Vivli Organization Administrator and Data Upload Guide For Vivli Platform Version 4.0

12 March 2026

Contents

1. Vivli Accounts for Members

1.1 Onboarding

- After your organization joins Vivli as a member, the Vivli team will begin your onboarding.
- The Vivli team will send you a draft member's page to complete.
- 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 the 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 1.3.3 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 provide your designated Organization Administrator(s) with appropriate rights on the Vivli platform.
- The Vivli team will also provide training on reviewing the data request, recording the decision on the Vivli platform, and uploading the data package for studies approved in the data request.
- The Vivli team will also send you the Vivli Organization Administrator and Data Upload Guide. Please see Section 1.3.7 Accessing the Vivli Organization Administrator and Data Upload Guide and other training resources .

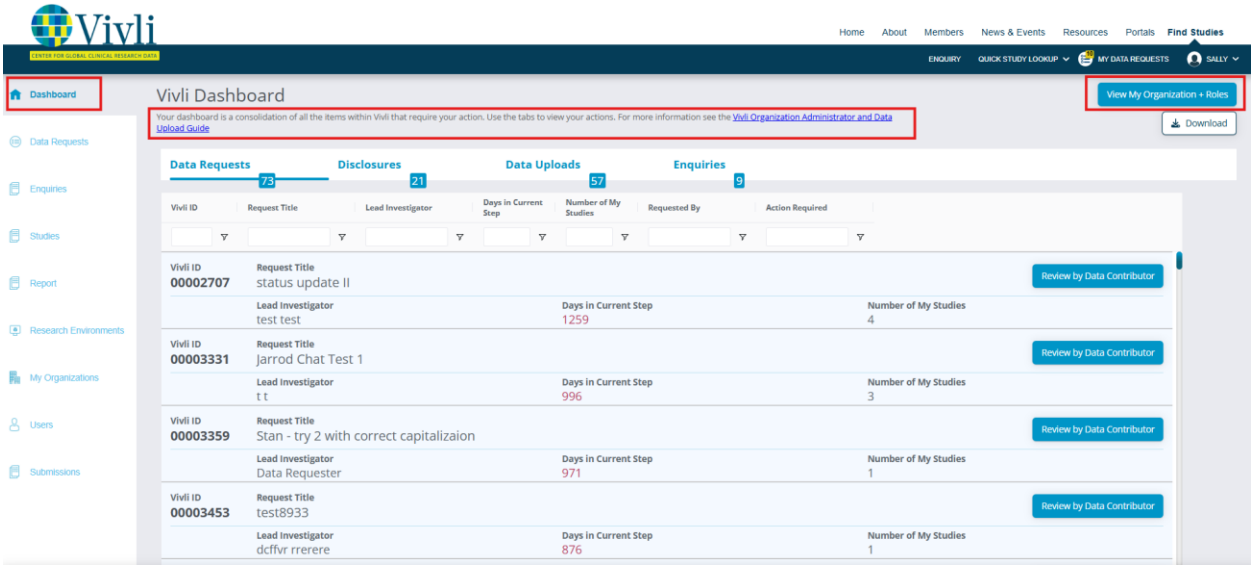
1.2 Creating your Vivli account

- You can become a user by signing up for the Vivli platform. Please see section 1.0 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 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 along with an updated member checklist so that the Vivli team can provide appropriate training for new team members or remove access to team members who have left the organization.

1.3 Vivli Dashboard for Organizational Administrators

- Once you have been given access as Organizational Administrator to your Organization, and have logged in, you will be taken to your Vivli Dashboard.
- On the dashboard, you can view the Organization that you are part of and your roles as part of your organization by clicking "View My Organization + Roles" button.

- You can also click on the link "Vivli Organization Administrator and Data Upload Guide" to view the PDF of the latest Guide



- You can track your actions:
  - data requests that require review and approval
  - studies that require data upload
  - public disclosures waiting for 30-day review
  - outstanding enquiries that require your review and response

  You can also download your actions to a csv file, by selecting each tab and clicking the 'Download' button

The report downloaded from Data Request includes the following fields:

- Vivli ID
- Request Title
- Lead Investigator
- Lead Investigator Affiliation
- Lead Investigator Country
- Data Contributors
- Days in Current Step
- Target Days for Current Workflow Step
- Total Number of Studies
- Number of My Studies
- Requested By
- Action Required
- Action Overdue

The report downloaded from Disclosure includes the following fields:

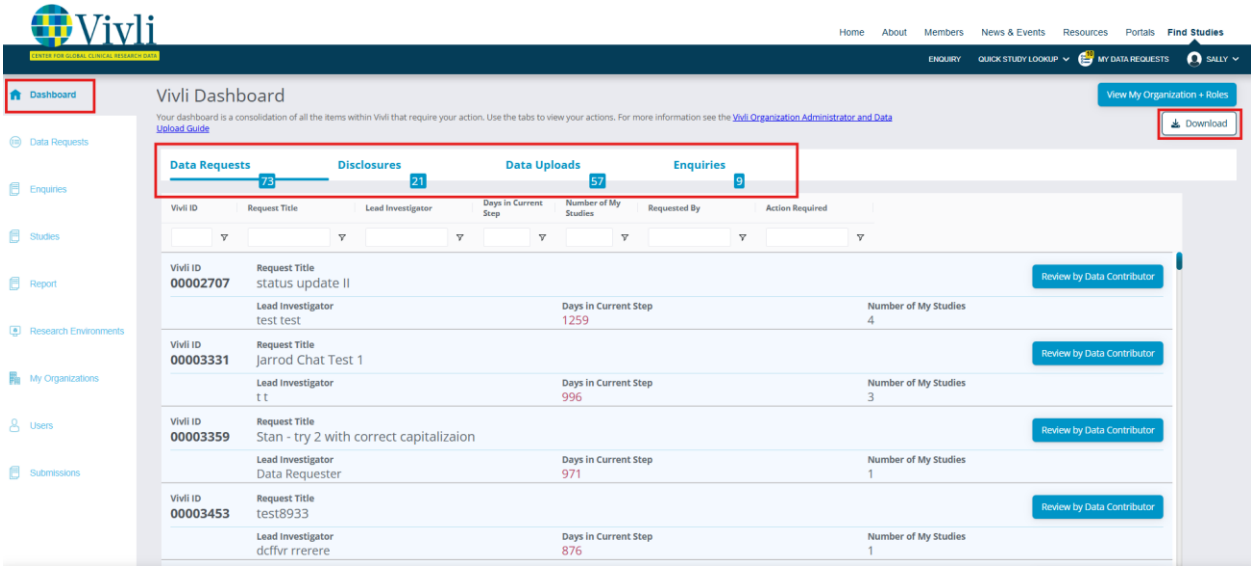
- ID
- Disclosure Title
- Disclosure Type
- Lead Investigator
- Data Contributors
- 30-Day Review
- Action Required

The report downloaded from Data Uploads includes the following fields:

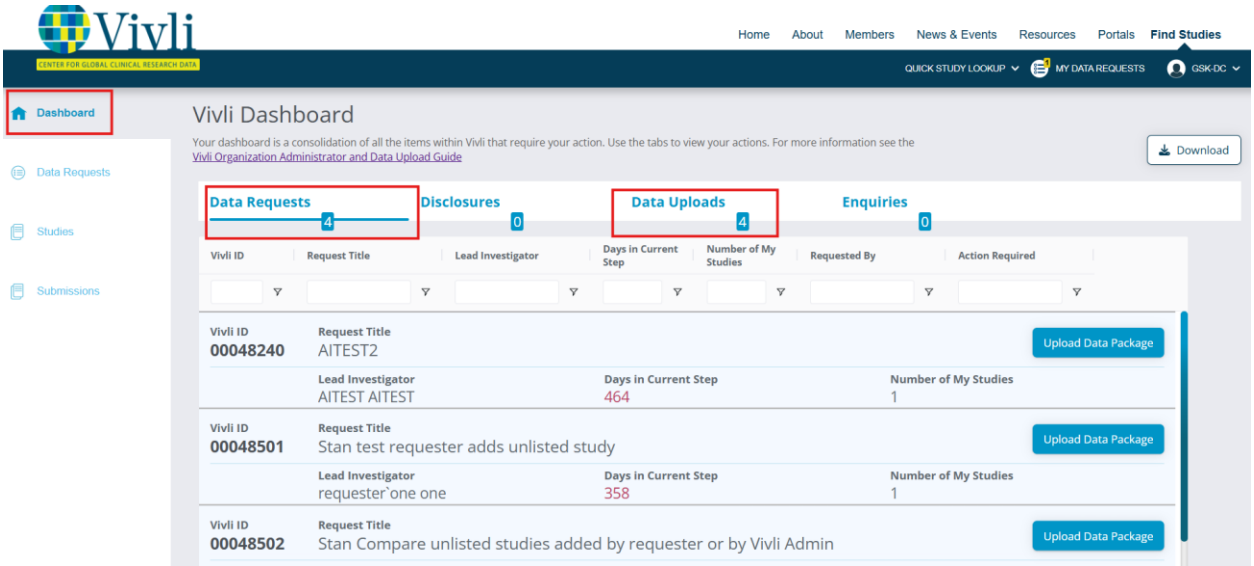
- Study ID
- Sponsor ID
- Study Title
- Data Request ID
- Request Type
- Availability
- Action Required

The report downloaded from Enquiries includes the following fields:

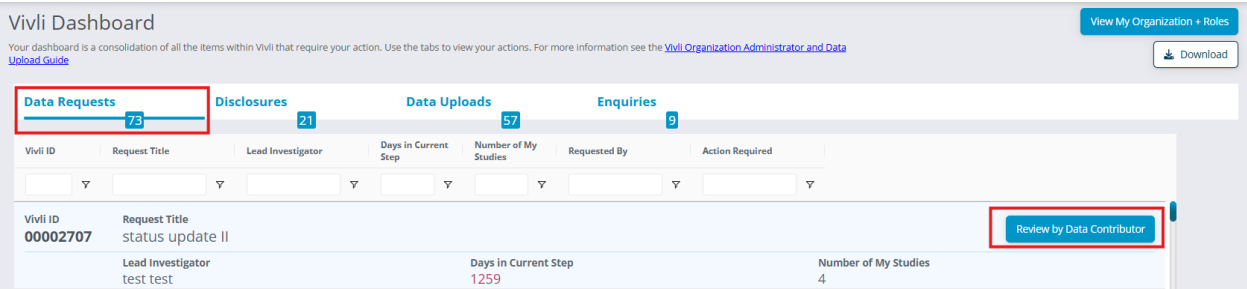
- Enquiry ID
- Total Number of Studies
- Number of My Studies
- Days in Current Step
- Requested By
- Action Required
- Action Overdue



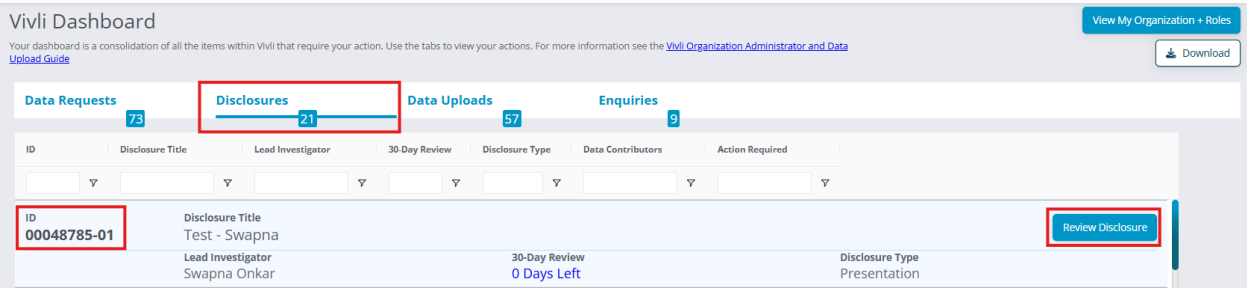
- A team member with the 'Data Uploader' role will only see records in the Data Requests and Data Uploads sections, and will only be able to access the Data Requests and Studies tabs on the left-hand toolbar:



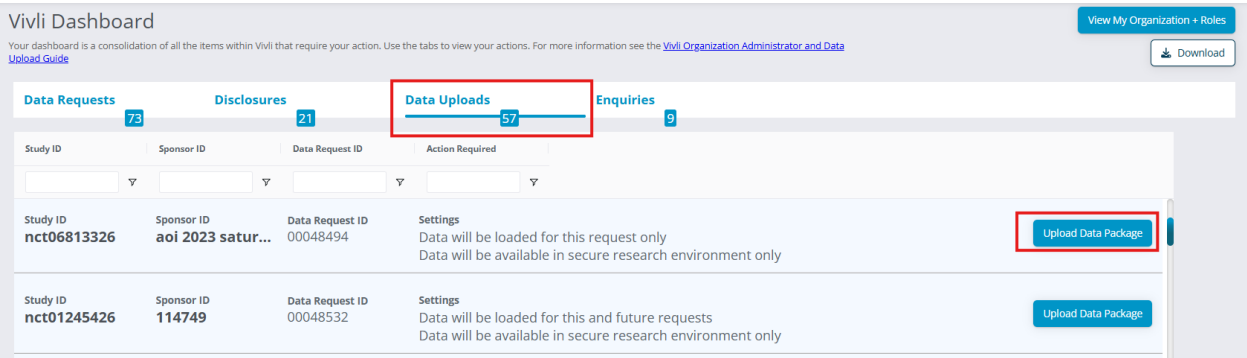
1. Data Requests – this section shows data requests waiting for decisions to be recorded or waiting for data to be uploaded. Clicking on the blue button for each row will take you into the data request so that you can complete the action. The 'Days in Current Step' field shows the number of days the action has been outstanding. This number will turn red when it is over the agreed target (21 days for data request review decision, 30 days for data upload). You will only see data requests awaiting a decision from your organization.



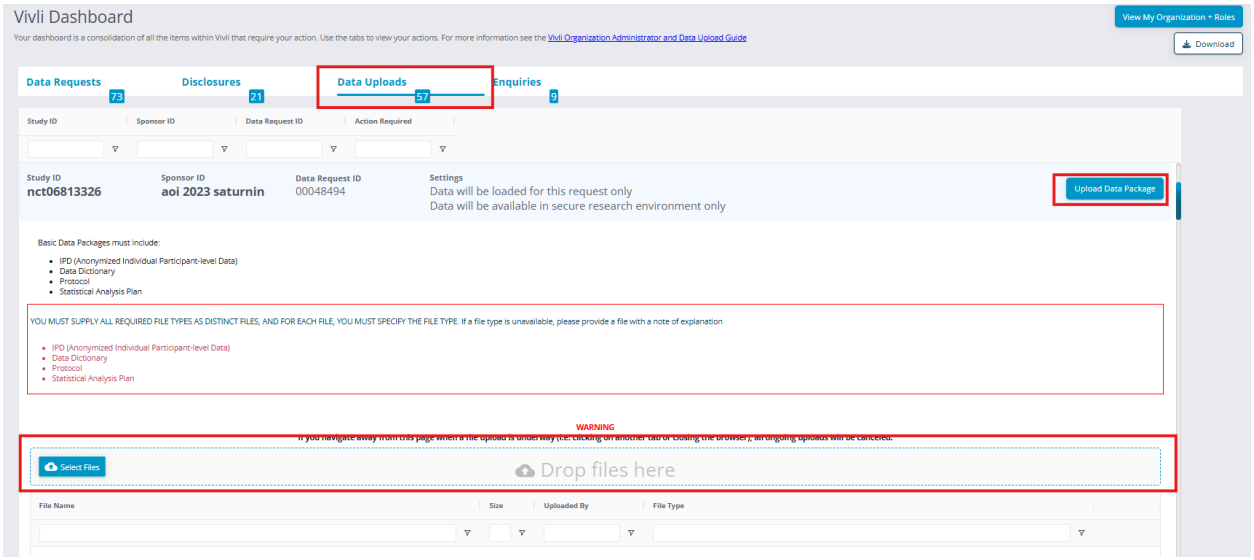
2. Disclosures – this section shows the publications that have been submitted and are waiting for feedback in the 30-day review. Clicking on the 'Review Disclosure' will take you into the public disclosure where you can record feedback. The ID consists of the data request ID + the Disclosure ID for that request. The 30-Day Review field shows the number of days the action has been outstanding. You will only see disclosures awaiting a decision from your organization, when you record a decision the review will be removed from your dashboard. If you have not recorded a decision after 30 days have passed, the review will be automatically removed from your dashboard.



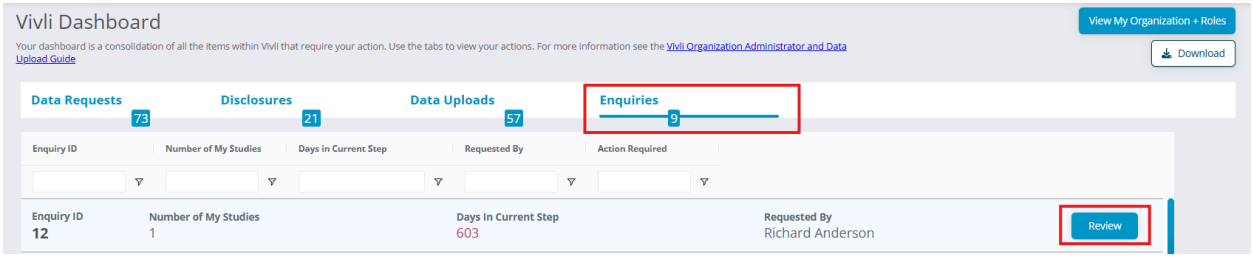
3. Data Uploads – this section shows each study from an approved data request waiting for data to be uploaded.



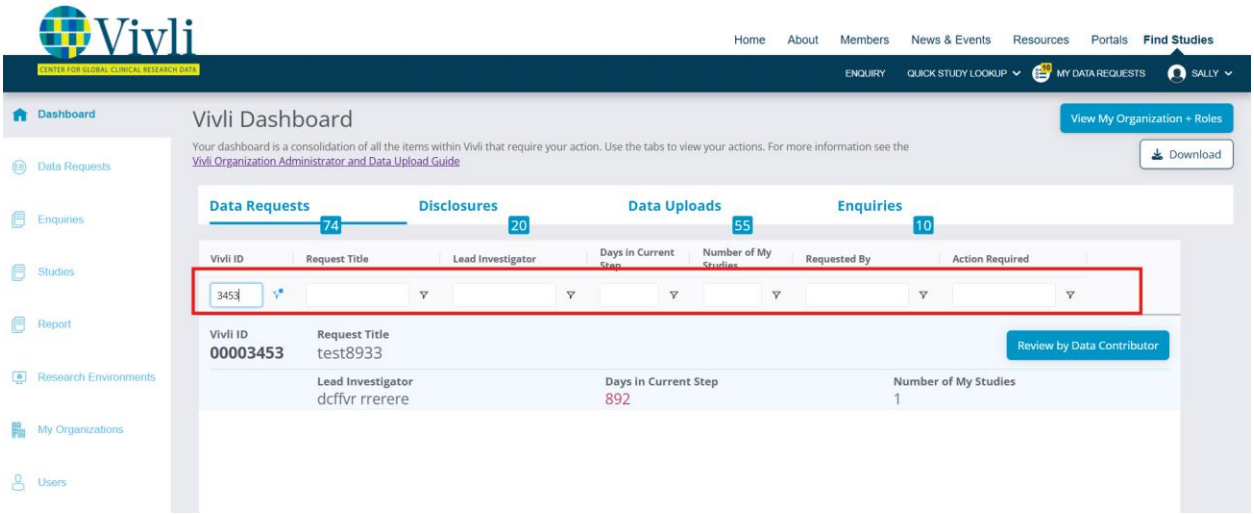
- Clicking on 'Upload Data Package' will open up a section where the data package files can be uploaded. For more information on uploading data packages, see Section 5.6 Steps to Upload Data Package



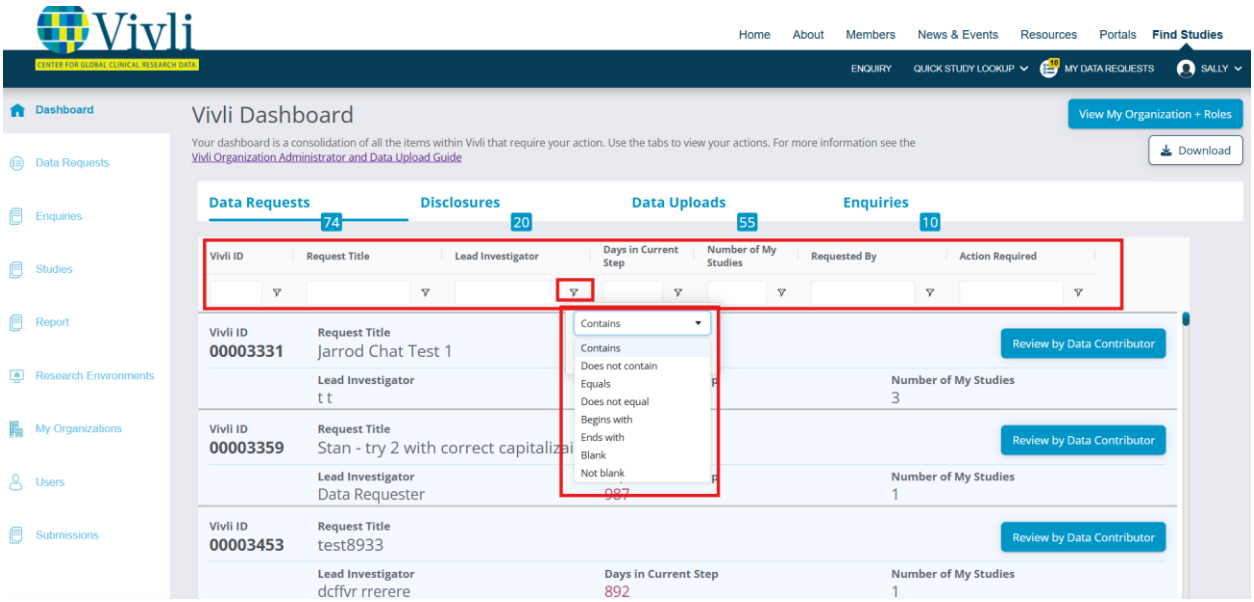
4. Enquiries – this section shows enquiries waiting for a decision. Clicking on the 'Review' button will take you into the relevant enquiry where you can record your decision.



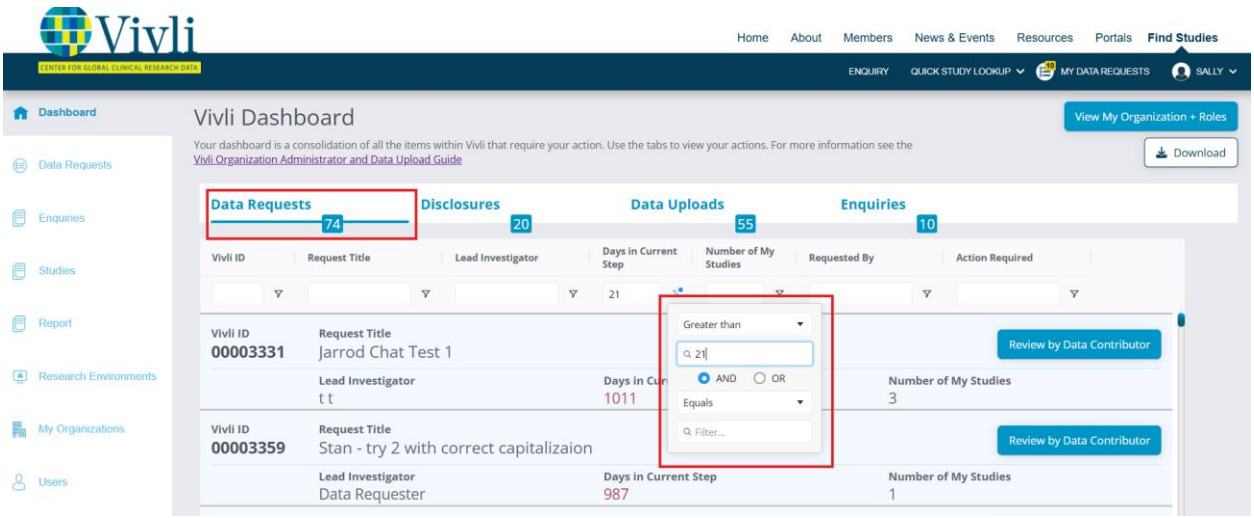
The header row includes filters that can be used to search for specific records:



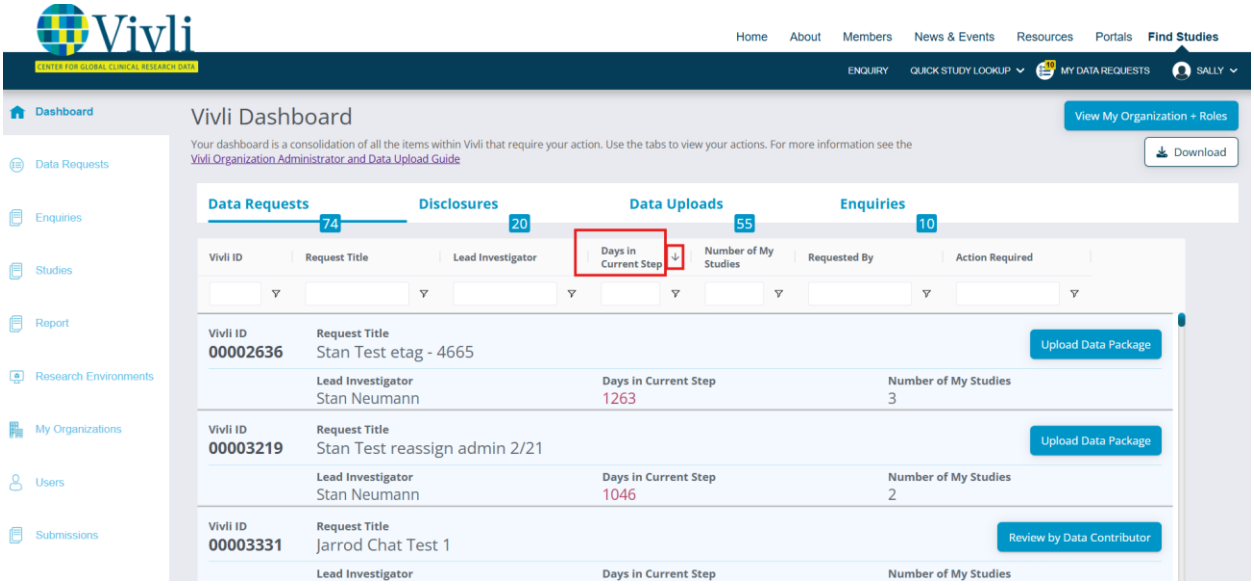
Clicking on the filter next to a search box will give a drop-down list of options for filtering the records:



You can use this feature to, for example, filter for overdue actions



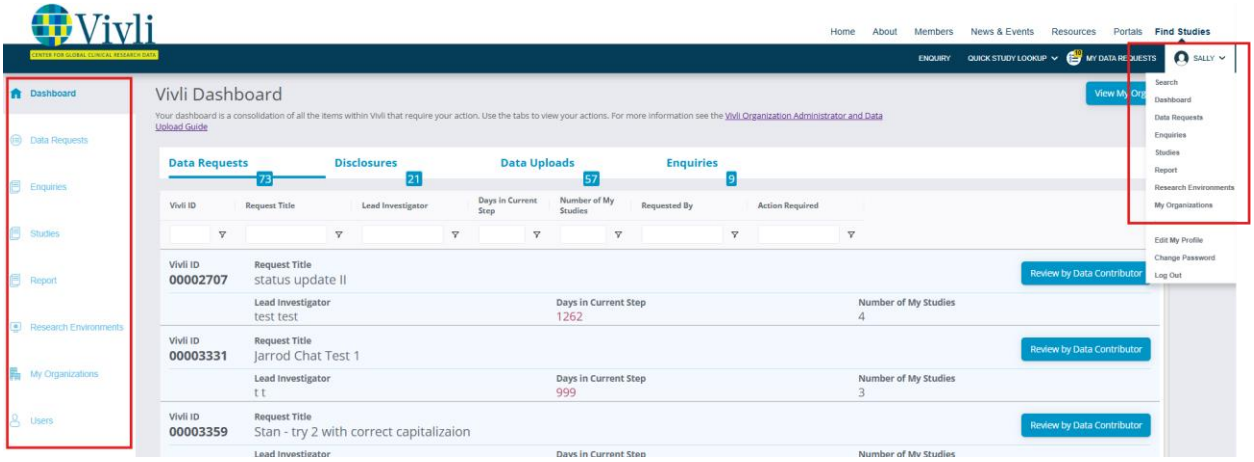
The headers can also be clicked to sort high to low:



On the left-hand side of the Dashboard, you can see the following tabs:

- Dashboard – This is the place to see the list of actions required for your organization. You can also view the Organization and roles that are part of your organization.
- Data requests - you can view data requests for studies from your organization
- Enquiries - you can view the Enquiries for studies from your organization
- Studies - you can view the studies listed on the platform by your organization
- Report - you can view several reports related to Data requests, Enquiries and Studies.
- Research Environment - you can view the number of Research Environments being used for analysis for approved data requests from your organization
- My Organizations – you can view the set of your Organization and team members
- Users – you can view all Vivli users from your organization

You may also navigate to the tab from the dropdown toolbar in the upper right-hand corner of the screen

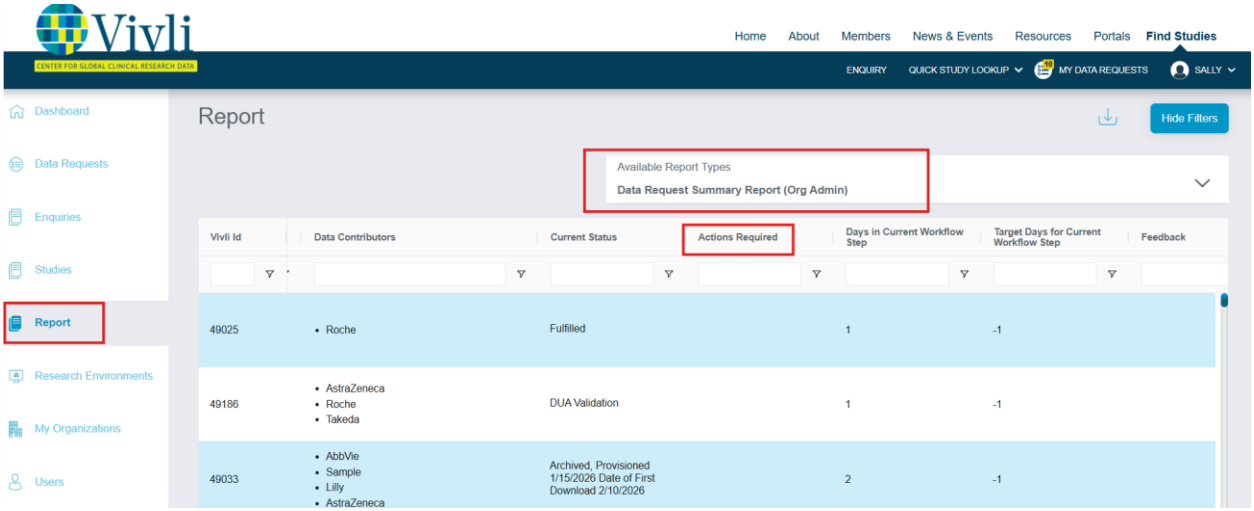


1.3.1 Reviewing My Actions

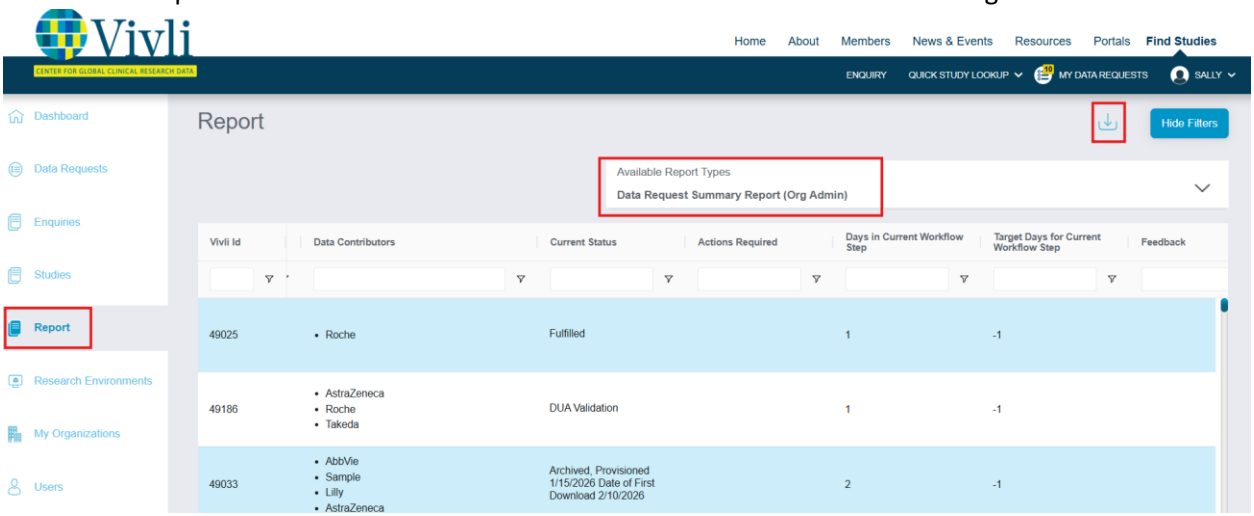
1. The main dashboard can be used to review outstanding platform actions (see section 1.3 Vivli Dashboard for Organizational Administrators above):

- Data request decisions
- Data upload
- Enquiry response
- Public disclosures review and feedback

2. To review all outstanding actions, including those that do not require an action to be taken on the platform such as answering questions from researchers or Vivli, there is a report in the ‘Reports’ tab, called ‘Data Request Summary Report’ which contains information on these other types of outstanding actions, and also Public Disclosure details.



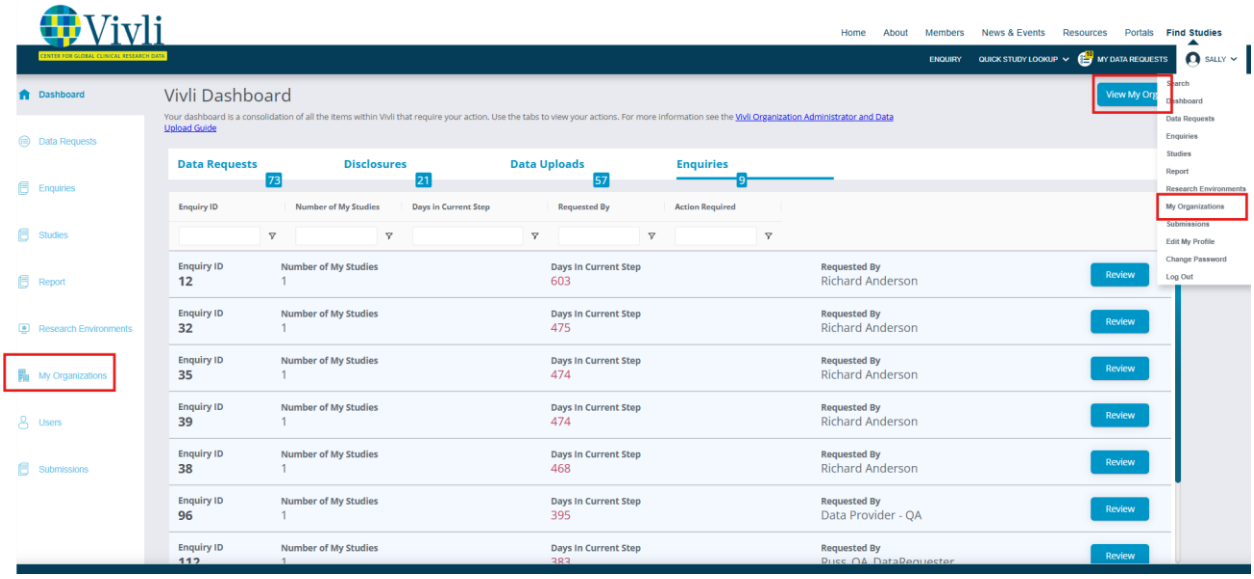
3. The report can be downloaded and reviewed to ensure all actions are being addressed:



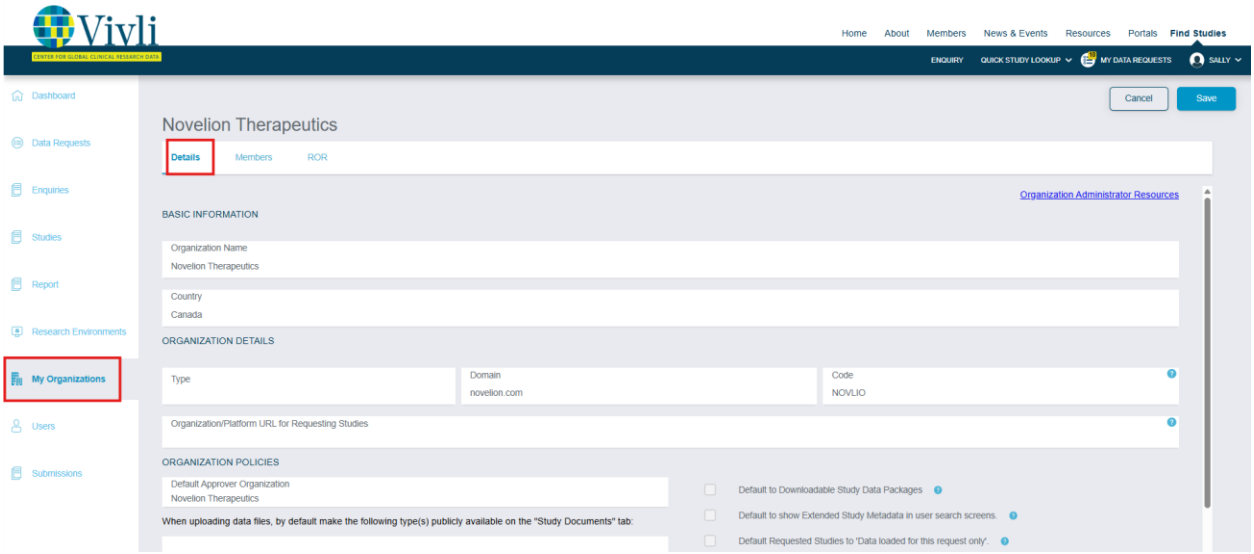
1.3.2 My Organizations tab

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

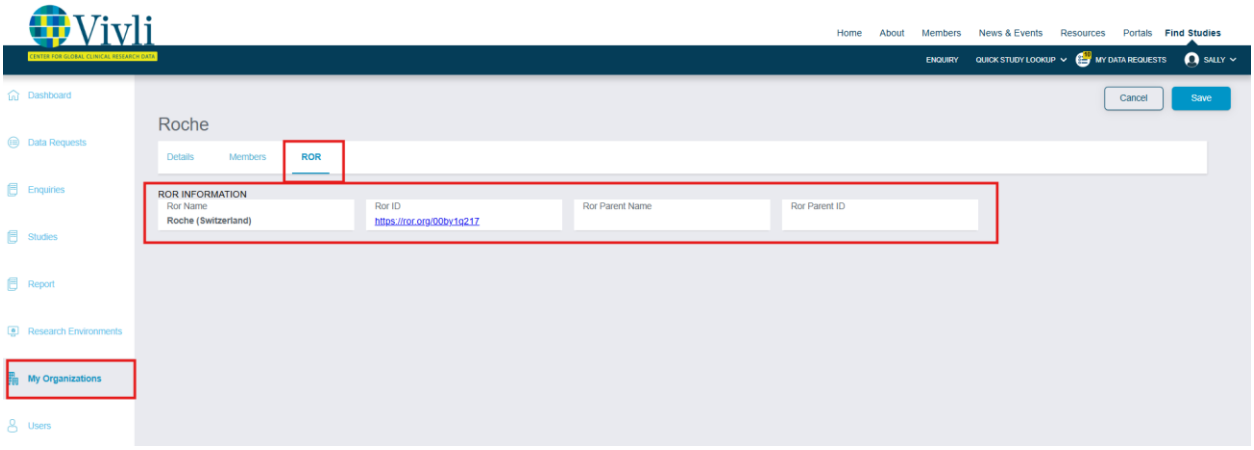
- From the Dashboard, you can navigate to **My Organization by clicking on "View My Organization _ Roles", or by** using the 'My Organizations' tab, or the dropdown toolbar in the upper right-hand corner of the screen:



You can view the Organization Details information (view-only) in the Details tab. To make any changes to the Organization policy please contact the Vivli team at support@vivli.org.



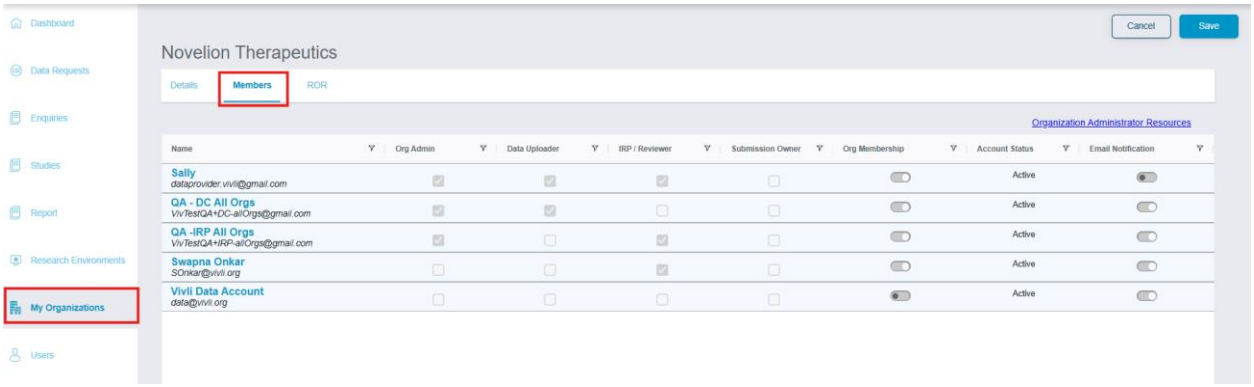
You can view your Research Organization Registry (ROR) ID information in the ROR tab (https://ror.org/). To make any changes to the ROR, please get in touch with the Vivli team at support@vivli.org. (Note: this is useful for metadata tracking and does not appear publicly.)



1.3.3 Team Members

- To add team members, ask them to become a user by signing up for the Vivli platform and guide them to section 1.0 of the User Quick Start Guide for the sign-up process. Note: the team members cannot be added to your organization until they have created a Vivli User Account.
- You can view the Team Member(s) information (view-only) in the 'Members' tab. Click on '**My Organizations' tab** 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:

- Once the team member creates an account, the team member's information and roles can be located under the 'Members' section.



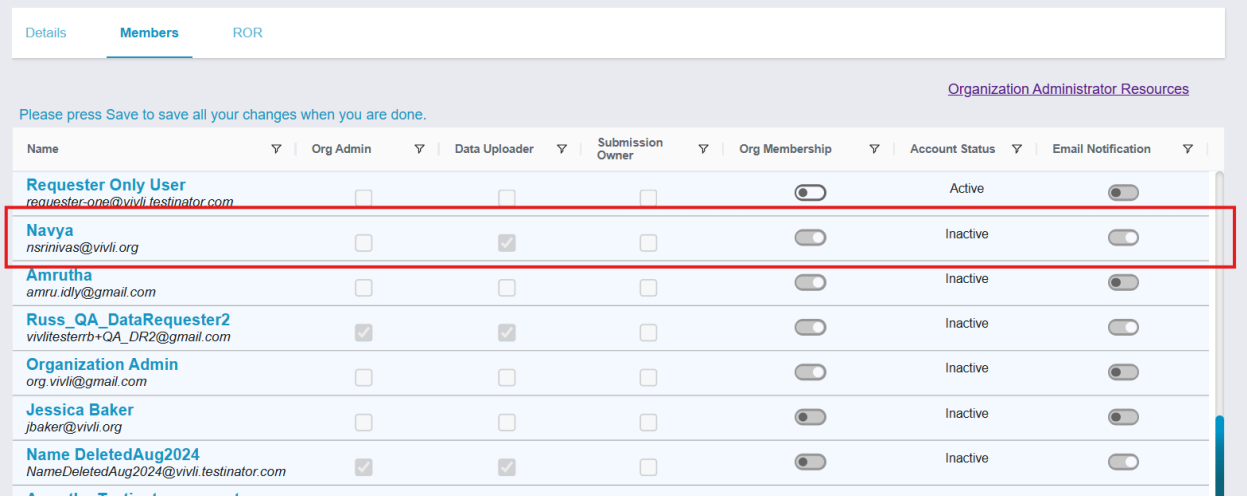
- The Members tab displays a list of all members associated with your Orgnaztaion

- To change the Organization Administrator or Data Uploader rights for your team member, please update the member checklist and contact the Vivli team at support@vivli.org so that they can provide training to the new team member, and give them access to the platform.

- Each team member will have roles assigned based on the member checklist represented by checkboxes next to their name.

- 'Org Membership' – denotes they are members of your organization. This can include anyone from your organization with a Vivli account, such as someone who has submitted a data request.
    - White/Grey toggle indicates that Org membership is enabled for that user.
    - Black/Grey toggle indicates that Org membership is disabled for that user.

- Email Notification – denotes the Vivli platform emails received by that user. By default, users are set to receive email notifications. However, Org Admins have the option to have their email notifications turned off. This is applicable only for the Org Admin role and not for other roles. If you want to stop receiving email notifications from the platform, please contact Vivli team at support@vivli.org.
    - White/Grey toggle indicates that Email notification is enabled for that user.
    - Black/Grey toggle indicates that Email notification is disabled for that user.



- You can also access the Vivli Organization Administrator and Data Upload Guide and other resources from the My Organization tab by clicking on 'Organization Administrator Resources'

1.3.4 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 team members from your organization may also join Vivli as users.
    - Those without any roles can set up a Vivli account but initially will only be able to request studies.
      Those accounts will also be listed under your 'Members' tab and also show up in the 'Users' List. For more information, please see Section 1.3.5. User Tab

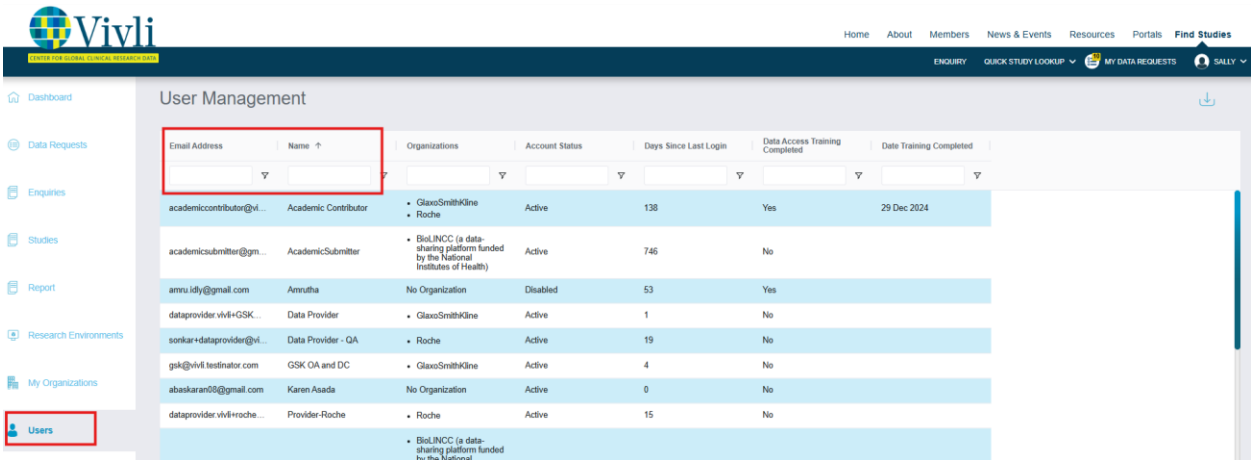
Please see the following table for an overview and description of these roles:

Vivli Member Role	Description	Rights & Responsibilities
Org Admin	• Main institutional contact(s) for operations on the Vivli platform. • Responsible for recording decisions.	• May view your organization's team members • 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. • Access the research environment and Report tabs on the Dashboard • View and record decisions for Enquiries
Data Uploader	• 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

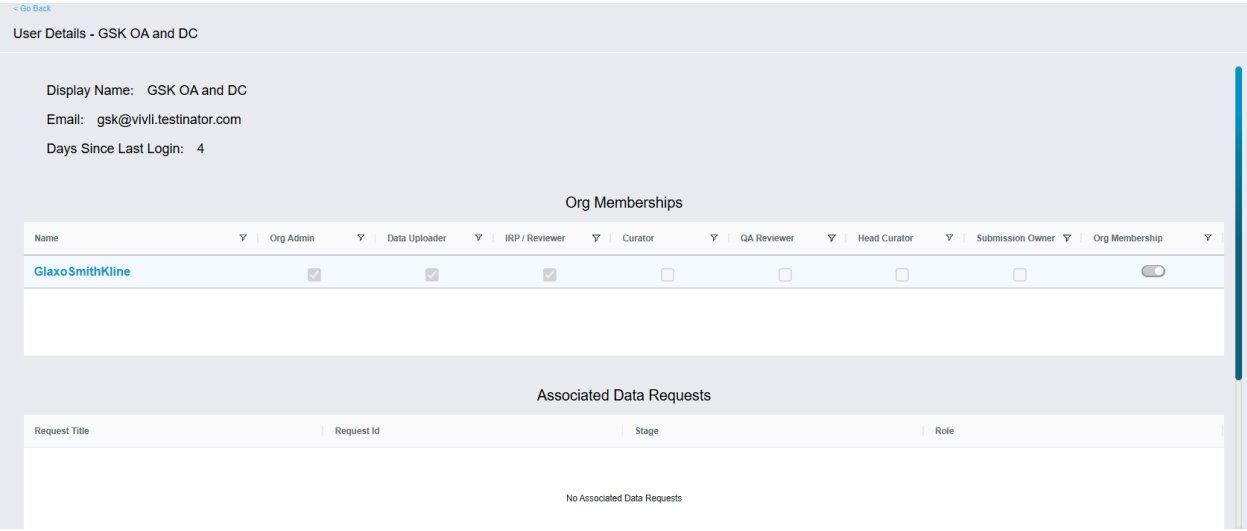
No Role Assigned	• May log on to the Vivli platform as a user, but only to create data requests	• Will appear on your organizational members' listing under 'Members' tab • No administrative rights
Org Membership	• The person is part of this organization	• They may be a data sharing team member, or anyone else from your organization who has created a Vivli account

1.3.5 User Tab

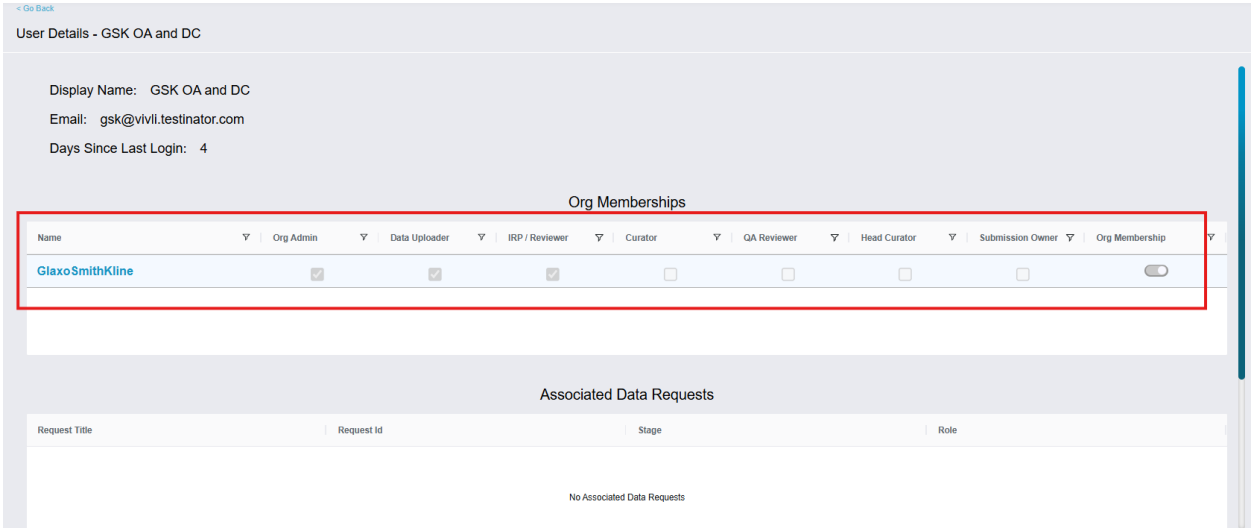
- You can see a list of all Vivli users related to your organization in the 'User' tab. You can search for a user account using one of the following fields by typing in the white blank box. For more information on how to filter through the headers, please see Section 4.5.1. Features of the report
    - Email address
    - Name
    - Organizations
    - Account Status (Active or Disabled)
    - Days since last login



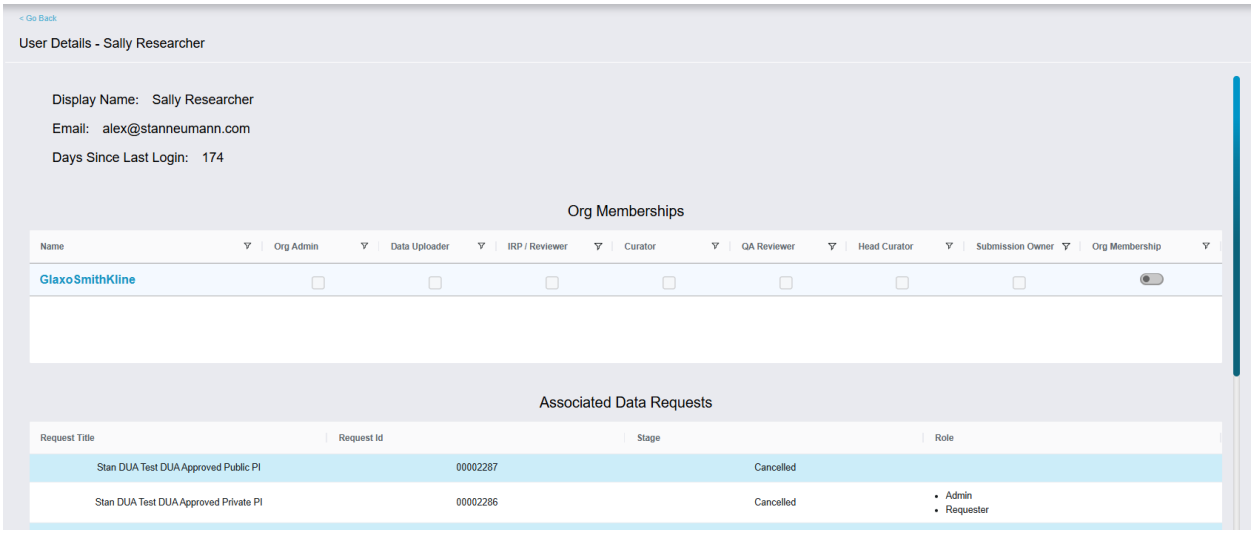
- If you click on the individual user, you will see a full display of the user:



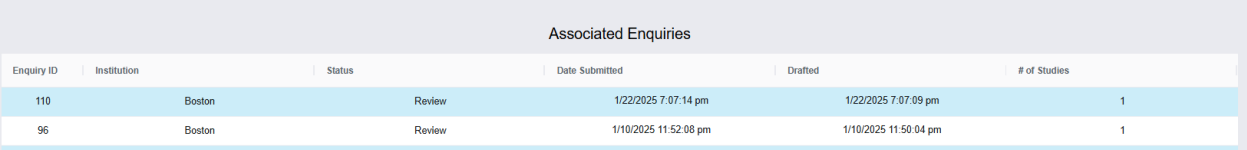
- If the user from your Organization is part of your current data-sharing team, you can see the assigned roles for each team member. For more information, please see Section 1.3.3 Team Members



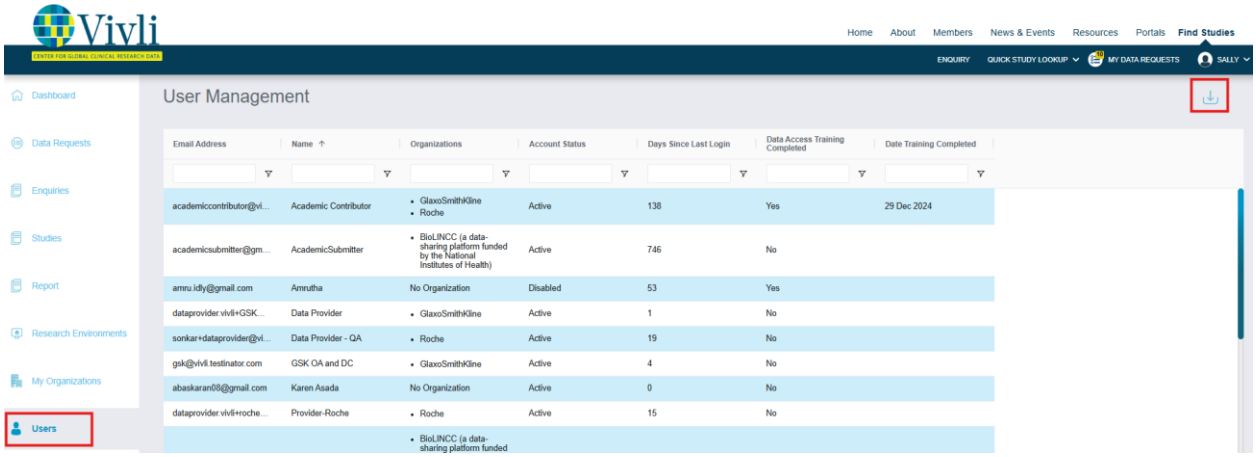
- If a user from your Organization is requesting your Organization's study data through Vivli, you can see the list of their associated data requests, request review status, and their role in the data request.



- If the user from your Organization has an Enquiry for your Organization's study data through Vivli, you can see the list of their associated Enquiries, Enquiry ID, Institution, Enquiry review status and the Number of studies included in the Enquiry.



- You can also export the user list to a CSV file by clicking the down arrow



The user list downloaded file contains:

- Email Address
- Name of the Individual
- Organizations
- Account Status
- Days Since Last Login
- Data Access Training Completed
- Date Training Completed
- Data Requests for User
- Enquiries for User

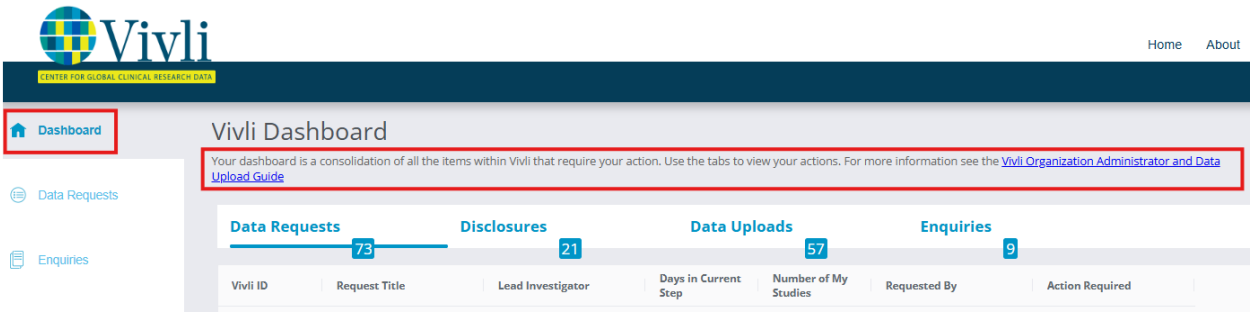
1.3.6 Active Platform Accounts

- 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 common inbox that members may use.
- If Vivli Member user accounts are inactive for six months, the Vivli team will email the user and inform the member's Organizational Administrators via Vivli summary. If the user wants to maintain their account, 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 deactivated. If the user wants their account re-activated, they can email support@vivli.org, and the Vivli team can re-activate this account at any time.

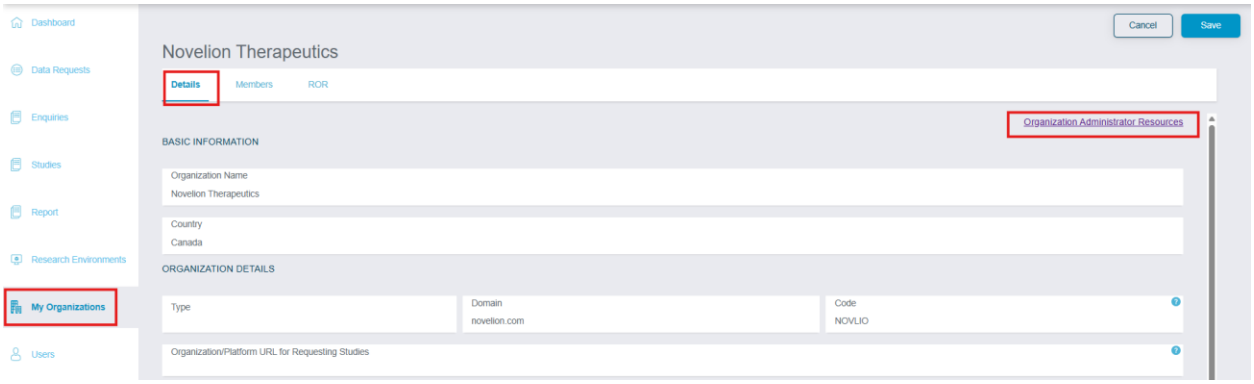
1.3.7 Accessing the Vivli Organization Administrator and Data Upload Guide and other training resources

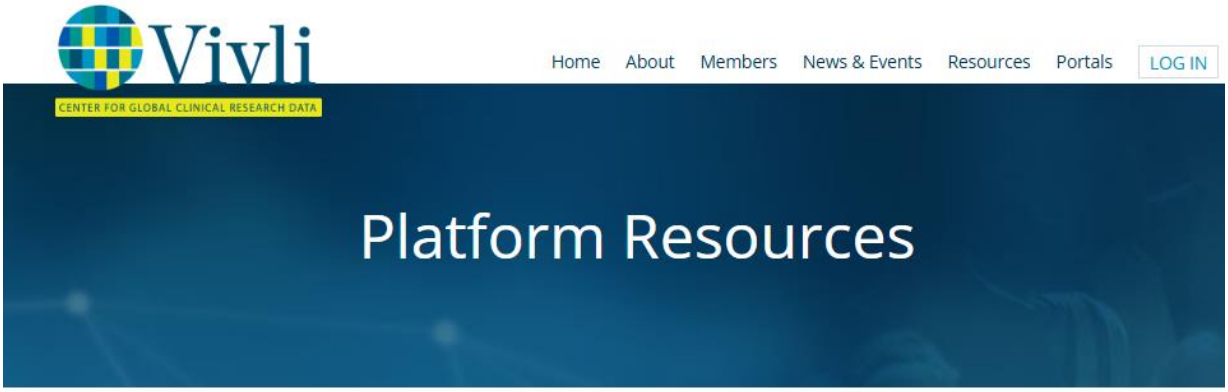
1. Log on and from the Dashboard, click the "Vivli Organization Administrator and Data Upload Guide":



Click the link to access the resources.

An Organization Administrator can also access these resources from the 'My Organizations' tab under 'Details' or 'Members' by clicking on 'Organization Administrator Resources':





Resource	Description	PDF
Vivli Data Contributor Guide	A comprehensive guide for data contributors including onboarding, listing studies, and more.	Download
Study enquiries demo	A video walkthrough for organizational administrators that shows how to find and interact with study enquiries on the platform.	Watch video
AI/ML Framework	A document outlining how to comply with Vivli data governance and export policies when using AI/ML models.	Download
How to review public disclosures	A video walkthrough for data contributors that shows how to review a public disclosure	Watch video
Organizational administrator training	A video walkthrough for organizational administrators on how to use the Vivli platform.	Watch video
How to upload a data package	A video walkthrough for data contributors that shows how to upload a data package.	Watch video

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.
- Organization Administrators 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

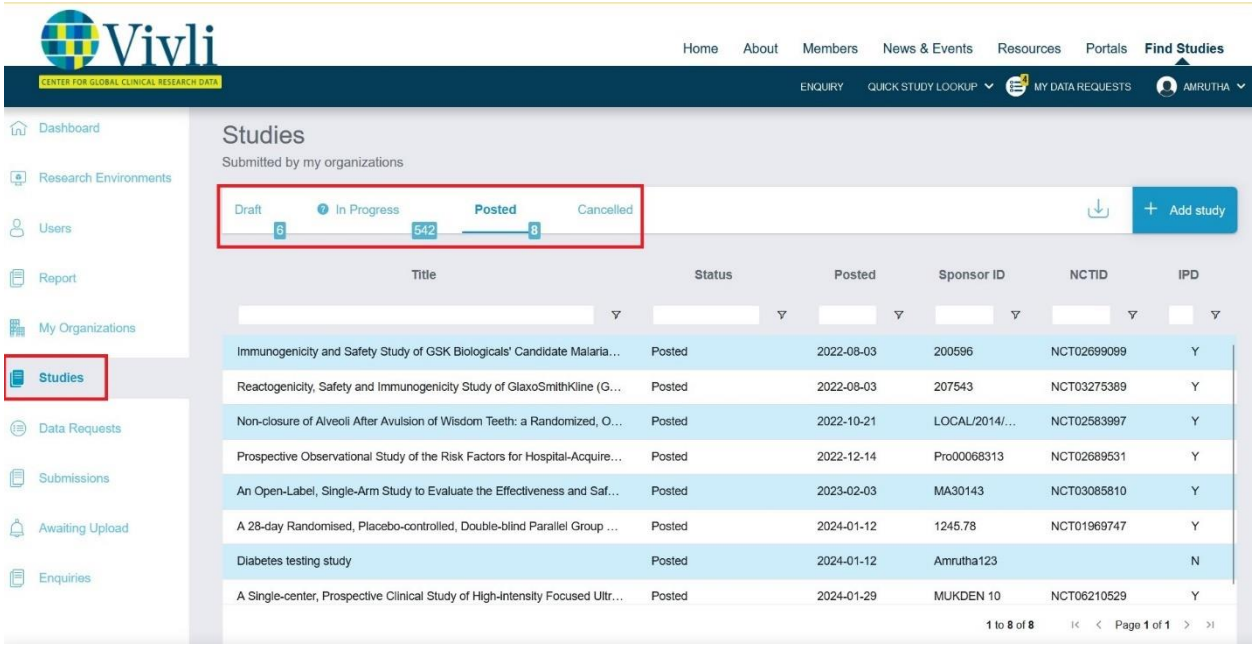
2.3 Removing Studies from the Vivli Search

To remove studies from the Vivli search, please contact Vivli at support@vivli.org and provide a detailed list of the studies that need to be removed

2.4 Studies Dashboard

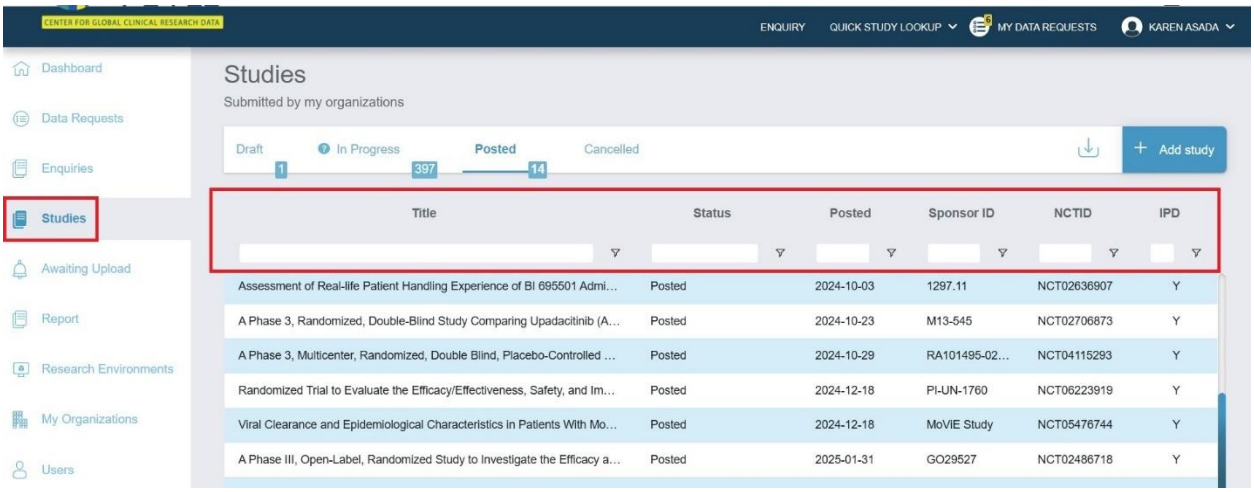
Studies Dashboard has 4 sections:

1. Draft – Includes studies where the study information is being filled out
2. In Progress –
   2a. Includes submitted studies that are in the process of being listed
   2b. Includes studies that are temporarily delisted and no longer searchable. (At any point organization administrators can request these studies to be posted again)
3. Posted – Includes studies that are visible to the public under the Vivli search
4. Cancelled – Includes studies that are permanently delisted (E.g. instances where the member is no longer the owner of the study)

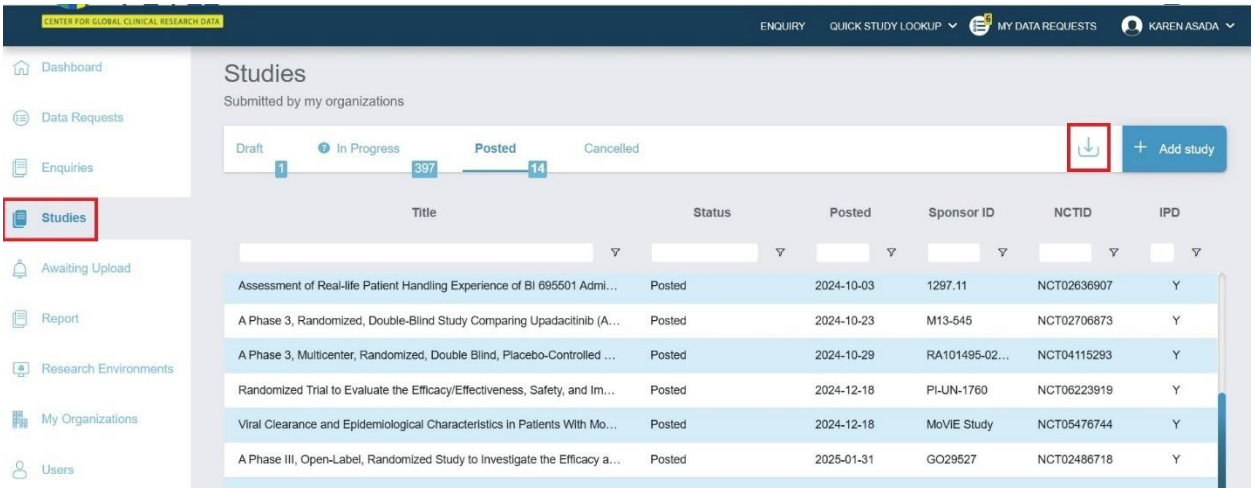


1. You may search for studies using one of the following fields by typing in the white blank box. For more information on how to filter through the headers, please see Section 4.5.1. Features of the report

- Study Title
- Posted date
- Sponsor ID
- NCT ID
- IPD (Y- Individual data package is stored on the platform; N- Individual data package is not stored)



2. 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.

