

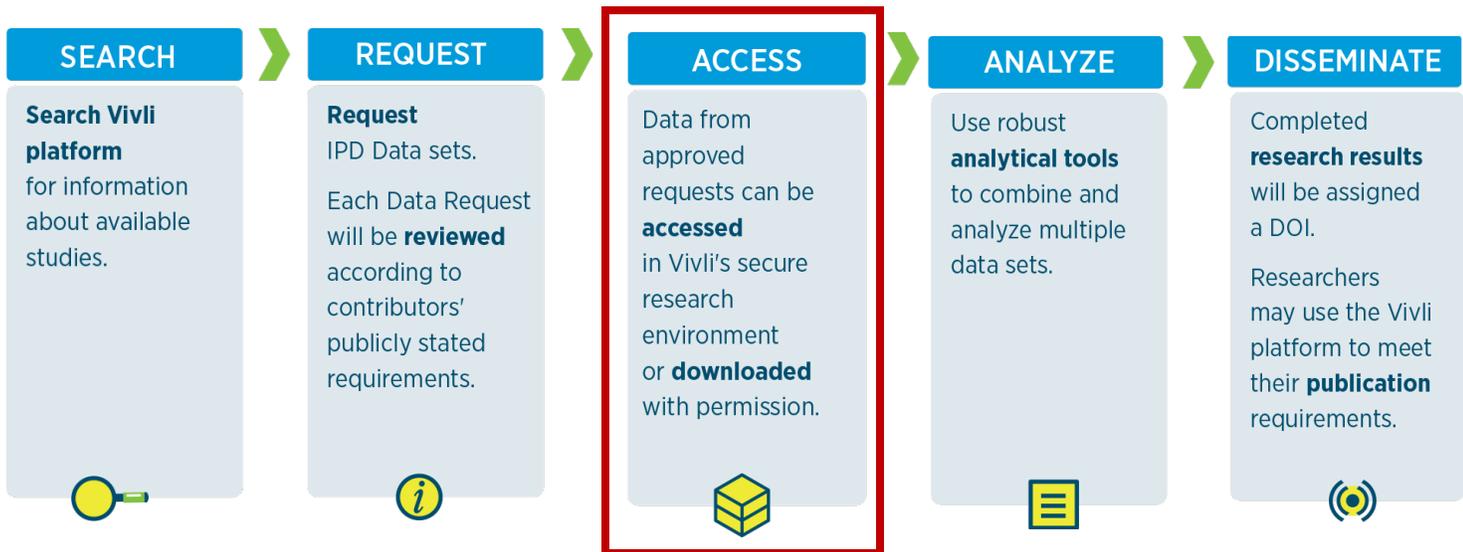


# How to Access Data for Analysis and Publication Process

## Contents

<b><u>1.0 DATA ACCESS INTRODUCTION.....</u></b>	<b><u>4</u></b>
<b><u>2.0 GETTING STARTED .....</u></b>	<b><u>4</u></b>
2.1 LOCATING THE DATA REQUEST AND SEEING HOW MANY STUDIES ARE AVAILABLE FOR ANALYSIS .....	5
2.2 STARTING THE SECURE RESEARCH ENVIRONMENT.....	7
2.3 SECURE RESEARCH ENVIRONMENT OPTIONS .....	10
2.4 INITIATING THE SECURE RESEARCH ENVIRONMENT.....	11
<b><u>3.0 ACCESS TO THE ENVIRONMENT.....</u></b>	<b><u>12</u></b>
3.1 ACCESSING THE SECURE RESEARCH ENVIRONMENT .....	12
3.2 WORKING IN THE RESEARCH ENVIRONMENT .....	14
3.2.1 FINDING YOUR DATA AND USING SPACE.....	14
3.2.2 IF YOU STARTED BEFORE ALL OF THE DATA WAS AVAILABLE .....	15
3.2.3 ADDITIONAL TIPS FOR WORKING IN THE RESEARCH ENVIRONMENT.....	16
3.3 DISCONNECTING FROM THE RESEARCH ENVIRONMENT.....	17
3.4 TEAM ACCESS TO SECURE RESEARCH ENVIRONMENT .....	19
3.5 ADDING ADDITIONAL SOFTWARE, TOOLS AND DATA DURING YOUR ANALYSIS.....	20
<b><u>4.0 STOPPING AND STARTING THE RESEARCH ENVIRONMENT .....</u></b>	<b><u>21</u></b>
4.1 STOPPING OR PAUSING THE RESEARCH ENVIRONMENT .....	21
4.2 RESTARTING THE RESEARCH ENVIRONMENT.....	23
<b><u>5.0 ADDING DATA PACKAGES TO THE RESEARCH ENVIRONMENT.....</u></b>	<b><u>25</u></b>
5.1 HOW WILL YOU KNOW WHEN DATA IS AVAILABLE?.....	25
5.2 HOW TO ADD ADDITIONAL DATA TO YOUR RESEARCH ENVIRONMENT AS IT BECOMES AVAILABLE .....	26
5.3 REFRESHING PREVIOUSLY LOADED DATA .....	27
<b><u>6.0 SAFETY CONCERNS.....</u></b>	<b><u>27</u></b>
<b><u>7.0 EXPORTING RESEARCH RESULTS.....</u></b>	<b><u>29</u></b>
7.1 REQUEST TO EXPORT RESULTS.....	31

<b>7.2 DOWNLOADING APPROVED RESULTS .....</b>	<b>38</b>
7.2.1 STEPS, EXPORTING RESULTS: .....	38
<b><u>8.0 PUBLICATION REVIEW.....</u></b>	<b>40</b>
<b>8.1 PUBLICATION FOLLOW UP BY VIVLI .....</b>	<b>40</b>
<b>8.2 PUBLICATION REVIEWS BY DATA CONTRIBUTORS .....</b>	<b>40</b>
<b>8.3 PUBLICATION NOTIFICATION BY DATA REQUESTOR .....</b>	<b>50</b>
<b>8.4 PUBLIC DISCLOSURE NOT POSSIBLE .....</b>	<b>51</b>
8.4.1 REASONS WHY ANALYSIS MAY NOT BE COMPLETED .....	52
<b><u>9.0 EXTENSIONS TO THE DATA USE AGREEMENT VIA THE DATA REQUEST PROGRESS REPORT</u></b>	<b><u>52</u></b>
<b>9.1 FAILURE TO MEET DUA OBLIGATIONS.....</b>	<b>53</b>
<b><u>10.0 PAYING FOR A RESEARCH ENVIRONMENT .....</u></b>	<b><u>53</u></b>
<b><u>11.0 PAUSING THE RESEARCH ENVIRONMENT .....</u></b>	<b><u>55</u></b>
<b><u>12.0 DEPROVISIONING THE RESEARCH ENVIRONMENT .....</u></b>	<b><u>55</u></b>
<b><u>13.0 DOWNLOADABLE DATA .....</u></b>	<b><u>56</u></b>
<b>13.1 TIPS FOR DOWNLOADING FILES FROM VIVLI .....</b>	<b>59</b>
<b><u>14.0 FEEDBACK AND SUPPORT.....</u></b>	<b><u>59</u></b>



## 1.0 Data Access Introduction

Your team's data request has been approved and your Data Use Agreement has been executed. Now that one of the studies from your request has been uploaded, your research team is able to begin analyzing the data. Depending on the access options available on your requested studies, you can either download the data ([See section 13.0](#) for more information) or you can access the data via a secure, cloud-based, isolated workspace known as a research environment.

- The Research Environment is a where users have access to various tools to analyze their data and conduct their research, including [R](#), [Python](#), [Jupyter](#), the Microsoft Office suite, STATA, and [SAS \(Academic-license only\)](#) depending on the type of the Research Environment selected. A [complete list of the software](#) included and versions in the Research Environment can be found on the Vivli website resources page.
- The Vivli Research Environment can also accept your own preferred analytical tools if you can provide the license key for the tool, or if it is an open-source tool. Your research team can load R packages from the CRAN repository yourself - R packages in other locations (such as Github) or Python packages can be added by the Vivli Team

## 2.0 Getting Started

- Once one of your requested studies data packages has been uploaded, you will be notified via email that your data is available.
- At this point, you may initiate the Secure Research Environment. Please note that only the Lead Researcher of the request can start the Research Environment.

Older research environment desktop

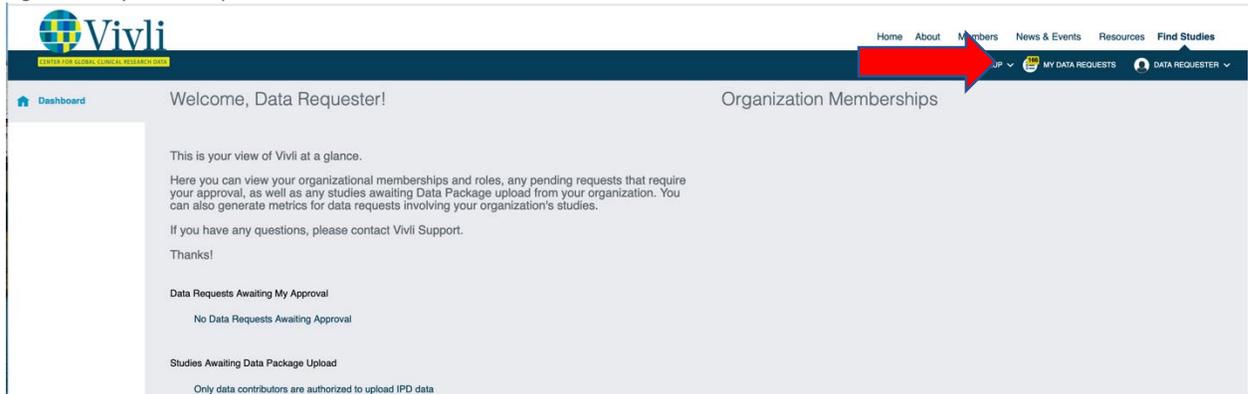
## Research environment desktop



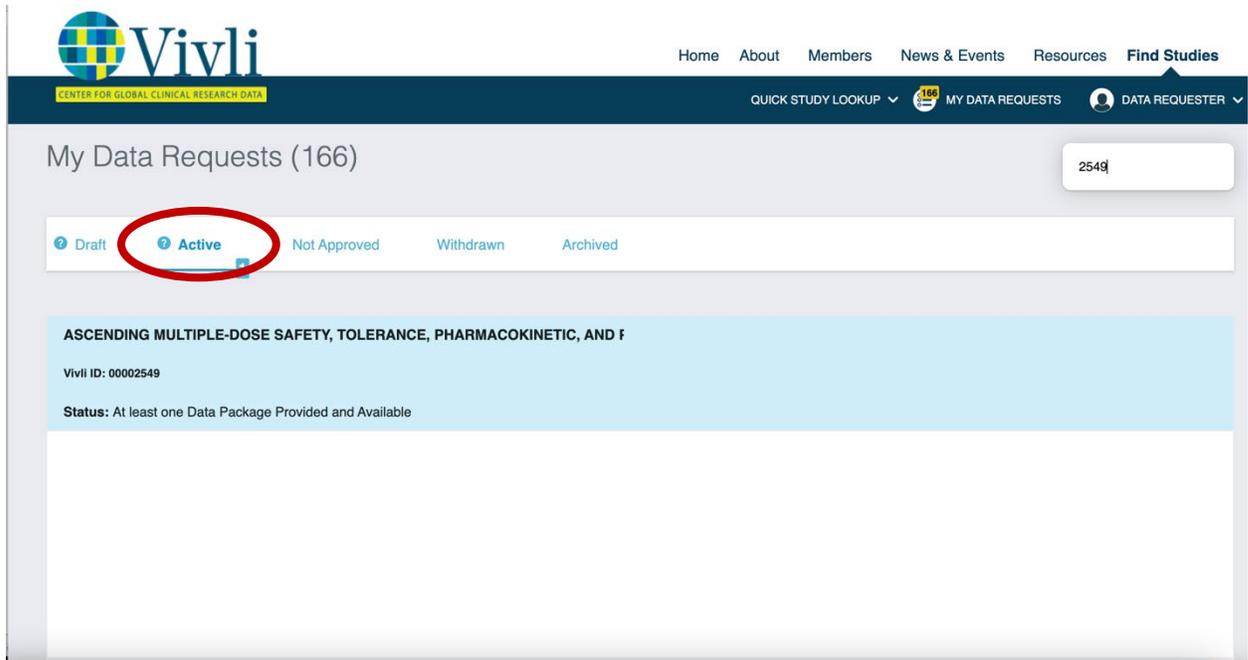
### 2.1 Locating the Data Request and seeing how many studies are available for analysis

1. Click on **My Data Requests** in the top right corner of the screen:

Figure 2 - My Data Requests

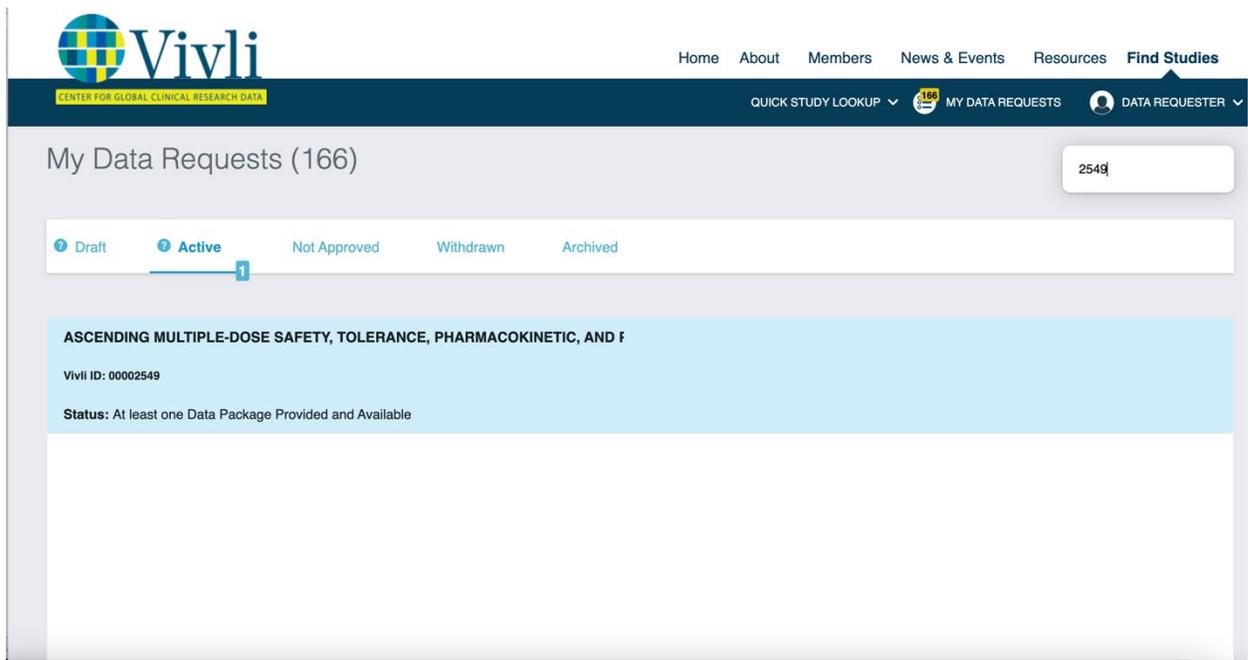


2. The request will appear under **Active**:



The screenshot shows the Vivli website interface. At the top, there is a navigation bar with the Vivli logo (Center for Global Clinical Research Data) on the left and links for Home, About, Members, News & Events, Resources, and Find Studies on the right. Below the navigation bar, there are dropdown menus for 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS' (showing 166 requests), and 'DATA REQUESTER'. The main heading is 'My Data Requests (166)' with a search input field containing '2549'. Below the heading is a filter bar with tabs: 'Draft', 'Active' (circled in red), 'Not Approved', 'Withdrawn', and 'Archived'. The 'Active' tab is selected, and a notification badge '1' is visible. Below the filter bar, a request card is displayed with the title 'ASCENDING MULTIPLE-DOSE SAFETY, TOLERANCE, PHARMACOKINETIC, AND F', 'Vivli ID: 00002549', and 'Status: At least one Data Package Provided and Available'.

3. If the request has been approved, the Data Use Agreement validated and the requested data from at least one requested study is available, the request will appear under “Active”, with a status of “At least one Data Package Provided and Available”



This screenshot is identical to the one above, showing the Vivli website interface. The 'Active' tab in the filter bar now has a blue notification badge with the number '1' next to it, indicating one active request. The rest of the page content, including the navigation bar, search field, and request card details, remains the same.

To determine **which** studies have been loaded, open the request and click on the Studies tab:

The screenshot shows the Vivli web application interface. At the top, there is a navigation bar with the Vivli logo and the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. The main navigation menu includes 'Home', 'About', 'Members', 'News & Events', 'Resources', and 'Find Studies'. Below this, there are links for 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'DATA REQUESTER'. The main content area is titled 'Ascending Multiple-dose Safety, Tolerance, Pharmacokinetic, and Pharmacodyna...' and includes a 'Print' button. On the left, there is a sidebar with the 'Studies' tab selected, and other options like 'Attachments', 'Request History', 'Signed Agreements', 'Safety Concerns', 'Chat', 'Research Team', 'Research Environment', and 'Request Details/Print View'. The main content area displays a list of studies under the heading 'VIVLI-LISTED AND PROVISIONED STUDIES'. The studies listed are:

- Ascending Multiple-dose Safety, Tolerance, Pharmacokinetic, and Pharmacodynam... (Awaiting Data Package upload by Data Contributor)
- A Patient Preference Evaluation Study of Fluticasone Furoate Nasal Spray and ... (Awaiting Data Package upload by Data Contributor)
- An Open Label Study of the Efficacy and Safety of Re-treatments With Rituxima... (Data Package Provided to Requestor)
- An Open Label, Non-comparative Study To Evaluate Parasitological Clearance Ra... (Awaiting Data Package upload by Data Contributor)

Below this list, there is a section for 'VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS'. At the bottom of the page, there is a footer with links for 'How To Guide', 'Privacy', 'Cookie Policy', 'EEA Disclosure Policy', and 'Contact Us', along with a copyright notice for 2017-2021 Vivli.

