



# How-To: Request Studies on Vivli

Vivli Platform Release 3.8

October 4, 2025

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## 1.0 Requesting Studies on Vivli – Overview

- The process starts with finding the 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 must 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.

The screenshot displays the Vivli search interface. At the top left is the Vivli logo with the tagline 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. The navigation menu includes Home, About, Members, News & Events, Resources, Portals, and Find Studies. A 'QUICK STUDY LOOKUP' dropdown menu is highlighted in red. Below the navigation is a banner with the text 'We are committed to advancing the knowledge around the COVID-19 pandemic' and buttons for 'Share trials' and 'Search for trials'. The main search area features a 'KEYWORD SEARCH' bar with the placeholder text 'What are you looking for today?' and a search icon. Below the search bar are four filter panels: 'STUDY DESIGN' (with sub-sections for INTERVENTIONAL STUDIES, OBSERVATIONAL STUDIES, and STUDY PHASE), 'SPONSOR INFORMATION' (with sub-sections for FUNDER, CONTRIBUTOR, and SAMPLE SIZE), 'LOCATION', and 'START DATE' (with 'END DATE' below it). Each filter panel contains 'Select Multiple' dropdown menus and a 'PICO Beta' label is visible near the search bar.



- 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 interface. At the top, there is a navigation bar with links for Home, About, Members, News & Events, Resources, Portals, and Find Studies. Below this is a banner with the text "We are committed to advancing the knowledge around the COVID-19 pandemic" and buttons for "Share trials" and "Search for trials". The main search area is titled "KEYWORD SEARCH" and "PICO Beta". A search bar contains the keyword "diabetes". To the right of the search bar are information and search icons. Below the search bar are several filter panels: "STUDY DESIGN" (Interventional, Observational, Study Phase), "SPONSOR INFORMATION" (Funder, Contributor, Sample Size), "LOCATION", and "START DATE" (From, To, End Date). At the bottom of the search area, a blue bar displays "86 Studies".

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

The screenshot shows the Vivli search results page. At the top, there is a navigation bar with links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a search bar with the text "What are you looking for today?" and a "CLOSE" button. The main content area is divided into a left sidebar with filters for "STUDY DESIGN", "OBSERVATIONAL STUDIES", "STUDY PHASE", "SPONSOR INFORMATION", and "SPONSOR". The main content area displays three study listings. Each listing includes the study title, IDs, condition or disease, and intervention/treatment. To the right of each listing are buttons for "Log in to Request Study" and "View Study Details". The "View Study Details" button for the first study is highlighted with a red box. The first study 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 study is "A Phase I, Randomized, Placebo-Controlled, Crossover Clinical Trial to Assess the Safety of Oral SRT2104 and Its Effects on Vascular Dysfunction in Otherwise Healthy Cigarette Smokers and Subjects With Type 2 Diabetes Mellitus". The third study is "A Single-Center, Non-Randomized, Open-Label, Comparative Study to Assess the Utility of Novel Technologies and Biomarkers as Methods for Measuring Human Pharmacodynamic Response to 8 Weeks of Administration of Rosiglitazone Maleate 4mg BID in Healthy Normal or Overweight Controls, Healthy Obese Subjects and Subjects With Type 2 Diabetes Mellitus (T2DM)".

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

The screenshot shows the Vivli website interface. At the top, there is a navigation bar with links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a dark blue header with the Vivli logo and the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. The main content area displays the title of a study: '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'. Below the title are four tabs: Study Details, Study Documents, Administrative Details, and Usage. The Study Details tab is active and shows the following information: 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), and Actual Enrollment (40). There is also a section for Locations.

- Some members may make the supporting documents available for search. This will be available for download (once you create a Vivli user account) from the Study Documents section

The screenshot shows the Vivli website interface. At the top, there is a navigation bar with links for Home, About, Members, News & Events, Resources, Portals, and Find Studies. Below this is a dark blue header with the Vivli logo and the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. The main content area displays the title of a study: 'Assessment of Real-life Patient Handling Experience of BI 695501 Administered Subcutaneously With an Autoinjector in Patients With Rheumatoid Arthritis: an Open-label, Interventional Clinical Trial Followed by an Extension Phase of BI 695501 Administered With a Prefilled Syringe'. Below the title are four tabs: Study Details, Study Documents, Administrative Details, and Usage. The Study Documents tab is active and shows a table of uploaded files. The table has columns for Filename, Size, and Uploaded By. One file is listed: 'V3DIG Data Dictionary Document...' with a size of 118.00kB and uploaded by Amrutha. A 'Download' button with a download icon is visible next to the file name. Below the table, there is a section for 'Links to Documents located elsewhere' with a button for 'ClinicalTrials'.

- Metrics on the usage and public disclosures involving studies (originating from Vivli data request) are available in the “Usage” section

**A Phase 3, Multicenter, Open-Label, Uncontrolled Study to Evaluate the Efficacy and Safety of Cx601 in the Treatment of Complex Perianal Fistulas in Adult Patients With Crohn's Disease**

Study Details | Study Documents | Administrative Details | View Data Package | **Usage**

**Usage**

Views 0	Download of Study Documents 0
Access of Data Package 0	All usage metrics from 02/19/2025 to 02/19/2...
Study data package included in an approved research proposal 2	

**Public Disclosures**

Rahman, Rifaquat, Ventz, Steffen, Redd, Robert, Fell, Geoffrey, Tan, Yujue, Orio, Peter, Tanner, Kirk, Wen, Patrick  
"Identifying appropriate external control datasets in support of future glioblastoma clinical trials leveraging external data".  
*Neuro-Oncology*, vol. , no. , Feb. 2025, pp. , doi: <https://doi.org/10.1093/neuonc/noaf031>

**Views:**

Vivli counts a view every time a user clicks on study Details for this study in a search, or displays the DOI page for this study. In effect this counts views of the study metadata.

## 1.2 Login/Account Setup

- You must be logged in as a Vivli user to begin your data request.
  - If you do not have a Vivli account, you will need to set one up before beginning a data request. To learn more about creating a Vivli account, please review our [Vivli User Account Quick Start guide](#).
- If you are not logged in, you will be prompted to do so. After you log in, you will return to the search results window:

**Vivli**  
Center for Clinical Evidence Analysis

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

ENQUIRE | QUICK STUDY LOOKUP | Sign up | Log in

diabetes CLOSE

**STUDY DESIGN**  
INTERVENTIONAL STUDIES  
Select Multiple

**OBSERVATIONAL STUDIES**  
Select Multiple

**STUDY PHASE**  
Select Multiple

**SPONSOR INFORMATION**  
SPONSOR TYPE  
Select Multiple

**SPONSOR**  
Select Multiple

**SAMPLE SIZE**  
Disabled   
1

**LOCATION**  
Select Multiple

**Clinical Assessment of GSK716155 for Type 2 Diabetes Mellitus -A Phase I/II Study to Investigate the Safety, Pharmacokinetics and Pharmacodynamics of GSK716155 in Japanese Subjects With Type 2 Diabetes Mellitus**

ID: NCT00530309 | GLP-107965  
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**

ID: 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**

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

**Log in to Request Study**

View Study Details

Number enrolled: 448  
Phase 2

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

**Log in to Request Study**

View Study Details

For anyone with an Active Vivli Account, a download button is available on the search results page, to the left of the “Close” link.



Clicking the download button will initiate a download of a CSV file containing one row for each entry in the search results, with the following columns:

- NCTID
- Sponsor Protocol Id
- Title
- Acronym
- Condition or Disease
- Intervention/Treatment
- Therapeutic Area
- Phase
- Number Enrolled
- Contributor
- Lead Sponsor Agency
- Funder
- Data Accessibility
- Data Availability
- Primary Registry URL
- URL to Request Study from Sponsor
- Other Resources for Study
- Primary DOI
- Brief Summary
- Additional Information
- Ages Eligible For Study
- Sexes Eligible For Study
- Accepts Healthy Volunteers
- Locations of Study sites
- Public Disclosures
- Vivli URL
- Study Posted Date



## 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**.

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/III 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

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

CLOSE

acy of Topiramate  
ge) With

**Request Study**

**+ Add New Request**

Number enrolled: 118  
Phase 3

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

### New Research Data Request

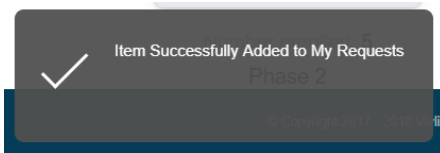
Enter a descriptive name for your research project.

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

Research Project Name

Ok Cancel

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



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

Home About Members News & Events Resources Find Studies

Click here to view your data requests. 267 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**  
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**  
Request Study  
View Study Details  
Number enrolled: 38  
Phase 1

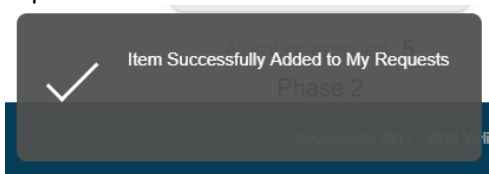
**A Single-Center, Non-Randomized, Open-Label, Comparative Study to Assess the Utility of Novel Technologies and Biomarkers as Methods for Measuring Human Pharmacodynamic Response to 8 Weeks of Administration of Rosiglitazone Maleate 4mg BID in Healthy Normal or Overweight Controls, Healthy Obese Subjects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

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us © Copyright 2017 - 2023 Vivli

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



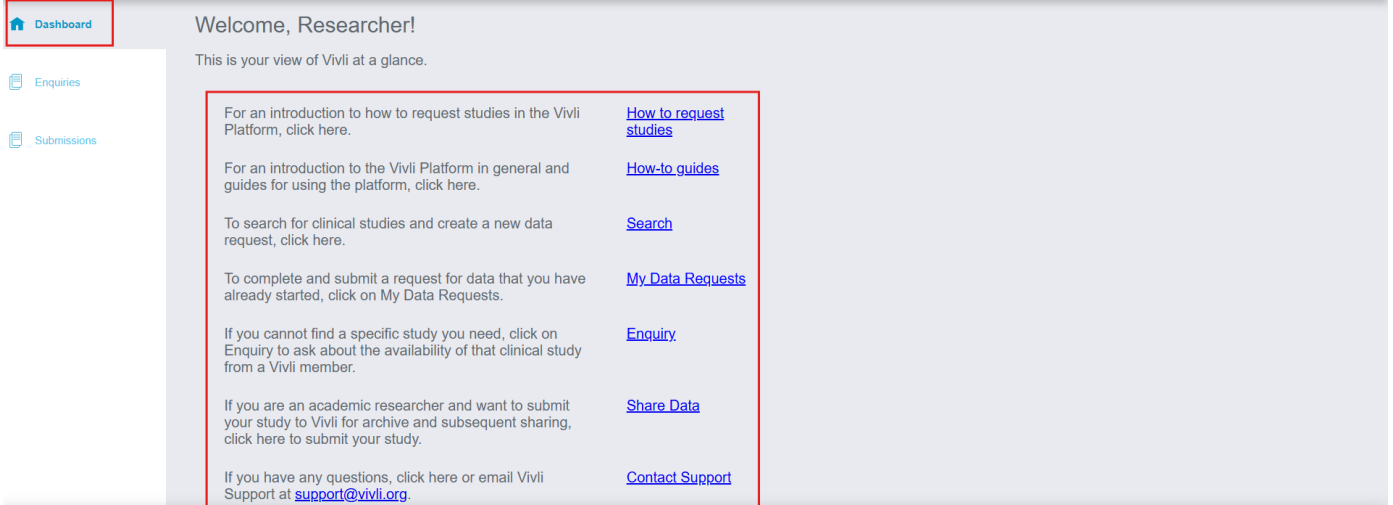
7. You will receive the same pop-up notification indicating that the study was added to your existing data request:



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

## 1.4 Dashboard

Your dashboard contains your name and links to Vivli resources that may be helpful in submitting your data request.



The screenshot shows the Vivli Researcher Dashboard. On the left is a navigation sidebar with 'Dashboard' (selected), 'Enquiries', and 'Submissions'. The main content area is titled 'Welcome, Researcher!' and contains a list of links with brief descriptions:

- For an introduction to how to request studies in the Vivli Platform, click here. [How to request studies](#)
- For an introduction to the Vivli Platform in general and guides for using the platform, click here. [How-to guides](#)
- To search for clinical studies and create a new data request, click here. [Search](#)
- To complete and submit a request for data that you have already started, click on My Data Requests. [My Data Requests](#)
- If you cannot find a specific study you need, click on Enquiry to ask about the availability of that clinical study from a Vivli member. [Enquiry](#)
- If you are an academic researcher and want to submit your study to Vivli for archive and subsequent sharing, click here to submit your study. [Share Data](#)
- If you have any questions, click here or email Vivli Support at [support@vivli.org](mailto:support@vivli.org). [Contact Support](#)

To edit your display name, please see Section 1.3 'Edit display name in profile' of the [Vivli User Account Quick Start guide](#)

## 2.0 Your Enquiries

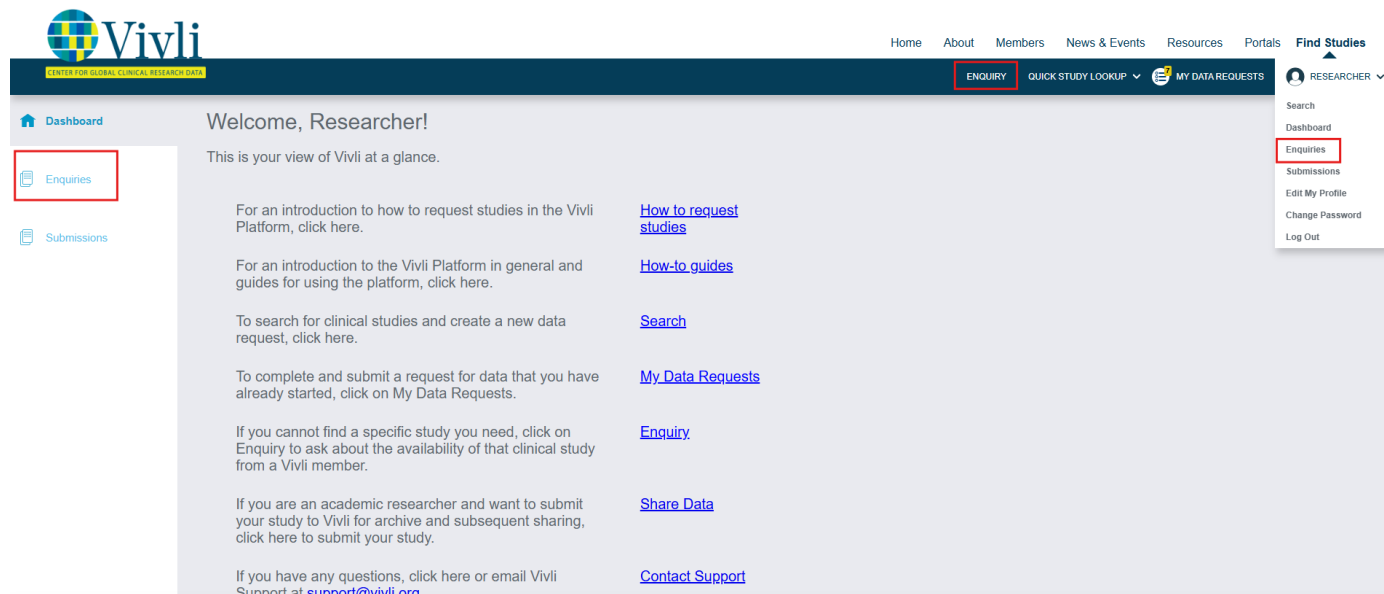
1. You can submit an enquiry using the Vivli platform <https://search.vivli.org/enquiries/> regarding the availability of a Vivli Member study not listed on Vivli or for additional study information not included in a study listing.
2. Enquiry tab Allows Vivli and Data Contributors to receive, respond, and track enquiries.
3. Please fill out one Enquiry form for multiple studies that will be part of one research project, even if the studies are from multiple Vivli Members.
  1. 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.
4. To create an enquiry, you must have a Vivli account. Please see [Section 1.2 Login/Account Setup](#) to create a new account
5. When submitting your enquiry, please ensure that you provide your full name as part of the submission process.

