



4

BRICS USER GUIDE

Data Dictionary: Form Structures



CHAPTER 4 - Data Dictionary

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he **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 Data Dictionary Objective

- 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 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 Account Management module from either the top navigation bar or the module icon.





4.6 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/collected data are properly represented and queryable by the Query Tool.

4.6.1 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 statuses and their corresponding attributes:

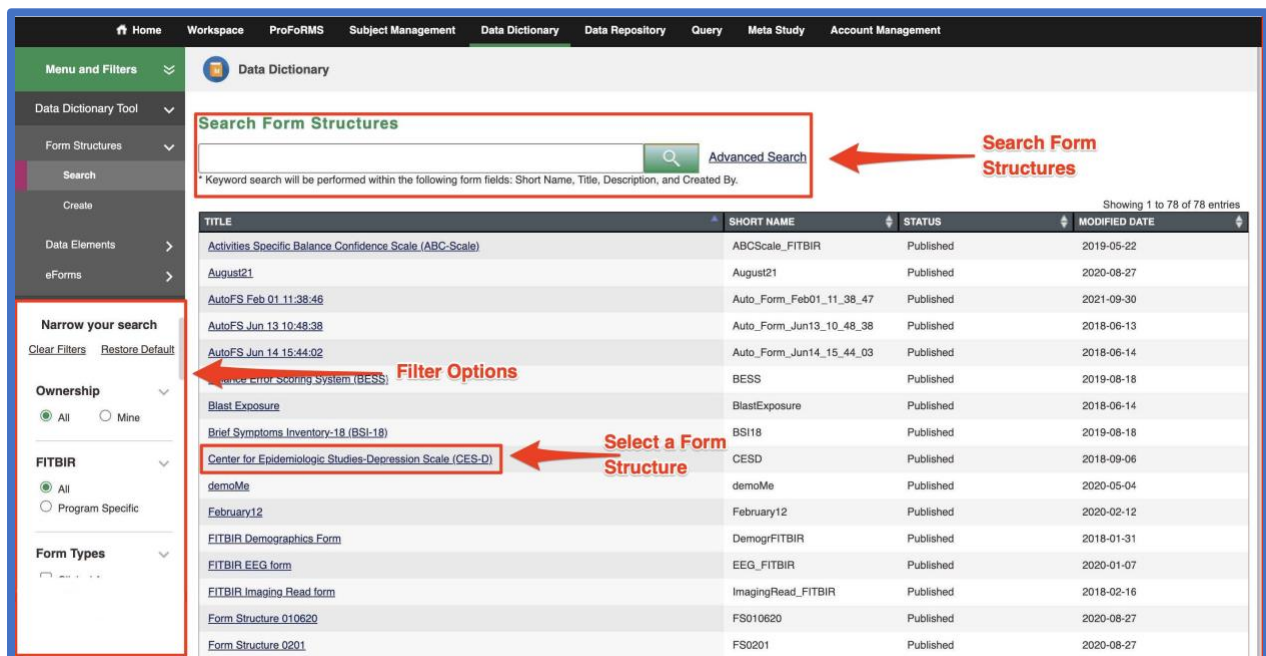
Type	Description	Visibility	Editable?	Data Validation?	Data Submission?
Draft	In a process of development.	Required to log in into portal. Available for the owner, admin and to whom were given permissions only	Yes	Yes	No
Awaiting publication	A publication has been requested for this FS	All users, including 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

4.6.3 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 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.



The screenshot displays the 'Data Dictionary' interface with the 'Search Form Structures' page. The search bar is highlighted with a red box and labeled 'Search Form Structures'. The table below shows a list of form structures with columns for Title, Short Name, Status, and Modified Date. The 'Center for Epidemiologic Studies-Depression Scale (CES-D)' entry is highlighted with a red box and labeled 'Select a Form Structure'. The sidebar on the left contains filter options, including 'Ownership', 'FITBIR', and 'Form Types', which are collectively labeled 'Filter Options'.

TITLE	SHORT NAME	STATUS	MODIFIED DATE
Activities_Specific Balance Confidence Scale (ABC-Scale)	ABCScale_FITBIR	Published	2019-05-22
August21	August21	Published	2020-08-27
AutoFS Feb 01 11:38:46	Auto_Form_Feb01_11_38_47	Published	2021-09-30
AutoFS Jun 13 10:48:38	Auto_Form_Jun13_10_48_38	Published	2018-06-13
AutoFS Jun 14 15:44:02	Auto_Form_Jun14_15_44_03	Published	2018-06-14
Brief Symptom Scoring System (BESS)	BESS	Published	2019-08-18
Blast Exposure	BlastExposure	Published	2018-06-14
Brief Symptoms Inventory-18 (BSI-18)	BSI18	Published	2019-08-18
Center for Epidemiologic Studies-Depression Scale (CES-D)	CESD	Published	2018-09-06
demoMe	demoMe	Published	2020-05-04
February12	February12	Published	2020-02-12
FITBIR Demographics Form	DemogrFITBIR	Published	2018-01-31
FITBIR EEG form	EEG_FITBIR	Published	2020-01-07
FITBIR Imaging Read form	ImagingRead_FITBIR	Published	2018-02-16
Form Structure 010620	FS010620	Published	2020-08-27
Form Structure 0201	FS0201	Published	2020-08-27

4.6.4 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.

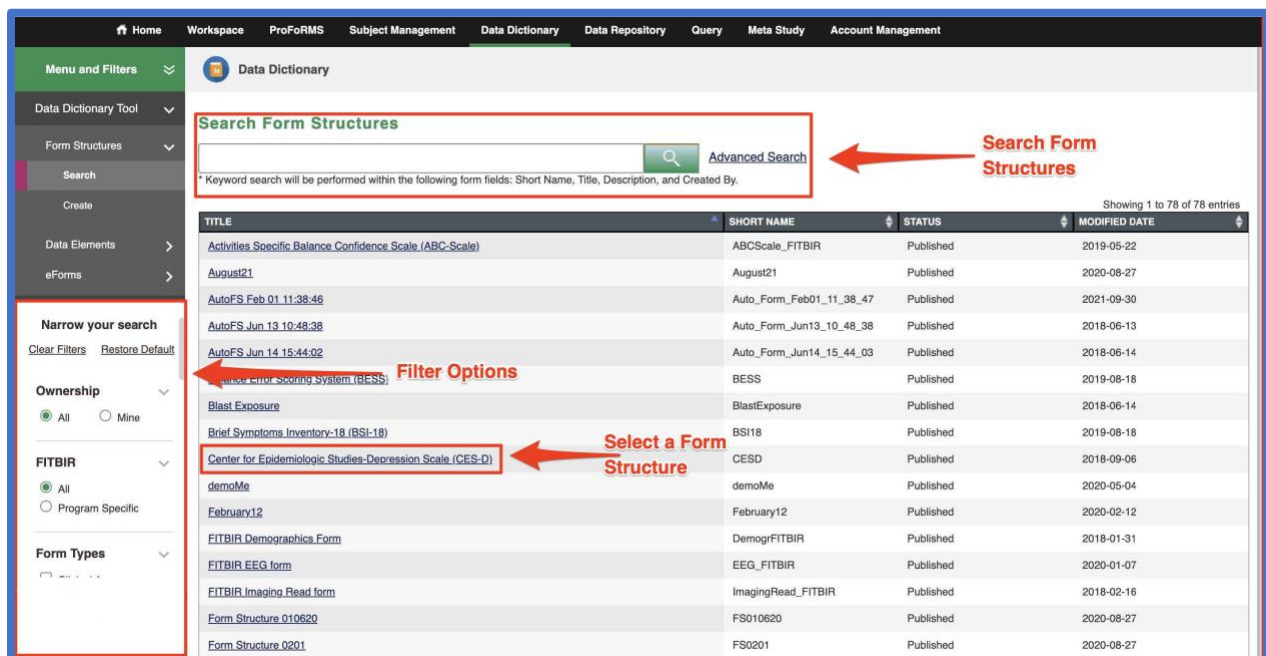
Default filter settings depend on the BRICS instance and can be set up when the BRICS instance is first set up. Default filter settings for FITBIR, are shown on the figure at the end of this chapter.