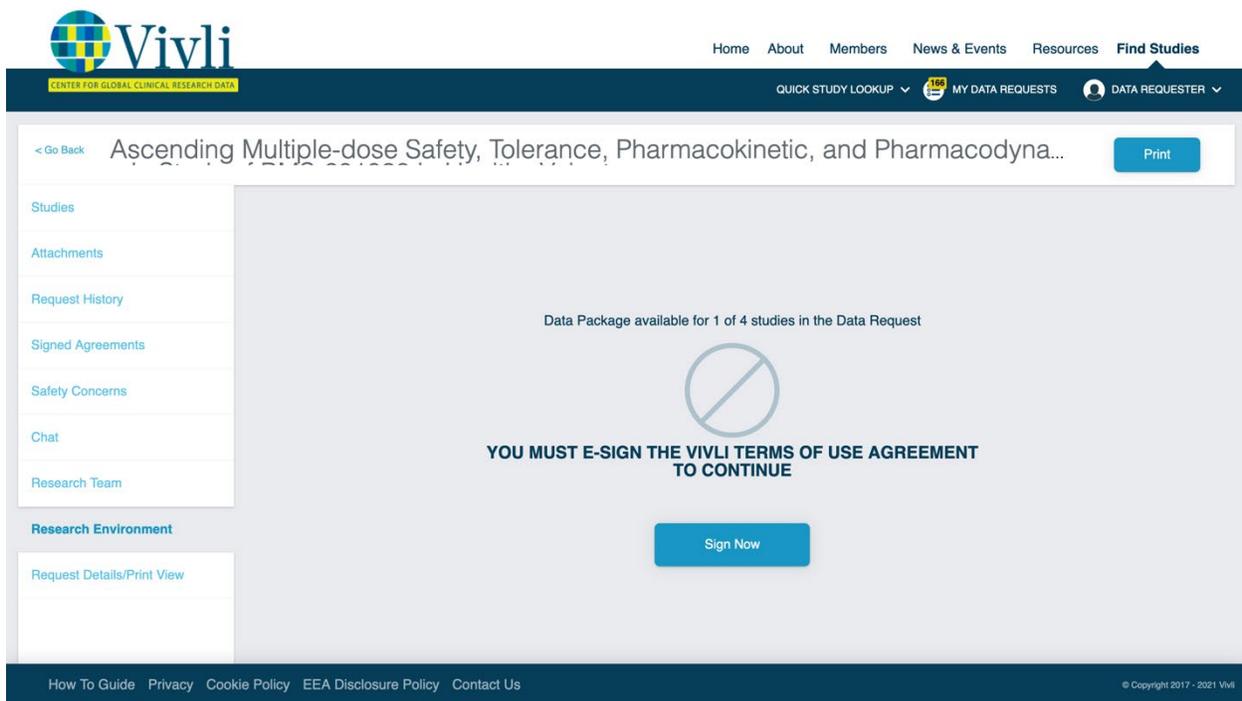
If you start the research environment before all of the data is available, then as additional data is made available, it will not automatically appear in the research environment– you will have to request that the new data be added to your research environment– see section “5.2 How to add additional data to your research environment as it becomes available”

## 2.2 Starting the Secure Research Environment

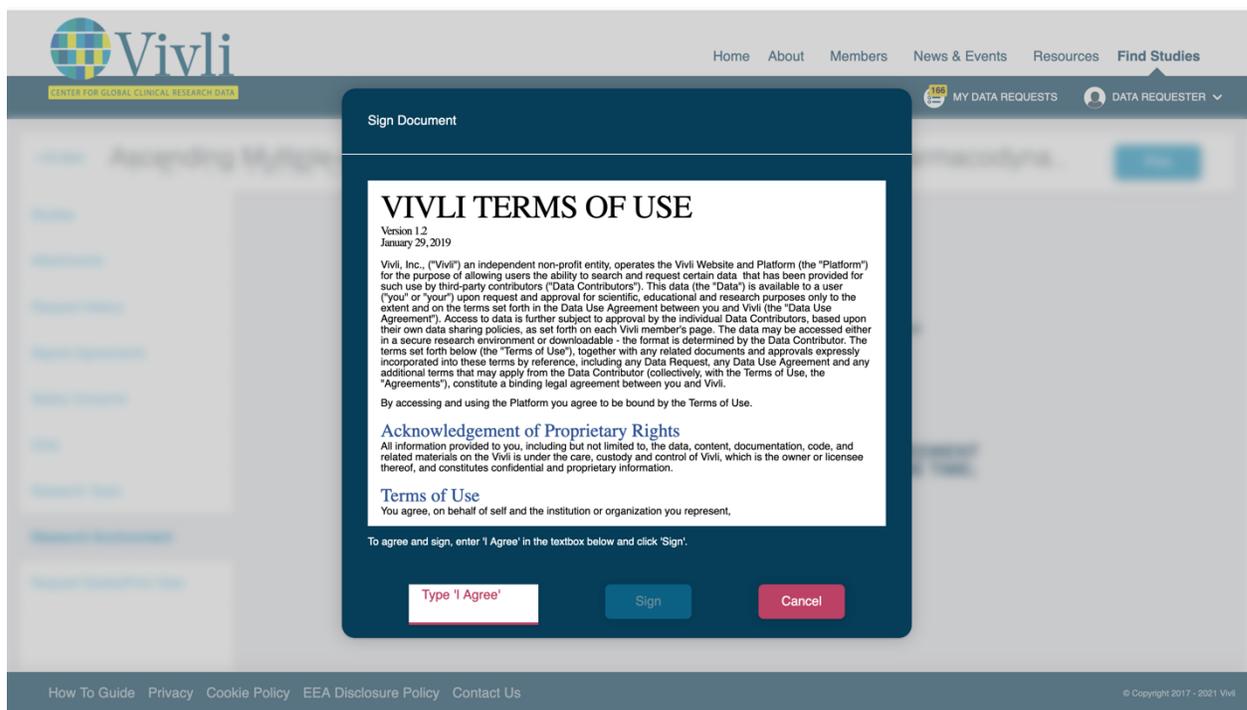
Once you have opened your request, click on the **Research Environment** tab on the left-hand side of your screen to begin initiating the environment.

Note: only the **Lead Researcher** may initiate the Research environment.

Please read and acknowledge the Vivli Terms of Use for the Research Environment. Click on **Sign Now**:



The following pop-up window will appear:



Type **I Agree** in the dialogue box and click **Sign**.

Each Team member accessing the Research Environment must Sign the Terms of Use when they first access the Research Environment.

The screenshot shows a web browser window with the Vivli logo and navigation menu at the top. A modal dialog box titled "Sign Document" is open in the center. The dialog contains the following text:

**VIVLI TERMS OF USE**  
Version 1.2  
January 29, 2019

Vivli, Inc., ("Vivli") an independent non-profit entity, operates the Vivli Website and Platform (the "Platform") for the purpose of allowing users the ability to search and request certain data that has been provided for such use by third-party contributors ("Data Contributors"). This data (the "Data") is available to a user ("you" or "your") upon request and approval for scientific, educational and research purposes only to the extent and on the terms set forth in the Data Use Agreement between you and Vivli (the "Data Use Agreement"). Access to data is further subject to approval by the individual Data Contributors, based upon their own data sharing policies, as set forth on each Vivli member's page. The data may be accessed either in a secure research environment or downloadable - the format is determined by the Data Contributor. The terms set forth below (the "Terms of Use"), together with any related documents and approvals expressly incorporated into these terms by reference, including any Data Request, any Data Use Agreement and any additional terms that may apply from the Data Contributor (collectively, with the Terms of Use, the "Agreements"), constitute a binding legal agreement between you and Vivli.

By accessing and using the Platform you agree to be bound by the Terms of Use.

**Acknowledgement of Proprietary Rights**  
All information provided to you, including but not limited to, the data, content, documentation, code, and related materials on the Vivli is under the care, custody and control of Vivli, which is the owner or licensee thereof, and constitutes confidential and proprietary information.

**Terms of Use**  
You agree, on behalf of self and the institution or organization you represent,

To agree and sign, enter 'I Agree' in the textbox below and click 'Sign'.

At the bottom of the dialog, there is a text input field containing the text "Type 'I Agree'" and "I Agree". A red circle highlights the input field. To the right of the input field are two buttons: "Sign" (blue) and "Cancel" (red).

=

## 2.3 Secure Research Environment Options

1. After you agree to the Terms of Use, the following options window will appear:

Data Package available for 1 of 1 studies in the Data Request  
Once the machine is started, the request cannot be sent back for revision.

Information on using the Research Environment is available [here](#).

RESEARCH ENVIRONMENT DETAILS

Advanced Options:

	Standard Environment	Premium Environment
Initial Cost	No charge for 365 days	No charge for 90 days
After Initial Period	\$12/Day after 365 days, 2 concurrent logins	\$25/Day after 90 days, 2 concurrent logins
Machine Size	2CPUx7GB	4CPUx14GB
Jupyter Notebook	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Python, R	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
STATA	<input type="checkbox"/>	<input type="checkbox"/>

Academic license for SAS.  
Alternative pricing applies for industry users of SAS, email [support@vivli.org](mailto:support@vivli.org) for details.

Start Standard Environment > Start Premium Environment >

2. Most research teams find that the standard environment meets their needs. If you need a larger environment, the Premium will normally suffice.

2b. If you need a dramatically larger environment, choose Advanced Options for additional environment size types. Please note that if you choose a larger size, you cannot move to a smaller size, but you can start with a smaller size and upgrade to a larger size research environment. In addition, the no charge period will change based upon the larger machine size that is used and will consider the no charge time already provided. For example, if you move from a standard to a premium, after 90 days, you will not be entitled to a further 90 days of no charge.

Data Package available for 1 of 1 studies in the Data Request  
Once the machine is started, the request cannot be sent back for revision.

Before starting the Research Environment, read the short introduction [here](#).

RESEARCH ENVIRONMENT DETAILS

Advanced Options:

	Premium Environment	Large Environment	Compute Optimized Environment	Memory Optimized Environment	Compute Optimized
Initial Cost	No charge for 90 days	\$65/Day	\$125/Day	\$275/Day	\$220/D
After Initial Period	\$25/Day after 90 days, 2 concurrent logins	\$65/Day	\$125/Day	\$275/Day	\$220/D
Machine Size	4CPUx14GB	16CPUx64GB	32CPUx64GB	64CPUx128GB	64CPUx50
Jupyter Notebook	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Python, R	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
STATA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Academic license for SAS.  
Alternative pricing applies for industry users of SAS, email [support@vivli.org](mailto:support@vivli.org) for details.

Start Premium Environment > Start Large Environment > Start Optimized Environment > Start Memory Optimized Environment > Start Memory Optimized >

4. Select the research environment appropriate for your needs and check the boxes as desired for the software you require and click the button “Start Environment”.

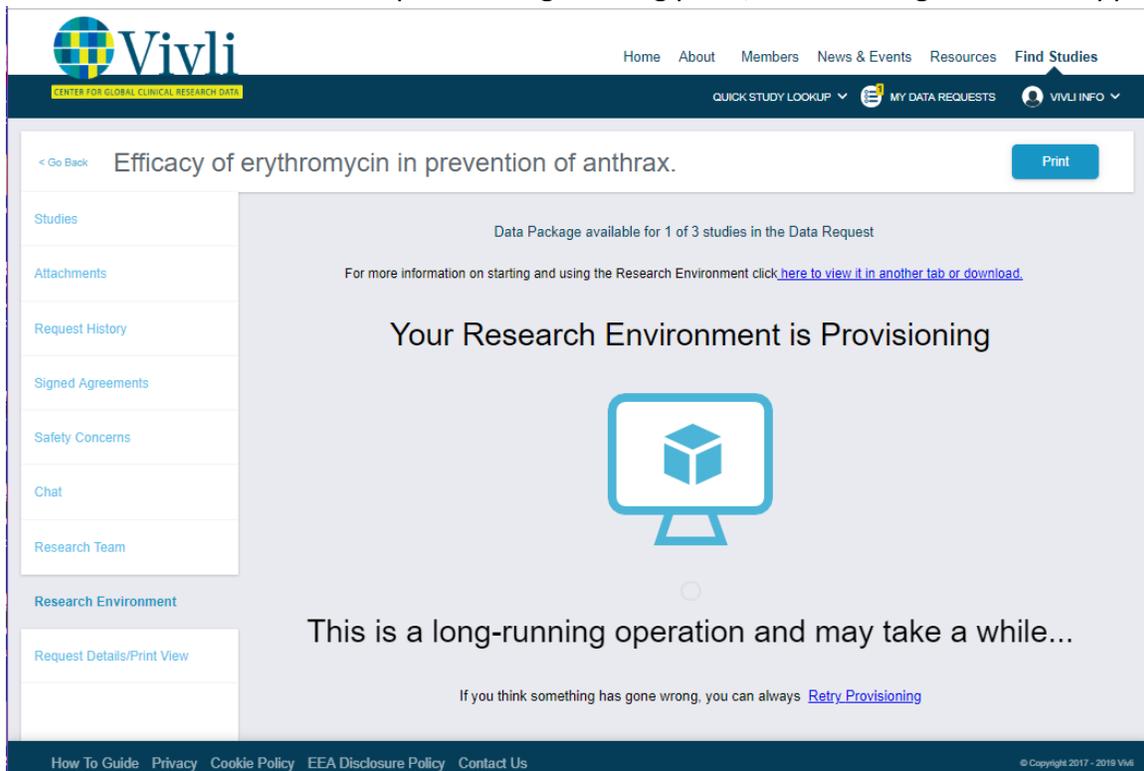
As you consider which environment to choose, if you don't want to use SAS, but if the data is provided as SAS data, the system includes three R-studio packages that can help:

- Foreign
- Haven
- SAS7bdat

When you click the "Start..." button, your selection is final, and the provisioning will begin. For more information, contact [support@vivli.org](mailto:support@vivli.org).

## 2.4 Initiating the Secure Research Environment

1. After selecting the size of the environment, the data will be provisioned into the Secure Research Environment. While provisioning is taking place, the following screen will appear:



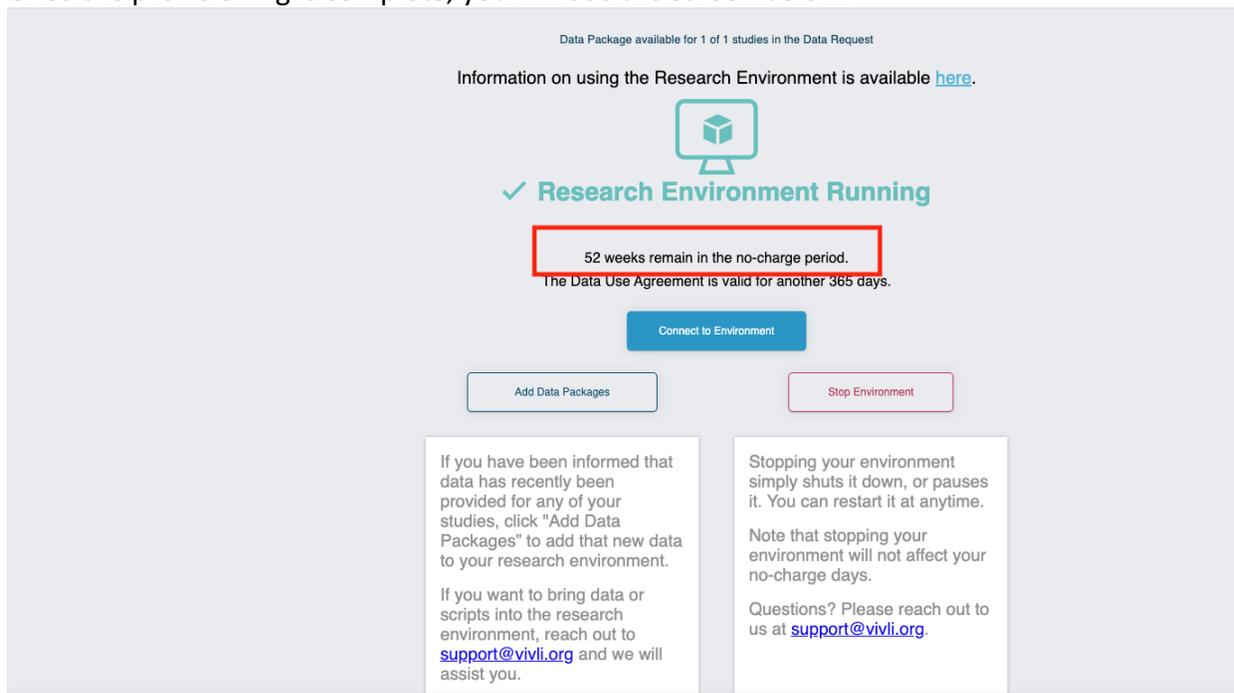
The screenshot shows the Vivli website interface. At the top, there is a navigation bar with the Vivli logo and the text "CENTER FOR GLOBAL CLINICAL RESEARCH DATA". The main navigation menu includes "Home", "About", "Members", "News & Events", "Resources", and "Find Studies". Below this, there are links for "QUICK STUDY LOOKUP", "MY DATA REQUESTS", and "VIVLI INFO". The main content area displays the title "Efficacy of erythromycin in prevention of anthrax." with a "Print" button. A sidebar on the left contains a list of menu items: "Studies", "Attachments", "Request History", "Signed Agreements", "Safety Concerns", "Chat", "Research Team", "Research Environment", and "Request Details/Print View". The central message reads: "Data Package available for 1 of 3 studies in the Data Request. For more information on starting and using the Research Environment click [here to view it in another tab or download](#). Your Research Environment is Provisioning". Below this is an icon of a computer monitor displaying a cube, and a progress indicator. The text continues: "This is a long-running operation and may take a while...". At the bottom, it says: "If you think something has gone wrong, you can always [Retry Provisioning](#)". The footer contains links for "How To Guide", "Privacy", "Cookie Policy", "EEA Disclosure Policy", and "Contact Us", along with the copyright notice "© Copyright 2017 - 2019 Vivli".

2. While the system is provisioning, you can exit this screen and allow the provisioning to proceed in the background. You will receive an email when the process is complete. This process typically takes 20-25 minutes.

## 3.0 Access to the Environment

### 3.1 Accessing the Secure Research Environment

1. Once the provisioning is complete, you will see the screen below:



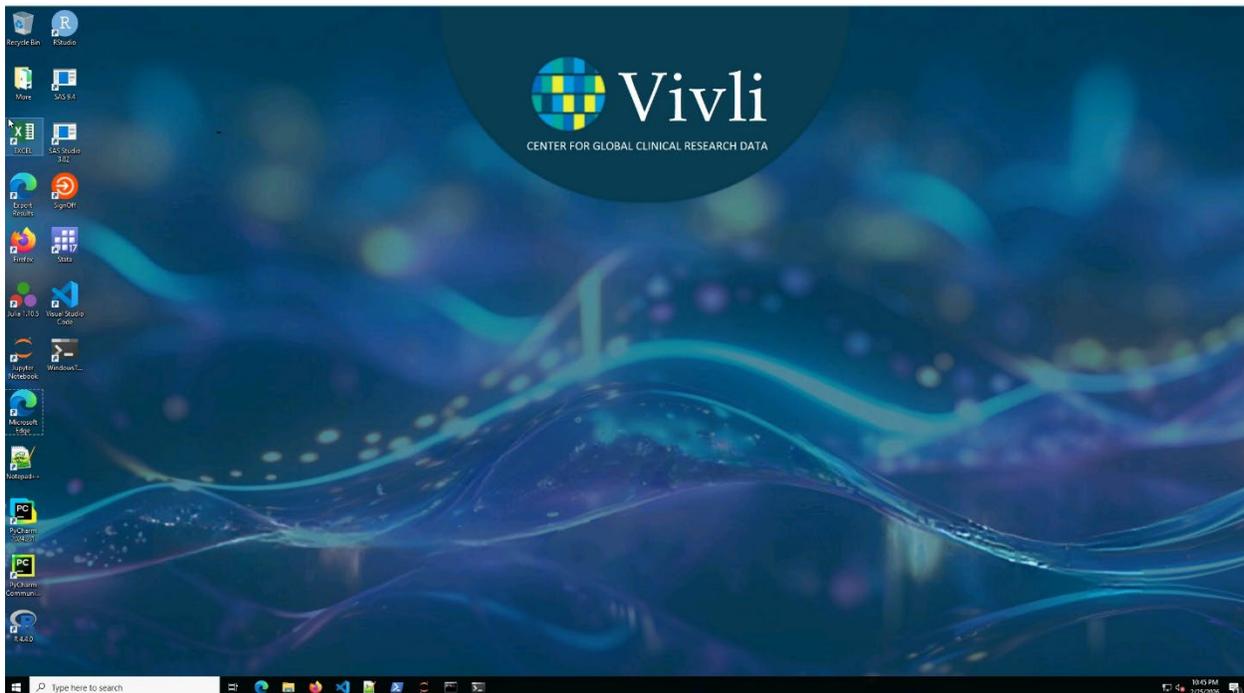
2. Then click on the box "Connect to Environment"

2. Connect to Environment

The number of weeks remaining in the no-charge period is calculated from when the research team starts the research environment. The number of weeks will be rounded up to the nearest number of weeks, including 1 week if less than 7 days remain. (e.g. "3 days" would display as "1 week"). Once there is no time remaining, the message is no longer shown on the screen.

