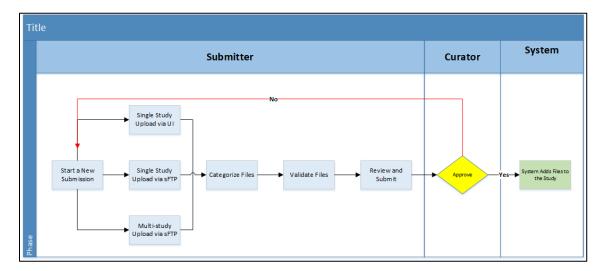
RADx® Data Hub

In the NIH RADx Data Hub, users with a Submitter role can submit documents (study documentation and README files), data files (non-harmonized and harmonized), and supporting files—metadata ("META") files and data dictionary ("DICT") files—for use by other research community members. After upload, the files must be categorized, validated, and reviewed prior to final submission and a subsequent RADx Data Hub curator review.

Important: The RADx Data Hub introduces the concept of "bundles," which consists of a harmonized or non-harmonized data file, a data dictionary file, and a metadata file. It is impossible to upload a data file without including these two required supporting files in the bundle. Study documents (e.g., README files) create standalone bundles and do not require supporting files.

Figure 1: File Submission Process



Step 1: Navigate to and Upload Files

There are three methods for uploading files as described in Table 1 below.

Table 1: The Three Upload Methods and Their Use Cases

Method	Use Case	
Via the User Interface (UI)	Best for file packages under 250 MB and/or when	
	uploading files to one study	
Via Single Study Secure File Transfer Protocol (sFTP)	Best for file packages over 250 MB	
Via Multiple Studies sFTP	Best for uploading files to multiple studies	
	simultaneously	



Note: When uploading a new version of an existing file, you should upload the new file with the exact same file name as the existing file. This will replace the existing file with the new file and update the version of the file within the study. Older versions will be available by request. Following the naming conventions found in Data File Naming Convention Guidance enables efficient file submission.

Uploading Files via the RADx Data Hub User Interface (UI)

This option allows you to upload files directly, via the RADx Data Hub UI. To use this option:

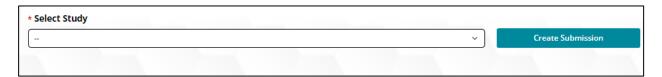
- 1. Click "Data Submission" under "Data Submitter" in the navigation bar.
- 2. Click "+ New Submission" to start a new files submission (Figure 2).

Figure 2: Submitter Dashboard



- 3. In the dropdown menu, select the study. The list contains studies aligned to your program (e.g., RADx-UP, RADx-rad, RADx Tech).
- 4. Click "Create Submission," which creates an ID number for the submission.

Figure 3: Study Dropdown and Create Submission Button



5. Click "Select File(s) to Upload," which opens the File Explorer.

Figure 4: Select File(s) to Upload Button



6. Select the file(s) you wish to submit and click "Open".

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Note: To select multiple files, hold the CTRL (For Windows)/Command (For Mac) button, and click the desired files.

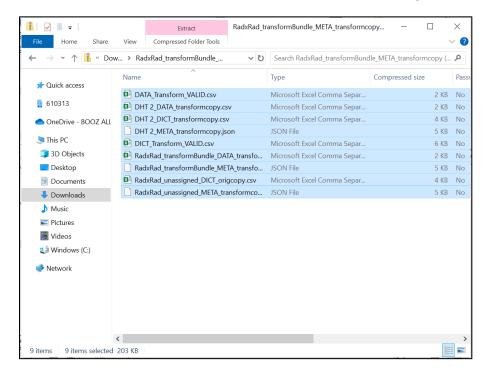


Figure 5: The File Explorer

7. Once you are done uploading the files, click the "Next Page" button. The system will navigate you to the Categorization step. Proceed to "Step 2: Categorize Files" in this document.

Note: The "Next Page" button will be disabled until at least one file is uploaded.

Uploading Files via Single Study sFTP – Example Using FileZilla

Note: Before using the sFTP function, you must have an sFTP account. This is separate from your RADx Data Hub account. Use the contact form in the navigation bar or footer to request an account, and the Support Team will assist you. The team typically responds to inquiries within 24 hours.

The sFTP function uses an external application to upload files. The sFTP function is preferred for larger file package uploads (> 250 MB). To use this option, follow the steps outlined below.

Note: The following steps show the sFTP process using FileZilla. Depending on your sFTP client, steps may differ.

- 1. Open the File Explorer. Create and name a new folder.
- 2. Add all files to be submitted to the new folder.
- 3. Download this blank <u>metadata.yaml</u> file, and fill out the following:

- **study_id (Required):** This unique study identifier can be located through the navigation bar. Under "Data Submitter," click "Data Submission." This will bring you to the Submitter Dashboard, where you can download all existing study keys by pressing "Download Study Key."
- **files (Optional):** Enter the names of the files in the upload.