- **Clear Filters:** clears all filters showing all Form Structures.
- **Restore Default:** restores filter settings default for the given instance of BRICS.
- **Ownership:** To search for FS by ownership. All – shows all FS. Mine – only FS datayou 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):** based on the standardinstruments/scales/batteries. NINDS/BRICS defined standard instruments asthose which 1) have publications, seminal papers, validity research, whichdescribes their creation, properties, administration, etc. 2) have well defineddocumentation and 3) widely used in the community
 - **Standard NINDS CDE FS:** is a sub-set of Standard FS, limited to those whichare recommended by NINDS to use for a particular disease category. More canbe found here: <https://www.commondataelements.ninds.nih.gov>
 - **Standard Modified:** created based on a modified standardinstrument. Some teams choose to modify standard instruments, so we use thisstandardization to accommodate it.
 - **Appendix:** created to provide additional DEs for a standard and StandardNINDS 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 thefilter list to see all currently supported diseases.

4.6.5 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 **CreatedBy**.
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.



The screenshot displays the 'Data Dictionary' interface for searching form structures. The search bar contains the text 'Search Form Structures' and an 'Advanced Search' button. Below the search bar, a table lists search results with columns: TITLE, SHORT NAME, STATUS, and MODIFIED DATE. The table shows various form structures, including 'Activities Specific Balance Confidence Scale (ABC-Scale)', 'August21', 'AutoFS Feb 01 11:38:46', 'AutoFS Jun 13 10:48:38', 'AutoFS Jun 14 15:44:02', 'Brief Symptom Scoring System (BESS)', 'Blast Exposure', 'Brief Symptom Inventory-18 (BSI-18)', 'Center for Epidemiologic Studies-Depression Scale (CES-D)', 'demoMe', 'February12', 'FITBIR Demographics Form', 'FITBIR EEG form', 'FITBIR Imaging Read form', 'Form Structure 010620', and 'Form Structure 0201'. Red arrows point to the search bar, the 'Advanced Search' button, the 'Filter Options' section on the left sidebar, and 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	2019-05-22
August21	August21	Published	2020-08-27
AutoFS Feb 01 11:38:46	Auto_Form_Feb01_11_38_47	Published	2021-09-30
AutoFS Jun 13 10:48:38	Auto_Form_Jun13_10_48_38	Published	2018-06-13
AutoFS Jun 14 15:44:02	Auto_Form_Jun14_15_44_03	Published	2018-06-14
Brief Symptom Scoring System (BESS)	BESS	Published	2019-08-18
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)	CESD	Published	2018-09-06
demoMe	demoMe	Published	2020-05-04
February12	February12	Published	2020-02-12
FITBIR Demographics Form	DemogrFITBIR	Published	2018-01-31
FITBIR EEG form	EEG_FITBIR	Published	2020-01-07
FITBIR Imaging Read form	ImagingRead_FITBIR	Published	2018-02-16
Form Structure 010620	FS010620	Published	2020-08-27
Form Structure 0201	FS0201	Published	2020-08-27

6. 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

4.6.6 Create Form Structures

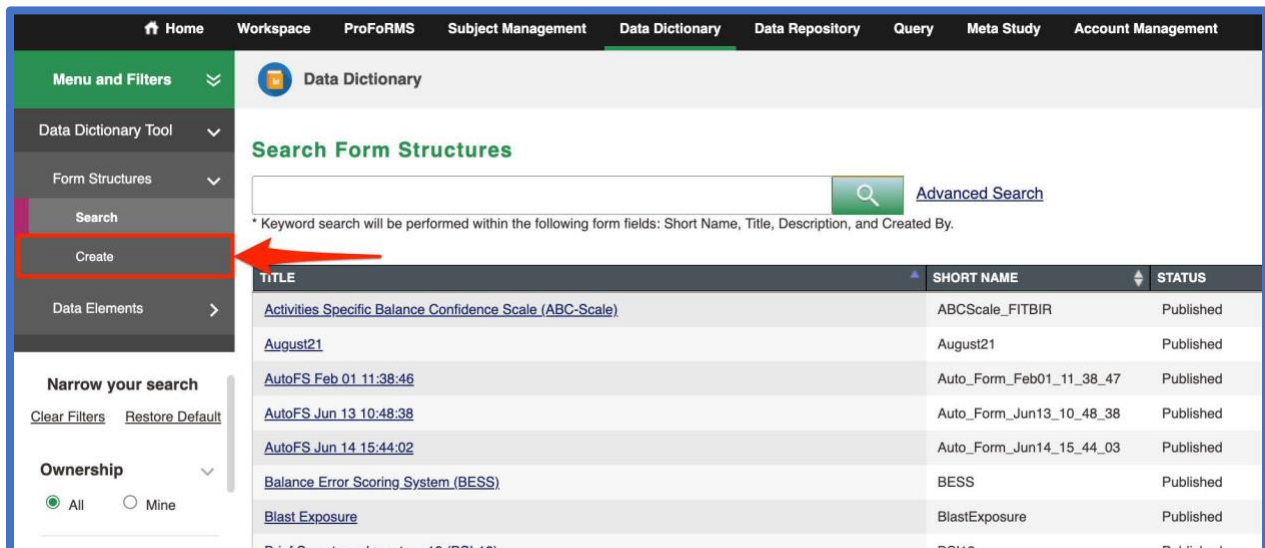
To be able to create form structures in BRICS, you should have the permissions to do that in Data Dictionary. Permissions/privileges are assigned to the user when he/she is requesting an account to the BRICS instance.

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

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

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

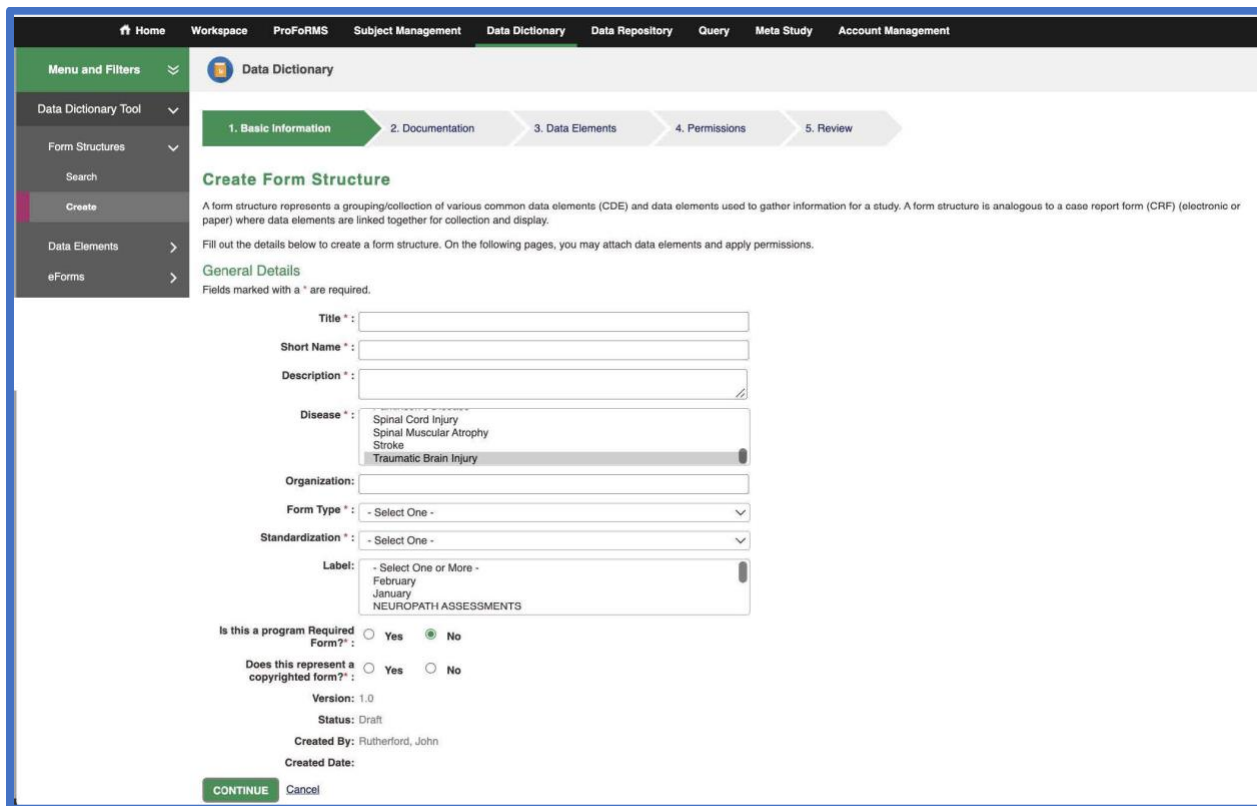
1. Login and navigate to the Data Dictionary module.
2. In the left navigation click Create under Form Structures