3. After clicking on "Connect to environment," the secure research environment will load in a new browser tab.
4. The secure research environment home screen opens automatically:



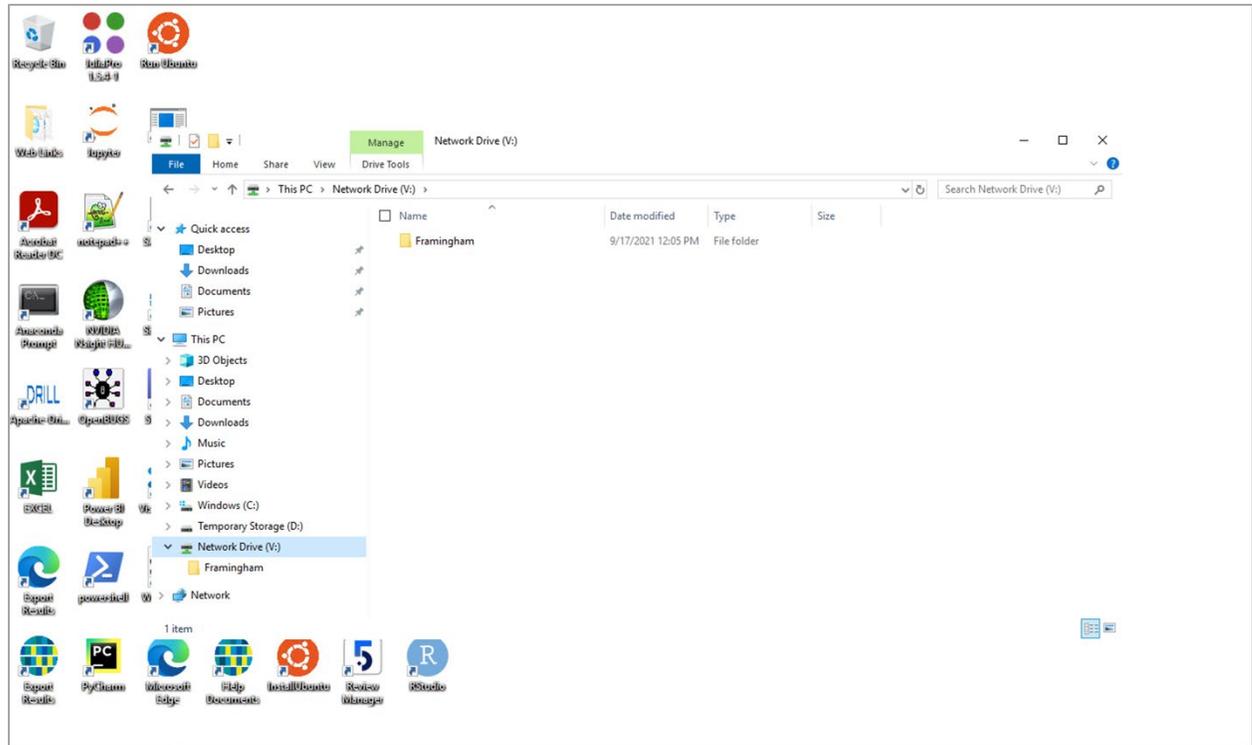


- Note that the first time you connect to the secure Research Environment, the system will be slower than normal as the system does some first-time configuration.

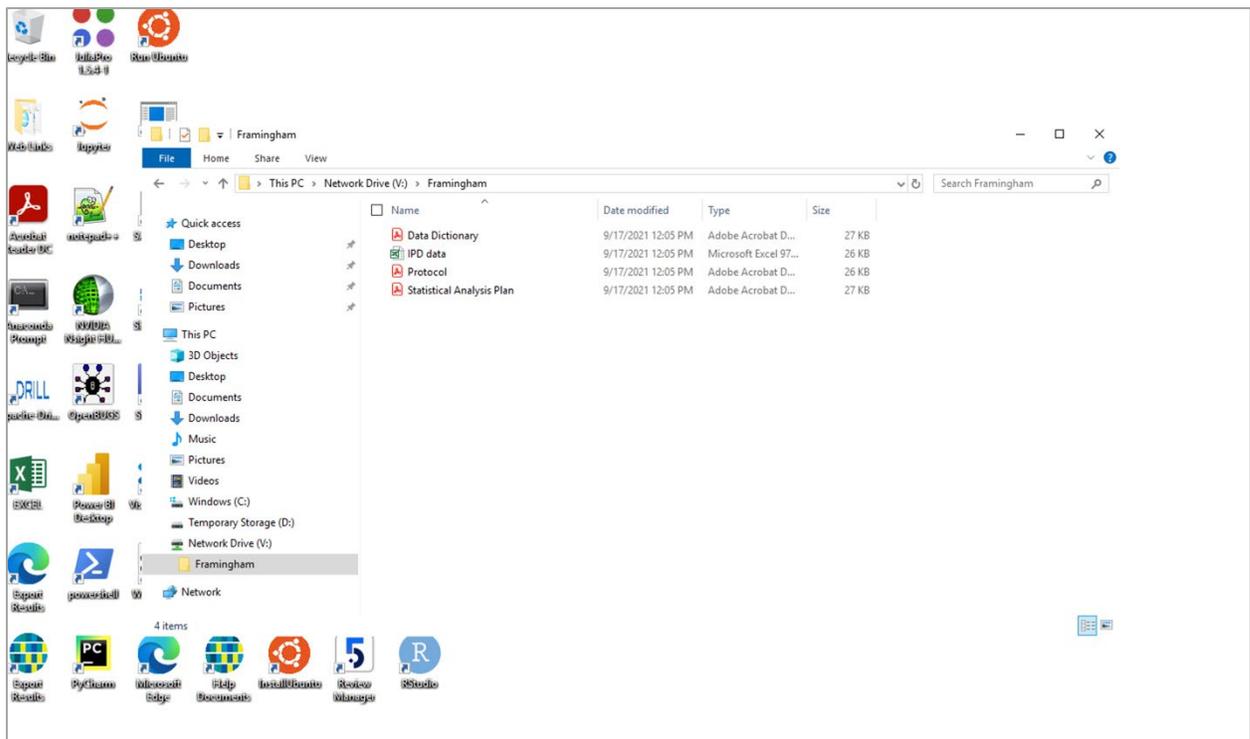
## 3.2 Working in the Research Environment

### 3.2.1 Finding your data and using space

#### 1. Open Disk V:



2. In the Network Drive (drive V: ) you will find one folder for each study that has been provided –the folder name will be the sponsor-assigned ID. Unlisted studies will appear with the ID you used to request the study. Within the ID, some characters that are not allowed for filenames will be replaced by an underscore character, including `\.:*?*<>|`



**Do not place any important data onto the temporary storage drive D: when the machine is stopped, even temporarily, the temporary storage will be deleted.**

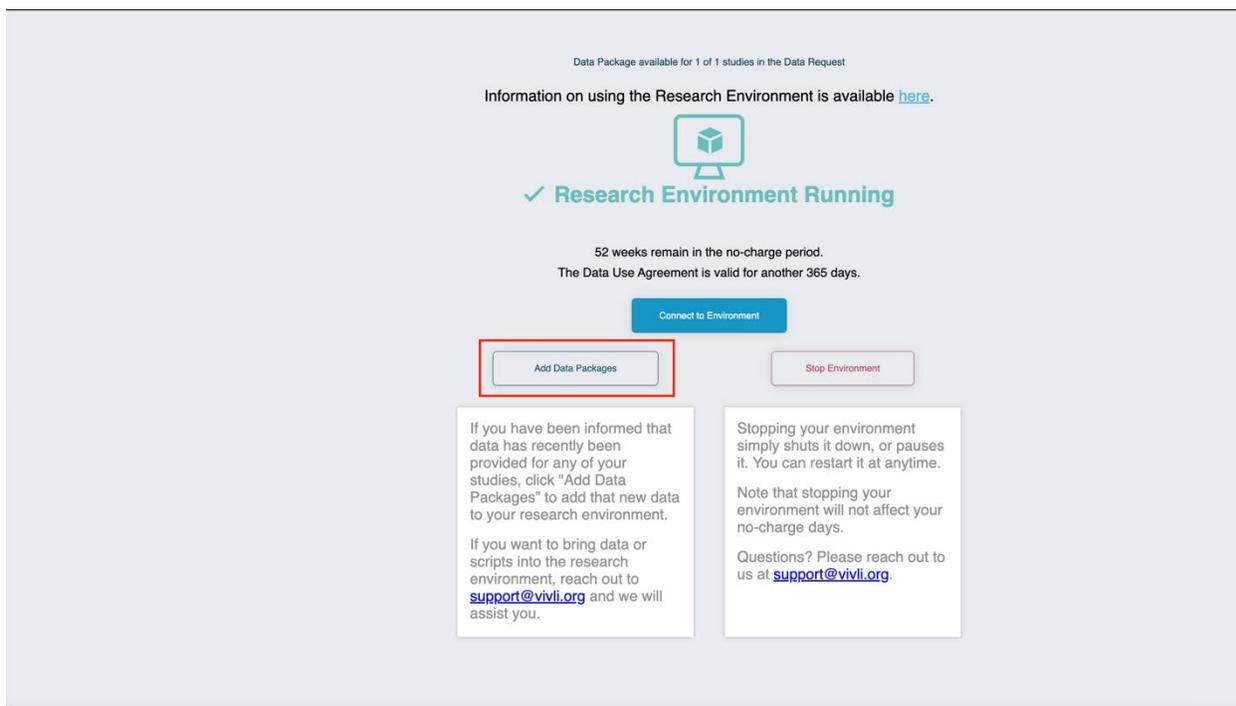
If the data has been provided in the form of a zip file, you can open the file as though it were a folder, and read the files in the zip file, but you will not be able to modify them in-place. To modify the files, you will need to copy the file(s) to a new, un-zipped folder. Alternatively, if you drag the icon representing the zip file onto another folder, 7-zip will offer to extract all of the files.

Additional network space will expand as you add files, up to a terabyte. We recommend that you not put anything but transient data onto C: drive. Data on the V: drive will be placed into long-term storage after you have completed your analysis.

**If you have questions about the data and what has been provided, use the Chat function within the Vivli platform. Please direct questions about the source data to the data contributors. Responses to questions about the source data is at the discretion of the data contributor.**

### 3.2.2 If you started before all of the data was available

If you have decided to start before *\*all\** of the data is available, then when additional data is provided by the contributor, it won't be added to your research environment automatically. [See Section 5.0](#) for instructions on how to load newly provided data.



### 3.2.3 Additional Tips for working in the Research Environment

From the research environment tab, you can review the (1) remaining no-charge period left in the environment and (2) the number of valid days remaining for the Data Use Agreement (DUA). –

- The no-charge period refers to how many weeks remain before billing will start for the environment selected (refer to Section 11.0 Paying for the Research Environment).
- When the no-charge days are less than 30 Days, the message is displayed **in red**.
- The DUA is valid for one year from the date it is signed and a request for extension will be required to continue analysis beyond this date (refer to Section 10.0 Extensions to the Data Use Agreement via the Data Request Progress Report).



### 3.3 Disconnecting from the research environment

- When you are done working with the research environment, unless you are leaving a long-running analysis running, we recommend that you Sign Out – this will free up memory and will allow other members of the research team to use the research environment.

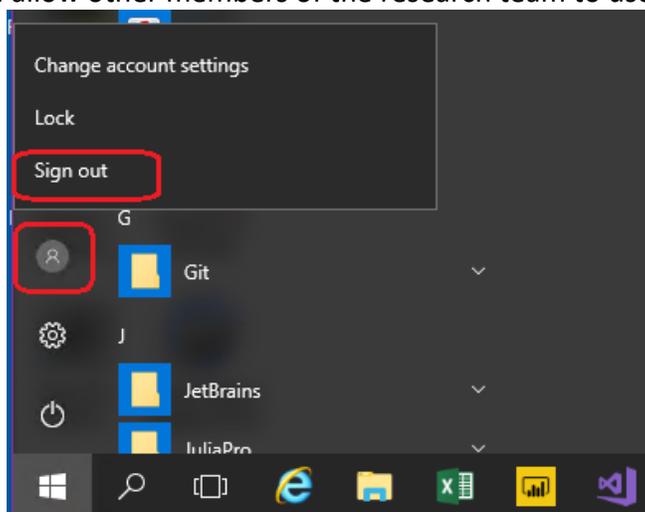
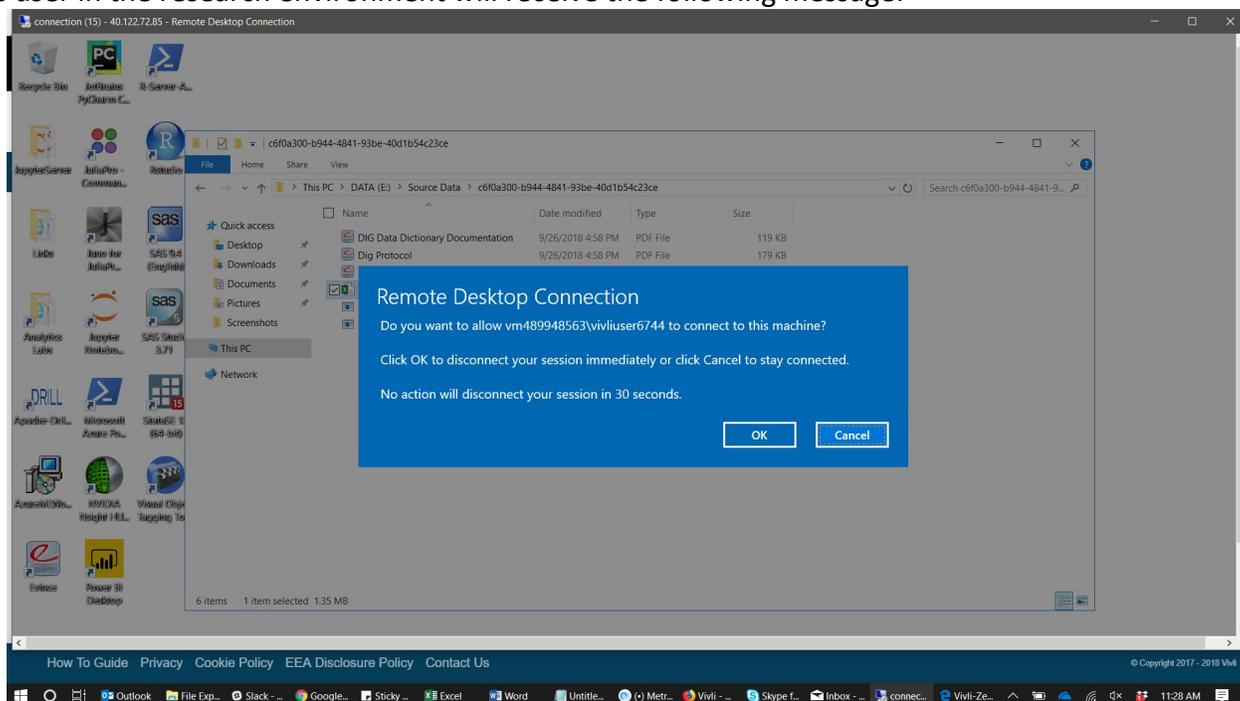


Figure 17 – How to Sign-out

- There is also an option to Sign Out by selecting the SignOff icon from the desktop.



- The user in the research environment will receive the following message:



- The user in the research environment must click **OK** to disconnect and allow their team member access. Save your work regularly, and especially before disconnecting.

### 3.4 Team Access to Secure Research Environment

- All members of the research team working in the research environment must have a signed Data Use Agreement (DUA) and have completed data access training. If a research team member is part of the same institution as the Principal Investigator, they are covered under the Principal Investigator’s DUA. If a team member is from another institution, they must sign a DUA before accessing the research environment.
- To add a user, the user must first create an account using the “Sign-up” link on the initial page. For information on creating an account, see the [User Quick Start Guide](#)

ADDITIONAL RESEARCHER  Activate user for accessing data request ?

First Name Richard	Last Name Anderson	ORCID ID ?
Email (editable until user is invited to data request) randerson@harvard.edu		Position at current organization Doctor
Employer, Company, Research Institute, or Primary Affiliation ? Brigham and Women's Hospital	Country United States of America	
Education, including professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. ? Medicine		
Name of the degree Doctor	Institution from where the degree was received Harvard	
Discipline ? Medicine	Year Received 1980	How many years of experience with secondary analysis 1-5 years
Please list any real or potential conflicts of interest and describe how these will be managed. If none, please enter None. None		

- When the research team is activated to access the data request, the request will appear on their “My Data Requests” screen and they will be given access to the data request. Once Vivli has validated that they are covered by a signed Data Use Agreement and have completed data access training, they will be given access to the research environment.
- Once your request has been submitted, you are unable to make changes to the research team. If you need to add or remove research team members, contact [support@vivli.org](mailto:support@vivli.org).

### 3.5 Adding additional software, tools and data during your analysis

During the course of your analysis, if you find that you need to load R scripts from the CRAN repository, you can do that yourself using the following steps:

- To install a CRAN package in R, use the `install.packages()` function. This simple command downloads the package from a specified repository (by default, CRAN) and installs it on your machine.
- If your research environment was provisioned before June 1<sup>st</sup>, 2023, please reach out to the Vivli Technical Team via [support@vivli.org](mailto:support@vivli.org) and we will complete a one-time update to point your machine to the latest replica of CRAN.

If you need any other R or Python scripts not pre-installed in the Vivli Research Environment, reach out to Vivli via chat or [support@vivli.org](mailto:support@vivli.org) and let them know the names of the additional scripts that you require and they will add them to your research environment. Any scripts that you have written or GitHub packages can be emailed to [support@vivli.org](mailto:support@vivli.org) and they will be added to the research environment; please include the request number of your environment to help Vivli locate the correct environment.

If you have additional software, please email Vivli at [support@vivli.org](mailto:support@vivli.org) with the name of the software and any license key, if required. If this software was not included in your request, Vivli

will need to reach out to the data contributors involved and ask for their agreement to include this software or data.

If you wish to add additional study data that is available on Vivli after your request is approved, you will need to submit a new request. Please note that this process can take an additional 2-5 months for review, approval and uploading of the additional data. Vivli strongly recommends that all studies needed for analysis are included before submitting your data request.



**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

## 4.0 Stopping and Starting the Research Environment

### 4.1 Stopping or Pausing the research environment

- Stopping the research environment is like powering off your laptop: nothing is lost, and the environment can be restarted quickly (less than 5 minutes).
- If you expect to leave the research environment idle for several days or longer, we recommend that you stop the Research Environment
- When you are ready to use the Research Environment again, you may restart it and the environment will be restarted with all the saved data as you left it.

