THIS PAGE HAS BEEN LEFT INTENTIONALLY BLANK

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:

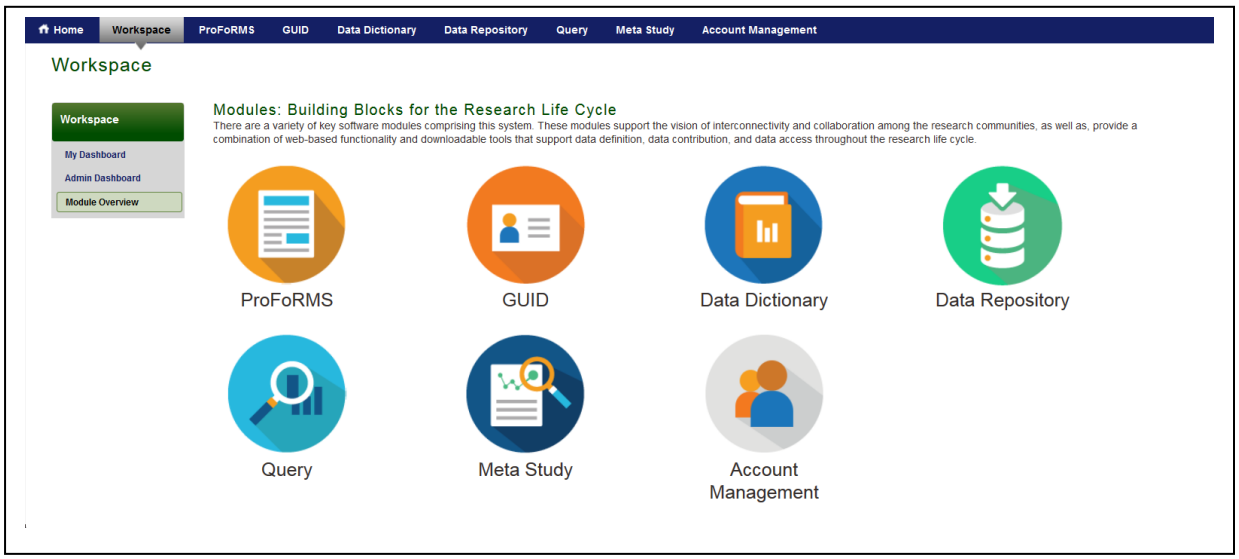
- Manage Studies
  - View Studies
  - Create a Study
  - Edit a Study
  - Submit Request to Approve Data Document
  - Add Form Structure
  - Search Studies
- Other Tools: Submission Tools, MIPAV Tool, and Download Tool (See **Chapter 9 MIPAV**, **Chapter 10 Data Validation**, and **Chapter 11 Download 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

ICON KEY

Notes

Important Information

Things to Note:

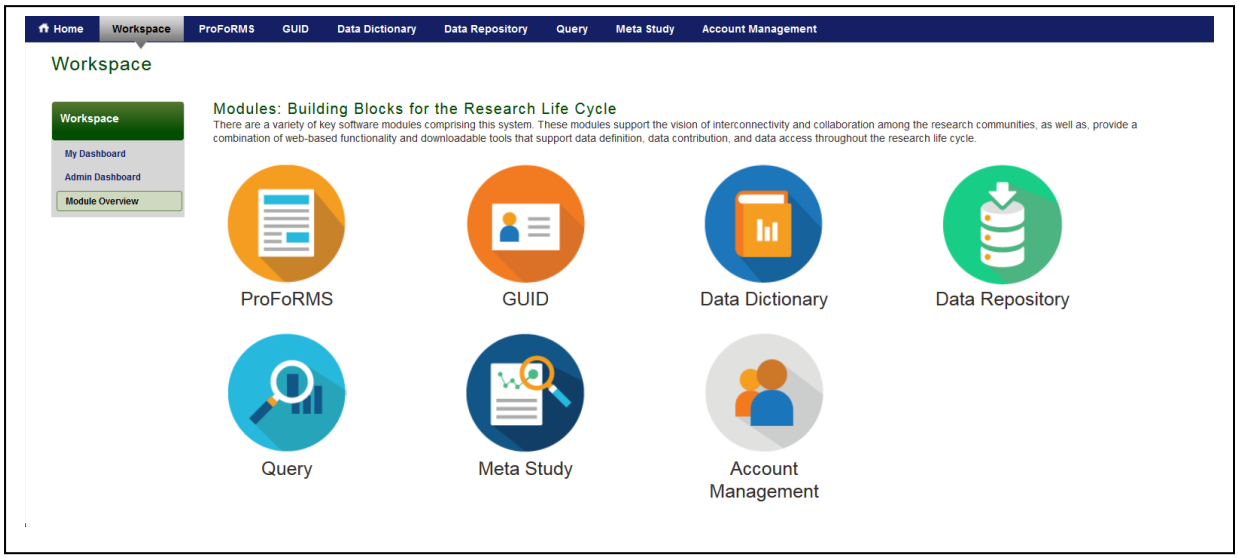
- The best user experience with navigating through the Data Repository module is with the latest Firefox browser
- Java Runtime Environment (JRE) version 8 or higher is required. Check your version of Java.

5.2.1 View Studies

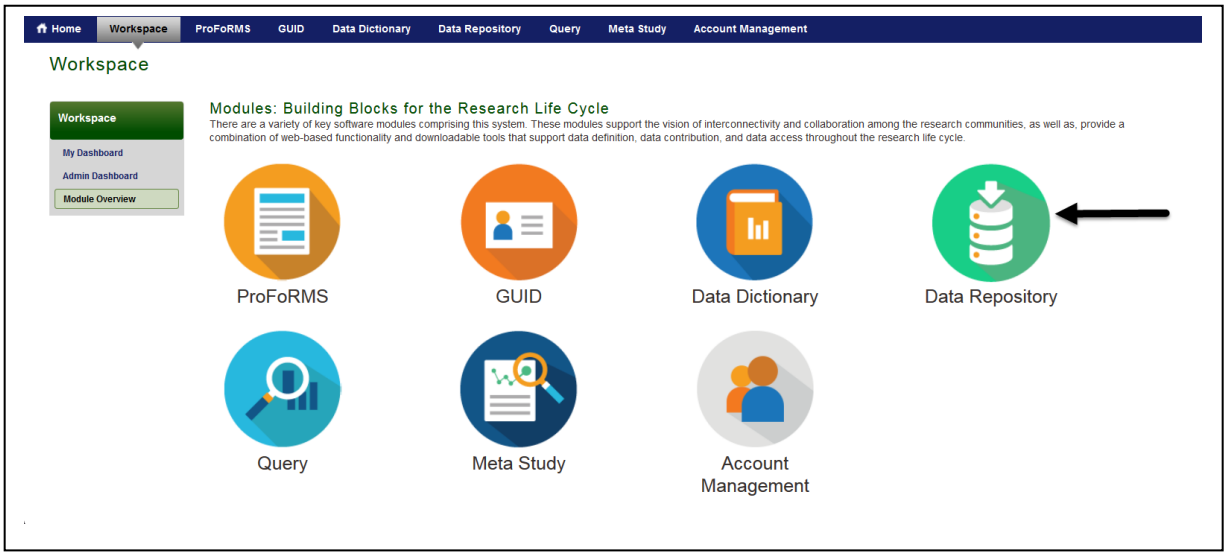
The **View Studies** lists the studies that the user has permission to view. The filters provided within the View Studies list allows users to filter the list by **Ownership**, **Data Submission Status**, and **Data Type**. The search capability allows users to search by: **Study Title**, **Organization, Study ID, Principle Investigator (PI), Funding Source,** and by the **Permission type** that the user holds for that particular study (Owner, Admin, Read, or Write).

