



4

BRICS USER GUIDE

Data Dictionary: Form Structures



CHAPTER 4 - Data Dictionary: Form Structures

The **Data Dictionary** module is used for defining data elements and form structures. The Data Dictionary enables users to search, create, and manage both Common Data Elements (CDE) and Unique Data Elements (UDE). Additionally, it allows for the creation and management of form structures (FS) and electronic forms (eFORMS).

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

4.1 Data Dictionary Objectives

- Browse existing Form Structures
- Search Form Structures
- Create Form Structures
- Browse existing Data Elements
- Search Data Elements
- Create Data Elements
- Import Data Elements
- Browse existing eForms
- Search eForms
- Create eForms

4.2 System Functions

The Data Dictionary module offers functionality for defining data elements, assigning alternate names (aliases), and setting translation rules. It ensures that users accessing shared data receive clear, standardized definitions and contextual information for each element.

4.3 Data Dictionary Module Features

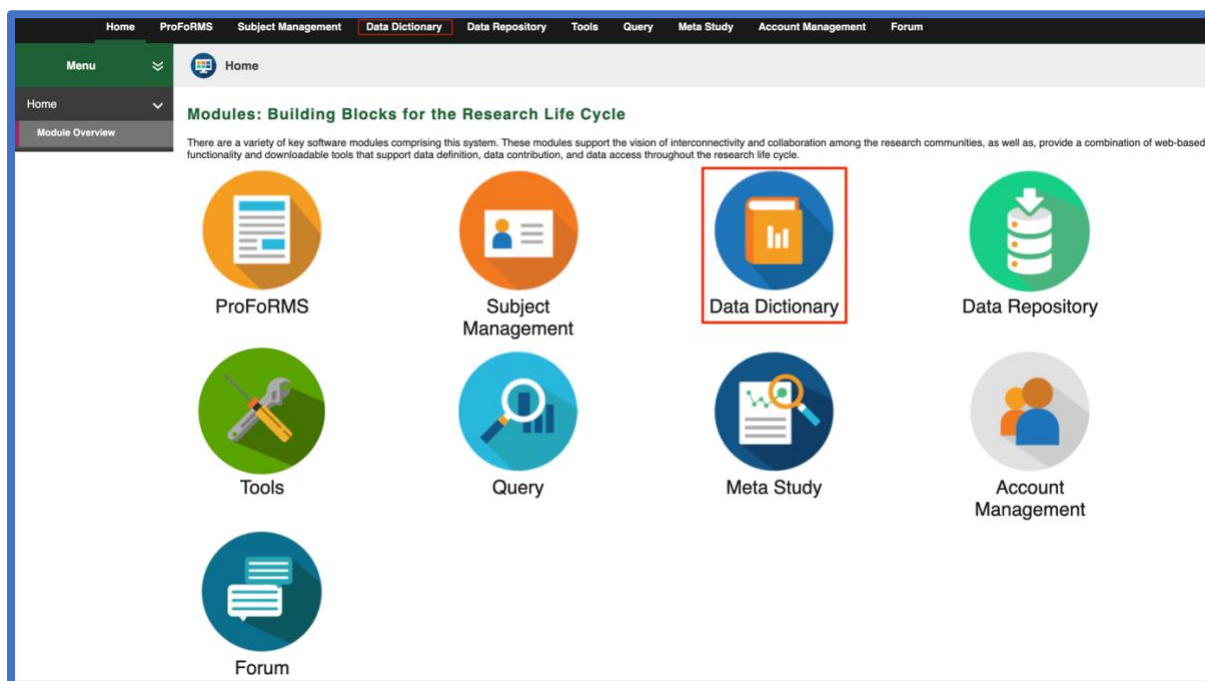
The **Data Dictionary Module** provides useful features for:

- Searching Data Elements
- Downloading Data Elements Results to XML, CSV and ZIP output formats
- Creating Data Elements
- Importing Data Elements

4.4 Module Navigation

The **Data Dictionary** module (including sub-modules) is available within the BRICS Workspace. **To access the Data Dictionary Module:** Perform the following actions:

1. Log into your BRICS instance and select the Data Dictionary module from either the top navigation bar or the module icon.



4.5 Form Structures

A form structure (FS) is a presentation of a given case report form (CRF) in BRICS system. A form structure represents an organized grouping/collection of various data elements (CDEs and UDEs). A form structure is analogous to a CRF (electronic or paper) where data elements are linked together for collection and display. **Form Structures** are used for:

- **Data Submission:**
The Form Structure is used as a container for submitting data via the Submission Tool validation process and upload the data to the Data Repository
- **Creating eFORMs (eCRFs) and collect data:**
The form structure provides a structure (or a template) for a form and a container for active data collection.
- **Querying Data:**
The form structure assures that uploaded/collected data are properly represented and queryable by the Query Tool.

NOTE: To be able to create form structures in BRICS, a user must have the permissions to do that in Data Dictionary. Permissions/privileges are assigned to the user when he/she is requesting an account to the BRICS instance.

4.5.1 Form Structures Publication

There are four different Status Types of Form Structures: Draft, Awaiting Publication, Published, and Shared Draft. After creating a Form Structure, it will be placed into Draft status. The owner, or an admin, can request publication for the Form Structure, in which the status will be changed to Awaiting Publication. While in Awaiting Publication it is viewable by all users, including the public site. After it has been reviewed and approved by an admin, the FS's status will change to Published and can be used for Data Submission.

