



Vivli Study Submission Guide Vivli Platform Version 3.1

30 August 2023

1 Table of Contents

1.0 SUBMITTING STUDIES ON VIVLI – OVERVIEW.....	2
1.1 LOGIN/ACCOUNT SETUP	3
1.2 DASHBOARD	4
2.0 STUDY SUBMISSION.....	5
2.1 INFORMATION ABOUT YOUR TEAM	5
2.2 YOUR ORGANIZATION	7
2.3 YOUR STUDY	7
2.4 DATA SHARING SETTINGS	9
2.5 AGREEMENTS.....	12
3.0 DATA PACKAGE UPLOAD	15
3.1 DATA PACKAGE REQUIREMENTS	16
3.2 DATA PACKAGE UPLOAD	16
4.0 MANAGING YOUR SUBMISSION	19
4.1 SUBMISSION STATUS	19
4.2 MAKING EDITS	19
4.3 WITHDRAWAL.....	20
5.0 VIEWING YOUR STUDY DETAILS	20
5.1 USING VIVLI SEARCH	20
5.2 STUDY DETAILS	21
5.3 STUDY DOCUMENTS	22
5.4 ADMINISTRATIVE DETAILS	22
5.5 USAGE	23
5.6 ADDING RESEARCH TEAM MEMBERS TO YOUR STUDY SUBMISSION	23
6.0 CONTACT THE VIVLI TEAM	24
6.1 USING THE PLATFORM CHAT.....	24
6.2 E-MAIL VIVLI SUPPORT.....	24

1.0 Submitting Studies on Vivli – Overview



- Vivli is here to make it as efficient and easy as possible to share your human-subject participant level data and supporting documents. The Vivli team will support you every step of the way. For more information, please see our webpage on [How to Share Data](#).
- Once you have created your Vivli account, you will be prompted to provide information about your study.
- The [Vivli Data Contribution Agreement](#) needs to be read, understood and signed by the Principal Investigator and an institution official.
- Vivli only accepts anonymized data. Your institution may provide support or Vivli has anonymization vendors who will offer support for this service.
- Once the submission has been accepted by the Vivli team, you will then be able to upload your anonymized data.
- Please note that this process is primarily intended for academic researchers. Please [reach out to Vivli](#), if you are a for-profit organization and want to take advantage of the Vivli platform to share your completed clinical research data.

1.1 Login/Account Setup

- To get started with the Study Submission process, visit <https://search.vivli.org/study-submission>
- If you do not already have a Vivli user account, click the 'Create Account' button. To learn more about creating a Vivli account, please review our [Vivli User Account Quick Start guide](#).

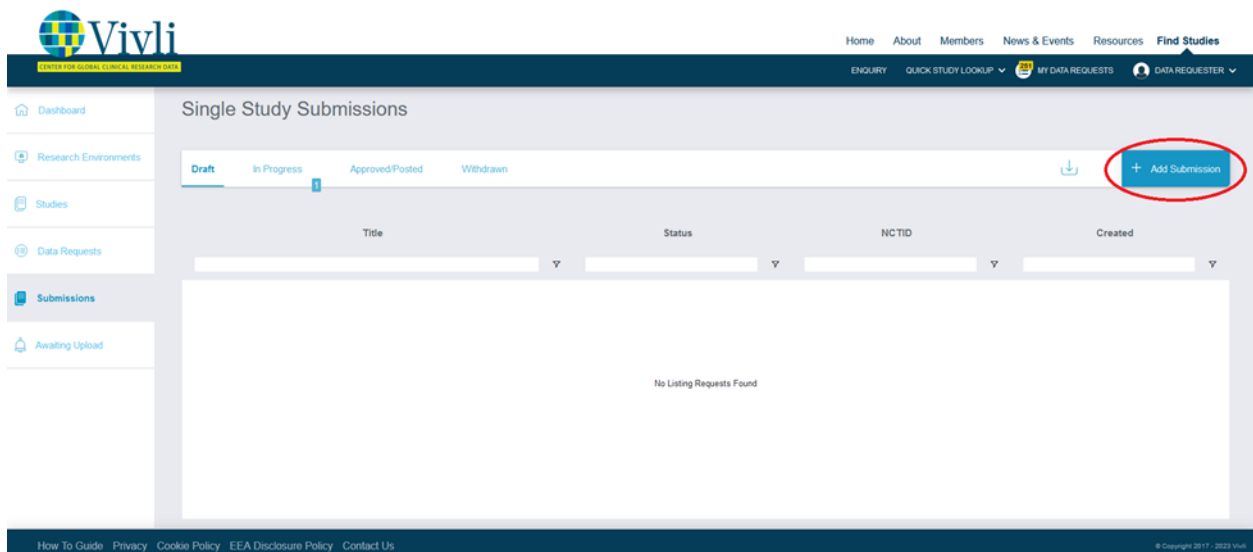


- If you are already a Vivli user, click the “Login” button.

