



How-To: Request Studies on Vivli

Vivli Release 3.0

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1.0 Requesting Studies on Vivli – Overview

- The process starts with finding studies you need – for assistance with the search, help is available on the [Vivli site](#).
- Once you have completed your search, you may request the data packages for the studies you would like to use for your analysis.
- To do this, the first step is to complete a Vivli Data Request Form on the Vivli platform. You may use “[Vivli Data Request Form Worksheet](#)” to start drafting your data request form offline.
- Your data request will be submitted to all relevant Data Contributors for review, according to the Data Contributor’s data sharing policies and criteria.
 - To learn more about individual Vivli Members’ data sharing policies, please see the [Vivli Members Page](#).
 - For an overview of the data request review process, please see the [Vivli Platform Process at a Glance](#).
 - Please review the [Vivli policy in brief](#) about active requests and active enquiries before submitting a data request.

1.1 Searching for studies on the Vivli platform

- To search for studies on the Vivli platform using the search page, <https://search.vivli.org/> enter a search term into the Keyword search bar where it says ‘What are you looking for today’, and use one of the drop-down filters. You may also use the quick study lookup option to search using NCT ID or Sponsor ID.

The screenshot displays the Vivli search interface. At the top, the Vivli logo is on the left, and navigation links (Home, About, Members, News & Events, Resources, Find Studies) are on the right. Below the navigation 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 shown 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 and click on the magnifying glass. The number of studies that include the search term will appear in the blue bar at the bottom of the page.

The screenshot shows the Vivli website's search interface. At the top, there's a navigation bar with links: Home, About, Members, News & Events, Resources, and Find Studies. Below this is a banner with the text "We are committed to advancing the knowledge around the COVID-19 pandemic" and buttons for "Share trials" and "Search for trials". The main search area has a "KEYWORD SEARCH" button (highlighted with a red box) and a "PICO Beta" option. The search bar contains the keyword "diabetes" (also highlighted with a red box). To the right of the search bar are icons for information (i) and search (magnifying glass). Below the search bar are filters for STUDY DESIGN, SPONSOR INFORMATION, LOCATION, and START/END DATE. At the bottom, a blue bar indicates "83 Studies" (highlighted with a red box).

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

The screenshot shows the Vivli website's search results page. The search bar at the top contains the keyword "diabetes". Below the search bar, there are three study results listed. Each result includes the study title, IDs, condition/disease, and intervention/treatment. To the right of each study result are buttons for "Log in to Request Study" and "View Study Details". The "View Study Details" button for the first study, "Clinical Assessment of GSK716155 for Type 2 Diabetes Mellitus", is highlighted with a red box. The left sidebar contains filters for STUDY DESIGN, SPONSOR INFORMATION, and STUDY PHASE.

- 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:

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

QUICK STUDY LOOKUP Sign up Log In

diabetes CLOSE

STUDY DESIGN
INTERVENTIONAL STUDIES
Select Multiple

OBSERVATIONAL STUDIES
Select Multiple

SAMPLE SIZE (Disabled)
mm/yyyy

LOCATION
Select Multiple

START DATE
FROM TO
mm/yyyy mm/yyyy

A Randomized, Double-Blind, Placebo-Controlled Insulin Tolerance Test Study to Assess the Safety, Tolerability, and Pharmacodynamics OF Pitolisant in Patients With Type 1 Diabetes

IDs: NCT04026750 | FPITO-T1D-01.01
Condition or Disease: Type 1 Diabetes, Hypoglycemia
Intervention/treatment: Pitolisant

Log in to Request Study

View Study Details

Number enrolled: 5
Phase 1

Treatment Preference for Weekly DPP-4 Inhibitors Versus Daily DPP-4 Inhibitors in Patients With Type 2 Diabetes Mellitus

IDs: NCT03231709 | Trelagliptin-4003
Condition or Disease: Type 2 Diabetes Mellitus
Intervention/treatment: Trelagliptin, Alogliptin

Log in to Request Study

View Study Details

Number enrolled: 60
Phase 4

Study of the QOL Evaluation of Trelagliptin in Patients With Type 2 Diabetes Mellitus

IDs: NCT03014479 | Trelagliptin-4002
Condition or Disease: Type 2 Diabetes
Intervention/treatment: Trelagliptin, Daily DPP-4 inhibitor

Log in to Request Study

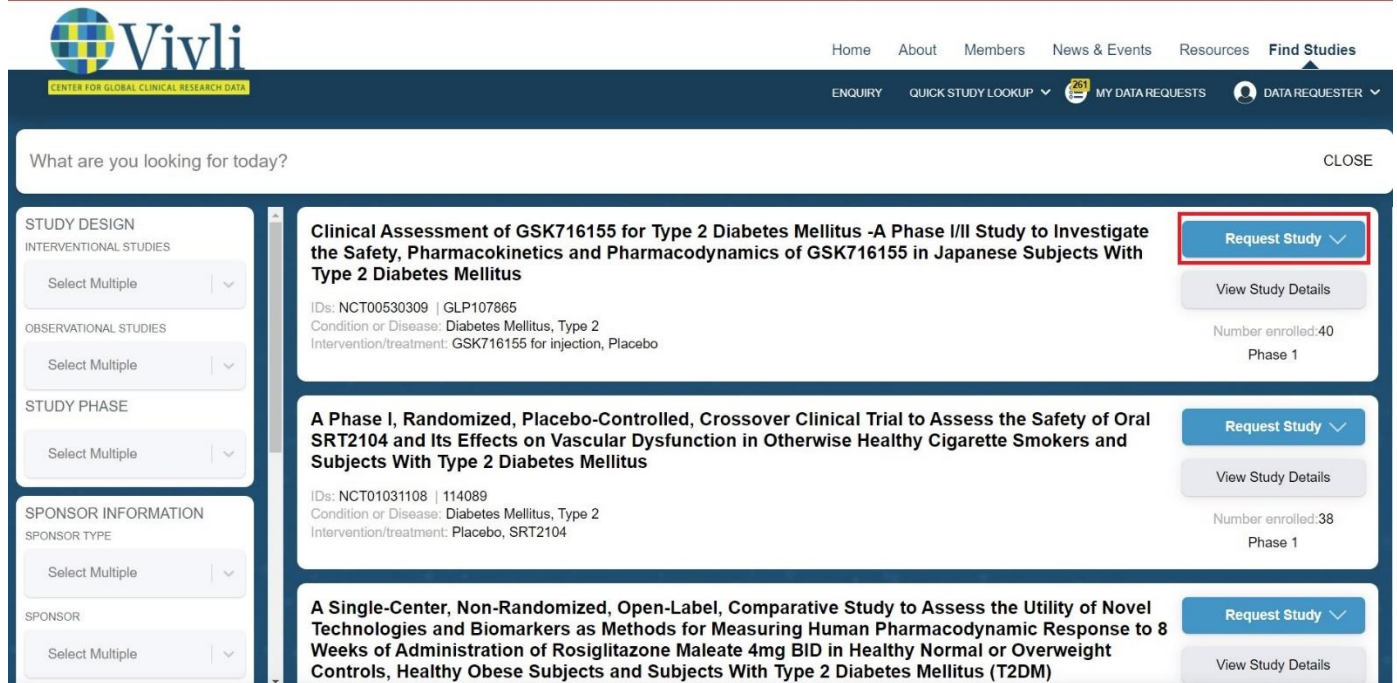
View Study Details

Number enrolled: 219
Phase 4

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

1.3 Add studies to your data request

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



The screenshot shows the Vivli website interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below the navigation bar 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, and SPONSOR INFORMATION (SPONSOR TYPE, 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 dropdown menu contains the option "+ Add New Request", which is highlighted by a red circle. The background of the dropdown menu is dark blue, and the text is white. The "Request Study" button is also visible at the top of the dropdown menu.

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

New Research Data Request

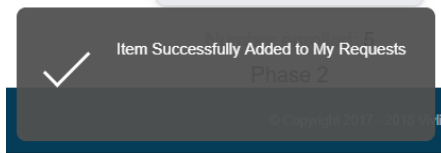
Enter a descriptive name for your research project.

If this is an additional study you want to add to the same project, then instead of entering a new project name here, click cancel and choose your previous project name from the drop-down on the "Request Study" button.

