



# How-To: Request Studies on Vivli

Vivli Platform Release 3.3

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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 studies you would like to use for your analysis.
- To do this, you will need 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 overview](#)
  - Please review the [Vivli policies in brief](#) about active requests and active enquiries before submitting a data request.

### 1.1 Searching for studies on the Vivli platform

- To search for studies on the Vivli platform using the search page, <https://search.vivli.org/> enter a search term into the Keyword search bar where it says ‘What are you looking for today’, and/or use the drop-down filters. 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 bar, a banner reads "We are committed to advancing the knowledge around the COVID-19 pandemic" with "Share trials" and "Search for trials" buttons. 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 "ENQUIRY" links, and a "QUICK STUDY LOOKUP" dropdown menu. Below the search bar, there 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, SPONSOR, and SAMPLE SIZE), "LOCATION", and "START DATE" (with "From" and "To" date pickers). A "1366 Studies" count is displayed at the bottom of the filter panels. The footer contains links for "How To Guide", "Privacy", "Cookie Policy", "EEA Disclosure Policy", and "Contact Us", along with a copyright notice "© Copyright 2017 - 2023 Vivli".

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

The screenshot shows the Vivli website's search interface. At the top, the Vivli logo and navigation links (Home, About, Members, News & Events, Resources, Find Studies) are visible. A banner at the top states, "We are committed to advancing the knowledge around the COVID-19 pandemic". Below this, there are 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 is a "PICO Beta" link. Below the search bar, there are filters for "STUDY DESIGN", "SPONSOR INFORMATION", "LOCATION", and "START DATE". The "STUDY DESIGN" filter shows "INTERVENTIONAL STUDIES" and "OBSERVATIONAL STUDIES" with "Select Multiple" dropdowns. The "SPONSOR INFORMATION" filter shows "SPONSOR TYPE" and "SPONSOR" with "Select Multiple" dropdowns. The "LOCATION" filter shows "Select Multiple" with a dropdown. The "START DATE" filter shows "From" and "To" date inputs. At the bottom of the search results, a blue bar indicates "83 Studies".

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

The screenshot shows the Vivli website's search results page. At the top, the Vivli logo and navigation links (Home, About, Members, News & Events, Resources, Find Studies) are visible. A banner at the top states, "We are committed to advancing the knowledge around the COVID-19 pandemic". Below this, there are 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 is a "PICO Beta" link. Below the search bar, there are filters for "STUDY DESIGN", "SPONSOR INFORMATION", "LOCATION", and "START DATE". The "STUDY DESIGN" filter shows "INTERVENTIONAL STUDIES" and "OBSERVATIONAL STUDIES" with "Select Multiple" dropdowns. The "SPONSOR INFORMATION" filter shows "SPONSOR TYPE" and "SPONSOR" with "Select Multiple" dropdowns. The "LOCATION" filter shows "Select Multiple" with a dropdown. The "START DATE" filter shows "From" and "To" date inputs. At the bottom of the search results, a blue bar indicates "83 Studies".

The search results page displays a list of studies. 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". It includes details such as IDs (NCT00530309 | GLP107865), Condition or Disease (Diabetes Mellitus, Type 2), and Intervention/treatment (GSK716155 for injection, Placebo). To the right of the study details are buttons for "Log in to Request Study" and "View Study Details". 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". It includes details such as IDs (NCT01031108 | 114089), Condition or Disease (Diabetes Mellitus, Type 2), and Intervention/treatment (Placebo, SRT2104). To the right of the study details are buttons for "Log in to Request Study" and "View Study Details". 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)". It includes details such as IDs (NCT01031108 | 114089), Condition or Disease (Diabetes Mellitus, Type 2), and Intervention/treatment (Placebo, SRT2104). To the right of the study details are buttons for "Log in to Request Study" and "View Study Details".

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

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP Sign up Log In

**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**

**Study Details** Study Documents Administrative Details Usage

Phase  
Phase 1

Condition or Disease  
Diabetes Mellitus, Type 2

Intervention/treatment  
GSK716155 for injection, Placebo

Brief Summary  
A Phase I/II study to investigate the safety, pharmacokinetics and pharmacodynamics of GSK716155 in Japanese subjects with type 2 diabetes mellitus

Ages Eligible For Study  
20 Years to 70 Years

Sexes Eligible For Study  
All

Accepts Healthy Volunteers  
No

Actual Enrollment  
40

Locations

## 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:

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP Sign up Log In

diabetes CLOSE

**STUDY DESIGN**  
INTERVENTIONAL STUDIES  
Select Multiple

**OBSERVATIONAL STUDIES**  
Select Multiple

**STUDY PHASE**  
Select Multiple

**SPONSOR INFORMATION**  
SPONSOR TYPE  
Select Multiple

**SPONSOR**  
Select Multiple

**SAMPLE SIZE**  
(Disabled) ☐

**LOCATION**  
Select Multiple

**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**

IDs: NCT00530309 | GLP107865  
Condition or Disease: Diabetes Mellitus, Type 2  
Intervention/treatment: GSK716155 for injection, Placebo

**Log in to Request Study**

**View Study Details**

Number enrolled: 40  
Phase 1

**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**

IDs: NCT01031108 | 114089  
Condition or Disease: Diabetes Mellitus, Type 2  
Intervention/treatment: Placebo, SRT2104

**Log in to Request Study**

**View Study Details**

Number enrolled: 38  
Phase 1

**A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Ranging Study of Oral GW677954 as a Monotherapy for 12 Weeks Duration in Patients With Type 2 Diabetes Mellitus**

IDs: NCT00196989 | ADG20001  
Condition or Disease: Diabetes Mellitus, Type 2  
Intervention/treatment: Pioglitazone, GW677954

**Log in to Request Study**

**View Study Details**

Number enrolled: 448  
Phase 2

**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)**

**Log in to Request Study**

**View Study Details**

## 1.3 Add studies to your data request

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

The screenshot shows the Vivli website interface. At the top, there is a navigation bar with links: Home, About, Members, News & Events, Resources, and Find Studies. Below this is a search bar with the text "What are you looking for today?" and a "CLOSE" button. On the left side, there are filters for "STUDY DESIGN" (INTERVENTIONAL STUDIES, OBSERVATIONAL STUDIES), "STUDY PHASE", "SPONSOR INFORMATION" (SPONSOR TYPE), and "SPONSOR". The main content area displays three clinical studies, each with a "Request Study" button highlighted by a red box. The studies are:

- 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**  
IDs: NCT00530309 | GLP107865  
Condition or Disease: Diabetes Mellitus, Type 2  
Intervention/treatment: GSK716155 for injection, Placebo  
Number enrolled: 40  
Phase 1
- 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**  
IDs: NCT01031108 | 114089  
Condition or Disease: Diabetes Mellitus, Type 2  
Intervention/treatment: Placebo, SRT2104  
Number enrolled: 38  
Phase 1
- 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)**  
Number enrolled: 118  
Phase 3

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

The screenshot shows a dropdown menu that appears after clicking the "Request Study" button. The menu contains the option "+ Add New Request", which is highlighted by a red circle. Other options visible in the menu include "View Study Details", "Number enrolled: 118", and "Phase 3".

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

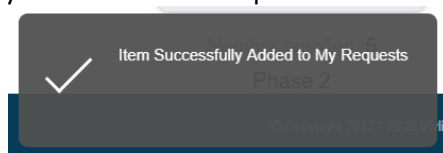


### New Research Data Request


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.

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:



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

[Click here to view your data requests.](#)


**MY DATA REQUESTS**


**DATA REQUESTER**

CLOSE

STUDY DESIGN

INTERVENTIONAL STUDIES

Select Multiple

OBSERVATIONAL STUDIES

Select Multiple

STUDY PHASE

Select Multiple

SPONSOR INFORMATION

SPONSOR TYPE

Select Multiple

SPONSOR

Select Multiple

**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**

Request Study
View Study Details

IDs: NCT00530309 | GLP107865  
Condition or Disease: Diabetes Mellitus, Type 2  
Intervention/treatment: GSK716155 for injection, Placebo

Number enrolled:40  
Phase 1

**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**

Request Study
View Study Details

IDs: NCT01031108 | 114089  
Condition or Disease: Diabetes Mellitus, Type 2  
Intervention/treatment: Placebo, SRT2104

Number enrolled:38  
Phase 1

**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)**

Request Study
View Study Details

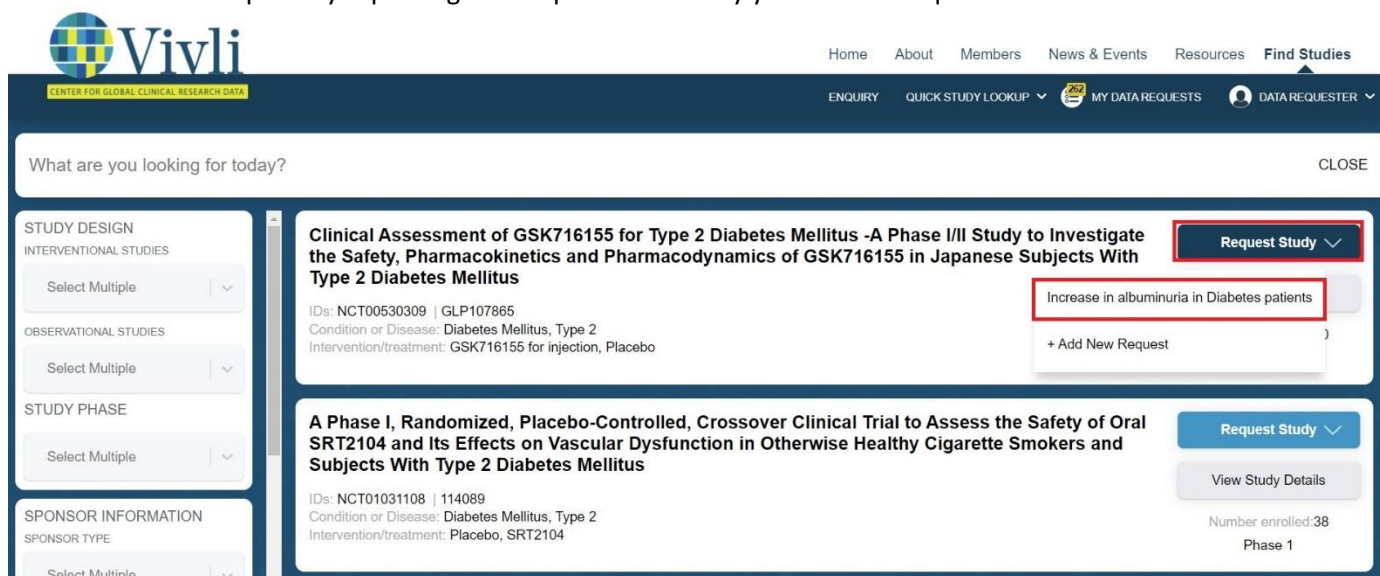
Item Successfully Added to My Requests

[How To Guide](#)
[Privacy](#)
[Cookie Policy](#)
[EEA Disclosure Policy](#)
[Contact Us](#)

