



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

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1. Accounts for Data Contributors

1.1 Onboarding

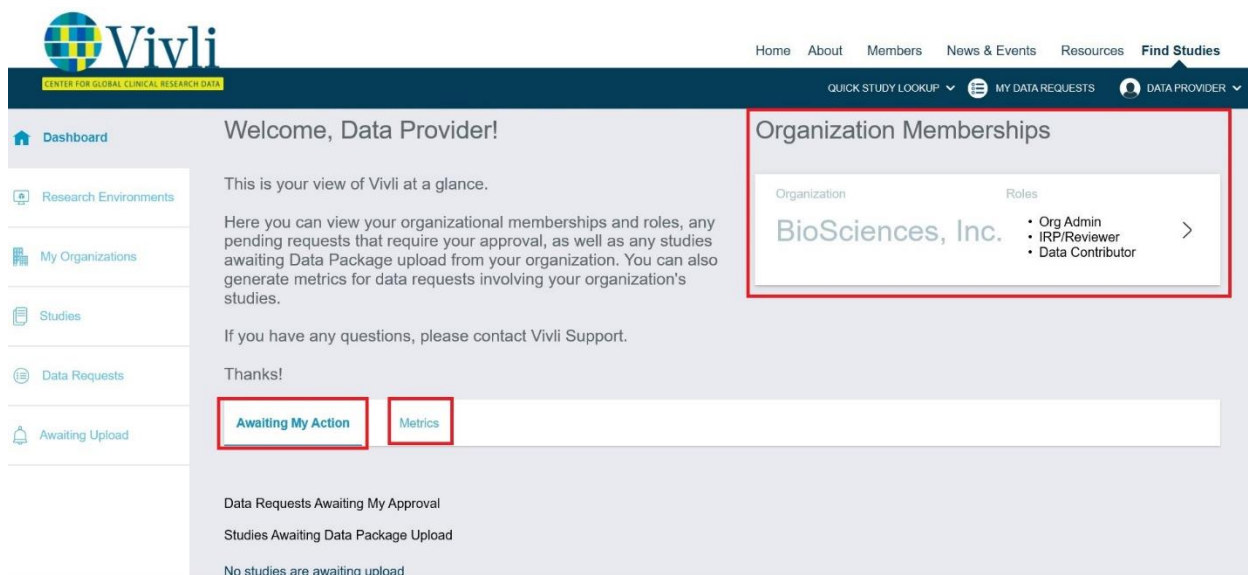
- After your organization joins Vivli as a member or Data Contributor, the Vivli team will begin your onboarding.
- The Vivli team will send you a draft member's page to fill out.
- The Vivli team will provide you with metadata sheets to fill out as part of the onboarding process. Please see [Section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

1.2 Creating your Vivli account

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

1.3 Vivli Dashboard for Organizational Administrators

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



Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

QUICK STUDY LOOKUP MY DATA REQUESTS DATA PROVIDER

Dashboard

Research Environments

My Organizations

Studies

Data Requests

Awaiting Upload

Welcome, Data Provider!

This is your view of Vivli at a glance.

Here you can view your organizational memberships and roles, any pending requests that require your approval, as well as any studies awaiting Data Package upload from your organization. You can also generate metrics for data requests involving your organization's studies.

If you have any questions, please contact Vivli Support.

Thanks!

Awaiting My Action **Metrics**

Data Requests Awaiting My Approval

Studies Awaiting Data Package Upload

No studies are awaiting upload

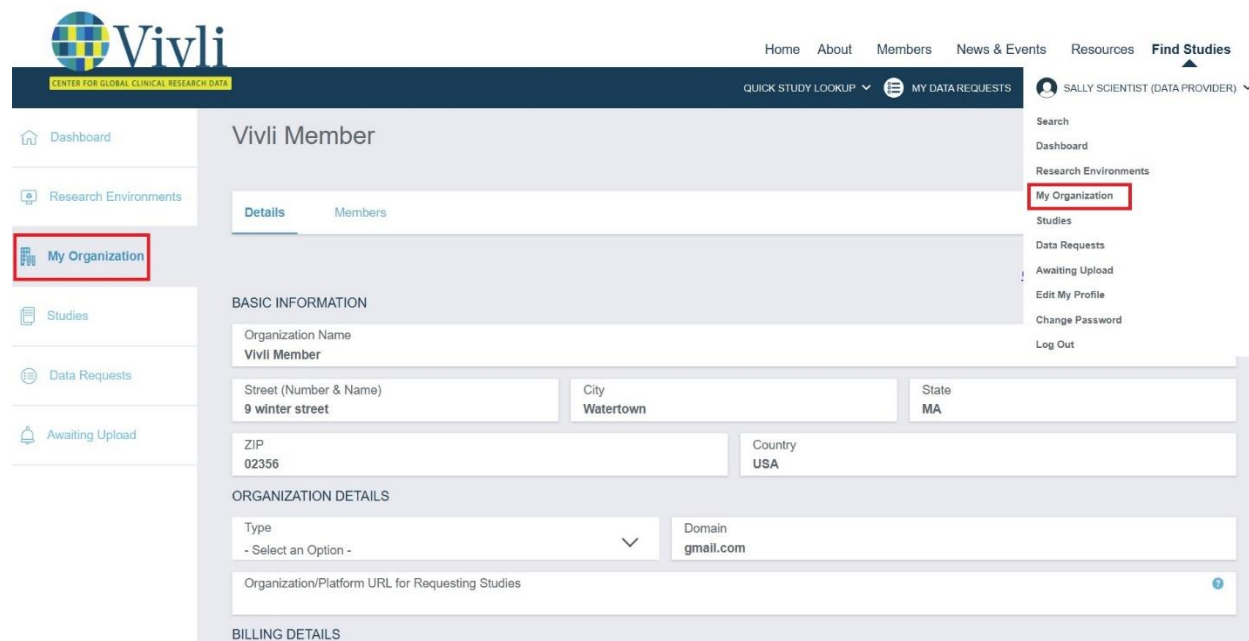
Organization Memberships

Organization	Roles
BioSciences, Inc.	<ul style="list-style-type: none"> Org Admin IRP/Reviewer Data Contributor

1.3.1 How to Edit My Organization details.

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

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



Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

QUICK STUDY LOOKUP MY DATA REQUESTS SALLY SCIENTIST (DATA PROVIDER)

Search

Dashboard

Research Environments

My Organization

Studies

Data Requests

Awaiting Upload

Edit My Profile

Change Password

Log Out

Vivli Member

Details Members

BASIC INFORMATION

Organization Name
Vivli Member

Street (Number & Name)
9 winter street

City
Watertown

State
MA

ZIP
02356

Country
USA

ORGANIZATION DETAILS

Type
- Select an Option -

Domain
gmail.com

Organization/Platform URL for Requesting Studies

BILLING DETAILS

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

The screenshot displays the Vivli Member profile page. The left sidebar contains navigation links: Dashboard, Research Environments, My Organization (highlighted with a red box), Studies, Data Requests, and Awaiting Upload. The main content area is titled 'Vivli Member' and includes a 'Details' tab (highlighted with a red box) and a 'Members' tab. A 'Save' button (highlighted with a red box) and a 'Cancel' button are located in the top right corner. The 'Details' tab shows the following information:

- BASIC INFORMATION**
 - Organization Name: Vivli Member
 - Street (Number & Name): 9 winter street
 - City: Watertown
 - State: MA
 - ZIP: 02356
 - Country: USA
- ORGANIZATION DETAILS**
 - Type: Industry (dropdown menu)
 - Domain: gmail.com
 - Organization/Platform URL for Requesting Studies: (text input field)

A link for 'Organization Administrator Resources' is visible on the right side of the page.

1.3.2 Adding Team Members

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

The screenshot displays the Vivli Member profile page. The left sidebar contains navigation links: Dashboard, Research Environments, My Organization (highlighted with a red box), Studies, Data Requests, and Awaiting Upload. The top right navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. A dropdown menu in the top right corner, labeled 'SALLY SCIENTIST (DATA PROVIDER)', contains links for Search, Dashboard, Research Environments, My Organization (highlighted with a red box), Studies, Data Requests, Awaiting Upload, Edit My Profile, Change Password, and Log Out. The main content area is titled 'Vivli Member' and has two tabs: Details (selected) and Members. The 'Details' tab is divided into three sections: BASIC INFORMATION, ORGANIZATION DETAILS, and BILLING DETAILS. The BASIC INFORMATION section includes fields for Organization Name (Vivli Member), Street (Number & Name) (9 winter street), City (Watertown), State (MA), ZIP (02356), and Country (USA). The ORGANIZATION DETAILS section includes a dropdown for Type (Set to '- Select an Option -') and a text field for Domain (gmail.com). The BILLING DETAILS section is currently empty.

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

The screenshot shows the Vivli Member page. The left sidebar has a red box around 'My Organization'. The main content area has a red box around the 'Members' tab. The 'Details' tab is also visible. The 'Members' tab shows a form to 'INVITE MEMBER WITH RIGHTS' with an 'Email' input field, 'Data Contributor' and 'Organization Administrator' checkboxes, and an 'Invite Member' button. Below this, it says '0 PENDING INVITE(S)'. At the bottom, there is a table of 'ORGANIZATION MEMBERS' with columns for Name, Org Admin, Data Contributor, and Org Membership. The table contains one entry: 'Sally Scientist (Data Provider)' with email 'dataprovder.vivli@gmail.com' and three 'Deactivate' buttons.

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

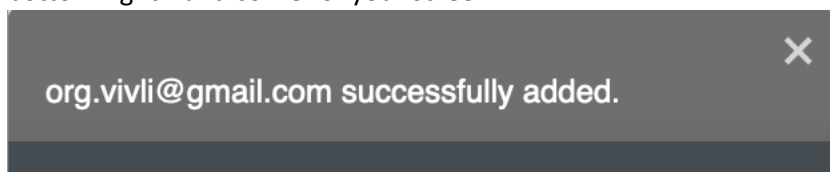
The screenshot shows the Vivli Member page. The left sidebar has a red box around 'My Organizations'. The main content area has a red box around the 'Add Member with Rights' form. The 'Details' tab is selected. The 'Add Member with Rights' form has an 'Email' input field with 'org.vivli@gmail.com', a checked 'Data Contributor' checkbox, and an unchecked 'Organization Administrator' checkbox. Below the form is an 'Add Member' button. The 'ORGANIZATION MEMBERS' table at the bottom shows one entry: 'QA - DC All Orgs' with email 'VivTestQA+DC-allOrgs@gmail.com' and three 'Deactivate' buttons.

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

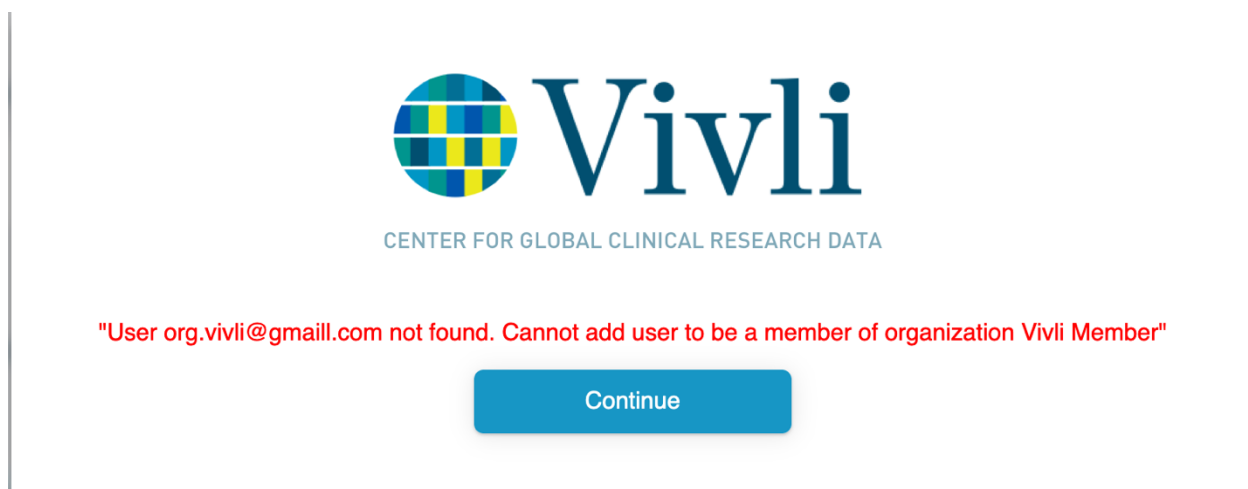
The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. The left sidebar contains a menu with Dashboard, Research Environments, Users, Report, My Organizations, Studies, Data Requests, Submissions, and Awaiting Upload. The main content area is titled 'Vivli Member' and has tabs for Details, Members, and ROR. The 'ADD MEMBER WITH RIGHTS' section is highlighted with a red box. It contains an email input field with 'org.vivli@gmail.com' and two checkboxes: 'Data Contributor' (checked) and 'Organization Administrator' (unchecked). Below this is an 'Add Member' button. The 'ORGANIZATION MEMBERS' table below shows a member 'QA - DC All Orgs' with 'Deactivate' buttons for each role. The footer contains links for How To Guide, Privacy, Cookie Policy, EEA Disclosure Policy, and Contact Us, along with a copyright notice for 2017-2024.

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

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



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



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

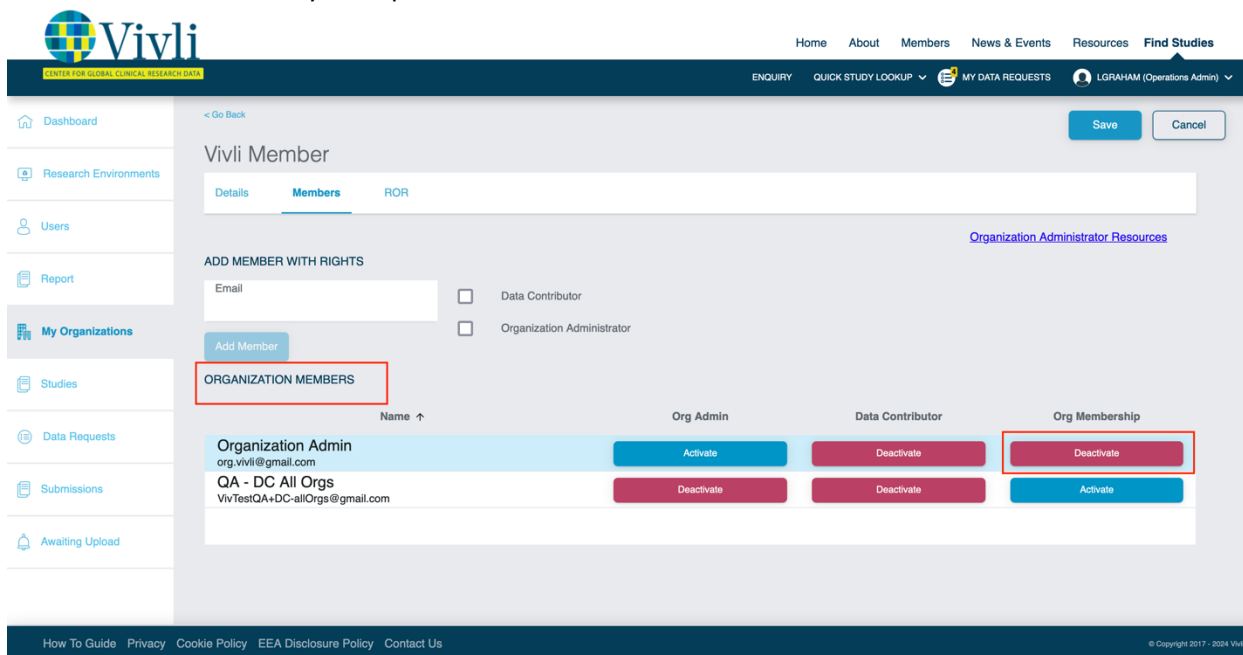
The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. A user profile dropdown for 'SALLY SCIENTIST (DATA PROVIDER)' is visible. The left sidebar contains links for Dashboard, Research Environments, My Organization, Studies, Data Requests, and Awaiting Upload. The main content area is titled 'Vivli Member' and has tabs for 'Details' and 'Members'. The 'Members' tab is active, showing an 'INVITE MEMBER WITH RIGHTS' section with an email input field and checkboxes for 'Data Contributor' and 'Organization Administrator'. Below this, it says '0 PENDING INVITE(S)'. A red box highlights the 'ORGANIZATION MEMBERS' section, which contains a table with columns: Name, Org Admin, Data Contributor, and Org Membership. The table lists 'Sally Scientist (Data Provider)' with email 'dataprovder.vivli@gmail.com'. Under 'Org Admin' is a 'Deactivate' button. Under 'Data Contributor' is an 'Activate' button. Under 'Org Membership' is a 'Deactivate' button. A 'Save' button is at the top right of the member details area.

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



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

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



1.3.3 Data Contributor Organizational Roles

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

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

Vivli Member Role	Description	Rights & Responsibilities
Organizational Administrator(s)	<ul style="list-style-type: none"> • Main institutional contact(s) for operations on the Vivli platform. • Responsible for recording decisions. 	<ul style="list-style-type: none"> • May add or deactivate your organization’s team members • Assign member roles except for Organizational Administrator rights (contact the Vivli team for this) • Update Organizational Page / Contact details • Responsible for keeping Vivli accounts up-to-date for the organization

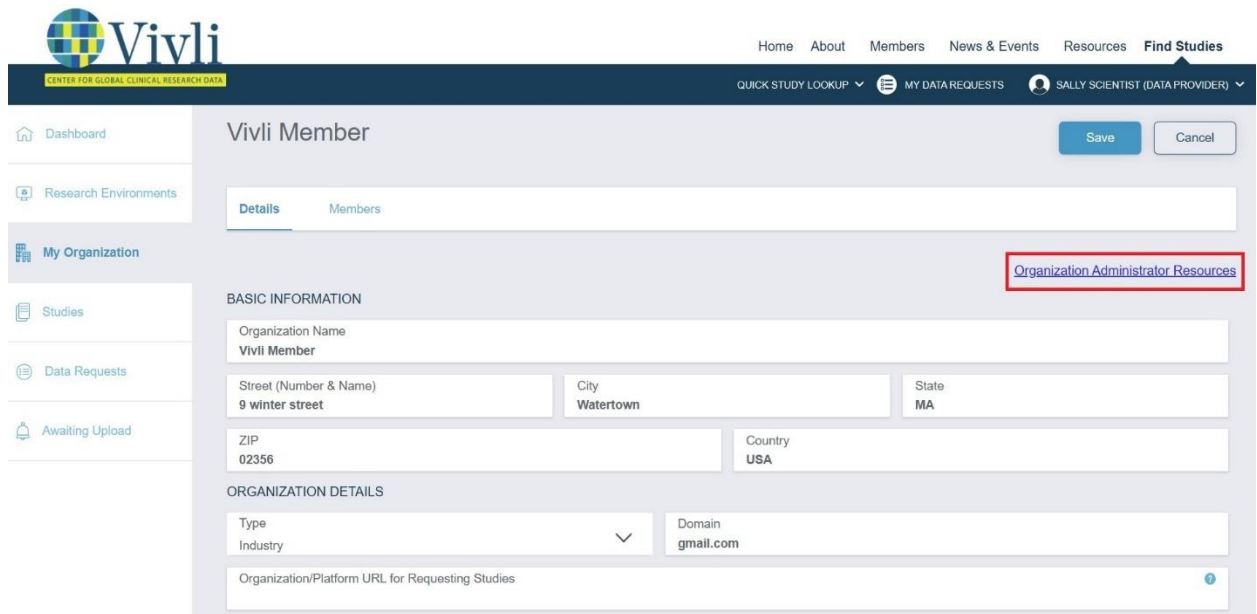
		<ul style="list-style-type: none"> • View the data request(s) and record the decisions for an Organization • Options are to approve a request, deny a request, or ask for revisions to the data request form. • Receive and respond to chat messages within the data request. • View the internal metrics of your Organization on the Dashboard • Access the Research environment and Report tabs on Dashboard
Data Contributor(s)	<ul style="list-style-type: none"> • Responsible for uploading data packages for approved requests, after the Data Requestor signs a Data Use Agreement 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • May log on to the Vivli platform as a user, but only to create data requests 	<ul style="list-style-type: none"> • Will appear on your organizational members' listing under Members • No administrative rights

1.3.4 Active Platform Accounts

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

1.3.5 Accessing the Vivli Data Contributor Guide

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



Vivli Member

[Save](#) [Cancel](#)

[Organization Administrator Resources](#)

BASIC INFORMATION

Organization Name
Vivli Member

Street (Number & Name)
9 winter street

City
Watertown

State
MA

ZIP
02356

Country
USA

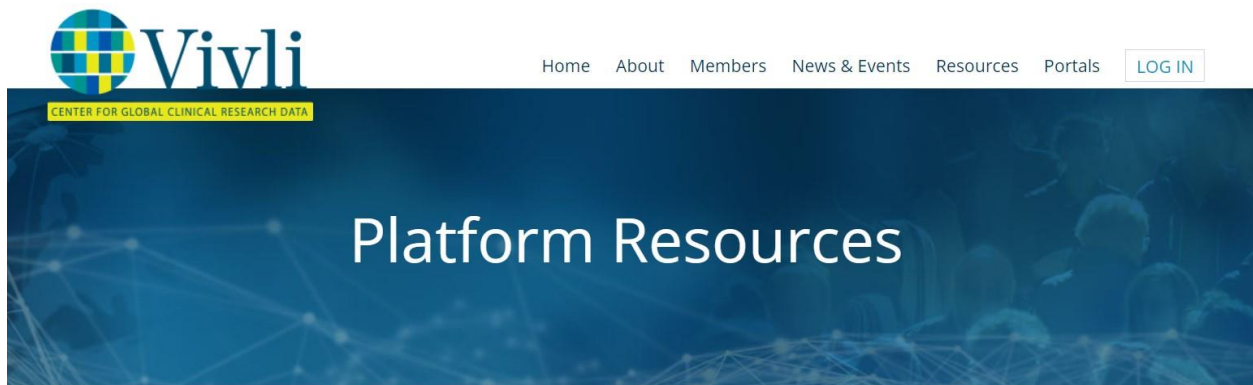
ORGANIZATION DETAILS

Type
Industry

Domain
gmail.com

Organization/Platform URL for Requesting Studies

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



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

2. Listing Studies – Process and Options

2.1 Listing Studies- Process

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

2.2 Listing Studies - Options

There are two types of Vivli Metadata sheets available:

Option	Applicability	Sheet used	Fields
<i>Bulk Metadata upload -CT.GOV listed studies</i>	Single or Multiple studies, all with NCT ID	Vivli Metadata Sheet NCT ID	<ul style="list-style-type: none"> • NCT ID • Study-specific URL (if applicable)
<i>Bulk Metadata upload -studies without NCT ID</i>	Multiple studies without NCT ID	Vivli Metadata Sheet Non-NCT ID	Contains several columns including but not limited to: <ul style="list-style-type: none"> • Sponsor ID • Study title • Medicine • Medical Condition • Phase • Sponsor Clinical Registry URLs • Eudra CT ID • Eudra CT URL • Sponsor

2.3 Listing a single study

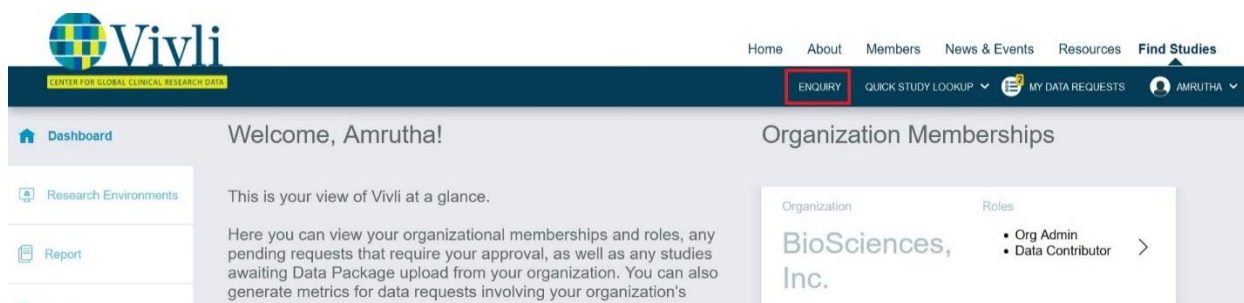
To list a single study, provide the NCT ID to the Vivli Administrator, who will complete the listing process.

2.4 Removing studies from the Vivli search

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

2.5 Study Enquiry Process

- A researcher submits an enquiry to Vivli regarding the availability of a study not listed on Vivli using the [Vivli Enquiry form](#)

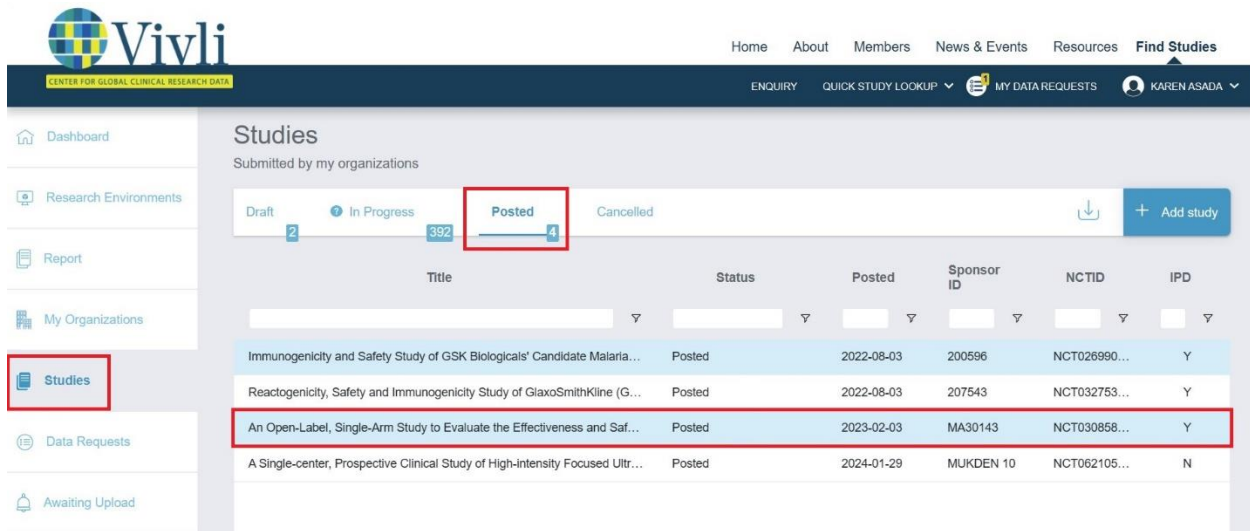


- Vivli Admin sends enquiry details via email including the Enquiry number, PI's name, Email, Study Sponsor/Data Contributor, Study ID, Study Title, and a brief description of the enquiry to the contact of the person at the Member organization to receive such enquiries.
- The contact person at the Member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

2.6 Supporting documents made available for researchers searching for studies

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

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



Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS KAREN ASADA

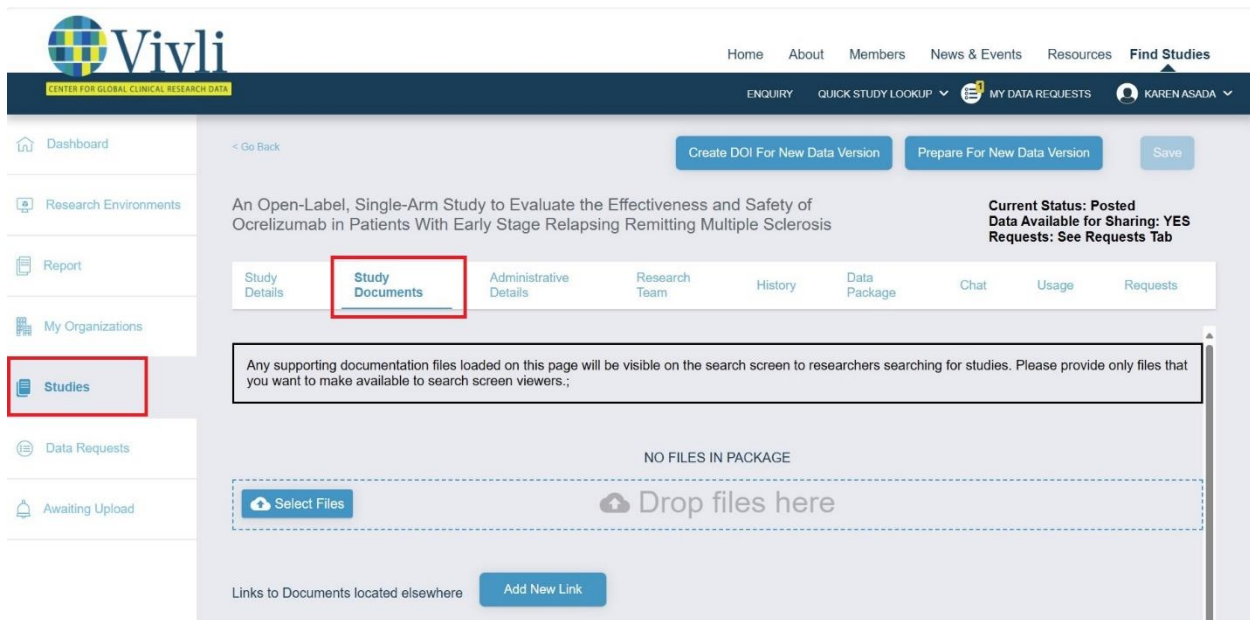
Studies
Submitted by my organizations

Draft 2 In Progress 392 **Posted 4** Cancelled

+ Add study

Title	Status	Posted	Sponsor ID	NCTID	IPD
Immunogenicity and Safety Study of GSK Biologicals' Candidate Malaria...	Posted	2022-08-03	200596	NCT026990...	Y
Reactogenicity, Safety and Immunogenicity Study of GlaxoSmithKline (G...	Posted	2022-08-03	207543	NCT032753...	Y
An Open-Label, Single-Arm Study to Evaluate the Effectiveness and Saf...	Posted	2023-02-03	MA30143	NCT030858...	Y
A Single-center, Prospective Clinical Study of High-Intensity Focused Ultr...	Posted	2024-01-29	MUKDEN 10	NCT062105...	N

2. Open the study and go to Study Documents



Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS KAREN ASADA

< Go Back

Create DOI For New Data Version Prepare For New Data Version Save

An Open-Label, Single-Arm Study to Evaluate the Effectiveness and Safety of Ocrelizumab in Patients With Early Stage Relapsing Remitting Multiple Sclerosis

Current Status: Posted
Data Available for Sharing: YES
Requests: See Requests Tab

Study Details **Study Documents** Administrative Details Research Team History Data Package Chat Usage Requests


Any supporting documentation files loaded on this page will be visible on the search screen to researchers searching for studies. Please provide only files that you want to make available to search screen viewers.;

NO FILES IN PACKAGE

Select Files Drop files here

Links to Documents located elsewhere Add New Link

A blue button with a white cloud icon and the text "Select Files".

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

A blue button with a white cloud icon and the text "Select Files".A light gray area with a dotted blue border, containing a white cloud icon and the text "Drop files here".

