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 (4.5.3)
❖ Search Form Structures (4.5.5)
❖ Create Form Structures (4.5.6)
❖ Import Form Structures (4.5.22)
❖ 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 or link on the navigation bar.

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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
4.5 Form Structures

A form structure (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 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/collection data are properly represented and queryable by the Query Tool.
4.5.1 Form Structures Publication

The 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 it's status will change to Published and can be used for Data Submission.

See the table below for details on the status's and their corresponding attributes.

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
<th>Visibility</th>
<th>Editable?</th>
<th>Data Validation?</th>
<th>Data Submission?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft</td>
<td>In a process of development</td>
<td>Required to log in into portal. Available for the owner, admin and to whom were given permissions only</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Awaiting publication</td>
<td>A publication has been requested for this FS</td>
<td>All users, including the public site</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Published</td>
<td>The FS which is available for public use</td>
<td>All users, including the public site</td>
<td>Limited. Can edit Title, Description, add/remove documentation.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Shared Draft</td>
<td>Form structures were created by the NINDS CDE Project. Provide recommendations for investigators of which CDEs to use.</td>
<td>All uses including the public site</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>
4.5.3 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. View the FS by clicking on FS title, it will open the FS page for view.

4.5.4 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.

- Clear Filters – clears all filters showing all Form Structures.
- Restore Default- restores filter settings default for the given instance of BRICS.
Ownership: To search for FS by ownership. All – shows all FS. Mine – only FS data you own

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) are 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 CDE: 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.
- 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.
- Unique: a FS 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.
4.5.5 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 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.

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

<table>
<thead>
<tr>
<th>Operator</th>
<th>Explanation</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>'' Quotation marks</td>
<td>Requires words to be searched as an exact phrase. When using this operator, all wildcard characters must be explicitly included.</td>
<td>&quot;Age&quot; will return results that have the whole word &quot;Age&quot; within them. It will not return manage or ages or aged.</td>
</tr>
<tr>
<td>? Question Mark</td>
<td>Matches exactly one character at the end of a search term.</td>
<td>me? will only match search terms that end with three-letter words starting with &quot;me&quot;, such as &quot;man&quot;, &quot;mad&quot;, &quot;map&quot;, and &quot;mal&quot;.</td>
</tr>
<tr>
<td>* Asterisk</td>
<td>Matches zero or more characters (including spaces)</td>
<td>*age will match any word ending with age, such as &quot;language&quot;, &quot;image&quot;, &quot;percentage&quot;, and &quot;just age&quot;.</td>
</tr>
</tbody>
</table>
4.5.6 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.
3. In the left navigation click Create under Form Structures

4. 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.
4.5.7 General Details Chevron

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, Preclinical. 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.
4.5.8 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.

4.5.9 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

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.
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.

4.5.10 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.

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.

4.5.11 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.
4.5.12 Adding Data Elements to a Group

Below is an example of From Administration group.

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.
4.5.13 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.

4.5.14 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 (4.5.16).

4.5.15 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.
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.

4.5.16 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, 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.

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)
4.5.17 Review Chevron

1. **Review**: Review all the data elements and make sure they are in the correct order and have the correct requirements (optional, 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.

4.5.18 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 4.5.17).

4.5.19 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:

1. From a **published** FS, by using **Create Draft Copy** option
2. From a **Shared Draft** FS by using **Create Draft Copy** option

3. 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. (Section 4.5.22)
4.5.20 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 4.5.21).
5. Contact your Operations team if you have any questions.

4.5.21 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:

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 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
   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.