



Vivli Data Contributor Guide  
For Vivli Platform Version 3.7  
24 May 2025

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## 1. Vivli Accounts for Members

### 1.1 Onboarding

- After your organization joins Vivli as a member, the Vivli team will begin your onboarding.
- The Vivli team will send you a draft member's page to complete.
- The Vivli team will provide you with metadata sheets to fill out as part of the onboarding process. Please see [Section 2 Listing Studies – Process and Options](#) for more information.
- The Vivli team will send you a copy of the member checklist which defines your data request review process and how your Organization should be set up on the Vivli platform.
- You will designate a person or persons within your organization to act as the Organization Administrator(s) on the Vivli platform. See [Section 1.3.3 Organization Roles](#) below for more information about the Organization Administrator's role. The Organization Administrator will create a Vivli account on the platform. The Vivli team will provide your designated Organization Administrator(s) with appropriate rights on the Vivli platform.
- The Vivli team will also provide training on reviewing the data request, recording the decision on the Vivli platform, and uploading the data package for studies approved in the data request.
- The Vivli team will also send you the Data Contributor guide. Please see [Section 1.3.6 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 1.0 of the [User Quick Start Guide](#) for the sign-up process.
- Before you create your account, please review our [Browser and System Requirements](#).
- If you have any issues creating your account, contact [support@vivli.org](mailto:support@vivli.org).
- Once you create your account, inform the Vivli team so that they can add you to your organization.
- During onboarding, Vivli Admin will assign you the roles based on your member checklist.
- After onboarding, if there are any changes to your team members or their roles, please inform the Vivli team at [support@vivli.org](mailto:support@vivli.org) along with an updated member checklist so that the Vivli team can provide appropriate training for new team members or remove access to team members who have left the organization.

### 1.3 Vivli Dashboard for Organizational Administrators

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

The screenshot shows the Vivli dashboard for user Karen Asada. The top navigation bar includes links for Home, About, Members, News & Events, Resources, Portals, and Find Studies. Below this is a secondary bar with ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and a user profile for KAREN ASADA. The left sidebar contains a list of dashboard tabs: Dashboard (highlighted with a red box), Data Requests, Enquiries, Studies, Awaiting Upload, Report, Research Environments, My Organizations, and Users. The main content area is titled 'Welcome, Karen Asada!' and contains a welcome message, a link to 'Organization Memberships' (highlighted with a red box), and a section for 'Data Requests Awaiting My Approval' (highlighted with a red box). This section displays a table with columns for Vivli ID, Amrutha workflow test 1/00 (Studies: 3), Requested By: Richard Anderson, Lead Researcher: Amrutha Baskaran, and At least one Data Package Provided and Available.

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

- Dashboard - you can view the Organization that you are part of and your roles as part of your organization.
- Data requests - you can view data requests for studies from your organization
- Enquiries - you can view the Enquiries for studies from your organization
- Studies - you can view the studies listed on the platform by your organization
- Awaiting upload - you can view the list of studies from your organization waiting for data upload (they are studies that were part of the approved data request)
- Report - you can view several reports related to Data requests, Enquiries and Studies.
- Research Environment - you can view the number of Research Environments being used for analysis for approved data requests from your organization
- My Organizations – you can view the set of your Organization and team members
- Users – you can view all Vivli users from your organization

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

The screenshot shows the Vivli dashboard for user Karen Asada. The top navigation bar includes links for Home, About, Members, News & Events, Resources, Portals, and Find Studies. The user's name, KAREN ASADA, is displayed in the top right corner with a dropdown arrow. The left sidebar contains a navigation menu with items: Dashboard, Data Requests, Enquiries, Studies, Awaiting Upload, Report, Research Environments, My Organizations, and Users. The main content area displays a welcome message, organization memberships for AbbVie (roles: Org Admin, Data Contributor), and data requests awaiting approval. A red box highlights the left sidebar navigation menu, and another red box highlights the user profile dropdown menu in the top right corner.

### 1.3.1 My Organizations tab

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

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

The screenshot shows the Vivli 'My Organizations' page for BioSciences, Inc. The top navigation bar includes links for Home, About, Members, News & Events, Resources, Portals, and Find Studies. The user's name, AMRUTHA, is displayed in the top right corner with a dropdown arrow. The left sidebar contains a navigation menu with items: Dashboard, Data Requests, Enquiries, Studies, Awaiting Upload, Report, Research Environments, My Organizations, and Users. The main content area displays details for BioSciences, Inc., including its name, country, domain, and code. A red box highlights the 'My Organizations' tab in the left sidebar, and another red box highlights the 'My Organizations' option in the user profile dropdown menu in the top right corner.

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

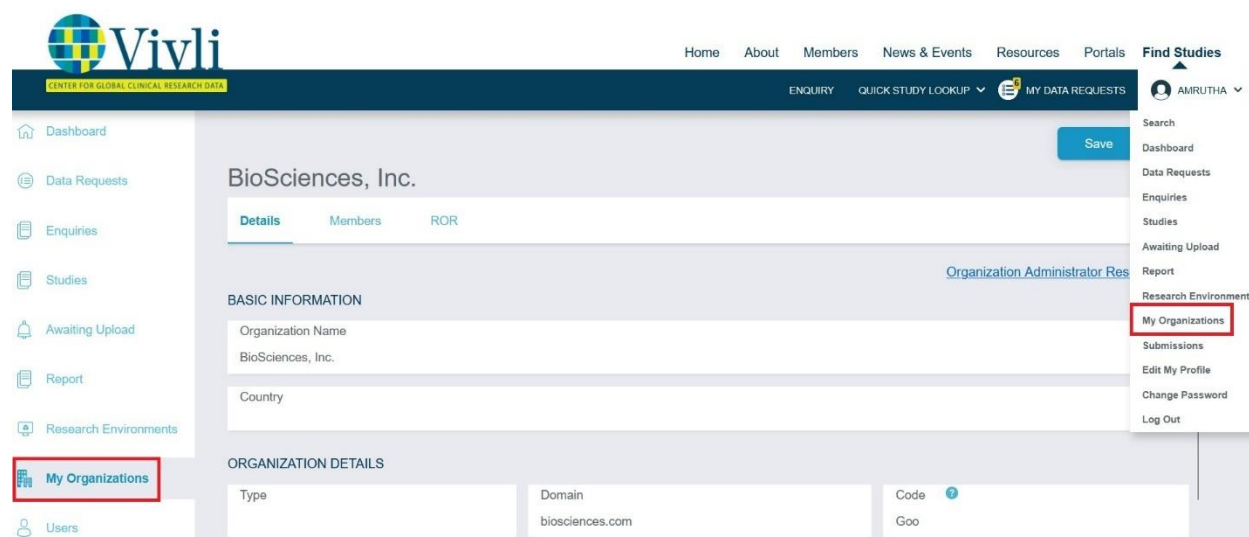
The screenshot shows the 'BioSciences, Inc.' organization details page. At the top right are 'Save' and 'Cancel' buttons. Below the organization name is a tab bar with 'Details' (highlighted with a red box), 'Members', and 'ROR'. To the right of the tabs is a link for 'Organization Administrator Resources'. The 'BASIC INFORMATION' section contains fields for 'Organization Name' (BioSciences, Inc.) and 'Country'. The 'ORGANIZATION DETAILS' section contains fields for 'Type', 'Domain' (biosciences.com), 'Code' (Goo), and 'Organization/Platform URL for Requesting Studies'.

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

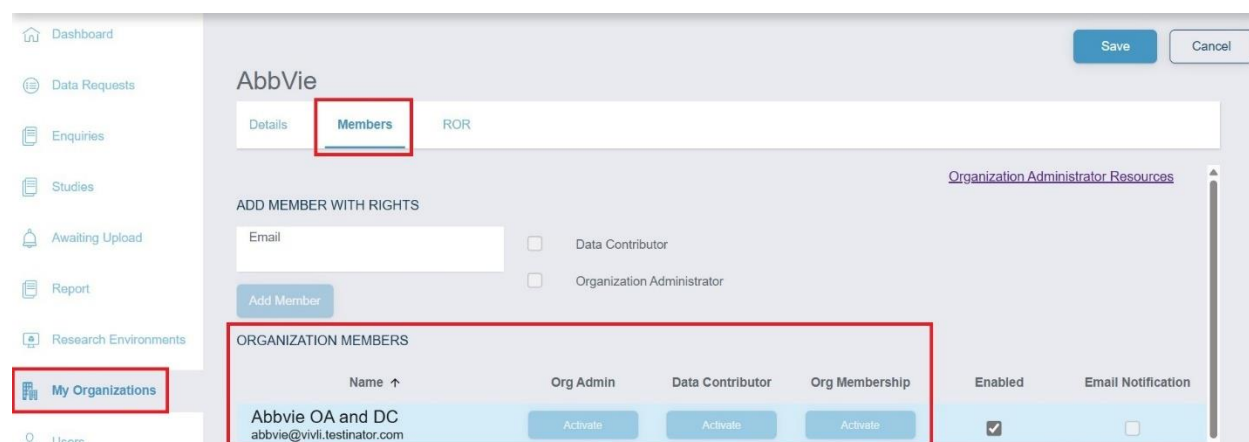
The screenshot shows the 'AbbVie' organization ROR information page. On the left is a sidebar with navigation links: Dashboard, Data Requests, Enquiries, Studies, Awaiting Upload, Report, Research Environments, My Organizations (highlighted with a red box), and Users. The main content area has a tab bar with 'Details', 'Members', and 'ROR' (highlighted with a red box). Below the tabs is a section titled 'ROR INFORMATION' (highlighted with a red box) containing fields for 'Ror Name' (AbbVie (United States)), 'Ror ID' (<https://ror.org/02g5p4n58>), 'Ror Parent Name', and 'Ror Parent ID'. 'Save' and 'Cancel' buttons are at the top right.

### 1.3.2 Team Members

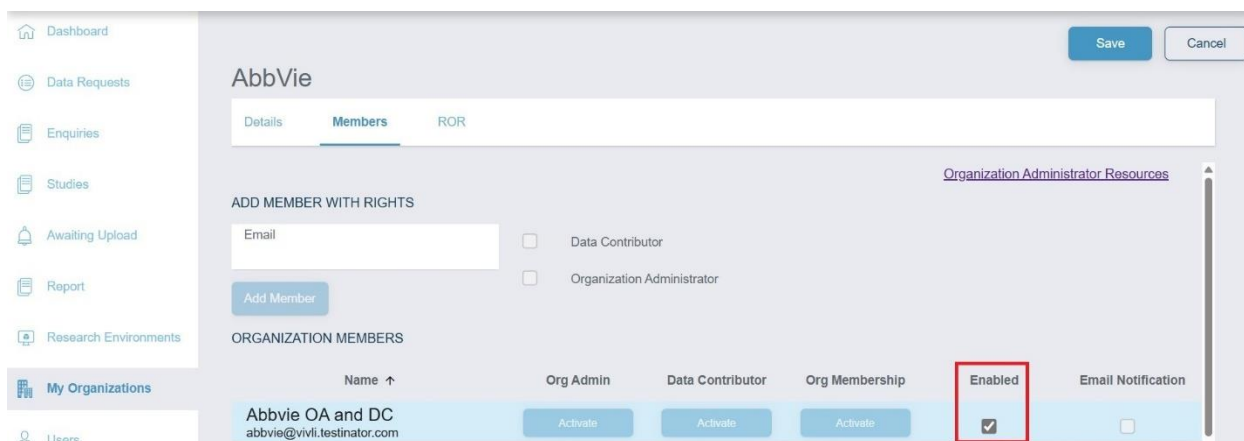
- To add team members, ask them to become a user by signing up for the Vivli platform and guide them to section 1.0 of the [User Quick Start Guide](#) for the sign-up process. Note: the team members cannot be added to your organization until they have created a Vivli User Account.
- You may view the Team Member(s) information (view-only) in the 'Members' tab. Click on '**My Organizations**' tab on the left-hand side of the screen, or navigate to '**My Organizations**' using the dropdown toolbar in the upper right-hand corner of the screen:



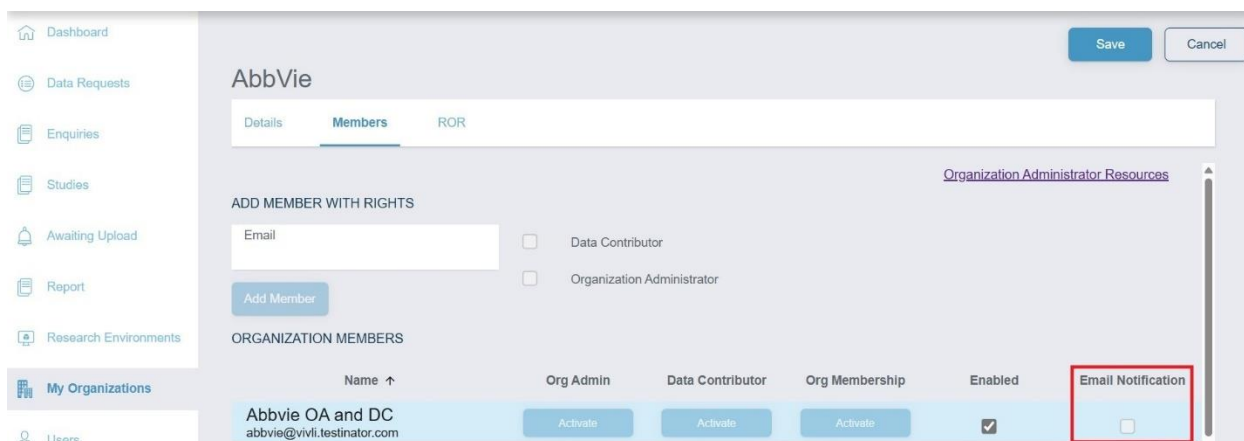
- Once the team member creates an account, the team member's information and roles can be located under the 'Members' field.



- To change the Organization Administrator or Data Contributor rights for your team member, please update the member checklist and contact the Vivli team at [support@vivli.org](mailto:support@vivli.org) so that they can provide training to the new team member, and give them access to the platform.
- If the team member's account is active, the 'Enabled' checkbox will be checked next to their name. Team members whose user account is disabled will not show up in the list under 'My Organization'. However, they will be visible under the 'User' tab. For more information, please see [Section 1.3.4. User Tab](#)



- All team members with the Organization Administrator role are designed to receive email notifications. The Email Notification checkbox is checked by default. If unchecked, the team member will stop receiving all emails moving forward. This is applicable only for the Organization Administrator role and not for other roles. If you want to stop receiving email notifications from the platform, please contact Vivli team at [support@vivli.org](mailto:support@vivli.org).



### 1.3.3 Organizational Roles

- A member of an Organization may be assigned multiple roles.
  - Each role may have more than one member from your Organization associated with it.
  - Additional team members from your organization may also join Vivli as users.
    - Those without any roles can set up a Vivli account but initially will only be able to request studies.
- Those accounts will also be listed under your 'Members' tab and also show up in the 'Users' List. For more information, please see [Section 1.3.4. User Tab](#)

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

Vivli Member Role	Description	Rights & Responsibilities
<b>Organizational Administrator(s)</b>	<ul style="list-style-type: none"> <li>• Main institutional contact(s) for operations on the Vivli platform.</li> <li>• Responsible for recording decisions.</li> </ul>	<ul style="list-style-type: none"> <li>• May view your organization's team members</li> <li>• View the data request(s) and record the decisions for an Organization</li> <li>• Options are to approve a request, deny a request, or ask for revisions to the data request form.</li> <li>• Receive and respond to chat messages within the data request.</li> <li>• Access the research environment and Report tabs on the Dashboard</li> <li>• View and record decisions for Enquiries</li> </ul>
<b>Data Contributor(s)</b>	<ul style="list-style-type: none"> <li>• Responsible for uploading data packages for approved requests, after the Data Requestor signs a Data Use Agreement</li> </ul>	<ul style="list-style-type: none"> <li>• Able to upload data packages for studies approved in a data request</li> <li>• Able to upload data packages for all studies at any time after the study is listed on the Vivli platform</li> </ul>
<b>No Role Assigned</b>	<ul style="list-style-type: none"> <li>• May log on to the Vivli platform as a user, but only to create data requests</li> </ul>	<ul style="list-style-type: none"> <li>• Will appear on your organizational members' listing under 'Members' tab</li> <li>• No administrative rights</li> </ul>

### 1.3.4 User Tab

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

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Portals Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS AMRUTHA

Dashboard Research Environments **Users** Report My Organization Studies Data Requests Submissions Awaiting Upload Enquiries

### User Management

Email Address	Name	Organizations	Account Status	Days Since Last Login
vivliautomation@gmail.com	anup (Vivli Admin)	• Biogen	Active	0
stan.neumann+reset12@gmail...	Stan Reset 12	• Biogen	Active	1186
sneumann@vivli.org	Stan Neumann (Vivli Admin)	• Biogen	Active	0
alex@stanneumann.com	Sally Researcher	No Organization	Active	901
VivTestQA+VivliAdmin@gmail.c...	QA Vivli Admin (Vivli Admin)	• Biogen	Active	304
VivTestQA+IRP-allOrgs@gmail...	QA -IRP All Orgs	• Biogen	Active	0
VivTestQA+DataRequester@g...	QA - Data Requester	• Biogen	Active	125
VivTestQA+DC-allOrgs@gmail...	QA - DC All Orgs	• Biogen	Active	0



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

< Go Back

User Details - Sally

Display Name: Sally  
Email: dataprovider.vivli@gmail.com  
Days Since Last Login: 2

Org Memberships

Name ↑	Org Admin	Curator	QA Reviewer	Data Contributor	IRP / Reviewer	Head Curator	Head QA Reviewer
AbbVie	Deactivate	N/A	N/A	Deactivate	N/A	N/A	N/A

- If the user from your Organization is part of your current data-sharing team, you can see the assigned roles for each team member. For more information, please see Section [1.3.2 Team Members](#)

< Go Back

User Details - Sally

Display Name: Sally  
Email: dataprovider.vivli@gmail.com  
Days Since Last Login: 2

Org Memberships

Name ↑	Org Admin	Curator	QA Reviewer	Data Contributor	IRP / Reviewer	Head Curator	Head QA Reviewer
AbbVie	Deactivate	N/A	N/A	Deactivate	N/A	N/A	N/A

- If the user from your Organization was previously part of your data-sharing team, you won't see any assigned role in your Organization. They are unable to take action on behalf of your Organization. Their Organization membership will be removed and will show as 'No Organization' on your view and their account will be disabled once they leave the data-sharing team. However, you can still see that historical information.

[< Go Back](#)

User Details - Amrutha

Display Name: Amrutha  
Email: amru.idly@gmail.com  
Days Since Last Login: 30

Org Memberships

Name ↑	Org Admin	Curator	QA Reviewer	Data Contributor	IRP / Reviewer	Head Curator	Head QA Reviewer
AbbVie	<button>Activate</button>	N/A	N/A	<button>Activate</button>	N/A	N/A	N/A

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

User Details - Amrutha

Associated Data Requests

Request Title	Request Id	Stage	Role
Evaluation of Differences in Trial and ...	00048506	Data Upload	• Additional Researcher
Amrutha 10785 Bug test	00048229	Vivli Form Check	• Admin • Requester
Cardiovascular outcomes in patients w...	00048053	IRP Review	• Additional Researcher
Stroke Outcomes in patients with Atria...	00048010	Data Upload	• Additional Researcher

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

Associated Enquiries					
Enquiry ID	Institution	Status	Date Submitted	Drafted	# of Studies
14	Rensselaer	Draft		6/24/2024 3:55:07 pm	1

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

The screenshot shows the Vivli User Management page. On the left is a sidebar with navigation links: Dashboard, Research Environments, Users (highlighted with a red box), Report, My Organization, Studies, Data Requests, Submissions, Awaiting Upload, and Enquiries. The main content area is titled 'User Management' and contains a table of users. Above the table are filters for Email Address, Name, Organizations, Account Status, and Days Since Last Login. A red box highlights a download icon in the top right corner of the table area.

Email Address	Name	Organizations	Account Status	Days Since Last Login
vivliautomation@gmail.com	anup (Vivli Admin)	• Biogen	Active	0
stan.neumann+reset12@gmail.com	Stan Reset 12	• Biogen	Active	1186
sneumann@vivli.org	Stan Neumann (Vivli Admin)	• Biogen	Active	0
alex@stanneumann.com	Sally Researcher	No Organization	Active	901
VivTestQA+VivliAdmin@gmail.com	QA Vivli Admin (Vivli Admin)	• Biogen	Active	304
VivTestQA+IRP-allOrgs@gmail.com	QA -IRP All Orgs	• Biogen	Active	0
VivTestQA+DataRequester@gmail.com	QA - Data Requester	• Biogen	Active	125
VivTestQA+DC-allOrgs@gmail.com	QA - DC All Orgs	• Biogen	Active	0

The user list downloaded file contains:

- Email Address
- Name of the Individual
- Organizations
- Account Status
- Days Since Last Login
- Data Requests for User

### 1.3.5 Active Platform Accounts

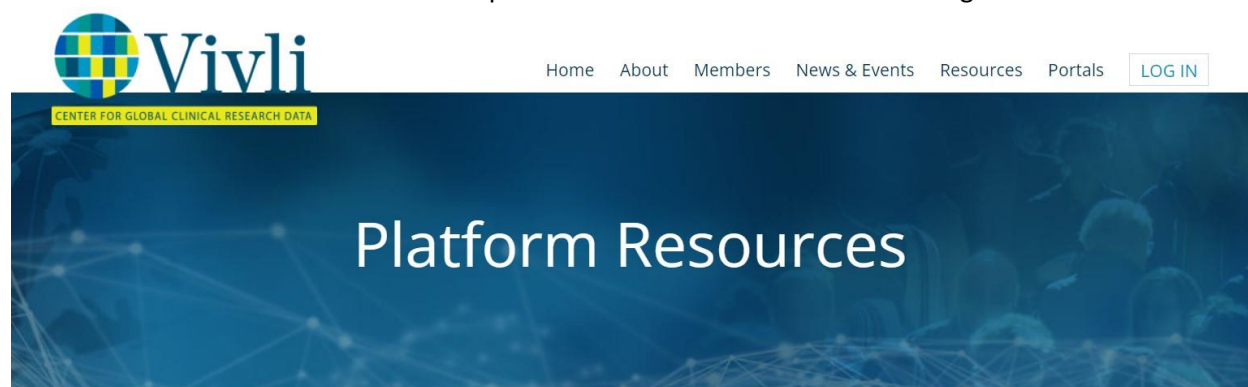
- As part of Vivli's security policy, for accounts to remain active on the platform, we need all users to log in every six months. This includes Steering Committee Members, Organizational Administrators, and any common inbox that members may use.

- If Vivli Member user accounts are inactive for six months, the Vivli team will email the user and inform the member's Organizational Administrators via Vivli summary. If the user wants to maintain their account, the user needs to log on to the platform. Unfortunately, the Vivli team cannot accept notifications via email to keep these accounts active.
- If this is not done within 10 business days, the account will be deactivated. If the user wants their account re-activated, they can email [support@vivli.org](mailto:support@vivli.org), and the Vivli team can re-activate this account at any time.

### 1.3.6 Accessing the Vivli Data Contributor Guide

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

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	<a href="#">Download</a>

## 2. Listing Studies – Process and Options

### 2.1 Listing Studies- Process

- To list your organization's studies, the Vivli administrator will provide you with metadata sheets to fill out as part of the onboarding process.
- Subsequently, the Vivli administrator will send the person(s) mentioned in your member checklist reminders on the first Tuesday of every month, to list additional studies.
- Organization Administrators can contact the Vivli administrators to list studies at any time and do not have to wait for the reminder email to send Vivli additional studies for listing.
- To list studies, complete the metadata sheet(s) with the necessary information and send it to [support@vivli.org](mailto: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"> <li>• NCT ID</li> <li>• Study-specific URL (if applicable)</li> </ul>
<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"> <li>• Sponsor ID</li> <li>• Study title</li> <li>• Medicine</li> <li>• Medical Condition</li> <li>• Phase</li> <li>• Sponsor Clinical Registry URLs</li> <li>• Eudra CT ID</li> <li>• Eudra CT URL</li> <li>• Sponsor</li> </ul>

### 2.3 Removing Studies from the Vivli Search

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

## 2.4 Studies Dashboard

Studies Dashboard has 4 sections:

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

The screenshot shows the Vivli Studies Dashboard. The top navigation bar includes links for Home, About, Members, News & Events, Resources, Portals, and Find Studies. The left sidebar contains links for Dashboard, Research Environments, Users, Report, My Organizations, Studies (highlighted with a red box), Data Requests, Submissions, Awaiting Upload, and Enquiries. The main content area is titled 'Studies' and 'Submitted by my organizations'. It features a tabbed interface with 'Draft', 'In Progress', 'Posted', and 'Cancelled' tabs. The 'Posted' tab is active, displaying a table of studies. The table has columns for Title, Status, Posted, Sponsor ID, NCTID, and IPD. The 'Studies' link in the sidebar is highlighted with a red box.

Title	Status	Posted	Sponsor ID	NCTID	IPD
Immunogenicity and Safety Study of GSK Biologicals' Candidate Malaria...	Posted	2022-08-03	200596	NCT02699099	Y
Reactogenicity, Safety and Immunogenicity Study of GlaxoSmithKline (G...	Posted	2022-08-03	207543	NCT03275389	Y
Non-closure of Alveoli After Avulsion of Wisdom Teeth: a Randomized, O...	Posted	2022-10-21	LOCAL/2014/...	NCT02583997	Y
Prospective Observational Study of the Risk Factors for Hospital-Acquire...	Posted	2022-12-14	Pro00068313	NCT02689531	Y
An Open-Label, Single-Arm Study to Evaluate the Effectiveness and Saf...	Posted	2023-02-03	MA30143	NCT03085810	Y
A 28-day Randomised, Placebo-controlled, Double-blind Parallel Group ...	Posted	2024-01-12	1245.78	NCT01969747	Y
Diabetes testing study	Posted	2024-01-12	Amrutha123		N
A Single-center, Prospective Clinical Study of High-Intensity Focused Ultr...	Posted	2024-01-29	MUKDEN 10	NCT06210529	Y

1. You may search for studies using one of the following fields by typing in the white blank box. For more information on how to filter through the headers, please see [Section 4.5.1. Features of the report](#)
  - Study Title
  - Posted date
  - Sponsor ID
  - NCT ID
  - IPD (Y- Individual data package is stored on the platform; N- Individual data package is not stored)

The screenshot shows the 'Studies' tab in the Vivli platform. The left sidebar contains navigation links: Dashboard, Data Requests, Enquiries, Studies (highlighted), Awaiting Upload, Report, Research Environments, My Organizations, and Users. The main content area is titled 'Studies' and 'Submitted by my organizations'. It features a status filter bar with 'Draft' (1), 'In Progress' (397), 'Posted' (14), and 'Cancelled'. A red box highlights the 'Posted' status and the 'Download' button (a downward arrow icon). Below the filter bar is a table of studies with columns: Title, Status, Posted, Sponsor ID, NCTID, and IPD. The table lists six studies, all with a status of 'Posted'.

Title	Status	Posted	Sponsor ID	NCTID	IPD
Assessment of Real-life Patient Handling Experience of BI 695501 Admi...	Posted	2024-10-03	1297.11	NCT02636907	Y
A Phase 3, Randomized, Double-Blind Study Comparing Upadacitinib (A...	Posted	2024-10-23	M13-545	NCT02706873	Y
A Phase 3, Multicenter, Randomized, Double Blind, Placebo-Controlled ...	Posted	2024-10-29	RA101495-02...	NCT04115293	Y
Randomized Trial to Evaluate the Efficacy/Effectiveness, Safety, and Im...	Posted	2024-12-18	PI-UN-1760	NCT06223919	Y
Viral Clearance and Epidemiological Characteristics in Patients With Mo...	Posted	2024-12-18	MoVIE Study	NCT05476744	Y
A Phase III, Open-Label, Randomized Study to Investigate the Efficacy a...	Posted	2025-01-31	GO29527	NCT02486718	Y

2. Data Contributors may download a list of their posted studies from the platform. Navigate to the Studies tab from the Dashboard, click on Posted, and click on the Download button.

This screenshot is identical to the one above, showing the 'Studies' tab with the 'Posted' status selected and the download button highlighted. The table of studies is the same as in the previous image.

3. The downloaded CSV file contains:

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



## 2.5 Individual Studies Format

- Click on individual study under the 'Posted' section

The screenshot shows the 'Studies' section of the Vivli Data Contributor Guide. The 'Posted' tab is selected, and a list of studies is displayed. The first study, 'Assessment of Real-life Patient Handling Experience of BI 695501 Admi...', is highlighted with a red box around its 'Posted' status.

Title	Status	Posted	Sponsor ID	NCTID	IPD
Assessment of Real-life Patient Handling Experience of BI 695501 Admi...	Posted	2024-10-03	1297.11	NCT02636907	Y
A Phase 3, Randomized, Double-Blind Study Comparing Upadacitinib (A...	Posted	2024-10-23	M13-545	NCT02706873	Y
A Phase 3, Multicenter, Randomized, Double Blind, Placebo-Controlled ...	Posted	2024-10-29	RA101495-02...	NCT04115283	Y
Randomized Trial to Evaluate the Efficacy/Effectiveness, Safety, and Im...	Posted	2024-12-18	PI-UN-1760	NCT06223919	Y
Viral Clearance and Epidemiological Characteristics in Patients With Mo...	Posted	2024-12-18	MoVIE Study	NCT05476744	Y
A Phase III, Open-Label, Randomized Study to Investigate the Efficacy a...	Posted	2025-01-31	GO29527	NCT02486718	Y

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

The screenshot shows the 'Study Details' page for a Phase 3 study. The 'Current Status: Posted' and 'Data Available for Sharing: YES' are highlighted with a red box.

**Study Details**

Phase: Phase 3

Condition or Disease: Rheumatoid Arthritis

Intervention/Treatment: Placebo to Upadacitinib, Methotrexate, Placebo to Methotrexate, Upadacitinib

Brief Summary From Registry (if available):

The objectives of Period 1 were the following: To compare the safety and efficacy of upadacitinib 7.5 mg once daily (OD) monotherapy (for participants in Japan only), 15 mg OD monotherapy, and 30 mg OD monotherapy versus weekly methotrexate monotherapy for the treatment of signs and symptoms of RA in methotrexate-naïve adults with moderately to severely active RA; To compare the efficacy of upadacitinib 15 mg OD monotherapy and upadacitinib 30 mg OD monotherapy versus weekly methotrexate monotherapy for prevention of structural progression in methotrexate-naïve adults with moderately to severely active RA. The objective of Period 2 is to evaluate the long-term safety, tolerability, and efficacy of upadacitinib 7.5 mg OD (for participants in Japan only), 15 mg OD, and 30 mg OD in adults with RA who have



- Each study has the following sections:

Center for Global Clinical Research Data

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS KAREN ASADA

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

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

A Phase 3, Randomized, Double-Blind Study Comparing Upadacitinib (ABT-494) Once Daily Monotherapy to Methotrexate (MTX) Monotherapy in MTX-Naïve Subjects With Moderately to Severely Active Rheumatoid Arthritis (SELECT-EARLY)

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

Phase  
Phase 3

Condition or Disease  
Rheumatoid Arthritis

Intervention/Treatment  
Placebo to Upadacitinib, Methotrexate, Placebo to Methotrexate, Upadacitinib

Brief Summary From Registry (if available)  
The objectives of Period 1 were the following: To compare the safety and efficacy of upadacitinib 7.5 mg once daily (OD) monotherapy (for participants in Japan only), 15 mg QD monotherapy, and 30 mg QD monotherapy versus weekly methotrexate monotherapy for the treatment of signs and symptoms of RA in methotrexate-naïve adults with moderately to severely active RA; To compare the efficacy of upadacitinib 15 mg QD monotherapy and upadacitinib 30 mg QD monotherapy versus weekly methotrexate monotherapy for prevention of structural progression in methotrexate-naïve adults with moderately to severely active RA. The objective of Period 2 is to evaluate the long-term safety, tolerability, and efficacy of upadacitinib 7.5 mg QD (for participants in Japan only), 15 mg QD, and 30 mg QD in adults with RA who have

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

Center for Global Clinical Research Data

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS KAREN ASADA

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

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

A Phase 3, Randomized, Double-Blind Study Comparing Upadacitinib (ABT-494) Once Daily Monotherapy to Methotrexate (MTX) Monotherapy in MTX-Naïve Subjects With Moderately to Severely Active Rheumatoid Arthritis (SELECT-EARLY)

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

Data Contributor Organization Name  
AbbVie

Lead Sponsor Agency  
AbbVie

Lead Sponsor Agency Class  
INDUSTRY

Therapeutic Areas  
Rheumatology x

Other Resources for Study  
http://vivli.org

Primary Registry Name  
ClinicalTrials.gov

Primary Registry Id  
NCT02706873

Primary Registry Url  
https://clinicaltrials.gov/show/NCT02706873

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

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

A Phase 3, Randomized, Double-Blind Study Comparing Upadacitinib (ABT-494) Once Daily Monotherapy to Methotrexate (MTX) Monotherapy in MTX-Naïve Subjects With Moderately to Severely Active Rheumatoid Arthritis (SELECT-EARLY)

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

10/23/24 1:30 pm	Status changed to QC Review of Curation - Reviewer Enlisted	Amrutha Baskaran abaskaran@vivli.org	Accepting for QC Review
10/23/24 1:30 pm	Status changed to Submitted to Vivli for Post-Check	Amrutha Baskaran abaskaran@vivli.org	k
10/23/24 1:30 pm	Status changed to Posted on Vivli	Amrutha Baskaran abaskaran@vivli.org	Approving Status Change
10/28/24 4:39 pm	IPD Package Uploaded	QA - DC All Orgs VivTestQA+DC- allOrgs@gmail.com	IPD Package uploaded was Available datapackage for study A Phase 3, Randomized, Double-Blind Study Comparing Upadacitinib (ABT-494) Once Daily Monotherapy to Methotrexate (MTX) Monotherapy in MTX-Naïve Subjects With Moderately to Severely Active Rheumatoid Arthritis'
2/11/25 9:09 am	Status changed to IPD Provided for Requested Study - for Data Request 00048423	Karen Asada abaskaran08@gmail.com	IPD uploaded to Request 00048423, titled Amrutha workflow test 1/30.

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

Dashboard < 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

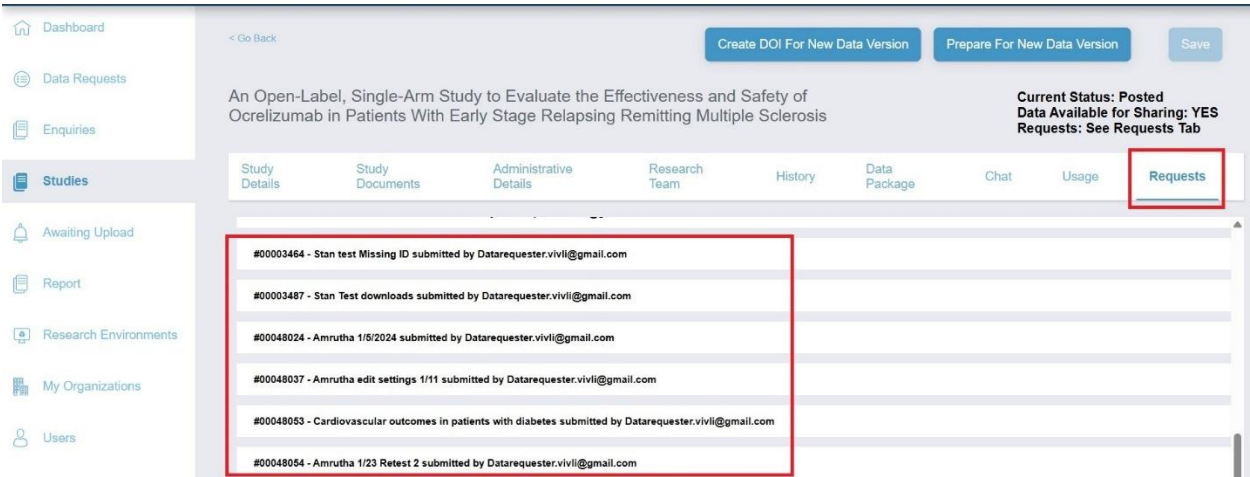
UPLOADED FILES

Filename	Size	Uploaded By	File Type	Publicly Available	Download
V3IPD dig.csv.xls	3.28MB	Karen Asada	File Type: IPD		Download
V3DIG Protocol.pdf	179.00kB	Karen Asada	File Type: Protocol	<input checked="" type="checkbox"/>	Download
V3DIG Data Dictionary Document...	118.00kB	Karen Asada	File Type: Data Dictionary	<input type="checkbox"/>	Download
V3DIG Statistical analysis pla...	160.00kB	Karen Asada	File Type: Statistical Analysis Plan	<input type="checkbox"/>	Download

7. Chat – Related to study submission

8. Usage – See [Section 2.6 Study Usage and Public Disclosure Metrics](#)

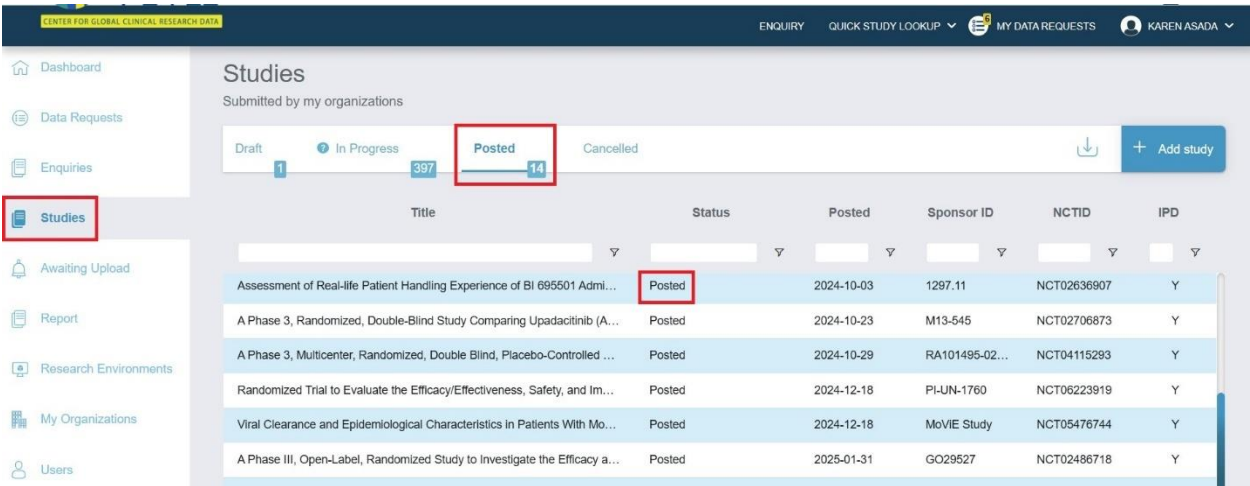
9. Requests – Data Requests related to this study (includes both drafts and submitted data requests). To download the request list, go to report and select “Studies (Org Admin)”. Please see [Section 4.5 Report of Data Requests and Studies](#)



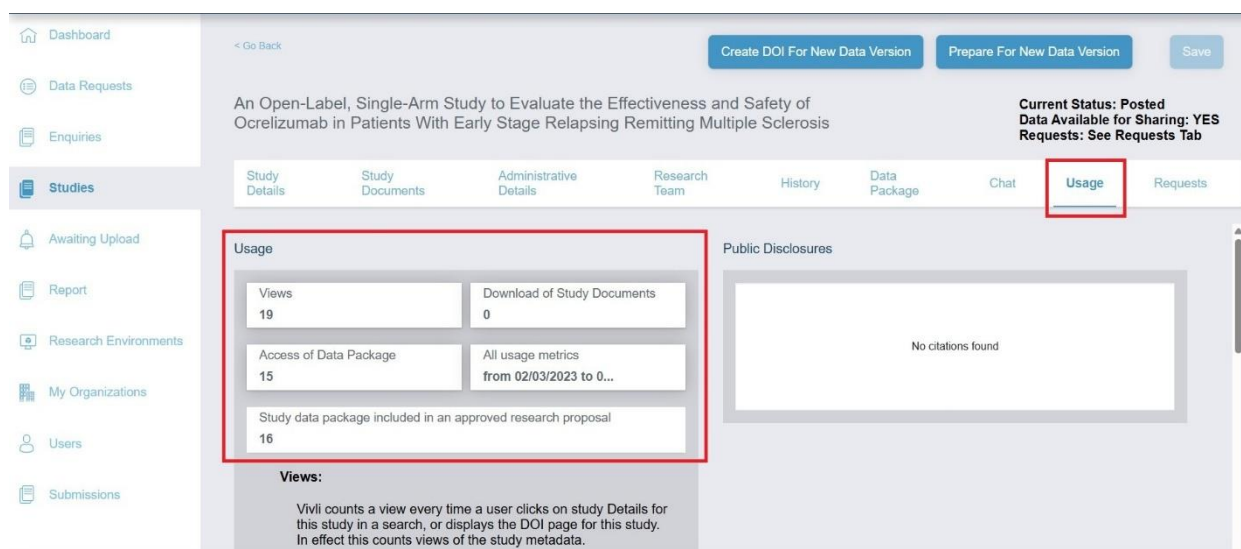
2.6 Study Usage and Public Disclosure Metrics

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

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



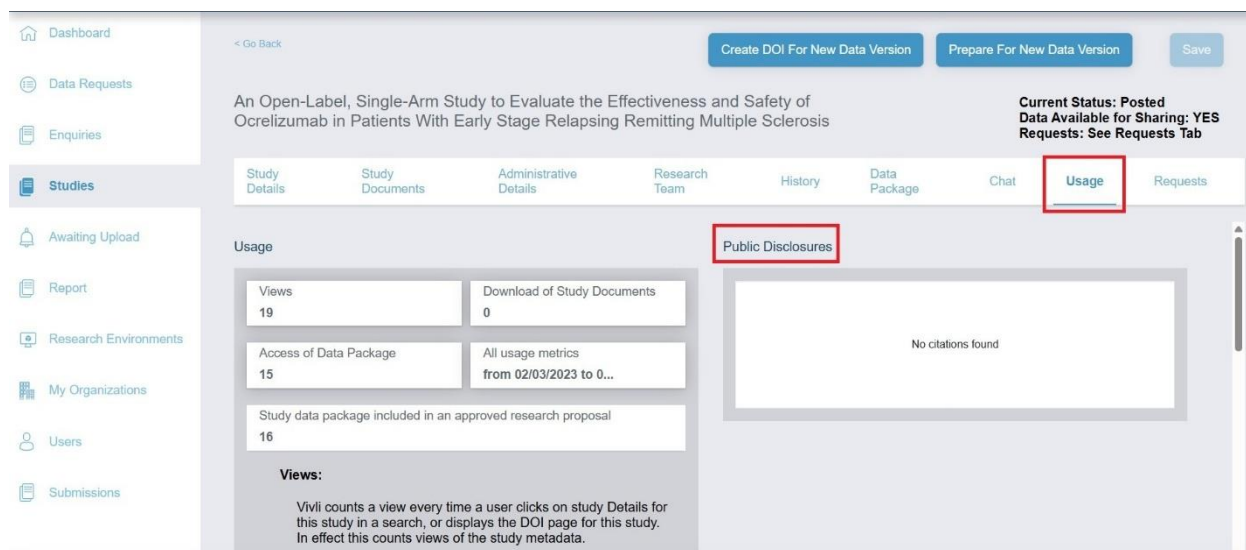
2. Open the study and click on the “Usage” tab.