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

The Study Documents tab is to be used for supporting documents that will help researchers determine if this study will support their research. This tab must not be used for uploading Individual Participant Data (IPD) since files on this tab are available to any user without placing a request. If the file you just asked to load contains Individual Participant Data, please click the Cancel button below. Individual Participant Data should be loaded only in the "Data Package" tab. If the file does not contain Individual Participant Data, check "This is not IPD, load this data" and click on OK

☐ This is not IPD, load this data

Ok

Cancel

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

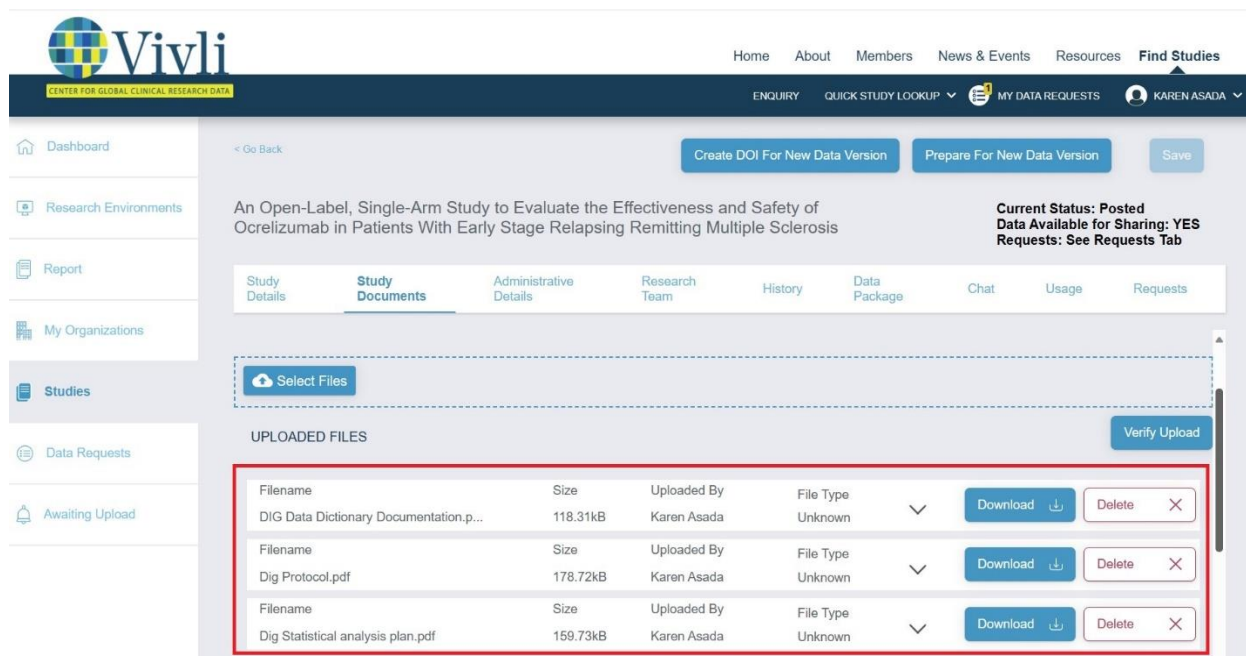
The Study Documents tab is to be used for supporting documents that will help researchers determine if this study will support their research. This tab must not be used for uploading Individual Participant Data (IPD) since files on this tab are available to any user without placing a request. If the file you just asked to load contains Individual Participant Data, please click the Cancel button below. Individual Participant Data should be loaded only in the "Data Package" tab. If the file does not contain Individual Participant Data, check "This is not IPD, load this data" and click on OK

☒ This is not IPD, load this data

Ok

Cancel

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



Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS KAREN ASADA

Dashboard Research Environments Report My Organizations Studies Data Requests Awaiting Upload

< Go Back Create DOI For New Data Version Prepare For New Data Version Save

An Open-Label, Single-Arm Study to Evaluate the Effectiveness and Safety of Ocrelizumab in Patients With Early Stage Relapsing Remitting Multiple Sclerosis

Current Status: Posted
Data Available for Sharing: YES
Requests: See Requests Tab

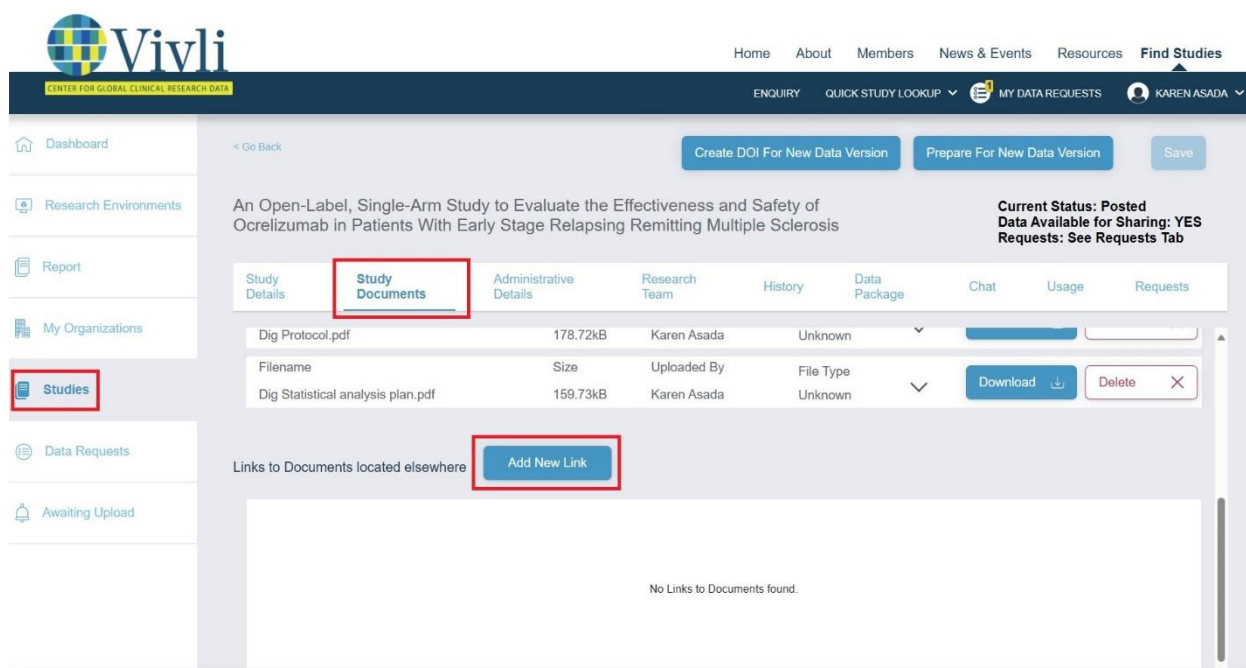
Study Details Study Documents Administrative Details Research Team History Data Package Chat Usage Requests

Select Files

UPLOADED FILES Verify Upload

Filename	Size	Uploaded By	File Type		Download	Delete
DIG Data Dictionary Documentation.p...	118.31kB	Karen Asada	Unknown	✓	Download	Delete
Dig Protocol.pdf	178.72kB	Karen Asada	Unknown	✓	Download	Delete
Dig Statistical analysis plan.pdf	159.73kB	Karen Asada	Unknown	✓	Download	Delete

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



Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS KAREN ASADA

Dashboard Research Environments Report My Organizations Studies Data Requests Awaiting Upload

< Go Back Create DOI For New Data Version Prepare For New Data Version Save

An Open-Label, Single-Arm Study to Evaluate the Effectiveness and Safety of Ocrelizumab in Patients With Early Stage Relapsing Remitting Multiple Sclerosis

Current Status: Posted
Data Available for Sharing: YES
Requests: See Requests Tab

Study Details Study Documents Administrative Details Research Team History Data Package Chat Usage Requests

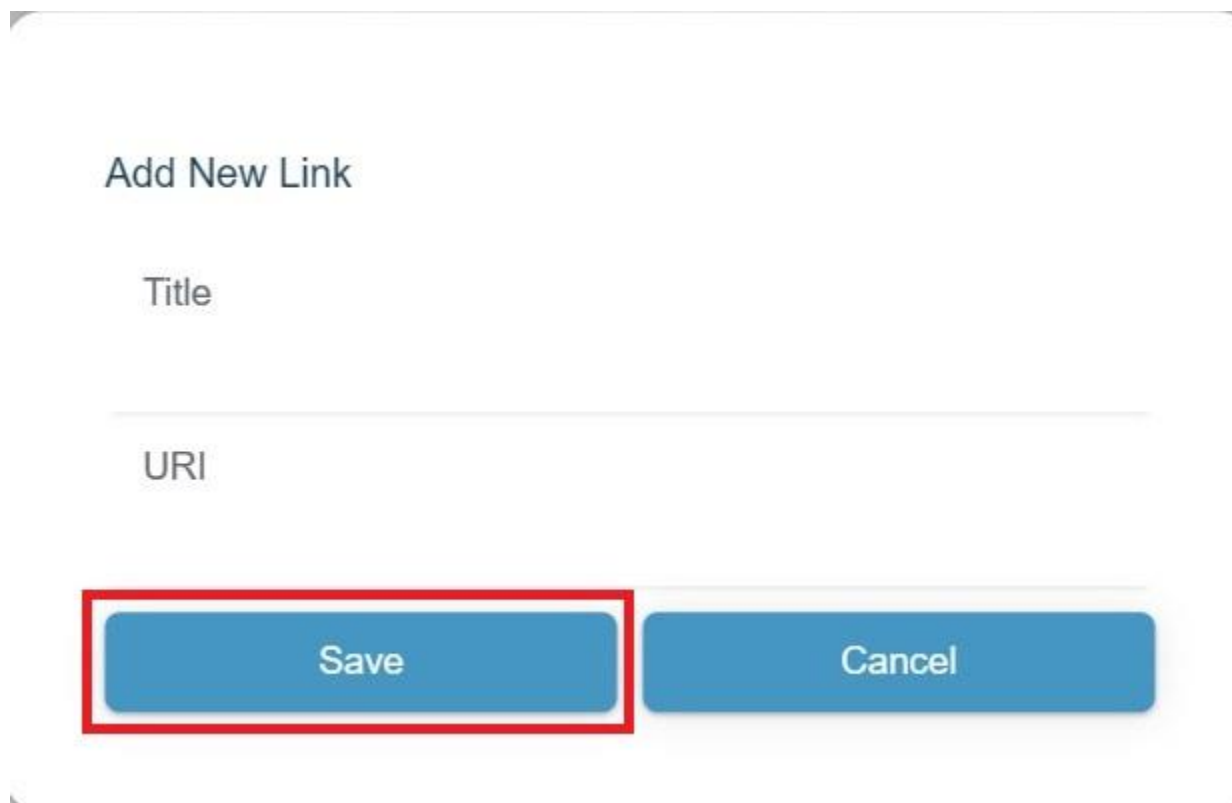
Dig Protocol.pdf 178.72kB Karen Asada Unknown ✓

Dig Statistical analysis plan.pdf 159.73kB Karen Asada Unknown ✓

Links to Documents located elsewhere Add New Link

No Links to Documents found.

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



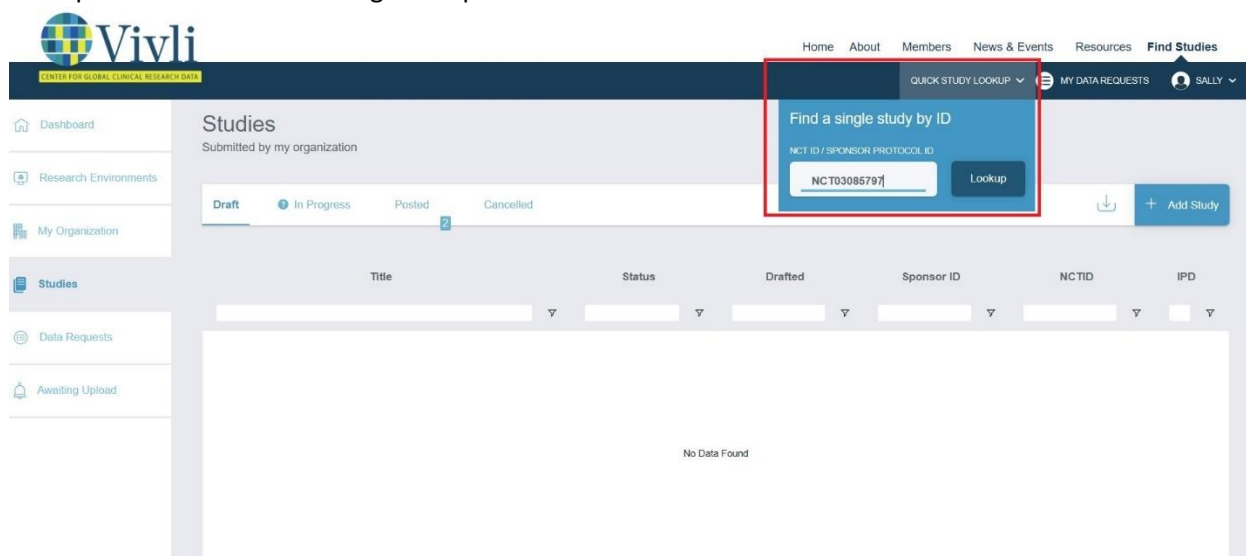
Add New Link

Title

URI

Save Cancel

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



Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

QUICK STUDY LOOKUP MY DATA REQUESTS SALLY

Studies
Submitted by my organization

Draft In Progress Posted Cancelled

Find a single study by ID

NCT ID / SPONSOR PROTOCOL ID

NCT03085797 Lookup

+ Add Study

Title	Status	Drafted	Sponsor ID	NCTID	IPD

No Data Found


12. Click the “view study details” button.

Quick Study Lookup results for **NCT01243606** CLOSE

Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Disorders
IDs: NCT01243606 | 1R01MH090053-01
Condition or Disease: Anxiety Disorders, Mood Disorders
Intervention/treatment: Single Diagnosis Treatment Protocol, Unified Protocol (UP)

[Request Study](#)
[View Study Details](#)
Number enrolled: 250
N/A

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



[Home](#)
[About](#)
[Members](#)
[News & Events](#)
[Resources](#)
[Find Studies](#)

[ENQUIRY](#)
[QUICK STUDY LOOKUP](#)
[MY DATA REQUESTS](#)
[DATA REQUESTER](#)

Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Disorders

[Study Details](#)
[Study Documents](#)
[Administrative Details](#)
[Usage](#)
[Research Team](#)

UPLOADED FILES

Filename	Size	Uploaded By	
DIG Data Dictionary Documentation.pdf	118.00kB	Data Requester	Download
Dig Protocol.pdf	179.00kB	Data Requester	Download
Dig Statistical analysis plan.pdf	160.00kB	Data Requester	Download

2.7 Study Usage and Public Disclosure Metrics

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

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

[Dashboard](#)
[Research Environments](#)
[Report](#)
[My Organizations](#)
[Studies](#)
[Data Requests](#)
[Awaiting Upload](#)

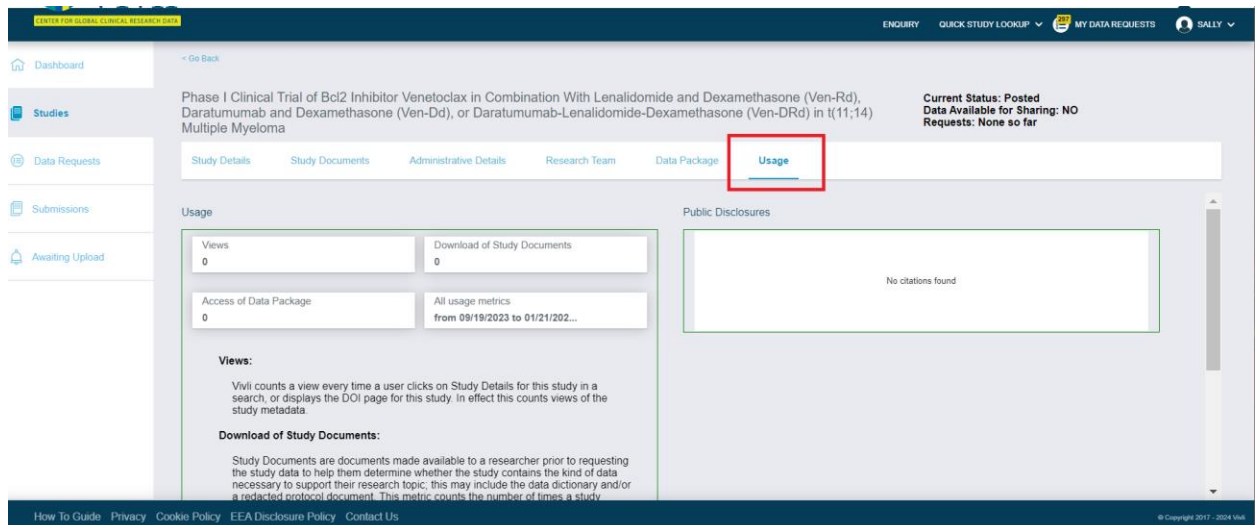
Studies
Submitted by my organizations

Draft 1
In Progress 1013
Posted 600
Cancelled

Title
Status
Posted
Sponsor ID
NCTID
IPD

A Randomised, Double-blind, Multi-centre Study to Evaluate the Efficacy ...	Posted	2023-05-24	114496	NCT01431950	Y
A Randomized, Double-blind, Double-dummy, Parallel-group, Placebo C...	Posted	2024-01-12	112060	NCT01181895	Y
A Randomized Double-Blind, Double Dummy, Placebo-Controlled, Parall...	Posted	2018-03-27	FFA109684	NCT00603746	Y
A Randomized Double-Blind, Double Dummy, Placebo-Controlled, Parall...	Posted	2018-03-27	FFA109685	NCT00603278	Y
A Multi-center, Randomized, Double-blind, Placebo-controlled, Five Peri...	Posted	2018-03-27	113310	NCT00980200	Y
A Single Centre, Randomised, Double-blind, Placebo-controlled, Four-w...	Posted	2018-03-27	112359	NCT00955383	Y

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



3. Under “Usage” will see the following fields:
 - a. Views
 - i. Vivli counts a view every time a user clicks on Study Details for this study in a search or displays the DOI page for this study. In effect this counts views of the study metadata.
 - b. Download of Study Documents
 - i. Study Documents are documents made available to a researcher prior to requesting the study data to help them determine whether the study contains the kind of data necessary to support their research topic; this may include the data dictionary and/or a redacted protocol document. This metric counts the number of times a study document is downloaded. For more information see Section 2.6 Supporting documents made available for researchers searching for studies
 - c. Access of Data Packages
 - i. The data package includes the data that is provided in response to the request and includes anonymized Individual Participant Data (IPD) and supporting documents. "Access" includes placing the data into a secure research environment or (when allowed) downloading the data.
 - d. All Usage Metrics
 - i. The data range here represents the range of dates during which the metrics above were collected. The start date is either the date the data collection feature was turned on, or the date the study was posted (whichever is later).

The end date is always 3 days before the current date, since it takes the system 3 days to process and tally the raw usage data.

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

The screenshot shows the Vivli Data Contributor interface. The top navigation bar includes 'ENQUIRY', 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and a user profile 'SALLY'. The left sidebar contains links to 'Dashboard', 'Studies', 'Data Requests', 'Submissions', and 'Awaiting Upload'. The main content area displays details for a 'Phase I Clinical Trial of Bcl2 Inhibitor Venetoclax in Combination With Lenalidomide and Dexamethasone (Ven-Rd), Daratumumab and Dexamethasone (Ven-Dd), or Daratumumab-Lenalidomide-Dexamethasone (Ven-DRd) in t(11;14) Multiple Myeloma'. The 'Current Status' is 'Posted' and 'Data Available for Sharing' is 'NO'. The 'Usage' tab is selected, showing metrics for 'Views' (0), 'Download of Study Documents' (0), 'Access of Data Package' (0), and 'All usage metrics from 09/19/2023 to 01/21/2024...'. The 'Public Disclosures' tab is also visible, showing 'No citations found'. The bottom of the page includes a footer with 'How To Guide', 'Privacy', 'Cookie Policy', 'EEA Disclosure Policy', 'Contact Us', and '© Copyright 2017 - 2024 Vivli'.

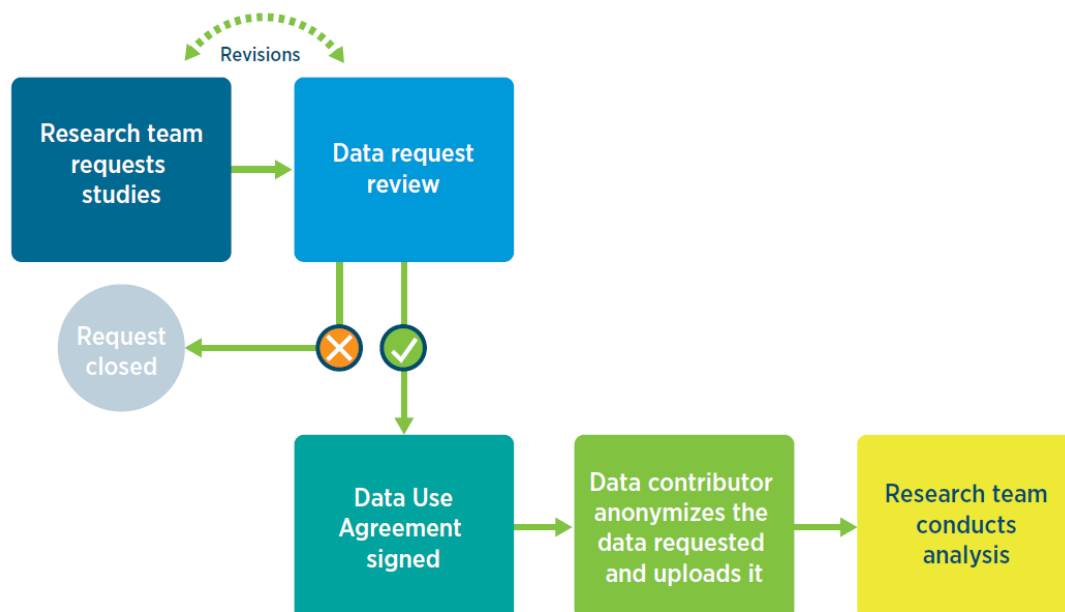
5. You may also view citations linked to a specific data request from by navigating to a data request and clicking on “Public Disclosures” tab. This tab is visible after the request reaches the data upload stage.

The screenshot shows the Vivli Data Contributor interface. The top navigation bar includes 'ENQUIRY', 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and a user profile 'SALLY'. The left sidebar contains links to 'Studies', 'Status Update', 'Attachments', 'Request History', 'Signed Agreements', 'Chat', 'Research Environment', 'Public Disclosures', and 'Request Details/Print View'. The main content area displays details for a 'Request: 48066, Pt: Heidi Lakes' with 'Status: Archived'. The 'Public Disclosures' tab is selected, showing 'Current Citations'. A citation is listed: 'Baskin, Jacqueline L, Pal, Ching-Hon, Reiss, Ulrike, Wilmas, Judith A, Metzger, Monika L, Ribeiro, Raul C and Howard, Scott C. "Management of occlusion and thrombosis associated with long-term indwelling central venous catheters". The Lancet vol. 374, no. 9684, Jul. 2009, pp. 159-169, doi: http://dx.doi.org/10.1016/S0140-6736(09)60220-8'. The bottom of the page includes a footer with 'How To Guide', 'Privacy', 'Cookie Policy', 'EEA Disclosure Policy', 'Contact Us', and '© Copyright 2017 - 2024 Vivli'.

3. Reviewing Data Requests

3.1 Overview

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

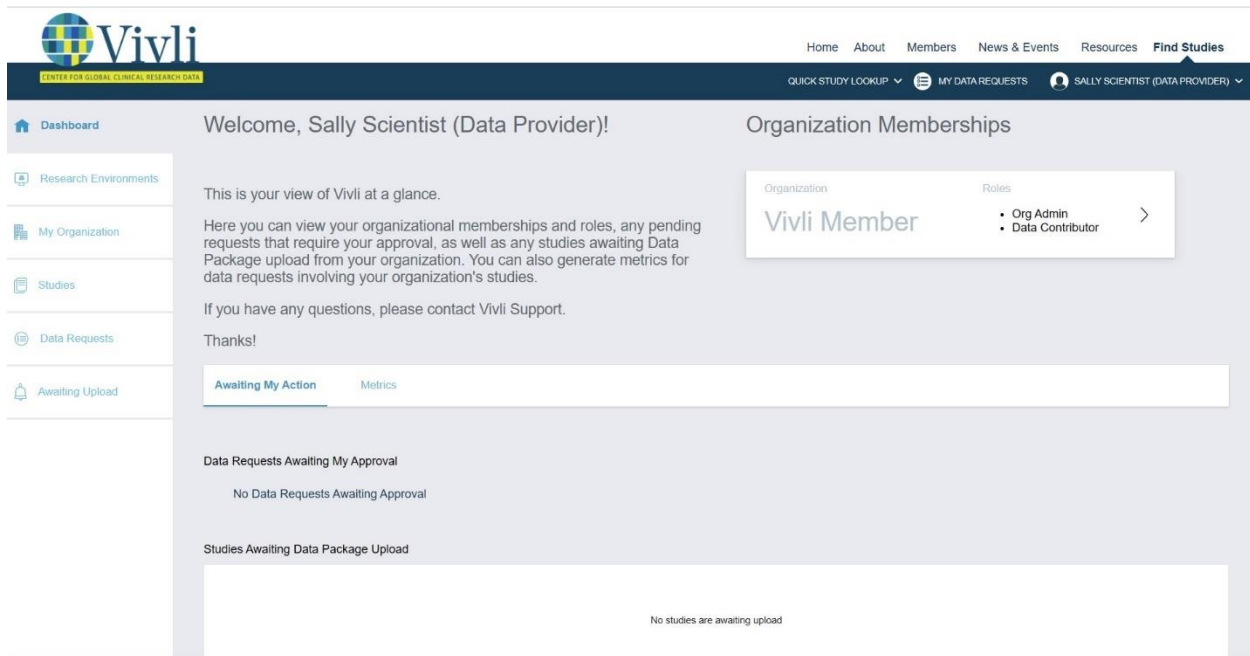


3.2 Data Request Review

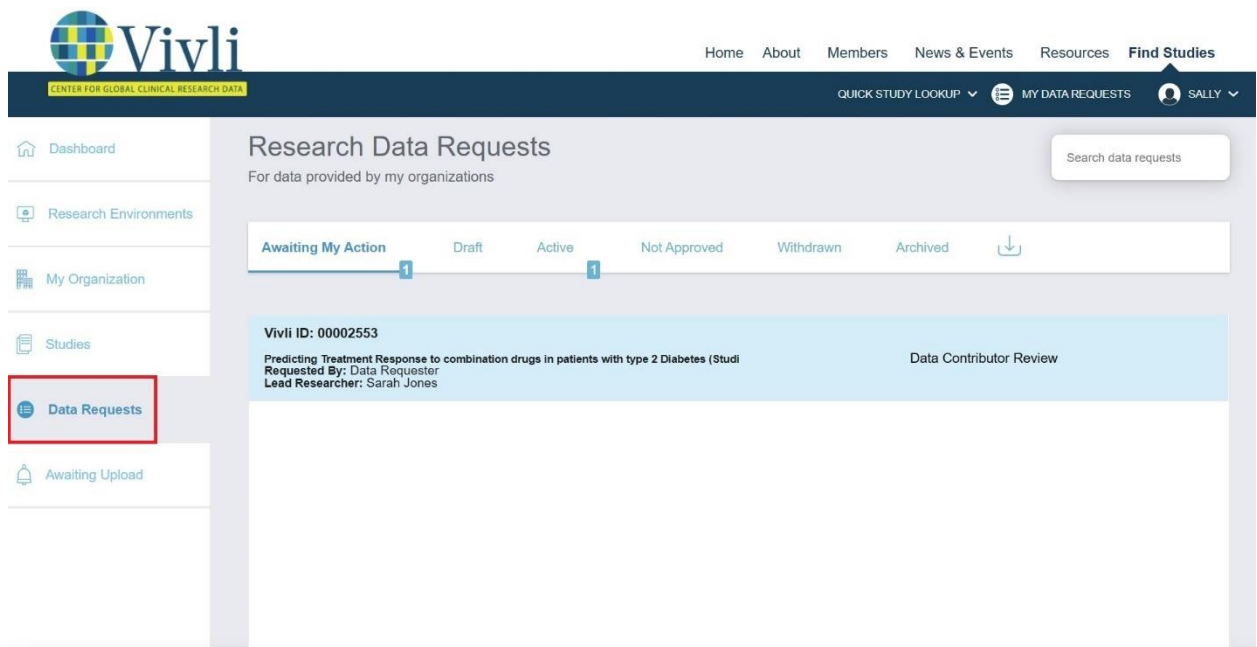
- You will receive an email notifying you when a data request is ready for review.
- Only Organizational Administrators can see and review Data Requests waiting for review for your organization.
- You must log in with your account to see Data Requests directed to your organization

3.2.1 Navigating to Data Requests

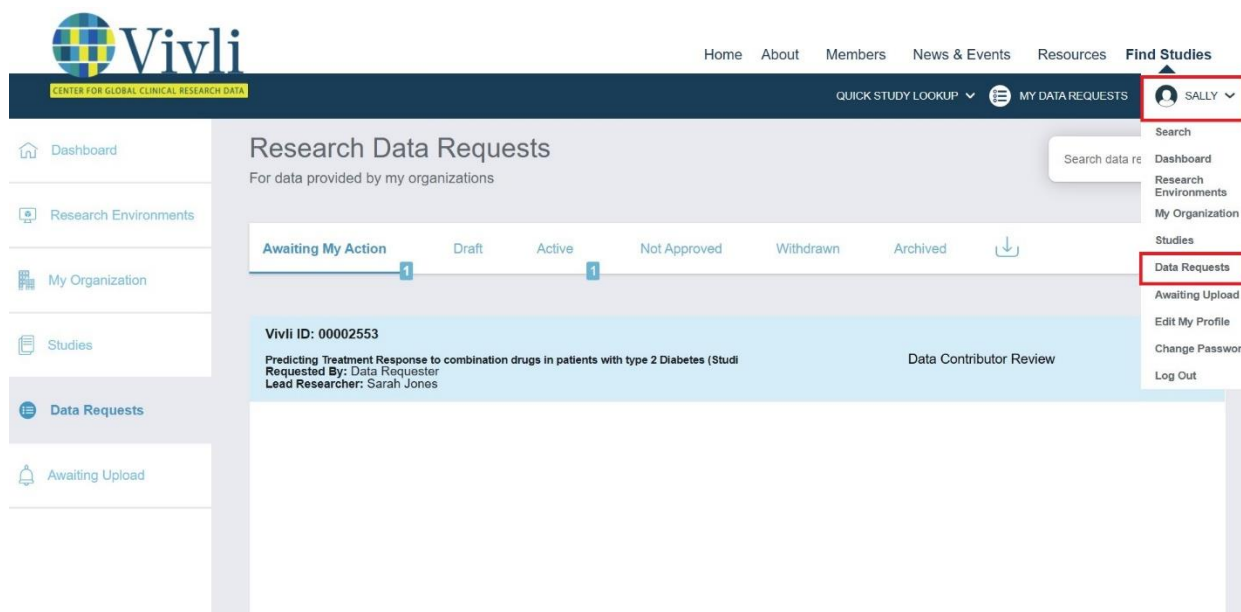
1. Log into your account



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

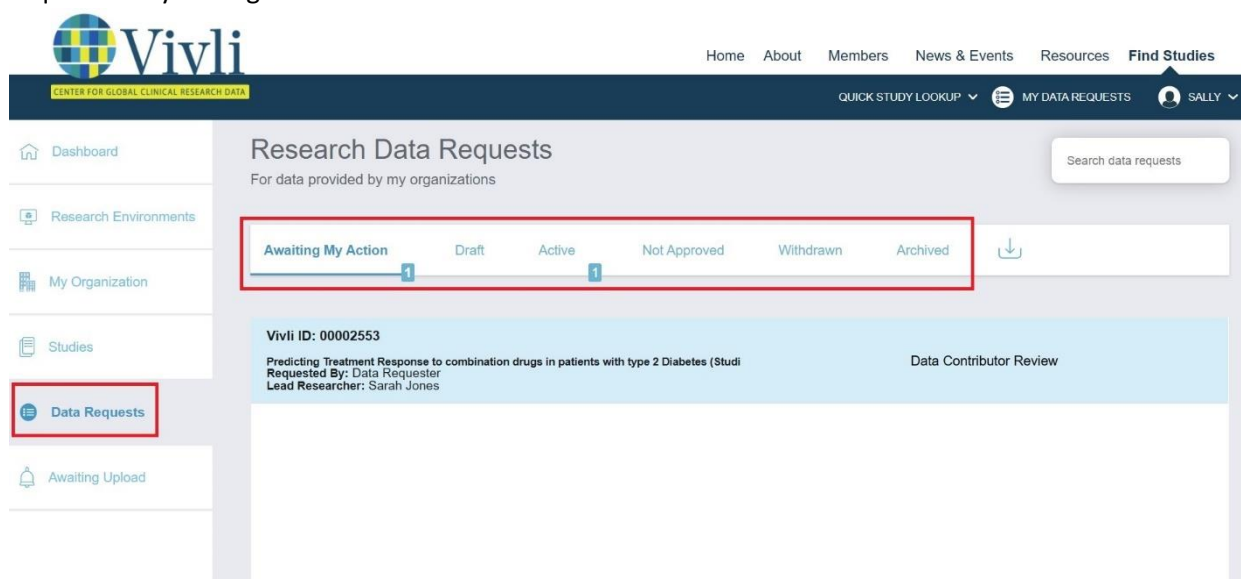


3. You can also use the dropdown menu on the upper right-hand corner of the screen:



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

- 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.



- The status bar contains 6 sections:

Awaiting My Action: Displays Data Requests that are awaiting your action.

Draft: Displays Data Requests that are being drafted but not yet submitted and hence don't have a Vivli ID.

Active: Displays Data Requests that are in progress. This includes requests in the Vivli form check stage, requests that were sent back for revision, requests in the Data Contributor Review stage, IRP review stage, DUA validation stage, awaiting data package upload stage, and requests where some or all of the data packages have been uploaded. It also displays requests that are currently in the analysis stage, awaiting results review and awaiting publication review.

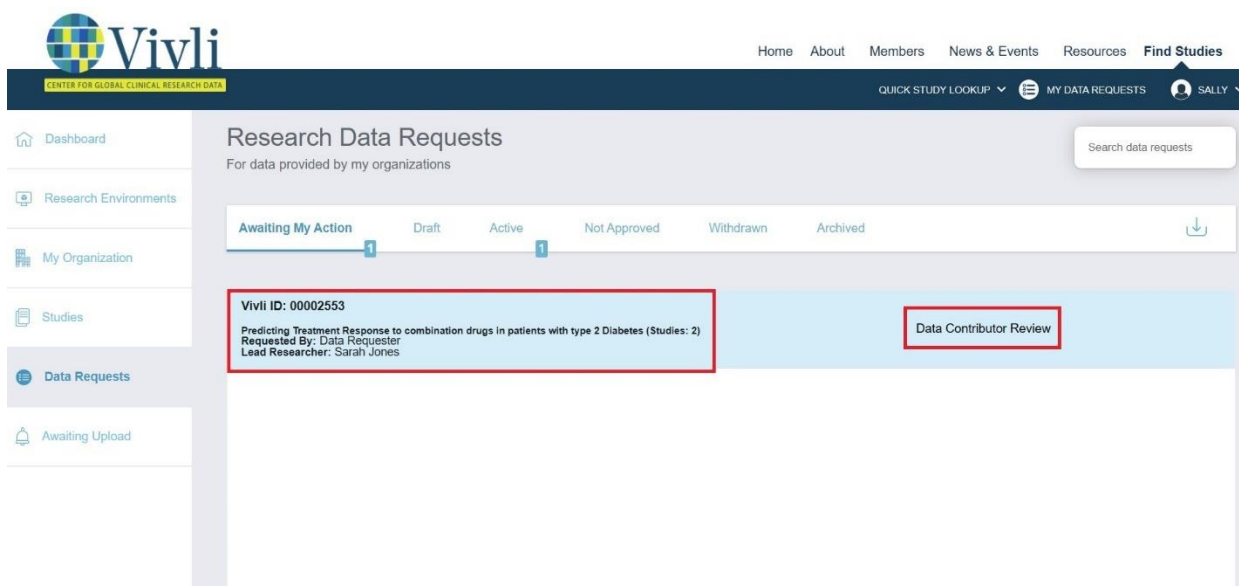
Not Approved: Displays Data Requests that are denied. It also temporarily displays requests where revisions were requested until the Vivli Admin moves the requests to draft.

Withdrawn: Displays Data Requests that were withdrawn

Archived: Displays Data Requests that were completed including those with publication or summary of results provided

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

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



3.2.2 Data Request Dashboard – Search Feature

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

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

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

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. A user profile for 'SALLY' is visible in the top right. The left sidebar contains a menu with options: Dashboard, Research Environments, My Organization, Studies, Data Requests (highlighted with a red box), and Awaiting Upload. The main content area is titled 'Research Data Requests' and includes a subtitle 'For data provided by my organizations'. A search bar in the top right of the main area contains the text '2553' and is highlighted with a red box. Below the search bar is a tabbed interface with tabs for 'Awaiting My Action', 'Draft', 'Active' (highlighted with a red box), 'Not Approved', 'Withdrawn', and 'Archived'. The 'Active' tab shows a data request entry with the following details: 'Vivli ID: 00002553', 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes (Studies: 2)', 'Requested By: Data Requester', 'Lead Researcher: Sarah Jones', and 'Data Contributor Review'. A red box highlights the 'Active' tab and the search bar.

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

This screenshot is identical to the one above, showing the Vivli Research Data Requests page. It highlights the search bar containing '2553' and the 'Active' tab in the tabbed interface. A red box also highlights the export button (a download icon) located at the end of the 'Active' tab.

The downloaded file contains:

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

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

3.2.3 Data Request Form

After navigating to your requests, you can review them.

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

- 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.

The screenshot displays the Vivli web application interface. At the top, the Vivli logo and navigation menu are visible. The main header area shows the request details: "Request: 3469, PI: Sarah Jones" and "Status: Data Contributor Review". Below this, there are action buttons: "X Cannot Fulfill", "X Request Revision", "Process Request", and "Print". The left sidebar contains a list of tabs: "Studies", "Status Update", "Attachments", "Request History", "Signed Agreements", "Chat", and "Request Details/Print View". The main content area is titled "Research Data Request: Predicting Treatment Response to combination drugs in patients with type 2 diabetes" and "Vivli ID: 00003469". It includes a section for "Comments from the Vivli Team" with a detailed message about a requested revision. Below this is the "Research Team" section, which lists the "Lead Investigator" as Sarah Jones, along with her contact information, education, and conflicts of interest.