## 2.1 Navigation and Enquiry Dashboard

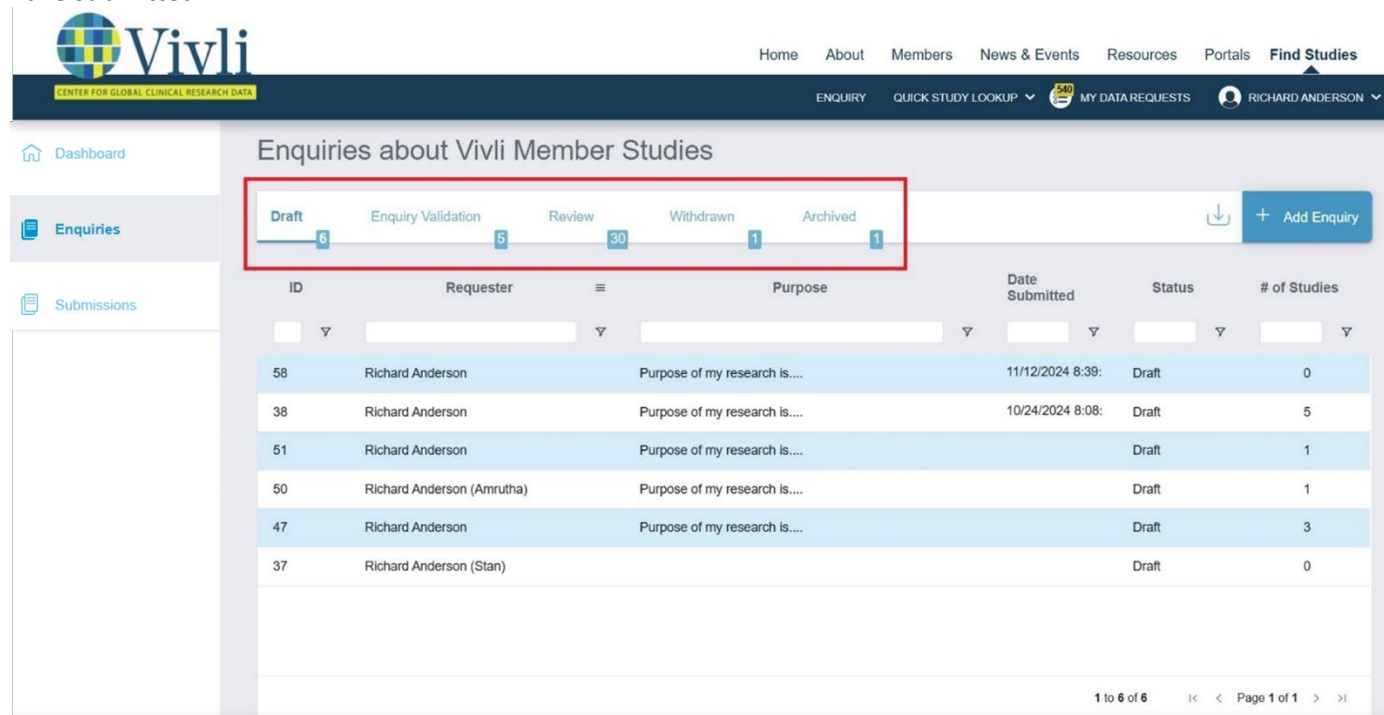
1. Once you have logged in to the dashboard, you can navigate to Enquiries using the toolbar on the left-hand



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 you have submitted



3. The status bar contains 5 sections, and you will receive email notifications for any updates:

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

**Enquiry Validation:** Displays Submitted Enquiries that are in Vivli's review. The Vivli team may request additional information, return the enquiry to Draft for any revision, or may process it forward for Data Contributors' Review. 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.

**Withdrawn:** Displays Enquiries that were withdrawn  
**Archived:** Displays Enquiries where the final decision is made.

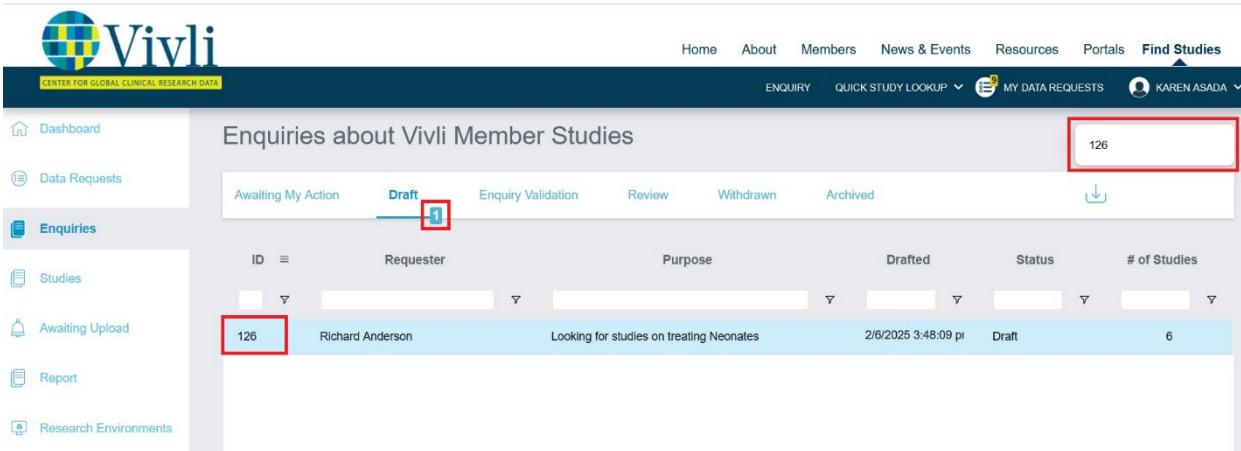
4. Each Enquiry recorded on the dashboard displays the Vivli Enquiry ID, Requester Name, Purpose of research, Date Submitted, Status of the Enquiry, and the Number of Studies in each Enquiry.

The screenshot shows the Vivli dashboard interface. At the top, there is a navigation bar with links for Home, About, Members, News & Events, Resources, Portals, and Find Studies. Below this is a secondary navigation bar with options for ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and a user profile for RICHARD ANDERSON. The main content area is titled 'Enquiries about Vivli Member Studies' and features a status filter bar with tabs for Draft (6), Enquiry Validation (5), Review (30), Withdrawn (1), and Archived (1). Below the filter bar is a table of enquiries. The table has the following columns: ID, Requester, Purpose, Date Submitted, Status, and # of Studies. A red box highlights the header row of the table. The table contains six rows of data, all with a status of 'Draft'.

ID	Requester	Purpose	Date Submitted	Status	# of Studies
58	Richard Anderson	Purpose of my research is...	11/12/2024 8:39:	Draft	0
38	Richard Anderson	Purpose of my research is...	10/24/2024 8:08:	Draft	5
51	Richard Anderson	Purpose of my research is...		Draft	1
50	Richard Anderson (Amrutha)	Purpose of my research is...		Draft	1
47	Richard Anderson	Purpose of my research is...		Draft	3
37	Richard Anderson (Stan)			Draft	0

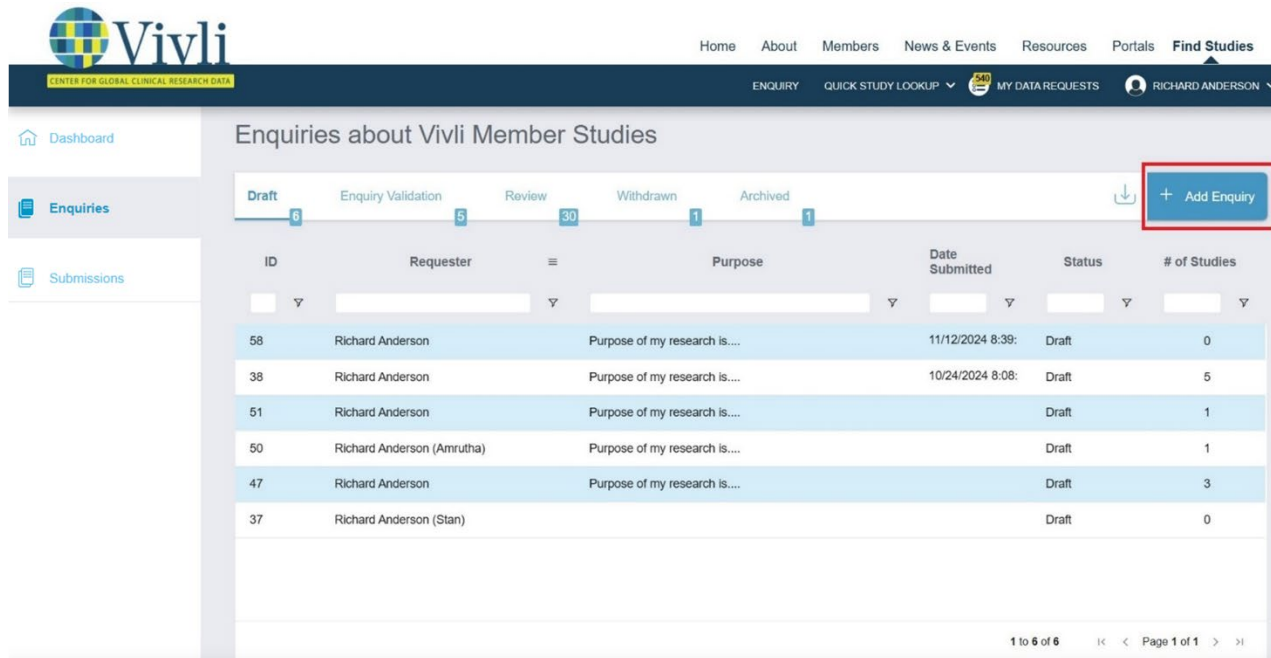
5. You may search for enquiries using one of the following fields (you can only view enquiries where one of your studies has been enquired). Search starts looking for the matching items as soon as you type the first letter, and is case-insensitive. The numbers point out the number of enquiries that match the search criteria and the status of the Enquiry:

- Enquiry ID
- Requester Name or Email
- Purpose of analysis
- NCT ID
- Sponsor ID
- Study Title
- Member Organization



## 2.2 Creating an Enquiry

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



In the Enquiry form, Requester Email and Requester Name is automatically pulled from your Vivli Account profile. If your name is incorrect, please edit the Requester Name. You may also update your profile display name. To edit your display name, please see Section 1.3 'Edit display name in profile' of the [Vivli User Account Quick Start guide](#)

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

Add Study Save Save & Notify Submit

Requester Email  
Datarequester.vivli@gmail.com

Requester Name  
Richard Anderson

Your Institution

Country  
- Select an Option -

Purpose

The [Vivli Members Page](#) provides information on each member and their policy for sharing datasets

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

Notify on "Save & Notify":

Data Contributor  
- Select an Option...

Sponsor:

Fill in your Institution name, select your country, and provide the purpose of your research. Before proceeding further, please click the Member's page link to review the data-sharing criteria of our members. Note: If your Enquiry is related to an existing data request on Vivli, please provide the project name and/or Vivli ID in the purpose of your research to link the enquiry with your existing data request.

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

Add Study Save Save & Notify Submit

Requester Email  
Datarequester.vivli@gmail.com

Requester Name  
Richard Anderson

Your Institution

Country  
- Select an Option -

Purpose

The [Vivli Members Page](#) provides information on each member and their policy for sharing datasets

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

Notify on "Save & Notify":

Data Contributor  
- Select an Option...

Sponsor:

2. Type in the study information:

- a. 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 the Clinicaltrials.gov website.
- b. 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

3. If a study is already listed on the Vivli platform, you will see a clickable note “This Study is listed on the Vivli Platform” which takes you to the listed study. 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.

NCT ID  
NCT02636907

OR

Sponsor ID  
1297.11

Study Title  
Assessment of Real-life Patient Handling Experience of BI 695501 Administered Subcutaneously With an Autoinjector in Patients With Rheumatoid Arthritis: an Open-label, Interventional Clinical Trial Followed by an Extension Phase of BI 695501 Administered With a Prefilled Syringe

Primary Completion Date: 2016-06-21

Clinical Trials: <https://clinicaltrials.gov/show/NCT02636907>

Notify on "Save & Notify":

Data Contributor  
AbbVie

Sponsor: Boehringer Ingelheim

This Study is listed on the Vivli Platform

4. 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 enquiry 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

5. 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

6. To delete a study, click the delete icon

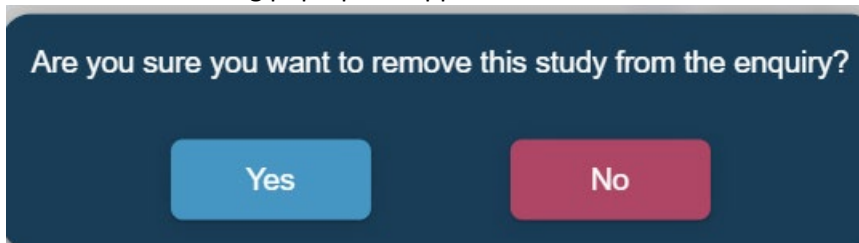
Please enter an NCT Id or Sponsor Id if the study is on clinicaltrials.gov, or enter the study title.

NCT ID NCT02064465	Study Title A Single-Dose, Open-Label, Randomized, Parallel-Group Study to Demonstrate the Bioequivalence of Lamotrigine Dispersible/Chewable Tablet (100mg) and Lamotrigine Compressed Tablet (100mg) in Healthy Chinese Male Subjects	Notify on "Save & Notify": <input type="checkbox"/>
OR		
Sponsor ID 200697		Data Contributor GlaxoSmithKline
		Sponsor: GlaxoSmithKline

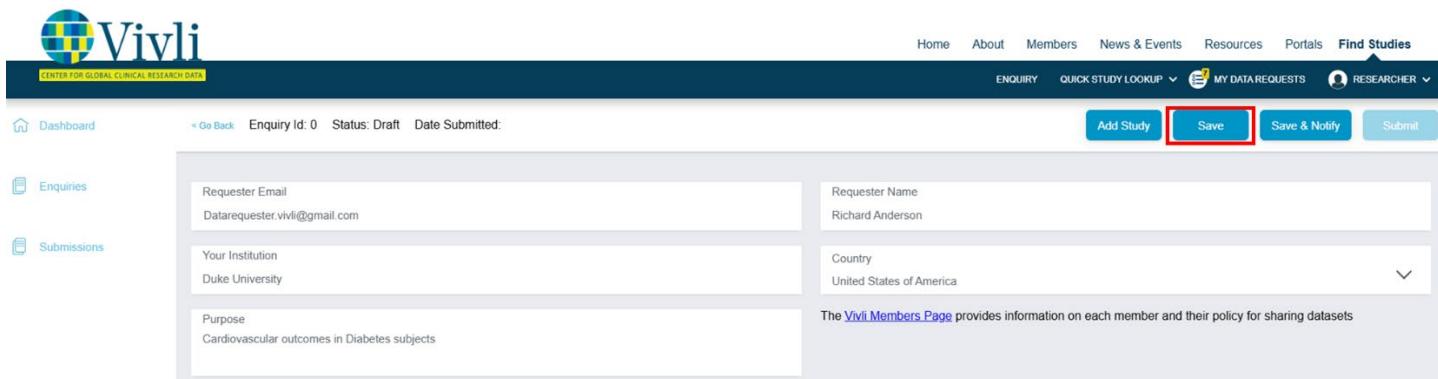
Primary Completion Date: 2014-07-08      Clinical Trials: <https://clinicaltrials.gov/show/NCT02064465>      [This Study](#) is listed on the Vivli Platform

Discussion:

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



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



The screenshot shows the Vivli website header with navigation links: Home, About, Members, News & Events, Resources, Portals, Find Studies. Below the header is a dark blue navigation bar with 'ENQUIRY', 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'RESEARCHER'. The main content area shows a form with the following fields:

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	The <a href="#">Vivli Members Page</a> provides information on each member and their policy for sharing datasets

At the top right of the form area, there are four buttons: 'Add Study', 'Save' (highlighted with a red box), 'Save & Notify', and 'Submit'. The status bar above the form shows 'Enquiry Id: 0', 'Status: Draft', and 'Date Submitted:'.



9. 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 Save & Notify 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	The <a href="#">Vivli Members Page</a> provides information on each member and their policy for sharing datasets

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

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

10. 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

Response <sup>?</sup> New	No Data Found
Reason <sup>?</sup> None	
<input type="text" value="Comment"/>	
<input type="button" value="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:	Status: <span style="color: red;">!</span>
--	---------	--------------	-------------------	--

11. 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 Save & Notify **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	The <a href="#">Vivli Members Page</a> provides information on each member and their policy for sharing datasets

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

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

12. If the Submit button is not enabled, look for the red exclamation mark which points the incomplete field. Please note that any field marked in red text is mandatory and must be filled out before the Submit button becomes enabled.

< Go Back Enquiry Id: 0 Status: Draft Date Submitted: Add Study Save Save & Notify **Submit**

Requester Email Datarequester.vivli@gmail.com	Requester Name Richard Anderson
Your Institution	Country - Select an Option -
Purpose	The <a href="#">Vivli Members Page</a> provides information on each member and their policy for sharing datasets

<b>+ NCT ID:</b>	<b>Study Title:</b>	<b>Data Contributor:</b>	<b>Status:</b> <span style="border: 1px solid red; padding: 2px;">!</span>
------------------	---------------------	--------------------------	--

13. 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: 209** Status: Enquiry Validation Date Submitted: 2025-09-25 Save Save & Notify

Requester Email Datarequester.vivli@gmail.com	Requester Name Richard Anderson
Your Institution Duke University	Country United States of America
Purpose Cardiovascular outcomes in diabetes patients	The <a href="#">Vivli Members Page</a> provides information on each member and their policy for sharing datasets


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

Primary Completion Date: 2018-07-26 Clinical Trials:


### 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  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  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 for 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: 0 Status: Draft Date Submitted:

Add Study Save Save & Notify Submit

Primary Completion Date: Clinical Trials:

Discussion:

Data Requested  
ParticipantData x | v

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):

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:

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

Data Requested:  
• Clinical Documents  
• ParticipantData

Response  
Response from data c...

