Vivli Single Study Submission Guide
Version 1.0

17 January 2023

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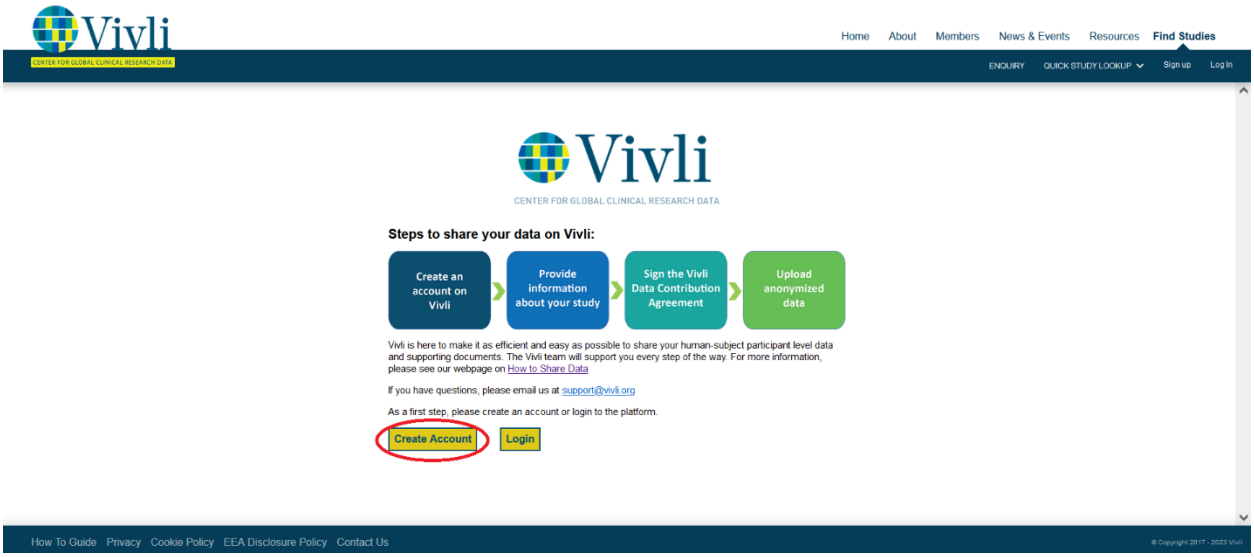
1.0 Submitting Studies on Vivli – Overview

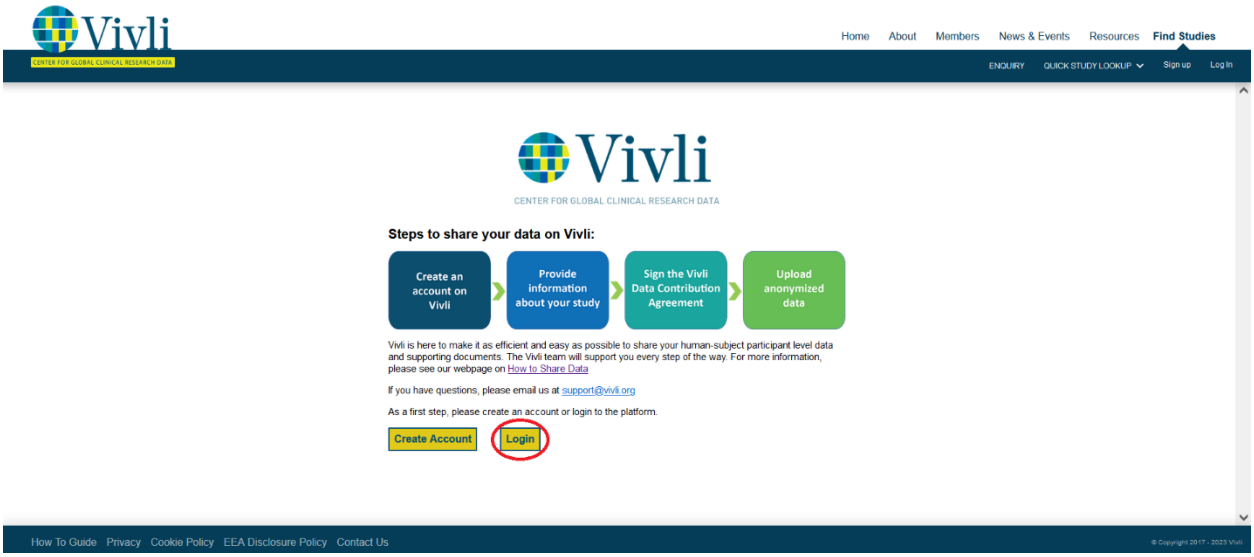
- Vivli is here to make it as efficient and easy as possible to share your human-subject participant level data and supporting documents. The Vivli team will support you every step of the way. For more information, please see our webpage on How to Share Data.
- Once you have created your Vivli account, you will be prompted to provide information about your study.
- The Vivli Data Contribution Agreement needs to be read, understood and signed by the Principal Investigator and an institution official.
- Vivli only accepts anonymized data. Your institution may provide support or Vivli has anonymization vendors who will offer support for this service.
- Once the submission has been accepted by the Vivli team, you will then be able to upload your anonymized data.

1.1 Login/Account Setup

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

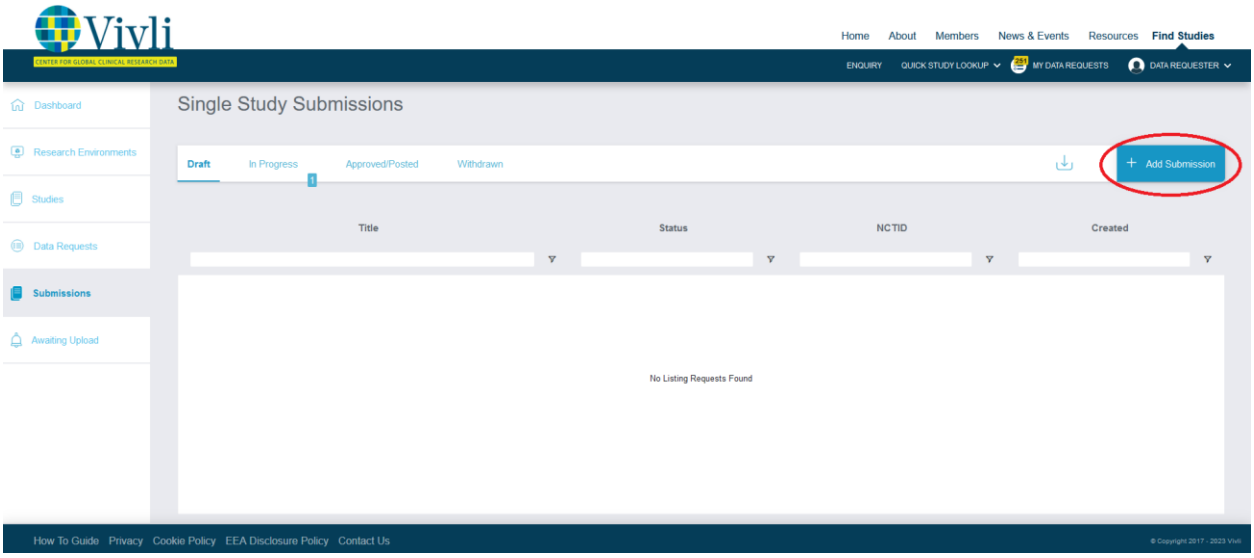


- If you are already a Vivli user, click the “Login” button.

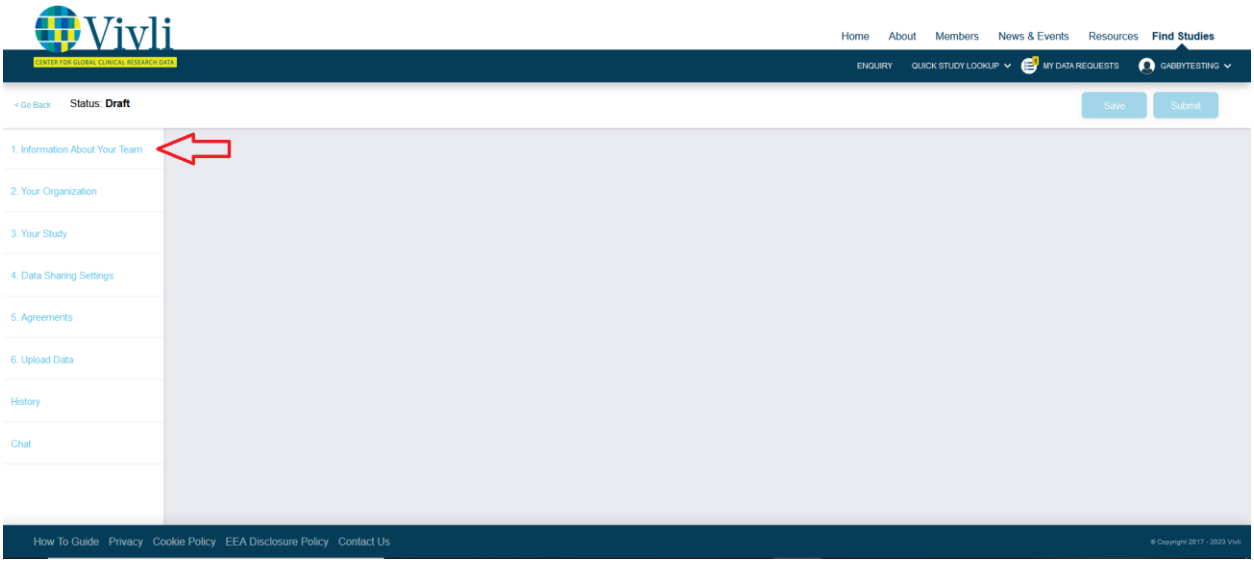


1.2 Dashboard

- Once you have logged into the platform, if you have already begun to create submissions, your account dashboard will appear.
- To submit a new study for sharing, 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.

