



Vivli Study Submission Guide

Vivli Platform Version 3.5

25 November 2024

1 Table of Contents

<u>1</u>	<u>SUBMITTING STUDIES ON VIVLI – OVERVIEW.....</u>	<u>3</u>
1.1	LOGIN/ACCOUNT SETUP	3
1.2	DASHBOARD	5
<u>2</u>	<u>STUDY SUBMISSION</u>	<u>7</u>
2.1	INFORMATION ABOUT YOUR TEAM.....	7
2.2	YOUR ORGANIZATION	11
2.3	YOUR STUDY.....	12
2.4	DATA SHARING SETTINGS	17
2.5	AGREEMENTS	19
<u>3</u>	<u>DATA PACKAGE UPLOAD</u>	<u>24</u>
3.1	DATA PACKAGE REQUIREMENTS.....	24
3.2	DATA PACKAGE UPLOAD	24
<u>4</u>	<u>MANAGING YOUR SUBMISSION</u>	<u>30</u>
4.1	SUBMISSION STATUS.....	30
4.2	MAKING EDITS	31
4.3	WITHDRAWAL	31
<u>5</u>	<u>VIEWING YOUR STUDY DETAILS.....</u>	<u>32</u>
5.1	USING VIVLI SEARCH	32
5.2	STUDY DETAILS.....	33
5.3	STUDY DOCUMENTS.....	33
5.4	ADMINISTRATIVE DETAILS	34
5.5	USAGE	35
5.6	ADDING RESEARCH TEAM MEMBERS TO YOUR STUDY SUBMISSION.....	36
5.7	INTEGRATING ORCID FOR RESEARCH TEAM MEMBERS	36
<u>6</u>	<u>CONTACT THE VIVLI TEAM</u>	<u>39</u>
6.1	USING THE PLATFORM CHAT	39
6.2	E-MAIL VIVLI SUPPORT	39

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.

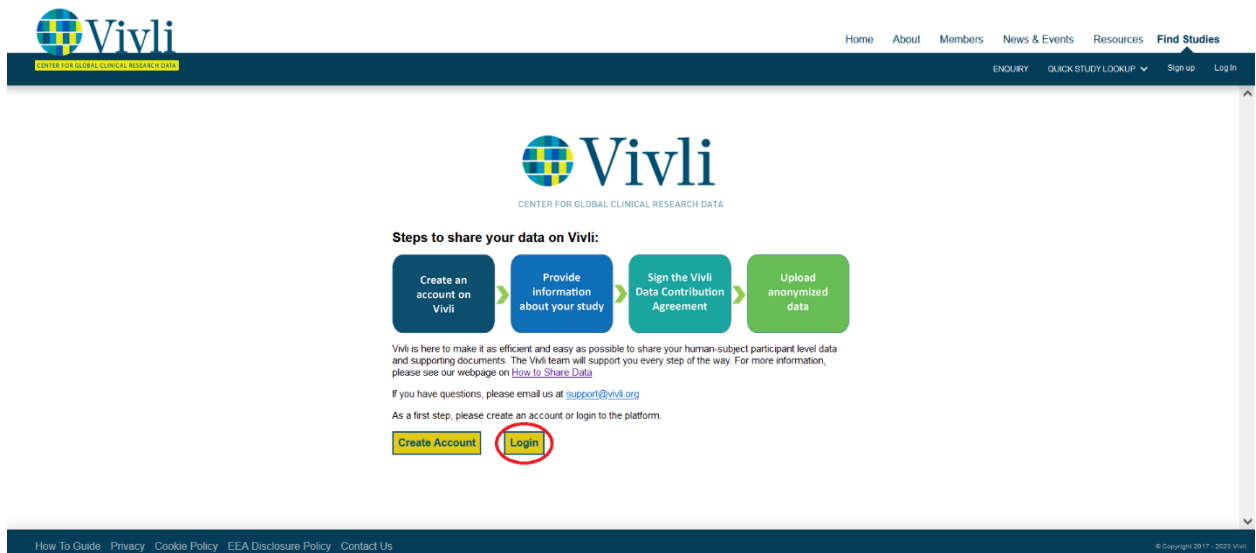
This process is for sharing your data on the Vivli platform. If you are interested in requesting data, please submit a Data Request. See our [How To – Requesting Studies](#) on submitting a Data Request.

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 Section 1.0 of 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. Your dashboard also contains links to Vivli resources which may be helpful to you in your study submission process

Center for Global Clinical Research Data

Home About Members News & Events Resources Portals Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RICHARD ANDERSON

Dashboard

Welcome, Richard Anderson!

This is your view of Vivli at a glance.

For an introduction to how to request studies in the Vivli Platform, click here. [How to request studies](#)

For an introduction to the Vivli Platform in general and guides for using the platform, click here. [How-to guides](#)

To search for clinical studies and create a new data request, click here. [Search](#)

To complete and submit a request for data that you have already started, click on My Data Requests. [My Data Requests](#)

If you cannot find a specific study you need, click on Enquiry to ask about the availability of that clinical study from a Vivli member. [Enquiry](#)

If you are an academic researcher and want to submit your study to Vivli for archive and subsequent sharing, click here to submit your study. [Share Data](#)

If you have any questions, click here or email Vivli Support at support@vivli.org. [Contact Support](#)

- 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.

Center for Global Clinical Research Data

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RICHARD ANDERSON

Dashboard Submissions Enquiries

Single Study Submissions

Draft 6 In Progress 17 Approved/Posted 6 Withdrawn 2

+ Add Submission

Title	Status	NCT ID	Sponsor ID	Created
	Draft			2024-11-01
	Draft			2024-07-17
	Draft			2024-06-11
	Draft			2024-01-05
	Draft	NCT03596801		2023-12-04
A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multinational Trial, to A...	Draft	NCT01225562	D5132C00001	2023-08-11

- 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.

The screenshot shows the Vivli platform interface. At the top, there's a navigation bar with links like Home, About, Members, News & Events, Resources, and Find Studies. Below this, a secondary bar contains links for ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and GABBY TESTING. The main header area shows a '< Go Back' button and 'Status: Draft'. On the left, a sidebar lists several tabs: 1. Information About Your Team (highlighted with a red arrow), 2. Your Organization, 3. Your Study, 4. Data Sharing Settings, 5. Agreements, 6. Upload Data, History, and Chat. The main content area is currently blank. At the bottom, there's a footer with links for How To Guide, Privacy, Cookie Policy, EEA Disclosure Policy, and Contact Us, along with a copyright notice for 2017-2023 Vivli.

- **Note:** This process is to SHARE data on the Vivli platform. If you are interested in requesting data on Vivli please submit a Data Request. See <https://vivli.org/resources/requestdata/> for guidance on requesting data.
- 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.

This screenshot shows the Vivli platform with the 'Your Study' tab selected in the left sidebar. The main content area is populated with study information:

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

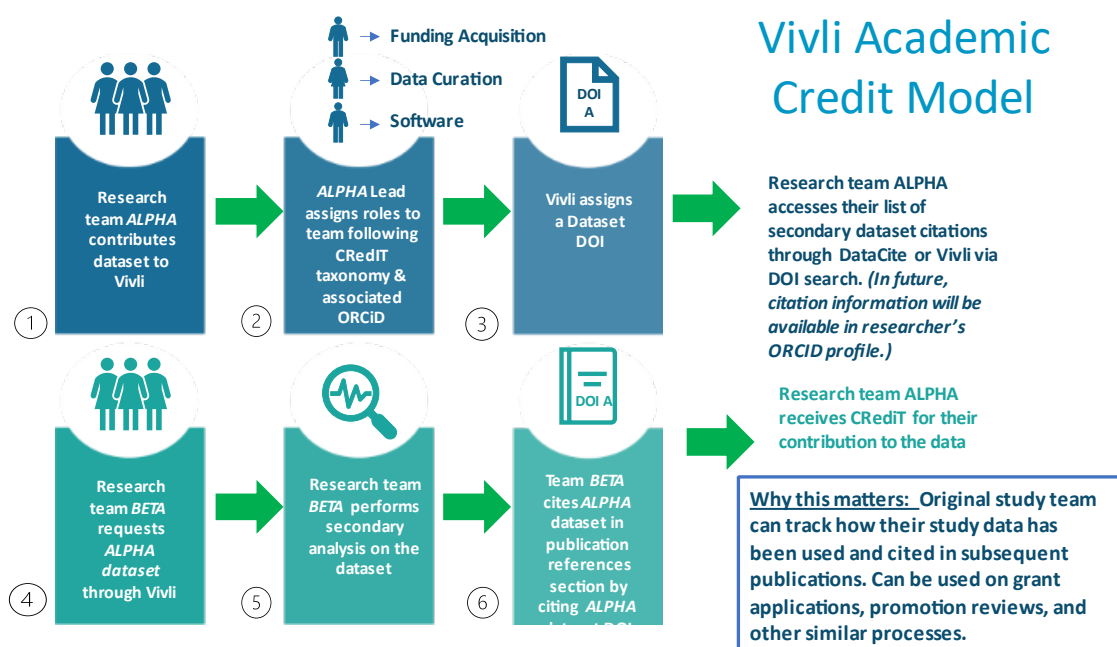
 Below this table, there's a note: 'Please include citations of any primary manuscripts and include any additional information that may be helpful to a researcher when requesting this data.' The status at the top right is 'Draft'. The left sidebar also shows other tabs like 'Information About Your Team', 'Your Organization', 'Data Sharing Settings', 'Agreements', and 'Upload Data'. The top navigation bar and footer are consistent with the previous screenshot.

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

The screenshot shows the Vivli platform interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, Portals, and Find Studies. The main header displays the study title: "A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multinational Trial, to Assess the Prevention of Thrombotic Events With Ticagrelor Com..." and the status "Draft". On the left, a sidebar lists navigation options: 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 "TELL US ABOUT THE RESEARCH TEAM" and includes instructions: "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." Below this, three buttons are visible: "Add Team Member" (highlighted with a red circle), "Next Page", and "Send Invitations to Team Members". A note at the bottom states: "Please note: This submission is for SHARING data on Vivli. If you are interested in requesting data on Vivli please submit a Data Request, see this link for guidance."

- 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.

This screenshot shows the "Add Team Member" form in the Vivli platform. The form is titled "TELL US ABOUT THE RESEARCH TEAM" and includes instructions: "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." The form fields are organized into three columns:

- Column 1:** Email address (jamesmith@edu.org), Given Name (Jane), and ROR ID.
- Column 2:** ORCID ID (0000-1111-0000-0000), Family Name (Smith), and Organization.
- Column 3:** CRediT Roles (a dropdown menu with selected roles: Funding acquisition, Project administration, and Supervision).

 Below the form fields are three buttons: "Add Team Member", "Next Page", and "Send Invitations to Team Members". A red circle highlights a red "X" button in the bottom right corner of the CRediT Roles dropdown menu. A note at the bottom states: "Please note: This submission is for SHARING data on Vivli. If you are interested in requesting data on Vivli please submit a Data Request, see this link for guidance."

- 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.

The screenshot shows the 'Add Team Member' form on the Vivli platform. The form is titled 'TELL US ABOUT THE RESEARCH TEAM' and contains several input fields: Email address (janesmith@edu.org), ORCID ID (0000-1111-0000-0000), Given Name (Jane), Family Name (Smith), ROR Id, and Organization. A dropdown menu for 'CRediT Role(s)' is open, showing a list of roles including Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Resources, Software, Validation, and Visualization. The dropdown is circled in red. The form also includes buttons for 'Add Team Member', 'Next Page', and 'Send Invitations to Team Members'. A note at the bottom states: 'Please note: This submission is for SHARING data on Vivli. If you are interested in requesting data on Vivli please submit a Data Request, see this link for guidance.'

- 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 of each research team member who is involved in this study
- Once all fields for the first team member are complete, use the "Add Team Member" button to create additional entries.

Vivli
CENTRE FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Portals Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RICHARD ANDERSON

< Go Back A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multinational Trial, to Assess the Prevention of Thrombotic Events With Ticagrelor Com... 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 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: janesmith@edu.org ORCID ID: 0000-1111-0000-0000 CRediT Role(s): Funding acquisition x Project administration x Supervision x

Given Name: Jane Family Name: Smith

ROR Id: Organization:

Add Team Member Next Page Send Invitations to Team Members

Please note: This submission is for SHARING data on Vivli. If you are interested in requesting data on Vivli please submit a Data Request, see this link for guidance.

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us © Copyright 2017 - 2024 Vivli

Vivli
CENTRE FOR GLOBAL CLINICAL RESEARCH DATA

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

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: datarequester.vivli@gmail.com ORCID ID: 0000-1111-0000-0000 CRediT Role(s): Methodology x Validation x

Given Name: Jane Family Name: Smith

ROR Id: Organization:

Email address: datacontributor2@gmail.com ORCID ID: 0000-0001-6752-5707 CRediT Role(s): Project administration x Resources x Software x

Given Name: Kelly Family Name: Sharp

ROR Id: Organization:

Add Team Member Next Page Send Invitations to Team Members

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us © Copyright 2017 - 2024 Vivli

- 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 the “Next Page” button to navigate to the next section.

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP 540 MY DATA REQUESTS RICHARD ANDERSON

< Go Back A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multinational Trial, to Assess the Pre... **Status: Draft** Withdraw **Save** Submit

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: datarequester.vivli@gmail.com ORCID ID: 0000-1111-0000-0000

Given Name: Study Family Name: Upload

ROR Id: Organization

CRediT Role(s): Data curation x Formal analysis x Methodology x Software x

Add Team Member **Next Page** Send Invitations to Team Members

Please note: This submission is for SHARING data on Vivli. If you are interested in requesting data on Vivli please submit a Data Request, see this [link](#) for guidance.

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.

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP 540 MY DATA REQUESTS RICHARD ANDERSON

< Go Back A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multinational Trial, to Assess the Pre... **Status: Draft** Withdraw **Save** Submit

2. Your Organization

TELL US ABOUT YOUR ORGANIZATION

Enter the full name of your organization
Duke 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.

Contact Vivli **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 the registration ID from clinicaltrials.gov. A red circle highlights the 'NCT ID (of the form NCT12345678)' field, which contains the value 'NCT05773040'. Below this, the form fields are populated: Title is 'A Phase 1 Study of JV-213 Autologous CD70b-targeting Chimeric Antigen Receptor T-cell Therapy in Adults With Relapsed or Refractory B-cell Lymphomas', Conditions is 'Lymphomas, B-cell Lymphomas', Interventions is 'JV-213, Leukapheresis', and Phase is 'Phase 1'. A footer note states: 'Please include citations of any primary manuscripts and include any additional information that may be helpful to a researcher when requesting this data.'

- 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 the registration ID from clinicaltrials.gov. A red circle highlights the 'Study is not Listed on ClinicalTrials.gov' checkbox, which is checked. The 'NCT ID (of the form NCT12345678)' field is empty. Below this, the form fields are empty: Title, Conditions, Interventions, and Phase. A footer note states: 'Please include citations of any primary manuscripts and include any additional information that may be helpful to a researcher when requesting this data.'

- 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 does not apply to your dataset, enter “N/A”.
 - If the Phase field does not apply to your dataset, select “N/A” from the dropdown menu.

ENTER FOR CLINICAL TRIALS REGISTRATION

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.

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2024 Vivli

- 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 the box and select “OK”.

