Vivli Study Submission Guide
Vivli Platform Version 3.5

25 November 2024

1 Table of Contents

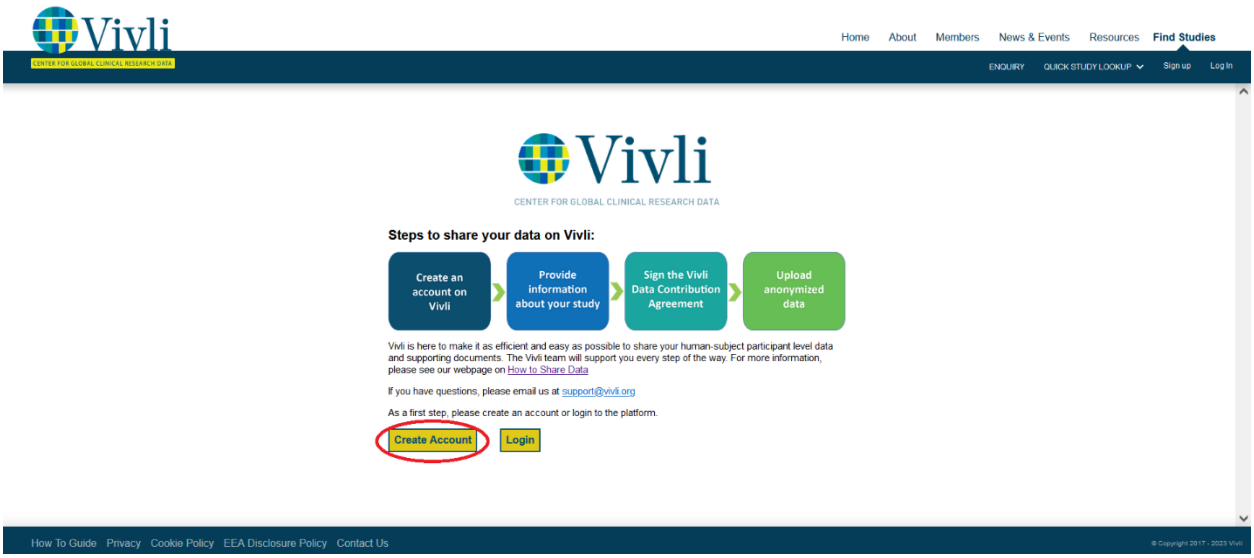
1 Submitting Studies on Vivli – Overview

- 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.

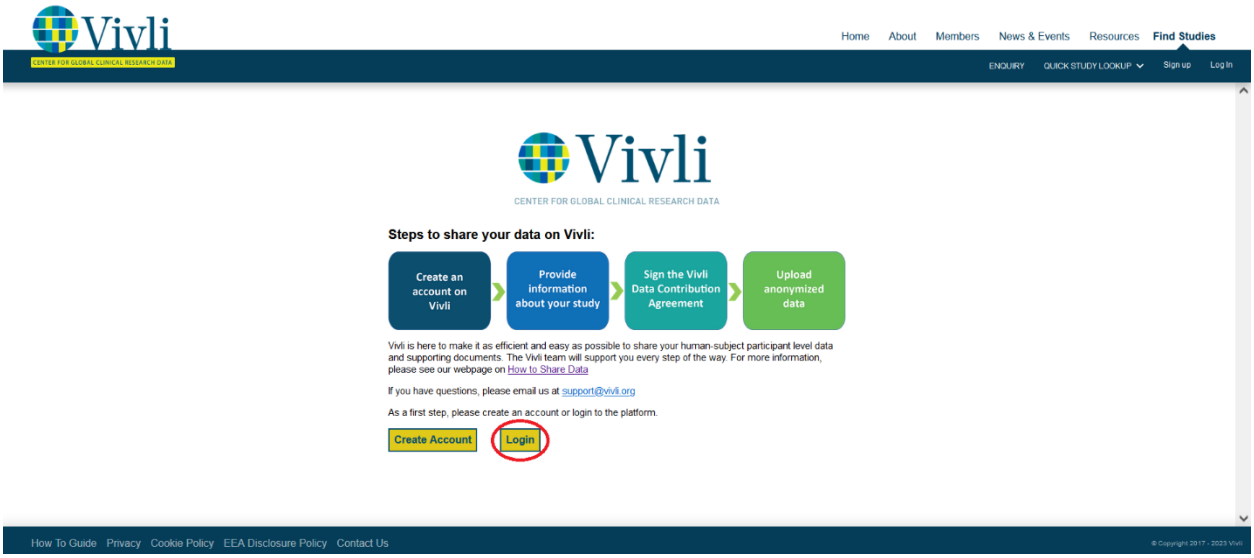
This process is for sharing your data on the Vivli platform. If you are interested in requesting data, please submit a Data Request. See our How To – Requesting Studies on submitting a Data Request.

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.

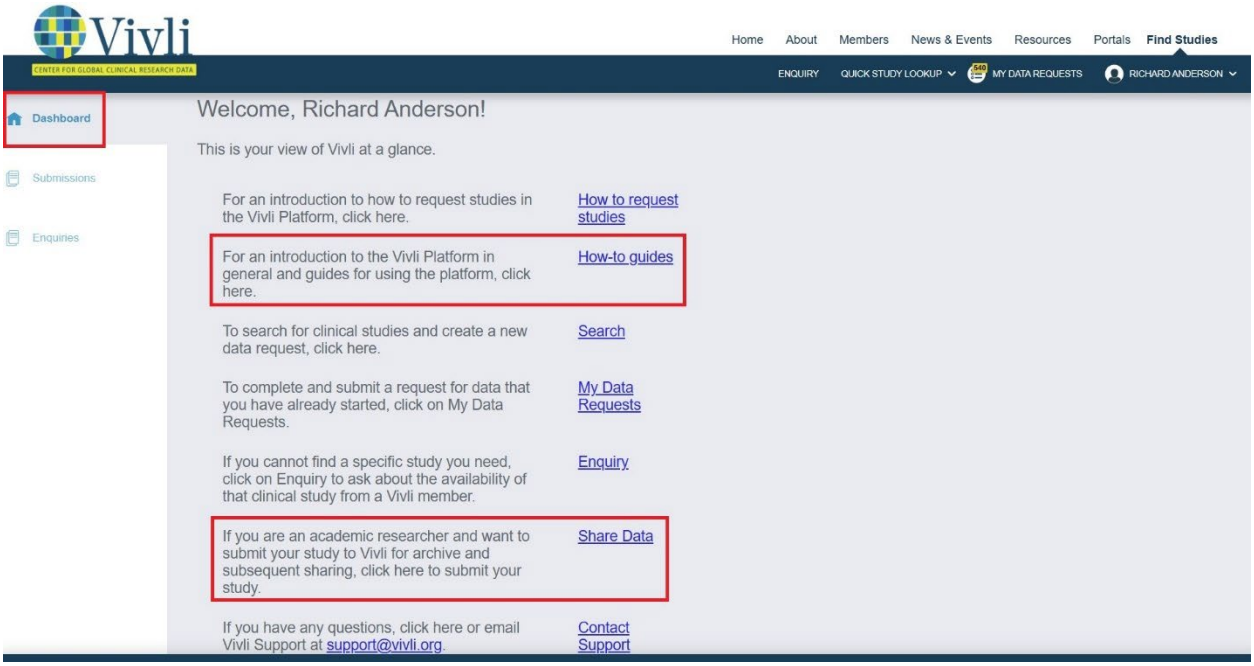


- If you are already a Vivli user, click the “Login” button.

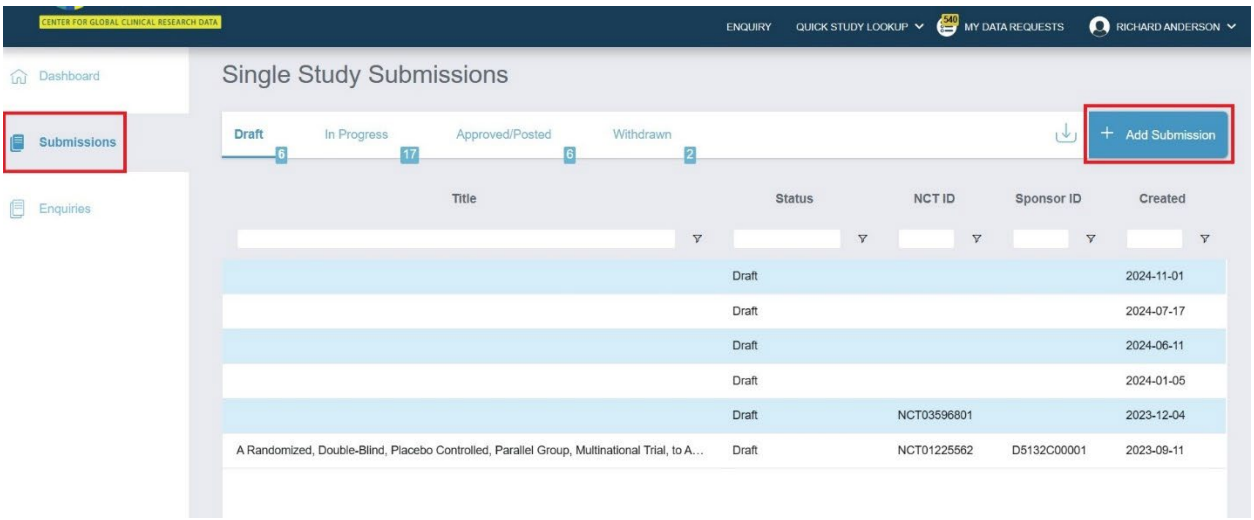


1.2 Dashboard

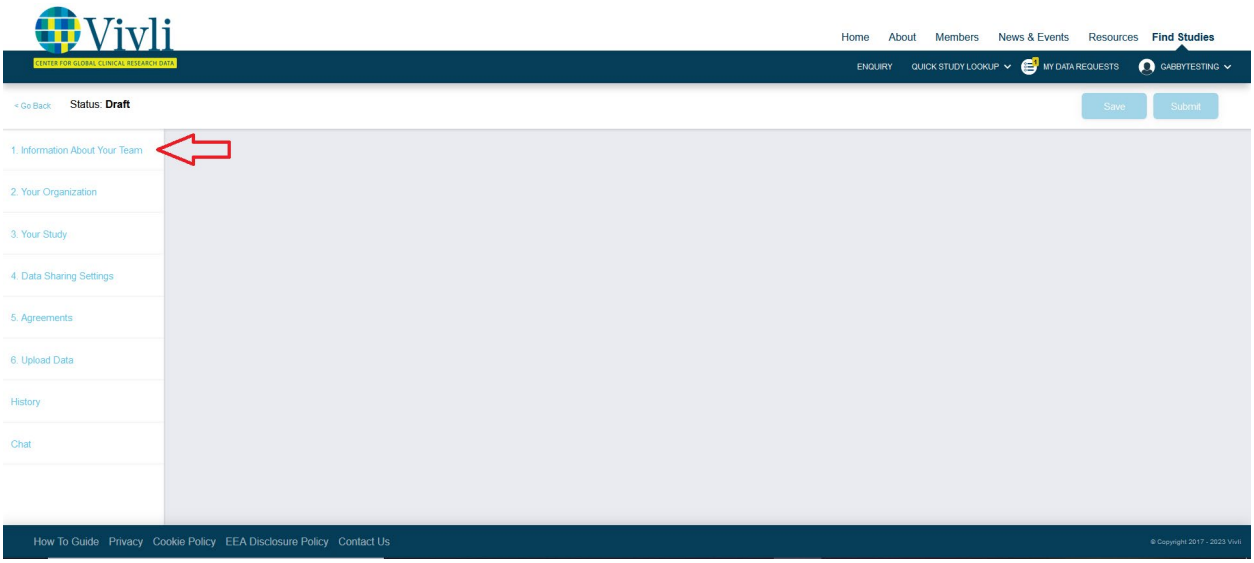
- Once you have logged into the platform, if you have already begun to create submissions, your account dashboard will appear. Your dashboard also contains links to Vivli resources which may be helpful to you in your study submission process



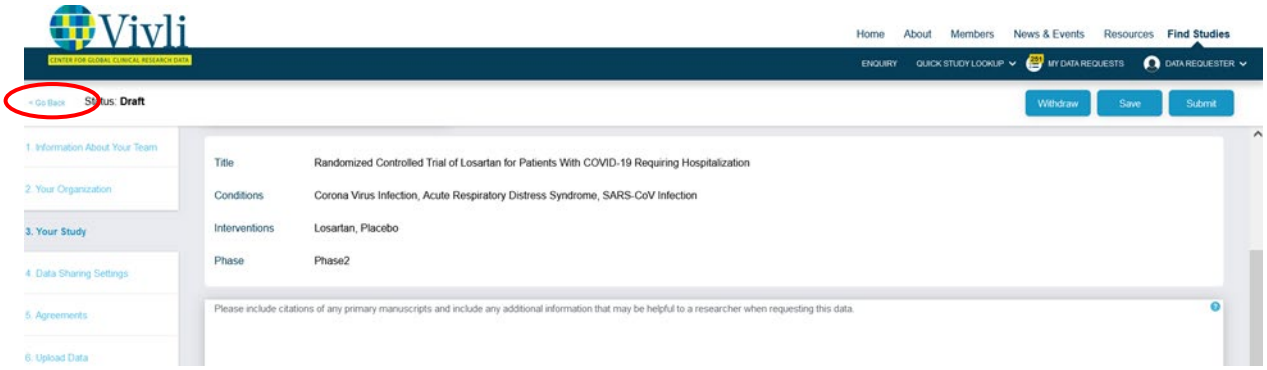
- To submit a new study for sharing, first click the "+ Add Submissions" button on the left panel and then click the blue "Add Submission" button in the upper right corner.



- 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.



- **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.

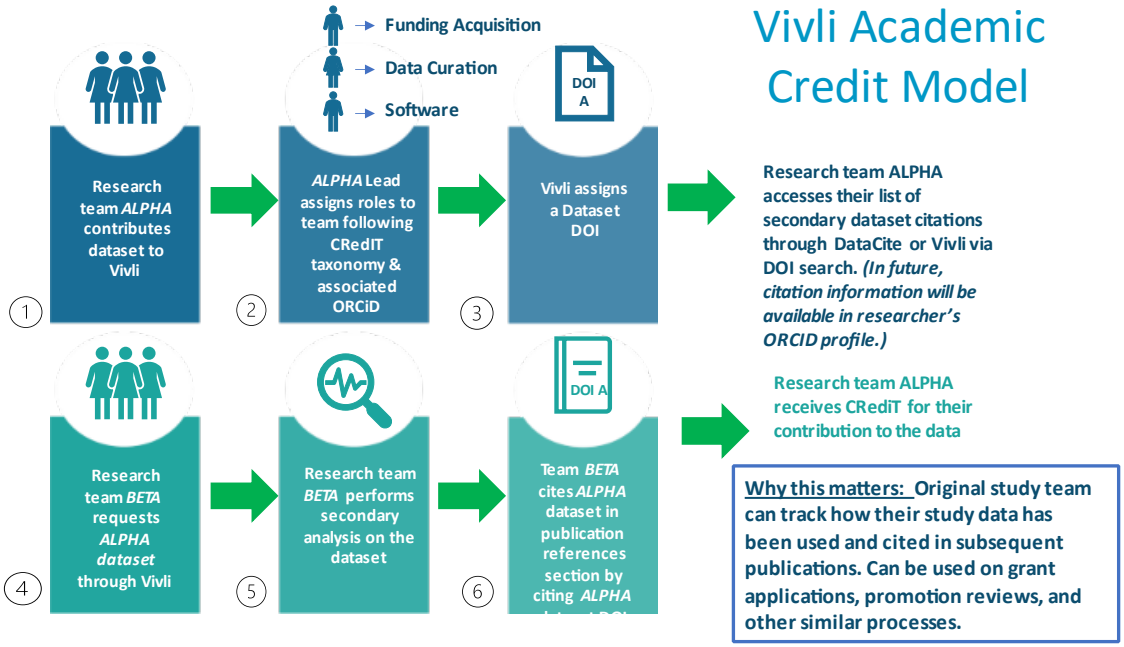


If at any time you are redirected from the Study Submission page within your dashboard, please navigate to https://search.vivli.org/study-submission and this will bring you back to the Study Submission page.

