



How-To: Request Studies on Vivli

Vivli Platform Release 3.4

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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:
 - Study Design (Interventional studies, Observational studies), Study Phase, Sponsor Information (Funder, Contributor), Sample Size, Location, Start Date, and End Date.
- You may also use the quick study lookup option to search using NCT ID or Sponsor ID.

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY **QUICK STUDY LOOKUP** Sign up Log in

We are committed to advancing the knowledge around the COVID-19 pandemic

Share trials Search for trials

KEYWORD SEARCH PICO Beta

What are you looking for today?

STUDY DESIGN
INTERVENTIONAL STUDIES
Select Multiple
OBSERVATIONAL STUDIES
Select Multiple
STUDY PHASE
Select Multiple

SPONSOR INFORMATION
FUNDER
Select Multiple
CONTRIBUTOR
Select Multiple
SAMPLE SIZE
(Disabled)

LOCATION
Select Multiple

START DATE
From To
mm/yyyy mm/yyyy
END DATE
From To
mm/yyyy mm/yyyy

- 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 search results page. At the top, the Vivli logo is on the left, and navigation links (Home, About, Members, News & Events, Resources, Portals, 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 bar contains the keyword "diabetes". Below the search bar, there are filters for STUDY DESIGN (INTERVENTIONAL STUDIES, OBSERVATIONAL STUDIES, STUDY PHASE), SPONSOR INFORMATION (FUNDER, CONTRIBUTOR, SAMPLE SIZE), LOCATION, and START/END DATE. A red box highlights the search bar and the "diabetes" text. Another red box highlights the "i" (info) and "Q" (search) icons. At the bottom, a red box highlights the "86 Studies" count.

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

The screenshot shows the Vivli study details page. 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 search bar contains the text "What are you looking for today?". The main content area displays three clinical trials. The first trial is "Clinical Assessment of GSK716155 for Type 2 Diabetes Mellitus -A Phase I/II Study to Investigate the Safety, Pharmacokinetics and Pharmacodynamics of GSK716155 in Japanese Subjects With Type 2 Diabetes Mellitus". The second trial is "A Phase I, Randomized, Placebo-Controlled, Crossover Clinical Trial to Assess the Safety of Oral SRT2104 and Its Effects on Vascular Dysfunction in Otherwise Healthy Cigarette Smokers and Subjects With Type 2 Diabetes Mellitus". The third trial is "A Single-Center, Non-Randomized, Open-Label, Comparative Study to Assess the Utility of Novel Technologies and Biomarkers as Methods for Measuring Human Pharmacodynamic Response to 8 Weeks of Administration of Rosiglitazone Maleate 4mg BID in Healthy Normal or Overweight Controls, Healthy Obese Subjects and Subjects With Type 2 Diabetes Mellitus (T2DM)". A red box highlights the "View Study Details" button for the first trial.

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

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

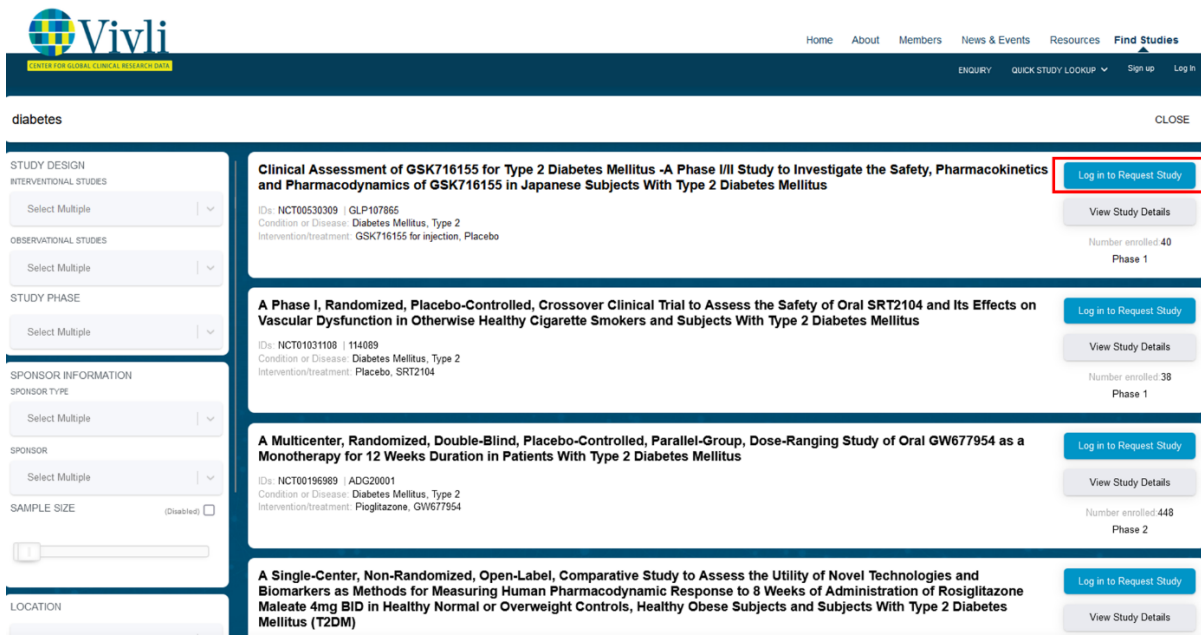
40

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:



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
Random 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 | GLP107965
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 | ADQ20091
Condition or Disease: Diabetes Mellitus, Type 2
Intervention/treatment: Pioglitazone, GW677954

Log in to Request Study

View Study Details

Number enrolled 448
Phase 2

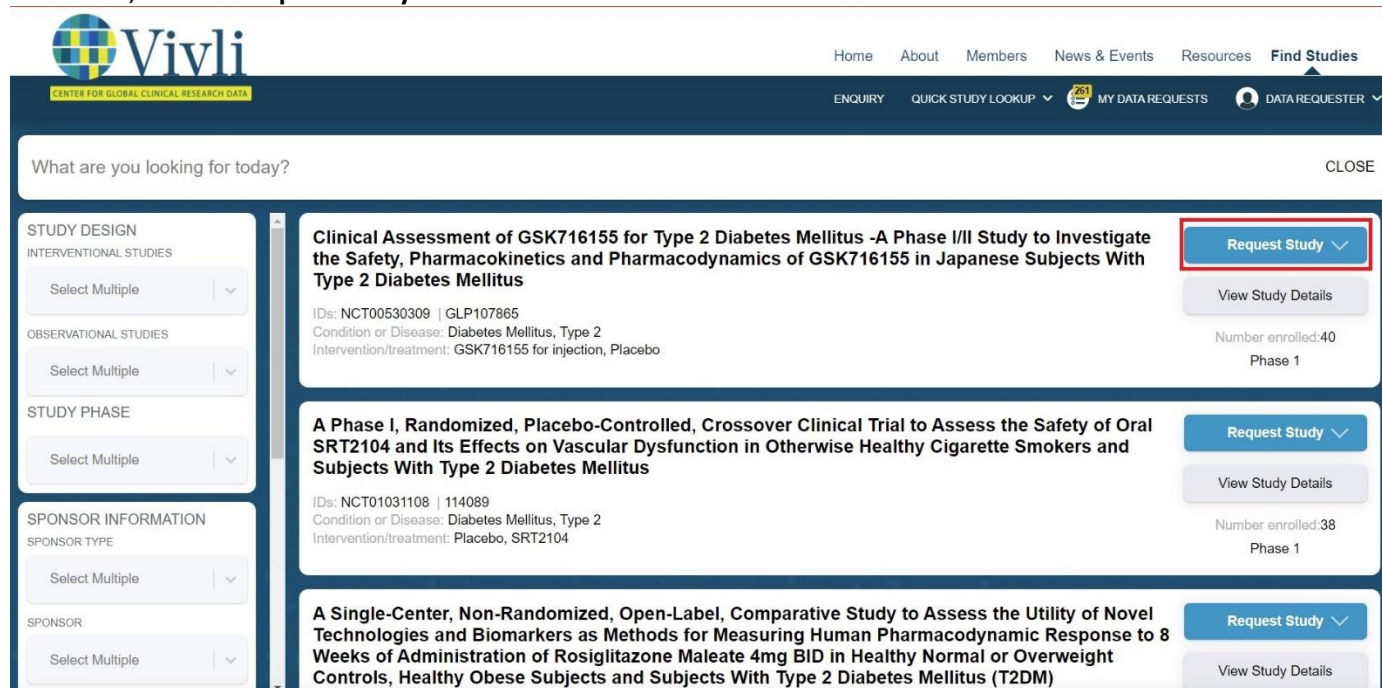
A Single-Center, Non-Randomized, Open-Label, Comparative Study to Assess the Utility of Novel Technologies and Biomarkers as Methods for Measuring Human Pharmacodynamic Response to 8 Weeks of Administration of Rosiglitazone Maleate 4mg BID in Healthy Normal or Overweight Controls, Healthy Obese Subjects and Subjects With Type 2 Diabetes Mellitus (T2DM)

Log in to Request Study

View Study Details

1.3 Add studies to your data request

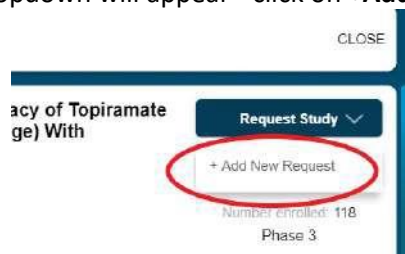
1. Starting a data request begins with the addition of studies. To add studies from a search to a Data Request Form, click on **Request Study**.



The screenshot shows the Vivli website interface. 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, 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 dropdown contains the option "+ Add New Request", which is highlighted by a red circle. The background of the dropdown shows the study details for the "Study of Topiramate (ge) With".

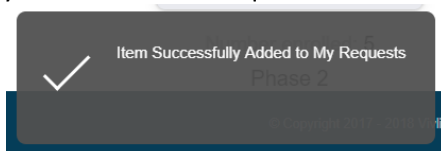
3. A dialogue box will pop up where you can provide the Research Project Name for your research project. **Note:** Your Project name must match the "Title of Proposed Research" within the data request form. This can be edited before submitting the data request for review. After entering a research project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

262
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

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

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

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

Request Study
View Study Details

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)

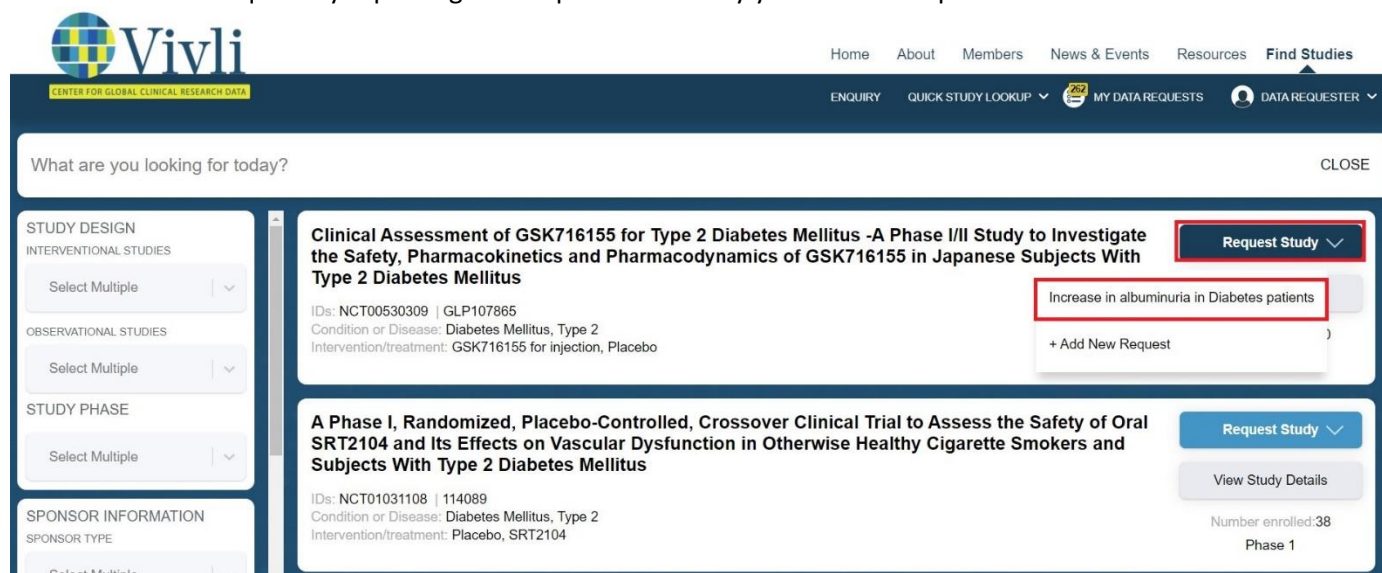
Request Study
View Study Details

Item Successfully Added to My Requests

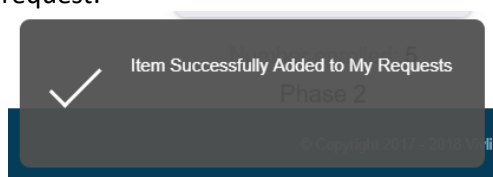
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- To add an additional study to an existing data request, click on **Request Study**. Then click on the existing data request's title from the dropdown. Note: If you have multiple studies to add to your research project, add them to the same request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



