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**Chapter**

**4**

**Data  
Dictionary – Data  
Elements**



## CHAPTER 4 – DATA DICTIONARY

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**T**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.

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### 4.1 OBJECTIVE

This chapter provides information for users on how to:

- ❖ Browse existing Data Elements
  - ❖ Search Data Elements
  - ❖ Create Data Elements
  - ❖ Import Data Elements
  - ❖ Browse existing eForms
  - ❖ Search eForms
  - ❖ Create eForms
- 

### 4.2 SYSTEM FUNCTIONS

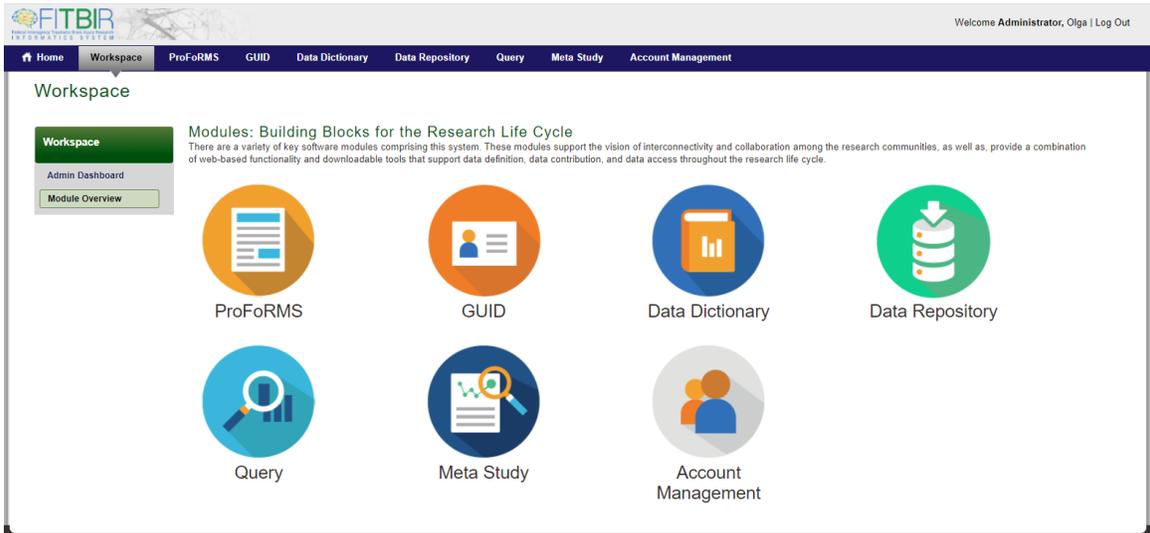
The Data Dictionary module provides the tools for defining the data you submit as well as provide alternate terms (aliasing) and translation rules for the same element. Importantly, the BRICS data dictionary provides those who have access to the data with clear and precise information about what it is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

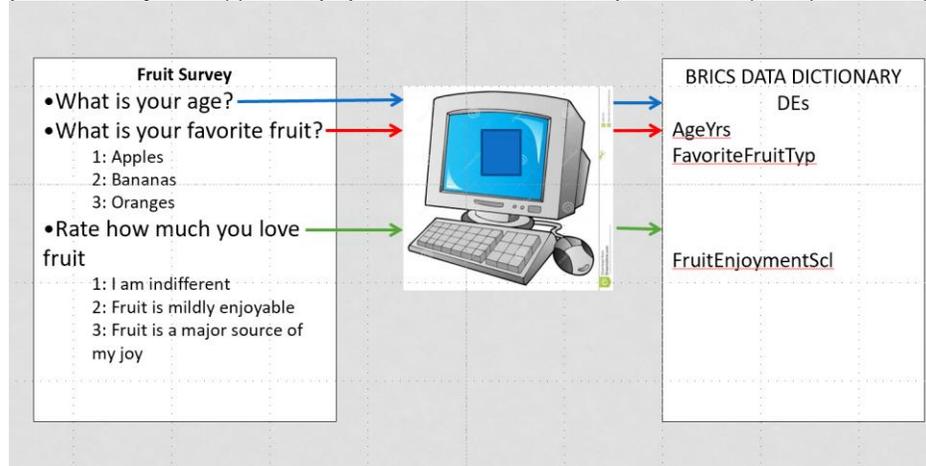
- ❖ Searching Data Elements
  - Downloading Data Elements Results to XML, CSV and ZIP output formats
- ❖ Creating Data Elements
- ❖ Importing Data Elements

## DATA ELEMENTS

### 5.1.1 Data Element Definition

#### A simple definition of a data element:

A data element (DE) is a logical unit of data, pertaining to information of one kind. It has a name, precise definition, and a set of permissible values (if applicable). A DE occupies the space provided by field(s) on a paper/electronic case report form (CRF) or field(s) in a database record.



#### In more elaborated terms:

The data element is a key foundational concept in an [ISO/IEC 11179 metadata registry](#). The purpose of this registry is to maintain a semantically precise structure of data elements.

According to ISO/IEC 11179 metadata registry, each data element:

1. Should be registered according to the Registration guidelines (11179-6)
2. Is uniquely identified within the register (11179-5)
3. Named according to Naming and Identification Principles (11179-5) See data element name
4. Defined by the Formulation of Data Definitions rules (11179-4)
5. Classified in a Classification Scheme (11179-2) See classification scheme
6. Data elements that store "Codes" or enumerated values must also specify the semantics of each of the code values with precise definitions.

### 5.1.2 Types of Data Elements Used in BRICS

**Common Data Elements (CDEs)** – the data elements which are widely adopted by the community and used across multiple studies/projects. An example: [NINDS CDE project](#)

**Unique Data Elements (UDEs)** – the data elements which are study/project specific, and designed to accommodate a specific set of data. A UDE is typically created when a CDE does not exist to accommodate the data.