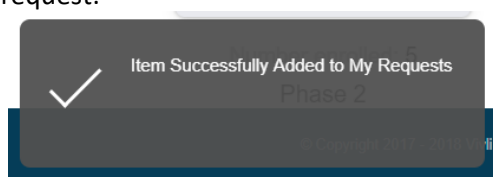
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6. To add an additional study to an existing data request, click on **Request Study**. Then click on the existing data request's title from the dropdown. Note: If you have multiple studies to add to your research project, add them to the same request by repeating this step for each study you want to request.



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



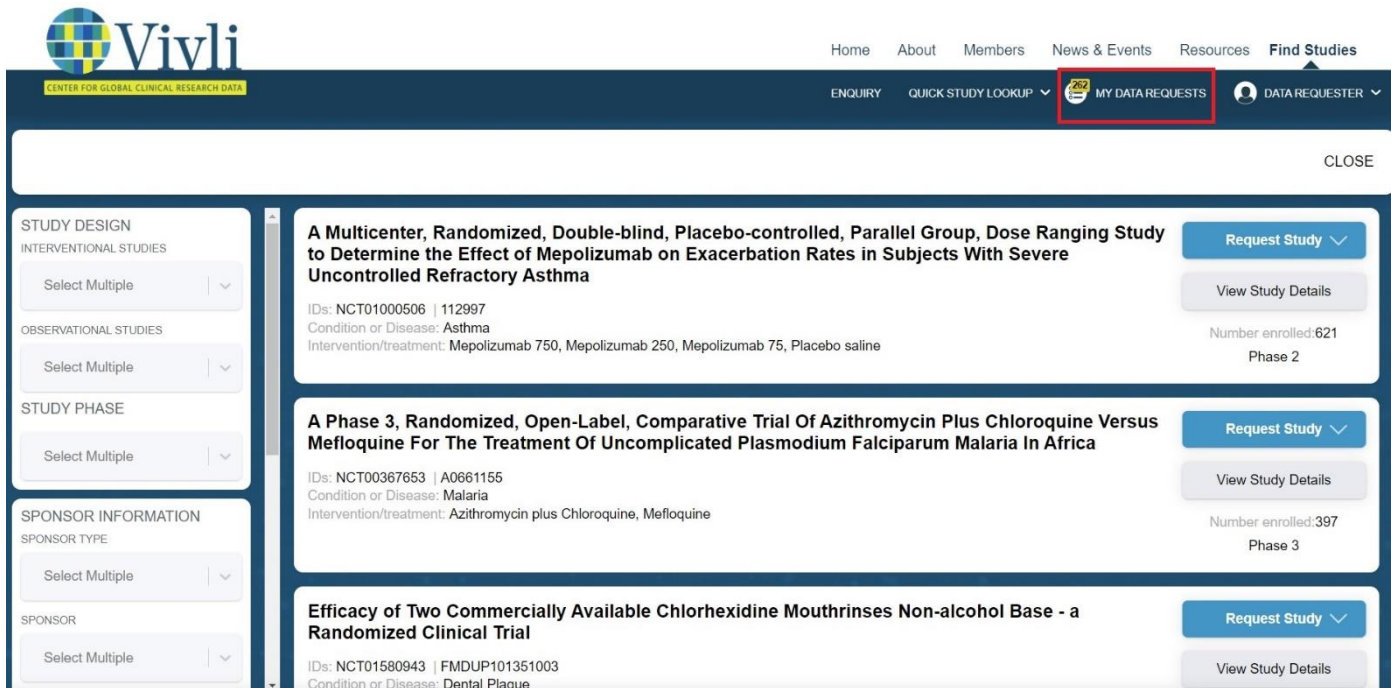
8. Once you have added all desired studies listed on the Vivli platform, you can complete the Data Request Form (See 2.0 Your Data Requests for more information).

## 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 of the six-month notification email the account will be deactivated. If you want your account re-activated, you can email us at [support@vivli.org](mailto: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:

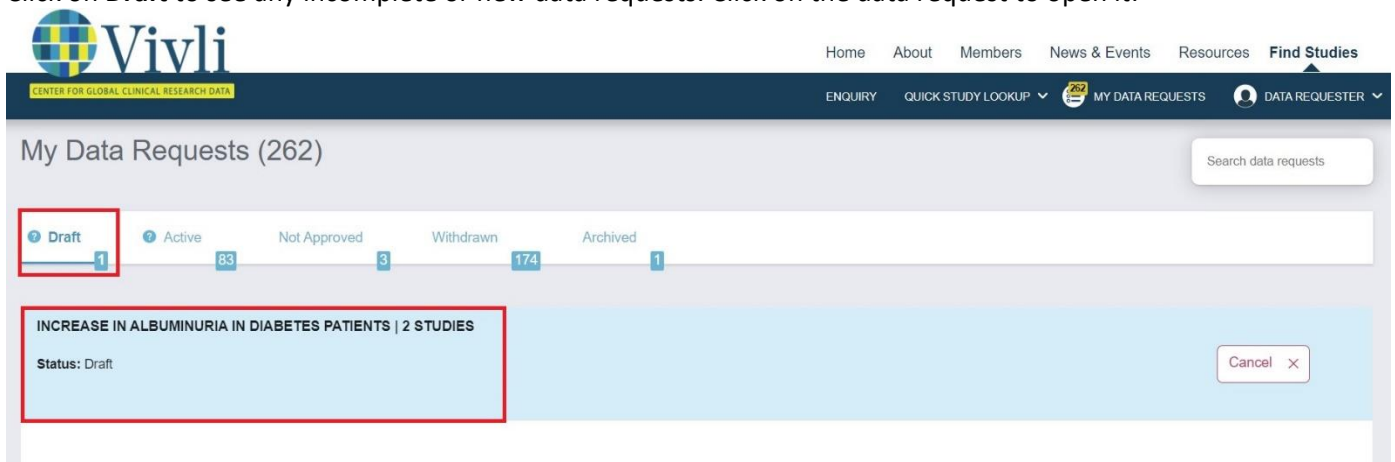


The screenshot shows the Vivli dashboard. In the top navigation bar, the 'MY DATA REQUESTS' link is highlighted with a red box. Below the navigation bar, there are filters for Study Design, Study Phase, and Sponsor Information. The main content area lists three studies:

- 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**  
IDs: NCT01000506 | 112997  
Condition or Disease: Asthma  
Intervention/treatment: Mepolizumab 750, Mepolizumab 250, Mepolizumab 75, Placebo saline  
Buttons: Request Study, View Study Details  
Number enrolled: 621, Phase 2
- A Phase 3, Randomized, Open-Label, Comparative Trial Of Azithromycin Plus Chloroquine Versus Mefloquine For The Treatment Of Uncomplicated Plasmodium Falciparum Malaria In Africa**  
IDs: NCT00367653 | A0661155  
Condition or Disease: Malaria  
Intervention/treatment: Azithromycin plus Chloroquine, Mefloquine  
Buttons: Request Study, View Study Details  
Number enrolled: 397, Phase 3
- Efficacy of Two Commercially Available Chlorhexidine Mouthrinses Non-alcohol Base - a Randomized Clinical Trial**  
IDs: NCT01580943 | FMDUP101351003  
Condition or Disease: Dental Plaque  
Buttons: Request Study, View Study Details

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

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



The screenshot shows the 'My Data Requests (262)' page. The 'Draft' tab is selected and highlighted with a red box. Below the tabs, a data request titled 'INCREASE IN ALBUMINURIA IN DIABETES PATIENTS | 2 STUDIES' is shown with a status of 'Draft'. The page also includes a search bar and a 'Cancel' button.

### 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 Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this, a secondary bar contains ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and RESEARCHER. The main content area displays the title 'Predicting Treatment Response to combination drugs in patients with type 2 diabetes' with an 'Edit Request Title' button highlighted in a red box. To the right of the title are 'Cancel', 'Save', and 'Submit' buttons. On the left, a sidebar lists various sections: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, Request History, and Chat. The 'Research Team' section is active, showing fields for LEAD RESEARCHER / STATISTICIAN, including First Name, Last Name, Email, Position, and Country. There is also a checkbox for 'Invite user to access data request' and a checkbox for 'Lead Researcher is also Statistician Researcher'.

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

The dialog box is titled 'Research Data Request Title'. It contains the instruction 'Enter a new title for your research data request'. Below this is a text input field with the placeholder text 'Title' and the current title 'Predicting Treatment Response to combi'. At the bottom of the dialog are two buttons: 'Save' (blue) and 'Cancel' (red).

## 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 and position, country, qualifications, degrees and where the degrees were obtained of all team members.
- Conflict of Interest Statement
- The title of the proposed research with a description of the study design (which should match the Project name)
- Lay summary explaining the relevance of the project to science and public health

- Brief description, main predictor variable and outcome elements, specific aims and objectives and hypothesis to be evaluated
- Purpose of analysis and outcomes
- Project timeline, dissemination and publication plan.
- Statistical Analysis Plan
- Information about funding
- Attestation
- All other required fields, including all data sets associated with the proposal
  - This includes studies you may request from Vivli; studies requested from other Data Sharing Platforms 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”.

