



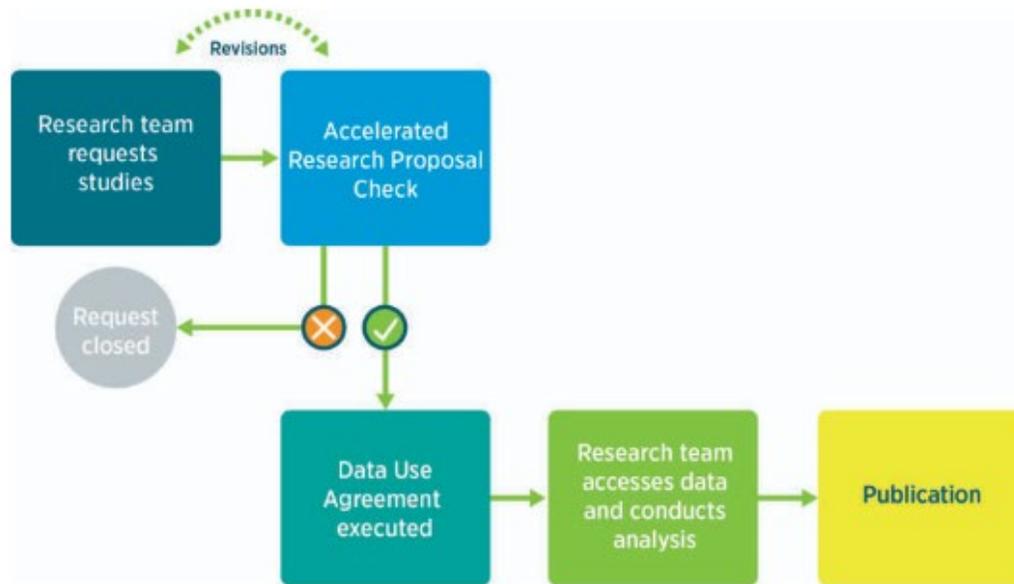
DATA^{FASEB}Works! Prize

How To: Request Studies on Vivli for the
DataWorks! Prize

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1.0 Requesting eligible Studies and completing a data request –Overview



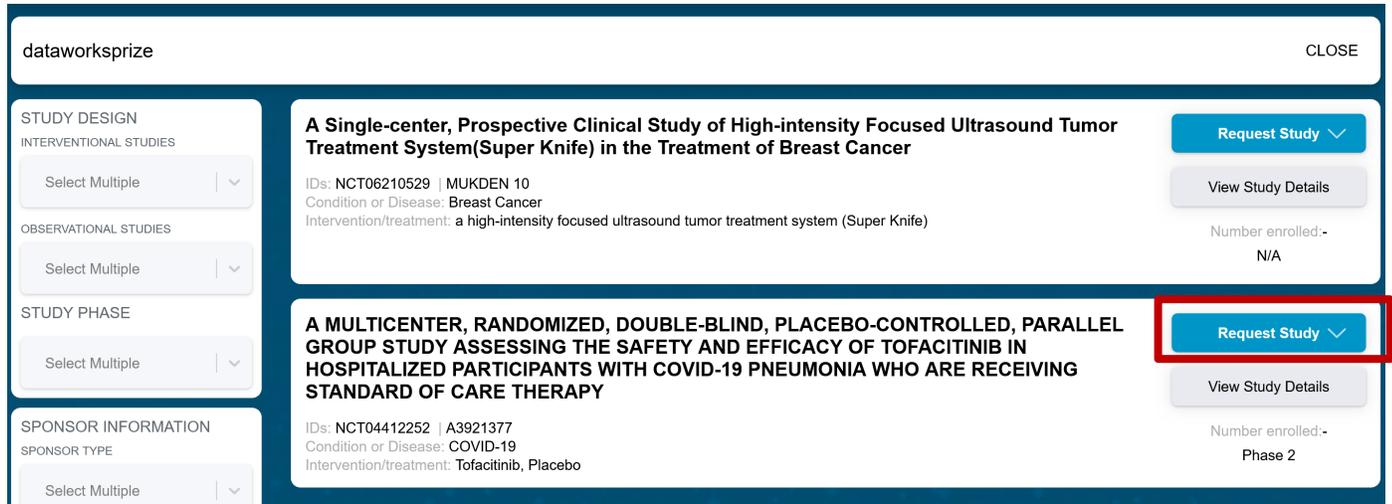
- Please refer to the DataWorks! Prize portal for information about the prize submission process. As Vivli is a managed access platform, please do request any Vivli data in plenty of time to meet the deadlines for the prize so that you will have all the data you so that you have the full six months to complete your project.
- Please go to the DataWorks! Prize portal to find out more information and view the eligible studies. <https://search.vivli.org/portal/dataworksprize>. Please note: Only studies that appear as part of the Dataworks portal are eligible so please ensure when searching that a search criteria is the term [Dataworksprize](https://search.vivli.org/portal/dataworksprize). If you have any questions about if a study is eligible, please reach out to Vivli via support@vivli.org.
- Once you have decided on studies that you want to include in your DataWorks! Prize submission, you will need to complete a Vivli data request form.
- You must be logged in as a Vivli user to begin your data request.
- If you do not have a Vivli account, you will need to set one up before beginning a data request. To learn more about creating a Vivli account, please review our [Vivli User Account Quick Start guide](#).

