

How to Access Data for Analysis and Publication Process

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1.0 Data Access Introduction

Your team's data request has been approved and your Data Use Agreement has been executed. Now that one of the studies from your request has been uploaded, your research team is able to begin analyzing the data. Depending on the access options available on your requested study(ies), you can either download the data (See section 12.0 for more information) or you can access the data via a secure, cloud-based, isolated workspace known as a research environment.

- The Research Environment is a where users have access to various tools to analyze their data and conduct their research, including <u>R</u>, <u>Python</u>, <u>Jupityr</u>, the Microsoft Office suite, STATA, and <u>SAS (Academic-license only)</u> depending on the type of the Research Environment selected. A <u>complete list of the software</u> included and versions in the Research Environment can be found on the Vivli website resources page.
- The Vivli Research Environment can also accept your own preferred analytical tools if you can provide the license key for the tool, or if it is an open-source tool. Publicly available R packages or Python scripts can be added by the Vivli team.

2.0 Before you start the secure research environment

- To access the research environment, your computer must have a tool called Remote Desktop. This tool opens a connection to the research environment and allows you to interact with the research environment as though it were your local machine.
- On Windows: Remote Desktop tool is already installed on the machine no setup is required.
- On Macintosh: users will need to go to the Apple Store. Download and install the Microsoft Remote Desktop.

Search Results for "microsoft remote desktop"



Figure 1 – Microsoft Remote Desktop

• Some networks may have enhanced security controls that prevent users from accessing the research environment. For help, contact support@vivli.org.

3.0 Getting Started

- Once one of your requested studies data packages has been uploaded, you will be notified via email that your data is available.
- At this point, you may initiate the Secure Research Environment. Please note that only the "Owner" of the data request can start the Research Environment.

3.1 Locating the Data Request and seeing how many studies are available for analysis

1. Click on **My Data Requests** in the top right corner of the screen:



2. The request will appear under Active:

Vivli	Home About Members News & Events Resources Find Studies
CENTER FOR GLOBAL CLINICAL RESEARCH DATA	QUICK STUDY LOOKUP 🗸 🤐 MY DATA REQUESTS 💽 DATA REQUESTER 🗸
My Data Requests (166)	2549
Draft Active Not Approved Withdrawn Archived	
ASCENDING MULTIPLE-DOSE SAFETY, TOLERANCE, PHARMACOKINETIC, AND F	
Vivii ID: 00002549	
Status: At least one Data Package Provided and Available	

Figure 3 - Fulfilled Requests

3. If the request has been approved, the Data Use Agreement validated and the requested data from at least one requested study is available, the request will appear under "Active", with a status of "At least one Data Package Provided and Available"



Figure 4 – At least one Data Package Provided

To determine **which** studies have been loaded, open the request and click on the Studies tab:

• U ivl ⁴	Home About Members New	s & Events Resources Find Studies
CENTER FOR GLOBAL CLINICAL RESEARCH DA	ATT. QUICK STUDY LOOKUP ~ 🔮	MY DATA REQUESTS 🚺 DATA REQUESTER 🗸
< Go Back Ascending	g Multiple-dose Safety, Tolerance, Pharmacokinetic, and Pharn	nacodyna Print
Studies		
Attachments	VIVLI-LISTED AND PROVISIONED STUDIES	
Request History	Ascending Multiple-dose Safety, Tolerance, Pharmacokinetic, and Pharmacodynam PI: Sponsor: BMS Study ID: AEGR-CV145-002 IRP/Approver: Novelion Therapeutics Awa Data Explosed ID: e0002549 Sponsor ID: AEGR-CV145-002 Data Contributor: Novelion Therapeutics IPO Updated: No	aiting Data Package upload by Data Contributor
Signed Agreements		
Safety Concerns	A Patient Preference Evaluation Study of Fluticasone Furcate Nasal Spray and PI: Sponsor: GlaxoSmithKline Study ID: NCT02397915 IRP/Approver: Wellcome Trust Data Request ID: 00002549 Sponsor ID: 201474 Data Contributor: GlaxoSmithKline IPD Uploaded: No	aiting Data Package upload by Data Contributor
Chat	An Onen Label Study of the Efficiency and Cafety of De tractmente With Dituyime	
Research Team	An Open Ladel Study of the Ladel Study of an Usaley of here dealine its what initialities. Plasponsers Informatical Rectine Study ID KCT02097745 IRP/Approver: Welcome Trust Data Contributor: Roche IPD Uploaded: No	Data Package Provided to Requestor
Research Environment	An Open Label, Non-comparative Study To Evaluate Parasitological Clearance Ra	
Request Details/Print View	Pit: Sponsor: Pitzer Study ID: NCT01103713 IRPI/Approver: Pitzer Inc. Data Request ID: 00002549 Awa Sponsor ID: A0661201 Data Contributor: Pitzer Inc. IPD Uploaded: No	aiting Data Package upload by Data Contributor
	VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS	
How To Guide Privacy Co	ookie Policy EEA Disclosure Policy Contact Us	© Copyright 2017 - 2021 Vi
5 0 1 0 1		

Figure 5 – Data Package Provided to Requestor

If you start the research environment before all of the data is available, then as additional data is made available, it will not automatically appear in the research environment– you will have to request that the new data be added to your research environment at a time that is convenient for you– see section "6.2 How to add additional data to your research environment as it becomes available"

3.2 Starting the Secure Research Environment

Once you have opened your request, click on the **Research Environment** tab on the left-hand side of your screen to begin initiating the environment. Please read and acknowledge the Vivli Terms of Use for the Research Environment. Click on **Sign Now**:

Uivli	Home About Members News & Events Resource	es Find Studies
CENTER FOR GLOBAL CLINICAL RESEARCH DATA	QUICK STUDY LOOKUP 🗸 👹 MY DATA REQUESTS	DATA REQUESTER 🗸
< Go Back Ascending	Multiple-dose Safety, Tolerance, Pharmacokinetic, and Pharmacodyna	Print
Studies Attachments		
Signed Agreements Safety Concerns	Data Package available for 1 of 4 studies in the Data Request	
Chat Research Team	YOU MUST E-SIGN THE VIVLI TERMS OF USE AGREEMENT TO CONTINUE	
Research Environment	Sign Now	
How To Guide Privacy Coo	kie Policy EEA Disclosure Policy Contact Us	© Copyright 2017 - 2021 Vivli

Figure 7 – Start Signing Process

4. The following pop-up window will appear:

Vivli	Home About Members	News & Events Resour	ces Find Studies
CENTER FOR GLOBAL CLINICAL RESEARCH DATA		MY DATA REQUESTS	DATA REQUESTER ~
Ascentra Multiple	Sign Document	reaction.	
-	VIVLI TERMS OF USE		
	Viol, Inc., ("Viol") an independent on sprofit entity, operates the Violi Weekele and Platform (the "Platform") for the purpose of allowing statest new application of search and request terminar disk. This takes in provided for such use by third-party contributors ("Data Contributors"). This data (the "Data") is available to a user ("you" or "your" upon request and approval to scientific, educational and research purposes only to the extent and on the terms set forth in the Data Use Agreement between you and Vivil (the "Data Use Agreement"). Access to data is further subject to approval by the individual Data Contributors, Isaed upon the state of the terms and proval to approve the the individual Data Contributors, Isaed upon the state of the state of the terms and the terms and the terms and the state of the terms and terms and terms and the terms and terms and the terms and terms and terms and terms and terms and terms and the terms and term		
	In a secure research environment or downloadable - the format is determined by the Data Contributor. The terms set forth below (Mer "Timms of Use"), beginter with any related documents and approvals expressly incorporated into these terms by reference, including any Data Request, any Data Use Agreement and any additional terms that may apply from the Data Contributor (collectively, with the Terms of Use, the "Agreements"), constitute a binding logal agreement between you and Wint.		
-	By accessing and using the Platform you agree to be bound by the Terms of Use. Acknowledgement of Proprietary Rights All information provided to you, including but to the limited to, the data, content, documentation, code, and related materials on the VWI is under the care, custody and control of VWI, which is the owner or licensee thereord, and constitutes confidential and proprietary information.	1	
And a second sec	Terms of Use You agree, on behalf of self and the institution or organization you represent,		
	To agree and sign, enter 1 Agree' in the textbox below and click 'Sign'. Type 'I Agree' Sign Cancel	J	
How To Guide Privacy Cookie Policy EEA D	isclosure Policy Contact Us		© Copyright 2017 - 2021 Vivli

Figure 8 - Terms of Use Pop-Up

5. Type I Agree in the dialogue box and click Sign.

Each Team member accessing the Research Environment must Sign the Terms of Use when they first access the Research Environment.

