Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Study Submission Checklist

The following information is what you will need to have available to begin the study submission process. If you have any questions, please refer to the Study Submission Guide.

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. Don't forget to list yourself as part of the study team, if appropriate.			
☐	First and last name		
☐	Email address		
☐	ORCID iD		
☐	CRedIT Role(s)	*CRediT (Contributor Roles Taxonomy) is a high-level taxonomy, including 14 roles, that can be used to represent the roles typically played by contributors to research outputs. The roles describe each contributor's specific contribution to the scholarly output. See https://credit.niso.org/ for more information.*	

2. YOUR ORGANIZATION If you have more than 2 studies that you want to share at this time, please contact Vivli by emailing support@vivli.org as we have other ways to make this process more efficient for you.			
☐	Organization Name	*In order to post your study on the platform, Vivli needs to associate the study with either an existing organization or a new organization within the Vivli Platform. Please provide the Organization Name as it should be displayed on the study listing.*	

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3. YOUR STUDY			
☐	NCT ID		
☐	Sponsor ID	*If your study is not registered on clinicaltrials.gov and, therefore, does not have an NCT ID, enter the Sponsor Protocol ID, Title, Conditions, Interventions, and Phase, according to your study. Note: Sponsor Protocol ID is a mandatory field to complete. (If you do not have a Sponsor Protocol ID, reach out to Vivli and we will create one for you.)*	
☐	Any citations related to your study data	*Any information that you provide in this 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.*	
☐	Funder information and Grant ID (optional)	*If the study was funded by your organization, leave this as N/A. If it was funded by an external funder, enter the name in free text box and click "Search ROR". You may add multiple funders.*	
☐	Contact name and email for invoice payment	*If the study was funded by an external funder, we expect that the grant included funds to support the sharing of the data. Vivli will issue an invoice for the cost of posting the study. Please provide the email of a contact within your organization who can manage payment of that invoice; normally this will be someone who oversees external grants.*	

4. DATA SHARING SETTINGS

Review process for requests for data: When a research team requests your study, an Accelerated Research Proposal Review will be conducted within 3 business days. Once the review is complete, 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.

☐	Does your data need to be embargoed?	*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.*	
☐	Are you willing to be contacted by any researchers?	*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.*	
☐	Will you need help anonymizing your data?	*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.*	

5. AGREEMENTS (VIVLI DATA CONTRIBUTION AGREEMENT - DCA)

The Principal Investigator (PI) and an Institutional Official (IO) will need to read, acknowledge, and sign a Data Contribution Agreement (DCA). If your institution already has a Master DCA in place, we do not require institutional signature for future submissions. Once you submit your study, the Vivli team will reach out in the study submission chat verifying the PI and IO name and email and then send the appropriate DUA to the corresponding emails via DocuSign.

6. DATA PACKAGE UPLOAD

Once the study is processed and the Data Contribution Agreement signed, the study will appear in the Vivli Search and you will receive an email from Vivli inviting you to upload the anonymized data and study documents. For more information regarding data package requirements, please see section 3.1 of the Study Submission Guide.

☐	Anonymized, individual patient-level data (IPD) - *required*	

☐	Statistical analysis plan - *required*	
☐	Protocol - *required*	
☐	Data dictionary - *required*	
☐	Additional supporting documents - *not required*	