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



- 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

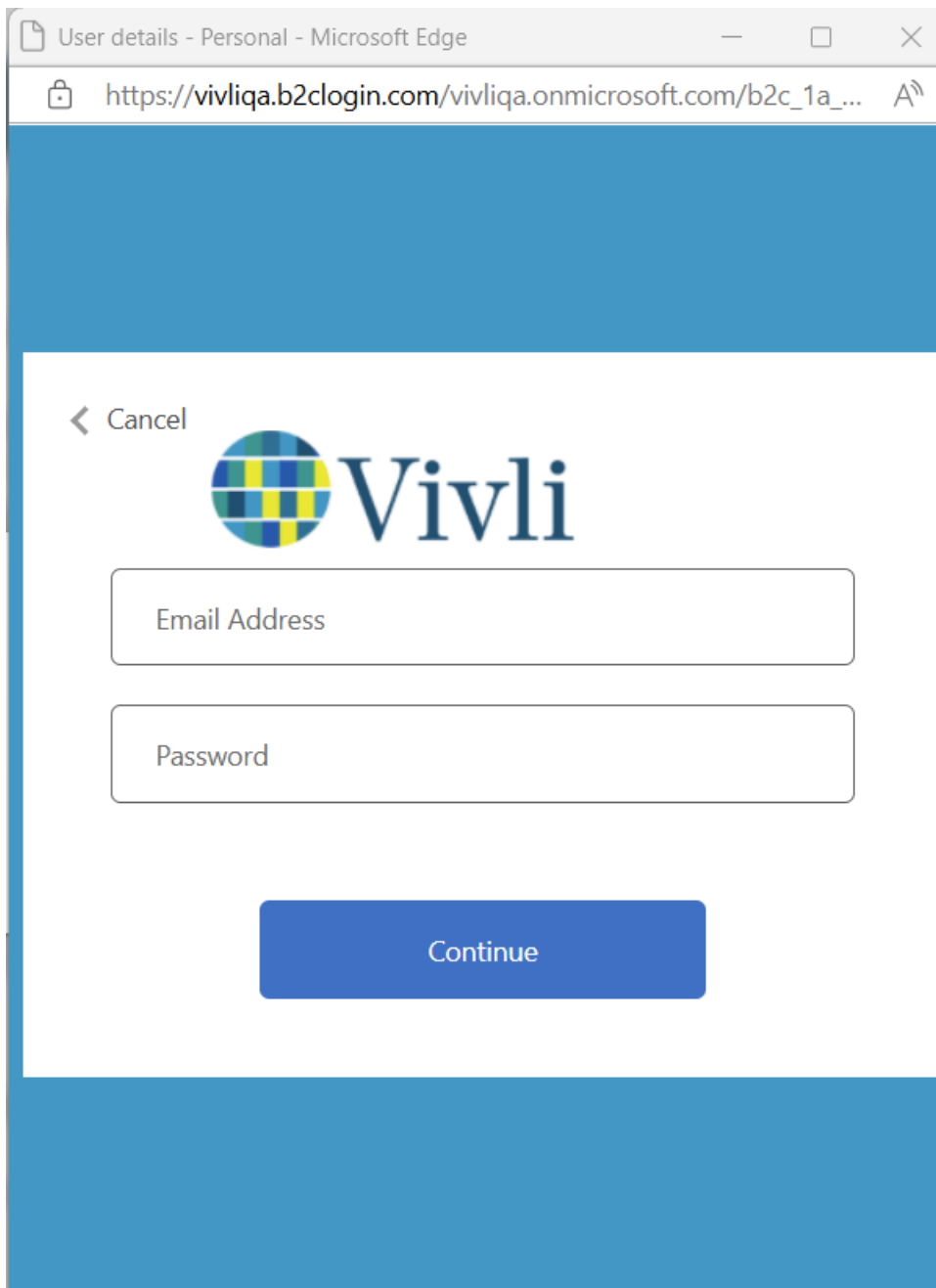
- As part of Vivli's security policy, for accounts to remain active on the platform, users must log in every six months.
- If you have not logged in for more than six months, the Vivli team will email you asking that you log in to your account. The Vivli team cannot accept notifications via email to keep these accounts active. It will require you to log in every six months.
- 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 and, we can re-activate your account at any time.

1.5 Edit display name in profile

1. To edit your display name, click “Edit My Profile” on the right hand side of the platform underneath your name

The screenshot displays the Vivli user interface. At the top, the Vivli logo is on the left, and navigation links (Home, About, Members, News & Events, Resources, Portals, Find Studies) are on the right. Below the logo is the text "CENTER FOR GLOBAL CLINICAL RESEARCH DATA". The main header area contains links for "ENQUIRY", "QUICK STUDY LOOKUP", and "MY DATA REQUESTS" (with a 459 badge). A user profile dropdown menu is open on the right, showing options: Search, Dashboard, Enquiries, Edit My Profile (highlighted with a red box), Change Password, and Log Out. The main content area is titled "Welcome, Data Requester!" and includes a "Dashboard" link in the sidebar. The dashboard content includes a welcome message, a section for "Organization Memberships" (stating the user is not a member), and sections for "Data Requests Awaiting My Approval" (showing no requests) and "Studies Awaiting Data Package Upload" (stating only authorized contributors can upload IPD data).

2. You will be prompted to log in again with your credentials




The screenshot shows a Microsoft Edge browser window with the title "User details - Personal - Microsoft Edge". The address bar displays the URL "https://vivliqa.b2clogin.com/vivliqa.onmicrosoft.com/b2c_1a_...". The main content area has a blue header and a white login form. The form includes a "Cancel" link with a left arrow, the Vivli logo (a circular icon with a grid of colored squares followed by the text "Vivli"), an "Email Address" input field, a "Password" input field, and a blue "Continue" button.

3. Provide your full name and click **Continue**

User details - Personal - Microsoft Edge

https://vivliqa.b2clogin.com/vivliqa.onmicrosoft.com/B...