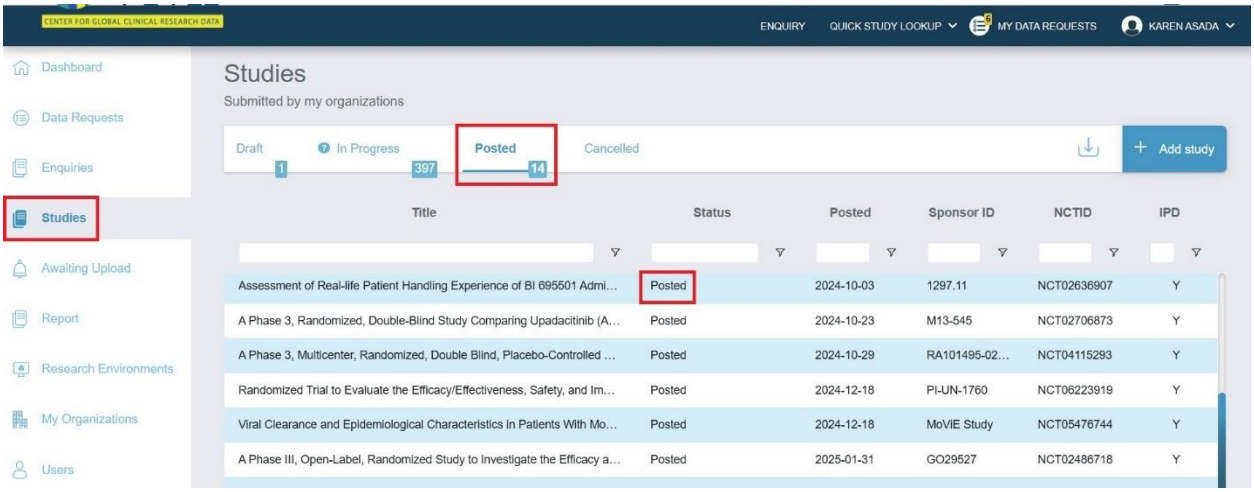


3. The downloaded CSV file contains:

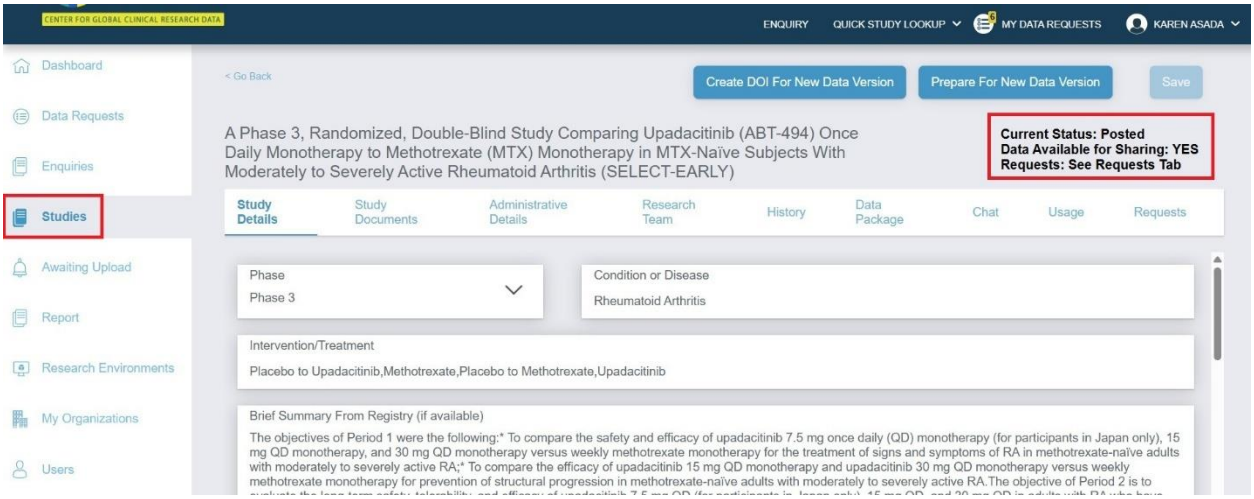
- Study Title
- Study Status
- Posted date
- Sponsor ID
- NCTID
- IPD
- Primary DOI

2.5 Individual Studies Format

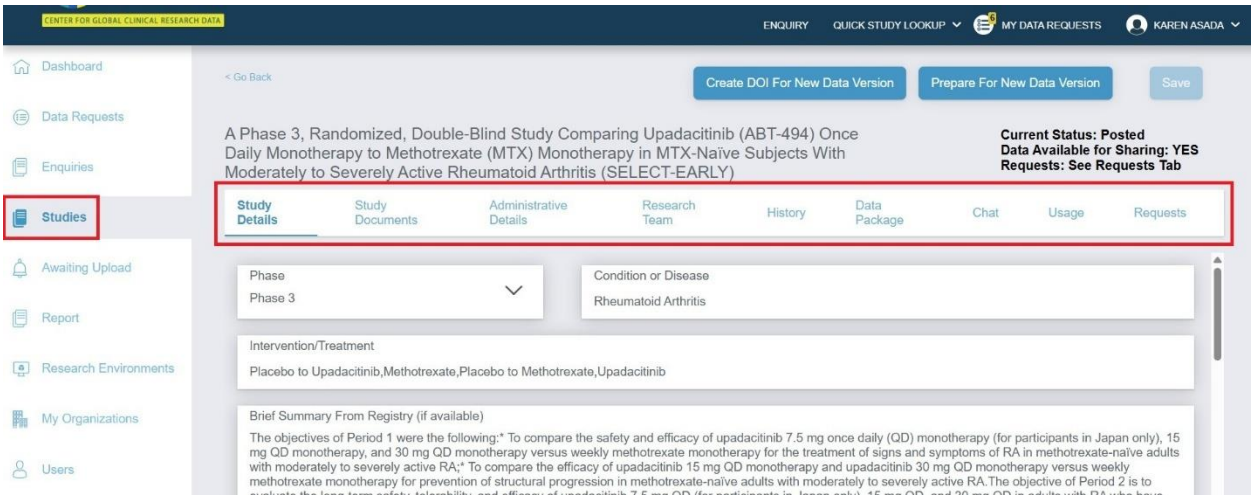
- Click on individual study under the ‘Posted’ section



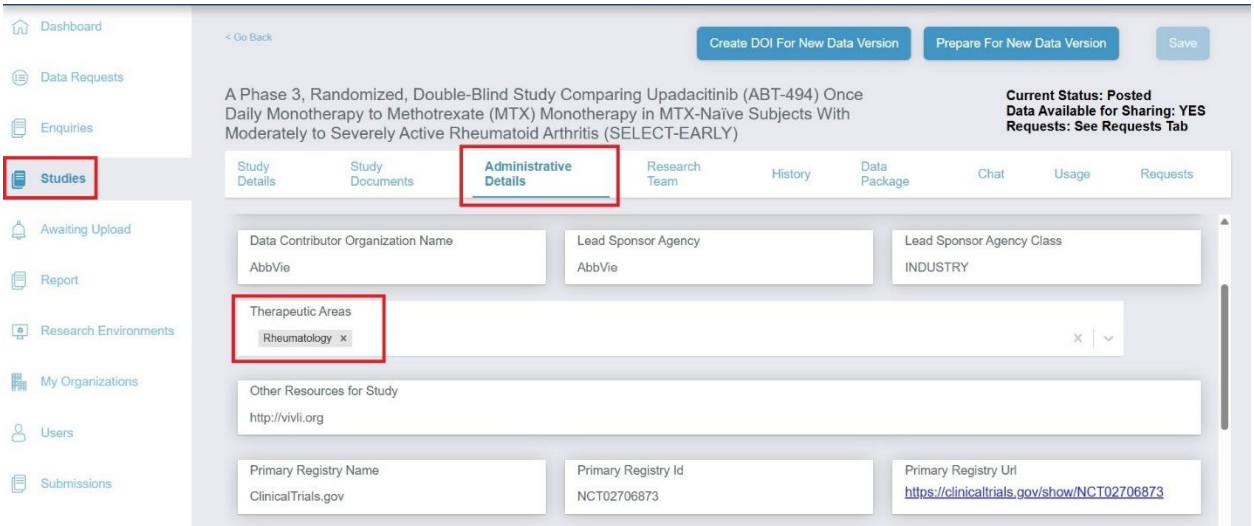
- The study contains the study title on the left. Study status, Data Available for Sharing, and related data requests are shown in the upper right.



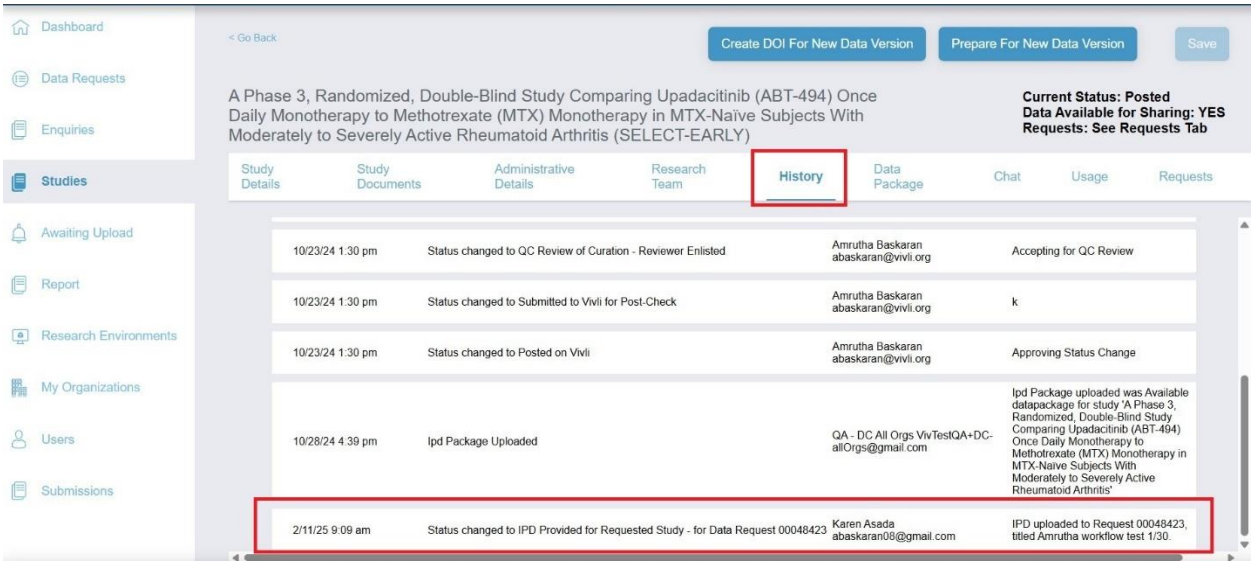
- Each study has the following sections:



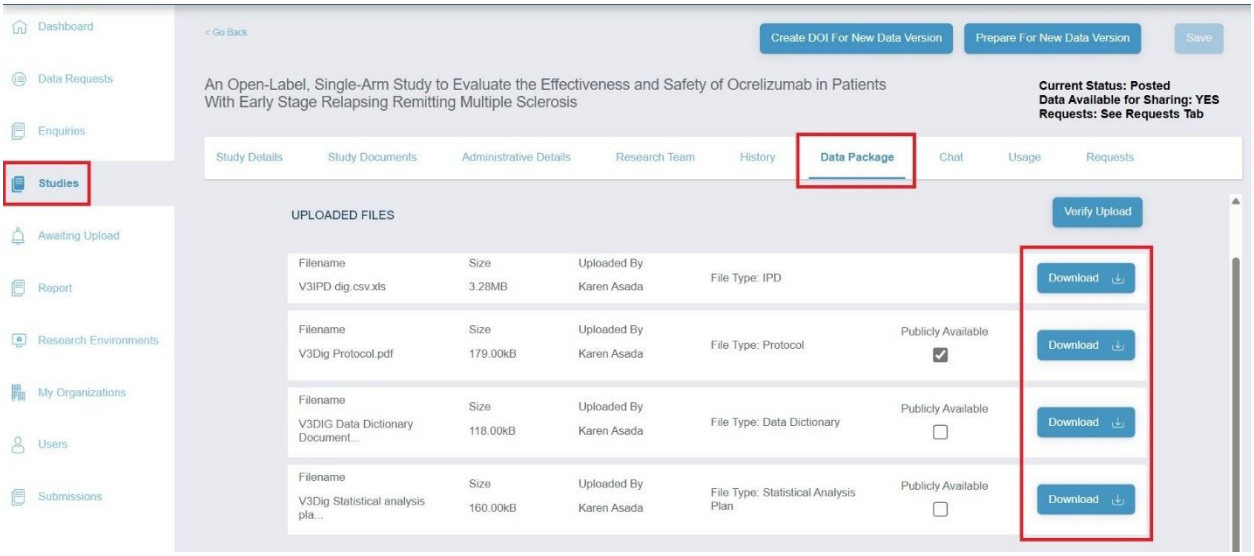
1. Study Details – Includes study metadata
2. Study Documents – Please see Section 5.12 Supporting Documents for Researchers Searching For Studies
3. Administrative Details – Includes data contributor name, Study ID, DOI, study Therapeutic area



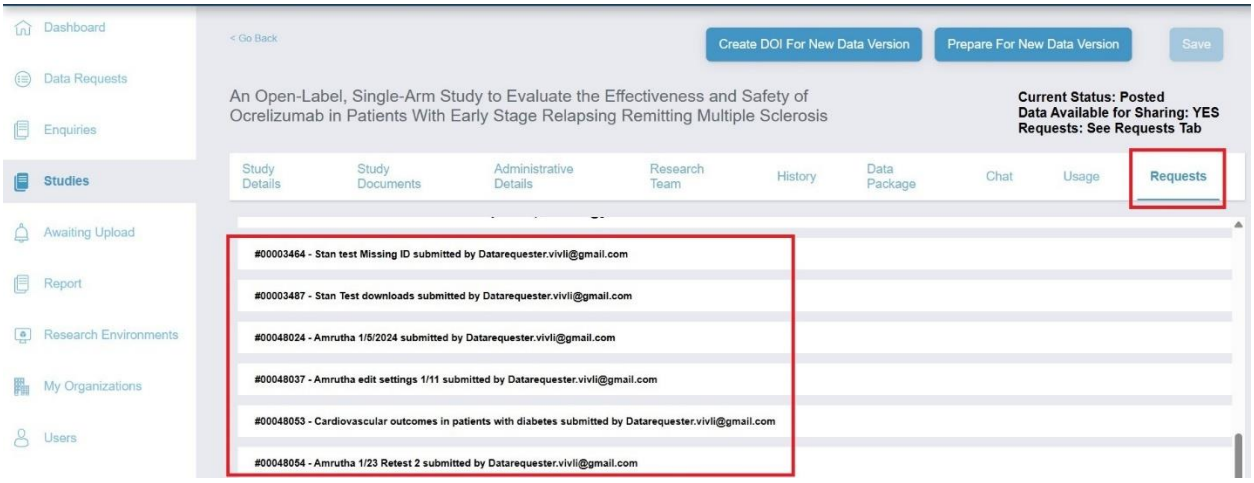
4. Research Team – Includes information about the Research team who contributed the data (if applicable)
5. History – Includes history of study listing and data package upload to the study. A history entry will be written to the study history whenever data is loaded to a specific request, with the request number included.



6. Data Package – Displays the existing data package that is stored in the platform. Please see Section 5.5 Upload Data Package Directly into the Study



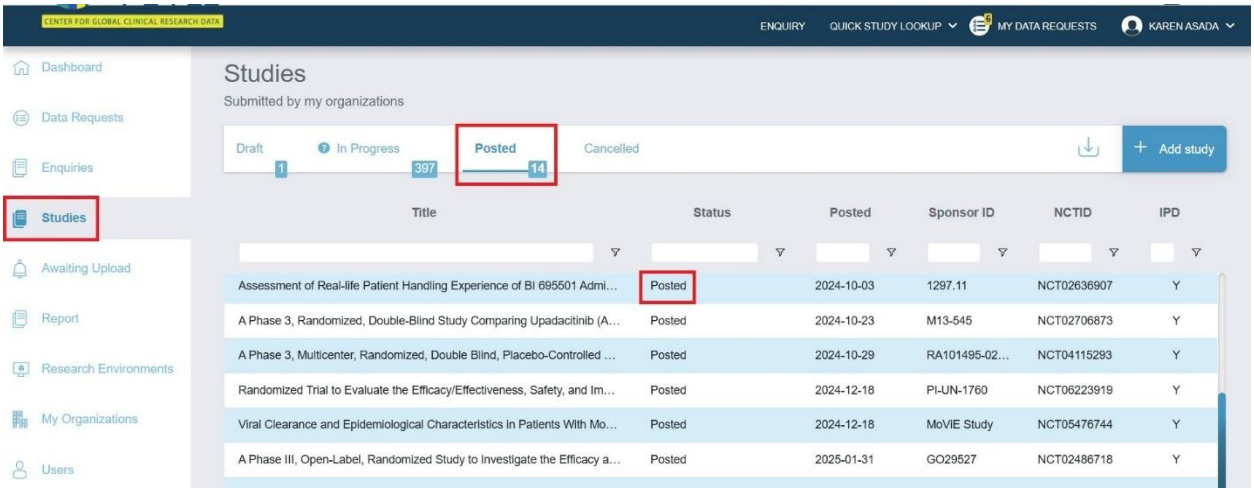
7. Chat – Related to study submission
8. Usage – See Section 2.6 Study Usage and Public Disclosure Metrics
9. Requests – Data Requests related to this study (includes both drafts and submitted data requests). To download the request list, go to report and select “Studies (Org Admin)”. Please see Section 4.5 Report of Data Requests and Studies



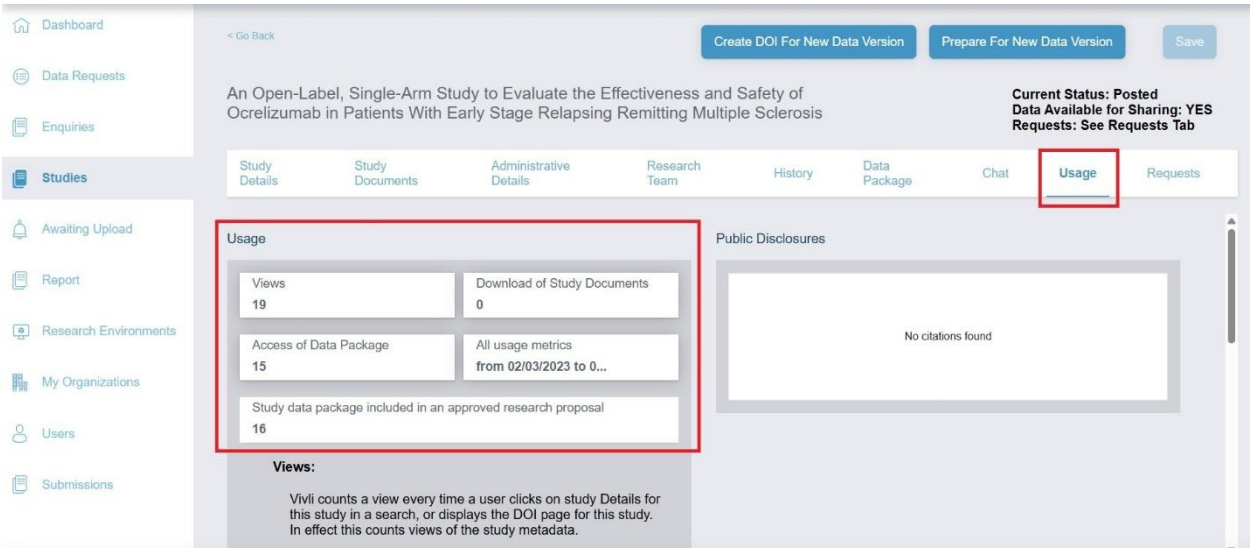
2.6 Study Usage and Public Disclosure Metrics

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.

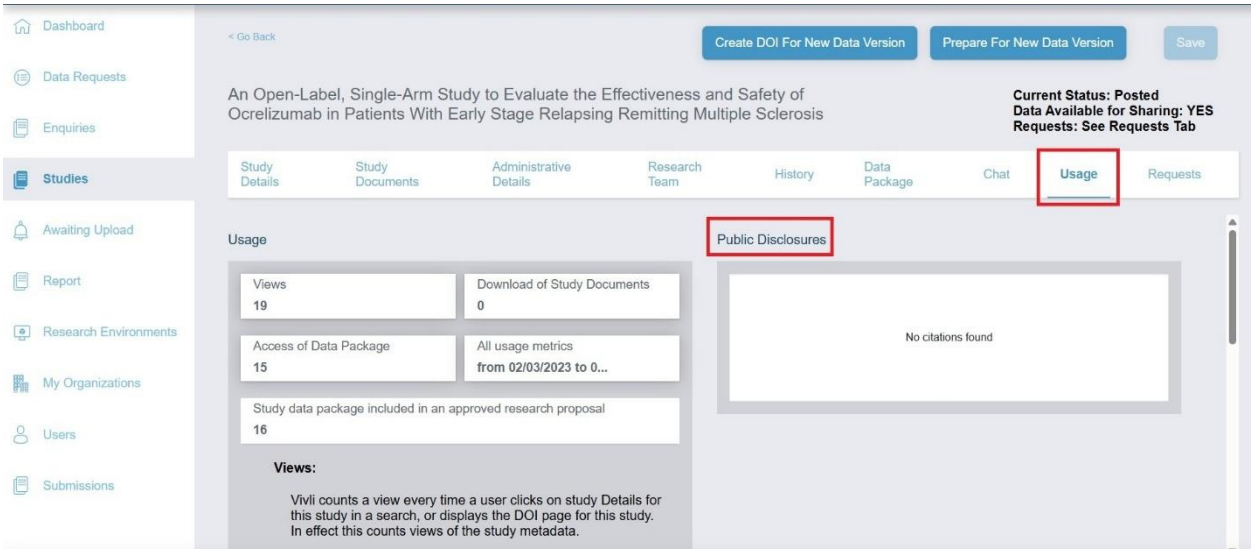


2. Open the study and click on the “Usage” tab.

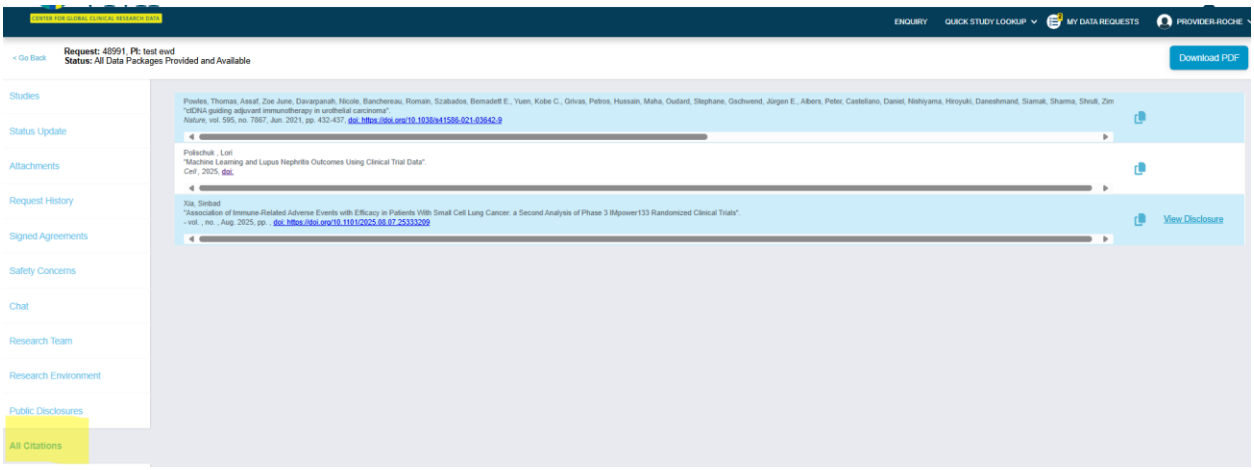


3. Under “Usage” will see the following fields:
    a. Views:
    Vivli counts a view every time a user clicks on study Details for this study in a search or displays the DOI page for this study. In effect, this counts views of the study metadata.
    b. Download of study documents:
    Study documents 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. This metric counts the number of times a study document is downloaded. For more information see Section 5.12 Supporting Documents for Researchers Searching For Studies
    c. Total Access of Data Packages:
    The data package includes the data that is provided in response to the request, and includes anonymized Individual Participant Data (IPD) and supporting documents. "Access" includes placing the data into a secure research environment or (when allowed) downloading the data. Every time a data package is accessed by download or re-uploaded into a secure research environment, including if the data package is accessed multiple times in the same research proposal, this is counted.
    d. Study data package included in an approved research proposal:
    This metric counts the number of times a data package is included in an approved research proposal.
    e. All Usage Metrics:
    The data range here represents the range of dates during which the metrics above were collected. The start date is either the date the data collection feature was turned on, or the date the study was posted (whichever is later). The end date is always 3 days before the current date since it takes the system 3 days to process and tally the raw usage data.

4. The “Public Disclosures” field includes all Public Disclosures linked to this study through a Vivli Data Request.
    a. When a public disclosure is published and the citation is received as part of the Vivli data request, the citation is entered into the Data Request and linked to the Study(s) involved in that Data Request. For more information, please see Section 7 Public Disclosures & Publications & Summary of Results

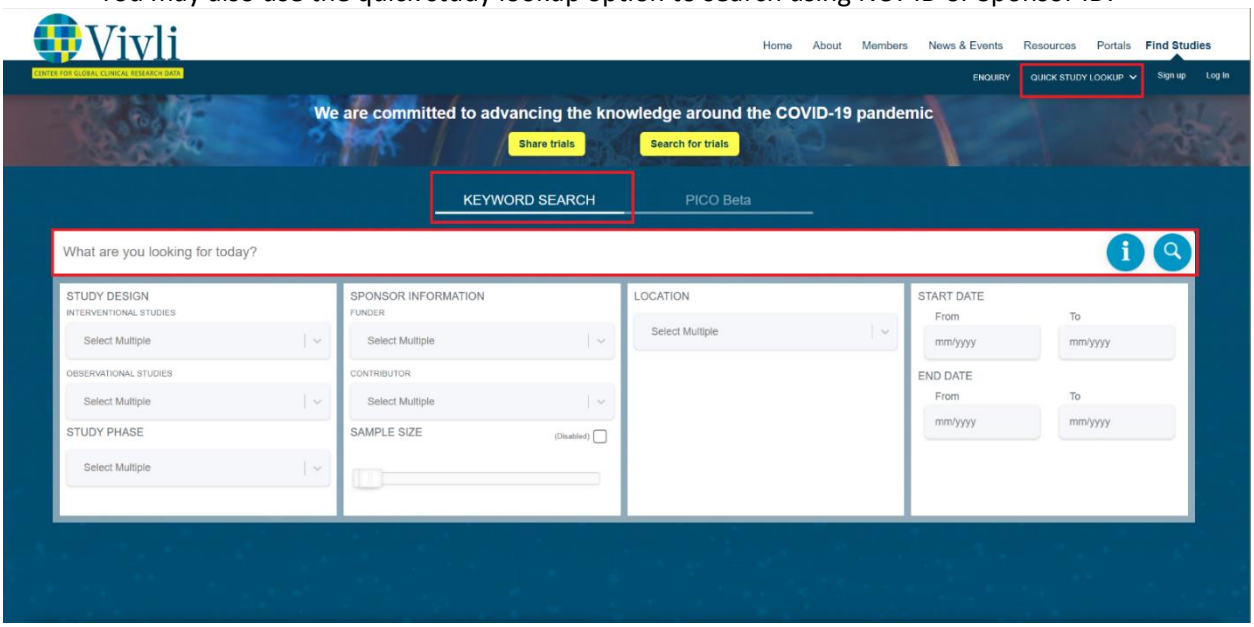


5. You may also view citations linked to a specific data request form by navigating to a data request and clicking on the “Citations” tab. This tab is visible after the request reaches the data upload stage.



2.7 Study Search Results– Download

- To search for studies on the Vivli platform using the search page, https://search.vivli.org/ enter a search term into the “Keyword search” bar where it says, ‘What are you looking for today’. You may also use the quick study lookup option to search using NCT ID or Sponsor ID.



For anyone with an active Vivli Account, a download button is available on the search results page, to the left of the “Close” link.

Clicking the download button will initiate a download of a CSV file containing one row for each entry in the search results, with the following columns:

- NCTID
- Sponsor Protocol Id
- Title
- Acronym
- Condition or Disease
- Intervention/Treatment
- Therapeutic Area
- Phase
- Number Enrolled
- Contributor
- Lead Sponsor Agency
- Funder
- Data Accessibility
- Data Availability
- Primary Registry URL
- URL to Request Study from Sponsor
- Other Resources for Study
- Primary DOI
- Brief Summary
- Additional Information
- Ages Eligible For Study
- Sexes Eligible For Study
- Accepts Healthy Volunteers
- Locations of Study sites
- Public Disclosures
- Vivli URL
- Study Posted Date

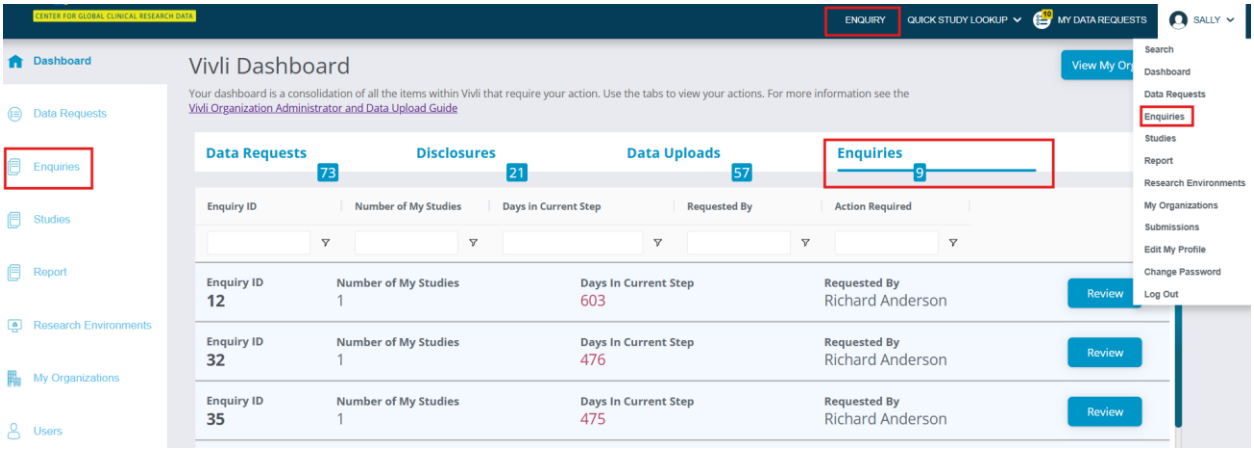
3. Study Process

1. A researcher can submit an enquiry using the Vivli platform regarding the availability of a Vivli Member study *not listed* on Vivli using the Vivli platform. Enquiry tab allows Vivli and Organization Administrators to receive, respond to, and track enquiries in one place.

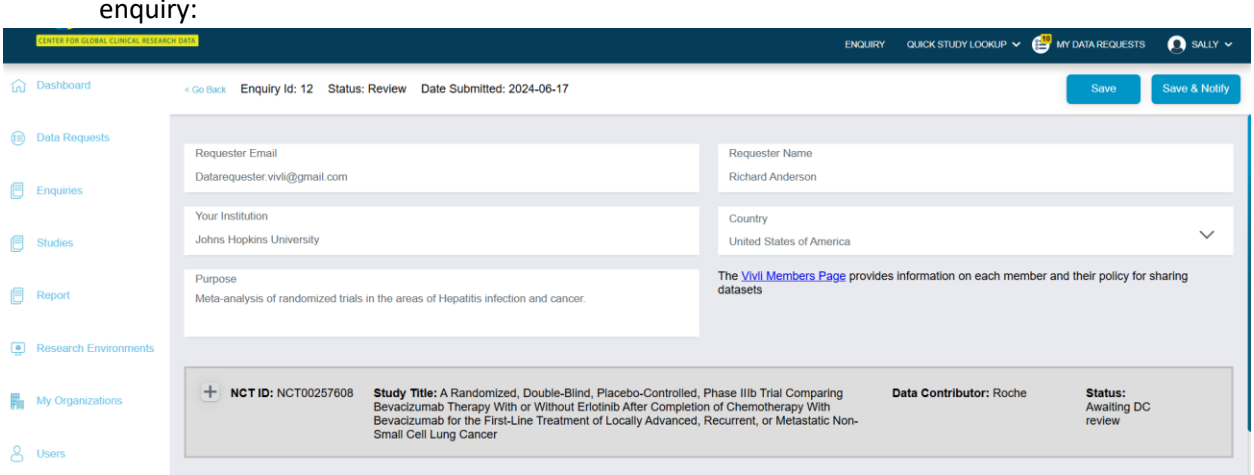
2. The researcher fills out one Enquiry form for multiple studies that will be part of a single research project, even if the studies are from multiple Vivli Members.
3. Vivli Members will see the entire Enquiry form, with studies from that member on the top and editable, and studies from other contributors below their studies and as read-only, including any feedback and decisions made by the other Vivli Members.
4. Only Organizational Administrators can see and review Enquiries waiting for review for your organization.

3.1 Navigation and Enquiry Dashboard

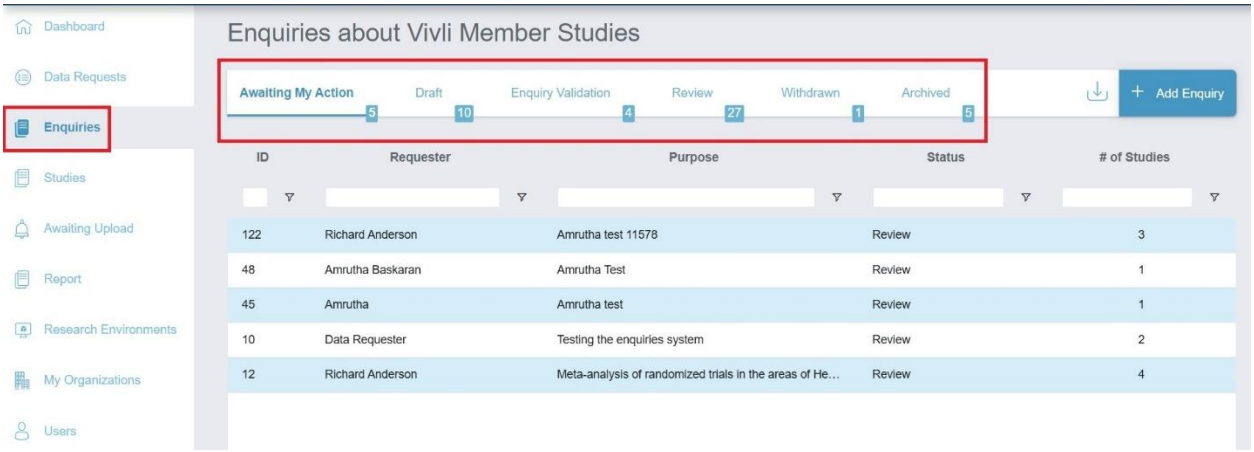
1. Once you have logged in to the dashboard, you can navigate to Enquiries using the Enquiries tab in the dashboard to see Enquiries with outstanding reviews. The toolbar on the left-hand side of the screen, or the dropdown menu on the upper right-hand corner of the screen or the top center of the screen can be used to see all of your organizations enquiries.



2. In the main dashboard, clicking on the 'Review' button next to a specific enquiry will take you directly into that enquiry, see Section 3.2 Enquiry Format for details of how to navigate an enquiry:



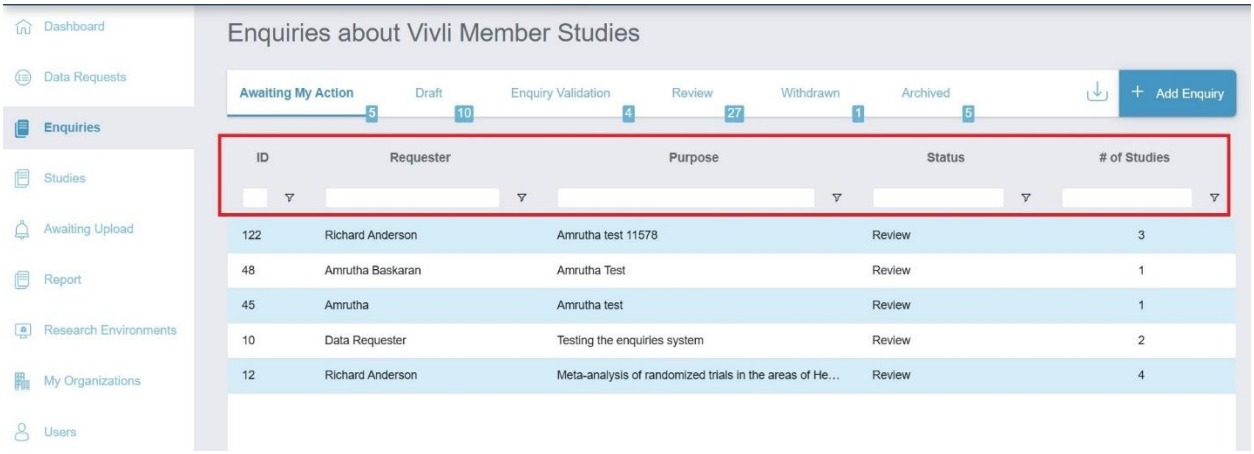
3. The other methods of navigating will take you into the Enquiries dashboard. The Enquiries Dashboard displays a status bar at the top of the page which displays all the Enquiries for your organization's studies.



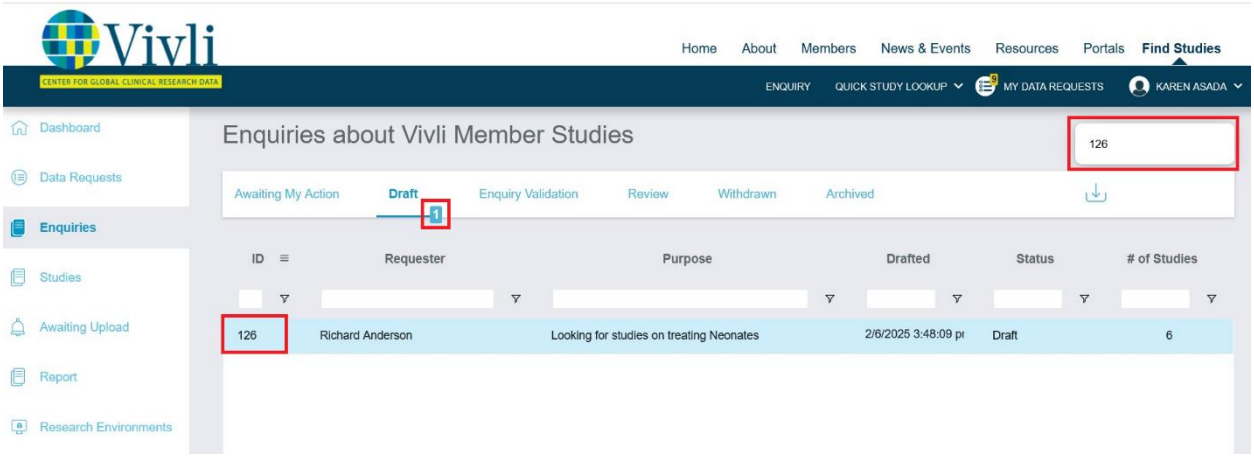
4. The status bar contains 6 sections:

Awaiting my Action: Displays Enquiries that needs your decision. It includes Enquiries where at least one of any contributor's studies does not have a final response.
Draft: Displays Enquiries that are being drafted but not yet submitted.
Enquiry Validation: Displays Submitted Enquiries that are in Vivli's review.
Review: Displays Enquiries that are in review by Members. This includes Enquiries awaiting your action and Closed Enquiries.
Withdrawn: Displays Enquiries that were withdrawn
Archived: Displays Enquiries where the final decision is made.

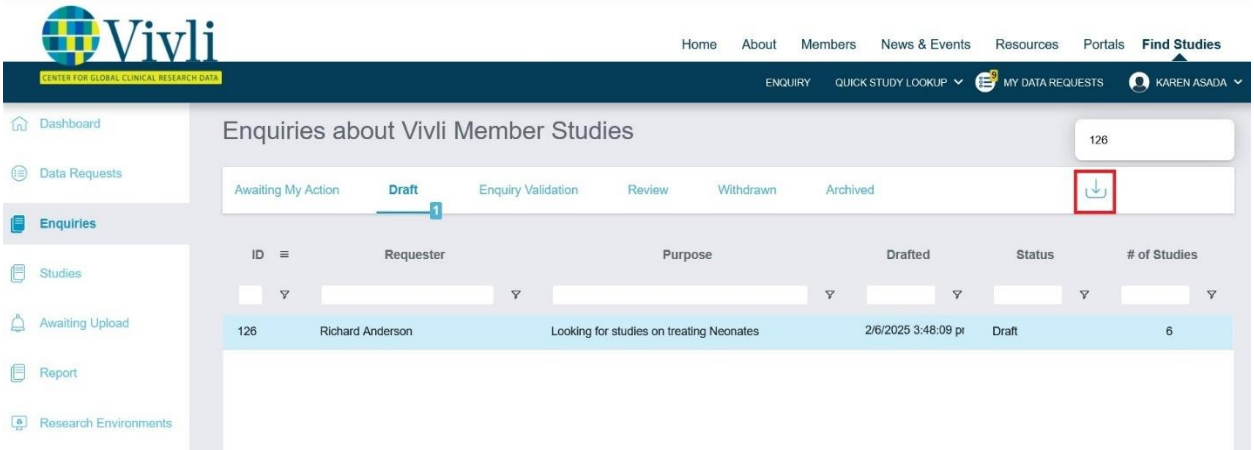
5. Each Enquiry recorded on the dashboard displays the Vivli Enquiry ID, Requester Name, Purpose of research, Date Submitted, Status of the Enquiry, and the Number of Studies in each Enquiry.
   Note: The Enquiries are sorted to show the most recently submitted at the top



6. You may search for Enquiries using one of the following fields (you can only view Enquiries where one of your studies has been enquired). Search starts looking for the matching items as soon as you type the first letter and is case-insensitive. The numbers point out the number of enquiries that match the search criteria and the status of the enquiry:
   - Enquiry ID
   - Requester Name or Email
   - Purpose of analysis
   - NCT ID
   - Sponsor ID
   - Study Title
   - Member Organization



7. You can export all your Enquiries to a CSV file by clicking the down arrow.

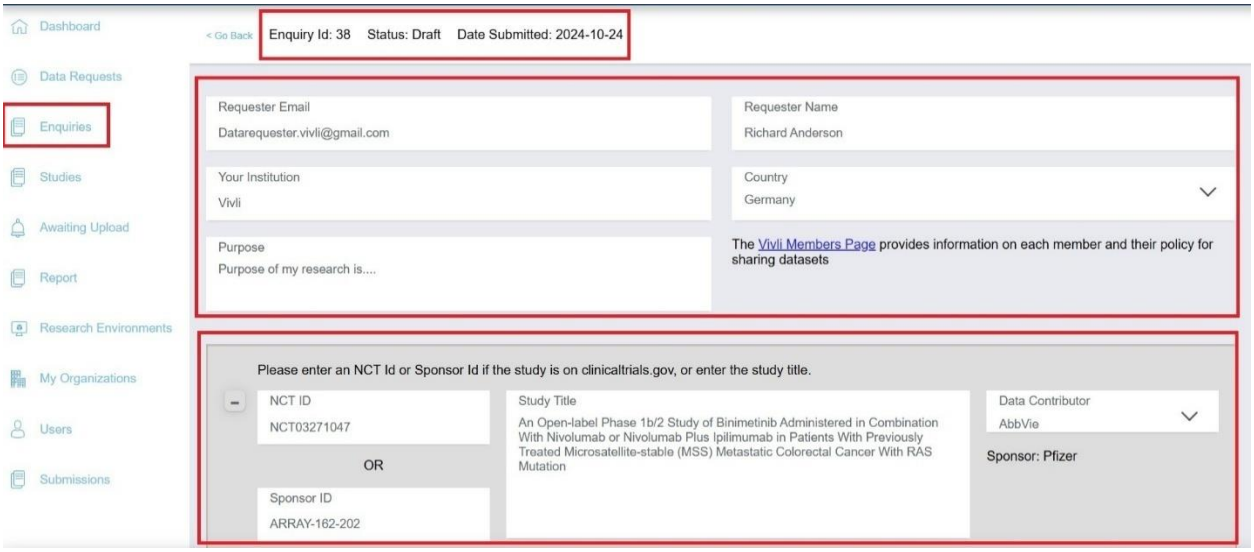


8. The downloaded file contains:

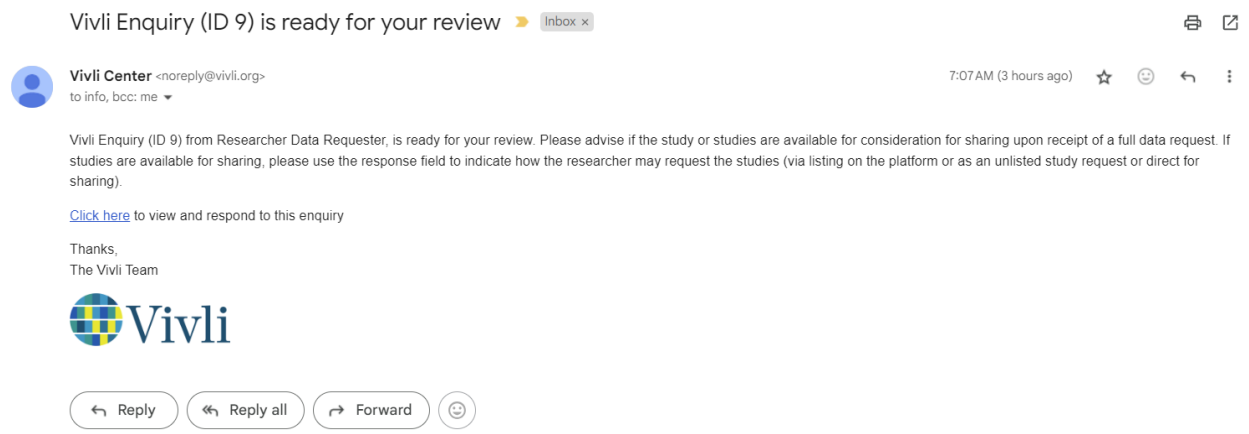
- Vivli Enquiry ID
- Requester Name
- Purpose of research
- Date Submitted
- Status of the Enquiry
- Number of Studies

3.2 Enquiry Format

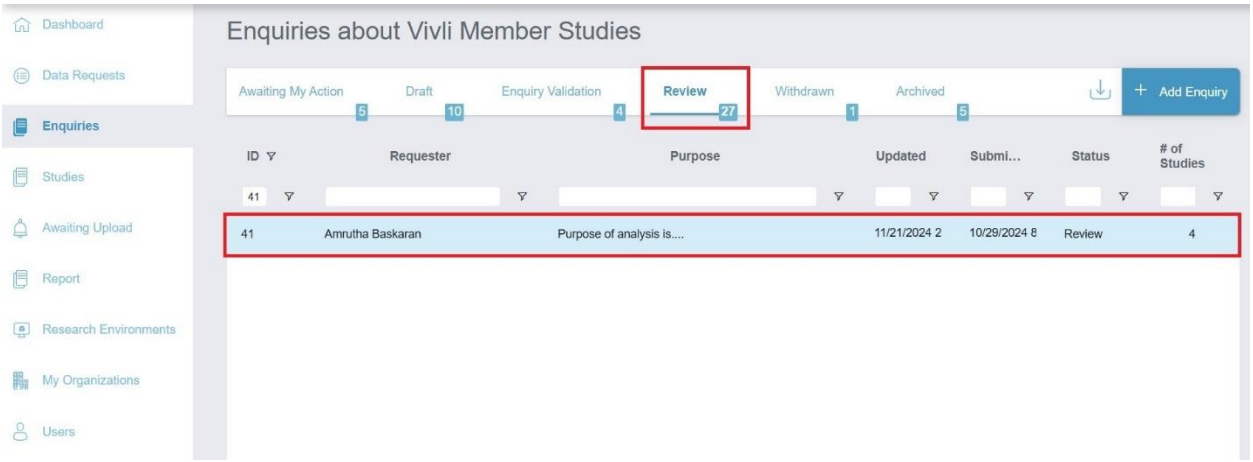
1. You can view a draft Enquiry by clicking on the Enquiry but you cannot respond or record a decision.



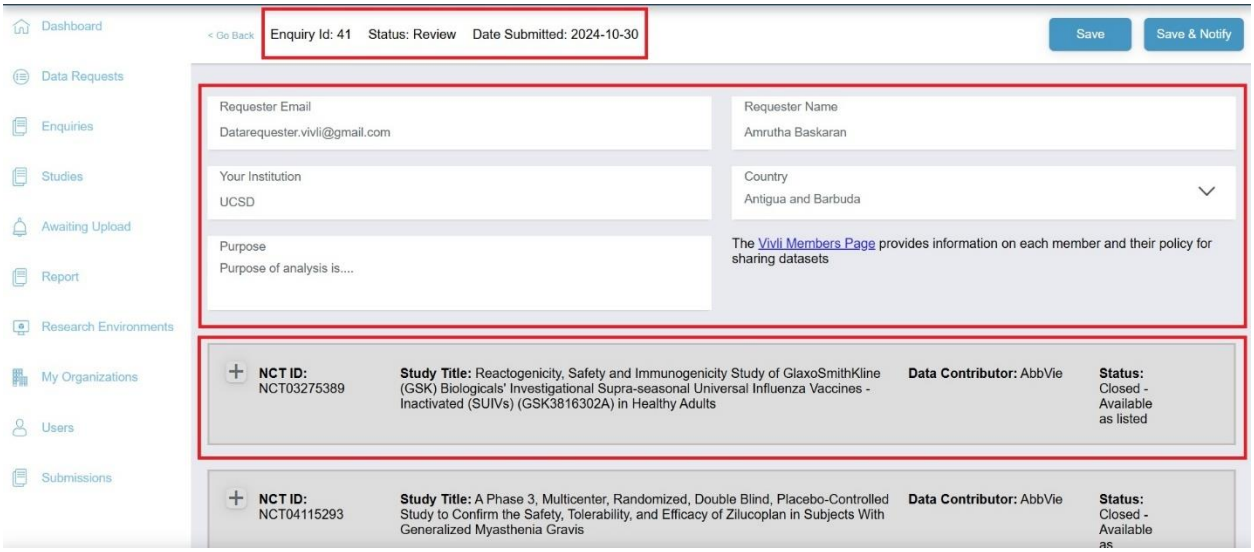
2. You will receive an email notifying you when an Enquiry is ready for review.



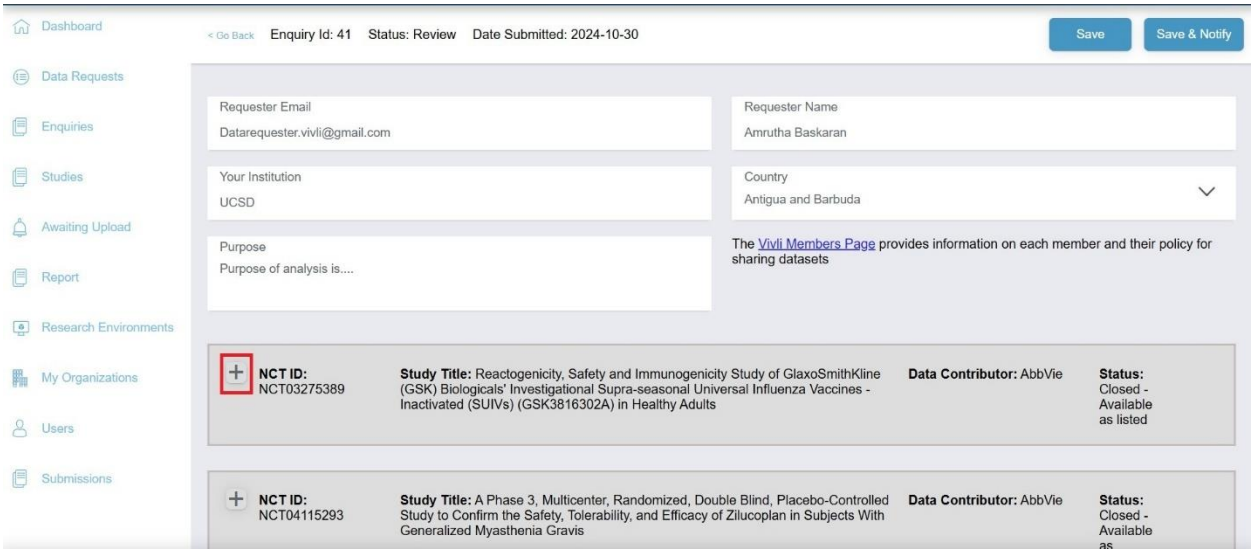
3. To view a submitted Enquiry, go to the "Review" Status bar and click on the Enquiry



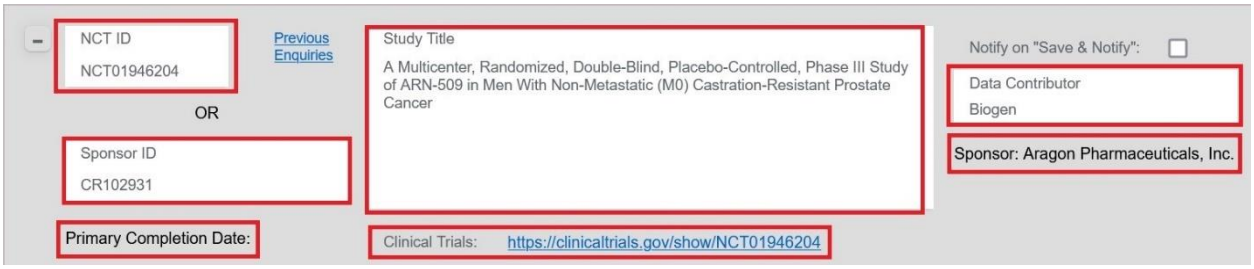
4. When you open the Enquiry, you can see Enquiry ID, Status, and Date Submitted on the top. The body of the Enquiry contains the Requester's Email, Requester Name, Requester Institution, Country, purpose of their Enquiry and a link to the Vivli Member's page. Then you can see the list of studies for which they have submitted an Enquiry. Note: If an Enquiry is related to the existing data request, Vivli team will place a note in the Purpose field.



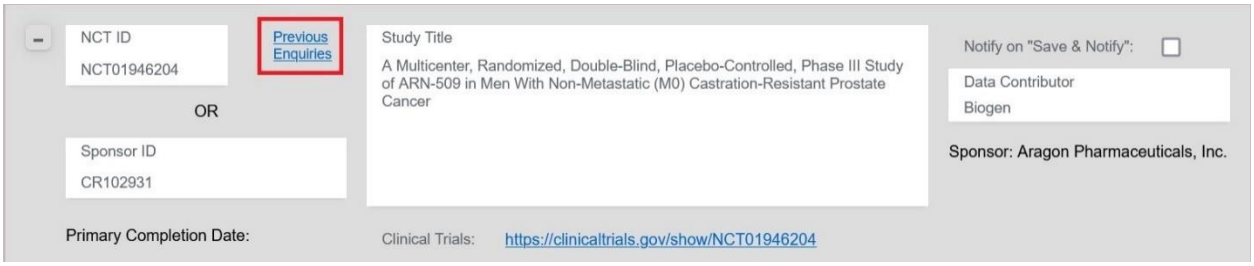
5. If an Enquiry has multiple studies, click the **+** button to expand the study information. You can also see the details of other Member studies at the bottom of the Enquiry form as read-only.



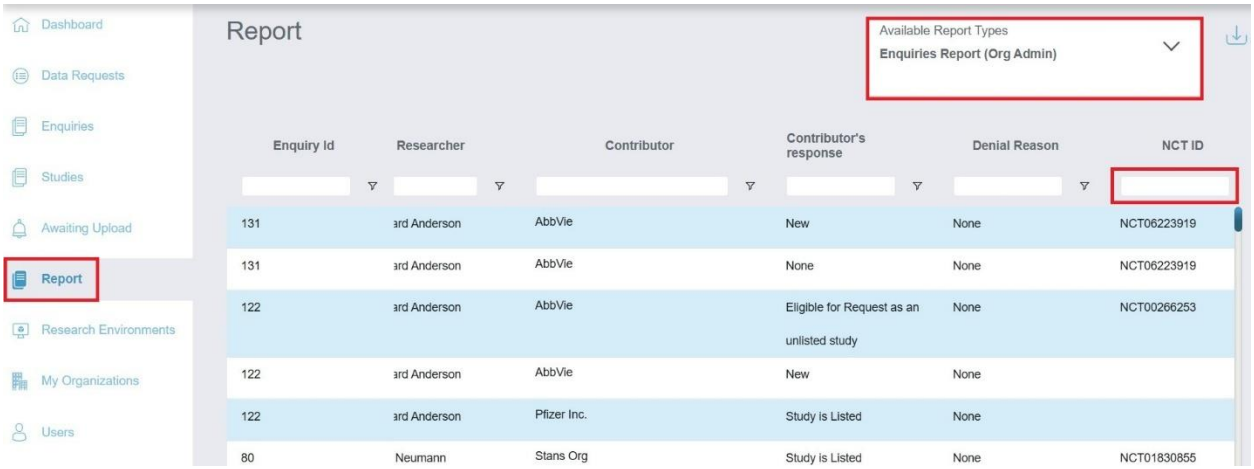
6. For studies registered on Clinicaltrials.gov, you can see the NCT ID, Sponsor ID, Study completion date (Actual Study Completion, not Estimated), Study Title, Clinical trials link, and Sponsor name. This information is pulled from the Clinicaltrials.gov website. In addition, you can see the Data Contributor name completed by the Data Requester.



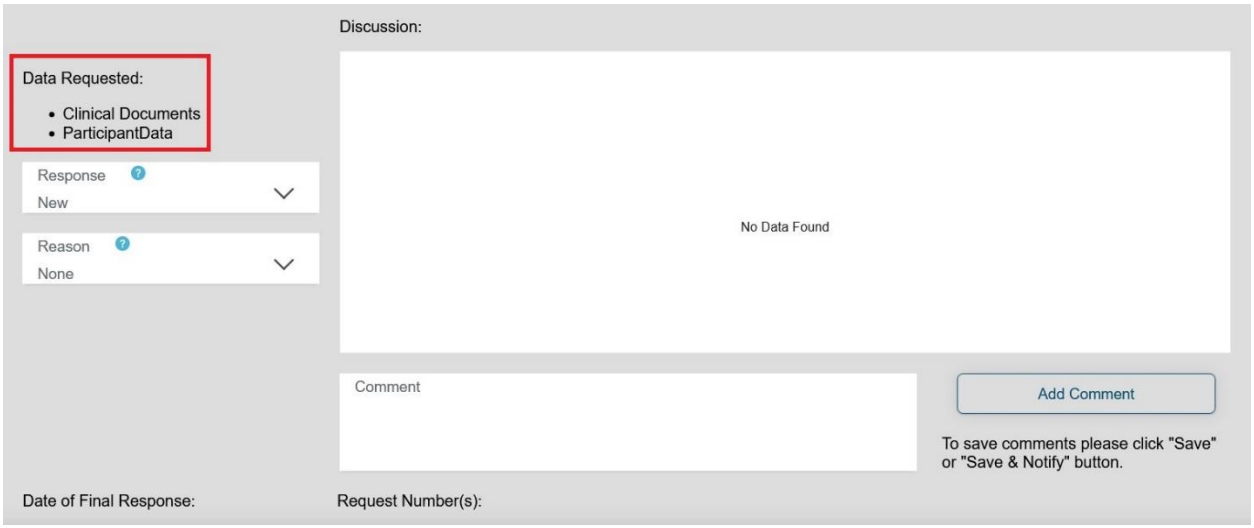
7. In addition, for studies registered on Clinicaltrials.gov, you can track previous enquires for the same study by clicking the "Previous Enquiries"



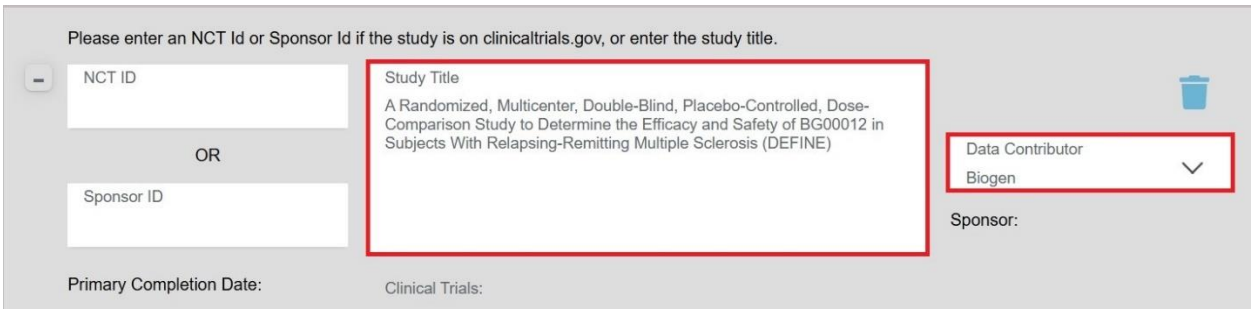
8. This will open the Enquiries report under the Report tab on the Vivli platform. You can type in the NCT ID to find previous enquiries and see your previous response. For more information see Section 3.4 Enquiries Report



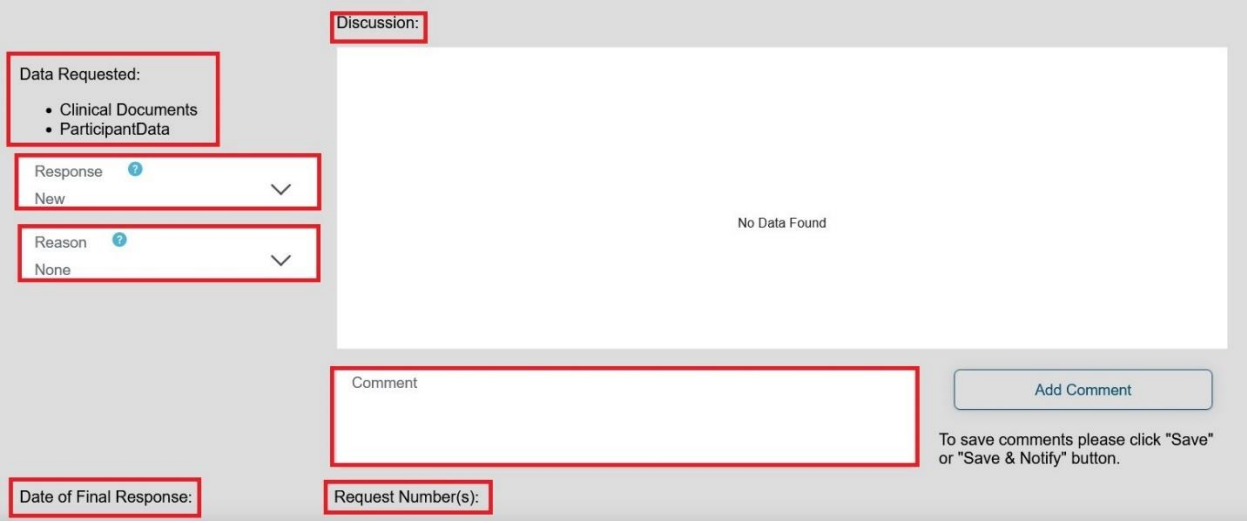
9. If a study is already listed on the Vivli platform, you will see a clickable note “This Study is listed on the Vivli Platform” which takes you to the listed study. In such cases, pay attention to the data requested field and the discussion field if the researcher is asking for more information about the study.



10. For studies not registered on Clinicaltrials.gov, you can see the Study Title or relevant information provided by the researcher. In addition, you can see the Data Contributor name filled by the Data Requester.



11. In addition, each study will have the following fields:
    a. **Data requested**: This is the type of data requested by the Researcher. Three options available are Clinical Documents, Participant Data, and Summary Data. They can select one or more options.
    b. **Responses**: This includes updates to the Enquiry discussion and decisions made by the Data Contributor. Below are the available options:
        i. None – No responses
        ii. New – Meaning no one has responded yet – this is the initial default value
        iii. Response from Requester – The Requester has added information to the discussion. This is automatically set when the Researcher responds.
        iv. Response from Data Contributor – The Data Contributor has added information to the discussion. This is automatically set once you add a comment and click Save or Save and Notify.
        v. Response from Vivli – The Vivli Admin has added information to the discussion. This is automatically set when the Vivli team responds.
        vi. Eligible for Request as an Unlisted Study
        vii. Study is Listed
        viii. Not Available
    c. **Reason** – When the response is Not Available, the reason field provides more information. The following is the dropdown list:
        i. Study Completion Date criteria is not yet met.
        ii. Data Sharing Prohibited by Consent, Legal, Regulatory, or Contractual Constraints.
        iii. Indications have not received market authorization.
        iv. Likelihood of re-identification of patients given small number of patients and/or involves a rare disease.
        v. Not responsible for Data Sharing – The Data Contributor specified in the Enquiry is not the one responsible for sharing this data
        vi. Other (See Discussion)
    d. **Comment** – The Organization Administrator can add a comment about the Enquiry
    e. **Discussion** – This includes all the comments provided by the Researcher, Vivli Admin, and Organization Administrator for this specific study
    f. **Internal Information** – This field is only visible to Vivli Admin and the Organization Administrator. You may add internal notes in this section for studies that belong to your Organization.
    g. **Date of Final Response** – Date when you make a final decision
    h. **Request Number(s)** –associated Data request ID.



3.3 Recording Enquiry Decision

1. Record the decision individually for each study within the enquiry form.
2. An update of open enquiry requests is included in the Vivli summary. Please see Section 11.4 Vivli Summary to Organizational Administrators. Please do not respond to the enquiries through the Vivli summary or directly to the researcher, instead please respond via the Enquiry tab on the platform.
3. The 

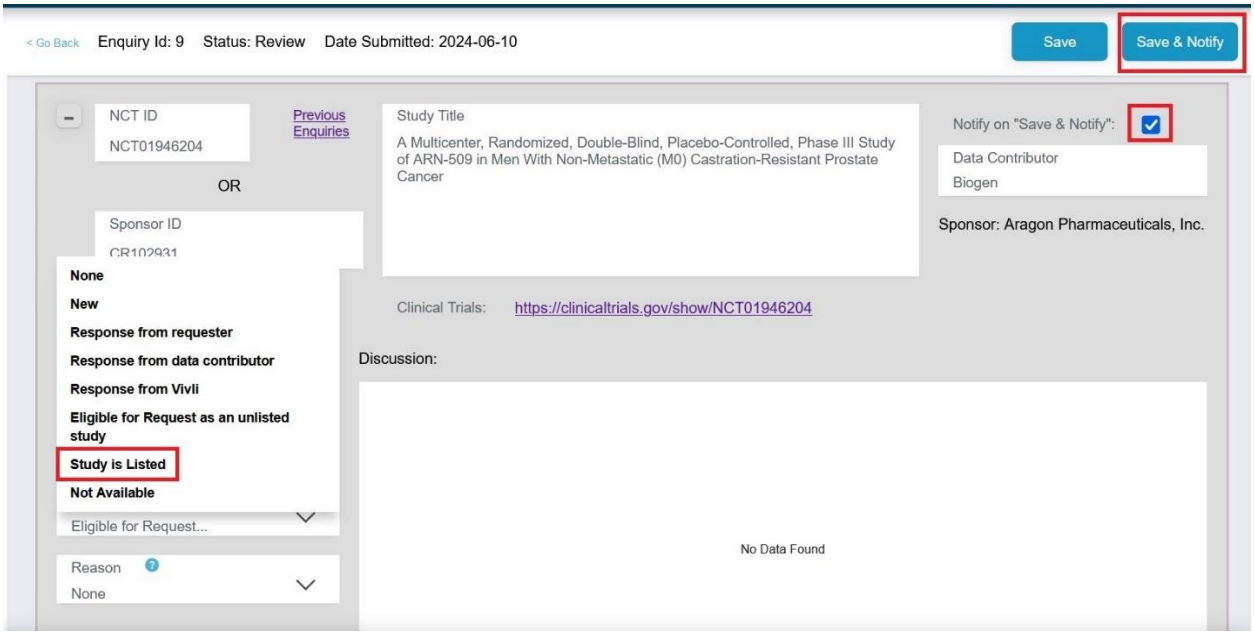
button allows you to save any information you provided on the enquiry but don't notify the researcher and the Vivli Admin
4. The 

button allows you to save any information on the enquiry and notify the researcher and the Vivli Admin
5. If you are responding to multiple studies in an enquiry, you may choose to use the Save the changes and at the end, you can click Save & Notify.

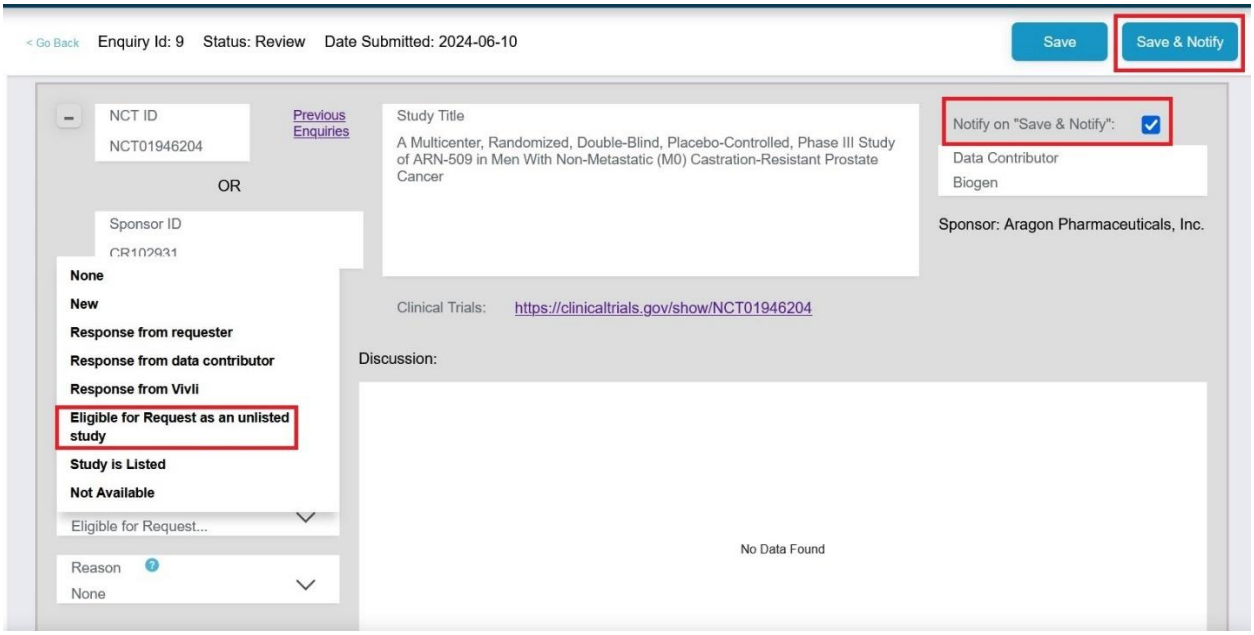
3.3.1 Eligible for Request

If the given study is Eligible for a data request, then you need to determine how to make the study available for the researcher. For studies not registered on Clinicaltrials.gov and if the Sponsor ID is blank, please provide the Sponsor ID if the study is eligible for a data request.

1. If you want to make the study available in the search on the Vivli platform, then select the option "Study is Listed" under Responses. Click on the "Save & Notify" Blue button on the top to notify the Researcher.



2. If you do not want to list the study, then select the option “Eligible for Request as an Unlisted Study” under Responses. Click the “Save & Notify” Blue button on the top to notify the Researcher.

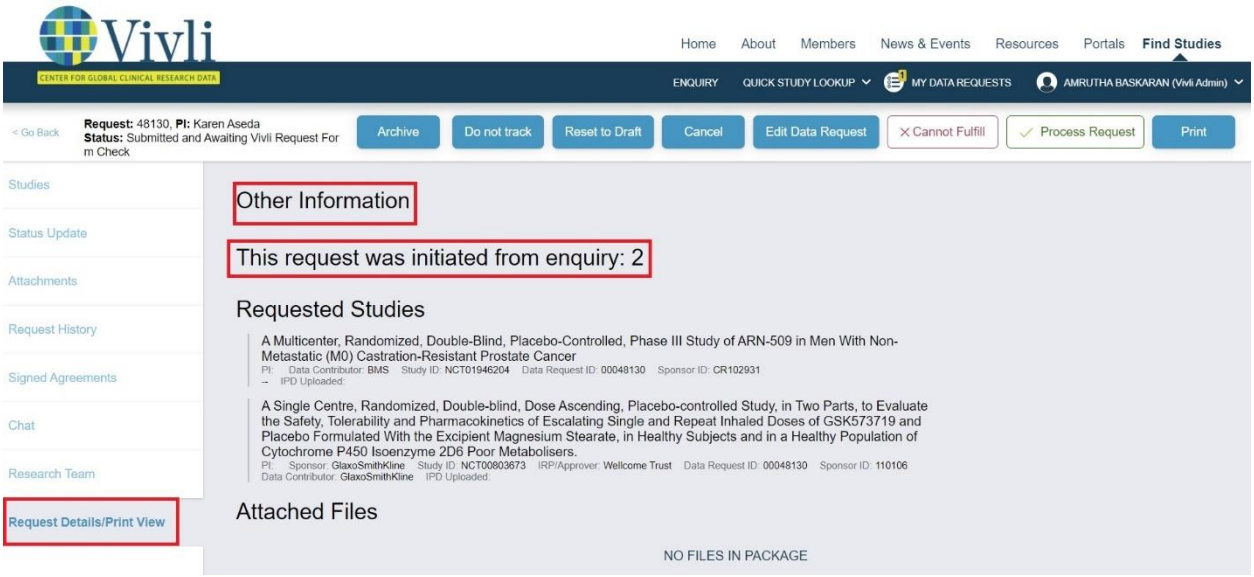


2. If you select either of the options above, you will see an automated comment placed in the discussion. "The data contributor has provided a final response on the availability of this study"

3. If the Sponsor ID field for that study is empty, please provide a Sponsor ID so this study can be requested in a data request. If your study is listed on clinicaltrials.gov, please provide the sponsor ID associated with that listing. If it is not listed on clinicaltrials.gov, please provide an internal sponsor ID. Once you've added the Sponsor ID, please click the “Save & Notify” button on top."
4. Once you record your decision, you can see the date of the final response at the bottom of the page. Note: Once you make a final decision, the discussion panel will be closed for new entries by the researcher. You may continue to add comments as needed.

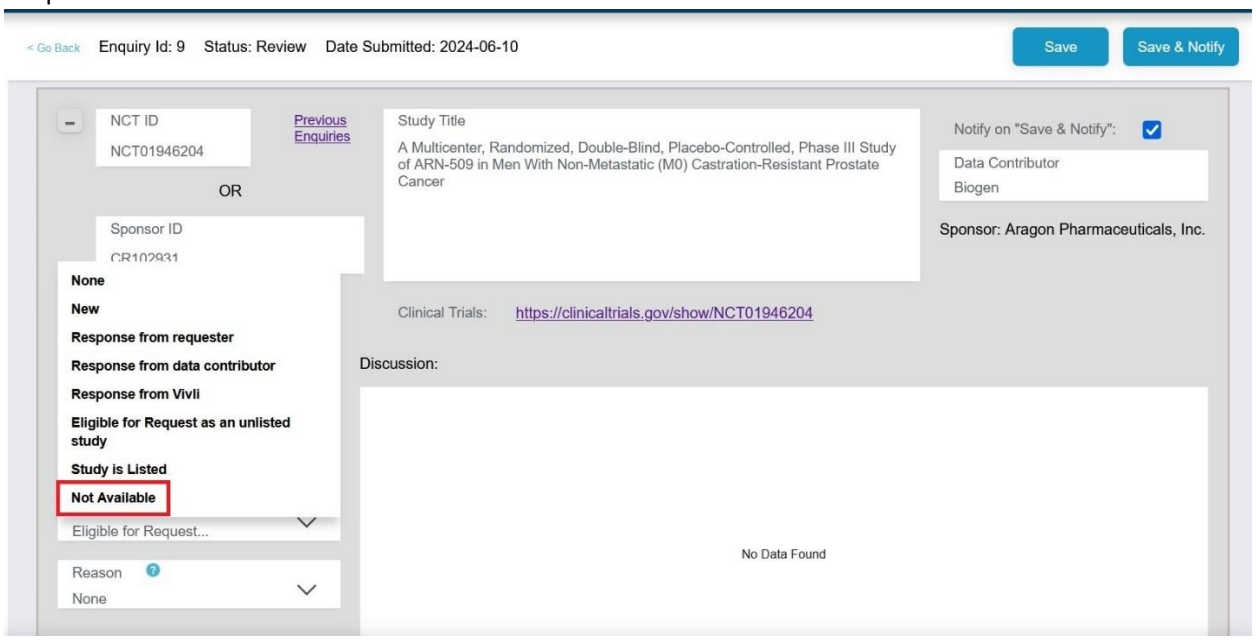
5. The researcher can add studies from the Enquiry directly into the data request form. In such instances, the Enquiry will display the associated Data request ID once the data request is submitted on the platform.

6. A note will also be placed in the data request form under other information stating “This request was initiated from enquiry ID (s)”.

