



How-To: Request Studies on Vivli

Vivli Platform Release 3.6

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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, the Vivli logo is on the left, and navigation links (Home, About, Members, News & Events, Resources, Portals, Find Studies) are on the right. Below the navigation bar, a banner reads "We are committed to advancing the knowledge around the COVID-19 pandemic" with "Share trials" and "Search for trials" buttons. The main search area features a "KEYWORD SEARCH" bar with the placeholder text "What are you looking for today?". To the right of the search bar are "PICO Beta" and "ENQUIRY" links, and a "QUICK STUDY LOOKUP" dropdown menu. Below the search bar, there are four filter panels: "STUDY DESIGN" (Interventional and Observational studies), "SPONSOR INFORMATION" (Funder and Contributor), "LOCATION" (Select Multiple), and "START DATE" (From and To mm/yyyy). The "END DATE" panel is also visible with "From" and "To" mm/yyyy fields. The "SAMPLE SIZE" panel is disabled.

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

The screenshot shows the Vivli website's search interface. At the top, there is a navigation bar with links: 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 icons for information (i) and search (magnifying glass). Below the search bar are several filter categories: STUDY DESIGN (INTERVENTIONAL STUDIES, OBSERVATIONAL STUDIES, STUDY PHASE), SPONSOR INFORMATION (FUNDER, CONTRIBUTOR, SAMPLE SIZE), LOCATION, and START/END DATE. At the bottom of the search results area, a blue bar indicates "86 Studies".

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

The screenshot shows the Vivli website's search results page. At the top, there is a navigation bar with links: Home, About, Members, News & Events, Resources, and Find Studies. Below this is a search bar with the text "What are you looking for today?" and a "CLOSE" button. The main content area displays a list of studies. Each study entry includes a title, ID, condition or disease, and intervention/treatment. To the right of each study entry 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 studies listed are:

- Clinical Assessment of GSK716155 for Type 2 Diabetes Mellitus -A Phase I/II Study to Investigate the Safety, Pharmacokinetics and Pharmacodynamics of GSK716155 in Japanese Subjects With Type 2 Diabetes Mellitus**
IDs: NCT00530309 | GLP107865
Condition or Disease: Diabetes Mellitus, Type 2
Intervention/treatment: GSK716155 for injection, Placebo
Number enrolled: 40
Phase 1
- A Phase I, Randomized, Placebo-Controlled, Crossover Clinical Trial to Assess the Safety of Oral SRT2104 and Its Effects on Vascular Dysfunction in Otherwise Healthy Cigarette Smokers and Subjects With Type 2 Diabetes Mellitus**
IDs: NCT01031108 | 114089
Condition or Disease: Diabetes Mellitus, Type 2
Intervention/treatment: Placebo, SRT2104
Number enrolled: 38
Phase 1
- A Single-Center, Non-Randomized, Open-Label, Comparative Study to Assess the Utility of Novel Technologies and Biomarkers as Methods for Measuring Human Pharmacodynamic Response to 8 Weeks of Administration of Rosiglitazone Maleate 4mg BID in Healthy Normal or Overweight Controls, Healthy Obese Subjects and Subjects With Type 2 Diabetes Mellitus (T2DM)**
Number enrolled: 38
Phase 1

- 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. The header includes the Vivli logo and navigation links: Home, About, Members, News & Events, Resources, and Find Studies. Below the header, the study title is displayed: "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, there are four tabs: Study Details, Study Documents, Administrative Details, and Usage. The Study Details tab is selected. The main content area displays 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
- Actual Enrollment: 40
- Locations: (empty field)

- 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. The header includes the Vivli logo and navigation links: Home, About, Members, News & Events, Resources, Portals, and Find Studies. Below the header, the study title is displayed: "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, there are four tabs: Study Details, Study Documents, Administrative Details, and Usage. The Study Documents tab is selected. The main content area displays the following information:

- UPLOADED FILES: A table with columns: Filename, Size, Uploaded By, and a Download button. The table contains one row: V3DIG Data Dictionary Document..., 118.00kB, Amrutha. The Download button is highlighted with a red box.
- Links to Documents located elsewhere: A section with a link to ClinicalTrials, which is highlighted with a red box.

- 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	

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.

Public Disclosures

Rahman, Rifaquat, Ventz, Steffen, Redd, Robert, Fell, Geoffrey, Tan, Yujue, Onio, 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>

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 THE ONLY PLACE WHERE YOU CAN FIND ALL THE DATA YOU NEED

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP Sign up Log In

diabetes CLOSE

STUDY DESIGN

INTERVENTIONAL STUDIES

Select Multiple

OBSERVATIONAL STUDIES

Select Multiple

STUDY PHASE

Select Multiple

SPONSOR INFORMATION

SPONSOR TYPE

Select Multiple

SPONSOR

Select Multiple

SAMPLE SIZE

(Disabled) ☐

LOCATION

Select Multiple

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

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

Log in to Request Study

View Study Details

Number enrolled: 40
Phase 1

A Phase I, Randomized, Placebo-Controlled, Crossover Clinical Trial to Assess the Safety of Oral SRT2104 and Its Effects on Vascular Dysfunction in Otherwise Healthy Cigarette Smokers and Subjects With Type 2 Diabetes Mellitus

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

1.3 Add studies to your data request

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

The screenshot shows the Vivli website interface. On the left, there are filters for STUDY DESIGN (INTERVENTIONAL STUDIES, OBSERVATIONAL STUDIES), STUDY PHASE, and SPONSOR INFORMATION (SPONSOR TYPE, SPONSOR). The main content area displays three clinical studies, each with a 'Request Study' button highlighted by a red box. The studies are:

- Clinical Assessment of GSK716155 for Type 2 Diabetes Mellitus -A Phase I/II Study to Investigate the Safety, Pharmacokinetics and Pharmacodynamics of GSK716155 in Japanese Subjects With Type 2 Diabetes Mellitus**
IDs: NCT00530309 | GLP107865
Condition or Disease: Diabetes Mellitus, Type 2
Intervention/treatment: GSK716155 for injection, Placebo
Number enrolled: 40
Phase 1
- A Phase I, Randomized, Placebo-Controlled, Crossover Clinical Trial to Assess the Safety of Oral SRT2104 and Its Effects on Vascular Dysfunction in Otherwise Healthy Cigarette Smokers and Subjects With Type 2 Diabetes Mellitus**
IDs: NCT01031108 | 114089
Condition or Disease: Diabetes Mellitus, Type 2
Intervention/treatment: Placebo, SRT2104
Number enrolled: 38
Phase 1
- A Single-Center, Non-Randomized, Open-Label, Comparative Study to Assess the Utility of Novel Technologies and Biomarkers as Methods for Measuring Human Pharmacodynamic Response to 8 Weeks of Administration of Rosiglitazone Maleate 4mg BID in Healthy Normal or Overweight Controls, Healthy Obese Subjects and Subjects With Type 2 Diabetes Mellitus (T2DM)**
Number enrolled: 118
Phase 3

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

The screenshot shows a dropdown menu that appears after clicking the 'Request Study' button. The dropdown contains the option '+ Add New Request', which is highlighted by a red circle. Other options visible include 'Request Study' and 'View Study Details'.

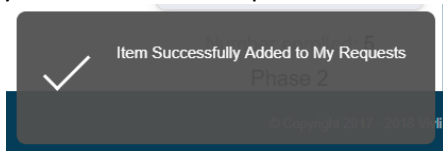
3. A dialogue box will pop up where you can provide the Research Project Name for your research project. **Note:** Your Project name must match the "Title of Proposed Research" within the data request form. This can be edited before submitting the data request for review. After entering a research project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

New Research Data Request

Enter a descriptive name for your research project.

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

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



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

Home About Members News & Events Resources Find Studies

Click here to view your data requests. MY DATA REQUESTS DATA REQUESTER

What are you looking for today? CLOSE

STUDY DESIGN
INTERVENTIONAL STUDIES
Select Multiple

OBSERVATIONAL STUDIES
Select Multiple

STUDY PHASE
Select Multiple

SPONSOR INFORMATION
SPONSOR TYPE
Select Multiple

SPONSOR
Select Multiple

Clinical Assessment of GSK716155 for Type 2 Diabetes Mellitus -A Phase I/II Study to Investigate the Safety, Pharmacokinetics and Pharmacodynamics of GSK716155 in Japanese Subjects With Type 2 Diabetes Mellitus
IDs: NCT00530309 | GLP107865
Condition or Disease: Diabetes Mellitus, Type 2
Intervention/treatment: GSK716155 for injection, Placebo
Request Study View Study Details
Number enrolled:40
Phase 1

A Phase I, Randomized, Placebo-Controlled, Crossover Clinical Trial to Assess the Safety of Oral SRT2104 and Its Effects on Vascular Dysfunction in Otherwise Healthy Cigarette Smokers and Subjects With Type 2 Diabetes Mellitus
IDs: NCT01031108 | 114089
Condition or Disease: Diabetes Mellitus, Type 2
Intervention/treatment: Placebo, SRT2104
Request Study View Study Details
Number enrolled:38
Phase 1

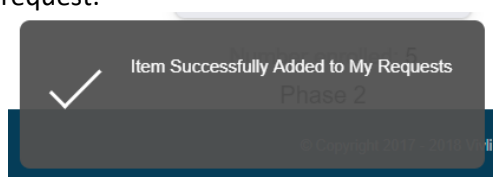
A Single-Center, Non-Randomized, Open-Label, Comparative Study to Assess the Utility of Novel Technologies and Biomarkers as Methods for Measuring Human Pharmacodynamic Response to 8 Weeks of Administration of Rosiglitazone Maleate 4mg BID in Healthy Normal or Overweight Controls, Healthy Obese Subjects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

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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 2.0 Your Data Requests for more information).