Uivli	Home About Members	News & Events Resou	rces Find Studies
CENTER FOR GLOBAL CLINICAL RESEARCH DATA		MY DATA REQUESTS	🔵 DATA REQUESTER 🗸
Apograding Mydlighe	Sign Document	ernacistyra.	
	VIVLI TERMS OF USE Version 12 January 29,2019 Vivi, Inc., (Y/Viri?) an independent non-profit entity, operates the Vivi Website and Platform (the "Platform") for the purpose of allowing users the ability to search and request certain data that has been provided for		
	such use by third-party contributors ("Data Contributors"). This data (the "Data") is available to a user ('you' or 'you'' your request and approval to centrific, educational and research purposes only to the extent and on the terms set forth in the Data Use Agreement between you and Wivi (the "Data Use and the state of the Data Use Agreement between you and Wivi (the "Data Use the count data sharing policies, as set forth on each Wivi mether's pape. The data may be accessed either in a secure research environment or downloadable - the format is determined by the Data Contributor. The terms set for the blow (the "Terms of Use"), together with any related documents and approvals expressly incorporated into these terms by reference, including any Data Request, any Data Use Agreement and any additional terms that may apply from the Data Contributor (Date) with the "Terms of Use, the		
	By accessing and using the Platform you agree to be bound by the Terms of Use. A successing and using the Platform you agree to be bound by the Terms of Use. A linformation provided to you, including but not limited to, the data, content, documentation, code, and related materials on the Vivil is under the care, custody and control of Vivil, which is the owner or licensee thereod, and constitutes continential and proprietary Information.	-	
	$Terms \ of \ Use$ You agree, on behalf of self and the institution or organization you represent,		
	To agree and sign, enter 'I Agree' in the textbox below and click 'Sign'.		
	Type 'I Agree' Sign Cancel		
How To Guide Privacy Cookie Policy EEA D	isclosure Policy Contact Us		© Copyright 2017 - 2021 Vivli

Figure 9 - Terms of Use Read, Acknowledge and Sign

3.3 Secure Research Environment Options

		8-1	
Studies	Data	a Package available for 1 of 1 studies in the Da	ta Request
	Once the	machine is started, the request cannot be com	CALL OF TOWSION
Attachments	Before starting the R	lesearch Environment, read th	e short introduction here.
Request History	RESEARCH ENVIRONMENT DETAILS		
Signed Agreements	Advanced Options:	Standard Environment	Premium Environment
	Initial Cost	No charge for 365 days	No charge for 90 days
Safety Concerns			
Chat	After Initial Period	\$12/Day after 365 days, 2 concurrent logins	\$25/Day after 90 days, 2 concurrent logins
Chat	Machine Size	2CPUx7GB	4CPUx14GB
Research Team			
	Jupyter Notebook	*	*
Research Environment	Python, R	*	*
Request Details/Print View			
	STATA		
	Academic license for SAS		
			3
		Start Standard Environment	Start Premium Environment

1. After you agree to the Terms of Use, the following options window will appear:

2.. Most research teams find that the standard environment meets their needs. If you need a larger environment, the Premium will normally suffice.

2b. If you need a dramatically larger environment, choose Advanced Options for additional environment size types. Please note that if you choose a larger size, you cannot move to a smaller size, but you can start with a smaller size and upgrade to a larger size research environment. In addition, the no charge period will change based upon the larger machine size that is used and will take into account the no charge time already provided. For example, if you move from a standard to a premium, after 90 days, you will not be entitled to a further 90 days of no charge.



4. Select the research environment appropriate for your needs and check the boxes as desired for the software you require and click the button "Start Environment".

As you consider which environment to choose, if you don't want to use SAS, but if the data is provided as SAS data, the system includes three R-studio packages that can help:

- Foreign
- Haven
- SAS7bdat

When you click the "Start..." button, your selection is final, and the provisioning will begin. For more information, contact <u>support@vivli.org</u>.

3.4 Initiating the Secure Research Environment

1. After selecting the size of the environment, the data will be provisioned into the Secure Research Environment. While provisioning is taking place, the following screen will appear:

	Home About Members News & Events Resources Find Studies
CENTER FOR GLOBAL CLINICAL RESEARCH DATA	QUICK STUDY LOOKUP 🗸 📑 MY DATA REQUESTS 💽 VIVLI INFO 🗸
< Go Back Efficacy of	erythromycin in prevention of anthrax.
Studies	Data Package available for 1 of 3 studies in the Data Request
Attachments	For more information on starting and using the Research Environment click here to view it in another tab or download.
Request History	Your Research Environment is Provisioning
Signed Agreements	
Safety Concerns	
Chat	
Research Team	
Research Environment	0
Request Details/Print View	This is a long-running operation and may take a while
	If you think something has gone wrong, you can always Retry Provisioning
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Figure 11 - Provisioning notification

2. While the system is provisioning, you can exit this screen and allow the provisioning to proceed in the background. You will receive an email when the process is complete. This process typically takes 10 minutes.

4.0 Access to the Environment

- 4.1 Accessing the Secure Research Environment
- 1. Once the provisioning is complete, you will see the screen below:

🖶 Vivli		Home	About	Members	News & Events	Resource	es Find Studies
CENTER FOR GLOBAL CLINICAL RESEARCH DATA			QUICK	STUDY LOOKUP	🗸 进 MY DATA REQU	JESTS (👂 DATA REQUESTER 🗸
< Go Back Assessing the in	mpact of lifestyle choices on heart health						Print
Studies							
Attachments	Data Package available for 1 of 1 studies in the Data Request						
Request History	Before requesting results, read the short introduction here.						
Signed Agreements							
Safety Concerns	✓ Research Environment Running						
Research Results	Username: vivliuser9193						
Chat	1. Copy Password to Clipboard 2. Connect to Environment						
Research Team	Copy your Password, Connect to Environment, and paste password (CTRL-V) when prompted - Then click "Connect" or "OK" to continue.						
Research Environment	Add Pute Backness						
Request Details/Print View	Stopping your environment simply shuts it down, but deprovisioning	ant .					
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Figure 12 - Initiate Research Environment

2. Right click on the box "Copy Password to Clipboard" to copy the hidden password:

1. Copy Password to Clipboard

3. Then click on the box "Connect to Environment"



4. After clicking on "Connect to environment," confirm the program you want to use (note that the exact screen you see depends on the browser you are using):



Figure 13 - Remote Desktop Connection Notification (Windows)

5. Follow the prompt to enter the hidden password using the Paste tool, Control-V or Command V:

	Home About Members News & Events Resources Find Studies
CENTER FOR GLOBAL CLINICAL RESEARCH DATA	QUICK STUDY LOOKUP 🗸 🥶 WY DATA REQUESTS 🚺 DATA REQUESTS
Go Back Hepatitis Project	Print
Studies Attachments Request History Signed Agreements Safety Concerns Chut	Windows Security × Enter your credentials These credentials will be used to connect to 40.113.219.91. viviluser3216 password Remember me More choices OK Cancel
Request Details/Print View	Stop Environment Deprovision Environment Stopping your environment simply shuts it down, but deprovisioning your environment will permanently delete it.
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Figure 14 - Paste hidden password pop-up

The username and password will not match your Vivli username and password.

6. Depending on your computer's security settings, a warning may appear. Click **connect** to continue opening the Secure Research Environment:



Figure 1 - Security warning pop-up



7. The secure research environment home screen opens automatically:

Figure 16 - Secure Research Environment Home Screen

- Note that the first time you connect to the Research Environment, the system will be slower than normal as the system does some first-time configuration.
- You **must** have Microsoft Remote Desktop installed on your device or the Secure Research Environment will not open. (See section 2.0 <u>Before You Start</u>.)
- The Microsoft Remote desktop locks down the Secure Research Environment to keep the data secure. You may not bring any files directly into or out of the Secure Research Environment once it starts. You are unable to connect to the internet. And you are unable to copy and paste between the research environment and your local computer.
- Do not save the password and the Remote Desktop file and re-use them. Follow the steps above in <u>Accessing the Secure Research Environment</u> section 4.1 and copy the password each time and click "Connect to Environment".

4.2 Working in the Research Environment

- 4.2.1 Finding your data and using space
 - 1. Open Disk V: and you find a folder entitled "Source Data"



Figure 24 - Open source data

2. In the Network Drive (drive V:) you will find one folder for each study that has been provided –the folder name will be the sponsor-assigned ID. Unlisted studies will appear with the ID you used to request the study. Within the ID, some characters that are not allowed for filenames will be replaced by an underscore character, including /\:*?*<>|



Figure 25 - Open source data – files

Do not place any important data onto the temporary storage drive D:- when the machine is stopped, even temporarily, the temporary storage will be deleted.