Reason  
None



Comment

Add Comment

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

Date of Final Response: Request Number(s):

7. The copy icon next to the posted comment allows you to copy the comment and paste it.



Discussion:			
2/12/2025 1:27:49 pm	Karen Asada	The data contributor has provided a final response on the availability of this study	
2/12/2025 1:27:49 pm	Karen Asada	Please see the member's page at <a href="https://vivli.org/members/ourmembers/">https://vivli.org/members/ourmembers/</a> for more details on the member's data sharing policy	

8. 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:

- **Responses:** This includes updates to the Enquiry discussion and decisions made by the Data Contributor:
  - a. None – No responses
  - b. New – Meaning no one has responded yet – this is the initial default value
  - c. 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.
    - i. Response from data contributor – The Data Contributor has added information to the discussion. This is automatically set once the Data Contributor responds.
    - ii. Response from Vivli – The Vivli Admin has added information to the discussion. This is automatically set when the Vivli team responds.
  - d. Eligible for Request as an Unlisted Study – You can add this study to your data request. For the next steps, see [Section 2.5 Adding studies to your data request](#)
  - e. Study is Listed - You can add this study to your data request. For the next steps, see [Section 2.5 Adding studies to your data request](#)
  - f. Not Available – Study is not available. No Action is needed from you
- **Reason** – When the response is Not Available, the reason field provides more information. You will see an automated comment placed in the discussion saying, "Please see the member's page at <https://vivli.org/members/ourmembers/> for more details on the member's data sharing policy"

Discussion:			
2/12/2025 1:27:49 pm	Karen Asada	The data contributor has provided a final response on the availability of this study	
2/12/2025 1:27:49 pm	Karen Asada	Please see the member's page at <a href="https://vivli.org/members/ourmembers/">https://vivli.org/members/ourmembers/</a> for more details on the member's data sharing policy	

- a. **Comment** – You, Vivli Admin, and Data Contributors can add a comment about the Enquiry. Once the final decision is made, you will no longer be able to add a comment to the discussion.
- b. **Discussion** – This includes all the comments provided by you, Vivli Admin, and Data Contributor for this specific study
- c. **Date of Final Response** – Date when the Data Contributor makes a final decision
- d. **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.](#)

Discussion:

Data Requested:

- Clinical Documents
- ParticipantData

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):

#### 2.4.1 Enquiry Study Status for Individual Studies

In addition to the overall Enquiry status, there is a Study-level Status that combines the Enquiry's status with the decision about the Study.

Here is the list of study-level statuses:

1. For studies with no decision recorded yet.
  - a. Awaiting Initial submission Overall Enquiry is in draft and has never been submitted
  - b. Awaiting Resubmission - Overall Enquiry is in draft after being sent back to draft for revision
  - c. Awaiting Validation (Overall Enquiry is in the Enquiry Validation state)
  - d. Awaiting DC review - Overall Enquiry is In review
  - e. Withdrawn (Overall Enquiry is in Withdrawn)
  - f. Archived (Overall Enquiry is in Archived)
2. For studies with decisions already recorded - e.g. response of Available or Not Available
  - a. Closed - Available as listed (Independent of the overall Enquiry status)
  - b. Closed - Available as unlisted (Independent of the overall Enquiry status)
  - c. Closed - Not Available (Independent of the overall Enquiry status)

Study-level Status is visible in the following areas:

## 1. Closed Enquiry Study panel, on the right next to the Data Contributor name

< Go Back   Enquiry Id: 54   Status: Review   Date Submitted: 2024-11-06   Save   Save & Notify   Request Available Studies ▾

Requester Email Datarequester.vivli@gmail.com	Requester Name Richard Anderson
Your Institution Boston University	Country United States of America
Purpose Purpose of analysis is.....	

<b>NCT ID:</b> NCT06210529	<b>Study Title:</b> A Single-center, Prospective Clinical Study of High-intensity Focused Ultrasound Tumor Treatment System(Super Knife) in the Treatment of Breast Cancer	<b>Data Contributor:</b> Roche	<b>Status:</b> Closed - Available as listed
<b>NCT ID:</b> NCT00086593	<b>Study Title:</b> A Multicenter, Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of a Flexible Dose of Lamotrigine Compared to Placebo as an Adjunctive Therapy to an Atypical Antipsychotic Agent(s) in Subjects With Schizophrenia	<b>Data Contributor:</b> GlaxoSmithKline	<b>Status:</b> Closed - Available as listed

## 2. Open the Enquiry Study panel, on the left side below the Reason field

**-** NCT ID: NCT00086593   OR   Sponsor ID: 101464   Study Title: A Multicenter, Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of a Flexible Dose of Lamotrigine Compared to Placebo as an Adjunctive Therapy to an Atypical Antipsychotic Agent(s) in Subjects With Schizophrenia   Notify on "Save & Notify":    Data Contributor: GlaxoSmithKline   Sponsor: GlaxoSmithKline

Primary Completion Date: 2005-07-31   Clinical Trials: <https://clinicaltrials.gov/show/NCT00086593>   This Study is listed on the Vivli Platform

Discussion:

Data Requested:

- Clinical Documents
- ParticipantData

Response: Study is Listed

**Closed - Available as listed**

Reason: None

No Data Found

## 2.5 Adding studies to your data request

1. If a study is eligible for request, you will see an automated comment placed in the discussion. "The data contributor has provided a final response on the availability of this study"

Discussion:

11/27/2024 5:39:39 pm	Karen Asada	- The data contributor has provided a final response on the availability of this study	
12/20/2024 8:58:55 am	Amrutha Baskaran	Test	

- 2. You can add studies from the Enquiry directly into the data request form.
  - a. If the study is unlisted, you can add them immediately.
  - b. 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).

3. Open the Enquiry, click the **Request Available Studies** button, and click the down arrow next to it. (if you have multiple studies, please wait until you receive a decision on the studies before adding them to your request). This will allow you to add all the available studies to your data request.

< Go Back   Enquiry Id: 54   Status: Review   Date Submitted: 2024-11-06   **Save**   **Save & Notify**   **Request Available Studies** ▾

Requester Email Datarequester.vivli@gmail.com	Requester Name Richard Anderson
Your Institution Boston University	Country United States of America
Purpose Purpose of analysis is.....	

<b>+</b> NCT ID: NCT06210529	<b>Study Title:</b> A Single-center, Prospective Clinical Study of High-intensity Focused Ultrasound Tumor Treatment System(Super Knife) in the Treatment of Breast Cancer	<b>Data Contributor:</b> Roche	<b>Status:</b> Closed - Available as listed
<b>+</b> NCT ID: NCT00086593	<b>Study Title:</b> A Multicenter, Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of a Flexible Dose of Lamotrigine Compared to Placebo as an Adjunctive Therapy to an Atypical Antipsychotic Agent(s) in Subjects With Schizophrenia	<b>Data Contributor:</b> GlaxoSmithKline	<b>Status:</b> Closed - Available as listed

4. Alternatively, you may click the **Request Study** button under individual studies and click the down arrow next to it. Note: you have to take the below steps for each study in the Enquiry that is available for the data request and add it to the same data request.

How-To: Requesting Studies on Vivli

Version 3.8

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

Request Study ▼

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

Notify on "Save & Notify":

Data Contributor  
Data Contributor

Sponsor: Aragon Pharmaceuticals, Inc.

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

Discussion:

Data Requested:	6/10/2024 2:42:07 pm	Stan Neumann	Comment from Vivli Admin
<ul style="list-style-type: none"> <li>Clinical Documents</li> <li>ParticipantData</li> </ul>	6/11/2024 6:32:25 am	Amrutha	Comment from DC

Response ?

Study is Listed

---

Reason ?

None

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

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

Request Study ▼

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

Albumin increase in diabetes mellitus patients

Heparin use in the patients with stroke

ILT TC3027

Increase in albuminuria in Diabetes patients

Increase in albuminuria in Diabetes patients

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

6. 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

NCT ID  
NCT0194620...

OR

Sponsor ID  
CR102931

Primary Completion Date:

Data Requested:

- Clinical Documents

Response ?

Study is Listed

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

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

Discussion:

Notify on "Save"

Outcomes

+ Add New Request

Sponsor: Aragon Pharmaceuticals, Inc.

7. You will be prompted to provide a new project name. Note: Special characters are not accepted in the 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

8. The following notification will appear

9. 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](#)

10. 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)”.

11.

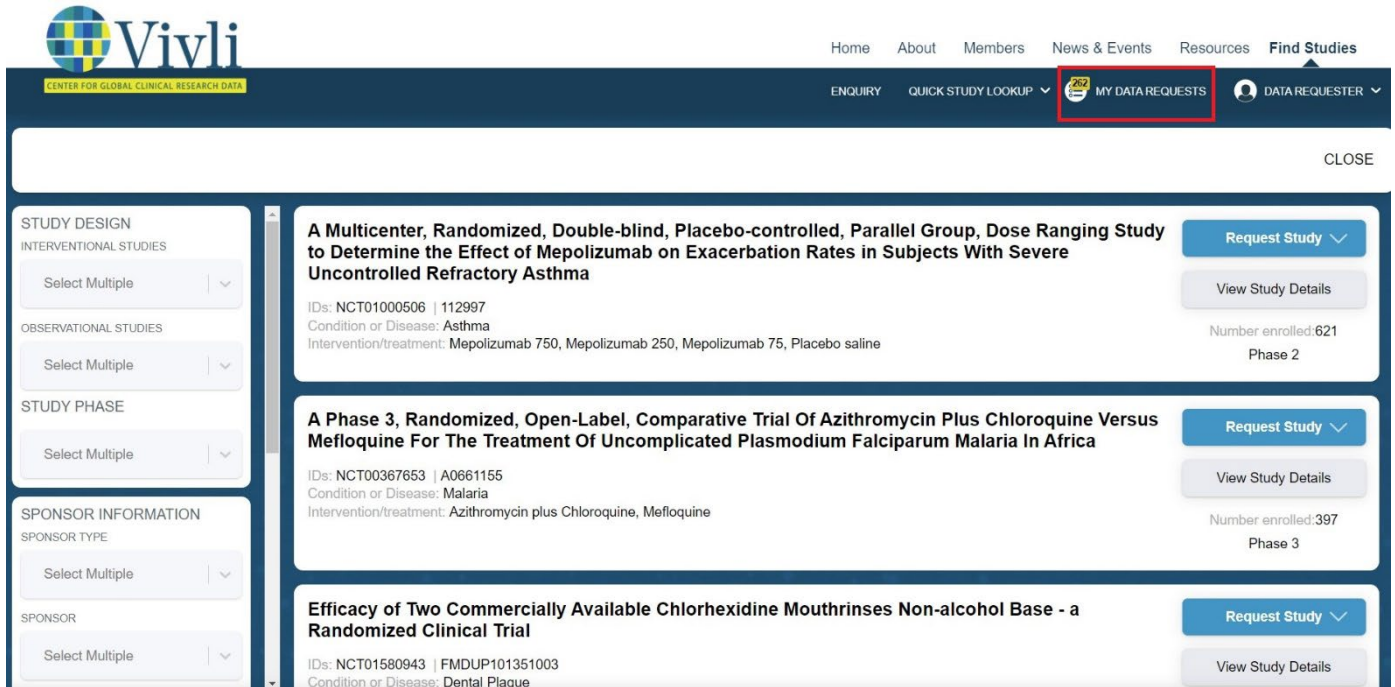
The enquiry will display the associated Data request ID once the data request is submitted on the platform

Date of Final Response: 2024-05-10

Request Number(s): 00048130

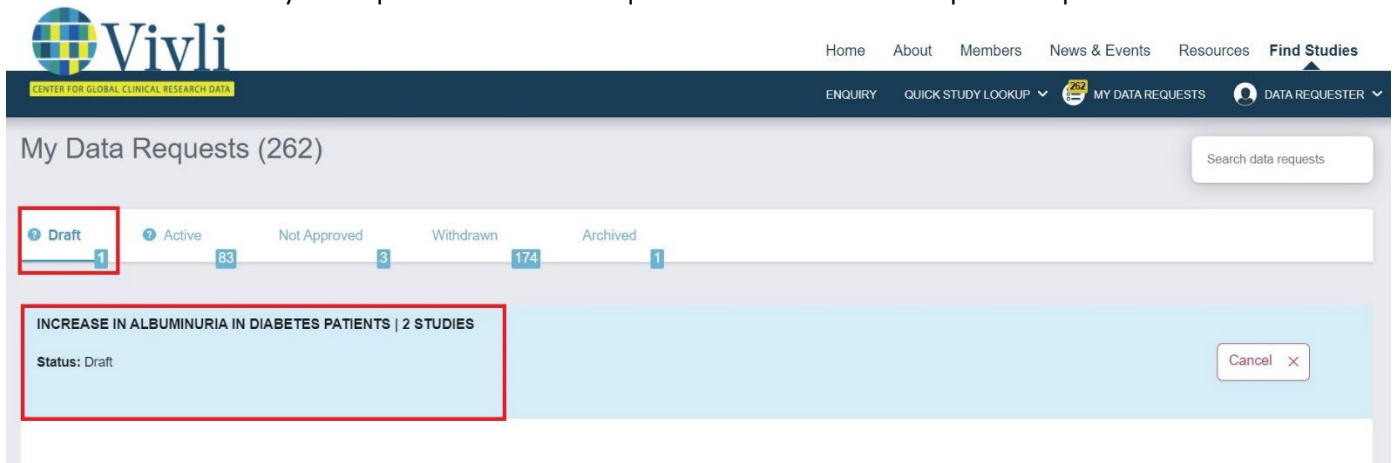
### 3.0 Your Data Requests

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



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

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



### 3.1 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, 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; 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.