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

1. Login to the system.
2. Navigate to the Workspace landing page.

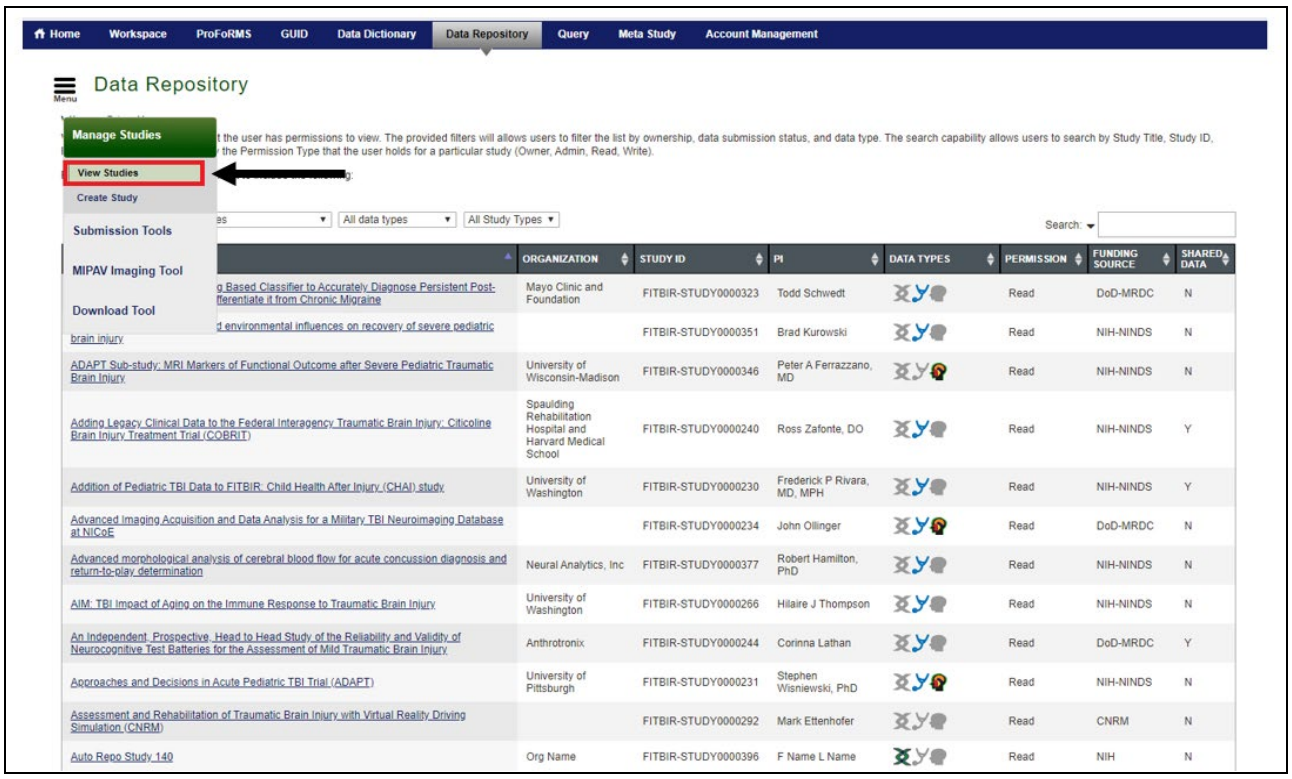


3. Click the **Data Repository** module icon.



4. Click the Menu on the left-side tool bar to select the View Studies. **Note**: By default, the system brings you to the View Studies from the Workspace landing page.

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



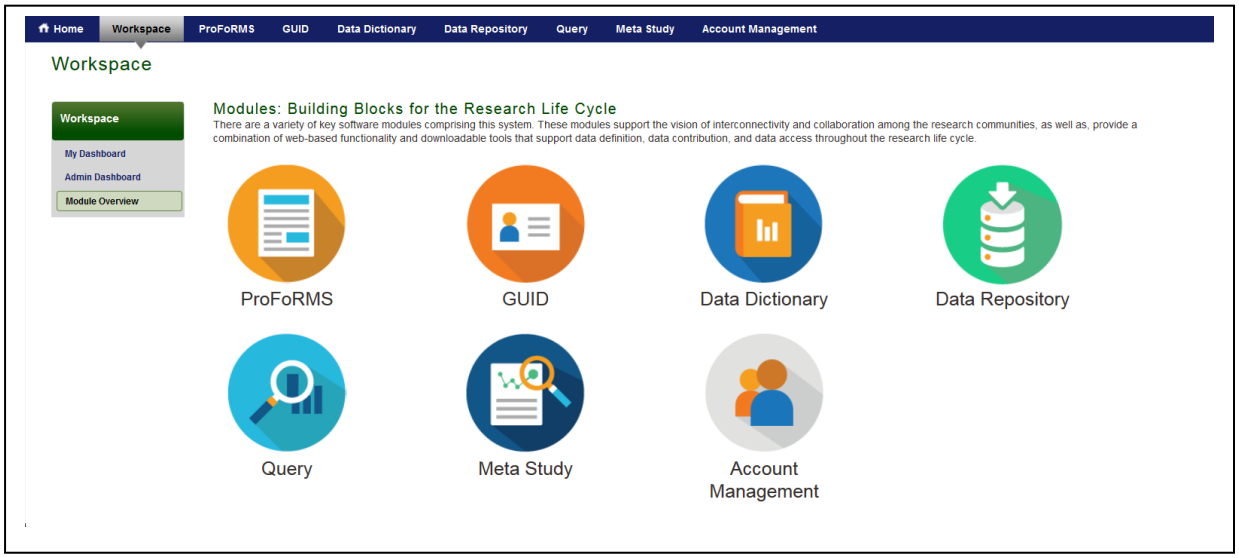
	ORGANIZATION	STUDY ID	PI	DATA TYPES	PERMISSION	FUNDING SOURCE	SHARED DATA
g Based Classifier to Accurately Diagnose Persistent Post-fferentiate it from Chronic Migraine	Mayo Clinic and Foundation	FITBIR-STUDY0000323	Todd Schwedt		Read	DoD-MRDC	N
d environmental influences on recovery of severe pediatric brain injury		FITBIR-STUDY0000351	Brad Kurowski		Read	NIH-NINDS	N
ADAPT Sub-study: MRI Markers of Functional Outcome after Severe Pediatric Traumatic Brain Injury	University of Wisconsin-Madison	FITBIR-STUDY0000346	Peter A Ferrazzano, MD		Read	NIH-NINDS	N
Adding Legacy Clinical Data to the Federal Interagency Traumatic Brain Injury: Citicoline Brain Injury Treatment Trial (COBRIT)	Spaulding Rehabilitation Hospital and Harvard Medical School	FITBIR-STUDY0000240	Ross Zafonte, DO		Read	NIH-NINDS	Y
Addition of Pediatric TBI Data to FITBIR: Child Health After Injury (CHAI) study	University of Washington	FITBIR-STUDY0000230	Frederick P Rivara, MD, MPH		Read	NIH-NINDS	Y
Advanced Imaging Acquisition and Data Analysis for a Military TBI Neuroimaging Database at NICoE		FITBIR-STUDY0000234	John Ollinger		Read	DoD-MRDC	N
Advanced morphological analysis of cerebral blood flow for acute concussion diagnosis and return-to-play determination	Neural Analytics, Inc	FITBIR-STUDY0000377	Robert Hamilton, PhD		Read	NIH-NINDS	N
AIM: TBI Impact of Aging on the Immune Response to Traumatic Brain Injury	University of Washington	FITBIR-STUDY0000266	Hilaire J Thompson		Read	NIH-NINDS	N
An Independent, Prospective, Head to Head Study of the Reliability and Validity of Neurocognitive Test Batteries for the Assessment of Mild Traumatic Brain Injury	Anthrotronix	FITBIR-STUDY0000244	Corinna Lathan		Read	DoD-MRDC	Y
Approaches and Decisions in Acute Pediatric TBI Trial (ADAPT)	University of Pittsburgh	FITBIR-STUDY0000231	Stephen Wisniewski, PhD		Read	NIH-NINDS	N
Assessment and Rehabilitation of Traumatic Brain Injury with Virtual Reality Driving Simulation (CNRM)		FITBIR-STUDY0000292	Mark Ettenhofer		Read	CNRM	N
Auto Repo Study 140	Org Name	FITBIR-STUDY0000396	F Name L Name		Read	NIH	N