See the table below for details on the statuses and their corresponding attributes:

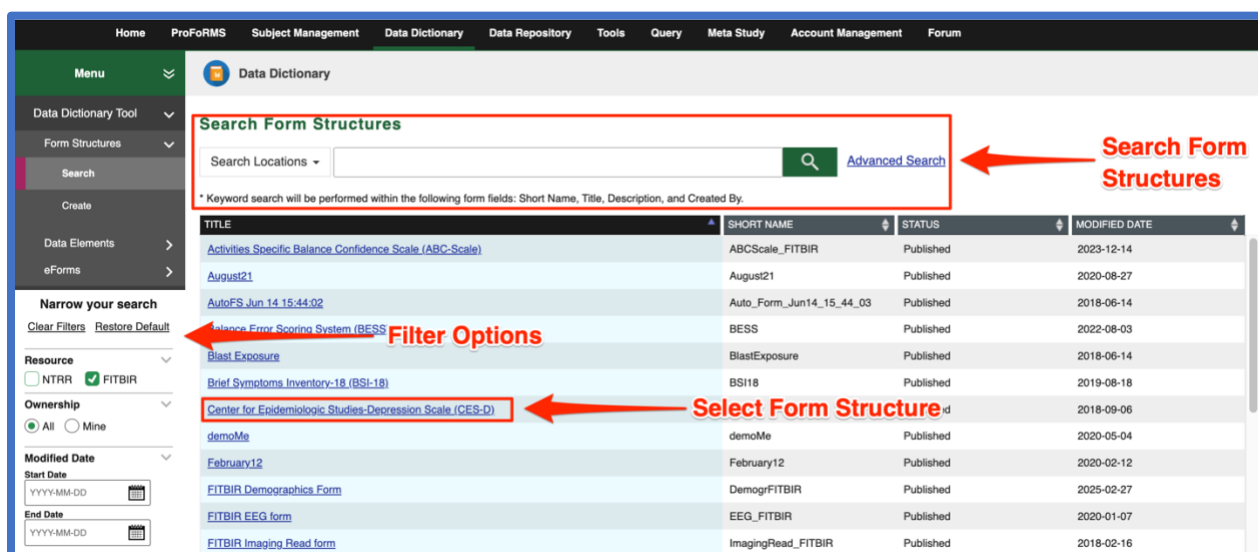
Type	Description	Visibility	Editable?	Data Validation?	Data Submission?
Draft	In a process of development.	Required to log in into portal. Available for the owner, admin and to whom were given permissions only	Yes	Yes	No
Awaiting publication	A publication has been requested for this FS	All users, including the public site	Yes	Yes	No
Published	The FS which is available for public use	All users, including the public site	Limited. Can edit Title, Description, add/remove documentation.	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	Yes	No	No

4.5.2 Browse Form Structures

Clicking the Data Dictionary module icon automatically redirects to the **Data Dictionary>Search Form Structures** page, which by default lists all published form structures which exists in a given instance of BRICS.

On that page users can:

1. Browse From Structures.
2. Sort/filter FS by title (alphabetically), short name, status, and modified date.
3. View the FS by clicking on FS title, it will open the FS page for view.



Search Form Structures

Search Locations: [Advanced Search](#)

* Keyword search will be performed within the following form fields: Short Name, Title, Description, and Created By.

TITLE	SHORT NAME	STATUS	MODIFIED DATE
Activities Specific Balance Confidence Scale (ABC-Scale)	ABCScale_FITBIR	Published	2023-12-14
August21	August21	Published	2020-08-27
AutoFS Jun 14 15:44:02	Auto_Form_Jun14_15_44_03	Published	2018-06-14
Beck Depression Inventory-2 (BDI-2)	BDI2	Published	2022-08-03
Blast Exposure	BlastExposure	Published	2018-06-14
Brief Symptom Inventory-18 (BSI-18)	BSI18	Published	2019-08-18
Center for Epidemiologic Studies-Depression Scale (CES-D)	demoMe	Published	2018-09-06
demoMe	demoMe	Published	2020-05-04
February12	February12	Published	2020-02-12
FITBIR Demographics Form	DemogrFITBIR	Published	2025-02-27
FITBIR EEG form	EEG_FITBIR	Published	2020-01-07
FITBIR Imaging Read form	ImagingRead_FITBIR	Published	2018-02-16

Filter Options: Resource (NTRR, FITBIR), Ownership (All, Mine), Modified Date (Start Date, End Date).

Select Form Structure: Center for Epidemiologic Studies-Depression Scale (CES-D)

4.5.3 Filter Form Structures

To limit the number of form structures displayed in the Data Dictionary, BRICS provides options to filter form structures by the set of pre-defined filters, organized as check boxes. The list of filter options is shown below.

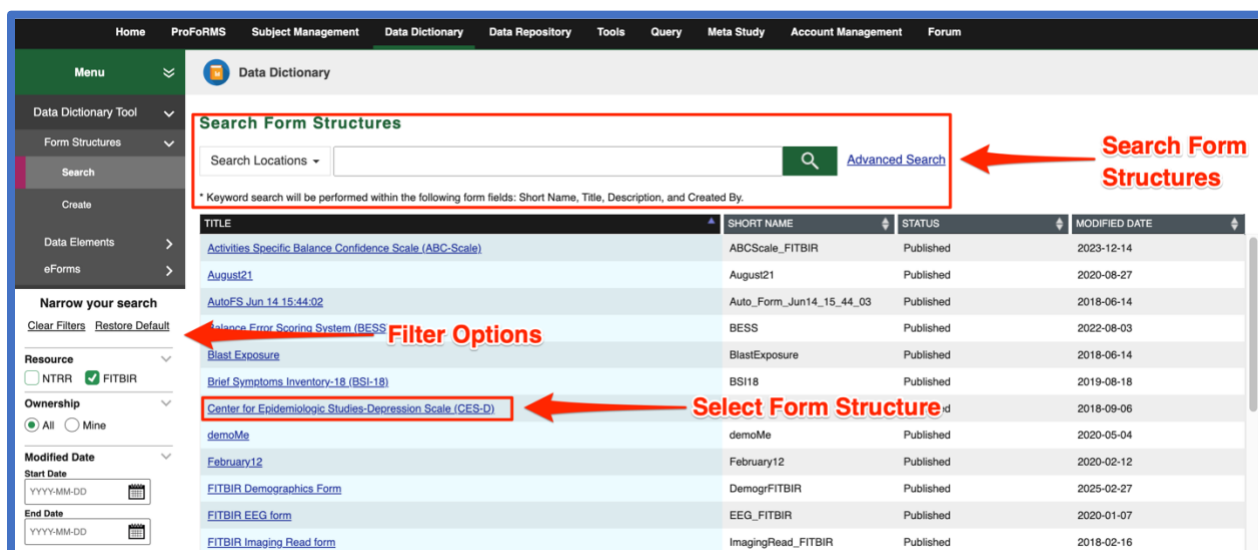
Default filter settings depend on the BRICS instance and can be set up when the BRICS instance is first set up. Default filter settings for FITBIR, are shown on the figure at the end of this chapter.

