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Chapter

4

Data Dictionary - Form Structures

CHAPTER 4 – DATA DICTIONARY

The **Data Dictionary** module is used for defining data elements and form structures. Data Dictionary allows users to search. Create and manage Common Data Elements (CDE) and Unique Data Elements (UDE), create and manage 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 OBJECTIVE

This chapter provides information for users on how to:

- Browse existing Form Structures (5.1.3)
- Search Form Structures (5.1.5)
- Create Form Structures (5.1.6)
- Import Form Structures (5.1.22)
- Browse existing Data Elements
- Search Data Elements
- Create Data Elements
- Import Data Elements
- Browse existing eForms
- Search eForms
- Create eForms

4.2 SYSTEM FUNCTIONS

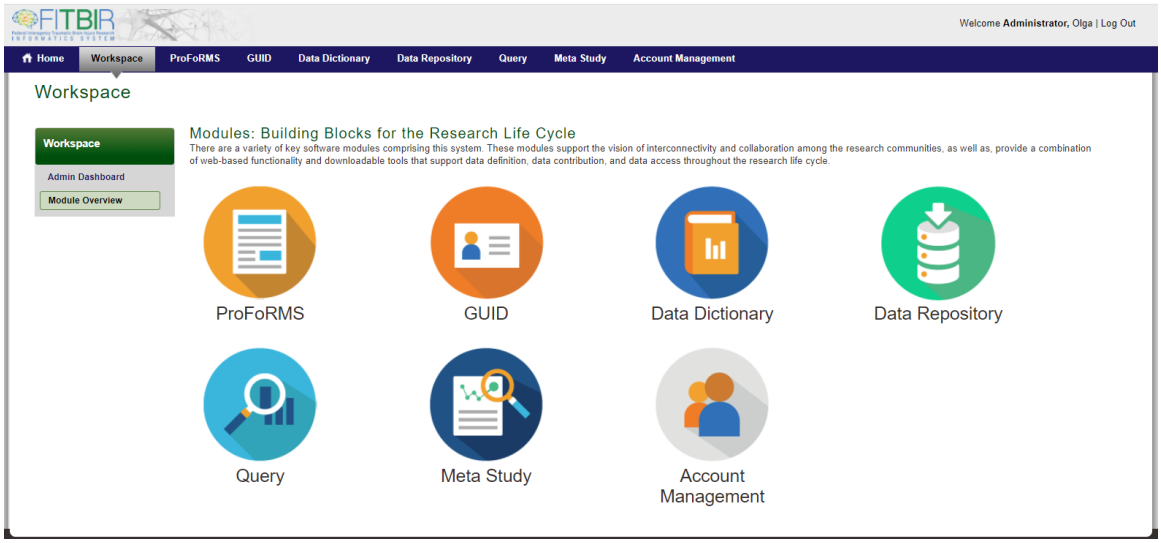
The Data Dictionary module provides the tools for defining the data you submit as well as provide alternate terms (aliasing) and translation rules for the same element. Importantly, the BRICS data dictionary provides those who have access to the data with clear and precise information about what it is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



4.4 Data Dictionary Module capabilities

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

- Searching Form Structures
- Creating Form Structures
- Searching Data Elements
  - Downloading Data Elements Results to XML, CSV and ZIP output formats
- Creating Data Elements
- Importing Data Elements
- Searching eFORMs
- Creating e-Form
  - Add Section
  - Add Data Element
  - Add Text
  - Edit Form Layout
  - Save eFORM

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FORM STRUCTURES

A form (FS) is a presentation of a given 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 case report form (CRF) (electronic or paper) where data elements are linked together for collection and display.

Form Structures are used to:

- Upload data to the Data Repository. The form structure provides a container for uploaded data. The Submission Tool 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 properly represented and queryable by the Query Tool.

5.1.1 Form structures adhere to a strict publication process prior to researchers can submit data to that particular form structure.

1. FS are initially created in **Draft state** – they can be modified and data elements may be removed or added to the form structure. At that point a FS is only visible in the data dictionary to its owner and BRICS admin.
2. After FS has been properly reviewed – it can be assigned **Awaiting Publication state (AWP)** . At this point data can be validated the FS in the Validation Tab/Submission Tool, but it cannot be uploaded to the database until it is validated.
3. Once the data have been validated against AWP one 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 Upload Tool/Submission Tool.

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5.1.2 Life Cycle 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.

