Vivli Data Contributor Guide
For Vivli Platform Version 3.3
10 February 2024

Contents

1. Accounts for Data Contributors

1.1 Onboarding

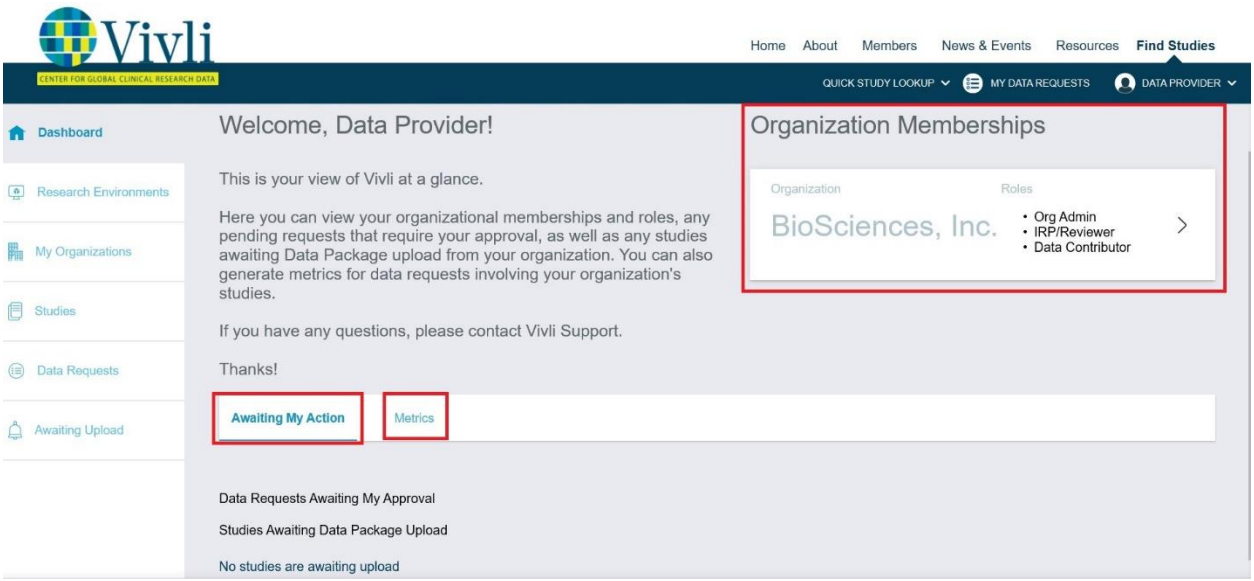
- After your organization joins Vivli as a member or Data Contributor, the Vivli team will begin your onboarding.
- The Vivli team will send you a draft member's page to fill out.
- The Vivli team will provide you with metadata sheets to fill out as part of the onboarding process. Please see Section 2 Listing Studies – Process and Options for more information.
- The Vivli team will send you a copy of the member checklist which defines your data request review process and how your Organization should be set up on Vivli platform.
- You will designate a person or persons within your organization to act as the Organization Administrator(s) on the Vivli platform. See Section 1.33 Data Contributor Organization Roles below for more information about the Organization Administrator's role. The Organization Administrator will create a Vivli account on the platform. The Vivli team will send your designated Organization Administrator(s) an invitation to join the Vivli platform.
- The Vivli team will also provide training on how to review the data request, how to record the decision on the Vivli platform, and how to upload the data package for studies approved in the data request.
- The Vivli team will also send you the Data Contributor guide. Please see Section 1.3.5 Accessing the Vivli Data Contributor Guide.

1.2 Creating your Vivli account

- You can become a user by signing up for the Vivli platform. Please see section 2.0 of the User Quick Start Guide for the sign-up process.
- Before you create your account, please review our Browser and System Requirements.
- If you have any issues creating your account, contact support@vivli.org.
- Once you create your account, inform the Vivli team so that they can issue you an invitation to add you to your organization.
- During onboarding, Vivli Admin will assign you the roles based on your member checklist.
- After onboarding, if there are any changes to your team members or their roles, please inform the Vivli team at support@vivli.org so that they can update the member checklist and provide appropriate training for new team members.

1.3 Vivli Dashboard for Organizational Administrators

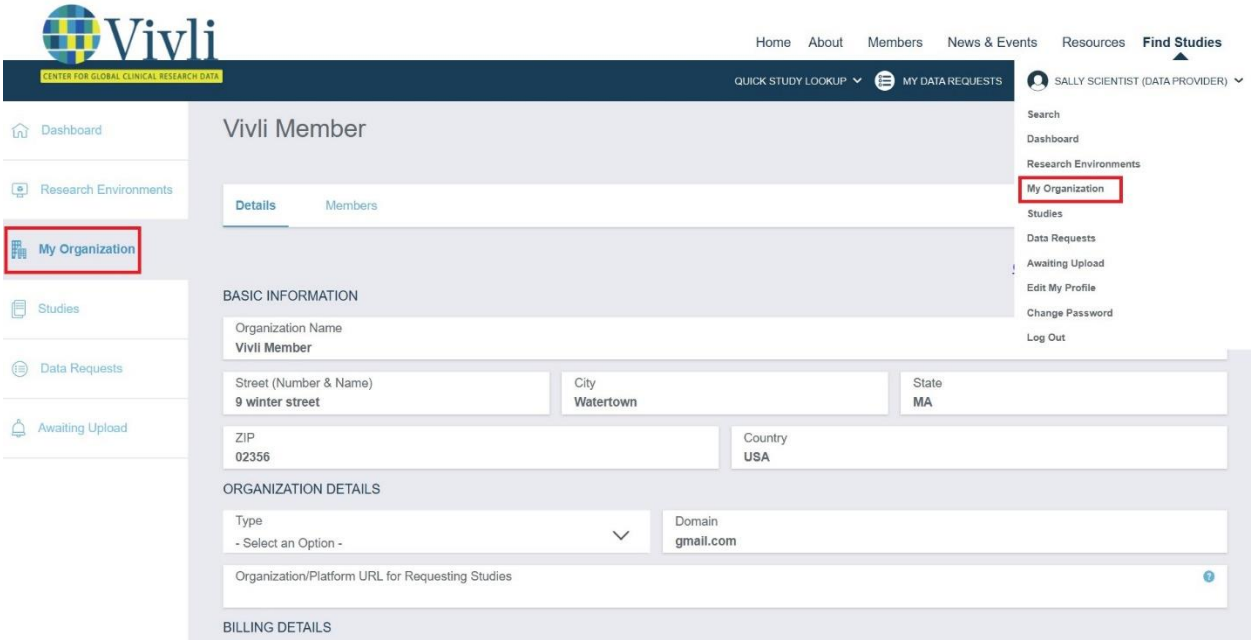
- Once you have been given privileges as Organizational Administrators to your Organization, and have logged in, you will be taken to your Vivli Dashboard.
- On the dashboard, you may view the Organization that you are part of and your roles as part of your organization.
- You may track Data Requests that require review and approval.
- You may track Data Requests and/or Studies needing data package uploads that are awaiting your action.
- You may also view the metrics for your organization.



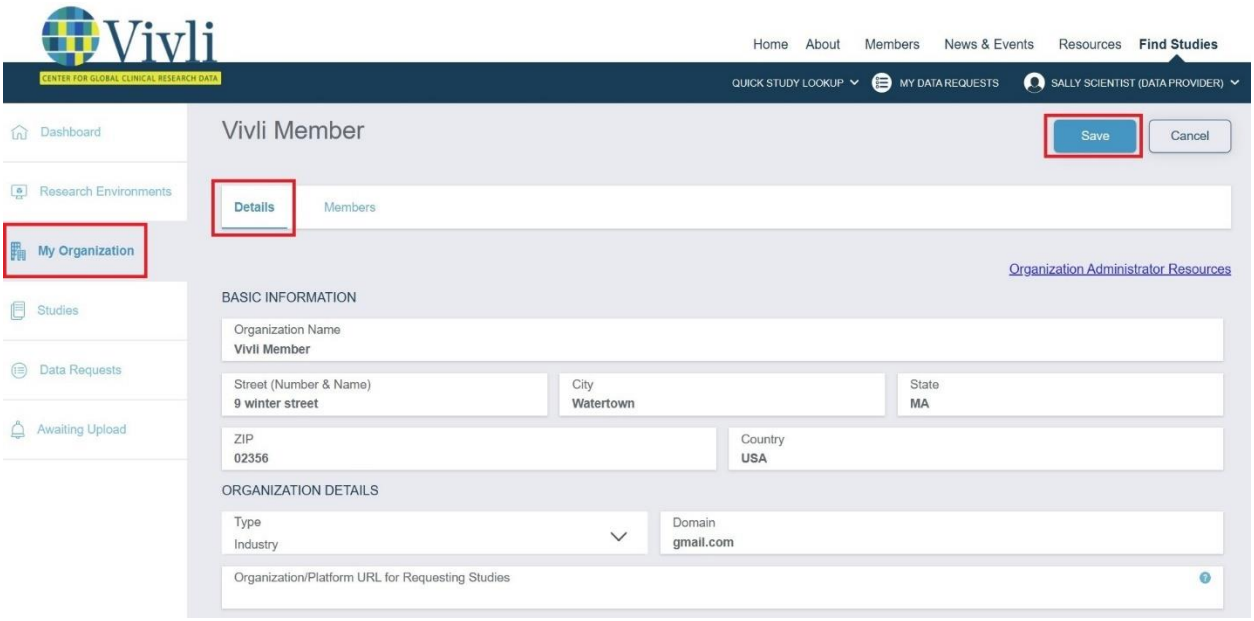
1.3.1 How to Edit My Organization details.

Only the Organizational Administrator can invite other members of your organization to join Vivli and set up permissions for them.

12. From the Dashboard, you can navigate to **My Organization** using the My Organization tab, or the dropdown toolbar in the upper right-hand corner of the screen:

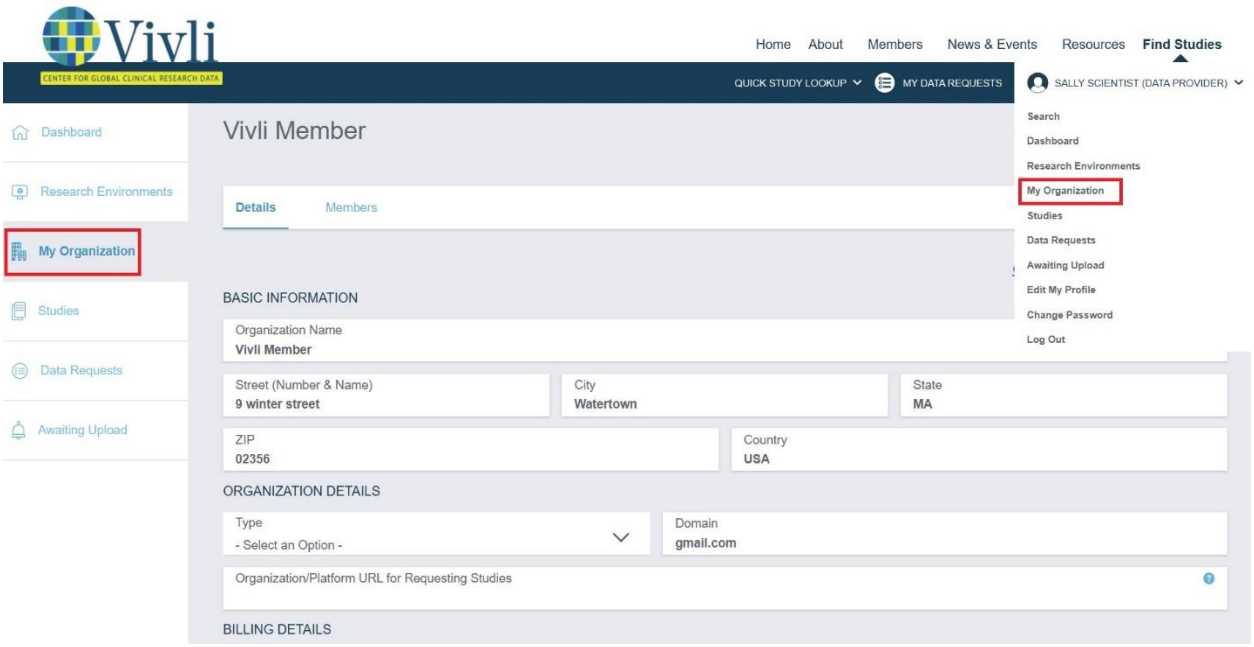


13. You may edit the contact information and click **Save** (To make any changes to Organization policy please contact the Vivli team at support@vivli.org**.**

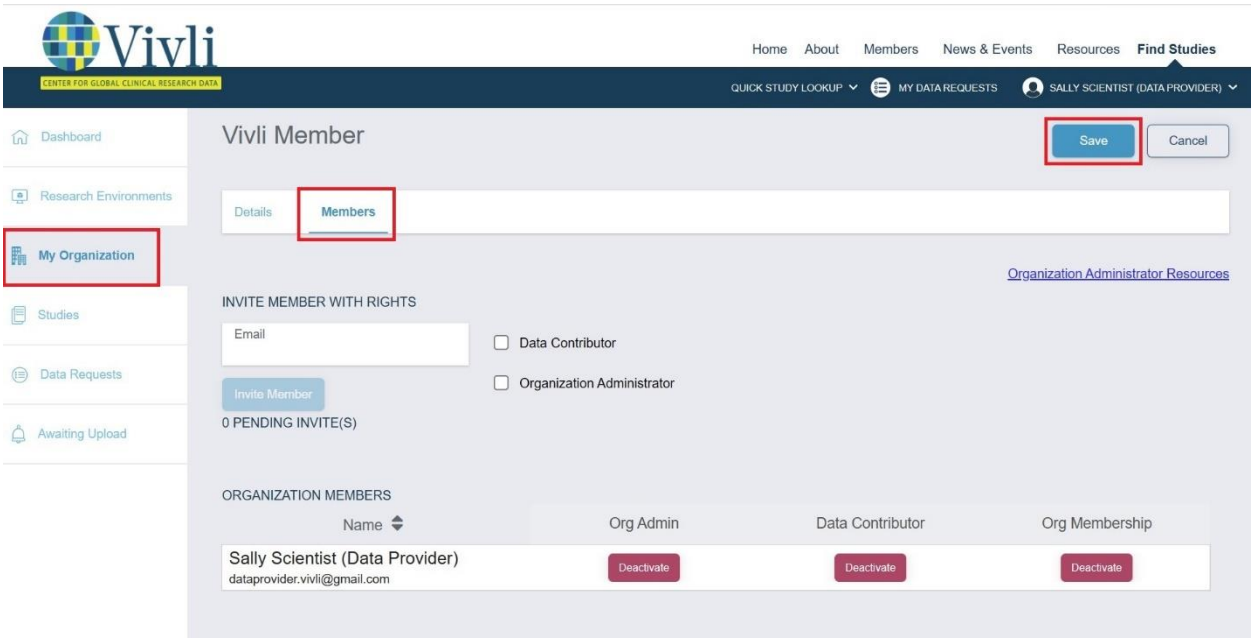


1.3.2 Adding Team Members

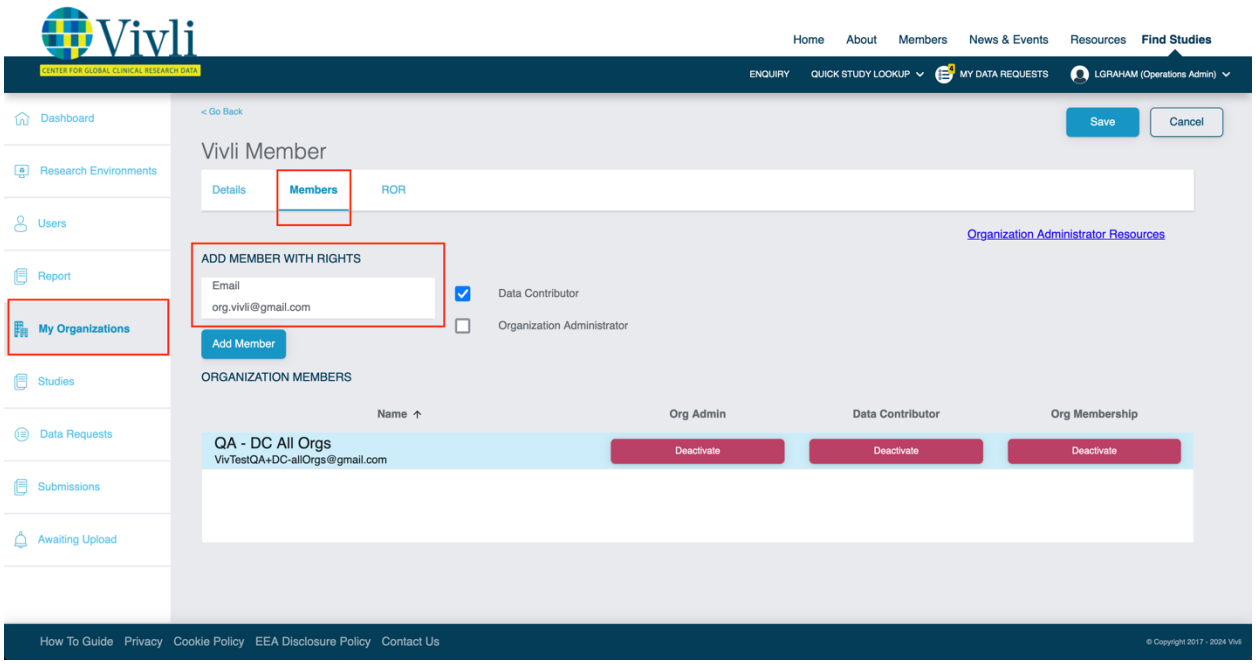
1. To add team members, ask them to become a user by signing up for the Vivli platform and guide them to section 2.0 of the User Quick Start Guide for the sign-up process. Note: the team member cannot be added to your organization until they have created a Vivli User Account.
2. Click on **My Organizations** on the left-hand side of the screen, or navigate to **My Organizations** using the dropdown toolbar in the upper right-hand corner of the screen:



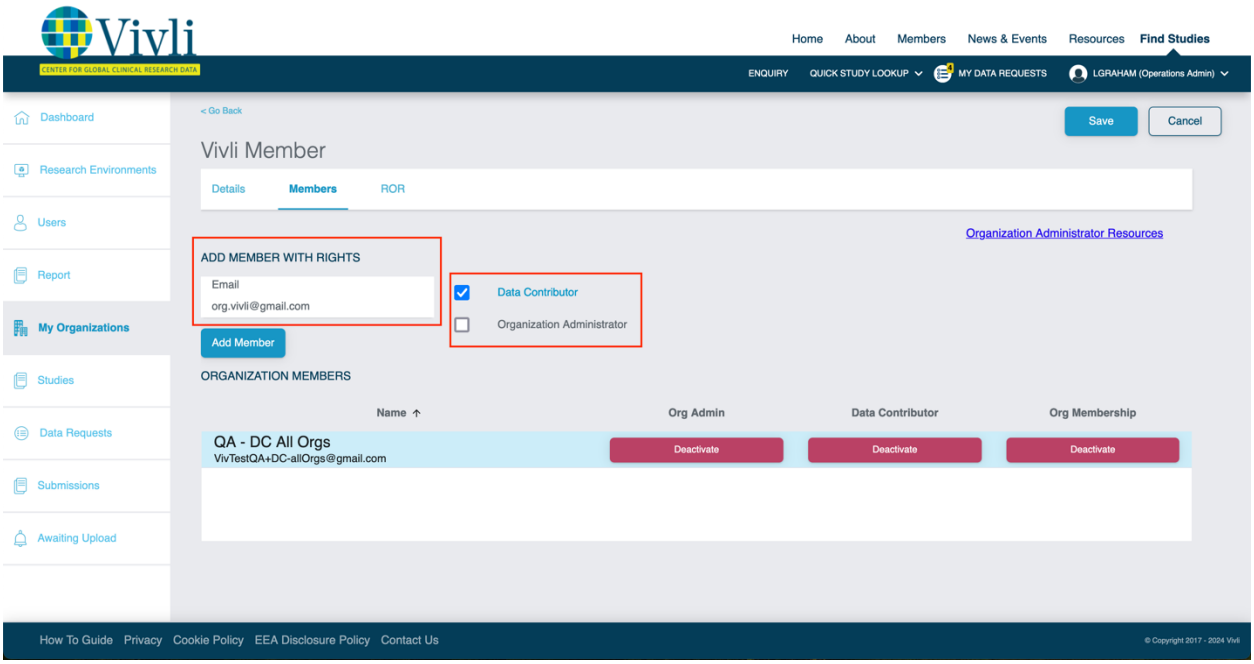
3. To add team members from the Details page, click on the **Members tab:**



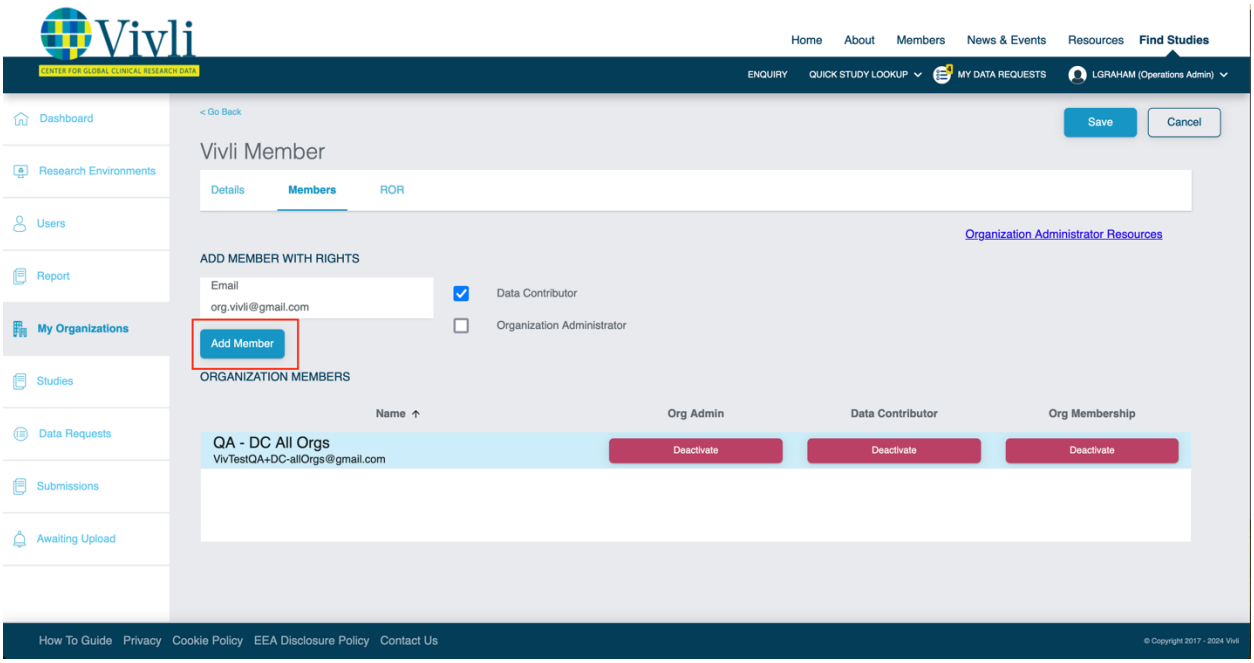
4. You can add the team member to your organization, by simply entering their email in the box, **Add Member with Rights:**



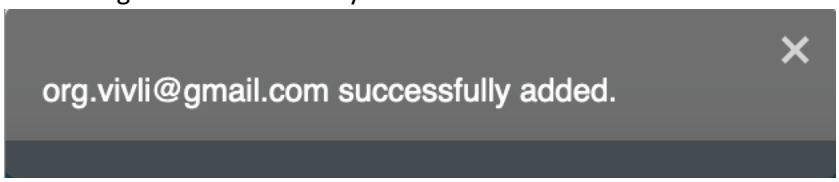
5. After entering their email address, check the box to the right of the email input, indicating their role(s) within the organization:



- **Note:** You may skip this step if you do not want to assign the team member a role. This member will have the right to submit a data request, which is what all users have as a standard on the Vivli platform. After entering the team member's email and selecting their role, click **Add Member:**

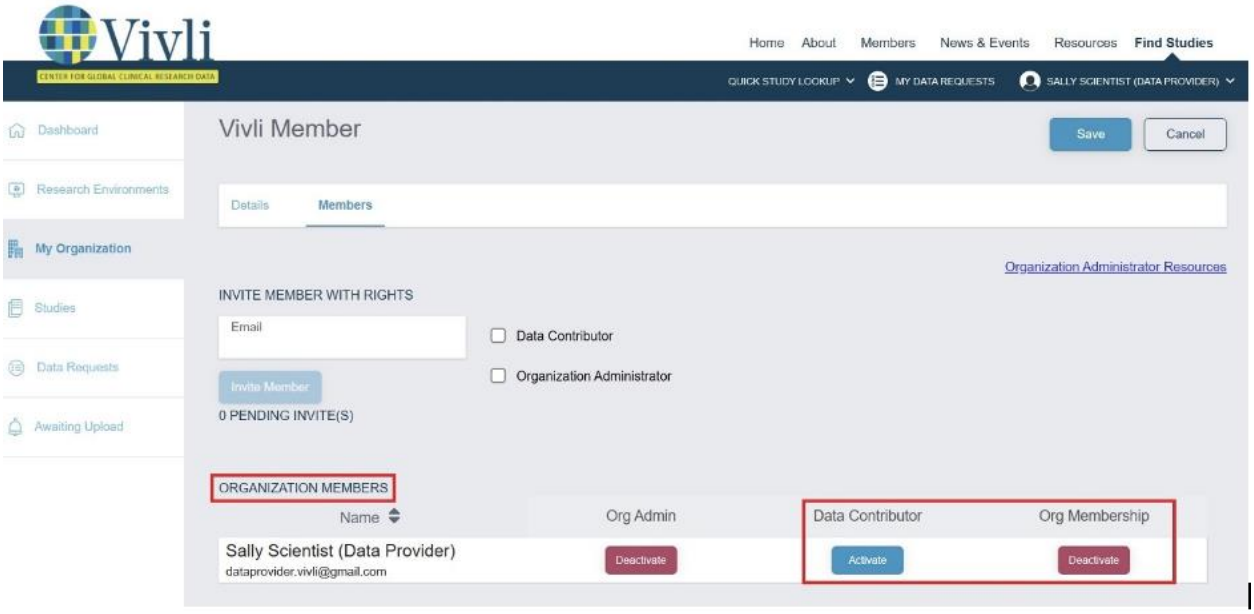


6. After adding the team member, the following confirmation pop-up should appear briefly in the bottom right-hand corner of your screen:

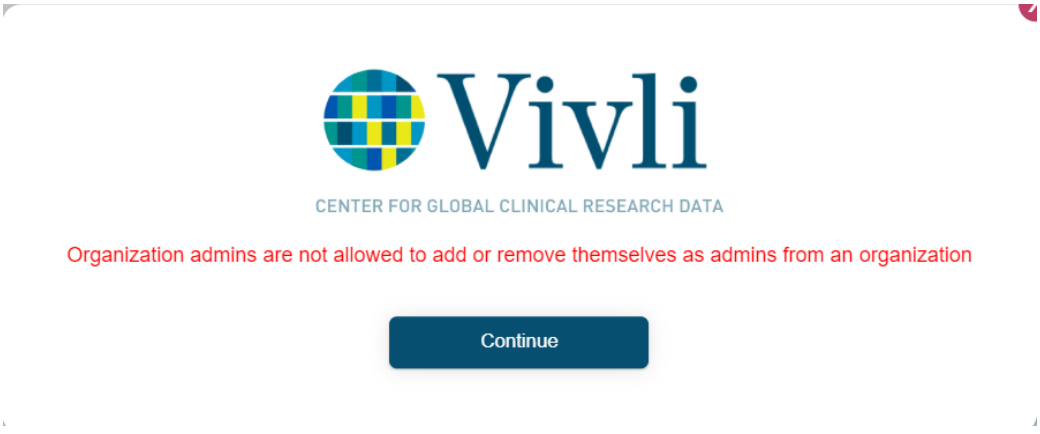


7. If the team member hasn't signed up for a Vivli account, then you will receive the following prompt:

8. Once the team member is added to the organization, the team member's information and roles can be located under the “Organization Members” field. You may remove their roles at any time by clicking on the **Activate/Deactivate button:**

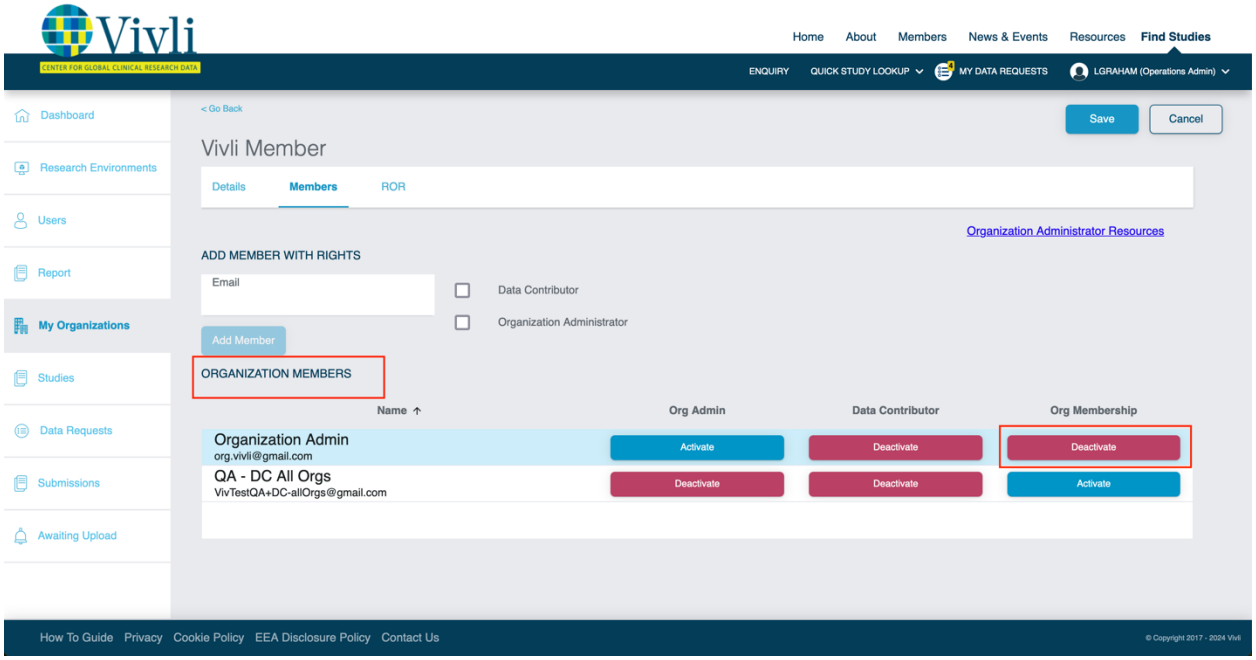


9. To change the Organization Administrator rights for your team member, please contact the Vivli team at support@vivli.org so that they can provide training to the new member, add them to the member checklist, and give them access to the platform. If you click the Activate/Deactivate button under the Org Admin, you will see the following message:



10. To deactivate a member from your organization, you may click on the **Deactivate** button under the “Org Membership”. To reactivate a member from your organization, you may click on the **Activate**

button under the “Org Membership”. If you Activate or Deactivate a team member, please inform the Vivli team so that they can update the member checklist:



1.3.3 Data Contributor Organizational Roles

- A member of an Organization may be assigned multiple roles.
- Each role may have more than one member from your Organization associated with it.
- Additional persons from your organization may also join Vivli as users.
    - Those persons can set up a Vivli account but initially will only be able to request studies.
    - Those accounts will also be listed under your Organizational Dashboard

Please see the following table for an overview and description of these roles:

Vivli Member Role	Description	Rights & Responsibilities
Organizational Administrator(s)	• Main institutional contact(s) for operations on the Vivli platform. • Responsible for recording decisions.	• May add or deactivate your organization’s team members • Assign member roles except for Organizational Administrator rights (contact the Vivli team for this) • Update Organizational Page / Contact details • Responsible for keeping Vivli accounts up-to-date for the organization

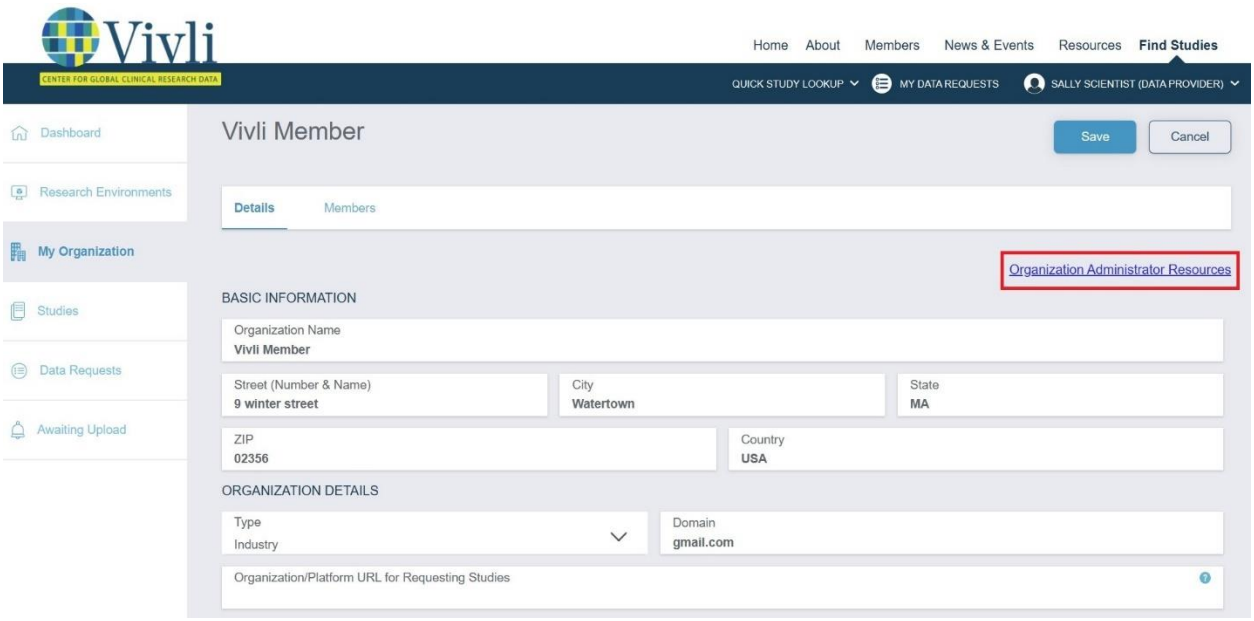
		• View the data request(s) and record the decisions for an Organization • Options are to approve a request, deny a request, or ask for revisions to the data request form. • Receive and respond to chat messages within the data request. • View the internal metrics of your Organization on the Dashboard • Access the Research environment and Report tabs on Dashboard
Data Contributor(s)	• Responsible for uploading data packages for approved requests, after the Data Requestor signs a Data Use Agreement	• Able to upload data packages for studies approved in a data request • Able to upload data packages for all studies at any time after the study is listed on the Vivli platform
No Role Assigned	• May log on to the Vivli platform as a user, but only to create data requests	• Will appear on your organizational members' listing under Members • No administrative rights

1.3.4 Active Platform Accounts

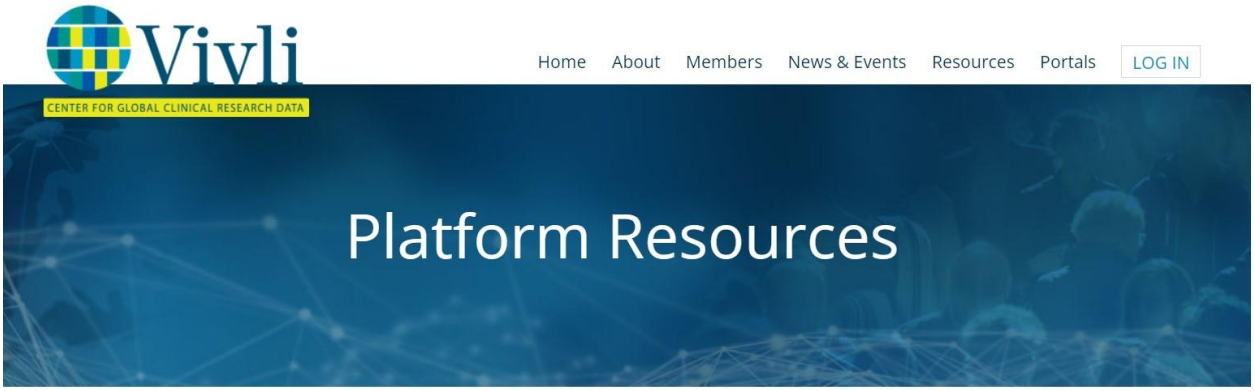
- As part of Vivli's security policy, for accounts to remain active on the platform, we need all users to log in every six months. This includes Steering Committee Members, Organizational Administrators, and any shared inboxes that members may use.
- For users who are part of an organization that is a member of Vivli, if those accounts are inactive for six months, the Vivli team will inform that member's Organizational Administrators and ask them to follow up. If a user wants to maintain their account, the Vivli policy is that the user needs to log on to the platform. Unfortunately, the Vivli team cannot accept notifications via email to keep these accounts active.
- If this is not done within 10 business days, the account will be de-activated. If a user wants their account re-activated, we can re-activate this account at any time by emailing support@vivli.org.

1.3.5 Accessing the Vivli Data Contributor Guide

1. Log on as an Organizational Administrator and open the My Organization page and click the "Organization Administrator Resources":



2. Click the download button to view the updated version of the Data Contributor guide:



Resource	Description	PDF
Vivli Data Contributor Guide	Data Contributor Guide for Vivli platform release 3.3	Download

2. Listing Studies – Process and Options

2.1 Listing Studies- Process

- To list your organization's studies, the Vivli administrator will provide you with metadata sheets to fill out as part of the onboarding process.
- Subsequently, the Vivli administrator will send the person(s) mentioned in your member checklist reminders on the first Tuesday of every month, to list additional studies.
- Data contributors can contact the Vivli administrators to list studies at any time and do not have to wait for the reminder email to send Vivli additional studies for listing.
- To list studies, complete the Metadata sheet(s) with the necessary information and send it to support@vivli.org.

2.2 Listing Studies - Options

There are two types of Vivli Metadata sheets available:

Option	**Applicability**	**Sheet used**	**Fields**
Bulk Metadata upload -CT.GOV listed studies	Single or Multiple studies, all with NCT ID	Vivli Metadata Sheet NCT ID	• NCT ID • Study-specific URL (if applicable)
Bulk Metadata upload -studies without NCT ID	Multiple studies without NCT ID	Vivli Metadata Sheet Non-NCT ID	Contains several columns including but not limited to: • Sponsor ID • Study title • Medicine • Medical Condition • Phase • Sponsor Clinical Registry URLs • Eudra CT ID • Eudra CT URL • Sponsor

2.3 Listing a single study

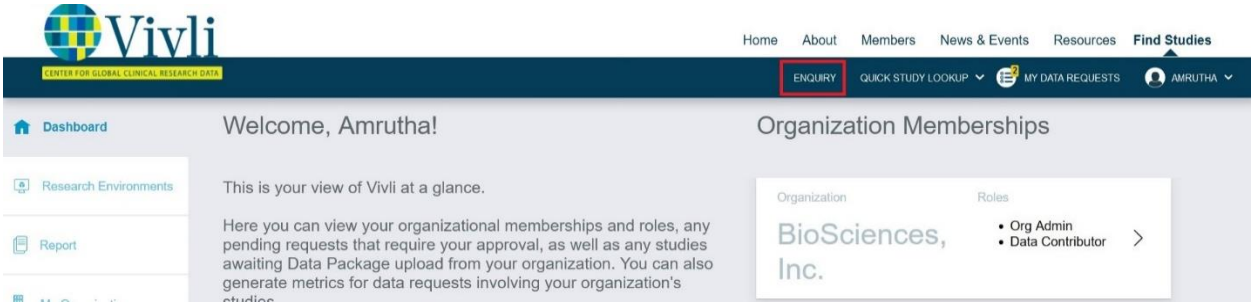
To list a single study, provide the NCT ID to the Vivli Administrator, who will complete the listing process.

2.4 Removing studies from the Vivli search

To remove studies from the Vivli search, please contact Vivli at support@vivli.org.

2.5 Study Enquiry Process

- A researcher submits an enquiry to Vivli regarding the availability of a study not listed on Vivli using the *Vivli Enquiry form*

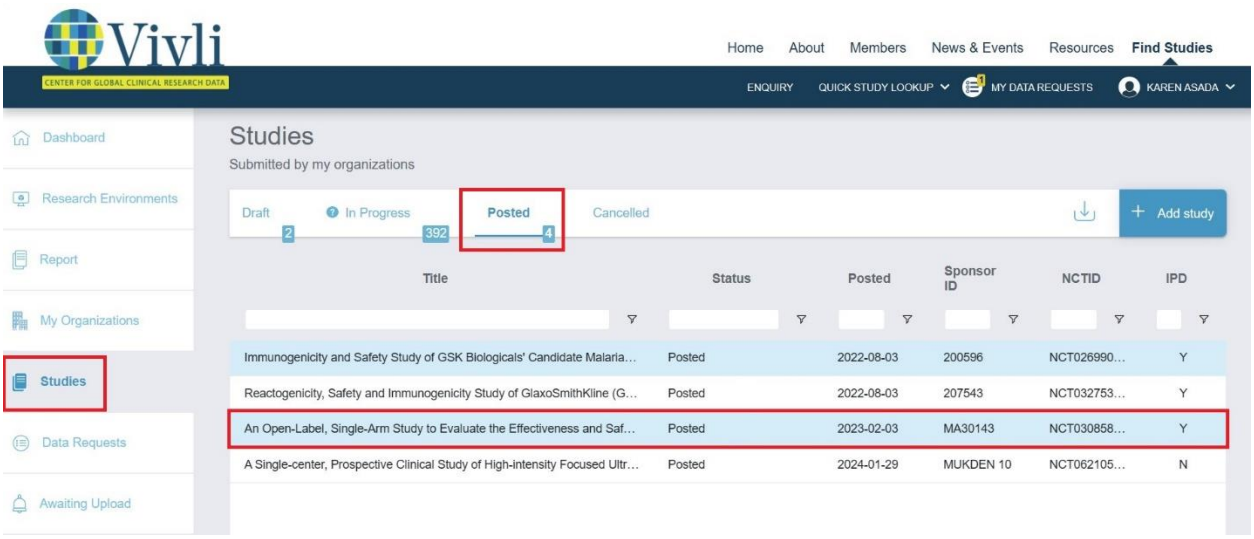


- Vivli Admin sends enquiry details via email including the Enquiry number, PI's name, Email, Study Sponsor/Data Contributor, Study ID, Study Title, and a brief description of the enquiry to the contact of the person at the Member organization to receive such enquiries.
- The contact person at the Member organization responds to the original email from Vivli and provides an update on the study availability status (i.e. available for sharing, in process, out of scope, etc.). If the study is available for sharing, please let the Vivli team know if the study can be listed on the Vivli platform for general request or should be made available only for the researcher.
- An update of open enquiry requests is included in the data request summary. Please see Section 10.3 for data request summary information. Please do not respond to the enquiries through the data request summary or directly to the researcher, instead please respond to the original email sent Vivli about the enquiry.
- Vivli communicates the Member organization's study availability status (i.e. available for sharing, in process, out of scope, etc.) to the researcher and provides instructions for submitting a data request, where applicable.

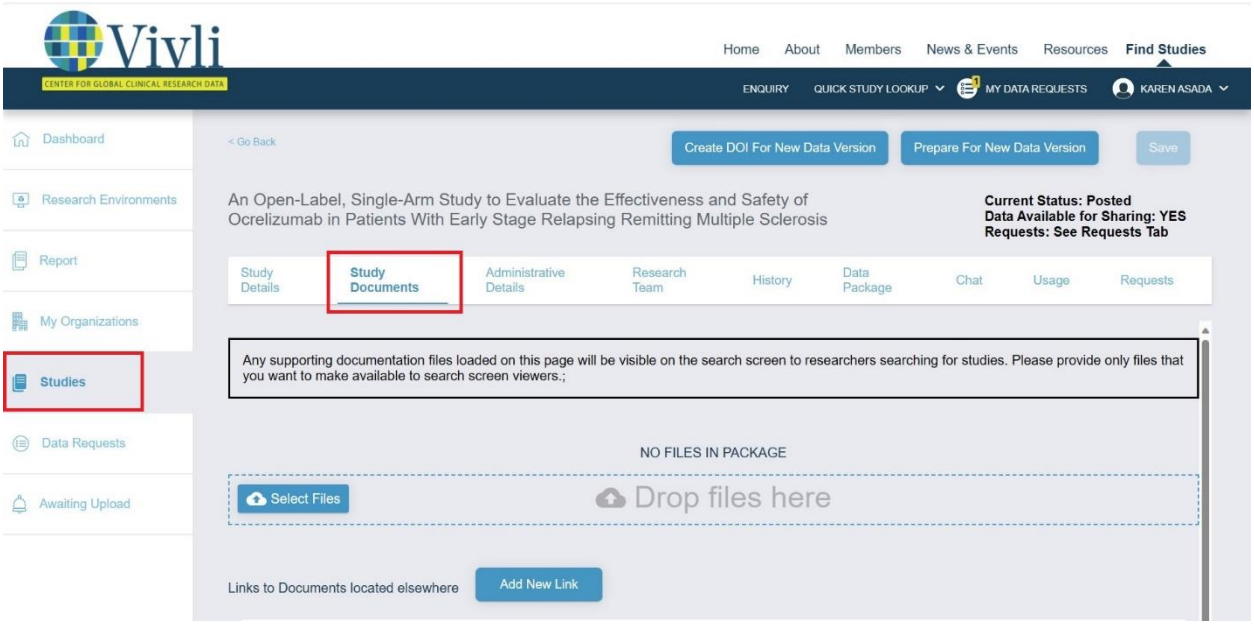
2.6 Supporting documents made available for researchers searching for studies

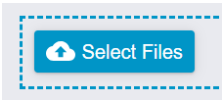
For certain studies, you may choose to make the supporting documents such data dictionary, protocol, and/or the statistical analysis plan, available to researchers while they are searching for studies. You may load supporting documentation files at any time, including after the study has been posted. If you would like to do so, please take the following steps:

1. Go to the studies tab and go to the posted section.

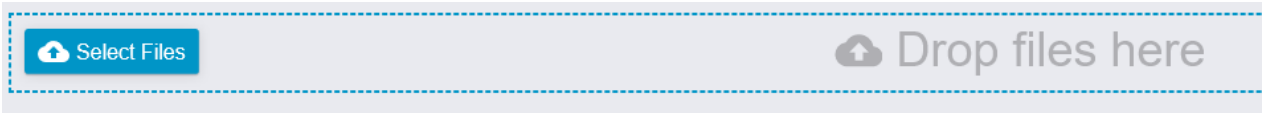


2. Open the study and go to Study Documents

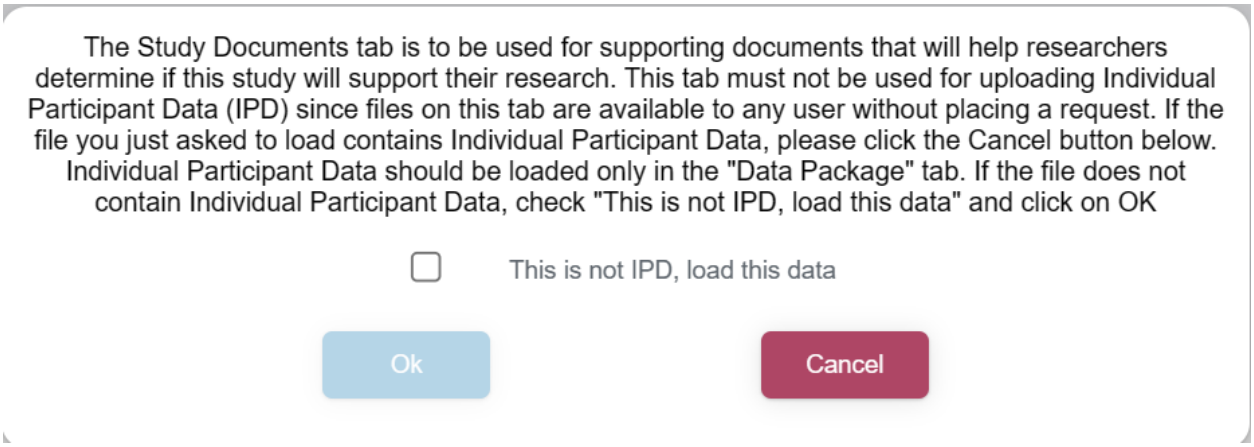


3. Now click on 

to choose files to upload. A window will pop up allowing the data contributor to select the files of their computer. After selecting the files, click **Open.**
4. The data contributor may also drag files into the submit window indicated by the dotted blue box:

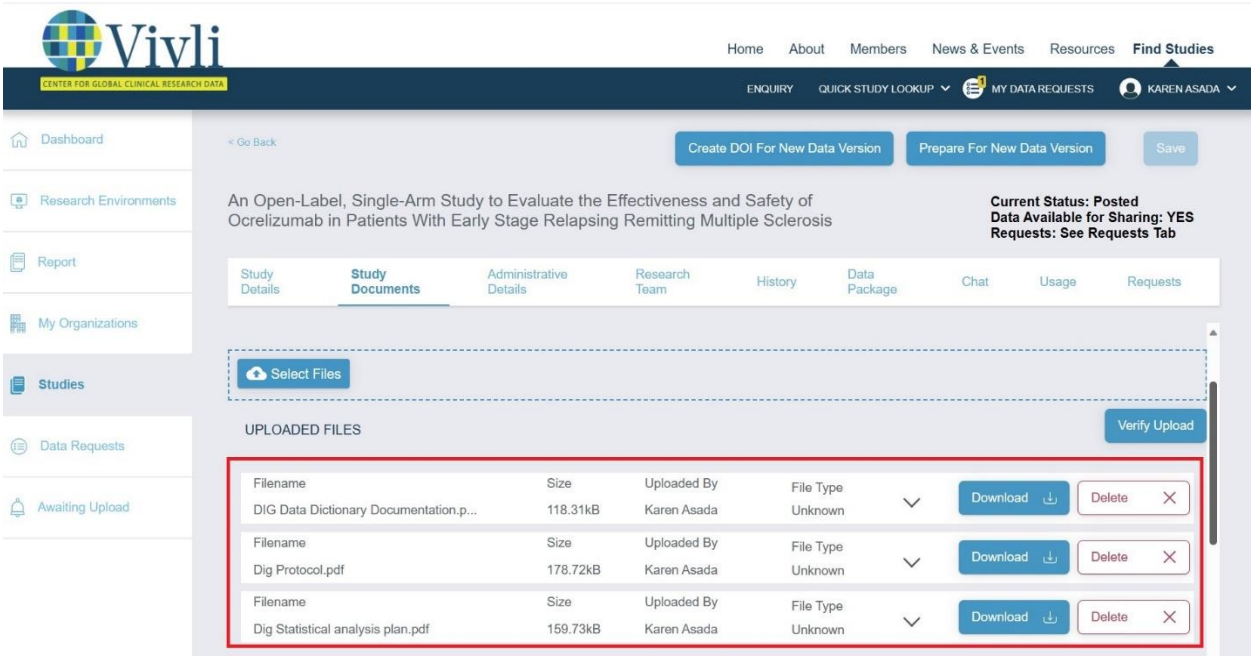


5. **Note**: Individual participant data (IPD) should NOT be uploaded in this section
6. The following window may appear to confirm that IPD files are not uploaded in this section

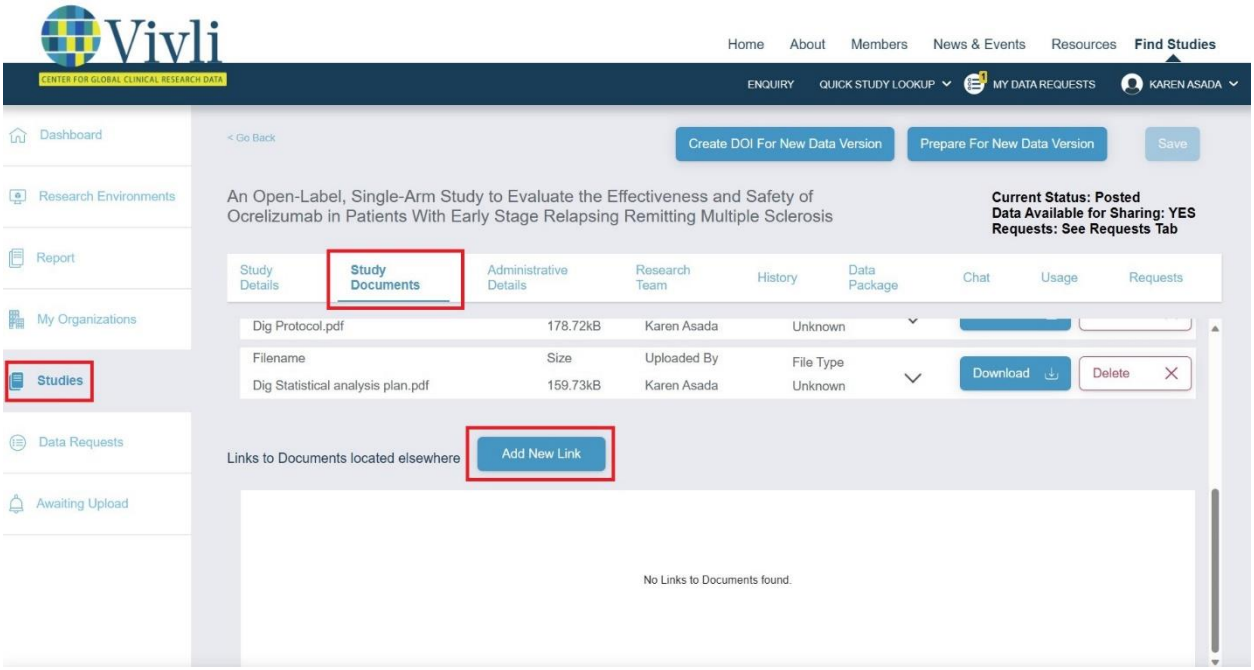


7. Check the checkbox to confirm that the files are not IPD and then click OK.

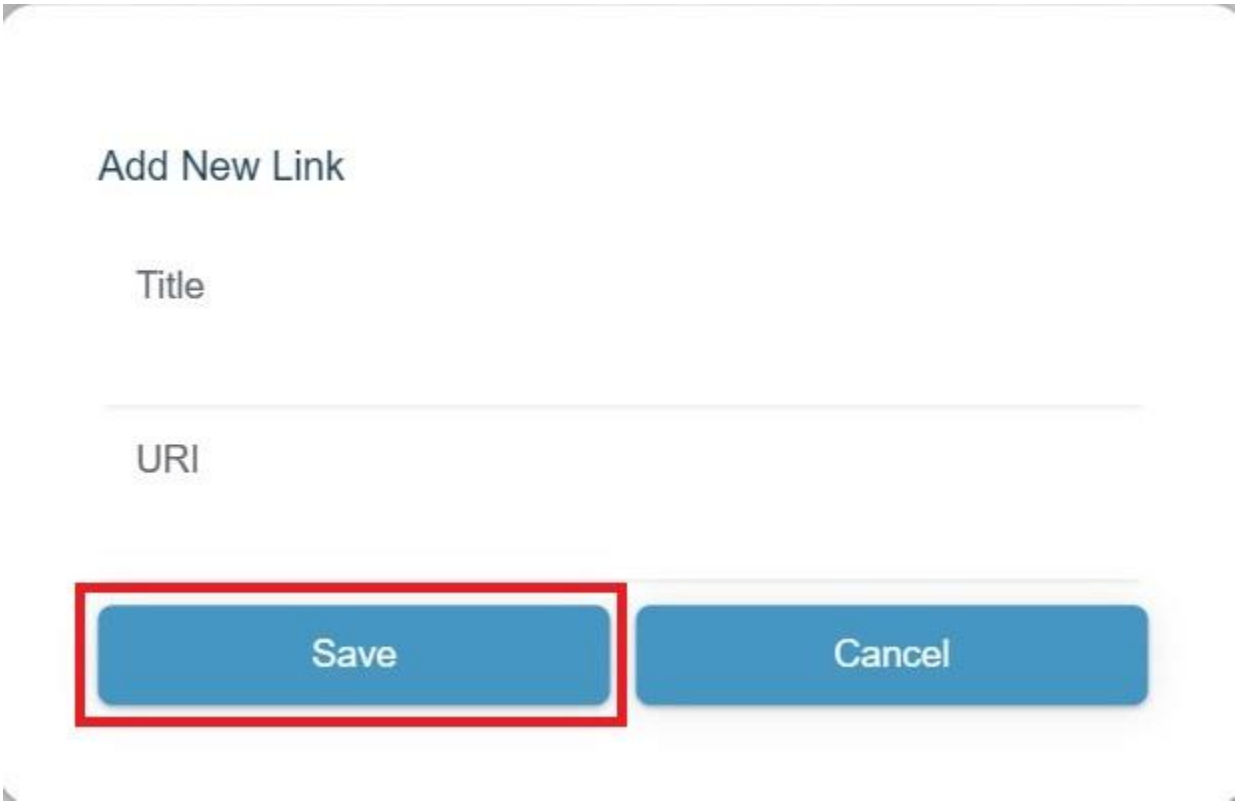
8. You can download the loaded files. You can delete any files by clicking the “delete” button:



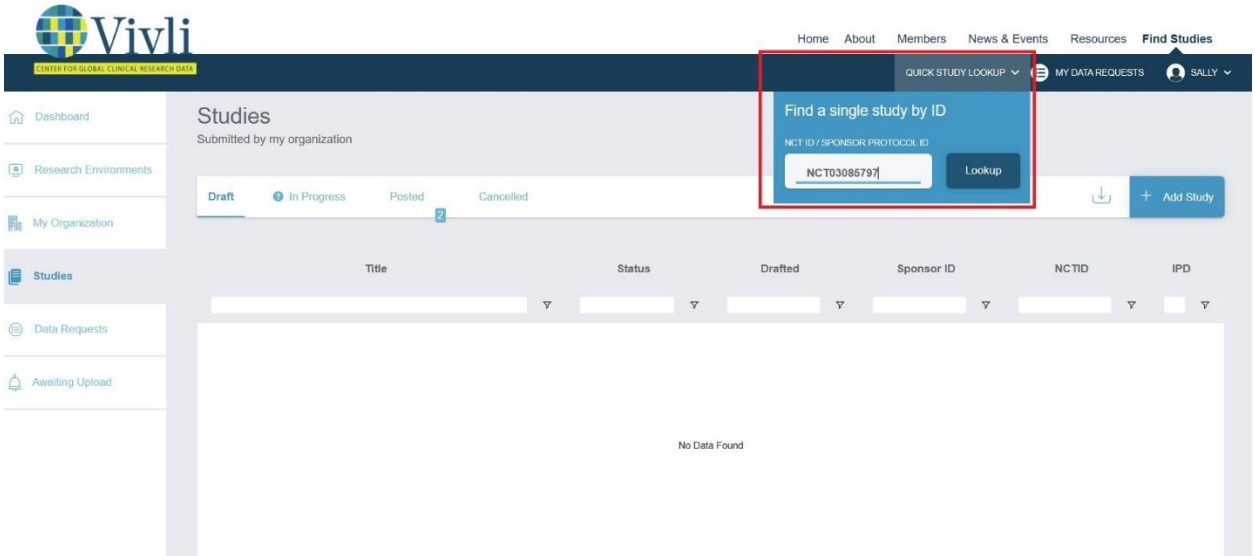
9. You may also Add link to the external website that links to study documents.