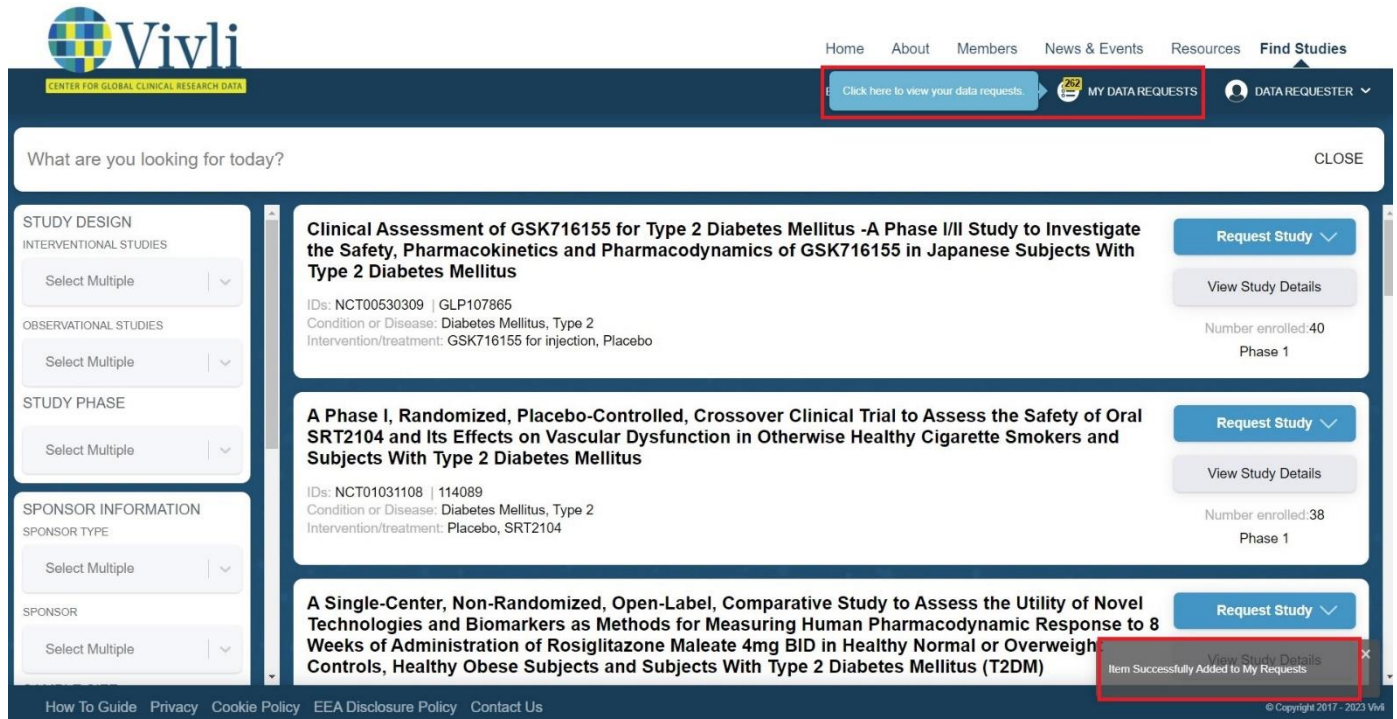
Ok

Cancel

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



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



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

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Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

What are you looking for today? CLOSE

STUDY DESIGN
INTERVENTIONAL STUDIES
Select Multiple

OBSERVATIONAL STUDIES
Select Multiple

STUDY PHASE
Select Multiple

SPONSOR INFORMATION
SPONSOR TYPE
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
Request Study
Increase in albuminuria in Diabetes patients
+ Add New Request

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
Request Study
View Study Details
Number enrolled: 38
Phase 1

diabetes CLOSE

STUDY DESIGN
INTERVENTIONAL STUDIES
Select Multiple

OBSERVATIONAL STUDIES
None Available

SAMPLE SIZE (Disabled) ☐

LOCATION
Select Multiple

START DATE
FROM TO
mm/yyyy mm/yyyy

END DATE
FROM TO
mm/yyyy mm/yyyy

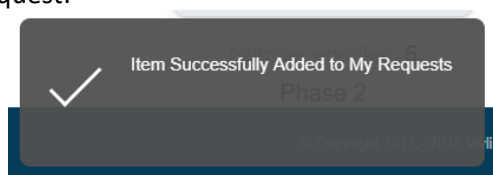
Effects of Cystic Fibrosis and Cystic Fibrosis Related Diabetes on Brain Structure and Cognitive Function
IDs: NCT03820349 | MED-2018-26438
Condition or Disease: Cystic Fibrosis
Intervention/treatment:
Request Study
View Study Details
Number enrolled: 28

A Randomized, Double-blind, Single-dose, Placebo Controlled, 2-way Cross-over Study Evaluating Effect of Albiglutide on Cholecystokinin-induced Gallbladder Emptying in Fasting Healthy Subjects
IDs: NCT02496221 | 201834
Condition or Disease: Diabetes Mellitus, Type 2
Intervention/treatment: Albiglutide 50 mg, Placebo, CCK (Kinevac)
Request Study
Diabetes Meta-analysis
+ Add New Request

200699: A Clinical Study to Evaluate Four Doses of Umeclidinium Bromide in Combination With Fluticasone Furoate in COPD Subjects With an Asthmatic Component
IDs: NCT02164539 | 200699
Condition or Disease: Pulmonary Disease, Chronic Obstructive
Intervention/treatment: FF, UMEC, VI
Request Study
View Study Details
Number enrolled: 338
Phase 2

A Randomized, Double-blind (Sponsor Unblinded), Placebo Controlled, Repeat Dose Study Investigating Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of GSK2330672 in Type 2 Diabetes Patients Taking Metformin
Request Study

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



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

1.4 Active Platform Accounts

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

2.0 Your Data Requests

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

The screenshot shows the Vivli website interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. A red box highlights the 'MY DATA REQUESTS' link in the top right corner. Below the navigation bar, the page is divided into a sidebar and a main content area. The sidebar contains filters for STUDY DESIGN (INTERVENTIONAL STUDIES, OBSERVATIONAL STUDIES), STUDY PHASE, and SPONSOR INFORMATION (SPONSOR TYPE, SPONSOR). The main content area displays three study listings. Each listing includes a title, IDs, Condition or Disease, Intervention/treatment, and buttons for 'Request Study' and 'View Study Details'. The first study is 'A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group, Dose Ranging Study to Determine the Effect of Mepolizumab on Exacerbation Rates in Subjects With Severe Uncontrolled Refractory Asthma'. The second study is 'A Phase 3, Randomized, Open-Label, Comparative Trial Of Azithromycin Plus Chloroquine Versus Mefloquine For The Treatment Of Uncomplicated Plasmodium Falciparum Malaria In Africa'. The third study is 'Efficacy of Two Commercially Available Chlorhexidine Mouthrinses Non-alcohol Base - a Randomized Clinical Trial'.

This will take you to your data requests page, where you can navigate to complete the Vivli Data Request Form and check the status of any previously submitted data requests. For guidance on how to fill out the data request, please see Vivli [Data Request Form worksheet](#).

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

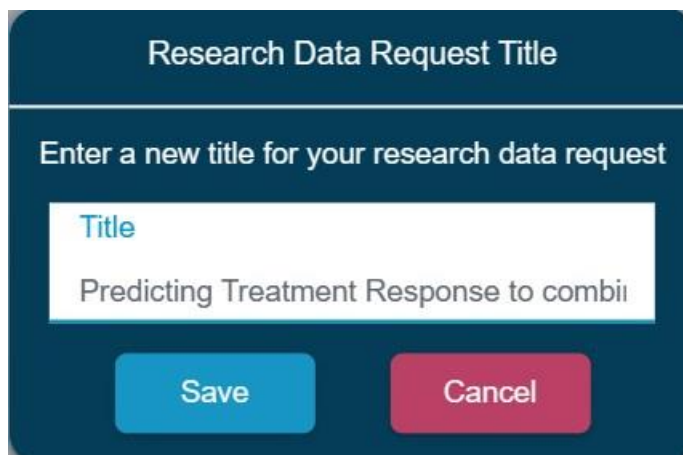
Click on the data request to open it.

2.1 Editing a data request

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

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

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



Research Data Request Title

Enter a new title for your research data request

Title

Predicting Treatment Response to combi

Save Cancel


2.2 Completing a data request

To complete a data request, you must add all required information to the Data Request Form.

For guidance, please see [Vivli Data Request Form Worksheet](#). Please note that the data request must include:



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

For more information on requesting studies not listed on Vivli, please see Section 4.0, Requesting data from studies not listed on Vivli, but available for provisioning into the Secure Research Environment.



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

QUICK STUDY LOOKUP  MY DATA REQUESTS  DATA REQUESTER

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

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

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


First Name Last Name Position

Email (editable until user is invited ...) ORCID ID Employer, Company, Research Institute,...

Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that a...