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

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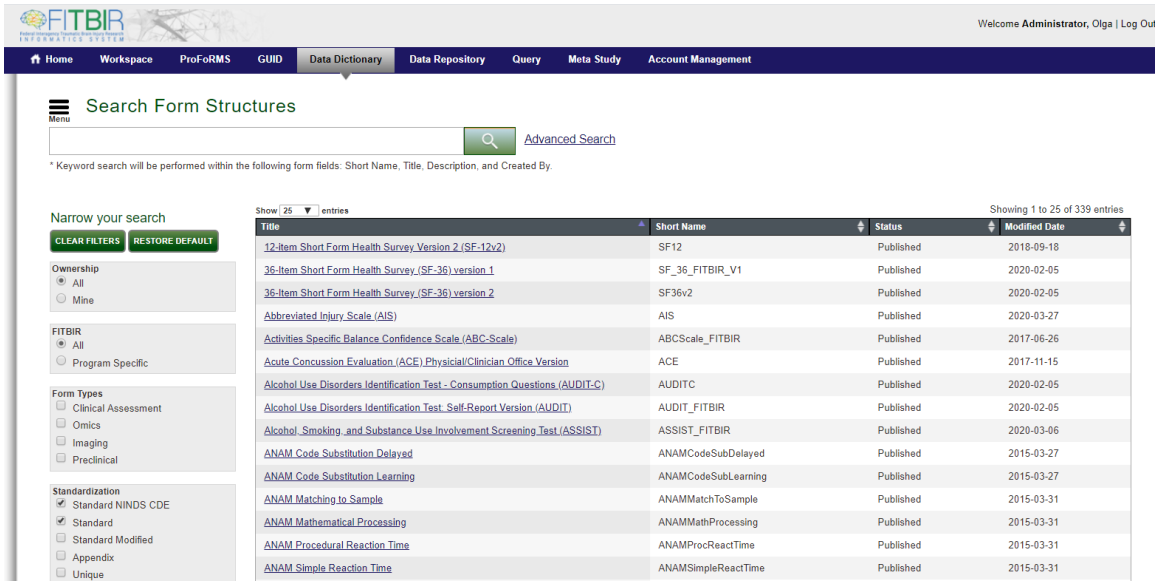
5.1.3 Browse Form Structures

When you click the Data Dictionary module icon, you are automatically redirected 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 you can:

1. Browse FS
2. Sort/filter FS by title (alphabetically), short name, status and modified date
3. Change the number of FS per page (25 by default)
4. View the FS by clicking on FS title, it will open the FS page for view.



5.1.4 Filter Form Structures

In order 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.

- Ownership:– to search for FS by ownership. All – shows all FS. Mine -is includes only FS data you own
- Instance of BRICS Program (e.g. FITBIR) (All, Specific):
  - All – shows all FS

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- Program Specific- shows only those FS which are defined as recommended/specific by the program.

❖ Form Types: Clinical Assessment, Omics, Imaging

- FS which created to collect clinical data are assigned Clinical Assessment
- FS which created to collect Genomics, Proteomics and like data, are assigned Omics
- FS created to collect imaging data are assigned Imaging

❖ Standardization: Standard NINDS CDE, Standard, Standard Modified, Appendix, Unique

- Standard form structures (FS) are FS created 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 FS – is 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 – is a FS which created based on a modified standard instrument. Some teams choose to modify standard instruments, so we use this standardization to accommodate it.
- Unique – a FS based on a unique study specific form/instrument
- Appendix- is a FS 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.

❖ 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. AS for now, the following disease categories are supported: 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.

❖ Clear Filters – clears all filters

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- Restore Default- restores filter settings default for the given instance of BRICS.

To relax filter settings- un-check all filter check boxes. That will result in displaying all FS.

