

Vivli Study Submission Guide Vivli Platform Version 3.3 28 February 2024

1 Table of Contents

<u>1</u>	SUBMITTING STUDIES ON VIVLI – OVERVIEW
1.1	LOGIN/ACCOUNT SETUP
1.2	DASHBOARD
<u>2</u>	STUDY SUBMISSION
2.1	INFORMATION ABOUT YOUR TEAM
2.2	YOUR ORGANIZATION
2.3	Your Study10
2.4	DATA SHARING SETTINGS
2.5	AGREEMENTS
<u>3</u>	DATA PACKAGE UPLOAD
3.1	DATA PACKAGE REQUIREMENTS
3.2	DATA PACKAGE UPLOAD
<u>4</u>	MANAGING YOUR SUBMISSION
4.1	SUBMISSION STATUS
4.2	MAKING EDITS
4.3	WITHDRAWAL
<u>5</u>	VIEWING YOUR STUDY DETAILS
5.1	Using Vivli Search
5.2	STUDY DETAILS
5.3	STUDY DOCUMENTS
5.4	Administrative Details
5.5	USAGE
5.6	Adding Research Team Members to your study submission
5.7	INTEGRATING ORCID FOR RESEARCH TEAM MEMBERS
<u>6</u>	CONTACT THE VIVLI TEAM
6.1	USING THE PLATFORM CHAT
6.2	E-MAIL VIVLI SUPPORT

1 Submitting Studies on Vivli – Overview



- Vivli is here to make it as efficient and easy as possible to share your human-subject participant level data and supporting documents. The Vivli team will support you every step of the way. For more information, please see our webpage on <u>How to Share Data</u>.
- Once you have created your Vivli account, you will be prompted to provide information about your study.
- The <u>Vivli Data Contribution Agreement</u> needs to be read, understood and signed by the Principal Investigator and an institution official.
- Vivli only accepts anonymized data. Your institution may provide support or Vivli has anonymization vendors who will offer support for this service.
- Once the submission has been accepted by the Vivli team, you will then be able to upload your anonymized data.
- Please note that this process is primarily intended for academic researchers. Please <u>reach out to</u> <u>Vivli</u>, if you are a for-profit organization and want to take advantage of the Vivli platform to share your completed clinical research data.

This process is for <u>sharing</u> your data on the Vivli platform. If you are interested in <u>requesting</u> data, please submit a Data Request. See our <u>How-to guide</u> on submitting a Data Request.

1.1 Login/Account Setup

- To get started with the Study Submission process, visit <u>https://search.vivli.org/study-submission</u>
- If you do not already have a Vivli user account, click the 'Create Account' button. To learn more about creating a Vivli account, please review our <u>Vivli User Account Quick Start guide</u>.

• Vivli	Home	About	Members	News &	Events Re	sources	Find Stu	lies	
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Create an account on Vivii P and about your study Vivii is here to make it as efficient and easy as possible to share your human-subject participant level data and supporting documents. The Vivii team will support you every step of the way. For more information, please see our webpage on <u>How to Share Zata</u>									
As a first step, please create an account or login to the platform. Create Account Login Login									
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• If you are already a Vivli user, click the "Login" button.

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1.2 Dashboard

- Once you have logged into the platform, if you have already begun to create submissions, your account dashboard will appear.
- To submit a new study for sharing, first click the "+ Add Submissions" button on the left panel and then click the blue "Add Submission" button in the upper right corner.

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• If you do not have any active submissions, the platform will initiate a new draft submission. Click on the "Information About Your Team" tab to begin completing the submission form.

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3. Your Study					
4 Data Sharing Settings					
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6. Upload Data					
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• At any time, to navigate back to your dashboard, click on the "Go back" button and the left panel will then display "Dashboard" at the top. Please make sure to click "Save" to save any changes.

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2. Your Organization	Conditions	Corona Virus Infection, Acute Respiratory Distress Syndrome, SARS-CoV Infection	
3. Your Study	Interventions	Losartan, Placebo	
4 Data Sharing Settings	Phase	Phase2	
5. Agreements	Please include citat	ions of any primary manuscripts and include any additional information that may be helpful to a researcher when requesting this data.	0
6. Upload Data			

If at any time you are redirected from the Study Submission page within your dashboard, please

navigate to <u>https://search.vivli.org/study-submission</u> and this will bring you back to the Study Submission page.

2 Study Submission

2.1 Information About Your Team

The names that you enter using "Add Team Member" will get public recognition for their contributions to the study. You can select one or more CRediT roles - for a list of the available roles and descriptions, click on the Help icon at the top of the field. See the following diagram as to why this is important and then follow the steps in this section to provide your team with CRediT.



• Use the "Add Team Member" button to add all research team members to the study

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3. Your Study	Add Team Member Next Page	
4. Data Sharing Settings		
5. Agreements		
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- Complete all required fields:
 - Email Address: Enter the best email address of each research team member
 ORCID ID: Enter the ORCID ID of each research team member. If a research team
 member does not have an ORCID ID, remove the team member by clicking the red "X" as this is a required field.

