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Chapter

5

Data Repository



CHAPTER 5 – DATA REPOSITORY

The **Data Repository** is the central hub of the BRICS system, providing functionality to manage study information, and contribute, upload, and store the research data associated with each study.

The Data Repository module is closely related to the Data Dictionary module which provides long term repository for research data.

5.1 OBJECTIVE

The **Data Repository Tool** provides useful features for:

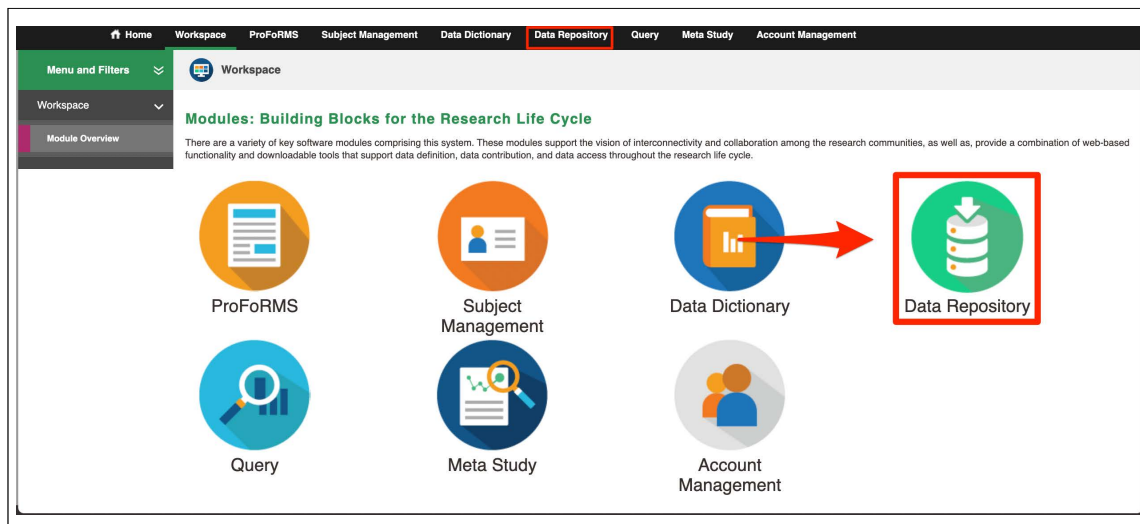
- ❖ Manage Studies
 - View Studies
 - Create a Study
 - Edit a Study
 - Submit Request to Approve Data Document
 - Add Form Structure
 - Search Studies
- ❖ Other Tools: Submission Tools, Image Packaging Tool, and Download Tool (See [Chapter 9 Image Packagin Tool](#), [Chapter 10 Data Validation](#), and [Chapter 11 Download Tool](#)) are located within the Data Repository module. Please refer to the above-referenced chapters for additional information.

5.2 MODULE NAVIGATION

The **Data Repository** module (including sub-modules) are available within the BRICS Workspace

To Access the Data Repository Module: Perform the following actions:

1. Login to the system.
2. Navigate to the Workspace landing page
3. Click the Data Repository module icon

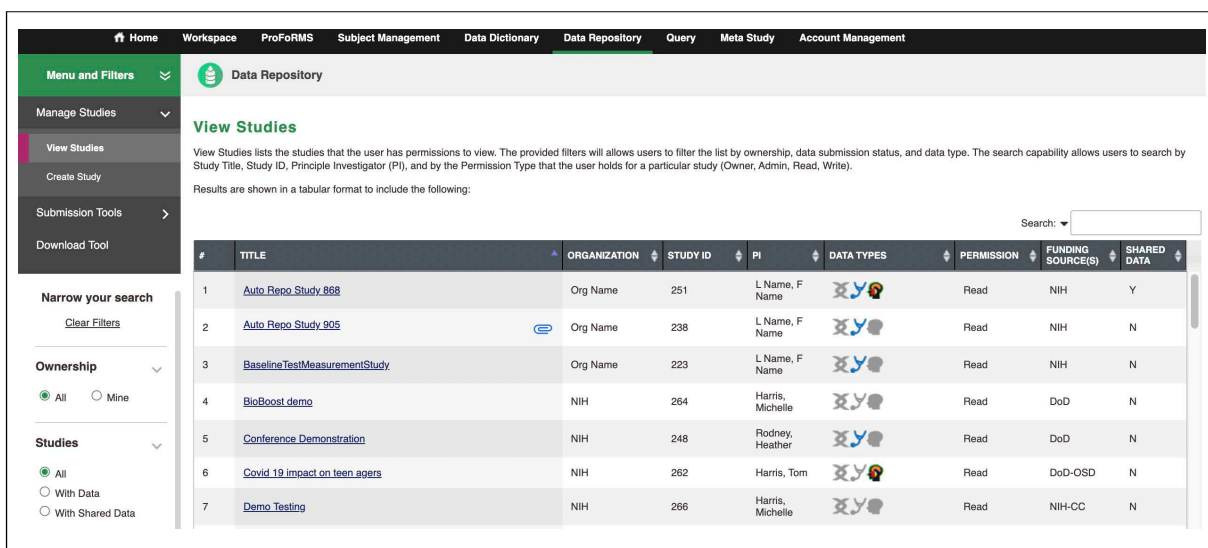


5.2.1 View Studies

The **View Studies** lists the studies that the user has permission to view. The filters provided within the View Studies list allows users to filter the list by **Ownership**, **Studies**, **Data Types** and **Study Types**. The search capability allows users to search by many different fields. Click into the Search box to see all searchable fields.

To View Studies in Data Repository: Perform the following actions:

1. Open the **Data Repository**. When opening the Data Repository page, you will be taken to the view studies page.



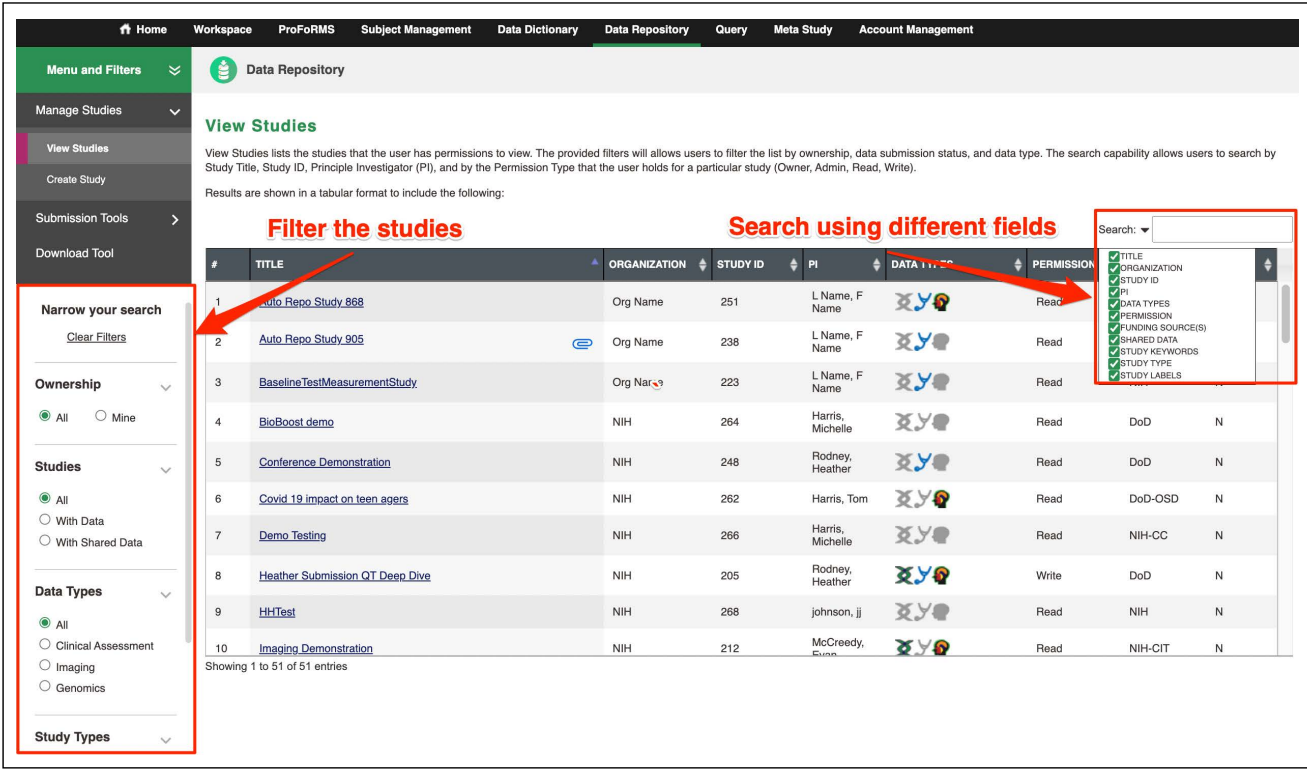
View Studies

View Studies lists the studies that the user has permissions to view. The provided filters will allow users to filter the list by ownership, data submission status, and data type. The search capability allows users to search by Study Title, Study ID, Principle Investigator (PI), and by the Permission Type that the user holds for a particular study (Owner, Admin, Read, Write).