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

< 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

**LEAD RESEARCHER / STATISTICIAN**

☐ Invite user to access data request ☒ Lead Researcher is also Statistician Researcher

First Name Last Name ORCID ID

Email (editable until ...) Position

Employer, Company, Research Institute, or Pr... Country  
United States of America

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. Character Count: 0/1000

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

## 2.2.1 Adding Files or Other Information to your data request

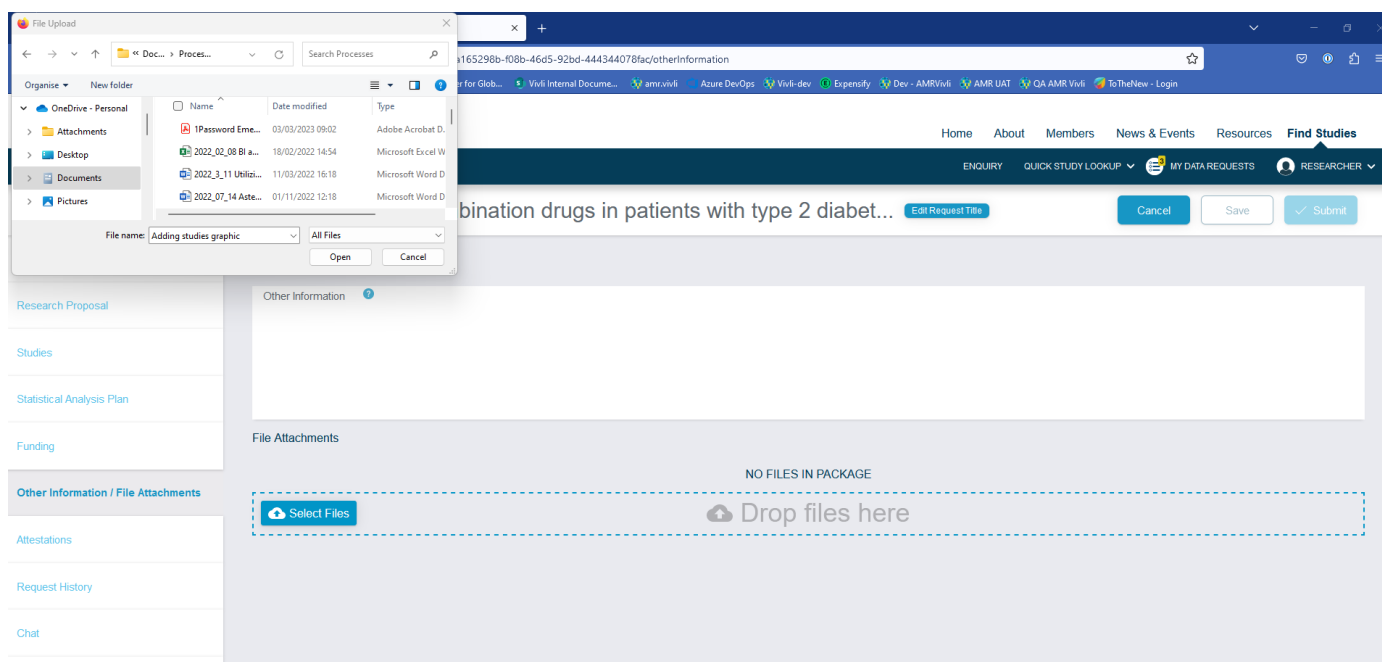
1. You may also attach files to your data request using the **Other Information/File Attachments** tab:

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a secondary bar with ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and RESEARCHER. The main header displays the Vivli logo and the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. The breadcrumb trail shows '< Go Back' followed by 'Predicting Treatment Response to combination drugs in patients with type 2 diabet...'. The left sidebar contains a list of tabs: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments (highlighted with a red box), Attestations, Request History, and Chat. The main content area is divided into two sections: 'Other Information' with a text input field and an information icon, and 'File Attachments' which displays 'NO FILES IN PACKAGE' and a dashed box containing a 'Select Files' button and the text 'Drop files here'.

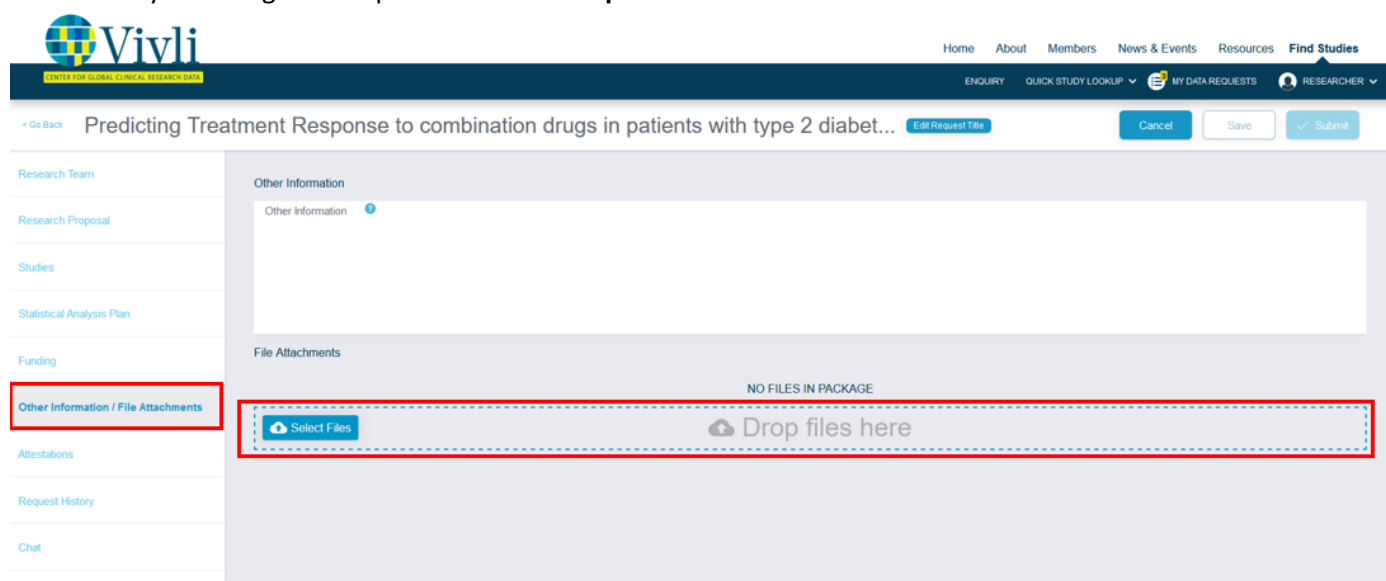
2. Click on **Select Files** to choose a file:

This screenshot is identical to the one above, showing the same Vivli web application interface. The 'Other Information / File Attachments' tab is highlighted in the sidebar. In this view, the 'Select Files' button within the 'File Attachments' section is highlighted with a red box, indicating the next step in the process.

3. Then simply select the file from your computer:



4. You may also drag and drop files into the ‘Drop files here’ box:





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

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Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

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

Research Team

Research Proposal

Studies

Statistical Analysis Plan

Funding

**Other Information / File Attachments**

Attestations

Request History

Chat

Other Information

Other Information ⓘ

File Attachments

Select Files

UPLOADED FILES

Filename	Size	Uploaded By	File Type	
Study protocol.pdf	4.81kB	Researcher	Unknown	▼ Delete ✕

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

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

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

Research Team

Research Proposal

Studies

Statistical Analysis Plan

Funding

**Other Information / File Attachments**

Attestations

Request History

Chat

Other Information

Other Information ⓘ

File Attachments

Select Files

UPLOADED FILES

Filename	Size	Uploaded By	File Type	
Study protocol.pdf	4.81kB	Researcher	Unknown	▼ Delete ✕

File Type

Unknown

Research Proposal Supplement

Funding information

Statistical Analysis Plan

Other

Unknown

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

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a secondary navigation bar with links for ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and RESEARCHER. The main content area is titled 'Predicting Treatment Response to combination drugs in patients with type 2 diabet...' and includes buttons for 'Edit Request Title', 'Cancel', 'Save', and 'Submit'. On the left, a sidebar menu lists various sections: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments (highlighted with a red box), Attestations, Request History, and Chat. The main content area is divided into two sections: 'Other Information' and 'File Attachments'. The 'Other Information' section contains a large text input area, which is highlighted with a red box. The 'File Attachments' section includes a 'Select Files' button and a table of uploaded files. The table has columns for Filename, Size, Uploaded By, and File Type. A 'Delete' button with a red 'X' icon is highlighted with a red box in the bottom right corner of the table.

Filename	Size	Uploaded By	File Type
Study protocol.pdf	4.81kB	Researcher	Unknown

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

This screenshot is similar to the previous one, showing the same Vivli web application interface. The 'Other Information' text area is highlighted with a red box. The 'File Attachments' section is also visible, showing the 'Select Files' button and the table of uploaded files. The 'Delete' button is also visible in the bottom right corner of the table.

Filename	Size	Uploaded By	File Type
Study protocol.pdf	4.81kB	Researcher	Unknown

## 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:

The screenshot displays the Vivli Data Request Form 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, a tagline reads 'CENTRE FOR GLOBAL CLINICAL RESEARCH DATA'. The main header area shows the title 'Predicting Treatment Response to combination drugs in patients with type 2 diabet...' and buttons for 'Cancel', 'Save' (highlighted with a red box), and 'Submit'. The left sidebar contains a menu with options like Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments (selected), Attestations, Request History, and Chat. The main content area is divided into 'Other Information' (a text input field) and 'File Attachments' (a dashed box with a 'Select Files' button). Below this is a table titled 'UPLOADED FILES' with columns for Filename, Size, Uploaded By, and File Type. One file, 'Study protocol.pdf', is listed with a size of 4.81kB, uploaded by 'Researcher', and of type 'Unknown'. A 'Delete' button is visible next to the file entry.