The screenshot shows the BRICS Data Dictionary interface. The top navigation bar includes Home, Workspace, ProFoRMS, Subject Management, Data Dictionary (active), Data Repository, Query, Meta Study, and Account Management. The left sidebar contains a 'Menu and Filters' section with a dropdown arrow, and a 'Data Dictionary Tool' section with a dropdown arrow. Under 'Data Dictionary Tool', there are three items: 'Form Structures' (with a dropdown arrow), 'Search', and 'Create' (highlighted with a red box and a red arrow pointing to it). Below 'Form Structures' is 'Data Elements' with a right-pointing arrow. The main content area is titled 'Data Dictionary' and 'Search Form Structures'. It features a search input field, a search button, and an 'Advanced Search' link. Below the search field, a note states: '* Keyword search will be performed within the following form fields: Short Name, Title, Description, and Created By.' A table of form structures is displayed below the search area, with columns for TITLE, SHORT NAME, and STATUS. The table lists several entries, including 'Activities Specific Balance Confidence Scale (ABC-Scale)', 'August21', 'AutoFS Feb 01 11:38:46', 'AutoFS Jun 13 10:48:38', 'AutoFS Jun 14 15:44:02', 'Balance Error Scoring System (BESS)', and 'Blast Exposure', all with a status of 'Published'.

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

- 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**:

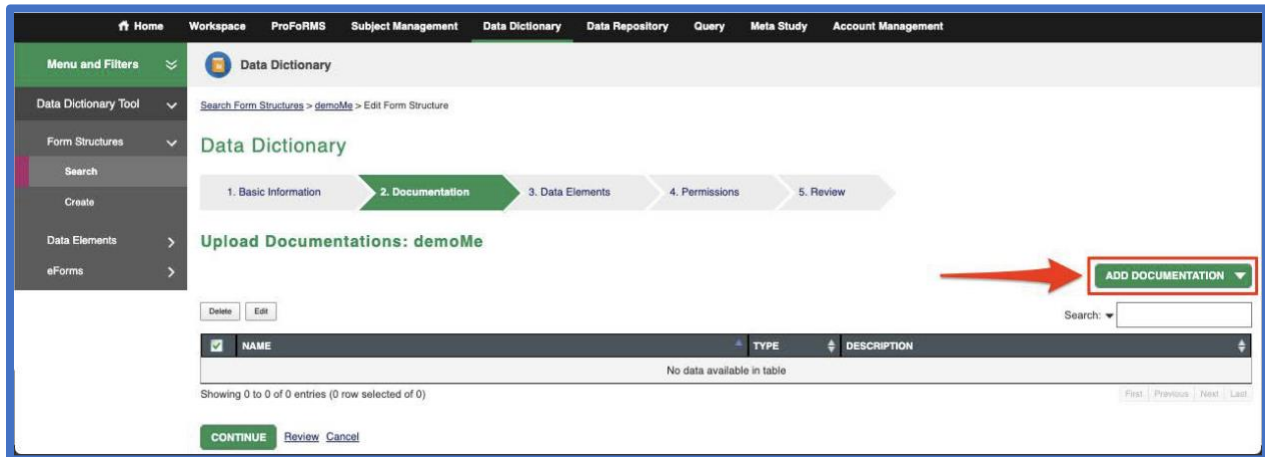


Complete all required fields marked with an * asterisk:

- 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.
- 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.
- Is this a program Required Form***: Choose Yes or No.
- Does this represent a copyrighted form***: Choose Yes or No.

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

4. **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.



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

4.6.6.1 Main Group and Form Administration Group creation:

5. Data Elements Chevron:

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 is the **Main group**.

NOTE about Main Group:

- It does not have a name DE.
- GUID is the first DE in the group. It must be present in all BRICS FS, and it must have the status “required”.

To create a 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:
 - 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.

Example of a Form Administration Group:

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

4.6.6.2 Adding data elements to groups:

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.

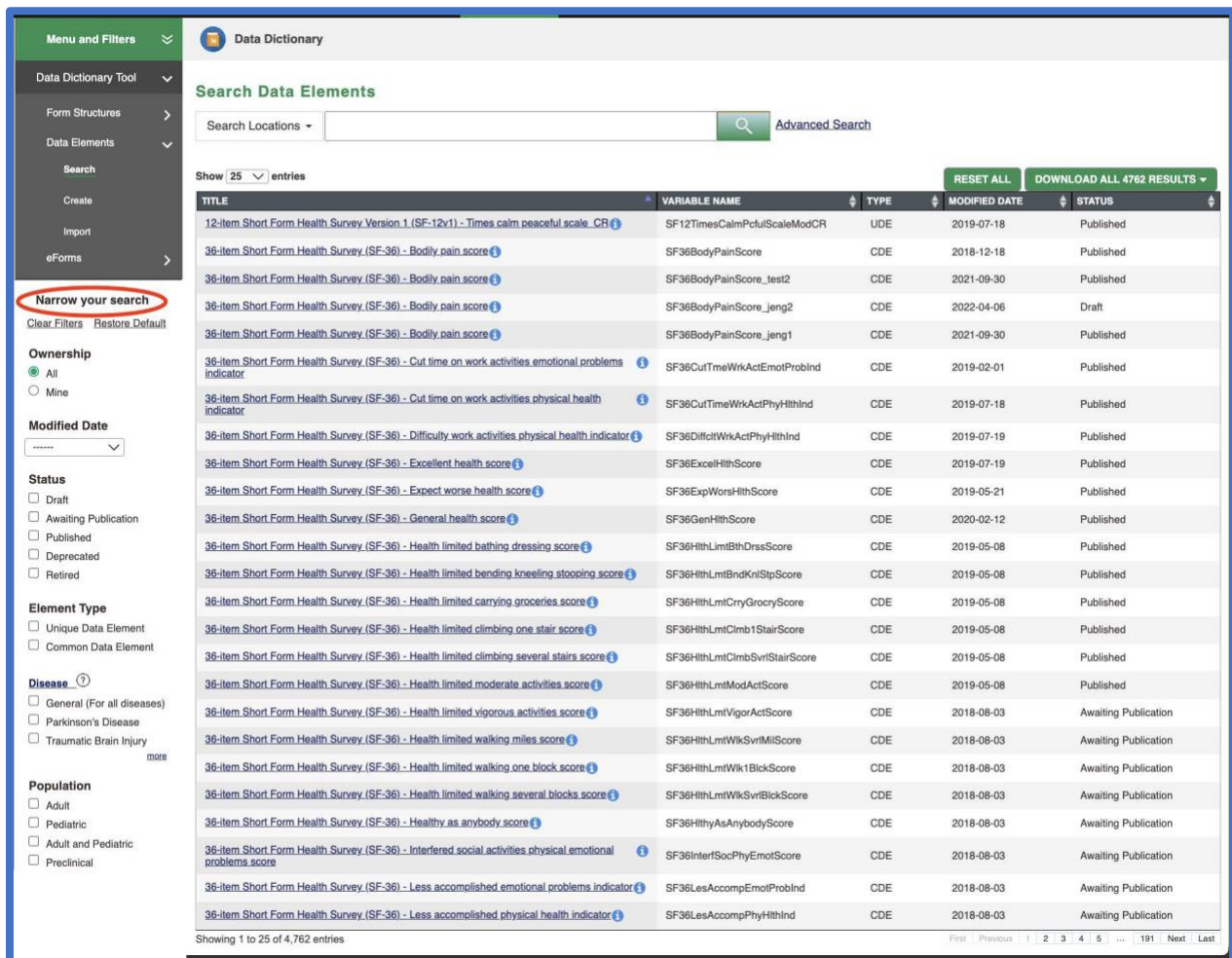
NOTE: to be added the DE must already exist in the data dictionary.

