



How-To: Request Studies on Vivli

Vivli Release 3.0

January 19, 2023

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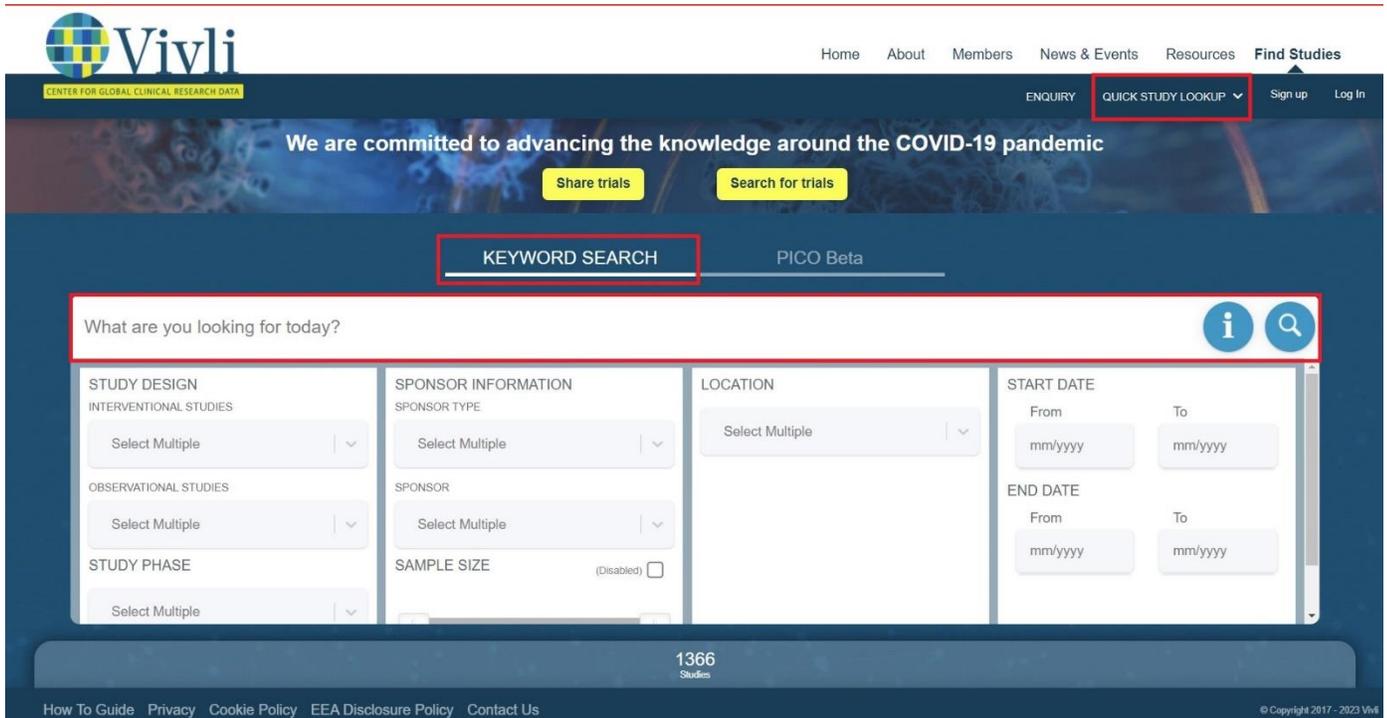
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1.0 Requesting Studies on Vivli – Overview

- 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.



The screenshot displays the Vivli search interface. At the top, the Vivli logo is on the left, and navigation links (Home, About, Members, News & Events, Resources, Find Studies) are on the right. Below the navigation is a banner with the text "We are committed to advancing the knowledge around the COVID-19 pandemic" and buttons for "Share trials" and "Search for trials". The main search area features a "KEYWORD SEARCH" bar with the placeholder text "What are you looking for today?". To the right of the search bar are "PICO Beta" and "QUICK STUDY LOOKUP" options. Below the search bar are four filter panels: "STUDY DESIGN" (with sub-sections for INTERVENTIONAL STUDIES, OBSERVATIONAL STUDIES, and STUDY PHASE), "SPONSOR INFORMATION" (with sub-sections for SPONSOR TYPE and SPONSOR), "LOCATION", and "START DATE" (with "From" and "To" date pickers). The "END DATE" filter is also present. At the bottom, the interface shows "1366 Studies" and a footer with links for "How To Guide", "Privacy", "Cookie Policy", "EEA Disclosure Policy", and "Contact Us".

- 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.

The screenshot shows the Vivli website's search interface. At the top, there is a navigation bar with links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a banner with the text "We are committed to advancing the knowledge around the COVID-19 pandemic" and buttons for "Share trials" and "Search for trials". The main search area features a "KEYWORD SEARCH" input field with the word "diabetes" entered. To the right of the input field are icons for help (i) and search (magnifying glass). Below the search bar are several filter categories: STUDY DESIGN (INTERVENTIONAL STUDIES, OBSERVATIONAL STUDIES, STUDY PHASE), SPONSOR INFORMATION (SPONSOR TYPE, SPONSOR, SAMPLE SIZE), LOCATION, and START/END DATE. At the bottom of the search results area, a blue bar displays "83 Studies".

- To view more information, click on "View Study Details"

The screenshot shows the Vivli website's search results page. The search bar at the top contains the text "What are you looking for today?". Below the search bar are filter categories: STUDY DESIGN (INTERVENTIONAL STUDIES, OBSERVATIONAL STUDIES, STUDY PHASE), SPONSOR INFORMATION (SPONSOR TYPE, SPONSOR), and LOCATION. The main content area displays three study results. The first study is titled "Clinical Assessment of GSK716155 for Type 2 Diabetes Mellitus -A Phase I/II Study to Investigate the Safety, Pharmacokinetics and Pharmacodynamics of GSK716155 in Japanese Subjects With Type 2 Diabetes Mellitus". The second study is titled "A Phase I, Randomized, Placebo-Controlled, Crossover Clinical Trial to Assess the Safety of Oral SRT2104 and Its Effects on Vascular Dysfunction in Otherwise Healthy Cigarette Smokers and Subjects With Type 2 Diabetes Mellitus". The third study is titled "A Single-Center, Non-Randomized, Open-Label, Comparative Study to Assess the Utility of Novel Technologies and Biomarkers as Methods for Measuring Human Pharmacodynamic Response to 8 Weeks of Administration of Rosiglitazone Maleate 4mg BID in Healthy Normal or Overweight Controls, Healthy Obese Subjects and Subjects With Type 2 Diabetes Mellitus (T2DM)". For each study, there are buttons for "Log in to Request Study" and "View Study Details". The "View Study Details" button for the first study is highlighted with a red box.

- 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**.

The screenshot shows the Vivli website interface. At the top left is the Vivli logo with the tagline "CENTER FOR GLOBAL CLINICAL RESEARCH DATA". The navigation bar includes "Home", "About", "Members", "News & Events", "Resources", and "Find Studies". Below the navigation bar are links for "ENQUIRY", "QUICK STUDY LOOKUP", "MY DATA REQUESTS", and "DATA REQUESTER". A search bar at the top asks "What are you looking for today?". On the left side, there are filter sections for "STUDY DESIGN" (Interventional Studies, Observational Studies), "STUDY PHASE", "SPONSOR INFORMATION" (Sponsor Type), and "SPONSOR". The main content area displays three study listings, each with a "Request Study" button highlighted in a red box. The first study is "Clinical Assessment of GSK716155 for Type 2 Diabetes Mellitus - A Phase I/III Study to Investigate the Safety, Pharmacokinetics and Pharmacodynamics of GSK716155 in Japanese Subjects With Type 2 Diabetes Mellitus" (NCT00530309 | GLP107865), with 40 enrolled subjects in Phase 1. The second study is "A Phase I, Randomized, Placebo-Controlled, Crossover Clinical Trial to Assess the Safety of Oral SRT2104 and Its Effects on Vascular Dysfunction in Otherwise Healthy Cigarette Smokers and Subjects With Type 2 Diabetes Mellitus" (NCT01031108 | 114089), with 38 enrolled subjects in Phase 1. The third study is "A Single-Center, Non-Randomized, Open-Label, Comparative Study to Assess the Utility of Novel Technologies and Biomarkers as Methods for Measuring Human Pharmacodynamic Response to 8 Weeks of Administration of Rosiglitazone Maleate 4mg BID in Healthy Normal or Overweight Controls, Healthy Obese Subjects and Subjects With Type 2 Diabetes Mellitus (T2DM)".

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

This close-up screenshot shows a study card for "Efficacy of Topiramate (Topamax) With". A "Request Study" dropdown menu is open, and the option "+ Add New Request" is circled in red. Below the dropdown, the text "Number enrolled: 118" and "Phase 3" is visible. A "CLOSE" button is located at the top right of the card.

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

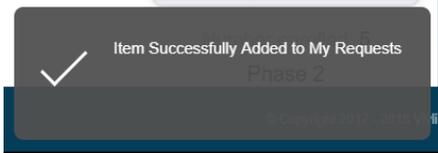
Enter a descriptive name for your research project.

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.