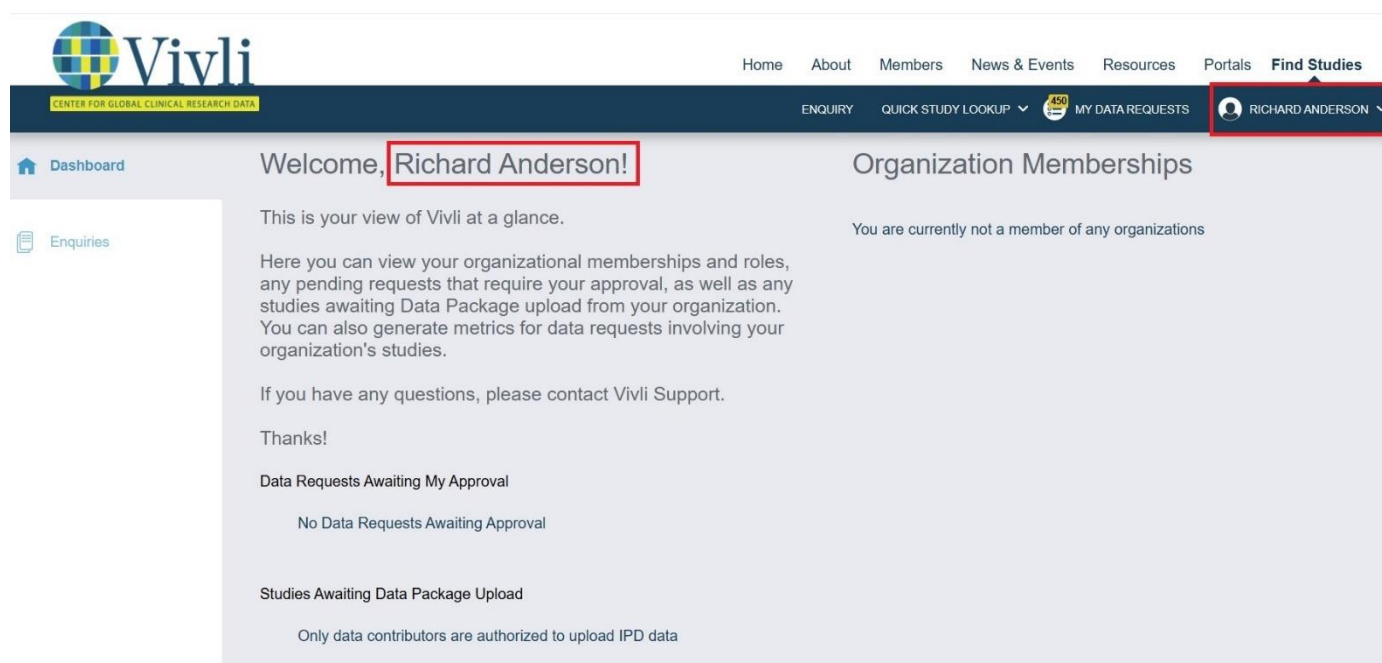
< Cancel

 Vivli

Richard Anderson

Continue

4. The system will bring you to the Dashboard where you can see the updated name

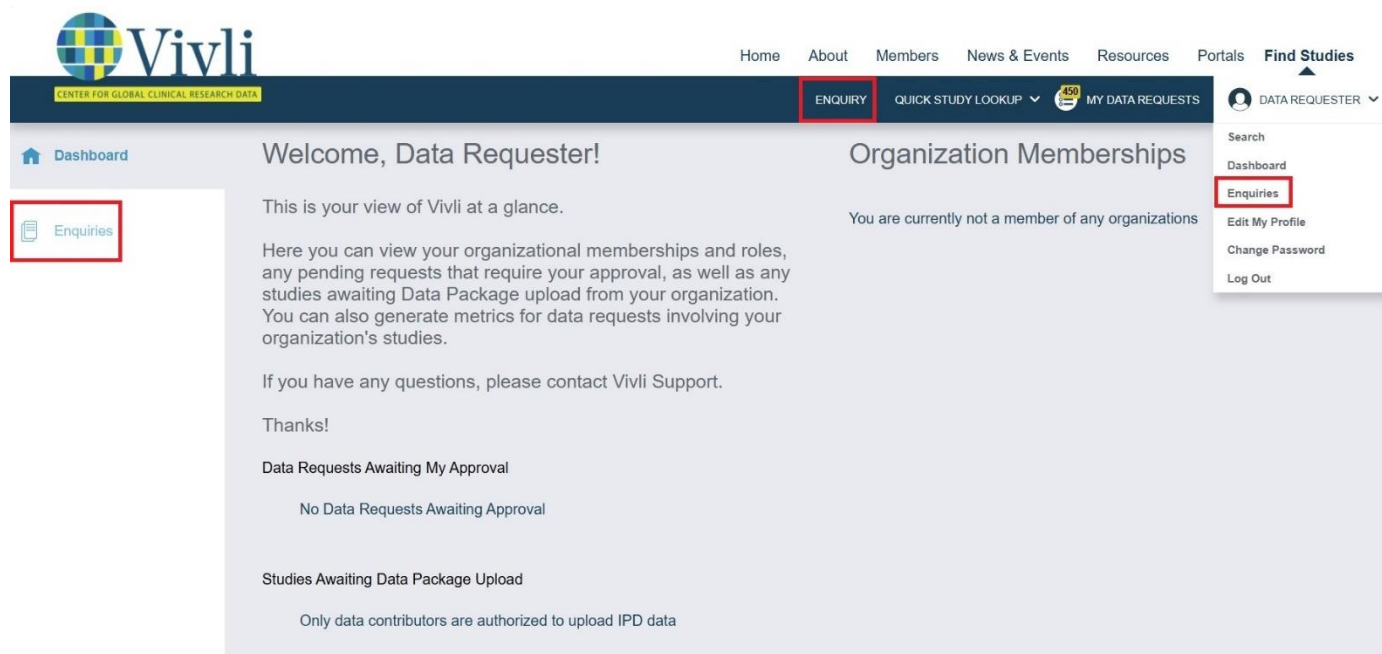


2.0 Your Enquiries

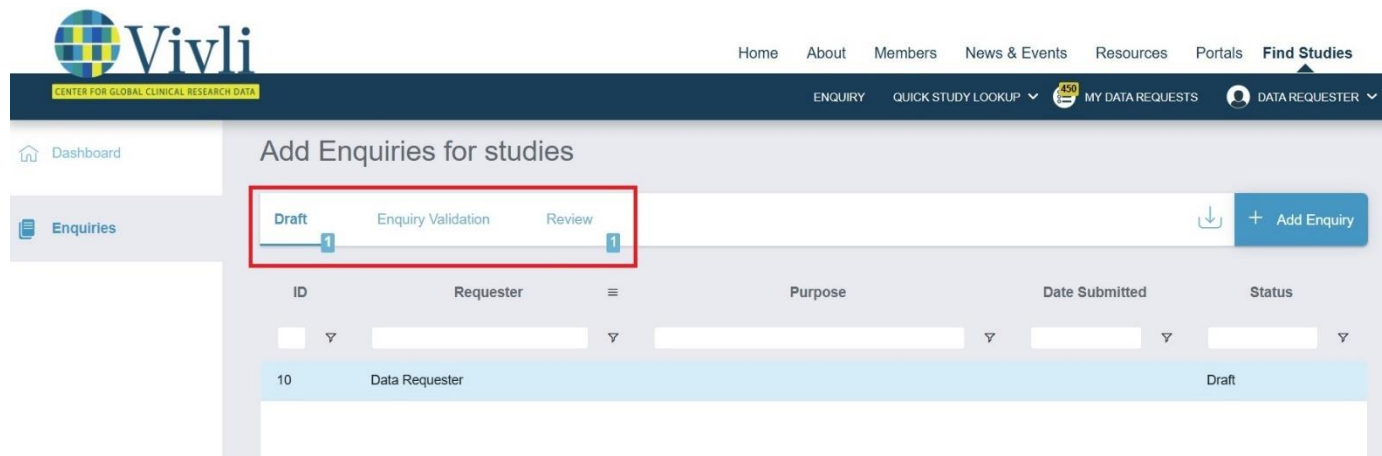
1. You can submit an enquiry using the Vivli platform <https://search.vivli.org/enquiries/> regarding the availability of a Vivli Member study not listed on Vivli or for additional study information not included in a study listing.
2. Enquiry tab Allows Vivli and Data Contributors to receive, respond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

2.1 Navigation and Enquiry Dashboard

1. Once you have logged in to the dashboard, you can navigate to Enquiries using the toolbar on the left-hand side of the screen. You can also use the dropdown menu on the upper right-hand corner of the screen or the top center of the screen



2. The Enquiries Dashboard displays a status bar at the top of the page which displays all the Enquiries for your organization's studies.



3. The status bar contains 3 sections:

Draft: Displays Enquiries that are being drafted but not yet submitted.

Enquiry Validation: Displays Submitted Enquiries that are in Vivli review. The Vivli team may request you more information or send it back for any revision or may process it forward. You will receive an email notification for any updates.

Review: Displays Enquiries that are in review by the Data Contributors. It also includes Enquiry where decisions are made.

4. Each Enquiry recorded on the dashboard displays the Vivli Enquiry ID, Requester Name, Purpose of research, Date Submitted, and Status of the Enquiry.

2.2 Creating an Enquiry

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

2. In the Enquiry form, Requester Email and Requester Name is automatically pulled from your Vivli Account profile. If your name is incorrect, please **stop** here and update your profile. Do not hit the Save button. Please see [Section 1.5 Edit display name](#) in profile for more information.

< Go Back Enquiry Id: 0 Status: Draft Date Submitted:

Add Study Save Submit

Requester Email
Datarequester.vivli@gmail.com

Requester Name
Data Requester

Your Institution

Country
- Select an Option -

Purpose

Please enter an NCT Id or Sponsor Id if the study is on clinicaltrials.gov, or enter the study title.

- NCT ID

Study Title

OR

Sponsor ID

Data Contributor
- Select an Opti...

Sponsor:

3. Fill in your Institution name, select your country, and provide the purpose of your research

< Go Back Enquiry Id: 0 Status: Draft Date Submitted:

Add Study Save Submit

Requester Email
Datarequester.vivli@gmail.com

Requester Name
Data Requester

Your Institution

Country
- Select an Option -

Purpose

Please enter an NCT Id or Sponsor Id if the study is on clinicaltrials.gov, or enter the study title.

- NCT ID

Study Title

OR

Sponsor ID

Data Contributor
- Select an Opti...

Sponsor:

4. Type in the study information:

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

Please enter an NCT Id or Sponsor Id if the study is on clinicaltrials.gov, or enter the study title.

NCT ID
NCT00536120

OR

Sponsor ID
101MS404

Study Title
A Randomized, Open-Label Study to Assess the Effects of Tysabri Treatment on Vaccination Response and Lymphocyte Subsets in Subjects With Relapsing Forms of Multiple Sclerosis

Primary Completion Date: 2009-12-31

Clinical Trials: <https://clinicaltrials.gov/show/NCT00536120>

Data Contributor
- Select an Opti...

Sponsor: Biogen

Discussion:

Data Requested
- Select Multiple -

Response ?
New

Reason ?
None

No Data Found

5. If a study is already listed on the Vivli platform, you will see a note in red. At this point, you may stop your enquiry and go to the search page to add the study to your data request. Please see [Section 1.1 Searching for studies on the Vivli platform](#). Do not hit the Save button. If you need to enquire about further information on the study, you can continue to proceed with the Enquiry.

Please enter an NCT Id or Sponsor Id if the study is on clinicaltrials.gov, or enter the study title.

NCT ID
NCT02583997

OR

Sponsor ID
LOCAL/2014/PL-01

Study Title
Non-closure of Alveoli After Avulsion of Wisdom Teeth: a Randomized, Open, Multicenter Trial

Primary Completion Date: 2018-07-26

Clinical Trials: <https://clinicaltrials.gov/show/NCT02583997>

Data Contributor
- Select an Opti...

Sponsor: Centre Hospitalier Universitaire de Nîmes

This Study is listed on the Vivli Platform

6. Select the Data Contributor from the dropdown list. If a Data Contributor is not listed in the Data Contributor dropdown, they are likely not a member of Vivli and therefore, the study is unlikely to be shared via the Vivli platform. We recommend reaching out directly to the data contributor to learn more

about their data sharing policies. Some Vivli Members may require that enquiries be submitted via their own portals and will not accept enquiries via the Vivli platform.

Please enter an NCT Id or Sponsor Id if the study is on clinicaltrials.gov, or enter the study title.

NCT ID

NCT00536120

OR

Sponsor ID

101MS404

Study Title

A Randomized, Open-Label Study to Assess the Effects of Tysabri Treatment on Vaccination Response and Lymphocyte Subsets in Subjects With Relapsing Forms of Multiple Sclerosis

Data Contributor

- Select an Opti...

Sponsor: Biogen

Primary Completion Date: 2009-12-31 Clinical Trials: <https://clinicaltrials.gov/show/NCT00536120>

Discussion:

Data Requested

- Select Multiple -

Response ?

New

Reason ?

None

No Data Found

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

Please enter an NCT Id or Sponsor Id if the study is on clinicaltrials.gov, or enter the study title.

NCT ID

NCT00536120

OR

Sponsor ID

101MS404

Study Title

A Randomized, Open-Label Study to Assess the Effects of Tysabri Treatment on Vaccination Response and Lymphocyte Subsets in Subjects With Relapsing Forms of Multiple Sclerosis

Data Contributor

- Select an Opti...

Sponsor: Biogen

Primary Completion Date: 2009-12-31 Clinical Trials: <https://clinicaltrials.gov/show/NCT00536120>

Discussion:

Data Requested

- Select Multiple -

Response ?

New


Reason ?

None

No Data Found

8. To delete a study, click the delete icon

Please enter an NCT Id or Sponsor Id if the study is on clinicaltrials.gov, or enter the study title.


<input type="text" value="NCT ID"/> <input type="text" value="NCT02583997"/>	<input type="text" value="Study Title"/> Non-closure of Alveoli After Avulsion of Wisdom Teeth: a Randomized, Open, Multicenter Trial	
OR		
<input type="text" value="Sponsor ID"/> <input type="text" value="LOCAL/2014/PL-01"/>		

Primary Completion Date: 2018-07-26 Clinical Trials: <https://clinicaltrials.gov/show/NCT02583997> Data Contributor: - Select an Opti...
Sponsor: Centre Hospitalier Universitaire de Nîmes This Study is listed on the Vivli Platform

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

Are you sure you want to remove this study from the enquiry?

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

 **Vivli** CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP 450 MY DATA REQUESTS RICHARD ANDERSON

Dashboard < Go Back Enquiry Id: 0 Status: Draft Date Submitted:

Enquiries

<input type="text" value="Requester Email"/> Datarequester.vivli@gmail.com	<input type="text" value="Requester Name"/> Richard Anderson
<input type="text" value="Your Institution"/> Duke University	<input type="text" value="Country"/> United States of America
<input type="text" value="Purpose"/> Cardiovascular outcomes in Diabetes subjects	

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

< Go Back Enquiry Id: 0 Status: Draft Date Submitted:

Add Study **Save** **Submit**

Requester Email
Datarequester.vivli@gmail.com

Requester Name
Richard Anderson

Your Institution
Duke University

Country
United States of America

Purpose
Cardiovascular outcomes in Diabetes subjects

Please enter an NCT Id or Sponsor Id if the study is on clinicaltrials.gov, or enter the study title.

☐ NCT ID
NCT02583997

OR

☐ Sponsor ID
LOCAL/2014/PL-01

Study Title
Non-closure of Alveoli After Avulsion of Wisdom Teeth: a Randomized, Open, Multicenter Trial

Data Contributor
AbbVie

Sponsor: Centre Hospitalier Universitaire de Nimes

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

< Go Back Enquiry Id: 0 Status: Draft Date Submitted:

Add Study **Save** **Submit**

Data Requested

- Select Multiple -

Response ?

New

Reason ?

None

No Data Found

Comment

Add Comment

To save comments please click "Save" or "Save & Notify" button.

Date of Final Response:

Request Number(s):

+ NCT ID:

Study Title:

Data Contributor:

Response: !
New

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

< Go Back Enquiry Id: 0 Status: Draft Date Submitted:

Add Study Save **Submit**

Requester Email
Datarequester.vivli@gmail.com

Requester Name
Richard Anderson

Your Institution
Duke University

Country
United States of America

Purpose
Cardiovascular outcomes in Diabetes subjects

Please enter an NCT Id or Sponsor Id if the study is on clinicaltrials.gov, or enter the study title.

☐ NCT ID
NCT02583997

OR

☐ Sponsor ID
LOCAL/2014/PL-01

Study Title
Non-closure of Alveoli After Avulsion of Wisdom Teeth: a Randomized, Open, Multicenter Trial

Data Contributor
AbbVie

Sponsor: Centre Hospitalier Universitaire de Nîmes

14. If the Submit button is not enabled, look for the red exclamation mark which points the incomplete field

< Go Back Enquiry Id: 0 Status: Draft Date Submitted:

Add Study Save **Submit**

Requester Email
Datarequester.vivli@gmail.com

Requester Name
Richard Anderson

Your Institution
Duke University

Country
United States of America

Purpose
Cardiovascular outcomes in Diabetes subjects

	NCT ID: NCT02583997	Study Title: Non-closure of Alveoli After Avulsion of Wisdom Teeth: a Randomized, Open, Multicenter Trial	Data Contributor: AbbVie	Response: New
	NCT ID:	Study Title:	Data Contributor:	Response: New

15. Once submitted, the enquiry moves to the Enquiry Validation stage. You can see the Enquiry ID, Enquiry Status, and the Date Submitted on the top of the request and in the Dashboard. Please see [Section 2.1 Navigation and Enquiry Dashboard](#)

< Go Back Enquiry Id: 11 Status: Enquiry Validation Date Submitted: 2024-06-12 Save

Requester Email Datarequester.vivli@gmail.com	Requester Name Richard Anderson
Your Institution Duke University	Country United States of America
Purpose Cardiovascular outcomes in Diabetes subjects	

<input type="checkbox"/> NCT ID NCT02583997 OR Sponsor ID LOCAL/2014/PL-01	Study Title Non-closure of Alveoli After Avulsion of Wisdom Teeth: a Randomized, Open, Multicenter Trial	Data Contributor AbbVie Sponsor: Centre Hospitalier Universitaire de Nîmes
--	---	--

2.3 Enquiry Discussion

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

Save

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

Save & Notify

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

< Go Back Enquiry Id: 10 Status: Draft Date Submitted:

Add Study Save Submit

Primary Completion Date: Clinical Trials:

Discussion:

Data Requested

ParticipantData x

Response ?