- **Clear Filters:** Clears all filters showing all Form Structures.
- **Restore Default:** Restores filter settings default for the given instance of BRICS.
- **Resource:** Select the resource(s) you wish to view.
- **Ownership:** To search for FS by ownership. All – shows all FS. Mine – only FS that you own
- **Modified Date:** Search based on a date range that the form structure was modified on.
- **Instance of BRICS Program (e.g. FITBIR) (All, Specific):**
 - All – shows all FS
 - Program Specific- shows only those FS which are defined as recommended/specific by the program.
- **Form Types:**
 - **Clinical Assessment:** FS which created to collect clinical data
 - **Omics:** FS which created to collect Genomics, Proteomics and like data
 - **Imaging:** FS created to collect imaging data
 - **Preclinical:** FS created to collect preclinical data
- **Standardization:**
 - **Standard form structures (FS):** Based on the standard instruments/scales/batteries. NINDS/BRICS defined standard instruments as those which 1) have publications, seminal papers, validity research, which describes their creation, properties, administration, etc. 2) have well defined documentation and 3) widely used in the community
 - **Standard NINDS CDE FS:** A sub-set of Standard FS, limited to those which are recommended by NINDS to use for a particular disease category. More can be found here: <https://www.commondataelements.ninds.nih.gov>
 - **Standard Modified:** Created based on a modified standard instrument. Some teams choose to modify standard instruments, so we use this standardization to accommodate it.
 - **Appendix:** Created to provide additional DEs for a standard and Standard NINDS FS, to accommodate additional data, which do not fit into Standard FS. BRICS has special naming conventions for appendices.
 - **Unique:** Based on a unique study specific form/instrument
- **Labels:** Filters FS by the custom labels assigned to FS in a given BRICS instance. Assigning labels is admin privilege.
- **Status:** Draft, Awaiting Publication, Published, Archived, Shared Draft
- **Form Copyright Status:** All, Copyrighted, Non-Copyrighted
- **Diseases:** BRICS has an option to assign a given FS to a specific disease category. This allows to separate FS created for specific disease needs. Click "more" in the filter list to see all currently supported diseases.

4.5.4 Search Form Structures

To search Form Structures, perform the following actions:

1. Navigate to the **Data Dictionary** module. The Search Form Structures page appears.
2. In the search textbox, enter the search keyword to search. Keyword search will be performed within the form fields using the **Short Name, Title, Description** and **Created By**.
3. Click the Magnify Glass icon. The system will perform the search you specified.
4. You may also consider using **Advanced Search option** to make your search more specific.
5. By default, the search is performed within the limits defined by filter settings (refer to section [4.5.3](#)). Which means if you cannot find the FS in question, click Clear Filters and try again. Please note that FS in Draft status does not show up for the initial search, you must click Clear Filters for the results to return with the FS in draft status.



The screenshot shows the 'Data Dictionary' module interface. The 'Search Form Structures' section is highlighted with a red box. A red arrow points to the 'Search Form Structures' text on the right. Another red arrow points to the 'Advanced Search' link. A third red arrow points to the 'Filter Options' text, which is positioned over the 'Clear Filters' and 'Restore Default' buttons. A fourth red arrow points to the 'Select Form Structure' text, which is positioned over the 'Center for Epidemiologic Studies-Depression Scale (CES-D)' entry in the table.

TITLE	SHORT NAME	STATUS	MODIFIED DATE
Activities Specific Balance Confidence Scale (ABC-Scale)	ABCScale_FITBIR	Published	2023-12-14
August21	August21	Published	2020-08-27
AutoFS Jun 14 15:44:02	Auto_Form_Jun14_15_44_03	Published	2018-06-14
Balance Error Scoring System (BESS)	BESS	Published	2022-08-03
Blast Exposure	BlastExposure	Published	2018-06-14
Brief Symptom Inventory-18 (BSI-18)	BSI18	Published	2019-08-18
Center for Epidemiologic Studies-Depression Scale (CES-D)	demoMe	Published	2018-09-06
demoMe	demoMe	Published	2020-05-04
February12	February12	Published	2020-02-12
FITBIR Demographics Form	DemogrFITBIR	Published	2025-02-27
FITBIR EEG form	EEG_FITBIR	Published	2020-01-07
FITBIR Imaging Read form	ImagingRead_FITBIR	Published	2018-02-16

- Advance Search provides the following search options, which can be viewed by clicking on the Advances Search link.

Advanced Search Capability

- BASIC SEARCH: All results will contain all key words. Search terms are not case sensitive. Searching **man age** will return **human ages**, **manage** and **man age** but not **age man**.
- ADVANCED SEARCH: The following operators can be used to perform an advanced search.

Operator	Explanation	Example
"" Quotation marks	Requires words to be searched as an exact phrase. When using this operator, all wild-card characters must be explicitly included.	"Age" will return results that have the whole word Age within them. It will not return manage or ages or aged.
? Question Mark	Matches exactly one character at the end of a search term.	ma? will only match search terms that end with three-letter words starting with ma, such as man, mad, map, and mat
* Asterisk	Matches zero or more characters (including spaces)	*age will match any word ending with age, such as language, image, percentage , and just age

4.6.5 Create Form Structures

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

- Without the Form Structure Template
- With the Form Structure Template

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

- Login and navigate to the Data Dictionary module.
- In the left navigation click Create under Form Structures