If the data has been provided in the form of a zip file, you can open the file as though it were a folder, and read the files in the zip file, but you will not be able to modify them in-place. To modify the files, you will need to copy the file(s) to a new, un-zipped folder.

Additional network space will expand as you add files, up to a terabyte. We recommend that you not put anything but transient data onto C: drive. Data on the V: drive will be placed into long-term storage after you have completed your analysis. If you have questions about the data and what has been provided, use the Chat function within the Vivli platform or email <u>support@vivli.org</u>; Please direct questions about the source data to the data contributors. Responses to questions about the source data is at the discretion of the data contributor.

4.2.2 If you started before all of the data was available

If you have decided to start before *all* of the data is available, then when additional data is provided by the contributor, it won't be added to your research environment automatically. <u>See Section 6.0</u> for instructions on how to load newly provided data.

1. Copy Passwor	d to Clipboard 2.	Connect to Environment
Consumer Decourse	d. Connect to Environ	howesen aten hire from
CODY YOUI Password	G, OOTHOLLIM ENVIRON	mone, ana posto pasamora
(CTRL-V) when pron	npted - Then click "C	onnect" or "OK" to continue.
(CTRL V) when pron	npted - Then click "C	onnect" or "OK" to continue

4.2.3 Additional Tips for working in the Research Environment

Normally, remote desktop will start up in full screen mode, with a small control on the top of the screen:





You can drag this control bar from side to side if needed, and you can also use this toolbar to minimize the secure research environment screen, if you need to access the Vivli platform, your email, or any other applications.

1. To minimize the window but keep it visible, click on the minimize option in the toolbar:



Figure 60 - minimize window

2. To collapse the window entirely, click on the collapse option in the toolbar:



Figure 61 - collapse window

4.3 Disconnecting from the research environment

• When you are done working with the research environment, we recommend that you Sign Out – this will allow other members of the research team to use the research environment.



• Only two team members can use the Secure Research Environment at a time. If a third member tries to log on, they will be given the option of disconnecting a team member:



• The user that you select will be automatically disconnected:



• The user in the research environment will receive the following message:

S connectio	n (15) - 40.12	2.72.85 - Ren	note Desktop Connection	5 5	- 🗆 ×
Recycle Bin	Jettinains PyCharm C	R-Server-A			
appyten/Server	Autication - Comman	Rsitudio		1-93be-40d1b54c23ce - X V D DATA (E) > Source Data > c6f0a300-b944-4841-93be-40d1b54c23ce V U Search c6f0a300-b944-4841-9_ /2	
Links	Juno ier Juliaita	SAS 9.4 (Togisti)	Quick access Cuick access Desktop Desktop Downloads Cuick	ime Date modified Type Size DIG Data Dictionary Documentation 9/26/2018 4:58 PM PDF File 119 KB Dig Protocol 9/26/2018 4:58 PM PDF File 179 KB Dig Protocol 9/26/2018 4:58 PM PDF File 179 KB	
Analytics Labs	Lapyter Notebo	SAS Stuck	Documents * Documents * Documents * Documents * Documents * This PC	Remote Desktop Connection Do you want to allow vm489948563\viviliuser6744 to connect to this machine? Click OK to disconnect your session immediately or click Cancel to stay connected.	
	bilarosoft Azere Ros	States: 1 (65 off)	🚸 Network	No action will disconnect your session in 30 seconds.	
Angenetisto.	NVIDIA Religite HUL	Visual Obje Tagging To			
Evince	Power Bl Desktop		6 items 1 item selected 1.35 MB		
< How	To Guide	Privacy	Cookie Policy EEA Disclos	sure Policy Contact Us	© Copyright 2017 - 2018 Vivli
€ O <i>Figure</i>	⊒† <mark>∞</mark> ουτ 20 - ch	look 🕞 F nange	le Exp Slack So Google	📱 Sticky_ 🗴 Excel 📷 Word 🚛 Untitle_ 💿 (r) Metr_ 🍯 Vivli 💿 Skype f_ 🚔 Inbox 🖳 Connecc. 🔮 Vivli -Ze_ 🧄 📾 🐔 🌾 d	× 👪 11:28 AM 📮

• The user in the research environment must click **OK** to disconnect and allow their team member access. Save your work regularly, and especially before disconnecting.

4.4 Team Access to Secure Research Environment

- All members of the research team working in the research environment must have a signed Data Use Agreement (DUA). If a research team member is part of the same institution as the Principal Investigator, they are covered under the Principal Investigator's DUA. If a team member is from another institution, they must sign a DUA before accessing the research environment.
- The data request administrator may add team members and may invite any of the team members to access the data request, which also grants access to the Research Environment.
- To invite a user, the user being invited must first create an account using the "Sign-up" link on the initial page. For information on creating an account, see the <u>User Quick Start Guide</u>
- Once the Research team member creates a Vivli Account, the data request administrator may invite any of the team members to access the data request and the research

environment.

Vivli		Home	About	Members	News & Events	Resources	Find Studies
CENTER FOR GLOBAL CLINICAL RESEARCH DATA			QUICK	STUDY LOOKU	p 🗸 🔮 my data	REQUESTS	
< Go Back Malaria Stud	dy 1						Print
Studies							
Attachments	RESEARCHERS						Add +
Request History	Ida Sim (LEAD RESEARCHER / STATISTICIAN)						
Signed Agreements					ſ	nvite Member to	Access Data Request
Safety Concerns							
Research Results							
Chat							
Research Team							
Research Environment							
Request Details/Print View							

Figure 21 - change user notification

- When the research team members accept that invitation, the data request will appear on their "My Data Requests" screen and they will be given access to the data request. Once Vivli has validated that they are covered by a signed Data Use Agreement, they will be given access to the research environment.
- To remove a team member who is no longer involved in the project, click on the three dots to the right of their name, and click on "Remove Team Member"

RESEARCHERS	Add +
Ida Sim (LEAD RESEARCHER)	1
John Wood (STATISTICIAN RESEARCHER)	:
	Invite Member to Access Data Request
	Remove Team Member

Figure 22 - change user notification

• Reminder: you are unable to change the Principal Investigator or the Lead Statistician. If you need to change the statistician or Principal Investigator, contact support@vivli.org.

4.5 Adding additional software, tools and data during your analysis

During the course of your analysis, if you find that you need to load R scripts from the CRAN repository, you can do that yourself using the following steps:

- To install a CRAN package in R, use the install.packages() function. This simple command downloads the package from a specified repository (by default, CRAN) and installs it on your machine
 - or
- In RStudio go to Tools → Install Packages and in the Install from option select Repository (CRAN) and then specify the packages you want

If you need any other R or Python scripts not pre-installed in the Vivli Research Environment, reach out to Vivli via chat or support@vivli.org and let them know the names of the additional scripts that you require and they will add them to your research environment. Any scripts that you have written can be emailed to support@vivli.org and let them know the names of the additional scripts that you require and they will add them to your research environment. Any scripts that you have written can be emailed to support@vivli.org and they will be added to the research environment; please include the request number of your environment to help Vivli locate the correct environment.

If you have additional software, please email Vivli at <u>support@vivli.org</u> with the name of the software and any license key, if required. If this software was not included in your request, Vivli will need to reach out to the data contributors involved and ask for their agreement to include this software or data.

If you wish to add additional study data that is available on Vivli after your request is approved, you will need to submit a new request. Please note that this process can take an additional 2-5 months for review, approval and uploading of the additional data. Vivli strongly recommends that all studies needed for analysis are included before submitting your data request.



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

5.0 Stopping and Starting the Research Environment

5.1 Stopping or Pausing the research environment

- Stopping the research environment is like powering off your laptop: nothing is lost, and the environment can be restarted quickly (less than 5 minutes).
- If you expect to leave the research environment idle for several days or longer, we recommend that you stop the Research Environment.
- When you are ready to use the Research Environment again, you may restart it and the environment will be restarted with all the saved data as you left it.

