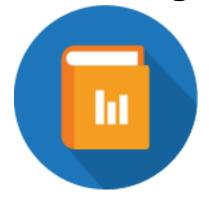
Chapter

# Data Dictionary





# **CHAPTER 4 – DATA DICTIONARY**



he **Data Dictionary** module is used for defining and validating data. Data Dictionary allows users to search for Common Data Elements (CDE), create and manage Unique Data Elements (UDE), browse, define, use and re-use electronic forms (eCRFs) and form structures across the studies.

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

#### 4.1 OBJECTIVE

This chapter provides information for users on how to:

- ❖ Search Form Structures
- Create Form Structures
- ❖ Search Data Elements
- Create Data Elements
- Import Data Elements
- Search eForms
- Create eForms
- ❖ Import Form Structure
- Import Data Element Schema
- ❖ Browse existing Data Elements
- **❖** Browse Form Structures
- **♦** Browse eForms

#### 4.2 System Functions

The Data Dictionary module provides the tools for defining the data you submit as well as provide alternate terms (aliasing) and translation rules for the same element. Importantly, the BRICS data dictionary provides those who have access to the data with clear and precise information about what it is they are accessing.

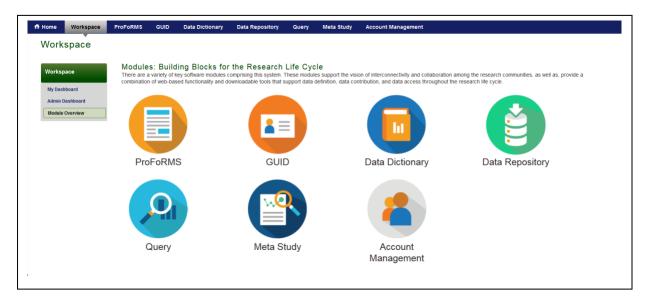


# 4.3 MODULE NAVIGATION

The Data Dictionary module (including sub-modules) are available within the BRICS Workspace.

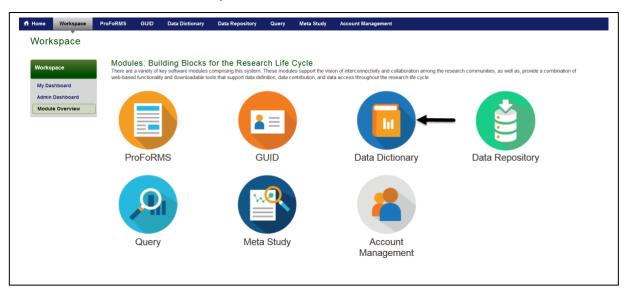
To Access the Data Dictionary Module: Perform the following actions:

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

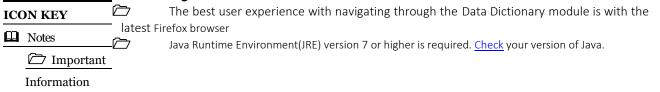




# 3. Click the Data Dictionary module icon



#### Things to Note:





#### 4.4 DATA DICTIONARY TOOL

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

- Searching Form Structures
- Creating Form Structures
- Searching Data Elements
  - o Downloading Data Elements Results to XML, CSV and ZIP output formats
- Creating Data Elements
- Importing Data Elements
- ❖ Searching e-Forms
  - o Downloading Data Elements Results to XML, CSV and ZIP output formats
- Creating e-Form
  - o Upload Published Form Structure
  - o Save Form
  - o Add Section
  - o Add Data Element
  - o Add Text
  - o Edit Form Layout

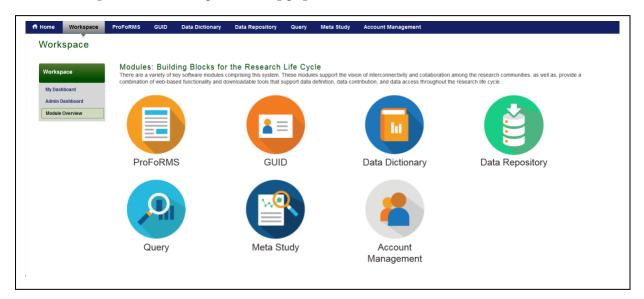
The **Data Dictionary Tool** also has a simple search box for performing keyword search within the forms fields using: **Short Name**, **Tittle**, **Description**, and **Created By**.



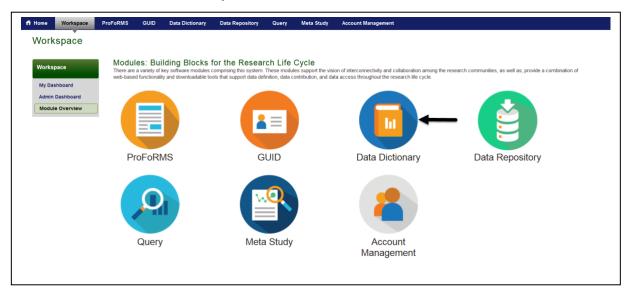
# 4.4.1 Accessing the Data Dictionary Tool

To Access the Data Dictionary Tool: Perform the following actions:

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

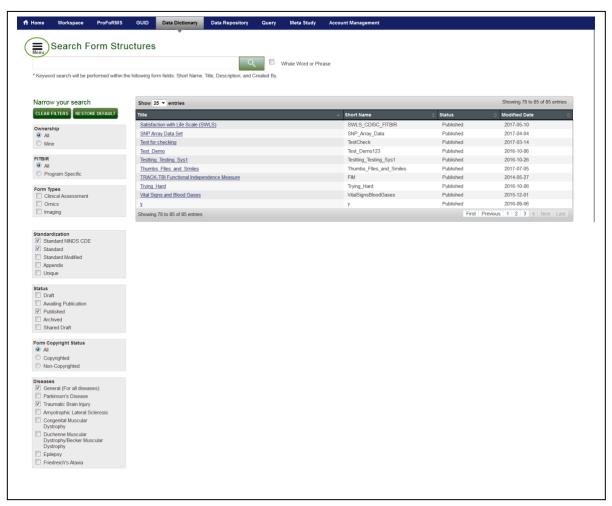


**3.** Click the **Data Dictionary** module.



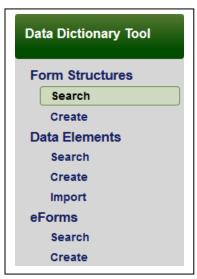


4. Click the Menu on the left-side tool bar.





5. The **Data Dictionary Tool** menu opens and expands as shown below:





#### 4.4.2 Form Structures

A form structure represents a grouping/collection of various Common Data Elements (CDE) and Unique Data Elements (UDE) used to gather information for a study. A form structure is analogous to a case report form (CRF) (electronic or paper) where data elements are linked together for collection and display.

Form structures are the containers for data elements. They are "vehicles" by which data is submitted to BRICS. They adhere to a strict publication process prior to researchers submitting data to that particular form structure. They are initially created in draft state – they can be modified and data elements may be removed or added to the form structure. Research data can be validated using a draft form structure in the <u>Validation Tab/Submission Tool</u>, but it cannot be uploaded to the database until it is validated.

Once the study team has validated research data using the Validation Tool, and is ready to upload data to the database, you may request publication of the form structure. Once the form structure has been approved by a BRICS administrator, it will be in a "**Published**" state, and can then be used to upload research data via the <u>Upload Tool/Submission Tool</u>.

#### **Form Structures** are used to:

- Upload data to the <u>Data Repository</u>. The form structure provides a container for uploaded data. The <u>Submission Tool</u> validates the uploaded data against the corresponding form structure.
- Create eforms (eCRFs) and collect data. The form structure provides a structure (or a template) for a form and a container for active data collection.
- ❖ The form structure assures that uploaded/collected data are queryable by the Query Tool.



# **4.4.3 Types of Form Structures**

There are four different Status of Form Structures found in BRICS. The table below details the various form types and the corresponding attributes.

Туре	Description	Visibility	Editable?	Data Validation Use?	Data Submission Use?
Draft	In a process of development	Required to log in into portal. Available for the owner and Administrator only	Yes	Yes	No
Awaiting publication	A publication has been requested for this FS	Required to log in into portal	By administrator only	Yes	No
Published	The FS which is available for public use	All users including the public site	By administrator only	Yes	Yes
Shared Draft	Form structures were created by the NINDS CDE Project. Provide recommendations for investigators of which CDEs to use.	All uses including the public site	By administrator only	Yes	No



#### **Things to Note:**

Shared Draft Form Structures are created and supported by the NINDS CDE Project.

A shared draft form structure provides a list of CDEs recommended to use for a particular CRF by the Notes

NINDS CDE Project.

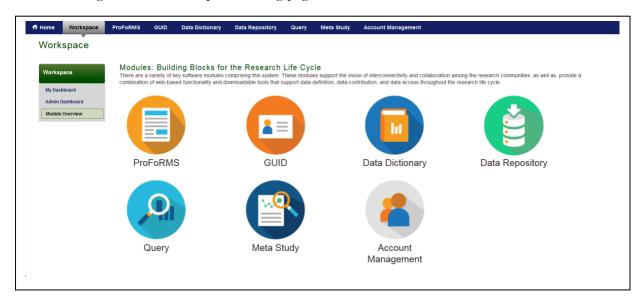
Investigators are required to use Shared Draft Form Structures as reference when creating their own form structures.

All Shared Draft Form Structures require the addition of the Main group and Form Administration group before they can be published to the system.

#### **4.4.4 Search Form Structures**

To Search Form Structures: Perform the following actions:

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



#### Things to Note:

ICON KEY

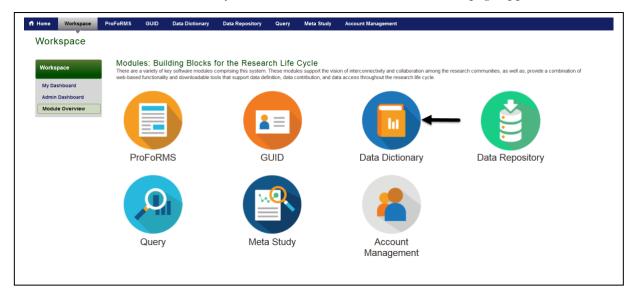
Notes

Important
Information

Instead of starting from nothing you may find shared draft or published form structures available in the Data Dictionary that may serve as a starting point for you by selecting "Browse Form Structures" from the left-hand Menu icon in the data dictionary.