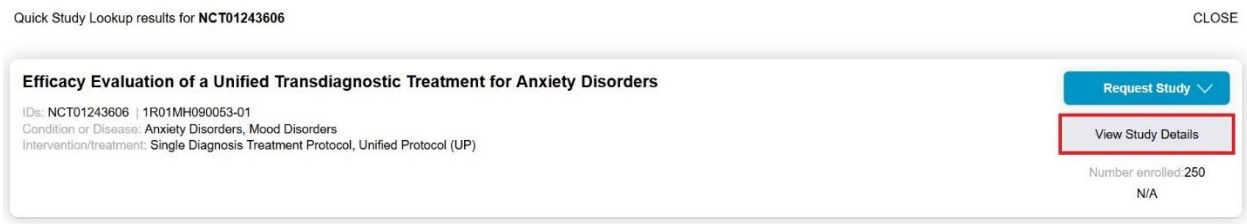
10. Add in the Title and URL and click Save.



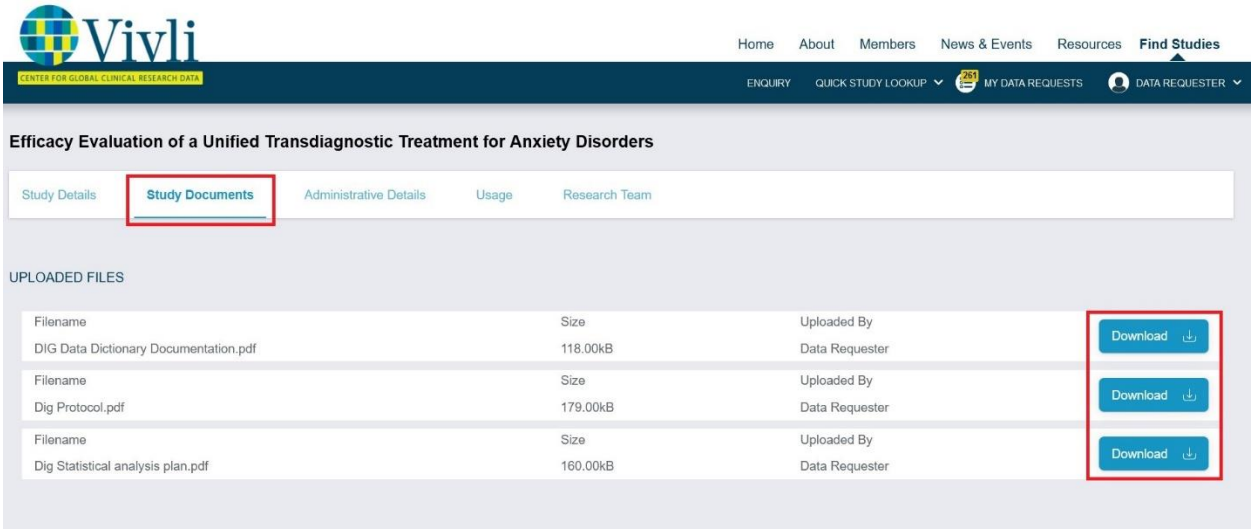
11. You can perform a quick search for the study by typing in the study ID in the "Quick study lookup" search box and clicking Lookup:



12. Click the “view study details” button.



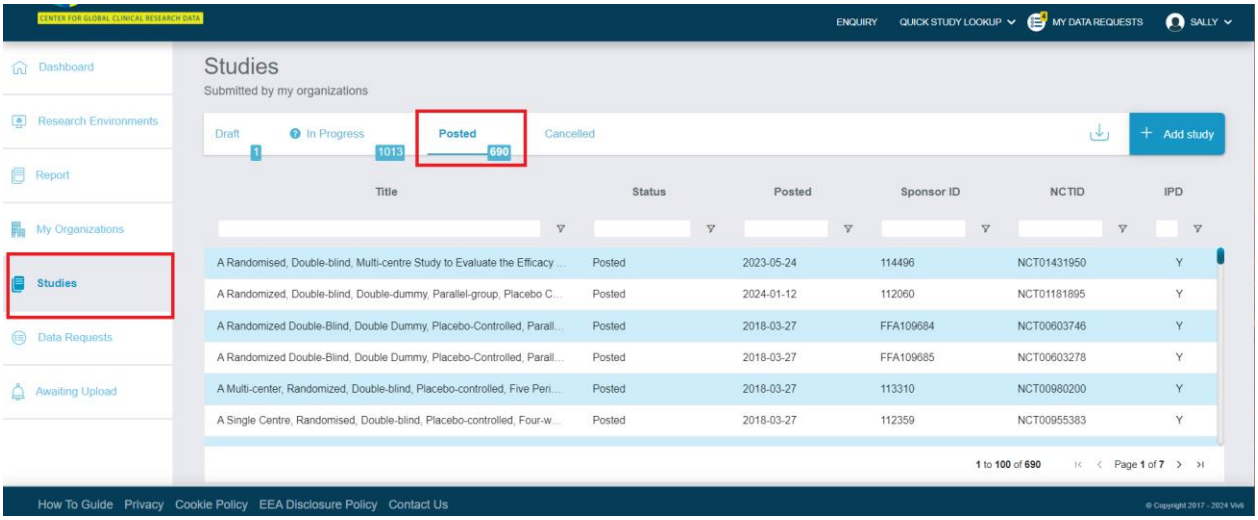
13. Click the “Study documents” section to view the loaded supplemental documents.



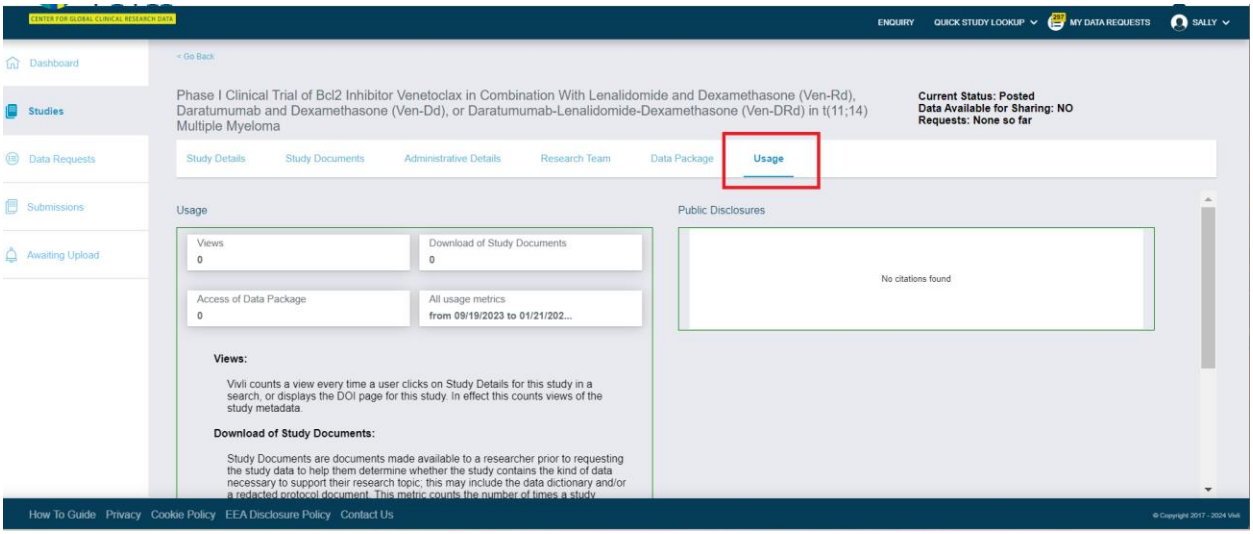
2.7 Study Usage and Public Disclosure Metrics

Metrics on the usage and public disclosures involving studies are available on the “Usage” tab.

1. Go to the studies tab and go to the posted section.



2. Open the study and click on the “Usage” tab.

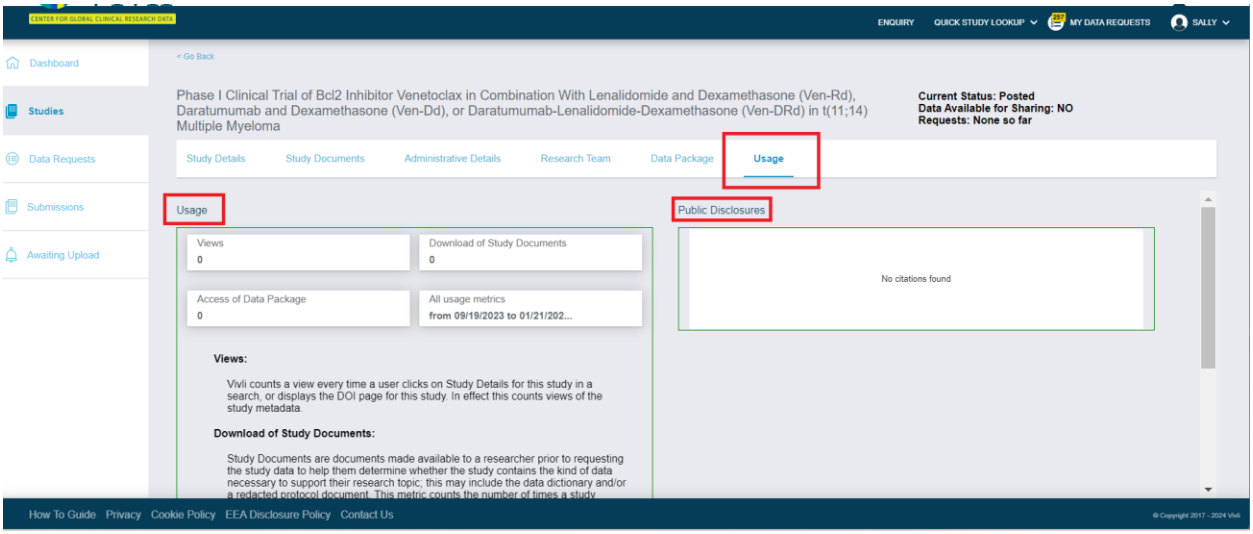


3. Under “Usage” will see the following fields:
    a. Views
        i. Vivli counts a view every time a user clicks on Study Details for this study in a search or displays the DOI page for this study. In effect this counts views of the study metadata.
    b. Download of Study Documents
        i. Study 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. For more information see Section 2.6 Supporting documents made available for researchers searching for studies

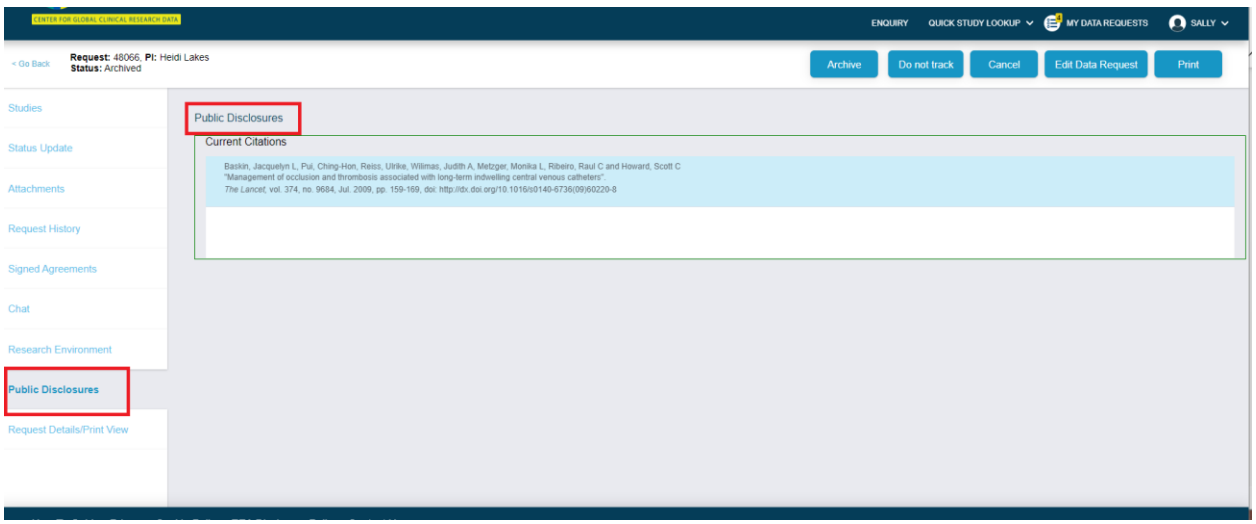
    c. Access of Data Packages
        i. The data package includes the data that is provided in response to the request and includes anonymized Individual Participant Data (IPD) and supporting documents. "Access" includes placing the data into a secure research environment or (when allowed) downloading the data.
    d. All Usage Metrics
        i. 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.

4. Under “Public Disclosures” you will see Public Disclosures which have been linked to this study through a Vivli Data Request.
    a. When a public disclosure is published and the citation is received, the citation is entered into the Data Request, and linked to the Study(s) involved in that Data Request (See 6.3: Public Disclosure on the Data Request)



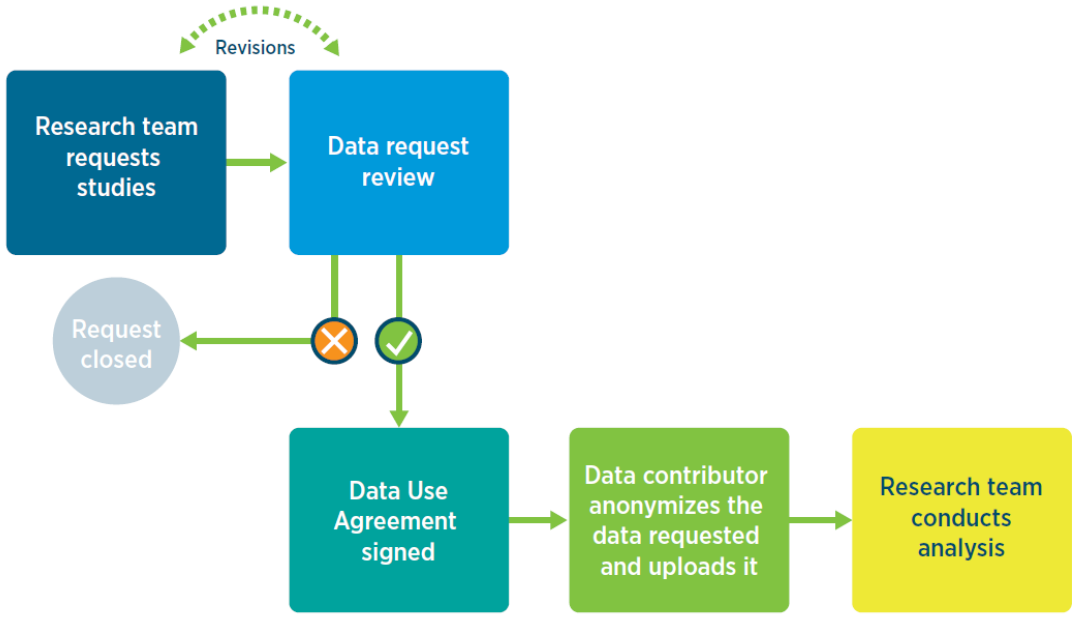
5. You may also view citations linked to a specific data request from by navigating to a data request and clicking on “Public Disclosures” tab. This tab is visible after the request reaches the data upload stage.



3. Reviewing Data Requests

3.1 Overview

- Vivli respects Data Contributors' data sharing policies as noted in their member's page.
- Organizational Administrators are notified of any request for their data.
- Team members with only the Data Contributor rights cannot view or review the data requests until it reaches the data upload stage.
- Information about the approval, reasons for rejection, DUA and publications can be found in the publicly available Metrics on the Vivli website Metrics Page.
- Below is the overall review process

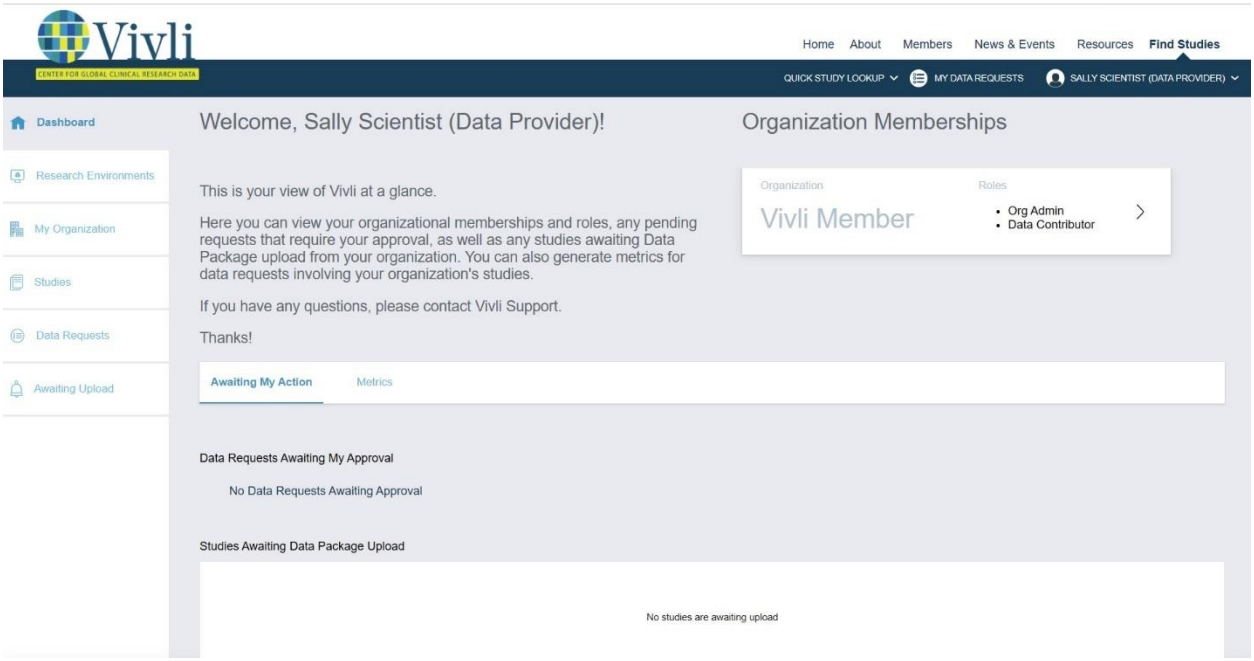


3.2 Data Request Review

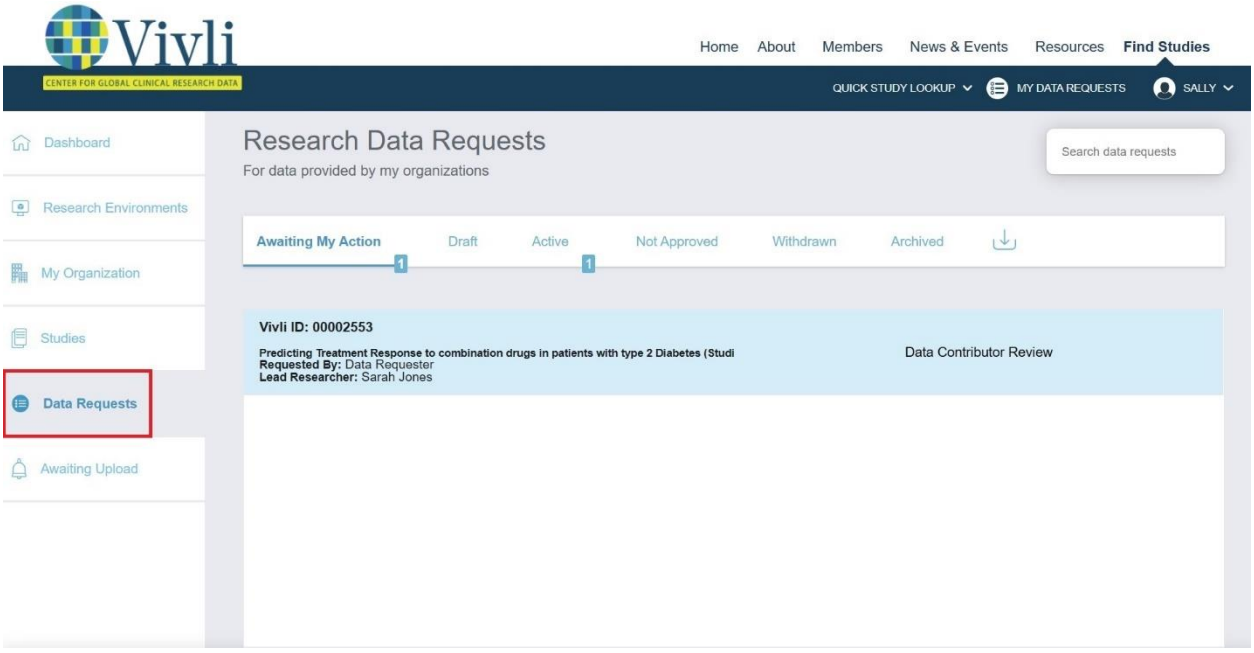
- You will receive an email notifying you when a data request is ready for review.
- Only Organizational Administrators can see and review Data Requests waiting for review for your organization.
- You must log in with your account to see Data Requests directed to your organization

3.2.1 Navigating to Data Requests

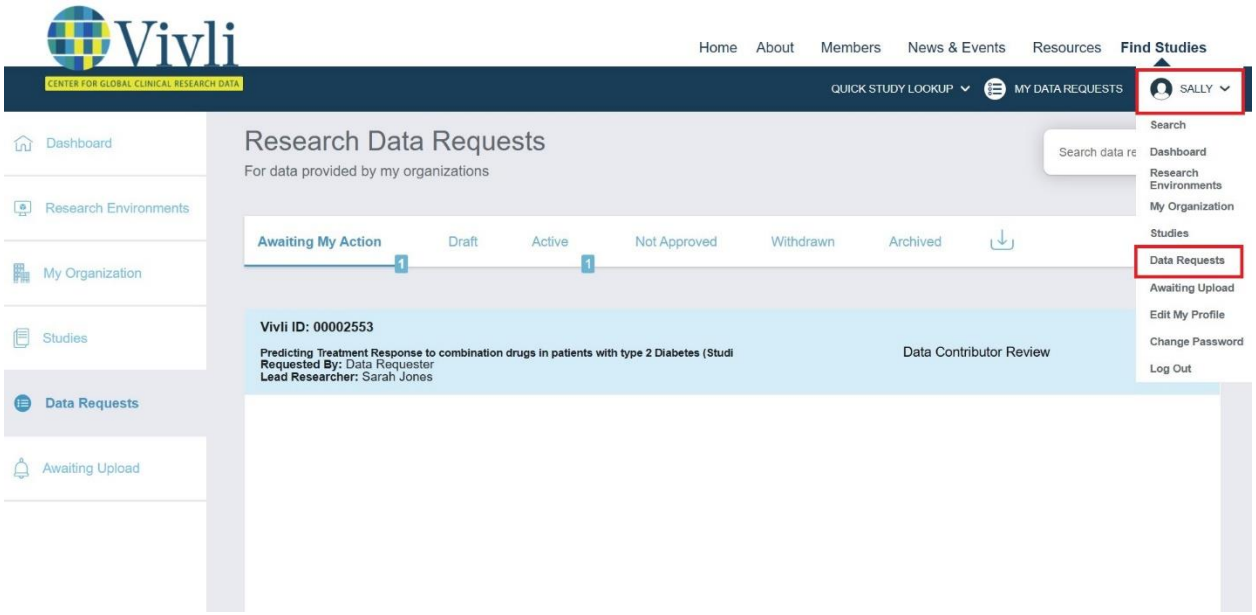
1. Log into your account



2. Once you have logged in to the dashboard, you can navigate to Data Requests using the toolbar on the left-hand side of the screen:

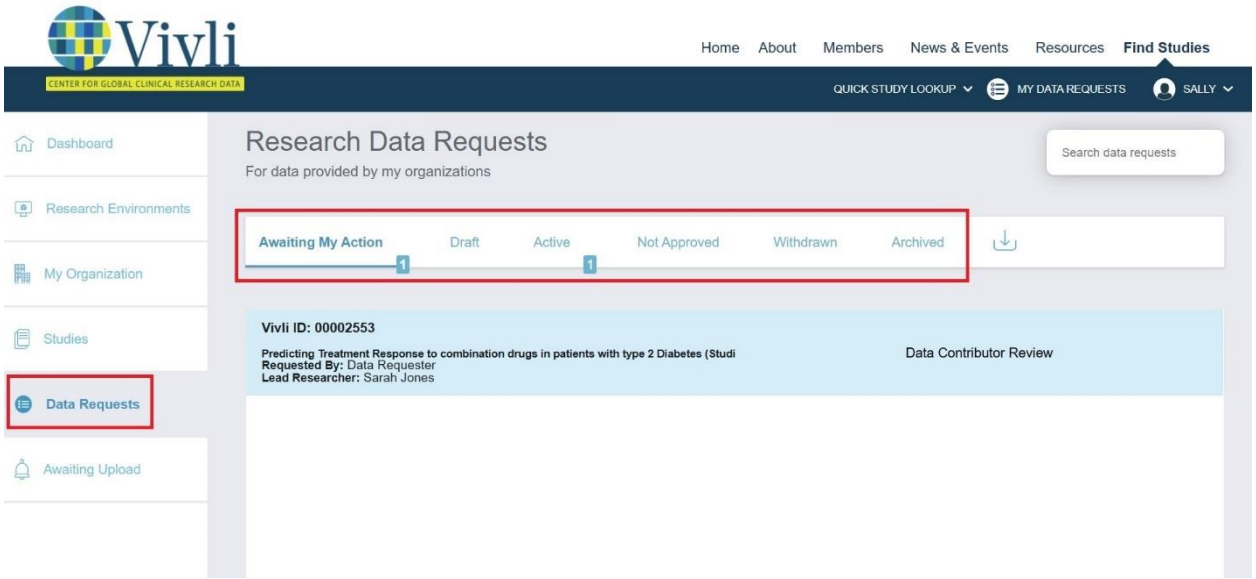


3. You can also use the dropdown menu on the upper right-hand corner of the screen:



Note: Please ignore the "My Data Requests" located along the top of your Dashboard. That link is for data requestors to access their data request forms.

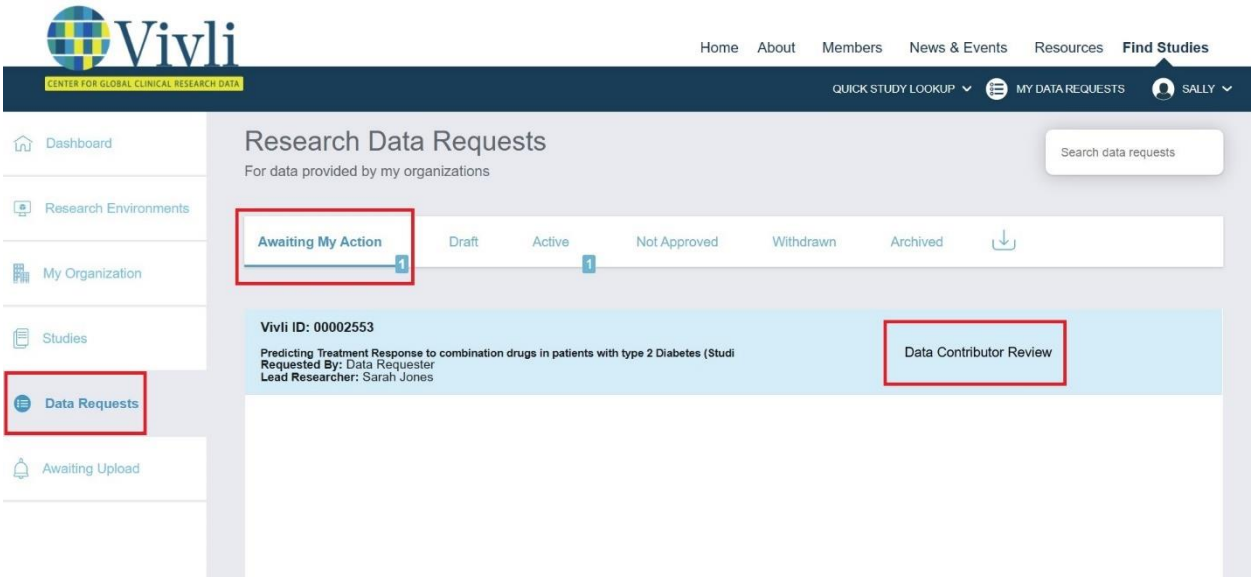
4. The Data Requests Dashboard displays a status bar at the top of the page which displays all the data requests for your organization's studies.



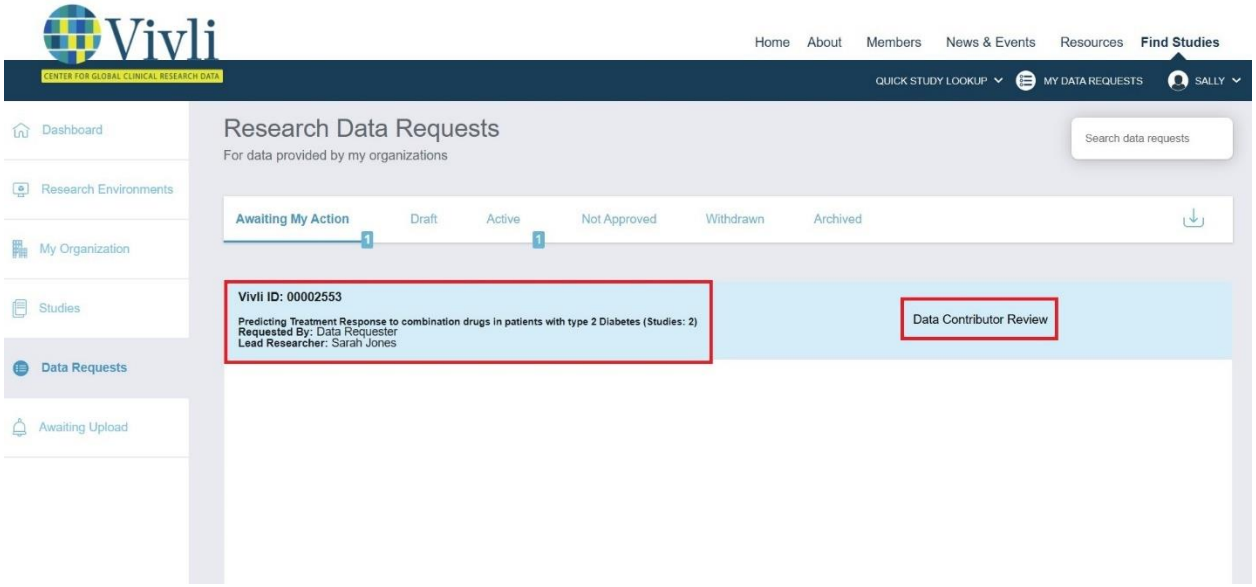
5. The status bar contains 6 sections:

Awaiting My Action: Displays Data Requests that are awaiting your action.
Draft: Displays Data Requests that are being drafted but not yet submitted and hence don't have a Vivli ID.
Active: Displays Data Requests that are in progress. This includes requests in the Vivli form check stage, requests that were sent back for revision, requests in the Data Contributor Review stage, IRP review stage, DUA validation stage, awaiting data package upload stage, and requests where some or all of the data packages have been uploaded. It also displays requests that are currently in the analysis stage, awaiting results review and awaiting publication review.
Not Approved: Displays Data Requests that are denied. It also temporarily displays requests where revisions were requested until the Vivli Admin moves the requests to draft.
Withdrawn: Displays Data Requests that were withdrawn
Archived: Displays Data Requests that were completed including those with publication or summary of results provided

6. The Awaiting My Action section displays a quick view of all the Data Requests that are awaiting your action including requests waiting for approval and requests where data upload is required. By default, the requests are sorted by request number, in descending order (this amounts to the newest first)



7. Each data request recorded on the dashboard displays the Vivli ID, Project name, Total studies count in parenthesis at the end of the Project name, Lead Investigator Name, Submitter Name, and current status of the data request. From the request dashboard, reviewers can also hover over lengthy request titles to view the full title.

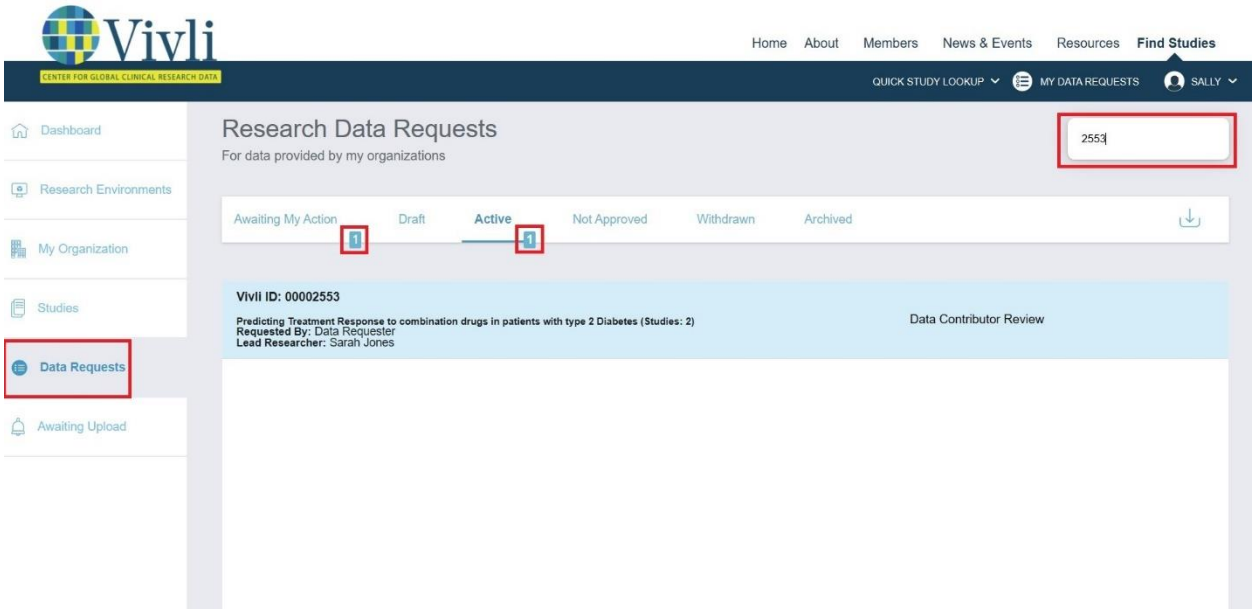


3.2.2 Data Request Dashboard – Search Feature

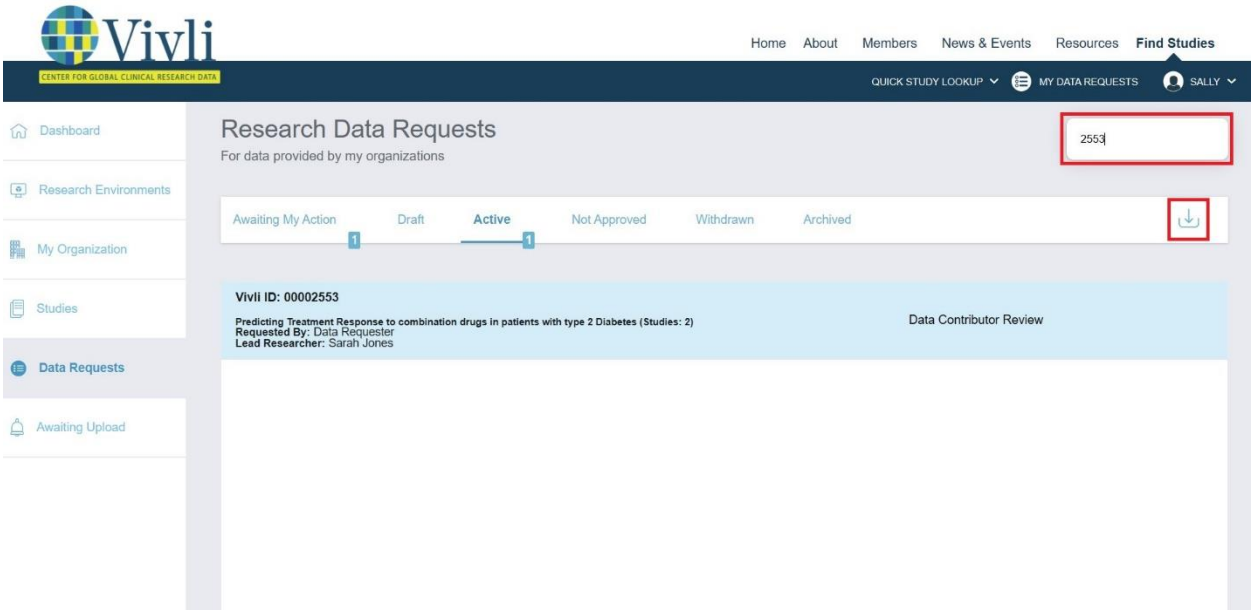
You may search for data requests using one of the following fields (you can only view data requests where one of your studies has been requested):

- Data Request Title/Project Name
- Data Request ID,
- Submitter Name or Email
- Lead Investigator Name or Email
- Data Contributor Organization

Note that after clicking on the Data Requests tab, you should wait until the requests are displayed before initiating the search. The numbers point out the number of requests that match the search criteria and the status of the data request.



Once you search for a particular data request or particular search criteria, you can export all visible records to a CSV file. You can also export all your data requests to a CSV file without any filtering.



The downloaded file contains:

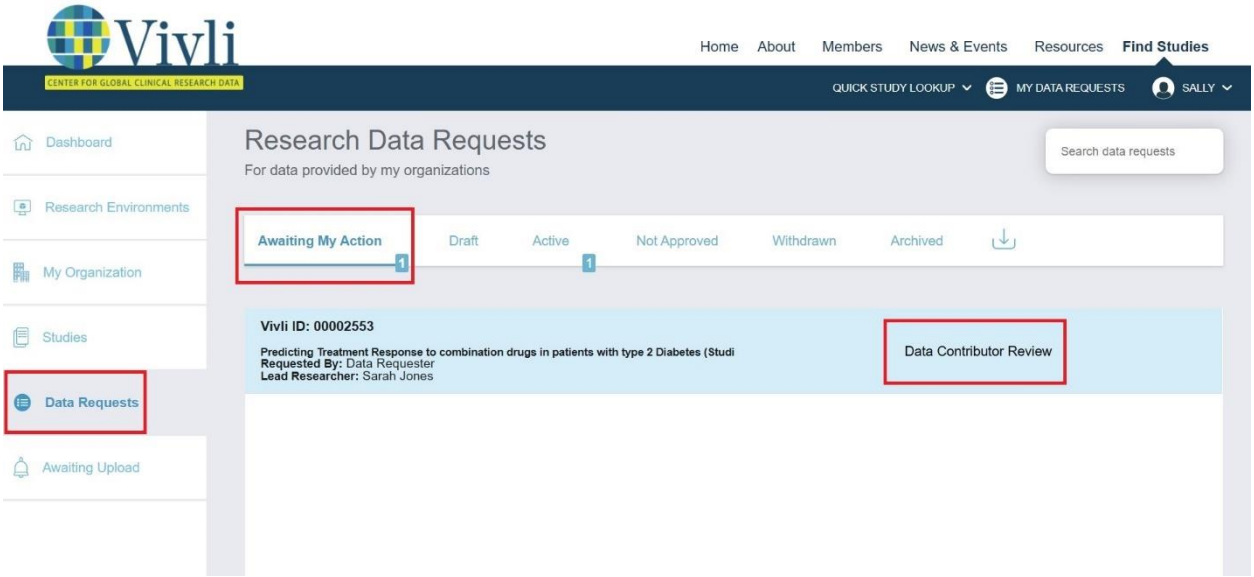
- Data Request ID,
- Request Title/Project Name
- Submitter/Requester Name and Email
- Lead Investigator Name and Email
- Request Status
- Date of the last action
- Data Contributor Organizations

	A	B	C	D	E	F	G	H	I
1	Request ID	Request Title	Requester	Requester's Email	Principal Investigator	PI Email	Request Status	Date of Last Action	Data Contributor Organization
2	Vivli ID: 00001261	Stan Test Hotfix - 9/13	Ida Sim	datarequester.vivli@gmail.cc	Ida Sim	a@b.coma	Draft	2/5/2019 15:21	ImmPort (a data-sharing platfo
3	Vivli ID: 00001301	Asthma Meta Analysis	Ida Sim	datarequester.vivli@gmail.cc	Ida Sim	datarequester.vivli@gma	DUAValidated	10/25/2018 12:58	GlaxoSmithKline
4	Vivli ID: 00001323	Notification Validation	Data Requester	datarequester.vivli@gmail.cc	Stan Neumann	sneumann@vivli.org	Fulfilled	12/13/2018 14:43	GlaxoSmithKline
5	Vivli ID: 00001254	Test DoNotTrack Property for Data Requ	Elizabeth Connolly	econnolly@bluemetal.com	Ida Sim	ida.sim@ucsf.edu	Cancelled	3/16/2019 20:20	GlaxoSmithKline
6	Vivli ID: 00001255	Stans Asthma Study 8/9 PM	Ida Sim	datarequester.vivli@gmail.cc	Stan Neumann	stann@bluemetal.com	Cancelled	10/3/2018 22:21	GlaxoSmithKline
7	Vivli ID: 00001256	Stan - Test delete and re-add 8/10	Ida Sim	datarequester.vivli@gmail.cc	Stan Neumann	Stann@bluemetal.com	Cancelled	10/3/2018 22:21	GlaxoSmithKline
8	Vivli ID: 00001257	Stan - test upload problem 8/10 AM	Ida Sim	datarequester.vivli@gmail.cc	a a	a@b.c	Cancelled	9/6/2018 10:10	GlaxoSmithKline

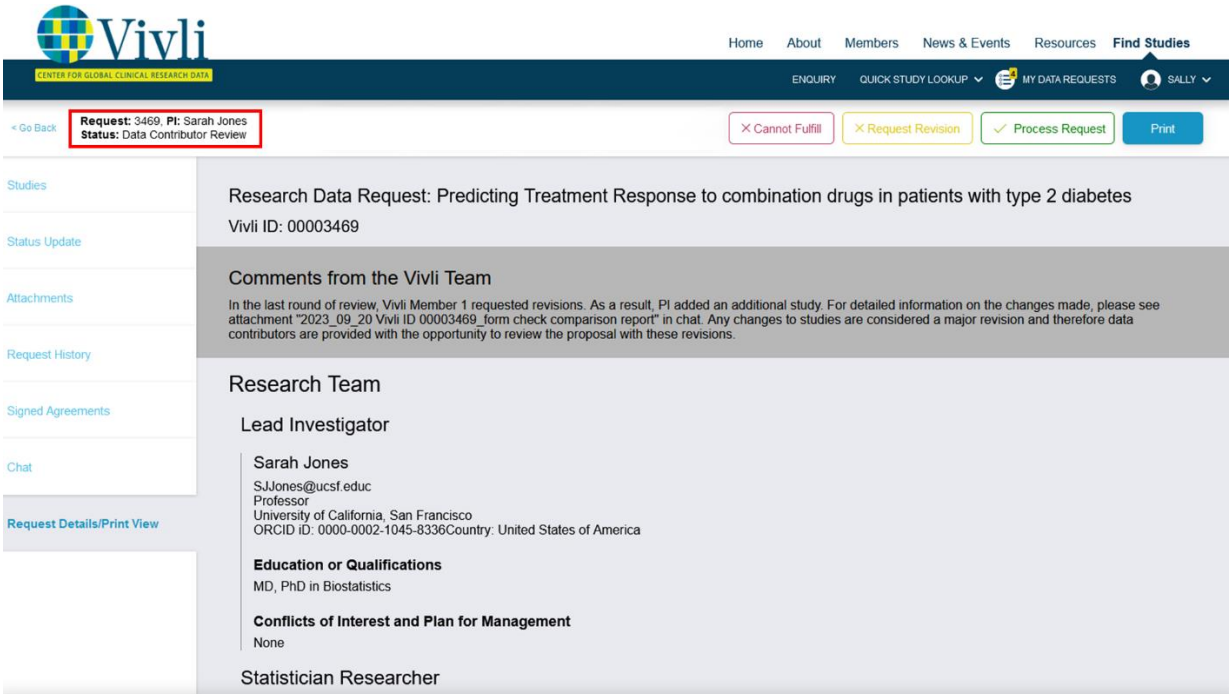
3.2.3 Data Request Form

After navigating to your requests, you can review them.

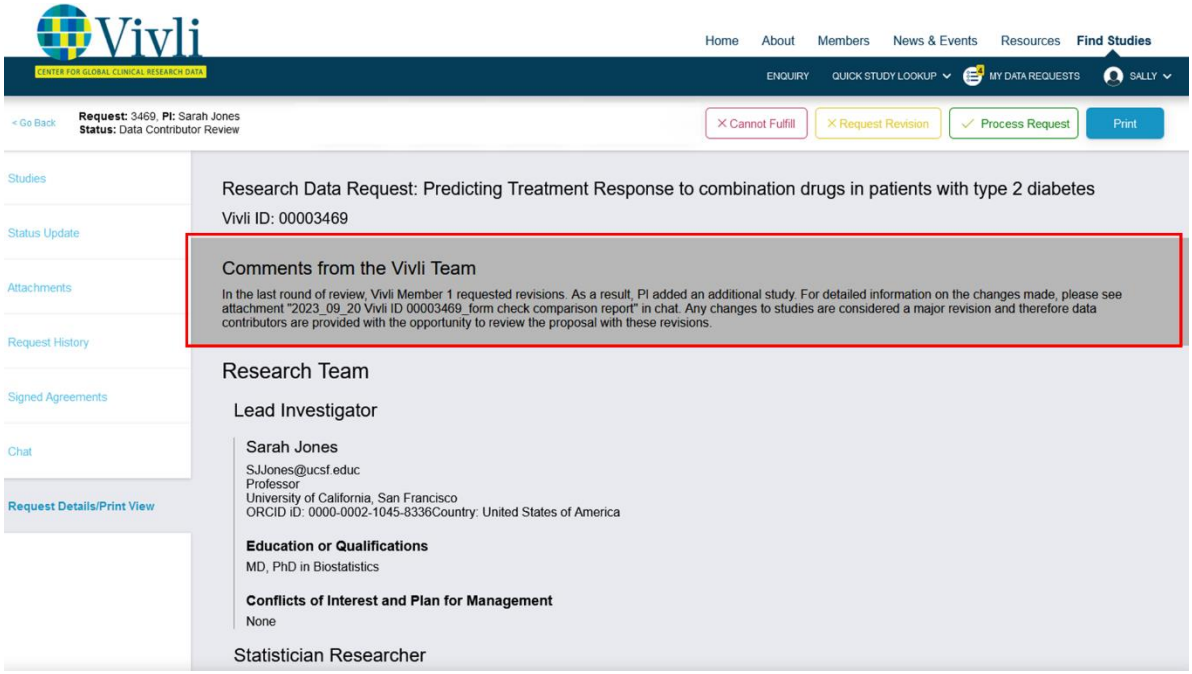
1. First, click on the Data Request Project name and it will take you to a Request details screen. Data Requests appearing on this screen have already gone through the Vivli Admin form check and are ready for Data Contributor or IRP review.