2.2.1 Adding Files or Other Information to your data request

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



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QUICK STUDY LOOKUP  MY DATA REQUESTS  DATA REQUESTER

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


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

Other Information

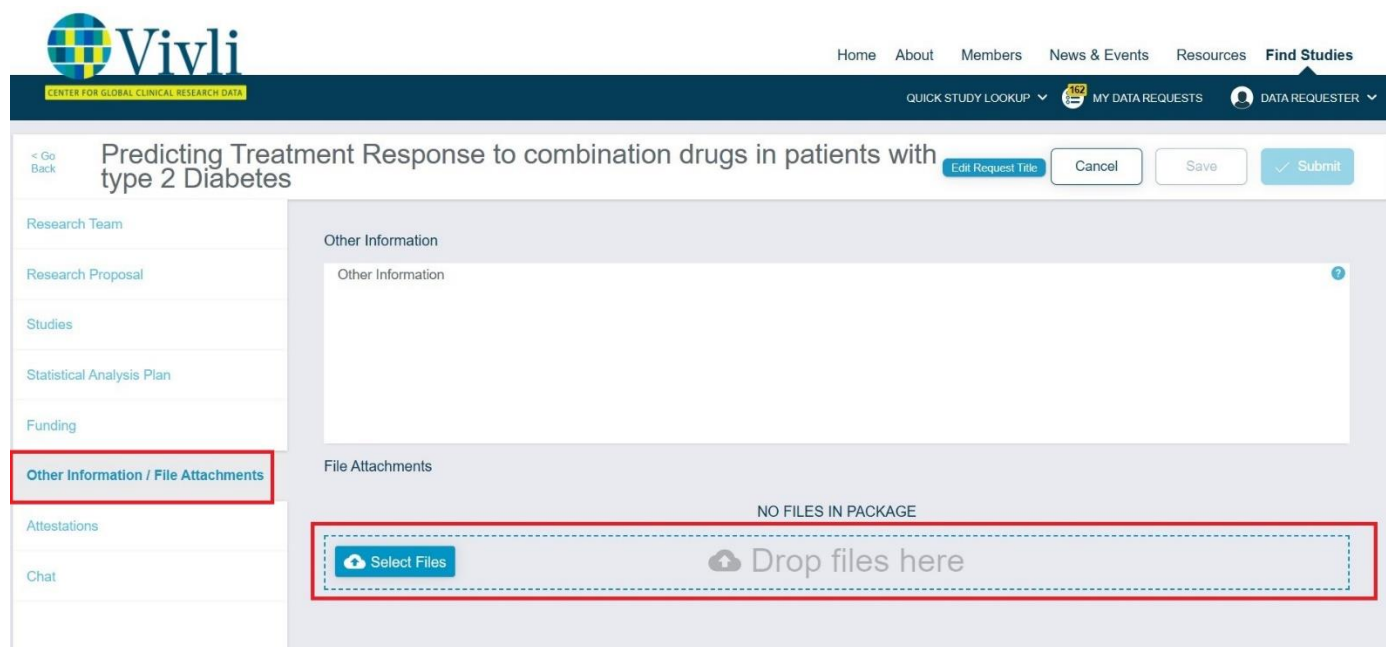
Other Information

File Attachments

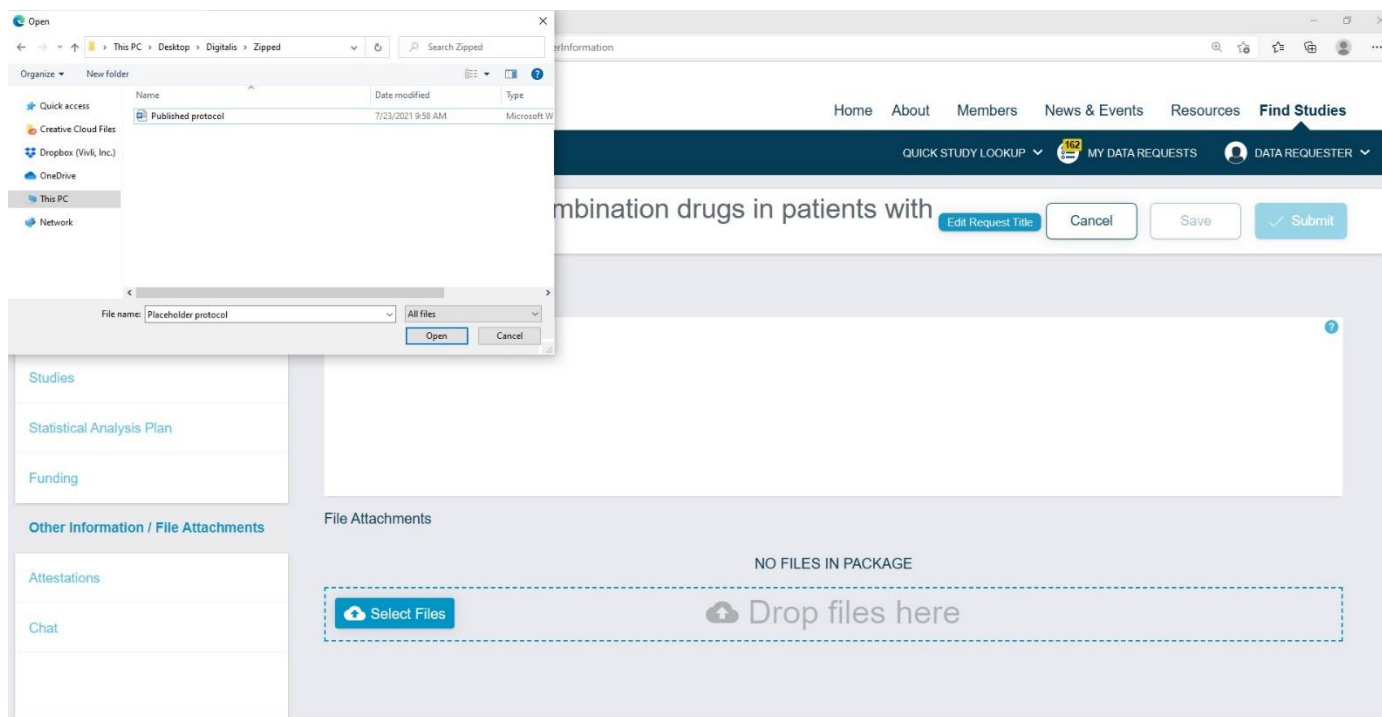
NO FILES IN PACKAGE

[Select Files](#)  Drop files here

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



2. Then simply select the file from your computer:



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

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. The main header displays the study title: "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 (highlighted with a red box), Attestations, and Chat. The main content area is divided into two sections: "Other Information" and "File Attachments". The "File Attachments" section displays "NO FILES IN PACKAGE" and a large dashed box labeled "Drop files here" with a "Select Files" button. The "Drop files here" box is highlighted with a red border.

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

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 study title: "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 (highlighted with a red box), Attestations, and Chat. The main content area is divided into two sections: "Other Information" and "File Attachments". The "File Attachments" section displays "UPLOADED FILES" and a table with the following data:

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

The table is highlighted with a red border.

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

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. The main header displays the Vivli logo and the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. The page title is 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes'. The left sidebar contains a list of sections: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments (highlighted with a red box), Attestations, and Chat. The main content area shows the 'Other Information / File Attachments' section. It includes a 'Select Files' button and a table of 'UPLOADED FILES'. The table has columns for Filename, Size, and Uploaded By. A file named 'Published protocol.docx' is listed with a size of 11.74kB and uploaded by 'Data Requester'. A dropdown menu is open next to the file, showing options: Research Proposal Supplement, Funding Information, Statistical Analysis Plan, Other, and Unknown. The 'Delete' button is also visible next to the file.

6. 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. The main header displays the Vivli logo and the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. The page title is 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes'. The left sidebar contains a list of sections: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments (highlighted with a red box), Attestations, and Chat. The main content area shows the 'Other Information / File Attachments' section. It includes a 'Select Files' button and a table of 'UPLOADED FILES'. The table has columns for Filename, Size, Uploaded By, and File Type. A file named 'Published protocol.docx' is listed with a size of 11.74kB and uploaded by 'Data Requester'. The 'File Type' column shows 'Unknown' with a dropdown arrow. A red box highlights the 'Delete' button next to the file.

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

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

QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

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

Research Team
Research Proposal
Studies
Statistical Analysis Plan
Funding

Other Information / File Attachments

Attestations
Chat

Other Information

Other Information
Type in additional information

File Attachments

Select Files

UPLOADED FILES

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

2.3 Saving your data request

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

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

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

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

Research Team
Research Proposal
Studies
Statistical Analysis Plan
Funding

Other Information / File Attachments

Attestations
Chat

Other Information

Other Information
Type in additional information here

File Attachments

Select Files Drop files here

UPLOADED FILES

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

2.4 Adding Research Team Members

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

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

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a dark blue header with the Vivli logo and the text "CENTER FOR GLOBAL CLINICAL RESEARCH DATA". The main content area is titled "Predicting Treatment Response to combination drugs in patients with type 2 Diabetes". On the left, there is a sidebar with navigation links: Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, and Chat. The "Research Team" section is highlighted with a red box. It contains a form for the "LEAD RESEARCHER" with fields for First Name, Last Name, Position, Email (editable until user is invited to data ...), ORCID ID, and Employer, Company, Research Institute, or Prim... There is also a checkbox labeled "Lead Researcher is also Statistician Researcher" which is highlighted with a red box. Below these fields is a text area for "Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed...". At the bottom of the form, there is a text area 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**:

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

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

Research Team

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

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

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

ADDITIONAL RESEARCHERS Add +

3. The following dialogue box will appear:

ADDITIONAL RESEARCHER ☐ Invite user to access data request

First Name Last Name Position

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

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

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

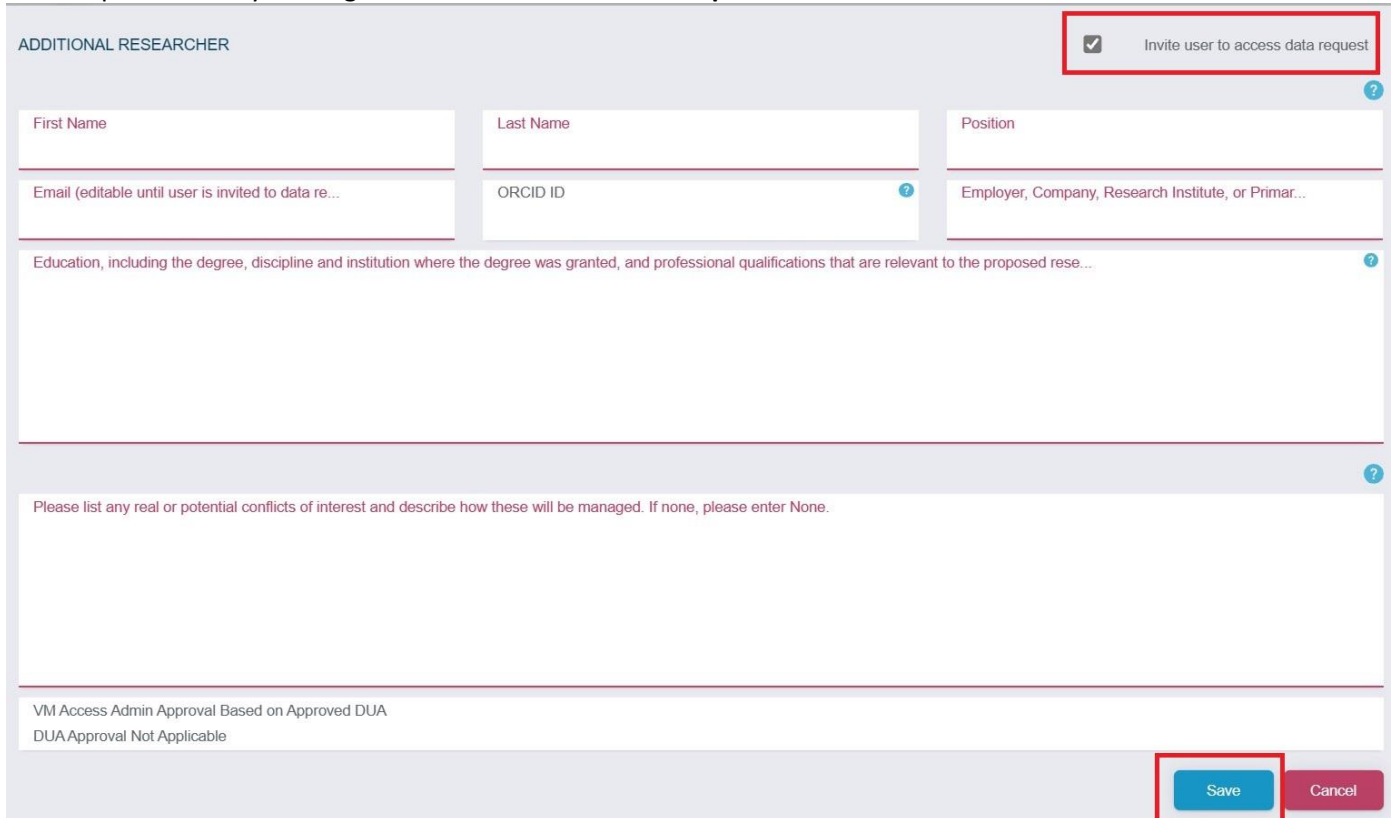
VM Access Admin Approval Based on Approved DUA
DUA Approval Not Applicable

Save Cancel

4. Complete all fields, and click



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

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

2.5 Deleting research team members

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

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

3. The following pop-up will appear:

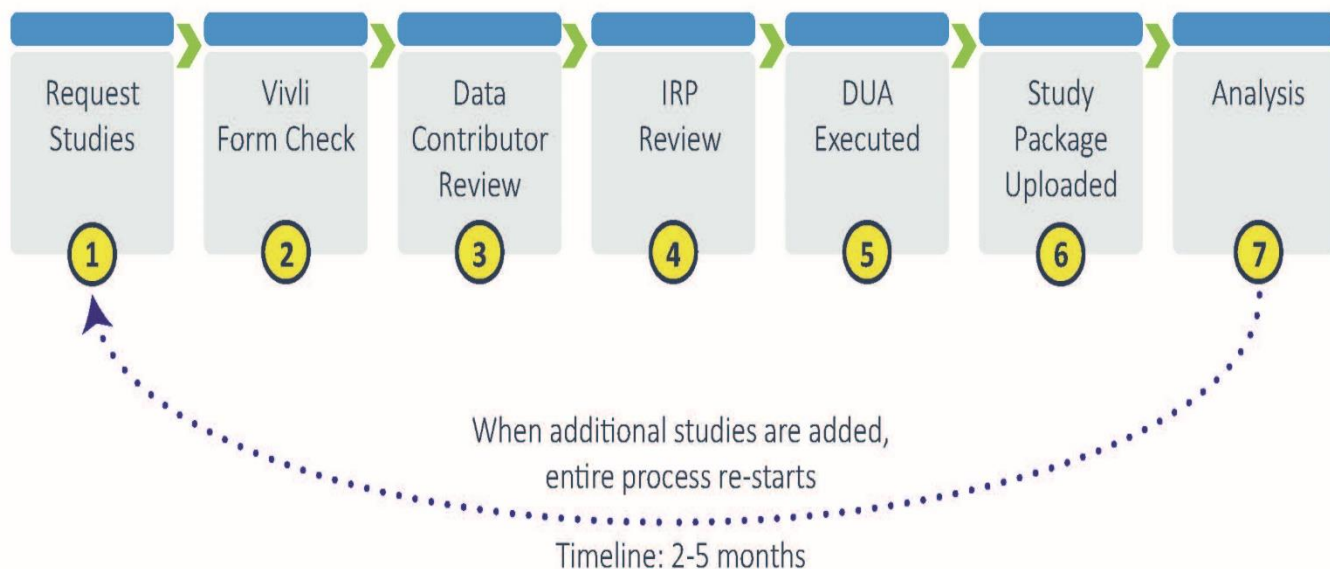


4. Click on **Ok** to remove the team member.

2.6 Submitting your data request

1. Once the Data Request Form is complete, you may submit it for review.
2. Do not submit a form before it is complete, as you will be unable to make changes once it has been submitted.
3. Please make sure that you have added all the desired studies to your data request as adding it later will lead to additional delays
4. Please note that according to Vivli policy, any changes to the Lead Investigator, Lead Statistician, their conflict of interest, adding and removal of studies in the request, changes to the Statistical Analysis Plan will require that Data contributors have the opportunity to re-review your data request and have it go through their entire approval process. This allows the reviewers of a request to know which data sets will be combined into the same analysis environment. This entire process could take an additional 2-5 months. Hence, please finalize your plans ahead of time to avoid any delays later.

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



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

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

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

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

[< Go Back](#)

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

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

[Research Team](#)
[Research Proposal](#)
[Studies](#)
[Statistical Analysis Plan](#)
[Funding](#)
[Other Information / File Attachments](#)

[Attestations](#)

[Chat](#)

Certify Complete and Accurate

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


☒ I certify the information provided is complete and accurate.


Data Use Agreement

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

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



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

7. If the Submit button is still light blue  and does not respond to a click, you have a required field that is not completed. You can look in each of the tabs on the left for a field outlined in red which indicates that a required field needs to be completed. Be sure to review the Research Proposal tab, Statistical Analysis Plan tab, Attestations (you need to check a checkbox) and the Research Team tab (you need to specify both a Lead Researcher and a Statistician. Please fill out all the details of the additional researcher(s), if applicable).



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

CENTER FOR GLOBAL CLINICAL RESEARCH DATA

QUICK STUDY LOOKUP  MY DATA REQUESTS  DATA REQUESTER

[< Go Back](#)

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

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

[Research Team](#)
[Research Proposal](#)
[Studies](#)
[Statistical Analysis Plan](#)
[Funding](#)
[Other Information / File Attachments](#)

[Attestations](#)

[Chat](#)

Certify Complete and Accurate

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

☐ I certify the information provided is complete and accurate.

Data Use Agreement

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

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

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

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

The screenshot shows the Vivli website's 'My Data Requests' page. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this, a secondary bar contains 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS' (with a 162 badge), and 'DATA REQUESTER'. The main heading is 'My Data Requests (162)'. A search bar is located on the right. The status bar below the heading shows five categories: Draft (1), Active (103), Not Approved (2), Withdrawn (56), and Archived (1). The 'Active' category is highlighted with a red box. Below the status bar, two data request entries are visible, each with a title, Vivli ID, and status. The first entry is 'PREDICTING TREATMENT RESPONSE TO COMBINATION DRUGS IN PATIENTS V' with Vivli ID 00002555 and status 'Submitted and Awaiting Vivli Request Form Check'. The second entry is 'PREDICTING TREATMENT RESPONSE TO COMBINATION DRUGS IN PATIENTS V' with Vivli ID 00002553 and status 'At least one Data Package Provided and Available'.