< Go Back Status: Draft			Withdraw Save Submit
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2. Your Organization	The names that you enter using "Add Team Member" will get public rec on the Help icon at the top of the field.	ognition for their contributions to the study. You can select one or more CR	lediT roles - for a list of the available roles and descriptions, click
3. Your Study	Email address	(D) ORCID iD	CRediT Role(s)
	academicsubmitter@gmail.com	0000-1111-0000-0000	Data curation × Project administration × × V
4. Data Sharing Settings	Given Name	Family Name	
	Jane	Smith	
5. Agreements	ROR Id	Organization	
History			
	Add Team Member	Next Page Send Invitations to Team	Members
Chat			

- If, at any time, the research team member creates an ORCID ID, the team member may be added back into the research team for your study. (If you have already submitted the study, just ask the Vivli team to add the team member by emailing support@vivli.org or by sending a message in chat)
- Given Name: Enter the given name, or first name, of each research team member
- Family Name: Enter the family name, or last name, of each research team member
- CRediT Roles: Select CRediT role(s) for each team member from the list that appears in the dropdown box: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.

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Information About Your Team Z. Your Organization	TELL US ABOUT THE RESEARCH TEAM The names that you enter using "Add Team Member" will g Help icon at the top of the field.	et public recognition for their contributions to the study. You can selec	t one or more CRediT roles - for and of the available roles and des	riptions, click on the
3. Your Study 4. Data Sharing Settings	Email address datarequester.vivli@gmail.com Given Name	ORCID ID 0000-1111-0000-0000 Family Name	CRedit Role(s) • - Select Multiple -	, in the second se
5. Agreements	Sally ROR Id	Smith Organization	Eurospitalization Data curation Formal analysis Euroding acquisition	•
6. Upload Data History	Add Team Member	Next Page S	Investigation Send Invitations to carm M Methodology Protect administration	
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■ For m	nore information regarding	g CRediT roles , please visit		e Copyright 2017 - 2024 Viv

- For more information regarding CRediT roles , please vis https://credit.niso.org/.
- The following fields are automatically updated from ORCID once the user authorizes with ORCID:
 - ROR Id: Research Organization Registry (ROR) of each research team member's organization.
 - Organization: The organization each research team member is associated with in regard to their involvement in this study
- Once all fields for the first team member are complete, use the "Add Team Member" button to create additional entries.

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3. Your Study	Email address datarequester vivli@ormail.com	D	ORCID ID 0000-1111-0000-0000	CRediT Role(s)	Validation ×	x
4. Data Sharing Settings	Given Name Jane		Family Name Smith	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		8
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2. Your Organization	Email address datarequester.vivli@gmail.com	ORCID iD 0000-1111-0000-0000	CRediT Role(s) Methodology X Validation X X V
3. Your Study	Given Name Jane	Family Name Smith	0
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3. Upload Data	Email address datacontributor2@gmail.com	ORCID iD 0000-0001-6752-5707	CRediT Role(s) Project administration x Resources x Software X
fistory	Given Name Kelly	Family Name Sharp	
Chat	ROR Id	Organization	
	Add Team Member	Next Page Send	Invitations to Team Members
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- Click the "Send Invitations to Team Members" button. This email will be sent once the submission is finalized and will prompt Research Team Members to update their ORCID credits. See <u>section</u> <u>5.7, Integrating ORCID for Research Team Members</u>
- Once all team members have been entered and roles have been assigned, hit "Save" and click "Next Page" button to navigate to the next section.

2.2 Your Organization

- Enter the name of the Organization/Institution that will be displayed as the Data Contributor for the study and the number of studies that will be submitted. Please note that each study will need to be submitted separately.
- If you plan to submit more than two studies, use the "Contact Us" button so that we can make the submission process more efficient for you.
- Once these fields are complete, hit "Save" and use the "Next Page" button to navigate to the next section.

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2. Your Organization	TELL US ABOUT YOUR ORGANIZATION Enter the full name of your organization
3. Your Study	Boston University
4. Data Sharing Settings	How many studies do you expect to submit at this time 1
5. Agreements	If you have more than 2 studies that you want to share at this time, please contact Vivil by emailing support@vivil.org as we have other ways to make this process more efficient for you.
6. Upload Data	Contact Wv4 Next Page
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2.3 Your Study

• If your study is registered on clinicaltrials.gov and has an NCT ID, enter the registration ID from clinicaltrials.gov. This will automatically populate the Title, Conditions, Interventions and Phase information from clinicaltrials.gov.

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2. Your Organization	TELL US ABOUT YOUR STUDY Enter the registration ID from clinicaltrials gov. This will bring in information about your study from clinicaltrials gov. If you want to submit a study that has not been registered on clinicaltrials nov. reach out to support@vxil.org.	
3. Your Study	Shufu is not listed on Clinical Trials over	
4. Data Sharing Settings	Notion State Laboration Contrain Trade 300 NCT06773040	
5. Agreements	Title A Phase 1 Study of JV-213 Autologous CD79b-targeting Chimeric Antigen Receptor T-cell Therapy in Adults With Relapsed or Refractory B-cell Lymphomas	
6. Upload Data	Conditions Lymphomas, B-cell Lymphomas	
History	Interventions JV-213, Leukapheresis	
	Phase Phase1	
Chat	Please include citations of any primary manuscripts and include any additional information that may be helpful to a researcher when requesting this data.	
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• If your study is not registered on clinicaltrials.gov and, therefore, **does not have an NCT ID**, check the box that says "Study is not listed on clinicaltrials.gov".