5.2.2 Edit Studies

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

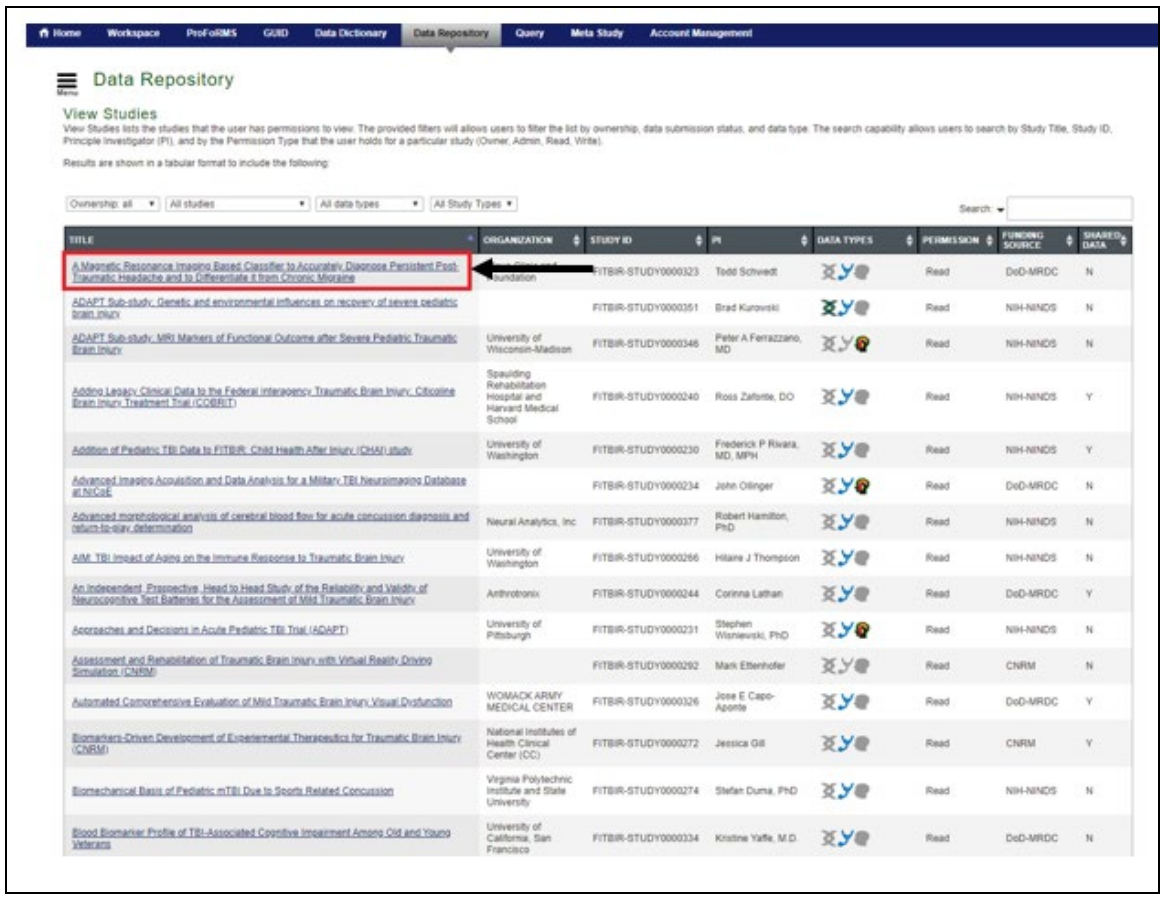
To Edit Studies in Data Repository: **Perform the following actions:**

1. Login to the system.
2. Navigate to the Workspace landing page.

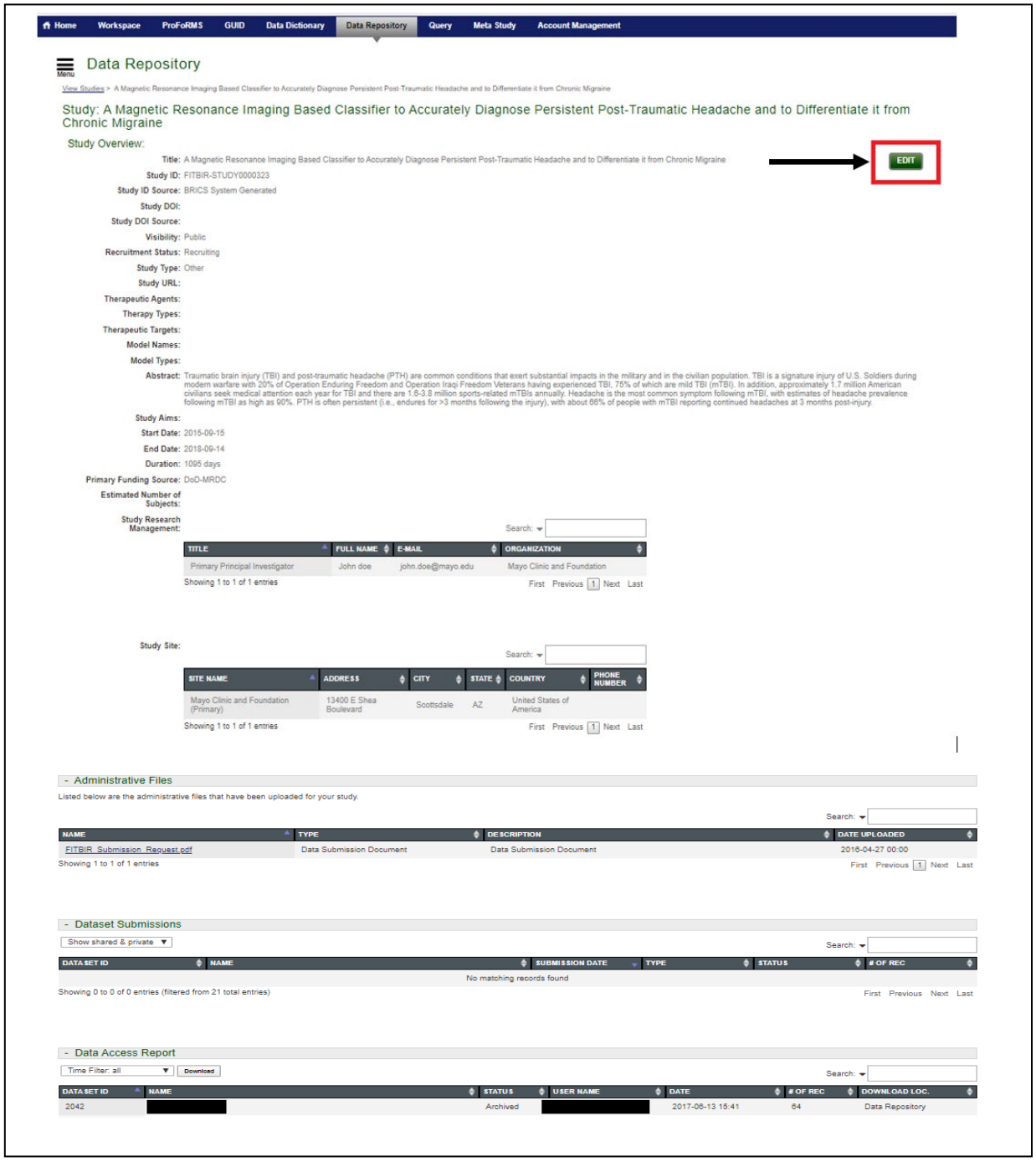


3. Click the **Data Repository** module icon.

4. By default, the system brings you to the View Studies from the Workspace landing page. From the Data Repository View Studies list page, select the study you like to edit by clicking on the study link as shown below:

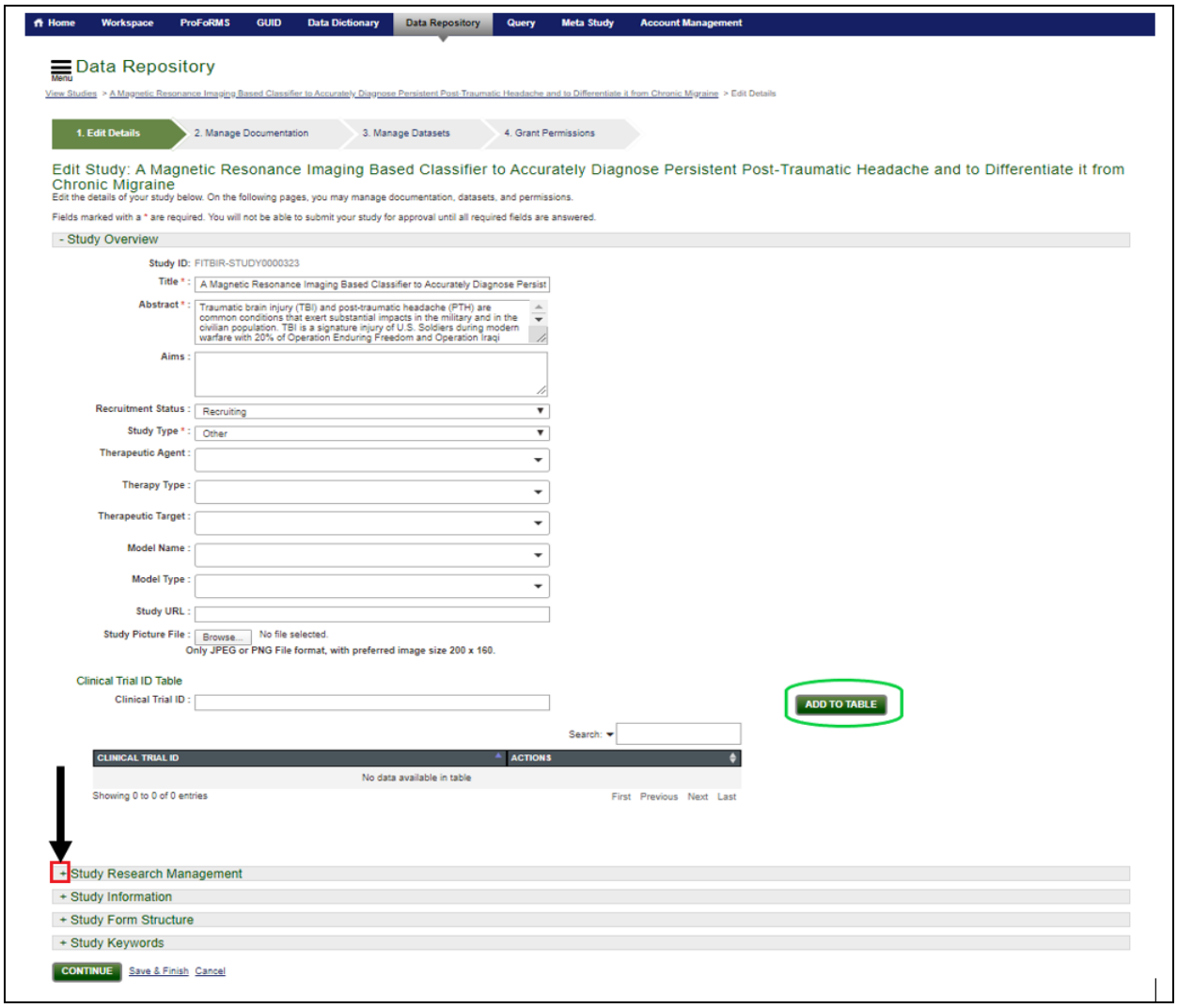


5. The Study Overview page appears. Click the **Edit** button.

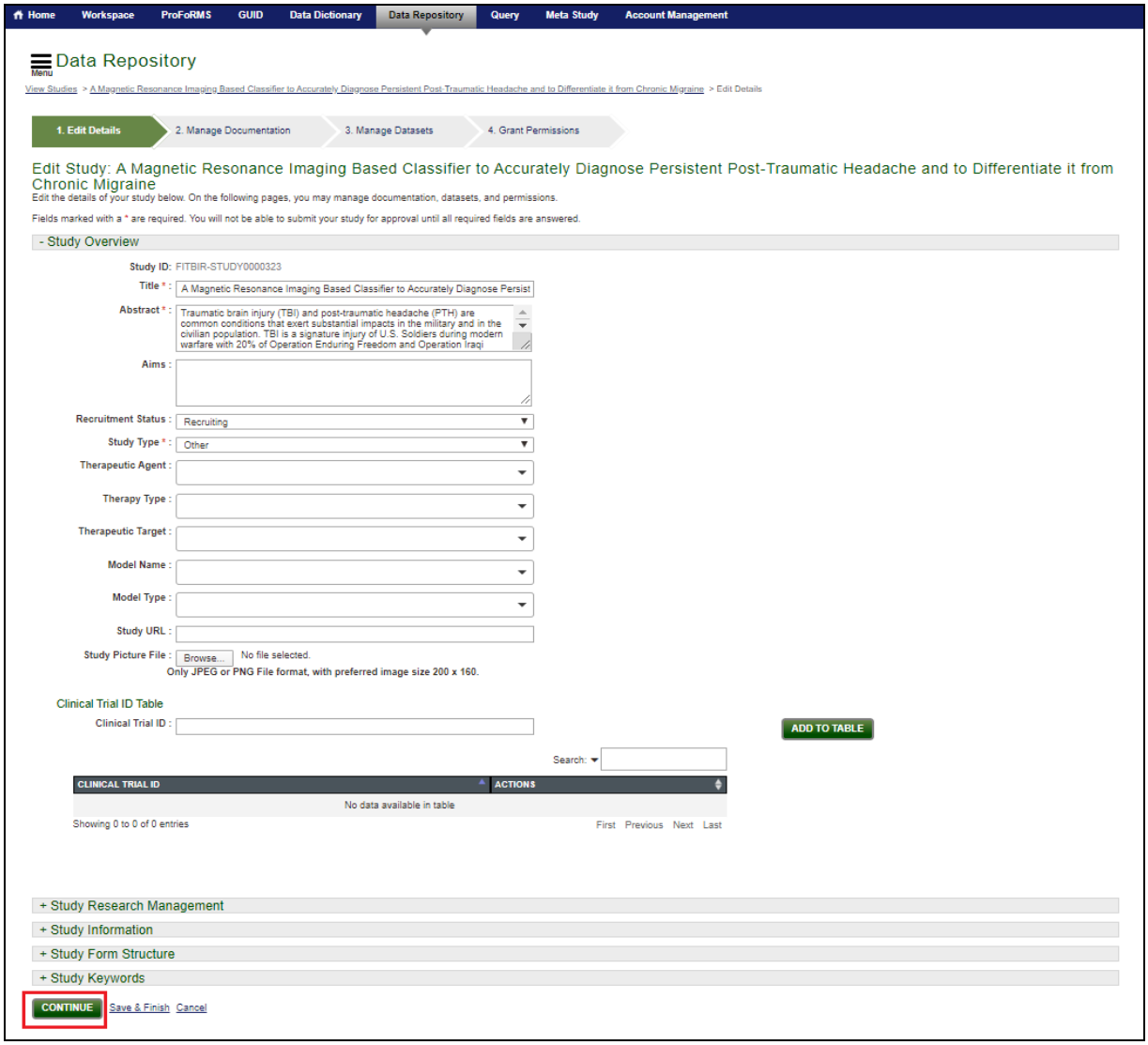


6. Edit the details of your study as shown below. Clicking on the **[+]** expansion icon expands the various section (**Study Research Management**, **Study Information**, **Study Form Structure**, and **Study Keywords**) for additional study details.