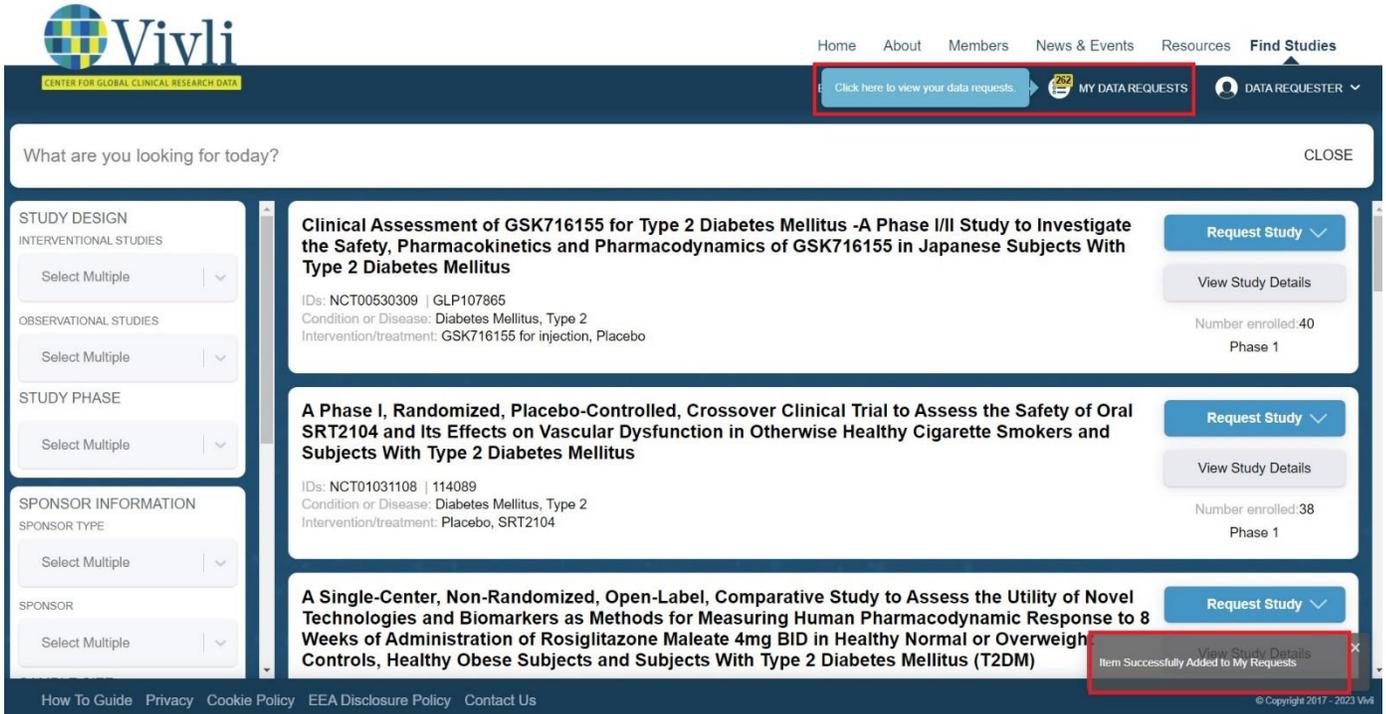
Ok

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:

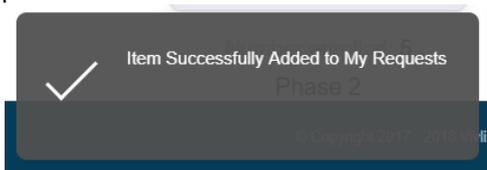


5. You will also get a notification that you may review **My Data Requests** to see the new request:



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:



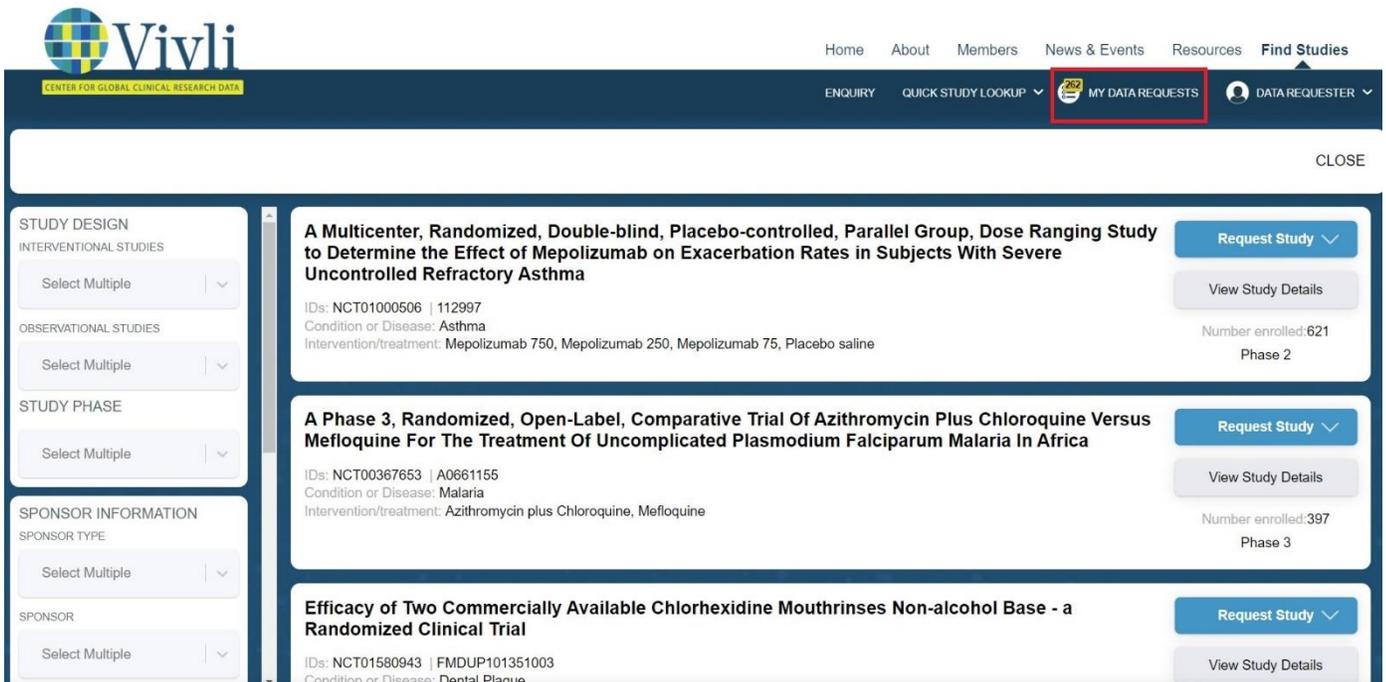
9. Once you have added all desired studies listed on the Vivli platform, you can complete the Data Request Form (See 2.0 Your Data Requests for more information).

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:



The screenshot shows the Vivli website interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. A red box highlights the 'MY DATA REQUESTS' link in the top right corner. Below the navigation bar, there is a search bar and a 'CLOSE' button. The main content area is divided into a left sidebar with filters for Study Design, Observational Studies, Study Phase, Sponsor Information, and Sponsor. The main area displays a list of clinical studies. Each study entry includes the study title, IDs, Condition or Disease, and Intervention/treatment. Each entry also has a 'Request Study' button and a 'View Study Details' button. The first study is 'A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group, Dose Ranging Study to Determine the Effect of Mepolizumab on Exacerbation Rates in Subjects With Severe Uncontrolled Refractory Asthma'. The second study is 'A Phase 3, Randomized, Open-Label, Comparative Trial Of Azithromycin Plus Chloroquine Versus Mefloquine For The Treatment Of Uncomplicated Plasmodium Falciparum Malaria In Africa'. The third study is 'Efficacy of Two Commercially Available Chlorhexidine Mouthrinses Non-alcohol Base - a Randomized Clinical Trial'.

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:

My Data Requests (262)

Search data requests

Draft 1
Active 83
Not Approved 3
Withdrawn 174
Archived 1

INCREASE IN ALBUMINURIA IN DIABETES PATIENTS | 2 STUDIES

Status: Draft

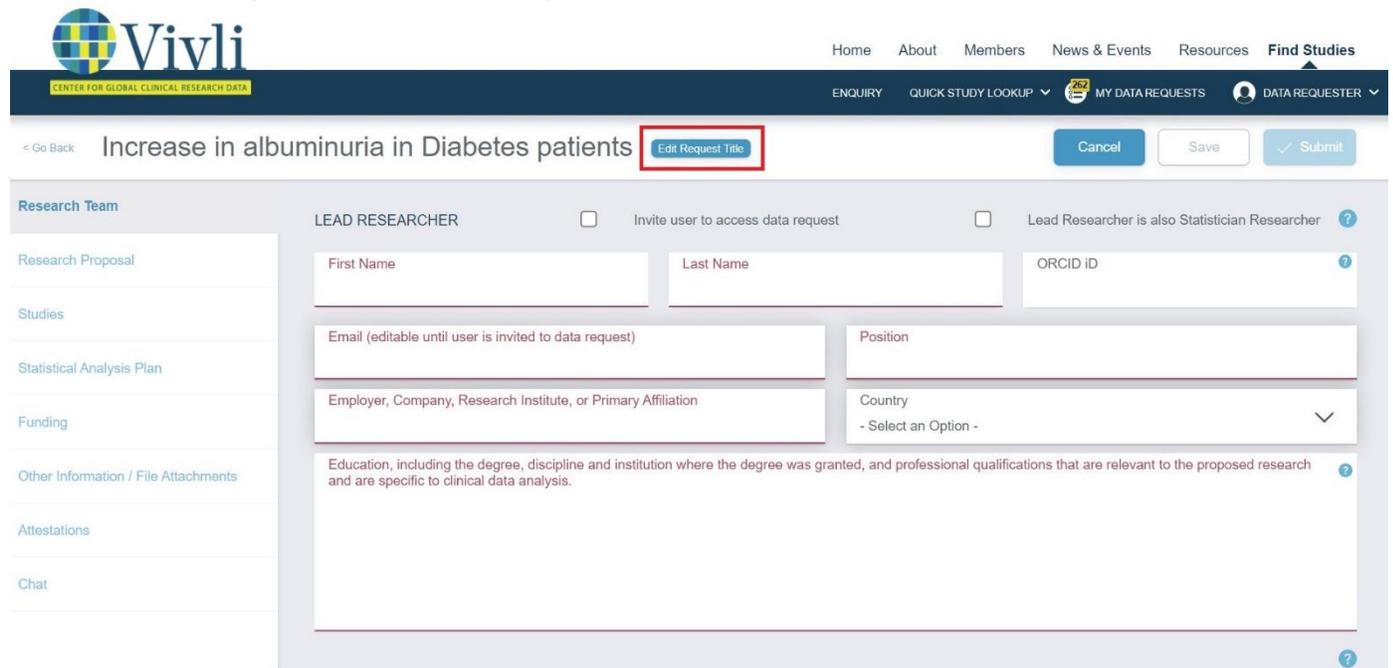
Cancel

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:



The screenshot shows the 'Edit Request Title' form for a data request titled 'Increase in albuminuria in Diabetes patients'. The form includes a sidebar with navigation options: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, and Chat. The main form area contains the following fields and options:

- LEAD RESEARCHER** (checkbox) Invite user to access data request (checkbox) Lead Researcher is also Statistician Researcher (checkbox)
- First Name (text input)
- Last Name (text input)
- ORCID iD (text input)
- Email (editable until user is invited to data request) (text input)
- Position (text input)
- Employer, Company, Research Institute, or Primary Affiliation (text input)
- Country (dropdown menu: - Select an Option -)
- Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. (text area)

Buttons for 'Cancel', 'Save', and 'Submit' are located at the top right of the form.