ENTER FOR CLINICAL TRIALS REGISTRATION

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

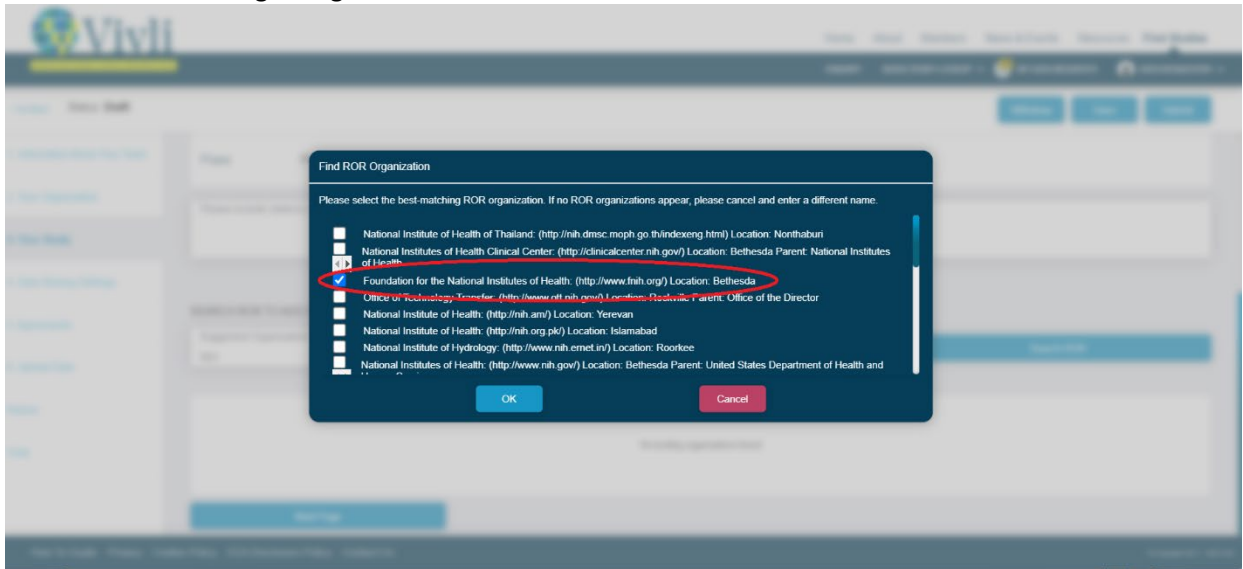
Search ROR

No funding organizations found

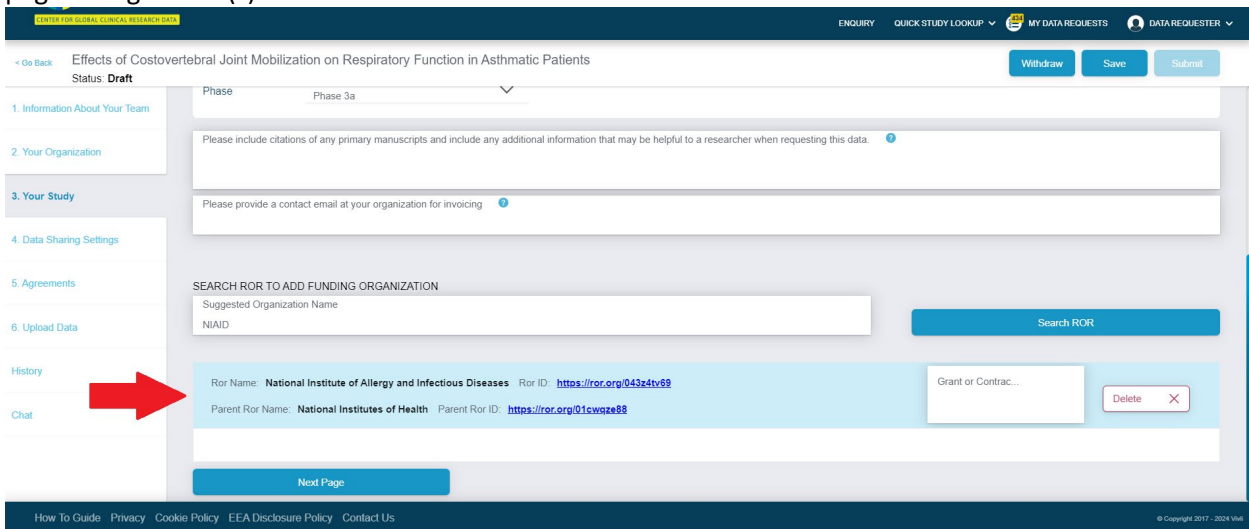
Next Page

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

- Check the appropriate funder name. If you typed the incorrect name, refresh your screen to search for the right Organization.



- Once the funder is added and saved, you will see a table appear at the bottom of the “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: welcome 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/029chgv08	Grant or Contract Id	Delete X
Parent Ror Name: Parent Ror ID:		

Next Page

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

- 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/029chgv08	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:		

Next Page

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

- Please fill out the Grant or Contract ID for each funder, if available.

- 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. 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 to academic and non-profit researchers who want to share their clinical data. Visit our [Share Data](#) page for more information on the 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 completed, hit "Save" and click "Next Page" to navigate to the next section.

The screenshot shows the 'Your Study' page in the Vivli platform. The status is 'Draft'. The left sidebar contains links for 'Information About Your Team', 'Your Organization', 'Your Study', 'Data Sharing Settings', 'Agreements', 'Upload Data', 'History', and 'Chat'. The main content area is titled 'SEARCH ROR TO ADD FUNDING ORGANIZATION'. It features a search bar with 'Suggested Organization Name: wellcome' and a 'Search ROR' button. Below the search bar, there is a table of suggested organizations:

Ror Name	Ror ID	Grant or Contract Id	Delete
Foundation for the National Institutes of Health	https://ror.org/00k86s899		<input type="button" value="Delete"/>
Wellcome Trust	https://ror.org/029chg908		<input type="button" value="Delete"/>

A red arrow points to the 'Wellcome Trust' entry. At the bottom of the table, there is a 'Next Page' button. The footer contains links for 'How To Guide', 'Privacy', 'Cookie Policy', 'EEA Disclosure Policy', and 'Contact Us'.

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.

The screenshot shows the 'Data Sharing Settings' page in the Vivli platform. The status is 'Draft'. The left sidebar contains links for 'Information About Your Team', 'Your Organization', 'Your Study', 'Data Sharing Settings', 'Agreements', 'Upload Data', 'History', and 'Chat'. The main content area is titled 'DATA SHARING SETTINGS' and includes a 'Review process for requests for data:' section. The first question is 'Does your data need to be embargoed?' with radio buttons for 'Yes' (selected) and 'No'. Below this is a text field for 'Embargo data until' with the value 'COMING'. The second question is 'Data requesters may want to contact you for questions and/or collaboration. Are you willing to be available by email to requesters?' with radio buttons for 'Yes' and 'No' (selected). The third question is 'All data provided to Vivli must be anonymized. Will you need help anonymizing your data?' with radio buttons for 'Yes' and 'No' (selected). At the bottom, there is a note: 'Study data packages must include at least 4 file types - click here for more information.' and a 'Next Page' button. The footer contains links for 'How To Guide', 'Privacy', 'Cookie Policy', 'EEA Disclosure Policy', and 'Contact Us'.

- 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'.

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

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
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

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, hit “Save” and use the “Next Page” button to navigate to the next section.

2.5 Agreements

- Click the blue “Begin 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 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

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:

By: *Principal Investigator*

Name: Principal Investigator

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 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 it.

ENTER FOR GLOBAL CLINICAL RESEARCH DATA

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RICHARD ANDERSON

< Go Back A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multinational Trial, to Assess the Prevention of Thrombotic Events With Ticagrelor Com... 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 and acknowledge, and an Institutional Official will need to sign this Data Contribution Agreement (DCA). If your institution already has a Master DCA in place, we do not require an 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 learn more about the Data Contribution Agreement and start the execution process:

Begin 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 to notify Vivli to begin processing the study.

*If the submit button is not available, required fields may be incomplete. Check that all required fields on all tabs are complete and click Submit.

You will receive an email from Vivli with next steps for Data Upload once the Data Contribution Agreement is complete.

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2024 Vivli

- 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-NMRT	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	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

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2024 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 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.