Results are shown in a tabular format to include the following:

| # | TITLE | ORGANIZATION | STUDY ID | PI | DATA TYPES | PERMISSION | FUNDING SOURCE(S) | SHARED DATA |
|---|---|--------------|----------|------------------|------------|------------|-------------------|-------------|
| 1 | Auto Repo Study 868 | Org Name | 251 | L Name, F Name | | Read | NIH | Y |
| 2 | Auto Repo Study 905 | Org Name | 238 | L Name, F Name | | Read | NIH | N |
| 3 | BaselineTestMeasurementStudy | Org Name | 223 | L Name, F Name | | Read | NIH | N |
| 4 | BioBoost demo | NIH | 264 | Harris, Michelle | | Read | DoD | N |
| 5 | Conference Demonstration | NIH | 248 | Rodney, Heather | | Read | DoD | N |
| 6 | Covid_19_impact_on_teen_agers | NIH | 262 | Harris, Tom | | Read | DoD-OSD | N |
| 7 | Demo_Testing | NIH | 266 | Harris, Michelle | | Read | NIH-CC | N |

2. To search for a study use the search text box and/or the filters section.



Filter the studies

Search using different fields

| # | TITLE | ORGANIZATION | STUDY ID | PI | DATA TYPES | PERMISSION | FUNDING SOURCE(S) |
|----|---|--------------|----------|------------------|------------|------------|-------------------|
| 1 | Auto Repo Study 868 | Org Name | 251 | L Name, F Name | | Read | |
| 2 | Auto Repo Study 905 | Org Name | 238 | L Name, F Name | | Read | |
| 3 | BaselineTestMeasurementStudy | Org Name | 223 | L Name, F Name | | Read | |
| 4 | BioBoost demo | NIH | 264 | Harris, Michelle | | Read | DoD N |
| 5 | Conference Demonstration | NIH | 248 | Rodney, Heather | | Read | DoD N |
| 6 | Covid 19 impact on teen agers | NIH | 262 | Harris, Tom | | Read | DoD-OSD N |
| 7 | Demo Testing | NIH | 266 | Harris, Michelle | | Read | NIH-CC N |
| 8 | Heather Submission QT Deep Dive | NIH | 205 | Rodney, Heather | | Write | DoD N |
| 9 | HHTest | NIH | 268 | johnson, jj | | Read | NIH N |
| 10 | Imaging Demonstration | NIH | 212 | McCreedy, Evan | | Read | NIH-CIT N |

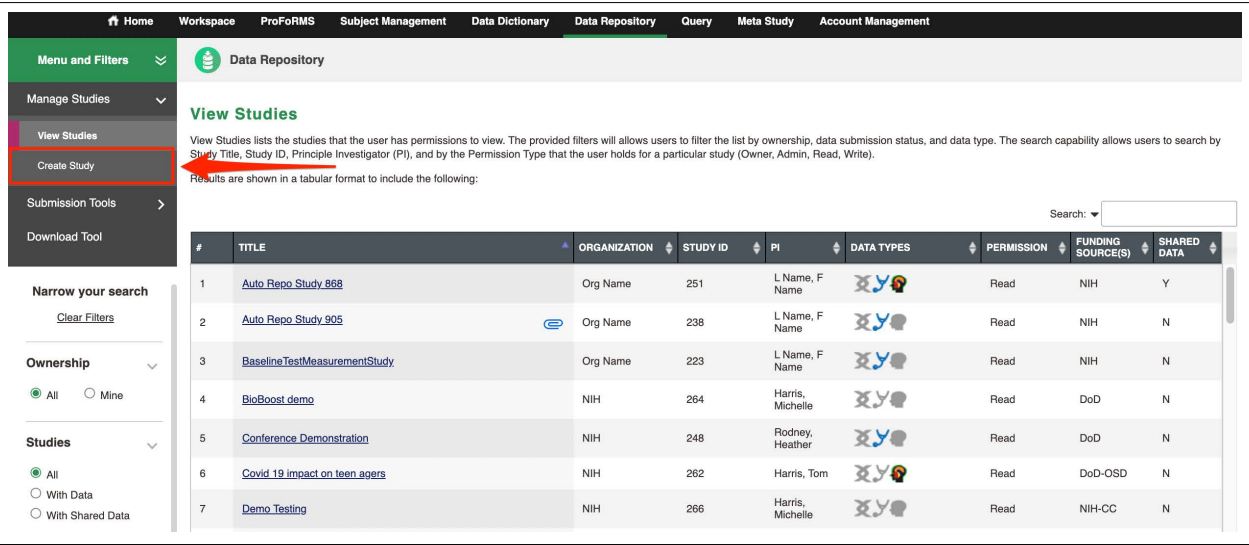
Showing 1 to 51 of 51 entries

5.2.2 Create Study

The **Create Study** functionality allows users with permission to create a study by providing the relevant information requested and submitting the request which will be reviewed by a BRICS Systems Administrator. Once approved by the Systems Administrator, users may begin to submit data to the system.

To Create a Study in Data Repository: Perform the following actions:

1. Login to the system.
2. Navigate to the **Data Repository** Module and click **Create Study**



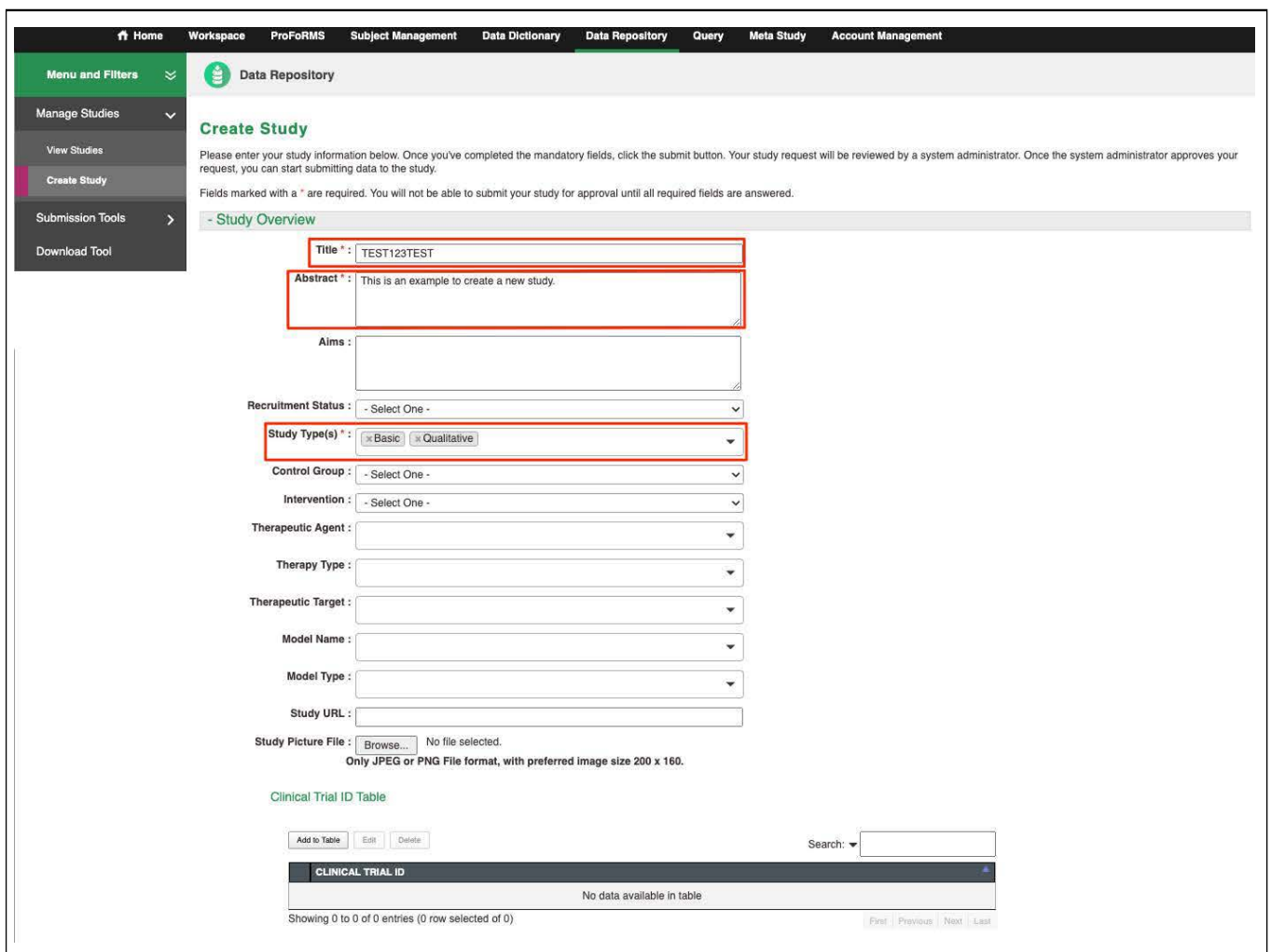
The screenshot shows the BRICS Data Repository interface. The top navigation bar includes Home, Workspace, ProFORMS, Subject Management, Data Dictionary, Data Repository (selected), Query, Meta Study, and Account Management. The left sidebar contains 'Menu and Filters', 'Manage Studies', 'View Studies', 'Create Study' (highlighted with a red box and arrow), 'Submission Tools', and 'Download Tool'. Below the sidebar is a search filter section with 'Narrow your search', 'Clear Filters', 'Ownership' (All, Mine), and 'Studies' (All, With Data, With Shared Data). The main content area is titled 'View Studies' and includes a search bar and a table of study results.

| # | TITLE | ORGANIZATION | STUDY ID | PI | DATA TYPES | PERMISSION | FUNDING SOURCE(S) | SHARED DATA |
|---|---|--------------|----------|------------------|------------|------------|-------------------|-------------|
| 1 | Auto Repo Study 868 | Org Name | 251 | L Name, F Name | | Read | NIH | Y |
| 2 | Auto Repo Study 905 | Org Name | 238 | L Name, F Name | | Read | NIH | N |
| 3 | BaselineTestMeasurementStudy | Org Name | 223 | L Name, F Name | | Read | NIH | N |
| 4 | BioBoost demo | NIH | 264 | Harris, Michelle | | Read | DoD | N |
| 5 | Conference Demonstration | NIH | 248 | Rodney, Heather | | Read | DoD | N |
| 6 | Covid 19 Impact on teen agers | NIH | 262 | Harris, Tom | | Read | DoD-OSD | N |
| 7 | Demo Testing | NIH | 266 | Harris, Michelle | | Read | NIH-CC | N |

3. Fill out the **Create Study** data. To create the study you must fill out all of the required fields (All fields with an *asterisk are required.)

NOTE: When the Create Study page first opens, all the tabs aside from Study Overview will be closed. You must click them to expand them. For example: Click **+ Study Research Management** to expand that section.

See photos below for a quick view of all required fields.



Data Repository

Create Study

Please enter your study information below. Once you've completed the mandatory fields, click the submit button. Your study request will be reviewed by a system administrator. Once the system administrator approves your request, you can start submitting data to the study.

Fields marked with a * are required. You will not be able to submit your study for approval until all required fields are answered.

- Study Overview

Title * : TEST123TEST

Abstract * : This is an example to create a new study.

Aims :

Recruitment Status : - Select One -

Study Type(s) * : Basic Qualitative

Control Group : - Select One -

Intervention : - Select One -

Therapeutic Agent :

Therapy Type :

Therapeutic Target :

Model Name :

Model Type :

Study URL :

Study Picture File : No file selected.
Only JPEG or PNG File format, with preferred image size 200 x 160.

Clinical Trial ID Table

Search:

| CLINICAL TRIAL ID |
|----------------------------|
| No data available in table |

Showing 0 to 0 of 0 entries (0 row selected of 0) First Previous Next Last

- Study Research Management

Research Management Table

Search:

| | ROLE | FULL NAME | E-MAIL | ORGANIZATION | ORCID |
|-----------------------|--------------------------------|-----------------|------------------------------|--------------|-------|
| <input type="radio"/> | Primary Principal Investigator | John P Doe | | Demo Org | |
| <input type="radio"/> | Data Manager | John Rutherford | jpatrickrutherford@gmail.com | BRICS | |

Showing 1 to 2 of 2 entries (0 row selected of 2) First | Previous | Next | Last

Create a Primary Principal Investigator →

- Study Information

Start Date * :

End Date * :

Estimated Number of Subjects :

Funding Source(s) * :

Site Table

Search:

| | SITE NAME | ADDRESS | CITY | STATE | COUNTRY | PHONE NUMBER |
|-----------------------|----------------------|-------------|---------------|-------|--------------------------|--------------|
| <input type="radio"/> | Test Lab 1 (Primary) | 123 Main St | San Francisco | CA | United States of America | 1234561234 |

Showing 1 to 1 of 1 entries (0 row selected of 1) First | Previous | Next | Last

Create a Primary Test Site →

Grant Table

Search:

| GRANT/PROJECT ID | GRANT/PROJECT NAME | GRANT/PROJECT FUNDER NAME |
|-----------------------|--------------------|---------------------------|
| <input type="radio"/> | DR080205 TEST_TEST | John Doe |

Showing 1 to 1 of 1 entries (0 row selected of 1) First | Previous | Next | Last

- Study Form Structure

Add Form Structures you initially intend to use to the table below by clicking on the "Add Form Structure" button. When you click the button, you will be presented with a list of published Form Structures to choose from. If you don't know the Form Structures you intend to use or if the forms haven't been created yet, leave this section blank. You can add your Form Structures to the study at a later time or when you submit data to your study. When submitting data, the system will automatically add the Form Structure used to the study's Form Structure list.

Search:

| FORM STRUCTURE TITLE | SHORT NAME | FORM TYPE | ACTIONS |
|----------------------------|------------|-----------|---------|
| No data available in table | | | |

Showing 0 to 0 of 0 entries First | Previous | Next | Last

- Study Keywords and Labels

Associate Keywords

Associating keywords to the study promotes reuse and improves the search capability.

Filter Keywords: ADD KEYWORD

Sort By: Name Frequency

Available Keywords

- LEIA (3)
- submission (2)
- test (1)
- testing (2)

<<

>>

Current Keywords

Associate Labels

Filter Labels: ADD LABEL

Sort By: Name Frequency

Available Labels

- test (1)
- LEIA (2)
- testing (2)

<<

>>

Current Labels

Upload your Data Submission Document. →

Approved Data Submission Document

Your study cannot be approved until you upload the required documentation. Please upload your Approved Submission document.