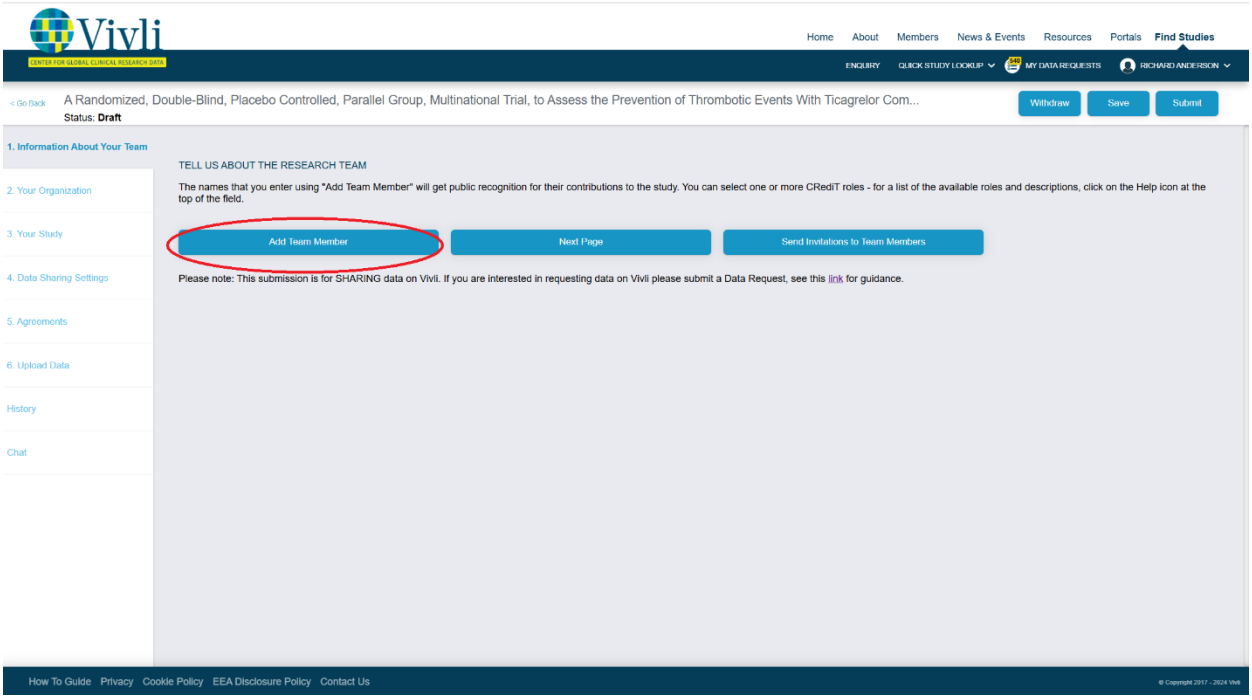
2 Study Submission

2.1 Information About Your Team

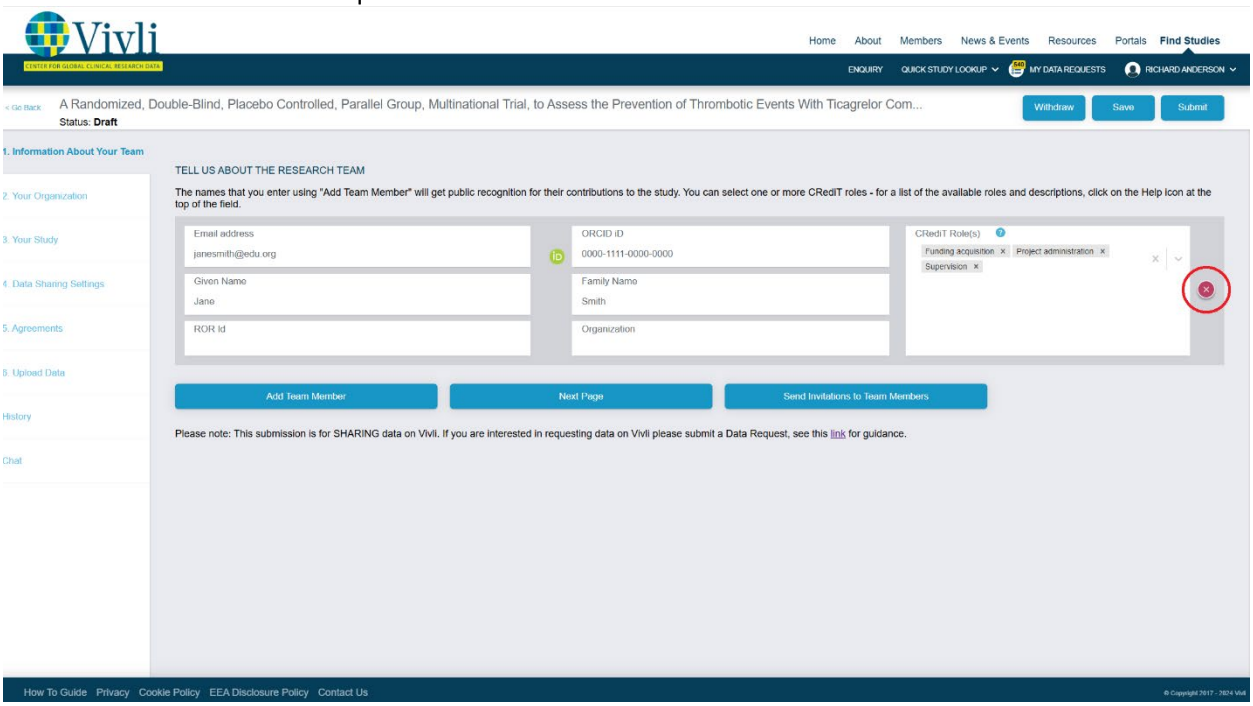
The names that you enter using "Add Team Member" will get public recognition for their contributions to the study. You can select one or more CRediT roles - for a list of the available roles and descriptions, click on the Help icon at the top of the field. See the following diagram as to why this is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

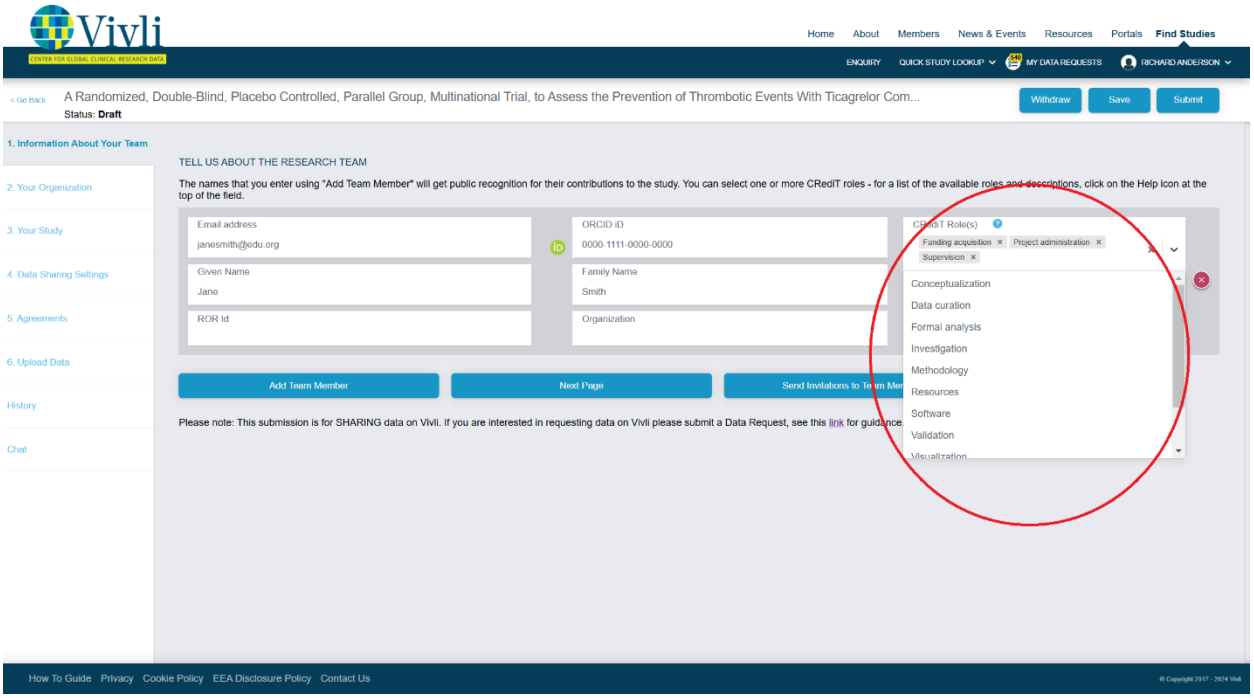


- Complete all required fields:
  - Email Address: Enter the best email address of each research team member
    ORCID ID: Enter the ORCID ID of each research team member. If a research team member does not have an ORCID ID, remove the team member by clicking the red “X” as this is a required field.



- 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)

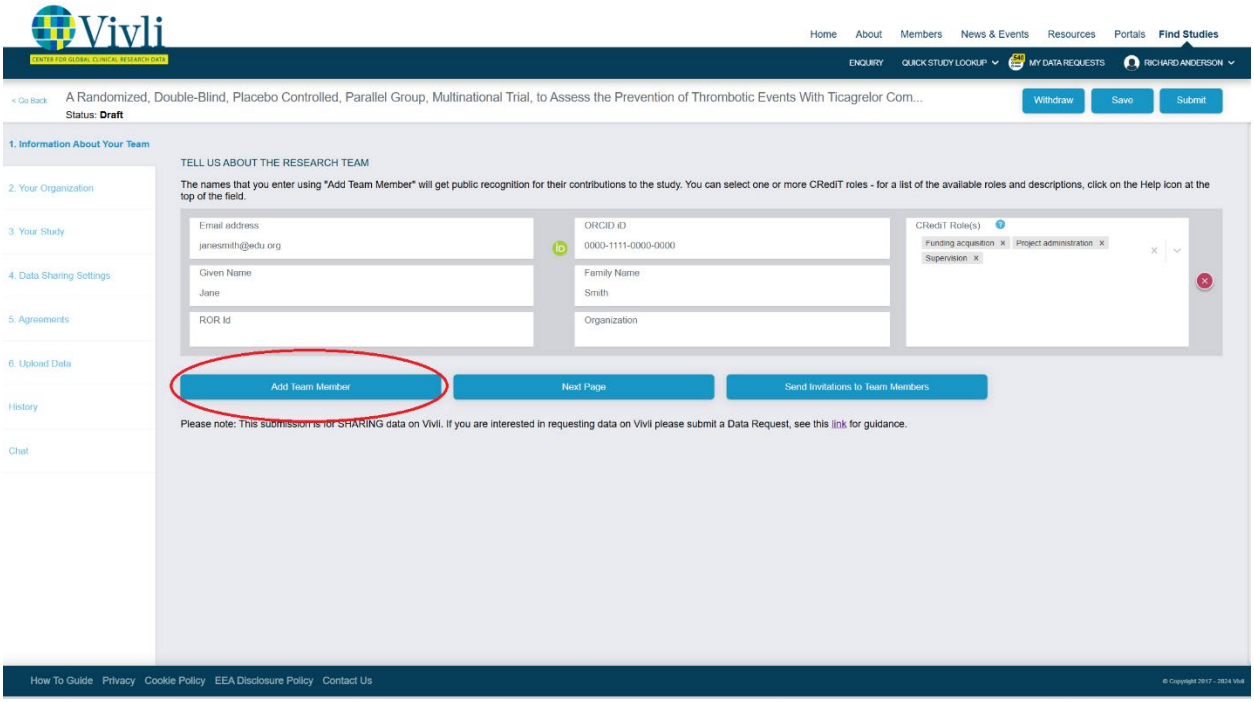
  - Given Name: Enter the given name, or first name, of each research team member
  - Family Name: Enter the family name, or last name, of each research team member
  - CRediT Roles: Select CRediT role(s) for each team member from the list that appears in the dropdown box: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.

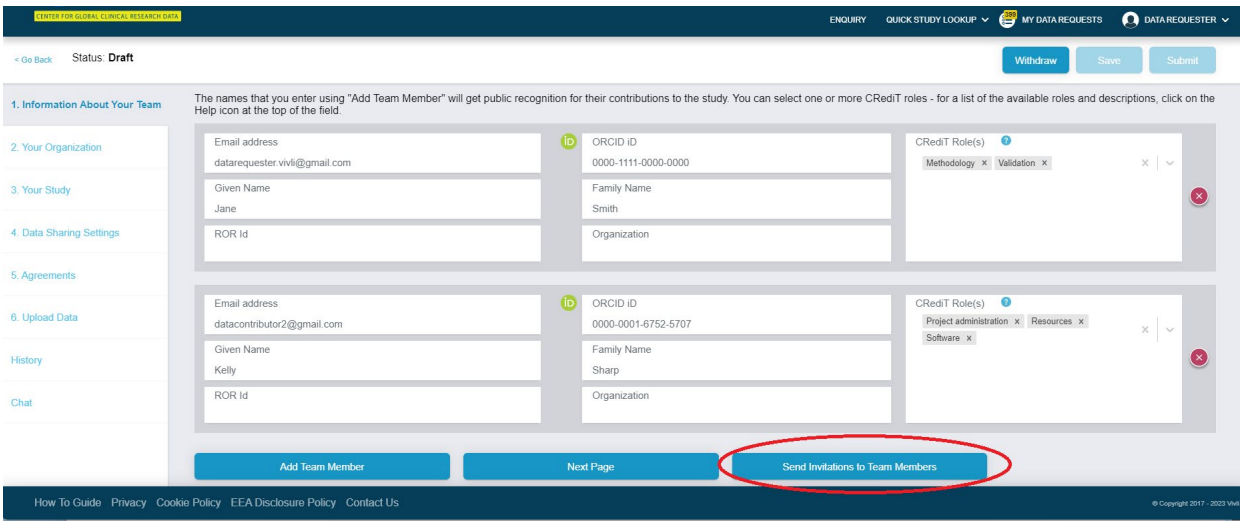


- For more information regarding CRediT roles, please visit https://credit.niso.org/.

- 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 of each research team member who is involved in this study

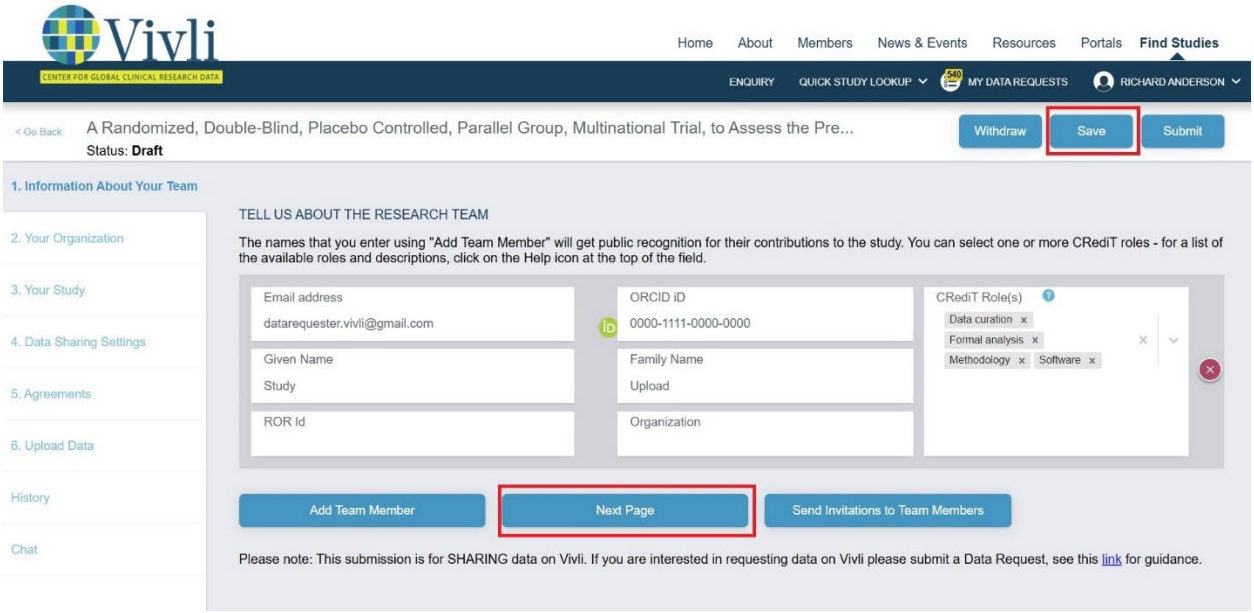
- Once all fields for the first team member are complete, use the "Add Team Member" button to create additional entries.





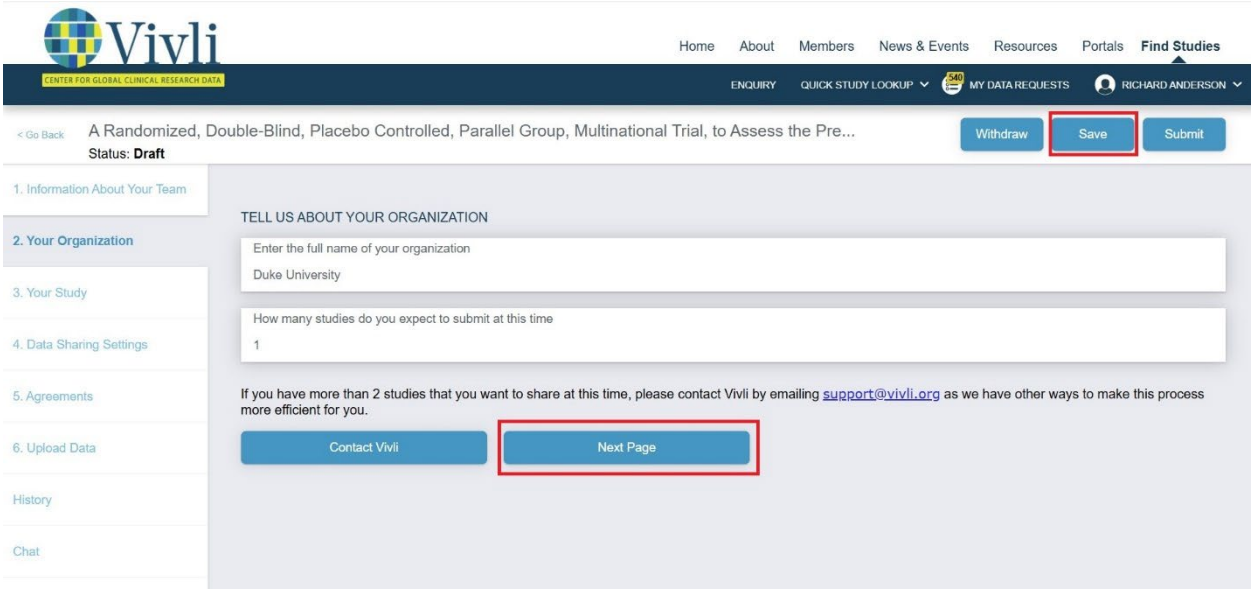
- Click the “Send Invitations to Team Members” button. This email will be sent once the submission is finalized and will prompt Research Team Members to update their ORCID credits. See section 5.7, Integrating ORCID for Research Team Members

- 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.



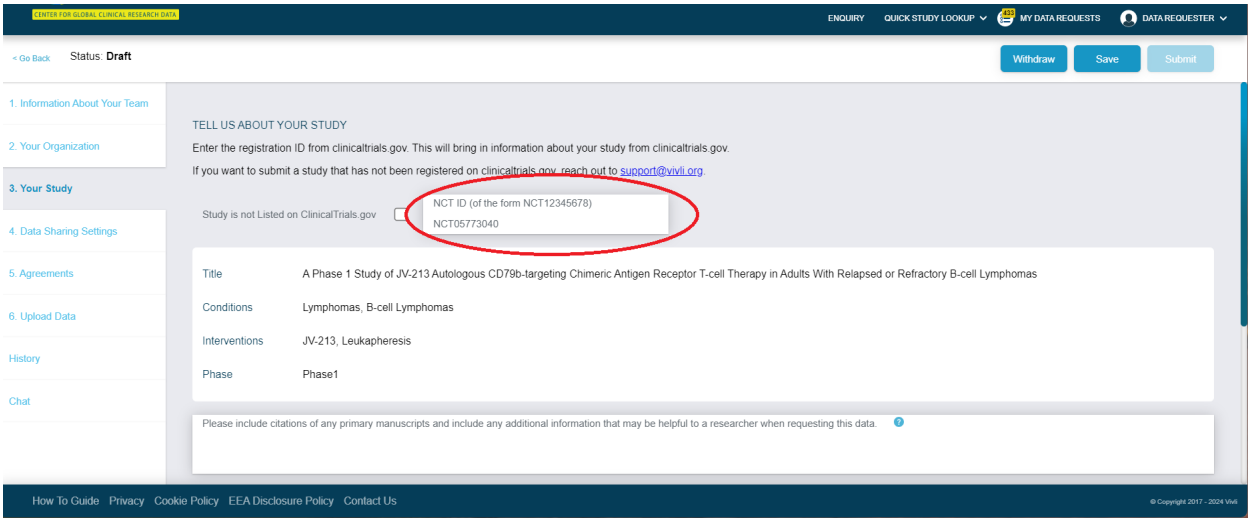
2.2 Your Organization

- 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.