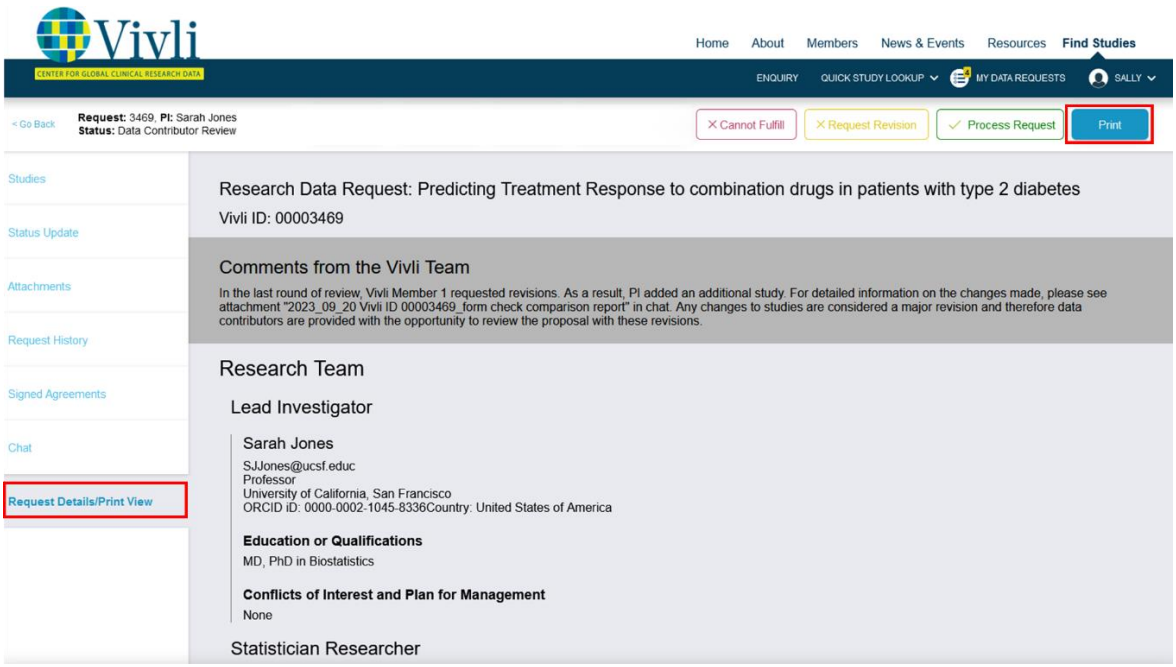
2. When you open the data request, you can see the Vivli Request number, PI name, and the Current status of the data request on the top.

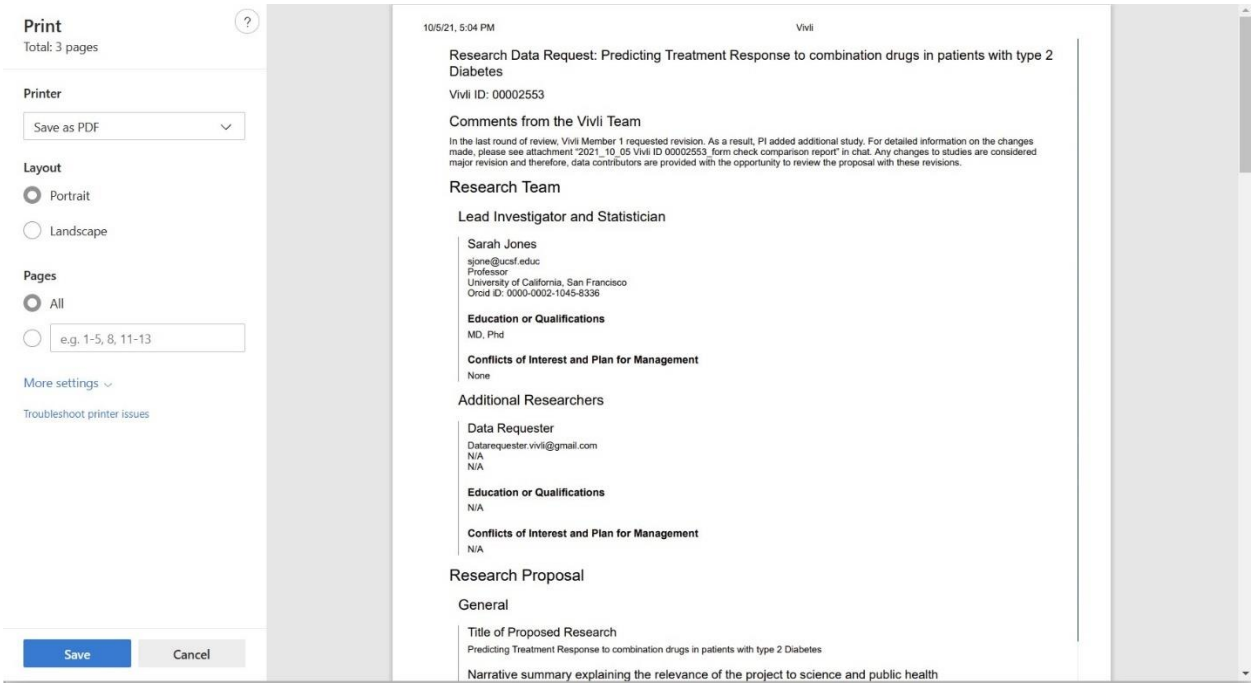


3. In the "Request Details/print view" tab of the data request form, the last comments, if any entered during the Vivli form check approval will be displayed on top.

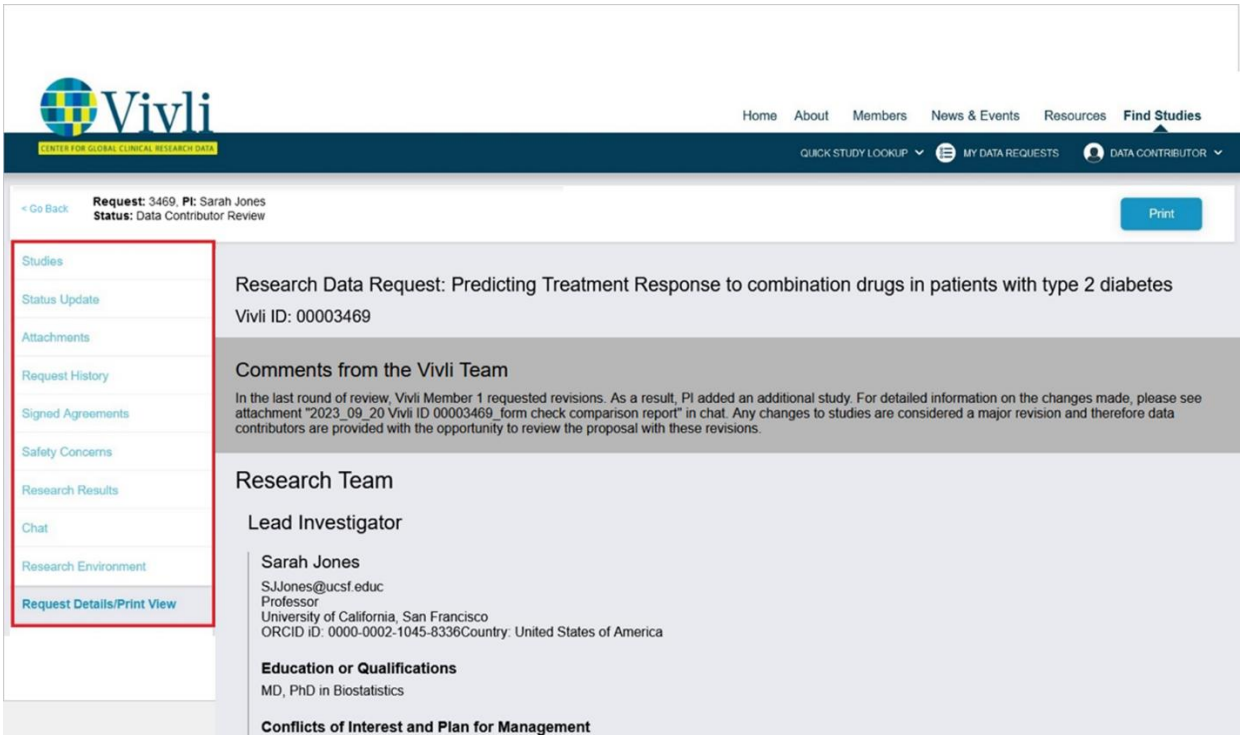


4. Reviewers can read the Data Request Form online, or print a pdf copy by clicking on the “print” button:

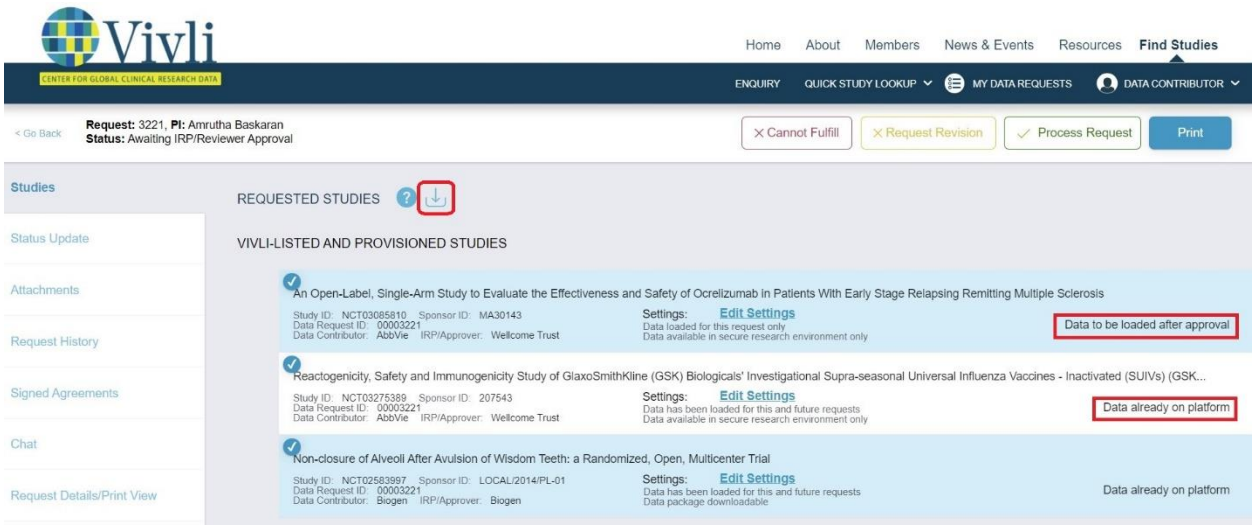




The additional tabs on the left contain information about the data request:



- **Studies tab:** lists all the studies associated with the data request. The studies tab also provides information about the availability of the stored data package. If there was a stored data package for that study on the Vivli platform, *at the time the researcher added the study to the data request*, you will see a note next to the study card as, “Data already on the platform”. If the study didn’t have a stored data package, for that study on the Vivli platform, *at the time the researcher added the study to the data request*, you will see a note next to the study card as “Data to be loaded after approval”. The studies tab within the data request has a download button that provides a CSV list of all the studies in that data request. The CSV contains the following fields: Sponsor ID, Study ID, IPD Uploaded, Study Title, Principal Investigator of the study (not data request), Sponsor Name, Data Contributor Name, IRP/Approver Name, and Data Request ID. For multi-sponsor data requests, you will see a list of all the sponsor studies in the Studies tab.



	A	B	C	D	E	F	G	H	I	J
1	Sponsor ID	Study Id	Ipd Uploaded	Study Title	Principal Investigat	Sponsor Name	Data Contributor Na	IRP/Approver Name	Data Request Id	
2	P42-05		TRUE	A Multicenter, Placebo-Controlled, Para		Vivli Member	Vivli Member	IRP Organization	2553	
3	205687	NCT03085797	FALSE	A Randomised, Double-blind, Parallel G		Vivli Member	Vivli Member	IRP Organization	2553	
4										

- **Status Update tab:** Please see Section 3.5.3. Status Update
- **Attachments tab**: any other documents included by the data requestor. Note: attachments are also visible at the end of the "Request Details/Print View" tab. Please 'download a copy of the attachments for your review.
- **Request history tab**: shows the history of the data request, including decisions recorded by you or by other Data Contributor Organizations involved in your data request. Request history also shows Vivli form checks, Data Contributor review, IRP review, DUA validation events, Data package upload, when data packages are accessed via Research Environment or through download (based on member's data-sharing criteria), Results exported, and when Safety concerns are reported and when Research Environment was deprovisioned.
- **Signed Agreements tab**: shows the executed signed Data Use Agreement and any further DUA extension forms. Note: You will see the executed DUA after the request is approved and the DUA is executed.
- **Chat tab**: Open chat is used to communicate with all parties to the data request; for more information, please see section 10.1 Chat.
  Once the research environment is started, the following tabs will appear on the data request.
- **Safety Concerns**: Please see Section 8. Safety reporting
- **Research Results**: Results requested by the researcher.
- **Research Environment**: Research environment tab can be accessed only by the researcher.

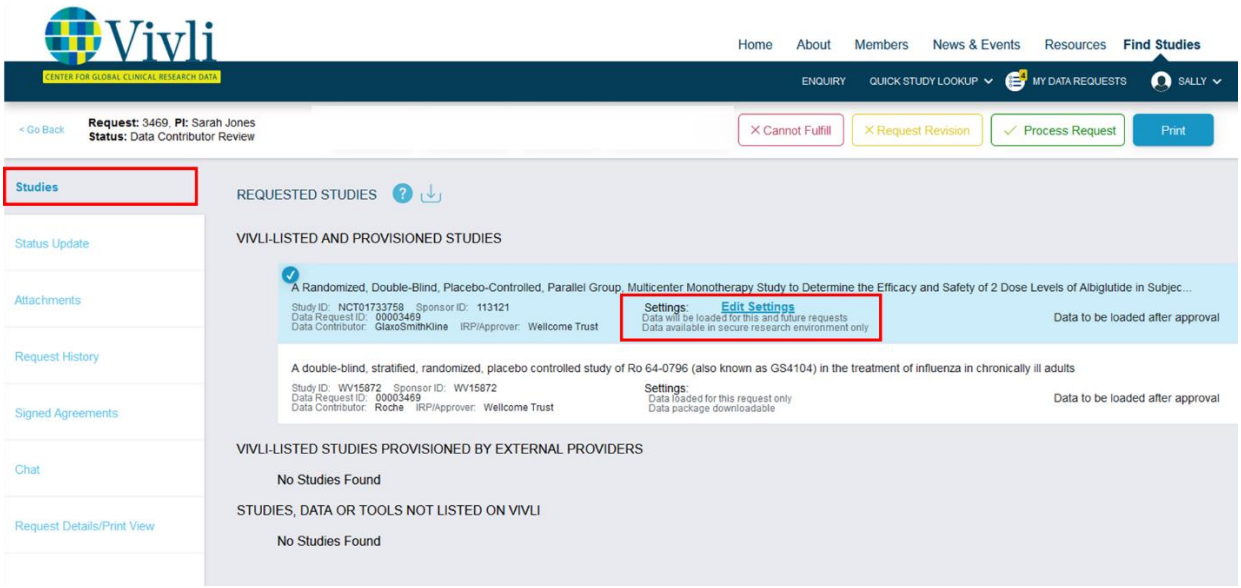
After reviewing the Data Request Form, the Organizational Administrator will move to the next step of the request review process.

3.2.4 Vivli Policies in Brief

Policies in brief for researchers is available on Vivli's website. Researchers are provided with this information while drafting the data request. Policies in brief provides a synopsis of the key policies that govern the interactions between researchers and data contributors during the lifecycle of a research proposal. These policies, in addition to being available on the website, are pointed out to researchers once they submit a request.

3.3 Study settings at Data Contributor Review

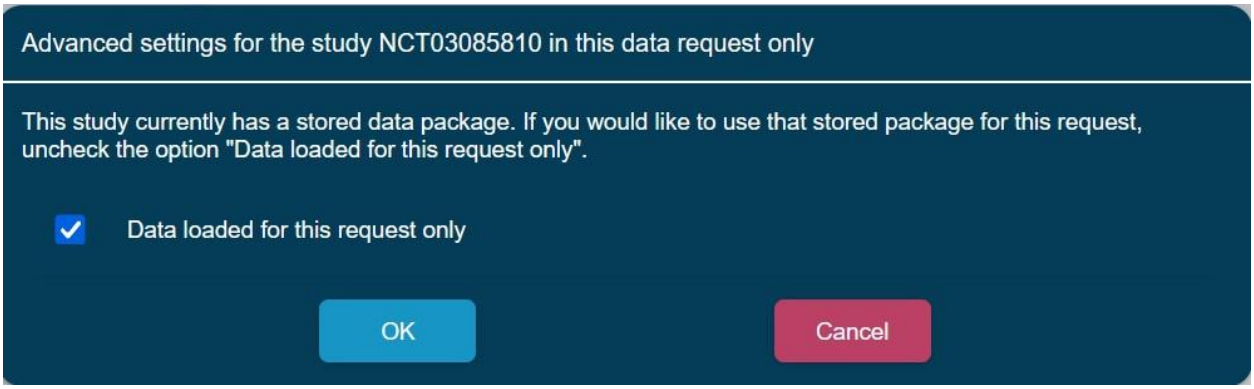
Org Admins have the opportunity to specify the study data storage behavior of each study within the data request. i.e. a specific data package to be uploaded just for this particular request or not. The current settings are below the "Edit Settings" button.



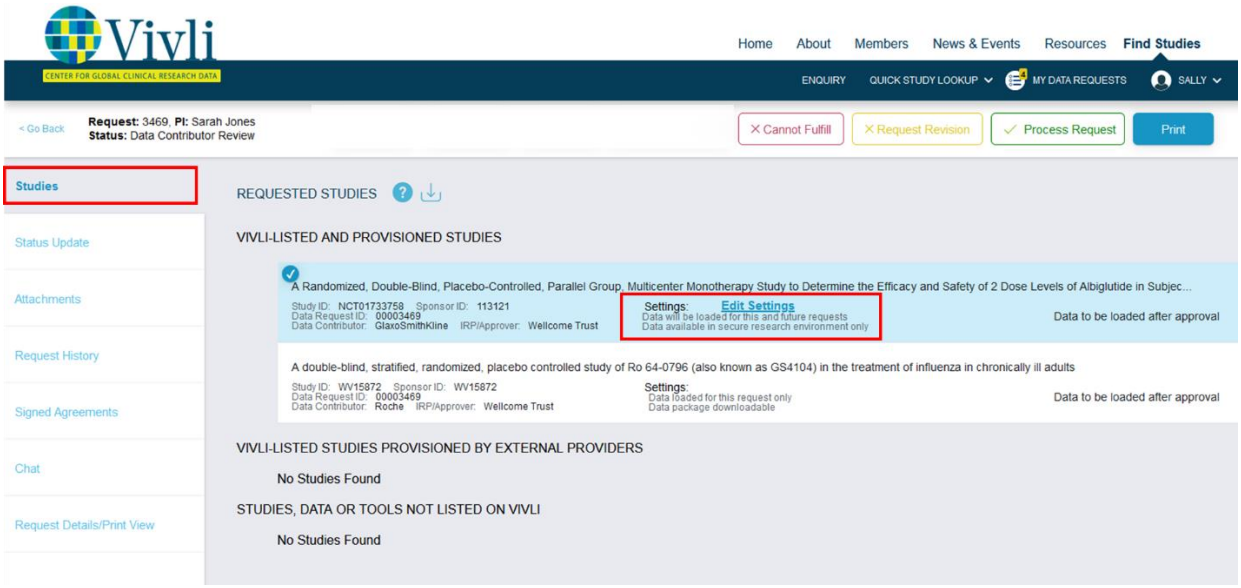
To make the changes, click on "Edit Settings".

The following pop-up will display over the page:

- To load a specific data package for this particular study for this particular request, click the checkbox “Data loaded for this request only.”
- To load a full data package for this particular study which can be stored in the secured vault for automatic provision, please uncheck the checkbox “Data loaded for this request only.”

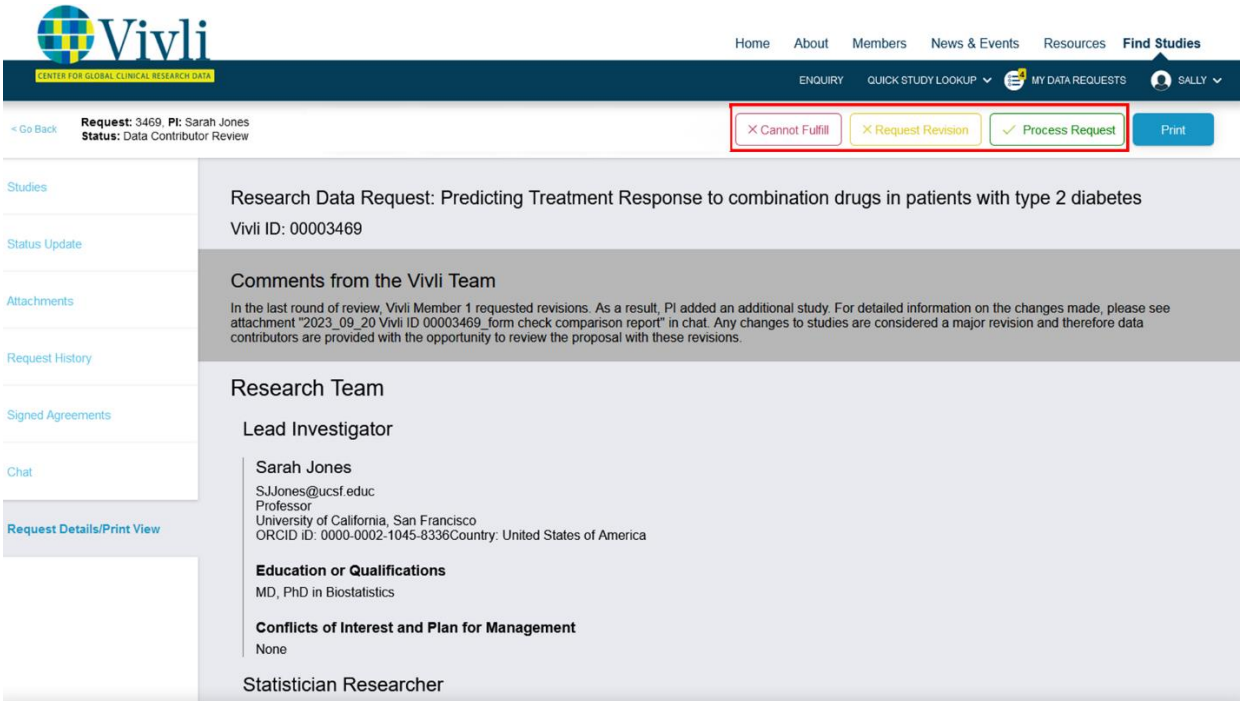


In addition, the Org Admins can see whether a particular study package is downloadable or not within this data request. This is viewable and not editable by the Org Admins. To make any changes to the download setting, please contact Vivli at support@.vivli.org.



3.4 Recording a Decision about a Data Request

To record the decision, you may use the options available in the upper right-hand corner of the screen.



The data request decision options are:

3.4.1 Cannot Fulfill

You may use this option if the data request or all the studies in the data request don't meet your Data Contributor policy in accordance with your members' page

Any reason for being unable to fulfill a request needs to be transparent and listed as a reason for not sharing on your member's page.

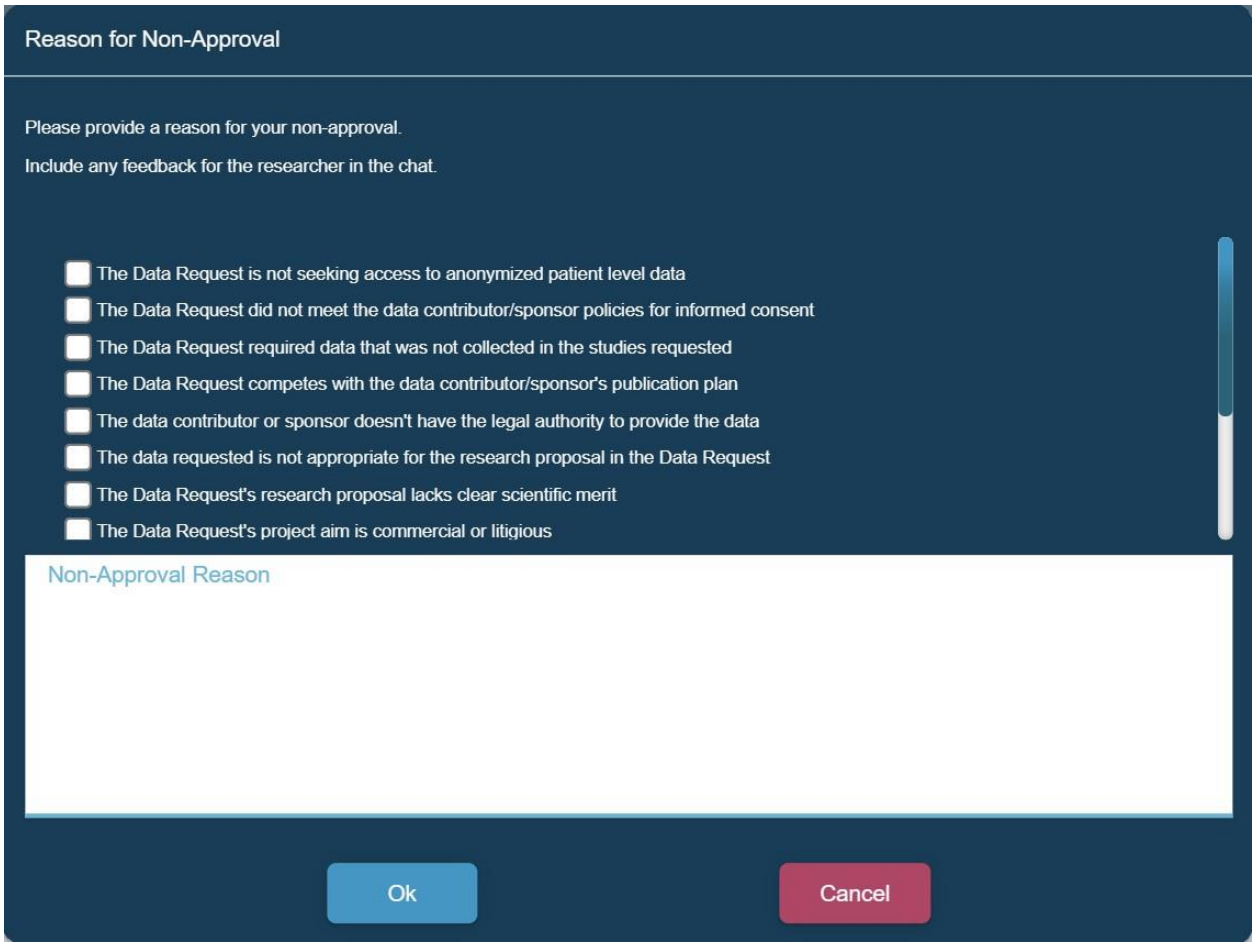
When recording the decision on the platform, click "Cannot fulfill" button and then choose the appropriate checkbox that matches your member's page. Please don't leave the reason for non-approval as blank. Please also check "other reason for non-approval" checkbox to provide more context as to why the request falls outside your policy.

Examples: this policy is out of scope of our data sharing policy as the trial is still ongoing or this study is out of scope due to ongoing litigation.

If you do decide to not approve a request, Vivli will reach out to you to confirm that this reason is listed and transparent on your member's page. Any final rejections will be reflected in the public metrics once the data request governance process, including DUA execution, has been completed.

1. If the Data Contributor cannot fulfill the request for any reason, click **Cannot Fulfill:**

2. A dialogue box will pop-up where you can provide the reason the Data Contributor cannot fulfill the Data Request. Choose the appropriate checkbox that matches your member's page. Please don't leave the reason for denial as blank:



Reasons for Non-Approval include:

- The Data Request is not seeking access to anonymized participant-level data
- The Data Request did not meet the data contributor/sponsor policies for informed consent
- The Data Request required data that was not collected in the studies requested

- The Data Request competes with the data contributor/sponsor's publication plan
- The data contributor or sponsor doesn't have the legal authority to provide the data
- The data requested is not appropriate for the research proposal in the Data Request
- The Data Request's research proposal lacks clear scientific merit
- The Data Request's project aim is commercial or litigious
- The Data Request is Out of Scope
- The data requested is unavailable
- The data requested cannot be shared due to ongoing regulatory activities
- The data requested was not collected in English

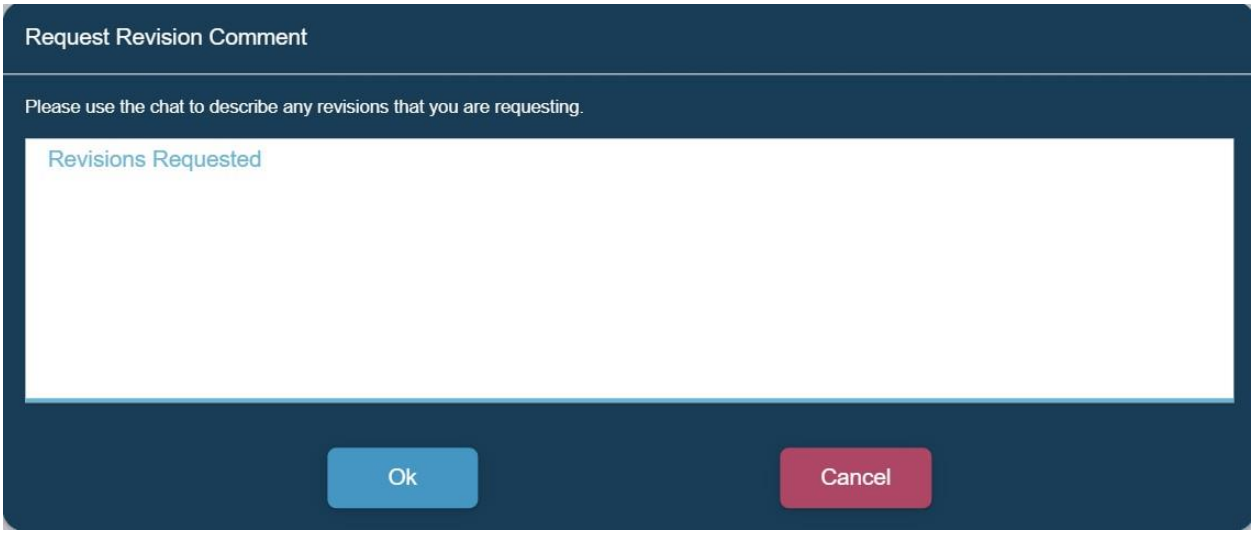
3. To describe any other reason for non-approval, check “other reason for non-approval” and use the comment box. (Please note this reason for non-approval will need to appear on your member’s page).
4. Enter the reason(s) and press **Ok.** This will send an automated email to the Data Requestor and Vivli Administrator informing them of the decision.
5. This Data Request will now be categorized as “Not Approved” in the Data Request status bar and Data Requestor may see your comments regarding the revision in the request history section.
6. Your decision will be recorded in the Request history of the Data Request.
7. For multi-sponsor requests, if your organization has recorded its decision but another organization has not, the request will remain in the Data Contributor review stage under the **Active** status bar. Vivli team will follow up with the other appropriate member to record their decision. Once all the decisions are recorded, the Researcher may remove the denied studies and move forward with the rest of the studies from other members.

3.4.2 Request Revision

You may use this option to request a revision to a particular section of the data request form. Another scenario is if you are willing to approve some of the requested study data but not all i.e. some studies were denied. In this case, please let the Researcher know which studies don't meet your Data Contributor policy and your reason for rejecting the studies in accordance with your members' page. Please see section 3.4.1 above for the list of reasons for non-approval. You can request the researcher to remove those studies from your data request. Please note that partial rejection of studies will be published on the Metrics page once the request passes the DUA Validation stage. For minor revisions and fixing errors, please reach out to the Vivli Admin via open chat before clicking the revision button. Then Vivli Admin can make the changes on behalf of the Research team without sending the request back to drafts. This allows for a more efficient process for all involved.

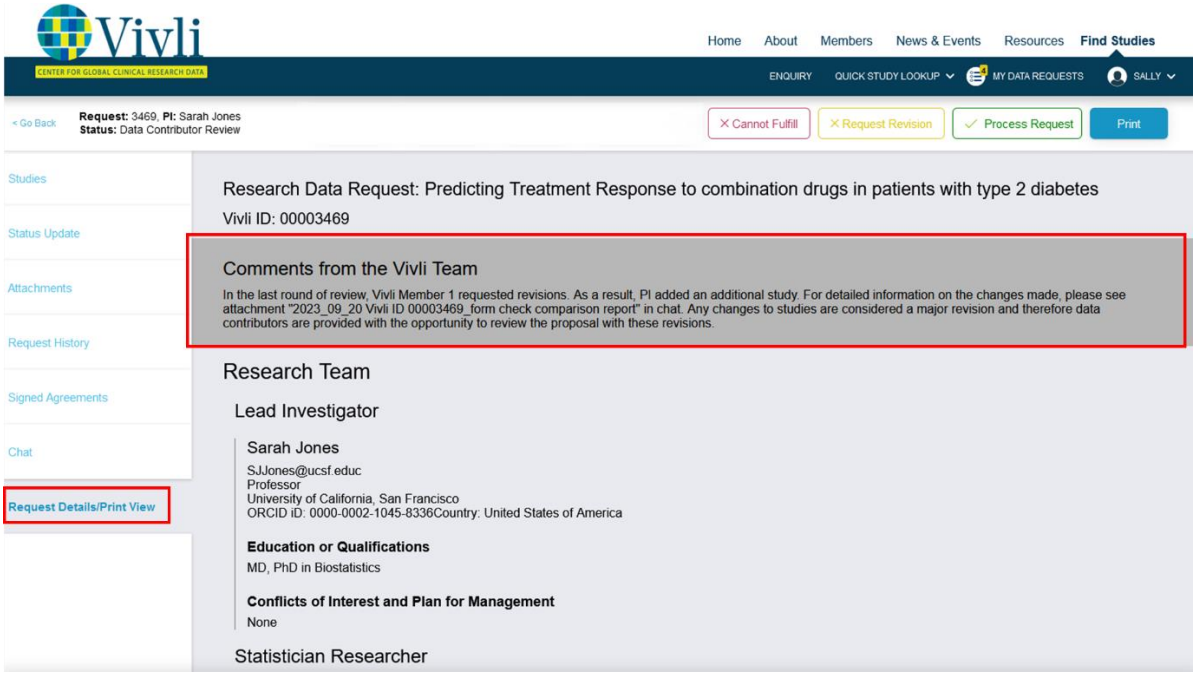
1. If the Data Contributor requires revisions to the Data Request Form, click **Request Revision**:

2. A dialogue box will appear where you can enter the details on the requested revisions. It is **best practice** to post your revision comments in the open chat for easy access to the Data Requester. If you have long comments, please use chat instead of request history:

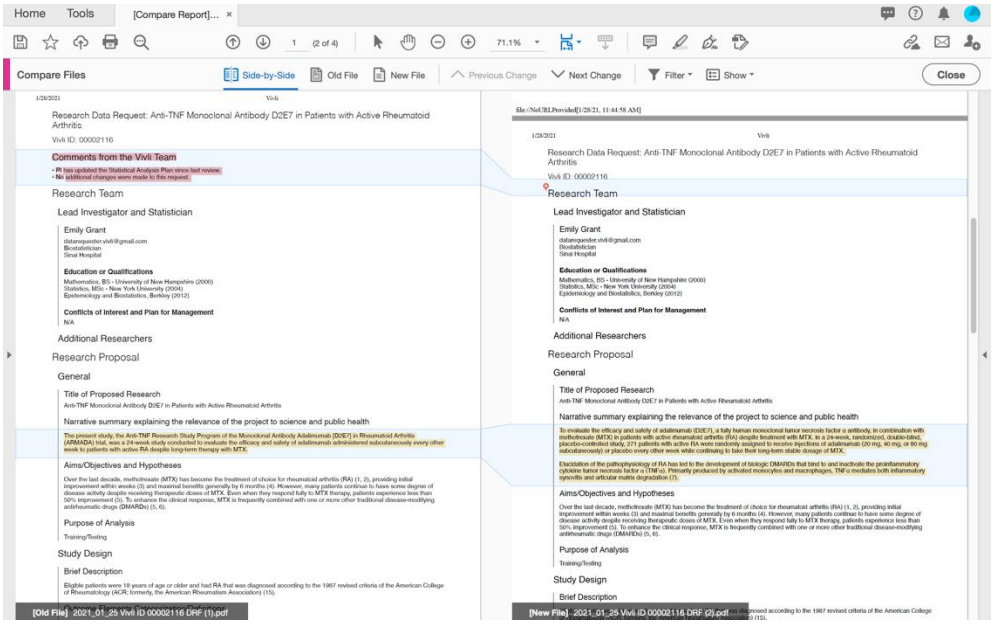


3. When finished, click **Ok** and this will send an automated email to the Data Requestor informing them of your decision.
4. This Data Request will now be categorized as "Not Approved" in the Data Request status bar and remain in that status until the Vivli Admin resets it to drafts for the data requester to make the revisions. At this stage, the data request will be in the drafts section.
5. The Data Requestor can review your comments regarding the revision in the request history section.

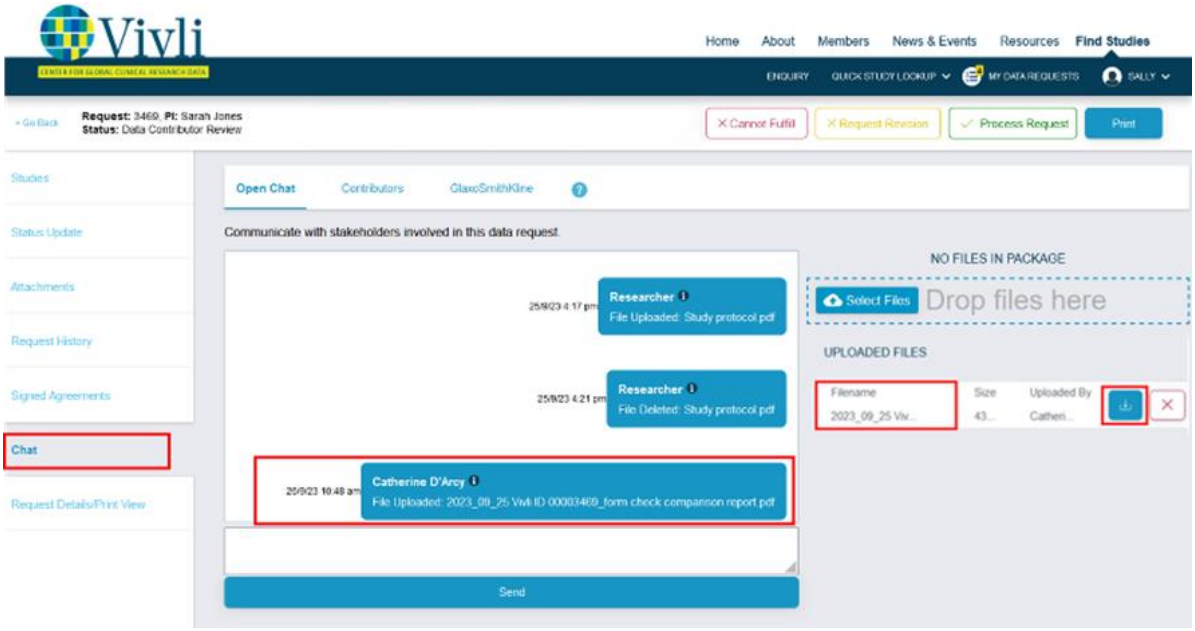
6. Once the Data Requester has revised and re-submitted their request, Vivli Admin will summarize the changes and post their comments during the Vivli form check stage.
7. The Organizational Administrator may see the Vivli form check comments in the "Print" view and may review the request again if it's a major revision.



8. In addition, the Vivli team will post a form check comparison report which shows the comparison between the previous version and the current version of the data request form via open chat as an attachment. For more information on major versus minor revisions to data requests, please see



3.4.4 Major versus minor revisions to data requests.



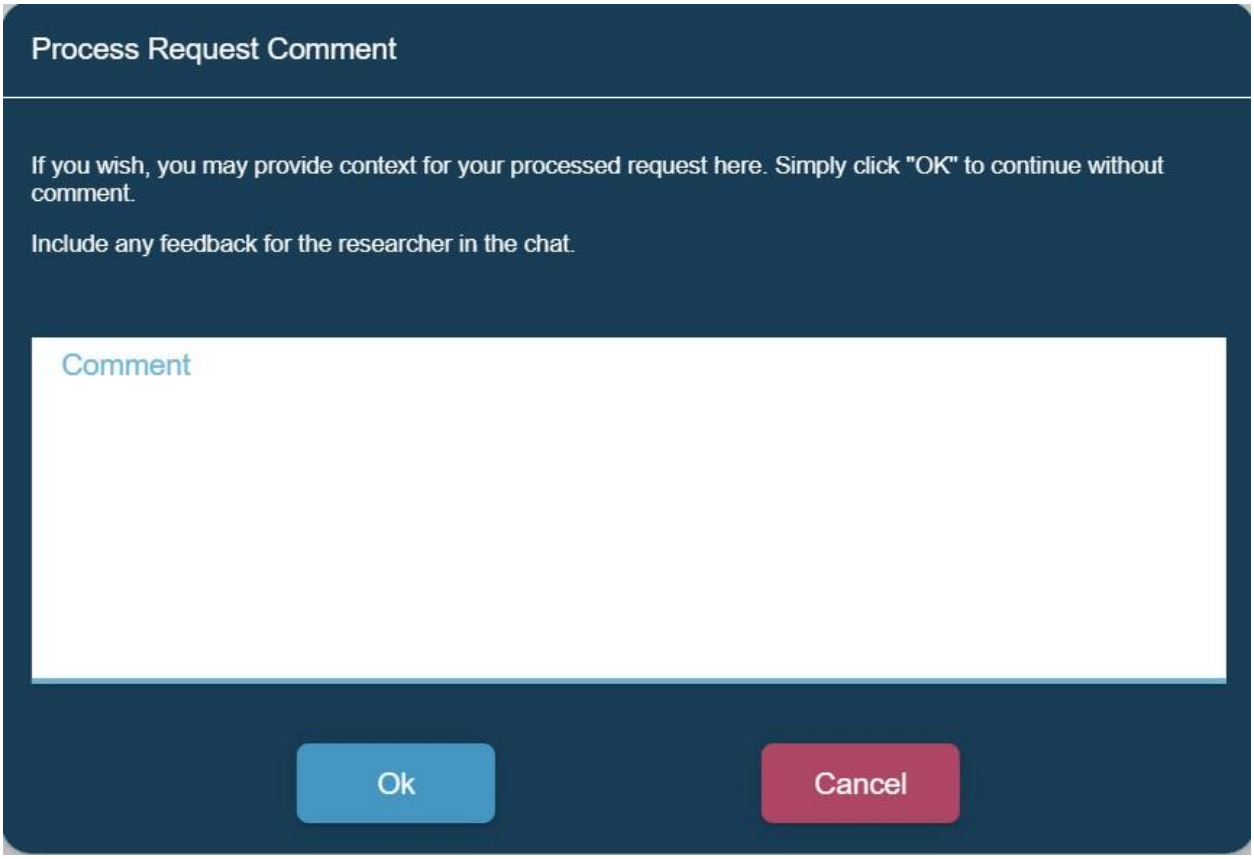
9. Your decision will be recorded in the Request history of the Data Request.
10. For multi-sponsor requests, if your organization has recorded its decision but another organization has not, the request will remain in the Data Contributor review stage under the **Active** status bar. Vivli team will follow up with the appropriate member to record their decision.

3.4.3 Process Request

You may use this option if the data request or all the studies in the data request meets your Data Contributor policy in accordance with your members' page.

1. To send the request to the next stage in the Data Contributor's review model, click **Process Request:**

2. A dialogue box will pop up where the data contributor may enter any comments (optional):



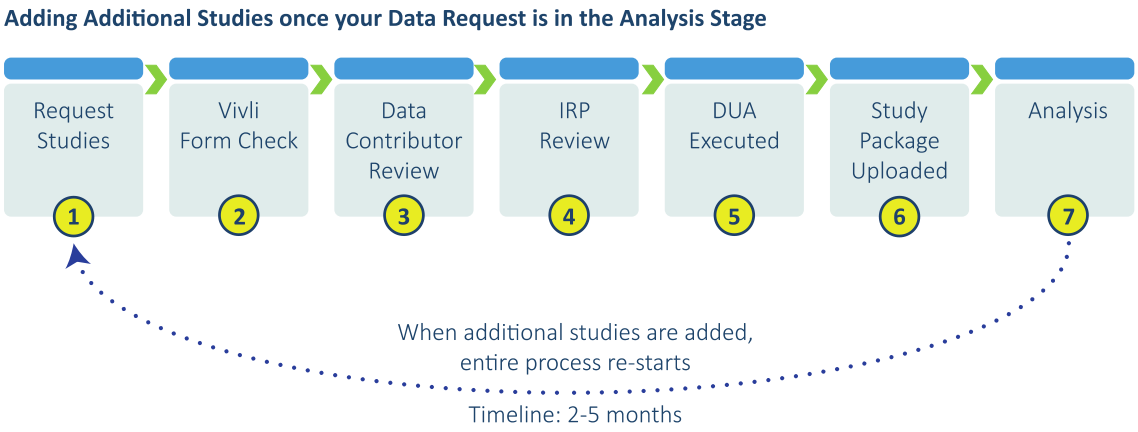
3. Click **Ok** to continue.
4. The request will now be sent automatically to the next stage in your process and the concerned person will be notified via email.
5. The Data Request will now be categorized as **Active** in your Data Request status bar.
6. Your decision will be recorded in the Request history of the Data Request.
7. For multi-sponsor requests, if your organization has recorded its decision but another organization has not, the request will remain in the Data Contributor review stage under the **Active** status bar. Vivli team will follow up with the appropriate member to record their decision.

3.4.4 Major versus minor revisions to data requests

Change	Classification (major / minor)
Change to Primary Investigator	Major
Change to Lead Statistician	Major
Adding or Removing Studies	Major
Change to Statistical Analysis Plan	Major
Change to Conflict of Interest Statement	Major

Other Personnel Changes	Minor
Changes to the Lay Summary (e.g. Spelling out acronyms)	Minor

- If a data requester makes any major changes to the data request form i.e Changes to Primary Investigator, Lead Statistiscian, their conflict of interest or changes to Statistical analysis plan **before the review process is complete**, Vivli team will make changes on the researchers behalf and inform the data contributors via chat.
- If a data requester makes any major changes to the data request form i.e. Changes to Primary Investigator, Lead Statistiscian, their conflict of interest or changes to Statistical analysis plan **after the data request review process is complete**, Vivli will reach out to data contributors via "Contributors" chat (visible to Data Contributors and Vivli Admins) to ask if they approve this change. If all data contributors approve, the Vivli administrator will make this change on behalf of the data requester and will record this change as a note to file and upload it in the signed agreements tab. If one of the Data Contributor/IRP requests this change go through formal approval, the Vivli team will send the data request back for review to all other relevant Data Contributors according to their chosen data request governance process.
- If a data requester wants to add any studies from **an existing data contributor who has already reviewed this data request after the data review process is complete**, Vivli will reach out to data contributors via "Contributors" chat (visible to Data Contributors and Vivli Admins) to ask if they approve this change. If all data contributors approve, the Vivli administrator will add the studies on behalf of the data requester and will record this change as a note to file and upload it in the signed agreements tab. The DUA will also need to be re-executed along with the updated data request form. If one of the Data Contributor/IRP requests this change go through formal approval, the Vivli team will send the data request back for review to all other relevant Data Contributors according to their chosen data request governance process.
- If a data requester wants to add any studies from **a new data contributor who has not reviewed the data request after the review process is complete**, the data request will require submission of a new request. A new DUA will also need to be executed. Analysis conducted in the existing Research Environment can be made available in the new Environment for combination with subsequent data analysis. Before resubmission, the Researcher will be encouraged to ensure they have a full list of the studies that they will be requesting, and all participating research team members listed before submitting a new request. This is to avoid unnecessary work for both the Research Team and the data contributors involved.



3.4.5 Withdrawal process

A Data Request could be withdrawn for many reasons. If a Research team decides to withdraw their request, they can reach out to the Vivli team via chat or through support@vivli.org and provide their reasons for withdrawal.

A Data Request will be considered to be non-responsive when it has met the following criteria:

- When the request has been submitted and returned to Drafts for revision (and)
- Has not been revised, resubmitted, or progressed to the next stage of review (and)
- No response is received from the Research Team to Vivli Admin for 4 months following bi-weekly check-ins in chat and via email.

After 4 months, the Vivli Admin will place a note in chat, and send it via email (if provided), informing the Researcher that multiple attempts to contact them have been unsuccessful and their request will be considered withdrawn and moved to the Withdrawn state on the platform. If a Researcher responds to this message within 30 days, the request can continue through the process. After 30 days, the request is considered abandoned. The researcher may contact Vivli at support@vivli.org anytime to move the request back from withdrawn to drafts.

If the data request was submitted for Data Contributor review, then Vivli will upload the note to file in the signed agreements tab detailing the reasons for withdrawal and withdraw the request on their behalf. The data request is moved to the withdrawn section of the Data Request Dashboard. The withdrawal decision is recorded in the request history of the data request. Withdrawn requests are reflected on the Metrics page.

3.4.6 Target timeline for the review process

1. Vivli Form Check Initial Response	2. Vivli form check Complete	3. Data Contributor initial response	4. DC final decision	5. Approving Entity/ IRP first response	6. Approving entity's final decision	7. Approval to DUA executed (7&8 run in parallel)	8. Approval to data packages loaded	Overall Timing Steps
2 days		21 days		30 days			30 days	2-5 Months (60-150 days)

Note: Targets are focused on what Vivli and members could control

3.4.7 Summary level and document only data request

Vivli members have the option to use Vivli platform for document-only and summary-level data requests. This will be specified in the Vivli Member Checklist.

Here is a lighter-weight process for such data requests:

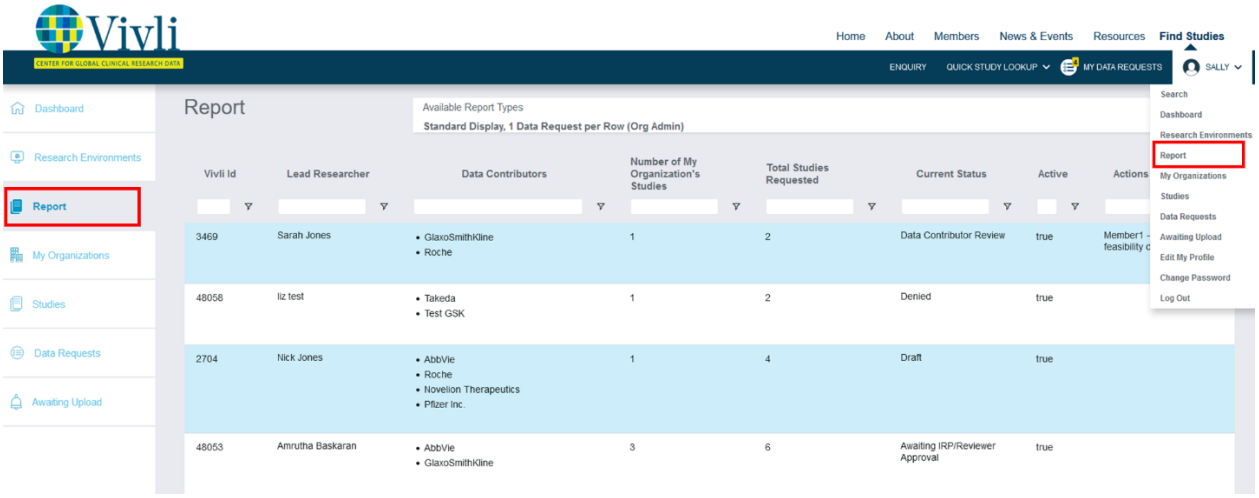
1. Researcher submits the data request
2. Vivli Admin notes on the top of the data request if this is a summary-level or document only request
3. Org Admins sets the study setting by checking the checkbox "Data loaded for this request only". See Section 3.3 of the Data Contributor guide
4. Org Admins records the Data Contributor review as standard
5. Data request skips IRP review
6. Standard Data Use Agreement and security addendum is signed
7. Data Upload the specific data just for this data request
8. Summary-level data and documents to be downloaded by the researcher

9. These requests are not counted toward the number of requests that are included as part of a member's yearly allocation of data requests.

Vivli Form Check	Data Contributor Review	IRP	Standard DUA with Downloadable Rider	Documents and summary-level data Downloaded
		X		

3.5 Report of data requests

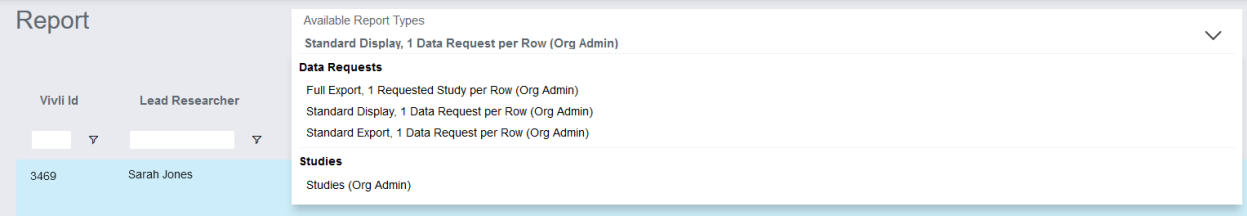
The report is a "tab" on the left of the Dashboard. It is also a menu choice on the drop-down menu when clicking on your name.