9. The status bar contains 5 sections:

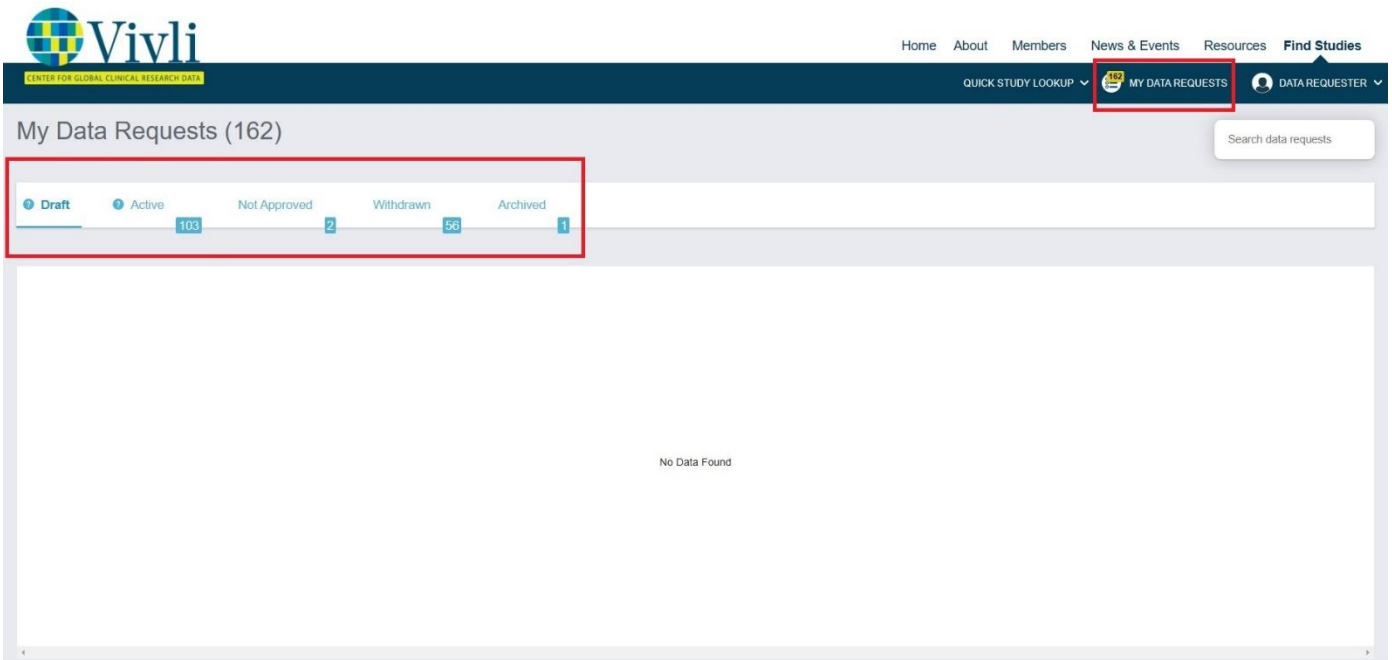
Drafts: Displays Data Requests that are being drafted but not yet submitted and hence don't have a Vivli ID.

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

Not Approved: Displays Data Requests that are denied. It also temporarily displays requests where revisions were requested until the Vivli Admin moves the requests to draft.

Withdrawn: Displays Data Requests that were withdrawn

Archived: Displays Data Requests that were completed including those with publication or summary of results provided



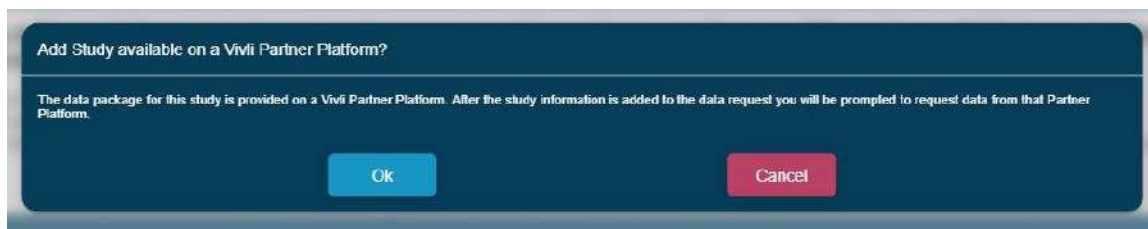
3.0 Requesting Vivli-listed studies provisioned by external providers

3.1 Overview

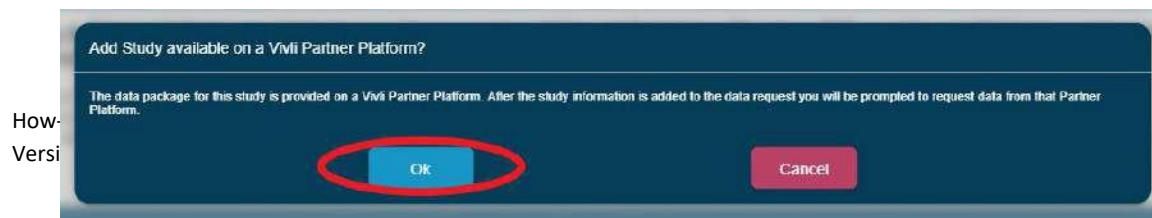
- Some studies are listed and searchable on both the Vivli platform as well as on other platforms that are Partner Platforms with Vivli.
- In addition to completing the Vivli request form, you will need to request such studies directly through the Partner Platform.
- After the relevant Data Contributor(s)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

3.2 Requesting studies provisioned by external providers

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

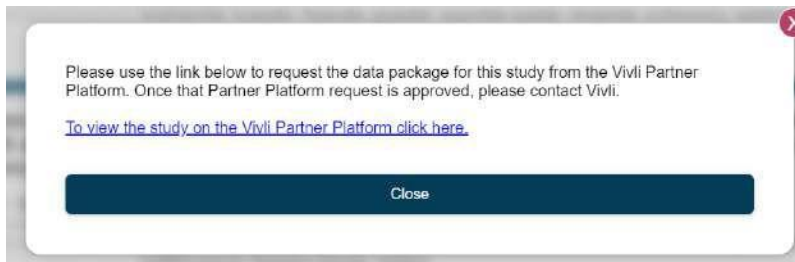


2. Click on **OK** to add the study to the Data Request Form:

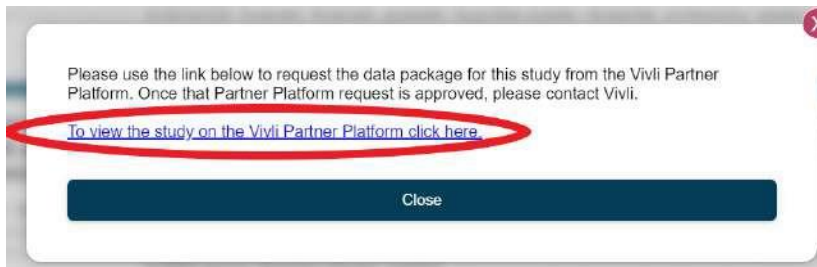


How-
Versi

4. The following pop-up will appear:



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



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

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

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

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

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

Research Team

Research Proposal

Studies

Statistical Analysis Plan

Funding

Other Information / File Attachments

Attestations

Chat

REQUESTED STUDIES ? ↓

VIVLI-LISTED AND PROVISIONED STUDIES

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

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

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

A Randomised, Double-blind, Multicentre Phase II/III Study to Compare the Eff...
PI: Sponsor: AstraZeneca Study ID: NCT00384176 IRP/Approver: Project Data Sphere, LLC Data Request ID: Data to be loaded after approval Remove x >
Sponsor ID: D6480C00013
Data Contributor: Project Data Sphere, LLC IPD Uploaded: No

- After all the Data Contributors associated with the request have approved it and you have signed a Data Use Agreement, all the data package(s) will be provisioned directly into the secure research environment.

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

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

4.1 Process Overview

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

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

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

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

1. To add the study to a Vivli Data Request Form, first open data requests by clicking on **My Data Requests** in the top right-hand corner of the browser:
2. Next, open the data request to add the external study. Then, scroll down and click on **Add+** adjacent to **STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI**, in the bottom corner of the screen:

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

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

Research Team
Research Proposal

Studies

Statistical Analysis Plan
Funding
Other Information / File Attachments
Attestations
Request History
Chat

REQUESTED STUDY TYPES ? ↓

VIVLI-LISTED AND PROVISIONED STUDIES

Effects of Cystic Fibrosis and Cystic Fibrosis Related Diabetes on Brain Stru...
PI: Sponsor: University of Minnesota Study ID: NCT03820349 IRP/Approver: Wellcome Trust Data Request ID: 00002555 Data already on platform Remove x >
Sponsor ID: MED-2018-26439
Data Contributor: GlaxoSmithKline IPD Uploaded: Yes

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 Data already on platform Remove x >
Sponsor ID: 201834
Data Contributor: GlaxoSmithKline IPD Uploaded: Yes

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

No Studies Found

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI Add +

No Studies Found

3. 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

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

Request Studies, Data, or Tools not listed on Vivli

OWN" and provide a name and a description for the data, tool, or script. You will be notified when to upload the data, tool or script and the Vivli team will support you in this process.