### 5.1.3 Some Important Features of a Data Element in BRICS

- ❖ **Variable Name** – a unique variable name/ID of the Data Element.
- ❖ **Title** - a brief description for the Data Element; it should represent the essence of the question associated with the DE through discrete concepts.
- ❖ **Definition** - An explanation of the nature, scope, or meaning of the DE.
- ❖ **Guidelines**- Additional details about the DE beyond the definition. This may include instructions to the patient on how to respond to a question, instructions on how to conduct a laboratory test, etc.
- ❖ **Reference** - Information describing the history or origin of a DE, as well as its scientific validity. This can include references to journal articles, Vocabularies or Data Standards, review process, validation, owner or creator, or other information.
- ❖ **Permissible Values** - The set of possible values or responses. A Value Set often includes concepts from established Vocabularies or Data Standards. For laboratory tests, a value set may include a range of permissible values and indicate the required units. For a survey question, the value set may be a list of possible responses.

More in [Data Element Import Template Explained](#)

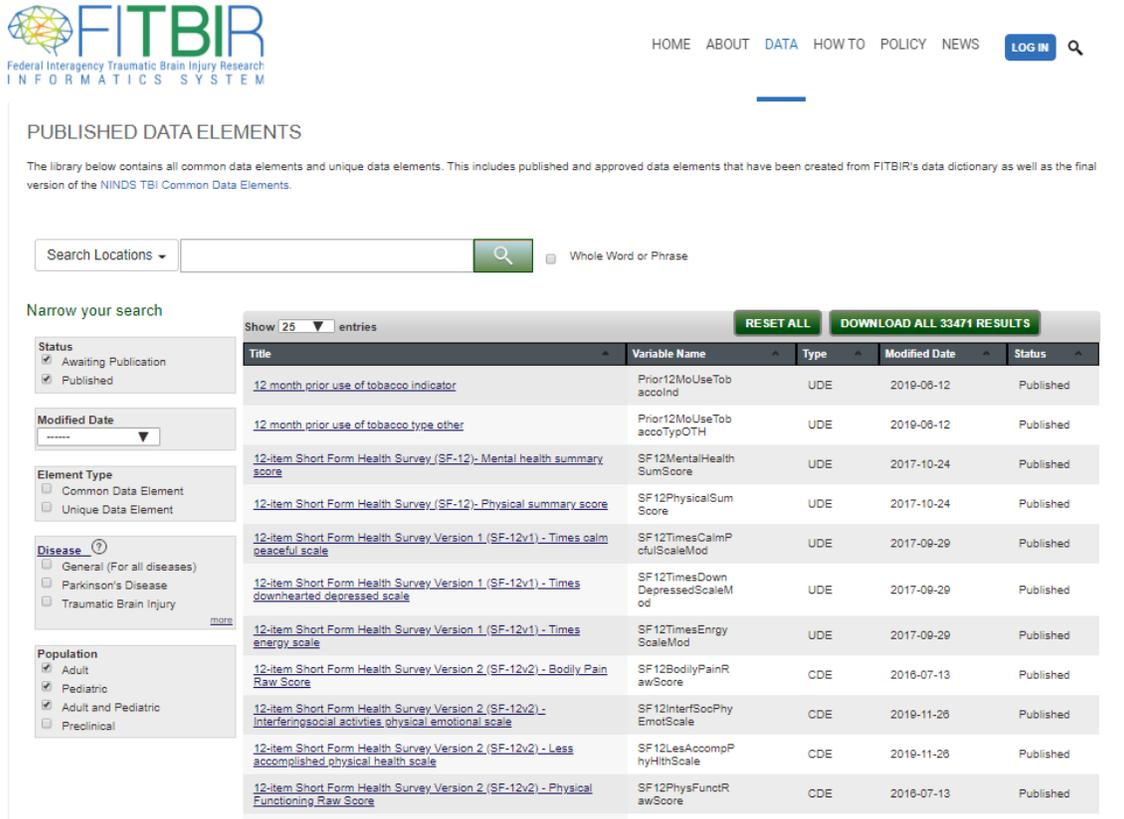
### 5.1.1 Life Cycle of Data Elements in BRICS

Type	Description	Visibility	Editable?	Data Validation?	Data Submission?
<b>Draft</b>	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
<b>Awaiting publication</b>	A publication has been requested for this DE	All users, including the public site	Yes	Yes	No
<b>Published</b>	The DE which is complete and available for public use	All users, including the public site	Limited. Can edit Title, Description, add/remove documentation.	Yes	Yes

### 5.1.2 Browse Data Elements

You can browse data elements on BRICS public site data dictionary and portal (login required).

E.g. on FITBIR public site, the published and awaiting publication data elements are available via the following link (<https://fitbir.nih.gov/content/data-dictionary>)



**FITBIR**  
Federal Interagency Traumatic Brain Injury Research  
INFORMATICS SYSTEM

HOME ABOUT DATA HOW TO POLICY NEWS **LOG IN** 🔍

#### PUBLISHED DATA ELEMENTS

The library below contains all common data elements and unique data elements. This includes published and approved data elements that have been created from FITBIR's data dictionary as well as the final version of the NINDS TBI Common Data Elements.

Search Locations ▾  🔍  Whole Word or Phrase

Narrow your search

Status  
 Awaiting Publication  
 Published

Modified Date

Element Type  
 Common Data Element  
 Unique Data Element

Disease ⓘ  
 General (For all diseases)  
 Parkinson's Disease  
 Traumatic Brain Injury [more](#)