How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us

© Copyright 2017 - 2023 Vivli

- To view the history of the Study Submission, click on the tab that says "History". 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 when the study is sent to curation, date the study is posted to the Vivli platform, etc.)

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

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 and asking you to provide the team member who will upload the data package. The team member who will be responsible for uploading data will need to create an account and they will then be given data contributor access for the data upload. After the data is uploaded, data contributor access to upload data will be removed. If data needs to be re-uploaded at any time, reach out to the Vivli team at support@Vivli.org and access may be re-granted.

- 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. You may also log in to the Vivli platform and find the submission under the Dashboard (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 user Richard Anderson. The left sidebar has a 'Submissions' tab highlighted with a red box. The top right dropdown menu also has 'Submissions' highlighted with a red box. The main content area displays a welcome message and several links for getting started, such as 'How to request studies', 'How-to guides', 'Search', 'My Data Requests', 'Enquiry', 'Share Data', and 'Contact Support'.

- In the Submissions tab, 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. At the top, there are tabs for 'Draft' (6), 'In Progress' (17), 'Approved/Posted' (6), and 'Withdrawn' (2). The 'Approved/Posted' tab is highlighted with a red box. Below the tabs is a table of submissions. The first row is highlighted, and the 'Approved' status is highlighted with a red box.

Title	Status	NCT ID	Sponsor ID	Approved
A Phase 3, Randomized, Double-Blind Study Comparing Upadacitinib (ABT-494) Once D...	Approved	NCT02706873	M13-545	2024-10-23
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	P50MH07724...	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	1R01MH0900...	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).

Filename	Size	Uploaded By	File Type	Action
Protocol.pdf	179.00kB	Data Contributor	Unknown	Delete X
Digitalis_demoData.zip	2.37MB	Data Contributor	Unknown	Uploading

- To make supporting documents publicly available to researchers, check the box that says "Publicly available". This will make the documents available to researchers who have a Vivli account during their study search. This will help researchers to finalize the studies before submitting their Vivli data request.
 - Note: Files that have the file type "IPD" and "Analysis ready dataset" will not have the option to check "Publicly available" as Individual Participant Data (IPD) is NOT available without submitting a request.

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

[Select Files](#)

UPLOADED FILES

Filename	Size	Uploaded By	File Type	Publicly Available	Download	Remove
SAP.docx	11.73kB	Data Provider	Stats...	<input type="checkbox"/>	Download	Remove
Data Dictionary.docx	11.73kB	Data Provider	Data D...	<input type="checkbox"/>	Download	Remove
IPD.docx	11.72kB	Data Provider	IPD	<input type="checkbox"/>	Download	Remove
Protocol.docx	11.74kB	Data Provider	Protoc...	<input type="checkbox"/>	Download	Remove

[Verify Upload](#)

[Submit Files](#)

[Add New Link](#)

Links to Documents located elsewhere

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

[Select Files](#)

UPLOADED FILES

Filename	Size	Uploaded By	File Type	Publicly Available	Download	Remove
SAP.docx	11.73kB	Data Provider	Stats...	<input checked="" type="checkbox"/>	Download	Remove
Data Dictionary.docx	11.73kB	Data Provider	Data D...	<input checked="" type="checkbox"/>	Download	Remove
IPD.docx	11.72kB	Data Provider	IPD	<input checked="" type="checkbox"/>	Download	Remove
Protocol.docx	11.74kB	Data Provider	Protoc...	<input type="checkbox"/>	Download	Remove

[Verify Upload](#)

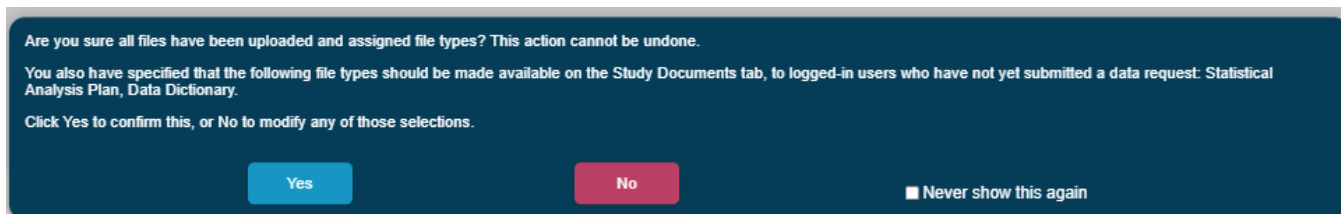
[Submit Files](#)

[Add New Link](#)

Links to Documents located elsewhere

- 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”

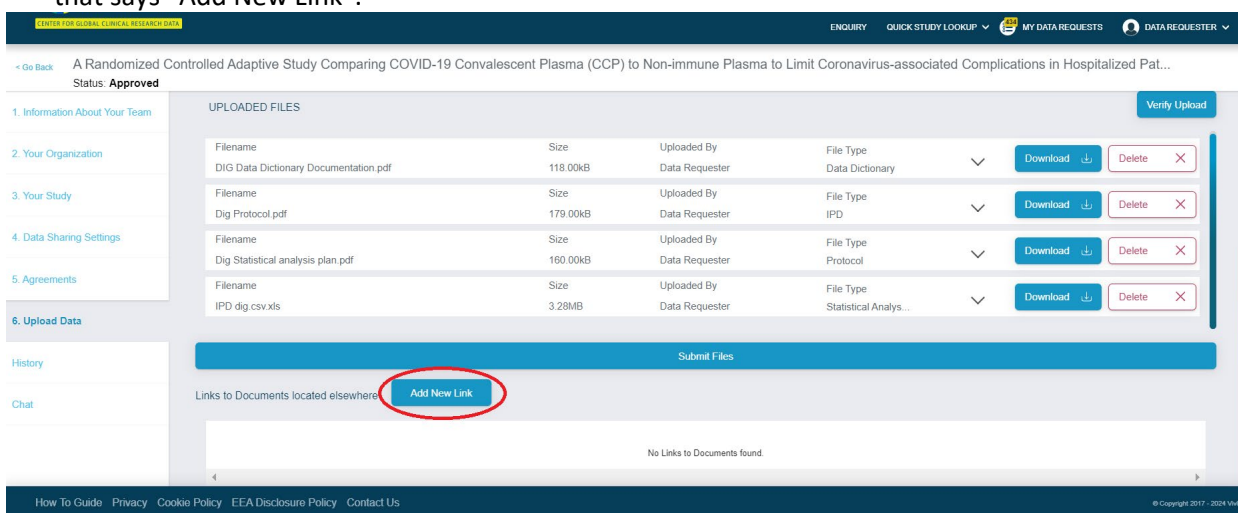
- Ensure all the files are loaded, then click the **'Submit Files'** button.
- You will be directed to a pop-up confirming that you have uploaded all files and assigned file types. Additionally, the files that you have chosen to be made publicly available will be displayed and you will be asked to confirm you have selected the correct file(s) to be made publicly available.
 - Click the blue 'Yes' button to proceed. Or click the red button "No" to adjust your selections and you will be re-routed to the Upload Data page again.