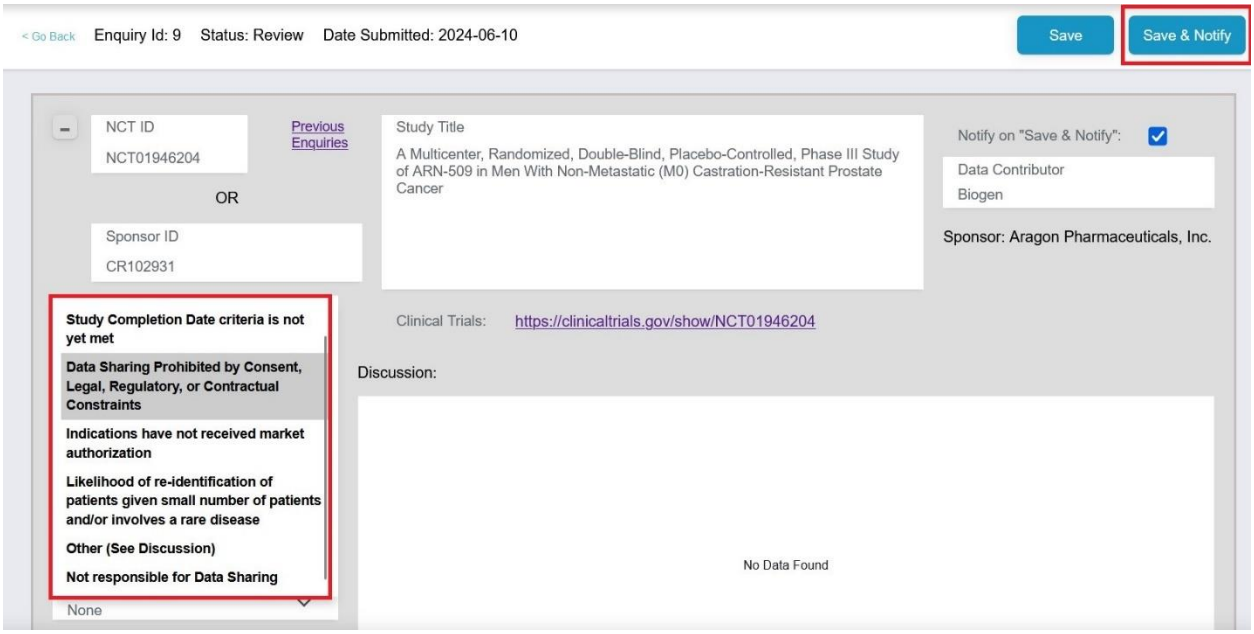


3.3.2 Not Available for Request

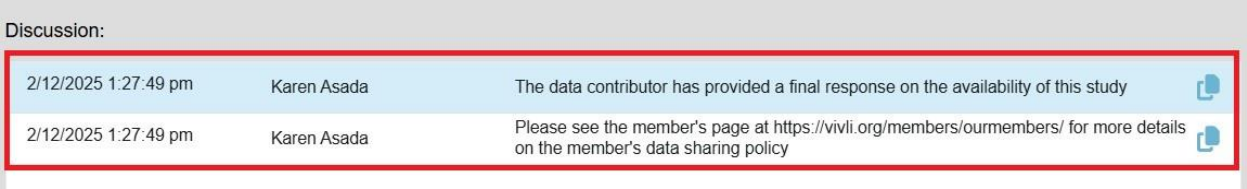
1. If the given study is not available to request, then select the option “Not Available” under Responses.



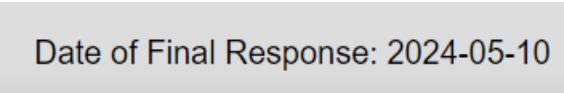
2. Select the reason for non-availability from the dropdown menu. Click the “Save & Notify” blue button on the top to notify the Researcher.



3. If you select the Not Available decision, you will see an automated comment placed in the discussion saying, "Please see the member's page at https://vivli.org/members/ourmembers/ for more details on the member's data sharing policy".

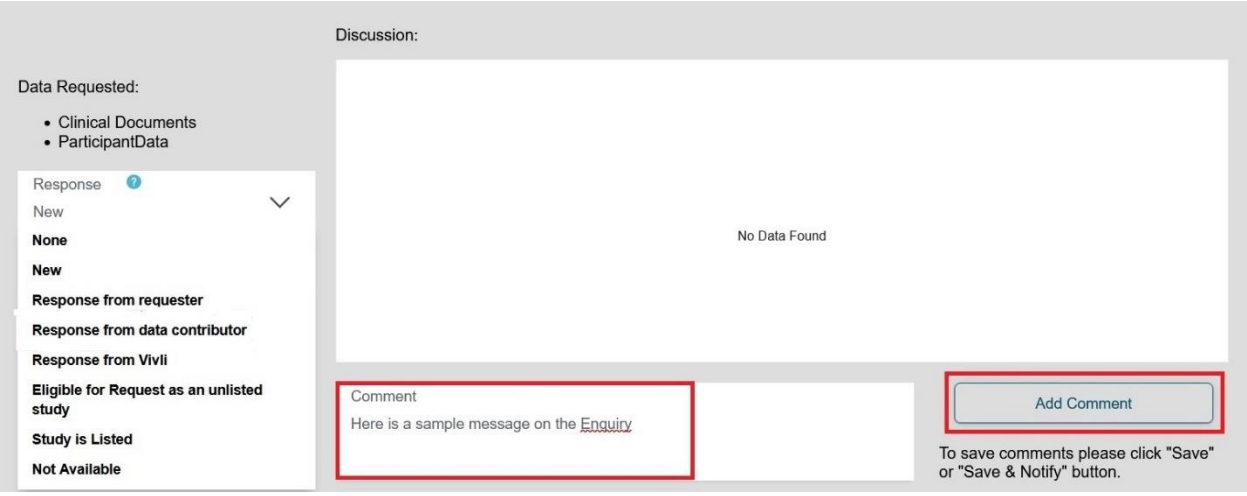


4. Once you record your decision, you can see the date of the final response at the bottom of the page. Note: Once you make a final decision, the discussion panel will be closed for new entries by the researcher. You may continue to add comments as needed.

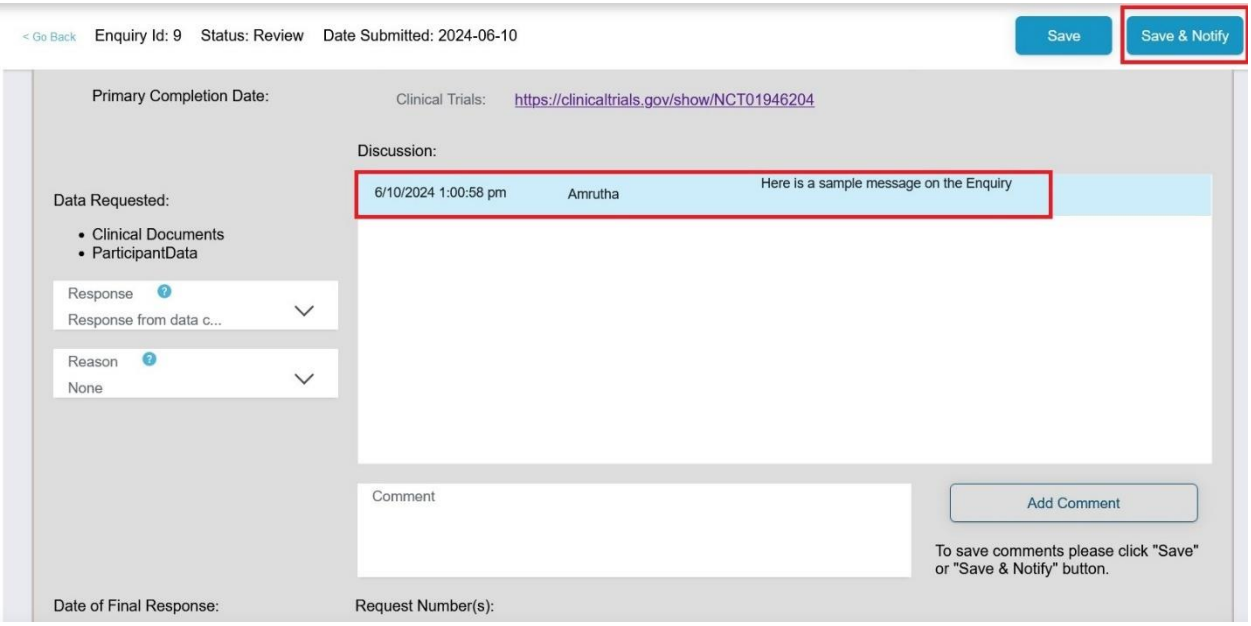


3.3.3 Enquiry Feedback to Researcher via Discussion field

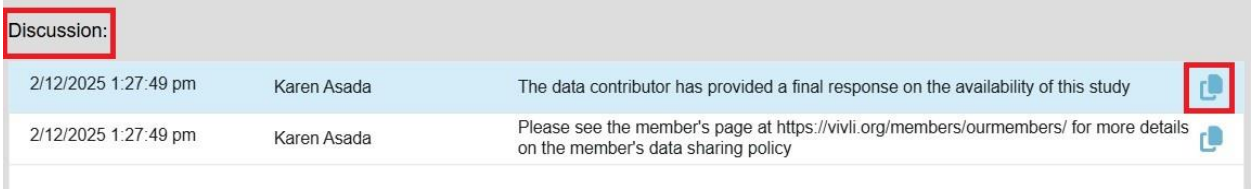
1. You may add comments in the discussion field to obtain additional information from the researcher, explain a reason for non-availability, or provide more information on the availability.
2. Type in your comments in the comments field and click the “Add comment” button.



3. Your comments will show up in the Discussion field. Click on the “Save & Notify” blue button on the top to notify the Researcher.



4. The copy icon next to posted comment allows you to copy the comment and paste it.



5. When the researcher responds, you will receive an email notification and their response will be displayed in the discussion field.
6. Note: Once you make a final decision, the discussion panel will be closed for new entries by the researcher. You may continue to add comments as needed.

3.3.4 Enquiry Study Status for Individual Studies

In addition to the overall Enquiry status, there is a Study-level Status that combines the Enquiry's status with the decision about the Study. This will make it easier for the Organization Administrators to view an enquiry and quickly determine the status of the studies within that enquiry.

1. For Studies with No decision Recorded yet.

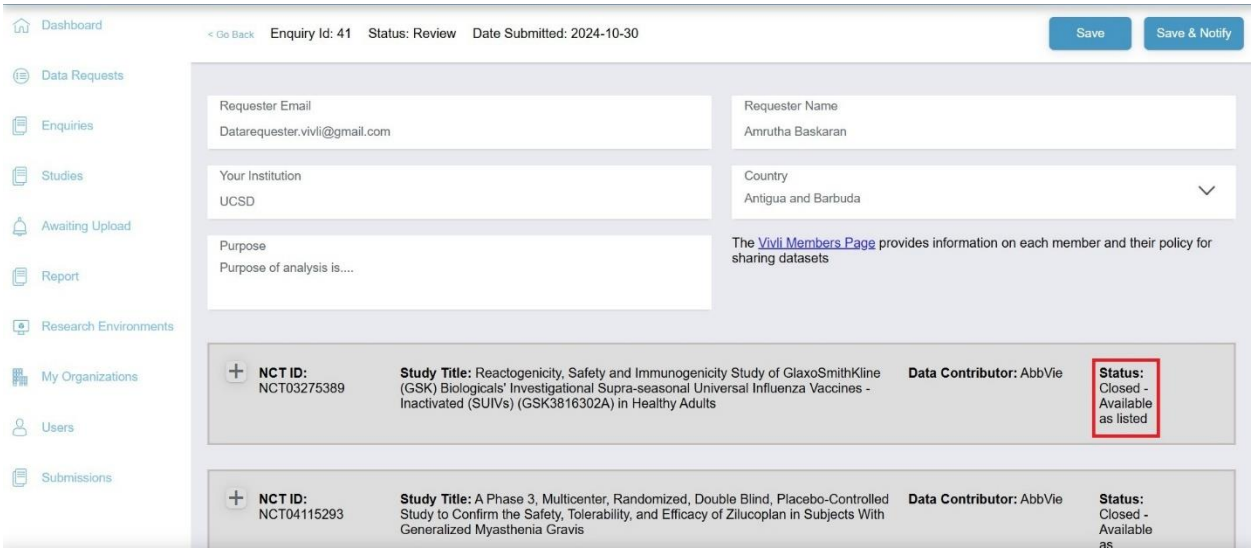
   a. Awaiting Initial submission Overall Enquiry is in draft and has never been submitted
   b. Awaiting Resubmission - Overall Enquiry is in draft after being sent back to draft for revision
   c. Awaiting Validation (Overall Enquiry is in state Enquiry Validation)
   d. Awaiting DC review - Overall Enquiry is in review
   e. Withdrawn (Overall Enquiry is in Withdrawn)
   f. Archived (Overall Enquiry is in Archived)

2. For Studies with decisions already recorded - e.g. response of Available or Not Available

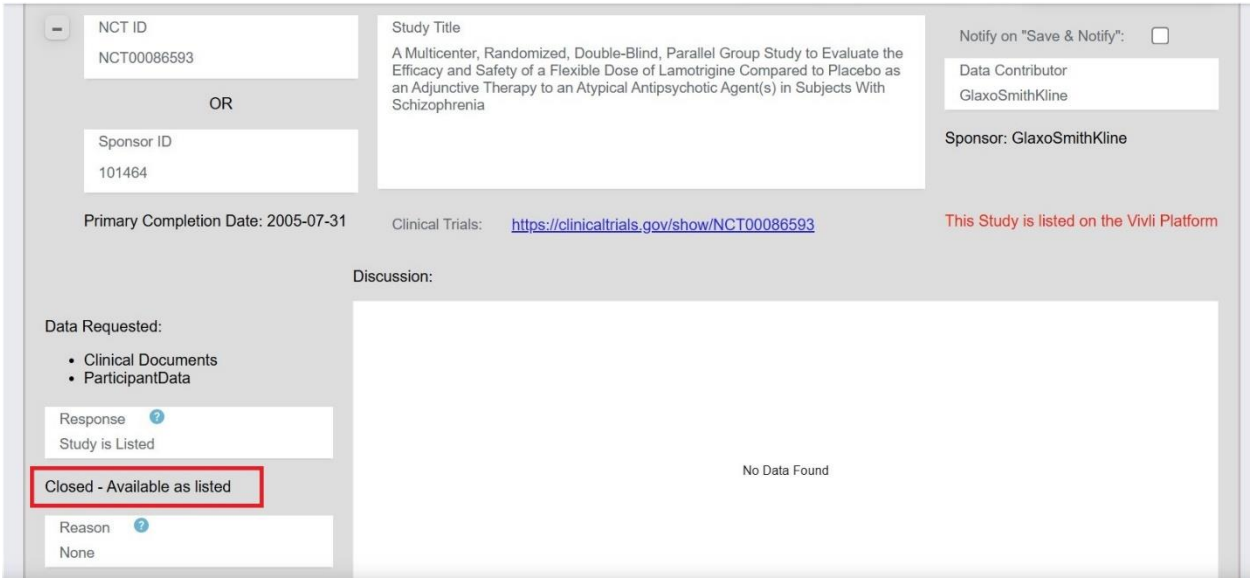
   a. Closed - Available as listed (Independent of the overall Enquiry status)
   b. Closed - Available as unlisted (Independent of the overall Enquiry status)
   c. Closed - Not Available (Independent of the overall Enquiry status)

Study-level Status is visible in the following areas:

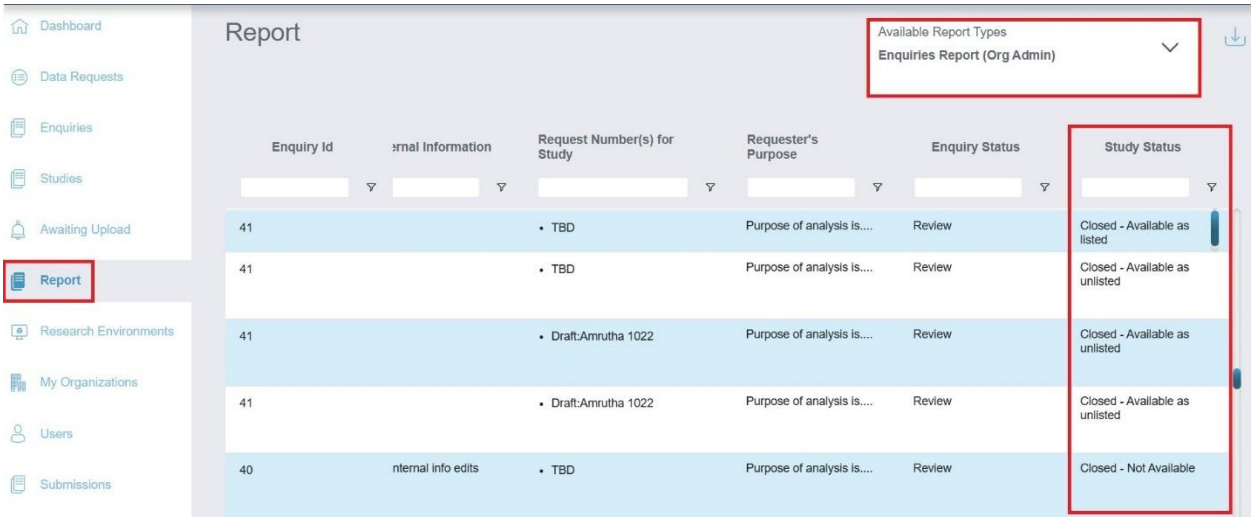
1. Closed Enquiry Study panel, on the right side next to the Data Contributor name



2. Open the Enquiry Study panel, on the left side below the ‘Reason’ field

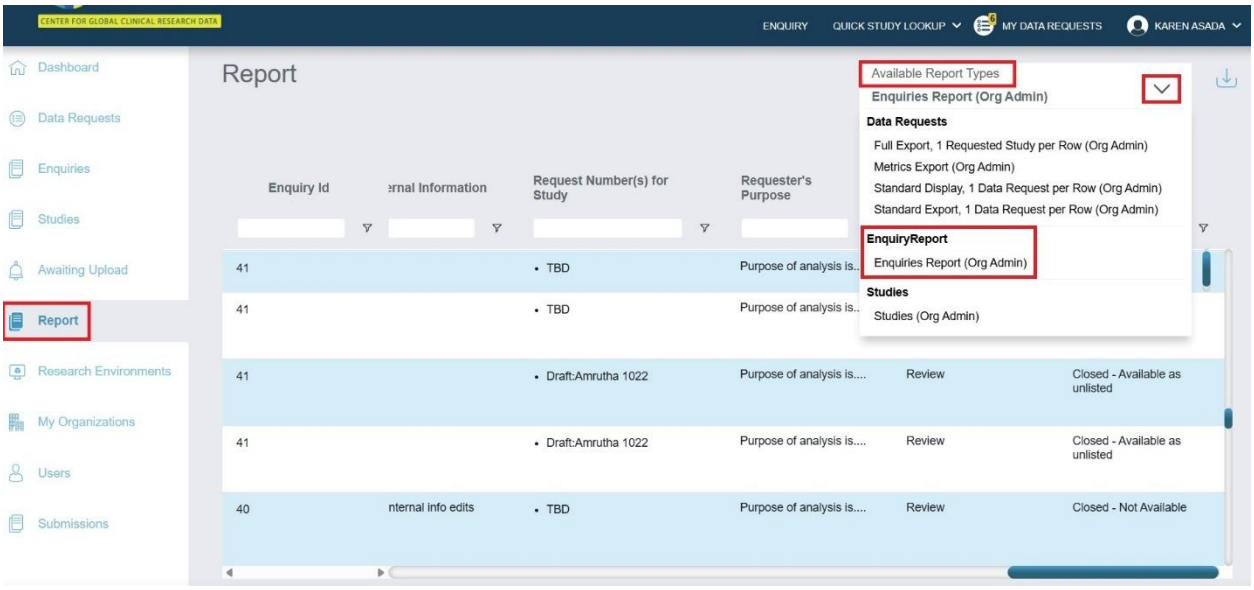


3. Enquiry Report, for each Study, the status shown in a column labeled "Study Status", in position after the "Enquiry Status" field



3.4 Enquiries Report

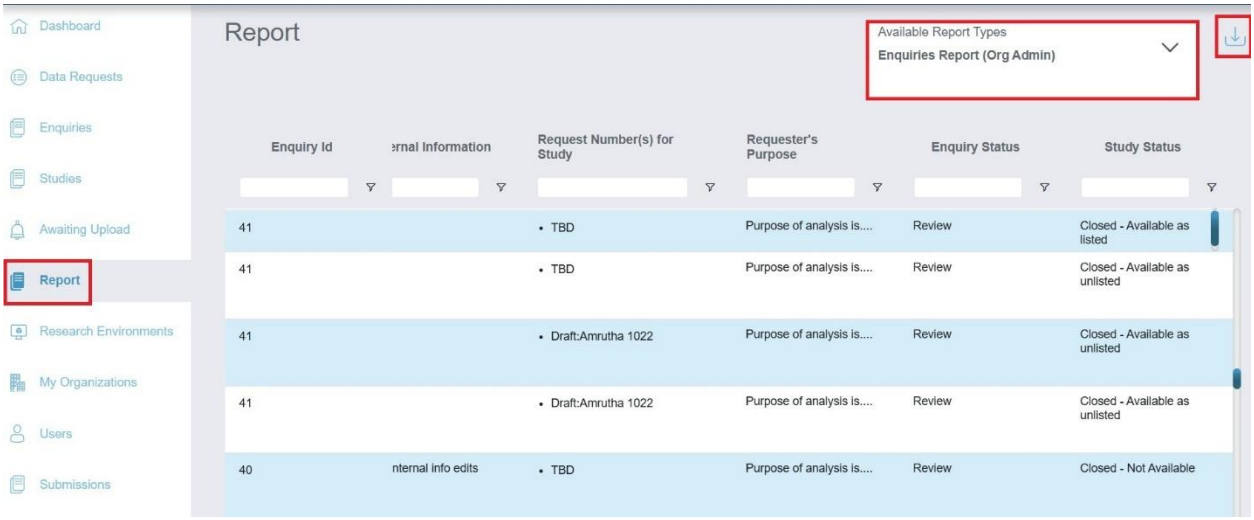
1. The Enquiries report will contain one row per requested study in a given Enquiry. If an Enquiry has multiple studies, there will be multiple rows under the same Enquiry ID



2. The following fields are displayed in the Enquiries report (the scrolling bar is at the bottom of the report to scroll to the right):

- Enquiry ID
- Researcher (Enquirer)
- Contributor
- Contributor's Response
- Denial Reason
- NCT ID
- Sponsor ID
- Study Title
- Discussion
- Date Submitted
- Date Final Response
- Researcher Institution
- Study Primary Completion Date
- Internal Information
- Request number(s) for study
- Requester's Purpose
- Enquiry Status
- Study Status

3. You can also export all your enquiries to a CSV file by clicking the down arrow.



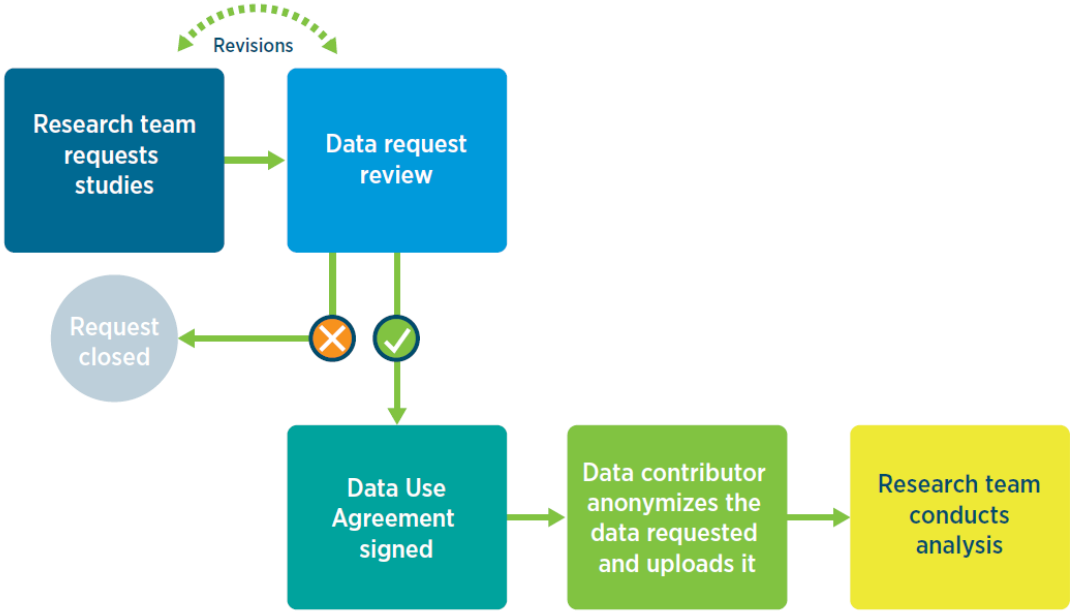
4. The downloaded file contains:

- Enquiry ID
- Researcher
- Contributor
- Contributor's response
- Denial Reason
- NCT ID
- Sponsor ID
- Study Title
- Discussion
- Date Submitted
- Date Final Response
- Researcher Institution
- Study Primary Completion Date
- Internal Information
- Request Number(s) for Study
- Requester's Purpose
- Enquiry Status
- Study Status

4. Reviewing Data Requests

4.1 Overview

- Vivli respects Members' data-sharing policies as noted on their member's page.
- Organizational Administrators are notified of any request for their data.
- Team members with only the Data Uploader rights cannot view or review the data requests until they reach the data upload stage.
- Information about the approval, reasons for non-approval, DUA, and public disclosures are publicly available Metrics on the Vivli website Metrics Page.
- Below is the overall review process

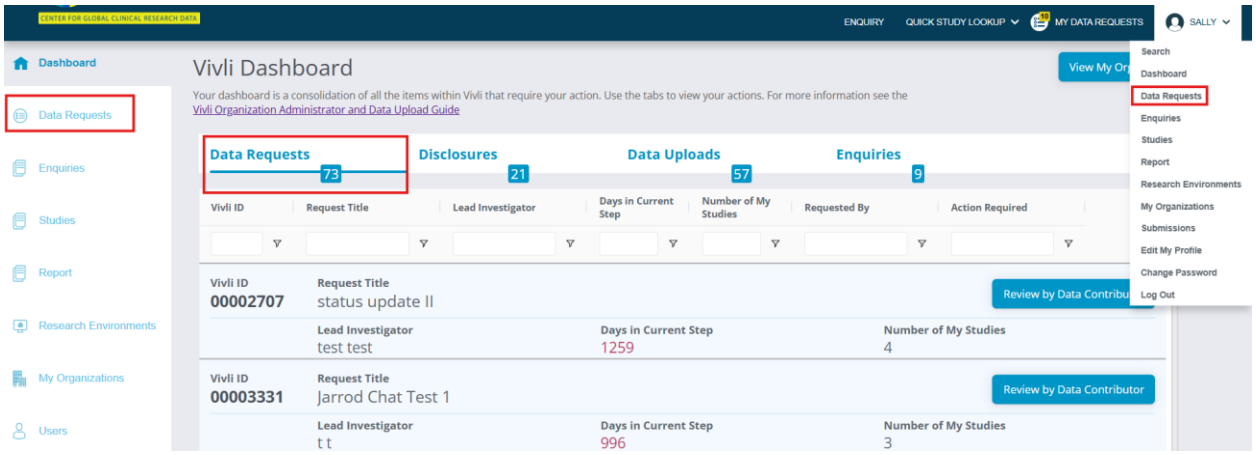


4.2 Data Request Review

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

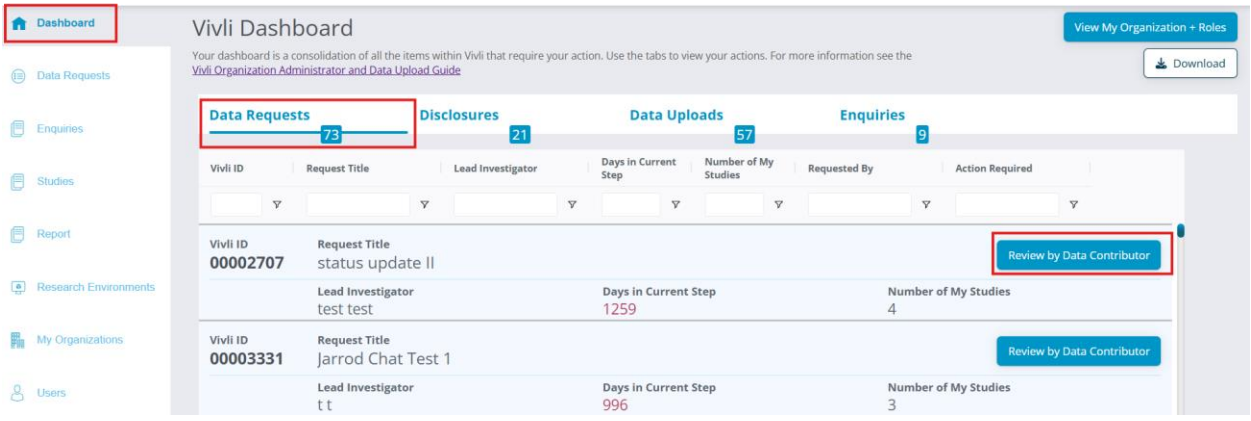
4.2.1 Navigating to Data Requests

1. Once you have logged in to the dashboard, you can navigate to all of your organizations Data Requests using the toolbar on the left-hand side of the screen, or the dropdown menu on the upper right-hand corner of the screen. To view data requests with outstanding actions, use the 'Data Requests' tabs of the main Dashboard:



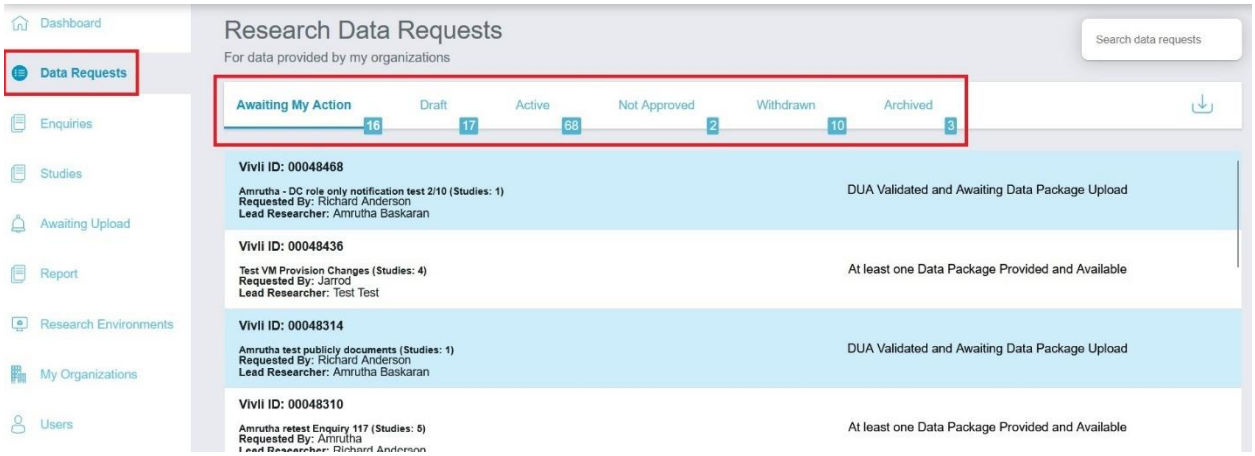
Note: Please ignore the "My Data Requests" located at the top of your dashboard. That link is for data requestors to access their data request forms.

2. Clicking on the blue buttons on the main dashboard will take you into a specific data request that requires an action such as recording your review decision, or uploading data



3. Clicking on the side bar or the drop-down will take you into the "Data Requests" dashboard that will show you all of your organizations data requests.

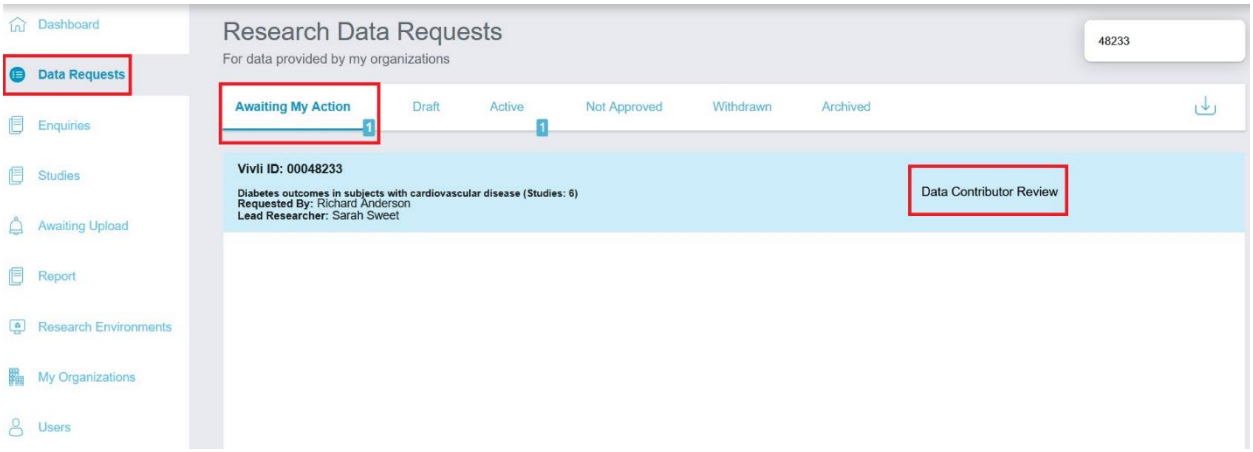
4. The “Data Requests” Dashboard displays a status bar at the top of the page which displays all the data requests for your organization’s studies.



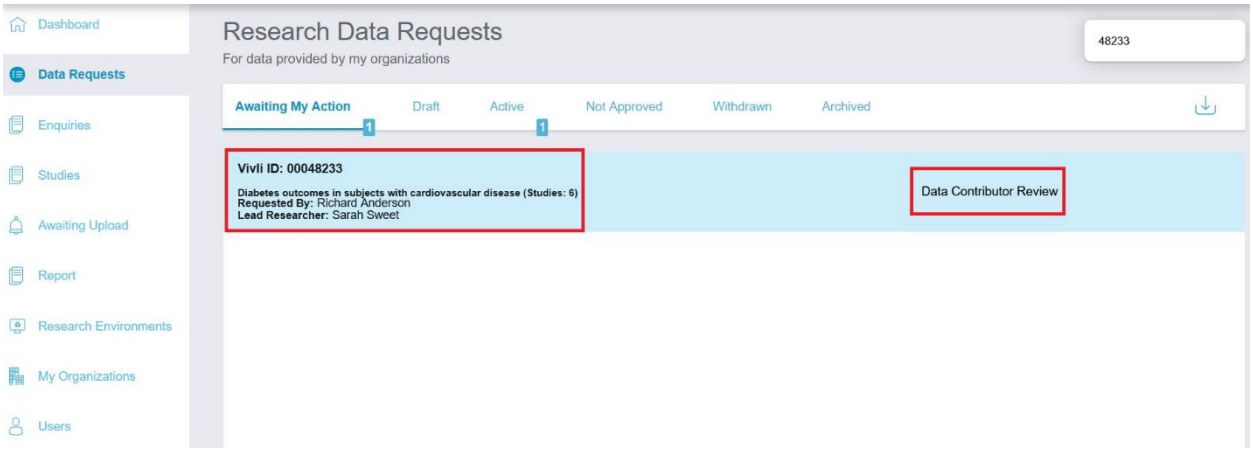
5. The status bar contains 6 sections:

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 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 awaiting 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, Requester's 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.

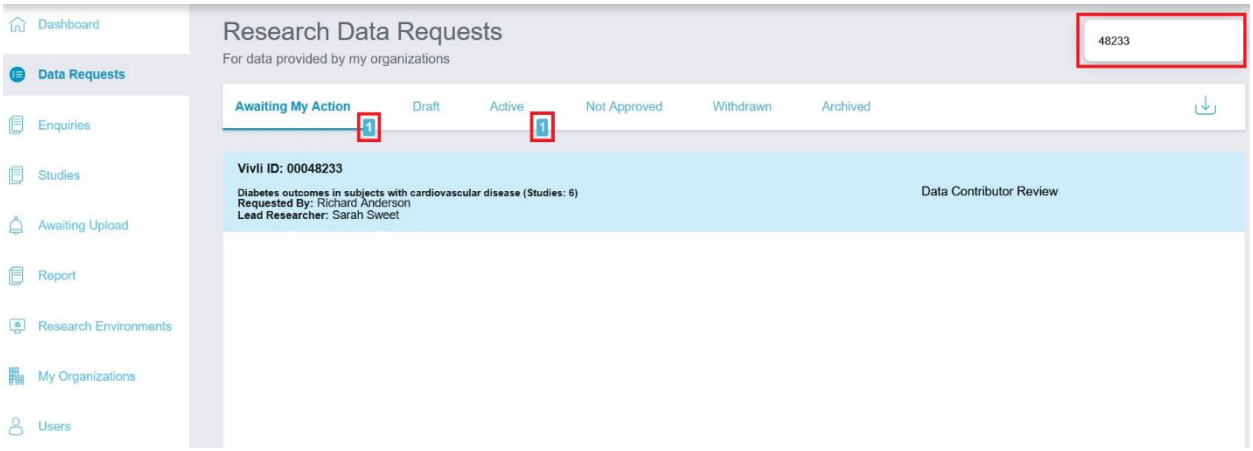


4.2.2 Data Request Dashboard – Search Feature

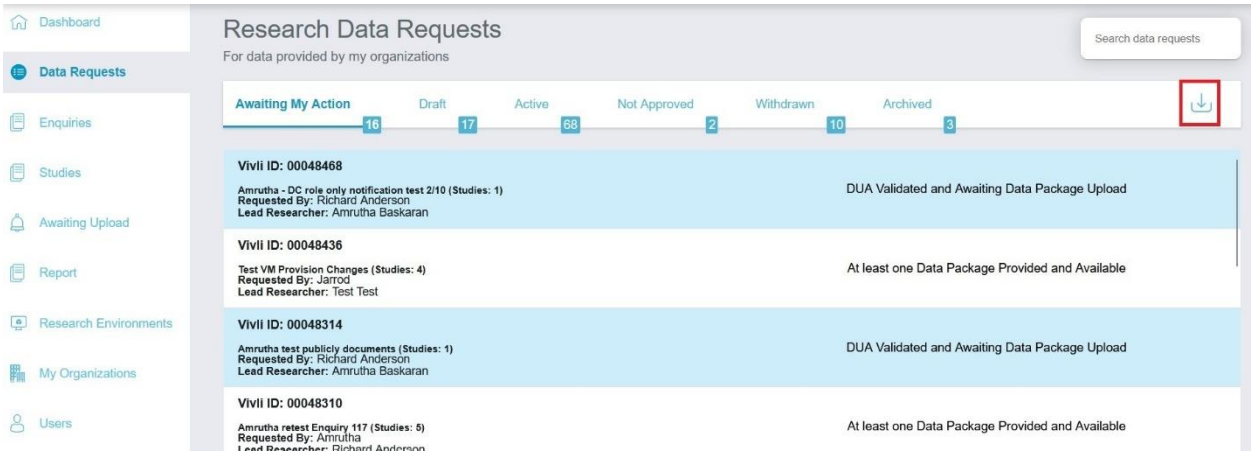
1. You may search for data requests using one of the following fields (you can only view data requests where one of your studies has been requested):

- Data Request Title/Project Name
- Data Request ID
- Submitter Name or Email
- Lead Investigator Name or Email
- Member 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.



2. Once you search for a particular data request, you can export all visible records to a CSV file by clicking the down arrow. You can also export all your data requests to a CSV file without any filtering.

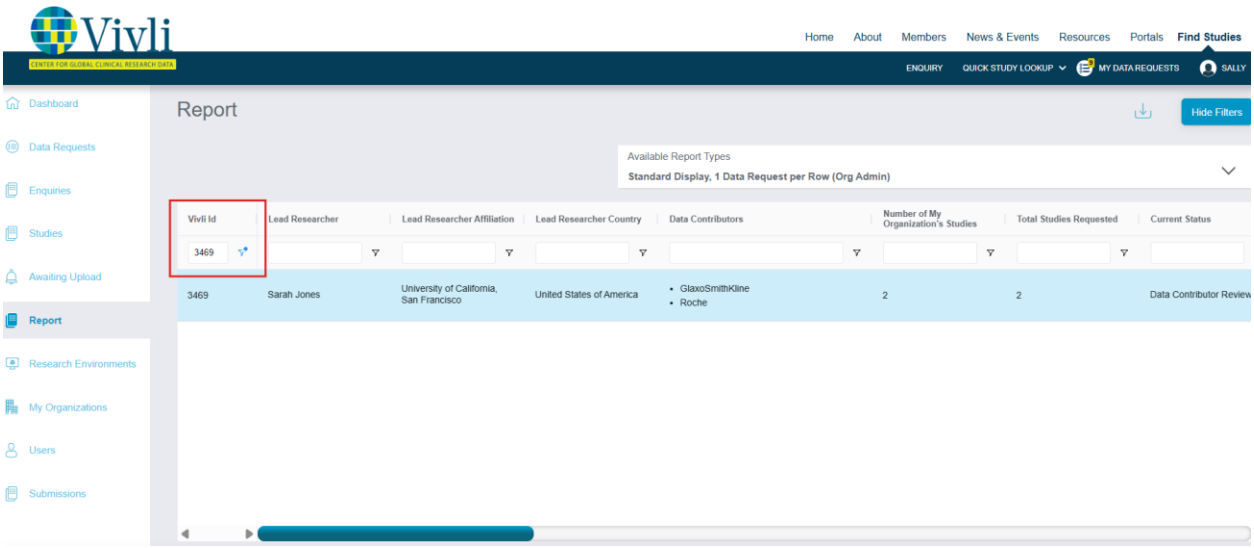


3. The downloaded file contains:

- Data Request ID
- Request Title/Project Name

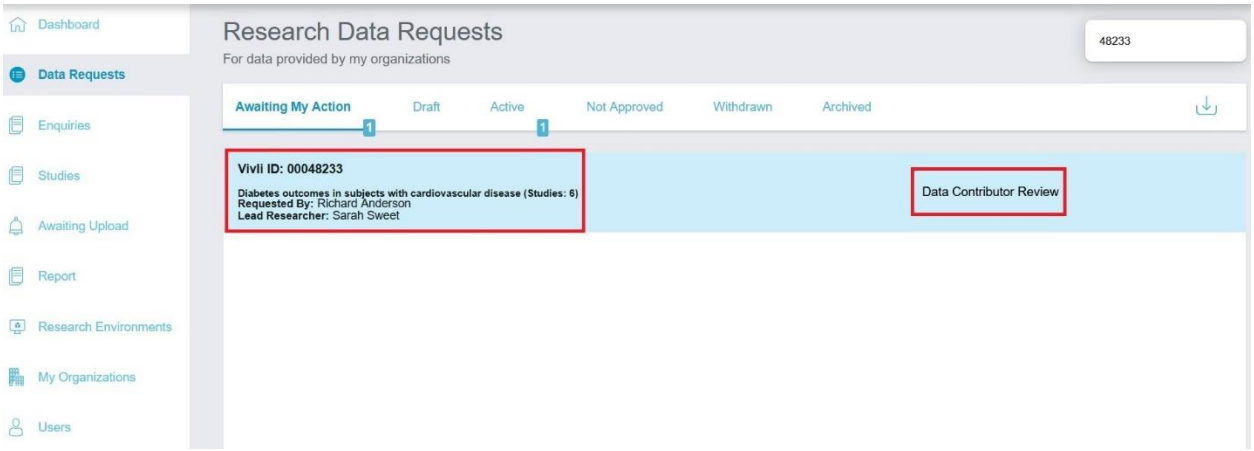
- Submitter/Requester Name and Email
- Lead Investigator Name and Email
- Request Status
- Date of the last action
- Data Contributor Organizations

4. An alternative way to navigate a data request is to go to the 'Reports' tab. The Standard Display report will automatically appear, and enter, for example the Vivli ID or the researcher name into the filter, and the associated requests will appear. Click on the record to be taken into the request.

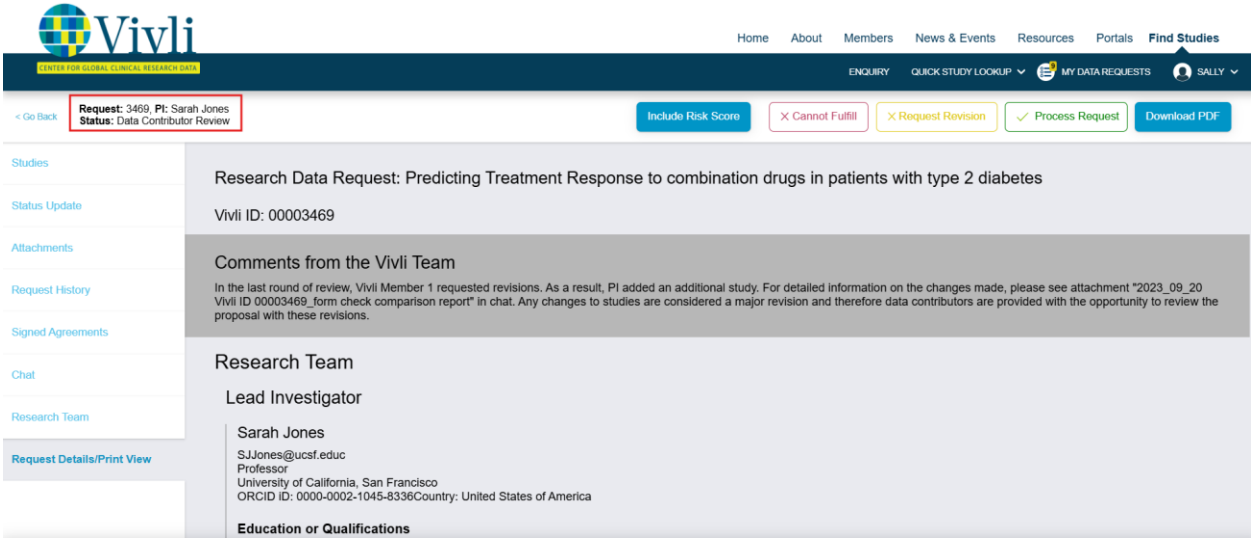


4.2.3 Data Request Form

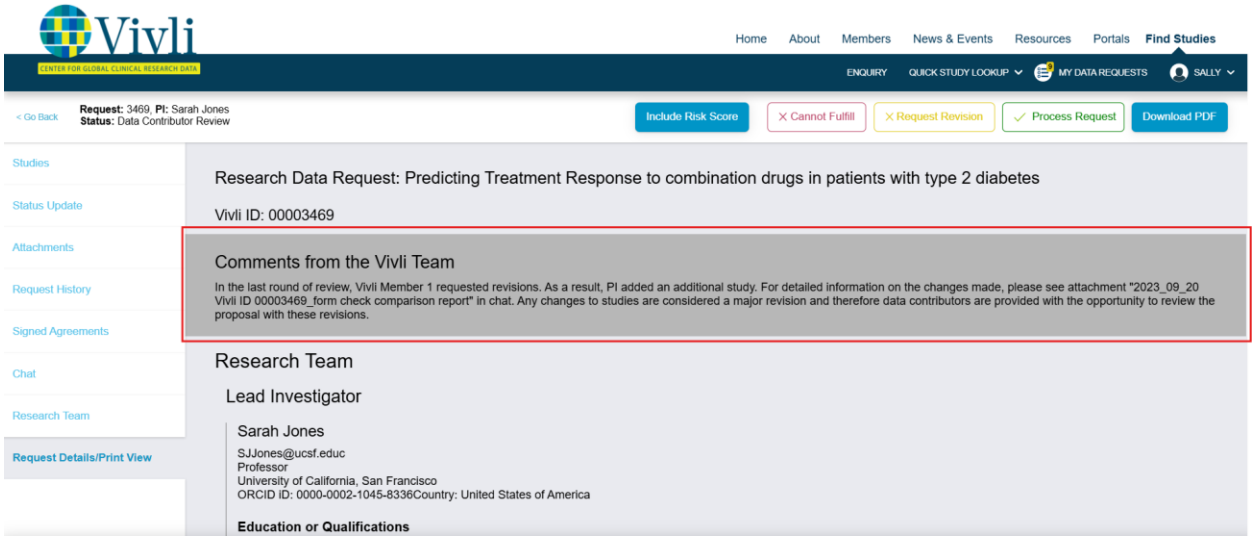
1. First, click on the Data Request Project name and it will take you to a Request details screen. Data Requests appearing on this screen have already gone through the Vivli Admin form check and are ready for Data Contributor or IRP review.



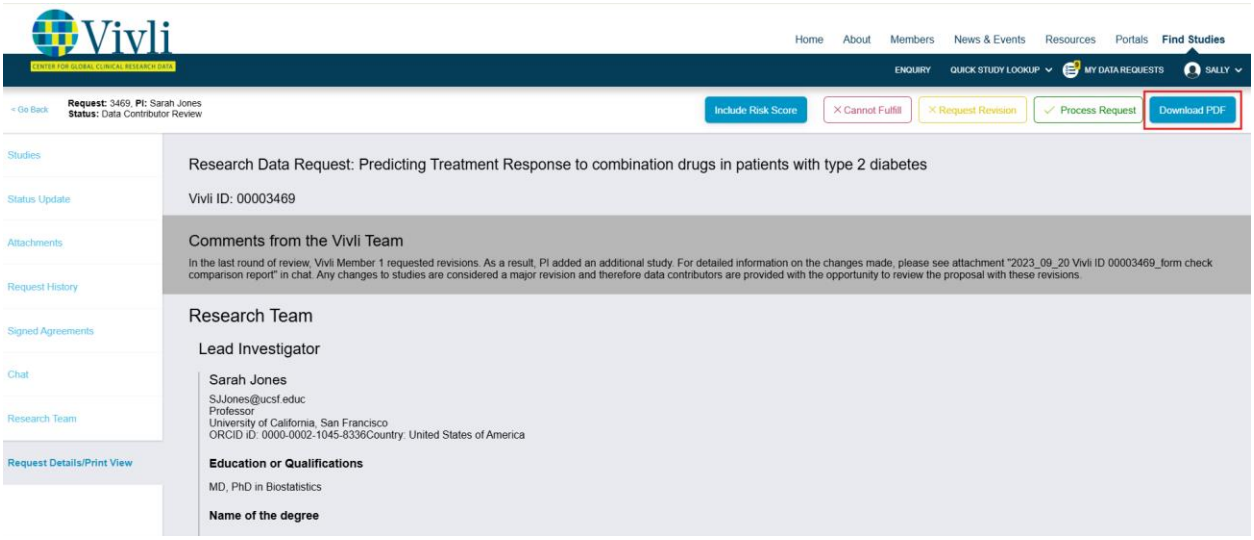
2. When you open the data request, you can see the Vivli Request number, PI name, and the current status of the data request on the top.



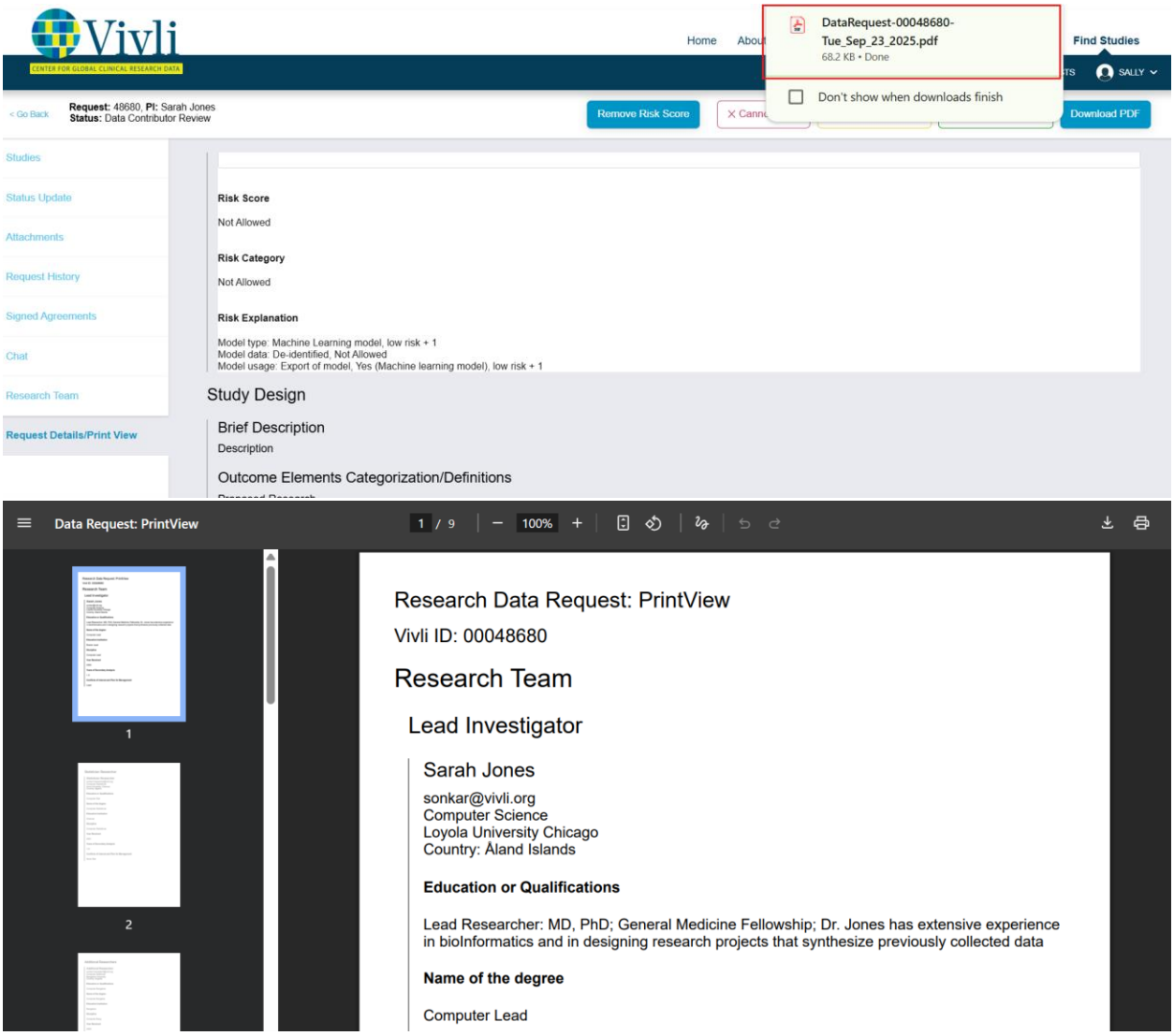
3. In the “Request Details/print view” tab of the data request form, the last comments, if any entered during the Vivli form check approval will be displayed on top.



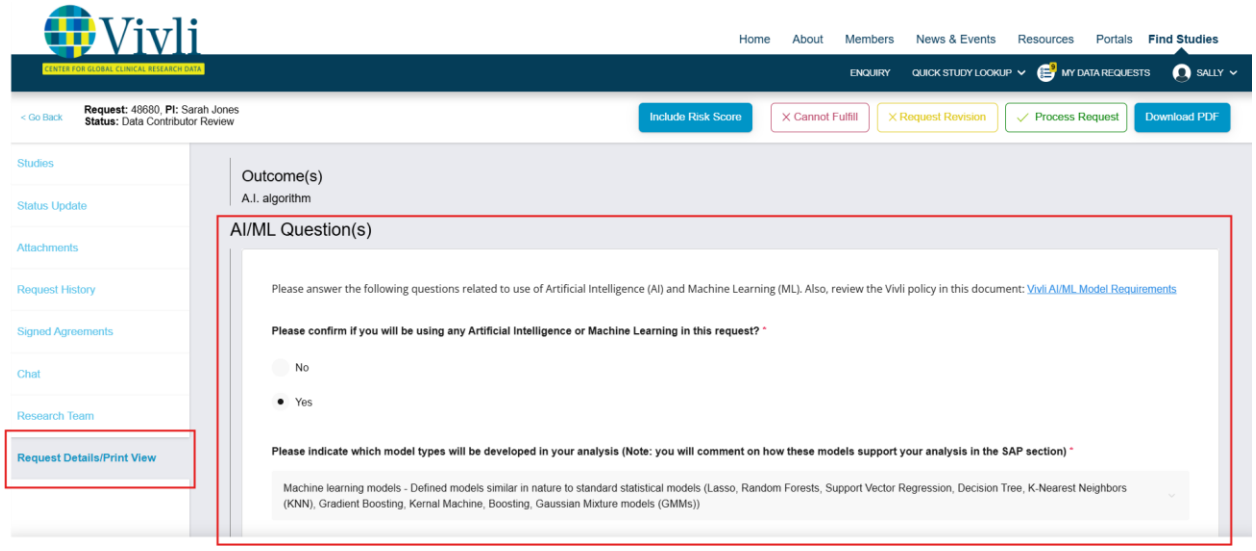
4. The data request form can be viewed online, or downloaded as a PDF. To download the PDF version, click on ‘Download PDF’ in the top right corner.



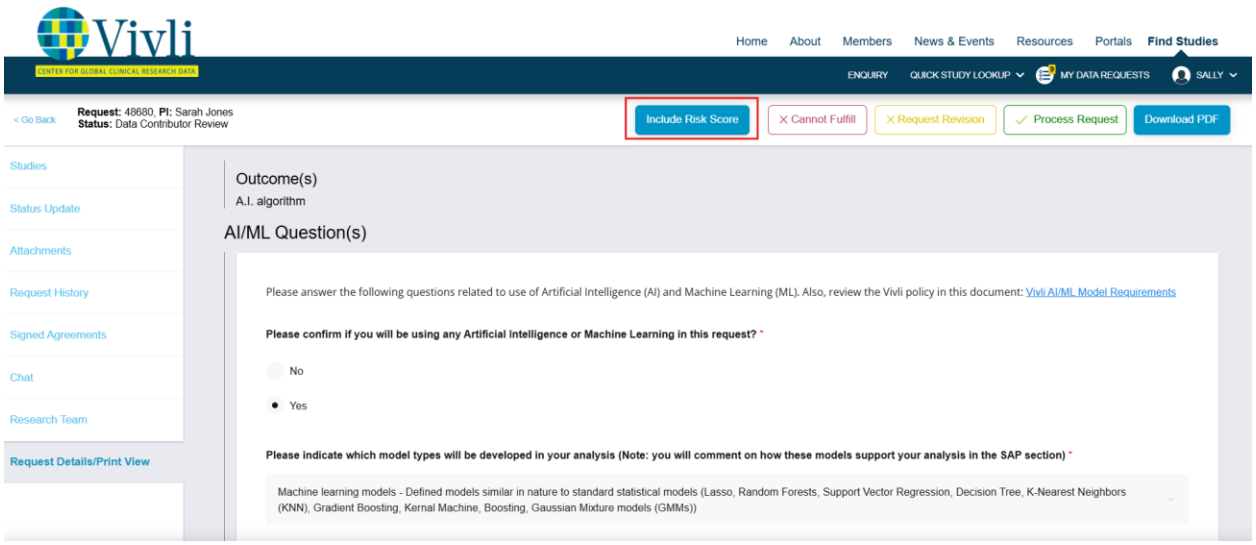
5. A PDF version of the request will be downloaded to your machine and can be opened and saved or printed



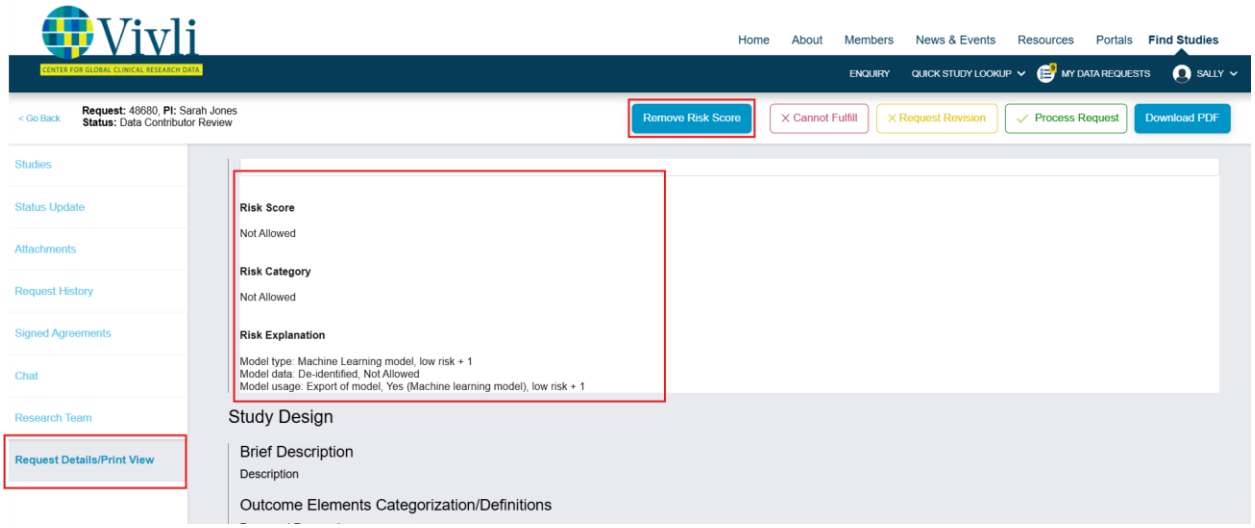
6. All the newly submitted data request form will embed the responses filled out by the Researcher related to Artificial Intelligence and Machine Learning.



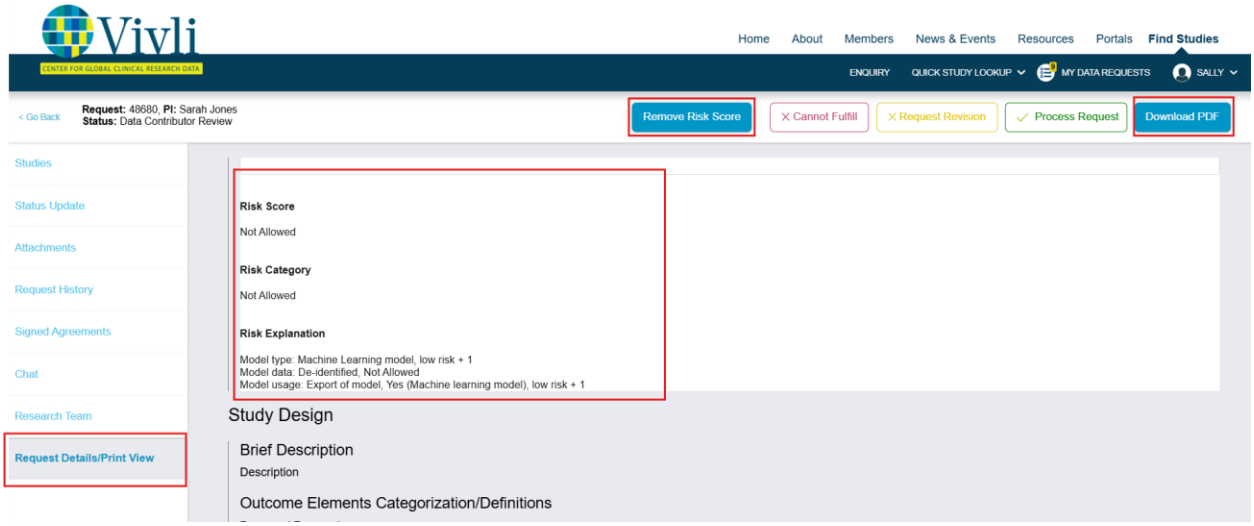
7. You may view the risk score and its explanation by clicking the blue button “Include Risk Score”

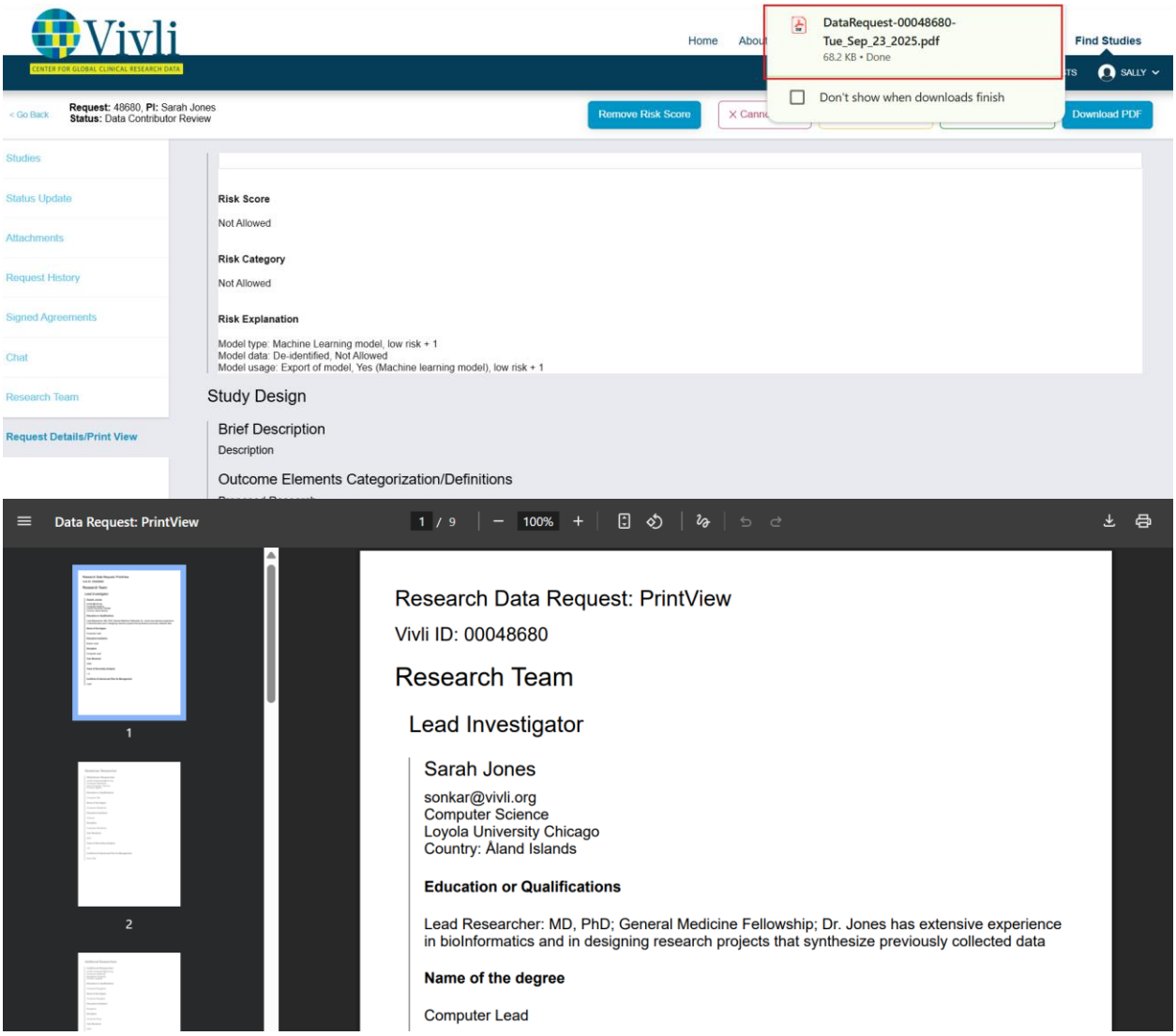


8. This will uncover the Risk score and Risk Explanation in the data request form. Note, that researchers have the option to select more than one model type but the score will reflect the highest risk selection.



9. Reviewers can read the Data Request Form online, or download a PDF copy by clicking on the "Download PDF" button. Ensure to click "Include Risk Score" button to include the risk score and explanation.





4.2.4 Artificial Intelligence (AI) and Machine Learning (ML) request review

Vivli AI/ML requests will have a calculated risk score based on researchers' response. This score is derived using the following criteria:

1. **Model Type** – Researcher indicates what type of model(s) will be developed in the analysis

Model Type	Risk Level	Examples	Comments	Scoring
1. Machine Learning Models	**Low**	Lasso, Random Forests, Support Vector Regression, Decision Tree, K-Nearest Neighbors (KNN), Gradient Boosting, Kernal Machine, Boosting, Gaussian Mixture models (GMMs)	Defined models similar in nature to standard statistical models. Used for structured data and low risk of unintended outputs. Interpretable, well-defined models.	+1
2. Artificial Neural Networks (ANNs) and Similar Algorithms	**Moderate**	Artificial Neural Networks (ANNs), Convolutional Neural Networks (CNNs), Recurrent Neural Networks (RNNs), Transformer Models (non-generative)	Powerful. Some consider these "black box" models due to difficulty interpreting how decisions are made within models. Increased complexity, some difficulty in controlling outputs.	+2
3. Generative Models / Large Language Models (LLMs)	**High Risk**	GPT, Generative Adversarial Networks (GANs), Diffusion models	Concerns that these may "contain" external data and may allow for identification of complex patterns	+10

2. **Model data** – Researcher confirms the type of data that will be used to train the model. Note, Vivli only allows anonymized data to be imported.

Model Data	Risk Level	Explanation	Scoring
Untrained or No external data is incorporated	**Very low**	Model is untrained on any data or Model does not contain embedded external data	+0
Anonymized data is contained in my model	**Low**	Model is trained on and includes anonymized data (example clinical trial/registry data that is anonymized)	+1
De-identified data is contained in my model *	**Not Allowed**	Model is trained on and includes de-identified data (example clinical trial data that has identifiers de-identified, pseudonymized)	Not allowed
Identifiable data is contained in my model *	**Not Allowed**	Model is trained on and includes identifiable data or large datasets that may have significant overlap with requested data (EMR of large hospital system for example)	Not allowed
Unknown	**Not Allowed**		Not allowed

3. **Model usage** – Researcher indicates if the model will be exported from the Vivli secure research environment. The export of artificial neural networks (ANNs) and generative/large language models (LLMs) are not allowable.

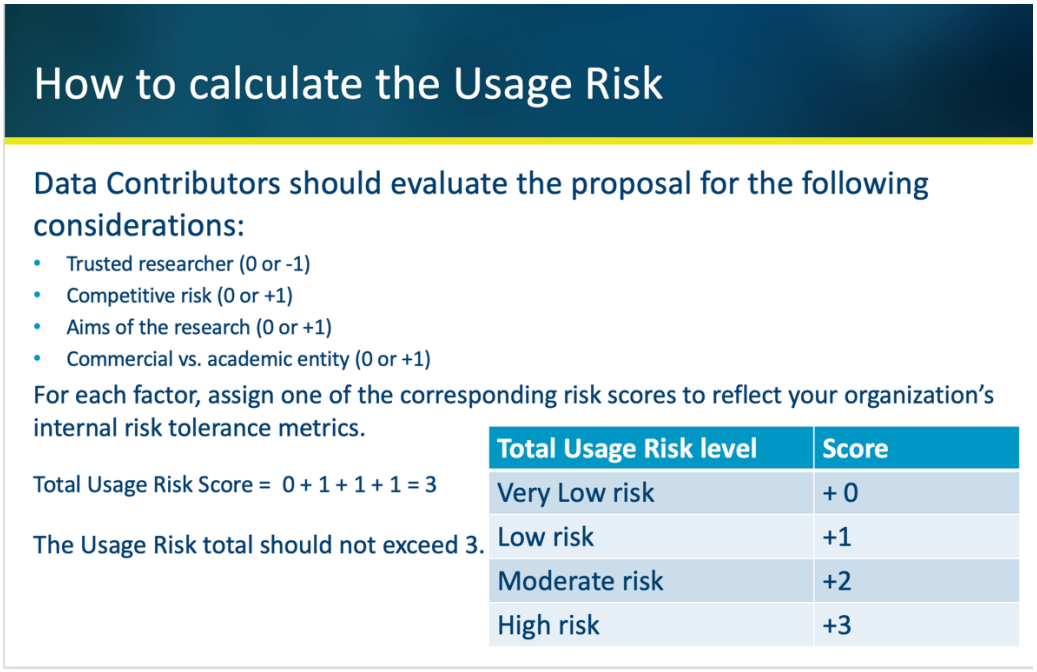
Model Usage	Risk Level	Examples	Scoring
Export of models (No)	**Low**	Data is used to confirm that a model is performing as expected, adjust algorithms parameters, or to build custom model using the data in the environment. May take the learnings and create a model externally with other data.	+0
Export of model type 1 (Yes) – ELEMENT 1	**Low**	Exporting a Lasso, Random Forests, Support Vector Regression, Decision Tree, K-Nearest Neighbors (KNN), Gradient Boosting, Kernal Machine, Boosting, Gaussian Mixture models (GMMs)	+1
Export of model type 2 or 3 (Yes) - ELEMENT 1	**Not Allowed***	Data used to create, train, or validate a model. The model / algorithm does need to be exported.	Not allowed

4. **Usage risk** – The Data Contributor evaluates whether the proposed data use aligns with your organization's internal risk tolerance across four key areas – competitive risk, trusted request history, aim of the research, and commercial vs. academic institution.

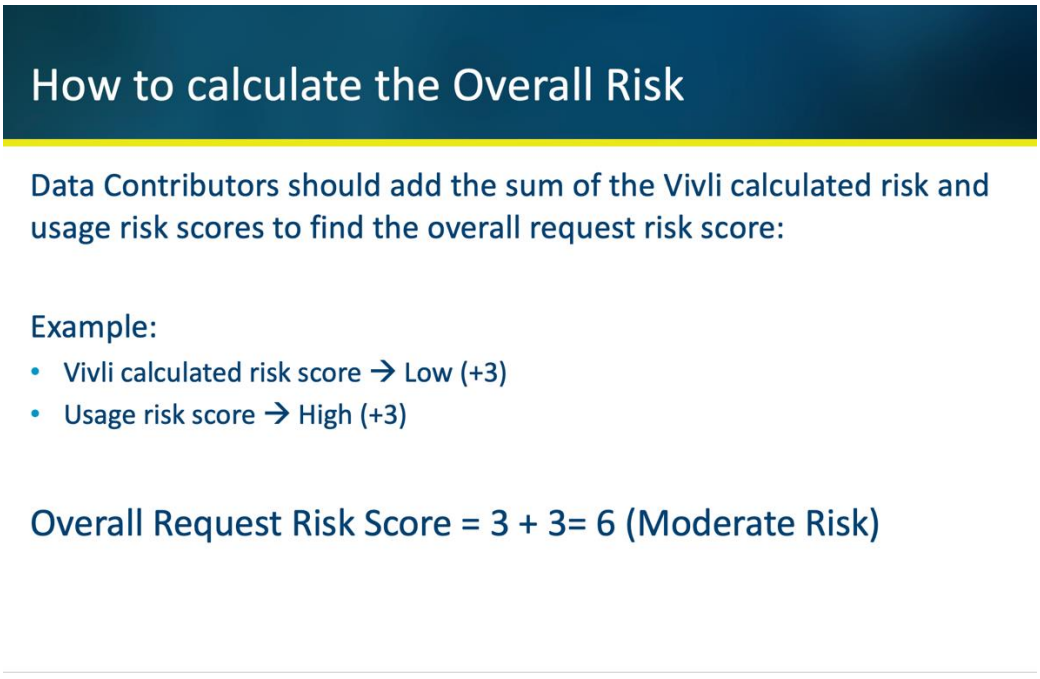
Note, the Vivli Team provides the researchers prior experience with Vivli requests in the data request comments of the form check to inform the trusted researcher variable. If the researcher has a prior track record of Vivli requests, working with data contributors, or is a key opinion leader, this may be considered very low risk.