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

Research Data Request Title

Enter a new title for your research data request

Title

Predicting Treatment Response to combi

Save Cancel

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.

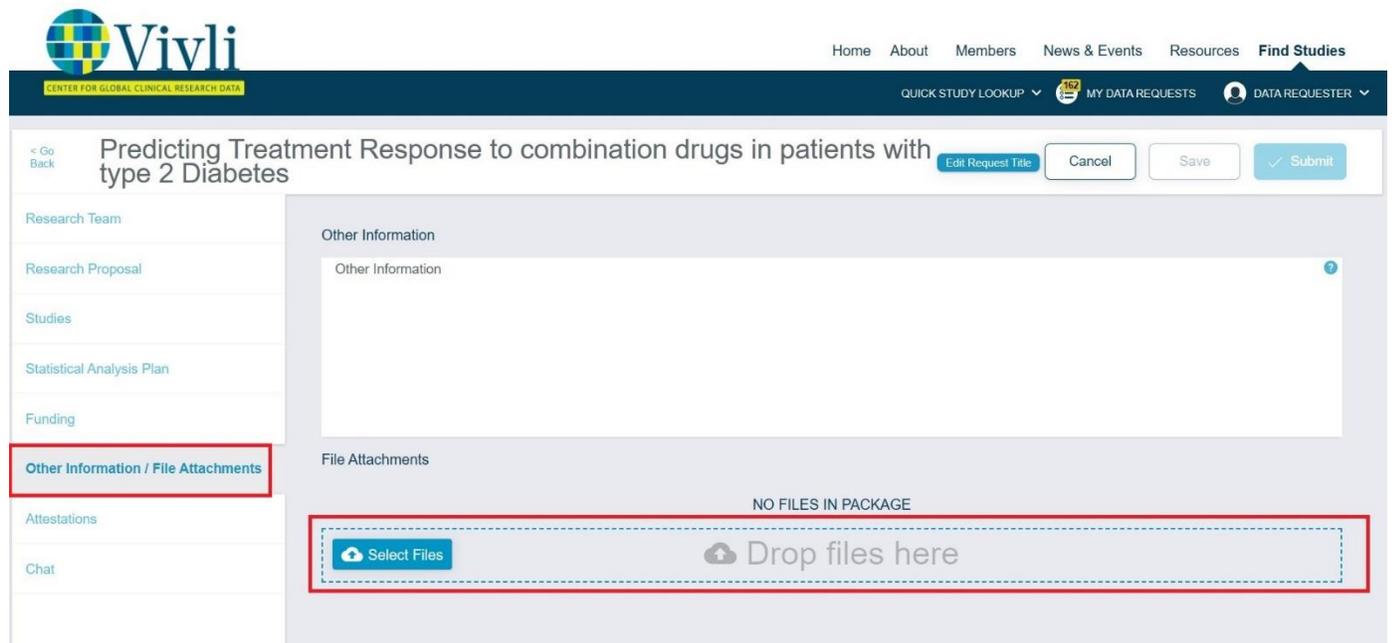
The screenshot shows the Vivli web application interface. At the top, there is a navigation bar with the Vivli logo and the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. The main navigation menu includes 'Home', 'About', 'Members', 'News & Events', 'Resources', and 'Find Studies'. Below this, there are links for 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'DATA REQUESTER'. The main content area is titled 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes'. On the left, a sidebar contains a list of tabs: 'Research Team', 'Research Proposal', 'Studies', 'Statistical Analysis Plan', 'Funding', 'Other Information / File Attachments', 'Attestations', and 'Chat'. The 'Research Team' tab is highlighted with a red border. The main content area shows the 'LEAD RESEARCHER' section with two checkboxes: 'Invite user to access data request' and 'Lead Researcher is also Statistician Researcher'. Below these are input fields for 'First Name', 'Last Name', 'Position', 'Email (editable until user is invited ...)', 'ORCID ID', and 'Employer, Company, Research Institute,...'. There is also a large text area for 'Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that a...'. At the top right of the main content area, there are buttons for 'Edit Request Title', 'Cancel', 'Save', and 'Submit'.

2.2.1 Adding Files or Other Information to your data request

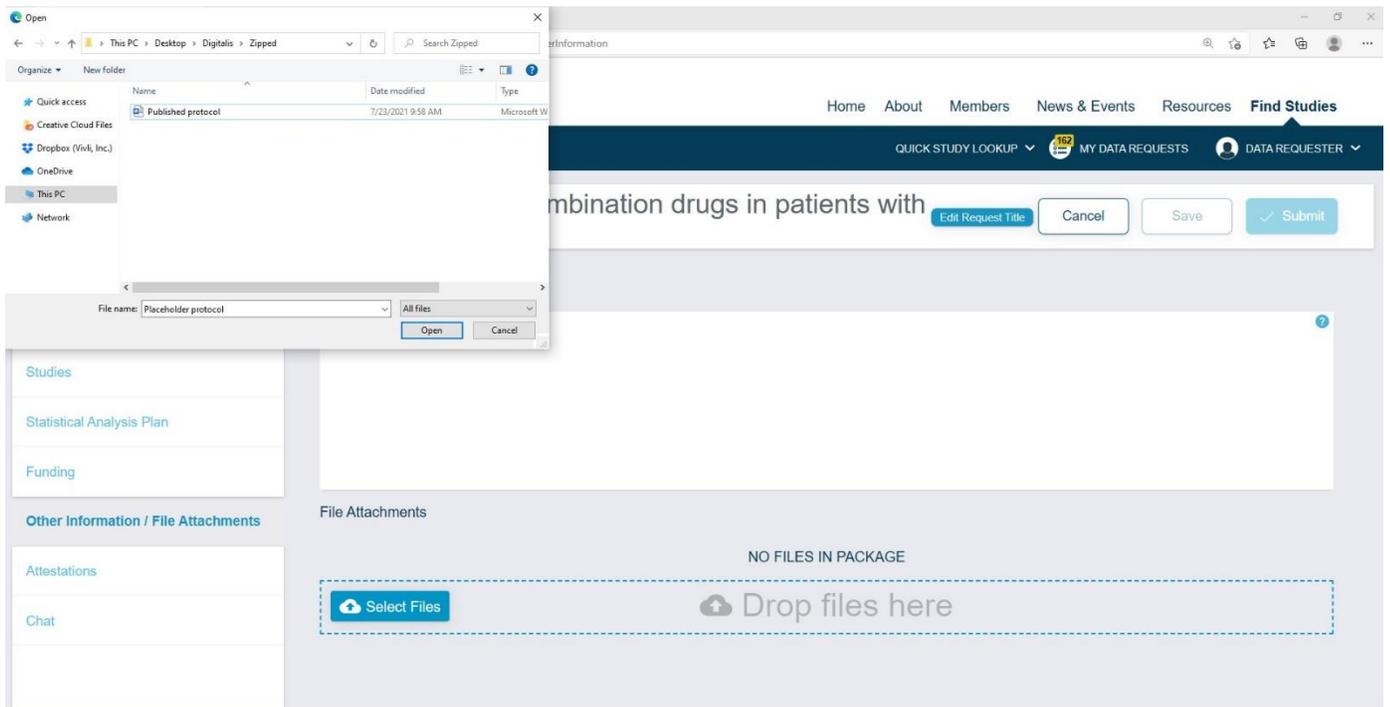
You may also attach files to your data request using the **Other Information/File Attachments** tab:

The screenshot shows the Vivli web application interface. At the top, there is a navigation bar with the Vivli logo and the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. The main navigation menu includes 'Home', 'About', 'Members', 'News & Events', 'Resources', and 'Find Studies'. Below this, there are links for 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'DATA REQUESTER'. The main content area is titled 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes'. On the left, a sidebar contains a list of tabs: 'Research Team', 'Research Proposal', 'Studies', 'Statistical Analysis Plan', 'Funding', 'Other Information / File Attachments', 'Attestations', and 'Chat'. The 'Other Information / File Attachments' tab is highlighted with a red border. The main content area shows the 'Other Information' section with a text area for 'Other Information'. Below this is the 'File Attachments' section, which displays 'NO FILES IN PACKAGE' and a dashed box containing a 'Select Files' button and the text 'Drop files here'.

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:

The screenshot shows the Vivli web application interface. The top navigation bar includes 'Home', 'About', 'Members', 'News & Events', 'Resources', and 'Find Studies'. The main header displays the Vivli logo and 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. The page title is 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes'. The left sidebar contains a menu with items: 'Research Team', 'Research Proposal', 'Studies', 'Statistical Analysis Plan', 'Funding', 'Other Information / File Attachments' (highlighted with a red box), 'Attestations', and 'Chat'. The main content area has a top bar with 'Edit Request Title', 'Cancel', 'Save', and 'Submit' buttons. Below this is the 'Other Information' section with a text input field. The 'File Attachments' section shows 'NO FILES IN PACKAGE' and a large dashed box labeled 'Drop files here' with a 'Select Files' button. A red box highlights the 'Drop files here' area.

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

The screenshot shows the Vivli web application interface with the 'Other Information / File Attachments' menu item highlighted in the sidebar. The 'File Attachments' section now displays 'UPLOADED FILES' with a table of files. A red box highlights the table and the 'Delete' button.