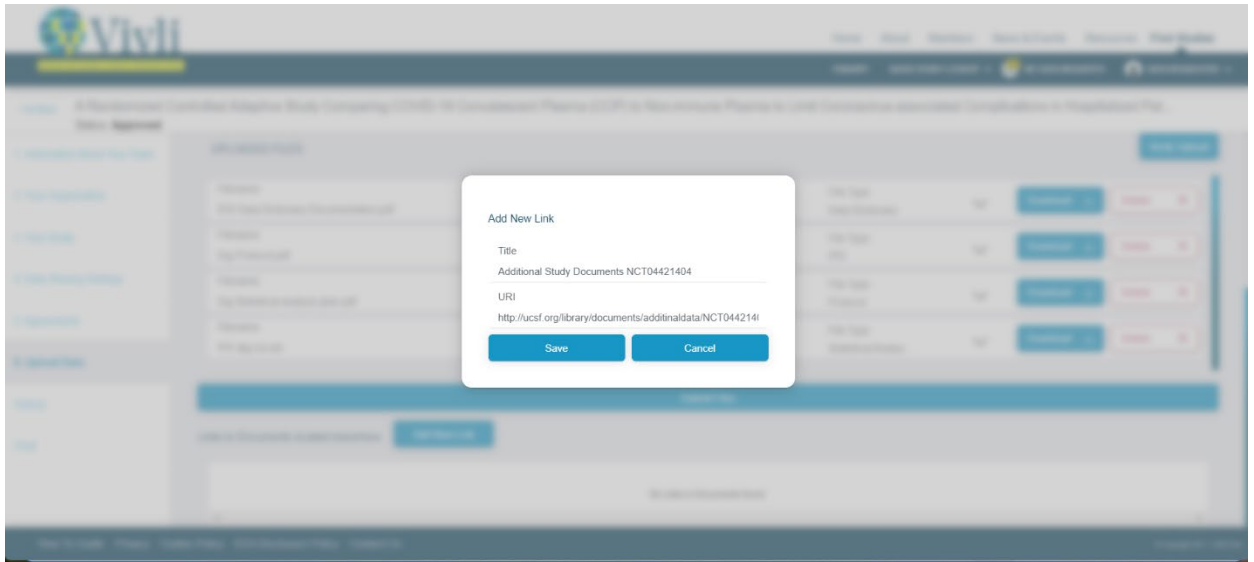
- You will receive confirmation of successful upload. Click the 'Continue' button to return to your submission.



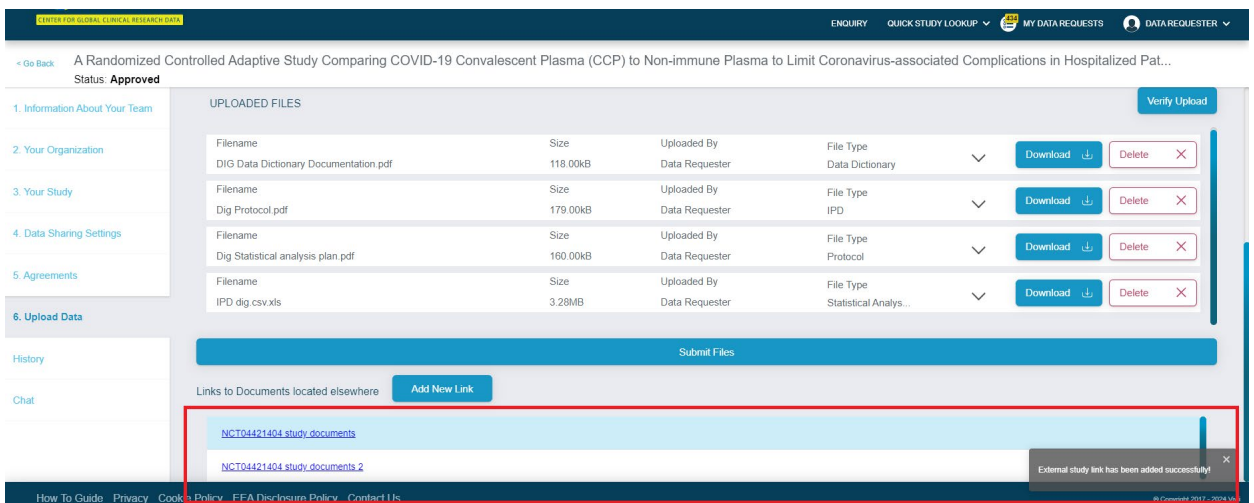
- Once study documents are uploaded, if there are further documents that are available for your study at an external link, and you would like to provide a link to the documents, click the button that says "Add New Link".



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



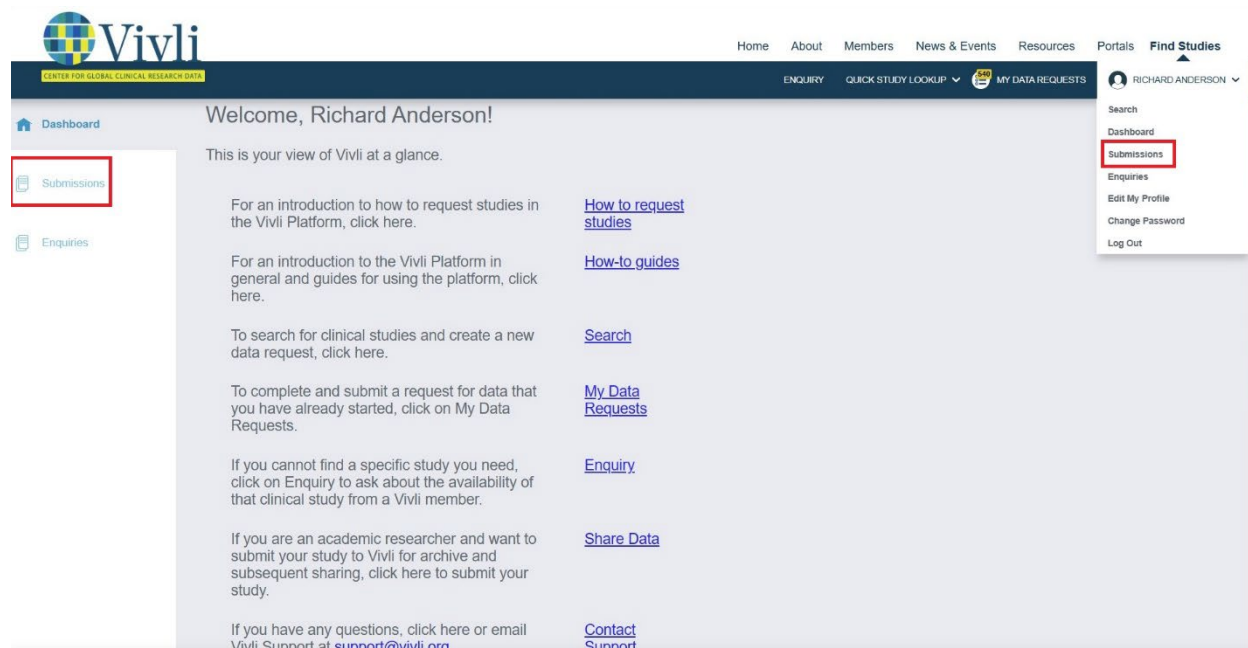
- You may add multiple links to external documents. Once you press ‘Save’, you will see a popup appear that says, “External study link has been loaded properly” and the link(s) to the document(s) will appear on the bottom of the page.