Risk Level	Factor	Scoring
Very Low	Trusted researcher (prior track record of Vivli requests or working w/a member e.g., KOL)	0 or - 1
Low	Competitive Risk	0 or +1
Moderate	Aims of the research (training of a product, creating an algorithm for publication, patient care, placebo vs. active arm)	0 or + 1
Higher	Commercial vs. Academic Entity	0 or + 1

5. Data contributors should calculate the usage risk to reflect their organization's internal risk tolerance metrics. The usage risk metrics should not exceed + 3.



5. **Overall risk level for AI/ML request** - Data Contributors should add the sum of all factors to find the overall request risk score:



6. **Communication of Not Allowable AI/ML requests** - If the request remains a low, moderate, or high-risk request, the data contributor will continue with the feasibility process and record their decision. If the calculation of usage risks causes the request to exceed 12 points, the request is **Not Allowable,** and the Data Contributor should:

- Reach out in Contributor chat
- Record a denial decision on the platform

Request history

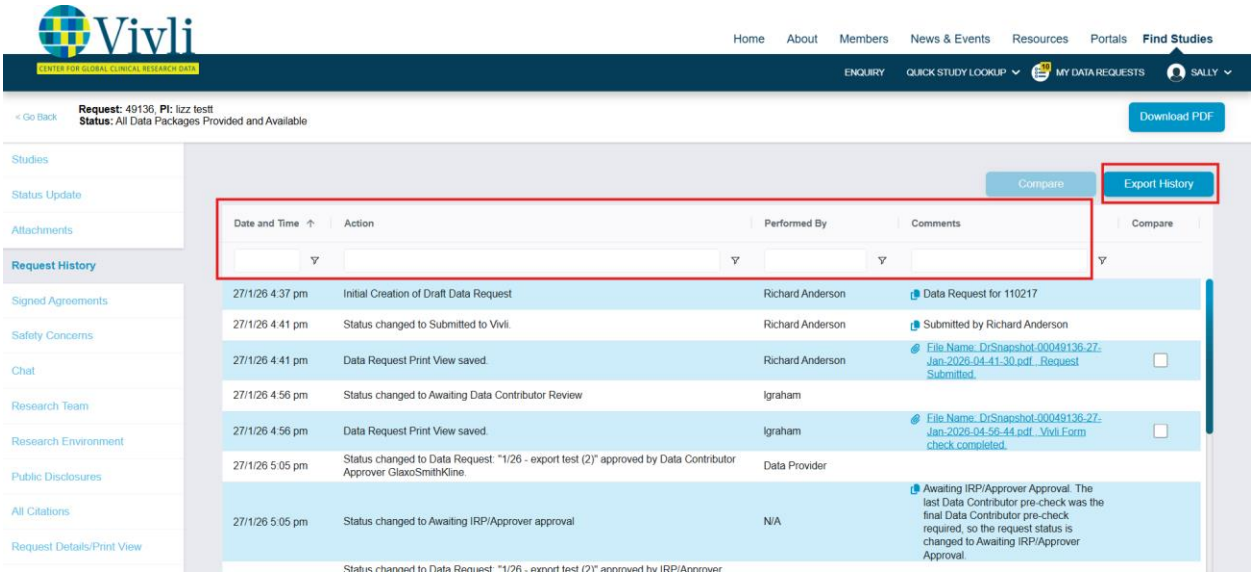
The request history tab shows the history of the data request, including decisions recorded by you or by other member organizations involved in your data request. Request history also shows Vivli form checks, data contributor review, IRP review, DUA validation events, data package upload, when data packages are accessed via Research Environment or through download (based on member's data-sharing criteria), results exported, Research Environment de-provisioned, request archival and request withdrawal.

The request history holds PDF versions of the request form which are automatically saved each time the request is submitted, and each time it passes Vivli form checks and is processed for data contributor review. The Vivli admin, researcher, or data contributor can compare the PDF versions within this tab.

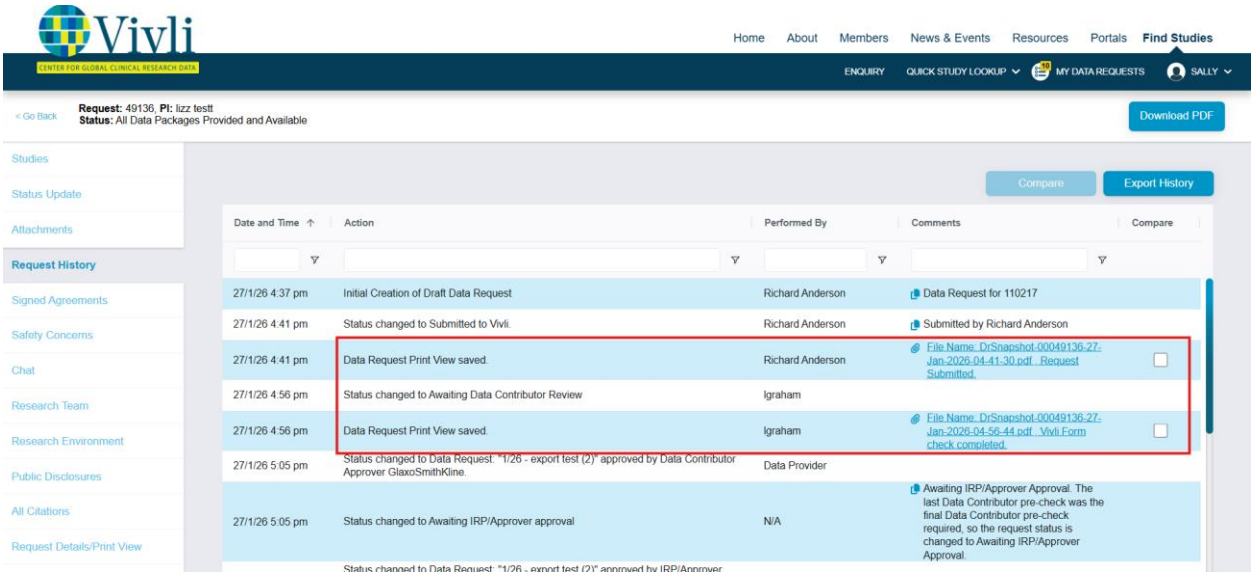
The Vivli admin can also manually save a copy of the PDF at any stage if changes are needed to the data request.

Features:

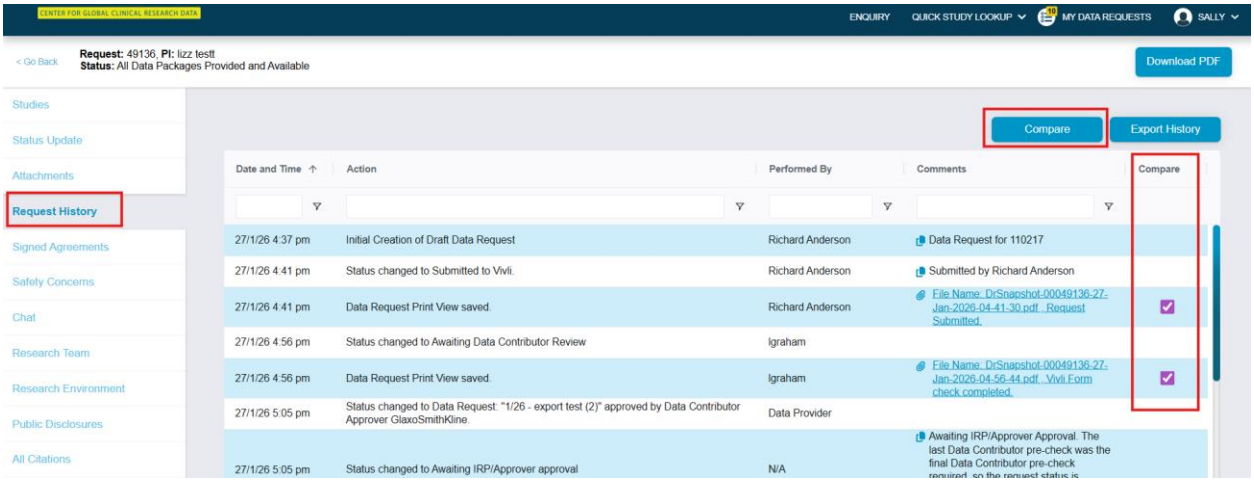
1. The request history can be filtered using the top row of available filters, and it can also be exported to a .csv format by clicking the 'Export History' button.



2. The request history holds a PDF version of the data request form which is saved each time the request is submitted or passes Vivli form checks and is processed for data contributor review. These different versions can be downloaded and viewed by clicking on the file name in the 'Comments' column.



3. Two versions of the saved PDFs can be compared by checking the boxes in the ‘Compare’ column, and clicking the ‘Compare’ button



4. A compare PDF will be downloaded, which will show the two documents with differences highlighted

Note: The two-page view can differ from browser to browser.

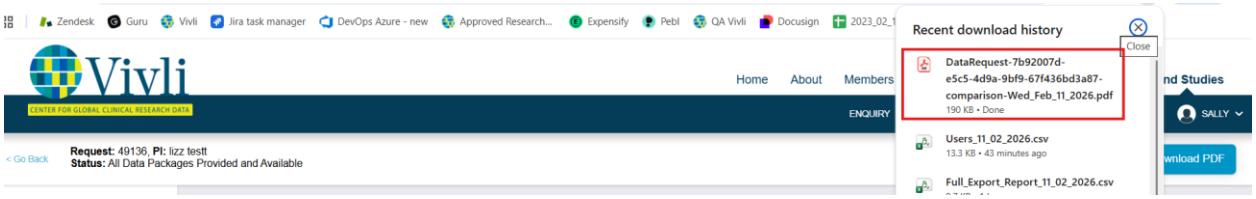
For pdf compare, to open 2 page view:

In Acrobat: click on menu in the title bar - in the drop down click on View -> Page Display -> 2 Page View

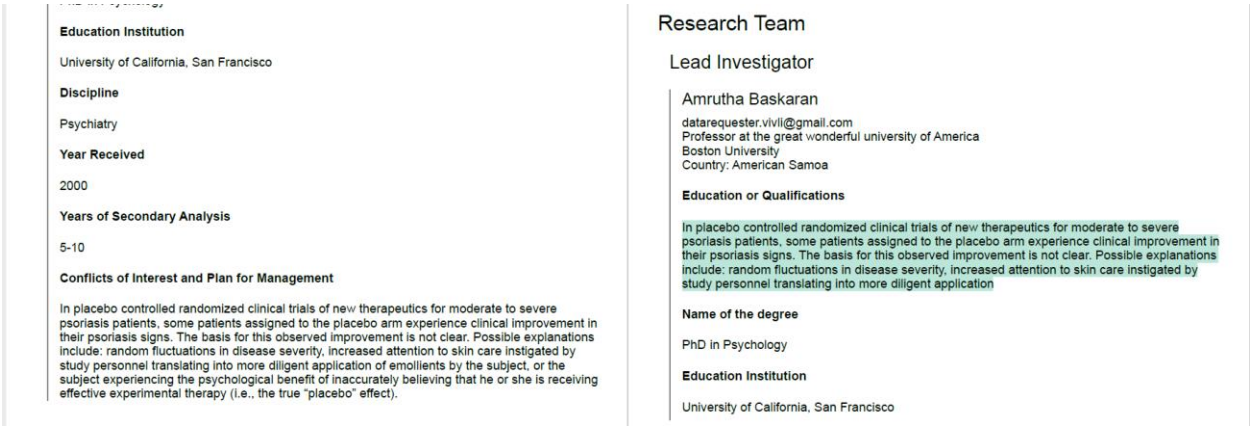
In Chrome, or Firefox: Click on the three dots on the upper right, and choose Two Page View

In Edge: In the ribbon, about in the middle is an icon that looks like two pages - that has an drop down to choose between 1 page and 2 pages.

In Safari - Right click and select "two page continuous"



Green highlighted sections indicates text that has been inserted:



Education Institution

University of California, San Francisco

Discipline

Psychiatry

Year Received

2000

Years of Secondary Analysis

5-10

Conflicts of Interest and Plan for Management

In placebo controlled randomized clinical trials of new therapeutics for moderate to severe psoriasis patients, some patients assigned to the placebo arm experience clinical improvement in their psoriasis signs. The basis for this observed improvement is not clear. Possible explanations include: random fluctuations in disease severity, increased attention to skin care instigated by study personnel translating into more diligent application of emollients by the subject, or the subject experiencing the psychological benefit of inaccurately believing that he or she is receiving effective experimental therapy (i.e., the true "placebo" effect).

Research Team

Lead Investigator

Amrutha Baskaran

datarequester.vivli@gmail.com
Professor at the great wonderful university of America
Boston University
Country: American Samoa

Education or Qualifications

In placebo controlled randomized clinical trials of new therapeutics for moderate to severe psoriasis patients, some patients assigned to the placebo arm experience clinical improvement in their psoriasis signs. The basis for this observed improvement is not clear. Possible explanations include: random fluctuations in disease severity, increased attention to skin care instigated by study personnel translating into more diligent application

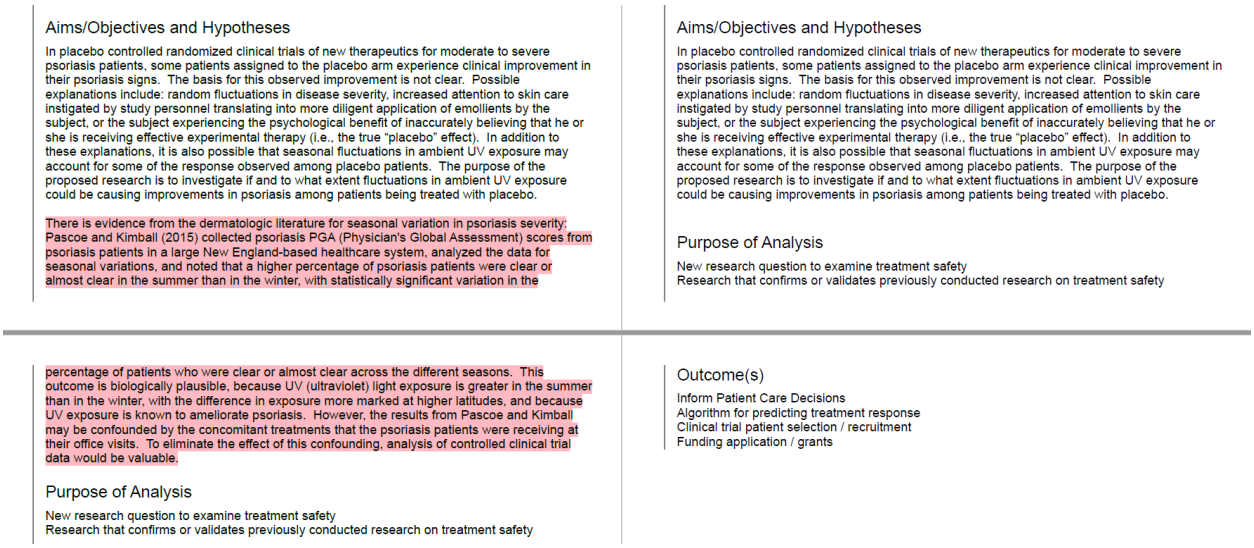
Name of the degree

PhD in Psychology

Education Institution

University of California, San Francisco

Red highlighted sections indicate text that has been deleted:



Aims/Objectives and Hypotheses

In placebo controlled randomized clinical trials of new therapeutics for moderate to severe psoriasis patients, some patients assigned to the placebo arm experience clinical improvement in their psoriasis signs. The basis for this observed improvement is not clear. Possible explanations include: random fluctuations in disease severity, increased attention to skin care instigated by study personnel translating into more diligent application of emollients by the subject, or the subject experiencing the psychological benefit of inaccurately believing that he or she is receiving effective experimental therapy (i.e., the true "placebo" effect). In addition to these explanations, it is also possible that seasonal fluctuations in ambient UV exposure may account for some of the response observed among placebo patients. The purpose of the proposed research is to investigate if and to what extent fluctuations in ambient UV exposure could be causing improvements in psoriasis among patients being treated with placebo.

There is evidence from the dermatologic literature for seasonal variation in psoriasis severity: Pascoe and Kimball (2015) collected psoriasis PGA (Physician's Global Assessment) scores from psoriasis patients in a large New England-based healthcare system, analyzed the data for seasonal variations, and noted that a higher percentage of psoriasis patients were clear or almost clear in the summer than in the winter, with statistically significant variation in the

Aims/Objectives and Hypotheses

In placebo controlled randomized clinical trials of new therapeutics for moderate to severe psoriasis patients, some patients assigned to the placebo arm experience clinical improvement in their psoriasis signs. The basis for this observed improvement is not clear. Possible explanations include: random fluctuations in disease severity, increased attention to skin care instigated by study personnel translating into more diligent application of emollients by the subject, or the subject experiencing the psychological benefit of inaccurately believing that he or she is receiving effective experimental therapy (i.e., the true "placebo" effect). In addition to these explanations, it is also possible that seasonal fluctuations in ambient UV exposure may account for some of the response observed among placebo patients. The purpose of the proposed research is to investigate if and to what extent fluctuations in ambient UV exposure could be causing improvements in psoriasis among patients being treated with placebo.

Purpose of Analysis

New research question to examine treatment safety
Research that confirms or validates previously conducted research on treatment safety

percentage of patients who were clear or almost clear across the different seasons. This outcome is biologically plausible, because UV (ultraviolet) light exposure is greater in the summer than in the winter, with the difference in exposure more marked at higher latitudes, and because UV exposure is known to ameliorate psoriasis. However, the results from Pascoe and Kimball may be confounded by the concomitant treatments that the psoriasis patients were receiving at their office visits. To eliminate the effect of this confounding, analysis of controlled clinical trial data would be valuable.

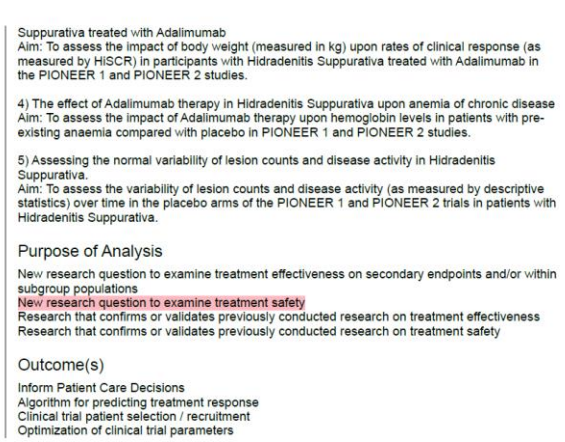
Purpose of Analysis

New research question to examine treatment safety
Research that confirms or validates previously conducted research on treatment safety

Outcome(s)

Inform Patient Care Decisions
Algorithm for predicting treatment response
Clinical trial patient selection / recruitment
Funding application / grants

Blue/purple highlighted sections indicate text has been moved from one section to another



Suppurativa treated with Adalimumab
Aim: To assess the impact of body weight (measured in kg) upon rates of clinical response (as measured by HiSCR) in participants with Hidradenitis Suppurativa treated with Adalimumab in the PIONEER 1 and PIONEER 2 studies.

4) The effect of Adalimumab therapy in Hidradenitis Suppurativa upon anemia of chronic disease
Aim: To assess the impact of Adalimumab therapy upon hemoglobin levels in patients with pre-existing anaemia compared with placebo in PIONEER 1 and PIONEER 2 studies.

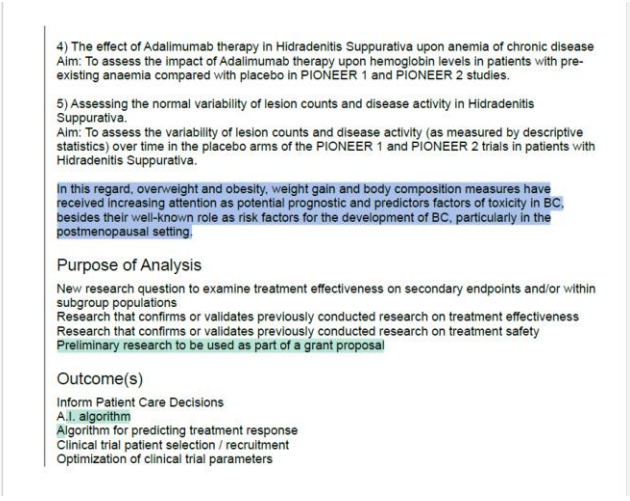
5) Assessing the normal variability of lesion counts and disease activity in Hidradenitis Suppurativa.
Aim: To assess the variability of lesion counts and disease activity (as measured by descriptive statistics) over time in the placebo arms of the PIONEER 1 and PIONEER 2 trials in patients with Hidradenitis Suppurativa.

Purpose of Analysis

New research question to examine treatment effectiveness on secondary endpoints and/or within subgroup populations
New research question to examine treatment safety
Research that confirms or validates previously conducted research on treatment effectiveness
Research that confirms or validates previously conducted research on treatment safety

Outcome(s)

Inform Patient Care Decisions
Algorithm for predicting treatment response
Clinical trial patient selection / recruitment
Optimization of clinical trial parameters



4) The effect of Adalimumab therapy in Hidradenitis Suppurativa upon anemia of chronic disease
Aim: To assess the impact of Adalimumab therapy upon hemoglobin levels in patients with pre-existing anaemia compared with placebo in PIONEER 1 and PIONEER 2 studies.

5) Assessing the normal variability of lesion counts and disease activity in Hidradenitis Suppurativa.
Aim: To assess the variability of lesion counts and disease activity (as measured by descriptive statistics) over time in the placebo arms of the PIONEER 1 and PIONEER 2 trials in patients with Hidradenitis Suppurativa.

In this regard, overweight and obesity, weight gain and body composition measures have received increasing attention as potential prognostic and predictors factors of toxicity in BC, besides their well-known role as risk factors for the development of BC, particularly in the postmenopausal setting.

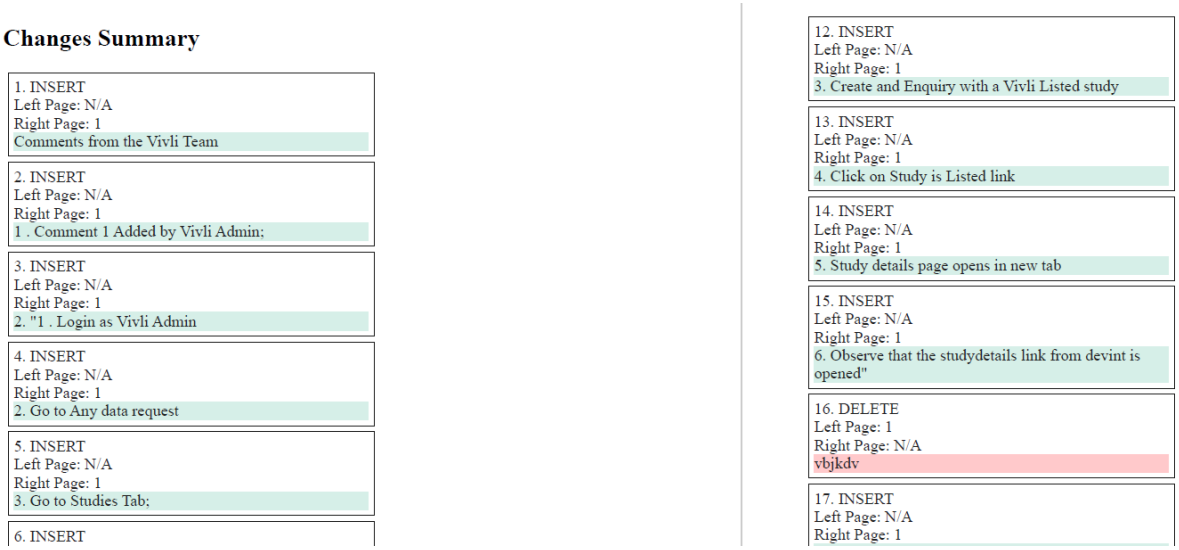
Purpose of Analysis

New research question to examine treatment effectiveness on secondary endpoints and/or within subgroup populations
Research that confirms or validates previously conducted research on treatment effectiveness
Research that confirms or validates previously conducted research on treatment safety
Preliminary research to be used as part of a grant proposal

Outcome(s)

Inform Patient Care Decisions
A.I. algorithm
Algorithm for predicting treatment response
Clinical trial patient selection / recruitment
Optimization of clinical trial parameters

There is a summary at the end of the document of all changes made:



Changes Summary

1. INSERT
Left Page: N/A
Right Page: 1
Comments from the Vivli Team

2. INSERT
Left Page: N/A
Right Page: 1
1 . Comment 1 Added by Vivli Admin;

3. INSERT
Left Page: N/A
Right Page: 1
2. "1 . Login as Vivli Admin

4. INSERT
Left Page: N/A
Right Page: 1
2. Go to Any data request

5. INSERT
Left Page: N/A
Right Page: 1
3. Go to Studies Tab;

6. INSERT

12. INSERT
Left Page: N/A
Right Page: 1
3. Create and Enquiry with a Vivli Listed study

13. INSERT
Left Page: N/A
Right Page: 1
4. Click on Study is Listed link

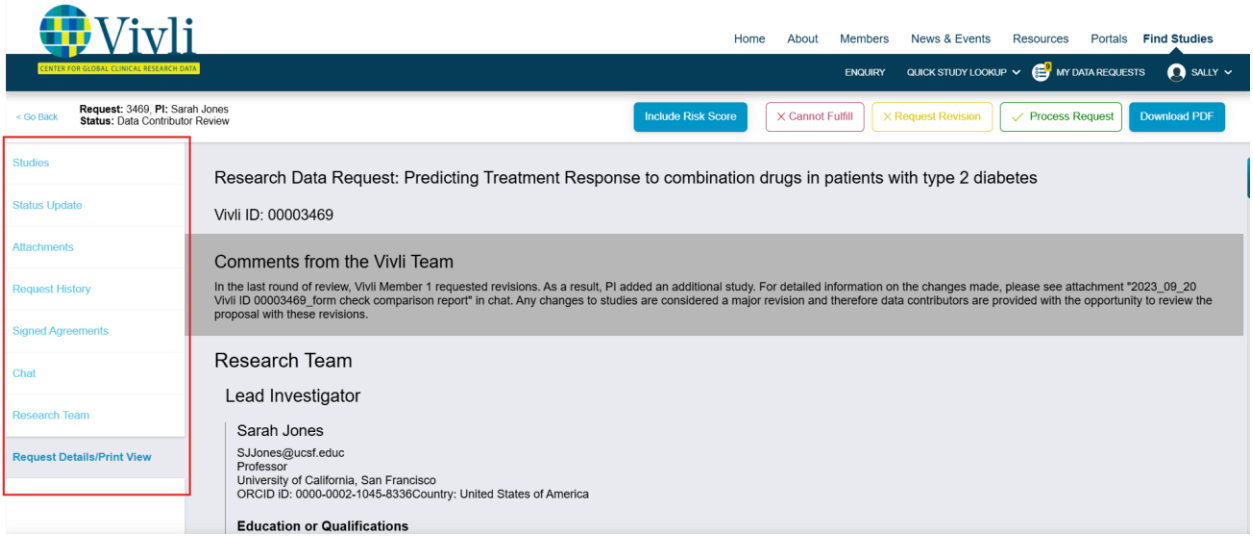
14. INSERT
Left Page: N/A
Right Page: 1
5. Study details page opens in new tab

15. INSERT
Left Page: N/A
Right Page: 1
6. Observe that the studydetails link from devint is opened"

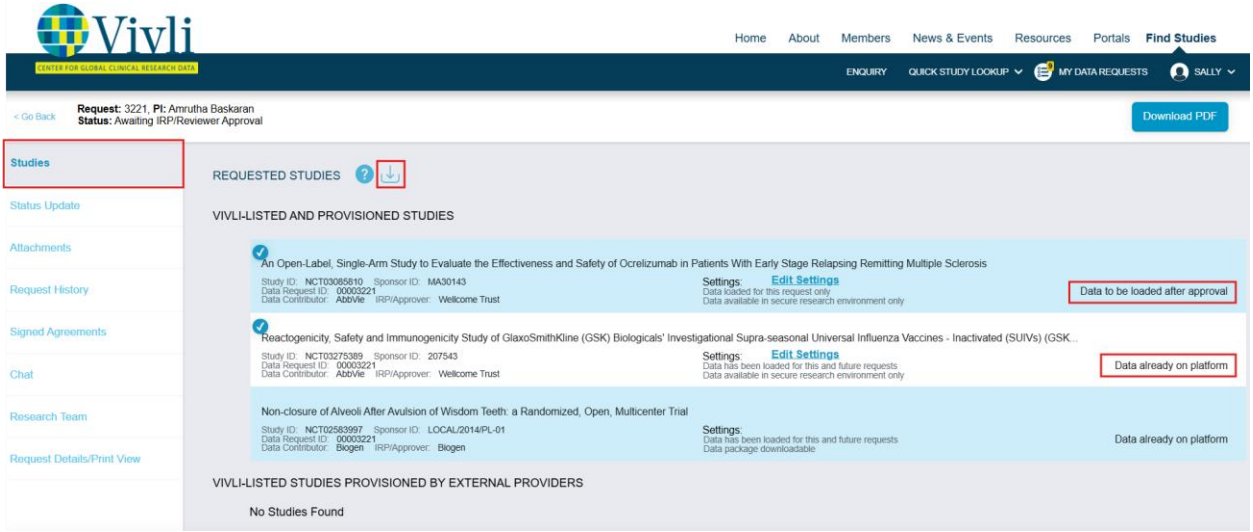
16. DELETE
Left Page: 1
Right Page: N/A
vbjkdv

17. INSERT
Left Page: N/A
Right Page: 1

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



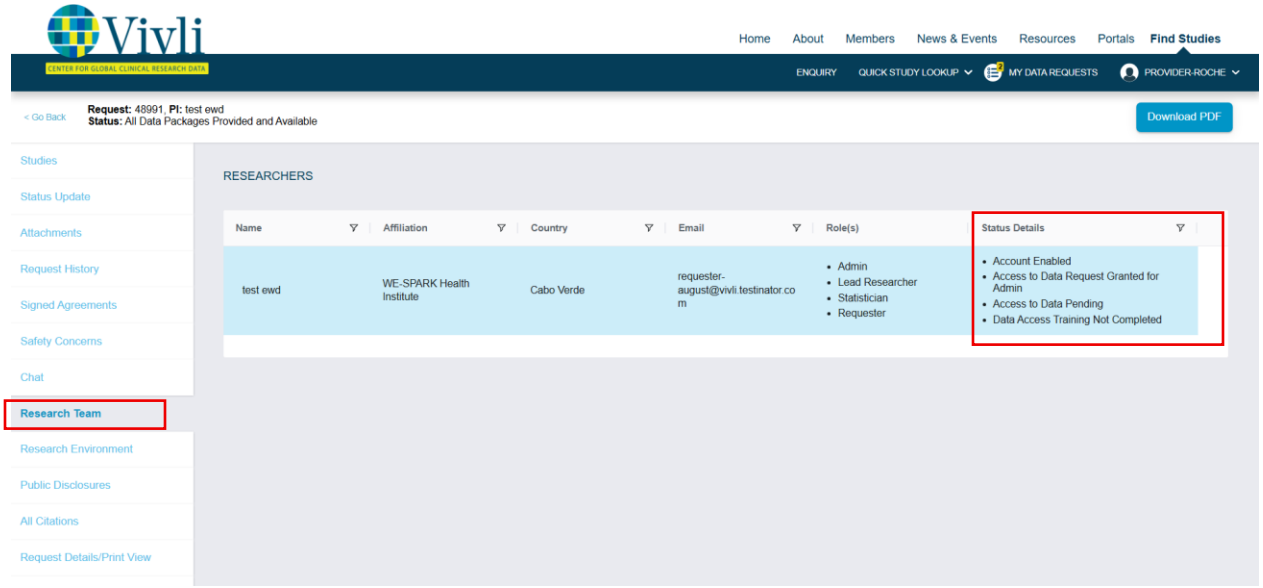
- **Studies tab:** lists all the studies associated with the data request. Studies appear sorted by data contributor name (alphabetically) with your Organization's studies appearing on top. The studies tab also provides information about the availability of the stored data package. If there was a stored 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 4.5.3. Status Update. For the DUA Subtab, please see Section 4.6. Data Use Agreement
- **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 Member 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, reported Safety concerns, Research Environment provisioned, Research Environment de-provisioned, Request Archival and Request Withdrawal.
- **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**: Please see section 11.1 Chat.
- **Research Team** tab: Shows all of the Researchers in the Research Team and lists information about their Affiliation, Country, Email, Role(s) and Status Details.
    - **Status Details**:

- **Account Enabled**: Means this Researcher has an active Vivli account. All Lead Researchers must have an Active Vivli Account and Access to the Data Request.
- **No Account**: Means the Researcher does not have an Active Vivli Account.
- **Access to Data Request Granted for Admin**: Means this Researcher can access the Data Request form as an Admin.
- **Access to Data Request**: Means the Researcher has access to the Data Request form.
- **Access to Data Request Pending**: Means the Researcher cannot yet access the Data Request form.
- **Access to Data Request Denied**: Means the Researcher cannot access the Data Request form.
- **Access to Data Granted**: Means the Researcher can access the data.
- **Access to Data Denied**: Means the Researcher cannot access the data.
- **Data Access Training Completed**: Data Access Training has been completed.
- **Data Access Not Completed**: Data Access training has not been completed.



- **Public Disclosures: Shows the individual public disclosures submitted by the Researcher for the 30-day review.** (This tab is visible after the request reaches the data upload stage).
- **Citations**: List of final citations linked to the specific data request. (This tab is visible after the request reaches the data upload stage).

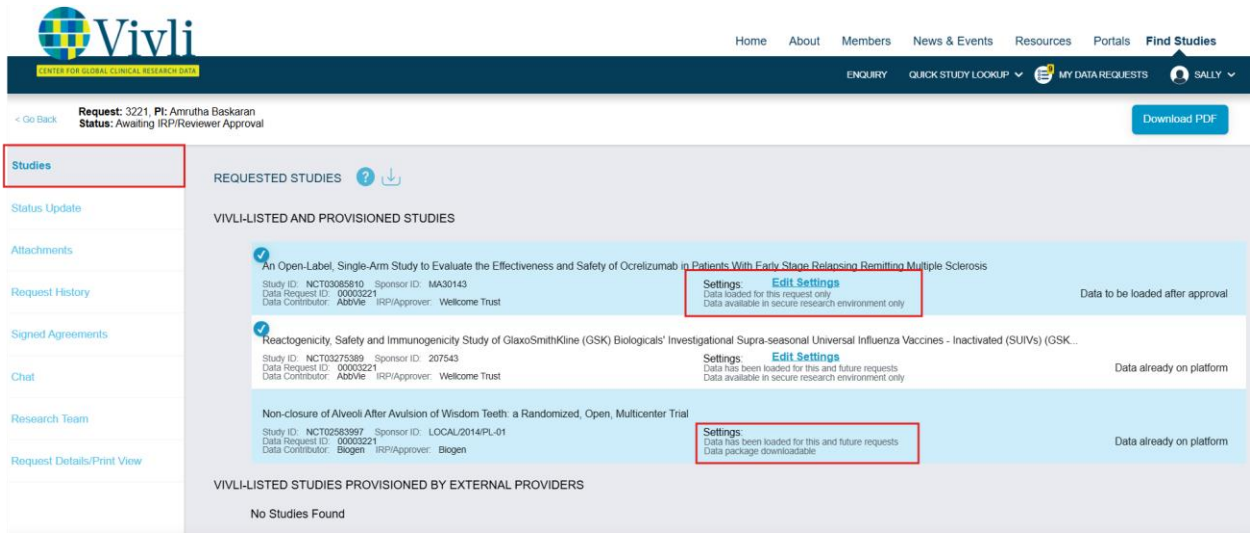
  Once the secure research environment is started, the following tabs will appear on the data request.
- **Safety Concerns**: Please see Section 10. Safety reporting
- **Research Results**: Results requested by the researcher.
- **Secure Research Environment**: Secure research environment tab can be accessed only by the researcher.

4.2.5 Vivli Policies in Brief

Policies in brief for researchers are available on Vivli's website. Researchers are provided with this information while drafting the data request. Policies in brief provide a synopsis of the key policies that govern the interactions between researchers and Vivli Members 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.

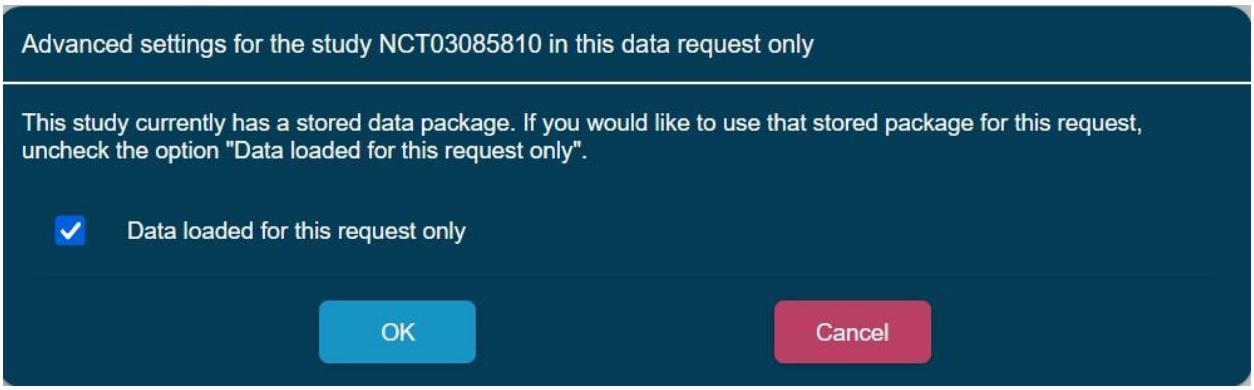
4.3 Study Settings at Data Contributor Review

Organizational Administrators 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”.

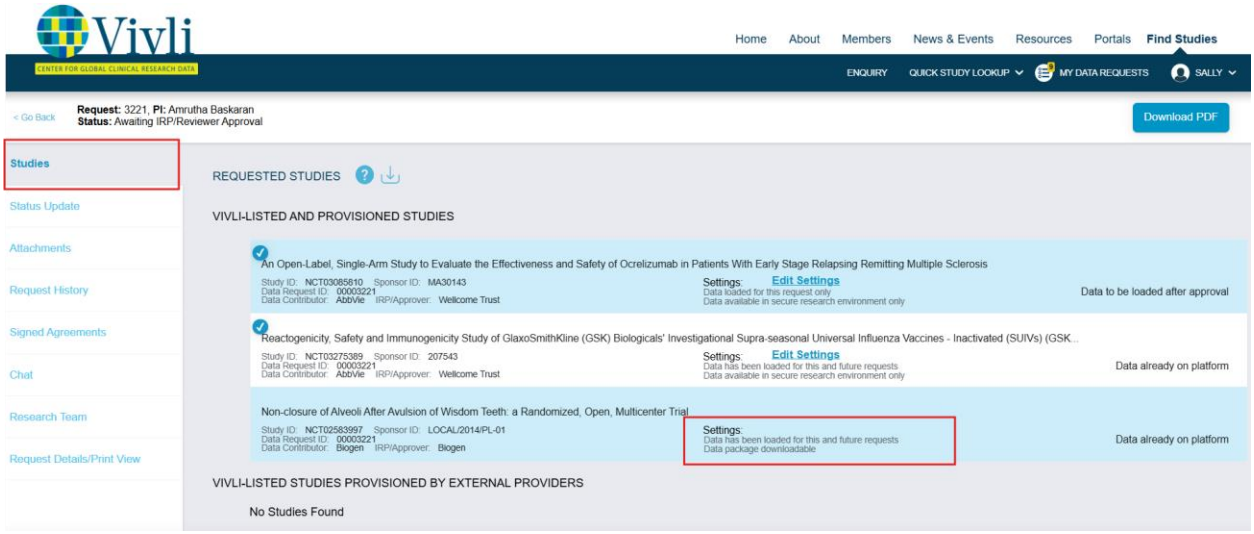


The following pop-up will display on the page:

- 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.”



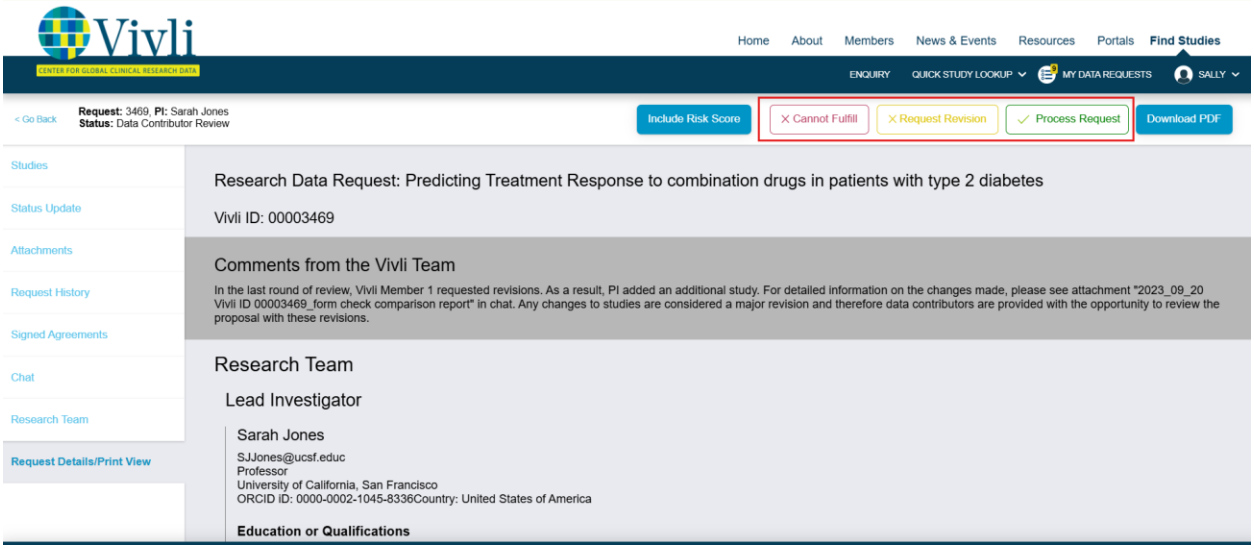
In addition, the Organization Administrators can see whether a particular study package is available in the secure research environment only or downloadable (view only)To make any changes to the download setting, please contact Vivli at support@.vivli.org.



Note: Edit settings are available only for listed studies and not for unlisted studies added to the data request.

4.4 Recording a Decision about a Data Request

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



The data request decision options are:

4.4.1 Cannot Fulfill

1. You may use this option if the data request or all the studies in the data request don't meet your Organization's Data-Sharing policy in accordance with your members' page

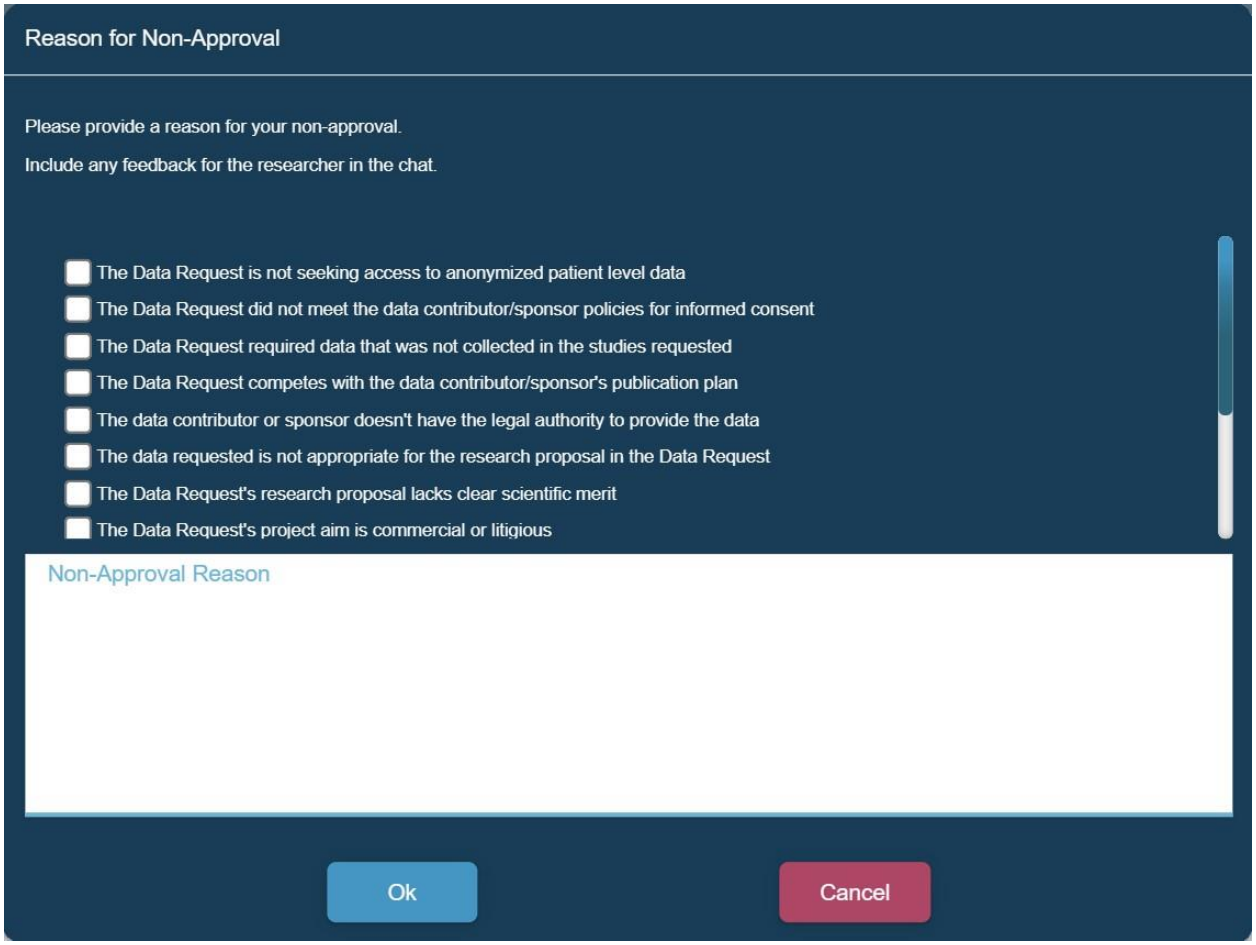
2. Any reason for being unable to fulfill a request needs to be transparent and listed as a reason for not sharing on your member's page.

3. When recording the decision on the platform, click the "Cannot fulfill" button and then choose the appropriate checkbox that matches your member's page. Please don't leave the reason for non-approval blank. Please also check the "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 the scope of our data sharing policy as the trial is still ongoing or this study is out of scope due to ongoing litigation.

4. If the Organizational Administrators cannot fulfill the request for any reason, click **Cannot Fulfill:**

5. A dialogue box will pop up where you can provide the reason for non-approval. Choose the appropriate checkbox that matches your member's page. Please don't leave the reason for Non-Approval blank:



6. 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

7. 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).

8. 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.

9. This Data Request will now be categorized as “Not Approved” in the Data Request status bar and 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's team will follow up with the other appropriate member to record their decision. Once all the decisions are recorded, the researcher may remove the not approved studies and move forward with the rest of the studies from other members.

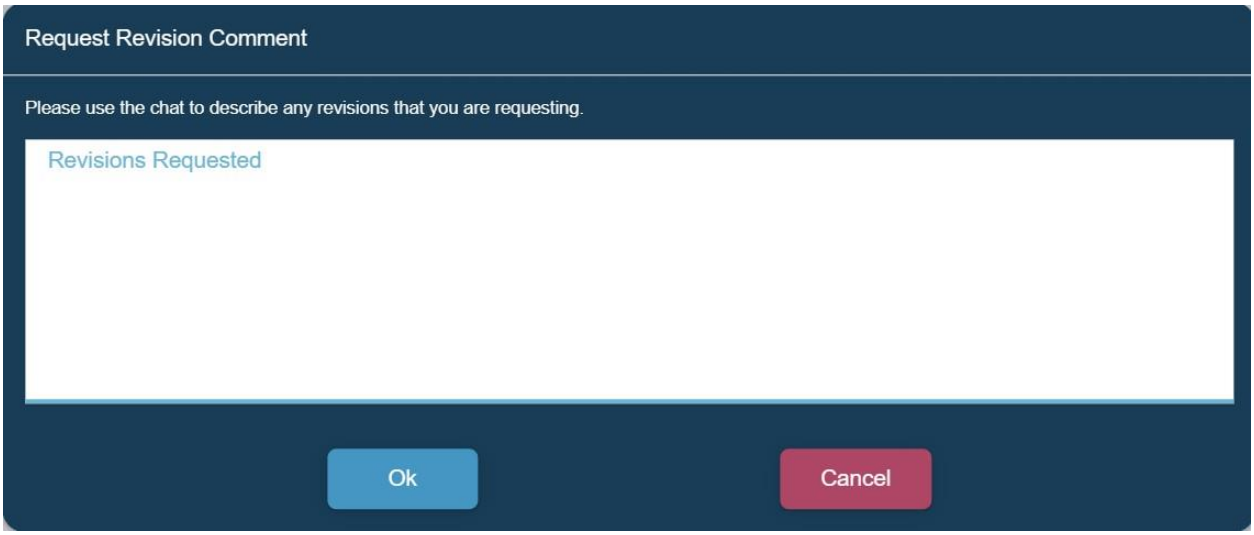
11. If a request is not approved, Vivli will reach out to you to confirm that this reason is listed and transparent on your member’s page. Any final non-approvals will be reflected in the public metrics once the data request governance process, including DUA execution, has been completed.

4.4.2 Request Revision

1. 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 non-approved. In this case, please let the Researcher know which studies don't meet your Organization Data Sharing policy and your reason for non-approval of the studies in accordance with your members' page. Please see section 4.4.1 Cannot Fulfill 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 non-approvals 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.

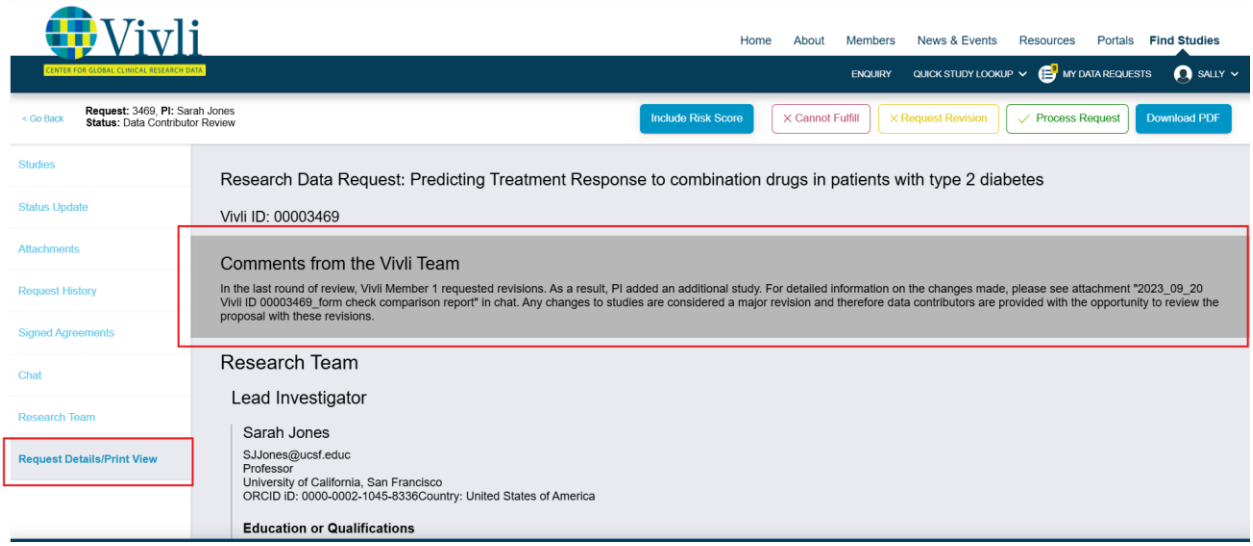
1. If the Organizational Administrators require revisions to the Data Request Form, click **Request Revision**:

2. A dialogue box will appear where you can enter the details of 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:

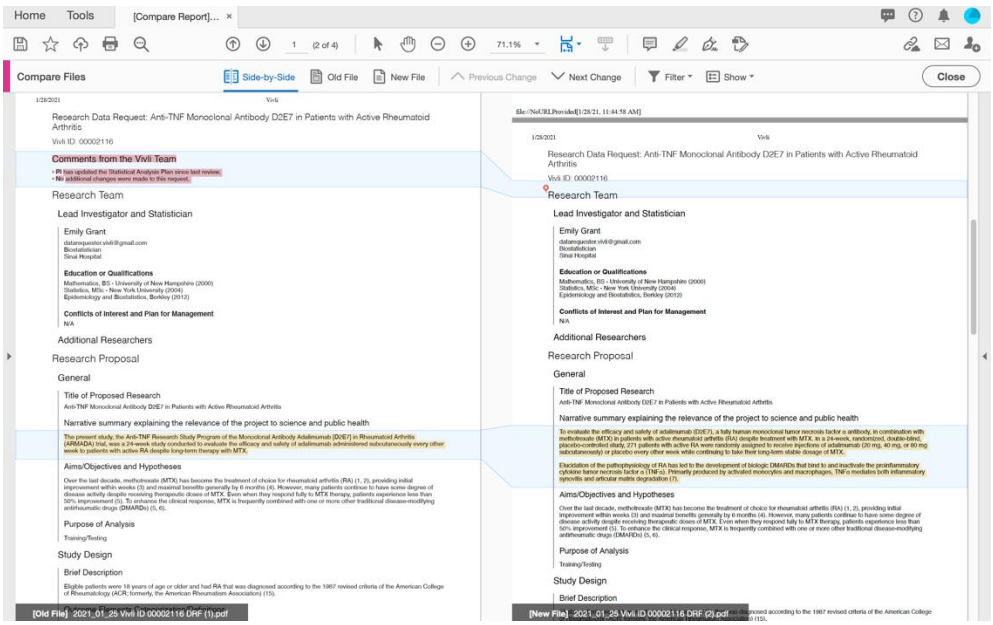


3. When finished, click **OK** and this will send an automated email to the Data Requestor informing them of your decision.

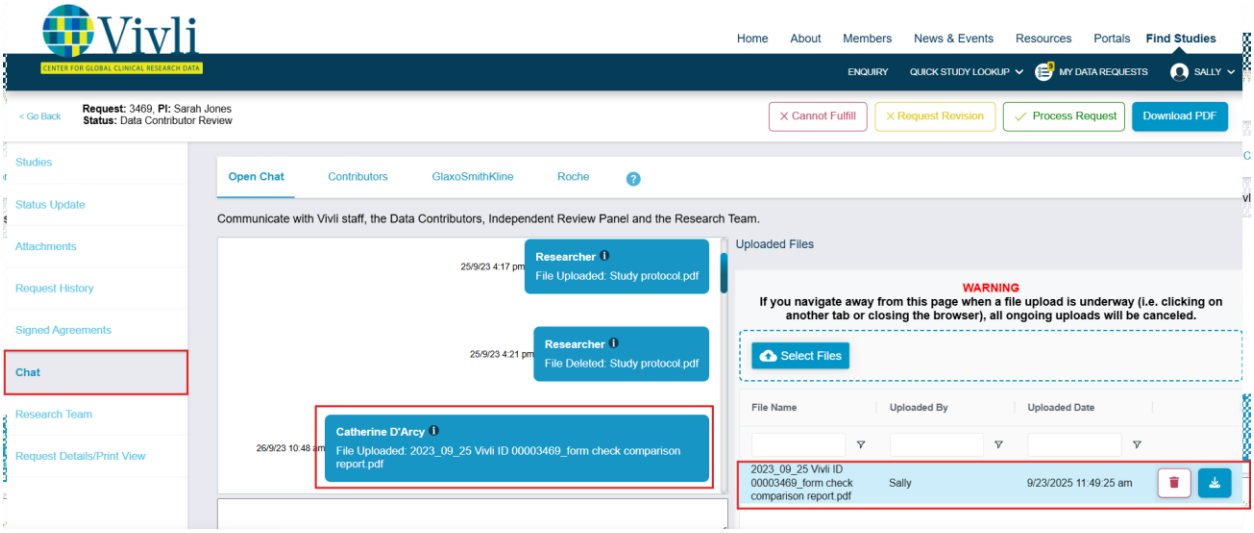
4. This Data Request will now be categorized as “Not Approved” in the Data Request status bar and remain in that status until the Vivli Admin resets it to drafts for the data requester to make the revisions. At this stage, the data request will be in the drafts section.
5. The Data Requestor can review your comments regarding the revision in the request history section.
6. Once the Data Requester has revised and re-submitted their request, the 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 Section 4.4.4 Major Versus Minor Revisions to Data Requests.



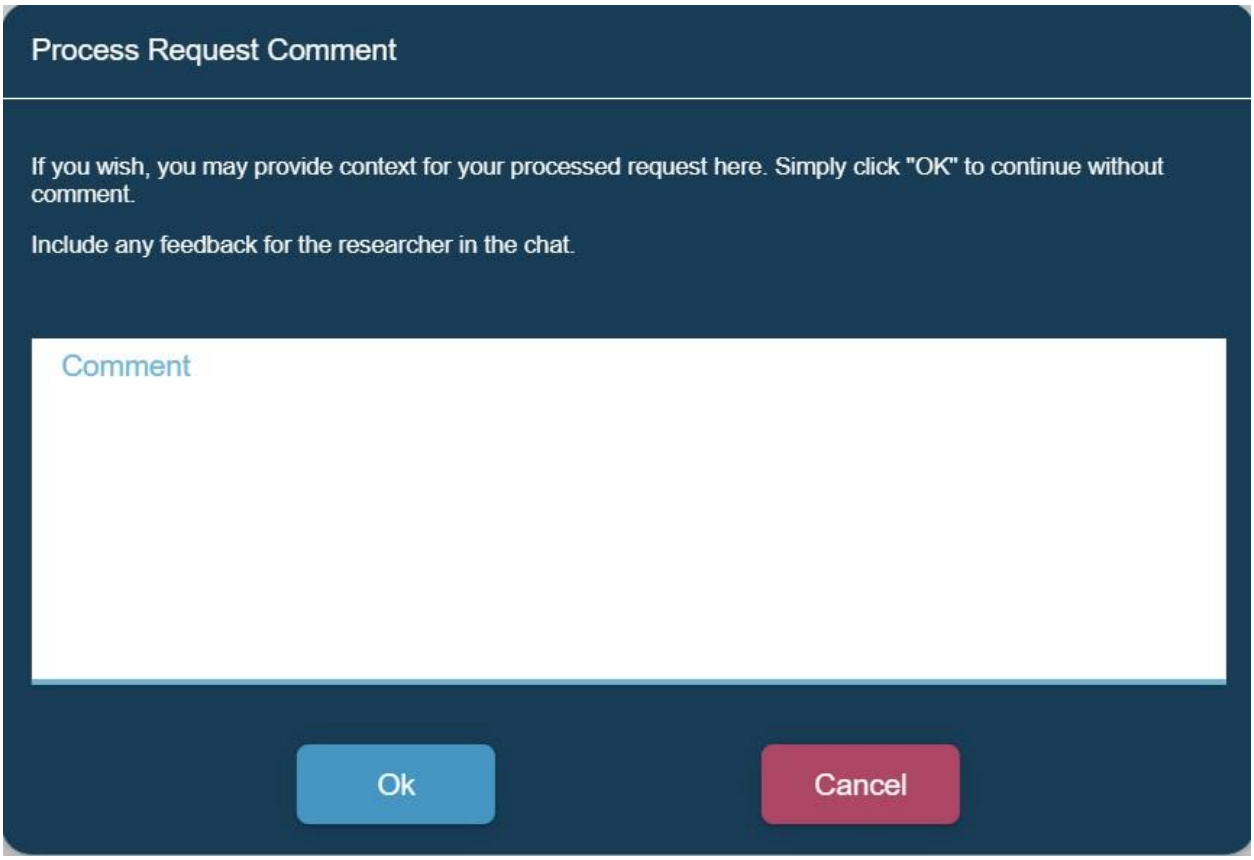
9. Your decision will be recorded in the Request history of the Data Request.
10. For multi-sponsor requests, if your organization has recorded its decision but another organization has not, the request will remain in the Data Contributor review stage under the **Active** status bar. Vivli's team will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

4.4.3 Process Request

You may use this option if the data request or all the studies in the data request meet your Organization's Data Sharing policy in accordance with your members' page.

1. To send the request to the next stage, click **Process Request:**

2. A dialogue box will pop up where the Organizational Administrator 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's team will follow up with the appropriate member to record their decision.

4.4.4 Major Versus Minor Revisions to Data Requests

Change	Classification (major/minor)
Change of Primary Investigator's institution to a for-profit entity	Major
Change of Lead Statistician's institution to a for-profit entity	Major
Change to Statistical Analysis Plan/upload of external data not mentioned in the data request	Major
Change to Conflict of Interest or funding Statement	Major
Change to Primary Investigator or their institution (academic)	Minor
Change to Lead Statistician or their institution (academic)	Minor
Adding or Removing Studies	Approval by member who owns studies
Other Personnel Changes	Minor
Other changes to the request form excluding the statistical analysis plan (e.g. Spelling out acronyms)	Minor

- If a data requester wants to make any major changes to the data request form as defined above **before the review process is complete**, depending on the stage of the review, the Vivli team will either make changes on the researchers' behalf and inform the Organizational Administrators via chat, or send the request back to draft for them to make the changes and resubmit for review.
- If a data requester makes any major changes to the data request form as defined above **after the data request review process is complete**, Vivli will reach out to Organizational Administrators via "Contributors" chat (visible to Organizational Administrators and Vivli Admins) to ask if they approve this change. If all Organizational Administrators' 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. The DUA will also need to be re-executed along with the updated data request form. If one of the Organizational administrators requests this change go through formal approval, the Vivli team will inform the data requester that they must submit a new data request.
- For minor changes to the Primary Investigator, Vivli will notify the Organizational Administrators via "Contributors" chat (visible to Organizational Administrators and Vivli Admins) of the change, and allow 1 week for comments before making the change on the requester's behalf.
- 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 Organizational Administrators via "Contributors" chat (visible to Organizational Administrators and Vivli Admins) to ask if the data contributor approves this change. If they 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 the data contributor requests this change go through formal approval, the Vivli team will inform the data requester that they must submit a new data

request. (Please note that this is not typical and most members review in chat as this is most efficient for all stakeholders).

- If a data requester wants to add any studies from **a different Vivli Member who has not reviewed the data request after the review process is complete**, the data requester will be required to submit a new request. A new DUA will also need to be executed. Analysis conducted in the existing secure Research Environment can be made available in the new Environment for combination with subsequent data analysis if all of the original studies are included in the new submission. 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 Vivli Members involved.

Key factors that influence the timeline:

- If Institution has an existing master DUA with Vivli or needs to execute a Master DUA
- Requesters response time to questions and feedback by data contributors
- Number of studies being requested

4.4.5 Withdrawal

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 has been received from the Research Team to Vivli Admin for 5 months following bi-weekly follow-ups in chat

After 5 months, the Vivli Admin will place a note in chat 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, the request can continue through the process. Otherwise, the request is considered abandoned. The researcher may contact Vivli at support@vivli.org anytime to move the request back from withdrawn to drafts.

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.

4.4.5 Target Timeline for the Review Process

1. Vivli Form Check Initial Response	2. Vivli form check Complete	3. Data Contributor's (DC) initial response	4. DC's 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

4.4.6 Summary-level and Document-only Data Request

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

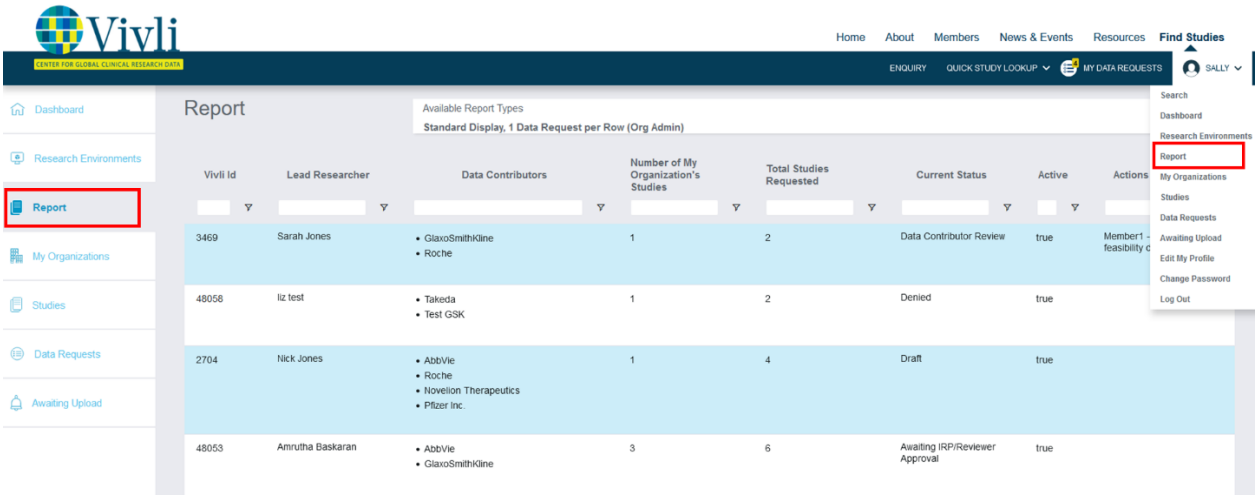
Here is a lighter-weight process for such data requests:

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. Organization Administrators the study setting by checking the checkbox “Data loaded for this request only”. See Section 4.3 Study Settings at Data Contributor Review
4. Vivli Admin will reach out to the Organization Administrator via “Contributors” chat to confirm if the member agrees to skip the IRP review and make the summary level data available for download
5. Organization Administrator records the Data Contributor review as a standard
6. Data request skips IRP review
7. Standard Data Use Agreement and security addendum is signed
8. Data Upload the specific data just for this data request
9. Summary-level data and documents to be downloaded by the researcher
10. 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		

4.5 Reports

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 nine types of reports:

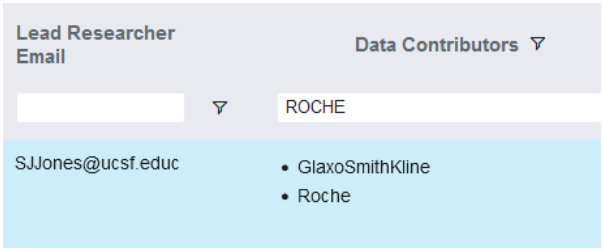
1. Standard Display, 1 Data Request per row (Org Admin), is the default option which is a display-oriented report and contains an overview of the request.
2. Standard Export, 1 Data Request per row, adds more information on requested studies, and many fields from the data request form.
3. Full Export, 1 Requested Study per Row, repeats the standard export row once for each requested study.
4. Studies (Org Admin), a list of the studies a Vivli Member has listed on the Vivli platform, with study details and usage metrics
5. Enquiries Report (Org Admin), 1 enquiry per row, a list of the enquiries submitted for a Vivli Member
6. Metric Export (Org Admin), a detailed report of metrics for all data requests, including days taken between steps in the review process and mean values for comparison to other data contributors
7. Public Disclosures (Org Admin), a report of all public disclosures submitted through the new public disclosures tab within a data request
8. Data Request Summary Report (Org Admin), a report to show all data requests including outstanding actions and those that do not require an action. See Section 1.3.1 Reviewing My Actions.
9. Research Team Report, a report to show the list of all research team members included in their data requests and associated details like the country of research.

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

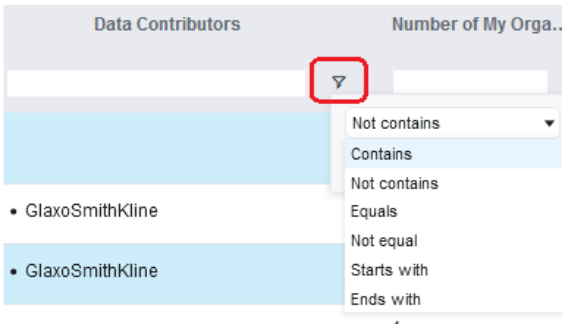
4.5.1. Features of the Report

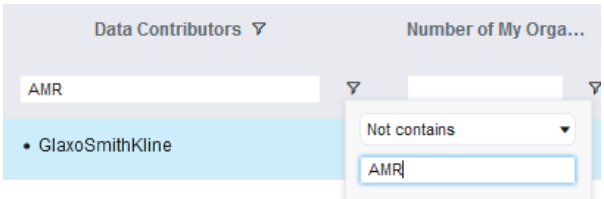
The download icon allows you to download what is currently displayed (and filtered)

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



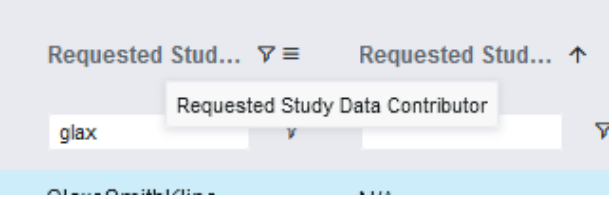
When you see a funnel next to the white field, you can use that to specify a different type of filter, such as Not Contains. Contains, Equals, Not equal, Starts with and Ends with.





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.