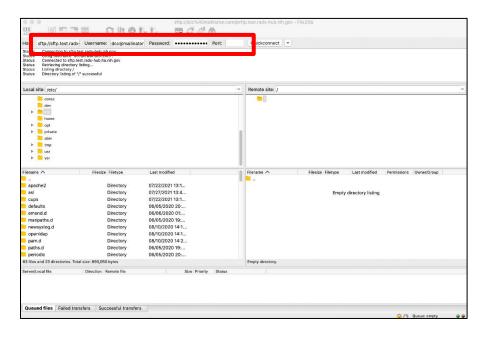
Figure 6: Blank metadata.yaml File

```
study_id: Insert Study UUID (required)
files:
   - Insert Data File Name.extension (optional)
```

- 4. Store the metadata.yaml file in the folder created in Step 1.
- 5. Add the study folder to a parent folder and compress the parent folder into a zip file.
- 6. Open the sFTP client and fill in the following fields:
 - a. Host: Enter "https://radxdatahub.nih.gov/"
 - b. User Name: Assigned by the RADx Data Hub Support Team
 - c. Password: Assigned by the RADx Data Hub Support Team
 - d. Port: Enter "22"

Note: FileZilla may have a different UI and processes than other sFTP clients.

Figure 7: sFTP Window in FileZilla

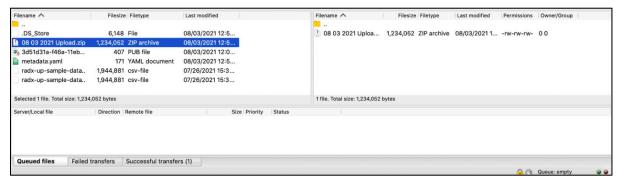


7. Connect to the RADx Data Hub Server. The status will indicate if the connection was successful. If the connection failed, contact the RADx Data Hub Support Team.



8. Find and select the zip folder, created in the earlier step, and drag it into the RADx Data Hub window within FileZilla to securely transfer and upload to the RADx Data Hub.

Figure 8: File Transfer Pane in FileZilla



- 9. Depending on the upload size, files may not be visible in the RADx Data Hub for a few minutes. You will receive an email if the upload was successful, and you can return to the Data Hub to complete the submission. If you have not received an email, check the RADx Data Hub to see if the files were submitted. If not, you will need to upload the files again. Verify that you followed the steps for uploading files correctly and contact the RADx Data Hub Support Team if problems continue.
- 10. Return to the RADx Data Hub, go to the navigation menu, and select "Data Submitter." Then click "Data Submission."
- 11. Locate the study in the dashboard and click the link in the ID column. This will bring you to the Categorize Files step, where you can proceed with the submission.

Uploading Files via Multiple Studies sFTP – Example Using FileZilla

The sFTP function allows you to upload multiple studies' files simultaneously. This process is similar to uploading files for one study. To upload multiple studies via sFTP, follow the steps outlined below.

Note: The following steps show the sFTP process using FileZilla. Depending on your sFTP client, steps may differ.

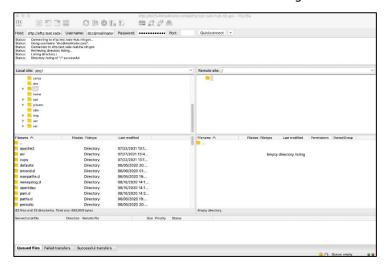
- 1. Open the "File Explorer" and create a new folder for each study in the upload.
- 2. Add all the files for the submission packages into the appropriate new folders.
- 3. Download this blank metadata.yaml file and enter the following details for each study:
 - a. study_id (Required): To find the unique study identifier, go to the navigation bar, find "Data Submitter," and click "Data Submission." This will bring you to the Submitter Dashboard where you can download all existing study keys by pressing "Download Study Key."
 - b. files (Optional): Enter the name of each file in the upload.
- 4. Store the metadata.yaml files in the appropriate study folders.
- 5. Compress all study folders into a single zip file.

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- 6. Open the sFTP client, and fill in the following fields:
 - a. User Name: Assigned by the RADx Data Hub Support Team
 - b. Password: Assigned by the RADx Data Hub Support Team
 - c. Host: Enter "22"
 - d. Domain: Enter "https://radxdatahub.nih.gov/"

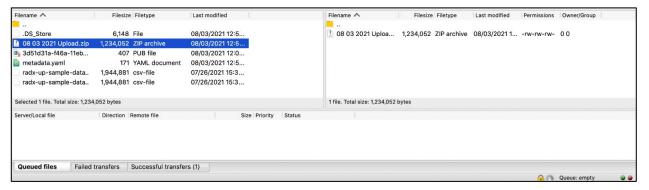
Note: FileZilla may have a different UI and processes than other sFTP clients.