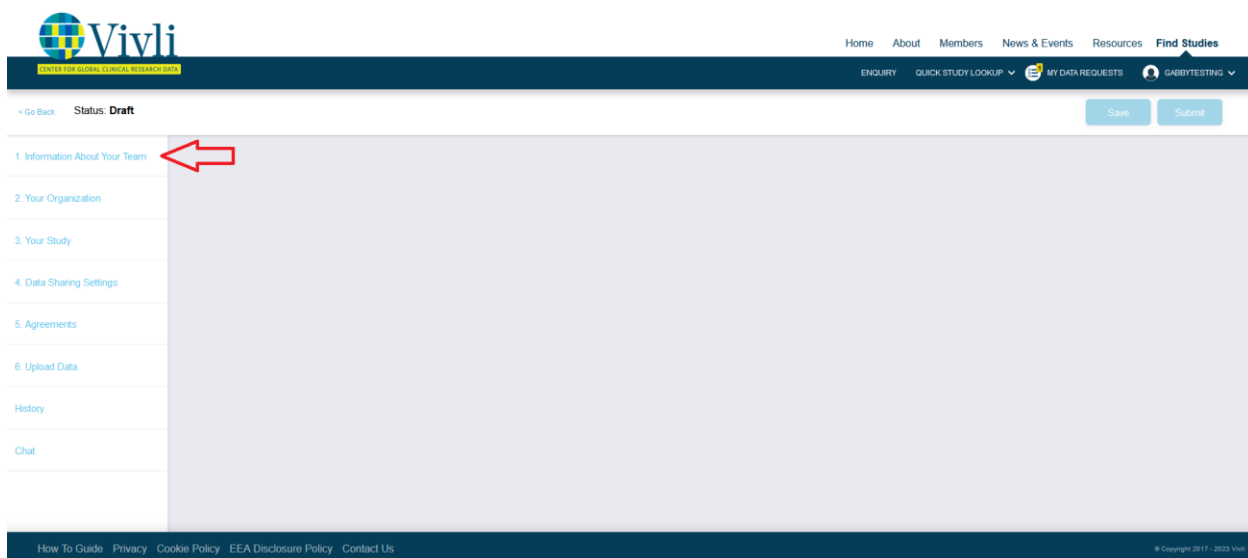


1.2 Dashboard

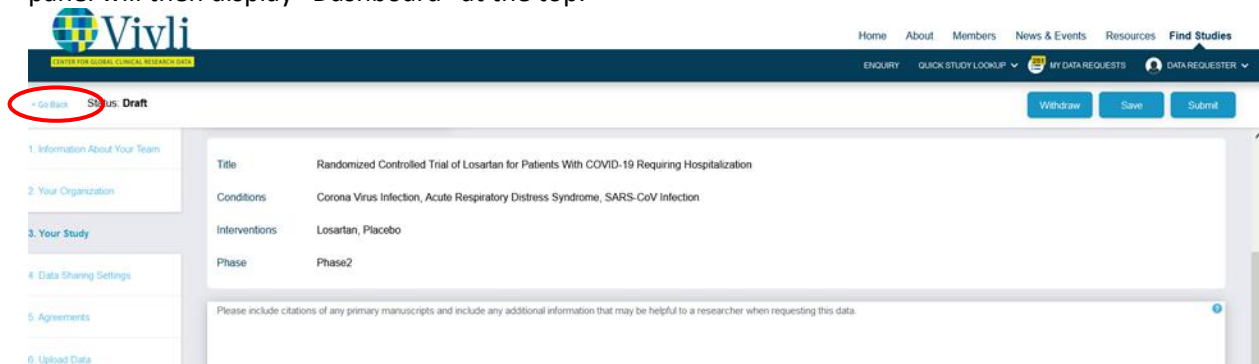
- Once you have logged into the platform, if you have already begun to create submissions, your account dashboard will appear.
- To submit a new study for sharing, first click the “Studies” button on the left panel and then click the blue “Add Submission” button in the upper right corner.



- If you do not have any active submissions, the platform will initiate a new draft submission. Click on the “Information About Your Team” tab to begin completing the submission form.



- At any time, to navigate back to your dashboard, click on the “Go back” button and the left panel will then display “Dashboard” at the top.



If at any time you are redirected from the Study Submission page within your dashboard, please navigate to <https://search.vivli.org/study-submission> and this will bring you back to the Study Submission page.

2.0 Study Submission

2.1 Information About Your Team

The names that you enter using "Add Team Member" will get public recognition for their contributions to the study. You can select one or more CRediT roles - for a list of the available roles and descriptions, click on the Help icon at the top of the field.

- Use the “Add Team Member” button to add all research team members to the study

The screenshot shows the Vivli platform interface. At the top, there is a navigation bar with the Vivli logo and links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a secondary navigation bar with links for ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and DATA REQUESTER. The main content area is titled '1. Information About Your Team' and contains a section 'TELL US ABOUT THE RESEARCH TEAM'. Below this section, there is a red oval highlighting the 'Add Team Member' button. To the right of this button is a 'Next Page' button. The left sidebar contains links for '2. Your Organization', '3. Your Study', '4. Data Sharing Settings', '5. Agreements', '6. Upload Data', 'History', and 'Chat'. The bottom of the page has a footer with links for 'How To Guide', 'Privacy', 'Cookie Policy', 'EEA Disclosure Policy', and 'Contact Us'.

- Complete all required fields. For more information regarding CRediT roles, please visit <https://credit.niso.org/>.
- Once all fields for the first team member are complete, use the “Add Team Member” button to create additional entries.

This screenshot shows the Vivli platform interface with the 'Add Team Member' button highlighted in red. The form fields are as follows:

TELL US ABOUT THE RESEARCH TEAM		
The names that you enter using "Add Team Member" will get public recognition for their contributions to the study. You can select one or more CRediT roles - for a list of the available roles and descriptions, click on the Help icon at the top of the field.		
Email address academicsubmitter@gmail.com	ORCID ID 1234-5678-9101-1121	CRediT Role(s) Data curation x Project administration x
Given Name John	Family Name Smith	

Below the form fields, the 'Add Team Member' button is highlighted in red, and the 'Next Page' button is visible to its right. The left sidebar and footer are the same as in the previous screenshot.

1. Information About Your Team

TELL US ABOUT THE RESEARCH TEAM

The names that you enter using "Add Team Member" will get public recognition for their contributions to the study. You can select one or more CRediT roles - for a list of the available roles and descriptions, click on the Help icon at the top of the field.

Email address: academic.submitter@gmail.com
ORCID ID: 1234-5678-9101-1121
Given Name: John
Family Name: Smith
CRediT Role(s): Data curation, Project administration

Buttons: Add Team Member, Next Page

- Once all team members have been entered and roles have been assigned, click the “Next Page” button to navigate to the next section.

2.2 Your Organization

- Enter the name of the Organization/Institution that will be displayed as the Data Contributor for the study and the number of studies that will be submitted. Please note that each study will need to be submitted separately.
- If you plan to submit more than two studies, use the “Contact Us” button so that we can make the submission process more efficient for you.
- Once these fields are complete, use the “Next Page” button to navigate to the next section.

2. Your Organization

TELL US ABOUT YOUR ORGANIZATION

Enter the full name of your organization
Boston University

How many studies do you expect to submit at this time
1

If you have more than 2 studies that you want to share at this time, please contact Vivli by emailing support@vivli.org as we have other ways to make this process more efficient for you.

Buttons: Contact Vivli, Next Page

2.3 Your Study

- Enter the registration ID from clinicaltrials.gov. This will automatically populate the Title, Conditions, Interventions and Phase information from clinicaltrials.gov. If you want to submit a study that was

not registered on clinicaltrials.gov, please email Vivli support@vivli.org and we will assist you.

The screenshot shows the Vivli platform registration form, Step 3: Your Study. The form includes fields for NCT ID, Title, Conditions, Interventions, and Phase. The NCT ID field is circled in red.

TELL US ABOUT YOUR STUDY
Enter the registration ID from clinicaltrials.gov. This will bring in information about your study from clinicaltrials.gov.
If you want to submit a study that has not been registered on clinicaltrials.gov, reach out to support@vivli.org.