Request: 3469, PI: Sarah Jones
Status: Data Contributor Review

X Cannot Fulfill X Request Revision Process Request Print

Research Data Request: Predicting Treatment Response to combination drugs in patients with type 2 diabetes
Vivli ID: 00003469

Comments from the Vivli Team
In the last round of review, Vivli Member 1 requested revisions. As a result, PI added an additional study. For detailed information on the changes made, please see attachment "2023_09_20 Vivli ID 00003469_form check comparison report" in chat. Any changes to studies are considered a major revision and therefore data contributors are provided with the opportunity to review the proposal with these revisions.

Research Team
Lead Investigator
Sarah Jones
S.Jones@ucsf.edu
Professor
University of California, San Francisco
ORCID ID: 0000-0002-1045-8336Country: United States of America

Education or Qualifications
MD, PhD in Biostatistics

Conflicts of Interest and Plan for Management
None

Statistician Researcher

- 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.

This screenshot shows the same Vivli interface as the previous one, but with the "Request Details/print view" tab selected in the left sidebar. The main content area remains the same, but the "Comments from the Vivli Team" section is now highlighted with a red border, indicating it is the active view. The rest of the interface, including the header, navigation, and research team details, is identical to the previous screenshot.

Request: 3469, PI: Sarah Jones
Status: Data Contributor Review

X Cannot Fulfill X Request Revision Process Request Print

Research Data Request: Predicting Treatment Response to combination drugs in patients with type 2 diabetes
Vivli ID: 00003469

Comments from the Vivli Team
In the last round of review, Vivli Member 1 requested revisions. As a result, PI added an additional study. For detailed information on the changes made, please see attachment "2023_09_20 Vivli ID 00003469_form check comparison report" in chat. Any changes to studies are considered a major revision and therefore data contributors are provided with the opportunity to review the proposal with these revisions.

Research Team
Lead Investigator
Sarah Jones
S.Jones@ucsf.edu
Professor
University of California, San Francisco
ORCID ID: 0000-0002-1045-8336Country: United States of America

Education or Qualifications
MD, PhD in Biostatistics

Conflicts of Interest and Plan for Management
None

Statistician Researcher

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

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS SALLY

< Go Back Request: 3469, PI: Sarah Jones Status: Data Contributor Review

Cannot Fulfill Request Revision Process Request **Print**

Studies

Status Update

Attachments

Request History

Signed Agreements

Chat

Request Details/Print View

Research Data Request: Predicting Treatment Response to combination drugs in patients with type 2 diabetes

Vivli ID: 00003469

Comments from the Vivli Team

In the last round of review, Vivli Member 1 requested revisions. As a result, PI added an additional study. For detailed information on the changes made, please see attachment "2023_09_20 Vivli ID 00003469_form check comparison report" in chat. Any changes to studies are considered a major revision and therefore data contributors are provided with the opportunity to review the proposal with these revisions.

Research Team

Lead Investigator

Sarah Jones
SJJones@ucsf.edu
Professor
University of California, San Francisco
ORCID ID: 0000-0002-1045-8336 Country: United States of America

Education or Qualifications
MD, PhD in Biostatistics

Conflicts of Interest and Plan for Management
None

Statistician Researcher

Print
Total: 3 pages

Printer
Save as PDF

Layout
☒ Portrait
☐ Landscape

Pages
☒ All
☐ e.g. 1-5, 8, 11-13

More settings
Troubleshoot printer issues

10/6/21, 5:04 PM Vivli

Research Data Request: Predicting Treatment Response to combination drugs in patients with type 2 Diabetes

Vivli ID: 00002553

Comments from the Vivli Team

In the last round of review, Vivli Member 1 requested revision. As a result, PI added additional study. For detailed information on the changes made, please see attachment "2021_10_05 Vivli ID 00002553_form check comparison report" in chat. Any changes to studies are considered major revision and therefore, data contributors are provided with the opportunity to review the proposal with these revisions.

Research Team

Lead Investigator and Statistician

Sarah Jones
sjones@ucsf.edu
Professor
University of California, San Francisco
Orcid ID: 0000-0002-1045-8336

Education or Qualifications
MD, PhD

Conflicts of Interest and Plan for Management
None

Additional Researchers

Data Requester
Datarequester.vivli@gmail.com
N/A
N/A

Education or Qualifications
N/A

Conflicts of Interest and Plan for Management
N/A

Research Proposal

General

Title of Proposed Research
Predicting Treatment Response to combination drugs in patients with type 2 Diabetes

Narrative summary explaining the relevance of the project to science and public health

Save Cancel

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

The screenshot shows the Vivli Data Contributor interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a dark blue bar with 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'DATA CONTRIBUTOR'. The main content area is titled 'Request: 3469, PI: Sarah Jones' with a status of 'Data Contributor Review'. A left sidebar contains a list of tabs: Studies, Status Update, Attachments, Request History, Signed Agreements, Safety Concerns, Research Results, Chat, Research Environment, and Request Details/Print View. The main content area displays the research title 'Predicting Treatment Response to combination drugs in patients with type 2 diabetes', the Vivli ID '00003469', and a section for 'Comments from the Vivli Team' and 'Research Team' information.

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

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

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

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

3.2.4 Vivli Policies in Brief

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

3.3 Study settings at Data Contributor Review

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

The screenshot displays the Vivli Data Contributor Review interface. At the top, the Vivli logo and navigation menu are visible. The main header shows the request details: "Request: 3469, Pt: Sarah Jones" and "Status: Data Contributor Review". Below this, there are buttons for "Cannot Fulfill", "Request Revision", "Process Request", and "Print".

The left sidebar contains a list of navigation options: "Studies" (highlighted with a red box), "Status Update", "Attachments", "Request History", "Signed Agreements", "Chat", and "Request Details/Print View".

The main content area is titled "REQUESTED STUDIES" and "VIVLI-LISTED AND PROVISIONED STUDIES". It lists two studies:

- Study 1:** A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter Monotherapy Study to Determine the Efficacy and Safety of 2 Dose Levels of Albiglutide in Subjec...
Study ID: NCT01733758 | Sponsor ID: 113121
Data Request ID: 00003469 | Data Contributor: GlaxoSmithKline | IRP/Approver: Wellcome Trust
Settings: [Edit Settings](#) (highlighted with a red box)
Data available in secure research environment only
Data to be loaded after approval
- Study 2:** A double-blind, stratified, randomized, placebo controlled study of Ro 64-0796 (also known as GS4104) in the treatment of influenza in chronically ill adults
Study ID: WV15872 | Sponsor ID: WV15872
Data Request ID: 00003469 | Data Contributor: Roche | IRP/Approver: Wellcome Trust
Settings: [Edit Settings](#)
Data loaded for this request only
Data package downloadable
Data to be loaded after approval

Below the studies, there are sections for "VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS" and "STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI", both showing "No Studies Found".

To make the changes, click on “Edit Settings”.

The following pop-up will display over the page:

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

Advanced settings for the study NCT03085810 in this data request only

This study currently has a stored data package. If you would like to use that stored package for this request, uncheck the option “Data loaded for this request only”.

☒ Data loaded for this request only

OK Cancel

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

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ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS SALLY

< Go Back Request: 3469, Pt: Sarah Jones Status: Data Contributor Review

X Cannot Fulfill X Request Revision Process Request Print

Studies

REQUESTED STUDIES

VIVLI-LISTED AND PROVISIONED STUDIES

A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter Monotherapy Study to Determine the Efficacy and Safety of 2 Dose Levels of Abiglutide in Subjec...
Study ID: NCT01733759 Sponsor ID: 113121
Data Request ID: 00003469
Data Contributor: GlaxoSmithKline IRP/Approver: Wellcome Trust
Settings: Edit Settings
Data will be loaded for this and future requests
Data available in secure research environment only
Data to be loaded after approval

A double-blind, stratified, randomized, placebo controlled study of Ro 64-0796 (also known as GS4104) in the treatment of influenza in chronically ill adults
Study ID: WV15872 Sponsor ID: WV15872
Data Request ID: 00003469
Data Contributor: Roche IRP/Approver: Wellcome Trust
Settings: Edit Settings
Data loaded for this request only
Data package downloadable
Data to be loaded after approval

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

No Studies Found

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI

No Studies Found

3.4 Recording a Decision about a Data Request

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

The screenshot shows the Vivli Data Contributor Review page for Request 3469, PI: Sarah Jones. The page title is "Research Data Request: Predicting Treatment Response to combination drugs in patients with type 2 diabetes" with Vivli ID: 00003469. In the top right corner, there are three buttons: "X Cannot Fulfill" (red), "X Request Revision" (yellow), and "✓ Process Request" (green), all of which are highlighted with a red box. Below these buttons is a "Print" button. The left sidebar contains links for "Studies", "Status Update", "Attachments", "Request History", "Signed Agreements", "Chat", and "Request Details/Print View". The main content area includes "Comments from the Vivli Team" and "Research Team" information for Lead Investigator Sarah Jones, including her contact details, education, and conflicts of interest.

The data request decision options are:

Three buttons are shown: "X Cannot Fulfill" (red), "X Request Revision" (yellow), and "✓ Process Request" (green).

3.4.1 Cannot Fulfill

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

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

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

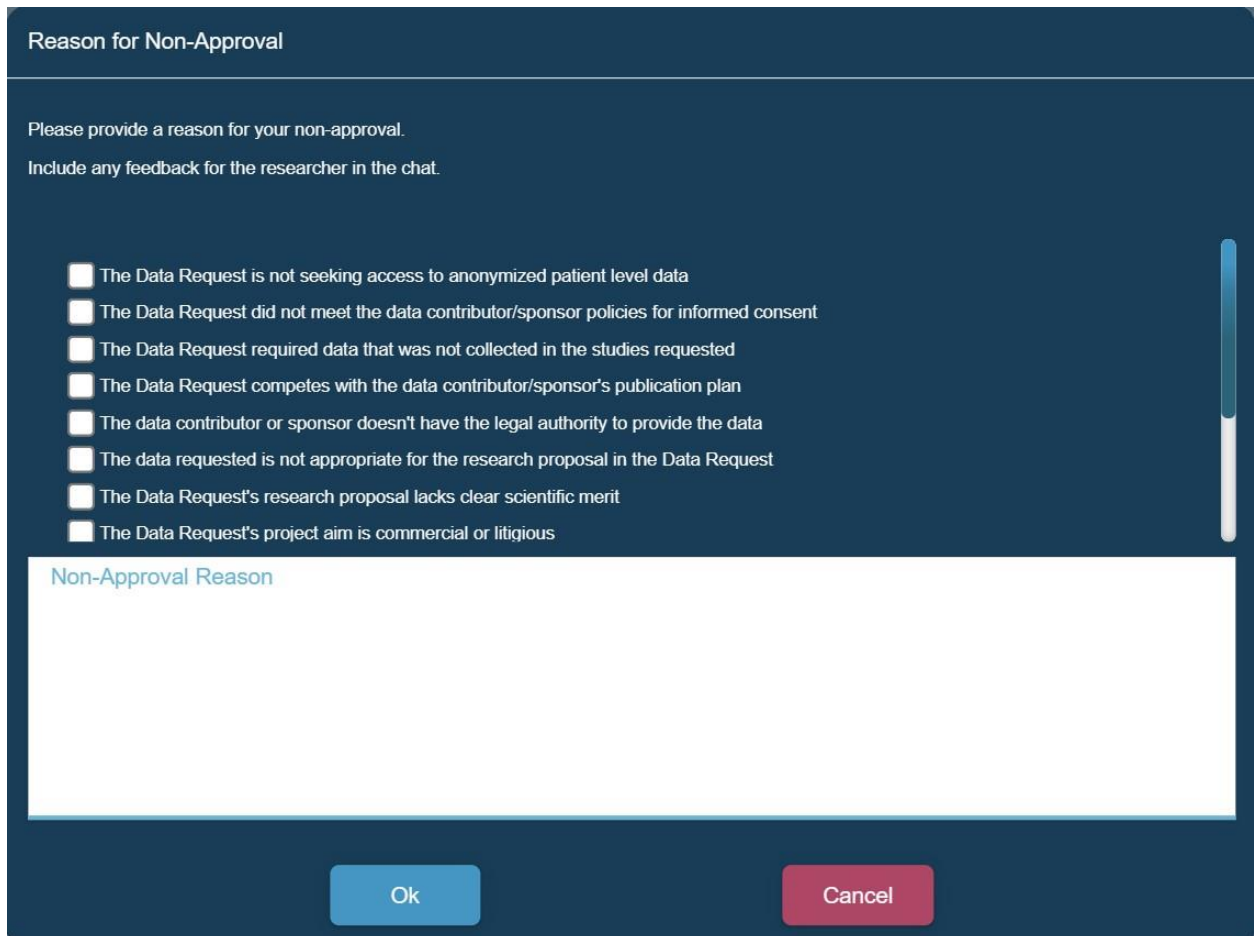
Examples: this policy is out of scope of our data sharing policy as the trial is still ongoing or this study is out of scope due to ongoing litigation.

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

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



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



Reason for Non-Approval

Please provide a reason for your non-approval.
Include any feedback for the researcher in the chat.

- ☐ The Data Request is not seeking access to anonymized patient 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

Non-Approval Reason

Ok Cancel

Reasons for Non-Approval include:

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

- The Data Request competes with the data contributor/sponsor's publication plan
 - The data contributor or sponsor doesn't have the legal authority to provide the data
 - The data requested is not appropriate for the research proposal in the Data Request
 - The Data Request's research proposal lacks clear scientific merit
 - The Data Request's project aim is commercial or litigious
 - The Data Request is Out of Scope
 - The data requested is unavailable
 - The data requested cannot be shared due to ongoing regulatory activities
 - The data requested was not collected in English
3. To describe any other reason for non-approval, check “other reason for non-approval” and use the comment box. (Please note this reason for non-approval will need to appear on your member’s page).
 4. Enter the reason(s) and press **Ok**. This will send an automated email to the Data Requestor and Vivli Administrator informing them of the decision.
 5. This Data Request will now be categorized as “Not Approved” in the Data Request status bar and Data Requestor may see your comments regarding the revision in the request history section.
 6. Your decision will be recorded in the Request history of the Data Request.
 7. For multi-sponsor requests, if your organization has recorded its decision but another organization has not, the request will remain in the Data Contributor review stage under the **Active** status bar. Vivli team will follow up with the other appropriate member to record their decision. Once all the decisions are recorded, the Researcher may remove the denied studies and move forward with the rest of the studies from other members.

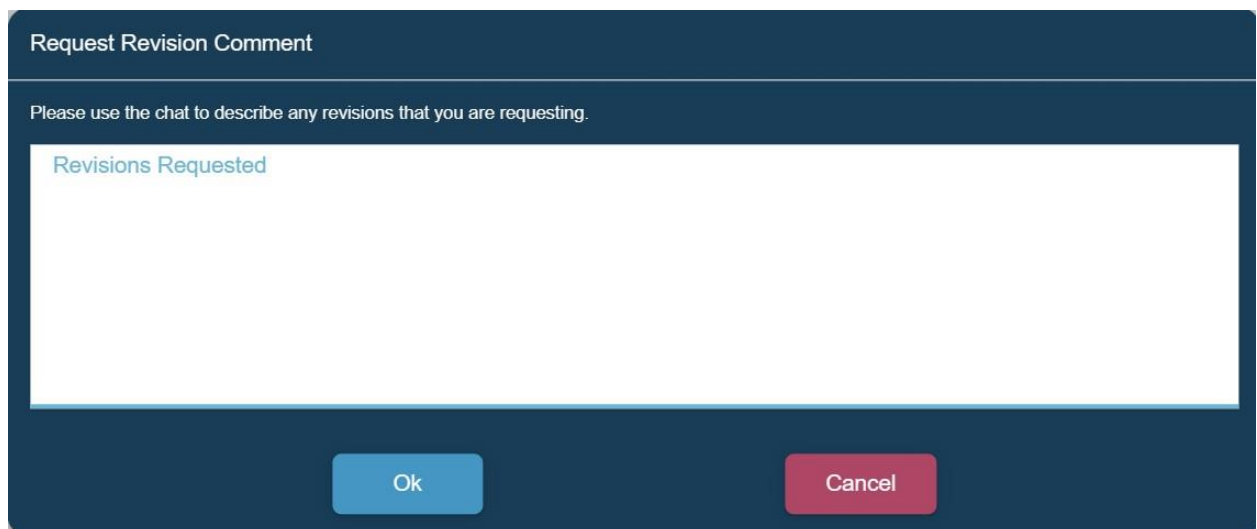
3.4.2 Request Revision

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

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



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



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

- Once the Data Requester has revised and re-submitted their request, Vivli Admin will summarize the changes and post their comments during the Vivli form check stage.
- 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.

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ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS SALLY

Request: 3469, PI: Sarah Jones
Status: Data Contributor Review

X Cannot Fulfill X Request Revision ✓ Process Request Print

Studies

Research Data Request: Predicting Treatment Response to combination drugs in patients with type 2 diabetes
Vivli ID: 00003469

Comments from the Vivli Team

In the last round of review, Vivli Member 1 requested revisions. As a result, PI added an additional study. For detailed information on the changes made, please see attachment "2023_09_20 Vivli ID 00003469_form check comparison report" in chat. Any changes to studies are considered a major revision and therefore data contributors are provided with the opportunity to review the proposal with these revisions.

Research Team

Lead Investigator

Sarah Jones
S.Jones@ucsf.edu
Professor
University of California, San Francisco
ORCID ID: 0000-0002-1045-8336Country: United States of America

Education or Qualifications

MD, PhD in Biostatistics

Conflicts of Interest and Plan for Management

None

Statistician Researcher

Request Details/Print View

- 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

Home Tools [Compare Report]...

Compare Files Side-by-Side Old File New File Previous Change Next Change Filter Show

1/20/2021 Vivli

Research Data Request: Anti-TNF Monoclonal Antibody D2E7 in Patients with Active Rheumatoid Arthritis
Vivli ID: 00002116

Comments from the Vivli Team

PI has updated the Statistical Analysis Plan once last review.
No additional changes were made to the request.

Research Team

Lead Investigator and Statistician

Emily Grant
emiligrant@chd.org
Biostatistician
Boston Children's Hospital

Education or Qualifications

Mathematics, BS - University of New Hampshire (2000)
Statistics, MSc - New York University (2004)
Epidemiology and Biostatistics, Berkeley (2012)

Conflicts of Interest and Plan for Management

NA

Additional Researchers

Research Proposal

General

Title of Proposed Research
Anti-TNF Monoclonal Antibody D2E7 in Patients with Active Rheumatoid Arthritis

Narrative summary explaining the relevance of the project to science and public health

The present study is part of the Research Program of the Monoclonal Antibody D2E7 in Rheumatoid Arthritis (D2E7-RA) trial, which is a phase II, randomized, double-blind, placebo-controlled study of D2E7 in patients with active RA who were previously treated with TNF inhibitors. The study aims to evaluate the efficacy and safety of D2E7 in patients with active RA who were previously treated with TNF inhibitors. The study is a phase II, randomized, double-blind, placebo-controlled study of D2E7 in patients with active RA who were previously treated with TNF inhibitors. The study aims to evaluate the efficacy and safety of D2E7 in patients with active RA who were previously treated with TNF inhibitors.

Aims/Objectives and Hypotheses

Over the last decade, methotrexate (MTX) has become the treatment of choice for rheumatoid arthritis (RA) (1, 2), providing initial improvement within weeks (3) and sustained benefits generally by 6 months (4). However, many patients continue to have some degree of disease activity despite receiving therapeutic doses of MTX. Even when they respond fully to MTX therapy, patients experience less than 50% improvement (5). To enhance the clinical response, MTX is frequently combined with one or more other traditional disease-modifying antirheumatic drugs (DMARDs) (5, 6).

Purpose of Analysis

Training/Testing

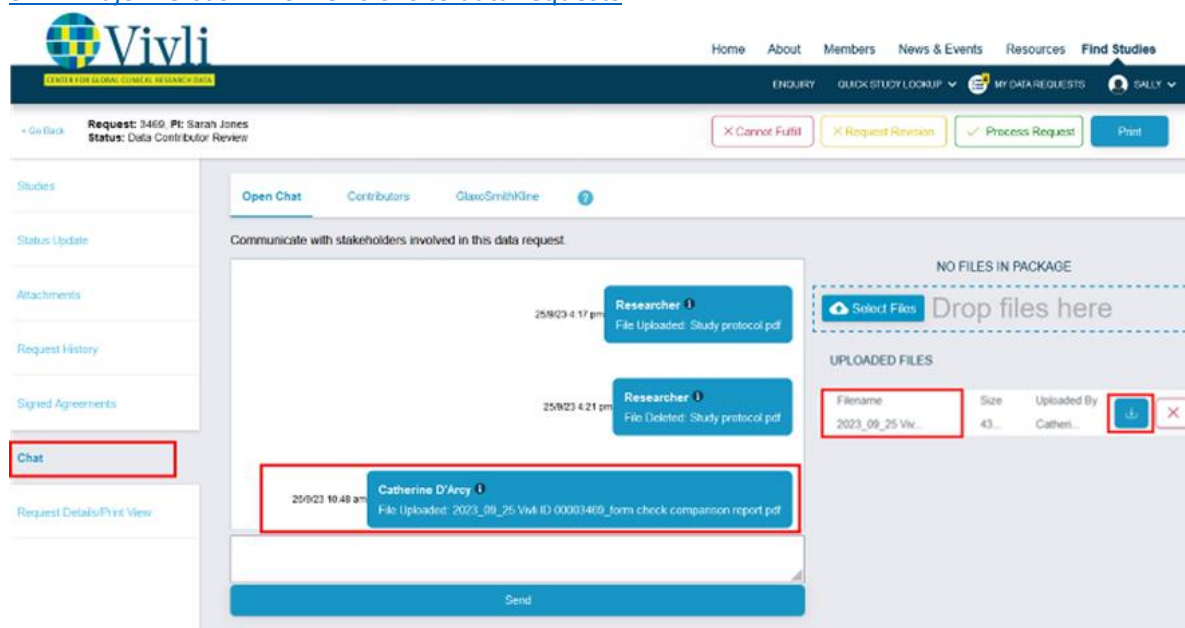
Study Design

Brief Description

Eligible patients were 18 years of age or older and had RA that was diagnosed according to the 1987 revised criteria of the American College of Rheumatology (ACR) (7). The American Rheumatism Association (17).

[Old File] 2021_01_25 Vivli ID 00002116 DRF (1).pdf [New File] 2021_01_25 Vivli ID 00002116 DRF (2).pdf

3.4.4 Major versus minor revisions to data requests.



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

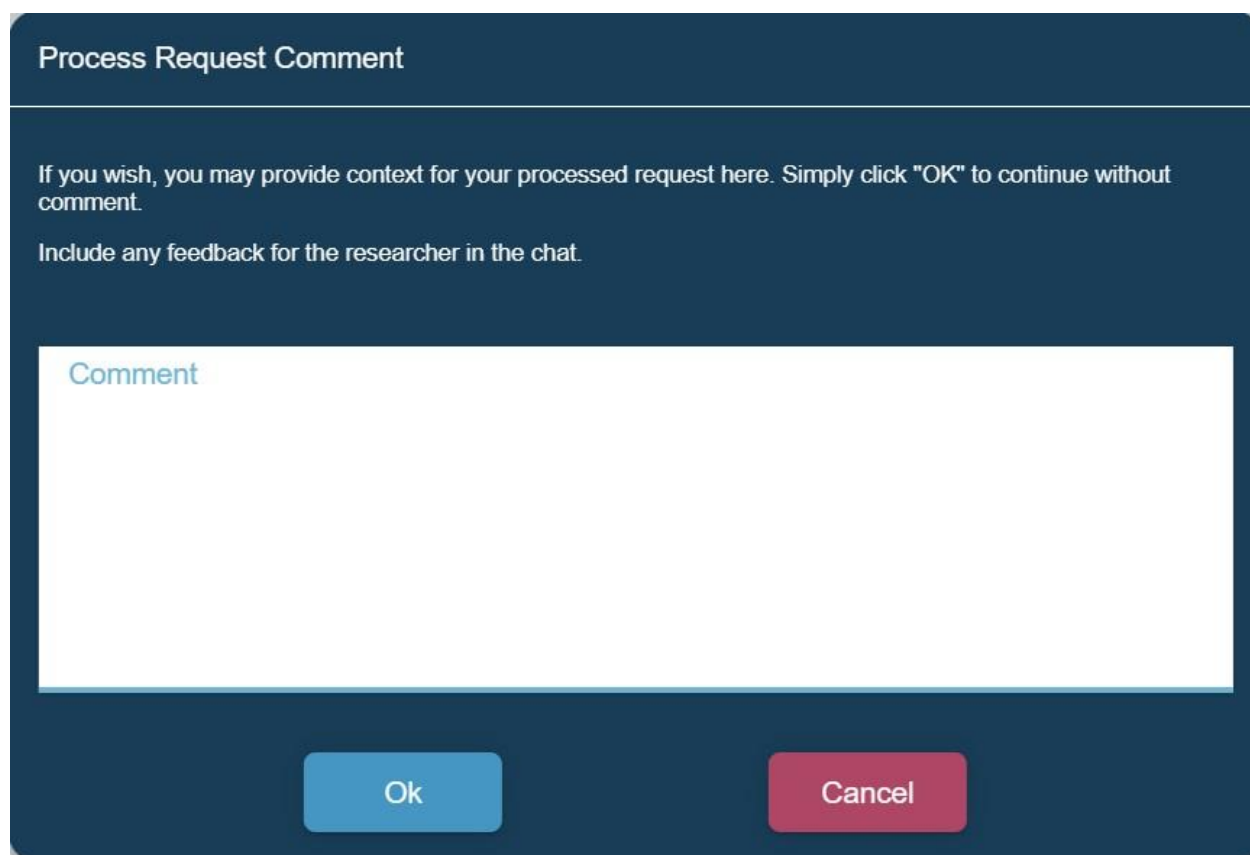
3.4.3 Process Request

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

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



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



The image shows a dark blue dialog box titled "Process Request Comment". Inside, there is a light blue header bar with the title. Below the header, there is a text area with a light blue border. The text area contains the following text: "If you wish, you may provide context for your processed request here. Simply click 'OK' to continue without comment." and "Include any feedback for the researcher in the chat." Below the text area, there are two buttons: a blue "Ok" button and a red "Cancel" button.

Process Request Comment

If you wish, you may provide context for your processed request here. Simply click "OK" to continue without comment.

Include any feedback for the researcher in the chat.

Comment

Ok Cancel

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

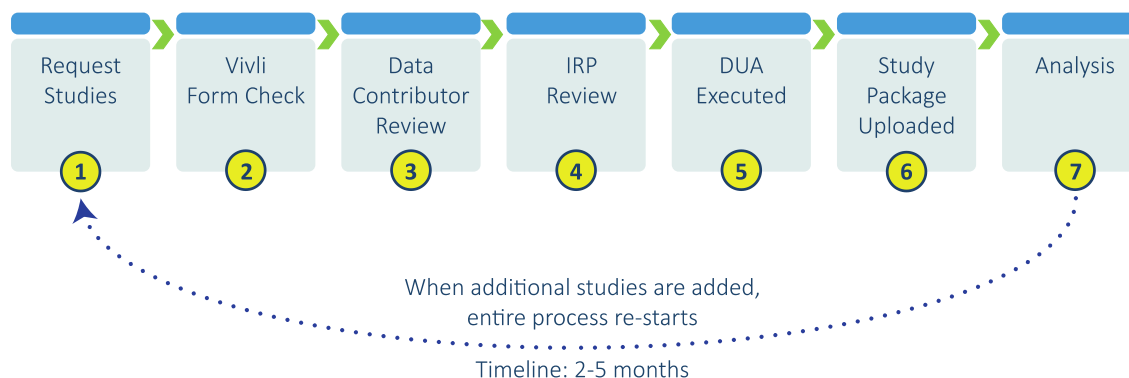
3.4.4 Major versus minor revisions to data requests

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

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

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

Adding Additional Studies once your Data Request is in the Analysis Stage



3.4.5 Withdrawal process

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

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

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

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

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

3.4.6 Target timeline for the review process

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

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

3.4.7 Summary level and document only data request

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

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

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

- 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 X	Standard DUA with Downloadable Rider	Documents and summary-level data Downloaded
------------------	-------------------------	-----------------	--------------------------------------	---

3.5 Report of data requests

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

The screenshot shows the Vivli dashboard interface. On the left sidebar, the 'Report' tab is highlighted with a red box. In the top right corner, a user profile dropdown menu is open, with the 'Report' option highlighted by a red box. The main content area displays a table titled 'Report' with the following columns: Vivli Id, Lead Researcher, Data Contributors, Number of My Organization's Studies, Total Studies Requested, Current Status, Active, and Actions. The table contains four rows of data requests.


Vivli Id	Lead Researcher	Data Contributors	Number of My Organization's Studies	Total Studies Requested	Current Status	Active	Actions
3469	Sarah Jones	<ul style="list-style-type: none"> GlaxoSmithKline Roche 	1	2	Data Contributor Review	true	Member1 - feasibility c
48058	Iiz test	<ul style="list-style-type: none"> Takeda Test GSK 	1	2	Denied	true	
2704	Nick Jones	<ul style="list-style-type: none"> AbbVie Roche Novelion Therapeutics Pfizer Inc. 	1	4	Draft	true	
48053	Amrutha Baskaran	<ul style="list-style-type: none"> AbbVie GlaxoSmithKline 	3	6	Awaiting IRP/Reviewer Approval	true	

There are four types of reports:

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

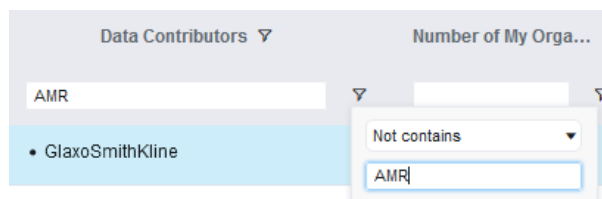
The default report shown on opening the Reports tab is the Standard Display.

3.5.1. Features of the report

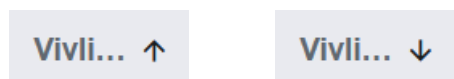
Download icon allows you to download what is currently displayed (and filtered) 

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

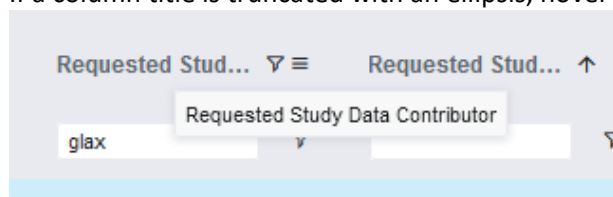
When you see a funnel next to the white field, you can use that to specify a different type of filter, such as Not Contains. Contains, Equals, Not equal, Starts with and Ends with.



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



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



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

3.5.2. Fields included in the report

1. Standard Display, 1 Data Request per row, includes the following fields:
 - Vivli ID
 - Lead Researcher
 - Data Contributors (comma-separated list)
 - Number of My Organization's Studies – Number of studies from your organization included in the request.
 - Total Studies Requested – Number of studies from all data contributors included in the request.
 - Current Status – Draft, Vivli Form check, Form check failed, Data Contributor Review, Awaiting IRP/Reviewer Approval, DUA Validation, Awaiting Data Package Upload, Partially Fulfilled, Fulfilled, Denied, Cancelled, and Archived
 - Active (True or False) - Includes data requests from the time it is submitted for form check until the final publication is published. Excludes all draft requests.
 - Actions Required – Action required by all the data contributors at a particular stage as set by the Vivli admin. This complements the decisions and uploads required field.
 - Decisions and Uploads Required – This is automatically set by the Vivli platform and will always be up to the minute
 - Days in Current Workflow Step – Number of days the request in the particular step. It is computed automatically, in real-time. If it is greater than the Target Days for Current Workflow

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

- Target Days for Current Workflow Step – 21 days for Data Contributor review, 30 days for IRP review, 30 days for Data Upload and 30 days for Publication review
 - Feedback – For Data Contributor to provide any comments in response to weekly summary comments. For more information, please see section [3.5.3. Status Update](#)
 - Request Review Status – shows Form check, Data Contributor review, and IRP review decision
 - DUA Status – Pending DUA, DUA execution, DUA extension, and DUA closure
 - Data Upload Status – Updates on data upload status
 - Results Export Requests – Includes Date and whether approved
 - Publication Status – Includes courtesy review, public disclosure acceptance, published disclosures, and summary of results.
 - Additional Notes – Revision of previous Vivli ID#, transition request #, and Pending chat question or other pending issues.
 - Date Submitted to Data Contributor –The date when the request was first submitted to the Data Contributor review.
 - Date of Last Change –Records any change, including updates you or the Vivli admin make to the status update.
2. Standard Export, 1 Data Request per row includes the fields above and includes the following additional fields:
- Title – Request title
 - Lead Researcher Affiliation
 - Lead Researcher Title
 - Lead Researcher Email
 - Date First Published
 - Main Predictor/Independent Variable
 - Publication Plan
 - Brief Description
 - Aims, Objectives, Hypotheses
 - Purpose of Analysis
 - Therapeutic Area
 - All Studies Included by Sponsor ID/NCT ID
3. Full Export, 1 Requested Study per Row, repeats the standard export row once for each requested study. This is to support the analysis of the requested studies. It includes studies provided by all contributors. It includes the fields above except “All Studies Included by Sponsor ID/NCT ID” and includes the following additional fields:
- Requested Study Data Contributor – Name of a data contributor. To see studies from your organization, filter by “Requested Study Data Contributor”

- Requested Study NCT ID
- Requested Study Sponsor ID

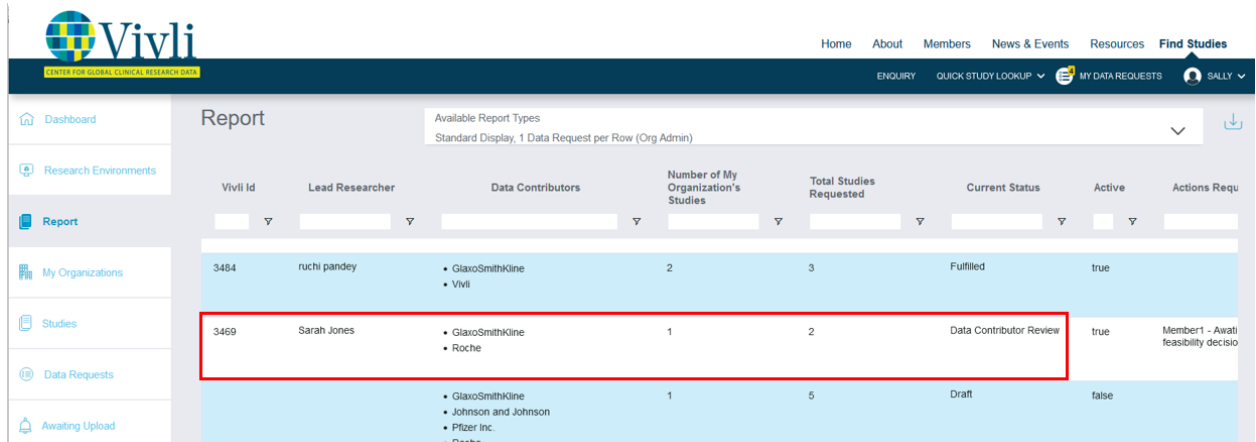
Tip: If you use the expanded report, and filter on a study ID or NCT ID, you can quickly see what requests include that study and their status.