Population  
 Adult  
 Pediatric  
 Adult and Pediatric  
 Preclinical

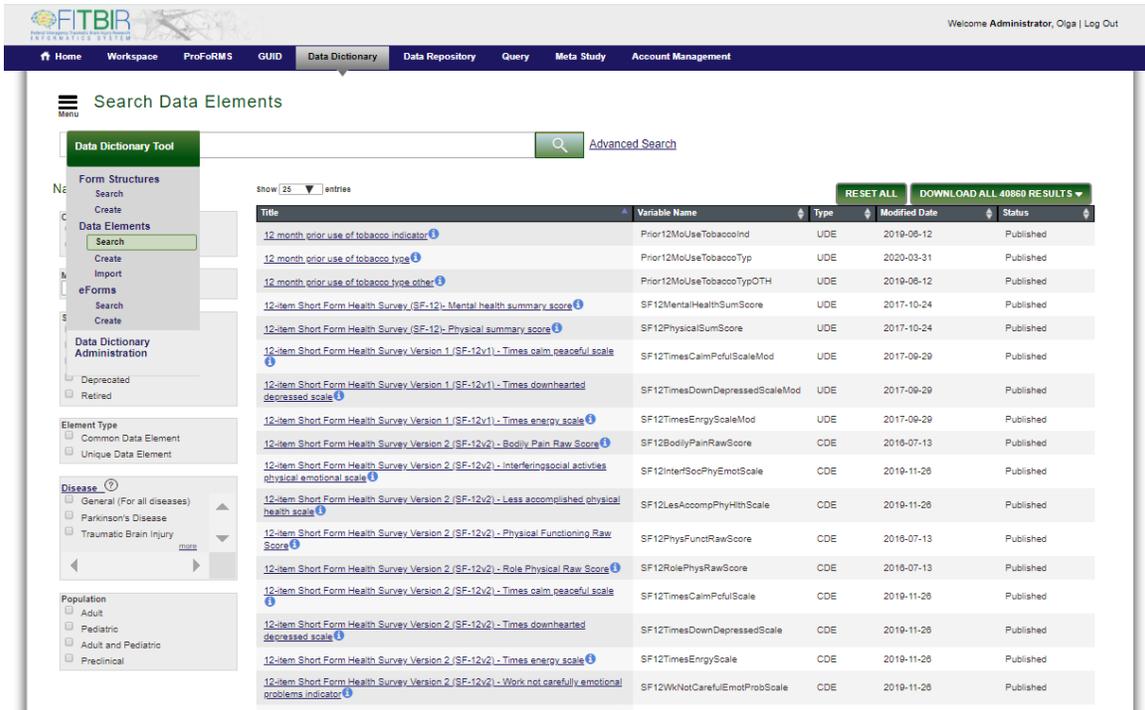
Show 25 entries **RESET ALL** **DOWNLOAD ALL 33471 RESULTS**

Title	Variable Name	Type	Modified Date	Status
<a href="#">12-month prior use of tobacco indicator</a>	Prior12MoUseTobaccoInd	UDE	2019-06-12	Published
<a href="#">12-month prior use of tobacco type other</a>	Prior12MoUseTobaccoTypeOTH	UDE	2019-06-12	Published
<a href="#">12-item Short Form Health Survey (SF-12) - Mental health summary score</a>	SF12MentalHealthSumScore	UDE	2017-10-24	Published
<a href="#">12-item Short Form Health Survey (SF-12) - Physical summary score</a>	SF12PhysicalSumScore	UDE	2017-10-24	Published
<a href="#">12-item Short Form Health Survey Version 1 (SF-12v1) - Times calm/peaceful scale</a>	SF12TimesCalmPeacefulScaleMod	UDE	2017-09-29	Published
<a href="#">12-item Short Form Health Survey Version 1 (SF-12v1) - Times downhearted/depressed scale</a>	SF12TimesDownDepressedScaleMod	UDE	2017-09-29	Published
<a href="#">12-item Short Form Health Survey Version 1 (SF-12v1) - Times energy scale</a>	SF12TimesEnergyScaleMod	UDE	2017-09-29	Published
<a href="#">12-item Short Form Health Survey Version 2 (SF-12v2) - Bodily Pain Raw Score</a>	SF12BodilyPainRawScore	CDE	2016-07-13	Published
<a href="#">12-item Short Form Health Survey Version 2 (SF-12v2) - Interfering social activities, physical/emotional scale</a>	SF12InterfSocPhyEmotScale	CDE	2019-11-26	Published
<a href="#">12-item Short Form Health Survey Version 2 (SF-12v2) - Less accomplished physical health scale</a>	SF12LessAccomplishedPhysHlthScale	CDE	2019-11-26	Published
<a href="#">12-item Short Form Health Survey Version 2 (SF-12v2) - Physical Functioning Raw Score</a>	SF12PhysFuncRawScore	CDE	2016-07-13	Published

On that page you can:

1. Browse data elements,
2. Search data elements,
3. Sort data elements by Title, Variable Name, Type, Status, and Modified Date.
4. Use the check boxes on the left side panel to filter data elements by Status, Type, Disease category, Population, etc.

The same actions could be performed when you log in into portal.

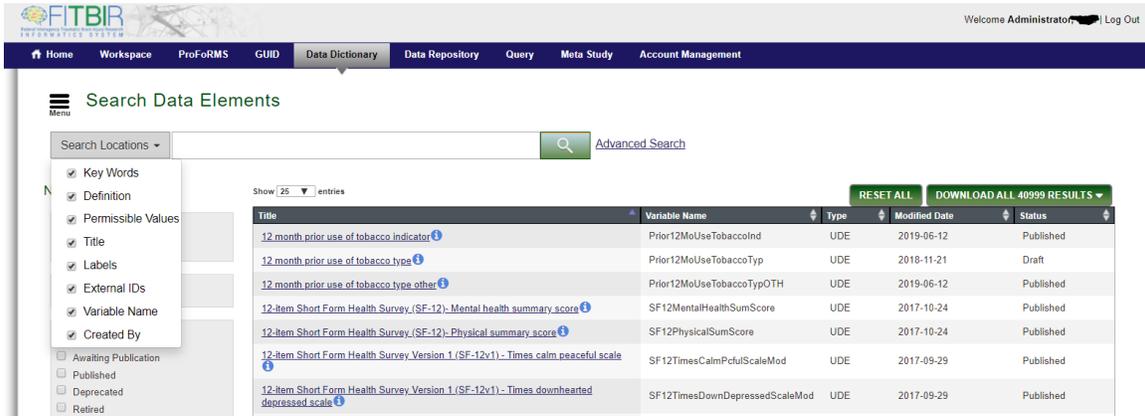


### 5.1.3 Search Data Elements

You can search for data elements using specified search terms on both BRICS public site and portal (login required).