To Stop the Research Environment:

- 1. Login to the Vivli Platform
- 2. Navigate to the Research Environment, and click on the button "Stop Environment":

CENTER FOR GLOBAL CLINICAL RESEARCH DATA		Home About	Members	News & Events кup ү 🗐 мүр	Resources	Find Studies
< Go Back Efficacy of er	rythromycin in prevention o	of anthrax.				Print
Studies	Data Package	available for 2 of 3 stu	idies in the D	ata Request		
Attachments	For more information on starting and usin	ng the Research Environ	ment click <u>her</u>	e to view it in anot!	her tab or down	load.
Request History]			
Signed Agreements						
Safety Concerns	✓ Researce	ch Enviro	nmen	t Runni	ng	
Research Results	Us	ername: vivli	user787	1		
Chat	1. Copy Password	I to Clipboard	2. Connect to	Environment		
Research Team	Copy your Password	I, Connect to Envi	ronment, a	nd paste pass	word	
Research Environment	(CTRL-V) when prom	npted - Then Click '	"Connect" (or "OK" to con		
Request Details/Print View	Add Data Packages	Stop Environme	int	Deprovision E	nvironment	
	Stopping your enviro	onment simply shu vironment will perm	ts it down, nanently de	but deprovisio elete it.	oning	
How To Guide Privacy Cookie I	Policy FFA Disclosure Policy Contact Us					© Copyright 2017 - 2

Figure 31 – Stop Research Environment

This will stop the secure research environment.

5.2 Restarting the research environment

To restart the research environment:

- 1. Login to the Vivli Platform
- 2. Navigate to the research environment:

- U Vivli	Home About Members News & Events Resources Find Studies						
CENTER FOR GLOBAL CLINICAL RESEARCH DATA	QUICK STUDY LOOKUP 🗸 📴 MY DATA REQUESTS 🔹 VIVLI INFO 🗸						
< Go Back Efficacy of	erythromycin in prevention of anthrax.						
Studies	Data Package available for 1 of 3 studies in the Data Request						
Attachments	For more information on starting and using the Research Environment click here to view it in another tab or download.						
Request History							
Signed Agreements	The second se						
Safety Concerns							
Research Results	Research Environment Stopped						
Chat	Username: vivliuser7871						
Research Team							
Research Environment	Add Data Packages Start Research Environment Deprovision Environment						
Request Details/Print View	Starting your environment will make it so you can connect, but deprovisioning your environment will permanently delete it.						
How To Guide Privacy Coo	kie Policy EEA Disclosure Policy Contact Us @CopyHight 2017-2019 Vu						

Figure 32 - Start Research Environment

3. Click on **Start Research Environment** – the platform will tell you that the research environment is starting:



Figure 33 - Research Environment restarting

After approximately 5 minutes, the system will display the "Running" screen:

Vivli Center for Global Clinical Research Data		Home About Memb QUICK STUD	ers News & Events r Lookup ү 🔁 мүр	Resources	Find Studies
< Go Back Efficacy of er	ythromycin in prevention o	of anthrax.			Print
Studies	Data Package	e available for 1 of 3 studies in t	ne Data Request		
Attachments	For more information on starting and usin	ng the Research Environment clic	k here to view it in anoth	ner tab or down	load.
Request History					
Signed Agreements					
Safety Concerns	✓ Researce	ch Environme	ent Runni	ng	
Research Results	Us	sername: vivliuser7	871		
Chat	1. Copy Password	d to Clipboard 2. Conn	ect to Environment		
Research Team	Copy your Password	d, Connect to Environmer	t, and paste pass	word	
Research Environment	(CTRL-V) when prom	npted - Then click "Conne	ct" or "OK" to con		
Request Details/Print View	Add Data Packages	Stop Environment	Deprovision Er	nvironment	
	Stopping your enviro	onment simply shuts it do vironment will permanentl	wn, but deprovisio y delete it.	oning	
How To Guide Privacy Cookie P	Policy EEA Disclosure Policy Contact Us				© Copyright 2017 - 20

Figure 34 - Research Environment running

After restarting the machine, the first login may take a few minutes.

6.0 Adding Data Packages to the Research Environment

If you started the Research Environment before all the data was provided, then as additional data packages are loaded into the system, they will not be placed into your Research Environment automatically. You will however receive an email notification that additional data has been provided. When you are ready, you can ask the system to add the additional data packages to your Research Environment.

6.1 How will you know when data is available?

As additional data packages are loaded into the system and made available, you will receive an email notification. Within the Vivli Platform, you can look at the "Active" tab, select the request you are interested in:

	Home About Members News & Events Resources Find Stu
y Data Requests (166)	adiox struar Lookar V 🥃 ur bitis Hibblette 🚺 bitis Hibble
Draft O Active Not Approved Withdrawn Archived	
SCENDING MULTIPLE-DOSE SAFETY, TOLERANCE, PHARMACOKINETIC, AND PHARMACODYNAMIC STUDY OF BMS-201038 IN HEALTHY	
latus: Al least one Data Package Provided and Available	

Figure 35 – Available data packages

To determine *which* studies have been uploaded, click on the studies tab, and this page will provide a status of each study:

Vivli	Home	About Members News & Events Resources Find Studies
CENTER FOR GLOBAL CLINICAL RESEARCH DAT		QUICK STUDY LOOKUP 🗸 👹 MY DATA REQUESTS 🛛 🗕 DATA REQUESTER 🗸
< Go Back Ascending	g Multiple-dose Safety, Tolerance, Pharmacokinetic, and Pharmacodynamic Study of BMS-201	1038 in Healthy Volunteers
Studies	REQUESTED STUDY TYPES 🅦 👃 Ascending Multiple-dose Safety, Tolerance, Pharmacokinetic, an Pharmacodynamic Study of BMS-201038 in Healthy Volunteers	ıd
Attachments	VIVLI-LISTED AND PROVISIONED STUDIES	
Request History	Accending Multiple-does Safety, Tolerance, Pharmacokinetic, and Pharmacodynam Pt: Sprince: Bills: Study ID: AEGR-CV145402, R01/approxe: Newton Therapeulos: Data Request ID: 00022549 Sponsor ID: AEGR-CV145402 Data Contributor: Newton Therapeulos: PD Uppoate: No	Awaiting Data Package upload by Data Contributor
Signed Agreements	A Patient Preference Evaluation Study of Puticascore Fundate Nasal Spray and Pt: Sprunz: - GlasschmitHilder - Study (D), NOT(2007H5 IIPP/leprover: Welsome Trust: Data Request ID: 00002549 Sprunzr ID: 201474 Data Controllarur: GlasschmitHilder = 00 optioada	Awaiting Data Package upload by Data Contributor
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Chat	An Open Label, Non-comparative Study To Evaluate Parasitoticgical Clearance Ra Pr. Sponzer, Piterra, Study C. NCTO102131 (IPPAprover: Piter Inc. Data Neguest D: 0002549 Sponsor ID: A6641201 Data Comparative Piter Para, Pr. 9 Updated: No.	Awating Data Package upload by Data Contributor
Research Team	VIVLI-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS	
Research Environment	No Studies Found STUDIES, DATA OR TOOLS NOT LISTED ON VIVLI	
Request Details/Print View	No Studies Found	
How To Guide Privacy Coo	kle Policy EEA Disclosure Policy Contact Us	© Copyright 2017 - 3021 Vit

Figure 36 – Available data packages

6.2 How to add additional data to your research environment as it becomes available

Once you have determined that you are ready to ask the platform to load the additional data into your research environment, open the data request, select the Research Environment tab, and click on the "Add Data Packages" button:

Uivli	Home About	Members News & Events Resources Find Studies						
CENTER FOR GLOBAL CLINICAL RESEARCH DATA	QUIC	K STUDY LOOKUP 🗸 📴 MY DATA REQUESTS 🗕 VIVLI INFO 🗸						
< Go Back Efficacy of e	erythromycin in prevention of anthrax.	Print						
Studies	Data Package available for 2 of 3 studi	ies in the Data Request						
Attachments	For more information on starting and using the Research Environment	ent click here to view it in another tab or download.						
Request History								
Signed Agreements	aned Agreements							
Safety Concerns	✓ Research Environ	ment Running						
Research Results	Username: vivliu	ser7871						
Chat	1. Copy Password to Clipboard 2	. Connect to Environment						
Research Team	Copy your Password, Connect to Enviro	nment, and paste password						
Research Environment	(CTRL-V) when prompted - Then click "Connect" or "OK" to continue.							
Request Details/Print View	Add Data Packages Stop Environment	t Deprovision Environment						
Stopping your environment simply shuts it down, but deprovisioning your environment will permanently delete it.								
How To Guide Privacy Cookie	e Policy EEA Disclosure Policy Contact Us	@ Copyright 2017 - 2019 Vivil						

Figure 37 – Add data packages



Figure 38 – Research Environment Adding data packages

6.3 Refreshing previously loaded data

The Vivli platform determines what new data should be loaded by looking for an existing folder with the appropriate name: if it finds a folder in the Research Environment with the original folder name for the study, it will leave that existing folder alone. This means that:

- If you have started to make changes to previously loaded data (e.g. for harmonization), your changes will **not** be overwritten.
- If you would like a fresh copy of the data for any reason, you can simply rename the existing folder, and the system will load a fresh copy of the data package.
- If you rename a data folder for any other reason, the system will load a fresh copy of the data using the original folder name. If the extra copy is redundant, delete it.