Filename	Size	Uploaded By	File Type	
Published protocol.docx	11.74kB	Data Requester	Unknown	Delete X

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

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. The main header displays the Vivli logo and the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. The page title is 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes'. The left sidebar contains a list of menu items: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments (highlighted in red), Attestations, and Chat. The main content area shows a 'File Attachments' section with a 'Select Files' button. Below this is a table of 'UPLOADED FILES' with the following data:

Filename	Size	Uploaded By	File Type	
Published protocol.docx	11.74kB	Data Requester	Unknown	Delete X

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

This screenshot is identical to the previous one, but with the 'Delete' button in the table highlighted in red. The table data is as follows:

Filename	Size	Uploaded By	File Type	
Published protocol.docx	11.74kB	Data Requester	Unknown	Delete X

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

< Go Back Predicting Treatment Response to combination drugs in patients with type 2 Diabetes Edit Request Title Cancel Save Submit

- Research Team
- Research Proposal
- Studies
- Statistical Analysis Plan
- Funding
- Other Information / File Attachments**
- Attestations
- Chat

Other Information

Other Information
Type in additional information

File Attachments

Select Files

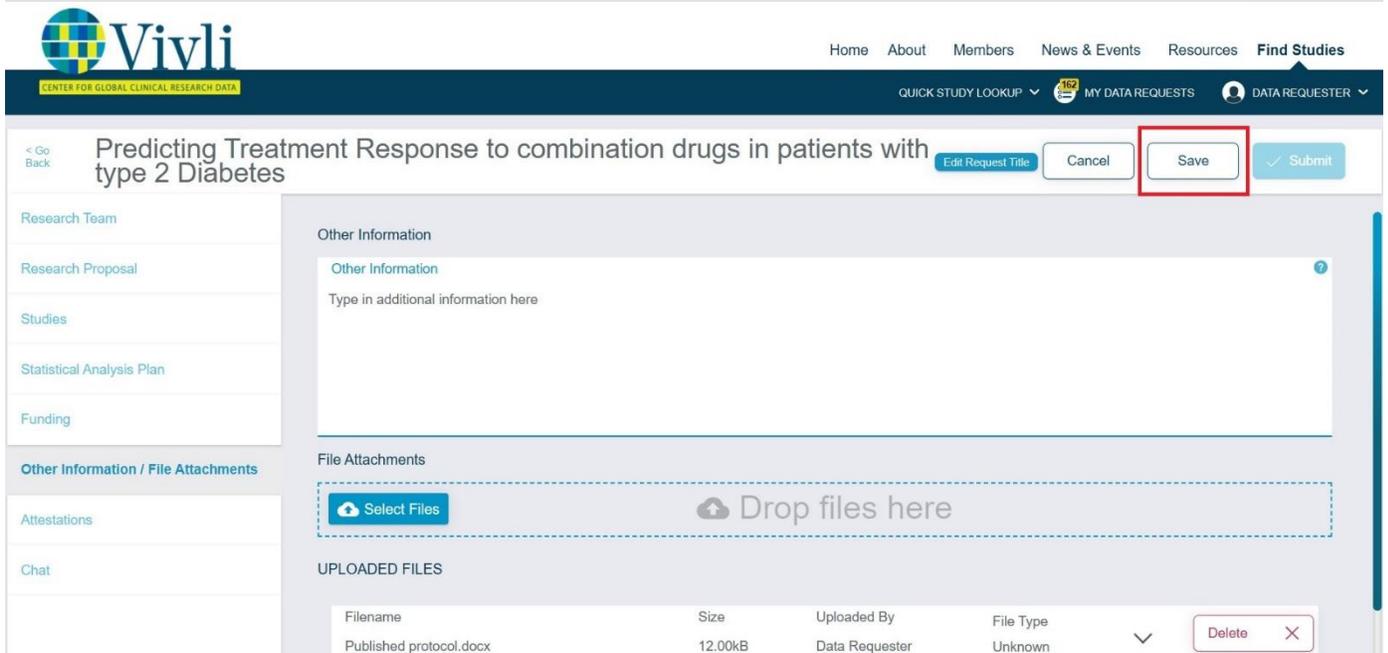
UPLOADED FILES

Filename	Size	Uploaded By	File Type	
Published protocol.docx	11.74kB	Data Requester	Unknown	Delete X

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:



< Go Back Predicting Treatment Response to combination drugs in patients with type 2 Diabetes Edit Request Title Cancel **Save** Submit

- Research Team
- Research Proposal
- Studies
- Statistical Analysis Plan
- Funding
- Other Information / File Attachments**
- Attestations
- Chat

Other Information

Other Information
Type in additional information here

File Attachments

Select Files Drop files here

UPLOADED FILES

Filename	Size	Uploaded By	File Type	
Published protocol.docx	12.00kB	Data Requester	Unknown	Delete X

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

The screenshot shows the Vivli web application interface. At the top, there is a navigation bar with the Vivli logo and the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. The main header includes 'Home About Members News & Events Resources Find Studies'. Below the header, there is a search bar and navigation links for 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'DATA REQUESTER'. The main content area is titled 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes'. On the left, there is a sidebar with a 'Research Team' section highlighted in red. The main form area has a 'LEAD RESEARCHER' section with a checkbox 'Invite user to access data request' and another checkbox 'Lead Researcher is also Statistician Researcher' highlighted in red. The form includes fields for 'First Name', 'Last Name', 'Position', 'Email (editable until user is invited to data ...)', 'ORCID ID', and 'Employer, Company, Research Institute, or Prim...'. There is also a large text area for 'Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed...' and a section for 'Please list any real or potential conflicts of interest and describe how these will be managed. If none, please enter None.'

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

Vivli Home About Members News & Events Resources **Find Studies**

QUICK STUDY LOOKUP 162 MY DATA REQUESTS DATA REQUESTER

< Go Back Predicting Treatment Response to combination drugs in patients with type 2 Diabetes Edit Request Title Cancel Save Submit

Research Team

Research Proposal

Studies

Statistical Analysis Plan

Funding

Other Information / File Attachments

Attestations

Chat

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

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

ADDITIONAL RESEARCHERS Add +

- The following dialogue box will appear:

ADDITIONAL RESEARCHER Invite user to access data request

First Name Last Name Position

Email (editable until user is invited to data re...) ORCID ID Employer, Company, Research Institute, or Primar...

Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed rese...

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

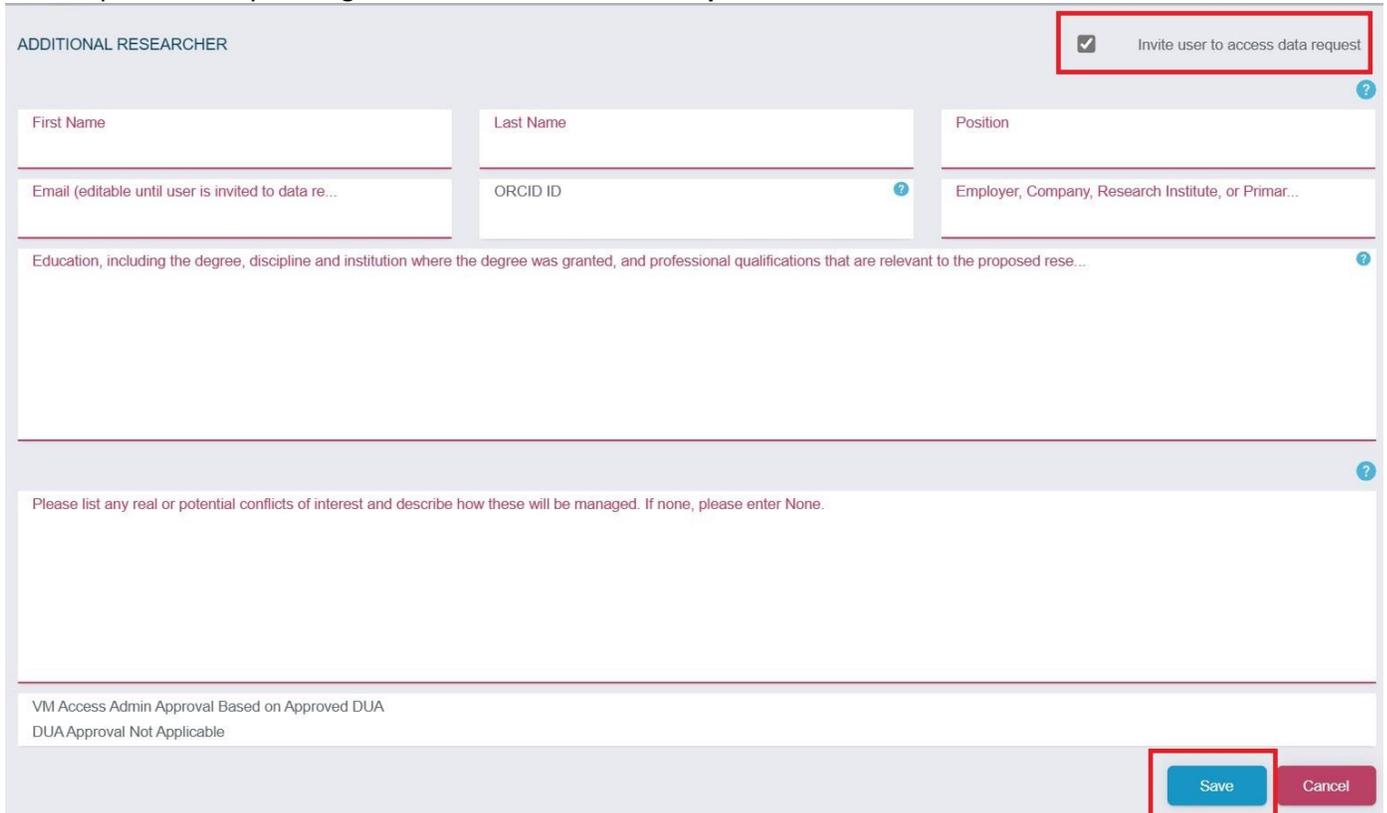
VM Access Admin Approval Based on Approved DUA
DUA Approval Not Applicable

Save Cancel

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**:

A screenshot of a web form titled "ADDITIONAL RESEARCHER". The form has a light gray header with the title on the left and a checkbox labeled "Invite user to access data request" on the right, which is checked and highlighted with a red box. Below the header are several input fields: "First Name", "Last Name", "Position", "Email (editable until user is invited to data re...)", "ORCID ID", and "Employer, Company, Research Institute, or Primar...". There is a large text area for "Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed rese...". Below that is another text area with the instruction "Please list any real or potential conflicts of interest and describe how these will be managed. If none, please enter None." At the bottom left, there is a section for "VM Access Admin Approval Based on Approved DUA" and "DUA Approval Not Applicable". At the bottom right, there are two buttons: a blue "Save" button and a red "Cancel" button, both highlighted with red boxes.