1.4 Active Platform Accounts

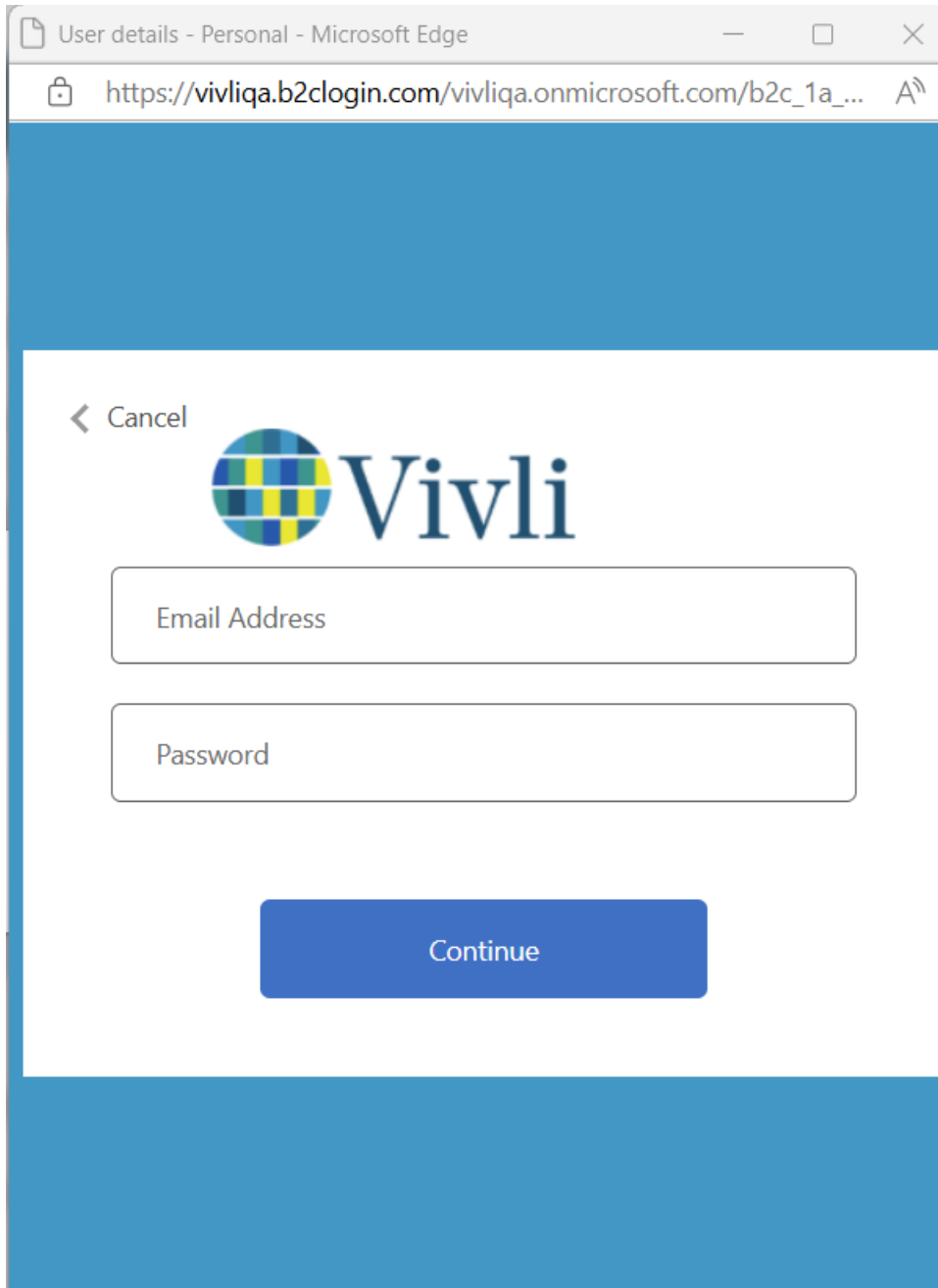
1. As part of Vivli's security policy, for accounts to remain active on the platform, users must log in every six months.
2. If you have not logged in for more than six months, the Vivli team will email you asking that you log in to your account. The Vivli team cannot accept notifications via email to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

1.5 Edit display name in profile

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

The screenshot shows the Vivli platform interface. At the top, the Vivli logo is on the left, and navigation links (Home, About, Members, News & Events, Resources, Portals, Find Studies) are on the right. Below the logo, a yellow banner reads "CENTER FOR GLOBAL CLINICAL RESEARCH DATA". The main header bar contains "ENQUIRY", "QUICK STUDY LOOKUP", and "MY DATA REQUESTS". The user's name "RICHARD ANDERSON" is displayed in the top right corner, with a dropdown menu open below it. The dropdown menu includes options: Search, Dashboard, Submissions, Enquiries, **Edit My Profile** (highlighted with a red box), Change Password, and Log Out. The main content area is titled "Welcome, Richard Anderson!" and "This is your view of Vivli at a glance." It contains several informational paragraphs with corresponding links: "How to request studies", "How-to guides", "Search", "My Data Requests", "Enquiry", "Share Data", and "Contact Support". On the left side, there is a sidebar with "Dashboard", "Submissions", and "Enquiries" links.

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




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

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

User details - Personal - Microsoft Edge

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

< Cancel

 Vivli

Richard Anderson

Continue

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

The screenshot shows the Vivli website dashboard. At the top, the Vivli logo is on the left, and navigation links (Home, About, Members, News & Events, Resources, Portals, Find Studies) are on the right. Below the navigation bar, a dark blue header contains links for ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and a user profile for RICHARD ANDERSON, which is highlighted with a red box. The main content area is titled 'Welcome, Richard Anderson!' and 'This is your view of Vivli at a glance.' It lists several actions with corresponding links: 'How to request studies', 'How-to guides', 'Search', 'My Data Requests', 'Enquiry', 'Share Data', and 'Contact Support'. A sidebar on the left contains links for Dashboard, Submissions, and Enquiries.

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

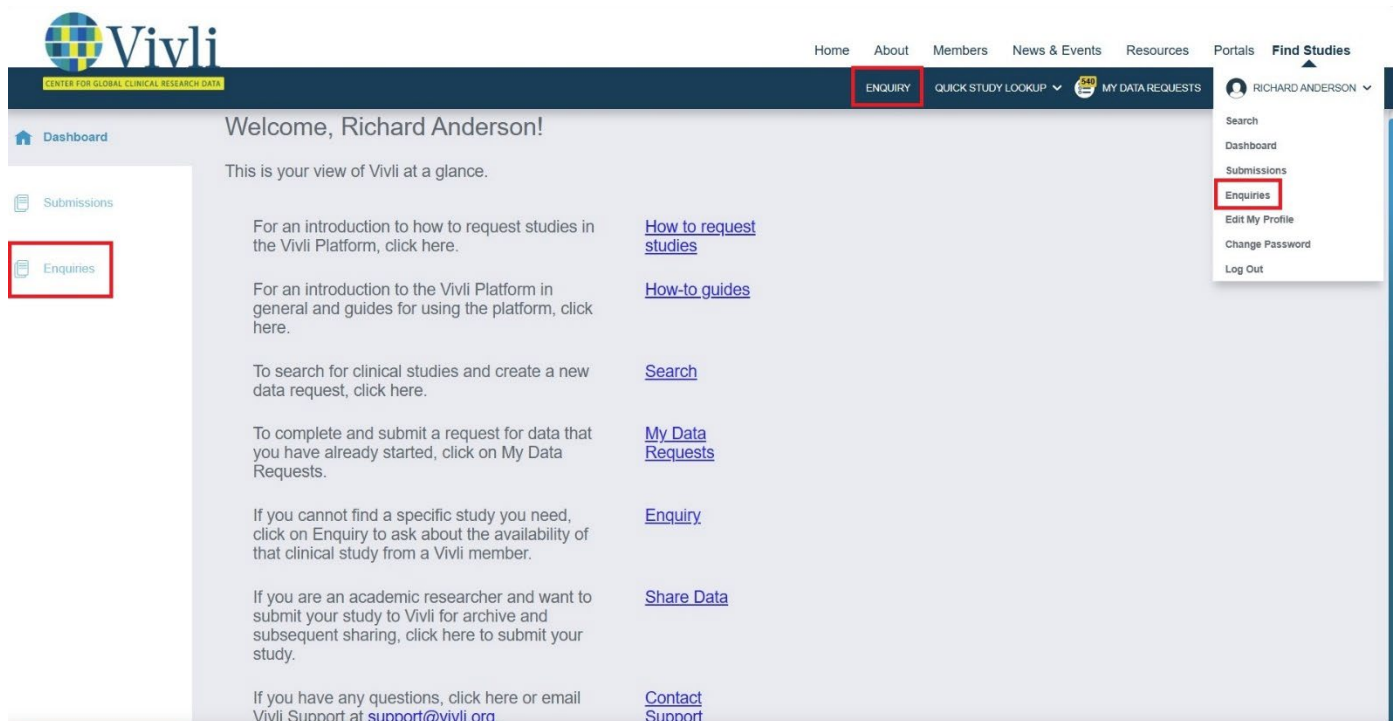
This screenshot is similar to the previous one, showing the Vivli dashboard for Richard Anderson. A red box highlights a section of the dashboard containing links to various resources: 'How to request studies', 'How-to guides', 'Search', 'My Data Requests', 'Enquiry', and 'Share Data'. The sidebar on the left also has a red box around the 'Dashboard' link. The rest of the page layout, including the top navigation and the 'Welcome' message, remains the same.

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.
4. For more information on Vivli Members, please visit the [Member Page](#). Some Vivli Members may require that enquiries be submitted via their own portals. Enquiries will be answered at the discretion of the Member. Please note that most members do not share studies where the primary completion date has not yet been reached.
5. To create an enquiry, you must have a Vivli account. Please see [Section 1.2 Login/Account Setup](#) to create a new account
6. 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.

Enquiries about Vivli Member Studies

Status Bar: Draft (6), Enquiry Validation (5), Review (30), Withdrawn (1), Archived (1)

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

1 to 6 of 6 Page 1 of 1

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 with the 'Enquiries about Vivli Member Studies' section. The top navigation bar includes links for Home, About, Members, News & Events, Resources, Portals, and Find Studies. The user is logged in as RICHARD ANDERSON. The left sidebar shows the Dashboard, Submissions, and Enquiries sections. The main content area displays a table of enquiries with columns for ID, Requester, Purpose, Date Submitted, Status, and # of Studies. The table is filtered by 'Draft' status, showing 6 results. The 'Add Enquiry' button is highlighted in the top right corner.

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

2.2 Creating an Enquiry

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

This screenshot is identical to the one above, showing the Vivli dashboard with the 'Enquiries about Vivli Member Studies' section. The 'Add Enquiry' button in the top right corner is highlighted with a red box, indicating the next step in the process.

2. 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. Please see [Section 1.5 Edit display name](#) in profile for more information.

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

Add Study Save 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

OR

Sponsor ID

Study Title

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

OR

Sponsor ID

Study Title

Notify on "Save & Notify": ☐

Data Contributor

- Select an Option...

Sponsor:

3. Type in the study information:

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

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

NCT ID
NCT00536120

OR

Sponsor ID
101MS404

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

Primary Completion Date: 2009-12-31

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

Data Contributor
- Select an Opti...

Sponsor: Biogen

Discussion:

Data Requested
- Select Multiple -

Response ?
New

Reason ?
None

No Data Found

- 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

- 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.

OR

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

- Select an Opti...

Sponsor: Biogen

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

Discussion:

- Select Multiple -

New

None

No Data Found

- 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.

OR

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

- Select an Opti...

Sponsor: Biogen

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

Discussion:

- Select Multiple -


New

None

No Data Found

7. To delete a study, click the delete icon

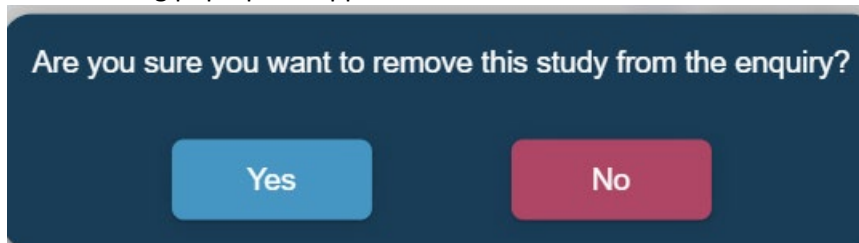
Please enter an NCT Id or Sponsor Id if the study is on clinicaltrials.gov, or enter the study title.

<input type="text" value="NCT ID"/> NCT02064465	<input type="text" value="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 <input type="text" value="Sponsor ID"/> 200697		<div>Data Contributor GlaxoSmithKline</div> <div>Sponsor: GlaxoSmithKline</div>


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

Discussion:

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



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

 **Vivli**
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RICHARD ANDERSON

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

Enquiries

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	

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

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

Add Study Save Submit

Requester Email
Datarequester.vivli@gmail.com

Requester Name
Richard Anderson

Your Institution
Duke University

Country
United States of America

Purpose
Cardiovascular outcomes in Diabetes subjects

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

NCT ID
NCT02583997

OR

Sponsor ID
LOCAL/2014/PL-01

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

Data Contributor
AbbVie

Sponsor: Centre Hospitalier Universitaire de Nimes

11. 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 ?
New

Reason ?
None

No Data Found

Comment

Add Comment

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

Date of Final Response: Request Number(s):

+ NCT ID: Study Title: Data Contributor: Status: !