If you are requesting clinical trial data from a Vivli member, then as the provider of the data select the member's name, provide the NCT ID or the Sponsor ID of the study, and a description of the study. Vivli does not guarantee that the Vivli member will approve the data request. For more information, please see our [Members page](#).

Select provider of the data

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.

5. The following notification will appear:

Request Studies, Data, or Tools not listed on Vivli

If you will be providing your own data, tools or scripts, then as the provider, select "I WILL BRING MY OWN" and provide a name and a description for the data, tool, or script. You will be notified when to upload the data, tool or script and the Vivli team will support you in this process.

If you are requesting clinical trial data from a Vivli member, then as the provider of the data select the member's name, provide the NCT ID or the Sponsor ID of the study, and a description of the study. Vivli does not guarantee that the Vivli member will approve the data request. For more information, please see our [Members page](#).

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

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

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

Add Another Study, Data, or Tool

Back

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

Request Studies, Data, or Tools not listed on Vivli

If you will be providing your own data, tools or scripts, then as the provider, select "I WILL BRING MY OWN" and provide a name and a description for the data, tool, or script. You will be notified when to upload the data, tool or script and the Vivli team will support you in this process.

If you are requesting clinical trial data from a Vivli member, then as the provider of the data select the member's name, provide the NCT ID or the Sponsor ID of the study, and a description of the study. Vivli does not guarantee that the Vivli member will approve the data request. For more information, please see our [Members page](#).

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

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

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

Add Another Study, Data, or Tool

Back

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

Request Studies, Data, or Tools not listed on Vivli

If you will be providing your own data, tools or scripts, then as the provider, select "I WILL BRING MY OWN" and provide a name and a description for the data, tool, or script. You will be notified when to upload the data, tool or script and the Vivli team will support you in this process.

If you are requesting clinical trial data from a Vivli member, then as the provider of the data select the member's name, provide the NCT ID or the Sponsor ID of the study, and a description of the study. Vivli does not guarantee that the Vivli member will approve the data request. For more information, please see our [Members page](#).


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

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

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

Add Another Study, Data, or ToolBack

8. The studies will appear in the study list



CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

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

[Go Back](#)

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

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

Research Team

Research Proposal

Studies

Statistical Analysis Plan

Funding

Other Information / File Attachments

Attestations

Request History

Chat

REQUESTED STUDY TYPES ?

VIVLI-LISTED AND PROVISIONED STUDIES

Effects of Cystic Fibrosis and Cystic Fibrosis Related Diabetes on Brain Stru...
PI: Sponsor: University of Minnesota Study ID: NCT03820349 IRPI/Approver: Wellcome Trust Data Request ID: 00002555 Sponsor ID: MED-2019-26438
Data Contributor: GlaxoSmithKline IPD Uploaded: Yes Data already on platform [Remove](#) >

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

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

No Studies Found

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI [Add +](#)

Study Title
PI: Data Contributor: Pfizer Inc. Study ID: NCT012345678 Data Request ID: 00002555 Sponsor ID: false
IPD Uploaded: No Data to be loaded after approval [Remove](#) >

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

How-To: Requesting Studies on Vivli
Version 3.0

34

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

5.1 Adding your own data

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

The screenshot shows the Vivli web application interface. At the top, there is a navigation bar with links: Home, About, Members, News & Events, Resources, and Find Studies. Below this is a dark blue header with the Vivli logo and the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. On the right side of the header, there are links for 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS' (with a notification badge), and 'DATA REQUESTER'.

The main content area is titled 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes'. On the left, there is a sidebar with a list of items: Research Team, Research Proposal, Studies (highlighted), Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, Request History, and Chat.

The main content area is divided into sections. The first section is 'REQUESTED STUDY TYPES' with a help icon and a download icon. Below this is 'VIVLI-LISTED AND PROVISIONED STUDIES'. This section contains two study entries:

- 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 Data already on platform Remove X >
- 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 Data already on platform Remove X >

Below these entries is the section 'VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS'. It states 'No Studies Found'. At the bottom of this section, there is a red-bordered box containing the text 'STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI' and an 'Add +' button.

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

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

I WILL BRING M...



123456

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

Data collected during my own clinical trial

Submit

Cancel

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

Request Studies, Data, or Tools not listed on Vivli

If you will be providing your own data, tools or scripts, then as the provider, select "I WILL BRING MY OWN" and provide a name and a description for the data, tool, or script. You will be notified when to upload the data, tool or script and the Vivli team will support you in this process.

If you are requesting clinical trial data from a Vivli member, then as the provider of the data select the member's name, provide the NCT ID or the Sponsor ID of the study, and a description of the study. Vivli does not guarantee that the Vivli member will approve the data request. For more information, please see our [Members page](#).


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

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

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

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

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS
No Studies Found

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI [Add +](#)

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

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

The [Vivli secure research environment](#) is a cloud-based remote workspace. The Vivli secure research environment allows research teams to access data and conduct analyses in a shared workspace that is equipped with analytical tools and may be flexibly configured. Download a complete [list](#) of Software and R packages available in the research environment. If you plan to bring in additional study data, statistical tools or scripts for use in the Vivli research environment, not included in the PDF, please list each specific tool or package in the studies section, under “Studies, Data, Tools (Not listed on Vivli)” section in the studies tab. It is Vivli policy that any data, statistical tools or scripts needs to be included in this section of the data request during the review process. Requests for additional data, tools or scripts after the review process is complete may lead to additional delays.

5.2.1 Adding Scripts or Tools to your Data Request Form

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

Request Studies, Data, or Tools not listed on Vivli

upload the data, tool or script and the Vivli team will support you in this process.

If you are requesting clinical trial data from a Vivli member, then as the provider of the data select the member's name, provide the NCT ID or the Sponsor ID of the study, and a description of the study. Vivli does not guarantee that the Vivli member will approve the data request. For more information, please see our [Members page](#).

Select provider of the data

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

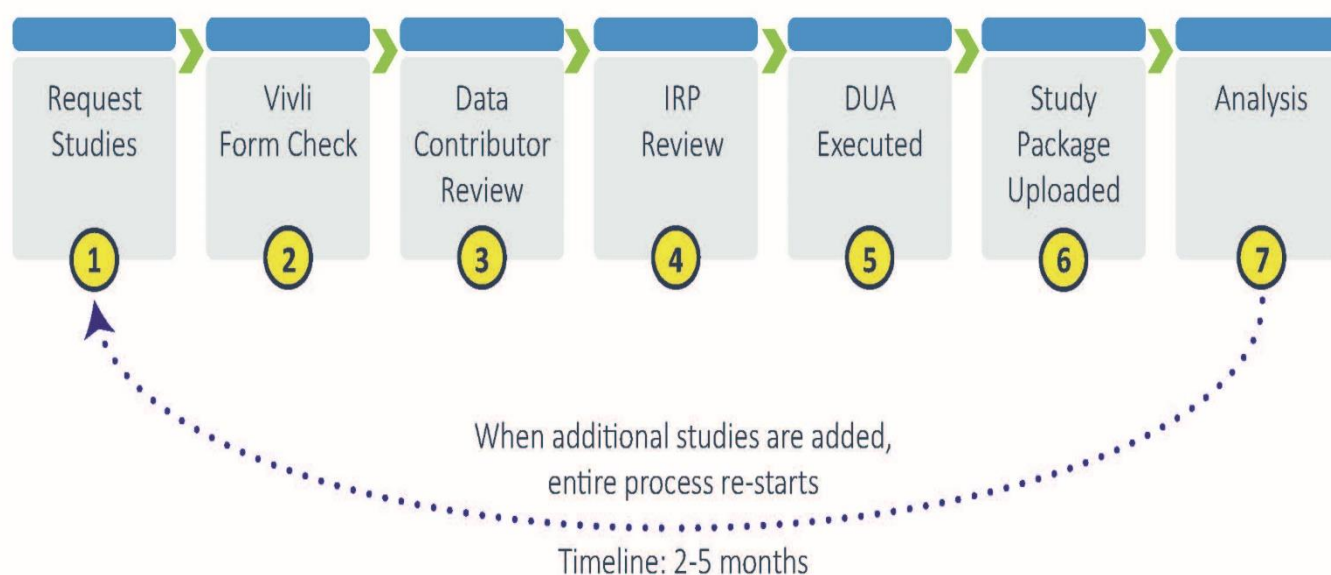
6.0 Modifying or revising your data request

6.1 Overview

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

PLEASE NOTE: According to Vivli policy, any changes to the Lead Investigator, Lead Statistician, their conflict of interest, adding and removal of studies in the request, changes to the Statistical Analysis Plan will require that Data contributors have the opportunity to re-review your data request and have it go through their entire approval process. This allows the reviewers of a request to know which data sets will be combined into the same analysis environment. This entire process could take an additional 2-5 months. Hence, please finalize your plans ahead of time to avoid any delays later.

