

Vivli Study Submission Guide Vivli Platform Version 3.7 24 May 2025

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1 Submitting Studies on Vivli – Overview



- Vivli is here to make it as efficient and easy as possible to share your completed clinical research 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 – Requesting Studies</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 Section 1.0 of our <u>Vivli User Account Quick Start</u> <u>guide</u>.



• If you are already a Vivli user, click the "Login" button.



1.2 Dashboard

• Once you have logged into the platform, if you have already begun to create submissions, your account dashboard will appear. Your dashboard also contains links to Vivli resources which may be helpful to you in your study submission process

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_		This is your view of Vivli at a glance.								
2	Submissions	For an introduction to how to request studies in the Vivli Platform, click here.	How to request studies							
E	Enquiries	For an introduction to the Vivli Platform in general and guides for using the platform, click here.	How-to guides							
		To search for clinical studies and create a new data request, click here.	Search							
		To complete and submit a request for data that you have already started, click on My Data Requests.	<u>My Data</u> Requests							
		If you cannot find a specific study you need, click on Enquiry to ask about the availability of that clinical study from a Vivli member.	<u>Enquiry</u>							
		If you are an academic researcher and want to submit your study to Vivli for archive and subsequent sharing, click here to submit your study.	Share Data							
		If you have any questions, click here or email Vivli Support at <u>support@vivli.org</u> .	Contact Support							

• 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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	Characterization Of Resistance Against Live-att	tenuated Diarrhoeagenic E. Coli	Draft		NCT	02541695		NL54064.081.15	2023-04	-19

• 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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2. Your Organization	
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4. Data Sharing Settings	
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- Note: This process is to SHARE data on the Vivli platform. If you are interested in requesting data on Vivli please submit a Data Request. See https://vivli.org/resources/requestdata/ for guidance on requesting data.
- 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.

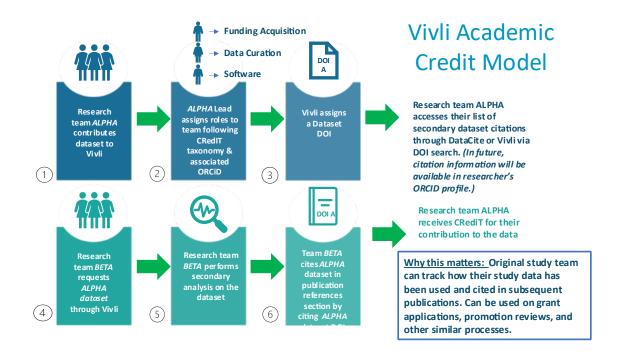
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	Title	Randomized Controlled Trial of Losartan for Patients With COVID-19 Requiring Hospitalization					
2. Your Organization	Conditions	Corona Virus Infection, Acute Respiratory Distress Syndrome, SARS-CoV Infection					
3. Your Study	Interventions	Losartan, Placebo					
4 Data Sharing Settings	Phase	Phase2					
5 Agreements	Please include cita	tions of any primary manuscripts and include any additional information that may be helpful to a researcher when requesting this dat	ita.				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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1. Information About Your Team	TELL US ABOUT THE RESEARCH TEAM
2. Your Organization	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.
3. Your Study	Add Team Member Next Page Send Instations to Team Members
4. Data Sharing Settings	Please note: This submission is for SHARING data on Vivil. If you are interested in requesting data on Vivil please submit a Data Request, see this link for guidance.
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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.

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3. Your Study	Email address janesmth@edu.org	0	ORCID ID 0000-1111-0000-0000		Fundin	Role(s) g acquisition × Project administration × ision ×	×	
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- 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 <u>support@vivli.org</u> 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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3. Your Study 4. Data Sharing Settings	Email address janesmith@edu.org Given Name	6	ORCID ID 0000-1111-0000-0000 Family Name		Func	T Role(s)	
5. Agreements 6. Upload Data	Jano ROR Id		Smith Organization		Data o	uration I analysis	
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- For more information regarding CRediT roles, please visit 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 of each research team member who is involved 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 janesmith@edu.org	0	ORCID ID 0000-1111-0000-0000		Fundin		Project administration X	×	
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5. Agreements	ROR Id		Organization						
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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 the "Next Page" button to navigate to the next section.