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5. Agreements	Title	
6. Upload Data	Conditions	
History	Interventions Phase	
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- Enter the Sponsor Protocol ID, Title, Conditions, Interventions, and Phase, according to your study. Note: Sponsor Protocol ID is a mandatory field to complete. (This may be an internal ID or acronym for your study. If you do not have a Sponsor Protocol ID, reach out to Vivli and we will create one for you.)
 - Title, Conditions, and Interventions are free text fields, and you may enter multiple conditions and interventions, if applicable.
 - o If the Interventions or Conditions field is not applicable to your dataset, enter "N/A".
 - If the Phase field is not applicable to your dataset, select "N/A" from the dropdown menu.

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5. Agreements	Title	A Phase 1 Study of JV-213 Autologous CD79b-targeting Chimeric Antigen Receptor T-cell Therapy in Adults With Relapsed or Refractory B-cell Lymphomas	_
6. Upload Data	Conditions	Lymphomas,B-cell Lymphomas	
History	Interventions	JV-213,Leukapheresis	
Chat	Filase	Phase 3a	
	Please include citation	ns of any primary manuscripts and include any additional information that may be helpful to a researcher when requesting this data. 🛛 🛛	
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- Any information that you provide in the "Additional Information" field will be visible to researchers searching for studies. You can include any citations related to your clinical research, or any other information that might be used by the researcher to determine whether your study will support their research.
- Search ROR to add Funding Organization(s). Use the search field to search for the primary funder. If the study was funded by your organization, leave this blank. If it was funded by an external funder, type in the name of the funder in the free-text box and select "Search ROR". A box will appear. Choose the name of the organization from the list that appears inside of the box and select "OK".

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3. Your Study	Please provide a contact email at your organization for invoicing
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5. Agreements	SEARCH ROR TO ADD FUNDING ORGANIZATION Suggested Organization Name
6. Upload Data	NH Search ROR
History	
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• Check the appropriate funder name

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	Find ROR Organization
	Please select the best-matching ROR organization. If no ROR organizations appear, please cancel and enter a different name.
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	Foundation for the National Institutes of Health: (http://www.fnih.org/) Location: Bethesda
	National Institute of Health: (http://mh.org.pk/) Location: Yerevan National Institute of Health: (http://mh.org.pk/) Location: Islamabad
	National institute of hydrology (http://www.nih.gov/) Location: Robinee National Institutes of Health: (http://www.nih.gov/) Location: Bethesda Parent: United States Department of Health and
	Carcel

• Once the funder is added and saved, you will see a table appear at the bottom of "Your Study" page listing funder(s) and associated ROR information.

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1. Information About Your Team	Phase Phase 3a	
2. Your Organization	Please include citations of any primary manuscripts and include any additional information that may be helpful to a researcher when requesting this data.	0
3. Your Study	Please provide a contact email at your organization for invoicing	
4. Data Sharing Settings		
5. Agreements	SEARCH ROR TO ADD FUNDING ORGANIZATION	
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• To add an additional funder, repeat the steps by typing in the name of the additional funder in the free text box and selecting "Search ROR". Choose the name of the organization from the box that appears and select "OK". You will see the additional funder's information listed in the table as an entry below the originally selected funder.

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3. Your Study			
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Chat	Ror Name: Wellcome Trust. Ror ID: https://ror.org/029chgv08	Grant or Contract Id	Delete X
	Parent Ror Name: Parent Ror ID:		
	Next Page		

- Repeat this process as needed, to add additional funders.
- To delete a funder, select the button that says "Delete" and then select "Save".

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3. Your Study		
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6. Upload Data	Ror Name: Wellcome Trust Ror ID: https://ror.org/028chgv08	Grant or Contract Id
History	Parent Ror Name: Parent Ror ID:	1 Delete X
Chat	Ror Name: Foundation for the National Institutes of Health Ror ID: https://ror.org/00k85s890	Grant or Contract Id
	Parent Ror Name: Parent Ror ID:	
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How To Guide Privacy Cookie	Policy EEA Disclosure Policy Contact Us	@ Cxpyright 2917 - 2023 Vivi

• Depending on your selection, you may be prompted to provide a contact email address for invoicing.

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< Go Back Effects of Costovert Status: Draft	ebral Joint Mobilization on Respiratory Function in Asthmatic Patients		Withdraw	ve Submit
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2. Your Organization	Phase Phase 3a			
3. Your Study	Please include citations of any primary manuscripts and include any additional information that may be helpful to a researcher when requesting this dat	a. 🚺		
4. Data Sharing Settings				_
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6. Upload Data	SEARCH ROR TO ADD FUNDING ORGANIZATION			
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	Ror Name: Foundation for the National Institutes of Health Ror ID: <u>https://ror.org/00k85s890</u> Parent Ror Name: Parent Ror ID:	Grant or Co	ntrac	Delete X
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- If your academic institution is a member of Vivli there is no cost to deposit data in Vivli's platform starting in 2023. Please check our <u>members</u> page if you are unsure of the status of your institution.
- If your academic institution is not a member, there is a one-time cost to use Vivli's managed access process for clinical trials data. These costs apply only for academic and non-profit researchers who want to share their clinical data. Visit our <u>Share Data</u> page for more information on costs associated with sharing your data. If you are from a for-profit organization please <u>reach out to Vivli</u> and we can discuss how you can take advantage of the Vivli platform to share your completed clinical research.
- Once all fields have been complete, hit "Save" and click "Next Page" to navigate to the next section.