NCT ID (of the form NCT12345678)
NCT04312009

Title: Randomized Controlled Trial of Losartan for Patients With COVID-19 Requiring Hospitalization
Conditions: Corona Virus Infection, Acute Respiratory Distress Syndrome, SARS-CoV Infection
Interventions: Losartan, Placebo
Phase: Phase2

Please include citations of any primary manuscripts and include any additional information that may be helpful to a researcher when requesting this data.

Select the name of your primary funder
Grant/Contract ID

- Any information that you provide in the “Additional Information” field will be visible to researchers searching for studies. You can include any citations related to your clinical research, or any other information that might be used by the researcher to determine whether your study will support their research.
- Use the drop-down menu to select the primary funder. If the study was funded by your organization, leave this at N/A. If it was funded by an external funder, choose the name from the drop-down list. If your external funder is not on the list, choose “Other”.

The screenshot shows the Vivli platform registration form, Step 3: Your Study. The form includes fields for Title, Conditions, Interventions, and Phase. The drop-down menu for the primary funder is circled in red.

Title: Randomized Controlled Trial of Losartan for Patients With COVID-19 Requiring Hospitalization
Conditions: Corona Virus Infection, Acute Respiratory Distress Syndrome, SARS-CoV Infection
Interventions: Losartan, Placebo
Phase: Phase2

Please include citations of any primary manuscripts and include any additional information that may be helpful to a researcher when requesting this data.

Select the name of your primary funder
Other

Grant/Contract ID

Please provide a contact email at your organization for invoicing
invoicing@bu.edu

Next Page

- Depending on your selection, you may be prompted to provide a contact email address for invoicing.
 - If your academic institution is a member of Vivli there is no cost to deposit data in Vivli’s platform starting in 2023. Please check our [members](#) page if you are unsure of the status of your institution.

- If your academic institution is not a member, there is a one-time cost to use Vivli's managed access process for clinical trials data. These costs apply only for academic and non-profit researchers who want to share their clinical data. Visit our [Share Data](#) page for more information on costs associated with sharing your data. If you are from a for-profit organization please [reach out to Vivli](#) and we can discuss how you can take advantage of the Vivli platform to share your completed clinical research.
- Once all fields have been complete, click "Next Page" to navigate to the next section.

The screenshot displays the Vivli platform interface for a study submission. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. The main content area is titled '3. Your Study' and contains a form with the following fields:

- Title:** Randomized Controlled Trial of Losartan for Patients With COVID-19 Requiring Hospitalization
- Conditions:** Corona Virus Infection, Acute Respiratory Distress Syndrome, SARS-CoV Infection
- Interventions:** Losartan, Placebo
- Phase:** Phase2
- Citations:** A text area for including citations of any primary manuscripts.
- Primary Funder:** A dropdown menu with 'Other' selected.
- Grant/Contract ID:** A text field.
- Contact Email:** A text field with the placeholder 'Please provide a contact email at your organization for invoicing' and the example 'invoicing@bu.edu'.

A red circle highlights the 'Next Page' button at the bottom of the form.

2.4 Data Sharing Settings

- **Accelerated Review** -- When a research team requests your study, an Accelerated Research Proposal Review will be conducted within 3 business days. Vivli will manage the execution of the Data Use Agreement. Once these steps are completed, the Vivli team will work with the researcher to access the data and support them until they have published their results. If you have any questions about this process, please reach out to the Vivli team in chat.

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back Azithromycin for Prevention of Disease Progression in Patients With Mild or Moderate COVID-19

Status: **Draft** Withdraw Save Submit

1. Information About Your Team
2. Your Organization
3. Your Study
4. Data Sharing Settings
5. Agreements
6. Upload Data
History
Chat

Send a message to Vivli with questions or requests - we will normally respond within a day, and you will receive an email notification when a response is available.

Enter message here

Send

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2023 Vivli

- **Embargo** -- If you need to embargo your data, we will make the study available for researchers to request, but the data itself will not be provided until the embargo date has passed. This might be necessary, for example, if the data itself cannot be provided until the results of the study are published.

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back Randomized Controlled Trial of Losartan for Patients With COVID-19 Requiring Hospitalization

Status: **Draft** Withdraw Save Submit

1. Information About Your Team
2. Your Organization
3. Your Study
4. Data Sharing Settings
5. Agreements
6. Upload Data
History
Chat

DATA SHARING SETTINGS

Review process for requests for data:

When a research team requests your study, an Accelerated Research Proposal Review will be conducted within 3 business days. Vivli will manage the execution of the Data Use Agreement. Once these steps are completed, the Vivli team will work with the researcher to access the data and support them until they have published their results. If you have any questions about this process, please reach out to the Vivli team in chat.

Does your data need to be embargoed?

☒ Yes ☐ No

Embargo data until

DD/MM/YYYY

Data requesters may want to contact you for questions and/or collaboration. Are you willing to be available by email to requesters?

☐ Yes ☒ No

All data provided to Vivli must be anonymized. Will you need help anonymizing your data?

☐ Yes ☒ No

Study data packages must include at least 4 file types - click here for more information.

Next Page

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2023 Vivli

- If you are willing to be contacted, the Vivli team will email you any requests for collaboration or questions. Making yourself available for contact does not imply a commitment to collaborate on any or all requests – it is your decision to answer questions or collaborate on a case-by-case basis.

Vivli
PLATFORM FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

Go Back Randomized Controlled Trial of Losartan for Patients With COVID-19 Requiring Hospitalization Status: Draft Withdraw Save Submit

1. Information About Your Team
2. Your Organization
3. Your Study
4. Data Sharing Settings
5. Agreements
6. Upload Data
History
Chat

DATA SHARING SETTINGS

Review process for requests for data:

When a research team requests your study, an Accelerated Research Proposal Review will be conducted within 3 business days. Vivli will manage the execution of the Data Use Agreement. Once these steps are completed, the Vivli team will work with the researcher to access the data and support them until they have published their results. If you have any questions about this process, please reach out to the Vivli team in chat.

Does your data need to be embargoed?
☐ Yes ☒ No

Data requesters may want to contact you for questions and/or collaboration. Are you willing to be available by email to requesters?
☐ Yes ☒ No

All data provided to Vivli must be anonymized. Will you need help anonymizing your data?
☐ Yes ☒ No

Study data packages must include at least 4 file types - click here for more information.

Next Page

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

- If you need help anonymizing your clinical research data, Vivli can connect you with vendors who can help. Please note that it is the data contributor's responsibility to ensure that the data is appropriately anonymized.