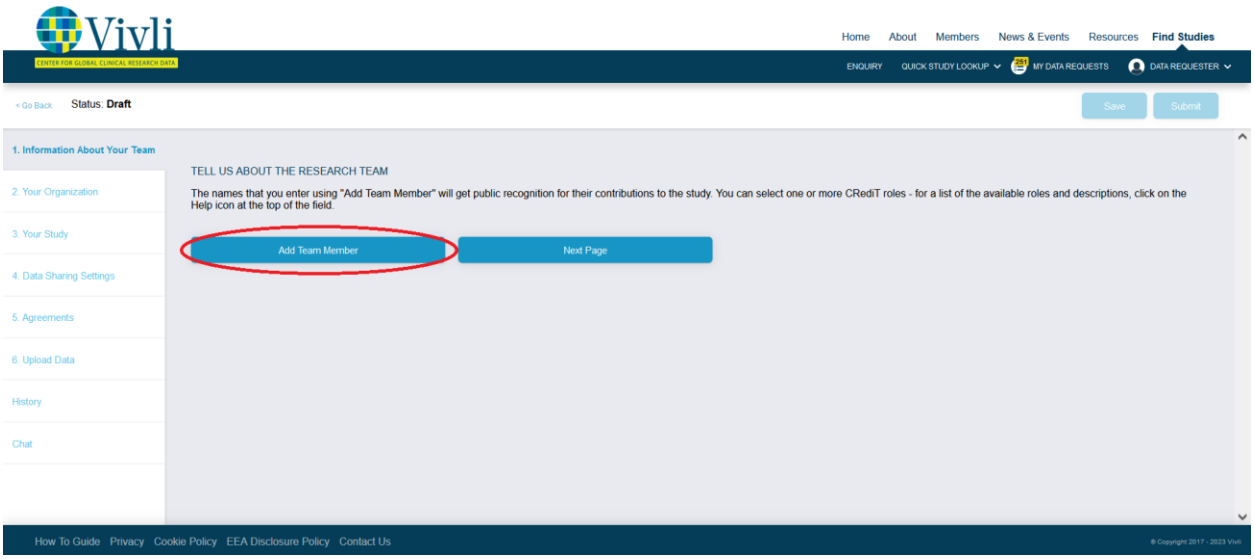


2.0 Study Submission

2.1 Information About Your Team

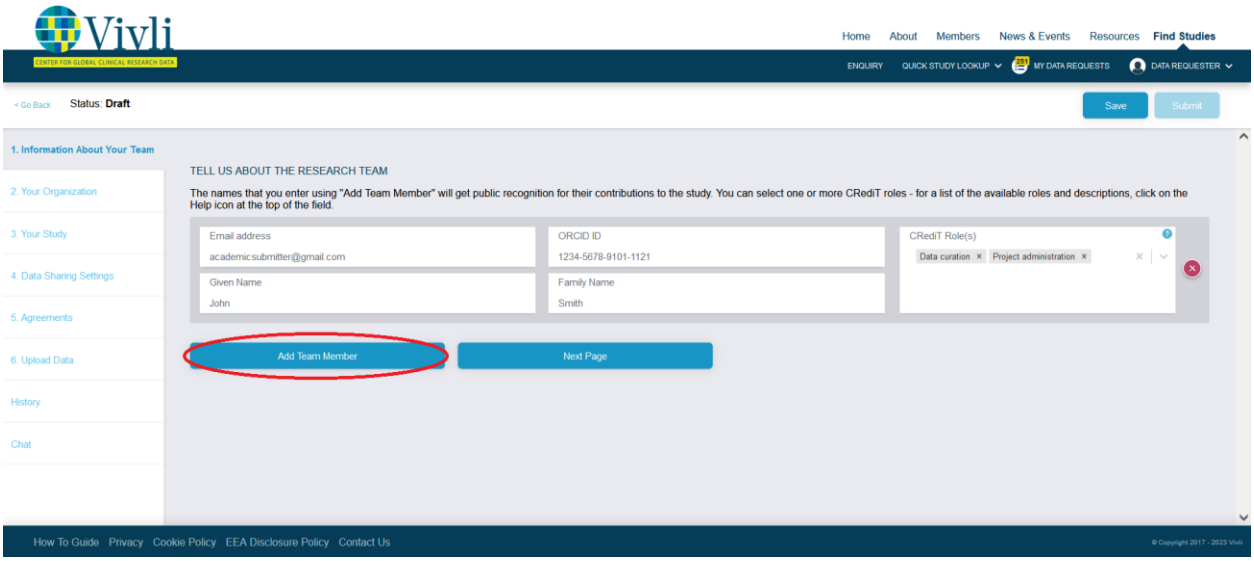
The names that you enter using "Add Team Member" will get public recognition for their contributions to the study. You can select one or more CRediT roles - for a list of the available roles and descriptions, click on the Help icon at the top of the field.

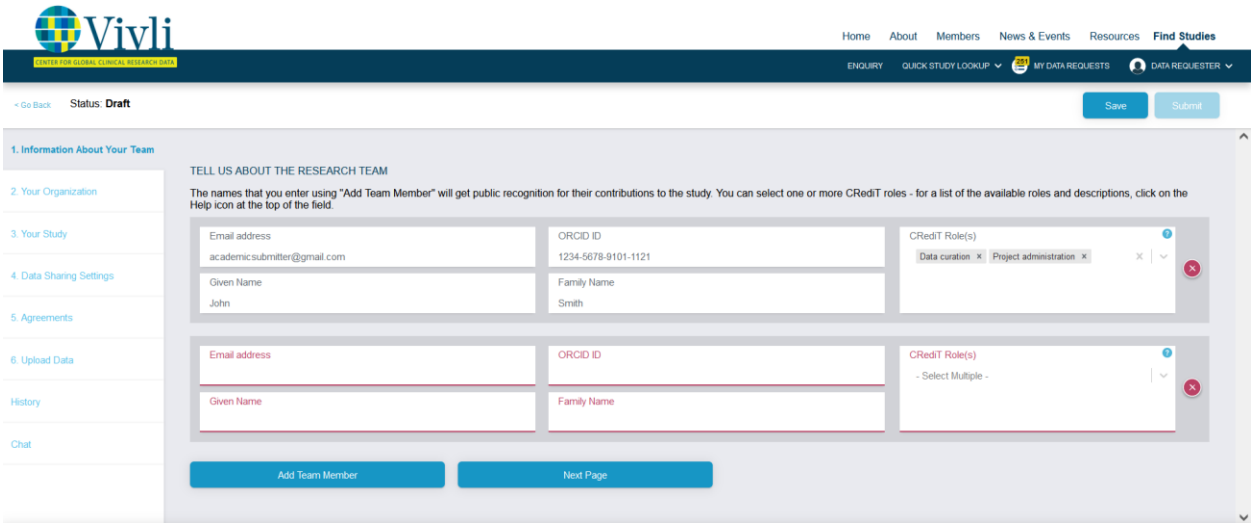
- Use the “Add Team Member” button to add all research team members to the study



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

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





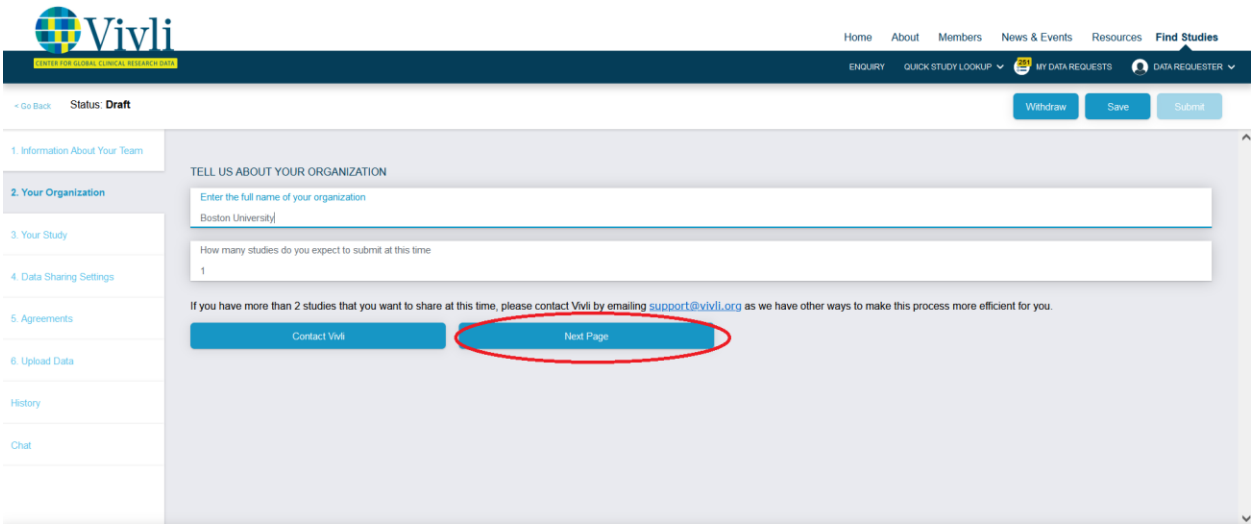
- Once all team members have been entered and roles have been assigned, click the “Next Page” button to navigate to the next section.

2.2 Your Organization

- Enter the name of the Organization/Institution that will be displayed as the Data Contributor for the study and the number of studies that will be submitted. Please note that each study will need to be submitted separately.

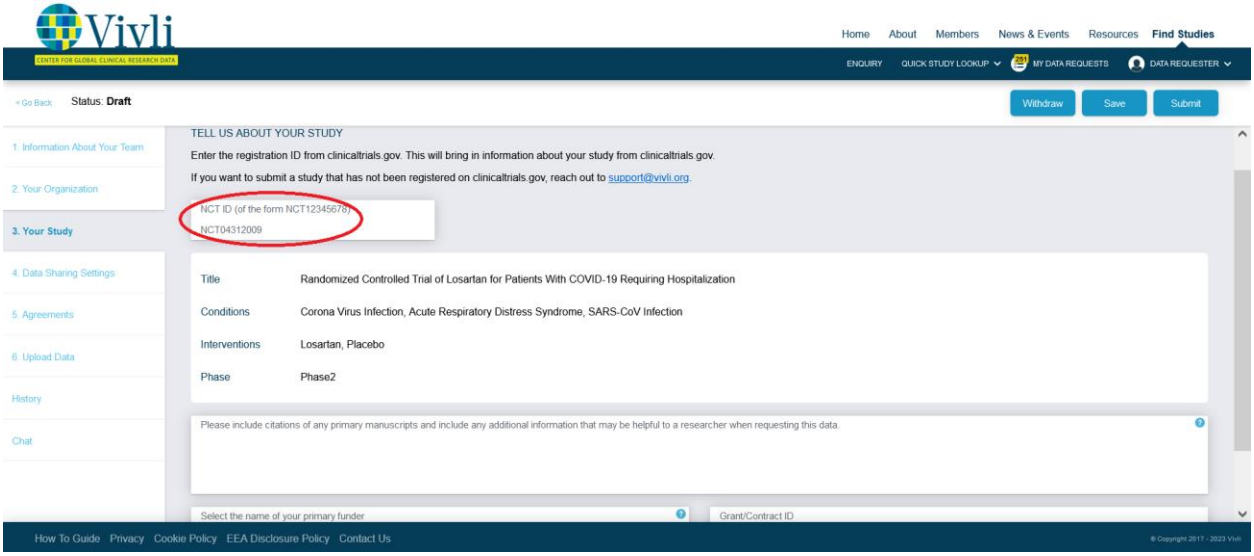
- If you plan to submit more than two studies, use the “Contact Us” button so that we can make the submission process more efficient for you.

- Once these fields are complete, use the “Next Page” button to navigate to the next section.



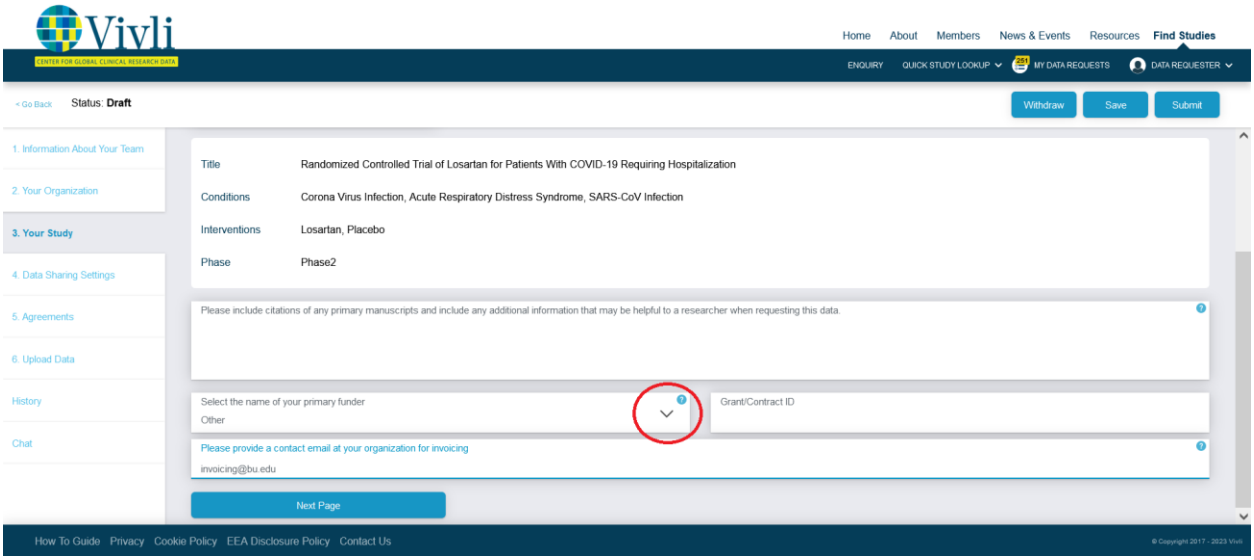
2.3 Your Study

- Enter the registration ID from clinicaltrials.gov. This will automatically populate the Title, Conditions, Interventions and Phase information from clinicaltrials.gov. If you want to submit a study that was not registered on clinicaltrials.gov, please email Vivli support@vivli.org and we will assist you.