Data Submission Document * : emailreceipt_20200131R0394689533.pdf

SUBMIT REQUEST Cancel

Study Overview: Complete all required fields marked with an ***asterisk**:

- ❖ **Title***
- ❖ **Abstract***
- ❖ **Aims**
- ❖ **Recruitment Status**
- ❖ **Study Type(s)***
- ❖ **Other Study Type:**
- ❖ **Control Group**
- ❖ **Intervention**
- ❖ **Therapeutic Agent**
- ❖ **Therapy Type**
- ❖ **Therapeutic Target**
- ❖ **Model Name**
- ❖ **Model Type**
- ❖ **Study URL**
- ❖ **Study Picture File:** Click **Browse...** to select a JPEG or PNG file.
- ❖ **Clinical Trial ID:** Click add to table to add a Clinical Trial ID.

Study Research Management - You are required to create a *Primary Principal Investigator**.**
Select the "Add to the Table" button.

- ❖ **Role*:** You are **required** to have exactly 1 **Primary Principal Investigator**
- ❖ **First Name***
- ❖ **Middle Initial**
- ❖ **Last Name***
- ❖ **Suffix**
- ❖ **E-Mail**
- ❖ **Organization Name***
- ❖ **ORCID**
- ❖ **Picture File**

Study Information: Complete all required fields marked with an *asterisk:

- ❖ **Start Date***
- ❖ **End Date***
- ❖ **Estimated Number of Subjects**
- ❖ **Primary Funding Source***
- ❖ **Site Table*:** You are required to have a **Primary Site*** Click the "Add to Table" button.
 - **Site Name***
 - **Address**
 - **Country**
 - **City**
 - **Phone Number**
- ❖ **Grant Table**
 - **Grant/Project ID**
 - **Grant/Project Name**
 - **Grant/Project Funders Name**

Study Form Structure:

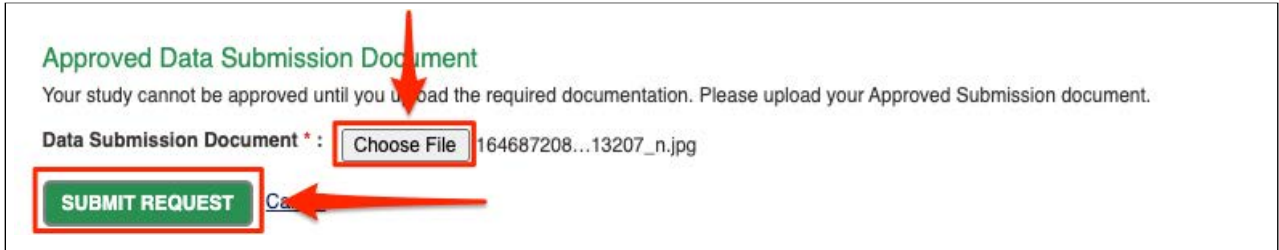
- ❖ **Form Structures:** Add Form Structures you initially intend to use to the table. If you don't know what the Form Structures you intend to use are then you can add form structures to your study at a later time.

Study Keywords and Labels:

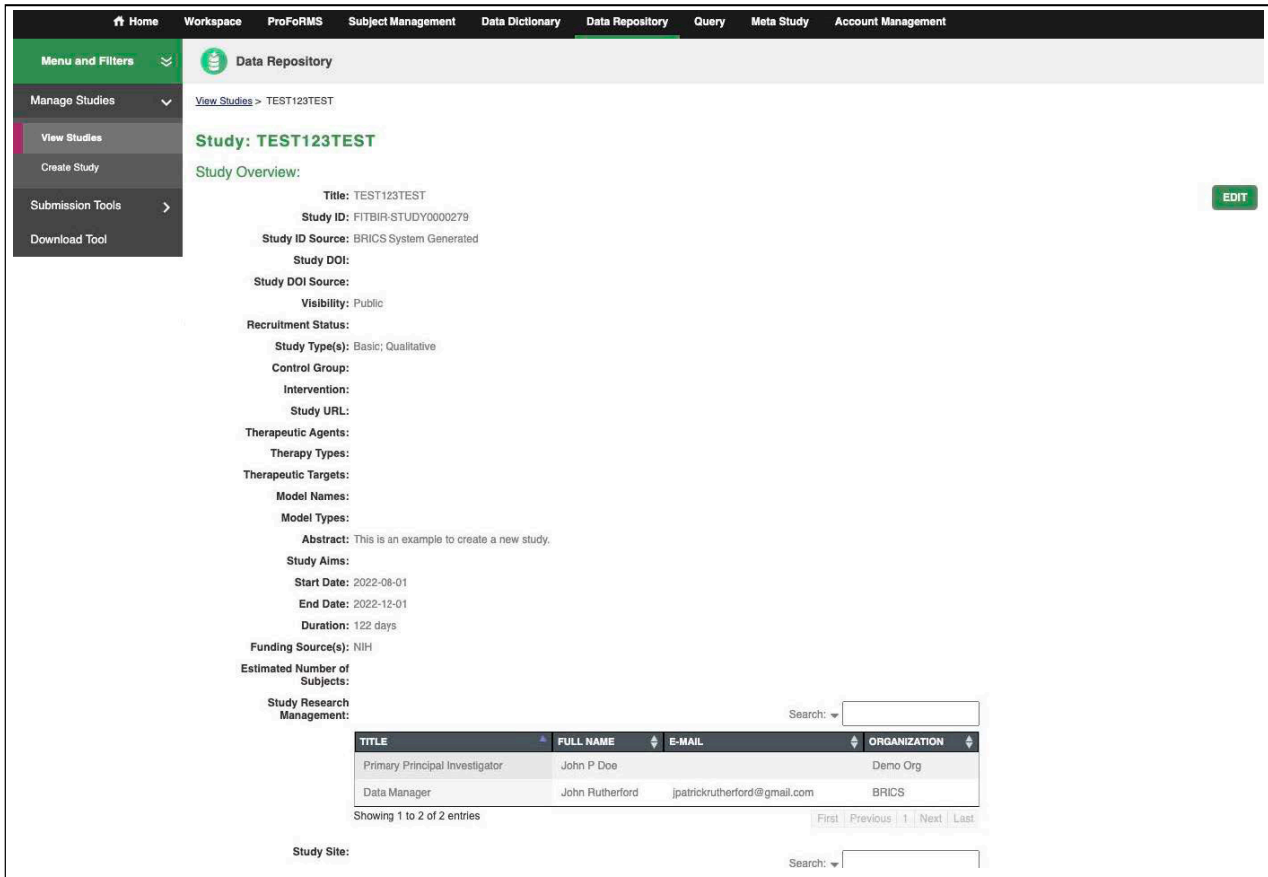
- ❖ **Associate Keywords:** Add any keywords you wish to be associated with your study.
- ❖ **Associate Labels:** Add any labels you wish to be associated with your study.

Approved Data Submission Document*: Your study cannot be approved until you upload the required documentation. Please upload your Approved Submission document. Click **Choose File** to browse your computer and upload your document.

- After filling out all of the required data. Click the **Submit Request** button.
NOTE: Your study cannot be approved if the data submission document(s) are not uploaded.
Please make sure you upload your data submission documents.



- If all required information is filled out. Then your request to create your study will be submitted and you will be redirected to the Study Overview page for your study.
NOTE: When you request to create the study, it will be reviewed by an admin for approval/rejection. Afterwards, you will receive an email notification with the status of the study.



Study: TEST123TEST

Study Overview:

Title: TEST123TEST

Study ID: FITBIR-STUDY0000279

Study ID Source: BRICS System Generated

Study DOI:

Study DOI Source:

Visibility: Public

Recruitment Status:

Study Type(s): Basic; Qualitative

Control Group:

Intervention:

Study URL:

Therapeutic Agents:

Therapy Types:

Therapeutic Targets:

Model Names:

Model Types:

Abstract: This is an example to create a new study.