## To Stop the Research Environment:

1. Login to the Vivli Platform
2. Navigate to the Research Environment, and click on the button “Stop Environment”:

The screenshot shows the Vivli Research Environment dashboard. On the left is a navigation menu with items: Studies, Attachments, Request History, Signed Agreements, Safety Concerns, Research Results, Chat, Research Team, Research Environment (highlighted), Public Disclosures, and Request Details/Print View. The main content area has a header: "Information on using the Research Environment is available [here](#)." Below this is a green checkmark icon and the text "✓ Research Environment Running". A status message says "365 Days remain in no-charge period. The Data Use Agreement is valid for another 365 days." There are three buttons: "Connect to Environment" (blue), "Add Data Packages" (grey), and "Stop Environment" (grey, highlighted with a red border). Below the buttons are two informational boxes. The left box explains how to add data packages and provides the support email [support@vivli.org](mailto:support@vivli.org). The right box explains that stopping the environment pauses it and also provides the support email [support@vivli.org](mailto:support@vivli.org). The footer contains links for "How To Guide", "Privacy", "Cookie Policy", "EEA Disclosure Policy", and "Contact Us", along with a copyright notice "© Copyright 2017 - 2024 Vivli".

This will stop the secure research environment.

Note: Once you click “Stop Environment”, billing and no-charge time will not automatically pause. Please reach out to the Vivli team if you would like to pause your billing and the Vivli team will provide next steps.

## 4.2 Restarting the research environment

To restart the research environment:

1. Login to the Vivli Platform
2. Navigate to the research environment; the start button will be where the Stop button was located:

Data Package available for 3 of 5 studies in the Data Request

Information on using the Research Environment is available [here](#).



### Research Environment Stopped

351 Days remain in no-charge period.  
The Data Use Agreement is valid for another 351 days.

[Add Data Packages](#) [Start Research Environment](#)

If you have been informed that data has recently been provided for any of your studies, click "Add Data Packages" to add that new data to your research environment.

If you want to bring data or scripts into the research environment, reach out to [support@vivli.org](mailto:support@vivli.org) and we will assist you.

Stopping your environment simply shuts it down, or pauses it. You can restart it at anytime.

Note that stopping your environment will not affect your no-charge days.

Questions? Please reach out to us at [support@vivli.org](mailto:support@vivli.org).

3. Click on **Start Research Environment** – the platform will tell you that the research environment is starting:

The screenshot shows the Vivli web interface. At the top left is the Vivli logo with the tagline 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. 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 DATA REQUESTER. A status bar at the top indicates 'Request: 48056, Title: Liz - testing study added to request in process' and 'Status: At least one Data Package Provided and Available'. A 'Print' button is visible in the top right. The main content area features a large heading 'Your Research Environment is Starting' above a computer monitor icon displaying a cube. Below the icon, it says 'This is a long-running operation and may take a while...' and 'If you think something has gone wrong, you can always [Retry Starting](#)'. A left sidebar contains a menu with items like Studies, Attachments, Request History, Signed Agreements, Safety Concerns, Research Results, Chat, Research Team, Research Environment (highlighted), Public Disclosures, and Request Details/Print View. The footer contains links for How To Guide, Privacy, Cookie Policy, EEA Disclosure Policy, and Contact Us, along with a copyright notice for 2017-2024 Vivli.

4. After approximately 5 minutes, the system will display the “Running” screen:

The screenshot shows the Vivli web interface with the 'Research Environment Running' screen. The main heading is 'Information on using the Research Environment is available [here](#).' Below this is a computer monitor icon displaying a cube with a checkmark, followed by the heading '✓ Research Environment Running'. The text indicates '365 Days remain in no-charge period. The Data Use Agreement is valid for another 365 days.' There are three buttons: 'Connect to Environment' (blue), 'Add Data Packages' (grey), and 'Stop Environment' (red). Below these are two informational boxes. The left box explains that if data has recently been provided for any studies, users should click 'Add Data Packages' to add that new data to their research environment. It also notes that if users want to bring data or scripts into the research environment, they should reach out to [support@vivli.org](mailto:support@vivli.org). The right box explains that stopping the environment simply shuts it down or pauses it, and that users can restart it at any time. It also notes that stopping the environment will not affect their no-charge days and provides the contact information [support@vivli.org](mailto:support@vivli.org). The left sidebar and footer are identical to the previous screenshot.

After restarting the machine, the first login may take a few minutes.

## 5.0 Adding Data Packages to the Research Environment

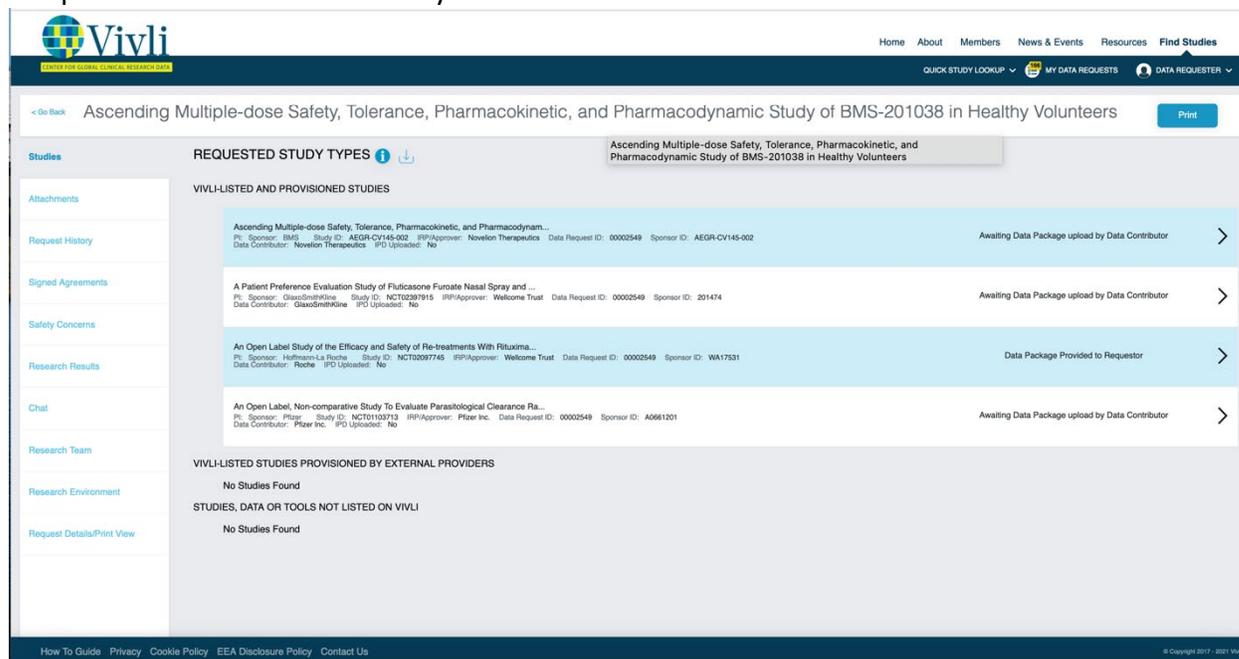
If you started the Research Environment before all the data was provided, then as additional data packages are loaded into the system, they will not be placed into your Research Environment automatically. You will however receive an email notification that additional data has been provided. When you are ready, you can ask the system to add the additional data packages to your Research Environment.

### 5.1 How will you know when data is available?

As additional data packages are loaded into the system and made available, you will receive an email notification. Within the Vivli Platform, you can look at the “Active” tab, select the request you are interested in:

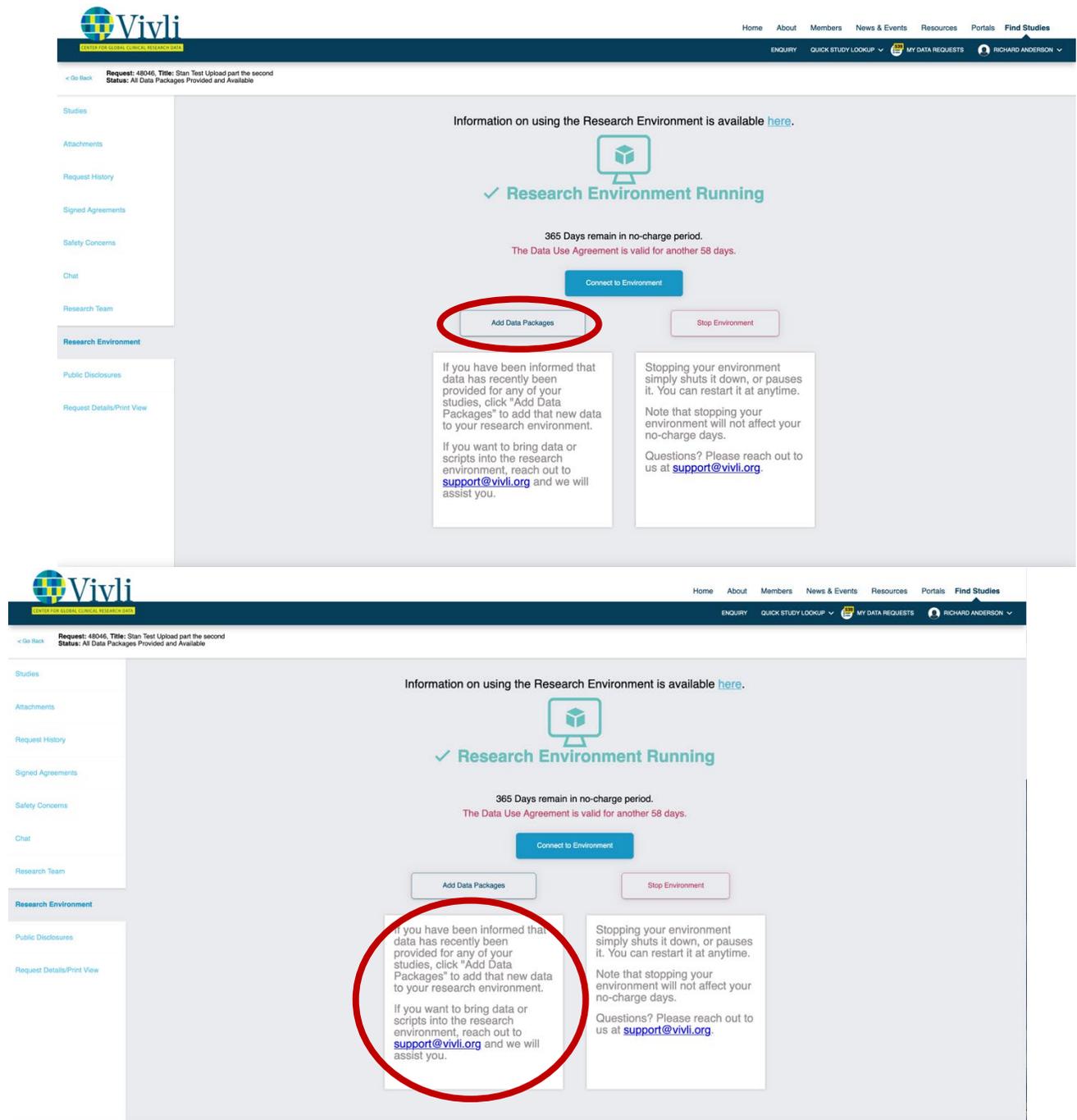


To determine **which** studies have been uploaded, click on the studies tab, and this page will provide a status of each study:



## 5.2 How to add additional data to your research environment as it becomes available

Once you have determined that you are ready to ask the platform to load the additional data into your research environment, open the data request, select the Research Environment tab, and click on the “Add Data Packages” button:



### 5.3 Refreshing previously loaded data

The Vivli platform determines what new data should be loaded by looking for an existing folder with the appropriate name: if it finds a folder in the Research Environment with the original folder name for the study, it will leave that existing folder alone. This means that:

- If you have started to make changes to previously loaded data (e.g. for harmonization), your changes will **not** be overwritten.
- If you would like a fresh copy of the data for any reason, you can simply rename the existing folder, and the system will load a fresh copy of the data package.
- If you rename a data folder for any other reason, the system will load a fresh copy of the data using the original folder name. If the extra copy is redundant, delete it.

## 6.0 Safety Concerns

If you discover any information regarding the safety or risks of a product related to their requested data, you must inform Vivli and the Data Contributor of this discovery within 24 hours, per the terms of the Data Use Agreement.

The steps for reporting safety concerns are as follows:

1. Login to the Vivli Platform.

2. Click on the “Safety Concerns” tab on the dashboard:

The following screen will appear:

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 the navigation bar, there is a header section with a breadcrumb trail: < Go Back Ascending Multiple-dose Safety, Tolerance, Pharmacokinetic, and Pharmacodynamic Study of BMS-201038 in Healthy Volunteers. A Print button is located in the top right corner of the header.

The main content area is divided into a left sidebar and a main form area. The sidebar contains several tabs: Studies, Attachments, Request History, Signed Agreements, Safety Concerns (which is currently selected), Research Results, Chat, Research Team, Research Environment, and Request Details/Print View. The main form area contains the following elements:

- A heading: Supply your contact information and safety concern description below, then click 'Submit Safety Concern' to continue.
- A form with three input fields:
  - Name: Data Requester
  - Email Address: Datarequester.vivli@gmail.com
  - Phone Number: (empty)
- A text area labeled Describe the Safety Concern.
- A Submit Safety Concern button.
- A section labeled Previously Submitted Safety Concerns, which is currently empty.

At the bottom of the page, there is a footer with links for How To Guide, Privacy, Cookie Policy, EEA Disclosure Policy, and Contact Us, along with a copyright notice: © Copyright 2017 - 2021 Vivli.

3. Complete the form and click on **Submit Safety Concerns**:

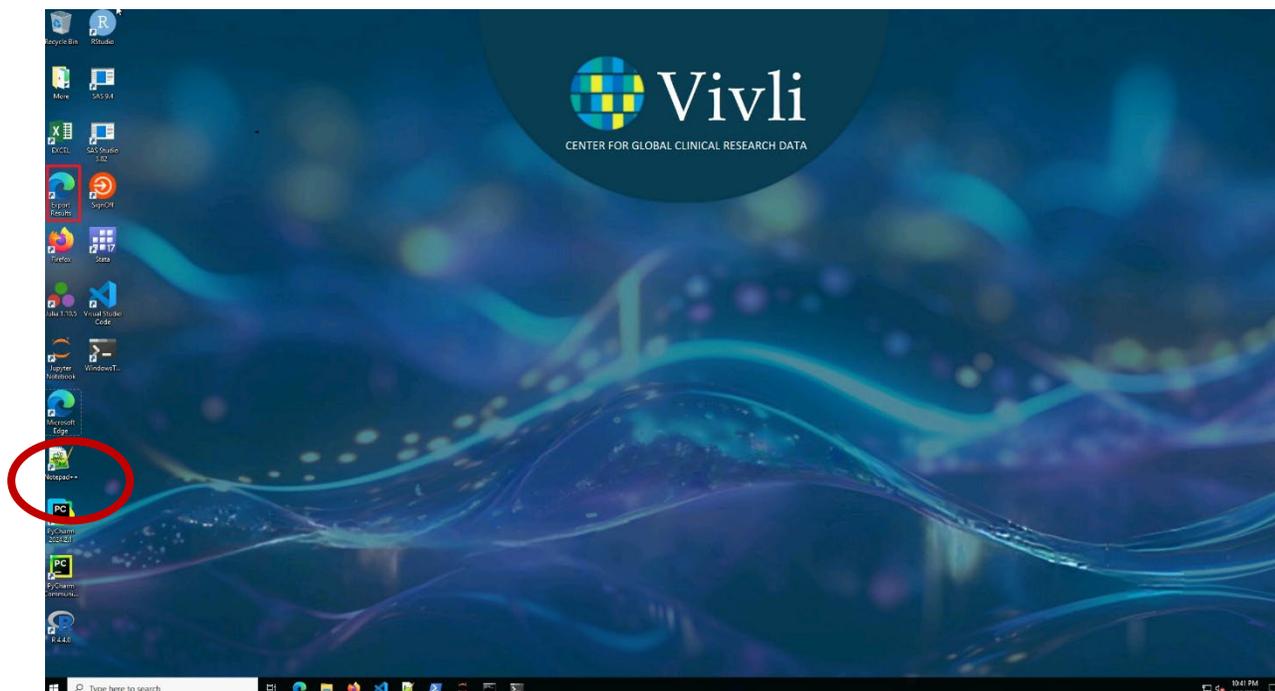
This screenshot shows the same Vivli web application interface as the previous one, but with the form fields filled out. The form now contains the following data:

- Name: Data Requester
- Email Address: Datarequester.vivli@gmail.com
- Phone Number: 555-555-5555
- Describe the Safety Concern: Safety concern

The Submit Safety Concern button is still present, and the Previously Submitted Safety Concerns section remains empty. The rest of the interface, including the sidebar and footer, is identical to the previous screenshot.

## 7.0 Exporting Research Results

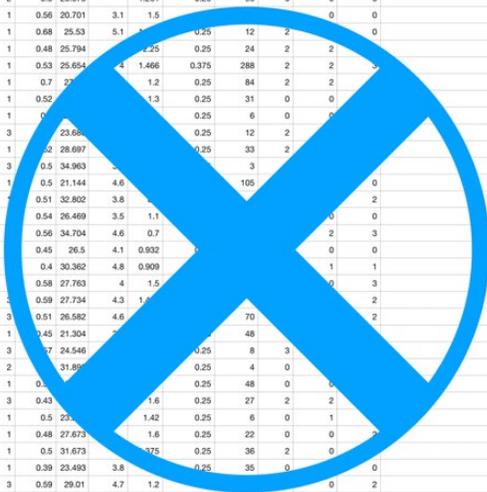
If you have preliminary or final results from your analysis, you may request the ability to export summary results from the Secure Research Environment. Any custom scripts you may have developed during the research can also be exported with the results. A shortcut to submit this request is on the desktop.



When submitting your request to export results, please note that Individual Participant Data (IPD) requested from this study will need to remain in the Vivli secure research environment. As such, there should be no attempt to try to remove IDP data or re-identify individual participants in the study you are requesting. Per your signed Data Use Agreement, any results derived from your analysis in the Vivli Research Environment, which will be used in subsequent presentation or publication, should be obtained by submitting a request for removal of this data.

Results exports should not include any individual participant data in the results. Acceptable results export is limited to summary representation of data (e.g. means, standard deviations, counts), derived data (e.g. slopes, clin pharm parameters) data, analytical and representations of results (e.g. graph), scripts or programs that you developed in the Research Environment. The following graphic is an example of a request to export results spreadsheet, including IPD, which would not be approved.