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

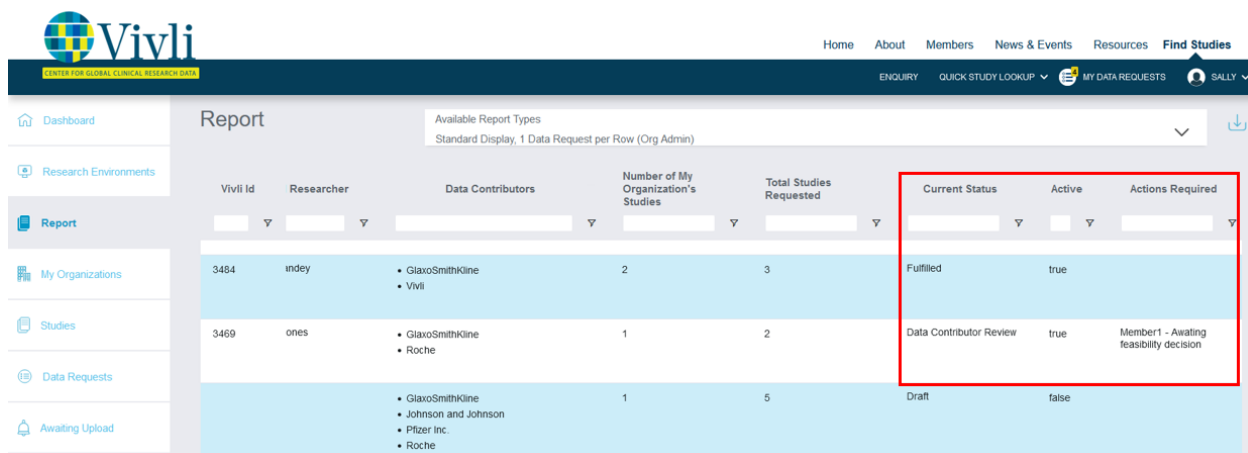
- NCT Id
- Sponsor Protocol Id
- Posted Date
- Submitted Date
- Org Name
- Study Title
- Ror Names
- Parent Ror Names
- Citation Count
- Study Metadata Doi
- Is Data Uploaded
- Conditions
- Interventions
- Data Requests Count

3.5.3. Status Update

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

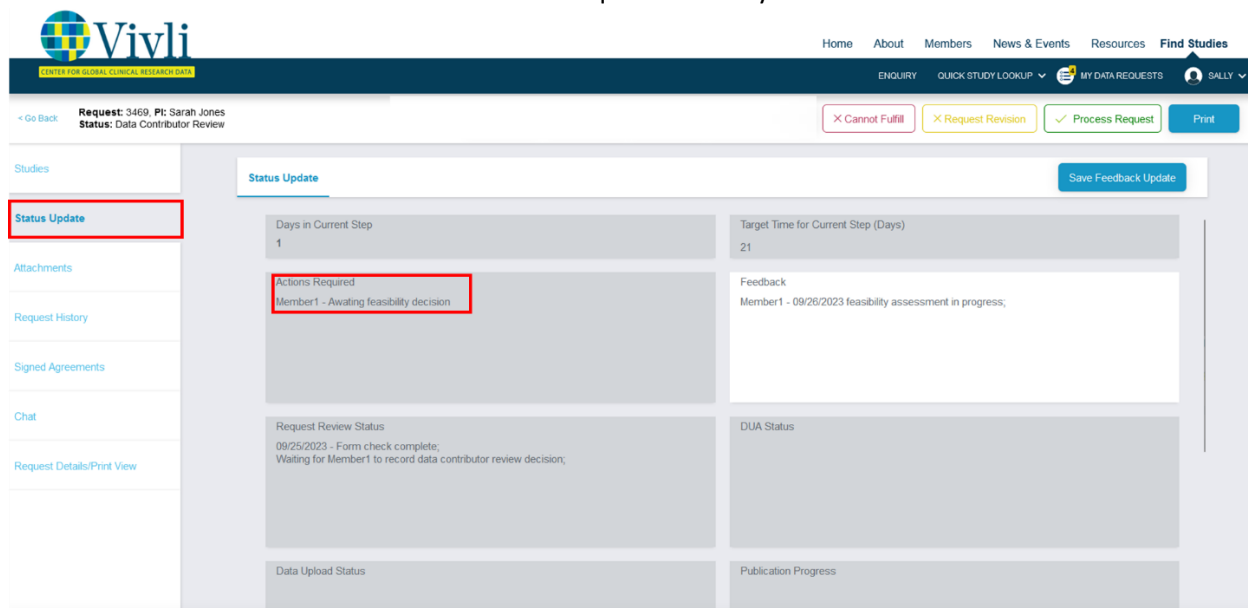


Vivli Id	Lead Researcher	Data Contributors	Number of My Organization's Studies	Total Studies Requested	Current Status	Active	Actions Required
3484	ruchi pandey	GlaxoSmithKline Vivli	2	3	Fulfilled	true	
3469	Sarah Jones	GlaxoSmithKline Roche	1	2	Data Contributor Review	true	Member1 - Await feasibility decision
		GlaxoSmithKline Johnson and Johnson Pfizer Inc. Roche	1	5	Draft	false	



Vivli Id	Researcher	Data Contributors	Number of My Organization's Studies	Total Studies Requested	Current Status	Active	Actions Required
3484	indey	<ul style="list-style-type: none"> GlaxoSmithKline Vivli 	2	3	Fulfilled	true	
3469	ones	<ul style="list-style-type: none"> GlaxoSmithKline Roche 	1	2	Data Contributor Review	true	Member1 - Awaiting feasibility decision
		<ul style="list-style-type: none"> GlaxoSmithKline Johnson and Johnson Pfizer Inc. Roche 	1	5	Draft	false	

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



Request: 3469, PI: Sarah Jones
Status: Data Contributor Review

Buttons: Cannot Fulfill Request Revision Process Request Print

Status Update

Days in Current Step: 1

Target Time for Current Step (Days): 21

Actions Required
Member1 - Awaiting feasibility decision

Feedback
Member1 - 09/26/2023 feasibility assessment in progress;

Request Review Status
09/25/2023 - Form check complete;
Waiting for Member1 to record data contributor review decision;

DUA Status

Data Upload Status

Publication Progress

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

The screenshot shows the 'Status Update' form in the Vivli system. The left sidebar contains links: Studies, Status Update (highlighted), Attachments, Request History, Signed Agreements, Chat, and Request Details/Print View. The main content area has a 'Status Update' tab. At the top, there's a header with 'Request: 3469, PI: Sarah Jones' and 'Status: Data Contributor Review'. Action buttons include 'Cannot Fulfill', 'Request Revision', 'Process Request', and 'Print'. The form fields are arranged in a grid: 'Days in Current Step' (1), 'Target Time for Current Step (Days)' (21), 'Actions Required' (Member1 - Awaiting feasibility decision), 'Feedback' (Member1 - 09/26/2023 feasibility assessment in progress; - highlighted in white), 'Request Review Status' (09/25/2023 - Form check complete; Waiting for Member1 to record data contributor review decision;), 'DUA Status', 'Data Upload Status', and 'Publication Progress'.

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

This screenshot is identical to the previous one, showing the 'Status Update' form. The 'Save Feedback Update' button at the top right is now highlighted with a red box, indicating the next step in the process.

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

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

3.6 Data Use Agreement (DUA)

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

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this, there's a header for the current request: "Request: 2553, PI: Sarah Jones" and "Status: At least one Data Package Provided and Available". A sidebar on the left contains links for Studies, Attachments, Request History, Signed Agreements (highlighted with a red box), Safety Concerns, Chat, Research Environment, and Request Details/Print View. The main content area displays a message: "The Data Usage Agreement (DUA) has been signed and is available for download below. If more than one DUA version was uploaded, the latest is the signed and validated version." Below this message is a table titled "UPLOADED FILES".

Filename	Date	Size	Uploaded By	Download
2021_10_05 Vivli ID 00002553_DUA exe...	10-5-21 5:38 pm	674.00kB	Amrutha Baskara...	Download

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

The screenshot shows the Vivli web application interface, specifically the "Request History" tab. The top navigation bar and header are the same as in the previous screenshot. The sidebar on the left has "Request History" highlighted with a red box. The main content area displays a list of status changes for the request. The last entry in the list is highlighted with a red box.

Date	Status Change	By	Action
10/5/21 5:36 pm	Status changed to Data Request: "Predicting Treatment Response to combination drugs in patients with type 2 Diabetes" with Id 31e30c7e-421c-493b-b130-4961d1d9c470, approved by Data Contributor Approver.	Sally dataprovider.vivli@gmail.com	
10/5/21 5:36 pm	Status changed to Awaiting IRP/Approver Approval. The last Data Contributor pre-check was the final Data Contributor pre-check required, so the request status is changed to Awaiting IRP/Approver Approval.		
10/5/21 5:38 pm	Status changed to Data Request: "Predicting Treatment Response to combination drugs in patients with type 2 Diabetes" with Id 31e30c7e-421c-493b-b130-4961d1d9c470, approved by IRP/Approver.	Amrutha Baskaran abaskaran@vivli.org	
10/5/21 5:38 pm	Status changed to Approved The last Approval was the final Approval required, so the request status is changed to Approved.		
10/5/21 5:39 pm	Status changed to Awaiting DUA Validation	Amrutha Baskaran abaskaran@vivli.org	Begin DUA Validation
10/5/21 5:39 pm	Status changed to Data Use Agreement (DUA) Validated by Vivli Admin	Amrutha Baskaran abaskaran@vivli.org	

4. Uploading data packages

Data Packages for the listed studies can be provided:

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

4.1 Vivli Dashboard for Data Contributors

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

The screenshot shows the Vivli dashboard interface. At the top is the Vivli logo and navigation links: Home, About, Members, News & Events, Resources, Find Studies. Below this is a dark blue header with 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and a user profile for 'SALLY'. The main content area is divided into three columns. The left column contains a sidebar with 'Dashboard' (highlighted with a red box), 'Research Environments', 'Studies', 'Data Requests', and 'Awaiting Upload'. The middle column displays a welcome message 'Welcome, Sally!' and a summary of organizational memberships and roles. The right column shows a table of organizational memberships. At the bottom, there is a section for 'Data Requests Awaiting My Approval' with a specific study example.

Organization	Roles
Vivli Member	• Data Contributor

Data Requests Awaiting My Approval

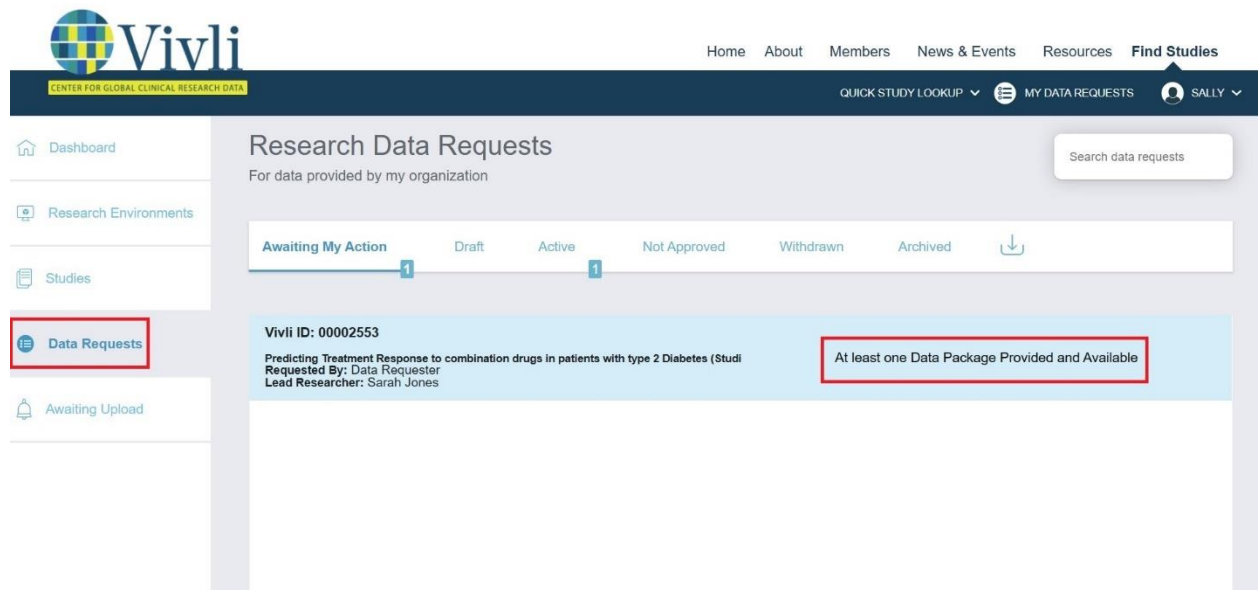
Vivli ID: 00002553

Predicting Treatment Response to combination drugs in patients with type 2 Diabetes (Stuc
Requested By: Data Requester
Lead Researcher: Sarah Jones

At least one Data Package Provided and Available

4.2 Data Upload Notification

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



4.3 General upload guidelines

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

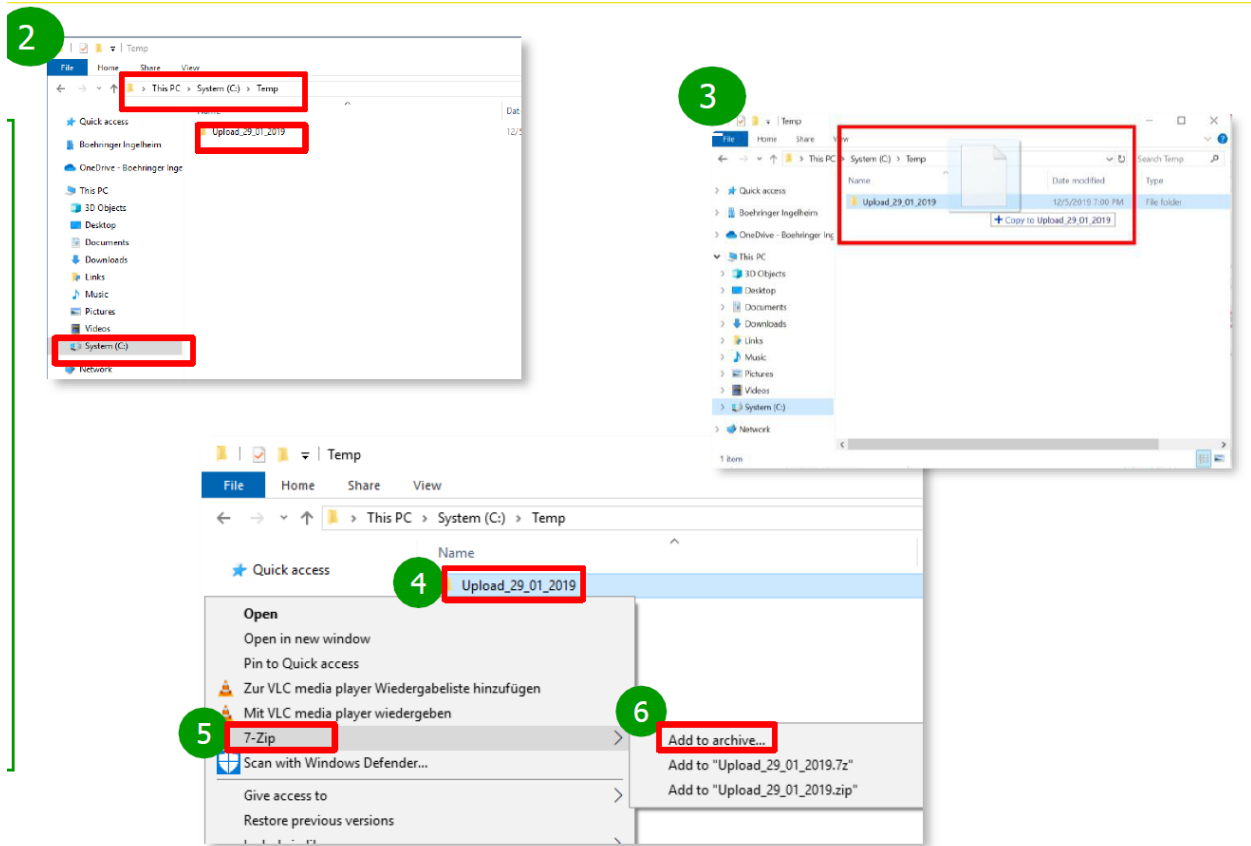
- Once you start the upload, leave the computer running and the browser open. The progress of the upload is shown in the button to the right of the "card" that is created for the file.
- Other upload tips:
 - If it is practical, uploading is faster in the evening or overnight, as you are competing with less traffic on the internet.
 - Before starting the upload, it can be useful to reboot your computer - this can free up some memory and reset some elements of the operating system.
- After uploading study data and then clicking Submit Files, if you refresh the browser very quickly, the system may still be in the process of finalizing the storage.
 - In this case, it may display "Make Data Available"; if you see this after submitting files, give the system a minute or so to complete and refresh the browser again.
 - If Make Data Available does not clear after a minute or so, this generally indicates a problem occurred -reach out to Vivli and we'll be able to reset things.
- If a network hiccup happens during the upload and the system displays "Upload Failed" for a given file, we recommend you tell the Vivli system to delete the file, close the data request, and re-open it before trying again.

4.3.1 Zip archive process

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

Create a zip archive to store the confidential files in.

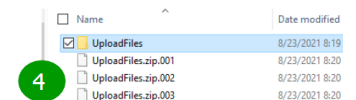
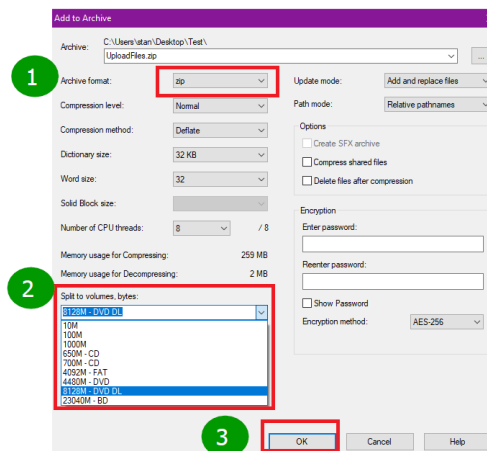
- 1 **Download 7-zip**
(<https://www.7-zip.org/download.html>)
- 2 **Create a new folder** on your local machine.
- 3 **Add the files to be provided** into the folder. You can do this for example by Drag&Drop.
- 4 To create a zip archive right click on the folder.
- 5 In the dropdown menu select **7-Zip**.
- 6 Click on **Add to Archive**.



- Choose the format and volume sizes

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

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



4.4 Loading Data package

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



4.4.1 Steps: Uploading Data Package to an approved request

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

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

Dashboard

If you have any questions, please contact Vivli Support.

Thanks!

Awaiting My Action Metrics

Data Requests Awaiting My Approval

Vivli ID: 00002553

Predicting Treatment Response to combination drugs in patients with type 2 Diabetes (Studies: 2)
Requested By: Data Requester
Lead Researcher: Sarah Jones

At least one Data Package Provided and Available

Studies Awaiting Data Package Upload

A Randomised, Double-blind, Parallel Group Phase III Study to Assess the Clinical...
PI: Sponsor: Vivli Member Study ID: NCT03085797 IRP/Approver: IRP Organization Data Request ID: 00002553 Sponsor ID: 205687
Data Contributor: Vivli Member IPD Uploaded: No

Upload Data Package

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

Vivli

Home About Members News & Events Resources Find Studies

QUICK STUDY LOOKUP MY DATA REQUESTS SALLY

Awaiting Upload

A Randomised, Double-blind, Parallel Group Phase III Study to Assess the Clinical...
PI: Sponsor: Vivli Member Study ID: NCT03085797 IRP/Approver: IRP Organization Data Request ID: 00002553 Sponsor ID: 205687
Data Contributor: Vivli Member IPD Uploaded: No

Upload Data Package

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

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

QUICK STUDY LOOKUP MY DATA REQUESTS SALLY

Dashboard
Research Environments
Studies
Data Requests
Awaiting Upload

Research Data Requests

For data provided by my organization

Search data requests

Awaiting My Action Draft Active Not Approved Withdrawn Archived

Vivli ID: 00002553
Predicting Treatment Response to combination drugs in patients with type 2 Diabetes (Study)
Requested By: Data Requester
Lead Researcher: Sarah Jones

At least one Data Package Provided and Available

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

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

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

QUICK STUDY LOOKUP MY DATA REQUESTS SALLY

< Go Back Request: 2553, PI: Sarah Jones
Status: At least one Data Package Provided and Available Print

Studies
Attachments
Request History
Signed Agreements
Safety Concerns
Chat
Research Environment
Request Details/Print View

REQUESTED STUDY TYPES

VIVLI-LISTED AND PROVISIONED STUDIES

A Multicenter, Placebo-Controlled, Parallel-Design, Dose-Response Evaluation ...
PI: Sponsor: Vivli Member Study ID: P42-05 IRP/Approver: IRP Organization Data Request ID: 00002553
Sponsor ID: P42-05
Data Contributor: Vivli Member IPD Uploaded: No Data Package Provided to Requestor

A Randomised, Double-blind, Parallel Group PhIII Study to Assess the Clinical ...
PI: Sponsor: Vivli Member Study ID: NCT03085797 IRP/Approver: IRP Organization
Data Request ID: 00002553 Sponsor ID: 205687
Data Contributor: Vivli Member IPD Uploaded: No Upload Data Package

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

No Studies Found

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI

No Studies Found

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

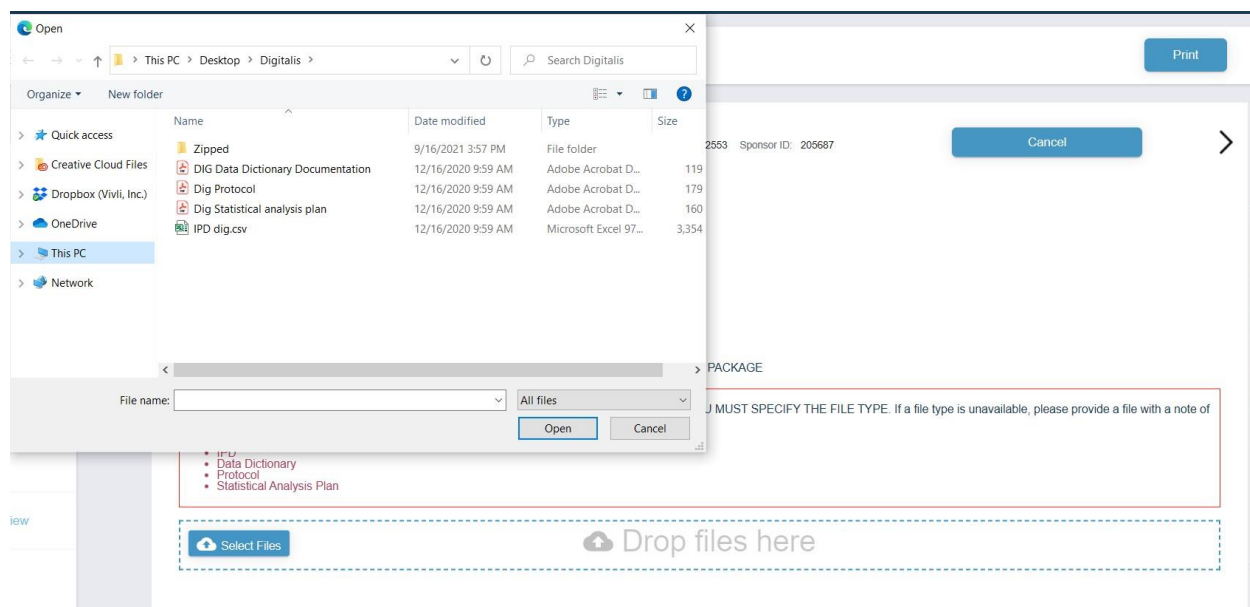
The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. The user is logged in as SALLY. The main content area displays the 'REQUESTED STUDY TYPES' and 'VIVLI-LISTED AND PROVISIONED STUDIES' sections. The 'Studies' sidebar on the left is highlighted with a red box. The 'Upload Data Package' button in the 'VIVLI-LISTED AND PROVISIONED STUDIES' section is also highlighted with a red box.

4) The following window will appear:

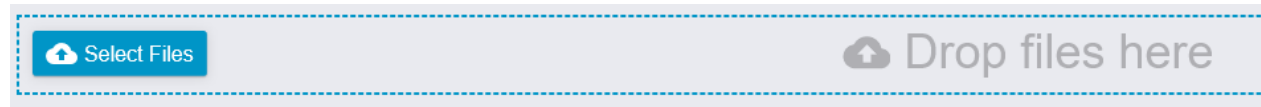
The screenshot shows the 'Upload study Data Package' window in the Vivli web application. The window displays the study details and the required file types for the data package. The 'Select Files' button is highlighted with a red box. The window also includes a 'Drop files here' area and a 'Cancel' button.

5) Now click on **Select Files** to choose files to upload.

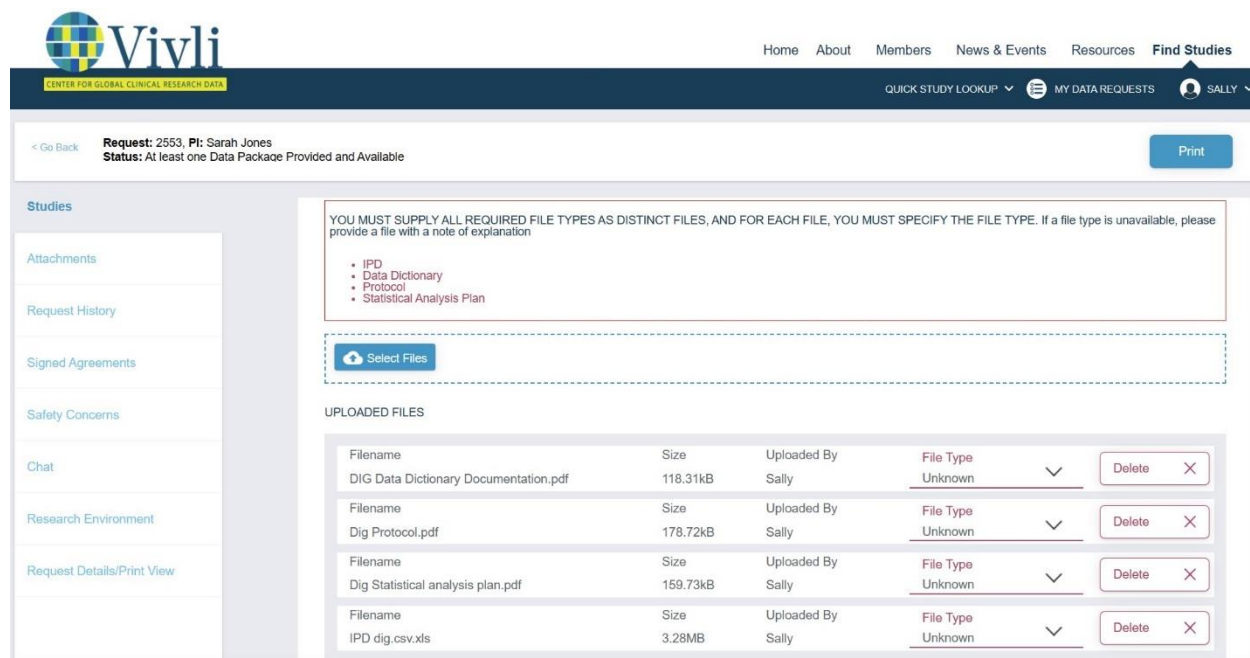
6) A window will pop up allowing the data contributor to select the files of their computer:



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



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



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

The screenshot shows the Vivli Data Contributor interface. At the top, there's a navigation bar with links like ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and DATA REQUESTER. Below this, a sidebar on the left contains a list of steps: 1. Information About Your Team, 2. Your Organization, 3. Your Study, 4. Data Sharing Settings, 5. Agreements, 6. Upload Data, History, and Chat. The main area is titled 'A Randomized Controlled Adaptive Study Comparing COVID-19 Convalescent Plasma (CCP) to Non-immune Plasma to Limit Coronavirus-associated Complications in Hospitalized P...'. It shows a status of 'Approved' and a message about uploading study data packages. A 'Select Files' button is visible. Below this, a table lists 'UPLOADED FILES' with columns for Filename, Size, and File Type. A dropdown menu is open, showing a list of file types: Unknown, IPD, Data Dictionary, Protocol, Statistical Analysis Plan, Analysis-Ready Dataset, CSR (may be redacted), Analysis-ready Dataset, Annotated Case Report Form, and Other. The dropdown is highlighted with a red box. The table shows files like 'DIG Data Dictionary Documentation.pdf', 'Dig Protocol.pdf', 'Dig Statistical analysis plan.pdf', and 'IPD dig.csv.xls'.

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

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

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

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

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

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

The screenshot shows the 'Upload Data' section of the Vivli Data Contributor interface. The main content area displays a table of uploaded files with columns for Filename, Size, Uploaded By, and File Type. A 'Verify Upload' button is highlighted in the top right corner. A pop-up message at the bottom right states: 'All data has been successfully uploaded and stored in the system.' The interface also includes a sidebar with navigation links and a footer with copyright information.

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

- 19) If you plan to upload data packages for multiple studies in the data request, click Submit files for one study, refresh the screen and then click Submit files for the next study.
- 20) When finished, click **Submit Files** to load the data package into the Vivli Platform.

The screenshot shows the Vivli Data Contributor interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. The user is logged in as Sally. The main content area displays a request for study data with a status of 'At least one Data Package Provided and Available'. A sidebar on the left contains links for Studies, Attachments, Request History, Signed Agreements, Safety Concerns, Chat, Research Environment, and Request Details/Print View. The main area shows a list of uploaded files with columns for Filename, Size, Uploaded By, File Type, and a Delete button. The 'Submit Files' button at the bottom is highlighted with a red border.

Filename	Size	Uploaded By	File Type	Delete
DIG Data Dictionary Documentation.pdf	118.31kB	Sally	Data Dictio...	Delete
Dig Protocol.pdf	178.72kB	Sally	File Type Protocol	Delete
Dig Statistical analysis plan.pdf	159.73kB	Sally	File Type Statistical...	Delete
IPD dig.csv.xls	3.28MB	Sally	File Type IPD	Delete

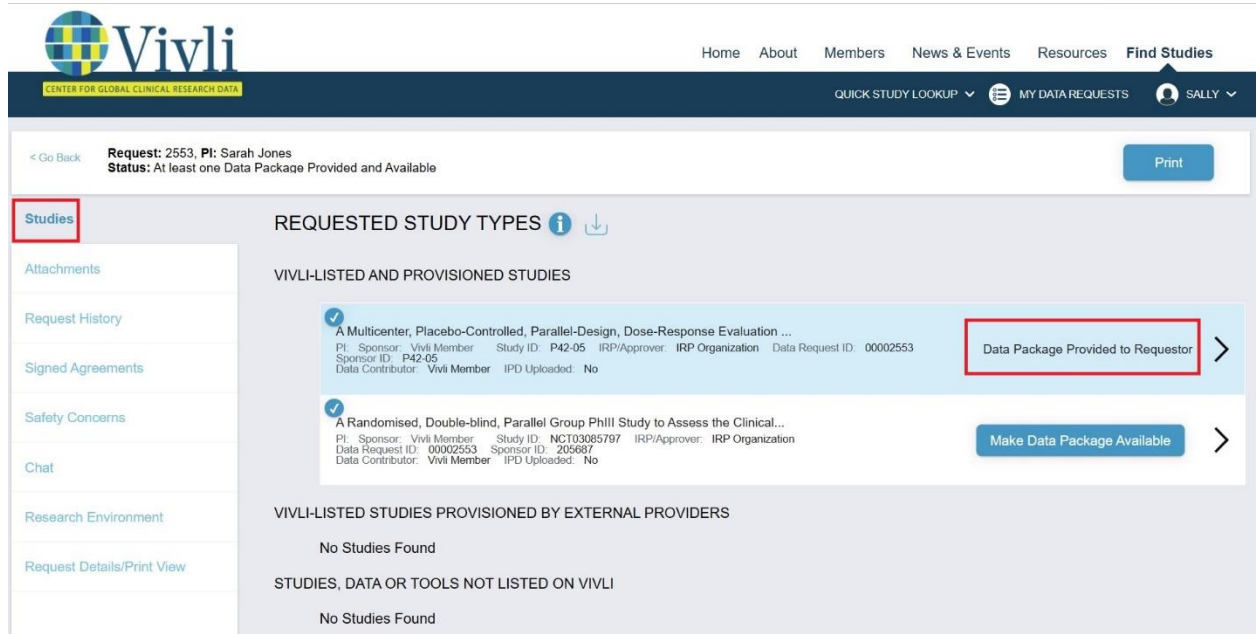
- 21) The following pop-up will appear:

The screenshot shows a confirmation pop-up dialog with a dark blue background. The text inside reads: 'Are you sure all files have been uploaded and assigned file types? This action cannot be undone.' There are two buttons at the bottom: a blue 'Yes' button and a red 'No' button.

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



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



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

The screenshot shows the Vivli web application interface. At the top, there is a navigation bar with links: Home, About, Members, News & Events, Resources, and Find Studies. Below this is a sub-navigation bar with 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and a user profile 'SALLY'. The main content area is titled 'Request: 2553, PI: Sarah Jones' and 'Status: At least one Data Package Provided and Available'. A 'Print' button is in the top right. On the left, a sidebar contains links: Studies (highlighted with a red box), Attachments, Request History, Signed Agreements, Safety Concerns, Chat, Research Environment, and Request Details/Print View. The main area is titled 'REQUESTED STUDY TYPES' and 'VIVLI-LISTED AND PROVISIONED STUDIES'. It shows two study entries. The first entry is highlighted with a red box and contains the following details: 'A Multicenter, Placebo-Controlled, Parallel-Design, Dose-Response Evaluation ...', 'PI: Sponsor: Vivli Member', 'Study ID: P42-05', 'IRP/Approver: IRP Organization', 'Data Request ID: 00002553', 'Data Package Provided to Requestor', and 'Data Contributor: Vivli Member IPD Uploaded: No'. The second entry is 'A Randomised, Double-blind, Parallel Group PhIII Study to Assess the Clinical...', 'PI: Sponsor: Vivli Member', 'Study ID: NCT03085797', 'IRP/Approver: IRP Organization', 'Data Request ID: 00002553', 'Sponsor ID: 205687', 'Data Contributor: Vivli Member IPD Uploaded: No', and a 'Make Data Package Available' button. Below this, it says 'VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS' and 'No Studies Found'. At the bottom, it says 'STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI' and 'No Studies Found'.