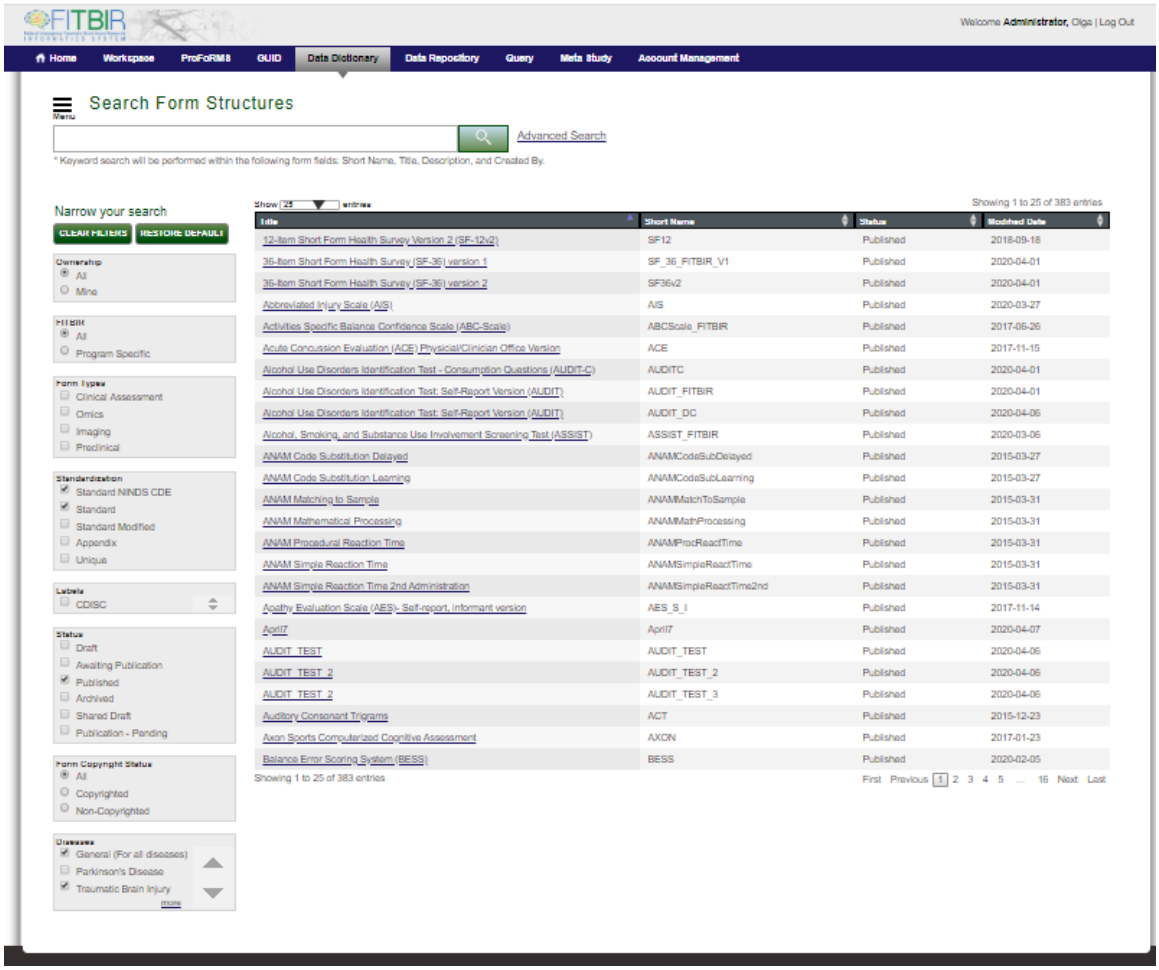

Figure 1.Default filter settings for FITBIR

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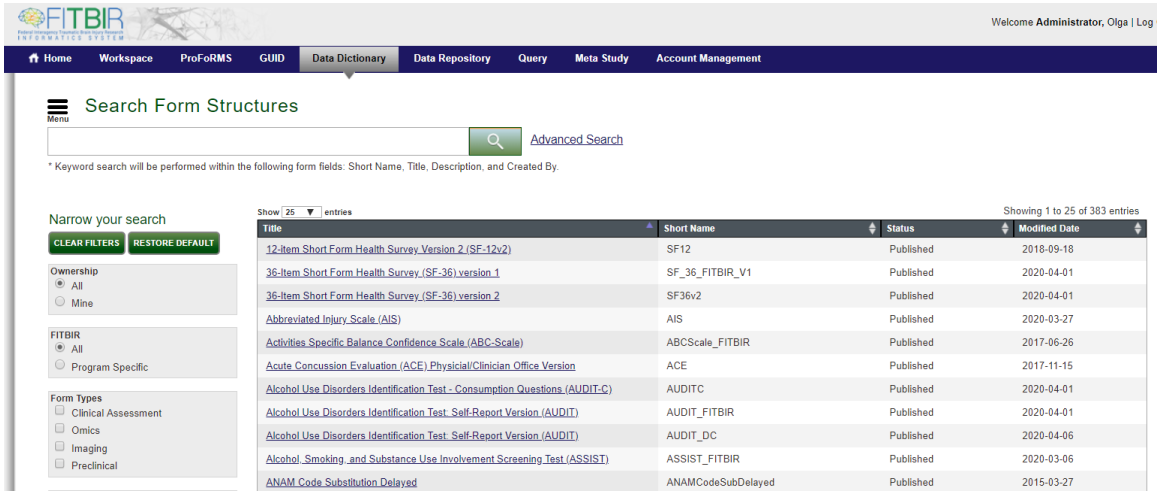
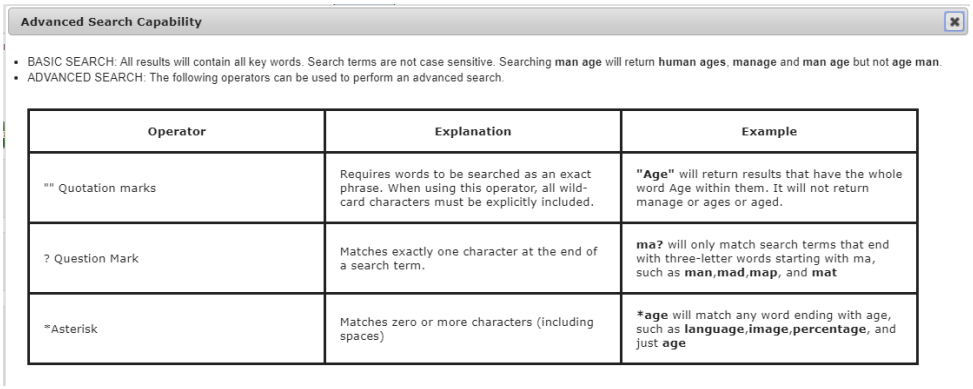
5.1.5 Search Form Structures

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 **Search** button. 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 5.1.3.). Which means if you cannot find the FS in question, un-check all filters and try again.