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

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

Add Study Save **Submit**

Requester Email
Datarequester.vivli@gmail.com

Requester Name
Richard Anderson

Your Institution
Duke University

Country
United States of America

Purpose
Cardiovascular outcomes in Diabetes subjects

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

NCT ID
NCT02583997

OR

Sponsor ID
LOCAL/2014/PL-01

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

Data Contributor
AbbVie

Sponsor: Centre Hospitalier Universitaire de Nîmes

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

+ NCT ID: Study Title: Data Contributor: Status: **!**

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

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

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

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

2.3 Enquiry Discussion

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



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



3. The **Save & Notify** button allows you to save any information on the enquiry and notify the Data Contributor and the Vivli Admin
4. If you are responding to multiple studies in the same Enquiry, you may choose to use the **Save** button 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: 10 Status: Draft Date Submitted:

Add Study Save Submit

Primary Completion Date: Clinical Trials:

Discussion:

Data Requested

ParticipantData x

Response ?

New

Reason ?

None

No Data Found

Comment

Here is a sample message on the enquiry

Add Comment

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

Date of Final Response: Request Number(s):

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

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

Save Save & Notify

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

Discussion:

Data Requested:

- Clinical Documents
- ParticipantData

Response ?

Response from data c...

Reason ?

None

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



Comment

Add Comment

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

Date of Final Response: Request Number(s):

7. 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 https://vivli.org/members/ourmembers/ 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:

- a. **Responses:** This includes updates to the Enquiry discussion and decisions made by the Data Contributor:
 - i. None – No responses
 - ii. New – Meaning no one has responded yet – this is the initial default value
 - iii. Response from requester – You have added information to the discussion. This is automatically set when you add a comment and click Save or Save and Notify.
 - iv. Response from data contributor – The Data Contributor has added information to the discussion. This is automatically set once the Data Contributor responds.
 - v. Response from Vivli – The Vivli Admin has added information to the discussion. This is automatically set when the Vivli team responds.
 - vi. Eligible for Request as an Unlisted Study – You can Add this study to your data request. For the next steps, see [Section 2.5 Adding studies to your data request](#)
 - vii. Study is Listed - You can Add this study to your data request. For the next steps, see [Section 2.5 Adding studies to your data request](#)
 - viii. Not Available – Study is not available. No Action is needed from you
- b. **Reason** – When the response is Not Available, the reason field provides more information. 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 https://vivli.org/members/ourmembers/ for more details on the member's data sharing policy	

- c. **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.
- d. **Discussion** – This includes all the comments provided by you, Vivli Admin, and Data Contributor for this specific study
- e. **Date of Final Response** – Date when the Data Contributor makes a final decision
- f. **Request Number(s)** – You can add studies from the Enquiry directly into the data request form. In such instances, the Enquiry will display the associated Data request ID once the data request is

submitted on the platform. For more information [See Section 2.5 Adding Studies to your data request.](#)

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.

- Awaiting Initial submission Overall Enquiry is in draft and has never been submitted
- Awaiting Resubmission - Overall Enquiry is in draft after being sent back to draft for revision
- Awaiting Validation (Overall Enquiry is in the Enquiry Validation state)
- Awaiting DC review - Overall Enquiry is In review
- Withdrawn (Overall Enquiry is in Withdrawn)
- Archived (Overall Enquiry is in Archived)

2. For Studies with decisions already recorded - e.g. response of Available or Not Available

- Closed - Available as listed (Independent of the overall Enquiry status)
- Closed - Available as unlisted (Independent of the overall Enquiry status)
- 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.....	

NCT ID:
NCT06210529

Study Title: A Single-center, Prospective Clinical Study of High-intensity Focused Ultrasound Tumor Treatment System(Super Knife) in the Treatment of Breast Cancer

Data Contributor: Roche

Status:
Closed - Available as listed

NCT ID:
NCT00086593

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

Data Contributor: GlaxoSmithKline

Status:
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

Primary Completion Date: 2005-07-31

Clinical Trials: <https://clinicaltrials.gov/show/NCT00086593>

Discussio

Data Requested:

- Clinical Documents
- ParticipantData

Response [?]
Study is Listed

Closed - Available as listed

Reason [?]
None

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


This Study is listed on the Vivli Platform

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.....	

	NCT ID: NCT06210529	Study Title: A Single-center, Prospective Clinical Study of High-intensity Focused Ultrasound Tumor Treatment System(Super Knife) in the Treatment of Breast Cancer	Data Contributor: Roche	Status: Closed - Available as listed
	NCT ID: NCT00086593	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	Data Contributor: GlaxoSmithKline	Status: 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.

The screenshot shows the Vivli interface for an enquiry. At the top, there's a header with "< Go Back", "Enquiry Id: 9", "Status: Review", and "Date Submitted: 2024-06-10". On the right, there are "Save" and "Save & Notify" buttons. The main content area has a "Request Study" button with a dropdown arrow, which is highlighted with a red box. Below this, there are input fields for "NCT ID" (NCT01946204) and "Sponsor ID" (CR102931), separated by an "OR" label. To the right, there's a "Study Title" field with the text "A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men With Non-Metastatic (M0) Castration-Resistant Prostate Cancer". Further right, there's a "Notify on 'Save & Notify':" checkbox and two "Data Contributor" fields. Below these, there's a "Sponsor: Aragon Pharmaceuticals, Inc." field. At the bottom, there's a "Primary Completion Date:" field and a "Clinical Trials:" link to "https://clinicaltrials.gov/show/NCT01946204". On the left, there's a "Data Requested:" section with a list: "Clinical Documents" and "ParticipantData". Below that, there's a "Response" section with a "Study is Listed" button and a "Reason" section with a "None" button. In the center, there's a "Discussion:" table with two rows: one from Stan Neumann on 6/10/2024 and one from Amrutha on 6/11/2024.

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

The screenshot shows the Vivli interface for an enquiry, similar to the previous one. The "Request Study" button is highlighted with a red box, and its dropdown menu is open, showing a list of data requests: "Albumin increase in diabetes mellitus patients", "Heparin use in the patients with stroke", "ILT TC3027", "Increase in albuminuria in Diabetes patients", and "Increase in albuminuria in Diabetes patients". The rest of the interface is the same as in the previous screenshot.

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

Request Study ▾

Outcomes

+ Add New Request

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

OR

Sponsor ID: CR102931

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

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

Discussion:

Data Requested:

- Clinical Documents

Response ? Study is Listed ▾

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

The screenshot shows the Vivli 'MY DATA REQUESTS' page. The user is Richard Anderson. The page displays a data request form for Enquiry ID 9, which is in 'Review' status and was submitted on 2024-06-10. The form includes fields for Requester Email (Datarequester.vivli@gmail.com), Requester Name (Data Requester), Your Institution (Boston University), Country (United States of America), Purpose (To find the CV outcomes in Cancer patients), NCT ID (NCT01946204), 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), and Sponsor ID (CR102931). A 'Request Study' button is located next to the Study Title. A notification box at the bottom right states 'Item Successfully Added to My Requests'.

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)”.

The screenshot shows the Vivli 'MY DATA REQUESTS' page. The user is Amrutha Baskaran (Vivli Admin). The page displays a data request form for Request ID 48130, which is in 'Submitted and Awaiting Vivli Request For m Check' status. The form includes fields for Requester Email, Requester Name, Your Institution, Country, Purpose, NCT ID, Study Title, and Sponsor ID. A 'Request Study' button is located next to the Study Title. A notification box at the bottom right states 'Item Successfully Added to My Requests'.

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 Editing a data request

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

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

The screenshot shows the Vivli website interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this, a secondary bar contains links for ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and RESEARCHER. The main header area displays the title 'Predicting Treatment Response to combination drugs in patients with type 2 diabetes' and a red box highlights the 'Edit Request Title' button. To the right of the title are 'Cancel', 'Save', and 'Submit' buttons. On the left, a sidebar lists various sections: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, Request History, and Chat. The main content area is titled 'LEAD RESEARCHER / STATISTICIAN' and includes a checkbox for 'Invite user to access data request' and a checked checkbox for 'Lead Researcher is also Statistician Researcher'. Below these are input fields for First Name, Last Name, Email, Position, Employer, Company, Research Institute, or Pr..., and Country (set to United States of America). There is also a field for ORCID ID and a large text area for 'Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis.' A character count of 0/1000 is shown. At the bottom, a note asks the user to list any real or potential conflicts of interest.

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

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

3.2 Completing a data request

To complete a data request, you must add all required information to the Data Request Form. For guidance, please see [Vivli Data Request Form Worksheet](#). Please note that the data request must include:

- The name, contact information, primary affiliation and position, country, qualifications, degrees, and where the degrees were obtained of all team members.
- Conflict of Interest Statement
- The title of the proposed research with a description of the study design (which should match the Project name)
- Lay summary explaining the relevance of the project to science and public health
- Brief description, main predictor variable, outcome elements, specific aims and objectives, and

- hypothesis to be evaluated
- Purpose of analysis and outcomes
- Project timeline, dissemination, and publication plan.
- Statistical Analysis Plan
- Information about funding
- Attestation
- All other required fields, including all data sets associated with the proposal
 - This includes studies you may request from Vivli; studies requested from other Data Sharing Platforms or Portals; and any additional data, tools, and scripts that you want to bring into the Vivli platform. If you will not be bringing studies into the Vivli platform but they are part of your overall research analysis plan, then please add this list of studies as an attachment.

For more information on requesting studies not listed on Vivli, please see Section 5.0 Requesting data from studies not listed on Vivli, but available for provisioning into the Secure Research Environment.

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

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

Research Team

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

LEAD RESEARCHER / STATISTICIAN

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

First Name Last Name ORCID ID

Email (editable until ...) Position

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

Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. Character Count: 0/1000

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

3.2.1 Adding Files or Other Information to your data request

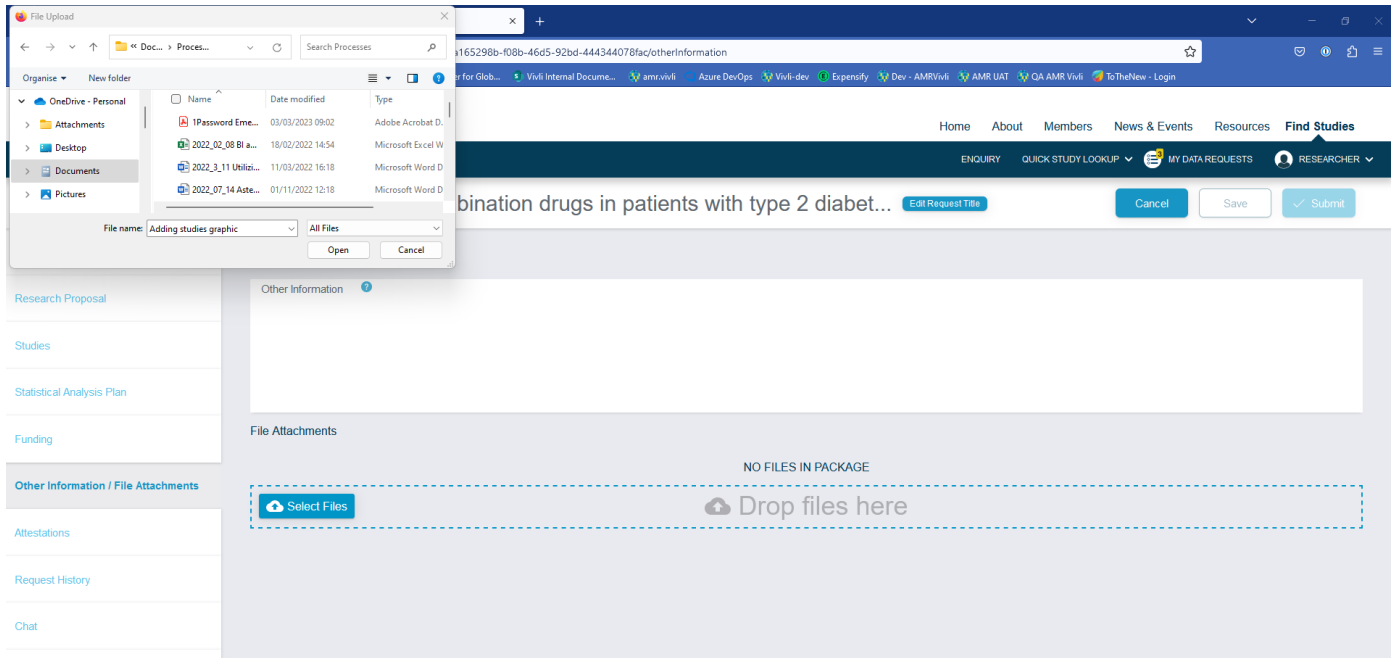
1. You may also attach files to your data request using the **Other Information/File Attachments** tab:

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a dark blue header with ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and RESEARCHER. The main content area is titled 'Predicting Treatment Response to combination drugs in patients with type 2 diabet...'. On the left, a sidebar lists various tabs: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments (highlighted with a red box), Attestations, Request History, and Chat. The 'Other Information / File Attachments' tab is active, showing two sections: 'Other Information' and 'File Attachments'. The 'Other Information' section is empty. The 'File Attachments' section displays 'NO FILES IN PACKAGE' and a dashed box containing a 'Select Files' button and the text 'Drop files here'.

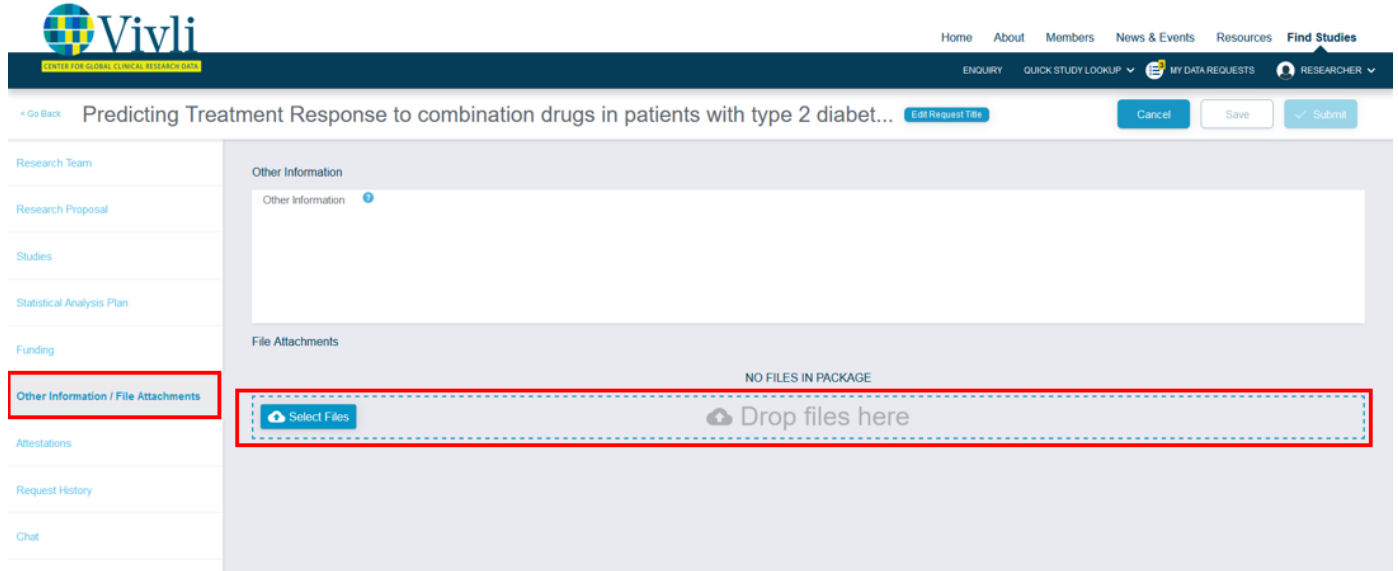
2. Click on **Select Files** to choose a file:

This screenshot is identical to the one above, showing the Vivli web application interface. The 'Other Information / File Attachments' tab is active. In this view, a red box highlights the 'Select Files' button and the 'Drop files here' text within the 'File Attachments' section, indicating the next step in the process.

3. Then simply select the file from your computer:



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



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

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. The main header displays the title 'Predicting Treatment Response to combination drugs in patients with type 2 diabet...' and buttons for 'Edit Request Title', 'Cancel', 'Save', and 'Submit'. The left sidebar contains a list of navigation items: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments (highlighted with a red box), Attestations, Request History, and Chat. The main content area is divided into 'Other Information' and 'File Attachments'. The 'UPLOADED FILES' table is as follows:

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

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

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. The main header displays the title 'Predicting Treatment Response to combination drugs in patients with type 2 diabet...' and buttons for 'Edit Request Title', 'Cancel', 'Save', and 'Submit'. The left sidebar contains a list of navigation items: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments (highlighted with a red box), Attestations, Request History, and Chat. The main content area is divided into 'Other Information' and 'File Attachments'. The 'UPLOADED FILES' table is as follows:

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

The 'File Type' dropdown menu is open, showing the following options:

- Unknown
- Research Proposal Supplement
- Funding Information
- Statistical Analysis Plan
- Other
- Unknown

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

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

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

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

Other Information

Other Information

File Attachments

Select Files

UPLOADED FILES

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

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

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

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

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

Other Information

Other Information

File Attachments

Select Files

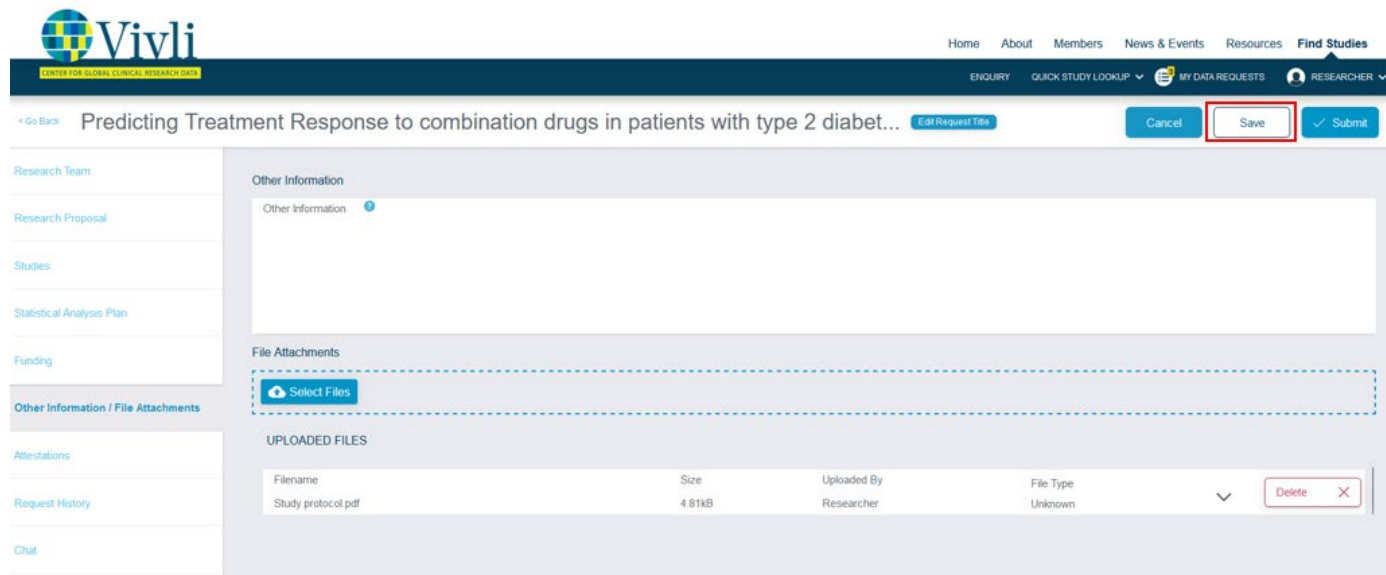
UPLOADED FILES

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

3.3 Saving your data request

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

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



The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a secondary bar with ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and RESEARCHER. The main header displays the title "Predicting Treatment Response to combination drugs in patients with type 2 diabet..." and buttons for "Edit Request Title", "Cancel", "Save" (highlighted with a red box), and "Submit". A left sidebar contains a menu with items like Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments (selected), Attestations, Request History, and Chat. The main content area is divided into "Other Information" (with a text input field) and "File Attachments" (with a "Select Files" button). Below these is a table titled "UPLOADED FILES" with columns for Filename, Size, Uploaded By, and File Type. One file, "Study protocol.pdf", is listed with a size of 4.81kB, uploaded by "Researcher", and of type "Unknown". A "Delete" button is visible next to the file entry.

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 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.

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

< Go Back Predicting Treatment Response Edit Request Title Cancel Save Submit

Research Team

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

First Name Last Name ORCID ID

Email Position

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

Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. Character Count: 0/1000

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

VM Access Admin Approval Based on Approved DUA

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

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

< Go Back Predicting Treatment Respo... Edit Request Title Cancel Save Submit

Research Team

Research Proposal

Studies

Statistical Analysis Plan

Funding

Other Information / File Attachments

Attestations

Chat

Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. Character Count: 0/1000

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

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

ADDITIONAL RESEARCHERS Add +

7. The following dialogue box will appear:

ADDITIONAL RESEARCHER ☐ Activate user for accessing data request ?

First Name Last Name ORCID ID ?

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

Employer, Company, Research Institute, or Primary Aff... Country
- Select an Option -

Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. ? Character Count: 0/1000

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

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

OK Cancel

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

First Name Last Name ORCID ID ?

Ema... Position

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

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

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

Please see below for my education including degree, discipline and institution where the degree was granted. I also included qualifications specific to this analysis

Education of Lead Researcher:
Bachelor's Degree from University of California, San Francisco where I obtained a degree in Biological Life Sciences in 1998
Master's Degree from University of California, San Francisco where I obtained a degree in Epidemiology in 2000
PhD from University of California, San Francisco where I obtained a degree in Epidemiology in 2006

Other qualifications:
Bachelor's Degree from University of California, San Francisco where I obtained a degree in Biological Life Sciences in 1998

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

9. 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.

Center for Global Clinical Research Data

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

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

Research Team !

Research Proposal

Studies

Statistical Analysis Plan

Funding

Other Information / File Attachments

Attestations

Chat

LEAD RESEARCHER - No Account

☐ Activate user for accessing data request

☐ Lead Researcher is also Statistician Researcher ?

First Name Sarah Last Name Jones ORCID ID ?

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


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

Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. PhD Biostatistics UCSD 1999 MS Biostatistics UCSD 1995 Character Count: 54/1000

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

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

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10. Complete all fields, and click 
11. Please ask the research team member to "sign up" for a Vivli account. They can follow Section 1.0 of the [Vivli User Account Quick Start guide](#)
12. 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**:

ADDITIONAL RESEARCHER

☒ Activate user for accessing data request ?

First Name Last Name ORCID iD ?