Figure 9: sFTP Window in FileZilla



- 7. Connect to the RAD Data Hub Server. The status will indicate if the connection was successful. If the connection failed, contact the RADx Data Hub Support Team.
- 8. Find and select the zip folder containing multiple studies, created in Step 7, and drag it into the RADx Data Hub window within FileZilla to securely transfer and upload to the RADx Data Hub.

Figure 10: File Transfer Pane



- 9. Depending on the upload size, study files may not be visible in the RADx Data Hub for a few moments. You will receive an email if the upload for each study was successful and can return to the Data Hub to complete the submission. If you have not received an email check the RADx Data Hub to see if the files were submitted. If not, you will need to upload the files again. Verify that you followed the steps for uploading files correctly and contact the RADx Data Hub Support Team if problems continue.
- 10. Return to the RADx Data Hub, go to the navigation menu, select "Data Submitter," and select the Data Submission option.
- 11. Locate a study in the dashboard and click the link in the ID column. Each study from the sFTP package will have its own submission ID. Proceed through the submission workflow for every study uploaded.

Step 2: Categorize Files

Once the files are uploaded, they need to be categorized. The system will make an initial attempt of categorization by analyzing the file names in accordance with the Data File Naming Convention
Guidance
to automatically categorize and bundle them (Note: A bundle consists of a non-harmonized or harmonized data file, a metadata file, and data dictionary file). The results of the initial categorization attempt will be presented on the File Categorization page in three tables: Bundled Files, Study Documents, and Unassigned Files (see Figure 11). If you upload via sFTP and files are able to be categorized into full bundles using the naming conventions, you will skip this step and validation will begin immediately.

Note: The below example shows harmonized files not categorized. The process will be slightly different if, for example, only metadata and data dictionary files were not categorized.

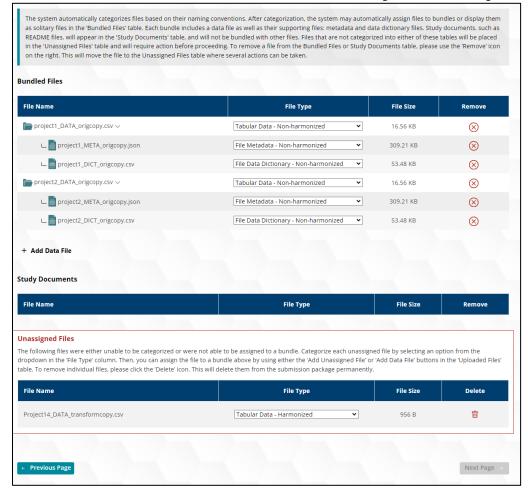


Figure 11: File Categorization Page

To categorize and bundle the files in the Unassigned Files table:

1. If the Unassigned Files table contains any data files, select the appropriate category for such files (see Figure 12). The system records the category and makes it available under "Add Data Files" in the Uploaded Files table.

Figure 12: Unassigned Files Table



File Upload Standard Operating Procedures (SOP)

2. Scroll up to the Bundled Files table. Click "Add Data Files," and select the appropriate files. The system will display them in the Uploaded Files table.

Figure 13: Bundled Files Table



Scroll down to the Unassigned Files table. Select a category for any uncategorized, unassigned
data dictionary and metadata files. The system will record the category and make it available in
the Add Unassigned Files dropdown.

Study Documents Data Files Image Data File Name File Size Sequence Data Tabular Data - Non-harmonized \otimes project1_README.html 274.79 KB Tabular Data - Harmonized Metadata File Metadata - Non-harmonized File Metadata - Har **Unassigned Files Data Dictionary** The following files were either unable to be categorized or were not ab ed file by selecting an option from the File Data Dictionary - Non-harmonized dropdown in the 'File Type' column. Then, you can assign the file to a b ndle 'Add Data File' buttons in the 'Uploaded Files' File Data Dictionary - Harmonized table. To remove individual files, please click the 'Delete' icon. This will **Study Documents** Eligibility Criteria File Name File Size Delete Study Protocol Study Documentation README 1.97 MB Î project1_DATA_transformcopy.csv Uncategorized project1_META_transformcopy.json 313.4 KB Ī 131.93 KB î project1_DICT_transformcopy.csv File Data Dictionary - Harmonized

Figure 14: File Type Dropdown in the Unassigned Files Table

4. Scroll up to the Bundled Files table. Click "Add Unassigned File" and select from the list of categorized data dictionary and metadata files. The system will add the file to the appropriate bundle.