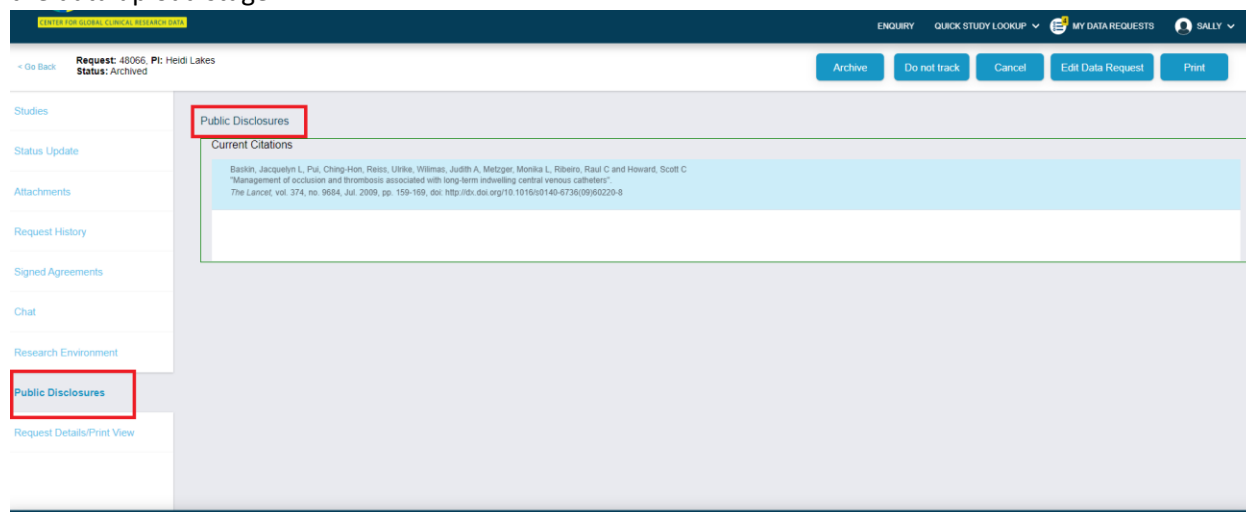
3. Under “Usage” will see the following fields:

- Views:**  
Vivli counts a view every time a user clicks on study Details for this study in a search or displays the DOI page for this study. In effect, this counts views of the study metadata.
- Download of study documents:**  
Study documents are documents made available to a researcher prior to requesting the study data to help them determine whether the study contains the kind of data necessary to support their research topic; this may include the data dictionary and/or a redacted protocol. This metric counts the number of times a study document is downloaded. For more information see [Section 5.12 Supporting Documents for Researchers Searching For Studies](#)
- Total Access of Data Packages:**  
The data package includes the data that is provided in response to the request, and includes anonymized Individual Participant Data (IPD) and supporting documents. "Access" includes placing the data into a secure research environment or (when allowed) downloading the data. Every time a data package is accessed by download or re-uploaded into a research environment, including if the data package is accessed multiple times in the same research proposal, this is counted.
- Study data package included in an approved research proposal:**  
This metric counts the number of times a data package is included in an approved research proposal.
- All Usage Metrics:**  
The data range here represents the range of dates during which the metrics above were collected. The start date is either the date the data collection feature was turned on, or the date the study was posted (whichever is later). The end date is always 3 days before the current date since it takes the system 3 days to process and tally the raw usage data.

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



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





## 2.7 Study Search Results– Download

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

The screenshot shows the Vivli search interface. At the top, there's a navigation bar with links: Home, About, Members, News & Events, Resources, Portals, and Find Studies. Below this is a banner with the text "We are committed to advancing the knowledge around the COVID-19 pandemic" and buttons for "Share trials" and "Search for trials". The main search area has a "KEYWORD SEARCH" tab selected, with a search bar containing the placeholder text "What are you looking for today?". To the right of the search bar are icons for information and search. Below the search bar are several filter sections: "STUDY DESIGN" (with sub-sections for INTERVENTIONAL STUDIES, OBSERVATIONAL STUDIES, and STUDY PHASE), "SPONSOR INFORMATION" (with sub-sections for FUNDER, CONTRIBUTOR, and SAMPLE SIZE), "LOCATION", and "START DATE" (with "From" and "To" date pickers). Each filter section has a "Select Multiple" dropdown menu.

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

The screenshot shows the Vivli search results page. The search bar at the top contains the text "diabetes". To the right of the search bar is a "CLOSE" link and a download icon (a square with a downward arrow). Below the search bar, there are two study results displayed. Each result includes a title, IDs, Condition or Disease, Intervention/treatment, and buttons for "Request Study" and "View Study Details". The first study is titled "Clinical Assessment of GSK716155 for Type 2 Diabetes Mellitus -A Phase I/II Study to Investigate the Safety, Pharmacokinetics and Pharmacodynamics of GSK716155 in Japanese Subjects With Type 2 Diabetes Mellitus" and has IDs NCT00530309 | GLP107865. The second study is titled "A Phase I, Randomized, Placebo-Controlled, Crossover Clinical Trial to Assess the Safety of Oral SRT2104 and Its Effects on Vascular Dysfunction in Otherwise Healthy Cigarette Smokers and Subjects With Type 2 Diabetes Mellitus" and has IDs NCT01031108 | 114069. Both studies are Phase 1 trials.

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

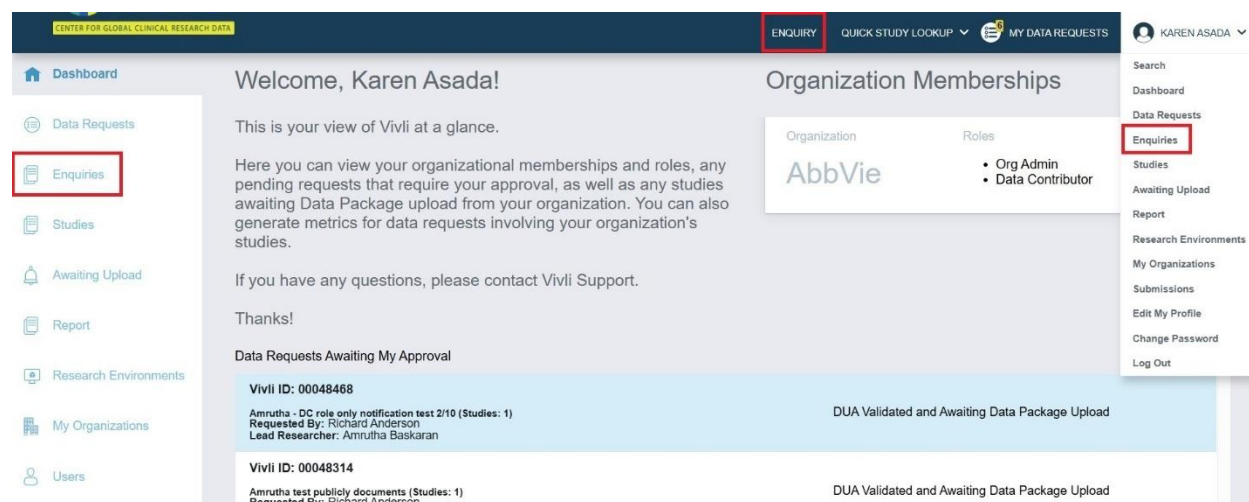
- NCTID
- Sponsor Protocol Id
- Title
- Acronym
- Condition or Disease
- Intervention/Treatment
- Therapeutic Area
- Phase
- Number Enrolled
- Contributor
- Lead Sponsor Agency
- Funder
- Data Accessibility
- Data Availability
- Primary Registry URL
- URL to Request Study from Sponsor
- Other Resources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

### 3. Study Process

1. A researcher can submit an enquiry using the Vivli platform regarding the availability of a Vivli Member study not listed on Vivli using the Vivli platform. Enquiry tab allows Vivli and Organization Administrators to receive, respond to, and track enquiries in one place.
2. The researcher fills out one Enquiry form for multiple studies that will be part of a single research project, even if the studies are from multiple Vivli Members.
3. Vivli Members will see the entire Enquiry form, with studies from that member on the top and editable, and studies from other contributors below their studies and as read-only, including any feedback and decisions made by the other Vivli Members.
4. Only Organizational Administrators can see and review Enquiries waiting for review for your organization.

#### 3.1 Navigation and Enquiry Dashboard

1. Once you have logged in to the dashboard, you can navigate to Enquiries using the toolbar on the left-hand side of the screen. You can also use the dropdown menu on the upper right-hand corner of the screen or the top center of the screen



2. The Enquiries Dashboard displays a status bar at the top of the page which displays all the Enquiries for your organization's studies.



Enquiries about Vivli Member Studies

Awaiting My Action 5 Draft 10 Enquiry Validation 4 Review 27 Withdrawn 1 Archived 5

+ Add Enquiry

ID	Requester	Purpose	Status	# of Studies
122	Richard Anderson	Amrutha test 11578	Review	3
48	Amrutha Baskaran	Amrutha Test	Review	1
45	Amrutha	Amrutha test	Review	1
10	Data Requester	Testing the enquiries system	Review	2
12	Richard Anderson	Meta-analysis of randomized trials in the areas of He...	Review	4

3. The status bar contains 6 sections:

**Awaiting my Action:** Displays Enquiries that needs your decision. It includes Enquiries where at least one of any contributor's studies does not have a final response.

**Draft:** Displays Enquiries that are being drafted but not yet submitted.

**Enquiry Validation:** Displays Submitted Enquiries that are in Vivli's review.

**Review:** Displays Enquiries that are in review by Members. This includes Enquiries awaiting your action and Closed Enquiries.

**Withdrawn:** Displays Enquiries that were withdrawn

**Archived:** Displays Enquiries where the final decision is made.

4. Each Enquiry recorded on the dashboard displays the Vivli Enquiry ID, Requester Name, Purpose of research, Date Submitted, Status of the Enquiry, and the Number of Studies in each Enquiry.

**Note:** The Enquiries are sorted to show the most recently submitted at the top

Enquiries about Vivli Member Studies

Awaiting My Action 5 Draft 10 Enquiry Validation 4 Review 27 Withdrawn 1 Archived 5

+ Add Enquiry

ID	Requester	Purpose	Status	# of Studies
122	Richard Anderson	Amrutha test 11578	Review	3
48	Amrutha Baskaran	Amrutha Test	Review	1
45	Amrutha	Amrutha test	Review	1
10	Data Requester	Testing the enquiries system	Review	2
12	Richard Anderson	Meta-analysis of randomized trials in the areas of He...	Review	4

5. You may search for Enquiries using one of the following fields (you can only view Enquiries where one of your studies has been enquired). Search starts looking for the matching items as

soon as you type the first letter and is case-insensitive. The numbers point out the number of enquiries that match the search criteria and the status of the enquiry:

- Enquiry ID
- Requester Name or Email
- Purpose of analysis
- NCT ID
- Sponsor ID
- Study Title
- Member Organization

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, Portals, and Find Studies. The user is logged in as KAREN ASADA. The left sidebar contains links for Dashboard, Data Requests, Enquiries, Studies, Awaiting Upload, Report, and Research Environments. The main content area is titled 'Enquiries about Vivli Member Studies' and features a search bar with the number '126'. Below the search bar, there are tabs for 'Awaiting My Action', 'Draft', 'Enquiry Validation', 'Review', 'Withdrawn', and 'Archived'. The 'Draft' tab is selected, and a red box highlights the '126' count in the top right corner. Below the tabs, there is a table with columns: ID, Requester, Purpose, Drafted, Status, and # of Studies. The first row of the table is highlighted in blue and contains the following data: ID: 126, Requester: Richard Anderson, Purpose: Looking for studies on treating Neonates, Drafted: 2/6/2025 3:48:09 pm, Status: Draft, # of Studies: 6. A red box highlights the '126' ID in the first row of the table.

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

The screenshot shows the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, Portals, and Find Studies. The user is logged in as KAREN ASADA. The left sidebar contains links for Dashboard, Data Requests, Enquiries, Studies, Awaiting Upload, Report, and Research Environments. The main content area is titled 'Enquiries about Vivli Member Studies' and features a search bar with the number '126'. Below the search bar, there are tabs for 'Awaiting My Action', 'Draft', 'Enquiry Validation', 'Review', 'Withdrawn', and 'Archived'. The 'Draft' tab is selected, and a red box highlights the down arrow icon in the top right corner of the table. Below the tabs, there is a table with columns: ID, Requester, Purpose, Drafted, Status, and # of Studies. The first row of the table is highlighted in blue and contains the following data: ID: 126, Requester: Richard Anderson, Purpose: Looking for studies on treating Neonates, Drafted: 2/6/2025 3:48:09 pm, Status: Draft, # of Studies: 6.

7. The downloaded file contains:

- Vivli Enquiry ID

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

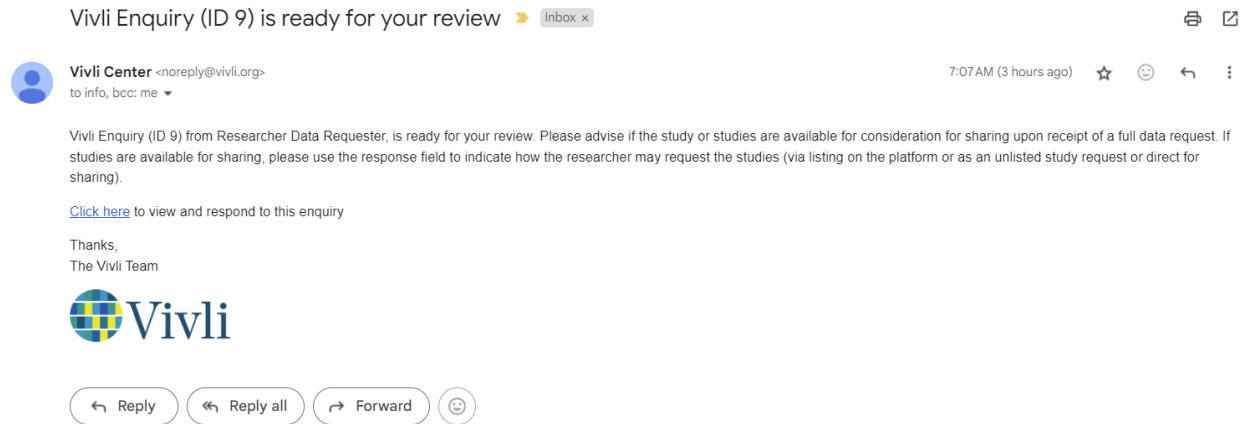
## 3.2 Enquiry Format

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

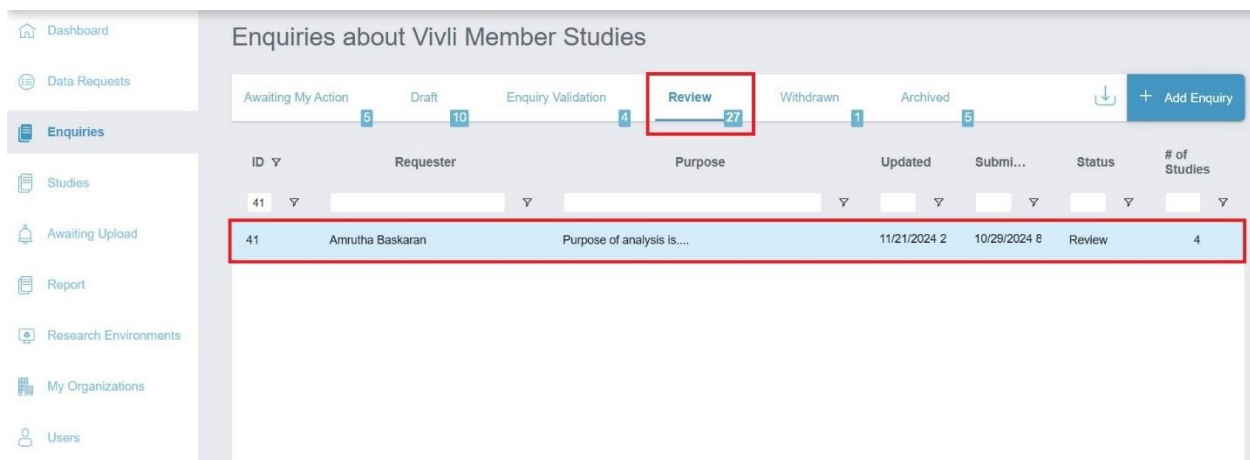
The screenshot displays the Vivli Data Contributor web application interface. On the left is a sidebar menu with options: Dashboard, Data Requests, Enquiries (highlighted with a red box), Studies, Awaiting Upload, Report, Research Environments, My Organizations, Users, and Submissions. The main content area shows a draft enquiry for 'Enquiry Id: 38' with a status of 'Draft' and a submission date of '2024-10-24'. The enquiry form is divided into two main sections. The top section contains fields for 'Requester Email' (Datarequester.vivli@gmail.com), 'Requester Name' (Richard Anderson), 'Your Institution' (Vivli), and 'Country' (Germany). It also includes a 'Purpose' field with the text 'Purpose of my research is....' and a link to the 'Vivli Members Page'. The bottom section is for study identification, with a prompt to enter an NCT ID or Sponsor ID if the study is on clinicaltrials.gov, or the study title. It features input fields for 'NCT ID' (NCT03271047) and 'Sponsor ID' (ARRAY-162-202), separated by an 'OR' label. A 'Study Title' field contains the text: 'An Open-label Phase 1b/2 Study of Binimetinib Administered in Combination With Nivolumab or Nivolumab Plus Ipilimumab in Patients With Previously Treated Microsatellite-stable (MSS) Metastatic Colorectal Cancer With RAS Mutation'. To the right of these fields are dropdown menus for 'Data Contributor' (AbbVie) and 'Sponsor' (Pfizer).

< Go Back		Enquiry Id: 38		Status: Draft	Date Submitted: 2024-10-24
Requester Email Datarequester.vivli@gmail.com		Requester Name Richard Anderson			
Your Institution Vivli		Country Germany			
Purpose Purpose of my research is....		The <a href="#">Vivli Members Page</a> provides information on each member and their policy for sharing datasets			
Please enter an NCT Id or Sponsor Id if the study is on clinicaltrials.gov, or enter the study title.					
NCT ID NCT03271047		OR		Study Title An Open-label Phase 1b/2 Study of Binimetinib Administered in Combination With Nivolumab or Nivolumab Plus Ipilimumab in Patients With Previously Treated Microsatellite-stable (MSS) Metastatic Colorectal Cancer With RAS Mutation	
Sponsor ID ARRAY-162-202					
				Data Contributor AbbVie	
				Sponsor: Pfizer	

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



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



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

The screenshot shows the Vivli Data Contributor interface. At the top, a navigation bar includes a home icon, 'Dashboard', and a status bar for 'Enquiry Id: 41', 'Status: Review', and 'Date Submitted: 2024-10-30'. There are 'Save' and 'Save & Notify' buttons. A sidebar on the left lists navigation options: Dashboard, Data Requests, Enquiries, Studies, Awaiting Upload, Report, Research Environments, My Organizations, Users, and Submissions. The main content area contains a form for 'Enquiry Id: 41'. The form has two columns. The left column contains 'Requester Email' (Datarequester.vivli@gmail.com), 'Your Institution' (UCSD), and 'Purpose' (Purpose of analysis is....). The right column contains 'Requester Name' (Amrutha Baskaran), 'Country' (Antigua and Barbuda), and a link to the 'Vivli Members Page'. Below the form is a table of studies. The first study is highlighted with a red box. It has a '+' button, NCT ID: NCT03275389, Study Title: Reactogenicity, Safety and Immunogenicity Study of GlaxoSmithKline (GSK) Biologicals' Investigational Supra-seasonal Universal Influenza Vaccines - Inactivated (SUIVs) (GSK3816302A) in Healthy Adults, Data Contributor: AbbVie, and Status: Closed - Available as listed. The second study is also visible below it.

NCT ID	Study Title	Data Contributor	Status
NCT03275389	Reactogenicity, Safety and Immunogenicity Study of GlaxoSmithKline (GSK) Biologicals' Investigational Supra-seasonal Universal Influenza Vaccines - Inactivated (SUIVs) (GSK3816302A) in Healthy Adults	AbbVie	Closed - Available as listed
NCT04115293	A Phase 3, Multicenter, Randomized, Double Blind, Placebo-Controlled Study to Confirm the Safety, Tolerability, and Efficacy of Zilucoplan in Subjects With Generalized Myasthenia Gravis	AbbVie	Closed - Available as listed

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

This screenshot is identical to the one above, showing the Vivli Data Contributor interface. The red box in the first study row of the table is slightly larger, encompassing the '+' button and the NCT ID.

NCT ID	Study Title	Data Contributor	Status
NCT03275389	Reactogenicity, Safety and Immunogenicity Study of GlaxoSmithKline (GSK) Biologicals' Investigational Supra-seasonal Universal Influenza Vaccines - Inactivated (SUIVs) (GSK3816302A) in Healthy Adults	AbbVie	Closed - Available as listed
NCT04115293	A Phase 3, Multicenter, Randomized, Double Blind, Placebo-Controlled Study to Confirm the Safety, Tolerability, and Efficacy of Zilucoplan in Subjects With Generalized Myasthenia Gravis	AbbVie	Closed - Available as listed

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

The screenshot shows a form with the following fields and values:

- NCT ID:** NCT01946204
- Sponsor ID:** CR102931
- Study Title:** A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men With Non-Metastatic (M0) Castration-Resistant Prostate Cancer
- Clinical Trials:** <https://clinicaltrials.gov/show/NCT01946204>
- Data Contributor:** Biogen
- Sponsor:** Aragon Pharmaceuticals, Inc.

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

The screenshot shows the same form as above, but with the “Previous Enquiries” link highlighted in a red box.

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

The screenshot shows the “Report” tab in the Vivli platform. The table displays the following data:

Enquiry Id	Researcher	Contributor	Contributor's response	Denial Reason	NCT ID
131	ard Anderson	AbbVie	New	None	NCT06223919
131	ard Anderson	AbbVie	None	None	NCT06223919
122	ard Anderson	AbbVie	Eligible for Request as an unlisted study	None	NCT00266253
122	ard Anderson	AbbVie	New	None	
122	ard Anderson	Pfizer Inc.	Study is Listed	None	
80	Neumann	Stans Org	Study is Listed	None	NCT01830855

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

This screenshot shows the study details for NCT02636907. The interface includes a sidebar with a minus icon, a search bar, and a "Previous Enquiries" link. The main content area displays the study title, sponsor ID (1297.11), and primary completion date (2016-06-21). A red box highlights the note "This Study is listed on the Vivli Platform" in the bottom right corner.

NCT ID: NCT02636907

OR

Sponsor ID: 1297.11

Study Title: Assessment of Real-life Patient Handling Experience of BI 695501 Administered Subcutaneously With an Autoinjector in Patients With Rheumatoid Arthritis: an Open-label, Interventional Clinical Trial Followed by an Extension Phase of BI 695501 Administered With a Prefilled Syringe

Notify on "Save & Notify": ☐

Data Contributor: AbbVie

Sponsor: Boehringer Ingelheim

Primary Completion Date: 2016-06-21

Clinical Trials: <https://clinicaltrials.gov/show/NCT02636907>

[This Study is listed on the Vivli Platform](#)

This screenshot shows the discussion and data requested fields. The "Data Requested" section is highlighted with a red box and lists "Clinical Documents" and "ParticipantData". The "Response" dropdown is set to "New" and the "Reason" dropdown is set to "None". The "Discussion" field is empty, and the "Add Comment" button is visible. The "Date of Final Response" and "Request Number(s)" fields are also present.

Discussion:

Data Requested:

- Clinical Documents
- ParticipantData

Response: New

Reason: None

No Data Found

Comment

Add Comment

To save comments please click "Save" or "Save & Notify" button.

Date of Final Response:

Request Number(s):

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

This screenshot shows the study title and data contributor fields. The "Study Title" field is highlighted with a red box and contains the text "A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Dose-Comparison Study to Determine the Efficacy and Safety of BG00012 in Subjects With Relapsing-Remitting Multiple Sclerosis (DEFINE)". The "Data Contributor" dropdown is also highlighted with a red box and shows "Biogen". The "Sponsor" field is empty.

Please enter an NCT Id or Sponsor Id if the study is on clinicaltrials.gov, or enter the study title.

NCT ID

OR

Sponsor ID

Study Title: A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Dose-Comparison Study to Determine the Efficacy and Safety of BG00012 in Subjects With Relapsing-Remitting Multiple Sclerosis (DEFINE)

Data Contributor: Biogen

Sponsor:

Primary Completion Date:

Clinical Trials:

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




The screenshot displays the Vivli Data Contributor interface. On the left, there are several form fields: 'Data Requested' with a list containing 'Clinical Documents' and 'ParticipantData'; 'Response' with a dropdown menu showing 'New'; 'Reason' with a dropdown menu showing 'None'; 'Date of Final Response:'; and 'Request Number(s):'. The main area is titled 'Discussion:' and contains a large text box with the text 'No Data Found'. Below this, there is a 'Comment' text box and an 'Add Comment' button. A note at the bottom right states: 'To save comments please click "Save" or "Save & Notify" button.'


### 3.3 Recording Enquiry Decision

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



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



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

### 3.3.1 Eligible for Request

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

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

< Go Back Enquiry Id: 9 Status: Review Date Submitted: 2024-06-10 Save Save & Notify

NCT ID  
NCT01946204

OR

Sponsor ID  
CR102931

None  
New  
Response from requester  
Response from data contributor  
Response from Vivli  
Eligible for Request as an unlisted study  
**Study is Listed**  
Not Available

Eligible for Request...

Reason  
None

Study Title  
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men With Non-Metastatic (M0) Castration-Resistant Prostate Cancer

Notify on "Save & Notify": ☒

Data Contributor  
Biogen

Sponsor: Aragon Pharmaceuticals, Inc.

Clinical Trials: <https://clinicaltrials.gov/show/NCT01946204>

Discussion:

No Data Found

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

< Go Back Enquiry Id: 9 Status: Review Date Submitted: 2024-06-10 Save Save & Notify

NCT ID

NCT01946204

OR

Sponsor ID

CR102931

None

New

Response from requester

Response from data contributor

Response from Vivli

Eligible for Request as an unlisted study

Study is Listed

Not Available

Eligible for Request...

Reason

None

Previous Enquiries

Study Title

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men With Non-Metastatic (M0) Castration-Resistant Prostate Cancer

Clinical Trials: <https://clinicaltrials.gov/show/NCT01946204>

Discussion:

No Data Found

Notify on "Save & Notify": ☒

Data Contributor

Biogen

Sponsor: Aragon Pharmaceuticals, Inc.

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

Discussion:

11/27/2024 5:39:39 pm	Karen Asada	- The data contributor has provided a final response on the availability of this study	
12/20/2024 8:58:55 am	Amrutha Baskaran	Test	

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

Date of Final Response: 2024-05-10

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

Date of Final Response: 2024-05-10

Request Number(s): 00048130

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

The screenshot displays the Vivli Data Contributor web application. The top navigation bar includes links for Home, About, Members, News & Events, Resources, Portals, and Find Studies. Below this is a secondary navigation bar with ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and a user profile for AMRUTHA BASKARAN (Vivli Admin). The main content area shows a data request form for Request: 48130, PI: Karen Aseda. The status is 'Submitted and Awaiting Vivli Request Form Check'. Action buttons include Archive, Do not track, Reset to Draft, Cancel, Edit Data Request, Cannot Fulfill, Process Request, and Print. A sidebar on the left contains links for Studies, Status Update, Attachments, Request History, Signed Agreements, Chat, Research Team, and Request Details/Print View. The main form area has sections for Other Information, Requested Studies, and Attached Files. The Other Information section contains the text 'This request was initiated from enquiry: 2'. The Requested Studies section lists two studies: 'A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men With Non-Metastatic (M0) Castration-Resistant Prostate Cancer' and 'A Single Centre, Randomized, Double-blind, Dose Ascending, Placebo-controlled Study, in Two Parts, to Evaluate the Safety, Tolerability and Pharmacokinetics of Escalating Single and Repeat Inhaled Doses of GSK573719 and Placebo Formulated With the Excipient Magnesium Stearate, in Healthy Subjects and in a Healthy Population of Cytochrome P450 Isoenzyme 2D6 Poor Metabolisers'. The Attached Files section shows 'NO FILES IN PACKAGE'.

**Other Information**

This request was initiated from enquiry: 2

**Requested Studies**

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men With Non-Metastatic (M0) Castration-Resistant Prostate Cancer  
PI: Data Contributor: BMS Study ID: NCT01946204 Data Request ID: 00048130 Sponsor ID: CR102931  
- IPD Uploaded:

A Single Centre, Randomized, Double-blind, Dose Ascending, Placebo-controlled Study, in Two Parts, to Evaluate the Safety, Tolerability and Pharmacokinetics of Escalating Single and Repeat Inhaled Doses of GSK573719 and Placebo Formulated With the Excipient Magnesium Stearate, in Healthy Subjects and in a Healthy Population of Cytochrome P450 Isoenzyme 2D6 Poor Metabolisers.  
PI: Sponsor: GlaxoSmithKline Study ID: NCT00803673 IRP/Approver: Wellcome Trust Data Request ID: 00048130 Sponsor ID: 110106  
Data Contributor: GlaxoSmithKline IPD Uploaded:

**Attached Files**

NO FILES IN PACKAGE

### 3.3.2 Not Available for Request

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

< Go Back Enquiry Id: 9 Status: Review Date Submitted: 2024-06-10 Save Save & Notify

NCT ID

NCT01946204

OR

Sponsor ID

CR102931

None

New

Response from requester

Response from data contributor

Response from Vivli

Eligible for Request as an unlisted study

Study is Listed

**Not Available**

Eligible for Request...

Reason

None

Previous Enquiries

Study Title

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men With Non-Metastatic (M0) Castration-Resistant Prostate Cancer

Notify on "Save & Notify": ☒

Data Contributor

Biogen

Sponsor: Aragon Pharmaceuticals, Inc.

Clinical Trials: <https://clinicaltrials.gov/show/NCT01946204>

Discussion:

No Data Found

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

< Go Back Enquiry Id: 9 Status: Review Date Submitted: 2024-06-10 Save Save & Notify

NCT ID

NCT01946204

OR

Sponsor ID

CR102931

Study Completion Date criteria is not yet met

Data Sharing Prohibited by Consent, Legal, Regulatory, or Contractual Constraints

Indications have not received market authorization

Likelihood of re-identification of patients given small number of patients and/or involves a rare disease

Other (See Discussion)

Not responsible for Data Sharing

None

Previous Enquiries

Study Title

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men With Non-Metastatic (M0) Castration-Resistant Prostate Cancer

Notify on "Save & Notify": ☒

Data Contributor

Biogen

Sponsor: Aragon Pharmaceuticals, Inc.



Clinical Trials: <https://clinicaltrials.gov/show/NCT01946204>

Discussion:

No Data Found

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

Discussion:

2/12/2025 1:27:49 pm	Karen Asada	The data contributor has provided a final response on the availability of this study	
2/12/2025 1:27:49 pm	Karen Asada	Please see the member's page at <a href="https://vivli.org/members/ourmembers/">https://vivli.org/members/ourmembers/</a> for more details on the member's data sharing policy	

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

Date of Final Response: 2024-05-10


### 3.3.3 Enquiry Feedback to Researcher via Discussion field


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

Discussion:

Data Requested:

- Clinical Documents
- ParticipantData

Response 

New 

**None**

**New**

Response from requester

Response from data contributor

Response from Vivli

Eligible for Request as an unlisted study

Study is Listed

Not Available

No Data Found

Comment

Here is a sample message on the Enquiry

Add Comment

To save comments please click "Save" or "Save & Notify" button.

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

< Go Back Enquiry Id: 9 Status: Review Date Submitted: 2024-06-10

Save Save & Notify

Primary Completion Date: Clinical Trials: <https://clinicaltrials.gov/show/NCT01946204>

Discussion:

6/10/2024 1:00:58 pm Amrutha Here is a sample message on the Enquiry

Data Requested:

- Clinical Documents
- ParticipantData

Response Response from data c...

Reason None

Comment

Add Comment

To save comments please click "Save" or "Save & Notify" button.

Date of Final Response: Request Number(s):

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

Discussion:

2/12/2025 1:27:49 pm	Karen Asada	The data contributor has provided a final response on the availability of this study	
2/12/2025 1:27:49 pm	Karen Asada	Please see the member's page at <a href="https://vivli.org/members/ourmembers/">https://vivli.org/members/ourmembers/</a> for more details on the member's data sharing policy	

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

### 3.3.4 Enquiry Study Status for Individual Studies

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

#### 1. For Studies with No decision Recorded yet.

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

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

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

Study-level Status is visible in the following areas:

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

The screenshot displays the Vivli Data Contributor interface. On the left is a sidebar with navigation links: Dashboard, Data Requests, Enquiries, Studies, Awaiting Upload, Report, Research Environments, My Organizations, Users, and Submissions. The main content area shows an 'Enquiry Id: 41' with a status of 'Review' and a submission date of '2024-10-30'. Below this, there are input fields for 'Requester Email' (Datarequester.vivli@gmail.com), 'Requester Name' (Amrutha Baskaran), 'Your Institution' (UCSD), and 'Country' (Antigua and Barbuda). A 'Purpose' field is also present. A table below lists two studies. The first study, with NCT ID NCT03275389, has a status of 'Closed - Available as listed' highlighted with a red box. The second study, with NCT ID NCT04115293, has a status of 'Closed - Available as listed'.

NCT ID	Study Title	Data Contributor	Status
NCT03275389	Reactogenicity, Safety and Immunogenicity Study of GlaxoSmithKline (GSK) Biologicals' Investigational Supra-seasonal Universal Influenza Vaccines - Inactivated (SUIVs) (GSK3816302A) in Healthy Adults	AbbVie	Closed - Available as listed
NCT04115293	A Phase 3, Multicenter, Randomized, Double Blind, Placebo-Controlled Study to Confirm the Safety, Tolerability, and Efficacy of Zilucoplan in Subjects With Generalized Myasthenia Gravis	AbbVie	Closed - Available as listed



## 2. Open the Enquiry Study panel, on the left side below the 'Reason' field

The screenshot shows the 'Enquiry Study' panel. On the left, there are input fields for 'NCT ID' (NCT00086593), 'Sponsor ID' (101464), and 'Reason' (None). The 'Data Requested' section lists 'Clinical Documents' and 'ParticipantData'. The 'Study Title' field contains a long text about a clinical trial. The 'Primary Completion Date' is 2005-07-31, and the 'Clinical Trials' link is provided. The 'Sponsor' is GlaxoSmithKline. The 'Study Status' is 'Closed - Available as listed', which is highlighted with a red box. The 'Enquiry Status' is 'Review'.

