

BRICS USER GUIDE

Data Dictionary: eFORMS





CHAPTER 4 - Data Dictionary

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:

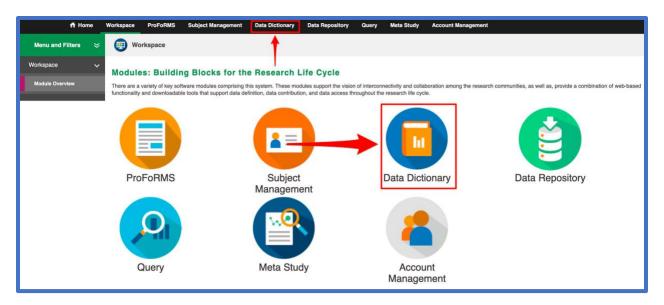
- Searching Data Elements
- Downloading Data Elements Results to XML, CSV and ZIP output formats
- Creating Data Elements
- Importing Data Elements



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.





4.7 eFORMs

An electronic form (eFORM) is a grouping/collection of various questions and related Common and Unique Data Elements (CDEs and UDEs) used to gather information for a study. An electronic form is analogous to a case report form (CRF) (electronic or paper) where data elements are linked together for collection and display. **Data Submission**:

4.7.1 eForm Standardization (Standard vs Non-Standard)

Below are the eForm Standardizations found in BRICS:

- Standard eForms are available for users with Dictionary eForm privilege.
- Non-standard eForms will be available only to users with permissions to the eForm.
- These users would have to be assigned permissions to the eForm under the eFORMs permissions tab by the operations team.
- eForms can be used to collect data in a protocol within the ProFORMS module. The availability of an eForm in the protocol is dependent upon the eForm standardization status.



4.7.2 Search eForms

To Search eForms: Perform the following actions:

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. Login and navigate to the Data Dictionary module.
- 2. Select **eForms** on the left-side tool bar.

ff Hor	me	Workspace ProFoRMS Subject Management Data Dictionary	Data Repository Query Meta Study Account I	Management	
Menu and Filters		Data Dictionary			
Data Dictionary Tool		Search Form Structures			
Form Structures			Q Advanced Search		
Search		* Keyword search will be performed within the following form fields: Short Name			
Create					
					Showing 1 to 78 of 78
		TITLE	SHORT NAME	\$ STATUS	Showing 1 to 78 of
Data Elements		TITLE Activities Specific Balance Confidence Scale (ABC-Scale)	ABCScale_FITBIR	STATUS Published	
Data Elements eForms				and presented and	MODIFIED DATE
	> >	Activities Specific Balance Confidence Scale (ABC-Scale)	ABCScale_FITBIR	Published	* MODIFIED DATE 2019-05-22
	> >	Activities Specific Balance Confidence Scale (ABC-Scale)	ABCScale_FITBIR August21	Published Published	MODIFIED DATE 2019-05-22 2020-08-27
	> >	Activities Specific Balance Confidence Scale (ABC-Scale)	ABCScale_FITBIR August21 Auto_Form_Feb01_11_38_47	Published Published Published	MODIFIED DATE 2019-05-22 2020-08-27 2021-09-30

3. Select the Search under eForms from the expanded drop-down.

Menu and Filters	≈	Data Dictionary			
Data Dictionary Tool	~	Search Form Structures			
Form Structures	~		Ivanced Search		
Search Create		* Keyword search will be performed within the following form fields: Short Name, Title, Description, and Created	By.		Showing 1 to 78 of 78 entries
		TITLE	SHORT NAME	STATUS	MODIFIED DATE
Data Elements	>	Activities Specific Balance Confidence Scale (ABC-Scale)	ABCScale_FITBIR	Published	2019-05-22
eForms	~	August21	August21	Published	2020-08-27
Search		55 Eeb 01 11:38:46	Auto_Form_Feb01_11_38_47	Published	2021-09-30
Create		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
		Balance Error Scoring System (BESS)	BESS	Published	2019-08-18
		Blast Exposure	BlastExposure	Published	2018-06-14



You can now see the available eForms. Use the search box to narrow down the results.
 5.