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



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5.1.6 Create Form Structures

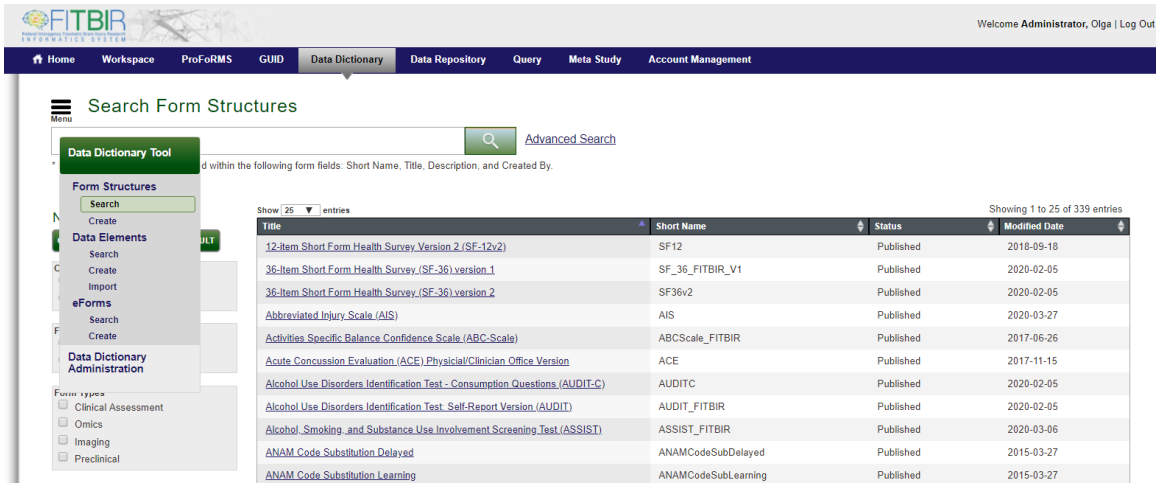
To be able to create form structures in BRICS, you should have the permissions to do that in Data Dictionary. Permissions/privileges are assigned to the user when he/she is requesting an account to the BRICS instance.

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

- ❖ Without the Form Structure Template and;
- ❖ With the Form Structure Template, refer to 5.1.19

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

1. Login to the system.
2. Navigate to the Data Dictionary module.
3. Click the **Data Dictionary** module. The Search Form Structures page appears.
4. Click the hamburger menu on the left-side tool bar. The Data Dictionary Module 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. 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.

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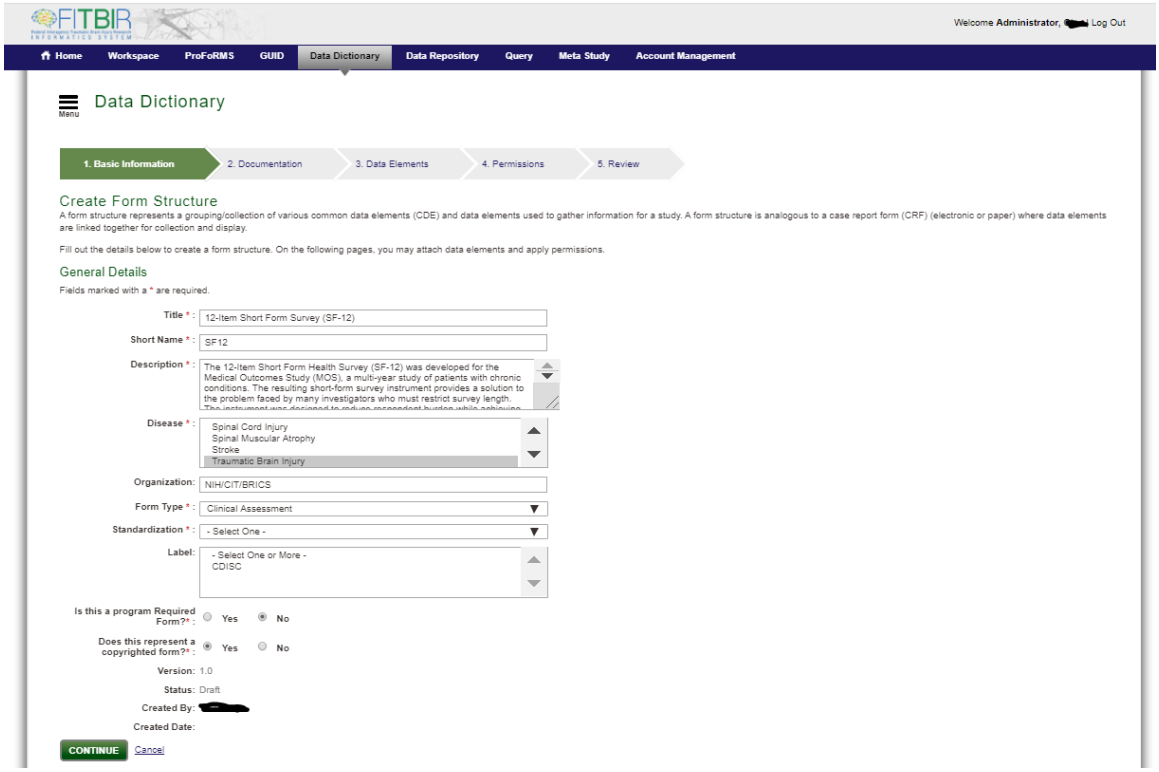

5.1.7 Basic Information chevron

7. Complete all required fields marked with an *asterisk:
   - ❖ Title – please follow the standards defined in your BRUCS 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.
   - ❖ Disease – select as many disease categories as you need. Use Ctrl+Right mouse click to select multiple disease categories.
   - ❖ Form Type - Clinical Assessment, Omics, Imaging. Choose one.
   - ❖ Standardization – select one from the list available for your BRICS instance.
   - ❖ Labels- select one, if your instance has labels.
   - ❖ Does this represent a copyrighted form? Choose Yes or No.