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CENTER FOR GLOBAL CLINICAL RESEARCH DATA					ENQUIRY	QUICK	STUDY LOOKUP	🗸 😁 MY DATA RE	QUESTS 🧕	DATA REQUESTER	~
< Go Back Status: Draft								Withdraw	Save	Submit	
1. Information About Your Team	Title	Randomized Controlled Trial of Losartan for Patient	s With COVID-19 Requiring Hospital	ization							'
2. Your Organization	Conditions	Corona Virus Infection, Acute Respiratory Distress S	Syndrome, SARS-CoV Infection								
3. Your Study	Interventions	Losartan, Placebo									
4. Data Sharing Settings	Phase	Phase2									
5. Agreements	Please include citati	ons of any primary manuscripts and include any additional in	formation that may be helpful to a resea	rcher when requesting this data	9.					0	
6. Upload Data											
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Chat	Please provide a co	tact email at your organization for invoicing								0	
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2.4 Data Sharing Settings

- Accelerated Review -- When a research team requests your study, an Accelerated Research Proposal Review will be conducted within 3 business days. Vivli will manage the execution of the Data Use Agreement. Once these steps are completed, the Vivli team will work with the researcher to access the data and support them until they have published their results. If you have any questions about this process, please reach out to the Vivli team in chat. See <u>Section 6.1 Using</u> the Platform Chat
- **Embargo** -- If you need to embargo your data, we will make the study available for researchers to request, but the data itself will not be provided until the embargo date has passed. This might be necessary, for example, if the data itself cannot be provided until the results of the study are published. Select yes and provide a Embargo date for this option.

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3. Your Study	completed. Be Mid-base efficiency with the researcher to access the data and support them until they have published their results. If you have any questions about this process, please reach out to the VMI to Does your data need to be embargoed?	am in chat.
4. Data Sharing Settings	© Yes ○ No	
6 Agreements	Embargo data unti IDRAMIYY	
6. Upload Data	Data requesters may want to contact you for questions and/or collaboration. Are you willing to be available by email to requesters?	Θ
History	Yes No All data provided to Vivil must be anonymized. Will you need help anonymizing your data?	0
Chat	⊖Yes ⊛No	
	Study data packages must include at least 4 file types - click here for more information.	
	Not Page	
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- If you are willing to be contacted, the Vivli team will email you any requests for collaboration or questions. Making yourself available for contact does not imply a commitment to collaborate on any or all requests it is your decision to answer questions or collaborate on a case-by-case basis.
- The email address used for the submission will be used as the contact email for this study if you select 'Yes'.

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4. Data Sharing Settings	Does your data need to be embargoed?	0
5. Agreements	Data requesters may want to contact you for questions and/or collaboration. Are you willing to be available by email to requesters?	0
6. Upload Data	All data provided to Vivii must be anonymized. Will you need help anonymizing your data?	0
History	⊖ Yes @ No	
Chat	Study data packages must include at least 4 file types - click here for more information. Next Page	
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• If you need help anonymizing your clinical research data, Vivli can connect you with vendors who can help. Please note that it is the data contributor's responsibility to ensure that the data is appropriately anonymized.

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1. Information About Your Team		^
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	Does your data need to be embargoed?	0
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5. Agreements	Data requesters may want to contact you for questions and/or collaboration. Are you willing to be available by email to requesters?	0
	⊖ Yes @ No	
6. Upload Data	All data provided to Vivil must be anonymized. Will you need help anonymizing your data?	0
History	© Yes ONO	
	We will connect you with a vendor who will help with your data anonymization. Please note that a third-party agreement with the anonymization vendor and additional anonymization charges will apply.	
Chat		
	Study data packages must include at least 4 file types - click here for more information.	
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• Once all Data Sharing Settings have been selected, hit "Save" and use the "Next Page" button to navigate to the next section.

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	Does your data need to be embargoed?	0
Data Sharing Settings	⊖ Yes	
Agreements	Data requesters may want to contact you for questions and/or collaboration. Are you willing to be available by email to requesters?	0
	⊖Yes ⊚No	
Upload Data	All data provided to V/vli must be anonymized. Will you need help anonymizing your data?	0
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	Vivi will connect you with a vendor who will help with your data anonymization. Please note that a third-party agreement with the anonymization vendor and additional anonymization charges will apply.	
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2.5 Agreements

• Click the blue "Sign Data Contribution Agreement" button. This will open a new browser tab to begin the DocuSign legal agreement signing process that will allow you to provide some basic information about you and your organization.