**To Search Data Elements:** Perform the following actions:

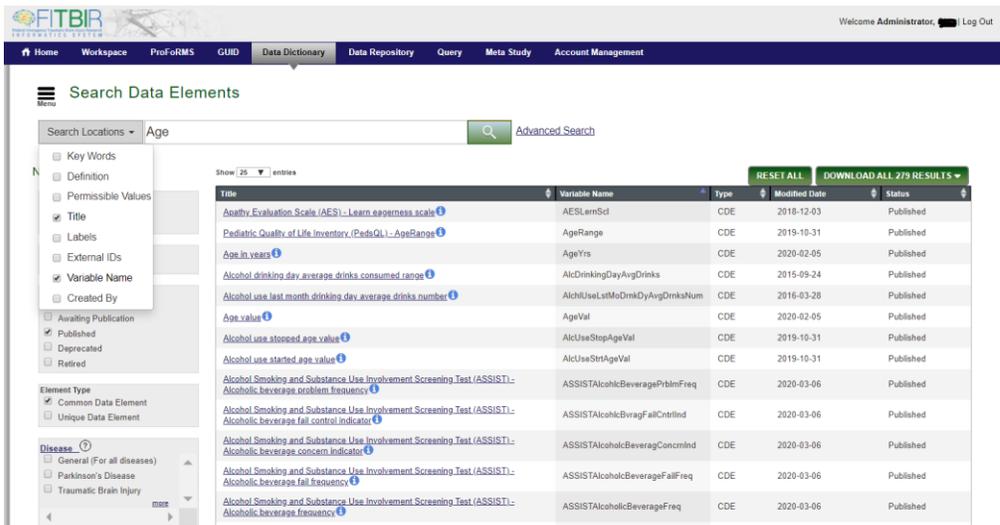
1. Log in into the system. Navigate to the Data Dictionary module.
2. Click the **Data Dictionary** module. The Search Form Structures page appears.
3. Click the **hamburger menu** the left-side tool bar.
4. Click the **Data Dictionary** Module menu opens and expands
5. Select **Search** under Data Elements from the left-hand drop-down menu.
6. Using the search text-box, enter the search keyword to search.
7. Keyword search will be performed within the form fields using the Search Locations (Keywords, Definition, Permissible Values, External IDs, Variable Name, Created Date).
8. You might want to limit your search options by using “Search Locations” options.



The screenshot shows the FITBIR Data Dictionary interface. The search criteria are set to 'Advanced Search'. The search results table is as follows:

Title	Variable Name	Type	Modified Date	Status
12 month prior use of tobacco indicator	Prior12MoUseTobaccoInd	UDE	2019-06-12	Published
12 month prior use of tobacco type	Prior12MoUseTobaccoTyp	UDE	2018-11-21	Draft
12 month prior use of tobacco type other	Prior12MoUseTobaccoTypOTH	UDE	2019-06-12	Published
12-item Short Form Health Survey (SF-12)-Mental health summary score	SF12MentalHealthSumScore	UDE	2017-10-24	Published
12-item Short Form Health Survey (SF-12)-Physical summary score	SF12PhysicalSumScore	UDE	2017-10-24	Published
12-item Short Form Health Survey Version 1 (SF-12v1) - Times calm peaceful scale	SF12TimesCalmPcfuScaleMod	UDE	2017-09-29	Published
12-item Short Form Health Survey Version 1 (SF-12v1) - Times downhearted depressed scale	SF12TimesDownDepressedScaleMod	UDE	2017-09-29	Published

10. You may also narrow your search by selecting the check-box beside the criteria you wish to search (Ownership, Status, Modified Date, Element Type, Form Types, Standardization, Diseases, Population).
11. Click the Search button to process your search results.
12. When search results appear in the data element table, you can review it in the table, or use the DOWNLOAD button to download the search result.