If you are not logged in, you will be prompted to do so. After you log in, you will return to the search results window:

The screenshot shows the 'dataworksprize' search results page. On the left, there are filters for 'STUDY DESIGN' (Interventional Studies, Observational Studies), 'STUDY PHASE', 'SPONSOR INFORMATION' (Sponsor Type, Sponsor), and 'SAMPLE SIZE'. The main content area displays three study entries, each with a title, ID, condition/disease, intervention/treatment, and buttons for 'Log in to Request Study' and 'View Study Details'. The first study is 'Oxygen-Ozone as Adjuvant Treatment in Early Control of Disease Progression in Patients With COVID-19 Associated With Modulation of the Gut Microbial Flora' (NCT04366089). The second is 'An Open-label, Randomized Controlled Trial of Hydroxychloroquine and Azithromycin for COVID-19 Infection on Hospitalized, Noncritical Patients' (NCT04322123). The third is 'Treating COVID-19 With Hydroxychloroquine: A Multicenter Randomized, Double-blind, Placebo-controlled Clinical Trial in Hospitalized Adults' (NCT04369742).

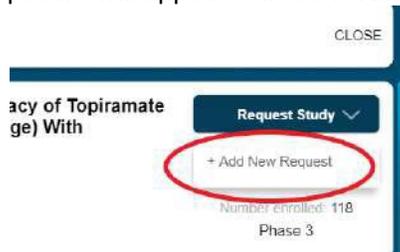
1.1 Add studies to your data request

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



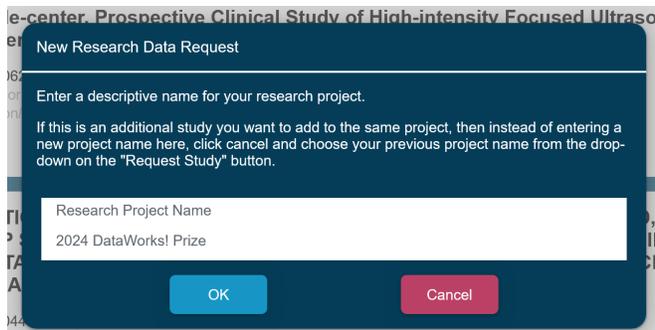
The screenshot shows the 'dataworksprize' interface with a 'CLOSE' button in the top right. On the left, there are filters for 'STUDY DESIGN' (INTERVENTIONAL STUDIES, OBSERVATIONAL STUDIES), 'STUDY PHASE', and 'SPONSOR INFORMATION' (SPONSOR TYPE), each with a 'Select Multiple' dropdown. The main area displays two study cards. The first card is titled 'A Single-center, Prospective Clinical Study of High-intensity Focused Ultrasound Tumor Treatment System(Super Knife) in the Treatment of Breast Cancer' and has a 'Request Study' button. The second card is titled 'A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL GROUP STUDY ASSESSING THE SAFETY AND EFFICACY OF TOFACITINIB IN HOSPITALIZED PARTICIPANTS WITH COVID-19 PNEUMONIA WHO ARE RECEIVING STANDARD OF CARE THERAPY' and has a 'Request Study' button highlighted with a red box. Below each card is a 'View Study Details' button and the number of enrolled participants.

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



The screenshot shows a dropdown menu for a study card. The dropdown is open, showing the '+ Add New Request' option circled in red. The study card title is partially visible as 'acy of Topiramate (ge) With'. Below the dropdown, the text 'Number enrolled: 118' and 'Phase 3' is visible. A 'CLOSE' button is in the top right of the dropdown area.

