



Vivli Study Submission Guide
Vivli Platform Version 3.4
15 June 2024

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1 Submitting Studies on Vivli – Overview



- Vivli is here to make it as efficient and easy as possible to share your completed clinical research 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.

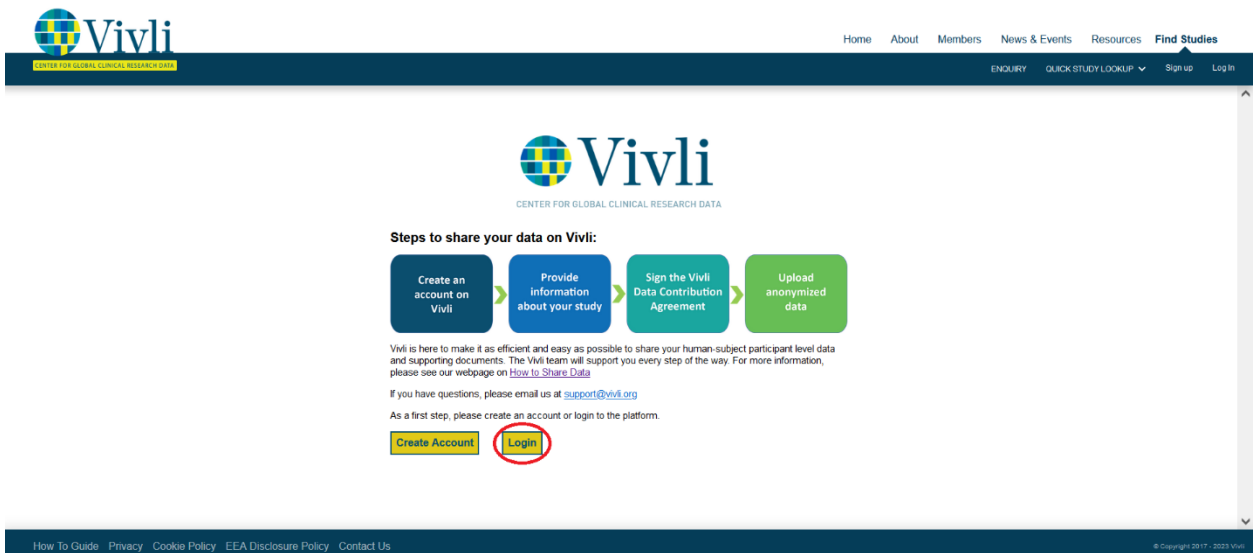
This process is for sharing your data on the Vivli platform. If you are interested in requesting data, please submit a Data Request. See our [How-to guide](#) on submitting a Data Request.

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](#).

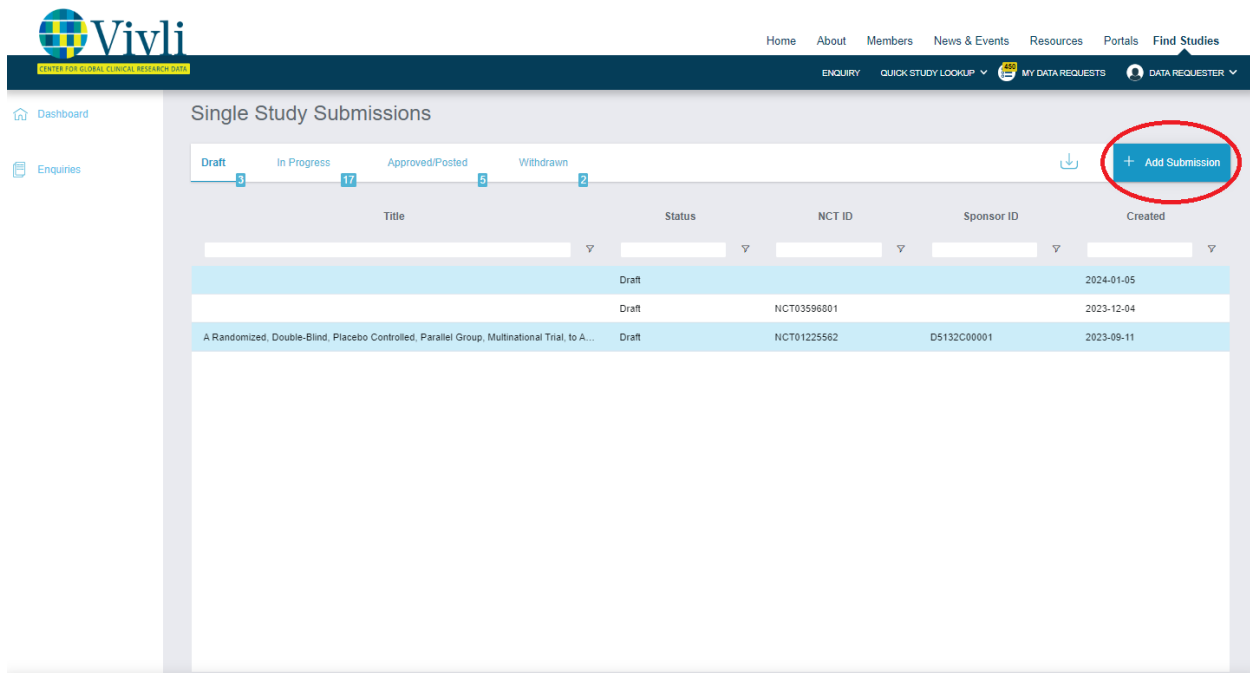


- If you are already a Vivli user, click the “Login” button.

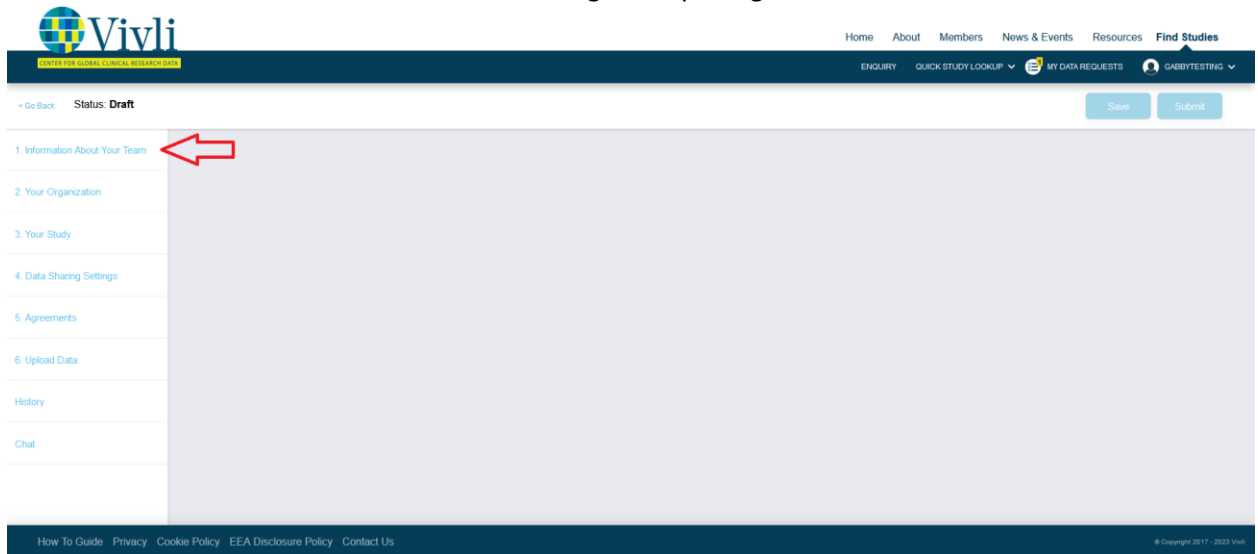


1.2 Dashboard

- 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 “+ Add Submissions” 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. Please make sure to click “Save” to save any changes.

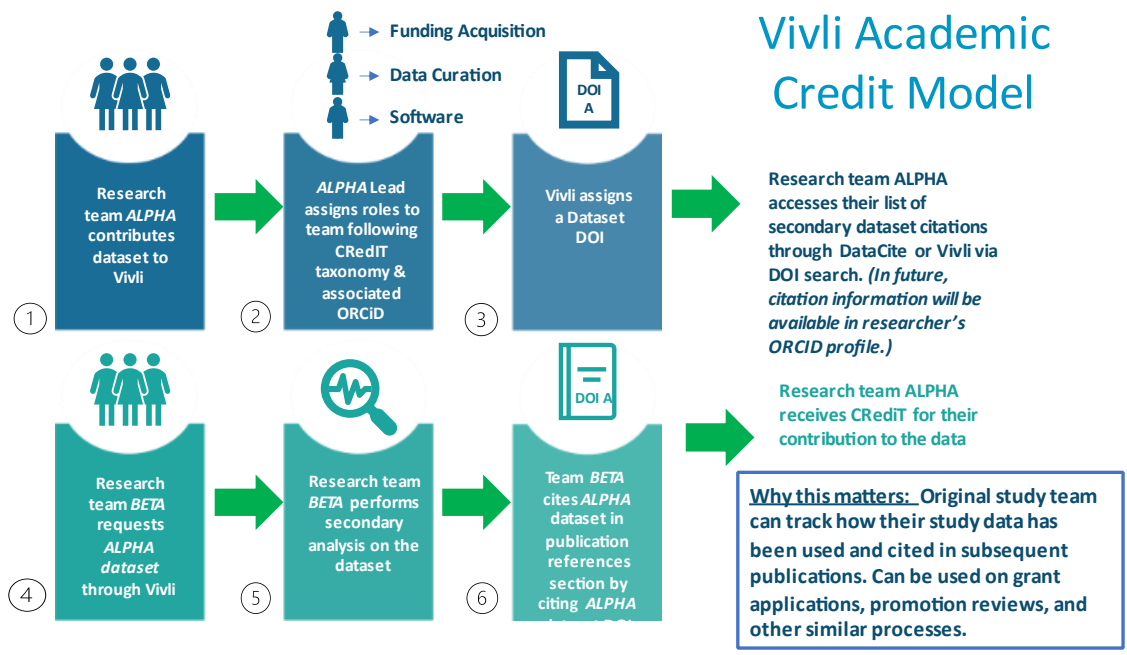


If at any time you are redirected from the Study Submission page within your dashboard, please navigate to <https://search.vivli.org/study-submission> and this will bring you back to the Study Submission page.