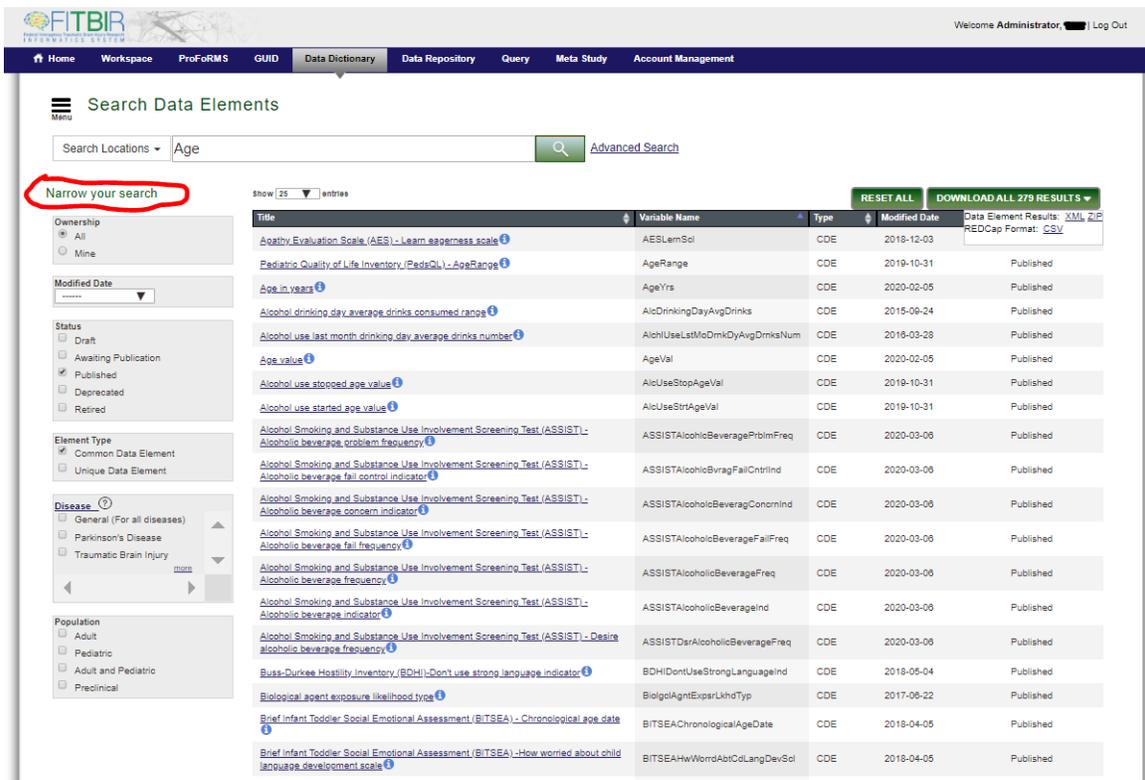


The screenshot shows the FITBIR Data Dictionary interface with search criteria set to 'Age'. The search results table is as follows:

Title	Variable Name	Type	Modified Date	Status
Healthy Evaluation Scales (AES) - Learn awareness scale	AESLernScl	CDE	2018-12-03	Published
Pediatric Quality of Life Inventory (PedsQL) - AgeRange	AgeRange	CDE	2019-10-31	Published
Age in years	AgeYrs	CDE	2020-02-05	Published
Alcohol drinking day average drinks consumed range	AlcDrinkingDayAvgDrinks	CDE	2015-09-24	Published
Alcohol use last month drinking day average drinks number	AlcUseLstMoDrnkDayAvgDrnkNum	CDE	2016-03-28	Published
Age value	AgeVal	CDE	2020-02-05	Published
Alcohol use stopped age value	AlcUseStopAgeVal	CDE	2019-10-31	Published
Alcohol use started age value	AlcUseStrAgeVal	CDE	2019-10-31	Published
Alcohol Smoking and Substance Use Involvement Screening Test (ASSIST) - Alcohol beverage problem frequency	ASSISTAlcoholBeveragePblmFreq	CDE	2020-03-06	Published
Alcohol Smoking and Substance Use Involvement Screening Test (ASSIST) - Alcohol beverage fall control indicator	ASSISTAlcoholBvragFallCtrlInd	CDE	2020-03-06	Published
Alcohol Smoking and Substance Use Involvement Screening Test (ASSIST) - Alcohol beverage concern indicator	ASSISTAlcoholBeveragConcernInd	CDE	2020-03-06	Published
Alcohol Smoking and Substance Use Involvement Screening Test (ASSIST) - Alcohol beverage fall frequency	ASSISTAlcoholBeverageFallFreq	CDE	2020-03-06	Published
Alcohol Smoking and Substance Use Involvement Screening Test (ASSIST) - Alcohol beverage frequency	ASSISTAlcoholBeverageFreq	CDE	2020-03-06	Published

### 5.1.4 To Narrow Your Search Results

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



**Search Data Elements**

Search Locations: Age

**Narrow your search**

Ownership:  All  Mine

Modified Date: [Dropdown]

Status:  Draft  Awaiting Publication  Published  Deprecated  Retired

Element Type:  Common Data Element  Unique Data Element

Disease:  General (For all diseases)  Parkinson's Disease  Traumatic Brain Injury

Population:  Adult  Pediatric  Adult and Pediatric  Preclinical

Title	Variable Name	Type	Modified Date	Data Element Results
Alcohol Evaluation Scale (AES) - Learn eagerness scale	AESLemSci	CDE	2018-12-03	Published
Pediatric Quality of Life Inventory (PedsQL) - Age Range	AgeRange	CDE	2019-10-31	Published
Age in years	AgeYrs	CDE	2020-02-05	Published
Alcohol drinking day average drinks consumed range	AlcDrinkingDayAvgDrinks	CDE	2015-09-24	Published
Alcohol use last month drinking day average drinks number	AlcUseLastMoDrnkDyAvgDrinksNum	CDE	2016-03-28	Published
Age value	AgeVal	CDE	2020-02-05	Published
Alcohol use stopped age value	AlcUseStopAgeVal	CDE	2019-10-31	Published
Alcohol use started age value	AlcUseStrtAgeVal	CDE	2019-10-31	Published
Alcohol Smoking and Substance Use Involvement Screening Test (ASSIST) - Alcohol beverage problem frequency	ASSISTAlcoholicBeveragePrblmFreq	CDE	2020-03-06	Published
Alcohol Smoking and Substance Use Involvement Screening Test (ASSIST) - Alcohol beverage fall control indicator	ASSISTAlcoholicBvrngFallCntrlInd	CDE	2020-03-06	Published
Alcohol Smoking and Substance Use Involvement Screening Test (ASSIST) - Alcohol beverage concern indicator	ASSISTAlcoholicBeveragConcnrInd	CDE	2020-03-06	Published
Alcohol Smoking and Substance Use Involvement Screening Test (ASSIST) - Alcohol beverage fall frequency	ASSISTAlcoholicBeverageFallFreq	CDE	2020-03-06	Published
Alcohol Smoking and Substance Use Involvement Screening Test (ASSIST) - Alcohol beverage frequency	ASSISTAlcoholicBeverageFreq	CDE	2020-03-06	Published
Alcohol Smoking and Substance Use Involvement Screening Test (ASSIST) - Alcohol beverage indicator	ASSISTAlcoholicBeverageInd	CDE	2020-03-06	Published
Alcohol Smoking and Substance Use Involvement Screening Test (ASSIST) - Desire alcohol beverage frequency	ASSISTDsrAlcoholicBeverageFreq	CDE	2020-03-06	Published
Buss-Durkee Hostility Inventory (BDHI) - Don't use strong language indicator	BDHIDontUseStrongLanguageInd	CDE	2018-05-04	Published
Biological agent exposure likelihood type	BiologAgntExpsrLkhdTyp	CDE	2017-08-22	Published
Brief Infant Toddler Social Emotional Assessment (BITSEA) - Chronological age date	BITSEACHronologicalAgeDate	CDE	2018-04-05	Published
Brief Infant Toddler Social Emotional Assessment (BITSEA) - How worried about child language development scale	BITSEAHwWorrdAbtCclLangDevSci	CDE	2018-04-05	Published

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

**Status** (refer to 5.1.1 for more information about DE status)

- Draft – only draft DE will be searched for
- Awaiting publication – limits to DEs in Awaiting Publication (AWP) state
- Published – only published DEs will be searched for

**Element Type** – limits the search by either Common or Unique data elements, or both when both check boxes are un-checked.