3. A dialogue box will pop up where you can provide the Research Project Name for your research project. **Note:** Your Project name must match the "Title of Proposed Research" within the data request form. This can be edited before submitting the data request for review. After entering a research project name, click **Ok** to create the data request. **In the title, please start your Title with 2024 DataWorks! Prize**



The screenshot shows a 'New Research Data Request' dialog box. It has a title bar 'New Research Data Request' and a 'CLOSE' button. The main text says 'Enter a descriptive name for your research project.' Below this is a note: 'If this is an additional study you want to add to the same project, then instead of entering a new project name here, click cancel and choose your previous project name from the dropdown on the "Request Study" button.' There is a text input field for 'Research Project Name' containing the text '2024 DataWorks! Prize'. At the bottom, there are 'OK' and 'Cancel' buttons.

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

The screenshot shows the Vivli platform interface. At the top, there is a navigation bar with links for Home, About, Members, News & Events, Resources, Portals, and Find Studies. Below this is a search bar with the text 'dataworksprize' and a 'CLOSE' button. The main content area is divided into several sections:

- STUDY DESIGN:** Includes filters for INTERVENTIONAL STUDIES and OBSERVATIONAL STUDIES, each with a 'Select Multiple' dropdown.
- STUDY PHASE:** Includes a 'Select Multiple' dropdown.
- SPONSOR INFORMATION:** Includes filters for SPONSOR TYPE and SPONSOR, each with a 'Select Multiple' dropdown.
- SAMPLE SIZE:** Includes a 'Select Multiple' dropdown and a '(Disabled)' checkbox.

The main content area displays two study listings:

- A Single-center, Prospective Clinical Study of High-intensity Focused Ultrasound Tumor Treatment System(Super Knife) in the Treatment of Breast Cancer**
 - IDs: NCT06210529 | MUKDEN 10
 - Condition or Disease: Breast Cancer
 - Intervention/treatment: a high-intensity focused ultrasound tumor treatment system (Super Knife)
- A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED GROUP STUDY ASSESSING THE SAFETY AND EFFICACY OF TOFACITINIB IN HOSPITALIZED PARTICIPANTS WITH COVID-19 PNEUMONIA WHO ARE RECEIVING STANDARD OF CARE THERAPY**
 - IDs: NCT04412252 | A3921377
 - Condition or Disease: COVID-19
 - Intervention/treatment: Tofacitinib, Placebo

A 'Request Study' dropdown menu is open, showing options such as '2024 DataWorks! Prize', 'Albumin increase in diabetes mellitus patients', 'EOC 7-2-24 QA Test Req 4', 'EOC 7-2-24 Test Req 5', 'EOC 7-2-24 Test Req 6', and 'EOC 7-2-24 Test Req QA 3'.

- Once you have added all desired studies listed on the Vivli platform, you can complete the Data Request Form.

1.2 Completing a data request

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

- The name, contact information, primary affiliation and position, country, qualifications, degrees and where the degrees were obtained of all team members.
 - Conflict of Interest Statement
 - The title of the proposed research with a description of the study design (which should match the Project name). Reminder: please begin your title with **2024 DataWorks! Prize**
 - Lay summary explaining the relevance of the project to science and public health
 - Studies
 - Statistical Analysis Plan
 - Information about funding
 - Attestation
- (For all other fields, put the phrase n/a)

1.3 Adding Research Team Members

- Individuals activated for a data request will be able to view and edit the Data Request Form
- How-To: Requesting Studies on Vivli for DataWorks! Prize
Version 3.4

- If your team member is from a different institution than the Lead Investigator and they would like to access the data, they will need to have a DUA in place from their institution before accessing the data.

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

The screenshot shows the Vivli web application interface. At the top, there is a navigation bar with the Vivli logo and menu items: Home, About, Members, News & Events, Resources, and Find Studies. Below this is a secondary navigation bar with links for ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and RESEARCHER. The main content area is titled 'Predicting Treatment Response' and includes a 'Go Back' link, an 'Edit Request Title' button, and 'Cancel', 'Save', and 'Submit' buttons. The 'Research Team' section is highlighted with a red box. It contains a 'LEAD RESEARCHER' section with a checkbox for 'Activate user for accessing data request' and another checkbox for 'Lead Researcher is also Statistician Researcher', which is also highlighted with a red box. The form includes fields for First Name, Last Name, ORCID ID, Email, Position, Employer, Company, Research Ins..., and Country. There is also a text area for 'Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis.' and a section for 'Please list any real or potential conflicts of interest and describe how these will be managed. If none, please enter None.' The sidebar on the left contains links for Research Proposal, Studies, Statistical Analysis Plan, Funding, Other Information / File Attachments, Attestations, and Chat.