4 Managing your Submission

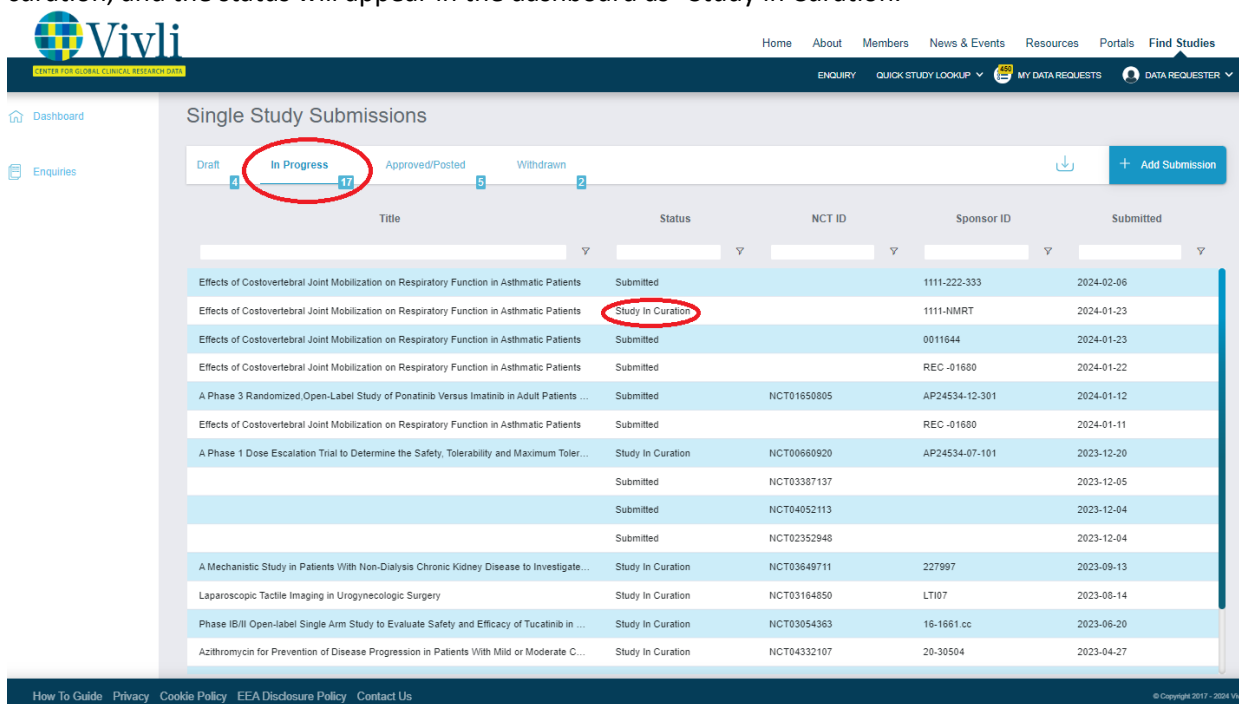
4.1 Submission Status

- You may check the progress of your submission via the Submissions dashboard.



The screenshot shows the Vivli dashboard for Richard Anderson. The sidebar on the left has a 'Submissions' link highlighted with a red box. The main content area is titled 'Welcome, Richard Anderson!' and contains several links for getting started, such as 'How to request studies', 'How-to guides', 'Search', 'My Data Requests', 'Enquiry', and 'Share Data'. A dropdown menu in the top right corner also has 'Submissions' highlighted with a red box.

- 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.”

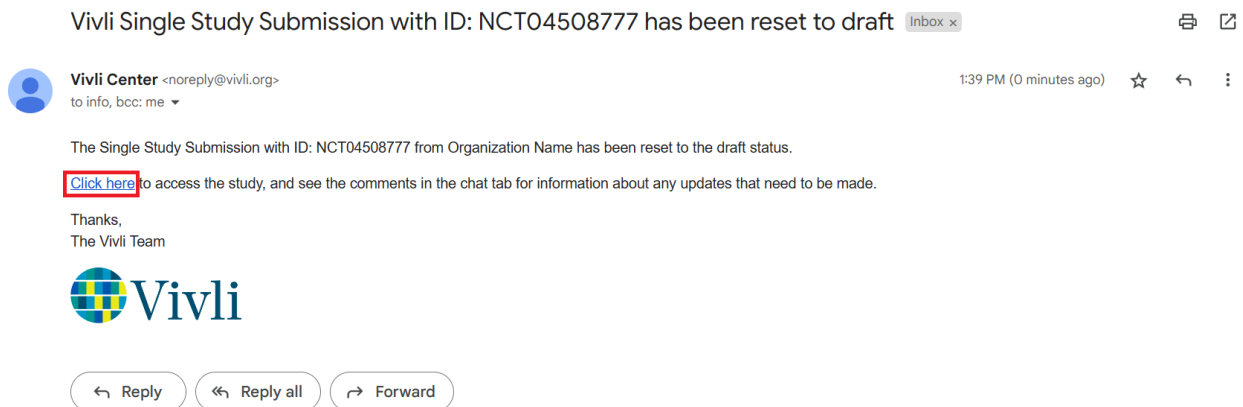


The screenshot shows the 'Single Study Submissions' dashboard. At the top, there are tabs for 'Draft' (4), 'In Progress' (17), 'Approved/Posted' (5), and 'Withdrawn' (2). The 'In Progress' tab is highlighted with a red circle. Below the tabs is a table of submissions. The table has columns for Title, Status, NCT ID, Sponsor ID, and Submitted. One row is highlighted with a red circle, 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-NMRT	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	NCT02352948		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/III 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

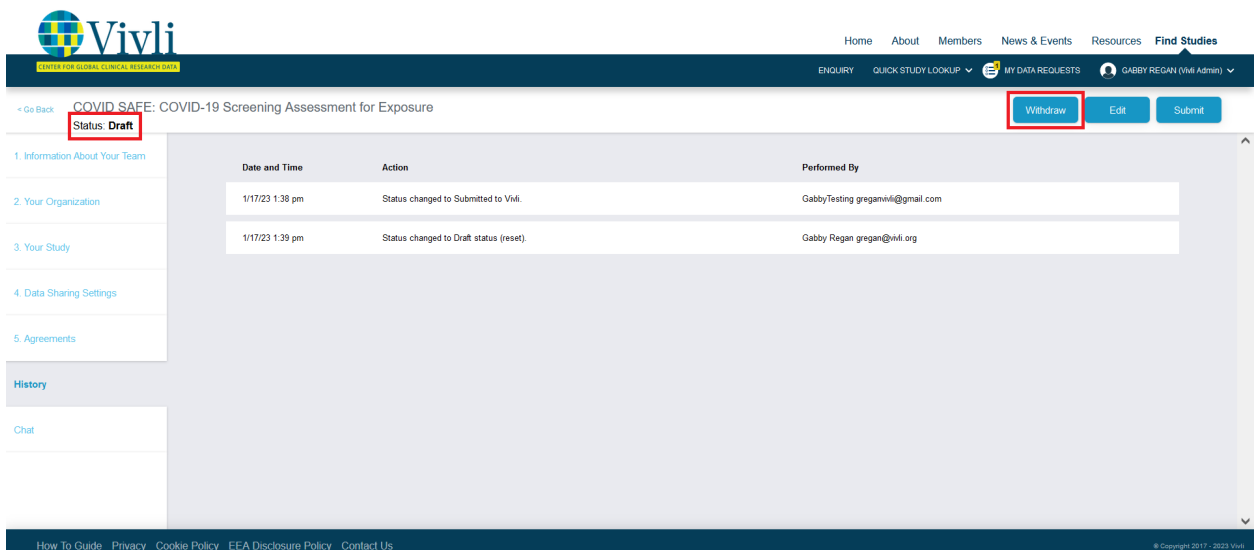
4.2 Making Edits

- 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: Home, About, Members, News & Events, Resources, Portals, and Find Studies. Below this is a banner with the text "We are committed to advancing the knowledge around the COVID-19 pandemic" and buttons for "Share trials" and "Search for trials". The main search area is titled "KEYWORD SEARCH" and "PICO Beta". A search bar contains the text "NCT01243606". Below the search bar, there are four columns of filters: STUDY DESIGN (INTERVENTIONAL STUDIES, OBSERVATIONAL STUDIES, STUDY PHASE), SPONSOR INFORMATION (FUNDER, CONTRIBUTOR, SAMPLE SIZE), LOCATION, and START DATE (From, To). Each filter has a "Select Multiple" dropdown. At the bottom of the search results, a blue bar indicates "1 Studies".

- 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.

The screenshot shows the Vivli search interface with the study details for NCT01243606. The search bar contains the text "NCT01243606". Below the search bar, there are four columns of filters: STUDY DESIGN (INTERVENTIONAL STUDIES, OBSERVATIONAL STUDIES, STUDY PHASE), SPONSOR INFORMATION (SPONSOR TYPE, SPONSOR, SAMPLE SIZE), LOCATION, and START DATE (From, To). Each filter has a "Select Multiple" dropdown. The main content area displays the study details for "Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Disorders". The details include the NCT ID (NCT01243606), the IRB ID (1R01MH090053-01), the Condition or Disease (Anxiety Disorders, Mood Disorders), and the Intervention/treatment (Single Diagnosis Treatment Protocol, Unified Protocol (UP)). On the right side, there is a "Request Study" button and a "View Study Details" button, which is circled in red. Below the "View Study Details" button, it says "Number enrolled: 250" and "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.