Vivli
PLATFORM FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

Go Back Randomized Controlled Trial of Losartan for Patients With COVID-19 Requiring Hospitalization Status: Draft Withdraw Save Submit

1. Information About Your Team
2. Your Organization
3. Your Study
4. Data Sharing Settings
5. Agreements
6. Upload Data
History
Chat

DATA SHARING SETTINGS

Review process for requests for data:

When a research team requests your study, an Accelerated Research Proposal Review will be conducted within 3 business days. Vivli will manage the execution of the Data Use Agreement. Once these steps are completed, the Vivli team will work with the researcher to access the data and support them until they have published their results. If you have any questions about this process, please reach out to the Vivli team in chat.

Does your data need to be embargoed?
☐ Yes ☒ No

Data requesters may want to contact you for questions and/or collaboration. Are you willing to be available by email to requesters?
☐ Yes ☒ No

All data provided to Vivli must be anonymized. Will you need help anonymizing your data?
☒ Yes ☐ No

Vivli will connect you with a vendor who will help with your data anonymization. Please note that a third-party agreement with the anonymization vendor and additional anonymization charges will apply.

Study data packages must include at least 4 file types - click here for more information.

Next Page

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

- Once all Data Sharing Settings have been selected, use the “Next Page” button to navigate to the next section.

2.5 Agreements

- Click the blue “Sign Data Contribution Agreement” button. This will open a new browser tab to begin the DocuSign legal agreement signing process that will allow you to provide some basic information about you and your organization.

- The Principal Investigator and an Institutional Official will need to read, acknowledge and sign this [Data Contribution Agreement \(DCA\)](#). If you don't know who your institution official is, in most organizations a good place to start is the Grants and Contract office. See an example email template to send to this office that provides instructions [here](#).
- Instructions for signing the agreement:
 1. The DocuSign PowerForm provides basic instructions for you and your institutional official. When you are ready to sign the agreement, please provide the Full Name and email address in both the

Principal Investigator and Institutional Official fields. Next, click “Begin Signing.”

PowerForm Signer Information

Thank you for your interest in sharing your studies using Vivli.

The Principal Investigator and an Institutional Official will need to read, acknowledge and sign this Data Contribution Agreement (DCA). If you don't know who your institution official is, in most organizations a good place to start is the Grants and Contract office. See an example email template to send to this office that provides instructions here: <https://vivli.org/template-email-for-data-contributors/>.

The DCA provides the principal investigator and the institution to be a third-party beneficiary to any subsequent Data Use Agreement (DUA) that is signed when your data is requested.

The DUA runs between Vivli and an applicable Data User and is the agreement under which Vivli grants a data user limited rights to use the data and licenses back to the applicable Contributor for any newly created intellectual property. The Vivli agreements are the product of extensive negotiation with the organizations that contribute data to Vivli, and as such, the agreement is non-negotiable.

Please enter your name and email to begin the signing process.

Principal Investigator

Your Name: *
Full Name

Your Email: *
Email Address

Please provide information for any other signers needed for this document.

Institutional Official

Name:
Full Name

Email:
Email Address

BEGIN SIGNING

Principal Investigator (Please provide their information below)

Your Name: *
Name of Principal Investigator

Your Email: *
Principal Investigator's Email Address

Please provide information for any other signers needed for this document.

Institutional Official (Please refer to instructions above to determine who this is)

Name:
Name of Institutional Official

Email:
Institutional Official's Email Address

BEGIN SIGNING

2. Click the box that says you agree to use electronic records and signatures. Then, click Continue.

Please read the Electronic Record and Signature Disclosure.

☒ I agree to use electronic records and signatures.

CONTINUE FINISH LATER OTHER ACTIONS ▾

3. The Principal Investigator will need to complete the required fields (outlined in red), including Organization Name (p.1), Business Address (p.1 and p.6), Acknowledgement (p.8), NCT ID (p.9), and Agreed and Acknowledged (p.11). Once all required fields have been completed, click the yellow “Finish” button:

Enter your title

FINISH FINISH LATER OTHER ACTIONS

AGREED AND ACKNOWLEDGED:

By: *Principal Investigator*

Name: Principal Investigator

Title: **Required - Title** Principal Investigator

Date: 1/17/2023

FILL IN

4. The agreement will then be routed to the Institutional Official for signature.

- Once you have signed the agreement it will be sent to an individual who can sign on behalf of your organization. If you have any questions about this, please use the chat function.
- After you have initiated the DCA process, you must click the “Submit” button in the upper right corner to begin the Vivli review process. You do not need to wait for the Data Contribution Agreement to be executed before you submit.

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back Randomized Controlled Trial of Losartan for Patients With COVID-19 Requiring Hospitalization
Status: Draft

Withdraw Save **Submit**

1. Information About Your Team
2. Your Organization
3. Your Study
4. Data Sharing Settings
5. Agreements
6. Upload Data
History
Chat

AGREEMENTS

The Principal Investigator and an Institutional Official will need to read, acknowledge, and sign this Data Contribution Agreement (DCA). If your institution already has a Master DCA in place, we do not require institutional signature for future submissions. If you are unsure whether your institution has a Master agreement in place, please reach out to support@vivli.org.

Click below to start the signing process.

Sign Data Contribution Agreement

At a minimum, Vivli will make the data available for 10 years. On an ongoing basis, Vivli evaluates its data holdings with regard to maintaining access and reserves the right to discontinue the distribution of data collections when deemed appropriate.

WHAT'S NEXT

Once you have initiated the Data Contribution Agreement signing process, please click the Submit button, if available, to notify Vivli to begin processing the study.

Once the study is processed and the Data Contribution Agreement signed, the study will appear in the Vivli Search and you will receive an email from Vivli inviting you to upload the anonymized data. Follow the link in the email or return to the Submissions tab, choose this submission and choose "Upload Data."

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2023 Vivli

- Once the study has been submitted, your study will automatically appear in the Submissions dashboard under “In Progress.”

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

Dashboard Research Environments Studies Data Requests **Submissions** Awaiting Upload

Single Study Submissions

Draft **In Progress** Approved/Posted Withdrawn

+ Add Submission

Title	Status	NCTID	Submitted
Randomized Controlled Trial of Losartan for Patients With COVID-19 Requiring Hospitali...	Submitted	NCT04312009	2023-01-05
University of Washington Alzheimer's Disease Research Center (UW ADRC) Imaging & ...	Study in Curation	NCT04437290	2022-12-08

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2023 Vivli

- You will not be able to upload your anonymized data until the metadata has been curated, your Data Contribution Agreement has been executed and the study has been posted/accepted. When this is complete, you will be contacted.