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

- Use the drop-down menu to select the primary funder. If the study was funded by your organization, leave this at N/A. If it was funded by an external funder, choose the name from the drop-down list. If your external funder is not on the list, choose “Other”.

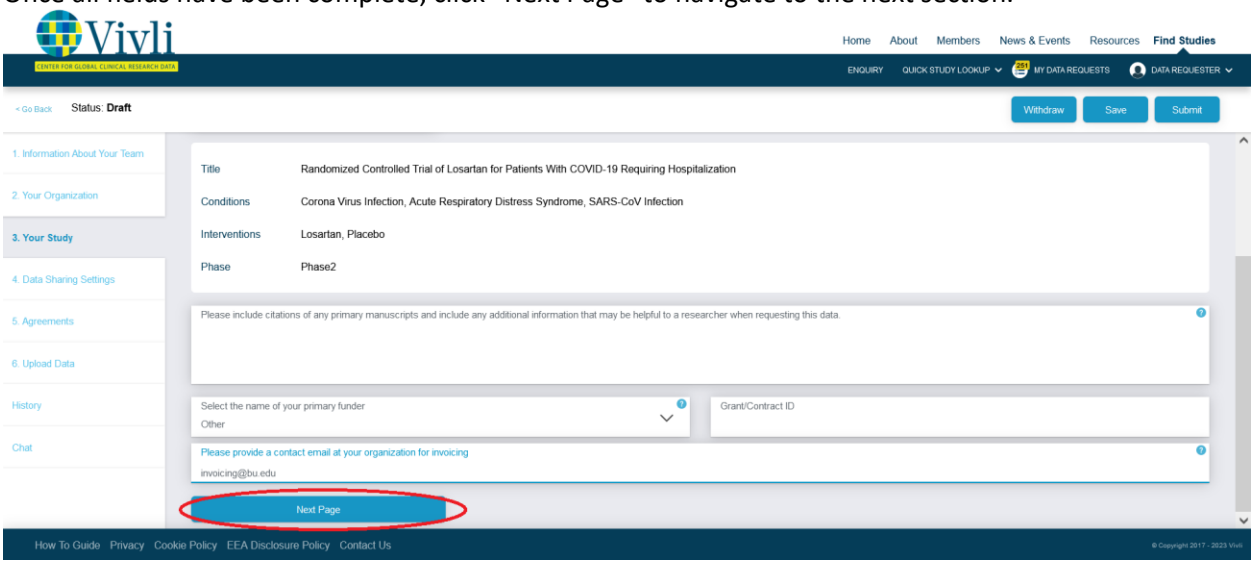


- Depending on your selection, you may be prompted to provide a contact email address for invoicing.

    - If your academic institution is a member of Vivli there is no cost to deposit data in Vivli's platform starting in 2023. Please check our members page if you are unsure of the status of your institution.

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

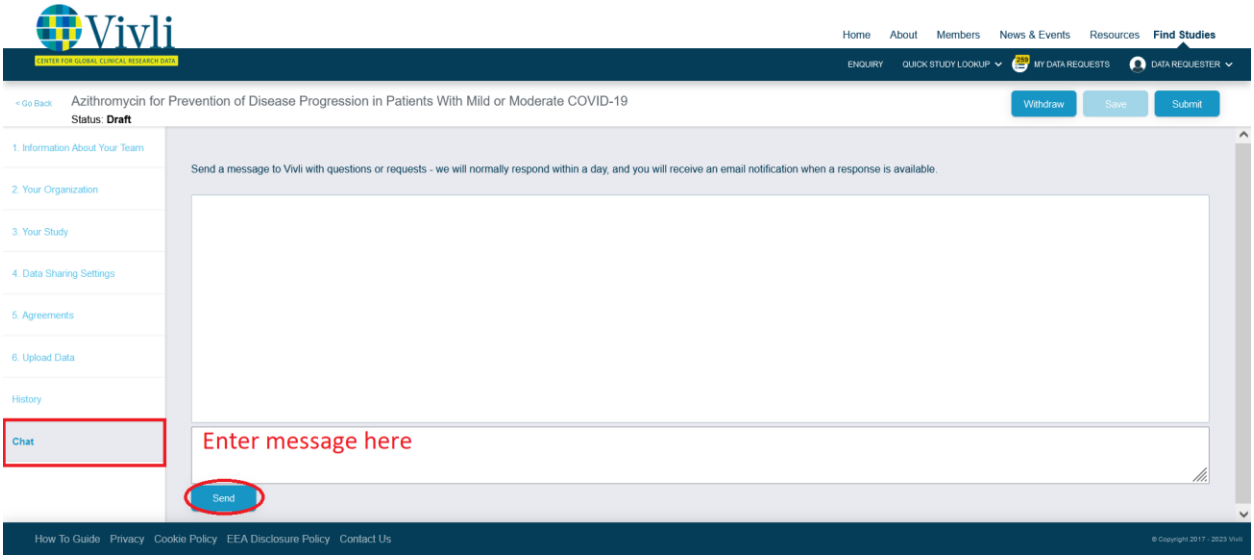
- Once all fields have been complete, click "Next Page" to navigate to the next section.



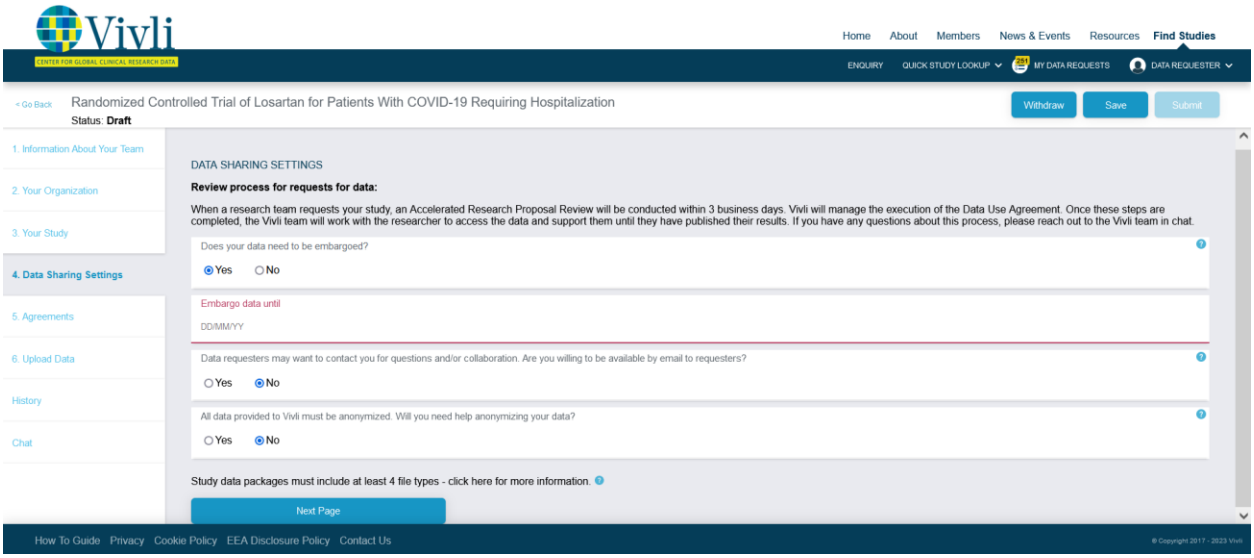
2.4 Data Sharing Settings

- **Accelerated Review** -- When a research team requests your study, an Accelerated Research

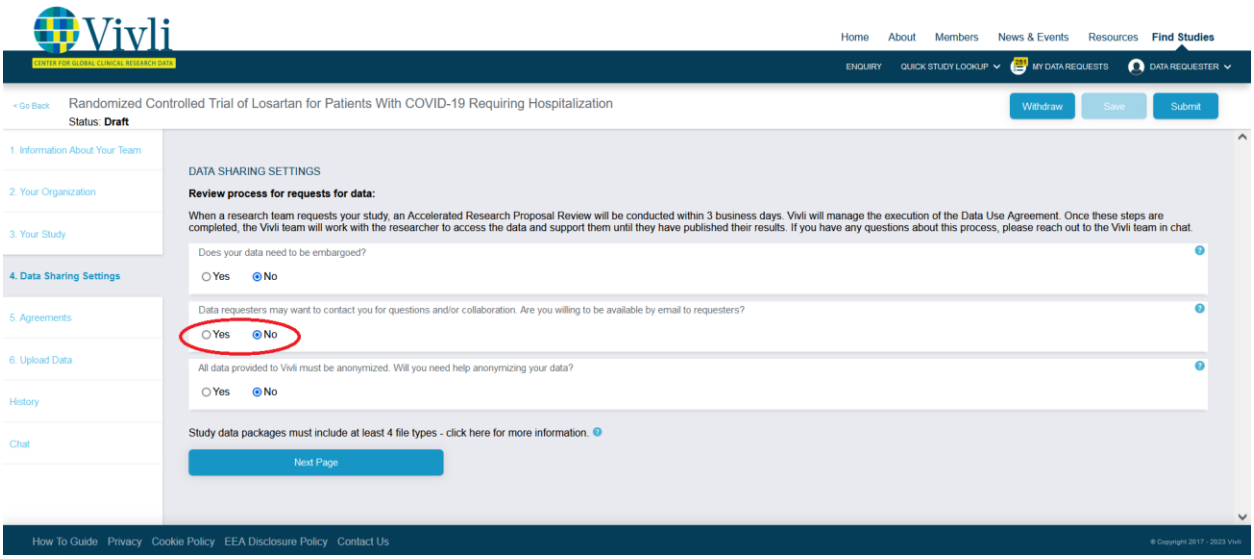
Proposal Review will be conducted within 3 business days. Vivli will manage the execution of the Data Use Agreement. Once these steps are completed, the Vivli team will work with the researcher to access the data and support them until they have published their results. If you have any questions about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



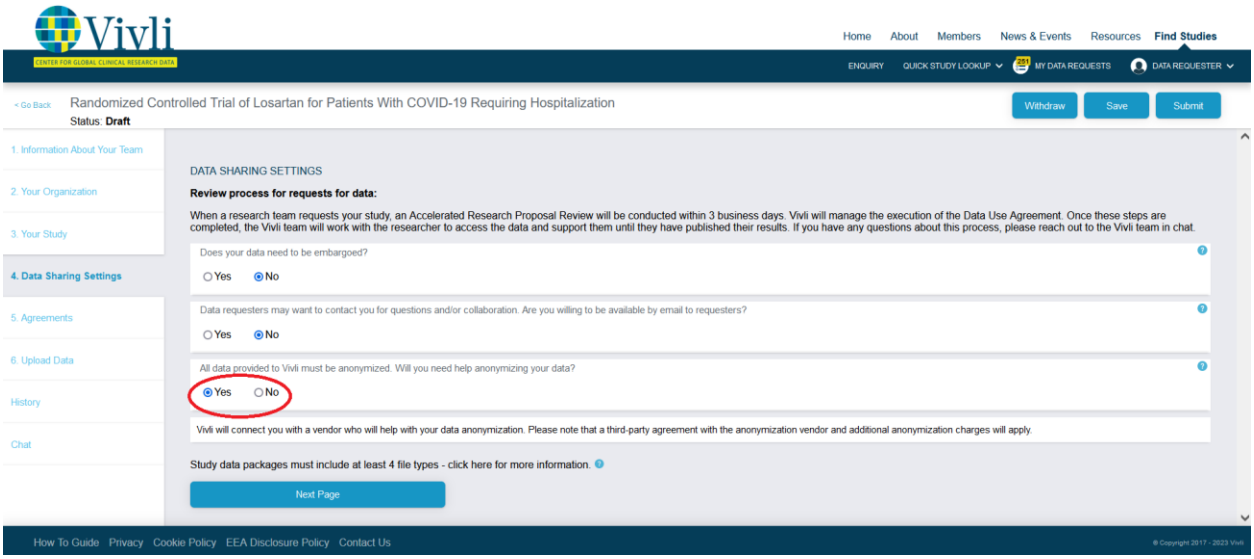
- **Embargo** -- If you need to embargo your data, we will make the study available for researchers to request, but the data itself will not be provided until the embargo date has passed. This might be necessary, for example, if the data itself cannot be provided until the results of the study are published.