New

Reason ?

None

No Data Found

Comment

Here is a sample message on the enquiry

Add Comment

To save comments please click "Save" or "Save & Notify" button.

Date of Final Response: Request Number(s):

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

< Go Back Enquiry Id: 9 Status: Review Date Submitted: 2024-06-10

Save Save & Notify

Primary Completion Date: Clinical Trials: <https://clinicaltrials.gov/show/NCT01946204>

Discussion:

Data Requested:

- Clinical Documents
- ParticipantData

Response ?

Response from data c...

Reason ?

None

6/10/2024 1:00:58 pm Amrutha Here is a sample message on the Enquiry

Comment

Add Comment

To save comments please click "Save" or "Save & Notify" button.

Date of Final Response: Request Number(s):

7. If the Vivli team or Data Contributor provides their comments, you will receive an email notification and their response will be displayed in the discussion field.

2.4 Enquiry Response

Each study will have the following fields:

- a. **Responses:** This includes updates to the Enquiry discussion and decisions made by the Data Contributor:
 - i. None – No responses
 - ii. New – Meaning no one has responded yet – this is the initial default value
 - iii. Response from requester – You have added information to the discussion. This is automatically set when you add a comment and click Save or Save and Notify.
 - iv. Response from data contributor – The Data Contributor has added information to the discussion. This is automatically set once the Data Contributor responds.
 - v. Response from Vivli – The Vivli Admin has added information to the discussion. This is automatically set when the Vivli team responds.
 - vi. Eligible for Request as an Unlisted Study – You can Add this study to your data request. For next steps, see [Section 2.5 Adding studies to your data request](#)
 - vii. Study is Listed - You can Add this study to your data request. For next steps, see [Section 2.5 Adding studies to your data request](#)
 - viii. Not Available – Study is not available. No Action is needed from you
- b. **Reason** – When the response is Not Available, the reason field provides more information. Other
- c. **Comment** – You, Vivli Admin and Data Contributors can add a comment about the Enquiry
- d. **Discussion** – This includes all the comments provided by you, Vivli Admin, and Data Contributor for this specific study
- e. **Date of Final Response** – Date when Data Contributor makes a final decision
- f. **Request Number(s)** – You can add studies from the Enquiry directly into the data request form. In such instances, the Enquiry will display the associated Data request ID once the data request is submitted on the platform. For more information [See Section 2.5 Adding Studies to your data request.](#)

The screenshot displays the Vivli Enquiry interface. On the left, under 'Data Requested:', there are two bullet points: 'Clinical Documents' and 'ParticipantData'. Below these are two dropdown menus: 'Response' (currently set to 'New') and 'Reason' (currently set to 'None'). Both dropdowns have a red box around them. To the right of these is a large 'Discussion:' area with a red box around the label, which currently displays 'No Data Found'. Below the discussion area is a 'Comment' input field and an 'Add Comment' button. At the bottom left, there are two more fields: 'Date of Final Response:' and 'Request Number(s):', both with red boxes around their labels. At the bottom right, there is a note: 'To save comments please click "Save" or "Save & Notify" button.'

2.5 Adding studies to your data request

1. If a study is Eligible for Request, you can add studies from the Enquiry directly into the data request form.
 - If the study is unlisted, you can add them immediately.
 - If the study is listed, wait for instructions from the Vivli admin when the study is ready to be added (this might take a couple of days).
2. Open the Enquiry and scroll down to studies. Click the **Request Study** button and click the down arrow next to it.

The screenshot shows the Vivli Enquiry form for Enquiry Id: 9, Status: Review, Date Submitted: 2024-06-10. The form includes fields for NCT ID (NCT01946204), Sponsor ID (CR102931), and Study Title (A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men With Non-Metastatic (M0) Castration-Resistant Prostate Cancer). A red box highlights the 'Request Study' button with a dropdown arrow. Below the button, there are fields for 'Data Contributor' and 'Sponsor: Aragon Pharmaceuticals, Inc.'. A table titled 'Discussion' shows two entries: one from Stan Neumann on 6/10/2024 and another from Amrutha on 6/11/2024. The 'Data Requested' section lists 'Clinical Documents' and 'ParticipantData'. The 'Response' section shows 'Study is Listed' and the 'Reason' section shows 'None'.

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

This screenshot shows the same Vivli Enquiry form as the previous one, but with the 'Request Study' dropdown menu open. The dropdown menu lists several data requests: 'Albumin increase in diabetes mellitus patients', 'Heparin use in the patients with stroke', 'ILT TC3027', 'Increase in albuminuria in Diabetes patients', and 'Increase in albuminuria in Diabetes patients'. The 'Request Study' button is highlighted with a red box, and the dropdown menu is also highlighted with a red box.

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

< Go Back Enquiry Id: 1 Status: Review Date Submitted: 2024-06-13 Save Save & Notify

Request Study ▾

Notify on "Save" Outcomes

Data Contribution Data Contribution

+ Add New Request

Sponsor: Aragon Pharmaceuticals, Inc.

NCT ID: NCT0194620... [Previous Enquiries](#)

OR

Sponsor ID: CR102931

Study Title: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men With Non-Metastatic (M0) Castration-Resistant Prostate Cancer

Primary Completion Date: Clinical Trials: <https://clinicaltrials.gov/show/NCT01946204>

Discussion:

Data Requested:

- Clinical Documents

Response ? Study is Listed ▾

5. You will be prompted to provide a new project name.

New Research Data Request

Enter a descriptive name for your research project.

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

Research Project Name

OK Cancel

6. The following notification will appear

Home About Members News & Events Resources Portals Find Studies

Click here to view your data requests. MY DATA REQUESTS RICHARD ANDERSON

Dashboard < Go Back Enquiry Id: 9 Status: Review Date Submitted: 2024-06-10 Save Save & Notify

Enquiries

Requester Email
Datarequester.vivli@gmail.com

Requester Name
Data Requester

Your Institution
Boston University

Country
United States of America

Purpose
To find the CV outcomes in Cancer patients

NCT ID
NCT01946204

OR

Sponsor ID
CR102931

Study Title
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men With Non-Metastatic (M0) Castration-Resistant Prostate Cancer

Request Study

Notify on "Save & Notify": ☐

Data Contributor
Data Contributor

Item Successfully Added to My Requests

7. Note: you have to take the above steps for each study in the Enquiry that is available for the data request and add it to the same data request.

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

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

Home About Members News & Events Resources Portals Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS AMRUTHA BASKARAN (Vivli Admin)

< Go Back Request: 48130, PI: Karen Aseda Status: Submitted and Awaiting Vivli Request Form Check Archive Do not track Reset to Draft Cancel Edit Data Request Cannot Fulfill Process Request Print

Studies

Status Update

Attachments

Request History

Signed Agreements

Chat

Research Team

Request Details/Print View

Other Information

This request was initiated from enquiry: 2

Requested Studies

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men With Non-Metastatic (M0) Castration-Resistant Prostate Cancer
PI: Data Contributor: BMS Study ID: NCT01946204 Data Request ID: 00048130 Sponsor ID: CR102931
IPD Uploaded:

A Single Centre, Randomized, Double-blind, Dose Ascending, Placebo-controlled Study, in Two Parts, to Evaluate the Safety, Tolerability and Pharmacokinetics of Escalating Single and Repeat Inhaled Doses of GSK573719 and Placebo Formulated With the Excipient Magnesium Stearate, in Healthy Subjects and in a Healthy Population of Cytochrome P450 Isoenzyme 2D6 Poor Metabolisers.
PI: Sponsor: GlaxoSmithKline Study ID: NCT00803673 IRP/Approver: Wellcome Trust Data Request ID: 00048130 Sponsor ID: 110106
Data Contributor: GlaxoSmithKline IPD Uploaded:

Attached Files

NO FILES IN PACKAGE

10. Also, the Enquiry form will display the associated Data request ID

How-To: Requesting Studies on Vivli

Version 3.4

3.0 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. Below this, a secondary navigation bar contains ENQUIRY, QUICK STUDY LOOKUP, and MY DATA REQUESTS (highlighted with a red box). A user profile icon labeled DATA REQUESTER is also visible. The main content area displays a list of studies with filters on the left for Study Design, Study Phase, and Sponsor Information. Three study cards are shown, each with a 'Request Study' button and a 'View Study Details' button. The first study is a multicenter, randomized, double-blind study for asthma. The second is a phase 3 study for malaria. The third is a clinical trial for dental plaque.

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.

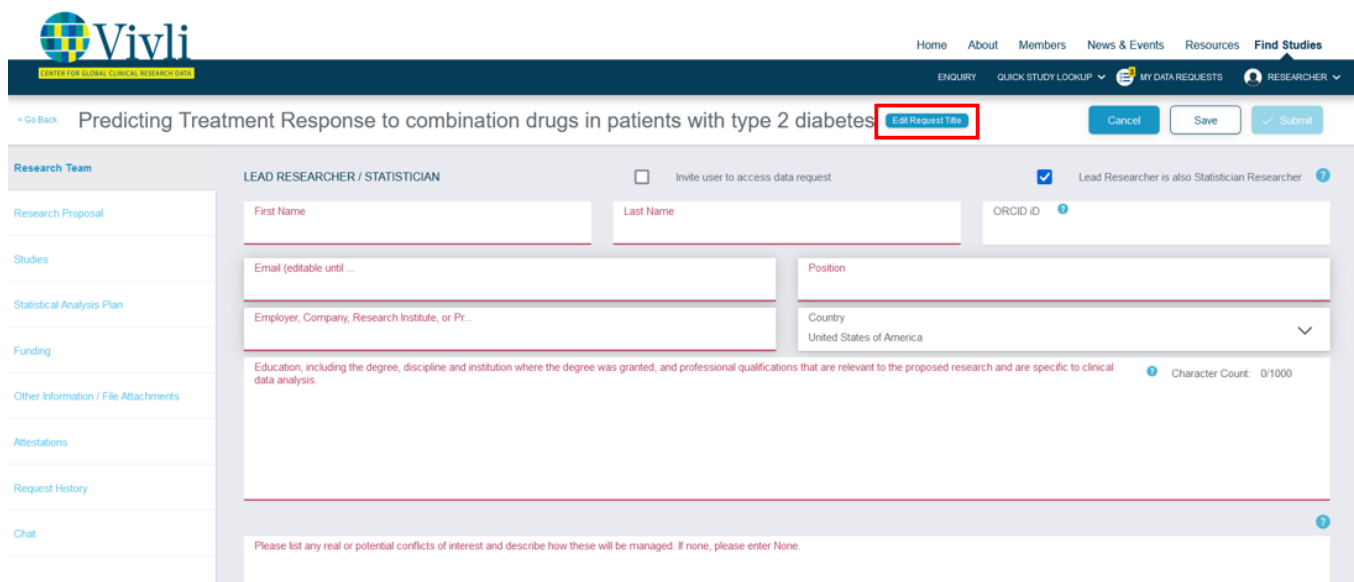
Click on **Draft** to see any incomplete or new data requests. Click on the data request to open it:

The screenshot shows the 'My Data Requests (262)' page. The top navigation bar is the same as the previous screenshot. Below the header, there is a search bar and a tabbed interface. The 'Draft' tab is selected and highlighted with a red box. Other tabs include Active (83), Not Approved (3), Withdrawn (174), and Archived (1). Below the tabs, a data request card is highlighted with a red box. The card title is 'INCREASE IN ALBUMINURIA IN DIABETES PATIENTS | 2 STUDIES' and the status is 'Draft'. A 'Cancel' button is visible in the top right corner of the card.

3.1 Editing a data request

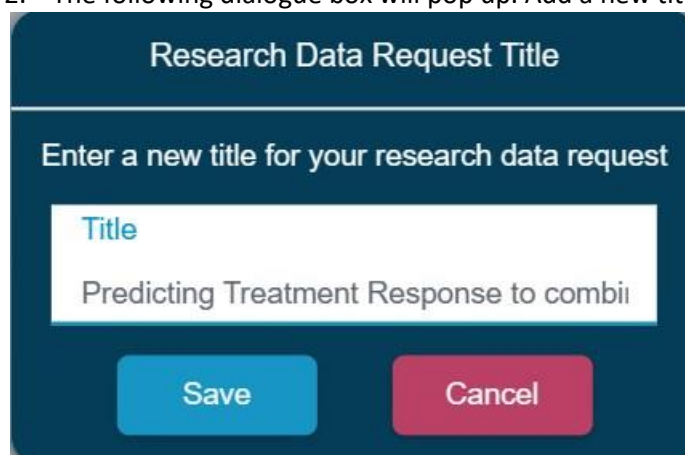
You may edit the Project name of your data request as it will appear on the Data Request Form and Vivli Dashboard. The Project name of your data request should be the same as the “Title of Proposed Research” as it appears on the Data Request Form.