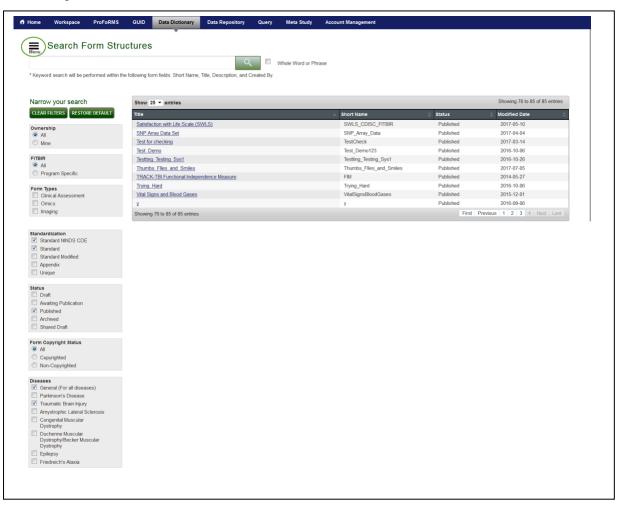


**3.** Click the **Data Dictionary** module. The Search Form Structures page appears.



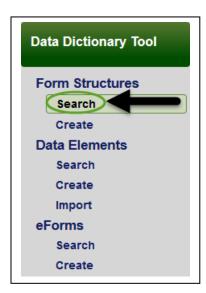


4. Click the Menu on the left-side tool bar. The Data Dictionary Tool menu opens and expands.



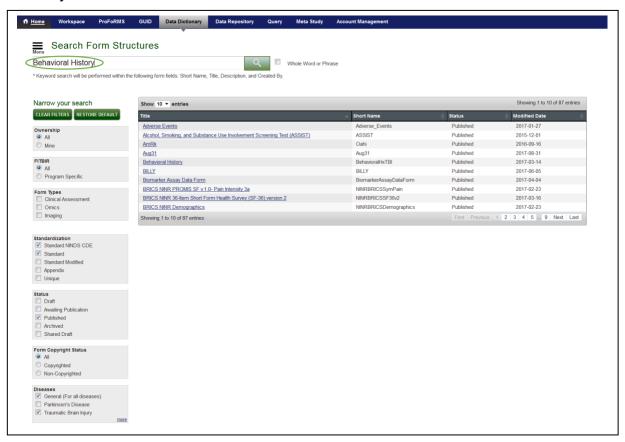
**5.** Click **Search** under the Form Structures tab using the left side menu to navigate through the sub-menus. The Search Form Structures page appears.





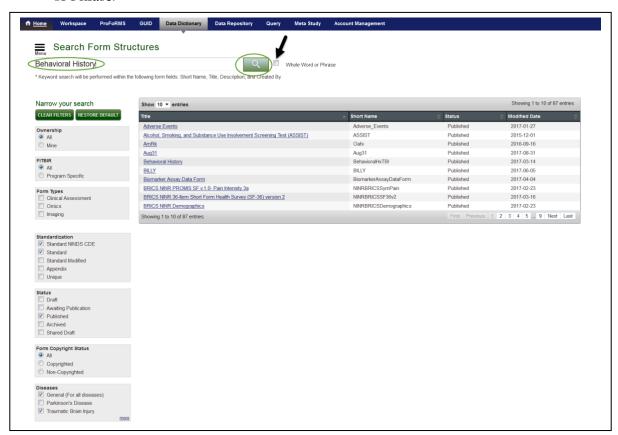


6. Using the search text-box, enter the search keyword to search. Keyword search will be performed within the form fields using the *Short Name*, *Tittle*, *Description* and *Created By*.



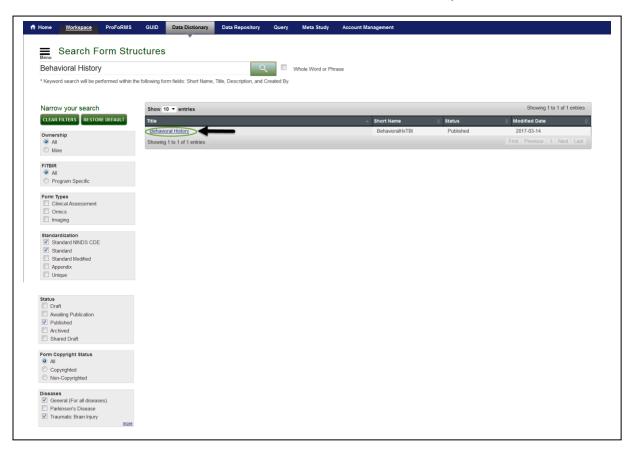


7. Click the **Search** button. You may also select the "check-box" to to search by Whole Word or Phrase.





**8.** The search returns the form structures relevant to the search keyword.





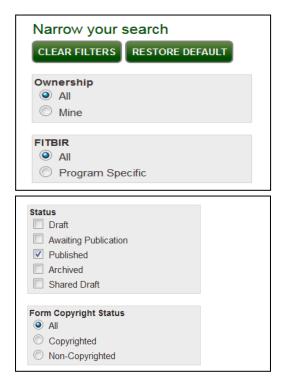
#### 4.4.1 Additional Search Features

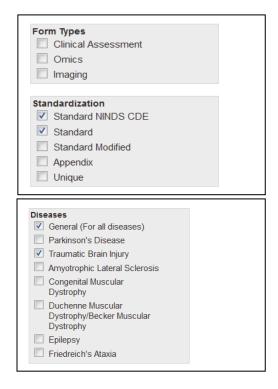
#### **Buttons:**

- ❖ Clear Filters use this button to clear your search criteria
- Restore Default use this button to restore to the default search field

#### Check-box:

- ❖ Ownership (All, Mine) to search for data by ownership. This includes data you may own
- ❖ FITBIR (All, Program Specific) TBD
- ❖ Form Types (Clinical Assesment, Omics, Imaging)
- Standardization (Standard NINDS CDE, Standard, Standard Modified, Appendix, Unique)
- Status (Draft, Awaiting Publication, Published, Archived, Shared Draft)
- Form Copyright Status (All, Copyrighted, Non-Copyrighted)
- Diseases (General (For all diseases), Parkinson's Diseases, Traumatic Brain Injury, Amyotrophic Lateral Sclerosis, Congenital Muscular Dystrophy, Duchenne Muscular Dystrophyia/Becker Muscular Dystrophy, Epilepsy, Friedreich's Ataxia)







#### **4.4.2 Create Form Structures**

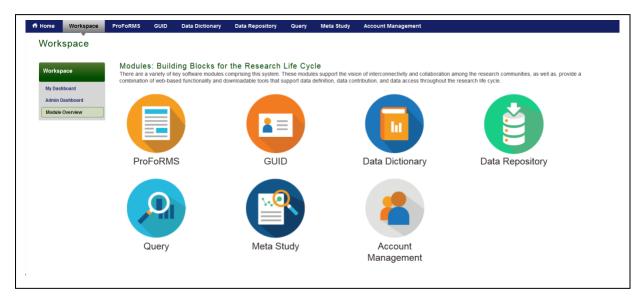
To be able to create form structures in BRICS, you <u>MUST</u> have the correct permissions to <u>Data Dictionary</u>. This level of permissions also allows the user to view, define, create, and modify the Unique Data Elements, and form structures. However, to create, modify and/or edit Common Data Elements (CDE), it must go through a review process with the NINDS.

There are two distinct steps for creating a Form Structure in BRICS:

- Without the Form Structure Template and;
- ❖ With the Form Structure Template

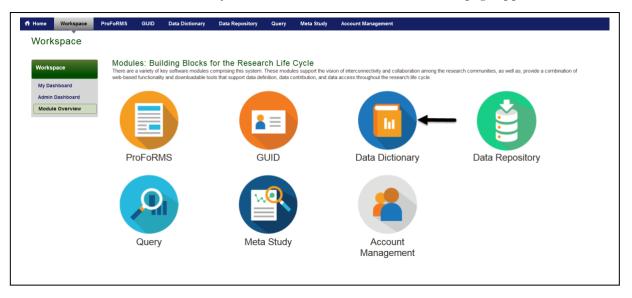
To Create Form Structures Without Using the Form Structure Template: Perform the following actions:

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



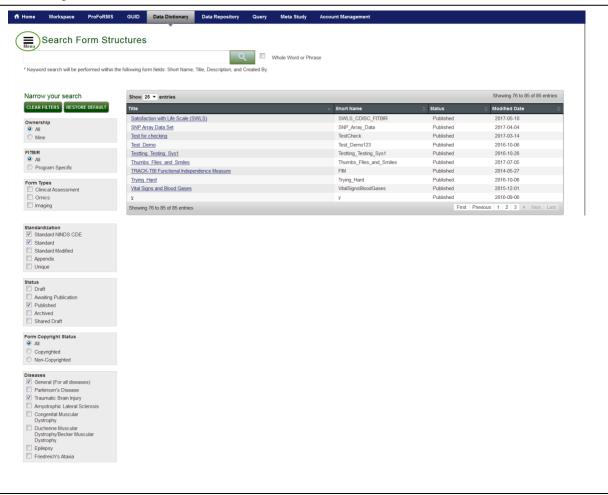


**3.** Click the **Data Dictionary** module. The Search Form Structures page appears.



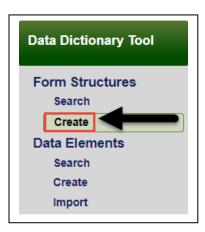


4. Click the Menu on the left-side tool bar. The Data Dictionary Tool menu opens and expands



**5.** Select **Create** under Form Structures from the left-hand drop-down menu. The Create Form Structure General Details page appears.