There are four types of reports:

1. Standard Display, 1 Data Request per row, is the default option which is a display-oriented report and contains an overview of the request.
2. Standard Export, 1 Data Request per row, adds more information on requested studies, and many fields from the data request form.
3. Full Export, 1 Requested Study per Row, repeats the standard export row once for each requested study.
4. Studies, a list of the studies a data contributor has listed on the Vivli platform, with study details and usage metrics

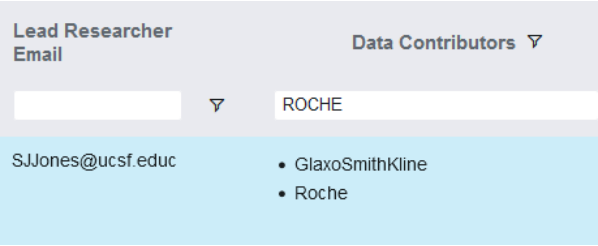
The default report shown on opening the Reports tab is the Standard Display.



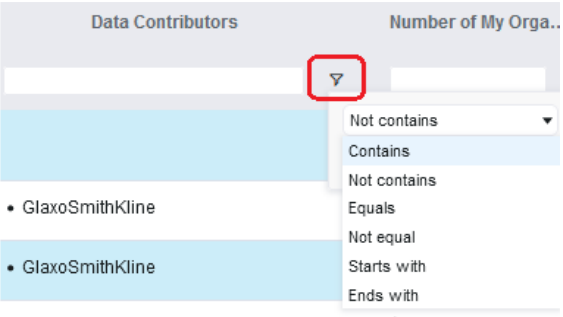
3.5.1. Features of the report

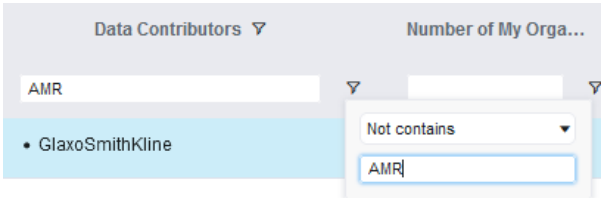
Download icon allows you to download what is currently displayed (and filtered) 

When you type into the white text entry field at a column heading, you filter the list to items that Contain what you enter



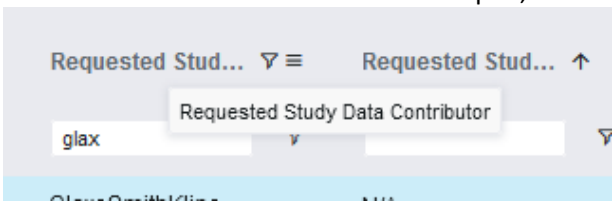
When you see a funnel next to the white field, you can use that to specify a different type of filter, such as Not Contains. Contains, Equals, Not equal, Starts with and Ends with.





To filter the field in ascending or descending order, click on the Title name. The upward and downward arrow shows whether it is in ascending or descending order.

If a column title is truncated with an ellipsis, hover over the title to see the whole title



To scroll the report, use the scrolling bar at the bottom and right side of the screen.

3.5.2. Fields included in the report

1. Standard Display, 1 Data Request per row, includes the following fields:

- Vivli ID
- Lead Researcher
- Data Contributors (comma-separated list)
- Number of My Organization's Studies – Number of studies from your organization included in the request.
- Total Studies Requested – Number of studies from all data contributors included in the request.
- Current Status – Draft, Vivli Form check, Form check failed, Data Contributor Review, Awaiting IRP/Reviewer Approval, DUA Validation, Awaiting Data Package Upload, Partially Fulfilled, Fulfilled, Denied, Cancelled, and Archived
- Active (True or False) - Includes data requests from the time it is submitted for form check until the final publication is published. Excludes all draft requests.
- Actions Required – Action required by all the data contributors at a particular stage as set by the Vivli admin. This complements the decisions and uploads required field.
- Decisions and Uploads Required – This is automatically set by the Vivli platform and will always be up to the minute
- Days in Current Workflow Step – Number of days the request in the particular step. It is computed automatically, in real-time. If it is greater than the Target Days for Current Workflow

Step, we put an asterisk on Days in Current Step to indicate "overdue". If Target Days for Current Workflow Step is -1, there is no target (e.g. for the Analysis phase).

- Target Days for Current Workflow Step – 21 days for Data Contributor review, 30 days for IRP review, 30 days for Data Upload and 30 days for Publication review
- Feedback – For Data Contributor to provide any comments in response to weekly summary comments. For more information, please see section 3.5.3. Status Update
- Request Review Status – shows Form check, Data Contributor review, and IRP review decision
- DUA Status – Pending DUA, DUA execution, DUA extension, and DUA closure
- Data Upload Status – Updates on data upload status
- Results Export Requests – Includes Date and whether approved
- Publication Status – Includes courtesy review, public disclosure acceptance, published disclosures, and summary of results.
- Additional Notes – Revision of previous Vivli ID#, transition request #, and Pending chat question or other pending issues.
- Date Submitted to Data Contributor –The date when the request was first submitted to the Data Contributor review.

- Date of Last Change –Records any change, including updates you or the Vivli admin make to the status update.

2. Standard Export, 1 Data Request per row includes the fields above and includes the following additional fields:

- Title – Request title
- Lead Researcher Affiliation
- Lead Researcher Title
- Lead Researcher Email
- Date First Published
- Main Predictor/Independent Variable
- Publication Plan
- Brief Description
- Aims, Objectives, Hypotheses
- Purpose of Analysis
- Therapeutic Area
- All Studies Included by Sponsor ID/NCT ID

3. Full Export, 1 Requested Study per Row, repeats the standard export row once for each requested study. This is to support the analysis of the requested studies. It includes studies provided by all contributors. It includes the fields above except "All Studies Included by Sponsor ID/NCT ID" and includes the following additional fields:

    - Requested Study Data Contributor – Name of a data contributor. To see studies from your organization, filter by "Requested Study Data Contributor"

- Requested Study NCT ID
- Requested Study Sponsor ID

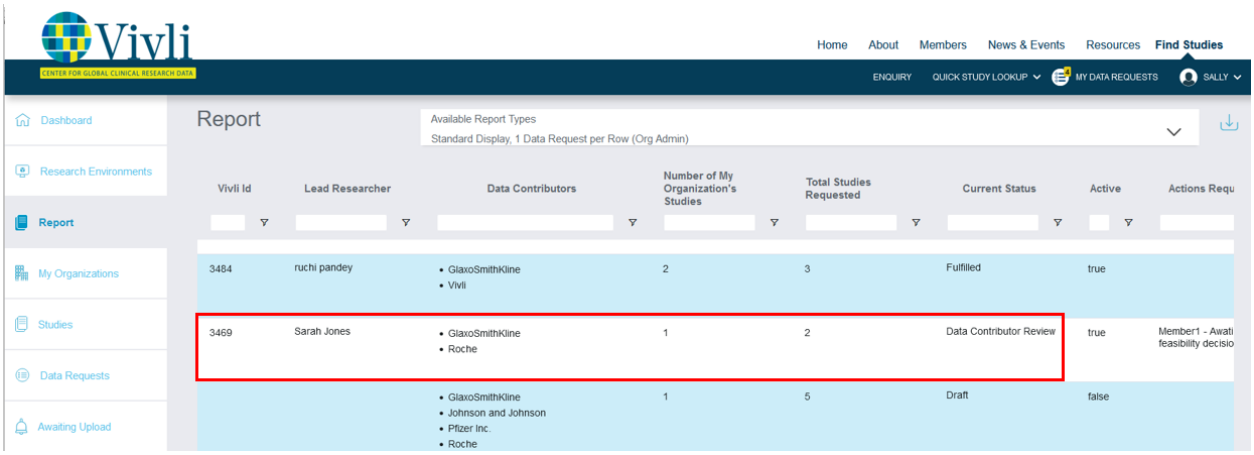
Tip: If you use the expanded report, and filter on a study ID or NCT ID, you can quickly see what requests include that study and their status.

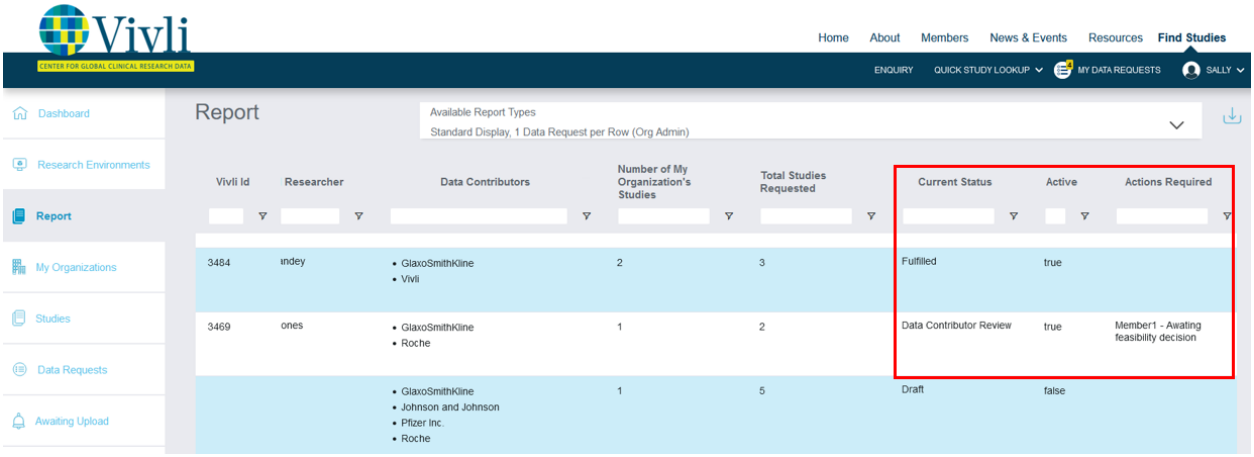
4. Studies, has a row per listed study for your organization, with some study metadata and usage metrics

- NCT Id
- Sponsor Protocol Id
- Posted Date
- Submitted Date
- Org Name
- Study Title
- Ror Names
- Parent Ror Names
- Citation Count
- Study Metadata Doi
- Is Data Uploaded
- Conditions
- Interventions
- Data Requests Count

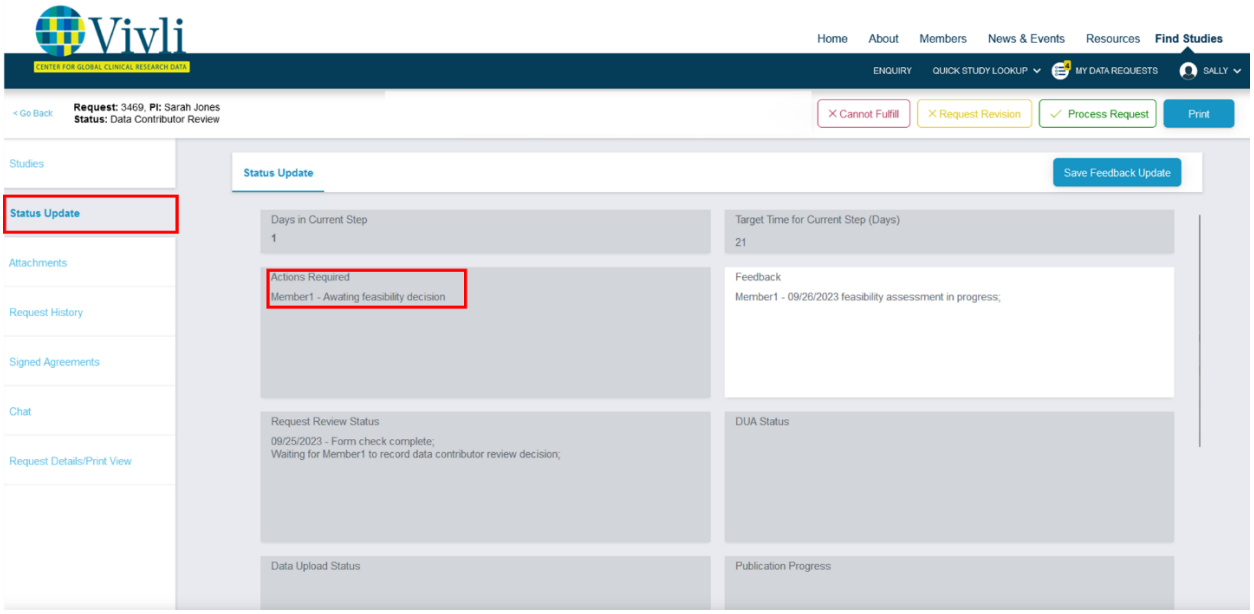
3.5.3. Status Update

1. Status updates can be accessed by clicking the data request from the report tab. The request opens in a new request tab “Status Update”, which allows you to see several fields quickly, and provide feedback on “Actions Required” or any other issue.

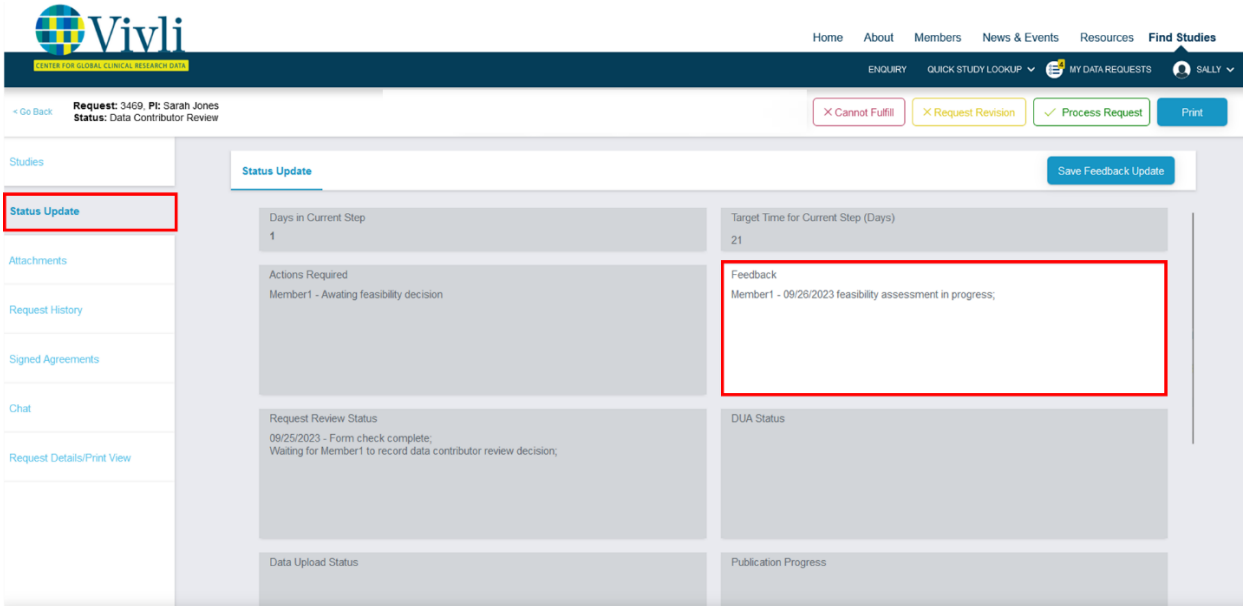




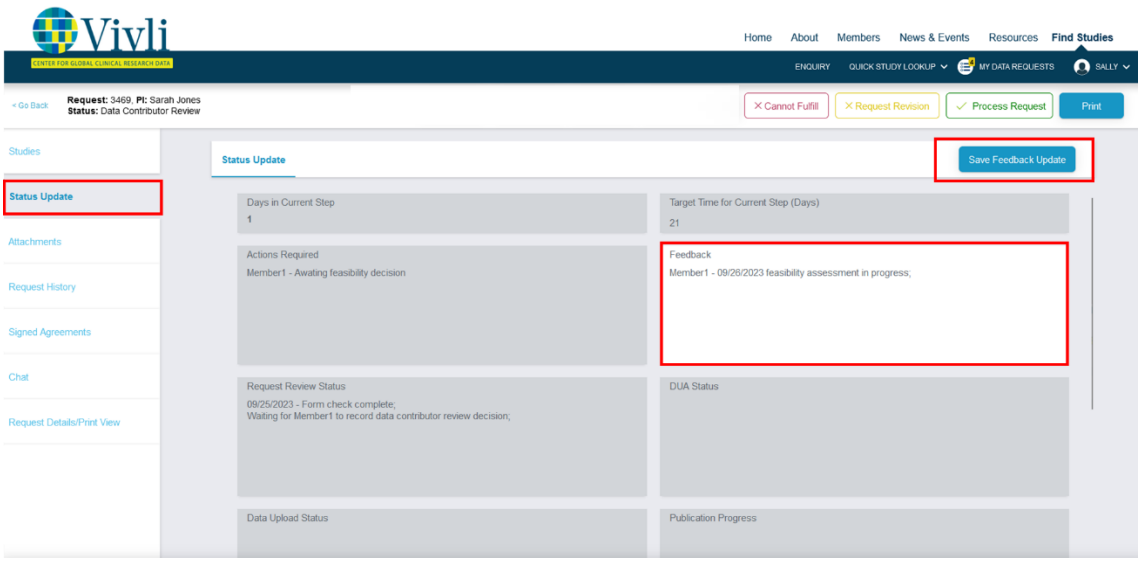
2. Alternatively, the status update can be accessed directly on the data request form. Actions for data contributors are entered into the 'Action Required' field by Vivli.



3. The feedback field is editable (marked in white). All other fields are locked (marked in grey).



4. Note that the feedback field is shared among all contributors. This field is how data contributors can provide updates to Vivli and all data contributors involved such as the anonymization timeline, review timeline, etc. that is relevant to the current step. Vivli team will periodically delete contents that are no longer relevant. Format to use: DC name/Date/Any comments.

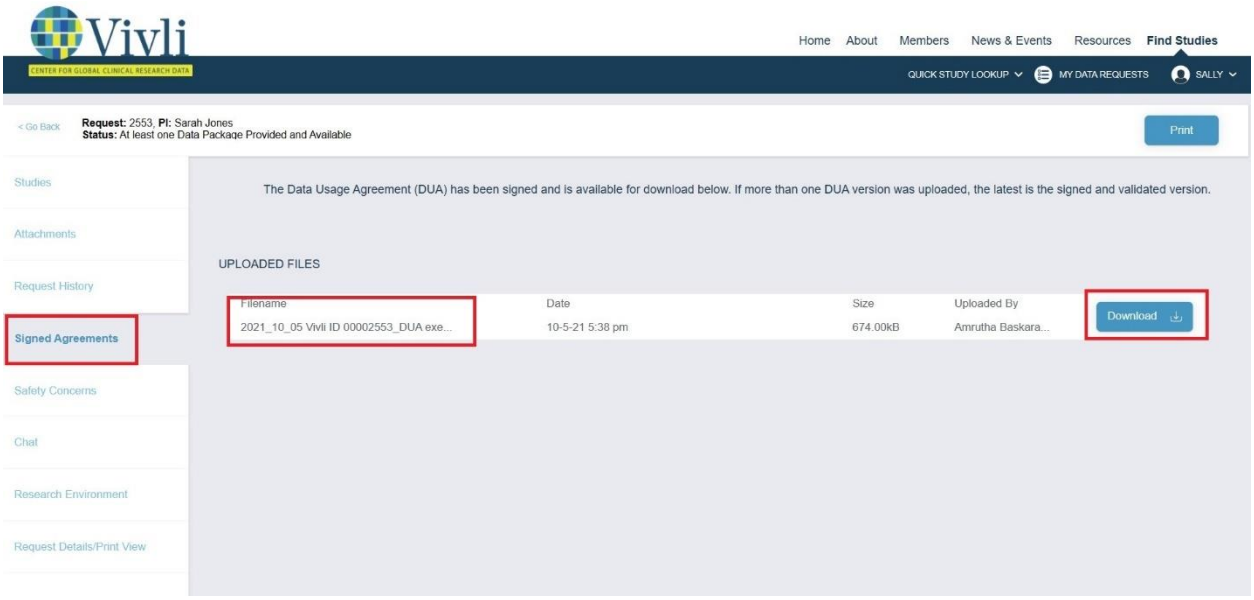


5. Once you make the changes, click the “Save Feedback Update” button at the top of the page.

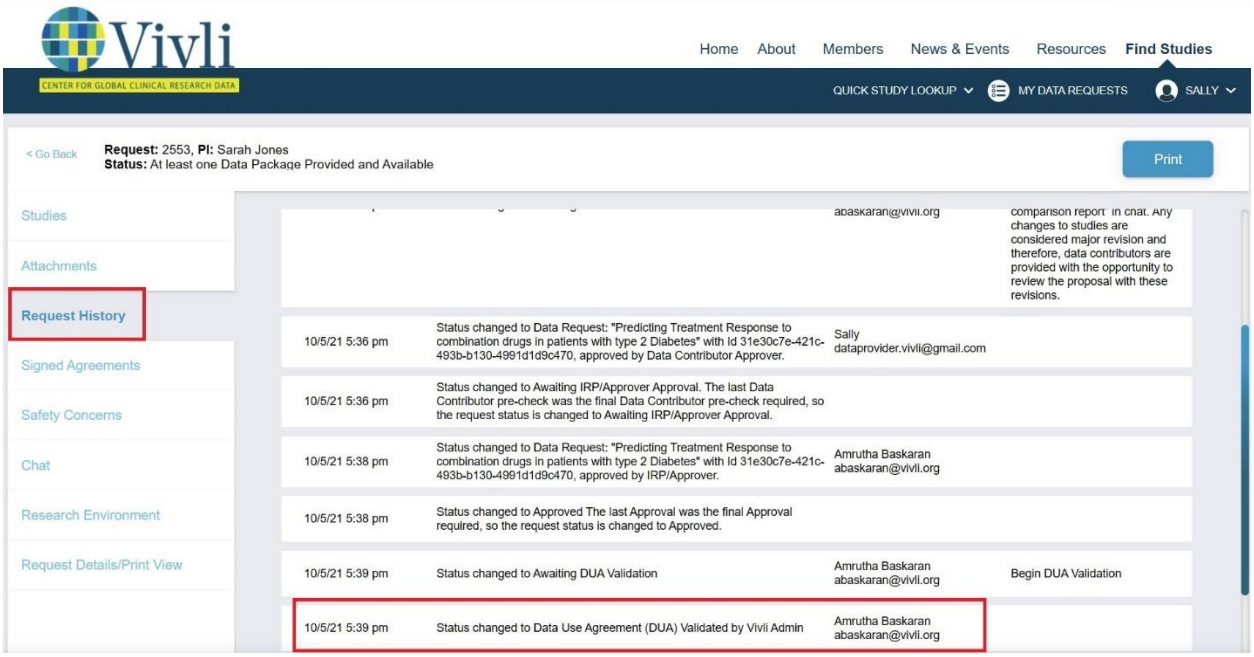
   To scroll through the information in each field, click on the field and use the cursor keys on your keyboard to scroll up and down within the field.

3.6 Data Use Agreement (DUA)

- Organizational Administrators and Data Contributors will be notified via email when the DUA has been signed, uploaded, and executed by the Vivli Administrator.
- The signed DUA will be available for download under the **Signed Agreements** tab of the data request.



- In addition, DUA validation is reflected in the data request history.



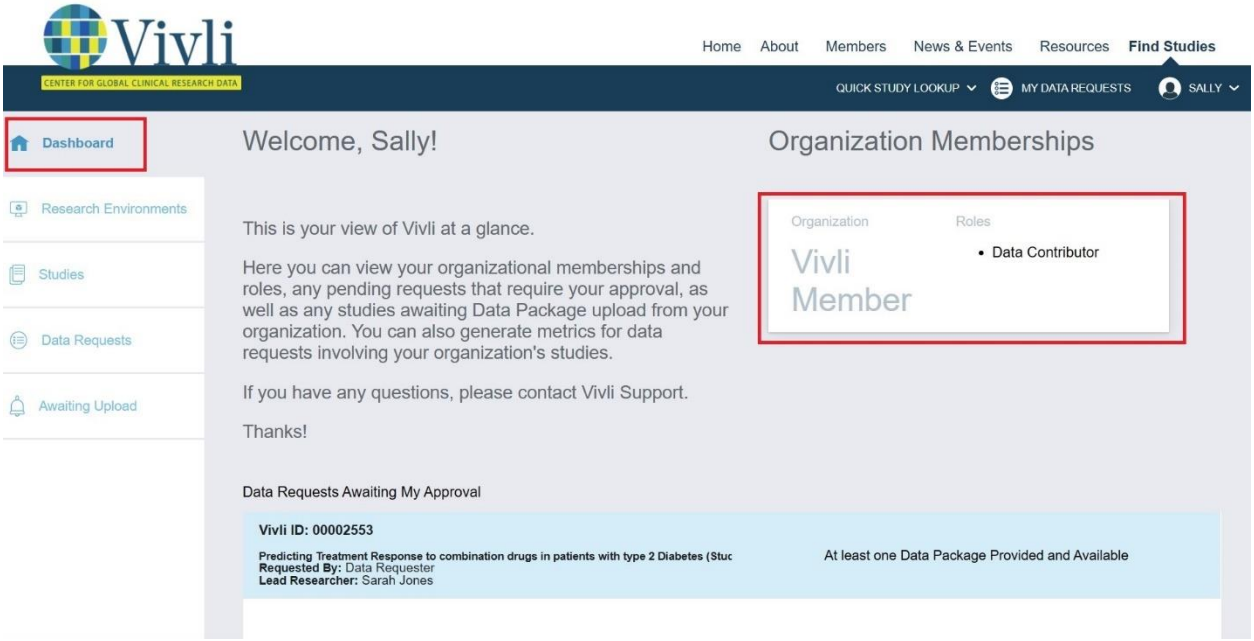
4. Uploading data packages

Data Packages for the listed studies can be provided:

- At the time of listing the study on the Vivli platform
- Before any user has requested the data.
- While a request is under review
- Once the request has been approved and the Data Use Agreement is signed, uploaded, and approved by the Vivli administrator if the data was not previously provided, the Data Contributor uploads their data package so that the Data Requestor can start their Secure Research Environment.
- By default, Organizational Administrators are given Data Contributor rights.

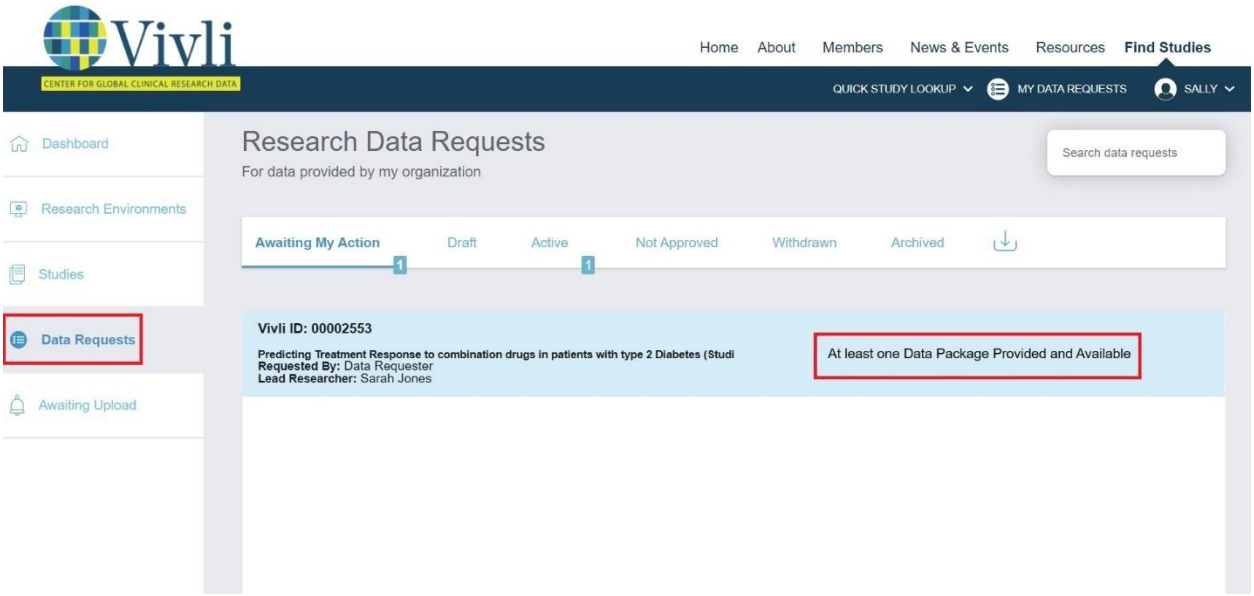
4.1 Vivli Dashboard for Data Contributors

- Once you have been given data contributor privileges to your Organization and you have logged in, you will be taken to your Vivli Dashboard.
- On the dashboard, you may view the Organization that you are part of and your roles as part of your Organization.
- You may track studies needing data package upload that are awaiting your action, (a) either on the dashboard (shown below), (b) on the Data Requests tab on the left, or (c) on the Awaiting Upload tab on the left. For more information, see Section 4.4.1 Steps: Uploading Data Package to an approved request



4.2 Data Upload Notification

- Once the Data Use Agreement is executed, the Data Contributors will receive an email notification to upload the data package. Only the team member with the Data Contributor rights can upload the data package.
- Data Contributor will not receive any chat notifications. If the Data Requestor has any comments on the data packages needed, they will reach out to the Organizational Administrator via open chat.
- Organizational Administrators and Data Contributors can see the status of a request if the DUA has been approved and the system is waiting for data in the Data Request Status bar, under **Active**, or under **Awaiting My Action. Note:** Those with Data Contributor rights cannot see other data requests that are in a different stage of the review process.



4.3 General upload guidelines

- The data package upload times vary considerably based on your bandwidth. The observed range is from 300-400 Megabytes/hour to 5-6 Gigabytes/hour.
- When you have many or large files, using zip or 7-zip is highly recommended:
    - If the study contains more than 6-10 files, zip the data. You can leave the documents separate from the zip containing the data. Compression can reduce the size of textual data to 10% of the original or more; in addition, uploading a small number of files is easier and makes the system faster.
    - If you have large files, zipping can reduce the size by as much as 90% for files with textual content.
    - If you have very large files, 7-zip allows you to break them up into sections.
    - If the zipped files are large (more than 1 Gb or so), it is best to load them one at a time rather than all at once. In your computer settings, set Power Plan to sleep "Never" when plugged in. (The sleep setting will interrupt the upload).

    - Once you start the upload, leave the computer running and the browser open. The progress of the upload is shown in the button to the right of the "card" that is created for the file.
- Other upload tips:
    - If it is practical, uploading is faster in the evening or overnight, as you are competing with less traffic on the internet.
    - Before starting the upload, it can be useful to reboot your computer - this can free up some memory and reset some elements of the operating system.

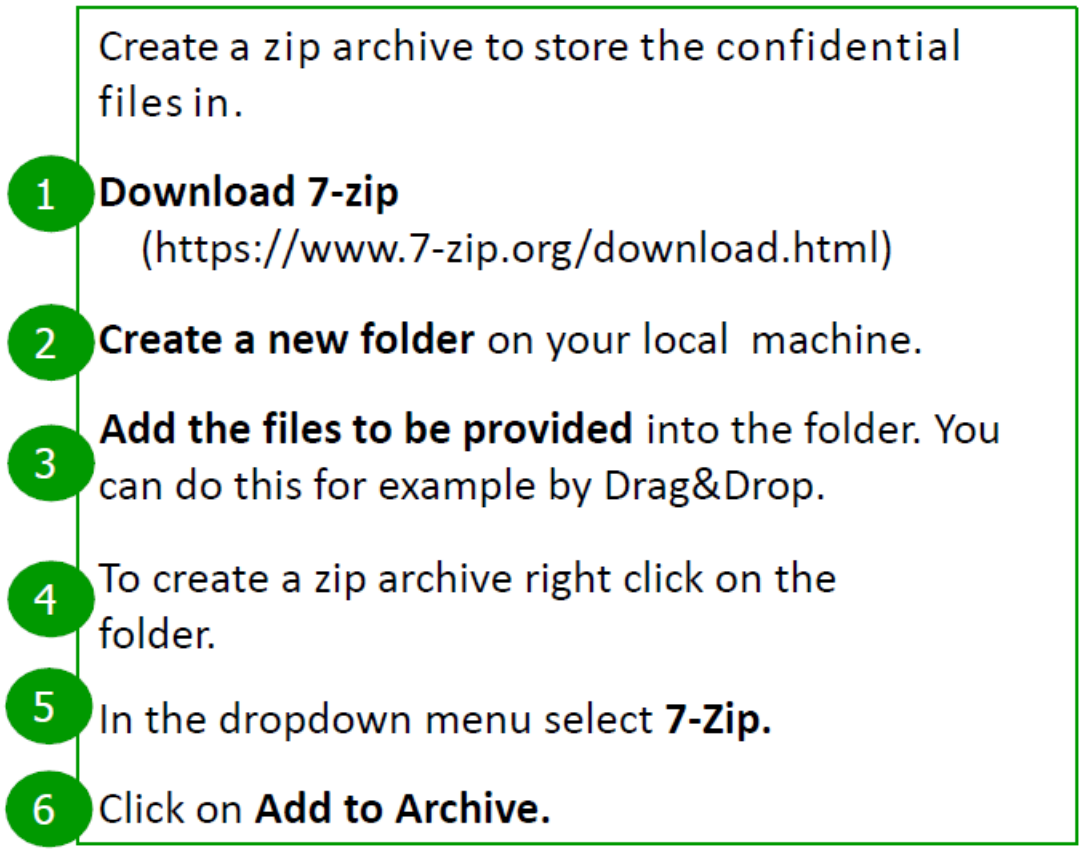
• After uploading study data and then clicking Submit Files, if you refresh the browser very quickly, the system may still be in the process of finalizing the storage.

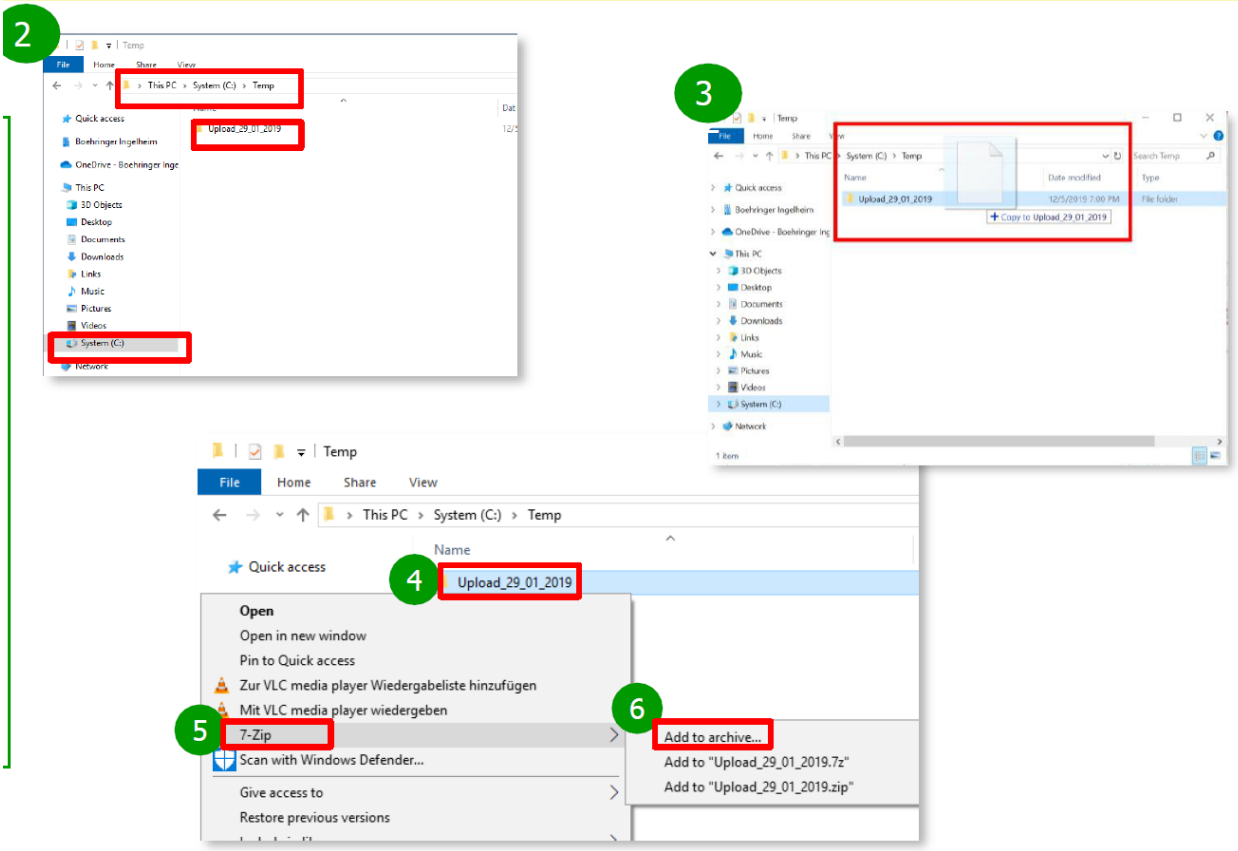
    - In this case, it may display "Make Data Available"; if you see this after submitting files, give the system a minute or so to complete and refresh the browser again.
    - If Make Data Available does not clear after a minute or so, this generally indicates a problem occurred -reach out to Vivli and we'll be able to reset things.

• If a network hiccup happens during the upload and the system displays "Upload Failed" for a given file, we recommend you tell the Vivli system to delete the file, close the data request, and re-open it before trying again.

4.3.1 Zip archive process

When preparing large files, create a zip archive. The process is outlined below

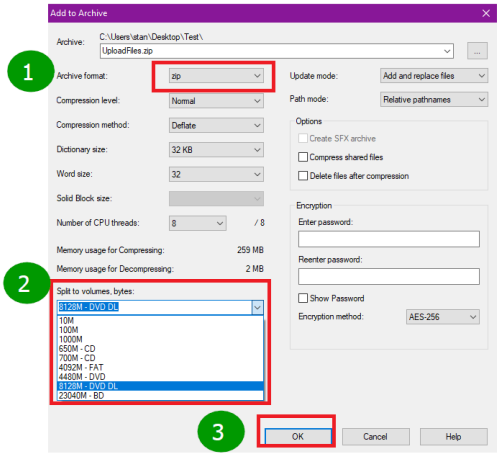


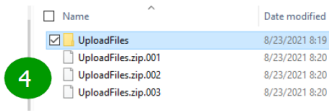


- Choose the format and volume sizes

The Add to Archive window of 7-zip will open.

1. Select Archive format to be **zip**.
2. If the total size to be uploaded will be greater than about 10 Gb, under Split to volumes, bytes, select either
   8128M (This is about 8 Gb) or
   23040M (this is about 23 Gb)
3. Click OK to start the creation of the archive(s)
4. If you asked to split the volumes, this will create a series of files with extensions of .001, .002, etc





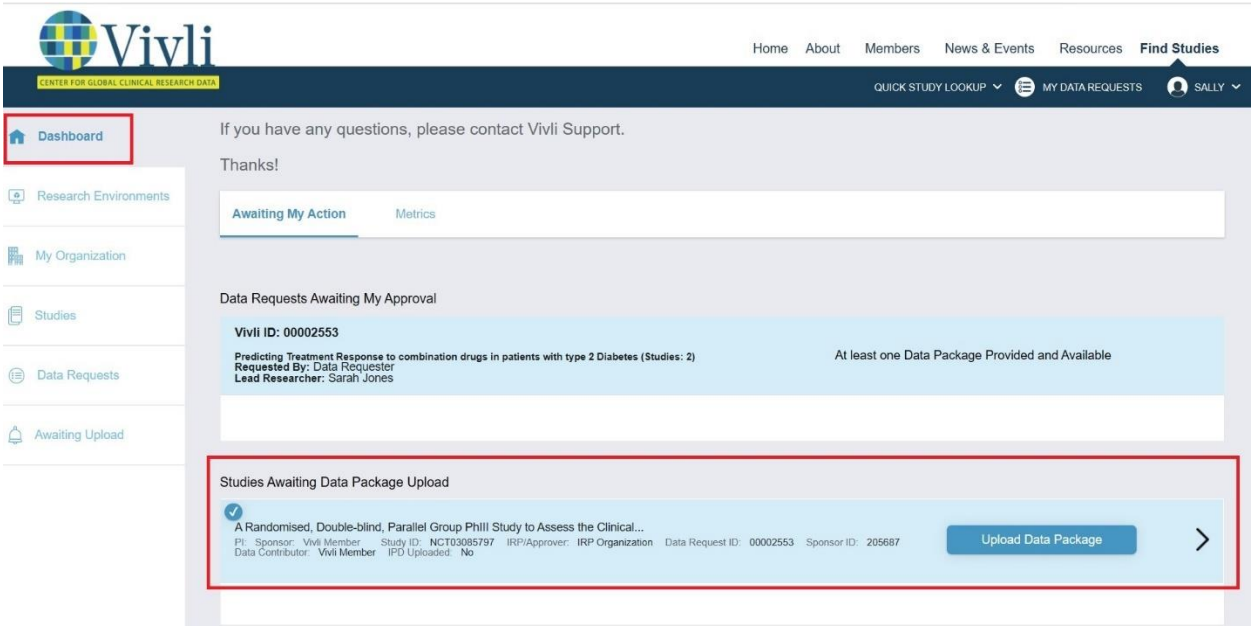
4.4 Loading Data package

- Only the Data Contributor can upload the data package.
- This data package is either provisioned into the research environment or made available for download, depending on the decision of the Data Contributor as to how to make it available for use at the time of listing the study.
- Once uploaded, the data package will be stored securely on the Vivli platform.
- As a security measure and to prevent accidental uploads of files, the Vivli platform uses a list of acceptable file types. If you attempt to upload a file type not on that list of acceptable types, you will get the message shown below. Please reach out to support@vivli.org to add a file type to the acceptable list.

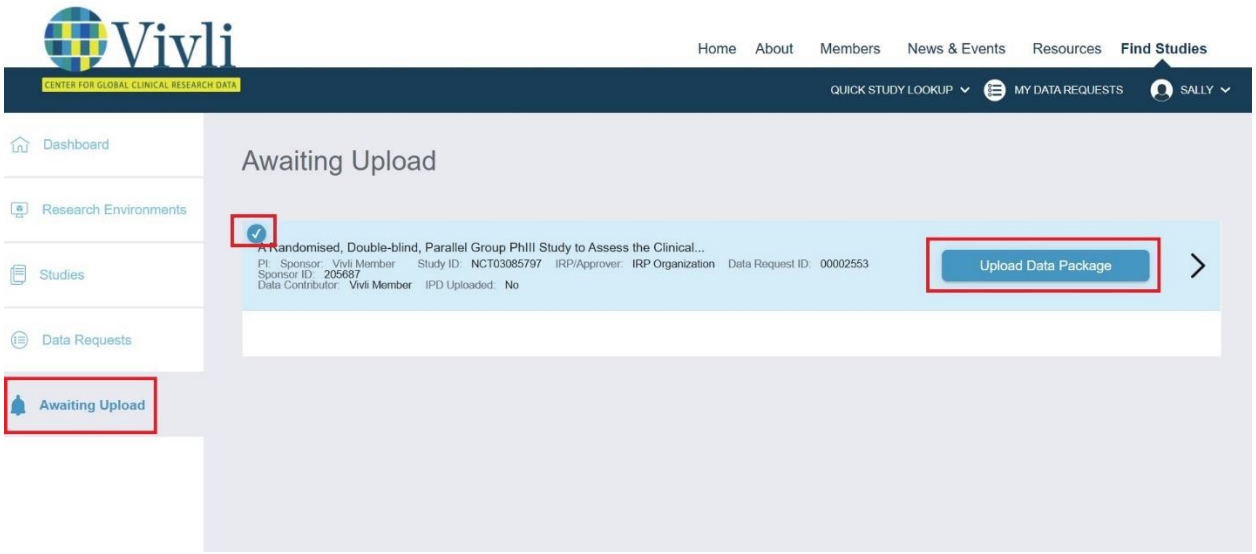
4.4.1 Steps: Uploading Data Package to an approved request

When an approved data request is awaiting data upload from your organization, you can locate the specific study needing upload by any of the following three methods:

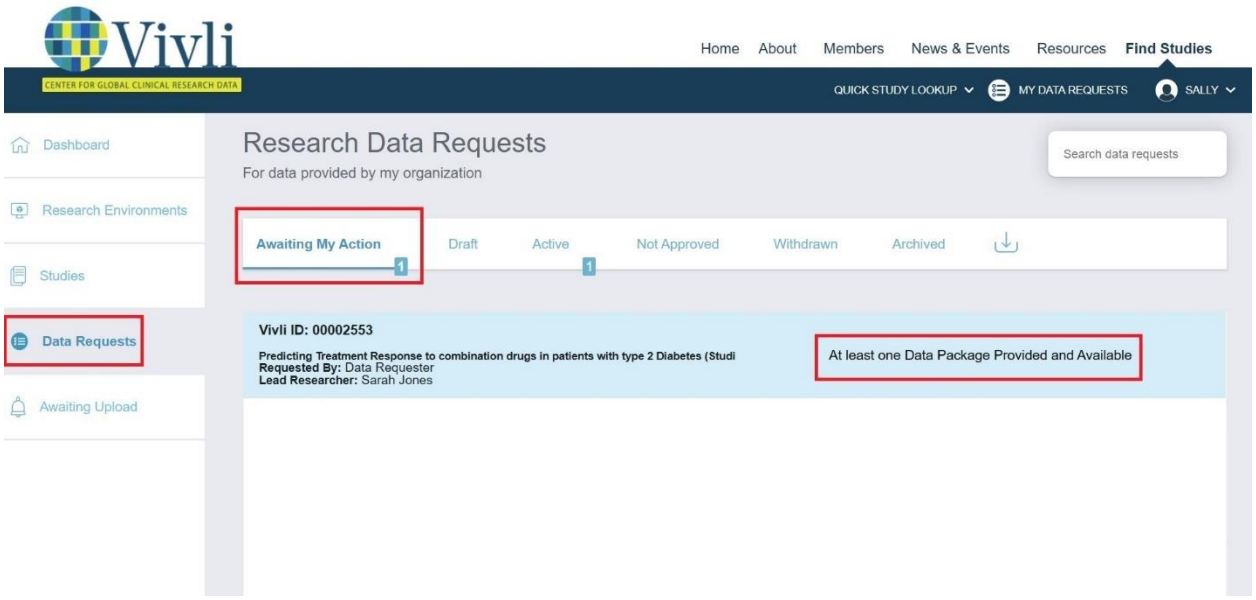
Method 1: On the dashboard that is shown at the time of login, scroll down to the Awaiting My Action section. This will list only the studies that are awaiting upload from your organization.



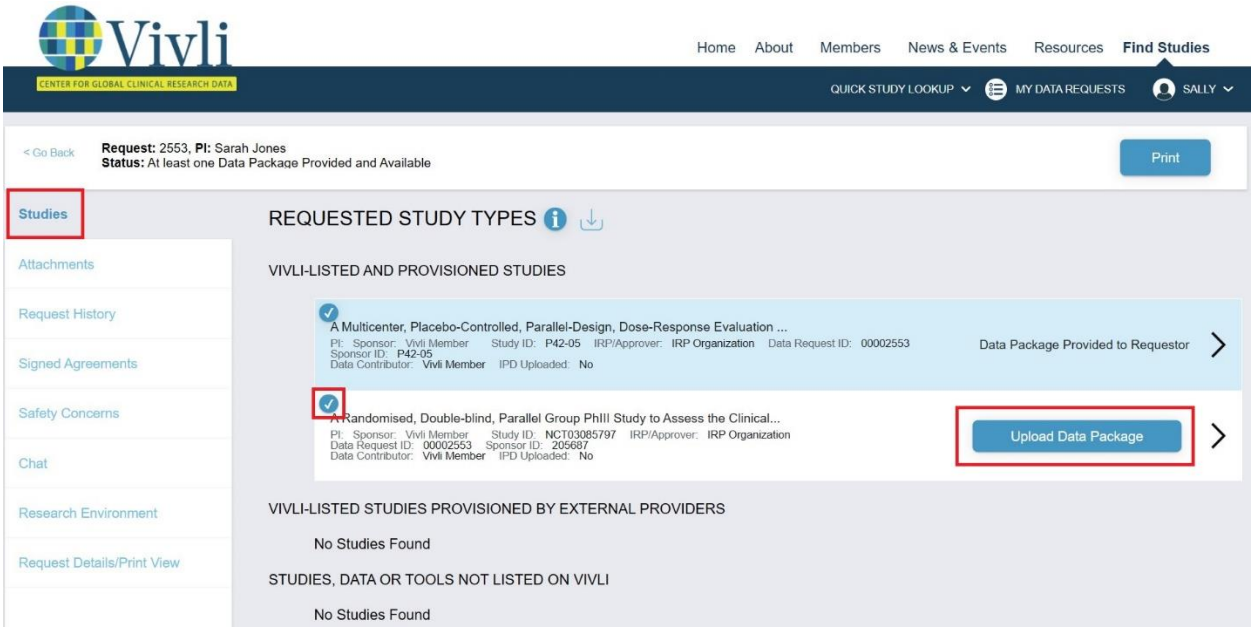
Method 2: On the left side of the screen, click on the Awaiting Upload tab:



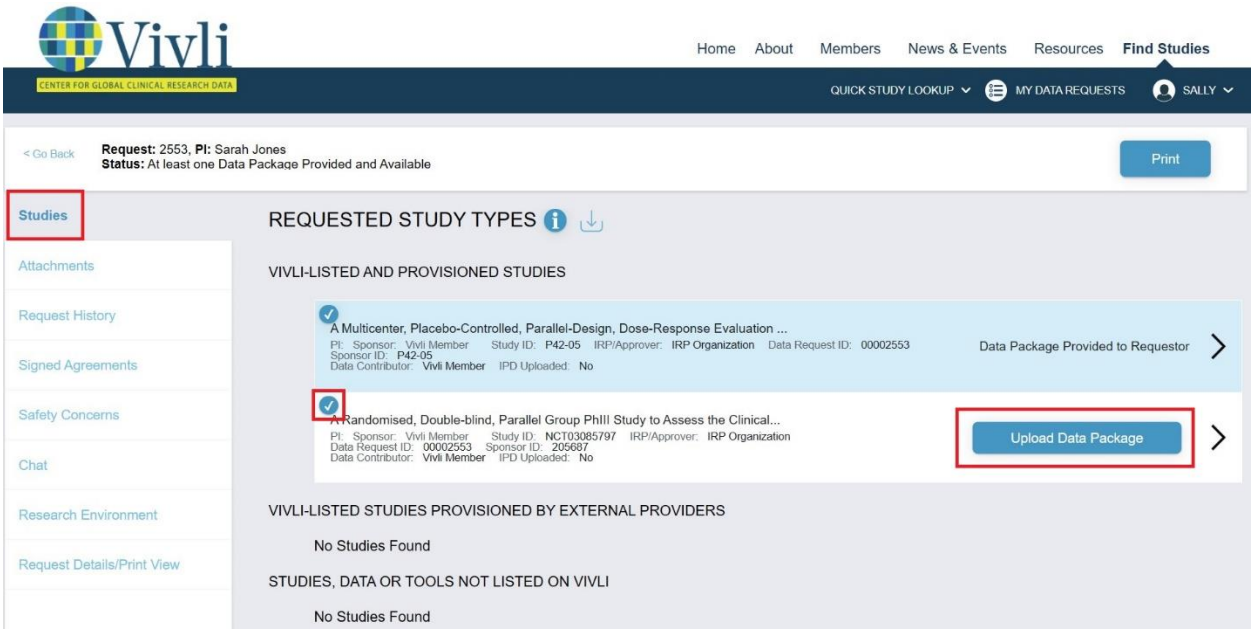
Method 3: If you want to view all the data package uploads for a particular data request, click on the Data Request tab on the left side and type in the data request ID to locate the data request– data requests in need of a data upload will be listed under Awaiting My Action:



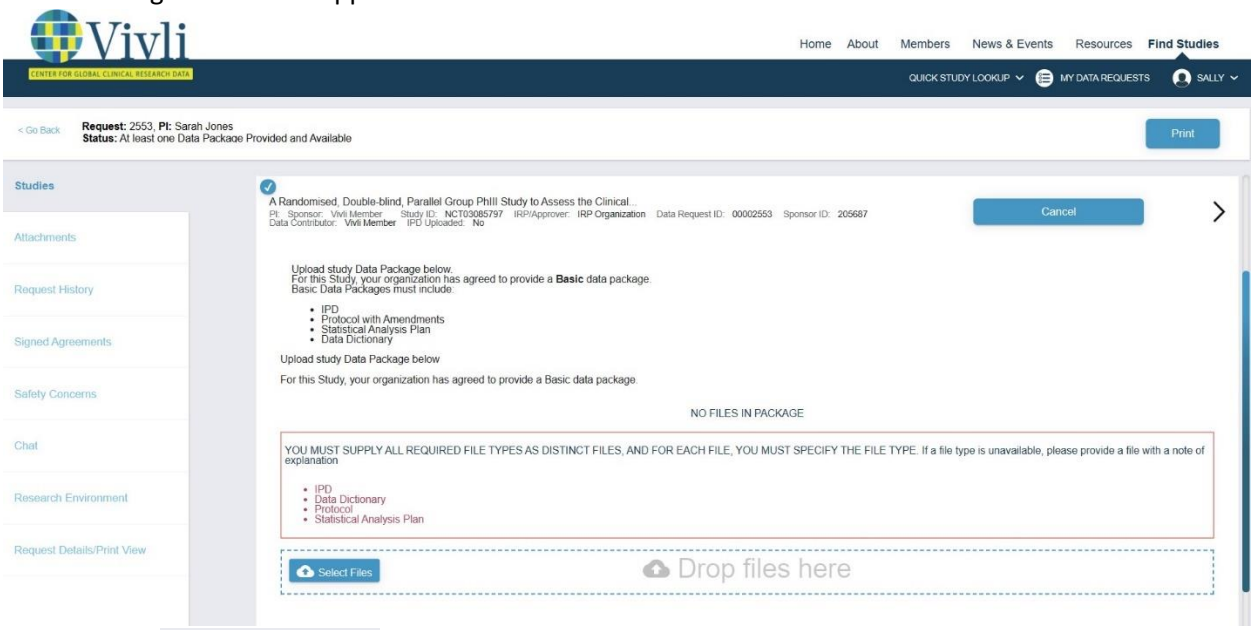
Click on the data request, and then click on Studies on the left:



1) Whichever approach you take, the following steps describe how to upload the data:
2) Next, find the study referenced in the email notification and click on **Upload Data Package.**
3) **Note:** The check sign on the left of the study helps you to identify studies that are part of your Organization versus studies that belong to other Organizations:



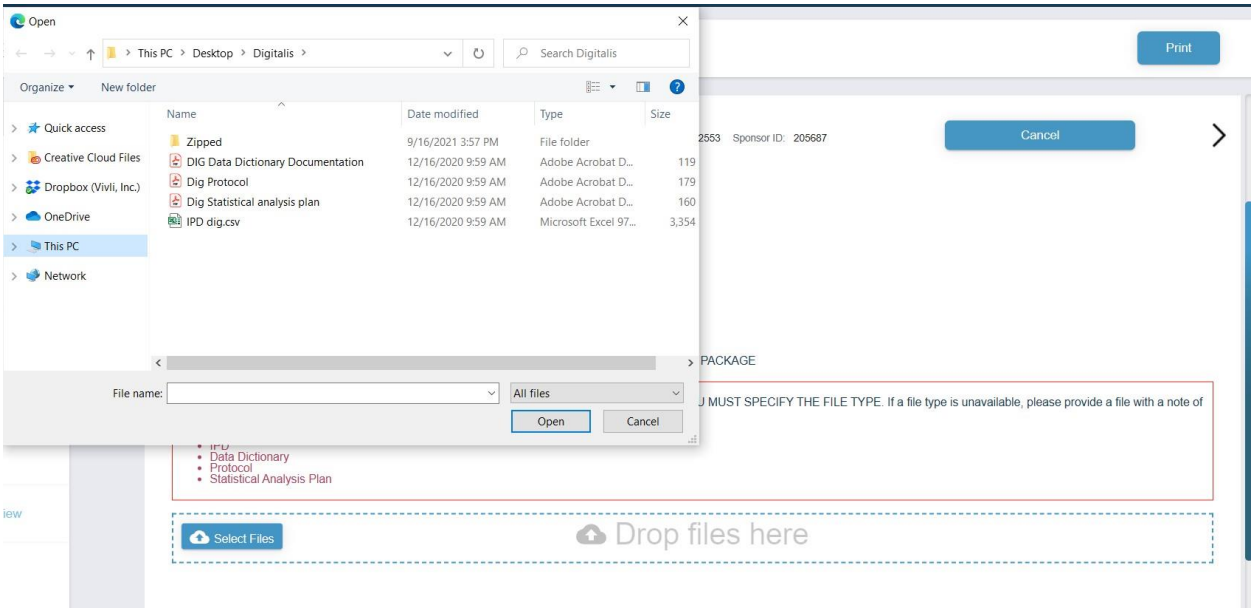
4) The following window will appear:



5) Now click on 

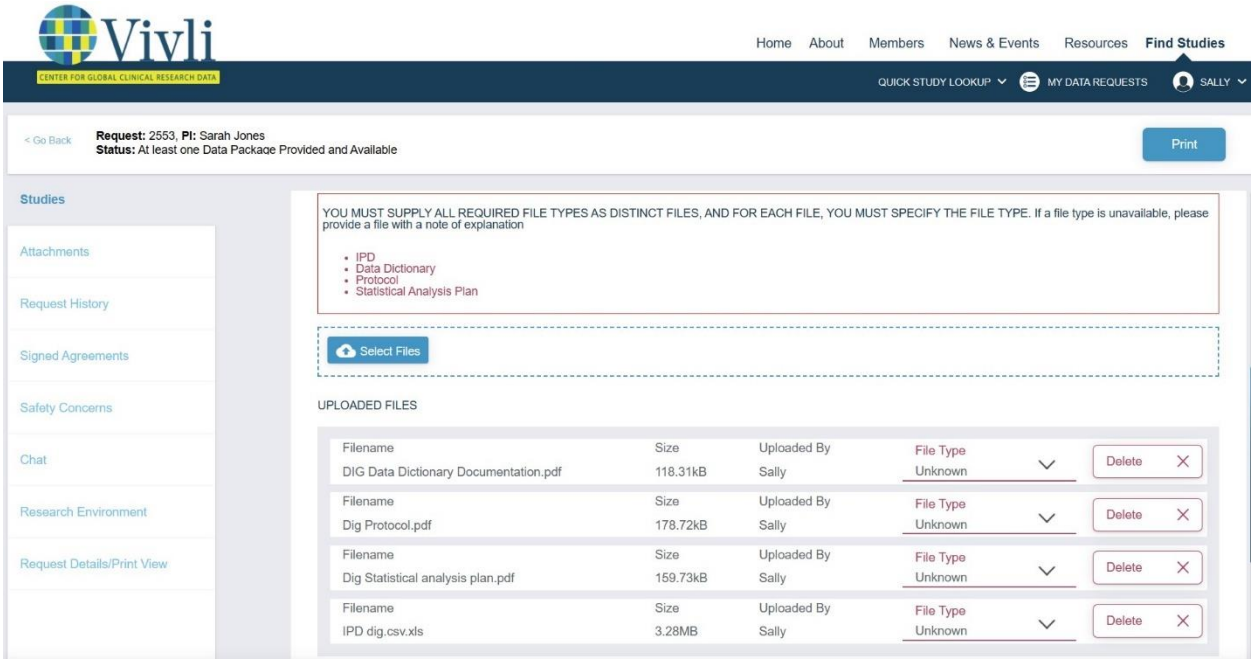
to choose files to upload.