7.0 Safety Concerns

If you discover any information regarding the safety or risks of a product related to their requested data, you must inform Vivli and the Data Contributor of this discovery within 24 hours, per the terms of the Data Use Agreement.

The steps for reporting safety concerns are as follows:

1. Login to the Vivli Platform.

2. Click on the "Safety Concerns" tab on the dashboard:

The following screen will appear:

Uivli	Home About Members News & Events Resources Find Studies
CENTER FOR GLOBAL CUNICAL RESEARCH DATA	a ouck stlovi lookup v 👹 my data requests 👔 data requester v
«Go Back Ascending	g Multiple-dose Safety, Tolerance, Pharmacokinetic, and Pharmacodynamic Study of BMS-201038 in Healthy Volunteers
Studies	Supply your contact information and safety concern description below, then click 'Submit Safety Concern' to continue.
Attachments	Name Data Requester
Request History	Email Address Phone Number Datarequester.vivil@gmail.com
Signed Agreements	Describe the Safety Concern
Safety Concerns	Submit Safety Concern
Research Results	
Chat	Previously Submitted Safety Concerns
Research Team	
Research Environment	
Request Details/Print View	
How To Guide Privacy Cool	Akie Policy EEA Disclosure Policy Contact Us scowywy 2017-2021

Figure 39 - Safety Concerns tab

3. Complete the form and click on Submit Safety Concerns:

Vivli	li	Home About Members News & Events Resources Find Stud	dies
CENTER FOR GLOBAL CLINICAL RESEARCH DA		QUICK STUDY LOOKUP 🗸 🕮 MY DATA REQUESTS 👔 DATA REQUE	ester 🗸
< Go Back Ascending	ng Multiple-dose Safety, Tolerance, Pharmacokinetic, and Pharmacodynamic Study o	of BMS-201038 in Healthy Volunteers	
Studies	Supply your contact information and safety concern description below, then click 'Submit Safety Concern' to continue.		
Attachments	Name Data Requester		
Request History	Email Address Phone Number Datarequester.vivli@gmail.com 555-5555		
Signed Agreements	Describe the Safety Concern Safety concern		
Safety Concerns	Submit Safety Concern		
Research Results			
Chat	Previously Submitted Safety Concerns		
Research Team			
Research Environment			
Request Details/Print View			
How To Guide Privacy Cor	Cookie Policy EEA Disclosure Policy Contact Us	. © Copyright 20	017 - 2021 VM

Figure 402 - Submit safety concerns

8.0 Exporting Research Results

If you have preliminary or final results from your analysis, you may request the ability to export summary results from the Secure Research Environment. Any custom scripts you may have developed during the research can also be exported with the results. A shortcut to submit this request is on the desktop.



When submitting your request to export results, please note that Individual Participant Data (IPD) requested from this study will need to remain in the Vivli secure research environment. As such, there should be no attempt to try to remove IDP data or re-identify individual participants in the study you are requesting. Per your signed Data Use Agreement, any results derived from your analysis in the Vivli Research Environment, which will be used in subsequent presentation or publication, should be obtained by submitting a request for removal of this data.

Results exports should not include any individual participant data in the results. Acceptable results export is limited to summary representation of data (e.g. means, standard deviations, counts), derived data (e.g. slopes, clin pharm parameters) data, analytical and representations of results (e.g. graph), scripts or programs that you developed in the Research Environment. The following graphic is an example of a request to export results spreadsheet, including IPD, which would not be approved.



Please note that all results should be submitted through the results export option.

8.1 Request to Export Results

- 1. From the Vivli Research Environment, double click the Export Results icon on the Desktop.
- 2. Enter the Vivli User credentials you use to log onto the Vivli Platform your username will be your email address.

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Co To be most productive with Microsoft Com/vivliqa.b2clogin.com/vivliqa.onmicrosoft.com/b2c_1a_signi					
Cign in with your email address Caseword Career of your password? Sign in					

3. From the dropdown menu, select your Vivli request. Please note, if you have more than one Vivli request which has a secure research environment, each request will appear in the menu.



4. Create a new results request.

CENTER FOR GLOBAL CLINICAL RESEARCH DATA
Assessing the impact of lifestyle choices on heart health
Create New Results Request
No Result Requests Found
0 to 0 of 0 I< < Page 0 of 0 > >I
© Copyright 2017 - 2021 Viviti
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Annual the request of the second second second second the
Create New Result Request? Yes No

5. Drag and drop, or select files, to copy your files into the export folder. If your results are organized into more than one folder, we recommend that you place the files into a single zip file before placing them in the results folder. 7-zip is included on the research

environment for that purpose. Similarly, if you have more than 5-10 files, place them into a single zip file.

<image/> According the impact of lifestyle choices on heart health Acquesting export of research results, use Drag and Drop to drop the results have been reviewed and approved, you will connect to the main YoliP Platform to download the results. Reminder - exported individual participant data is not allowed. NOFIES IN PACKAGE CONTROL NOR CONTROL CONTROL NOR CONTROL CONTROL NOR CONTROL CONTROL NOR CONTROL CONTROL NOR CONTROL CONTROL NOR CONTROL CONTROL NOR CONTROL CONTROL CONTROL NOR CONTROL CONTROL NOR CONTROL NOR CONTROL CONTROL NOR CONTROL CONTROL NOR CONTROL NOR CONTROL CONTROL NOR CONTROL NOR CONTROL NOR CONTROL CONTROL NOR CONTROL NOR CO		
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6. Submit files for review.

C Vivili	
Submit Files? Are you sure all files have been uploaded? This action car	not be undone.
Yes No	
CENTER FOR GLOBAL CLINICAL RESEARCH DATA	
Assessing the impact of lifestyle choices on heart health	(Request by Data Requester on 2021- 10-01)
	Create New Results Request
2021-10-01 Data Requester	Result Request in Progress
	1 to 1 of 1 IC ≺ Page 1 of 1 > →I
Results not yet available for this request.	

Please note, the processing time for a results export request is 5-7 business days. You will receive an email notification when a decision is recorded on the platform and can also monitor by checking the Research Results tab on the platform.

8.2 Downloading Approved Results

Once the request to export results is approved, the data requestor may download their results.

8.2.1 Steps, Exporting Results:

- 1. Login to the Vivli Platform
- 2. Navigate to My Data Requests and select the request:

Vivli	Home About Members News & Events Resources Find Studies
CENTER FOR GLOBAL CLINICAL RESEARCH DATA	QUICK STUDY LOOKUP 🗸 😁 MY DATA REQUESTS 🛛 💽 DATA REQUESTER 🗸
My Data Requests (166)	2545
Draft O Active Not Approved Withdrawn Archived	
ASSESSING THE IMPACT OF LIFESTYLE CHOICES ON HEART HEALTH I 1 STUDY	
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3. Click on Research Results:

Vivli		Home	e About Members N	ews & Events Resources Find Studies
CENTER FOR GLOBAL CLINICAL RESEARCH DATA			QUICK STUDY LOOKUP 🗸	😬 MY DATA REQUESTS 💽 DATA REQUESTER 🗸
< Go Back Assessing th	ne impact of lifestyle choices o	n heart health		Print
Studies				
Attachments	To request export of research results, connect to Vivili Platform password. Use Drag and Drop to dr and approved, you will return back here to downlo	the research environment, click on the Export Results icon on the de op the requested files onto the "Drop files here" control, then click su ad the results. Reminder - exporting individual participant data is no	sktop. In the browser window ubmit when they are complete t allowed.	r, log in with your email address and e. When the results have been reviewed
Request History	2021-10-01	Data Requester	Res	sult Retrieval Succeeded
Signed Agreements				
Straty Concerns				
Research Results			1 to	1 of 1 IC < Page 1 of 1 > >I
Chat	Result Request Status: Result Retrieval Succeed	ed		
Research Team	UPLOADED FILES			
Research Environment	Filename result export.txt	Size <1 kB	Uploaded By Data Requester	Download 🛓
Request Details/Print View				
How To Guide Privacy Cookie	Policy EEA Disclosure Policy Contact Us			© Copyright 2017 - 2021

If you have made more than one request, click on the row corresponding to your most recent request – this will be on the top of the list. The row you have selected will be shown in dark blue.