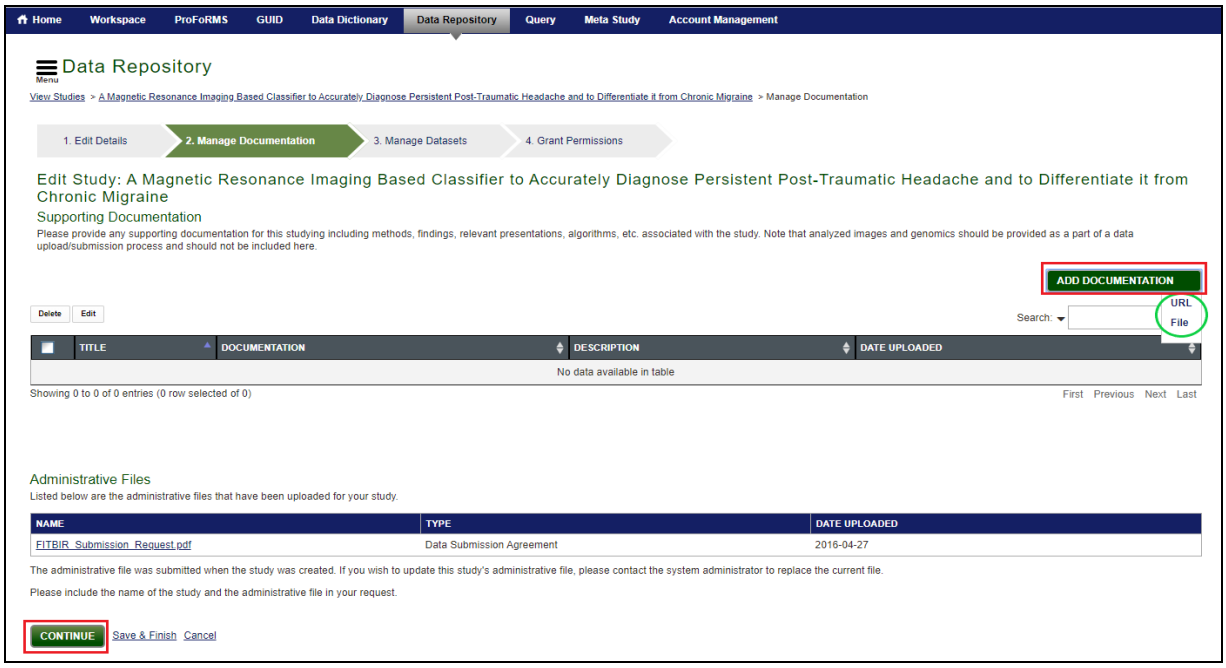
   On the following pages, you may manage **documentation**, **datasets**, and **permissions**. **Note**: Fields marked with an asterisk ***** are required. You will not be able to submit your study for approval until all required fields are answered.



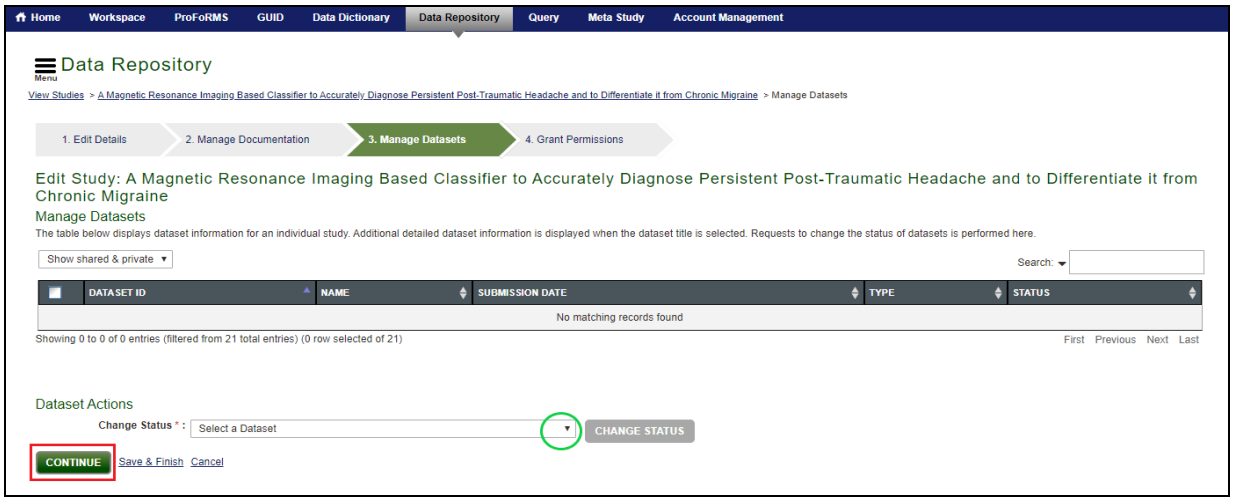
7. Click the **Continue** button when complete.



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



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.

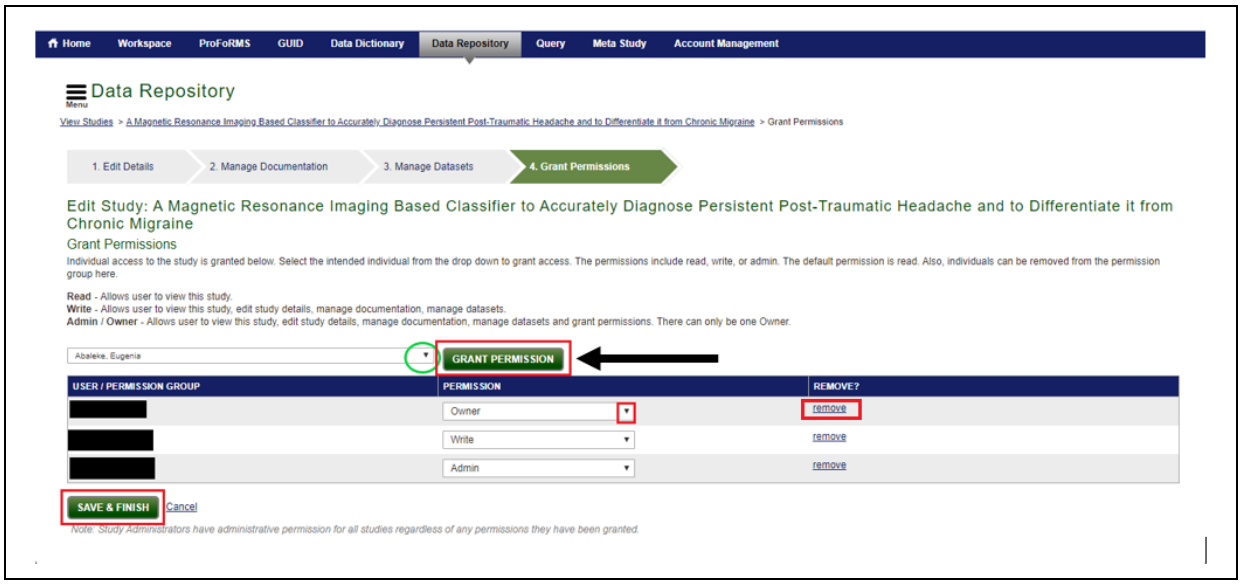


10. In the **Grant Permissions** section, individual access to the study profile and datasets can be granted to users during submission. The different permissions are **Read, Write**, and **Admin**. Other users will have Read access once the datasets have been shared.