## 2.4 Adding Research Team Members

- Individuals activated for a data request will be able to view and edit the Data Request Form
- 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 to have a DUA in place from their institution before accessing the data.

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

The screenshot shows the Vivli website interface for the 'Predicting Treatment Response' form. The 'Research Team' section is highlighted with a red box. Within this section, the 'LEAD RESEARCHER' area contains several input fields: 'First Name', 'Last Name', 'Email', 'Position', 'Employer, Company, Research Ins...', and 'Country'. A checkbox labeled 'Lead Researcher is also Statistician Researcher' is highlighted with a red box. Below these fields 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 research and are specific to clinical data analysis.' At the bottom of the form, there is a section for 'Please list any real or potential conflicts of interest and describe how these will be managed. If none, please enter None.'

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

The screenshot shows the same Vivli website interface, but scrolled down to the 'ADDITIONAL RESEARCHERS' section. The 'Research Team' section is still visible on the left. The 'ADDITIONAL RESEARCHERS' section contains 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 research and are specific to clinical data analysis.' Below this is another section for 'Please list any real or potential conflicts of interest and describe how these will be managed. If none, please enter None.' At the bottom of the form, there is a section for 'VM Access Admin Approval Based on Approved DUA' and 'DUA Approval Not Applicable'. The 'Add +' button in the lower right corner is highlighted with a red box.

3. The following dialogue box will appear:

**ADDITIONAL RESEARCHER** Activate user for accessing data request ?

First Name  Last Name  ORCID iD

Email (editable until user is invited to da...  Position

Employer, Company, Research Institute, or Primary Aff...  Country

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. Character Count: 0/1000

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

4. Note that the character limit in the Education text field is 1000 characters. If the number of characters entered exceeds this limit, a pop up will appear alerting you that the Education/qualification field exceeds the limit:

First Name  Last Name  ORCID iD

Ema...  Position

Employer, Company, Research Ins...  Country

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. Character Count: 1223/1000

Please see below for my education including degree, discipline and institution where the degree wa granted. I also included qualifications specific to this analysis  
Education of Lead Researcher:  
Bachelor's Degree from University of California, San Francisco where I obtained a degree in Biological Life Sciences in 1998  
Master's Degree from University of California, San Francisco where I obtained a degree in Epidemiology in 2000  
PhD from University of California, San Francisco where I obtained a degree in Epidemiology in 2006

Other qualifications:

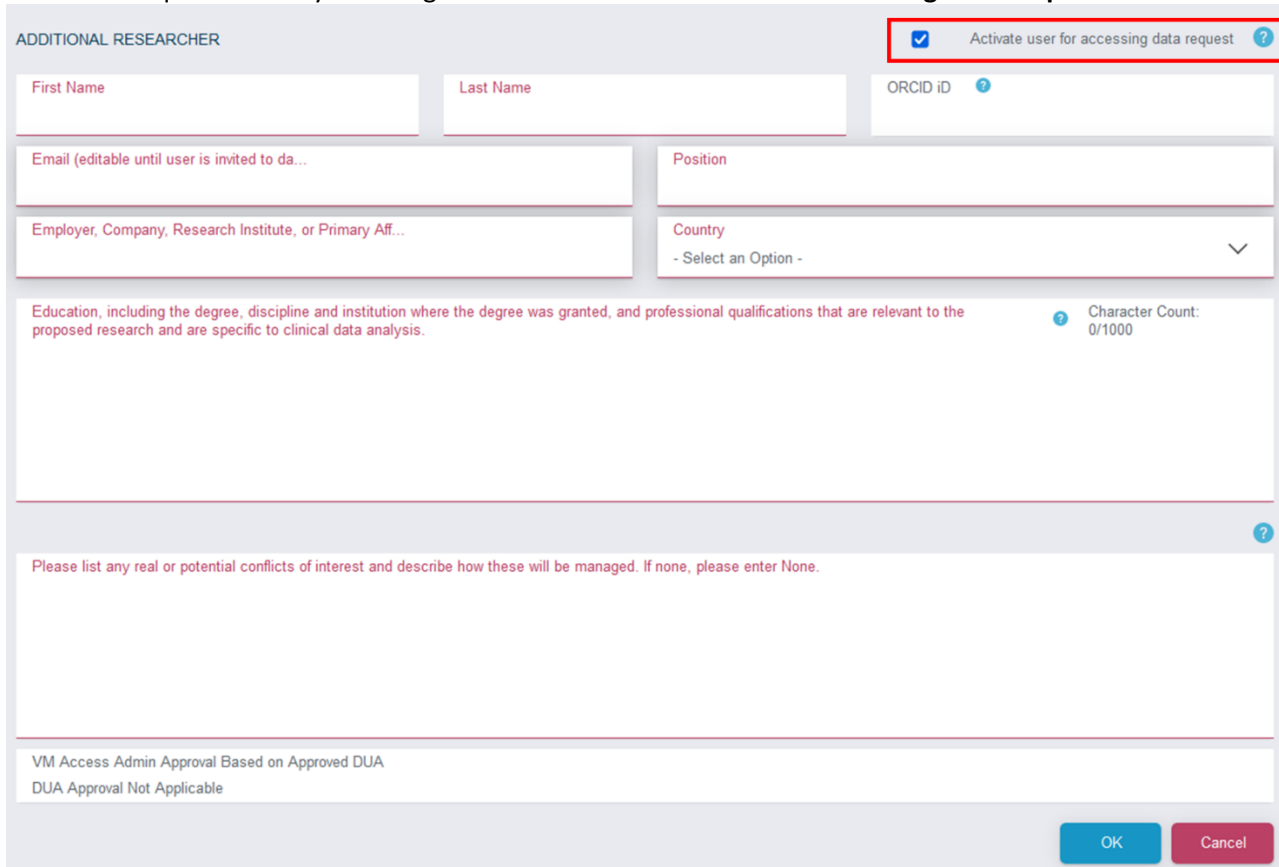
Please list any real or potential conflicts of interest and describe how these will be managed. If none, please enter None.

5. Complete all fields, and click



6. 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](#)

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

The image shows a web form titled "ADDITIONAL RESEARCHER". At the top right, there is a checkbox labeled "Activate user for accessing data request" which is checked, and it is highlighted with a red rectangular box. Below the title, there are several input fields: "First Name", "Last Name", and "ORCID iD" (with a help icon). Below these are "Email (editable until user is invited to da...)" and "Position". Further down are "Employer, Company, Research Institute, or Primary Aff..." and "Country" (a dropdown menu showing "- Select an Option -"). 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 research and are specific to clinical data analysis." is present, with a "Character Count: 0/1000" indicator. Below the education field is a section for "Please list any real or potential conflicts of interest and describe how these will be managed. If none, please enter None." At the bottom, there is a section for "VM Access Admin Approval Based on Approved DUA" and "DUA Approval Not Applicable". The form ends with "OK" and "Cancel" buttons.



- On the main data request form, click **Save**. The team member will be automatically added to the data request.

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

**Research Team**

LEAD RESEARCHER / STATISTICIAN ☐ Activate user for accessing data request ☒ Lead Researcher is also Statistician Researcher ?

First Name Sarah Last Name Jones ORCID ID ?

Email (editable until user is invited to data...) sarah.jones@ucsd.utorg Position Biostatistician

Employer, Company, Research Institute, or Primary Affil... Country United States of America

University of California, San Diego

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. Character Count: 129/1000

PhD in Biostatistics (University of California, San Diego, 1999)  
MS in Biostatistics (University of California, San Diego, 1995)

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

None

## 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:

- Open your draft data request and Click on the **Research Team** tab:
- Under **ADDITIONAL RESEARCHERS**, click on the three vertical dots in the lower right-hand corner and select **Remove Team member**:

Vivli  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP 434 MY DATA REQUESTS DATA REQUESTER

< Go Back Albumin in... 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.

na

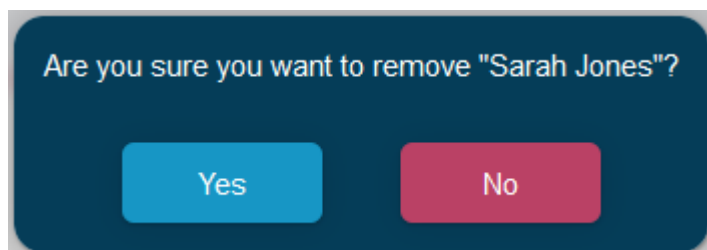
VM Access Admin Approval Based on Approved DUA  
DUA Approval Not Applicable

**ADDITIONAL RESEARCHERS**

Sarah Jones (ADDITIONAL RESEARCHER)