4. Here, you will see if the request to export results has been approved:

Uivli	Home About Members News & Events Resources Find Studies
CENTER FOR GLOBAL CLINICAL RESEARCH DATA	QUICK STUDY LOOKUP 🗸 👹 MY DATA REQUESTS 👔 DATA REQUESTER 🔪
< Go Back Assessing	the impact of lifestyle choices on heart health
Studies	
Attachments	To request export of research results, connect to the research environment, click on the Export Results icon on the desktop. In the browser window, log in with your email address and Vivil Platform password. Use Drag and Drop to drop the requested files is onto the "Drop files here" control, then click submit when they are complete. When the results have been reviewed and approved, you will return back here to download the results. Reminder - exporting individual participant data is not allowed.
Request History	2021-10-01 Data Requester Result Request in Progress
Signed Agreements	2021-10-01 Data Requester Result Retrieval Succeeded
Safety Concerns	
Research Results	1 to 2 of 2 ic < Page 1 of 1 > >i
Chat	Results not yet available for this request.
Research Team	
Research Environment	
Request Details/Print View	

5. If the request to export results has been approved, click on **Download**:

Uivli		Home	About Members	News & Events Reso	ources Find Studies
CENTER FOR GLOBAL CLINICAL RESEARCH DATA			QUICK STUDY LOOKUP	✓ ≝ MY DATA REQUESTS	DATA REQUESTER ~
< Go Back Assessing	the impact of lifestyle choices of	on heart health			Print
Studies					
Attachments	To request export of research results, connect to Vivli Platform password. Use Drag and Drop to d and approved, you will return back here to down	the research environment, click on the Export Results icon on the de frop the requested files onto the "Drop files here" control, then click su load the results. Reminder - exporting individual participant data is no	sktop. In the browser win Ibmit when they are comp t allowed.	dow, log in with your email plete. When the results hav	address and ve been reviewed
Request History	2021-10-01	Data Requester		Result Retrieval Succeeded	
Signed Agreements	2021-10-01	Data Requester		Result Retrieval Succeeded	
Safety Concerns					
Research Results				1 to 2 of 2 IC C Pag	elofi > >i
Chat	Result Request Status: Result Retrieval Succeed	ded			
Chat	UPLOADED FILES				
Research Team	Filename	Size	Uploaded By		
Research Environment	result export.txt	< 1 kB	Data Requester	Do	wnload 🕹
Request Details/Print View					
How To Guide Privacy Coo	kie Policy FFA Disclosure Policy Contact Us				© Convright 2017 - 2021

If a review of the results identifies the presence of Individual Participant Data (IPD) in the result files, the Result Requests screen will display a message indicating that, and you will need to remove the IPD from the results files before requesting subsequent export of results again.

6. Once the *final* results are exported, please reach out to the Vivli Team via chat and we will provide next steps for deprovisioning the research environment and progression to publication.

9.0 Publication Review

9.1 Publication Follow up by Vivli

The Vivli administrator sends periodic reminders (at 3 months, 9 months and 1 year) to the researchers to get an update on the status of any potential publications from the time final results from the research environment are downloaded or a year after the downloadable data package was made available to the Data Requestor.

9.2 Publication Reviews by Data Contributors

- Once your researcher team has completed your analysis and you are ready to submit your findings for dissemination, either through a learned forum such a publication or conference abstract, requestors must submit to Vivli a copy of any Publication materials at least 30 days prior to submission. Please submit this publication using the Chat function.
- The following acknowledgement should be added to the dissemination of findings. Also, please use the following language in your acknowledgment section:

This [publication or presentation, as applicable] is based on research using data from data contributors ***Data Contributor(s) Name*** that has been made available through Vivli, Inc. Vivli has not contributed to or approved, and is not in any way responsible for, the contents of this publication.

- During this 30-day review period, data contributors may provide you with non-binding comments regarding the scientific content. They may also possibly request the deletion of any confidential information (confidential information as defined in the signed DUA).
- Once the 30-day publication review period is up or once all data contributors have commented on the manuscript, whichever comes first, the research team may submit their manuscript.
- The Vivli team will follow up monthly to check on the status.

9.3 Publication Notification by Data Requestor

- Once your team has been notified that your publication has been accepted by the journal and the DOI for your citation made available, please let the Vivli team know via chat.
- The Vivli team will then update your data request on the Vivli website by including the statistical analysis plan and the DOI to the publication.
- If this is your final analysis for the research project, please let Vivli know and if will move your analysis to long-term storage. See <u>section 12.0 Stopping the Research Environment</u>. Vivli team will send you a survey about your experience on Vivli platform.
- If you have more publications linked to this research project, please follow step 9.2 Publication Reviews by Data Contributors for each subsequent publication.

9.4 Public disclosure not possible

If for whatever reason, you are unable to publish your results. You can provide a summary report of your findings and Vivli will publish this report on its website. For an example see: https://vivli.org/identification-of-biomarkers-associated-with-specific-sleep-variables/. Vivli will then de-provision your research environment and your project will be complete.

Alternatively, you may fulfill the obligations under the Vivli DUA and submit to a pre-print server such as <u>https://www.medrxiv.org/</u>. This preprint server was started by the BMJ and Yale and is a free distribution server for preprints of articles covering all aspects of research. Once posted you would receive a DOI so it would be citable and discoverable. You can cite this on your CV and continue to submit to other journals if you like.

9.4.1 Reasons why analysis may not be completed

If the analysis is not completed, this fact and the reason that it was not completed, should be stated as a summary of the research.

- The analysis may not be performed or completed due to the following reasons:
 - Technical e.g. datasets can't be combined, the research questions can't be answered, data mapping isn't possible
 - Scientific e.g. the studies can't be combined due to design differences or endpoint differences

Logistical - e.g. the Data Requestor loses funding or key research personnel
 According to Vivli policy, if a user fails to meet their DUA obligations and does not respond
 with reasons why their analysis has not been completed, they are unable to submit a
 subsequent request from Vivli.

10.0 Extensions to the Data Use Agreement

- The Vivli team will reach out to the Data Requestors for an update on the data request and analysis 90 days prior to the 1-year DUA expiration.
- The Vivli Administrator sends them the Request to Extend Access to the Data form.
- To request an extension, the Lead Researcher fills out the Request to Extend Access to the Data form
- Vivli team will follow up on the Data Access Extension form 45 days, 30 days, 3 weeks, 2 weeks and 1 week prior to the DUA expiration.
- Based on the response, Vivli makes the decision regarding extending access to the data in six-month intervals up to a maximum of 2 years. These extensions are only granted due to extenuating circumstances. After that, any extensions will need to be reviewed by the Data Contributors who may approve or decline the extension. Vivli will respond in 10 business days with a decision that has been reached and upload the Extension decision document via Signed Agreements on the Vivli platform.

- If no response is received before the end of the Data Use Agreement, Vivli team stops the Research Environment and remove the team's access to the research environment on the day of DUA expiration.
- If no response is received within 60 days of DUA expiration, Vivli team will deprovision the Research Environment and the request will be considered withdrawn which may result in losing the analysis done thus far.
- Note: For any requests for downloadable data, Vivli team will request for evidence of data destruction as per the data security addendum.
- Note that an extension to the Data Use Agreement (a legal agreement) is entirely separate from the No Charge period on the Research environment and does not extend the No Charge period.

10.1 Failure to meet DUA obligations

According to Vivli policy, if a user fails to meet their DUA obligations, they are unable to submit a subsequent request from Vivli.

11.0 Paying for a Research Environment

The cost and length of courtesy billing periods for the Secure Research Environment access are available on the Vivli <u>website</u>. Please note these charges are subject to change.

Note that the courtesy billing period (i.e., the length of time where you will not be charged) begins on the date you first provision the Research Environment, which usually is later than the date that the Data Use Agreement is signed. Renewing the Data Use Agreement does not extend the courtesy billing period.

As you near the end of your courtesy billing period, Vivli will send you notices via email to the email addresses of the research team members on the data request. In these notices we will remind you of the end date of your courtesy billing period. **We will ask you to provide payment via a credit card once your courtesy billing period has ended.** Charges will be automatically completed on the same day of the month, approximately every 30 days, as when payment is first submitted for the next month's usage. A constant 30 days per month will be charged, and your subscription will be cancelled and no further charges made as soon as you submit a public disclosure for courtesy review.

If no payment method is arranged, access to the Research Environment will be revoked.

Please note that you will be responsible for all charges once your courtesy billing usage period has ended. Once you have completed your research, submitted a public disclosure for courtesy review, and stopped your secure research environment then this will stop the accrual of additional fees. See <u>section 12.0</u> for further information about stopping the research environment.