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1. Information About Your Team							^
2. Your Organization	AureEment IS The Principal Investigator and an Institutional Official will need to read, acknowledge, and sign this Data Contribution Agreement (DCA). If yo already base a Master DCA in place, we do not require inditutional signature for future submissions. If you are unsure whether your inditinonal	ur institutio	n				
3. Your Study	agreement in place, please reach out to <u>support@vvvl org</u> . Click below to start the signing process.	nus a mus					
4. Data Sharing Settings	Sign Data Contribution Agreement						
5. Agreements	At a minimum, Wvi will make the data available for 10 years. On an ongoing basis, Vvil evaluates its data holdings with regard to maintaining reserves the right to discontinue the distribution of data collections when deemed appropriate.	g access ar	nd				
6. Upload Data	WHAT'S NEXT						
History	Once you have initiated the Data Contribution Agreement signing process, please click the Submit button, if available, to notify Vivi to begin the study.	processing					
Chat	Once the study is processed and the Data Contribution Agreement signed, the study will appear in the Vivil Search and you will receive an er inviting you to upload the anonymized data. Follow the link in the email or return to the Submissions tab, choose this submission and choose Data."	mail from Vi "Upload	wli				
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• The Principal Investigator and an Institutional Official will need to read, acknowledge and sign this <u>Data Contribution Agreement (DCA)</u>. If you don't know who your institution official is, in most organizations a good place to start is the Grants and Contract office. See an example email template to send to this office that provides instructions <u>here</u>.

- Instructions for signing the agreement:
 - 1. The DocuSign PowerForm provides basic instructions for you, institutional official. When you are ready to sign the agreement, please provide the Full Name and email address in both the Principal Investigator and Institutional Official fields.

If you are not the PI of the study, you may enter your contact information in the last section if you wish to be copied on communication for visibility. Next, click "Begin Signing."

PowerForm Signer Information

Thank you for your interest in sharing your studies using Vivli.

The Principal Investigator and an Institutional Official will need to read, acknowledge and sign this Data Contribution Agreement (DCA). If you don't know who your institution official is, in most organizations a good place to start is the Grants and Contract office. See an example email template to send to this office that provides instructions here: https://vivii.org/template-email-fordata-contributors/.

The DCA provides the principal investigator and the institution to be a third-party beneficiary to any subsequent Data Use Agreement (DUA) that is signed when your data is requested.

The DUA runs between Vivil and an applicable Data User and is the agreement under which Vivil grants a data user limited rights to use the data and licenses back to the applicable Contributor for any newly created intellectual property. The Vivil agreements are the product of extensive negotiation with the organizations that contribute data to Vivil, and as such, the agreement is nonnegotiable.

PowerForm Signer Information

Thank you for your interest in sharing your studies using Vivli.

The Principal Investigator will need to read and acknowledge, and an Institutional Official will need to sign this Data Contribution Agreement (DCA).

The DCA provides the institution to be a third-party beneficiary to any subsequent Data Use Agreement (DUA) that is signed when your data is requested. The DUA runs between Vivli and an applicable Data User and is the agreement under which Vivli grants a data user limited rights to use the data and licenses back to the applicable Contributor for any newly created intellectual property. The Vivli agreements are the product of extensive negotiation with the organizations that contribute data to Vivli, and as such, the agreement is non-negotiable.

If you don't know who your institution official is, in most organizations a good place to start is the Grants and Contract office. See an example email template to send to this office that provides instructions here: https://vivli.org/template-email-fordata-contributors/.

Please enter contact information for the Principal Investigator (PI) and Institution Official below.

Once you click the "Begin Signing" button below, the Data Contributor Agreement will first be sent to the PI to complete their acknowledgment and provide information regarding the study. The subject line of this email will be "Please DocuSign: Vivli Academic Data Contributor Agreement".

Once the PI submits the envelope, it will be sent to the Institution Official for signature.

Once the Institution official signs the agreement, it will be sent to Vivli to be fully executed. You will receive an email from Vivli with the fully executed copy and next steps for Data Upload once the Once the Institution official signs the agreement, it will be sent to Vivli to be fully executed. You will receive an email from Vivli with the fully executed copy and next steps for Data Upload once the Data Contribution Agreement is complete.

If you are completing this form but are not the PI or institution official and would like to be copied on the envelope, you may add your contact information in the "Proxy" field.

If you have any questions, please reach

Please enter your name and email to begin the signing process.

Required* Contact information for the Principal Investigator of the study
Your Name: *
Full Name
Your Email: *
Email Address
Please provide information for any other signers needed for this document.
Required* Contact information for the person responsible for signing on behalf of your organization
Name:
Full Name
Email:
Email Address

Name:]
Full Name	
Email:	
Email Address	
If you are not and would like	the PI but you are completing this form to be copied for visibility
If you are not and would like Name:	the PI but you are completing this form to be copied for visibility
If you are not and would like Name: Full Name	the PI but you are completing this form to be copied for visibility
If you are not and would like Name: Full Name Email:	the PI but you are completing this form to be copied for visibility
If you are not i and would like Name: Full Name Email: Email Address	the PI but you are completing this form to be copied for visibility

2. Click the box that says you agree to use electronic records and signatures. Then, click Continue.

|--|

3. The Principal Investigator will need to complete the required fields (outlined in red), including Organization Name (p.1), Business Address (p.1 and p.6), Acknowledgement (p.8), NCT ID or Sponsor Protocol ID (p.9), and Agreed and Acknowledged (p.11). Once all required fields have been completed, click the yellow "Finish" button:

Enter your title							FINISH	FINISH LATER	OTHER ACTIONS •
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4. The agreement will then be routed to the Institutional Official for signature.

- Once you have signed the agreement it will be sent to an individual who can sign on behalf of your organization. If you have any questions about this process, please use the chat function.
- After you have <u>initiated</u> the DCA process, you must <u>click the "Submit" button</u> in the upper right corner to begin the Vivli review process. You do not need to wait for the Data Contribution Agreement to be executed before you submit.