6) A window will pop up allowing the data contributor to select the files of their computer:

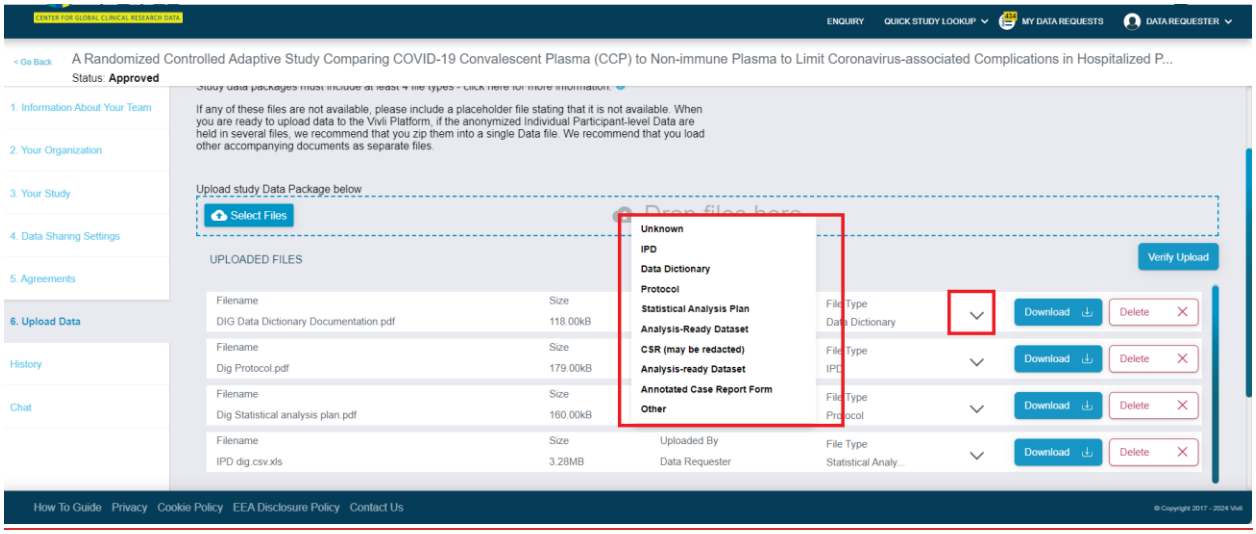


7) After selecting the files, click **Open.**
8) The data contributor may also drag files into the submit window indicated by the dotted blue box:

9) The files should appear under **Uploaded Files.** You can delete any files by clicking the "delete" button:



10) Use the dropdown menu on the right-hand side to validate the **File Type** for each file before submitting files:



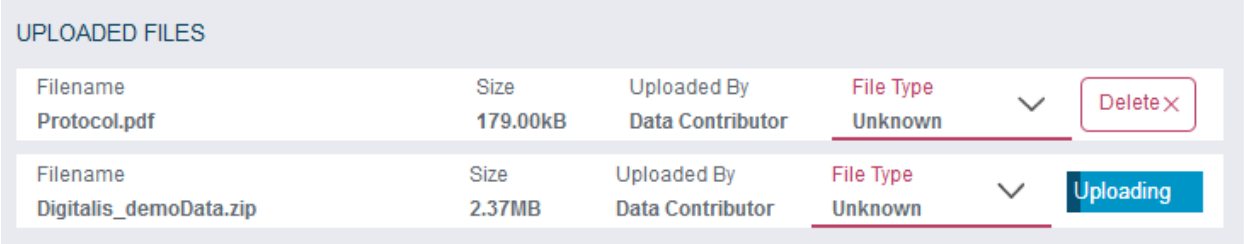
11) If the data contributor has different formats of the same file (for example, an Analysis-Ready dataset SAS file and an Analysis-Ready dataset .csv file), they can select the same file type for all applicable files from the dropdown menu. **Note:** You can't upload an empty file or upload two files with the exact same name.

12) Here is the list of what is included in a data package

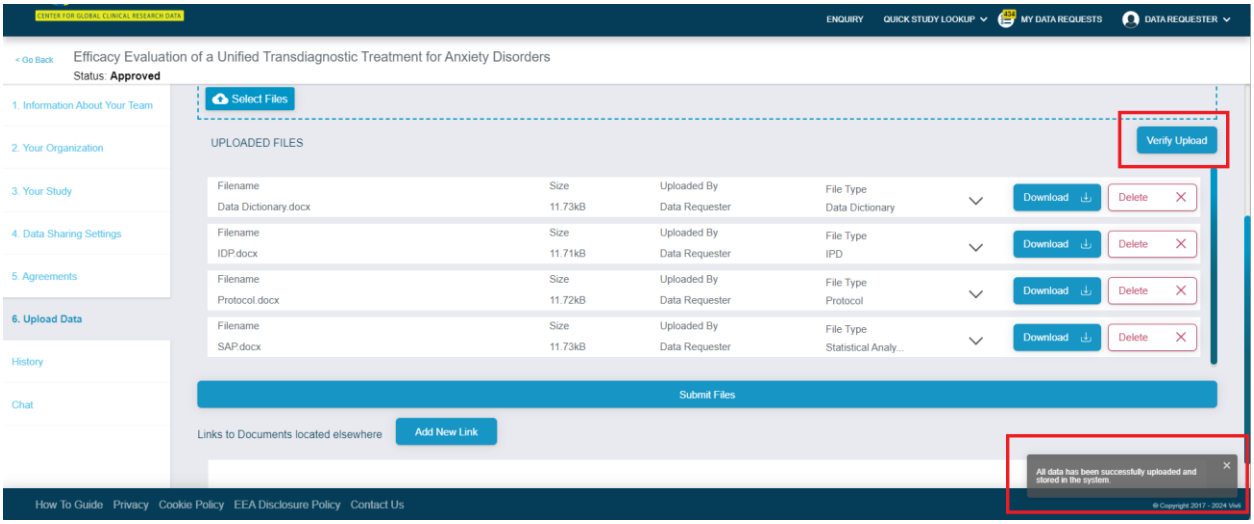
	Item	Description
Recommended	Study Protocol	Final protocol with all amendments
Recommended	Data dictionary	Detailed descriptions of each variable in the dataset, including the definition, source, coding, etc. of the variable
Recommended	Statistical Analysis Plan	Description of the principal features of the analysis described in the protocol
Recommended	Clinical Study Report (CSR)	Report that summarizes the efficacy and safety data from the study (after regulatory decision)
Recommended	IPD dataset	Final cleaned individual participant-level data, de-identified/anonymized
Recommended	Anonymization Guidance	What anonymization method was used for the data
Optional	Analytic code	Software code used to carry out prespecified and additional analyses
Optional	Analysis ready IPD data set	Dataset in a format used to carry out a sponsor's analyses

Optional	Case report forms	Forms used to collect the data that is described in the protocol for each trial participant

13) For any additional file types for data upload, select the "Other" file type option to upload the files. **Note:** If you do not have any of the basic study documents available (Study Protocol, Data dictionary, or Statistical Analysis Plan, please upload a Word document explaining which files are available, in lieu of the missing file type.
14) There are two steps involved: uploading the data and then once uploaded, submitting the data to Vivli. The data package upload happens while you see the progress bar with the label "Uploading".



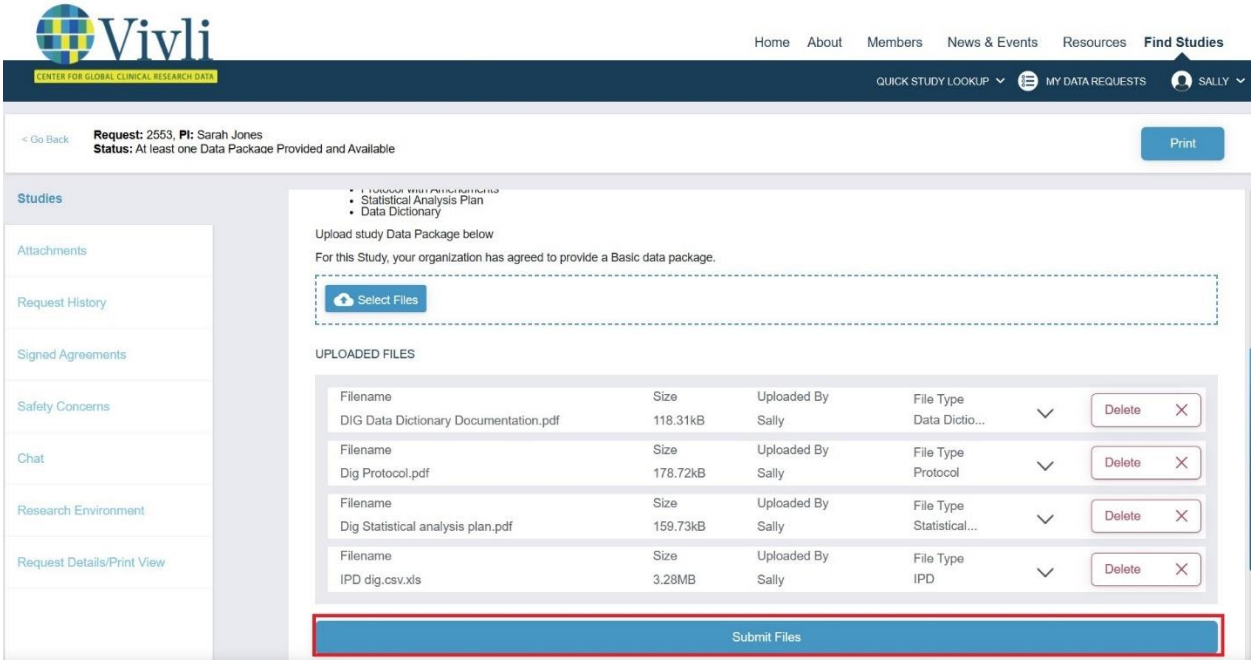
15) If the upload of any file(s) fails, Close the request, refresh the browser, re-open the request, click on "Upload Files" and delete the file that failed before moving forward.
16) Click the button that says "Verify Upload" to confirm that your files have been successfully uploaded.
17) A pop-up will appear at the bottom right screen that says "All data has been successfully uploaded and stored in the system"



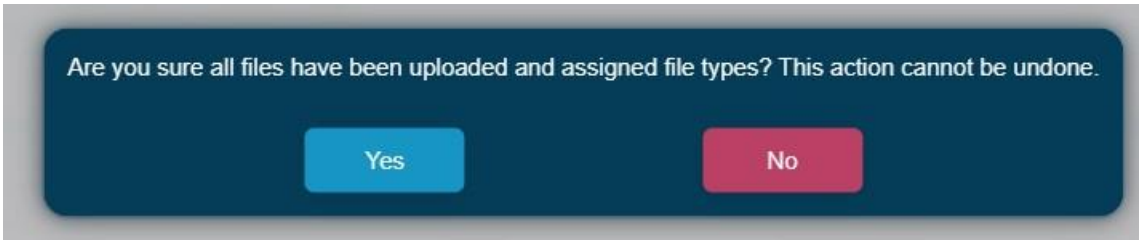
18) **Important Note:** Ensure that all the files have been loaded before clicking the submit button. Once you click the Submit button, you cannot load further documents to the same study.

19) If you plan to upload data packages for multiple studies in the data request, click Submit files for one study, refresh the screen and then click Submit files for the next study.

20) When finished, click **Submit Files** to load the data package into the Vivli Platform.

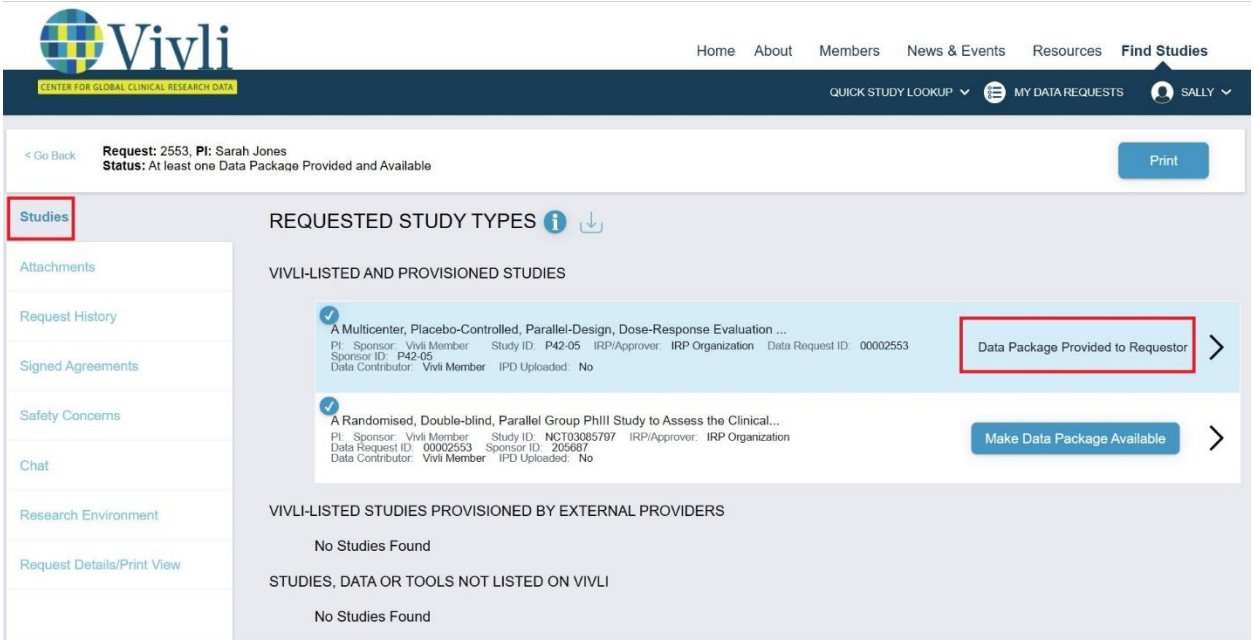


21) The following pop-up will appear:

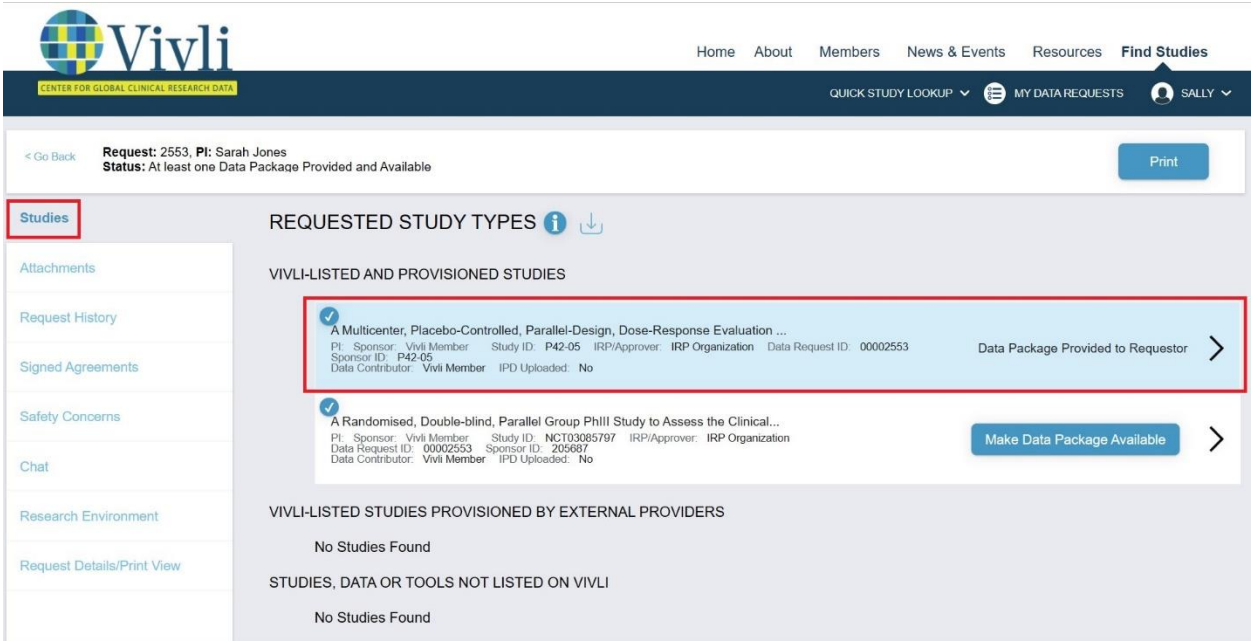


22) Click **Ok** to submit the files. The following confirmation will appear:

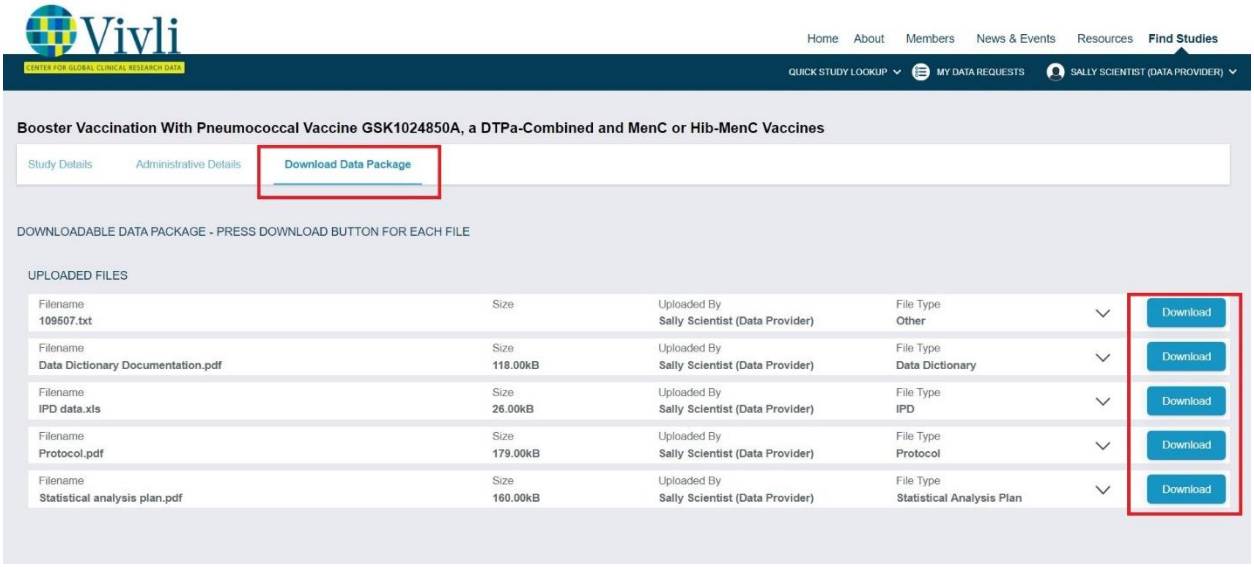
23) Once the data package has been successfully loaded onto the platform, the Organizational Administrator will see the "Data Package Provided to Requestor" note next to the study record in the studies section of the data request.



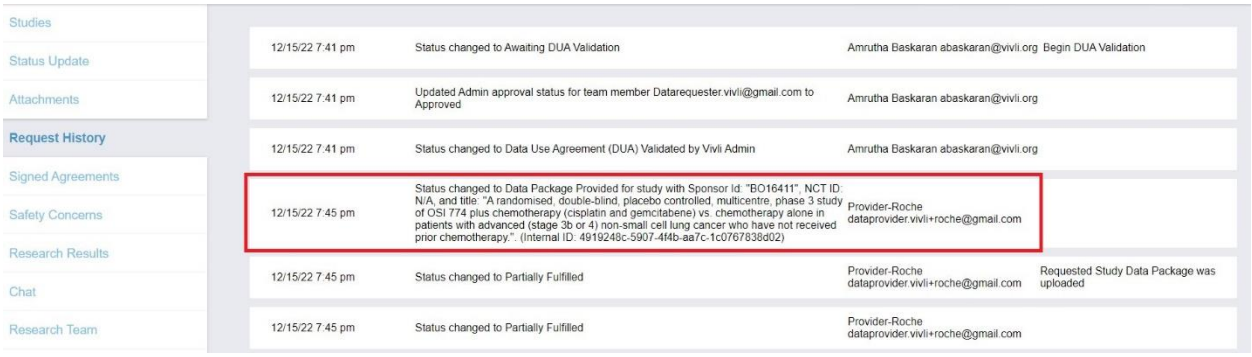
24) To view the data provided to a specific data request, click anywhere in the study record box representing the study. This will open up a new tab.



25) Then go to the **Download Data Package** tab to display any files previously uploaded. Click on the download button to see the version of the files provided to the Researcher

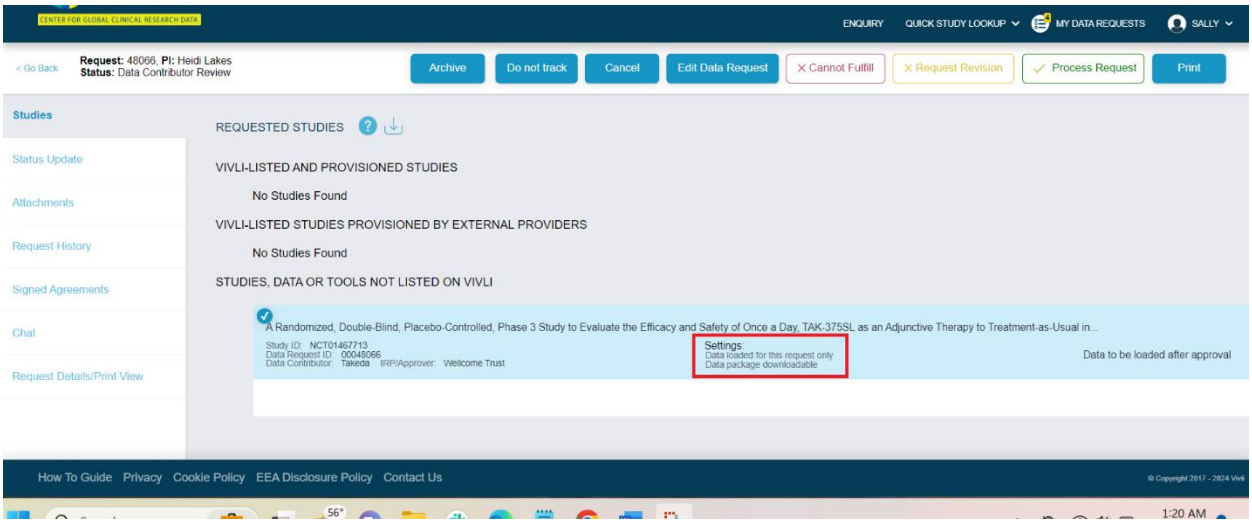


26) The data package upload and download action will be recorded in the Request history of the Data Request and includes the study ID in the history entry.

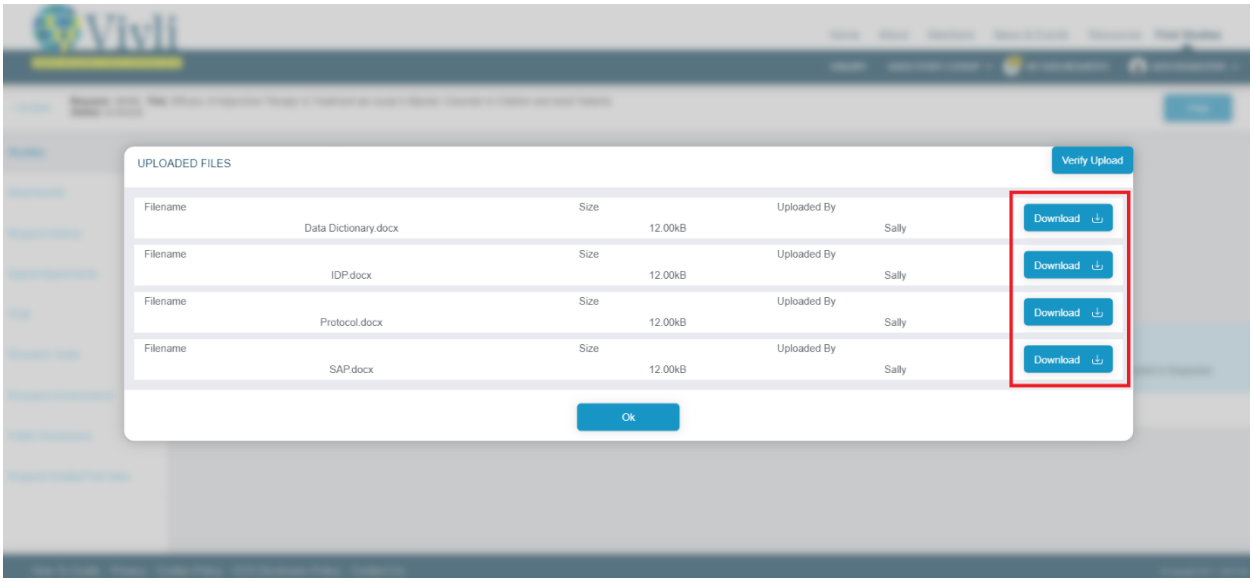


27) Once <u>all</u> the data packages from all the data contributors have been successfully uploaded, the request status will change to “All Data Packages Provided and Available” under the **Active** status bar.

28) For multi-sponsor requests, if your organization has uploaded all of its data but another data contributor has not, the request is still in a partially fulfilled state i.e. “At least one Data Package Provided and Available” status. Vivli team will follow up with the appropriate member to upload their data package.
29) For unlisted studies, you have the option to make the study downloadable. To change the study settings for downloadable data, contact a Vivli admin.
30) If the study is downloadable, after all study data is uploaded, the Research Team will have the ability to download the study data.
31) Data will be loaded as “For this Request Only” following steps in section *4.4.6, Steps: Uploading data to only one data request*



32) After the data package is uploaded, click into the study and you will see a field that says "Uploaded Files" where the study data files may be downloaded by clicking on the "Download" button on the right.



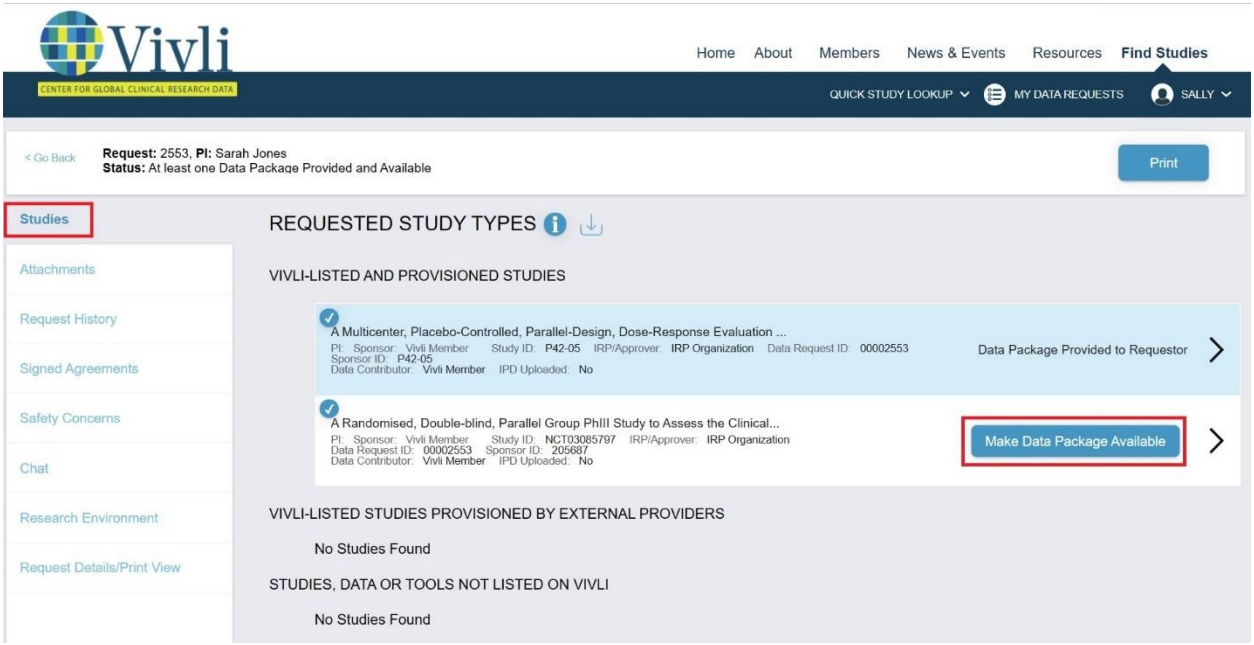
4.4.2 Steps: Make Data Package Available

If you have data packages previously loaded for a data request and if the same data package is requested by any other Data Requestor after the data was loaded, the review process will be followed and if approved and the Data Use Agreement is signed, then the data package will be provisioned for use or download by the subsequent Data Requester.

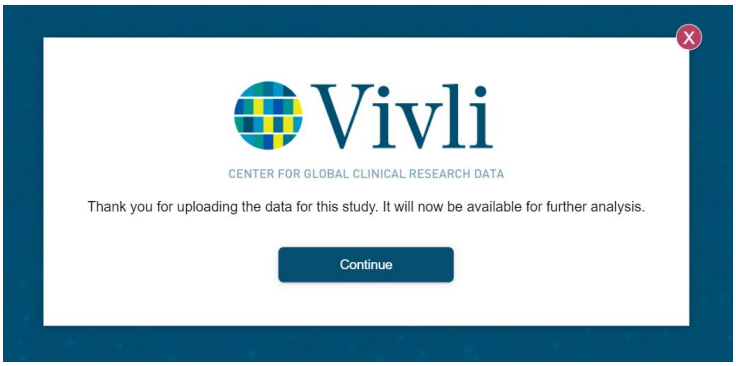
In most cases, that will be an entirely automatic step. In other words, that study will not appear in your "Awaiting Upload" section. Instead, the data package will be automatically loaded for the data request and the action will be recorded in the request history of the data request.

However, in some cases where the second data request was submitted before the data was uploaded for the first request, you will still see the study in the Awaiting Upload section. In such cases, please take the following steps.

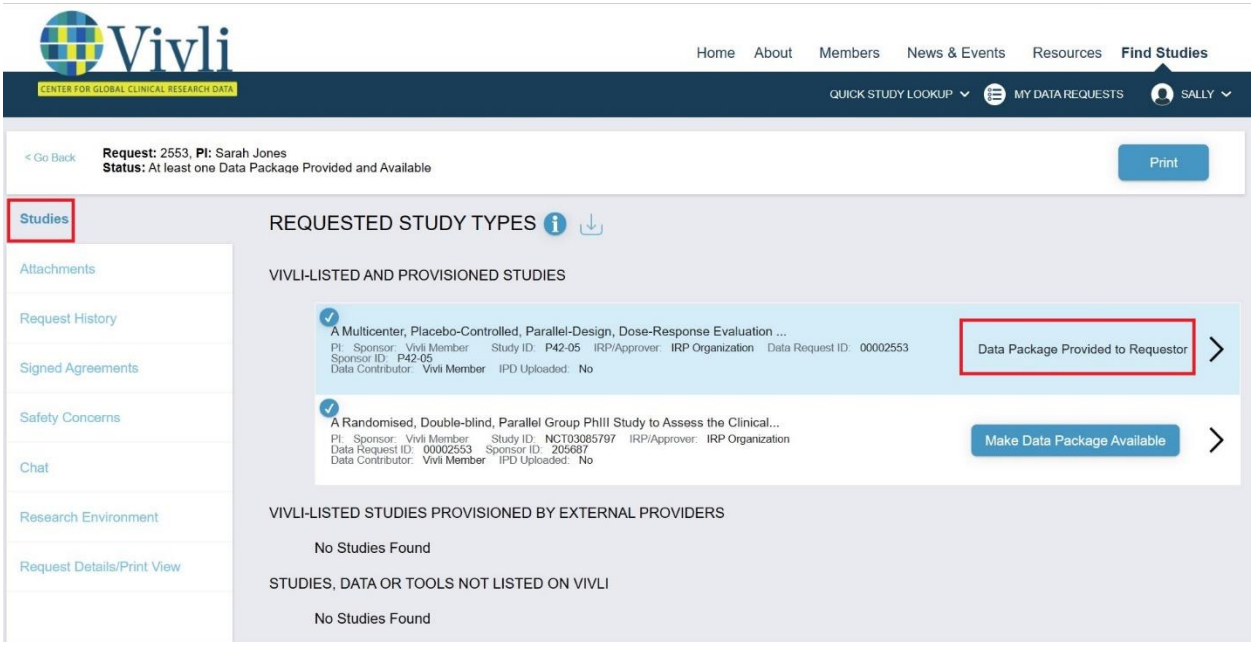
9. Locate and navigate to the study needing your action using the three different approaches described in the previous section. The only difference is that instead of a button "Upload Data" you will see a button labeled "Make Data Package Available":



10. Click **Ok** to submit the files. The following confirmation will appear:



11. Once the data package has been successfully loaded onto the platform, the Organizational Administrator will see the "Data Package Provided to Requestor" note next to the study record in the studies section of the data request.

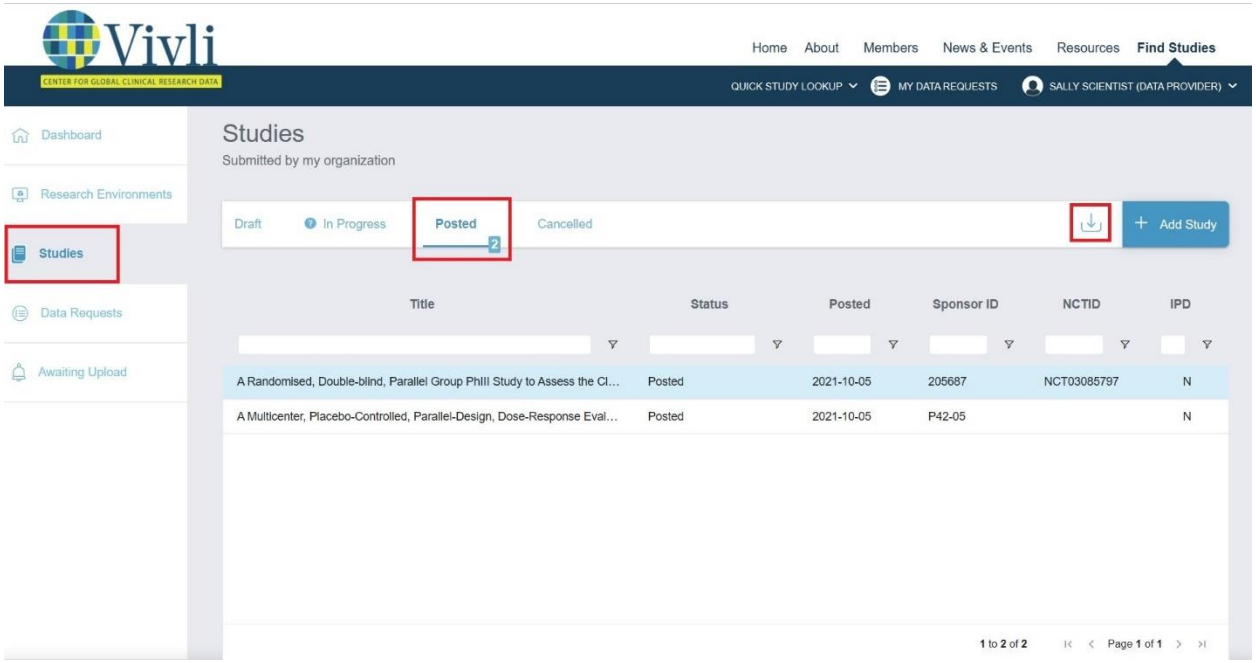


12. The data package upload action will be recorded in the Request history of the Data Request.

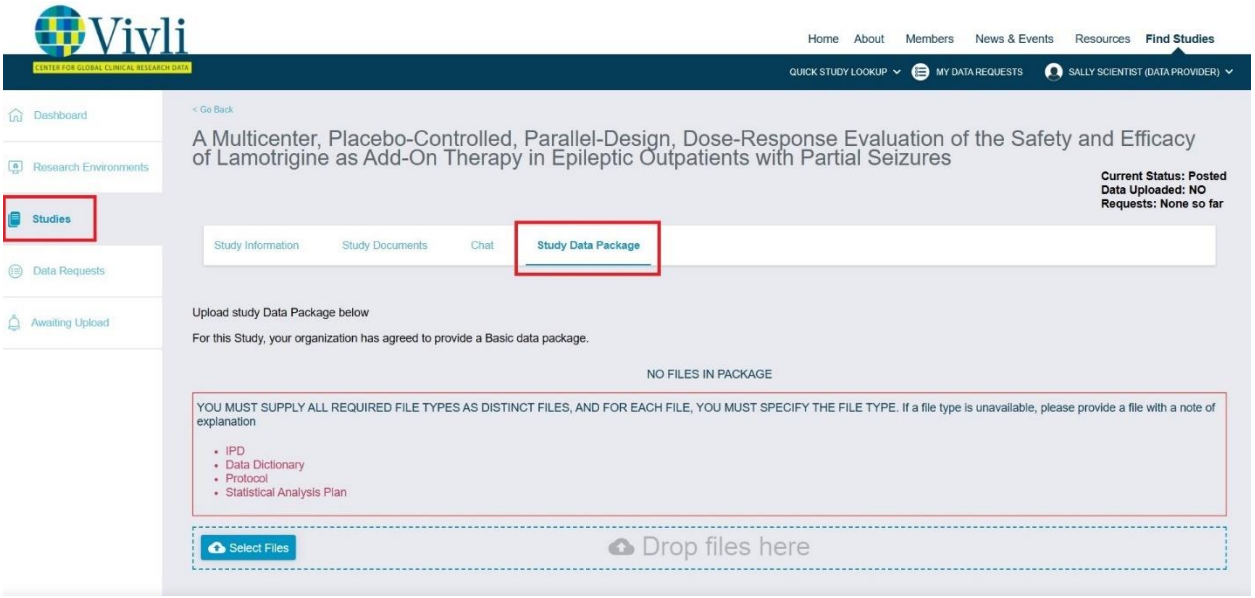
4.4.3 Steps: Uploading data while request undergoing review

Data Contributors also have the ability to upload data and update study data packages while the request is in the review process if the study is listed (this option is not available for unlisted studies)

1. While a request is in the review process, navigate to the Studies tab from the dashboard.

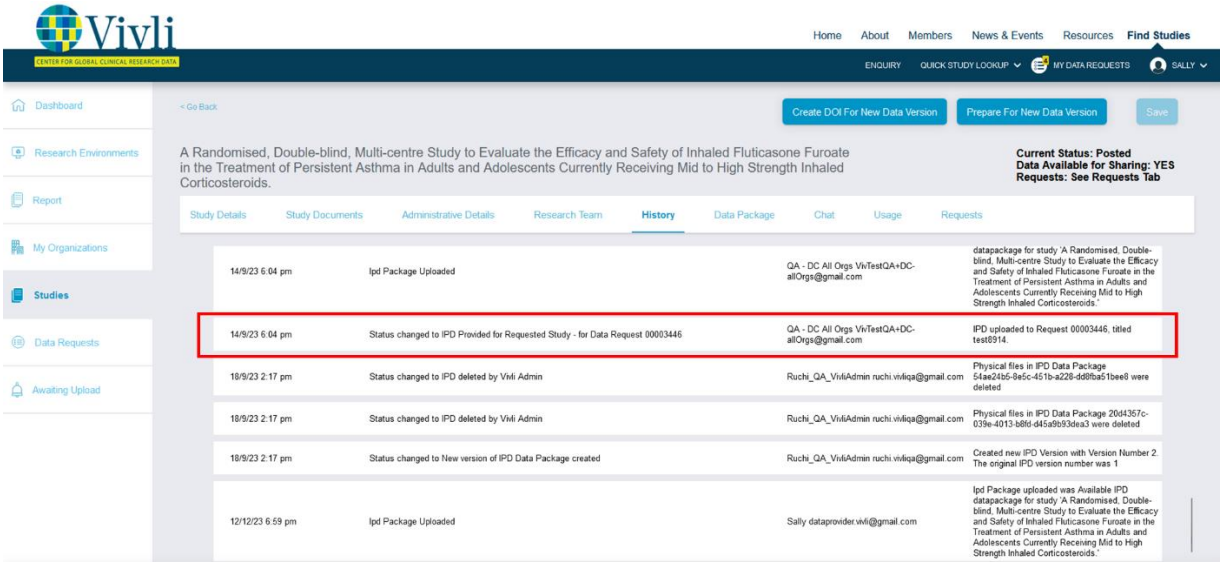


2. Open the study and select the Study Data Package tab and upload the data package. See section 4.4.1 for the steps for uploading the data package. Also, note that the requests associated with this study will be listed on the upper right.

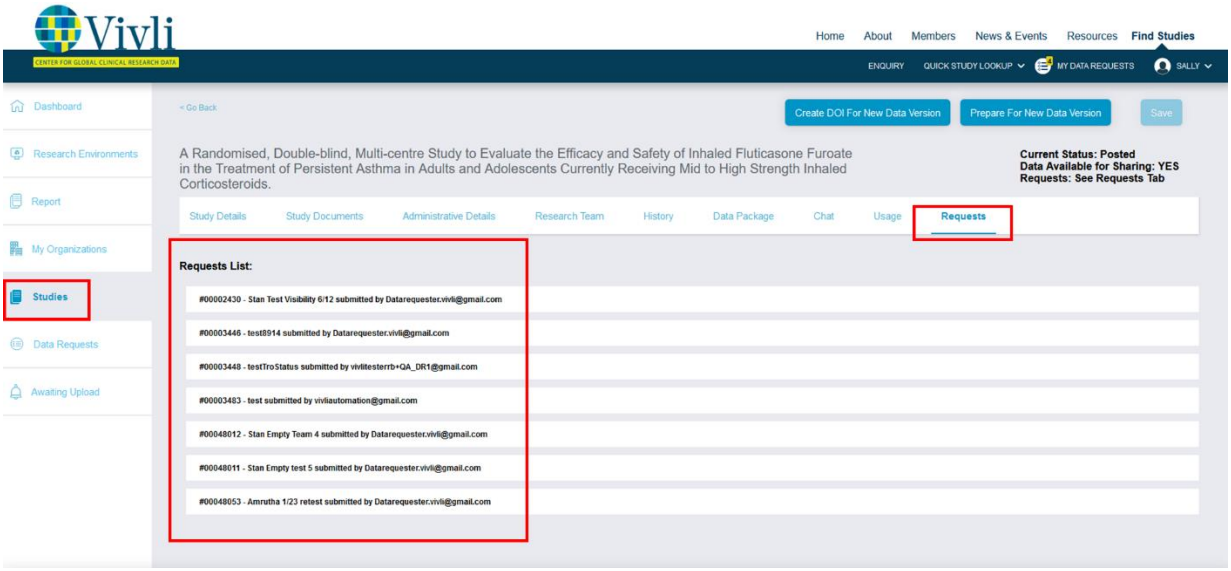


3. Once the request reaches the Data upload stage, the data package will be loaded to the data request. Please section 4.4.2 Steps Make Data Package Available for more details.

4. When a data contributor uploads IPD to a requested study from a data request, and no study template ID exists yet, the request history will record when the data was uploaded, including the date/time and the person who did it. Additionally, it will display the request number for data requests for this study. If the data is uploaded to this request only, the request history will include this information.

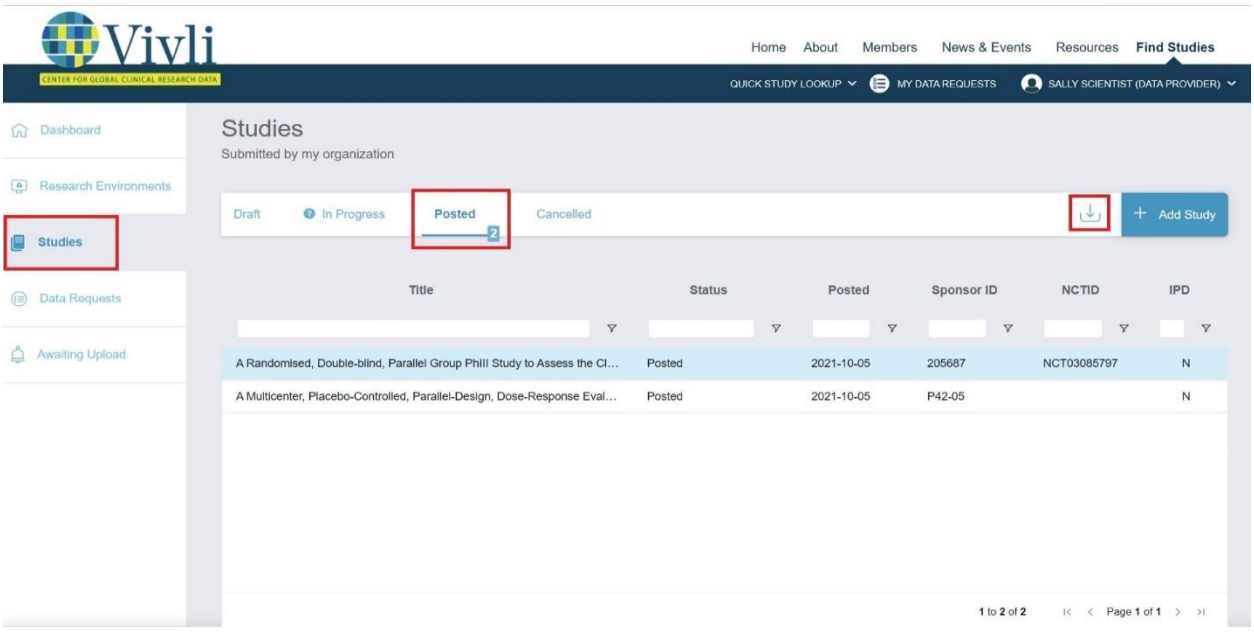


Data contributors can also see all requests that the study data has been uploaded to in the 'Requests' tab:



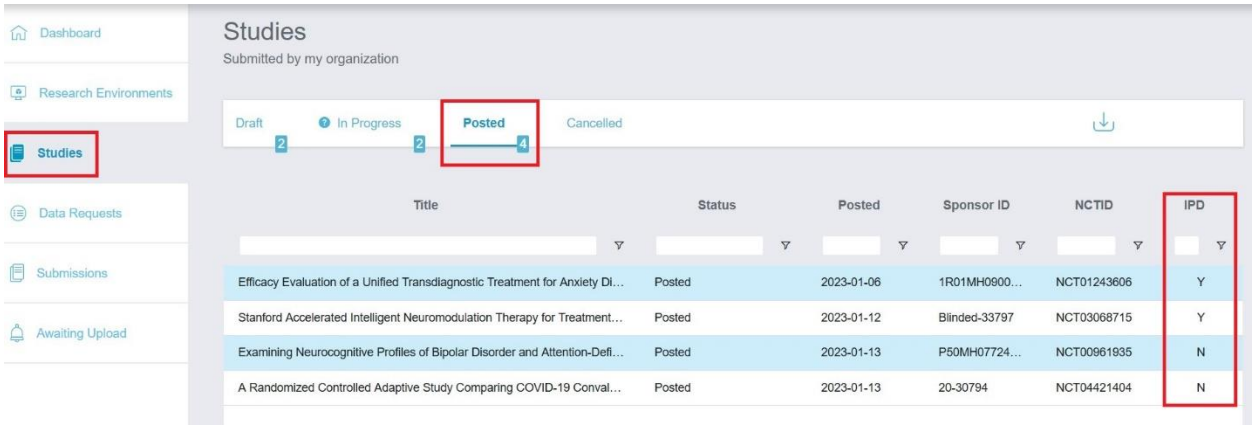
4.4.4 Studies list and stored data package

At any point in time, Data Contributors may download a list of their posted studies from the platform. Navigate to the Studies tab from the Dashboard, click on Posted, and click on the download button.