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



6.2 Modification after submission

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

6.3 Requested revisions to your data request

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

6.3.1 Steps for revising request

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

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

My Data Requests (162)

Search data requests

Draft **Active** 103 Not Approved 2 Withdrawn 56 Archived 1

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

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

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

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

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

< Go Back Print

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

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 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 QUICK STUDY LOOKUP, MY DATA REQUESTS, and DATA REQUESTER. The main content area displays a form for a data request titled 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes'. On the left, there is a sidebar with a list of steps: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments (highlighted with a red box), Attestations, and Chat. The main form area has a title bar with buttons for Edit Request Title, Cancel, Save, and Submit. Below the title bar, there is a section for Other Information with a text area. Underneath that is a section for File Attachments with a message 'NO FILES IN PACKAGE' and a dashed box containing a 'Select Files' button and a 'Drop files here' instruction.

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

6.4 Deleting Data Requests

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

6.5 Withdrawal process

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

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

- When the request has been submitted and returned to Drafts for revision (and)
- Has not been revised, resubmitted, or progressed to the next stage of review (and)
- No response is received from the Research Team to Vivli Admin for 4 months following check-ins via chat after 1 and 4 months.

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

7.0 Communications

7.1 Open Chat

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

7.2 Steps for creating a chat message

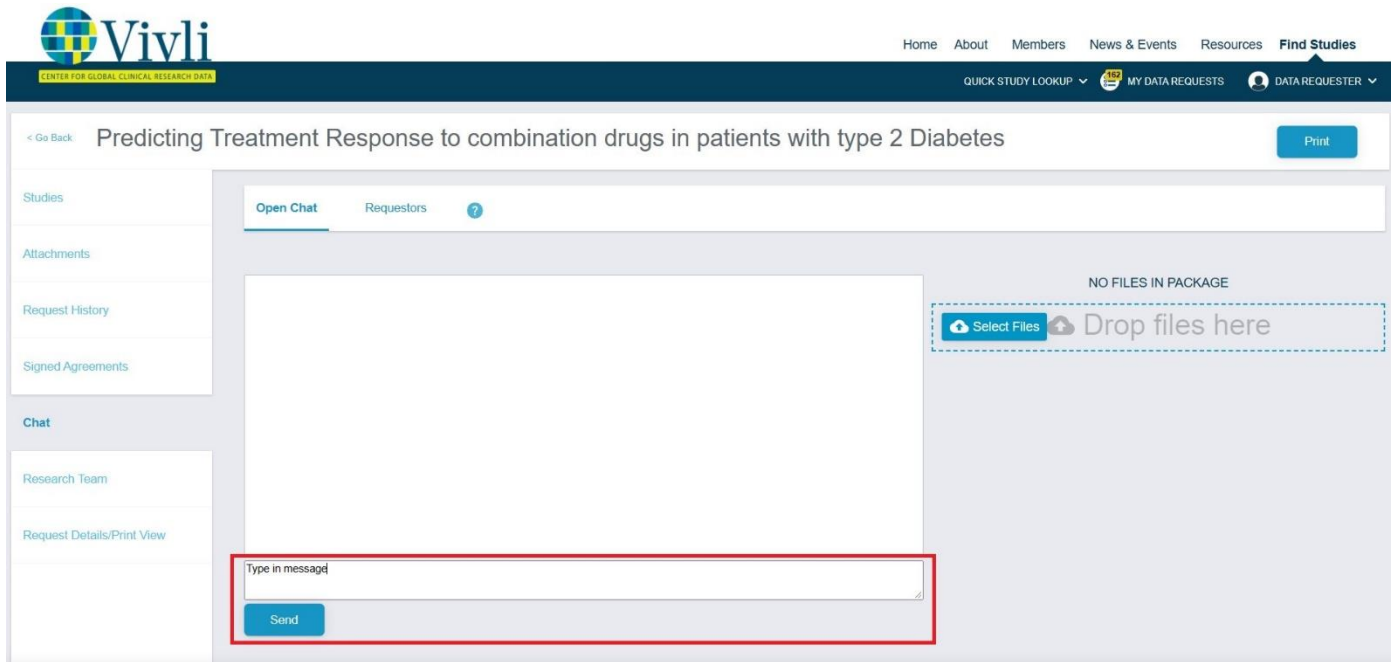
1. Log on to the platform and Go to **My data requests** tab:

The screenshot shows the Vivli website's 'My Data Requests' page. The header includes the Vivli logo and navigation links: Home, About, Members, News & Events, Resources, and Find Studies. Below the header, there's a search bar and a tabbed interface for data requests. The 'Active' tab is selected, showing 103 requests. Below the tabs, two data request entries are visible. The first entry is titled 'PREDICTING TREATMENT RESPONSE TO COMBINATION DRUGS IN PATIENTS V' with Vivli ID: 00002555 and Status: Submitted and Awaiting Vivli Request Form Check. The second entry has the same title, Vivli ID: 00002553, and Status: At least one Data Package Provided and Available.

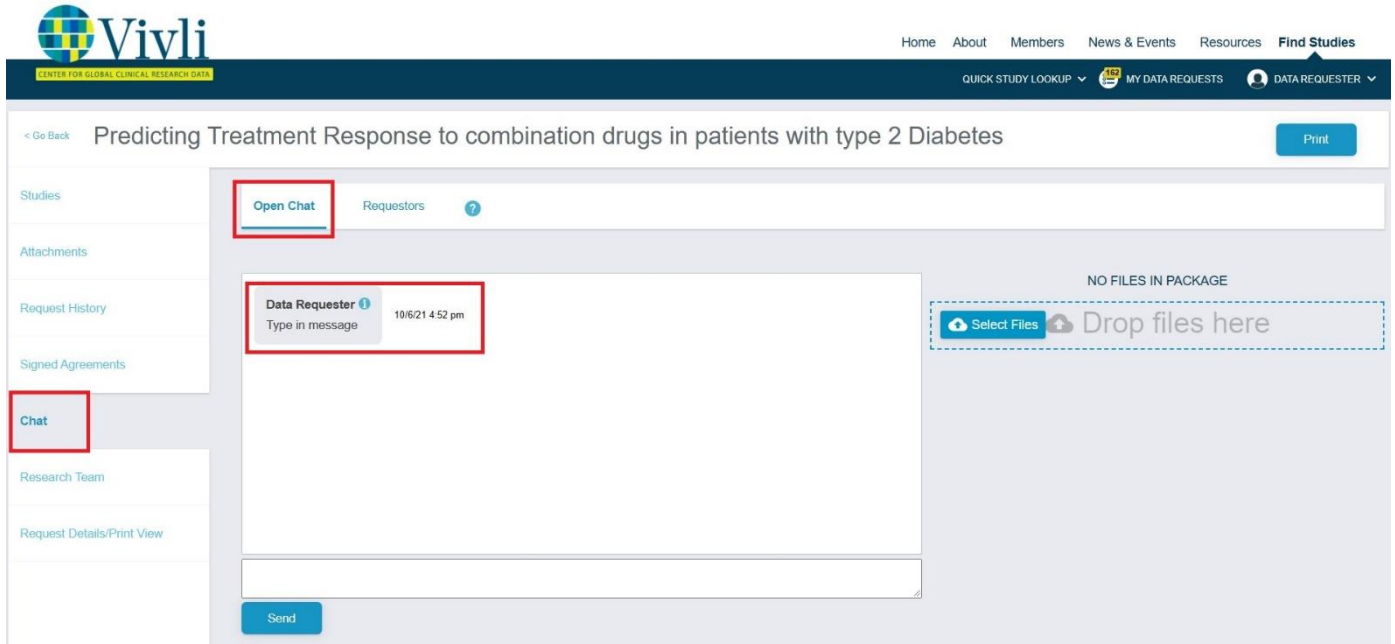
2. Open data request and click on **Chat** tab on the left-hand side of the screen and go to **Open chat**:

The screenshot shows the 'Open Chat' interface for a specific data request titled 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes'. The left sidebar contains a list of tabs: Studies, Attachments, Request History, Signed Agreements, Chat (highlighted with a red box), Research Team, and Request Details/Print View. The main area shows the 'Open Chat' tab selected, with a 'Requestors' section containing a question mark icon. Below this is a large text input area with a 'Send' button. To the right, there's a section for file uploads with the text 'NO FILES IN PACKAGE' and a dashed box containing 'Select Files' and 'Drop files here' buttons. A 'Print' button is located in the top right corner.