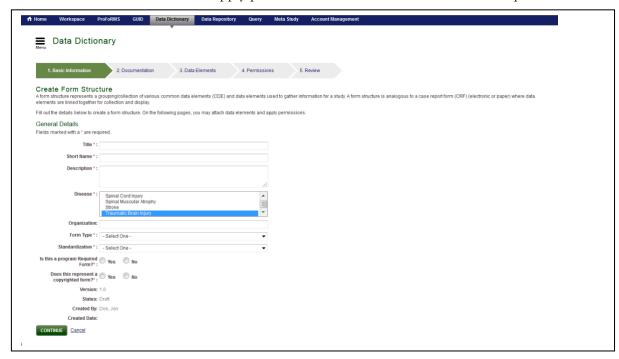




- **6. Basic Information:** Complete all required fields marked with an \*asterisk:
  - ❖ Tittle
  - Short Name (character limit applies)
  - Description
  - Form Type
  - Does this represent a copyrighted form?
  - Documentation is optional, but BRICS Operations encourage uploading a copy of your case report form.

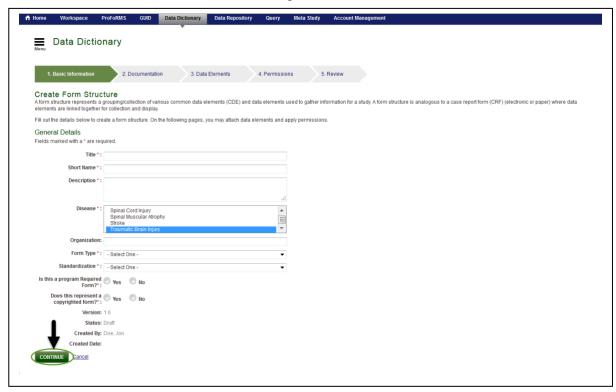


**7.** Fill out the general details below to create a form structure. On the following pages, you may attach data elements and apply permissions. Fields marked with a \* are required.

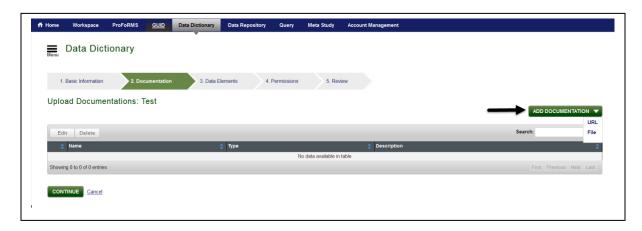




8. Click the Continue button when complete.

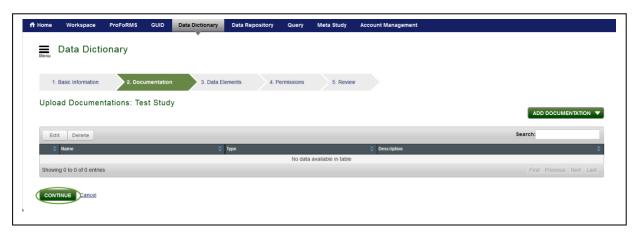


9. Documentation: Click the Add Documentation button to select the desired file or URL.

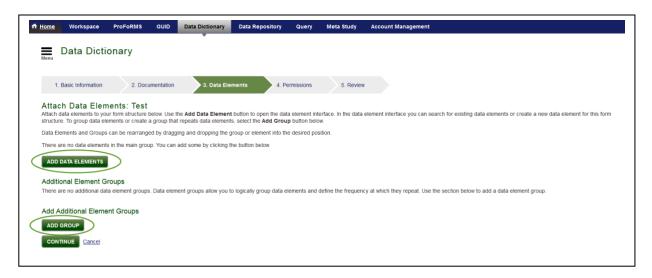




10. Click the Continue button.



10. Data Elements: Attach data elements to your form structure below by using the Add Data Element button to open the data element interface. In the data element interface, you can search for existing data elements or create a new data element for this form structure. To group data elements or create a group that repeats data elements, select the Add Group button below.



#### **Things to Note:**

ICON KEY Notes ☐ Important ☐

The Main Group and Form Administration are standardized group of data elements that must be included in all BRICS Form Structures, including standardized, addendum, and "homespun" form structures to provide consistency and context for all data submitted to the BRICS database.

You **DO NOT** need to add a new group to add the Main Group.

Information



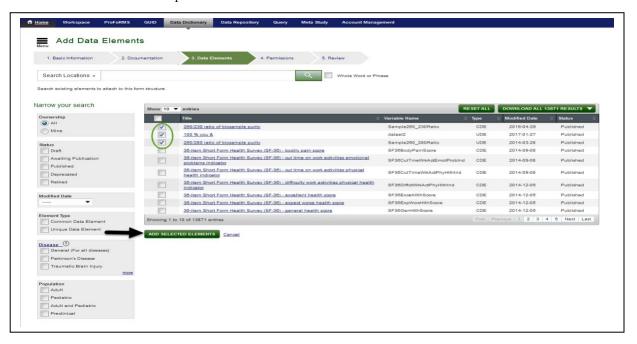
11. In the data element interface, you can search for existing data elements which you would like to add your form structure. Note: Now, a new data element cannot be created rather, Data Elements can only be added.

Select the data elements by checking the check-box next to the desired data element. Once you are done searching and checking off data elements; Click the **Add Selected Elements** button. The selected data elements will be added to your group in the **order in which they were selected.** [It is a best practice to add your data elements to your form structure in the order that they appear on the form].

To adjust the order of data elements within an element group once they have been added to a form structure, simply click on the data element, drag, and drop the data elements to the desired position.

There are three statuses for the optionality of a data element:

- Required: Validation tool will produce an error and not allow the dataset to pass if a cell is left blank for the data element.
  - o GUID should always be required
- Recommended: Validation tool will produce a warning, but still allow the data set to pass if a cell is left blank for that data element
  - o The default is recommended
- Optional: Validation tool will NOT produce error or warning and will allow that data set to pass if a cell is left blank for that data element.





**12.** To group data elements or create a group that repeats data elements, Select the **Add Group** button below.

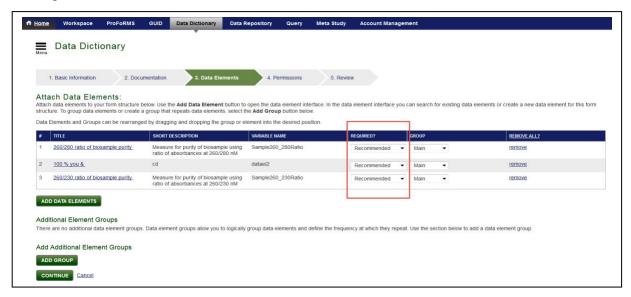


- **13.** Enter the Group Name which corresponds with the form structure; Select the number of times you wish the question to be repeated [*It is a best practice to select "Up to" if unsure*]. Enter the Threshold (the number which will correspond with your choice for "number of times repeated" above).
- **14.** Click on the "Save Group" button.





**15.** After the Main Group, create the Form Administration Group. This group contains **Eight** (8) data elements to identify the background of how the forms were administered. This group will be a part of all forms in the BRICS system. These data elements define what time point the CRF was taken, and who filled out the form.



#### Things to Note:

The Main Group must contain the following elements with the corresponding optionality:

Notes	_	
[☐ Imp	Туре	Data Submission Use?
Informat	ionnaUID	REQUIRED
	SubjectIDNum	OPTIONAL
	AgeYrs	RECOMMENDED
	VisitDate	RECOMMENDED
	SiteName	RECOMMENDED
	DaysSinceBaseline	OPTIONAL
	ContextType	RECOMMENDED
	ContextTypeOTH	RECOMMENDED
	DataSource	RECOMMENDED
	DataSourceOTH	RECOMMENDED
	CaseContrlInd	OPTIONAL
	GeneralNotesText	OPTIONAL
		L



**16.** Change the requirements for the data elements to whatever is appropriate for your study using the drop-down menu. [It is a best practice to change the data elements from "**Optional**" to "**Recommended**"

#### **Adjusting the Order of Element Groups**

a. Click on the title bar of the group and drag and drop the group to the desired position.Note: The Main Group cannot be moved

# **Editing Data Element Group Settings**

- a. Click on the "Edit Group" button
- **b.** Make the desired changes

#### Removing Data Element Group

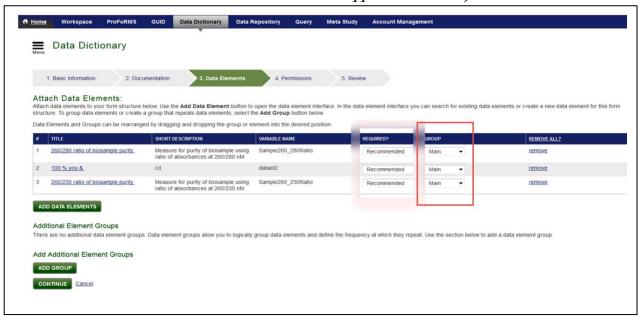
- a. Click on the "Remove Group" text
- **b.** Once you are finished creating your groups and adding your data elements, click on "Continue."

### **Removing Data Element From Form Structure**

a. Under the "Removal All?" column, click on "Remove" text

#### **Moving Data Elements Between Groups**

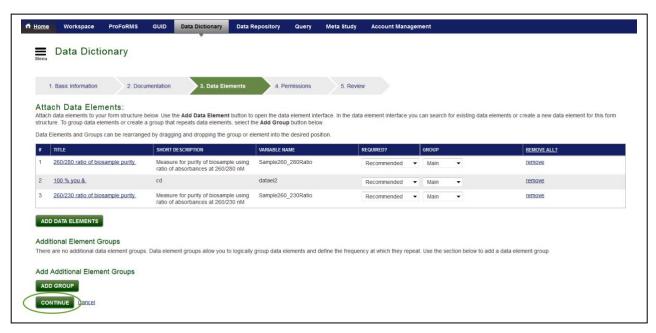
**a.** Using the drop-down menu in the Group column, for each data element, select which new element group you would like to move the data element. (*It is a best practice to do this in the order that the data elements appear on the form*).