• Once the study has been submitted, your study will automatically appear in the Submissions dashboard under "In Progress."

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Data Requests	Title	Status	NCTID	Submitt	ed V
Submissions	Randomized Controlled Trial of Losartan for Patients With COVID-19 Requiring Hospitali	Submitted	NCT04312009	2023-01-05	
Availing Upload	University of Washington Akteemen's Disease Research Center (UW ADRC) Imaging &	Study in Curation	NCT04437290	2022-12-08	
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• You will not be able to upload your anonymized data until the metadata has been curated, your Data Contribution Agreement has been executed and the study has been posted/accepted. When this is complete, you will be notified via email.

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2. Your Organization Vour requised You will be able to upload the data when it has been accepted and the Data Contribution Agreement has been executed. 3. Your Study Study data packages must include at least 4 file types - click here for more information. • If any of these files are not awareable, besen enclide a placeholder file stating that it is not available. When you are ready to upload data to the Vivi Pittorm, if the anonymized Individual Participant-tweet Data are held in several files, we recommend that you zo them into a single Data file. We recommend that you load other accompanying documents as separate files. 6. Uplead Data Lubes Sharing Settings	1. Information About Your Team								^
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• To view the history of the Study Submission, click on the tab that says "History".

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Information About Your Team	Date and Time	Action	Perf	ormed By			
Your Organization	8/14/23 8:25 pm	Status changed to Submitted to Vivli.	Data	Requester	r Datarequester.vivli@gmail.com	n	
Your Study	8/14/23 8:34 pm	Status changed to Study In Curation.	Stan	Neumann	sneumann@vivli.org		
Data Sharing Settings	8/14/23 9:12 pm	Status changed to Approved/Posted.	Stan	Neumann	sneumann@vivli.org		
Agreements							
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• This will show you the history of the submission with details that show the date and time of an action performed, and who the action was performed by (e.g. date of submission, date the study is sent to curation, date the study is posted to the Vivli platform etc.)

3 Data Package Upload

3.1 Data Package Requirements

- It is expected that all data packages will include the following 4 file types to support the researcher's use of your data:
 - Study Protocol Final protocol with all amendments
 - **Data Dictionary** Detailed descriptions of each variable in the dataset, including the definition, source, coding, etc. of the variable
 - Statistical Analysis Plan Description of the principal features of the analysis described in the protocol
 - o IPD Dataset Final cleaned individual participant-level data, anonymized
- Any other documents that may be useful to the researcher can be included and will be welcomed.
- If any of these files are not available, please include a placeholder file stating that it is not available.
- When you are ready to upload data to the Vivli Platform, if the anonymized Individual Participantlevel Data are held in several files, we recommend that you zip them into a single Data file. We recommend that you load other accompanying documents as separate files.

3.2 Data Package Upload

- Once the Data Contribution Agreement is executed and the study is posted, the study will appear in the Vivli Search
- You will receive an email from Vivli inviting you to upload the anonymized data and supporting documents. Follow the link in the email or return to the Submissions tab, choose your Submission

under Approved/Posted section. (Note: You will be unable to upload any data or documents until the Data Contribution Agreement is executed.)

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Studies	Draft In Progress Approved/Posted Withdrawn 4 16 5 2			لي + Add Submission
Data Requests	Title	Status	NCTID	Approved
	Ϋ		7	▽
Submissions	Survey on the Human Papilloma Virus Vaccination in Girls With Cystic Fibrosis Followed	Approved	NCT03653377	2023-08-14
Awaiting Upload	A Randomized Controlled Adaptive Study Comparing COVID-19 Convalescent Plasma (Approved	NCT04421404	2023-01-13
	Examining Neurocognitive Profiles of Bipolar Disorder and Attention-Deficit Hyperactivity	Approved	NCT00961935	2023-01-13
	Stanford Accelerated Intelligent Neuromodulation Therapy for Treatment-Resistant Depre	Approved	NCT03068715	2023-01-12
	Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Disorders	Approved	NCT01243606	2023-01-06
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• From the Dashboard, under 'Approved/Posted,' click on the study for which you are ready to upload your anonymized data.

Vivl	i		Home About Members	News & Events Resources Find Studies
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Research Environments	Draft In Progress Approved/Posted Withdrawn			+ Add Submission
L Studies	Title	Status	NCTID	Annroved
Data Requests	1116	∀	γ γ	× ×
Submissions	Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Disorders	Approved	NGT01243606	2023-01-06
Awaiting Upload				
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• Click on the 'Upload Data' tab and then you may use either the blue 'Select Files' button or drag and drop the appropriate files.

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1. Information About Your Team	UPLOAD THE STUDY DATA
2. Your Organization	Your request has been accepted and the Data Contribution Agreement has been executed - your study is available for requesting. Please upload the data below.
	Study data packages must include at least 4 file types - click here for more information. •
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4. Data Sharing Settings	several files, we recommend that you zp them into a single Data file. We recommend that you load other accompanying documents as separate files.
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• Use the dropdown menu on the right-hand side to validate the File Type for each file before submitting files (Note: If you are missing the protocol, data dictionary, or Statistical analysis plan, please create a Word file with a note saying this is unavailable and upload it as a placeholder and validate the file type from the list available).