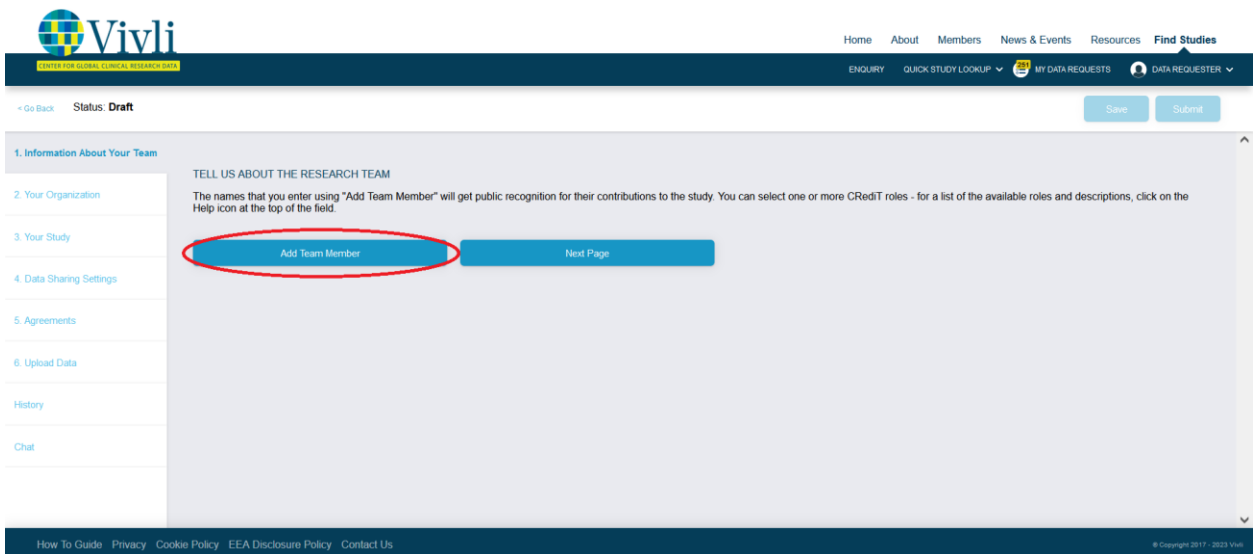
2 Study Submission

2.1 Information About Your Team

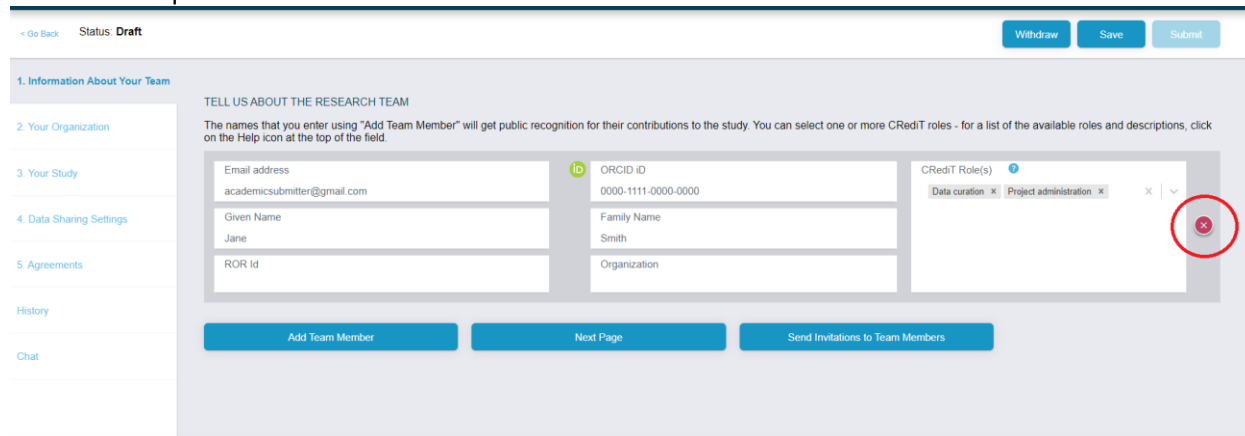
The names that you enter using "Add Team Member" will get public recognition for their contributions to the study. You can select one or more CRediT roles - for a list of the available roles and descriptions, click on the Help icon at the top of the field. See the following diagram as to why this is important and then follow the steps in this section to provide your team with CRediT.



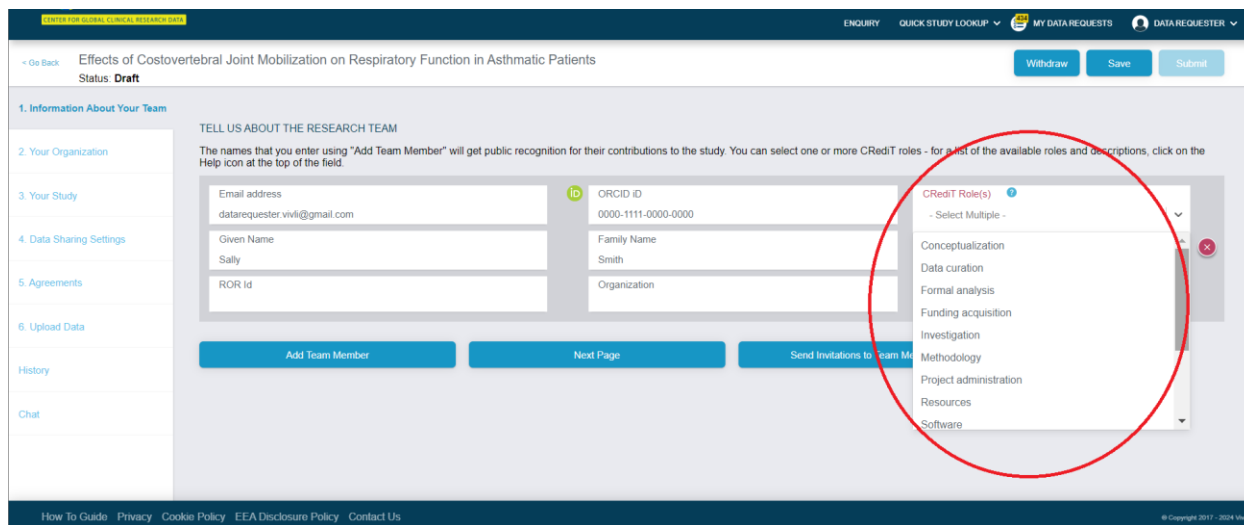
- Use the "Add Team Member" button to add all research team members to the study



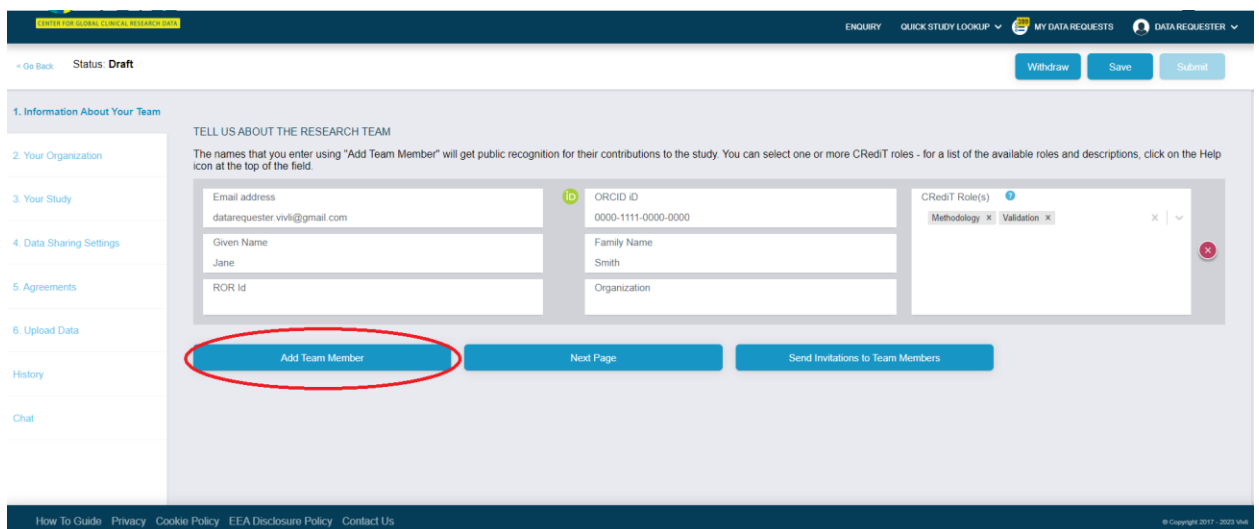
- Complete all required fields:
 - Email Address: Enter the best email address of each research team member
 - ORCID ID: Enter the ORCID ID of each research team member. If a research team member does not have an ORCID ID, remove the team member by clicking the red “X” as this is a required field.



- If, at any time, the research team member creates an ORCID ID, the team member may be added back into the research team for your study. (If you have already submitted the study, just ask the Vivli team to add the team member by emailing support@vivli.org or by sending a message in chat)
 - Given Name: Enter the given name, or first name, of each research team member
 - Family Name: Enter the family name, or last name, of each research team member
 - CRediT Roles: Select CRediT role(s) for each team member from the list that appears in the dropdown box: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.



- For more information regarding CRedit roles , please visit <https://credit.niso.org/>.
- The following fields are automatically updated from ORCID once the user authorizes with ORCID:
 - ROR Id: Research Organization Registry (ROR) of each research team member’s organization.
 - Organization: The organization each research team member is associated with in regard to their involvement in this study
- Once all fields for the first team member are complete, use the “Add Team Member” button to create additional entries.



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.

1. Information About Your Team

2. Your Organization

3. Your Study

4. Data Sharing Settings

5. Agreements

6. Upload Data

History

Chat

Buttons: Add Team Member, Next Page, Send Invitations to Team Members

- Click the “Send Invitations to Team Members” button. This email will be sent once the submission is finalized and will prompt Research Team Members to update their **ORCID** credits. See [section 5.7, Integrating ORCID for Research Team Members](#)
- Once all team members have been entered and roles have been assigned, hit “Save” and click “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, hit “Save” and use the “Next Page” button to navigate to the next section.

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

Go Back 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

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 Us, Next Page

2.3 Your Study

- If your study is registered on clinicaltrials.gov and **has an NCT ID**, enter the registration ID from clinicaltrials.gov. This will automatically populate the Title, Conditions, Interventions and Phase information from clinicaltrials.gov.