Remove Team Member  
Activate Member for Access to Data Request

3. The following pop-up will appear:

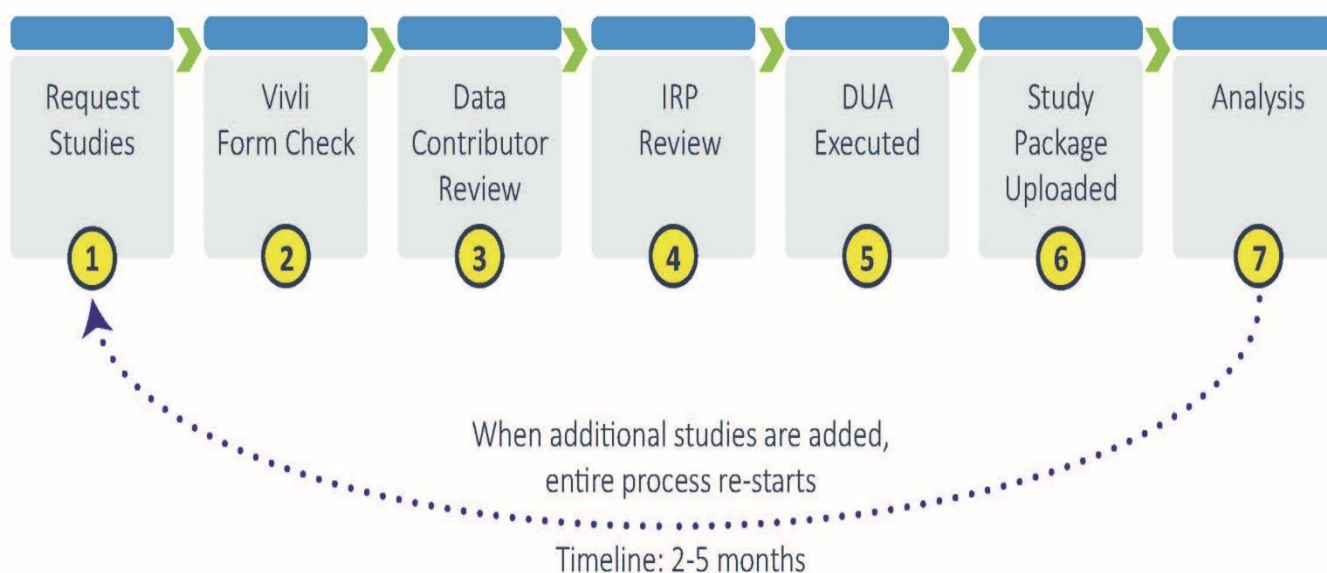


4. Click on **Yes** to remove the team member.

## 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. If you have ongoing enquiries for studies involved in this project, please wait until all the enquiries are closed before submitting the data request.
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:

The screenshot shows the Vivli website interface for a data request titled "Predicting Treatment Response to combination drugs in patients with type 2 diabetes". The left sidebar contains a list of tabs: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations (highlighted with a red box), and Chat. The main content area is titled "Certify Complete and Accurate" and contains a checkbox labeled "I certify the information provided is complete and accurate." which is checked. Below this is a section for the "Data Use Agreement" with text explaining the requirements for data access and a link to the DUA form. The top right of the form has buttons for "Cancel", "Save", and "Submit".

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

This screenshot is identical to the previous one, showing the same data request form. However, the "Submit" button in the top right corner is now highlighted with a red box, indicating it is the next step in the process.

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 including the "Country" field).

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

< 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](mailto:support@vivli.org).

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

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

My Data Requests (3) Search data requests

Draft **Active** Not Approved Withdrawn Archived

PREDICTING TREATMENT RESPONSE TO COMBINATION DRUGS IN PATIENTS WITH TYPE 2 DIABETES | 1 §

Vivli ID: 00003469

Status: Submitted and Awaiting Vivli Request Form Check

9. The status bar contains 5 sections:

**Draft:** Displays Data Requests that are being drafted but not yet submitted and hence don't have a Vivli ID.

**Active:** Displays Data Requests that are in progress. This includes requests in the Vivli form check stage, requests that were sent back to drafts, requests in the Data Contributor Review stage, IRP review stage, DUA validation stage, awaiting data package upload stage, requests where some or all of the data packages have been uploaded. It also displays requests that are currently in the analysis stage, awaiting results review and awaiting publication review.

**Not Approved:** Displays Data Requests that are 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

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

### My Data Requests (3)

Search data requests

Draft Active Not Approved Withdrawn Archived

1 2 1

**PREDICTING TREATMENT RESPONSE TO COMBINATION DRUGS IN PATIENTS WITH TYPE 2 DIABETES | 1**

Vivli ID: 00003469

Status: Submitted and Awaiting Vivli Request Form Check

## 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

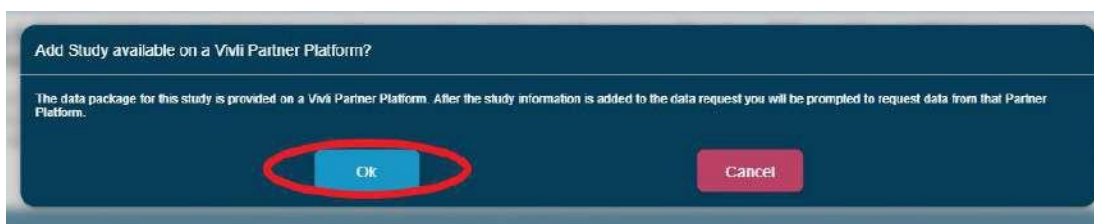
1. If the study you are searching for is on the Vivli Platform but provisioned by an external provider, it will appear on the Studies page when you search for studies as described in section 1.1, *Searching for studies on the Vivli platform*.
2. When attempting to add a study in this category to a Data Request Form, the following pop-up will appear:

**Add study available on a partner platform?**

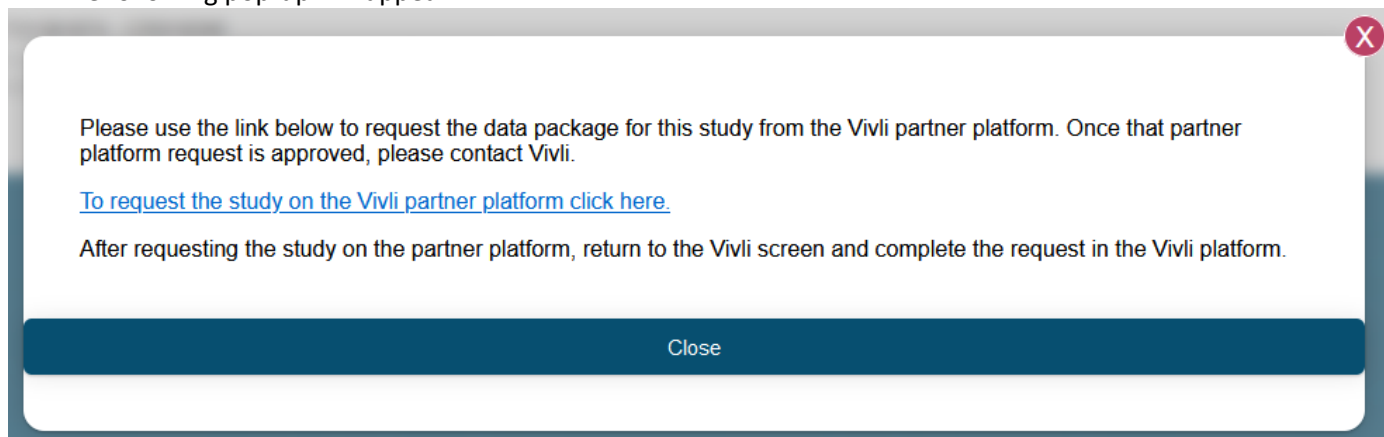
The data package for this study is provided on a partner platform. After the study information is added to the data request you will be prompted to request data from that partner platform.

Yes No

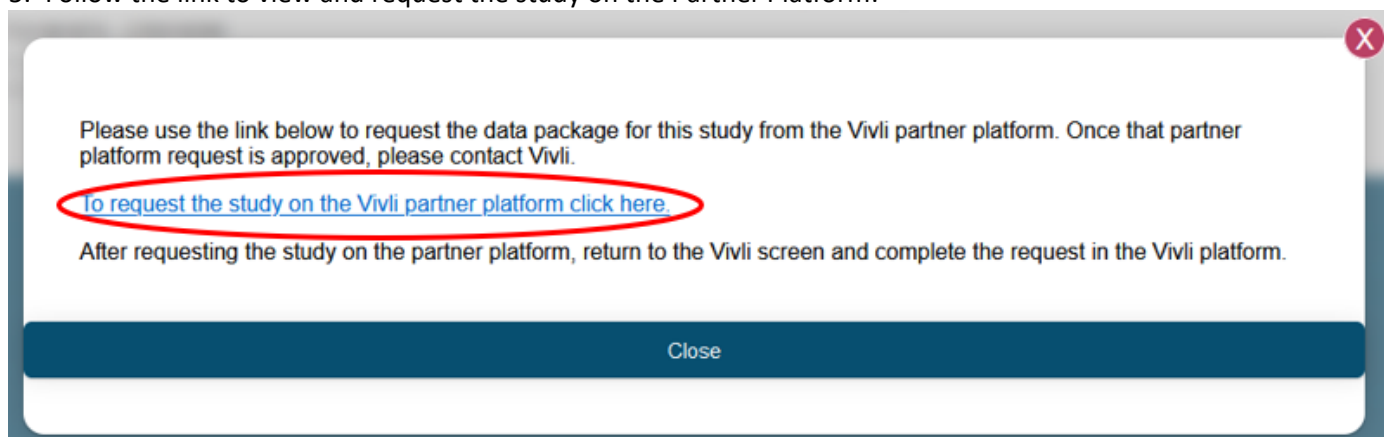
3. Click on **Yes** to add the study to the Data Request Form:



4. The following pop-up will appear:



5. Follow the link to view and request the study on the Partner Platform:



Note: this link will open up the Partner Platform Website in another browser tab.

6. Complete and submit the request on the Partner Platform, as well as the Vivli Data Request Form.



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

The screenshot displays the Vivli Data Request Form interface. The sidebar on the left contains navigation links: Research Team, Research Proposal, **Studies** (highlighted with a red box), Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, and Chat. The main content area is titled "Predicting Treatment Response to combination drugs in patients with type 2 diabetes". It features a "REQUESTED STUDIES" section with a download icon and a "VIVLI-LISTED AND PROVISIONED STUDIES" section. Two studies are listed in the Vivli-listed section:

- Study 1:** A Multicenter, Open-Label Conversion of Valproate Monotherapy to Lamotrigine Monotherapy in Patients With Epilepsy. Study ID: NCT00043914, Sponsor ID: LAM40013, Data Request ID: [blank], Data Contributor: GlaxoSmithKline, IRP/Approver: Wellcome Trust. Data to be loaded after approval. Remove button.
- Study 2:** Randomized, Open-Label Study of Abiraterone Acetate (JNJ-212082) Plus Prednisone With or Without Exemestane in Postmenopausal Women With ER+ Metastatic Breast Cancer Progre... Study ID: NCT01381874, Sponsor ID: CR018286, Data Request ID: [blank], Data Contributor: Johnson and Johnson, IRP/Approver: YODA Project. Data to be loaded after approval. Remove button.