4.5.2. Fields Included in the Report

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

- Vivli ID
- Lead Researcher
- Lead Researcher affiliation
- Lead Research country
- 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, Not Approved, 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 Vivli Members at a particular stage as set by the Vivli admin. This complements the decisions and uploads the 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 the Target Days for the 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 Organizational Administrators to provide any comments in response to weekly summary comments. For more information, please see Section 4.5.3. Status Update
- Request Review Status – shows Form check, Data Contributor review, and IRP review decision
- DUA Execution
- DUA Expiration
- 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 Title
- Lead Researcher Email
- Date First Published
- Main Predictor/Independent Variable
- Publication Plan
- Brief Description
- Aims, Objectives, Hypotheses
- Purpose of Analysis
- Outcomes
- Therapeutic Area (of the data request)
- Public disclosures
- Number of Public disclosures

- All Studies Included by Sponsor ID/NCT ID
- Data Request DOI

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:

    - Lead Sponsor Agency
    - 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
    - Version of data
    - Phase

- # participants
- IRP Name

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 (Org Admin)*, has a row per listed study for your organization, with some study metadata and usage metrics

- NCT Id
- Sponsor Protocol Id
- Secondary ID
- Posted Date
- Submitted Date
- Org Name
- Lead Sponsor Agency
- Lead Sponsor Class
- Approving Organization
- Study Title
- Funder Names
- Parent Funder Names
- Citation Count
- Study Metadata Doi
- Is Data Uploaded
- Version of Data
- Conditions
- Interventions
- Therapeutic Areas (of the study, assigned by Vivli using 'Conditions' and a standard therapeutic area list)
- All Data Requests Count (includes submitted requests only)
- Contained in All Requests
- Approved Data Requests Count (includes requests that has passed DUA validation)
- Approved Data Requests
- # Participants
- Study Documents (See Section 5.12 Supporting Documents for Researchers Searching For Studies)
- Public Disclosures
- Last Updated

5. *Enquiries Report*, has one row per requested study in a given Enquiry. For more information, please see Section 3.4 Enquiries Report

6. *Metrics Export, 1 Data Request per row*, includes the following fields:

- Request Number
- Name of Lead Researcher
- Request Title
- Therapeutic Area
- Data Contributors
- # of My Org's Studies
- # Studies for All Orgs
- NCT IDs from My Org
- Study Sponsor IDs From my Org
- # Participants for My Org's Studies
- # Participants for All Orgs' Studies
- Outcomes Specified by Requester
- Current Request Status
- Current Stage
- Start Date of Current Step
- Date First Submitted to Vivli
- Date entered DC Review
- "1" if ever reached DC Review
- "1" if My Org ever Requested Revisions
- "1" if My Org ever Rejected
- "1" if My Org ever Approved
- Days to My Org's DC Decision
- Target for DC Review
- Mean Days to Decision for All DCs, All Requests
- Total Days My Org spent in DC Review
- Max Days to Decision for All Orgs
- Most Recent Decision by My Org
- Date of My Org's Most Recent Decision
- Date entered IRP Review
- "1" if ever reached IRP Review
- "1" if my IRP ever Requested Revisions
- "1" if my IRP ever Rejected
- "1" if my IRP ever Approved
- Days to my IRP's Decision
- Target for IRP Review
- Mean Days to Decision for All IRPs, All Requests

- Total Days My Org spent in IRP Review
- Max Days to Decision for All IRPs
- Most Recent Decision By My IRP
- Date of My IRP's Most Recent Decision
- List of IRPs
- Date Entered DUA Review
- "1" if ever Reached DUA Approval
- Total Days in DUA Approval
- Mean Days in DUA Approval for all Requests
- Date Available for Upload Data
- Days to Upload All My Org's Data
- Target Days to Upload All My Org's Data
- Date All Data from All DCs Uploaded
- Research Environment Provisioned Date
- Research Environment Deprovisioned Date
- Days Research Environment Available
- Date First Download of my Org's Data
- Date First Public Disclosure
- Public Disclosure Citations
- # Public Disclosures
- Contributor
- Report Run Date

7. Public Disclosures, *1 Disclosure ID per Row*, includes the following fields:

- Vivli ID
- Lead Researcher
- Lead Researcher Affiliation
- Disclosure ID
- Public Disclosure Current Status
- Data Contributors
- Studies Included
- Disclosure Title
- Disclosure Type
- Journal/Conference Name
- Review Start Date
- Review End Date
- Review Details
- Disclosure Published Date
- Public Disclosure Links
- Citation and DOIs
- Total Public Disclosures in Request
- Current Request Status

- Therapeutic Area
- DUA Expiration
- Results Export Requests
- Data Request DOI

8. *Data Request Summary, 1 Data Request per Row*, includes the following fields:

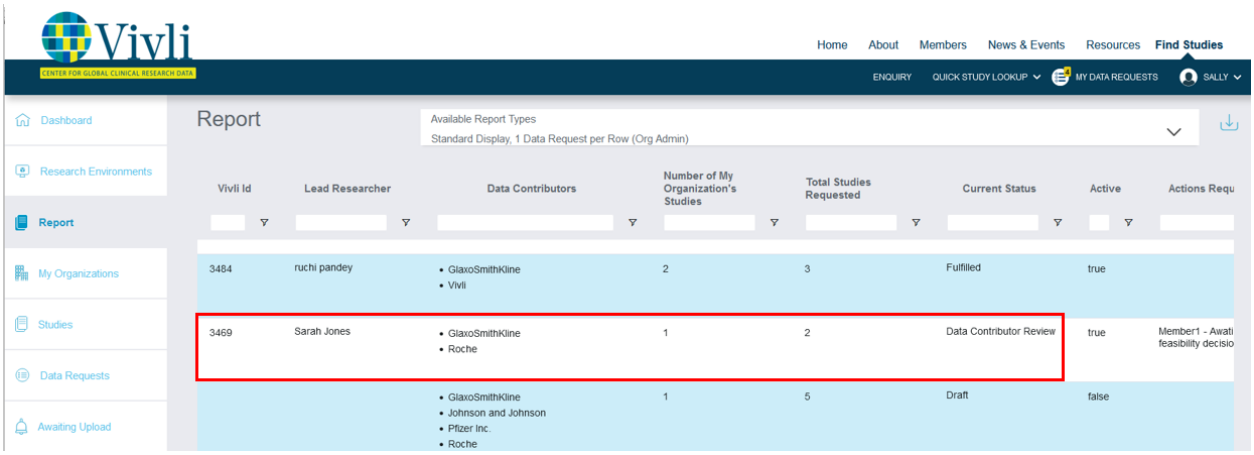
- Vivli ID
- Title
- Lead Researcher
- Lead Researcher Affiliation
- Lead Researcher Country
- Data Contributors
- Current Status
- Actions Required
- Days in Current Workflow Step
- Target Days for Current Workflow Step
- Feedback
- Additional Notes
- Public Disclosure Citations
- Number of Public Disclosures

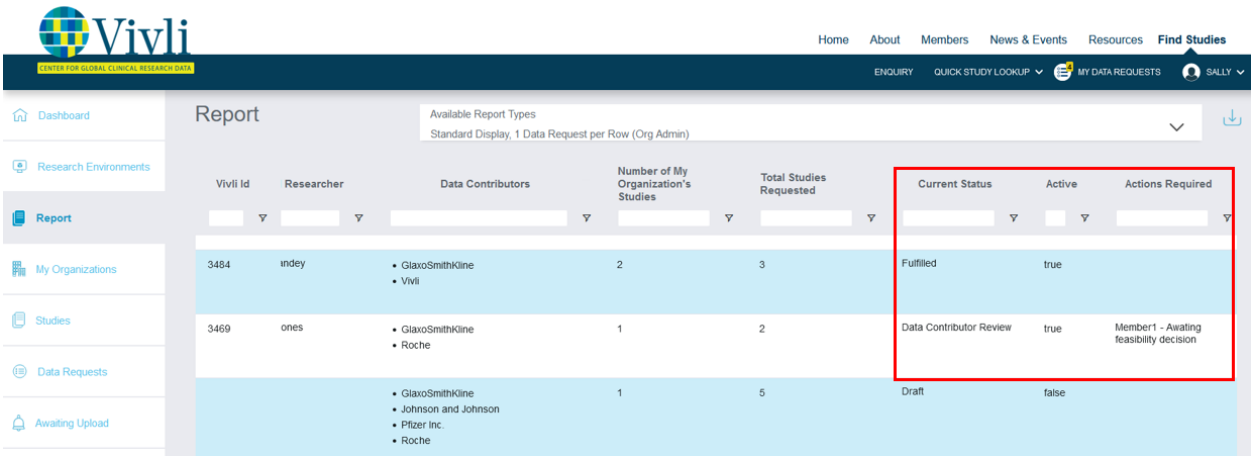
9. *Research Team Report, 1 Research Team Member per Row*, includes the following fields:

- Researcher Name
- Data Request ID
- Request Title
- Researcher Email
- Account Status
- Account Display Name
- Data Request Status
- Date Submitted for Form Check
- Role(s)
- Institution
- Institution DUA expiration
- Country
- Country Analysis Conducted
- Access to the Data Request
- Access to the Data
- Data Access Training Completed
- SRE Status
- Downloadable Study

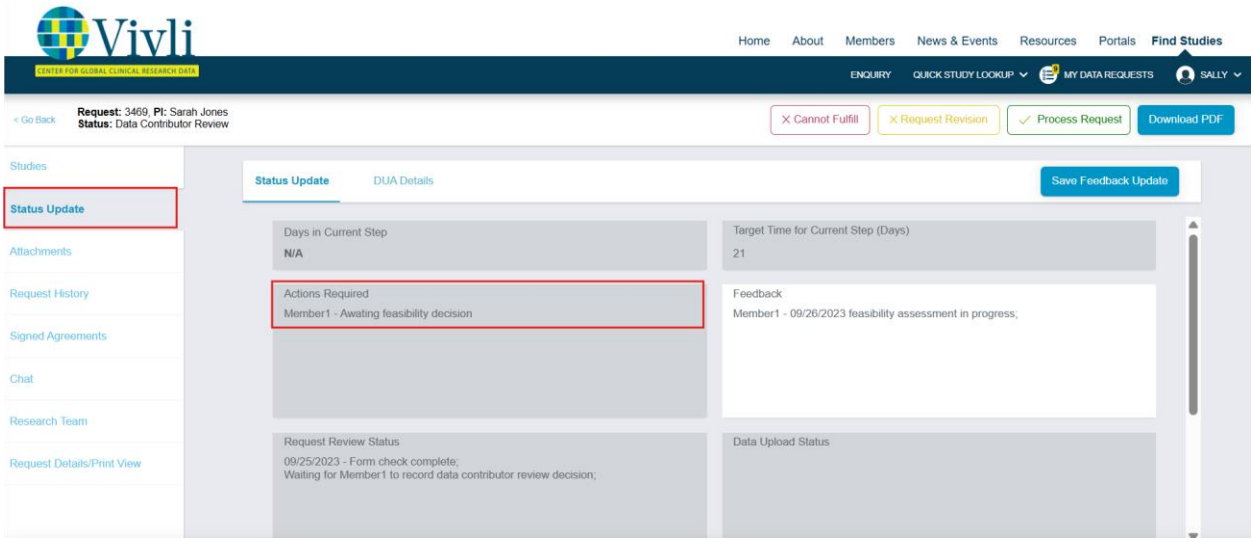
4.5.3. Status Update

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.

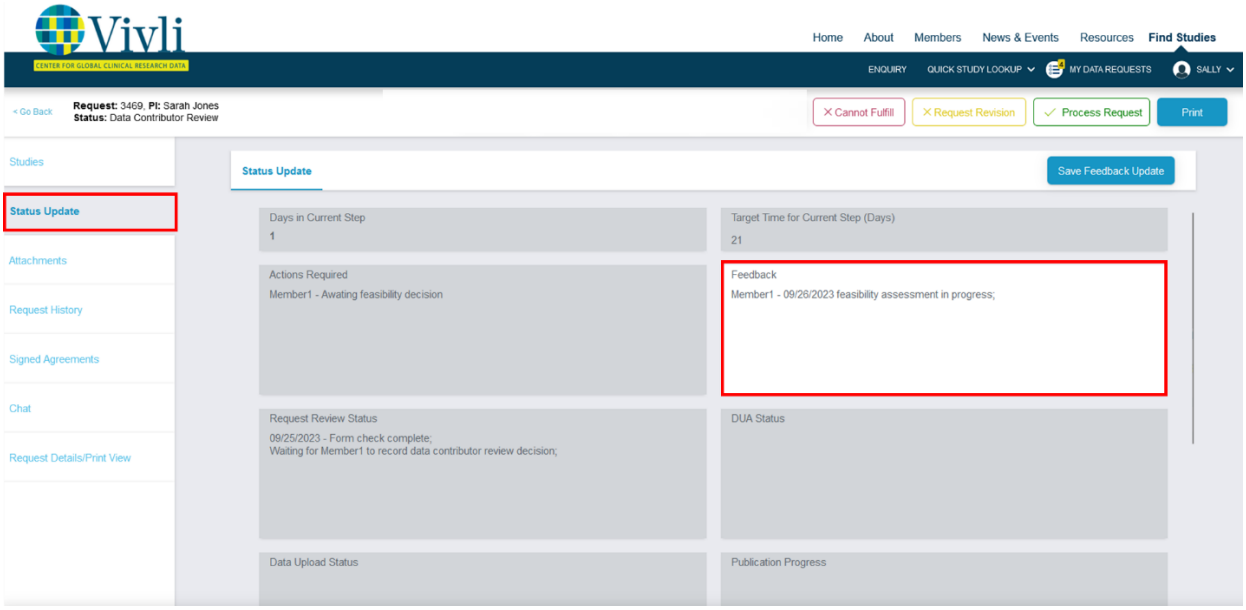




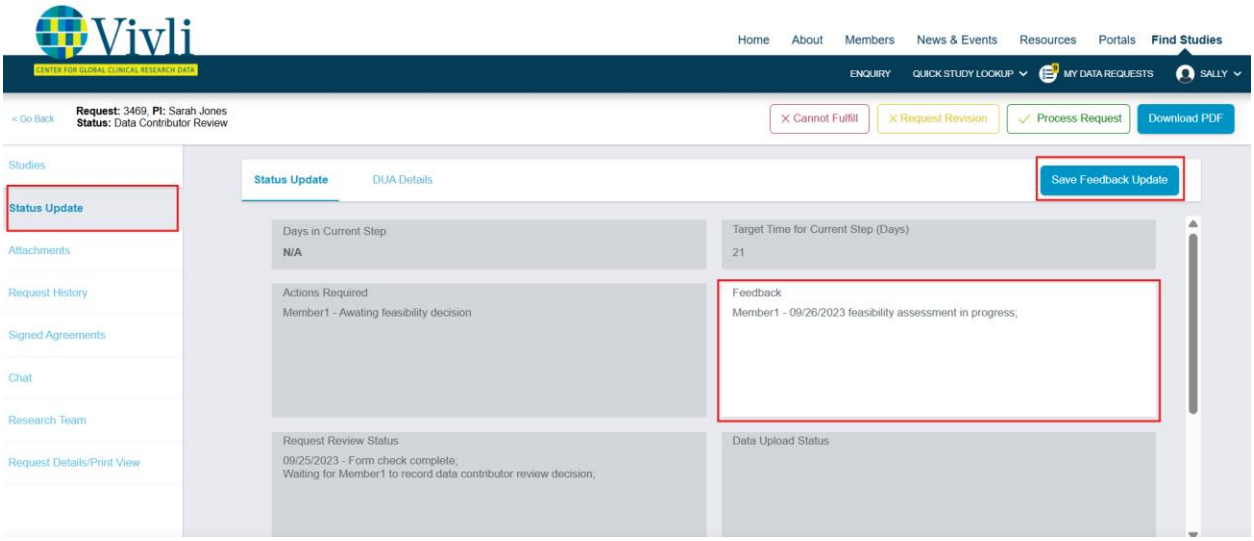
2. Alternatively, the status update can be accessed directly on the data request form. Actions for Organizational Administrator are entered into the ‘Action Required’ field by Vivli.



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



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

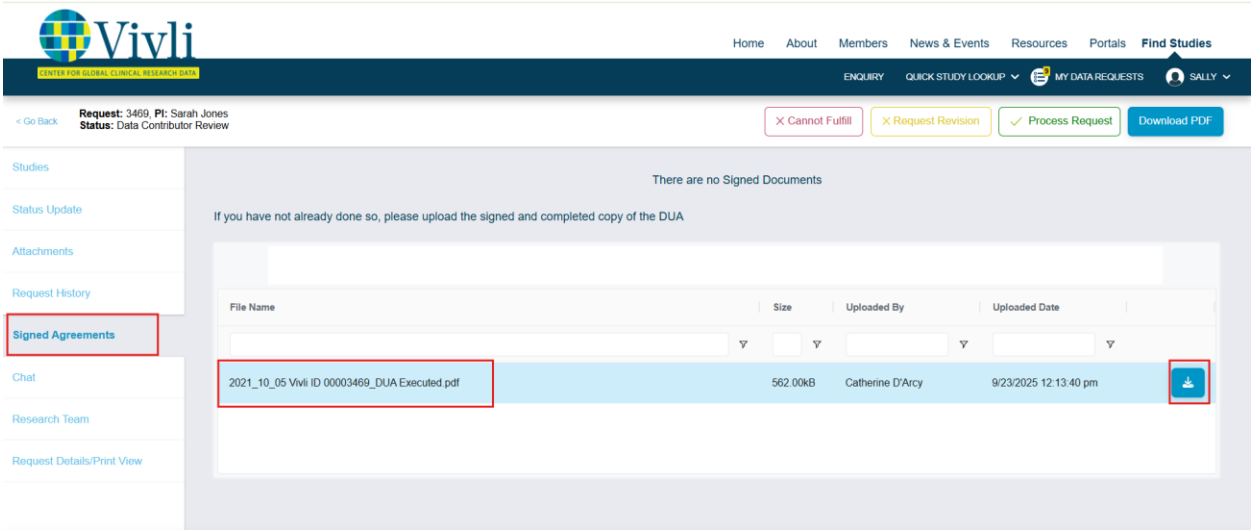


5. Once you make the changes, click the “Save Feedback Update” button at the top of the page.

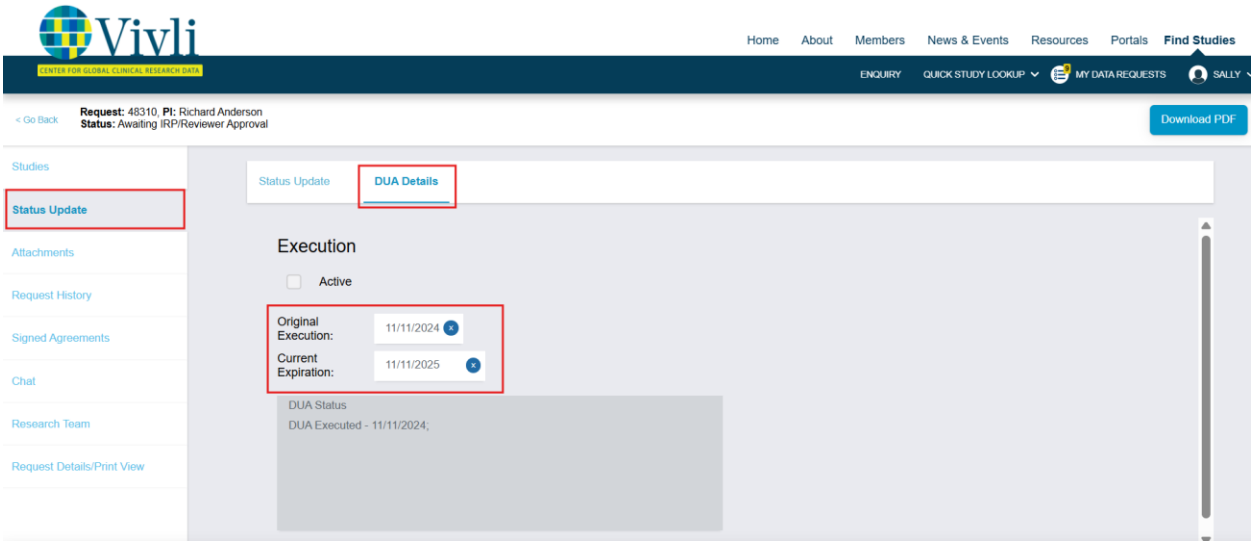
   To scroll through the information in each field, click on the field and use the cursor keys on your keyboard to scroll up and down within the field.

4.6 Data Use Agreement (DUA)

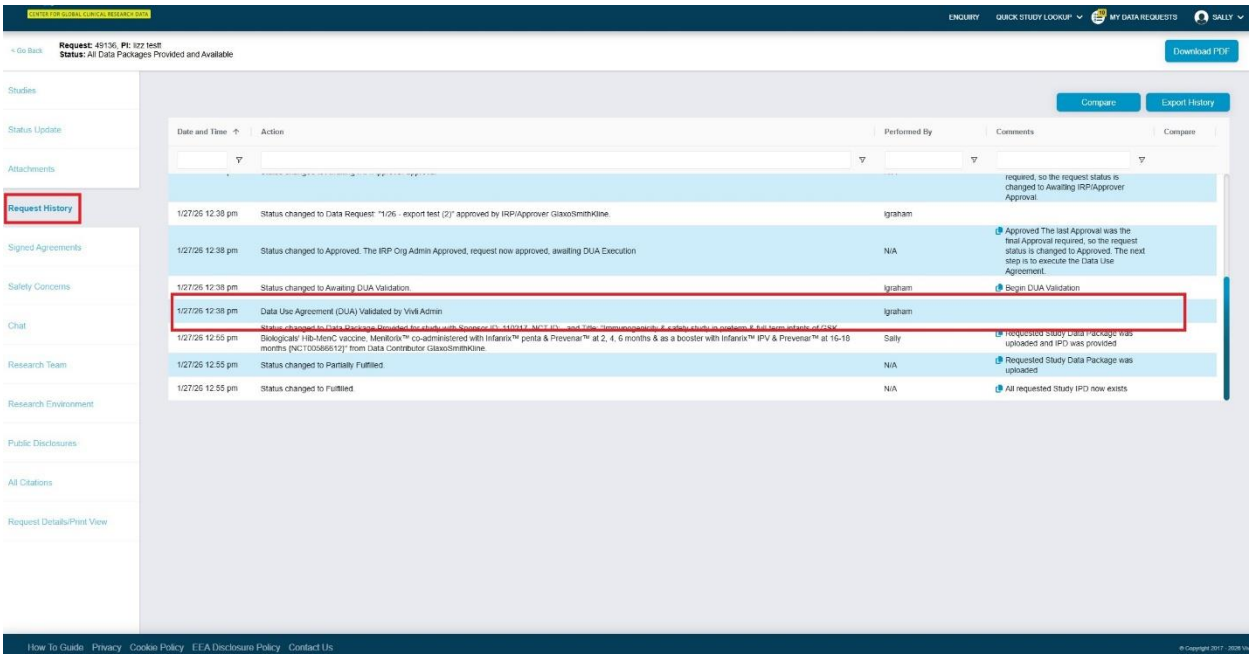
- Organizational Administrators and Data Uploaders will be notified via email when the DUA has been signed, uploaded, and executed by the Vivli Administrator.
- The signed DUA will be available for download under the **Signed Agreements** tab of the data request.



- The DUA Details subtab adjacent to the Status Update, provides the original execution and current expiration of the DUA for the Principal Investigator. In addition, you can see the DUA Status field which contains additional information filled in by the Vivli Admin,



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

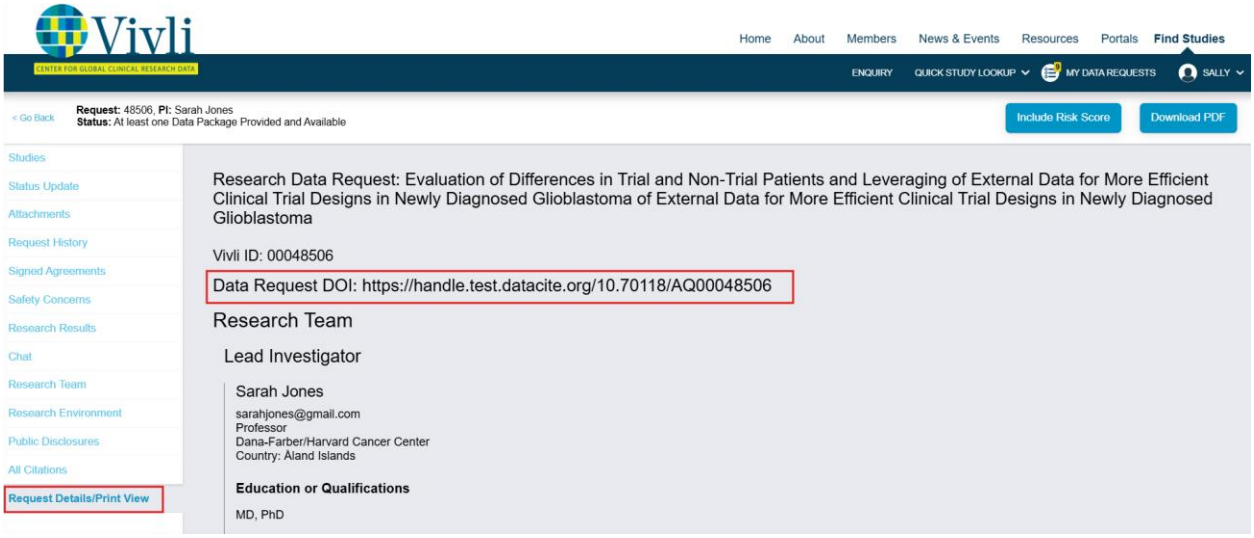


- Once the request is approved and a Data Use Agreement is executed, Vivli team will publish on its website using the Vivli data request DOI:
    - Project Name
    - Name & Affiliation of the Lead Researcher

- Funding Sources
- Conflict of Interest Statement
- Lay Summary of Research Proposal
- List of requested studies

After your publication is published, Vivli will publish the following information related to the data request:

- Statistical Analysis Plan
- Publication Citation



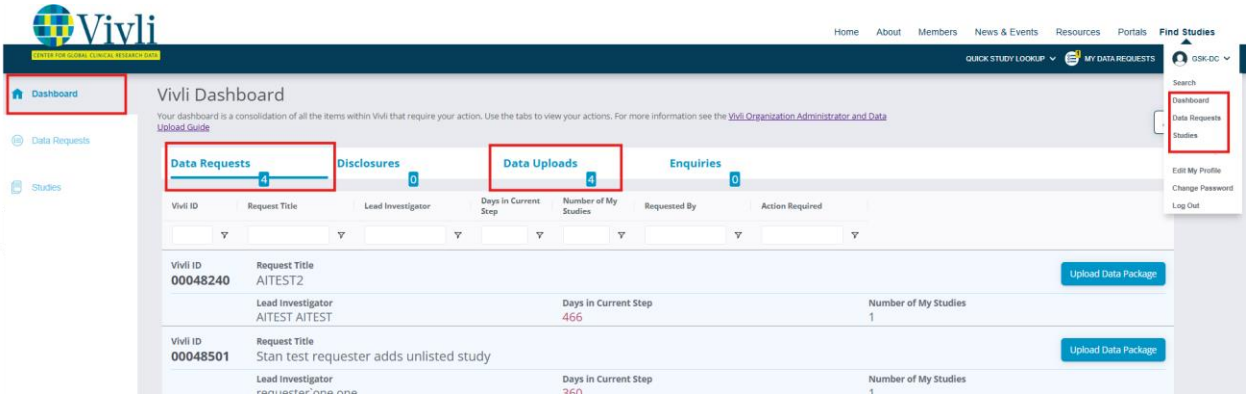
5. Data package upload

- Data Packages for the listed studies can be uploaded:
  a. Directly into the study at any time
  b. Directly to an approved data request once the Data Use Agreement is signed
- Only the team member with the Data Uploader rights can upload the data package. By default, Organizational Administrators are given Data Uploader rights.
- This data package is either provisioned into the secure research environment or made available for download, depending on the decision of the Vivli Member at the time of listing the study, or during the review of the data request.
- Once uploaded, the data package will be stored securely on the Vivli platform (Exceptions are the unlisted studies and those that are marked for request-only upload. Please see Section 4.3 Study Settings at Data Contributor Review).
- 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.

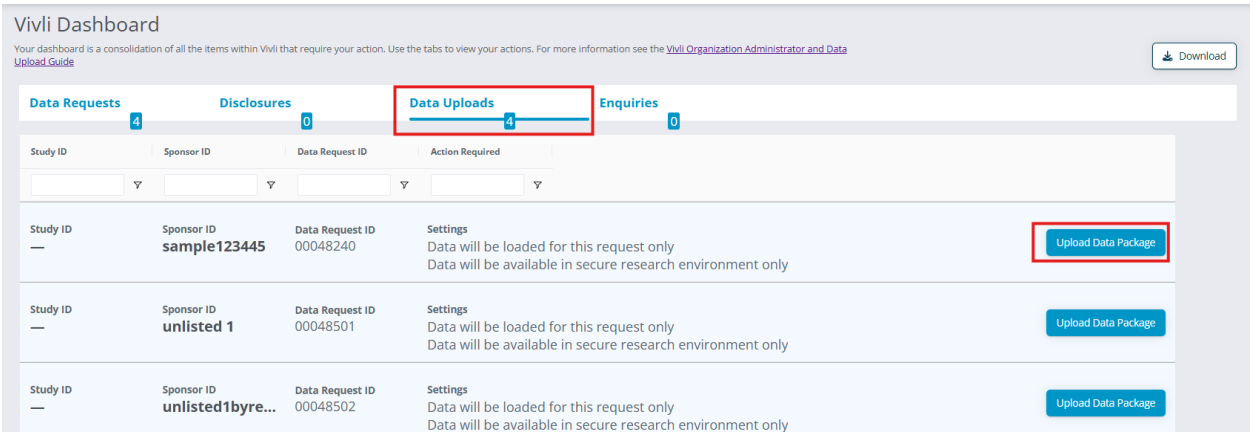
5.1 Vivli Dashboard for Data Uploaders

- Once you have been given data uploader privileges to your Organization and you have logged in, you will be taken to your Vivli Dashboard.

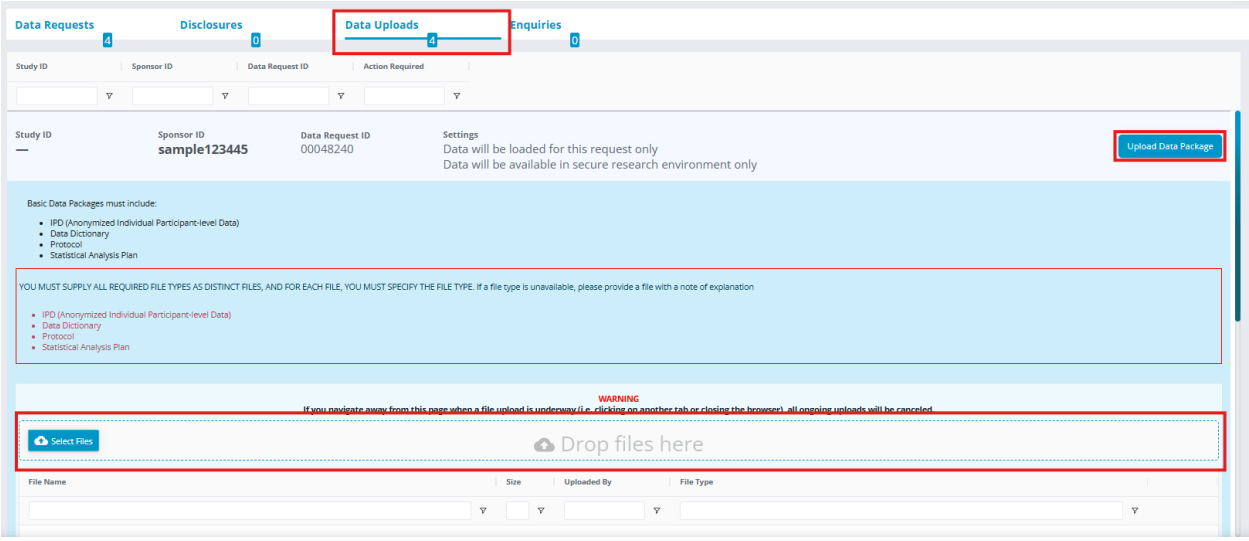
- You can track studies needing data package upload that are awaiting your action, either (a) on the main dashboard (shown below), under 'Data Uploads' (b) on the main dashboard under 'Data Requests' , (c) on the Data Requests tab on the left, or (d) by selecting 'Data Requests' on dropdown list under your name. For more information, see Section 5.4 Uploading Data Package to an Approved Request and Section 5.5 Upload Data Package Directly into the Study



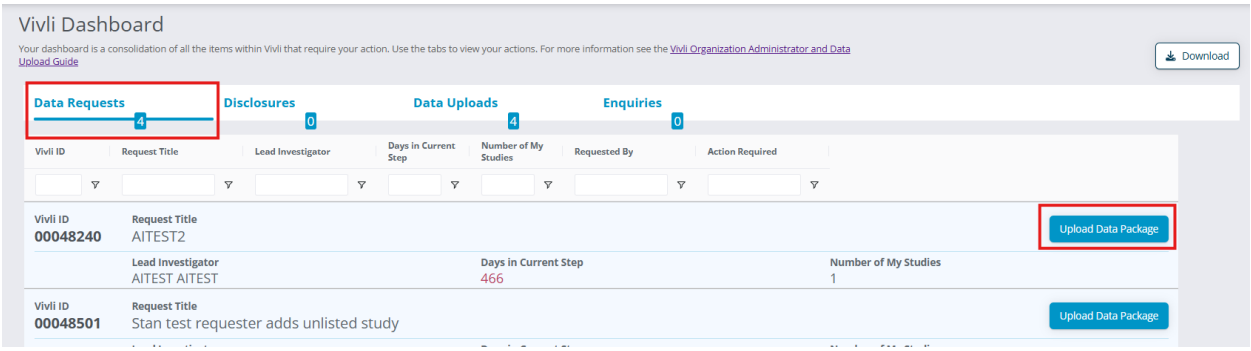
(a) The main dashboard 'Data Uploads' tab shows the studies from approved requests waiting for data to be uploaded.



Clicking on the blue 'Upload Data Package' button will open up a new section into which the data can be directly uploaded.



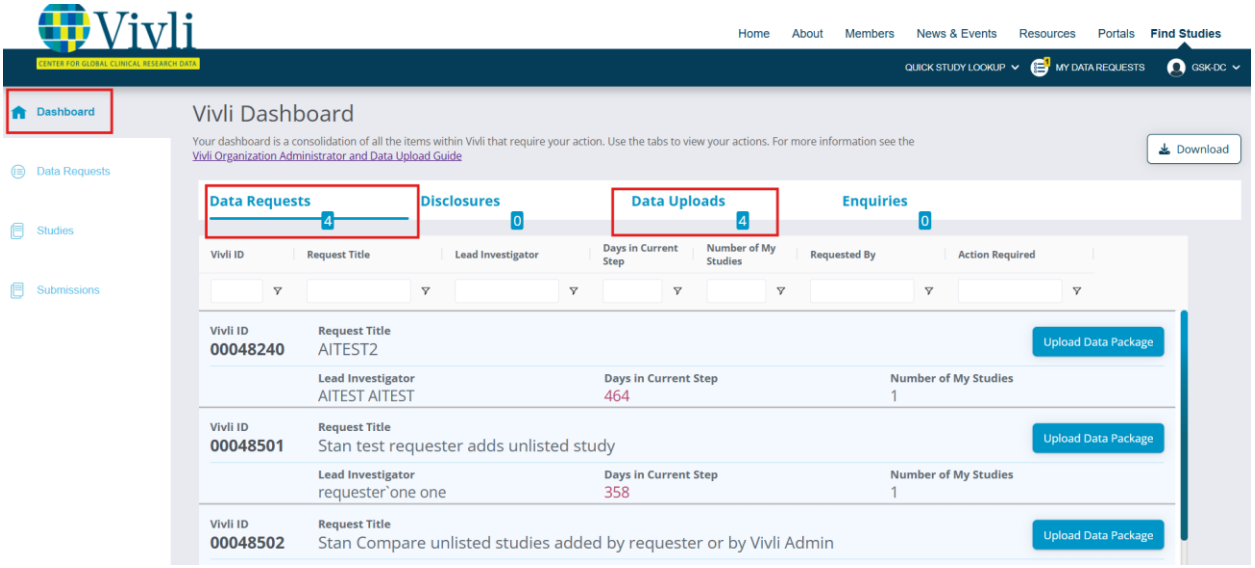
(b) The main dashboard 'Data Requests' tab shows approved data requests that are waiting for data to be uploaded. Clicking on the blue 'Upload Data Package' button will take you into the data request, where you can navigate to the Studies tab and upload the data packages.



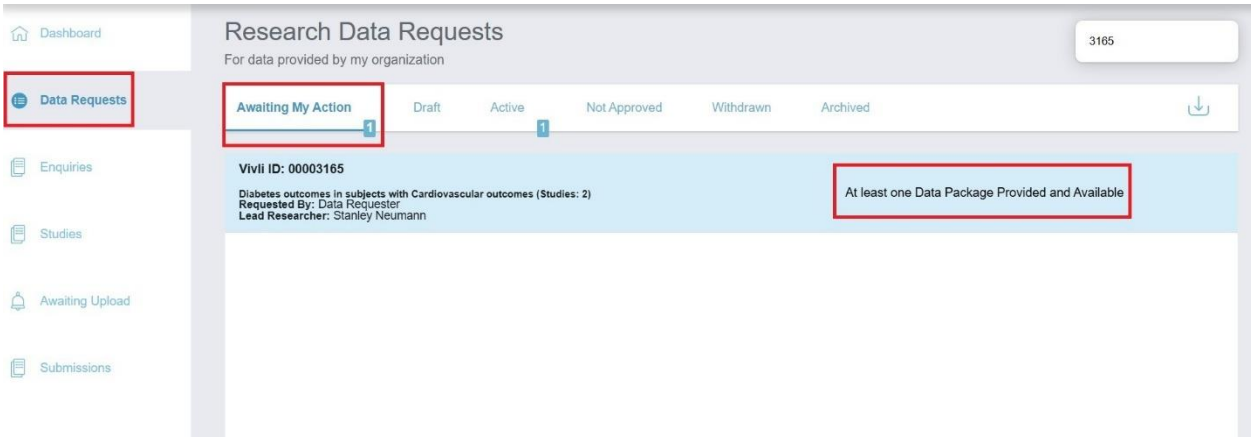
Options (c) and (d) will take you into the data request dashboard where you can search for a specific data request and go into it to upload the data, see Section 5.4 Uploading Data Package to an Approved Request

5.2 Data Upload Notification

- Once the Data Use Agreement is executed, the Data Uploader will receive an email notification to upload the data package. Data Uploader 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 Uploaders can see the status of a request if the DUA has been approved and the system is waiting for data on the main Dashboard



- Or, in the Data Request Status bar, under **Active**, or under **Awaiting My Action. Note:** Those with Data Uploader rights cannot see other data requests that are in a different stage of the review process.



5.3 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

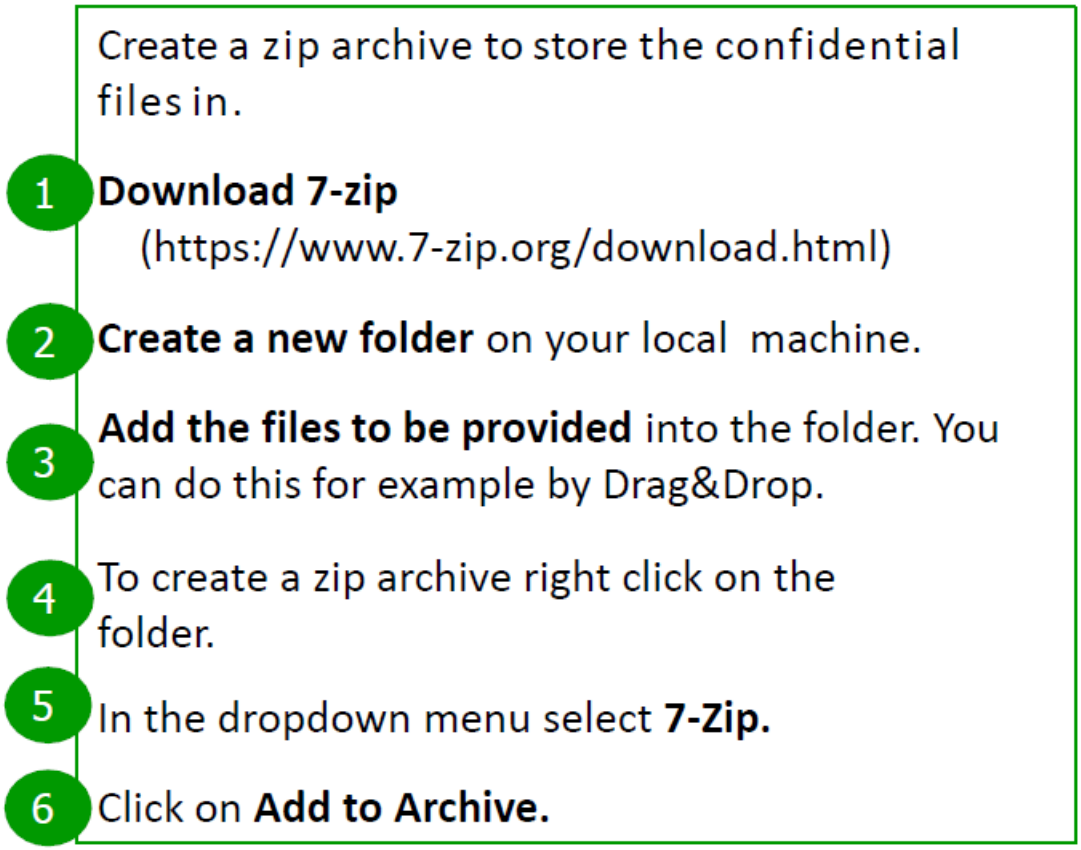
the size of textual data to 10% of the original or more; in addition, uploading a small number of files is easier and makes the system faster.
    - If you have large files, zipping can reduce the size by as much as 90% for files with textual content.
    - If you have very large files, 7-zip allows 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.

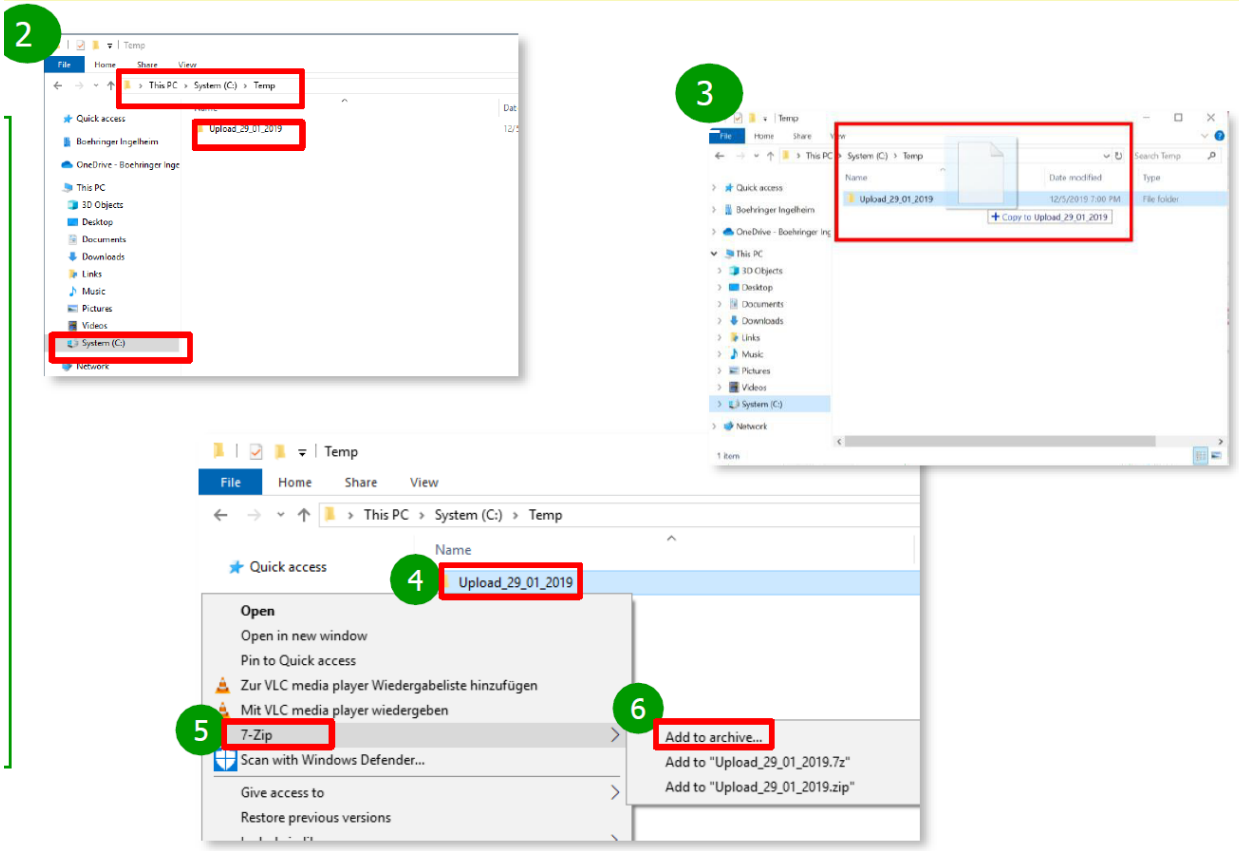
- After uploading study data and then clicking Submit Files, if you refresh the browser very quickly, the system may still be in the process of finalizing the storage.
    - In this case, it may display "Make Data Available"; if you see this after submitting files, give the system a minute or so to complete 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.
    - Do not navigate away from the upload page when a file upload is underway (i.e. clicking on another tab or closing the browser), as all ongoing uploads will be canceled.

- 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.

5.3.1 Zip Archive Process

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

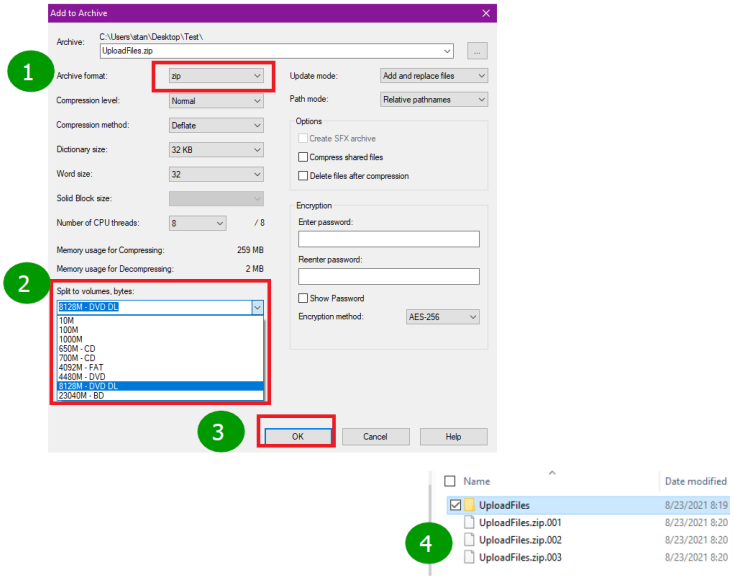




- Choose the format and volume sizes

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

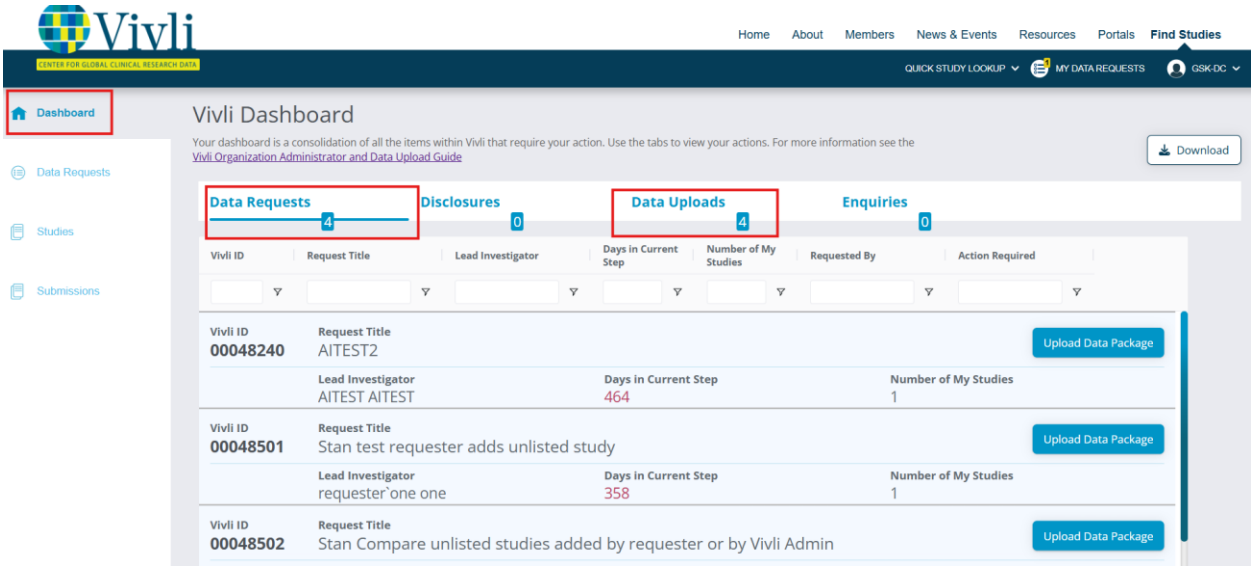
1. Select Archive format to be **zip**.
2. If the total size to be uploaded will be greater than about 10 Gb, under Split to volumes, bytes, select either
   8128M (This is about 8 Gb) or
   23040M (this is about 23 Gb)
3. Click OK to start the creation of the archive(s)
4. If you asked to split the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



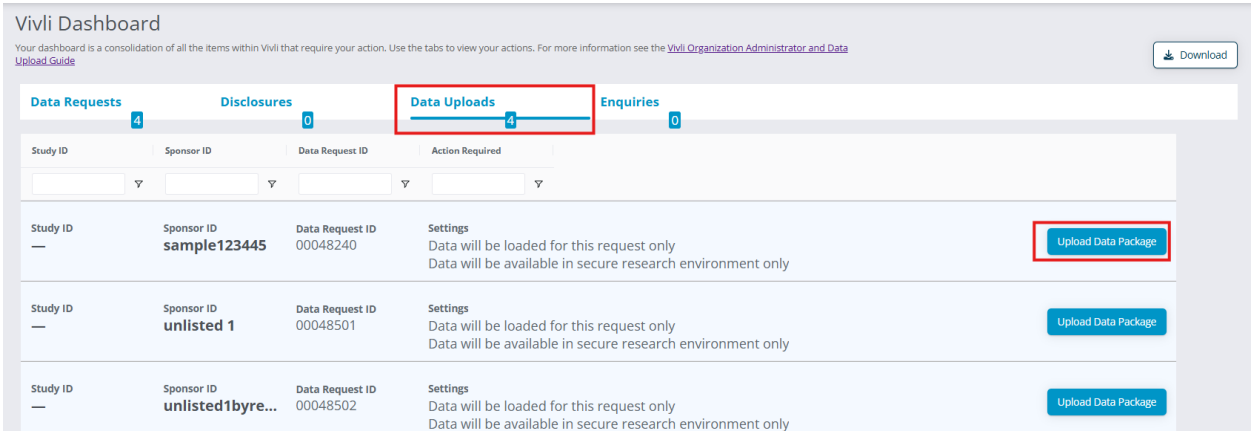
5.4 Upload Data Package to an Approved Data Request

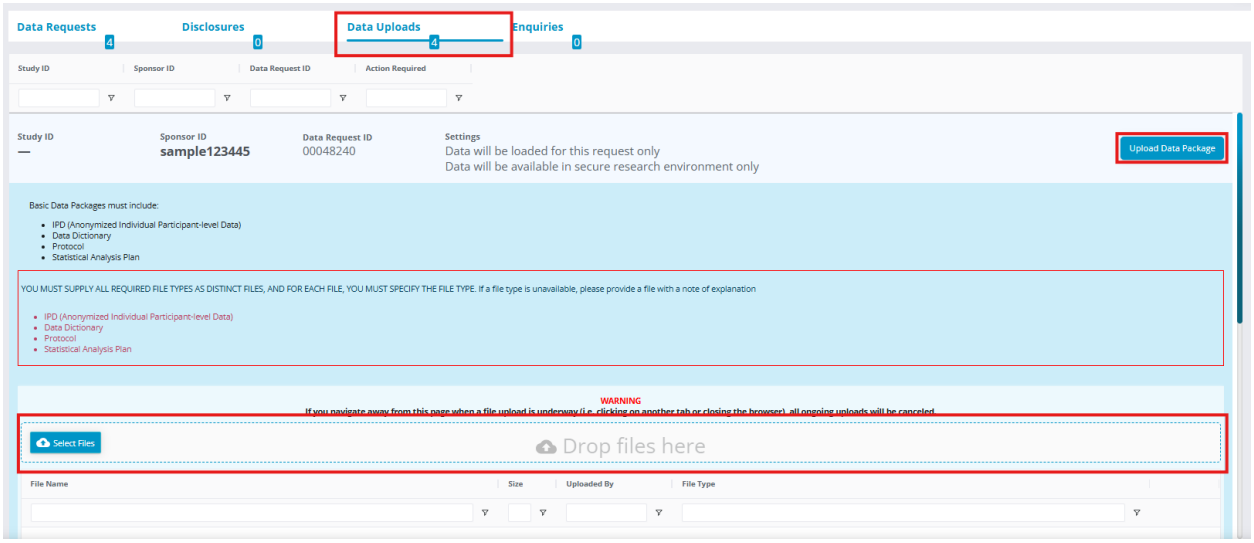
1. Once the data request is approved and the DUA is signed, you can upload the data package into the data request.

2. From the main dashboard, go to the Data Requests section to see all data requests waiting for a data upload, or to the Data Uploads section to see studies from approved requests waiting for a data upload.

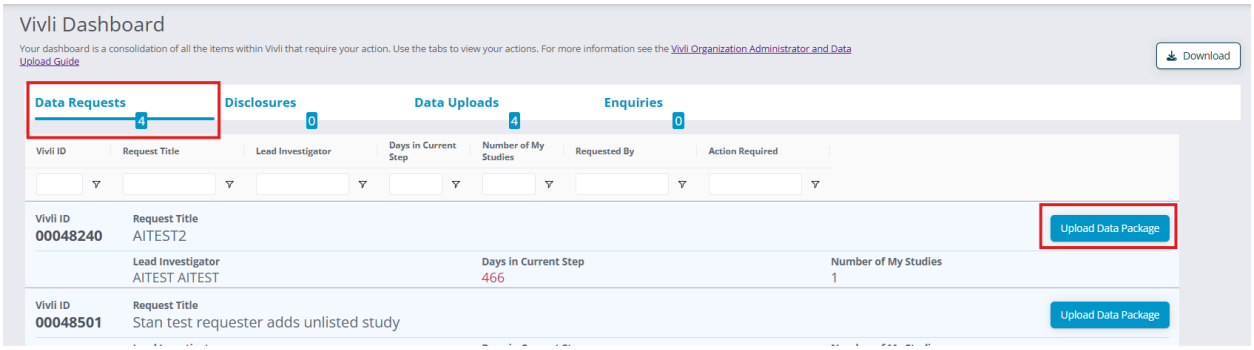


3. In the 'Data Uploads' section, clicking on 'Upload Data Package' next to the relevant study will open up a new section where the data package can be directly uploaded. See 5.1 Vivli Dashboard for Data Uploaders for further information on how to upload data in the 'Data Uploads' section.

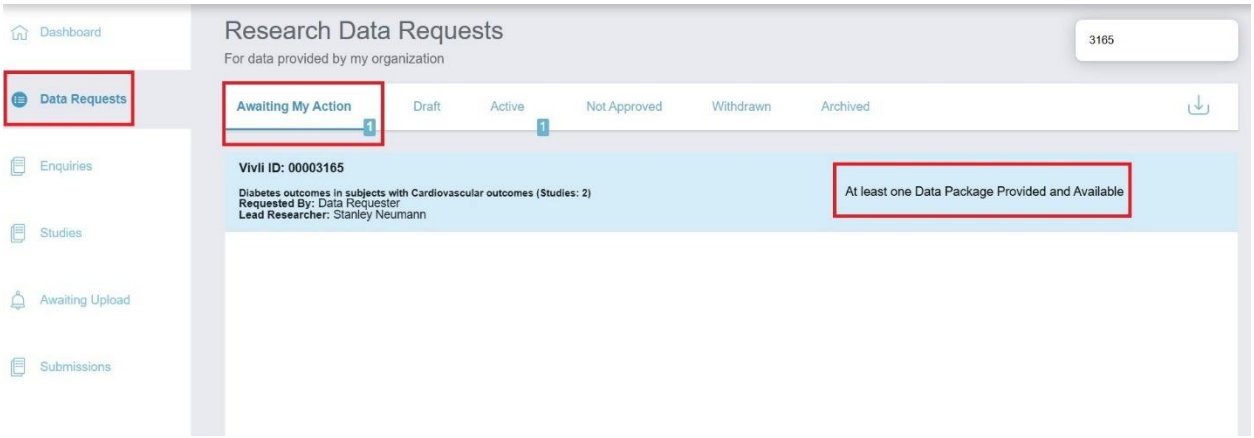




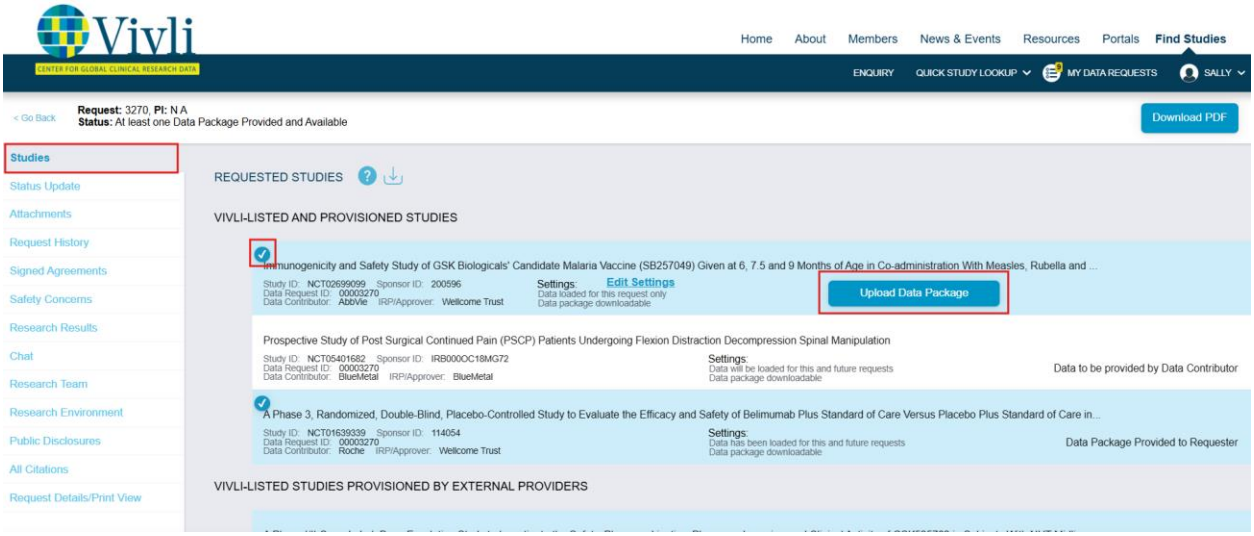
4. Alternatively, in the 'Data Requests' section, clicking on the blue 'Upload Data Package' button will take you into the data request, where you can navigate to the Studies tab and upload the data packages, (see details below).



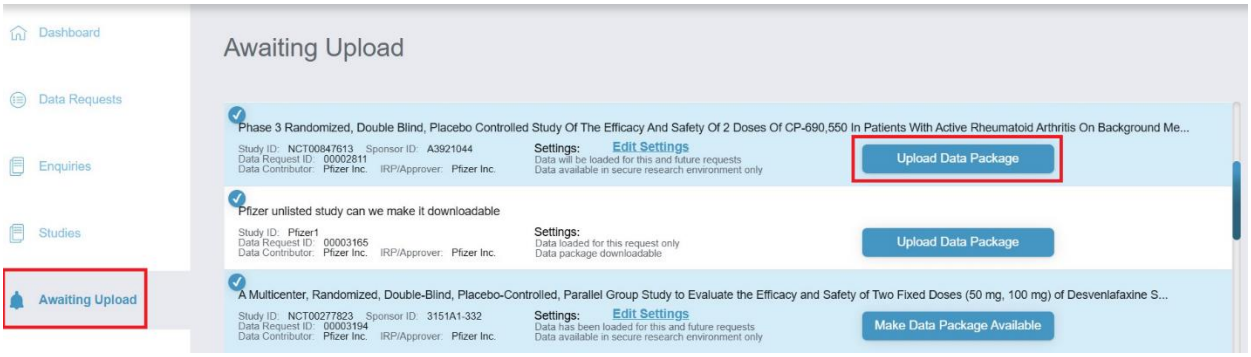
5. Or, you can click on the Data Request tab on the left menu. Locate the data request under the Awaiting My Action section:



6. Click on the data request, and then click on the Studies tab on the left. 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. Click the blue “Upload Data Package” button

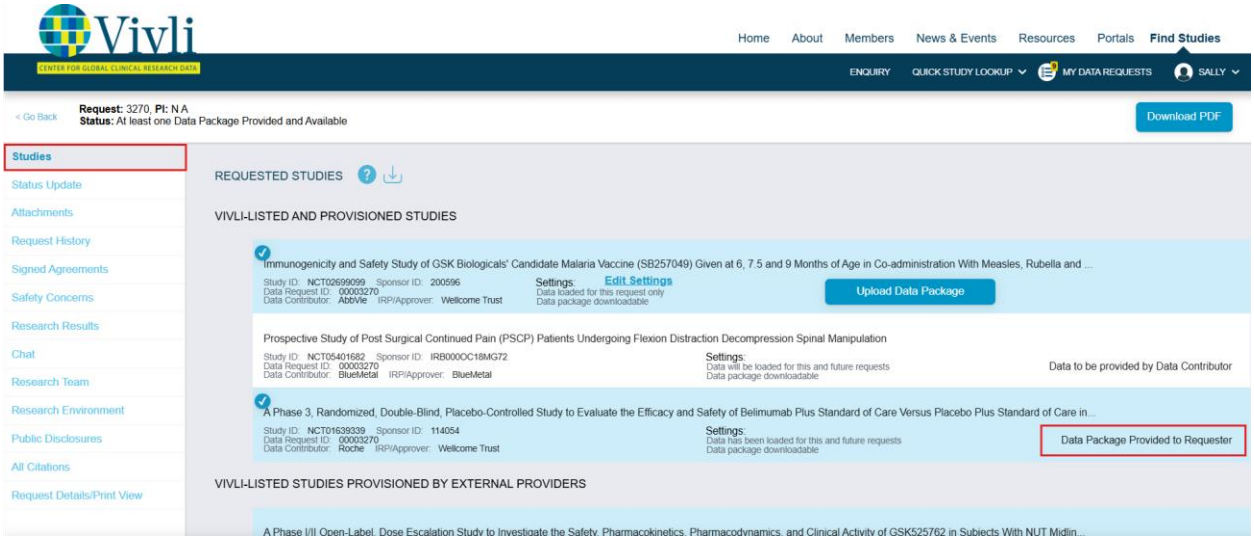


7. Alternatively, you can also locate the studies needing upload on the left menu under the Awaiting Upload tab. Click the blue “Upload Data Package” button

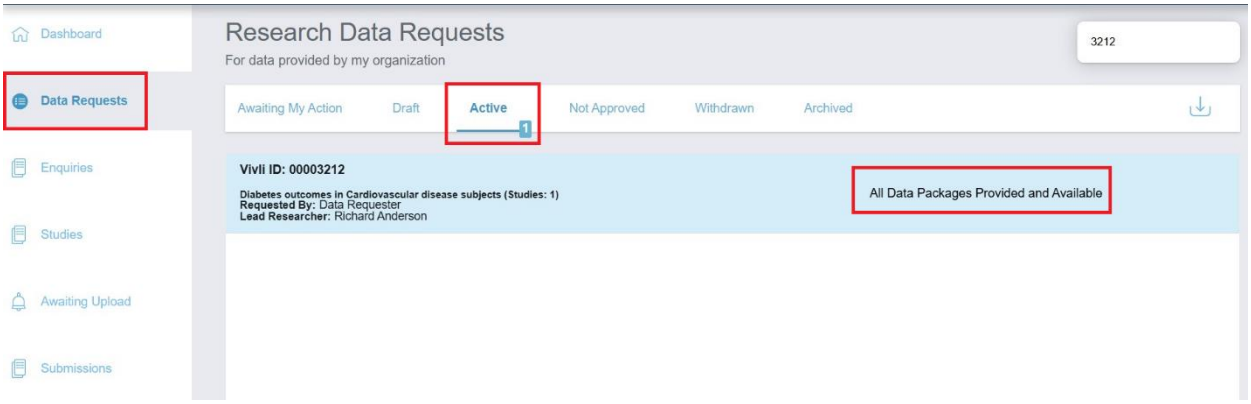


8. For the next steps on uploading the data, please see Section 5.6 Steps to Upload Data Package

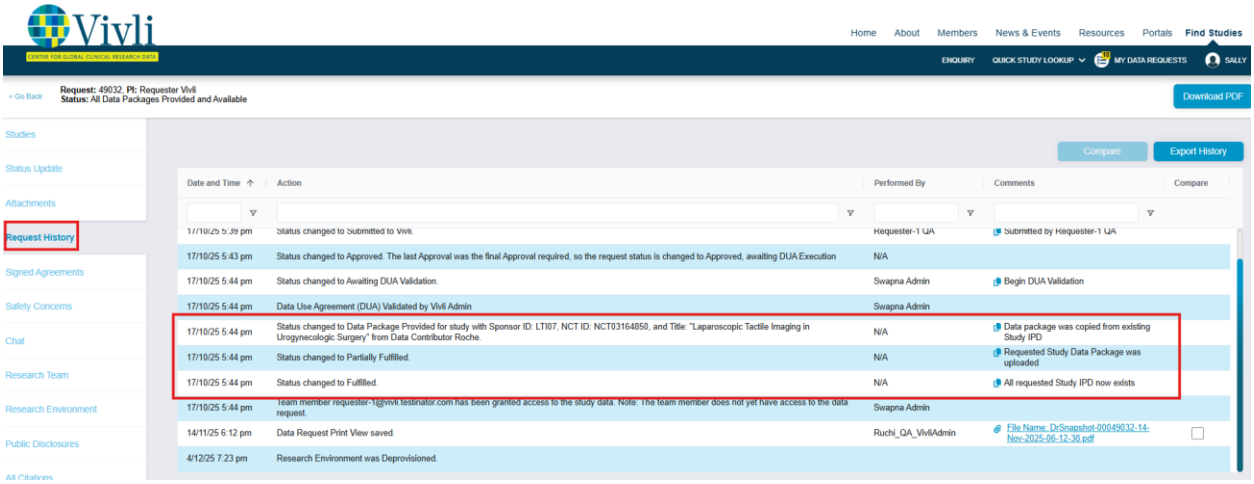
9. Once the data package has been successfully loaded onto the request, the Organizational Administrator will see the “Data Package Provided to Requestor” note next to the study record in the studies section of the data request.



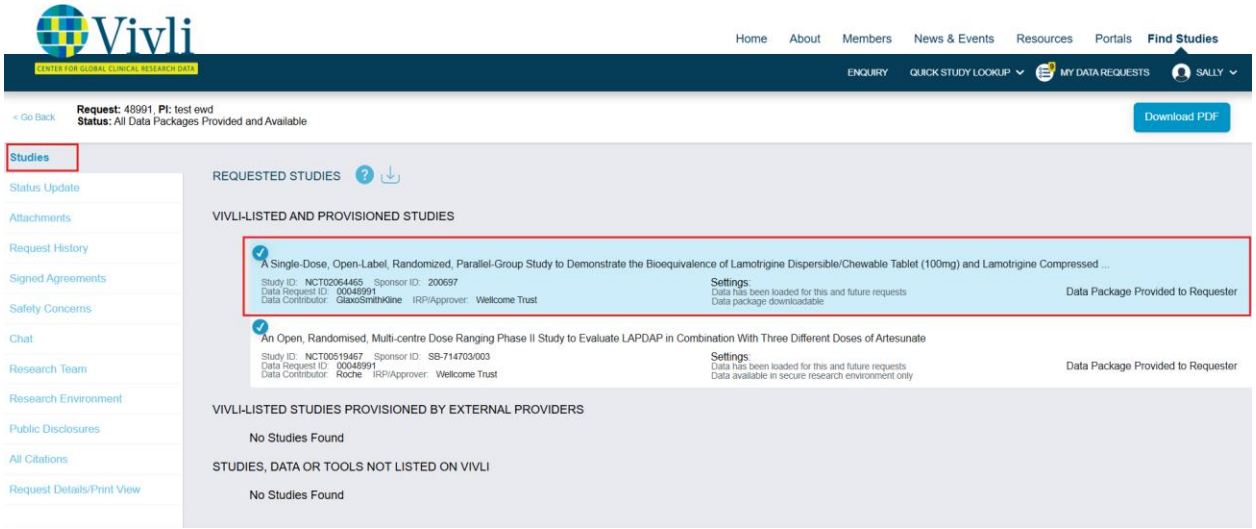
10. For multi-sponsor requests, if your organization has uploaded all of its data but another data contributor has not, the request is still in a partially fulfilled state i.e. “At least one Data Package Provided and Available” status. Vivli team will follow up with the appropriate member to upload their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



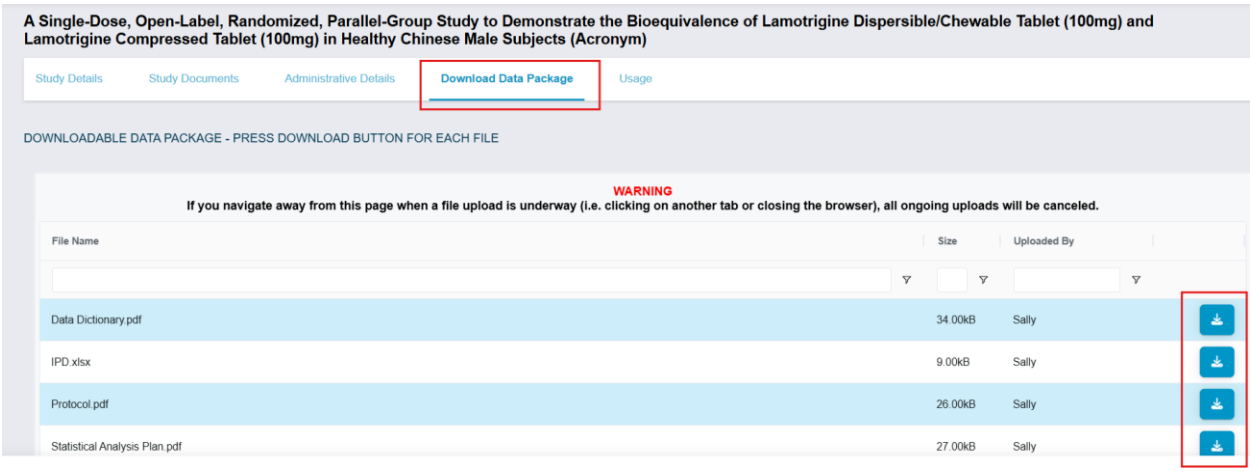
9. The data package upload and download action will be recorded in the Request history of the Data Request and includes the study ID in the history entry.



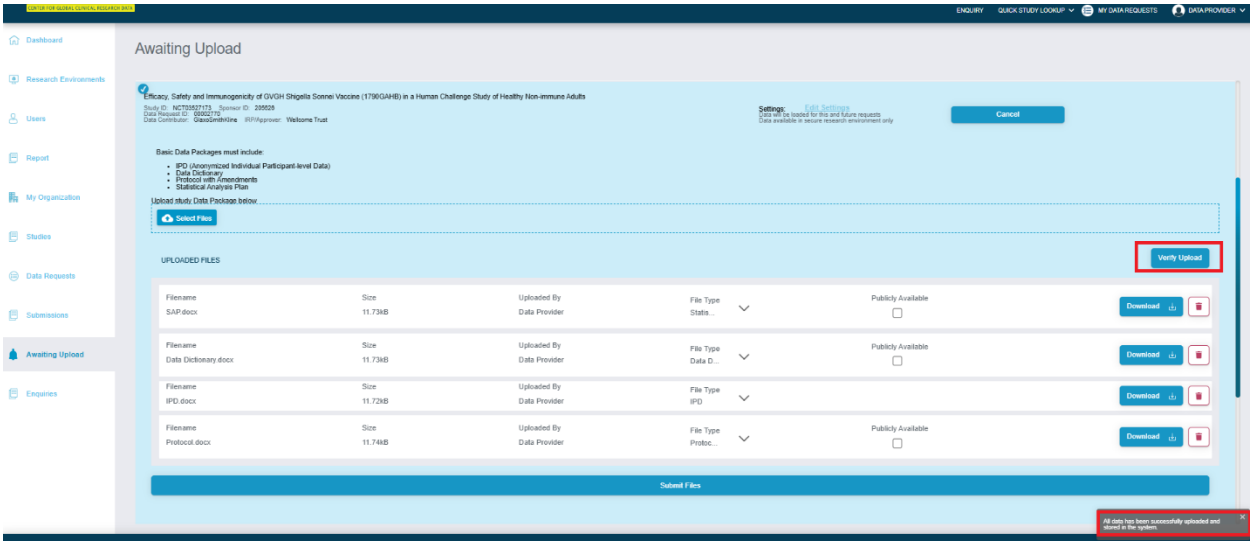
10. To view the data provided to a specific data request for a listed study, click anywhere in the study record box representing the study. This will open up a new tab. Note: This is not available for unlisted studies



11. 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



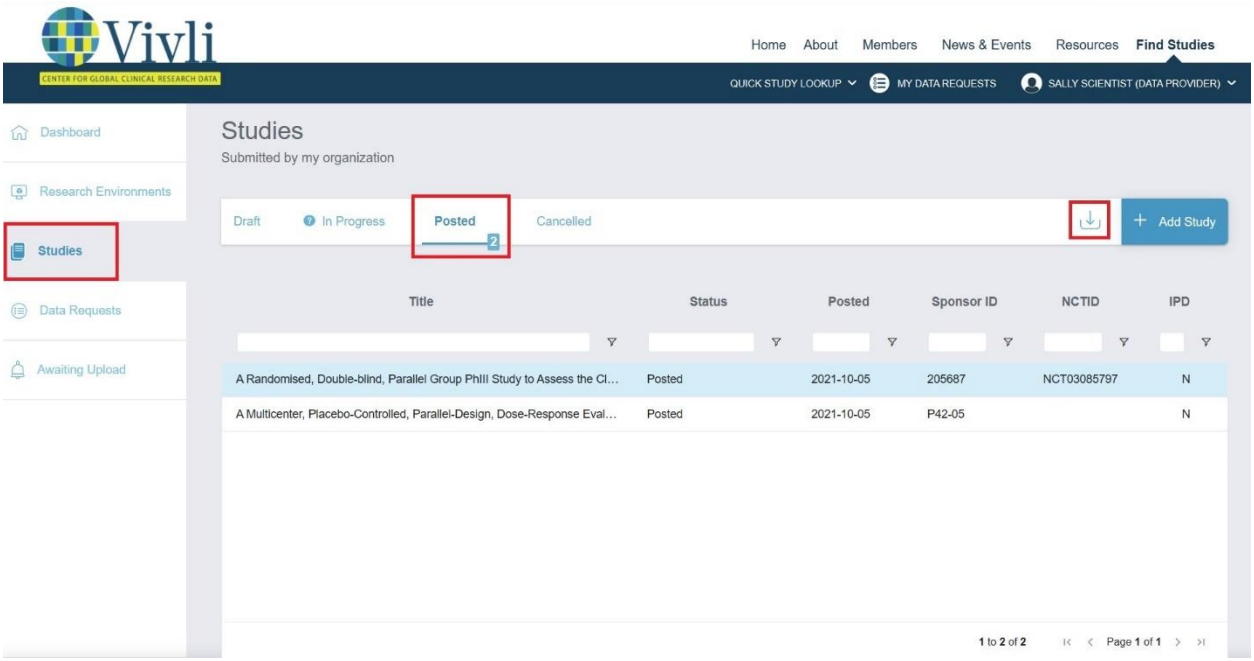
12. Click the button that says “Verify Upload” to confirm that your files have been successfully uploaded. A pop-up will appear at the bottom right screen that says “All data has been successfully uploaded and stored in the system”



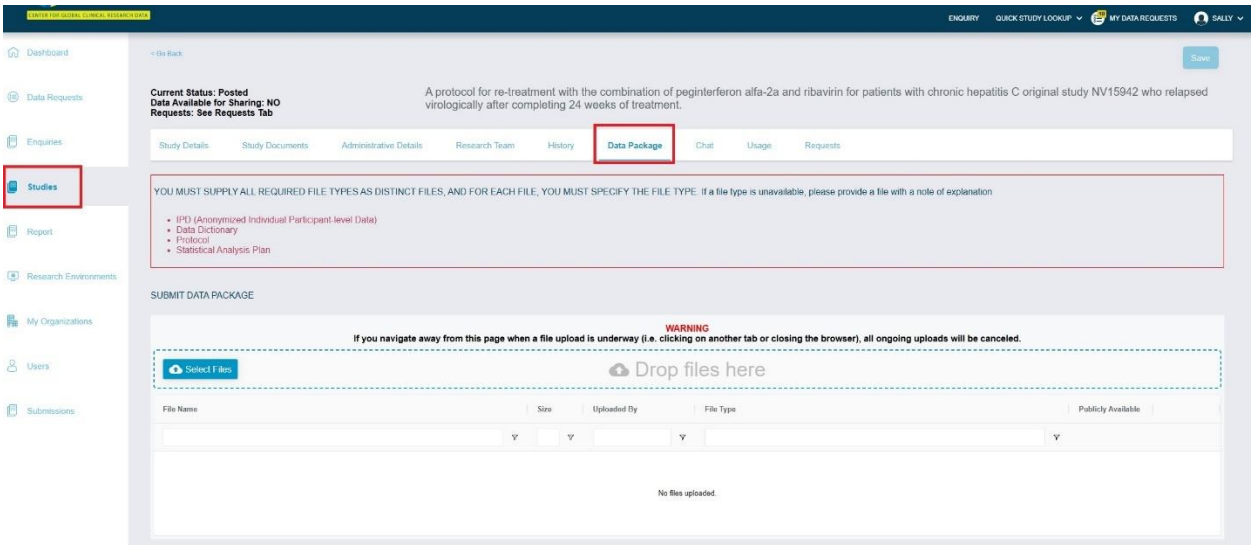
5.5 Upload Data Package Directly into the Study

For listed studies, Data Contributors can upload study data packages directly into the study at any time (this option is not available for unlisted studies).