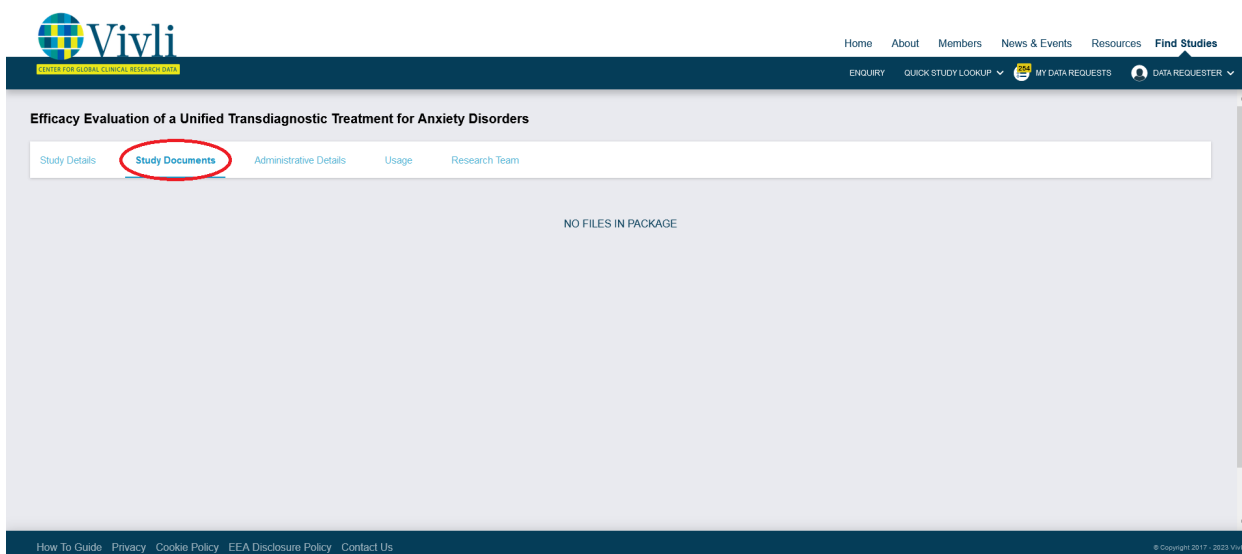
The screenshot displays the Vivli platform interface. At the top, the Vivli logo is on the left, and navigation links (Home, About, Members, News & Events, Resources, Find Studies) are on the right. Below the navigation bar, a dark blue header contains links for ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and DATA REQUESTER. The main content area is titled 'Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Disorders'. Below this title, there are five tabs: 'Study Details' (highlighted with a red circle), 'Study Documents', 'Administrative Details', 'Usage', and 'Research Team'. The 'Study Details' tab is active, showing a form with the following fields: 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), and Actual Enrollment (250). At the bottom, there are links for How To Guide, Privacy, Cookie Policy, EEA Disclosure Policy, and Contact Us, along with a copyright notice for 2017-2023.

5.3 Study Documents

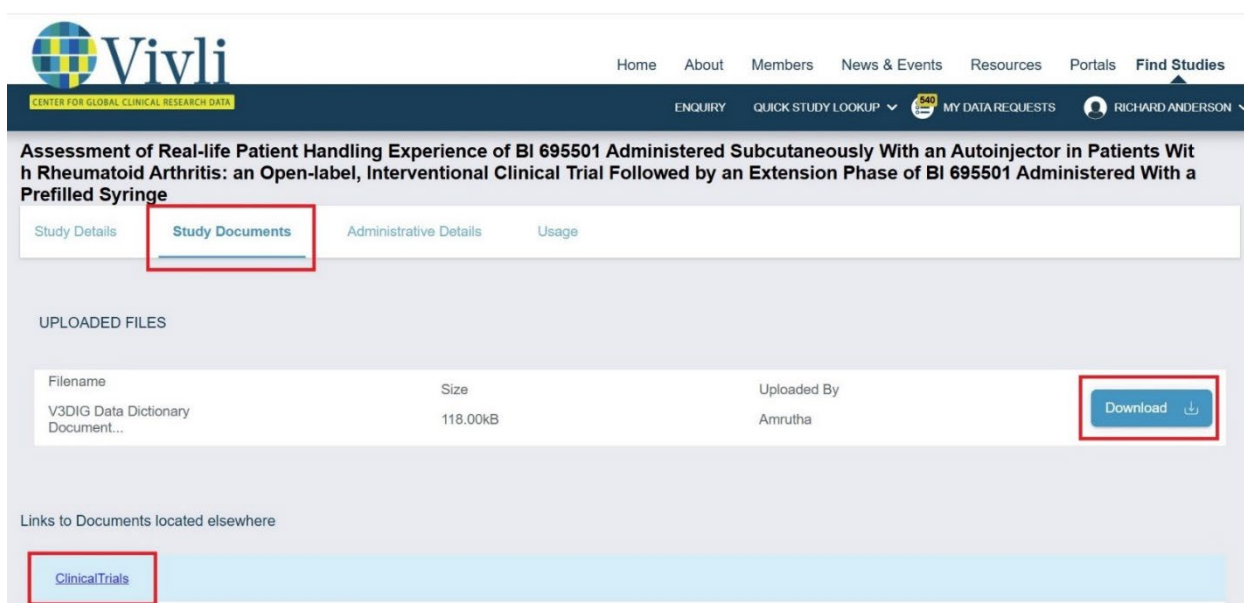
The 'Study Documents' tab is provided to share documents with searchers to help them determine whether the dataset can support their research - this typically will include documents like the Data Dictionary or the Protocol. The supporting documents are uploaded and will be made available during the study data upload process (See [Section 3.2 Data Package Upload](#)).

The study documents should not include the anonymized individual participant-level data (IPD).

The 'Study Documents' tab will initially appear empty until you have uploaded data and declared which documents should be made publicly available to researchers.



- Once you have uploaded study data and have checked the box stating “Publicly Available” appear here, the files will appear in this 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 the Vivli website.

Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Disorders

Study Details | Study Documents | **Administrative Details** | Usage | Research Team

Vivli DOI https://handle.stage.datacite.org/10.70118/AQ00003191	Vivli ID VIV00003191	Sponsor Protocol ID 1R01MH090053-01	Acronym
Data Package DOI(s) Available for this Study https://handle.stage.datacite.org/10.70118/AQ00003191.0			
Lead Sponsor Agency Boston University Charles River Campus		Lead Sponsor Agency Class Other	
Collaborator Agency National Institute of Mental Health (NIMH)		Collaborator Agency Class NIH	
Data Contributor Organization Name Boston University			

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

© Copyright 2017 - 2023 Vivli

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.
 - **Public Disclosures:** Public Disclosures field includes all Public Disclosures linked to this study through a Vivli Data Request. When a public disclosure is published and the citation is received as part of the Vivli data request, the citation is entered into the Data Request, and linked to the Study(s) involved in that Data Request. It will be initially blank. Once your studies are included in publications, you can see the publication reference here.

Randomized Evaluation of Dabigatran Etxilate Compared to warfarin in pulmonaRy Vein Ablation: Assessment of an Uninterrupted periproCedUral antlcoagulation sStrategy (The RE-CIRCUIT Trial)

Study Details Study Documents Administrative Details **Usage**

Usage

Views	Download of Study Documents
5	0
Access of Data Package	All usage metrics
0	from 06/18/2022 to 11/17/2...

Views:

Vivli counts a view every time a user clicks on Study Details for this study in a search, or displays the DOI page for this study. In effect this counts views of the study metadata.

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.