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



The screenshot shows the Vivli website interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this, a secondary navigation bar contains links for 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'. A red box highlights the 'Edit Request Title' button. To the left of the main form is a sidebar with a 'Research Team' section containing links for Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, Request History, and Chat. The main form itself is titled 'LEAD RESEARCHER / STATISTICIAN' and includes fields for First Name, Last Name, Email, Position, Employer, Company, Research Institute, or Pr..., Country (set to United States of America), and ORCID ID. There is also a section for Education and a character count for a text area.

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' and 'Cancel'.

3.2 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 5.0 Requesting data [from studies not listed on Vivli, but available for provisioning into the Secure Research Environment.](#)

The screenshot displays 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 header shows the Vivli logo and the title of the current request: "Predicting Treatment Response to combination drugs in patients with type 2 diabetes". A sidebar on the left, highlighted with a red box, lists the following sections: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, Request History, and Chat. The "Research Team" section is currently active, showing a form for the "LEAD RESEARCHER / STATISTICIAN". This form includes fields for First Name, Last Name, ORCID ID, Email (with an editability note), Position, Employer, Company, Research Institute, or Pr..., and Country (currently set to United States of America). There is also a checkbox for "Lead Researcher is also Statistician Researcher" which is checked. 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, along with a "Character Count: 0/1000" indicator. At the bottom of the form, there is a field for "Please list any real or potential conflicts of interest and describe how these will be managed. If none, please enter None."

3.2.1 Adding Files or Other Information to your data request

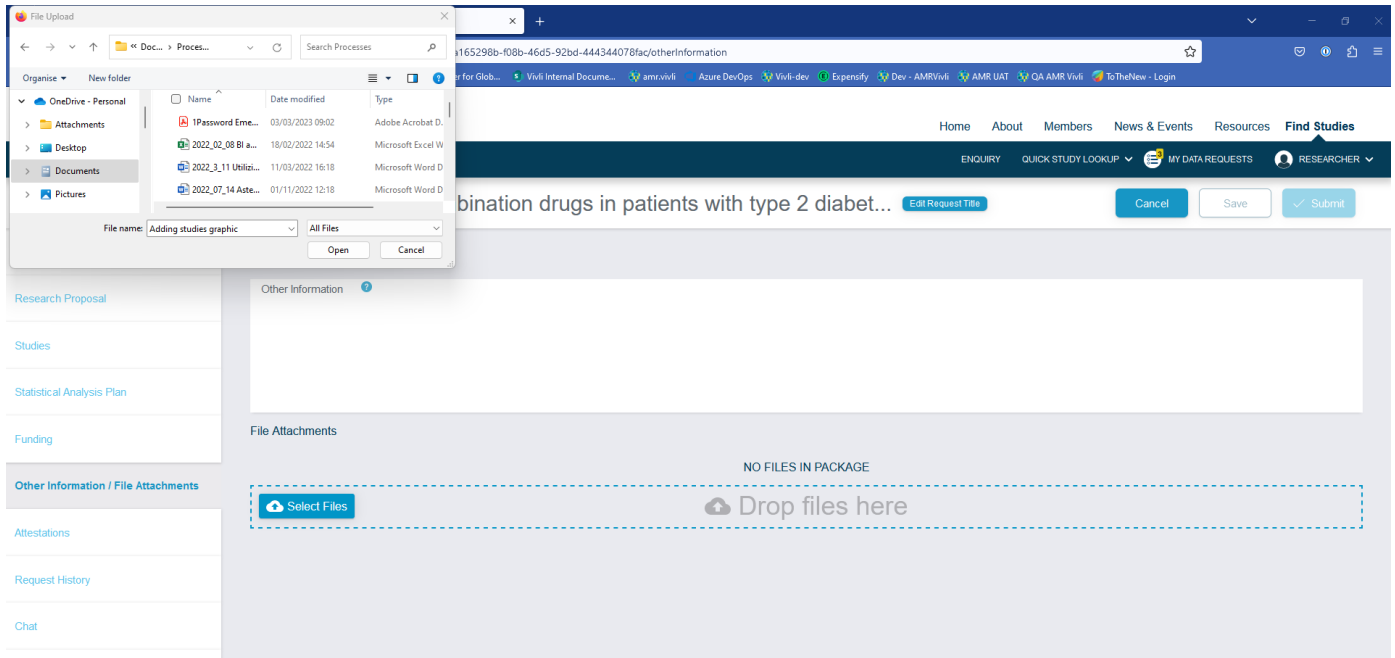
1. You may also attach files to your data request using the **Other Information/File Attachments** tab:

The screenshot shows the Vivli web 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 'ENQUIRY', 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'RESEARCHER'. The main content area has a sidebar on the left with 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 panel displays the 'Other Information / File Attachments' section. It features a text area for 'Other Information' and a 'File Attachments' section. The 'File Attachments' section shows 'NO FILES IN PACKAGE' and a dashed box with a 'Select Files' button and a 'Drop files here' prompt.

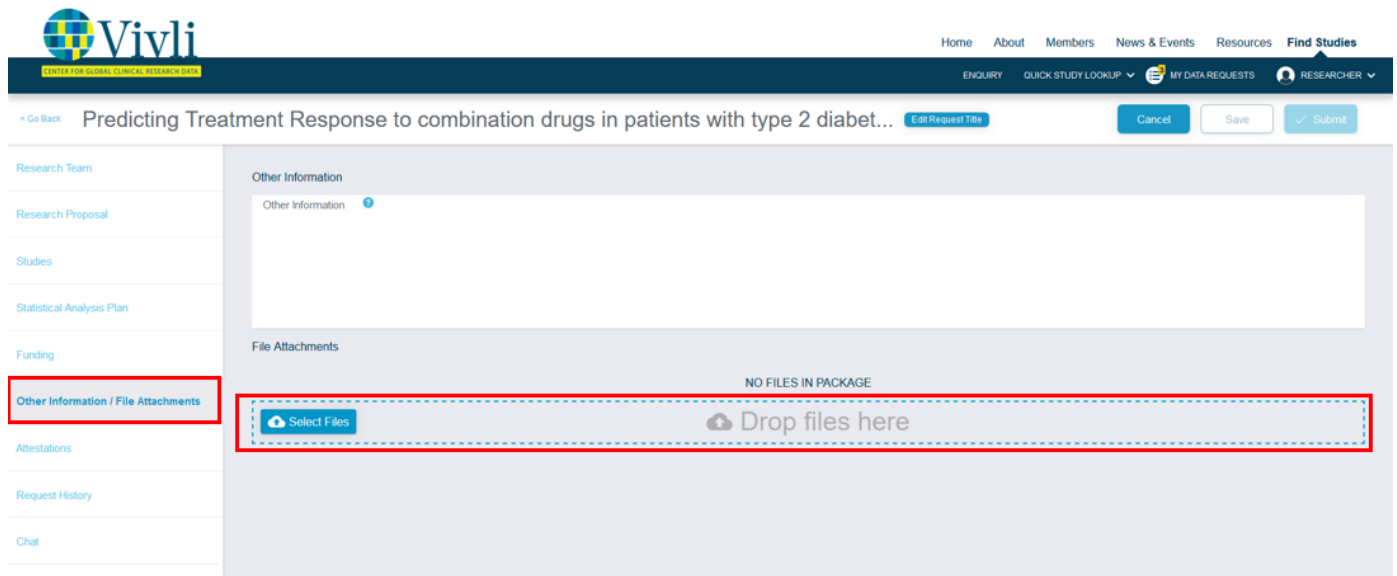
2. Click on **Select Files** to choose a file:

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

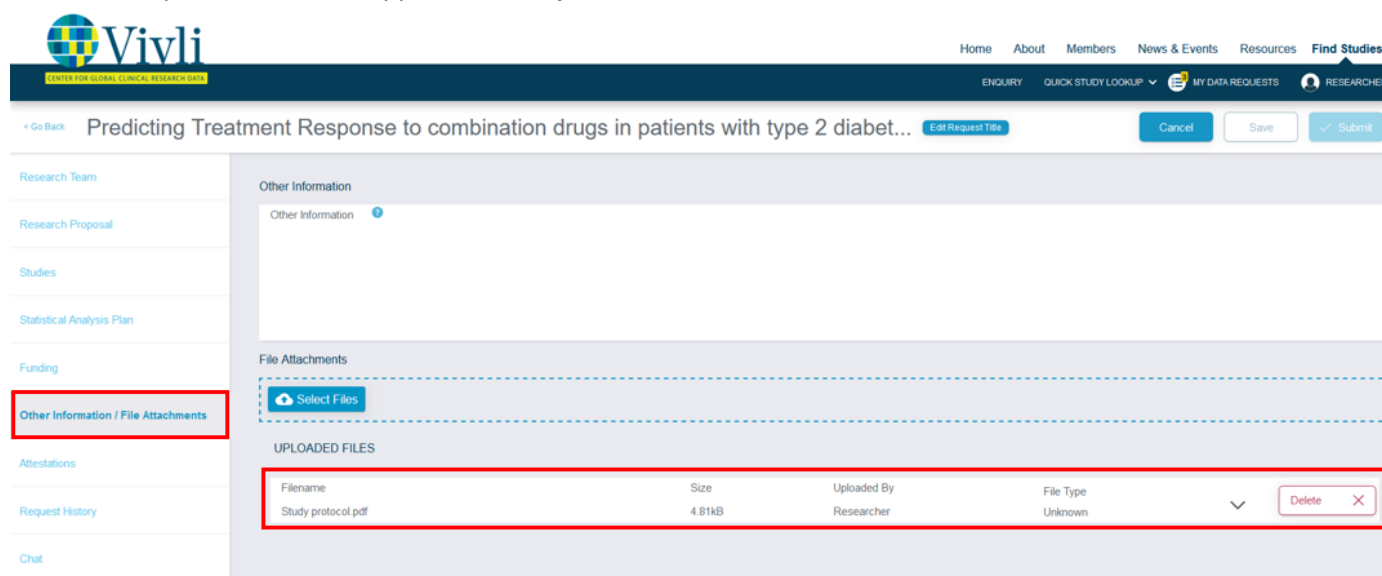
3. Then simply select the file from your computer:



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



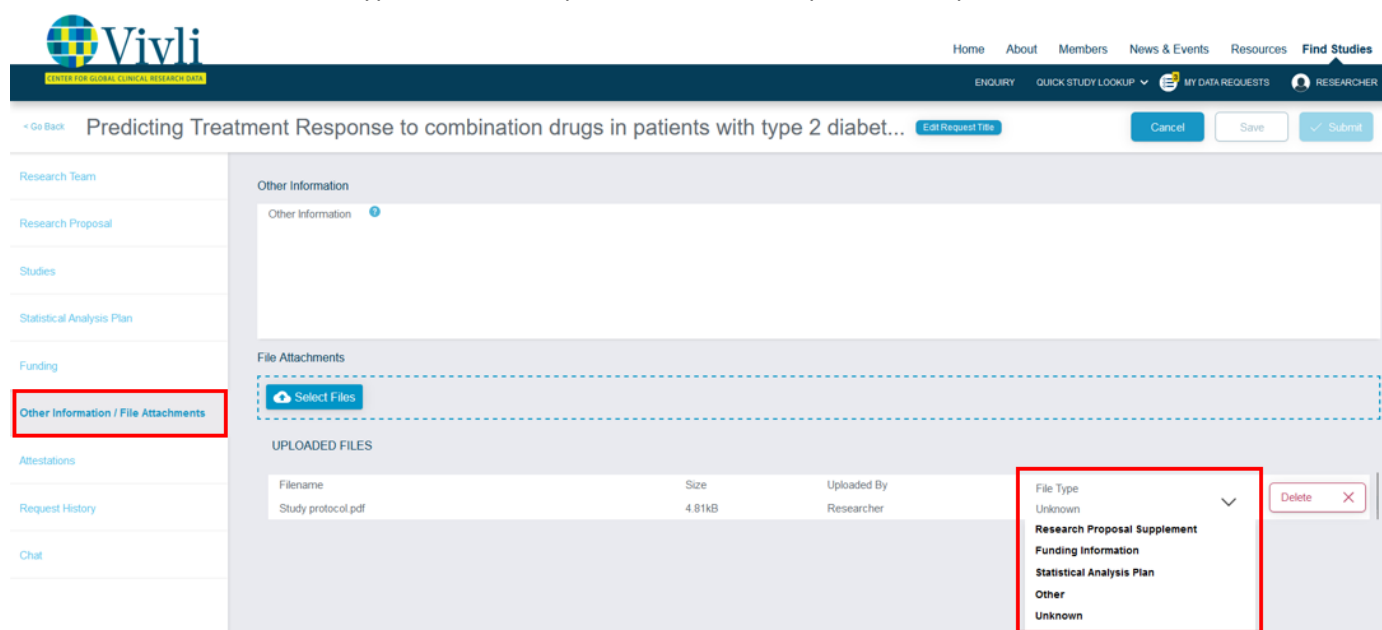
5. Your uploaded files will appear under **Uploaded files**:



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 title 'Predicting Treatment Response to combination drugs in patients with type 2 diabetes...' and buttons for 'Edit Request Title', 'Cancel', 'Save', and 'Submit'. The left sidebar contains a list of menu items: 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 'File Attachments' section includes a 'Select Files' button and a table titled 'UPLOADED FILES'. The table has columns for Filename, Size, Uploaded By, File Type, and a Delete button. The first row shows a file named 'Study protocol.pdf' with a size of 4.81kB, uploaded by 'Researcher', and a file type of 'Unknown'.