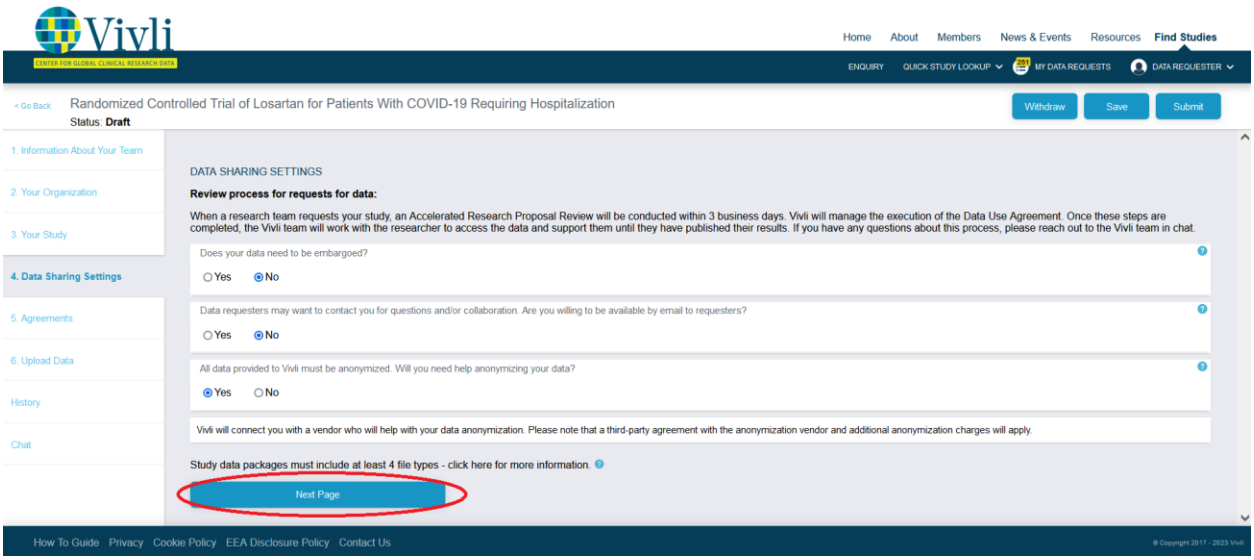
- If you are willing to be contacted, the Vivli team will email you any requests for collaboration or questions. Making yourself available for contact does not imply a commitment to collaborate on any or all requests – it is your decision to answer questions or collaborate on a case-by-case basis.



- 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.

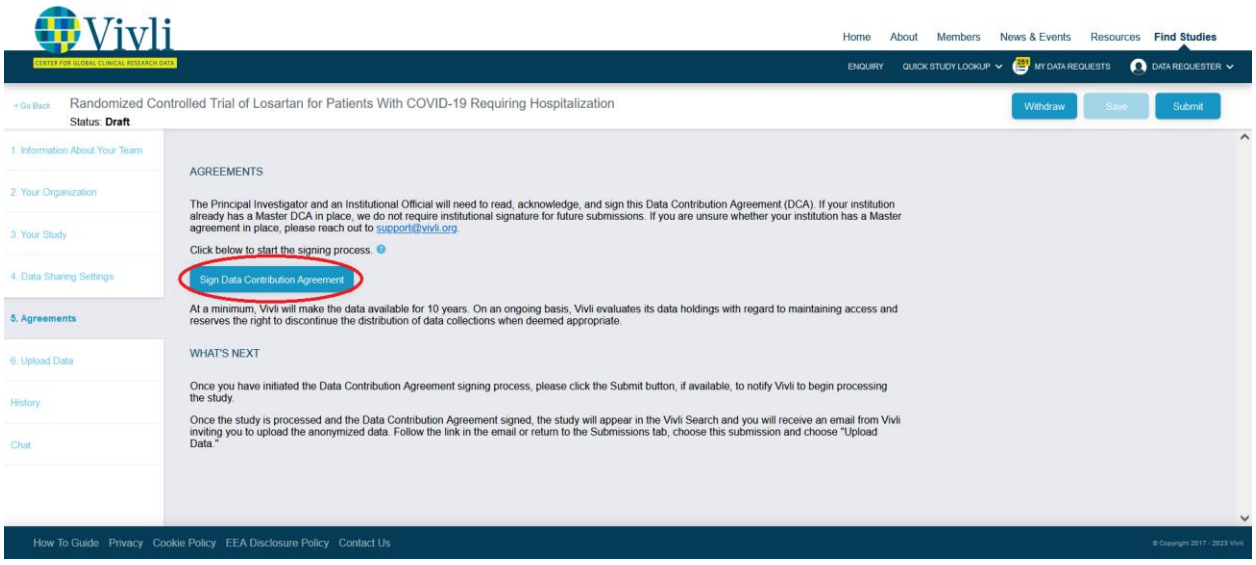


- Once all Data Sharing Settings have been selected, use the "Next Page" button to navigate to the next section.



2.5 Agreements

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

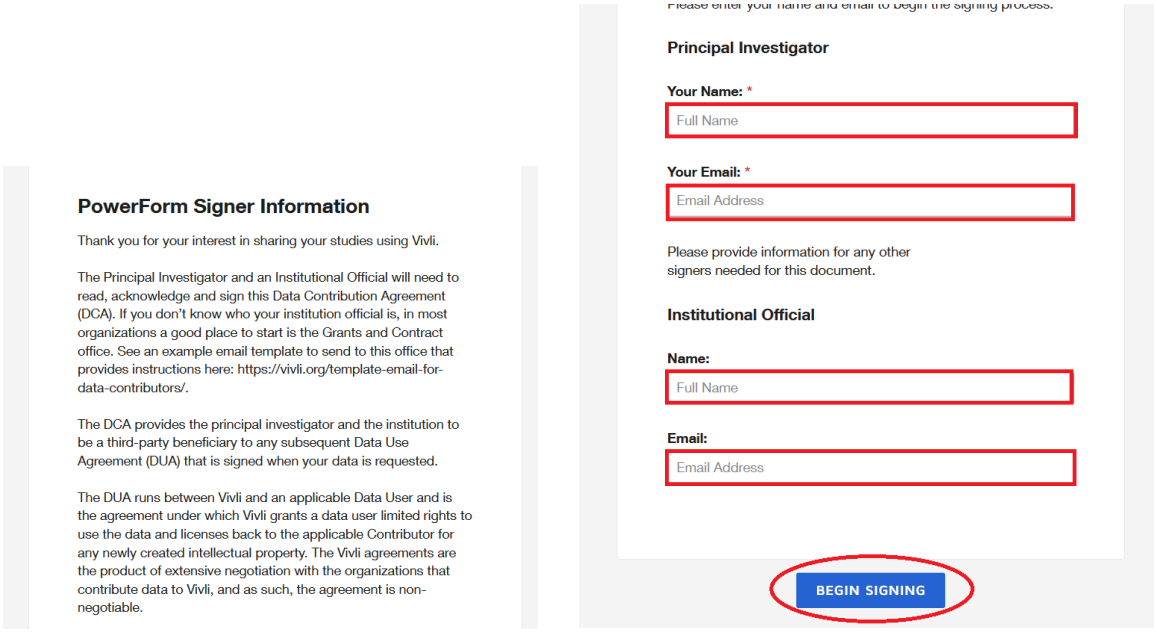


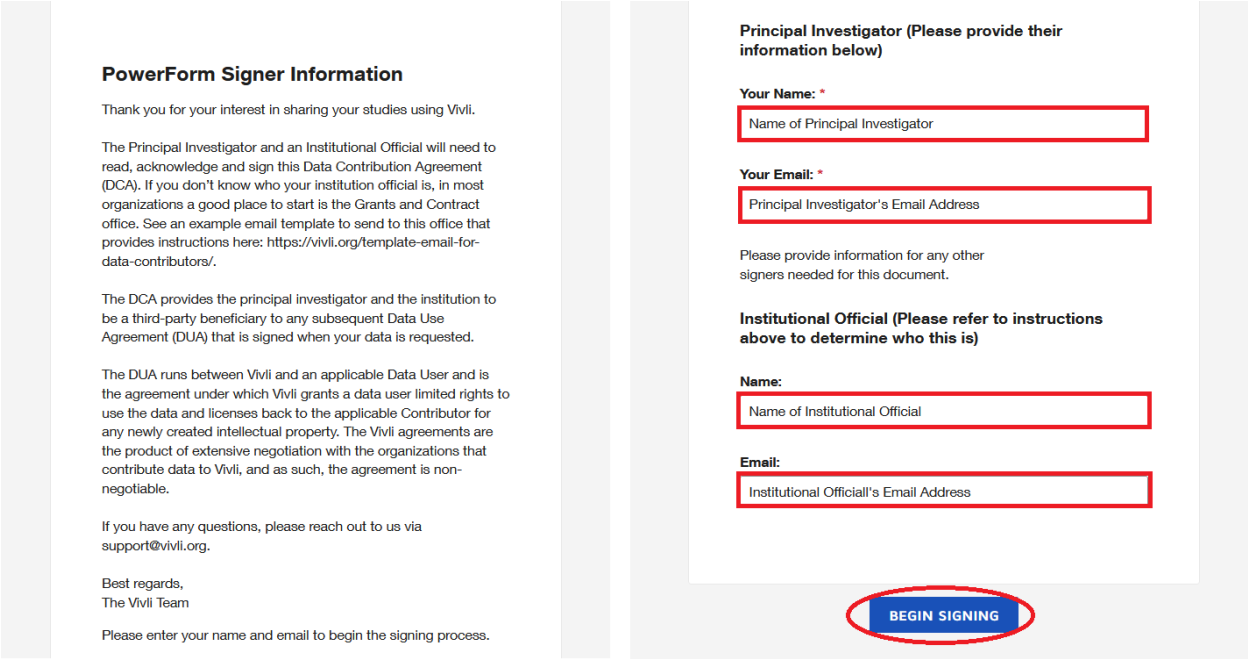
- The Principal Investigator and an Institutional Official will need to read, acknowledge and sign this Data Contribution Agreement (DCA). If you don’t know who your institution official is, in most organizations a good place to start is the Grants and Contract office. See an example email template to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