- At the end of your courtesy billing period, the Vivli team will email you with the appropriate link to sign up for subscription billing for the secure Research Environment within 1 week of your courtesy billing end date. The subject line will be "Action Required: Vivli Research Environment ALERT – Payment Request to Maintain Access to data request"
- 2. Upon opening the link, you will be directed to the PayPal page where you can login with your PayPal account or enter the credit/debit card number to be used for billing.

	P
	Pay with PayPal
	With a PayPal account, you're eligible for Purchase Protection and Rewards.
	Email or mobile number
	Password
	Forgot password?
	Log In
	or
	Pay with Debit or Credit Card
	united and the second
P PayPa	₩ \$750.00 USD ~
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PayPal G We don't share Country/Region United State	Vivi INC × Subscription Details: \$750.00 USD for each month (Renews until you cancel) Starts on: Feb 21, 2023
PayPal G PayPal G We don't share Country/Region United State	Vivil INC × Subscription Details: \$750.00 USD for each month (Renews until you cancel) Starts on: Feb 21, 2023 Monthly Premium Research Environment Usage \$750.00 USD
PayPal G PayPal G We don't share Country/Region United State	Vivil INC × Subscription Details: × \$750.00 USD for each moth (Renews unit) you cancel) × Starts on: Feb 21, 2023 PayPal is the safer, each way to pay Monthly Premium Research Environment Usage \$750.00 USD Total \$750.00 USD
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3. After entering the credit card details, click the Agree & Subscribe button. Please note that you will be charged every 30 days on approximately the same date each month going forward.

Email
The security you want.
The protection you deserve.
Creating a PayPal account is optional but you'll get PayPal Purchase Protection on all eligible purchases, plus faster checkout every time you shop. See terms
Create a PayPal account? (It only takes a moment.)
Password
No, I don't want an account now. We'll save your PayPal info for future purchases with Vivil INC. If you hold a valance, we'll use it first. If your chosen payment method is unavailable, we'll ny the other payment methods in your wallet.

4. Lastly, you should receive confirmation from PayPal that you have Successfully signed up for your subscription for the Research Environment and also a receipt of your first payment to the email address shared with PayPal.

If you have any questions about this process, please contact Vivli at support@vivli.org.

12.0 Pausing the Research Environment

- When you have submitted your publication for review and are awaiting feedback, you may reach out to the Vivli Team in chat to request a "pause" of your research environment. This will preserve any remaining courtesy billing days for subsequent analysis, if required. If you are paying for your environment, requesting to "pause" will stop the accrual of additional fees.
- Once your research environment has been stopped, this will stop the accrual of additional fees until a request to re-access has been submitted.
- Important: Before requesting to "pause" the environment, please copy any data that you
 might need later access to onto the Network Drive (Drive V:\). Once disabled, access to
 content in the Research Environment will be terminated. Note that long-term archive will
 ONLY save the contents of drive V. Data saved in any other drive will be deleted: so please
 place any essential data to Drive V.
- If you need access to data while your request is "paused", simply reach out to the Vivli Team in chat or via <u>support@vivli.org</u> and will provide next steps for resuming your analysis.

13.0 Deprovisioning the Research Environment

- When you have completed your research, exported your final results and published your findings, the Vivli team will provide next steps, as needed, to deprovision your research environment and prepare data for long term archive.
- Important: Before requesting to deprovision the environment, please copy any data that you might need later access to onto the Network Drive (Drive V:\). Once disabled, access to content in the Research Environment will be terminated. Note that long-term archive will ONLY save the contents of drive V. Data saved in any other drive will be deleted: so please place any essential data to Drive V.
- Shortly after your research environment has been marked for deprovisioning, Vivli will place a copy of the contents of the data disk into long-term archive.
- If you need access to data held in the Vivli long-term archive, please send a request to the Vivli Team via <u>support@vivli.org</u> including the Data Request number and Project Name. Processing this request takes 5-7 days.
- If you need access to long-term storage data for a new research project, to address a different question and/or if you are requesting additional data, you will need to create and submit a new data request on the Vivli platform. In the Narrative, reference the original data request, including the request number.

Vivli	Home About Members News & Events Resources Find Studies				
CENTER FOR GLOBAL CLINICAL RESEARCH DATA	QUICK STUDY LOOKUP V 🔁 MY DATA REQUESTS 💽 VIVLI INFO				
< Go Back Efficacy of	< Go Back Efficacy of erythromycin in prevention of anthrax.				
Studies	Data Package available for 1 of 3 studies in the Data Request				
Attachments	For more information on starting and using the Research Environment click here to view it in another tab or download,				
Request History					
Signed Agreements					
Safety Concerns	✓ Research Environment Running				
Research Results	Username: vivliuser7871				
Chat	1. Copy Password to Clipboard 2. Connect to Environment				
Research Team	Copy your Password, Connect to Environment, and paste password				
Research Environment (CTRL-V) when prompted - Then Click "Connect" or "OK" to continue.					
Request Details/Print View	Add Data Packages Stop Environment Deprovision Environment				
Stopping your environment simply shuts it down, but deprovisioning your environment will permanently delete it.					
How To Guide Privacy Cook	kie Policy EEA Disclosure Policy Contact Us © Copyright 2017-201				

1. To deprovision the environment, go to the launch page for the research environment:

Figure 53 - Launch page

2. Click on Deprovision Environment:

Uivli	Home About Members News & Events Resources Find Studies			
CENTER FOR GLOBAL CLINICAL RESEARCH DATA	QUICK STUDY LOOKUP Y 🗐 MY DATA REQUESTS VIVLI INFO			
< Go Back Efficacy of	erythromycin in prevention of anthrax.			
Studies	Data Package available for 1 of 3 studies in the Data Request			
Attachments	For more information on starting and using the Research Environment click here to view it in another tab or download.			
Request History				
Signed Agreements				
Safety Concerns	✓ Research Environment Running			
Research Results	Username: vivliuser7871			
Chat	1. Copy Password to Clipboard 2. Connect to Environment			
Research Team	Copy your Password, Connect to Environment, and paste password			
(CTRL-V) when prompted - Then click "Connect" or "OK" to continue. Research Environment				
Request Details/Print View	Add Data Packages Stop Environment Deprovision Environment			
	Stopping your environment simply shuts it down, but deprovisioning your environment will permanently delete it.			
How To Guide Privacy Cool	kie Policy EEA Disclosure Policy Contact Us © Copyright 2017 - 201			

Figure 54 - Deprovision Environment

3. The following pop-up will appear:

Deprovision Research Environment?				
Deprovisioning your research environment will destroy all data that is be undone. Are you SURE you want to proceed?	not stored in the Results folder of the data drive. This action cannot			
Ok	Cancel			

Figure 55 - Deprovision confirmation pop-up

4. Click **Ok** to Deprovision the research environment:



Figure 56 - Deprovision confirmation pop-up, OK

5. The following screen will appear, and you may navigate away from this screen at any time:



Figure 57 - Deprovisioning working screen

6. If you remain on this screen, then the process is complete, the following screen will appear:

🤯 Vivli		QUICK STUDY LOOKUP 🗸	MY DATA REQUESTS	👤 IDA SIM 🗸
< Go Back Hepatitis	Project			Print
Studies	Research environment no longer provisioned.			
Attachments				
Request History				
Signed Agreements				
Safety Concerns				
Research Results				
Chat				
Research Team				
Research Environment				
Request Details/Print View				
				© Copyright 2017 - 2018 Vivli

Figure 358 - Deprovision complete screen

Note, Vivli will also send an automatic email indicating that deprovisioning has been completed.

If you accidentally deprovision a research environment, contact Vivli at <u>support@vivli.org</u>. Vivli will re-provision the environment, including any results files.