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:



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 title 'Predicting Treatment Response to combination drugs in patients with type 2 diabetes...' and buttons for 'Edit Request Title', 'Cancel', 'Save', and 'Submit'. The left sidebar contains a list of menu items: 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 'File Attachments' section includes a 'Select Files' button and a table titled 'UPLOADED FILES'. The table has columns for Filename, Size, Uploaded By, File Type, and a Delete button. The first row shows a file named 'Study protocol.pdf' with a size of 4.81kB, uploaded by 'Researcher', and a file type of 'Unknown'. The file type dropdown menu is open, showing options: Unknown, Research Proposal Supplement, Funding Information, Statistical Analysis Plan, Other, and Unknown.

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

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

Vivli
UNIVERSITY OF MEDICINE, DUBLIN, 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 X

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

Vivli
UNIVERSITY OF MEDICINE, DUBLIN, 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 X

3.3 Saving your data request

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

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

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 title 'Predicting Treatment Response to combination drugs in patients with type 2 diabetes...' and buttons for 'Edit Request Title', 'Cancel', 'Save' (highlighted with a red box), and 'Submit'. A left sidebar contains a list of navigation items: 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 sections: 'Other Information' with a text input field, 'File Attachments' with a 'Select Files' button, and 'UPLOADED FILES' which contains a table of uploaded files.

Filename	Size	Uploaded By	File Type	
Study protocol.pdf	4.81kB	Researcher	Unknown	<input type="checkbox"/> <input type="button" value="Delete"/>

3.4 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 a Statistician Researcher, select the checkbox as shown below
How-To: Requesting Studies 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 [Edit Request Title](#) [Cancel](#) [Save](#) [Submit](#)

Research Team

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

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

First Name Last Name ORCID ID

Email Position

Employer, Company, Research Ins... Country
- Select an Option -

Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. 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

- 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**

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

< Go Back Predicting Treatment Respo... [Edit Request Title](#) [Cancel](#) [Save](#) [Submit](#)

Research Team

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

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

ADDITIONAL RESEARCHERS [Add +](#)

- 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 - Select an Option -

Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. ? 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

OK
Cancel

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**
Select an Option

Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. ? Character Count: 1223/1000

Education or Qualifications length must be less than or equal to 1000 characters long

Please see below for my education including degree, discipline and institution where the degree was 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:
Bachelor's Degree from University of California, San Francisco where I obtained a degree in Biological Life Sciences in 1998

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

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

required field is input, the exclamation mark will disappear.

ENTER FOR QUAL CLINICAL RESEARCH DATA

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 !

LEAD RESEARCHER - No Account ☐ 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.edu **Position**

Employer, Company, Research Institute, or Primary Affili... UCSD 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. PhD Biostatistics UCSD 1999 MS Biostatistics UCSD 1995 Character Count: 54/1000

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

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

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6. Complete all fields, and click



- Please ask the research team member to "sign up" for a Vivli account. They can follow Section 1.0 of the [Vivli User Account Quick Start guide](#)
- 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**:

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
- Select an Option -

Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. ? 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

OK Cancel

9. 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 Last Name ORCID ID ?

Sarah Jones

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

sarah.jones@ucsd.utorg Biostatiscian

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

University of California, San Diego 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: 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

3.5 Deleting research team members

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

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

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 (with a 434 badge), and DATA REQUESTER. The main content area is titled 'Albumin in...' and has a 'Go Back' link and an 'Edit Request Title' button. On the left, there is a sidebar with tabs: Research Team (highlighted with a red box), Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, and Chat. The main content area has a large text input field for conflicts of interest, a section for 'VM Access Admin Approval Based on Approved DUA' with 'DUA Approval Not Applicable', and a section for 'ADDITIONAL RESEARCHERS'. In this section, 'Sarah Jones (ADDITIONAL RESEARCHER)' is listed, and a red box highlights the three vertical dots next to her name. To the right of this section, there is a red box highlighting the 'Remove Team Member' button, which also has an 'Activate Member for Access to Data Request' option below it.

3. The following pop-up will appear:

The screenshot shows a confirmation pop-up dialog box with a dark blue background. The text inside the box asks 'Are you sure you want to remove "Sarah Jones"?'. Below the text are two buttons: a blue button labeled 'Yes' and a pink button labeled 'No'.

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

4.0 Requesting Vivli-listed studies provisioned by external providers

4.1 Overview

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

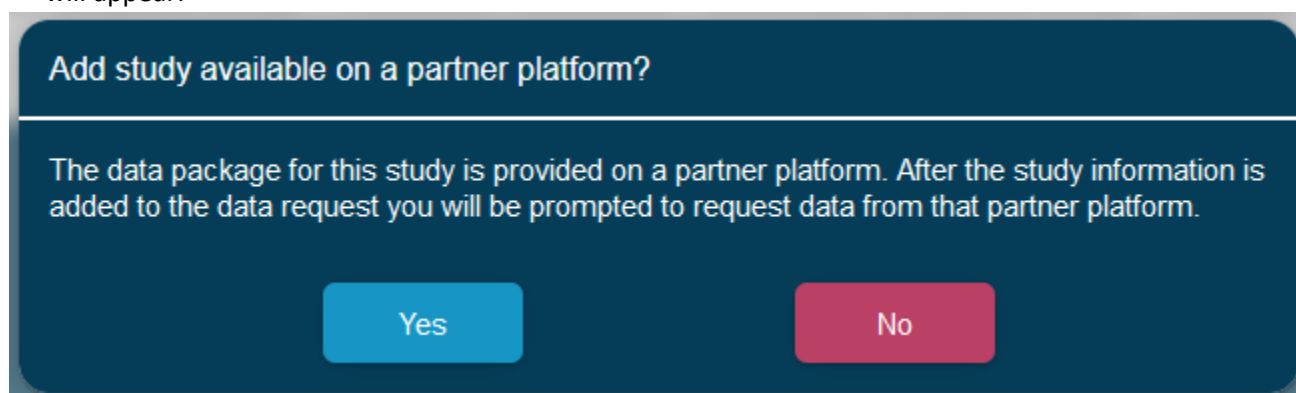
How-To: Requesting Studies on Vivli

Version 3.4

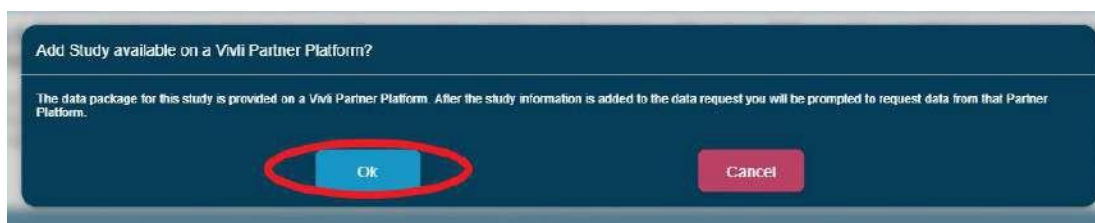
- After the relevant Data Contributor(s) have approved your request, you will sign a Data Use Agreement (DUA). The Data Contributor will then provision the data from their platform into the secure research environment.

4.2 Requesting studies provisioned by external providers

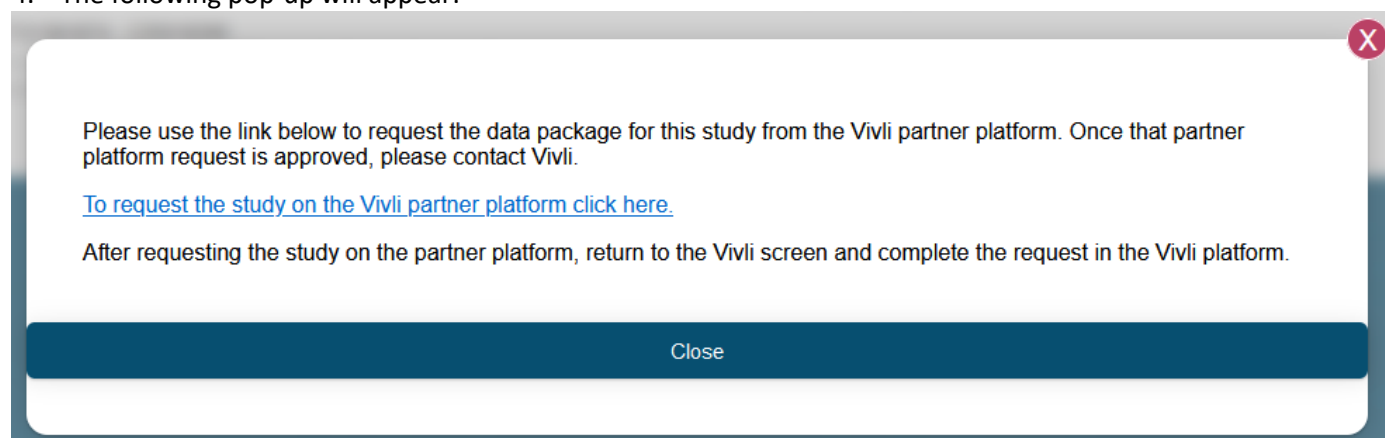
1. If the study you are searching for is on the Vivli Platform but provisioned by an external provider, it will appear on the Studies page when you search for studies as described in section 1.1, *Searching for studies on the Vivli platform*.
2. When attempting to add a study in this category to a Data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



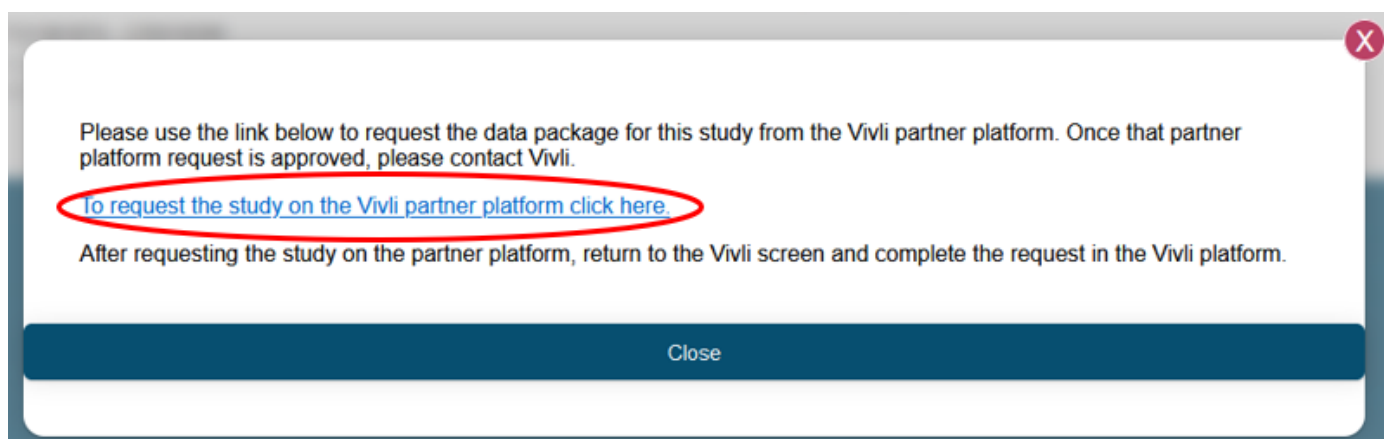
3. Click on **Yes** to add the study to the Data Request Form:



4. The following pop-up will appear:



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



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

6. Complete and submit the request on the Partner Platform, as well as the Vivli Data Request Form.
7. When you review the studies tab on your Data Request Form, the study will be categorized as **Vivli-Listed Studies Provisioned by External Providers**:

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

5.0 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**.