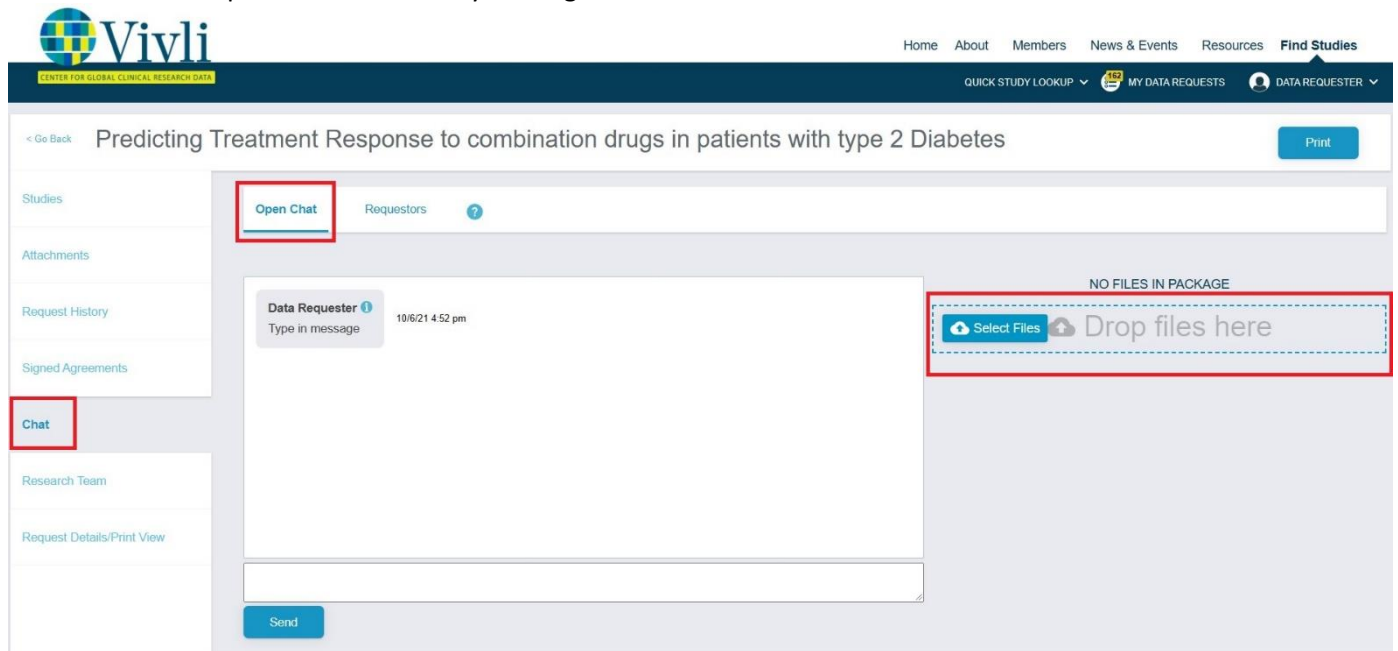
3. Enter your message in the chat message box and click **Send**:



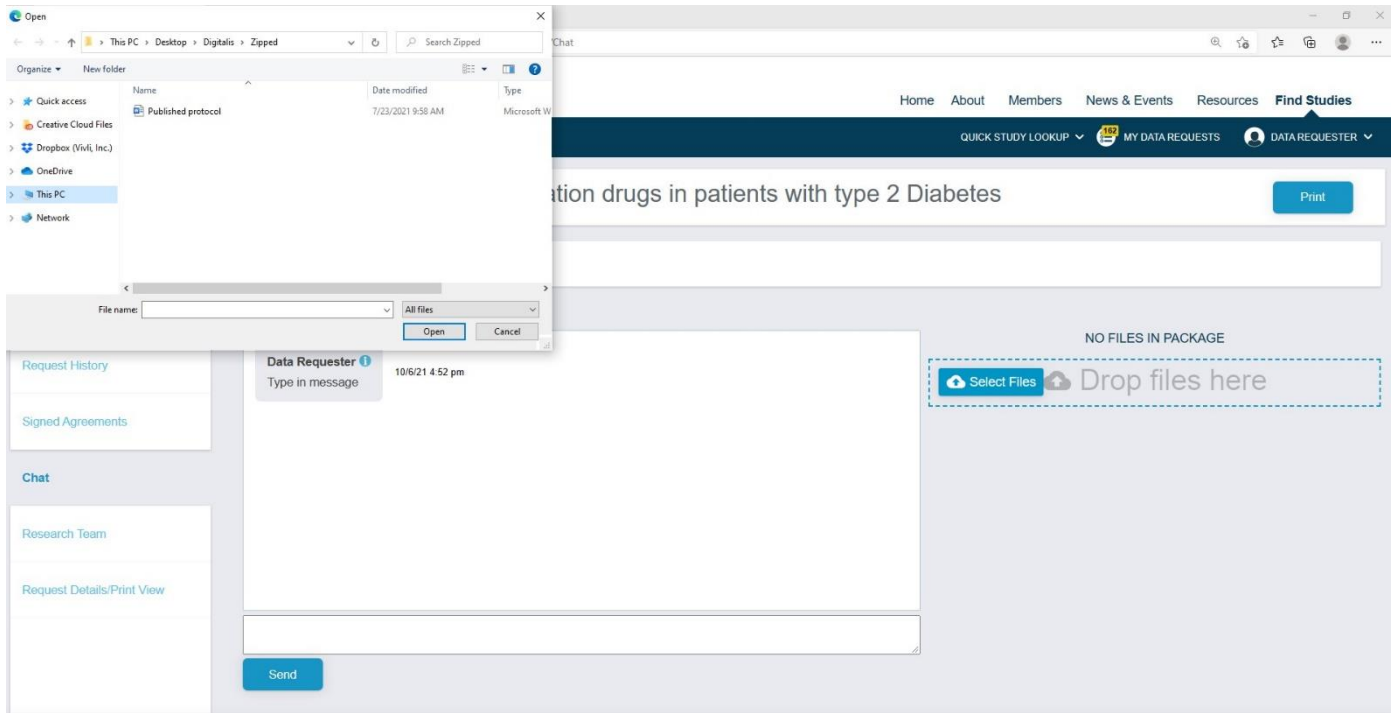
4. The message will now appear in the Chat record for all users (to see your just-entered chat message, you may need to click Refresh on your browser), and response will also appear in the chat record:



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



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



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

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. Below this is a secondary navigation bar with "QUICK STUDY LOOKUP", "MY DATA REQUESTS", and "DATA REQUESTER". The main content area is titled "Predicting Treatment Response to combination drugs in patients with type 2 Diabetes". On the left, a sidebar contains 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 shows a message from "Data Requester" at 10/6/21 4:52 pm with the text "Type in message". Below this, another message from "Data Requester" at 10/6/21 4:56 pm says "File Uploaded: Published protocol.docx". To the right of the chat area, there is a "Select Files" button and an "UPLOADED FILES" section. This section contains a table with columns for Filename, Size, and Uploaded By. The table lists a file named "Published protoc..." with a size of "11..." and uploaded by "Data Re...". To the right of the file name, there are two buttons: a download icon and a red 'X' button (highlighted with a red box).

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

This screenshot is identical to the previous one, but with additional red boxes highlighting the deletion process. The "Chat" link in the sidebar remains highlighted. The message "File Uploaded: Published protocol.docx" is still present. The "UPLOADED FILES" table is still shown. The red 'X' button next to the file name "Published protoc..." is now highlighted with a red box, indicating it is the target for deletion.

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. Below this is a secondary navigation bar with "QUICK STUDY LOOKUP", "MY DATA REQUESTS", and "DATA REQUESTER". The main content area is titled "Predicting Treatment Response to combination drugs in patients with type 2 Diabetes". On the left is a sidebar with links for Studies, Attachments, Request History, Signed Agreements, Chat, Research Team, and Request Details/Print View. The chat window shows a message from "Data Requester" at 10/6/21 4:52 pm saying "Type in message". Below it, another message from "Data Requester" at 10/6/21 4:56 pm says "File Uploaded: Published protocol.docx". To the right of the chat window is a "Select Files" button and an "UPLOADED FILES" table. The table has columns for Filename, Size, and Uploaded By. It contains one entry: "Published protoc..." with size "11..." and uploaded by "Data Re...". A red box highlights the "Download" arrow icon in the "Uploaded By" column.

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

This screenshot shows the same Vivli interface as the previous one, but the chat history now includes a third message from "Data Requester" at 10/6/21 5:01 pm that says "File Deleted: Published protocol.docx". This message is highlighted with a red box. The "UPLOADED FILES" table on the right now displays "NO FILES IN PACKAGE" instead of the previous file entry.

11. Chats are posted when you click "Send" which permits you to write and read distinct paragraphs

12. Chat messages automatically scroll to the most recent post instead of the first.

13. In chat, files are sorted by date, newest on top, and the hover text displays the filename, date, and person who uploaded it.

14. Posted chat messages are visible immediately.

7.3 Emails

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

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

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

8.0 Data Use Agreement

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

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

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

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

Studies

Attachments

Request History

Signed Agreements

Chat

Research Team

Request Details/Print View

There are no Signed Documents

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

Select Files

UPLOADED FILES

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

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

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

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

Studies

Attachments

Request History

Signed Agreements

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

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

- Statistical Analysis Plan
- Publication Citation

9.0 Data Package Upload & Accessing the data

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

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