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Status: Draft Tell US ABOUT THE RESEARCH TEAM Your Organization TELL US ABOUT THE RESEARCH TEAM Your Study 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 - the available roles and descriptions, click on the Help icon at the top of the field. Your Study Email address Your Study ORCID ID Data Sharing Settings ORCID ID Given Name Upload Study ROR Id Upload Organization Add Team Member Next Page Send Invitations to Team Members	ANDERSO	IICHARI	rs 🙆 i	MY DATA REQUESTS	окир 🗸 🚝	JDY LOOI	QUICK STUD	ENQUIRY				R FOR GLOBAL CLINICAL RESEARCH DATA	CENTER F
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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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1. Information About Your Team	TELL US ABOUT YOUR ORGANIZATION
2. Your Organization	Enter the full name of your organization Duke University
3. Your Study	How many studies do you expect to submit at this time
4. Data Sharing Settings	1
5. Agreements	If you have more than 2 studies that you want to share at this time, please contact Vivii by emailing support@vivil.org as we have other ways to make this process more efficient for you.
6. Upload Data	Contact Vivii Next Page
History	
Chat	

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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1. Information About Your Team		
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 <u>now reach</u> out to <u>support@vvvii org</u> .	
3. Your Study	in you waik to submit a study link has not been registered on clinicalitatismo rear from to subcongrowning.	
4. Data Sharing Settings	Study is not Listed on ClinicalTrials gov	
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	
T IISON Y	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.	
How To Guide Privacy Coc	kie Policy EEA Disclosure Policy Contact Us @Computer:	2017 - 2024 Vivli

• 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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1. Information About Your Team		
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 gov, reach out to <u>support@vvil.org</u> .	
3. Your Study	NCT ID (of the form NCT12345678)	
4. Data Sharing Settings	Study is not Listed on Clinical Trials gov	
5. Agreements	Title	
6. Upload Data	Conditions	
History	Interventions Phase	
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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- 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 does not apply to your dataset, enter "N/A".
 - If the Phase field does not apply to your dataset, select "N/A" from the dropdown menu.

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1. Information About Your Team			
	TELL US ABOUT YO	UR STUDY	
2. Your Organization	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.gov, reach out to support@vivil.org.	
3. Your Study			
	Study is not Listed a	Sponsor Protocol ID	
4. Data Sharing Settings		2022-0938	
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	
	Interventions	JV-213.Leukapheresis	
History			
	Phase	Phase 3a V	
Chat			
	Please include citati	ons 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 the box and select "OK".

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1. Information About Your Team	Please include citations of any primary manuscripts and include any additional information that may be helpful to a researcher when requesting this data.
2. Your Organization	
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
6. Upload Data	Suggested Organization Name NIH Search ROR
History	
Chat	No funding organizations found
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• Check the appropriate funder name. If you typed the incorrect name, refresh your screen to search for the right Organization.

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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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	 National Institutes of Health: (http://www.nih.gov/) Location: Bethesda Parent: United States Department of Health and	
	Cancel	

• Once the funder is added and saved, you will see a table appear at the bottom of the "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	
6. Upload Data	Suggested Organization Name NIAID	Search ROR
History	Ror Name: National Institute of Allergy and Infectious Diseases Ror ID: https://ror.org/043z4tv69	Grant or Contrac
Chat	Parent Ror Name: National Institutes of Health Parent Ror ID: https://ror.org/01cwgz88	Delete X
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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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- 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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• Please fill out the Grant or Contract ID for each funder, if available.

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

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- If your academic institution is a member of Vivli there is no cost to deposit data in Vivli's platform. 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 to academic and non-profit researchers who want to share their clinical data. Visit our <u>Share Data</u> page for more information on the 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 completed, hit "Save" and click "Next Page" to navigate to the next section.