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:

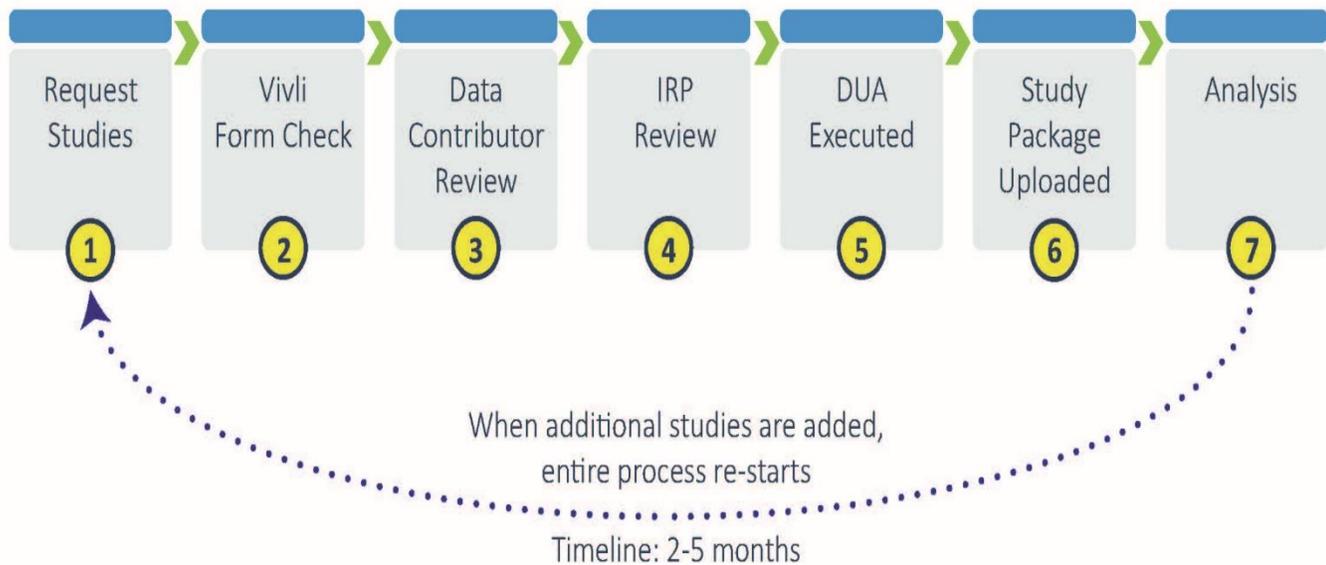


4. Click on **Ok** to remove the team member.

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.

Adding Additional Studies once your Data Request is in the Analysis Stage



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



Home About Members News & Events Resources Find Studies

QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back Predicting Treatment Response to combination drugs in patients with type 2 Diabetes Edit Request Title Cancel Save Submit

Research Team

Research Proposal

Studies

Statistical Analysis Plan

Funding

Other Information / File Attachments

Attestations

Chat

Certify Complete and Accurate

Please check the box below to indicate that you as the Lead Researcher certify that the information provided is complete and accurate, and that you assume full responsibility for the research.

I certify the information provided is complete and accurate.

Data Use Agreement

Please note that all Data Requestors wishing to receive access to data must execute the Data Use Agreement (DUA) before the data can be provided. The DUA is the product of extensive negotiation with the organizations that contribute data to Vivli, and as such, the agreement is non-negotiable. The DUA form must be completed and signed and is available [here](#).

You can either fill out the DUA form and sign it digitally, or print it out, sign it and scan it as PDF. Once the DUA has been signed by your organization, please upload it using the Signed Agreements tab of this data request (visible once the data request is submitted).

If you have any questions regarding the DUA, please contact a Vivli admin at support@vivli.org.

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

< Go Back Predicting Treatment Response to combination drugs in patients with type 2 Diabetes Edit Request Title Cancel Save Submit

- Research Team
- Research Proposal
- Studies
- Statistical Analysis Plan
- Funding
- Other Information / File Attachments

Attestations

Chat

Certify Complete and Accurate

Please check the box below to indicate that you as the Lead Researcher certify that the information provided is complete and accurate, and that you assume full responsibility for the research.

I certify the information provided is complete and accurate.

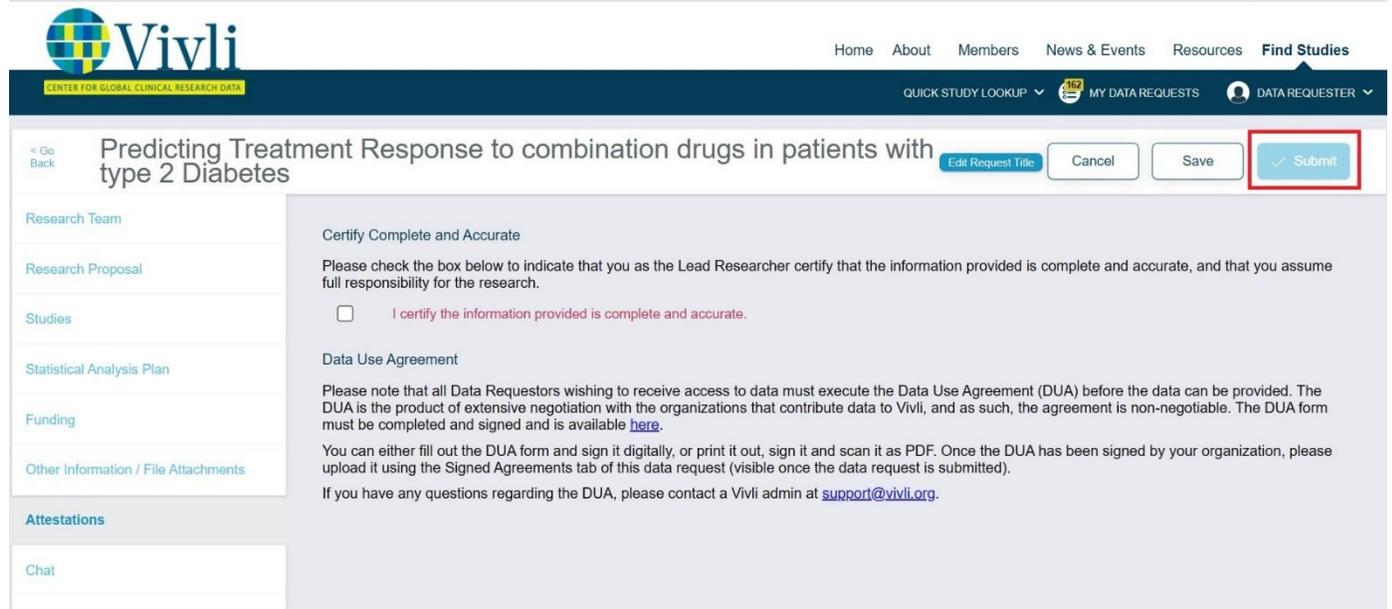
Data Use Agreement

Please note that all Data Requestors wishing to receive access to data must execute the Data Use Agreement (DUA) before the data can be provided. The DUA is the product of extensive negotiation with the organizations that contribute data to Vivli, and as such, the agreement is non-negotiable. The DUA form must be completed and signed and is available [here](#).

You can either fill out the DUA form and sign it digitally, or print it out, sign it and scan it as PDF. Once the DUA has been signed by your organization, please upload it using the Signed Agreements tab of this data request (visible once the data request is submitted).

If you have any questions regarding the DUA, please contact a Vivli admin at support@vivli.org.

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).



< Go Back Predicting Treatment Response to combination drugs in patients with type 2 Diabetes Edit Request Title Cancel Save Submit

- Research Team
- Research Proposal
- Studies
- Statistical Analysis Plan
- Funding
- Other Information / File Attachments

Attestations

Chat

Certify Complete and Accurate

Please check the box below to indicate that you as the Lead Researcher certify that the information provided is complete and accurate, and that you assume full responsibility for the research.

I certify the information provided is complete and accurate.

Data Use Agreement

Please note that all Data Requestors wishing to receive access to data must execute the Data Use Agreement (DUA) before the data can be provided. The DUA is the product of extensive negotiation with the organizations that contribute data to Vivli, and as such, the agreement is non-negotiable. The DUA form must be completed and signed and is available [here](#).

You can either fill out the DUA form and sign it digitally, or print it out, sign it and scan it as PDF. Once the DUA has been signed by your organization, please upload it using the Signed Agreements tab of this data request (visible once the data request is submitted).

If you have any questions regarding the DUA, please contact a Vivli admin at support@vivli.org.

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

The screenshot shows the Vivli website interface. At the top, there is a navigation bar with links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a dark blue header with 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS' (with a '162' badge), and 'DATA REQUESTER'. The main content area is titled 'My Data Requests (162)' and includes a search bar. A status bar below the title has five sections: Draft, Active (103), Not Approved (2), Withdrawn (56), and Archived (1). The 'Active' section is highlighted with a red box. Below the status bar, two data request entries are shown, each with a title, Vivli ID, and status. The first entry is 'PREDICTING TREATMENT RESPONSE TO COMBINATION DRUGS IN PATIENTS W' with Vivli ID 00002555 and status 'Submitted and Awaiting Vivli Request Form Check'. The second entry is 'PREDICTING TREATMENT RESPONSE TO COMBINATION DRUGS IN PATIENTS W' with Vivli ID 00002553 and status 'At least one Data Package Provided and Available'.