Home

Workspace

ProFoRMS

Subject Management

Data Dictionary

Data Repository

Query

Meta Study

Account Management

Menu and Filters

Data Dictionary Tool

Form Structures

Search

Create

Data Elements

Data Dictionary

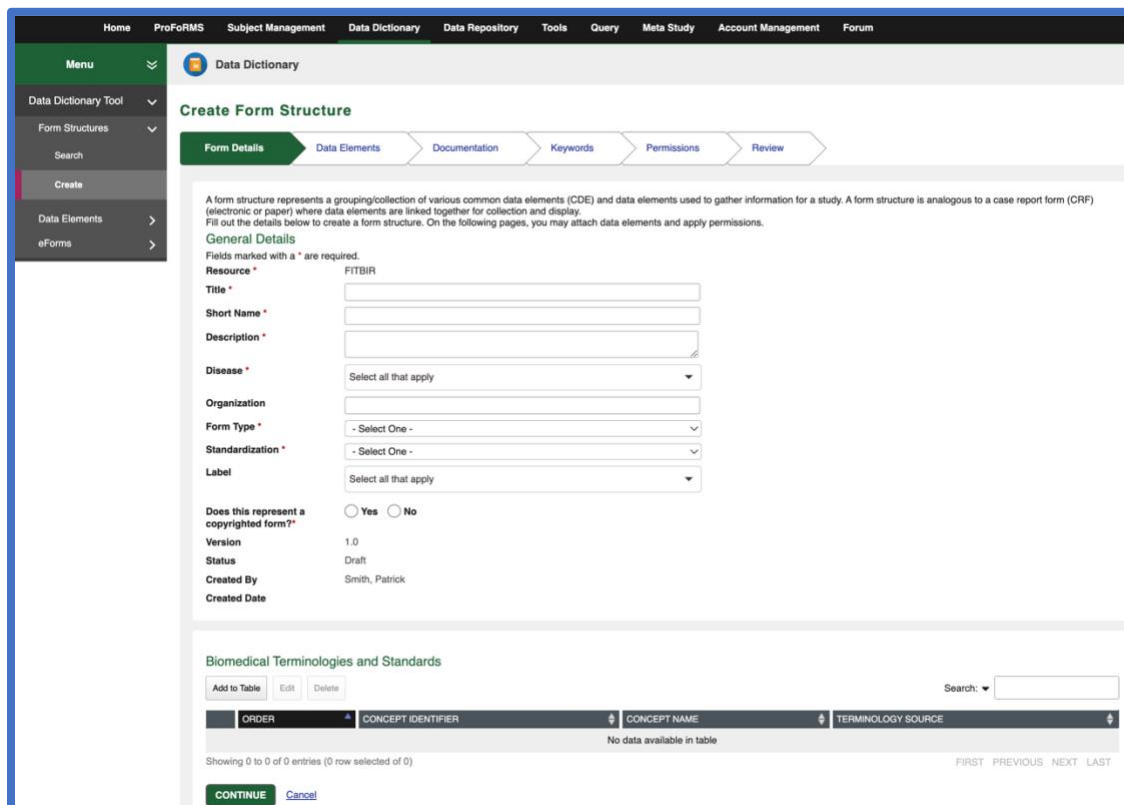
Search Form Structures

* Keyword search will be performed within the following form fields: Short Name, Title, Description, and Created By.

TITLE	SHORT NAME	STATUS
Activities Specific Balance Confidence Scale (ABC-Scale)	ABCScale_FITBIR	Published
August21	August21	Published
AutoFS Feb 01 11:38:46	Auto_Form_Feb01_11_38_47	Published
AutoFS Jun 13 10:48:38	Auto_Form_Jun13_10_48_38	Published
AutoFS Jun 14 15:44:02	Auto_Form_Jun14_15_44_03	Published
Balance Error Scoring System (BESS)	BESS	Published
Blast Exposure	BlastExposure	Published

4.6.5.1 Form Details Chevron:

1. Follow the process as it is guided by chevrons. Each chevron page has a lot of information, helping you to fill out all required fields.
Starting with the Basic Information chevron:



Complete all required fields marked with an * asterisk:

- **Title***: Please follow the standards defined in your BRICS instance for FS title. Typically the title should contain FS name and version if any. If FS created to represent the standard instrument, its title must contain the name of the instrument and the version if any.
- **Short Name***: Limited by 30 characters. Must be unique within the given instance of BRICS.
- **Description***: Limited to 1000 characters. Provide the detailed description of the FS. Include all information which will help to better identify the FS.
- **Diseases***: Select as many disease categories as needed. Use Ctrl+Right mouse click to select multiple disease categories.
- **Organization**: The organization that the user creating the FS belongs to.
- **Form Type***: Clinical Assessment, Omics, Imaging, Preclinical. Choose one.
- **Standardization***: Select one from the list available for your BRICS instance.
- **Label**: Select one, if the associated instance has labels.
- **Is this a program Required Form? ***: Choose Yes or No.
- **Does this represent a copyrighted form***: Choose Yes or No.
- **Biomedical Terminologies and Standards**: Add relevant data to the table when necessary.

Select **Continue** when finished to move onto the Data Elements chevron.

4.6.5.2 Data Elements Chevron - Main Group and Form Administration Group:

There are 2 groups which are required for all FS, including Standardized, Unique, Appendices, etc. in all instances of BRICS. These are the **Main Group** and **The Form Administration**.

These groups are meant to provide consistency and context for all data submitted to the BRICS database. The DE content of these groups could vary, but not very much.

The first group to be populated under the Data Elements Chevron automatically is the **Main group**.

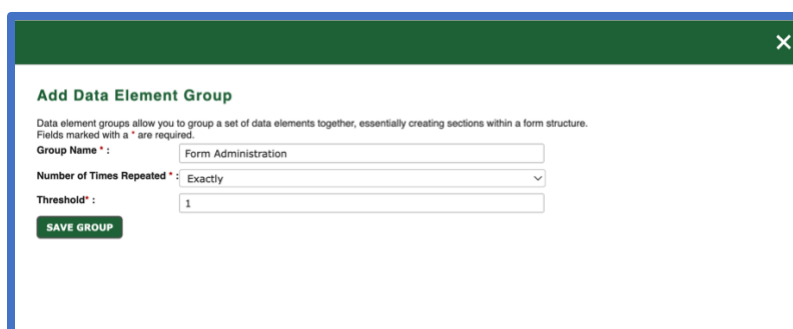
Main Group:

- **GUID** should be the first DE added to the main group. It must be present in all BRICS Form Structures, and it must have the status “**required**”.