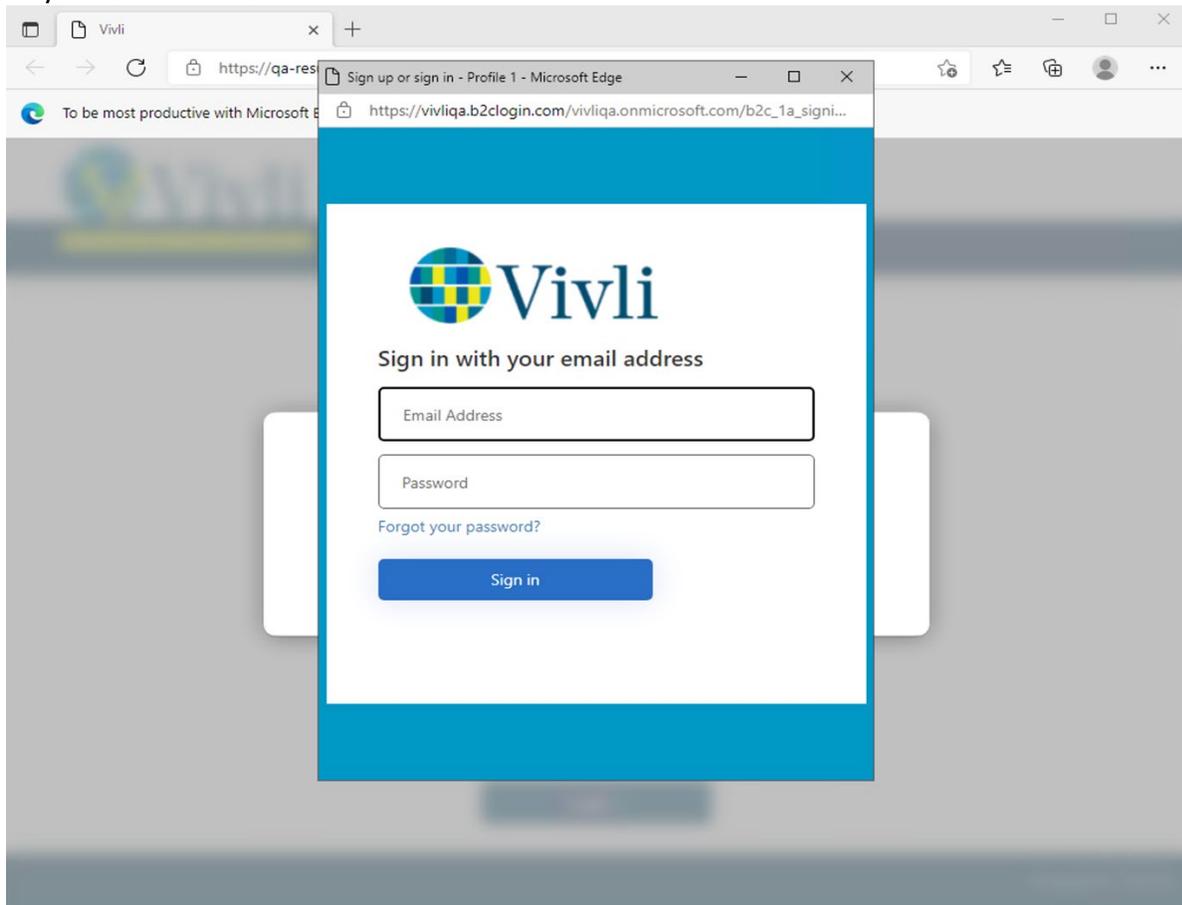
ID	TRMT	AGE	RACE	SEX	EJF_PER	EJFMETH	CHESTX	BMI	KLEVEL	CREAT	DIGDOSER	CHFDUR	RALES	ELEVJVP	PEDEMA	RESTDYS	EXERTDYS	ACTLIMIT	S3	PUL
1	0	66	1	1	40	2	0.5	20.073		1.261	0.25	96	0	0	0	0	1	1	0	
2	0	77	1	1	12	1	0.56	20.701	3.1	1.5						0	2	2	1	
3	0	72	1	2	36	1	0.68	25.53	5.1		0.25	12	2		0	2	3	3	0	
4	1	57	1	1	31	1	0.48	25.794		1.25	0.25	24	2	2		0	3	3	3	
5	0	74	1	1	15	1	0.53	25.654		1.466	0.375	288	2	2		2	2	0	0	
6	0	69	2	2	45	1	0.7	27.7		1.2	0.25	84	2	2		2	3	3	2	
7	1	64	1	2	30	1	0.52	27.7		1.3	0.25	31	0	0		0	1	0	0	
8	1	60	2	1	39	1	0.5	27.7			0.25	6	0	0		2	2	2	0	
9	0	74	2	1	33	3	0.5	23.62			0.25	12	2			2	3	3	2	
10	1	64	1	2	24	1	0.52	28.697			0.25	33	2			2	3	2	0	
11	1	61	1	2	44	3	0.5	34.963				3				3	3	3	0	
12	1	56	1	1	23	1	0.5	21.144	4.6			105		0		1	1	3	0	
13	0	66	1	2	42	2	0.51	32.802	3.8							2	1	3	3	
14	0	49	1	1	37	1	0.54	26.469	3.5	1.1						0	3	3	0	
15	0	74	1	1	39	1	0.56	34.704	4.6	0.7				2	3	0	2	3	3	
16	0	73	1	1	40	1	0.45	26.5	4.1	0.932				0	0	2	3	3	0	
17	1	69	2	1	30	1	0.4	30.362	4.8	0.909				1	1	1	1	1	1	
18	0	49	1	1	26	1	0.58	27.763	4	1.5				0	3	3	3	3	0	
19	1	65	1	1	20	2	0.59	27.734	4.3	1.6					2	2	2	3	2	
20	1	78	1	1	31	3	0.51	26.582	4.6	1.6		70		2		2	2	1	1	
21	1	71	1	1	37	1	0.45	21.304				48				2	1	1	0	
22	0	35	1	1	35	3	0.37	24.546			0.25	8	3			3	3	3	1	
23	1	56	1	2	11	2	0.31	19.94			0.25	4	0			3	3	1	0	
24	1	57	1	1	30	1	0.4	27.7			0.25	48	0			3	3	3	0	
25	0	76	1	1	25	3	0.43	27.7		1.6	0.25	27	2	2		2	3	3	3	
26	1	60	1	1	26	1	0.5	23.3		1.42	0.25	6	0	1		0	1	2	1	
27	0	65	2	2	34	1	0.48	27.673		1.6	0.25	22	0	0		0	2	2	2	
28	0	60	1	1	24	1	0.5	31.673		0.75	0.25	36	2	0		2	3	2	3	
29	1	69	1	1	41	1	0.39	23.493	3.8		0.25	35	0	0		0	2	0	3	
30	1	69	1	1	30	3	0.59	29.01	4.7	1.2				0	2	3	3	3	0	
31	1	74	1	2	30	3	0.72	24.691	3.8	1.5	0.25	84	0	0	0	0	3	3	0	



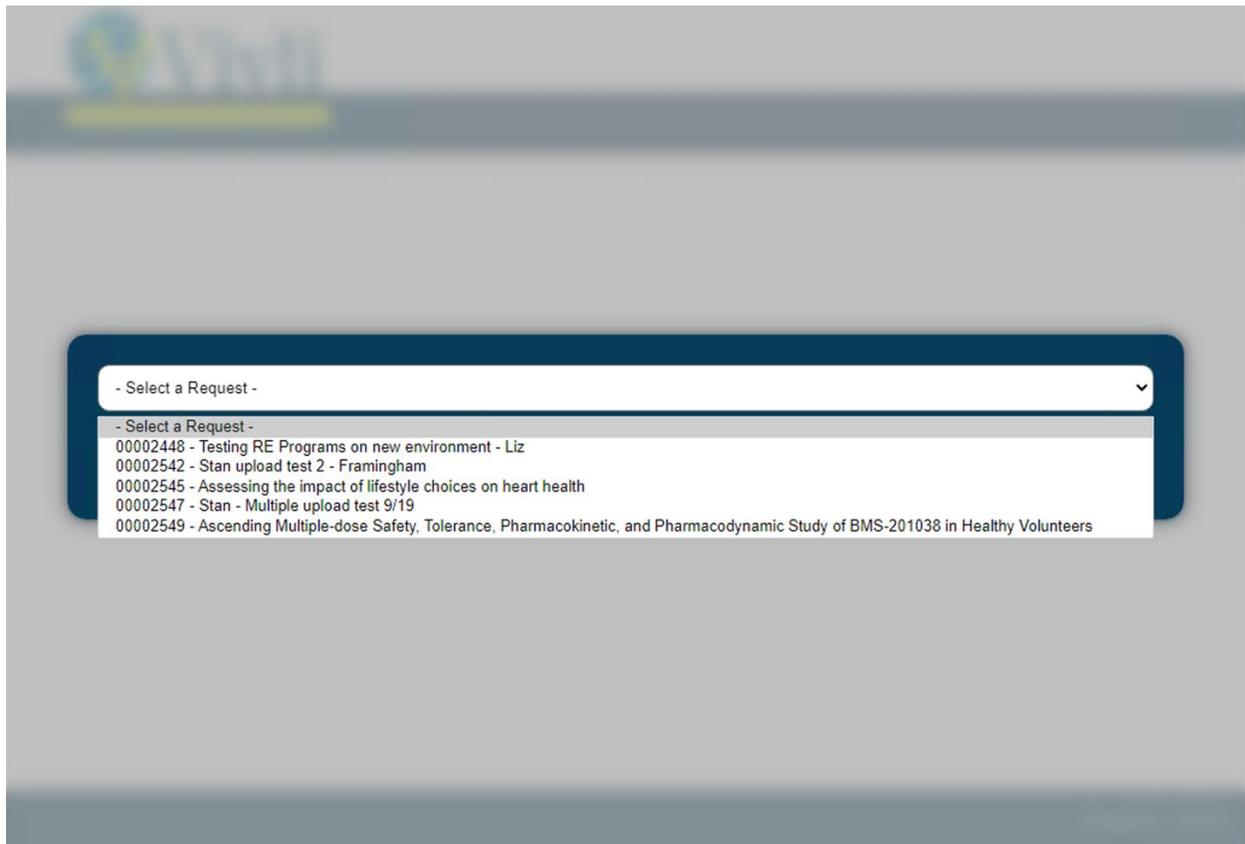
Please note that all results should be submitted through the results export option.

## 7.1 Request to Export Results

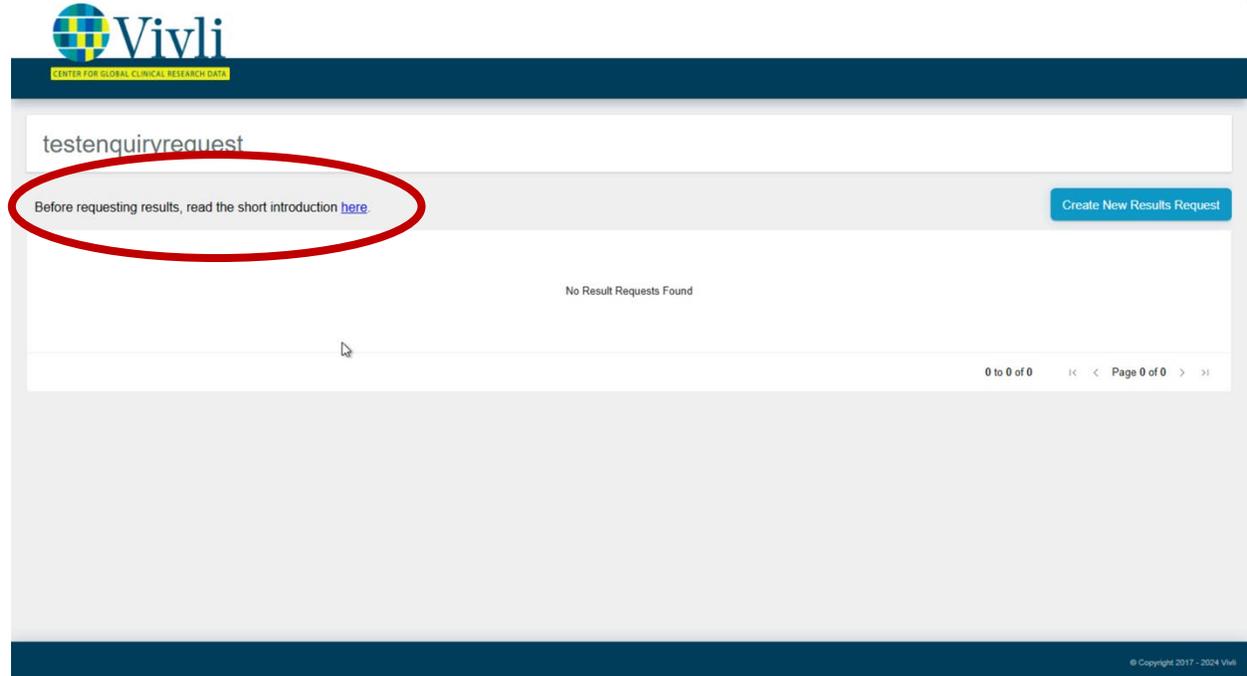
1. From the Vivli Research Environment, double click the Export Results icon on the Desktop.
2. Enter the Vivli User credentials you use to log onto the Vivli Platform – your username will be your email address.



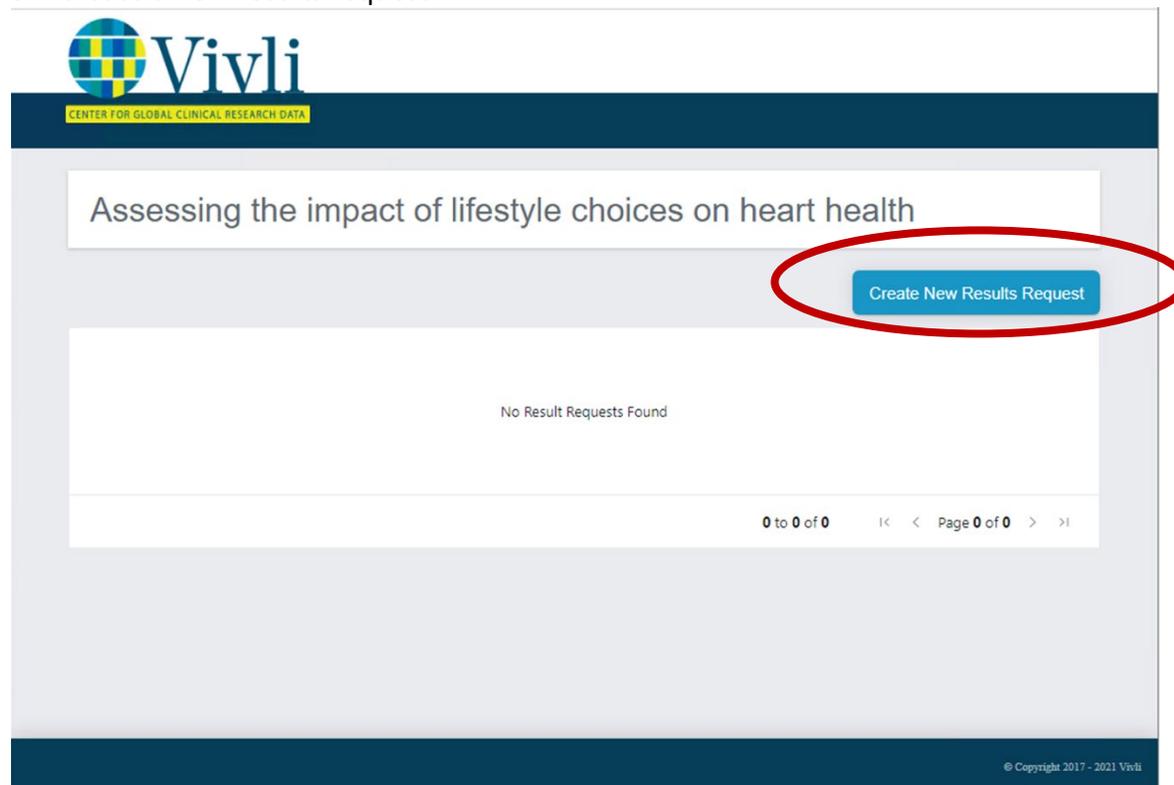
3. From the dropdown menu, select your Vivli request. Please note, if you have more than one Vivli request which has a secure research environment, each request will appear in the menu.

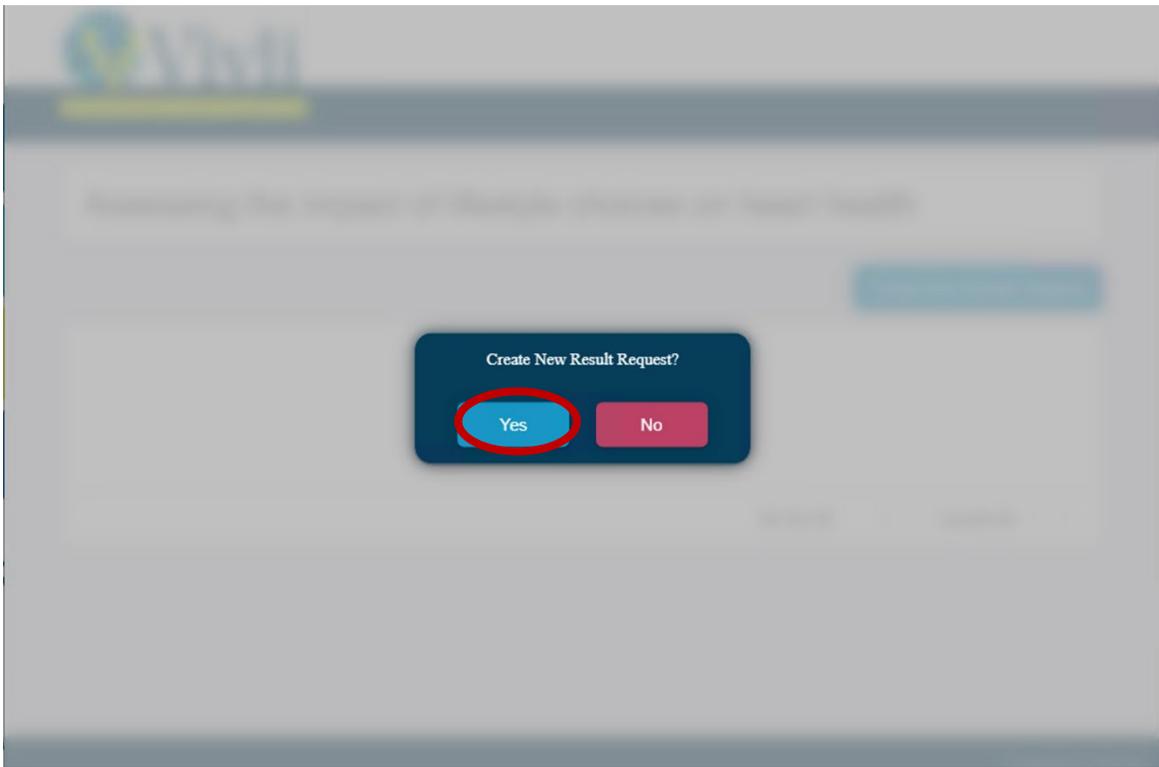


4. From the results export menu, select the help text to open the Vivli Research Environment guide. Section 8.0 Exporting Research Results has detailed instructions for submitting this request.



5. Create a new results request.





6. Drag and drop, or select files, to copy your files into the export folder. If your results are organized into more than one folder, we recommend that you place the files into a single zip file before placing them in the results folder. 7-zip is included on the research environment for that purpose. Similarly, if you have more than 5-10 files, place them into a single zip file.

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

## Assessing the impact of lifestyle choices on heart health

### Requesting export of research results

To request export of research results, use Drag and Drop to drop the requested files onto the "Drop files here" control, then click submit when they are complete. When the results have been reviewed and approved, you will connect to the main Vivli Platform to download the results. Reminder - exporting individual participant data is not allowed.

NO FILES IN PACKAGE

[Select Files](#) Drop files here

© Copyright 2017 - 2021 Vivli

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

## Assessing the impact of lifestyle choices on heart health

### Requesting export of research results

To request export of research results, use Drag and Drop to drop the requested files onto the "Drop files here" control, then click submit when they are complete. When the results have been reviewed and approved, you will connect to the main Vivli Platform to download the results. Reminder - exporting individual participant data is not allowed.