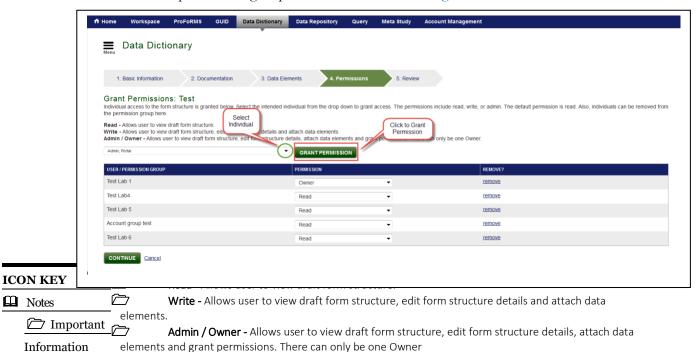


Motes Notes

17. Click the Continue button.



18. Grant Permissions: Select the intended individual from the drop-down menu to grant permission. Click on the Grant Permission button. . Once added, chose the desired level of permission to that form structure: The permissions include: Read, Write, or Admin/OwnerThe default permission is Read. Additionally, individuals can be removed from the permission group from here. See Removing Permissions below.



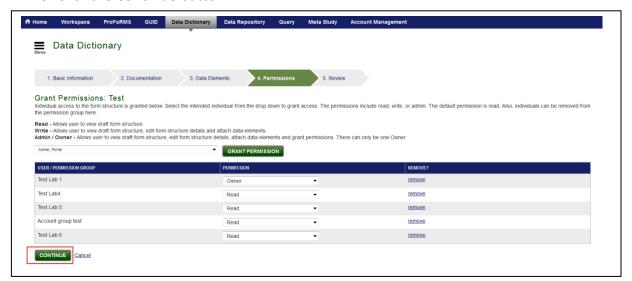


There can only be ONE Owner per form structure (by default it is the creator of the form structure, but can be changed)

## **Removing Permissions**

- **1.** Search for form structure
- 2. Select "Edit" form the Menu on the right
- **3.** Click on the "3. Permissions" chevron
- **4.** Click the "remove" button
- 5. The user will no longer have Admin/Write/Read privileges to your form structure

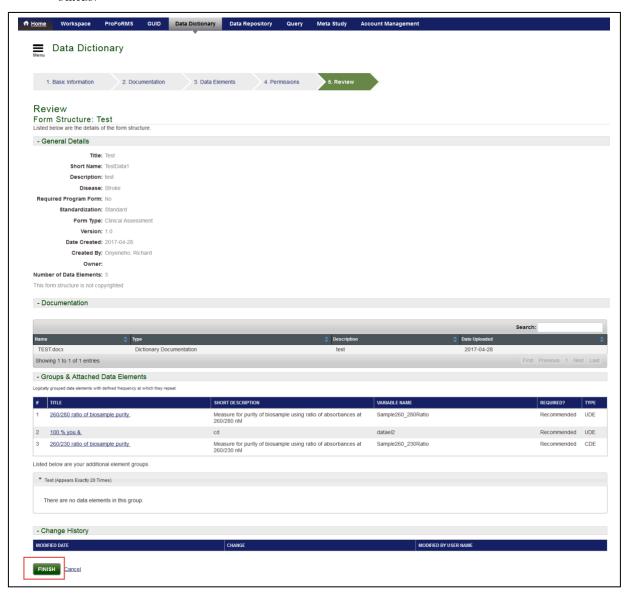
#### 19. Click the Continue button.





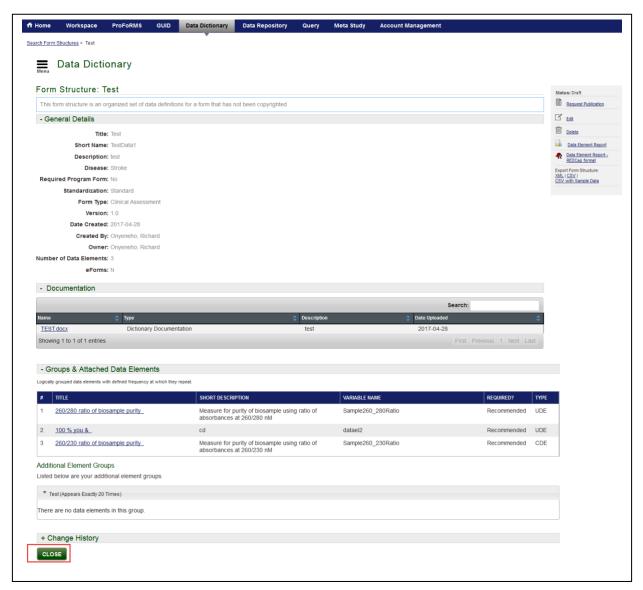
**20. Review**: Review all the data elements and make sure they are in the correct order and have the correct requirements (optionality, group, threshold, etc.)

If there are no issues; click the **Finish** button. The Form Structure will be saved in **DRAFT** status.





**21. Final Review**: Review the details of the Form Structure. Click the **Finish** button to display the Form Structure.





#### **Published Form Structures**

- 1. If you find a published form structure that is applicable to your study, you may use it as-is OR create a draft copy to adjust it to your needs. When in doubt, please contact your Operations team prior to creating a form structure.
- 2. Be SURE the Published Form Structure contains the appropriate Main Group
- 3. If not, contact your Operations Team
- **4.** If it is a STANDARDIZED form, then please follow the rules below for creating an **addendum form structure** (Section 4.4.1).

#### 4.4.1 Addendum Form Structures

Addendum form structures must be created if there are study-specific data elements you would like to add to a standardized instrument in the BRICS data dictionary to hold these extra data elements. **Note**: If the data elements you are adding affects the summary scores of the standardized form structure you will have to make a new form structure

#### To Create and Addendum: Perform the following actions:

- **1.** Login to the system.
- 2. Navigate to the Workspace landing page
- **3.** Follow these naming conventions:
  - a. Title: Form Name and acronym followed by Appendix and FITBIR study number
  - **b. Example**: Patient Health Questionnaire 9 (PHQ9) Appendix for FITBIR \_Study0000217
  - **c. Short Name**: Form Name/Acronym you are building the appendix for\_Appdx\_Number portion of FITBIR Study ID
  - d. Example: PHQ9\_Appdx\_0000217
- **4.** In addition to adding the study-specific data elements, you **MUST** include the data elements in the **MAIN GROUP** and the **FORM ADMINISTRATION GROUP** listed above.



#### 4.4.2 Data Elements

A Data Element (DE) is an information that describes a piece of data to be collected in a study. The DE does not include the data themselves. Attributes of DEs often include:

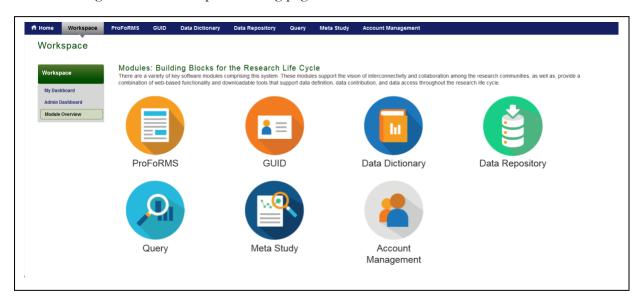
- ❖ Name The name of the Data Element. A short version of the name or a code may be used in addition to the name.
- **Definition** An explanation of the nature, scope, or meaning of the DE.
- ❖ Guidelines- Additional details about the DE beyond the definition. This may include instructions to the patient on how to respond to a question, instructions on how to conduct a laboratory test, etc.
- \* Reference Information describing the history or origin of a DE, as well as its scientific validity. This can include references to journal articles, Vocabularies or Data Standards, review process, validation, owner or creator, or other information.
- ❖ Permissible Values The set of possible values or responses. A Value Set often includes concepts from established Vocabularies or Data Standards. For laboratory tests, a value set may include a range of permissible values and indicate the required units. For a survey question, the value set may be a list of possible responses.



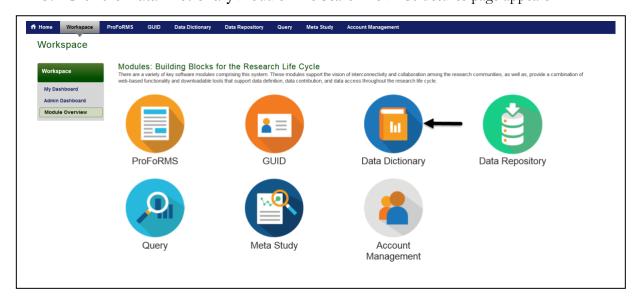
#### **4.4.1 Search Data Elements**

To Search Data Elements: Perform the following actions:

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

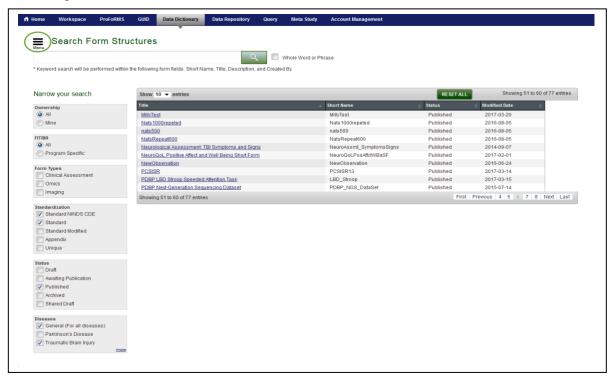


3. Click the Data Dictionary module. The Search Form Structures page appears.

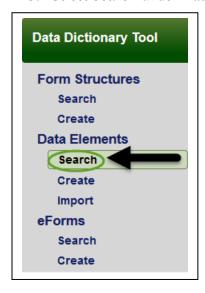




4. Click the Menu on the left-side tool bar. The Data Dictionary Tool menu opens and expands



5. Select **Search** under Data Elements from the left-hand drop-down menu.

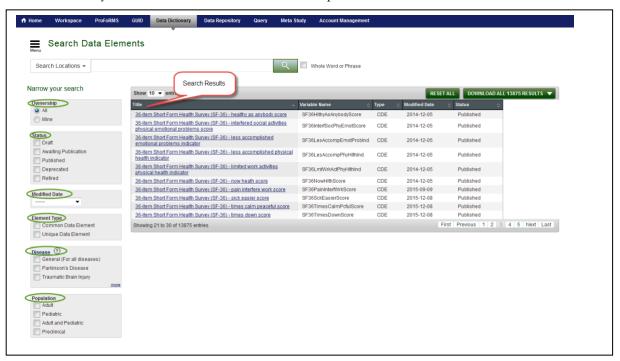


6. Using the search text-box, enter the search keyword to search. Keyword search will be performed within the form fields using the Search Locations (*Keywords, Definition*,



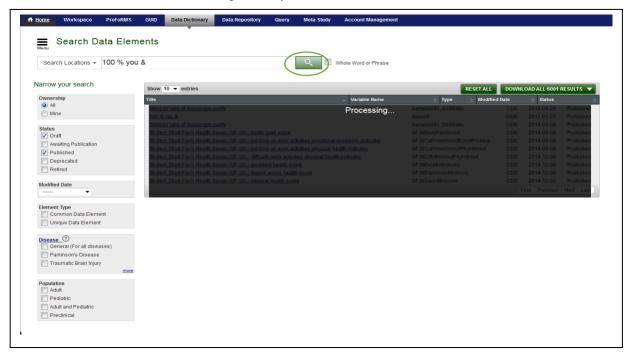
Permissible Values, External IDs, Variable Name, Created Date). You may also narrow your search by selecting the check-box beside the criteria you wish to search (Ownership, Status, Modified Date, Element Type, Form Types, Standardization,, Diseases, Population).

You may also click on the search results to open the Data Element.

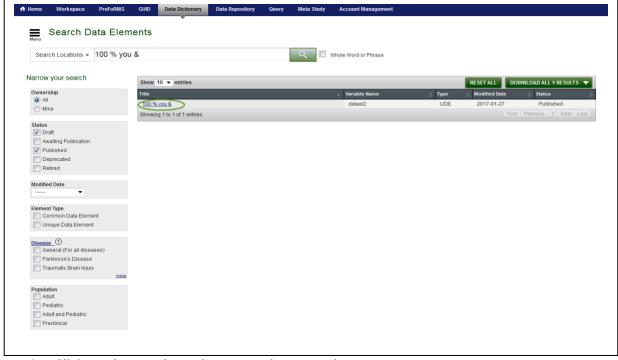




7. Click the **Search** button to process your search results.

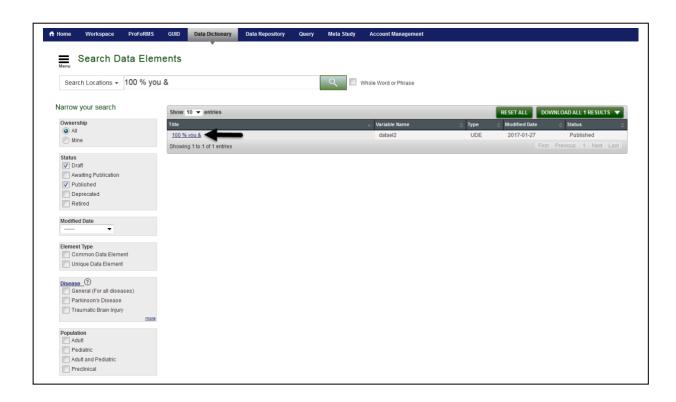


8. The search returns the Data Element relevant to the search criteria- 100% you &



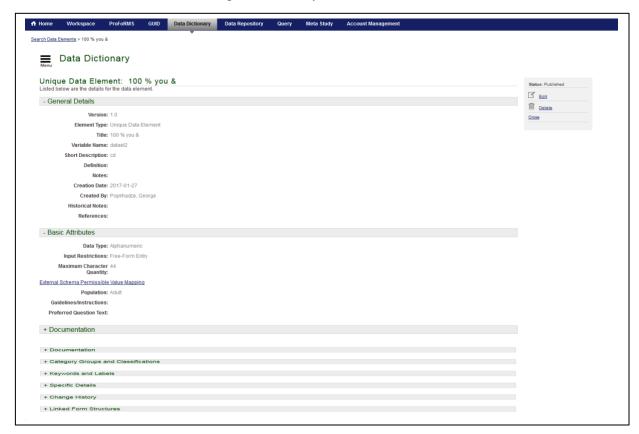
9. Click on the search result to open the Data Element.







**10.** The Data Element search opens – 100% you &.



## **Edit Data Elements**

- 1. Search for Data Element
- 2. Select "Edit" form the Menu on the right
- **3.** Edit the details for your data element. On the following pages, you may define the type of data captured and associate keywords (Fields marked with a \* are required.)
- **4.** Associate keywords to the data element (promotes reuse and improves the ability to search for data elements).

#### **Delete Data Elements**

- 1. Search for Data Element
- 2. Select "Delete" form the Menu on the right
- 3. Click on the "3. Permissions" chevron
- 4. Click the "remove" button
- 5. The user will no longer have Admin/Write/Read privileges to the form structure

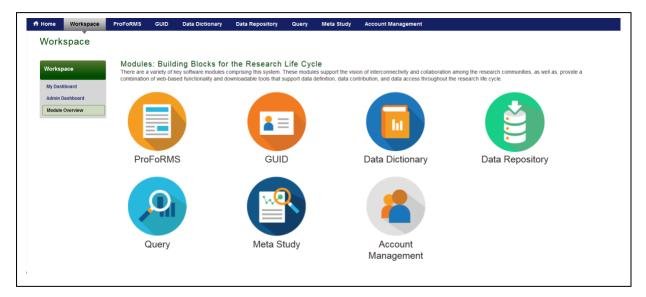


#### **4.4.2 Create Data Elements**

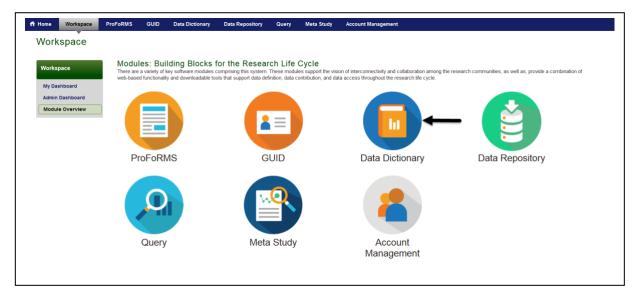
Data Elements created by the users in the data dictionary must have the "Unique Data Element" type. Unique Data Elements (UDEs) (unlike Common data elements) belong to a dataset (e.g. disease specific, form specific, media/modality specific, etc.) and cannot be used in any other datasets. They are defined within a dataset to capture very specific data and do not have a life outside of that dataset, or outside of a very specific form (eCRF). Single Data Elements can be created through BRICS. For multiple Data Elements, to be created, the data element template must be used.

### To Create Data Elements: Perform the following actions:

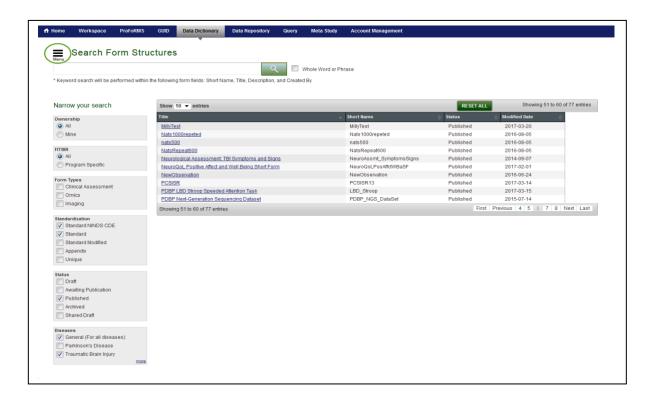
- **1.** Login to the system.
- 2. Navigate to the Workspace landing page



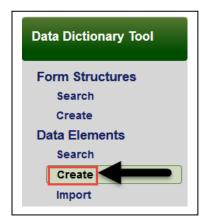
3. Click the Data Dictionary module. The Search Form Structures page appears.







**5.** Select the **Create** under Data Elements from the left-hand drop-down menu. The Create Form Structure General Details page appears.



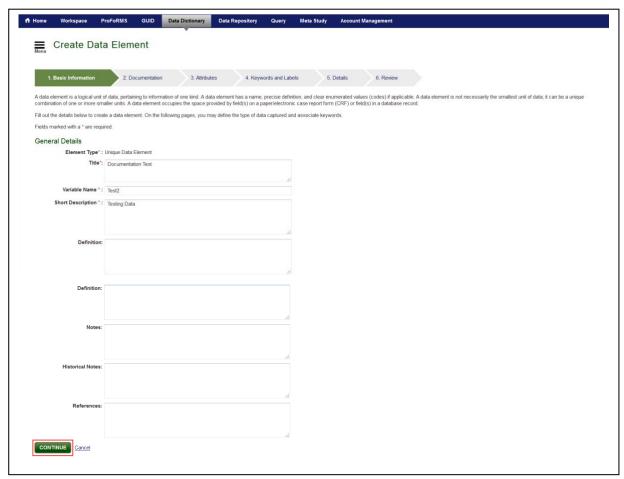
**6. Basic Information:** Fill out the details below to create a data element. On the following pages, you may define the type of data captured and associate keywords. Fields marked with a \* are required (*Element Type, Tittle, Variable Name*).