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

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RESEARCHER

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

Research Team

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

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

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

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

ADDITIONAL RESEARCHERS [Add +](#)

3. The following dialogue box will appear:

ADDITIONAL RESEARCHER Activate user for accessing data request ?

First Name Last Name ORCID ID ?

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

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

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

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

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

[OK](#) [Cancel](#)

4. Note that the character limit in the Education text field is 1000 characters. If the number of characters entered

exceeds this limit, a pop up will appear alerting you that the Education/qualification field exceeds the limit:

The screenshot shows a form with several input fields. A red box highlights the 'Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis.' field. A red error message box is overlaid on the field, stating: 'Education or Qualifications length must be less than or equal to 1000 characters long'. To the right of the field, a character count is shown: 'Character Count: 1223/1000'. Below the field, there is a text area containing the following text: 'Please see below for my education including degree, discipline and institution where the degree wa granted. I also included qualifications specific to this analysis Education of Lead Researcher: Bachelor's Degree from University of California, San Francisco where I obtained a degree in Biological Life Sciences in 1998 Master's Degree from University of California, San Francisco where I obtained a degree in Epidemiology in 2000 PhD from University of California, San Francisco where I obtained a degree in Epidemiology in 2006 Other qualifications:'. Below this is another text area with the instruction: 'Please list any real or potential conflicts of interest and describe how these will be managed. If none, please enter None.'

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

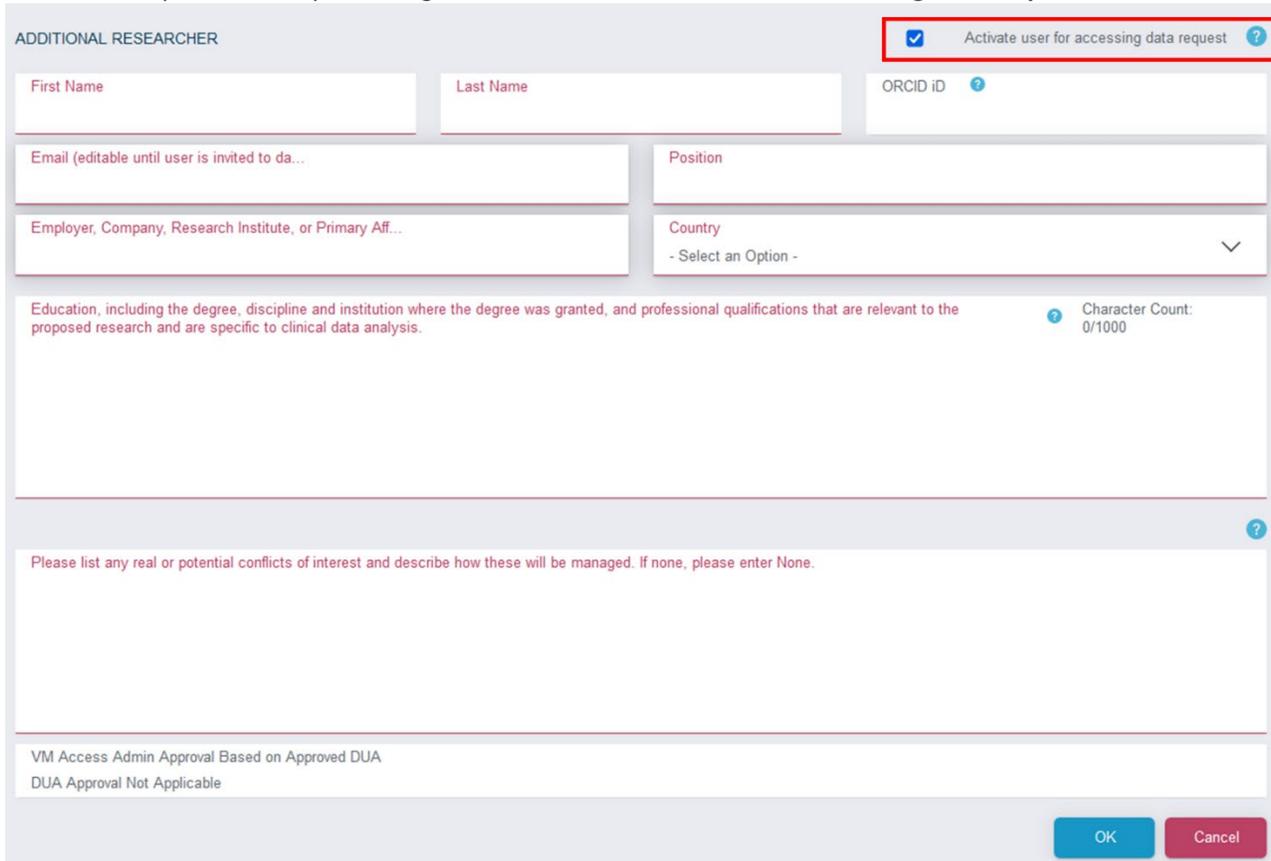
The screenshot shows the 'Research Team' section of a web application. The 'Research Team' tab is selected and circled in red. The 'Position' field is outlined in red. The 'Research Team' tab on the left has a red exclamation mark. The form contains the following information: LEAD RESEARCHER - No Account, Activate user for accessing data request, Lead Researcher is also Statistician Researcher. First Name: Sarah, Last Name: Jones, ORCID ID. Email (editable until user is invited to data...): sarah.jones@ucsd.edu, Position. Employer, Company, Research Institute, or Primary Affili...: UCSD, Country: United States of America. Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis. Character Count: 54/1000. PhD Biostatistics UCSD 1999, MS Biostatistics UCSD 1995. Please list any real or potential conflicts of interest and describe how these will be managed. If none, please enter None. None. VM Access Admin Approval Based on Approved DUA, DUA Approval Not Applicable.