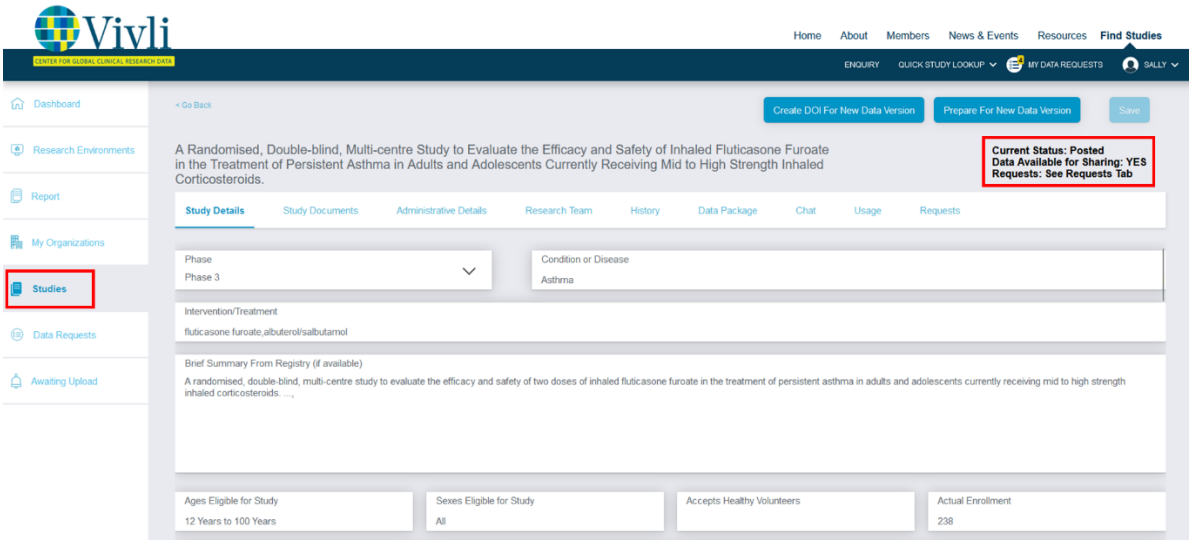


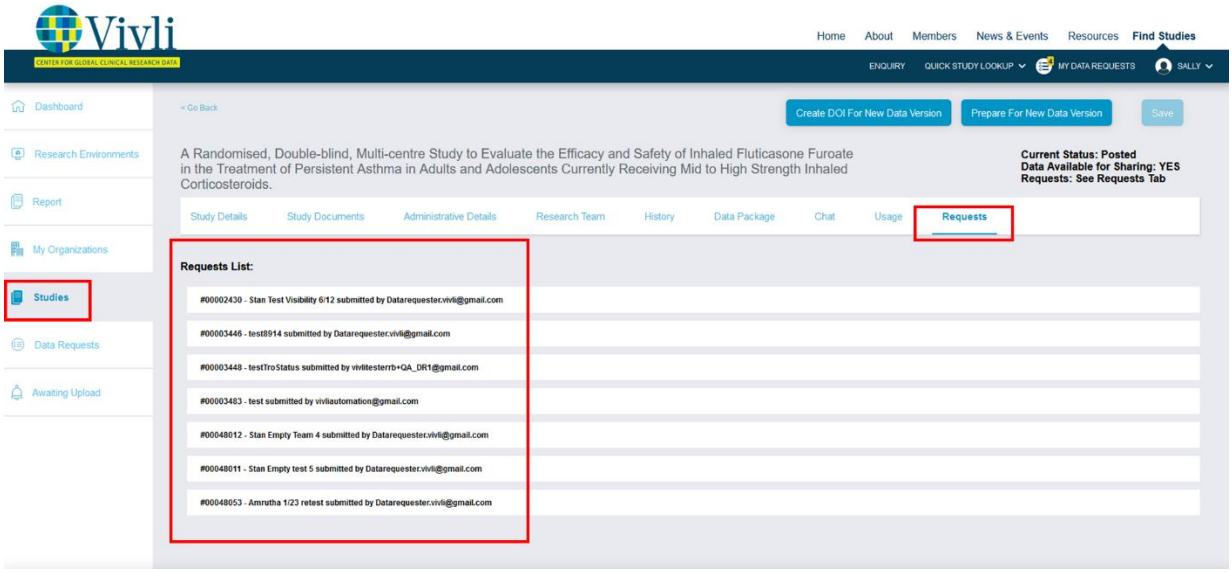
If a posted study has a stored data package, this will be visible in the following two places from the studies tab:

- From the list of posted studies, the IPD column will indicate “Y” for data available and “N” for data not uploaded.

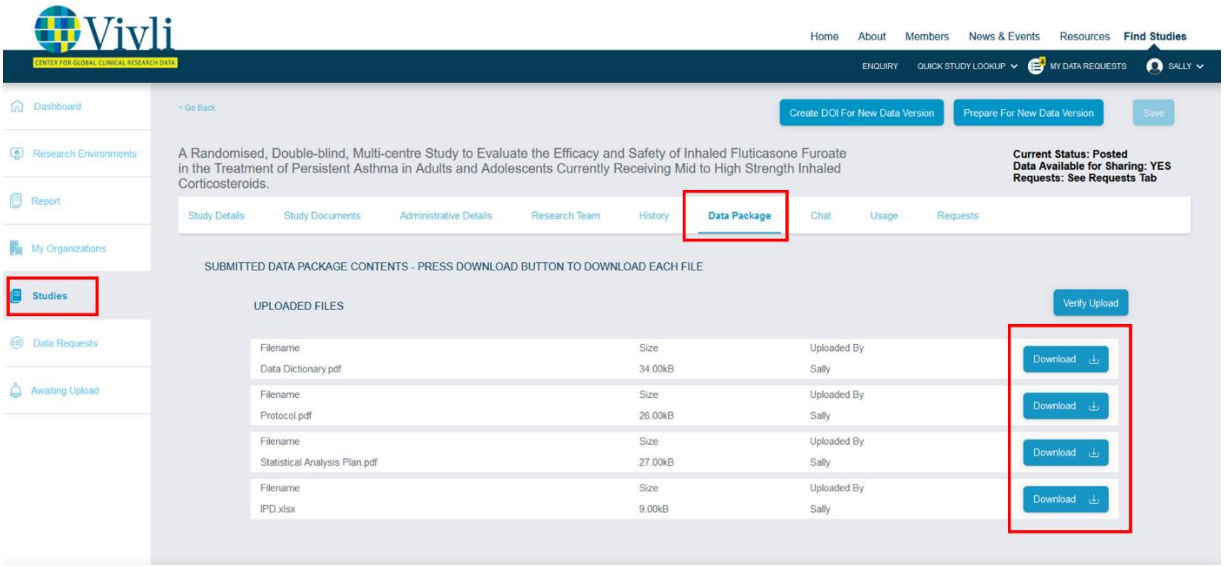


- When a posted study is selected, whether data is available is shown in the upper right, and the data requests for which this study has been made available will be listed under the “Requests” tab.





If the study has data that has been loaded, this information will be shown in the upper right. Additionally, the "Data Package" tab will be displayed – this will allow the Data Contributor to download the files that have been loaded, for example as a way of validating that the correct version of the files has been loaded.



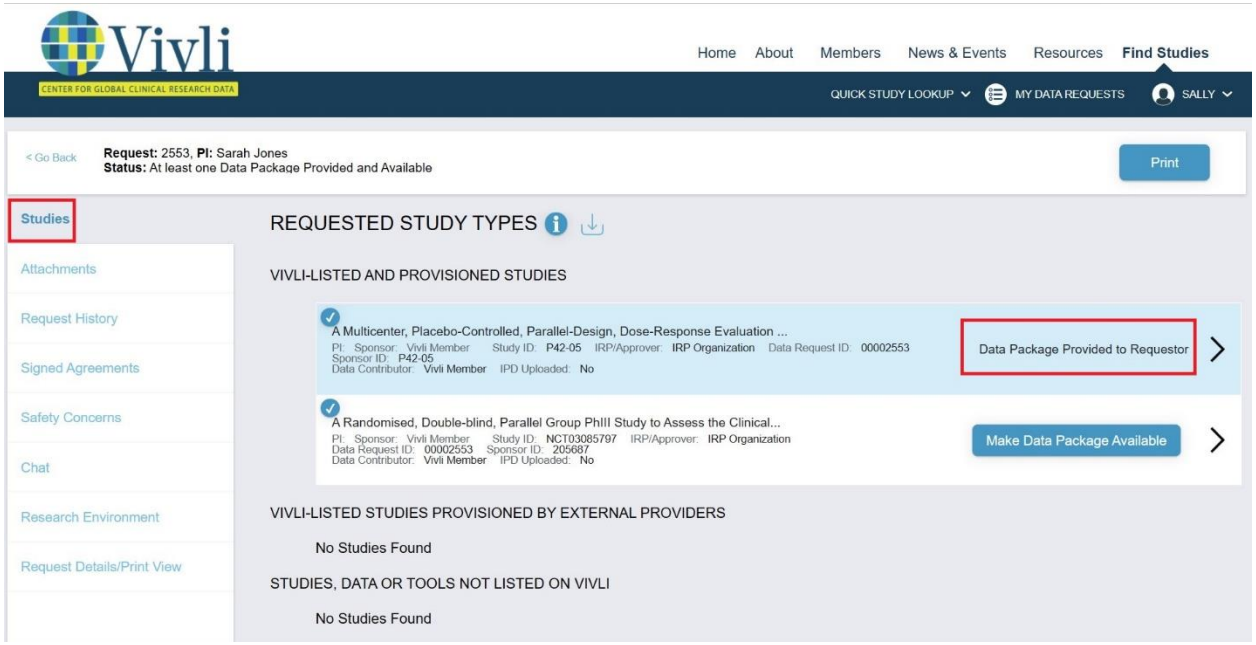
A history entry will be written to the study history whenever data is loaded to a specific request, with the request number included.

At the request level

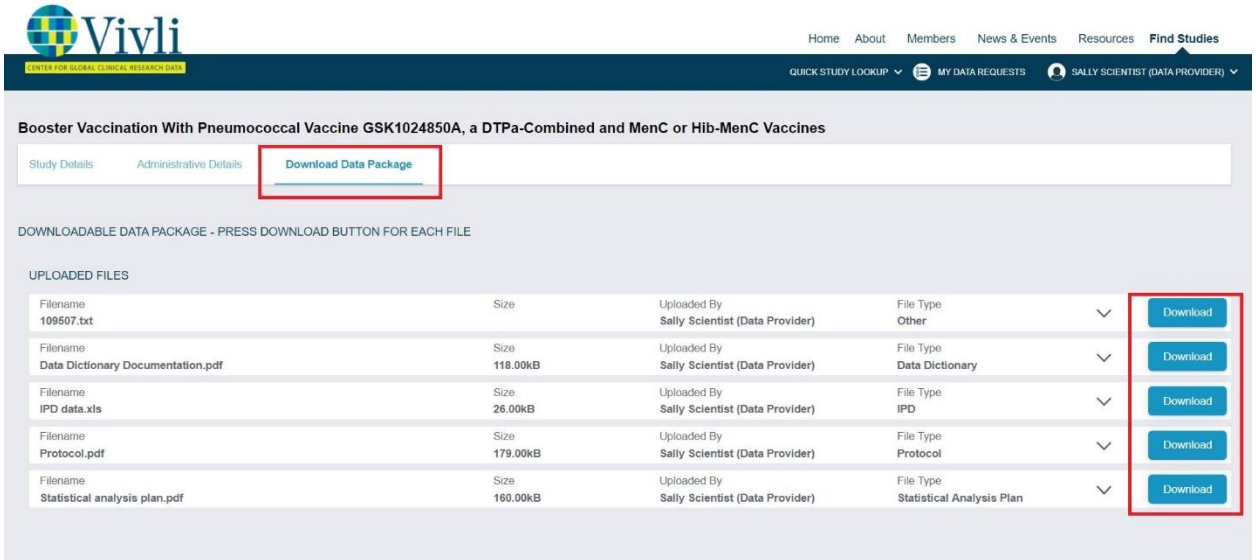
- Within a data request, the Data Contributor can see the stored data package provided to the requestor by navigating to the request and then selecting the Studies tab. Note that this data might be different from the data in the posted study if the data in the posted study was updated

since the data was provided to this particular request. Viewing the data through the request provides a way to validate what data was provided as part of this specific request.

- To view the data provided to a specific data request, open the data request and click on the studies tab.

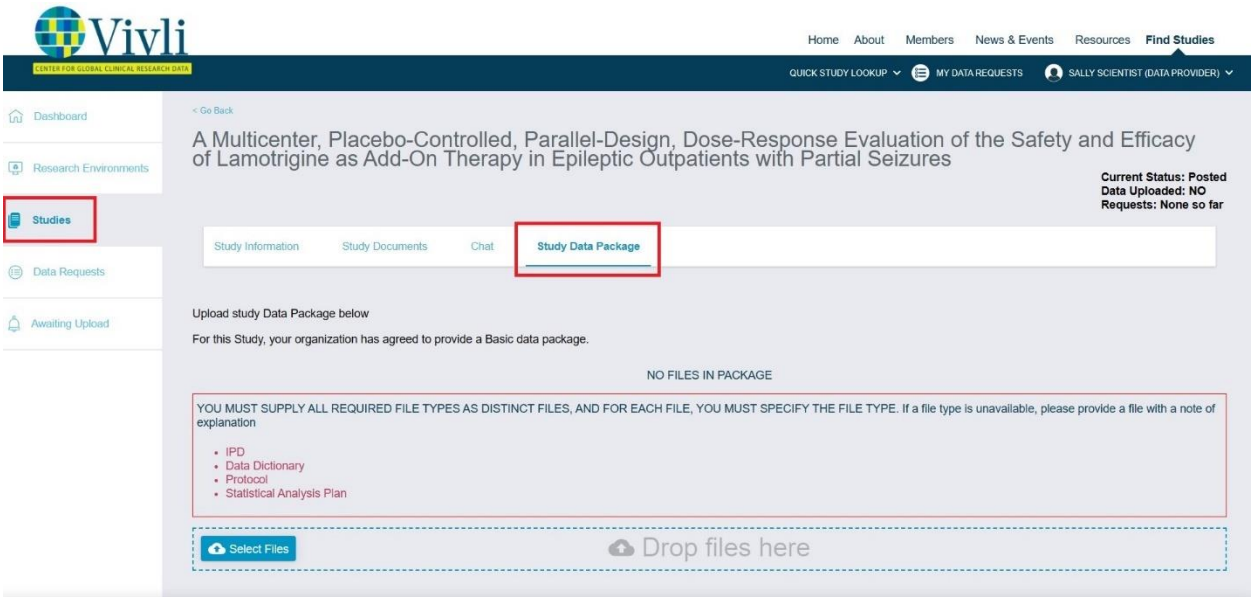


- Click anywhere in the white box representing the study. This will open up a new tab. Then go to the **Download Data Package** tab to display any files previously uploaded. Click on the download button to see the version of the files provided to the Researcher



4.4.5 Steps: Upload a New Version of the Data Package

1. Reach out to Vivli support at support@vivli.org to delete the stored data package. The Vivli team will respond to you once the data package is deleted.
2. If you are ready to upload the new version of data at this time, choose the Study Data Package tab and upload the new version of the data.



Note that if you are not ready to upload data at this time, you will be prompted to upload data when the data request has completed DUA approval.

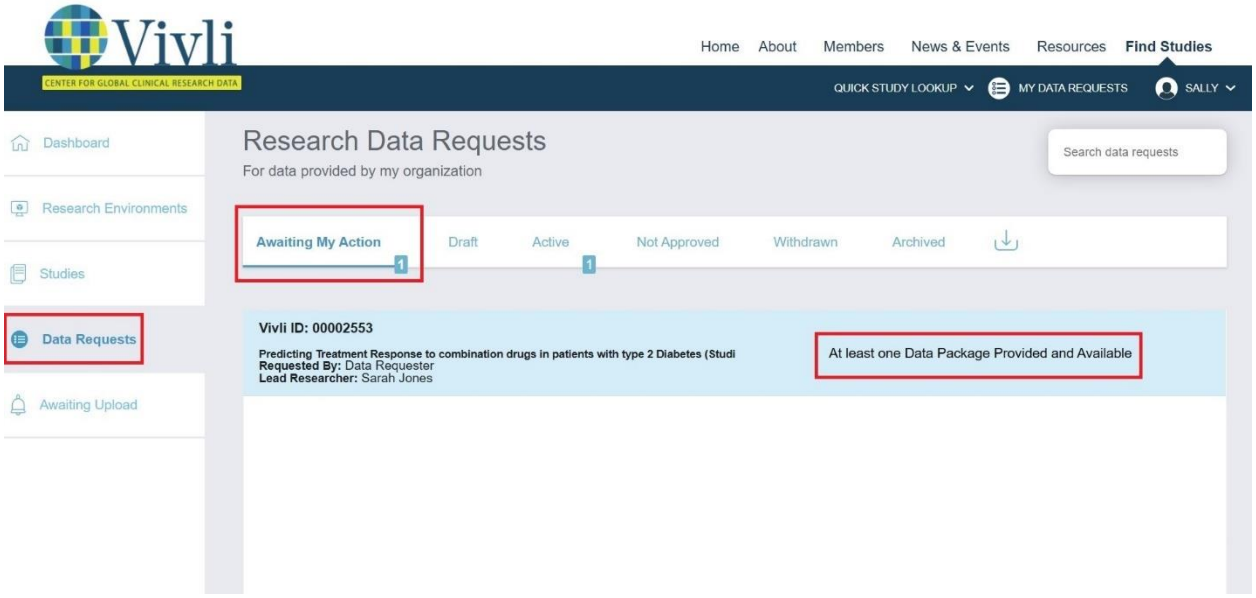
4.4.6 Steps: Uploading data to only one data request

By default, the data package uploaded to the Vivli platform is stored in the secured vault and is automatically provisioned to the next researcher when their request is approved and when their DUA is executed. However, Org Admins can make selections for a data request when a data request is in the review process. This means that when a data package is uploaded in the context of a specific request, the data is to be loaded only to that request, and not automatically stored in the secure vault for the next researcher. The option is only available for *studies listed* on the Vivli platform.

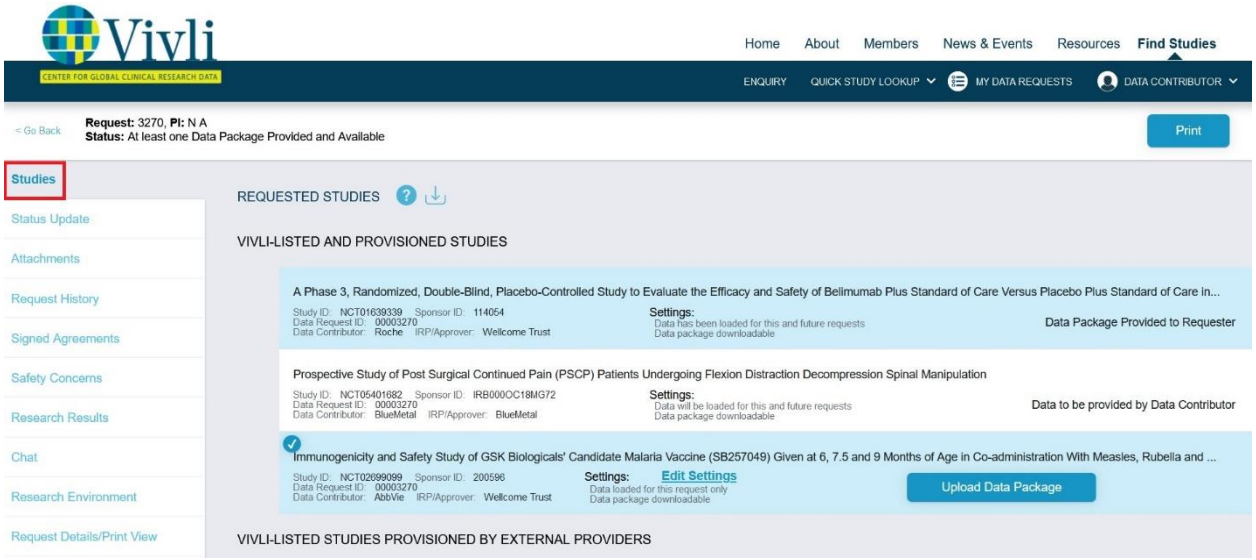
Org Admins have the option to make this selection at the Data Contributor review stage. Please see section 3.3 Study Settings at Data Contributor Review. This setting will be visible (but not settable) on requests that have been fulfilled (data package uploaded).

To upload the data package for a particular data request only, take the following steps:

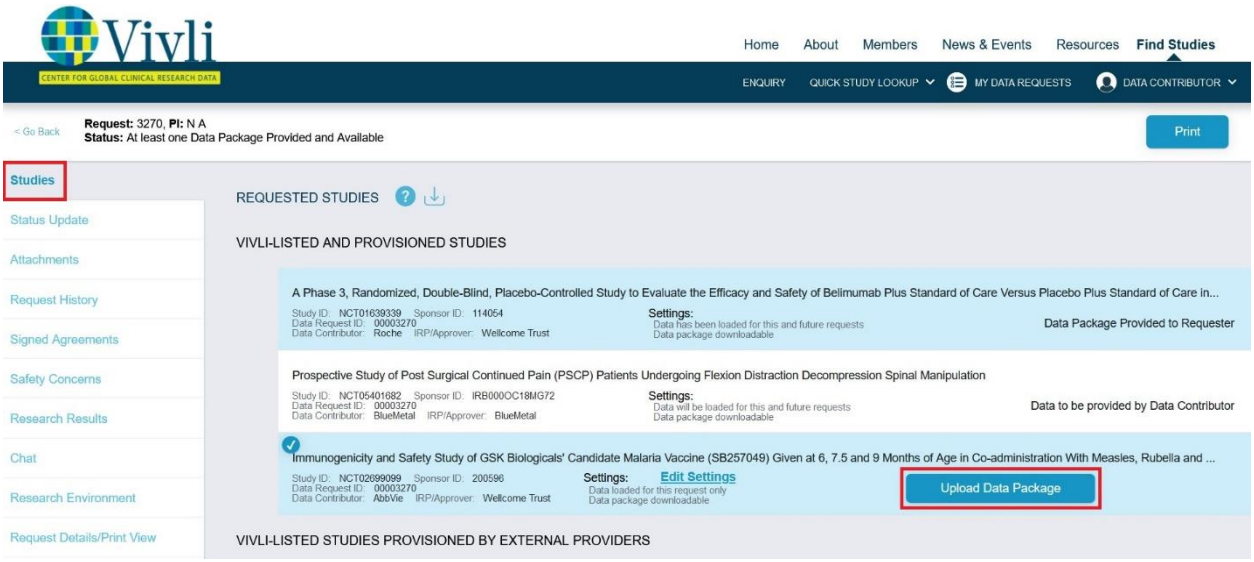
1. Click on the Data Request tab on the left side and type in the data request ID to locate the data request– data requests in need of a data upload will be listed under Awaiting My Action:



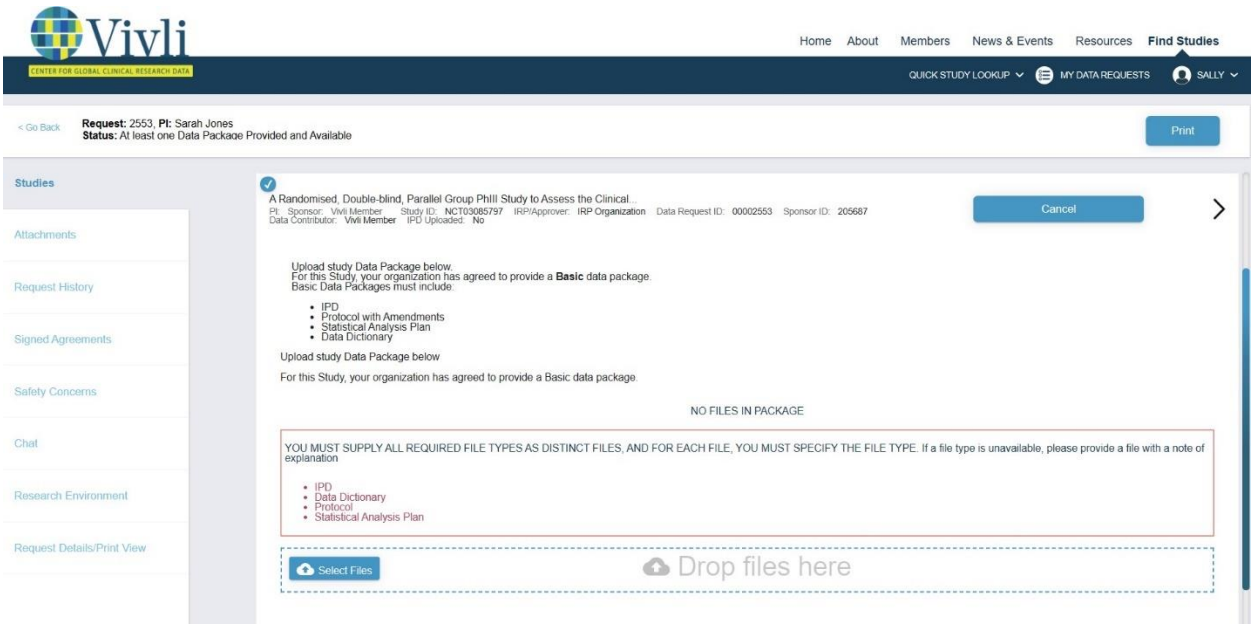
2. Click on the data request, and then click on Studies on the left:



1. Click on **Upload Data Package.**

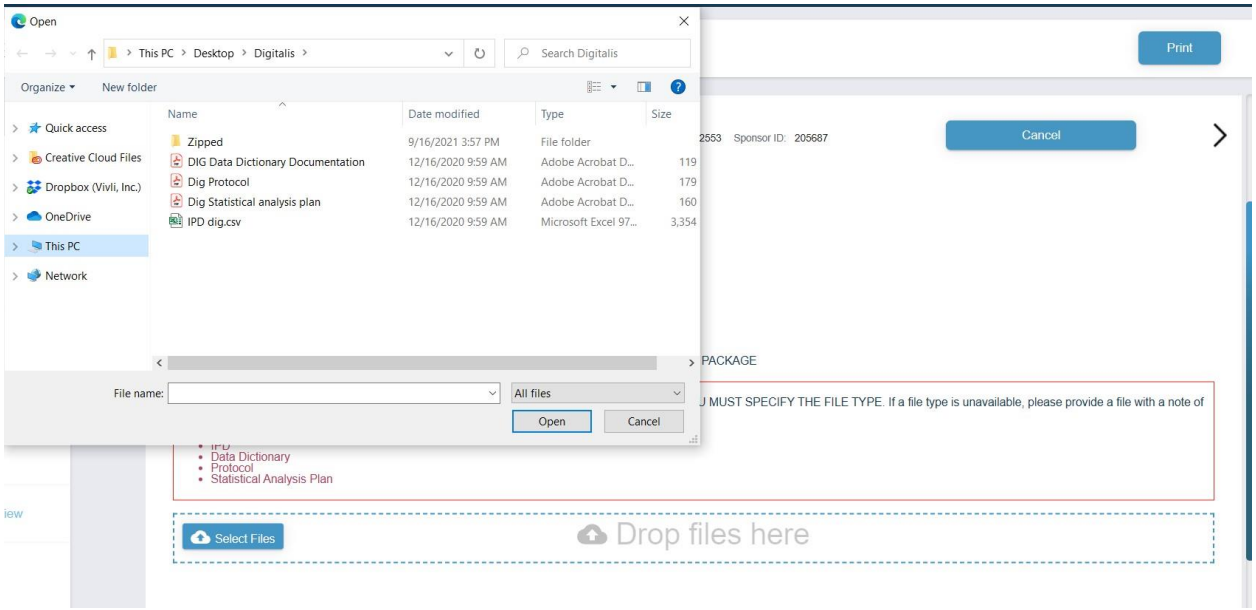


The following window will appear:



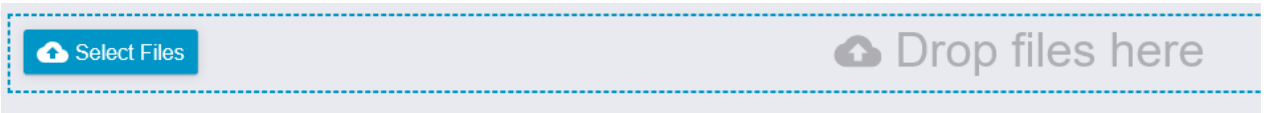
5. Now click on  to choose files to upload.

6. A window will pop up allowing the data contributor to select the files of their computer:

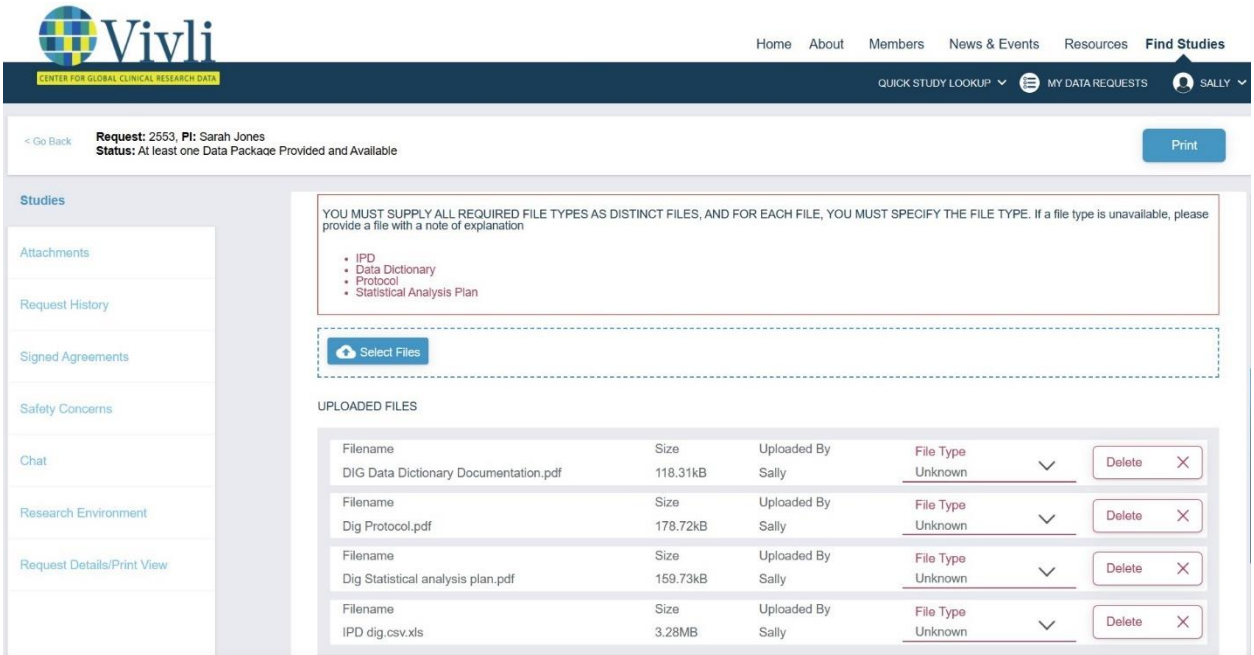


7. After selecting the files, click **Open.**

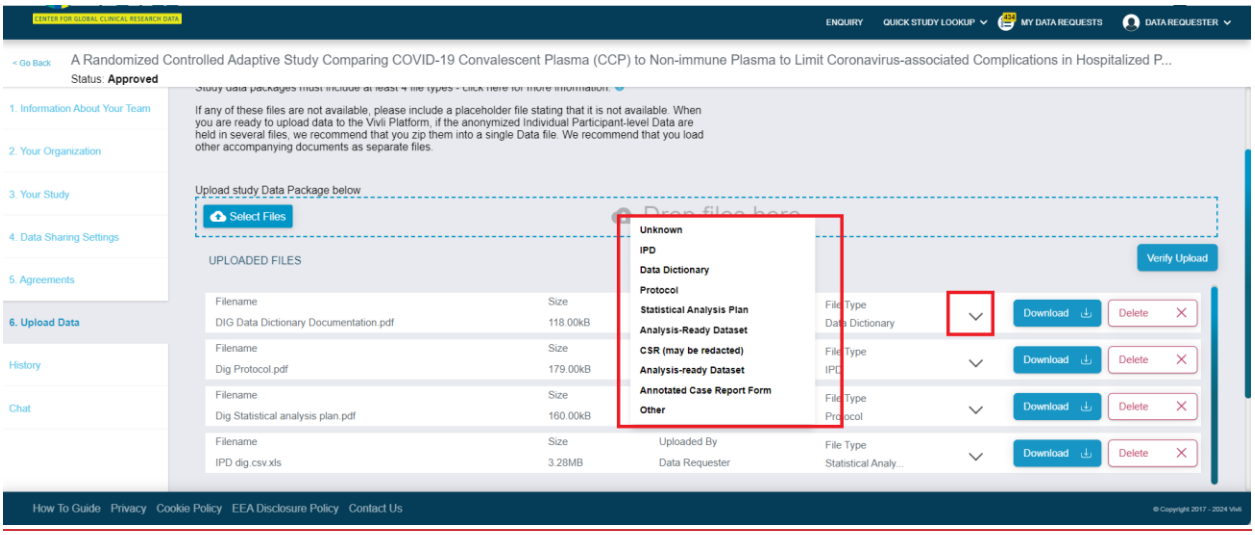
8. The data contributor may also drag files into the submit window indicated by the dotted blue box:



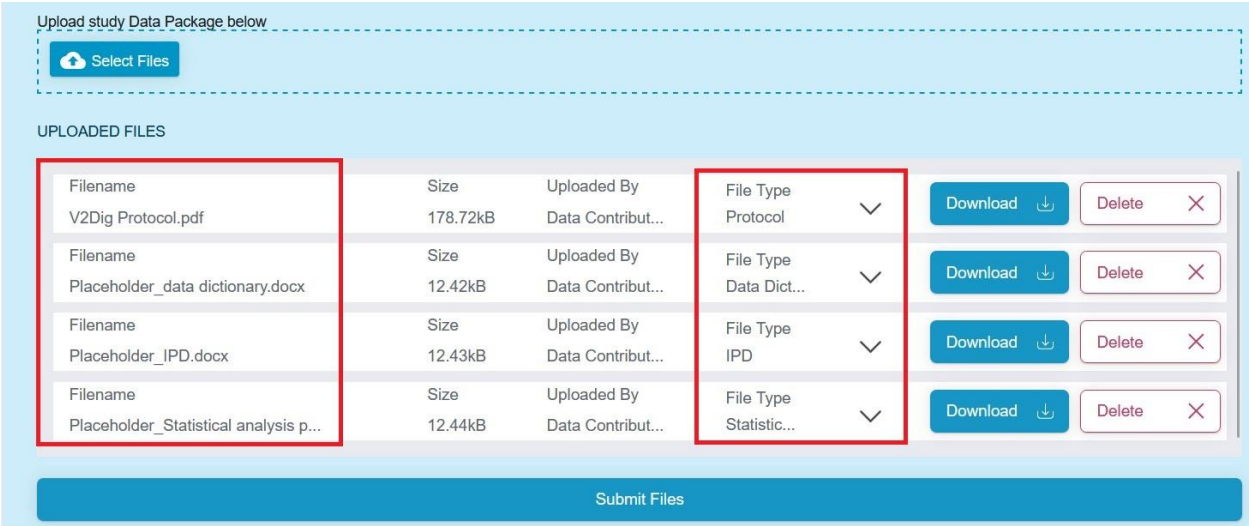
9. The files should appear under **Uploaded Files.** You can delete any files by clicking the “delete” button:



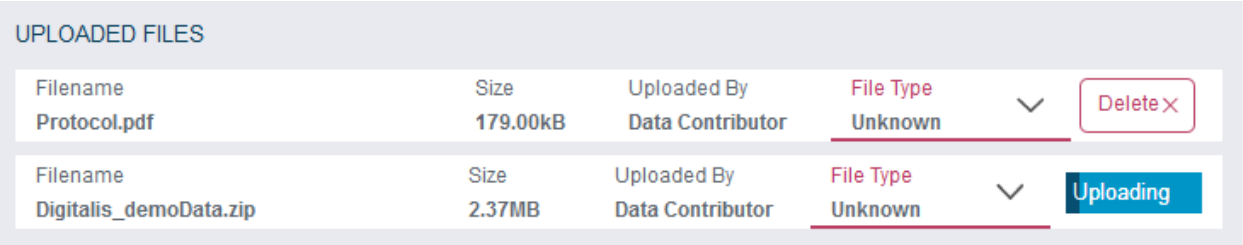
10. Use the dropdown menu on the right-hand side to validate the **File Type** for each file before submitting files:



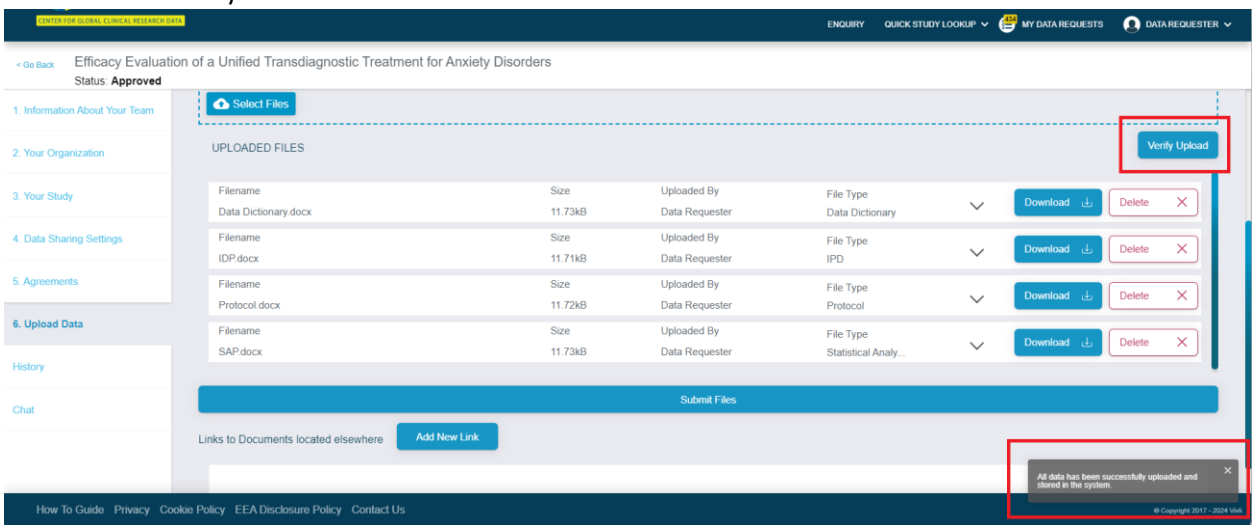
11. If the data contributor has different formats of the same file (for example, an Analysis-Ready dataset SAS file and an Analysis-Ready dataset .csv file), they can select the same file type for all applicable files from the dropdown menu. **Note:** You can't upload an empty file or upload two files with the exact same name.
12. For summary level request or document-only request, you can upload the requested information. To enable the submit button, you can upload placeholder files (i.e. upload a word document explaining it is a placeholder file) for the other required documents and select the file type.



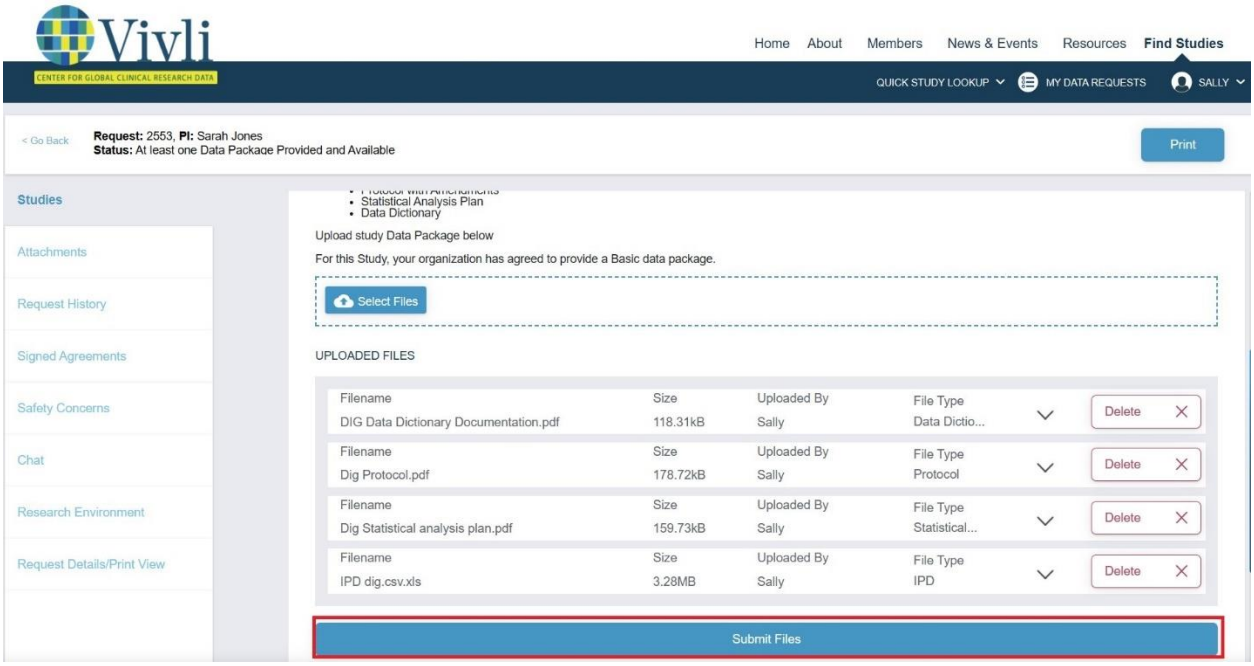
13. There are two steps involved: uploading the data and then once uploaded, submitting the data to Vivli. The data package upload happens while you see the progress bar with the label "Uploading".



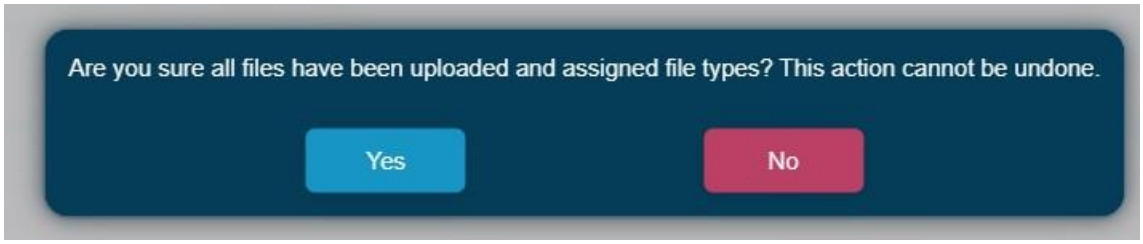
14. If the upload of any file(s) fails, Close the request, refresh the browser, re-open the request, click on "Upload Files" and delete the file that failed before moving forward.
15. Click the button that says "Verify Upload" to confirm that your files have been successfully uploaded.
16. A pop-up will appear at the bottom right screen that says "All data has been successfully uploaded and stored in the system"



17. **Important Note:** Ensure that all the files have been loaded before clicking the submit button. Once you click the Submit button, you cannot load further documents to the same study.
18. If you plan to upload data packages for multiple studies in the data request, click Submit files for one study, refresh the screen and then click Submit files for the next study.
19. When finished, click **Submit Files** to load the data package into the Vivli Platform.

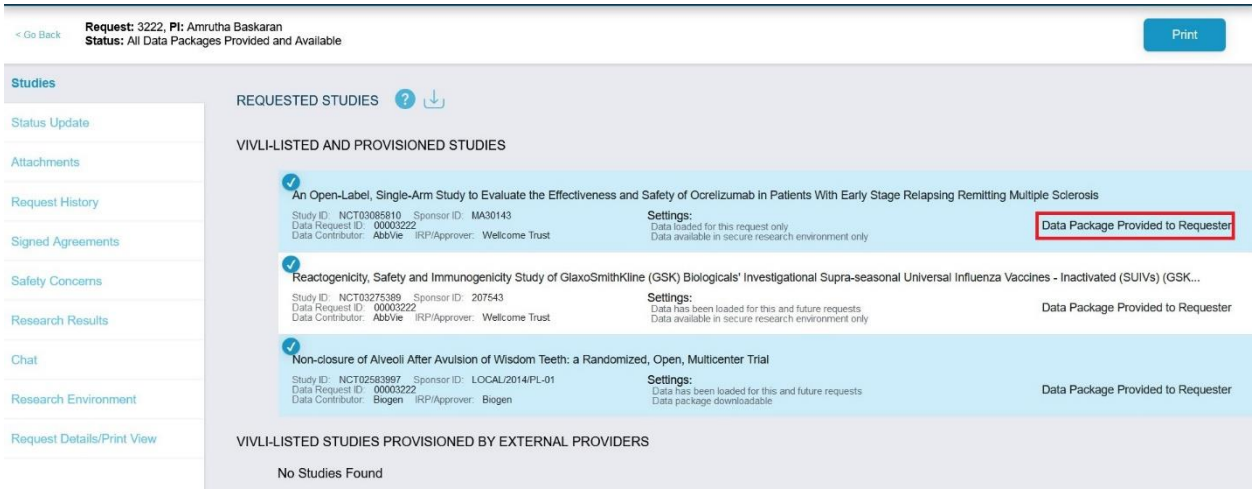


18. The following pop-up will appear:

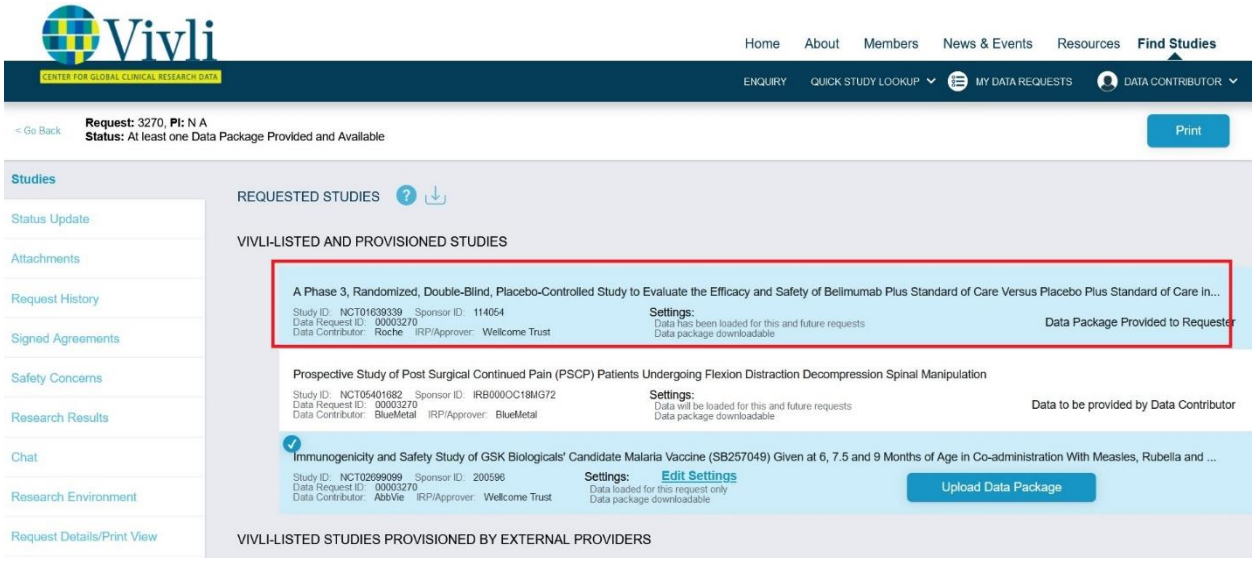


19. Click **Ok** to submit the files. The following confirmation will appear:

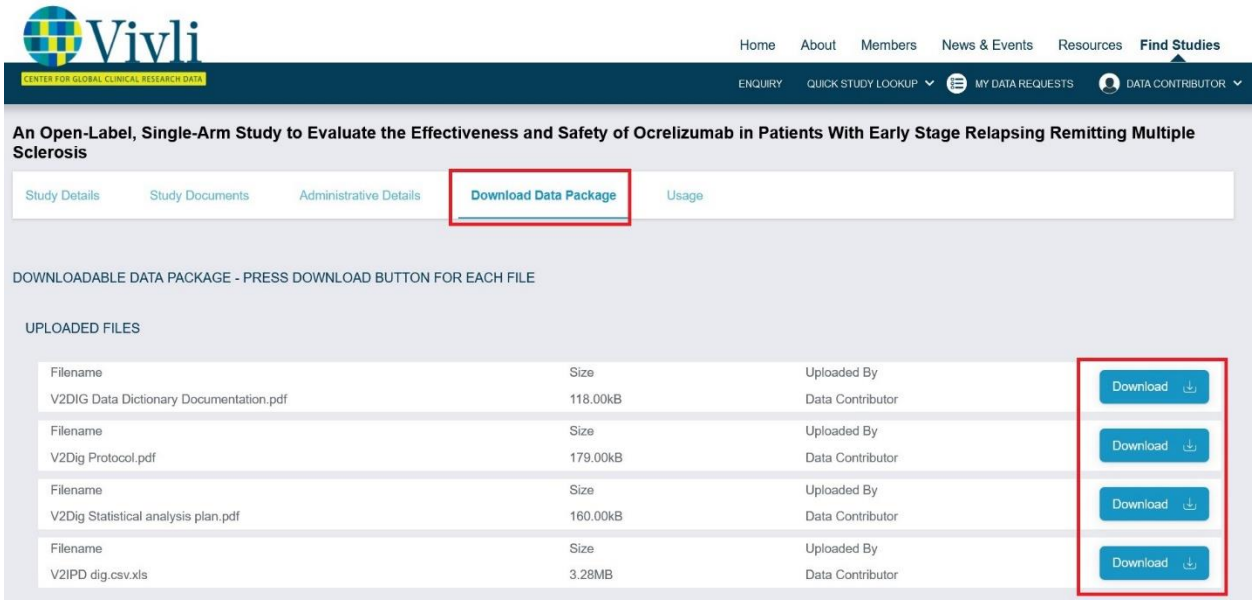
1 20. Once the data package has been successfully loaded onto the platform, the Organizational Administrator will see the “Data Package Provided to Requestor” note next to the study record in the studies section of the data request.



21. A data request history entry will be written to the Request history.
22. To view the data provided to a specific data request, click anywhere in the study record box representing the study. This will open up a new tab.



23. Then go to the **Download Data Package** tab to display any files previously uploaded. Click on the download button to see the version of the files provided to the Researcher



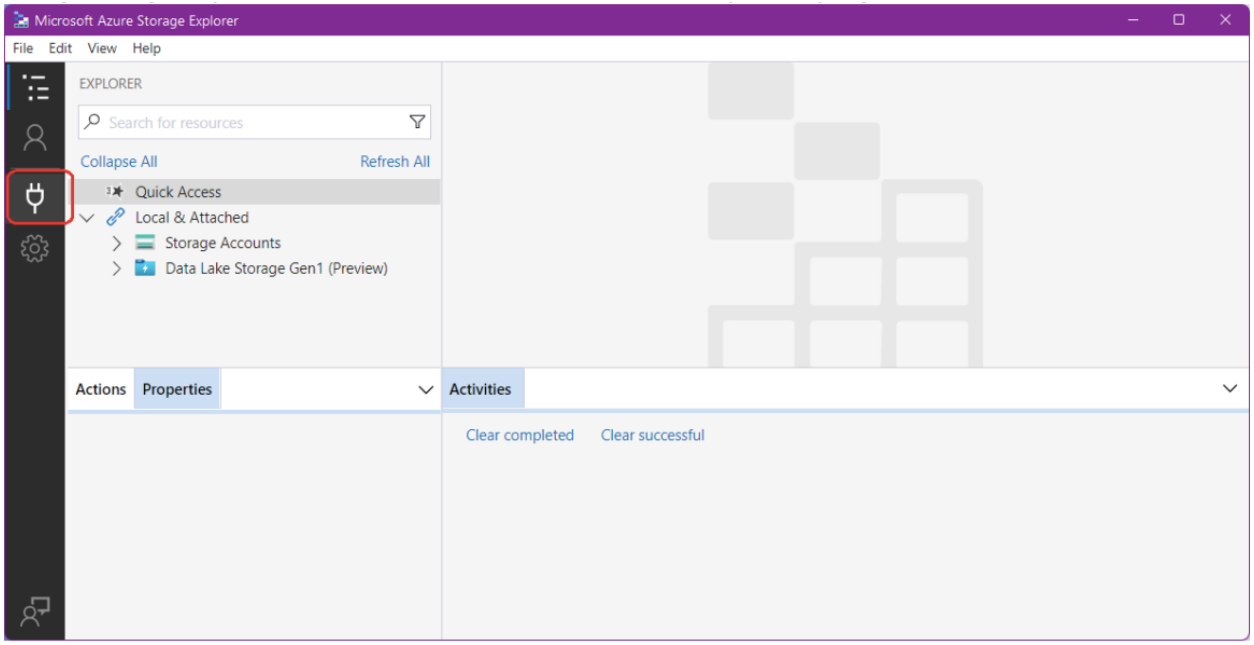
24. Once <u>all</u> the data packages from all the data contributors have been successfully uploaded, the request status will change to “All Data Packages Provided and Available” under the **Active** status bar.

25. For multi-sponsor requests, if your organization has uploaded all of its data but another data contributor has not, the request is still in a partially fulfilled state i.e. “At least one Data Package Provided and Available” status. Vivli team will follow up with the appropriate member to upload their data package.