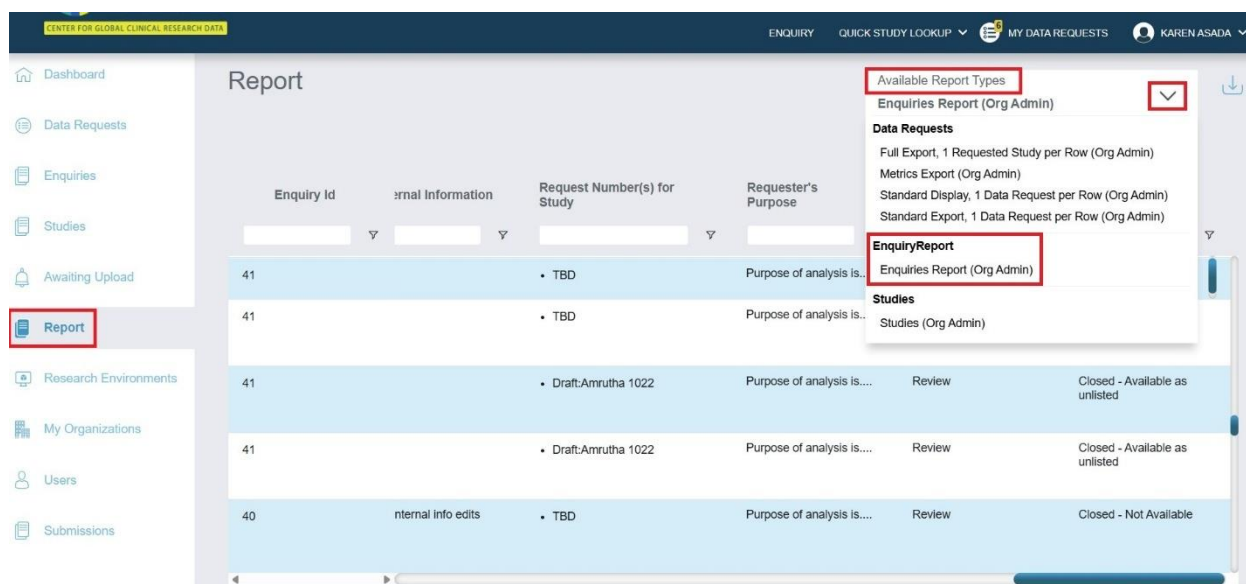
## 3. Enquiry Report, for each Study, the status shown in a column labeled "Study Status", in position after the "Enquiry Status" field

The screenshot shows the 'Enquiry Report' table. The table has columns for 'Enquiry Id', 'Request Number(s) for Study', 'Requester's Purpose', 'Enquiry Status', and 'Study Status'. The 'Study Status' column is highlighted with a red box. The table contains five rows of data, each representing a different study or request.

Enquiry Id	Request Number(s) for Study	Requester's Purpose	Enquiry Status	Study Status
41	• TBD	Purpose of analysis is....	Review	Closed - Available as listed
41	• TBD	Purpose of analysis is....	Review	Closed - Available as unlisted
41	• Draft:Amrutha 1022	Purpose of analysis is....	Review	Closed - Available as unlisted
41	• Draft:Amrutha 1022	Purpose of analysis is....	Review	Closed - Available as unlisted
40	• TBD	Purpose of analysis is....	Review	Closed - Not Available

### 3.4 Enquiries Report

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



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

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

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

The screenshot shows the 'Report' section of the Vivli Data Contributor interface. The left sidebar has a 'Report' tab highlighted. The main area displays a table of enquiries. A dropdown menu for 'Available Report Types' is open, showing 'Enquiries Report (Org Admin)' and a download icon.

Enquiry ID	Internal Information	Request Number(s) for Study	Requester's Purpose	Enquiry Status	Study Status
41		• TBD	Purpose of analysis is....	Review	Closed - Available as listed
41		• TBD	Purpose of analysis is....	Review	Closed - Available as unlisted
41		• Draft:Amrutha 1022	Purpose of analysis is....	Review	Closed - Available as unlisted
41		• Draft:Amrutha 1022	Purpose of analysis is....	Review	Closed - Available as unlisted
40	nternal info edits	• TBD	Purpose of analysis is....	Review	Closed - Not Available

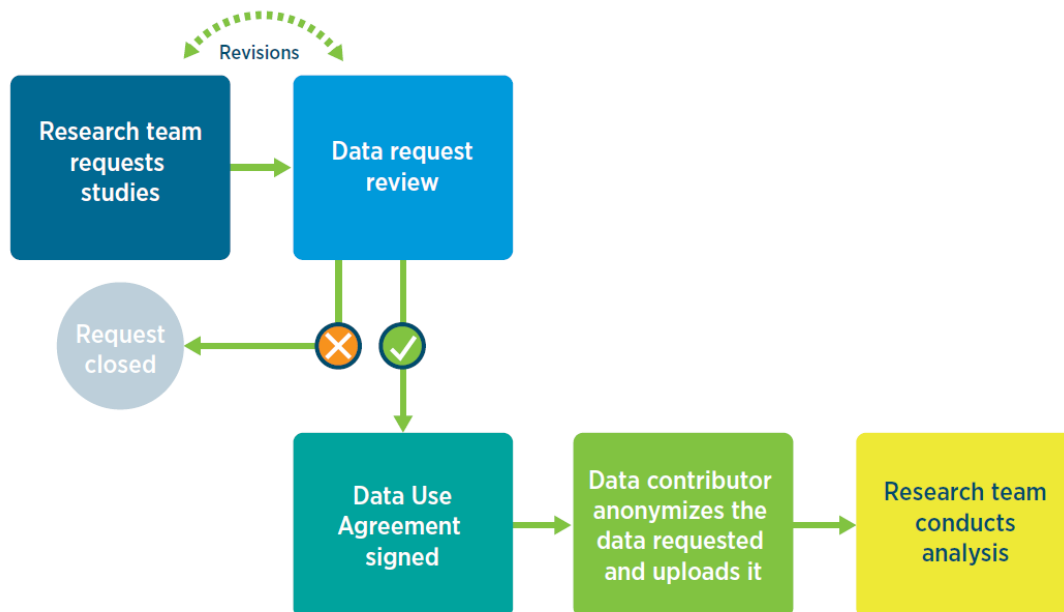
4. The downloaded file contains:

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

## 4. Reviewing Data Requests

### 4.1 Overview

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

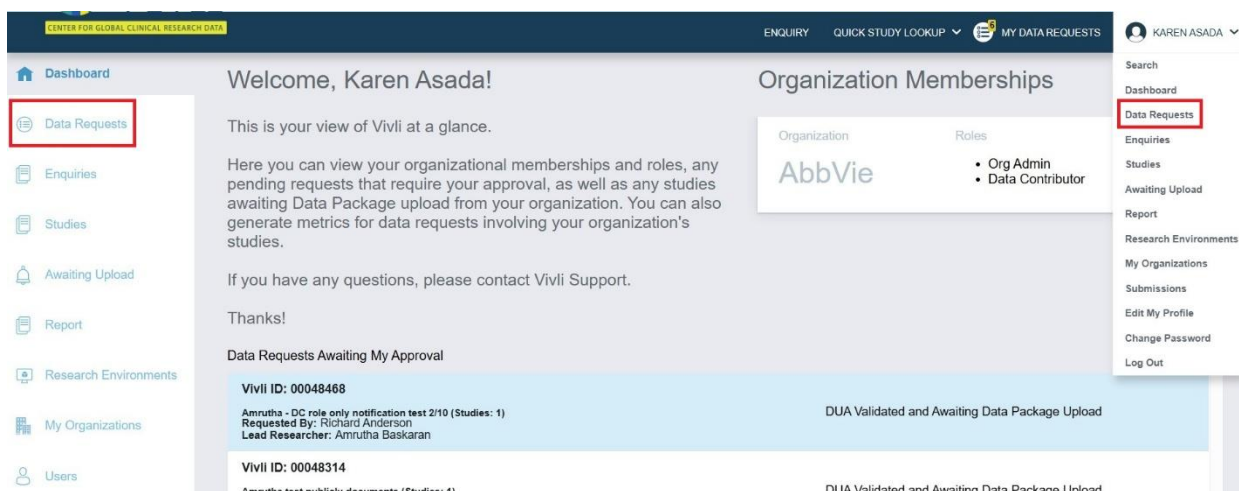


### 4.2 Data Request Review

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

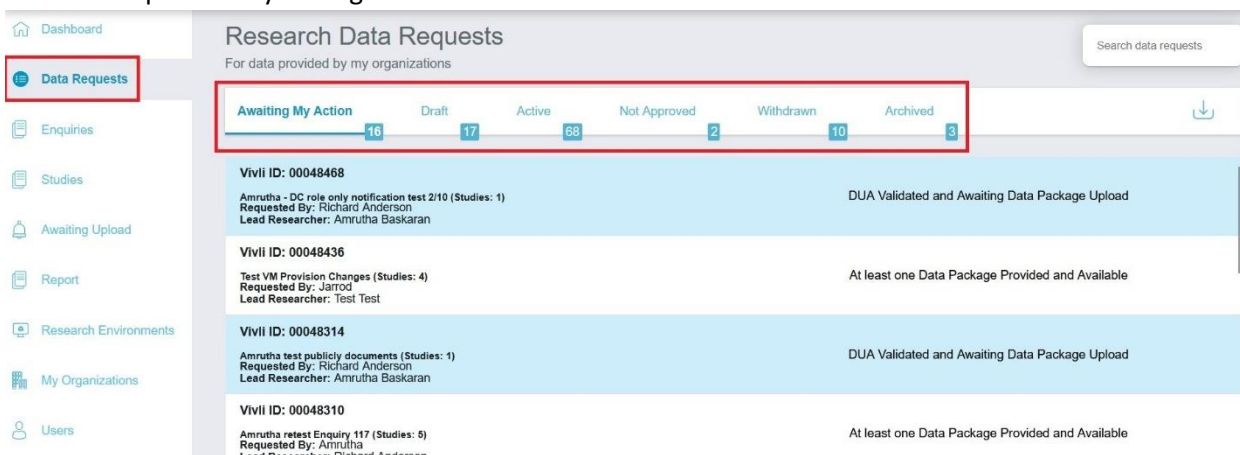
### 4.2.1 Navigating to Data Requests

1. Once you have logged in to the dashboard, you can navigate to Data Requests using the toolbar on the left-hand side of the screen. You can also use the dropdown menu on the upper right-hand corner of the screen:



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

2. 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.



3. The status bar contains 6 sections:

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

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

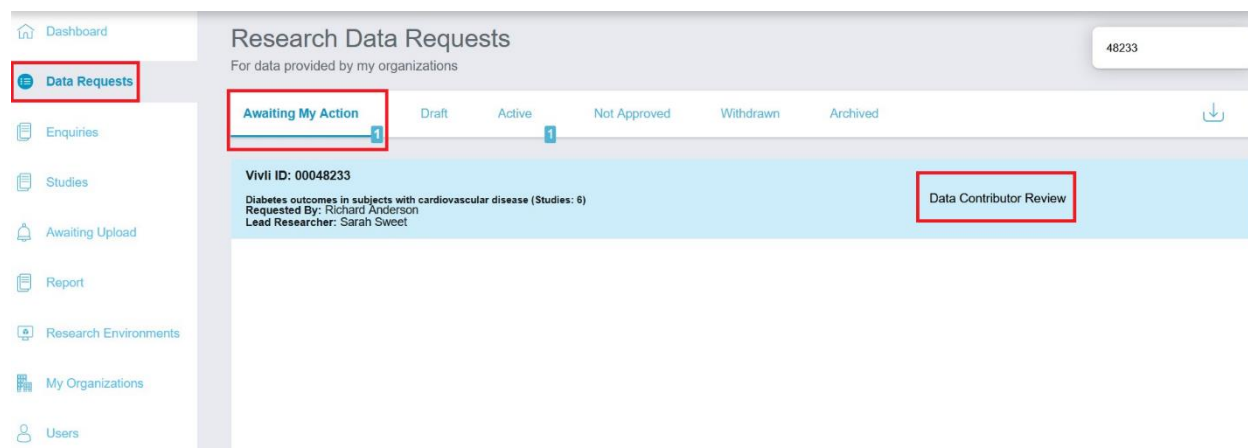
**Active:** Displays Data Requests that are in progress. This includes requests in the Vivli form check stage, requests that were sent back for revision, requests in the Data Contributor Review stage, IRP review stage, DUA validation stage, awaiting data package upload stage, and requests where some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

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

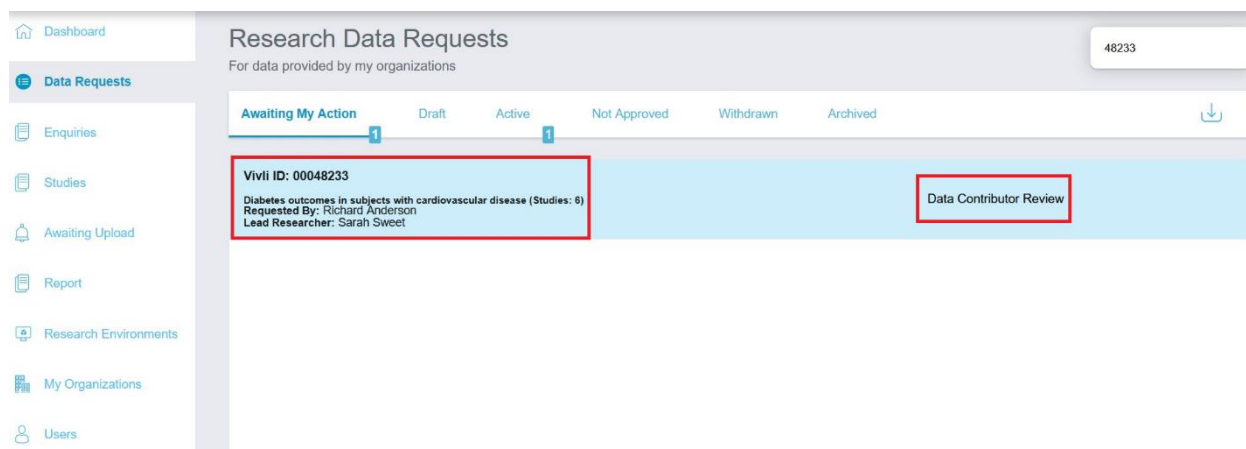
**Withdrawn:** Displays Data Requests that were withdrawn.

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

4. The 'Awaiting My Action' section displays a quick view of all the Data Requests 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)



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

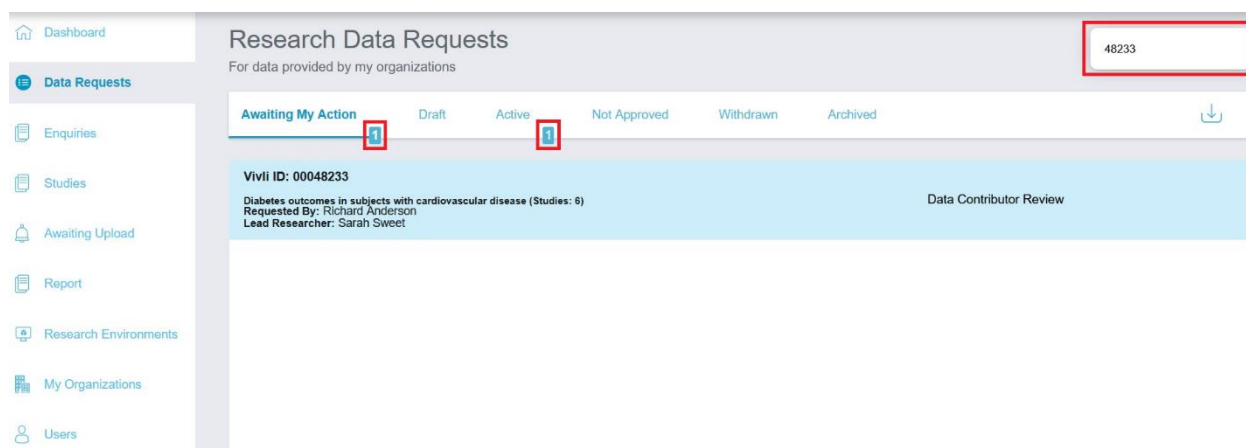


#### 4.2.2 Data Request Dashboard – Search Feature

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

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

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



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

The screenshot displays the 'Research Data Requests' page. On the left is a sidebar with navigation links: Dashboard, Data Requests (selected), Enquiries, Studies, Awaiting Upload, Report, Research Environments, My Organizations, and Users. The main content area has a header 'Research Data Requests' with a sub-header 'For data provided by my organizations' and a search bar 'Search data requests'. Below the header is a status filter bar with tabs: Awaiting My Action (16), Draft (17), Active (68), Not Approved (2), Withdrawn (10), and Archived (3). A red box highlights a download icon (a square with a downward arrow) in the top right corner of the table. The table lists four data requests with their details and status.

Vivli ID	Request Details	Status
00048468	Amrutha - DC role only notification test 2/10 (Studies: 1) Requested By: Richard Anderson Lead Researcher: Amrutha Baskaran	DUA Validated and Awaiting Data Package Upload
00048436	Test VM Provision Changes (Studies: 4) Requested By: Jarrod Lead Researcher: Test Test	At least one Data Package Provided and Available
00048314	Amrutha test publicly documents (Studies: 1) Requested By: Richard Anderson Lead Researcher: Amrutha Baskaran	DUA Validated and Awaiting Data Package Upload
00048310	Amrutha retest Enquiry 117 (Studies: 5) Requested By: Amrutha Lead Researcher: Richard Anderson	At least one Data Package Provided and Available

3. The downloaded file contains:

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



### 4.2.3 Data Request Form

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

4. 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.

5. 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.

The screenshot shows the Vivli Data Contributor Review page for Request 3469, PI: Sarah Jones. The status is "Data Contributor Review". The page includes a sidebar with navigation options: Studies, Status Update, Attachments, Request History, Signed Agreements, Chat, and Request Details/Print View (highlighted). The main content area displays the request title: "Research Data Request: Predicting Treatment Response to combination drugs in patients with type 2 diabetes" and the Vivli ID: 00003469. A red box highlights the "Comments from the Vivli Team" section, which contains the following text: "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." Below the comments, the "Research Team" section is visible, including the Lead Investigator, Sarah Jones, and her contact information.

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

The screenshot shows the Vivli Data Contributor Review page for Request 48680, PI: Sarah Jones. The status is "Data Contributor Review". The page includes a sidebar with navigation options: Studies, Status Update, Attachments, Request History, Signed Agreements, Chat, and Request Details/Print View (highlighted). The main content area displays the request title: "A.I. algorithm". A red box highlights the "AI/ML Question(s)" section, which contains the following text: "Please answer the following questions related to use of Artificial Intelligence (AI) and Machine Learning (ML). Also, review the Vivli policy in this document: [Vivli AI/ML Model Requirements](#)". Below this, there is a question: "Please confirm if you will be using any Artificial Intelligence or Machine Learning in this request? \*". The "Yes" option is selected. Another question follows: "Please indicate which model types will be developed in your analysis (Note: you will comment on how these models support your analysis in the SAP section) \*". The selected option is "Machine learning models - Defined models similar in nature to standard statistical models (Lasso, Random Forests, Support Vector Regression, Decision Tree...". A final question is visible: "Will your analysis include the use of existing trained models \*".

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

The screenshot shows the 'Data Contributor Review' interface for Request 48680, PI: Sarah Jones. The status is 'Data Contributor Review'. At the top right, there are several buttons: 'Include Risk Score' (highlighted with a red box), 'Cannot Fulfill', 'Request Revision', 'Process Request', and 'Print'. On the left sidebar, there are links for 'Studies', 'Status Update', 'Attachments', 'Request History', 'Signed Agreements', 'Chat', and 'Request Details/Print View'. The main content area is titled 'A.I. algorithm' and 'AI/ML Question(s)'. It contains a form with the following questions:

- Please answer the following questions related to use of Artificial Intelligence (AI) and Machine Learning (ML). Also, review the Vivli policy in this document: [Vivli AI/ML Model Requirements](#)
- Please confirm if you will be using any Artificial Intelligence or Machine Learning in this request? \*
  - ☐ No
  - ☒ Yes
- Please indicate which model types will be developed in your analysis (Note: you will comment on how these models support your analysis in the SAP section) \*
  - Machine learning models - Defined models similar in nature to standard statistical models (Lasso, Random Forests, Support Vector Regression, Decision Tree...
- Will your analysis include the use of existing trained models \*

8. This will uncover the Risk score and Risk Explanation in the data request form

The screenshot shows the same interface as before, but now the 'Risk Score' and 'Risk Explanation' section is highlighted with a red box. The 'Yes' radio button is selected. Below the questions, there is a link: [Please review Section 4.0 of the Vivli DUA \(Intellectual Property\) and confirm understanding that Members have royalty free worldwide license to all products developed with their data.](#)

The highlighted section contains the following information:

- Risk Score**  
Not Allowed
- Risk Category**  
Not Allowed
- Risk Explanation**  
Model type: Machine Learning model, low risk + 1  
Model data: De-identified, Not Allowed  
Model usage: Export of model, Yes (Machine learning model), low risk + 1

9. Reviewers can read the Data Request Form online, or print a PDF copy by clicking on the “print” button. Ensure to click “Include Risk Score” button to include the risk score and explanation. For best print experience, please use Chrome, Microsoft Edge or Safari browser.

[< Go Back](#)**Request: 48680, PI: Sarah Jones**  
**Status: Data Contributor Review**

Include Risk Score

✕ Cannot Fulfill

✕ Request Revision

✓ Process Request

Print

Studies

Status Update

Attachments

Request History

Signed Agreements

Chat

Request Details/Print View

A.I. algorithm

AI/ML Question(s)

Please answer the following questions related to use of Artificial Intelligence (AI) and Machine Learning (ML). Also, review the Vivli policy in this document: [Vivli AI/ML Model Requirements](#)

**Please confirm if you will be using any Artificial Intelligence or Machine Learning in this request? \***

☐ No

☒ Yes

**Please indicate which model types will be developed in your analysis (Note: you will comment on how these models support your analysis in the SAP section) \***

Machine learning models - Defined models similar in nature to standard statistical models (Lasso, Random Forests, Support Vector Regression, Decision Tree...)

**Will your analysis include the use of existing trained models \***

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

Save

Cancel

10/5/21, 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

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 secondary navigation 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 'Research Data Request: Predicting Treatment Response to combination drugs in patients with type 2 diabetes', the Vivli ID '00003469', comments from the Vivli Team, and the research team information for Lead Investigator Sarah Jones.

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

	A	B	C	D	E	F	G	H	I	J
1	Sponsor ID	Study Id	IpD Uploaded	Study Title	Principal 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 4.5.3. Status Update](#). For the DUA Subtab, please see [Section 4.6. Data Use Agreement](#)
- **Attachments tab:** any other documents included by the data requestor. Note: attachments are also visible at the end of the “Request Details/Print View” tab. Please download a copy of the attachments for your review.
- **Request history tab:** shows the history of the data request, including decisions recorded by you or by other Member Organizations involved in your data request. Request history also shows Vivli form checks, Data Contributor review, IRP review, DUA validation events, Data package upload, when data packages are accessed via Research Environment or through download (based on member’s data-sharing criteria), Results exported, reported Safety concerns, Research Environment provisioned, Research Environment de-provisioned, Request Archival and Request Withdrawal.
- **Signed Agreements tab:** shows the executed signed Data Use Agreement and any further DUA extension forms. Note: You will see the executed DUA after the request is approved and the DUA is executed.
- **Chat tab:** Please see section [11.1 Chat](#).
- **Public Disclosure:** Final citations linked to the specific data request. (This tab is visible after the request reaches the data upload stage).

*Once the research environment is started, the following tabs will appear on the data request.*

- **Safety Concerns:** Please see [Section 10. Safety reporting](#)

- **Research Results:** Results requested by the researcher.
- **Research Environment:** Research environment tab can be accessed only by the researcher.

#### 4.2.4 Vivli Policies in Brief

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



### 4.3 Study Settings at Data Contributor Review

Organizational Administrators have the opportunity to specify the study data storage behavior of each study within the data request. i.e. a specific data package to be uploaded just for this particular request or not. The current settings are below the “Edit Settings” button. To make the changes, click on “Edit Settings”.

The screenshot shows the Vivli Data Contributor Review interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this, there are buttons for ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and a user profile for SALLY. The main content area is titled "REQUESTED STUDIES" and "VIVLI-LISTED AND PROVISIONED STUDIES". It lists two studies with their respective settings. The first study, NCT01733758, has settings: "Data will be loaded for this and future requests" and "Data available in secure research environment only". The second study, WV15872, has settings: "Data loaded for this request only" and "Data package downloadable". Both studies have a checkbox for "Data to be loaded after approval". The interface also includes a sidebar with links for Status Update, Attachments, Request History, Signed Agreements, Chat, and Request Details/Print View.

The following pop-up will display on the page:

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

The pop-up is titled "Advanced settings for the study NCT03085810 in this data request only". It contains the text: "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'." Below this text is a checkbox labeled "Data loaded for this request only" which is currently checked. At the bottom of the pop-up are two buttons: "OK" and "Cancel".



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

The screenshot displays the Vivli web application interface. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a sub-navigation bar with ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and a user profile for SALLY. The main content area is titled 'REQUESTED STUDIES' and contains a section for 'VIVLI-LISTED AND PROVISIONED STUDIES'. Two study entries are visible. The first study, '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...', has a 'Settings' button highlighted with a red box. The second study, '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', also has a 'Settings' button. Below these 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'. A left sidebar contains links for Status Update, Attachments, Request History, Signed Agreements, Chat, and Request Details/Print View. At the top of the main content area, there are buttons for 'Cannot Fulfill', 'Request Revision', 'Process Request', and 'Print'.

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

## 4.4 Recording a Decision about a Data Request

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

The screenshot displays the Vivli web application interface. At the top, the Vivli logo and navigation menu are visible. The main content area shows a research data request for "Predicting Treatment Response to combination drugs in patients with type 2 diabetes" with Vivli ID: 00003469. The status is "Data Contributor Review". In the upper right corner, there are three decision buttons: "X Cannot Fulfill", "X Request Revision", and "✓ Process Request", each enclosed in a red box. Below these buttons, the interface shows a sidebar with navigation links (Studies, Status Update, Attachments, Request History, Signed Agreements, Chat, Request Details/Print View) and a main content area with details about the request, including comments from the Vivli Team and the research team information for Sarah Jones, Lead Investigator.

The data request decision options are:

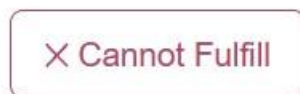


#### 4.4.1 Cannot Fulfill

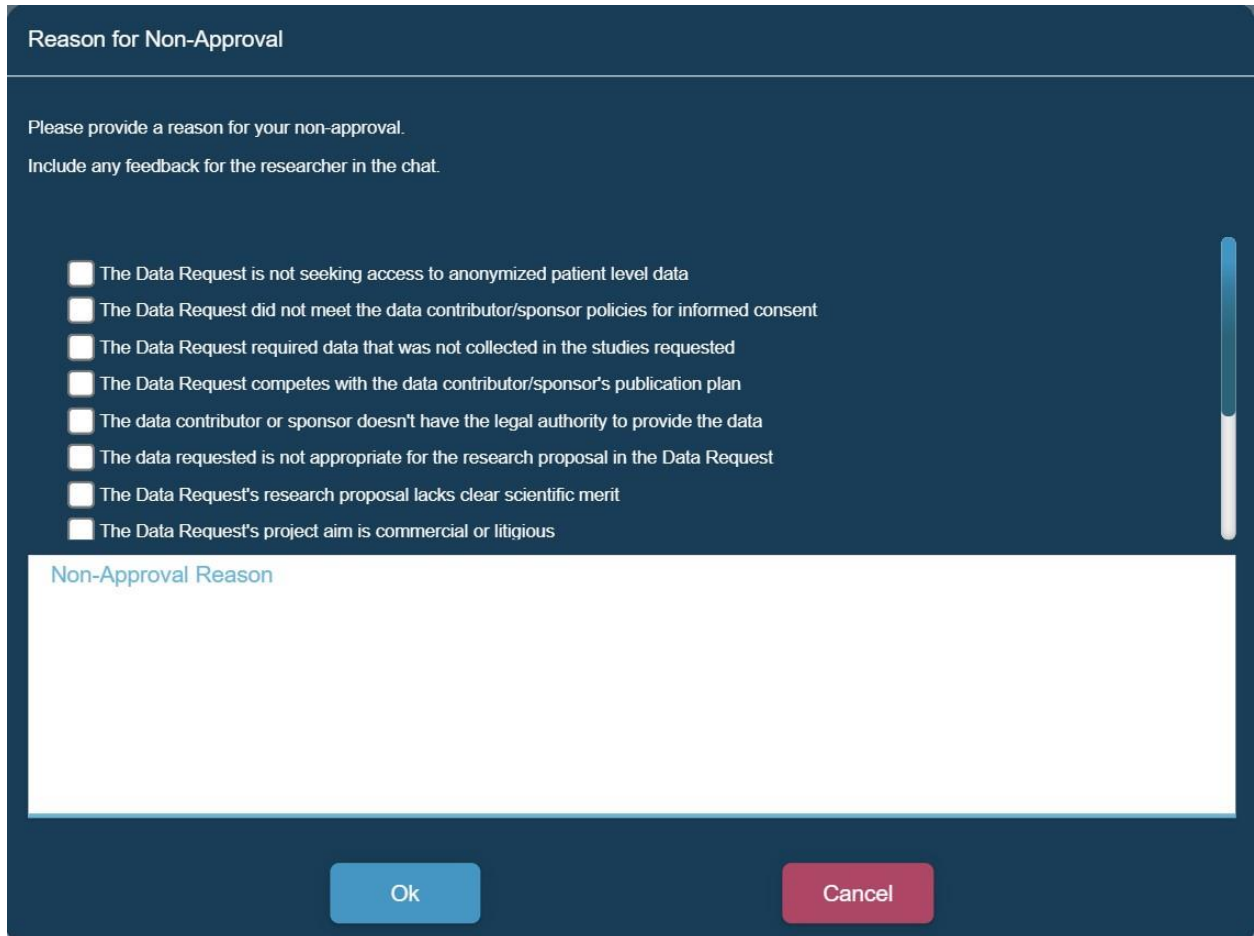
1. You may use this option if the data request or all the studies in the data request don't meet your Organization's Data-Sharing policy in accordance with your [members' page](#)
2. Any reason for being unable to fulfill a request needs to be transparent and listed as a reason for not sharing on your member's page.
3. When recording the decision on the platform, click the "Cannot fulfill" button and then choose the appropriate checkbox that matches your member's page. Please don't leave the reason for non-approval blank. Please also check the "other reason for non-approval" checkbox to provide more context as to why the request falls outside your policy.

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

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



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



**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

6. Reasons for Non-Approval include:

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

7. To describe any other reason for non-approval, check “other reason for non-approval” and use the comment box. (Please note this reason for non-approval will need to appear on your member’s page).
8. Enter the reason(s) and press **Ok**. This will send an automated email to the Data Requestor and Vivli Administrator informing them of the decision.
9. This Data Request will now be categorized as “Not Approved” in the Data Request status bar and your decision will be recorded in the Request history of the Data Request
9. For multi-sponsor requests, if your organization has recorded its decision but another organization has not, the request will remain in the Data Contributor review stage under the **Active** status bar. Vivli's team will follow up with the other appropriate member to record their decision. Once all the decisions are recorded, the researcher may remove the not approved studies and move forward with the rest of the studies from other members.
10. If a request is not approved, Vivli will reach out to you to confirm that this reason is listed and transparent on your member’s page. Any final non-approvals will be reflected in the public [metrics](#) once the data request governance process, including DUA execution, has been completed.

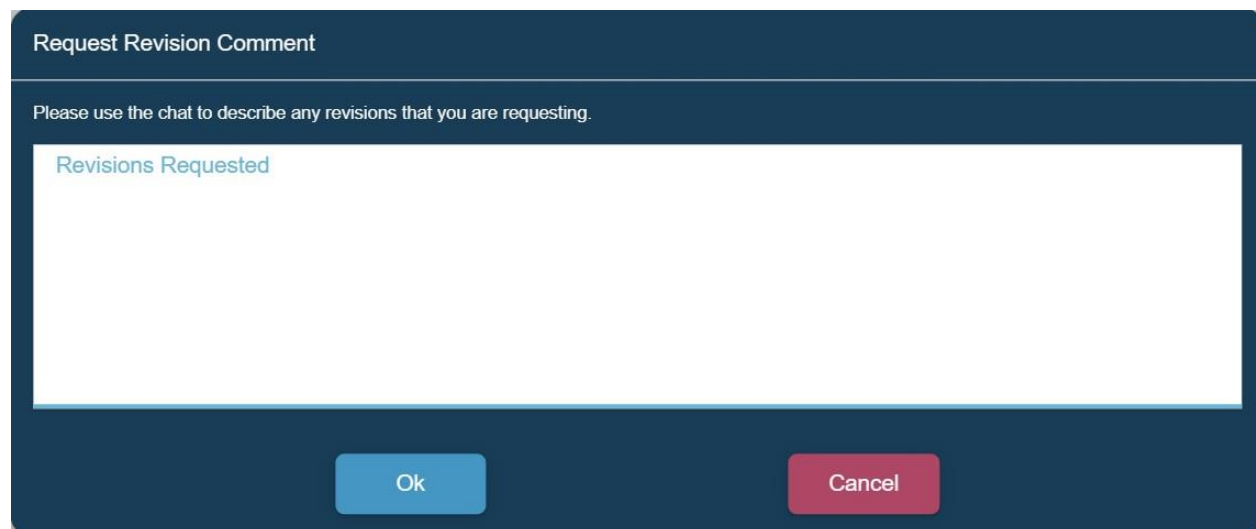
#### 4.4.2 Request Revision

1. You may use this option to request a revision to a particular section of the data request form. Another scenario is if you are willing to approve some of the requested study data but not all i.e. some studies were non-approved. In this case, please let the Researcher know which studies don't meet your Organization Data Sharing policy and your reason for non-approval of the studies in accordance with your [members' page](#). Please see [section 4.4.1 Cannot Fulfill](#) for the list of reasons for non-approval. You can request the researcher to remove those studies from your data request. Please note that partial non-approvals of studies will be published on the [Metrics page](#) once the request passes the DUA Validation stage. For minor revisions and fixing errors, please reach out to the Vivli Admin via open chat before clicking the revision button. Then Vivli Admin can make the changes on behalf of the Research team without sending the request back to drafts. This allows for a more efficient process for all involved.

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



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



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

- 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, the 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.

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

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: 0000-0002-1045-8336 Country: United States of America

**Education or Qualifications**  
MD, PhD in Biostatistics

**Conflicts of Interest and Plan for Management**  
None

**Statistician Researcher**

- 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

Home Tools [Compare Report]...

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

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 (SAP) text request.  
No additional changes were made to this request.

**Research Team**

**Lead Investigator and Statistician**

Emily Grant  
emilgrant@vivli.com  
Biostatistics  
Sina Hospital

**Education or Qualifications**  
Mathematics, BS - University of New Hampshire (2000)  
Statistics, MS - New York University (2002)  
Epidemiology and Biostatistics, Berkeley (2012)

**Conflicts of Interest and Plan for Management**  
N/A

**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, the Anti-TNF Research Study Program of the Monoclonal Antibody Addressable (D2E7) in Rheumatoid Arthritis (GRADA) trial, was a 24-week study conducted to evaluate the efficacy and safety of adalimumab administered subcutaneously every other week to patients with active RA despite long-term therapy with MTX.

**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 maximal benefits generally by 6 months (4). However, many patients continue to have some degree of active disease despite receiving optimal 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) (6, 7).

**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; formerly, the American Rheumatism Association) (15).

[Old File] 2021\_01\_25 Vivli ID 00002116 DRF (1).pdf [New File] 2021\_01\_25 Vivli ID 00002116 DRF (2).pdf

open chat as an attachment. For more information on major versus minor revisions to data requests, please see Section [4.4.4 Major Versus Minor Revisions to Data Requests](#).

The screenshot displays the Vivli Data Contributor interface. At the top, the Vivli logo is on the left, and navigation links (Home, About, Members, News & Events, Resources, Find Studies) are on the right. Below the navigation bar, a status bar shows 'Request: 3469, Pt: Sarah Jones' and 'Status: Data Contributor Review'. Action buttons include 'X Cannot Fulfill', 'X Request Revision', '✓ Process Request', and 'Print'.

The main interface is divided into a left sidebar and a central content area. The sidebar contains links for 'Studies', 'Status Update', 'Attachments', 'Request History', 'Signed Agreements', 'Chat' (highlighted with a red box), and 'Request Details/Print View'. The central content area is titled 'Open Chat' and shows a chat window for 'GlaxoSmithKline'. The chat window displays messages from 'Researcher' and 'Catherine D'Arcy'. A red box highlights a message from Catherine D'Arcy: 'File Uploaded: 2023\_09\_25 Vivli ID 00003469\_form check comparison report.pdf'. To the right of the chat window is a file upload section titled 'NO FILES IN PACKAGE' with a 'Select Files' button and a 'Drop files here' area. Below this is a table of 'UPLOADED FILES' with columns for 'Filename', 'Size', and 'Uploaded By'. A red box highlights the 'Filename' column, showing '2023\_09\_25 Viv...'. Another red box highlights the 'Uploaded By' column, showing 'Cather...'. A red box also highlights the 'X' button next to the file name.

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



#### 4.4.3 Process Request

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

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



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

### 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's team will follow up with the appropriate member to record their decision.

#### 4.4.4 Major Versus Minor Revisions to Data Requests

Change	Classification (major/minor)
Change to Primary Investigator or their institution	Major
Change to Lead Statistician or their institution	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 the Primary Investigator, Lead Statistician, their conflict of interest, or changes to the Statistical analysis plan **before the review process is complete**, the Vivli team will make changes on the researchers' behalf and inform the Organizational Administrators via chat.
- If a data requester makes any major changes to the data request form i.e. Changes to the Primary Investigator, Lead Statistician, their conflict of interest, or changes to the Statistical analysis plan **after the data request review process is complete**, Vivli will reach out to Organizational Administrators via “Contributors” chat (visible to Organizational Administrators and Vivli Admins) to ask if they approve this change. If all Organizational Administrators’ approve, the Vivli administrator will make this change on behalf of the data requester and will record this change as a note to file and upload it in the signed agreements tab. The DUA will also need to be re-executed along with the updated data request form. If one of the Organizational administrators requests this change go through formal approval, the Vivli team will send the data request back for review to all other relevant Organizational administrators 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 Organizational Administrators via “Contributors” chat (visible to Organizational Administrators and Vivli Admins) to ask if they approve this change. If all Organizational Administrators' approve, the Vivli administrator will 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 Organizational Administrators requests this change go through formal approval, the Vivli team will send the data request back for review to all other relevant Organizational Administrators according to their chosen data request governance process.
- If a data requester wants to add any studies from **a different Vivli Member who has not reviewed the data request after the review process is complete**, the data request will require the 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 Vivli Members involved.



**Key factors that influence the timeline:**

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

#### 4.4.5 Withdrawal

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

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

- When the request has been submitted and returned to Drafts for revision (and)
- Has not been revised, resubmitted, or progressed to the next stage of review (and)
- No response has been received from the Research Team to Vivli Admin for 5 months following bi-weekly follow-ups in chat

After 5 months, the Vivli Admin will place a note in chat informing the Researcher that multiple attempts to contact them have been unsuccessful and their request will be considered withdrawn and moved to the Withdrawn state on the platform. If a Researcher responds to this message, the request can continue through the process. Otherwise, the request is considered abandoned. The researcher may contact Vivli at [support@vivli.org](mailto:support@vivli.org) anytime to move the request back from withdrawn to drafts.

The data request is moved to the withdrawn section of the Data Request Dashboard. The withdrawal decision is recorded in the request history of the data request. Withdrawn requests are reflected on the [Metrics page](#).

#### 4.4.5 Target Timeline for the Review Process

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

#### 4.4.6 Summary-level and Document-only Data Request

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

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

1. Researcher submits the data request
2. Vivli Admin notes on the top of the data request if this is a summary-level or document-only request
3. Organization Administrators the study setting by checking the checkbox “Data loaded for this request only”. See [Section 4.3 Study Settings at Data Contributor Review](#)
4. Vivli Admin will reach out to the Organization Administrator via “Contributors” chat to confirm if the member agrees to skip the IRP review and make the summary level data available for download
5. Organization Administrator records the Data Contributor review as a standard
6. Data request skips IRP review
7. Standard Data Use Agreement and security addendum is signed
8. Data Upload the specific data just for this data request
9. Summary-level data and documents to be downloaded by the researcher
10. These requests are not counted toward the number of requests that are included as part of a member’s yearly allocation of data requests.