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

The screenshot shows the Vivli web application interface. At the top, there is a navigation bar with links: Home, About, Members, News & Events, Resources, and Find Studies. Below this is a sub-navigation bar with 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and a user profile 'SALLY SCIENTIST (DATA PROVIDER)'. The main content area is titled 'Booster Vaccination With Pneumococcal Vaccine GSK1024850A, a DTPa-Combined and MenC or Hib-MenC Vaccines'. Below this, there are three tabs: 'Study Details', 'Administrative Details', and 'Download Data Package' (highlighted with a red box). The main area is titled 'DOWNLOADABLE DATA PACKAGE - PRESS DOWNLOAD BUTTON FOR EACH FILE'. Below this, it says 'UPLOADED FILES'. There is a table with the following columns: Filename, Size, Uploaded By, File Type, and a 'Download' button. The table contains five rows of data:

Filename	Size	Uploaded By	File Type	Download
109507.txt		Sally Scientist (Data Provider)	Other	Download
Data Dictionary Documentation.pdf	118.00kB	Sally Scientist (Data Provider)	Data Dictionary	Download
IPD data.xls	26.00kB	Sally Scientist (Data Provider)	IPD	Download
Protocol.pdf	179.00kB	Sally Scientist (Data Provider)	Protocol	Download
Statistical analysis plan.pdf	160.00kB	Sally Scientist (Data Provider)	Statistical Analysis Plan	Download

The 'Download' buttons in the table are highlighted with a red box.

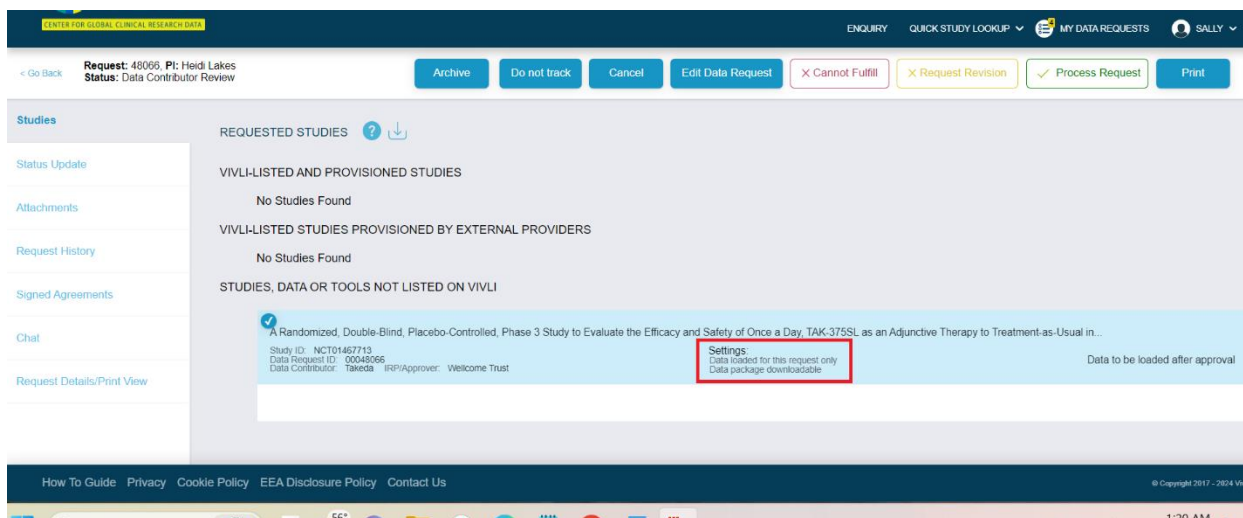
- 26) The data package upload and download action will be recorded in the Request history of the Data Request and includes the study ID in the history entry.

Studies	12/15/22 7:41 pm	Status changed to Awaiting DUA Validation	Amrutha Baskaran abaskaran@vivli.org	Begin DUA Validation
Status Update	12/15/22 7:41 pm	Updated Admin approval status for team member Datarequester.vivli@gmail.com to Approved	Amrutha Baskaran abaskaran@vivli.org	
Attachments	12/15/22 7:41 pm	Status changed to Data Use Agreement (DUA) Validated by Vivli Admin	Amrutha Baskaran abaskaran@vivli.org	
Request History	12/15/22 7:45 pm	Status changed to Data Package Provided for study with Sponsor Id: "BO16411", NCT ID: N/A, and title: "A randomised, double-blind, placebo controlled, multicentre, phase 3 study of OSI 774 plus chemotherapy (cisplatin and gemcitabine) vs. chemotherapy alone in patients with advanced (stage 3b or 4) non-small cell lung cancer who have not received prior chemotherapy." (Internal ID: 4919248c-5907-444b-aa7c-1c0767838d02)	Provider-Roche dataprovder.vivli+roche@gmail.com	
Signed Agreements	12/15/22 7:45 pm	Status changed to Partially Fulfilled	Provider-Roche dataprovder.vivli+roche@gmail.com	Requested Study Data Package was uploaded
Safety Concerns	12/15/22 7:45 pm	Status changed to Partially Fulfilled	Provider-Roche dataprovder.vivli+roche@gmail.com	
Research Results				
Chat				
Research Team				

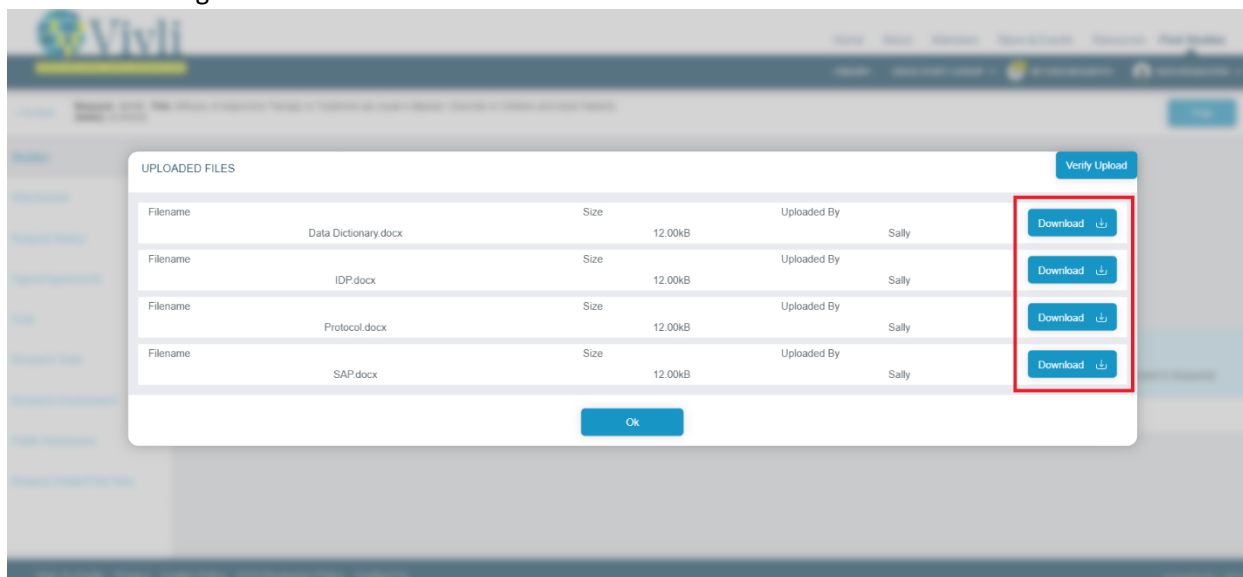
- 27) Once all the data packages from all the data contributors have been successfully uploaded, the request status will change to “All Data Packages Provided and Available” under the **Active** status bar.

Dashboard	Research Data Requests	For data provided by my organizations	Search data requests
Research Environments	Awaiting My Action	Draft	Active
Report	14	11	155
Users	Not Approved	Withdrawn	Archived
My Organizations	3	67	1
Studies			
Data Requests			
Awaiting Upload			
	Vivli ID: 00002553	Predicting Treatment Response to combination drugs in patients with type 2 Diabetes (Studies: 2)	At least one Data Package Provided and Available
	Vivli ID: 00002550	Stan - Test new image 10/6 (Studies: 2)	All Data Packages Provided and Available
	Vivli ID: 00002549	Ascending Multiple-dose Safety, Tolerance, Pharmacokinetic, and Pharmacodynamic Study of BMS-201	At least one Data Package Provided and Available
	Vivli ID: 00002548	Stan Multiple Upload 9/28 (Studies: 5)	At least one Data Package Provided and Available
	Vivli ID: 00002547		

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



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



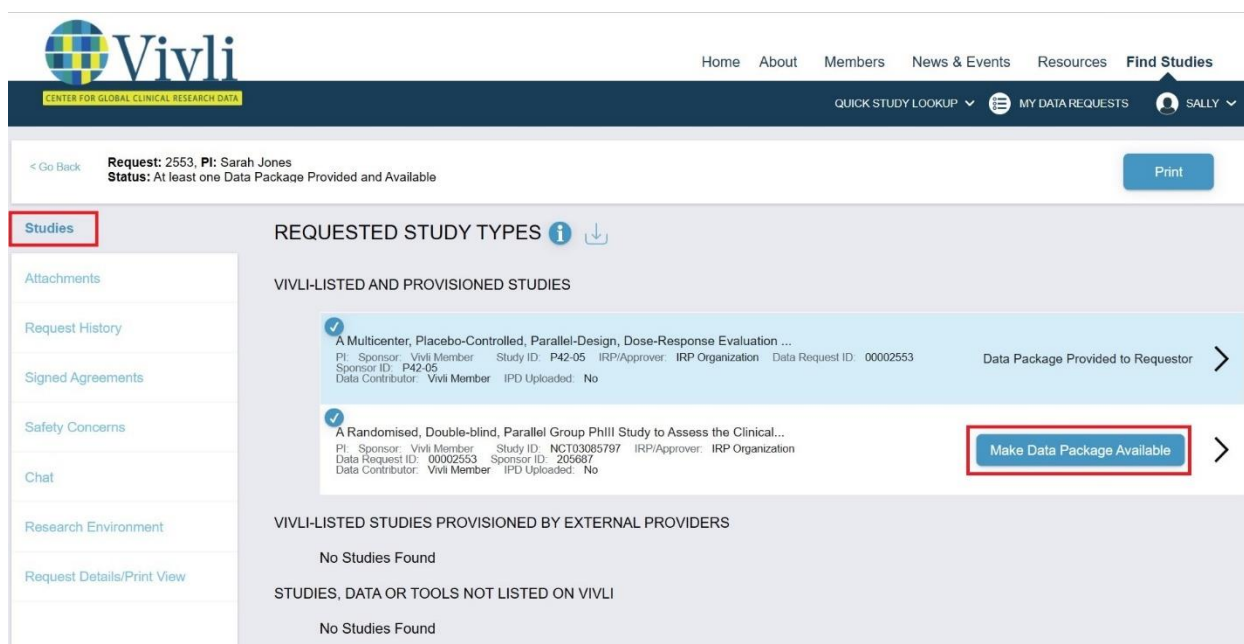
4.4.2 Steps: Make Data Package Available

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

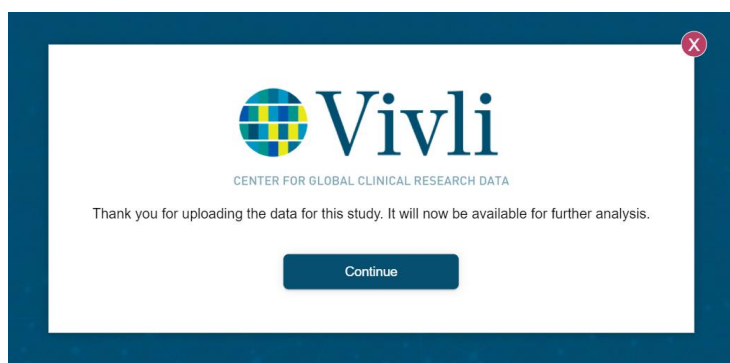
In most cases, that will be an entirely automatic step. In other words, that study will not appear in your “Awaiting Upload” section. Instead, the data package will be automatically loaded for the data request and the action will be recorded in the request history of the data request.

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

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



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



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

Request: 2553, PI: Sarah Jones
Status: At least one Data Package Provided and Available

Studies

REQUESTED STUDY TYPES

VIVLI-LISTED AND PROVISIONED STUDIES

A Multicenter, Placebo-Controlled, Parallel-Design, Dose-Response Evaluation ...
PI: Sponsor: Vivli Member Study ID: P42-05 IRP/Approver: IRP Organization Data Request ID: 00002553
Sponsor ID: P42-05 Data Contributor: Vivli Member IPD Uploaded: No **Data Package Provided to Requestor**

A Randomised, Double-blind, Parallel Group Phase III Study to Assess the Clinical...
PI: Sponsor: Vivli Member Study ID: NCT03085797 IRP/Approver: IRP Organization
Data Request ID: 00002553 Sponsor ID: 205687 Data Contributor: Vivli Member IPD Uploaded: No **Make Data Package Available**

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS
No Studies Found

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI
No Studies Found

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

4.4.3 Steps: Uploading data while request undergoing review

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

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

Studies
Submitted by my organization

Draft **In Progress** **Posted** **Cancelled** **+ Add Study**

Title	Status	Posted	Sponsor ID	NCTID	IPD
A Randomised, Double-blind, Parallel Group Phase III Study to Assess the Clinical...	Posted	2021-10-05	205687	NCT03085797	N
A Multicenter, Placebo-Controlled, Parallel-Design, Dose-Response Eval...	Posted	2021-10-05	P42-05		N

1 to 2 of 2 Page 1 of 1

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

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Find Studies

QUICK STUDY LOOKUP MY DATA REQUESTS SALLY SCIENTIST (DATA PROVIDER)

Dashboard Research Environments **Studies** Data Requests Awaiting Upload

< Go Back

A Multicenter, Placebo-Controlled, Parallel-Design, Dose-Response Evaluation of the Safety and Efficacy of Lamotrigine as Add-On Therapy in Epileptic Outpatients with Partial Seizures

Current Status: Posted
Data Uploaded: NO
Requests: None so far

Study Information Study Documents Chat **Study Data Package**

Upload study Data Package below
For this Study, your organization has agreed to provide a Basic data package.

NO FILES IN PACKAGE

YOU MUST SUPPLY ALL REQUIRED FILE TYPES AS DISTINCT FILES, AND FOR EACH FILE, YOU MUST SPECIFY THE FILE TYPE. If a file type is unavailable, please provide a file with a note of explanation

- IPD
- Data Dictionary
- Protocol
- Statistical Analysis Plan

Select Files Drop files here

- Once the request reaches the Data upload stage, the data package will be loaded to the data request. Please [section 4.4.2](#) Steps Make Data Package Available for more details.
- When a data contributor uploads IPD to a requested study from a data request, and no study template ID exists yet, the request history will record when the data was uploaded, including the date/time and the person who did it. Additionally, it will display the request number for data requests for this study. If the data is uploaded to this request only, the request history will include this information.

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Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS SALLY

Dashboard Research Environments Report My Organizations **Studies** Data Requests Awaiting Upload

< Go Back

Create DOI For New Data Version Prepare For New Data Version Save

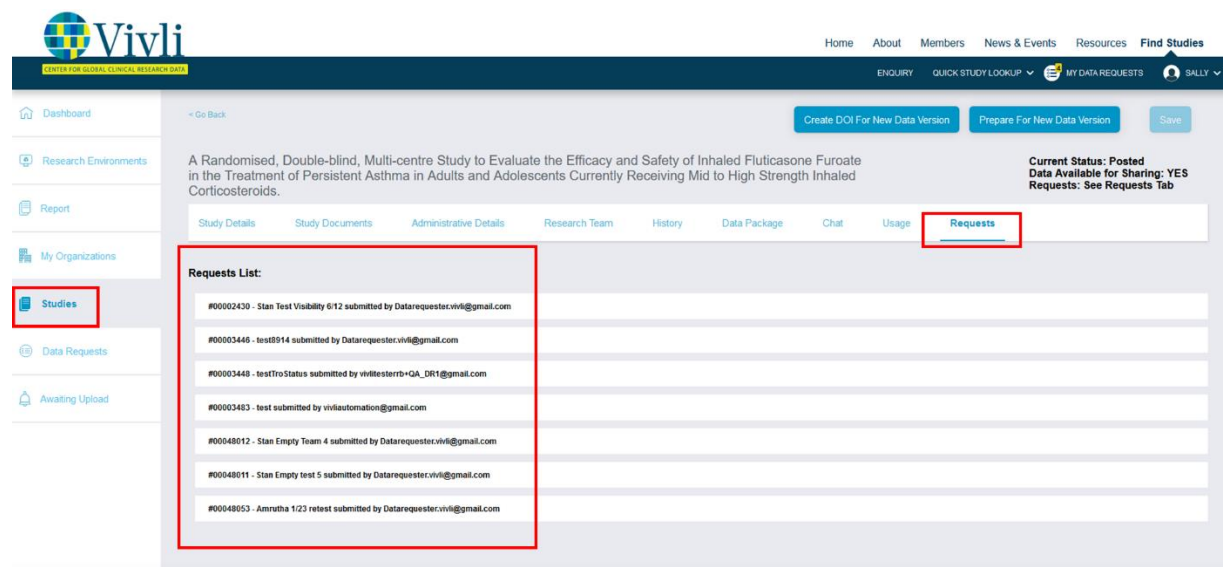
A Randomised, Double-blind, Multi-centre Study to Evaluate the Efficacy and Safety of Inhaled Fluticasone Furoate in the Treatment of Persistent Asthma in Adults and Adolescents Currently Receiving Mid to High Strength Inhaled Corticosteroids.

Current Status: Posted
Data Available for Sharing: YES
Requests: See Requests Tab

Study Details Study Documents Administrative Details Research Team **History** Data Package Chat Usage Requests

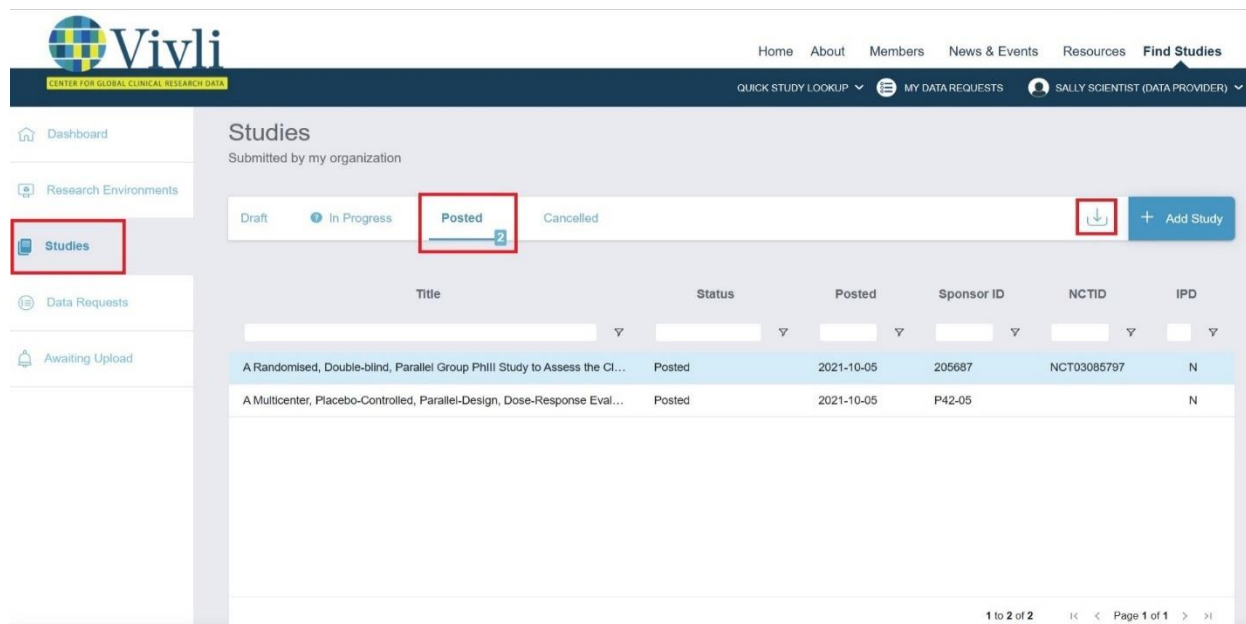
14/9/23 5:04 pm	IpD Package Uploaded	GA - DC All Orgs ViTestQA+DC-aiOrg@gmail.com	datapackage for study 'A Randomised, Double-blind, Multi-centre Study to Evaluate the Efficacy and Safety of Inhaled Fluticasone Furoate in the Treatment of Persistent Asthma in Adults and Adolescents Currently Receiving Mid to High Strength Inhaled Corticosteroids.'
14/9/23 5:04 pm	Status changed to IPD Provided for Requested Study - for Data Request 00003446	GA - DC All Orgs ViTestQA+DC-aiOrg@gmail.com	IPD uploaded to Request 00003446, titled test0514.
18/9/23 2:17 pm	Status changed to IPD deleted by Vivli Admin	Ruchi_QA_VivliAdmin.ruchi.vivliqa@gmail.com	Physical files in IPD Data Package 51a2d465-9e5c-451b-a228-d89ba51bee8 were deleted
18/9/23 2:17 pm	Status changed to IPD deleted by Vivli Admin	Ruchi_QA_VivliAdmin.ruchi.vivliqa@gmail.com	Physical files in IPD Data Package 20d4357c-039e-4013-b886-d45a9593de3a were deleted
18/9/23 2:17 pm	Status changed to New version of IPD Data Package created	Ruchi_QA_VivliAdmin.ruchi.vivliqa@gmail.com	Created new IPD Version with Version Number 2. The original IPD version number was 1
12/12/23 6:59 pm	IpD Package Uploaded	Sally.dataprovider.vivli@gmail.com	IpD Package uploaded was Available IPD datapackage for study 'A Randomised, Double-blind, Multi-centre Study to Evaluate the Efficacy and Safety of Inhaled Fluticasone Furoate in the Treatment of Persistent Asthma in Adults and Adolescents Currently Receiving Mid to High Strength Inhaled Corticosteroids.'

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



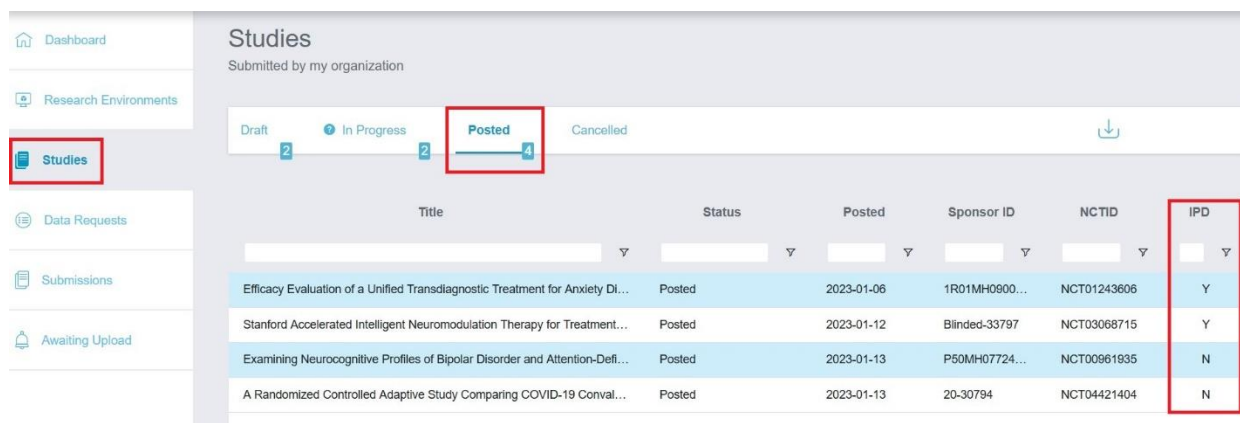
4.4.4 Studies list and stored data package

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



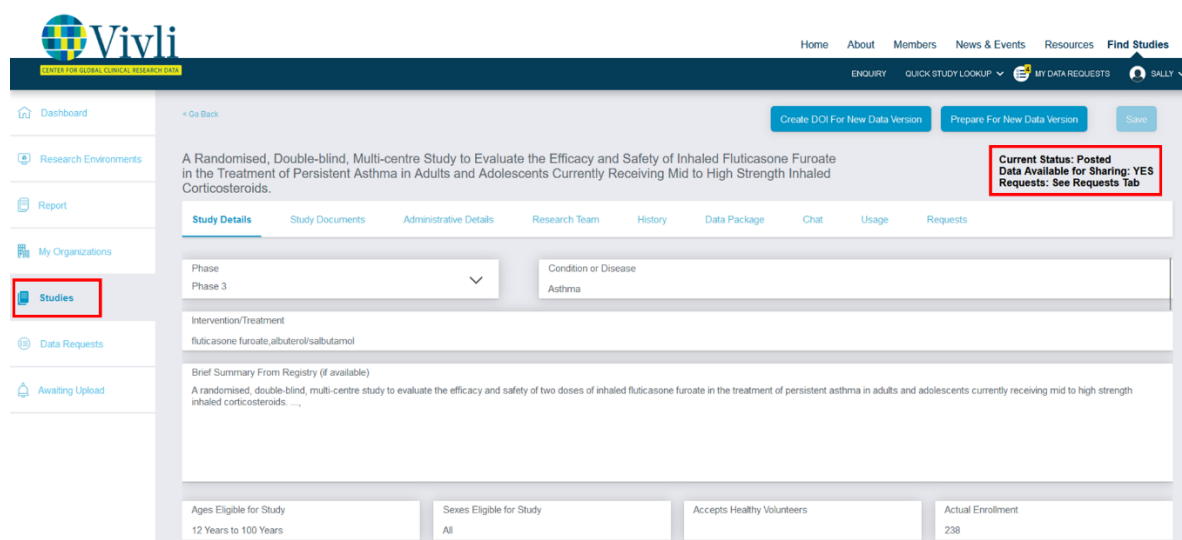
If a posted study has a stored data package, this will be visible in the following two places from the studies tab:

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



Title	Status	Posted	Sponsor ID	NCTID	IPD
Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Di...	Posted	2023-01-06	1R01MH0800...	NCT01243606	Y
Stanford Accelerated Intelligent Neuromodulation Therapy for Treatment...	Posted	2023-01-12	Blinded-33797	NCT03068715	Y
Examining Neurocognitive Profiles of Bipolar Disorder and Attention-Defi...	Posted	2023-01-13	P50MH07724...	NCT00961935	N
A Randomized Controlled Adaptive Study Comparing COVID-19 Conval...	Posted	2023-01-13	20-30794	NCT04421404	N

- 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.



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Home About Members News & Events Resources Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS SALLY

Dashboard Research Environments Report My Organizations Studies Data Requests Awaiting Upload

Go Back

Create DOI For New Data Version Prepare For New Data Version Save

A Randomised, Double-blind, Multi-centre Study to Evaluate the Efficacy and Safety of Inhaled Fluticasone Furoate in the Treatment of Persistent Asthma in Adults and Adolescents Currently Receiving Mid to High Strength Inhaled Corticosteroids.

Study Details Study Documents Administrative Details Research Team History Data Package Chat Usage Requests

Phase
Phase 3

Condition or Disease
Asthma

Intervention/Treatment
fluticasone furoate,albuterol/salbutamol

Brief Summary From Registry (if available)
A randomised, double-blind, multi-centre study to evaluate the efficacy and safety of two doses of inhaled fluticasone furoate in the treatment of persistent asthma in adults and adolescents currently receiving mid to high strength inhaled corticosteroids. ...

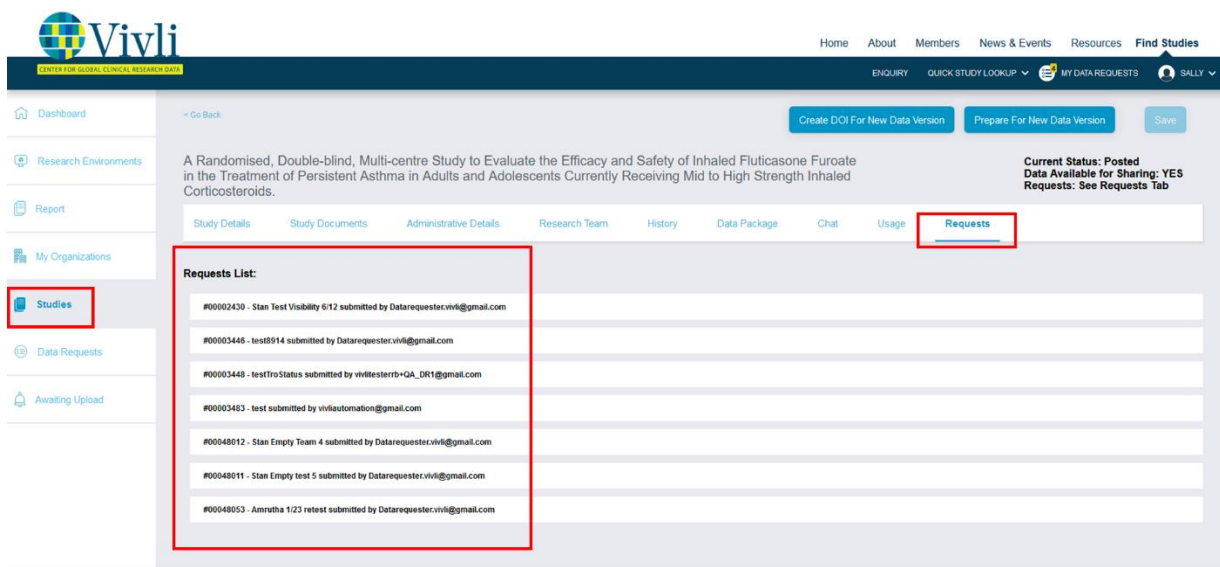
Ages Eligible for Study
12 Years to 100 Years

Sexes Eligible for Study
All

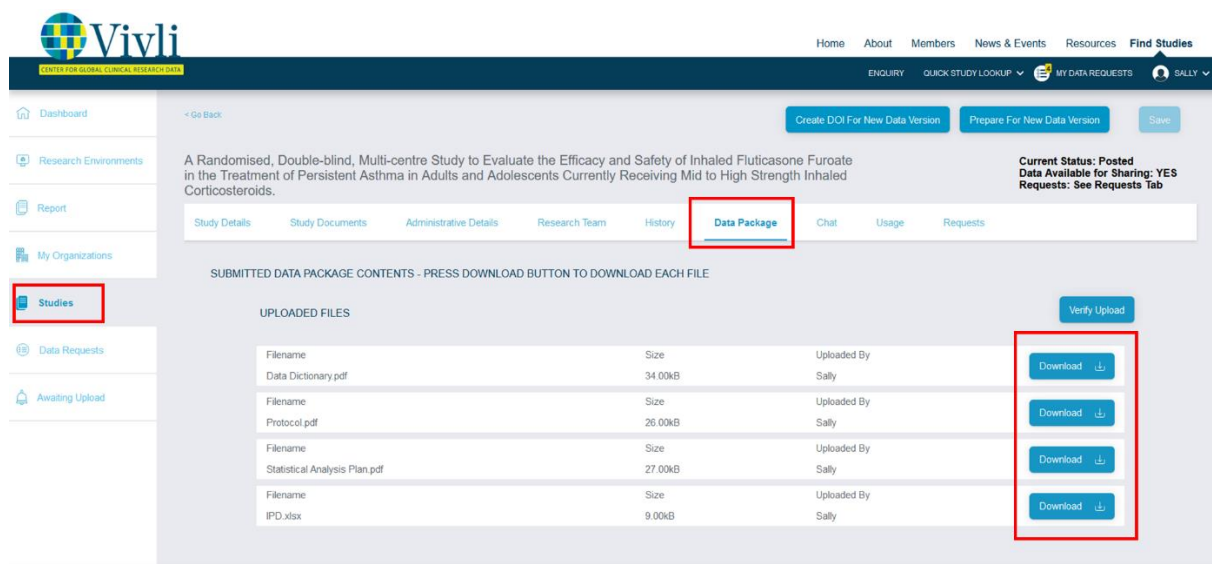
Accepts Healthy Volunteers

Actual Enrollment
238

Current Status: Posted
Data Available for Sharing: YES
Requests: See Requests Tab



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



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

At the request level

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

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

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

The screenshot shows the Vivli web application interface. At the top, there is a navigation bar with the Vivli logo and links for Home, About, Members, News & Events, Resources, and Find Studies. Below this, a dark blue header contains a search bar and links for QUICK STUDY LOOKUP, MY DATA REQUESTS, and a user profile for SALLY. The main content area is titled 'Request: 2553, PI: Sarah Jones' and 'Status: At least one Data Package Provided and Available'. A sidebar on the left lists various tabs: Studies (highlighted with a red box), Attachments, Request History, Signed Agreements, Safety Concerns, Chat, Research Environment, and Request Details/Print View. The main content area is divided into sections: 'REQUESTED STUDY TYPES' with a download icon, 'VIVLI-LISTED AND PROVISIONED STUDIES' showing two study entries with details like PI, Sponsor, Study ID, IRP/Approver, IRP Organization, Data Request ID, and Data Contributor. The first study entry has a 'Data Package Provided to Requestor' button (highlighted with a red box) and the second has a 'Make Data Package Available' button. Below these are sections for 'VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS' and 'STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI', both showing 'No Studies Found'.