   Click **Continue** when complete. You will be re-directed to the next chevron.

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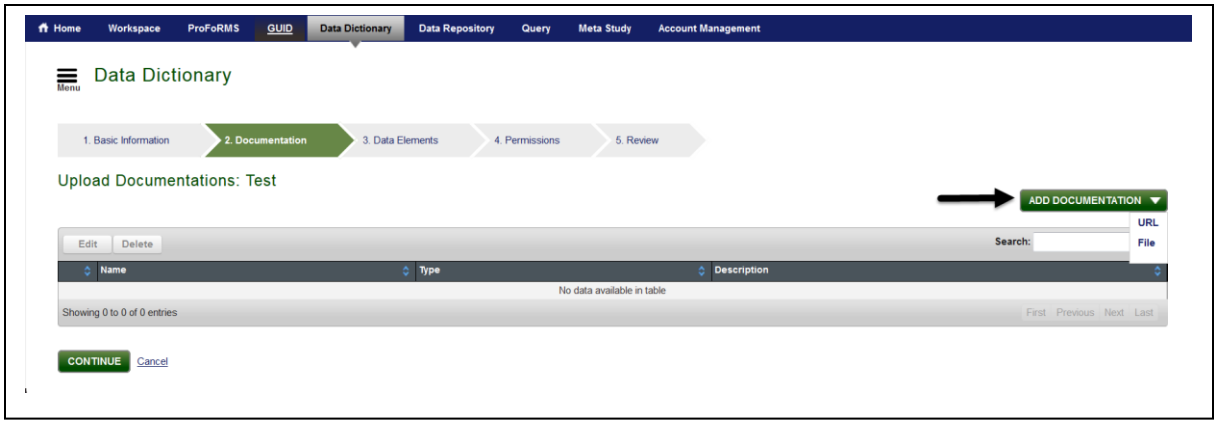
5.1.8 Documentation chevron:

1. Click the **Add Documentation** button to select the desired file or URL.
2. Documentation is optional, but BRICS Operations encourage uploading all documentation which were used to create a FS.



Click Continue when complete. You will be re-directed to the next chevron.

5.1.9 Data Elements chevron

Important: there are 2 groups which are must for all FS, including standardized, unique, appendices, etc. in all instances of BRICS. These are:

- The Main Group
- The Form Administration are standardized group of data elements that must be included in all BRICS

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 Main group for FITBIR instance contains the following set of nine data elements.

#	TITLE	SHORT DESCRIPTION	VARIABLE NAME	REQUIRED?	TYPE
1	GUID	Global Unique ID which uniquely identifies a subject	GUID	Required	CDE
2	Subject identifier number	An identification number assigned to the participant/subject within a given protocol or a study.	SubjectIDNum	Optional	CDE
3	Age in years	Value for participant's subject age recorded in years.	AgeYrs	Recommended	CDE
4	Vital status	Status of participant/subject as alive or dead	VitStatus	Optional	CDE
5	Visit date	Actual interview or visit date	VisitDate	Recommended	CDE
6	Site name	The name of the site for the study	SiteName	Recommended	CDE
7	Days since baseline	The number of days since baseline	DaysSinceBaseline	Optional	CDE
8	Case control indicator	Indicator of whether subject is in the case or control arm of the study	CaseControlInd	Optional	CDE
9	General notes text	General notes	GeneralNotesTxt	Optional	CDE

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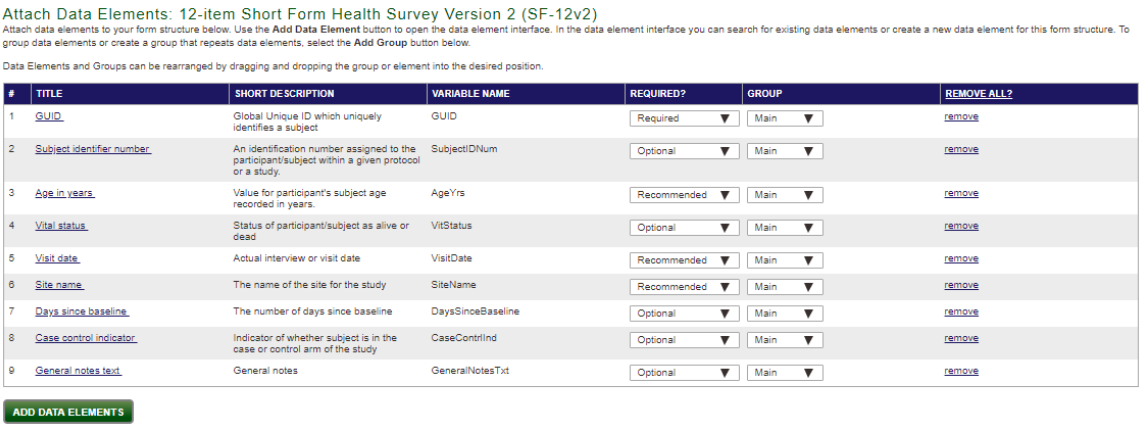
Important: please note that GUID often is the first DE in the Main group and it is required. GUID provides the unique identifier for a subject across all BRICS studies/instances. It must be present in all BRISC FS and it must have the status REQUIRED.