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

Go Back Randomized Controlled Trial of Losartan for Patients With COVID-19 Requiring Hospitalization **Withdraw**

Status: Study in Curation

1. Information About Your Team
2. Your Organization
3. Your Study
4. Data Sharing Settings
5. Agreements
6. Upload Data

History
Chat

UPLOAD THE STUDY DATA

Your request is being reviewed. You will be able to upload the data when it has been accepted and the Data Contribution Agreement has been executed.

Study data packages must include at least 4 file types - click here for more information.

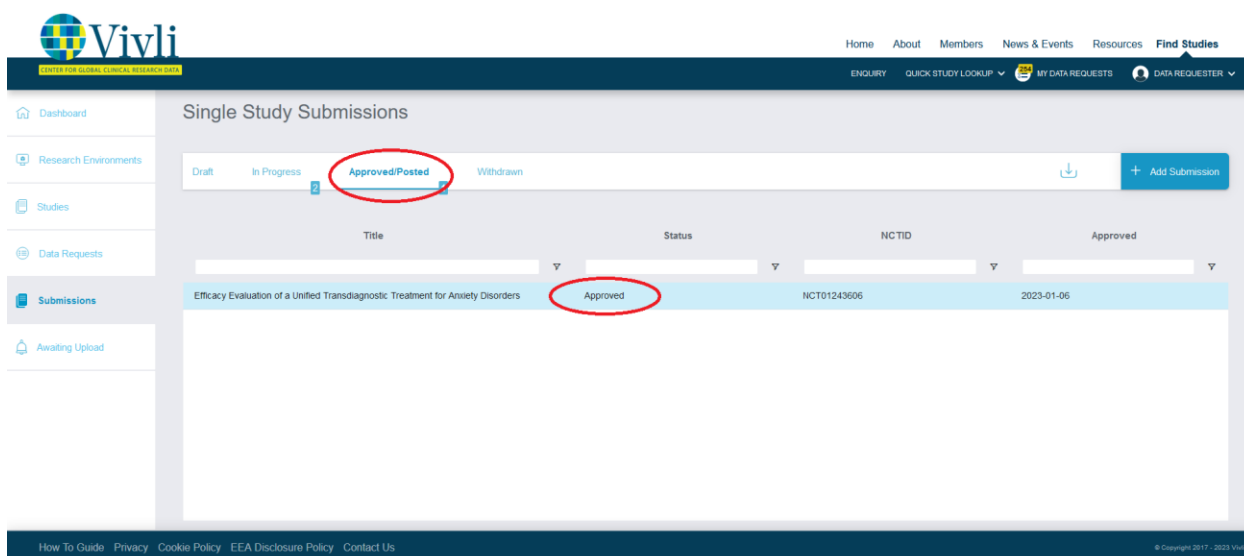
If any of these files are not available, please include a placeholder file stating that it is not available. When you are ready to upload data to the Vivli Platform, if the anonymized Individual Participant-level Data are held in several files, we recommend that you zip them into a single Data file. We recommend that you load other accompanying documents as separate files.

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2023 Vivli

3.0 Data Package Upload

Once the study is processed and the Data Contribution Agreement signed, the study will appear in the Vivli Search, and you will receive an email from Vivli inviting you to upload the anonymized data. Follow the link in the email or return to the Submissions tab, choose this submission, and choose "Upload Data."



3.1 Data Package Requirements

- It is expected that all data packages will include the following 4 file types to support the researcher's use of your data:
 - Study Protocol** - Final protocol with all amendments
 - Data Dictionary** - Detailed descriptions of each variable in the dataset, including the definition, source, coding, etc. of the variable
 - Statistical Analysis Plan** - Description of the principal features of the analysis described in the protocol
 - IPD Dataset** - Final cleaned individual participant-level data, anonymized
- Any other documents that may be useful to the researcher can be included and will be welcomed.
- If any of these files are not available, please include a placeholder file stating that it is not available.
- When you are ready to upload data to the Vivli Platform, if the anonymized Individual Participant-level Data are held in several files, we recommend that you zip them into a single Data file. We recommend that you load other accompanying documents as separate files.

3.2 Data Package Upload

- The Vivli Team will reach out once the Data Contribution Agreement has been executed and you are approved to upload your anonymized study data and supporting documents.
- From the Dashboard, under 'Approved/Posted,' click on the study for which you are ready to upload your anonymized data.
- Click on the 'Upload Data' tab and then you may use either the blue 'Select Files' button or drag and drop the appropriate files.

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Disorders
Status: **Approved**

1. Information About Your Team
2. Your Organization
3. Your Study
4. Data Sharing Settings
5. Agreements
6. Upload Data
History
Chat

UPLOAD THE STUDY DATA

Your request has been accepted and the Data Contribution Agreement has been executed - your study is available for requesting. Please upload the data below.

Study data packages must include at least 4 file types - click here for more information.

If any of these files are not available, please include a placeholder file stating that it is not available. When you are ready to upload data to the Vivli Platform, if the anonymized Individual Participant-level Data are held in several files, we recommend that you zip them into a single Data file. We recommend that you load other accompanying documents as separate files.

Upload study Data Package below

NO FILES IN PACKAGE

YOU MUST SUPPLY ALL REQUIRED FILE TYPES AS DISTINCT FILES, AND FOR EACH FILE, YOU MUST SPECIFY THE FILE TYPE. If a file type is unavailable, please provide a file with a note of explanation

- IPD (Anonymized Individual Participant-level Data)
- Data Dictionary
- Protocol
- Statistical Analysis Plan

Select Files Drop files here

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2023 Vivli

- Use the dropdown menu on the right-hand side to validate the File Type for each file before submitting files (Note: If you are missing the protocol, data dictionary, or Statistical analysis plan, please create a Word file with a note and upload it as a placeholder and validate the file type).

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Disorders
Status: **Approved**

1. Information About Your Team
2. Your Organization
3. Your Study
4. Data Sharing Settings
5. Agreements
6. Upload Data
History
Chat

• IPD (Anonymized Individual Participant-level Data)
• Data Dictionary
• Protocol
• Statistical Analysis Plan

Select Files

UPLOADED FILES

Filename	Size	Uploaded By	File Type	Download	Delete
NCT01243606_Data Dictionary.docx	11.71kB	Data Requester	Unknown	Download	Delete
NCT01243606_IPD.docx	11.69kB	Data Requester	IPD	Download	Delete
NCT01243606_Protocol.docx	11.69kB	Data Requester	Data Dictionary	Download	Delete
NCT01243606_SAP.docx	11.69kB	Data Requester	Protocol	Download	Delete
			Statistical Analysis Plan		
			Analysis-Ready Dataset		
			CSR (may be redacted)		
			Analysis-ready Dataset		
			Annotated Case Report Form		
			Other		

Submit Files

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2023 Vivli

- Ensure all the files are loaded, then click the 'Submit Files' button.