[Select Files](#)

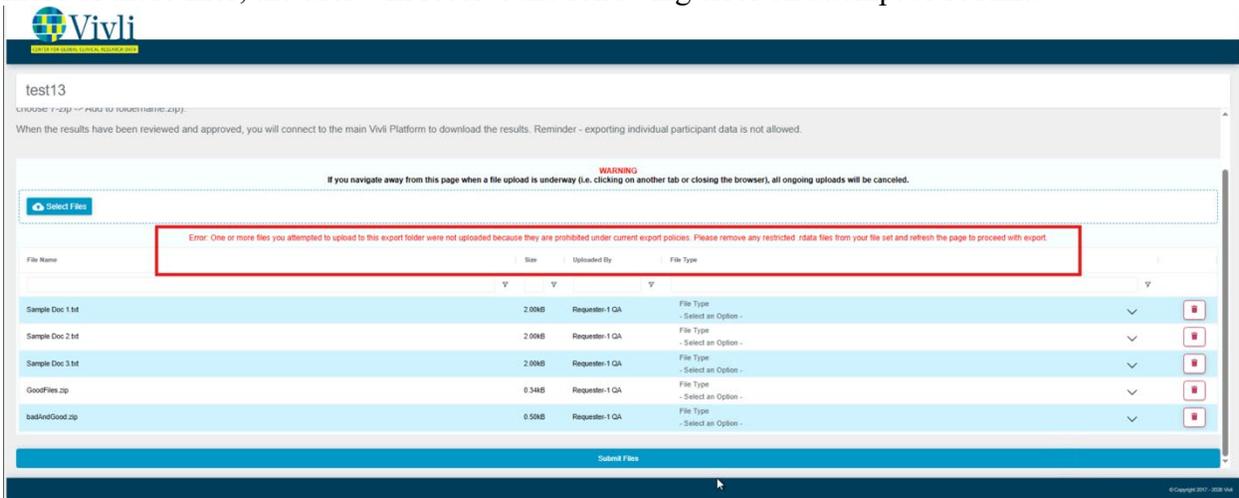
UPLOADED FILES

Filename	Size	Uploaded By	
result export.txt	0.02kB	Data Requester	Delete X

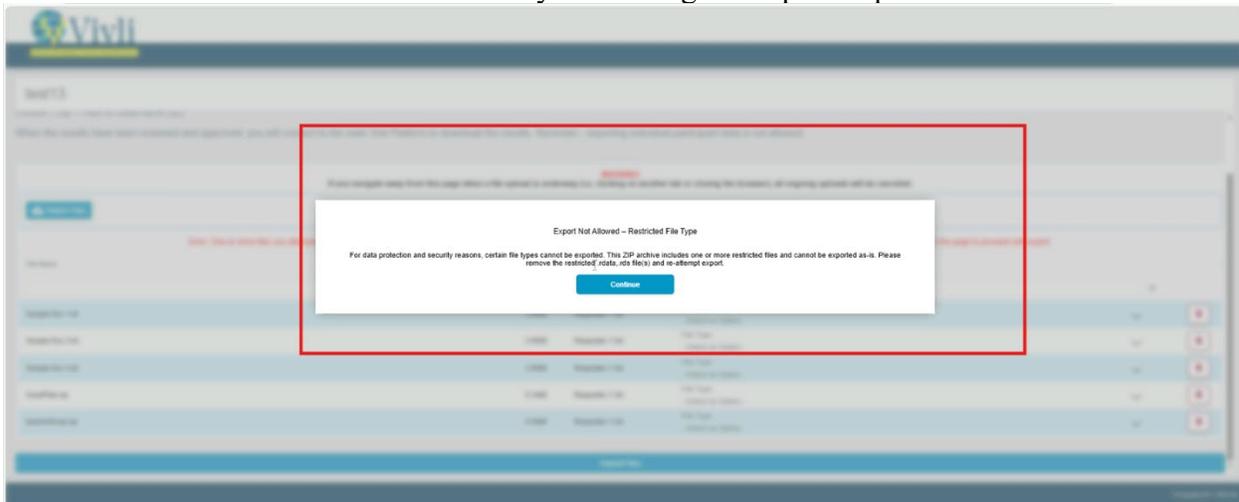
[Submit Files](#)

© Copyright 2017 - 2021 Vivli

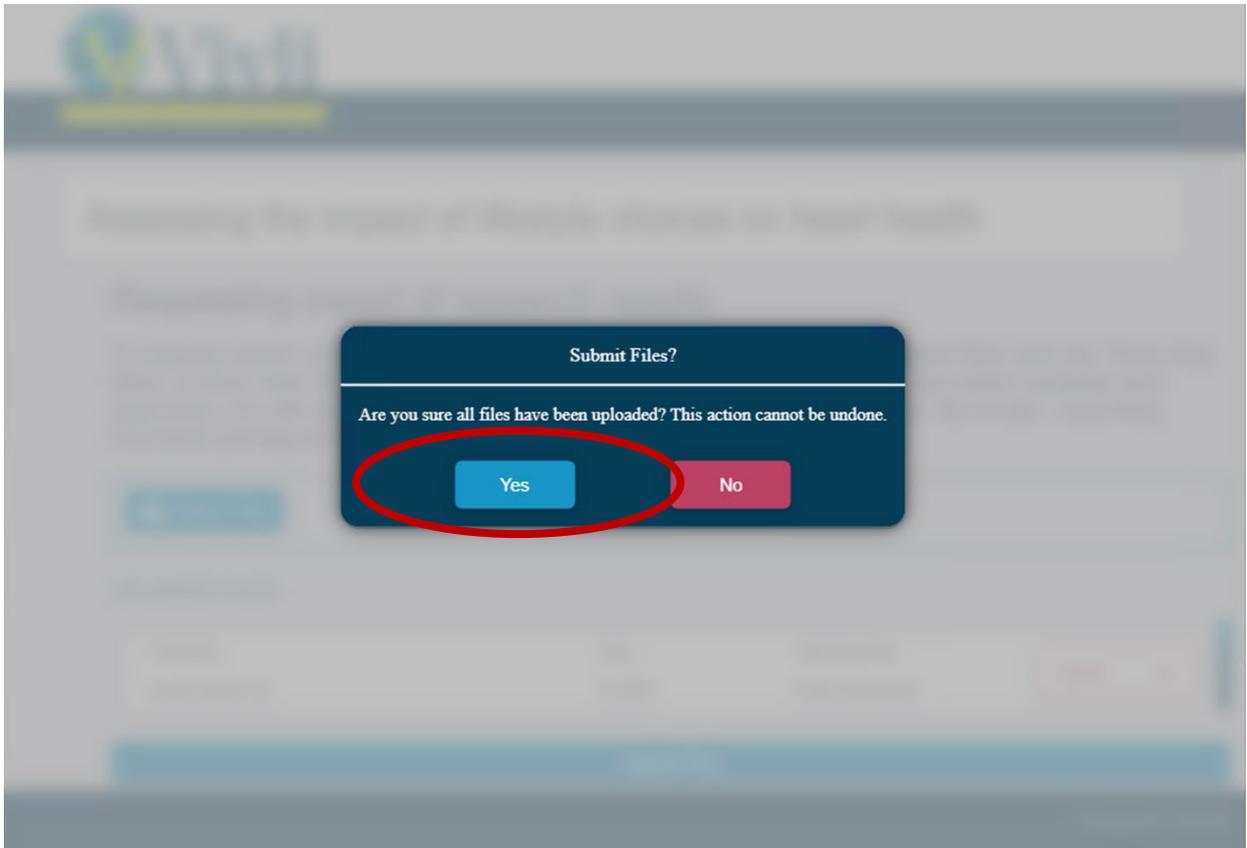
Note, certain file types are not permitted to be exported from the secure Vivli research environment (e.g., .Rdata, .rda, .rds, and similar formats). If an export request includes one or more of these files, the user will receive the following error on attempt to submit.



If a zipped file includes a prohibited file type, it will also produce an error on attempts to submit. Please remove the disallowed file and retry submitting the export request.



7. Submit files for review.



**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Assessing the impact of lifestyle choices on heart health (Request by Data Requester on 2021-10-01)

Create New Results Request

2021-10-01	Data Requester	Result Request in Progress

1 to 1 of 1 |< < Page 1 of 1 > >|

Results not yet available for this request.

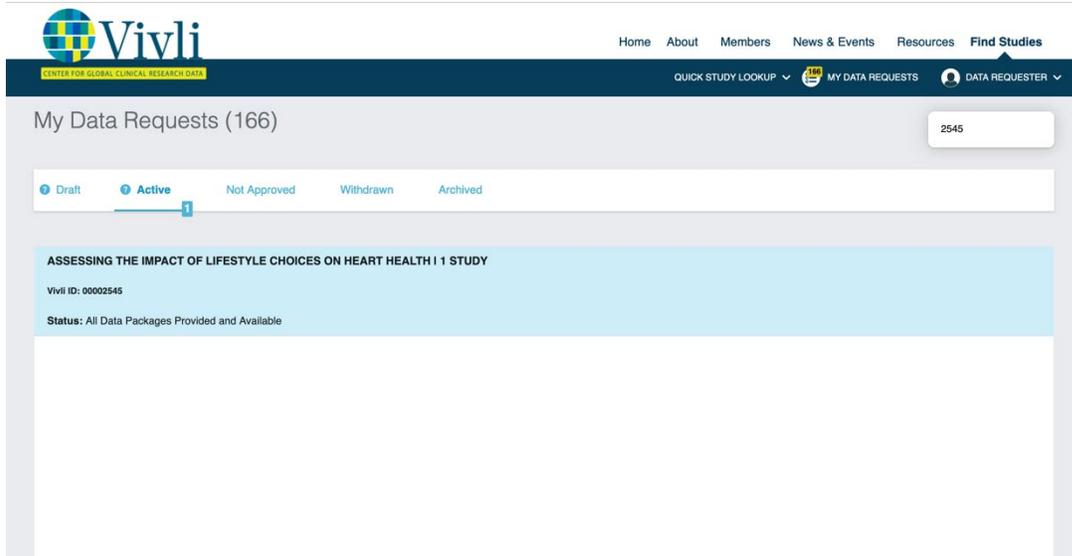
Please note, the processing time for a results export request is 5-7 business days. You will receive an email notification when a decision is recorded on the platform and can also monitor by checking the Research Results tab on the platform.

## 7.2 Downloading Approved Results

Once the request to export results is approved, the data requestor may download their results.

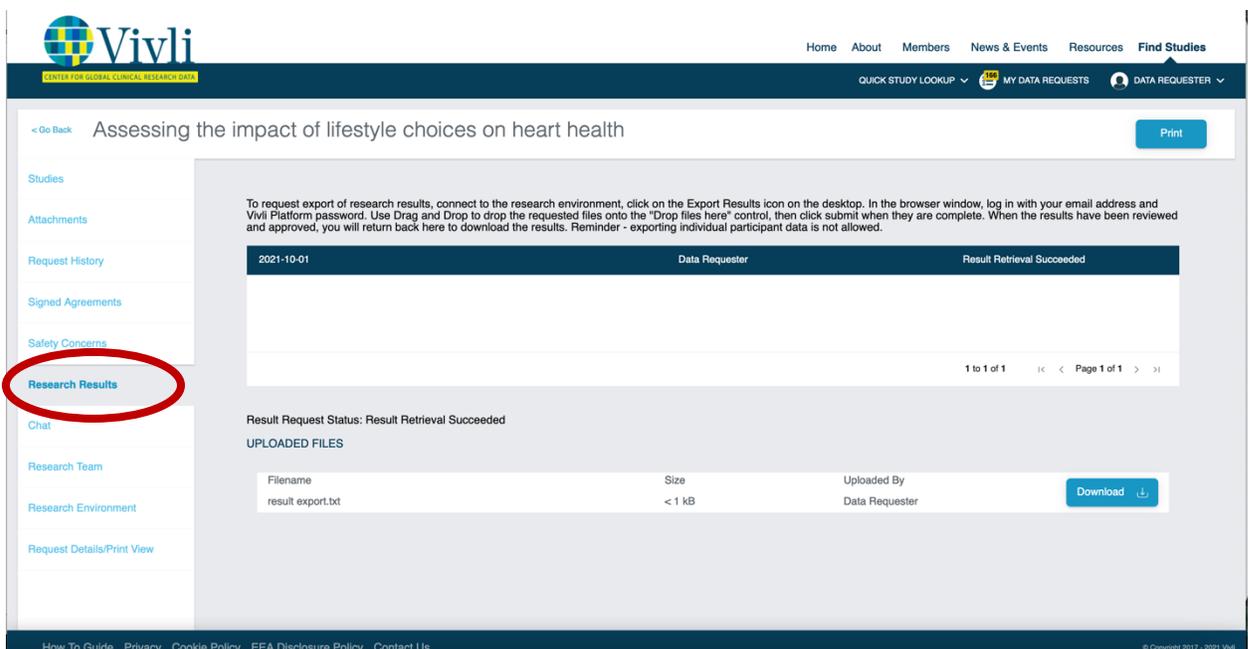
### 7.2.1 Steps, Exporting Results:

1. Login to the Vivli Platform
2. Navigate to **My Data Requests** and select the request:



The screenshot shows the Vivli platform interface. At the top, there is a navigation bar with links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a sub-navigation bar with 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'DATA REQUESTER'. The main content area is titled 'My Data Requests (166)' and includes a search box with the number '2545'. There are tabs for 'Draft', 'Active', 'Not Approved', 'Withdrawn', and 'Archived'. A specific request is highlighted in a light blue box: 'ASSESSING THE IMPACT OF LIFESTYLE CHOICES ON HEART HEALTH | 1 STUDY' with Vivli ID: 00002545 and Status: All Data Packages Provided and Available.

3. Click on **Research Results**:



The screenshot shows the Vivli platform interface for the study 'Assessing the impact of lifestyle choices on heart health'. The page has a navigation bar with links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a sub-navigation bar with 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'DATA REQUESTER'. The main content area is titled 'Assessing the impact of lifestyle choices on heart health' and includes a 'Print' button. There is a section for 'UPLOADED FILES' with a table showing a file named 'result export.txt' with a size of '< 1 kB' and uploaded by 'Data Requester'. A 'Download' button is visible next to the file. The 'Research Results' tab in the left sidebar is circled in red.

If you have made more than one request, click on the row corresponding to your most recent request – this will be on the top of the list. The row you have selected will be shown in dark blue.

4. Here, you will see if the request to export results has been approved:

The screenshot shows the Vivli platform interface. The header includes the Vivli logo and navigation links: Home, About, Members, News & Events, Resources, Find Studies. Below the header, there are dropdown menus for 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'DATA REQUESTER'. The main content area is titled 'Assessing the impact of lifestyle choices on heart health'. On the left, there is a sidebar with navigation options: Studies, Attachments, Request History, Signed Agreements, Safety Concerns, Research Results, Chat, Research Team, Research Environment, and Request Details/Print View. The main content area contains a table with two rows of request data:

2021-10-01	Data Requester	Result Request In Progress
2021-10-01	Data Requester	Result Retrieval Succeeded

Below the table, there is a message: 'Results not yet available for this request.'

5. If the request to export results has been approved, click on **Download**:

The screenshot shows the Vivli platform interface. The header includes the Vivli logo and navigation links: Home, About, Members, News & Events, Resources, Find Studies. Below the header, there are dropdown menus for 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'DATA REQUESTER'. The main content area is titled 'Assessing the impact of lifestyle choices on heart health'. On the left, there is a sidebar with navigation options: Studies, Attachments, Request History, Signed Agreements, Safety Concerns, Research Results, Chat, Research Team, Research Environment, and Request Details/Print View. The main content area contains a table with two rows of request data:

2021-10-01	Data Requester	Result Retrieval Succeeded
2021-10-01	Data Requester	Result Retrieval Succeeded

Below the table, there is a message: 'Result Request Status: Result Retrieval Succeeded'. Underneath, there is a section titled 'UPLOADED FILES' with a table:

Filename	Size	Uploaded By
result export.txt	< 1 kB	Data Requester

A red circle highlights the 'Download' button next to the file name.

If a review of the results identifies the presence of Individual Participant Data (IPD) in the result files, the Result Requests screen will display a message indicating that, and you will need to remove the IPD from the results files before requesting subsequent export of results again.

6. Once the **final** results are exported, please reach out to the Vivli Team via chat and we will provide next steps for deprovisioning the research environment and progression to publication.

## 8.0 Publication Review

### 8.1 Publication Follow up by Vivli

The Vivli administrator sends periodic reminders (at 3 months, 9 months and 1 year) to the researchers to get an update on the status of any potential publications from the time final results from the research environment are downloaded or a year after the downloadable data package was made available to the Data Requestor.

### 8.2 Publication Reviews by Data Contributors

- Once your research team has completed your analysis and you are ready to submit your findings for dissemination, either through a learned forum such as a publication or conference abstract, requestors must submit to Vivli a copy of any Publication materials at least 30 days prior to submission.
  - During this 30-day review period, 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).
  - Once the 30-day publication review period is up or once all data contributors have commented on the manuscript, whichever comes first, the research team may submit their publication to a learned forum. The Vivli team will follow up quarterly to check on the status and progress toward publication.
  - If you are submitting an abstract to a conference or learned forum and it is accepted as a poster or presentation, the new material (poster, presentation, etc.) must be submitted for the 30-day review period.
  - If you have completed a revision of a previously reviewed public disclosure the revised material must be provided.
    - If there are significant changes, the submitted material will undergo an additional 30-day review period.
    - If there are only minor changes, an additional 30-day review is not necessary.
    - You may provide the revised material via chat if the 30-day review period has passed.
- 8.2.1 Submit your publication materials through the Vivli platform for review
    1. Navigate to the “Public Disclosures” tab within your data request.

CENTER FOR GLOBAL CLINICAL RESEARCH DATA ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RICHARD ANDERSON

< Go Back **Request: 2601, Title: Comparative safety and effectiveness of cognitive enhancers for Alzheimer's dementia**  
**Status: All Data Packages Provided and Available**

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

As per the Data Use Agreement (DUA), Researcher(s) should send any public disclosures (manuscripts, abstracts, posters, slides, etc.) to Data Contributor(s) via this form at least 30 days prior to submission of materials to a learned forum or journal. As per the DUA, during the 30-day review period, Data Contributor(s) may provide non-binding comments regarding the scientific content. They may also possibly request the deletion of any confidential information (as defined in the DUA). [Add Disclosure](#)

Disclosure ID ↓	Title	Type	Data Contributor(s)	Status
00002601-01	Comparative safety and effectiveness of cognitive enhancers for Alzheimer's dementia	Manuscript	• Takeda	30-Day Review

Page Size: 20 1 to 1 of 1 Page 1 of 1

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us © Copyright 2017 - 2025 Vivli

2. Click “Add Disclosure” to add a new public disclosure for review.

CENTER FOR GLOBAL CLINICAL RESEARCH DATA ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RICHARD ANDERSON

< Go Back **Request: 2601, Title: Comparative safety and effectiveness of cognitive enhancers for Alzheimer's dementia**  
**Status: All Data Packages Provided and Available**

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

As per the Data Use Agreement (DUA), Researcher(s) should send any public disclosures (manuscripts, abstracts, posters, slides, etc.) to Data Contributor(s) via this form at least 30 days prior to submission of materials to a learned forum or journal. As per the DUA, during the 30-day review period, Data Contributor(s) may provide non-binding comments regarding the scientific content. They may also possibly request the deletion of any confidential information (as defined in the DUA). [Add Disclosure](#)

Disclosure ID ↓	Title	Type	Data Contributor(s)	Status
00002601-01	Comparative safety and effectiveness of cognitive enhancers for Alzheimer's dementia	Manuscript	• Takeda	30-Day Review

Page Size: 20 1 to 1 of 1 Page 1 of 1

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us © Copyright 2017 - 2025 Vivli

3. Fill out all required information from the tabs on the left. A unique ID that begins with the Vivli Request ID followed by a two-digit sequence will be generated for your public disclosure.