The next group is From Administration, which intent is to provide the information on how the instrument was administered.

5.1.10 Adding the Main group of data elements

1. The first group to be populated under the Data Elements chevron is the Main group. Please note that it does not have a name.


Attach Data Elements: 12-item Short Form Health Survey Version 2 (SF-12v2)

Attach data elements to your form structure below. Use 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.

Data Elements and Groups can be rearranged by dragging and dropping the group or element into the desired position.

#	TITLE	SHORT DESCRIPTION	VARIABLE NAME	REQUIRED?	GROUP	REMOVE ALL?
1	GUID	Global Unique ID which uniquely identifies a subject	GUID	Required	Main	remove
2	Subject identifier number	An identification number assigned to the participant/subject within a given protocol or a study.	SubjectIDNum	Optional	Main	remove
3	Age in years	Value for participant's subject age recorded in years.	AgeYrs	Recommended	Main	remove
4	Vital status	Status of participant/subject as alive or dead	VitStatus	Optional	Main	remove
5	Visit date	Actual interview or visit date	VisitDate	Recommended	Main	remove
6	Site name	The name of the site for the study	SiteName	Recommended	Main	remove
7	Days since baseline	The number of days since baseline	DaysSinceBaseline	Optional	Main	remove
8	Case control indicator	Indicator of whether subject is in the case or control arm of the study	CaseControlInd	Optional	Main	remove
9	General notes text	General notes	GeneralNotesTxt	Optional	Main	remove

ADD DATA ELEMENTS

2. Attach data elements to the Main by using the **Add Data Element** button(refer to 5.1.12) 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.

5.1.11 Adding All Other Groups including the Form Administration group

1. Create a group by using **Add Group** button.
2. Provide the group name. **Important:** the group name must be unique within the form structure.
3. Provide the group repeatability settings. The repeatability settings are as follows:

   At least – provides the min number the group must be repeated.

   Exactly- provides the exact number the group must be repeated. That is a tricky setting, we recommend contacting OPS when you plan to use it.

   Up to – provides the max number the group will be repeated. Up to=0, means the group could be repeated indefinitely.

5.1.12 Adding Data Elements to a Group

Below is an example of From Administration group in FITBIR.

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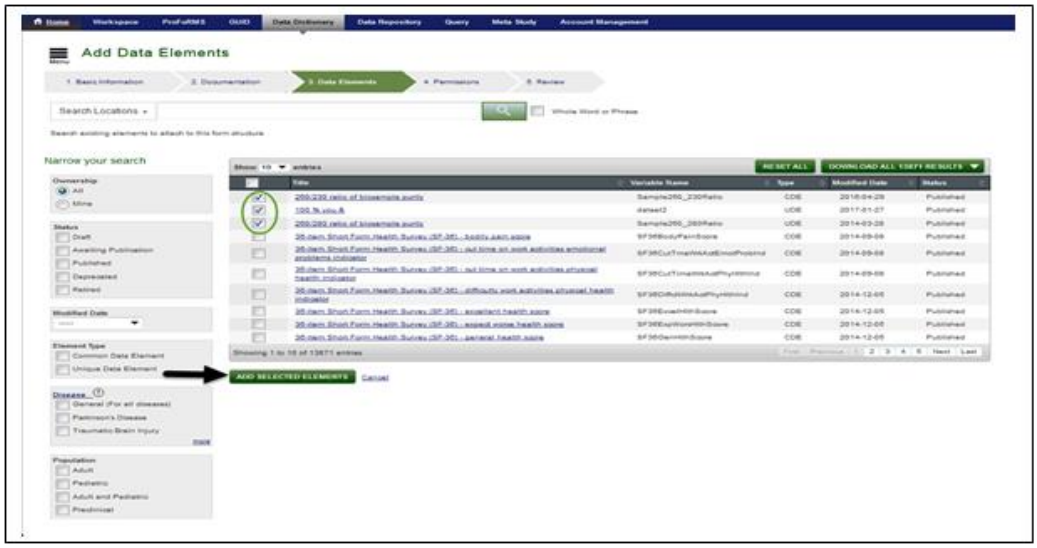
Form Administration (Appears Up To 1 Time)

#	TITLE	SHORT DESCRIPTION	VARIABLE NAME	REQUIRED?	TYPE
1	Context type	The context to which the questions were answered	ContextType	Recommended	CDE
2	Context type other text	The free-text related to ContextType specifying other text	ContextTypeOTH	Recommended	CDE
3	Data source	Source of the data provided on the case report form	DataSource	Recommended	CDE
4	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	CDE

1. After the group name and repeatability is set up, use Add Data Elements button to assess the data element interface, where you can search for existing data elements which you would like to add your form structure. **Note** in order to be added the DE must already exist in the data dictionary.
2. 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].