Below these studies is a section titled "STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI" with an "Add +" button. At the bottom, it states "No Studies Found".

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**.

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

< 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

REQUESTED STUDIES ?

VIVLI-LISTED AND PROVISIONED STUDIES

A Multicenter, Open-Label Conversion of Valproate Monotherapy to Lamotrigine Monotherapy in Patients With Epilepsy  
Study ID: NCT00043914 Sponsor ID: LAM40013  
Data Request ID: Data Contributor: GlaxoSmithKline IRP/Approver: Wellcome Trust  
Data to be loaded after approval Remove X

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

Randomized, Open-Label Study of Abiraterone Acetate (JNJ-212082) Plus Prednisone With or Without Exemestane in Postmenopausal Women With ER+ Metastatic Breast Cancer Progre...  
Study ID: NCT01381874 Sponsor ID: CR018286  
Data Request ID: Data Contributor: Johnson and Johnson IRP/Approver: YODA Project  
Data to be loaded after approval Remove X

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.

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

< 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

REQUESTED STUDIES ?

VIVLI-LISTED AND PROVISIONED STUDIES

A Multicenter, Open-Label Conversion of Valproate Monotherapy to Lamotrigine Monotherapy in Patients With Epilepsy  
Study ID: NCT00043914 Sponsor ID: LAM40013  
Data Request ID: Data Contributor: GlaxoSmithKline IRP/Approver: Wellcome Trust  
Data to be loaded after approval Remove X

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

Randomized, Open-Label Study of Abiraterone Acetate (JNJ-212082) Plus Prednisone With or Without Exemestane in Postmenopausal Women With ER+ Metastatic Breast Cancer Progre...  
Study ID: NCT01381874 Sponsor ID: CR018286  
Data Request ID: Data Contributor: Johnson and Johnson IRP/Approver: YODA Project  
Data to be loaded after approval Remove X

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI Add +

No Studies Found

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. If you have access to a study which is included in your project but is not listed on the Vivli platform, you will need to add this to your data request.
2. To add the study to a Vivli Data Request Form, first open data requests by clicking on **My Data Requests** in the top right-hand corner of the browser:
3. 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. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies, along with a user profile dropdown for 'RESEARCHER'. The main content area is titled 'Predicting Treatment Response to combination drugs in patients with type 2 diabetes'. The left sidebar contains navigation links: Research Team, Research Proposal, Studies (highlighted with a red box), Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, and Chat. The main content area is divided into sections for 'REQUESTED STUDIES', 'VIVLI-LISTED AND PROVISIONED STUDIES', and 'VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS'. Each section lists a study with details like Study ID, Sponsor ID, Data Request ID, and Data Contributor. At the bottom, there is a section titled 'STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI' with an 'Add +' button highlighted by a red box.

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... ▼

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

5. Complete all fields, including selection of the Provider of the data from a dropdown menu and then click **submit**. Note: If a specific Data Provider is not available in the dropdown, reach out to [support@vivli.org](mailto:support@vivli.org):

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

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

Pfizer Inc. ▼

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.

6. 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



7. 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

8. 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



## 9. The studies will appear in the study list

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 title of the study request: "Predicting Treatment Response to combination drugs in patients with type 2 diabetes". The sidebar on the left contains navigation options: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, and Chat. The main content area is divided into sections: REQUESTED STUDIES, VIVLI-LISTED AND PROVISIONED STUDIES, and VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS. Each section contains a list of studies with details like Study ID, Sponsor ID, Data Request ID, and Data Contributor. A red box highlights the "STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI" section, which includes a study titled "ABC-156".

10. 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:

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

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

Research Team

Research Proposal

**Studies**

Statistical Analysis Plan

Funding

Other Information / File Attachments

Attestations

Chat

REQUESTED STUDIES ?

VIVLI-LISTED AND PROVISIONED STUDIES

A Multicenter, Open-Label Conversion of Valproate Monotherapy to Lamotrigine Monotherapy in Patients With Epilepsy  
Study ID: NCT00043914 Sponsor ID: LAM40013  
Data Request ID: [redacted]  
Data Contributor: GlaxoSmithKline IRP/Approver: Wellcome Trust  
Data to be loaded after approval Remove X

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

Randomized, Open-Label Study of Abiraterone Acetate (JNJ-212062) Plus Prednisone With or Without Exemestane in Postmenopausal Women With ER+ Metastatic Breast Cancer Progre...  
Study ID: NCT01381874 Sponsor ID: CR018285  
Data Request ID: [redacted]  
Data Contributor: Johnson and Johnson IRP/Approver: YODA Project  
Data to be loaded after approval Remove X

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI Add +

No Studies Found

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... ▼

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

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:

### 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 ToolBack

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



CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

[QUICK STUDY LOOKUP](#) [MY DATA REQUESTS](#) [DATA REQUESTER](#)

[Research Team](#)  
[Research Proposal](#)  
**[Studies](#)**  
[Statistical Analysis Plan](#)  
[Funding](#)  
[Other Information / File Attachments](#)  
[Attestations](#)  
[Request History](#)  
[Chat](#)

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

[Edit Request Title](#) [Cancel](#) [Save](#) [Submit](#)

**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-2018-26436 Data Contributor: GlaxoSmithKline IPD Uploaded: Yes	Data already on platform	<a href="#">Remove</a> <a href="#">×</a> <a href="#">&gt;</a>
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	<a href="#">Remove</a> <a href="#">×</a> <a href="#">&gt;</a>

**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	<a href="#">Remove</a> <a href="#">×</a>
---	----------------------------------	--

## 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

I WILL BRING M... ▼

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

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



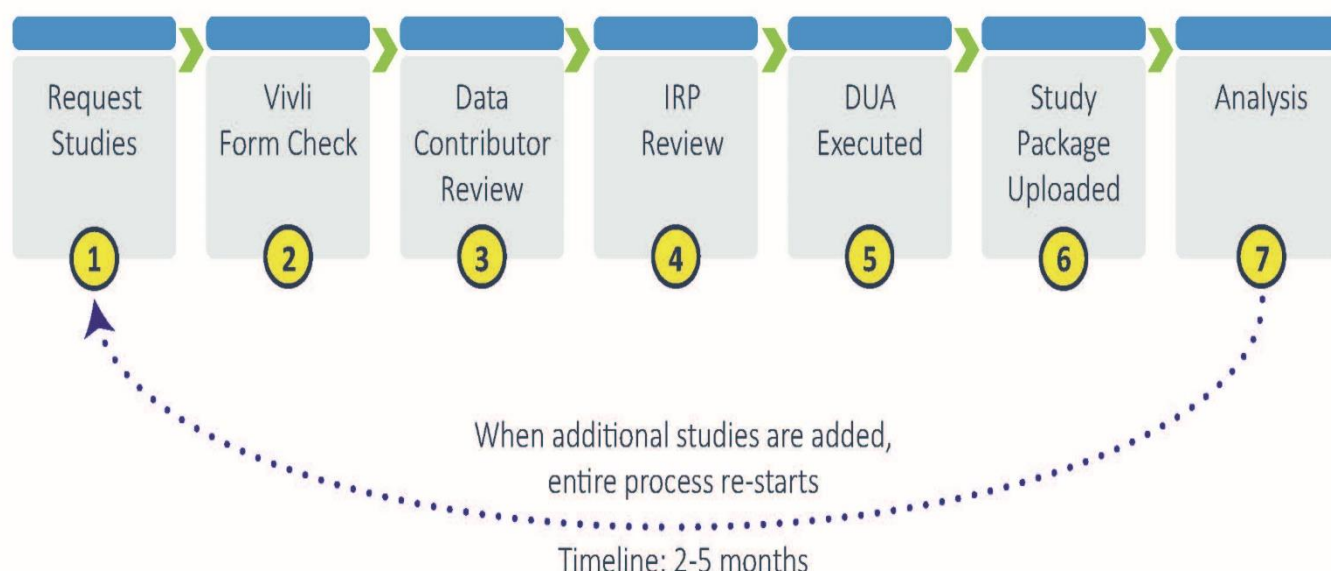
## 6.0 Modifying or revising your data request

### 6.1 Overview

- If necessary, you may modify your data request. Please review the [Vivli policies in brief](#) about active requests and active enquiries before submitting a data request.
- You can make as many changes as needed before submitting your data request.
- If the research team associated with a data request changes, you must update the request or you can reach out to the Vivli team via open chat while your data request is being reviewed. For minor changes, 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 will be withdrawn after 4 months.

How-To: Requesting Studies on Vivli

Version 3.3

### 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 (3)

Search data requests

1 Draft 2 **Active** 1 Not Approved Withdrawn Archived

PREDICTING TREATMENT RESPONSE TO COMBINATION DRUGS IN PATIENTS WITH TYPE 2 DIAI

Vivli ID: 00003469

Status: Draft

Cancel X

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

Request History

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:



The screenshot shows the Vivli web application interface. At the top, there's a navigation bar with links like Home, About, Members, News & Events, Resources, and Find Studies. Below this, a header bar contains 'ENQUIRY', 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'RESEARCHER'. The main content area is titled 'Predicting Treatment Response to combination drugs in patients with type 2 diabetes...'. On the left, a sidebar lists various options: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments (highlighted with a red box), Attestations, Request History, and Chat. The main content area is divided into three sections: 'Other Information' with a text input field, 'File Attachments' with a dashed box and a 'Select Files' button, and 'UPLOADED FILES' with a table. The table has columns for Filename, Size, Uploaded By, File Type, and a Delete button. The first row shows 'Study protocol.pdf', '4.81kB', 'Researcher', 'Unknown', and a Delete button.

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

## 6.4 Deleting Draft Data Requests

You may delete your draft data request at any time. You may contact Vivli via open chat or email at [support@vivli.org](mailto:support@vivli.org) anytime to move the request back from withdrawn to drafts.