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

## 4.5 Reports

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

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, the user profile dropdown menu is open, and the 'Report' option is highlighted with a red box. The main content area displays a table titled 'Report' with the following data:


Vivli ID	Lead Researcher	Data Contributors	Number of My Organization's Studies	Total Studies Requested	Current Status	Active	Actions
3469	Sarah Jones	GlaxoSmithKline Roche	1	2	Data Contributor Review	true	Member1 - feasibility c
48058	Iiz test	Takeda Test GSK	1	2	Denied	true	
2704	Nick Jones	AbbVie Roche Novelion Therapeutics Pfizer Inc.	1	4	Draft	true	
48053	Amrutha Baskaran	AbbVie GlaxoSmithKline	3	6	Awaiting IRP/Reviewer Approval	true	

There are six types of reports:

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

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

#### 4.5.1. Features of the Report

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

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

Lead Researcher Email	Data Contributors ▾
<input type="text"/>	<input type="text" value="ROCHE"/>
SJJones@ucsf.edu	<ul style="list-style-type: none"><li>• GlaxoSmithKline</li><li>• Roche</li></ul>

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.

Data Contributors	Number of My Orga..
<input type="text"/>	<input type="text"/>
<div>▾</div>	<div>▾</div>
<ul style="list-style-type: none"><li>• GlaxoSmithKline</li></ul>	<div>Not contains ▾</div>
<ul style="list-style-type: none"><li>• GlaxoSmithKline</li></ul>	<div>Contains</div>
	<div>Not contains</div>
	<div>Equals</div>
	<div>Not equal</div>
	<div>Starts with</div>
	<div>Ends with</div>

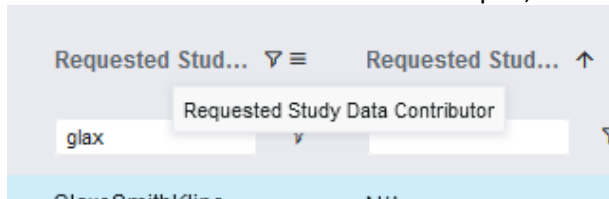
  

Data Contributors ▾	Number of My Orga...
<input type="text" value="AMR"/>	<input type="text"/>
<ul style="list-style-type: none"><li>• GlaxoSmithKline</li></ul>	<div>Not contains ▾</div>
	<div>AMR</div>

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.

Vivli... ↑	Vivli... ↓
------------	------------

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



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

#### 4.5.2. Fields Included in the Report

1. *Standard Display, 1 Data Request per row*, includes the following fields:
  - Vivli ID
  - Lead Researcher
  - Lead Researcher affiliation
  - Lead Research country
  - Data Contributors (comma-separated list)
  - Number of My Organization's Studies – Number of studies from your organization included in the request.
  - Total Studies Requested – Number of studies from all data contributors included in the request.
  - Current Status – Draft, Vivli Form check, Form check failed, Data Contributor Review, Awaiting IRP/Reviewer Approval, DUA Validation, Awaiting Data Package Upload, Partially Fulfilled, Fulfilled, 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 Vivli Members at a particular stage as set by the Vivli admin. This complements the decisions and uploads the required field.
  - Decisions and Uploads Required – This is automatically set by the Vivli platform and will always be up to the minute
  - Days in Current Workflow Step – Number of days the request in the particular step. It is computed automatically, in real time. If it is greater than the Target Days for Current Workflow Step, we put an asterisk on Days in Current Step to indicate “overdue”. If the Target Days for the Current Workflow Step is -1, there is no target (e.g. for the Analysis phase).
  - Target Days for Current Workflow Step – 21 days for Data Contributor review, 30 days for IRP review, 30 days for Data Upload, and 30 days for Publication review
  - Feedback – For Organizational Administrators to provide any comments in response to weekly summary comments. For more information, please see [Section 4.5.3. Status Update](#)
  - Request Review Status – shows Form check, Data Contributor review, and IRP review decision
  - DUA Execution
  - DUA Expiration
  - DUA Status – Pending DUA, DUA execution, DUA extension, and DUA closure
  - Data Upload Status – Updates on data upload status



- Results Export Requests – Includes Date and whether approved
  - Publication Status – Includes courtesy review, public disclosure acceptance, published disclosures, and summary of results.
  - Additional Notes – Revision of previous Vivli ID#, transition request #, and Pending chat question or other pending issues.
  - Date Submitted to Data Contributor –The date when the request was first submitted to the Data Contributor review.
  - Date of Last Change –Records any change, including updates you or the Vivli admin make to the status update.
2. *Standard Export, 1 Data Request per row* includes the fields above and includes the following additional fields:
- Title – Request title
  - Lead Researcher Title
  - Lead Researcher Email
  - Date First Published
  - Main Predictor/Independent Variable
  - Publication Plan
  - Brief Description
  - Aims, Objectives, Hypotheses
  - Purpose of Analysis
  - Outcomes
  - Therapeutic Area (of the data request)
  - Public disclosures
  - Number of Public disclosures
  - All Studies Included by Sponsor ID/NCT ID
  - Data Request DOI
3. *Full Export, 1 Requested Study per Row*, repeats the standard export row once for each requested study. This is to support the analysis of the requested studies. It includes studies provided by all contributors. It includes the fields above except “All Studies Included by Sponsor ID/NCT ID” and includes the following additional fields:
- Lead Sponsor Agency
  - Requested Study Data Contributor – Name of a data contributor. To see studies from your organization, filter by “Requested Study Data Contributor”
  - Requested Study NCT ID
  - Requested Study Sponsor ID
  - Version of data
  - Phase

- # participants
- IRP Name

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

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

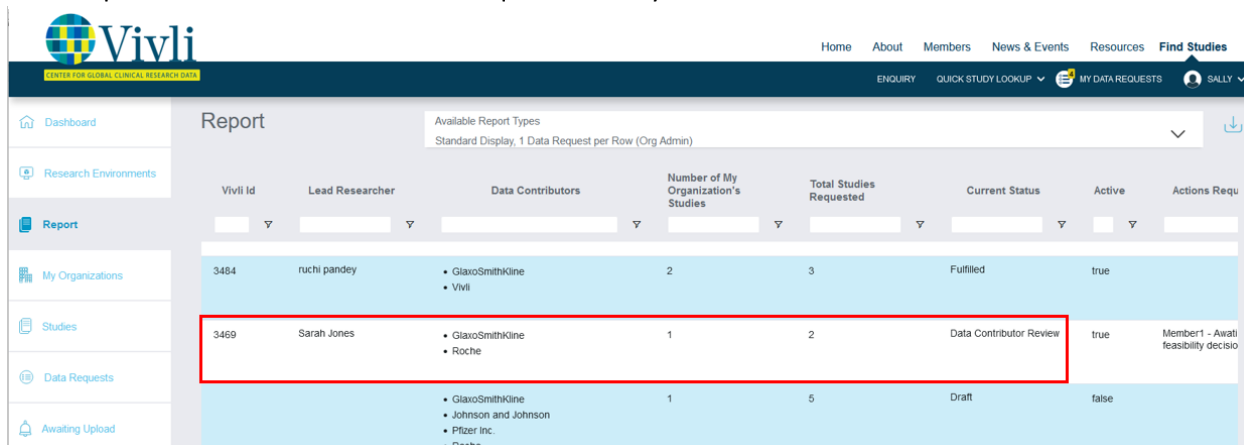
- NCT Id
- Sponsor Protocol Id
- Secondary ID
- Posted Date
- Submitted Date
- Org Name
- Lead Sponsor Agency
- Lead Sponsor Class
- Approving Organization
- Study Title
- Ror Names
- Parent Ror Names
- Citation Count
- Study Metadata Doi
- Is Data Uploaded
- Version of Data
- Conditions
- Interventions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

5. *Enquiries Report*, has one row per requested study in a given Enquiry. For more information, please see [Section 3.4 Enquiries Report](#)
  
6. *Metrics Export, 1 Data Request per row*, includes the following fields:
  - Request Number
  - Name of Lead Researcher
  - Request Title
  - Therapeutic Area
  - Data Contributors
  - # of My Org's Studies
  - # Studies for All Orgs
  - NCT IDs from My Org
  - Study Sponsor IDs From my Org
  - # Participants for My Org's Studies
  - # Participants for All Orgs' Studies
  - Outcomes Specified by Requester
  - Current Request Status
  - Current Stage
  - Start Date of Current Step
  - Date First Submitted to Vivli
  - Date entered DC Review
  - "1" if ever reached DC Review
  - "1" if My Org ever Requested Revisions
  - "1" if My Org ever Rejected
  - "1" if My Org ever Approved
  - Days to My Org's DC Decision
  - Target for DC Review
  - Mean Days to Decision for All DCs, All Requests
  - Total Days My Org spent in DC Review
  - Max Days to Decision for All Orgs
  - Most Recent Decision by My Org
  - Date of My Org's Most Recent Decision
  - Date entered IRP Review
  - "1" if ever reached IRP Review
  - "1" if my IRP ever Requested Revisions
  - "1" if my IRP ever Rejected
  - "1" if my IRP ever Approved
  - Days to my IRP's Decision
  - Target for IRP Review
  - Mean Days to Decision for All IRPs, All Requests

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

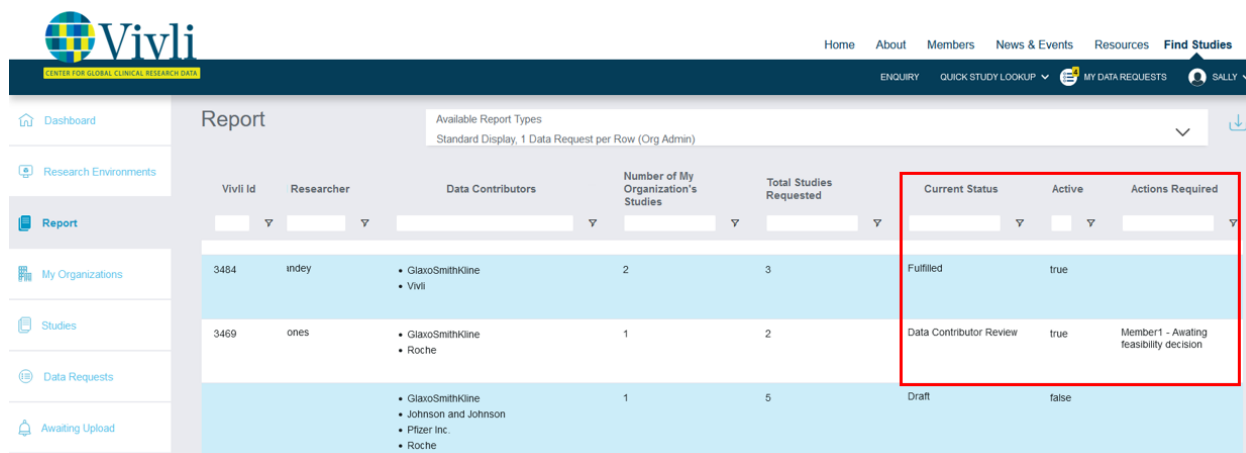
#### 4.5.3. Status Update

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



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 left sidebar contains a menu with options: Dashboard, Research Environments, Report (selected), My Organizations, Studies, Data Requests, and Awaiting Upload. The main content area is titled 'Report' and displays a table of data requests. The table has columns for Vivli ID, Lead Researcher, Data Contributors, Number of My Organization's Studies, Total Studies Requested, Current Status, Active, and Actions Required. The row for Vivli ID 3469, led by Sarah Jones, is highlighted with a red box. This row shows 'Data Contributor Review' as the current status and 'Member1 - Await feasibility decision' as the action required.

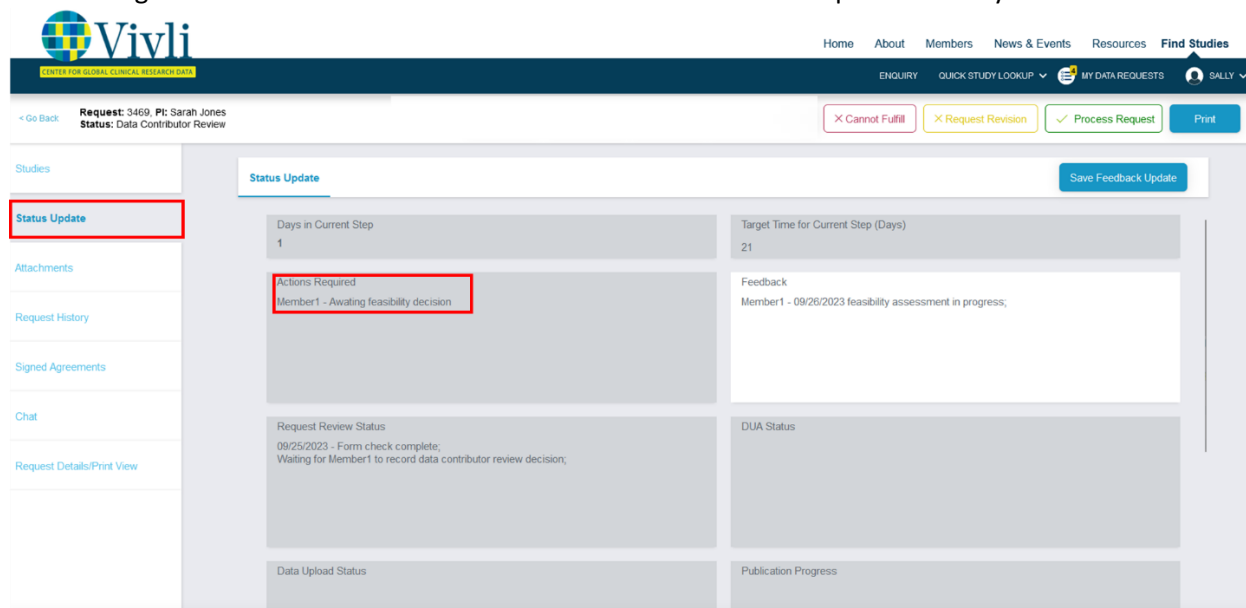
Vivli ID	Lead Researcher	Data Contributors	Number of My Organization's Studies	Total Studies Requested	Current Status	Active	Actions Required
3464	ruchi pandey	GlaxoSmithKline Vivli	2	3	Fulfilled	true	
3469	Sarah Jones	GlaxoSmithKline Roche	1	2	Data Contributor Review	true	Member1 - Await feasibility decision
		GlaxoSmithKline Johnson and Johnson Pfizer Inc. Roche	1	5	Draft	false	



The screenshot shows the Vivli 'Report' page. A red box highlights the 'Current Status', 'Active', and 'Actions Required' columns for three data requests.

Vivli Id	Researcher	Data Contributors	Number of My Organization's Studies	Total Studies Requested	Current Status	Active	Actions Required
3484	indey	• GlaxoSmithKline • Vivli	2	3	Fulfilled	true	
3469	ones	• GlaxoSmithKline • Roche	1	2	Data Contributor Review	true	Member1 - Awaiting feasibility decision
		• 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 Organizational Administrator are entered into the 'Action Required' field by Vivli.



The screenshot shows the 'Status Update' form for request 3469. A red box highlights the 'Actions Required' field.

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

**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:**

**Publication Progress:**

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

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, a sub-navigation bar shows 'ENQUIRY', 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and a user profile for 'SALLY'. The main content area is titled 'Request: 3469, PI: Sarah Jones' and 'Status: Data Contributor Review'. A sidebar on the left lists various options: Status Update (highlighted with a red box), Attachments, Request History, Signed Agreements, Chat, and Request Details/Print View. The main form area is titled 'Status Update' and contains several fields: 'Days in Current Step' (1), 'Target Time for Current Step (Days)' (21), 'Actions Required' (Member1 - Awaiting feasibility decision), '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'. The 'Feedback' field is highlighted with a red box and contains the text 'Member1 - 09/28/2023 feasibility assessment in progress;'. A 'Save Feedback Update' button is located at the top right of the form.

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

This screenshot is identical to the previous one, showing the same Vivli web application interface. The 'Status Update' tab is selected, and the 'Feedback' field is highlighted with a red box. The 'Save Feedback Update' button at the top right is also highlighted with a red box.

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

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

## 4.6 Data Use Agreement (DUA)

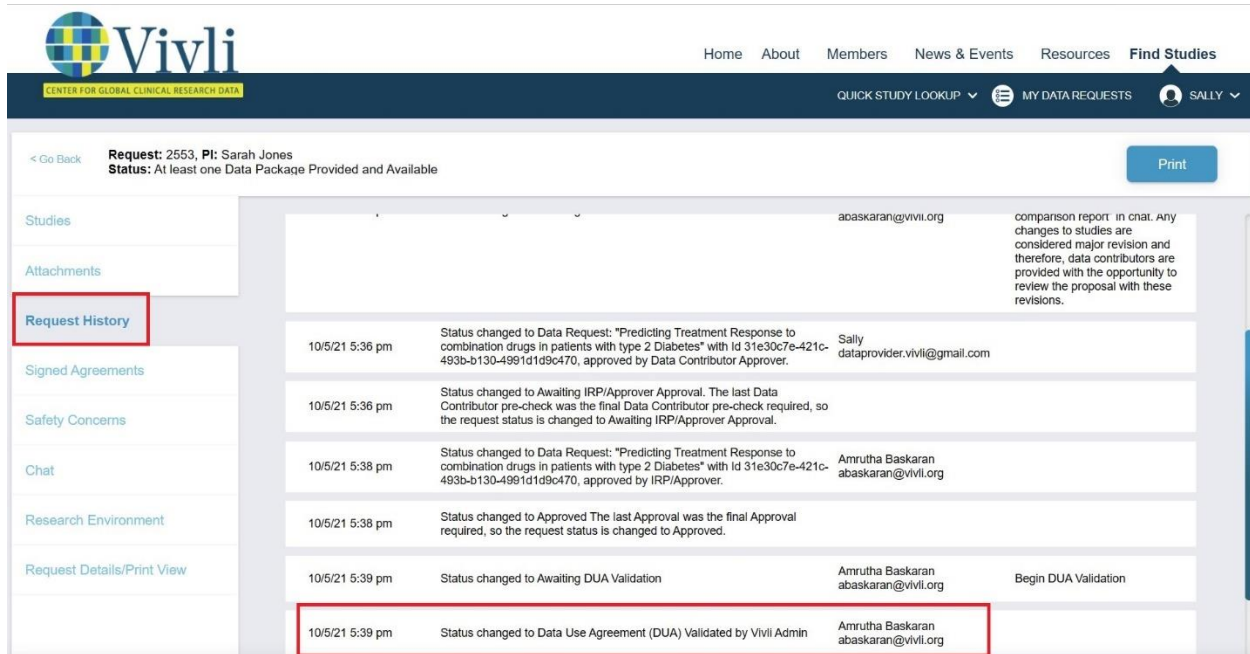
- Organizational Administrators and Data Contributors will be notified via email when the DUA has been signed, uploaded, and executed by the Vivli Administrator.
- The signed DUA will be available for download under the **Signed Agreements** tab of the data request.

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 with 'Request: 2553, PI: Sarah Jones' and 'Status: At least one Data Package Provided and Available'. The left sidebar contains various tabs: 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' with columns: Filename, Date, Size, and Uploaded By. A single row is shown with the filename '2021\_10\_05 Vivli ID 00002553\_DUA exe...', date '10-5-21 5:38 pm', size '674.00kB', and uploaded by 'Amrutha Baskara...'. A 'Download' button with a download icon is highlighted with a red box next to the filename.

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

The screenshot shows the Vivli web application interface with the 'DUA Details' subtab selected. The top navigation bar is the same as the previous screenshot. The header shows 'Request: 48310, PI: Richard Anderson' and 'Status: At least one Data Package Provided and Available'. The left sidebar has the same tabs, but 'Status Update' is highlighted with a red box. The main content area has two subtabs: 'Status Update' and **DUA Details** (highlighted with a red box). Under 'DUA Details', there's a section titled 'Execution' with a checkbox labeled 'Active' that is checked. Below this is a table with two rows: 'Original Execution:' with the date '11/11/2024' and 'Current Expiration:' with the date '11/11/2025'. This table is highlighted with a red box. Below the table is a section titled 'DUA Status' with the text 'DUA Executed - 11/11/2024;'. The 'Print' button is visible in the top right corner.

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



The screenshot shows the Vivli Data Contributor Guide 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 Request History for Request 2553, PI: Sarah Jones. The status is "At least one Data Package Provided and Available". The Request History table shows the following entries:

Timestamp	Status Change	By	Details
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-b130-4991d1d9c470, 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-b130-4991d1d9c470, 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	



- Once the request is approved and a Data Use Agreement is executed, Vivli team will publish on its website using the Vivli data request DOI:
  - Project Name
  - Name & Affiliation of the Lead Researcher
  - Funding Sources
  - Conflict of Interest Statement
  - Lay Summary of Research Proposal
  - List of requested studies

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

- Statistical Analysis Plan
- Publication Citation

The screenshot displays the Vivli website interface. At the top, the Vivli logo is on the left, and navigation links (Home, About, Members, News & Events, Resources, Portals, Find Studies) are on the right. Below the logo, a dark blue header contains links like ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and a user profile for KAREN ASADA. The main content area shows a research data request titled "Evaluation of Differences in Trial and Non-Trial Patients and Leveraging of External Data...". A sidebar on the left lists various request details like Studies, Status Update, Attachments, Request History, Signed Agreements, Safety Concerns, Research Results, Chat, Research Team, Research Environment, Public Disclosures, and Request Details/Print View (which is highlighted). The main content area includes the request title, Vivli ID: 00048506, and a red-bordered box containing the Data Request DOI: <https://handle.test.datacite.org/10.70118/AQ00048506>. Below this, the Research Team section lists the Lead Investigator, Sarah Jones, with her email, title, affiliation, and country. The Education or Qualifications section lists MD, PhD.

## 5. Data package upload

- Data Packages for the listed studies can be uploaded:
  - a. Directly into the study at the time of listing the study on the Vivli platform or while a request is under review
  - b. Directly to an approved data request once the Data Use Agreement is signed
- Only the team member with the Data Contributor rights can upload the data package. By default, Organizational Administrators are given Data Contributor rights.
- This data package is either provisioned into the research environment or made available for download, depending on the decision of the Vivli Member 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 (Exceptions are the unlisted studies and those that are marked for request-only upload. Please see [Section 4.3 Study Settings at Data Contributor Review](#)).
- As a security measure and to prevent accidental uploads of files, the Vivli platform uses a list of acceptable file types. If you attempt to upload a file type not on that list of acceptable types, you will get the message shown below. Please reach out to [support@vivli.org](mailto:support@vivli.org) to add a file type to the acceptable list.



## 5.1 Vivli Dashboard for Data Contributors

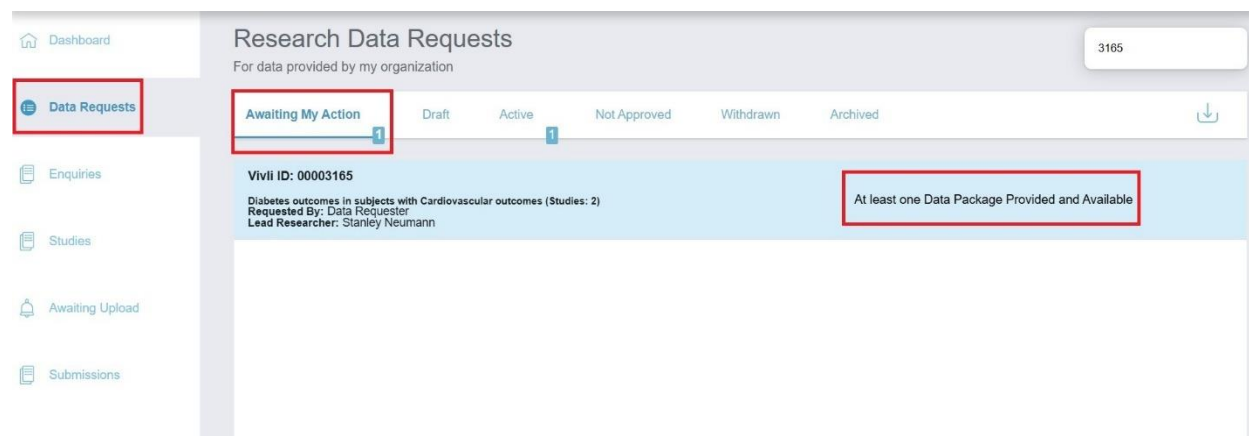
- Once you have been given data contributor privileges to your Organization and you have logged in, you will be taken to your Vivli Dashboard.
- On the dashboard, you may view the Organization that you are part of and your roles as part of your Organization.
- You may track studies needing data package 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 5.4 Uploading Data Package to an Approved Request](#)

The screenshot shows the Vivli dashboard interface. At the top, the Vivli logo is on the left, and navigation links (Home, About, Members, News & Events, Resources, Find Studies) are on the right. Below the navigation bar, there's a dark blue header with 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and a user profile 'SALLY'. The main content area is divided into three sections. On the left is a sidebar with icons and labels: 'Dashboard' (highlighted with a red box), 'Research Environments', 'Studies', 'Data Requests', and 'Awaiting Upload'. The central section is titled 'Welcome, Sally!' and contains a welcome message, a description of the dashboard's purpose, and a 'Data Requests Awaiting My Approval' section. The 'Data Requests Awaiting My Approval' section shows a specific request with details: 'Vivli ID: 00002553', 'Predicting Treatment Response to combination drugs in patients with type 2 Diabetes (Stuc)', 'Requested By: Data Requester', 'Lead Researcher: Sarah Jones', and a status bar indicating 'At least one Data Package Provided and Available'. On the right is a section titled 'Organization Memberships' which contains a table with columns 'Organization' and 'Roles'. The table shows 'Vivli Member' as the organization and 'Data Contributor' as the role (highlighted with a red box).

Organization	Roles
Vivli Member	• Data Contributor

## 5.2 Data Upload Notification

- Once the Data Use Agreement is executed, the Data Contributors will receive an email notification to 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.



### 5.3 General Upload Guidelines

- The data package upload times vary considerably based on your bandwidth. The observed range is from 300-400 Megabytes/hour to 5-6 Gigabytes/hour.
- When you have many or large files, using zip or 7-zip is highly recommended:
  - If the study contains more than 6-10 files, zip the data. You can leave the documents separate from the zip containing the data. Compression can reduce the size of textual data to 10% of the original or more; in addition, uploading a small number of files is easier and makes the system faster.
  - If you have large files, zipping can reduce the size by as much as 90% for files with textual content.
  - If you have very large files, 7-zip allows you to break them up into sections.
  - If the zipped files are large (more than 1 GB or so), it is best to load them one at a time rather than all at once. In your computer settings, set Power Plan to sleep "Never" when plugged in. (The sleep setting will interrupt the upload).
  - Once you start the upload, leave the computer running and the browser open. The progress of the upload is shown in the button to the right of the "card" that is created for the file.
- Other upload tips:
  - If it is practical, uploading is faster in the evening or overnight, as you are competing with less traffic on the internet.
  - Before starting the upload, it can be useful to reboot your computer - this can free up some memory and reset some elements of the operating system.
- After uploading study data and then clicking Submit Files, if you refresh the browser very quickly, the system may still be in the process of finalizing the storage.

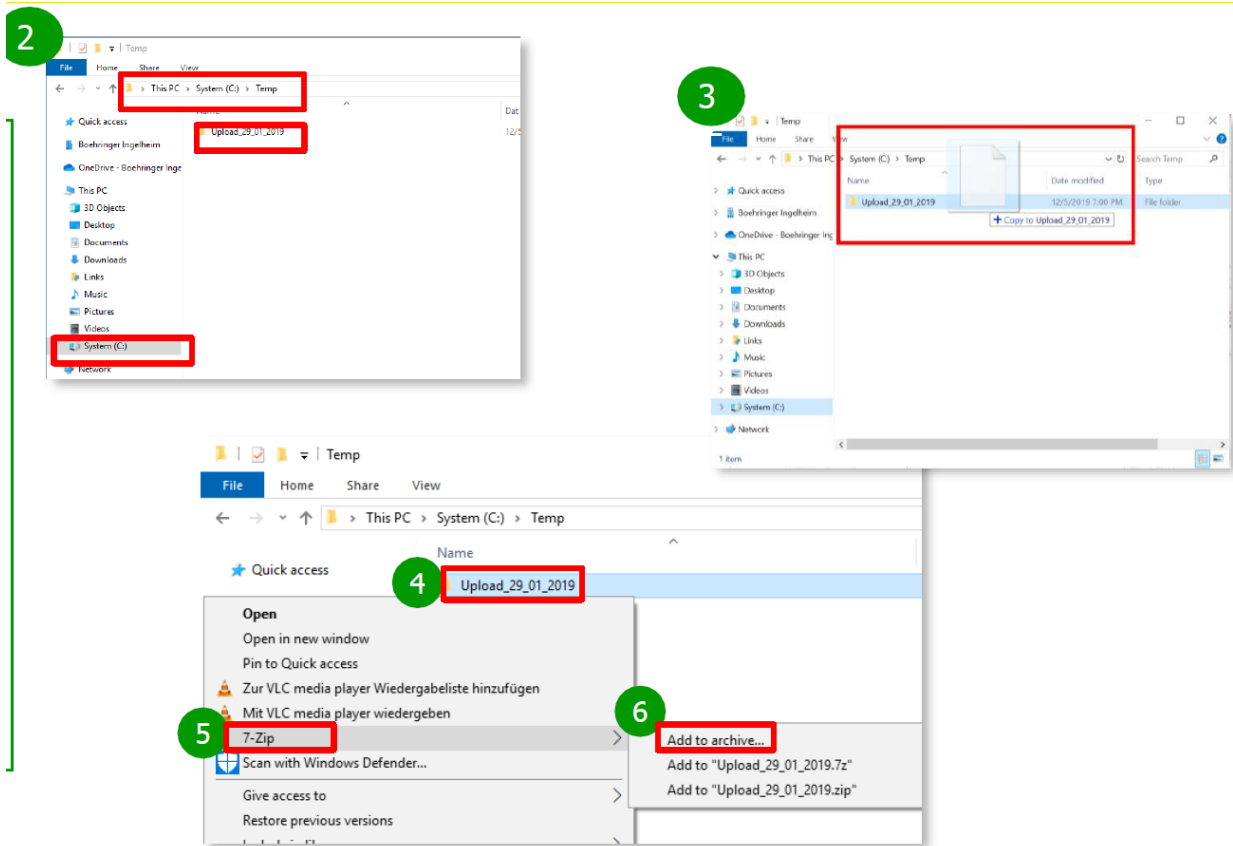
- In this case, it may display "Make Data Available"; if you see this after submitting files, give the system a minute or so to complete and refresh the browser again.
- If Make Data Available does not clear after a minute or so, this generally indicates a problem occurred -reach out to Vivli and we'll be able to reset things.
- If a network hiccup happens during the upload and the system displays "Upload Failed" for a given file, we recommend you tell the Vivli system to delete the file, close the data request, and re-open it before trying again.

### 5.3.1 Zip Archive Process

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

Create a zip archive to store the confidential files in.

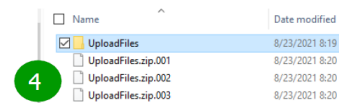
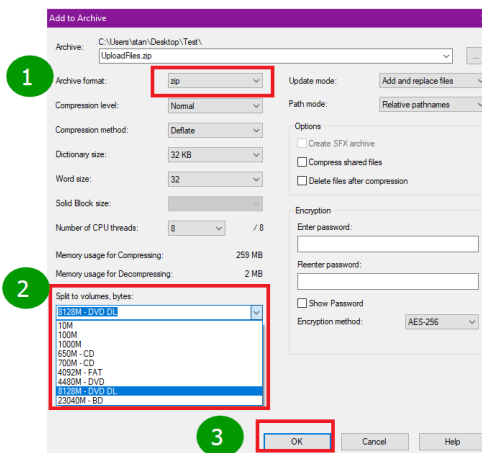
- 1 Download 7-zip**  
(<https://www.7-zip.org/download.html>)
- 2 Create a new folder** on your local machine.
- 3 Add the files to be provided** into the folder. You can do this for example by Drag&Drop.
- 4** To create a zip archive right click on the folder.
- 5** In the dropdown menu select **7-Zip**.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



## 5.4 Upload Data Package to an Approved Data Request

1. Once the data request is approved and the DUA is signed, you can upload the data package into the data request.
2. Click on the Data Request tab on the left menu. Locate the data request under the Awaiting My Action section:

The screenshot shows the 'Research Data Requests' dashboard. On the left, the 'Data Requests' tab is selected. The main content area displays a list of requests under the 'Awaiting My Action' tab. A specific request is highlighted, showing its ID (00003165) and details. A red box highlights the status 'At least one Data Package Provided and Available'.

3. Click on the data request, and then click on the Studies tab on the left. Note: The check sign on the left of the study helps you to identify studies that are part of your Organization versus studies that belong to other Organizations. Click the blue “Upload Data Package” button

The screenshot shows the Vivli website. The top navigation bar includes 'Home', 'About', 'Members', 'News & Events', 'Resources', and 'Find Studies'. The left sidebar shows the 'Studies' tab selected. The main content area displays a list of studies under the 'REQUESTED STUDY TYPES' section. A specific study is highlighted, showing its title and details. A red box highlights the 'Upload Data Package' button.



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

- For the next steps on uploading the data, please see [Section 5.6 Steps to Upload Data Package](#)
- Once the data package has been successfully loaded onto the request, the Organizational Administrator will see the “Data Package Provided to Requestor” note next to the study record in the studies section of the data request.

- 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.
- 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**  
For data provided by my organization

3212

**Data Requests**

Awaiting My Action Draft **Active** Not Approved Withdrawn Archived

**Vivli ID: 00003212**  
Diabetes outcomes in Cardiovascular disease subjects (Studies: 1)  
Requested By: Data Requester  
Lead Researcher: Richard Anderson

All Data Packages Provided and Available

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

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	
<b>Request History</b>	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-5907-4f4b-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				

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

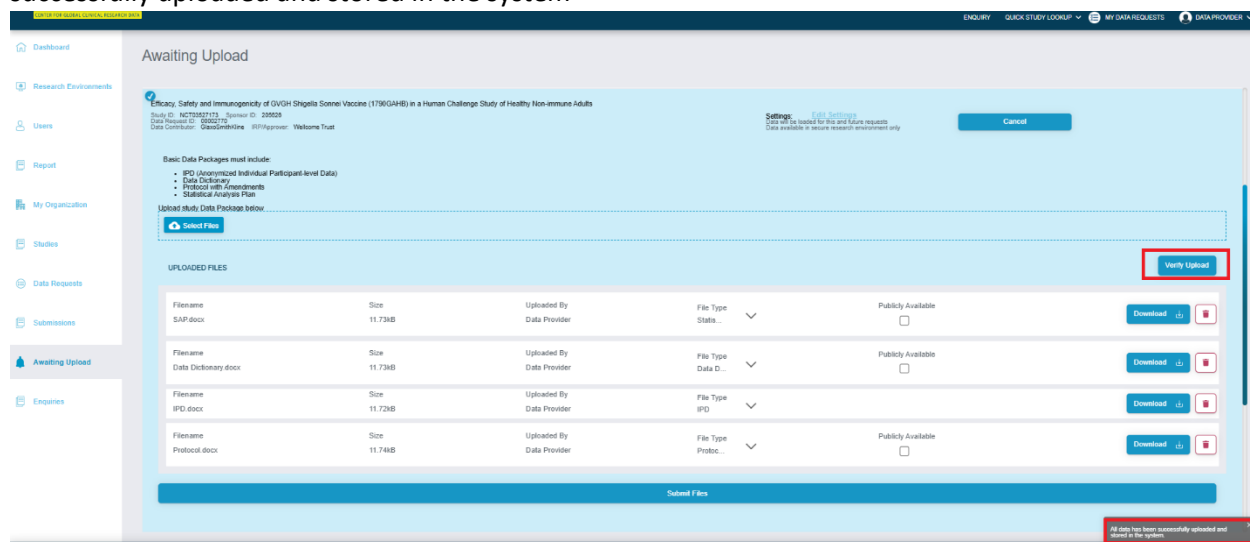
The screenshot shows the Vivli 'Find Studies' page. The header includes the Vivli logo and navigation links: Home, About, Members, News & Events, Resources, and Find Studies. Below the header, there's a section for 'Request: 2553, PI: Sarah Jones' with a status 'At least one Data Package Provided and Available'. A sidebar on the left lists various options: 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 titled 'REQUESTED STUDY TYPES' and shows 'VIVLI-LISTED AND PROVISIONED STUDIES'. Two study entries are listed, each with a red box highlighting its details and a 'Data Package Provided to Requestor' button. Below this, 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'.

- 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 'Download Data Package' page. The header is similar to the previous page, but the 'Find Studies' link is now highlighted. Below the header, there's a section for 'Booster Vaccination With Pneumococcal Vaccine GSK1024850A, a DTPa-Combined and MenC or Hib-MenC Vaccines'. A sidebar on the left lists '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's a section for 'UPLOADED FILES' which contains a table of files. The table has columns for Filename, Size, Uploaded By, File Type, and a Download button (highlighted with a red box). The files listed are: 109507.txt, Data Dictionary Documentation.pdf, IPD data.xls, Protocol.pdf, and Statistical analysis plan.pdf.

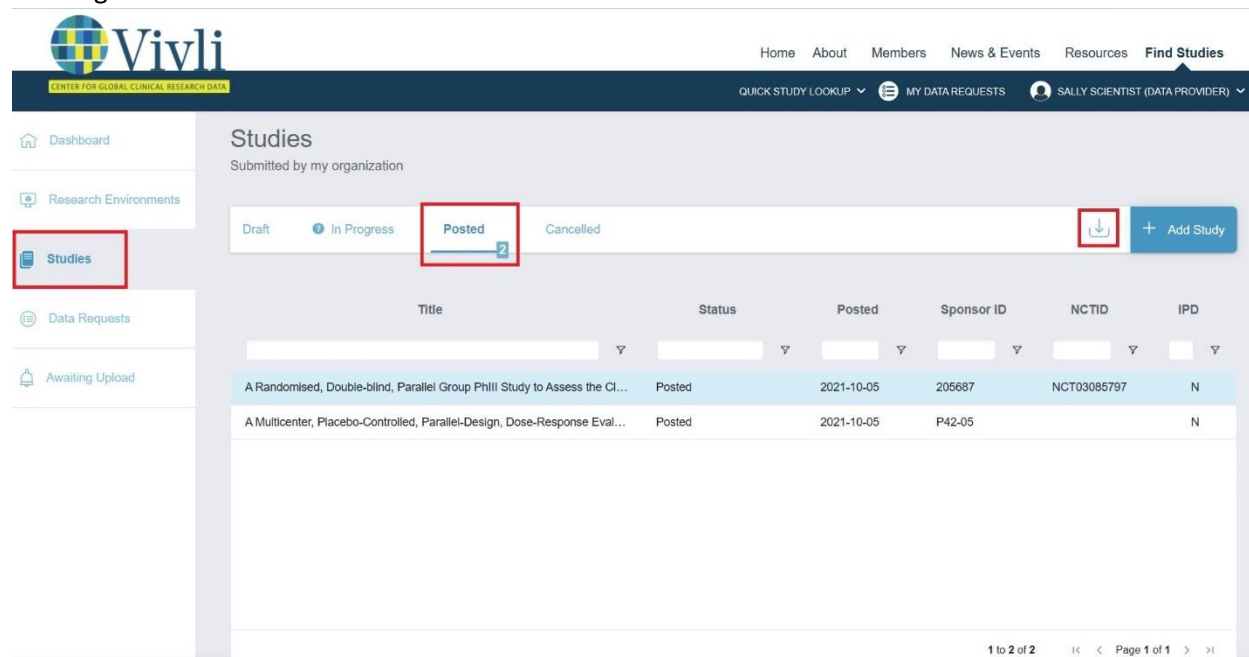
Filename	Size	Uploaded By	File Type	Download
109507.txt		Sally Scientist (Data Provider)	Other	Download
Data Dictionary Documentation.pdf	118.00kB	Sally Scientist (Data Provider)	Data Dictionary	Download
IPD data.xls	26.00kB	Sally Scientist (Data Provider)	IPD	Download
Protocol.pdf	179.00kB	Sally Scientist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

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

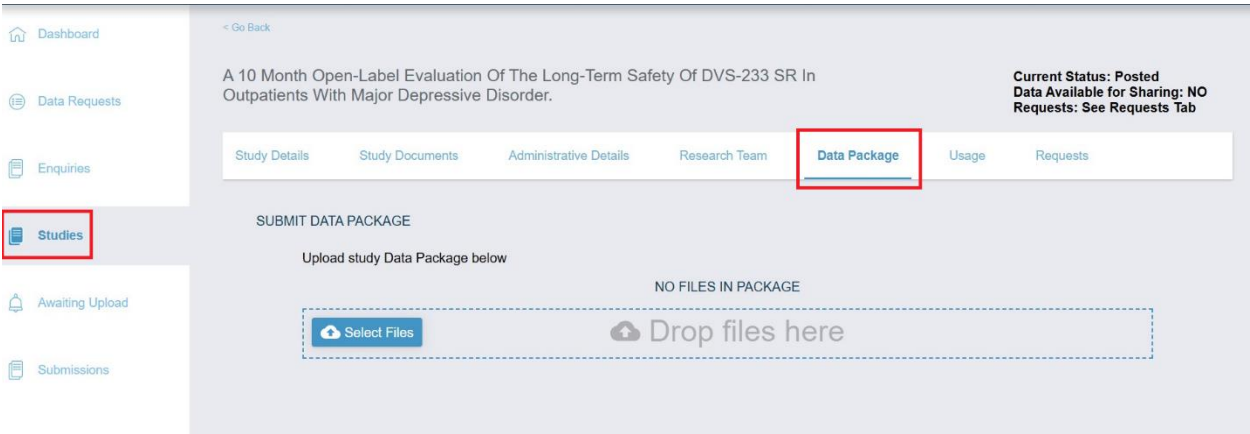


## 5.5 Upload Data Package Directly into the Study

- For listed studies, Data Contributors can upload study data packages directly into the study at the time of listing the study on the Vivli platform or before the request is approved (this option is not available for unlisted studies)
- Navigate to the Studies tab from the dashboard.