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

Employer, Company, Research Institute, or Primary Affil... Country
- Select an Option -

Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. ? Character Count: 0/1000

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

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

OK Cancel

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

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

Research Team

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

First Name Last Name ORCID iD ?

Sarah Jones

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

sarah.jones@ucsd.utorg Biostatistician

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

University of California, San Diego United States of America

Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. ? Character Count: 129/1000

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

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

None

14. 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.
15. 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):
 - Conflict of interest statement and plan for mitigation:
 - *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*
16. 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.

3.5 Deleting research team members

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

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

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a dark blue header with 'ENQUIRY', 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'DATA REQUESTER'. The main content area is titled 'Albumin in...' and has a 'Go Back' link and an 'Edit Request Title' button. On the left, a sidebar lists various tabs: Research Team (highlighted with a red box), Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, and Chat. The main content area has a large text input field for conflicts of interest, followed by a section for 'VM Access Admin Approval Based on Approved DUA' and 'DUA Approval Not Applicable'. Below this is the 'ADDITIONAL RESEARCHERS' section, which lists 'Sarah Jones (ADDITIONAL RESEARCHER)'. A red box highlights the three vertical dots next to her name. Another red box highlights the 'Remove Team Member' option in the dropdown menu.

3. The following pop-up will appear:

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

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

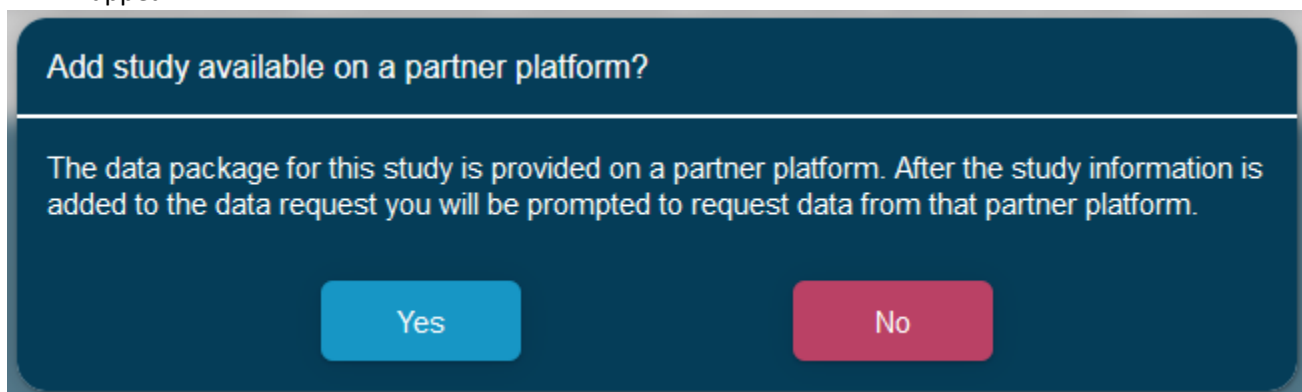
4.0 Requesting Vivli-listed studies provisioned by external providers

4.1 Overview

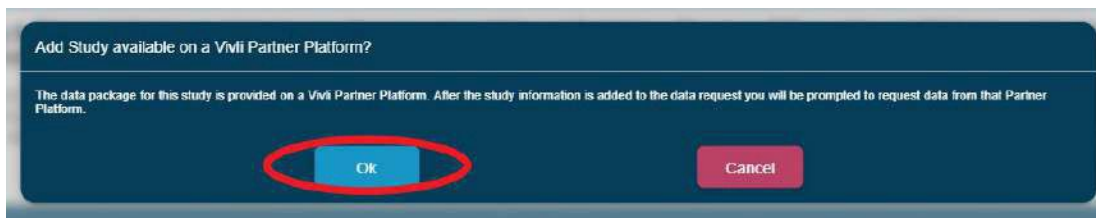
- Some studies are listed and searchable on both the Vivli platform as well as on other platforms that are Partner Platforms with Vivli.
- In addition to completing the Vivli request form, you will need to request such studies directly through the Partner Platform.
- After the relevant Data Contributor(s)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

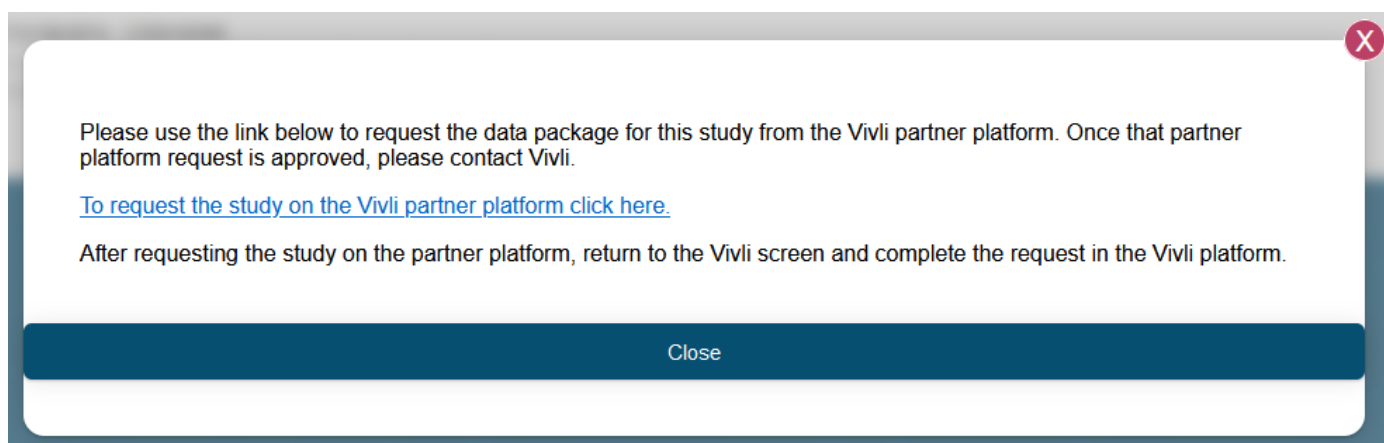
1. If the study you are searching for is on the Vivli Platform but provisioned by an external provider, it will appear on the Studies page when you search for studies as described in [Section 1.1, Searching for studies on the Vivli platform](#).
2. When attempting to add a study in this category to a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



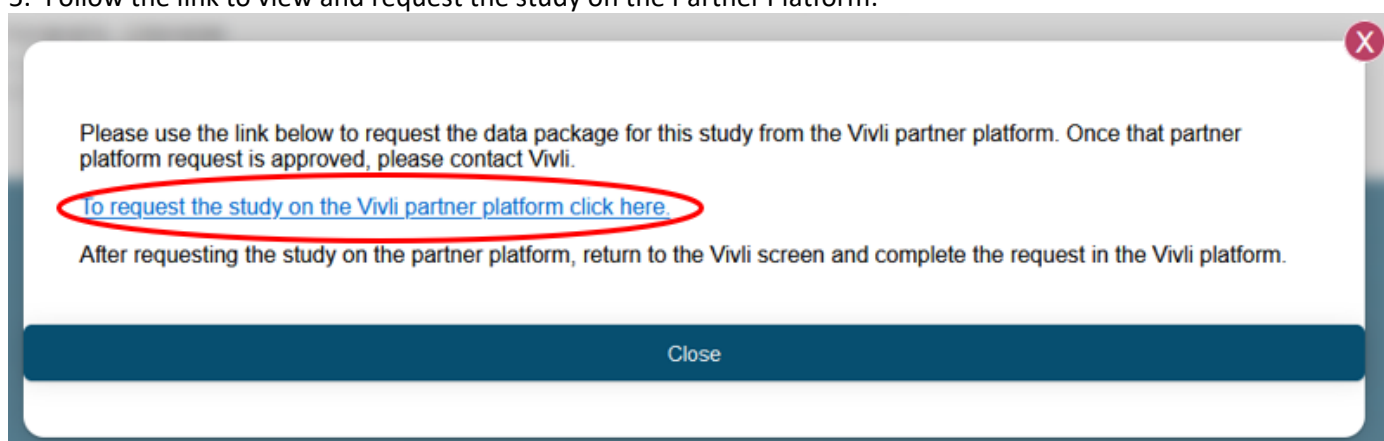
3. Click on **Yes** to add the study to the Data Request Form:



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:**

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

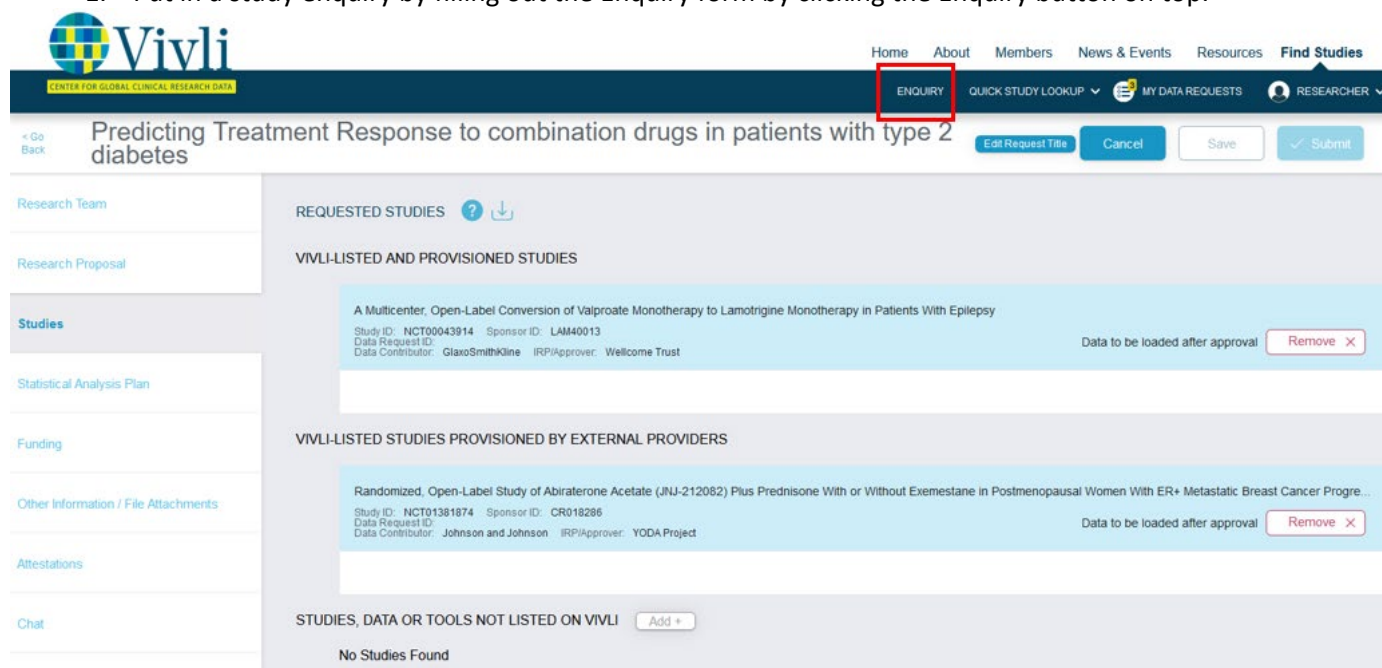
5.0 Requesting data from studies not listed on Vivli, but available for provisioning into the Secure Research Environment