## 6.5 Withdrawal process for submitted data request

If you decide to withdraw your request once it is submitted, you can reach out to the Vivli team via open chat or through [support@vivli.org](mailto: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](mailto:support@vivli.org) anytime to move the request back from withdrawn to drafts.

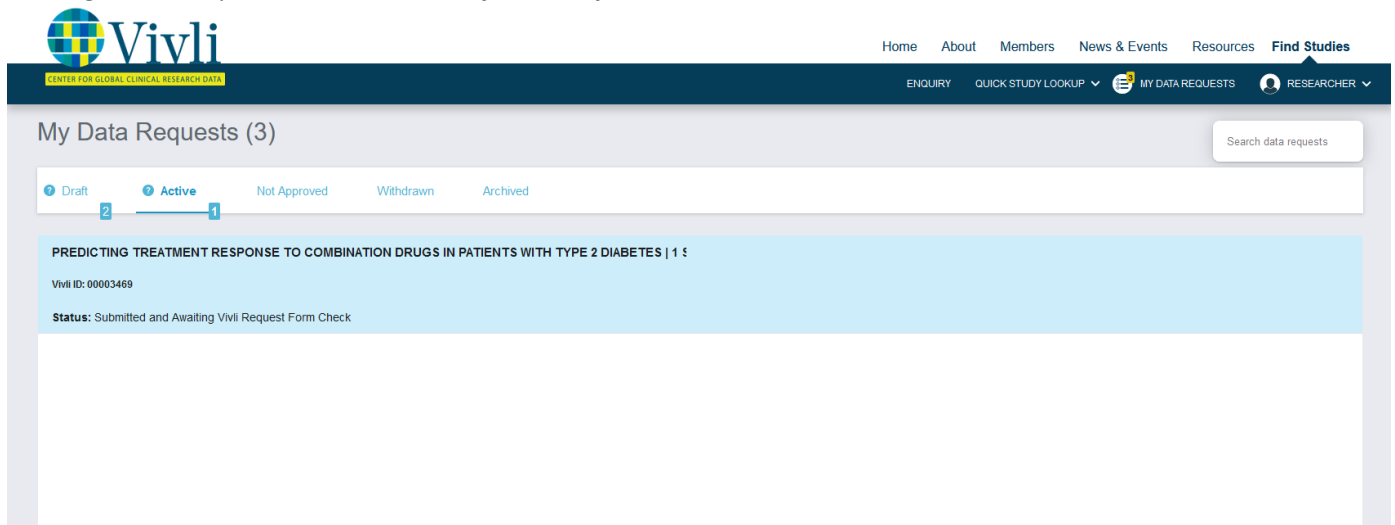
## 7.0 Communications

### 7.1 Open Chat

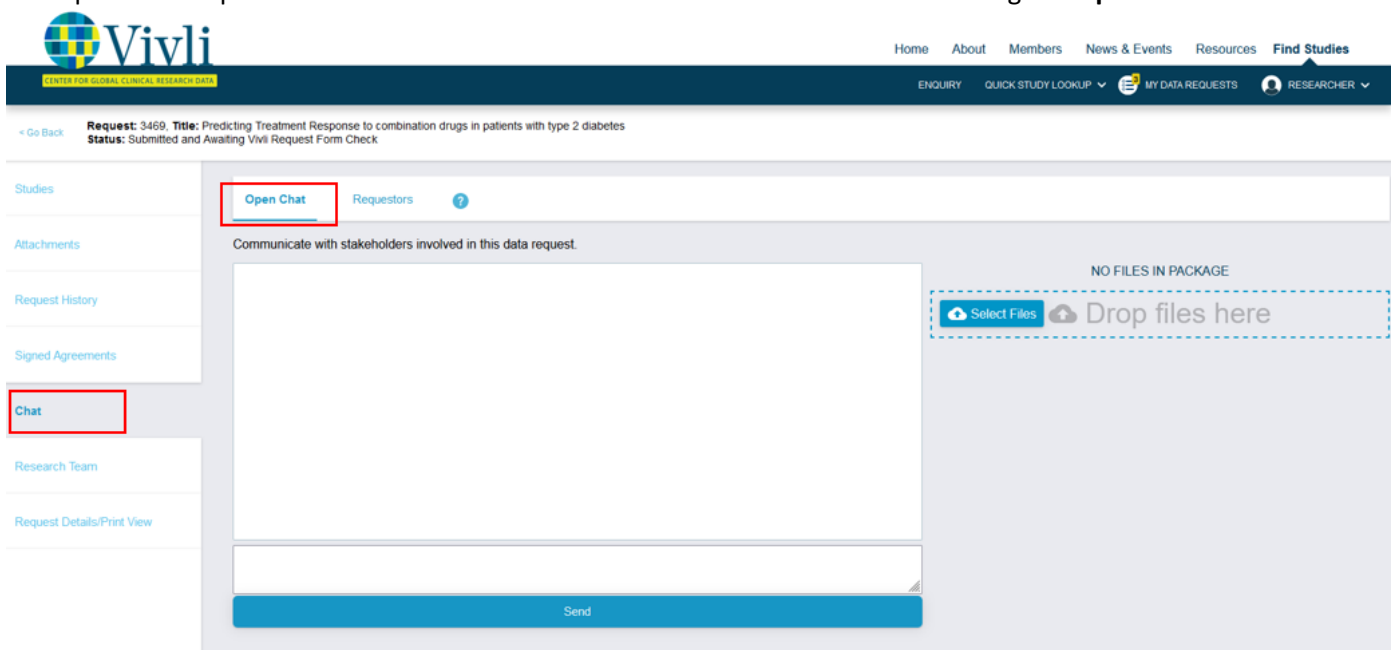
- You can use the open chat within the data request to communicate with the Vivli team, and the data contributors or review entities associated with your data request.
- Please note that messages in open chat are visible to all persons attached to a data request.
- When any other party enters a message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

### 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**:



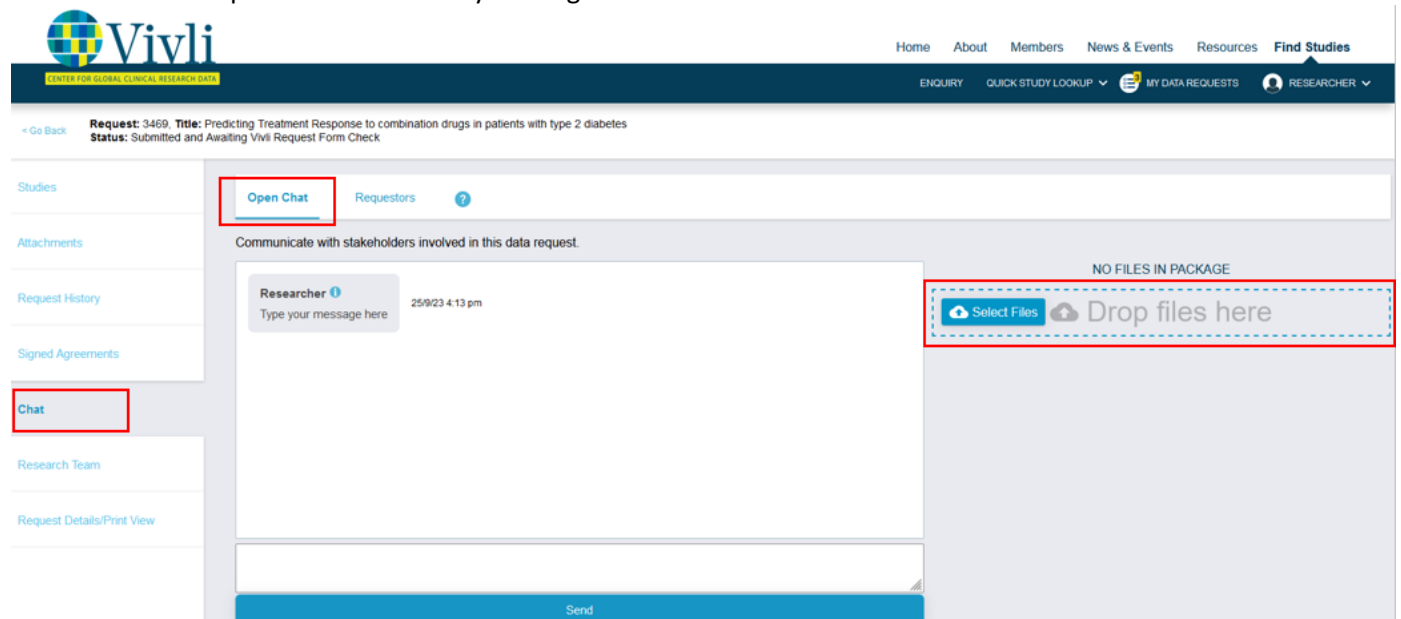
3. Enter your message in the chat message box and click **Send**:

The screenshot shows the Vivli website interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a secondary navigation bar with ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and RESEARCHER. The main content area is titled 'Request: 3469, Title: Predicting Treatment Response to combination drugs in patients with type 2 diabetes' and 'Status: Submitted and Awaiting Vivli Request Form Check'. On the left sidebar, the 'Chat' option is highlighted with a red box. The main chat area has a tab labeled 'Open Chat' and a sub-tab 'Requestors'. Below the tabs, there is a text input box with the placeholder 'Type your message here' and a blue 'Send' button, both highlighted with red boxes. To the right of the input box, there is a dashed box labeled 'NO FILES IN PACKAGE' with a 'Select Files' button and a 'Drop files here' area.