5.1 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.

5.2 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. The main header shows the Vivli logo and the title 'Predicting Treatment Response to combination drugs in patients with type 2 diabetes'. A sidebar on the left contains links for 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: 'REQUESTED STUDIES' with a help icon and download arrow, 'VIVLI-LISTED AND PROVISIONED STUDIES' with a study entry for 'A Multicenter, Open-Label Conversion of Valproate Monotherapy to Lamotrigine Monotherapy in Patients With Epilepsy', and 'VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS' with a study entry for 'Randomized, Open-Label Study of Abiraterone Acetate (JNJ-212082) Plus Prednisone With or Without Exemestane in Postmenopausal Women With ER+ Metastatic Breast Cancer Progre...'. At the bottom, a section titled 'STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI' is highlighted with a red box, featuring an 'Add +' button. Below this section, it states '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. 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:

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

SubmitCancel

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

The screenshot shows a web page with a dark blue header containing the text "Request Studies, Data, or Tools not listed on Vivli". The main content area is white and contains the following text:

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.

Below the text, there are two buttons: a blue button labeled "Add Another Study, Data, or Tool" and a red button labeled "Back". The "Back" button is highlighted with a red rectangular border.

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

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-212062) 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 +

ABC-156
Study ID: NCT012345678
Data Request ID:
Data Contributor: Pfizer Inc. IRP/Approver: Pfizer Inc.
Data to be loaded after approval Remove X

How-To: Requesting Studies on Vivli

Version 3.4

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

6.1 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. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. The main header area displays the Vivli logo and the title 'Predicting Treatment Response to combination drugs in patients with type 2 diabetes'. Below the header, there is a sidebar with 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 two sections: 'REQUESTED STUDIES' and 'VIVLI-LISTED AND PROVISIONED STUDIES'. The 'REQUESTED STUDIES' section shows a study titled 'A Multicenter, Open-Label Conversion of Valproate Monotherapy to Lamotrigine Monotherapy in Patients With Epilepsy' with details like Study ID: NCT00043914, Sponsor ID: LAM40013, Data Request ID, and Data Contributor: GlaxoSmithKline. The 'VIVLI-LISTED AND PROVISIONED STUDIES' section shows a study titled 'Randomized, Open-Label Study of Abiraterone Acetate (JNJ-212062) Plus Prednisone With or Without Exemestane in Postmenopausal Women With ER+ Metastatic Breast Cancer Progre...'. Both studies have a 'Remove' button. At the bottom, there is a section titled 'STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI' with an 'Add +' button. The text 'No Studies Found' is displayed below this section.

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](#)

[Predicting Treatment Response to combination drugs in patients with type 2 Diabetes](#)

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

[Research Team](#)

[Research Proposal](#)

[Studies](#)

[Statistical Analysis Plan](#)

[Funding](#)

[Other Information / File Attachments](#)

[Attestations](#)

[Request History](#)

[Chat](#)

REQUESTED STUDY TYPES [?](#) [↓](#)

VIVLI-LISTED AND PROVISIONED STUDIES

Effects of Cystic Fibrosis and Cystic Fibrosis Related Diabetes on Brain Stru...
PI: Sponsor: University of Minnesota Study ID: NCT03820349 IRP/Approver: Wellcome Trust Data Request ID: 00002555
Sponsor ID: MED-2018-26436 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](#) [>](#)

6.2 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.

6.2.1 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

7.0 Submitting your data request

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




Key factors that influence the timeline:

- If Institution has an existing master DUA with Vivli or needs to execute a Master DUA
 - Requesters response time to questions and feedback by data contributors
 - Number of studies being requested
- Before submitting a Data Request Form, the Lead Researcher must attest that all the information provided is accurate and complete:

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 'CENTRE 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, 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 the 'Data Use Agreement' section, which includes a paragraph explaining the DUA process and a link to the DUA form. The 'Attestations' section is highlighted with a red box.

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

The screenshot shows the Vivli website interface for a data request form titled "Predicting Treatment Response to combination drugs in patients with type 2 diabetes". The form is divided into several sections: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, and Chat. The "Submit" button in the top right corner is highlighted with a red box. The "Attestations" section contains a checkbox for "Certify Complete and Accurate" which is checked, and a "Data Use Agreement" section with a link to the DUA form.

- 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). If there is missing information in the Research Team field, a red exclamation mark (!) will appear in the Research Team tab on the left.

This screenshot is identical to the one above, showing the Vivli Data Request Form with the "Submit" button highlighted in red. It illustrates the state of the form before submission, where the "Submit" button is still light blue and the "Attestations" section is visible.

7.1 Data Request Status

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

How-To: Requesting Studies on Vivli

Version 3.4

- 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

Your data request will go through the following steps:

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

7.2 Research team account status

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

- No account – A research team member doesn't have a Vivli account. Once they sign up for an account, you can activate the user for data access. Please see [Section 3.4 Adding Research Team Members](#).
- Account Enabled – They have an active account on Vivli
- Account Disabled – They haven't logged into the Vivli platform for more than 180 days so their account is disabled and they can no longer access the data request, Please see [Section 1.4 Active Platform Accounts](#)

The screenshot shows the Vivli interface for a specific data request. At the top, it displays the request ID (48130) and title (Cardiovascular events in subjects with diabetes), along with the status (Submitted and Awaiting Vivli Request Form Check). On the left, a sidebar contains navigation links: Studies, Attachments, Request History, Signed Agreements, Chat, Research Team (highlighted with a red box), and Request Details/Print View. The main area is titled 'RESEARCHERS' and contains a table of team members. Each row shows a researcher's name and role, their account status (highlighted with red boxes), and their access status (Access Granted) and DUA approval status (DUA Approval Required). A red box also highlights the 'Research Team' tab in the sidebar.

Researcher Name (Role)	Account Status	Access Status	DUA Approval Status
Richard Wilson (LEAD RESEARCHER / STATISTICIAN)	No Account		
Emily Wilson (DATA REQUEST ADMINISTRATOR)	Account Enabled	Access Granted	DUA Approval Required
Henry Anderson (ADDITIONAL RESEARCHER)	Account Disabled	Access Granted	DUA Approval Required
Karen Asada (ADDITIONAL RESEARCHER)	Account Enabled	Access Granted	DUA Approval Required

8.0 Modifying or revising your data request

8.1 Overview

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



Key factors that influence the timeline:

- If Institution has an existing master DUA with Vivli or needs to execute a Master DUA
- Requesters response time to questions and feedback by data contributors
- Number of studies being requested

8.2 Modification after submission

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

8.3 Requested revisions to your data request

- At times, the Data Contributor, Independent Review Panel (IRP), or Vivli may request that you make changes to your data request.
- If this is the case, you will be notified 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 the requested changes, the data request will be withdrawn after 4 months.

8.3.1 Steps for revising request

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

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 diabet...'. 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 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' which contains a table with the following data:

Filename	Size	Uploaded By	File Type	
Study protocol.pdf	4.81kB	Researcher	Unknown	<input type="button" value="Delete"/>

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

8.4 Deleting Draft Data Requests

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

8.5 Withdrawal process for submitted data request

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

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

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

After 4 months, the request is considered abandoned and moved to the withdrawn status. You may contact Vivli at support@vivli.org anytime to move the request back from withdrawn to drafts.

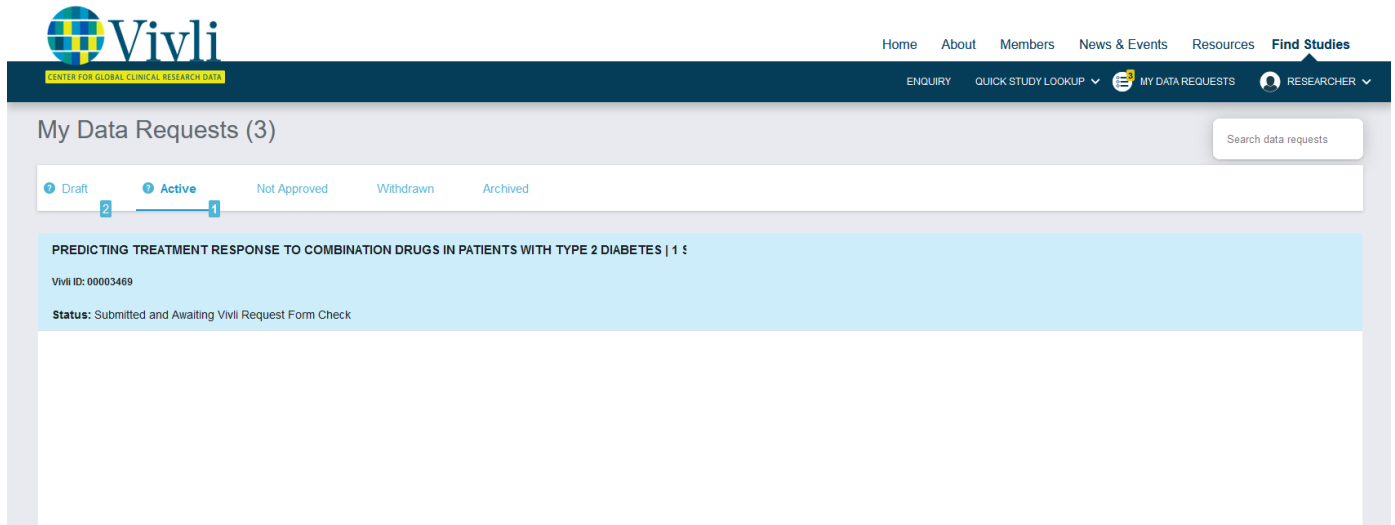
9.0 Communications

9.1 Open Chat

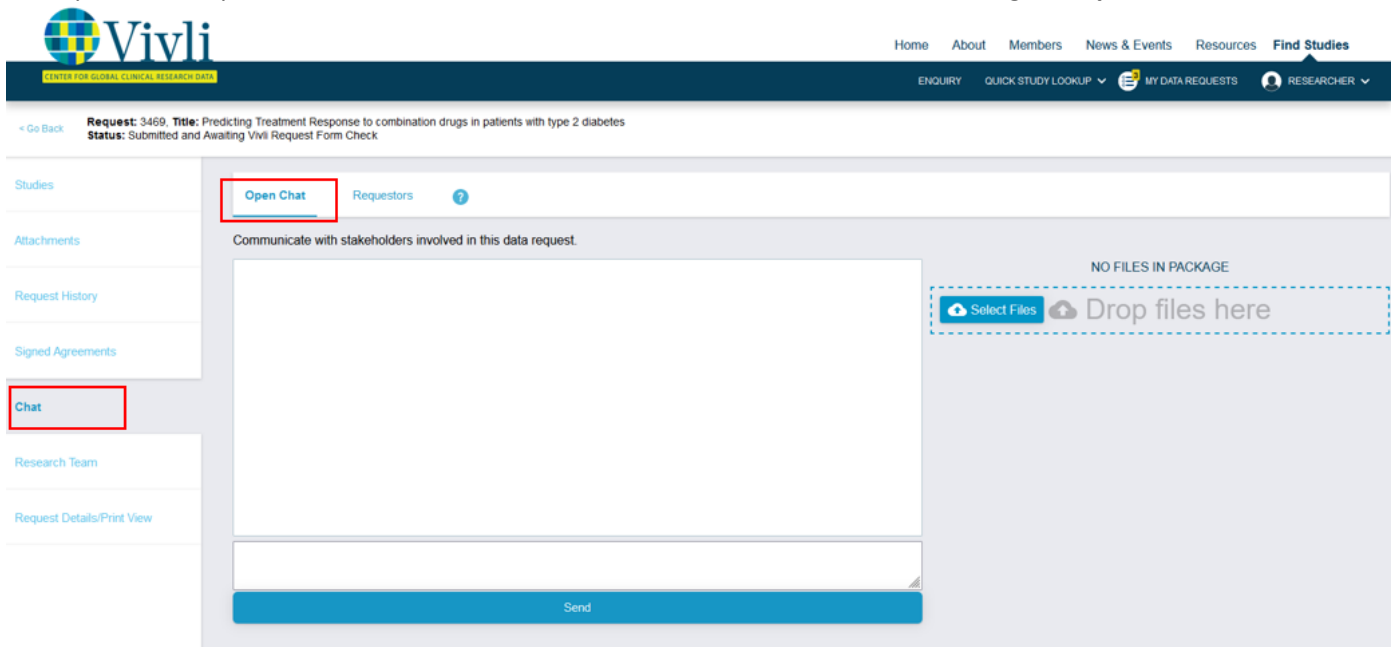
- You can use the open chat within the data request to communicate with the Vivli team, and the data contributors or review entities associated with your data request.
- Please note that messages in open chat are visible to all persons attached to a data request.
- When any other party enters a message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