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2. Your Organization	held in several flies, we recommend that you zip them into a single Data file. We recommend that you load other accompanying documents as separate files.									
3. Your Study	Upload study Data Package below									
4. Data Sharing Settings	Select Files		Unknown							
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6. Upload Data	DIG Data Dictionary Documentation.pdf	118.00kB	Statistical Analysis Plan Analysis-Ready Dataset	Data Diction	ary 🗸 🗸	Download 🕁	Delete X			
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- Click the button that says "Verify Upload" to confirm that your files have been successfully uploaded.
- A pop-up will appear at the bottom right screen that says "All data has been successfully uploaded and stored in the system"

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3. Your Study	Filename Data Dictionary.docx	Size 11.73kB	Uploaded By Data Requester	File Type Data Dictionary	V Download 🕁	Delete X
4. Data Sharing Settings	Filename IDP.docx	Size 11.71kB	Uploaded By Data Requester	File Type IPD	V Download 🕁	Delete X
5. Agreements	Filename Protocol.docx	Size 11.72kB	Uploaded By Data Requester	File Type Protocol	V Download 🕁	Delete X
6. Upload Data	Filename SAP.docx	Size 11.73kB	Uploaded By Data Requester	File Type Statistical Analy	V Download 🕁	Delete X
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• Ensure all the files are loaded, then click the 'Submit Files' button.

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• You will be directed to a pop-up confirming that you have uploaded all files and assigned file types. Click the blue 'Yes' button to proceed.



• You will receive confirmation of successful upload. Click the 'Continue' button to return to your submission.



• Once study documents are uploaded, if there are further documents that are available for your study at an external link, and you would like to provide a link to the documents, click the button that says "Add New Link".

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• In the box that appears, type in the Title of the document and the URL and then click "Save"

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

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4 Managing your Submission

4.1 Submission Status

• You may check the progress of your submission via the Submissions dashboard. Once the study information has been accepted by a Vivli admin, the study will undergo metadata curation, and the status will appear in the dashboard as "Study in Curation."

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Submissions	Randomized Controlled Trial of Losartan for Patients With COVID-19 Requiring Hospitali	Study in Curation	NCT04312009	2023-01-05	
	University of Washington Alzheimer's Disease Research Center (UW ADRC) Imaging &	Study In Curation	NCT04437290	2022-12-08	
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4.2 Making Edits

- Once your submission has been submitted, you will be unable to make any changes. Please contact Vivli via chat or email at support@vivli.org if you need to make any changes to your submission.
- The Vivli team may send your submission back to drafts to request revisions. You will receive an email notification if you need to make updates to your submission.



4.3 Withdrawal

• You may withdraw your submission at any time while it is in the Draft state by clicking the blue "Withdraw" button in the upper right corner.

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1. Information About Your Team	Date and Time	Action	Performed By	Â
2. Your Organization	1/17/23 1:38 pm	Status changed to Submitted to Vivli.	GabbyTesting greganivli@gmail.com	
3. Your Study	1/17/23 1:39 pm	Status changed to Draft status (reset).	Gabby Regan gregan@i+ifi.org	
4. Data Sharing Settings				
5. Agreements				
History				
Chat				
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• Once you have submitted the study, you will need to contact Vivli via chat or email at support@vivli.org to withdraw.

5 Viewing your Study Details

5.1 Using Vivli Search

• To search for your study on Vivli, open https://search.vivli.org in your browser. Type in the clinicaltrials.gov identifier/NCT ID in the box marked 'What are you looking for today?' a '1' should appear on the blue bar at the bottom of the screen. Click the bar to view the results.

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• Verify that the correct study has been identified and click the 'View Study Details' button on the right to pull up the metadata for your submission.

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5.2 Study Details

• The first tab of the study listing contains the metadata pulled from clinicaltrials.gov and any additional metadata for the submission.

Using publicly available information and what you have provided to us, we have included key metadata elements. Of course, you can always send us additional information or updates for inclusion to add to the metadata about your study at any time either through chat or by emailing support@vivli.org.

Vivli			Home	About	Members	News & Events	Resour	rces Find Studies
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Efficacy Evaluation of a Unified Transdiagnostic	Treatment for Anxiety Disorders							
Study Details Study Documents Administrative Det	ails Usage Research Team							
Phase NA		Condition or Disease Anxiety Disorders, Mood Disorders						
Intervention/treatment Single Diagnosis Treatment Protocol, Unified Protocol (UP)								
Brief Summary Anxiety disorders are common chronic costly debilitation to g	alliv of life, and are more							
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during the last decade has revealed that commonalities in etio these disorders supersedes differences. At the same time, exa	ogy and latent structure among mination of extant single							~
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18 Years and older	All	No			250			
Locations								_
How To Guide Privacy Cookie Policy EEA Disclosure Policy	Contact Us							@ Copyright 2017 - 2023 1

5.3 Study Documents

The 'Study Documents' tab is provided to share documents with searchers to help them determine whether the dataset can support their research - this typically will include documents like the Data Dictionary or the Protocol. A Vivli admin will upload supporting documents once the study data has been uploaded. The study documents should not include the anonymized individual participant-level data. The 'Study Documents' tab will initially appear empty. Once your supporting documents are uploaded by the Vivli admin, they will be appear in the 'Study Documents' tab.

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Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Disorders				Â
Study Details Study Documents Administrative Details Usage Research Team				
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How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us				& Copyright 2017 - 2023 Vivli

 If there are further documents that are available for your study at an external link, and you would like to provide a link to the documents, you may do so. Please see <u>Section 3.2 Data Package</u> <u>Upload</u> for further details.