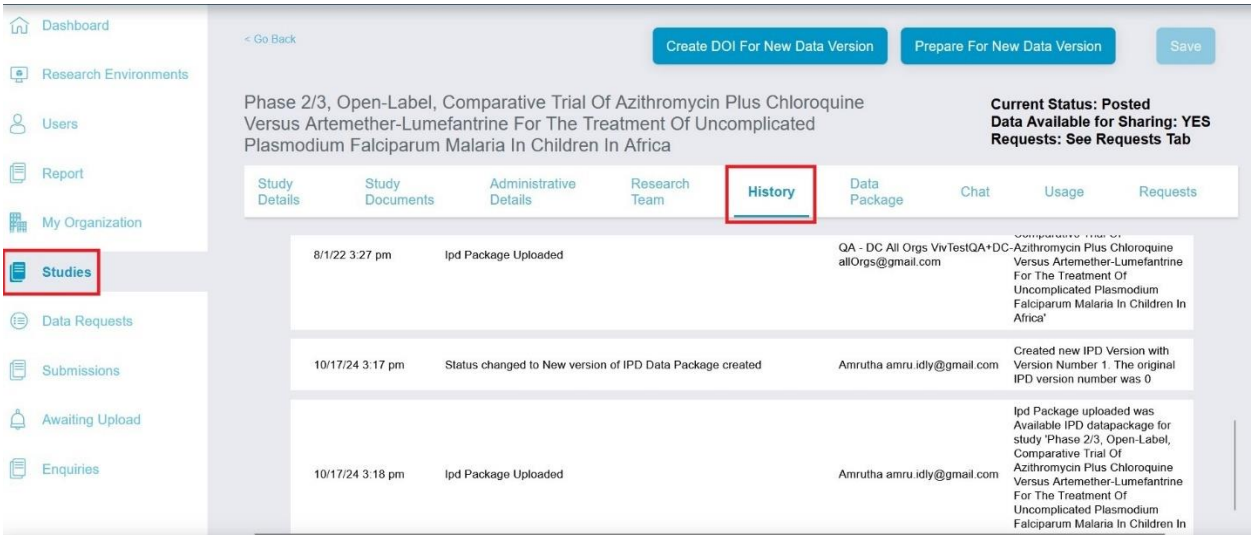
1. To add a new data package, navigate to the Studies tab from the dashboard. (See Section 5.8 Replace Data Package with a New Version to replace an existing data package)



2. Open the study, select the Data Package tab, and upload the data package.



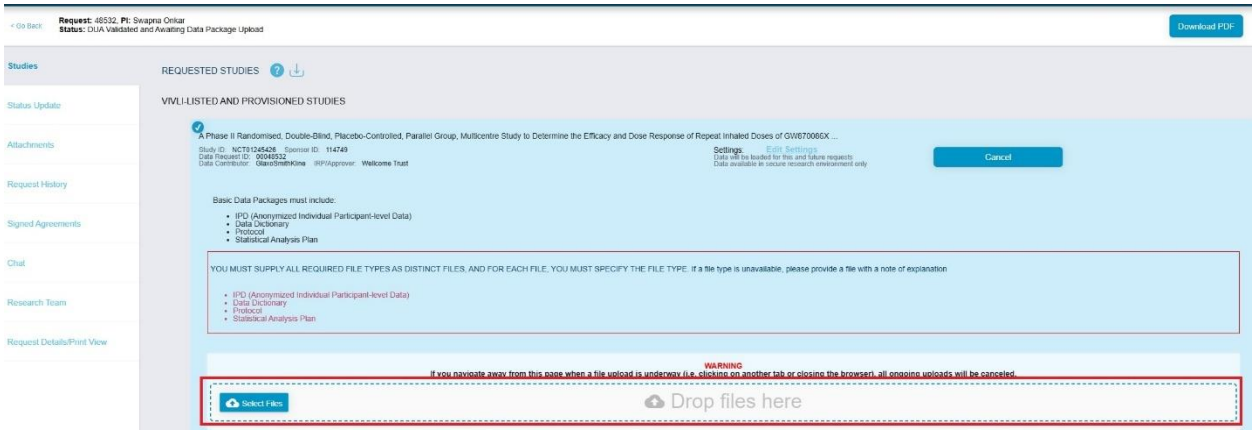
3. For the next steps on uploading the data, please see Section 5.6 Steps to Upload Data Package.
4. The data package upload action will be recorded in the Study history



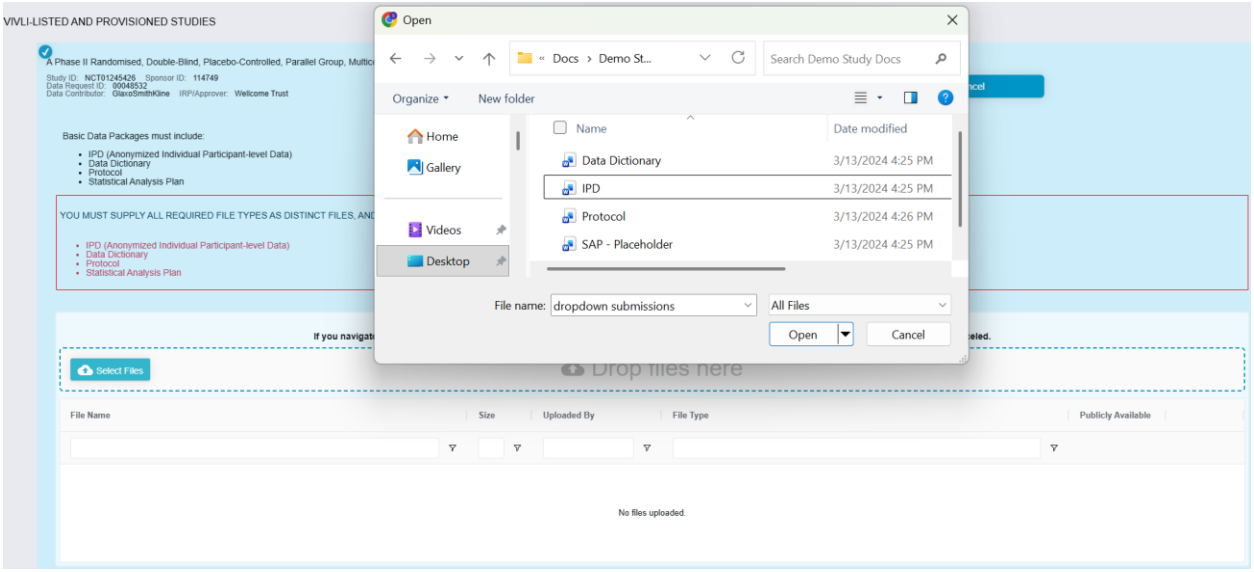
5. For subsequent data requests for this study, this version of the data package will be made available to the researcher. Please see Section 5.7 Stored Data Package and Subsequent Data Requests

5.6 Steps to Upload Data Package

1. To upload the data package, click on the “Select files” button

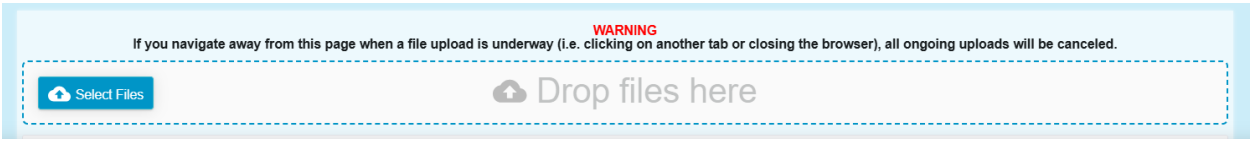


2. A window will pop up allowing the data contributor to select the files of their computer:

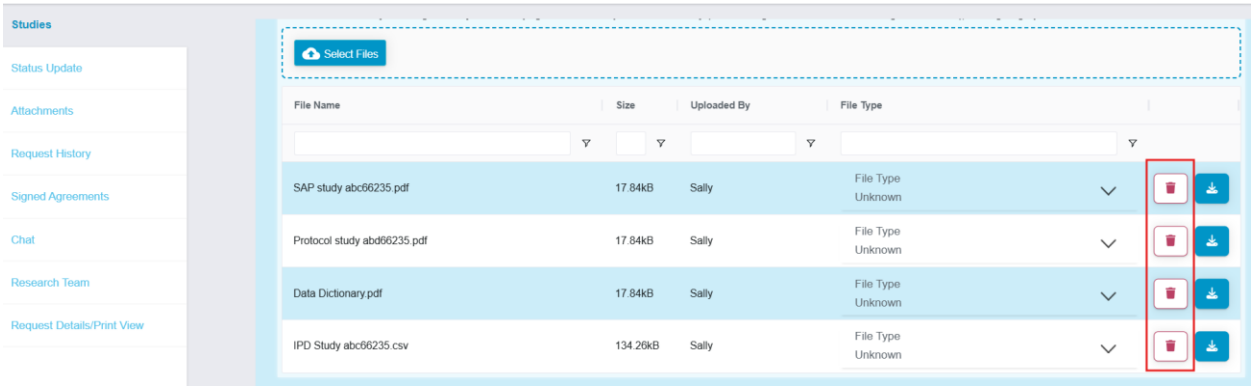


3. After selecting the files, click **Open. Do not navigate away from the upload page when a file upload is underway (i.e. clicking on another tab or closing the browser), as all ongoing uploads will be canceled.**

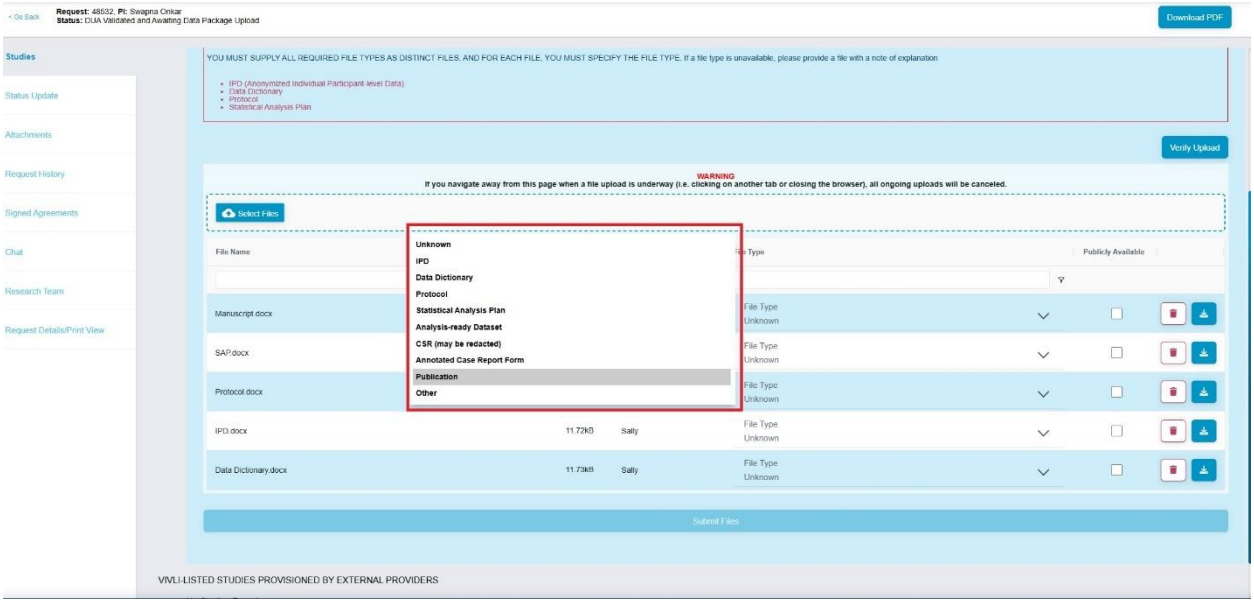
4. The data contributor may also drag files into the submit window indicated by the blue dotted box:



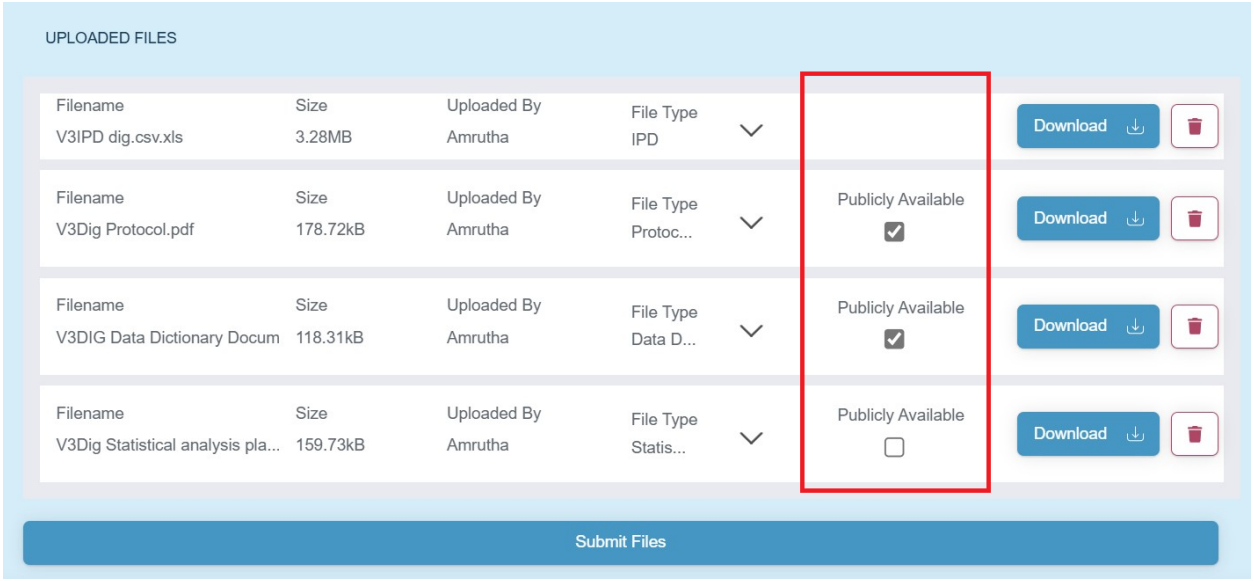
5. The files should appear below**.** You can delete any files by clicking the “delete” button:



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



7. After selecting the file types, you have the option to make the supporting documents available for the researcher to search. For more information, please see Section 5.12.1 Loading Supporting Documents at the Time of Data Upload



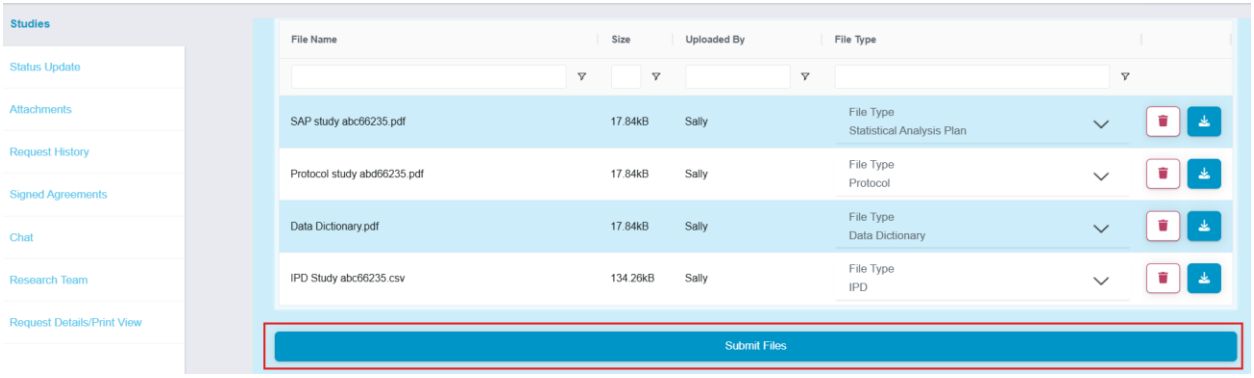
8. If the data contributor has different formats of the same file (for example, an Analysis-Ready dataset SAS file and an Analysis-Ready dataset .csv file), they can select the same file type for all applicable files from the dropdown menu. **Note:** You can't upload an empty file or upload two files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

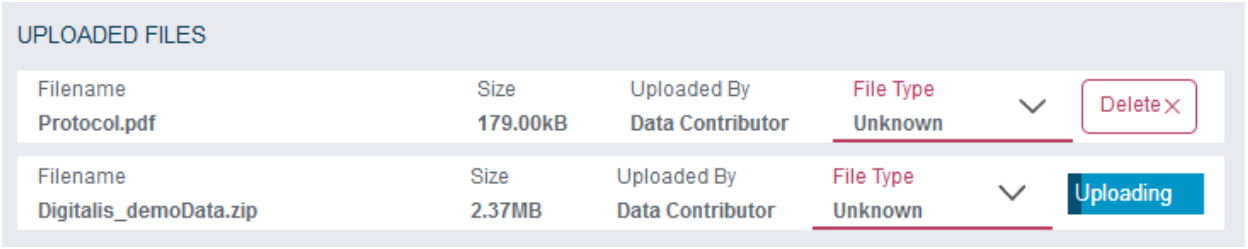
9. Here is the list of what is included in a data package

	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, 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	The 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
Optional	Publication	Peer-reviewed articles, reports, or preprints describing the study design, conduct, analyses, and results

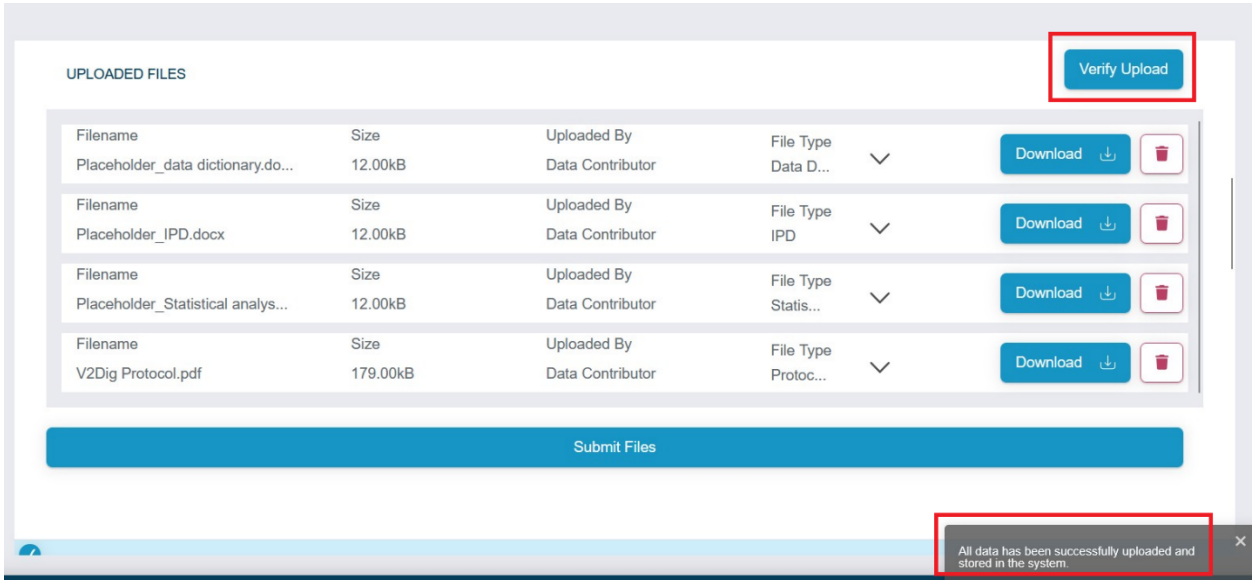
10. For any additional file types for data upload, select the "Other" file type option to upload the files. **Note:** If you do not have any of the basic study documents available (Study Protocol, Data dictionary, or Statistical Analysis Plan, please upload a Word document explaining which files are available, instead of the missing file type.

11. 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". **If you navigate away from a page on which an upload is underway (i.e. clicking on another tab or closing the browser), that will cancel the upload automatically**

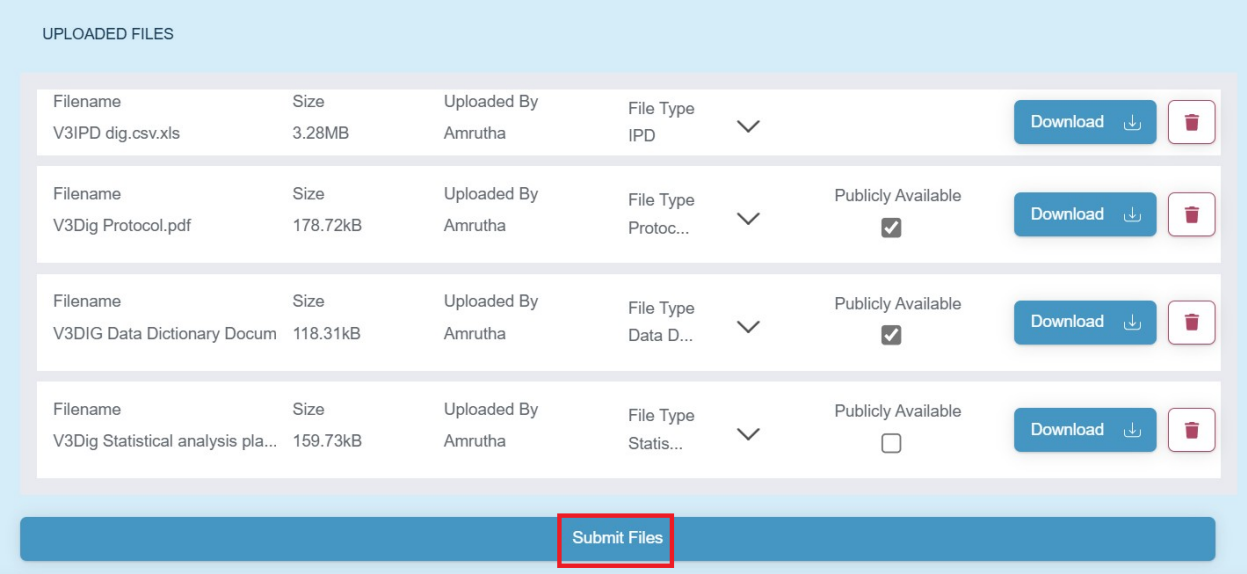




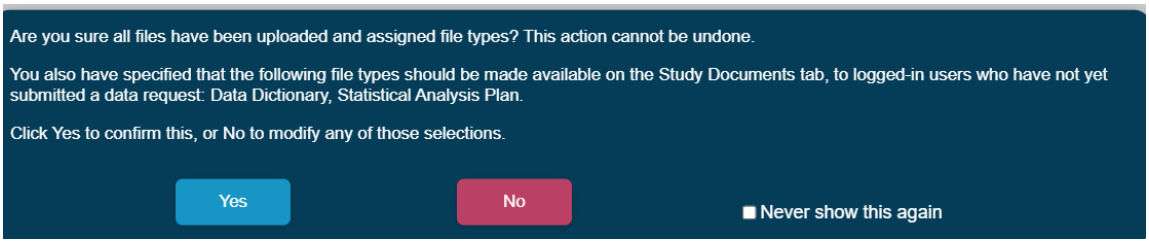
12. If the upload of any file(s) fails, Close the request, refresh the browser, re-open the request, click on "Upload Files" and delete the file that failed before moving forward.
13. Click the button that says "Verify Upload" to confirm that your files have been successfully uploaded.
14. A pop-up will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



15. **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.
16. 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.
17. When finished, click **Submit Files** to load the data package into the Vivli Platform.



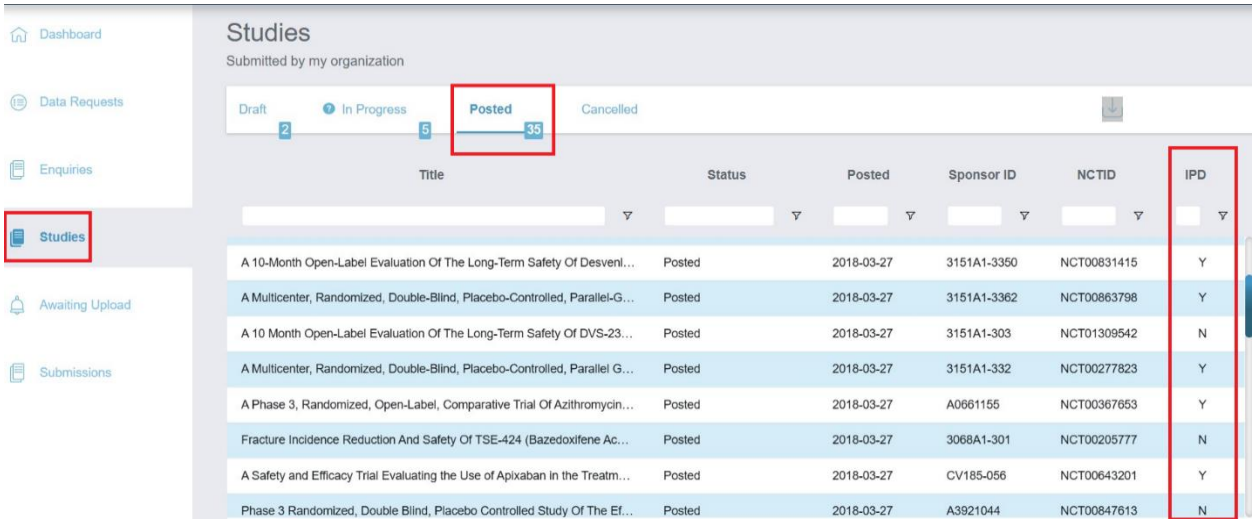
18. The following pop-up will appear:



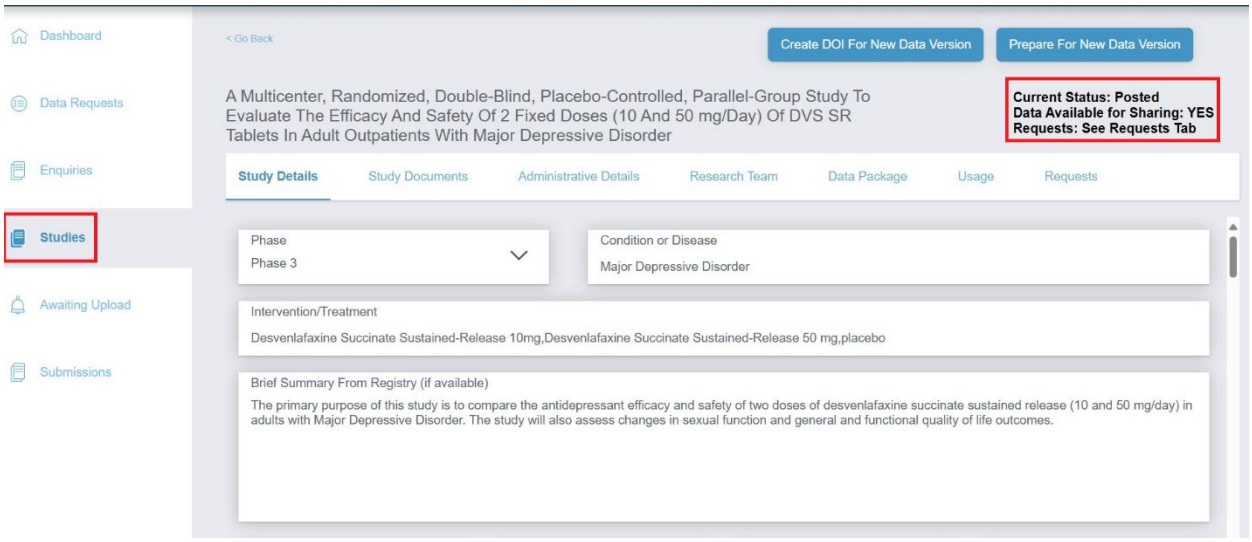
19. You will receive confirmation of successful upload. Click the 'Continue' button

5.7 Stored Data Package and Subsequent Data Request

1. If a posted study has a stored data package, this will be visible in the following two places from the studies tab:
2. From the list of posted studies, the IPD column will indicate “Y” for data available and “N” for data not uploaded.



3. 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.

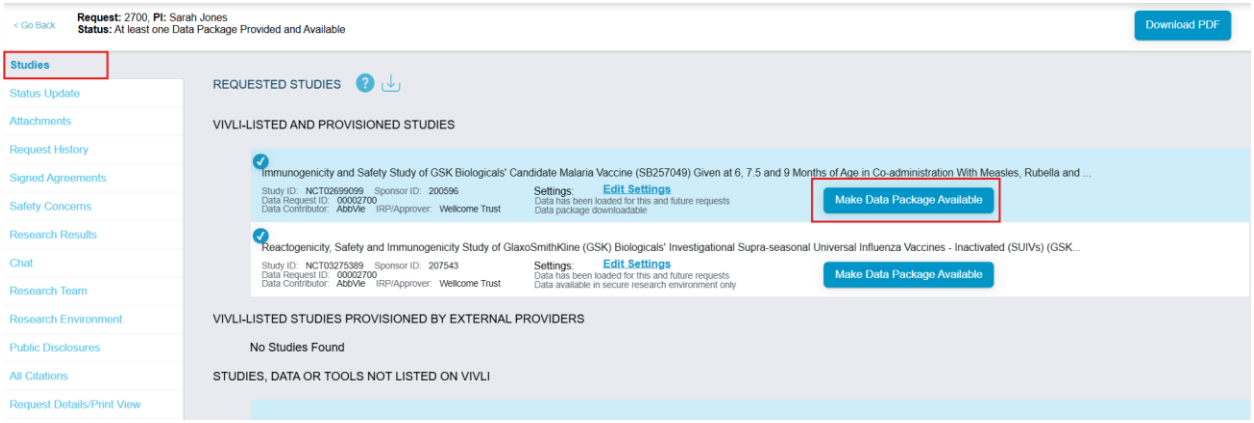


4. If you have data packages previously loaded for a data request and if the same data package is requested by any other Data Requestor after the data was loaded, the review process will be followed and if approved and the Data Use Agreement is signed, then the data package will be provided to the subsequent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

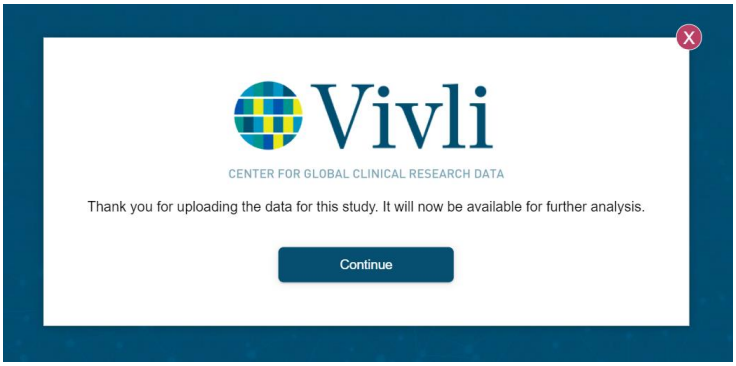
5. In most cases, that will be an entirely automatic step. In other words, that study will not appear in your “Awaiting Upload” section. Instead, the data package will be automatically loaded for the data request and the action will be recorded in the request history of the data request.

6. 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.

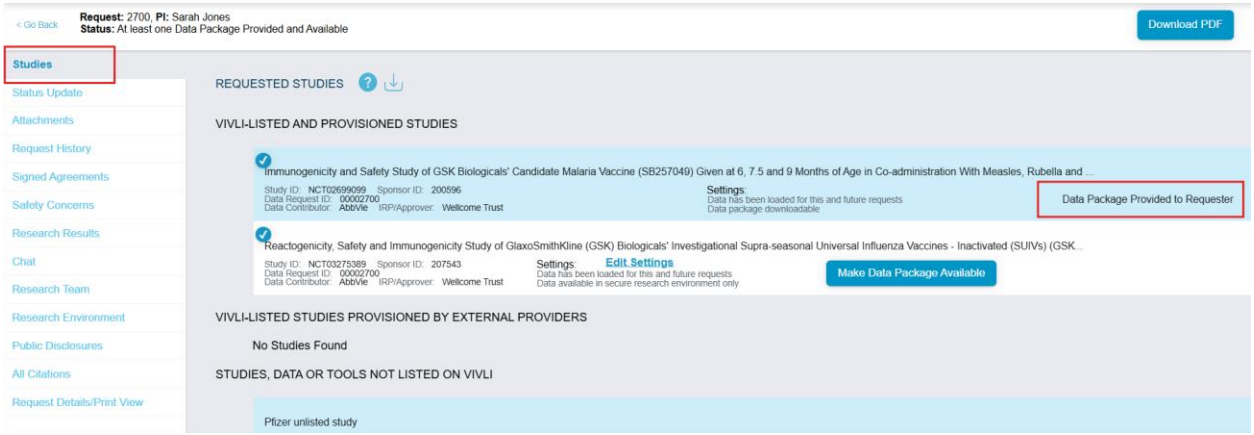
7. In such cases, navigate to the study needing your action as described in Section 5.4 Upload Data Package to an Approved Data Request. The only difference is that instead of a button "Upload Data" you will see a button labeled "Make Data Package Available":



8. Click **OK** to submit the files. The following confirmation will appear:



9. 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.

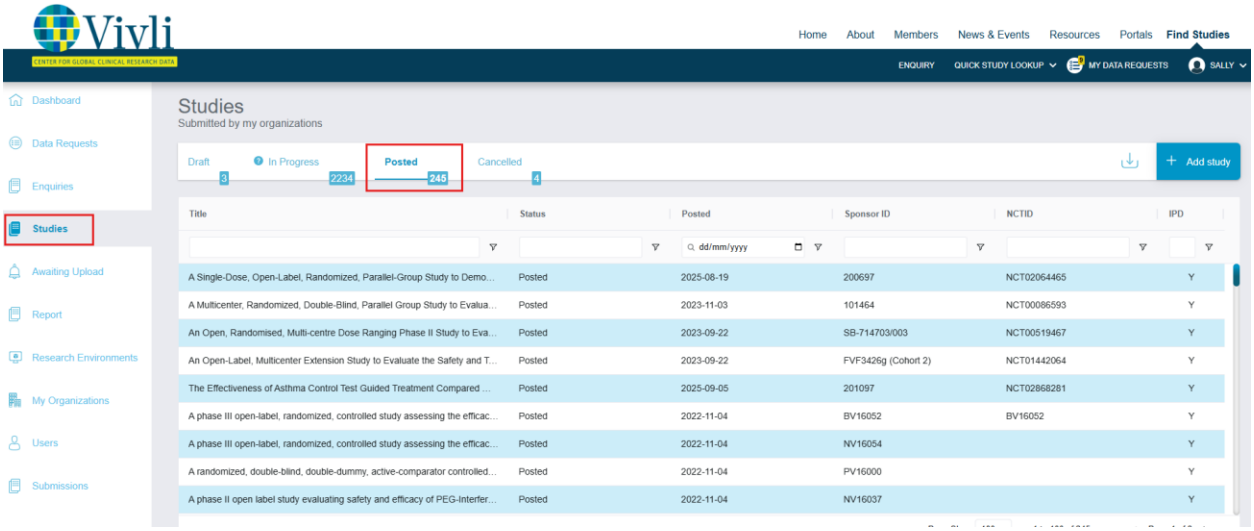


10. The data package upload action will be recorded in the Request History of the Data Request.

5.8 Replace Data Package With A New Version

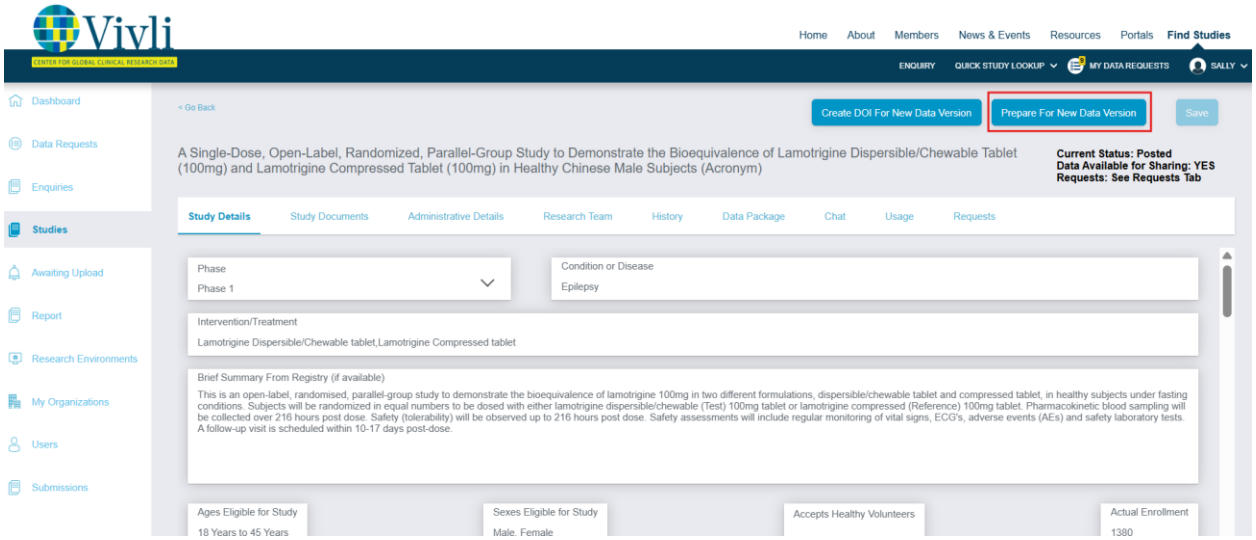
To REPLACE an existing data package and make the new version available for future requests, first follow the steps below:

1. If a posted study has a stored data package, but it needs to be replaced with an updated version, navigate to the Studies tab, and the 'Posted' section

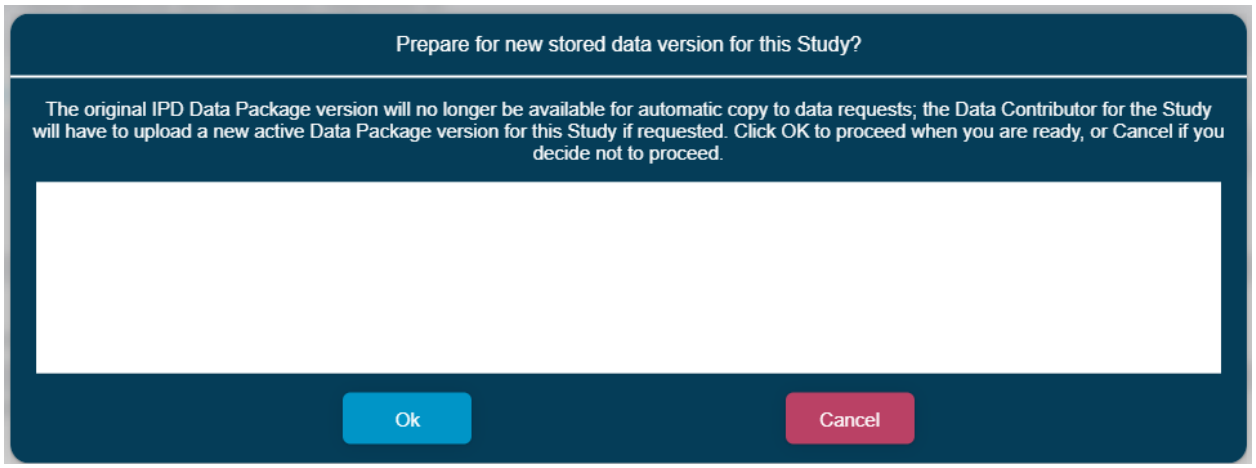


2. Use the filters at the top to find your study, and click into the record to be taken into the study details.

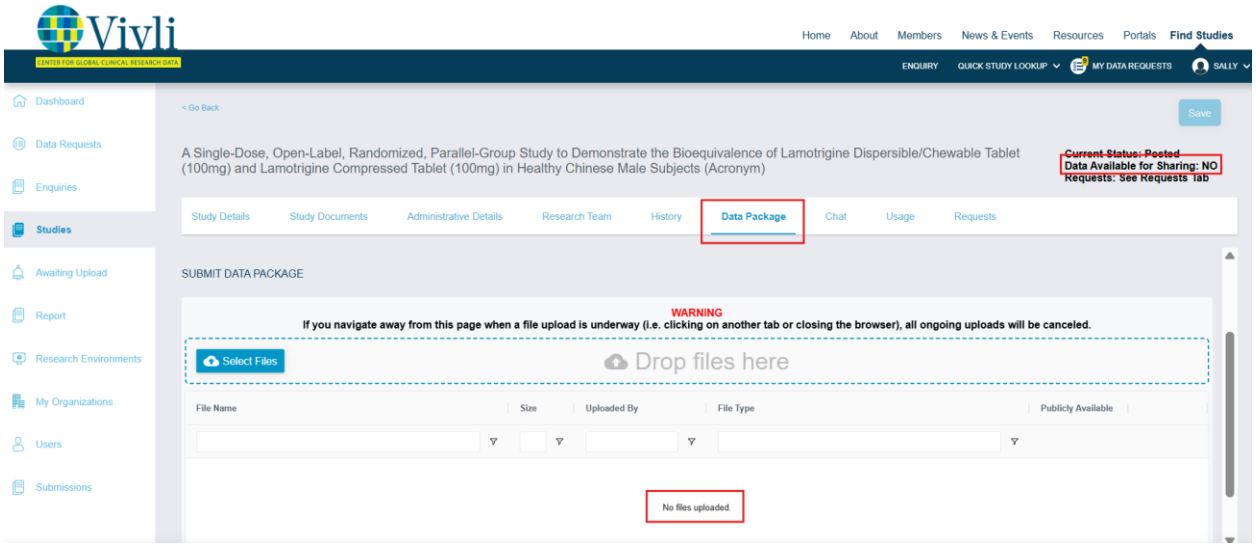
3. Click on ‘Prepare For New Data Version’.



4. A pop-up will appear advising you that the old data version will no longer be available if you proceed. Click ‘OK’ to continue and remove the old data version.



5. The Data Package tab will now not contain any files:



6. To add the updated data package, follow the steps in Section 5.5 Upload Data Package Directly into the Study and Section 5.6 Steps to Upload Data Package

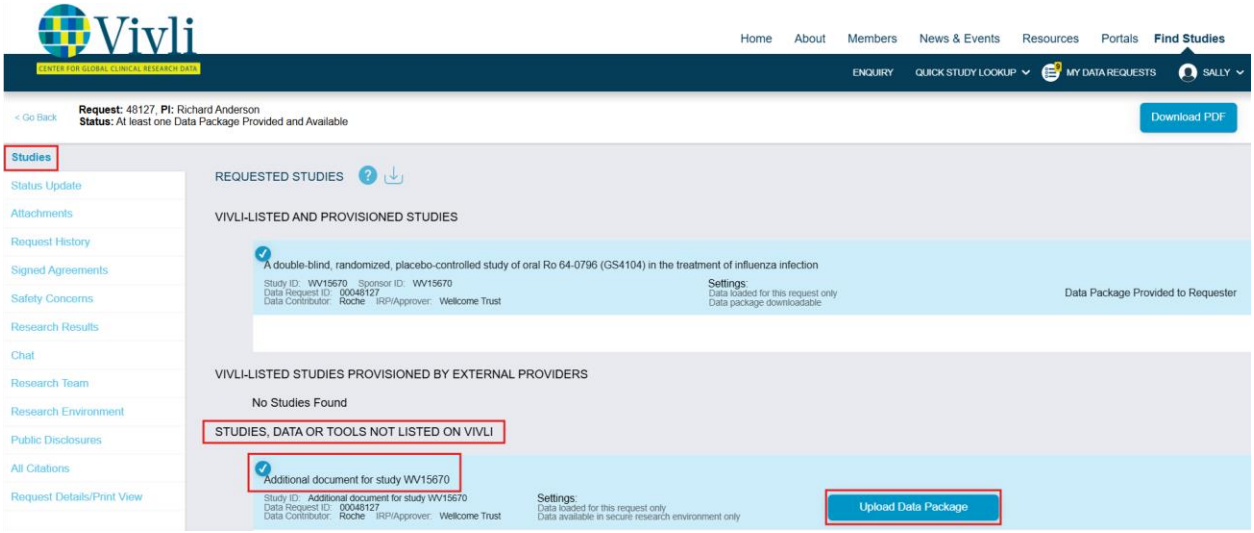
If you are not ready to upload data at this time, you will be prompted to upload data when the next data request with this study has completed DUA approval. For more information, please see Section 5.4 Upload Data Package to an Approved Data Request.

5.9 Upload Additional Data or Documents After the Initial Upload

1. Data Contributors can add study documents or additional data, or replace the data package that was provided to an existing approved data request in the analysis stage after the initial upload.

2. As a first step, reach out to the Vivli team at support@vivli.org to inform them whether you want to add the files for just one specific request and/or all for future requests of this study.

3. Based on your response, the Vivli admin may reset the study record so that you can upload the data package again,or add an unlisted placeholder record to allow you to add a one-off data package. To upload to an unlisted placeholder record, please go to the data request and under the studies tab, at the bottom under the “Studies, Data, or Tools Not Listed on Vivli” section, you will see an option to upload the additional data package.



4. You may have to upload placeholder documents due to the required file types for study upload.

5. For the next steps on uploading the data, please see Section 5.6 Steps to Upload Data Package

6. Once you load the file(s), please let the researcher know via chat that you have uploaded additional data or documents. The Vivli team will also give further instructions to the researcher to add these files to the secure research environment.

5.10 Uploading Data to Only One Data Request

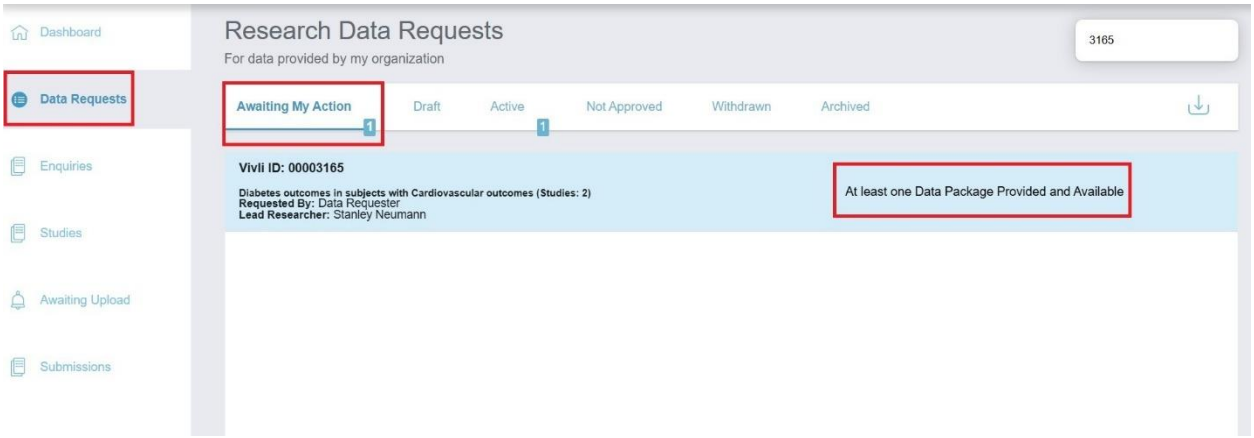
1. By default, the data package uploaded to the Vivli platform is stored in the secured vault and is automatically provisioned to the next researcher when their request is approved and when their DUA is executed. However, Organization Administrators can make selections for a data request when a data 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.

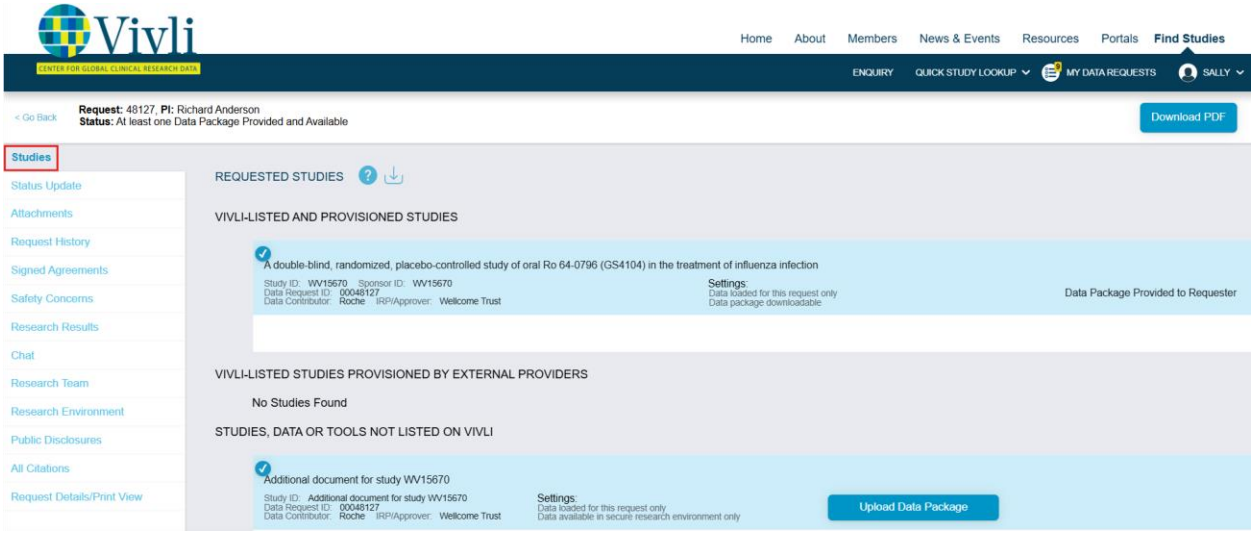
2. Organization Administrators have the option to make this selection at the Data Contributor review stage. Please see 4.3 Study settings at Data Contributor Review. This setting will be visible (but not settable) on requests that have been fulfilled (data package uploaded).

3. To upload the data package for a particular data request only, wait for the request to reach the Data upload stage.

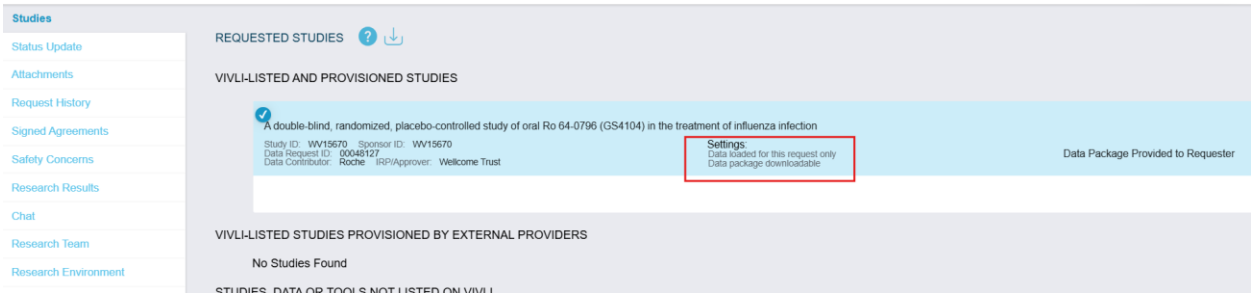
4. Click on the Data Request tab on the left side and type in the data request ID to locate the data request– data requests in need of a data upload will be listed under Awaiting My Action:



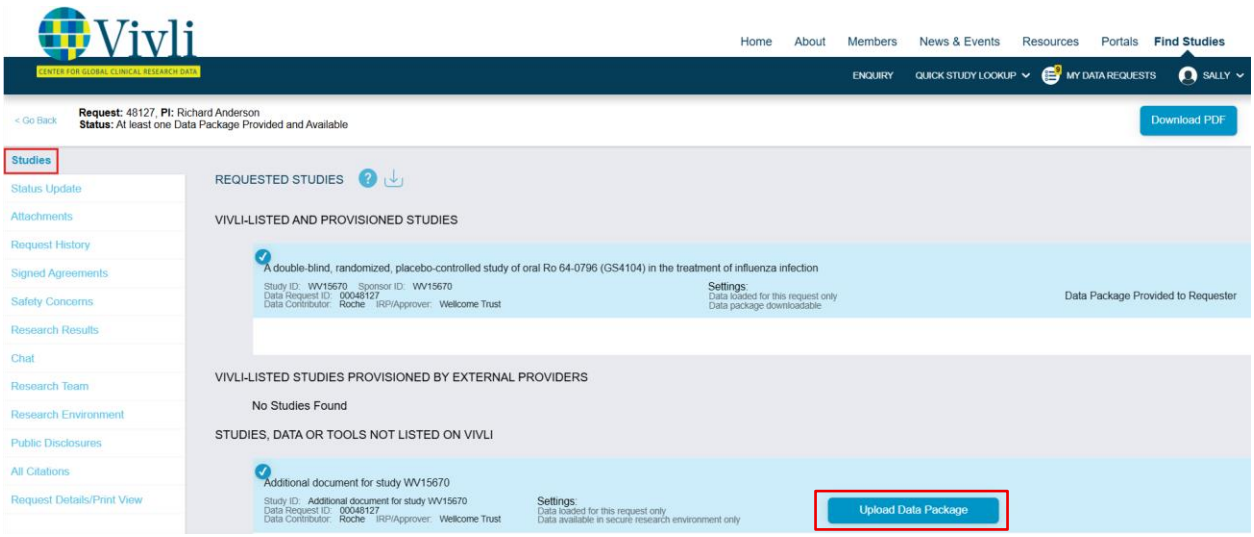
5. Click on the data request, and then click on Studies on the left:



6. You can see the study settings which note “Data loaded for this request only”. For more information, please see Section 4.3 Study Settings at Data Contributor Review



7. Click on **Upload Data Package.**



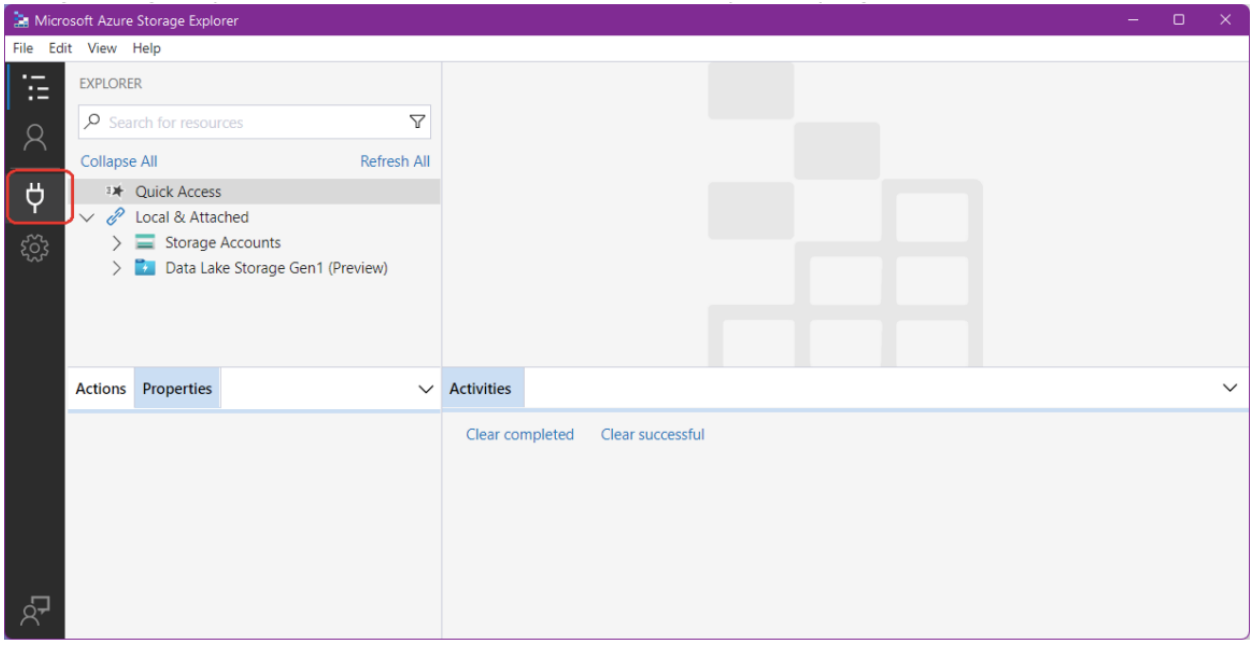
8. For the next steps on uploading the data, please see Section 5.6 Steps to Upload Data Package

5.11 Uploading Large Files And Data Packages

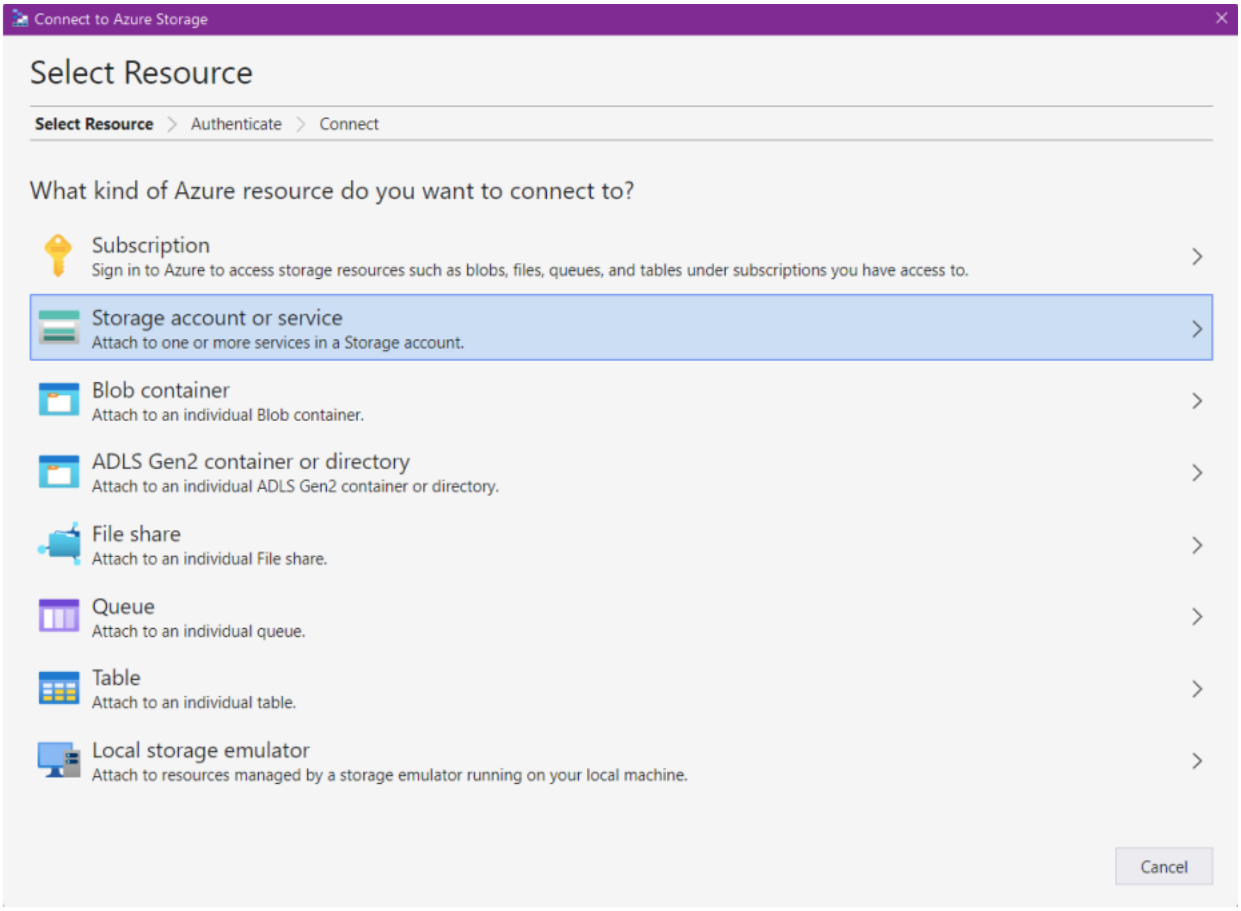
1. If you have not already had a discussion with Vivli at support@vivli.org about how the data will be organized and how it will be used, we recommend that you start with that, so that Vivli can advise on how best to package the data, e.g. into a single large zip file or a small number of individual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

2. Download and install the Azure Storage Explorer from the URL: https://azure.microsoft.com/enus/features/storage-explorer/ (you can also enter “Azure Storage

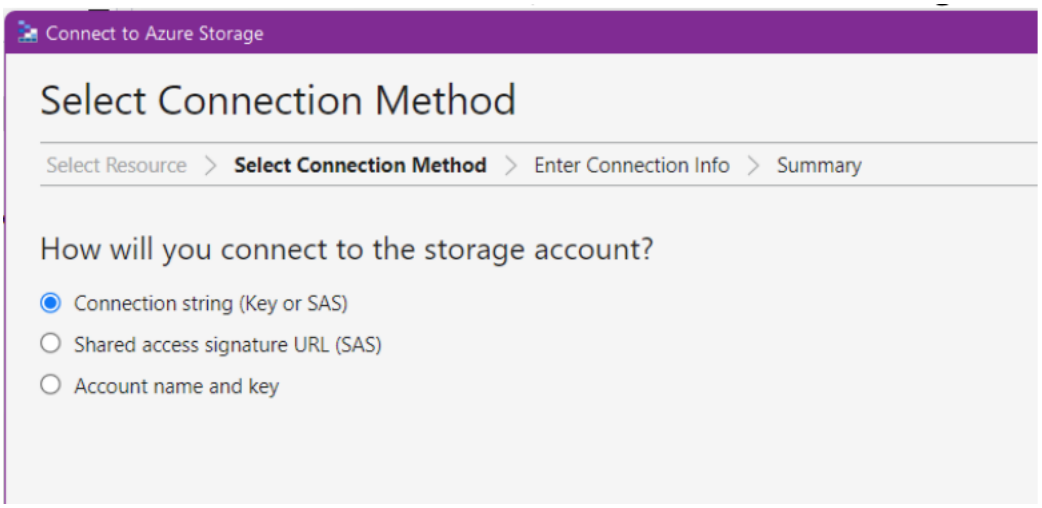
Explorer download" into your favorite search engine.) After starting Storage Explorer, click on the icon that looks like a power plug:

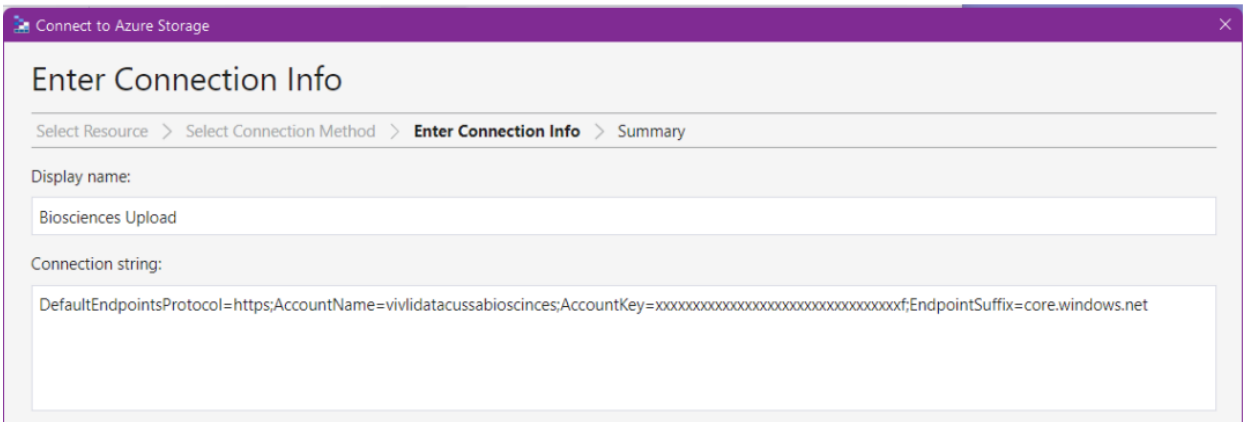


3. In the pop-up window pick "Storage account or service":

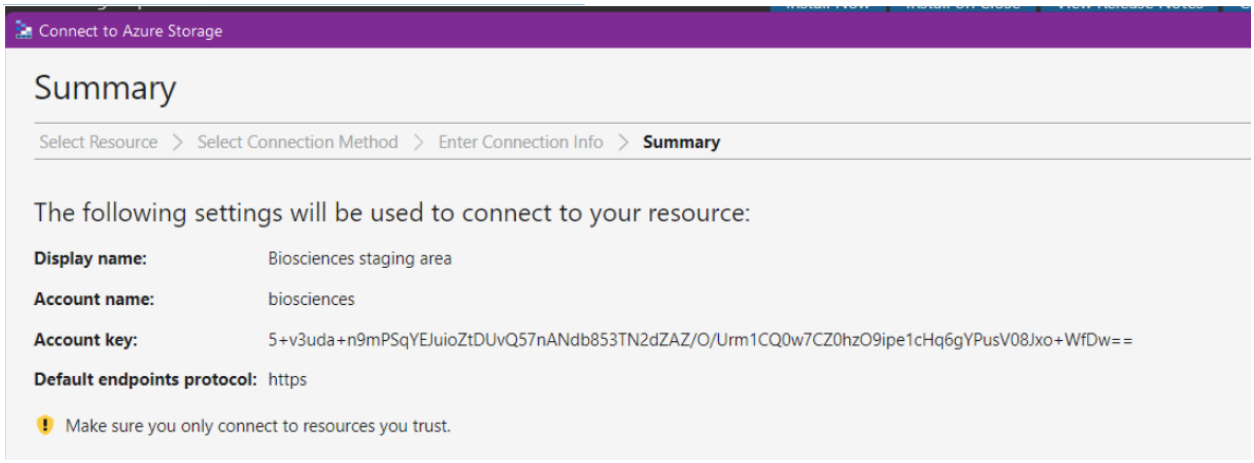


4. In the Select Connection Method window, choose Connection string:

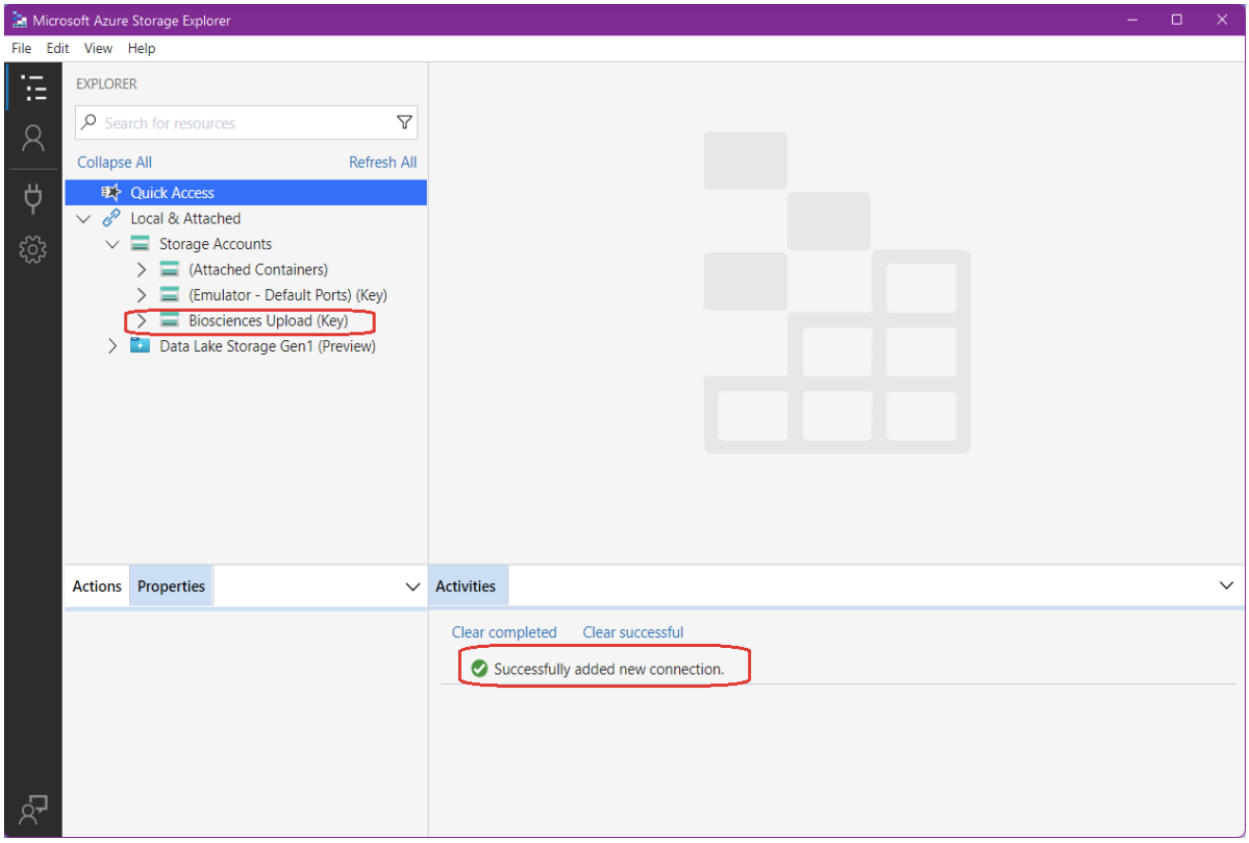




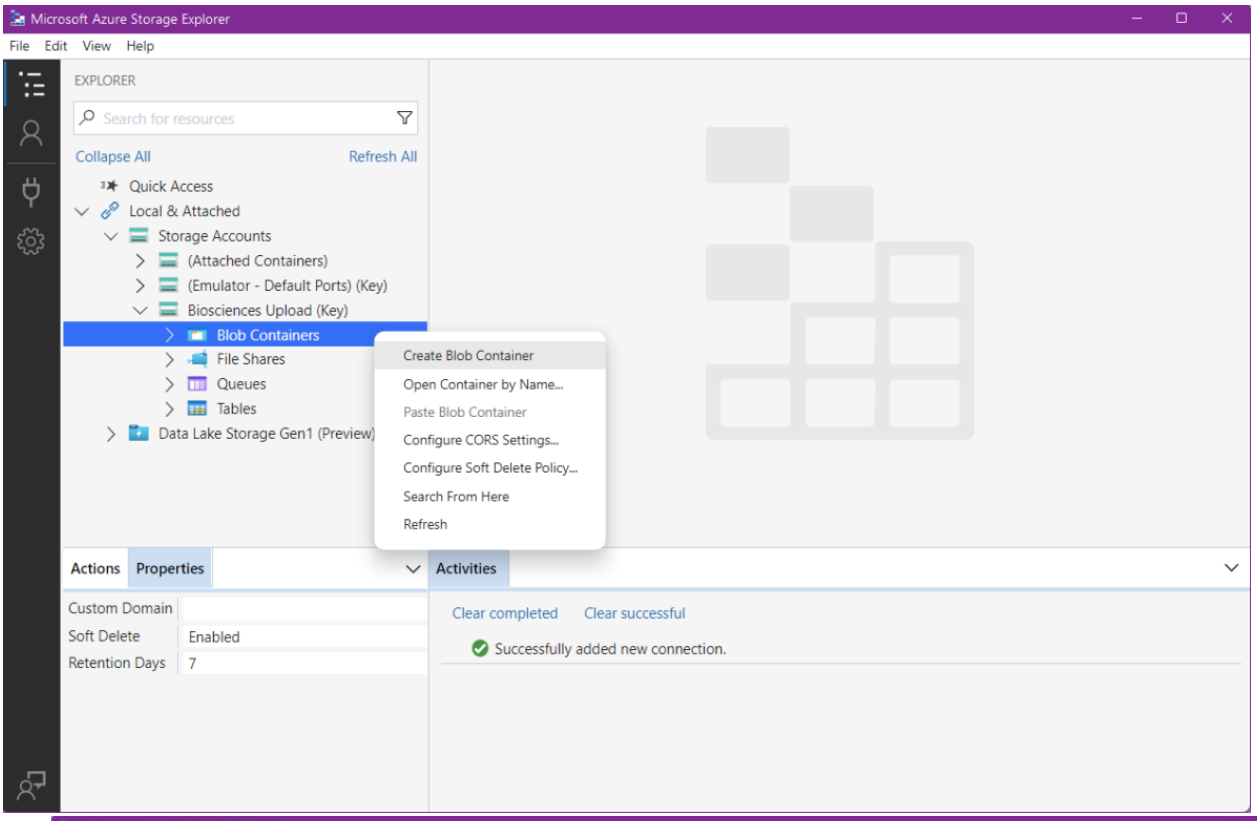
5. The display name should be the NCT or Sponsor ID for the study; the connection string must be the value sent to you separately from Vivli. On the summary/confirmation screen, click “Connect”:

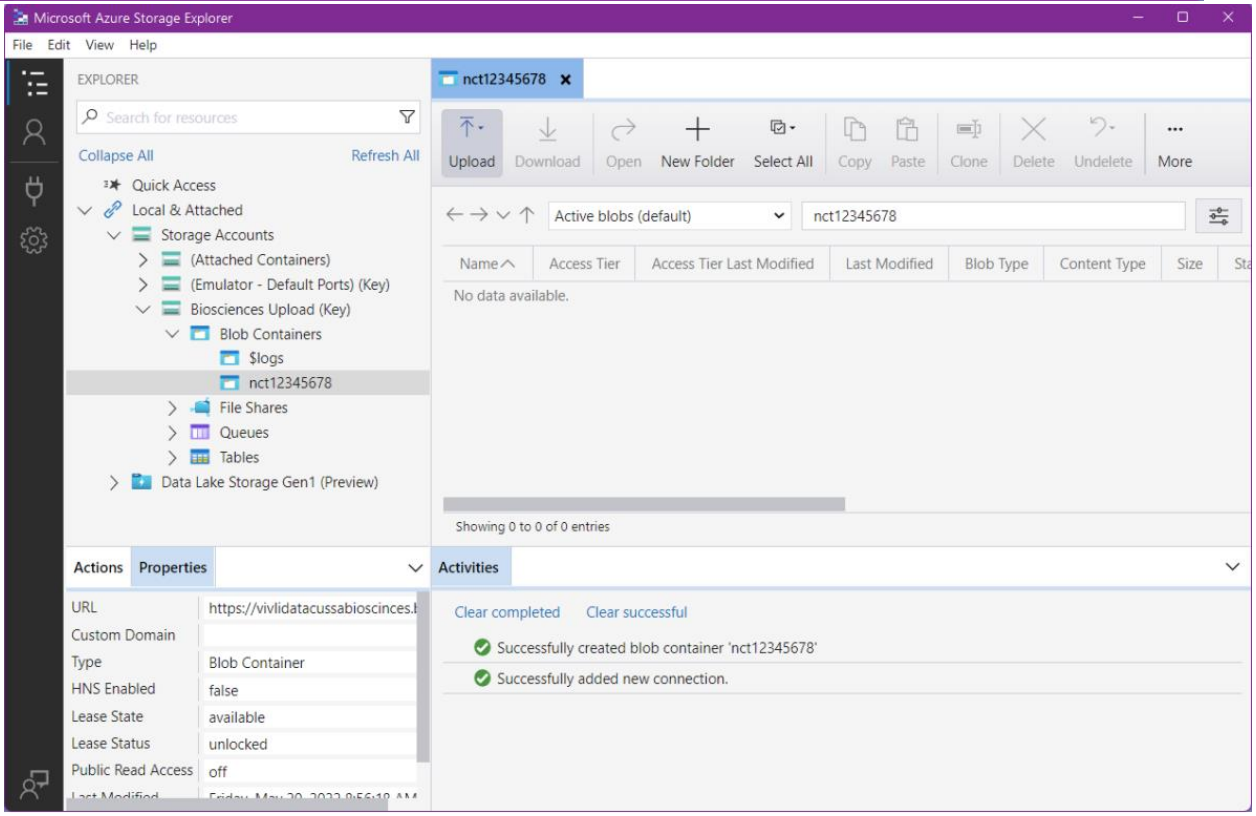


6. It should add the storage account to the list on the upper left, and report “Successfully added connection:

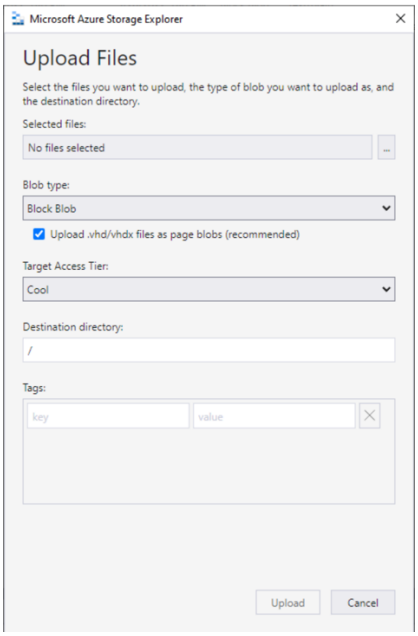


7. Click on the ">" to open the storage account, then right-click on Blob Containers and choose "Create Blob Container". Give it a name that represents the study (e.g. the NCT ID or sponsor ID). Note that container names are limited to numbers, lowercase letters, and hyphens, but no spaces or uppercase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

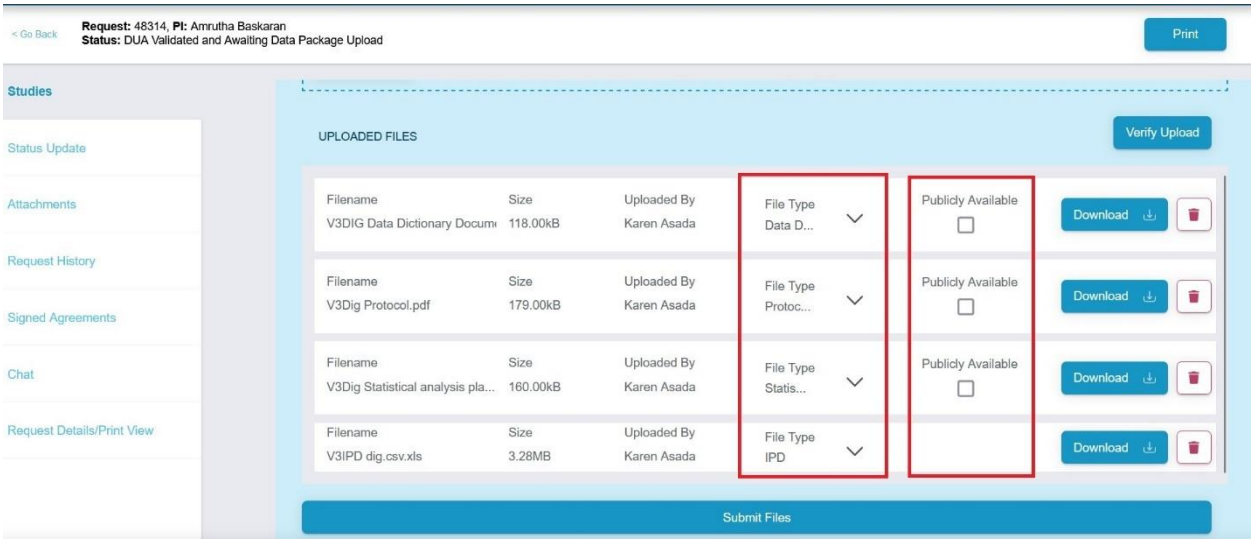
5.12 Supporting Documents for Researchers Searching For Studies

For listed studies, you may choose to make the supporting documents such as data dictionary, protocol, statistical analysis plan, and/or others, available to researchers on the search page while they are searching for studies. This will help a researcher with a Vivli account to review the study information and finalize it before adding it to their data request. Researchers have told us having access to the supporting documents is important when they are formulating their request so that they know that the studies they are requesting will actually help them answer their hypothesis.