2. Select the data elements by checking the checkbox next to the desired data element. Once 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].

3.

1. When search results appear in the data element table, you can review it in the table, or use the DOWNLOAD ALL RESULTS button at the top right of the table to download the search result.

If there are too many DEs found, use the controls on the left side panel, under “Narrow your search”:



The screenshot displays the 'Data Dictionary' search interface. On the left, a 'Menu and Filters' sidebar contains sections for 'Ownership', 'Modified Date', 'Status', 'Element Type', 'Disease', and 'Population'. The 'Narrow your search' section is highlighted with a red circle. The main area shows a search bar and a table of results with columns for Title, Variable Name, Type, Modified Date, and Status. The table lists various health survey items with their corresponding variable names and statuses.

TITLE	VARIABLE NAME	TYPE	MODIFIED DATE	STATUS
12-Item Short Form Health Survey, Version 1 (SF-12v1) - Times calm peaceful scale_CR	SF12TimesCalmPcfuScaleModCR	UDE	2019-07-18	Published
36-Item Short Form Health Survey (SF-36) - Bodily pain score	SF36BodyPainScore	CDE	2018-12-18	Published
36-Item Short Form Health Survey (SF-36) - Bodily pain score	SF36BodyPainScore_test2	CDE	2021-09-30	Published
36-Item Short Form Health Survey (SF-36) - Bodily pain score	SF36BodyPainScore_jeng2	CDE	2022-04-06	Draft
36-Item Short Form Health Survey (SF-36) - Bodily pain score	SF36BodyPainScore_jeng1	CDE	2021-09-30	Published
36-Item Short Form Health Survey (SF-36) - Cut time on work activities emotional problems indicator	SF36CutTimeWkActEmotProblnd	CDE	2019-02-01	Published
36-Item Short Form Health Survey (SF-36) - Cut time on work activities physical health indicator	SF36CutTimeWkActPhyHlthind	CDE	2019-07-18	Published
36-Item Short Form Health Survey (SF-36) - Difficulty work activities physical health indicator	SF36DiffcWkActPhyHlthind	CDE	2019-07-19	Published
36-Item Short Form Health Survey (SF-36) - Excellent health score	SF36ExcelHlthScore	CDE	2019-07-19	Published
36-Item Short Form Health Survey (SF-36) - Expect worse health score	SF36ExpWorsHlthScore	CDE	2019-05-21	Published
36-Item Short Form Health Survey (SF-36) - General health score	SF36GenHlthScore	CDE	2020-02-12	Published
36-Item Short Form Health Survey (SF-36) - Health limited bathing dressing score	SF36HlthLmtBthDrssScore	CDE	2019-05-08	Published
36-Item Short Form Health Survey (SF-36) - Health limited bending kneeling stooping score	SF36HlthLmtBndKnlStpScore	CDE	2019-05-08	Published
36-Item Short Form Health Survey (SF-36) - Health limited carrying groceries score	SF36HlthLmtCrryGrocyScore	CDE	2019-05-08	Published
36-Item Short Form Health Survey (SF-36) - Health limited climbing one stair score	SF36HlthLmtClimb1StairScore	CDE	2019-05-08	Published
36-Item Short Form Health Survey (SF-36) - Health limited climbing several stairs score	SF36HlthLmtClimbSvrStairScore	CDE	2019-05-08	Published
36-Item Short Form Health Survey (SF-36) - Health limited moderate activities score	SF36HlthLmtModActScore	CDE	2019-05-08	Published
36-Item Short Form Health Survey (SF-36) - Health limited vigorous activities score	SF36HlthLmtVigorActScore	CDE	2018-08-03	Awaiting Publication
36-Item Short Form Health Survey (SF-36) - Health limited walking miles score	SF36HlthLmtWkSvrMlthScore	CDE	2018-08-03	Awaiting Publication
36-Item Short Form Health Survey (SF-36) - Health limited walking one block score	SF36HlthLmtWk1BlckScore	CDE	2018-08-03	Awaiting Publication
36-Item Short Form Health Survey (SF-36) - Health limited walking several blocks score	SF36HlthLmtWkSvrBlckScore	CDE	2018-08-03	Awaiting Publication
36-Item Short Form Health Survey (SF-36) - Healthy as anybody score	SF36HlthAsAnybodyScore	CDE	2018-08-03	Awaiting Publication
36-Item Short Form Health Survey (SF-36) - Interfered social activities physical emotional problems score	SF36InterSocPhyEmotScore	CDE	2018-08-03	Awaiting Publication
36-Item Short Form Health Survey (SF-36) - Less accomplished emotional problems indicator	SF36LesAccompEmotProblnd	CDE	2018-08-03	Awaiting Publication
36-Item Short Form Health Survey (SF-36) - Less accomplished physical health indicator	SF36LesAccompPhyHlthind	CDE	2018-08-03	Awaiting Publication

Ownership - this option allows you to expand the search by selecting All DEs, or narrow your search by selecting only Des created by you.

Modified Date – See DE modified within a specified time range.

Status – See DE based on the status they have.

Element Type – See DE based off of Unique or Common DE.

Diseases – Limits the search for DE based off a specific disease it was created for.

Population – Limits DE’s of a specific population. Note that “Preclinical” is represented for DE’s that were created for animals.

4.5.7 Downloading Data Element Search Results

To download data element search results, use the big **DOWNLOAD** button. Note that the **DOWNLOAD** button shows the number of DEs found.

It provides the following options:

XML – downloads the list of DEs as an XML file.

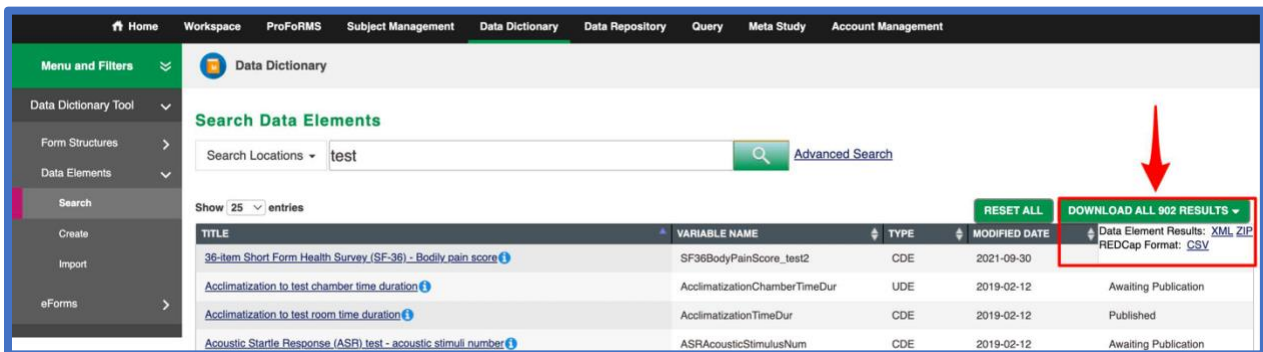
ZIP – downloads the list of DEs as a ZIP file. That is the most used option. The ZIP file has the following name “dataElementDetailExport.zip” contains 2 files:

- “dataElementDetailExport.csv” with a list of all DEs found. That is the file you need to review DE search results.
- “ExternalIDMapping.csv” which contains mapping of DEs to external dictionaries.

REDCap Format (CSV) – provides the option to download search results in REDCap Format.

NOTE:

The REDCap Data Element report guide is in 80% alignment with the REDCap standard. Please note that further refinement of the file is needed to upload correctly into the REDCap system.



The screenshot shows the 'Data Dictionary' search interface. The search term 'test' is entered in the search box. A red arrow points to the 'DOWNLOAD ALL 902 RESULTS' button, which is highlighted with a red box. The table below shows search results with columns for Title, Variable Name, Type, Modified Date, and a download menu.

