7.0 Communications .................................................................................................................. 33
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1.0 Requesting Studies on Vivli – Overview

- The process starts with finding studies you need – for assistance with the search, help is available on the Vivli site: click here.
- Once you have completed your search, you may request the data packages for the studies you would like to use for your analysis.
- To do this, you must first complete a Data Request Form.
- Your data request will be submitted to all relevant Data Contributors for review, according to the Data Contributor’s data sharing policies and criteria.
  - To learn more about individual Vivli Members’ data sharing policies, please see the Vivli Members Page.
  - For an overview of the data request review process, please see the Vivli Platform Process at a Glance.

1.1 Login/Account Setup

- You must be logged in as a Vivli user to begin your data request.
- If you do not have a Vivli account, you will need to set one up before beginning a data request. To learn more about creating a Vivli account, please review our Vivli How to Sign Up Guide.

If you are not logged in, you will be prompted to do so:

![Search Results Window](image)

*Figure 1 - Search Results Window*

After you log in, you will return to the search results window.
1.2 Add studies to your data request

1. To add studies from a search to a Data Request Form, click on **Request Study**.

![Request Study Dropdown](image)

**Figure 2 - Request Study Dropdown**

2. A dropdown will appear - click on **+Add New Request**:  

![+Add New Request](image)

**Figure 3 - +Add New Request**

3. A dialogue box will pop up where you can name your data request / research project (this can be edited before submitting the data request). After entering a research project name, click **Ok** to create the data request.

![New Request Dialogue pop-up](image)

**Figure 4 - New Request Dialogue pop-up**
4. A pop-up will briefly appear at the bottom of the screen, indicating that you have successfully added the study to the new data request:

![Successful Request pop-up](image)

**Figure 5 - Successful Request pop-up**

5. You will also get a notification that you may review **My Data Requests** to see the new request:

![New Request pop-ups (full screen)](image)

**Figure 6 - New Request pop-ups (full screen)**

6. To add an additional study to an existing data request, click on **Request Study**. Then click on the existing data request’s title from the dropdown:

![Add to Existing Request (dropdown)](image)

**Figure 7 – Add to Existing Request (dropdown)**
8. You will receive the same pop-up notification indicating that the study was added to your existing data request:

![Figure 8 – Successful Request pop-up (2)](image)

9. Once you have added all desired studies listed on the Vivli platform, you can complete the Data Request Form (See 2.0 Your Data Requests for more information).

### 2.0 Your Data Requests

To find your data requests, click on My Data Requests along the top right corner of the screen:

![Figure 9 - My Data Requests (Circled)](image)

This will take you to your data requests page, where you can navigate to complete the Data Request Form and check the status of any previously submitted data requests.
Click on Draft to see any incomplete or new data requests:

2.1 Editing a data request

You may also edit the name of your data request as it will appear on the Data Request Form and Vivli Dashboard. The name of your data request should be the same as it appears on the Data Request Form.

1. Click on Edit Request Title:
2. The following dialogue box will pop up. Add a new title and then click **Ok**:

![Figure 12 - Edit Request Title Dialogue Box pop-up](image)

2.2 Completing a data request

To complete a data request, you must add all **required information** to the **Data Request Form**. Please note that the data request must include:

- The name, contact information, qualifications, degrees and where the degrees were obtained of the Lead Investigator and Statistician
- Conflict of Interest Statement
- The title of the proposed research with a description of the study design
- Main outcomes of interest, specific aims and objectives and hypothesis to be evaluated
- Narrative summary explaining the relevant of the project to science and public health
- Project timeline, dissemination and publication plan.
- Statistical Analysis Plan
- Information about funding
- Attestation
- All other required fields, including all data sets associated with the proposal
  - This includes studies you may request from Vivli; studies requested from other Data Sharing Platforms or Portals; and any additional data, tools, and scripts that you want to bring into the Vivli platform. If you will not be bringing studies into the Vivli platform but they are part of your overall research analysis plan. Please add this list of studies as an attachment.