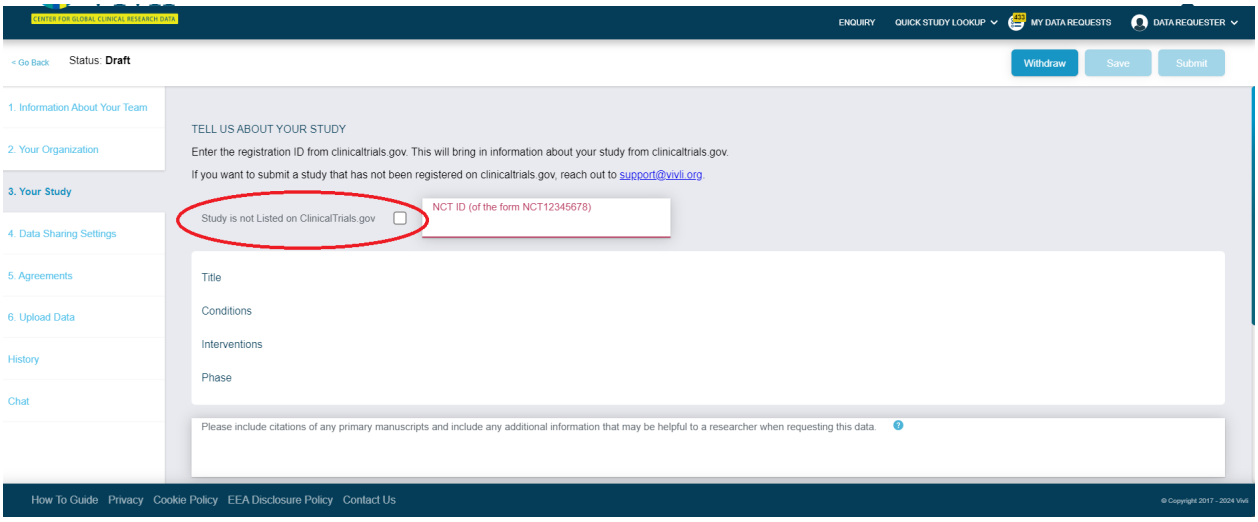


2.3 Your Study

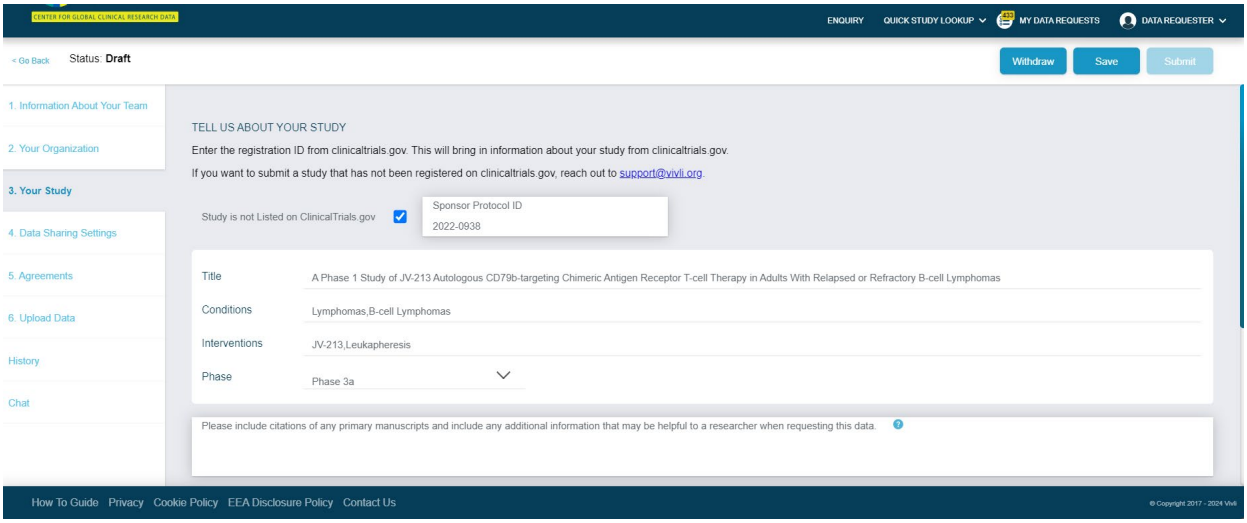
- If your study is registered on clinicaltrials.gov and **has an NCT ID**, enter the registration ID from clinicaltrials.gov. This will automatically populate the Title, Conditions, Interventions, and Phase information from clinicaltrials.gov.



- 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”.

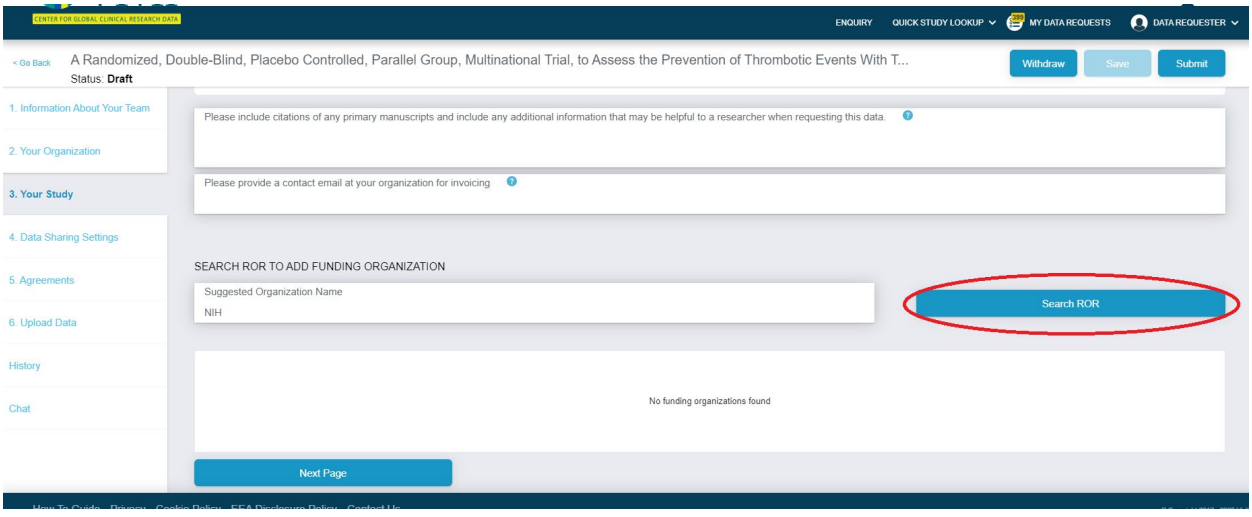


- Enter the Sponsor Protocol ID, Title, Conditions, Interventions, and Phase, according to your study. Note: Sponsor Protocol ID is a mandatory field to complete. (This may be an internal ID or acronym for your study. If you do not have a Sponsor Protocol ID, reach out to Vivli and we will create one 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.

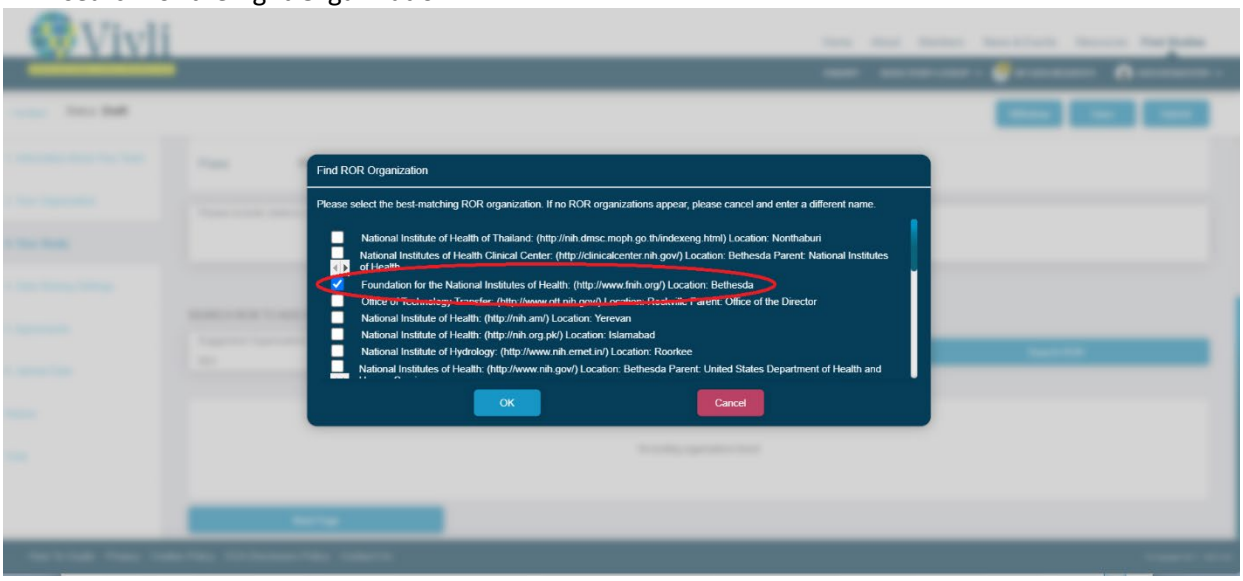


- Any information that you provide in the “Additional Information” field will be visible to researchers searching for studies. You can include any citations related to your clinical research, or any other information that might be used by the researcher to determine whether your study will support their research.

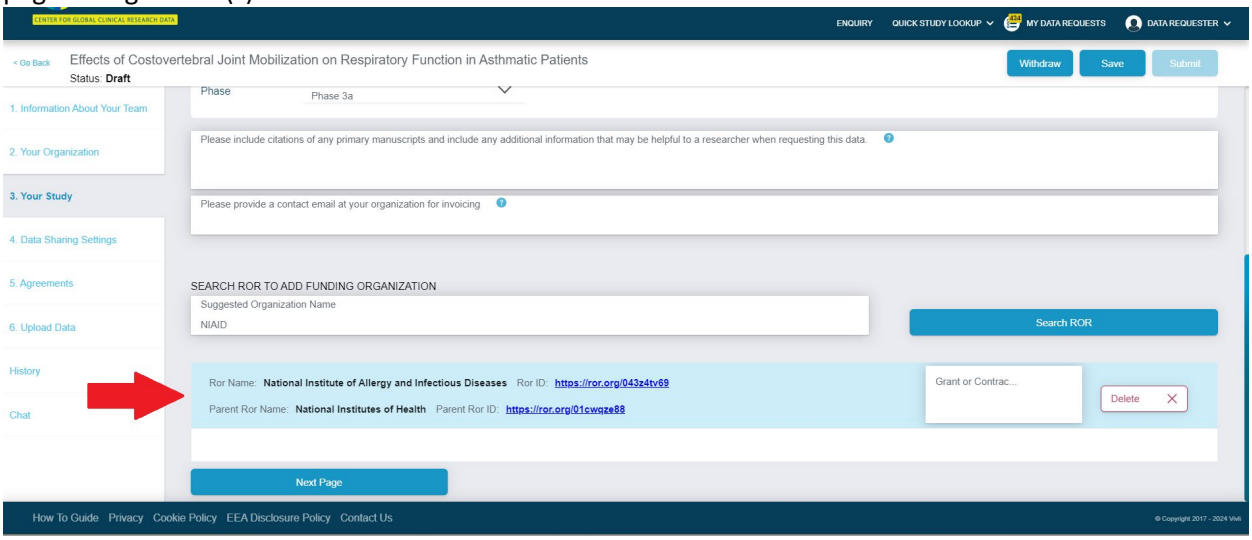
- Search ROR to add Funding Organization(s). Use the search field to search for the primary funder. If the study was funded by your organization, leave this blank. If it was funded by an external funder, type in the name of the funder in the free-text box and select “Search ROR”. A box will appear. Choose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



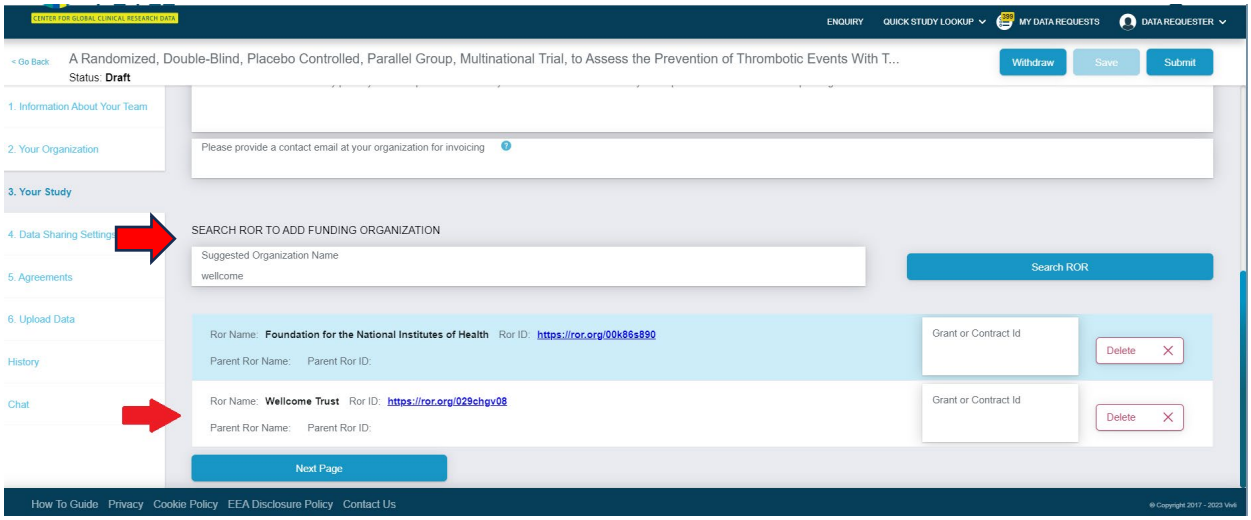
- Check the appropriate funder name. If you typed the incorrect name, refresh your screen to search for the right Organization.



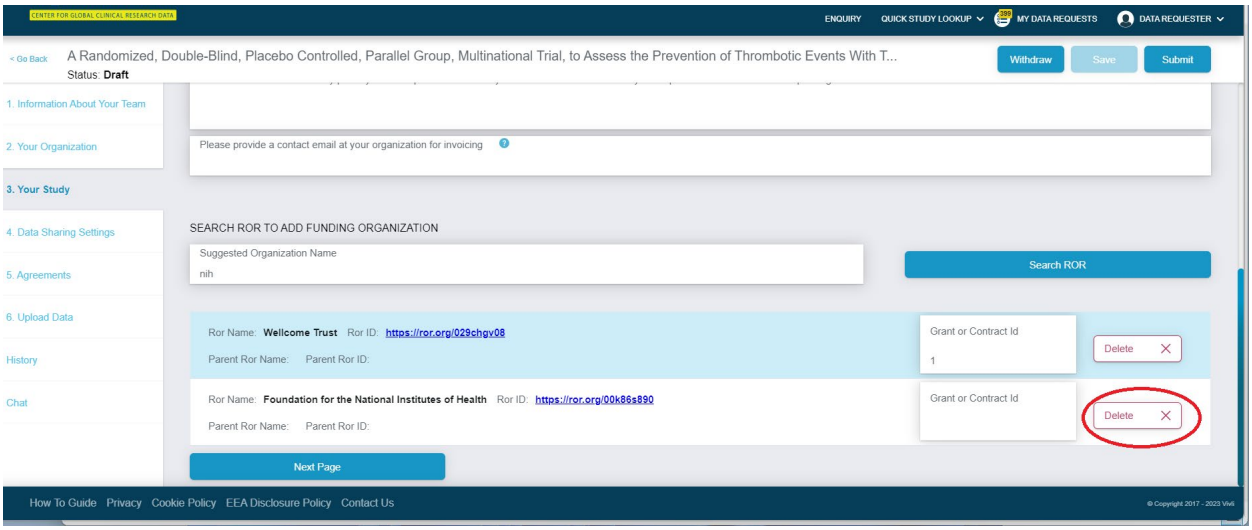
- Once the funder is added and saved, you will see a table appear at the bottom of the "Your Study" page listing funder(s) and associated ROR information.



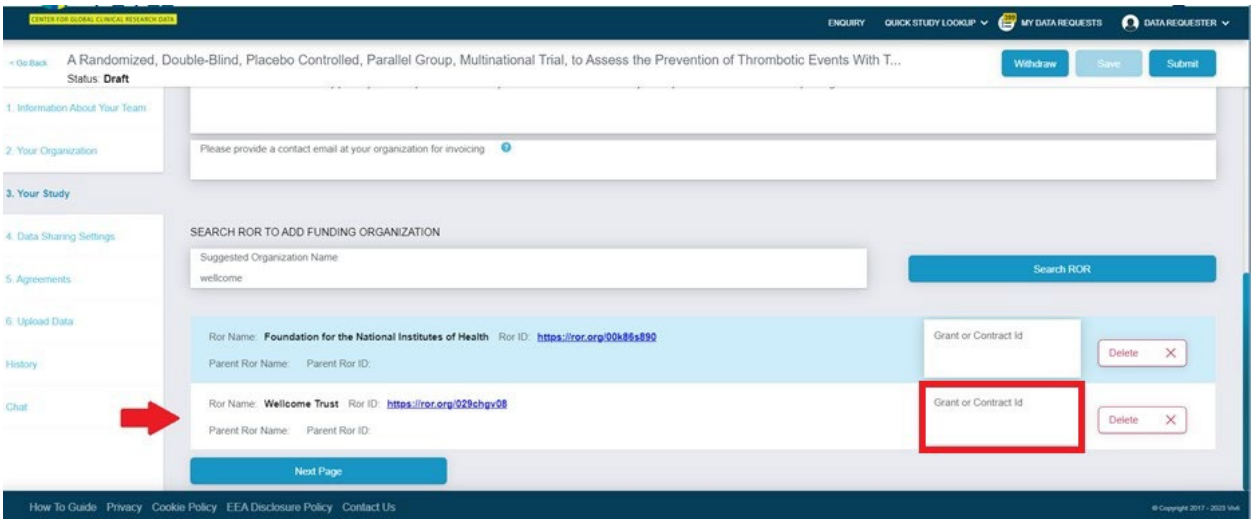
- To add an additional funder, repeat the steps by typing in the name of the additional funder in the free text box and selecting “Search ROR”. Choose the name of the organization from the box that appears and select “OK”. You will see the additional funder’s information listed in the table as an entry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



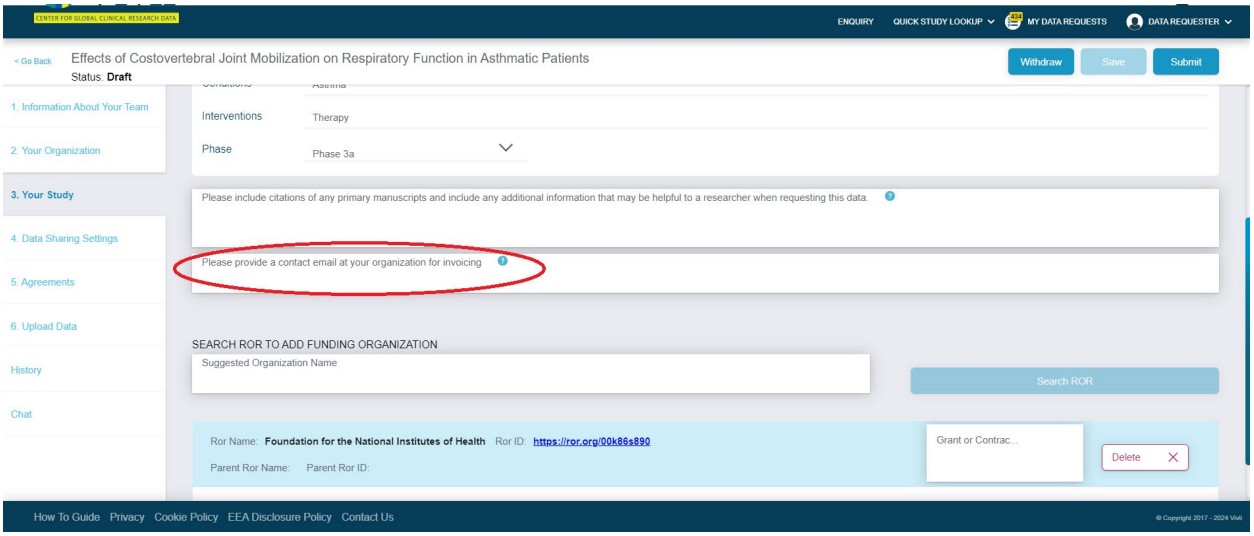
- Repeat this process as needed, to add additional funders.
- To delete a funder, select the button that says “Delete” and then select “Save”.