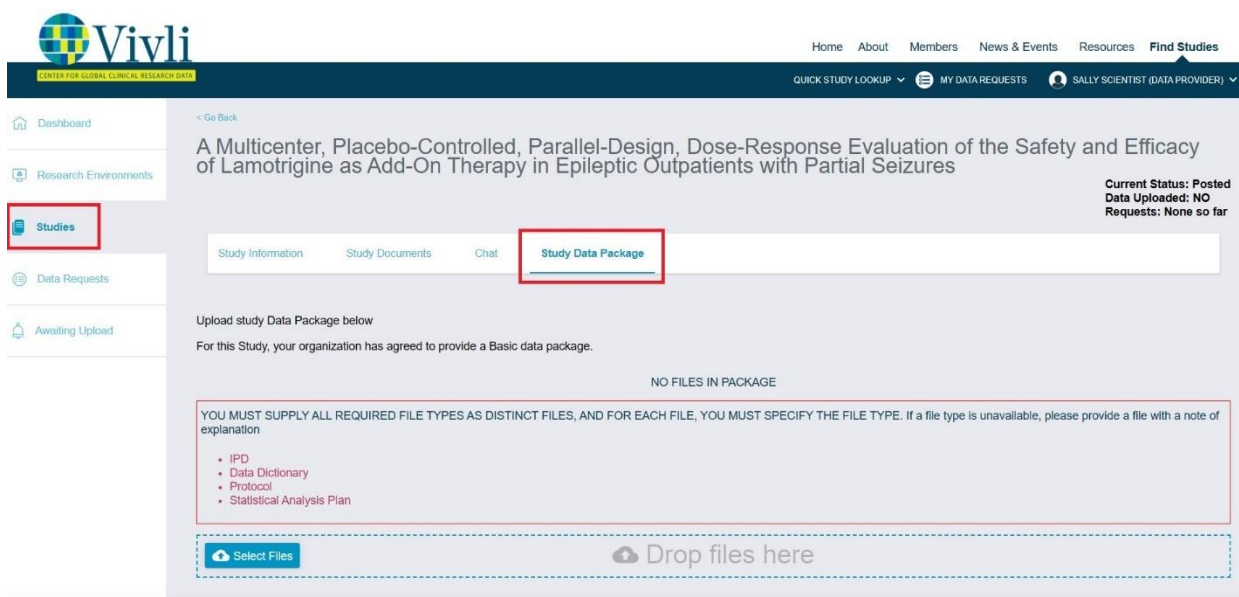
- Click anywhere in the white box representing the study. This will open up a new tab. Then go to the **Download Data Package** tab to display any files previously uploaded. Click on the download button to see the version of the files provided to the Researcher

The screenshot shows the Vivli web application interface for the 'Download Data Package' tab. The top navigation bar is the same as the previous screenshot. The main content area is titled 'Booster Vaccination With Pneumococcal Vaccine GSK1024850A, a DTPa-Combined and MenC or Hib-MenC Vaccines'. Below this, there are three tabs: Study Details, Administrative Details, and Download Data Package (highlighted with a red box). The main content area is titled 'DOWNLOADABLE DATA PACKAGE - PRESS DOWNLOAD BUTTON FOR EACH FILE'. Below this, there is a table of 'UPLOADED FILES' with columns for Filename, Size, Uploaded By, File Type, and a Download button (highlighted with a red box). The table contains five rows of data:

Filename	Size	Uploaded By	File Type	Download
109507.txt		Sally Scientist (Data Provider)	Other	Download
Data Dictionary Documentation.pdf	118.00kB	Sally Scientist (Data Provider)	Data Dictionary	Download
IPD data.xls	26.00kB	Sally Scientist (Data Provider)	IPD	Download
Protocol.pdf	179.00kB	Sally Scientist (Data Provider)	Protocol	Download
Statistical analysis plan.pdf	160.00kB	Sally Scientist (Data Provider)	Statistical Analysis Plan	Download

4.4.5 Steps: Upload a New Version of the Data Package

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



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

4.4.6 Steps: Uploading data to only one data request

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

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

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

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

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

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

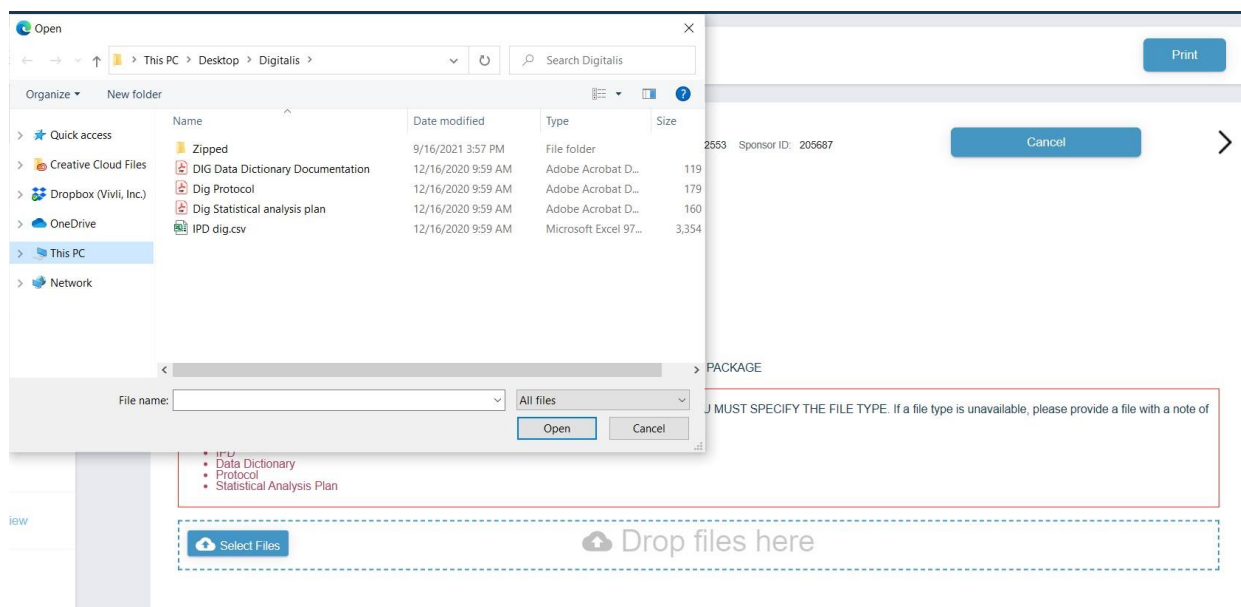
The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. The main content area is titled 'REQUESTED STUDIES' and 'VIVLI-LISTED AND PROVISIONED STUDIES'. A sidebar on the left contains links for Status Update, Attachments, Request History, Signed Agreements, Safety Concerns, Research Results, Chat, Research Environment, and Request Details/Print View. The main content area displays a list of studies with details such as Study ID, Sponsor ID, Data Contributor, and Settings. The 'Upload Data Package' button is highlighted with a red box.

The following window will appear:

The screenshot shows the 'Upload Data Package' window in the Vivli web application. The window displays instructions for uploading data packages, including a list of required file types (IPD, Data Dictionary, Protocol, Statistical Analysis Plan) and a 'Drop files here' area. The 'Select Files' button is highlighted with a red box.

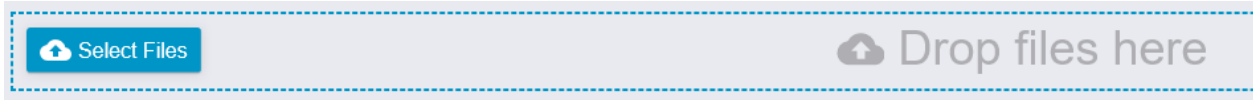
5. Now click on **Select Files** to choose files to upload.

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

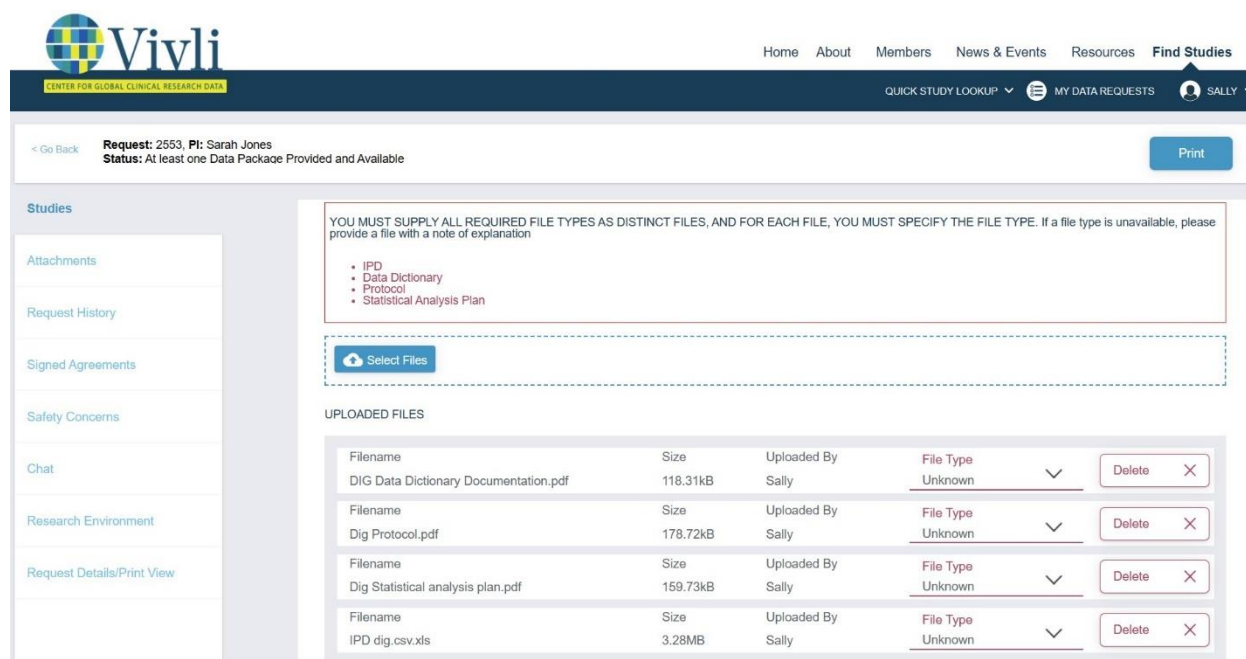


7. After selecting the files, click **Open**.

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



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



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

Upload study Data Package below

Select Files

UPLOADED FILES

Filename	Size	File Type	Download	Delete
DIG Data Dictionary Documentation.pdf	118.00kB	Data Dictionary	Download	Delete
Dig Protocol.pdf	179.00kB	IPD	Download	Delete
Dig Statistical analysis plan.pdf	160.00kB	Protocol	Download	Delete
IPD dig.csv.xls	3.28MB	Statistical Analy...	Download	Delete

- 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.
- For summary level request or document-only request, you can upload the requested information. To enable the submit button, you can upload placeholder files (i.e. upload a word document explaining it is a placeholder file) for the other required documents and select the file type.

Upload study Data Package below

Select Files

UPLOADED FILES

Filename	Size	Uploaded By	File Type	Download	Delete
V2Dig Protocol.pdf	178.72kB	Data Contribut...	Protocol	Download	Delete
Placeholder_data dictionary.docx	12.42kB	Data Contribut...	Data Dict...	Download	Delete
Placeholder_IPD.docx	12.43kB	Data Contribut...	IPD	Download	Delete
Placeholder_Statistical analysis p...	12.44kB	Data Contribut...	Statistic...	Download	Delete

Submit Files

- 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".

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

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

The screenshot shows the 'Upload Data' section of the Vivli Data Contributor interface. The main content area displays a table of uploaded files with columns for Filename, Size, Uploaded By, File Type, and actions (Download, Delete). The files listed are 'Data Dictionary.docx', 'IDP.docx', 'Protocol.docx', and 'SAP.docx'. A 'Verify Upload' button is highlighted in the top right of the table area. A notification box at the bottom right states 'All data has been successfully uploaded and stored in the system'.

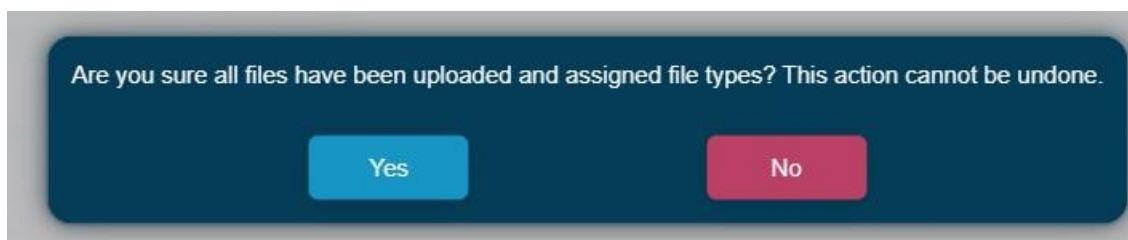
17. **Important Note:** Ensure that all the files have been loaded before clicking the submit button. Once you click the Submit button, you cannot load further documents to the same study.
18. If you plan to upload data packages for multiple studies in the data request, click Submit files for one study,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

The screenshot shows the Vivli Data Contributor interface. At the top, there is a navigation bar with the Vivli logo and links for Home, About, Members, News & Events, Resources, and Find Studies. Below the navigation bar, there is a header section with a 'QUICK STUDY LOOKUP' dropdown, a 'MY DATA REQUESTS' link, and a user profile for 'SALLY'. The main content area displays a study request for 'Request: 2553, PI: Sarah Jones' with a status of 'At least one Data Package Provided and Available'. A sidebar on the left contains links for Studies, Attachments, Request History, Signed Agreements, Safety Concerns, Chat, Research Environment, and Request Details/Print View. The main content area shows a list of required files: 'Data Package', 'Statistical Analysis Plan', and 'Data Dictionary'. Below this, there is a section for 'Upload study Data Package below' with a 'Select Files' button. A table titled 'UPLOADED FILES' lists the following files:

Filename	Size	Uploaded By	File Type		Delete
DIG Data Dictionary Documentation.pdf	118.31kB	Sally	Data Dictio...	▼	✕
Dig Protocol.pdf	178.72kB	Sally	File Type Protocol	▼	✕
Dig Statistical analysis plan.pdf	159.73kB	Sally	Statistical...	▼	✕
IPD dig.csv.xls	3.28MB	Sally	File Type IPD	▼	✕

At the bottom of the table, there is a red-bordered button labeled 'Submit Files'.

18. The following pop-up will appear:



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



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

< Go Back **Request: 3222, PI: Amrutha Baskaran** **Status: All Data Packages Provided and Available** [Print](#)

Studies

Status Update
Attachments
Request History
Signed Agreements
Safety Concerns
Research Results
Chat
Research Environment
Request Details/Print View

REQUESTED STUDIES ? ↓

VIVLI-LISTED AND PROVISIONED STUDIES

<p>✓ An Open-Label, Single-Arm Study to Evaluate the Effectiveness and Safety of Ocrelizumab in Patients With Early Stage Relapsing Remitting Multiple Sclerosis</p> <p>Study ID: NCT03085810 - Sponsor ID: MA30143 Data Request ID: 00003222 Data Contributor: AbbVie IRP/Approver: Wellcome Trust</p> <p>Settings: Data loaded for this request only Data available in secure research environment only</p> <p>Data Package Provided to Requester</p>
<p>✓ Reactogenicity, Safety and Immunogenicity Study of GlaxoSmithKline (GSK) Biologicals' Investigational Supra-seasonal Universal Influenza Vaccines - Inactivated (SUIVs) (GSK...</p> <p>Study ID: NCT03275389 - Sponsor ID: 207543 Data Request ID: 00003222 Data Contributor: AbbVie IRP/Approver: Wellcome Trust</p> <p>Settings: Data has been loaded for this and future requests Data available in secure research environment only</p> <p>Data Package Provided to Requester</p>
<p>✓ Non-closure of Alveoli After Avulsion of Wisdom Teeth: a Randomized, Open, Multicenter Trial</p> <p>Study ID: NCT02583987 - Sponsor ID: LOCAL/2014/PL-01 Data Request ID: 00003222 Data Contributor: Biogen IRP/Approver: Biogen</p> <p>Settings: Data has been loaded for this and future requests Data package downloadable</p> <p>Data Package Provided to Requester</p>

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

No Studies Found

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

REQUESTED STUDIES

VIVLI-LISTED AND PROVISIONED STUDIES

A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Belimumab Plus Standard of Care Versus Placebo Plus Standard of Care In...
 Study ID: NCT01639339 | Sponsor ID: 114054 | Settings: Data has been loaded for this and future requests
 Data Request ID: 00003270 | Data Contributor: Roche | IRP/Approver: Wellcome Trust | Data package downloadable
 Data Package Provided to Requester

Prospective Study of Post Surgical Continued Pain (PSCP) Patients Undergoing Flexion Distraction Decompression Spinal Manipulation
 Study ID: NCT05401682 | Sponsor ID: IRB000C18MG72 | Settings: Data will be loaded for this and future requests
 Data Request ID: 00003270 | Data Contributor: BlueMetal | IRP/Approver: BlueMetal | Data package downloadable
 Data to be provided by Data Contributor

Immunogenicity and Safety Study of GSK Biologicals' Candidate Malaria Vaccine (SB257049) Given at 6, 7.5 and 9 Months of Age in Co-administration With Measles, Rubella and ...
 Study ID: NCT02069099 | Sponsor ID: 200596 | Settings: Edit Settings
 Data Request ID: 00003270 | Data Contributor: AbbVie | IRP/Approver: Wellcome Trust | Data package downloadable
 Upload Data Package

VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

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

An Open-Label, Single-Arm Study to Evaluate the Effectiveness and Safety of Ocrelizumab in Patients With Early Stage Relapsing Remitting Multiple Sclerosis

Study Details | Study Documents | Administrative Details | **Download Data Package** | Usage

DOWNLOADABLE DATA PACKAGE - PRESS DOWNLOAD BUTTON FOR EACH FILE

UPLOADED FILES

Filename	Size	Uploaded By	Download
V2DIG Data Dictionary Documentation.pdf	118.00kB	Data Contributor	Download
V2Dig Protocol.pdf	179.00kB	Data Contributor	Download
V2Dig Statistical analysis plan.pdf	160.00kB	Data Contributor	Download
V2IPD dig.csv.xls	3.28MB	Data Contributor	Download

24. Once all 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.

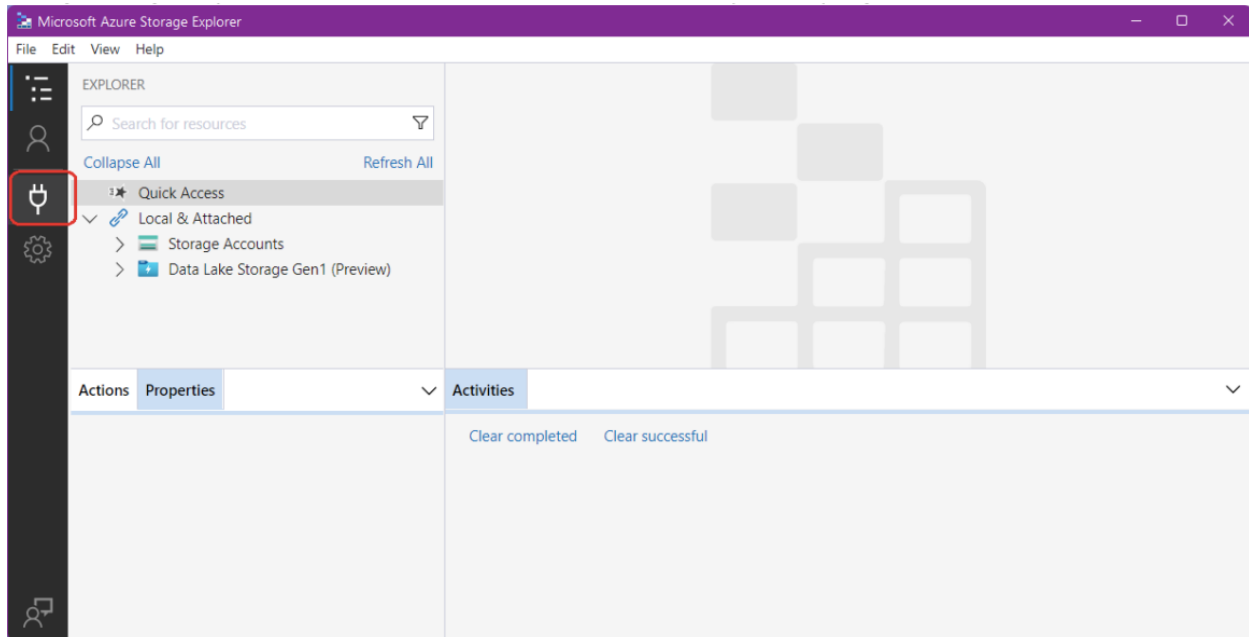
Research Data Requests		Search data requests
For data provided by my organizations		
Awaiting My Action 14 Draft 11 Active 155 Not Approved 3 Withdrawn 67 Archived 1		
Vivli ID: 00002553	Predicting Treatment Response to combination drugs in patients with type 2 Diabetes (Studies: 2) Requested By: Data Requester Lead Researcher: Sarah Jones	At least one Data Package Provided and Available
Vivli ID: 00002550	Stan - Test new image 10/5 (Studies: 2) Requested By: Data Requester Lead Researcher: q q	All Data Packages Provided and Available
Vivli ID: 00002549	Ascending Multiple-dose Safety, Tolerance, Pharmacokinetic, and Pharmacodynamic Study of BMS-201 Requested By: Data Requester Lead Researcher: Elle Researcher	At least one Data Package Provided and Available
Vivli ID: 00002548	Stan Multiple Upload 9/28 (Studies: 5) Requested By: Data Requester Lead Researcher: Stan (Gmail) Neumann	At least one Data Package Provided and Available
Vivli ID: 00002547		

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

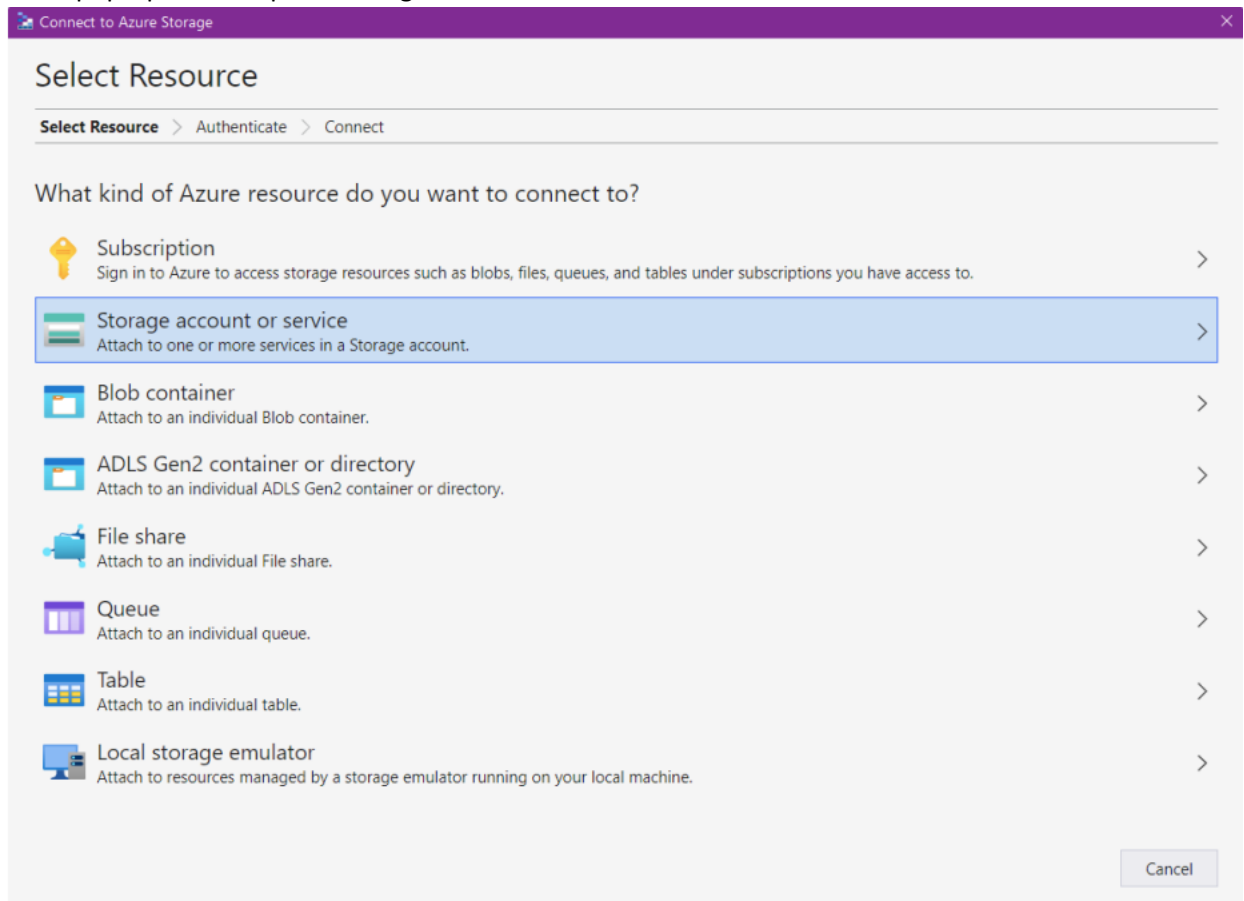
4.4.6 Uploading large files and data packages to the Vivli Platform:

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

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



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



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

Connect to Azure Storage

Select Connection Method

Select Resource > **Select Connection Method** > Enter Connection Info > Summary

How will you connect to the storage account?

☒ Connection string (Key or SAS)

☐ Shared access signature URL (SAS)

☐ Account name and key

Connect to Azure Storage

Enter Connection Info

Select Resource > Select Connection Method > **Enter Connection Info** > Summary

Display name:

Biosciences Upload

Connection string:

DefaultEndpointsProtocol=https;AccountName=vivlidatacussabioscines;AccountKey=xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxf;EndpointSuffix=core.windows.net

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

Connect to Azure Storage

Summary

Select Resource > Select Connection Method > Enter Connection Info > **Summary**

The following settings will be used to connect to your resource:

Display name: Biosciences staging area

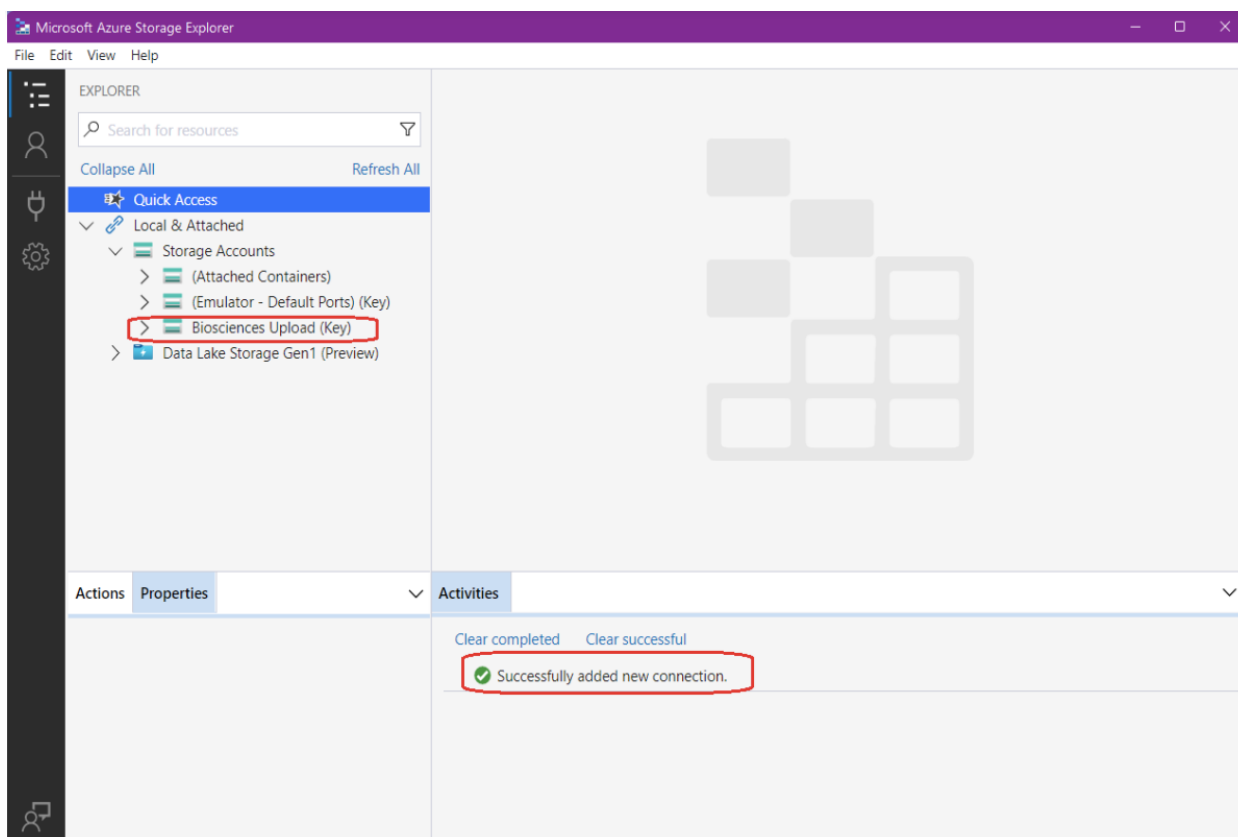
Account name: biosciences

Account key: 5+v3uda+n9mPSqYEJuioZtDUvQ57nANdb853TN2dZAZ/O/Urm1CQ0w7CZ0hzO9ipe1cHq6gYPusV08Jxo+WfDw==

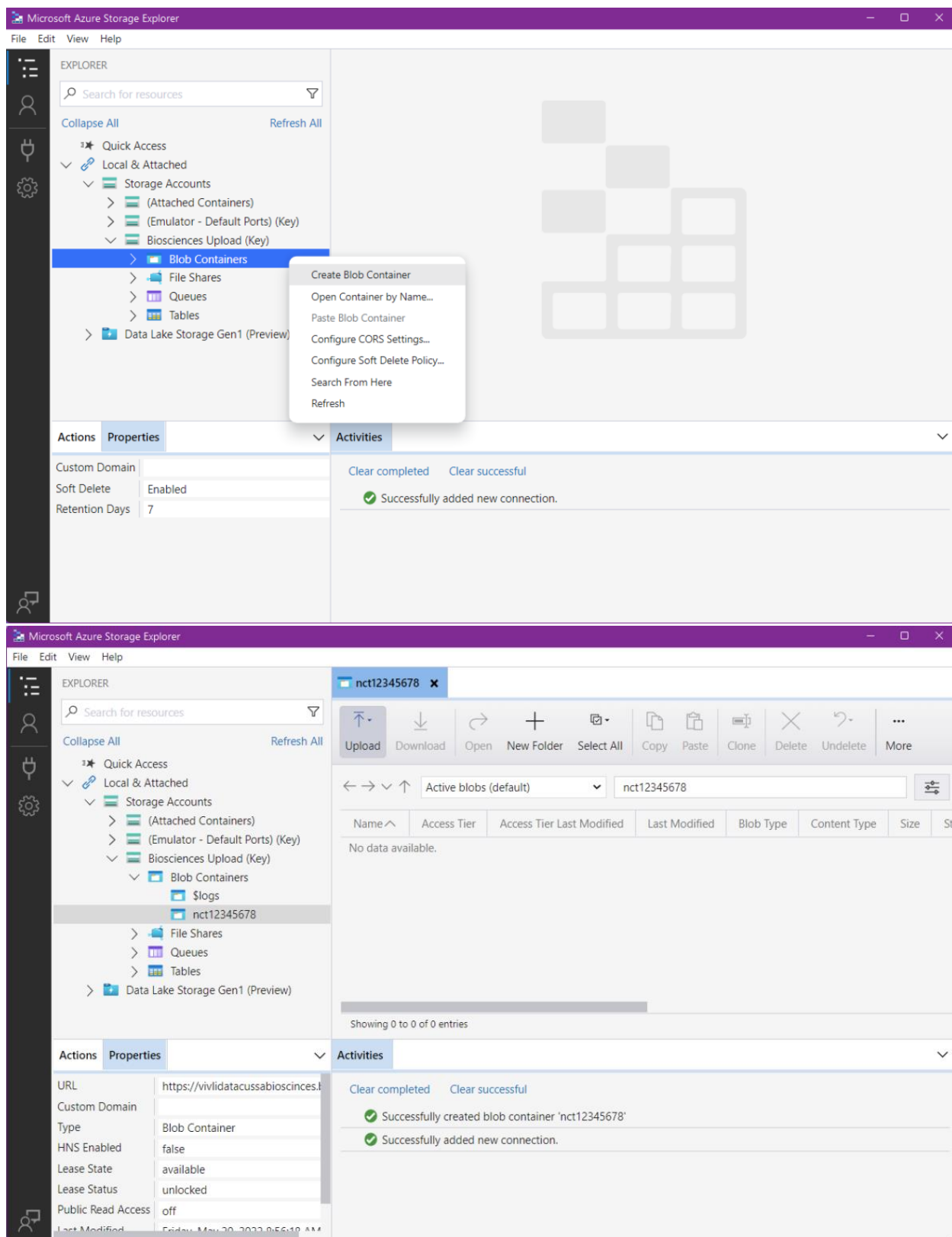
Default endpoints protocol: https

⚠ Make sure you only connect to resources you trust.

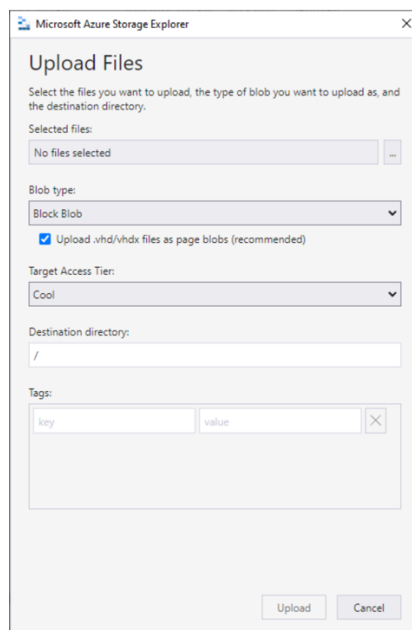
5. It should add the storage account to the list on the upper left, and report “Successfully added connection:



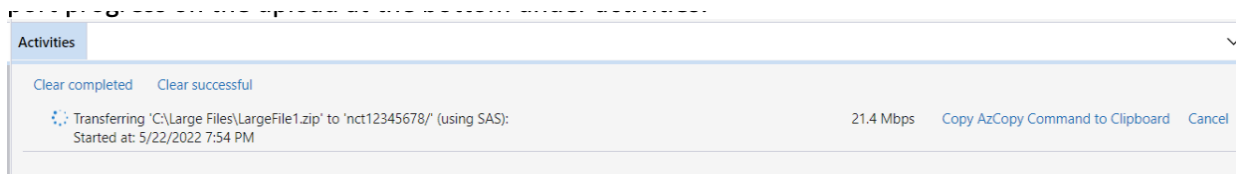
6. Click on the ">" to open the storage account, then right click on Blob Containers and choose "Create Blob Container". Give it a name that represents the study (e.g. the NCTId or sponsor ID). Note that container names are limited to numbers, lowercase letters and hyphens, but no spaces or uppercase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



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



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

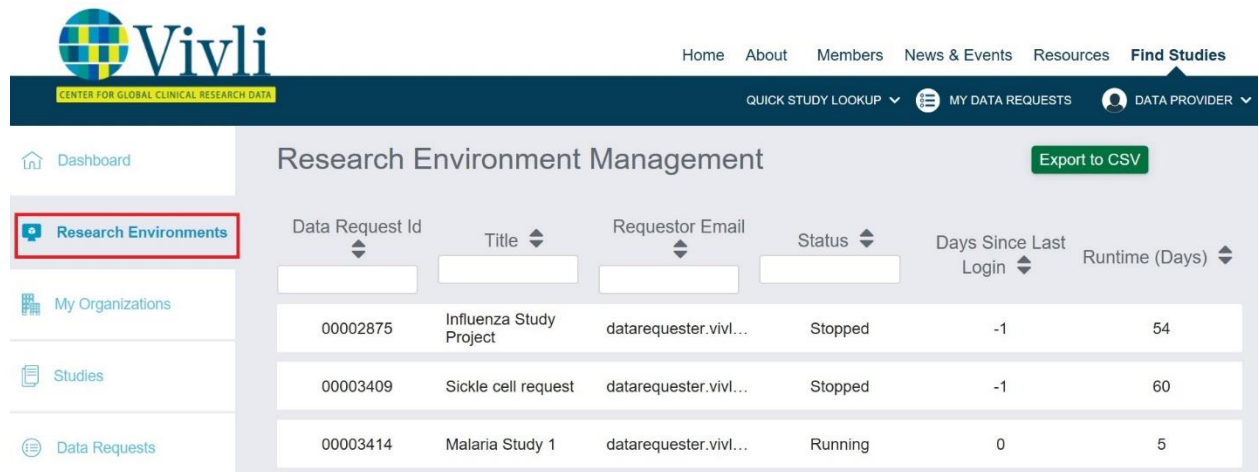


9. Note that Storage Explorer will remember the connection the next time you start Azure Storage Explorer – to get it to “forget”, right click on the storage account name (Biosciences in the example screenshots above) and choose “detach”. When you have completed the upload, notify Vivli at support@vivli.org

5. Research Environment monitoring

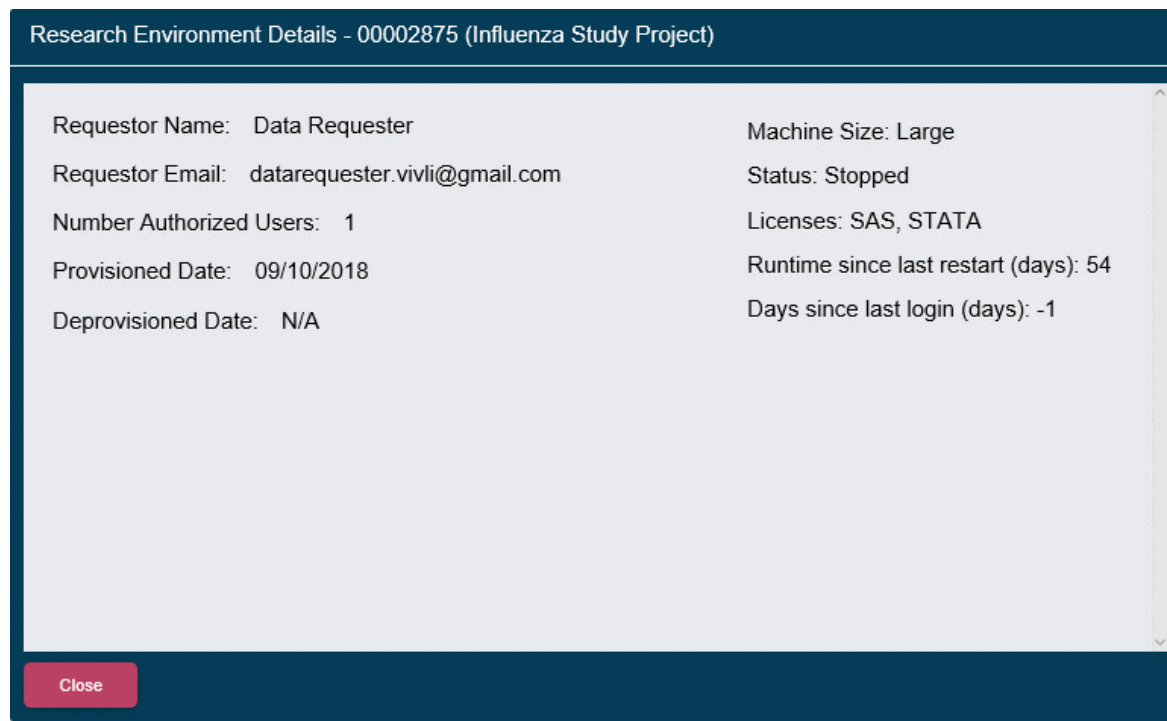
- Organizational Administrators for the Data Contributor Organization can monitor the progress of the Research environments for data requests containing at least one of their studies. Note: Those with only Data Contributor role cannot view this dashboard.