For more information on requesting studies not listed on Vivli, please see Section 4.0, Requesting Data from Studies not Listed on Vivli, but available for Provisioning into your Secured Research Environment.
2.2.1 Adding Files or Other Information to your data request

You may also attach files to your data request using the Other Information / File Attachments tab:

![Figure 13 - Other Information / File Attachments tab](image)

1. **Click on Select Files** to choose a file:

![Figure 14 - Select File](image)
Then simply select the file from your computer:

Figure 15 - Select file pop-up

2. You may also drag and drop files into the **Drop Files Here** box:

Figure 16 - Drop files here
3. After you select your file, the following upload progress bar will appear:

Figure 17 - File upload in progress

4. You can select the file type from the dropdown menu after upload is complete:

Figure 18 - File type
5. To delete the file, simply click on **Delete:**

![Figure 19 - Delete file](image)

6. To enter any other information, simply type into the dialogue box:

![Figure 20 - Other information dialogue box](image)
2.3 Saving your data request

You do not have to complete the Data Request Form in a single session; you can save the Data Request Form as many times as needed prior to submission.

To save a Data Request Form, click on **Save** in the top right corner of the screen:

*Figure 21 - Data Request Save*

2.4 Inviting research team members to view/edit data request

You may invite members of the research team to edit the Data Request Form by clicking **Invite user to access data request**:

*Figure 22 - Invite User to access data request*
2.5 Adding Research Team Members

1. Scroll down to add additional team members - click on Add+ in the lower right corner, opposite ADDITIONAL RESEARCHERS:

![Figure 23- Add additional researchers](image)

2. The following dialogue box will appear:

![Figure 24 - Additional Researchers Dialogue pop-up](image)

3. Complete all fields, and click Save

2.6 Deleting research team members

Follow these steps to remove a team member from your data request form while it is still in draft:

1. Open your draft request
2. Click on the Research Team tab:

![Research Team tab](image)

Figure 25 - Research Team tab

3. Under ADDITIONAL RESEARCHERS, click on the three vertical dots in the lower right-hand corner:

![Additional Researchers](image)

Figure 26 - Additional Researchers
4. The following pop-up will appear:

![Remove Team Member confirmation](image)

**Figure 27 - Remove Team Member confirmation**

5. Click on **Ok** to remove the team member.

### 2.7 About your research team

- Individuals added to a data request will be able to view and edit the Data Request Form
- Individuals added to a request will also have access to the Secured Research Environment
- These permissions can also be changed before starting the research environment and while the research environment is running.
- When you click on **Save** on the top, the system will send an email to the designated person to create a Vivli account; this is necessary to enable this person to modify the data request and to access the research environment.

### 2.8 Submitting your data request

- Once the Data Request Form is complete, you may submit it for review.
- Do not submit a form before it is complete, as you will be unable to make changes once it has been submitted.

1. Before submitting a Data Request Form, the Lead Researcher must attest that all the information provided is accurate and complete:

![Attestation check box](image)

**Figure 28 - Attestation check box**
2. To submit a Data Request Form, simply click the blue box marked **Submit** in the top right corner of the screen:

![Submit Request](image)

*Figure 29 - Submit Request*

If the Submit button is still light blue and does not respond to a click, you have a required field that is not completed – look in each of the tabs on the left for a field outlined in red.