### 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:

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

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

Other Information

Other Information ⓘ

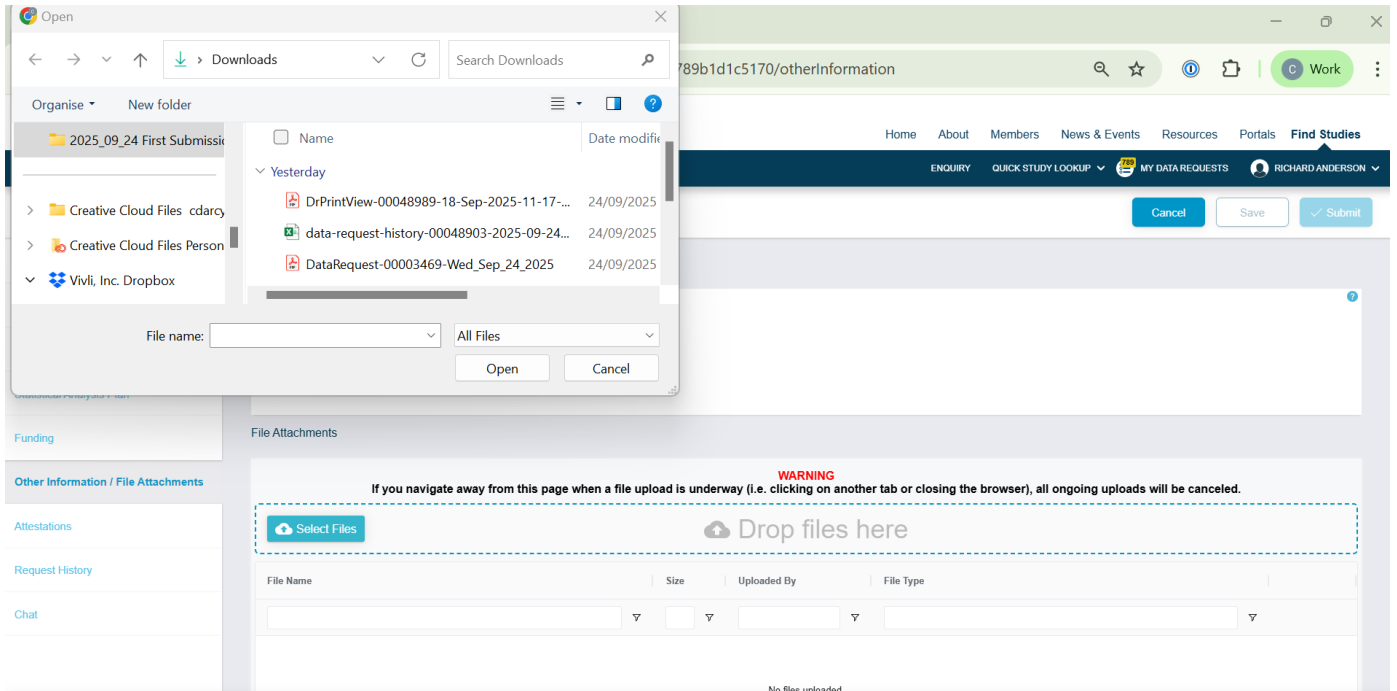
File Attachments

NO FILES IN PACKAGE

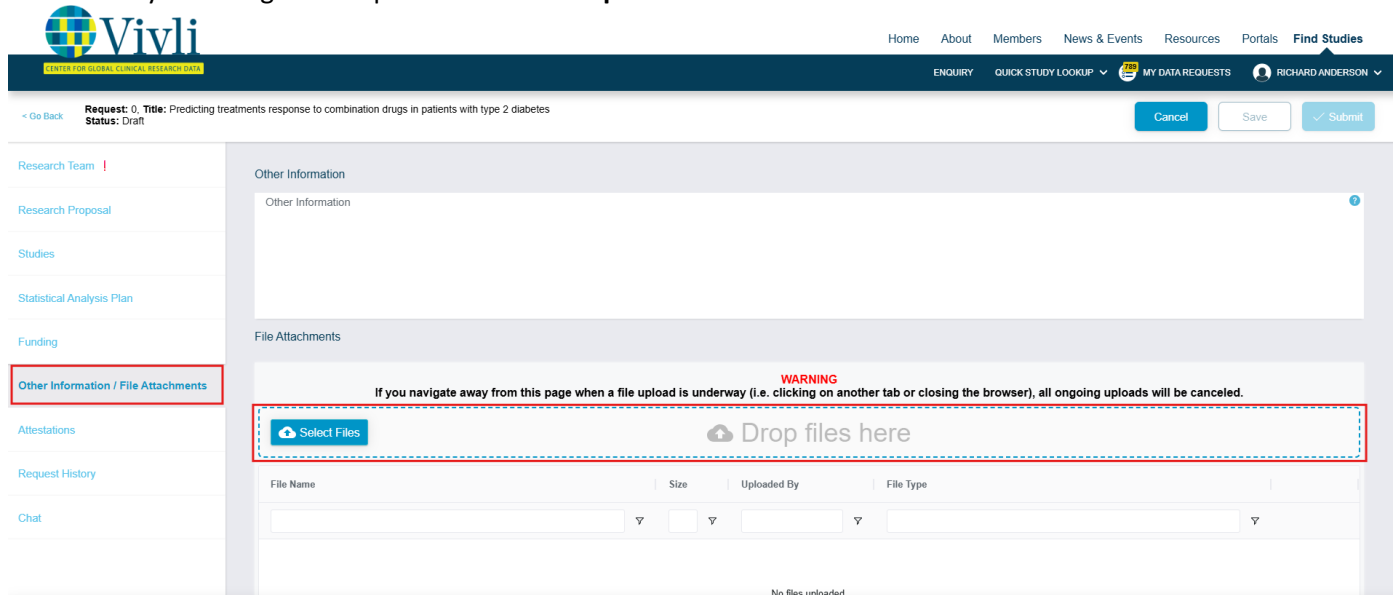
Select Files

Drop files here

- Then simply select the file from your computer. If you navigate away from this page when a file upload is underway (i.e. clicking on another tab or closing the browser), all ongoing uploads will be cancelled.:



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



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

< Go Back **Request: 0, Title: Predicting treatments response to combination drugs in patients with type 2 diabetes**  
Status: Draft

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

**WARNING**  
If you navigate away from this page when a file upload is underway (i.e. clicking on another tab or closing the browser), all ongoing uploads will be canceled.

Select Files

File Name	Size	Uploaded By	File Type
Data Dictionary.pdf	17.84kB	Richard Anderson	File Type Unknown

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

< Go Back **Request: 0, Title: Predicting treatments response to combination drugs in patients with type 2 diabetes**  
Status: Draft

Cancel Save Submit

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

File Attachments

**WARNING**  
If you navigate away from this page when a file upload is underway (i.e. clicking on another tab or closing the browser), all ongoing uploads will be canceled.

Select Files

File Name	Size	Uploaded By	File Type
Data Dictionary.pdf			<div style="border: 1px solid red; padding: 2px;">                     Research Proposal Supplement                      Funding Information                      Statistical Analysis Plan                      Other                      Unknown                 </div>

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



< Go Back **Request: 0, Title: Predicting treatments response to combination drugs in patients with type 2 diabetes**  
Status: Draft

Cancel Save Submit

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

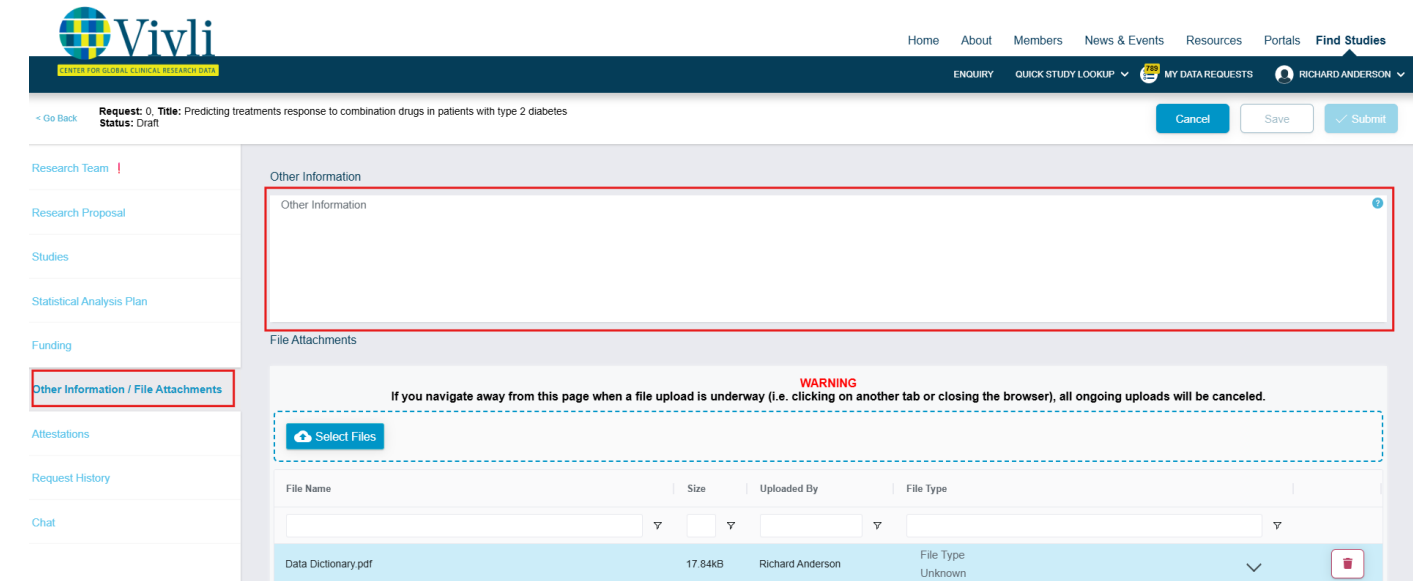
**File Attachments**

**WARNING**  
If you navigate away from this page when a file upload is underway (i.e. clicking on another tab or closing the browser), all ongoing uploads will be canceled.

Select Files

File Name	Size	Uploaded By	File Type
Data Dictionary.pdf	17.84kB	Richard Anderson	File Type Unknown

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



**Other Information**

Other Information

**File Attachments**

**WARNING**  
If you navigate away from this page when a file upload is underway (i.e. clicking on another tab or closing the browser), all ongoing uploads will be canceled.

Select Files

File Name	Size	Uploaded By	File Type
Data Dictionary.pdf	17.84kB	Richard Anderson	File Type Unknown

### 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

How-To: Requesting Studies on Vivli

Version 3.8

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. At the top, there is a navigation bar with the Vivli logo and the text "CENTER FOR GLOBAL CLINICAL RESEARCH DATA". The main header contains navigation links: Home, About, Members, News & Events, Resources, Portals, and Find Studies. Below this, there is a user profile section for RICHARD ANDERSON. The main content area displays a Data Request Form for Request 2553, titled "Predicting Treatment Response to combination drugs in patients with type 2 Diabetes". The status is "Draft". In the top right corner, there are three buttons: "Cancel", "Save", and "Submit". The "Submit" button is highlighted with a red box. The form is divided into sections: "Other Information" with a text input field, and "File Attachments" with a warning message and a file upload area. The file upload area includes a "Select Files" button, a "Drop files here" area, and a table with columns for File Name, Size, Uploaded By, and File Type.

### 3.4 Adding Research Team Members

1. When the request is in the **“Drafts”** stage, additional research team members may be added to a Data Request by the research team directly following the steps below.
2. Individuals activated for a data request will be able to view and edit the Data Request Form.
3. If the Data Use Agreement (DUA) covers the individual, they will have access to the Secure Research Environment.
  - If your team member is from a different institution than the Lead Researcher and would like to access the data, they will need to have a separate DUA in place from their institution before accessing the data.
4. These permissions can also be changed before starting the research environment and while the research environment is running.
5. If the Lead Researcher is also a Statistician Researcher, select the checkbox as shown below. Note: you are unable to add two Research team members with the same email address.

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

- The following dialogue box will appear:

ADDITIONAL RESEARCHER - No Account  Activate user for accessing data request ?

First Name Last Name ORCID ID ?

Email (editable until user is invited to data request) Position at current organization

Employer, Company, Research Institute, or Primary Affiliation ? Country  
Select One


Education, including professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. ?

Name of the degree Institution from where the degree was received

Discipline ? Year Received How many years of experience with secondary analysis  
- Select an Option -

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

8. 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.

 Home About Members News & Events Resources Portals Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RICHARD ANDERSON

< Go Back Request: 0. Title: Predicting treatments response to combination drugs in patients with type 2 diabetes Status: Draft Cancel Save Submit

Research Team !

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

First Name Sarah Last Name Jones ORCID ID ?

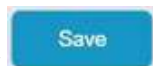
Email (editable until user is invited to data request) sarah.jones@duke.edu Position at current organization

Employer, Company, Research Institute, or Primary Affiliation ? Country  
Duke University United States of America

Education, including professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. ?  
MSc Biostatistics 1999  
PhD Public Health 2005

Name of the degree PhD Institution from where the degree was received  
Harvard

Discipline ? Year Received How many years of experience with secondary analysis  
Public Health 2005 1-5 years



9. Complete all fields, and click

10. Please ask the research team member to "sign up" for a Vivli account. They can follow Section 1.1 of the [Vivli User Account Quick Start guide](#)

11. 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 clicking **OK**:

The screenshot shows the 'ADDITIONAL RESEARCHER' form. At the top right, there is a checkbox labeled 'Activate user for accessing data request' which is checked. Below this are several input fields: 'First Name', 'Last Name', and 'ORCID ID'. The next row contains 'Email (editable until user is invited to data request)' and 'Position at current organization'. The following row has 'Employer, Company, Research Institute, or Primary Affiliation' and a 'Country' dropdown menu. Below that is a large text area for 'Education, including professional qualifications that are relevant to the proposed research and are specific to clinical data analysis.' The next row contains 'Name of the degree' and 'Institution from where the degree was received'. The final row has 'Discipline', 'Year Received', and 'How many years of experience with secondary analysis' with a dropdown menu. At the bottom, there is a note: 'Please list any real or potential conflicts of interest and describe how these will be managed. If none, please enter None.'

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

The screenshot shows the main data request form. At the top, it says 'Request: 0 Title: Predicting treatments response to combination drugs in patients with type 2 diabetes' and 'Status: Draft'. There are 'Cancel', 'Save', and 'Submit' buttons. Below this is the 'Research Team' section. It shows a 'LEAD RESEARCHER / STATISTICIAN' profile. At the top right of this section, there is a checkbox 'Activate user for accessing data request' which is unchecked, and a checked checkbox 'Lead Researcher is also Statistician Researcher'. The profile fields are: 'First Name: Sarah', 'Last Name: Jones', 'ORCID ID', 'Email (editable until user is invited to data request): sarah.jones@duke.edu', 'Position at current organization: Biostatistician', 'Employer, Company, Research Institute, or Primary Affiliation: Duke University', 'Country: United States of America', 'Education, including professional qualifications that are relevant to the proposed research and are specific to clinical data analysis: MSc Biostatistics 1999, PhD Public Health 2005', 'Name of the degree: PhD', 'Institution from where the degree was received: Harvard', 'Discipline: Public Health', 'Year Received: 2005', and 'How many years of experience with secondary analysis: 1-5 years'. On the left side, there is a navigation menu with items: 'Research Proposal', 'Studies', 'Statistical Analysis Plan', 'Funding', 'Other Information / File Attachments', 'Attestations', 'Request History', and 'Chat'.

13. If you would like to make changes to the Research team members including the Lead Researcher or Lead Statistician **during the review process, or after the data request is**

**approved**, please reach out to the Vivli team via platform chat or [support@vivli.org](mailto:support@vivli.org).

14. Please provide the following information when requesting to add an additional research team member:
  - First Name
  - Last Name
  - Email
  - Position at employer/institution
  - ORCID (if available)
  - Employer/company/institution name
  - Country location
  - Education (include qualifications, disciplines and institutions where they were obtained, and publications relevant to this analysis):
  - Conflict of interest statement and plan for mitigation
  - Name of highest or most relevant degree
  - Institution from where the degree was received
  - Discipline of the degree
  - Year Received
  - Number of years of experience with secondary analysis
  - *Note: If your team member is from a different institution we will need to ensure that they have a DUA in place from their institution before accessing the data*
15. Please note that according to Vivli policy, any changes to the Lead Researcher, Lead Statistician, their conflict of interest, adding and removal of studies in the request, or 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.

1. 

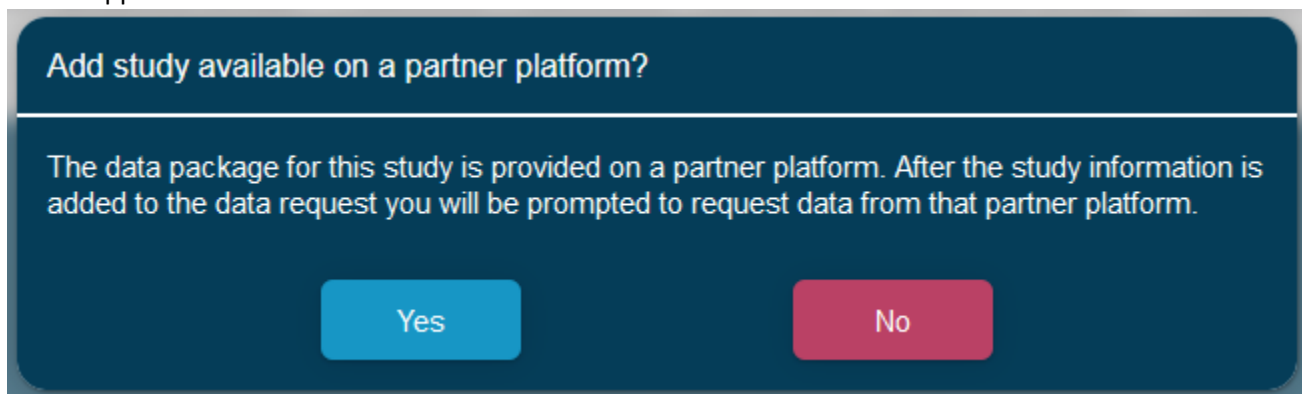
## 4.0 Requesting Vivli-listed studies provisioned by external providers

### 4.1 Overview

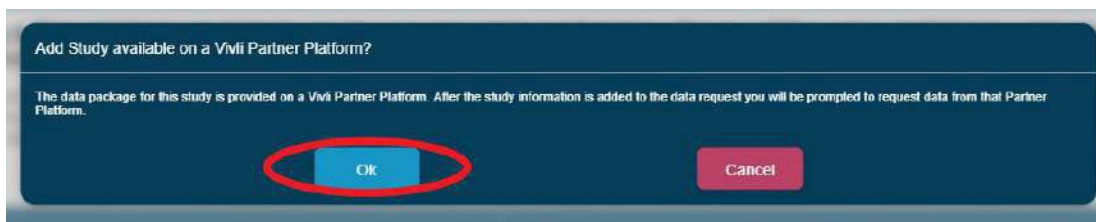
- Some studies are listed and searchable on both the Vivli platform as well as on other platforms that are Partner Platforms with Vivli.
- In addition to completing the Vivli request form, you will need to request such studies directly through the Partner Platform.
- After the relevant Data Contributor(s)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