**Disease** (not a very useful option so far) – limits the search by DEs created for a specific disease. This option only works in those instances of BRICS which fully support disease categories in data elements.

**Population** – limits DE search by DEs of a specific population. Note that “Preclinical” population refers to DEs which were created for animal studies.

### 5.1.5 Downloading DE Search Results

To download data element search results, use a big **DOWNLOAD** button. Note that the **DOWNLOAD** button contains the information number of DEs found, which is very helpful.

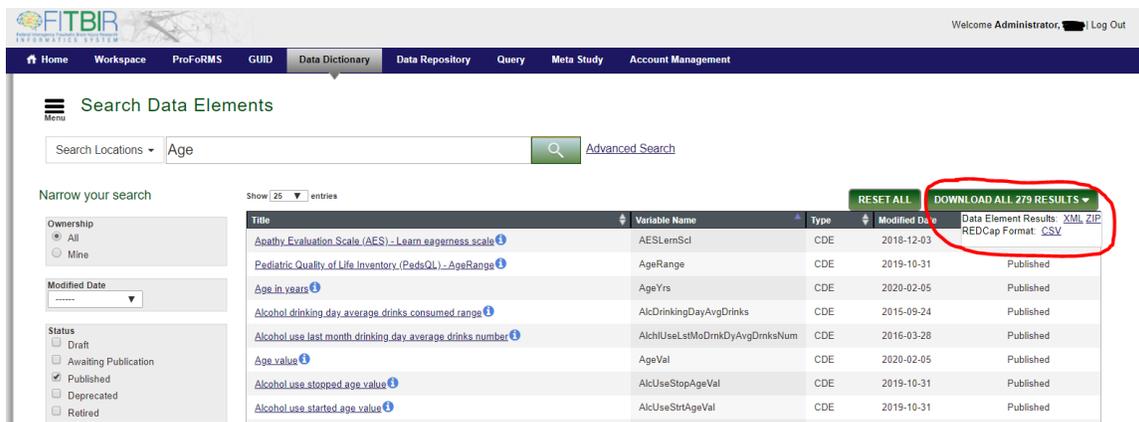
It provides the following options:

**XML** – downloads the list of DEs as an XNML 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:

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

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



The screenshot shows the BRICS web interface with a search for 'Age'. The results table includes columns for Title, Variable Name, Type, Modified Date, and Data Element Results. A red circle highlights the 'DOWNLOAD ALL 279 RESULTS' button, which has a dropdown menu showing 'XML ZIP' and 'REDCap Format: CSV'.

Title	Variable Name	Type	Modified Date	Data Element Results
Apathy Evaluation Scale (AES) - Learn eagerness scale	AESLernSci	CDE	2018-12-03	Published
Pediatric Quality of Life Inventory (PedsQL) - AgeRange	AgeRange	CDE	2019-10-31	Published
Age in years	AgeYrs	CDE	2020-02-05	Published
Alcohol drinking day average drinks consumed range	AlcDrinkingDayAvgDrinks	CDE	2015-09-24	Published
Alcohol use last month drinking day average drinks number	AlchlUseLstMoDrnkDyAvgDrinksNum	CDE	2016-03-28	Published
Age value	AgeVal	CDE	2020-02-05	Published
Alcohol use stopped age value	AlcUseStopAgeVal	CDE	2019-10-31	Published
Alcohol use started age value	AlcUseStrAgeVal	CDE	2019-10-31	Published

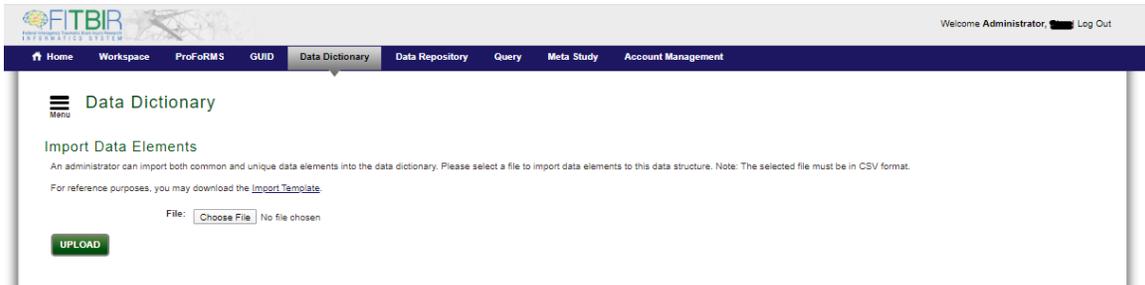
### 5.1.6 Creating/Editing Data Elements

Users of BRICS instance can create data elements (DEs) 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 5.1.7).

However, when creating multiple data elements, we strongly encourage using DE import template (refer to 5.1.11).



### 5.1.7 To Create Data Elements Using Web Interface

Perform the following actions:

1. Click the Data Dictionary module. The Search Form Structures page appears.
2. Navigate to the Data Dictionary>Data Elements.
3. Select the Create under Data Elements from the left-hand drop-down menu.
4. Follow the process as it is defined by chevrons.

#### Menu Create Data Element



A data element is a logical unit of data, pertaining to information of one kind. A data element has a name, precise definition, and clear enumerated values (codes) if applicable. A data element is not necessarily the smallest unit of data; it can be a unique combination of one or more smaller units. A data element occupies the space provided by field(s) on a paper/electronic case report form (CRF) or field(s) in a database record.