14.0 Downloadable data

Some Data Contributors will allow you to download their data directly from the Vivli Platform using the following process:

1. Log in and open your approved data request:

- Vivli	Hom	About	Members Ne	ws & Events	Resources	Find Studies	
CENTER FOR GLOBAL CLINICAL RESEARCH DA	•		QUICK STUDY LOO	KUP 🗸 🔮 M	Y DATA REQUEST	S 🕘 IDA SIM	Ļ
«Go Back Hepatitis	Project					Print	
Studies	REQUESTED STUDY TYPES 1						
Attachments	VIVLI-LISTED AND PROVISIONED STUDIES						
Request History	A Phase II Open Label, Dose-Escalation Study to Determine the Safety, Tolerability and Efficacy of Microsomal Trigtyceride Transfer Prote (MTP) Inhibitor BMS-201038 in Patients With Homozygous Familial Hypercholderolemia Pt Sponsor Agenton Pharmaceutical, hc. Study ID NCT01556068 IRPHoprover Vestati Data Request ID 0001280 Sponsor (D UP101	in	Data Packa	ge Provided to	Requestor	>	
Signed Agreements	VIVL-LISTED STUDIES PROVISIONED BY EXTERNAL PROVIDERS						
Safety Concerns	No Studies Found STUDIES PROVIDED ON VIVLI PARTNER PLATFORMS (NOT LISTED ON VIVLI) OR OTHER DATA						
Chat							
Research Team							
Research Environment							
Request Details/Print View							
How To Guide Privacy Co	okie Policy EEA Disclosure Policy Contact Us						

Figure 26 - Approved Data Request

2. Click on the study to get to the **Study details** screen:

							Home	About	Members	News & Even	s Resources	Find Studies
									QUICK STUDY	LOOKUP 🗸 📑	MY DATA REQUEST	s 😃 idas
Phase II Open La mozygous Fami	abel, Dose-Escalat ilial Hypercholeter	ion Study to olemia	Determine th	e Safety, Tolerability and	l Efficacy	of Microsomal Triglyceride Tra	nsfer Protein (I	MTP) Ir	nhibitor B	MS-201038	in Patients V	/ith
tudy Details A	dministrative Details	Download Data	a Package									
Phace						Condition or Disease						
hase 2						Homozygous Familial Hypercholester	rolemia					
rief Summary												
rief Summary The primary objective of bjectives of this study oncentrations at the e poprotein a [Lp(a)].	of this study is to evalua y included the evaluation nd of each 4-week dosin	te the safety and n of the pharmaco ng period compar	tolerability of 4 d odynamics of lomi ed to the Baselin	ses of lomitapide (AEGR-733; BN apide based on: - Percent chan a value of each parameter at the	IS-201038) gir ge in low-der end of the pro	ven as an initial low dose and then escalat sity lipoprotein cholesterol (LDL-C), total vvious dose phase(s) Changes in othe	ted through an addi cholesterol (TC), tr or plasma lipoproteir	tional 3 d iglycerid 1s: apolip	ose levels o es, and very oproteins (a	ver a 16-week p low density lipo po B, apo Al, ap	eriod. The secon protein cholester o All, apo CIII, apo	dary rol (VLDL-C) o E) and
ges Eligible For Study 3 Years and older			Sexes Eligible Fo All	r Study		Accepts Healthy Volunteers No		6	Actual Enrollm	ent		
tudy Start Date 6/2003				Study Completion Date 02/2004			Recruitment S Completed	Status				

Figure 27 - Study details screen

3. Click on Download Data Package:

				CONCESSION LOOKOP V	
Phase II Open Label, Dose-Escalation	Study to Determine the Safety,	Tolerability and Efficacy of Microsom	al Triglyceride Transfer Pro	tein (MTP) Inhibitor BMS-20103	8 in Patients With
mozygous Familial Hypercholeterole	mia				
tudy Details Administrative Details	Download Data Package				
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en resource autores mitapide Tel Summary he primary objective of this study is to evaluate to bjectives of this study included the evaluation of noncentrations at the end of each 4-week dosing p poprotein a [Lp(a]).	re safety and tolerability of & doses of ionitat the pharmacodynamics of ionitapide based eriod compared to the Baseline value of eac	pide (AEGR-733: BMS-201038) given as an initial or: - Percent change in low-density lipoprotein h parameter at the end of the previous dose pha	ow dose and then escalated through cholesterol (LDL-C), total cholesterol es(s) Changes in other plasma lipc	an additional 3 dose levels over a 16-week (TC), trighterides, and very low dentity lij oproteins: apolipoproteins (apo B, apo AI, a	x period. The secondary poprotein cholesterol (YLDL-C) apo All, apo CIII, apo E) and
emitapide mitapide reif Summary The primary objective of this study is to evaluate to glocitives of this study included the evaluation of oncernations at the end of each 4-week dowing p poportein a (pola). poportein for Study Years and object	te safety and tolerability of 6 dooes of fomila the pharmacodynamics of fomilapide based orfod compared to the Baseline value of eac sexes Eligible For Study	pide (AEOR-733: BM5-00108) given as an initial nt: - Percent change in low-dennity lipoprotein h parameter at the end of the previous dose pha Accepts Heal	ow dose and then escalated through cholesterol (LDL-D), total cholesterol ese(s) Changes in other plasma lipo hy Volunteers	an additional 3 dose levels over a 16-week (TC), trighyterides, and very low denith lip oproteins: apolipoproteins (apo B, apo A), a Actual Ervolment	k period. The secondary poprotein cholesterol (VLDL-G) apo All, apo Cill, apo E) and
emitapide mitapide hief Summary The primary objective of this study is to evaluate to becitives of this study included the evaluation of oncentrations at the end of each 4-week dosing p poprotein a (Lp(a)). ges Eligible For Study 3 Years and older	re safety and tolerability of 4 doses of lomita the pharmacodynamics of lomitapide based eriod compared to the Baseline value of eac Sexes Eligble For Study All	pide (AEGR-733: BMS-201038) given as an initial on: - Percent change in low-density lipoprotein h parameter at the end of the previous dose pha Accepts Heat No	ow dose and then escalated through cholesterol (LDL-C), total cholesterol es(s) Changes in other plasma lipc hy Volumeers	an additional 3 dose levels over a 18-week (TC), trighjeerides, and very low density lij poroteins: apolipoproteins (apo B, apo A, r Actual Enrollment 6	k period. The secondary poprotein cholesterol (VLDL-C) apo All, apo Cill, apo E) and
en retronor deal men. emitapide nef Summary he primary objective of this study is to evaluate to bjectives of this study included the evaluation of oncentrations at the end of each 4-week dosing p opportein a [Lp(a)]. ges Eligible For Study 3 Years and older tudy Start Date	re safety and tolerability of 4 doses of lomita the pharmacodynamics of iomitapide based eriod compared to the Baseline value of eac Sexes Eligible For Study All	pide (AEGR-733; BMS-201038) given as an initial or: - Percent change in low-density lipoprotein h parameter at the end of the previous dose pha Accepts Heal No	ow dose and then escalated through holesterol (LDL-C), total cholesterol ee(s) Changes in other plasma lipo hy Volunteers	an additional 3 dose levels over a 16-week (TC), triglycerides, and very low density li proteins: apolloporoteins (apo B, apo A, J Actual Errolment 6 utment Status	k period. The secondary poprotein cholesterol (VLDL-C) apo All, apo Cill, apo E) and

Figure 28 - Download Data Package

4. This will take you to the Download screen:

Uivli			Home About Members News & Events Resou	rces Find Studies
CENTER FOR GLOBAL CLINICAL RESEARCH DATA			QUICK STUDY LOOKUP 🗸 🔮 MY DATA RE	QUESTS 🗵 IDA SIM 🗸
A Phase II Open Label, Dose-Escalation Study to Deter Homozygous Familial Hypercholeterolemia	mine the Safety, Tolerability and Efficac	y of Microsomal Triglyceride Tra	nsfer Protein (MTP) Inhibitor BMS-201038 in Patie	nts With
Study Details Administrative Details Download Data Packag	e			
OWINLOADABLE DATA PACKAGE - PRESS DOWINLOAD BUTTON FC	R EACH FILE			
Filename test IPD.xlsx	Size 6.00kB	Uploaded By Jessica B Baker	File Type IPD	Download
Filename Test Protocol.docx	Size 13.00kB	Uploaded By Jessica B Baker	File Type Protocol with Amendments	Download
Filename Test SAP.docx	Size 13.00kB	Uploaded By Jessica B Baker	File Type Statistical Analysis Plan	Download
Filename TestFile.docx	Size 12.00kB	Uploaded By Jessica B Baker	File Type Data Dictionary	Download
How To Guide Privacy Cookie Policy EEA Disclosure Policy Conta	ct Us			& Copyright 2017 - 2018 V



5. Depending on your browser, a pop-up will appear:

Figure 30 - Downloadable data file selection pop-up

- 6. Select the target file, choose whether you would like to Save or Open the files and click **Ok**.
- 7. Repeat Step 6 for any additional files.

15.0 Feedback and Support

If you need technical help with your research environment, please email Vivli at <u>support@vivli.org</u> and we will assist you as soon as possible. Please provide as much information as you can to the problem, including the research proposal number, the time the problem and any messages you received from the platform occurred as this will make it easier for Vivli to diagnose and fix the issue.

If you ever have thoughts on how to improve the system or processes, please email <u>support@vivli.org</u> or reach out to Vivli via chat. When you have completed your project, Vivli will ask you to complete a short survey to help us continue to improve.