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Disorders

Status: **Approved**

1. Information About Your Team

2. Your Organization

3. Your Study

4. Data Sharing Settings

5. Agreements

6. Upload Data

History

Chat

Upload study Data Package below

Select Files

UPLOADED FILES

Filename	Size	Uploaded By	File Type	Download	Delete
NCT01243606_Data Dictionary.docx	11.71kB	Data Requester	Data Dictionary	Download	Delete
NCT01243606_IPD.docx	11.69kB	Data Requester	IPD	Download	Delete
NCT01243606_Protocol.docx	11.69kB	Data Requester	Protocol	Download	Delete
NCT01243606_SAP.docx	11.69kB	Data Requester	Statistical Analysis...	Download	Delete

Submit Files

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2023 Vivli

- You will be directed to a pop-up confirming that you have uploaded all files and assigned file types. Click the blue 'Yes' button to proceed.

Are you sure all files have been uploaded and assigned file types? This action cannot be undone.

Yes No

- You will receive confirmation of successful upload. Click the 'Continue' button to return to your submission.

Vivli

CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Thank you for uploading the data for this study. It will now be available for further analysis.

Continue

4.0 Managing your Submission

4.1 Submission Status

- You may check the progress of your submission via the Submissions dashboard. Once the study information has been accepted by a Vivli admin, the study will undergo metadata curation, and the status will appear in the dashboard as “Study in Curation.”

The screenshot shows the Vivli Submissions dashboard. The left sidebar contains navigation links: Dashboard, Research Environments, Studies, Data Requests, Submissions (highlighted), and Awaiting Upload. The main content area is titled 'Single Study Submissions' and features a status filter bar with 'Draft', 'In Progress' (circled in red), 'Approved/Posted', and 'Withdrawn'. Below this is a table with columns: Title, Status, NCTID, and Submitted. The table contains two rows. The first row has a title starting with 'Randomized Controlled Trial of Losartan for Patients With COVID-19 Requiring Hospital...', a status of 'Study in Curation' (circled in red), NCTID 'NCT04312009', and a submission date of '2023-01-05'. The second row has a title starting with 'University of Washington Alzheimer's Disease Research Center (UW ADRC) imaging & ...', a status of 'Study in Curation', NCTID 'NCT04437290', and a submission date of '2022-12-08'. The bottom of the page includes a footer with links like 'How To Guide', 'Privacy', 'Cookie Policy', 'EEA Disclosure Policy', and 'Contact Us', along with a copyright notice for 2017-2023.

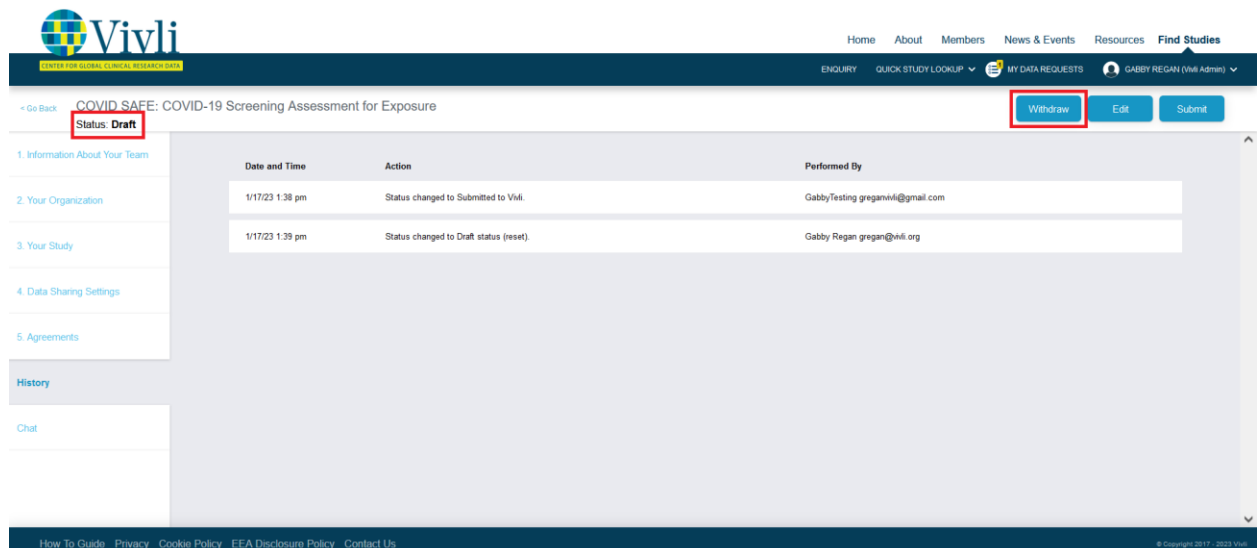
4.2 Making Edits

- Once your submission has been submitted, you will be unable to make any changes. Please contact Vivli via email at support@vivli.org if you need to make any changes to your submission.
- The Vivli team may send your submission back to drafts to request revisions. You will receive an email notification if you need to make updates to your submission.

The screenshot shows an email notification from Vivli Center. The subject line is 'Vivli Single Study Submission with ID: NCT04508777 has been reset to draft'. The email body states: 'The Single Study Submission with ID: NCT04508777 from Organization Name has been reset to the draft status. [Click here](#) to access the study, and see the comments in the chat tab for information about any updates that need to be made.' The email is signed 'Thanks, The Vivli Team' and includes the Vivli logo. At the bottom, there are buttons for 'Reply', 'Reply all', and 'Forward'. The email header shows it was received at 1:39 PM (0 minutes ago) and includes an 'Inbox x' label.

4.3 Withdrawal

- You may withdraw your submission at any time while it is in the Draft state by clicking the blue “Withdraw” button in the upper right corner.