Fill out the details below to create a data element. On the following pages, you may define the type of data captured and associate keywords.

Fields marked with a \* are required.

6. **Basic Information/General Details:** Fill out the details below to create a data element. On the following pages, you may define the type of data captured and associate keywords. Fields marked with **red asterisk (\*)** are required (Element Type, Title, Variable Name). Click **Continue**.
7. **Add Documentation:** Click the **Add Documentation** button. Add documentation if any. Click **Continue**.
9. **Attributes:** In this form, you will be describing the data that will be entered for this Data Element. Fields marked with a \* are required (***Permissible Value, Population, Use the diseases listed below to refine your search for domains and sub-domains, Data Restrictions***). Select a disease domain category.
10. **Keywords and Labels:** In this form, you will be associating keywords to the data element. This improved reuse and improves the ability to search for data elements. In the “**Filter Keywords**” textbox, enter your keyword and click the **Add Keyword** button. Click **Continue**.
11. **Details:** at this step, you will be describing the details of the Data Elements. Fields marked with a \* are required (***Submitting Organization Name, Steward Organization Name***). Click the **Continue** button.
12. **Review:** Review your Unique Data Element details. Click the **Save and Finish** button.
13. **Data Element Confirmation:** The data element will be created and a confirmation page appears. The data element will be in a DRAFT state until you request for it to be

published. Publication of data elements are subject to administrative review and approval. You may choose to publish a data element through two different methods:

1. Requesting publication from the data element screen itself, or
2. Published automatically when requesting the publication of a form structure with the draft data element attached.

### 5.1.8 Edit Data Elements

1. Search for Data Element (refer to 5.1.3).
2. Select “Edit” form the Menu on the right. Ten interface similar to 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 Des 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.

### 5.1.9 Deleting Data Elements

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, the last one. It shows all form structures which have a given DE.

- Linked Form Structures

Search:

Title	Short Name	Version	Status
<a href="#">Track TBI Interview</a>	TRACKTBI_Interview	1.0	Published

Showing 1 to 1 of 1 entries First Previous **1** Next Last

2. Does not have data submitted against it.
  3. For user convenience, only those DEs which satisfy ##1 and 2 have the “Delete” option available.
  4. If the “delete” option is not present for a given DE, you cannot delete it.
- #31 and 2 limit deletable DEs mostly to DRAFT DEs.

**To delete a DE (if you really need to)**

1. Search for the Data Element. Use Variable Name as a key.
2. Open the DE page.
3. Select “Delete” form the Menu on the right. If the DE is available for deletion, the “Delete” link will be available. If the “Delete” link is not available, the DE is not for deletion.



The screenshot shows the FITBIR Data Dictionary interface. The page title is "Data Dictionary" and the specific entry is "Form Structure: Abbreviated Speech Spatial Qualities Questionnaire". The status is "Draft". The "General Details" section includes:

- Title: Abbreviated Speech Spatial Qualities Questionnaire
- Short Name: aSSQ
- Description: The Abbreviated Speech Spatial Qualities Questionnaire (aSSQ) is a 9-question reduced version of the full 49 question version published by Gatehouse and Noble in the International Journal of Audiology (2004).
- Disease: Traumatic Brain Injury, General (For all diseases)
- Required Program Form: No
- Standardization: Unique
- Labels:
- Form Type: Clinical Assessment
- Version: 1.0
- Date Created: 2017-09-20
- Created By: Bressler, Scott
- Owner: Bressler, Scott
- Number of Data Elements: 2
- eForms: N

On the right side, there is a "Status: Draft" dropdown menu with options: "Revised Publication", "Edit", "Publish" (highlighted with a red circle), "Data Element Report", "Data Element Report - Attachments", and "Export Form Structure: XML | CSV | HTML | Attachments Data".

### 5.1.10 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.

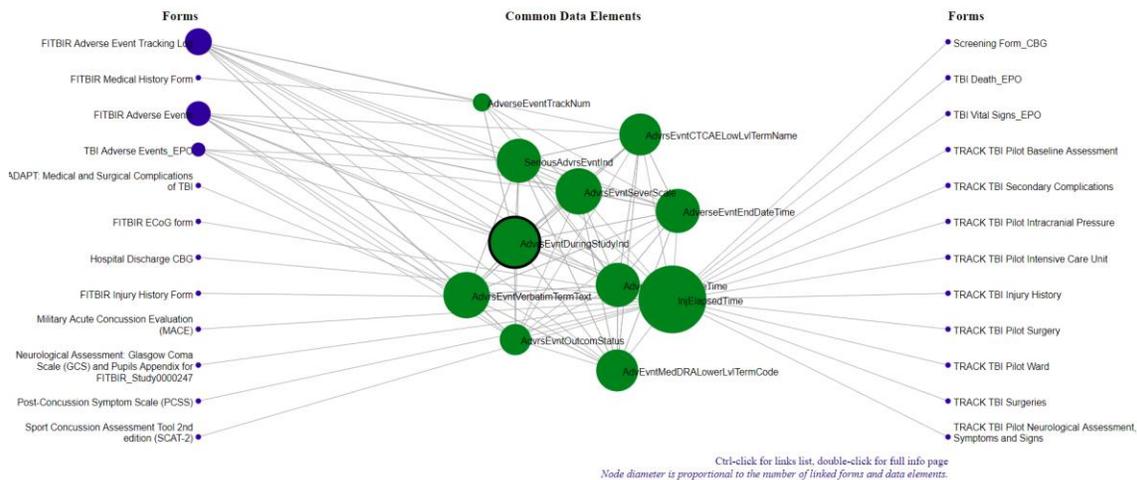
Not all DEs have the knowledge graph feature available. If a DE has knowledge graph available, the corresponding link appears on the DE page.