Public Disclosures

Kimata, Akira, Nogami, Akihiko, Yamasaki, Hiro, Ohigashi, Tomohiro, Goshio, Masahiko, Igarashi, Miyako, Sekiguchi
 "Optimal interruption time of dabigatran oral administration to ablation (O-A time) in patients with atrial fibrillation: Integrated analysis of 2 randomized controlled clinical trials"
Journal of Cardiology, vol. 77, no. 6, Jun. 2021, pp. 652-659, doi: <http://dx.doi.org/10.1016/j.jcc.2020.12.010>

...
 "Late-Breaking Science Abstracts and Featured Science Abstracts From the American Heart Association's Scientific Sessions 2019 and Late-Breaking Abstracts in Resuscitation Science From the Resuscitation Science Symposium 2019"
Resuscitation, vol. 165, pp. 35-36, Dec. 2020, doi: <https://doi.org/10.1016/j.resusc.2020.11.007>

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.

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Portals Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS RICHARD ANDERSON

A Randomized Controlled Adaptive Study Comparing COVID-19 Convalescent Plasma (CCP) to Non-immune Plasma to Limit Coronavirus-associated Complications in Hospitalized Patients (CAPRI)

Study Details Study Documents Administrative Details Usage **Research Team**

Given Name Sarah	Family Name Jones	ORCID ID 2222-3333-2222-3333	CRedit Role(s) <ul style="list-style-type: none"> Funding acquisition Formal analysis Data curation
---------------------	----------------------	---------------------------------	---

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	

 Authorize update to ORCID

- 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
sheldon.russel@mailinator.com
example@email.com or 0000-0001-2345-6789


Password


SIGN IN


Forgot your password or ORCID ID? [Register now](#)

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

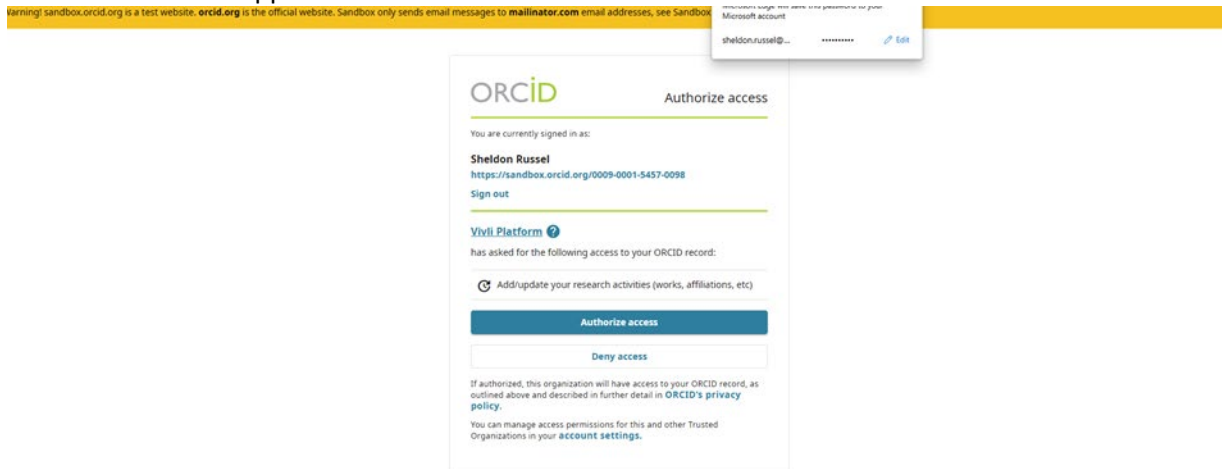
or

 **Access through your institution**

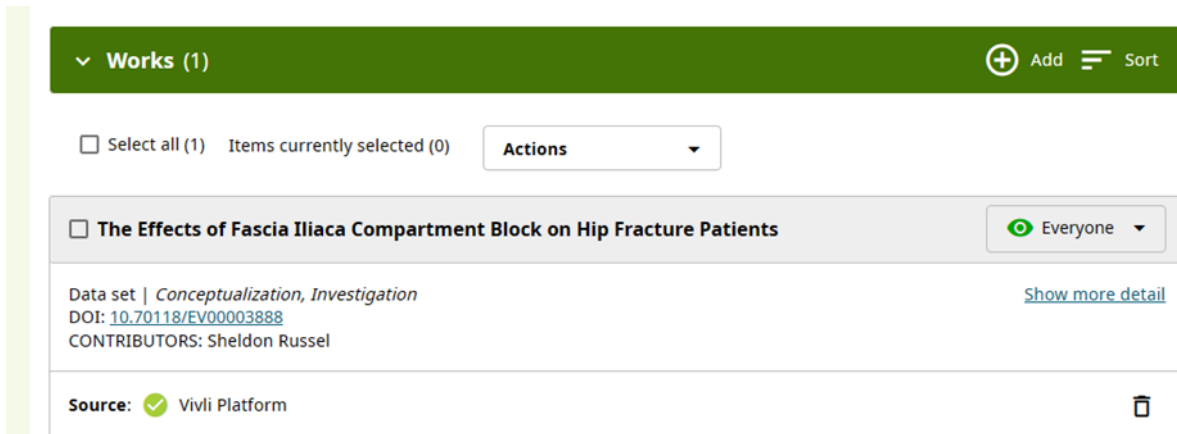
 **Sign in with Google**

 **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.

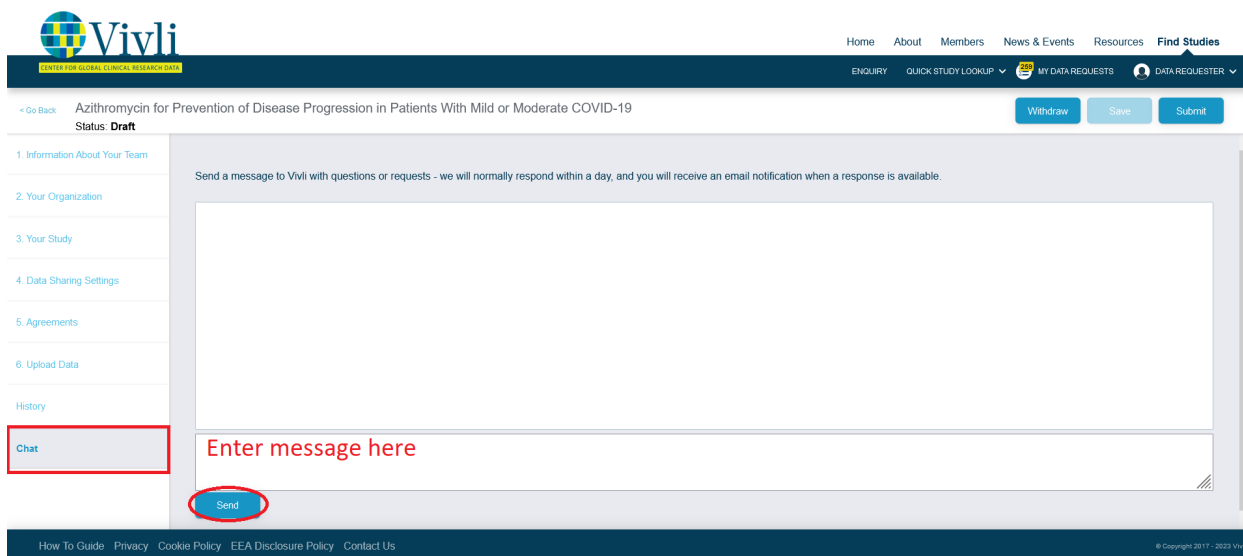


- If there are changes to the research team (a member is deleted, or roles are updated) this will be reflected in the user’s ORCID record.

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.



The screenshot shows the Vivli platform interface. At the top, the Vivli logo is on the left, and navigation links (Home, About, Members, News & Events, Resources, Find Studies) are on the right. Below the navigation bar, the page title is "Azithromycin for Prevention of Disease Progression in Patients With Mild or Moderate COVID-19". The status is "Draft". On the left sidebar, the "Chat" tab is highlighted with a red box. The main content area shows a message input field with the placeholder text "Enter message here" and a "Send" button circled in red. Above the input field, there is a message: "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 bottom of the page contains links for "How To Guide", "Privacy", "Cookie Policy", "EEA Disclosure Policy", and "Contact Us", along with a copyright notice "© Copyright 2017 - 2023 Vivli".

6.2 E-mail Vivli Support

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