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

5.1 Process Overview

To request data from Vivli Member studies that 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 shows the Vivli website interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. The 'ENQUIRY' button is highlighted with a red box. Below the navigation bar, the main content area displays a list of requested studies. The first study listed is 'A Multicenter, Open-Label Conversion of Valproate Monotherapy to Lamotrigine Monotherapy in Patients With Epilepsy'. The second study listed is 'Randomized, Open-Label Study of Abiraterone Acetate (JNJ-212062) Plus Prednisone With or Without Exemestane in Postmenopausal Women With ER+ Metastatic Breast Cancer Progre...'. The third section is 'STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI' with an 'Add +' button. The bottom of the page 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:



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

[ENQUIRY](#)
[QUICK STUDY LOOKUP](#)
[MY DATA REQUESTS](#)
[RESEARCHER](#)

[Go Back](#)

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

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

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

REQUESTED STUDIES

VIVLI-LISTED AND PROVISIONED STUDIES

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

Study ID: NCT00043914 Sponsor ID: LAM40013

Data Request ID: [redacted]

Data Contributor: GlaxoSmithKline IRPI Approver: Wellcome Trust

Data to be loaded after approval [Remove](#)

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: [redacted]

Data Contributor: Johnson and Johnson IRPI Approver: YODA Project

Data to be loaded after approval [Remove](#)

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:

Request Studies, Data, or Tools not listed on Vivli

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

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

Select provider of the data

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

Pfizer Inc. ▼

NCT012345678

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

Study Title

Submit

Cancel

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

6. The following notification will appear:

Request Studies, Data, or Tools not listed on Vivli

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

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

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

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

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

Add Another Study, Data, or Tool

Back

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

Request Studies, Data, or Tools not listed on Vivli

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

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

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

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

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

Add Another Study, Data, or Tool

Back

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

Request Studies, Data, or Tools not listed on Vivli

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

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

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


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

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

Add Another Study, Data, or Tool

Back

9. The studies will appear in the study list



Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

[ENQUIRY](#)
[QUICK STUDY LOOKUP](#)
[MY DATA REQUESTS](#)
[RESEARCHER](#)

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

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

REQUESTED STUDIES

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

VIVLI-LISTED AND PROVISIONED STUDIES

Randomized, Open-Label Study of Abiraterone Acetate (JNJ-212062) Plus Prednisone With or Without Exemestane in Postmenopausal Women With ER+ Metastatic Breast Cancer Prog...

Study ID: NCT01381874 Sponsor ID: CR018286
Data Request ID:
Data Contributor: Johnson and Johnson IRP/Approver: YODA Project

Data to be loaded after approval

Remove

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI

ABC-156

Study ID: NCT012345678
Data Request ID:
Data Contributor: Pfizer Inc. IRP/Approver: Pfizer Inc.

Data to be loaded after approval

Remove

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 displays the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. A sidebar on the left lists various sections: Research Team, Research Proposal, Studies (highlighted with a red box), Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, and Chat. The main content area is titled "Predicting Treatment Response to combination drugs in patients with type 2 diabetes". It displays two sections: "REQUESTED STUDIES" and "VIVLI-LISTED AND PROVISIONED STUDIES". The first 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 and Sponsor ID: LAM40013. The second section shows a study titled "Randomized, Open-Label Study of Abiraterone Acetate (JNJ-212062) Plus Prednisone With or Without Exemestane in Postmenopausal Women With ER+ Metastatic Breast Cancer Progre...". Both studies have a "Data to be loaded after approval" status and a "Remove" button. At the bottom, there is a section titled "STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI" with an "Add +" button, which is highlighted with a red box. 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... ▼

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

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

Complete all fields and click **submit**. **Note:** Please include the description of the additional data, 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 ToolBack

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



CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

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

[< Go Back](#)

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

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

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

REQUESTED STUDY TYPES [?](#) [↓](#)

VIVLI-LISTED AND PROVISIONED STUDIES

Effects of Cystic Fibrosis and Cystic Fibrosis Related Diabetes on Brain Stru...
PI: Sponsor: University of Minnesota Study ID: NCT03820349 IRP/Approver: Wellcome Trust Data Request ID: 00002555
Sponsor ID: MED-2018-26436 Data Contributor: GlaxoSmithKline IPD Uploaded: Yes

Data already on platform [Remove](#) [>](#)

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

Data already on platform [Remove](#) [>](#)

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

No Studies Found

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

Data collected during my own clinical trial
PI: Data Contributor: I WILL BRING MY OWN Study ID: false Data Request ID: 00002555 Sponsor ID: 123456
IPD Uploaded: No

Data to be loaded after approval [Remove](#) [>](#)

How-To: Requesting Studies on Vivli
Version 3.6

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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

I WILL BRING M... ▼

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

000000

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

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

Submit

Cancel

7.0 Submitting your data request

- Once the Data Request Form is complete, you may submit it for review.
- Do not submit a form before it is complete, as you will be unable to make changes once it has been submitted.
- Please make sure that you have added all the desired studies to your data request as adding it later will lead to additional delays. If you have ongoing enquiries for studies involved in this project, please wait until all the enquiries are closed before submitting the data request.
- Please note that according to Vivli policy, any changes to the Lead 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 left sidebar contains a navigation menu with items: Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations (highlighted with a red box), and Chat. The main content area includes a 'Certify Complete and Accurate' section with a checkbox labeled 'I certify the information provided is complete and accurate.' (checked), a 'Data Use Agreement' section with explanatory text, and a 'Support' link. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies, along with user-specific links for ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and RESEARCHER.

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

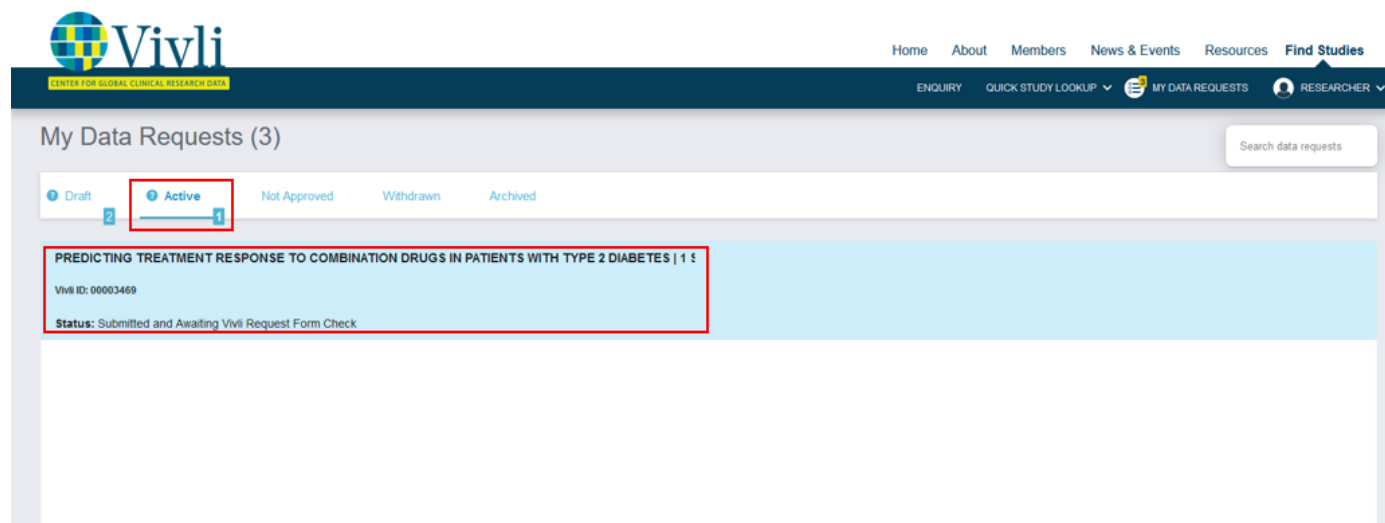
The screenshot shows the Vivli website interface for a data request titled "Predicting Treatment Response to combination drugs in patients with type 2 diabetes". The left sidebar contains tabs for Research Team, Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, and Chat. The main content area includes sections for "Certify Complete and Accurate" (with a checked checkbox), "Data Use Agreement", and a "Submit" button in the top right corner, which is highlighted with a red box. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies, along with user-specific links for ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and RESEARCHER.

- 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 for the same study title. The "Submit" button in the top right corner is highlighted with a red box. The interface elements, including the sidebar tabs and the main content area sections, are the same as in the previous image.

7.1 Data Request Status

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



The status bar contains 5 sections:

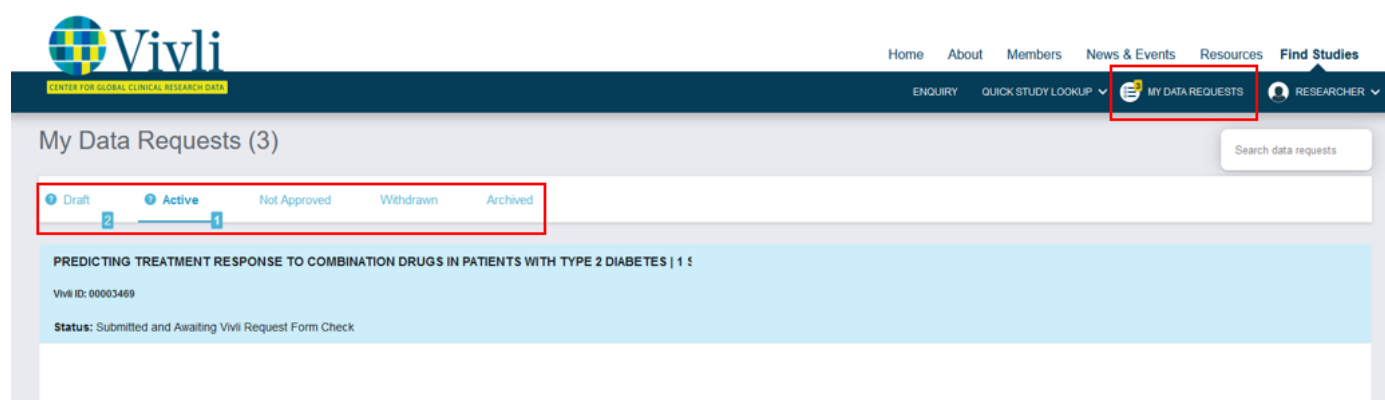
Draft: Displays Data Requests that are being drafted but not yet submitted and hence don't have a Vivli ID.

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

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

Withdrawn: Displays Data Requests that were withdrawn.

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



Your data request will go through the following steps:

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

7.2 Research team account status

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

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

< Go Back

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

Studies

Attachments

Request History

Signed Agreements

Chat

Research Team

Request Details/Print View

RESEARCHERS
Add +

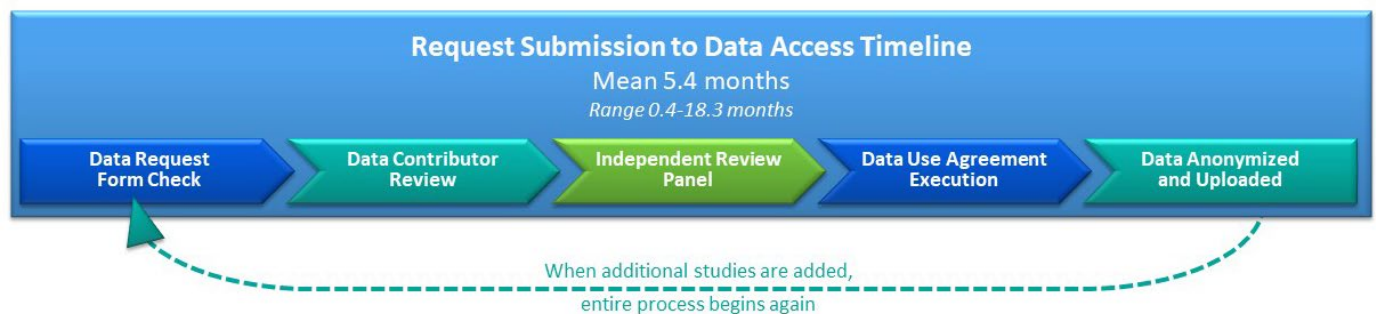
<div style="display: flex; align-items: center;"> <div> Richard Wilson (LEAD RESEARCHER / STATISTICIAN) - No Account </div> </div>	⋮
<div style="display: flex; align-items: center;"> <div> Emily Wilson (DATA REQUEST ADMINISTRATOR) - Account Enabled </div> </div>	Access Granted DUA Approval Required
<div style="display: flex; align-items: center;"> <div> Henry Anderson (ADDITIONAL RESEARCHER) - Account Disabled </div> </div>	Access Granted DUA Approval Required
<div style="display: flex; align-items: center;"> <div> Karen Asada (ADDITIONAL RESEARCHER) - Account Enabled </div> </div>	Access Granted DUA Approval Required

8.0 Modifying or revising your data request

8.1 Overview

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

PLEASE NOTE: 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. This allows the reviewers of a request to know which data sets will be combined into the same analysis environment. This entire process could take an additional 2-5 months. Hence, please finalize your plans ahead of time to avoid any delays later.