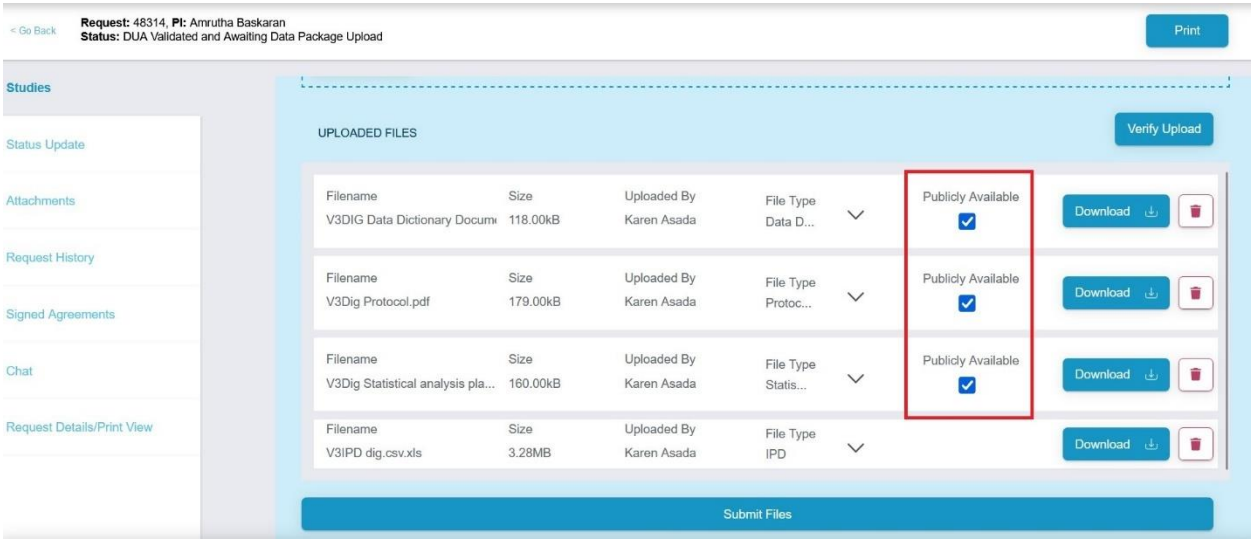
If you would like to specify which types are to be selected by default for your organization, please contact Vivli at support@vivli.org. You can uncheck the selection for individual studies at any time.

5.12.1 Loading Supporting Documents at the Time of Data Upload

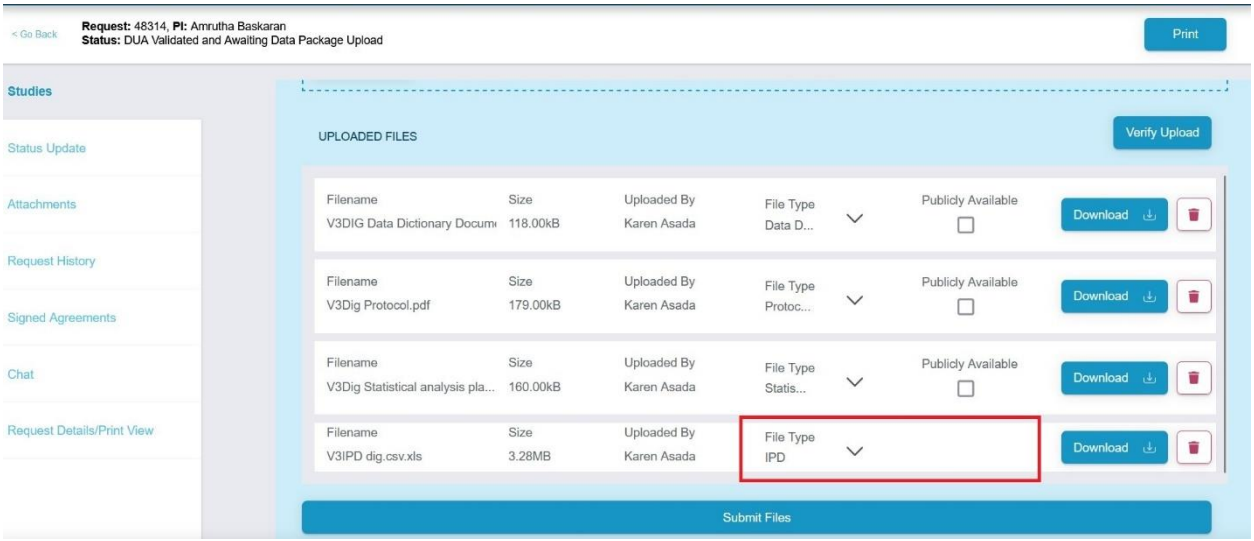
1. You may make supporting documents available to researchers on the search page during the study data package upload.
2. At the time of data upload, after selecting the file types, you have the option to make the supporting documents available for the researcher to search. For more information, please see Section 5.6 Steps to Upload Data Package



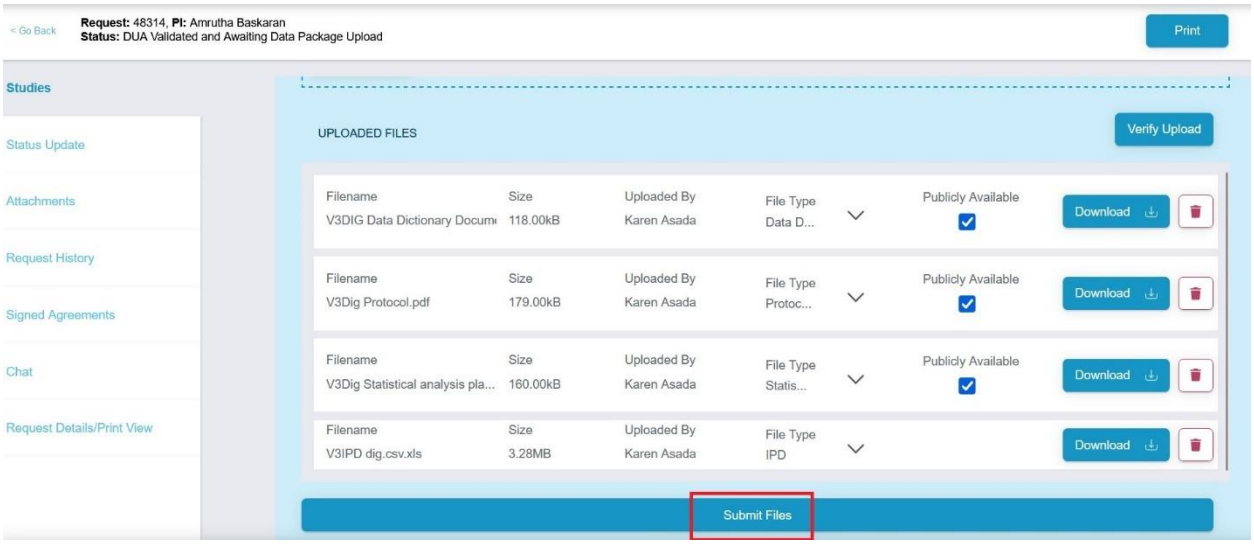
3. To make supporting documents available to researchers for search, check the box that says "Publicly Available" next to the document.



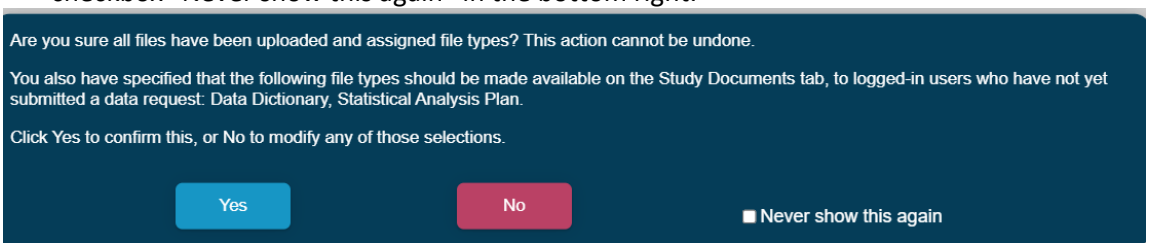
4. Note: Files that have the file type “IPD” and “Analysis ready dataset” will not have the option to check “Publicly Available” as Individual Participant Data (IPD) is NOT publicly available to researchers who have not signed the Data Use Agreement (DUA).



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

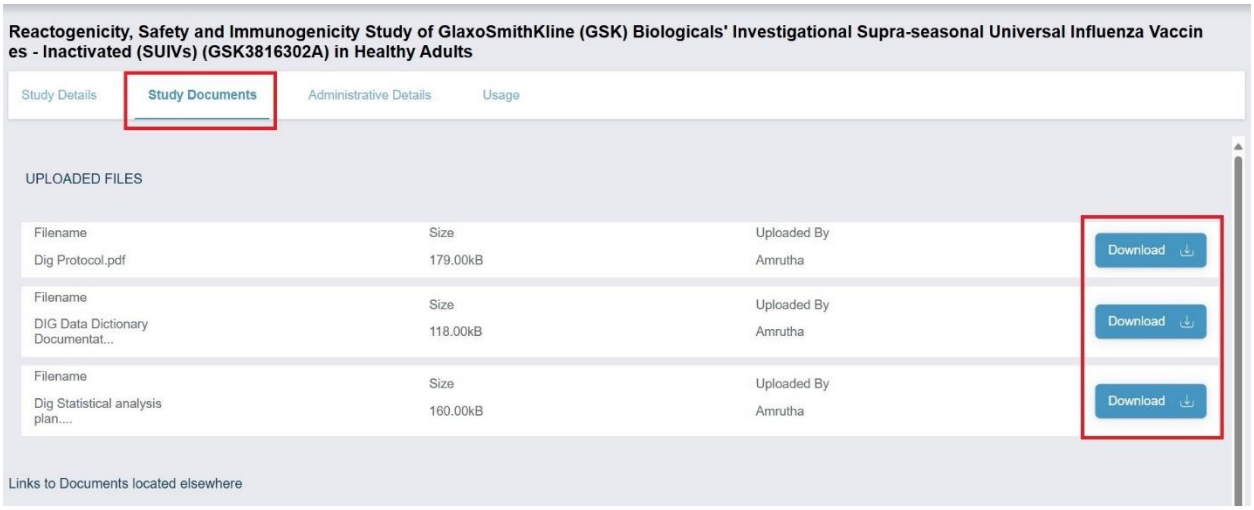


6. A pop-up confirms that you have uploaded all files and assigned file types. Additionally, the files that you have chosen to be made publicly available will be displayed and you will be asked to confirm you have selected the correct file(s) to be made publicly available. Click the blue 'Yes' button to proceed. Or click the red button "No" to adjust your selections and you will be re-routed to the Upload Data page again. If you do not wish to see this message again for other studies, check the checkbox "Never show this again" in the bottom right.



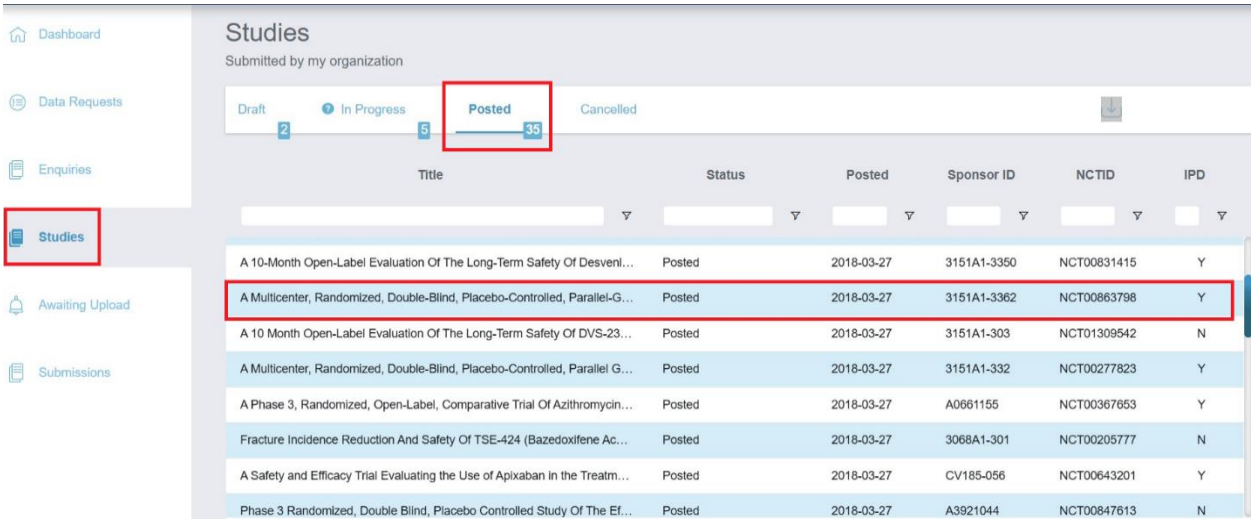
7. You will receive confirmation of successful upload. Click the ‘Continue’ but

8. The supporting documents that you have made publicly available will be visible to the researcher with a Vivli account on the search page.

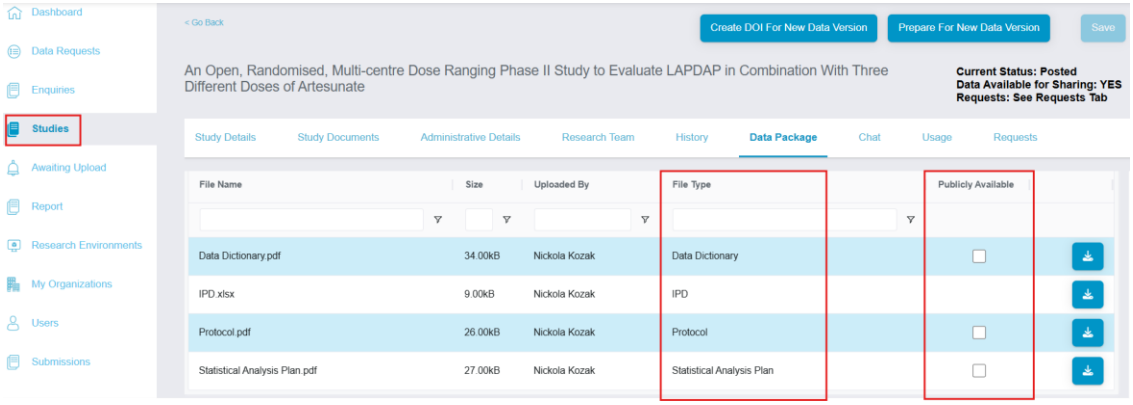


5.12.2 Loading Supporting Documents for Previously Uploaded Data Package

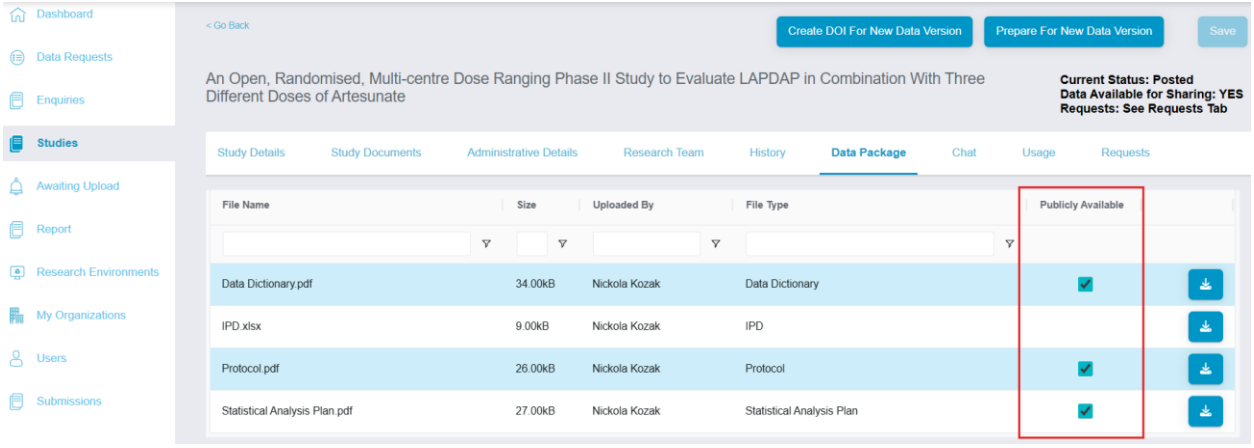
1. You can make supporting documents available to researchers on the search page after study data package upload stage.
2. Go to the studies tab and go to the posted section.



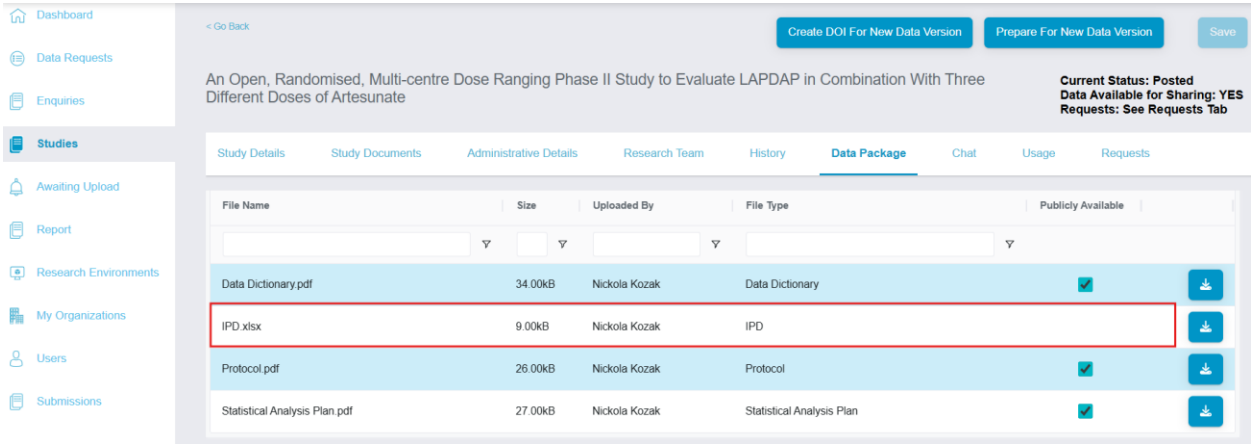
3. Open the study. In the study screens, the “Data Package” tab will have the option to select the files to be made publicly available next to file type



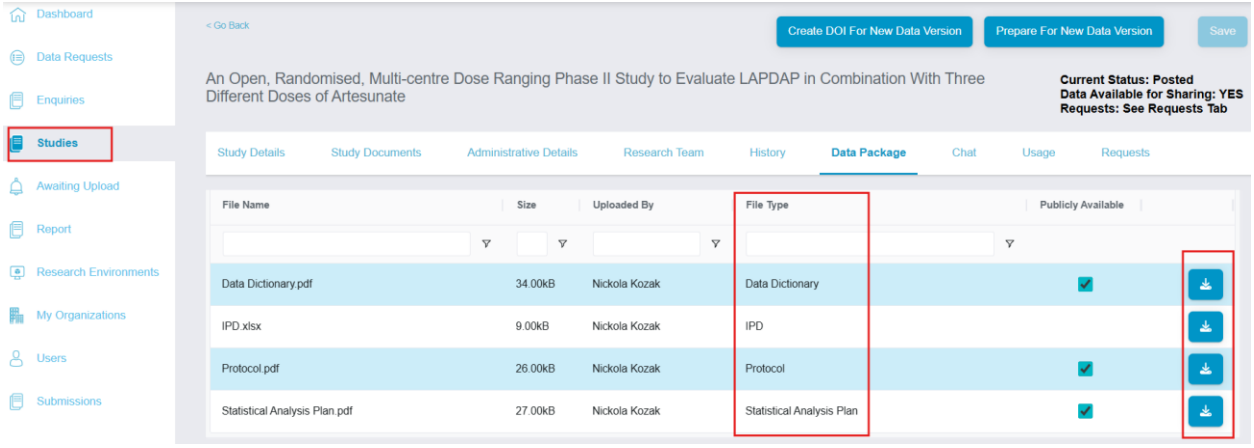
4. Check the box that says “Publicly Available” next to the document.



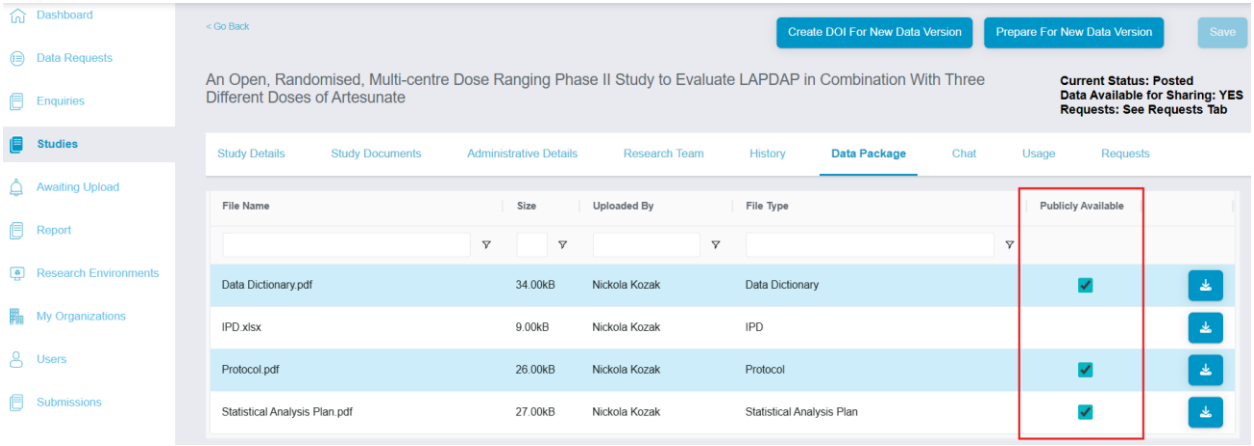
5. Note: Files that have the file type “IPD” and “Analysis ready dataset” will not have the option to check “Publicly Available” as Individual Participant Data (IPD) is NOT publicly available to researchers who have not signed the Data Use Agreement (DUA).



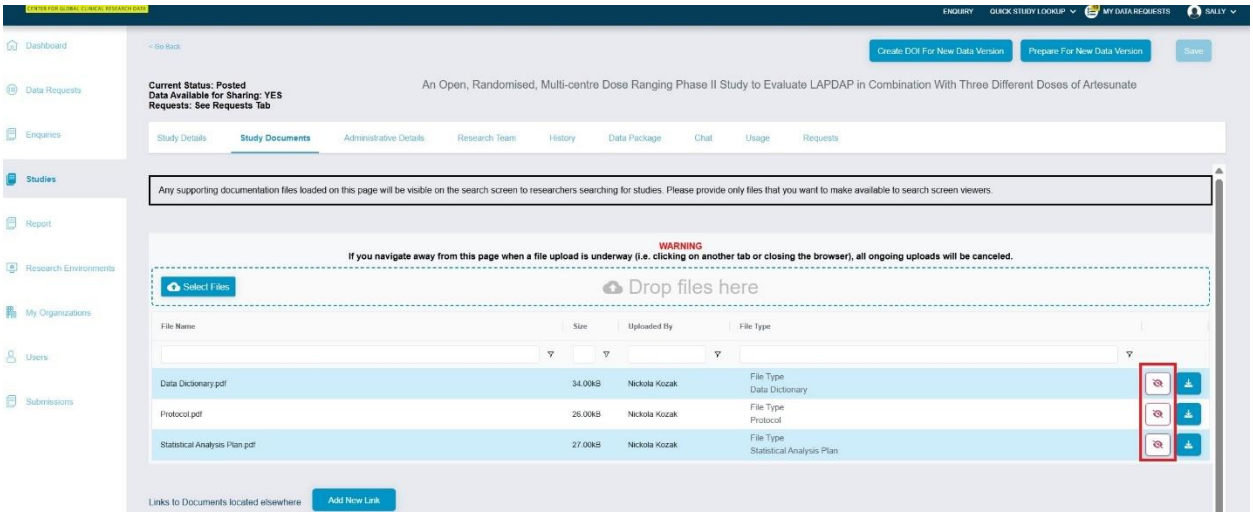
6. Go to the **Study Documents** tab to see these supporting documents which you have made publicly available. Click on the download button to see the version of the files provided to the Researcher as publicly available documents



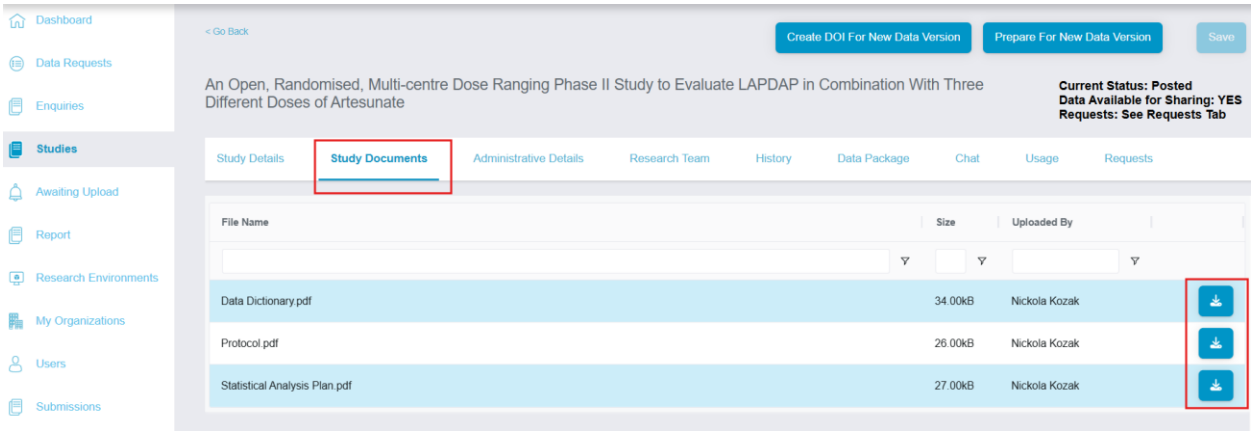
7. To remove the supporting document from the search page, navigate to the Data Package tab, and uncheck the box next to the document. The documents will disappear from the Study Documents section.



8. You may also click navigate to the “Study Documents” tab and click on the red eye icon to remove the supporting document from the search page. The documents will disappear from the Study Documents section.



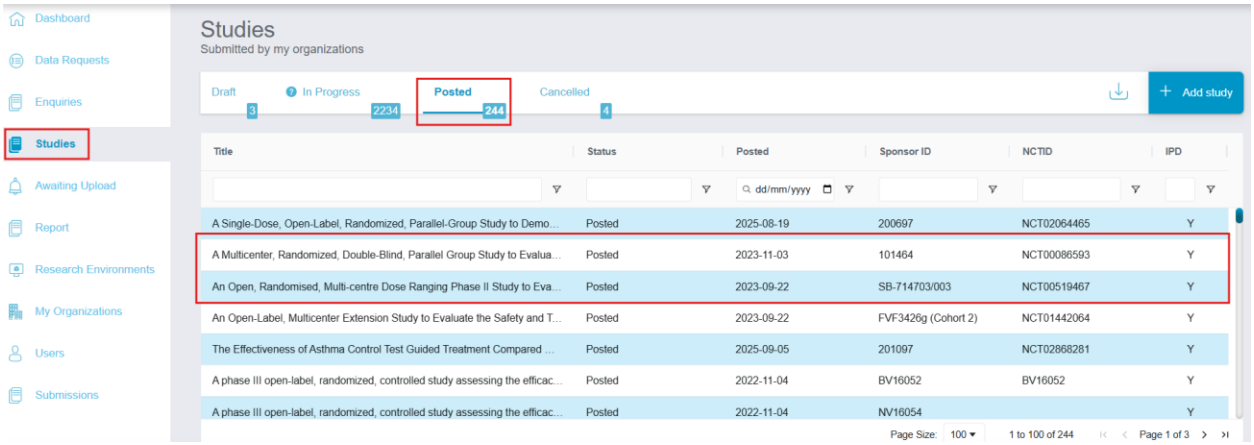
9. The supporting documents that you have made publicly available will be visible to the researcher with a Vivli account on the search page.



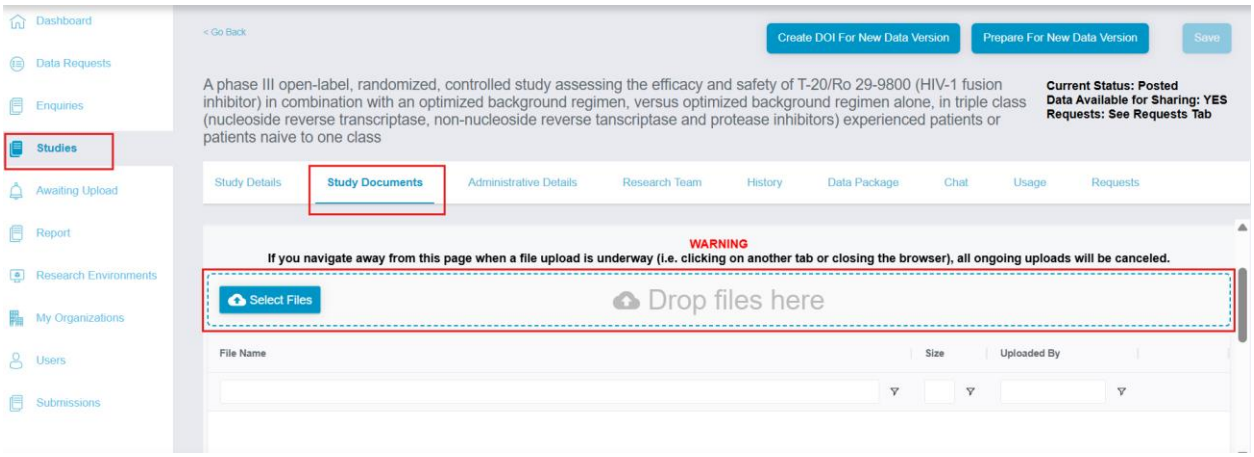
5.12.3 Loading Supporting Documents that are not part of Data Package

You may make supporting documents available to researchers on the search page that are not part of the study data package.

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



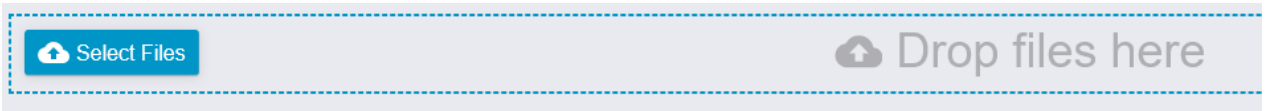
2. Open the study and go to Study Documents



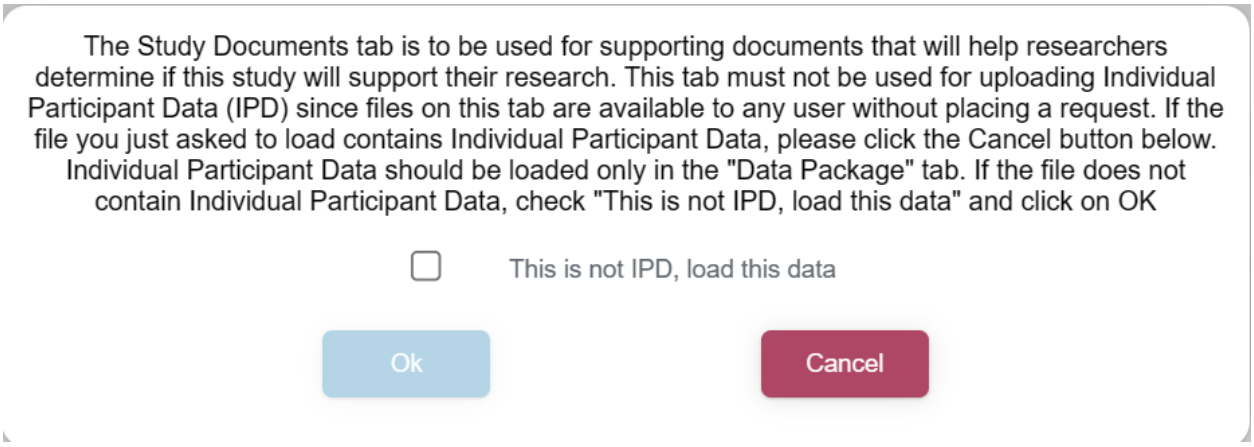
3. Now click on 

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 can also drag files into the submit window indicated by the dotted blue box:

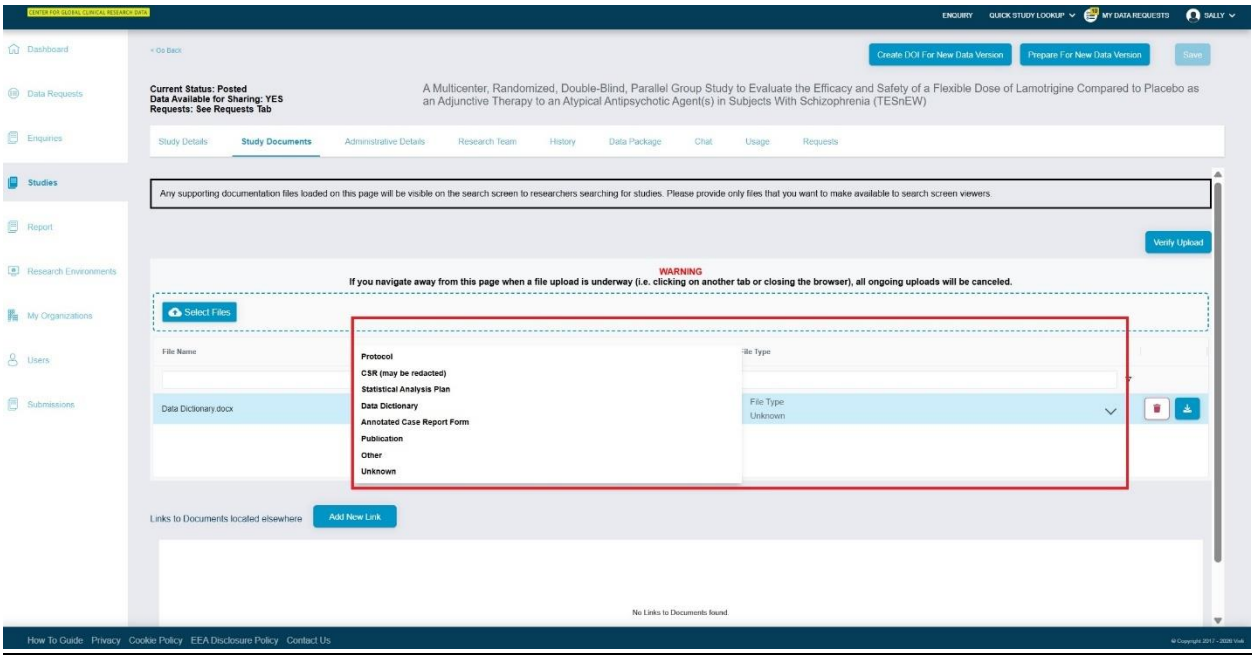


5. **Note**: Individual participant data (IPD) should NOT be uploaded in this section
6. The following window may appear to confirm that IPD files are not uploaded in this section

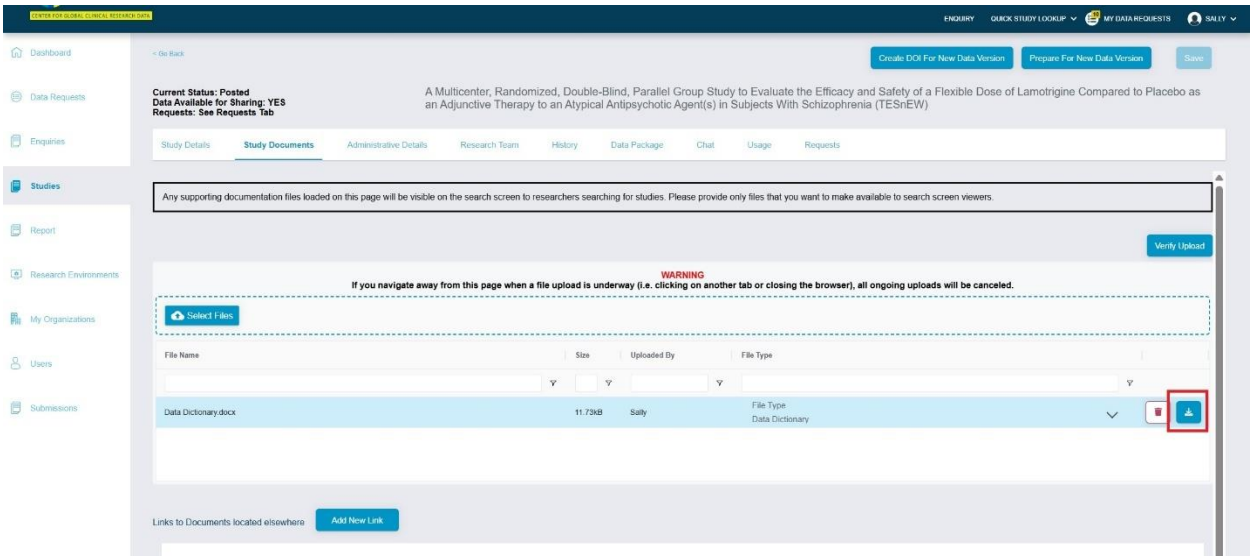


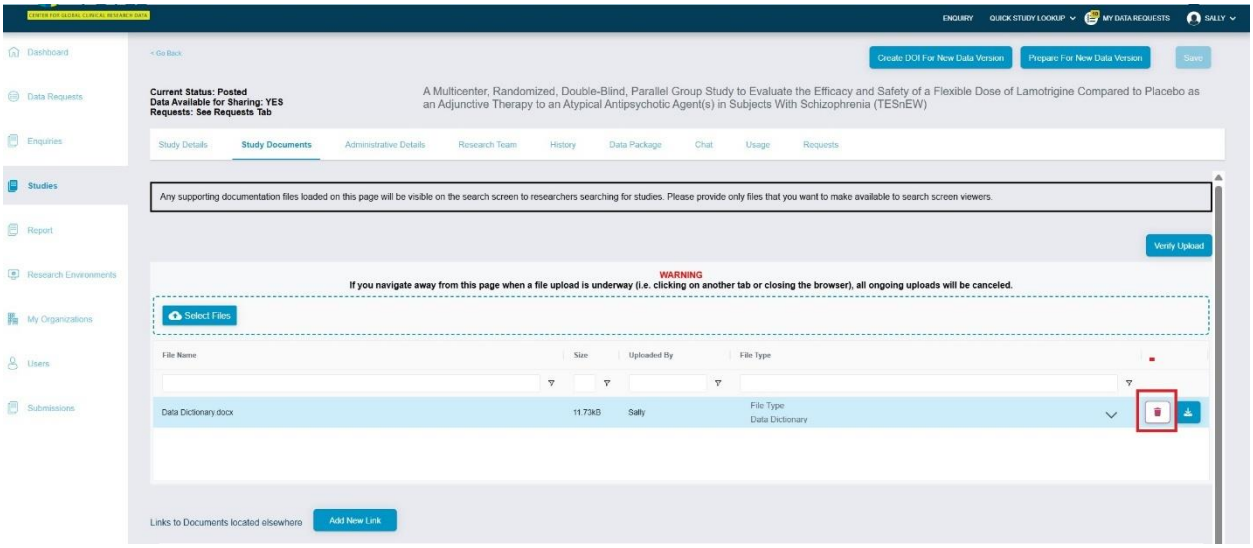
7. Check the checkbox to confirm that the files are not IPD and then click OK.

8. If you navigate away from a page on which an upload is underway (i.e. clicking on another tab or closing the browser), that will cancel the upload automatically
9. Select a file type for each supporting document in the drop-down menu.



10. You can download the loaded files. You can delete any files by clicking the "delete" button:



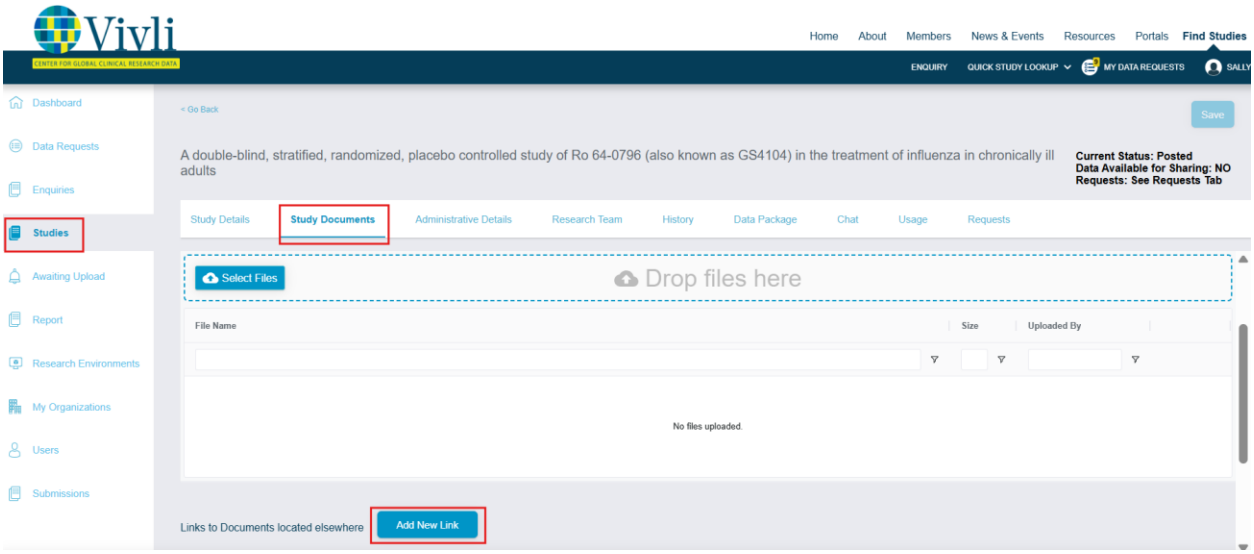


11. The supporting documents that you have made publicly available will be visible to the Researcher with a Vivli account on the search page.

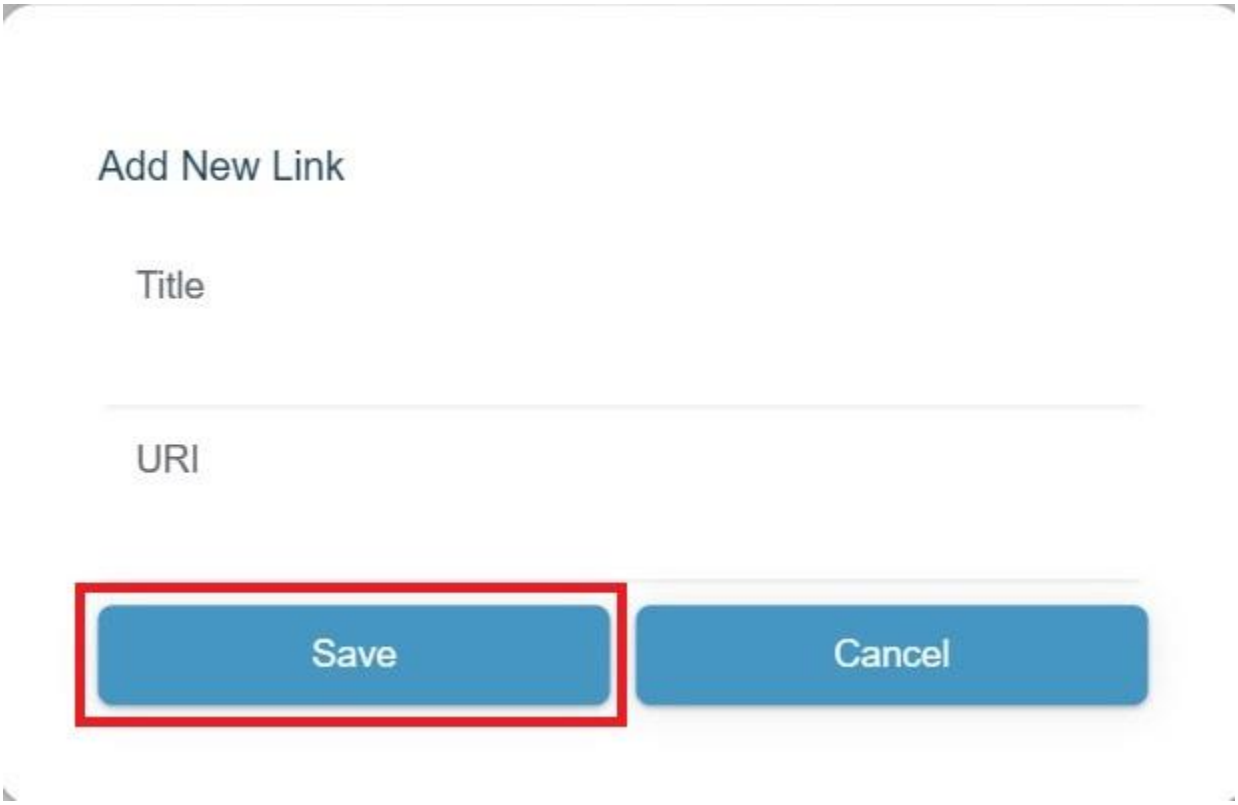
5.12.4 Providing Links to External Supporting Documents

1. If there are further documents that are available for your study at an external link, you can make the link available to researchers on the search page

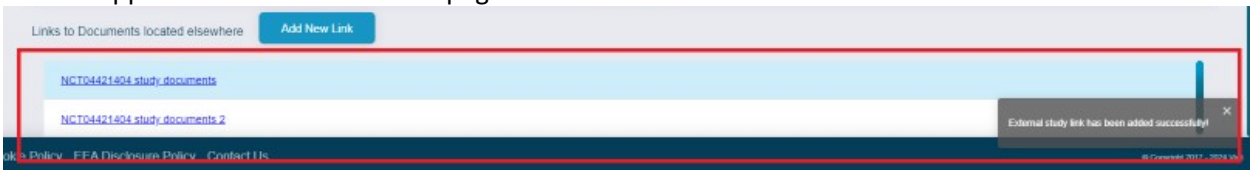
2. Go to Study Documents and click the blue button that says, “Add New Link”.



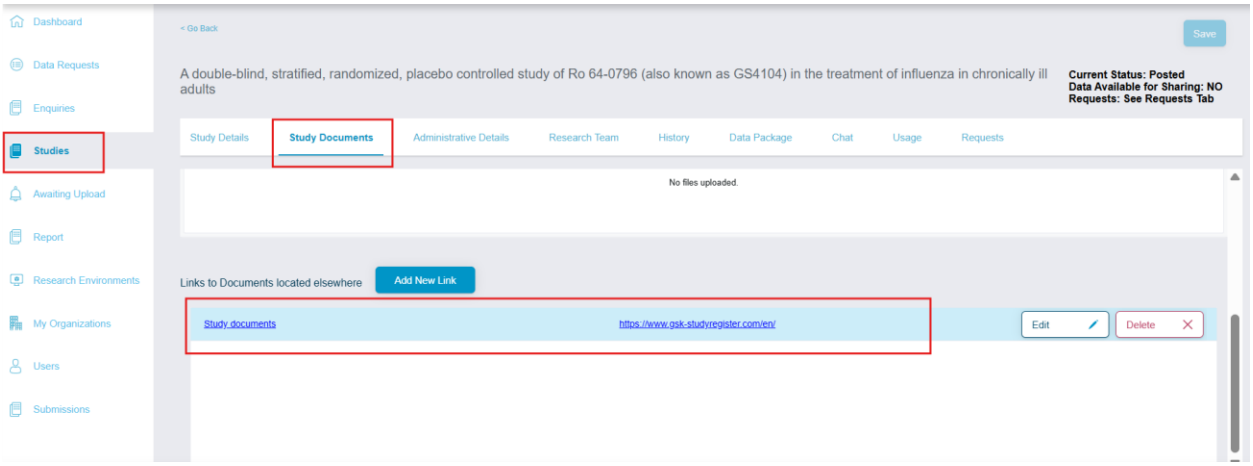
3. In the box that appears, type in the Title of the document and the URL, and then click “Save”



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

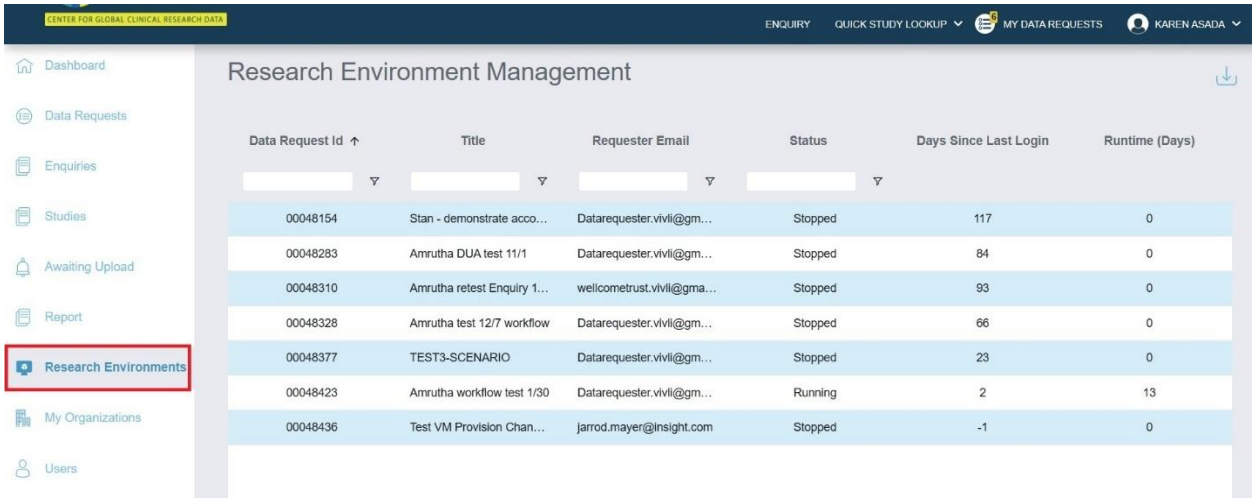


5. The External link to the documents that you have made publicly available will be visible to the Researcher with a Vivli account on the search page.

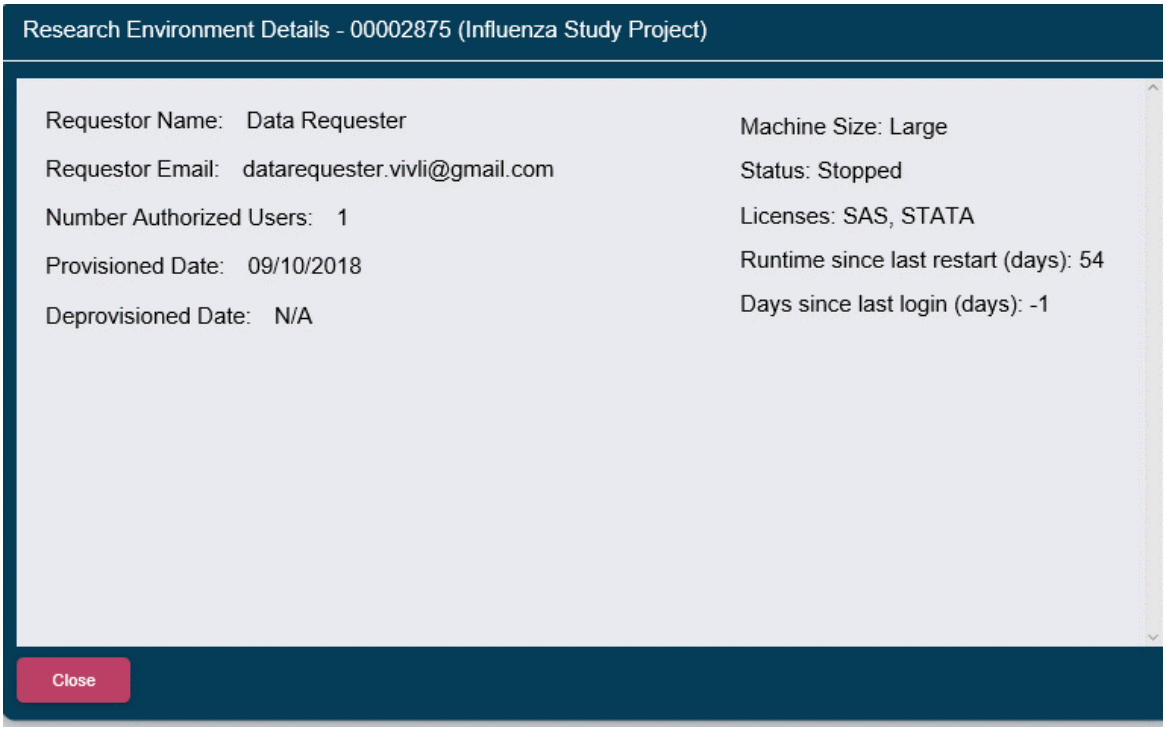


6. Secure Research Environment Monitoring

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



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



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

6.1 Software in the secure Research Environment

- The software available in the secure Research Environment is updated regularly and a comprehensive listing of the software and R packages is available in the secure Vivli Research Environment. The full list is on the Vivli website under “Software and R Packages Available in the Research Environment”: https://vivli.org/resources/resources/

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

6.2 Downloadable Data

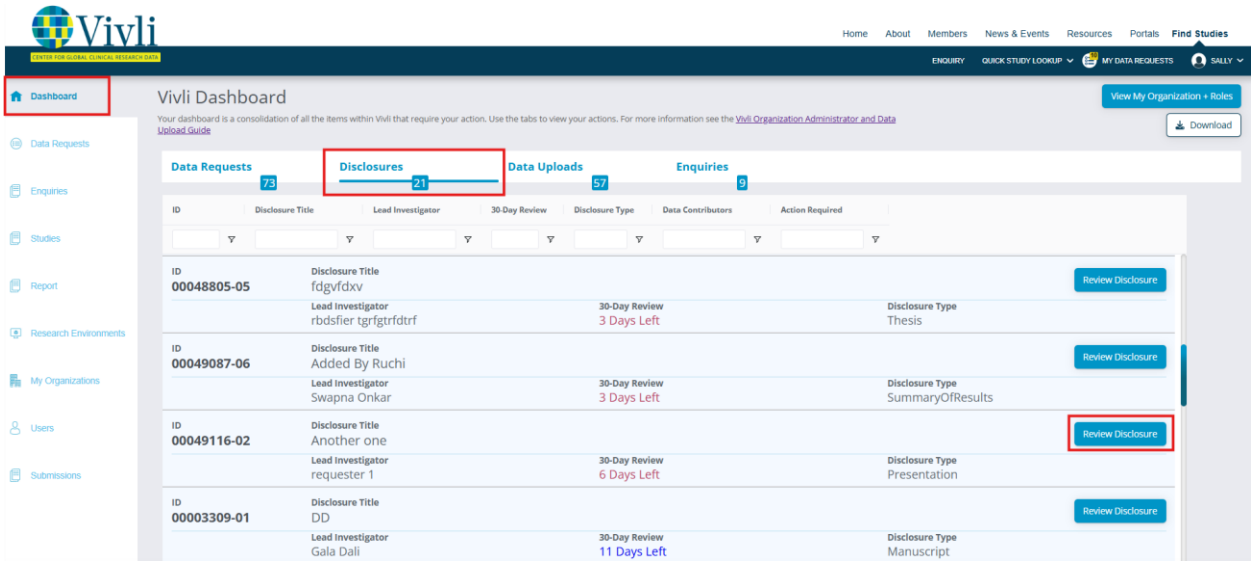
- If the study is made downloadable as per Vivli Member’s data sharing criteria, the research team will sign the Standard Data Use Agreement and security addendum.
- After the study data package is uploaded, the Research Team will have the ability to download the study data.
- After the completion of the analysis and public disclosures are signed, the research team is required to provide confirmation of the data destruction of the downloadable data.

7. Public Disclosures & Publications & Summary of Results

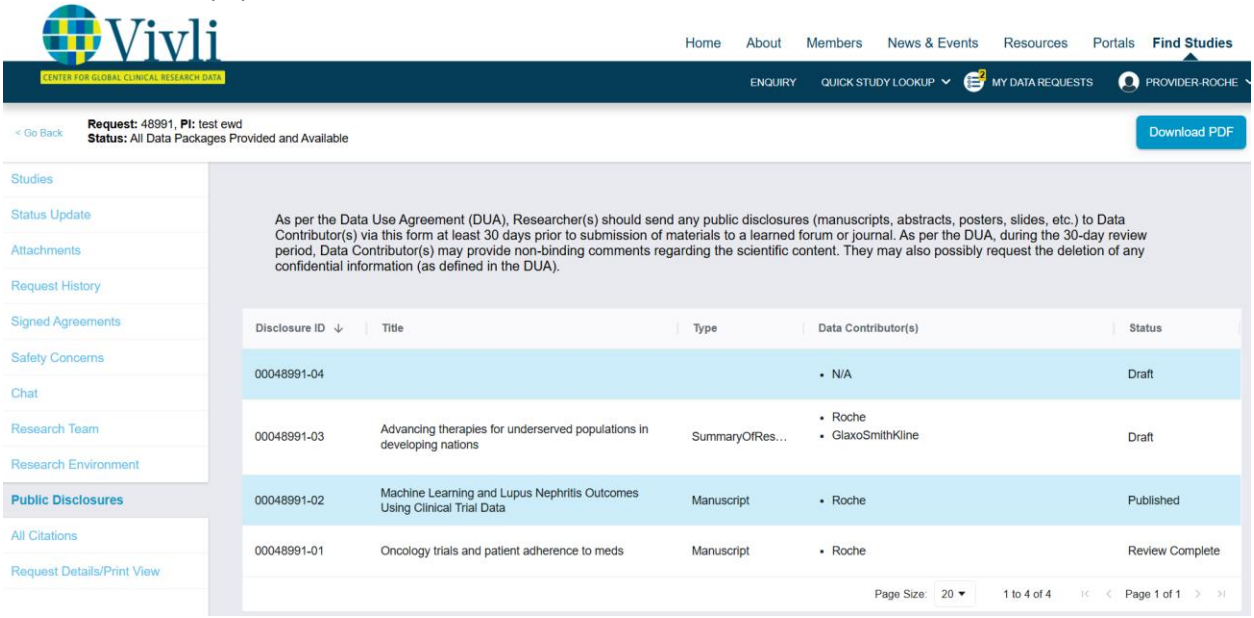
7.1 Review(s) by Vivli Members

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 Organizational Administrators for review.

You can see all publications waiting for your review in the main dashboard, under ‘Disclosures’. Clicking on the blue ‘Review Disclosure’ button will take you into the relevant data request public disclosure record where you can download or review the publication, or record your feedback.



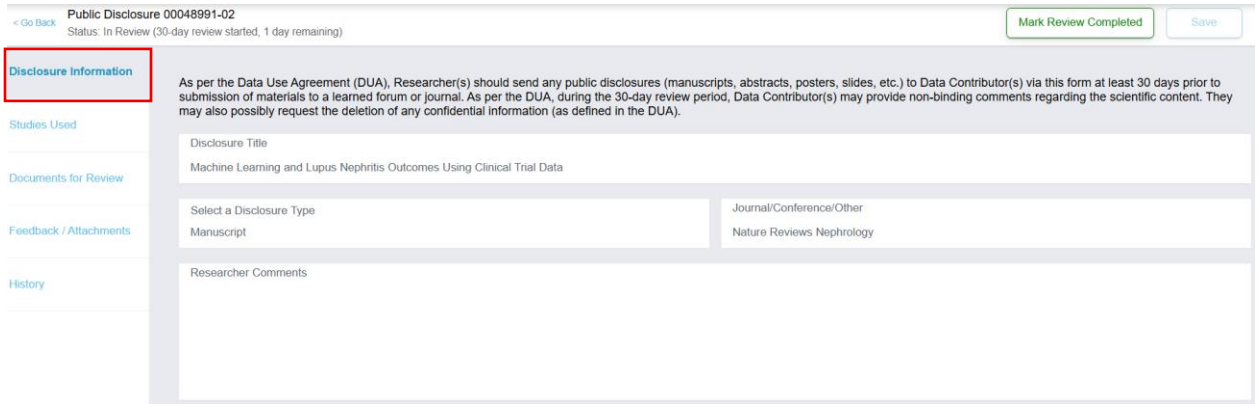
Data Requestors will provide Vivli the submitted copy of any public disclosure via the Public Disclosures tab at least 30 days prior to submission



1. Each submitted public disclosure will have a unique Disclosure ID that begins with the Vivli Request ID followed by a two-digit sequence. The Public disclosures tab will provide an overview of each public disclosure that has been submitted for review and the status of each disclosure for that individual request.

A Disclosure in the “Draft” status may be deleted by the Vivli admin only. If you believe a Draft is a duplicate submission, please reach out to the Vivli team via the Data Contributors chat and a Vivli admin will confirm and delete it, if needed.

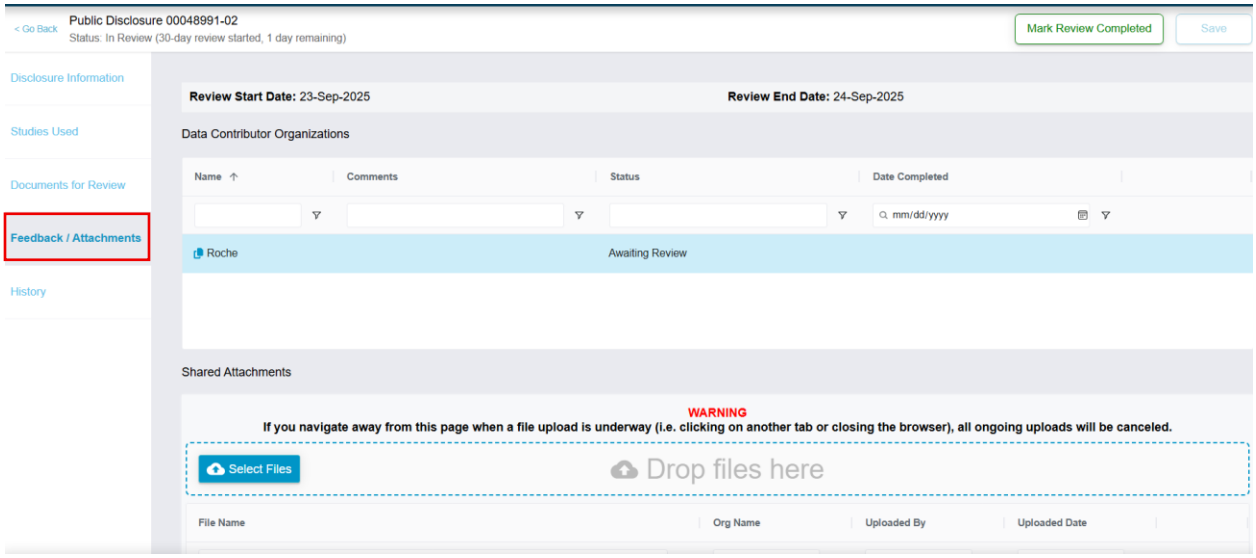
2. If a researcher indicates that they do not have publishable results, Vivli requests a summary of results from the Researcher. The Researcher will submit the summary via the "Public Disclosures" tab and select the Publication Type as "Summary of Results". This summary of results will be sent to the Organizational Administrators and will follow the 30-day review process for public disclosures.
3. Public Disclosure review statuses:
    - *Review Complete* – The review has been completed, or the 30-Day review period has expired.
    - *Not Published* – Review has been completed but the disclosure will not be published.
    - *Published* – The disclosure has been cited and published.
    - *Draft* – The disclosure is in a draft state and has not been submitted for review.
    - *30-Day Review* – The disclosure is in the 30-Day review period.
4. Once a Researcher has submitted a new public disclosure for review, the Vivli platform will notify the Organizational Administrator via email that a public disclosure has been submitted for courtesy review with an embedded link to the disclosure review page.
5. Organizational Administrators can utilize the link in the email or click on the Public Disclosures tab in the platform. When a disclosure record is clicked, a new page will appear with five tabs; *Disclosure Information, Studies Used, Documents for Review, Feedback/Attachments, and History*.



- The *Disclosure Information* tab provides a summary of the Public Disclosure, including Title, Type, the Journal or Conference where the disclosure will be published or presented and any Researcher Comments.
- The *Studies Used* tab displays which studies were included or excluded in the disclosure analysis. If no studies from a specific Data Contributor are included (in a

multi-sponsor data request), that contributor will not receive an email notification and no action will be required from them.

- The *Documents for Review* tab holds all documents that have been submitted and are available for review. The Researcher is only allowed to submit a maximum of 2 files per public disclosure.
- In the *Feedback/Attachments* tab, Organizational Administrator submits courtesy review comments as free text or attachment and marks the courtesy review as completed. Searchable text fields are available to filter Data Contributor Organization reviews related to the disclosure. This page also provides information on the courtesy review Start and End Dates and Data Contributor Organization review statuses.



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). 6. If the Organizational Administrator does not click 'Mark Completed,' the courtesy review will remain in the 'Awaiting Review' status until the 30-day period has ended.

6. Once the 30-day period has ended, the Vivli platform will automatically complete the review, and the Researcher will be notified. Otherwise, if all Data Contributors complete their review prior to the 30-day period, the review period will end, and the Researcher will be notified so that they may submit their disclosure to a learned forum.

- Once the courtesy review period has ended (either by Data Contributor completion or the expiration of the 30-day period), a Citations tab will appear when a disclosure has completed

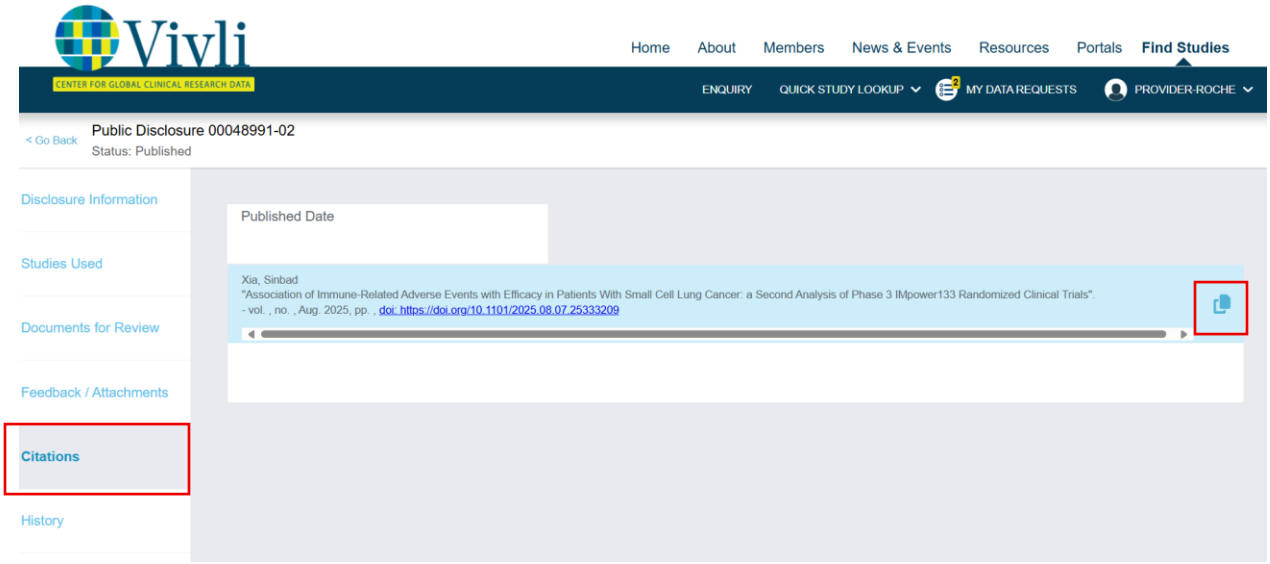
review. The Organizational Administrator will receive an email confirming the completion of the review.

7. When should a Vivli Member be considered an author on a manuscript or public disclosure?

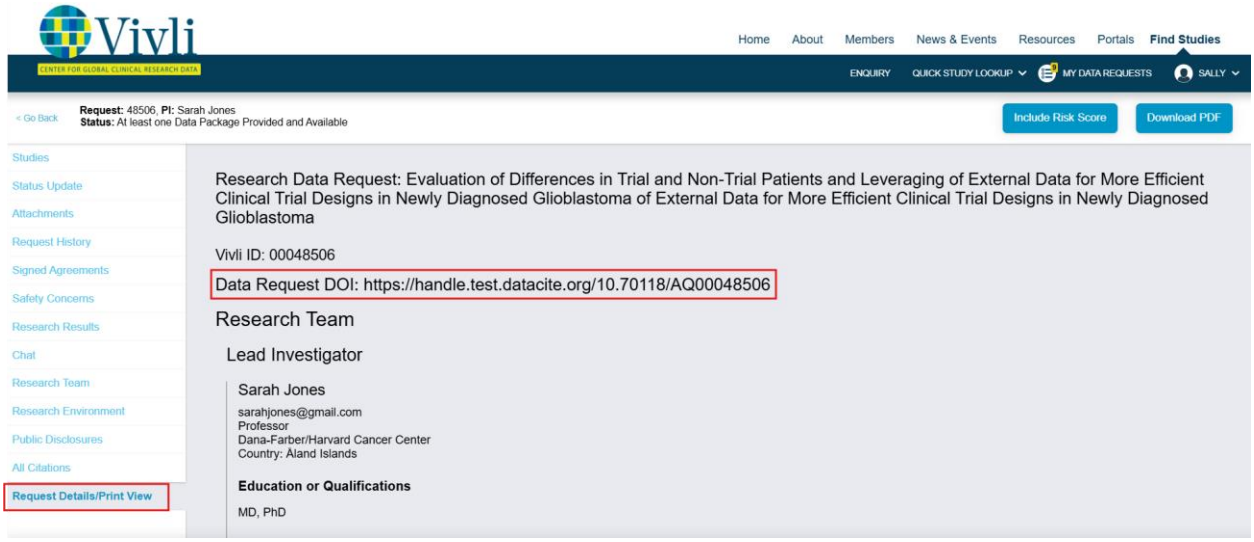
   It is Vivli's policy that the decision to appoint someone as an author should be made by applying the ICMJE authorship criteria (reviewed and agreed upon by the Steering Committee in May 2023).