F7



Data Request Id	Title	Requestor Email	Status	Days Since Last Login	Runtime (Days)
00002875	Influenza Study Project	datarequester.vivl...	Stopped	-1	54
00003409	Sickle cell request	datarequester.vivl...	Stopped	-1	60
00003414	Malaria Study 1	datarequester.vivl...	Running	0	5

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



Requestor Name: Data Requester	Machine Size: Large
Requestor Email: datarequester.vivli@gmail.com	Status: Stopped
Number Authorized Users: 1	Licenses: SAS, STATA
Provisioned Date: 09/10/2018	Runtime since last restart (days): 54
Deprovisioned Date: N/A	Days since last login (days): -1

Close

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

5.1 Software in the Research Environment

- The software available in the Research Environment is updated on a regular basis and a comprehensive listing of the software and R packages is available in the Vivli Research Environment. The full list is on the Vivli website, <https://vivli.org/resources/resources/>
- The current list applies only to new research environments – updates to software installed are not retroactive to existing research environments, although we can make updates to existing environments when requested.

6. Public Disclosures & Publications & Summary of results

6.1 Review(s) by Data Contributor

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

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

6.2 Publication Notification by Data Requestor

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

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

7. DUA extension

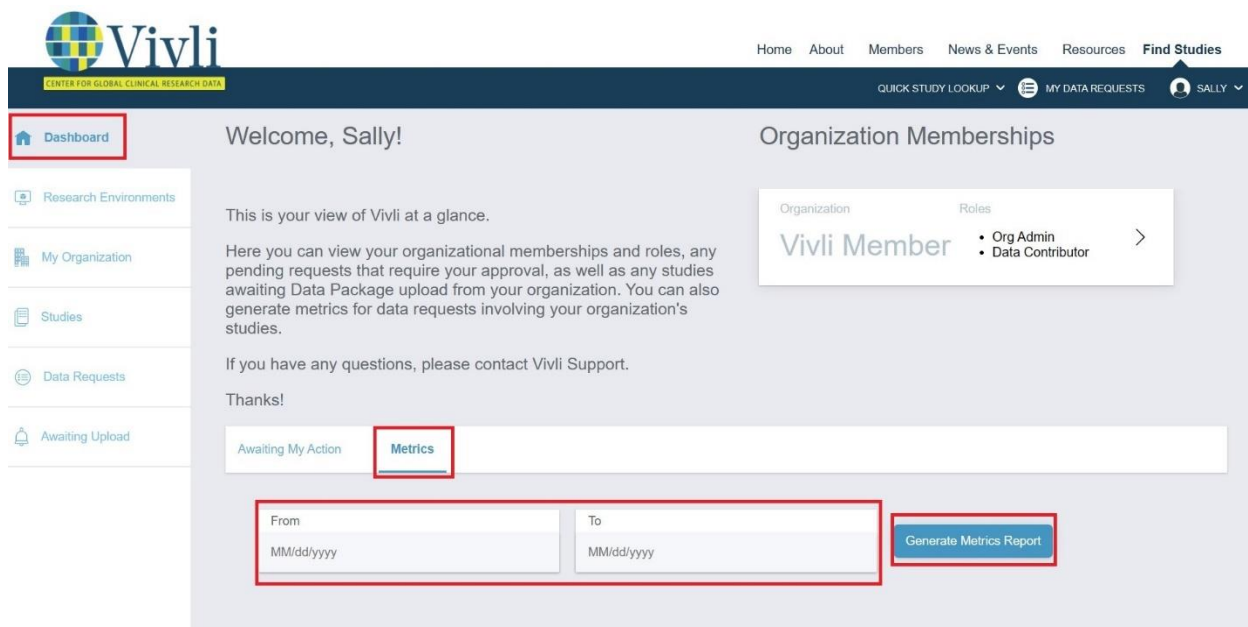
- According to Vivli policy, DUA extensions are given in 6-month intervals up to a maximum of 2 years. After that, any extensions will need to be reviewed by the Data Contributors who may approve or decline the extension.
- For the third extension, the Vivli team will reach out to the Data Contributor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

8. Safety reporting

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

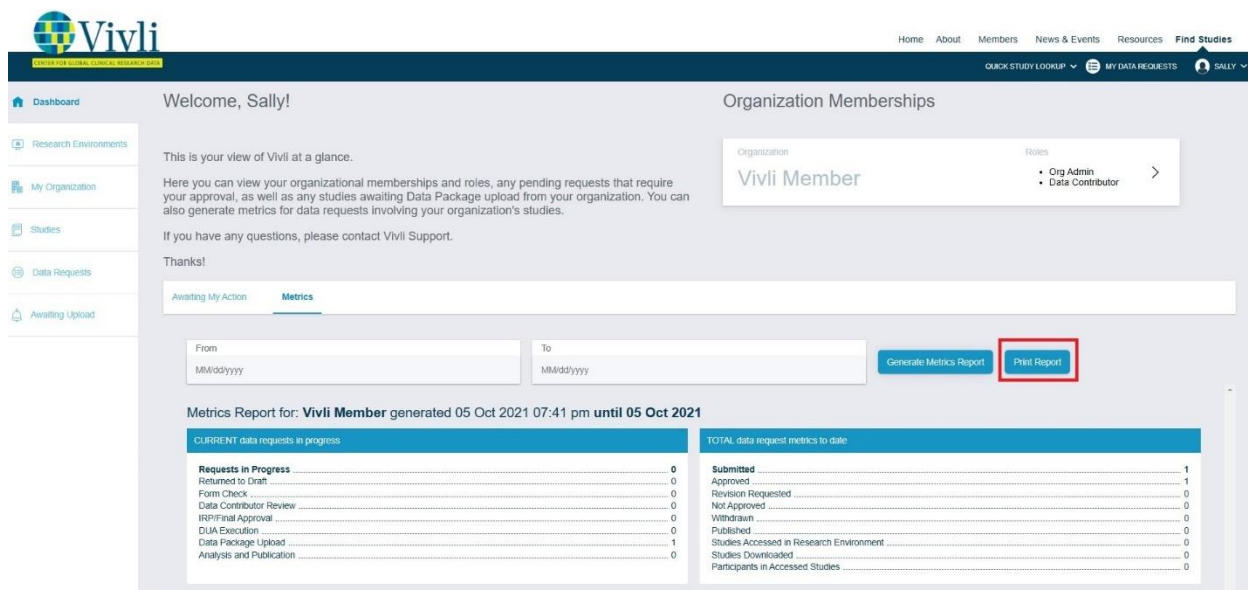
9. Metrics

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



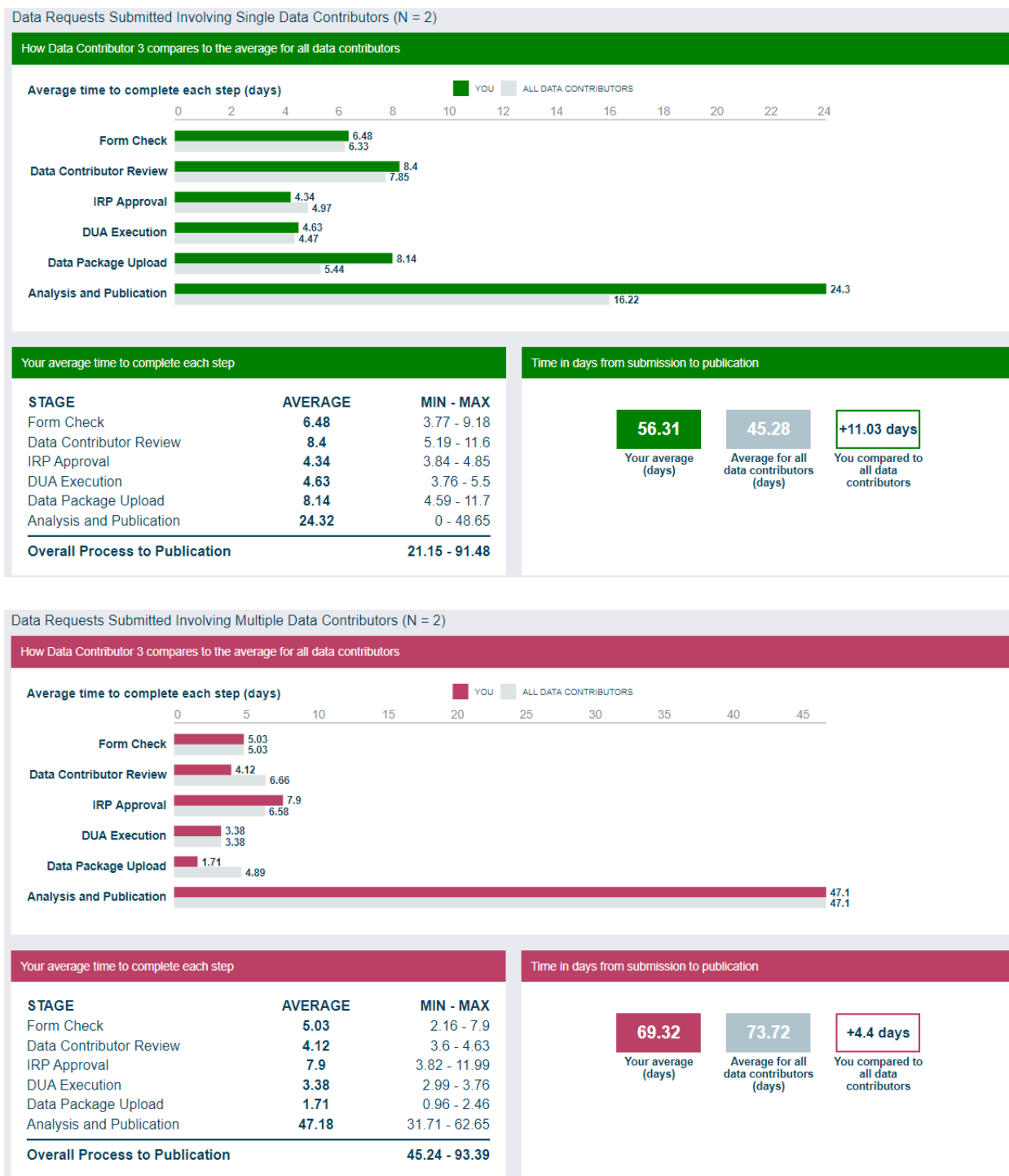
The screenshot shows the Vivli dashboard for a user named Sally. The left sidebar contains navigation links: Dashboard (highlighted with a red box), Research Environments, My Organization, Studies, Data Requests, and Awaiting Upload. The main content area is titled 'Welcome, Sally!' and 'Organization Memberships'. It includes a 'Metrics' tab (highlighted with a red box) and a 'Generate Metrics Report' button (highlighted with a red box). Below the button are two date input fields labeled 'From' and 'To', both with the placeholder 'MM/dd/yyyy'.

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



The screenshot shows the Vivli dashboard for a user named Sally. The left sidebar contains navigation links: Dashboard, Research Environments, My Organization, Studies, Data Requests, and Awaiting Upload. The main content area is titled 'Welcome, Sally!' and 'Organization Memberships'. It includes a 'Metrics' tab (highlighted with a red box) and a 'Print Report' button (highlighted with a red box). Below the button are two date input fields labeled 'From' and 'To', both with the placeholder 'MM/dd/yyyy'. Below the date fields, the text 'Metrics Report for: Vivli Member generated 05 Oct 2021 07:41 pm until 05 Oct 2021' is displayed. The report is divided into two sections: 'CURRENT data requests in progress' and 'TOTAL data request metrics to date'. The 'CURRENT data requests in progress' section shows a list of requests with their status and count. The 'TOTAL data request metrics to date' section shows a list of metrics with their count.

CURRENT data requests in progress		TOTAL data request metrics to date	
Requests in Progress	0	Submitted	1
Returned to Draft	0	Approved	1
Form Check	0	Revision Requested	0
Data Contributor Review	0	Not Approved	0
Re-final Approval	0	Withdrawn	0
CUA Execution	0	Published	0
Data Package Upload	1	Studies Accessed in Research Environment	0
Analysis and Publication	0	Studies Downloaded	0
		Participants in Accessed Studies	0



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

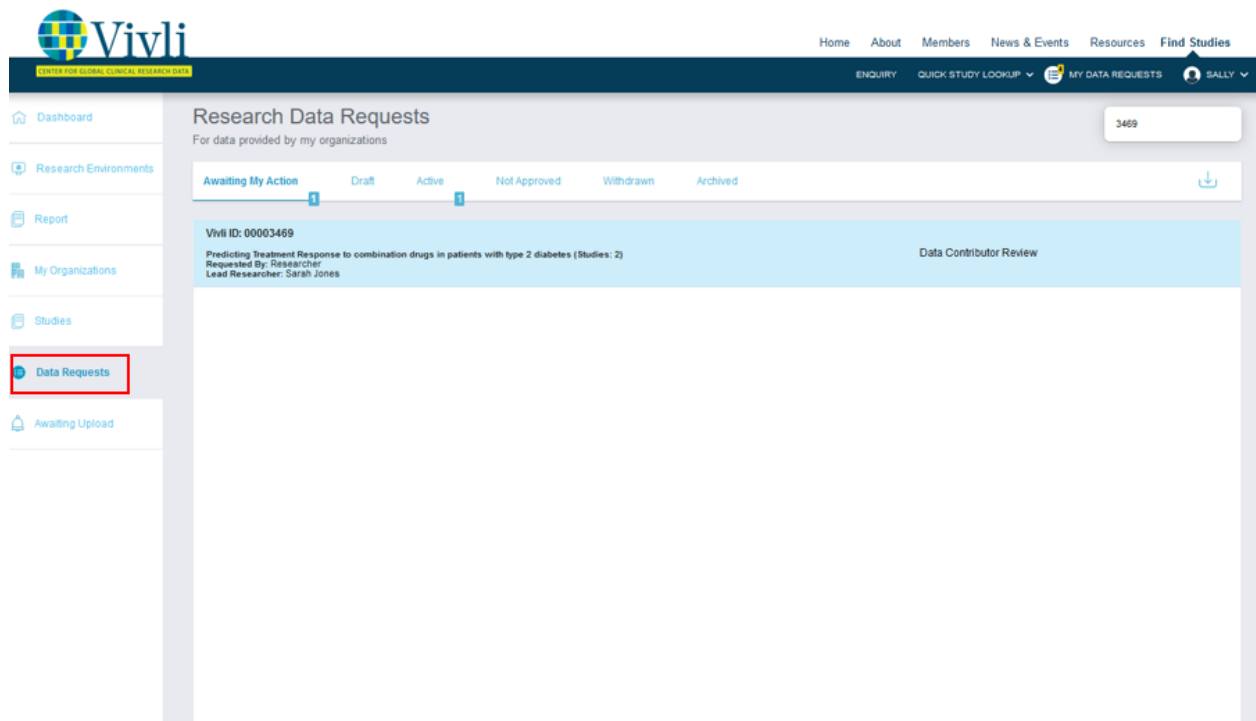
10. Communications

10.1 Chat

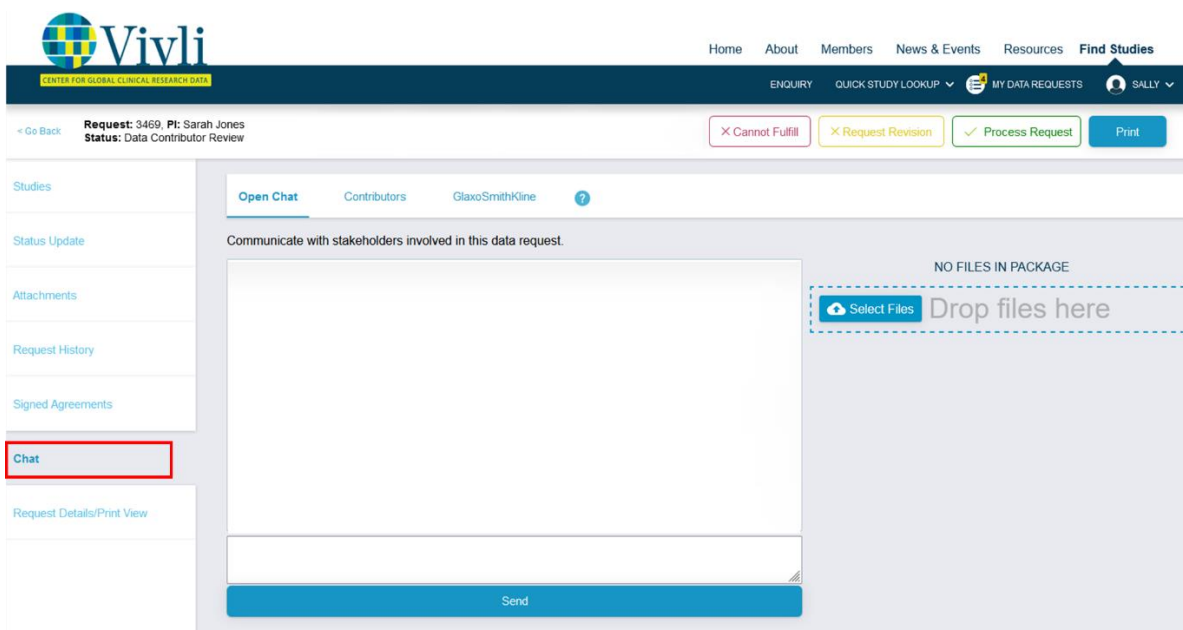
- You can use the **open chat** within the data request, to communicate with data requestors, the Vivli Administrators, members of your organization, delegated reviewers, and other data contributors associated with the specific request for your data.
- Please note that messages in the open chat are visible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

10.1.1 Open Chat

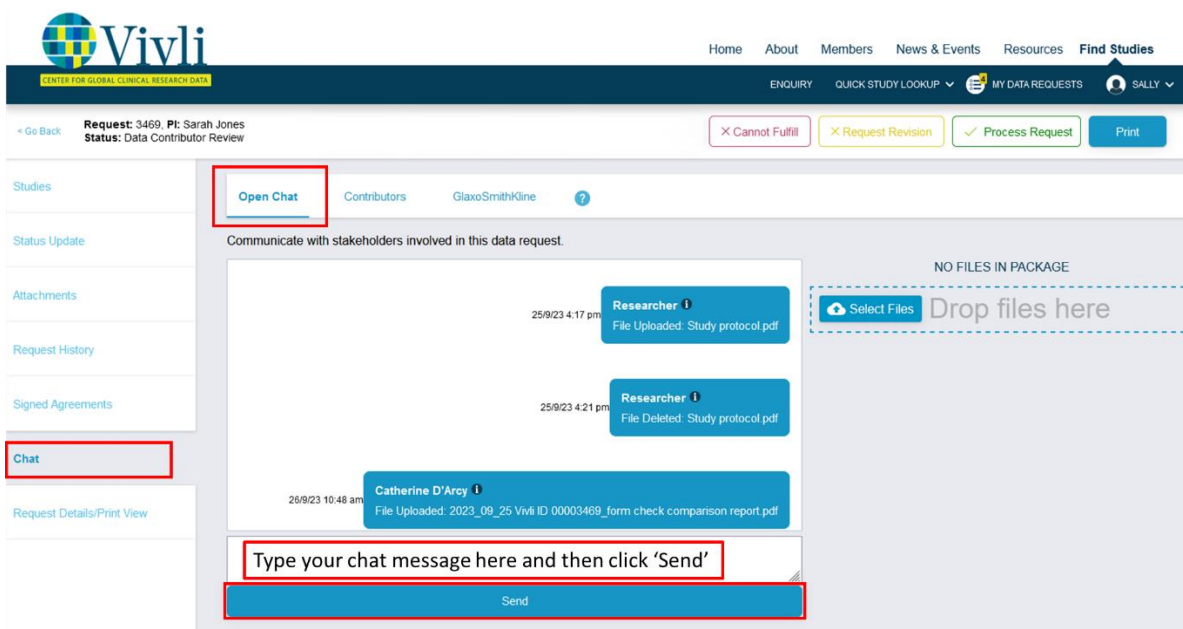
1. Log on to the platform:
2. Go to the **Data Request** tab:



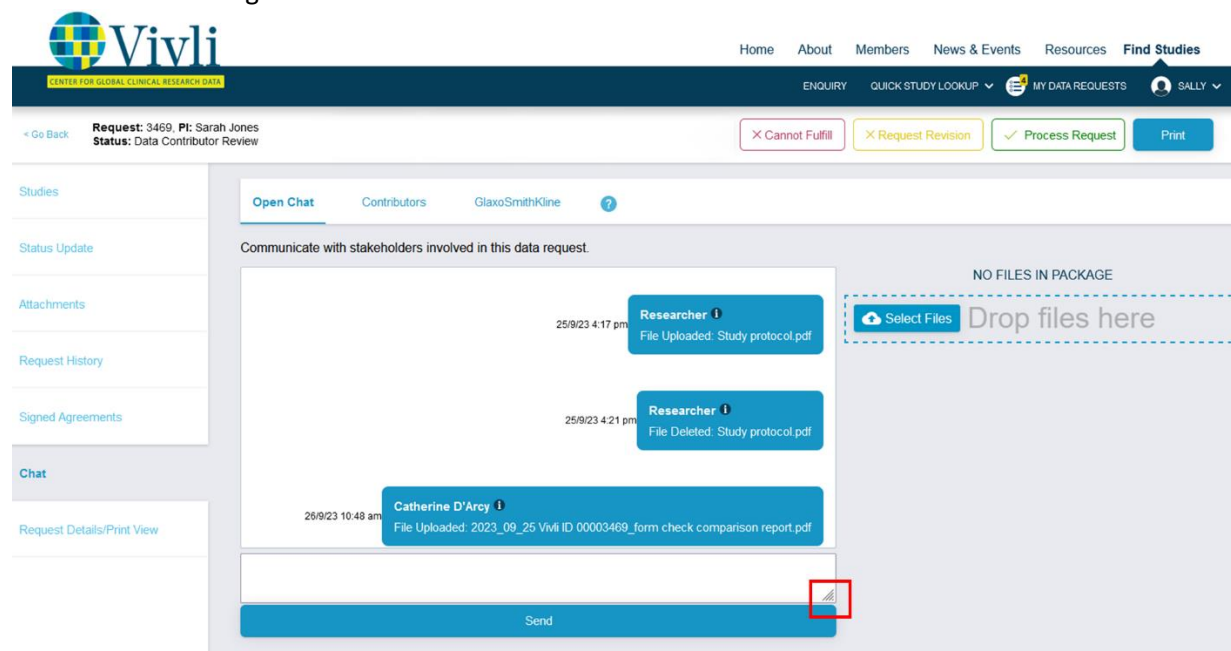
3. Open the applicable data request and click on the **Chat** tab on the left-hand side of the screen:



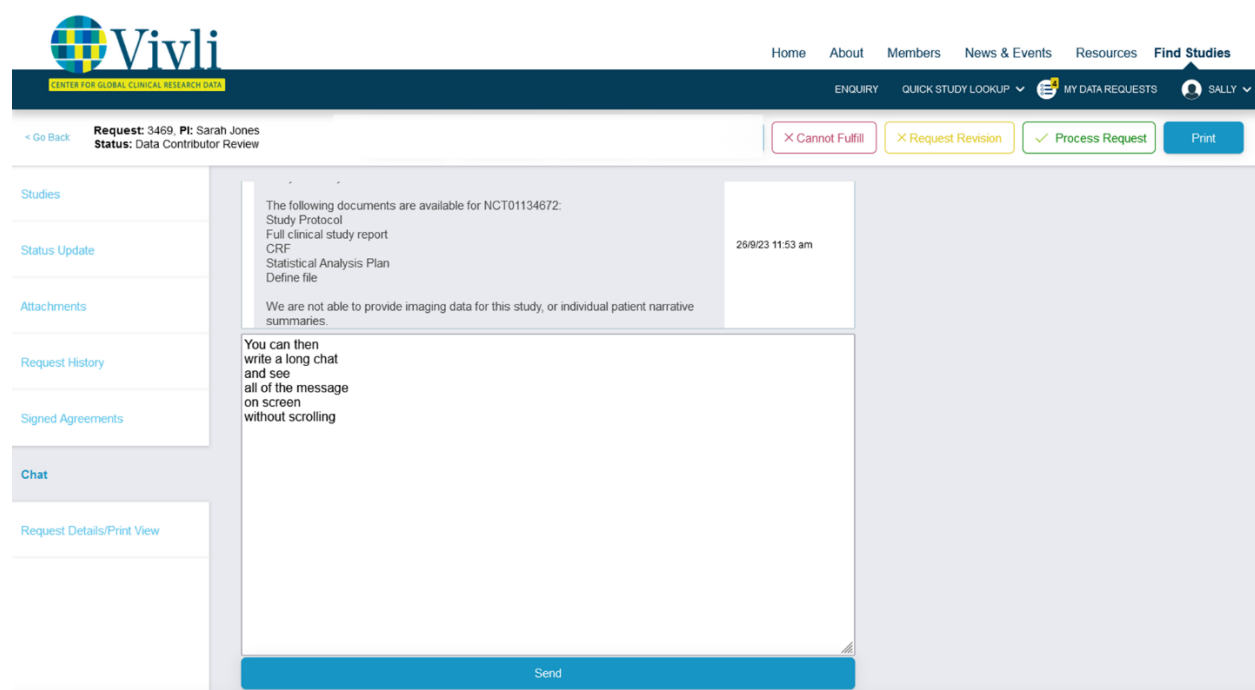
4. Enter your message in the chat message box under “Open chat” and click **Send**:



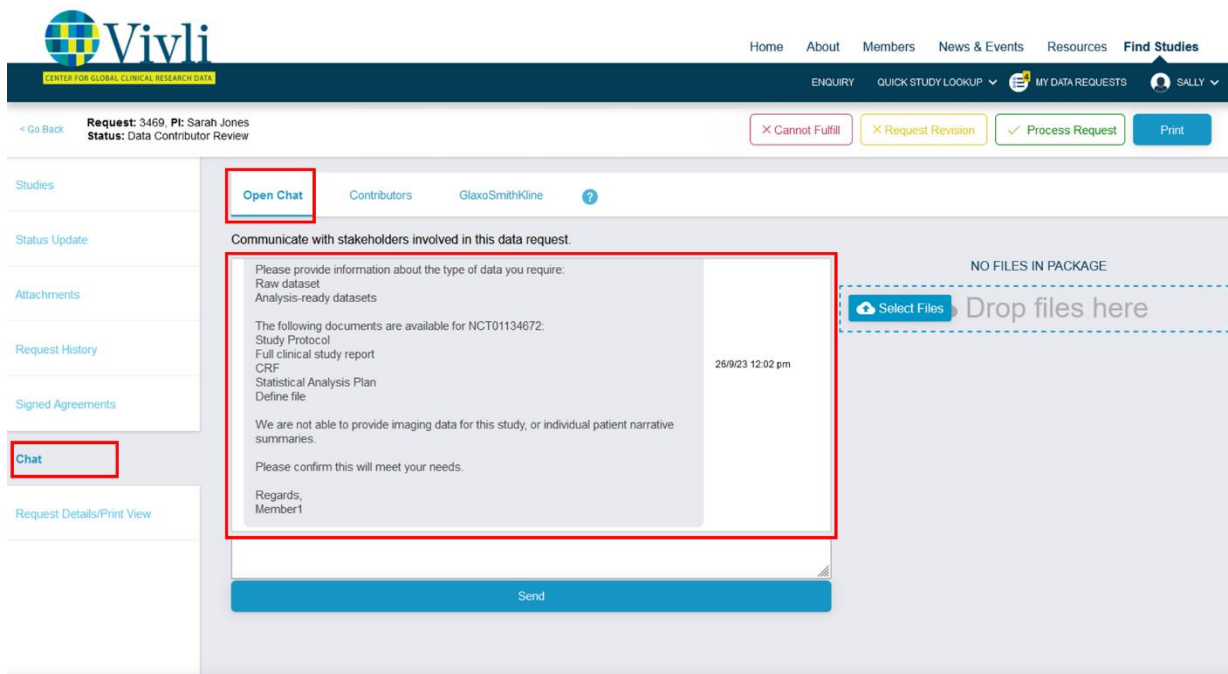
- In the chat window, there is a hash mark on the lower right of the text entry panel. Hover over it and the cursor changes to a double-headed arrow



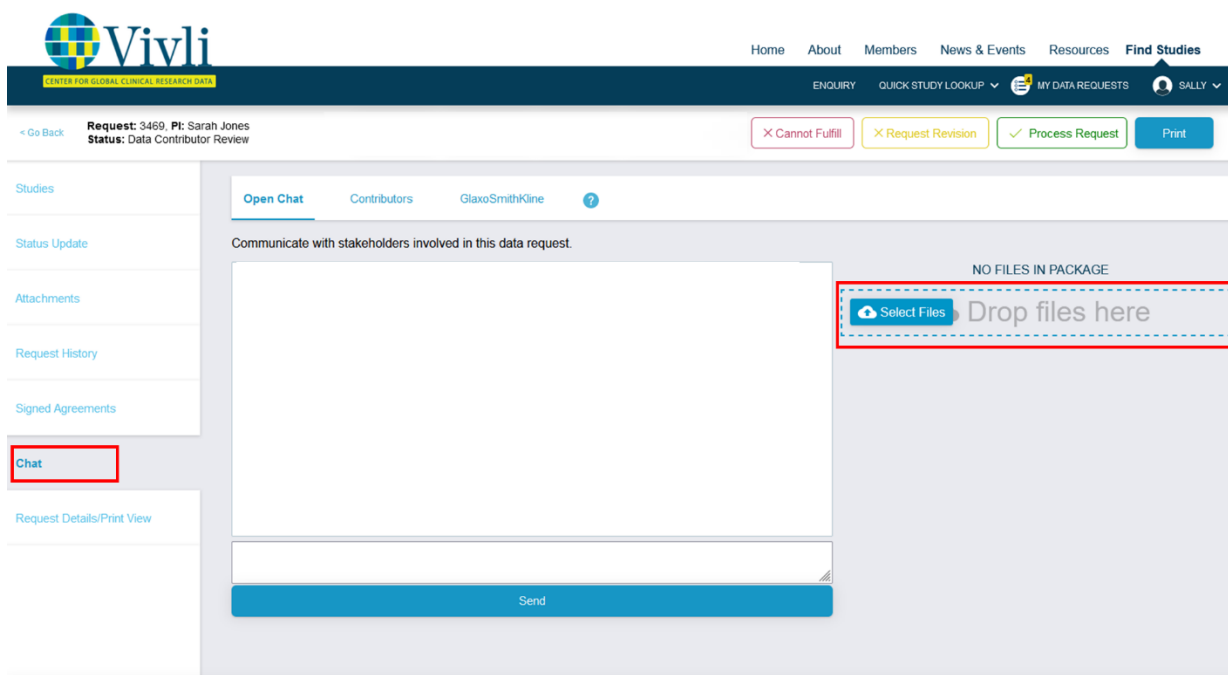
- Drag the arrow to enlarge the text entry area. Drag it off the edge of the screen to make it very large.