To grant access to study team members to the study profile and datasets, select a username from the Drop Down list. Click on the **Grant Permission** button. Select the permission access for the user. Note: Study Administrators have administrative permissions for **ALL** studies regardless of any permissions they have been granted. To remove users from the study profile, click **Remove.** Click **Save & Finish** to complete the process.

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.



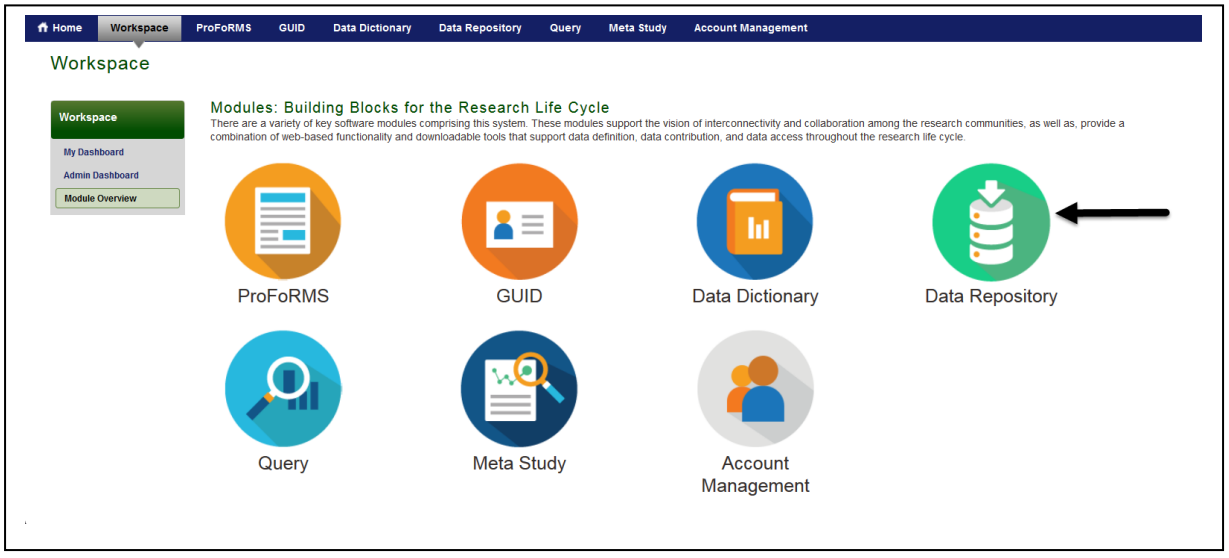
5.2.3 Create Study

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.

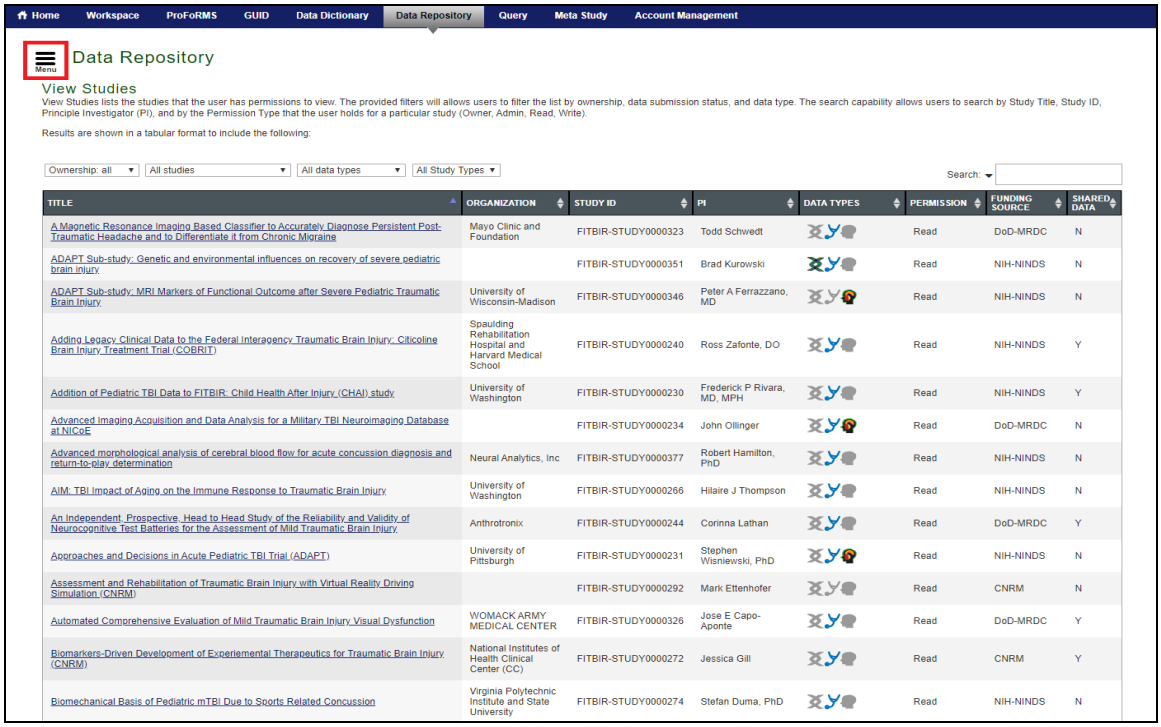
To Create a Study in Data Repository: Perform the following actions:

1. Login to the system.
2. Navigate to the Workspace landing page.

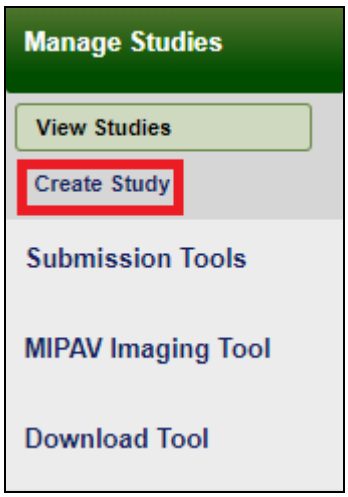
3. Click the **Data Repository** module icon.



4. Click the Menu on the left-side tool bar. The Data Repository Tool menu opens and expands.



5. Select **Create** under Form Structures from the left-hand drop-down menu. The Create Study general details page appears.