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



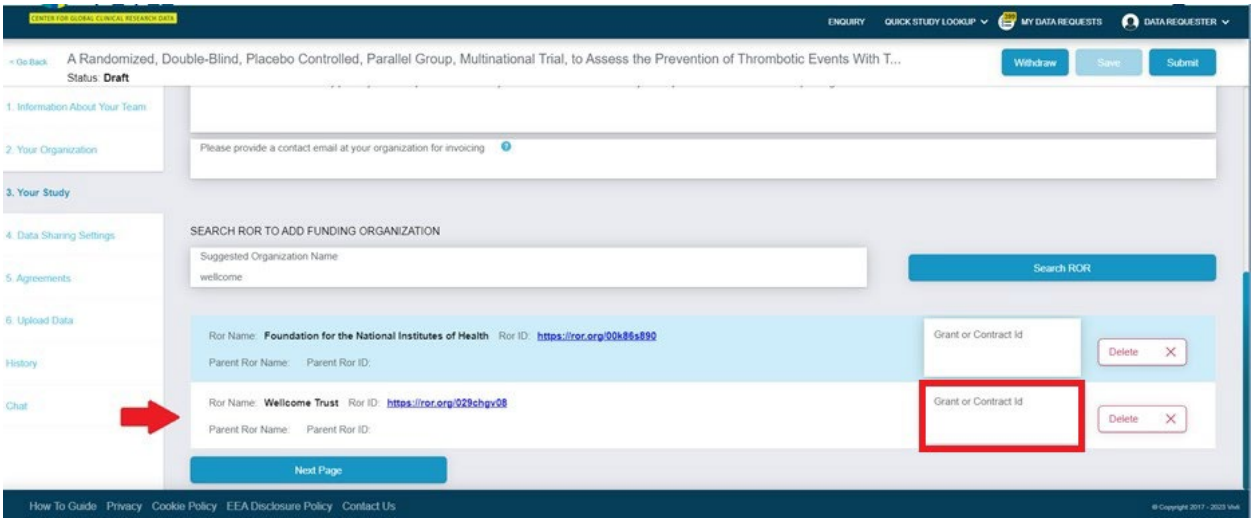
- Depending on your selection, you may be prompted to provide a contact email address for invoicing.



  - 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.

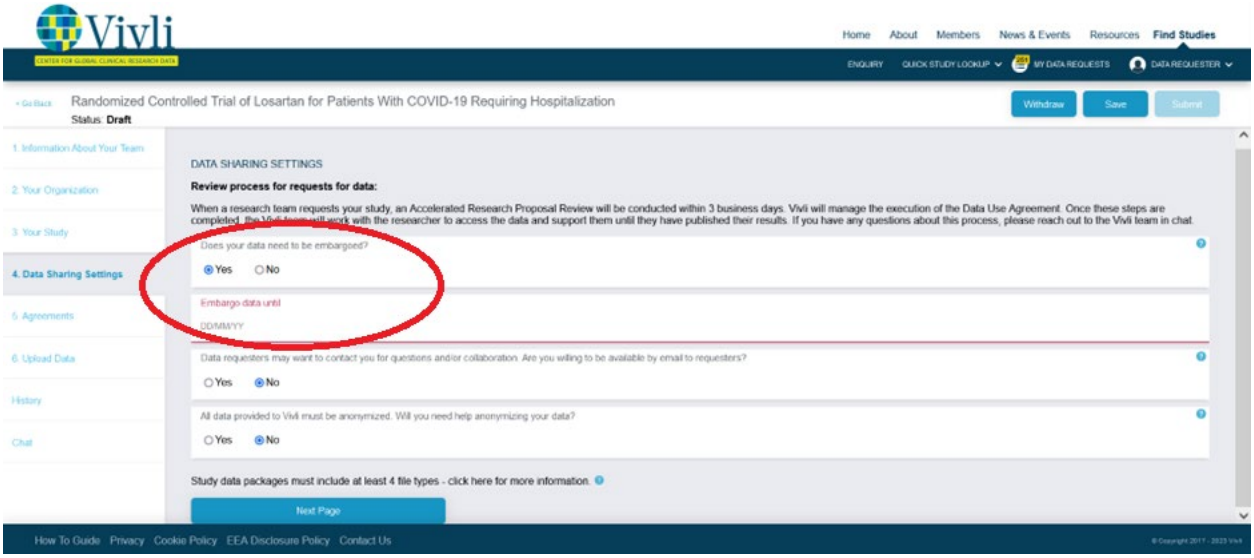
  - If your academic institution is not a member, there is a one-time cost to use Vivli's managed access process for clinical trials data. These costs apply only to academic and non-profit researchers who want to share their clinical data. Visit our Share Data page for more information on the costs associated 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.

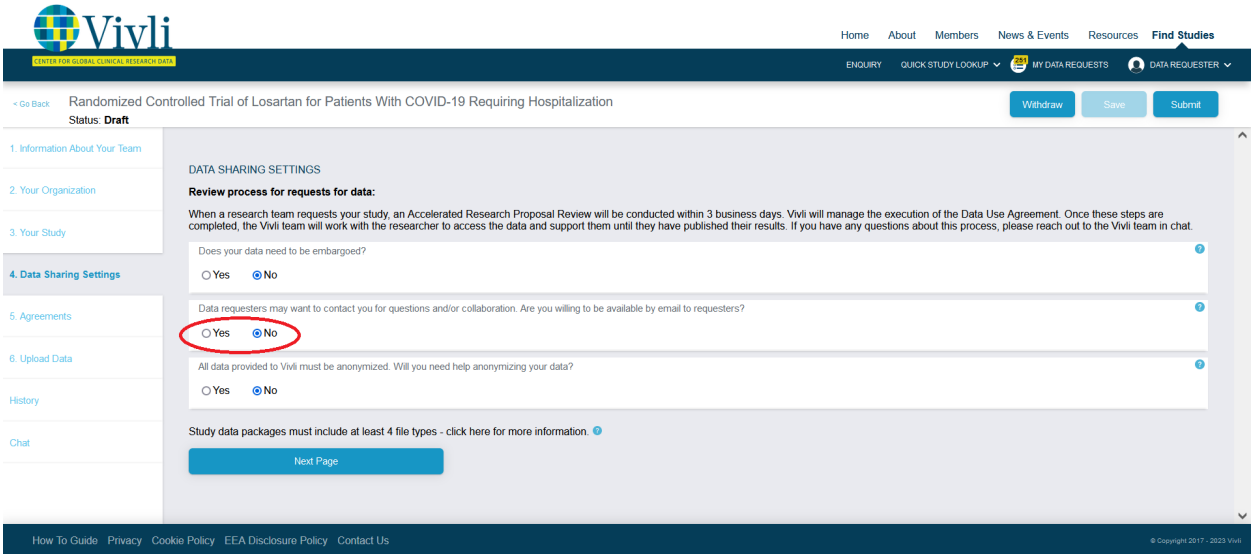


2.4 Data Sharing Settings

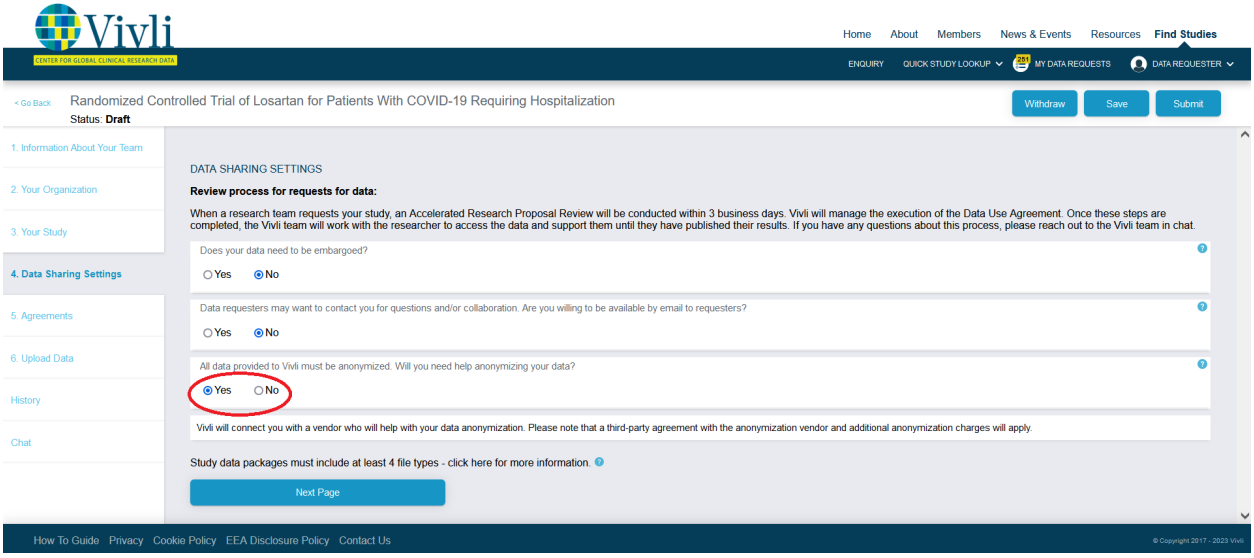
- **Accelerated Review** -- When a research team requests your study, an Accelerated Research Proposal Review will be conducted within 3 business days. Vivli will manage the execution of the Data Use Agreement. Once these steps are completed, the Vivli team will work with the researcher to access the 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.



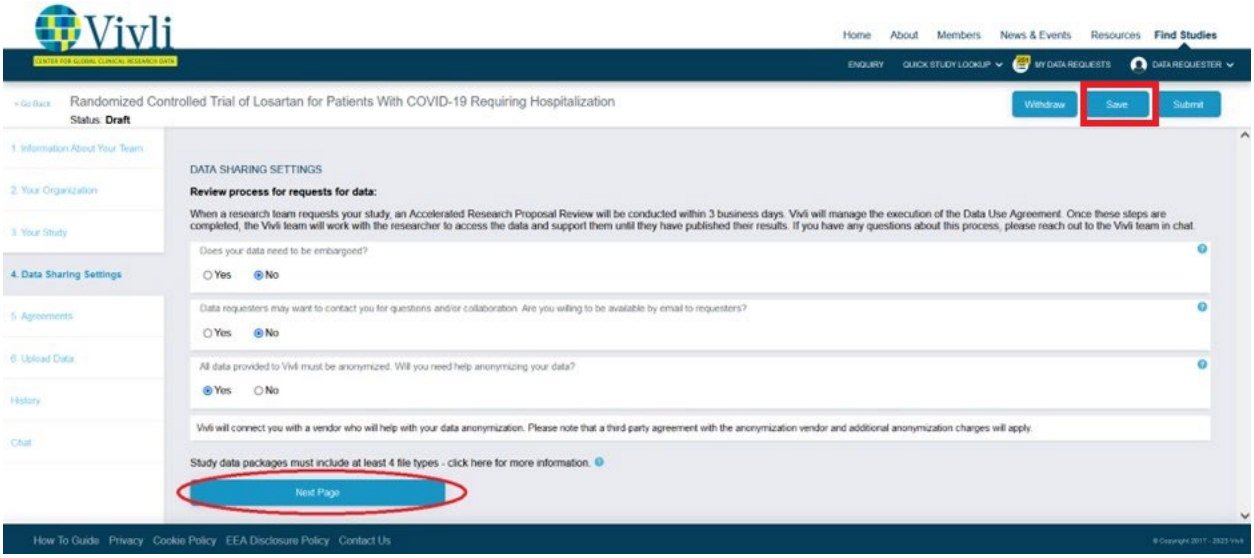
- If you are willing to be contacted, the Vivli team will email you any requests for collaboration or questions. Making yourself available for contact does not imply a commitment to collaborate on any or all requests – it is your decision to answer questions or collaborate on a case-by-case basis.
-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

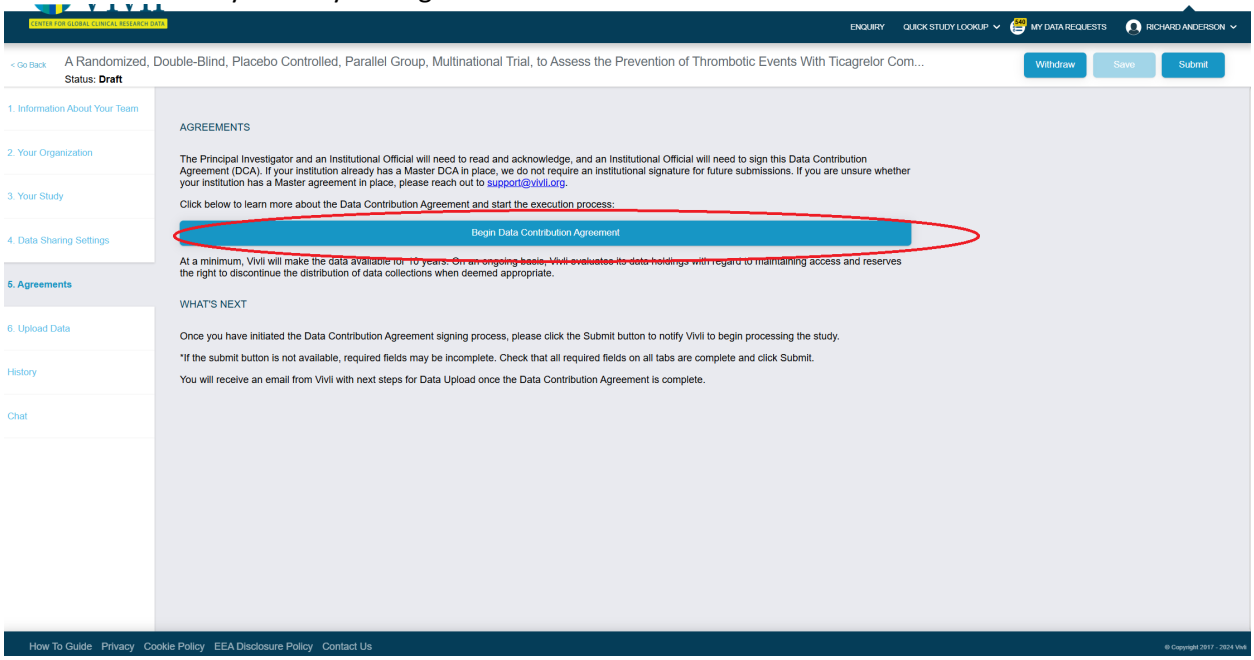


- Once all Data Sharing Settings have been selected, hit “Save” and use the “Next Page” button to navigate to the next section.



2.5 Agreements

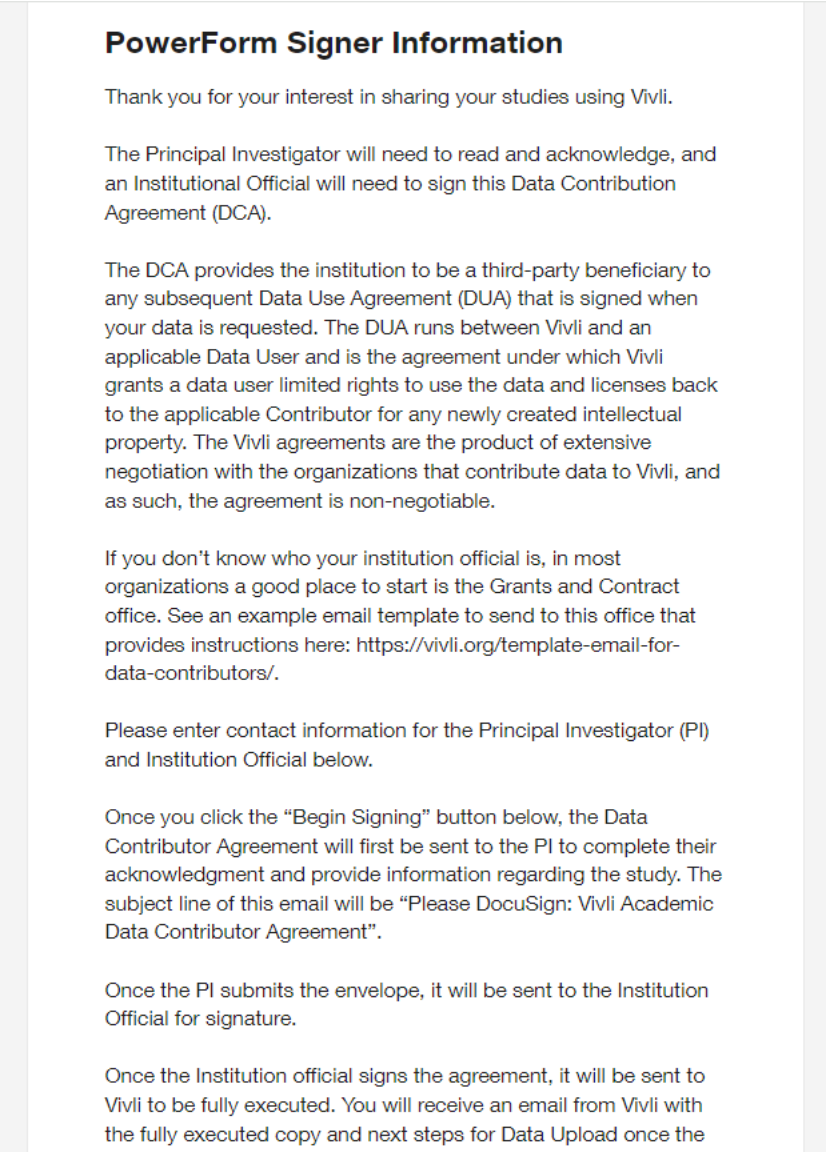
- Click the blue “Begin Data Contribution Agreement” button. This will open a new browser tab to begin the DocuSign legal agreement signing process that will allow you to provide some basic information about you and your organization.