The screenshot shows the 'Your Study' form in the Vivli platform. The status is 'Draft'. The form is titled 'TELL US ABOUT YOUR STUDY' and includes instructions to enter a registration ID from clinicaltrials.gov. A checkbox labeled 'Study is not Listed on ClinicalTrials.gov' is checked, and the NCT ID 'NCT05773040' is entered in the adjacent text field. Below this, the form is populated with study details: Title 'A Phase 1 Study of JV-213 Autologous CD79b-targeting Chimeric Antigen Receptor T-cell Therapy in Adults With Relapsed or Refractory B-cell Lymphomas', Conditions 'Lymphomas, B-cell Lymphomas', Interventions 'JV-213, Leukapheresis', and Phase 'Phase 1'. A footer note asks for citations of primary manuscripts.

- If your study is not registered on clinicaltrials.gov and, therefore, **does not have an NCT ID**, check the box that says “Study is not listed on clinicaltrials.gov”.

The screenshot shows the 'Your Study' form in the Vivli platform. The status is 'Draft'. The form is titled 'TELL US ABOUT YOUR STUDY' and includes instructions to enter a registration ID from clinicaltrials.gov. A checkbox labeled 'Study is not Listed on ClinicalTrials.gov' is checked. The NCT ID field is empty. Below this, the form fields for Title, Conditions, Interventions, and Phase are empty. A footer note asks for citations of primary manuscripts.

- Enter the Sponsor Protocol ID, Title, Conditions, Interventions, and Phase, according to your study. Note: Sponsor Protocol ID is a mandatory field to complete. (This may be an internal ID or acronym for your study. If you do not have a Sponsor Protocol ID, reach out to Vivli and we will create one for you.)
 - Title, Conditions, and Interventions are free text fields, and you may enter multiple conditions and interventions, if applicable.
 - If the Interventions or Conditions field is not applicable to your dataset, enter “N/A”.
 - If the Phase field is not applicable to your dataset, select “N/A” from the dropdown menu.

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back 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

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

Study is not Listed on ClinicalTrials.gov Sponsor Protocol ID
2022-0938

Title A Phase 1 Study of JV-213 Autologous CD79b-targeting Chimeric Antigen Receptor T-cell Therapy in Adults With Relapsed or Refractory B-cell Lymphomas
Conditions Lymphomas,B-cell Lymphomas
Interventions JV-213,Leukapheresis
Phase Phase 3a

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

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- 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.
- Search ROR to add Funding Organization(s). Use the search field to search for the primary funder. If the study was funded by your organization, leave this blank. If it was funded by an external funder, type in the name of the funder in the free-text box and select “Search ROR”. A box will appear. Choose the name of the organization from the list that appears inside of the box and select “OK”.

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multinational Trial, to Assess the Prevention of Thrombotic Events With T... 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

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

Please provide a contact email at your organization for invoicing

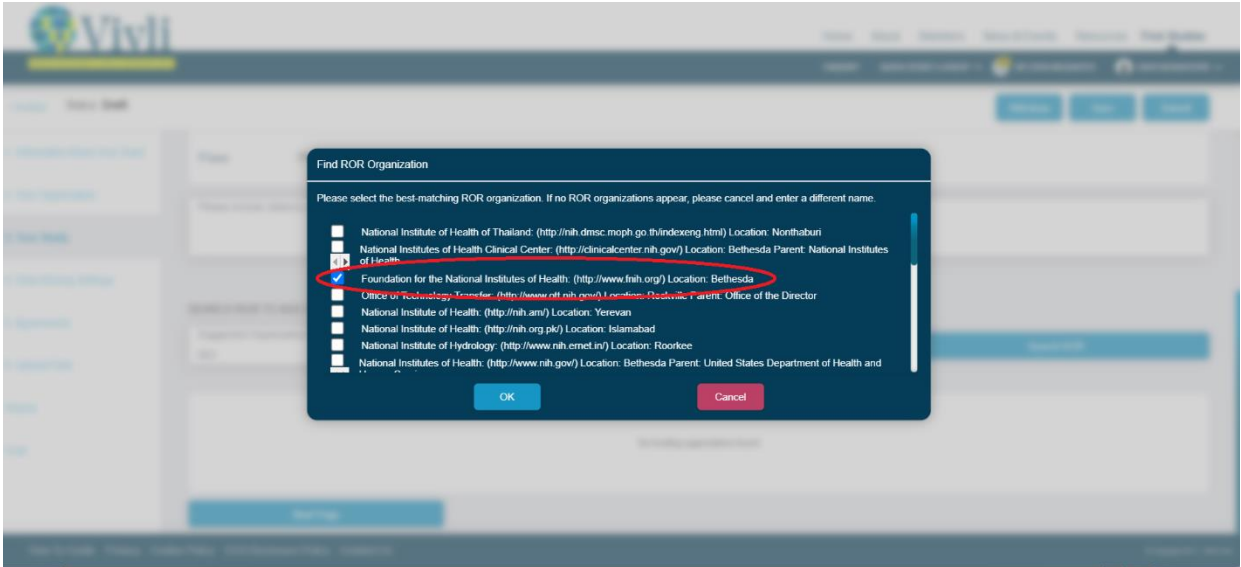
SEARCH ROR TO ADD FUNDING ORGANIZATION
Suggested Organization Name
NIH Search ROR

No funding organizations found

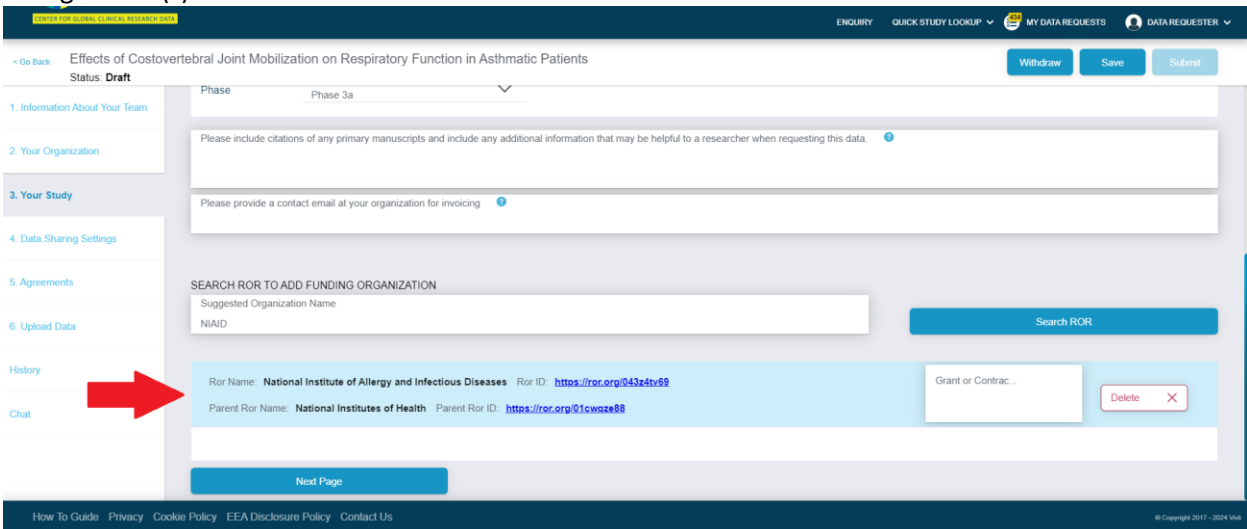
Next Page

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- Check the appropriate funder name



- Once the funder is added and saved, you will see a table appear at the bottom of “Your Study” page listing funder(s) and associated ROR information.



- To add an additional funder, repeat the steps by typing in the name of the additional funder in the free text box and selecting “Search ROR”. Choose the name of the organization from the box that appears and select “OK”. You will see the additional funder’s information listed in the table as an entry below the originally selected funder.

Center for Global Clinical Research Data

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multinational Trial, to Assess the Prevention of Thrombotic Events With T... Status: **Draft** Withdraw Save Submit

1. Information About Your Team

2. Your Organization Please provide a contact email at your organization for invoicing

3. Your Study

4. Data Sharing Settings **SEARCH ROR TO ADD FUNDING ORGANIZATION**

Suggested Organization Name wellcome Search ROR

Ror Name: **Foundation for the National Institutes of Health** Ror ID: <https://ror.org/00k86s890> Grant or Contract Id Delete X

Parent Ror Name: Parent Ror ID:

Ror Name: **Wellcome Trust** Ror ID: <https://ror.org/028chgv08> Grant or Contract Id Delete X

Parent Ror Name: Parent Ror ID:

Next Page

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- Repeat this process as needed, to add additional funders.
- To delete a funder, select the button that says “Delete” and then select “Save”.

Center for Global Clinical Research Data

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS DATA REQUESTER

< Go Back A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multinational Trial, to Assess the Prevention of Thrombotic Events With T... Status: **Draft** Withdraw Save Submit

1. Information About Your Team

2. Your Organization Please provide a contact email at your organization for invoicing

3. Your Study

4. Data Sharing Settings **SEARCH ROR TO ADD FUNDING ORGANIZATION**

Suggested Organization Name nih Search ROR

Ror Name: **Wellcome Trust** Ror ID: <https://ror.org/028chgv08> Grant or Contract Id Delete X

Parent Ror Name: Parent Ror ID: 1

Ror Name: **Foundation for the National Institutes of Health** Ror ID: <https://ror.org/00k86s890> Grant or Contract Id Delete X

Parent Ror Name: Parent Ror ID:

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- Depending on your selection, you may be prompted to provide a contact email address for invoicing.

The screenshot shows a web form for a study titled "Effects of Costovertebral Joint Mobilization on Respiratory Function in Asthmatic Patients". The status is "Draft". The form is divided into sections: 1. Information About Your Team, 2. Your Organization, 3. Your Study, 4. Data Sharing Settings, 5. Agreements, 6. Upload Data, History, and Chat. In the "Your Study" section, there is a field for "Please provide a contact email at your organization for invoicing" which is circled in red. Below this is a search bar for "SEARCH ROR TO ADD FUNDING ORGANIZATION" with a "Suggested Organization Name" field and a "Search ROR" button. At the bottom, there is a section for "Ror Name" and "Ror ID" with a "Grant or Contract" field and a "Delete" button.

- 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, hit "Save" and click "Next Page" to navigate to the next section.