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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> <u>the Platform Chat</u>
- **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 an Embargo date for this option.

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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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• 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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• 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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Study data packages must include at least 4 file types - click here for more information.	

2.5 Agreements

• Click the blue "Begin 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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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:

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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 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

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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 it.

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2. Your Org	ganization	The Principal Investigator and an Institutional Official will need to read and acknowledge, and an Institutional Official will need to sign this Data Contribution Agreement (IDCA). If your institution already has a Master DCA in place, we do not require an institutional signature for future submissions. If you are unsure whether		
3. Your Stu	udy	your institution has a Master agreement in place, please reach out to <u>support@vtvl.org</u> . Click below to learn more about the Data Contribution Agreement and start the execution process:		
4. Data Sh	aring Settings	Begin Data Contribution Agreement		
5. Agreem	ients	At a minimum, Vivii will make the data available for 10 years. On an ongoing basis, Vivi evaluates its data holdings with regard to maintaining access and reserves the right to discontinue the distribution of data collections when deemed appropriate.		
6. Upload I	Data	WHAT'S NEXT Once you have initiated the Data Contribution Agreement signing process, please click the Submit button to notify Vivil to begin processing the study.		
History		"If the submit button is not available, required fields may be incomplete. Check that all required fields on all tabs are complete and click Submit. You will receive an email from Vivil with next steps for Data Upload once the Data Contribution Agreement is complete.		
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• Once the study has been submitted, your study will automatically appear in the Submissions dashboard under "In Progress."

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Submissions	Survey on the Human Papilloma Virus Vaccination in Girls With Cystic Fibrosis Followed	Submitted	NCT03653	377	69HC	CL18_0144	2023-08	-14
	Multiple Daily Dose Phase I Safety And Pharmacokinetic Clinical Study Of Indole-3-Carbi	Submitted	NCT00033	345	KUM	C-8508-01	2024-05	-28
	Estimated Impact of Fungal Colonization in Cystic Fibrosis From Secondary Exploitation	Study In Curation	NCT03753	828	CHU	BX 2017/34	2025-03	-10
	Dry Needling for Treating Spasticity in Multiple Scierosis	Study In Curation	NCT05351	957	2017	_100	2023-01	-03
	Clinical and Molecular Impact of In-home Resonance-based Electromagnetic Field Prote	Submitted	NCT05001	646	ALT-	35-001	2023-08	-15
	A Pharmacoeconomic Study Comparing the Use of Mycophenolate Mofetil or Cyclophos	Submitted	NCT05195	086	CP3.	4.2	2023-06	-07
	A Multicentre, Randomised, Double-blind, Placebo-controlled, Phase 3 Study Evaluating	Study In Curation	NCT02446	899	D346	1C00004	2022-11	-28
		Submitted	NCT44444	444			2025-05	-21

• 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	Your request is being reviewed. 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.				
4. Data Sharing Settings	are ready to upload data to the Vvii Platform, if the anonymized individual Perticipant lave (Data are Wriet) you several like, 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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• To view the history of the Study Submission, click on the tab that says "History". 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 when the study is sent to curation, date the study is posted to the Vivli platform, etc.)

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Information About Your Team				
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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 and asking you to provide the team member who will upload the data package. The team member who will be responsible for uploading data will need to create an account and they will then be given data contributor access for the data upload. After the data is uploaded, data contributor access to upload data will be removed. If data needs to be re-uploaded at any time, reach out to the Vivli team at support@Vivli.org and access may be re-granted.

• Follow the link in the email or select Submissions in the dropdown menu from the top right corner, choose your Submission under Approved/Posted section. You may also log in to the Vivli platform and find the submission under the Dashboard (Note: You will be unable to upload any data or documents until the Data Contribution Agreement is executed.