  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.

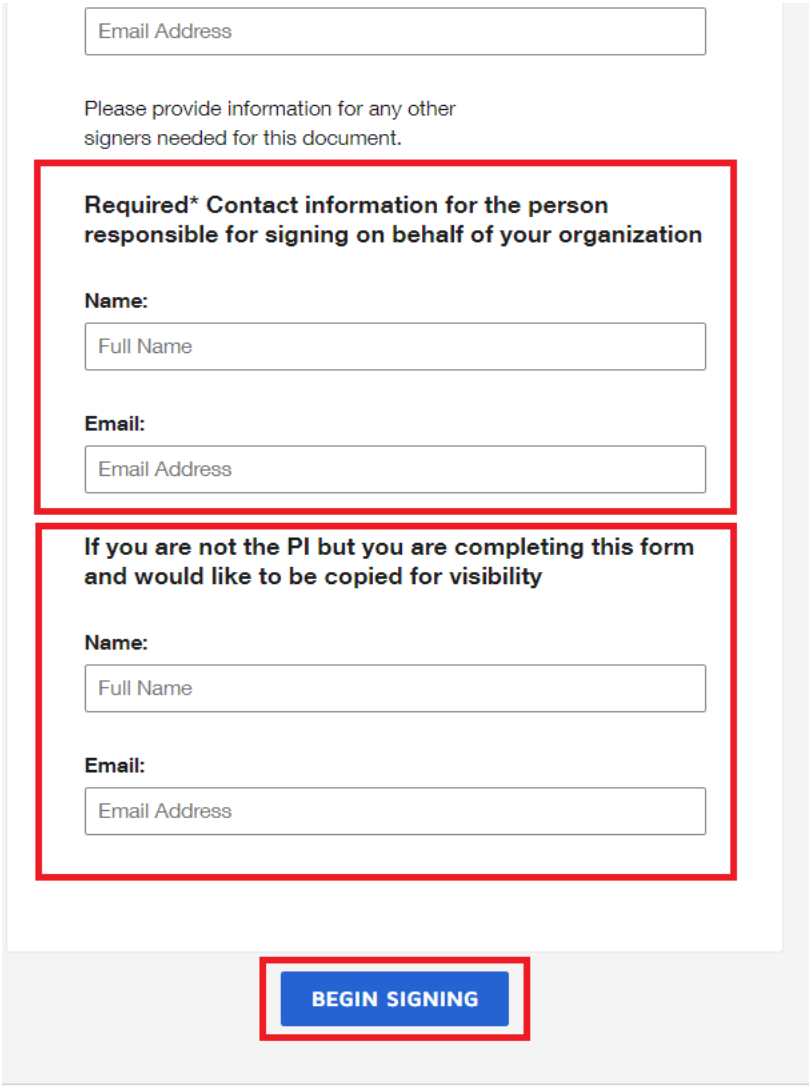
If you don't know who your institution official is, in most organizations a good place to start is the Grants and Contract office. See an example email template to send to this office that provides instructions here: https://vivli.org/template-email-for-data-contributors/.

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”.

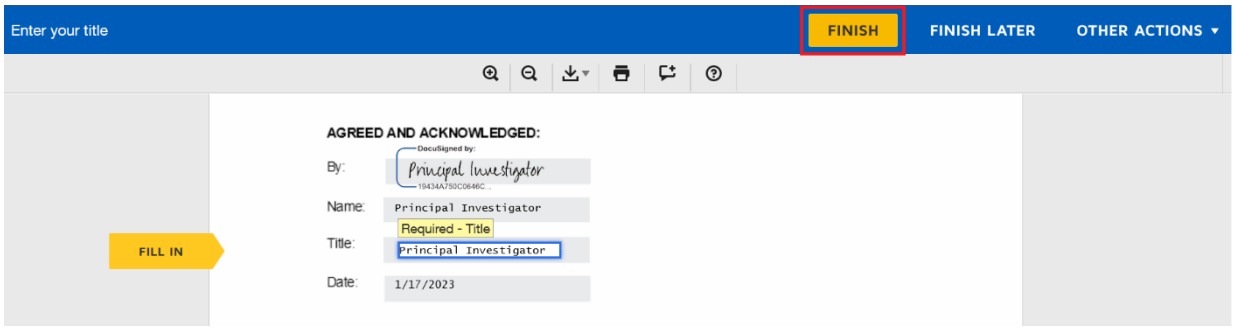
Once the PI submits the envelope, it will be sent to the Institution Official for signature.

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



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

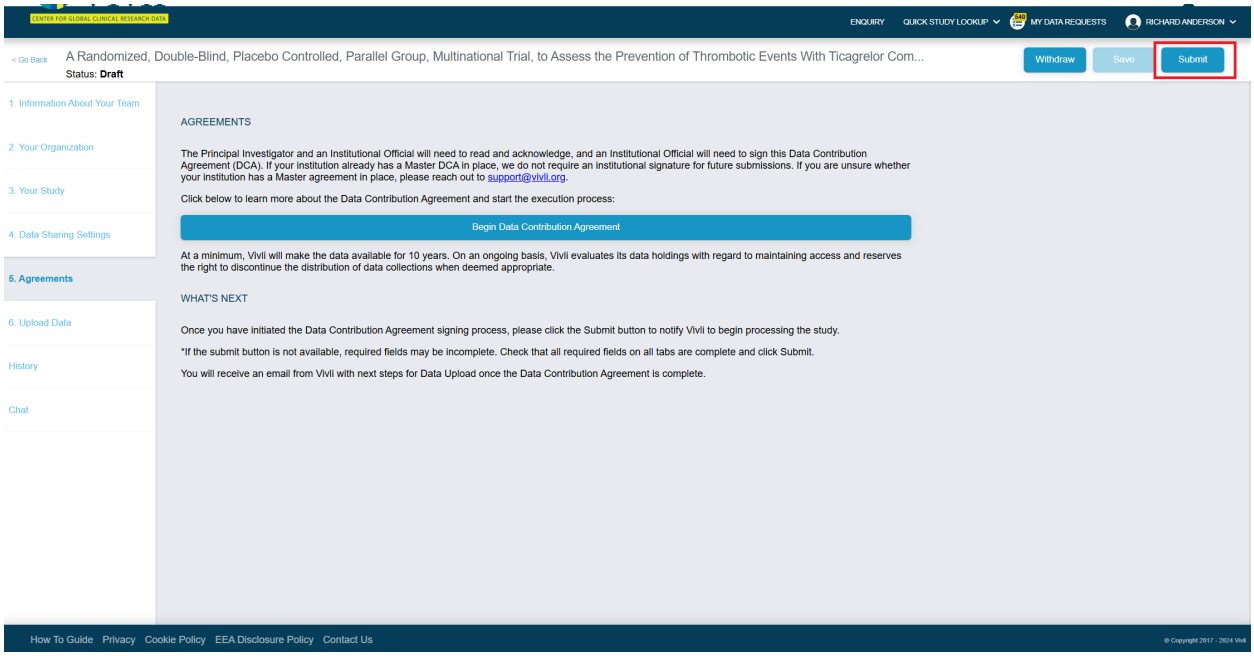
3. The Principal Investigator will need to complete the required fields (outlined in red), including Organization Name (p.1), Business Address (p.1 and p.6), Acknowledgement (p.8), NCT ID or Sponsor Protocol ID (p.9), and Agreed and Acknowledged (p.11). Once all required fields have been completed, click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



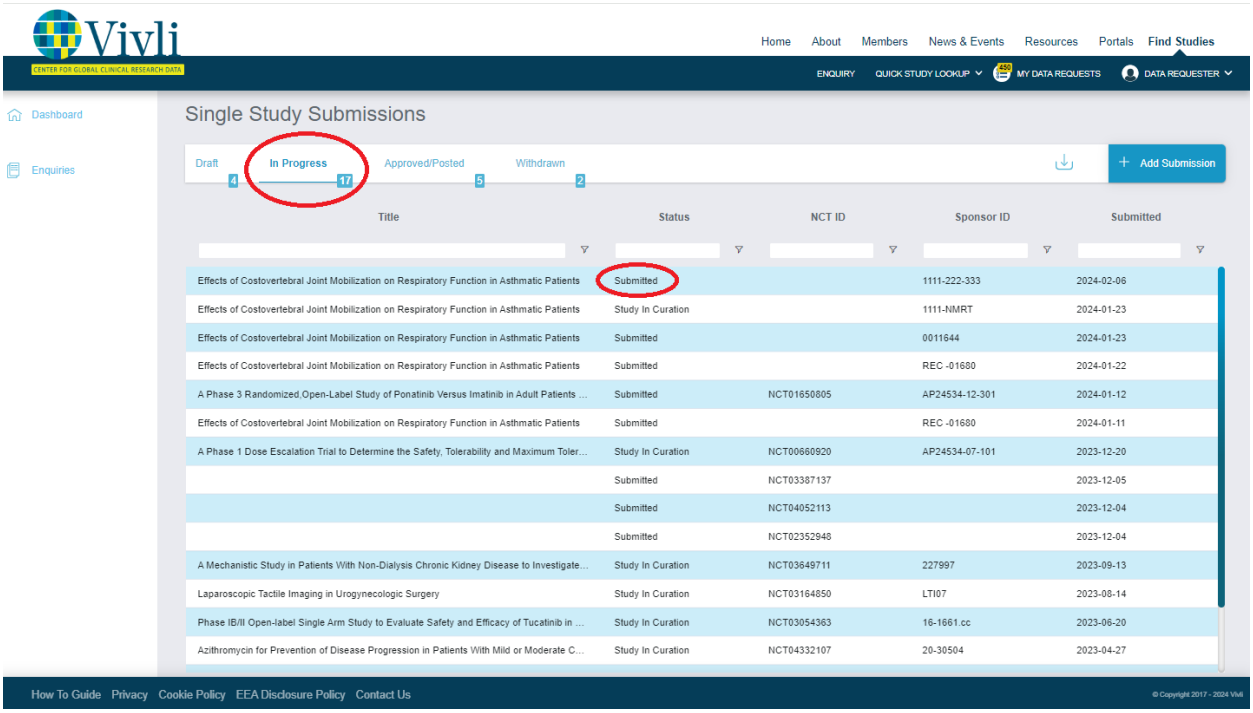
4. The agreement will then be routed to the Institutional Official for signature.

- 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.

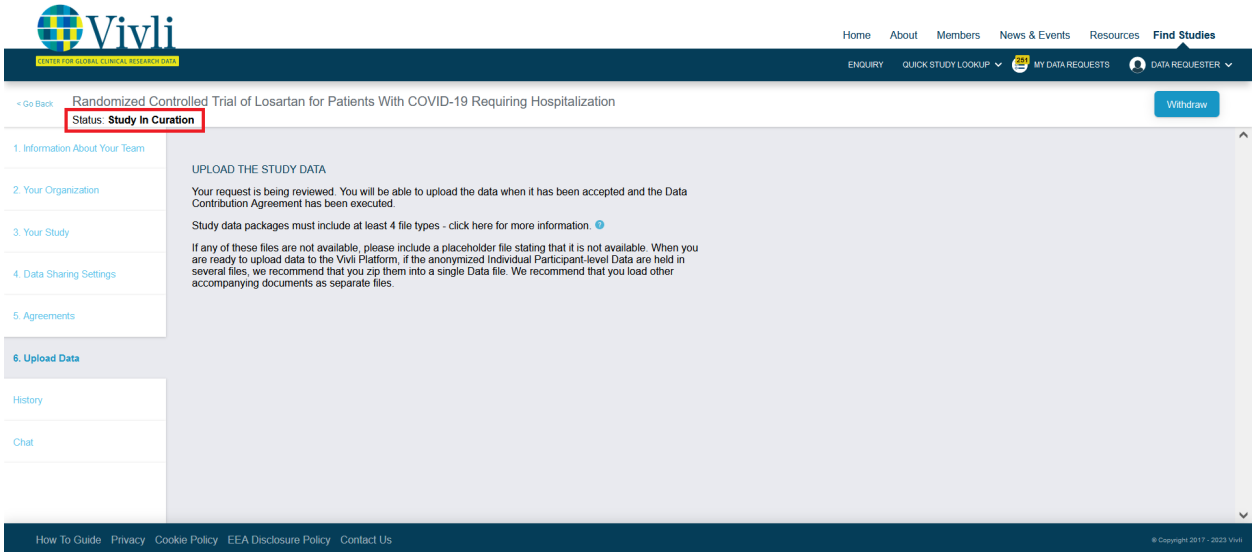
- After you have initiated the DCA process, you must click the "Submit" button in the upper right corner to begin the Vivli review process. You do not need to wait for the Data Contribution Agreement to be executed before you submit it.



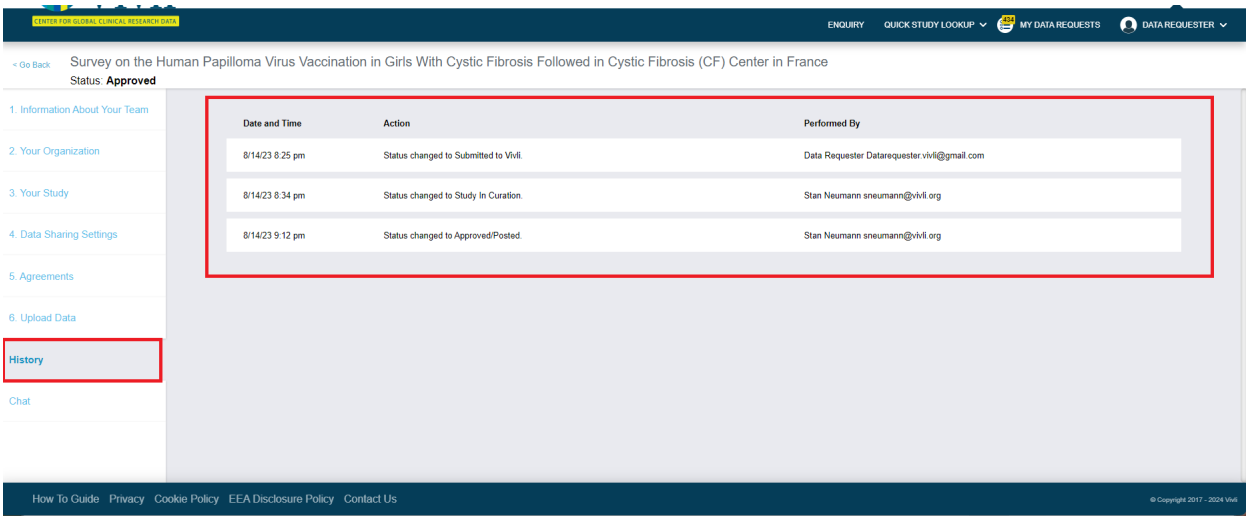
- Once the study has been submitted, your study will automatically appear in the Submissions dashboard under "In Progress."



- 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.



- 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.)



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.

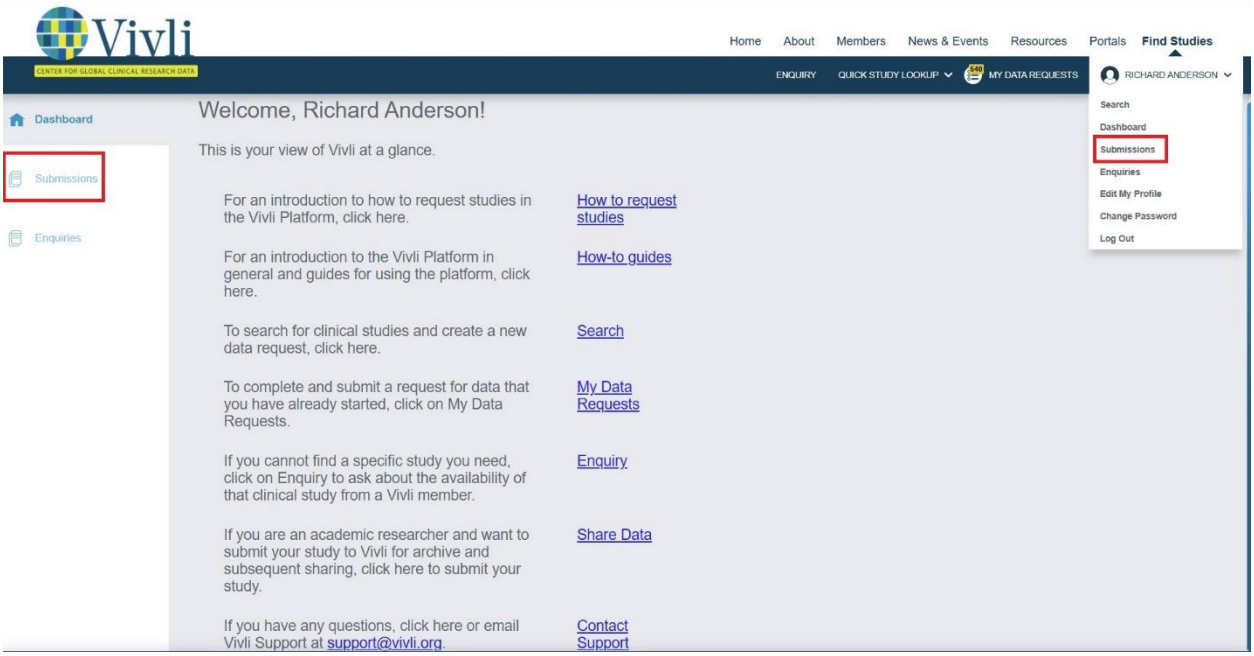
- If any of these files are not available, please include a placeholder file stating that it is not available.

- 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.

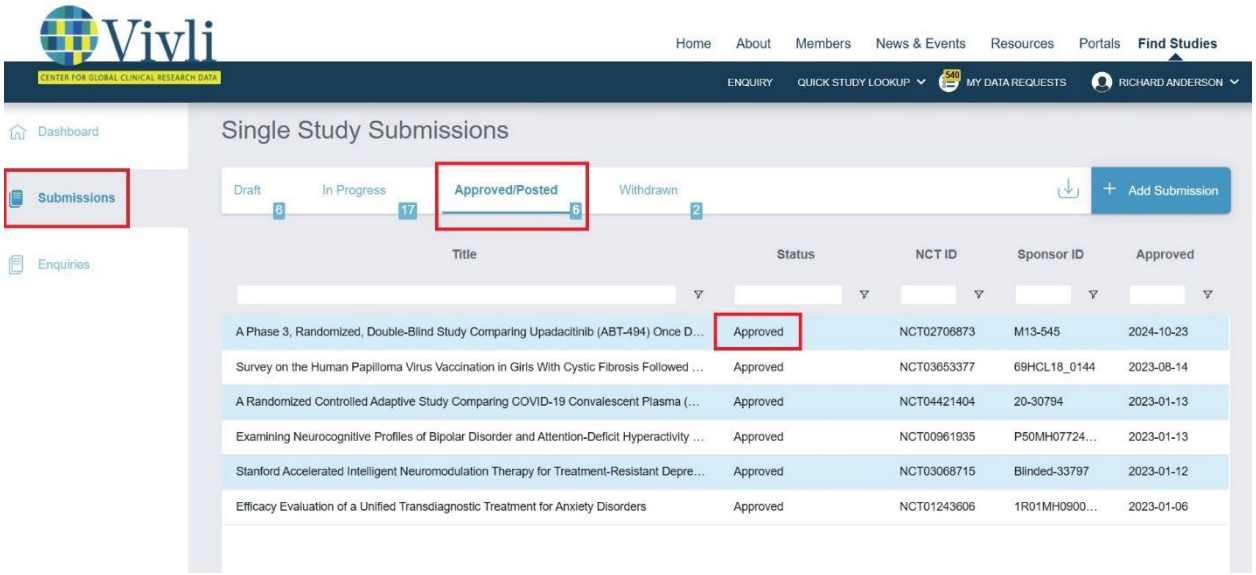
3.2 Data Package Upload

- 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.