The screenshot shows a web form for a study titled "Randomized Controlled Trial of Losartan for Patients With COVID-19 Requiring Hospitalization". The status is "Draft". The form is divided into sections: 1. Information About Your Team, 2. Your Organization, 3. Your Study, 4. Data Sharing Settings, 5. Agreements, 6. Upload Data, History, and Chat. In the "Your Study" section, there is a field for "Please provide a contact email at your organization for invoicing" with the email "invoicing@bu.edu" entered. Below this is a "Next Page" button which is circled in red. The form also includes fields for "Title", "Conditions", "Interventions", "Phase", "Select the name of your primary funder", and "Grant/Contract ID".

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. See [Section 6.1 Using the Platform Chat](#)
- **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. Select yes and provide an Embargo date for this option.

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

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
DDMMYY

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.](#)

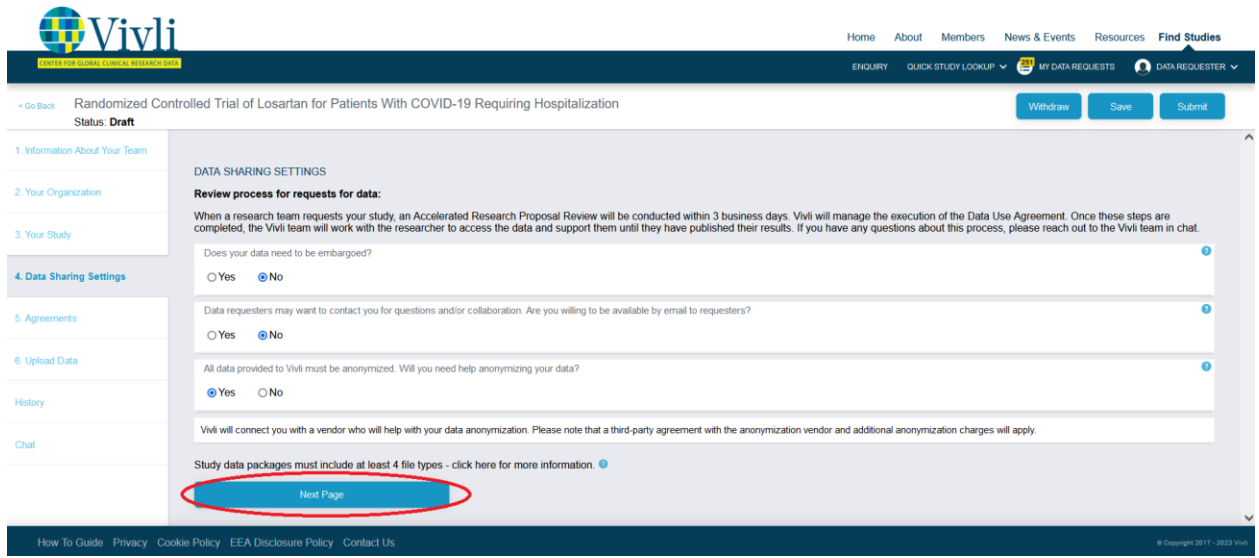
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- If you are willing to be contacted, the Vivli team will email you any requests for collaboration or questions. Making yourself available for contact does not imply a commitment to collaborate on any or all requests – it is your decision to answer questions or collaborate on a case-by-case basis.
- The email address used for the submission will be used as the contact email for this study if you select 'Yes'.

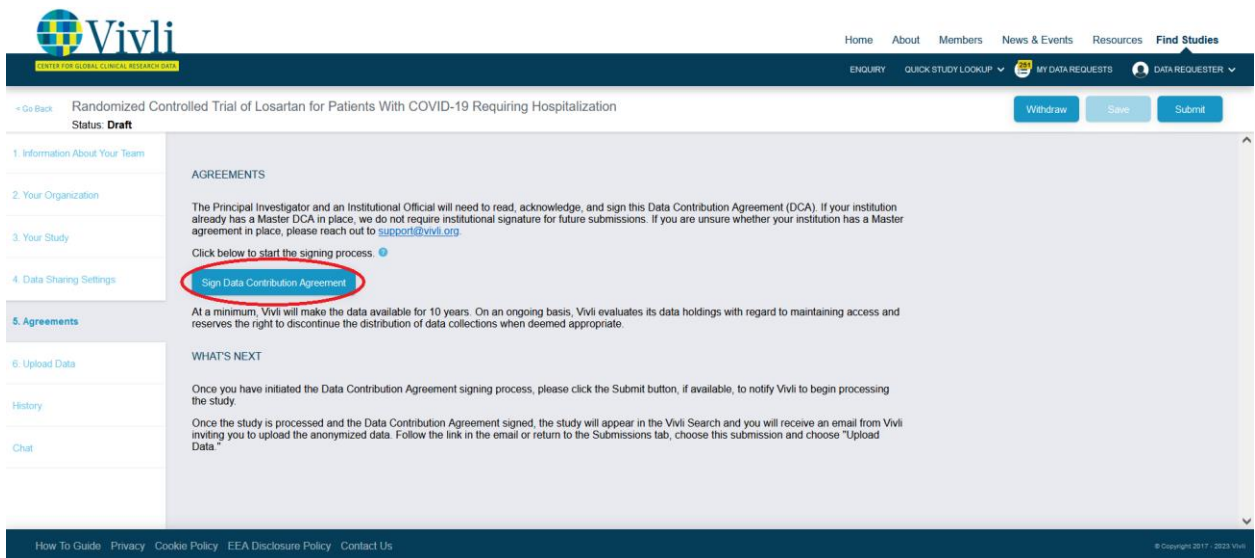
- If you need help anonymizing your clinical research data, Vivli can connect you with vendors who can help. Please note that it is the data contributor’s responsibility to ensure that the data is appropriately anonymized.

- Once all Data Sharing Settings have been selected, hit “Save” and 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, 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.

If you are not the PI of the study, you may enter your contact information in the last section if you wish to be copied on communication for visibility.

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.

PowerForm Signer Information

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

The Principal Investigator will need to read and acknowledge, and an Institutional Official will need to sign this Data Contribution Agreement (DCA).

The DCA provides 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.

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/>.

Please enter contact information for the Principal Investigator (PI) and Institution Official below.

Once you click the "Begin Signing" button below, the Data Contributor Agreement will first be sent to the PI to complete their acknowledgment and provide information regarding the study. The subject line of this email will be "Please DocuSign: Vivli Academic Data Contributor Agreement".

Once the PI submits the envelope, it will be sent to the Institution Official for signature.

Once the Institution official signs the agreement, it will be sent to Vivli to be fully executed. You will receive an email from Vivli with the fully executed copy and next steps for Data Upload once the

Once the Institution official signs the agreement, it will be sent to Vivli to be fully executed. You will receive an email from Vivli with the fully executed copy and next steps for Data Upload once the Data Contribution Agreement is complete.

If you are completing this form but are not the PI or institution official and would like to be copied on the envelope, you may add your contact information in the "Proxy" field.

If you have any questions, please reach

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

Required* Contact information for the Principal Investigator of the study

Your Name: *

Your Email: *

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

Required* Contact information for the person responsible for signing on behalf of your organization

Name:

Email:

Email Address

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

Required* Contact information for the person responsible for signing on behalf of your organization

Name:

Full Name

Email:

Email Address

If you are not the PI but you are completing this form and would like to be copied for visibility

Name:

Full Name

Email:

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 or Sponsor Protocol 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:

Deauthorized by:

By:

Name:

Title:

Date:

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 process, 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."

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

Single Study Submissions

Draft 4 **In Progress 17** Approved/Posted 5 Withdrawn 2

+ Add Submission

Title	Status	NCT ID	Sponsor ID	Submitted
Effects of Costovertebral Joint Mobilization on Respiratory Function in Asthmatic Patients	Submitted		1111-222-333	2024-02-06
Effects of Costovertebral Joint Mobilization on Respiratory Function in Asthmatic Patients	Study In Curation		1111-AMRT	2024-01-23
Effects of Costovertebral Joint Mobilization on Respiratory Function in Asthmatic Patients	Submitted		0011644	2024-01-23
Effects of Costovertebral Joint Mobilization on Respiratory Function in Asthmatic Patients	Submitted		REC -01680	2024-01-22
A Phase 3 Randomized, Open-Label Study of Ponatinib Versus Imatinib in Adult Patients ...	Submitted	NCT01650605	AP24534-12-301	2024-01-12
Effects of Costovertebral Joint Mobilization on Respiratory Function in Asthmatic Patients	Submitted		REC -01680	2024-01-11
A Phase 1 Dose Escalation Trial to Determine the Safety, Tolerability and Maximum Toler...	Study In Curation	NCT00660920	AP24534-07-101	2023-12-20
	Submitted	NCT03387137		2023-12-05
	Submitted	NCT04052113		2023-12-04
	Submitted	NCT02352946		2023-12-04
A Mechanistic Study in Patients With Non-Dialysis Chronic Kidney Disease to Investigate...	Study In Curation	NCT03649711	227997	2023-09-13
Laparoscopic Tactile Imaging in Urogynecologic Surgery	Study In Curation	NCT03164850	LT107	2023-08-14
Phase I/II Open-Label Single Arm Study to Evaluate Safety and Efficacy of Tucatinib in ...	Study In Curation	NCT03054393	16-1661 cc	2023-06-20
Azithromycin for Prevention of Disease Progression in Patients With Mild or Moderate C...	Study In Curation	NCT04332107	20-30504	2023-04-27

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- 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 notified via email.

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

Status: **Study in Curation** Withdraw

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.

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- To view the history of the Study Submission, click on the tab that says “History”.

Survey on the Human Papilloma Virus Vaccination in Girls With Cystic Fibrosis Followed in Cystic Fibrosis (CF) Center in France
Status: **Approved**

Date and Time	Action	Performed By
8/14/23 8:25 pm	Status changed to Submitted to Vivli	Data Requester Datarequester.vivli@gmail.com
8/14/23 8:34 pm	Status changed to Study in Curation	Stan Neumann sneumann@vivli.org
8/14/23 9:12 pm	Status changed to Approved/Posted	Stan Neumann sneumann@vivli.org

- This will show you the history of the submission with details that show the date and time of an action performed, and who the action was performed by (e.g. date of submission, date the study is sent to curation, date the study is posted to the Vivli platform etc.)