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

My Data Requests (162)

Draft
Active 103
Not Approved 2
Withdrawn 56
Archived 1

No Data Found

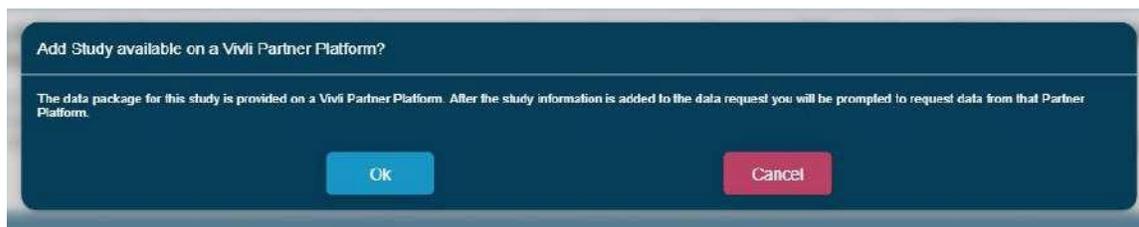
3.0 Requesting Vivli-listed studies provisioned by external providers

3.1 Overview

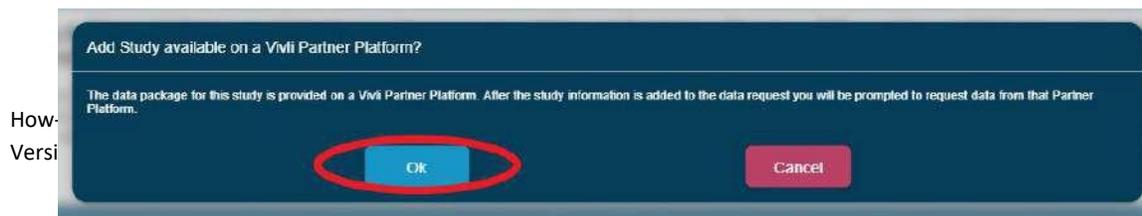
- Some studies are listed and searchable on both the Vivli platform as well as on other platforms that are Partner Platforms with Vivli.
- In addition to completing the Vivli request form, you will need to request such studies directly through the Partner Platform.
- After the relevant Data Contributor(s) 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:

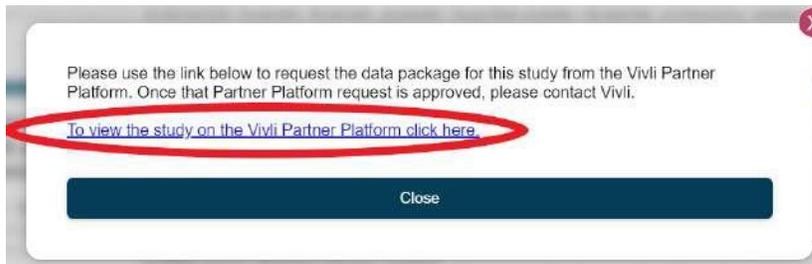


How-
Versi

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.

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

The screenshot shows the Vivli Data Request Form interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. The user is logged in as a Data Requester. The main content area displays the title of the request: "Increase in albuminuria in Diabetes patients". A sidebar on the left contains navigation options: Research Team, Research Proposal, Studies (selected), Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, and Chat. The main content area is titled "REQUESTED STUDIES" and shows a list of studies. A section titled "VIVLI-LISTED AND PROVISIONED STUDIES" contains three study entries. The first two studies are from GlaxoSmithKline. The third study, "A Randomised, Double-blind, Multicentre Phase II/III Study to Compare the Eff...", is highlighted with a red box and labeled "VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS". This study is from AstraZeneca and Project Data Sphere, LLC. Each study entry includes details such as PI, Sponsor, Study ID, IRP/Approver, Data Request ID, and Data Contributor, along with a status indicator and a "Remove" button.

- 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**.

Home About Members News & Events Resources **Find Studies**

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back Increase in albuminuria in Diabetes patients Edit Request Title Cancel Save Submit

Research Team

Research Proposal

Studies

Statistical Analysis Plan

Funding

Other Information / File Attachments

Attestations

Chat

VIVLI-LISTED AND PROVISIONED STUDIES

Clinical Assessment of GSK716155 for Type 2 Diabetes Mellitus -A Phase I/II S...
 PI: Sponsor: GlaxoSmithKline Study ID: NCT00530309 IRP/Approver: Wellcome Trust Data Request ID: Data to be loaded after approval Remove x >
 Sponsor ID: GLP107865 Data Contributor: GlaxoSmithKline IPD Uploaded: No

A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group, ...
 PI: Sponsor: GlaxoSmithKline Study ID: NCT01000506 IRP/Approver: Wellcome Trust Data Request ID: Data already on platform Remove x >
 Sponsor ID: 112997 Data Contributor: GlaxoSmithKline IPD Uploaded: Yes

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

A Randomised, Double-blind, Multicentre Phase II/III Study to Compare the Eff...
 PI: Sponsor: AstraZeneca Study ID: NCT00384176 IRP/Approver: Project Data Sphere, LLC Data Request ID: Data to be loaded after approval Remove x >
 Sponsor ID: D8480C0013 Data Contributor: Project Data Sphere, LLC IPD Uploaded: No

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI Add +

No Studies Found

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.

Home About Members News & Events Resources **Find Studies**

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back Increase in albuminuria in Diabetes patients Edit Request Title Cancel Save Submit

Research Team

Research Proposal

Studies

Statistical Analysis Plan

Funding

Other Information / File Attachments

Attestations

Chat

REQUESTED STUDIES ? ↓

VIVLI-LISTED AND PROVISIONED STUDIES

Clinical Assessment of GSK716155 for Type 2 Diabetes Mellitus -A Phase I/II S...
 PI: Sponsor: GlaxoSmithKline Study ID: NCT00530309 IRP/Approver: Wellcome Trust Data Request ID: Data to be loaded after approval Remove x >
 Sponsor ID: GLP107865 Data Contributor: GlaxoSmithKline IPD Uploaded: No

A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group, ...
 PI: Sponsor: GlaxoSmithKline Study ID: NCT01000506 IRP/Approver: Wellcome Trust Data Request ID: Data already on platform Remove x >
 Sponsor ID: 112997 Data Contributor: GlaxoSmithKline IPD Uploaded: Yes

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

A Randomised, Double-blind, Multicentre Phase II/III Study to Compare the Eff...
 PI: Sponsor: AstraZeneca Study ID: NCT00384176 IRP/Approver: Project Data Sphere, LLC Data Request ID: Data to be loaded after approval Remove x >
 Sponsor ID: D8480C0013 Data Contributor: Project Data Sphere, LLC IPD Uploaded: No

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:

The screenshot displays the Vivli web application interface. At the top, the Vivli logo and navigation menu are visible. The main content area shows a data request form for a study titled "Predicting Treatment Response to combination drugs in patients with type 2 Diabetes". The form includes a sidebar with navigation options such as "Research Team", "Research Proposal", "Studies", "Statistical Analysis Plan", "Funding", "Other Information / File Attachments", "Attestations", "Request History", and "Chat". The main content area is divided into sections: "REQUESTED STUDY TYPES", "VIVLI-LISTED AND PROVISIONED STUDIES", and "VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS". The "VIVLI-LISTED AND PROVISIONED STUDIES" section contains two study entries, each with a "Remove" button and a right arrow. The "VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS" section shows "No Studies Found". A red box highlights the "STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI" section, which contains an "Add +" button.

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

Members page.' Below the text are two input fields: 'Select provider of the data' with a dropdown menu showing 'Select Provide...' and a downward arrow, and 'Provide NCT or Sponsor ID of the study or the name of the tools or data' which is empty. Below these is a large text area with the placeholder 'Provide the study title, or the description of the study, data, or tools'."/>

Request Studies, Data, or Tools not listed on Vivli

If you will be providing your own data, tools or scripts, then as the provider, select "I WILL BRING MY OWN" and provide a name and a description for the data, tool, or script. You will be notified when to 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: Select Provide... ▼

Provide NCT or Sponsor ID of the study or the name of the tools or data: [Empty]

Provide the study title, or the description of the study, data, or tools

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

Request Studies, Data, or Tools not listed on Vivli

OWN" and provide a name and a description for the data, tool, or script. You will be notified when to 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: Pfizer Inc. ▼

Provide NCT or Sponsor ID of the study or the name of the tools or data: NCT012345678

Provide the study title, or the description of the study, data, or tools

Study Title

Submit Cancel

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:

Request Studies, Data, or Tools not listed on Vivli

If you will be providing your own data, tools or scripts, then as the provider, select "I WILL BRING MY OWN" and provide a name and a description for the data, tool, or script. You will be notified when to 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](#).

A study, data or tool provided by Pfizer Inc. was successfully added to the Data Request.

If you will be providing the data or tools or are requesting them using the Vivli Request Form, you can dismiss this window by clicking on Back.

[To access more information on Vivli member data sharing click here.](#)

[Add Another Study, Data, or Tool](#) [Back](#)

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

Request Studies, Data, or Tools not listed on Vivli

If you will be providing your own data, tools or scripts, then as the provider, select "I WILL BRING MY OWN" and provide a name and a description for the data, tool, or script. You will be notified when to 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](#).

A study, data or tool provided by Pfizer Inc. was successfully added to the Data Request.

If you will be providing the data or tools or are requesting them using the Vivli Request Form, you can dismiss this window by clicking on Back.

[To access more information on Vivli member data sharing click here.](#)

[Add Another Study, Data, or Tool](#) [Back](#)

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

Request Studies, Data, or Tools not listed on Vivli

If you will be providing your own data, tools or scripts, then as the provider, select "I WILL BRING MY OWN" and provide a name and a description for the data, tool, or script. You will be notified when to 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](#).

A study, data or tool provided by Pfizer Inc. was successfully added to the Data Request.

If you will be providing the data or tools or are requesting them using the Vivli Request Form, you can dismiss this window by clicking on Back.

[To access more information on Vivli member data sharing click here.](#)

Add Another Study, Data, or Tool

Back

8. The studies will appear in the study list

Predicting Treatment Response to combination drugs in patients with type 2 Diabetes

REQUESTED STUDY TYPES

VIVLI-LISTED AND PROVISIONED STUDIES

Effects of Cystic Fibrosis and Cystic Fibrosis Related Diabetes on Brain Stru...	Data already on platform	Remove X	>
A Randomized, Double-blind, Single-dose, Placebo Controlled, 2-way Cross-over...	Data already on platform	Remove X	>

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

No Studies Found

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI Add +

Study Title	Pfizer Inc.	Study ID	NCT01234567	Data Request ID	00002555	Sponsor ID	false	Data to be loaded after approval	Remove X
-------------	-------------	----------	-------------	-----------------	----------	------------	-------	----------------------------------	----------

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:

The screenshot displays the Vivli web application interface. At the top, the Vivli logo is on the left, and navigation links (Home, About, Members, News & Events, Resources, Find Studies) are on the right. Below the logo, the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA' is visible. The main header area includes 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'DATA REQUESTER'. The main content area is titled 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes'. On the left, there is a sidebar with navigation options: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, Request History, and Chat. The main content area is divided into sections: 'REQUESTED STUDY TYPES', 'VIVLI-LISTED AND PROVISIONED STUDIES', and 'VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS'. The 'VIVLI-LISTED AND PROVISIONED STUDIES' section contains two study entries, each with a 'Remove' button and a right arrow. The 'VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS' section shows 'No Studies Found' and a red box highlighting the text 'STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI' with an 'Add +' button next to it.