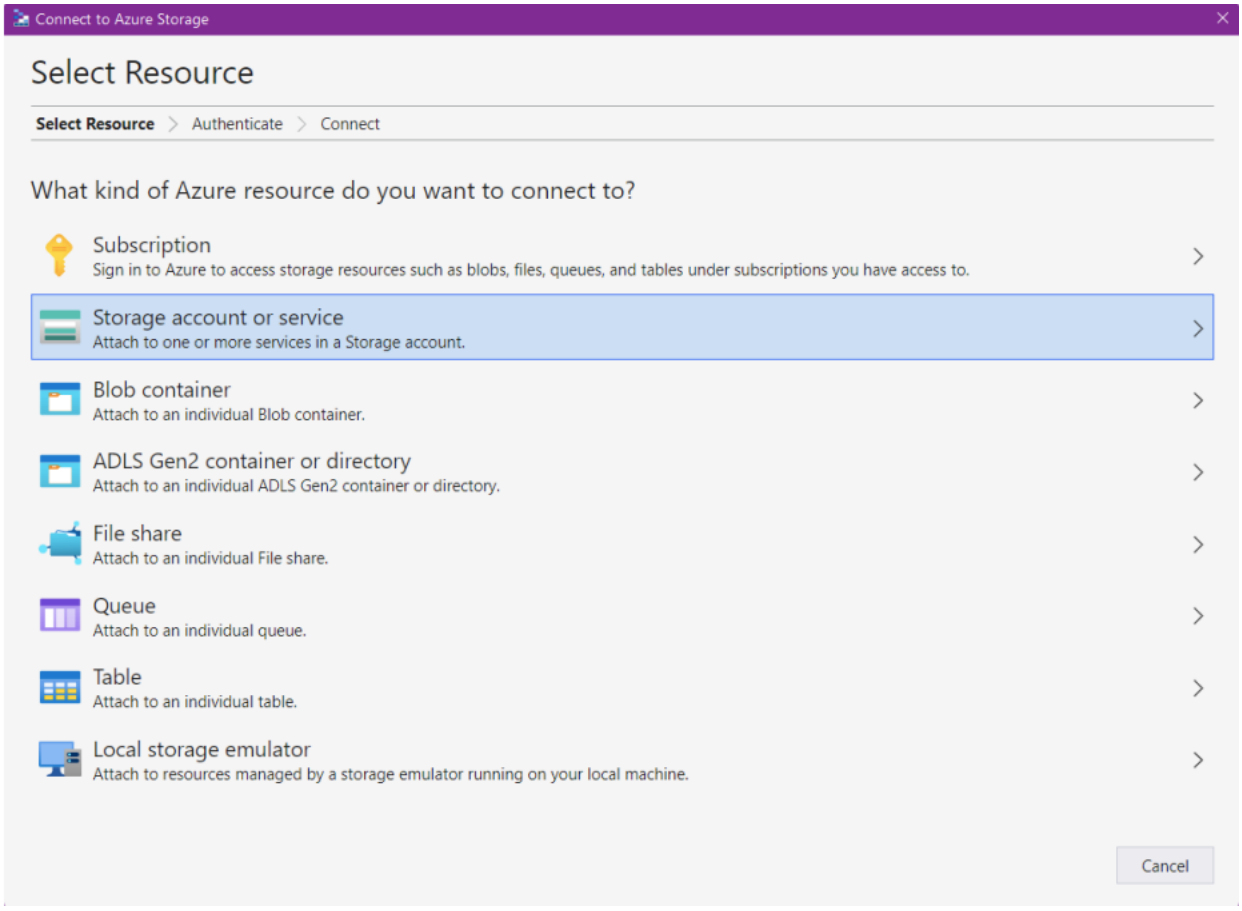
4.4.6 Uploading large files and data packages to the Vivli Platform:

If you have not already had a discussion with Vivli about how the data will be organized and how it will be used, we recommend that you start with that, so that Vivli can advise on how best to package the data, e.g. into a single large zip file or a small number of individual zip files.

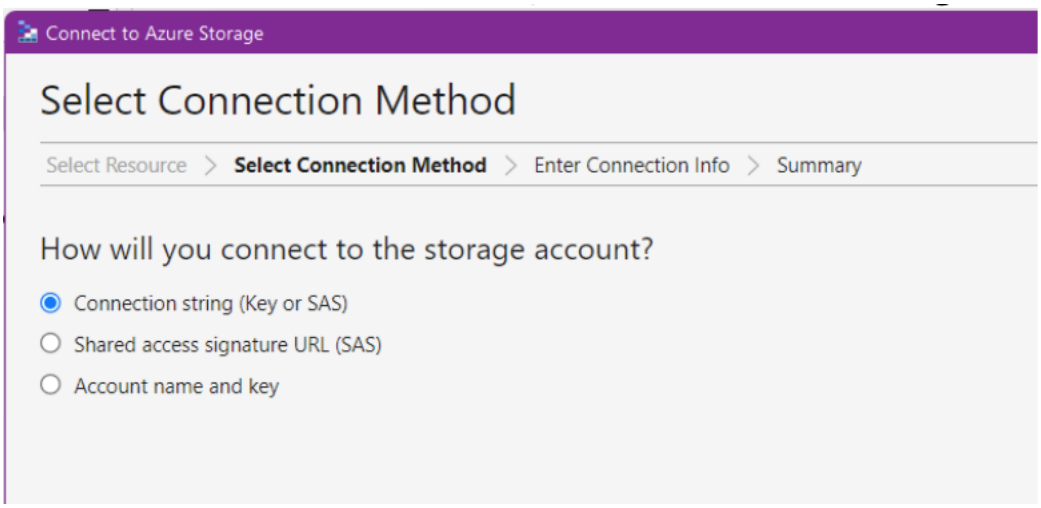
1. Download and install the Azure storage explorer from the URL: https://azure.microsoft.com/enus/features/storage-explorer/ (you can also enter “Azure Storage explorer download” into your favorite search engine.) After starting storage explorer, click on the icon that looks like a power plug:

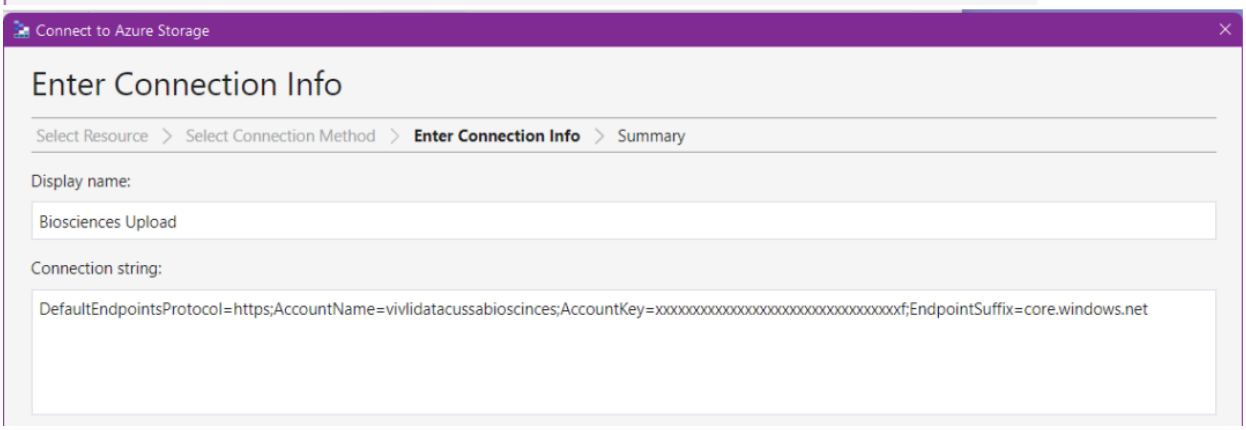


2. In the pop-up window pick “Storage account or service”:

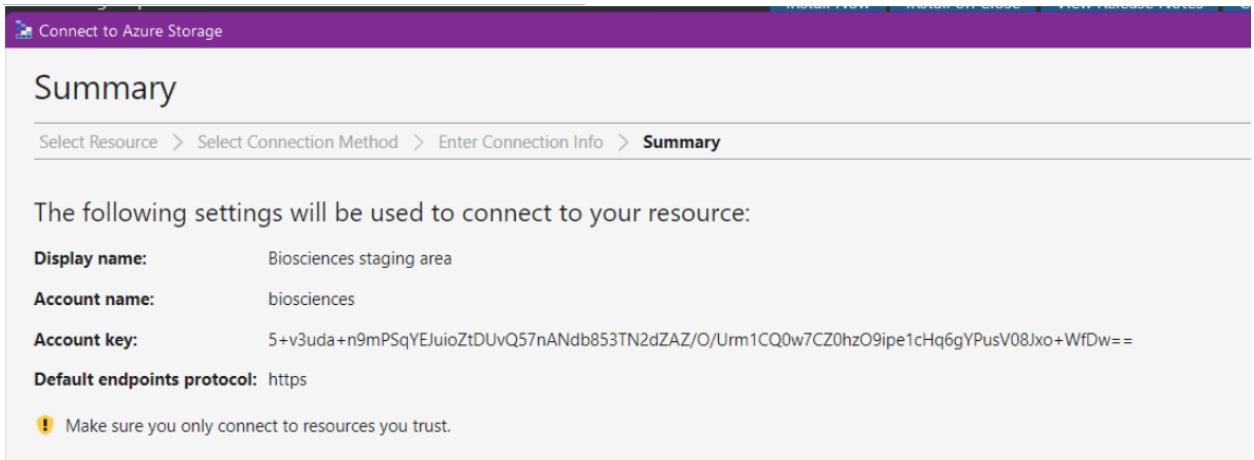


3. In the Select Connection Method window, choose Connection string:

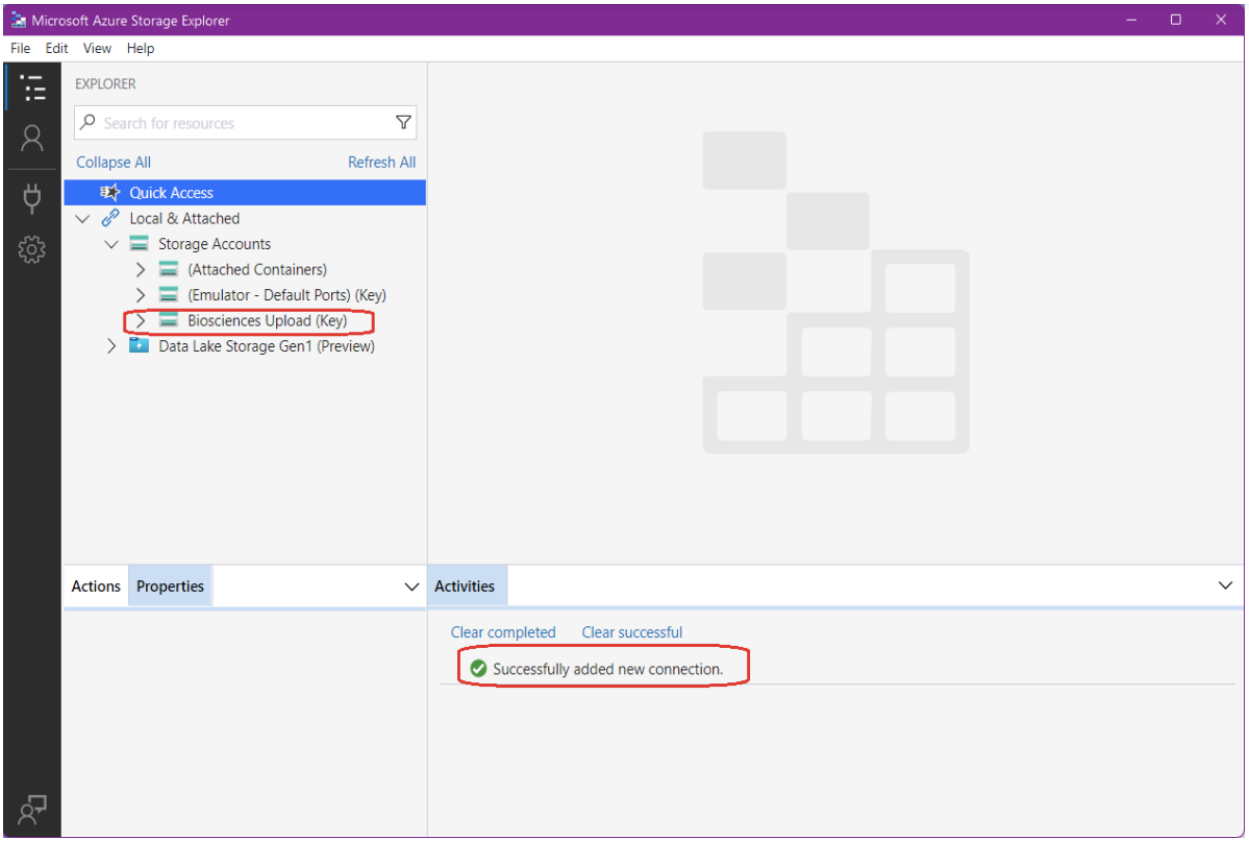




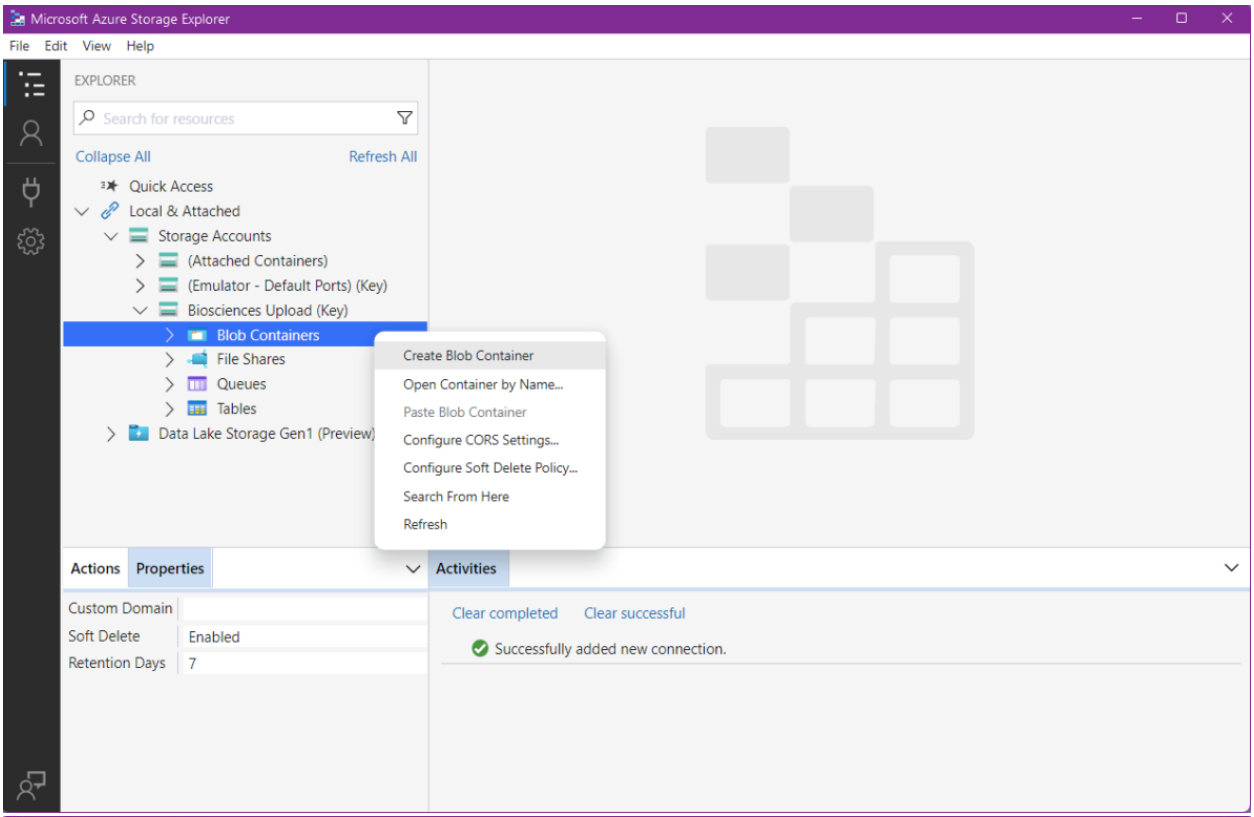
4. The display name should be the NCT or Sponsor ID for the study; the connection string must be the value sent to you separately from Vivli. On the summary/confirmation screen, click "Connect":

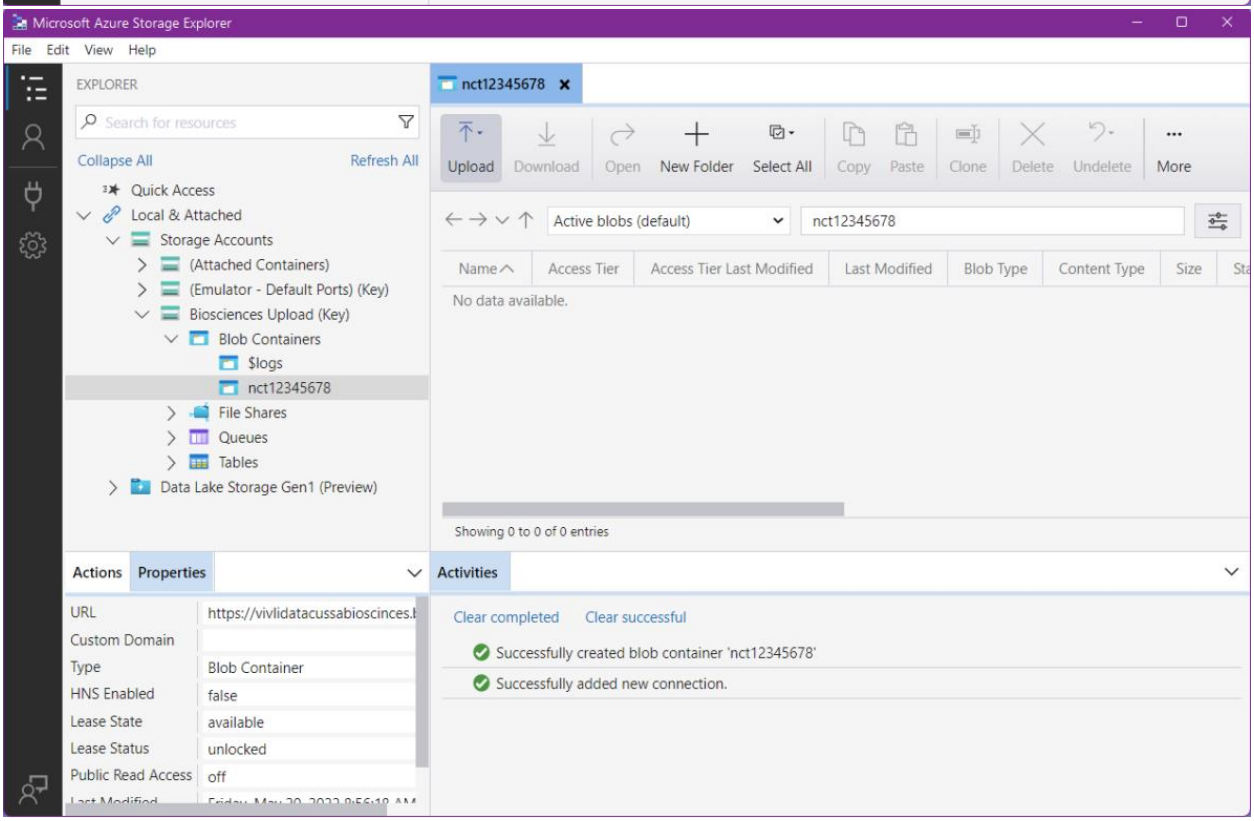


5. It should add the storage account to the list on the upper left, and report "Successfully added connection:

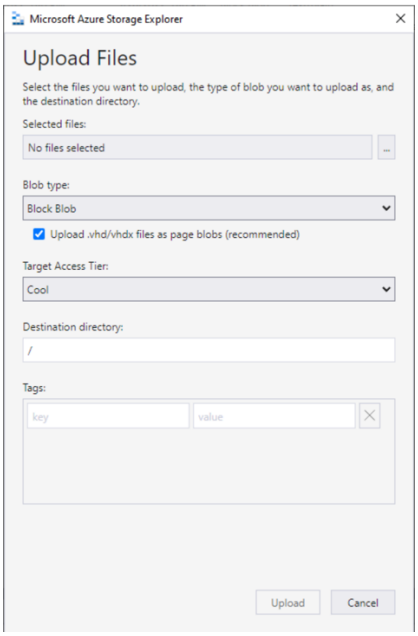


6. Click on the “>” to open the storage account, then right click on Blob Containers and choose “Create Blob Container”. Give it a name that represents the study (e.g. the NCTId or sponsor ID). Note that container names are limited to numbers, lowercase letters and hyphens, but no spaces or uppercase characters.

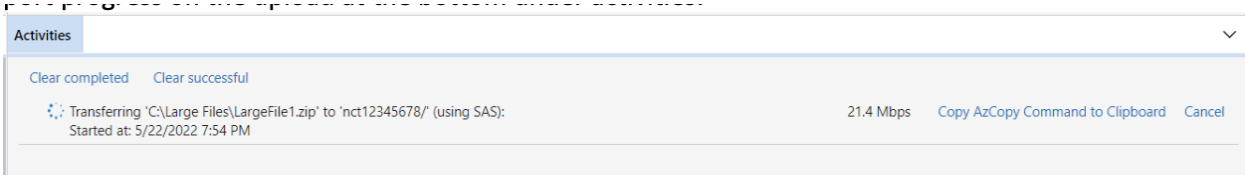

Microsoft Azure Storage Explorer
File Edit View Help
EXPLORER
Search for resources
Collapse All
Refresh All
Quick Access
Local & Attached
Storage Accounts
(Attached Containers)
(Emulator - Default Ports) (Key)
Biosciences Upload (Key)
Blob Containers
File Shares
Queues
Tables
Data Lake Storage Gen1 (Preview)
Create Blob Container
Open Container by Name...
Paste Blob Container
Configure CORS Settings...
Configure Soft Delete Policy...
Search From Here
Refresh
Actions
Properties
Activities
Custom Domain
Soft Delete
Enabled
Retention Days
7
Clear completed
Clear successful
Successfully added new connection.


Microsoft Azure Storage Explorer
File Edit View Help
EXPLORER
Search for resources
Collapse All
Refresh All
Quick Access
Local & Attached
Storage Accounts
(Attached Containers)
(Emulator - Default Ports) (Key)
Biosciences Upload (Key)
Blob Containers
$logs
nct12345678
File Shares
Queues
Tables
Data Lake Storage Gen1 (Preview)
nct12345678
Upload
Download
Open
New Folder
Select All
Copy
Paste
Clone
Delete
Undelete
More
Active blobs (default)
nct12345678
Name
Access Tier
Access Tier Last Modified
Last Modified
Blob Type
Content Type
Size
No data available.
Showing 0 to 0 of 0 entries
Actions
Properties
Activities
URL
Custom Domain
Type
Blob Container
HNS Enabled
false
Lease State
available
Lease Status
unlocked
Public Read Access
off
Clear completed
Clear successful
Successfully created blob container 'nct12345678'
Successfully added new connection.

7. From the ribbon at the top, click Upload and from the drop-down choose Upload Files. From the Target Access Tier choose “Cool”.



8. In general, we recommend uploading files that have been zipped; you can have a discussion with Vivli about whether a single zip file or several files will be more useful to the researchers; this can depend on how the data may be used. It will report progress on the upload at the bottom under activities:

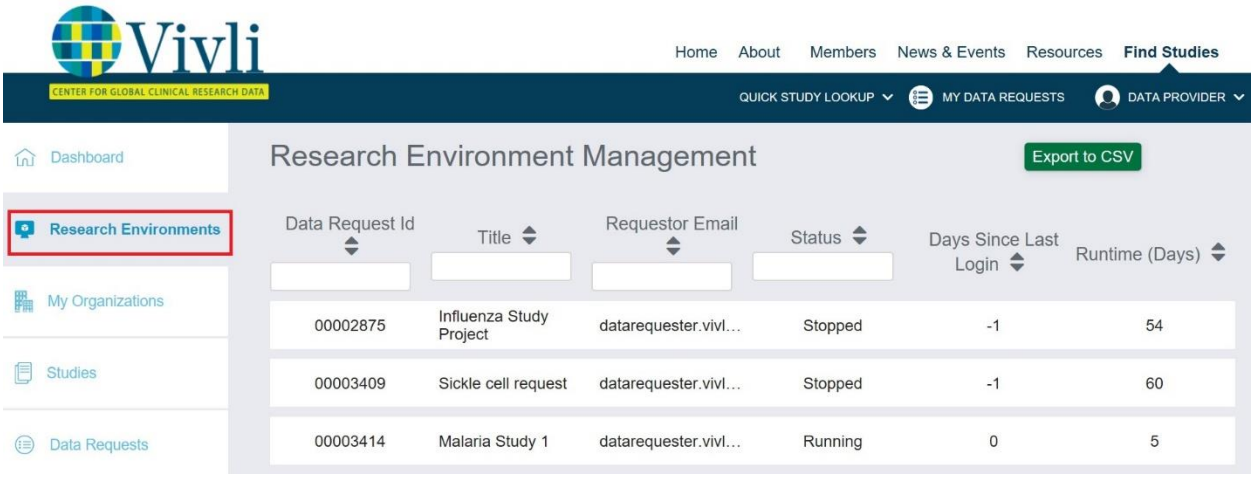


9. Note that Storage Explorer will remember the connection the next time you start Azure Storage Explorer – to get it to “forget”, right click on the storage account name (Biosciences in the example screenshots above) and choose “detach”. When you have completed the upload, notify Vivli at support@vivli.org

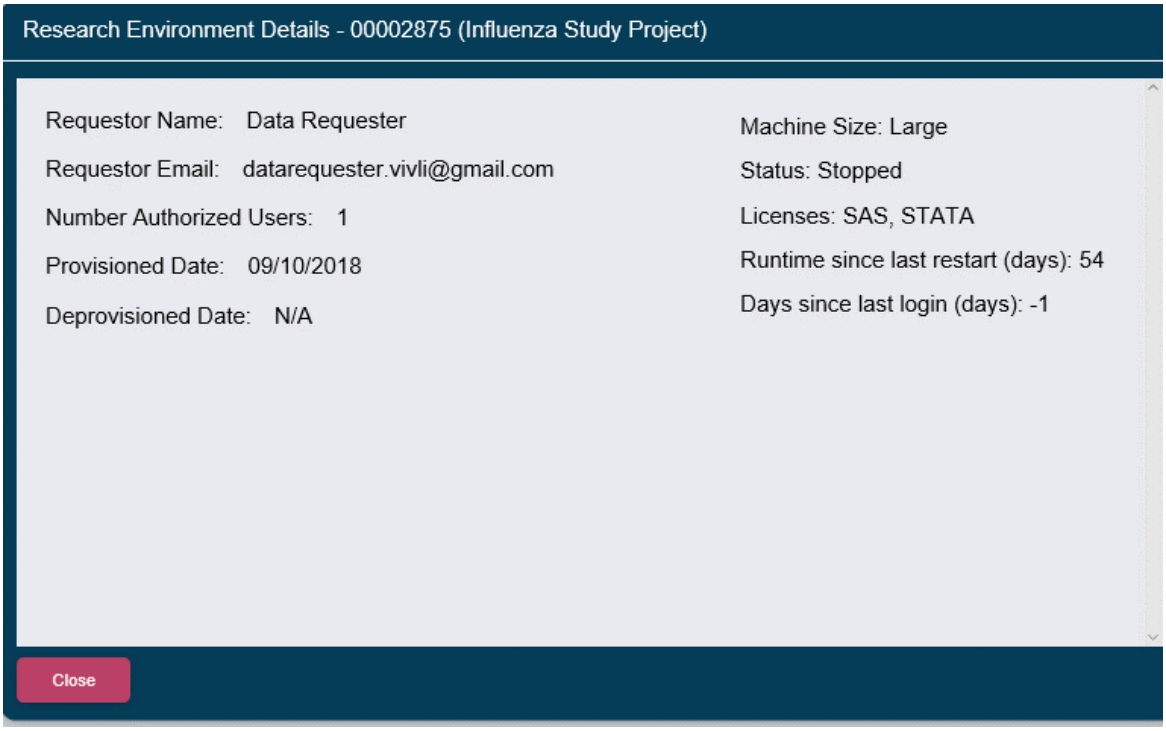
5. Research Environment monitoring

- Organizational Administrators for the Data Contributor Organization can monitor the progress of the Research environments for data requests containing at least one of their studies. Note: Those with only Data Contributor role cannot view this dashboard.

F7



- You may filter for a specific data request using the Data request ID, Title, Requestor Email, and Status of the Research Environment (Running, Stopped, and Deprovisioned)
- You may click on the Data Request ID to see details of a specific environment.



- The date when a Research Environment was started and deprovisioned will also be recorded in the Request history tab of the data request.

5.1 Software in the Research Environment

- The software available in the Research Environment is updated on a regular basis and a comprehensive listing of the software and R packages is available in the Vivli Research Environment. The full list is on the Vivli website, https://vivli.org/resources/resources/

- The current list applies only to new research environments – updates to software installed are not retroactive to existing research environments, although we can make updates to existing environments when requested.

6. Public Disclosures & Publications & Summary of results

6.1 Review(s) by Data Contributor

The Data Use Agreement requires Data Requestors to provide to Vivli, at least 30 days prior to submission, the submitted copy of any publication, which Vivli will make available to all Data Contributors for review.

1. Data Requestors will provide Vivli at least 30 days prior to submission, the submitted copy of any manuscript via the platform open chat under chat attachments.
2. The Vivli team will notify the Organizational Administrator regarding their courtesy review via Contributors chat (visible only to Vivli Admin and Organizational Administrators). The Organization Administrator will respond to the Data Requestor with their comments using the platform open chat.
3. As per the DUA, during this period if you would like to provide non-binding comments on the scientific content you may do so. You may also request the deletion of any confidential information (as defined in the DUA).
4. If a researcher indicates that they do not have publishable results, Vivli requests the summary of results from the Researcher. A summary of results will be sent to the Org Admins for 30-day courtesy review.
5. When should a data contributor be considered an author on a manuscript or public disclosure? It is Vivli policy that the decision to appoint someone as an author should be made by applying the ICMJE authorship criteria (reviewed and agreed by Steering Committee in May 2023).

6.2 Publication Notification by Data Requestor

- When a public disclosure based on the results obtained from the data request is published, the Data Requestor must inform Vivli.
- Vivli will notify the Data Contributor(s) about the publication via email.
- In addition, the link to the publication will also be made available for public view on Vivli's Metrics page linked to their approved request page.
- Once all the publications are published and the analysis is complete, the Vivli team will move the data request to the Archived section of the data request.
- For a summary of results, once the courtesy review is complete, the Statistical Analysis Plan (SAP) and the summary of results will be posted on the Vivli website under the approved request page. The summary of results will not be added to the publication table and will not be

counted under Publication metrics. Once the website is updated, Vivli Admin will notify the data requester via the platform chat and the Data Contributors via email that the summary of results has been published and archive the data request.

7. DUA extension

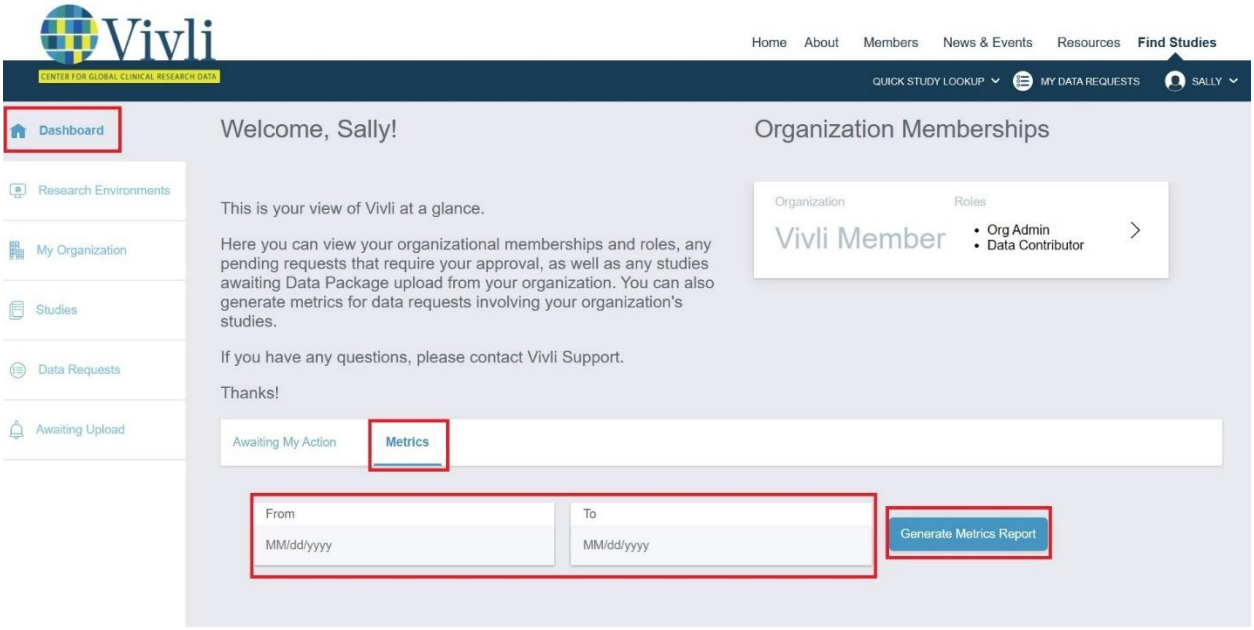
- According to Vivli policy, DUA extensions are given in 6-month intervals up to a maximum of 2 years. After that, any extensions will need to be reviewed by the Data Contributors who may approve or decline the extension.
- For the third extension, the Vivli team will reach out to the Data Contributor via the Contributors chat and share the PI's reason for the extension. The Vivli team will also include our recommendation about the extension. DUA extensions are given in six-month increments.
- If we do not receive a response in 1 month, Vivli will assume the approval of the DUA extension.

8. Safety reporting

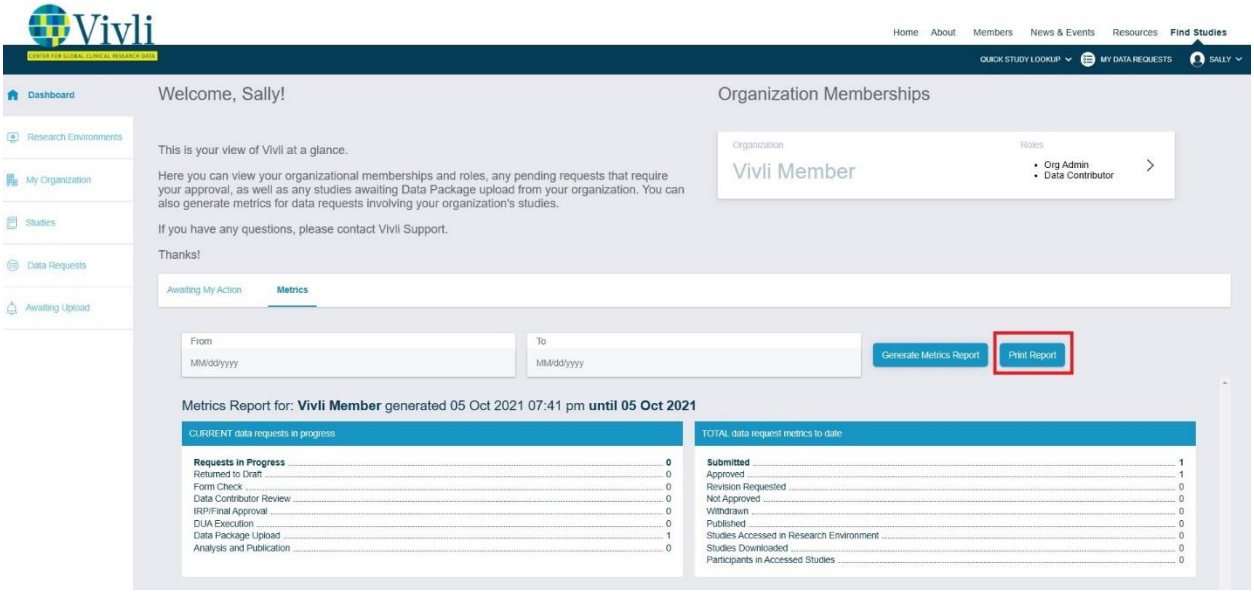
- During the course of the analyses, results review, or manuscript writing, if the Data Requestor comes across any safety concerns, they must report them within 24 hours via the Vivli platform reporting mechanism.
- All the Organization administrators involved in the data request will be notified automatically via email with the description of the safety concern reported.

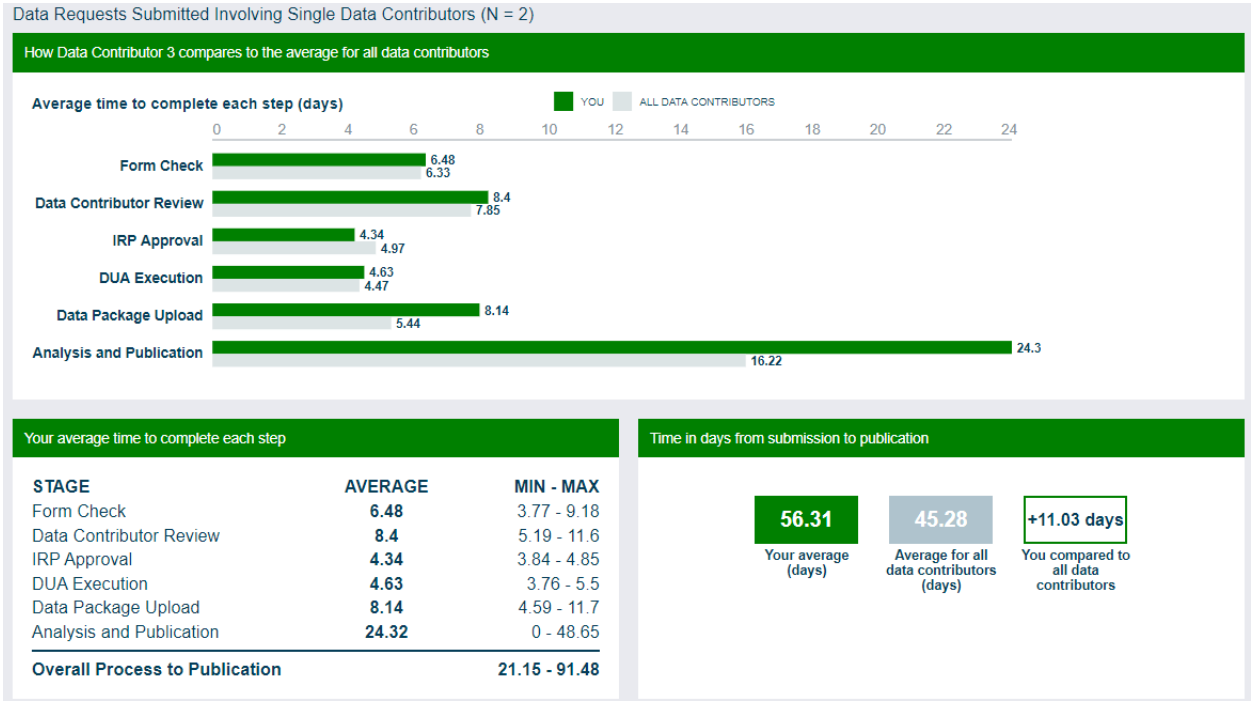
9. Metrics

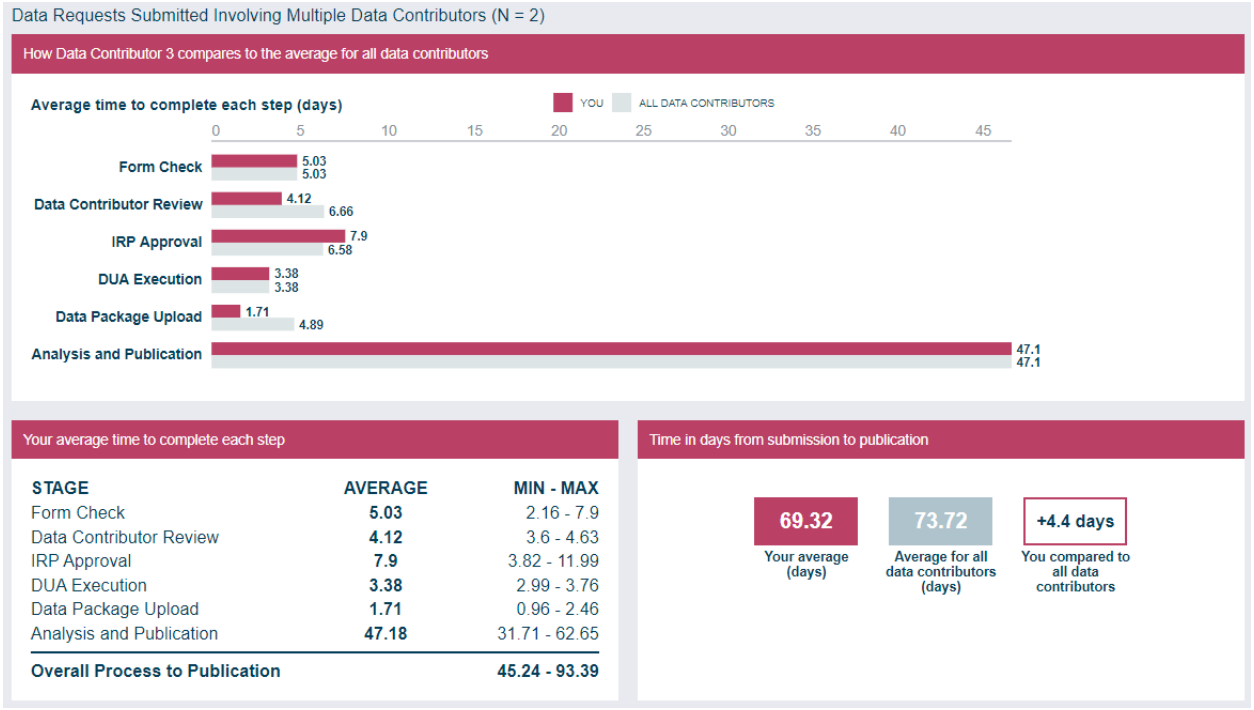
1. Organizational Administrators can view your organizational metrics from your Dashboard.
2. Click on Generate New Report and select the dates to generate the new metrics report. You may run this report at any time.



3. Click **Print Report** to generate a PDF of the report.







4. Publicly available metrics are available here: [Vivli Metrics. These are updated every other month.]

10. Communications

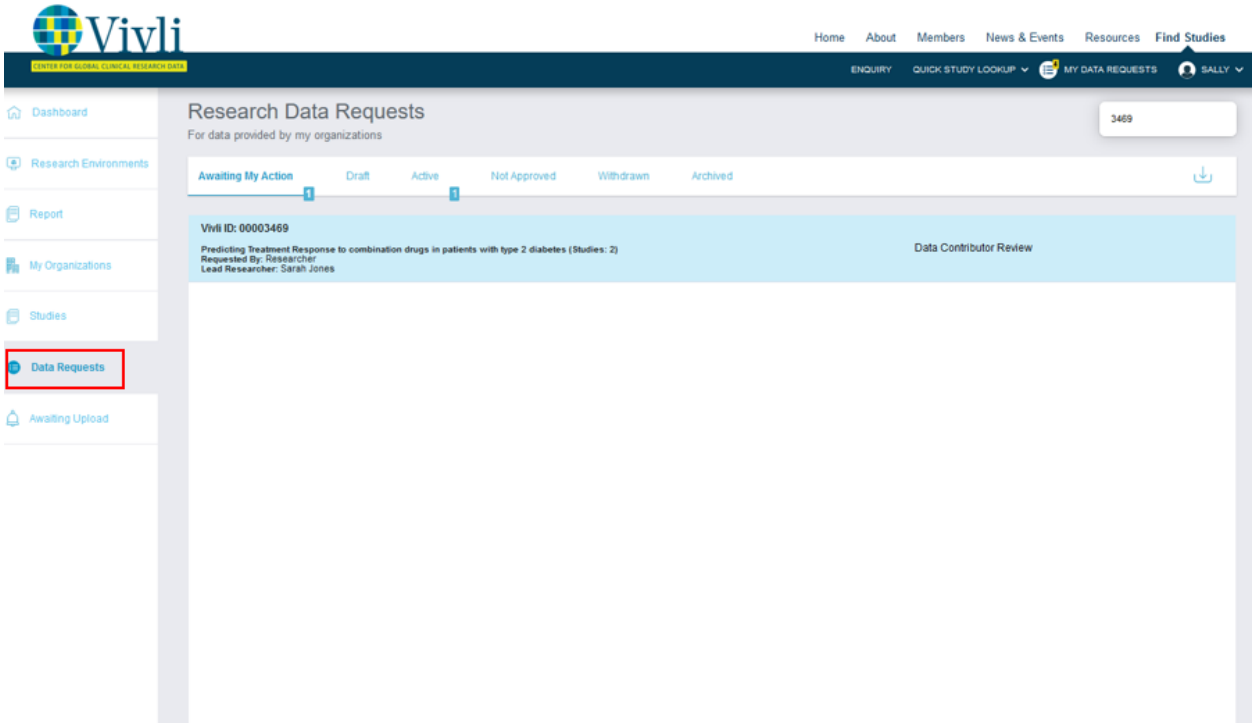
10.1 Chat

- You can use the **open chat** within the data request, to communicate with data requestors, the Vivli Administrators, members of your organization, delegated reviewers, and other data contributors associated with the specific request for your data.
- Please note that messages in the open chat are visible to all persons attached to a data request.
- When any other party enters a message in chat, you will receive an email notification containing the body of the chat message and the name of the person entering it.

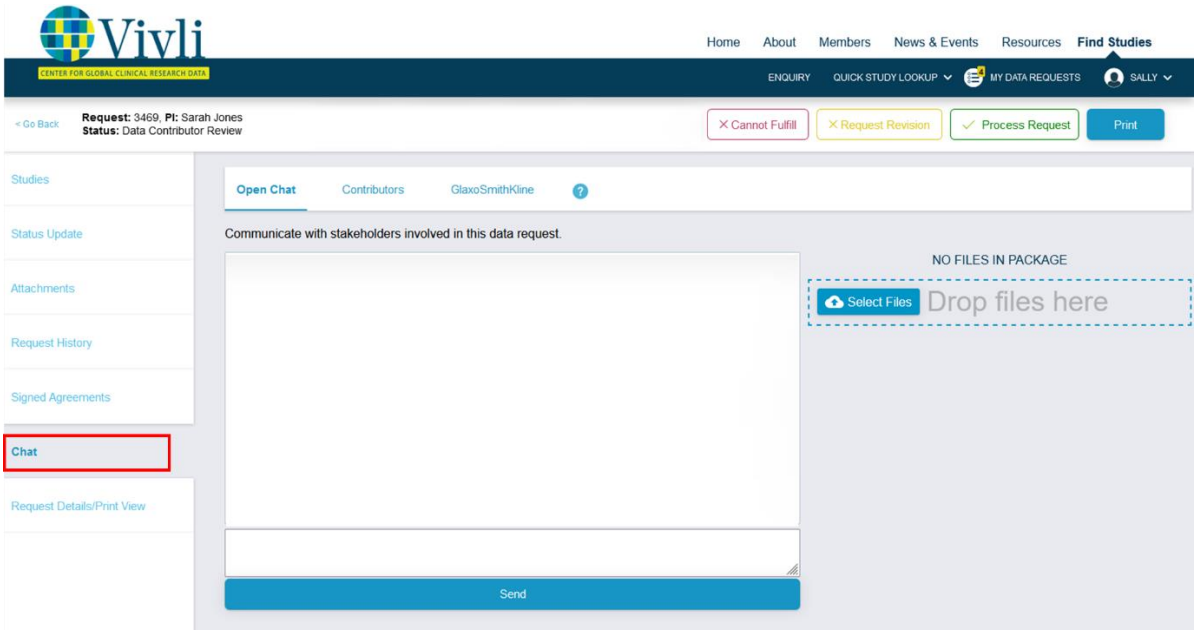
10.1.1 Open Chat

1. Log on to the platform:

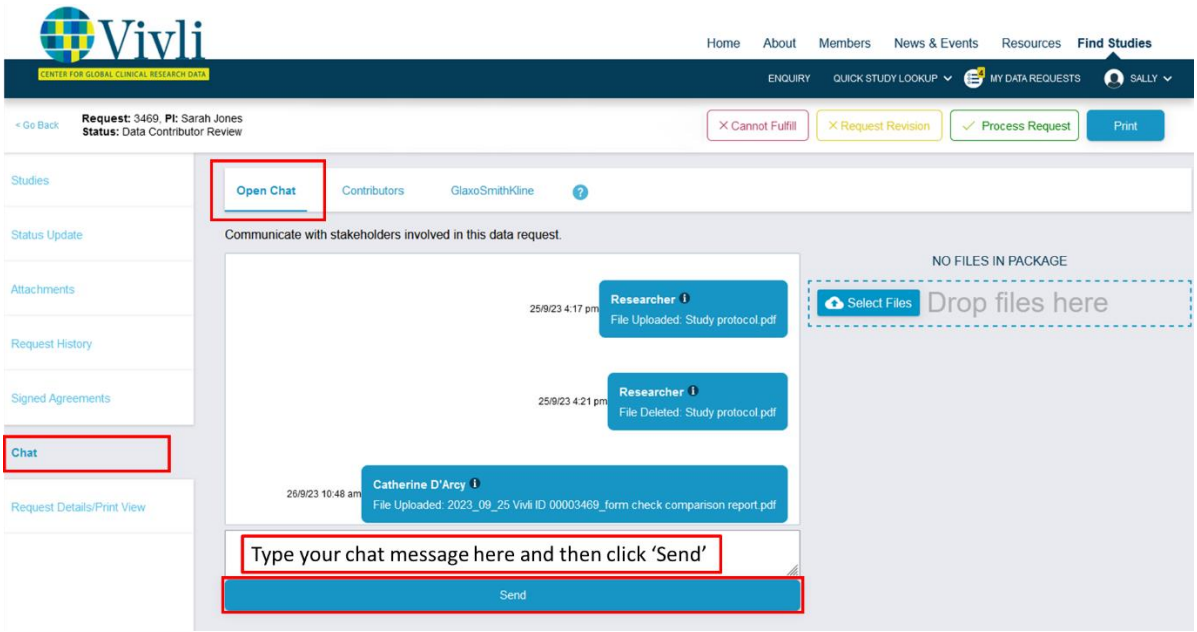
2. Go to the **Data Request** tab:



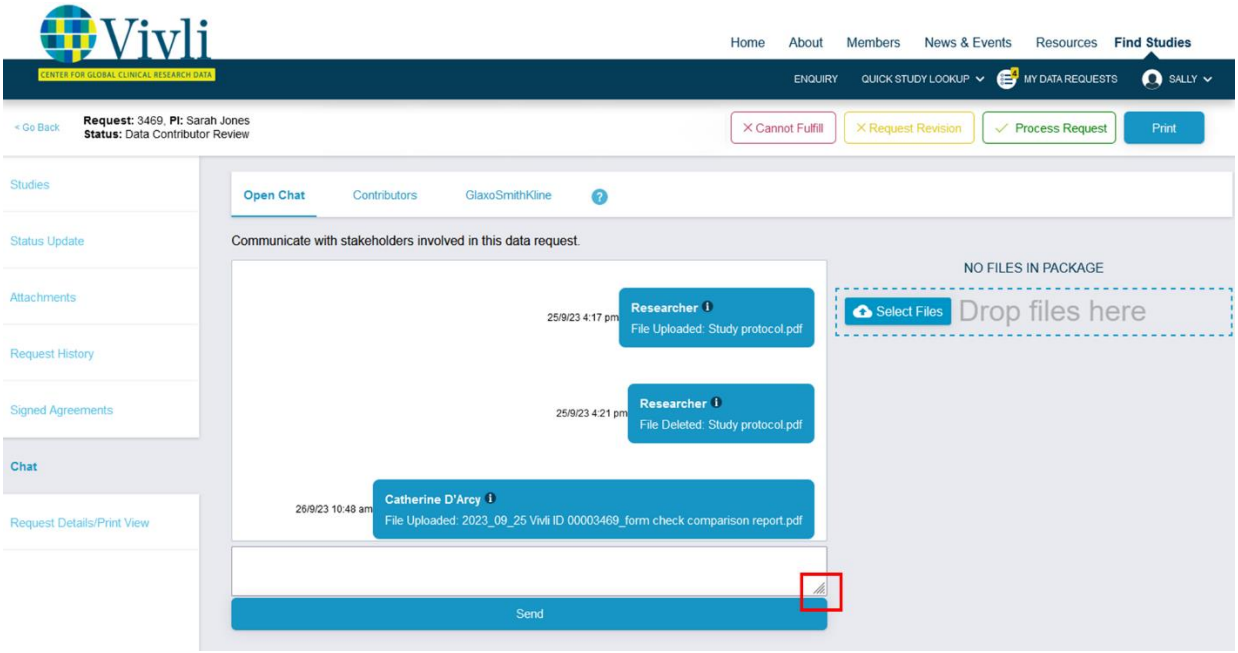
3. Open the applicable data request and click on the **Chat** tab on the left-hand side of the screen:



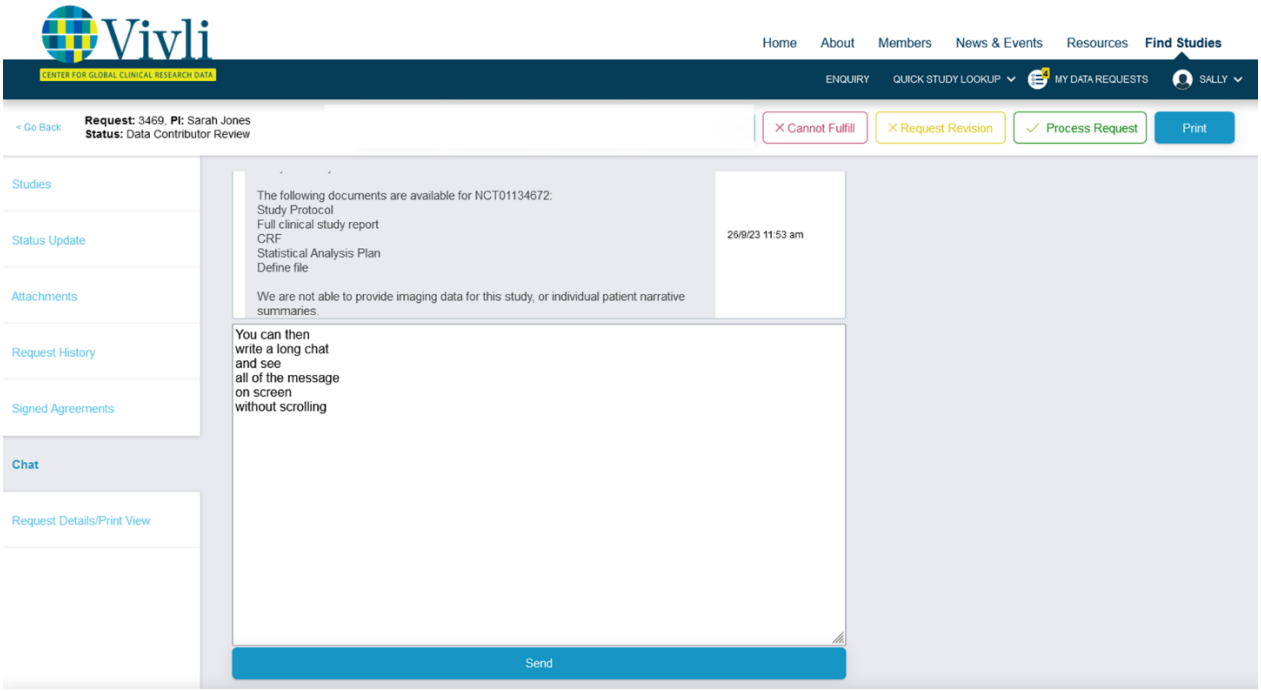
4. Enter your message in the chat message box under "Open chat" and click **Send:**



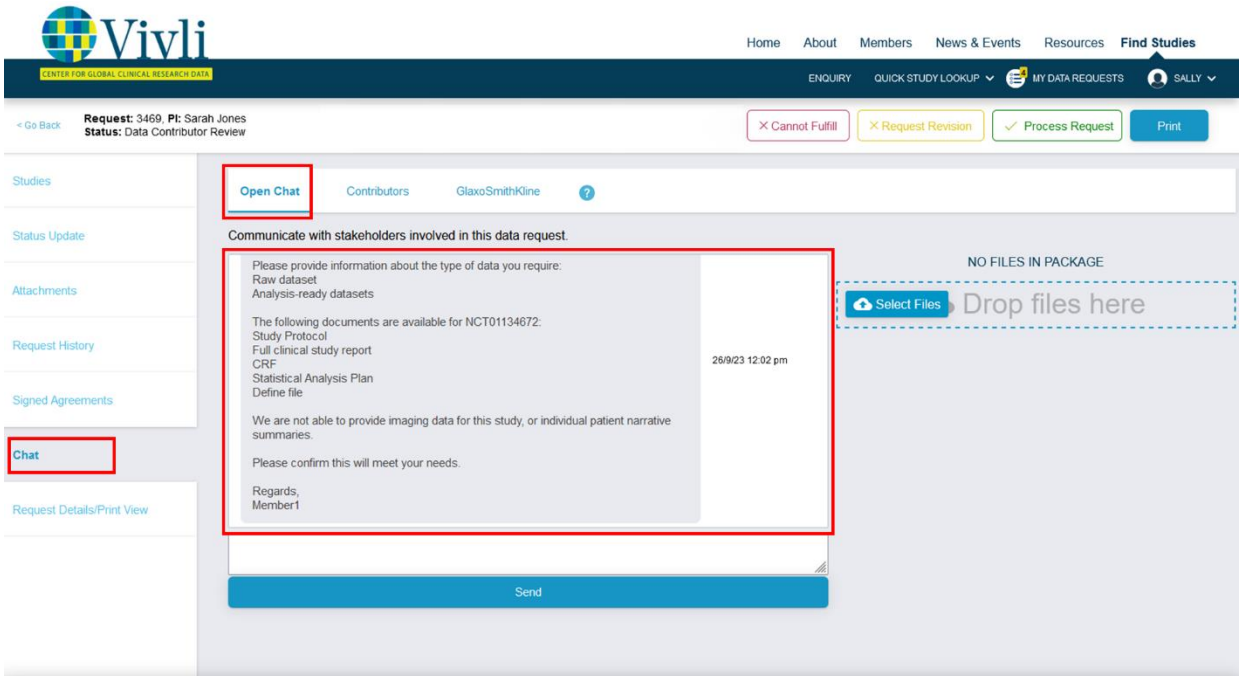
5. In the chat window, there is a hash mark on the lower right of the text entry panel. Hover over it and the cursor changes to a double-headed arrow



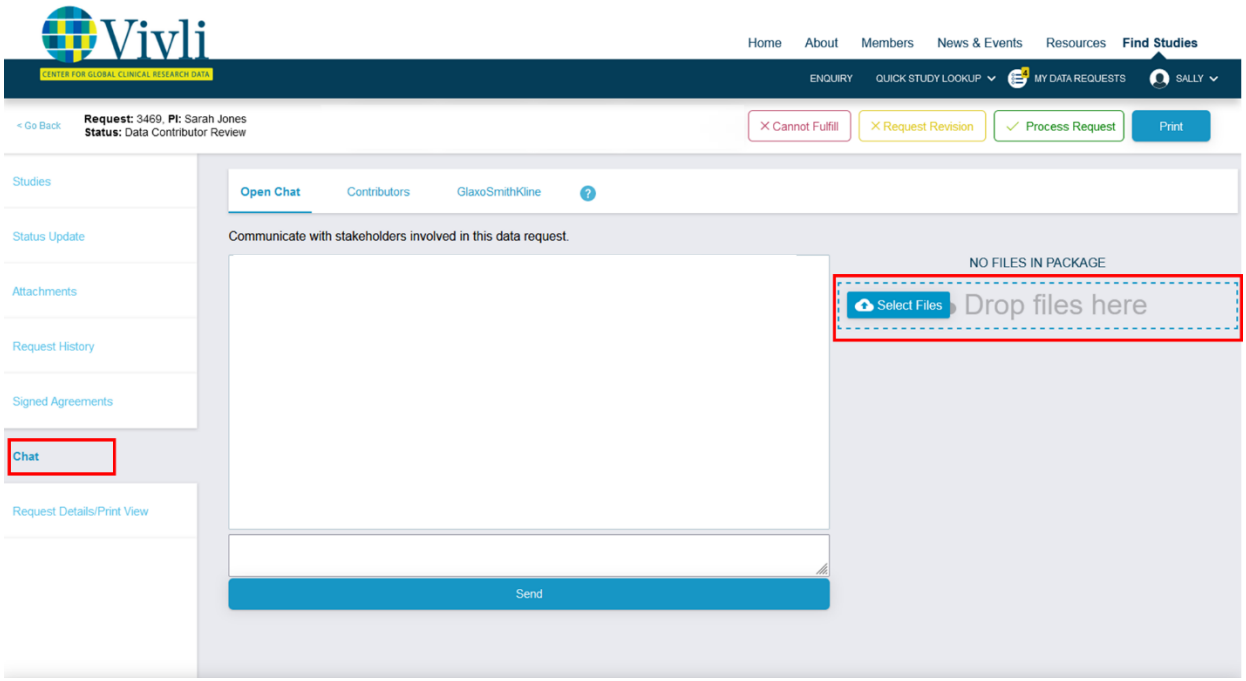
6. Drag the arrow to enlarge the text entry area. Drag it off the edge of the screen to make it very large.