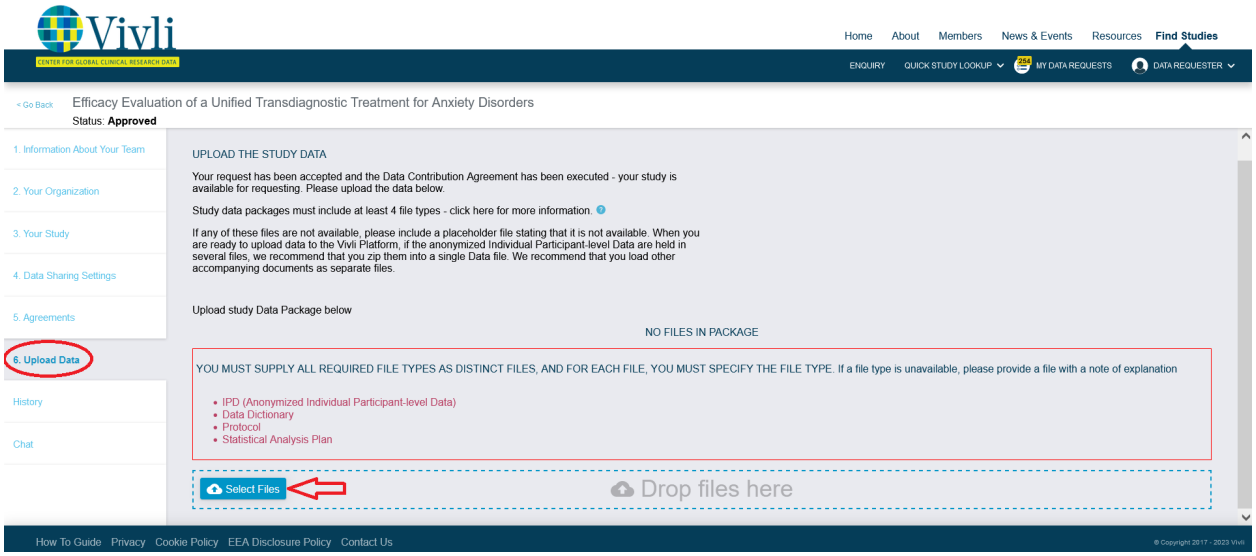
- Follow the link in the email or select Submissions in the dropdown menu from the top right corner, choose your Submission under Approved/Posted section. You may also log in to the Vivli platform and find the submission under the Dashboard (Note: You will be unable to upload any data or documents until the Data Contribution Agreement is executed.



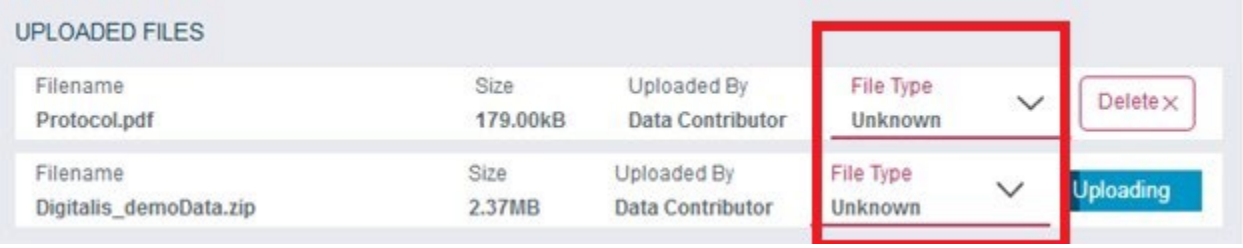
- In the Submissions tab, under 'Approved/Posted,' click on the study for which you are ready to upload your anonymized data.



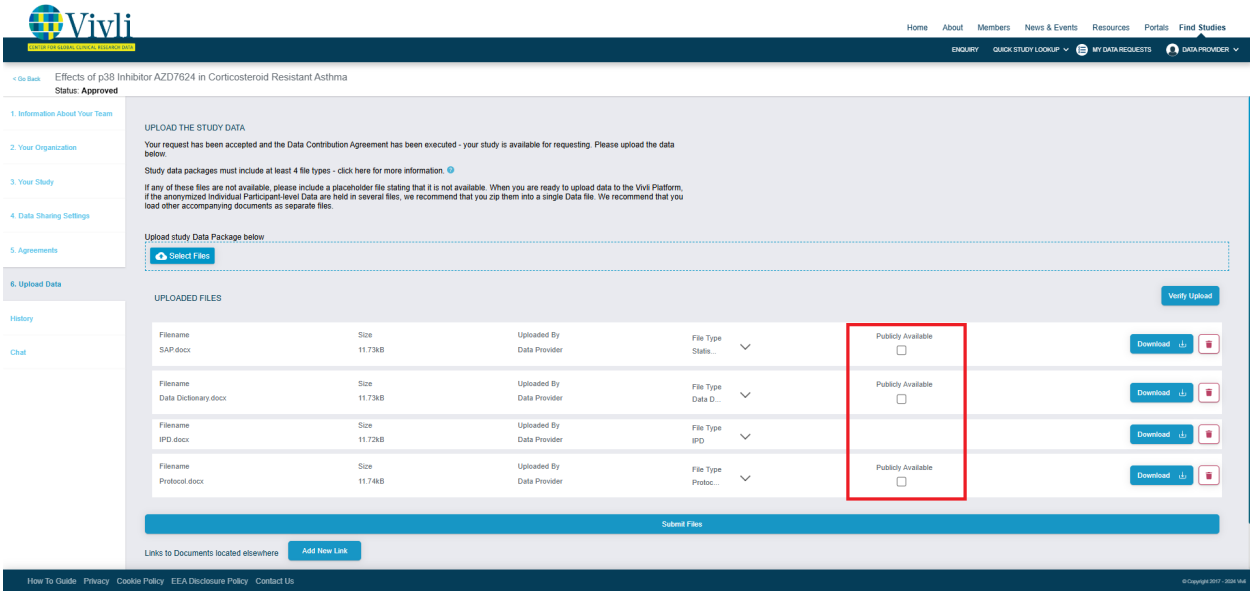
- Click on the 'Upload Data' tab and then you may use either the blue 'Select Files' button or drag and drop the appropriate files.

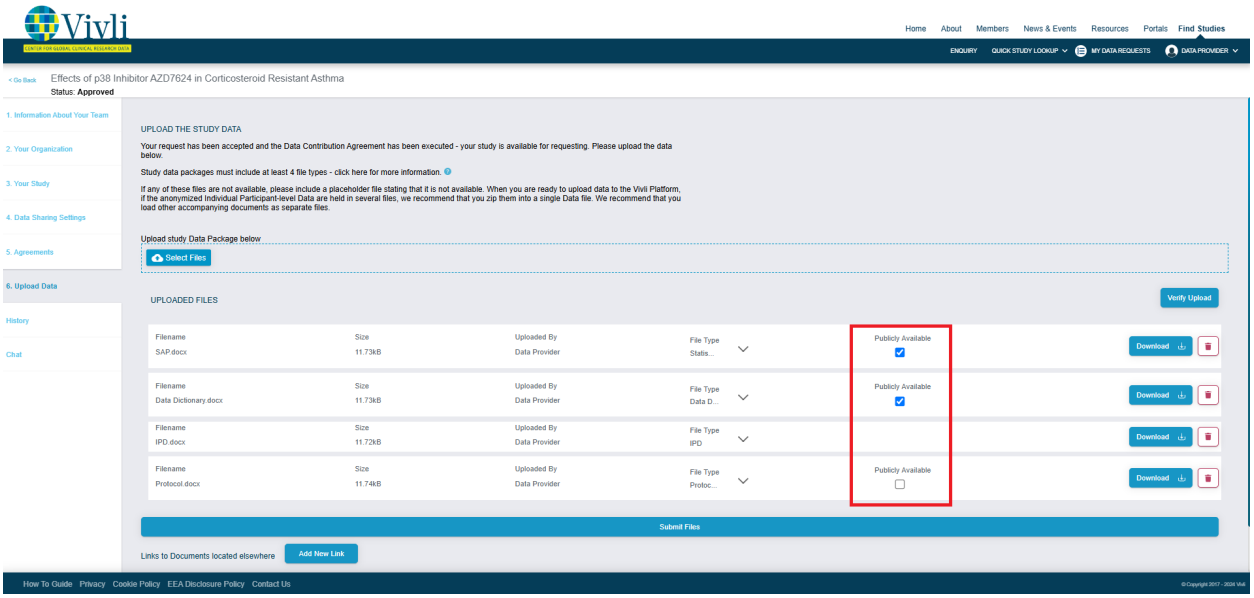


- Use the dropdown menu on the right-hand side to validate the File Type for each file before submitting files (Note: If you are missing the protocol, data dictionary, or Statistical analysis plan, please create a Word file with a note saying this is unavailable and upload it as a placeholder and validate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



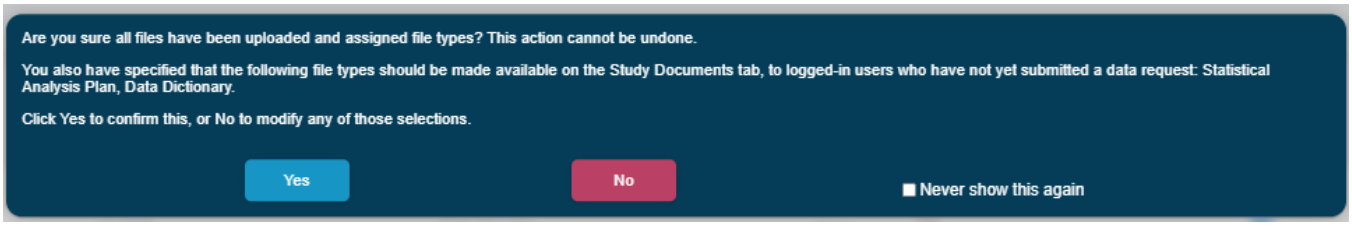
  - To make supporting documents publicly available to researchers, check the box that says "Publicly available". This will make the documents available to researchers who have a Vivli account during their study search. This will help researchers to finalize the studies before submitting their Vivli data 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.





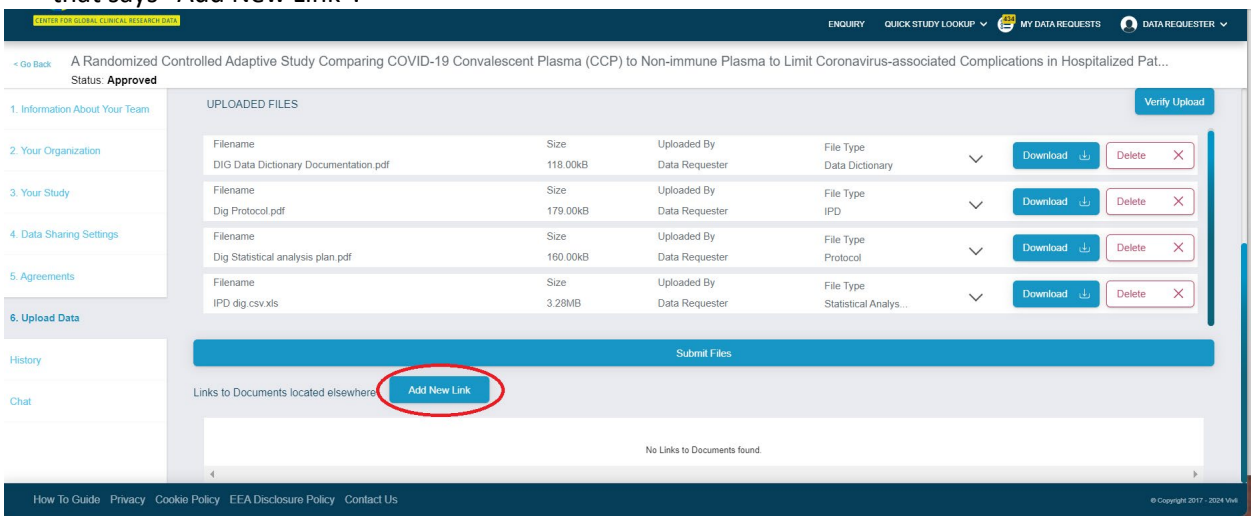
- Click the button that says “Verify Upload” to confirm that your files have been successfully uploaded.
- A pop-up will appear at the bottom right screen that says “All data has been successfully uploaded and stored in the system”

- 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.

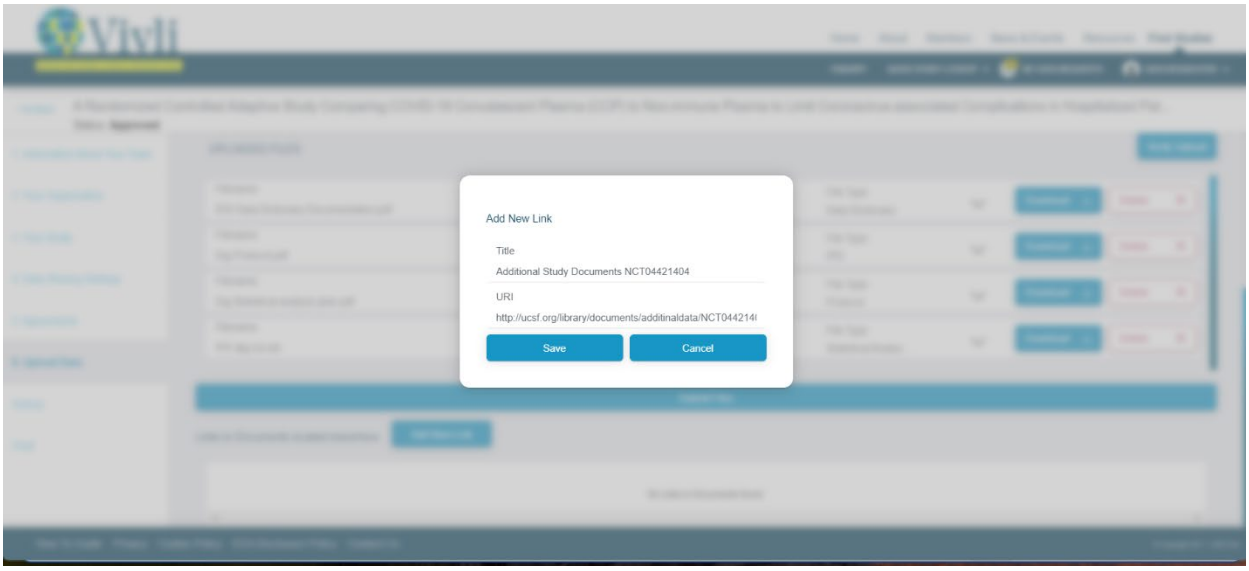


- You will receive confirmation of successful upload. Click the 'Continue' button to return to your submission.

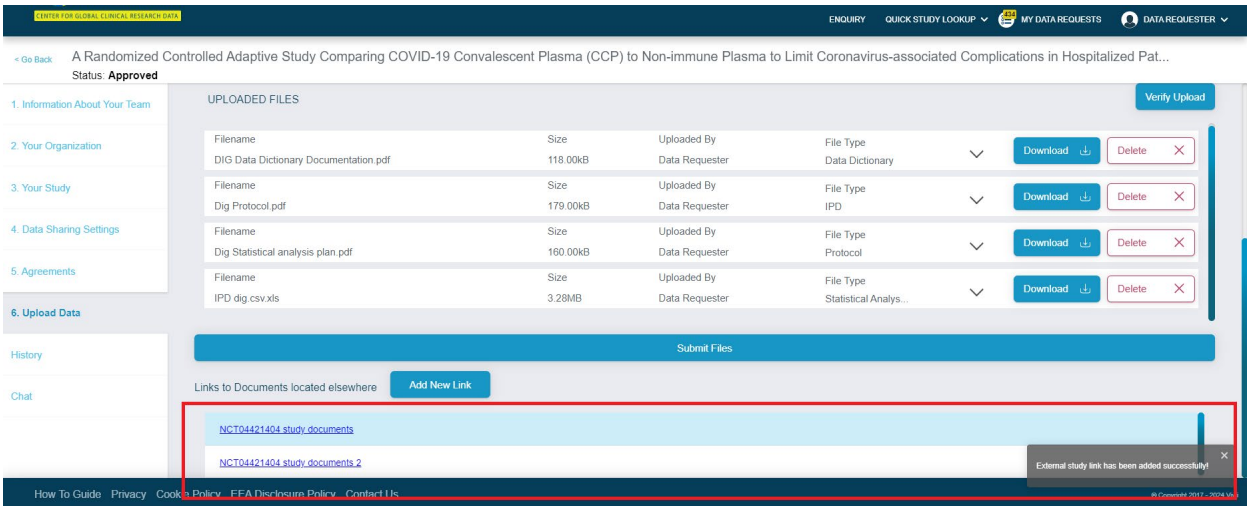
- Once study documents are uploaded, if there are further documents that are available for your study at an external link, and you would like to provide a link to the documents, click the button that says "Add New Link".