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

Request Studies, Data, or Tools not listed on Vivli

If you will be providing your own data, tools or scripts, then as the provider, select "I WILL BRING MY OWN" and provide a name and a description for the data, tool, or script. You will be notified when to 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 Provide NCT or Sponsor ID of the study or the name of the tools or data

Select Provide... [Text Input]

Provide the study title, or the description of the study, data, or tools

[Text Area]

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

Provide NCT or Sponsor ID of the study or the name of the tools or data

I WILL BRING M...



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:

Request Studies, Data, or Tools not listed on Vivli

If you will be providing your own data, tools or scripts, then as the provider, select "I WILL BRING MY OWN" and provide a name and a description for the data, tool, or script. You will be notified when to 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](#).

A study, data or tool provided by I WILL BRING MY OWN was successfully added to the Data Request.

If you will be providing the data or tools or are requesting them using the Vivli Request Form, you can dismiss this window by clicking on Back.

[To access more information on Vivli member data sharing click here.](#)

Add Another Study, Data, or Tool

Back

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



[Home](#) [About](#) [Members](#) [News & Events](#) [Resources](#) [Find Studies](#)

QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back

Predicting Treatment Response to combination drugs in patients with type 2 Diabetes

Edit Request Title Cancel Save Submit

Research Team

Research Proposal

Studies

Statistical Analysis Plan

Funding

Other Information / File Attachments

Attestations

Request History

Chat

REQUESTED STUDY TYPES ? ↓

VIVLI-LISTED AND PROVISIONED STUDIES

Effects of Cystic Fibrosis and Cystic Fibrosis Related Diabetes on Brain Stru...
PI: Sponsor: University of Minnesota Study ID: NCT03820349 IRP/Approver: Wellcome Trust Data Request ID: 00002555
Sponsor ID: MED-2018-25438 Data Contributor: GlaxoSmithKline IPD Uploaded: Yes Data already on platform Remove × >

A Randomized, Double-blind, Single-dose, Placebo Controlled, 2-way Cross-over...
PI: Sponsor: GlaxoSmithKline Study ID: NCT02496221 IRP/Approver: Wellcome Trust Data Request ID: 00002555 Sponsor ID: 201834
Data Contributor: GlaxoSmithKline IPD Uploaded: Yes Data already on platform Remove × >

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

No Studies Found

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI Add +

Data collected during my own clinical trial
PI: Data Contributor: I WILL BRING MY OWN Study ID: false Data Request ID: 00002555 Sponsor ID: 123456
- - IPD Uploaded: No Data to be loaded after approval Remove ×

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.

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 Provide NCT or Sponsor ID of the study or the name of the tools or data

I WILL BRING M... 000000

Provide the study title, or the description of the study, data, or tools

I want to use program <xyz> and can provide the license key to authorize its use in the Vivli Research Environment

Submit Cancel

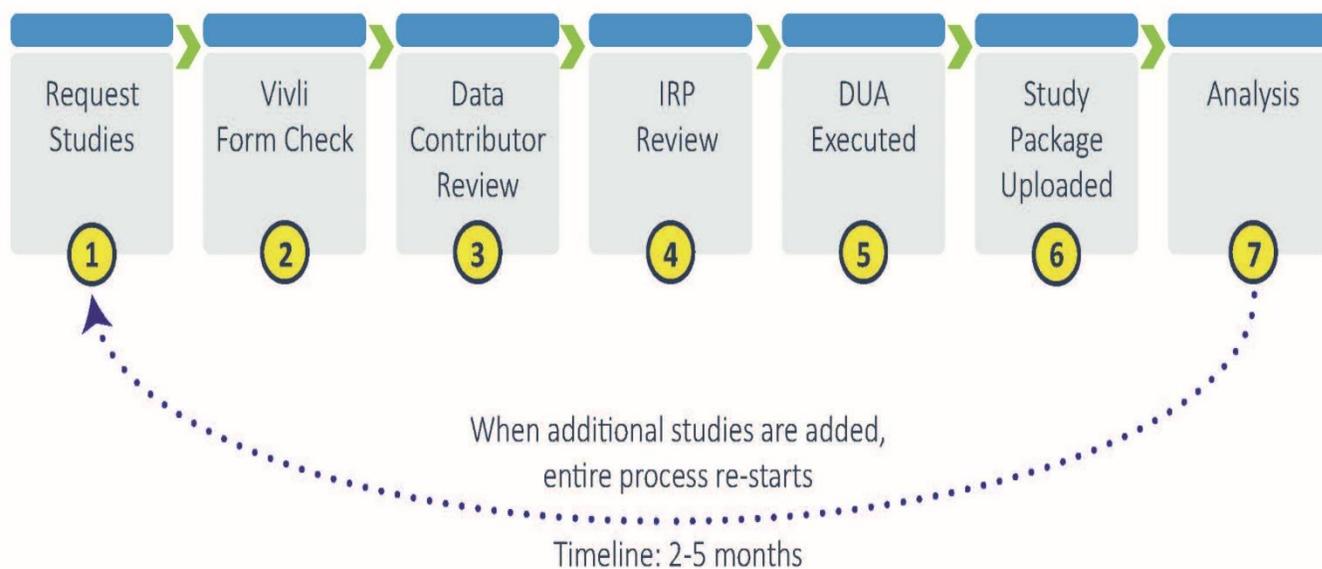
6.0 Modifying or revising your data request

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.

Adding Additional Studies once your Data Request is in the Analysis Stage



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:

My Data Requests (162)

Search data requests

Draft Active 103 Not Approved 2 Withdrawn 56 Archived 1

PREDICTING TREATMENT RESPONSE TO COMBINATION DRUGS IN PATIENTS WITH TYPE 2 DI/
Vivli ID: 00002555
Status: Draft

PREDICTING TREATMENT RESPONSE TO COMBINATION DRUGS IN PATIENTS WITH TYPE 2 DI/
Vivli ID: 00002553
Status: At least one Data Package Provided and Available

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

Predicting Treatment Response to combination drugs in patients with type 2 Diabetes

Print

Date and Time	Action	Performed By	Comments
10/6/21 3:57 pm	Status changed to Submitted To Vivli	Data Requester Datarequester.vivli@gmail.com	Submitted by Data Requester
10/6/21 4:04 pm	Status changed to Draft	Amrutha Baskaran abaskaran@vivli.org	Reset to Draft
10/6/21 4:40 pm	Status changed to Submitted To Vivli	Data Requester Datarequester.vivli@gmail.com	Submitted by Data Requester
10/6/21 4:41 pm	Status changed to Awaiting Data Contributor Review	Amrutha Baskaran abaskaran@vivli.org	

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:

The screenshot shows the Vivli website's 'My Data Requests' page. The top navigation bar includes 'Home', 'About', 'Members', 'News & Events', 'Resources', and 'Find Studies'. A secondary navigation bar contains 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS' (with a '162' badge), and 'DATA REQUESTER'. The main heading is 'My Data Requests (162)' with a search bar. Below this, there are tabs for 'Draft' (2), 'Active' (103), 'Not Approved' (2), 'Withdrawn' (56), and 'Archived' (1). Two request cards are displayed, both for the study 'PREDICTING TREATMENT RESPONSE TO COMBINATION DRUGS IN PATIENTS W'. The first card shows a status of 'Submitted and Awaiting Vivli Request Form Check' and a Vivli ID of 00002555. The second card shows a status of 'At least one Data Package Provided and Available' and a Vivli ID of 00002553.

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

The screenshot shows the Vivli website's 'Open Chat' interface for a specific data request. The page title is 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes'. The left sidebar has 'Chat' highlighted. The main content area shows 'Open Chat' and 'Requestors' tabs. There is a large text input area, a 'Send' button, and a file upload section with 'Select Files' and 'Drop files here' options. A 'Print' button is visible in the top right corner.

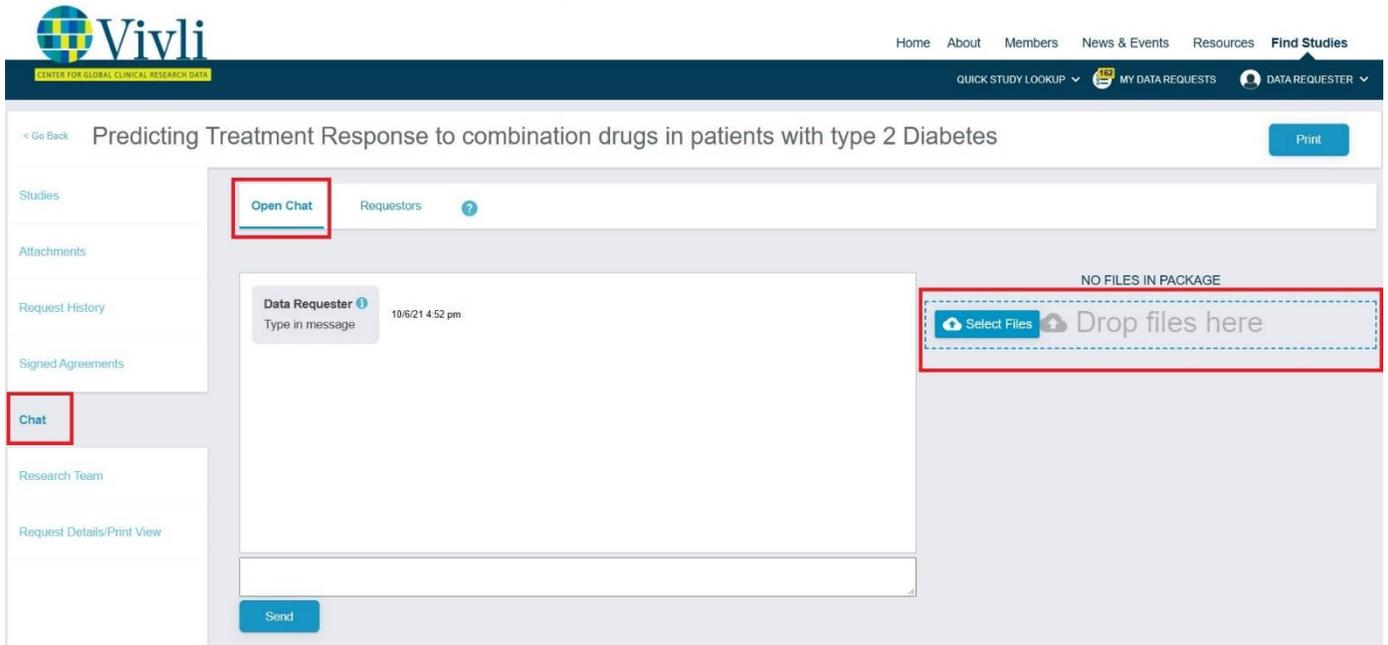
3. Enter your message in the chat message box and click **Send**:

The screenshot shows the Vivli website interface. At the top, there is a navigation bar with the Vivli logo and the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. The main navigation includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this, there are utility links: QUICK STUDY LOOKUP, MY DATA REQUESTS, and DATA REQUESTER. The main content area is titled 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes' and includes a 'Print' button. On the left, there is a sidebar with links for Studies, Attachments, Request History, Signed Agreements, Chat, Research Team, and Request Details/Print View. The central chat area has tabs for 'Open Chat' and 'Requestors'. A large text input field is present, with a red box highlighting it and the 'Send' button below it. To the right of the input field, there is a file upload area with the text 'NO FILES IN PACKAGE' and a 'Drop files here' instruction, along with a 'Select Files' button.

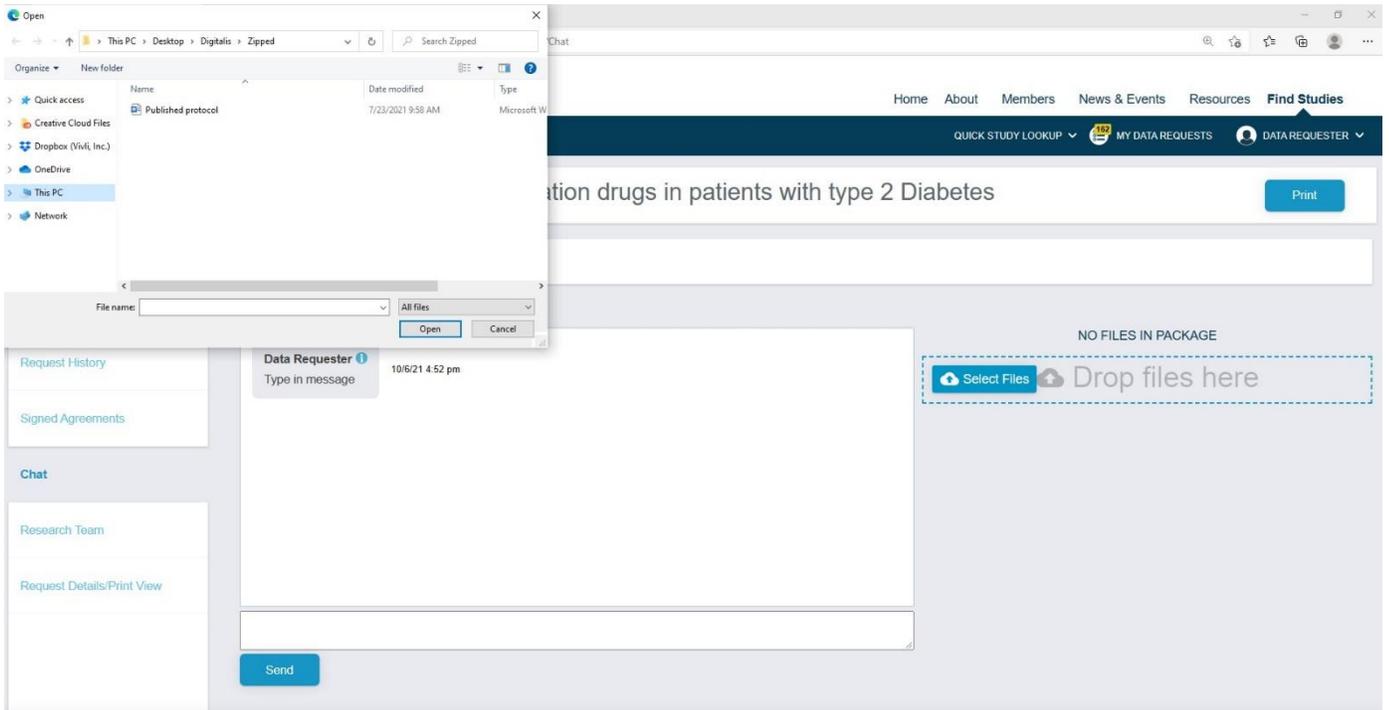
4. The message will now appear in the Chat record for all users (to see your just-entered chat message, you may need to click Refresh on your browser), and response will also appear in the chat record:

This screenshot shows the same Vivli website interface as the previous one, but now the chat message has been sent. The 'Open Chat' tab in the chat area is highlighted with a red box. The chat message is displayed as a bubble with the text 'Data Requester 10/6/21 4:52 pm Type in message'. The 'Chat' link in the left sidebar is also highlighted with a red box. The rest of the interface, including the navigation bar, sidebar, and file upload area, remains the same.

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:

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources **Find Studies**

QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back Predicting Treatment Response to combination drugs in patients with type 2 Diabetes Print

Studies

Attachments

Request History

Signed Agreements

Chat

Research Team

Request Details/Print View

Open Chat Requestors ?

Data Requester 10/6/21 4:52 pm
Type in message

Data Requester 10/6/21 4:56 pm
File Uploaded: Published protocol.docx

Select Files

UPLOADED FILES

Filename	Size	Uploaded By		
Published protoc...	11...	Data Re...	Download	Delete (X)

Send

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

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources **Find Studies**

QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back Predicting Treatment Response to combination drugs in patients with type 2 Diabetes Print

Studies

Attachments

Request History

Signed Agreements

Chat

Research Team

Request Details/Print View

Open Chat Requestors ?

Data Requester 10/6/21 4:52 pm
Type in message

Data Requester 10/6/21 4:56 pm
File Uploaded: Published protocol.docx

Select Files

UPLOADED FILES

Filename	Size	Uploaded By		
Published protoc...	11...	Data Re...	Download	Delete (X)

Send

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

The screenshot shows the Vivli website interface for a study titled "Predicting Treatment Response to combination drugs in patients with type 2 Diabetes". The chat window is open, showing a message from a "Data Requester" at 10/6/21 4:52 pm: "Type in message". A second message at 10/6/21 4:56 pm says "File Uploaded: Published protocol.docx". To the right, there is a "Select Files" button and an "UPLOADED FILES" table. The table has columns for "Filename", "Size", and "Uploaded By". One file is listed: "Published protoc..." with size "11..." and uploaded by "Data Re...". A red box highlights the download arrow icon in the table's action column.

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

The screenshot shows the same Vivli chat interface. The chat history now includes a third message at 10/6/21 5:01 pm: "File Deleted: Published protocol.docx". This message is highlighted with a red box. The "UPLOADED FILES" table is now empty, displaying "NO FILES IN PACKAGE". The "Select Files" button remains visible.

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.

< Go Back Predicting Treatment Response to combination drugs in patients with type 2 Diabetes

Print

- Studies
- Attachments
- Request History
- Signed Agreements**
- Chat
- Research Team
- Request Details/Print View

There are no Signed Documents

If you have not already done so, please upload the signed and completed copy of the DUA

Select Files

UPLOADED FILES

Filename	Size	Uploaded By
2021_10_05 Vivli ID 00002553_DUA executed final.pdf	673.80KB	Data Requester

Download

- 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**:

< Go Back Predicting Treatment Response to combination drugs in patients with type 2 Diabetes

Print

- Studies
- Attachments
- Request History**
- Signed Agreements
- Safety Concerns
- Chat
- Research Team
- Research Environment
- Request Details/Print View

10/5/21 4:04 pm	Status changed to Submitted To Vivli	Data Requester Datarequester.vivli@gmail.com	Submitted by Data Requester
10/5/21 4:10 pm	Status changed to Awaiting Data Contributor Review	Amrutha Baskaran abaskaran@vivli.org	In the last round of review, Vivli Member 1 requested revision. As a result, PI added additional study. For detailed information on the changes made, please see attachment "2021_10_05 Vivli ID 00002553_form check completion report" in chat. Any changes to studies are considered major revision and therefore, data contributors are provided with the opportunity to review the proposal with these revisions.
10/5/21 5:36 pm	Status changed to Data Request: "Predicting Treatment Response to combination drugs in patients with type 2 Diabetes" with Id 31e30c7e-421c-493b-b130-4991d1d9c470, approved by Data Contributor Approver.	Sally dataprovider.vivli@gmail.com	
10/5/21 5:36 pm	Status changed to Awaiting IRP/Approver Approval. The last Data Contributor pre-check was the final Data Contributor pre-check required, so the request status is changed to Awaiting IRP/Approver Approval.		
10/5/21 5:38 pm	Status changed to Data Request: "Predicting Treatment Response to combination drugs in patients with type 2 Diabetes" with Id 31e30c7e-421c-493b-b130-4991d1d9c470, approved by IRP/Approver.	Amrutha Baskaran abaskaran@vivli.org	
10/5/21 5:38 pm	Status changed to Approved The last Approval was the final Approval required, so the request status is changed to Approved.		
10/5/21 5:39 pm	Status changed to Awaiting DUA Validation	Amrutha Baskaran abaskaran@vivli.org	Begin DUA Validation
10/5/21 5:39 pm	Status changed to Data Use Agreement (DUA) Validated by Vivli Admin	Amrutha Baskaran abaskaran@vivli.org	

- 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.