Study Aims:

Start Date: 2022-08-01

End Date: 2022-12-01

Duration: 122 days

Funding Source(s): NIH

Estimated Number of Subjects:

Study Research Management:

| TITLE | FULL NAME | E-MAIL | ORGANIZATION |
|--------------------------------|-----------------|------------------------------|--------------|
| Primary Principal Investigator | John P Doe | | Demo Org |
| Data Manager | John Rutherford | jpatrickrutherford@gmail.com | BRICS |

Showing 1 to 2 of 2 entries

Study Site:

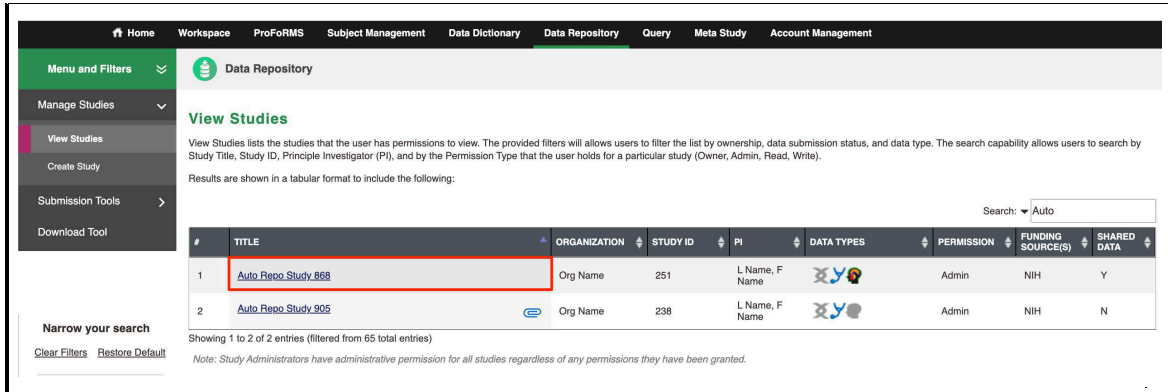
5.2.3 Edit Studies

The **Edit Studies** function allows the user to edit studies that the user has permissions to edit.

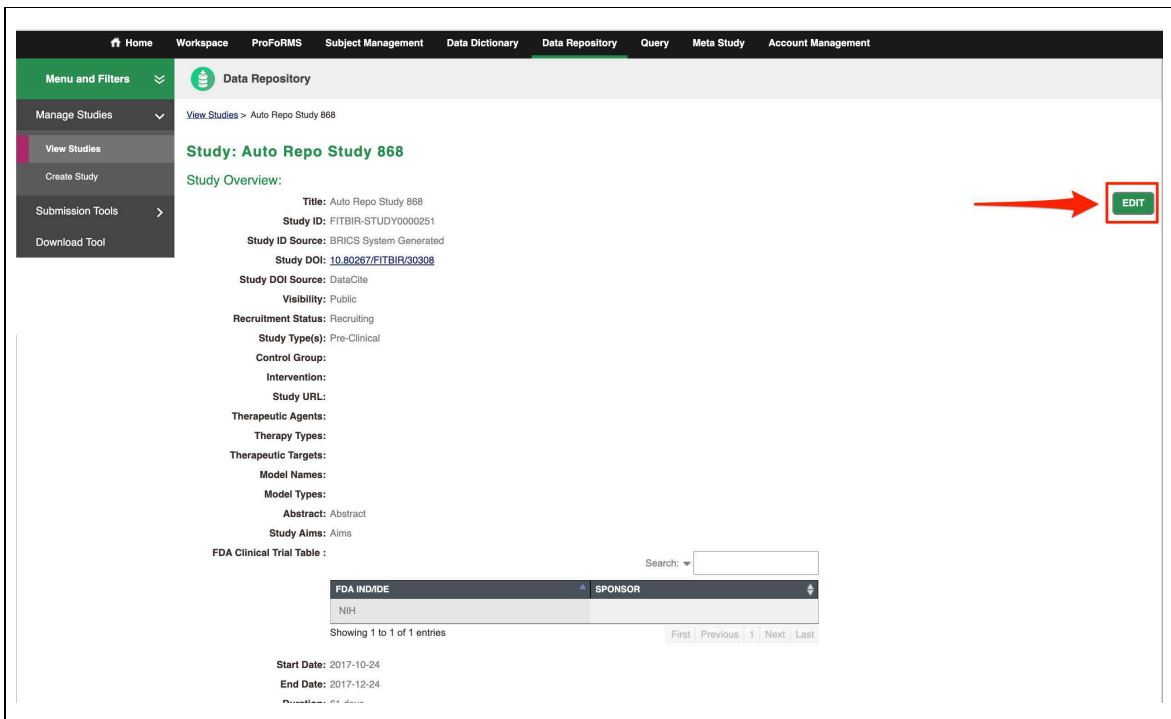
To Edit Studies in Data Repository: **Perform the following actions:**

1. Open the Data Repository module and the View Studies page will load.
2. Find the study you'd like to edit in the View Studies page and click on its name to open it.

NOTE: Use the search box and/or filters to easily find your study.

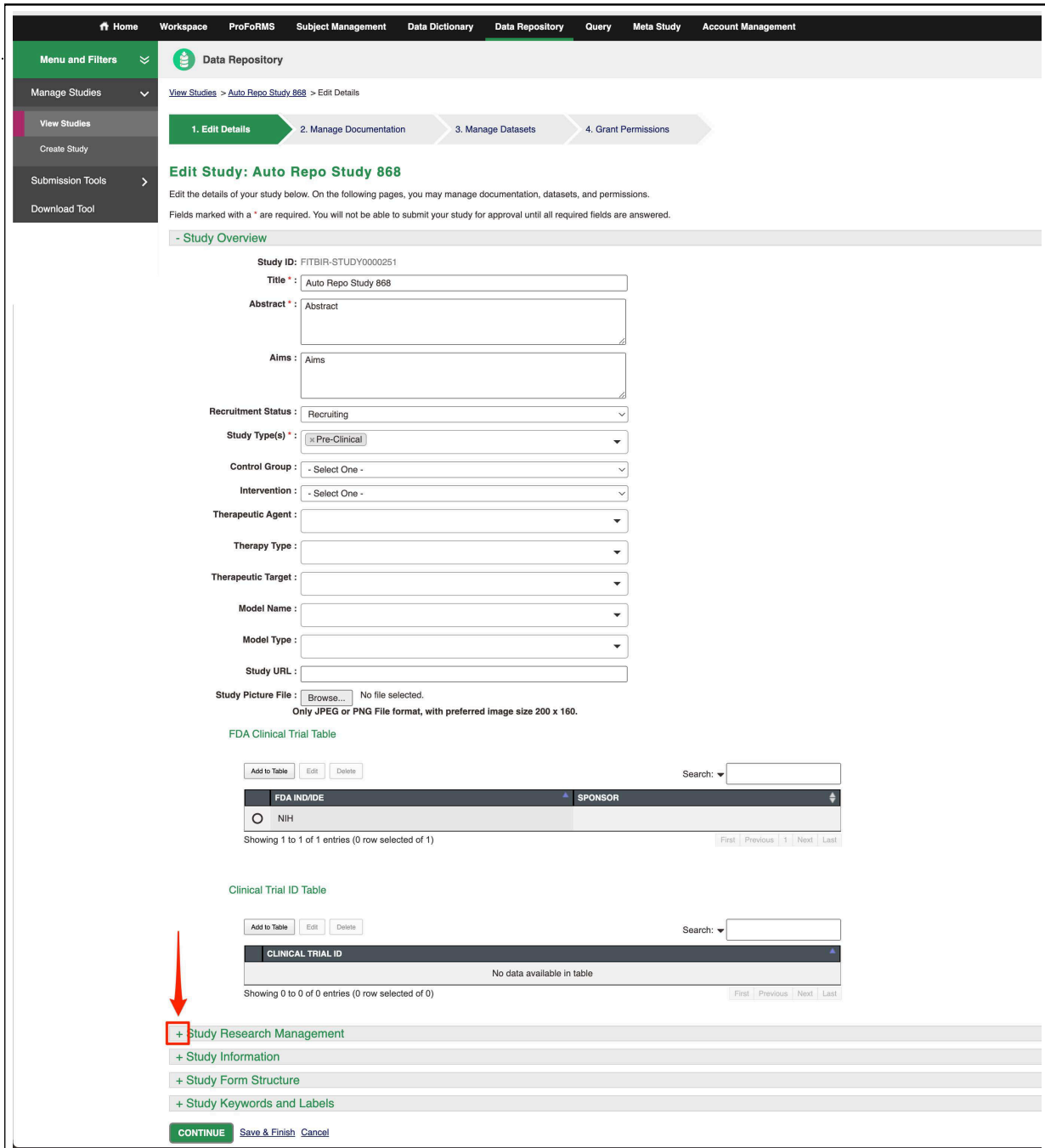


5. The Study Overview page appears. Click the **Edit** button.



6. Edit the details of your study as shown below. Clicking on the **[+]** expansion icon expands the various section (**Study Research Management**, **Study Information**, **Study Form Structure**, and **Study Keywords and Labels**) for additional study details.