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

- Title*
- Abstract*
- Aims
- Recruitment Status
- Study Type*
- Therapeutic Agent
- Therapy Type
- Therapeutic Target
- Model Name
- Model Type
- Study URL
- Study Picture File
- Clinical Trial ID

Study Research Management: Complete all required fields marked with an *asterisk:

- Role*
- First Name*
- Middle Initial
- Last Name*
- Suffix
- E-Mail
- Organization Name*
- ORCID
- Picture File

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

- Site Name*
- Address
- Country
- City
- Phone Number
- Start Date*
- End Date*
- Estimated Number of Subjects
- Primary Funding Source*

- Grant/Project ID

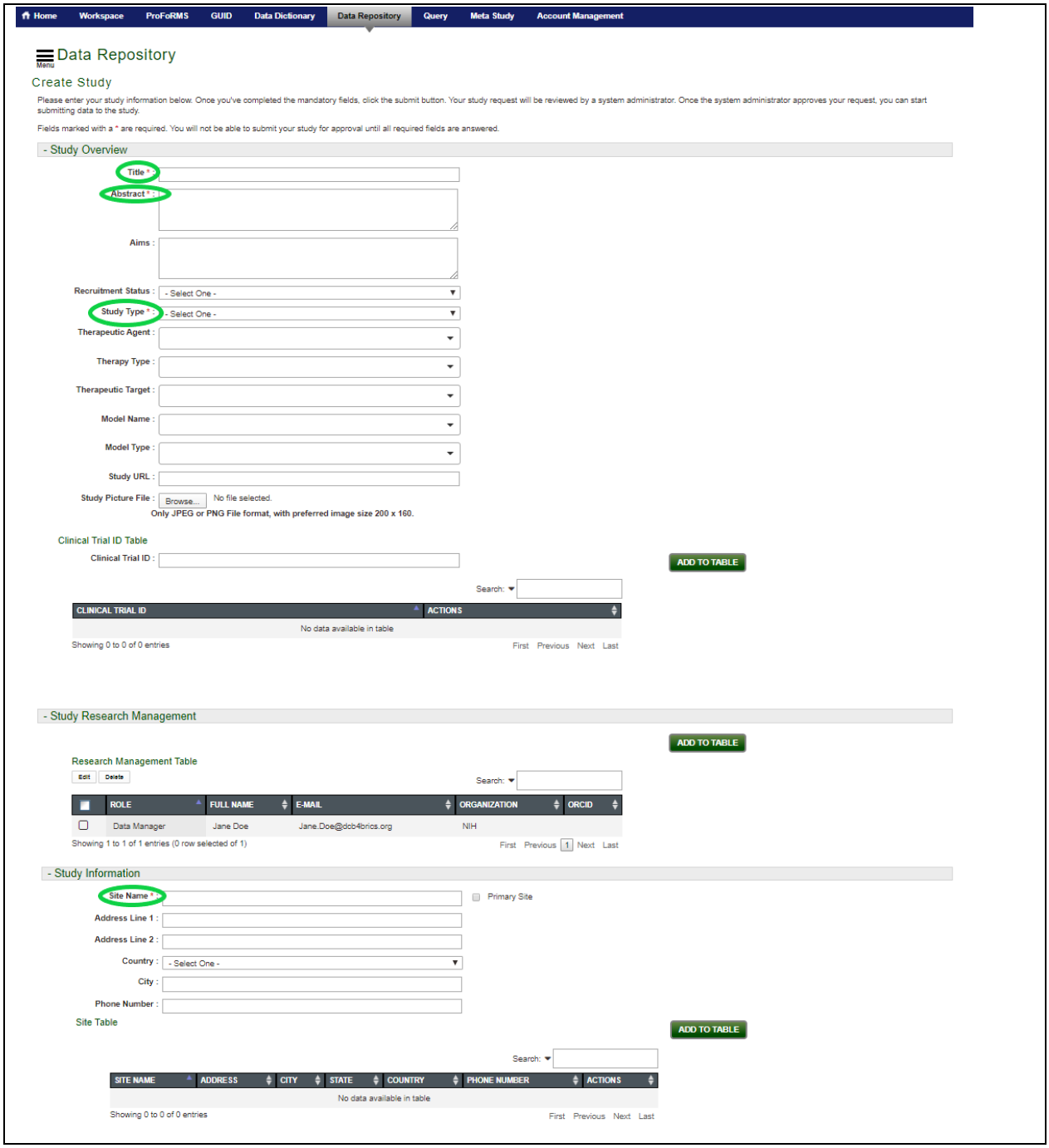
Study Form Structure:

- Form Structures

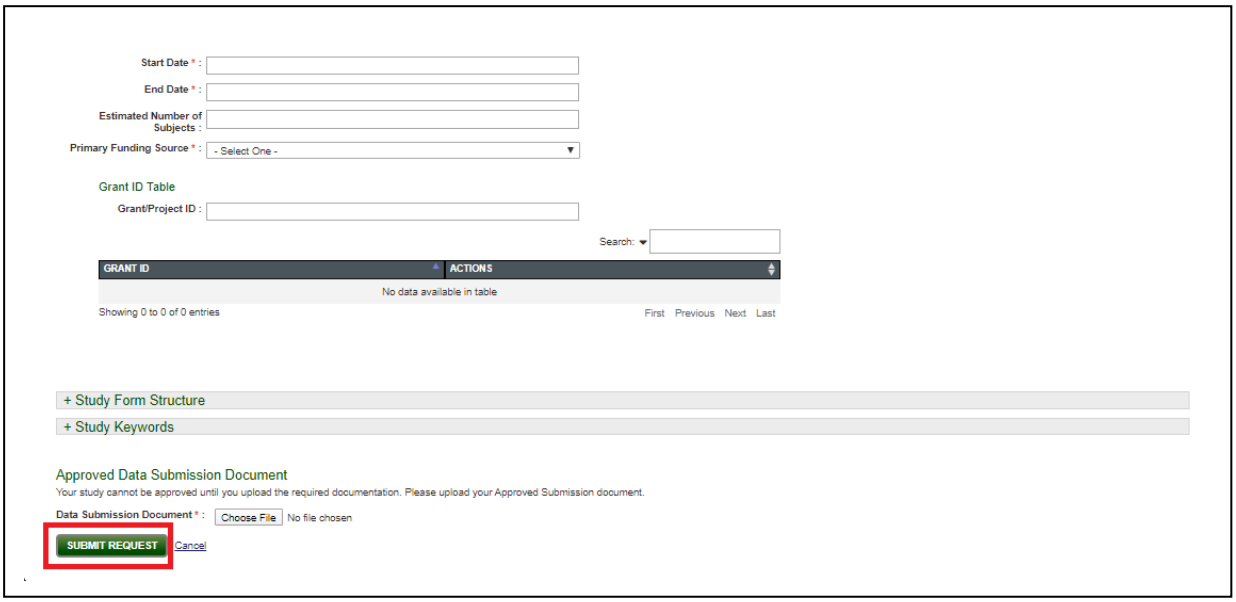
Study Keywords:

- Associated Keywords

7. Fill out the general details below to create a study. On the following pages, you may attach data elements and apply permissions. Fields marked with a * are required.



8. Click the **Submit Request** button**. Note:** Your study cannot be approved if the required data submission documentation(s) are not uploaded. Remember to submit your Approved Submission document.

