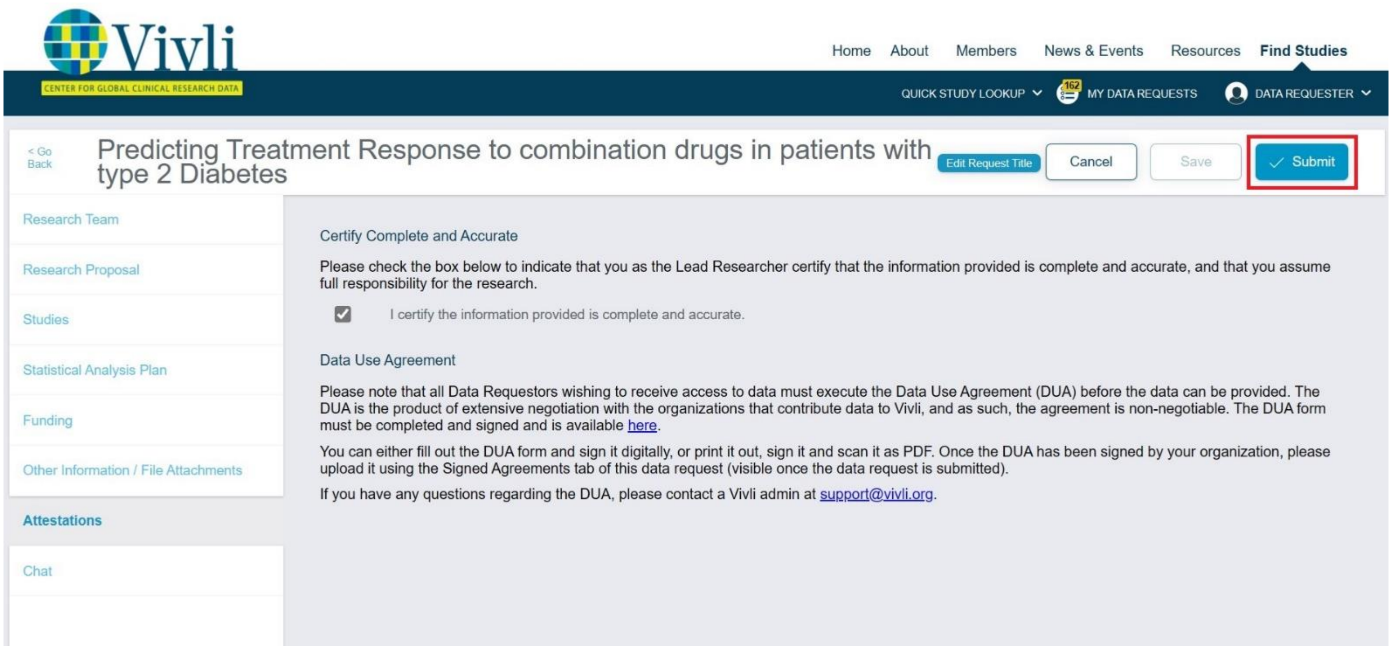
1. Once the Data Request Form is complete, you may submit it for review.
2. Do not submit a form before it is complete, as you will be unable to make changes once it has been submitted.
3. Please make sure that you have added all the desired studies to your data request as adding it later will lead to additional delays
4. Please note that according to Vivli policy, any changes to the Lead Investigator, 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.



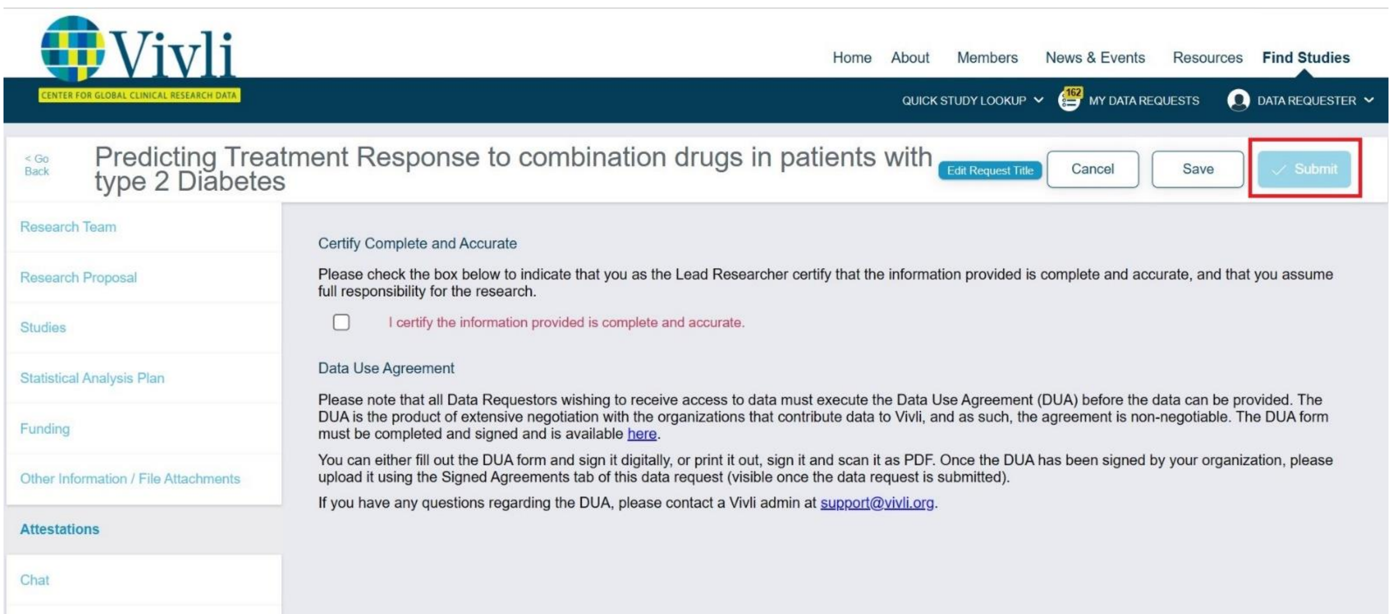
5. Before submitting a Data Request Form, the Lead Researcher must attest that all the information provided is accurate and complete:



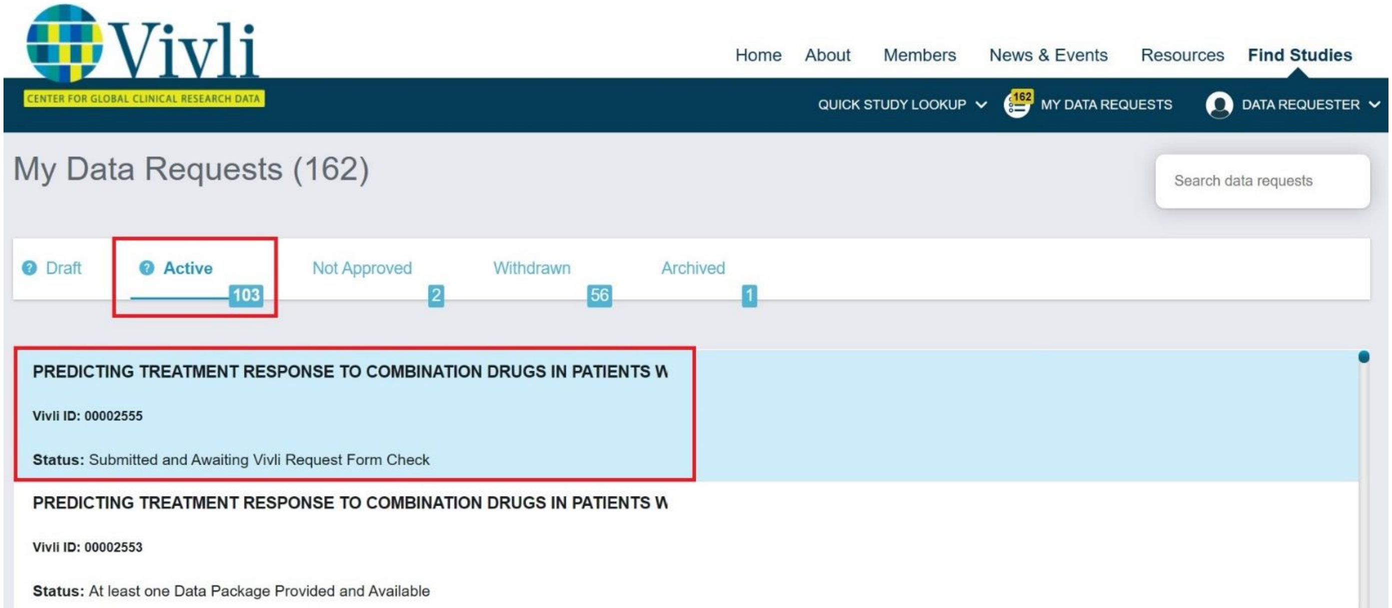
6. To submit a Data Request Form, simply click the blue box marked **Submit** in the top right corner of the screen:



7. 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 outlined in red 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).

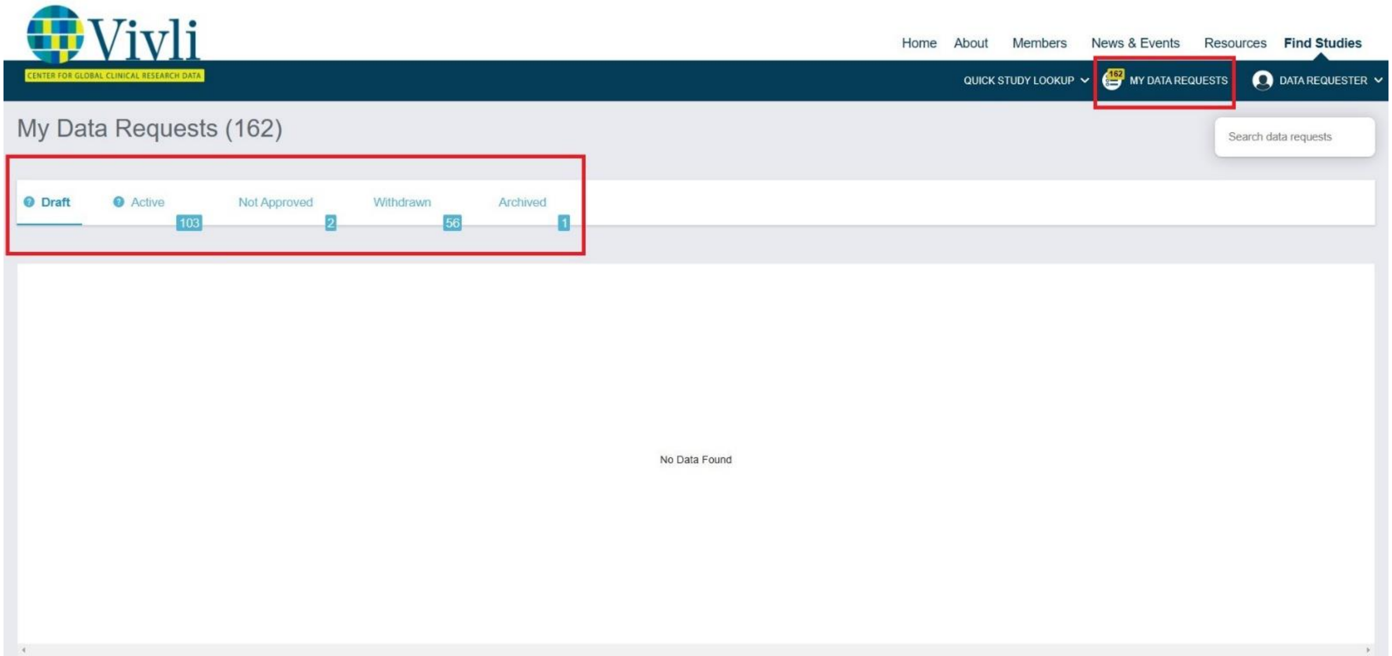


8. Once you click submit, the data request will now appear under **Active** in your Data Request Status bar:



9. The status bar contains 5 sections:

Drafts: 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 denied. 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 provided



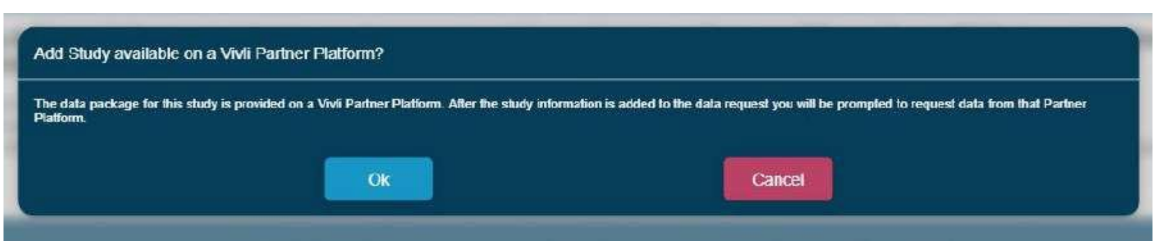
3.0 Requesting Vivli-listed studies provisioned by external providers

3.1 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.