Key factors that influence the timeline:

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

8.2 Modification after submission

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

8.3 Requested revisions to your data request

- At times, the Data Contributor, Independent Review Panel (IRP), or Vivli may request that you make changes to your data request.
- If this is the case, you will be notified on the Vivli Dashboard as well as via email.
- The specific changes requested will be placed in the Chat window.
- If you fail to make the requested changes, the data request will be withdrawn after 4 months.

8.3.1 Steps for revising request

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

The screenshot shows the 'My Data Requests (3)' page on the Vivli website. The 'Active' tab is selected and highlighted with a red box. Below the tabs, a request for 'PREDICTING TREATMENT RESPONSE TO COMBINATION DRUGS IN PATIENTS WITH TYPE 2 DIAI' is shown with a 'Status: Draft' label highlighted by a red box.

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

The screenshot shows the 'Request History' page for a specific data request. The 'Request History' tab is selected and highlighted with a red box. The page displays a table of request history entries.

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

You can review the request history and see any comments related to your data request. You may also review the chat associated with your request for any additional comments or use the chat to ask for any clarifications about the revision request.

3. From there, you may revise and resubmit the Data Request Form.
4. Use the **Other Information / File Attachments** tab to add any additional comments about the revision that don't fit in the rest of the fields:

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

8.4 Deleting Draft Data Requests

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

8.5 Withdrawal process for submitted data request

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

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

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

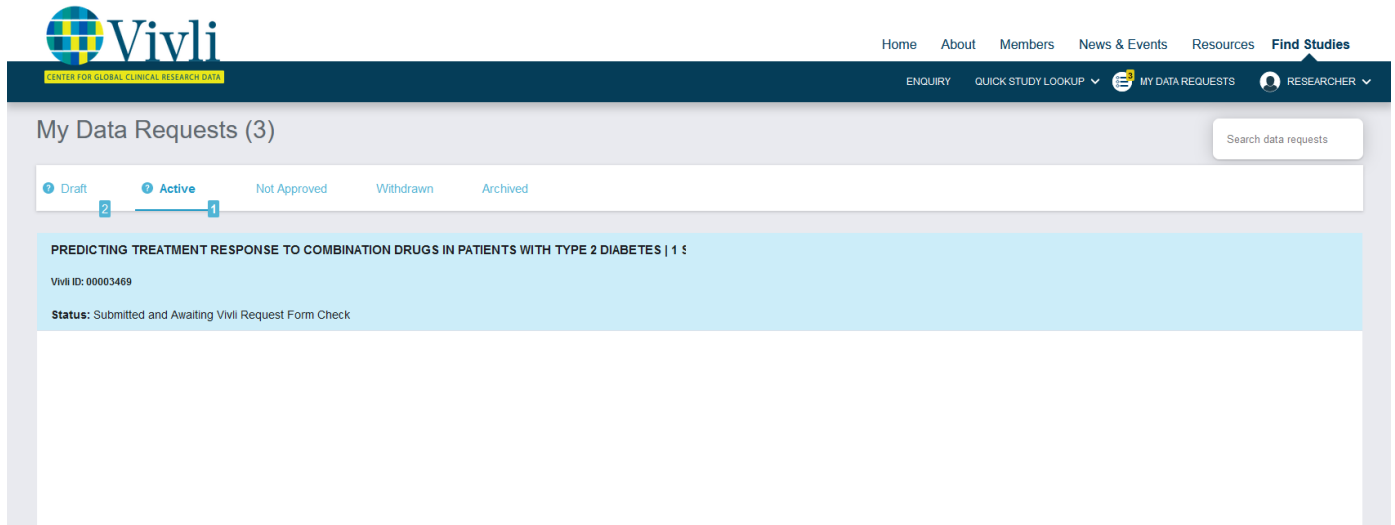
9.0 Communications

9.1 Open Chat

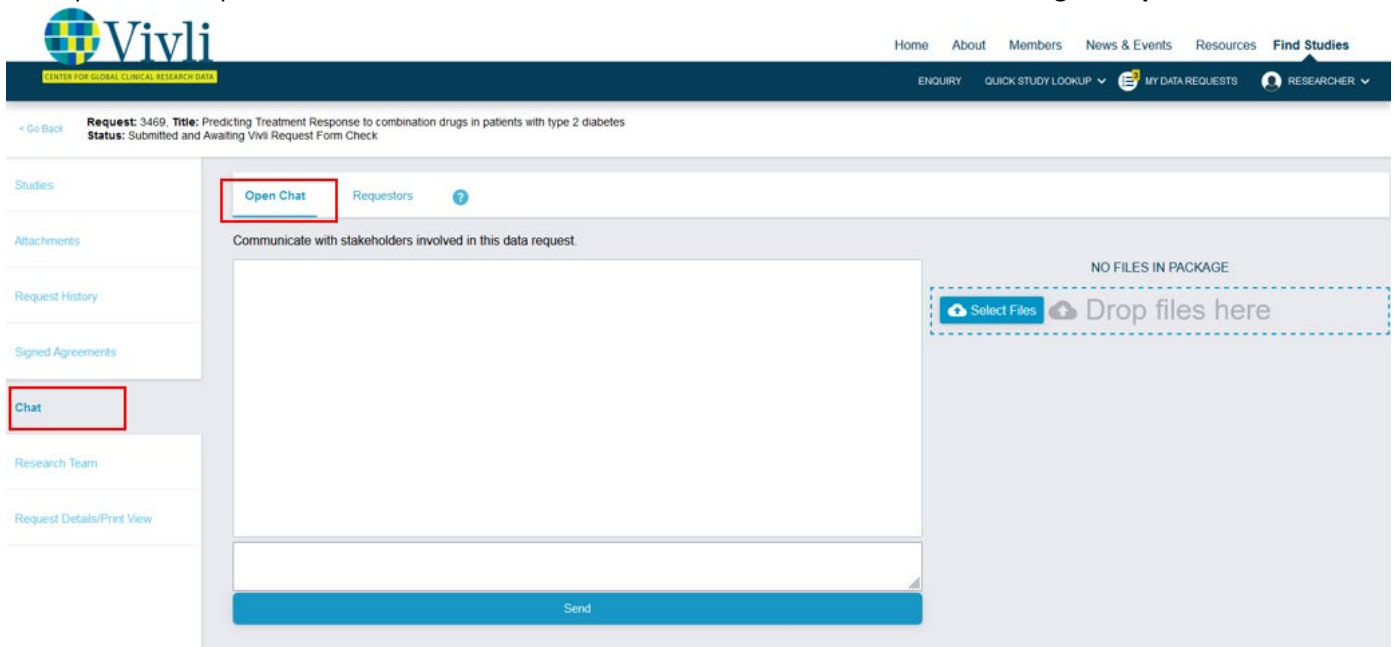
- You can use the open chat within the data request to communicate with the Vivli team, and the data contributors or review entities associated with your data request.
- Please note that messages in open chat are visible to all persons attached to a data request.
- When any other party enters a message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

9.2 Steps for creating a chat message

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



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



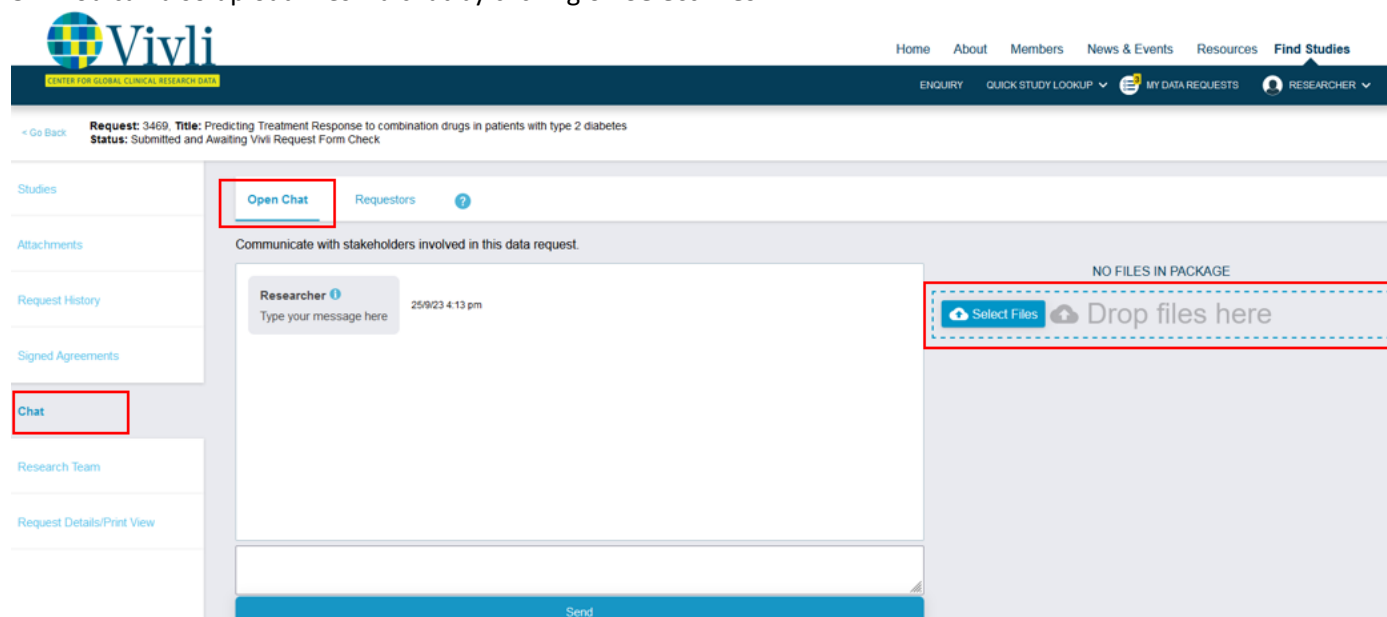
3. Enter your message in the chat message box and click **Send**:

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

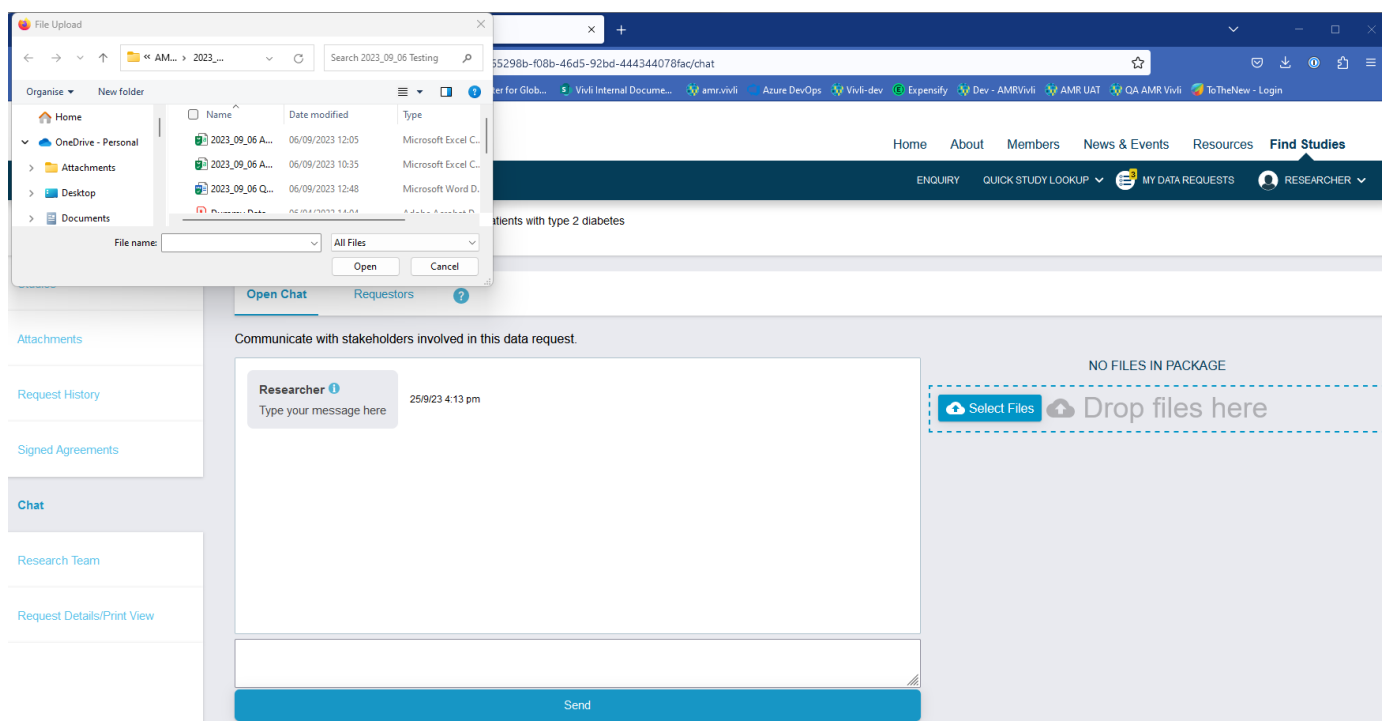
4. The message will now appear in the Chat record for all users (to see your just-entered chat message, you may need to click Refresh on your browser), and the response will also appear in the chat record:

The screenshot shows the Vivli website interface after a message has been sent. The top navigation bar and secondary navigation bar are the same as in the previous screenshot. The main content area is titled 'Request: 3469, Title: Predicting Treatment Response to combination drugs in patients with type 2 diabetes' and 'Status: Submitted and Awaiting Vivli Request Form Check'. On the left sidebar, the 'Chat' option is highlighted with a red box. The main chat area has a tab labeled 'Open Chat' and a sub-tab 'Requestors'. Below the tabs is a message from a 'Researcher' with the text 'Type your message here' and a timestamp '25/9/23 4:13 pm', both highlighted with red boxes. Below the message is a text input box with the placeholder 'Type your message here' and a blue 'Send' button, both highlighted with red boxes. To the right of the input box is a file upload area with the text 'NO FILES IN PACKAGE' and a dashed box containing 'Select Files' and 'Drop files here'.

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



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



7. **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 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 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:

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

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

This screenshot is similar to the previous one, showing the Vivli interface. The 'UPLOADED FILES' table is highlighted with a red box. The file 'Study protocol pd...' is listed with its size '4.81...' and uploaded by 'Researc...'. The delete button (X) next to the file name is highlighted with a red box.

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.

This file was added by another user - are you sure you want to delete this file: 2025_02_14 Vivli ID 48468 form check comparison report.pdf

Ok

Cancel

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

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this, there are links for ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and RESEARCHER. The main content area displays a chat window for a specific request (Request: 3469, Title: Predicting Treatment Response to combination drugs in patients with type 2 diabetes, Status: Submitted and Awaiting Vivli Request Form Check). The chat window shows a message from the Researcher: "File Uploaded: Study protocol.pdf" at 25/9/23 4:17 pm. To the right of the chat window, there is a section titled "UPLOADED FILES" which lists the uploaded file "Study protocol.pdf" with a size of 4.81 MB and an upload date of 25/9/23 4:17 pm. A red box highlights the download arrow icon next to the file name.

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

The screenshot shows the Vivli web application interface, similar to the previous one. The chat window shows a message from the Researcher: "File Deleted: Study protocol.pdf" at 25/9/23 4:21 pm. A red box highlights this message. To the right of the chat window, there is a section titled "NO FILES IN PACKAGE" with a "Select Files" button.

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 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
Status Change, data Request passed Vivli form check	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
Status Change, data Request - Revision requested or Request not approved	When your data request changes status to Revision or Not approved. If you have requested studies from multiple contributors, you will receive a notification after all the Data Contributors have recorded their decision.	Notify you of any changes in the status to your data requests.
Request Final Approval	When your data request is approved, by a delegated approver/IRP. If you have requested studies from multiple contributors, you will receive a notification after final approval.	Notify you of final approval.
DUA Approved	When the Vivli Admin has validated the DUA associated with the data request.	Notify you of the executed DUA.
Data Uploaded	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.
Research Environment was provisioned.	When you start the Research Environment.	Notify you when the Research Environment is ready to be used for analysis.
Request for results decision	When your request to export results is approved or/not approved.	Notify the status of the results export.

Data Request Archived	When the data request is Archived, the project is considered closed.	Notify that the lead researcher and research team have met the DUA obligations for public disclosure/summary of results and the data request is now archived.
Chat	When anyone associated with a data request enters a message in Chat. This includes chat messages from Open chat and Requester chat	Facilitate communication and the data request workflow
Enquiry	When anyone associated with a data request enters a comment or makes a decision	Facilitate communication and the Enquiry workflow.

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.

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

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a dark blue header with a search bar and user account options. The main content area is titled 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes'. On the left, a sidebar menu lists various tabs: Studies, Attachments, Request History, Signed Agreements (highlighted with a red box), Chat, Research Team, and Request Details/Print View. The main content area displays a message: 'There are no Signed Documents'. Below this, a dashed box contains a 'Select Files' button. Further down, a table titled 'UPLOADED FILES' shows a single file: '2021_10_05 Vivli ID 00002553_DUA executed final.pdf' with a size of 673.80kB, uploaded by 'Data Requester'. A 'Download' button is next to the file name.

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**

The screenshot shows the Vivli website interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a dark blue header with a 'QUICK STUDY LOOKUP' button and a 'MY DATA REQUESTS' button. The main content area is titled 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes'. On the left, a sidebar contains links for Studies, Attachments, Request History (highlighted), Signed Agreements, Safety Concerns, Chat, Research Team, Research Environment, and Request Details/Print View. The main content area displays a table of request history entries. The final entry, dated 10/5/21 5:39 pm, shows the status 'Status changed to Data Use Agreement (DUA) Validated by Vivli Admin' and is highlighted with a red box. Other entries show various status changes and approvals.

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.

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

[< Go Back](#)

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

Archive

Do not track

Reset to Draft

Cancel

Edit Data Request

Print

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

Research Team

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

RESEARCHERS

Add +

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

11.0 Data Package Upload

The Data Contributors will anonymize the data and upload the data into the platform. You will be notified via email when each 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.

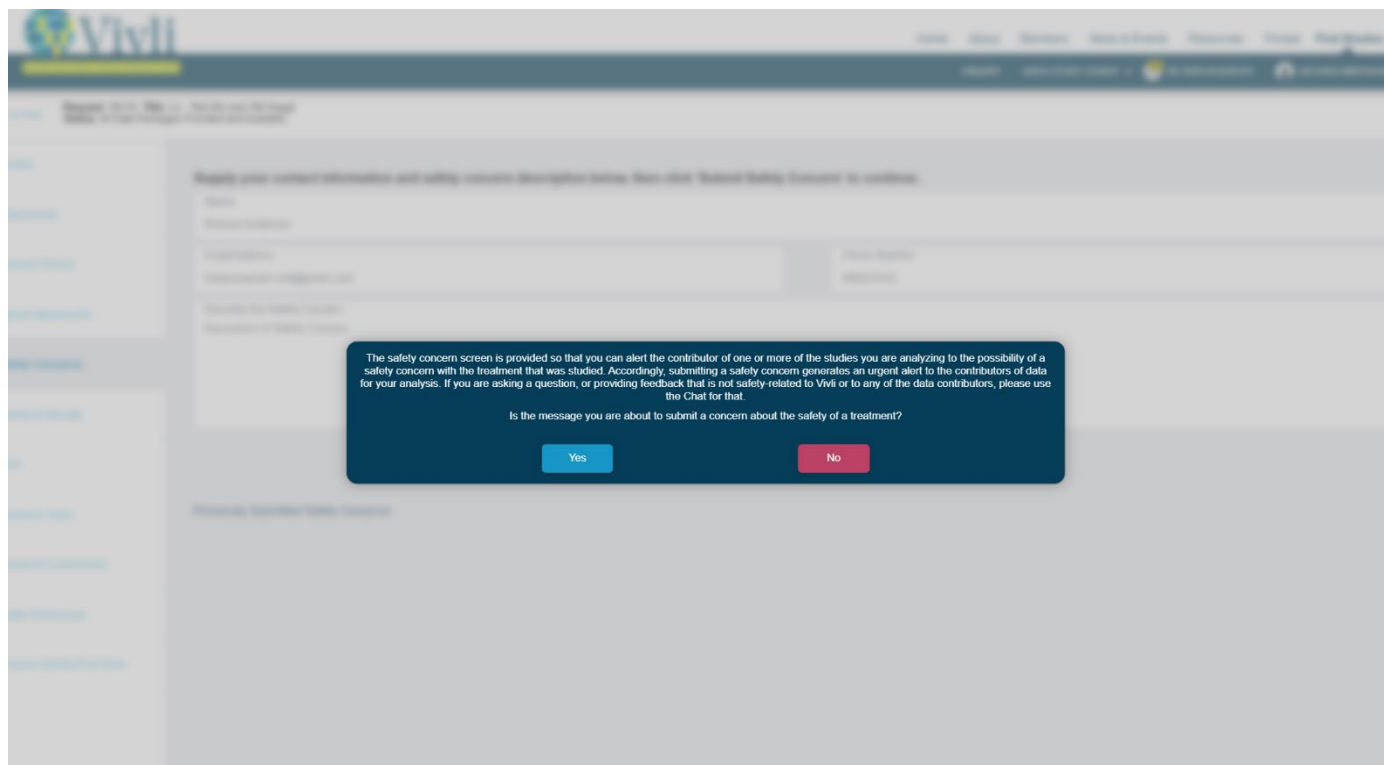
13.0 Safety Concerns Data Progress Report

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.

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 open chat](#) under chat attachments. Please let us know where your publication is going to be submitted and whether you are planning any additional public disclosures for this request. Vivli will send periodic follow-ups on the public disclosures.

Ensure to add the following language to your acknowledgment section:

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

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

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

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.