The Form Administration group should be added by the user.

To create a group:

1. Use the **Add Group** button.



2. Provide the group name. **The group name must be unique within the form structure.**
3. Provide the group repeatability settings. The repeatability settings are as follows:
 - a. **At least:** Provides the min number the group must be repeated.
 - b. **Exactly:** Provides the exact number the group must be repeated. That is a tricky setting, were commend contacting OPS when you plan to use it.
 - c. **Up to:** Provides the max number the group will be repeated. Up to=0, means the group could be repeated indefinitely.

Adding to a Group

1. After the group name and repeatability is set up, use **Add Data Elements** button to access the data element interface, where users can search for existing data to add to the form structure.
NOTE: To be added the DE must already exist in the data dictionary.
2. Select the data elements by checking the checkbox next to the desired data element. Once done searching and checking off data elements, click the Add Selected Elements button. The selected data elements will be added to the group in the order in which they were selected. [It is a best practice to add data elements to the form structure in the order that they appear on the form].
The same data element can be included in the same group only once.

Add Data Elements

1. Basic Information
2. Documentation
3. Data Elements
4. Permissions
5. Review

Search Locations
health
Advanced Search

Search existing elements to attach to this form structure

Show 10 entries

RESET ALL
DOWNLOAD ALL 80 RESULTS

	TITLE	VARIABLE NAME	TYPE	MODIFIED DATE	STATUS
<input checked="" type="checkbox"/>	12-item Short Form Health Survey Version 1 (SF-12v1) - Times calm peaceful scale CR	SF12TimesCalmPctulScaleModCR	UDE	2019-07-18	Published
<input checked="" type="checkbox"/>	36-item Short Form Health Survey (SF-36) - Bodily pain score	SF36BodyPainScore	CDE	2018-12-18	Published
<input checked="" type="checkbox"/>	36-item Short Form Health Survey (SF-36) - Bodily pain score	SF36BodyPainScore_est2	CDE	2021-09-30	Published
<input type="checkbox"/>	36-item Short Form Health Survey (SF-36) - Bodily pain score	SF36BodyPainScore_eng2	CDE	2022-04-06	Draft
<input type="checkbox"/>	36-item Short Form Health Survey (SF-36) - Bodily pain score	SF36BodyPainScore_eng1	CDE	2021-09-30	Published
<input type="checkbox"/>	36-item Short Form Health Survey (SF-36) - Cut time on work activities emotional problems indicator	SF36CutTimeWrkActEmotProblnd	CDE	2019-02-01	Published
<input type="checkbox"/>	36-item Short Form Health Survey (SF-36) - Cut time on work activities physical health indicator	SF36CutTimeWrkActPhyHlthInd	CDE	2019-07-18	Published
<input type="checkbox"/>	36-item Short Form Health Survey (SF-36) - Difficulty work activities physical health indicator	SF36DiffcWkActPhyHlthInd	CDE	2019-07-19	Published
<input type="checkbox"/>	36-item Short Form Health Survey (SF-36) - Excellent health score	SF36ExcelHlthScore	CDE	2019-07-19	Published
<input type="checkbox"/>	36-item Short Form Health Survey (SF-36) - Expect worse health score	SF36ExpWorsHlthScore	CDE	2019-05-21	Published

Showing 1 to 10 of 80 entries (filtered from 4,762 total entries) (3 rows selected of 4762)

First
Previous
1
2
3
4
5
...
8
Next
Last

ADD SELECTED ELEMENTS

Example of a Form Administration Group:

Additional Element Groups
Listed below are your additional element groups. You may add elements to a specific group or remove the group altogether.

▼ FORM ADMINISTRATION (APPEARS EXACTLY 1 TIME)

#	TITLE	SHORT DESCRIPTION	VARIABLE NAME	REQUIRED?	GROUP	REMOVE ALL?
1	Data source	Source of the data provided on the case report form	DataSource	Recommended ▼	Form Adm ▼	remove
2	Context type	The context to which the questions were answered	ContextType	Recommended ▼	Form Adm ▼	remove
3	Data source other text	The free-text field related to Data source specifying other text. Source of the data provided on the case report form	DataSourceOTH	Recommended ▼	Form Adm ▼	remove
4	Context type other text	The free-text field related to ContextType specifying other text	ContextTypeOTH	Recommended ▼	Form Adm ▼	remove

[ADD DATA ELEMENTS](#)
[EDIT GROUP](#)
[Remove Group](#)

4.6.5.3 Data Elements Chevron - Moving data elements around:

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.

4.6.5.4 Data Elements Chevron - Assigning the status of the data elements within the group:

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

- **Required:** A good setting to set if you need to make sure that data are always submitted against the data element. But keep in mind that the Validation tool will produce an error and not allow the dataset to pass validation if a cell is left blank for the data element.
 - GUID should always be required we recommend that Required setting is always used for GUID.
- **Recommended:** The Validation Tool will produce a warning, but still allows the data set to pass if a cell is left blank for that data element.
- **Optional:** The Validation Tool will NOT produce error or warning and will allow that dataset to pass if a cell is left blank for that data element.
- 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”.]
- Once all groups are created and DEs added, click Continue. You will be move to the Permissions Chevron.

4.6.5.5 Data Elements Chevron Editing DE group:

Adjusting the Order of Element Groups

1. Click on the title bar of the group.
2. Drag and drop the group to the desired position. **Note:**
 - a. The Main Group cannot be moved,
 - b. The Form Administration group must stay after the Main group.