3.2 Requesting studies provisioned by external providers

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



2. Click on **OK** to add the study to the Data Request Form:

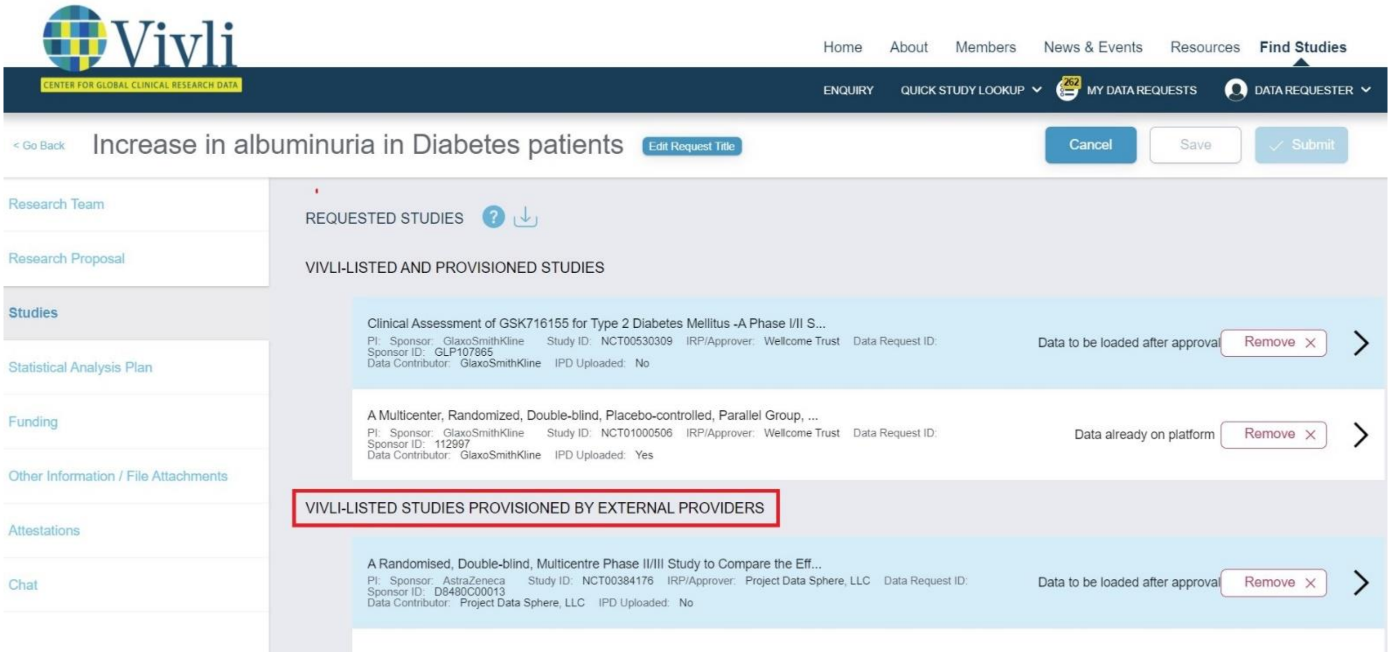
4. The following pop-up will appear:

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.

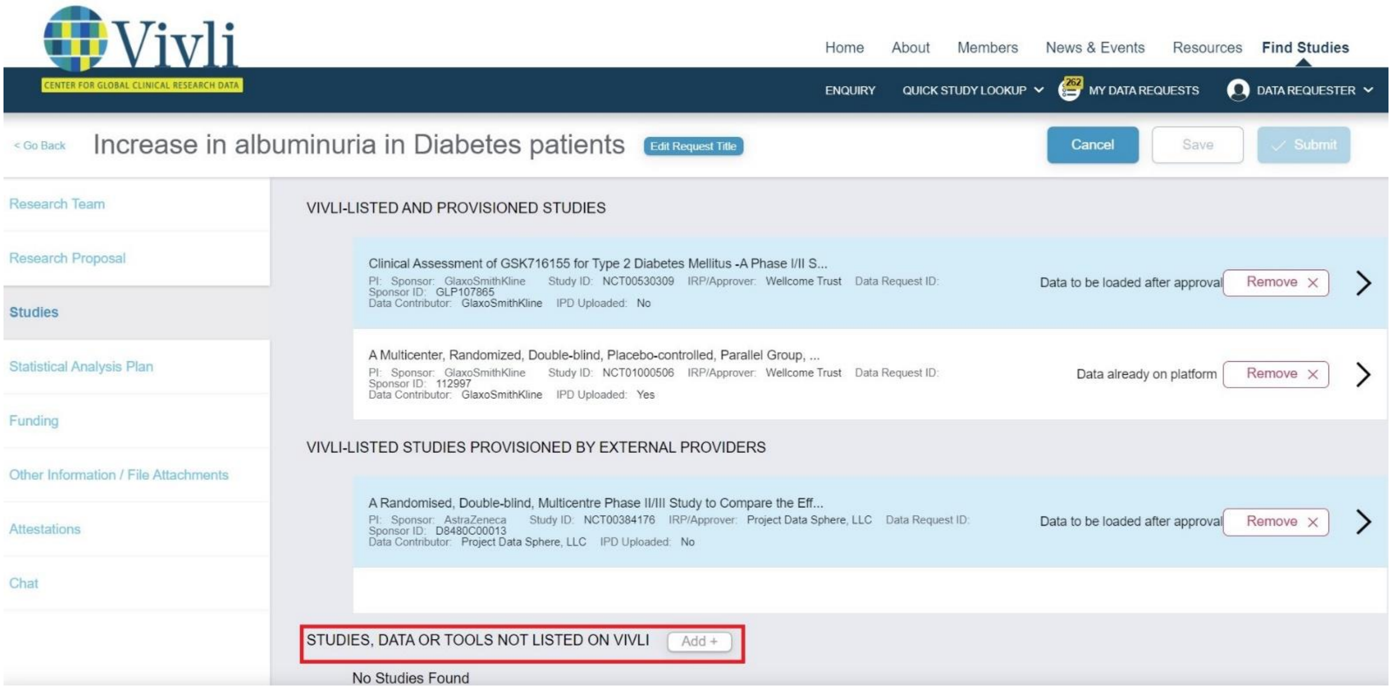
7. When you review the studies tab on your Data Request Form, the study will be categorized as **Vivli-Listed Studies Provisioned by External Providers:**



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.

4.0 Requesting data from studies not listed on Vivli, but available for provisioning into the Secure Research Environment

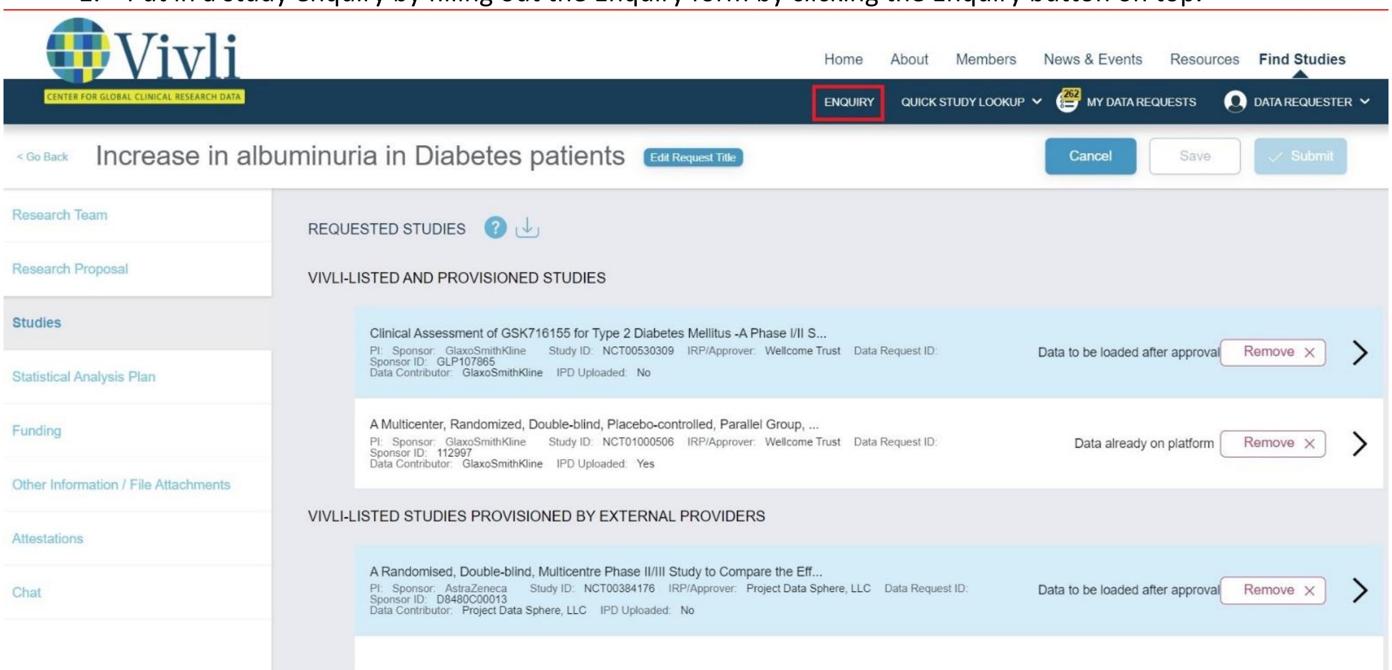
- You may add Vivli Member studies to your data request, even if they are not listed on the Vivli platform as some Vivli members do not list all available studies.
- Such studies will be designated on your Vivli Data Request Form as **STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI**.



4.1 Process Overview

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

1. Put in a study enquiry by filling out the Enquiry form by clicking the Enquiry button on top.

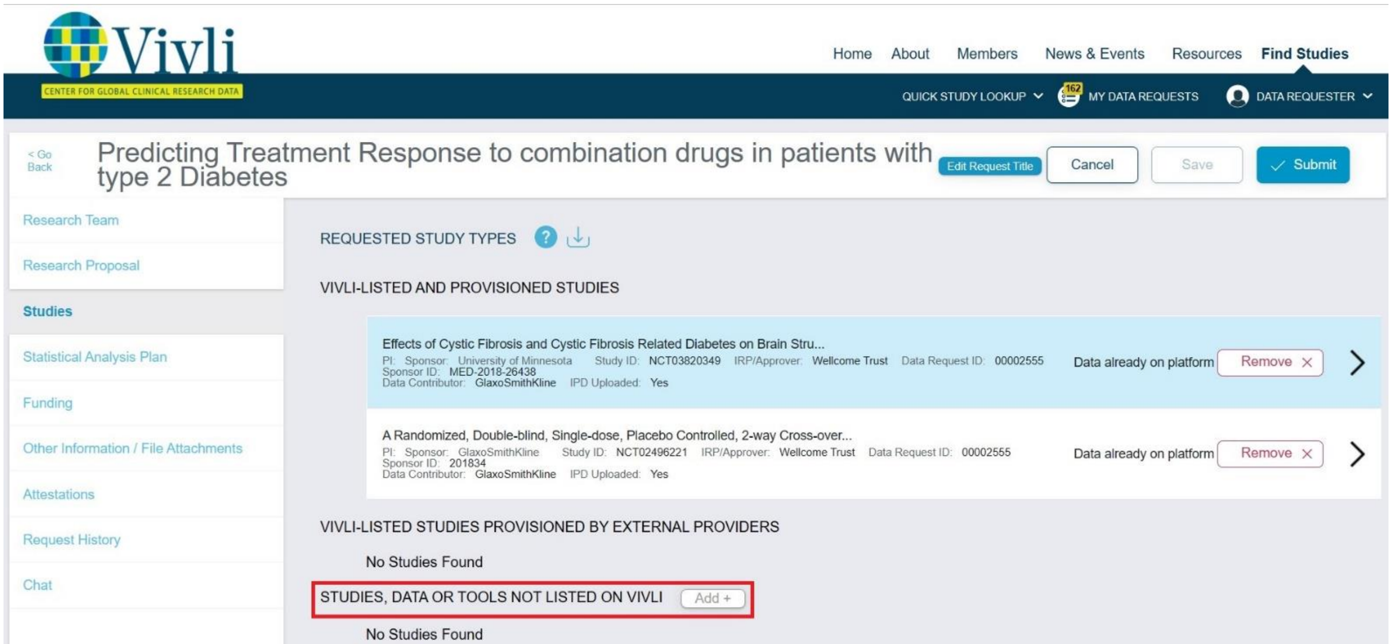


2. If the enquiry is approved and study is available for sharing, complete the Vivli Data Request Form for all studies to be analyzed on Vivli and add in the study.
3. After all Data Contributors have approved your request, all the data packages will be provisioned into your secure research environment.
4. Note: ***Do not submit*** a data request before all enquiries have been resolved as this will cause delays.

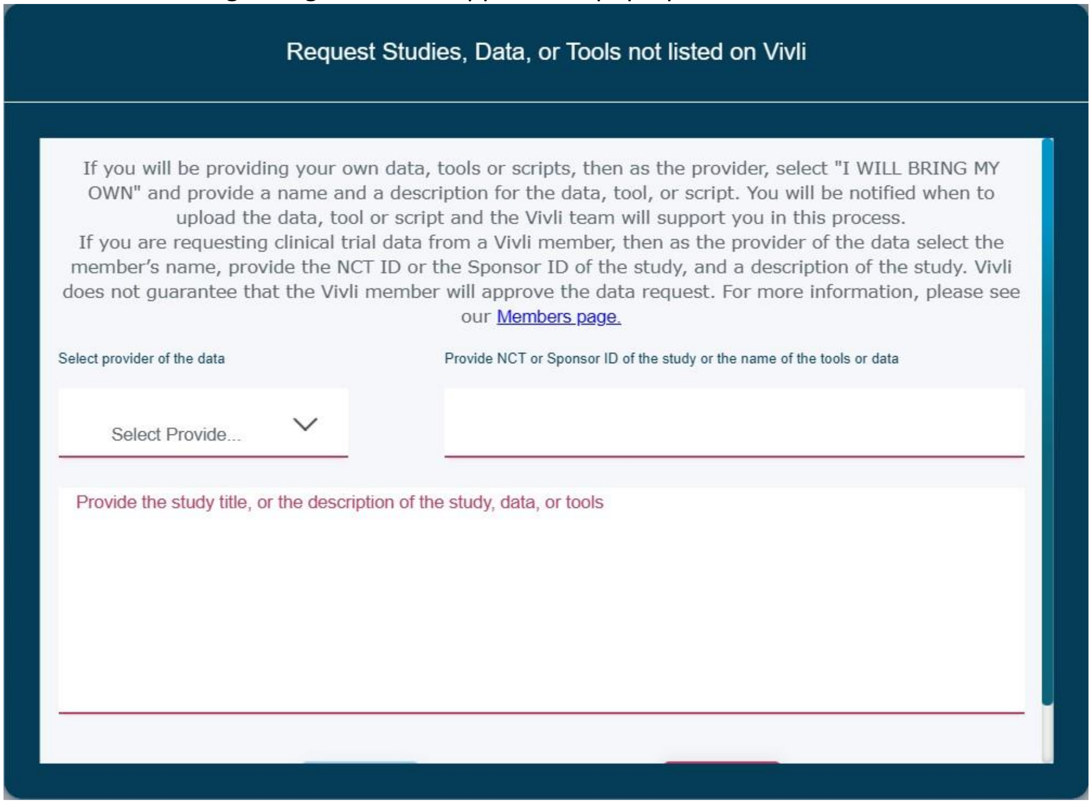
4.2 Steps for requesting data from studies provisioned on Vivli but not listed on Vivli

1. To add the study to a Vivli Data Request Form, first open data requests by clicking on **My Data Requests** in the top right-hand corner of the browser:

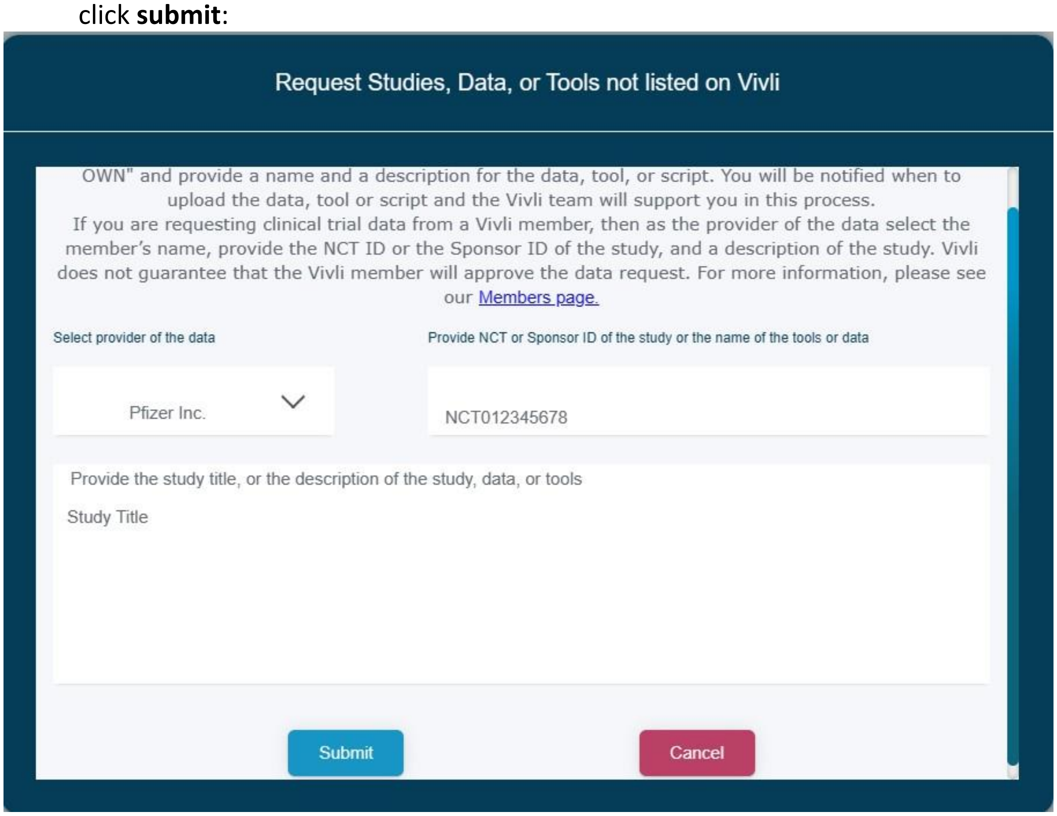
2. Next, open the data request to add the external study. Then, scroll down and click on **Add+** adjacent to **STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI**, in the bottom corner of the screen:



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

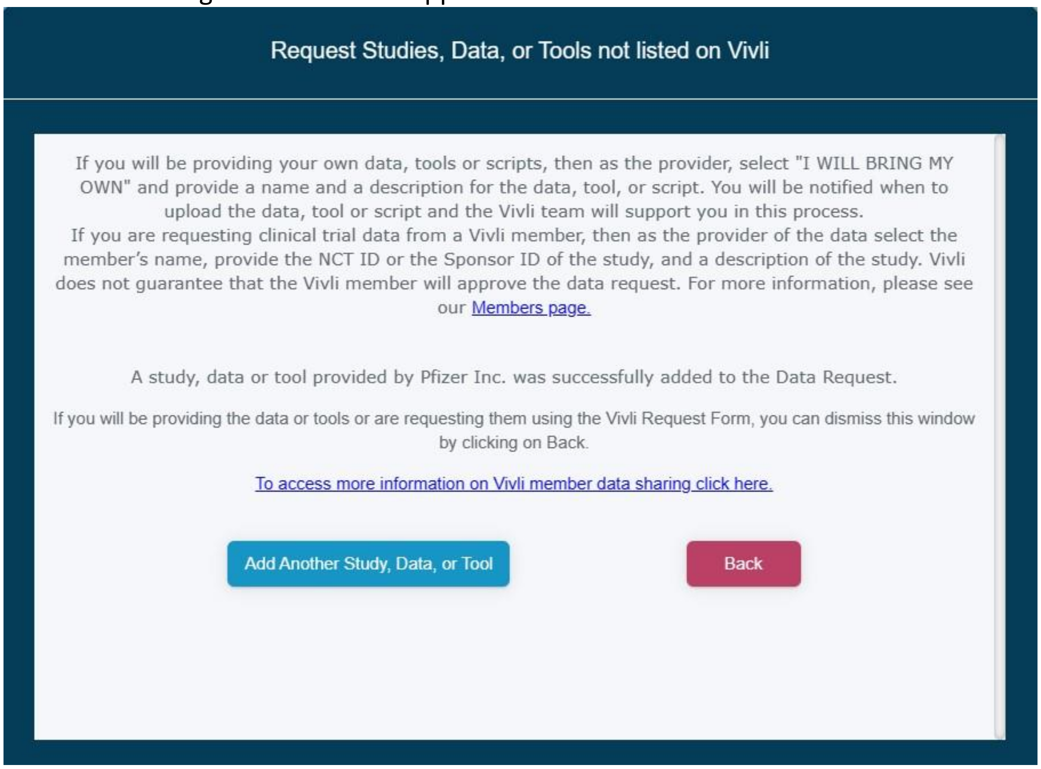


4. Complete all fields, including selection of the Provider of the data from a dropdown menu and then click **submit**:

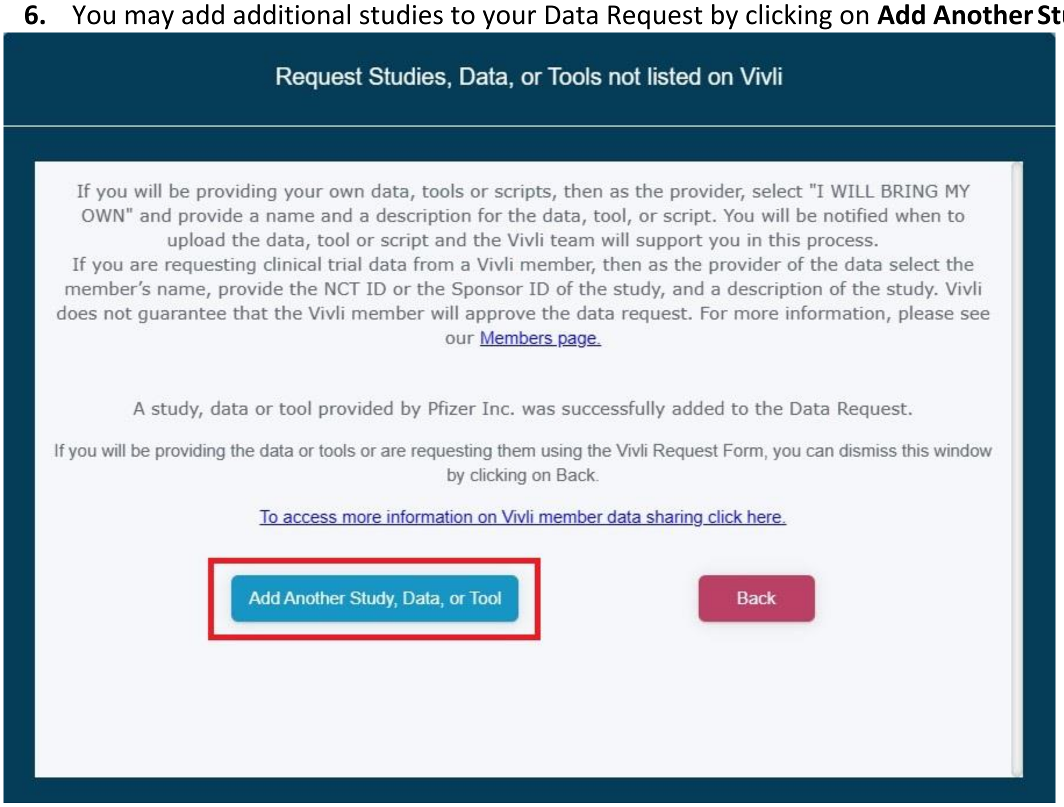


Note: Please add only one study in the dialogue box. If you wish to add additional studies, please complete this process, and repeat it for the additional studies.

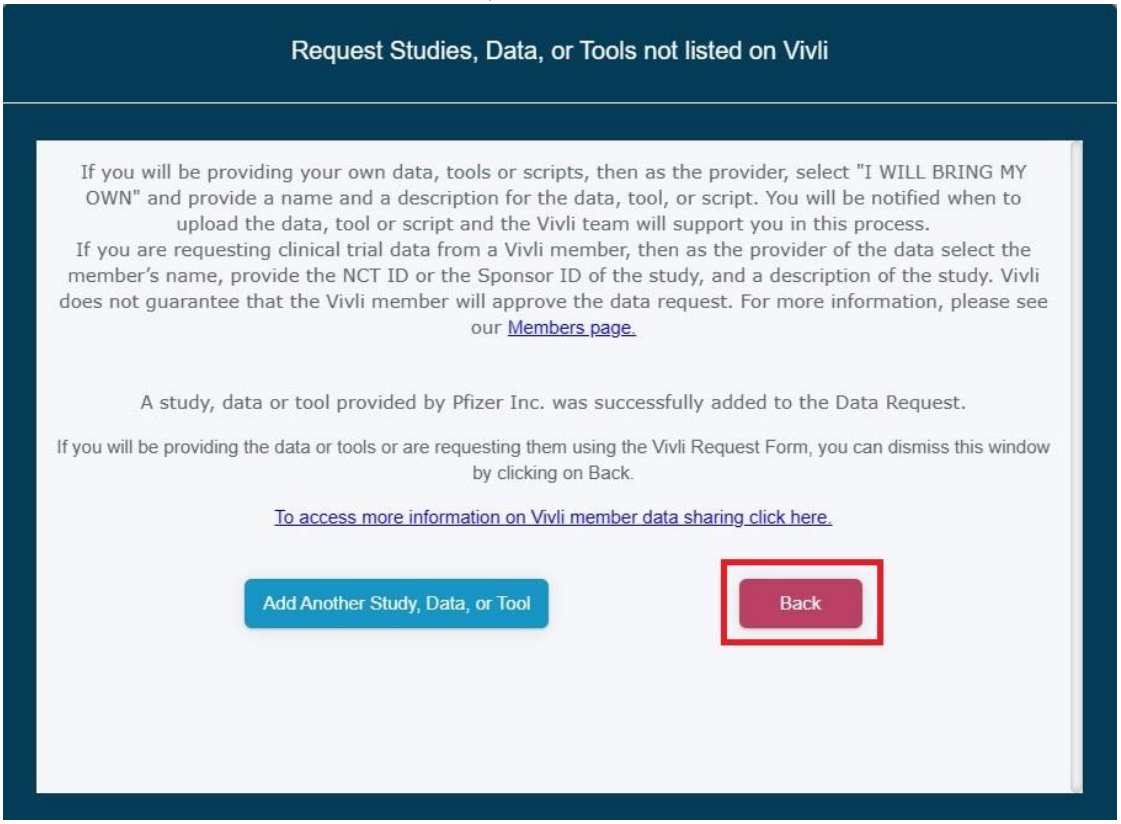
5. The following notification will appear:



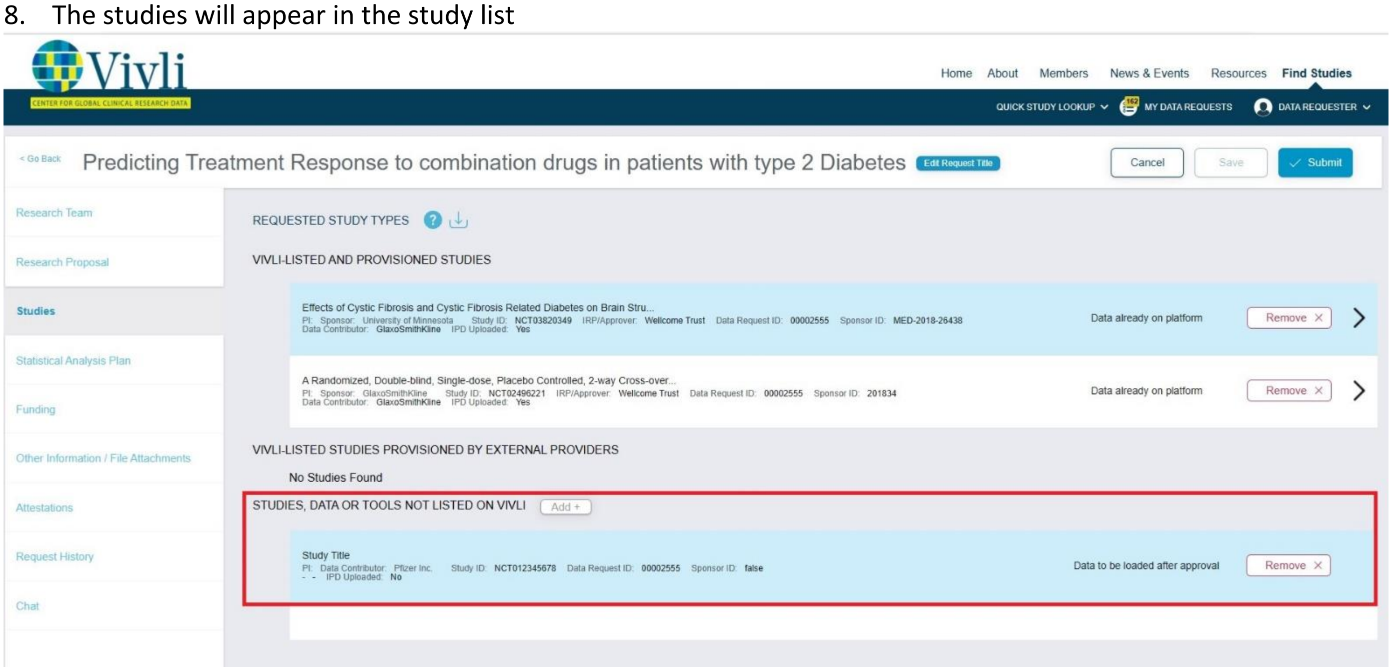
6. You may add additional studies to your Data Request by clicking on **Add Another Study:**