On the following pages, you may manage **documentation**, **datasets**, and **permissions**. **Note:** Fields marked with an asterisk * are required. You will not be able to submit your study for approval until all required fields are answered.



Menu and Filters

- Manage Studies
- View Studies
- Create Study
- Submission Tools
- Download Tool

Data Repository

View Studies > Auto Repo Study 868 > Edit Details

1. Edit Details 2. Manage Documentation 3. Manage Datasets 4. Grant Permissions

Edit Study: Auto Repo Study 868

Edit the details of your study below. On the following pages, you may manage documentation, datasets, and permissions.
Fields marked with a * are required. You will not be able to submit your study for approval until all required fields are answered.

- Study Overview

Study ID: FITBIR-STUDY0000251

Title *: Auto Repo Study 868

Abstract *: Abstract

Aims: Aims

Recruitment Status: Recruiting

Study Type(s) *: Pre-Clinical

Control Group: - Select One -

Intervention: - Select One -

Therapeutic Agent:

Therapy Type:

Therapeutic Target:

Model Name:

Model Type:

Study URL:

Study Picture File: Browse... No file selected.
Only JPEG or PNG File format, with preferred image size 200 x 160.

FDA Clinical Trial Table

Add to Table Edit Delete Search:

| FDA IND/IDE | SPONSOR |
|-------------|---------|
| NIH | |

Showing 1 to 1 of 1 entries (0 row selected of 1) First Previous 1 Next Last

Clinical Trial ID Table

Add to Table Edit Delete Search:

| CLINICAL TRIAL ID |
|----------------------------|
| No data available in table |

Showing 0 to 0 of 0 entries (0 row selected of 0) First Previous Next Last

+ Study Research Management

+ Study Information

+ Study Form Structure

+ Study Keywords and Labels

CONTINUE Save & Finish Cancel

7. Click the **Continue** button when complete.

Home
Workspace
ProFORMS
Subject Management
Data Dictionary
Data Repository
Query
Meta Study
Account Management

Menu and Filters

Manage Studies
View Studies
Create Study
Submission Tools
Download Tool

Data Repository

[View Studies](#) > [Demo Testing](#) > Edit Details

1. Edit Details
2. Manage Documentation
3. Manage Datasets
4. Grant Permissions

Edit Study: Demo Testing

Edit the details of your study below. On the following pages, you may manage documentation, datasets, and permissions.

Fields marked with a * are required. You will not be able to submit your study for approval until all required fields are answered.

- Study Overview

Study ID: FITBIR-STUDY0000266

Title * :

Abstract * :

Aims :

Recruitment Status :

Study Type(s) * :

Control Group :

Intervention :

Therapeutic Agent :

Therapy Type :

Therapeutic Target :

Model Name :

Model Type :

Study URL :

Study Picture File : No file selected.
Only JPEG or PNG File format, with preferred image size 200 x 160.

Clinical Trial ID Table

Search:

| CLINICAL TRIAL ID |
|----------------------------|
| No data available in table |

Showing 0 to 0 of 0 entries (0 row selected of 0) First | Previous | Next | Last

[+ Study Research Management](#)

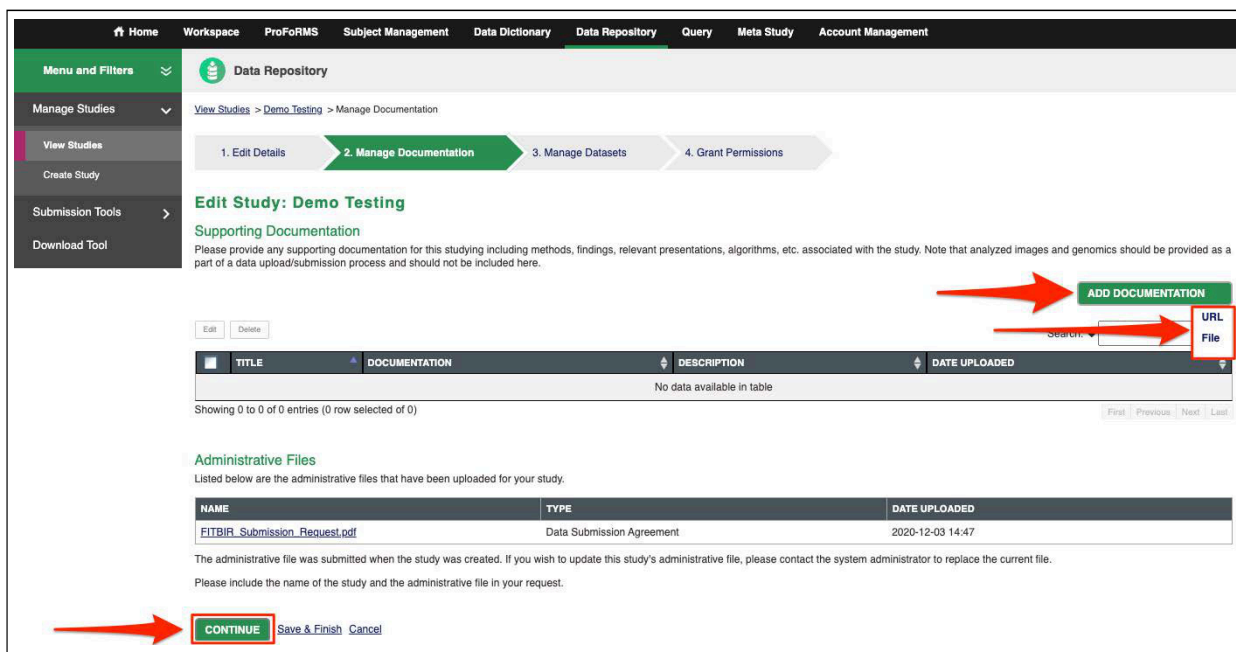
[+ Study Information](#)

[+ Study Form Structure](#)

[+ Study Keywords and Labels](#)

CONTINUE
Save & Finish Cancel

8. **Manage Documentation:** Click the **Add Documentation** button to select the desired file or URL to upload. Click the **Continue** button.



ADD DOCUMENTATION

URL
File

| TITLE | DOCUMENTATION | DESCRIPTION | DATE UPLOADED |
|----------------------------|---------------|-------------|---------------|
| No data available in table | | | |

Showing 0 to 0 of 0 entries (0 row selected of 0)