- Instructions for signing the agreement:

  1. The DocuSign PowerForm provides basic instructions for you and your institutional official. When you are ready to sign the agreement, please provide the Full Name and email address in both the

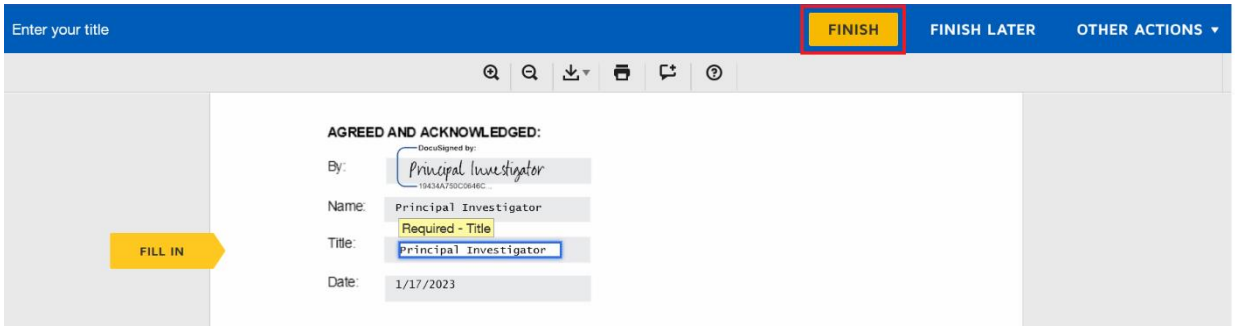
Principal Investigator and Institutional Official fields. Next, click “Begin Signing.”





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

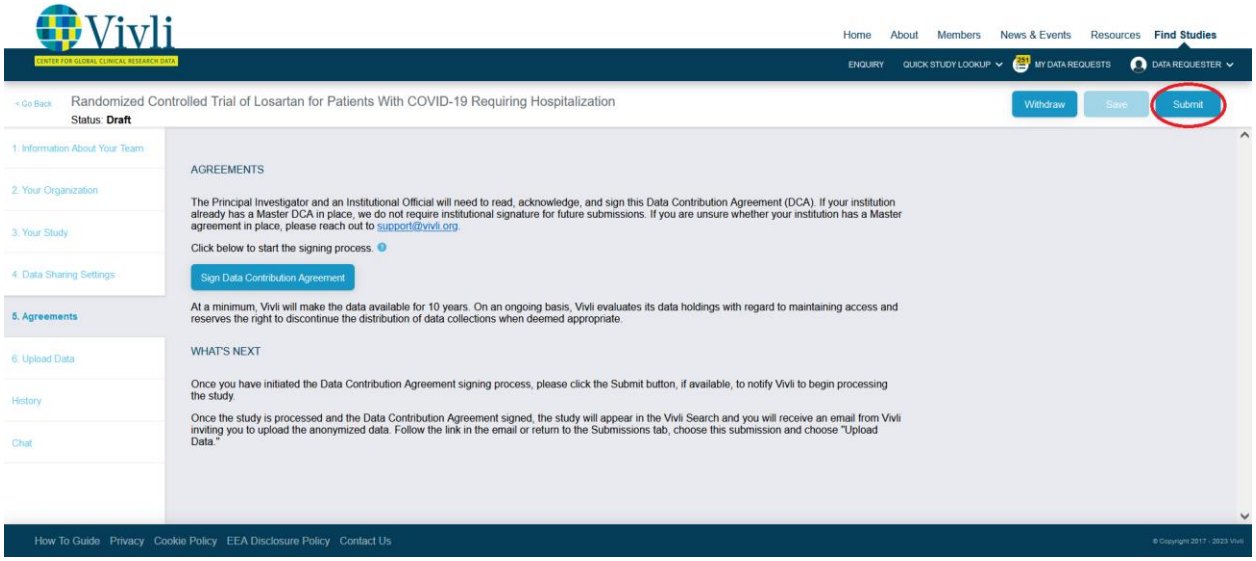
3. The Principal Investigator will need to complete the required fields (outlined in red), including Organization Name (p.1), Business Address (p.1 and p.6), Acknowledgement (p.8), NCT ID (p.9), and Agreed and Acknowledged (p.11). Once all required fields have been completed, click the yellow “Finish”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



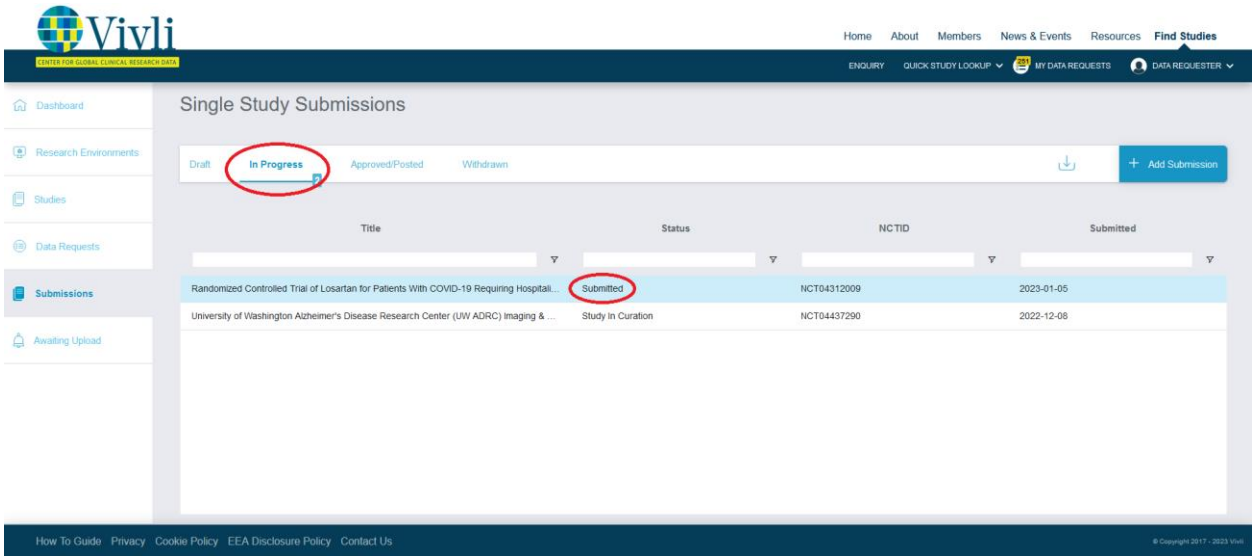
4. The agreement will then be routed to the Institutional Official for signature.

- 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, please use the chat function.

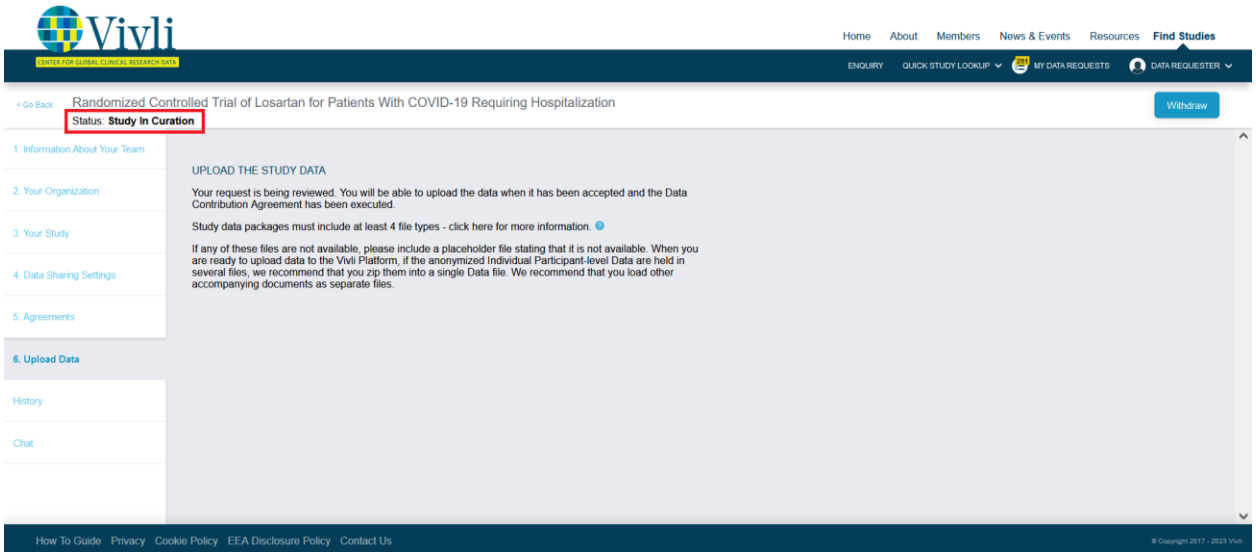
- After you have initiated the DCA process, you must click the "Submit" button in the upper right corner to begin the Vivli review process. You do not need to wait for the Data Contribution Agreement to be executed before you submit.



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

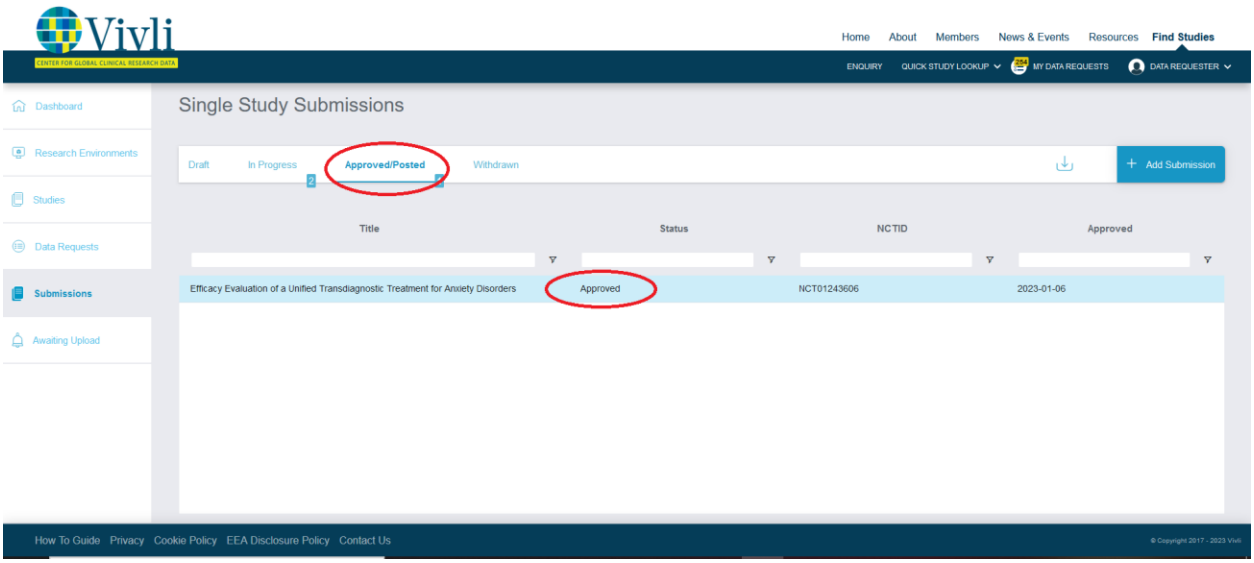


- You will not be able to upload your anonymized data until the metadata has been curated, your Data Contribution Agreement has been executed and the study has been posted/accepted.