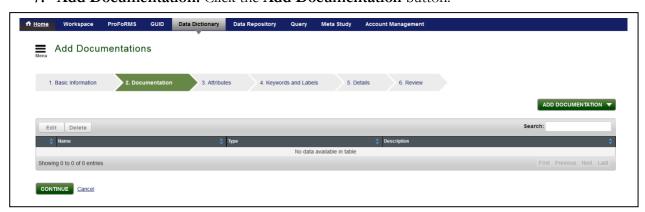
Home Workspace P	roFoRMS GUID Data Dictionary Data Repository Query Meta Study Account Management
Create Data	a Element
1. Basic Information	2. Documentation 3. Attributes 4. Keywords and Labels 5. Details 6. Review
A data element is a logical unit o combination of one or more sma	f data, pertaining to information of one kind. A data element has a name, precise definition, and clear enumerated values (codes) if applicable. A data element is not necessarily the smallest unit of data, it can be a unique lifer units. A data element occupies the space provided by field(s) on a paper/electronic case report form (CRF) or field(s) in a database record.
Fill out the details below to creat	e a data element. On the following pages, you may define the type of data captured and associate keywords.
Fields marked with a * are require	red.
General Details	
	Unique Data Element
Title*:	Documentation Test
	4
Variable Name *:	
Short Description *:	Testing Data
Definition:	
	d d
Definition:	
Notes:	
	A.
Historical Notes:	
References:	
	4



7. Click the **Continue** button.

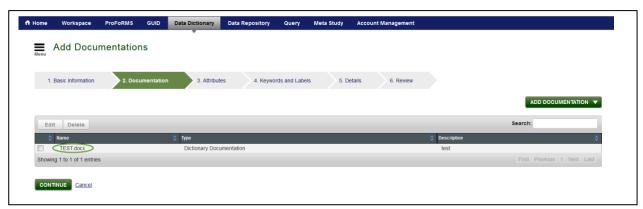


7. Add Documentation: Click the Add Documentation button.



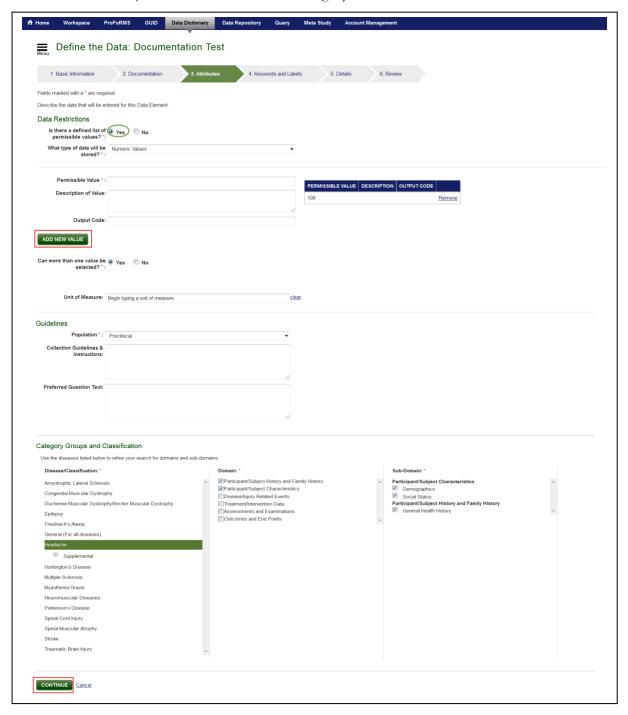


**8.** Click the **Continue** button.





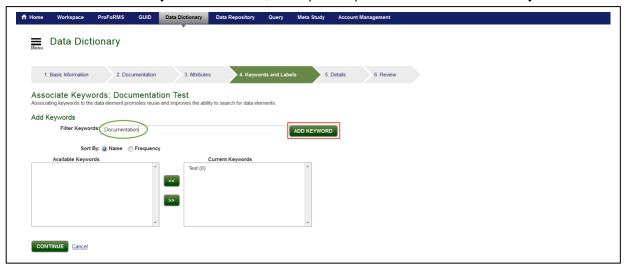
9. Attributes: In this form, you will be describing the data that will be entered for this Data Element. Fields marked with a \* are required (*Permissible Value, Population, Use the diseases listed below to refine your search for domains and sub-domains, Data Restrictions*). Select a disease domain category.



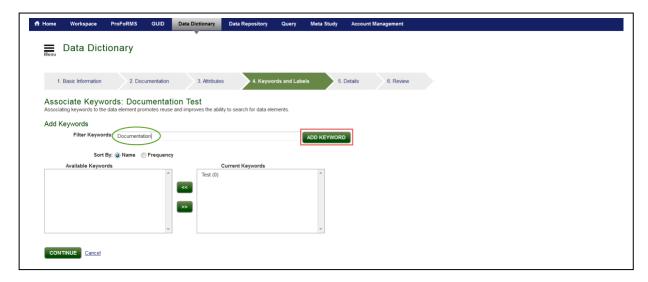


**10. Keywords and Labels**: In this form, you will be associating keywords to the data element. This improved reuse and improves the ability to search for data elements.

In the "Filter Keywords" textbox, enter your keyword and click the Add Keyword button.

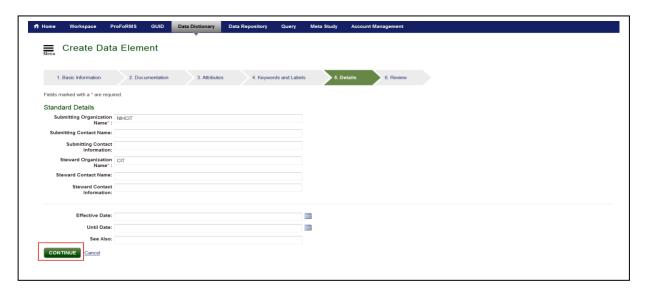


**11.** Click the **Continue** button.



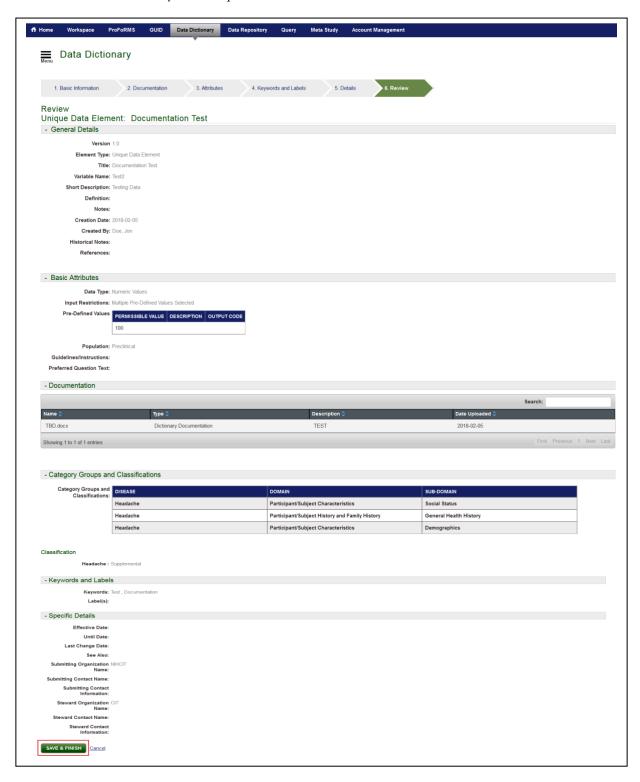


12. **Details**: In this form, you will be describing the details of the Data Elements. Fields marked with a \* are required (Submitting Organization Name, Steward Organization Name). Click the Continue button.



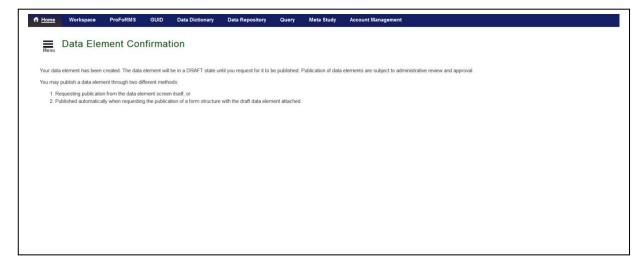


13. Review: Review your Unique Data Element details. Click the Save and Finish button.





- **14. Data Element Confirmation:** The data element will be created and a confirmation page appears. The data element will be in a DRAFT state until you request for it to be published. Publication of data elements are subject to administrative review and approval. You may choose to publish a data element through two different methods:
  - 1. Requesting publication from the data element screen itself, or
  - 2. Published automatically when requesting the publication of a form structure with the draft data element attached





# **Import Data Elements**

To import elements into the dictionary, use the **Data Element Import Template**. From Excel, you may create one data element per row. When creating your Data Elements, you may upload them to the BRICS dictionary by using the import function. All Data Elements must conform to the guidelines in this document or they will not be accepted into the BRICS dictionary.

Before importing data elements into the BRICS dictionary, the import file **MUST BE CONVERTED** from an XLS to a CSV file type!

The template is an MS Excel file (XLS), but you need to convert it to an CSV file. The following steps must be done before you can proceed with the Data Elements Import tool:

- 1. Remove all additional columns you added while working on adding the data elements to the template. These include:
  - a. the column where you calculate the number of characters for the variable Name attribute and
  - b. the column for the Permissible Value Counter macro.
- **2.** Save the file in <u>CSV</u> format.
- **3.** Run the Data Elements Import tool.