CENTER FOR GLOBAL CLINICAL RESEARCH DATA

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RICHARD ANDERSON

Public Disclosure 00002601-02  
Status: Draft (30-day review period has not been initiated)

Save Submit

**Disclosure Information**

As per the Data Use Agreement (DUA), Researcher(s) should send any public disclosures (manuscripts, abstracts, posters, slides, etc.) to Data Contributor(s) via this form at least 30 days prior to submission of materials to a learned forum or journal. As per the DUA, during the 30-day review period, Data Contributor(s) may provide non-binding comments regarding the scientific content. They may also possibly request the deletion of any confidential information (as defined in the DUA).

Disclosure Title

Select a Disclosure Type

- Manuscript
- Abstract
- Poster
- Presentation
- Thesis
- Summary of Results
- Other

Journal/Conference/Other

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2025 VHA

#### 4. Disclosure Information tab:

- Disclosure Title
- Disclosure Type (Manuscript, Abstract, Poster, Presentation, Thesis, Summary of Results)
  - If "Other", specify the disclosure type in the field that will appear "Please enter your Disclosure Type"

CENTER FOR GLOBAL CLINICAL RESEARCH DATA

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RICHARD ANDERSON

Public Disclosure 00002601-02  
Status: Draft (30-day review period has not been initiated)

Save Submit

**Disclosure Information**

As per the Data Use Agreement (DUA), Researcher(s) should send any public disclosures (manuscripts, abstracts, posters, slides, etc.) to Data Contributor(s) via this form at least 30 days prior to submission of materials to a learned forum or journal. As per the DUA, during the 30-day review period, Data Contributor(s) may provide non-binding comments regarding the scientific content. They may also possibly request the deletion of any confidential information (as defined in the DUA).

Disclosure Title

Analysis of safety and effectiveness of cognitive enhancers for Alzheimer's dementia

Select a Disclosure Type

Other

Please enter your Disclosure Type

Research Letter

Journal/Conference/Other

Journal of Alzheimer's Disease

Researcher Comments

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2025 VHA

- Journal/Conference/Other: Provide the name of the learned forum where your public disclosure will be submitted

Researcher comments: Provide any relevant comments in this field, for example: the provided disclosure is a revised version of a previously reviewed disclosure, the poster/presentation relates to a previously reviewed abstract, etc.

Public Disclosure 00002601-02  
Status: Draft (30-day review period has not been initiated)

Save Submit

**Disclosure Information**  
As per the Data Use Agreement (DUA), Researcher(s) should send any public disclosures (manuscripts, abstracts, posters, slides, etc.) to Data Contributor(s) via this form at least 30 days prior to submission of materials to a learned forum or journal. As per the DUA, during the 30-day review period, Data Contributor(s) may provide non-binding comments regarding the scientific content. They may also possibly request the deletion of any confidential information (as defined in the DUA).

**Studies Used**

**Documents for Review**

**History**

Disclosure Title  
Analysis of safety and effectiveness of cognitive enhancers for Alzheimer's dementia

Select a Disclosure Type  
Other

Please enter your Disclosure Type  
Research Letter

Journal/Conference/Other  
Journal of Alzheimer's Disease

Researcher Comments

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us © Copyright 2017 - 2025 Well

## 5. Studies Used:

- a. Review the list of requested studies and uncheck any studies that were not included in preparing the analysis for this disclosure.

Public Disclosure 00002607-01  
Status: Draft (30-day review period has not been initiated)

Save Submit

**Disclosure Information**  
Please review the list of requested studies and uncheck any studies that were not included in preparing the analysis for this disclosure. If you did not utilize a study for this public disclosure, please confirm in the open chat if you plan to submit more public disclosures using these studies based on other Data Contributor studies, as outlined in your research plan.

**Studies Used**

**Documents for Review**

**History**

Include All Studies Remove All Studies

	NCT ID	Sponsor ID	Data Contributor	Title
<input checked="" type="checkbox"/>	NCT00980200	113310	GlaxoSmithKline	A Multi-center, Randomized, Double-blind, Placebo-controlled, Five Period Cross-over Study to Evaluate the Efficacy and Safety of Selected Doses and Dose Intervals of GW62444 Administered Via a Novel Dry Powder Inhaler (NDPI) in Subjects ≥18 Years of Age With Persistent Asthma
<input checked="" type="checkbox"/>	NCT00655135	L299-016	Takeda	Phase 2 Randomized, Placebo-Controlled, Double-Blind, Parallel Group Study to Determine the Safety, Pharmacokinetics, and Effectiveness of LDP-02 in Patients With Mildly to Moderately Active Crohn's Disease

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us © Copyright 2017 - 2025 Well

- b. If you did not utilize a study for this public disclosure, please confirm in the open chat if you plan to submit more public disclosures using these studies based on other Data Contributor studies, as outlined in your research plan.
- c. To select all studies from your request, click the button "Include All Studies"

- d. To remove or deselect all studies from your request, click the button “Remove All Studies”

The screenshot shows the 'Public Disclosure 00002607-01' interface. At the top, there are navigation links for 'ENQUIRY', 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and a user profile for 'RICHARD ANDERSON'. Below this, the status is 'Draft (30-day review period has not been initiated)'. On the left, there are tabs for 'Disclosure Information', 'Studies Used', 'Documents for Review', and 'History'. The main content area contains a message: 'Please review the list of requested studies and uncheck any studies that were not included in preparing the analysis for this disclosure. If you did not utilize a study for this public disclosure, please confirm in the open chat if you plan to submit more public disclosures using these studies based on other Data Contributor studies, as outlined in your research plan.' To the right of this message are two buttons: 'Include All Studies' and 'Remove All Studies'. Below the message is a table with columns for NCT ID, Sponsor ID, Data Contributor, and Title. Two studies are listed: one from GlaxoSmithKline and one from Takeda. Each row has a checkbox on the left for selection.

NCT ID	Sponsor ID	Data Contributor	Title
<input type="checkbox"/> NCT00980200	113310	GlaxoSmithKline	A Multi-center, Randomized, Double-blind, Placebo-controlled, Five Period Cross-over Study to Evaluate the Efficacy and Safety of Selected Doses and Dose Intervals of GW62444 Administered Via a Novel Dry Powder Inhaler (NDPI) in Subjects ≥18 Years of Age With Persistent Asthma
<input type="checkbox"/> NCT00655135	L299-016	Takeda	Phase 2 Randomized, Placebo-Controlled, Double-Blind, Parallel Group Study to Determine the Safety, Pharmacokinetics, and Effectiveness of LDP-02 in Patients With Mildly to Moderately Active Crohn's Disease

- e. You may use the search criteria “NCT ID”, “Sponsor Id”, “Data Contributor” and “Title” to filter and search and the select individual studies by checking the box on the left.
6. Documents for Review
    - a. Ensure the following acknowledgement is included in your publication and uses the language below:
      - i. 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.
    - b. To add the acknowledgment to your publication, you may click “Copy Acknowledgment”. This will copy the text to your clipboard so you may paste it into your document.
    - c. Select the checkbox “I have included acknowledgment as required in the Vivli DUA” to confirm the acknowledgment is present.
      - i. *Exception: If you are submitting an abstract and there is a word limit, you may include the acknowledgment in the subsequent presentation or poster. Check the box “I am unable to include the acknowledgment as there is a word limit in the abstract. I will include the acknowledgment in the poster or oral presentation if selected.”*

Public Disclosure 00002607-01  
Status: Draft (30-day review period has not been initiated)

Disclosure Information

Please include the following text in your publication document before you upload it.

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.

[Copy Acknowledgement](#)

Documents for Review

I have included acknowledgment as required in the Vivli DJA

I am unable to include the acknowledgement as there is a word limit in the abstract. I will include the acknowledgement in the poster or oral presentation if selected

How To Guide | Privacy | Cookie Policy | EEA Disclosure Policy | Contact Us

- d. Upload your documents for review.
  - i. Click "Select Files" or drag and drop your files into the white box to upload your publication for review.
  - ii. Combine the documents into 1 or maximum of 2 files (e.g. 1 file containing the final draft of your publication and 1 file containing your attachments such as supplemental figures, graphs, etc.) before uploading.

Public Disclosure 00002607-01  
Status: Draft (30-day review period has not been initiated)

Disclosure Information

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.

[Copy Acknowledgement](#)

Documents for Review

I have included acknowledgment as required in the Vivli DJA

I am unable to include the acknowledgement as there is a word limit in the abstract. I will include the acknowledgement in the poster or oral presentation if selected

Combine the documents into 1 or maximum of 2 files (e.g. 1 file containing the final draft of your publication and 1 file containing your attachments such as supplemental figures, graphs, etc.).

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

[Select Files](#) | Drop files here

File Name	Size	Uploaded By	Uploaded Date

No files uploaded.

How To Guide | Privacy | Cookie Policy | EEA Disclosure Policy | Contact Us

- iii. To remove an uploaded file, click the red trashcan icon. To download your uploaded file, click the download icon to the right.

Center for Global Clinical Research Data

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RICHARD ANDERSON

Public Disclosure 00002607-01  
Status: Draft (30-day review period has not been initiated)

Save Submit

Disclosure Information

Studies Used

Documents for Review

History

I have included acknowledgment as required in the Vivli DUA

I am unable to include the acknowledgement as there is a word limit in the abstract. I will include the acknowledgment in the poster or oral presentation if selected

Combine the documents into 1 or maximum of 2 files (e.g. 1 file containing the final draft of your publication and 1 file containing your attachments such as supplemental figures, graphs, etc.).

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

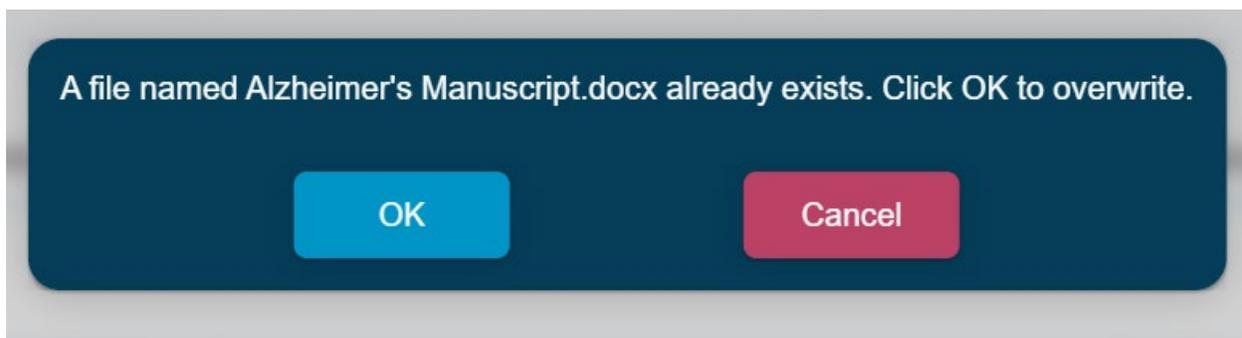
Select Files

File Name	Size	Uploaded By	Uploaded Date
Alzheimer's Manuscript.docx	12.99KB	Richard Anderson	9/25/2025 3:47:46 pm

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2025 Vivli

- iv. If you upload duplicate files, you will receive an error “A file name “XXXX” already exists. Click OK to overwrite”. Click “Cancel” to exit if this was in error.



If you navigate away from this page when a file upload is in progress, all ongoing uploads will be canceled.

7. Click “Submit” to submit your public disclosure for review.
  - a. Your public disclosure will be sent to data contributors to complete a 30-day review and the status will be “Status: In Review (30-day review started, 30 days remaining)”

Public Disclosure 00002607-01  
Status: Draft (30-day review period has not been initiated)

Save Submit

Disclosure Information  
Studies Used  
Documents for Review  
History

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.

Copy Acknowledgement

I have included acknowledgment as required in the Vivli DUA

I am unable to include the acknowledgement as there is a word limit in the abstract. I will include the acknowledgement in the poster or oral presentation if selected

Combine the documents into 1 or maximum of 2 files (e.g. 1 file containing the final draft of your publication and 1 file containing your attachments such as supplemental figures, graphs, etc.).

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

Select Files

File Name	Size	Uploaded By	Uploaded Date
Alzheimer's Manuscript.docx	12.99KB	Richard Anderson	9/25/2025 3:47:46 pm

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us © Copyright 2017 - 2025 Vivli

- b. The Vivli team may reach out with follow up questions via the Open chat if additional information is needed, which will not impact the “start” date for the 30-day review.

## 8.2.2 Status of Review

The 30-day review begins the day publication materials are submitted for review through the “Public Disclosure” tab and ends once the 30-day period is complete, or once all data contributors provide comments or confirm the review is complete, whichever is first.

- To view the status of the review and feedback received:
  - View “Status” at the top of your public disclosure entry to view the number of days left in the 30-day review of your publication
  - Click the tab “Feedback and Attachments” to view the individual status of each data contributors review and the feedback provided
  - In the table, you will see the name of the data contributor, the comments provided by the data contributor, the status of the review, and the date completed (once review is complete)
    - Data contributors may provide comments in free-text form, or upload attachments which you may download from this page
    - If there is an attachment, the paperclip icon will appear on the right side
    - Click on the paperclip icon to download the file
    - Use the Open chat, if needed, to respond to data contributor comments or questions during the review.

CENTER FOR GLOBAL CLINICAL RESEARCH DATA ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RICHARD ANDERSON

< Go Back **Public Disclosure 00002607-01**  
Status: Review Complete (30-Day review completed)

Disclosure Information **Review Start Date: 25-Sep-2025** **Review End Date: 25-Sep-2025**

Studies Used

Documents for Review

Feedback / Attachments

Citations

History

**Data Contributor Organizations**

Name ↑	Comments	Status	Date Completed
GlaxoSmithKline	review complete no comments	Review Complete	25-Sep-2025
Takeda	Please see attachment	Review Complete	25-Sep-2025

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us © Copyright 2017 - 2025 VMI

- You may also view the status of all public disclosures you have submitted from your data request page.
  - Navigate to your data request and click on the “Public Disclosures” page
  - On this page, you will see all the disclosures you have submitted for your data request, including the ID, Title, Type, Data Contributor(s), and the status of the review.

CENTER FOR GLOBAL CLINICAL RESEARCH DATA ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RICHARD ANDERSON

< Go Back **Request: 2807, Title: Comparative safety and effectiveness of cognitive enhancers for Alzheimer's dementia**  
**Status: All Data Packages Provided and Available**

Studies

Attachments

Request History

Signed Agreements

Safety Concerns

Research Results

Chat

Research Team

Research Environment

**Public Disclosures**

All Citations

Request Details/Print View

As per the Data Use Agreement (DUA), Researcher(s) should send any public disclosures (manuscripts, abstracts, posters, slides, etc.) to Data Contributor(s) via this form at least 30 days prior to submission of materials to a learned forum or journal. As per the DUA, during the 30-day review period, Data Contributor(s) may provide non-binding comments regarding the scientific content. They may also possibly request the deletion of any confidential information (as defined in the DUA). [Add Disclosure](#)

Disclosure ID ↓	Title	Type	Data Contributor(s)	Status
00002807-01	Analysis of cognitive enhancers for Alzheimer's dementia	Manuscript	<ul style="list-style-type: none"> <li>GlaxoSmithKline</li> <li>Takeda</li> </ul>	Review Complete

Page Size: 20 1 to 1 of 1 Page 1 of 1

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us © Copyright 2017 - 2025 VMI

- Statues:

- Review Complete – The review has been completed, or the 30-Day review period has expired.
  - Not Published – Review has been completed but the disclosure will not be published.
  - Published – The disclosure has been cited and published.
  - Draft – The disclosure is in a draft state and has not been submitted for review.
    - If there a draft disclosure needs to be removed, inform the Vivli team via the request chat and a Vivli admin may delete the draft disclosure on your behalf.
- History
    - Use the “History” tab to view the history of all disclosures created or submitted for your data request. You may also download any attachments associated with the public disclosure from this page.
    - History may be downloaded by clicking the “Export History” button

Public Disclosure 00002601-01  
Status: In Review (30-day review started, 30 days remaining)

Date and Time	Action	Performed By	Organization	Comments
9/25/25 2:54 pm	Created Disclosure 00002601-01	Richard Anderson	Sample	
9/25/25 3:06 pm	Review document uploaded	Richard Anderson	Sample	<a href="#">This is my Manuscript.docx</a>
9/25/25 3:11 pm	Status changed to Thirty Day Review started	Richard Anderson	Sample	

- Emails
  - The research team will receive the following emails from the Vivli platform related to the public disclosures:
    - When a disclosure is submitted for courtesy review
    - When a public disclosure is reset to draft by the Vivli Admins
    - Once a disclosure reaches the end of the review stage (once all data contributors have reviewed the publication or at the end of the 30-day period)
    - When a public disclosure is published by a Vivli Admin on the Vivli website

### 8.3 Publication Notification by Data Requestor

- Once your team has been notified that your publication has been accepted by the journal, notify the Vivli team via the Open chat. The Vivli team will then follow up on the progress toward publication and for the DOI and citation.
- When your publication has been published and the DOI for your citation made available, please let the Vivli team know via Open chat.
- The Vivli team will then update your data request on the Vivli website by including the statistical analysis plan and the DOI to the publication.
- The status of the public disclosure will be “Published”

The screenshot shows the Vivli Public Disclosure form for ID 00048991-02. The status is 'Published'. The disclosure title is 'Machine Learning and Lupus Nephritis Outcomes Using Clinical Trial Data'. The disclosure type is 'Manuscript' and the journal is 'Nature Reviews Nephrology'. The form includes a sidebar with navigation options: Disclosure Information, Studies Used, Documents for Review, Feedback / Attachments, Citations, and History. The main content area contains a text box for the disclosure title, a dropdown for the disclosure type, a dropdown for the journal/conference/other, and a text box for researcher comments. The footer contains links for How To Guide, Privacy, Cookie Policy, EEA Disclosure Policy, and Contact Us, along with a copyright notice for 2017-2025 Vivli.

- The Vivli team will also add the citation to your data request on the Vivli platform in the “Citations” tab of your public disclosure. The citation will be linked to the study(s) involved in your request as well and will be viewable when viewing study details on the Vivli platform.

- If this is your final analysis for the research project, please let Vivli know and if so, we will move your analysis to long-term storage and archive your request on the Vivli platform. See [section 12.0 Stopping the Research Environment](#). Vivli team will send you a survey about your experience on Vivli platform.
- If you have more publications linked to this research project, please follow step 9.2 Publication Reviews by Data Contributors for each subsequent publication.

#### 8.4 Public disclosure not possible

If for whatever reason you are unable to publish your results, you must provide a summary report of your findings and Vivli will publish this report on its website. For an example see: <https://vivli.org/identification-of-biomarkers-associated-with-specific-sleep-variables/>. Vivli will then de-provision your research environment and your project will be complete

- Alternatively, you may fulfill the obligations under the Vivli DUA and submit to a pre-print server such as <https://www.medrxiv.org/>. This preprint server was started by the BMJ and Yale and is a free distribution server for preprints of articles covering all aspects of research. Once posted you would receive a DOI so it would be citable and discoverable. You can cite this on your CV and continue to submit to other journals if you like.
  - Once your publication is posted on a pre-print server, please let the Vivli Team know via chat.
  - The Vivli team will then update your data request on the Vivli website by including the statistical analysis plan and the DOI to the publication. If your public disclosure is then published in a peer-reviewed journal, the Vivli team will replace the pre-print citation with the peer-reviewed citation.
  - The Vivli Team will follow up to check the status of publication in a peer-review journal.
  - Summary of results and disclosures for pre-print servers must be submitted via the 'Public Disclosure' tab for a 30-day review following the steps outlines in 9.2.1

- For summary of results submissions, enter “N/A” in “Name of Journal” as this field does not apply

#### 8.4.1 [Reasons why analysis may not be completed](#)

If the analysis is not completed, this fact and the reason that it was not completed, should be stated as a summary of the research.