3.0 Data Package Upload

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



3.1 Data Package Requirements

- It is expected that all data packages will include the following 4 file types to support the researcher's use of your data:
  - **Study Protocol** - Final protocol with all amendments
  - **Data Dictionary** - Detailed descriptions of each variable in the dataset, including the definition, source, coding, etc. of the variable
  - **Statistical Analysis Plan** - Description of the principal features of the analysis described in the protocol
  - **IPD Dataset** - Final cleaned individual participant-level data, anonymized

- Any other documents that may be useful to the researcher can be included and will be welcomed.

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

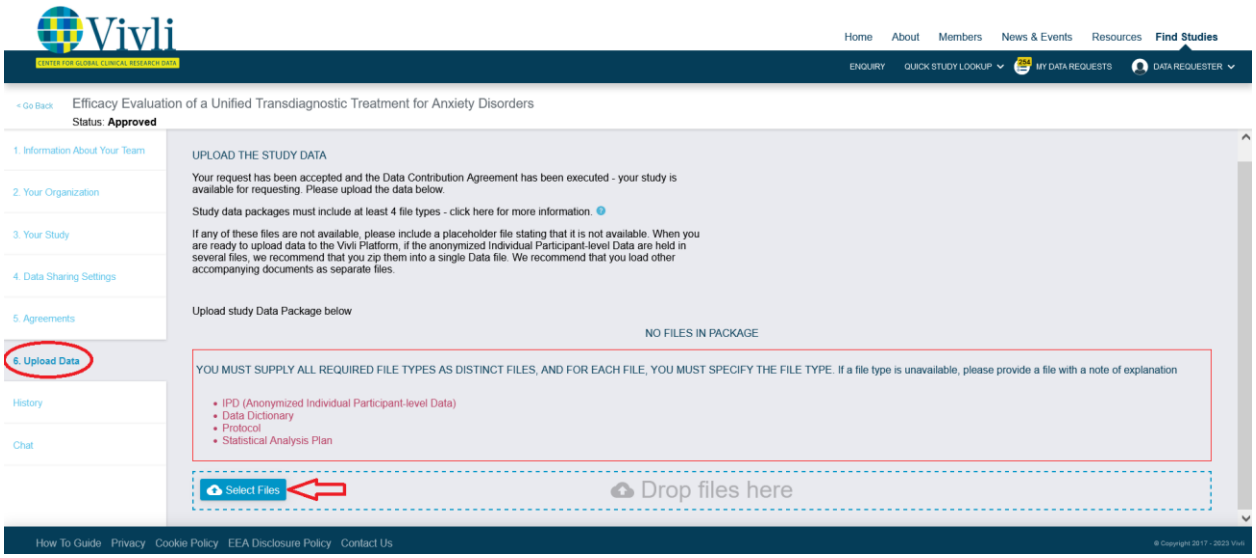
- When you are ready to upload data to the Vivli Platform, if the anonymized Individual Participant-level Data are held in several files, we recommend that you zip them into a single Data file. We recommend that you load other accompanying documents as separate files.

3.2 Data Package Upload

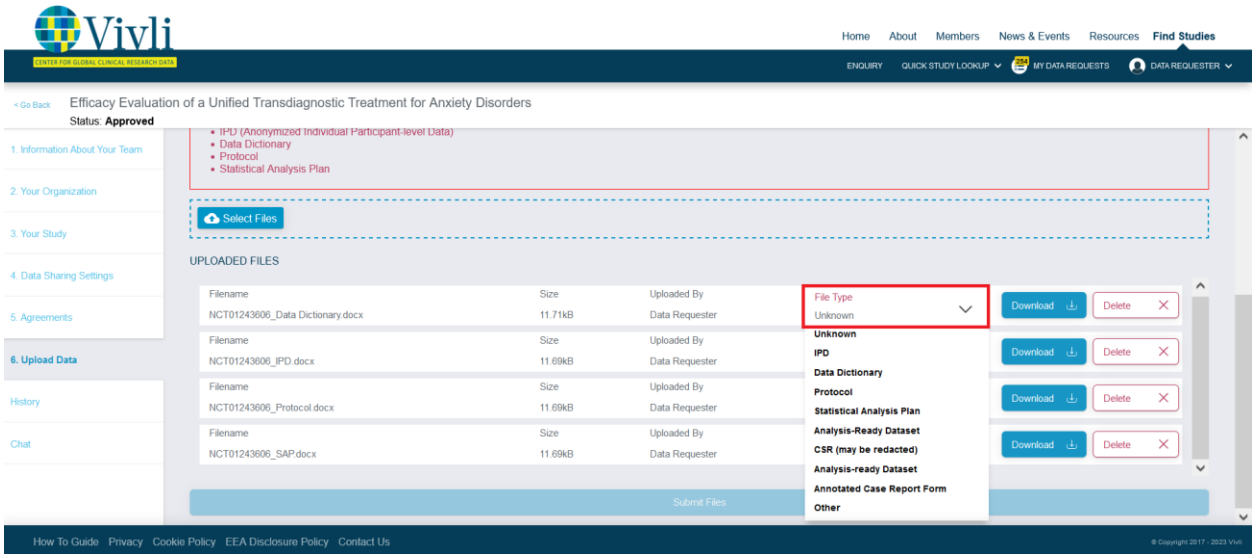
- The Vivli Team will reach out once the Data Contribution Agreement has been executed and you are approved to upload your anonymized study data and supporting documents.

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

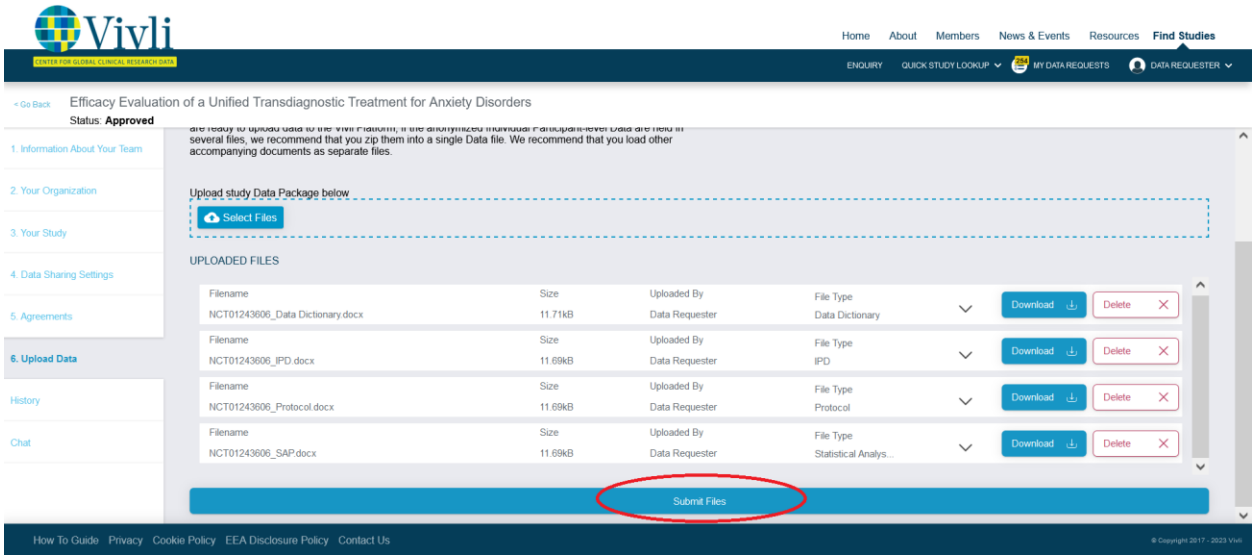
- Click on the 'Upload Data' tab and then you may use either the blue 'Select Files' button or drag and drop the appropriate files.



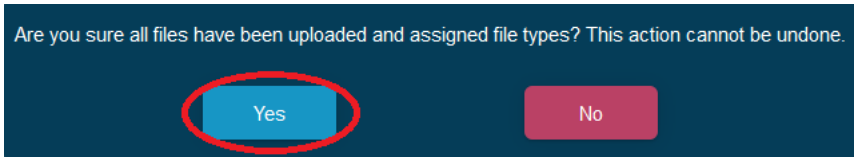
- Use the dropdown menu on the right-hand side to validate the File Type for each file before submitting files (Note: If you are missing the protocol, data dictionary, or Statistical analysis plan, please create a Word file with a note and upload it as a placeholder and validate the file type).



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



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

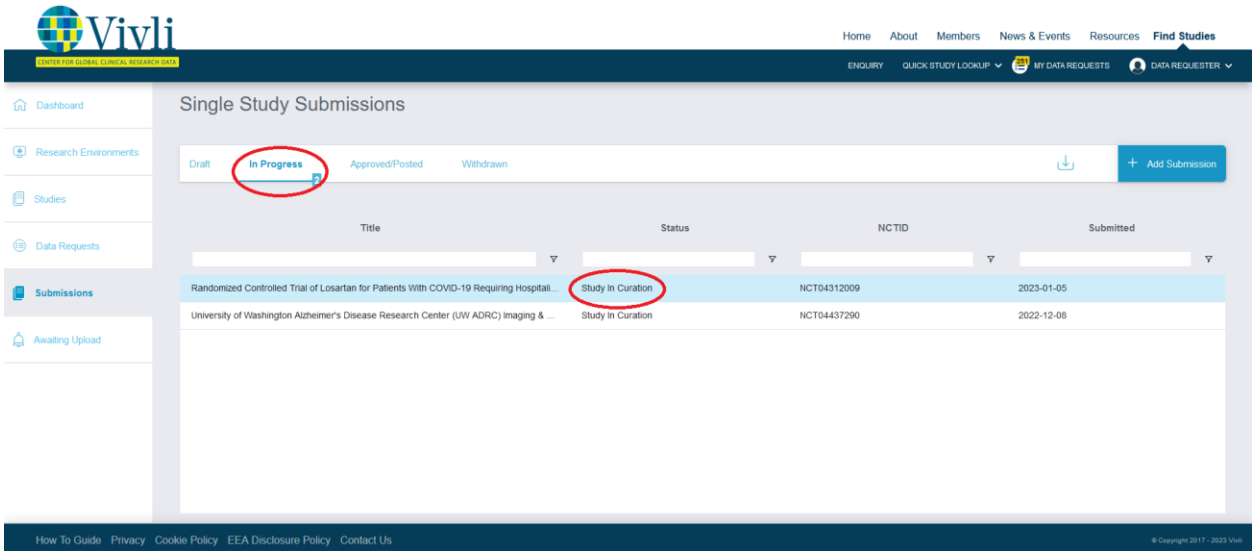


- You will receive confirmation of successful upload. Click the 'Continue' button to return to your submission.