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



8. The studies will appear in the study list

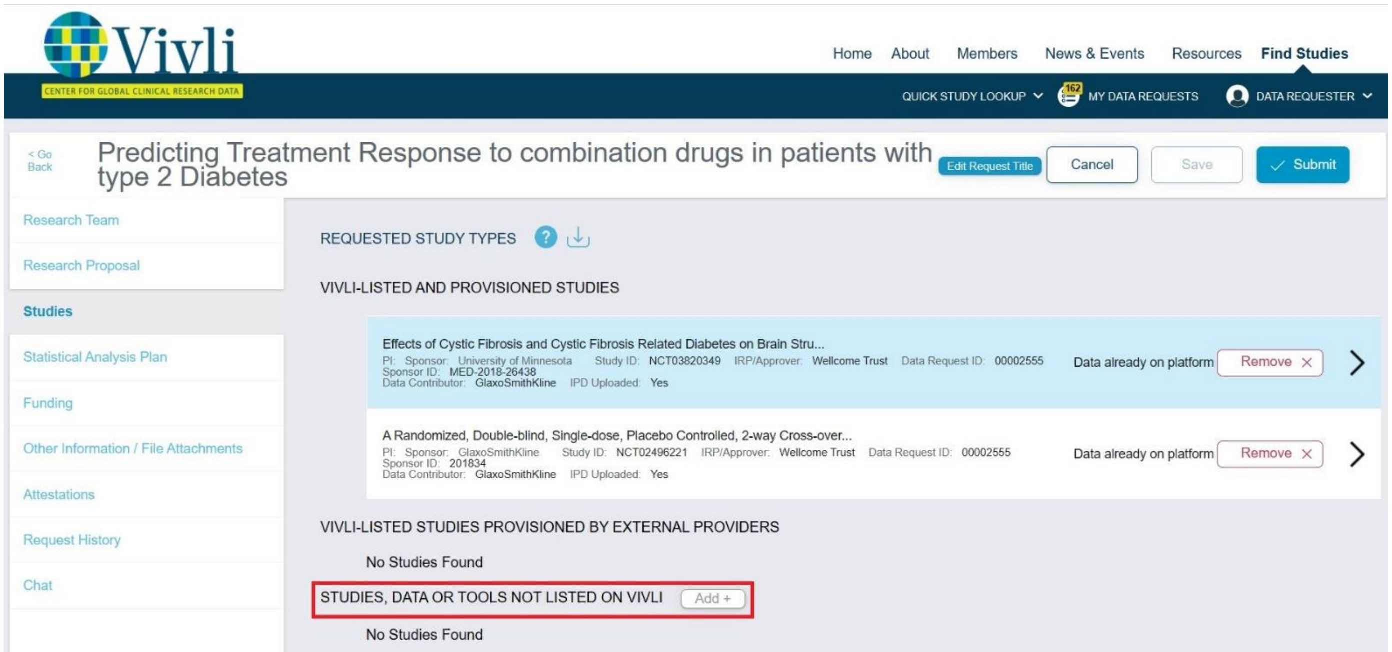


9. After all the Data Contributors associated with the request have approved it and you have signed a Data Use Agreement, all the data package(s) will be provisioned directly into the Secure Research Environment.

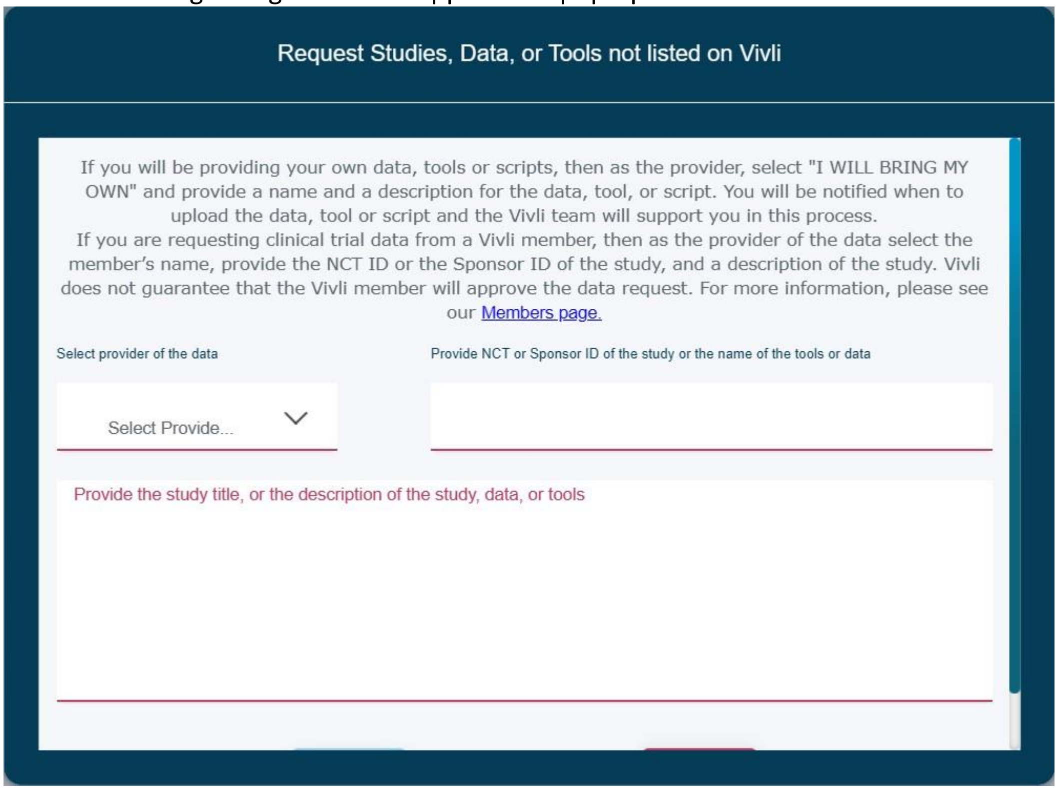
5.0 Requesting to add other data or tools / scripts (provided by you) for integration and use on Vivli

5.1 Adding your own data

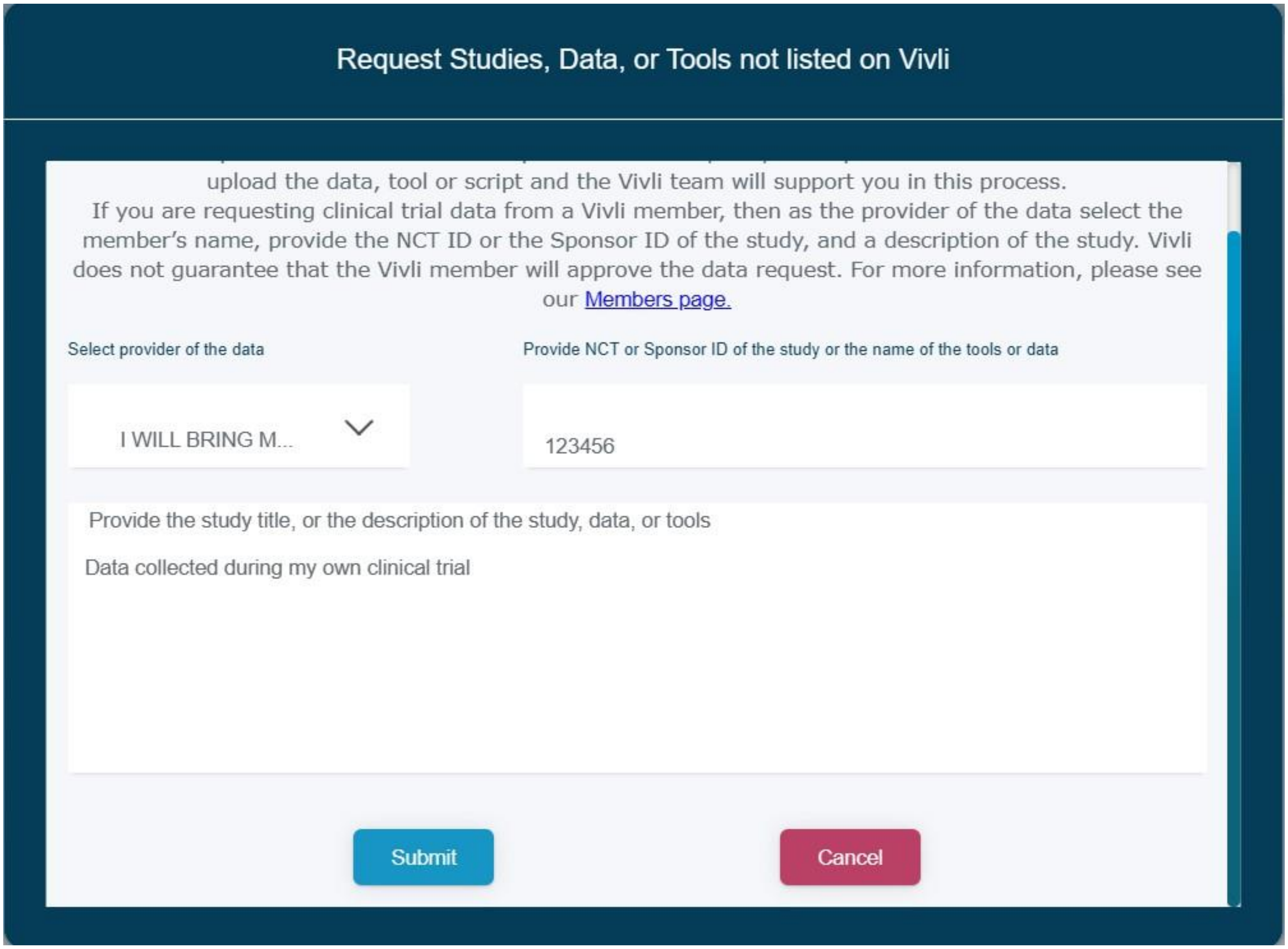
1. You may also request permission to bring in your own data packages to the Secure Research Environment. It is Vivli policy that any data, statistical tools, or scripts need to be included in the studies section of the data request during the review process.
2. Open your data requests by clicking on **My Data Requests** in the top right-hand corner of the browser:
3. Next, open the Data Request to add the external data. Then, scroll down and click on **Add+** adjacent to **STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI**, in the bottom right corner of your screen:



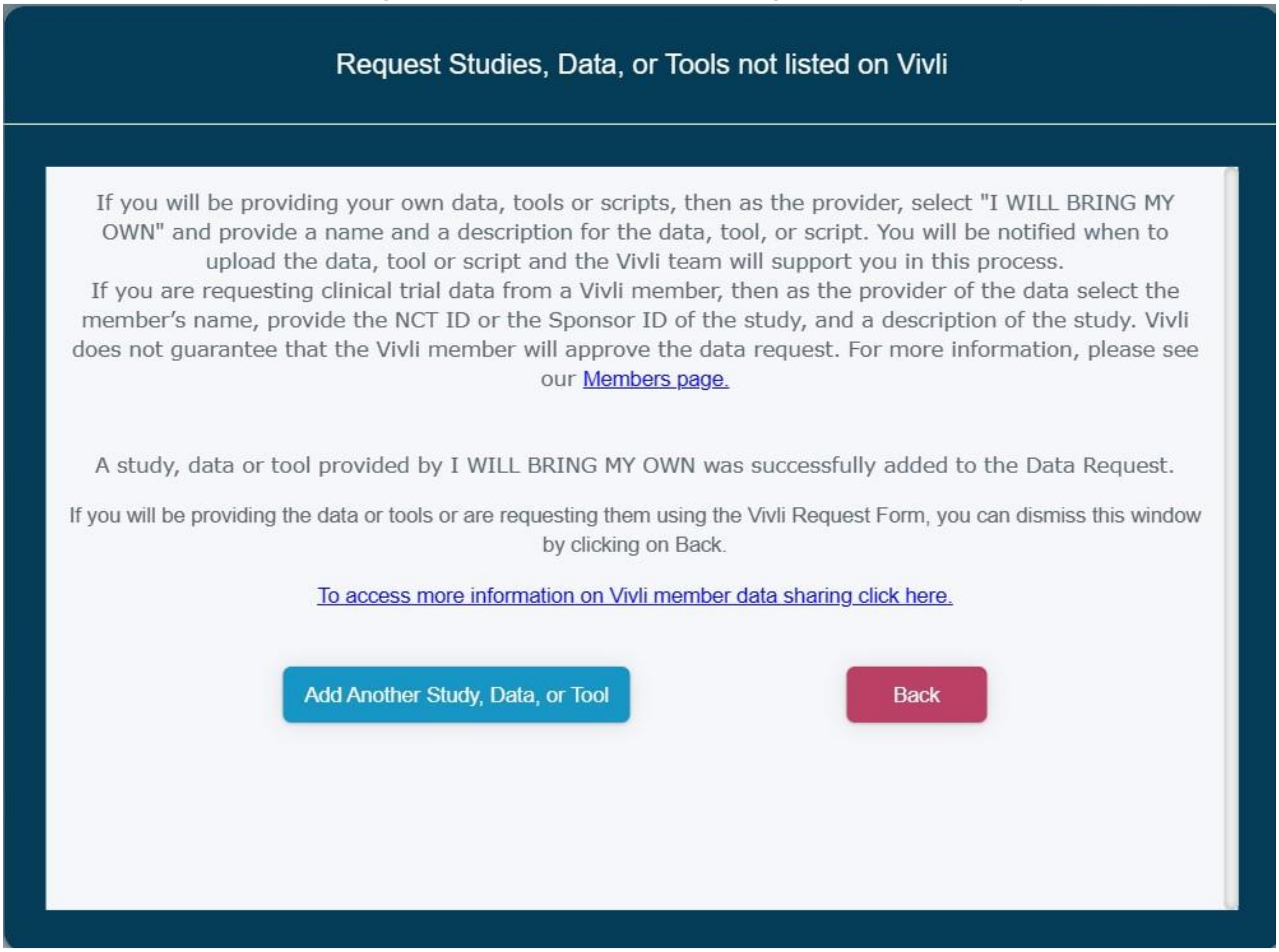
4. The following dialogue box will appear as a pop-up:



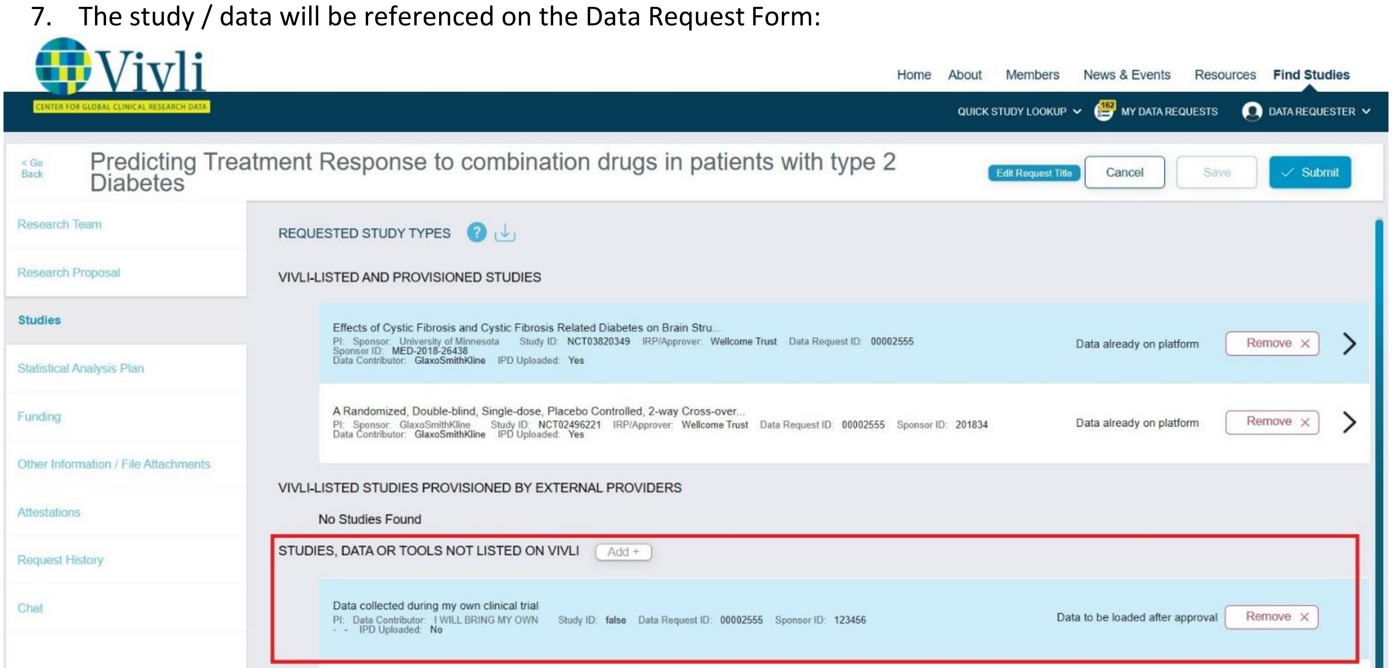
5. From the Dropdown menu under **Select provider of the data,** click on **I will bring my own.** Complete all fields and click **submit. Note:** Please include the description of the additional data, origin of the data, the size of the data package, scientific validity and how the external data adds value to the research purpose. Also indicate in the table if the Lead Investigator and Statistician is legally entitled to upload the additional data, e.g., the data is from a study performed by the Lead Statistician or Lead Investigator or is publicly available data that can be used for secondary analysis and that the study being uploaded is anonymized. As part of the Vivli request form, you tick a box acknowledging that you have permission to use that data for your analysis.


Request Studies, Data, or Tools not listed on Vivli
upload the data, tool or script and the Vivli team will support you in this process.
If you are requesting clinical trial data from a Vivli member, then as the provider of the data select the member's name, provide the NCT ID or the Sponsor ID of the study, and a description of the study. Vivli does not guarantee that the Vivli member will approve the data request. For more information, please see our Members page.
Select provider of the data
I WILL BRING M...
Provide NCT or Sponsor ID of the study or the name of the tools or data
123456
Provide the study title, or the description of the study, data, or tools
Data collected during my own clinical trial
Submit
Cancel

6. You will receive the following notification. You can click Back to go back to the data request:



7. The study / data will be referenced on the Data Request Form:

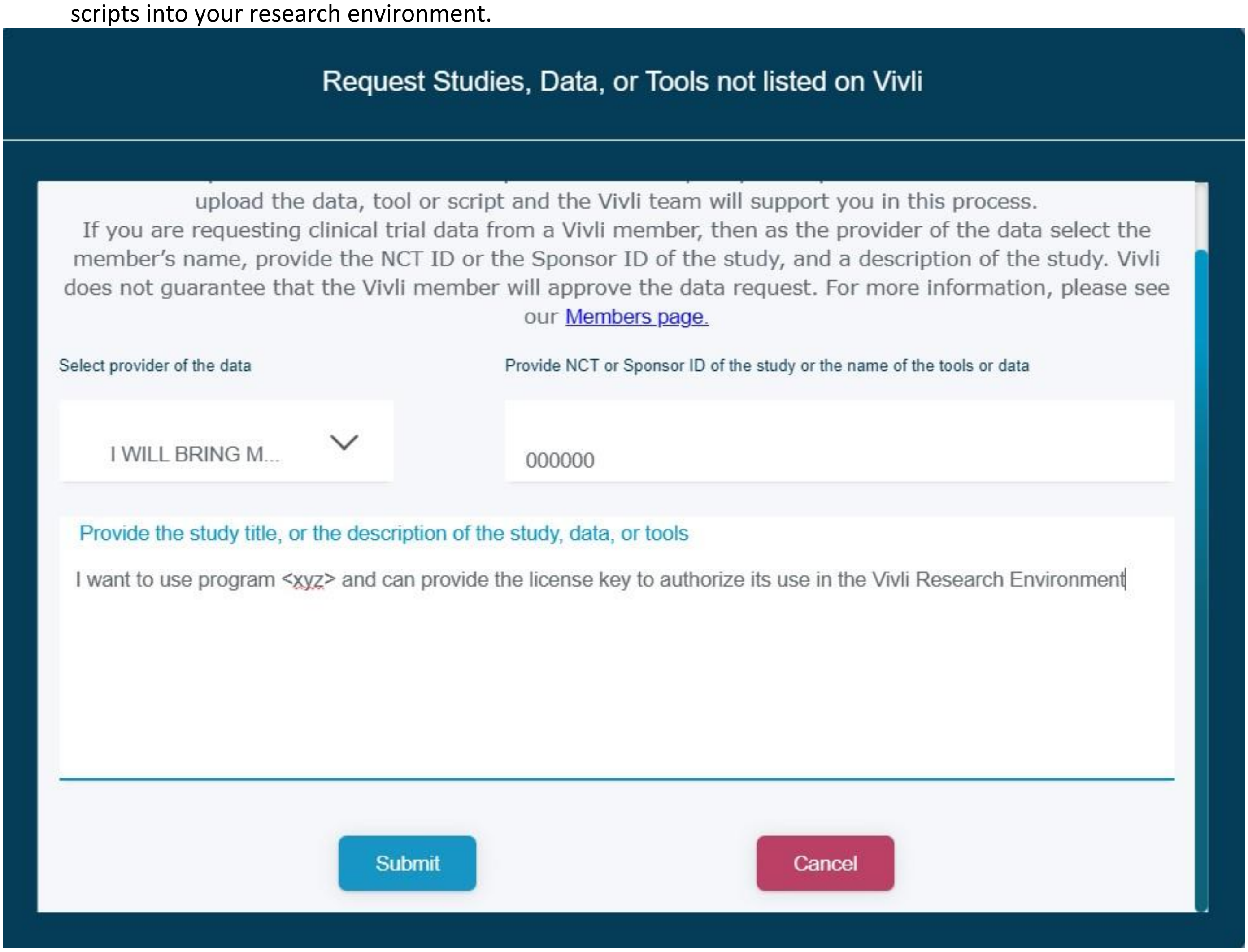


5.2 Adding scripts and tools for use in the Secure Research Environment

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 research environment. If you plan to bring in additional study data, statistical tools or scripts for use in the Vivli research environment, not included in the PDF, please list each specific tool or package in the studies section, under "Studies, Data, Tools (Not listed on Vivli)" section in the studies tab. It is Vivli policy that any data, statistical tools or scripts needs to be included in this section of the data request during the review process. Requests for additional data, tools or scripts after the review process is complete may lead to additional delays.

5.2.1 Adding Scripts or Tools to your Data Request Form

To do this, follow the process in Section 5.1 Adding your own data. Under Step 6, type a list of your tools or scripts in the dialogue box under **Provide either the study title or the description of the study** and click **submit.** After your Data Request is approved, Vivli will facilitate the upload process for your own data and scripts into your research environment.

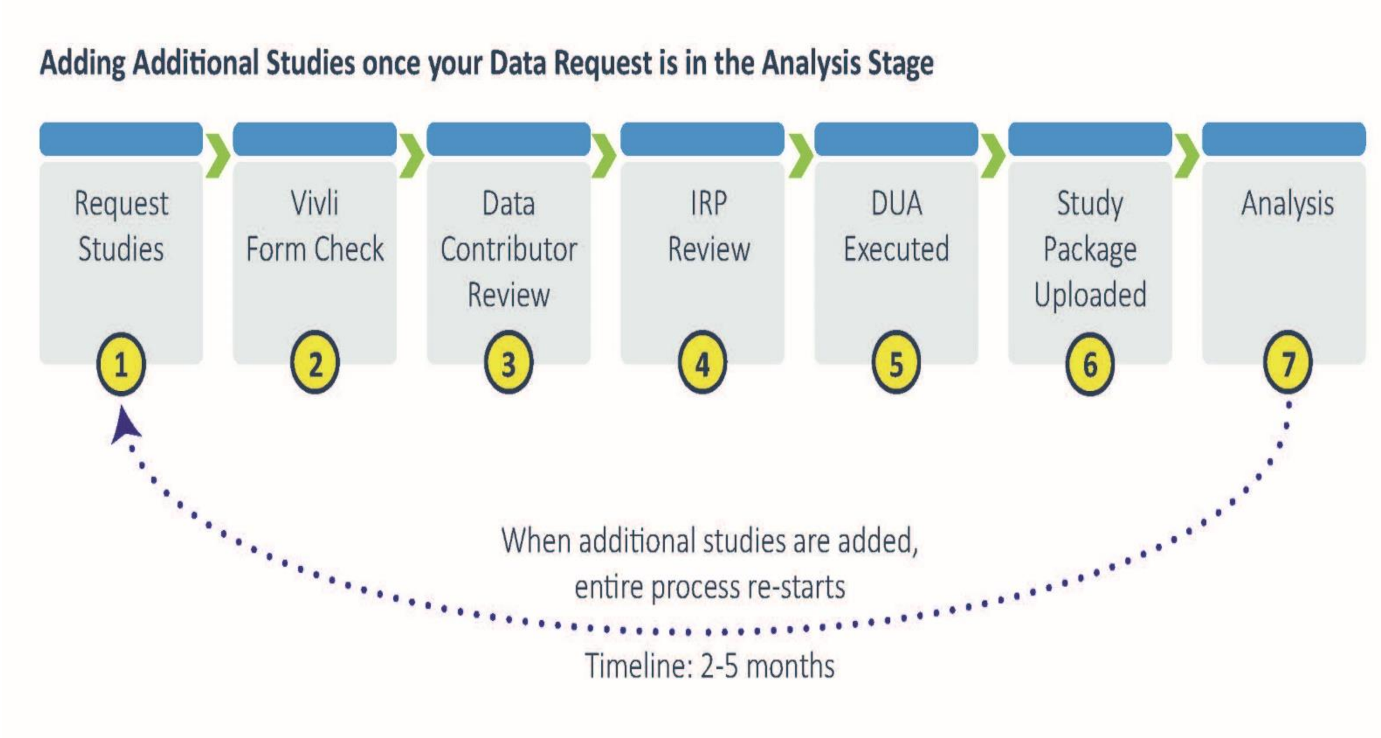


6.0 Modifying or revising your data request

6.1 Overview

- If necessary, you may modify your 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, Vivli team can make changes on your behalf.

PLEASE NOTE: According to Vivli policy, any changes to the Lead Investigator, 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.



6.2 Modification after submission

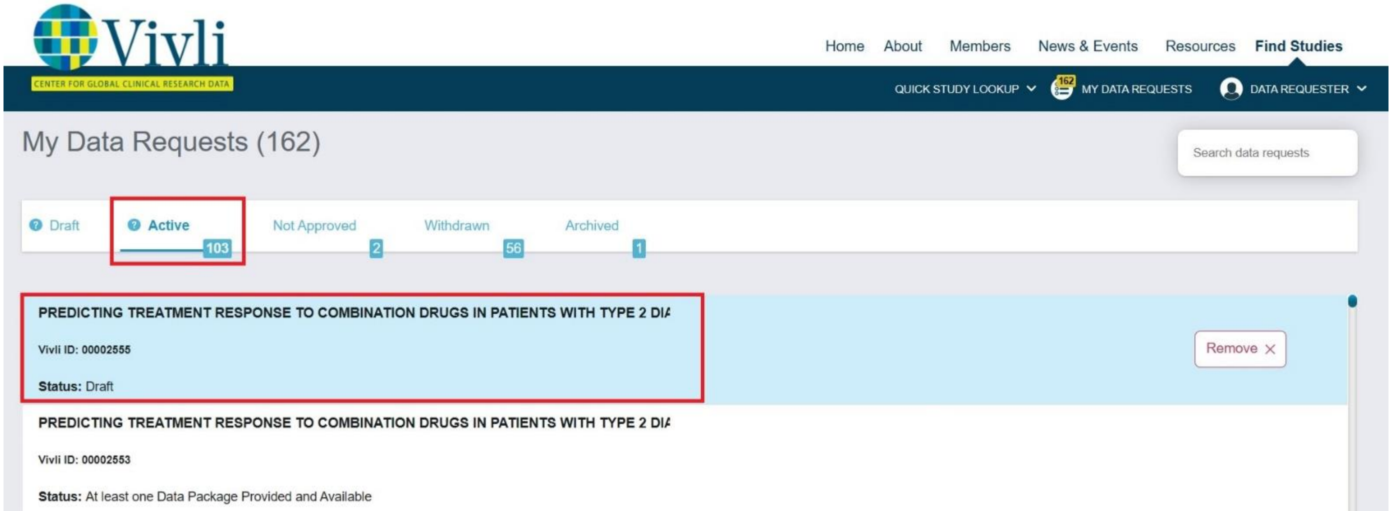
To modify your data request after you have submitted it, please contact Vivli via open chat on the platform.