3 Data Package Upload

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

- Once the Data Contribution Agreement is executed and the study is posted, the study will appear in the Vivli Search
- You will receive an email from Vivli inviting you to upload the anonymized data and supporting documents. Follow the link in the email or select Submissions in the dropdown menu from the top right corner, choose your Submission under Approved/Posted section. (Note: You will be unable to

upload any data or documents until the Data Contribution Agreement is executed.)

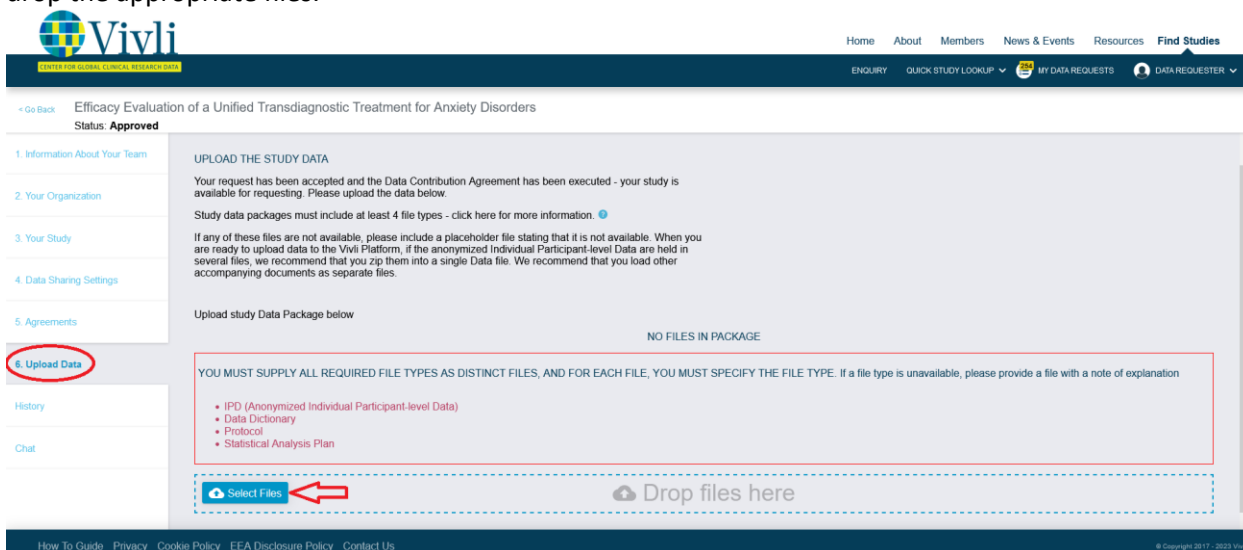
The screenshot shows the Vivli dashboard for a Data Requester. The header includes the Vivli logo and navigation links: Home, About, Members, News & Events, Resources, Portals, Find Studies. Below the header, there are tabs for ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and DATA REQUESTER. The main content area is titled 'Welcome, Data Requester!' and contains a message about organizational memberships and data requests. A dropdown menu is open, showing options: Search, Dashboard, Submissions (highlighted with a red box), Enquiries, Edit My Profile, Change Password, and Log Out.

- From the Dashboard, under 'Approved/Posted,' click on the study for which you are ready to upload your anonymized data.

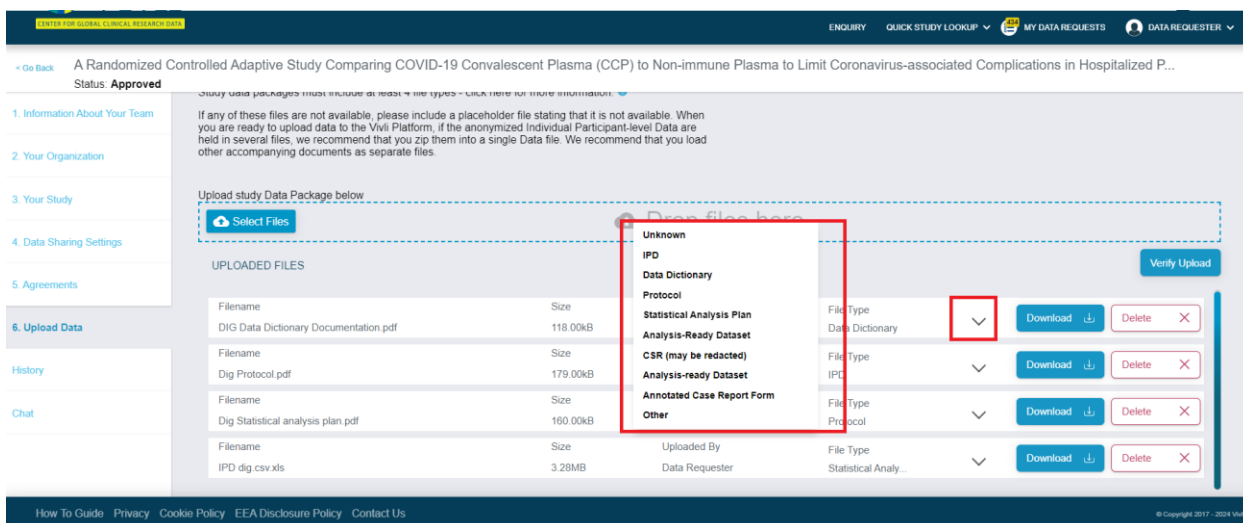
The screenshot shows the 'Single Study Submissions' page in the Vivli dashboard. The page has a header with the Vivli logo and navigation links. Below the header, there are tabs for Draft (4), In Progress (17), Approved/Posted (2), and Withdrawn (2). The 'Approved/Posted' tab is selected and circled in red. Below the tabs, there is a table of study submissions with columns for Title, Status, NCT ID, Sponsor ID, and Approved. The first row of the table is circled in red, and the 'Approved' status in that row is also circled in red.

Title	Status	NCT ID	Sponsor ID	Approved
Survey on the Human Papilloma Virus Vaccination in Girls With Cystic Fibrosis Followed ...	Approved	NCT03653377	69HCL18_0144	2023-08-14
A Randomized Controlled Adaptive Study Comparing COVID-19 Convalescent Plasma (...)	Approved	NCT04421404	20-30794	2023-01-13
Examining Neurocognitive Profiles of Bipolar Disorder and Attention-Deficit Hyperactivity ...	Approved	NCT00961935	P50MH077248-02	2023-01-13
Stanford Accelerated Intelligent Neuromodulation Therapy for Treatment-Resistant Depre...	Approved	NCT03068715	Blinded-33797	2023-01-12
Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Disorders	Approved	NCT01243606	1R01MH090053-01	2023-01-06

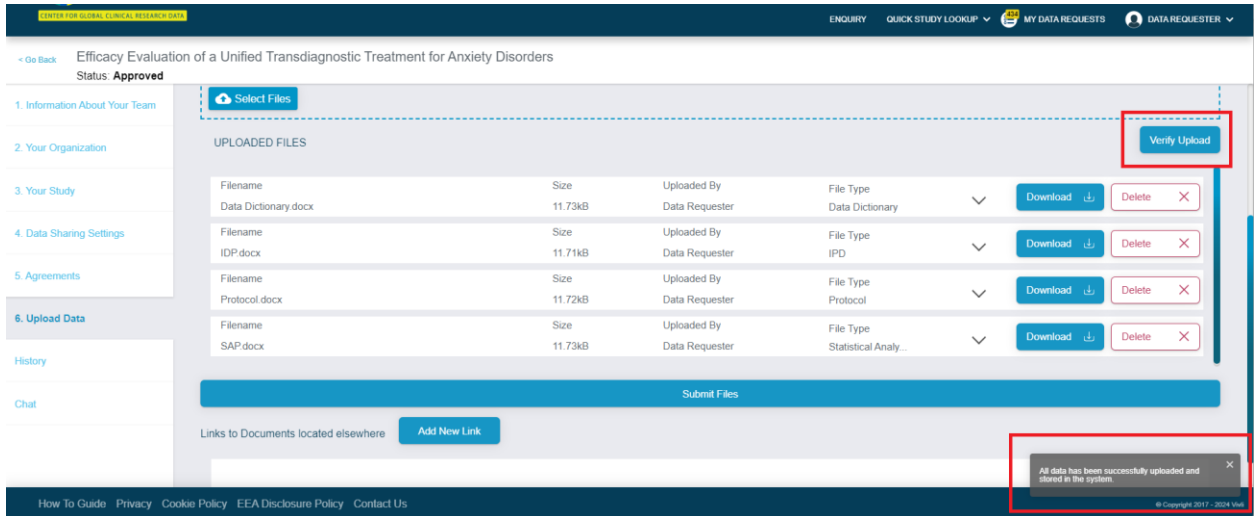
- Click on the 'Upload Data' tab and then you may use either the blue 'Select Files' button or drag and drop the appropriate files.



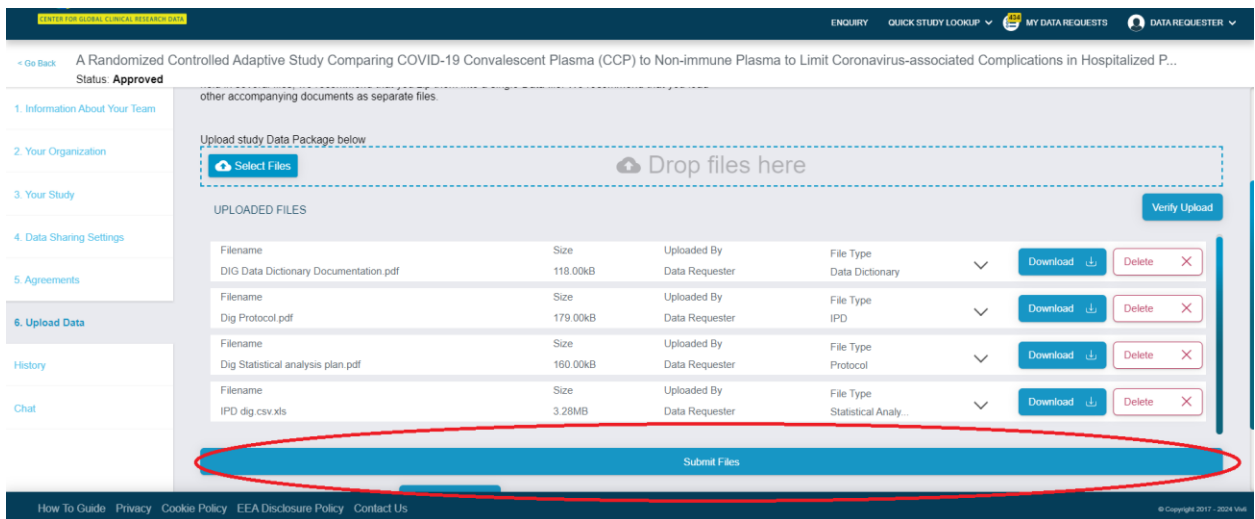
- Use the dropdown menu on the right-hand side to validate the File Type for each file before submitting files (Note: If you are missing the protocol, data dictionary, or Statistical analysis plan, please create a Word file with a note saying this is unavailable and upload it as a placeholder and validate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



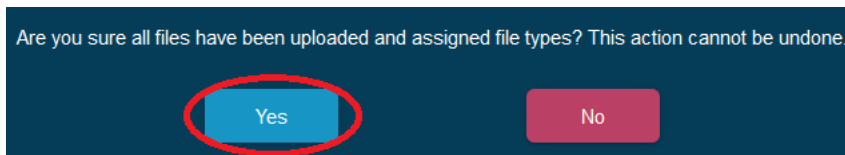
- Click the button that says "Verify Upload" to confirm that your files have been successfully uploaded.
- A pop-up will appear at the bottom right screen that says "All data has been successfully uploaded and stored in the system"



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



- 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.