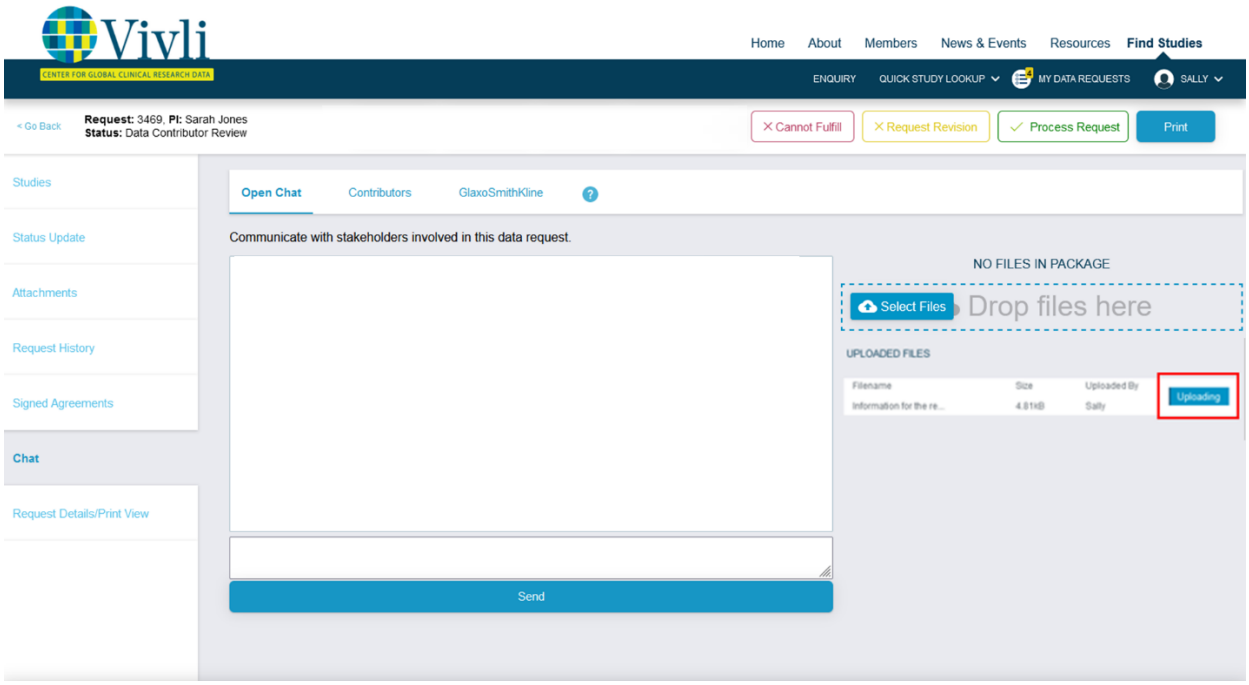
7. The message will now appear in the Chat record:



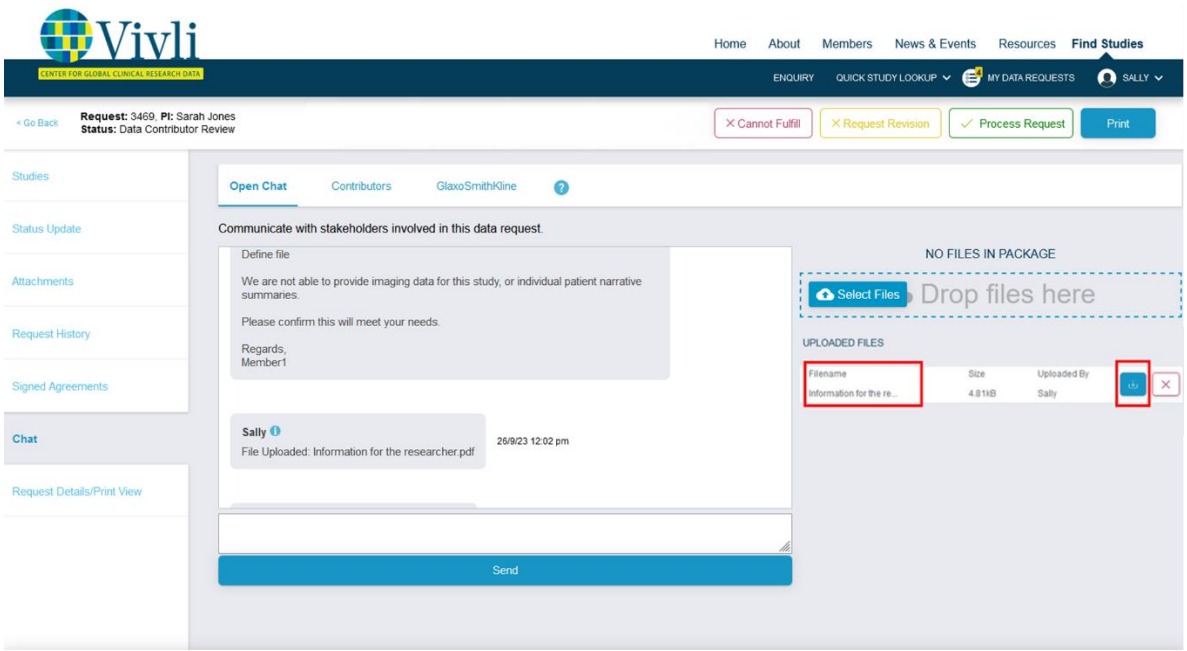
8. You can also upload files via chat by clicking on the **Select Files** button and selecting the file you wish to upload from your computer, or you may drag and drop the files into the dotted blue box**:**



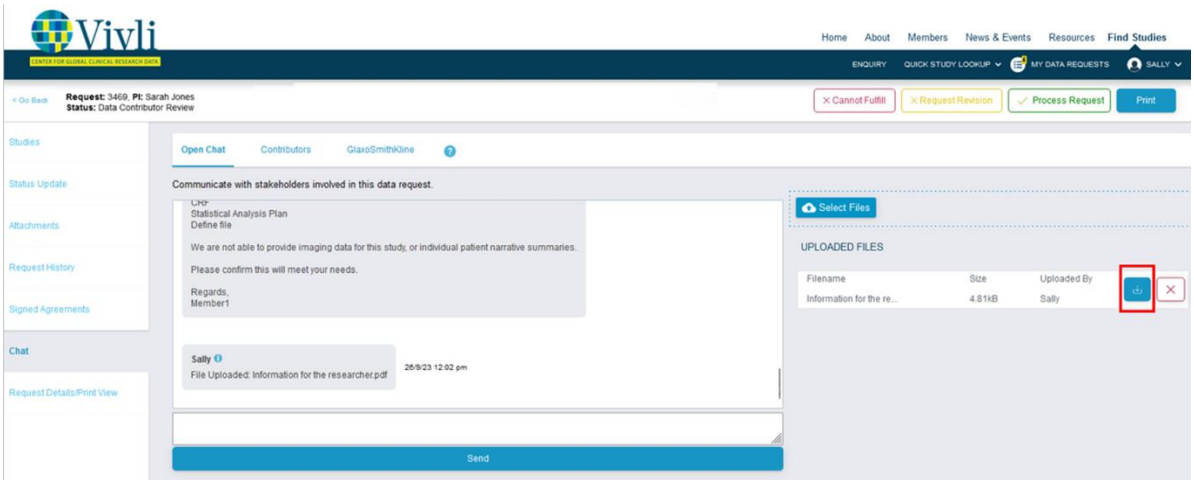
9. The upload bar will show the progress:



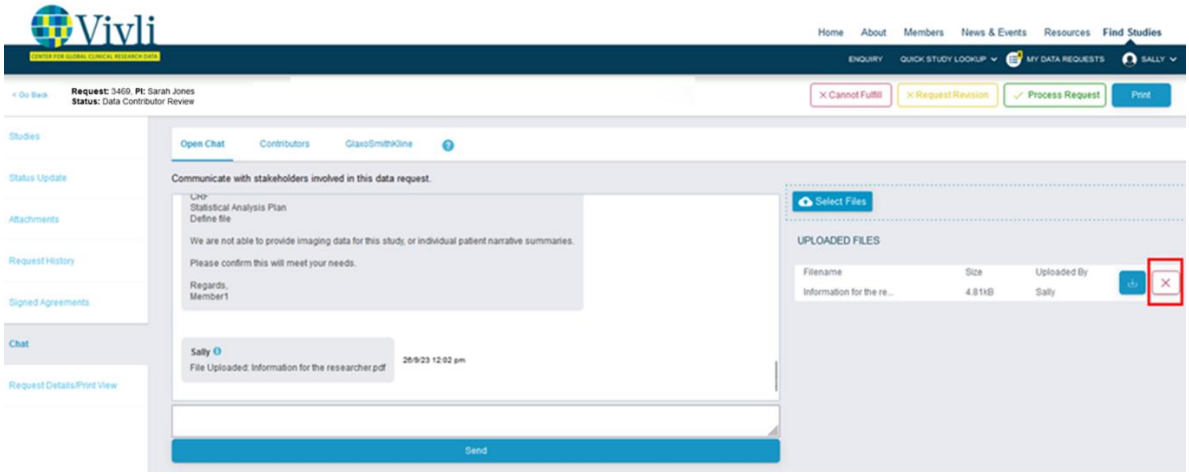
10. The history of the uploaded file will appear in the chat window:



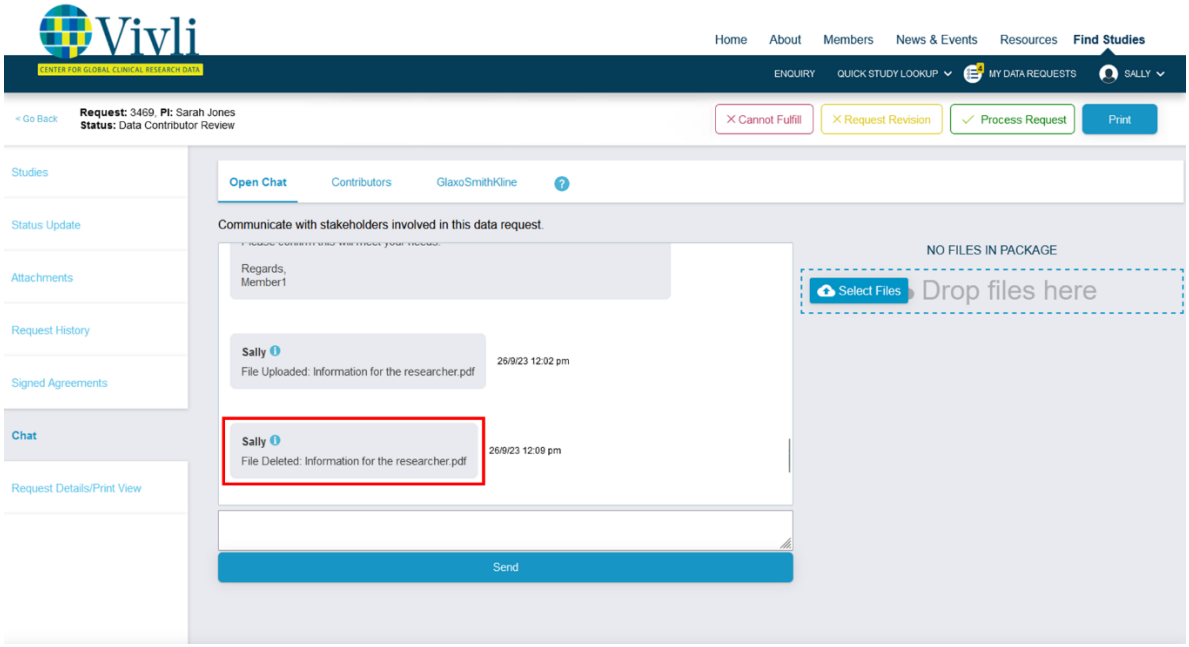
11. You may also download chat files by clicking on **Download:**



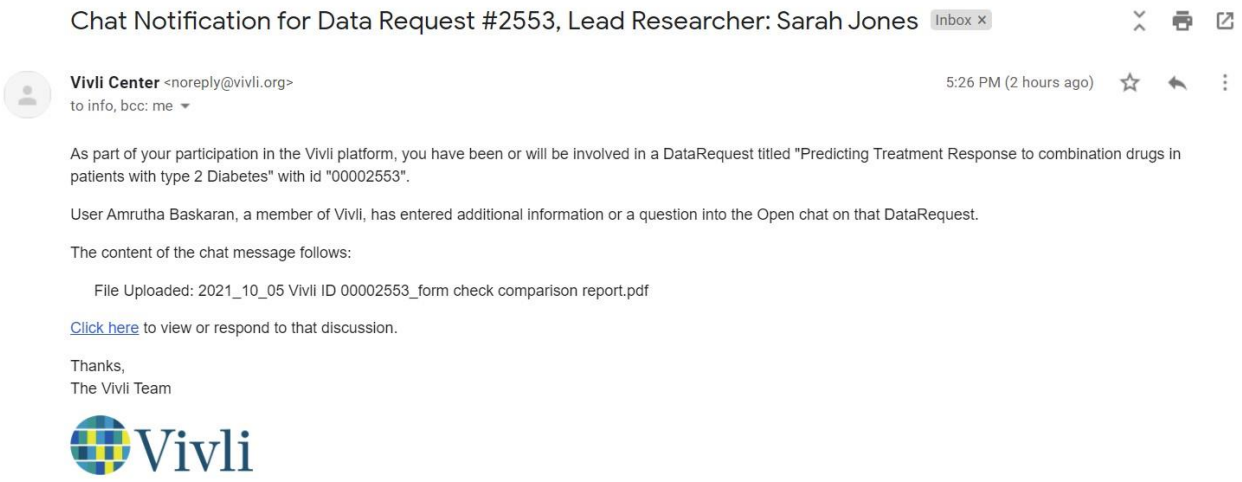
12. You can delete the uploaded file by clicking **delete**:



13. The deletion of the file will appear in the chat history:



14. Chats are posted when you click “Send” which permits you to write and read distinct paragraphs
15. Chat messages automatically scroll to the most recent post instead of the first.
16. In chat, files are sorted by date, newest on top, and the hover text displays the filename, date, and person who uploaded it.
17. Posted chat messages are visible immediately.
18. Chat email notifications will include the display name and organization of the uploader and the content of the chat. The subject line will include the Request ID and the name of the Lead Investigator.
19. Email notification of chat will include the content of the chat message in its original formatting.

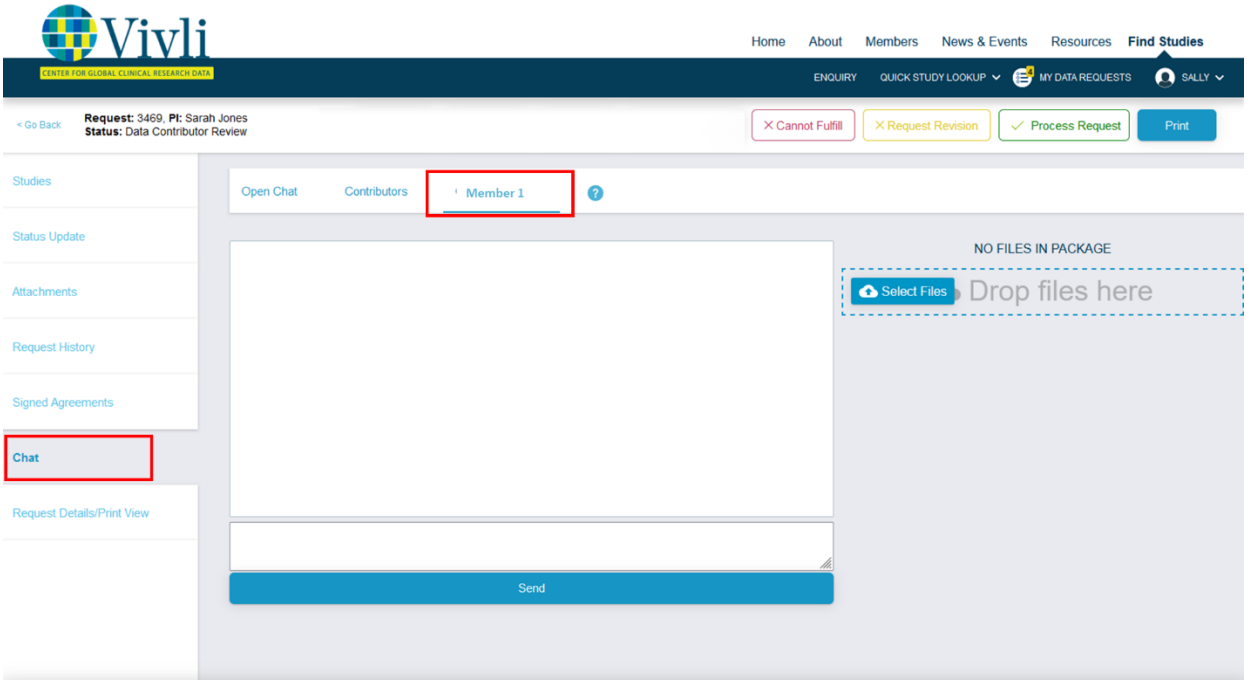


20. Note: Vivli Admins may set up automatic follow-ups for repeated follow-ups (E.g. revision, DUA, publication follow ups, etc.). Org Admins won't receive any there won't be any email notifications for such follow ups. Org Admins can see the chat messages on the chat window.

10.1.2 Private Chat

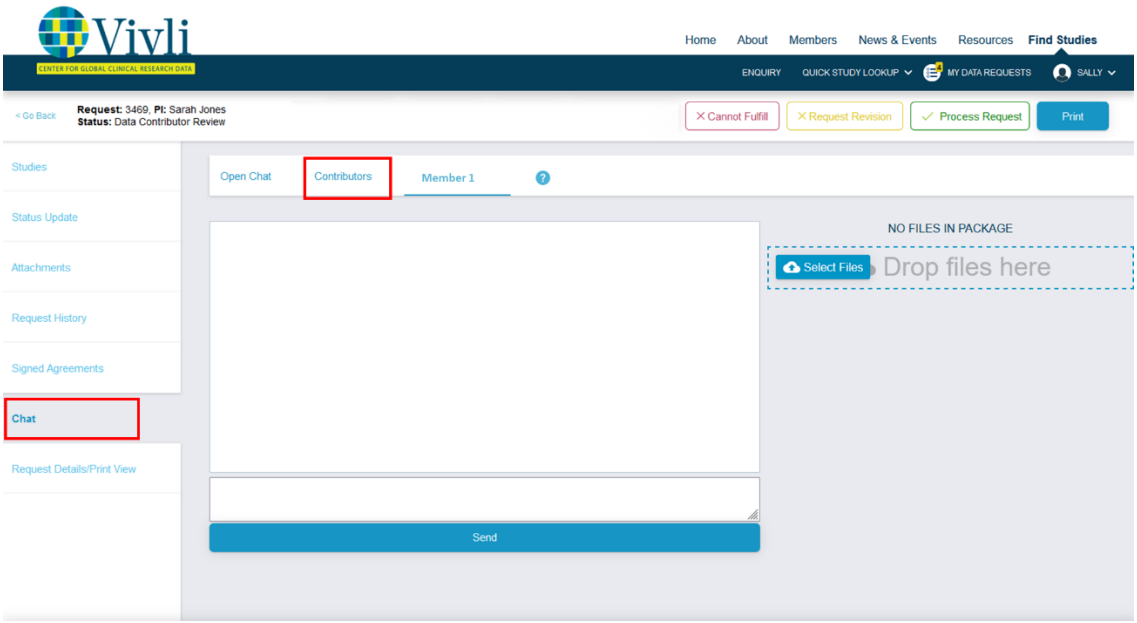
You may also open a private chat within the data request to communicate with other members of your organization.

Please note that private chat is visible to only members of your organization on the Vivli platform. When any other party in your organization enters a message in chat, you will receive an email notification.



10.1.3 Contributors Chat

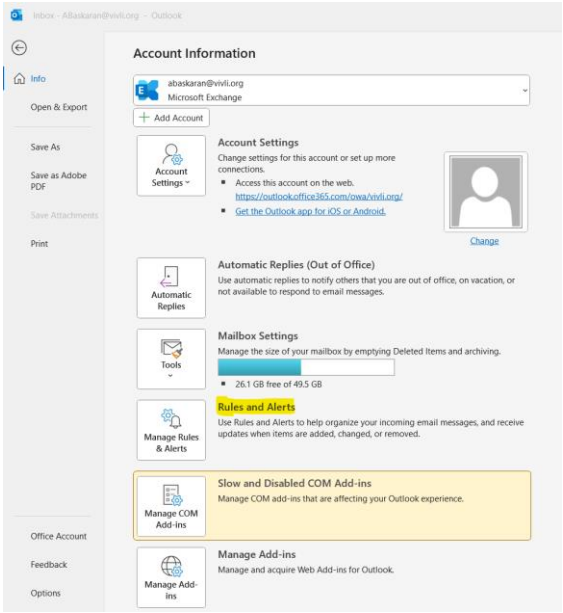
You may also open a Contributors chat within the data request to communicate with all the data contributors involved in the data request (but not the researcher). Organizational administrators will receive email notifications from this chat, but not those who have the Data Contributor role within an organization.



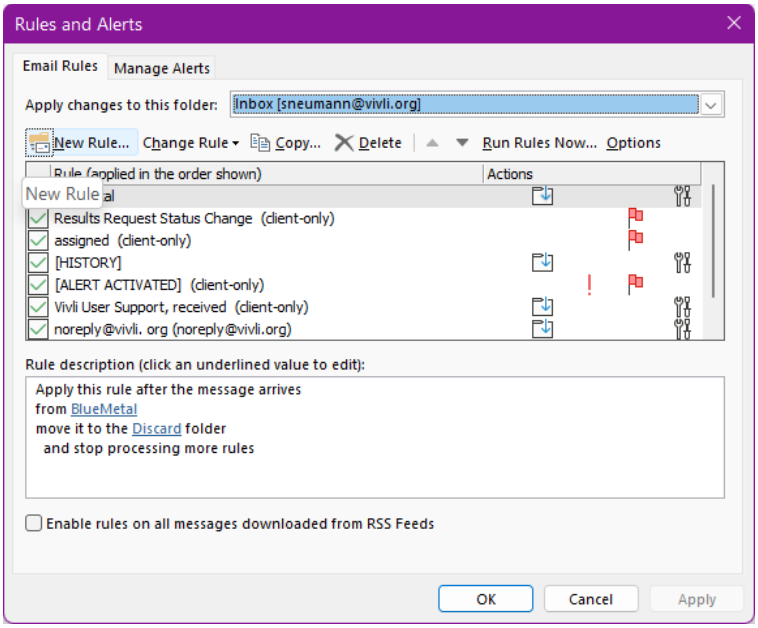
10.1.4 Setting up an inbox rule on Outlook to filter emails

Here are instructions for creating an inbox rule that can refile messages containing a specific sub-string in the subject line. The specifics are written for platform messages, but they can be generalized for other frequent messages that you don't want actively in your inbox.

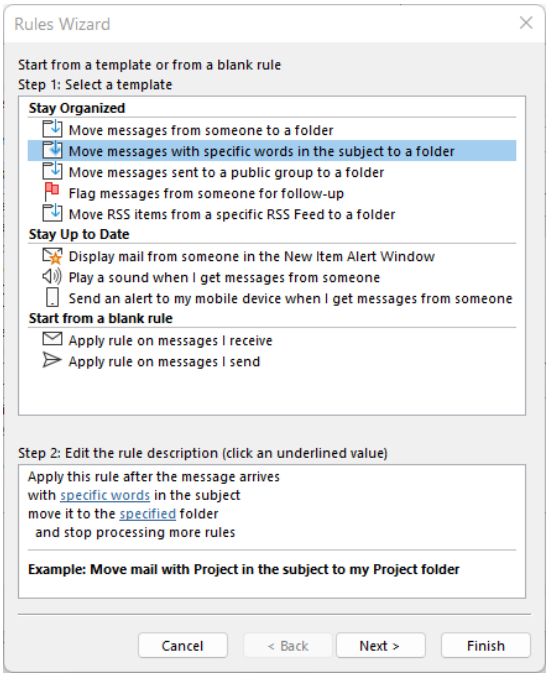
In Outlook, click File in the menu bar, then in the window that appears click on "Rules and Alerts"



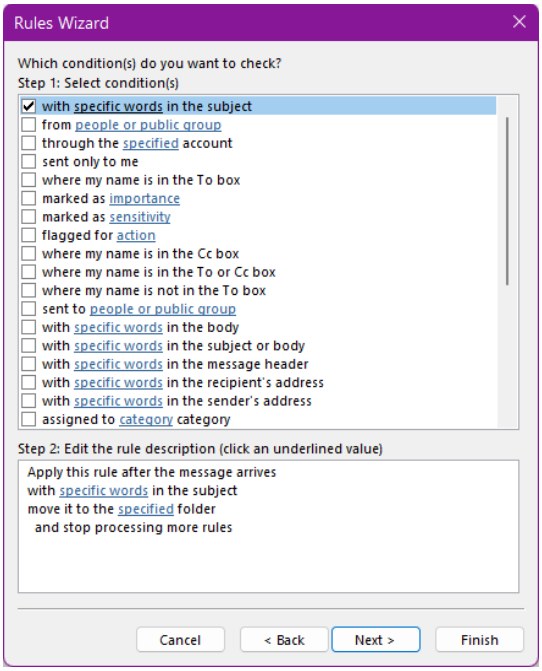
In the pop-up window, click New Rule:



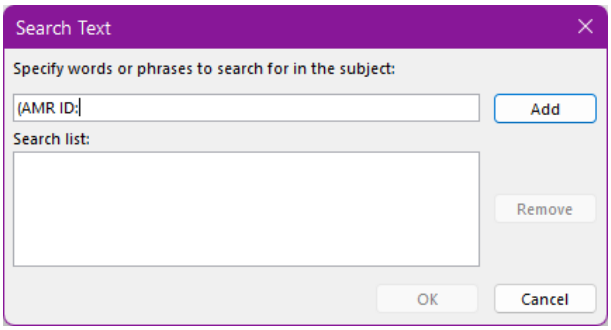
In the pop-up wizard, pick “Move messages with specific words in the subject to a folder”



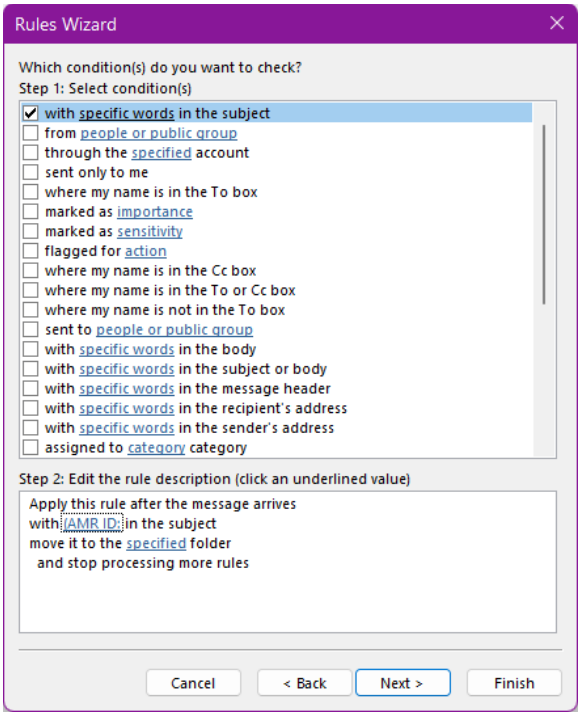
Click Next (it should display the choice “with specific words in the subject”),



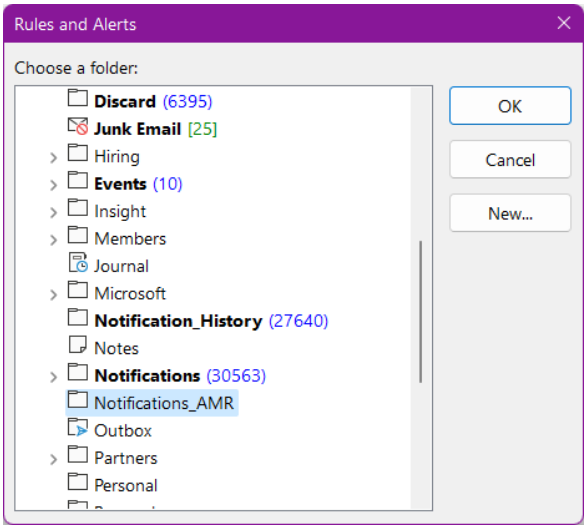
In the bottom half, click on “specific words” and enter “(AMR ID:” or “(Vivli:” or “(Chat Notification:”

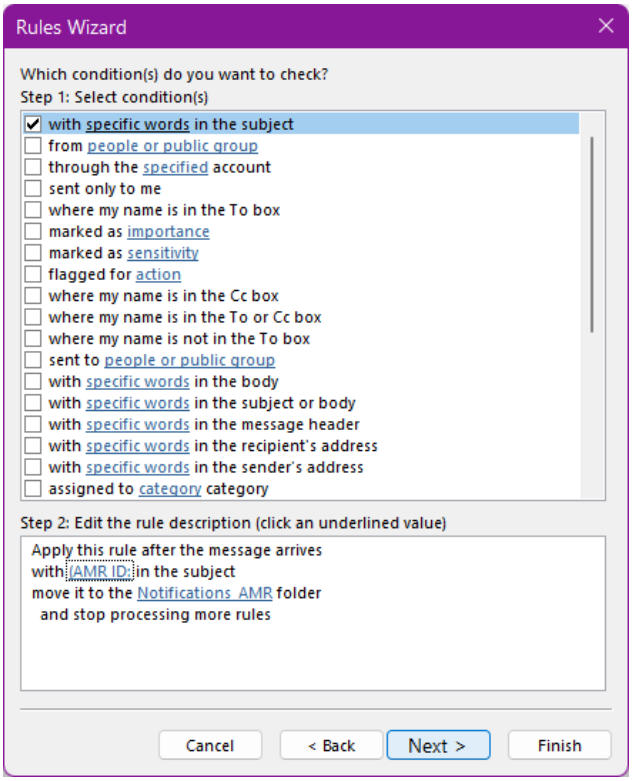


Click add to add it to the search list and then click OK:

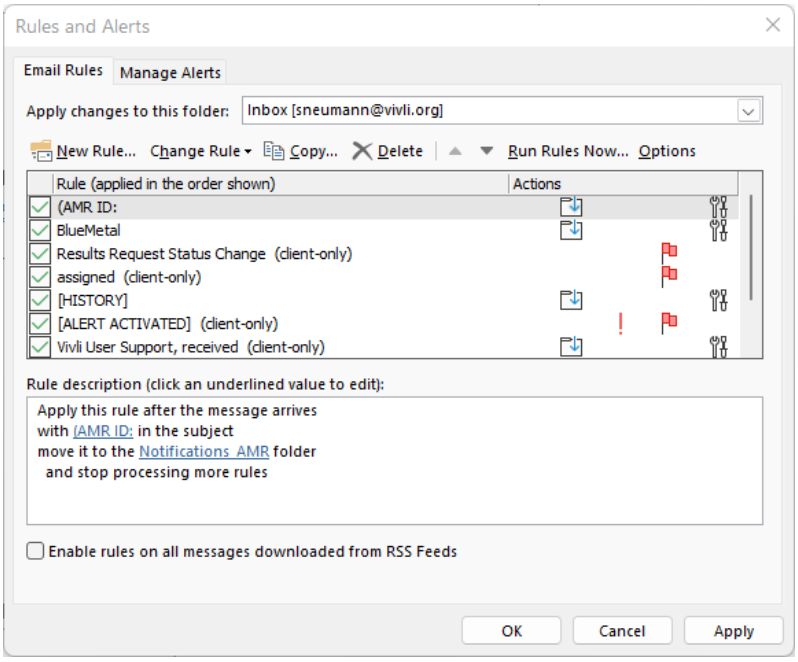


Back at the wizard, click on “specified” (as in ‘move it to the specified folder’); In the browse screen, select your destination folder and then click OK.





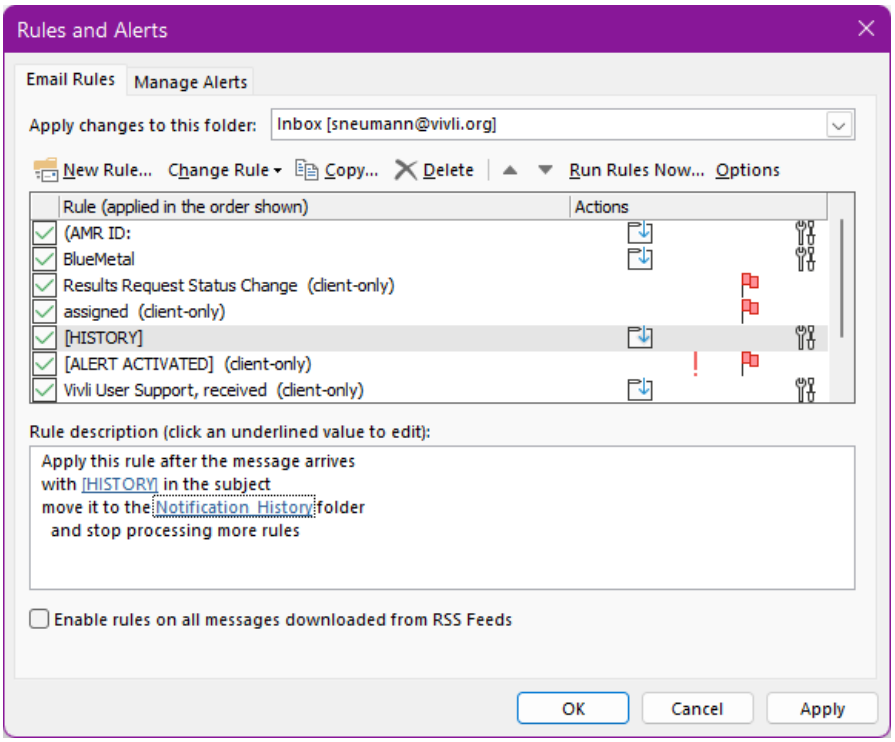
Click Finish and the rule should appear in the rule list:



Click OK to commit this.

(Note that this rule works only when you are in Outlook – if you read your email from your phone, the rule will not yet apply until you open it.

Also, note that there is an option to “Run rules now”, so you can refile messages that you received before setting up the rule.



10.2 Emails for Organizational Administrators

You will receive a number of automated emails from the Vivli platform, relating to your organizational account. Please see the table below for a synopsis:

Email	When sent	Purpose
Data Request Ready for Review	When a data request for your studies has been submitted	Notify you of the data request; prompt you to record your decisions if applicable
Data Request Non-Approval during Data Contributor review	For multi-sponsor requests that include your organization’s studies, an email is generated whenever any Vivli Member records their non-approval. The email also shows the reasons for non-approval.	Notify Organizational Administrators of any non-approvals to the data request.

Request Approved	When a data request for your studies is approved, by you or a delegated approver. For multi-sponsor requests, an email is generated after that last IRP records their final review decision	Notify of final governance approval
DUA Approved	When the Vivli Admin has validated the DUA associated with the data request	Notify Organizational Administrators and Data Contributors of approved DUA. Please work with your Data Contributor to upload the data package, if applicable.
Safety Concerns	When a data requestor logs a safety concern relating to any of the data associated with the request	Notify Organizational Administrators of safety concerns
Chat	When anyone associated with a data request enters a message in chat once the request reaches the Data Contributor Review stage for the first time. Once it reaches that stage, Org Admins will continue to receive notifications even if it goes back to draft for revisions.	Facilitate communication and the data request workflow
Research Environment deprovisioned	When the research environment is deprovisioned	Notify Organizational Administrators when analysis is complete
Data Request Archived	When the data request is Archived, the project is considered closed.	Notify Organizational Administrators that the lead researcher and research team have met the DUA obligations for public disclosure/summary of results and the data request is now archived.

10.3 Data Request Summary to Organization Administrators

- You will start receiving data request summaries from the Vivli team once you have the first data request that reaches the Data Contributor review stage.
- Data request summary emails are typically sent out every other Monday afternoon from support@vivli.org but the cadence may change depending on holidays. The Vivli team will aim to inform members in advance if there is a change in timing.
- The email contains the spreadsheet of data requests that require action from a data contributor and open and recently closed enquiries for your studies.
- It is also used to communicate other important updates or queries and will serve as a reminder if you have requests that are past the target timeline.
- For enquiry updates, please respond via the original enquiry email.
- Responses from data contributors will be done via the platform instead of emailing Vivli back a spreadsheet, this will create increased efficiencies for all involved. Use the feedback field on the Status Update to provide comments. See Section 3.5.3 Status Update for more information.

11. Support and Additional Information

11.1 Vivli Contact Information

Data Contributor User Support Contacts:

- General User Support: Support@vivli.org
- You may also use the Chat to contact the Vivli Admin

11.2 Data Use Agreement

The Vivli Data Use Agreement is posted online and available here: Data Use Agreement

11.3 Browser and System Requirements

Please review our browser and system requirements, as well as configure your browser to use the Vivli platform: Browser and System Requirements

11.4 Standard Process for Vivli-Member Engagement

- Please review the data request summary
- Check Data Contributor Manual for reminders on how to do tasks before emailing support@vivli.org for specific questions.
- Any changes to your policy (like the IRP change) or operations (team change), please update the member's checklist and email it to support@vivli.org

12. Instructions for using a printed copy of this document

If you would like to use this document in its printed form, you can change the Microsoft Word settings to display the URL addresses that are hyperlinks in the electronic version. To do this, change your Word settings as follows:

- Open the File menu and select 'Options'
- In the Options menu, select 'Advanced'
- In the Advanced menu, scroll to the 'Print' sub-menu; select and check the box for 'Print field codes instead of their values'
- After checking the relevant box, click 'OK' at the bottom of the pop-up menu, then print a copy of the document.
- The printed version of the document should replace hyperlinked text with text that looks like this:
- {HYPERLINK "https:…" etc. }
- This will allow you to navigate to relevant URLs using a printed version of this document

13. Document Information

Revision History			
Rev. #	**Author**	**Summary of Changes**	**Date**
1.0	Jessica Baker	Initial Version	July 10, 2018
1.1	Jessica Baker	Incorporates updates from Vivli release 1.2 including updated chat and DUA platform process	October 25, 2018
1.2	Amrutha Baskaran	1. Updated Section 1.2 – Creating your Vivli Account 2. Updated Section 1.3.2 – Adding members 3. Updated Section 3.3.1- Sending the Request to a Delegate 4. Added Section 5.0 - Research Environment Monitoring 5. Added Section 9.1.3 – Contributors chat	March 19, 2019
1.3	Amrutha Baskaran	1. Updated Section 1.2 Creating your Vivli account about updating the member checklist 2. Updated Section 1.3.2 Adding Team members 3. Updated Section 1.3.3 Data Contributor Organizational Roles 4. Updated Section 3.1 Reviewing Data Requests- Overview 5. Updated Section 3.2.1 Navigation to Data requests 6. Added Section 3.2.2 Data Request Dashboard – Search Feature 7. Updated Section 3.3 Recording a Decision about a Data Request 8. Added Section 4.1 Vivli Dashboard for Data Contributors 9. Updated Section 4.2 Notification 10. Updated Section 4.3 Loading Data package 11. Added Section 4.3.2 Make Data Package Available 12. Updated Section 6.0 Public Disclosures & Publications 13. Updated Section 9.2 Emails for Organizational Administrators	December 13, 2019
1.5	Liz Graham	1. Added Section 1.3.3 Organizational Administrator Resources 2. Added Section 2.5 Study Enquiry process 3. Updated Section 3.2.2 Data Request dashboard – Search Feature 4. Updated Section 3.2.3 Reviewing Requests 5. Updated Section 3.3.3 Request Revision 6. Updated Section 3.3.5 Major versus minor revisions to data requests 7. Added Section 3.3.6 Withdrawal process for non-response requests 8. Added Section 5.1 Software on the Research Environment 9. Updated 9.1.1 Steps, creating a chat message 10. Updated 9.2 Emails for Organizational Administrators Note: version 1.4 skipped to align with platform releases to avoid confusion	March 13, 2020
1.6	Liz Graham	1. Metrics--updated screenshots to reflect updated version 2. Updated process section 3.3.5 major and minor edits 3. Updated Section 4.3.1 Steps, Uploading Data Package 4. Added section 4.3.2 Steps, Download files that the Data Contributor previously uploaded 5. Updated Section 9.1.1 Steps, creating a chat message 6. Updated Section 9.2 Emails for Organizational Administrators	July 11, 2022

1.7	Liz Graham	1. Updated 3.2.1. Navigating to Data Requests 2. Updated Section 3.2.2. Data Request Dashboard with “Awaiting My Action” dashboard updates. 3. Updated Section 3.2.3. Reviewing Requests with Data Requests overlapping title user interface updated 4. Removed Section 3.3.1. Sending the request to a Delegate 5. Updated Section 4.1. Vivli Dashboard for Data Contributors with “Awaiting my Action” dashboard updates. 6. Section 4.3.1. Steps, Make Data Package Available study list updates. 7. Updated Section 4.3.2. Steps, Download files that the Data Contributor previously uploaded	March 6, 2021
2.0	Amrutha Baskaran	1. Updated screenshots throughout the manual to reflect the updated version of the platform 2. Added section 1.3.4 Active Platform Accounts 3. Updated Section 2.5 Study Enquiry Process 4. Added section 2.6 Supporting documents made available for researchers searching for studies 5. Updated Section 3.2.1 Navigating to Data Requests 6. Updated Section 3.2.3 Reviewing Requests 7. Updated Section 3.3.5 Withdrawal process 8. Added Section 3.3.6 Target timeline for the review process 9. Added Section 4.3 General upload guidelines 10. Added Section 4.3.1 Zip archive process 11. Updated Section 4.4.1 Steps: Uploading Data Package to an approved request 12. Updated Section 6.2 Publication Notification by Data Requestor 13. Added Section 9.3 Weekly summary to Organization Administrators	October 9, 2021
2.2	Amrutha Baskaran	1. Updated Section 3.2.3 Data Request form 2. Updated Section 3.3.1 Cannot Fulfill 3. Added Section 3.4 Report of data requests 4. Added Section 3.4.1. Features of the report 5. Added Section 3.4.2. Fields included in the report 6. Added Section 3.4.3. Status Update 7. Updated Section 4.4.5 Steps: Upload a New Version of the Data Package 8. Added Section 7.DUA extension 9. Updated Section 10.1.1 Steps, creating a chat message 10. Updated Section 10.3 Weekly summary to Organization Administrators 11. Added Section 11.4 Standard process for Vivli-Member Engagement	August 29, 2022
3.0	Amrutha Baskaran	1. Added Section 3.2.4 Vivli Policies in Brief 2. Updated Section 3.3.1 Cannot Fulfill 3. Updated Section 4.2 Data Upload Notification 4. Updated Section 10.1.1 Open Chat 5. Added Section 10.1.4 Setting up an inbox rule on Outlook to filter emails	January 19, 2023
3.1	Amrutha Baskaran	1. Added Section 3.3 Study settings at Data Contributor Review 2. Added Section 3.3.7 Summary level and document-only data request 3. Updated Section 3.4.3. Status Update 4. Added Section 4.4.6 Steps: Uploading data to only one data request	May 27, 2023

		5. Updated Section 6.0 Public Disclosures & Publications & Summary of results	
3.2	Catherine D'Arcy	1. Updated Section 3.2.3 Data Request Form 2. Updated Section 3.3 Study setting at Data Contributor Review 3. Updated Section 3.4 Recording a Decision about a Data Request 4. Updated Section 3.5 Report of data requests 5. Updated Section 10.1 Chat	September 26, 2023
3.3	Amrutha Baskaran, Catherine D'Arcy, Sarah Sweet, Elizabeth Graham	1. Updated Section 2.6 Supporting documents made available for researchers searching for studies 2. Updated Section 2.7 Study Usage and Public Disclosure Metrics 3. Updated Section 3.4.4 Major versus minor revisions to data requests 4. Updated Section 3.5 Report of data requests 5. Updated Section 3.5.2. Fields included in the report 6. Updated Section 4.4.1 Steps: Uploading Data Package to an approved request 7. Updated Section 4.4.3 Steps: Uploading data while request undergoing review 8. Updated Section 4.4.4 Studies list and stored data package 9. Added Section 4.4.6 Uploading large files and data packages to the Vivli Platform 10. Updated Section 10.1.1 Open Chat 11. Updated Section 10.2 Emails for Organizational Administrators	February 1, 2024

Approval History			
Name	**Job Title**	**Date Approved**	**Effective Date**
Version 1.0			July 11, 2018
Rebecca Li	Executive Director	July 11, 2018	
Version 1.1			October 25, 2018
Rebecca Li	Executive Director	October 25, 2018	
Version 1.2			March 20, 2019
Rebecca Li	Executive Director	March 20, 2019	
Version 1.3			December 14, 2019
Rebecca Li	Executive Director	December 13, 2019	
Version 1.4			n/a
Rebecca Li	Skipped to align with the platform version	n/a	
Version 1.5			March 13, 2020
Rebecca Li	Executive Director	March 13, 2020	
Version 1.6			July 10, 2020

Rebecca Li	Executive Director	July 10, 2020	
Version 1.7			March 6, 2021
Rebecca Li	Executive Director	March 6, 2021	
Version 2.0			October 9, 2021
Rebecca Li	Executive Director	October 8, 2021	
Version 2.2			August 27, 2022
Rebecca Li	Executive Director	August 19, 2022	
Version 3.0			January 19, 2023
Rebecca Li	Executive Director	January 18, 2023	
Version 3.1			May 27, 2023
Rebecca Li	Executive Director	May 26, 2023	
Version 3.2			September 30, 2023
Rebecca Li	Executive Director	September 26, 2023	
Version 3.3			February 10, 2024
Rebecca Li	Executive Director	February 1, 2024	