TITLE	VARIABLE NAME	TYPE	MODIFIED DATE	Data Element Results: XML, ZIP REDCap Format: CSV
36-Item Short Form Health Survey (SF-36) - Bodily pain score	SF36BodyPainScore_test2	CDE	2021-09-30	
Acclimatization to test chamber time duration	AcclimatizationChamberTimeDur	UDE	2019-02-12	Awaiting Publication
Acclimatization to test room time duration	AcclimatizationTimeDur	CDE	2019-02-12	Published
Acoustic Startle Response (ASR) test - acoustic stimuli number	ASRAcousticStimulusNum	CDE	2019-02-12	Awaiting Publication



4.5.8 Creating/Editing Data Elements

Users of BRICS instance can create data elements (DEs or Unque Data Elements) if there is no Common Data Elements (CDEs) to accommodate users' data. DEs created by the users in the data dictionary have the "Unique Data Element" type. Unique Data Elements (UDEs) (unlike Common data elements) belong to a specific study/dataset (e.g. disease specific, form specific, media/modality specific, etc. UDEs 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). To learn more about CDEs and UDEs refer to NINDS CDE project (<https://www.commondataelements.ninds.nih.gov/>)

A single DE can be created through BRICS web interface (refer to 4.5.13). However, when creating multiple data elements, we strongly encourage using DE import template (refer to 4.5.14).

4.5.9 Creating Data Elements

Perform the following actions:

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

In the left menu click Data Elements then select Create from the menu.

Follow the process as it is defined by chevrons:

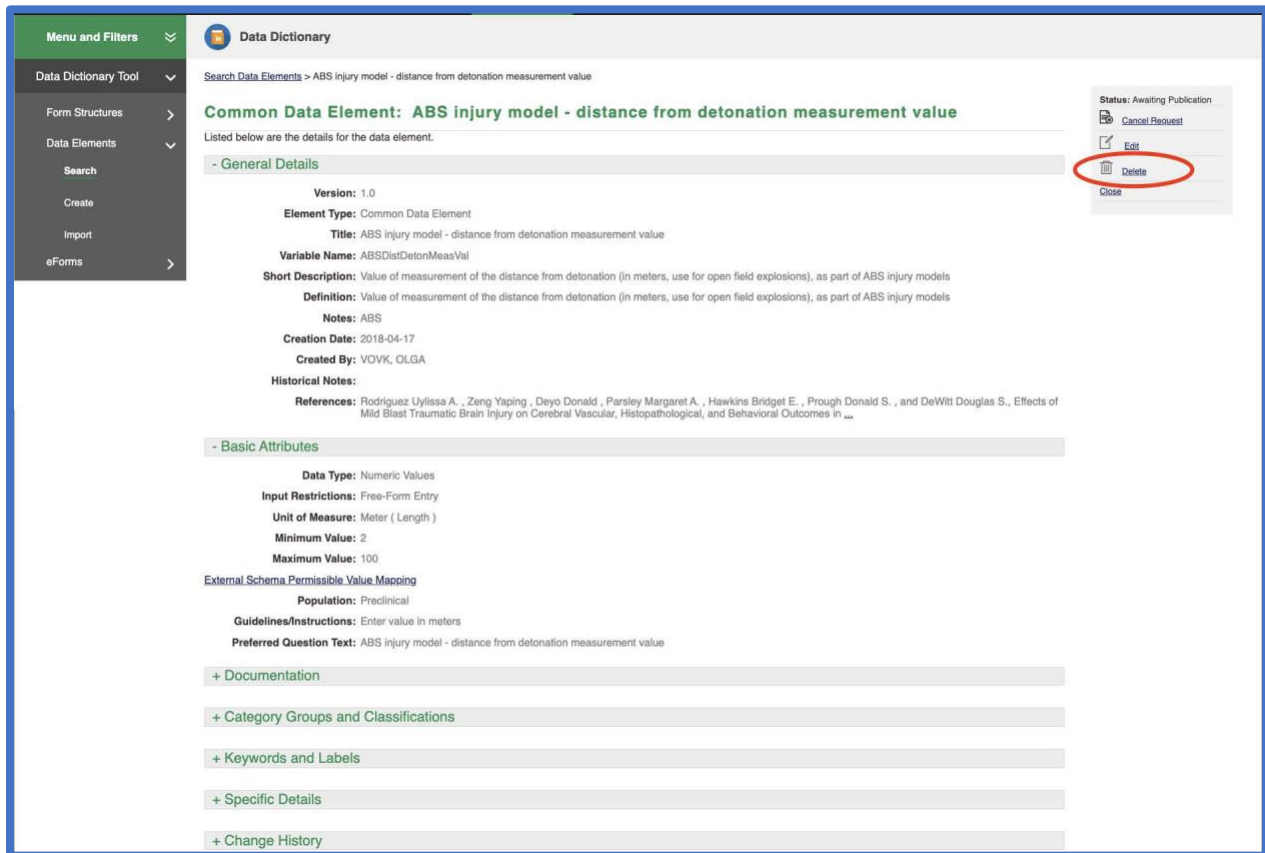
1. Basic Information/General Details: Fill out the details to create a data element. Fields marked with red asterisk (*) are required (Element Type, Title, Variable Name). Click Continue.
2. Add Documentation: Add any supporting documentation and click continue.
3. Attributes: In this form, you will 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.
4. Keywords and Labels: Here you can associate keywords to the data element. This will help search for the data element in the future. In the “Filter Keywords” textbox, enter your keyword and click the Add Keyword button. Click Continue.
5. Details: Here you describe the details of the Data Element. Fields marked with a * are required (Submitting Organization Name, Steward Organization Name). Click the Continue button.
6. Review: Review your Unique Data Element details. Click the Save and Finish button.
7. 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:
 - a. Requesting publication from the data element screen itself, or
 - b. Published automatically when requesting the publication of a form structure with the draft data element attached.

4.5.10 Edit Data Elements

1. Search for Data Element (refer to [4.5.5](#)).
2. Select “Edit” from the Menu on the right. The interface like Create Data Element appears.
3. Edit the details for your data element. Fields marked with a * are required. Follow the process defined by chevrons.
4. Please note that only DRAFT and AWAITING PUBLICATION DEs are fully editable. For PUBLISHED DE's you can only edit Title, Definition, Short Description, Guidelines, Notes, Keywords – the fields which comprise minor changes in a DE.
5. For a Published DE you cannot edit Variable Name, Permissible Values, min and max, Unit of Measure. The system will not let you. If you need to make changes in the above fields for published DE, please contact your BRICS operations team.

4.5.11 Edit Data Elements

1. Search for the Data Element. Use Variable Name as a key.
2. Open the DE page.
3. If the DE is available for deletion, the “Delete” link will be available on the right side menu (see picture below). If the “Delete” link is not available, see next page for explanation on why you cannot delete it.



The screenshot shows the 'Data Dictionary' interface. On the left is a navigation menu with options like 'Menu and Filters', 'Data Dictionary Tool', 'Form Structures', 'Data Elements', 'Search', 'Create', 'Import', and 'eForms'. The main content area displays details for a 'Common Data Element: ABS injury model - distance from detonation measurement value'. The details include Version (1.0), Element Type (Common Data Element), Title, Variable Name, Short Description, Definition, Notes, Creation Date, Created By, and Historical Notes. Below this are sections for 'Basic Attributes', 'External Schema Permissible Value Mapping', 'Documentation', 'Category Groups and Classifications', 'Keywords and Labels', 'Specific Details', and 'Change History'. On the right side, there is a 'Status: Awaiting Publication' box with buttons for 'Cancel Request', 'Edit', 'Delete', and 'Close'. The 'Delete' button is circled in red.

You can only delete a DE which:

1. Does not belong to any form structure. To view the form structures to which a given DE belongs to, open the DE in web interface and look at the “Linked Form Structures’ section. It shows all form structures that have the selected DE.
2. Does not have data submitted against it.