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



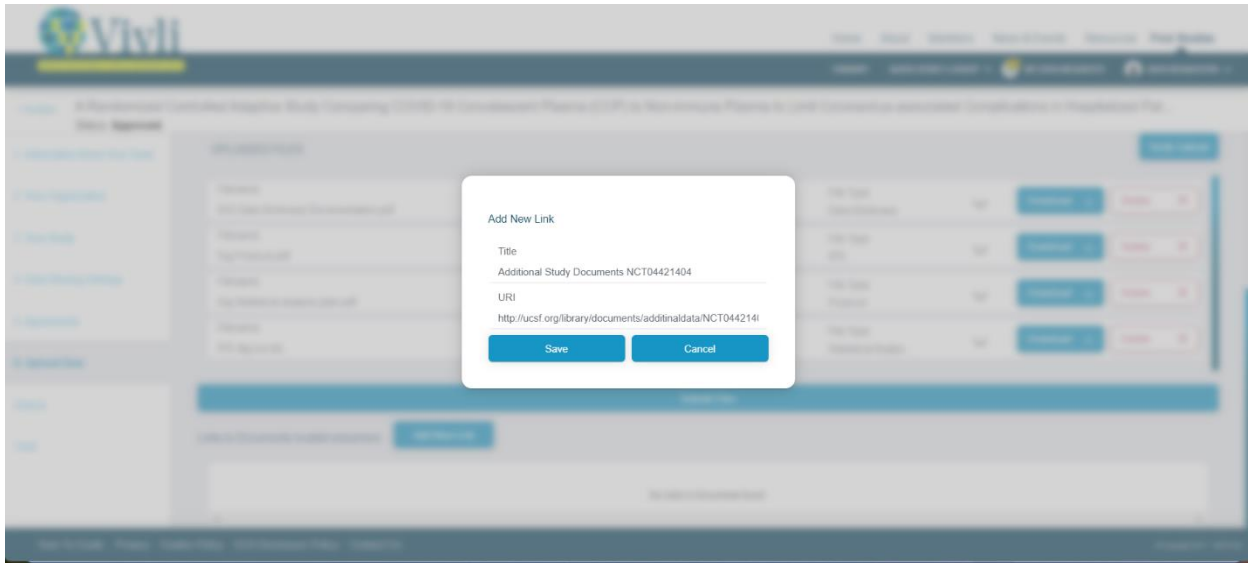
- Once study documents are uploaded, if there are further documents that are available for your study at an external link, and you would like to provide a link to the documents, click the button that says "Add New Link".

The screenshot shows the Vivli platform interface for a study titled 'A Randomized Controlled Adaptive Study Comparing COVID-19 Convalescent Plasma (CCP) to Non-immune Plasma to Limit Coronavirus-associated Complications in Hospitalized Pat...'. The status is 'Approved'. On the left, there is a navigation menu with items: '1. Information About Your Team', '2. Your Organization', '3. Your Study', '4. Data Sharing Settings', '5. Agreements', '6. Upload Data', 'History', and 'Chat'. The main content area is titled 'UPLOADED FILES' and contains a table with the following data:

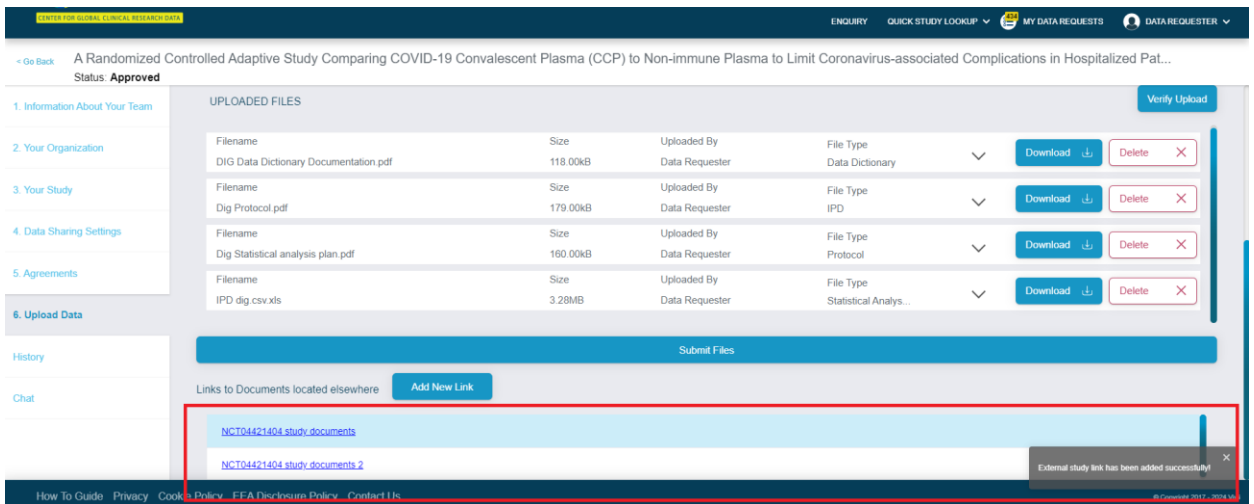
Filename	Size	Uploaded By	File Type	Download	Delete
DIG Data Dictionary Documentation.pdf	118.00kB	Data Requester	Data Dictionary	Download	Delete
Dig Protocol.pdf	179.00kB	Data Requester	IPD	Download	Delete
Dig Statistical analysis plan.pdf	160.00kB	Data Requester	Protocol	Download	Delete
IPD dig.csv.xls	3.28MB	Data Requester	Statistical Analys...	Download	Delete

Below the table, there is a 'Submit Files' button. Underneath that, there is a section titled 'Links to Documents located elsewhere:' with an 'Add New Link' button circled in red. Below this section, it says 'No Links to Documents found.' At the bottom of the page, there is a footer with links: 'How To Guide', 'Privacy', 'Cookie Policy', 'EEA Disclosure Policy', 'Contact Us', and a copyright notice: '© Copyright 2017 - 2024 Vivli'.

- In the box that appears, type in the Title of the document and the URL and then click “Save”



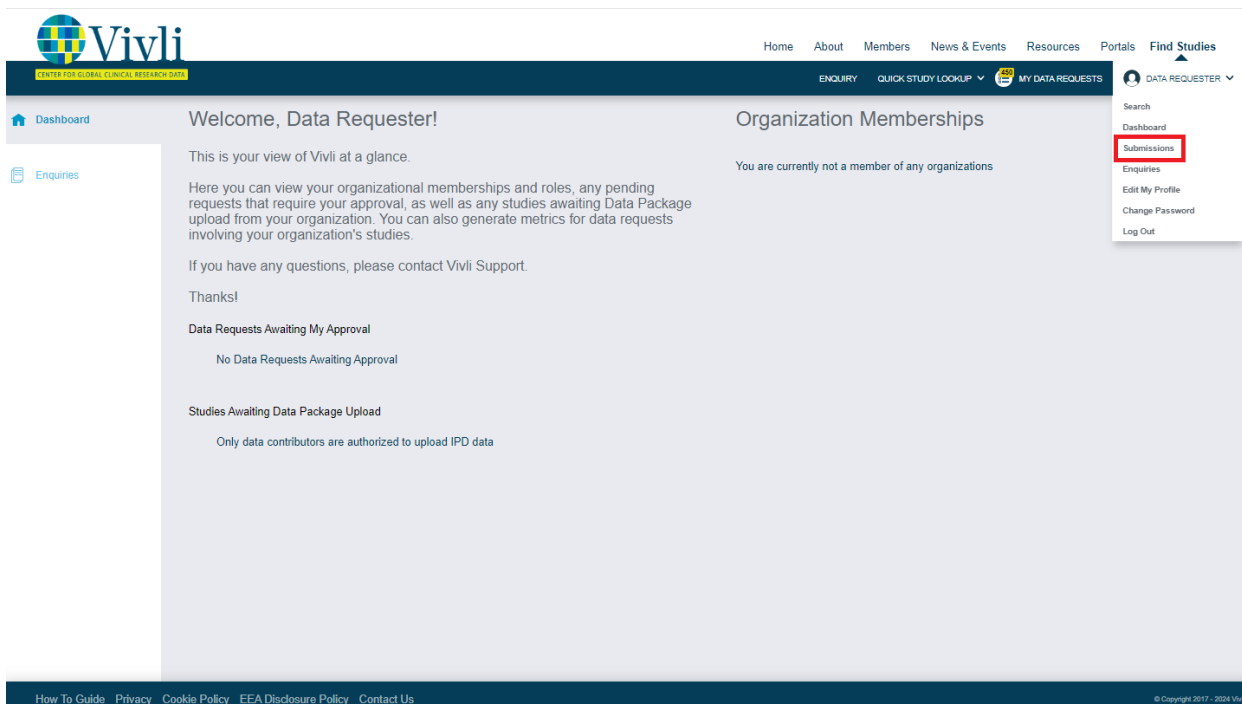
- You may add multiple links to external documents. Once you press ‘Save’, you will see a popup appear that says “External study link has been loaded properly” and the link(s) to the document(s) will appear on the bottom of the page.