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Enquiries	This is your view of Vivli at a glance. For an introduction to how to request studies in the Vivli Platform, click here. For an introduction to the Vivli Platform in general and guides for using the platform, click here. To search for clinical studies and create a new data request, click here.	How to request studies How-to guides Search							Dashboard Subinssions Enquines Edit My Profile Change Password Log Out
	To complete and submit a request for data that you have already started, click on My Data Requests.	<u>My Data</u> <u>Requests</u>							
	If you cannot find a specific study you need, click on Enquiry to ask about the availability of that clinical study from a Vivli member.	<u>Enquiry</u>							
	If you are an academic researcher and want to submit your study to Vivli for archive and subsequent sharing, click here to submit your study.	Share Data							
	If you have any questions, click here or email Vivli Support at <u>support@vivli.org</u> .	Contact Support							

• In the Submissions tab, under 'Approved/Posted,' click on the study for which you are ready to upload your anonymized data.

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	Randomized Trial of an Intervention to Impact Contraceptive Behavior, Unintended Pregn	Approved	NCT00230880	OSR# 04038166	2024-02-11
	Phase 2 Mindfulness Based Tinnitus Reduction (MBTR) Study: A Symptom Perception S	Approved	NCT01229709	H8935-35834-01	2024-02-11
	Characterizing Asthma Sputum Elasticity in the UCSF Severe Asthma Research Program	Approved	NCT02103348	14-13242	2024-02-11
	A Randomized Controlled Clinical Trial of an Algorithm Driven Sepsis Prediction Biomarker	Approved	NCT03015454	16-19647	2024-02-11
	Management of Meaningful Accompaniment as a Nursing Strategy to Reduce Patient An	Approved	NCT05639625	University of Concepcion	2023-07-24
	Study of Gynecological Follow-up Concerning Women With Multiple Sclerosis	Approved	NCT05248438	CHUBX 2021/49	2022-12-06

• Click on the 'Upload Data' tab and then you may use either the blue 'Select Files' button or drag and drop the appropriate files. If you navigate away from a page on which an upload is underway (i.e. clicking on another tab or closing the browser), that will cancel the upload automatically

Control QUICK STLUCT LOOK P PM ALREADEST PM ALREADEST - coa sea Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Disorders Status: Approved 1. Information Aload Your Team 2. Your Organization 3. Your Staty 1. Information Aload the team accepted and the Data Contribution Agreement has been executed - your study is evaluation for reatment for Anxiety Disorder for estating the fit is no readed in the study of these data below. 3. Your Staty Information end table the Were commend the types - cick here for more information. 4. Data Stating Settings Upload study Data Eachage must include a least 44 life types - cick here for more information. 6. Agreements Upload study Data Eachage below 6. Upload Date VOU MUST SUPPLY ALL REQUIRED FILE TYPES AS DISTINCT FILES, AND FOR EACH FILE, YOU MUST SPECIFY THE FILE TYPE. If a file type is unavailable, please provide a file with a note of explanation • (D) Anormized Individual Participant-level Data) • Distinct Files, Plana • (D) Anormized Individual Participant-level Data) • Statistical Analysis Plan • (D) Anormized Individual Participant-level Data) • Statistical Analysis Plan • (D) Anormized Individual Participant-level Data) • Statistical Analysis Plan • (D) Anormized Individual Participant-level Data) • Statistical Analysis Plan </th <th>Uivli</th> <th>Home About Members News & Events Resources Find Studies</th>	Uivli	Home About Members News & Events Resources Find Studies
Status Approved V 1. Information About Your Team UPLOAD THE STUDY DATA 2. Your Organization Vour requests has been accepted and the Data Contribution Agreement has been exceuted - your study is available for requesting. Please upload the data below. 3. Your Study Study data packages must include a lase Af file types - cick here for more information. • 4. Your Study 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 Vivi Platform, if the anonymized Individuel Participant-level Data are held in several files. 6. Apreements Upload study Data Package below 6. Apreements Vour Study Data Package below 9. POL (Anonymized Individual Participant-level Date) Place Advance 9. POL (Anonymized Individual Participant-level Date) Place Advance 9. Place Advance Place Advance Place Advance 9. Place Advance Place Advance Place Ad	CENTER FOR GLOBAL CLINICAL RESEARCH DA	EVOURY OUICK STUDYLOOKUP V 🕮 INY DATA REQUESTS DATA REQUESTER 🗸
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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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Filename Digitalis demoData.zip	Size 2.37MB	Uploaded By Data Contributor	File Type Unknown	\sim	Uploading