7.2 Publication Notification by Data Requestor

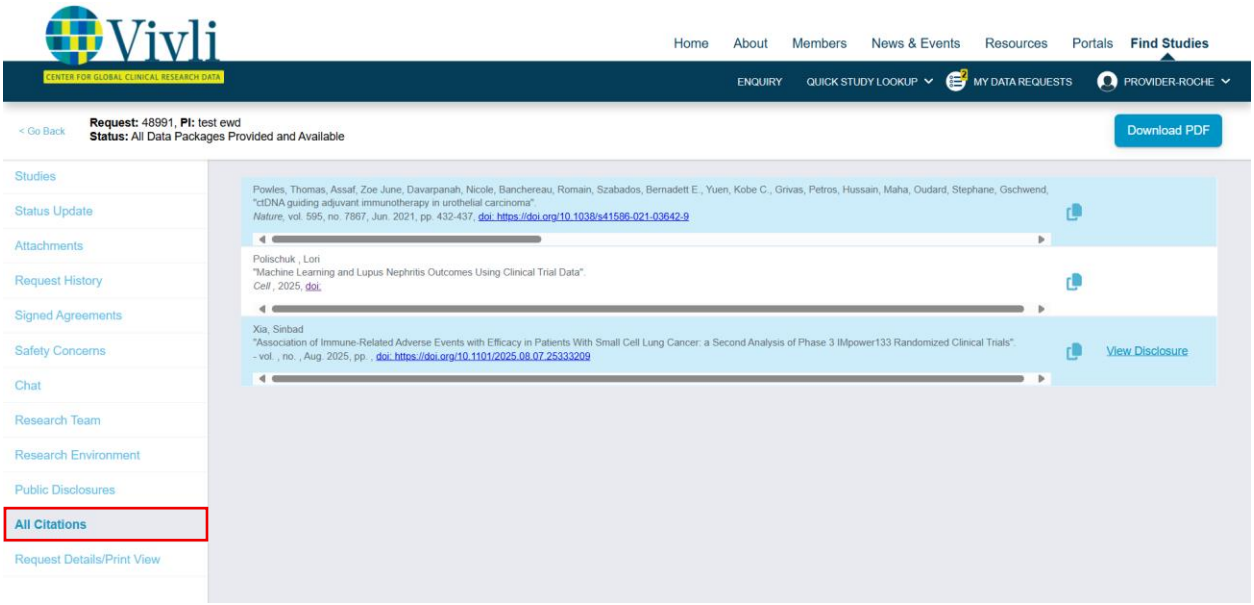
- When a public disclosure based on the results obtained from the data request is published, the Data Requestor must inform Vivli.
- Requestors will notify Vivli of a citation in chat or Vivli will identify a citation via search. A Vivli Administrator will submit the citation via the Public Disclosures tab (if a previous disclosure record exists). A link between the original disclosure and the associated citation will be made for ease of tracking and management. The citation can be copied to the clipboard by the Organizational Administrator using the copy icon for other workflows.
- Once the public disclosure is marked as 'Published' by a Vivli Administrator with the associated citation added to the record, the Organizational Administrator will be notified via email.



- In addition, the link to the publication will be made available for public view on Vivli's Metrics page linked to their approved request page i.e. data request DOI.



- You may view all citations linked to a specific data request form by navigating to a data request and clicking on the “All Citations” tab. This tab is visible after the request reaches the data upload stage.



- You may also view the citations linked to the study. Please see Section 2.6 Study Usage and Public Disclosure Metrics for more information.
- Once all the publications are published and the analysis is complete, the Vivli team will move the data request to the “Archived” stage.
- For a summary of results, once the 30-day 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. The Vivli Admin will archive the data request.

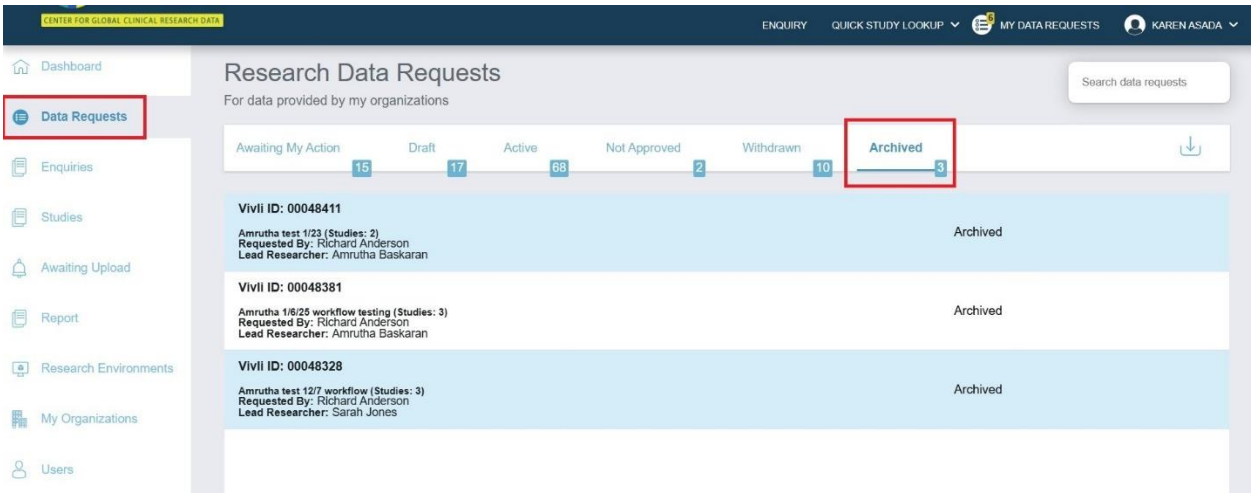
8. Data Progress Report

The Data Use Agreement allows for 1 year for accessing the data from the date it was executed by Vivli. Vivli will ask the researcher, 90 days before the DUA is about to expire, whether they require an extension. If they do, Vivli will send a Data Progress Report to the Researcher for completion . According to Vivli policy, DUA extensions are given in 1-year intervals.

Vivli will review a researcher team's progress and will grant this extension on a yearly basis. Executed Data Progress Report will be uploaded to the Signed Agreements tab.

9. Secure Research Environment Closure & Request Archival

Once all the publications are published and the analysis is complete, the Vivli team reaches to the research team to close the data request. The secure research environment will then be de-provisioned. For downloadable data, the research team is required to provide confirmation of the destruction of the data destruction. The data request will be moved to the Archived section of the data request dashboard.



10. 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.

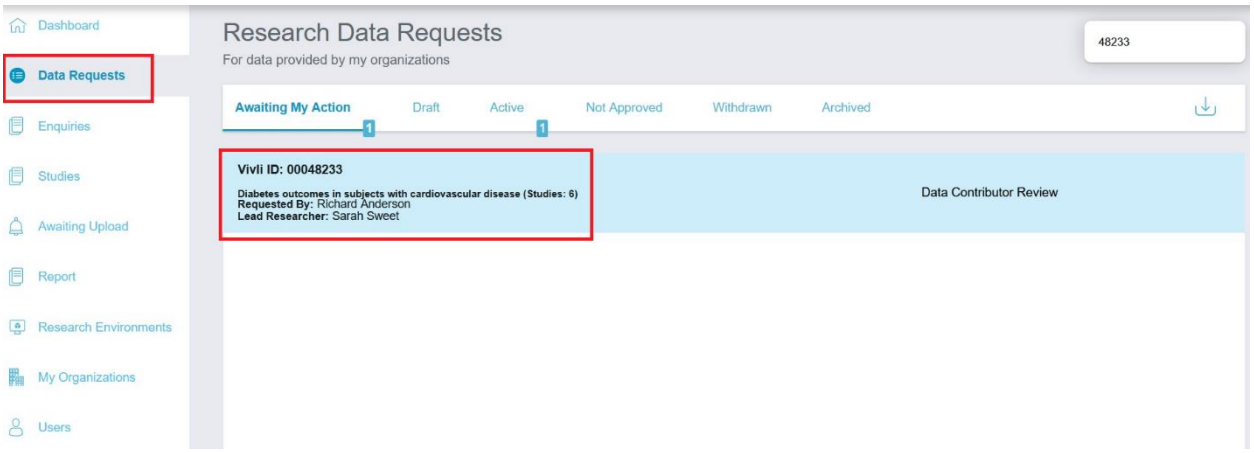
11. Communications

11.1 Chat

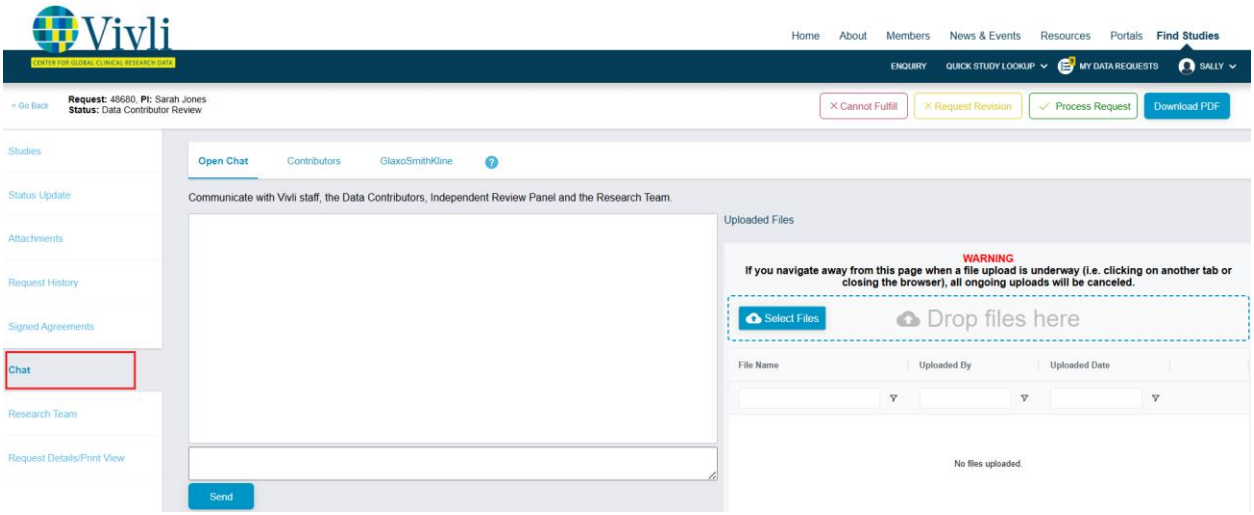
- You can use the **open chat** within the data request, to communicate with data requestors, the Vivli Administrators, members of your organization, delegated reviewers, and other Organizational Administrators associated with the specific request for your data.
- Please note that messages in the open 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.
- Once the data request reaches the data contributor review stage, organizational administrators will start receiving email notifications for the chat messages.

11.1.1 Open Chat

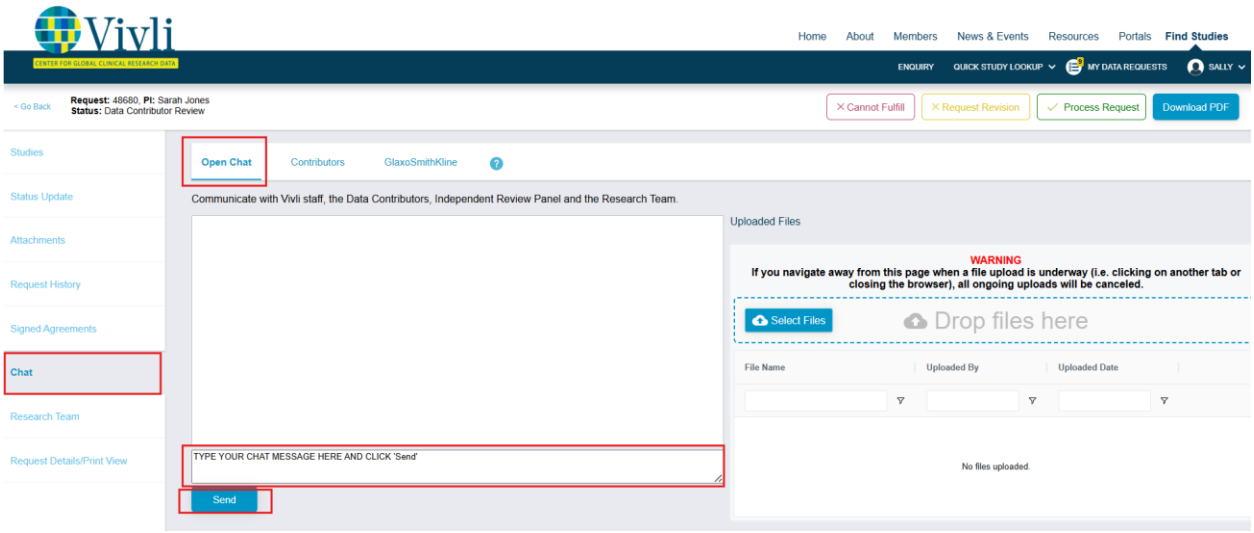
1. Log on to the platform:
2. Go to the **Data Request** tab:



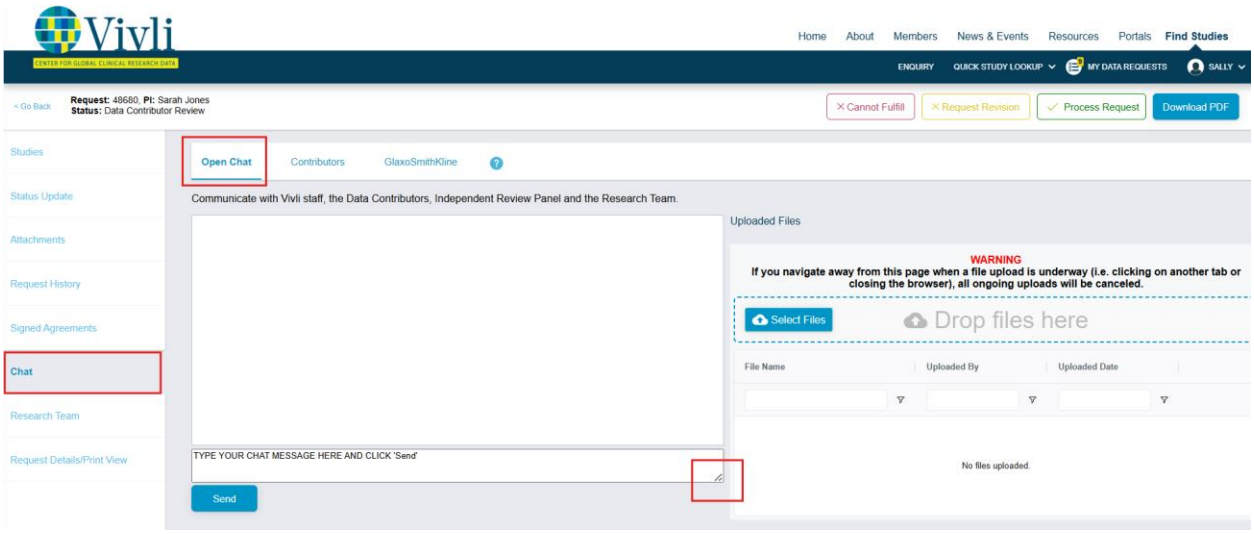
3. Open the applicable data request and click on the **Chat** tab on the left-hand side of the screen:



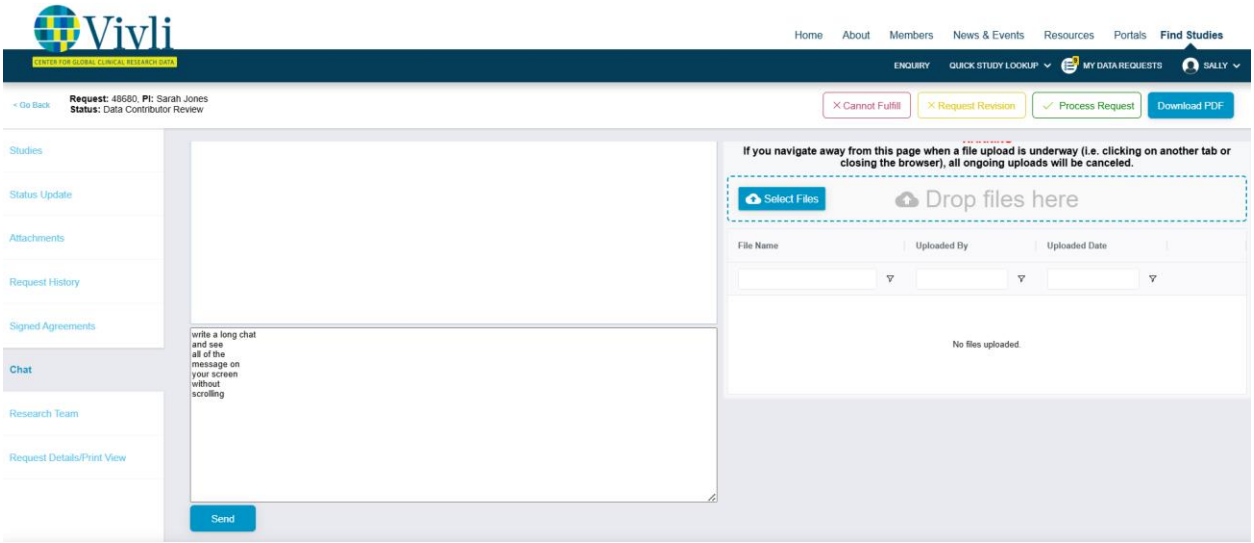
4. Enter your message in the chat message box under "Open chat" and click **Send:**



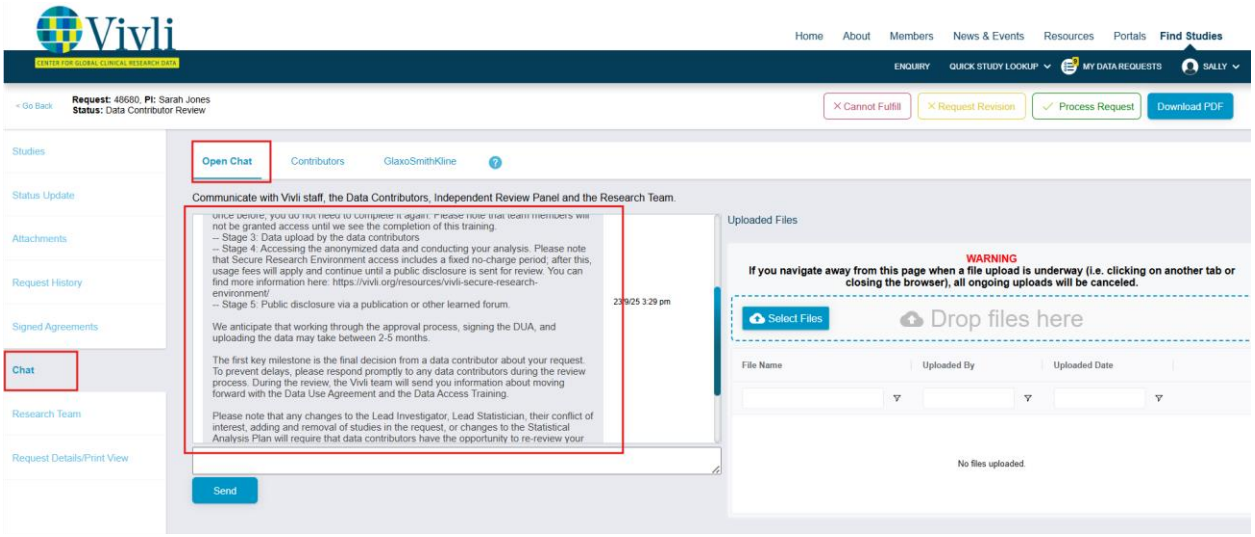
5. In the chat window, there is a hash mark on the lower right of the text entry panel. Hover over it and the cursor changes to a double-headed arrow



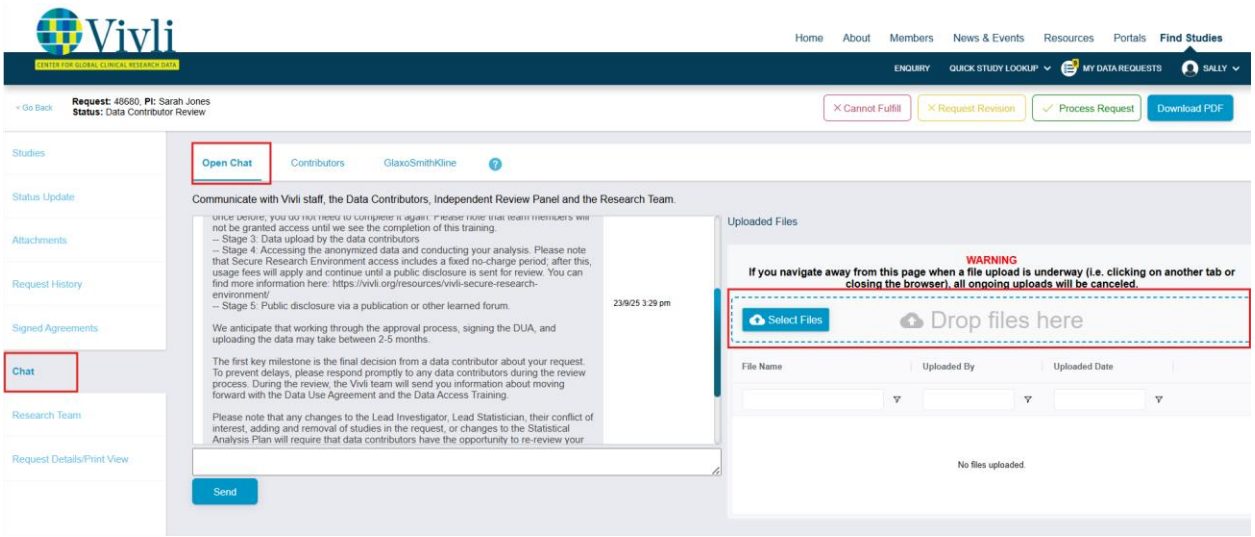
6. Drag the arrow to enlarge the text entry area. Drag it off the edge of the screen to make it very large.



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

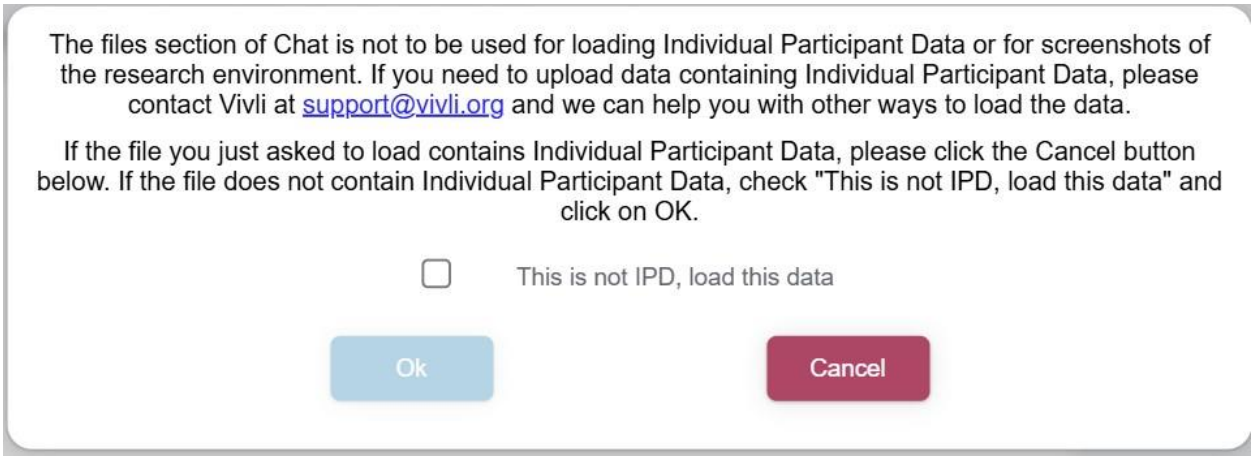


8. You can also upload files via chat by clicking on the **Select Files** button and selecting the file you wish to upload from your computer, or you may drag and drop the files into the dotted blue box**:**

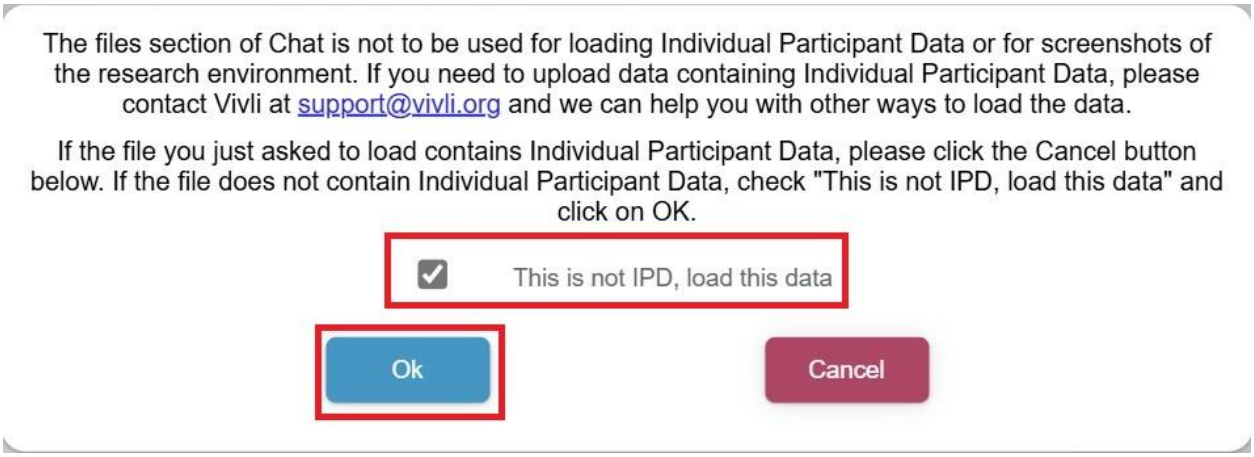


9. **Note**: Individual participant data (IPD) **should NOT** be uploaded in this section

10. The following window may appear to confirm that IPD files are not uploaded in this section

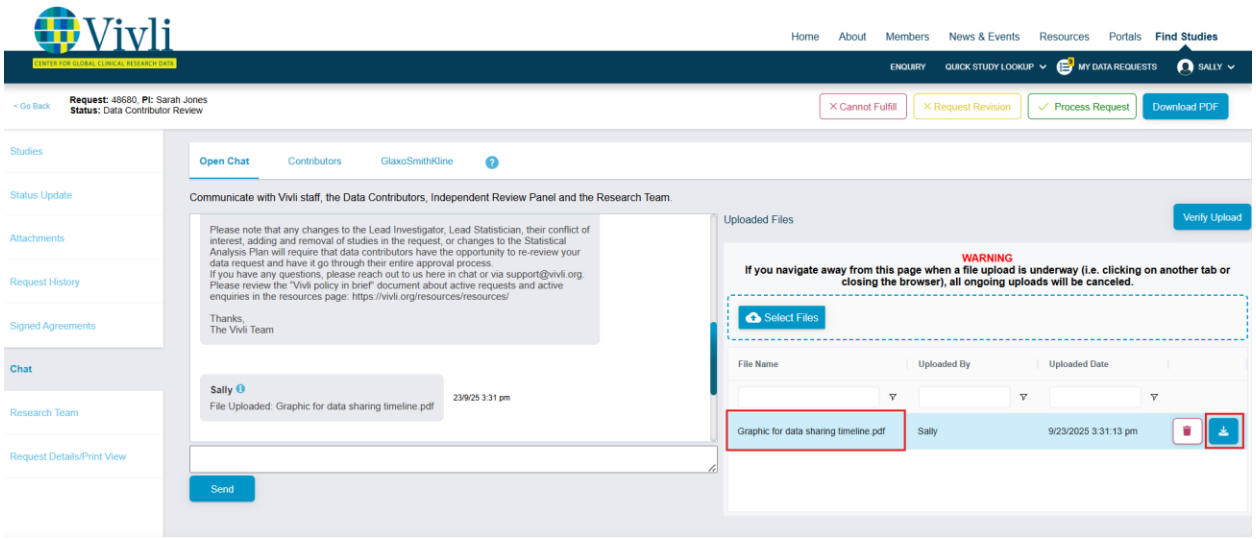


11. Check the checkbox to confirm that the files are not IPD and then click OK.

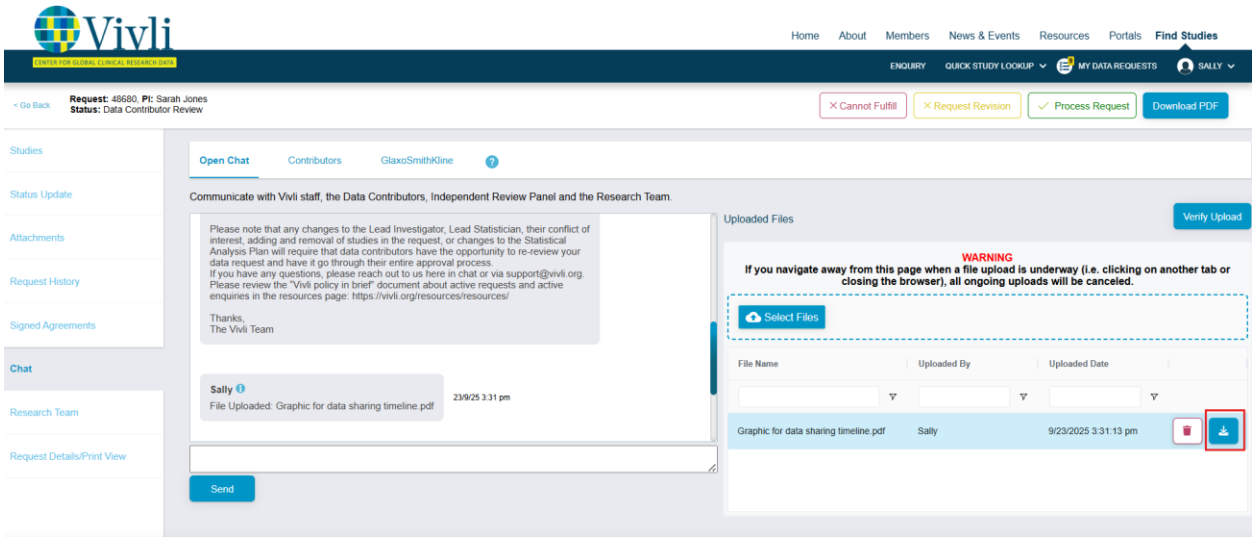


12. The upload bar will show the progress. **If you navigate away from a page on which an upload is underway (i.e. clicking on another tab or closing the browser), that will cancel the upload automatically**:

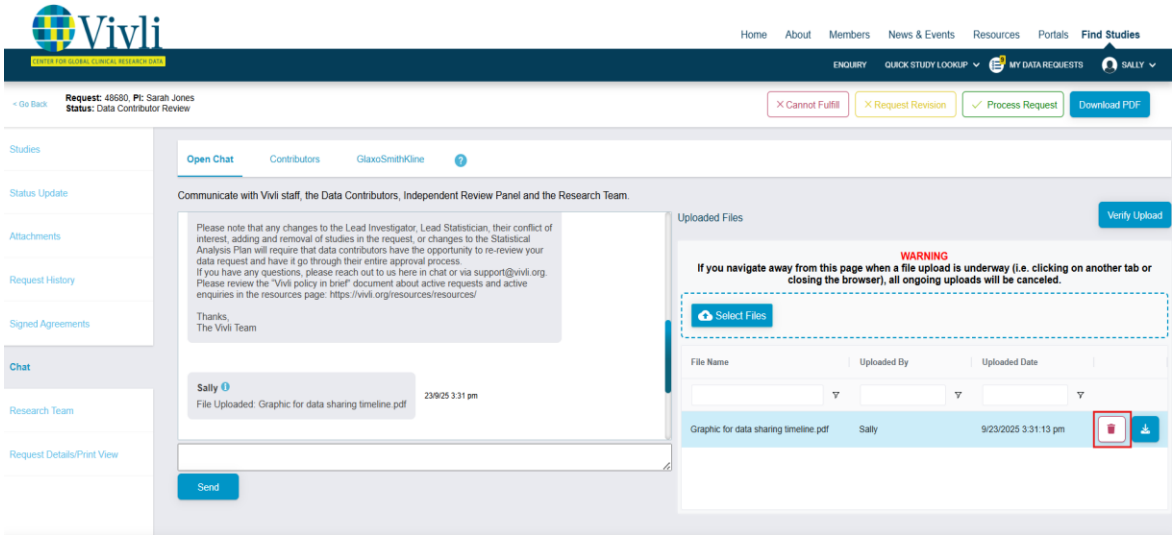
13. The history of the uploaded file will appear in the chat window:



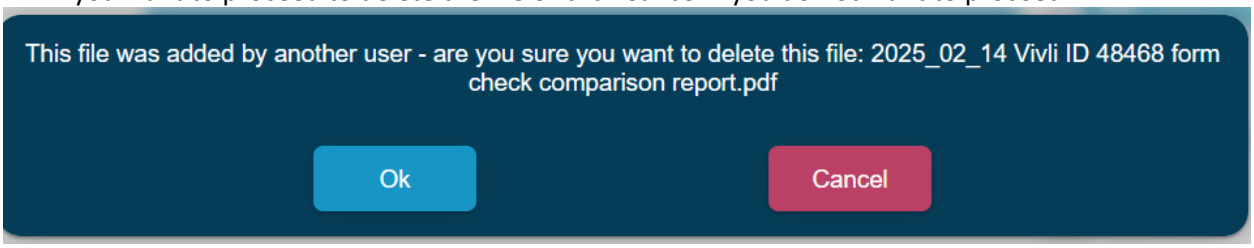
14. You may also download chat files by clicking on **Download:**



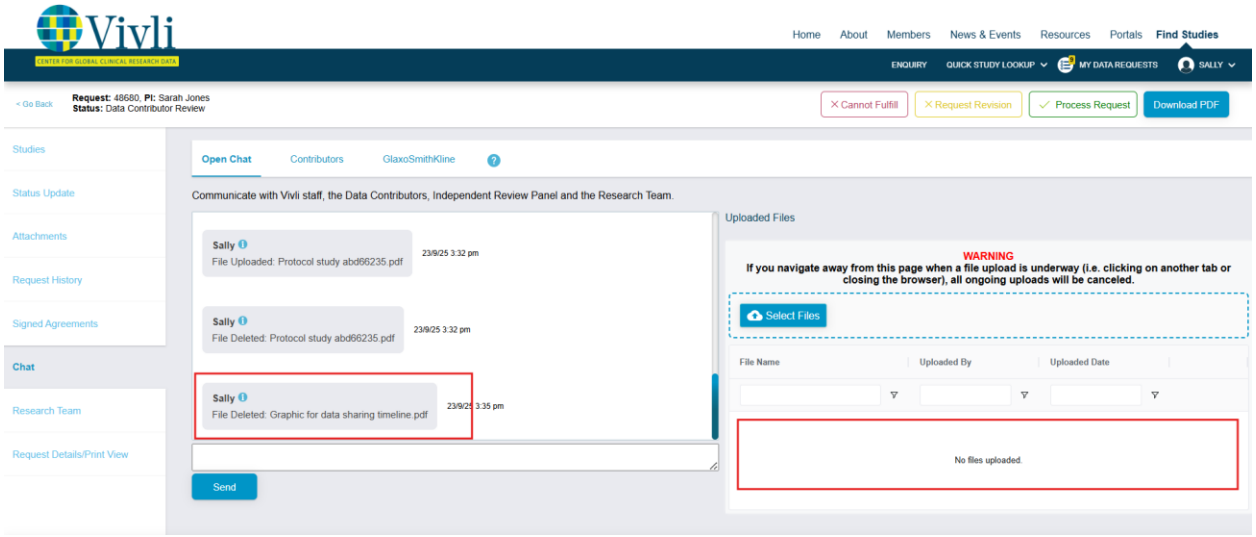
15. You can delete the uploaded file by clicking **delete**:



16. You will see a confirmation box asking you to confirm if you intended to delete the file "This file was added by another user - are you sure you want to delete this file: <filename>". Click Ok if you want to proceed to delete the file or click Cancel if you do not want to proceed.

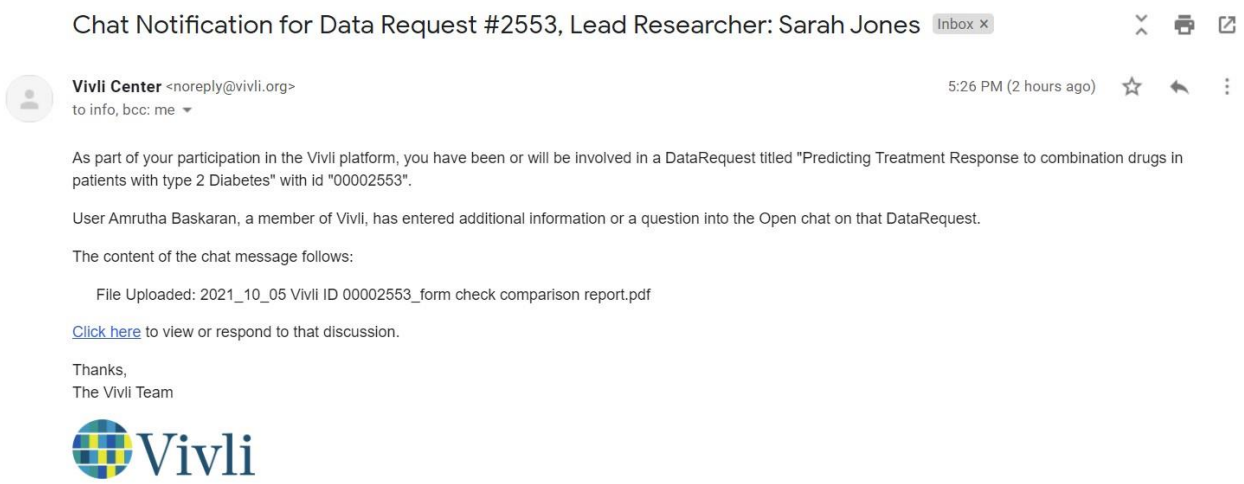


17. The deletion of the file will appear in the chat history:



18. Chat messages automatically scroll to the most recent post instead of the first.

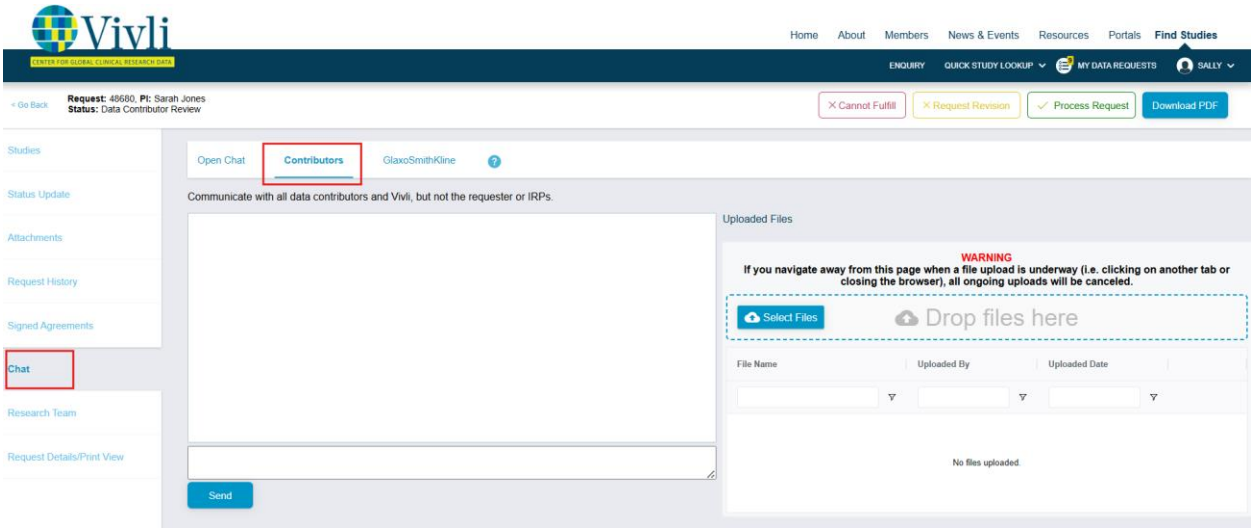
19. In chat, uploaded files are sorted by date, newest on top, and the hover text displays the filename, date, and person who uploaded it.
20. Posted chat messages are visible immediately.
21. Chat email notifications will include the display name and organization of the uploader and the content of the chat message in its original formatting. The subject line will include the Request ID and the name of the Lead Investigator.



22. Note: Vivli admins may set up automatic follow-ups for repeated follow-ups (E.g. revision, DUA, publication follow-ups, etc.). organizational administrators won't receive any email notifications for such follow-ups. Organization Administrators can see the chat messages in the open chat window.

11.1.2 Contributors Chat

You can also open a Contributors chat within the data request to communicate with all the Organizational Administrators involved in the data request (but not the researcher and the IRP) and the Vivli team. Organizational administrators will receive email notifications from this chat, but not those who have the Data Uploader role within an organization.

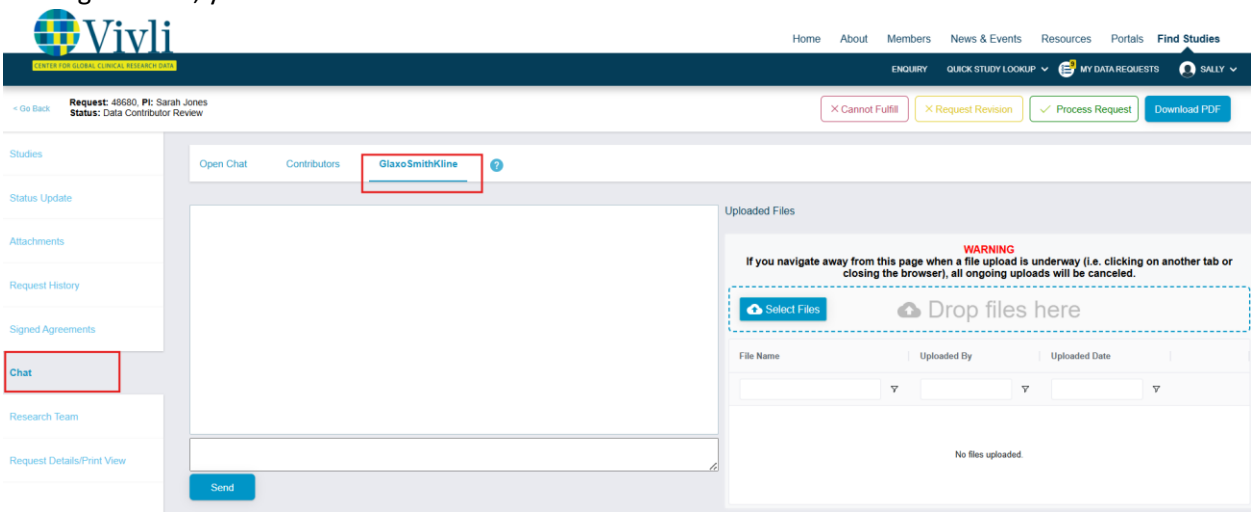


11.1.3 Private Chat

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

Please note that private chat is visible **only** to members of your organization on the Vivli platform. The Vivli team cannot see this information. When any other team member in your organization enters a

message in chat, you will receive an email notification.

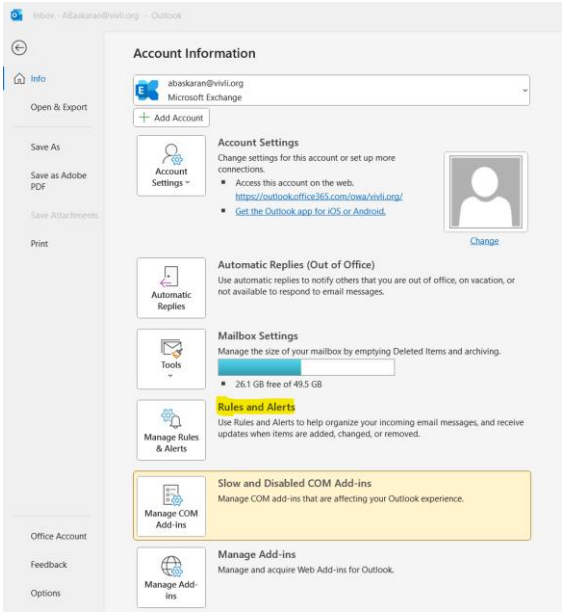


11.2 Setting up an Inbox Rule on Outlook to Filter Emails

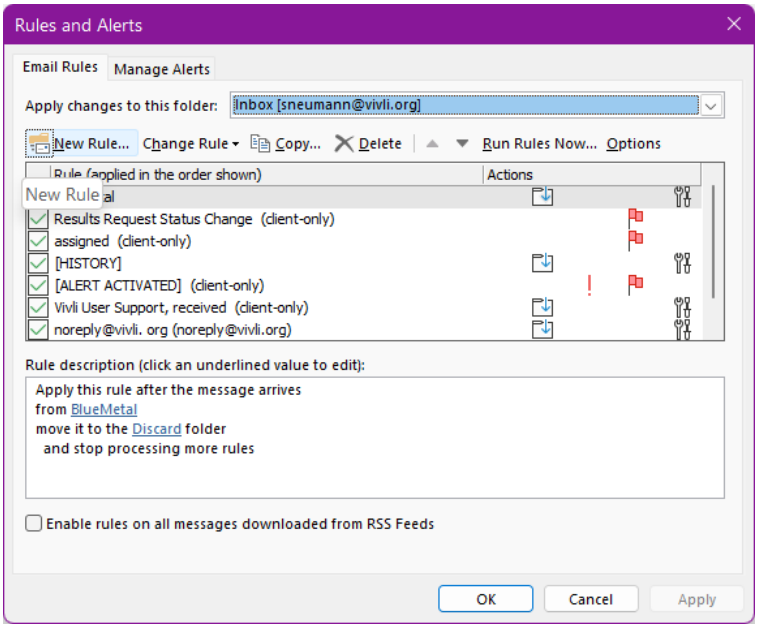
Here are instructions for creating an inbox rule that can refile messages containing a specific sub-string in the subject line. The specifics are written for platform messages, but they can be generalized for other frequent messages that you don't want actively in your inbox. If you want to disable your email notifications from the Vivli platform, you can do so from the My Organization tab. Please see section 1.3.2 Team Members.

First, you need to create a contact for the email address:noreply@vivli.org. You can open such a mail message, by right-clicking on the from address and it has a menu entry "add to outlook contacts". In Outlook, click File in the menu bar, then in the window that appears click on "Rules and Alerts".

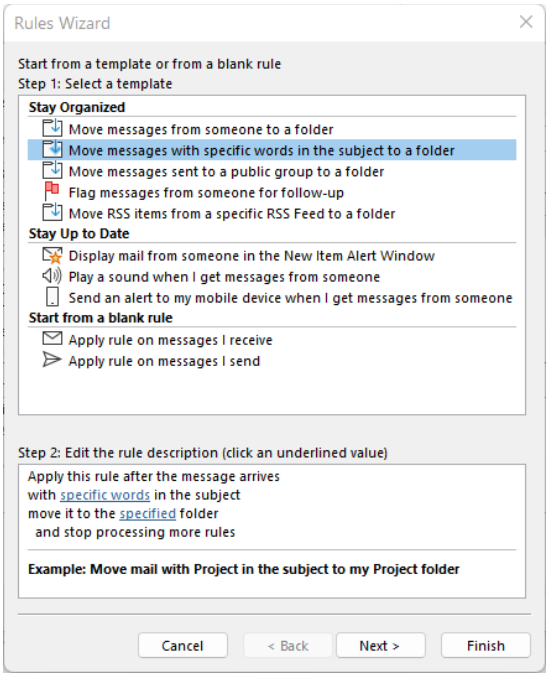
If you are using the new Outlook client, the rules are at Settings -> Mail -> Rules. If you are on the old Outlook client, click "File" then the button "Manage Rules and Alerts"



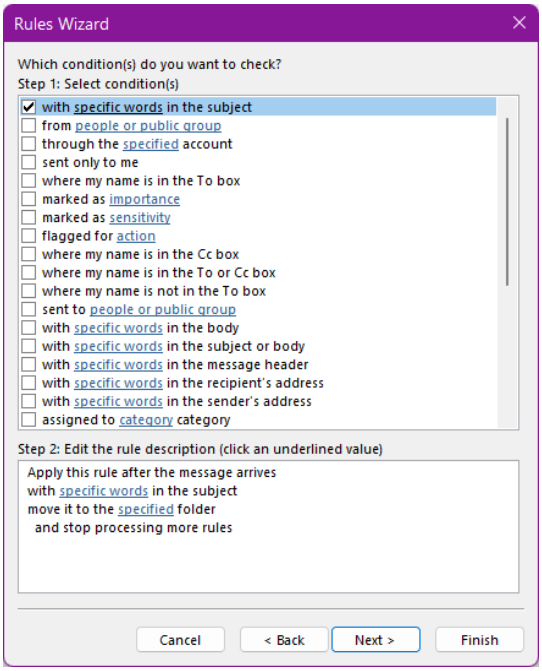
In the pop-up window, click New Rule:



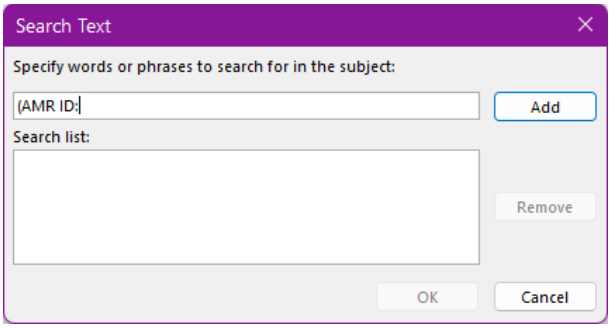
In the pop-up wizard, pick “Move messages with specific words in the subject to a folder”



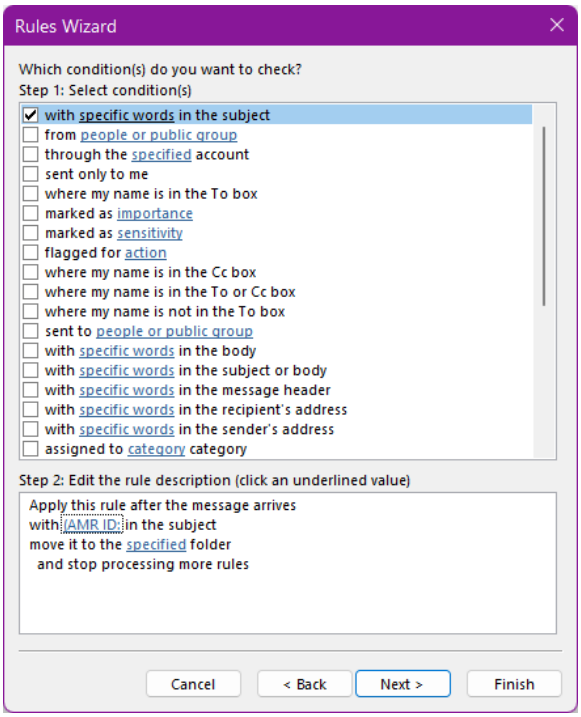
Click Next (it should display the choice “with specific words in the subject”),



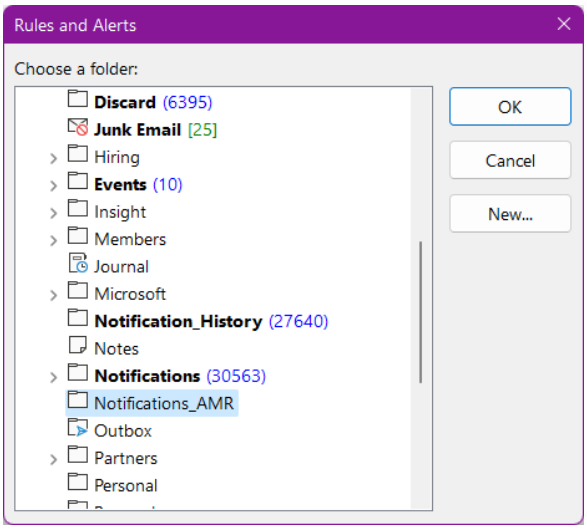
In the bottom half, click on “specific words” and enter “(AMR ID:” or “(Vivli:” or “(Chat Notification:”

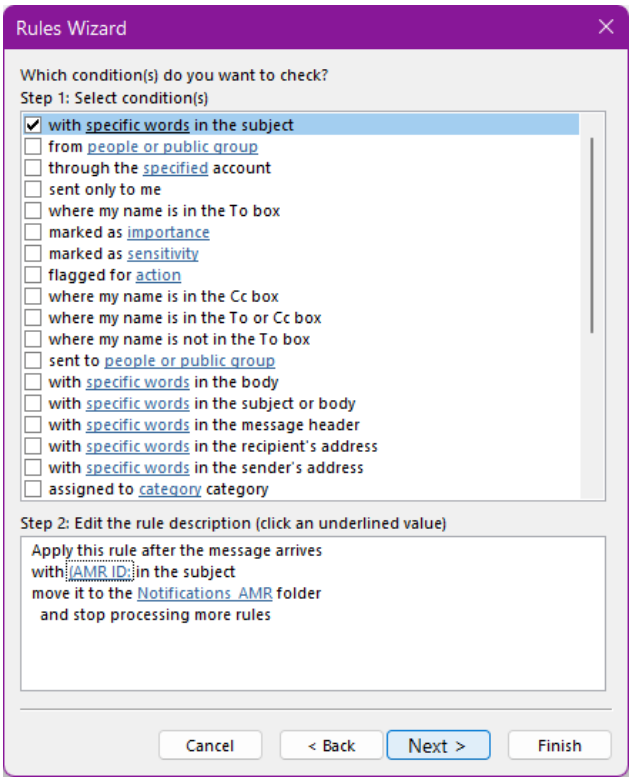


Click add to add it to the search list and then click OK:

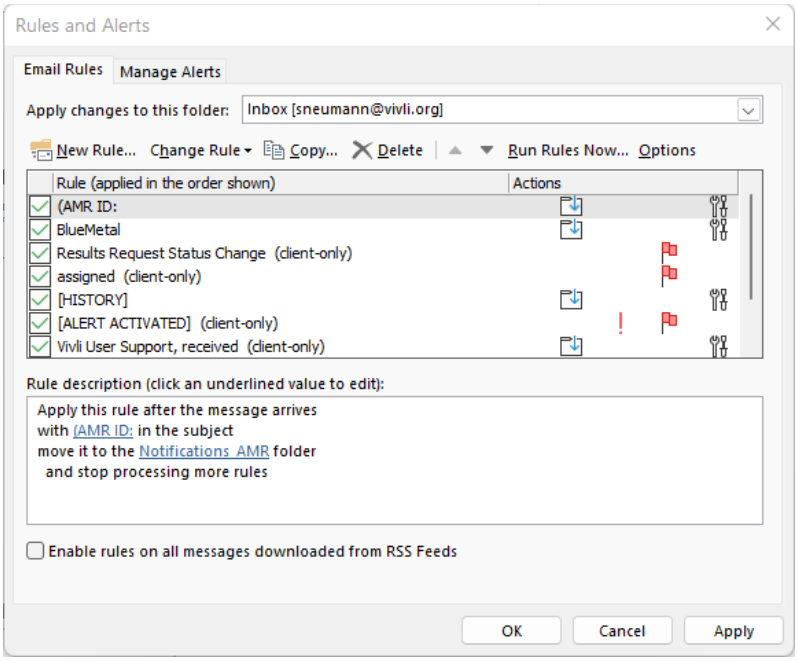


Back at the wizard, click on “specified” (as in ‘move it to the specified folder’); In the browse screen, select your destination folder and then click OK.


Rules and Alerts
Choose a folder:
Discard (6395)
Junk Email [25]
Hiring
Events (10)
Insight
Members
Journal
Microsoft
Notification_History (27640)
Notes
Notifications (30563)
Notifications_AMR
Outbox
Partners
Personal
OK
Cancel
New...


Rules Wizard
Which condition(s) do you want to check?
Step 1: Select condition(s)
with specific words in the subject
from people or public group
through the specified account
sent only to me
where my name is in the To box
marked as importance
marked as sensitivity
flagged for action
where my name is in the Cc box
where my name is in the To or Cc box
where my name is not in the To box
sent to people or public group
with specific words in the body
with specific words in the subject or body
with specific words in the message header
with specific words in the recipient's address
with specific words in the sender's address
assigned to category category
Step 2: Edit the rule description (click an underlined value)
Apply this rule after the message arrives
with [AMR ID:] in the subject
move it to the Notifications_AMR folder
and stop processing more rules
Cancel
< Back
Next >
Finish

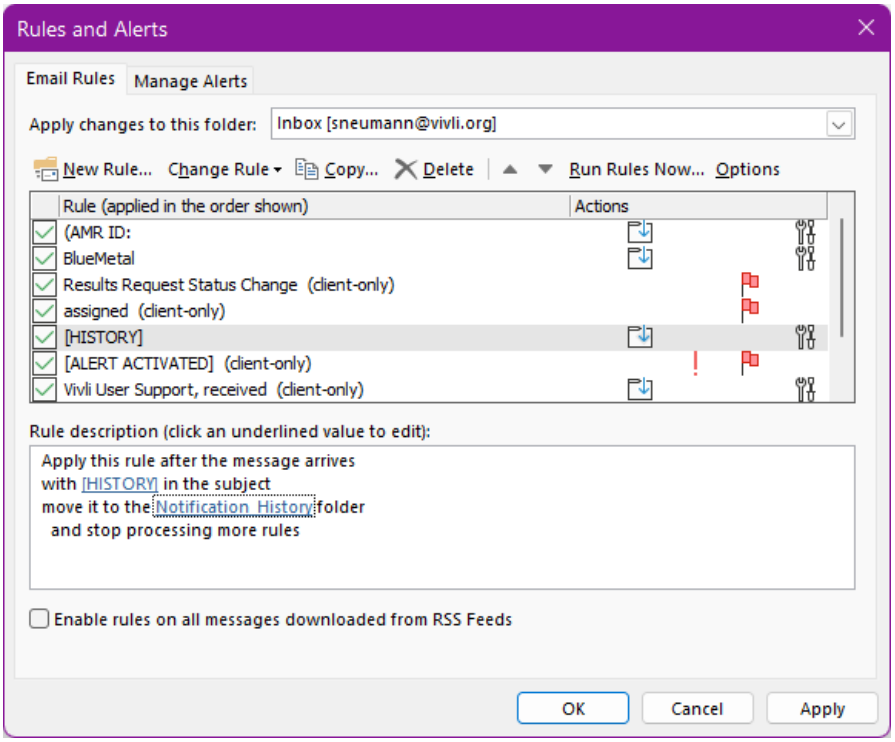
Click Finish and the rule should appear in the rule list:



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.



Here are a few examples of the rules:

a) from noreply@vivli.org check "move to specified folder", choose folder "Notifications" and check "stop processing more rules"

b) from platformsupport@vivli.org - action: check "move to specified folder", choose folder "Notifications" and check "stop processing more rules"11.2 Emails for Organizational Administrators

11.3 Automated Emails from Vivli Platform

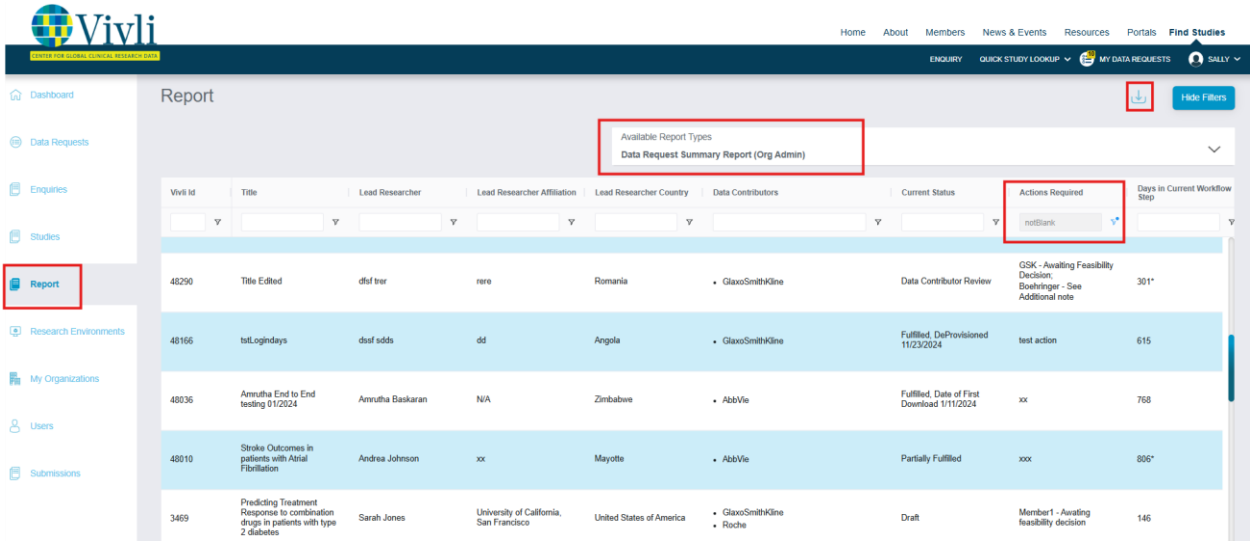
You will receive several automated emails from the Vivli platform, relating to your organizational account. Please see the table below for a synopsis:

Email	When sent	Purpose
Data Request Ready for Review	When a data request for your studies has been submitted	Notify Organizational Administrators 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 uploaders of approved DUA. Please work on uploading 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, Organization Administrators will continue to receive notifications even if it goes back to draft for revisions. This includes emails from Open chat and Contributors chat	Facilitate communication and the data request workflow.
Public Disclosure Submitted	When a public disclosure is submitted your organization. Your organization will have 30 days to review it.	To notify organizational administrators that a public disclosure has been received.
Public Disclosure closed	When a public disclosure review period has closed. It will be 30 days after the public disclosure was submitted or all organizations have approved the disclosure, whichever comes first.	To notify organizational administrators that a public disclosure review period has closed.

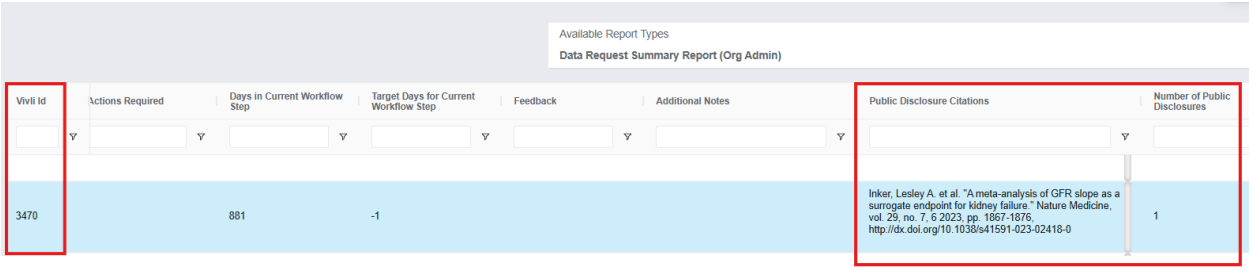
Research Environment deprovisioned	When the secure research environment is deprovisioned	Notify Organizational Administrators when the analysis is complete
Data Request Archived	When the data request is Archived, the project is considered closed.	Notify Organizational Administrators that the lead researcher and research team have met the DUA obligations for public disclosure/summary of results and the data request is now archived.
Enquiry ready for your review	When the Enquiry for your studies is submitted to review stage	Notify Organizational Administrators of the Enquiry and prompt you to record your decisions
Response provided by the Researcher or Vivli team for your Enquiry	When anyone associated with the Enquiry adds comments to the discussion notes in the Enquiry.	Notify Organizational Administrators of the update on the Enquiry.

11.4 Vivli Summary to Organization Administrators

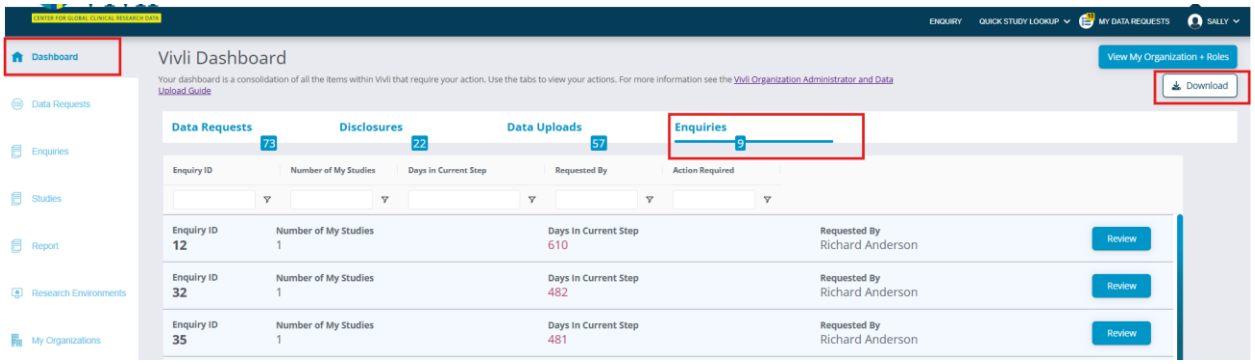
- You will start receiving summaries from the Vivli team once you have the first data request that reaches the Data Contributor review stage or your first Enquiry in the Review stage.
- Vivli summary emails are typically sent out every other Tuesday morning (US Eastern Time) from support@vivli.org but 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 a reminder to download your 'Data Request Summary Report' from the Reports section of the platform.
- The 'Data Request Summary' report contains information about data requests that require action as well as information on publication citations received.
    - Selecting 'Not blank' in the filter under the 'Actions Required' column will show all outstanding actions.
    - The report can be downloaded using the down-arrow in the top right.



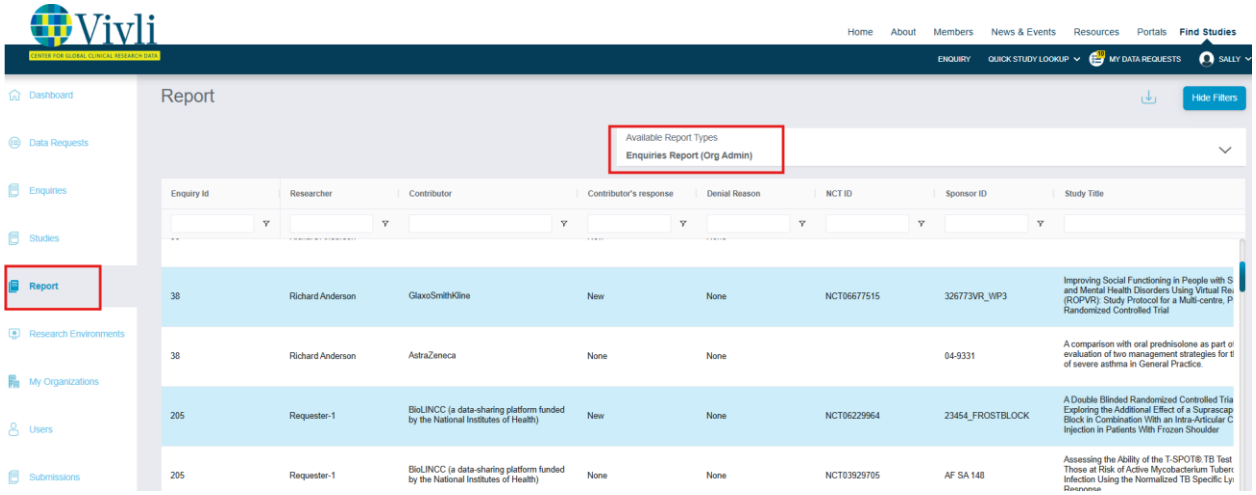
- Publication citations information can also be found in this report:



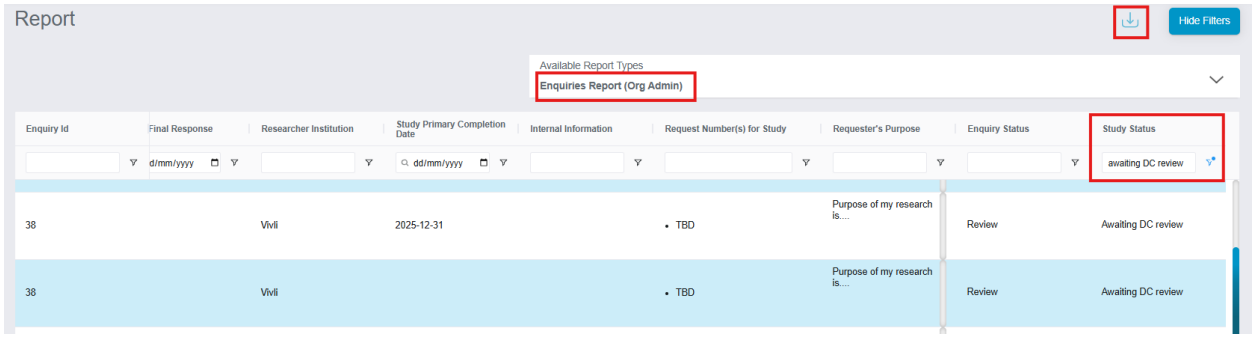
- A report of Enquiries with outstanding actions can be pulled down from the main dashboard page, by going onto the Enquiries section, and clicking the 'Download' button



- Alternatively you can use the 'Enquiries Report', which shows all of a member's enquiries:



- Filtering the 'Study Status' field for 'Awaiting DC review' will show all the open enquiries for a member. The report can be downloaded by clicking on the down-arrow in the top right:



- The email 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 main dashboard or the Enquiries tab on the platform. Please see Section 3.3 Recording Enquiry Decision for more information.
- Responses from Organizational Administrators should be made via the platform instead of emailing Vivli back a spreadsheet, this will create increased efficiency for all involved. Use the feedback field on the Status Update to provide comments. See Section 4.5.3 Status Update for more information.

12. Support and Additional Information

12.1 Vivli Contact Information

Vivli Member User Support Contacts:

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

12.2 Data Use Agreement

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

12.3 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

12.4 Standard Process for Vivli-Member Engagement

- Please review the Vivli summary
- Check Vivli Organization Administrator and Data Upload Guide or 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

13. 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.

14. 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 secure 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 the 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
3.4	Amrutha Baskaran	1. Updated Section 1.3.2 Adding Team Members 2. Added Section 1.3.4 User Lists 3. Removed Section 2.2 Submitting a Single Study 4. Removed Section 2.5 Study Enquiry Process 5. Added Section 2.7 Studies Dashboard 6. Added Section 3 Study Enquiry Process 7. Added Section 3.1 Navigation and Enquiry Dashboard 8. Added Section 3.2 Enquiry format 9. Added Section 3.3 Recording Enquiry Decision 10. Added Section 3.4 Enquiries Report 11. Updated Section 4.4.5 Withdrawal process 12. Added Section 5.4.6 Upload additional data or documents to a study after initial upload 13. Updated Section 8 DUA extension	June 12, 2024
3.5	Amrutha Baskaran	1. Updated Section 1.3.1 My Organization tab 2. Updated Section 1.3.2 Team Members 3. Added Section 2.5 Individual Studies Format 4. Updated Section 3.1 Navigation and Enquiry Dashboard 5. Updated Section 3.2 Enquiry Format 6. Updated Section 3.3.1 Eligible for Request	November 25, 2024

		7. Added Section 3.3.4 Enquiry Study Status for Individual Studies 8. Updated Section 4.2.3 Data Request Form 9. Updated Section 4.3 Study Settings at Data Contributor Review 10. Updated Section 4.4.6 Summary- level and Document-only Data Request 11. Updated Section 4.5.2. Fields Included in the Report 12. Updated Section 4.6 Data Use Agreement (DUA) 13. Rearranged Section 5 Data package uploads 14. Updated Section 5.4 Upload Loading Data Package to an Approved Data Request 15. Added Section 5.5 Upload Data Package Directly into the Study 16. Updated Section 5.6 Steps to Upload Data Package 17. Updated Section 5.7 Stored Data Package and Subsequent Data Request 18. Updated Section 5.8 Replace Data Package New Version 19. Updated Section 5.10 Uploading Data to Only One Data Request 20. Added Section 5.12 Supporting Documents for Researchers Searching For Studies 21. Added Section 6.2 Downloadable Data 22. Added Section 7.2 Publication Notification by Data Requestor 23. Added Section 9 secure Research Environment Closure & Request Archival 24. Removed Section 10 Metrics 25. Updated Section 11.1.1 Open Chat 26. Updated Section 11.21.4 Setting up an Inbox Rule on Outlook to Filter Emails	
3.6	Amrutha Baskaran	1. Updated Section 1.3 Vivli Dashboard for Organizational Administrators 2. Updated Section 1.3.2 Team Members 3. Updated Section 1.3.3 Organizational Roles 4. Updated Section 1.3.4 User Tab 5. Updated Section 2.6 Study Usage and Public Disclosure Metrics 6. Updated Section 3.1 Navigation and Enquiry Dashboard 7. Updated Section 3.2 Enquiry Format 8. Updated Section 3.3.1 Eligible for Request	February 24, 2025

		9. Updated Section 3.3.2 Not Available for Request 10. Updated Section 3.3.3 Enquiry Feedback to Researcher via Discussion field 11. Updated Section 4.5.2 Fields Included in the Report 12. Updated Section 11.1.1 Open Chat 13. Updated Section 11.3 Automated Emails from Vivli Platform	
3.7	Amrutha Baskaran	1. Added Section 2.7 Study Search Results– Download 2. Updated Section 3.1 Navigation and Enquiry Dashboard 3. Updated Section 4.2.3 Data Request Form (notes about AI/ML responses and risk scores) 4. Updated Section 4.5.2. Fields Included in the Report 5. Updated Section 4.6 Data Use Agreement (DUA) 6. Updated Section 5.6 Steps to Upload Data Package 7. Updated Section 5.12.3 Loading Supporting Documents that are not part of Data Package 8. Updated Section 11.1.1 Open Chat	May 24, 2025
3.8	Catherine D'Arcy	1. 4.2.3 Data Request Form and how to print to PDF and updated Research Team tab 2. 4.4.4 Updates to Major versus Minor Revisions to Data Requests 3. 5.5 Updates to Upload Data Package Directly into the Study and replace a data package 4. 7.1 Public Disclosures & Publications & Summary of Results Review(s) by members workflow introduced 5. 7.2 Publication Notification by Data Requestor updated 6. 11.3 Automated Emails from Vivli Platform updated to include public disclosure emails	
3.9	Catherine D'Arcy Sarah Sweet Lydia Weiblinger	1. Updated section 1.3 My Organizations - Updates to 1.3.2 My Organizations tab, 1.3.3 Team Members, 1.3.4 Organizational Roles, 1.3.5 User tab, 1.3.7 Accessing Vivli Organization Administrator and Data Upload Guide. 2. Updated section 3.1 Navigation and Enquiry Dashboard to include main dashboard 3. Updated section 4.2.1 Navigation to Data Requests to include main dashboard 4. Updated section 4.2.3 Data Request Form, Request History to include compare PDF 5. Updated section 4.4.4 Major Versus Minor Revisions to Data Requests for new process 6. Updated section 4.5 to include new reports for Data Request Summary, Research Team and Public Disclosures	

		7. Updated to section 5 - Inclusion of main dashboard into Data Package Upload section, and new process for replacing a data package, change data contributor to data uploader role 8. Updates to section 7. Public Disclosures, Publications & Summary of Results for main dashboard 9. Updates to section 11.4 Vivli Summary to Organization Administrators to include new process and reports	
4.0	Liz Graham	1. Updated section 4.2.4 Artificial Intelligence (AI) and Machine Learning (ML) request review to include usage risk update	

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	CEO	February 1, 2024	
Version 3.4			June 15, 2024
Rebecca Li	CEO	June 12, 2024	
Version 3.5			November 25, 2024
Rebecca Li	CEO	November 22, 2025	
Version 3.6			February 22, 2025
Rebecca Li	CEO	February 22, 2025	
Version 3.7			May 24, 2025
Rebecca Li	CEO	May 24, 2025	
Version 3.8			Oct. 4, 2025
Rebecca Li	CEO	Oct. 3, 2025	