Important: The same data element can be included in the same group only once.



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5.1.13 Adjusting the Order of DEs within the Group

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.

5.1.14 Assigning the Status of the DE within the Group

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

- **Required**: That is a good setting is 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 and get submitted, 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**: Validation tool will produce a warning, but still allow the data set to pass if a cell is left blank for that data element
  - The default setting for a DE within a FS 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.

3. 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**".]
4. Once all groups are created and DEs added, click Continue. You will be move to the Permissions chevron (5.1.16).

5.1.15 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 that : 1) the Main Group cannot be moved, 2) 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 you removed the group it cannot be restored automatically. If later you change your mind, you need to restore it manually.

Removing a Data Element from the group

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

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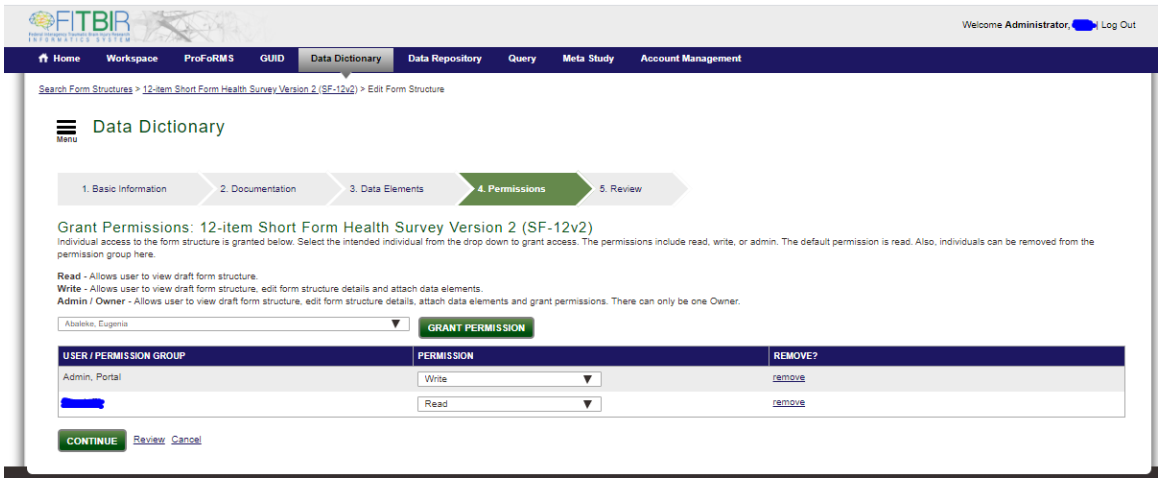
Moving Data Elements Between Groups

1. Using the drop-down menu in the Group column, for each data element, select which data element group you would like to move the data element. Please note that when you move the DE it disappears from the source group.
2. After moving a DE from one group to another, make sure that all Des appear in a proper order within a group.
3. It is a best practice to do this in the order that the data elements appear on the form.

5.1.16 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, chose 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.



Things to Note:

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

5.1.17 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.)

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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.

5.1.18 Removing Permissions

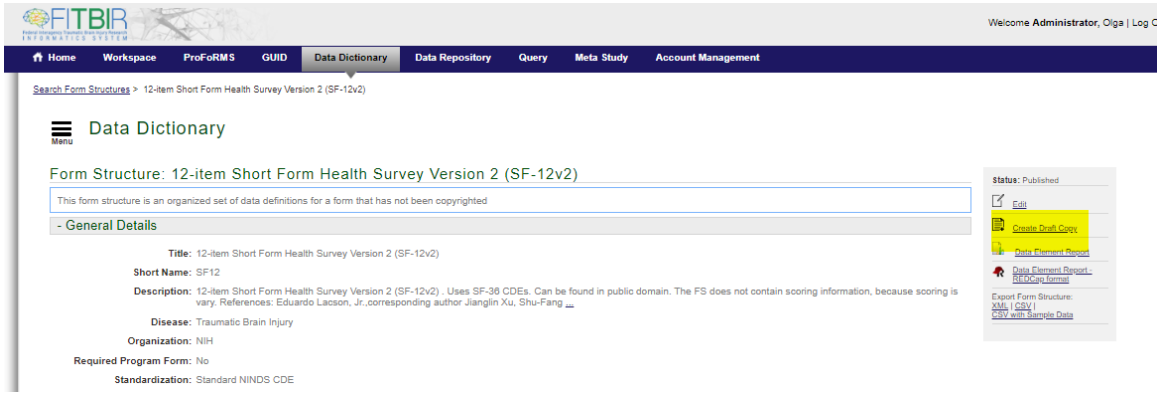
1. Search for form structure
2. Select "Edit" form the Menu on the right
3. Click on the "3. Permissions" chevron
4. Click the "remove" button
5. The user will no longer have Admin/Write/Read privileges to your form structure
6. Once all permissions have been assigned, click Continue. You will be move to the Review chevron 5.1.17).