6. Complete all fields, and click



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

8. Once the Research team members have created their Vivli account, you can activate them for accessing the Data Request Form by checking the checkbox **Activate user for accessing data request** and then click **OK**:

A screenshot of a web form titled "ADDITIONAL RESEARCHER". At the top right, there is a checkbox labeled "Activate user for accessing data request" which is checked and highlighted with a red box. Below this are several input fields: "First Name", "Last Name", and "ORCID ID" (with a help icon); "Email (editable until user is invited to da...)" and "Position"; "Employer, Company, Research Institute, or Primary Aff..." and "Country" (a dropdown menu showing "- Select an Option -"); and a large text area for "Education, including the degree, discipline and institution where the degree was granted, and professional qualifications that are relevant to the proposed research and are specific to clinical data analysis." with a character count of "0/1000". At the bottom, there is a text area for "Please list any real or potential conflicts of interest and describe how these will be managed. If none, please enter None." and a section for "VM Access Admin Approval Based on Approved DUA" with "DUA Approval Not Applicable". At the very bottom right are "OK" and "Cancel" buttons.

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

< Go Back **Increase in albuminuria in Diabetes patients** [Edit Request Title](#) [Cancel](#) [Save](#) [Submit](#)

Research Team

LEAD RESEARCHER / STATISTICIAN Activate user for accessing data request Lead Researcher is also Statistician Researcher [?](#)

First Name: Sarah Last Name: Jones ORCID iD: [?](#)

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

Employer, Company, Research Institute, or Primary Affil...: University of California, San Diego Country: United States of America [v](#)

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

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

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

None

1.4 Submitting your data request

- Once the Data Request Form is complete, you may submit it for review.
- Please make sure that you have added all the eligible DataWorks Prize studies to your data request as adding it later will lead to additional delays.
- Before submitting a Data Request Form, the Lead Researcher must attest that all the information provided is accurate and complete:

 **Vivli**
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

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

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

Research Team

Research Proposal

Studies

Statistical Analysis Plan

Funding

Other Information / File Attachments

Attestations

Chat

Certify Complete and Accurate

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

I certify the information provided is complete and accurate.

Data Use Agreement

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

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

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

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

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

2.0 Vivli Accelerated Review of your data request

Once submitted, your data request will go through a Vivli form check. It will be processed within 2 business days. We may request revisions. Please re-submit promptly.