6.3 Requested revisions to your data request

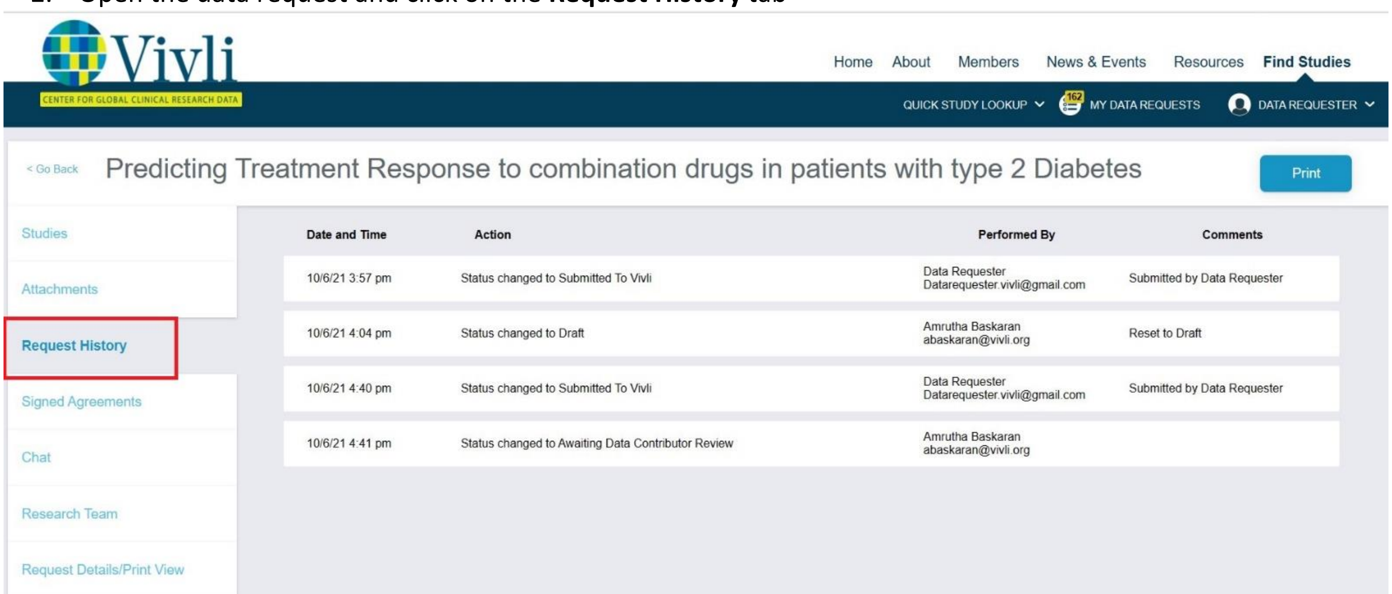
- At times, the Data Contributor, Independent Review Panel (IRP), or Vivli may request that you make changes to your data request.
- If this is the case, you will be notified on the Vivli Dashboard as well as via email.
- The specific changes requested will be placed in the Chat window.
- If you fail to make requested changes, the data request may not be fulfilled.

6.3.1 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:



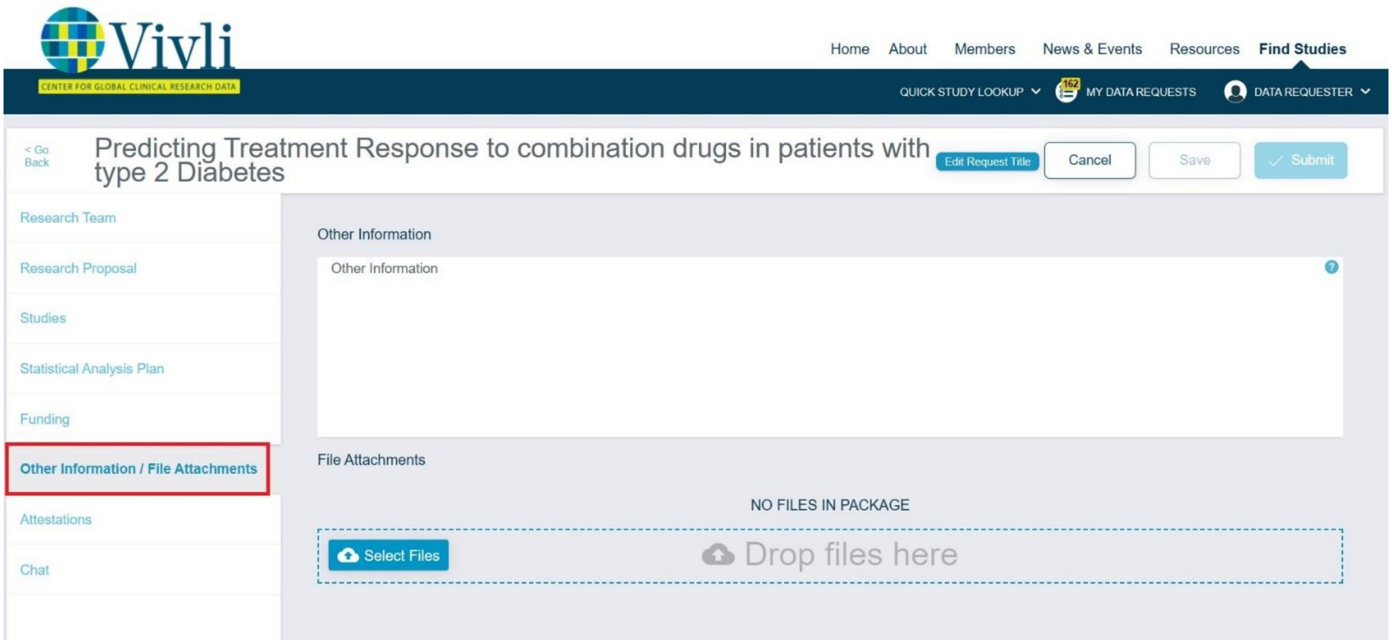
2. Open the data request and click on the **Request History** tab



You can review the request history and see any comments related to your data request. You may 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.

3. From there, 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 fit in the rest of the fields:



For more information on attaching files, see Section 2.2.1 Adding Files or Other Information to your data request.

6.4 Deleting Data Requests

Please note, if you delete your data request, the Vivli Administrators **will not** be able to retrieve it for you. Hence, please reach out to the Vivli team via chat or support@vivli.org if you would like to withdraw your data request.

6.5 Withdrawal process

If you decide to withdraw your request, you can reach out to the Vivli team via 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 is received from the Research Team to Vivli Admin for 4 months following check-ins via chat after 1 and 4 months.

After 4 months, the Vivli team will place a note in chat informing you that attempts to contact the Research team have been unsuccessful and your request will be considered withdrawn and moved to the Withdrawn state on the platform. If you respond to this message within 30 days, the request can continue through the process. After 30 days, 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. The same applies for inactive requests that are in drafts for more than 4 months.

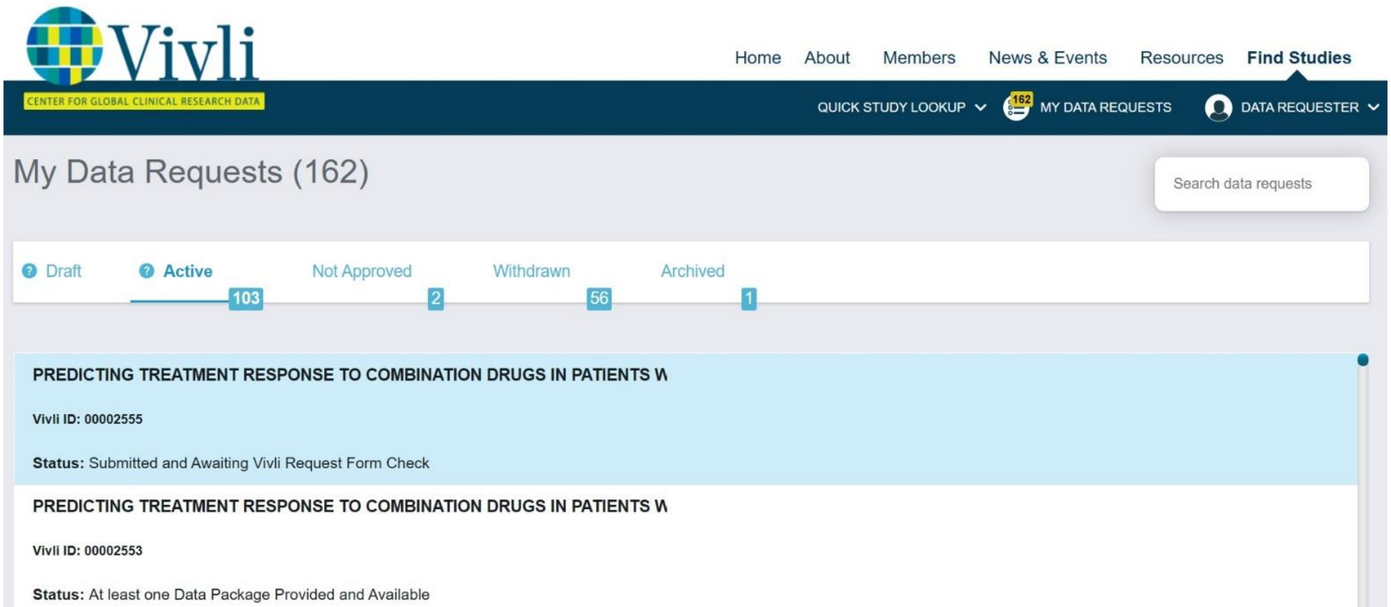
7.0 Communications

7.1 Open Chat

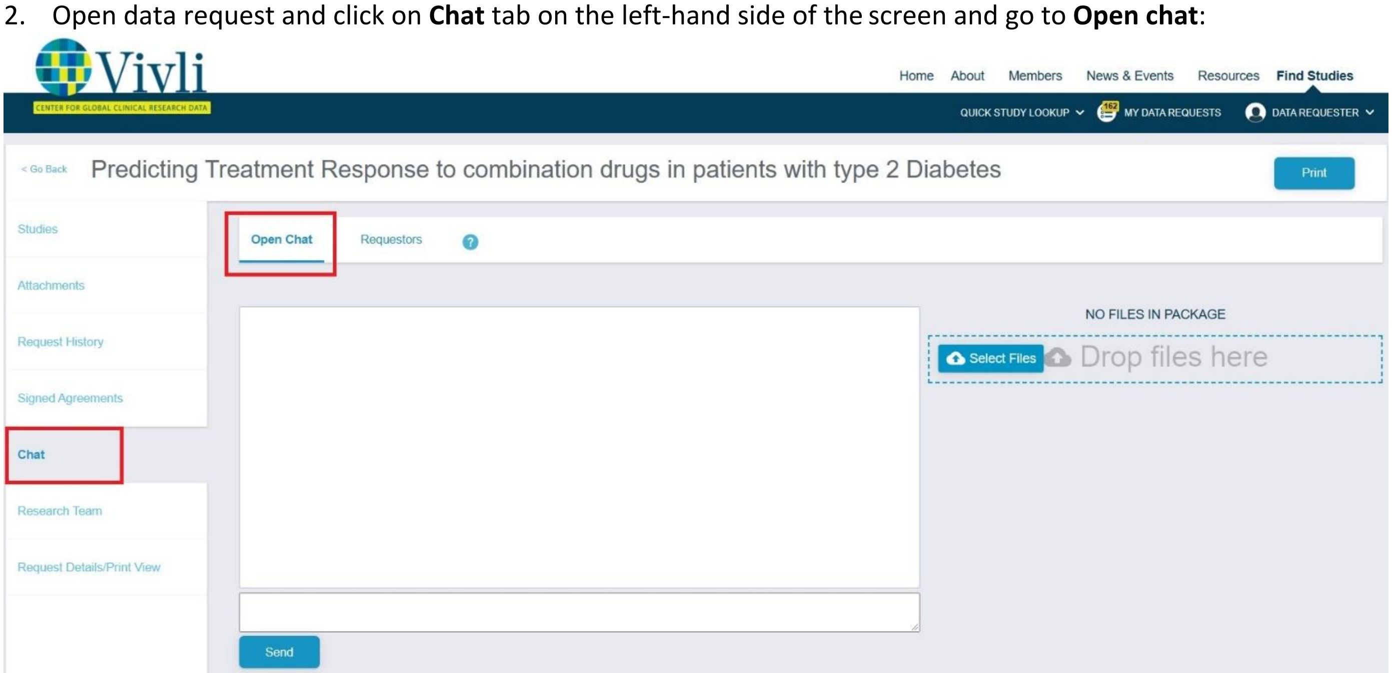
- You can use the open chat within the data request to communicate with the Vivli team, and the data contributors or review entities associated with your data request.
- Please note that messages in chat are visible to all persons attached to a data request.
- When any other party enters a message in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

7.2 Steps for creating a chat message

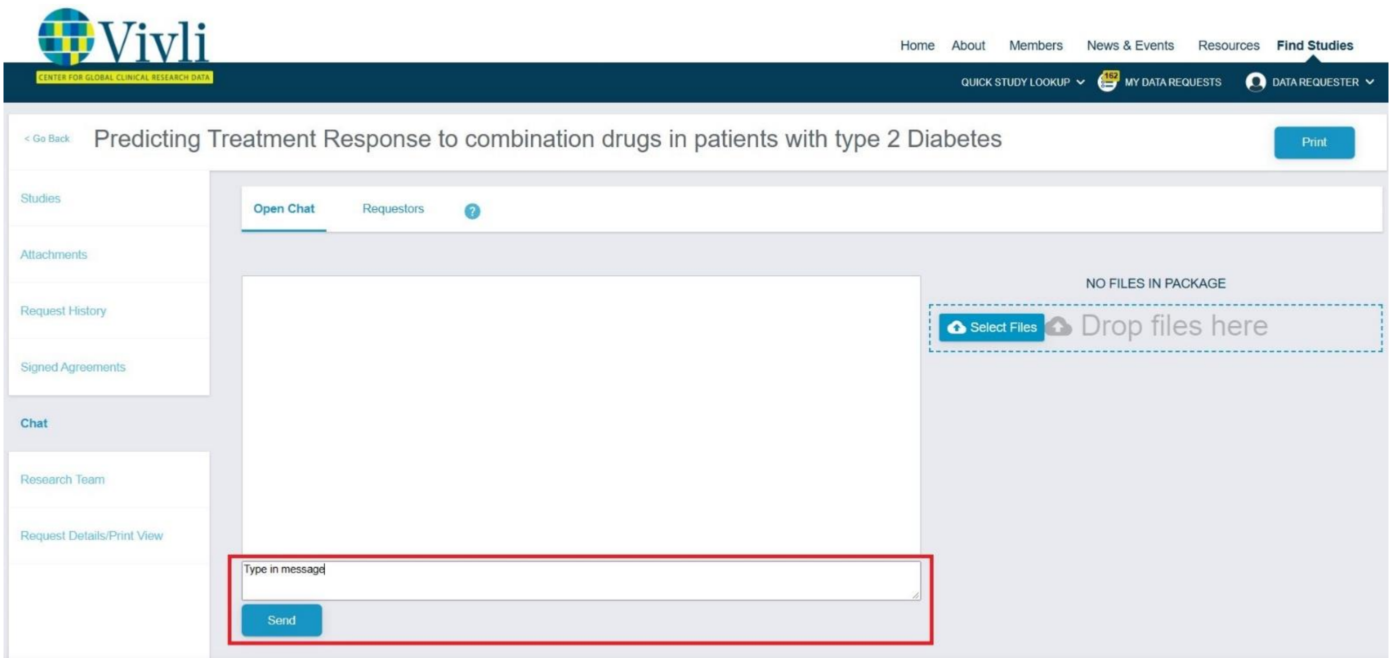
1. Log on to the platform and Go to **My data requests** tab:



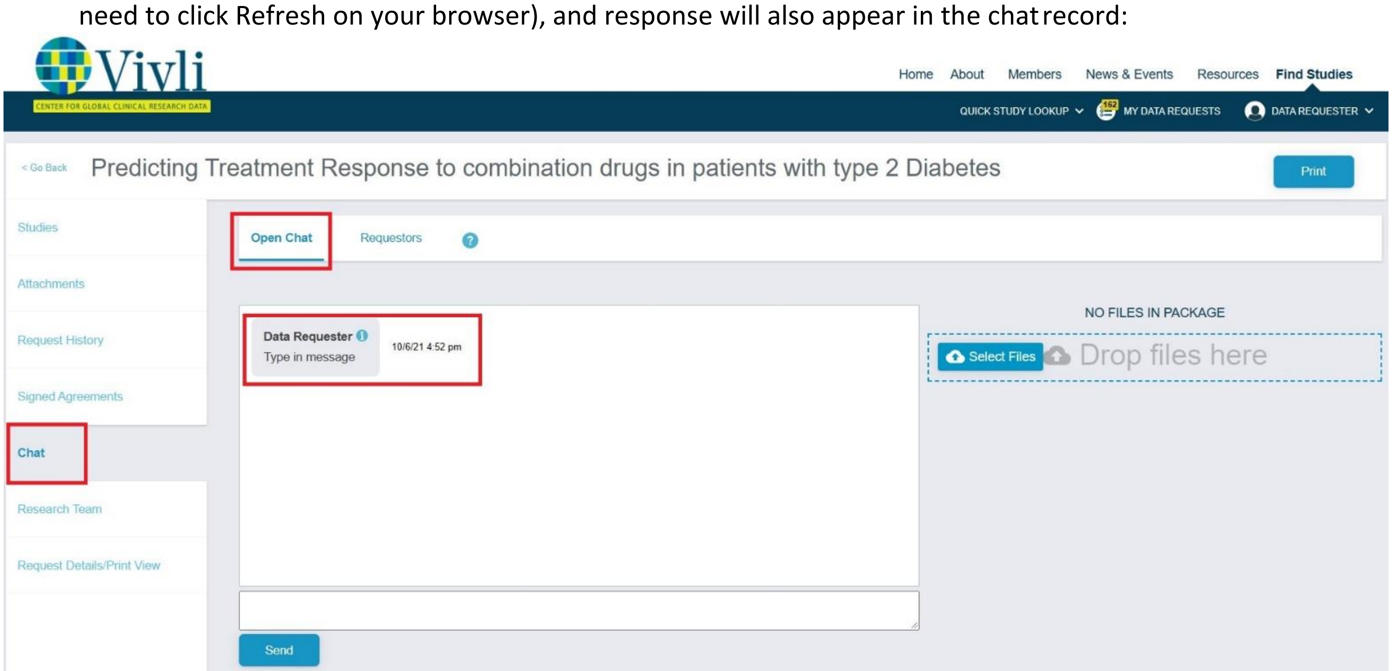
2. Open data request and click on **Chat** tab on the left-hand side of the screen and go to **Open chat**:



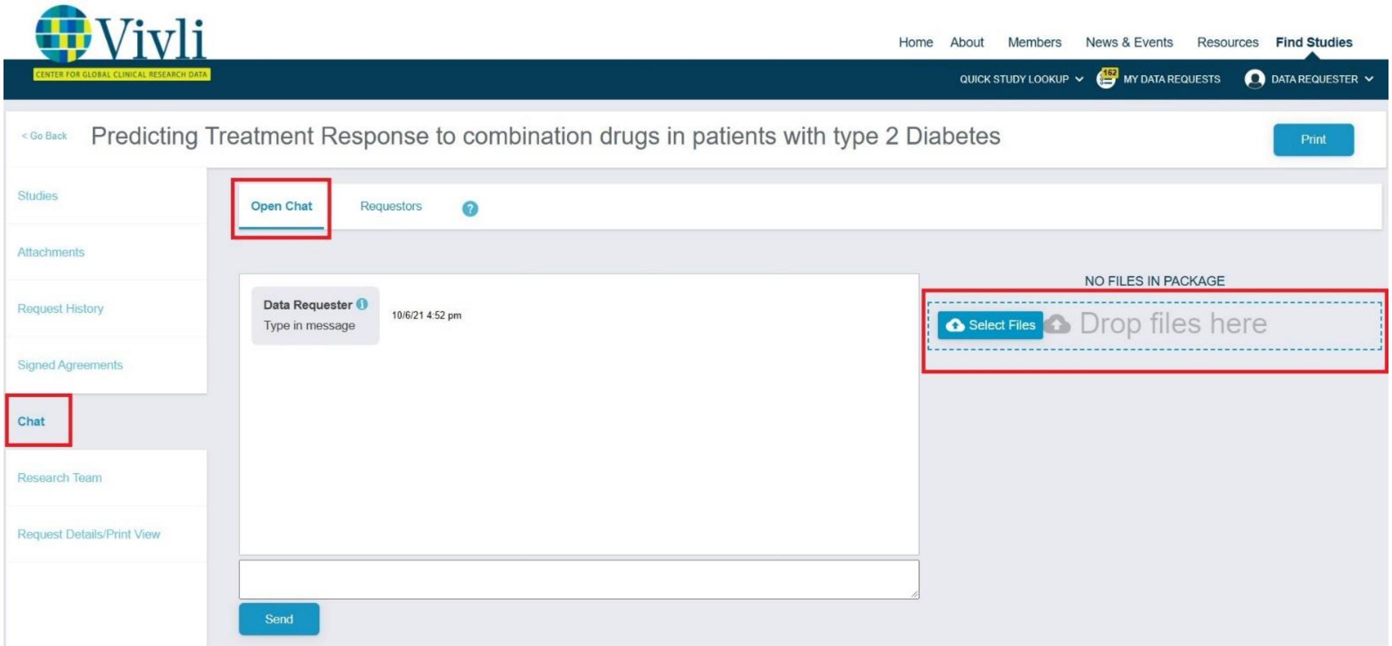
3. Enter your message in the chat message box and click **Send:**



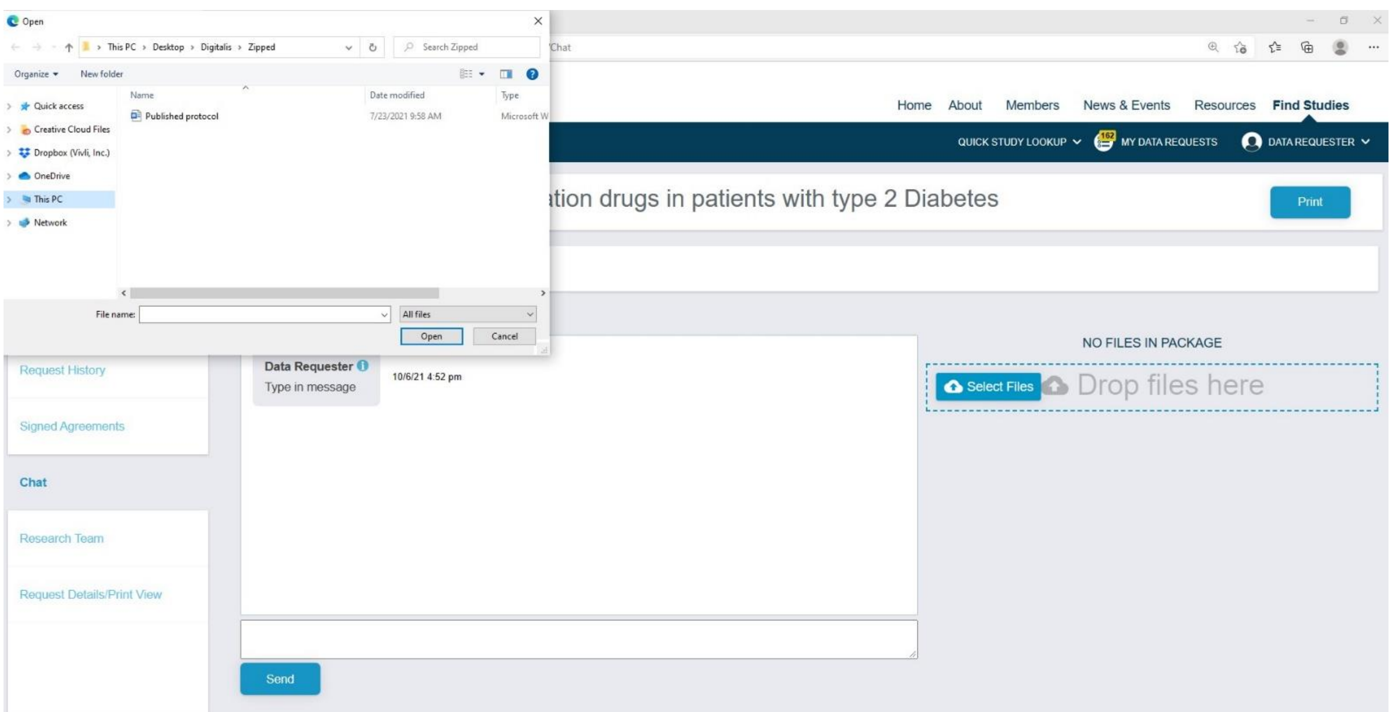
4. The message will now appear in the Chat record for all users (to see your just-entered chat message, you may need to click Refresh on your browser), and response will also appear in the chat record:



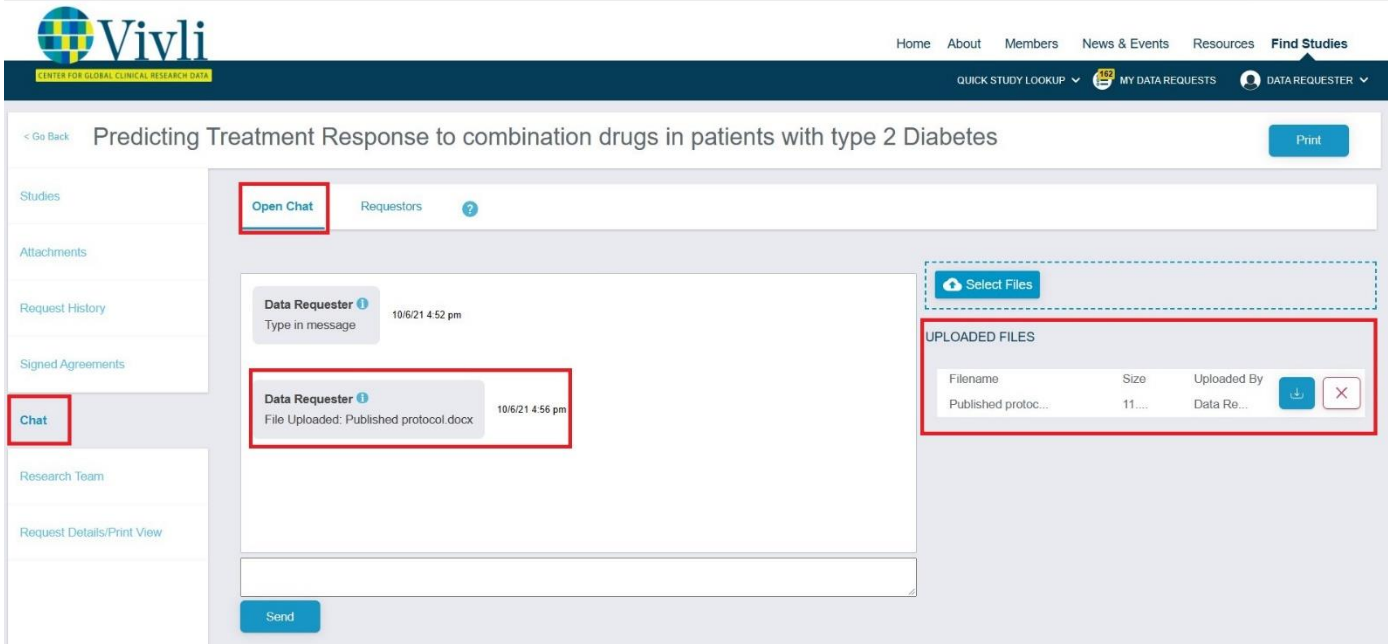
5. You can also upload files via chat by clicking on **Select Files:**