The screenshot shows the FITBIR Data Dictionary interface for a "Common Data Element: Adverse event during study indicator". The status is "Published". The "General Details" section includes:

- Version: 1.9
- Element Type: Common Data Element
- Title: Adverse event during study indicator
- Variable Name: AdvsEvtDuringStudyInd
- Short Description: Indicator of whether the participant/subject experienced any adverse events during the study
- Definition: Indicator of whether the participant/subject experienced any adverse events during the study
- Notes: CDISC CDASH AEYN. There is no relevant SDTM CDISC variable, the suggestion is to use AESTDY - Study Day of Start of Adverse Event and AEENDY Study Day of End of Adverse Event.
- Creation Date:
- Created By:
- Historical Notes: Adverse event during study indicator
- References: No references available

On the right side, there is a "Status: Published" dropdown menu with options: "Edit", "Knowledge Graph" (highlighted in yellow), and "Close".

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



On the knowledge graph, the DE for which knowledge graph was build if highlighted by 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.

### 5.1.11 Creating and Importing Multiple DEs

**For multiple DEs, to be created,**

1. The data element import template must be used – a CSV file available for download from Data Dictionary>Data Elements>Import Data Elements page.
2. The template should be populated with new DEs, one DE per row and saved as CSV file with a meaningful name
3. The CSV file then can be uploaded to the BRICS data dictionary via Data Dictionary>Data Elements>Import Data Elements page.

**Note,** 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).

### 5.1.12 Importing DEs into BRICS

1. Use the Data Element Import Template, which is available as a CSV file via Data Dictionary>Import Data Elements>Import Template link.
2. When the template is opened in MS Excel, you may populate it with multiple DEs, one data element per row.
3. After creating and reviewing DE, when you are satisfied with the result, you may upload DE CSV file to the BRICS dictionary by using the Import Data Elements function.

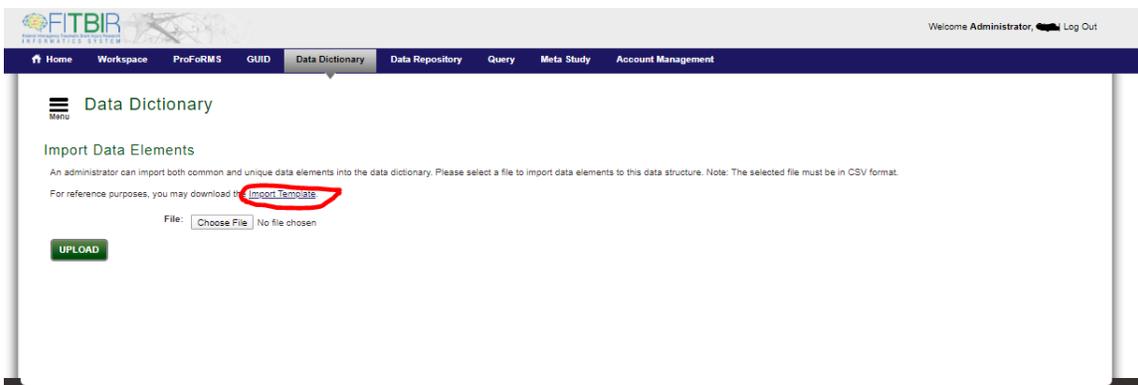
4. The Import Data Elements function performs the validation of submitted data elements to conformance with BRICS rules. If it finds any errors, it provides you with the descriptive error/warning log and does not allow to import the “wrong” DEs into the data dictionary.
5. You must fix the errors first, 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 DEs, we encourage you that you contact BRICS Operations and ask them to review you set of DEs.
- 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 an [CSV](#) file.

**The following steps must be done before you can proceed with the Data Elements Import tool:**

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



### 5.1.13 Data Element 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,

- 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.

### 1. 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
10. following format: Assessment Acronym + Title

Example:

Assessment: Buss Perry Aggression Questionnaire (BPAQ)

Title: Buss Perry Aggression Questionnaire (BPAQ) - provoked hit scale

Variable Name: BPAQProvokedHitScl

### 2. 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.

### **3. 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 cannot be abbreviated.
4. Must be one of the following: a) Common Data Element and 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.

### **4. 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.

### **5. 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

### **6. 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, biosample, thumbnail (image only files).

### **7. 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:
  - Free-Form Entry.
  - Multiple Pre-Defined Values Selected.
  - Single Pre-Defined Value Selected.

Examples:

- A. 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.
- B. 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.
- C. 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.

## 8. 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=4000 characters.
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”.

## 9. 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 Input Restrictions: 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.

## 10. 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.

## 11. 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 element.
4. Maximum 200 characters per one PV
5. No spaces before or after any semi-colon in the list.
6. The data from the PV field should be copied into PV Descriptions (e.g., Yes; No; Unknown) unless specific PV Descriptions have been provided.
7. 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.).
8. 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.

## 12. 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. Therapy rehabilitation 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. Ste Input Restrictions: to Free-Form Entry.

## 13. 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. The Permissible Value Descriptions list must have the same amount of descriptions as there are Permissible Values in the Permissible Value list.
6. The descriptions must match the order of the permissible value.
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 of the time, then the PV Description would show Never;,,,,,;All of the time.

#### **14. 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.

#### **15. 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:
  - Adult
  - Pediatric
  - Adult; Pediatric
  - Preclinical – for animal studies

#### **16. 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.

#### **17. 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.

## 18. 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.

## 19. 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. Or 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.

## 20. 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).

## 21. 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.

## 22. Historical Notes

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

## 23. 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.

#### **24. Effective Date**

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

#### **25. Until Date**

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

#### **26. 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.

#### **27. 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.

#### **28. 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:**

- 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.
- Note: Each Domain has one or more sub-domains.
- 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 in <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.

### 5.1.14 APPENDIX A: 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

<b>Representation Term</b>	<b>NINDS Data Type</b>	<b>Definition</b>	<b>Abbreviation for Variable Name</b>
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	Measr
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	Represents 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

<b>Representation Term</b>	<b>NINDS Data Type</b>	<b>Definition</b>	<b>Abbreviation for Variable Name</b>
		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