Editing Data Element Group Settings

1. Click on the “Edit Group” button.
2. Make the desired changes.

Removing Data Element Group

1. Click on the “Remove Group” link. Once removed, the group cannot be restored automatically.

Removing a Data Element from the group

1. Under the "Removal All?" column, click on “Remove” link.

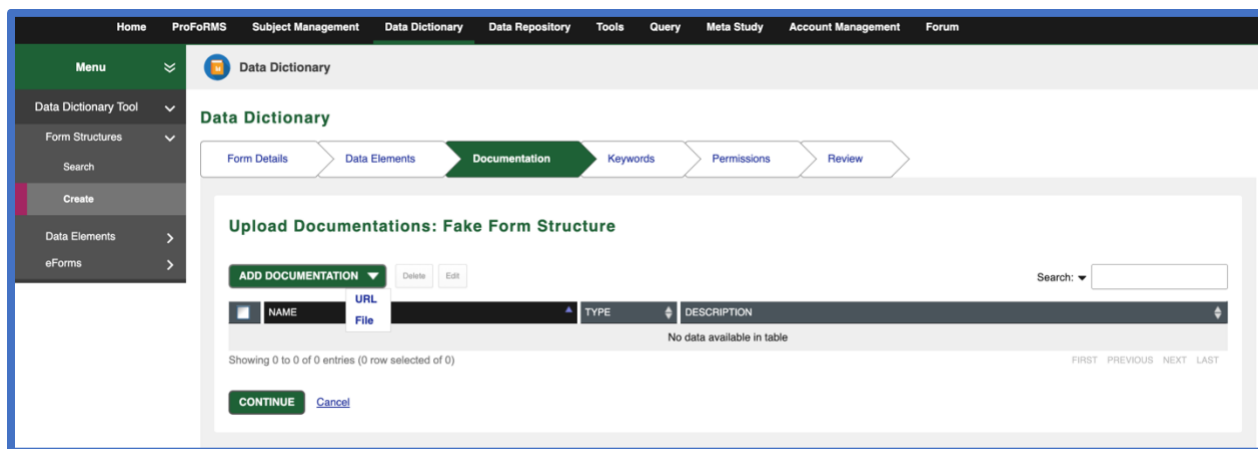
Moving Data Elements Between Groups

1. The data elements that are added have a Group column showing what group it is currently in. Use this drop-down menu to select which data element group you would like to move the data element. There will be a prompt to confirm moving the data element and then it will be removed from the current group and show in the group it was moved to.
2. After moving a DE from one group to another, make sure that all DEs appear in the proper order within the group.
3. It is a best practice to do this in the order that the data elements appear on the form.

4.6.5.6 Documentation Chevron

Click the Add Documentation button and select the desired file or URL.

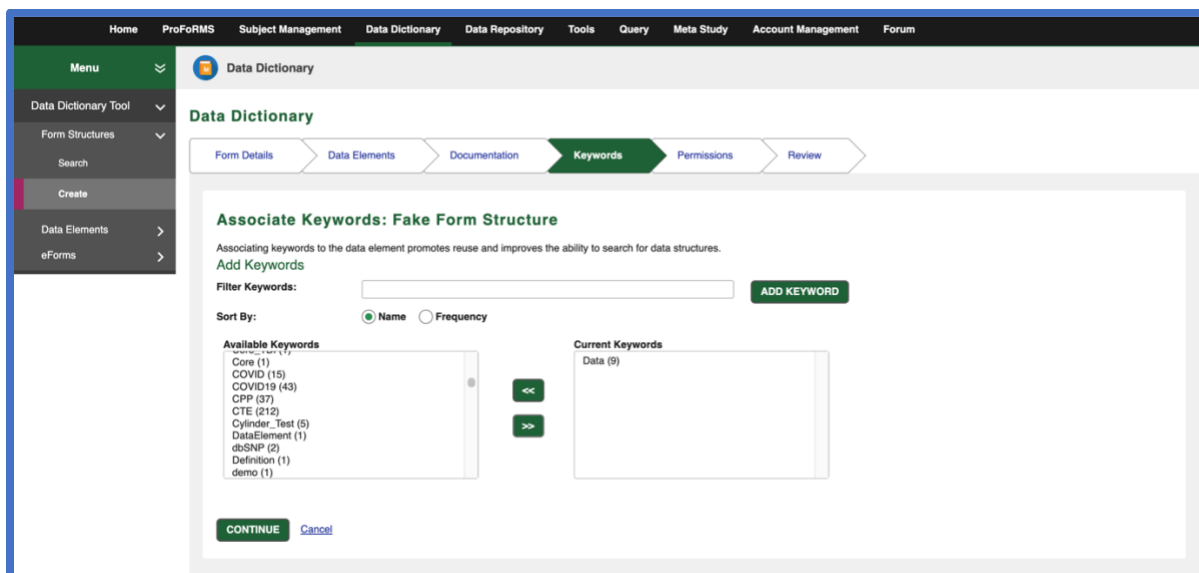
NOTE: Documentation is optional, but BRICS Operations encourage uploading all documentation used to create a FS.



The screenshot shows the BRICS Data Dictionary interface. The top navigation bar includes links for Home, ProFoRMS, Subject Management, Data Dictionary (active), Data Repository, Tools, Query, Meta Study, Account Management, and Forum. The left sidebar contains a Menu with options: Data Dictionary Tool, Form Structures, Search, Create, Data Elements, and eForms. The main content area is titled "Data Dictionary" and features a breadcrumb trail: Form Details > Data Elements > Documentation (active) > Keywords > Permissions > Review. Below the breadcrumb, there is a section titled "Upload Documentations: Fake Form Structure". This section includes an "ADD DOCUMENTATION" button with a dropdown arrow, and "Delete" and "Edit" buttons. A search bar is located to the right. Below these buttons is a table with columns: NAME, URL, TYPE, and DESCRIPTION. The table currently shows "No data available in table". At the bottom of the table, there are "CONTINUE" and "Cancel" buttons. The status bar at the bottom indicates "Showing 0 to 0 of 0 entries (0 row selected of 0)" and includes navigation links: FIRST, PREVIOUS, NEXT, LAST.