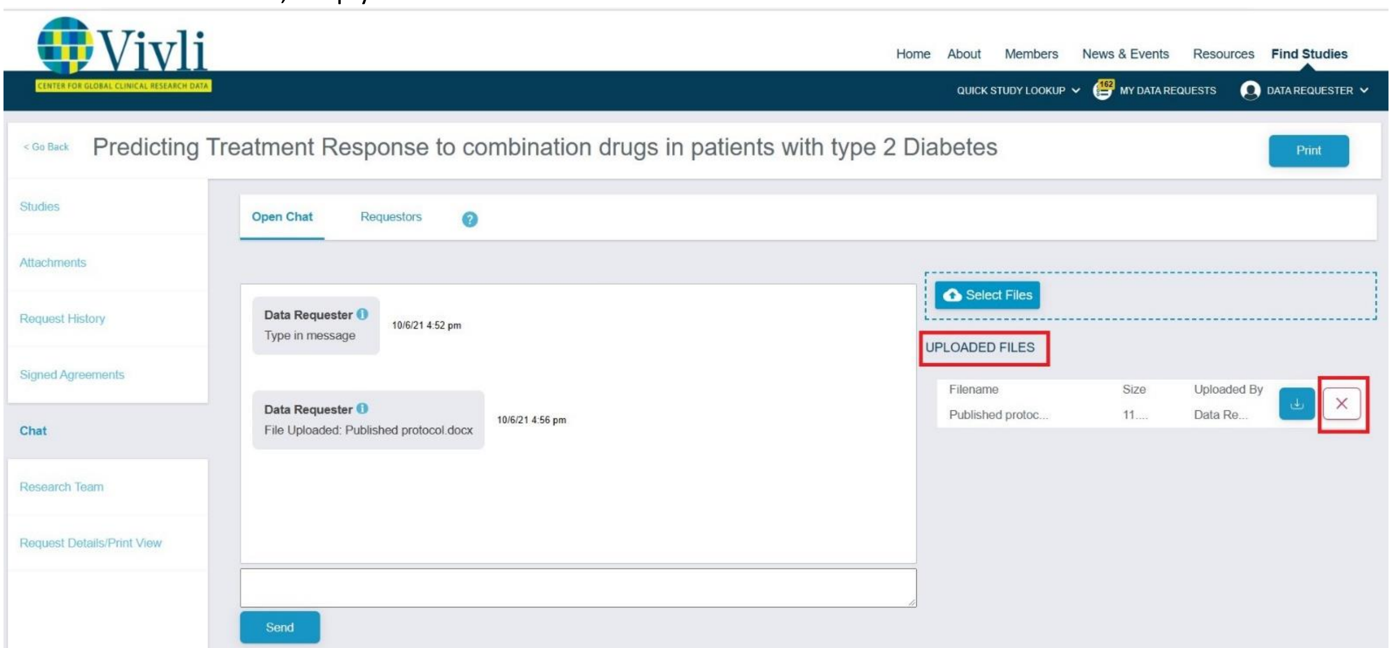
6. Select the file you wish to upload from your computer:



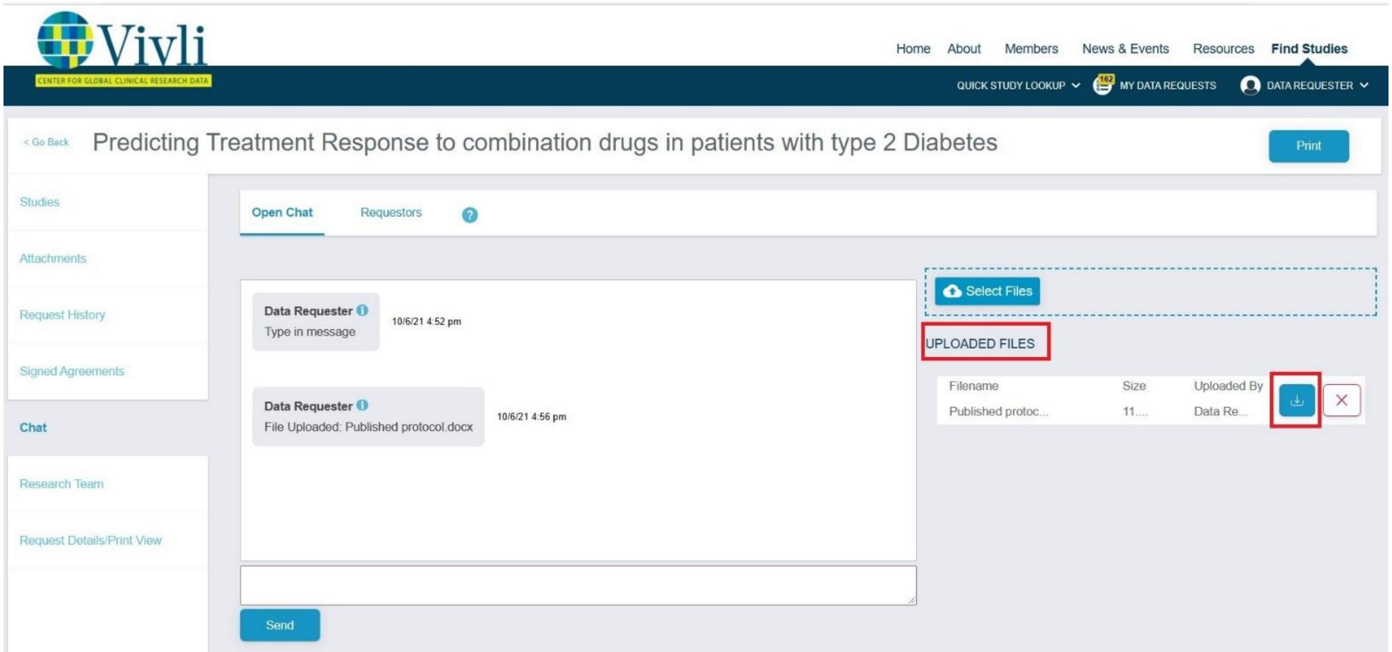
7. The uploaded file will appear in the file list on the right, and in the chat history:



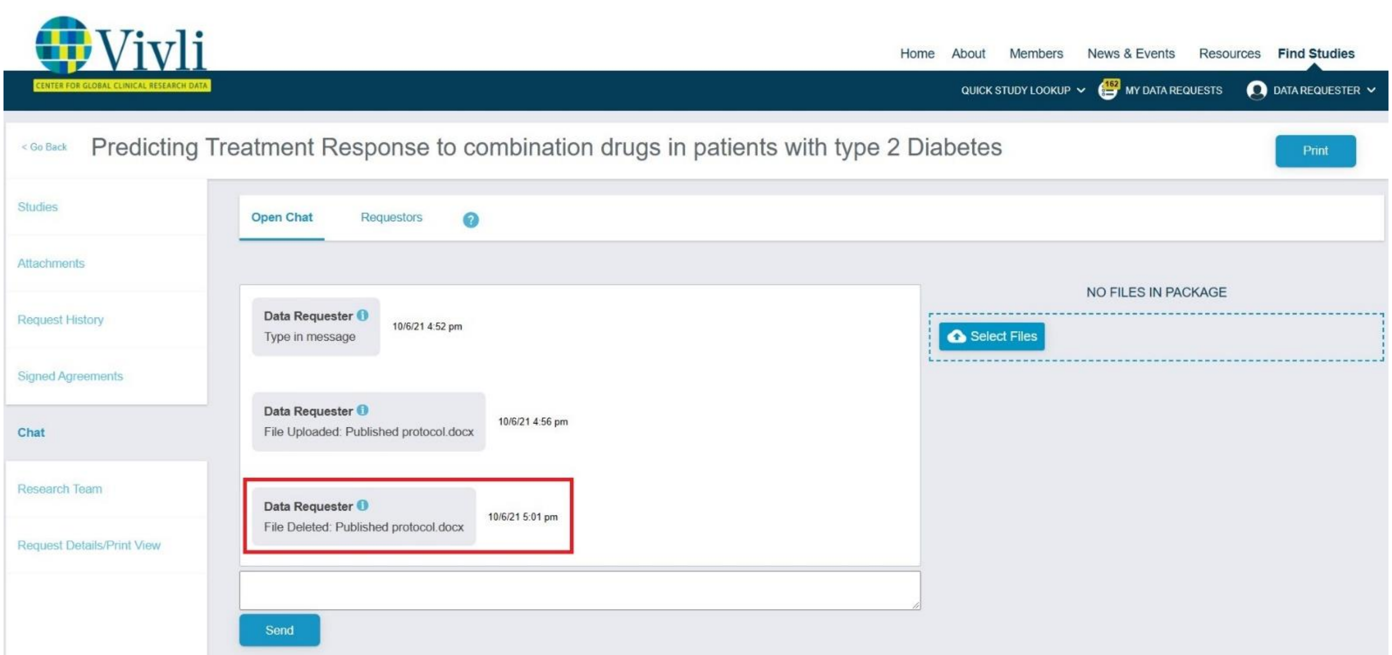
8. To delete the file, simply click on **the X next to it:**



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



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



11. Chats are posted when you click “Send” which permits you to write and read distinct paragraphs
12. Chat messages automatically scroll to the most recent post instead of the first.
13. In chat, files are sorted by date, newest on top, and the hover text displays the filename, date, and person who uploaded it.
14. Posted chat messages are visible immediately.

7.3 Emails

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

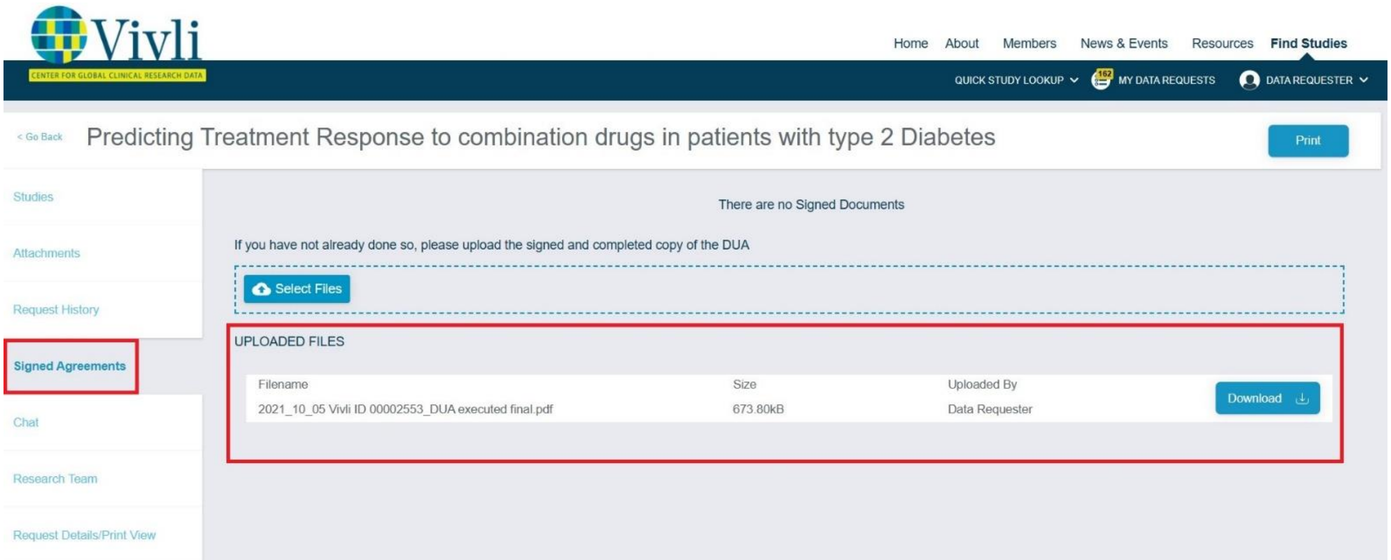
Email	When sent	Purpose
Status Change, data request	When your data request changes status	Notify you of any changes in status to your data requests;
Request Approved	When your data request is approved, by a delegated approver. If you have requested studies from multiple contributors, you will receive a notification when each has approved your request or requested revisions or denied your request.	Notify you of approval
DUA Approved	When the Vivli Admin has validated the DUA associated with the data request.	Notify you, as well as data contributors, of approved DUA.
Chat	When anyone associated with a data request enters a message in chat	Facilitate communication and the data request work flow

If you have any questions about these emails, you can contact user support via the platform chat function (see Section 7.1 Open Chat) or via email to support@vivli.org.

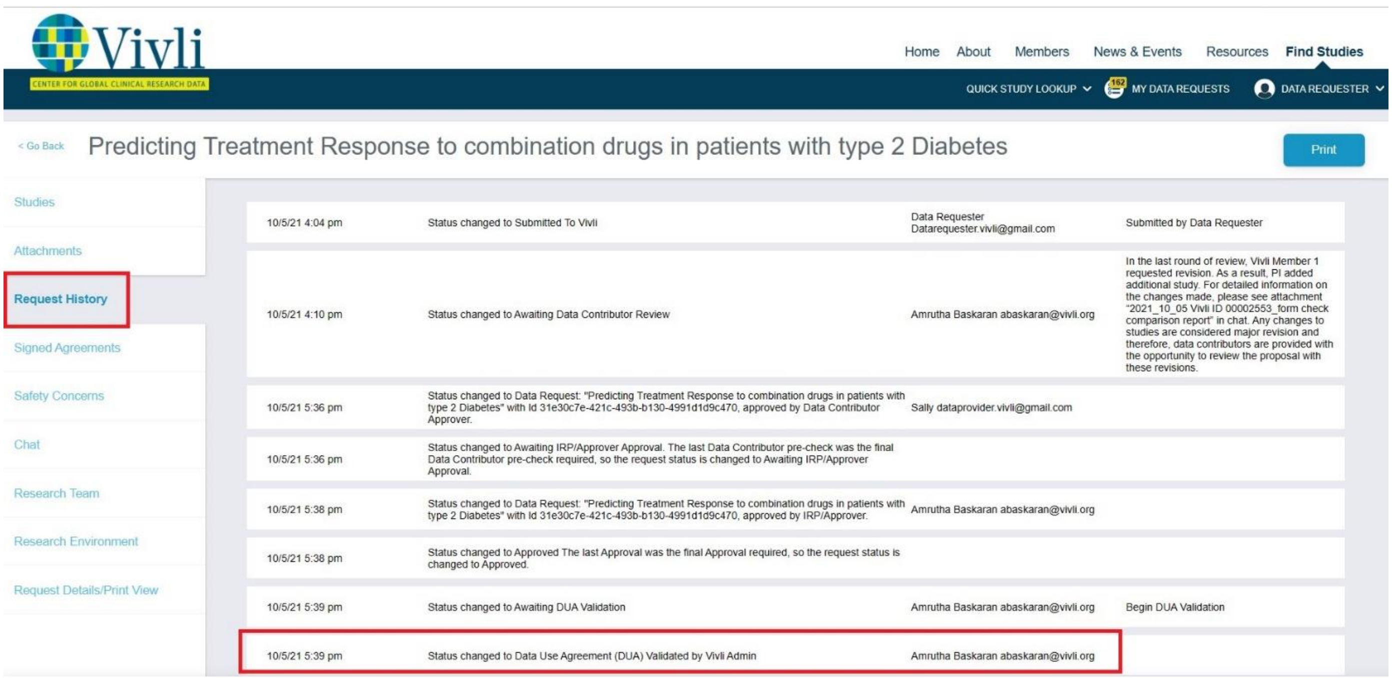
8.0 Data Use Agreement

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.
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 on its website:
   - Project Name
   - Name & Affiliation of the Principal Investigator / Lead Researcher
   - Funding Sources
   - Conflict of Interest Statement
   - Narrative 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

9.0 Data Package Upload & Accessing the data

The Data Contributors will anonymize the data and upload the data into the platform. You will be notified when the data packages have been uploaded.

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.