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



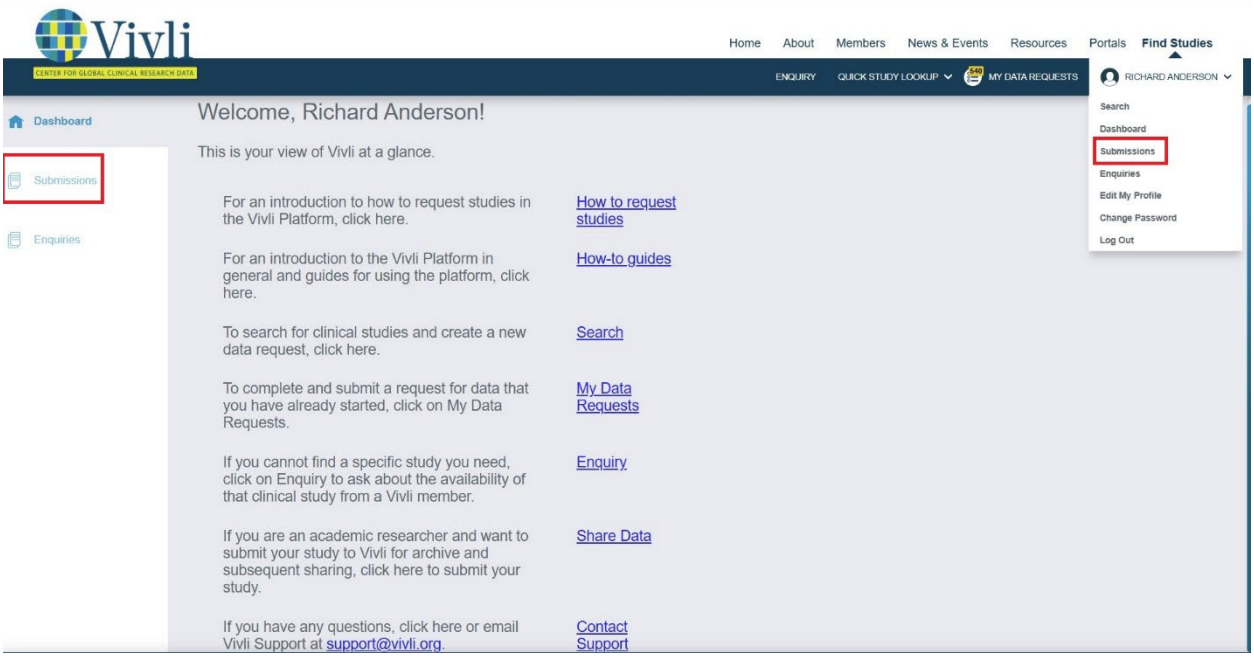
- You may add multiple links to external documents. Once you press ‘Save’, you will see a popup appear that says, “External study link has been loaded properly” and the link(s) to the document(s) will appear on the bottom of the page.



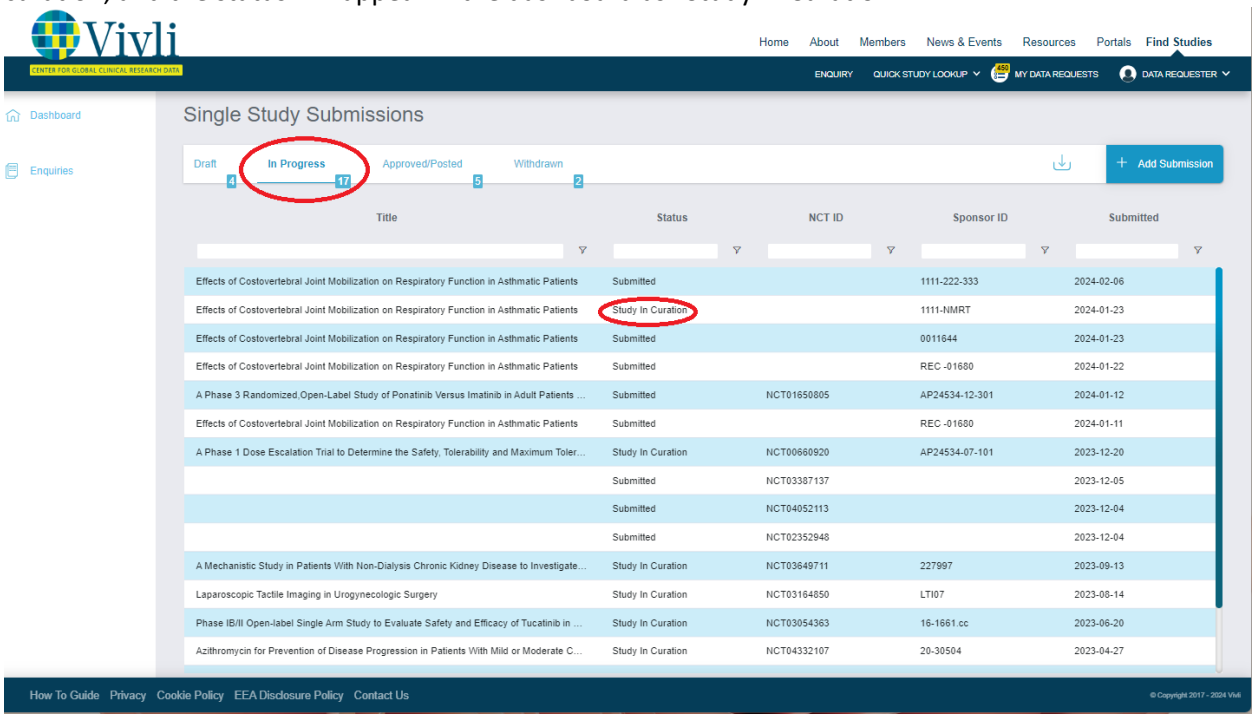
4 Managing your Submission

4.1 Submission Status

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



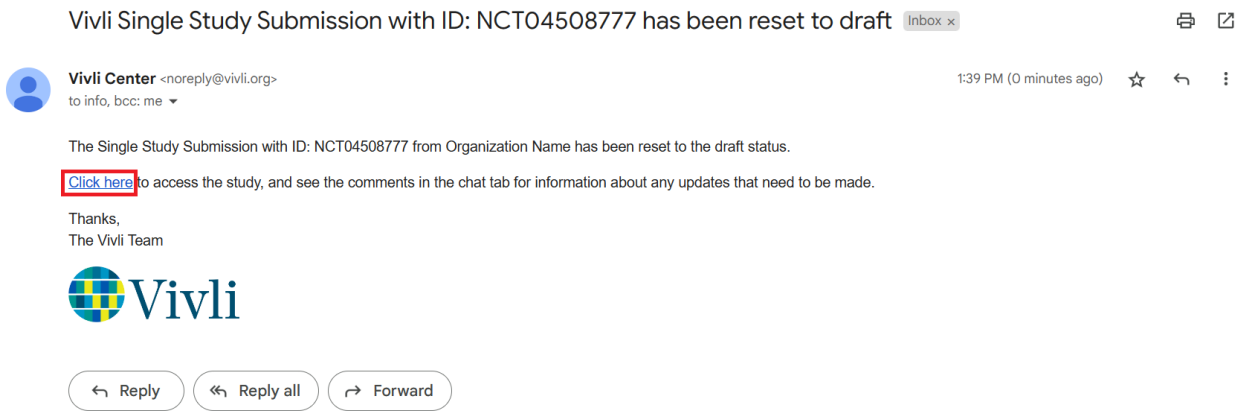
- Once the study information has been accepted by a Vivli admin, the study will undergo metadata curation, and the status will appear in the dashboard as “Study in Curation.”



4.2 Making Edits

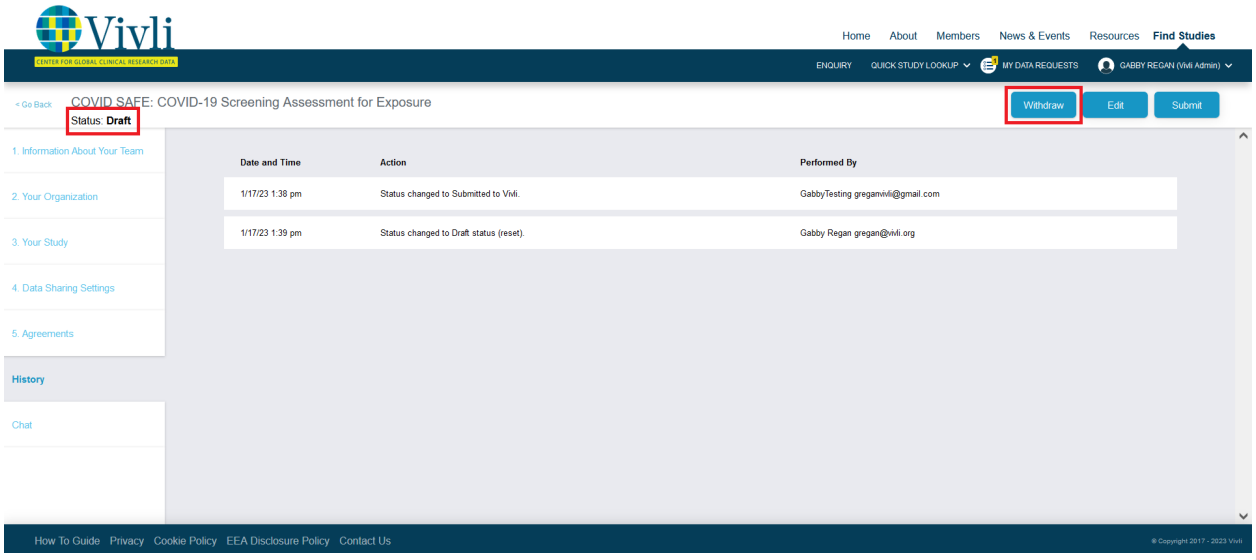
- Once your submission has been submitted, you will be unable to make any changes. Please contact Vivli via chat or email at support@vivli.org if you need to make any changes to your submission.

- 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.

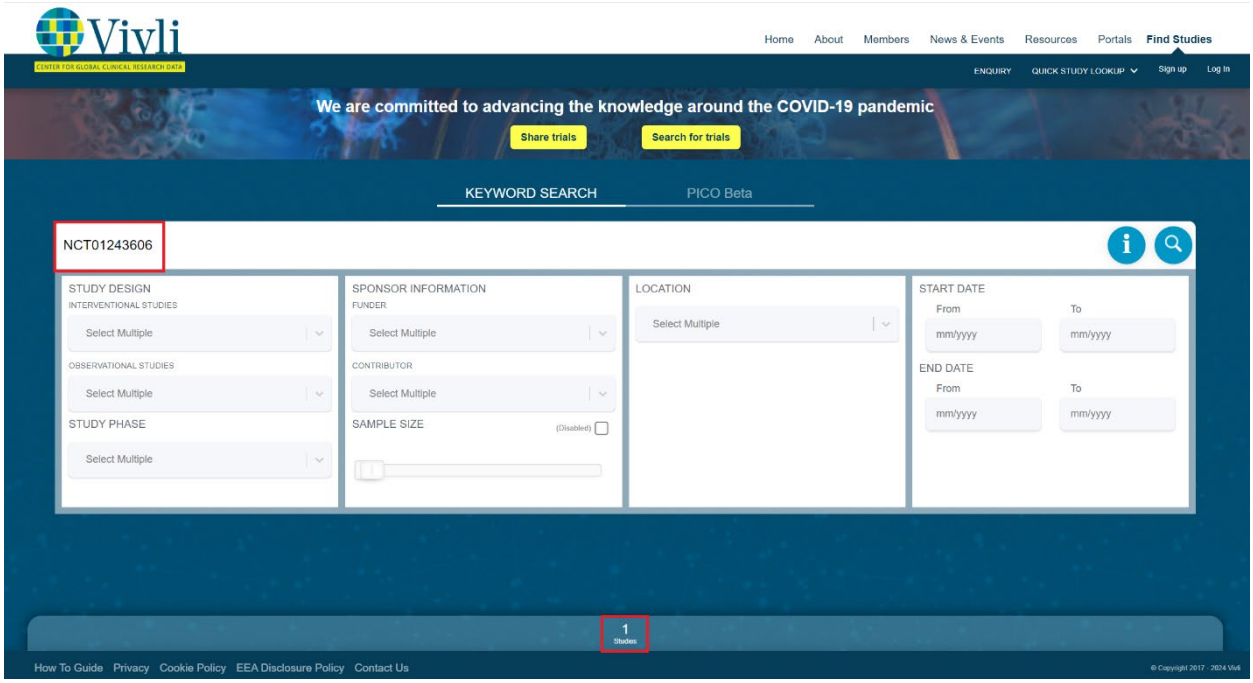


- Once you have submitted the study, you will need to contact Vivli via chat or email at support@vivli.org to withdraw.

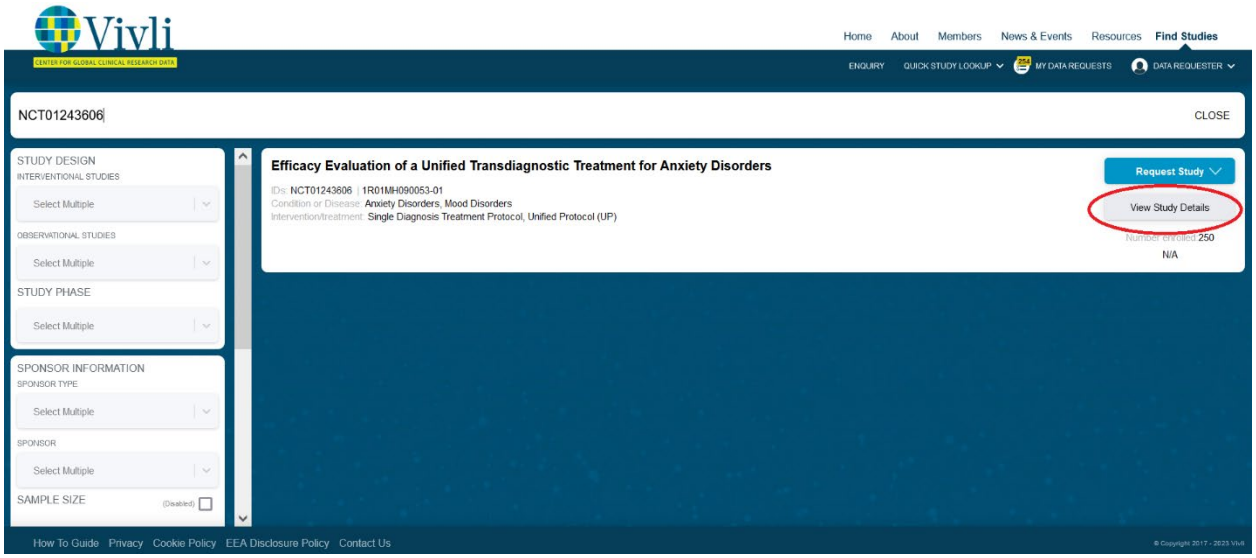
5 Viewing your Study Details

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.



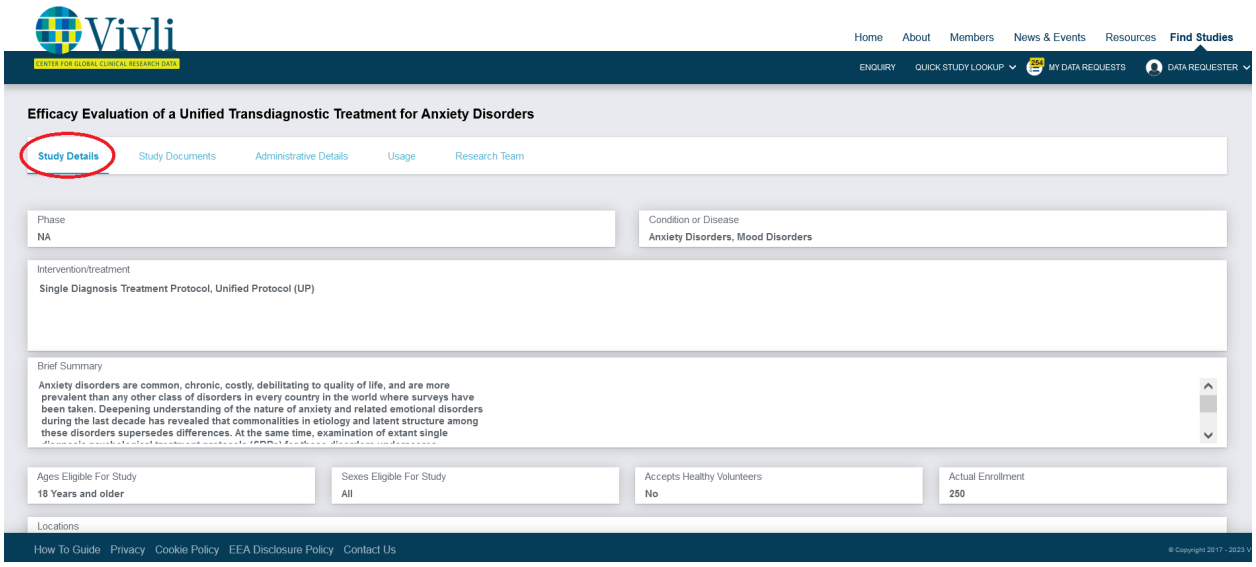
- Verify that the correct study has been identified and click the 'View Study Details' button on the right to pull up the metadata for your submission.



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.

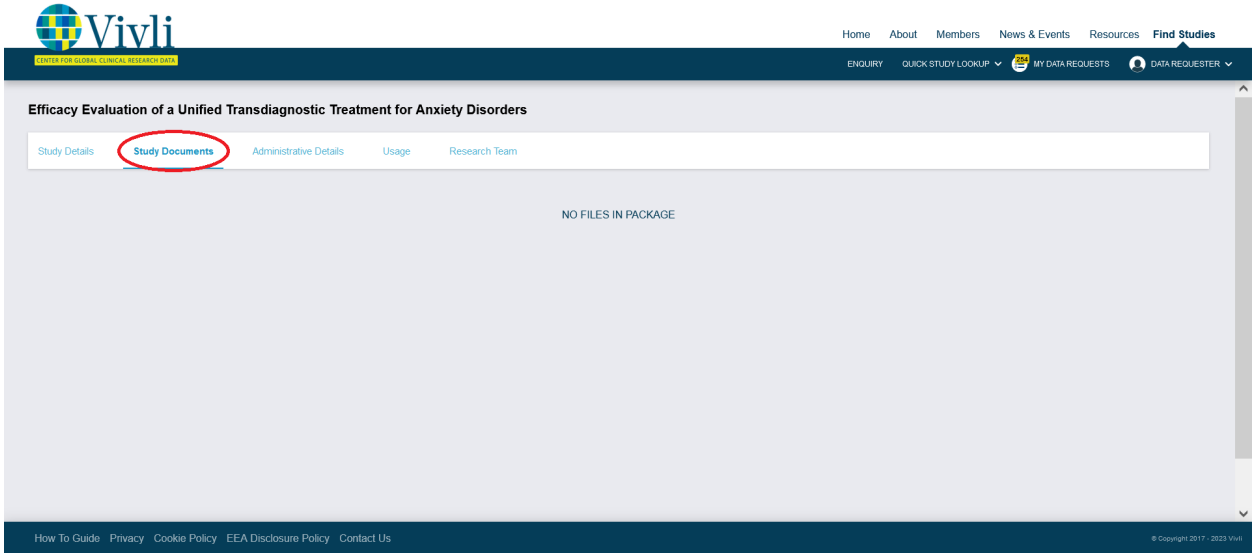


5.3 Study Documents

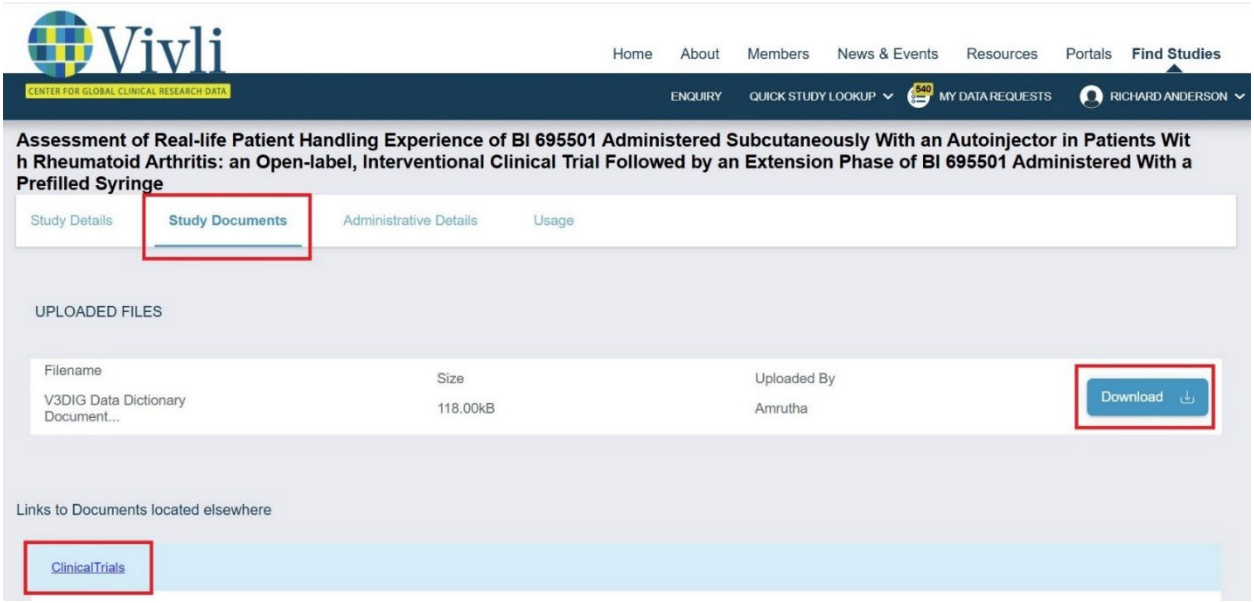
The 'Study Documents' tab is provided to share documents with searchers to help them determine whether the dataset can support their research - this typically will include documents like the Data Dictionary or the Protocol. The supporting documents are uploaded and will be made available during the study 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.