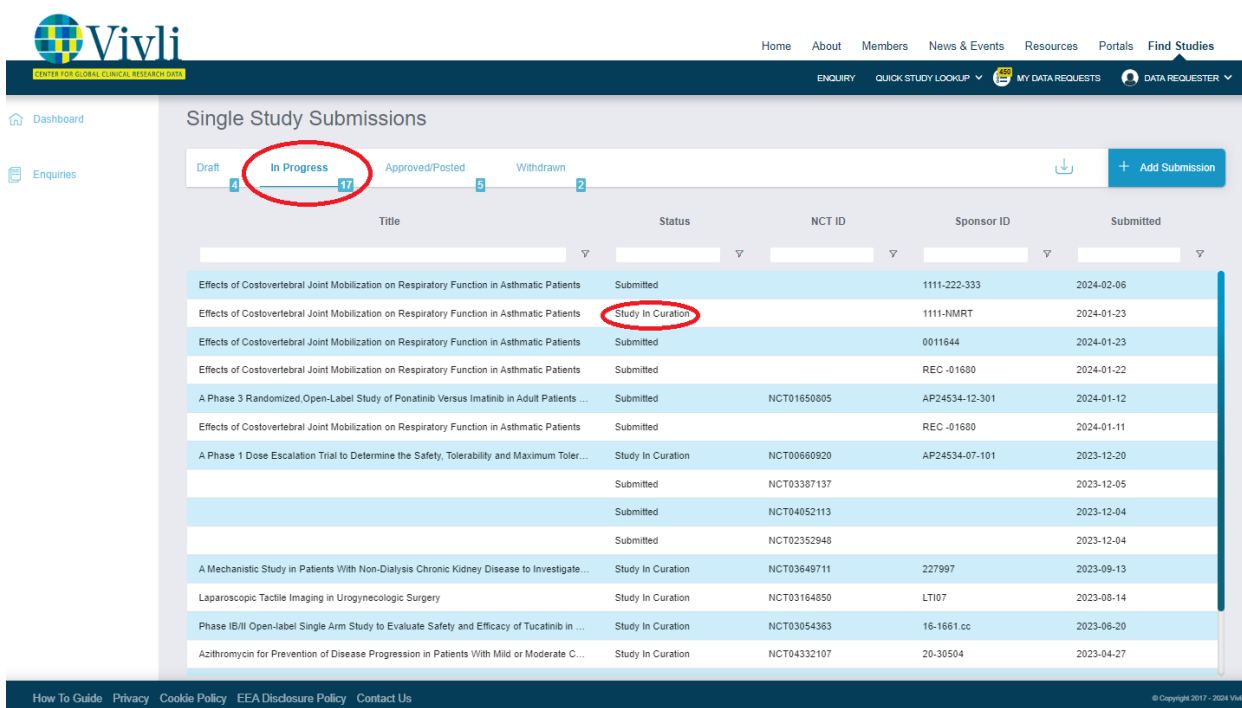
4 Managing your Submission

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 dashboard for a 'Data Requester'. The user profile dropdown menu is open, and the 'Submissions' option is highlighted with a red box. The dashboard content includes a welcome message, organization memberships, and sections for data requests and studies awaiting upload.

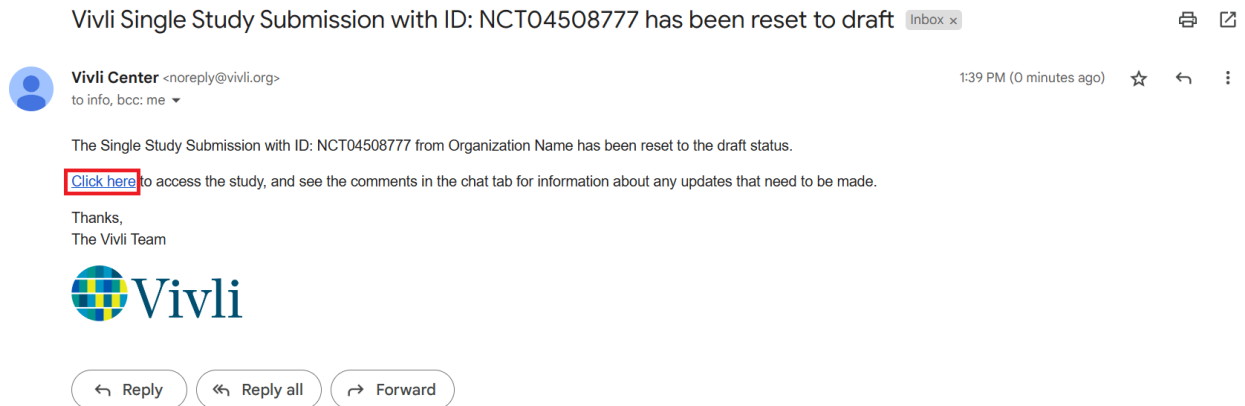


The screenshot shows the 'Single Study Submissions' dashboard. At the top, there are filters for Draft (4), In Progress (17), Approved/Posted (5), and Withdrawn (2). The 'In Progress' filter is circled in red. Below the filters is a table of study submissions. One row is circled in red, showing the status 'Study In Curation'.

Title	Status	NCT ID	Sponsor ID	Submitted
Effects of Costovertebral Joint Mobilization on Respiratory Function in Asthmatic Patients	Submitted		1111-222-333	2024-02-06
Effects of Costovertebral Joint Mobilization on Respiratory Function in Asthmatic Patients	Study In Curation		1111-NIMRT	2024-01-23
Effects of Costovertebral Joint Mobilization on Respiratory Function in Asthmatic Patients	Submitted		0011644	2024-01-23
Effects of Costovertebral Joint Mobilization on Respiratory Function in Asthmatic Patients	Submitted		REC-01680	2024-01-22
A Phase 3 Randomized Open-Label Study of Ponatinib Versus Imatinib in Adult Patients ...	Submitted	NCT01650805	AP24534-12-301	2024-01-12
Effects of Costovertebral Joint Mobilization on Respiratory Function in Asthmatic Patients	Submitted		REC-01680	2024-01-11
A Phase 1 Dose Escalation Trial to Determine the Safety, Tolerability and Maximum Toler...	Study In Curation	NCT00660920	AP24534-07-101	2023-12-20
	Submitted	NCT03387137		2023-12-05
	Submitted	NCT04052113		2023-12-04
	Submitted	NCT02352946		2023-12-04
A Mechanistic Study in Patients With Non-Dialysis Chronic Kidney Disease to Investigate...	Study In Curation	NCT03649711	227997	2023-09-13
Laparoscopic Tactile Imaging in Urogynecologic Surgery	Study In Curation	NCT03164850	LT107	2023-08-14
Phase IB/II Open-label Single Arm Study to Evaluate Safety and Efficacy of Tucatinib in ...	Study In Curation	NCT03054363	16-1661.cc	2023-06-20
Azithromycin for Prevention of Disease Progression in Patients With Mild or Moderate C...	Study In Curation	NCT04332107	20-30504	2023-04-27

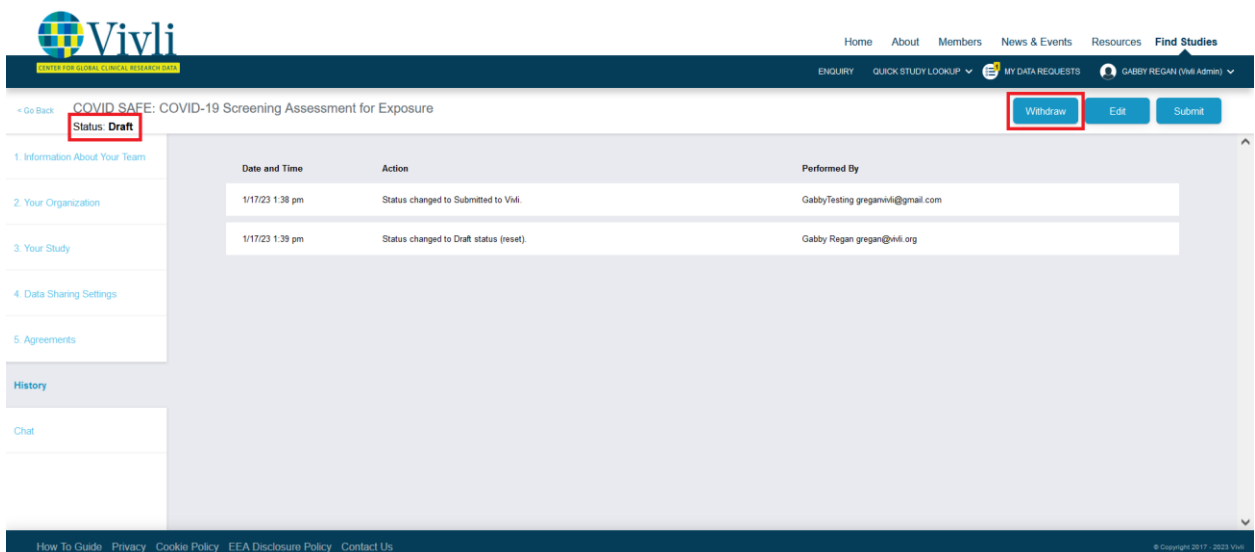
4.2 Making Edits

- Once your submission has been submitted, you will be unable to make any changes. Please contact Vivli via chat or 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.



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 chat or email at support@vivli.org to withdraw.

5 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.

The screenshot shows the Vivli search interface. At the top, there is a navigation bar with links for Home, About, Members, News & Events, Resources, Portals, and Find Studies. Below this is a banner with the text 'We are committed to advancing the knowledge around the COVID-19 pandemic' and buttons for 'Share trials' and 'Search for trials'. The main search area is titled 'KEYWORD SEARCH' and 'PICO Beta'. A search box contains the text 'NCT01243606'. Below the search box are several filter categories: 'STUDY DESIGN' (with sub-categories: INTERVENTIONAL STUDIES, OBSERVATIONAL STUDIES, STUDY PHASE), 'SPONSOR INFORMATION' (with sub-categories: FUNDER, CONTRIBUTOR), 'LOCATION', and 'START DATE' (with sub-categories: FROM, TO, END DATE). A 'SAMPLE SIZE' filter is also present but disabled. At the bottom of the search area, there is a blue bar with a '1' icon and the text '1 Studies'. 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'.

- 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.

NCT01243606

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 | IR01M-H090053-01
Condition or Disease: Anxiety Disorders, Mood Disorders
Intervention/treatment: Single Diagnosis Treatment Protocol, Unified Protocol (UP)

Request Study

View Study Details

Number enrolled: 250
N/A

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.