- To make supporting documents publicly available to researchers, check the box that says "Publicly available". This will make the documents available to researchers who have a Vivli account during their study search. This will help researchers to finalize the studies before submitting their Vivli data request.
 - Note: Files that have the file type "IPD" and "Analysis ready dataset" will not have the option to check "Publicly available" as Individual Participant Data (IPD) is NOT available without submitting a request.



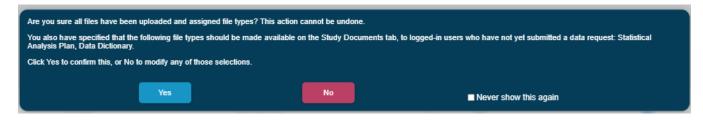
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				Submit Files		

- 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"

- Ensure all the files are loaded, then click the 'Submit Files' button.
- You will be directed to a pop-up confirming that you have uploaded all files and assigned file types. Additionally, the files that you have chosen to be made publicly available will be displayed and you will be asked to confirm you have selected the correct file(s) to be made publicly available.
 - Click the blue 'Yes' button to proceed. Or click the red button "No" to adjust your selections and you will be re-routed to the Upload Data page again.



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

CENTER FOR GLOBAL CLINICAL RESEARCH DATA
Thank you for uploading the data for this study. It will now be available for further analysis.

• 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".

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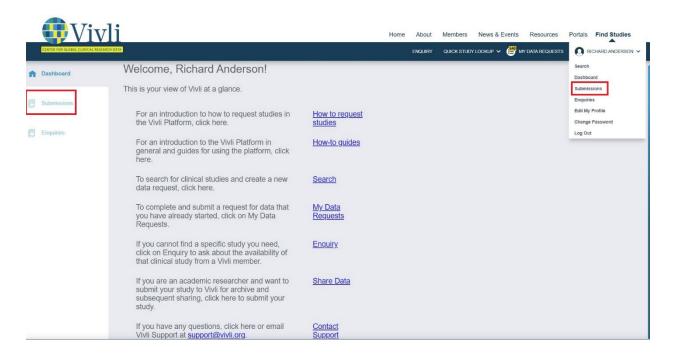
• You may add multiple links to external documents. Once you press 'Save', you will see a popup appear that says, "External study link has been loaded properly" and the link(s) to the document(s) will appear on the bottom of the page.

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4 Managing your Submission

4.1 Submission Status

• You may check the progress of your submission via the Submissions dashboard.

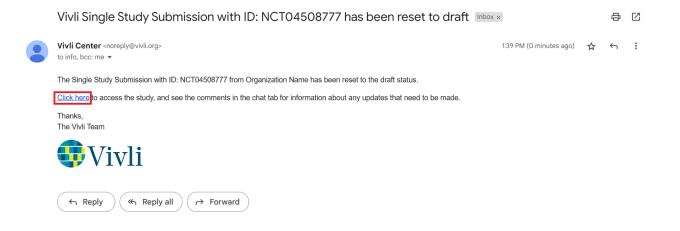


 Once the study information has been accepted by a Vivli admin, the study will undergo metadata curation, and the status will appear in the dashboard as "Study in Curation."