3.0 Data Use Agreement

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

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

4.0 Downloading data

Once the Data Use Agreement is executed, you will receive a notification to download the data directly from the Vivli Platform using the following process:

Log in and open your approved data request:

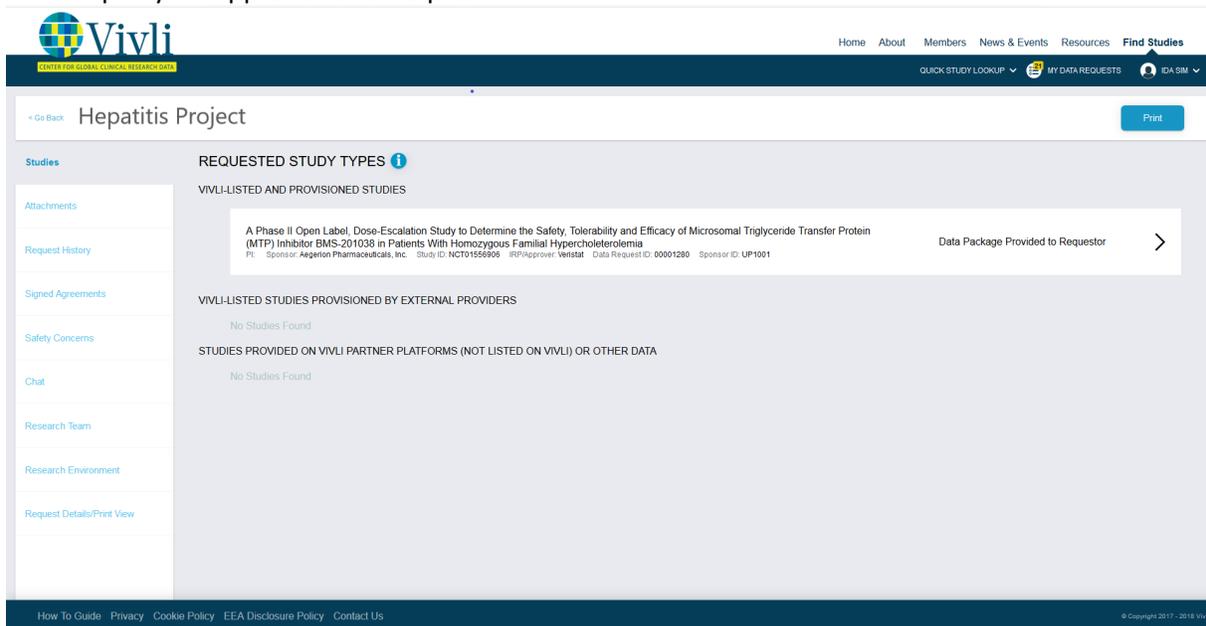


Figure 26 - Approved Data Request

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

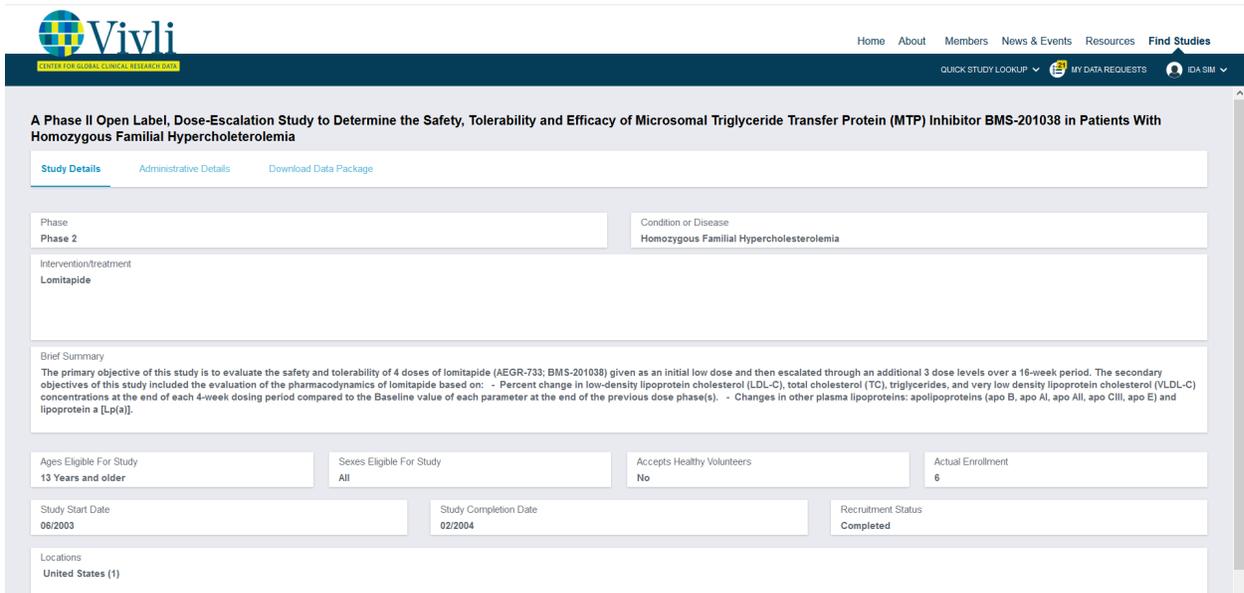


Figure 27 - Study details screen

- Click on Download Data Package:

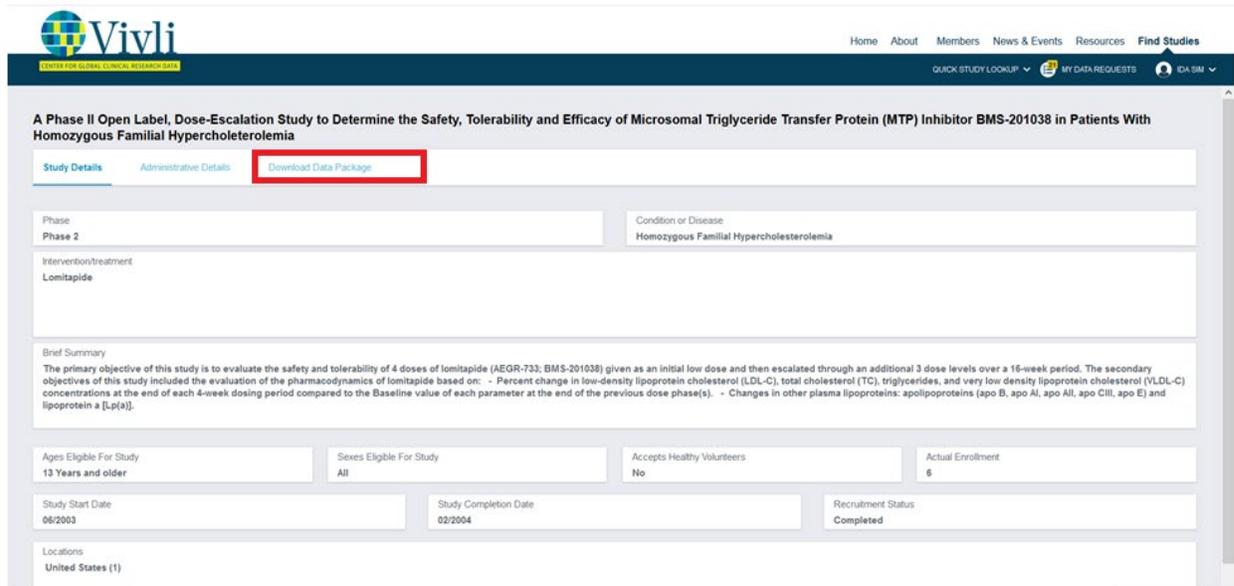


Figure 28 - Download Data Package

- This will take you to the Download screen:

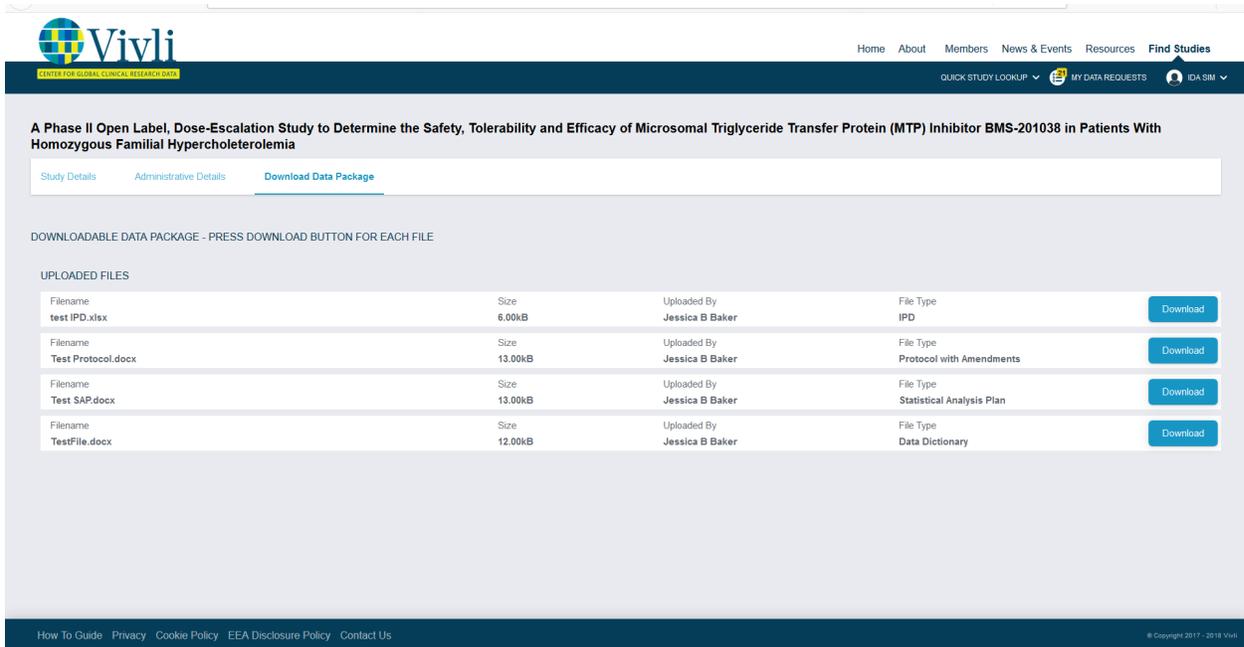


Figure 29 - Download Screen

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

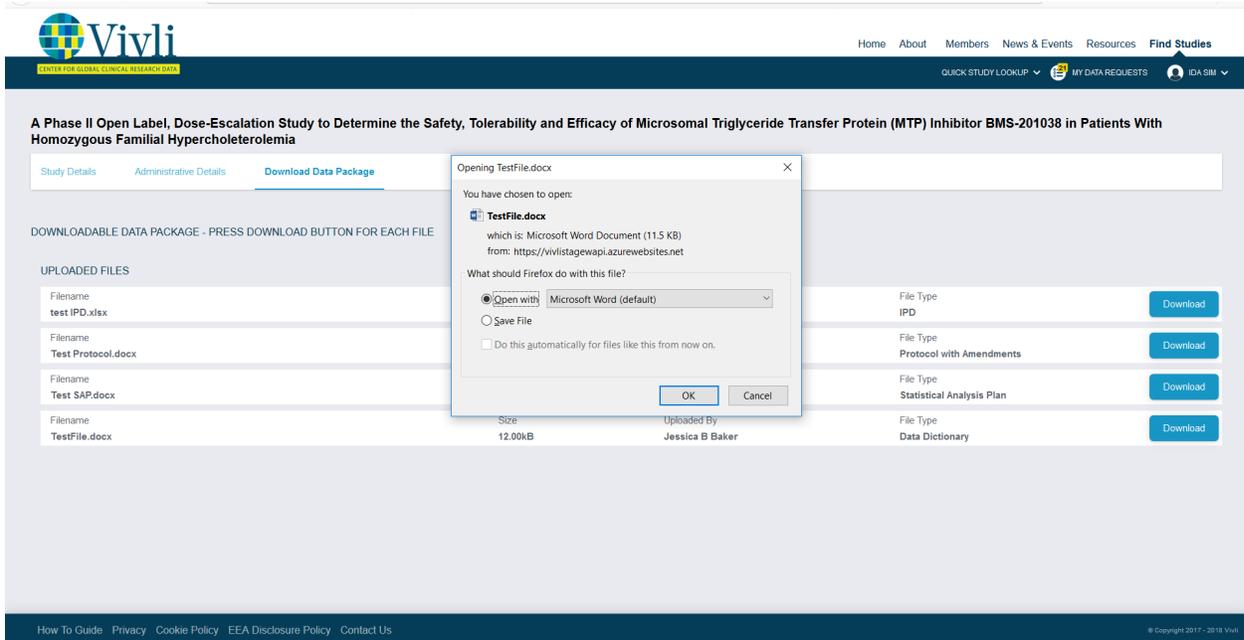


Figure 30 - Downloadable data file selection pop-up

5.0 Help and Support

5.1 Open Chat

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

5.2 Support email

If you need help with your request, please email Vivli at support@vivli.org and we will assist you as soon as possible. Please provide as much information as you can about your question or help needed, including the research proposal number.

If you ever have thoughts on how to improve the system or processes, please email 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.