NOTE:

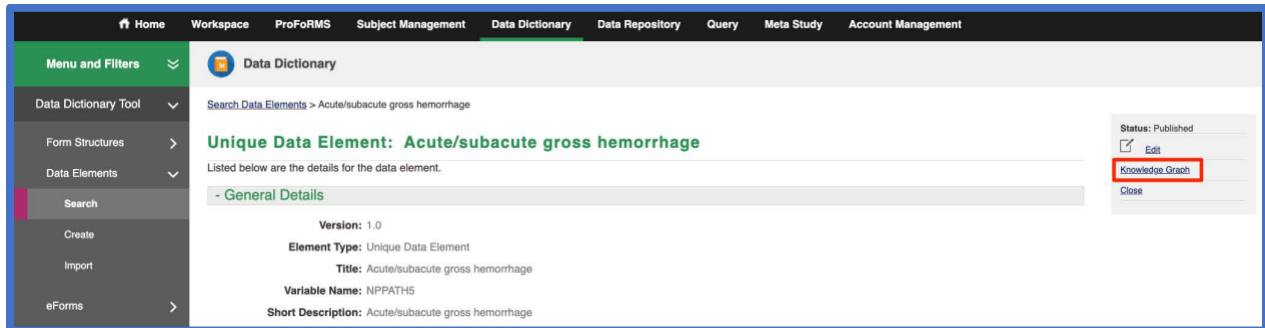
You cannot delete a DE if delete option is not available. The delete option will only be available if #1 and #2 from above are true. Because of those limitations, most of the DE’s that can be deleted will be those still in DRAFT status.

4.5.12 Knowledge Graph

The knowledge graph is available for those DEs, for which the DE linking information was added to the See Also column. It is available in the Data Dictionary and in the Query tool.

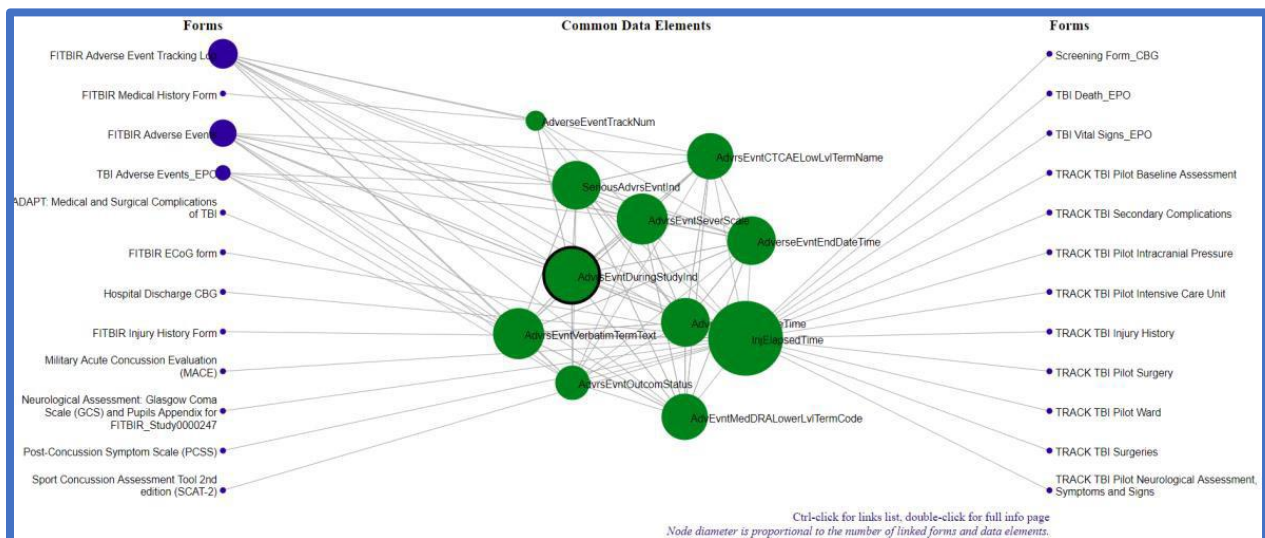
The knowledge graph shows connections between various DEs based on DE purpose, meaning, data collected.

Not all DEs have the knowledge graph feature available. If a DE has knowledge graph available, the corresponding link appears on the DE page.



The screenshot shows the 'Data Dictionary' tool interface. The main content area displays details for a 'Unique Data Element: Acute/subacute gross hemorrhage'. The details include: Version: 1.0, Element Type: Unique Data Element, Title: Acute/subacute gross hemorrhage, Variable Name: NPPATH5, and Short Description: Acute/subacute gross hemorrhage. On the right side, there is a 'Status: Published' section with 'Edit' and 'Close' buttons. A red box highlights the 'Knowledge Graph' link in the top right corner.

When you click on “Knowledge Graph” link, the graph appears in a separate tab:



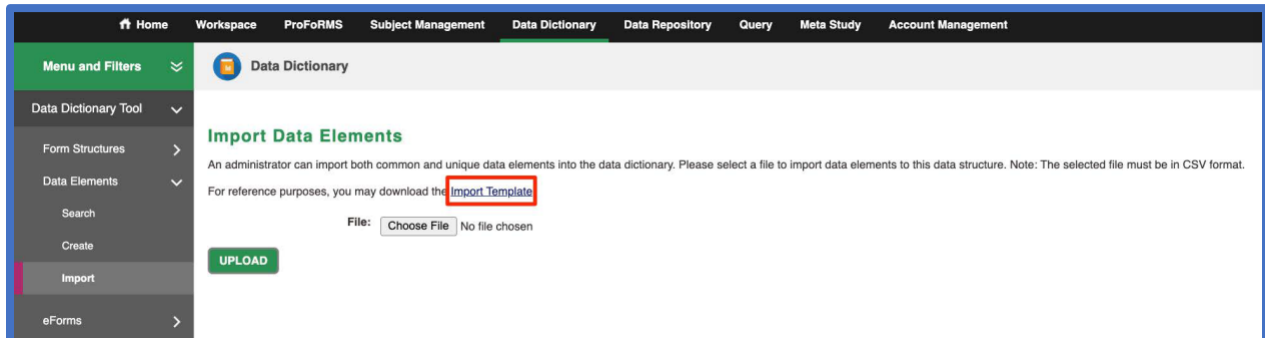
On the knowledge graph, the DE for which the knowledge graph was built is highlighted by a bold border.

It is connected to other DEs, which were listed in “See also” field for the given DE.

On the left and right side of the graph, form structures are listed to which the given DE belongs to.

4.5.13 Importing Multiple DE's

1. Use the Data Element Import Template, which is available as a CSV file via Data Dictionary>Import Data Elements>Import Template link.
 - a. Note (Optional) to save yourself some time, you can contact your BRICS operations team and ask them to provide you with the semi-automatic DE import template, which is a MS Excel macro available file (XLSM).



2. Open the downloaded template in MS Excel. You may populate it with multiple DEs (one per row.)
3. After creating and reviewing DE, when you are satisfied with the result, you may upload DECSV file to the BRICS dictionary by using the Import Data Elements function.
4. The Import Data Elements function performs the validation of submitted data elements to conformance with BRICS rules. If it finds any errors, it provides you with the descriptive error/warning log and does not allow to import the “wrong” DEs into the data dictionary.
5. You must fix the errors first, and then re-upload fixed DEs.

Some tricks of the trade:

- It is a good practice to perform a throughout review of DEs before uploading them into BRICS. Every time you create a new set of DE's, we encourage you that you contact BRICS Operations and ask them to review you set of DE's.
- Before importing data elements into the BRICS dictionary, the import file **MUST BE CONVERTED** to CSV file type!
- You might find in convenient to work on the DEs in MS Excel and save then template as a MS Excel XLS file with color coding and additional columns for comments.
- However, when it is time to upload DEs into BRICS you need to convert it to a 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 [CSV](#) format.
3. Run the Data Elements Import tool.

4.5.14 DE's Import Template Explained

All data elements must conform with the DE Import template and to the guidelines in this document or they will not be validated and accepted into the BRICS dictionary. The **Data Element Import template** has 65 columns. Rather a big number. In this section we are going to explain each column and highlight which columns are required and which can be left empty. However, we strongly recommend for the sake of good quality of data elements, to fill out all columns.

Variable Name

1. The unique variable name of the Data Element within the BRICS dictionary.
2. Required for all Data Elements.
3. 30 character maximum.
4. The first character must be an alphabetical character a-z or A-Z.
5. Must contain only alphanumeric characters and the special character underscore (_).
6. Must be camel cased, with the first letter of a word/abbreviation capitalized and all other letters lower case (i.e., TotalScore).
7. The Variable Name should match the Title.
8. Example: Title = Total Score, Variable name = TotalScore
9. For copyrighted materials, the Variable Name should follow the following format:
 - a. Assessment Acronym + Title.
 - i. Assessment: Buss Perry Aggression Questionnaire (BPAQ)
 - b. Title: Buss Perry Aggression Questionnaire (BPAQ) - provoked hit scale
 - c. Variable Name: BPAQProvokedHitSc10.