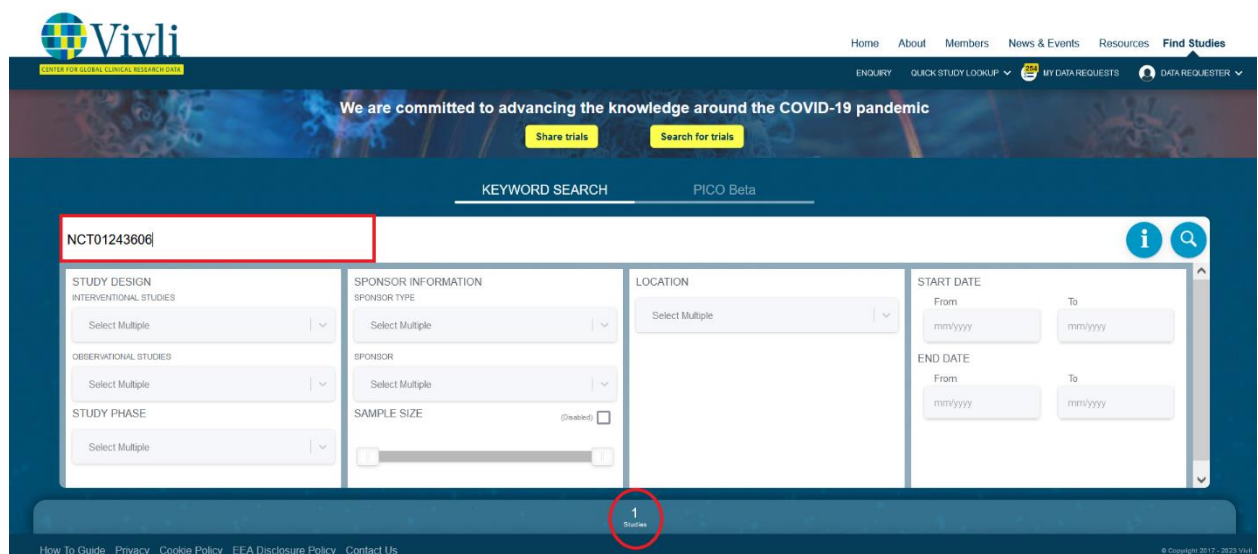


- Once you have submitted the study, you will need to contact Vivli via support@vivli.org to withdraw.

5.0 Viewing your Study Details

5.1 Using Vivli Search

- To search for your study on Vivli, open <https://search.vivli.org> in your browser. Type in the clinicaltrials.gov identifier/NCT ID in the box marked ‘What are you looking for today?’ a ‘1’ should appear on the blue bar at the bottom of the screen. Click the bar to view the results.



- Verify that the correct study has been identified and click the ‘View Study Details’ button on the right to pull up the metadata for your submission.

Vivli
CENTRE FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

NCT01243606 CLOSE

STUDY DESIGN
INTERVENTIONAL STUDIES
Select Multiple

OBSERVATIONAL STUDIES
Select Multiple

STUDY PHASE
Select Multiple

SPONSOR INFORMATION
SPONSOR TYPE
Select Multiple

SPONSOR
Select Multiple

SAMPLE SIZE (Disabled) ☐

Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Disorders

ID: NCT01243606 | 1R01MH090053-01
Condition or Disease: Anxiety Disorders, Mood Disorders
Intervention/treatment: Single Diagnosis Treatment Protocol, Unified Protocol (UP)

Request Study

Actual Enrollment: 250
N/A

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2023 Vivli

5.2 Study Details

- The first tab of the study listing contains the metadata pulled from clinicaltrials.gov and any additional metadata for the submission.

Using publicly available information and what you have provided to us, we have included key metadata elements. Of course, you can always send us additional information or updates for inclusion to add to the metadata about your study at any time either through chat or by emailing support@vivli.org.

Vivli
CENTRE FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Disorders

Study Details Study Documents Administrative Details Usage Research Team

Phase: NA

Condition or Disease: Anxiety Disorders, Mood Disorders

Intervention/treatment: Single Diagnosis Treatment Protocol, Unified Protocol (UP)

Brief Summary
Anxiety disorders are common, chronic, costly, debilitating to quality of life, and are more prevalent than any other class of disorders in every country in the world where surveys have been taken. Deepening understanding of the nature of anxiety and related emotional disorders during the last decade has revealed that commonalities in etiology and latent structure among these disorders supersedes differences. At the same time, examination of extant single