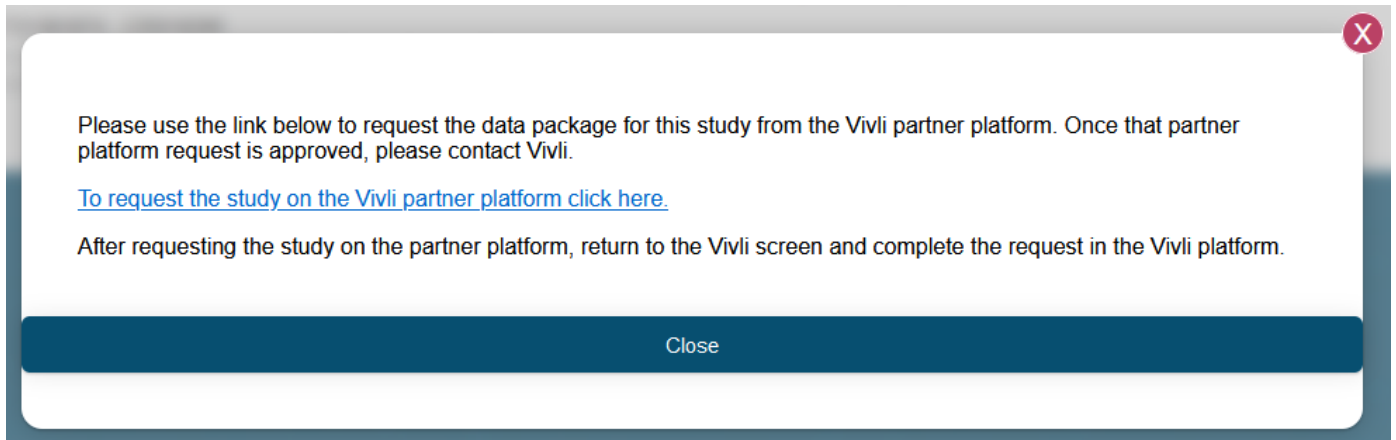


3. Click on **Yes** to add the study to the Data Request Form:

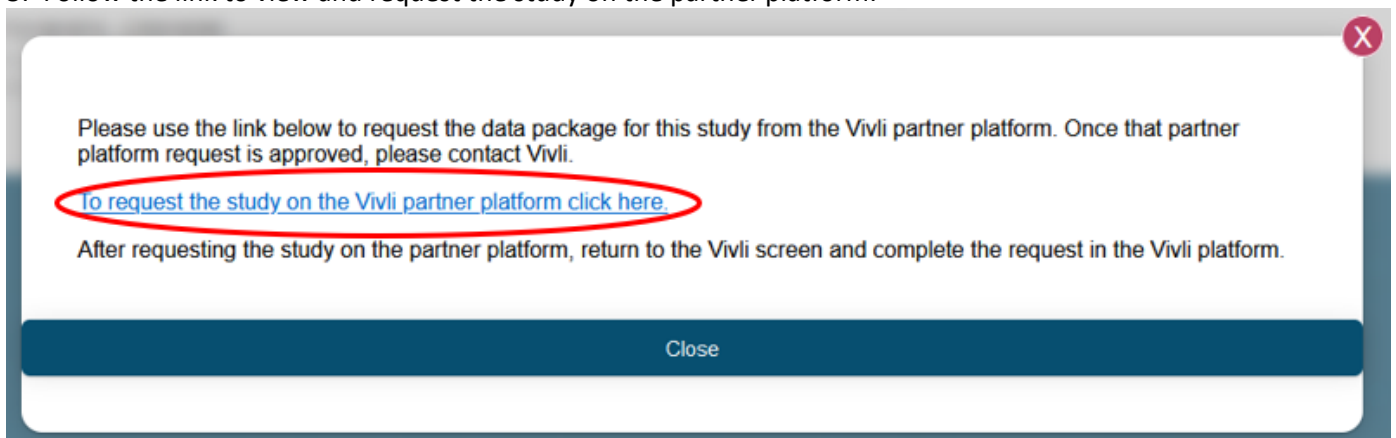


4. The following pop-up will appear:





5. Follow the link to view and request the study on the partner platform:



Note: this link will open up the partner platform website in another browser tab.

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

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

Research Team

Research Proposal

**Studies**

Statistical Analysis Plan

Funding

Other Information / File Attachments

Attestations

Chat

REQUESTED STUDIES ? ↓

VIVLI-LISTED AND PROVISIONED STUDIES

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

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

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

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI

No Studies Found

- 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**.

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

Research Team

Research Proposal

**Studies**

Statistical Analysis Plan

Funding

Other Information / File Attachments

Attestations

Chat

REQUESTED STUDIES ? ↓

VIVLI-LISTED AND PROVISIONED STUDIES

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

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

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

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI

No Studies Found

## 5.1 Process Overview

To request data from Vivli Member studies that are 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.

The screenshot displays the Vivli website interface. At the top, there is a navigation bar with links for Home, About, Members, News & Events, Resources, and Find Studies. Below this, a dark blue bar contains the 'ENQUIRY' button, which is highlighted with a red box. Other buttons in this bar include 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'RESEARCHER'. The main content area is titled 'Predicting Treatment Response to combination drugs in patients with type 2 diabetes'. On the left, there is a sidebar with navigation options: Research Team, Research Proposal, Studies (highlighted), Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, and Chat. The main content area is divided into several sections: 'REQUESTED STUDIES', 'VIVLI-LISTED AND PROVISIONED STUDIES', 'VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS', and 'STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI'. The 'VIVLI-LISTED AND PROVISIONED 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, and Data Contributor: GlaxoSmithKline. The 'VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS' section shows a study titled 'Randomized, Open-Label Study of Abiraterone Acetate (JNJ-212082) Plus Prednisone With or Without Exemestane in Postmenopausal Women With ER+ Metastatic Breast Cancer Prog...'. The 'STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI' section has an 'Add +' button and currently shows 'No Studies Found'.

2. If the enquiry is approved and the 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 that 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:

< Go Back

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

Edit Request Title Cancel Save Submit

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

### REQUESTED STUDIES ?

#### VIVLI-LISTED AND PROVISIONED STUDIES

A Multicenter, Open-Label Conversion of Valproate Monotherapy to Lamotrigine Monotherapy in Patients With Epilepsy

Study ID: NCT00043914 Sponsor ID: LAM40013  
 Data Request ID:  
 Data Contributor: GlaxoSmithKline IRP/Approver: Wellcome Trust

Data to be loaded after approval Remove X

#### VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

Randomized, Open-Label Study of Abiraterone Acetate (JNJ-212082) Plus Prednisone With or Without Exemestane in Postmenopausal Women With ER+ Metastatic Breast Cancer Progre...

Study ID: NCT01381874 Sponsor ID: CR018285  
 Data Request ID:  
 Data Contributor: Johnson and Johnson IRP/Approver: YODA Project

Data to be loaded after approval Remove X

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI Add +

No Studies Found

4. 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

Select Provide... ▼

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

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

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

### Request Studies, Data, or Tools not listed on Vivli

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

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

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

Pfizer Inc. ▼	NCT012345678
---------------	--------------

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

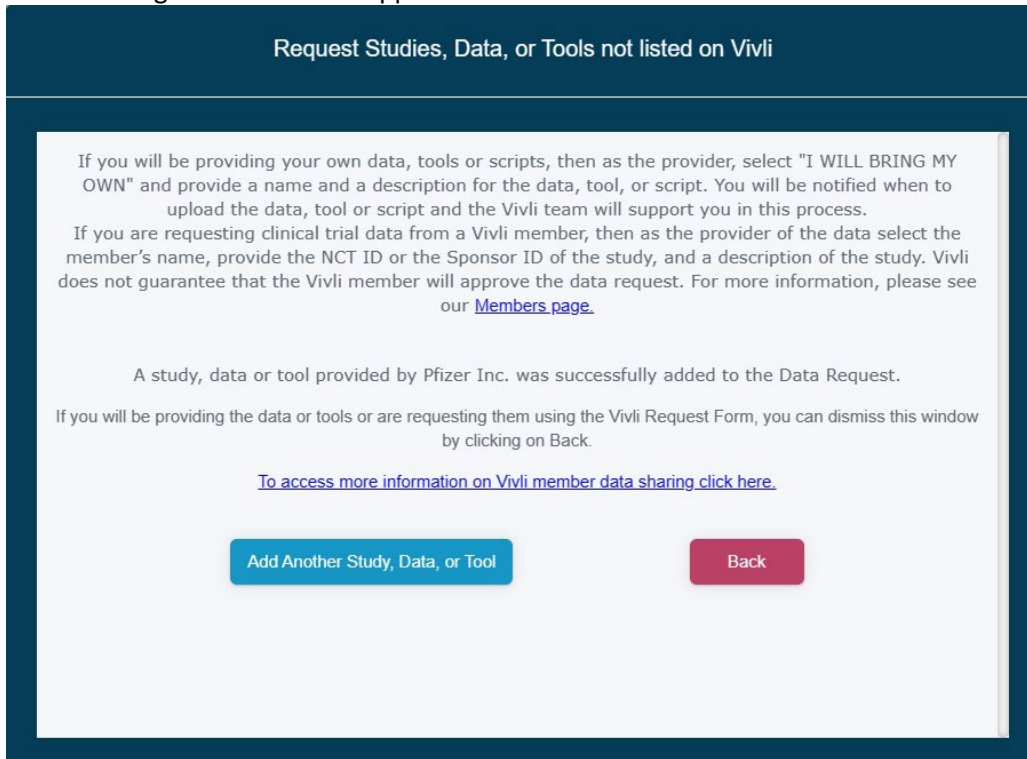
Study Title

SubmitCancel

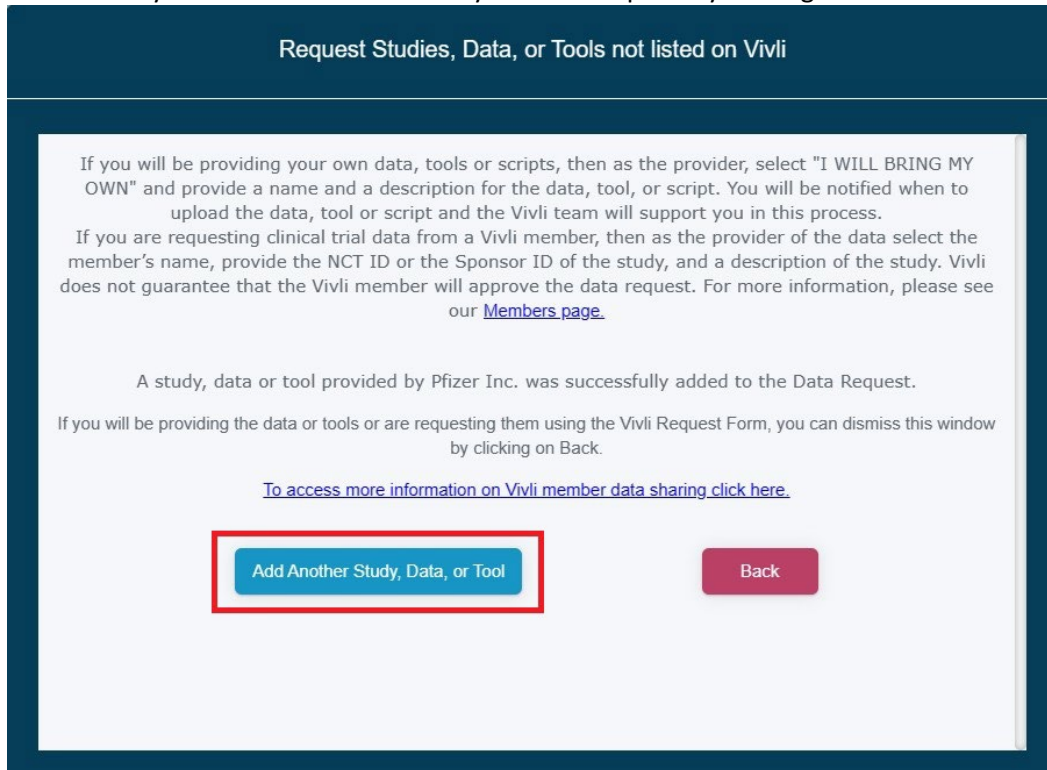
**Note:** Please add only one study in the dialogue box. If you wish to add additional studies, please complete this process, and repeat it for the additional studies.



6. The following notification will appear:



7. You may add additional studies to your data request by clicking on **Add Another Study:**



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

**Request Studies, Data, or Tools not listed on Vivli**

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

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

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

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

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

Add Another Study, Data, or Tool

Back

9. The studies will appear in the study list

The screenshot shows the Vivli website interface. At the top, there is a navigation bar with links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a header for a specific request: "Predicting Treatment Response to combination drugs in patients with type 2 diabetes". The main content area is divided into sections: "REQUESTED STUDIES", "VIVLI-LISTED AND PROVISIONED STUDIES", and "VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS". Each section contains a list of studies with details such as Study ID, Sponsor ID, Data Request ID, and Data Contributor. A red box highlights the "STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI" section, which contains a study entry for "ABC-156" with details: Study ID: NCT012345678, Data Request ID: [redacted], Data Contributor: Pfizer Inc., IRPI/Approver: Pfizer Inc. The "Back" button from the previous screenshot is also highlighted in red.

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



## 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 user is logged in as a RESEARCHER. The main content area is titled "Predicting Treatment Response to combination drugs in patients with type 2 diabetes". The left sidebar has a "Studies" tab highlighted with a red box. The main content area is divided into sections: "REQUESTED STUDIES" (with a help icon and download icon), "VIVLI-LISTED AND PROVISIONED STUDIES" (with a list of studies including "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 list of studies including "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 of the main content area, there is a red box highlighting the text "STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI" and an "Add +" button. Below this, it says "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... [Text Input Field]

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

[Large Text Input Area]

5. From the Dropdown menu under **Select provider of the data**, click on **I will bring my own**.

Complete all fields and click **submit**. **Note:** Please include the description of the additional data, the 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 Researcher and Statistician are legally entitled to upload the additional data, e.g., the data is from a study performed by the Lead Statistician or Lead Researcher or is publicly available data that can be used for secondary analysis and that the study being uploaded is anonymized. As part of the Vivli request form, you tick a box acknowledging that you have permission to use that data for your analysis.

## Request Studies, Data, or Tools not listed on Vivli

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

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

Select provider of the data

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

I WILL BRING M...



123456

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

Data collected during my own clinical trial

Submit

Cancel

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

## Request Studies, Data, or Tools not listed on Vivli

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

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

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


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

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

Add Another Study, Data, or Tool

Back

7. The study/data will be referenced on the data request form:



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

QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back

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

Edit Request Title Cancel Save Submit

RESEARCH TEAM

RESEARCH PROPOSAL

**STUDIES**

STATISTICAL ANALYSIS PLAN

FUNDING

OTHER INFORMATION / FILE ATTACHMENTS

ATTESTATIONS

REQUEST HISTORY

CHAT

REQUESTED STUDY TYPES

VIVLI-LISTED AND PROVISIONED STUDIES

Effects of Cystic Fibrosis and Cystic Fibrosis Related Diabetes on Brain Stru... PI: Sponsor: University of Minnesota Study ID: NCT03820349 IRP/Approver: Wellcome Trust Data Request ID: 00002555 Sponsor ID: MED2018-26438 Data Contributor: GlaxoSmithKline IPD Uploaded: Yes	Data already on platform <span>Remove</span> >
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 <span>Remove</span> >

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 <span>Remove</span> x
---	--

## 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's policy that any data, statistical tools, or scripts need 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 [6.1 Adding your own data](#). Under Step 6, type a list of your tools or scripts in the dialogue box under **Provide either the study title or the description of the study** and click **submit**. After your data request is approved, Vivli will facilitate the upload process for your own data and scripts into your research environment.

### Request Studies, Data, or Tools not listed on Vivli

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

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

<input type="text" value="I WILL BRING M..."/>	<input type="text" value="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



## 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 Researcher, 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 website interface for a data request titled 'Predicting Treatment Response to combination drugs in patients with type 2 diabetes'. The 'Attestations' section is highlighted with a red box and contains the following text:

**Certify Complete and Accurate**

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

I certify the information provided is complete and accurate.

**Data Use Agreement**


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

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

If you have any questions regarding the DUA, please contact a Vivli admin at [support@vivli.org](mailto:support@vivli.org).

- 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 tabs on the left: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, and Chat. The main content area contains sections for "Certify Complete and Accurate" (with a checked checkbox), "Data Use Agreement" (with explanatory text and a link), and a "Submit" button in the top right corner, which is highlighted with a red box. Other buttons for "Cancel" and "Save" are also visible.