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	Draft In Progress Approved/Posted Withdrawn					بل + مر	d Submissi
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missions	Estimated Impact of Fungal Colonization in Cystic Fibrosis From Secondary Exploitation	Study In Curation		NCT03753828	CHUBX 2017/34	2025-03-10	
	Dry Needling for Treating Spasticity in Multiple Sclerosis	Study In Curation		NCT05351957	2017_100	2023-01-03	
	A Multicentre, Randomised, Double-blind, Placebo-controlled, Phase 3 Study Evaluating	Study in Curation		NCT02446899	D3461C00004	2022-11-28	
		Submitted		NCT44444444		2025-05-21	
	Multiple Daily Dose Phase I Safety And Pharmacokinetic Clinical Study Of Indole-3-Carbi	Submitted		NCT00033345	KUMC-8508-01	2024-05-28	
	Clinical and Molecular Impact of In-home Resonance-based Electromagnetic Field Prote	Submitted		NCT05001646	ALT-BS-001	2023-08-15	
	Survey on the Human Papilloma Virus Vaccination in Girls With Cystic Fibrosis Followed	Submitted		NCT03653377	69HCL18_0144	2023-08-14	
	A Pharmacoeconomic Study Comparing the Use of Mycophenolate Mofetil or Cyclophos	Submitted		NCT05195086	CP3.4.2	2023-06-07	

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.

Vivli			Home About Members News & Events Resources Find Studies
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1. Information About Your Team	Date and Time	Action	Porformed By
2. Your Organization	1/17/23 1:38 pm	Status changed to Submitted to Vivli.	GabbyTesting greganivil@gmail.com
3. Your Study	1/17/23 1:39 pm	Status changed to Draft status (reset).	Gabby Regan gregan@virli.org
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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.

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CENTER FOR GLOBAL CLINICAL RESEARCH DATA			ENQUIRY	QUICK STUDY LOO	ikup 🗸 😤 My data requ	JESTS 💽 DATA REQUESTER
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Study Details Study Documents Administrative Details	Usage Research Team					
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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. The supporting documents are uploaded and will be made available during the study data upload process (See Section 3.2 Data Package Upload).

The study documents should not include the anonymized individual participant-level data (IPD).

The 'Study Documents' tab will initially appear empty until you have uploaded data and declared which documents should be made publicly available to researchers.

Vivli	Home	About I	Members	News & Events	Resource	s Find Studie	s
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Study Details Study Documents Administrative Details Usage Research Team							
NO FILES IN PACKAGE							
How To Guide Privacy Cookie Policy EEA Disclosure Policy Contlact Us						© Copyright 2017	2023 Vivli

• Once you have uploaded study data and have checked the box stating "Publicly Available" appear here, the files will appear in this tab.

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Assessment of Real-life Patient Ha h Rheumatoid Arthritis: an Open-I Prefilled Syringe								
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Links to Documents located elsewhere								
ClinicalTrials								

 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 the Vivli website.

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CENTER FOR GOAL CLINCE RELAKCIONE	ENQUIRY QUICK STUDY LOOKUP 🗸 😁 MY DATA REQUESTS 🗵 DATA REQUESTER 🗸
Efficacy Evaluation of a Unified Transdiagnostic Treatment for Anxiety Disorders	
Study Details Study Documents Administrative Details Usage Research Team	
Vvki DOI Vvki ID Sponsor Protocol ID https://handle.stage.datacite.org/10.70118/AQ00003191 VVki DI 1R01MH090083-01	Acronym
Data Package DOI(s) Available for this Study https://handle.stage_datacite.org/10.70118/AQ000003191.0	
Lead Sponsor Agency Boston University Charles River Campus	Lead Sponsor Agency Class Other
Collaborator Agency National Institute of Mental Health (NIMH)	Collaborator Agency Class NIH
Data Contributor Organization Name Boston University	
How To Guide Privacy Cookie Policy EEA Disclosure Policy Contact Us	@ Copyright 2017 - 2023 Vivil

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.
 - Public Disclosures: Public Disclosures field includes all Public Disclosures linked to this study through a Vivli Data Request. When a public disclosure is published and the citation is received as part of the Vivli data request, the citation is entered into the Data Request, and linked to the Study(s) involved in that Data Request. It will be initially blank. Once your studies are included in publications, you can see the publication reference here.