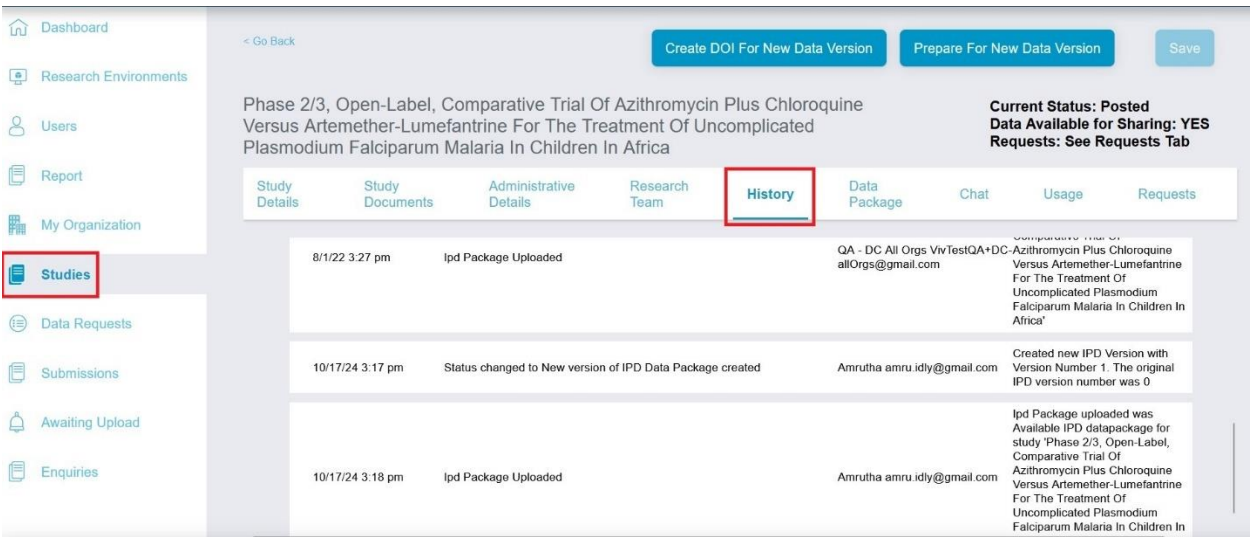


3. Open the study, select the Data Package tab, and upload the data package.



4. For the next steps on uploading the data, please see [Section 5.6 Steps to Upload Data Package](#)

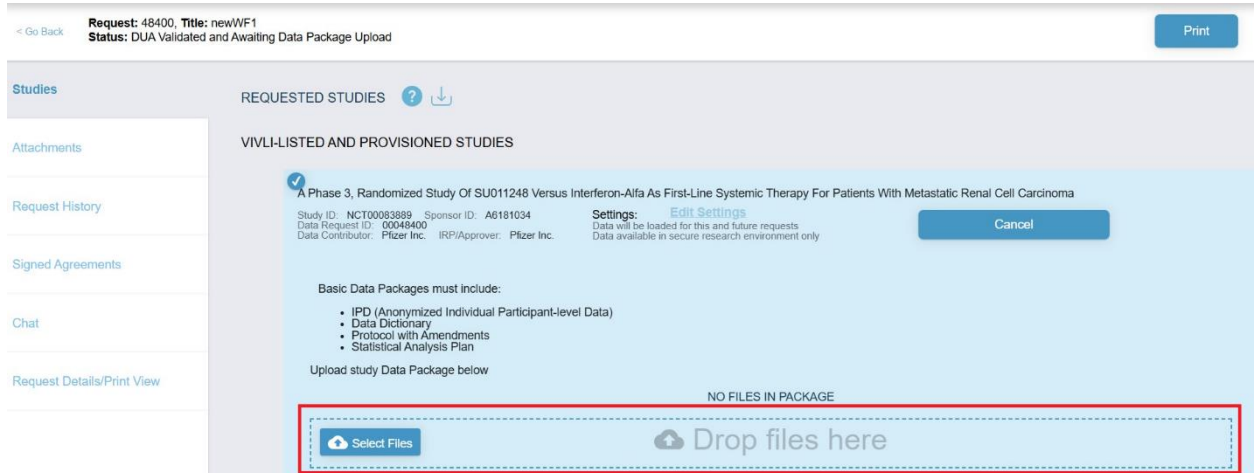
5. The data package upload action will be recorded in the Study history



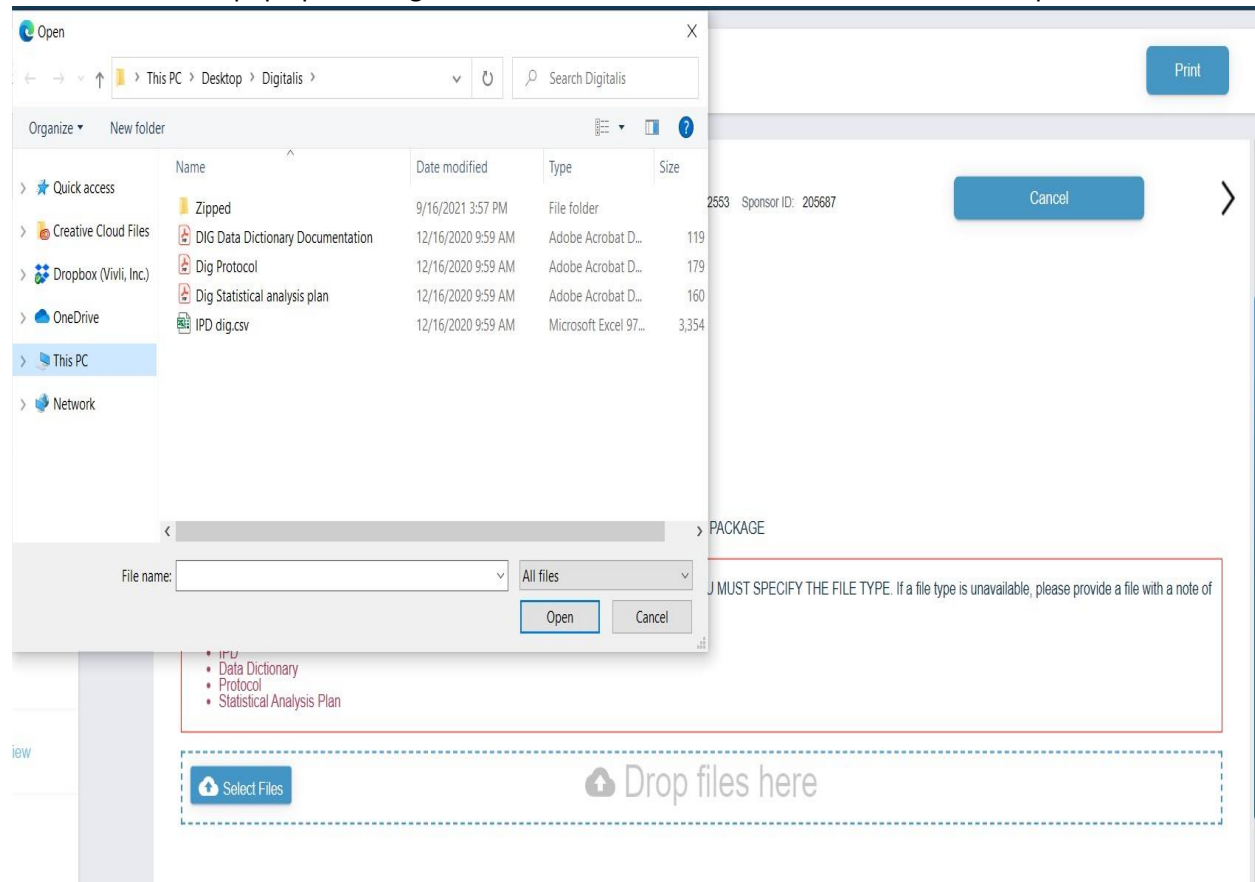
7. For subsequent data requests for this study, this version of the data package will be made available to the researcher. Please see [Section 5.7 Stored Data Package and Subsequent Data Requests](#)

## 5.6 Steps to Upload Data Package

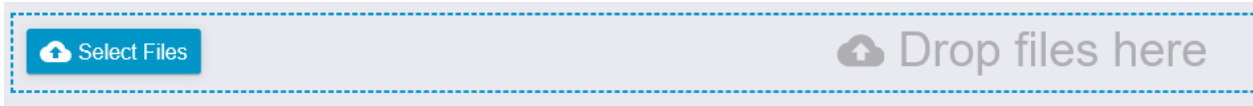
1. To upload the data package, click on the “Select files” button



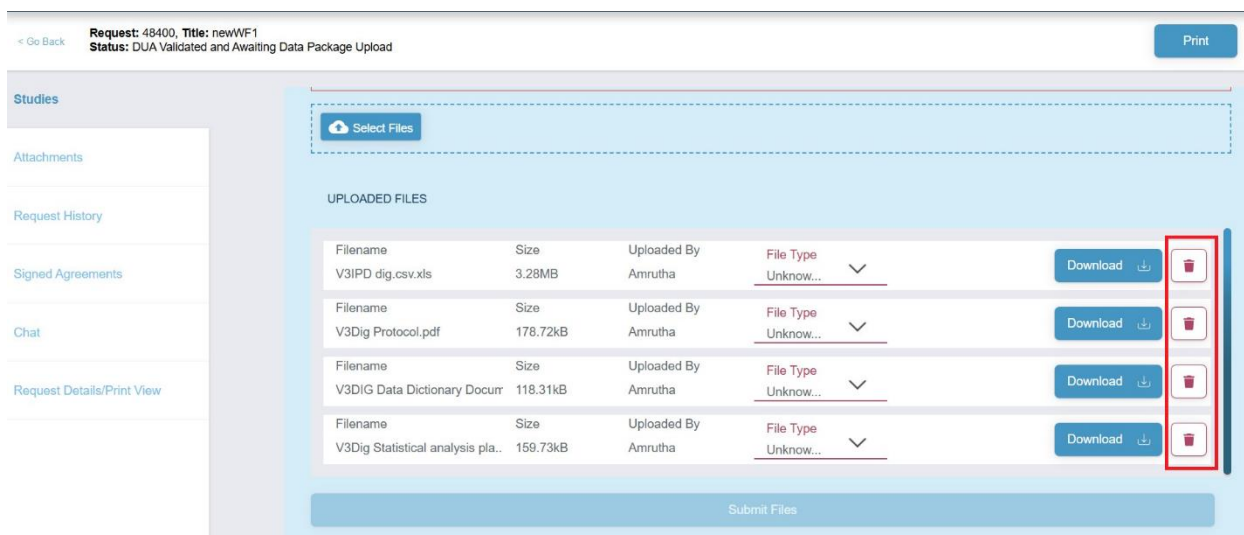
2. A window will pop up allowing the data contributor to select the files of their computer:



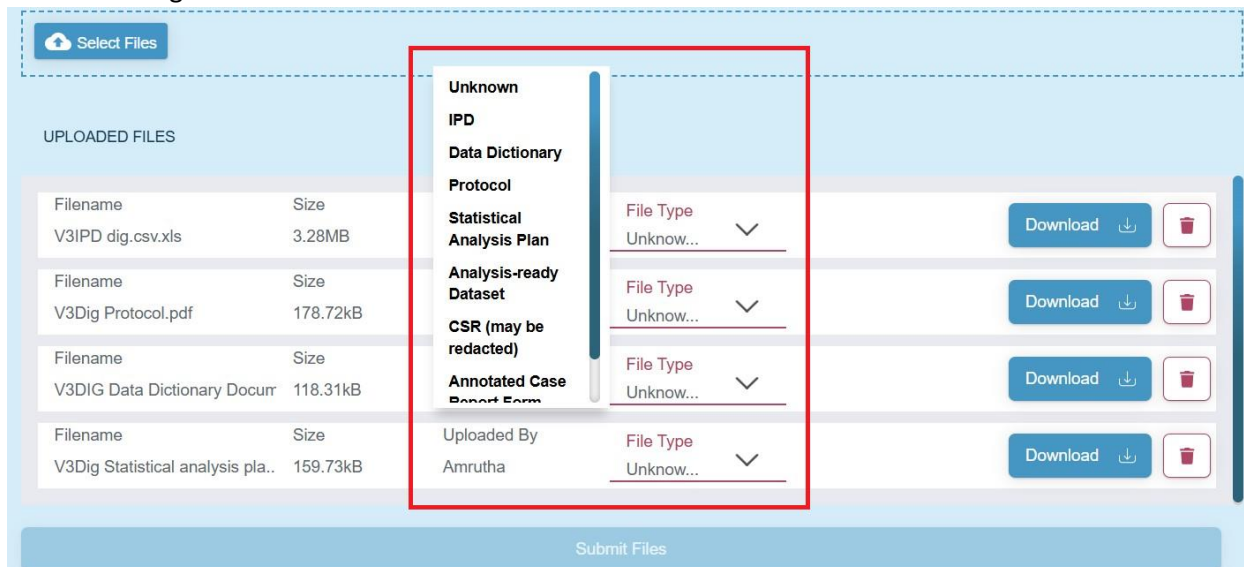
- After selecting the files, click **Open**.
- The data contributor may also drag files into the submit window indicated by the dotted blue box:



- 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:



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

UPLOADED FILES

Filename	Size	Uploaded By	File Type		
V3IPD dig.csv.xls	3.28MB	Amrutha	IPD		Download
V3Dig Protocol.pdf	178.72kB	Amrutha	Protoc...	Publicly Available <input checked="" type="checkbox"/>	Download
V3DIG Data Dictionary Docum	118.31kB	Amrutha	Data D...	Publicly Available <input checked="" type="checkbox"/>	Download
V3Dig Statistical analysis pla...	159.73kB	Amrutha	Statis...	Publicly Available <input type="checkbox"/>	Download

Submit Files

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

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

	Item	Description
Recommended	Study Protocol	Final protocol with all amendments
Recommended	Data dictionary	Detailed descriptions of each variable in the dataset, including the definition, source, coding, etc. of the variable
Recommended	Statistical Analysis Plan	Description of the principal features of the analysis described in the protocol
Recommended	Clinical Study Report (CSR)	Report that summarizes the efficacy and safety data from the study (after regulatory decision)
Recommended	IPD dataset	Final cleaned individual participant-level data, anonymized
Recommended	Anonymization Guidance	What anonymization method was used for the data



Optional	Analytic code	Software code used to carry out prespecified and additional analyses
Optional	Analysis-ready IPD data set	The dataset in a format used to carry out a sponsor's analyses
Optional	Case report forms	Forms used to collect the data that is described in the protocol for each trial participant

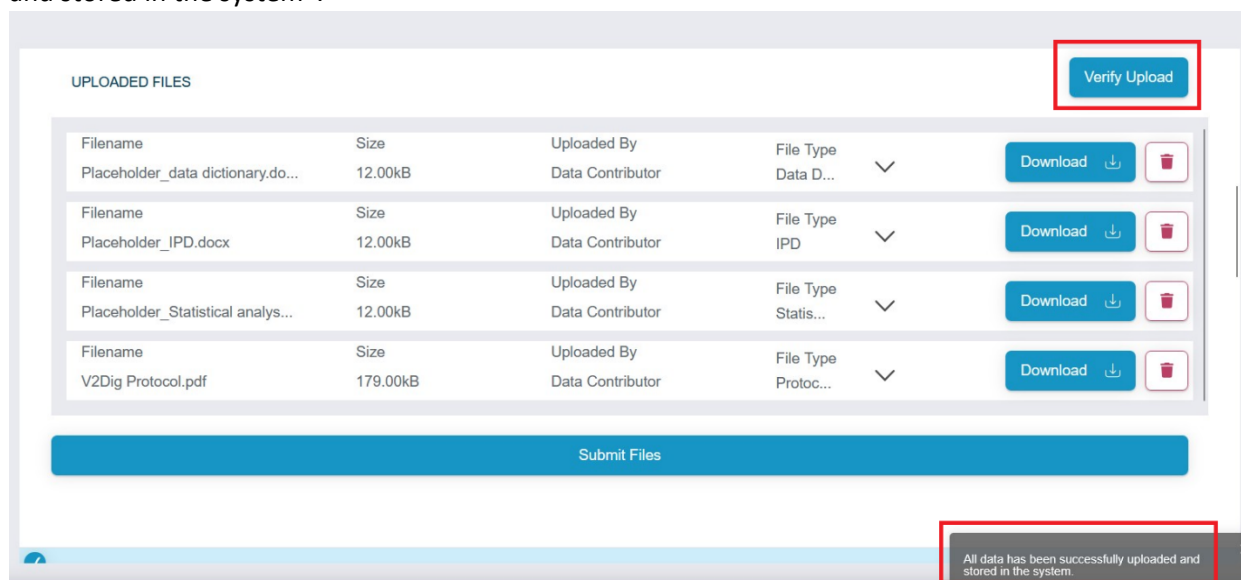
- For any additional file types for data upload, select the “Other” file type option to upload the files.  
**Note:** If you do not have any of the basic study documents available (Study Protocol, Data dictionary, or Statistical Analysis Plan, please upload a Word document explaining which files are available, instead of the missing file type.
- There are two steps involved: uploading the data and then once uploaded, submitting the data to Vivli. The data package upload happens while you see the progress bar with the label “Uploading”. **If you navigate away from a page on which an upload is underway (i.e. clicking on another tab or closing the browser), that will cancel the upload automatically**

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

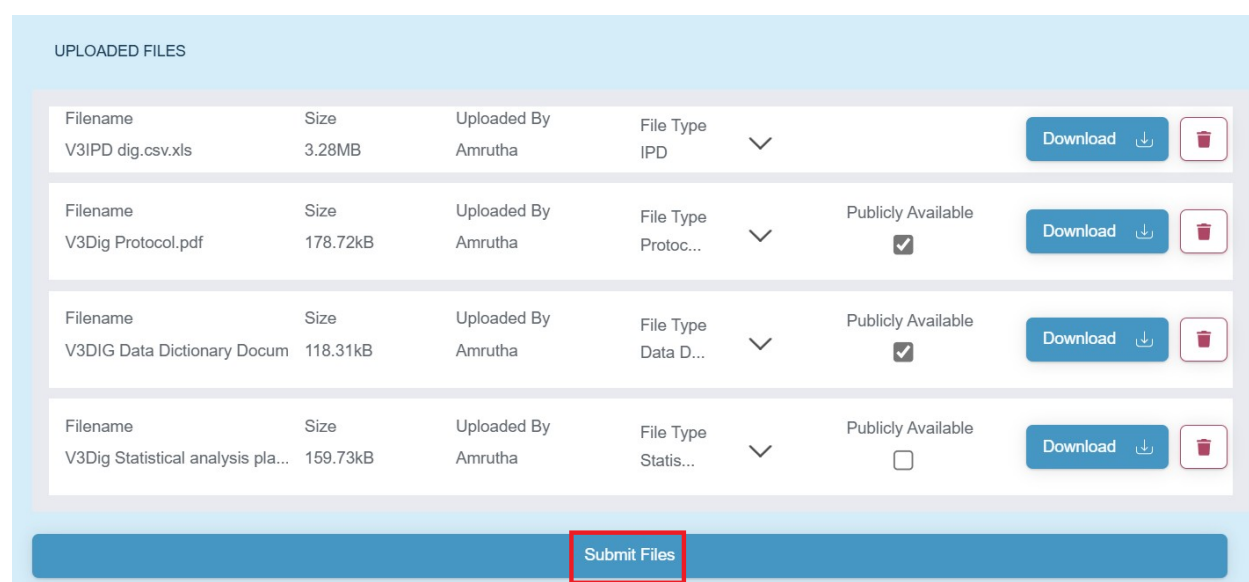
- If the upload of any file(s) fails, Close the request, refresh the browser, re-open the request, click on “Upload Files” and delete the file that failed before moving forward.
- Click the button that says “Verify Upload” to confirm that your files have been successfully uploaded.



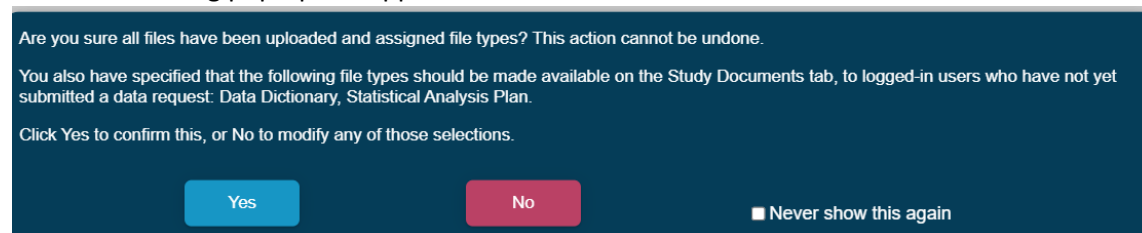
14. A pop-up will appear at the bottom right screen that says “All data has been successfully uploaded and stored in the system”.



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



18. The following pop-up will appear:

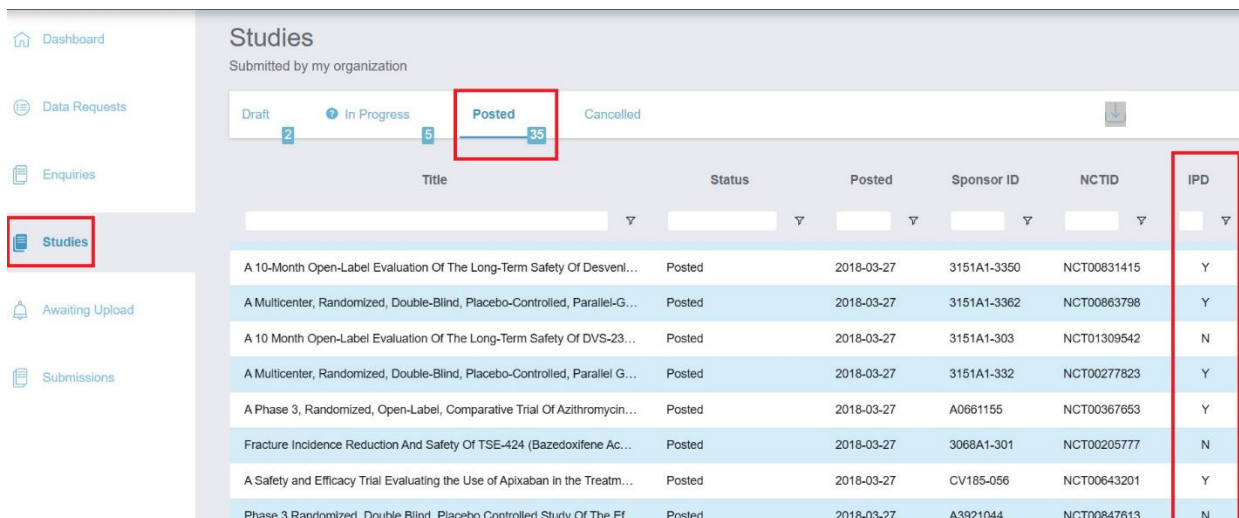


19. You will receive confirmation of successful upload. Click the 'Continue' button



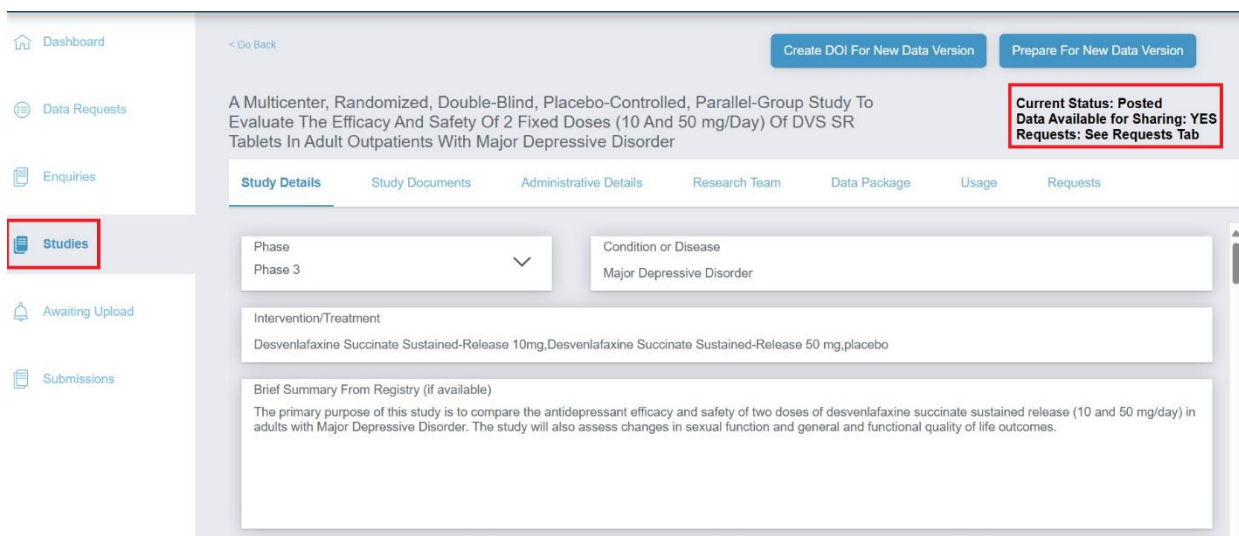
## 5.7 Stored Data Package and Subsequent Data Request

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



Title	Status	Posted	Sponsor ID	NCTID	IPD
A 10-Month Open-Label Evaluation Of The Long-Term Safety Of Desvenlaxine Succinate Sustained-Release 10mg, Desvenlaxine Succinate Sustained-Release 50 mg, placebo	Posted	2018-03-27	3151A1-3350	NCT00831415	Y
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study To Evaluate The Efficacy And Safety Of 2 Fixed Doses (10 And 50 mg/Day) Of DVS SR Tablets In Adult Outpatients With Major Depressive Disorder	Posted	2018-03-27	3151A1-3362	NCT00863798	Y
A 10 Month Open-Label Evaluation Of The Long-Term Safety Of DVS-23	Posted	2018-03-27	3151A1-303	NCT01309542	N
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study To Evaluate The Efficacy And Safety Of 2 Fixed Doses (10 And 50 mg/Day) Of DVS SR Tablets In Adult Outpatients With Major Depressive Disorder	Posted	2018-03-27	3151A1-332	NCT00277823	Y
A Phase 3, Randomized, Open-Label, Comparative Trial Of Azithromycin Versus Doxycycline In The Treatment Of Acute Bacterial Sinusitis In Adults	Posted	2018-03-27	A0661155	NCT00367653	Y
Fracture Incidence Reduction And Safety Of TSE-424 (Bazedoxifene Acetate) In Postmenopausal Women With Osteoporosis	Posted	2018-03-27	3068A1-301	NCT00205777	N
A Safety and Efficacy Trial Evaluating the Use of Apixaban in the Treatment of Acute Venous Thromboembolism	Posted	2018-03-27	CV185-056	NCT00643201	Y
Phase 3 Randomized, Double Blind, Placebo Controlled Study Of The Efficacy And Safety Of Desvenlafaxine Succinate Sustained-Release 10mg, Desvenlafaxine Succinate Sustained-Release 50 mg, placebo	Posted	2018-03-27	A3921044	NCT00847613	N

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



< Go Back

Create DOI For New Data Version Prepare For New Data Version

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study To Evaluate The Efficacy And Safety Of 2 Fixed Doses (10 And 50 mg/Day) Of DVS SR Tablets In Adult Outpatients With Major Depressive Disorder

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

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

Phase  
Phase 3

Condition or Disease  
Major Depressive Disorder

Intervention/Treatment  
Desvenlafaxine Succinate Sustained-Release 10mg, Desvenlafaxine Succinate Sustained-Release 50 mg, placebo

Brief Summary From Registry (if available)  
The primary purpose of this study is to compare the antidepressant efficacy and safety of two doses of desvenlafaxine succinate sustained release (10 and 50 mg/day) in adults with Major Depressive Disorder. The study will also assess changes in sexual function and general and functional quality of life outcomes.

4. If you have data packages previously loaded for a data request and if the same data package is requested by any other Data Requestor after the data was loaded, the review process will be followed and if approved and the Data Use Agreement is signed, then the data package will be provided to the subsequent Data Requester.
5. In most cases, that will be an entirely automatic step. In other words, that study will not appear in your “Awaiting Upload” section. Instead, the data package will be automatically loaded for the data request and the action will be recorded in the request history of the data request.
6. However, in some cases where the second data request was submitted before the data was uploaded for the first request, you will still see the study in the Awaiting Upload section.
7. In such cases, navigate to the study needing your action as described in [Section 5.4 Upload Data Package to an Approved Data Request](#). The only difference is that instead of a button “Upload Data” you will see a button labeled “Make Data Package Available”:

Request: 48428, Title: Stan Test Upload of listed study added late  
Status: At least one Data Package Provided and Available

Print

Studies

REQUESTED STUDIES ? ↓

VIVLI-LISTED AND PROVISIONED STUDIES

✓ Phase 2/3, Open-Label, Comparative Trial Of Azithromycin Plus Chloroquine Versus Artemether-Lumefantrine For The Treatment Of Uncomplicated Plasmodium Falciparum Malaria In...  
Study ID: NCT00677833 Sponsor ID: A0661157 Settings: Data has been loaded for this and future requests Data Package Provided to Requester  
Data Request ID: 00048428 Data Contributor: Pfizer Inc IRP/Approver: Pfizer Inc

✓ Repeated and Multiple Fecal Microbiota Transplantations Plus Partial Enteral Nutrition as the First-line Treatment in Active Pediatric Crohn's Disease  
Study ID: NCT05321758 Sponsor ID: 83663594 Settings: Edit Settings Data has been loaded for this and future requests Data available in secure research environment only  
Data Request ID: 00048428 Data Contributor: Pfizer Inc IRP/Approver: Wellcome Trust

Make Data Package Available

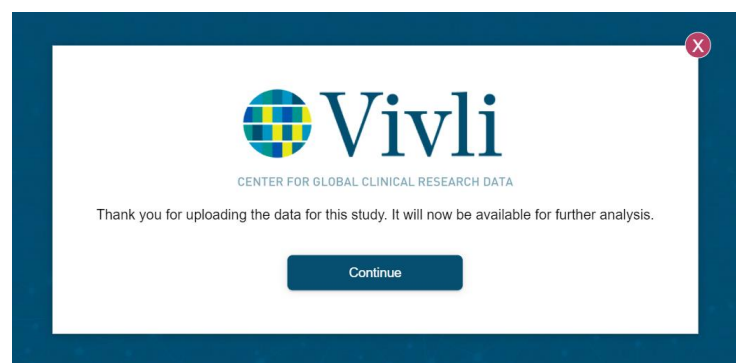
VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS

No Studies Found

STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI

No Studies Found

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



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

The screenshot displays the Vivli web application interface. At the top, the Vivli logo is on the left, and navigation links (Home, About, Members, News & Events, Resources, Find Studies) are on the right. Below the navigation bar, a dark blue header contains 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and a user profile 'SALLY'. The main content area shows a request page for 'Request: 2553, PI: Sarah Jones' with a status of 'At least one Data Package Provided and Available'. A sidebar on the left lists navigation options: '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 titled 'REQUESTED STUDY TYPES' and 'VIVLI-LISTED AND PROVISIONED STUDIES'. It lists two studies: 1. 'A Multicenter, Placebo-Controlled, Parallel-Design, Dose-Response Evaluation ...' with a 'Data Package Provided to Requestor' button (highlighted with a red box). 2. 'A Randomised, Double-blind, Parallel Group PhIII Study to Assess the Clinical...' with a 'Make Data Package Available' button. Below these, it states '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'.

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

## 5.8 Replace Data Package New Version

1. If you want to delete the stored data package on the platform, please email the Vivli team at [support@vivli.org](mailto: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 directly into the study, please see [Section 5.5 Upload Data Package Directly into the Study](#)
3. If you are not ready to upload data at this time, you will be prompted to upload data when the next data request with this study has completed DUA approval. For more information, please see [Section 5.4 Upload Data Package to an Approved Data Request](#).

## 5.9 Upload Additional Data or Documents After the Initial Upload

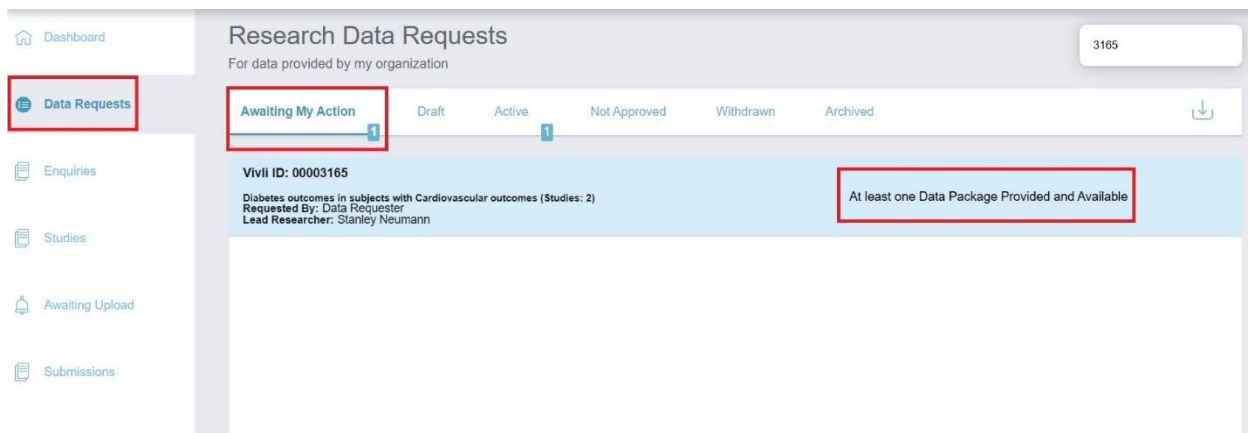
1. Data Contributors may add study documents or additional data to an existing approved data request in the analysis stage after the initial upload.
2. As a first step, reach out to the Vivli team at [support@vivli.org](mailto:support@vivli.org) to inform them whether you want to add additional documents for just one specific request and/or all for future requests of this study.
3. Based on your response, the Vivli admin may add an unlisted placeholder study to the request. Please go to the data request and under the studies tab, at the bottom under the “Studies, Data, or Tools Not Listed on Vivli” section, you will see an option to upload the entire data package.

The screenshot displays the Vivli web application interface. At the top, the Vivli logo and navigation menu are visible. The main content area is divided into sections for 'REQUESTED STUDIES' and 'VIVLI-LISTED AND PROVISIONED STUDIES'. A section titled 'STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI' contains an entry for 'Additional document for study WV15670'. A red box highlights this entry, and another red box highlights the 'Upload Data Package' button. The sidebar on the left contains navigation options such as 'Status Update', 'Attachments', 'Request History', 'Signed Agreements', 'Safety Concerns', 'Research Results', 'Chat', 'Research Environment', 'Public Disclosures', and 'Request Details/Print View'.

4. You may have to upload placeholder documents due to the required file types for study upload.
5. For the next steps on uploading the data, please see [Section 5.6 Steps to Upload Data Package](#)
6. Once you load the file(s), please let the researcher know via chat that you have uploaded additional data or documents. The Vivli team will also give further instructions to the researcher to add these files to the research environment.

## 5.10 Uploading Data to Only One Data Request

1. By default, the data package uploaded to the Vivli platform is stored in the secured vault and is automatically provisioned to the next researcher when their request is approved and when their DUA is executed. However, Organization Administrators can make selections for a data request when a data request is in the review process. This means that when a data package is uploaded in the context of a specific request, the data is to be loaded only to that request, and not automatically stored in the secure vault for the next researcher. The option is only available for *studies listed* on the Vivli platform.
2. Organization Administrators have the option to make this selection at the Data Contributor review stage. Please see [4.3 Study settings at Data Contributor Review](#). This setting will be visible (but not settable) on requests that have been fulfilled (data package uploaded).
3. To upload the data package for a particular data request only, wait for the request to reach the Data upload stage.
4. Click on the Data Request tab on the left side and type in the data request ID to locate the data request– data requests in need of a data upload will be listed under Awaiting My Action:





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

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 links: ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and DATA CONTRIBUTOR. The main header area displays the Vivli logo and the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. Below the header, there is a section for 'Request: 3270, PI: N A' and 'Status: At least one Data Package Provided and Available'. A 'Print' button is visible on the right. On the left side, there is a sidebar with a 'Studies' tab selected, which is highlighted with a red box. The main content area shows 'REQUESTED STUDIES' and 'VIVLI-LISTED AND PROVISIONED STUDIES'. Under 'VIVLI-LISTED AND PROVISIONED STUDIES', there are three study entries. The first entry is '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...'. The second entry is 'Prospective Study of Post Surgical Continued Pain (PSCP) Patients Undergoing Flexion Distraction Decompression Spinal Manipulation'. The third entry is '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 ...'. Each entry shows details like Study ID, Sponsor ID, Data Request ID, Data Contributor, and IRP/Approver. The 'Settings' for each study are also displayed, indicating whether data has been loaded for this and future requests or if the data package is downloadable. A 'Data Package Provided to Requester' button is visible for the first study, and a 'Data to be provided by Data Contributor' button is visible for the second study. A 'Upload Data Package' button is visible for the third study.