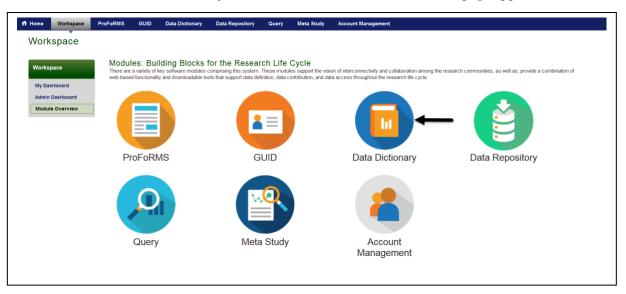
## **To Import Data Elements:** Perform the following actions:

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

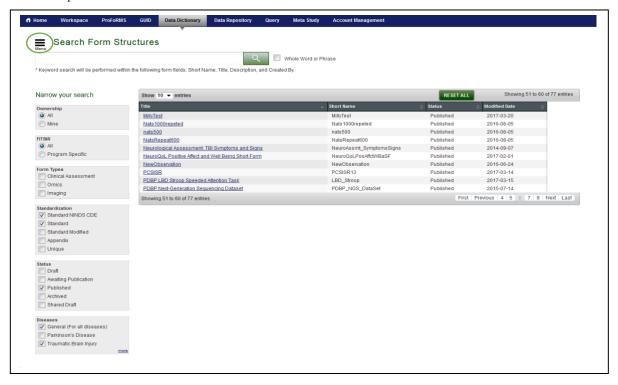




3. Click the **Data Dictionary** module. The Search Form Structures page appears.



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



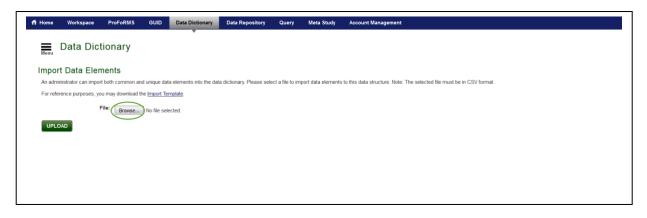


**5.** Select the **Import Data Elements** from the left-hand menu drop-down. The Import Data Element details page appears.



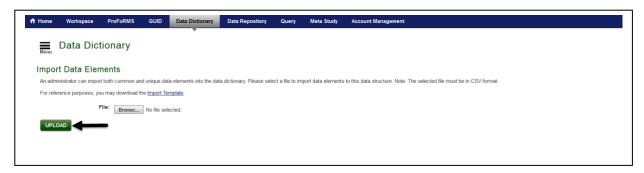
**6.** Click the **Browse** button to select a file to import data elements to this data structure. Only Administrator can import both Common and Unique Data Elements into the data dictionary.

**Note:** The selected file must be in CSV format. For reference purposes, you may download the Import Template.





7. Click the **Upload** button. Ensure there are no duplicate Data Elements. Note: If a duplicate exists, the Data Element will appear in RED.



### **4.4.1 eForms**

An electronic form (eForm) is a grouping/collection of various questions and related Common and Unique Data Elements (CDEs and UDEs) used to gather information for a study. An electronic form is analogous to a case report form (CRF) (electronic or paper) where data elements are linked together for collection and display.

# 4.4.1 eForm Standardization (Standard vs. Non- Standard)

Below are the eForm Standardizations found in BRICS:

- Standard eforms are available for all eForm users
- Non-standard eForms will be available only to users with permissions for a study/protocol.
- These users would have to be assigned permissions to the eForm under the eForm permissions tab.

# 4.4.2 eForm Privilege

Below are the eForm Privileges found in BRICS:

- ♦ Only BRICS Account Administrators can assign eForm privileges to a user within the users "Account Details" page.
- Only administrators can remove eForm privileges from a user within the users "Account Details" page
- ❖ Individual users can request eForm privileges in the same manner currently used to request Administrative privilege to Data Dictionary
- ❖ Users with the Data Dictionary eForm Privilege should have the ability to create, view, update or delete eForms according to the permissions assigned to them for a given eForm.
- Users with the Data Dictionary Administrator Privilege should have the ability to create, view, update or delete eForms.



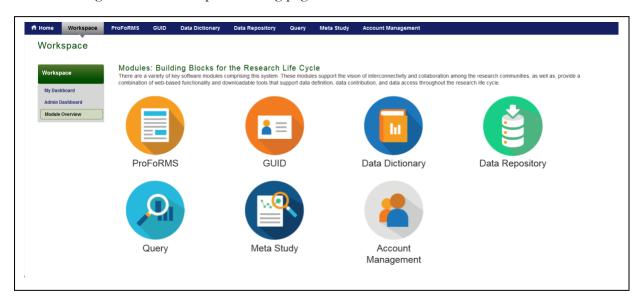
Users with Dictionary Privilege will be given the additional ability to view published eForms within the Form Structures Details page.



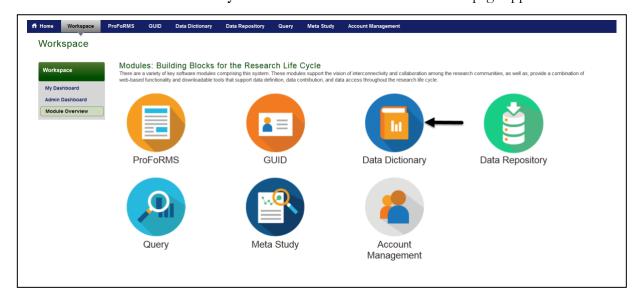
## 4.4.3 Search eForms

To Search eForms: Perform the following actions:

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

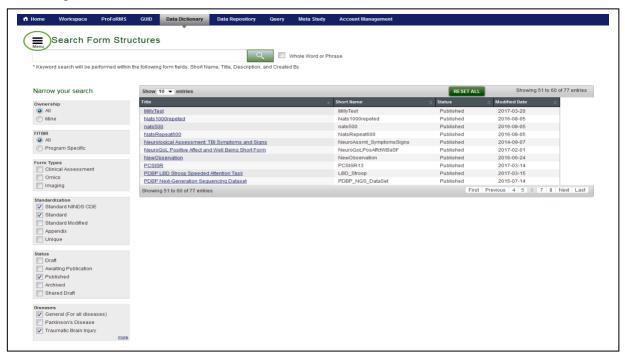


3. Click the Data Dictionary module. The Search Form Structures page appears.





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

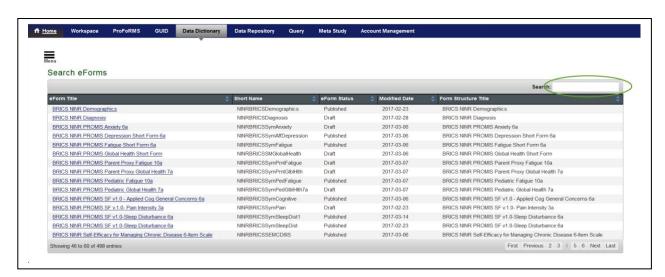


**5.** Select the **Search eForms** from the left-hand menu drop-down. The Search eForms page appears.

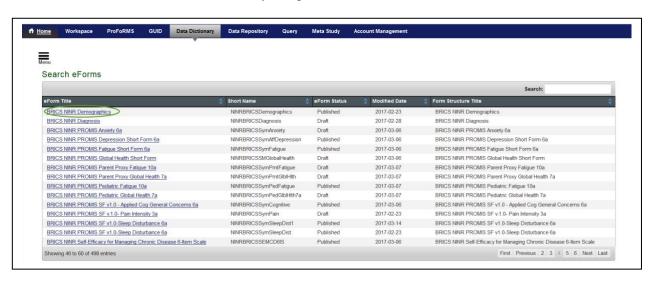


**6.** Using the search text-box, enter the search keyword to search. **Note:** Instead of starting from scratch you may find eForms available in the list of eForm entries.





7. Click on the desired eForm entry to open the eForm..

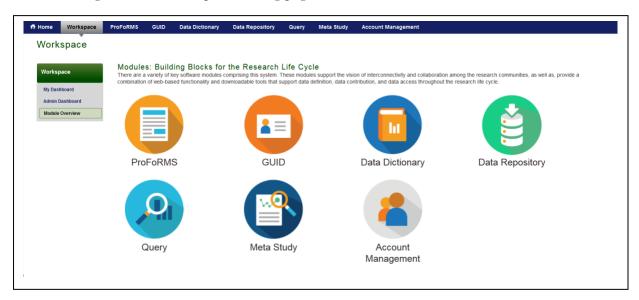




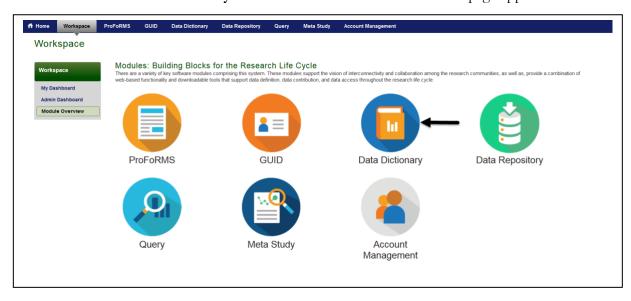
## 4.4.4 Create eForms

To Create eForms: Perform the following actions:

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

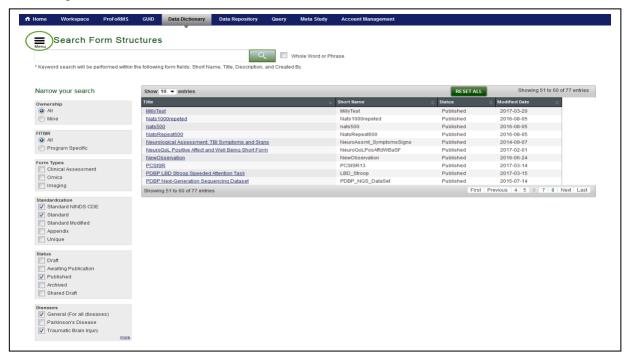


3. Click the Data Dictionary module. The Search Form Structures page appears.

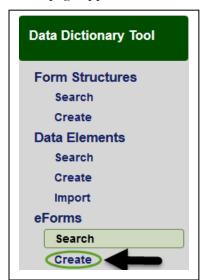




4. Click the Menu on the left-side tool bar. The **Data Dictionary Tool** menu opens and expands.

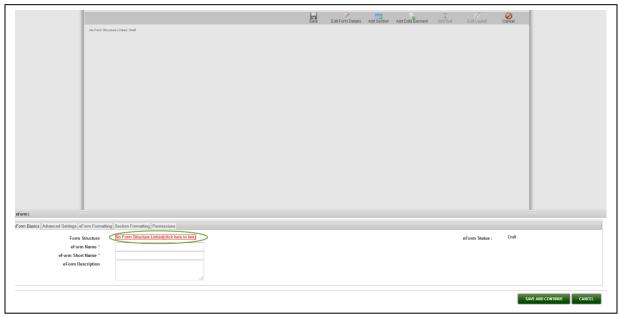


**5.** Select **Create** under eForms from the left-hand drop-down menu. The Forms Structure page appears.

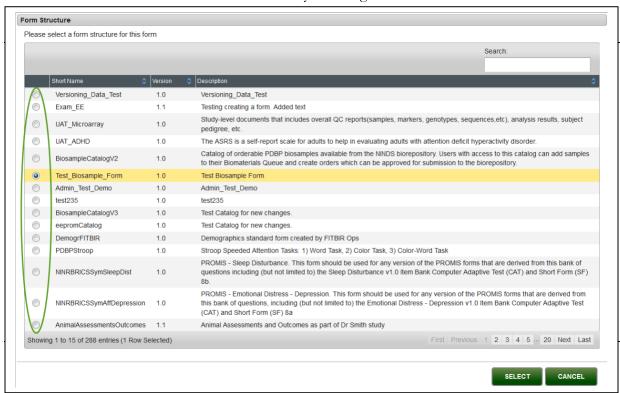




6. Click on the No Form Structure Linked (Click here to link).

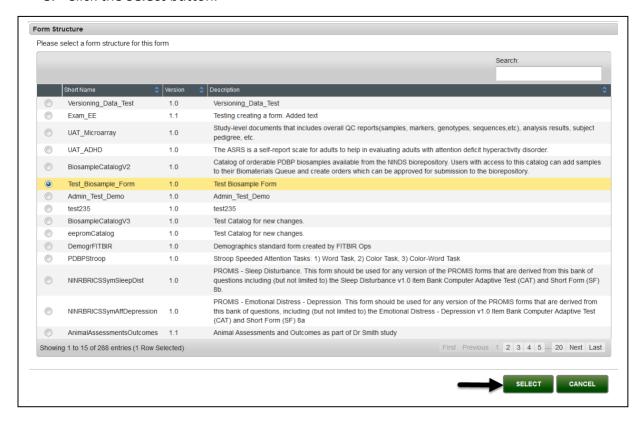


7. Select a **Form Structure** for this form by selecting the check-box beside the Short Name.

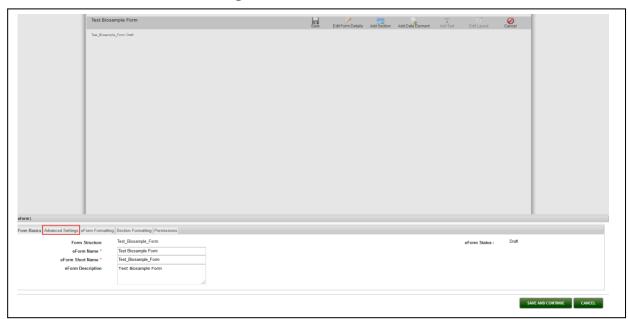




#### 8. Click the Select button.

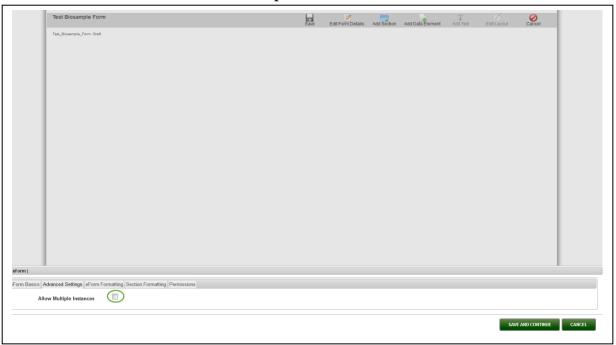


## 9. Select the **Advanced Settings** tab.

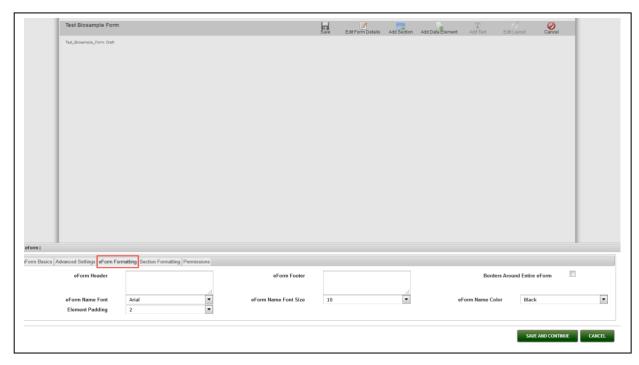




**10.** Select the check-box to allow **Multiple Instances**.

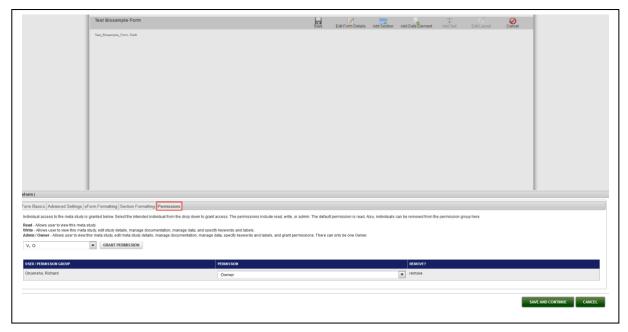


11. Select the **eFormatting** tab.

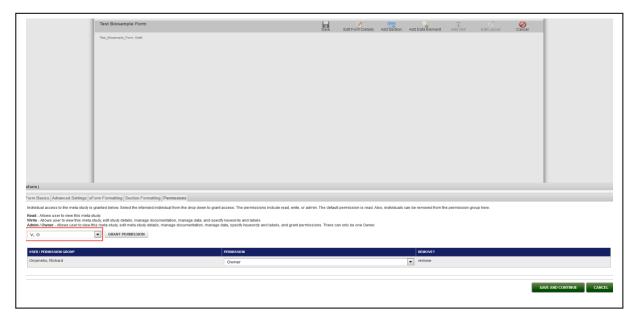




12. Select the **Permissions** tab.



**13.** Select the Individual access to grant permission from the drop-down menu. The permissions include: **Read, Write,** or **Admin**. The default permission is read. Also, individuals can be removed from the permission group here.





# ICON KEY

Notes

☐ Important

Information

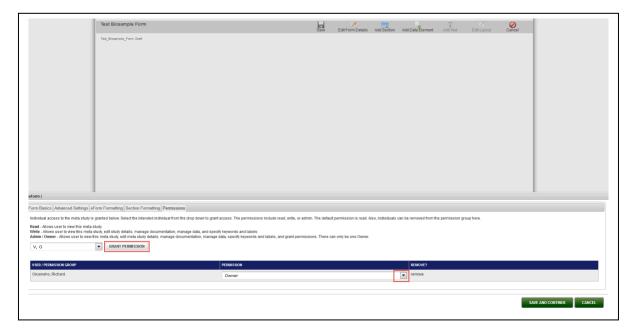
#### Things to Note:

Read - Allows user to view this meta study.

Write - Allows user to view this meta study, edit study details, manage documentation, manage data, and specify keywords and labels.

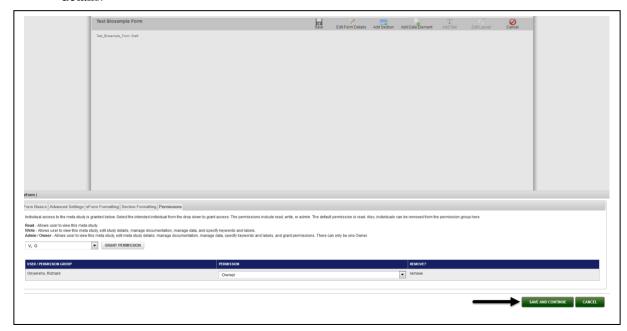
Admin/Owner - Allows user to view this meta study, edit meta study details, manage documentation, manage data, specify keywords and labels, and grant permissions. There can only be one Owner.

#### 14. Click the **Grant Permissions** button.





**15.** Click the **Save and Continue** button to create your form and retrieve the Form Structure details.





## 4.5 EXPLANATION OF COMMON TERMS

#### 4.5.1 Data Elements

A data element - as defined in BRICS - is a logical piece of information or a unit of data recounting to information of one kind. It is a basic unit of information built on standard structures having a unique meaning and distinct units or values.

A data element can occupy the space provided by field(s) on a paper/electronic case report form (CRF or eCRF) as well as field(s) in a database record.

The Data Dictionary contains all data elements - common and unique - used in the system. Each data element can be defined using the following basic parameters:

- ❖ Name or variable name
- Tittle
- Definition
- ❖ The type of data captured
- Clear enumerated values (codes or permissible values) if applicable.

Please note that the whole set of parameters used to define data elements depends on many factors including the purpose of research, data to capture, and many others. The basic set of parameters mentioned above is only a basic set.

The International Organization for Standardization/International Electrotechnical Commission (ISO/IEC 11179 technical standard) defines a data element as "a unit of data for which the definition, identification, representation, and permissible values are specified through a set of attributes." Such attributes include (but not limited to):

- ❖ The element's internal name,
- The element's data type,
- The element's title/caption presented to users,
- ❖ The element's detailed description,
- ❖ A basic validation information such as range checks, and information needed to fully define the data element.

A data element is not necessarily the smallest unit of data. Yet, it can be a unique combination of two or more smaller units.

For example, the data element "Date of Birth", if recorded as *dd.mm.yyyy*, contains three smaller units of information:

- \* The day of birth,
- ❖ The month of birth,
- ❖ And the year of birth.

However, for the data capturing purpose it was defined as a combination of these three information units.



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