Randomized Evaluation of Dab alntlcoagulation sTrategy (The		n in pulmonaRy Vein Ablation: Assessment of an Uninterrupted periproCedUra
Study Details Study Documents	Administrative Details Usage	
Jsage		Public Disclosures
Views 5	Download of Study Documents 0	Kimata, Akira, Nogami, Akihiko, Yamasaki, Hiro, Ohigashi, Tomohiro, Gosho, Masahiko, Igarashi, Miyako, Sekiguch "Optimal interruption time of dabigatran oral administration to ablation (O-A time) in patients with atrial fibrillation. Integrated analysis of 2 randomized controlled clinical trials". Journal of Cardiology vol 77. no 6, Jun 2021, pp 652569 doi: http://dx.doi.org/10.1016/j.jicc.2020.12.010
Access of Data Package 0	All usage metrics from 06/18/2022 to 11/17/2	"Late-Breaking Science Abstracts and Featured Science Abstracts From the American Heart Association's Scientific Sessions 2019 and Late-Breaking Abstracts in Resuscitation Science From the Resuscitation Science Symposium 2019".
search, or displays the DOI pay the study metadata. Download of Study Documents Study Documents are document requesting the study data to he the kind of data necessary to s	nts made available to a researcher prior to lip them determine whether the study contains upport their research topic; this may include the de protocol document. This metric counts the	Alex, delas, pol. 440, ep. 76. Top. 7017, ep. doi: blie filds del ansith 41841667000000000729

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.

NTER FOR GLOBAL CLINIC	NI RESEARCH DATA			Ho	ome	About ENQUIRY	Members QUICK STUD	News & I		Resources In data requests	Portals	Find Studies
		tive Study Comparing (Patients (CAPRI)	COVID-19	Convalescent Plasm	na (C	CP) to I	Non-immu	ne Plasr	na to I	∟imit Corona	ivirus-a	ssociate
tudy Details	Study Documents	Administrative Details	Usage	Research Team								
Siven Name Sarah		Family Name Jones		ORCID iD 2222-3333-2222-3333			 Form 	Role(s) ing acquisiti al analysis curation	on			

5.7 Integrating ORCID for Research Team Members

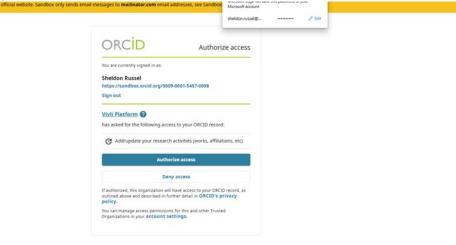
- During study submission, the dataset owner will have clicked the "Send Invitations to Team Members" Button, which sends an automatic email to researchers listed on the study after the study has been posted.
- Once an email is received, click the link within the email and you will be taken to a Vivli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

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actogenicity and Safety of Three Different Formulatio rogroups C and Y- Conjugate Vaccine and One Form	ons of GSK Biologicals' rulation of GSK Biologic	, Primary Vaccination Study to Evaluate the Immunogenicity, Combined Haemophilus Influenzae Type B-meningococcal zals' Haemophilus Influenzae Type B-meningococcal Serogrou MeningitecTM, Given Concomitantly With InfanrixTM Hexa in	рC					
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• You will be navigated to the ORCID login screen. Log in with your ORCID credentials.

Sign in	
Email or 16-digit ORCID ID	
sheldon.russel@mailinator.com	
example@email.com or 0000.0001.2345.6789	
(Password	
SIGN IN	
Forgot your password or ORCID ID?	
Don't have an ORCID iD yet? Register now	
or	
Access through your institution	
G Sign in with Google	

• 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.

✓ Works (1)	🕀 Add 📻 Sort
Select all (1) Items currently selected (0)	
The Effects of Fascia Iliaca Compartment Block on Hip Fracture Patients	• Everyone •
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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< Go Back Azithromycin for F Status: Draft	revention of Disease Progression in Patients With Mild or Moderate COVID-19			Withdraw	Save	Submit
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 i:	s available.			
3. Your Study						
4. Data Sharing Settings						
5. Agreements						
6. Upload Data						
History						
Chat	Enter message here					
	Send					11.
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6.2 E-mail Vivli Support

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