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

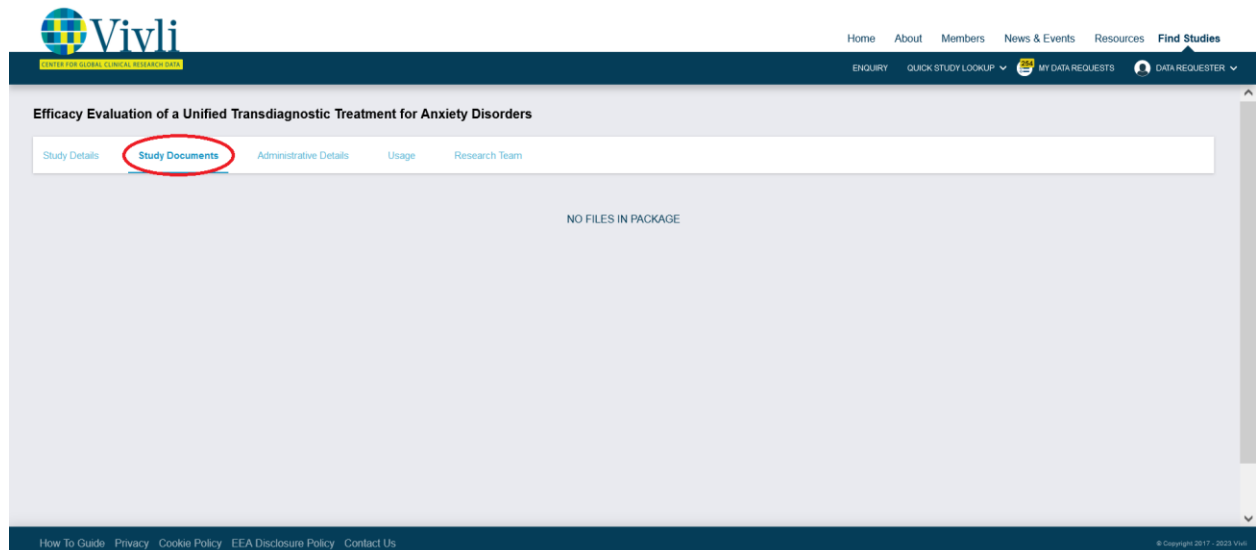
Actual Enrollment: 250

Locations

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. A Vivli admin will upload supporting documents once the study data has been uploaded. 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 by the Vivli admin, they will be appear in the 'Study Documents' tab.



- If there are further documents that are available for your study at an external link, and you would like to provide a link to the documents, you may do so. Please see [Section 3.2 Data Package Upload](#) for further details.

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. Please see the [ICMJE Data Sharing Requirements](#) on Vivli website.

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 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.

The screenshot shows the Vivli website interface. The navigation menu at the top includes 'Home', 'About', 'Members', 'News & Events', 'Resources', and 'Find Studies'. Below the navigation, there are tabs for 'Study Details', 'Study Documents', 'Administrative Details', 'Usage' (highlighted with a red circle), and 'Research Team'. The main content area shows three summary boxes: 'Views' (0), 'Download of Study Documents' (0), and 'Access of Data Package' (0). Below these is a section for 'All usage metrics from 01/06/2023 to 01/06/2023'. The 'Views' section explains that a view is counted when a user clicks on 'Study Details' or displays the 'DOI page'. The 'Download of Study Documents' section states that documents are made available to researchers to help them determine if the study contains necessary data. The 'Access of Data Packages' section notes that the data package includes individual participant data (IPD) and supporting documents. The 'All Usage Metrics' section explains the data range and processing time.

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 chat or email at support@vivli.org.

The screenshot shows the Vivli website interface with the 'Research Team' tab selected in the navigation menu (highlighted with a red circle). The main content area displays a table of research 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

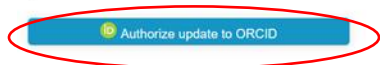
5.7 Integrating ORCID for Research Team Members

- During study submission, the dataset owner will have clicked the “Send Invitations to Team Members” Button, which sends an automatic email to researchers listed on the study after the study has been posted.
- Once an email is received, click the link within the email and you will be taken to a Vivli webpage containing the dataset title and the researcher’s information.
- Click “Authorize update to ORCID”.

A Phase II, Open (Partially Double-blind), Randomised, Controlled, Multicentre, Primary Vaccination Study to Evaluate the Immunogenicity, Reactogenicity and Safety of Three Different Formulations of GSK Biologicals' Combined Haemophilus Influenzae Type B-meningococcal Serogroups C and Y- Conjugate Vaccine and One Formulation of GSK Biologicals' Haemophilus Influenzae Type B-meningococcal Serogroup C Conjugate Vaccine Each Given Concomitantly With InfanrixTM Penta, Versus MeningitecTM, Given Concomitantly With InfanrixTM Hexa in Infants According to a 2-3-4 Month Schedule

The Study with the title above and ID **NCT00129116** was registered in the Vivli Platform.
 You have been asked by the study owner to view this page so that you can authorize Vivli to add the study and your roles in preparing the study into your ORCID® record.
 If this information is correct, click the Authorize button to login to ORCID and confirm your authorization.
 If the information is incorrect, please contact the Study owner to make corrections.

Email address sheldon.russel@mailinator.com	ORCID ID 0009-0001-5457-0098	CRediT Role(s) • Conceptualization • Investigation
Given Name Sheldon	Family Name Russel	



- You will be navigated to the ORCID login screen. Log in with your ORCID credentials.

Warning! sandbox.orcid.org is a test website. orcid.org is the official website. Sandbox only sends email messages to mailinator.com email addresses, see Sandbox FAQ for more information

Sign in

Email or 16-digit ORCID ID


example@email.com or 0000-0001-2345-6789


Password


SIGN IN

Forgot your password or ORCID ID?
 Don't have an ORCID ID yet? [Register now](#)

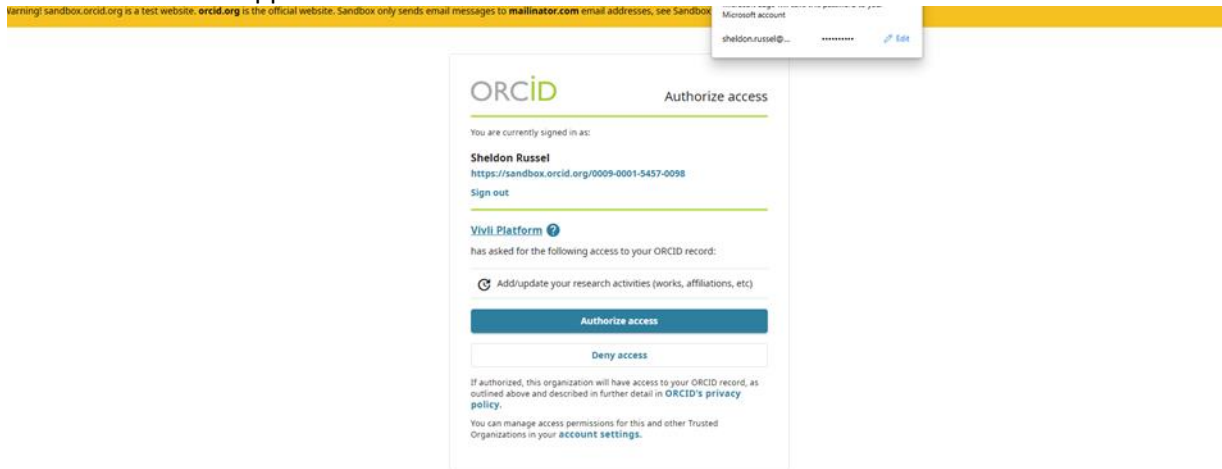
or

 **Access through your institution**

 **Sign in with Google**

 **Sign in with Facebook**

- Note: If you have not completed this process with Vivli before, you will need to press the “authorize access” button that appears.



- You will be redirected back to the Vivli study page and a “work entry” will now be created in ORCID.

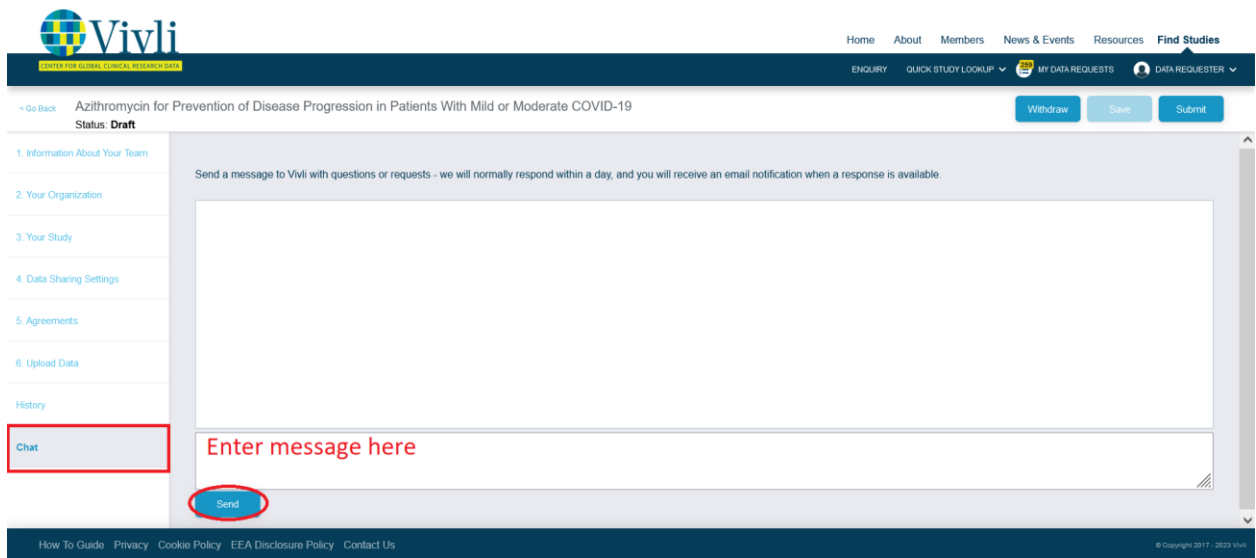


- If there are changes to the research team (a member is deleted, or roles are updated) this will be reflected in the user’s ORCID record.

6 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.



6.2 E-mail Vivli Support

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