5.1.19 Other Ways of Creating a Form Structure

In the above sections (5.1.6-5.1.17) we discussed the conventional way of creating a form structure from the very beginning.

There are other, sometimes easier ways to create a FS in BRICS:

From a published FS, by using Create Draft Copy option



From a Shared Draft FS by using Create Draft Copy option

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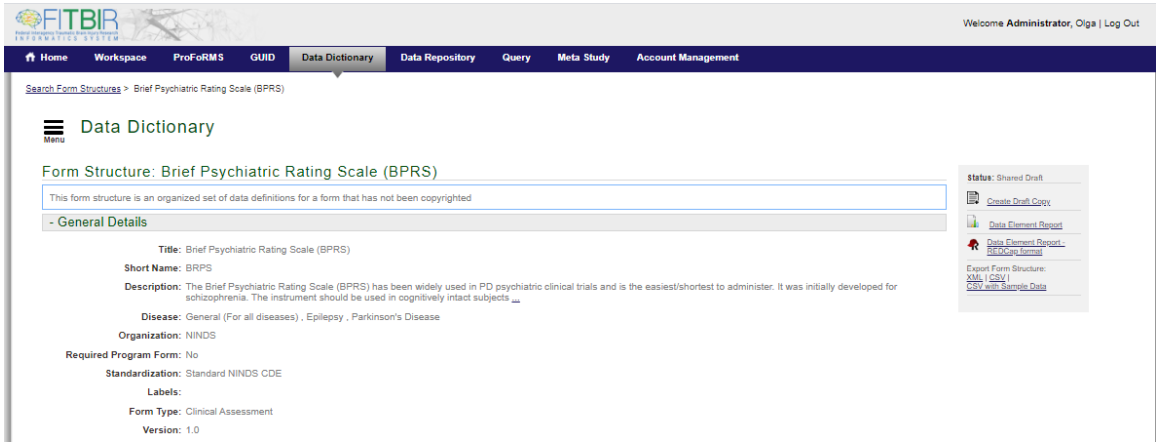

By exporting a FS as an XML file from one instance of BRICS and re-importing it in another instance of BRICS – that requires Admin privileges.

5.1.20 Copying Published Form Structures

1. If you find a published form structure that is applicable to your study, you may use it as-is.
2. OR you might want to use the Create Draft Copy option to create a copy of published FS and then edit it to adjust it to your needs.
3. When using Create Draft Copy option, make sure that your 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 (Section 4.4.1).**
5. Contact your Operations team if you have any questions.

5.1.21 Addendum Form Structures

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

3. Use or create a FS that represents the standard instrument as is.
4. Use addendum/appendix form structure to accommodate study-specific data elements you would like to add to a standardized instrument.

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:

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

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c. **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.

5.1.22 Export/Import a FS as an XML

This option only available for Admin user.

If you have Admin privileges, you can

1. Export a FS using "export as XML" option.

2. Import a FS as an XML using Data Dictionary Administration> Form Structures>Import option.
3. You can use this option to move FS from one instance of BRICS to another. E.g. for example, you first set up your study using a Demo instance of BRICS, and when you are satisfied with all FS/DEs, you can move all FS from to Production using XML.
4. Please note that before FS can be imported as an XML, all DEs which belong to a FS must be in the Data dictionary. That means that you must import DEs first, and then import a FS.

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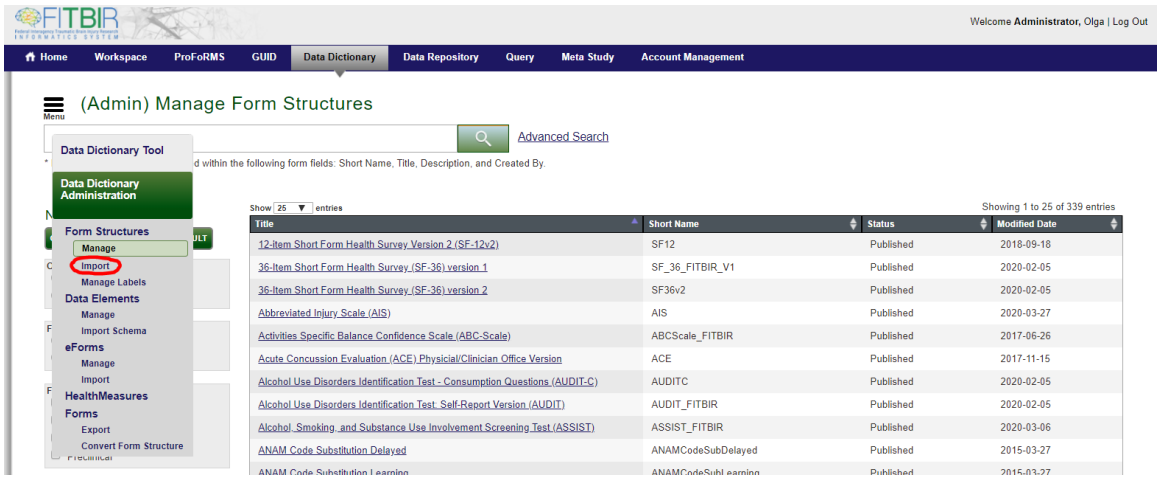

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