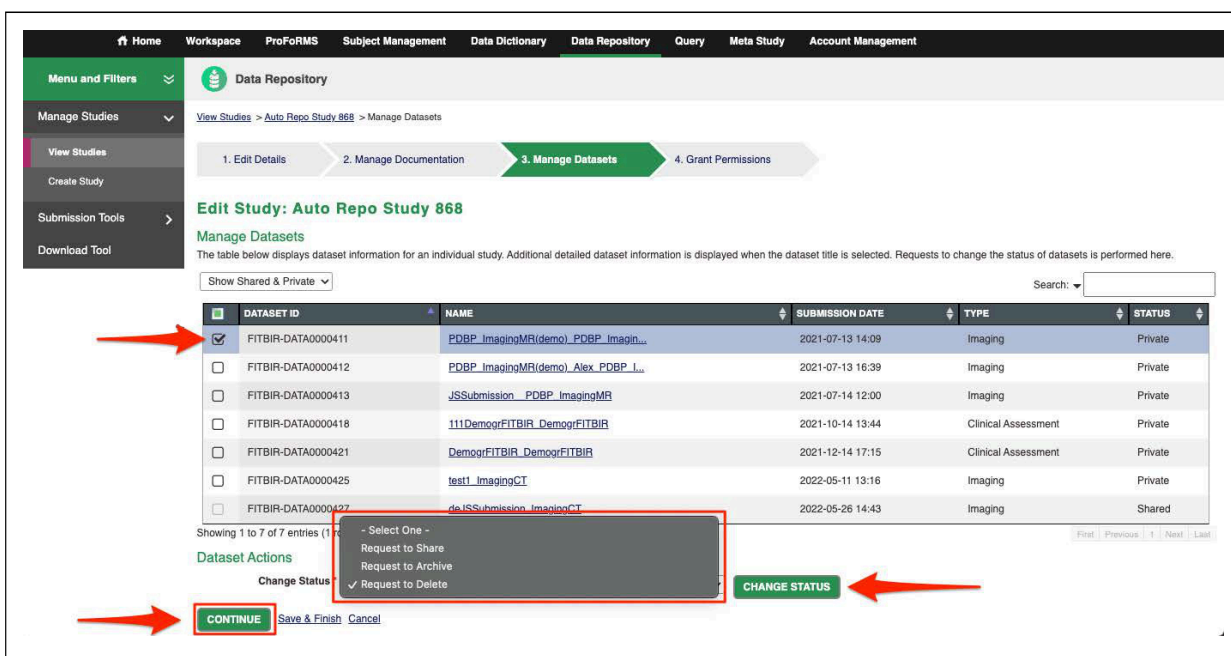
Administrative Files
Listed below are the administrative files that have been uploaded for your study.

| NAME | TYPE | DATE UPLOADED |
|-------------------------------|---------------------------|------------------|
| FITBIR_Submission_Request.pdf | Data Submission Agreement | 2020-12-03 14:47 |

The administrative file was submitted when the study was created. If you wish to update this study's administrative file, please contact the system administrator to replace the current file.
Please include the name of the study and the administrative file in your request.

CONTINUE Save & Finish Cancel

9. **Manage Datasets:** In the table below, the dataset information for an individual study is displayed when the dataset title is selected. You may request change to the status of datasets from here by selecting the drop-down menu beside “**Change Status**” to select a Dataset. Click the **Continue** button.



CHANGE STATUS

| DATASET ID | NAME | SUBMISSION DATE | TYPE | STATUS |
|--|-------------------------------------|------------------|---------------------|---------|
| <input checked="" type="checkbox"/> FITBIR-DATA0000411 | PDBP_ImagingMR(demo)_PDBP_Imagin... | 2021-07-13 14:09 | Imaging | Private |
| <input type="checkbox"/> FITBIR-DATA0000412 | PDBP_ImagingMR(demo)_Alex_PDBP_L... | 2021-07-13 16:39 | Imaging | Private |
| <input type="checkbox"/> FITBIR-DATA0000413 | JSSubmission_PDBP_ImagingMR | 2021-07-14 12:00 | Imaging | Private |
| <input type="checkbox"/> FITBIR-DATA0000418 | 111DemogrFITBIR_DemogrFITBIR | 2021-10-14 13:44 | Clinical Assessment | Private |
| <input type="checkbox"/> FITBIR-DATA0000421 | DemogrFITBIR_DemogrFITBIR | 2021-12-14 17:15 | Clinical Assessment | Private |
| <input type="checkbox"/> FITBIR-DATA0000425 | test1_ImagingCT | 2022-05-11 13:16 | Imaging | Private |
| <input type="checkbox"/> FITBIR-DATA0000427 | deISSubmission_ImagingCT | 2022-05-26 14:43 | Imaging | Shared |

Showing 1 to 7 of 7 entries (1 selected)

Dataset Actions

Change Status

- Select One -
- Request to Share
- Request to Archive
- Request to Delete

CHANGE STATUS

CONTINUE Save & Finish Cancel

10. In the **Grant Permissions** section, individual access to the study profile and datasets can be granted to users during submission. The different permissions are **Read**, **Write**, and **Admin**. Other users will have Read access once the datasets have been shared.

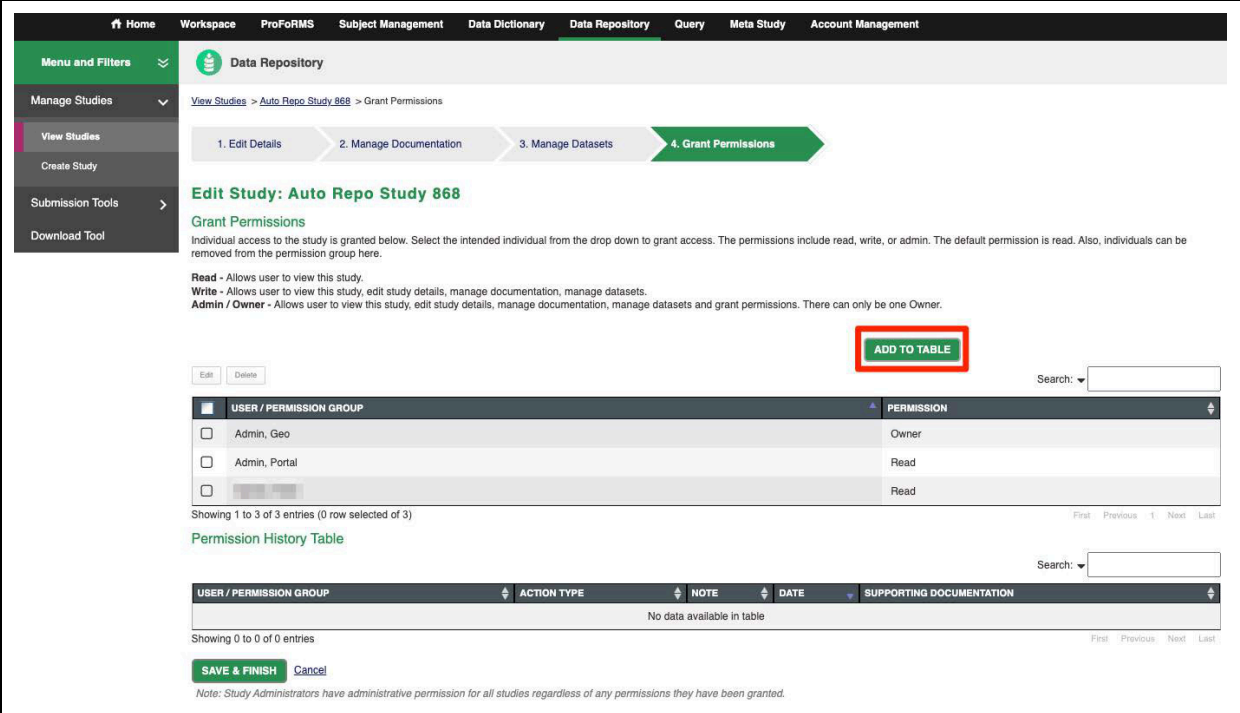
Below are the descriptions for the different permissions:

Read - Allows user to view this study.

Write - Allows user to view this study, edit study details, manage documentation, and manage datasets.

Admin / Owner - Allows user to view this study, edit study details, manage documentation, manage datasets and grant permissions. There can only be one Owner.

To grant access to study team members to the study profile and datasets, click on the **Add to Table** button.



Edit Study: Auto Repo Study 868
Grant Permissions
 Individual access to the study is granted below. Select the intended individual from the drop down to grant access. The permissions include read, write, or admin. The default permission is read. Also, individuals can be removed from the permission group here.

Read - Allows user to view this study.
Write - Allows user to view this study, edit study details, manage documentation, manage datasets.
Admin / Owner - Allows user to view this study, edit study details, manage documentation, manage datasets and grant permissions. There can only be one Owner.