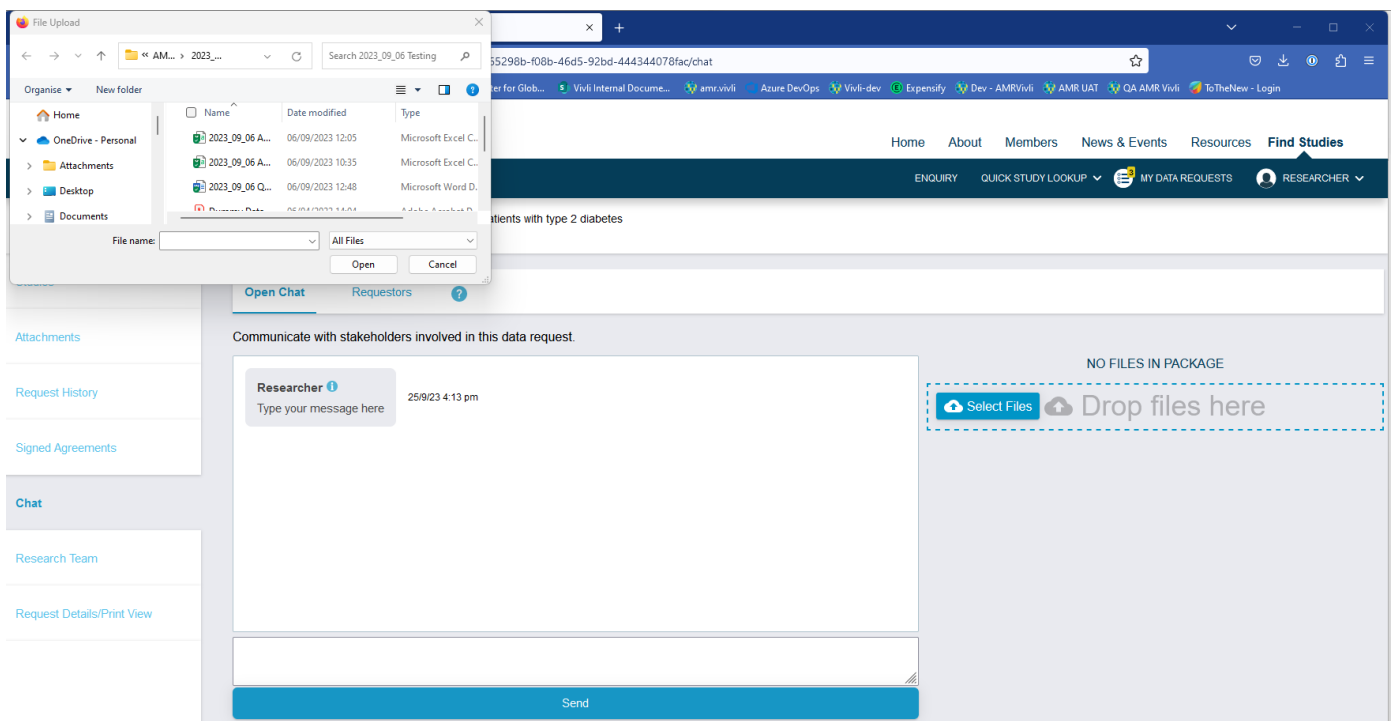
4. The message will now appear in the Chat record for all users (to see your just-entered chat message, you may need to click Refresh on your browser), and response will also appear in the chat record:

The screenshot shows the Vivli website interface after a message has been sent. The 'Open Chat' tab is highlighted with a red box. The chat area now displays a message from a 'Researcher' (indicated by a blue 'i' icon) with the text 'Type your message here' and a timestamp of '25/9/23 4:13 pm'. The message is enclosed in a red box. The 'Send' button is also visible at the bottom of the chat area.

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:

The screenshot shows the Vivli web application interface. At the top, there is a navigation bar with the Vivli logo and links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a secondary navigation bar with links for ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and RESEARCHER. The main content area is divided into a left sidebar and a central chat area. The sidebar contains links for Studies, Attachments, Request History, Signed Agreements, Chat (highlighted with a red box), Research Team, and Request Details/Print View. The central chat area has a header with 'Open Chat' (highlighted with a red box) and 'Requestors'. Below this is a message box with the text 'Communicate with stakeholders involved in this data request.' The chat history shows a message from 'Researcher' with the text 'Type your message here' and a timestamp of '25/9/23 4:13 pm'. Below this is a message from 'Researcher' with the text 'File Uploaded: Study protocol.pdf' and a timestamp of '25/9/23 4:17 pm'. To the right of the chat area is a 'Select Files' button and an 'UPLOADED FILES' table. The table has columns for Filename, Size, and Uploaded By. It contains one row with the filename 'Study protocol.pdf', size '4.81...', and uploaded by 'Researc...'. There are download and delete (X) buttons for each file. The 'X' button is highlighted with a red box.

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

This screenshot is similar to the previous one, but it highlights the deletion process. The 'UPLOADED FILES' table is highlighted with a red box. The 'X' button next to the file 'Study protocol.pdf' is also highlighted with a red box, indicating that clicking this button will delete the file from the upload list.

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

The screenshot shows the Vivli web application interface. The top navigation bar includes the Vivli logo, a tagline "CENTER FOR GLOBAL CLINICAL RESEARCH DATA", and links for Home, About, Members, News & Events, Resources, and Find Studies. A secondary navigation bar contains ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and a RESEARCHER dropdown menu. The main content area displays a chat window for a specific request (Request: 3469, Title: Predicting Treatment Response to combination drugs in patients with type 2 diabetes, Status: Submitted and Awaiting Vivli Request Form Check). The chat window has tabs for Open Chat and Requestors. The chat history shows two messages from a Researcher: a text message and a file upload message. To the right of the chat window is a file upload section with a "Select Files" button and an "UPLOADED FILES" table. The table has columns for Filename, Size, and Uploaded By. A file named "Study protocol.pdf" is listed with a size of 4.81 MB and uploaded by "Researcher". A download icon (a blue square with a white downward arrow) is highlighted with a red box next to the file name.

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

This screenshot shows the same Vivli chat interface as the previous one, but with a third message from the Researcher. The message says "File Deleted: Study protocol.pdf" and is timestamped 25/9/23 4:21 pm. This message is highlighted with a red box. The "UPLOADED FILES" table on the right is now empty, with the text "NO FILES IN PACKAGE" displayed above it.

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.

13. In chat, files are sorted by date, newest on top, and the hover text displays the filename, date uploaded, 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
<b>Status Change, data Request - Revision requested or Request not approved</b>	When your data request changes status to Revision or Not approved. If you have requested studies from multiple contributors, you will receive a notification when each has requested revisions or not approved your request.	Notify you of any changes in status to your data requests.
<b>Request Final Approval</b>	When your data request is approved, by a delegated approver/IRP. If you have requested studies from multiple contributors, you will receive a notification after final approval.	Notify you of final approval
<b>DUA Approved</b>	When the Vivli Admin has validated the DUA associated with the data request.	Notify you of executed DUA.
<b>Data Uploaded</b>	When requested Study Data Package from Data Contributor has been uploaded. If you have multiple studies, you will receive individual emails when each data package is uploaded. You will also receive an email when all data packages are loaded.	Notify you of data upload status to plan your analysis.
<b>Research Environment was provisioned</b>	When you start the Research Environment.	Notify you when the Research Environment is ready to be used for analysis.
<b>Request for results approved</b>	When your request to export results is approved or/not approved.	Notify the status of the results export.
<b>Data Request Archived</b>	When the data request is Archived, the project is considered closed.	Notify that the lead researcher and research team have met the DUA obligations for public disclosure/summary of results and the data request is now archived.
<b>Chat</b>	When anyone associated with a data request enters a message in chat	Facilitate communication and the data request work flow



## 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](mailto: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.

The screenshot displays the Vivli platform's 'Signed Agreements' section. The sidebar on the left contains navigation links: 'Studies', 'Attachments', 'Request History', 'Signed Agreements' (which is highlighted with a red box), 'Chat', 'Research Team', and 'Request Details/Print View'. The main content area has a header 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes' and a 'Print' button. Below the header, a message states 'There are no Signed Documents'. A dashed box contains a 'Select Files' button. Below this, a table titled 'UPLOADED FILES' is shown, with columns for 'Filename', 'Size', and 'Uploaded By'. A single file is listed: '2021\_10\_05 Vivli ID 00002553\_DUA executed final.pdf' with a size of '673.80kB' and uploaded by 'Data Requester'. A 'Download' button is located to the right of the file name. The table is also highlighted with a red box.

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

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 Histor**



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

[QUICK STUDY LOOKUP](#)
[152 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](#)
[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 comparison 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	

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
- Lay Summary of your Research Proposal
- List of requested studies

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

- Statistical Analysis Plan
- Publication Citation

## 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 via email when each the data package is uploaded and when all data packages are uploaded.

## 10.0 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. Further guidance will be provided when you reach this stage.

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

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

## 11.0 DUA Extension

The Data Use Agreement allows for 1 year for accessing the data from the date it was executed by Vivli. Vivli will send regular reminders when the DUA is about to expire. If you would like to apply for an extension, you have to complete the DUA extension form sent by Vivli and send the signed form back to us no later than 45 days before the expiration date of your access to the data requested in your research proposal. Please note that this is not the extension of your no-charge period of the Research Environment which may have a different end date based on when it was started. Vivli will reach out to you separately via email on that.

According to Vivli policy, DUA extensions are given in 6-month intervals up to a maximum of 2 years. After that, any extensions will need to be reviewed by the Data Contributors who may approve or decline the extension. It may take up to 30 days to receive a response from Data Contributors.

## 12.0 Public Disclosures & Publications & Summary of results

The [Data Use Agreement](#) requires Data Requestors to provide to Vivli, at least 30 days prior to journal submission, the submitted copy of any publication, which Vivli will make available to all Data Contributors for review. Please upload the abstract, poster, presentation, manuscript, etc. via the [platform open chat](#) under chat attachments. Please let us know where your publication is going to be submitted and whether you are planning any additional public disclosures for this request. Vivli will send periodic follow ups on the public disclosures.

Ensure to add the following language to your acknowledgement section:

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

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

Once all the publications are published and the analysis is complete, the Vivli team will move the data request to the Archived section of the data request.

If you do not have any publishable results, then you must send the summary of results to the Vivli team via open chat. The summary of the results will be sent to Data Contributors for a 30-day courtesy review. For a summary of results, once the courtesy review is complete, the Statistical Analysis Plan (SAP) and the summary of results will be posted on the Vivli website.