Title

1. Title represents the essence of the question through discrete concepts, breaking down the question into "What is the primary topic (Object); what is being asked about the topic(Property); and what is the anticipated response or answer (Representation)." Refer to APPENDIX A: REPRESENTATION TERMS GUIDE for more information.
2. Required for all Data Elements.
3. 255-character maximum.
4. Capitalization – First word is capitalized; all others are lowercase except for proper names.
5. Title should be created as a combination of Object + Property Qualifier(s) + Property +Representation Qualifier (s) + Representation Term.
6. The FIRST word of the Title is the main concept. This first term is the most important conceptual idea for a Data Element (consistent with the Object class term which is the first fundamental part of data element as described by ISO-11179) Suggested words include terms like "diagnosis," "adverse event," "imaging," "injury," "medical history," "symptoms," or "treatment." Words like "other" or "initial," that are adjectives/modifiers.
7. Based on ISO-11179 standard for the formulation of metadata, the FINAL word of the Title (DE name) is a representation term and should refer to the data type (e.g., indicator(Boolean), type (alphanumeric), scale 9alphanumeric), score, (numeric) etc.).
8. Titles should be unique. No two Data Elements should have the same.
9. For copyrighted instruments:

- a. The full name of the form should be the first part of the Data Element name with the acronym in parentheses.
- b. Add a hyphen.
- c. Provide a description of the data/question from the instrument. Example: Berg Balance Scale (BBS) - stand one leg scale.

Element Type

1. A designation of the Data Element as a Common Data Element (CDE) or Unique Data Element (UDE). All DE are first created as Unique Data Element
2. Required for all Data Elements.
3. Designation
4. Must be one of the following:
 - a. Common Data Element
 - b. Unique Data Element

*All Data Elements created outside of NINDS working groups will be designated Unique Data Elements.

Users can ONLY select Unique Data Element in the template.

Definition

1. The Definition should be a clear definition of the question preferably using the concepts in the Title.
2. The representation term, which is the FINAL work in Title, should be the FIRST word in Definition.
3. 4000 character maximum.
4. When a familiar acronym appears in the Data Element Title, the full name MUST be provided in the Definition field to ensure understanding.

Short Description

1. It is a concatenated version of the Definition field that is restricted to 255 characters. Use the Definition field as a starting point and reduce to 255 characters using abbreviations, where applicable.
2. Required for all Data Elements.
3. 255 character maximum

Datatype

1. Datatype determines the type of data this Data Element will store. User can select between alphanumeric, numeric, date or data and time, GUIDs, file, bio sample, thumbnail (image only files).

Input Restriction

1. This field determines the type of input that will be accepted. Free form elements allow for short paragraph answer input, and Pre-Defined Values force the user to select an input from the Permissible Values List.
2. Must be one of the following character strings:
 - a. Free-Form Entry.
 - b. Multiple Pre-Defined Values Selected.
 - c. Single predefined value.
3. If an enumerated list of values contains only numbers (even if PV Descriptions are alphanumeric), the Datatype can be "Numeric Values," with "Single Pre-Defined Value Selected" and a Minimum and Maximum value entered to define the range of acceptable answers.

4. When a CDE collects a Numeric Value, and there is a unit of measure for routinely capturing the data, add the unit to the column Unit of Measure. Accepted measurement units are provided in Appendix C.
5. If a permissible value of “Other, specify” is contained within an enumerated list for a given data element AND the Data Element is alphanumeric or numeric with an input restriction value of Single Pre-Defined or Multiple Pre-Defined, a corresponding “sister “data element is required to support the capture of the Other, specify information.

Common combinations of Datatype and Input Restrictions

1. For alphanumeric datatype, when input restrictions are set to “Free-Form Entry” then the column “Maximum Character Quantity” must also be also completed. Max=4000characters.
2. For Numeric Values- datatype, when combined with “Free-Form Entry” input restrictions, the Minimum and Maximum values should be also completed.
3. For Date or Date & Time- datatype column Input Restrictions should be Free-Form; for all CDEs collecting Date, the data will be collected using the ISO-8601 standard.
4. For GUID datatype Input Restrictions should only be “Free-Form, Entry”.
5. For File- datatype Input Restrictions should only be “Free-Form Entry”.
6. For Thumbnail- datatype, Input Restrictions should only be “Free- Form Entry”.

Maximum Character Quantity

1. The Maximum Character Quantity field determines the maximum number of characters a user may input into a Free-Form Entry, Alphanumeric Data Element. **Required field** for Data Elements with Datatype: Alphanumeric and InputRestrictions: Free-Form.
2. This field must be blank for other Datatypes or Input Restrictions.
3. This field must contain a numerical value between 1 and 4000. Be sure to set appropriate parameters (i.e., Social Security Number should have a size of 9).
4. Except: Bio-Sample Free-Form Entry, which currently cannot be greater than 100.

Minimum/Maximum Value

1. For a Free-Form, numerical Data Element, a user may specify a range of valid values by inputting a minimum and maximum value.
2. Only input data to these fields for Data Elements with Datatype: Numeric Values and Input Restrictions: Free-Form.
3. These fields must contain numbers.
4. The Minimum Value field must be less than the Maximum Value field.

Permissible Values

1. A list of values that can be used as valid input for this Data Element.
2. Required field for Data Elements with Input Restrictions: Multiple Pre-Defined Values Selected or Single Pre-Defined Value Selected.
3. Must contain a semi-colon delimited list of all possible unique permissible values for the data
4. element.
5. Maximum 200 characters per one PV
6. No spaces before or after any semi-colon in the list.
7. The data from the PV field should be copied into PV Descriptions (e.g., Yes; No; Unknown) unless specific PV Descriptions have been provided.
8. If a permissible value of “Other, specify” is contained within a Data Element, then a new Data Element must be created to support the other, specify text/data. The BRICS Input Restriction will be “Free- Form Entry” and provide a Size (up to 4000 characters, but most frequently limited to 255 characters.).
9. If a permissible value of “Other, specify” is contained within an enumerated list for a given Data Element AND the Data Element is alphanumeric or numeric with an input restriction value of Single Pre-Defined or Multiple Pre-Defined, a corresponding “sister” data element is required to support the capture of the Other, specify information.

To create “Other, specify” sister DE for a corresponding DE with the list of permissible values:

1. Create a corresponding Data Element with an input restriction of “Free-Form Entry” to accept the free-form entry information. This Data Element will complement the “sister/parent” data element (that has an enumerated permissible value list that includes ‘Other, specify’).
2. Variable Name: Copy parent CDE/UDE and change name to end with OTH.Ex. TherapuRehabSessDur (parent); TherpauRehabSessDurOTH(corresponding Data Element).
3. Title: Copy parent Title and add “other text” at the end of the title Ex. Therapyrehabilitation session duration (parent); Therapy rehabilitation session duration other text. Definition: Provide definition of element. Ex. The free-text field related to the duration of a therapeutic rehabilitation session, specifying other text.
4. Set Maximum Character Quantity to 4000 max characters.
5. Input Restrictions: to Free-Form Entry.

Permissible Value Descriptions

1. A list of descriptions that matches with the list of permissible values above.
2. Mandatory field for Data Elements with Input Restrictions: Multiple Pre-Defined Values Selected or Single Pre-Defined Value Selected.
3. Must contain a semi-colon delimited list of permissible value descriptions. The semi-colon character cannot be used in descriptions.
4. No spaces should be before or after any semi-colon in the list.
5. 5.The Permissible Value Descriptions list must have the same number of descriptions as there are Permissible Values in the Permissible Value list.
6. 6.The descriptions must match the order of the permissible value.
7. 7.When PVs are a numeric scale or scoring system (e.g., 1;2;3;4;5) and the PV Descriptions include text reporting the meaning of values, the PV Descriptions should be provided. Where no specific meaning is given for some values in the range, additional semicolons may be needed to skip undefined values (e.g., on a scale of 1 to 10 where 1=Never and 10=All the time, then the PV Description would show Never all the time.