ADD TO TABLE

| USER / PERMISSION GROUP | PERMISSION |
|--|------------|
| <input type="checkbox"/> Admin, Geo | Owner |
| <input type="checkbox"/> Admin, Portal | Read |
| <input type="checkbox"/> [Redacted] | Read |

Showing 1 to 3 of 3 entries (0 row selected of 3)

Permission History Table

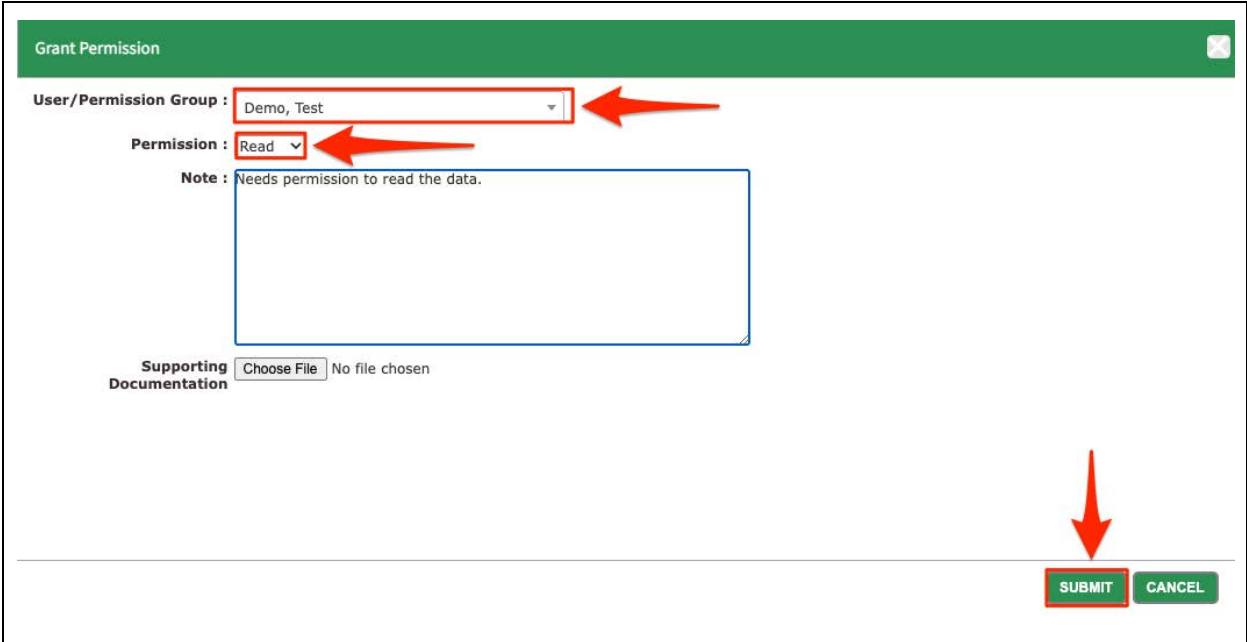
| USER / PERMISSION GROUP | ACTION TYPE | NOTE | DATE | SUPPORTING DOCUMENTATION |
|----------------------------|-------------|------|------|--------------------------|
| No data available in table | | | | |

Showing 0 to 0 of 0 entries

SAVE & FINISH [Cancel](#)

Note: Study Administrators have administrative permission for all studies regardless of any permissions they have been granted.

11. Select a username/permission group from the Drop Down list. Select the permission access for the user(s). **Note:** Study Administrators have administrative permissions for ALL studies regardless of any permissions they have been granted. Click **Choose File** button to select the supporting documentation to upload. Click **Submit**.



Grant Permission

User/Permission Group : Demo, Test

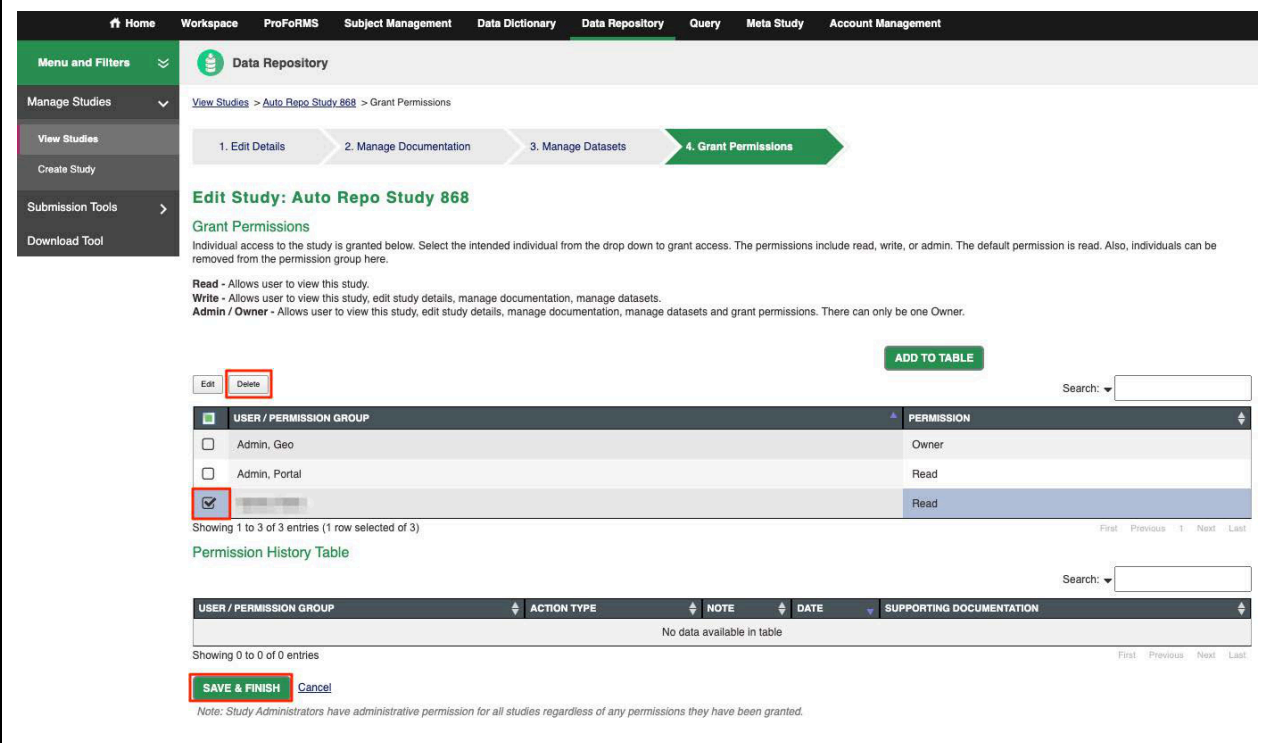
Permission : Read

Note : Needs permission to read the data.

Supporting Documentation Choose File No file chosen

SUBMIT CANCEL

To remove users from the study profile, choose the user/permission group and click **Delete**. Click **Save & Finish** to complete the process.



The screenshot shows the 'Grant Permissions' page for 'Auto Repo Study 868'. The breadcrumb trail is 'View Studies > Auto Repo Study 868 > Grant Permissions'. A progress bar indicates the current step is '4. Grant Permissions'. The page title is 'Edit Study: Auto Repo Study 868' and the sub-section is 'Grant Permissions'. A note explains that individual access is granted below and that permissions include read, write, or admin, with read as the default. It also states that only one Owner can exist.

Below the text, there are 'Edit' and 'Delete' buttons, with 'Delete' highlighted by a red box. An 'ADD TO TABLE' button is also present. A search bar is located to the right of the buttons.

| USER / PERMISSION GROUP | PERMISSION |
|--|------------|
| <input type="checkbox"/> Admin, Geo | Owner |
| <input type="checkbox"/> Admin, Portal | Read |
| <input checked="" type="checkbox"/> [Redacted] | Read |

Showing 1 to 3 of 3 entries (1 row selected of 3)

Below this table is a 'Permission History Table' with a search bar. The table is currently empty, showing 'No data available in table'.

At the bottom, there are 'SAVE & FINISH' and 'Cancel' buttons, with 'SAVE & FINISH' highlighted by a red box. A note at the very bottom states: 'Note: Study Administrators have administrative permission for all studies regardless of any permissions they have been granted.'

12. After clicking **Save & Finish**, you will be taken to the **Study Overview Page**.

THIS PAGE HAS BEEN LEFT INTENTIONALLY BLANK