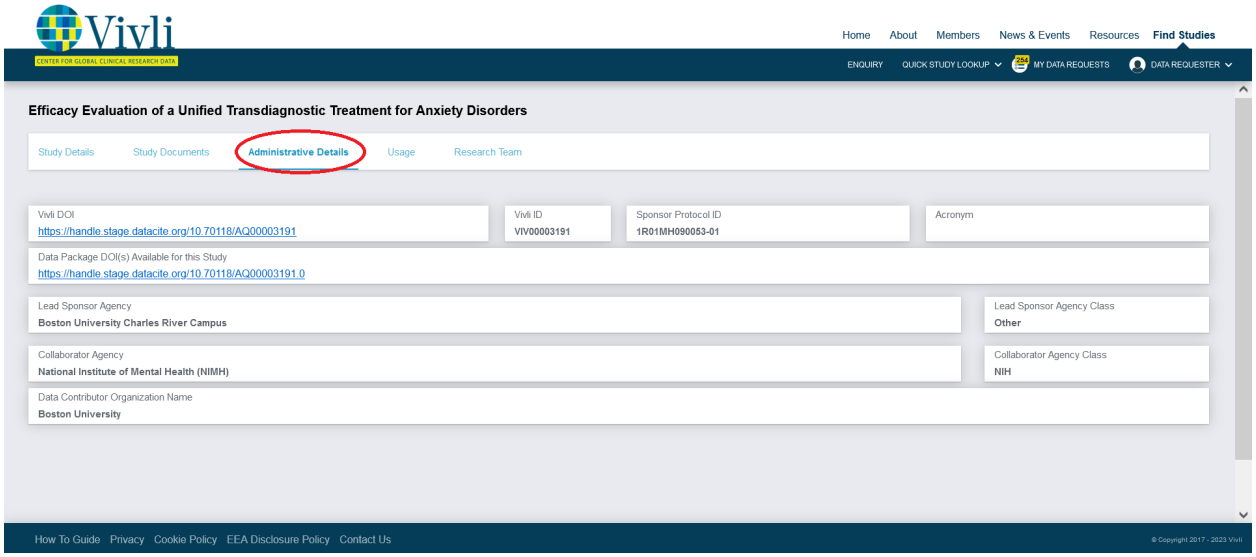


- If there are further documents that are available for your study at an external link, and you would like to provide a link to the documents, you may do so. Please see Section 3.2 Data Package Upload for further details.

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.



5.5 Usage

- The Usage tab displays the following metrics related to your study

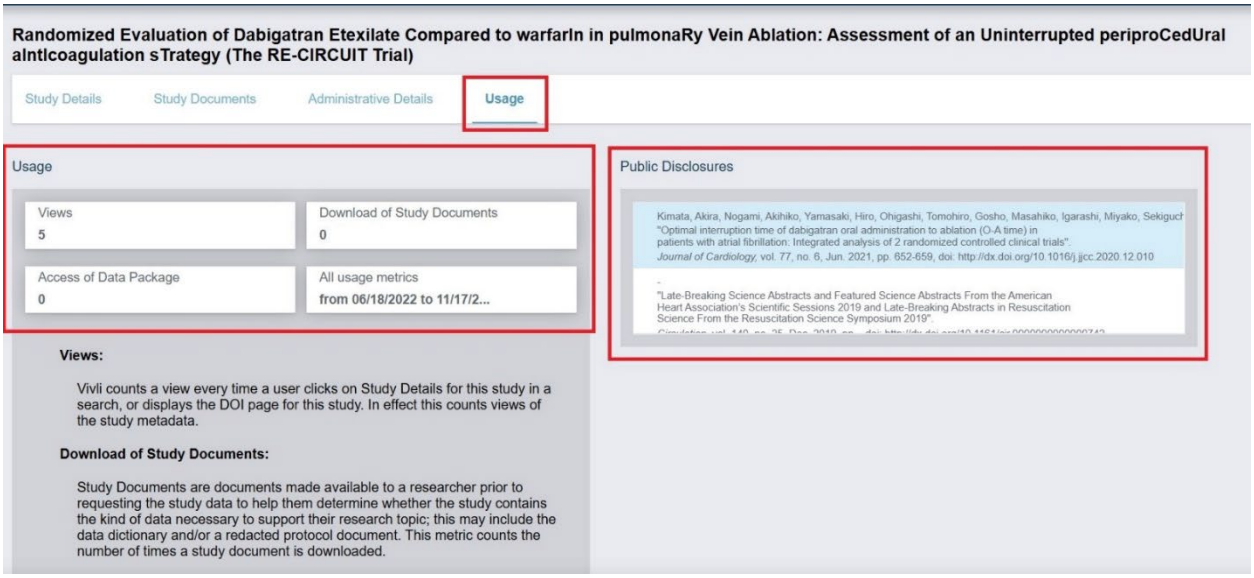
    - **Views**: Vivli counts a view every time a user clicks on Study Details for this study in a search, or displays the DOI page for this study. In effect this counts views of the study metadata.

    - **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.

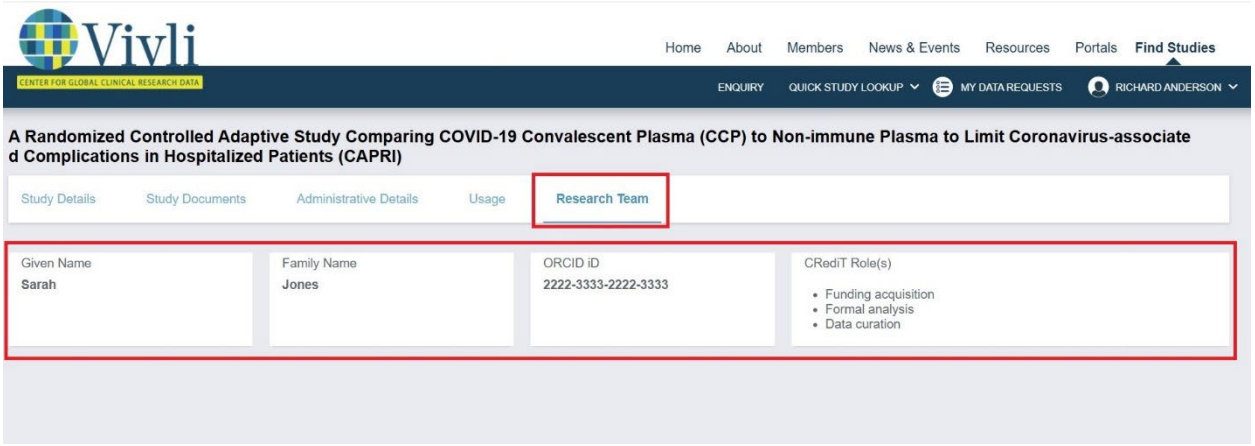
    - **All Usage Metrics**: The data range here represents the range of dates during which the metrics above were collected. The start date is either the date the data collection feature was turned on, or the date the study was posted (whichever is later). The end date is always 3 days before the current 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.



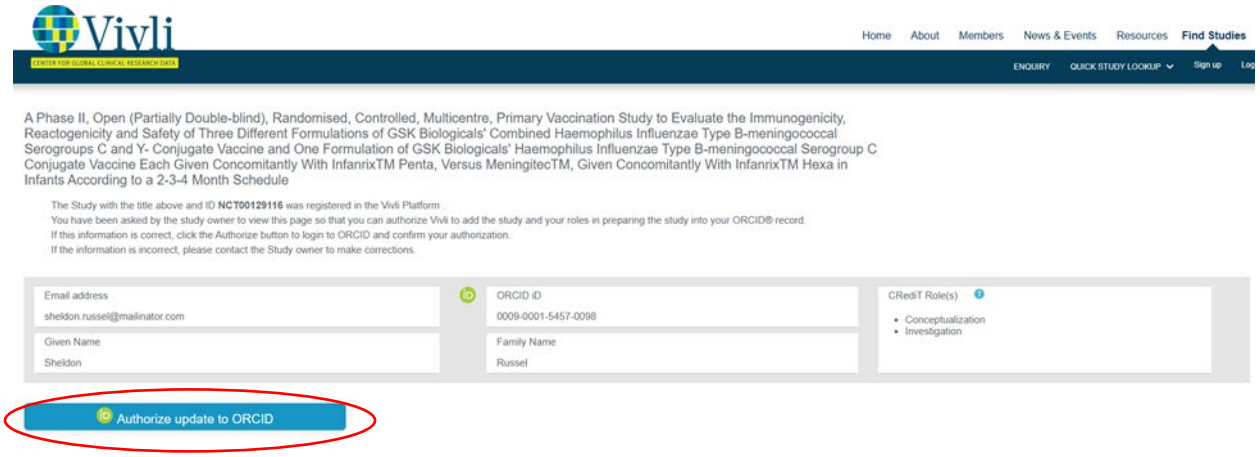
5.6 Adding Research Team Members to your study submission

- 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.

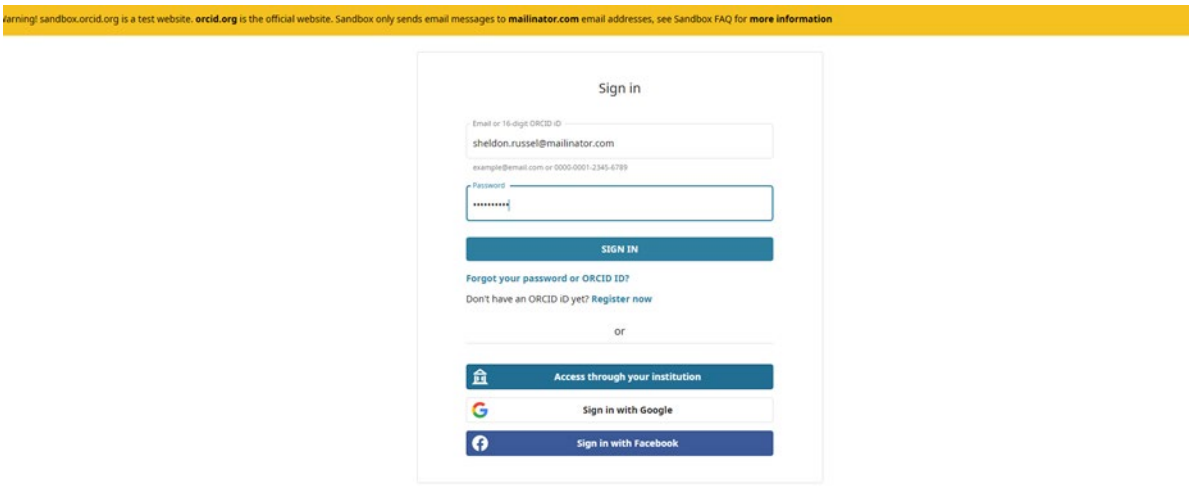


5.7 Integrating ORCID for Research Team Members

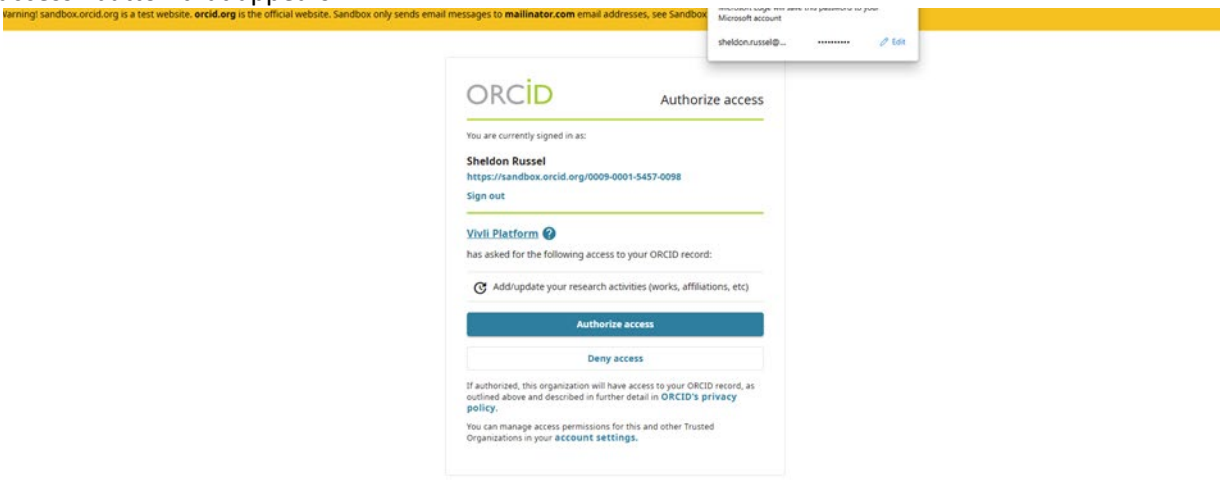
- During study submission, the dataset owner will have clicked the “Send Invitations to Team Members” Button, which sends an automatic email to researchers listed on the study after the study has been posted.
- Once an email is received, click the link within the email and you will be taken to a Vivli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



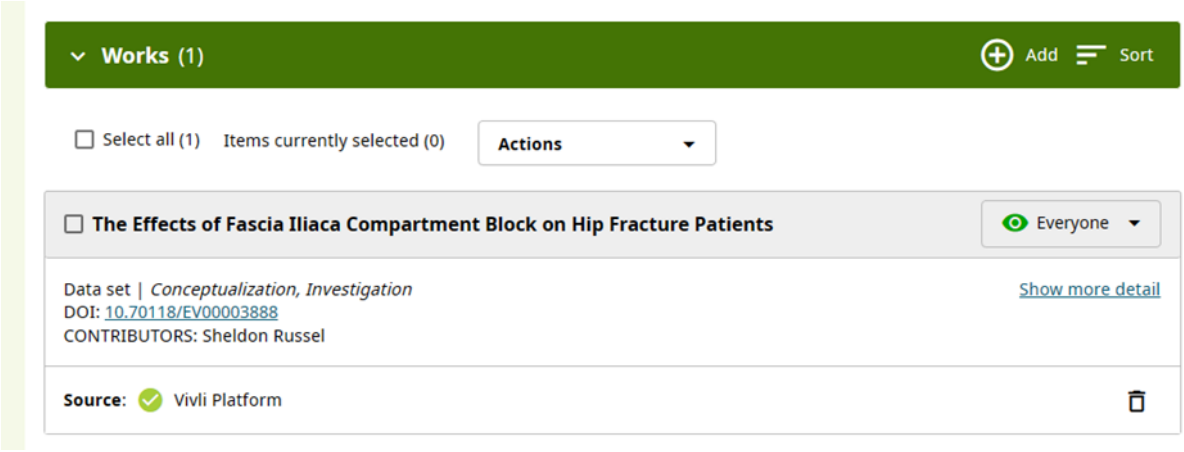
- You will be navigated to the ORCID login screen. Log in with your ORCID credentials.



- 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.

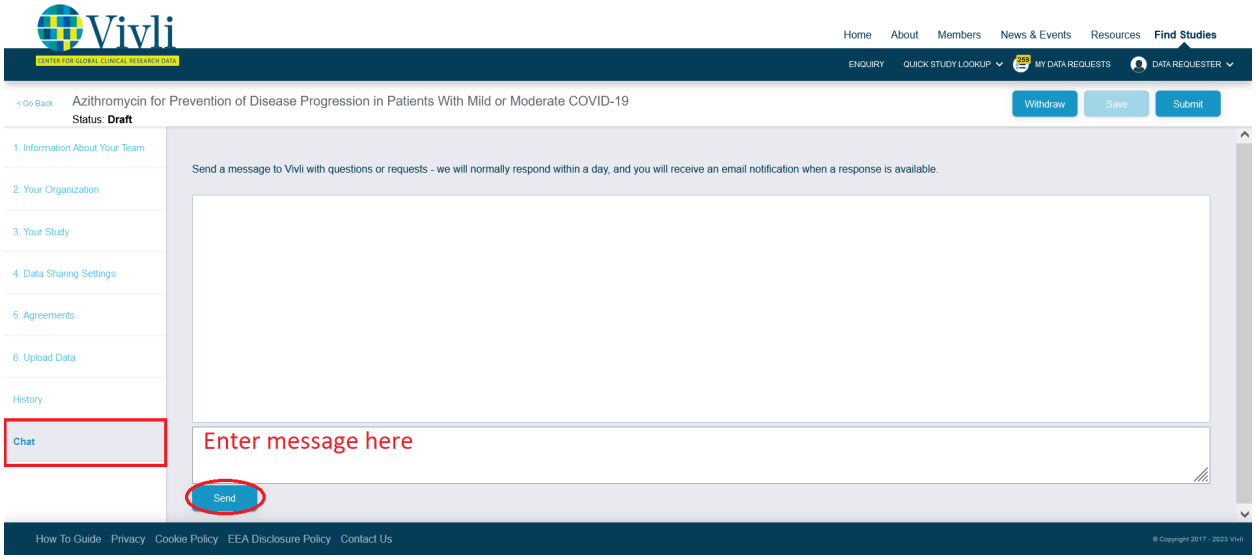


- If there are changes to the research team (a member is deleted, or roles are updated) this will be reflected in the user’s ORCID record.

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.