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

The screenshot shows the Vivli web application interface. At the top, there is a navigation bar with links: ENQUIRY, QUICK STUDY LOOKUP, MY DATA REQUESTS, and SALLY. Below this is a sub-navigation bar with links: Archive, Do not track, Cancel, Edit Data Request, X Cannot Fulfill, X Request Revision, Process Request, and Print. The main header area displays the Vivli logo and the text 'CENTER FOR GLOBAL CLINICAL RESEARCH DATA'. Below the header, there is a section for 'Request: 48066, PI: Heidi Lakes' and 'Status: Data Contributor Review'. A 'Print' button is visible on the right. On the left side, there is a sidebar with a 'Studies' tab selected, which is highlighted with a red box. The main content area shows 'REQUESTED STUDIES' and 'VIVLI-LISTED AND PROVISIONED STUDIES'. Under 'VIVLI-LISTED AND PROVISIONED STUDIES', there are two study entries. The first entry is 'A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Once a Day, TAK-375SL as an Adjunctive Therapy to Treatment-as-Usual in...'. The second entry is 'A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Once a Day, TAK-375SL as an Adjunctive Therapy to Treatment-as-Usual in...'. Each entry shows details like Study ID, Sponsor ID, Data Request ID, Data Contributor, and IRP/Approver. The 'Settings' for each study are also displayed, indicating whether data has been loaded for this request only or if the data package is downloadable. A 'Data to be loaded after approval' button is visible for the first study, and a 'Data to be loaded after approval' button is visible for the second study. A 'Data loaded for this request only' button is visible for the second study, which is highlighted with a red box.



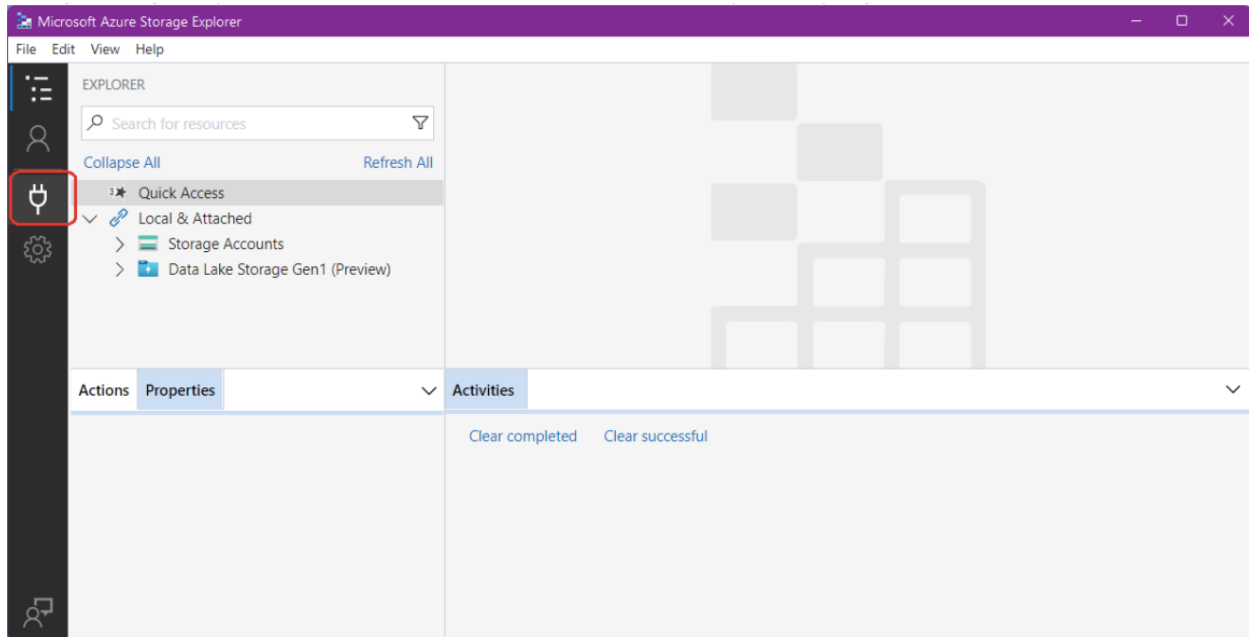
## 7. Click on **Upload Data Package**.

The screenshot shows the Vivli Data Contributor web application. The top navigation bar includes links for Home, About, Members, News & Events, Resources, and Find Studies. Below this is a dark blue header with 'ENQUIRY', 'QUICK STUDY LOOKUP', 'MY DATA REQUESTS', and 'DATA CONTRIBUTOR'. The main content area is titled 'REQUESTED STUDIES' and 'VIVLI-LISTED AND PROVISIONED STUDIES'. A sidebar on the left contains links like 'Status Update', 'Attachments', 'Request History', 'Signed Agreements', 'Safety Concerns', 'Research Results', 'Chat', 'Research Environment', and 'Request Details/Print View'. The 'Studies' link in the sidebar is highlighted with a red box. The main content area displays a list of studies. The first study is '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...'. The second study is 'Prospective Study of Post Surgical Continued Pain (PSCP) Patients Undergoing Flexion Distraction Decompression Spinal Manipulation'. The third study is '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 ...'. The 'Upload Data Package' button is highlighted with a red box.

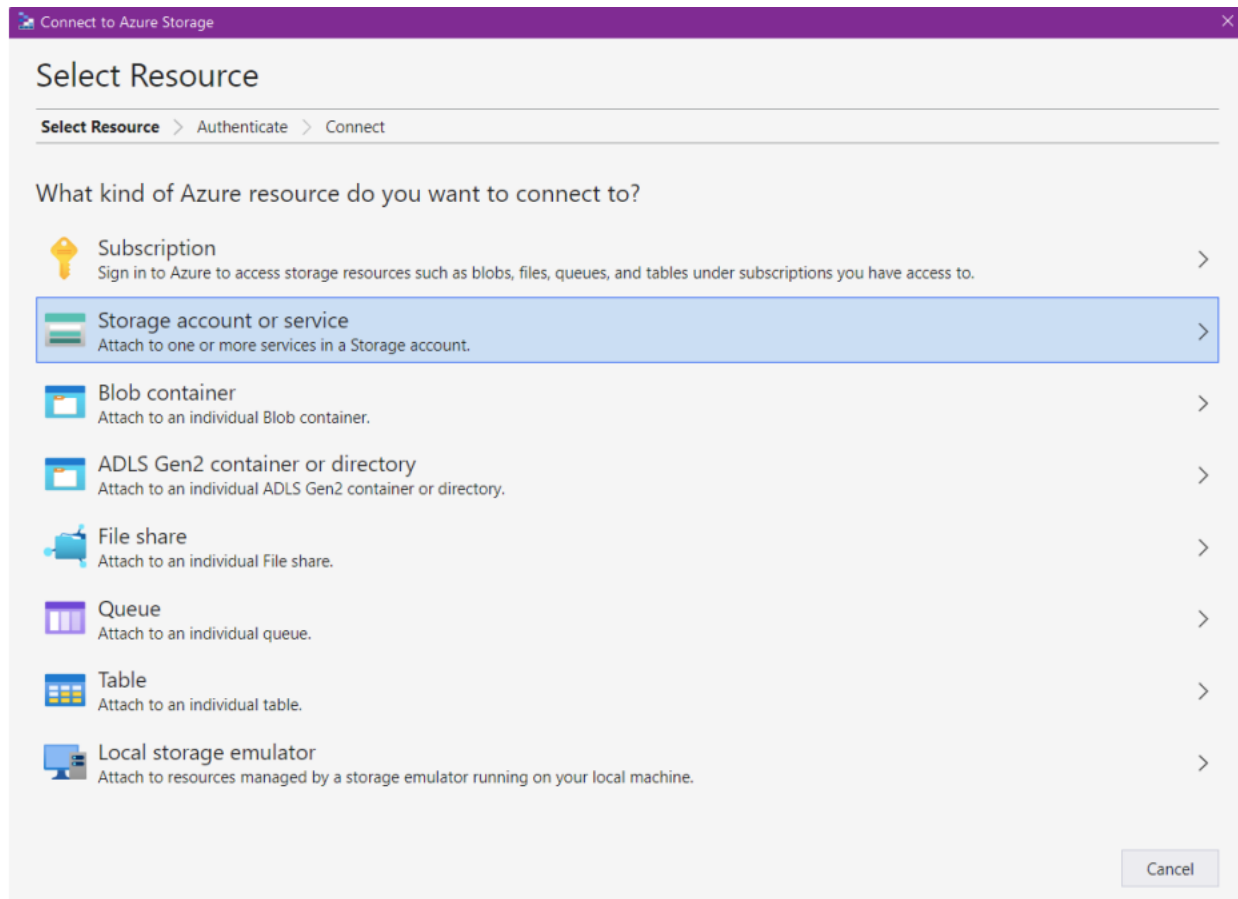
## 8. For the next steps on uploading the data, please see [Section 5.6 Steps to Upload Data Package](#)

### 5.11 Uploading Large Files And Data Packages


1. If you have not already had a discussion with Vivli at [support@vivli.org](mailto:support@vivli.org) about how the data will be organized and how it will be used, we recommend that you start with that, so that Vivli can advise on how best to package the data, e.g. into a single large zip file or a small number of individual zip files.
2. Download and install the Azure Storage Explorer from the URL: <https://azure.microsoft.com/enus/features/storage-explorer/> (you can also enter “Azure Storage Explorer download” into your favorite search engine.) After starting Storage Explorer, click on the icon that looks like a power plug:



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



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

 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

[illegible]

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


 Connect to Azure Storage

## Summary

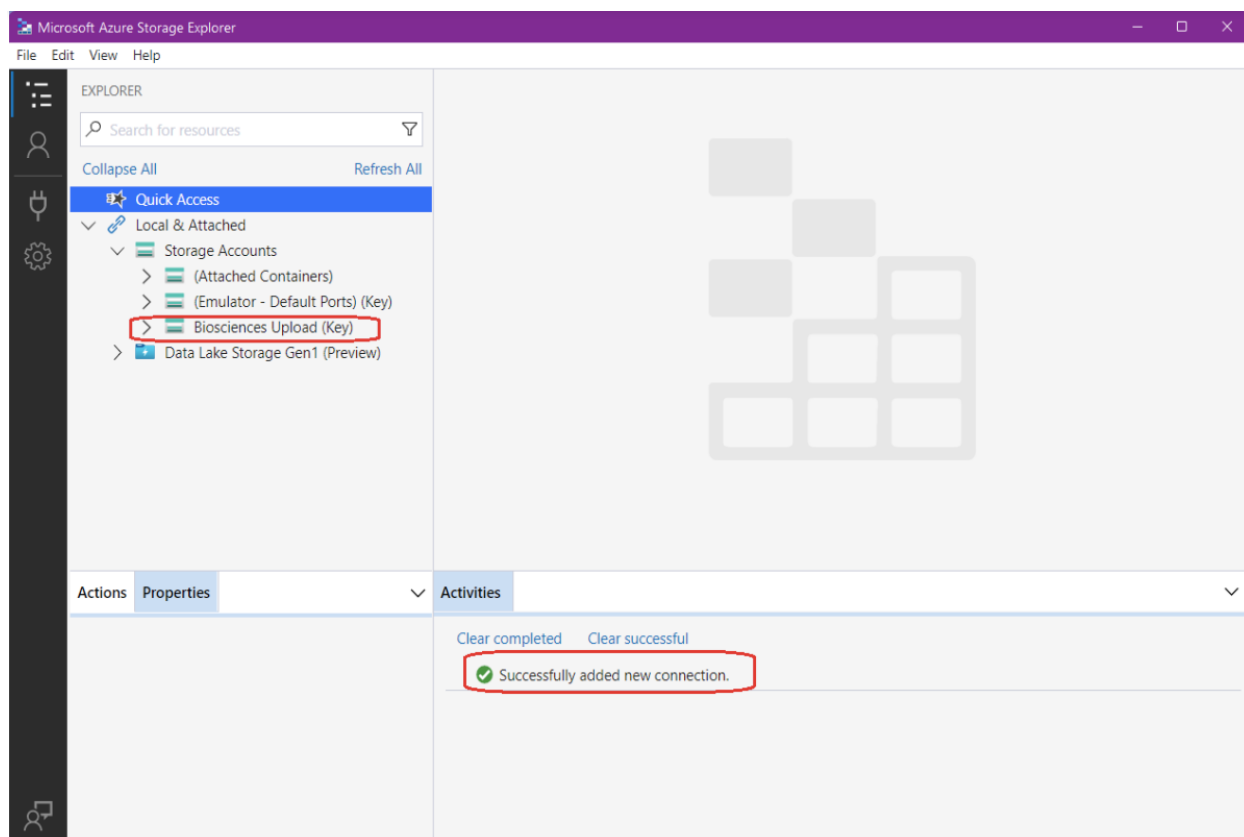
Select Resource > Select Connection Method > Enter Connection Info > **Summary**

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

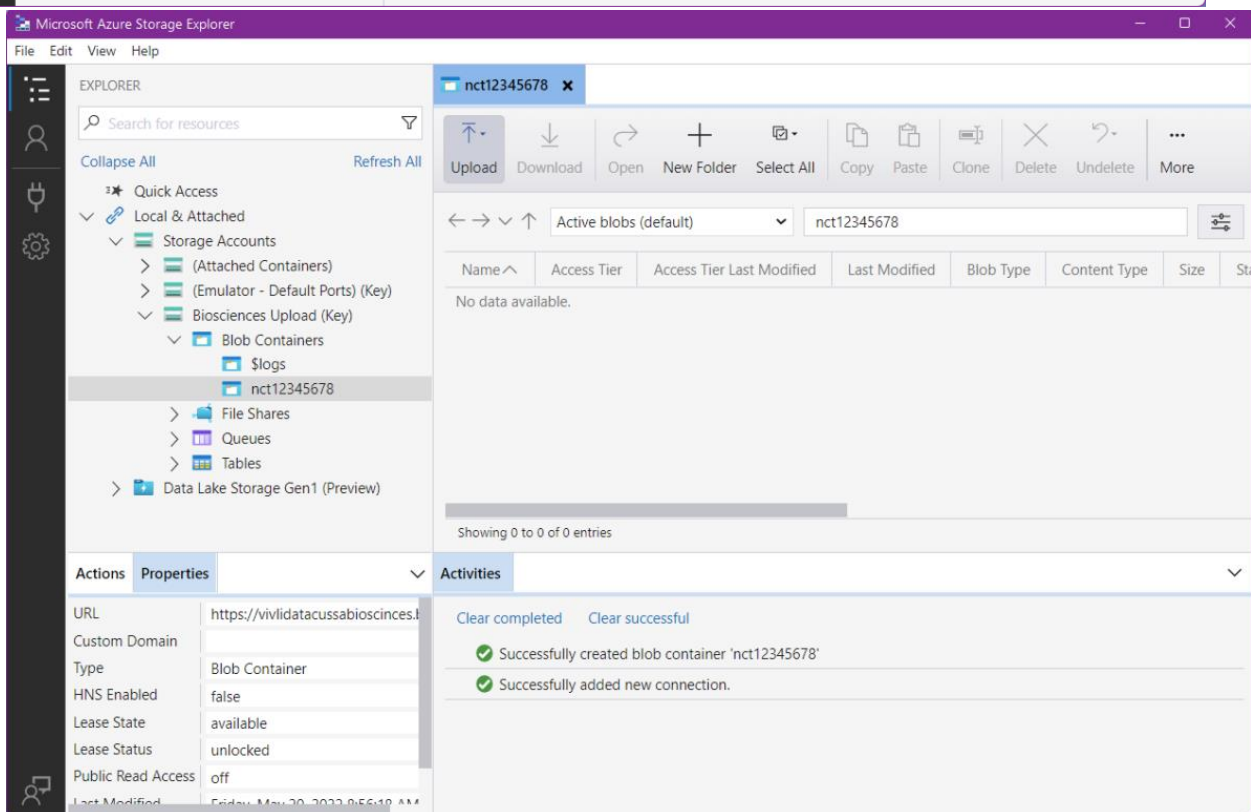
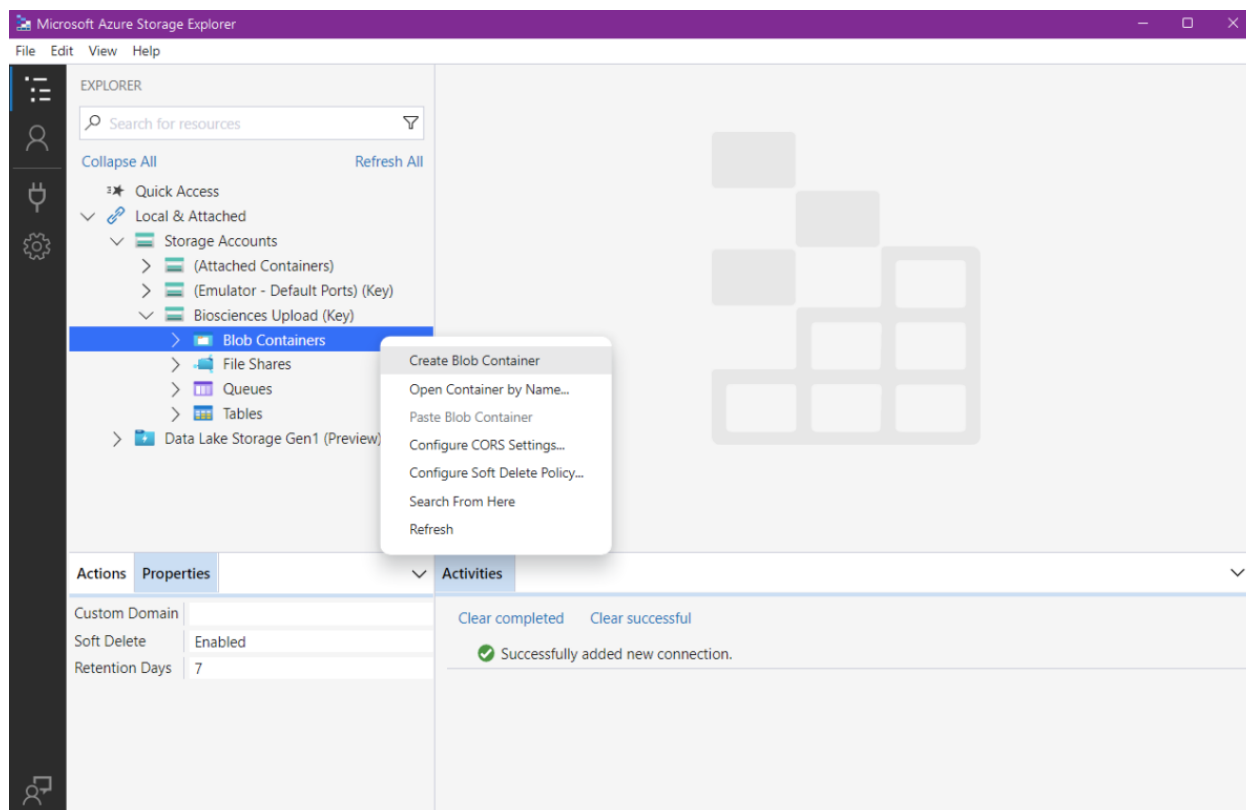
<b>Display name:</b>	Biosciences staging area
<b>Account name:</b>	biosciences
<b>Account key:</b>	5+v3uda+n9mPSqYEJuoZtDUvQ57nANdb853TN2dZAZ/O/Urm1CQ0w7CZ0hzO9ipe1cHq6gYPusV08Jxo+WfDw==
<b>Default endpoints protocol:</b>	https

 Make sure you only connect to resources you trust.

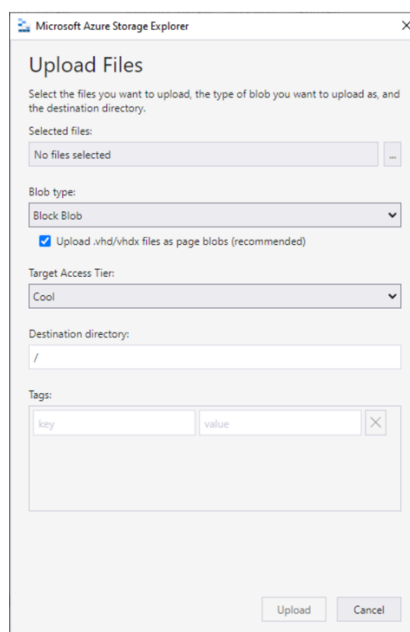
6. It should add the storage account to the list on the upper left, and report “Successfully added connection:



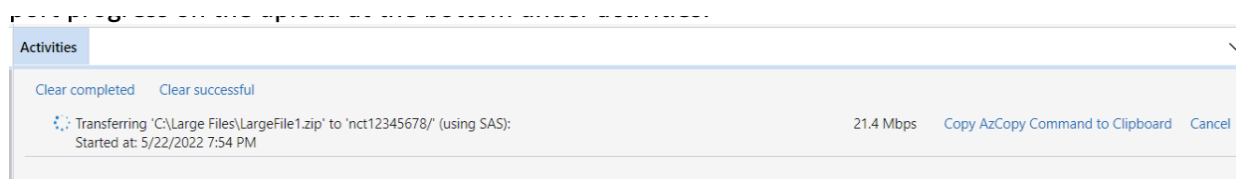
7. Click on the “>” to open the storage account, then right-click on Blob Containers and choose “Create Blob Container”. Give it a name that represents the study (e.g. the NCT ID or sponsor ID). Note that container names are limited to numbers, lowercase letters, and hyphens, but no spaces or uppercase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



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



- 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:



- 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](mailto:support@vivli.org)

## 5.12 Supporting Documents for Researchers Searching For Studies

For listed studies, you may choose to make the supporting documents such as data dictionary, protocol, statistical analysis plan, and/or others, available to researchers on the search page while they are searching for studies. This will help a researcher with a Vivli account to review the study information and finalize it before adding it to their data request.

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

### 5.12.1 Loading Supporting Documents at the Time of Data Upload

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

< Go Back Request: 48314, PI: Amrutha Baskaran Status: DUA Validated and Awaiting Data Package Upload Print

**Studies**

Status Update

Attachments

Request History

Signed Agreements

Chat

Request Details/Print View

**UPLOADED FILES** Verify Upload

Filename	Size	Uploaded By	File Type	Publicly Available	Download	
V3DIG Data Dictionary Docum...	118.00kB	Karen Asada	Data D...	<input type="checkbox"/>	Download	
V3Dig Protocol.pdf	179.00kB	Karen Asada	Protoc...	<input type="checkbox"/>	Download	
V3Dig Statistical analysis pla...	160.00kB	Karen Asada	Statis...	<input type="checkbox"/>	Download	
V3IPD dig.csv.xls	3.28MB	Karen Asada	IPD	<input type="checkbox"/>	Download	

Submit Files

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

< Go Back **Request: 48314, PI: Amrutha Baskaran** **Status: DUA Validated and Awaiting Data Package Upload** [Print](#)

**Studies**

Status Update

Attachments

Request History

Signed Agreements

Chat

Request Details/Print View

**UPLOADED FILES** [Verify Upload](#)

Filename	Size	Uploaded By	File Type	Publicly Available	Download	
V3DIG Data Dictionary Docum...	118.00kB	Karen Asada	Data D...	<input checked="" type="checkbox"/>	<a href="#">Download</a>	<a href="#">Delete</a>
V3Dig Protocol.pdf	179.00kB	Karen Asada	Protoc...	<input checked="" type="checkbox"/>	<a href="#">Download</a>	<a href="#">Delete</a>
V3Dig Statistical analysis pla...	160.00kB	Karen Asada	Statis...	<input checked="" type="checkbox"/>	<a href="#">Download</a>	<a href="#">Delete</a>
V3IPD dig.csv.xls	3.28MB	Karen Asada	IPD	<input type="checkbox"/>	<a href="#">Download</a>	<a href="#">Delete</a>

[Submit Files](#)

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

< Go Back **Request: 48314, PI: Amrutha Baskaran** **Status: DUA Validated and Awaiting Data Package Upload** [Print](#)

**Studies**

Status Update

Attachments

Request History

Signed Agreements

Chat

Request Details/Print View

**UPLOADED FILES** [Verify Upload](#)

Filename	Size	Uploaded By	File Type	Publicly Available	Download	
V3DIG Data Dictionary Docum...	118.00kB	Karen Asada	Data D...	<input type="checkbox"/>	<a href="#">Download</a>	<a href="#">Delete</a>
V3Dig Protocol.pdf	179.00kB	Karen Asada	Protoc...	<input type="checkbox"/>	<a href="#">Download</a>	<a href="#">Delete</a>
V3Dig Statistical analysis pla...	160.00kB	Karen Asada	Statis...	<input type="checkbox"/>	<a href="#">Download</a>	<a href="#">Delete</a>
V3IPD dig.csv.xls	3.28MB	Karen Asada	IPD	<input type="checkbox"/>	<a href="#">Download</a>	<a href="#">Delete</a>

[Submit Files](#)



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

< Go Back **Request: 48314, Pt: Amrutha Baskaran** **Status: DUA Validated and Awaiting Data Package Upload** Print

**Studies**

Status Update

Attachments

Request History

Signed Agreements

Chat

Request Details/Print View

**UPLOADED FILES** Verify Upload

Filename	Size	Uploaded By	File Type	Publicly Available	Download	
V3DIG Data Dictionary Docum...	118.00kB	Karen Asada	Data D...	<input checked="" type="checkbox"/>	Download	
V3Dig Protocol.pdf	179.00kB	Karen Asada	Protoc...	<input checked="" type="checkbox"/>	Download	
V3Dig Statistical analysis pla...	160.00kB	Karen Asada	Statis...	<input checked="" type="checkbox"/>	Download	
V3IPD dig.csv.xls	3.28MB	Karen Asada	IPD		Download	

Submit Files

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

Are you sure all files have been uploaded and assigned file types? This action cannot be undone.

You also have specified that the following file types should be made available on the Study Documents tab, to logged-in users who have not yet submitted a data request: Data Dictionary, Statistical Analysis Plan.

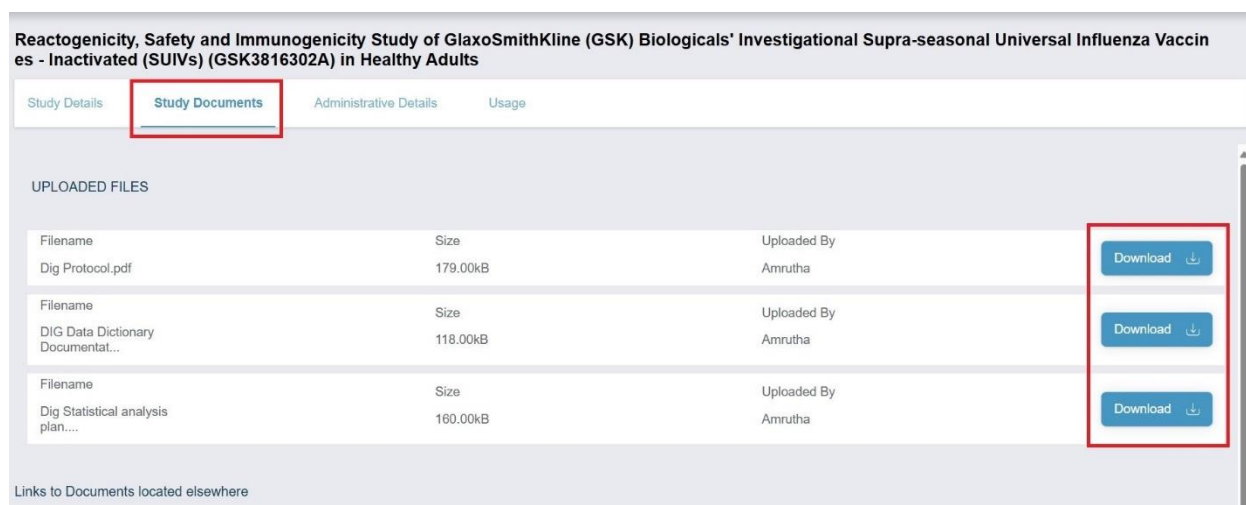
Click Yes to confirm this, or No to modify any of those selections.

Yes No ☐ Never show this again

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



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



## 5.12.2 Loading Supporting Documents for Previously Uploaded Data Package

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

**Studies**  
Submitted by my organization

Draft 2 In Progress 5 **Posted 35** Cancelled

Title	Status	Posted	Sponsor ID	NCTID	IPD
A 10-Month Open-Label Evaluation Of The Long-Term Safety Of Desven...	Posted	2018-03-27	3151A1-3350	NCT00831415	Y
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-G...	Posted	2018-03-27	3151A1-3362	NCT00863798	Y
A 10 Month Open-Label Evaluation Of The Long-Term Safety Of DVS-23...	Posted	2018-03-27	3151A1-303	NCT01309542	N
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel G...	Posted	2018-03-27	3151A1-332	NCT00277823	Y
A Phase 3, Randomized, Open-Label, Comparative Trial Of Azithromycin...	Posted	2018-03-27	A0861155	NCT00367653	Y
Fracture Incidence Reduction And Safety Of TSE-424 (Bazedoxifene Ac...	Posted	2018-03-27	3068A1-301	NCT00205777	N
A Safety and Efficacy Trial Evaluating the Use of Apixaban in the Treatm...	Posted	2018-03-27	CV185-056	NCT00643201	Y
Phase 3 Randomized, Double Blind, Placebo Controlled Study Of The Ef...	Posted	2018-03-27	A3921044	NCT00847613	N

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

< 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

UPLOADED FILES

Filename	Size	Uploaded By	File Type	Publicly Available	Download
V3IPD dig csv.xls	3.28MB	Karen Asada	File Type: IPD	<input checked="" type="checkbox"/>	Download
V3Dig Protocol.pdf	179.00kB	Karen Asada	File Type: Protocol	<input type="checkbox"/>	Download
V3DIG Data Dictionary Document...	118.00kB	Karen Asada	File Type: Data Dictionary	<input type="checkbox"/>	Download
V3Dig Statistical analysis pla...	160.00kB	Karen Asada	File Type: Statistical Analysis Plan	<input type="checkbox"/>	Download

Verify Upload

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

The screenshot shows the 'Data Package' tab in the Vivli Data Contributor interface. The 'UPLOADED FILES' table lists the following files:

Filename	Size	Uploaded By	File Type	Publicly Available	Download
V3IPD dig.csv.xls	3.28MB	Karen Asada	File Type: IPD	<input checked="" type="checkbox"/>	<a href="#">Download</a>
V3Dig Protocol.pdf	179.00kB	Karen Asada	File Type: Protocol	<input checked="" type="checkbox"/>	<a href="#">Download</a>
V3DIG Data Dictionary Document...	118.00kB	Karen Asada	File Type: Data Dictionary	<input checked="" type="checkbox"/>	<a href="#">Download</a>
V3Dig Statistical analysis pla...	160.00kB	Karen Asada	File Type: Statistical Analysis Plan	<input checked="" type="checkbox"/>	<a href="#">Download</a>

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

The screenshot shows the 'Data Package' tab in the Vivli Data Contributor interface. The 'UPLOADED FILES' table lists the following files:

Filename	Size	Uploaded By	File Type	Publicly Available	Download
V3IPD dig.csv.xls	3.28MB	Karen Asada	File Type: IPD		<a href="#">Download</a>
V3Dig Protocol.pdf	179.00kB	Karen Asada	File Type: Protocol	<input checked="" type="checkbox"/>	<a href="#">Download</a>
V3DIG Data Dictionary Document...	118.00kB	Karen Asada	File Type: Data Dictionary	<input checked="" type="checkbox"/>	<a href="#">Download</a>
V3Dig Statistical analysis pla...	160.00kB	Karen Asada	File Type: Statistical Analysis Plan	<input checked="" type="checkbox"/>	<a href="#">Download</a>

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

Dashboard

Data Requests

Enquiries

Studies

Awaiting Upload

Submissions

< Go Back

Create DOI For New Data Version

Prepare For New Data Version

Save

A Phase 3, Randomized, Active-controlled, Observer-blinded Trial To Assess The Lot Consistency, Safety, Tolerability, And Immunogenicity Of A Meningococcal Serogroup B Bivalent Rlp2086 Vaccine In Healthy Subjects Aged >=10 To <19 Years

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

Study Details

Study Documents

Administrative Details

Research Team

Data Package

Usage

Requests

UPLOADED FILES

Filename	Size	Uploaded By	File Type		
V2Dig Protocol.pdf	179.00kB	Amrutha	Protocol	Download	
V2DIG Data Dictionary Document...	118.00kB	Amrutha	Data Dictionary	Download	
V2Dig Statistical analysis pla...	160.00kB	Amrutha	Statistical Analysis Plan	Download	

Links to Documents located elsewhere

Add New Link

7. To remove the supporting document from the search page, click the hide button

Dashboard

Research Environments

Users

Report

My Organizations

Studies

Data Requests

Submissions

< 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

V3DIG Data Dictionary Document...	118.00kB	Karen Asada	Data Dictionary	Download	
V3Dig Protocol.pdf	179.00kB	Karen Asada	Protocol	Download	
V3Dig Statistical analysis pla...	160.00kB	Karen Asada	Statistical Analysis Plan	Download	

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

**Reactogenicity, Safety and Immunogenicity Study of GlaxoSmithKline (GSK) Biologicals' Investigational Supra-seasonal Universal Influenza Vaccines - Inactivated (SUIVs) (GSK3816302A) in Healthy Adults**

Study Details **Study Documents** Administrative Details Usage

UPLOADED FILES

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

Links to Documents located elsewhere

### 5.12.3 Loading Supporting Documents that are not part of Data Package

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

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

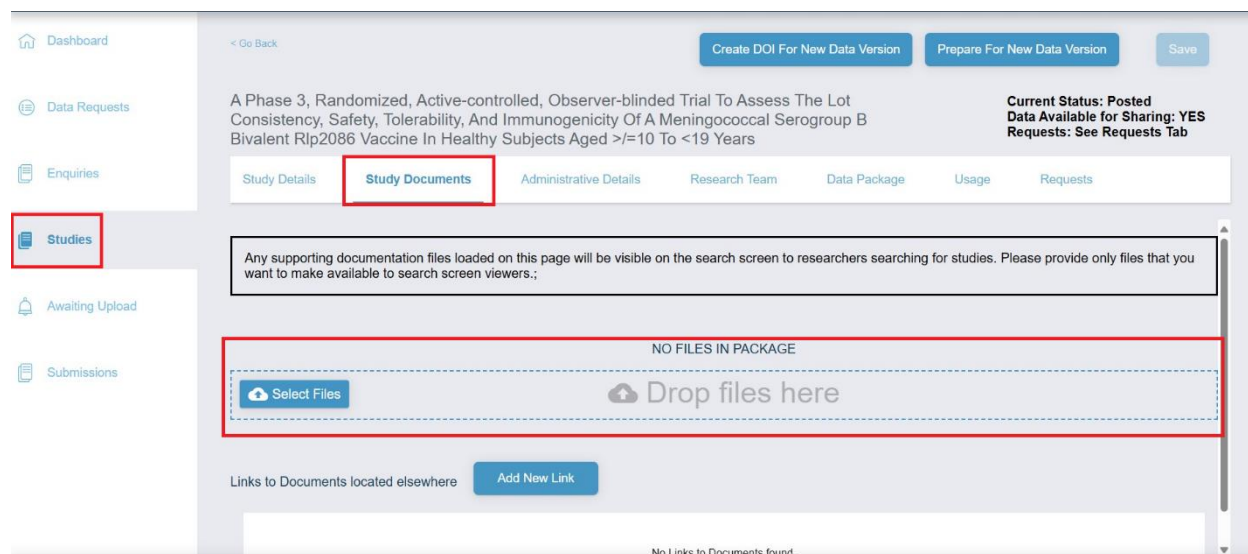
**Studies**  
Submitted by my organization


Draft 2 In Progress 5 **Posted 35** Cancelled

Title	Status	Posted	Sponsor ID	NCTID	IPD
A 10-Month Open-Label Evaluation Of The Long-Term Safety Of Desven...	Posted	2018-03-27	3151A1-3350	NCT00831415	Y
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-G...	Posted	2018-03-27	3151A1-3362	NCT00863798	Y
A 10 Month Open-Label Evaluation Of The Long-Term Safety Of DVS-23...	Posted	2018-03-27	3151A1-303	NCT01309542	N
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel G...	Posted	2018-03-27	3151A1-332	NCT00277823	Y
A Phase 3, Randomized, Open-Label, Comparative Trial Of Azithromycin...	Posted	2018-03-27	A0661155	NCT00367653	Y
Fracture Incidence Reduction And Safety Of TSE-424 (Bazedoxifene Ac...	Posted	2018-03-27	3068A1-301	NCT00205777	N
A Safety and Efficacy Trial Evaluating the Use of Apixaban in the Treatm...	Posted	2018-03-27	CV185-056	NCT00643201	Y
Phase 3 Randomized, Double Blind, Placebo Controlled Study Of The Ef...	Posted	2018-03-27	A3921044	NCT00847613	N

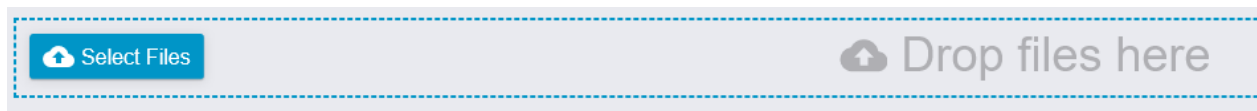


## 2. Open the study and go to Study Documents



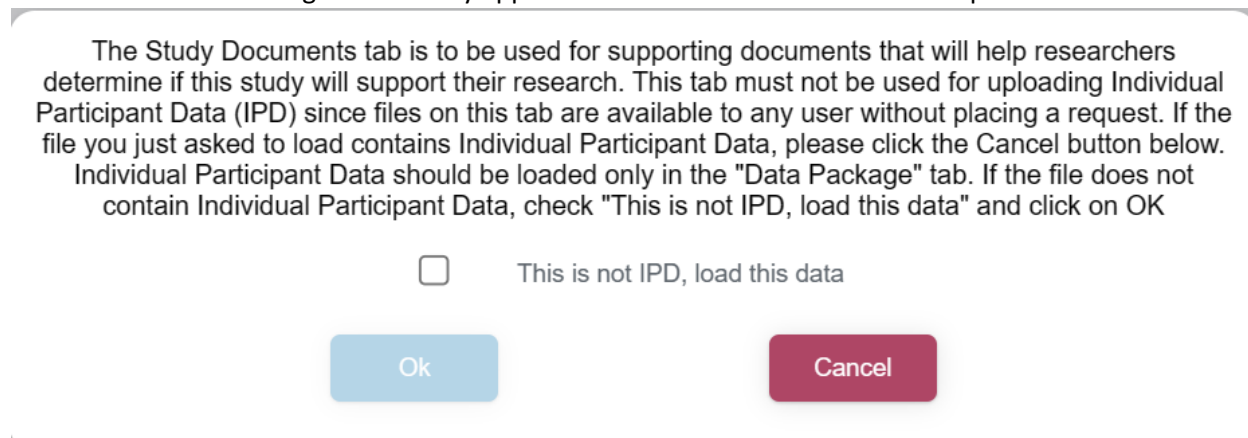
3. Now click on  to choose files to upload. A window will pop up allowing the data contributor to select the files of their computer. After selecting the files, click **Open**.