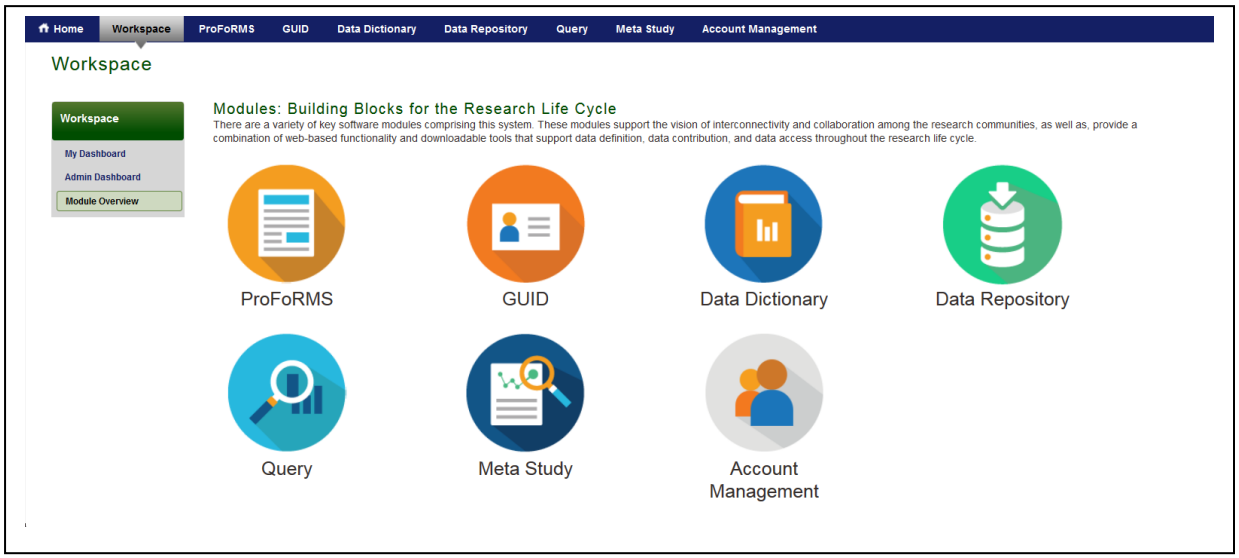


5.2.4 Search Studies

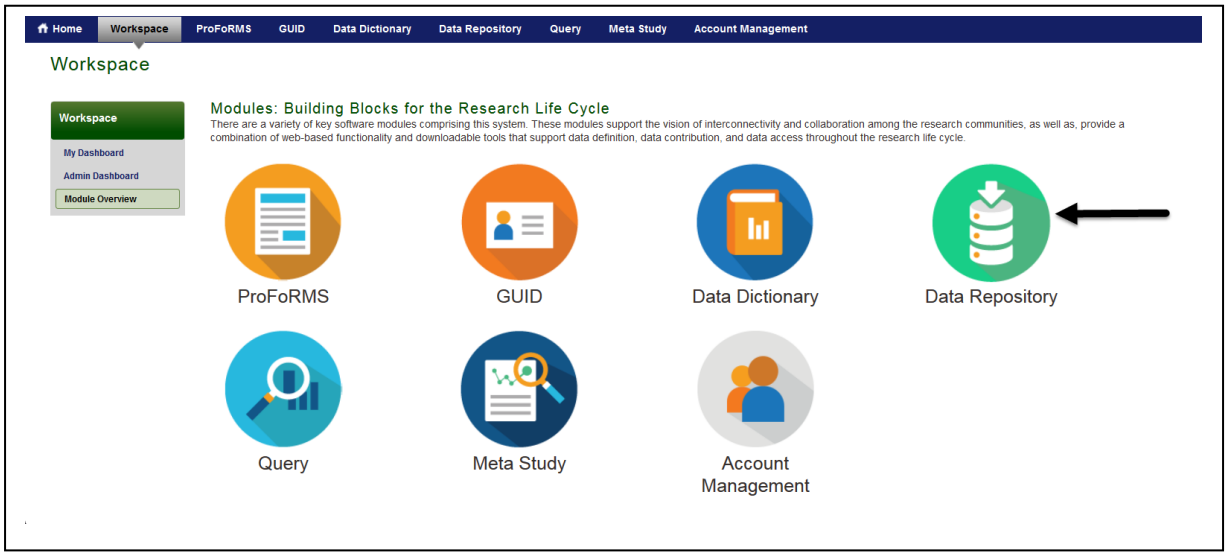
The search capability allows users to search by **Study Title**, **Study ID**, **Principle Investigator** (PI), and by the **Permission Type** that the user holds for a particular study (Owner, Admin, Read, or Write).

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

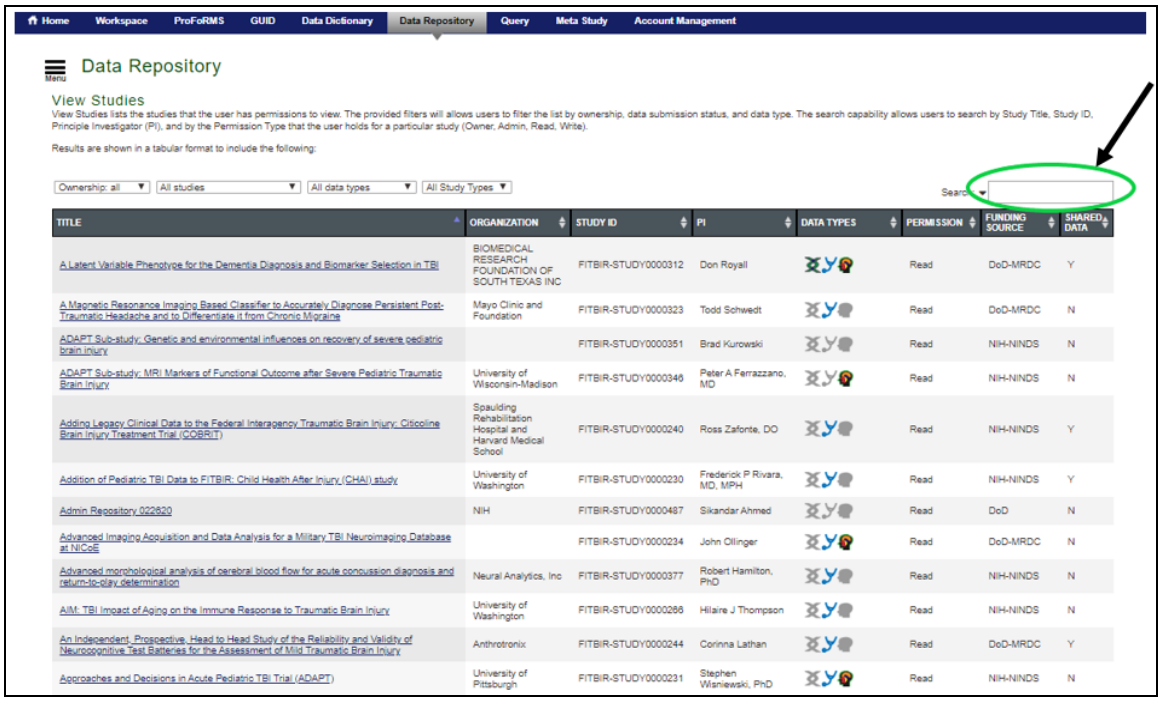
1. Login to the system.
2. Navigate to the Workspace landing page.



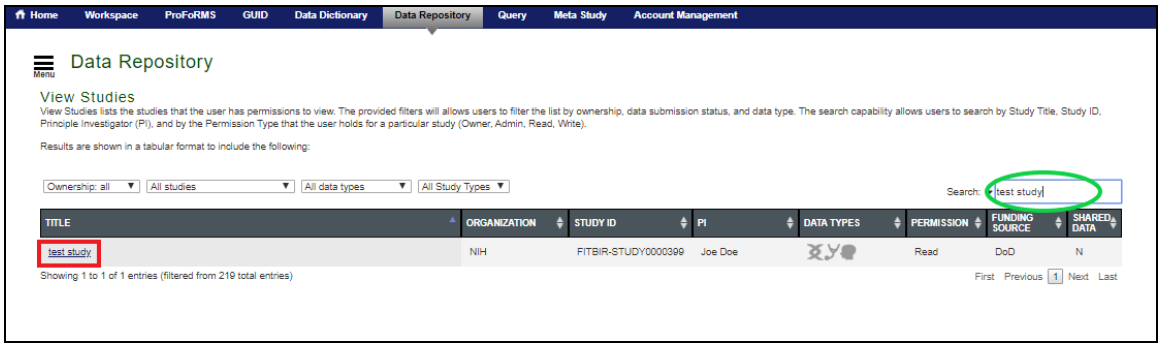
3. Click the **Data Repository** module icon.



4. By default, the system brings you to the View Studies from the Workspace landing page. In the search text-box, enter the **Study Title, Study ID, Principle Investigator (PI), and/or** by the **Permission Type** that the user holds for a particular study (Owner, Admin, Read, or Write).



5. In this example, “test study” was used for the search. The study appears in the View Studies list page as shown below:



THIS PAGE HAS BEEN LEFT INTENTIONALLY BLANK