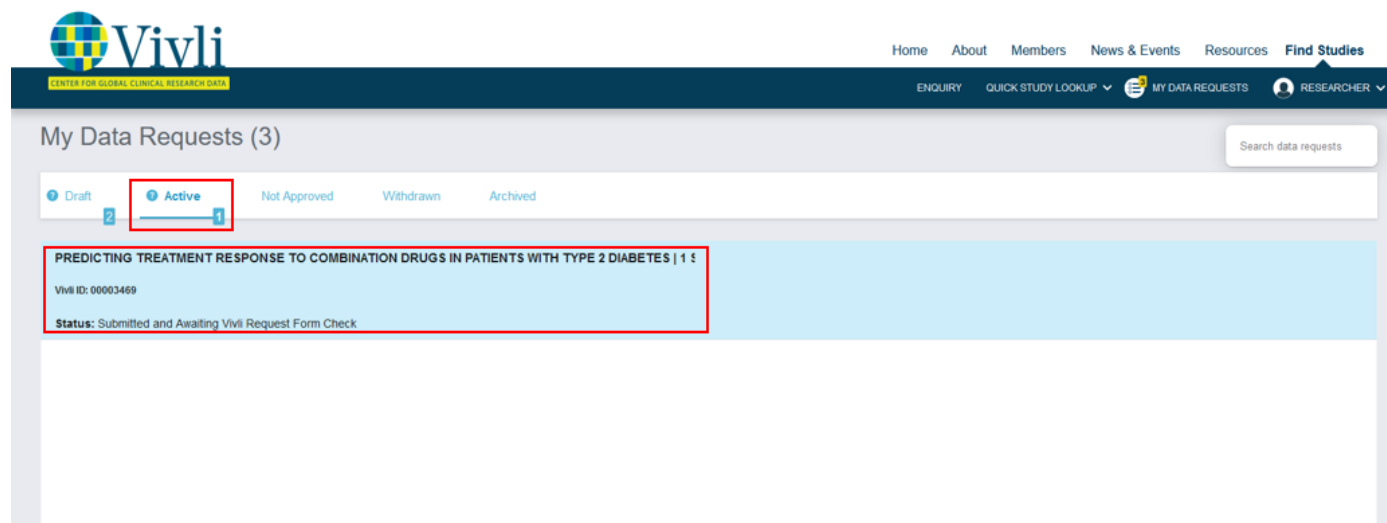
- If the Submit button is still light blue  and does not respond to a click, you have a required field that is not completed. You can look in each of the tabs on the left for a field outlined in red which indicates that a required field needs to be completed. Be sure to review the Research Proposal tab, 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. The "Submit" button in the top right corner is highlighted with a red box, indicating it is ready to be clicked. The form content, including the certification checkbox and the Data Use Agreement section, remains the same.



## 7.1 Data Request Status

Once you click submit, the data request will now appear under **Active** in your data request status bar:



The screenshot shows the Vivli website interface. At the top, there is a navigation bar with links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a dark blue header with 'ENQUIRY', 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'RESEARCHER'. The main content area is titled 'My Data Requests (3)' and features a status bar with five tabs: Draft (2), Active (1), Not Approved, Withdrawn, and Archived. The 'Active' tab is highlighted with a red box. Below the status bar, a data request card is visible with the title 'PREDICTING TREATMENT RESPONSE TO COMBINATION DRUGS IN PATIENTS WITH TYPE 2 DIABETES | 1', Vivli ID: 00003469, and Status: Submitted and Awaiting Vivli Request Form Check. A search bar for data requests is located in the top right corner.

The status bar contains 5 sections:

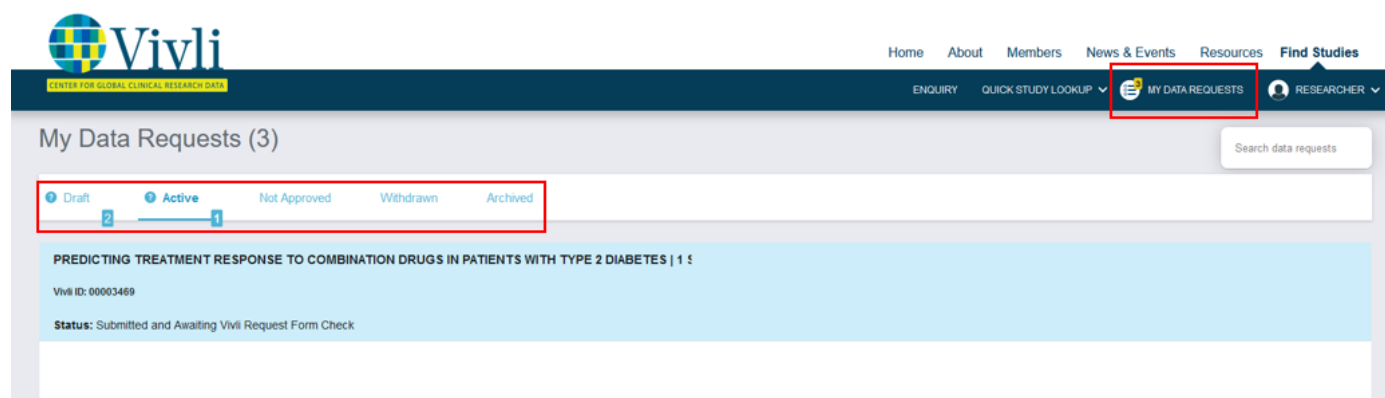
**Draft:** Displays data requests that are being drafted but not yet submitted and hence don't have a Vivli ID.

**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 not approved. 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



This screenshot is identical to the one above, showing the Vivli website interface with the 'Active' status bar highlighted. The layout, navigation, and data request card details are the same as in the previous image.

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.

- Account not found – 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](#)

< Go Back    **Request:** 48130    **Title:** Cardiovascular events in subjects with diabetes  
**Status:** Submitted and Awaiting Vivli Request Form Check

Studios	RESEARCHERS							
Attachments	Name	Affiliation	Country	Email	Role(s)	Status Details		
Request History	Richard Wilson	xx	Algeria	xx@s.com	<ul style="list-style-type: none"> <li>Lead Researcher</li> <li>Statistician</li> </ul>	<ul style="list-style-type: none"> <li>Account Not Found</li> <li>Access to Data Pending</li> <li>Access to Data Request Not Applicable</li> <li>Data Access Training Not Completed</li> </ul>		
Signed Agreements	Emily Wilson	xx	Angola	daterequester.vivli@gmail.com	<ul style="list-style-type: none"> <li>Admin</li> <li>Requester</li> </ul>	<ul style="list-style-type: none"> <li>Account Enabled</li> <li>Access to Data Request Granted</li> <li>Access to Data Pending</li> <li>Data Access Training Completed</li> </ul>		
Chat	Henry Anderson	xx	Panama	nsrinivas@vivli.org	<ul style="list-style-type: none"> <li>Additional Researcher</li> </ul>	<ul style="list-style-type: none"> <li>Account Disabled</li> <li>Access to Data Request Denied</li> <li>Access to Data Request Granted</li> <li>Access to Data Pending</li> <li>Data Access Training Not Completed</li> </ul>		
Research Team	Karen Asada	N/A		abaskaran08@gmail.com	<ul style="list-style-type: none"> <li>Additional Researcher</li> </ul>	<ul style="list-style-type: none"> <li>Account Enabled</li> <li>Access to Data Request Granted</li> <li>Access to Data Pending</li> <li>Data Access Training Not Completed</li> </ul>		
Request Details/Print View								

## 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, the Vivli team can make changes on your behalf.

**PLEASE NOTE:** According to Vivli policy, any changes to the Lead Researcher’s affiliation (to a commercial entity), Lead Statistician’s affiliation (to a commercial entity), their conflict of interest, , or 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.

Changes to a Lead Researcher or Statistician’s affiliation (to an academic institution), adding or removing studies, and personnel changes are considered minor changes.



#### 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:

The screenshot shows the 'My Data Requests (3)' page. At the top, there are navigation links: Home, About, Members, News & Events, Resources, and Find Studies. Below these are utility links: ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and RESEARCHER. The main content area has a search bar for 'Search data requests'. Below the search bar are tabs for 'Draft' (with a '2'), 'Active' (with a '1' and highlighted by a red box), 'Not Approved', 'Withdrawn', and 'Archived'. Under the 'Active' tab, a request is displayed with the title 'PREDICTING TREATMENT RESPONSE TO COMBINATION DRUGS IN PATIENTS WITH TYPE 2 DIAE', 'Vivli ID: 00003469', and 'Status: Draft' (highlighted by a red box). A 'Cancel' button is also visible.

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

The screenshot shows the 'Request History' page for a specific request. The page title is 'Request: 48130, Title: Cardiovascular events in subjects with diabetes' and the status is 'Submitted and Awaiting Vivli Request Form Check'. On the left, there is a sidebar with navigation options: Studies, Attachments, Request History (highlighted with a red box), Signed Agreements, Chat, Research Team, and Request Details/Print View. The main content area features a table with the following columns: Date and Time, Action, Performed By, and Comments. The table contains several rows of history. An 'Export History' button is highlighted with a red box in the top right corner.

Date and Time	Action	Performed By	Comments
10/5/24 4:11 am	Status changed to Submitted To Vivli	Karen Asada	Submitted by Karen Asada
11/6/24 7:20 pm	Status changed to Updated Admin (DUA) approval status for research team member nsrinivas@vivli.org to NeedsApproval	Amrutha Baskaran	
11/6/24 7:20 pm	Team member nsrinivas@vivli.org has been added to Research Environment Access. The team member does not yet have DUA approval status.	Amrutha Baskaran	
13/6/24 4:58 pm	Status changed to Updated Admin (DUA) approval status for research team member datarequester.vivli@gmail.com to NotApplicable	Amrutha Baskaran	
13/6/24 4:58 pm	Status changed to Updated Admin (DUA) approval status for research team member datarequester.vivli@gmail.com to NeedsApproval	Amrutha Baskaran	
13/6/24 4:58 pm	Team member datarequester.vivli@gmail.com has been added to Research Environment Access. The team member does not yet have DUA approval status.	Amrutha Baskaran	
13/6/24 4:58 pm	Changed Admin from Karen Asada (email: abaskaran06@gmail.com) to Emily Wilson (email datarequester.vivli@gmail.com).	Amrutha Baskaran	

You can review, filter and export 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 belong in other fields:

The screenshot shows the Vivli web application interface. At the top, there is a navigation bar with the Vivli logo and the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. The main navigation menu includes links for Home, About, Members, News & Events, Resources, Portals, and Find Studies. Below this, there are links for ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and RICHARD ANDERSON. The main content area is titled 'Request: 0, Title: Predicting cardiovascular outcomes for patients with type 2 diabetes' and 'Status: Draft'. On the left, there is a sidebar menu with options like 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 has a section for 'Other Information' and a section for 'File Attachments'. A warning message is displayed: 'WARNING: If you navigate away from this page when a file upload is underway (i.e. clicking on another tab or closing the browser), all ongoing uploads will be canceled.' Below the warning is a 'Select Files' button and a table of file attachments. The table has columns for File Name, Size, Uploaded By, and File Type. One file is listed: 'Data Dictionary.pdf', 17.84kB, uploaded by Richard Anderson, with a File Type of Unknown.

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](mailto: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](mailto:support@vivli.org) and provide your reasons for withdrawal.

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

- When the request has been submitted and returned to Drafts for revision (and)
- Has not been revised, resubmitted, or progressed to the next stage of review (and)
- No response has been 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](mailto:support@vivli.org) anytime to move the request back from withdrawn to drafts.

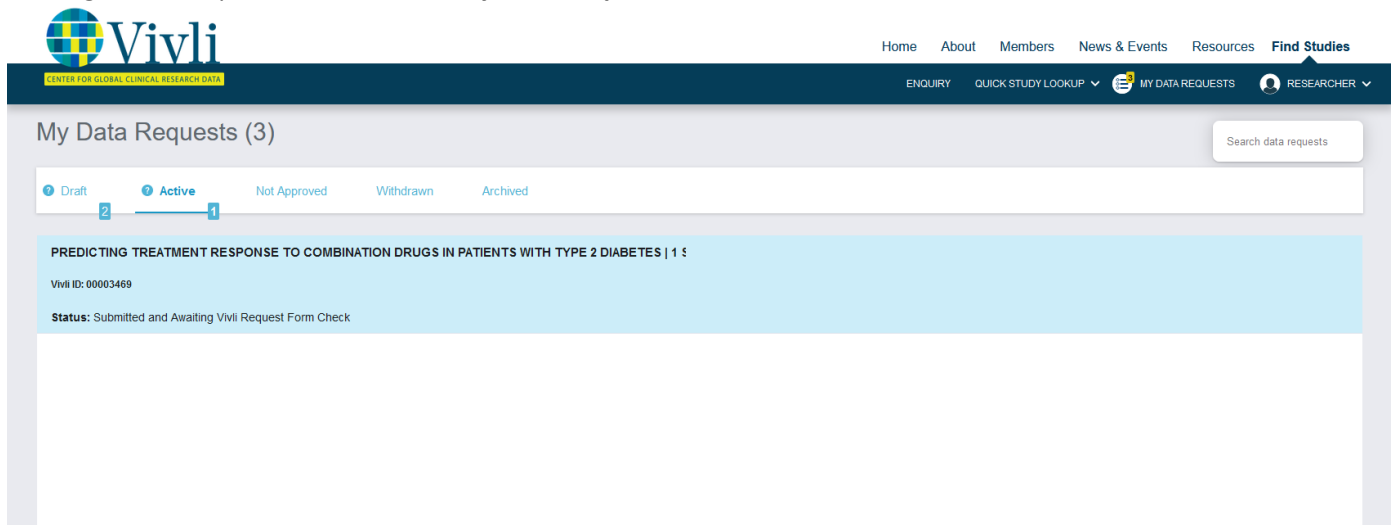
## 9.0 Communications

### 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.

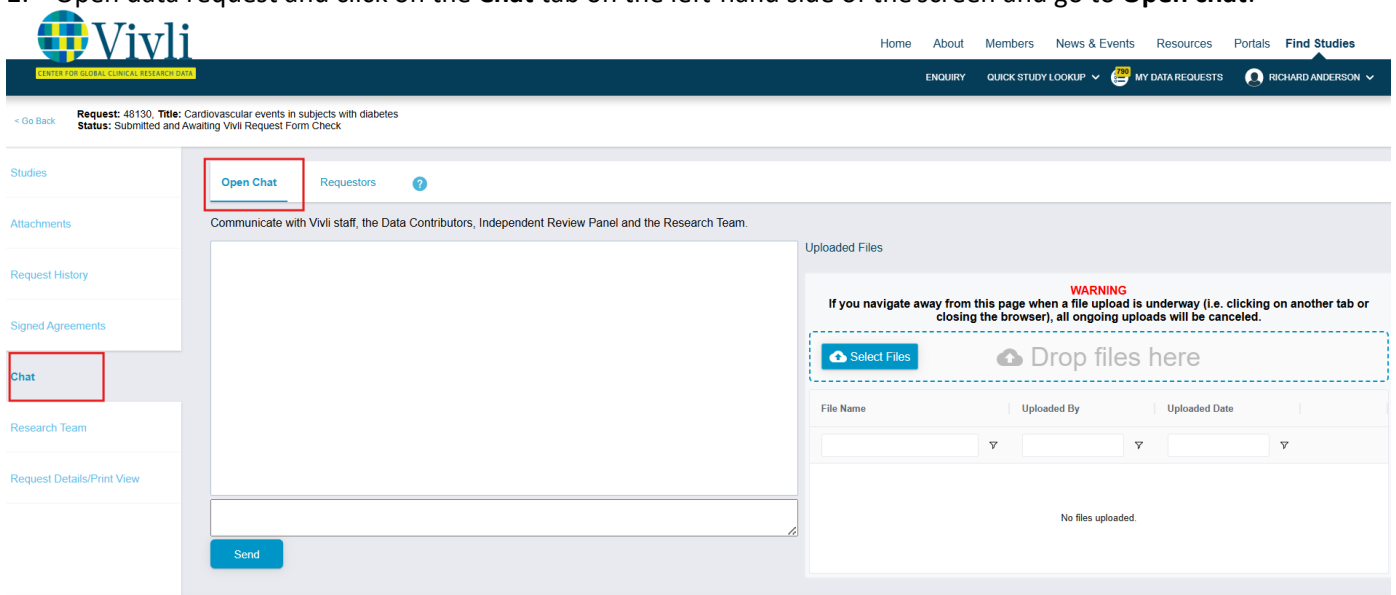
### 9.2 Steps for creating a chat message

1. Log on to the platform and Go to **My Data Requests** tab:



The screenshot shows the Vivli website's 'My Data Requests' page. The header includes the Vivli logo and navigation links: Home, About, Members, News & Events, Resources, Find Studies, ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and RESEARCHER. The main content area is titled 'My Data Requests (3)' and features a search bar and filter tabs: Draft (2), Active (1), Not Approved, Withdrawn, and Archived. The 'Active' tab is selected, displaying a request card for 'PREDICTING TREATMENT RESPONSE TO COMBINATION DRUGS IN PATIENTS WITH TYPE 2 DIABETES | 1'. The request ID is 00003469 and the status is 'Submitted and Awaiting Vivli Request Form Check'.

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



The screenshot shows the 'Open Chat' interface within a data request. The header includes the Vivli logo and navigation links: Home, About, Members, News & Events, Resources, Portals, Find Studies, ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and RICHARD ANDERSON. The main content area is titled 'Request: 48130, Title: Cardiovascular events in subjects with diabetes' and 'Status: Submitted and Awaiting Vivli Request Form Check'. The left sidebar contains navigation links: Studies, Attachments, Request History, Signed Agreements, Chat (highlighted with a red box), Research Team, and Request Details/Print View. The chat window is titled 'Open Chat' and contains the text 'Communicate with Vivli staff, the Data Contributors, Independent Review Panel and the Research Team.' The chat window has a text input field and a 'Send' button. To the right of the chat window is a file upload section with a 'Select Files' button, a 'Drop files here' area, and a table for uploaded files. A warning message states: 'WARNING: If you navigate away from this page when a file upload is underway (i.e. clicking on another tab or closing the browser), all ongoing uploads will be canceled.'