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



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

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



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


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. If you navigate away from a page on which an upload is underway (i.e. clicking on another tab or closing the browser), that will cancel the upload automatically
9. 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

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

Select Files

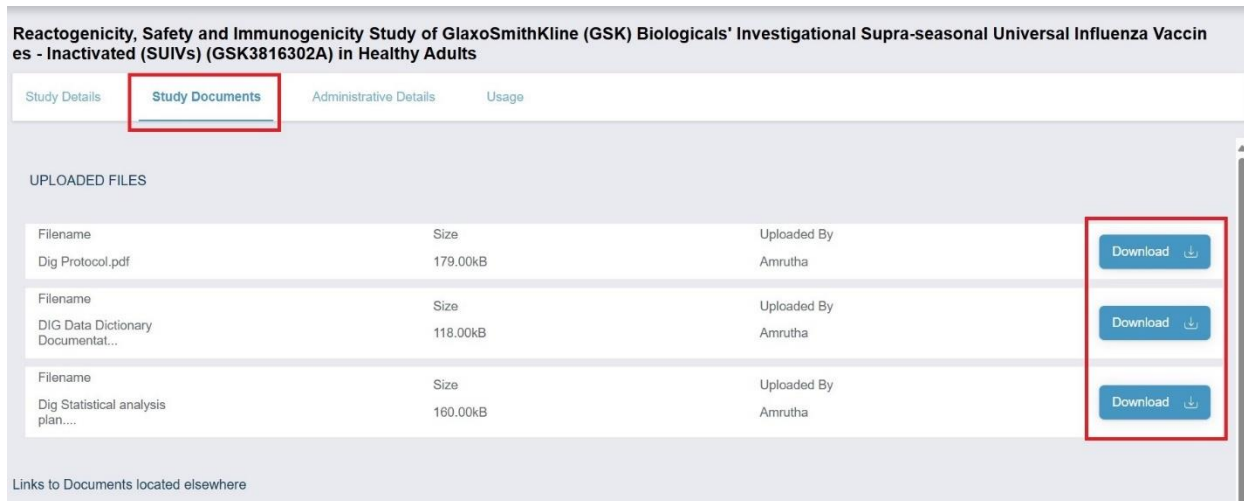
UPLOADED FILES

Filename	Size	Uploaded By	File Type		Download	Delete
DIG Data Dictionary Documentation.p...	118.31kB	Karen Asada	Unknown	▼	<a href="#">Download</a>	<a href="#">Delete</a>
Dig Protocol.pdf	178.72kB	Karen Asada	Unknown	▼	<a href="#">Download</a>	<a href="#">Delete</a>
Dig Statistical analysis plan.pdf	159.73kB	Karen Asada	Unknown	▼	<a href="#">Download</a>	<a href="#">Delete</a>

[Verify Upload](#)

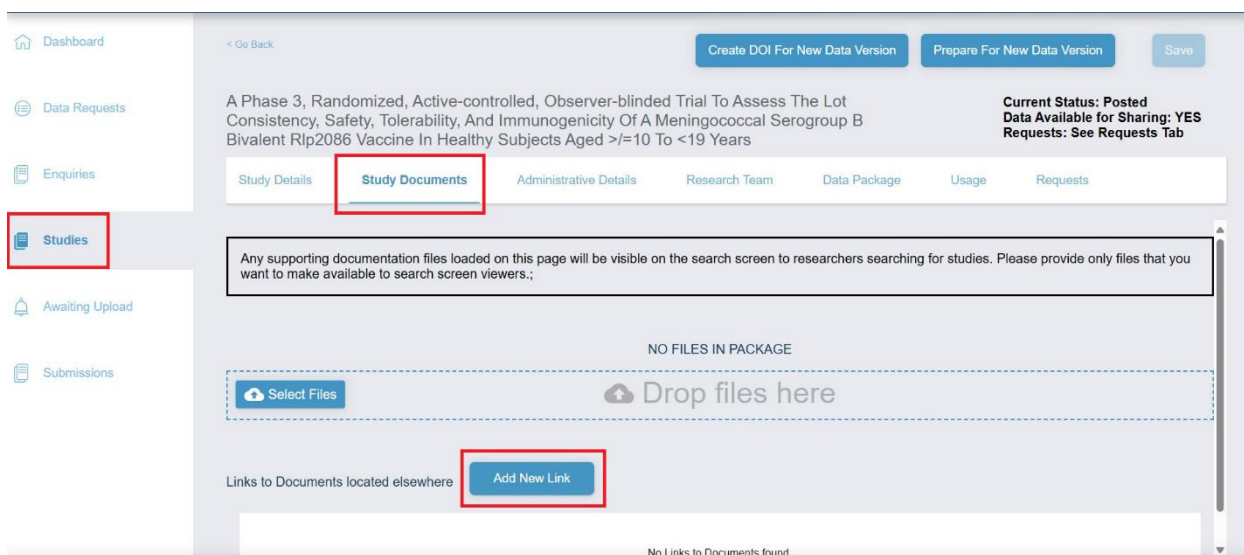


10. The supporting documents that you have made publicly available will be visible to the Researcher with a Vivli account on the search page.




#### 5.12.4 Providing Links to External Supporting Documents

1. If there are further documents that are available for your study at an external link, you can make the link available to researchers on the search page
2. Go to Study Documents and click the blue button that says, “Add New Link”.

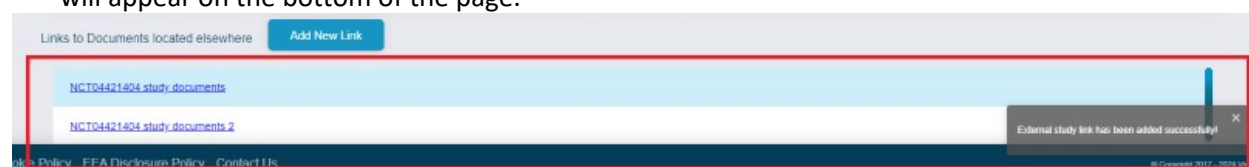


3. In the box that appears, type in the Title of the document and the URL, and then click “Save”




The screenshot shows a form titled "Add New Link". It has two input fields: "Title" and "URI". Below these fields are two buttons: "Save" and "Cancel". The "Save" button is highlighted with a red rectangular border.

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



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




HomeAboutMembersNews & EventsResourcesPortalsFind Studies

ENQUIRYQUICK STUDY LOOKUP540MY DATA REQUESTSRICHARD ANDERSON

### Assessment of Real-life Patient Handling Experience of BI 695501 Administered Subcutaneously With an Autoinjector in Patients With Rheumatoid Arthritis: an Open-label, Interventional Clinical Trial Followed by an Extension Phase of BI 695501 Administered With a Prefilled Syringe

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

#### UPLOADED FILES

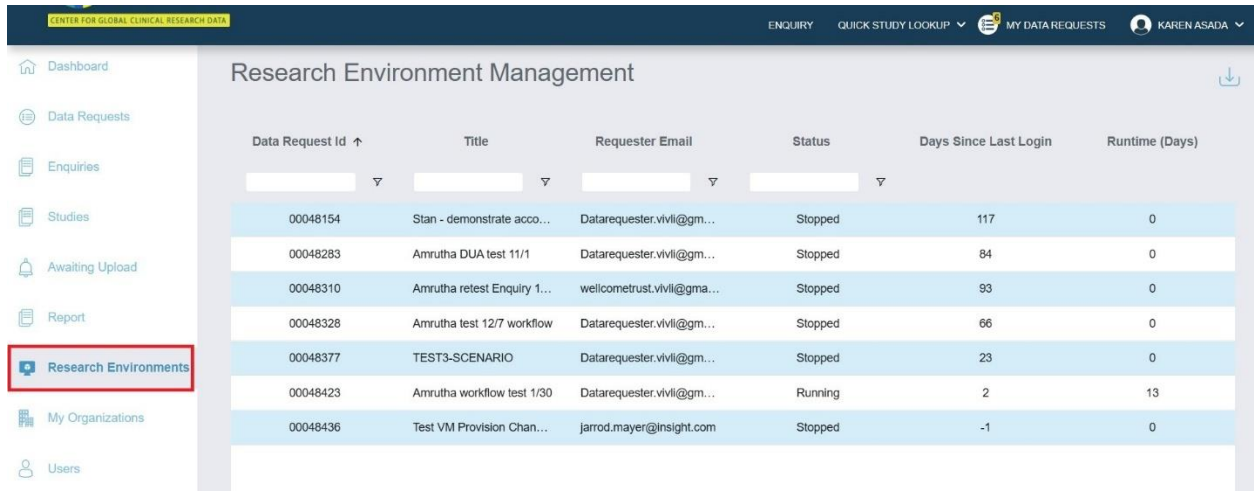
Filename	Size	Uploaded By	
V3DIG Data Dictionary Document...	118.00kB	Amrutha	<a href="#">Download</a> 

Links to Documents located elsewhere

[ClinicalTrials](#)

## 6. Research Environment Monitoring

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



Data Request Id ↑	Title	Requester Email	Status	Days Since Last Login	Runtime (Days)
00048154	Stan - demonstrate acco...	Datarequester.vivli@gm...	Stopped	117	0
00048283	Amrutha DUA test 11/1	Datarequester.vivli@gm...	Stopped	84	0
00048310	Amrutha retest Enquiry 1...	wellcometrust.vivli@gma...	Stopped	93	0
00048328	Amrutha test 12/7 workflow	Datarequester.vivli@gm...	Stopped	66	0
00048377	TEST3-SCENARIO	Datarequester.vivli@gm...	Stopped	23	0
00048423	Amrutha workflow test 1/30	Datarequester.vivli@gm...	Running	2	13
00048436	Test VM Provision Chan...	jarrod.mayer@insight.com	Stopped	-1	0

- 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 de-provisioned)
- You may click on the Data Request ID to see details of a specific environment.

Research Environment Details - 00002875 (Influenza Study Project)

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 de-provisioned will also be recorded in the Request history tab of the data request.

## 6.1 Software in the Research Environment

- The software available in the Research Environment is updated regularly 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 under “Software and R Packages Available in the Research Environment”: <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.

## 6.2 Downloadable Data

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

## 7. Public Disclosures & Publications & Summary of Results

### 7.1 Review(s) by Vivli Members

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

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 Organization Administrators for a 30-day courtesy review.
5. When should a Vivli Member be considered an author on a manuscript or public disclosure? It is Vivli's policy that the decision to appoint someone as an author should be made by applying the [ICMJE authorship criteria](#) (reviewed and agreed upon by the Steering Committee in May 2023).

### 7.2 Publication Notification by Data Requestor

- When a public disclosure based on the results obtained from the data request is published, the Data Requestor must inform Vivli.
- Vivli will notify the Vivli Member(s) about the publication via email.
- In addition, the link to the publication will be made available for public view on Vivli's [Metrics page](#) linked to their approved request page i.e. data request DOI.

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Home About Members News & Events Resources Portals Find Studies

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS KAREN ASADA

< Go Back Evaluation of Differences in Trial and Non-Trial Patients and Leveraging of External Data... Include Risk Score Print

Studies  
Status Update  
Attachments  
Request History  
Signed Agreements  
Safety Concerns  
Research Results  
Chat  
Research Team  
Research Environment  
Public Disclosures  
**Request Details/Print View**

Research Data Request: Evaluation of Differences in Trial and Non-Trial Patients and Leveraging of External Data for More Efficient Clinical Trial Designs in Newly Diagnosed Glioblastoma

Vivli ID: 00048506

Data Request DOI: <https://handle.test.datacite.org/10.70118/AQ00048506>

Research Team

Lead Investigator

Sarah Jones  
sarahjones@gmail.com  
Professor  
Dana-Farber/Harvard Cancer Center  
Country: Åland Islands

Education or Qualifications

MD, PhD

Name of the degree

PhD

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

**Vivli**  
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

ENQUIRY QUICK STUDY LOOKUP MY DATA REQUESTS SALLY

< Go Back Request: 48006, Pt: Heidi Lakes Status: Archived Archive Do not track Cancel Edit Data Request Print

Studies  
Status Update  
Attachments  
Request History  
Signed Agreements  
Chat  
Research Environment  
**Public Disclosures**  
Request Details/Print View

Public Disclosures

Current Citations

<p>Baskin, Jacquelyn L, Pui, Ching-Hon, Reiss, Ulrike, Wilimas, 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</p>
---

- You may also view the citations linked to the study. Please see [Section 2.6 Study Usage and Public Disclosure Metrics](#) for more information.
- Once all the publications are published and the analysis is complete, the Vivli team will move the data request to the Archived 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, the Vivli Admin will notify the data requester via the platform chat and the Vivli Members via email that the summary of results has been published and archive the data request.

## 8. Data Progress Report

The Data Use Agreement allows for 1 year for accessing the data from the date it was executed by Vivli. Vivli will send a Data Progress Report to the Researcher 90 days before the DUA is about to expire. Researchers can apply for an extension to the DUA by completing the Data Progress Report sent by Vivli. According to Vivli policy, DUA extensions are given in 1-year intervals.

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

## 9. Research Environment Closure & Request Archival

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

**Research Data Requests**  
For data provided by my organizations

Search data requests

Awaiting My Action 15 Draft 17 Active 68 Not Approved 2 Withdrawn 10 Archived 3

Vivli ID	Status
Vivli ID: 00048411 Amrutha test 1/23 (Studies: 2) Requested By: Richard Anderson Lead Researcher: Amrutha Baskaran	Archived
Vivli ID: 00048381 Amrutha 1/6/25 workflow testing (Studies: 3) Requested By: Richard Anderson Lead Researcher: Amrutha Baskaran	Archived
Vivli ID: 00048328 Amrutha test 12/7 workflow (Studies: 3) Requested By: Richard Anderson Lead Researcher: Sarah Jones	Archived



## 10. Safety Reporting

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

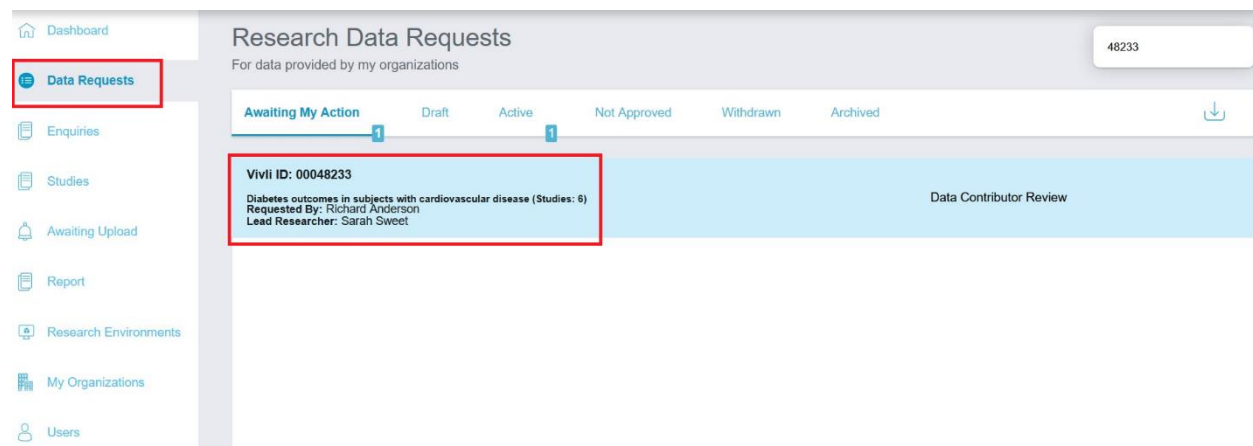
## 11. Communications

### 11.1 Chat

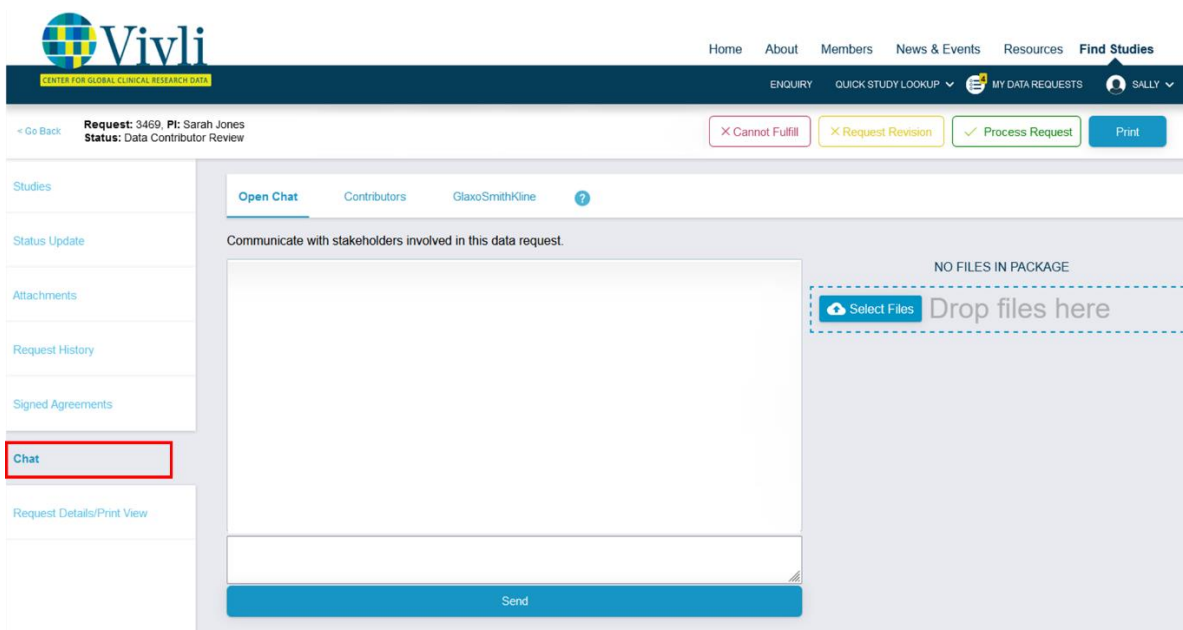
- You can use the **open chat** within the data request, to communicate with data requestors, the Vivli Administrators, members of your organization, delegated reviewers, and other Organizational Administrators associated with the specific request for your data.
- Please note that messages in the open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

#### 11.1.1 Open Chat

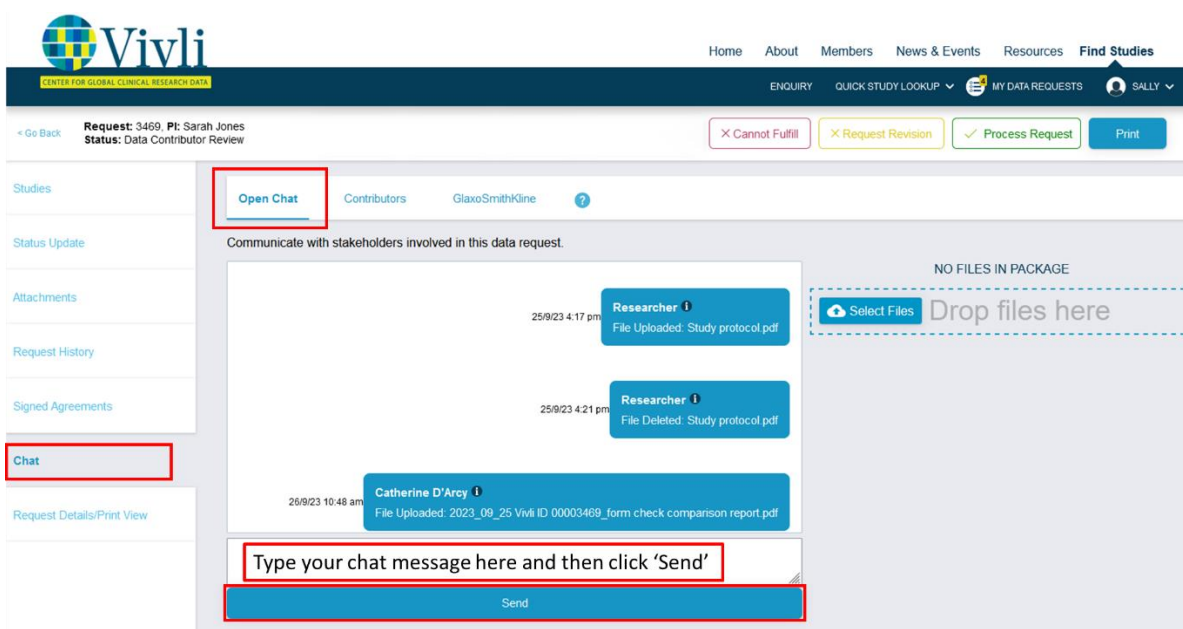
1. Log on to the platform:
2. Go to the **Data Request** tab:



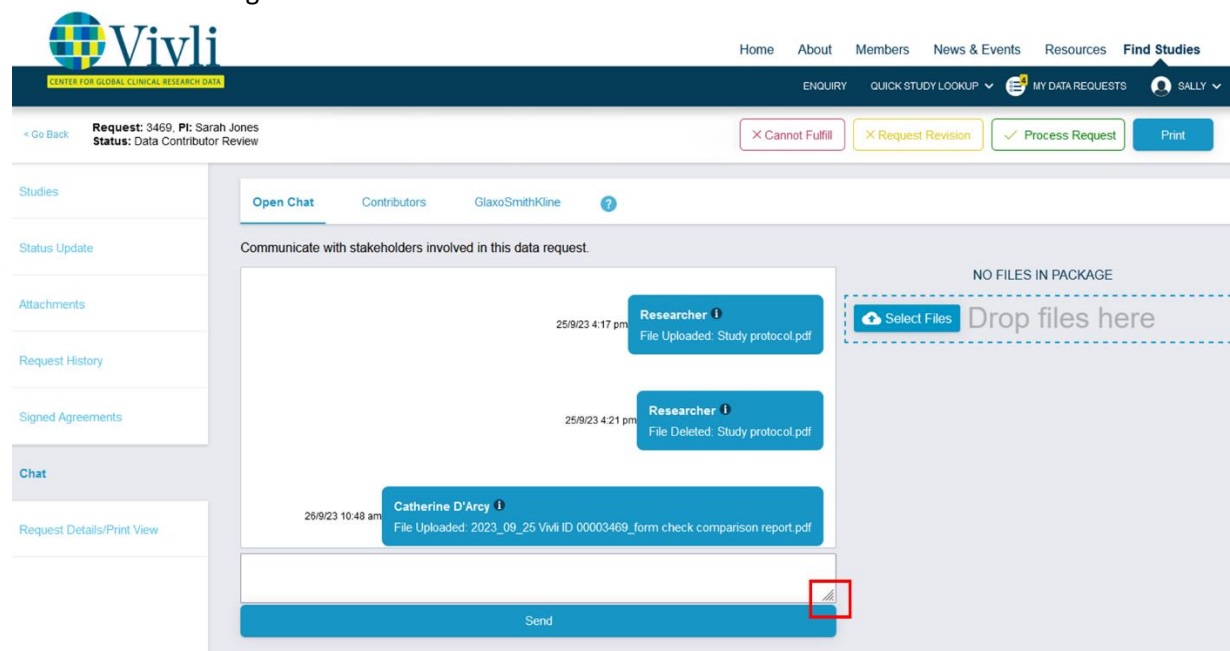
3. Open the applicable data request and click on the **Chat** tab on the left-hand side of the screen:



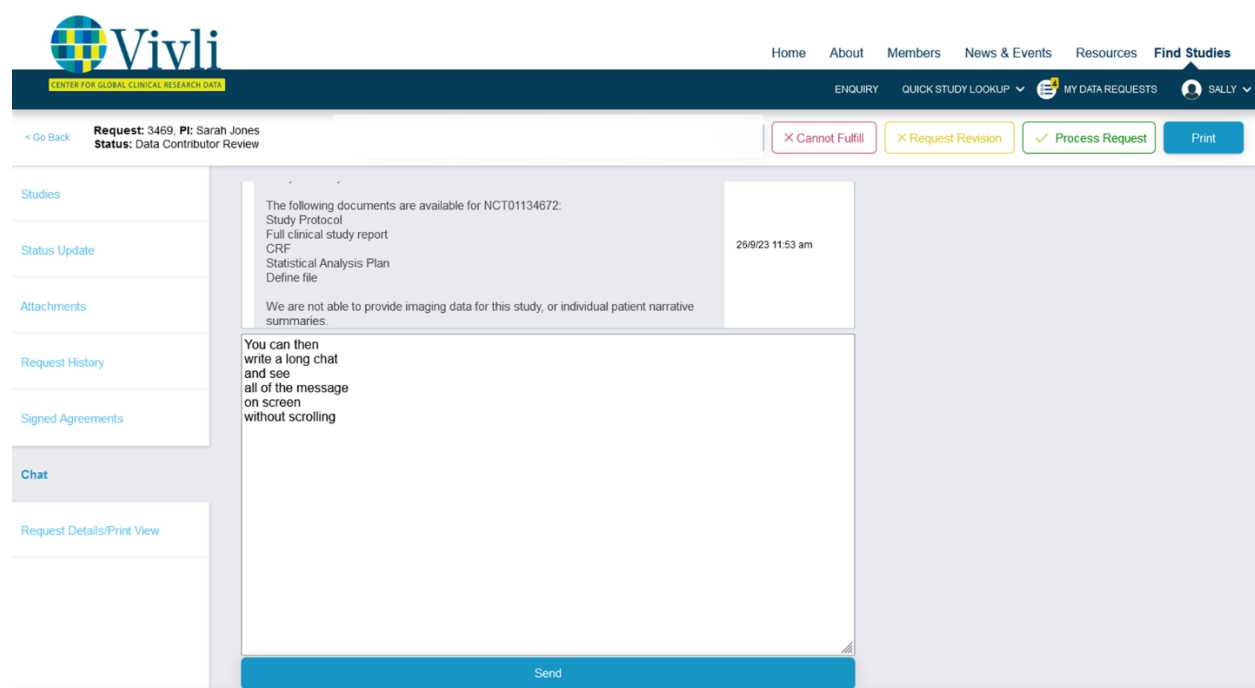
4. Enter your message in the chat message box under “Open chat” and click **Send**:



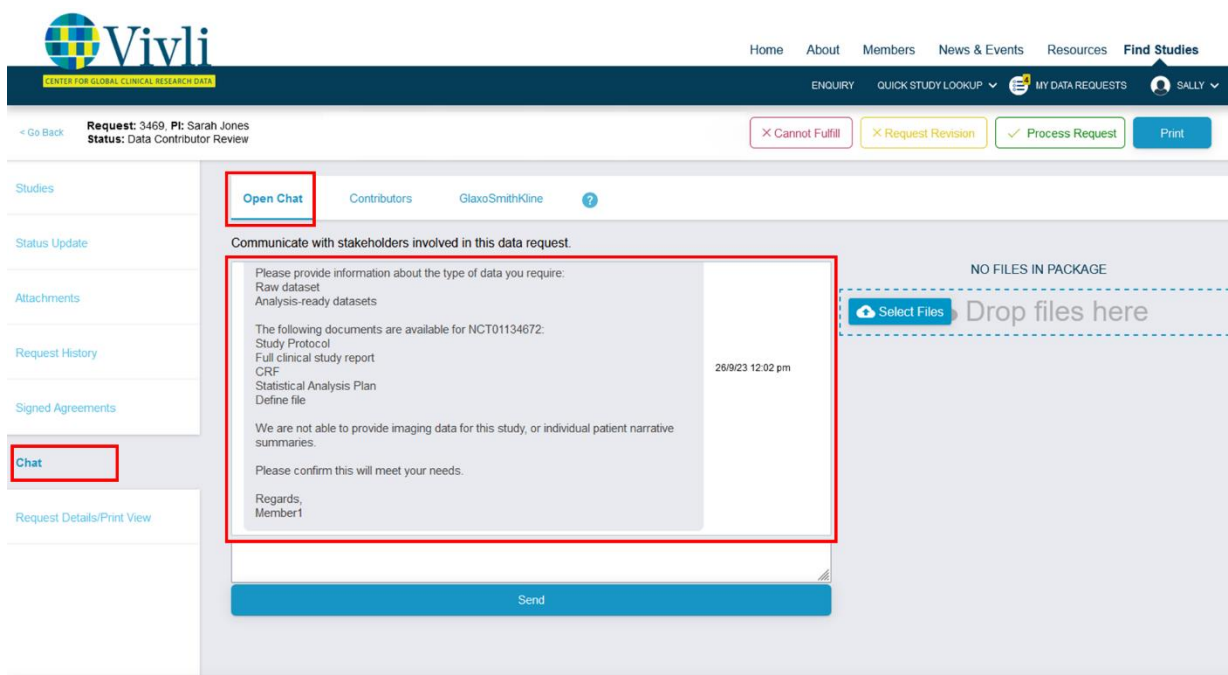
- In the chat window, there is a hash mark on the lower right of the text entry panel. Hover over it and the cursor changes to a double-headed arrow



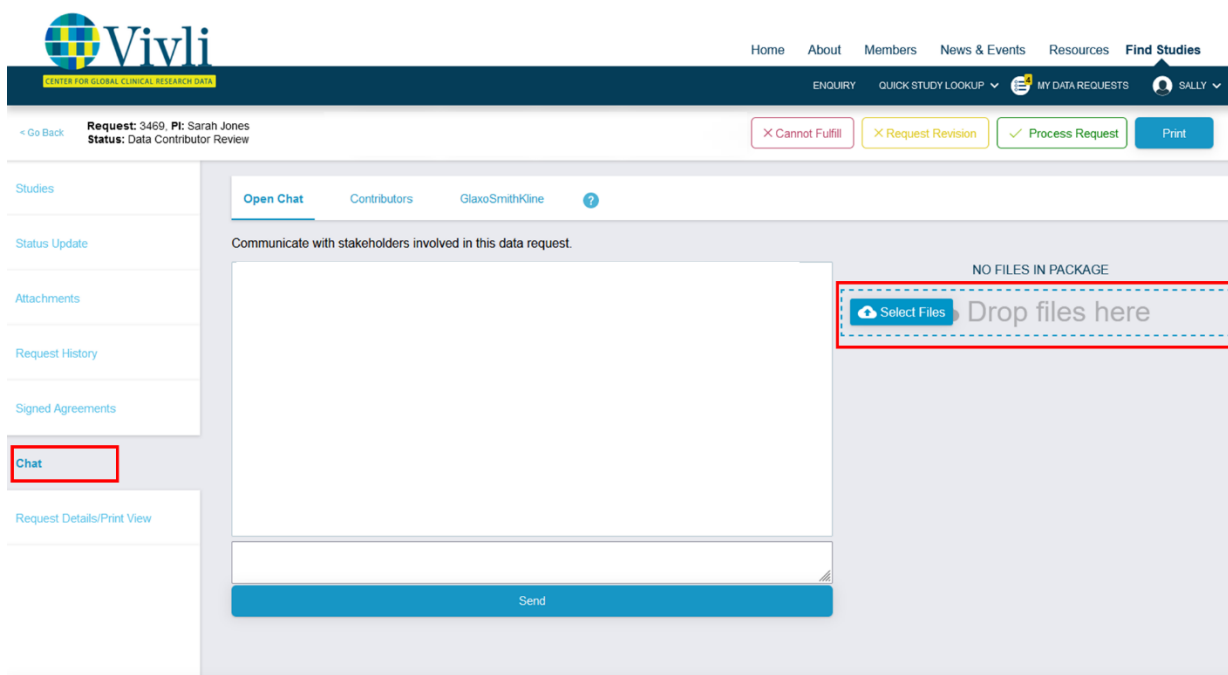
- Drag the arrow to enlarge the text entry area. Drag it off the edge of the screen to make it very large.



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

The files section of Chat is not to be used for loading Individual Participant Data or for screenshots of the research environment. If you need to upload data containing Individual Participant Data, please contact Vivli at [support@vivli.org](mailto:support@vivli.org) and we can help you with other ways to load the data.

If the file you just asked to load contains Individual Participant Data, please click the Cancel button below. 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

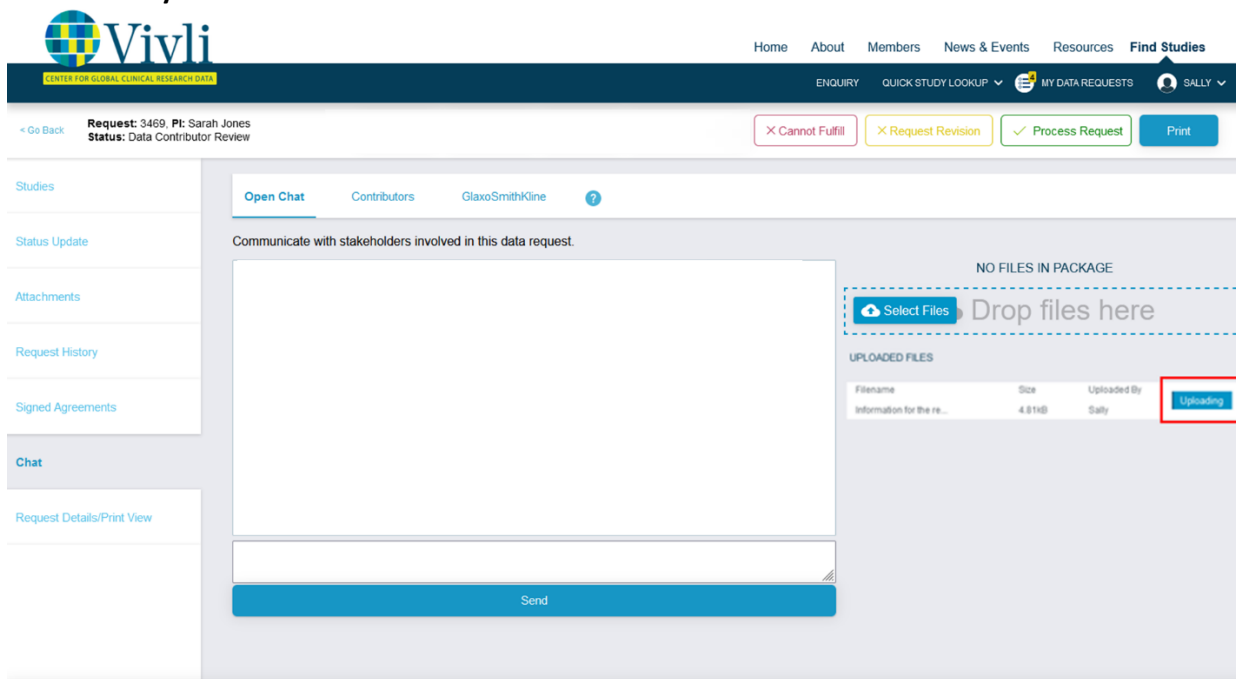
11. Check the checkbox to confirm that the files are not IPD and then click OK.

The files section of Chat is not to be used for loading Individual Participant Data or for screenshots of the research environment. If you need to upload data containing Individual Participant Data, please contact Vivli at [support@vivli.org](mailto:support@vivli.org) and we can help you with other ways to load the data.

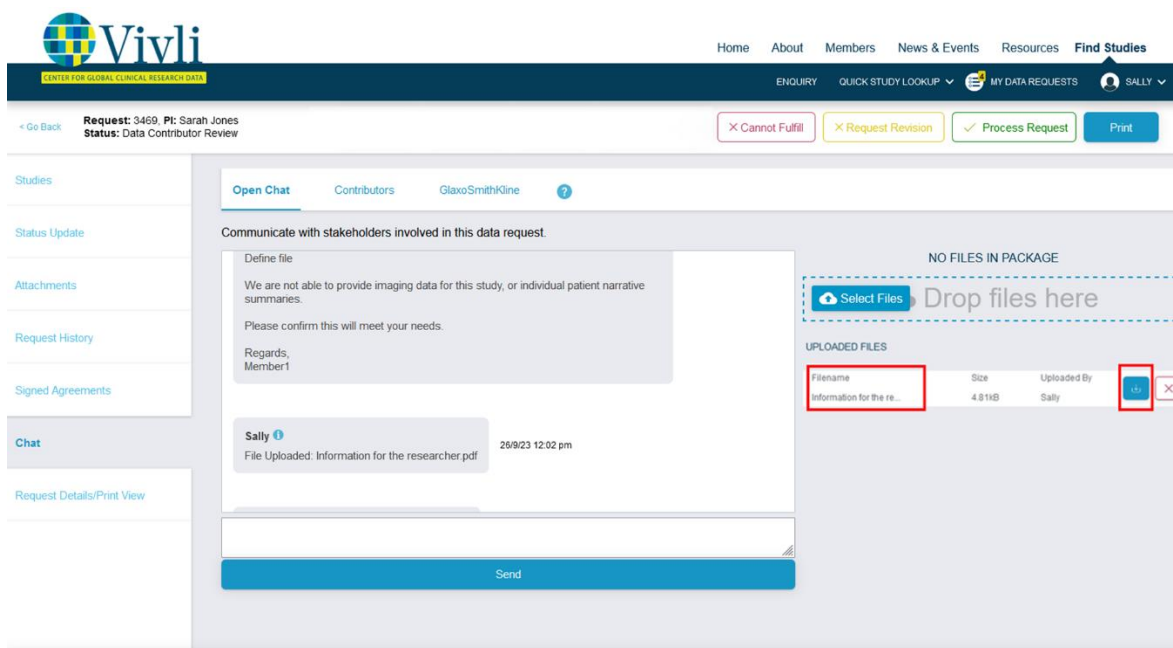
If the file you just asked to load contains Individual Participant Data, please click the Cancel button below. If the file does not contain Individual Participant Data, check "This is not IPD, load this data" and click on OK.