5.4 Administrative Details

• The 'Administrative Details' tab provides the Digital Object Identifier (DOI), the sponsor and other general information about the study.

You may want to use the DOI in your publication to direct researchers to where they can access the data underlying. Please see the <u>ICMJE Data Sharing Requirements</u> on Vivli website.

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Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Dis	sorders					
Study Details Study Documents Administrative Details Usage Resear	rch Team					
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Data Package DOI(s) Available for this Study https://handle.stage.datacite.org/10.70118/AQ00003191.0						
Lead Sponsor Agency Boston University Charles River Campus					Lead Sponsor Agency Other	Class
Collaborator Agency National Institute of Mental Health (NIMH)					Collaborator Agency C NIH	lass
Data Contributor Organization Name Boston University						

5.5 Usage

- The Usage tab displays the following metrics related to your study
 - **Views**: Vivli counts a view every time a user clicks on Study Details for this study in a search, or displays the DOI page for this study. In effect this counts views of the study metadata.
 - Download of Study Documents: Study Documents are documents made available to a researcher prior to requesting the study data to help them determine whether the study contains the kind of data necessary to support their research topic; this may include the data dictionary and/or a redacted protocol document. This metric counts the number of times a study document is downloaded.
 - Access of Data Packages: The data package includes the data that is provided in response to the request, and includes anonymized Individual Participant Data (IPD) and supporting documents. "Access" includes downloading the data.
 - All Usage Metrics: The data range here represents the range of dates during which the metrics above were collected. The start date is either the date the data collection feature was turned on, or the date the study was posted (whichever is later). The end date is always 3 days before the current date, since it takes the system 3 days to process and tally the raw usage data.

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CENTER FOR GLOBAL CLINICAL RESEARCH DATA.		ENQUIRY QUICK STUDY LOOKUP 🗸 👹 MY DATA REQUESTS 🜘 DATA REQUESTER 🗸
Study Details Study Documents Administrative Details Usage	Research Team	^
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All usage metrics from 01/06/2023 to 01/06/2023		
Views: Vivili counts a view every time a user clicks on Study Details for this study in	n a search, or displays the DOI page for this study. In effect this counts views of the stud	dy metadata.
Download of Study Documents: Study Documents are documents made available to a researcher prior to rr and/or a redacted protocol document. This metric counts the number of tim	equesting the study data to help them determine whether the study contains the kind of es a study document is downloaded.	data necessary to support their research topic; this may include the data dictionary
Access of Data Packages: The data package includes the data that is provided in response to the req (when allowed) downloading the data.	uest, and includes anonymized Individual Participant Data (IPD) and supporting docume	ants. "Access" includes placing the data into a secure research environment or
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5.6 Adding Research Team Members to your study submission

• The Research Team tab displays all research team members that were included as part of the study submission. If you would like to add additional research team members or correct any existing entries after submitting your study, please reach out to the Vivli admin via chat or email at support@vivli.org.

Vivli			Home About Members News & Ev	vents Resources Find Studies
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Study Details Study Documents	Administrative Details Usage	esearch Team		
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Gabriela	Regan	1234-5678-1234-5678	Data curation ×	∨
Siven Name	Family Name	ORCID ID	CRediT Role(s)	
101	Admin	1111-2222-3535-4444	Data curation ×	~

5.7 Integrating ORCID for Research Team Members

- During study submission, the dataset owner will have clicked the "Send Invitations to Team Members" Button, which sends an automatic email to researchers listed on the study after the study has been posted.
- Once an email is received, click the link within the email and you will be taken to a Vivli webpage containing the dataset title and the researcher's information.
- Click "Authorize update to ORCID".

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• You will be navigated to the ORCID login screen. Log in with your ORCID credentials.

/arning! sandbox.orcid.org is a test website. orcid.org is the official website. Sandbox only send	email messages to mailinator.com email addresses, see Sandbox FAQ for more informati	n
	Sign in	
	- Email or 16 digit. ORCID ID sheldon.russel@mailinator.com	
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	Don't have an ORCID iD yet? Register now	
	or	
	Access through your institution	
	G Sign in with Google	
	Sign in with Facebook	

• Note: If you have not completed this process with Vivli before, you will need to press the "authorize access" button that appears.



• You will be redirected back to the Vivli study page and a "work entry" will now be created in ORCID.

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Data set <i>Conceptualization, Investigation</i> DOI: <u>10.70118/EV00003888</u> CONTRIBUTORS: Sheldon Russel	Show more detail
Source: 🤣 Vivli Platform	Ō

• If there are changes to the research team (a member is deleted, or roles are updated) this will be reflected in the user's ORCID record.

6 Contact the Vivli Team

6.1 Using the Platform Chat

• Use the Chat tab on your submission to send a message to Vivli with questions or requests. We will normally respond within a day, and you will receive an email notification when a response is available.

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1. Information About Your Team						^
2. Your Organization	Send a message to Vivil with questions or requests - we will normally respond within a day, and you will receive an email notification when	a response is	available.			
3. Your Study						
4. Data Sharing Settings						
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History						
Chat	Enter message here					
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6.2 E-mail Vivli Support

• Alternatively, you may email the Vivli team at support@vivli.org.