The analysis may not be performed or completed due to the following reasons:

- Technical - e.g. datasets can't be combined, the research questions can't be answered, data mapping isn't possible
- Scientific - e.g. the studies can't be combined due to design differences or endpoint differences
- Logistical - e.g. the Data Requestor loses funding or key research personnel

According to Vivli policy, if a user fails to meet their DUA obligations and does not respond with reasons why their analysis has not been completed, the Vivli team will escalate to your institutional official who has signed off on the DUA and the team may be unable to submit a subsequent request on Vivli.

## 9.0 Extensions to the Data Use Agreement via the Data Request Progress Report

- Access to the data listed in the approved research proposal is valid for one year from when the Data Use Agreement (DUA) is executed.
- Prior to the 1-year DUA expiration, the Vivli team will reach out to the Data Requestors for an update on the data request and analysis by asking if the team would like to extend their access, beyond the DUA expiration date.
- If the team responds that they wish to extend access, the Vivli team will send the lead investigator the Data Request Progress Report via DocuSign.
- The Lead Researcher fills out the Data Request Progress Report to request an extension. If additional team members from other institutions have a signed DUA, they will acknowledge the completed Data Request Progress Report to extend their access as well.
- Vivli team will follow up on the Data Request Progress Report 1 week prior to the DUA expiration.
- Based on the response, Vivli makes the decision regarding extending access to the data in 1-year intervals. These extensions are only granted due to extenuating circumstances. Vivli will respond in 10 business days with a decision that has been reached and upload the document via Signed Agreements on the Vivli platform.
- If no response is received before the end of the Data Use Agreement, Vivli team stops the Research Environment and remove the team's access to the research environment on the day of DUA expiration.
- Note: For any requests for downloadable data, Vivli team will request evidence of data destruction as per the data security addendum.

- Note that an extension to the Data Use Agreement (a legal agreement) is entirely separate from the No Charge period on the Research environment and does not extend the No Charge period.

### 9.1 Failure to meet DUA obligations

According to Vivli policy, if a user fails to meet their DUA obligations, they are unable to submit a subsequent request from Vivli.

## 10.0 Paying for a Research Environment

The cost and length of no charge periods for the Secure Research Environment access are available on the Vivli [website](#). Please note these charges are subject to change.

Note that the no charge period (i.e., the length of time where you will not be charged) begins on the date you first provision the Research Environment, which usually is later than the date that the Data Use Agreement is signed. Per Vivli policy, the no charge period for the Vivli Research Environment begins at initiation and is not impacted by the days you actually use the environment; billing is not impacted by pausing. Renewing the Data Use Agreement does not extend the no charge period.

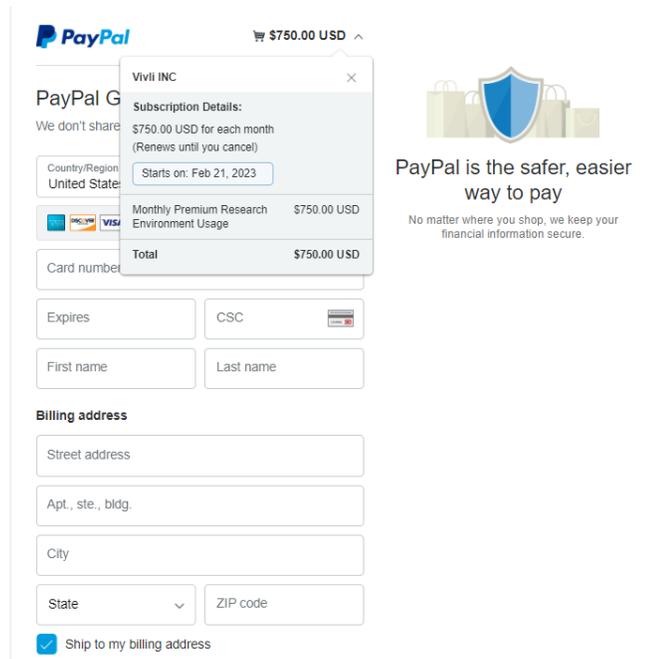
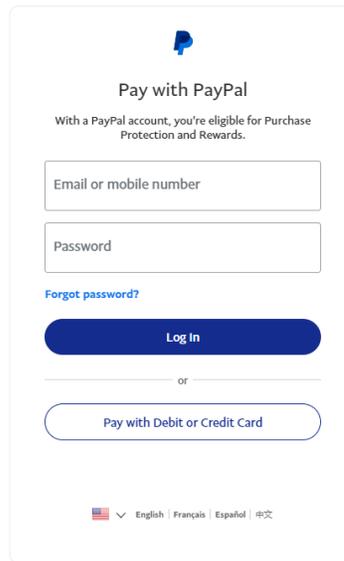
As you near the end of your no charge period, Vivli will send you notices via email to the email addresses of the research team members on the data request. In these notices we will remind you of the end date of your no charge period. **We will ask you to provide payment via a credit card once your no charge period has ended.** Charges will be automatically completed on the same day of the month, approximately every 30 days, as when payment is first submitted for the next month's usage. A constant 30 days per month will be charged, and your subscription will be cancelled and no further charges made as soon as you submit a public disclosure for courtesy review and confirm with the Vivli team you wish to stop using your research environment.

If no payment method is arranged, access to the Research Environment will be revoked.

Please note that you will be responsible for all charges once your no charge usage period has ended. Once you have submitted a public disclosure for courtesy review and confirmed with the Vivli team that you wish to stop your secure research environment then this will stop the accrual of additional fees. See [section 11.0](#) for further information about stopping the research environment.

1. At the end of your no charge period, the Vivli team will email you with the appropriate link to sign up for subscription billing for the secure Research Environment within 1 week of your no charge period end date. The subject line will be "Action Required: Vivli Research Environment ALERT – Payment Request to Maintain Access to data request"

2. Upon opening the link, you will be directed to the PayPal page where you can login with your PayPal account or enter the credit/debit card number to be used for billing.



3. After entering the credit card details, click the Agree & Subscribe button. Please note that you will be charged every 30 days on approximately the same date each month going forward.

**Contact Information**

Phone type  
Mobile

Phone number  
+1

Email

The security you want.  
The protection you deserve.

Creating a PayPal account is optional but you'll get **PayPal Purchase Protection** on all eligible purchases, plus faster checkout every time you shop. [See terms](#)

Create a PayPal account? (It only takes a moment.)

Yes, I'd like a PayPal account.

Password

No, I don't want an account now.

We'll save your PayPal info for future purchases with Vivli INC. If you hold a balance, we'll use it first. If your chosen payment method is unavailable, we'll try the other payment methods in your wallet.

**Agree & Subscribe**

4. Lastly, you should receive confirmation from PayPal that you have successfully signed up for your subscription for the Research Environment and also a receipt of your first payment to the email address shared with PayPal.

If you have any questions about this process, please contact Vivli at [support@vivli.org](mailto:support@vivli.org).

## 11.0 Pausing the Research Environment

- When you have submitted your publication for review and are awaiting feedback, you may reach out to the Vivli Team in chat to request a “pause” of your research environment. This will preserve any remaining no charge period days for subsequent analysis from peer review feedback. If you are actively paying for your environment, requesting to “pause” will stop the accrual of additional fees.
- Once your research environment has been stopped, this will stop the accrual of additional fees until a request to re-access has been submitted.
- **Important:** Before requesting to “pause” the environment, please copy any data that you might need later access to onto the Network Drive (Drive V:\). Once disabled, access to content in the Research Environment will be terminated. Note that long-term archive will ONLY save the contents of drive V. Data saved in any other drive will be deleted: so please place any essential data to Drive V. Remember to check your desktop and documents folders for any data you wish to be archived.
- If you need access to data while your request is “paused”, simply reach out to the Vivli Team in chat or via [support@vivli.org](mailto:support@vivli.org) and will provide next steps for resuming your analysis.

## 12.0 Deprovisioning the Research Environment

- When you have completed your research, exported your final results and published your findings, the Vivli team will provide next steps, as needed, to deprovision your research

environment and prepare data for long term archive. Please reach out when you have saved all data to which you may need future re-access to the V:drive then reach out to the Vivli Team via [support@vivli.org](mailto:support@vivli.org) to request deprovisioning.

- **Important:** Before requesting to deprovision the environment, please copy any data that you might need later access to onto the Network Drive (Drive V:\). Once disabled, access to content in the Research Environment will be terminated. Note that long-term archive will ONLY save the contents of drive V. Data saved in any other drive will be deleted: so please place any essential data to Drive V.
- Shortly after your research environment has been marked for deprovisioning, Vivli will place a copy of the contents of the data disk into long-term archive.
- If you need access to data held in the Vivli long-term archive, please send a request to the Vivli Team via [support@vivli.org](mailto:support@vivli.org) including the Data Request number and Project Name. Processing this request takes 5-7 days.
- If you need access to long-term storage data for a new research project, to address a different question and/or if you are requesting additional data, you will need to create and submit a new data request on the Vivli platform. In the Narrative, reference the original data request, including the request number.

## 13.0 Downloadable data

Some Data Contributors will allow you to download their data directly from the Vivli Platform using the following process:

1. Log in and open your approved data request:

The screenshot shows the Vivli platform interface for a 'Hepatitis Project'. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. A user profile icon is visible in the top right corner. The main content area is titled 'Hepatitis Project' and features a 'Print' button. Below the title, there are sections for 'REQUESTED STUDY TYPES' and 'VIVLI-LISTED AND PROVISIONED STUDIES'. A specific study is highlighted: 'A Phase II Open Label, Dose-Escalation Study to Determine the Safety, Tolerability and Efficacy of Microsomal Triglyceride Transfer Protein (MTP) Inhibitor BMS-201038 in Patients With Homozygous Familial Hypercholesterolemia'. The study details include the sponsor (Aegerion Pharmaceuticals, Inc.), study ID (NCT01555906), approval status (Approved), data request ID (00001280), and sponsor ID (UP1001). A 'Data Package Provided to Requestor' button is also present. The interface includes a left sidebar with navigation options like Attachments, Request History, Signed Agreements, Safety Concerns, Chat, Research Team, Research Environment, and Request Details/Print View. The footer contains links for How To Guide, Privacy, Cookie Policy, EEA Disclosure Policy, and Contact Us, along with a copyright notice for 2017-2018 Vivli.

2. Click on the study to get to the **Study details** screen:

**Vivli**  
CENTRE FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

QUICK STUDY LOOKUP MY DATA REQUESTS IDA SIM

### A Phase II Open Label, Dose-Escalation Study to Determine the Safety, Tolerability and Efficacy of Microsomal Triglyceride Transfer Protein (MTP) Inhibitor BMS-201038 in Patients With Homozygous Familial Hypercholesterolemia

**Study Details** Administrative Details Download Data Package

Phase: Phase 2  
Condition or Disease: Homozygous Familial Hypercholesterolemia

Intervention/treatment: Lomitapide

**Brief Summary**  
The primary objective of this study is to evaluate the safety and tolerability of 4 doses of lomitapide (AEQR-733; BMS-201038) given as an initial low dose and then escalated through an additional 3 dose levels over a 16-week period. The secondary objectives of this study included the evaluation of the pharmacodynamics of lomitapide based on: - Percent change in low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), triglycerides, and very low density lipoprotein cholesterol (VLDL-C) concentrations at the end of each 4-week dosing period compared to the Baseline value of each parameter at the end of the previous dose phase(s). - Changes in other plasma lipoproteins: apolipoproteins (apo B, apo AI, apo AII, apo CIII, apo E) and lipoprotein a [Lp(a)].

Ages Eligible For Study: 13 Years and older  
Sexes Eligible For Study: All  
Accepts Healthy Volunteers: No  
Actual Enrollment: 6

Study Start Date: 06/2003  
Study Completion Date: 02/2004  
Recruitment Status: Completed

Locations: United States (1)

3. Click on Download Data Package:

**Vivli**  
CENTRE FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

QUICK STUDY LOOKUP MY DATA REQUESTS IDA SIM

### A Phase II Open Label, Dose-Escalation Study to Determine the Safety, Tolerability and Efficacy of Microsomal Triglyceride Transfer Protein (MTP) Inhibitor BMS-201038 in Patients With Homozygous Familial Hypercholesterolemia

**Study Details** Administrative Details **Download Data Package**

Phase: Phase 2  
Condition or Disease: Homozygous Familial Hypercholesterolemia

Intervention/treatment: Lomitapide

**Brief Summary**  
The primary objective of this study is to evaluate the safety and tolerability of 4 doses of lomitapide (AEQR-733; BMS-201038) given as an initial low dose and then escalated through an additional 3 dose levels over a 16-week period. The secondary objectives of this study included the evaluation of the pharmacodynamics of lomitapide based on: - Percent change in low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), triglycerides, and very low density lipoprotein cholesterol (VLDL-C) concentrations at the end of each 4-week dosing period compared to the Baseline value of each parameter at the end of the previous dose phase(s). - Changes in other plasma lipoproteins: apolipoproteins (apo B, apo AI, apo AII, apo CIII, apo E) and lipoprotein a [Lp(a)].

Ages Eligible For Study: 13 Years and older  
Sexes Eligible For Study: All  
Accepts Healthy Volunteers: No  
Actual Enrollment: 6

Study Start Date: 06/2003  
Study Completion Date: 02/2004  
Recruitment Status: Completed

Locations: United States (1)

4. This will take you to the Download screen:

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

QUICK STUDY LOOKUP MY DATA REQUESTS IDA SIM

**A Phase II Open Label, Dose-Escalation Study to Determine the Safety, Tolerability and Efficacy of Microsomal Triglyceride Transfer Protein (MTP) Inhibitor BMS-201038 in Patients With Homozygous Familial Hypercholesterolemia**

Study Details Administrative Details **Download Data Package**

DOWNLOADABLE DATA PACKAGE - PRESS DOWNLOAD BUTTON FOR EACH FILE

UPLOADED FILES

Filename	Size	Uploaded By	File Type	Download
test IPD.xlsx	6.00kB	Jessica B Baker	IPD	Download
Test Protocol.docx	13.00kB	Jessica B Baker	Protocol with Amendments	Download
Test SAP.docx	13.00kB	Jessica B Baker	Statistical Analysis Plan	Download
TestFile.docx	12.00kB	Jessica B Baker	Data Dictionary	Download

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2018 Vivli

5. Depending on your browser, a pop-up will appear:

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

QUICK STUDY LOOKUP MY DATA REQUESTS IDA SIM

**A Phase II Open Label, Dose-Escalation Study to Determine the Safety, Tolerability and Efficacy of Microsomal Triglyceride Transfer Protein (MTP) Inhibitor BMS-201038 in Patients With Homozygous Familial Hypercholesterolemia**

Study Details Administrative Details **Download Data Package**

DOWNLOADABLE DATA PACKAGE - PRESS DOWNLOAD BUTTON FOR EACH FILE

UPLOADED FILES

Filename	Size	Uploaded By	File Type	Download
test IPD.xlsx	6.00kB	Jessica B Baker	IPD	Download
Test Protocol.docx	13.00kB	Jessica B Baker	Protocol with Amendments	Download
Test SAP.docx	13.00kB	Jessica B Baker	Statistical Analysis Plan	Download
TestFile.docx	12.00kB	Jessica B Baker	Data Dictionary	Download

Opening TestFile.docx

You have chosen to open:

**TestFile.docx**  
which is: Microsoft Word Document (11.5 KB)  
from: https://vivlistagewapi.azurewebsites.net

What should Firefox do with this file?

Open with Microsoft Word (default)

Save File

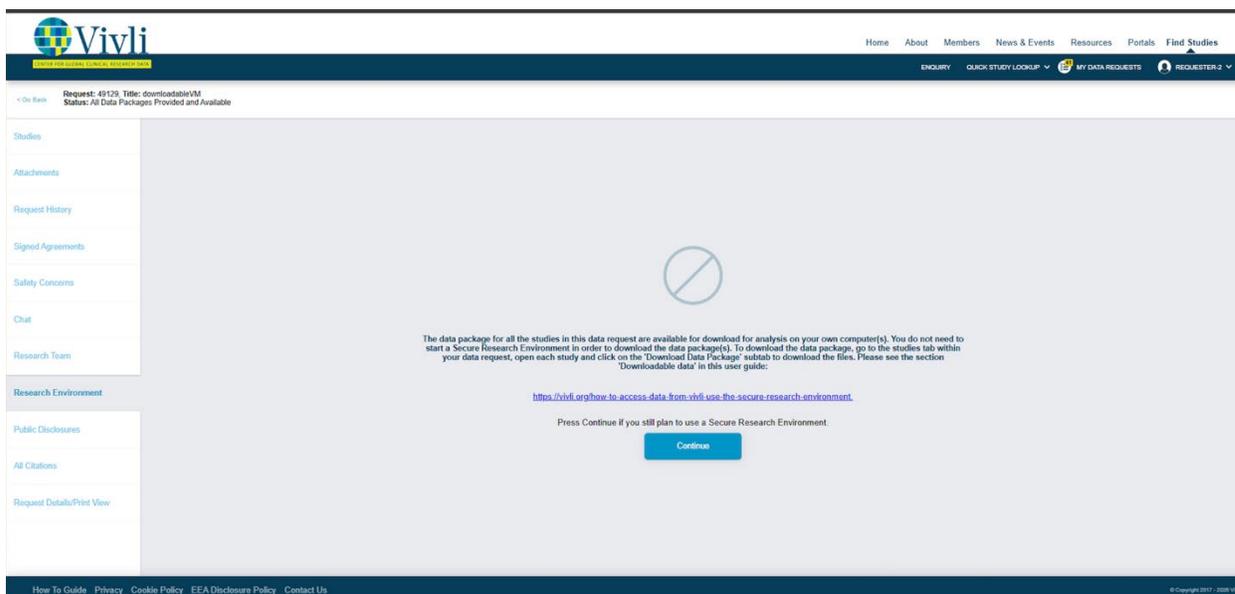
Do this automatically for files like this from now on.

OK Cancel

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2018 Vivli

6. Select the target file, choose whether you would like to Save or Open the files and click **Ok**.
7. Repeat Step 6 for any additional files.
8. The following reminder will appear if you select a secure research environment for downloadable studies.



### 13.1 Tips for downloading files from Vivli

When files are available for direct download from the Vivli platform, the usual approach to downloading files is to open the approved data request, open the studies tab, click on the "card" for the study, go the download data package tab and click "Download" for each individual file that you need to download.

If the size of the file is more than 1000MB, you should take a few extra precautions before starting the download

- In your computer settings, set Power Plan to sleep "Never" when plugged in. (sleeping will interrupt the download)
- Once you start the download, leave the computer running and the browser open.
- The progress of the download is shown in different places depending on the browser (for example for Chrome it is shown in the lower left, and for Firefox it is show in the upper right - note that for Firefox, the progress pop-up is taken down after a few minutes - you can check back on progress by clicking on the download icon on the upper right)
- If the download takes more than 30 minutes, the Vivli Platform will automatically log you out, but the download will continue until it is complete.
- Do not download more than one file at a time

## 14.0 Feedback and Support

If you need technical help with your research environment, please email Vivli at [support@vivli.org](mailto:support@vivli.org) and we will assist you as soon as possible. Please provide as much information as you can to the problem, including the research proposal number, the time the

problem and any messages you received from the platform occurred as this will make it easier for Vivli to diagnose and fix the issue.

If you ever have thoughts on how to improve the system or processes, please email [support@vivli.org](mailto:support@vivli.org) or reach out to Vivli via chat. When you have completed your project, Vivli will ask you to complete a short survey to help us continue to improve.

© 2026, Vivli