3. The data request will now appear under **In Progress** in your Data Request Toolbar:

![Data Requests in progress](image)

*Figure 30 - Data Requests in progress*

### 3.0 Requesting Vivli-listed studies provisioned by external providers

#### 3.1 Overview

- Some studies are listed and searchable on both the Vivli platform as well as on other platforms that are Partner Platforms with Vivli.
- In addition to completing the Vivli request form, you will need to request such studies directly through the Partner Platform.
- After the relevant Data Contributor(s) have approved your request, you will sign a Data Use Agreement (DUA). The Data Contributor will then provision the data from their platform into the secure research environment.
3.2 Requesting studies provisioned by external providers

1. When attempting to add a study in this category to a Data Request Form, the following pop-up will appear:

![Add Study / Partner Platform pop-up](image)

*Figure 31 – Add Study / Partner Platform pop-up*

2. Click on **OK** to add the study to the Data Request Form:

![Add Study / Partner Platform pop-up – OK](image)

*Figure 32 - Add Study / Partner Platform pop-up – OK*

4. The following pop-up will appear:

![Partner Platform Notification pop-up](image)

*Figure 33 - Partner Platform Notification pop-up*

5. Follow the link to view and request the study on the Partner Platform:

![Partner Platform external link](image)

*Figure 34 – Partner Platform external link*

**Note: this link will open up the Partner Platform Website in another browser tab.**

6. Complete and submit the request on the Partner Platform, as well as the Vivli Data Request Form.
7. When you review the studies tab on your Data Request Form, the study will be categorized as **Vivli-Listed Studies Provisioned by External Providers**:

![Figure 35 – Vivli-Listed Studies Provisioned by External Providers](image)

Note: you must still complete the Research Team tab of the Vivli Data Request Form:

![Figure 36 - Research Team tab, Data Request Form](image)

8. After all the Data Contributors associated with the request have approved it and you have signed a Data Use Agreement, all the data package(s) will be provisioned directly into the secure research environment.

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4.0 Requesting data from studies not listed on Vivli, but available for provisioning into the Secure Research Environment

- You may also add Vivli Member studies to their data request, even if they are not listed on the Vivli platform as some Vivli members do not list all available studies.
- Such studies will be designated on your Vivli Data Request Form as **STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI**.

4.1 Process Overview

To request data from studies not listed on Vivli, complete the following steps:

1. Request the data on the Vivli Partner platform.
2. Complete the Vivli Data Request Form for all studies to be analyzed on Vivli.
3. Add the identifying information for the external study to your Vivli Data Request Form.
4. After all Data Contributors have approved your request, all the data packages will be provisioned into your secure research environment.
4.2 Steps for requesting data from studies provisioned on Vivli but not listed on Vivli

1. To add the study to a Vivli Data Request Form, first open data requests by clicking on My Data Requests in the top right-hand corner of the browser:

![Figure 38 - My Data Requests](image)

2. Next, open the data request to add the external study. Then, scroll down and click on Add+ adjacent to STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI, in the bottom right corner of the screen:

![Figure 39 - Add Studies Provided on Vivli Partner Platforms](image)
3. The following dialogue box will appear as a pop-up:

![Partner Platform dialogue pop-up](image)

**Figure 40 - Partner Platform dialogue pop-up**

4. Complete all fields, including selection of the Provider of the data from a dropdown menu and then click **submit**:

![Partner Platform dialogue pop-up (completed)](image)

**Figure 41 - Partner Platform dialogue pop-up (completed)**

**Note:** only add one study in the dialogue box; if you wish to add additional studies from this or another Partner Platform, please complete this process and repeat it for the additional studies.
5. The following notification will appear:

![Figure 42 - Vivli Partner Platform notification](image)

6. You may add additional studies to your Data Request by clicking on **Add Another Study**:

![Figure 43 - Add another study](image)

7. After all the Data Contributors associated with the request have approved it and you have signed a Data Use Agreement, all the data package(s) will be provisioned directly into the Secured Research Environment.
5.0 Requesting to add other data or tools / scripts (provided by you) for integration and use on Vivli

5.1 Adding your own data

- You may also request permission to bring in your own data packages to the Secured Research Environment.
- To do so, you will follow these steps to add the studies or data to a Vivli Data Request Form:

1. Open your data requests by clicking on **My Data Requests** in the top right-hand corner of the browser:

   ![Figure 44 - My Data Requests](image)

   *Figure 44 - My Data Requests*
2. Next, open the Data Request to add the external study. Then, scroll down and click on Add+ adjacent to STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI, in the bottom right corner of your screen:

![Add Studies Provided on Vivli Partner Platforms](image)

*Figure 45 - Add Studies Provided on Vivli Partner Platforms*

3. The following dialogue box will appear as a pop-up:

![Partner Platform dialogue pop-up](image)

*Figure 46- Partner Platform dialogue pop-up*
4. From the Dropdown menu under **Select provider of the data**, click on **I will upload data myself**.