9.2 Steps for creating a chat message

1. Log on to the platform and Go to **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**:



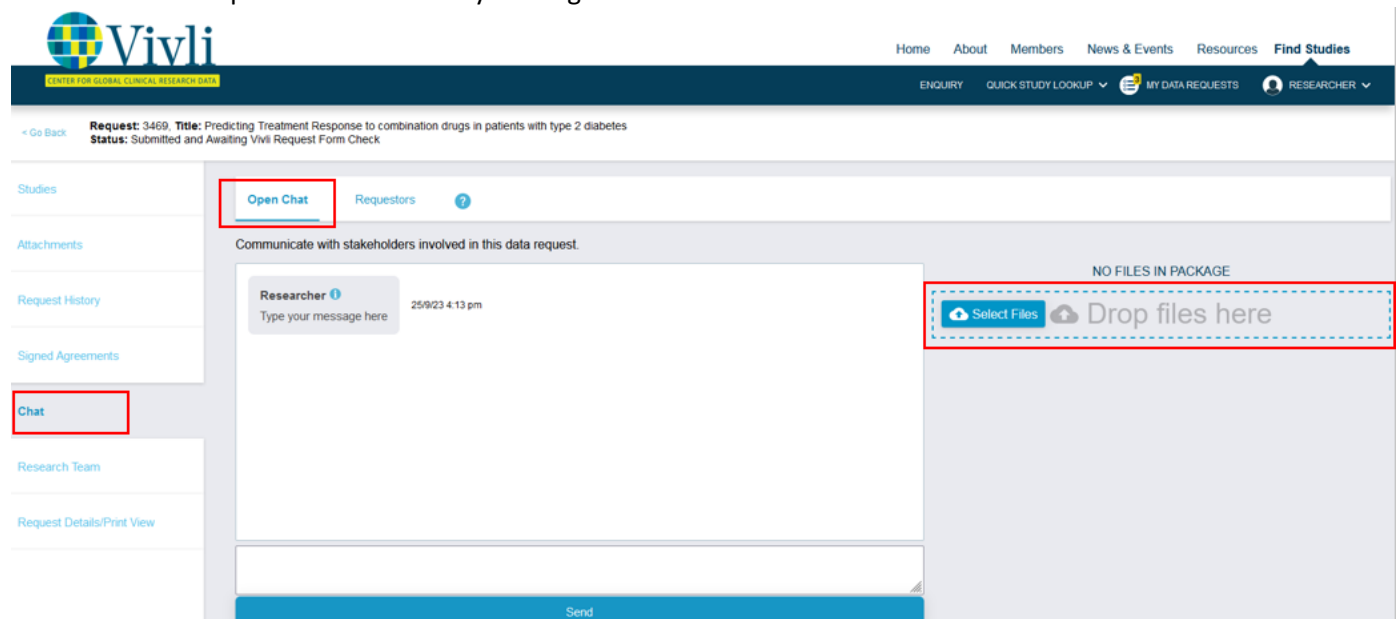
3. Enter your message in the chat message box and click **Send**:

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 displays a chat interface 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 left sidebar contains a list of navigation options: Studies, Attachments, Request History, Signed Agreements, Chat (highlighted with a red box), Research Team, and Request Details/Print View. The chat area has two tabs: 'Open Chat' (highlighted with a red box) and 'Requestors'. The 'Open Chat' tab shows a large text input box with the placeholder 'Type your message here' and a blue 'Send' button (highlighted with a red box). To the right of the input box is a file upload area with the text 'NO FILES IN PACKAGE' and a dashed box containing 'Select Files' and 'Drop files here'.

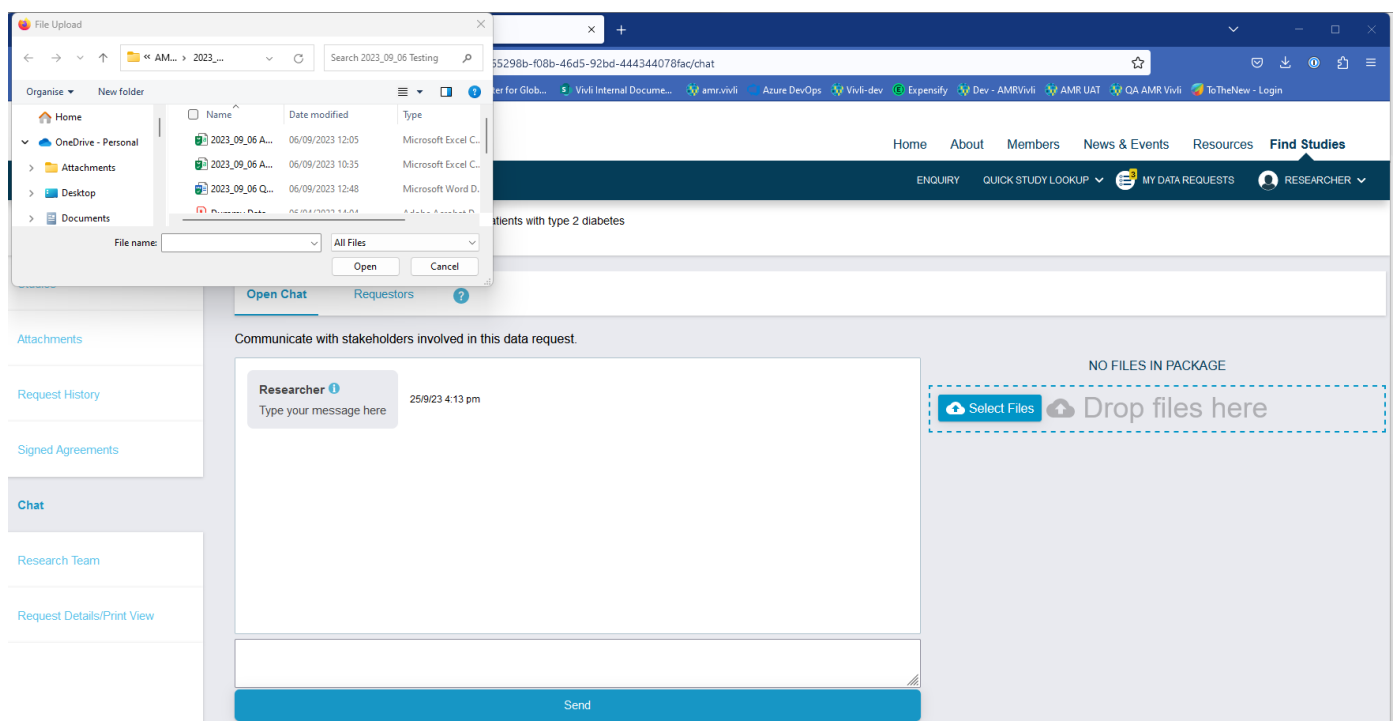
4. The message will now appear in the Chat record for all users (to see your just-entered chat message, you may need to click Refresh on your browser), and response will also appear in the chat record:

The screenshot shows the same Vivli website interface as the previous one, but with a message sent. The 'Open Chat' tab (highlighted with a red box) now displays a message from a 'Researcher' (highlighted with a red box) with the text 'Type your message here' and a timestamp of '25/9/23 4:13 pm' (highlighted with a red box). The 'Send' button is still visible at the bottom of the chat area. The file upload area on the right remains the same.

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



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



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

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 sub-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 main panel. 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 main panel displays a chat window titled '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' (highlighted with a red box) and 'Requestors'. The chat history shows a message from 'Researcher' at 25/9/23 4:13 pm and a file upload 'Study protocol.pdf' at 25/9/23 4:17 pm (highlighted with a red box). On the right side of the chat window, there is a 'Select Files' button and an 'UPLOADED FILES' table. The table has columns for Filename, Size, and Uploaded By. It lists the file 'Study protocol.pdf' with a size of 4.81... and an uploader 'Researc...' (highlighted with a red box). There are download and delete (X) buttons for each file (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 file 'Study protocol.pdf' is still listed, but the delete button (X) next to it is now highlighted with a red box, indicating that it should be clicked to delete the file.

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 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 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 a message from a Researcher at 25/9/23 4:13 pm and a file upload at 25/9/23 4:17 pm. To the right of the chat window, there is a section for UPLOADED FILES, which includes a table with columns for Filename, Size, and Uploaded By. The table shows a file named 'Study protocol.pdf' with a size of 4.81 MB, uploaded by 'Researc...'. A download arrow icon is highlighted with a red box, indicating where to click to download the file.

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 different message in the chat history. The message at 25/9/23 4:21 pm from the Researcher states 'File Deleted: Study protocol.pdf'. This message is highlighted with a red box. The 'UPLOADED FILES' section on the right now displays 'NO FILES IN PACKAGE' instead of the file list.

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.

9.3 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 - Revision requested or Request not approved	When your data request changes status to Revision or Not approved. If you have requested studies from multiple contributors, you will receive a notification when each has requested revisions or not approved your request.	Notify you of any changes in status to your data requests.
Request Final Approval	When your data request is approved, by a delegated approver/IRP. If you have requested studies from multiple contributors, you will receive a notification after final approval.	Notify you of final approval
DUA Approved	When the Vivli Admin has validated the DUA associated with the data request.	Notify you of executed DUA.
Data Uploaded	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.
Research Environment was provisioned	When you start the Research Environment.	Notify you when the Research Environment is ready to be used for analysis.
Request for results approved	When your request to export results is approved or/not approved.	Notify the status of the results export.
Data Request Archived	When the data request is Archived, the project is considered closed.	Notify that the lead researcher and research team have met the DUA obligations for public disclosure/summary of results and the data request is now archived.
Chat	When anyone associated with a data request enters a message in chat	Facilitate communication and the data request work flow
Enquiry	When anyone associated with a data request enters a comment or makes a decision	Facilitate communication and the Enquiry workflow

10.0 Data Use Agreement


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

1. Review the [Data Use Agreement](#).
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 shows the Vivli platform 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 a search bar and user options. The main content area is titled 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes'. On the left sidebar, the 'Signed Agreements' tab is highlighted with a red box. The main area shows a message: 'There are no Signed Documents'. Below this, a dashed box contains a 'Select Files' button. Further down, a table titled 'UPLOADED FILES' is highlighted with a red box. The table has columns for Filename, Size, and Uploaded By. A single row is visible with the filename '2021_10_05 Vivli ID 00002553_DUA executed final.pdf', a size of '673.80kB', and 'Data Requester' as the uploader. A 'Download' button is next to the row.

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 History**



[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

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

- DUA Approval Required – A research team member doesn't have DUA approval to proceed with analysis. When a new team member is added, you can see this status. Vivli Admin will review the DUA and provide further information on the next steps.
- Has Approval Required – A research team member has a Valid DUA to proceed with analysis. They can access the data
- DUA Approval Denied – A research team member doesn't have DUA approval to proceed with analysis. This could be due to failure to return the Data Progress report annually or non-payment of Research Environment payment or failure to meet some other DUA obligations. The Vivli Admin will keep you informed.

[< Go Back](#)

Request: 48010, PI: Andrea Johnson
Status: At least one Data Package Provided and Available

Archive

Do not track

Reset to Draft

Cancel

Edit Data Request

Print

[Studies](#)
[Status Update](#)
[Attachments](#)
[Request History](#)
[Signed Agreements](#)
[Safety Concerns](#)
[Chat](#)

Research Team

[Research Environment](#)
[Public Disclosures](#)
[Request Details/Print View](#)

RESEARCHERS

Add +

<div>Andrea Johnson (LEAD RESEARCHER) - Account Enabled</div>	Access Granted	Has DUA Approval	
<div>John Hopkins (DATA REQUEST ADMINISTRATOR) - Account Enabled</div>	Access Provided for Admin	Has DUA Approval	
<div>Vijay Rajan (STATISTICIAN RESEARCHER) - No Account</div>		DUA Approval Denied	
<div>Richard Anderson (ADDITIONAL RESEARCHER) - Account Enabled</div>	Access Granted	DUA Approval Required	

11.0 Data Package Upload

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

12.0 Research Environment and Results Export

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

The software available in the 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.

13.0 Data Progress Report

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

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

14.0 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 acknowledgment section:

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

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

If you do not have any publishable results, then you must send the summary of results to the Vivli team 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.

15.0 Research Environment Closure & Request Archival

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