Permissible Value Output Codes

1. A list of numeric codes, corresponding to the list of permissible values.
2. Mandatory field for Data Elements with Input Restrictions: Multiple Pre-Defined Values Selected or Single Pre-Defined Value Selected.
3. Must contain a semi-colon delimited list of permissible value output unique codes.
4. No spaces should be before or after any semi-colon in the list.

Population.All

1. The target population group for this data element
2. Required for all data elements.
3. Must be one of the following character strings:
 - a. Adult
 - b. Pediatric
 - c. Adult; Pediatric
 - d. Preclinical – for animal studies

Unit of Measure

1. For any entry type that must be recorded as a specific unit of measurement, a measurement unit should be provided.
2. Only one measurement unit can be entered this column for each Data Element.
3. When a Data Element collects a Numeric Value or Alphanumeric, and there is a unit of measure for routinely capturing the data, add the units to the column Unit of Measurement.

Guidelines/Instructions

1. A required field for including information about administration or other details that may be pertinent.
2. Contains any information useful for data collection and properly gathering input for this Data Element.
3. 4000 character maximum
4. If this column includes a comment that refers to another CDE, make sure the CDE Title is given, not text like “question b” from the form on which they appear. Reference the CDE, not the form question.

Notes

1. Any additional notes you would like others to be able to see when the element is published.
2. Any extra notes or messages related to this Data Element may be placed here.
3. 4000 character maximum.
4. If notes pertain to a specific disease type, be sure to indicate to which disease type the note refers. 5. For DEs which belong to a standardized instrument (CRF) we recommend that you include question number in Notes. 6. If the DE was imported from another dictionary, we recommend that you include that dictionary information in Notes.

Preferred Question Text

1. May contain one or more suggested questions a researcher may ask a patient or subject to get the proper input for this Data Element.
2. 4000 character maximum.
3. For a copyrighted instrument, the Question Text MUST match the instrument exactly. It should be left blank if the instrument publisher insists of not providing the question text.

4. For all other forms, this field should contain the question(s) shown on the CRF, but it must be meaningful content (e.g., not “if yes, specify”). Where needed, the form should be updated to show new Question Text.

Keywords

1. A list of keywords associated with this Data Element. Examples include assessment name, study title, battery name, etc. Whatever makes search for a given DE meaningful and easy.
2. 55 character maximum
3. Must begin with an alphabet character.
4. List of keywords must be in a semi-colon delimited list.
5. Keywords cannot have a space, but an underscore can be used instead (i.e., Head Injury).

References

1. A required field to provide references to the sources which were used to create a given DE
2. For copyrighted instruments must contain the copyright information and a link to the publisher.
3. 4000 character maximum.
4. If references are disease specific, be sure to indicate to which disease-type they pertain to.

Historical Notes

1. Background information about the data element.
2. 4000 characters maximum.

See Also

1. Contain a list of Variable names, divided by semicolon, of the data element which are related to a given data element.
2. The information in this field is used to populate Knowledge Graph.
3. 4000 characters maximum.

Effective Date

1. Identifies the date that an item became or will become available.
2. ISO Format: YYYY-MM-DD

Until Date

1. Identifies the date that an item is or will no longer be effective.
2. ISO Format: YYYY-MM-DD

Submitting Organization Name

1. The team, organization or unit within an organization that has submitted a given data element into the data dictionary. This information is important, because it allows to direct questions related to the DE to the team who created it.
2. It also gives a credit to the team who contributed DEs to the BRICS data dictionary.
3. Required for all Data Elements.
4. 255 characters maximum.

Steward Organization Name

1. The organization that maintains the data dictionary and provides the quality control for its data elements. For the BRICS data dictionary, Steward Organization is NIH/CIT/BRICS.
2. Required for all Data Elements.
3. 255 characters maximum.

Domain and Classification info (columns Y to BG) Domain/Sub-domain

1. The Domain (and Sub-Domain) of a Data Element defines the use of the DE within a given project, disease category, study domain. More information can be found on the NINDS CDE project site - <https://www.commondataelements.ninds.nih.gov/>
2. Required for all Data Elements.
3. For a list of valid Domains and Sub-Domains used in BRICS and relevant to your project, please contact BRICS Operations team.

Format:

1. Input must be in Domain.Sub-Domain format. For example, under the column heading Domain.Stroke, the value entered could be Outcomes and End Points.Quality of Life.
2. Note: Each Domain has one or more sub-domains.
3. A data element can have one or more Domain.SubDomain(s) per disease. If there is more than one Domain.SubDomain, please use a semi colon delimited list.

Classification

1. The classification of a given disease category. More at <https://www.commondataelements.ninds.nih.gov/glossary>
2. There are 4 classification categories designated for NINDS data elements: Core, Basic, Supplemental, Exploratory. Where Core DEs is data element that collects essential information applicable to any study, including either those which span across all disease and therapeutic areas or those that are specific to one disease area.
3. A classification is required for every disease category where a Domain. Subdomain is listed.
4. There can only be one Classification per disease (or sub-disease if present).
5. For all Unique Data Elements, the classification will ALWAYS be Supplemental.

4.5.15 Representation Terms Guide

Representation Term	NINDS Data Type	Definition	Abbreviation for Variable Name
Anatomic Site	Alphanumeric	the named location of, or within, the body of a living being	AnatSite
Category	Alphanumeric	the descriptive identification representing a level of intensity, defined meaning, or subjective measurement	Cat
Code	Alphanumeric OR Numeric Values	the selection from a system of defined categories for representation of data, often defined using stratification or hierarchical organization; data may have either a numeric or alphanumeric system assigned for coding	Code
Count	Numeric Values	the quantity of the specified item	Ct
Date	Date or Date & Time	the date on which an event was observed or occurred	Date
Date/Time	Date or Date & Time	the date and time when an event was observed or occurred	DateTime
Dose	Numeric Values	the quantity of an agent (such as drug, substance or energy) administered, taken, or absorbed at one time	Dose
Duration	Numeric Values	the value measuring a quantity or period of time during which an event or observation occurs	Dur
Frequency	Numeric Values	the number of occurrences counted for an event within a given time period	Freq
Grade	Alphanumeric OR Numeric Values	the position on a scale of intensity or amount or quality, of or relating to histology; data may have either a numeric or	Grade
Indicator	Alphanumeric	the response for yes/no/unknown/NA)	Ind
Integer	Numeric Values	a concept of quantity using only whole numbers greater than zero	Intg

Interval	Numeric Values	the period of time or the distance separating occurrences	Intrvl
Location	Alphanumeric	the field to describe the geographic area (not anatomic)	Loc
Measurement	Numeric Values	the size or magnitude of the specified item	Mearsr
Name	Alphanumeric	the words or language units by which an object is known	Name
Number	Numeric Values	a concept of quantity derived from zero and units or a numeral or string of numerals used for identification	Num
Range	Numeric Values	the value chosen from the limits or scale of variation for an event or the difference between the lowest and highest numerical values	Rng
Rate	Alphanumeric OR Numeric Values	the measurement of degree, speed, or frequency relative to time with regard to an observation or event; data may be a numeric quantity or may be reported by enumerated values with grouped ranges of values	Rt
Reason	Alphanumeric	the explanation of the cause of some phenomenon or action	Rsn
Scale	Numeric Values	Representins the position in a range of numeric values for level of intensity	Scl
Score	Numeric Values	Used in calculation for the position in a range of numeric values representing level of intensity,	Score
		defined meaning or subjective measurement	
Site	Alphanumeric	the field to describe the area (not anatomic)	Site
Source	Alphanumeric	the text describing where something is available or referenced	Source
Status	Alphanumeric	the condition or state at a particular time	Stat or Status



Text	Alphanumeric	the undefined field to capture descriptive information related to an item	Txt
Time	Date or Date & Time	the time at which an event was observed or occurred	Time
Type	Alphanumeric	the enumerate descriptive information to identify an item	Typ
Unit of Measure	Alphanumeric	the name of a reference standard used for measurement when determining a quantity	UoM
Value	Numeric Values	the numeric quantity measured, assigned or computed	Val