![Partner Platform dialogue pop-up – I will upload data myself.](image)

**Figure 47 - Partner Platform dialogue pop-up – I will upload data myself.**

5. Complete all fields and click **submit**:

![Completed dialogue box / own data](image)

**Figure 48 - Completed dialogue box / own data**

- Provide a description of the data package you plan to bring in and indicate whether you have permission to use this data package.
• If you need to provide any additional information about your own data package, you may do so under the Additional Information tab of your Data Request Form.

6. You will receive the following notification:

![Figure 49 - External study / data notification](image)

7. The study / data will be referenced on the Data Request Form:

![Figure 50 - Data Request Form / my data](image)
5.2 Adding scripts and tools for use in the Secure Research Environment

The Vivli secure research environment is a cloud-based remote workspace. The Vivli secure research environment allows research teams to access data and conduct analyses in a shared workspace that is equipped with analytical tools and may be flexibly configured. To download a complete list of Software and R packages available in the research environment, please click here.

If you would like to add your own tools or scripts, you must list them on your Data Request Form.

5.2.1 Adding Scripts or Tools to your Data Request Form

- If you would like to add your own tools or scripts to the secure research environment, you must list them on your Data Request Form.
- To do this, follow the process in 5.1 Adding your own data.
- Under Step 5, type a list of your tools or scripts in the dialogue box under Provide either the study title or the description of the study, and click submit:

![Figure 51 - dialogue box for own data / scripts](image)

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The tools and / or scripts will then be listed on your data request form.

After your Data Request is approved, the Vivli Admin will facilitate the upload process for your own data and scripts into your research environment.

6.0 Modifying or revising your data request

6.1 Overview

• If necessary, you may modify your data requests.
• You can make as many changes as needed before submitting your data request.
• If the research team associated with a data request changes, you must update the request or you can reach out to the Vivli team while your data request is being reviewed and they can make this change on your behalf.

PLEASE NOTE: If the identity of the Lead Investigator or Statistician changes after submission of a request, this is a major change to the data request. Major changes require that your data request be reviewed again by all relevant Data Contributors, even if they have already reviewed and approved the request.

• Other major changes include changes to the Statistical Analysis Plan, Plain Language Summary, or any other substantive changes to the research question, including adding or removing data sets from the research plan.
• Whether a change is major is at the discretion of Vivli, as well as the relevant Data Contributor or Independent Review Panel.

6.2 Modification after submission

To modify your data request after you have submitted it, please contact Vivli via chat on the platform.

6.3 Requested revisions to your data request

• At times, the Data Contributor, IRP, or Vivli may request that you make changes to your data request.
• If this is the case, you will be notified on the Vivli Dashboard as well as via email.
• The specific changes requested will be placed in the Chat window.
• If you fail to make requested changes, the data request may not be fulfilled.
6.3.1 Steps for revising request

1. If any party requests revisions to the Data Request Form, the Vivli Admin will return your data request to **Draft** in the data request bar:

![Request returned to draft](image)

**Figure 52 – Request returned to draft**

2. Open the data request and click on the **Request History** tab

![Request History](image)

**Figure 53 - Request History**

You can review the request history and see any comments related to your data request.