Figure 15: Add Unassigned File Button



5. After all files are categorized, the "Next Page" button will become active. Click it to move onto the file validation step.

Step 3: Validate Files

After all files are categorized, the system will run a validation algorithm to check files for compliance with CDE and PII data standards, among others. You can review errors in the Warning Report, if necessary. To validate files:

1. Click "Begin Validation" to run the validation checks. The process might take up to 15 minutes. After validation is complete, the screen will load a table displaying various types of warnings:

Table 2: Different Types of Validation Checks

Validation Check	Description	Applicable File Types
CDE	Checks to ensure compliance with the Core	Harmonized Data Files
	RADx Common Data Elements (CDEs).	
PII	Checks to ensure files do not contain any	Non-Harmonized and
	protected health information (PHI) or	Harmonized Data Files
	personally identifiable information (PII).	
Meta	Checks to ensure the metadata files follow	Metadata Files
	NIH standards.	
Dict	Checks to ensure the data dictionary files	Data Dictionaries
	follow NIH standards.	

Note: When you run the validation check, the system will only display files that fail validation.

- 2. Review the first four columns in the validation table, which can have four possible values:
 - a. **Green Checkmark:** The file passed validation.
 - b. Yellow Caution: The file has warnings present.
 - c. **Yellow Checkmark:** The file warnings were acknowledged, allowing the file to pass validation with warnings present.
 - d. **Dash:** The validation does not apply to the file.

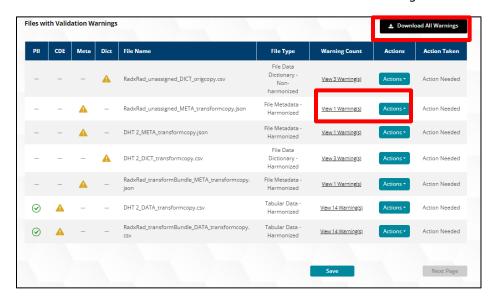


Figure 16: Validation Table

Review files with the yellow caution and address concerns. You can view errors by clicking "View Warnings" in the Validation table or by pressing "Download All Warnings," which downloads all warnings into a CSV file.

Warning Report

Dict

Dict Warnings

Required field not present

Error type: ERROR

Message: "Required field not present"

Line Number: 1

Solution: Datatype is a required field (column) but it is not present

Error type: ERROR

Message: "Required field not present"

Line Number: 1

Solution: Id is a required field (column) but it is not present

Error type: ERROR

Message: "Required field not present"

Line Number: 1

Solution: Id is a required field (column) but it is not present

Error type: ERROR

Message: "Required field not present"

Line Number: 1

Solution: Label is a required field (column) but it is not present

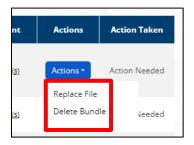
Line Number: 1

Solution: Label is a required field (column) but it is not present

Figure 17: Warning Report

4. Determine and complete the appropriate action for each file with a warning by selecting an option from the Actions menu. You can replace flagged files or delete the whole bundle. If a file in a harmonized bundle has exceptions, you can acknowledge them, so the file will pass validation. If you acknowledge the errors, the symbol in the table changes from a yellow caution sign to a yellow checkmark. All files must have an associated action before proceeding.

Figure 18: Actions Dropdown



5. Click "Next Page." The system will load a Review and Submit screen.

Step 4: Review and Submit Files

Once you reach the Review and Submit step, you will see a table displaying your bundles with a summary of all warnings and versioning information. The column labeled "Version" will indicate if the uploaded bundle will create a new version of a previously approved bundle. Review the table for accuracy, and press "Submit" if everything looks correct. If you notice an issue with a file or a bundle (e.g., failure to create a new version due to improper naming), delete the affected bundle by clicking trash can icon, and reupload the corrected bundle in a separate submission.

Upload Files or the 'Bundled Files' table are ready for submission. Press the Submit button to send the files to the RADx Data Hub team for review.

Submission ID: 2041

Study Name: (phs002575) SCALE UP Utah: A community-academic partnership to address COVID-19 Among Utah Community Health Centers

Bundled Files

Warnings File Name File Type File Size Version Delete

Warnings File Name File Type File Size Version Delete

DATA_Valid.csv Tabular Data - Non-harmonized 5.63 KB First

META_Valid json File Metadata - Non-harmonized 309.21 KB - - File Data Dictionary - Non-harmonized 53.48 KB - - -

File Data Dictionary - Non-harmonized 53.48 KB - - -

File Data Dictionary - Non-harmonized 53.48 KB - - -

File Data Dictionary - Non-harmonized 53.48 KB - - -

DICT_Valid.csv

Figure 19: Review and Submit Page