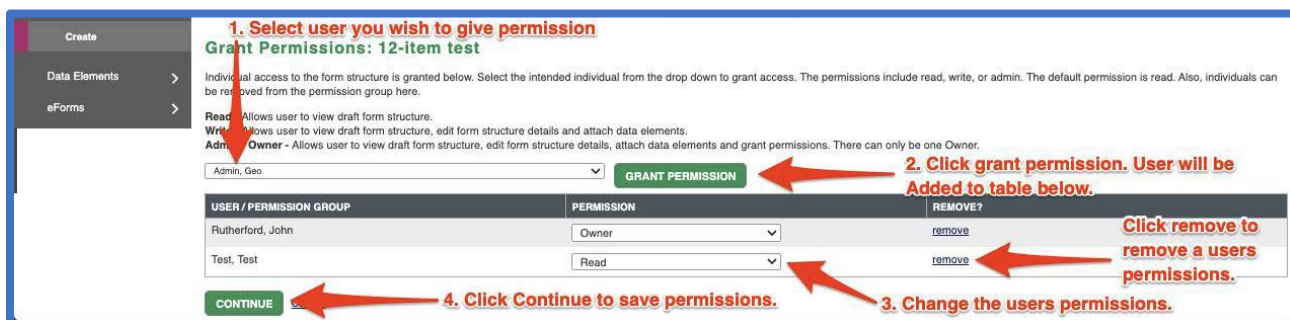
4.6.5.7 Keywords Chevron

Filter and select the keywords you wish to add to this FS. Select the keywords in the left table and then click the arrows in the middle to move them to be set to current keywords or remove them by moving them back to available keywords.



4.6.5.8 Permissions Chevron

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



USER / PERMISSION GROUP	PERMISSION	REMOVE?
Rutherford, John	Owner	remove
Test, Test	Read	remove

Things to Note:

1. Read - Allows user to view draft form structure.
2. Write - Allows user to view draft form structure, edit form structure details and attach data elements.
3. Admin / Owner - Allows user to view draft form structure, edit form structure details, attach data elements, and grant permissions.
4. There can only be one Owner per form structure (by default it is the creator of the form structure, but can be changed)

4.6.5.9 Review Chevron

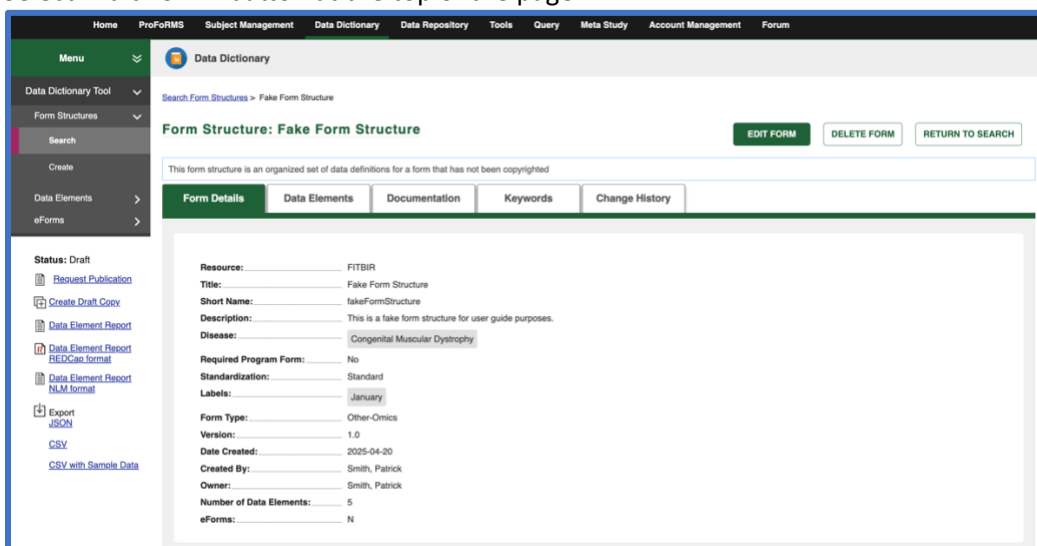
1. **Review:** Review all the data elements and make sure they are in the correct order and have the correct requirements (optionality, group, threshold, etc.)

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

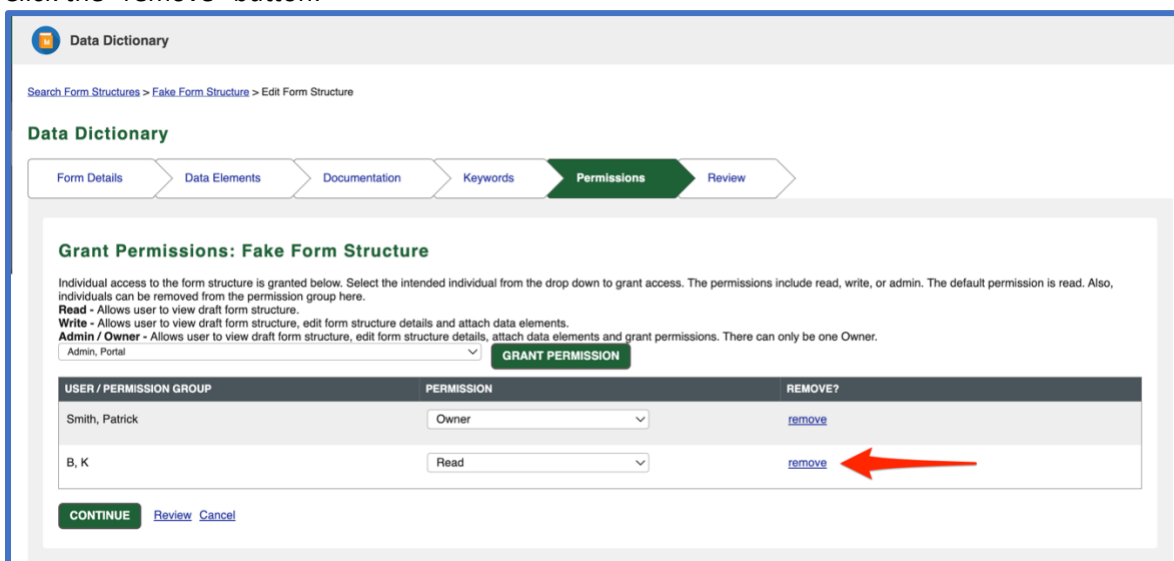
2. Final Review: Review the details of the Form Structure. Click the Finish button to display the Form Structure.