4.0 Managing your Submission

4.1 Submission Status

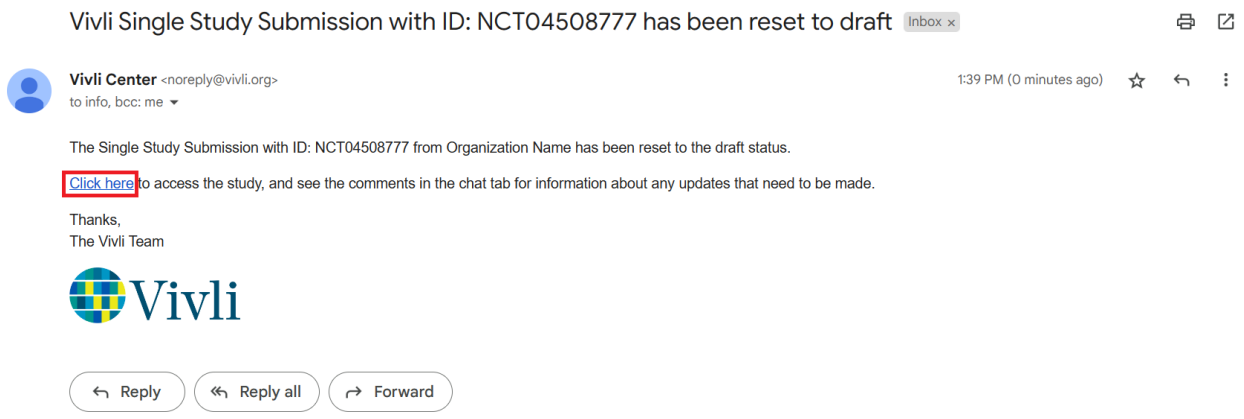
- You may check the progress of your submission via the Submissions dashboard. Once the study information has been accepted by a Vivli admin, the study will undergo metadata curation, and the status will appear in the dashboard as “Study in Curation.”



4.2 Making Edits

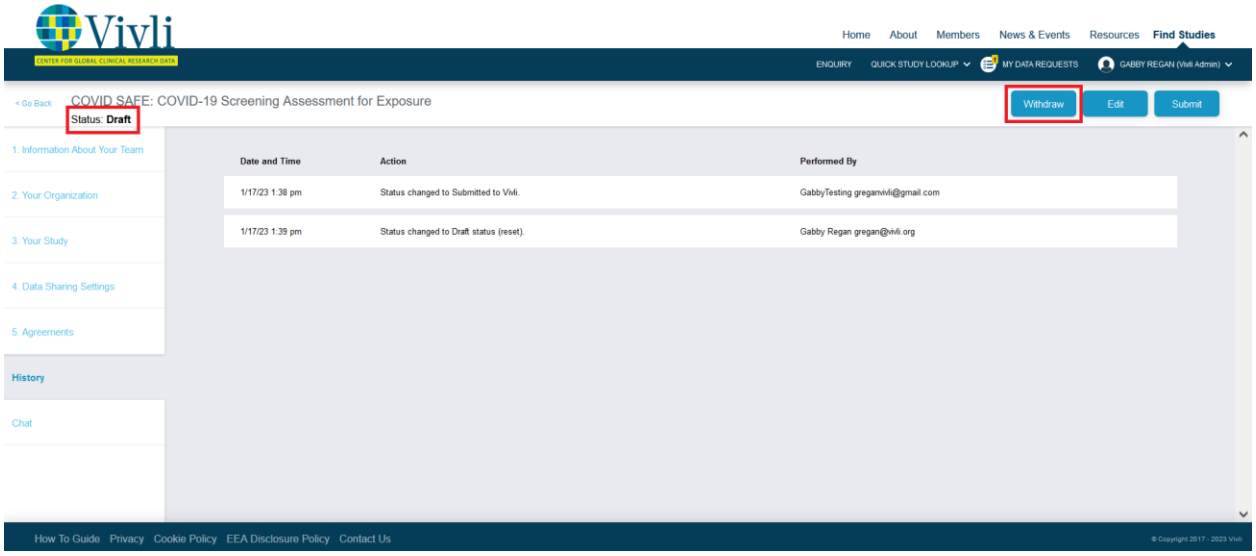
- Once your submission has been submitted, you will be unable to make any changes. Please contact Vivli via email at support@vivli.org if you need to make any changes to your submission.

- The Vivli team may send your submission back to drafts to request revisions. You will receive an email notification if you need to make updates to your submission.



4.3 Withdrawal

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

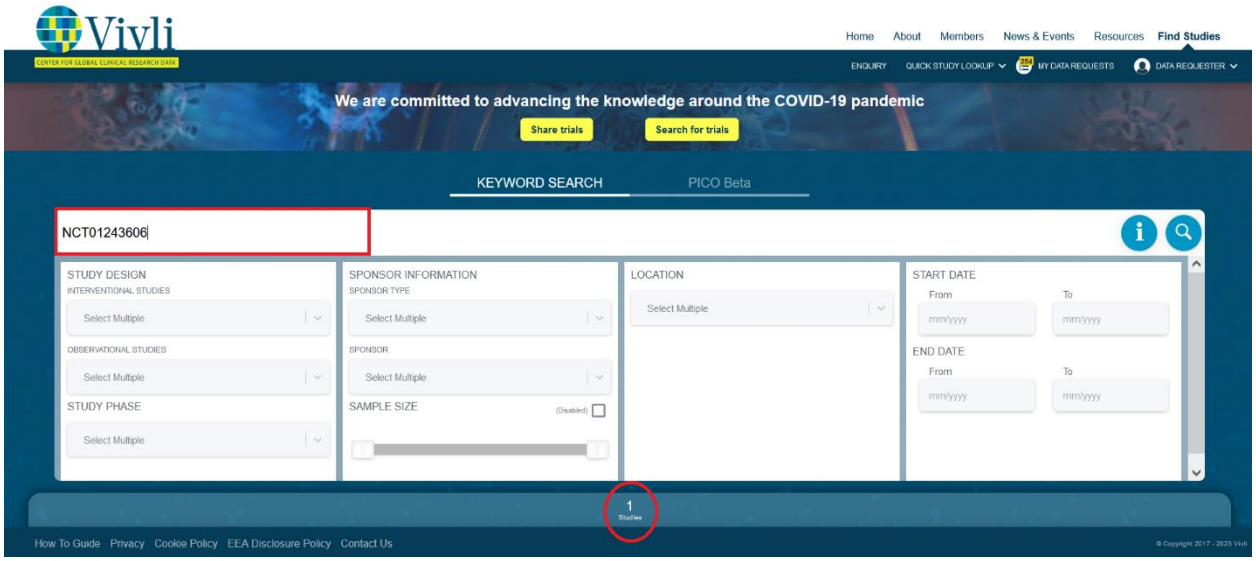


- Once you have submitted the study, you will need to contact Vivli via support@vivli.org to withdraw.

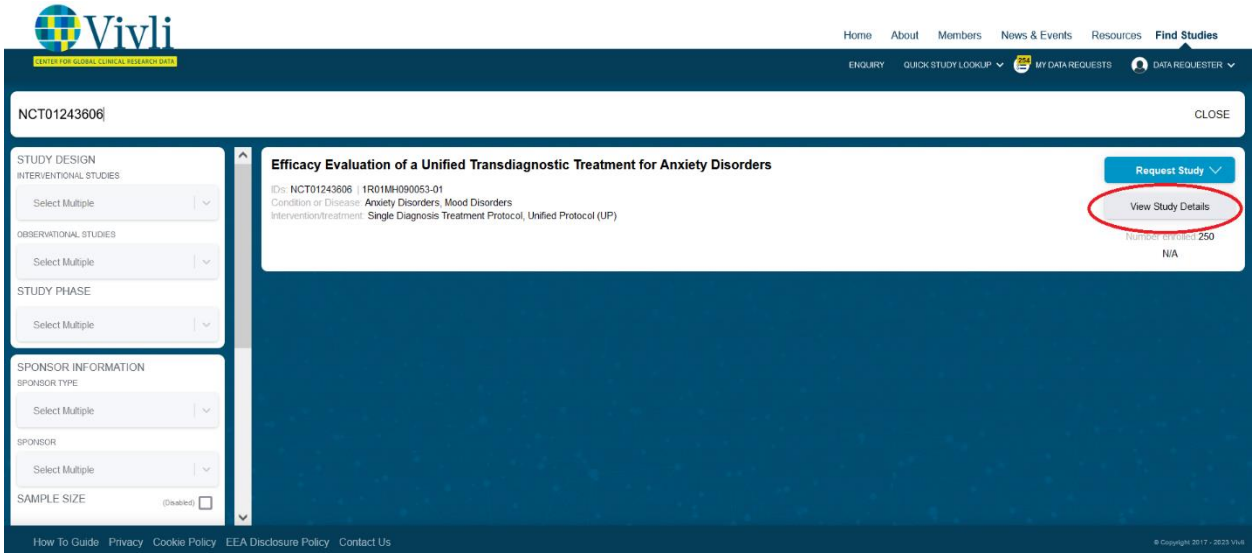
5.0 Viewing your Study Details

5.1 Using Vivli Search

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



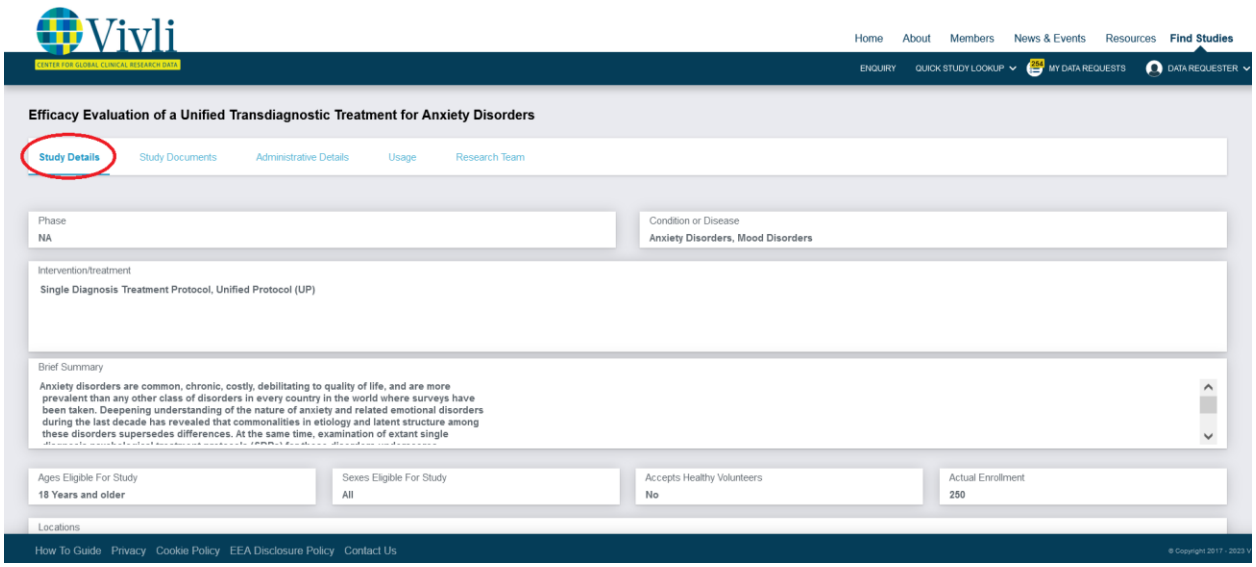
- Verify that the correct study has been identified and click the 'View Study Details' button on the right to pull up the metadata for your submission.