☒ This is not IPD, load this data

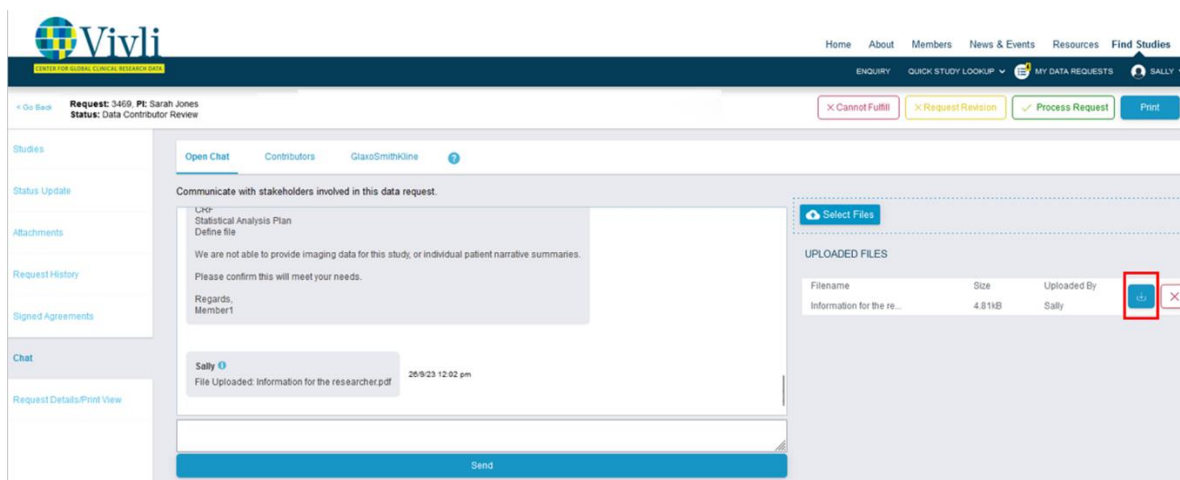
12. The upload bar will show the progress. **If you navigate away from a page on which an upload is underway (i.e. clicking on another tab or closing the browser), that will cancel the upload automatically:**



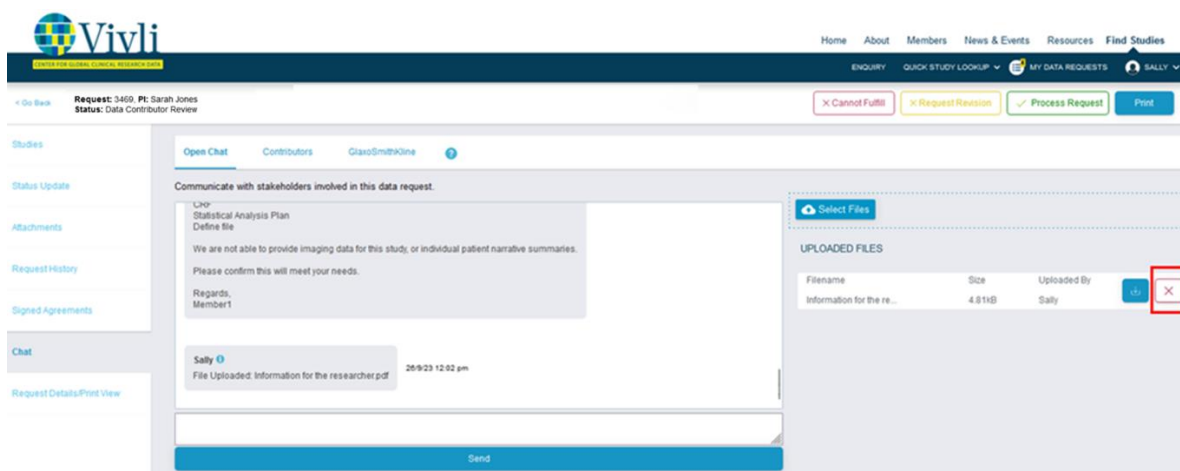
13. The history of the uploaded file will appear in the chat window:



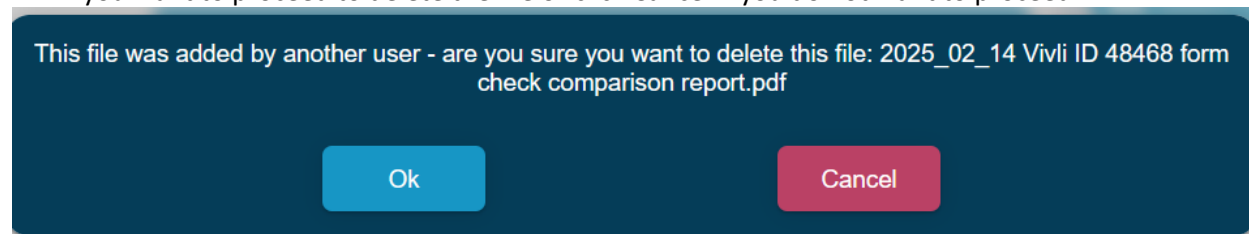
14. You may also download chat files by clicking on **Download**:



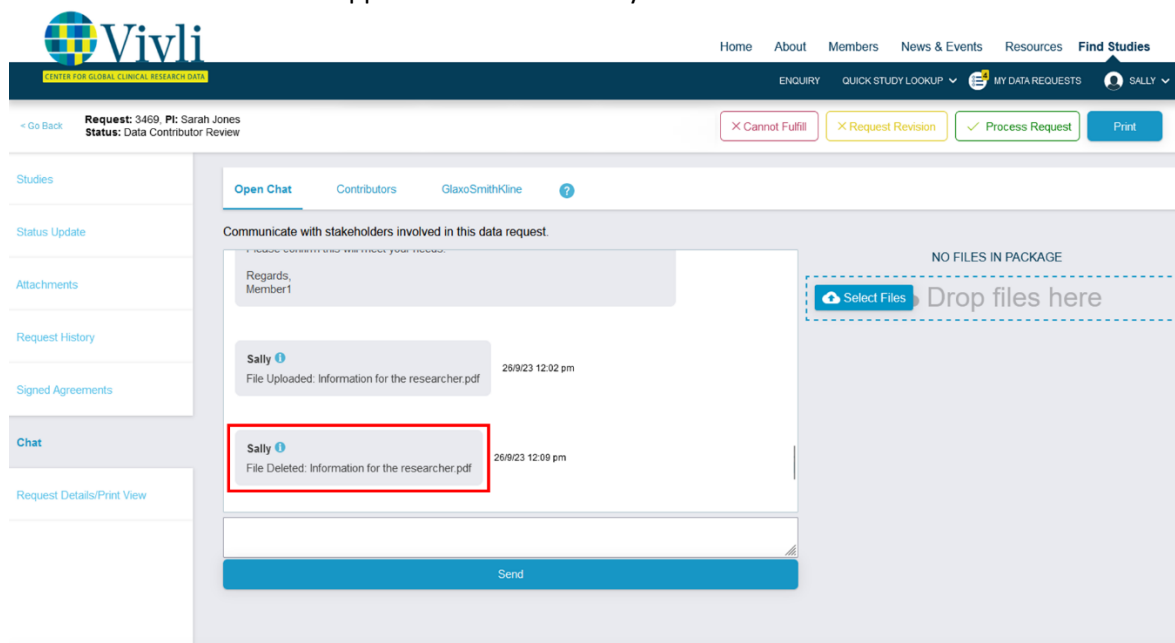
15. You can delete the uploaded file by clicking **delete**:



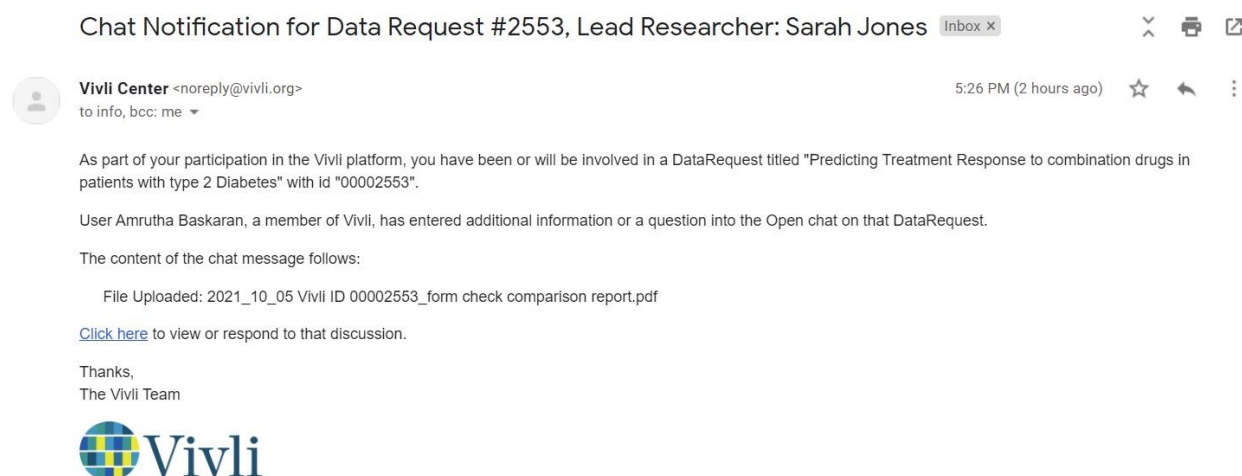
16. You will see a confirmation box asking you to confirm if you intended to delete the file "This file was added by another user - are you sure you want to delete this file: <filename>". Click Ok if you want to proceed to delete the file or click Cancel if you do not want to proceed.



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



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

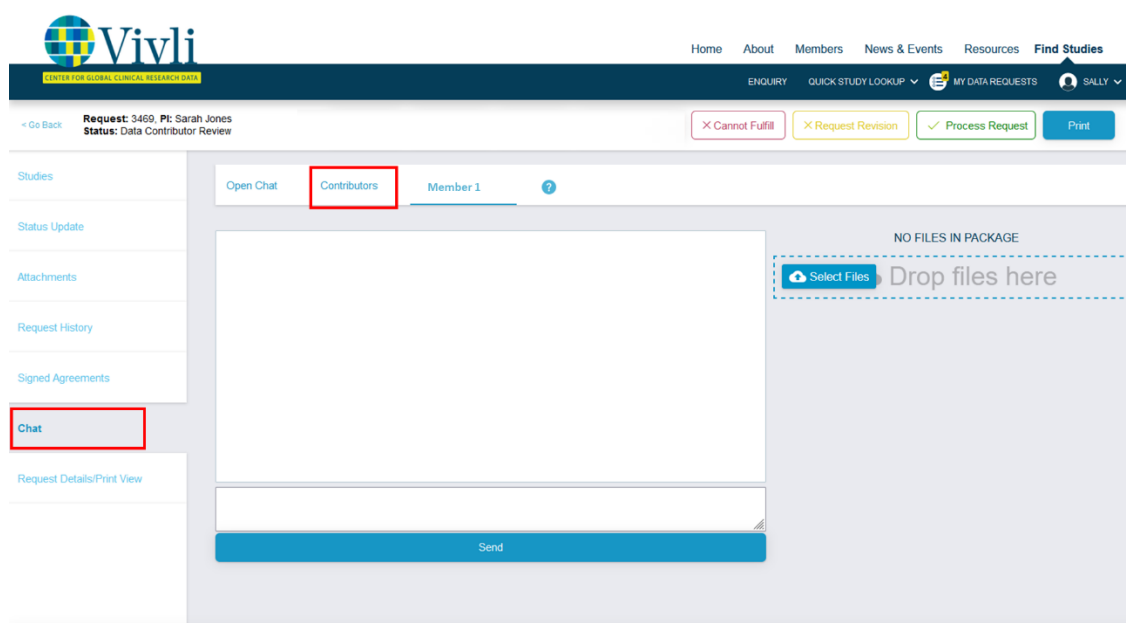




22. Note: Vivli admins may set up automatic follow-ups for repeated follow-ups (E.g. revision, DUA, publication follow-ups, etc.). organizational administrators won't receive any email notifications for such follow-ups. Organization Administrators can see the chat messages in the open chat window.

### 11.1.2 Contributors Chat

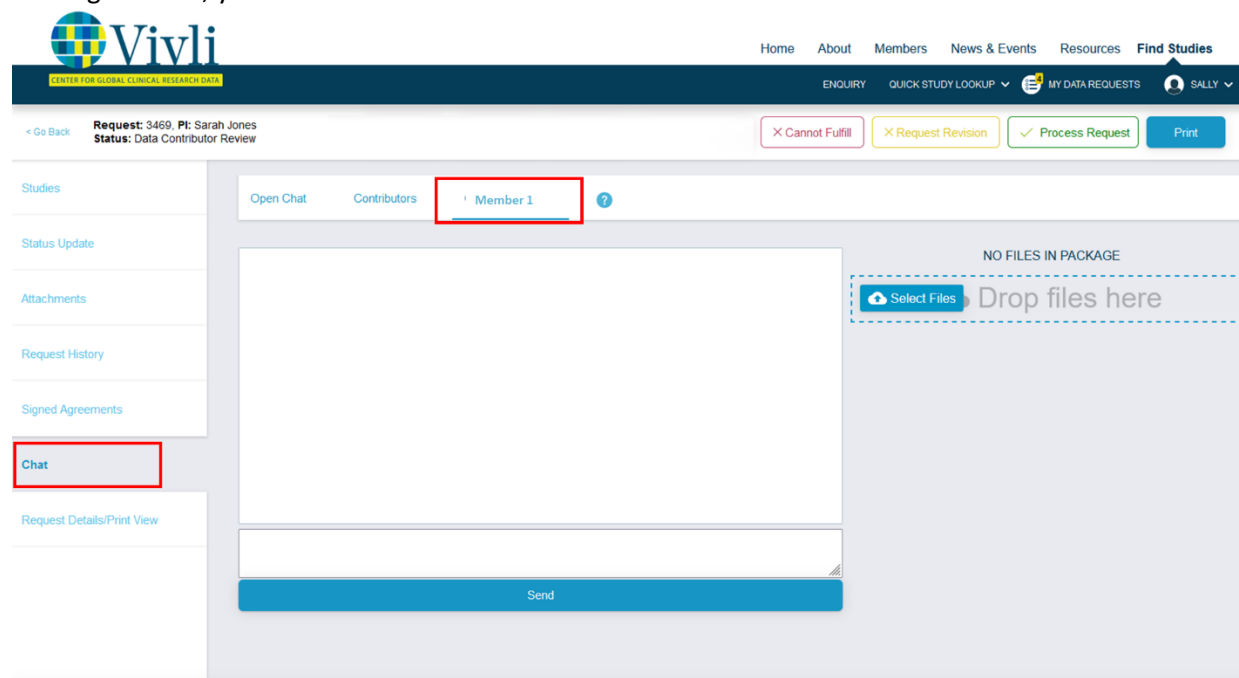
You may also open a Contributors chat within the data request to communicate with all the Organizational Administrators involved in the data request (but not the researcher and the IRP) and the Vivli team. Organizational administrators will receive email notifications from this chat, but not those who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



### 11.1.3 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 **only** to members of your organization on the Vivli platform. The Vivli team cannot see this information. When any other team member in your organization enters a message in chat, you will receive an email notification.

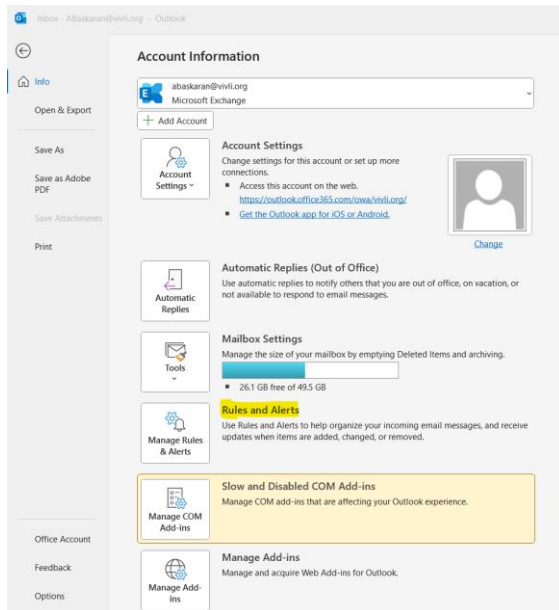


## 11.2 Setting up an Inbox Rule on Outlook to Filter Emails

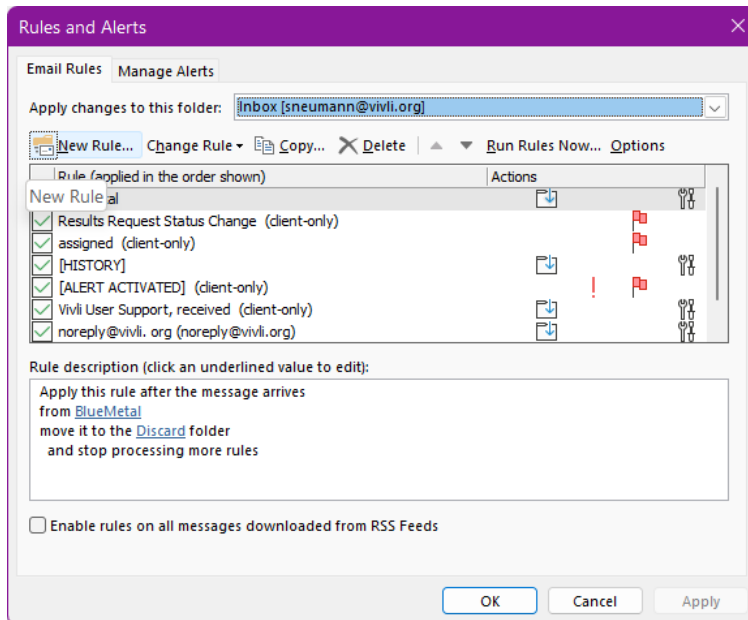
Here are instructions for creating an inbox rule that can refile messages containing a specific sub-string in the subject line. The specifics are written for platform messages, but they can be generalized for other frequent messages that you don't want actively in your inbox. If you want to disable your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

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

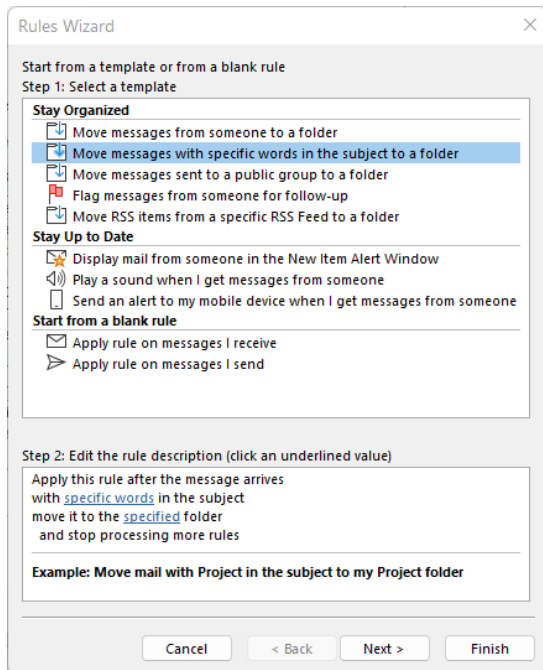
If you are using the new Outlook client, the rules are at Settings -> Mail -> Rules. If you are on the old Outlook client, click "File" then the button "Manage Rules and Alerts"



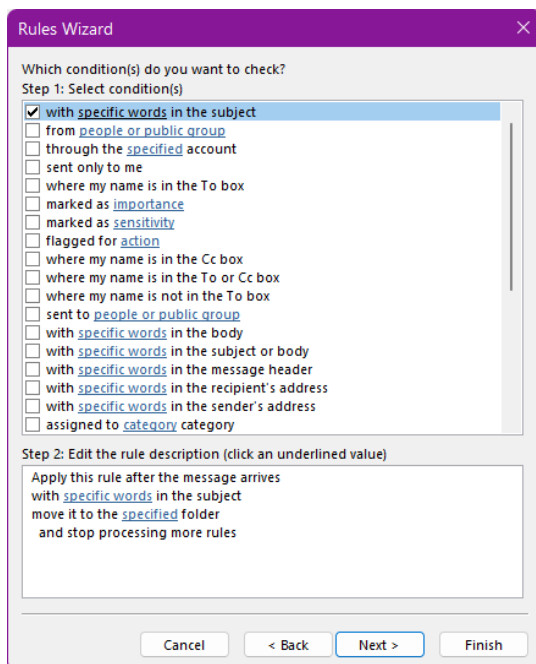
In the pop-up window, click New Rule:



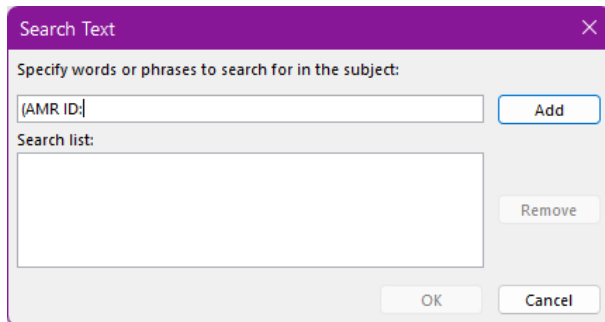
In the pop-up wizard, pick “Move messages with specific words in the subject to a folder”



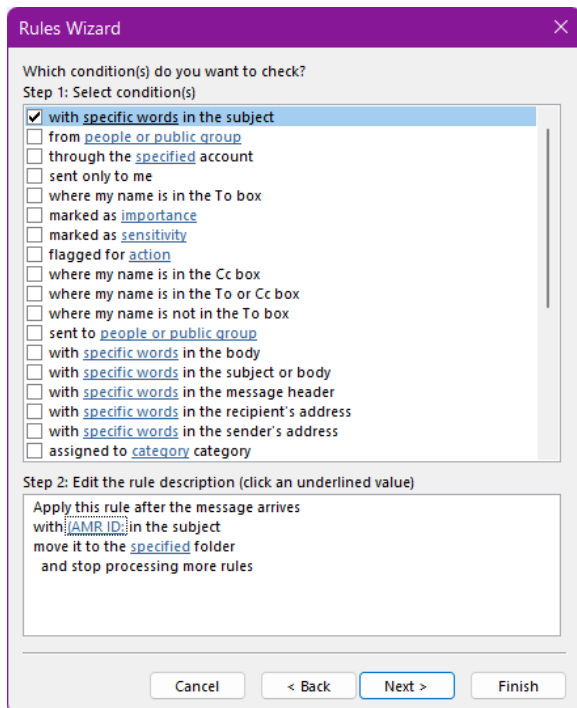
Click Next (it should display the choice “with specific words in the subject”),



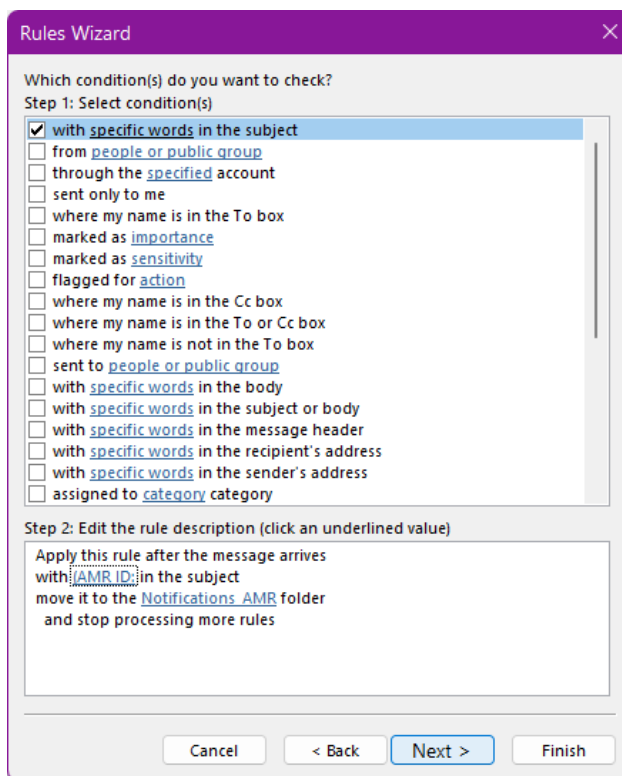
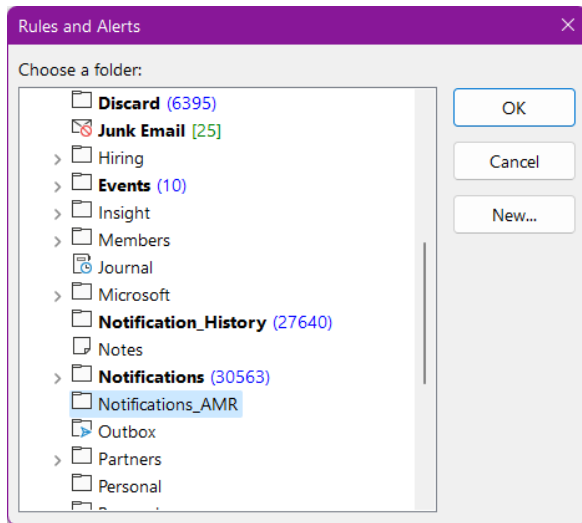
In the bottom half, click on “specific words” and enter “(AMR ID:” or “(Vivli:” or “(Chat Notification:”



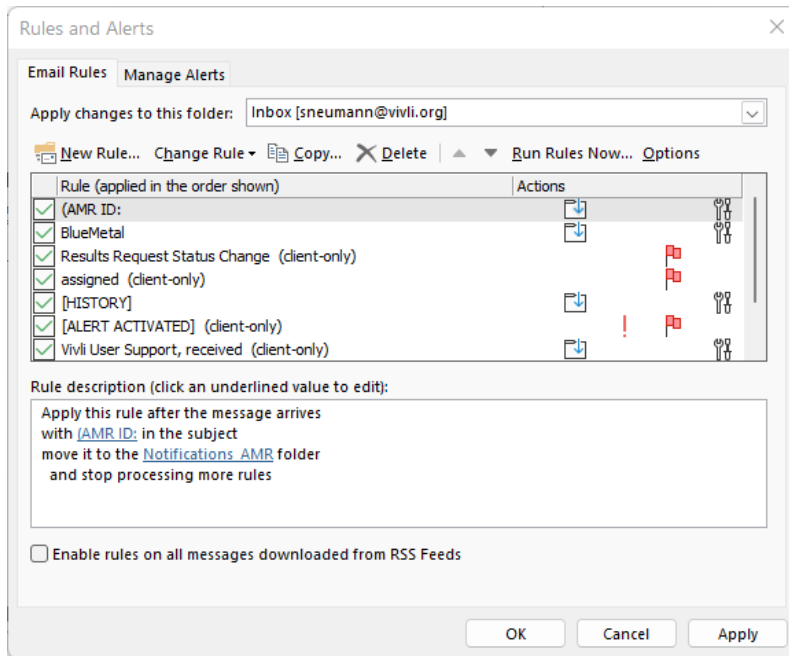
Click add to add it to the search list and then click OK:



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



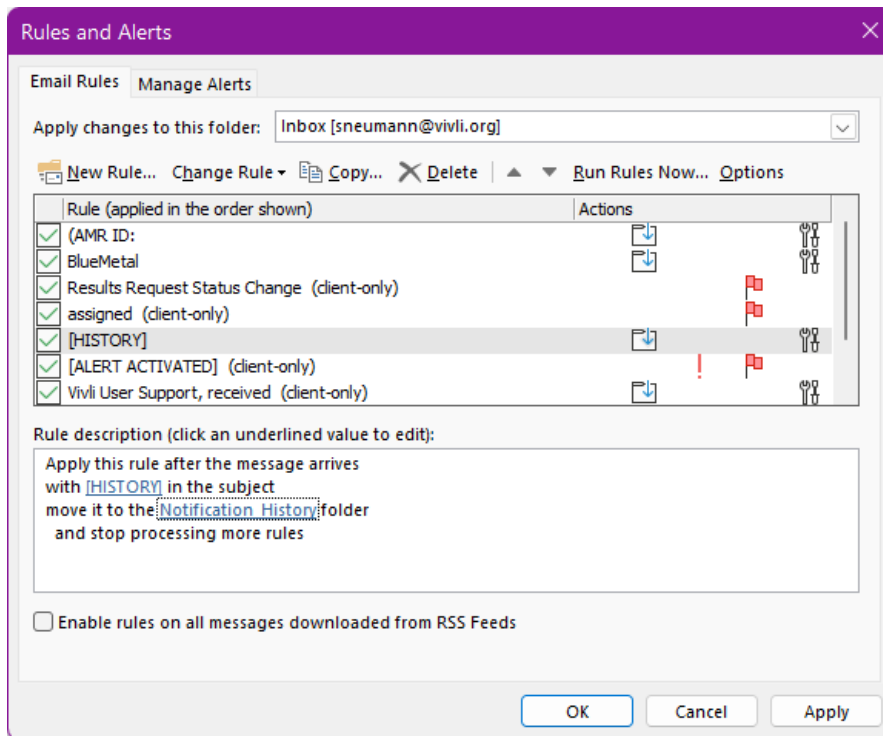
Click Finish and the rule should appear in the rule list:



Click OK to commit this.

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

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



Here are a few examples of the rules:

- from [noreply@vivli.org](mailto:noreply@vivli.org) check "move to specified folder", choose folder "Notifications" and check "stop processing more rules"
- from [platformsupport@vivli.org](mailto:platformsupport@vivli.org) - action: check "move to specified folder", choose folder "Notifications" and check "stop processing more rules"



### 11.3 Automated Emails from Vivli Platform

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

Email	When sent	Purpose
Data Request Ready for Review	When a data request for your studies has been submitted	Notify Organizational Administrators of the data request; prompt you to record your decisions if applicable
Data Request Non-Approval during Data Contributor Review	For multi-sponsor requests that include your organization's studies, an email is generated whenever any Vivli Member records their non-approval. The email also shows the reasons for non-approval.	Notify Organizational Administrators of any non-approvals to the data request.
Request Approved	When a data request for your studies is approved, by you or a delegated approver. For multi-sponsor requests, an email is generated after that last IRP records their final review decision.	Notify of final governance approval.
DUA Approved	When the Vivli Admin has validated the DUA associated with the data request	Notify organizational administrators and data contributors of approved DUA. Please work on uploading the data package, if applicable.
Safety Concerns	When a data requestor logs a safety concern relating to any of the data associated with the request	Notify organizational administrators of safety concerns.
Chat	When anyone associated with a data request enters a message in chat once the request reaches the Data Contributor Review stage for the first time. Once it reaches that stage, Organization Administrators will continue to receive notifications even if it goes back to draft for revisions. This includes emails from Open chat and Contributors chat	Facilitate communication and the data request workflow.
Research Environment deprovisioned	When the research environment is deprovisioned	Notify Organizational Administrators when the analysis is complete
Data Request Archived	When the data request is Archived, the project is considered closed.	Notify Organizational Administrators that the lead researcher and research team have met the DUA obligations for public disclosure/summary of results and the data request is now archived.

Enquiry ready for your review	When the Enquiry for your studies is submitted to review stage	Notify Organizational Administrators of the Enquiry and prompt you to record your decisions
Response provided by the Researcher or Vivli team for your Enquiry	When anyone associated with the Enquiry adds comments to the discussion notes in the Enquiry.	Notify Organizational Administrators of the update on the Enquiry.

## 11.4 Vivli Summary to Organization Administrators

- You will start receiving summaries from the Vivli team once you have the first data request that reaches the Data Contributor review stage or your first Enquiry in the Review stage.
- Vivli summary emails are typically sent out every other Monday afternoon from [support@vivli.org](mailto: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 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 Enquiries tab on the platform. Please see [Section 3.3 Recording Enquiry Decision](#) for more information.
- Responses from Organizational Administrators will be made 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 4.5.3 Status Update](#) for more information.

## 12. Support and Additional Information

### 12.1 Vivli Contact Information

Vivli Member User Support Contacts:

- General User Support: [Support@vivli.org](mailto:Support@vivli.org)
- You may also use the Chat to contact the Vivli Admin

### 12.2 Data Use Agreement

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

### 12.3 Browser and System Requirements

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

## 12.4 Standard Process for Vivli-Member Engagement

- Please review the Vivli summary
- Check Data Contributor Guide or reminders on how to do tasks before emailing [support@vivli.org](mailto: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](mailto:support@vivli.org)

## 13. Instructions for Using a Printed Copy of this Document

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

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

{HYPERLINK "https:..." etc. }

This will allow you to navigate to relevant URLs using a printed version of this document.

## 14. Document Information

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

1.7	Liz Graham	<ol style="list-style-type: none"> <li>Updated 3.2.1. Navigating to Data Requests</li> <li>Updated Section 3.2.2. Data Request Dashboard with “Awaiting My Action” dashboard updates.</li> <li>Updated Section 3.2.3. Reviewing Requests with Data Requests overlapping title user interface updated</li> <li>Removed Section 3.3.1. Sending the request to a Delegate</li> <li>Updated Section 4.1. Vivli Dashboard for Data Contributors with “Awaiting my Action” dashboard updates.</li> <li>Section 4.3.1. Steps, Make Data Package Available study list updates.</li> <li>Updated Section 4.3.2. Steps, Download files that the Data Contributor previously uploaded</li> </ol>	March 6, 2021
2.0	Amrutha Baskaran	<ol style="list-style-type: none"> <li>Updated screenshots throughout the manual to reflect the updated version of the platform</li> <li>Added section 1.3.4 Active Platform Accounts</li> <li>Updated Section 2.5 Study Enquiry Process</li> <li>Added section 2.6 Supporting documents made available for researchers searching for studies</li> <li>Updated Section 3.2.1 Navigating to Data Requests</li> <li>Updated Section 3.2.3 Reviewing Requests</li> <li>Updated Section 3.3.5 Withdrawal process</li> <li>Added Section 3.3.6 Target timeline for the review process</li> <li>Added Section 4.3 General upload guidelines</li> <li>Added Section 4.3.1 Zip archive process</li> <li>Updated Section 4.4.1 Steps: Uploading Data Package to an approved request</li> <li>Updated Section 6.2 Publication Notification by Data Requestor</li> <li>Added Section 9.3 Weekly summary to Organization Administrators</li> </ol>	October 9, 2021
2.2	Amrutha Baskaran	<ol style="list-style-type: none"> <li>Updated Section 3.2.3 Data Request form</li> <li>Updated Section 3.3.1 Cannot Fulfill</li> <li>Added Section 3.4 Report of data requests</li> <li>Added Section 3.4.1. Features of the report</li> <li>Added Section 3.4.2. Fields included in the report</li> <li>Added Section 3.4.3. Status Update</li> <li>Updated Section 4.4.5 Steps: Upload a New Version of the Data Package</li> <li>Added Section 7.DUA extension</li> <li>Updated Section 10.1.1 Steps, creating a chat message</li> <li>Updated Section 10.3 Weekly summary to Organization Administrators</li> <li>Added Section 11.4 Standard process for Vivli-Member Engagement</li> </ol>	August 29, 2022
3.0	Amrutha Baskaran	<ol style="list-style-type: none"> <li>Added Section 3.2.4 Vivli Policies in Brief</li> <li>Updated Section 3.3.1 Cannot Fulfill</li> <li>Updated Section 4.2 Data Upload Notification</li> <li>Updated Section 10.1.1 Open Chat</li> <li>Added Section 10.1.4 Setting up an inbox rule on Outlook to filter emails</li> </ol>	January 19, 2023
3.1	Amrutha Baskaran	<ol style="list-style-type: none"> <li>Added Section 3.3 Study settings at Data Contributor Review</li> <li>Added Section 3.3.7 Summary level and document-only data request</li> <li>Updated Section 3.4.3. Status Update</li> <li>Added Section 4.4.6 Steps: Uploading data to only one data request</li> </ol>	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"> <li>1. Updated Section 3.2.3 Data Request Form</li> <li>2. Updated Section 3.3 Study setting at Data Contributor Review</li> <li>3. Updated Section 3.4 Recording a Decision about a Data Request</li> <li>4. Updated Section 3.5 Report of data requests</li> <li>5. Updated Section 10.1 Chat</li> </ol>	September 26, 2023
3.3	Amrutha Baskaran, Catherine D'Arcy, Sarah Sweet, Elizabeth Graham	<ol style="list-style-type: none"> <li>1. Updated Section 2.6 Supporting documents made available for researchers searching for studies</li> <li>2. Updated Section 2.7 Study Usage and Public Disclosure Metrics</li> <li>3. Updated Section 3.4.4 Major versus minor revisions to data requests</li> <li>4. Updated Section 3.5 Report of data requests</li> <li>5. Updated Section 3.5.2. Fields included in the report</li> <li>6. Updated Section 4.4.1 Steps: Uploading Data Package to an approved request</li> <li>7. Updated Section 4.4.3 Steps: Uploading data while request undergoing review</li> <li>8. Updated Section 4.4.4 Studies list and stored data package</li> <li>9. Added Section 4.4.6 Uploading large files and data packages to the Vivli Platform</li> <li>10. Updated Section 10.1.1 Open Chat</li> <li>11. Updated Section 10.2 Emails for Organizational Administrators</li> </ol>	February 1, 2024
3.4	Amrutha Baskaran	<ol style="list-style-type: none"> <li>1. Updated Section 1.3.2 Adding Team Members</li> <li>2. Added Section 1.3.4 User Lists</li> <li>3. Removed Section 2.2 Submitting a Single Study</li> <li>4. Removed Section 2.5 Study Enquiry Process</li> <li>5. Added Section 2.7 Studies Dashboard</li> <li>6. Added Section 3 Study Enquiry Process</li> <li>7. Added Section 3.1 Navigation and Enquiry Dashboard</li> <li>8. Added Section 3.2 Enquiry format</li> <li>9. Added Section 3.3 Recording Enquiry Decision</li> <li>10. Added Section 3.4 Enquiries Report</li> <li>11. Updated Section 4.4.5 Withdrawal process</li> <li>12. Added Section 5.4.6 Upload additional data or documents to a study after initial upload</li> <li>13. Updated Section 8 DUA extension</li> </ol>	June 12, 2024
3.5	Amrutha Baskaran	<ol style="list-style-type: none"> <li>1. Updated Section 1.3.1 My Organization tab</li> <li>2. Updated Section 1.3.2 Team Members</li> <li>3. Added Section 2.5 Individual Studies Format</li> <li>4. Updated Section 3.1 Navigation and Enquiry Dashboard</li> <li>5. Updated Section 3.2 Enquiry Format</li> <li>6. Updated Section 3.3.1 Eligible for Request</li> </ol>	November 25, 2024

		<ol style="list-style-type: none"> <li>7. Added Section 3.3.4 Enquiry Study Status for Individual Studies</li> <li>8. Updated Section 4.2.3 Data Request Form</li> <li>9. Updated Section 4.3 Study Settings at Data Contributor Review</li> <li>10. Updated Section 4.4.6 Summary- level and Document-only Data Request</li> <li>11. Updated Section 4.5.2. Fields Included in the Report</li> <li>12. Updated Section 4.6 Data Use Agreement (DUA)</li> <li>13. Rearranged Section 5 Data package uploads</li> <li>14. Updated Section 5.4 Upload Loading Data Package to an Approved Data Request</li> <li>15. Added Section 5.5 Upload Data Package Directly into the Study</li> <li>16. Updated Section 5.6 Steps to Upload Data Package</li> <li>17. Updated Section 5.7 Stored Data Package and Subsequent Data Request</li> <li>18. Updated Section 5.8 Replace Data Package New Version</li> <li>19. Updated Section 5.10 Uploading Data to Only One Data Request</li> <li>20. Added Section 5.12 Supporting Documents for Researchers Searching For Studies</li> <li>21. Added Section 6.2 Downloadable Data</li> <li>22. Added Section 7.2 Publication Notification by Data Requestor</li> <li>23. Added Section 9 Research Environment Closure &amp; Request Archival</li> <li>24. Removed Section 10 Metrics</li> <li>25. Updated Section 11.1.1 Open Chat</li> <li>26. Updated Section 11.21.4 Setting up an Inbox Rule on Outlook to Filter Emails</li> </ol>	
3.6	Amrutha Baskaran	<ol style="list-style-type: none"> <li>1. Updated Section 1.3 Vivli Dashboard for Organizational Administrators</li> <li>2. Updated Section 1.3.2 Team Members</li> <li>3. Updated Section 1.3.3 Organizational Roles</li> <li>4. Updated Section 1.3.4 User Tab</li> <li>5. Updated Section 2.6 Study Usage and Public Disclosure Metrics</li> <li>6. Updated Section 3.1 Navigation and Enquiry Dashboard</li> <li>7. Updated Section 3.2 Enquiry Format</li> <li>8. Updated Section 3.3.1 Eligible for Request</li> </ol>	February 24, 2025

		9. Updated Section 3.3.2 Not Available for Request 10. Updated Section 3.3.3 Enquiry Feedback to Researcher via Discussion field 11. Updated Section 4.5.2 Fields Included in the Report 12. Updated Section 11.1.1 Open Chat 13. Updated Section 11.3 Automated Emails from Vivli Platform	
3.7	Amrutha Baskaran	1. Added Section 2.7 Study Search Results– Download 2. Updated Section 3.1 Navigation and Enquiry Dashboard 3. Updated Section 4.2.3 Data Request Form (notes about AI/ML responses and risk scores) 4. Updated Section 4.5.2. Fields Included in the Report 5. Updated Section 4.6 Data Use Agreement (DUA) 6. Updated Section 5.6 Steps to Upload Data Package 7. Updated Section 5.12.3 Loading Supporting Documents that are not part of Data Package 8. Updated Section 11.1.1 Open Chat	May 24, 2025

Approval History			
Name	Job Title	Date Approved	Effective Date
Version 1.0			July 11, 2018
Rebecca Li	Executive Director	July 11, 2018	
Version 1.1			October 25, 2018
Rebecca Li	Executive Director	October 25, 2018	
Version 1.2			March 20, 2019
Rebecca Li	Executive Director	March 20, 2019	
Version 1.3			December 14, 2019
Rebecca Li	Executive Director	December 13, 2019	
Version 1.4			n/a
Rebecca Li	Skipped to align with the platform version	n/a	
Version 1.5			March 13, 2020
Rebecca Li	Executive Director	March 13, 2020	
Version 1.6			July 10, 2020
Rebecca Li	Executive Director	July 10, 2020	
Version 1.7			March 6, 2021
Rebecca Li	Executive Director	March 6, 2021	



Version 2.0			October 9, 2021
Rebecca Li	Executive Director	October 8, 2021	
Version 2.2			August 27, 2022
Rebecca Li	Executive Director	August 19, 2022	
Version 3.0			January 19, 2023
Rebecca Li	Executive Director	January 18, 2023	
Version 3.1			May 27, 2023
Rebecca Li	Executive Director	May 26, 2023	
Version 3.2			September 30, 2023
Rebecca Li	Executive Director	September 26, 2023	
Version 3.3			February 10, 2024
Rebecca Li	CEO	February 1, 2024	
Version 3.4			June 15, 2024
Rebecca Li	CEO	June 12, 2024	
Version 3.5			November 25, 2024
Rebecca Li	CEO	November 22, 2025	
Version 3.6			February 22, 2025
Rebecca Li	CEO	February 22, 2025	
Version 3.7			May 24, 2025
Rebecca Li	CEO	May 24, 2025	