4.6.6 Removing Permissions

1. Search for form structure
2. Select “Edit Form” button at the top of the page.



3. Click on the “Permissions” Chevron.
4. Click the “remove” button.



USER / PERMISSION GROUP	PERMISSION	REMOVE?
Smith, Patrick	Owner	remove
B, K	Read	remove

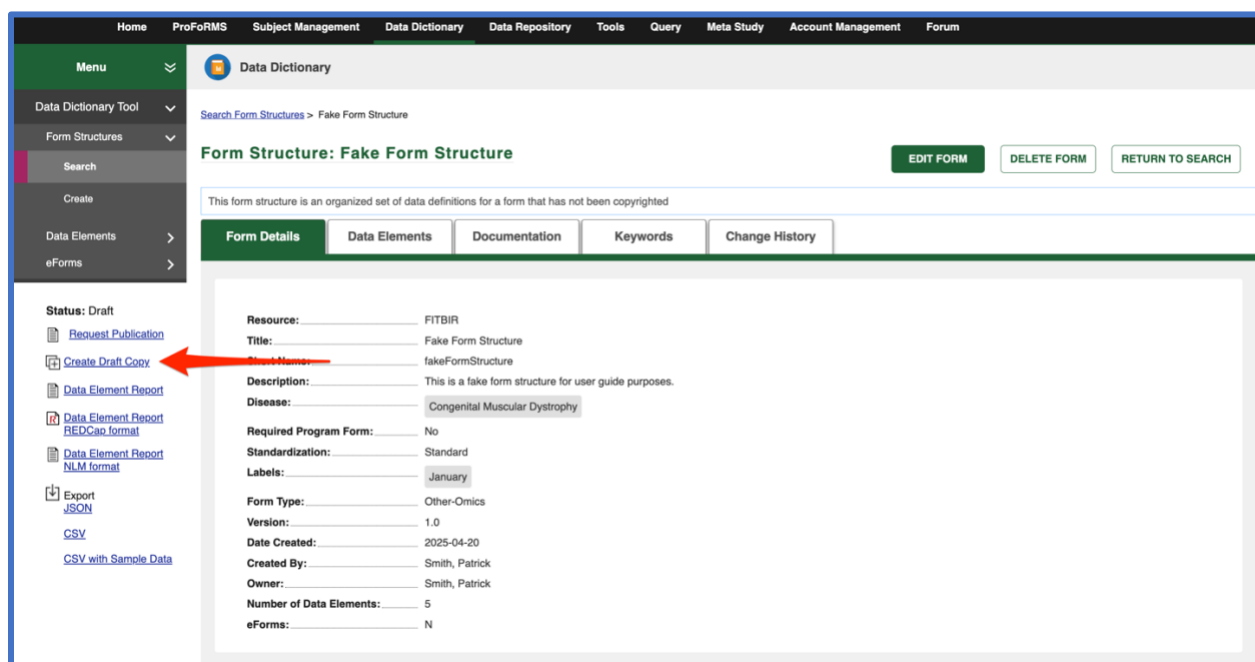
The user will no longer have Admin/Write/Read privileges to your form structure.

- Once all permissions have been assigned, click Continue. Review and save changes under the Review Chevron.

4.6.7 Other ways of creating a Form Structure

In the above sections we discussed the conventional way of creating a form structure from the very beginning. There are alternative ways to create a form structure as well:

- From a published FS, by using Create Draft Copy option.
- From a Shared Draft FS by using Create Draft Copy option.



The screenshot shows the BRICS Data Dictionary interface. The top navigation bar includes links for Home, ProFoRMS, Subject Management, Data Dictionary (active), Data Repository, Tools, Query, Meta Study, Account Management, and Forum. The left sidebar contains a menu with options like Data Dictionary Tool, Form Structures, Search, Create, Data Elements, and eForms. The main content area displays the 'Form Structure: Fake Form Structure' page. A red arrow points to the 'Create Draft Copy' link in the sidebar. The form details section shows the following information:

Resource:	FITBIR
Title:	Fake Form Structure
Short Name:	fakeFormStructure
Description:	This is a fake form structure for user guide purposes.
Disease:	Congenital Muscular Dystrophy
Required Program Form:	No
Standardization:	Standard
Labels:	January
Form Type:	Other-Omics
Version:	1.0
Date Created:	2025-04-20
Created By:	Smith, Patrick
Owner:	Smith, Patrick
Number of Data Elements:	5
eForms:	N

- By exporting a FS as an XML file from one instance of BRICS and re-importing it in another instance of BRICS – that requires Admin privileges.

4.6.8 Copying published Form Structures

1. If there is a published form structure that is applicable to, use it as-is.
2. OR use the Create Draft Copy option to create a copy of a published FS and then edit it to adjust it to your needs.
3. When using Create Draft Copy option, make sure that the new FS contains the appropriate Main Group.
4. If it is a STANDARDIZED form, then please follow the rules below for creating an **addendum form structure**.
5. Contact the Operations team to ask any additional questions.

4.6.9 Addendum Form Structures

If the study uses standard instruments which are either modified or have added additional questions to accommodate your study needs, to preserve data harmonization and data standards in BRICS, we recommend that you follow this procedure:

1. Use or create a FS that represents the standard instrument as is.
2. Use addendum/appendix form structure to accommodate study-specific data elements needed be to add to a standardized instrument.

NOTE: If the data elements being added affect the summary scores of the standardized form structure, the user will have to make a new Unique form structure.

To Create and Addendum: Perform the following actions:

1. Create a FS following these naming conventions.
2. Appendix/addendum 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. Note: If the data elements you are adding affects the summary scores of the standardized form structure you will have to make a new Unique form structure **To Create and Addendum:** Perform the following actions:
 - d. **Short Name:** Form Name/Acronym you are building the appendix for_Appdx_Number portion of FITBIR Study ID **d. Example:** PHQ9_Appdx_0000217
3. 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.