5.2 Study Details

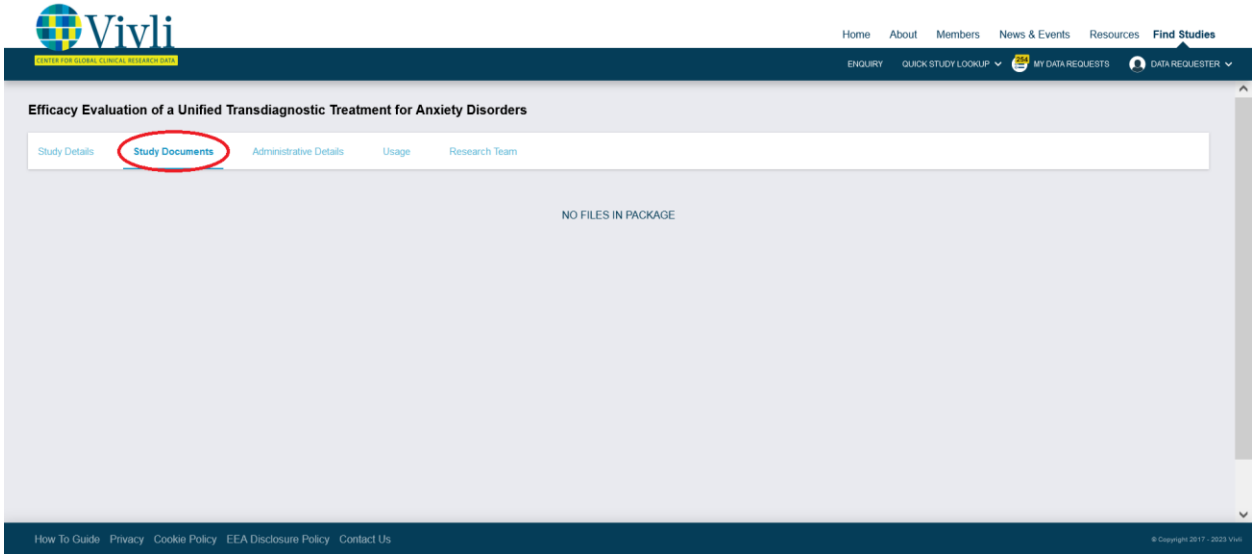
- The first tab of the study listing contains the metadata pulled from clinicaltrials.gov and any additional metadata for the submission.

  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

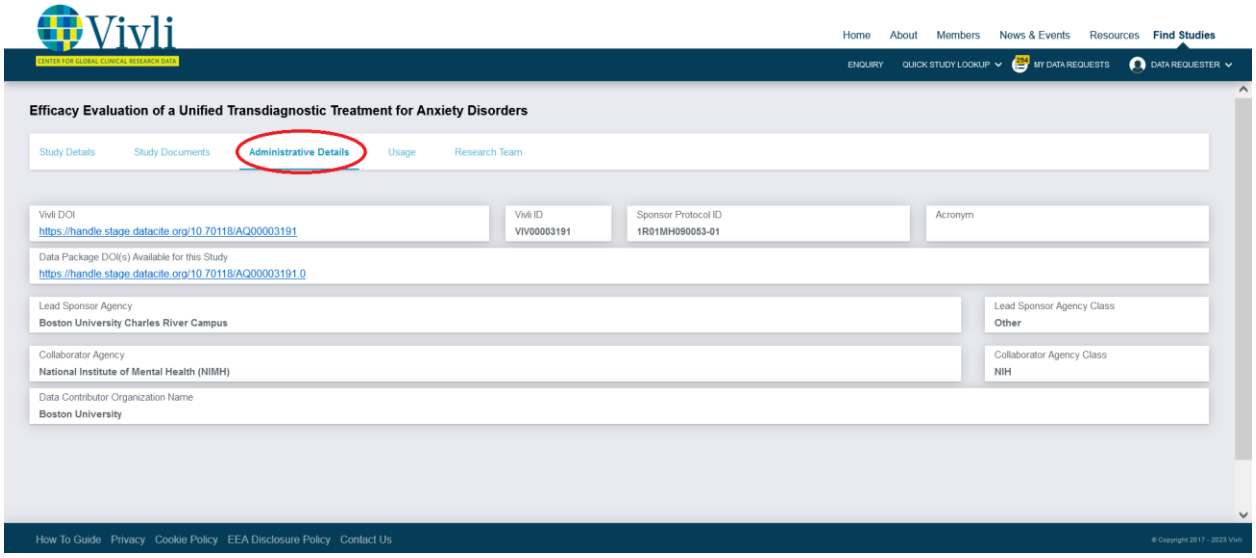
The 'Study Documents' tab is provided to share documents with searchers to help them determine whether the dataset can support their research - this typically will include documents like the Data Dictionary or the Protocol. The study documents should not include the anonymized individual participant-level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



5.4 Administrative Details

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

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



5.5 Usage

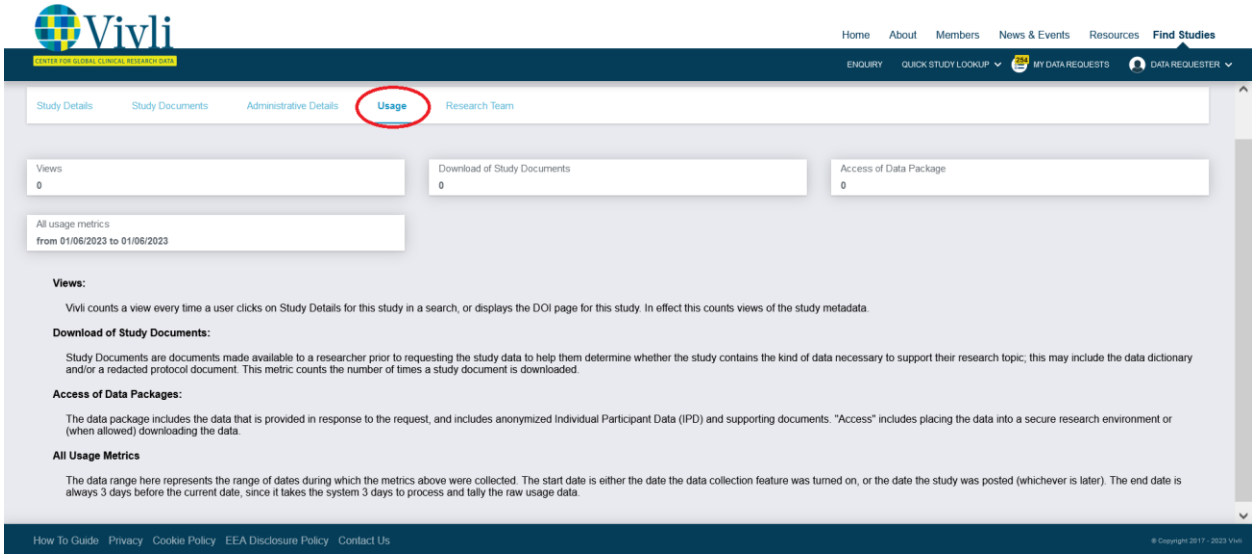
- The Usage tab displays the following metrics related to your study

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

    - **Download of Study Documents**: Study Documents are documents made available to a researcher prior to requesting the study data to help them determine whether the study contains the kind of data necessary to support their research topic; this may include the data dictionary and/or a redacted protocol document. This metric counts the number of times a study document is downloaded.

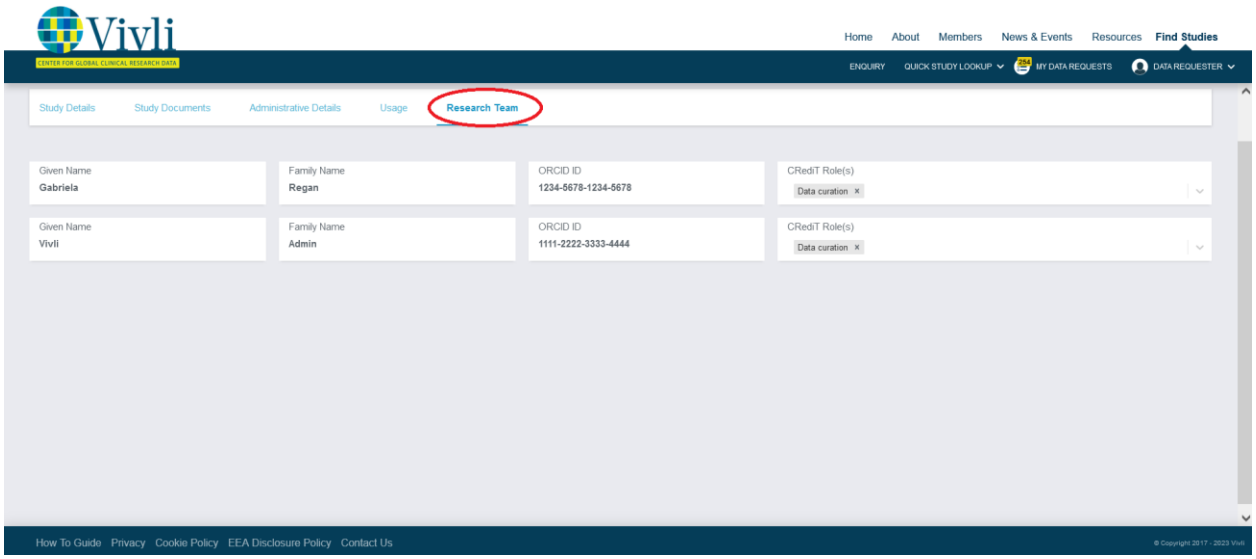
    - **Access of Data Packages**: The data package includes the data that is provided in response to the request, and includes anonymized Individual Participant Data (IPD) and supporting documents. "Access" includes placing the data into a secure research environment or (when allowed) downloading the data.

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



5.6 Adding Research Team Members to your study submission

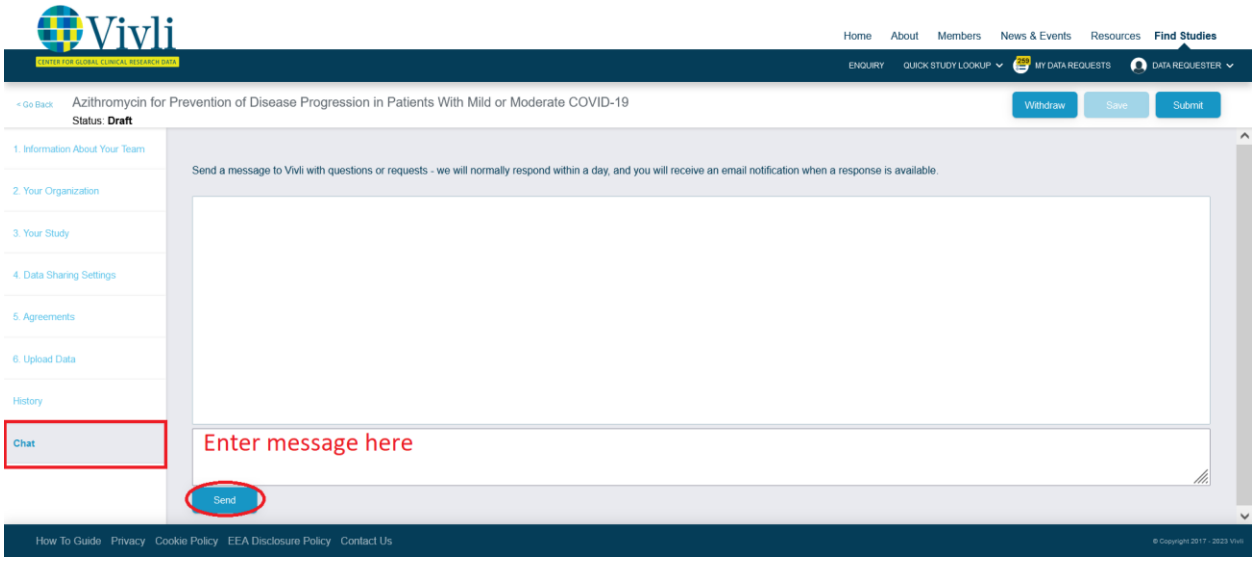
- The Research Team tab displays all research team members that were included as part of the study submission. If you would like to add additional research team members or correct any existing entries after submitting your study, please reach out to the Vivli admin via support@vivli.org.



6.0 Contact the Vivli Team

6.1 Using the Platform Chat

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



6.2 E-mail Vivli Support

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