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



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



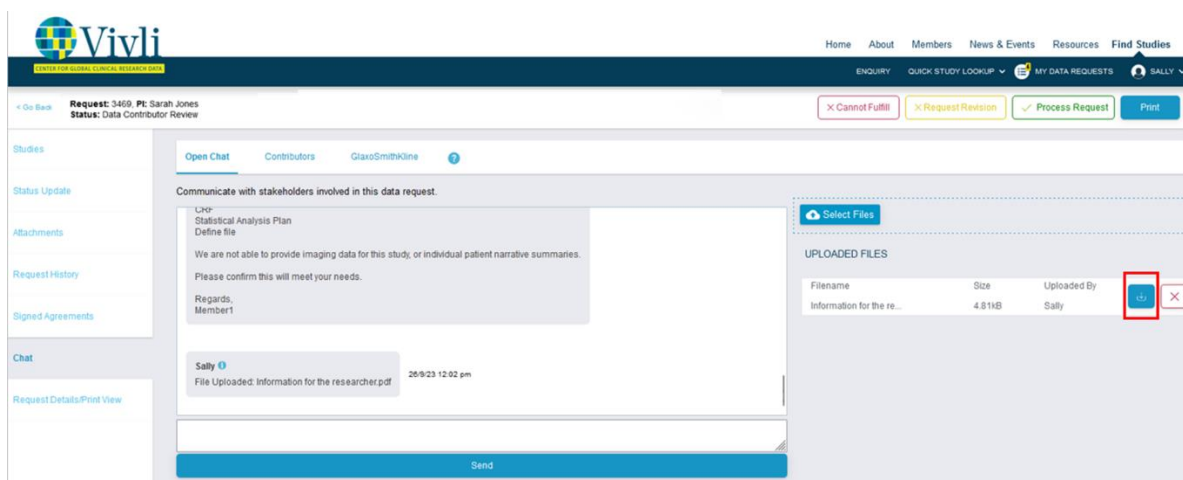
9. The upload bar will show the progress:

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. The user is logged in as SALLY. The main content area displays a chat window for a request (Request: 3469, PI: Sarah Jones, Status: Data Contributor Review). The chat window has tabs for Open Chat, Contributors, and GlaxoSmithKline. The chat area shows a message from the user: "We are not able to provide imaging data for this study, or individual patient narrative summaries. Please confirm this will meet your needs. Regards, Member1". The chat input field is empty, and the Send button is visible. On the right side of the chat window, there is a file upload section titled "NO FILES IN PACKAGE". It includes a "Select Files" button and a "Drop files here" area. Below this, there is a table of uploaded files. The table has columns for Filename, Size, and Uploaded By. The first row shows a file named "Information for the re..." with a size of 4.81kB, uploaded by Sally. The status of the upload is "Uploading", which is highlighted with a red box.

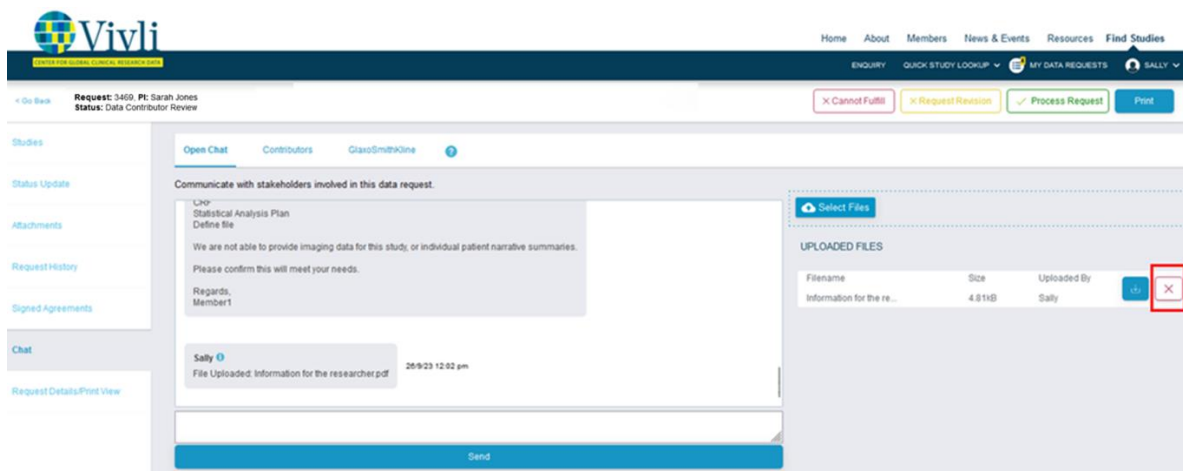
10. The history of the uploaded file will appear in the chat window:

The screenshot shows the Vivli web application interface, similar to the previous one, but with additional chat history. The chat window now shows a message from Sally: "File Uploaded: Information for the researcher pdf" with a timestamp of 26/9/23 12:02 pm. The chat input field is empty, and the Send button is visible. On the right side of the chat window, the file upload section is still present. The table of uploaded files now shows the file "Information for the re..." with a size of 4.81kB, uploaded by Sally. The status of the upload is "Uploading", which is highlighted with a red box. The chat window also shows a message from the user: "Define file. We are not able to provide imaging data for this study, or individual patient narrative summaries. Please confirm this will meet your needs. Regards, Member1".

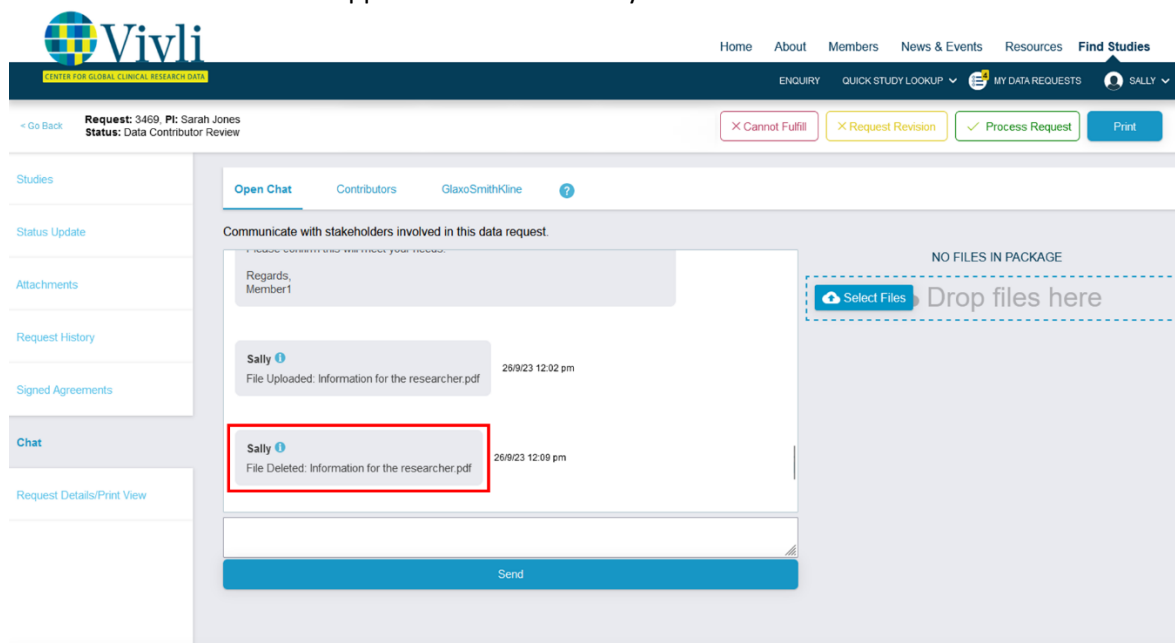
11. You may also download chat files by clicking on **Download**:



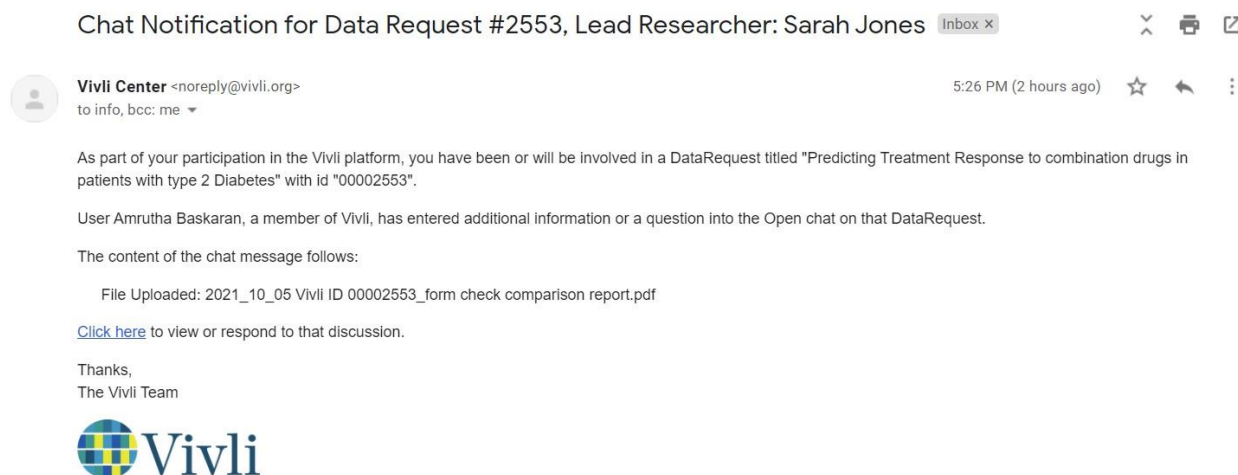
12. You can delete the uploaded file by clicking **delete**:



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



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

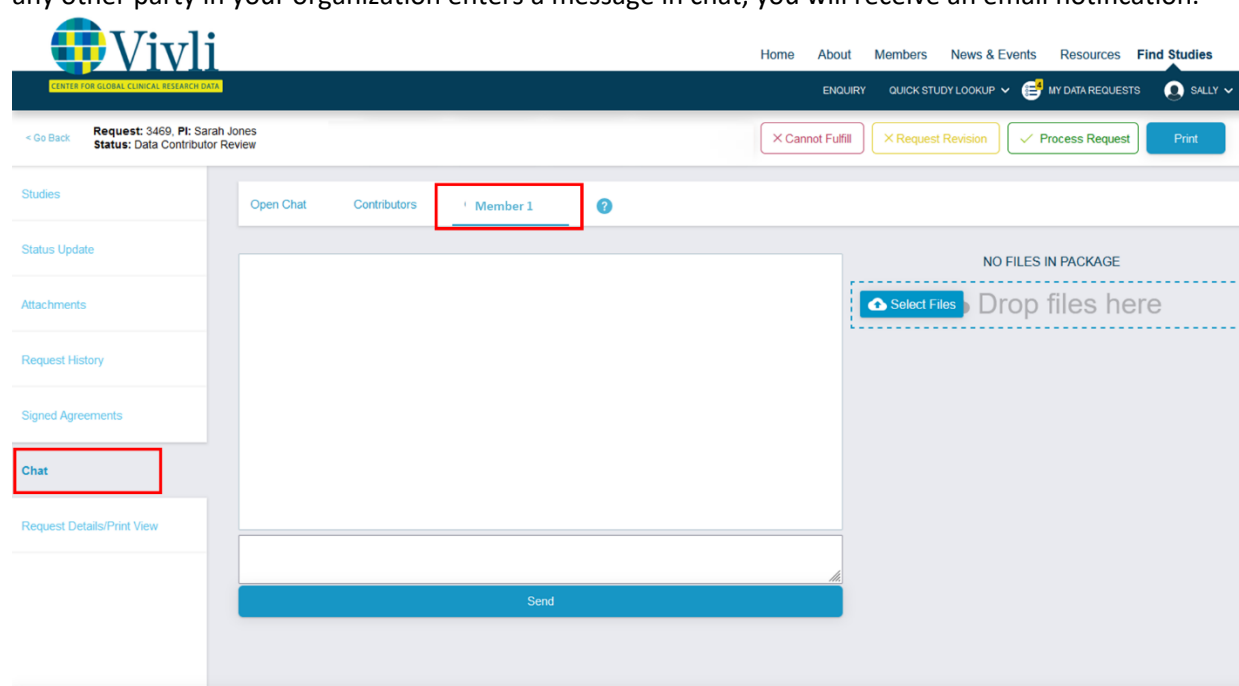


20. Note: Vivli Admins may set up automatic follow-ups for repeated follow-ups (E.g. revision, DUA, publication follow ups, etc.). Org Admins won't receive any there won't be any email notifications for such follow ups. Org Admins can see the chat messages on the chat window.

10.1.2 Private Chat

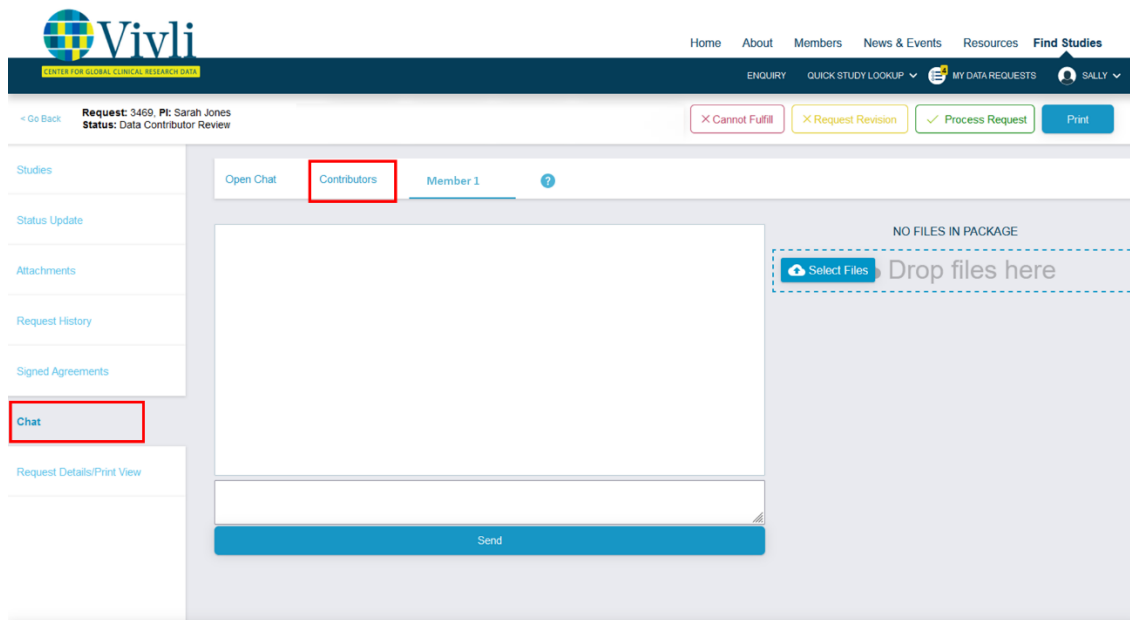
You may also open a private chat within the data request to communicate with other members of your organization.

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



10.1.3 Contributors Chat

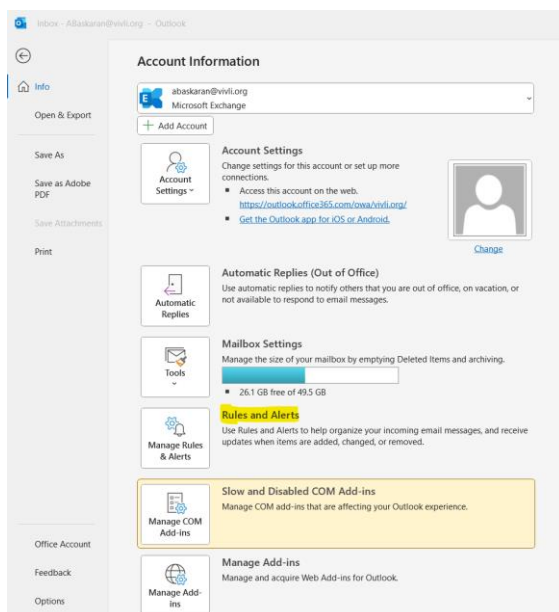
You may also open a Contributors chat within the data request to communicate with all the data contributors involved in the data request (but not the researcher). Organizational administrators will receive email notifications from this chat, but not those who have the Data Contributor role within an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



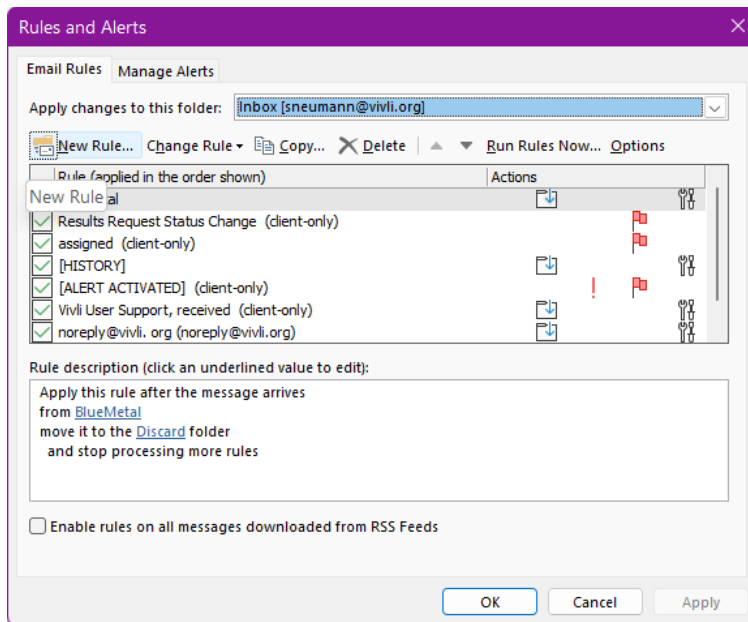
10.1.4 Setting up an inbox rule on Outlook to filter emails

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

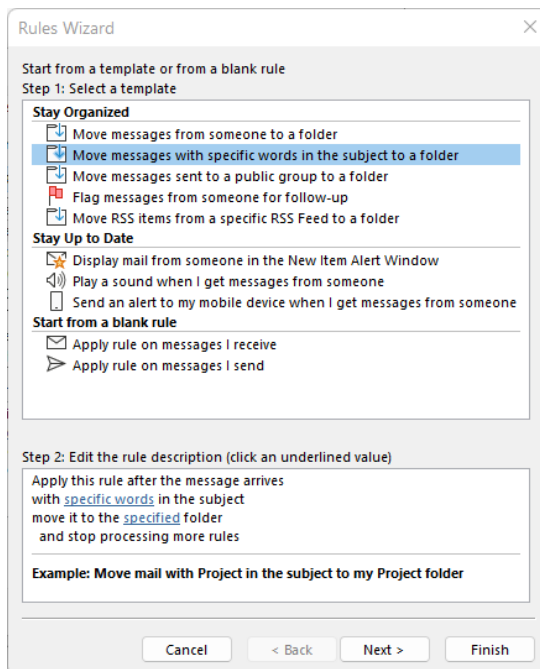
In Outlook, click File in the menu bar, then in the window that appears click on "Rules and Alerts"



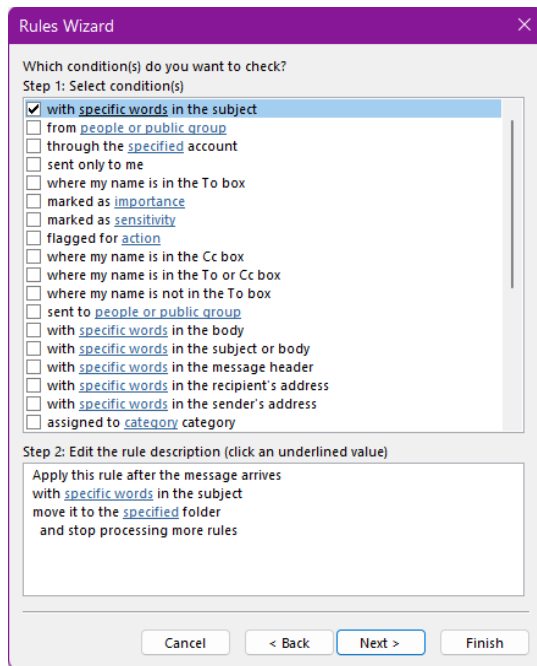
In the pop-up window, click New Rule:



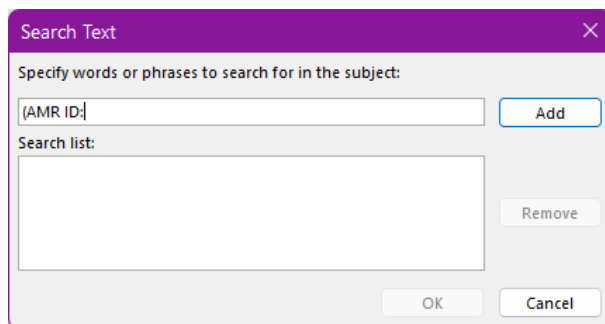
In the pop-up wizard, pick “Move messages with specific words in the subject to a folder”



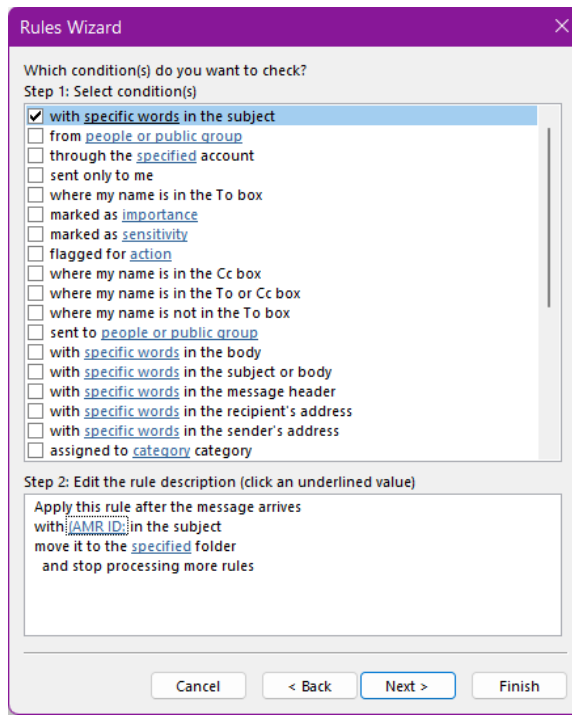
Click Next (it should display the choice “with specific words in the subject”),



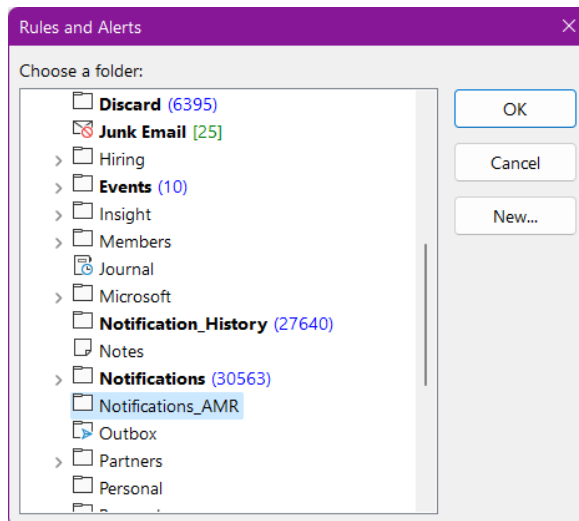
In the bottom half, click on “specific words” and enter “(AMR ID:” or “(Vivli:” or “(Chat Notification:”

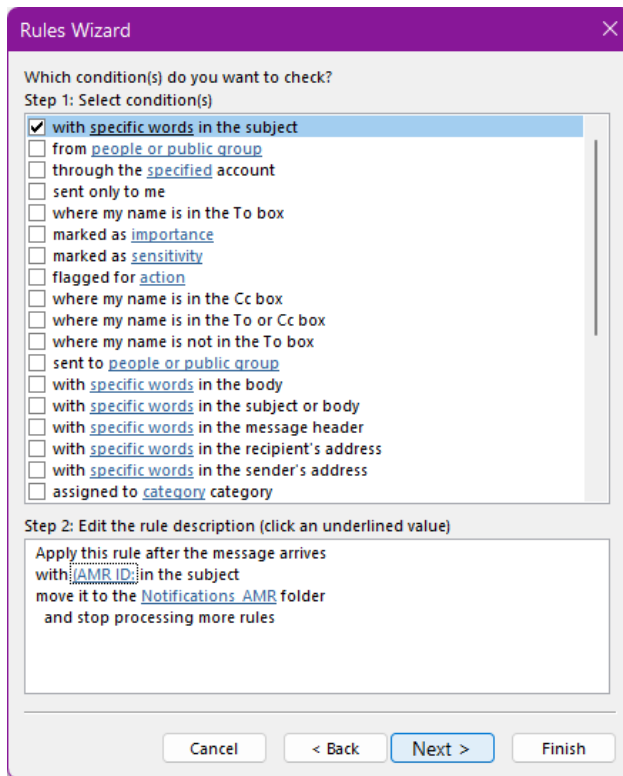


Click add to add it to the search list and then click OK:

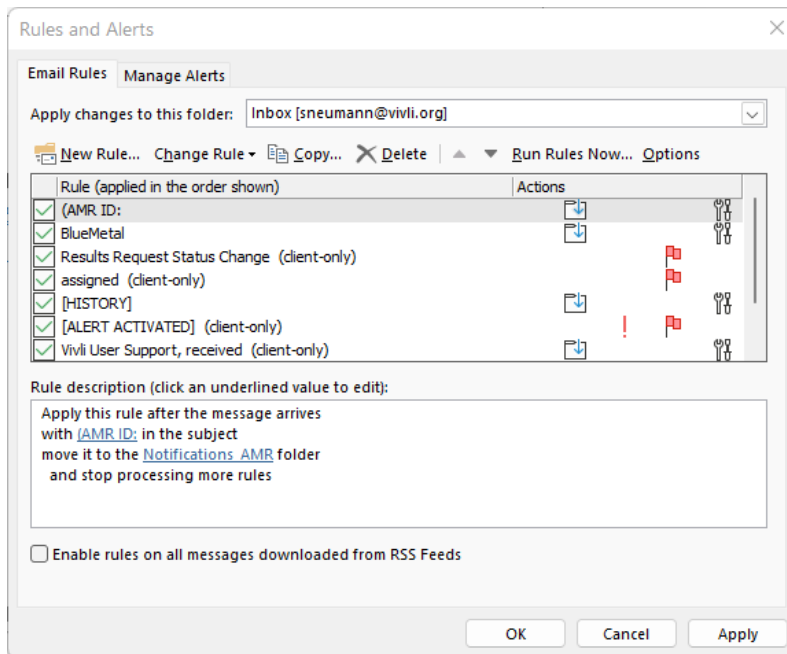


Back at the wizard, click on “specified” (as in ‘move it to the specified folder’); In the browse screen, select your destination folder and then click OK.





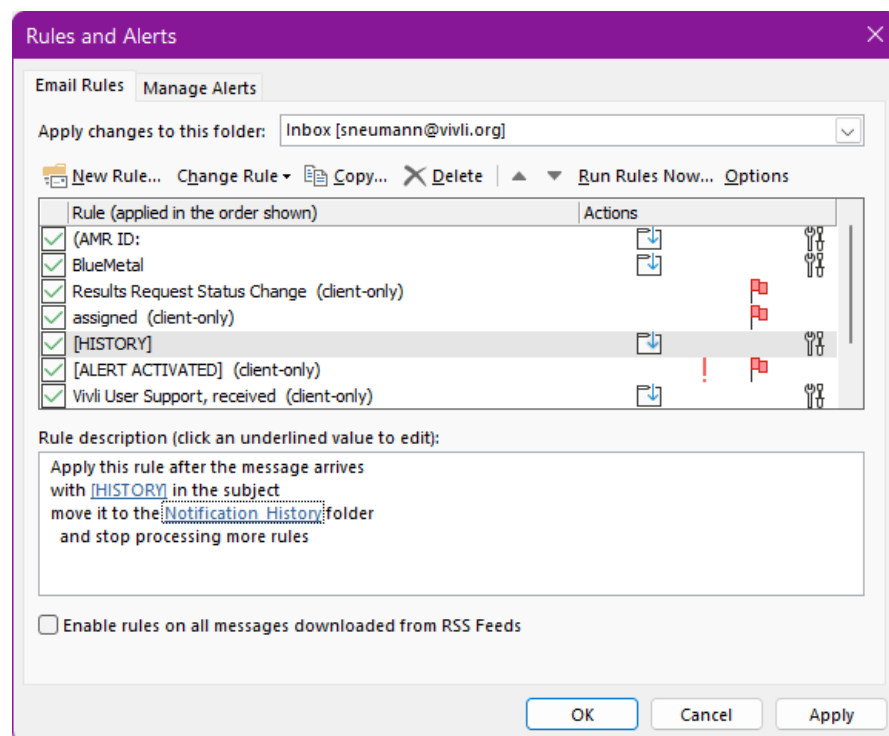
Click Finish and the rule should appear in the rule list:



Click OK to commit this.

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

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



10.2 Emails for Organizational Administrators

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

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

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

10.3 Data Request Summary to Organization Administrators

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

11. Support and Additional Information

11.1 Vivli Contact Information

Data Contributor User Support Contacts:

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

11.2 Data Use Agreement

The Vivli Data Use Agreement is posted online and available here: [Data Use Agreement](#)

11.3 Browser and System Requirements

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

11.4 Standard Process for Vivli-Member Engagement

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

12. Instructions for using a printed copy of this document

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

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

13. Document Information

Revision History			
Rev. #	Author	Summary of Changes	Date
1.0	Jessica Baker	Initial Version	July 10, 2018
1.1	Jessica Baker	Incorporates updates from Vivli release 1.2 including updated chat and DUA platform process	October 25, 2018
1.2	Amrutha Baskaran	<ol style="list-style-type: none"> Updated Section 1.2 – Creating your Vivli Account Updated Section 1.3.2 – Adding members Updated Section 3.3.1- Sending the Request to a Delegate Added Section 5.0 - Research Environment Monitoring Added Section 9.1.3 – Contributors chat 	March 19, 2019
1.3	Amrutha Baskaran	<ol style="list-style-type: none"> Updated Section 1.2 Creating your Vivli account about updating the member checklist Updated Section 1.3.2 Adding Team members Updated Section 1.3.3 Data Contributor Organizational Roles Updated Section 3.1 Reviewing Data Requests- Overview Updated Section 3.2.1 Navigation to Data requests Added Section 3.2.2 Data Request Dashboard – Search Feature Updated Section 3.3 Recording a Decision about a Data Request Added Section 4.1 Vivli Dashboard for Data Contributors Updated Section 4.2 Notification Updated Section 4.3 Loading Data package Added Section 4.3.2 Make Data Package Available Updated Section 6.0 Public Disclosures & Publications Updated Section 9.2 Emails for Organizational Administrators 	December 13, 2019
1.5	Liz Graham	<ol style="list-style-type: none"> Added Section 1.3.3 Organizational Administrator Resources Added Section 2.5 Study Enquiry process Updated Section 3.2.2 Data Request dashboard – Search Feature Updated Section 3.2.3 Reviewing Requests Updated Section 3.3.3 Request Revision Updated Section 3.3.5 Major versus minor revisions to data requests Added Section 3.3.6 Withdrawal process for non-response requests Added Section 5.1 Software on the Research Environment Updated 9.1.1 Steps, creating a chat message Updated 9.2 Emails for Organizational Administrators <p>Note: version 1.4 skipped to align with platform releases to avoid confusion</p>	March 13, 2020
1.6	Liz Graham	<ol style="list-style-type: none"> Metrics--updated screenshots to reflect updated version Updated process section 3.3.5 major and minor edits Updated Section 4.3.1 Steps, Uploading Data Package Added section 4.3.2 Steps, Download files that the Data Contributor previously uploaded Updated Section 9.1.1 Steps, creating a chat message Updated Section 9.2 Emails for Organizational Administrators 	July 11, 2022

1.7	Liz Graham	<ol style="list-style-type: none"> Updated 3.2.1. Navigating to Data Requests Updated Section 3.2.2. Data Request Dashboard with “Awaiting My Action” dashboard updates. Updated Section 3.2.3. Reviewing Requests with Data Requests overlapping title user interface updated Removed Section 3.3.1. Sending the request to a Delegate Updated Section 4.1. Vivli Dashboard for Data Contributors with “Awaiting my Action” dashboard updates. Section 4.3.1. Steps, Make Data Package Available study list updates. Updated Section 4.3.2. Steps, Download files that the Data Contributor previously uploaded 	March 6, 2021
2.0	Amrutha Baskaran	<ol style="list-style-type: none"> Updated screenshots throughout the manual to reflect the updated version of the platform Added section 1.3.4 Active Platform Accounts Updated Section 2.5 Study Enquiry Process Added section 2.6 Supporting documents made available for researchers searching for studies Updated Section 3.2.1 Navigating to Data Requests Updated Section 3.2.3 Reviewing Requests Updated Section 3.3.5 Withdrawal process Added Section 3.3.6 Target timeline for the review process Added Section 4.3 General upload guidelines Added Section 4.3.1 Zip archive process Updated Section 4.4.1 Steps: Uploading Data Package to an approved request Updated Section 6.2 Publication Notification by Data Requestor Added Section 9.3 Weekly summary to Organization Administrators 	October 9, 2021
2.2	Amrutha Baskaran	<ol style="list-style-type: none"> Updated Section 3.2.3 Data Request form Updated Section 3.3.1 Cannot Fulfill Added Section 3.4 Report of data requests Added Section 3.4.1. Features of the report Added Section 3.4.2. Fields included in the report Added Section 3.4.3. Status Update Updated Section 4.4.5 Steps: Upload a New Version of the Data Package Added Section 7.DUA extension Updated Section 10.1.1 Steps, creating a chat message Updated Section 10.3 Weekly summary to Organization Administrators Added Section 11.4 Standard process for Vivli-Member Engagement 	August 29, 2022
3.0	Amrutha Baskaran	<ol style="list-style-type: none"> Added Section 3.2.4 Vivli Policies in Brief Updated Section 3.3.1 Cannot Fulfill Updated Section 4.2 Data Upload Notification Updated Section 10.1.1 Open Chat Added Section 10.1.4 Setting up an inbox rule on Outlook to filter emails 	January 19, 2023
3.1	Amrutha Baskaran	<ol style="list-style-type: none"> Added Section 3.3 Study settings at Data Contributor Review Added Section 3.3.7 Summary level and document-only data request Updated Section 3.4.3. Status Update 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	<ol style="list-style-type: none"> Updated Section 3.2.3 Data Request Form Updated Section 3.3 Study setting at Data Contributor Review Updated Section 3.4 Recording a Decision about a Data Request Updated Section 3.5 Report of data requests Updated Section 10.1 Chat 	September 26, 2023
3.3	Amrutha Baskaran, Catherine D'Arcy, Sarah Sweet, Elizabeth Graham	<ol style="list-style-type: none"> Updated Section 2.6 Supporting documents made available for researchers searching for studies Updated Section 2.7 Study Usage and Public Disclosure Metrics Updated Section 3.4.4 Major versus minor revisions to data requests Updated Section 3.5 Report of data requests Updated Section 3.5.2. Fields included in the report Updated Section 4.4.1 Steps: Uploading Data Package to an approved request Updated Section 4.4.3 Steps: Uploading data while request undergoing review Updated Section 4.4.4 Studies list and stored data package Added Section 4.4.6 Uploading large files and data packages to the Vivli Platform Updated Section 10.1.1 Open Chat Updated Section 10.2 Emails for Organizational Administrators 	February 1, 2024

Approval History			
Name	Job Title	Date Approved	Effective Date
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Rebecca Li	Executive Director	March 20, 2019	
Version 1.3			December 14, 2019
Rebecca Li	Executive Director	December 13, 2019	
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Rebecca Li	Skipped to align with the platform version	n/a	
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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	
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Rebecca Li	Executive Director	October 8, 2021	
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Rebecca Li	Executive Director	January 18, 2023	
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Version 3.3			February 10, 2024
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