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

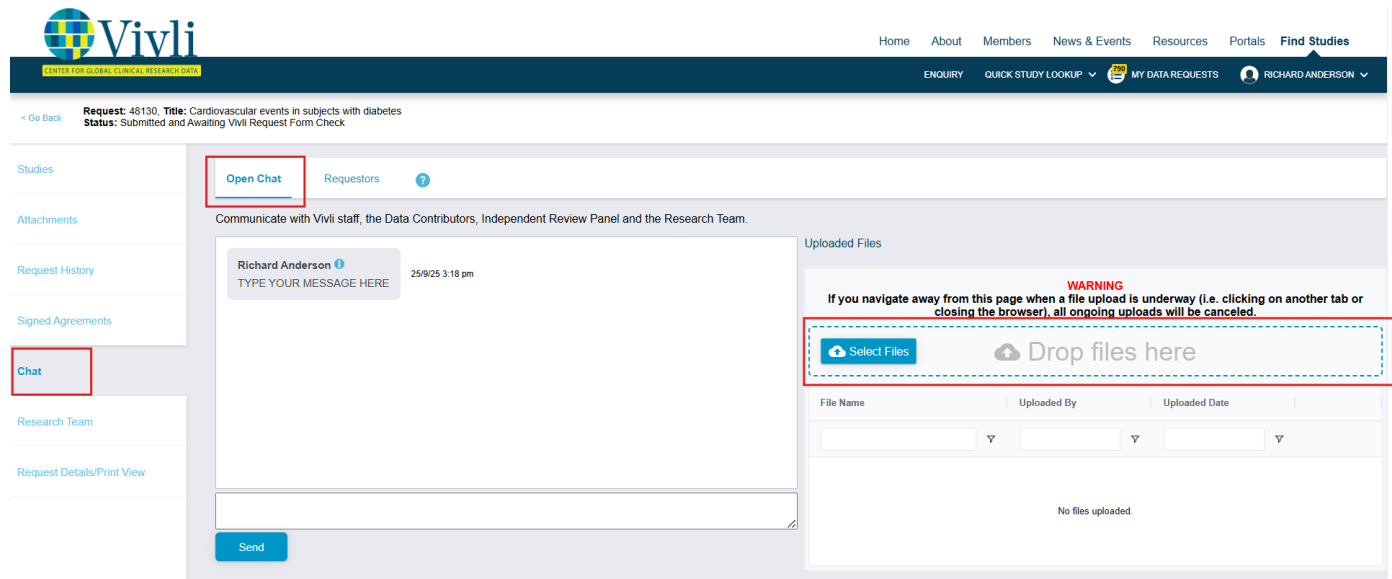
The screenshot shows the Vivli web application interface. At the top, there is a navigation bar with the Vivli logo and the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. The main navigation menu includes 'Home', 'About', 'Members', 'News & Events', 'Resources', 'Portals', and 'Find Studies'. Below this, there are links for 'ENQUIRY', 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'RICHARD ANDERSON'. The main content area displays a chat window for a specific request (Request: 48130, Title: Cardiovascular events in subjects with diabetes, Status: Submitted and Awaiting Vivli Request Form Check). The chat window has a sidebar with options: 'Studies', 'Attachments', 'Request History', 'Signed Agreements', 'Chat' (highlighted with a red box), 'Research Team', and 'Request Details/Print View'. The chat area itself has an 'Open Chat' button (highlighted with a red box) and a 'Requestors' section with a question mark icon. Below this is a text input field with the placeholder 'TYPE YOUR MESSAGE HERE' and a 'Send' button (highlighted with a red box). To the right of the chat area is a file upload section titled 'Uploaded Files'. It contains a warning message: 'WARNING: If you navigate away from this page when a file upload is underway (i.e. clicking on another tab or closing the browser), all ongoing uploads will be canceled.' Below the warning is a 'Select Files' button and a 'Drop files here' area. There is also a table with columns for 'File Name', 'Uploaded By', and 'Uploaded Date', and a 'No files uploaded.' message.

- 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 the response will also appear in the chat record:

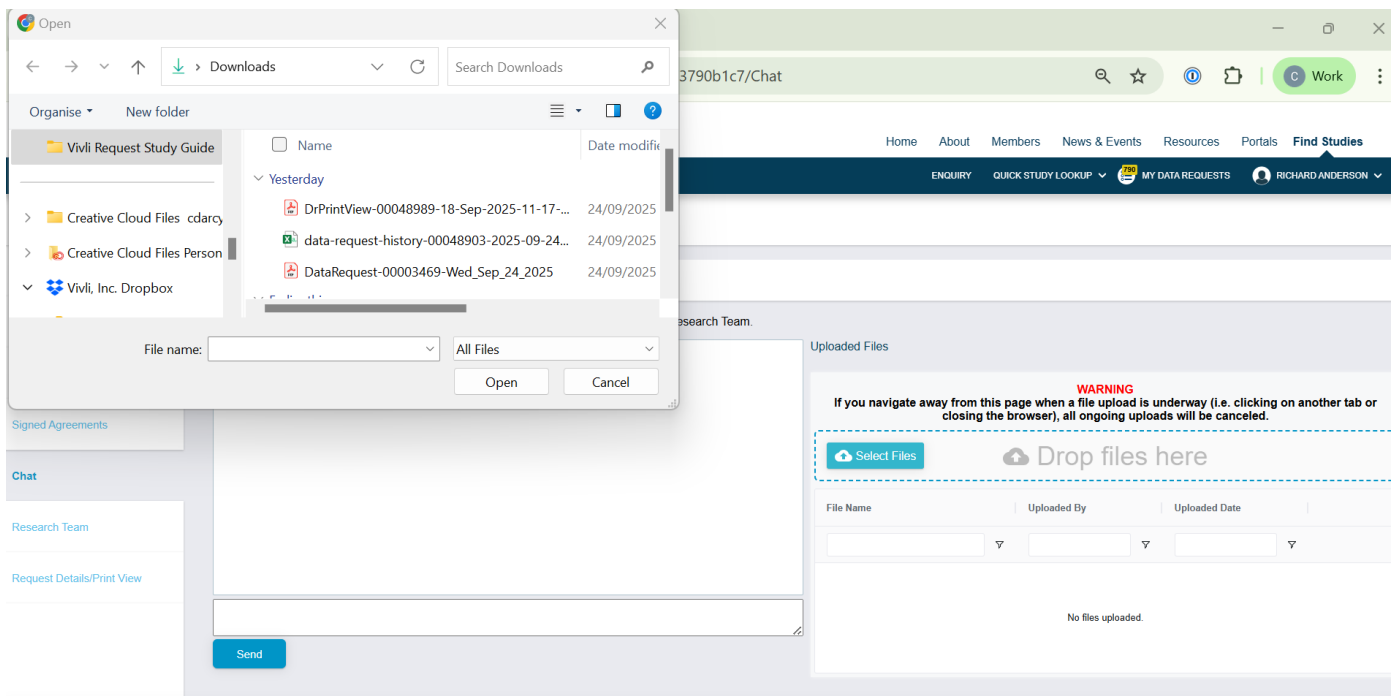
This screenshot shows the same Vivli chat interface as the previous one, but now a chat message has been sent. The 'Open Chat' button is still highlighted with a red box. In the chat area, a message from 'Richard Anderson' is visible, with the text 'TYPE YOUR MESSAGE HERE' and a timestamp of '25/9/25 3:18 pm'. The message is highlighted with a red box. The rest of the interface, including the sidebar, navigation bar, and file upload section, remains the same as in the previous screenshot.

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





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



7. **Note:** Individual participant data (IPD) **should NOT** be uploaded in this section

8. The following window may appear to confirm that IPD files are not uploaded in this section

The files section of Chat is not to be used for loading Individual Participant Data or for screenshots of the research environment. If you need to upload data containing Individual Participant Data, please contact Vivli at [support@vivli.org](mailto:support@vivli.org) and we can help you with other ways to load the data.

If the file you just asked to load contains Individual Participant Data, please click the Cancel button below. If the file does not contain Individual Participant Data, check "This is not IPD, load this data" and click on OK.

This is not IPD, load this data

Ok

Cancel

9. Check the checkbox to confirm that the files are not IPD and then click OK.

The files section of Chat is not to be used for loading Individual Participant Data or for screenshots of the research environment. If you need to upload data containing Individual Participant Data, please contact Vivli at [support@vivli.org](mailto:support@vivli.org) and we can help you with other ways to load the data.

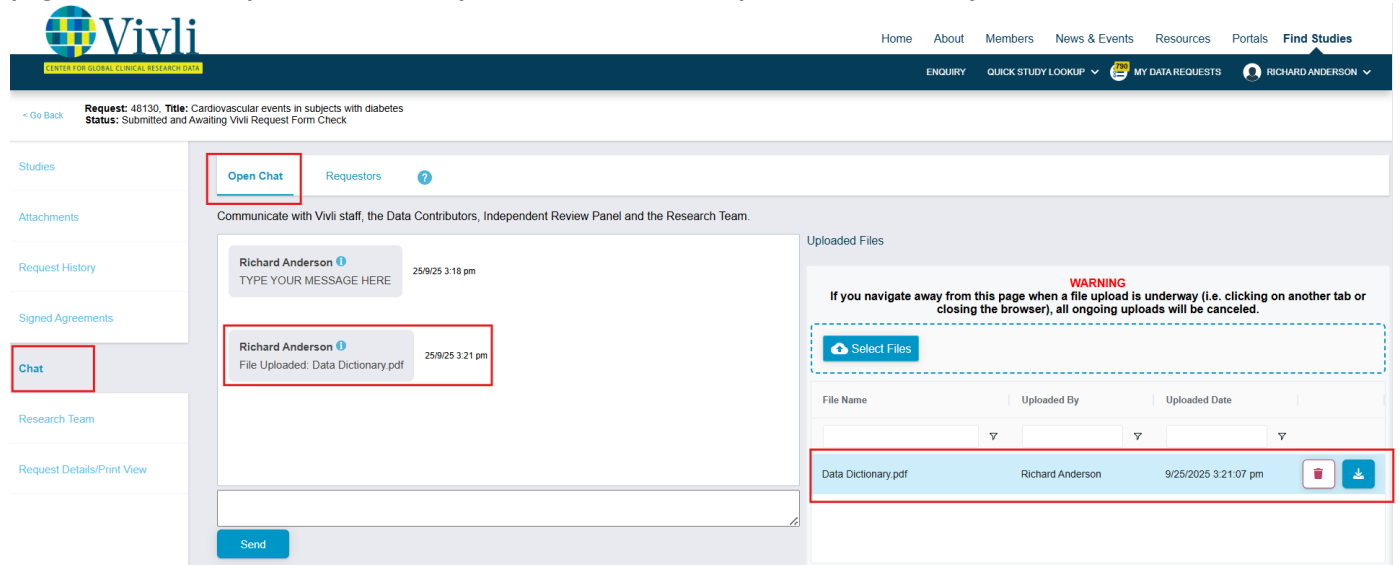
If the file you just asked to load contains Individual Participant Data, please click the Cancel button below. If the file does not contain Individual Participant Data, check "This is not IPD, load this data" and click on OK.

This is not IPD, load this data

Ok

Cancel

10. The uploaded file will appear in the file list on the right, and in the chat history. **If you navigate away from a page on which an upload is underway, that will cancel the upload automatically:**



Request: 48130, Title: Cardiovascular events in subjects with diabetes  
Status: Submitted and Awaiting Vivli Request Form Check

Home About Members News & Events Resources Portals Find Studies  
ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RICHARD ANDERSON

< Go Back

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

Open Chat Requestors

Communicate with Vivli staff, the Data Contributors, Independent Review Panel and the Research Team.

Richard Anderson 25/9/25 3:18 pm  
TYPE YOUR MESSAGE HERE

Richard Anderson 25/9/25 3:21 pm  
File Uploaded: Data Dictionary.pdf

Send

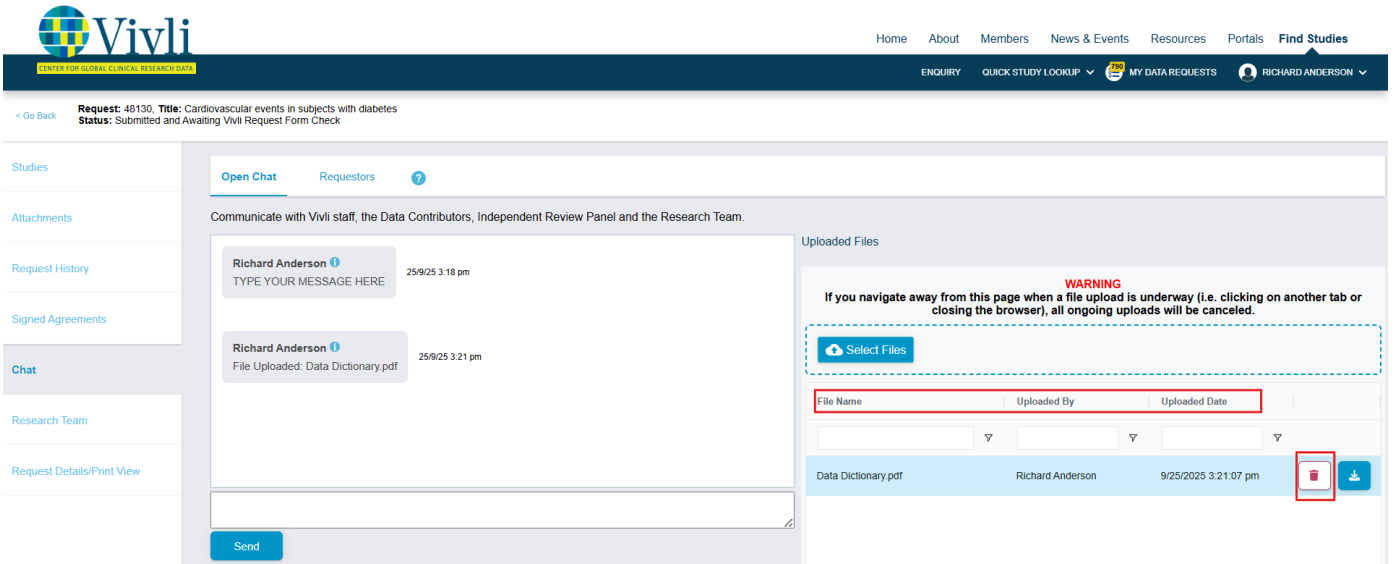
Uploaded Files

**WARNING**  
If you navigate away from this page when a file upload is underway (i.e. clicking on another tab or closing the browser), all ongoing uploads will be canceled.

Select Files

File Name	Uploaded By	Uploaded Date
Data Dictionary.pdf	Richard Anderson	9/25/2025 3:21:07 pm

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



Request: 48130, Title: Cardiovascular events in subjects with diabetes  
Status: Submitted and Awaiting Vivli Request Form Check

Home About Members News & Events Resources Portals Find Studies  
ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RICHARD ANDERSON

< Go Back

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

Open Chat Requestors

Communicate with Vivli staff, the Data Contributors, Independent Review Panel and the Research Team.

Richard Anderson 25/9/25 3:18 pm  
TYPE YOUR MESSAGE HERE

Richard Anderson 25/9/25 3:21 pm  
File Uploaded: Data Dictionary.pdf

Send

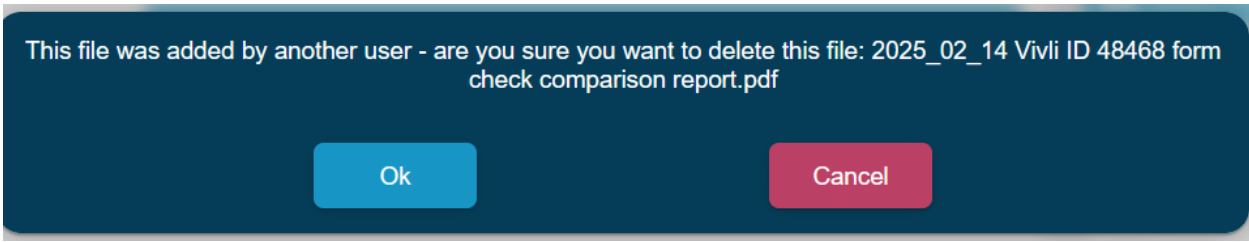
Uploaded Files

**WARNING**  
If you navigate away from this page when a file upload is underway (i.e. clicking on another tab or closing the browser), all ongoing uploads will be canceled.