You may also review the chat associated with your request for any additional comments or use the chat to ask for any clarifications about the revision request.
3. From there, you may revise and resubmit the Data Request Form:

![Data Request Form Draft Overview](image)

*Figure 54 - Data Request Form Draft Overview*

4. Use the **Other Information / File Attachments** tab to add any additional comments about the revision, including the specific response to the nature of the requested revisions:

![Data Request Form, Other Information tab](image)

*Figure 55 - Data Request Form, Other Information tab*

For more information on attaching files, see [Section 2.2.1, 2.2.1 Adding Files or Other Information to your data request](#)
6.4 Deleting Data Requests

Please note, if you delete your data request, the Vivli Administrators will not be able to retrieve it for you.

7.0 Communications

7.1 Chat

- You can use the chat within the data request to communicate with your team, the Vivli Administrators, and the data contributors or review entities associated with your data request.
- Please note that messages in 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.

7.2 Steps, creating a chat message

1. Log on to the platform.

2. Go to data request tab:

![Figure 46- Data Request Status Bar](image-url)
3. Open data request and click on **Chat tab** on the left-hand side of the screen:

![Figure 47 - chat tab](image)

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

![Figure 48 - chat window](image)
5. The message will now appear in the Chat record for all users (to see your just-entered chat message, you may need to click Refresh on your browser), and response will also appear in the chat record:

![Figure 49 - submitted chat](image)

6. You can also upload files via chat by clicking on **Select Files**:

![Figure 50 - upload files, chat](image)
7. Select the file you wish to upload from your computer:

![Select files for upload](image1)

*Figure 51 - select files for upload, chat*

8. The upload bar will show the progress:

![Upload status](image2)

*Figure 52 - upload status, chat*
9. The uploaded file will appear in the file list on the right, and in the chat history:

![Figure 53 - uploaded file, chat](image)

10. To delete the file, simply click on **Delete:**

![Figure 56 - delete file, chat](image)
11. The deletion of the file will appear in the chat history:

![Figure 55 - deleted file, chat history](image)

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

![Figure 56 - download file, chat](image)

### 8.0 Data Use Agreement

All Data Requestors must execute the Data Use Agreement before receiving the data. The Data Use Agreement is the product of extensive negotiation with the organizations that contribute data to Vivli, and as such, the agreement is non-negotiable. If you have any questions about the Data Use Agreement, contact support@vivli.org.

1. Access the Data Use Agreement form here: [Vivli Data Use Agreement](#)
2. Vivli will send you the Data Use Agreement via DocuSign for your signature and if needed, that of an institutional official at your organization.
3. Once your data request is approved, Vivli will execute this document and load it into the platform.
4. :
After your Data Use Agreement has been reviewed and verified, you will receive an email notification. You will also be able to see this on your **Request History**:

![Validated Data Use Agreement, Request History](image)

*Figure 62 - Validated Data Use Agreement, Request History*
9.0 Data Package Upload

1. The Data Contributors will anonymize the data and upload the data into the platform. You will be notified when the data packages have been uploaded. You can then download the data, if possible, or you can start the research environment. Further guidance will be provided when you reach this stage.

10.0 Emails

You will receive a number of automated emails from the Vivli platform, relating to your data request.

<table>
<thead>
<tr>
<th>Email</th>
<th>When sent</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status Change, data request</td>
<td>When your data request for changes status</td>
<td>Notify you of any changes in status to your data requests;</td>
</tr>
<tr>
<td>Request Approved</td>
<td>When your data request for your studies is approved, by you or a delegated approver. If you have requested studies from multiple contributors, you will receive a notification when each has approved your request or requested revisions or denied your request.</td>
<td>Notify of you of approval</td>
</tr>
<tr>
<td>DUA Approved</td>
<td>When the Vivli Admin has validated the DUA associated with the data request.</td>
<td>Notify you as well as data contributors of approved DUA.</td>
</tr>
<tr>
<td>Chat</td>
<td>When anyone associated with a data request enters a message in chat</td>
<td>Facilitate communication and the data request work flow</td>
</tr>
</tbody>
</table>

If you have any questions about these emails, you can contact user support via the platform chat function (see Section 7.1 Chat) or via email to support@vivli.org.