Ages Eligible For Study: 18 Years and older

Sexes Eligible For Study: All

Accepts Healthy Volunteers: No

Actual Enrollment: 250

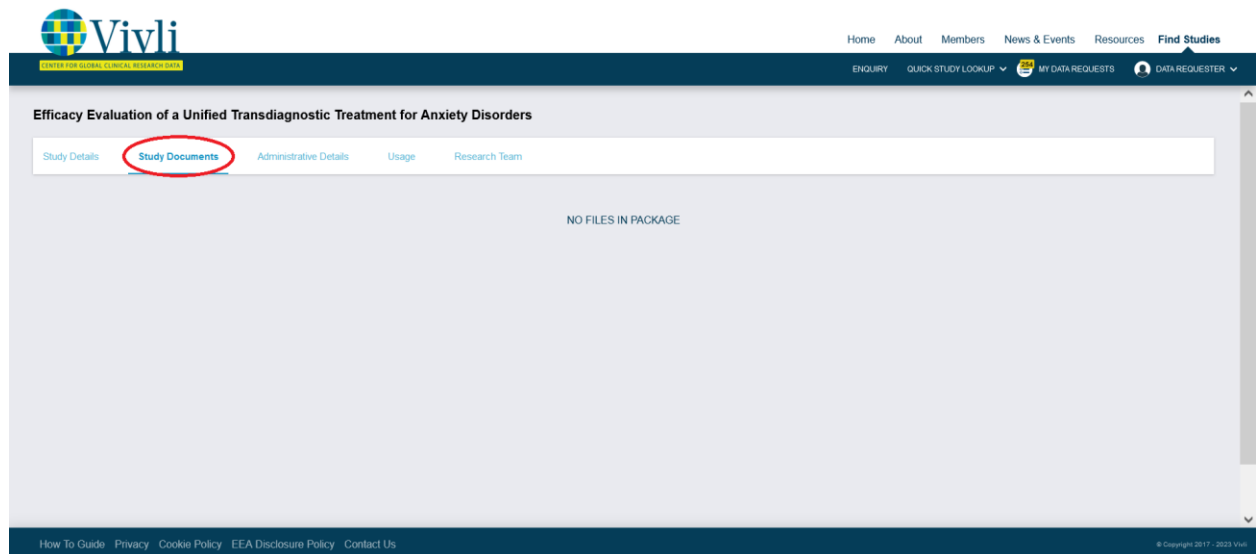
Locations

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2023 Vivli

5.3 Study Documents

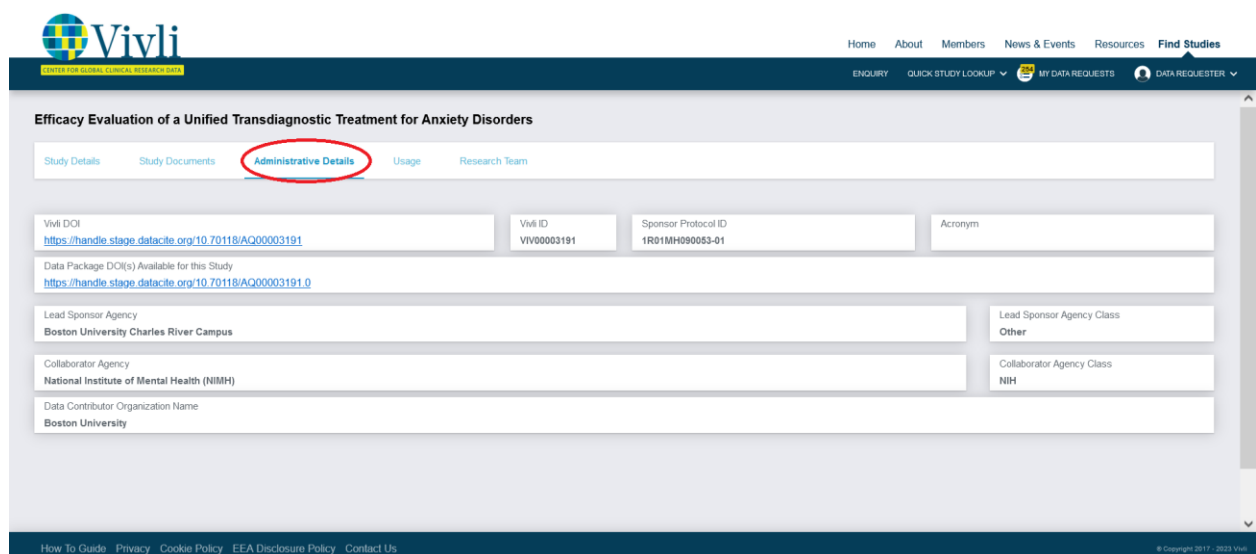
The 'Study Documents' tab is provided to share documents with searchers to help them determine whether the dataset can support their research - this typically will include documents like the Data Dictionary or the Protocol. The study documents should not include the anonymized individual participant-level data. The 'Study Documents' tab will initially appear empty. Once your supporting documents are uploaded, they will be appear in the 'Study Documents' tab.



5.4 Administrative Details

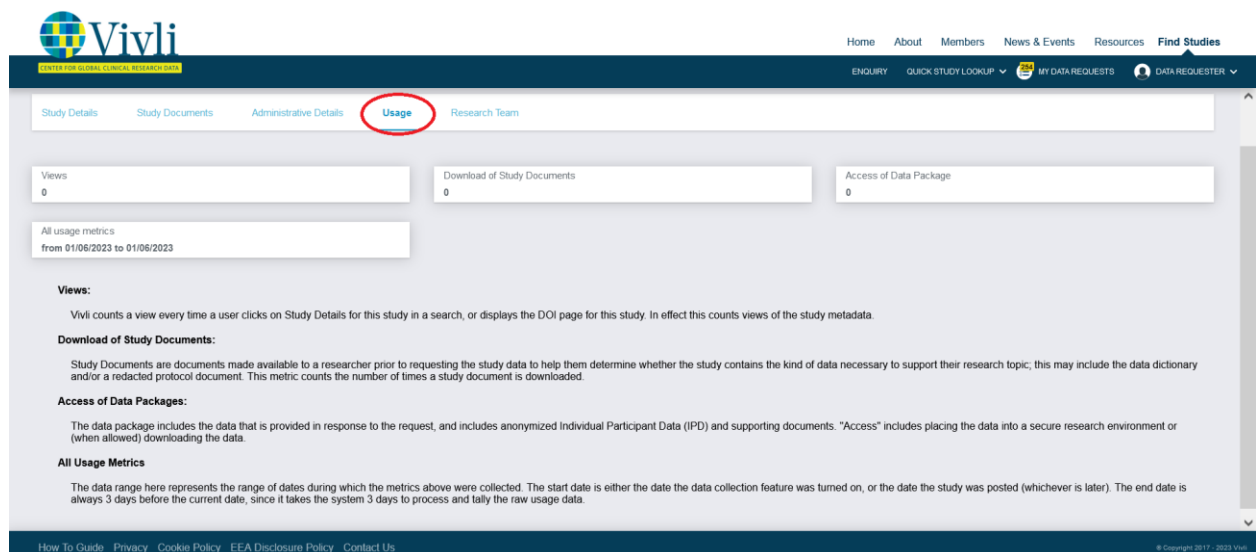
- The 'Administrative Details' tab provides the Digital Object Identifier (DOI), the sponsor and other general information about the study.

You may want to use the DOI in your publication to direct researchers to where they can access the data underlying



5.5 Usage

- The Usage tab displays the following metrics related to your study
 - **Views:** Vivli counts a view every time a user clicks on Study Details for this study in a search, or displays the DOI page for this study. In effect this counts views of the study metadata.
 - **Download of Study Documents:** Study Documents are documents made available to a researcher prior to requesting the study data to help them determine whether the study contains the kind of data necessary to support their research topic; this may include the data dictionary and/or a redacted protocol document. This metric counts the number of times a study document is downloaded.
 - **Access of Data Packages:** The data package includes the data that is provided in response to the request, and includes anonymized Individual Participant Data (IPD) and supporting documents. "Access" includes placing the data into a secure research environment or (when allowed) downloading the data.
 - **All Usage Metrics:** The data range here represents the range of dates during which the metrics above were collected. The start date is either the date the data collection feature was turned on, or the date the study was posted (whichever is later). The end date is always 3 days before the current date, since it takes the system 3 days to process and tally the raw usage data.



5.6 Adding Research Team Members to your study submission

- The Research Team tab displays all research team members that were included as part of the study submission. If you would like to add additional research team members or correct any existing entries after submitting your study, please reach out to the Vivli admin via support@vivli.org.

The screenshot shows the 'Research Team' tab in the Vivli platform. The table lists two team members:

Given Name	Family Name	ORCID ID	CRedit Role(s)
Gabriela	Regan	1234-5678-1234-5678	Data curation x
Vivli	Admin	1111-2222-3333-4444	Data curation x

6.0 Contact the Vivli Team

6.1 Using the Platform Chat

- Use the Chat tab on your submission to send a message to Vivli with questions or requests. We will normally respond within a day, and you will receive an email notification when a response is available.

The screenshot shows the 'Chat' tab in the Vivli platform. The interface includes a sidebar with a 'Chat' tab highlighted, a main area with a message input field, and a 'Send' button circled in red. The input field contains the text 'Enter message here'.

6.2 E-mail Vivli Support

- Alternatively, you may email the Vivli team at support@vivli.org.