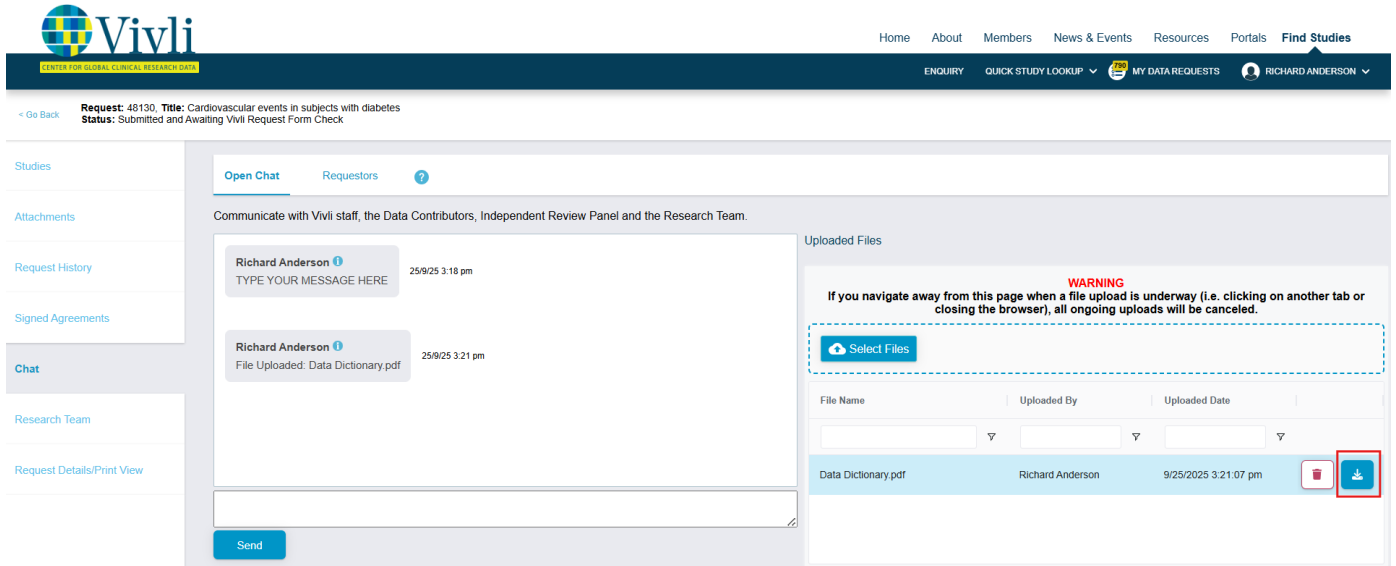
Select Files

File Name	Uploaded By	Uploaded Date
Data Dictionary.pdf	Richard Anderson	9/25/2025 3:21:07 pm

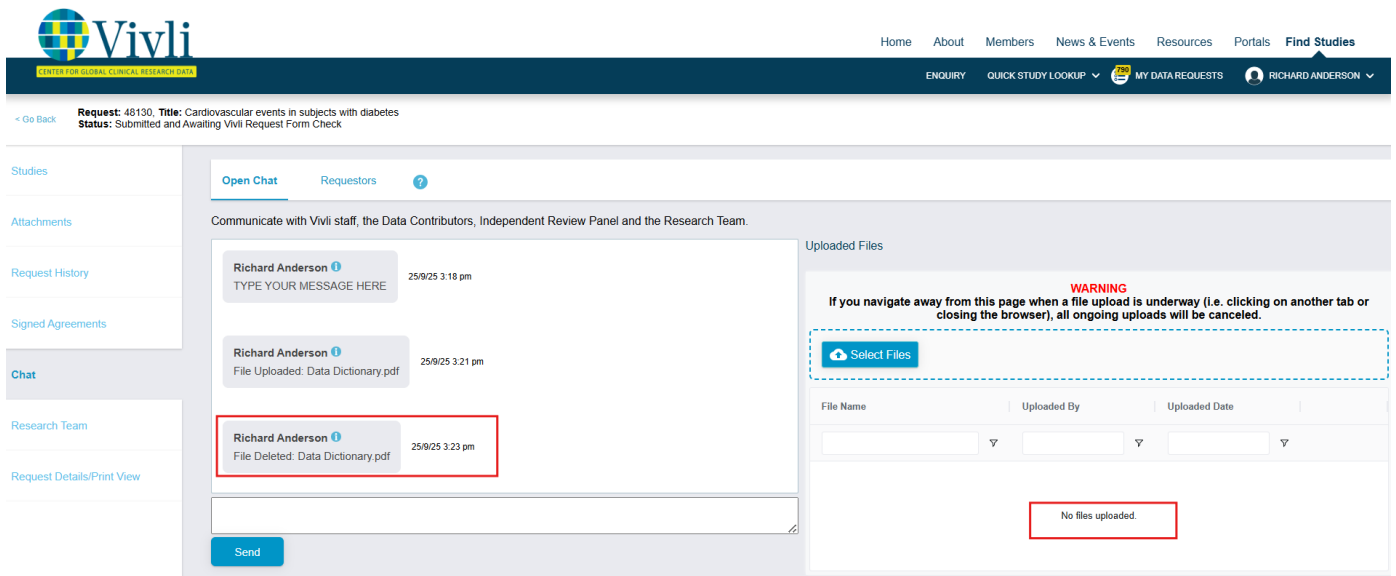
12. You will see a confirmation box asking you to confirm if you intended to delete the file "This file was added by another user - are you sure you want to delete this file: <filename>". Click Ok if you want to proceed to delete the file or Click Cancel if you do not want to proceed.



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



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



15. Chats are posted when you click “Send” which permits you to write and read distinct paragraphs

16. Chat messages automatically scroll to the most recent post.

17. In chat, files are sorted by date, newest on top, and the hover text displays the filename, date uploaded, and How-To: Requesting Studies on Vivli

person who uploaded it.

18. Posted chat messages are visible immediately.

### 9.3 Emails from Platform

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

Email	When sent	Purpose
<b>Status Change, data Request passed Vivli form check</b>	When your data request passes the Vivli form check for completeness	Notify you when the review process has commenced. The email lists the next steps in the data request review process
<b>Status Change, data Request - Revision requested or Request not approved</b>	When your data request changes status to Revision or Not approved. If you have requested studies from multiple contributors, you will receive a notification after all the Data Contributors have recorded their decision.	Notify you of any changes in the status to your data requests.
<b>Request Final Approval</b>	When your data request is approved, by a delegated approver/IRP. If you have requested studies from multiple contributors, you will receive a notification after final approval.	Notify you of final approval.
<b>DUA Approved</b>	When the Vivli Admin has validated the DUA associated with the data request.	Notify you of the executed DUA.
<b>Data Uploaded</b>	When requested Study Data Package from the 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 the data upload status to plan your analysis.
<b>Research Environment was provisioned.</b>	When you start the research environment.	Notify you when the Research Environment is ready to be used for analysis.
<b>Request for results decision</b>	When your request to export results is approved or/not approved.	Notify the status of the results export.
<b>Data Request Archived</b>	When the data request is Archived, the project is considered closed.	Notify that the lead researcher and research team have met the DUA obligations for public disclosure/summary of results and the data request is now

		archived.
<b>Chat</b>	When anyone associated with a data request enters a message in chat. This includes chat messages from Open chat and Requester chat	Facilitate communication and the data request workflow
<b>Enquiry</b>	When anyone associated with a data request enters a comment or makes a decision	Facilitate communication and the Enquiry workflow.
<b>Public Disclosure submitted</b>	When a disclosure is submitted, an email is sent to notify the team that the 30-day review period has began.	Notify the research team that the disclosure was received and the 30-day review period has begun
<b>Public Disclosure re-set to “Drafts”</b>	When a public disclosure is re-set to the “Drafts” stage.	Notify the research team that the public disclosure has been re-set to drafts by the Vivli team so that the researcher can modify the form
<b>Public Disclosure 30-day review complete</b>	When a disclosure reaches the end of the review stage (once all data contributors have completed review or the 30-day period is complete) .	Notify the research team that the 30-day review is complete and the publication may be submitted to a learned forum.

Note: Only users with active Vivli accounts and who are activated in the data request will receive automated emails. [See 3.4, Adding Research Team Members](#), for instructions on adding research team members to a data request and activating members for a data request.

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

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

The Data Usage Agreement (DUA) has been signed and is available for download below. If more than one DUA version was uploaded, the latest is the signed and validated version.

**WARNING**  
If you navigate away from this page when a file upload is underway (i.e. clicking on another tab or closing the browser), all ongoing uploads will be canceled.

Select Files

Drop files here

File Name	Size	Uploaded By	Uploaded Date
Vivli_DUA Signed-demo purposes.pdf	2.24MB	Amrutha Baskaran	8/5/2022 9:53:35 pm

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**

Request: 2545, Title: Assessing the impact of lifestyle choices on heart health  
Status: All Data Packages Provided and Available

Export History

Date and Time	Action	Performed By	Comments
17/9/21 12:40 pm	Status changed to Submitted To Vivli	Data Requester	Submitted by Data Requester
17/9/21 12:40 pm	Status changed to Awaiting IRP/Approver approval	Stan Neumann	
17/9/21 12:41 pm	Status changed to Data Request: "Assessing the impact of lifestyle choices on heart health" with Id c91b7e99-5ddf-481d-b7a2-e5be88b37a6b, approved by IRP/Approver.	Stan Neumann	
17/9/21 12:41 pm	Status changed to Approved The last Approval was the final Approval required, so the request status is changed to Approved.	Stan Neumann	
17/9/21 12:41 pm	Status changed to Awaiting DUA Validation	Stan Neumann	Begin DUA Validation
17/9/21 12:41 pm	Status changed to Data Use Agreement (DUA) Validated by Vivli Admin	Stan Neumann	
17/9/21 12:41 pm	Status changed to Data Package Provided for study with Id a89e1fef-ae82-4114-93ce-aa0ab96f02c	Stan Neumann	Data package was copied from existing Study IPD
17/9/21 12:41 pm	Status changed to Fulfilled	Stan Neumann	All requested Study IPD now exists.
17/9/21 12:41 pm	Updated Admin approval status for team member Datarequester vivli@gmail.com to Approved	Stan Neumann	
17/9/21 1:05 pm	Research environment infrastructure has been created	Data Requester	

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 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.

- Access to Data Pending – A research team member doesn’t have DUA approval to proceed with analysis, or they haven’t completed data access training. 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.
- Access to Data Granted – A research team member has a valid DUA and has completed data access training so can proceed with analysis. They can access the data.
- Access to Data Denied – A research team member doesn’t have DUA approval to proceed with analysis, or hasn’t completed data access training. 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.

Name	Affiliation	Country	Email	Role(s)	Status Details
Andrea Johnson	xx	Mayotte	abaskaran08@gmail.com	Lead Researcher	<ul style="list-style-type: none"> <li>Account Enabled</li> <li>Access to Data Request Granted</li> <li>Access to Data Granted</li> <li>Data Access Training Not Completed</li> </ul>
John Hopkins	N/A	Afghanistan	Datarequester.vivli@gmail.com	Admin, Requester	<ul style="list-style-type: none"> <li>Account Enabled</li> <li>Access to Data Request Granted for Admin</li> <li>Access to Data Granted</li> <li>Data Access Training Completed</li> </ul>
Vijay Rajan	zz	Antigua and Barbuda	praveen.gji@gmail.com	Statistician	<ul style="list-style-type: none"> <li>Account Not Found</li> <li>Access to Data Denied</li> <li>Access to Data Request Not Applicable</li> <li>Data Access Training Not Completed</li> </ul>
Richard Anderson	xx	Antarctica	amru.idly@gmail.com	Additional Researcher	<ul style="list-style-type: none"> <li>Account Enabled</li> <li>Access to Data Request Granted</li> <li>Access to Data Pending</li> <li>Data Access Training Completed</li> </ul>

## 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 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 Safety Concerns

The safety concern tab is available so that you can alert the contributor of one or more of the studies you are analyzing to the possibility of a safety concern with the treatment that was studied. Accordingly, submitting a safety concern generates an urgent alert to the contributors of data for your analysis.

To submit a safety concern, select the “Safety Concerns” tab of your data request dashboard and complete required fields.

< Go Back **Request:** 48010, **Title:** Stroke Outcomes in patients with Atrial Fibrillation  
**Status:** At least one Data Package Provided and Available

Studies  
Attachments  
Request History  
Signed Agreements  
**Safety Concerns**  
Chat  
Research Team  
Research Environment  
Public Disclosures  
All Citations  
Request Details/Print View

**Supply your contact information and safety concern description below, then click 'Submit Safety Concern' to continue.**

Name  
Richard Anderson

Email Address  
Datarequester.vivli@gmail.com

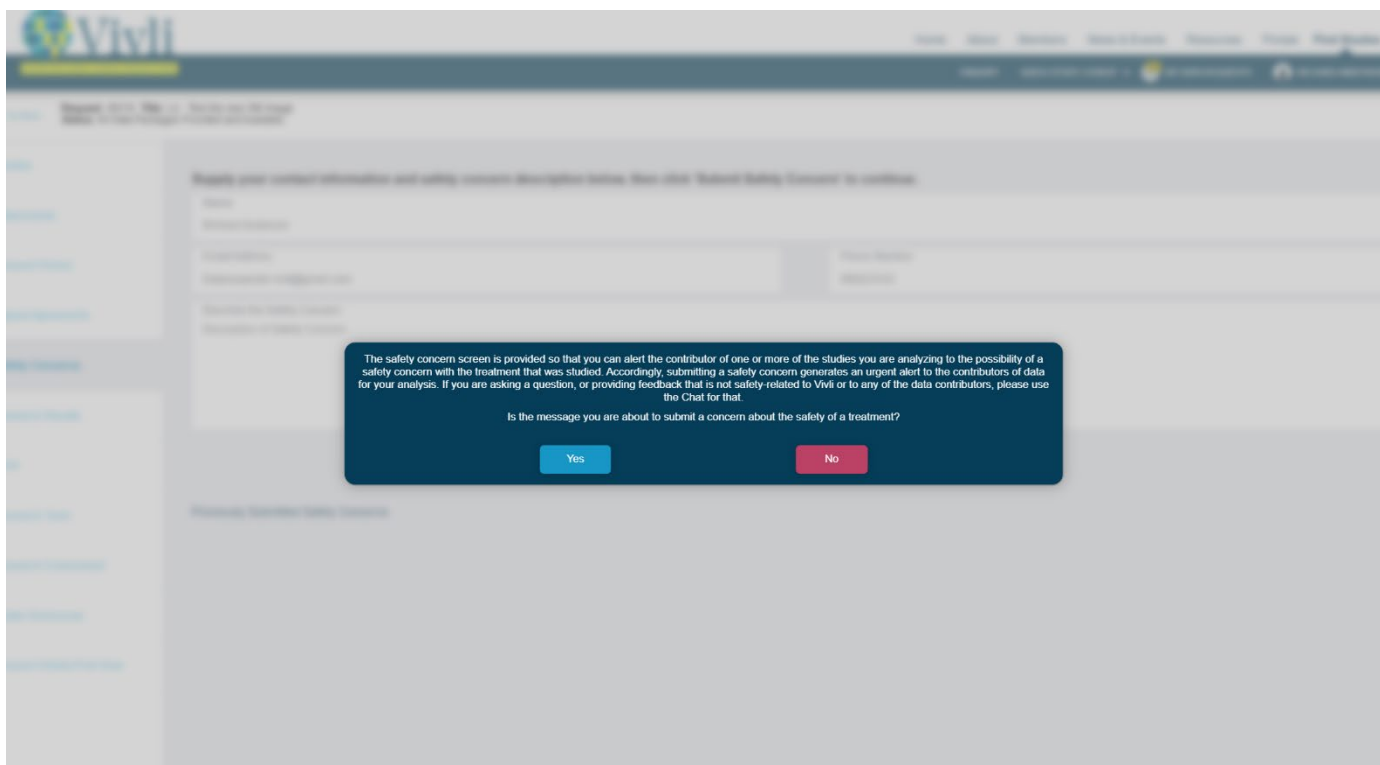
Phone Number

Describe the Safety Concern

Submit Safety Concern

Before pressing “Submit”, a message will appear to confirm that the message you are about to submit is a concern about the safety of a treatment.

- Press “Yes” if you wish to submit the safety concern or press “No” to return to the previous screen.



If you are asking a question, or providing feedback that is not safety-related to Vivli or to any of the data contributors, please use Open Chat for communication. Please see [Section 9.1 Open Chat](#) for more information.

## 14.0 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.

## 15.0 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](#) in the “Public Disclosures” tab.. Please

complete all required fields within the “Public Disclosures” tab and let us know whether you are planning any additional public disclosures for this request via the platform chat. 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 the “Public Disclosures” tab 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.

The screenshot shows the Vivli website interface. At the top, there is a navigation bar with links for Home, About, Members, News & Events, Resources, Portals, and Find Studies. Below this is a dark blue header with 'ENQUIRY', 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and a user profile for 'RICHARD ANDERSON'. The main content area displays a research data request for ID 48506, titled 'Evaluation of Differences in Trial and Non-Trial Patients and Leveraging of External Data for More Efficient Clinical Trial Designs in Newly Diagnosed Glioblastoma'. The status is 'At least one Data Package Provided and Available'. A red box highlights the 'Data Request DOI: https://handle.test.datacite.org/10.70118/AQ00048506'. The 'Research Team' section lists Sarah Jones as the Lead Investigator, with her contact information and qualifications (MD, PhD) listed. A sidebar on the left contains various navigation options, with 'Request Details/Print View' highlighted by a red box.

## 16.0 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 the long-term storage of the analyzed data. The research environment will then be de-provisioned and we will move the data request to the Archived section of the data request.