f H	ome	Workspace	ProFoRMS	Subject Management	Data Dictionary	Data Repository	Query I	Meta Study	Account Management	
Menu and Filters		📵 Data	Dictionary							
Data Dictionary Tool		Search e	eForms							
Form Structures										
Data Elements										Search: -
eForms		EFORM TITLE	E		A SHORT NA	ME	STATUS	\$ мо	DIFIED DATE 🛛 🌲	FORM STRUCTURE TITLE
Search		AAAFITBIR	Demographics	Form	AAADem	ogrFITBIR	PUBLISHE	ED 20	18-07-01 14:20	FITBIR Demographics Form
Create		ABC Demo f	for Self Reporti	09	ABCScale	e_FITBIR	PUBLISHE	ED 20	19-05-22 11:36	Activities Specific Balance Confidence Scale (ABC-Scale
Create		Activities Sp	ecific Balance	Confidence Scale (ABC-Sca	e) mine		DRAFT	20	20-05-04 12:15	Activities Specific Balance Confidence Scale (ABC-Scale
wnership		August21			August21		DRAFT	20	19-08-21 09:52	August21
All		Auto EFOR	м		Auto_EF0	ORM2	PUBLISHE	ED 203	21-09-09 12:32	AutoFS Feb 01 11:38:46
Mine		Auto EFOR	IM		Auto_EF0	DRM	DRAFT	203	21-09-09 12:31	AutoFS Feb 01 11:38:46
		Balance Erro	or Scoring Syst	em (BESS)	BESS		DRAFT	203	21-07-22 16:24	Balance Error Scoring System (BESS)
		Balance Erro	or Scoring Syst	em (BESS)	\$55		PUBLISHE	ED 203	21-09-09 12:24	Balance Error Scoring System (BESS)
		Balance Erro	or Scoring Syst	em (BESS)	Error_De	mo	PUBLISHE	ED 203	21-09-09 12:24	Balance Error Scoring System (BESS)
		Blast Expose	ure		BlastExp	osure	PUBLISHE	ED 20	18-07-19 11:54	Blast Exposure
		Demographi	ics		Demogra	phics_15	DRAFT	20	18-05-31 14:51	PDBP Demographics
		Demographi	ics 001		eFormNa	me_Jun_22_2018	DRAFT	20	18-06-22 13:31	FS_Title_Jun 13 13:55:33
		Demographi	ics_Virtual		Demogra	phics_15_Virtual	DRAFT	203	20-06-17 15:21	PDBP Demographics_Virtual
		eFormTitle_I	Dec 17 14:35:2	4	eFormNa	me_Dec_17_14_32_11	PUBLISHE	ED 203	21-12-17 14:35	FS_Title_Dec 17 14:34:01
		eFormTitle	Jun 13 11:36:2	3	eFormNa	me_Jun_13_11_36_05	PUBLISHE	ED 20	18-06-13 11:36	FS_Title_Jun 13 11:33:47
		eFormTitle_	Jun 13 13:44:5	9	eFormNa	me_Jun_13_13_44_42	PUBLISHE	ED 20	18-06-13 13:44	FS_Title_Jun 13 13:42:27
			Jun 13 13:58:0	8	eFormNa	me Jun 13 13 57 49	PUBLISHE	ED 20	18-06-13 13:58	FS Title Jun 13 13:55:33

6. Click on the eForms title to open it.

ff Ho	me	Workspace ProFoRMS Subject Management Dat	a Dictionary Data Repository	Query Meta	Study Account Manage	ment
Menu and Filters		Data Dictionary				
Data Dictionary Tool		Search eForms				
Form Structures		Search of Onna				
Data Elements						Search: 👻
eForms		EFORM TITLE	A SHORT NAME	\$ STATUS	MODIFIED DATE	FORM STRUCTURE TITLE
Search		AAAFITBIR Demographics Form	AAADemogrFITBIR	PUBLISHED	2018-07-01 14:20	FITBIR Demographics Form
Create		ABC Demo for Self Reporting	ABCScale_FITBIR	PUBLISHED	2019-05-22 11:36	Activities Specific Balance Confidence Scale (ABC-Scale)
Create		Activities Specific Balance Confidence Scale (ABC-Scale)	mine	DRAFT	2020-05-04 12:15	Activities Specific Balance Confidence Scale (ABC-Scale)
nership		August21	August21	DRAFT	2019-08-21 09:52	August21
All		Auto_EFORM	Auto_EFORM2	PUBLISHED	2021-09-09 12:32	AutoFS Feb 01 11:38:46
Mine		Auto_EFORM	Auto_EFORM	DRAFT	2021-09-09 12:31	AutoFS Feb 01 11:38:46
		Balance Error Scoring System (BESS)	DEOS	DRAFT	2021-07-22 16:24	Balance Error Scoring System (BESS)
		Balance Error Scoring System (BESS)	\$\$\$	PUBLISHED	2021-09-09 12:24	Balance Error Scoring System (BESS)
		Balance Error Scoring System (BESS)	Error_Demo	PUBLISHED	2021-09-09 12:24	Balance Error Scoring System (BESS)
		Blast Exposure	BlastExposure	PUBLISHED	2018-07-19 11:54	Blast Exposure
		Demographics	Demographics_15	DRAFT	2018-05-31 14:51	PDBP Demographics
		Demographics 001	eFormName_Jun_22_2018	DRAFT	2018-06-22 13:31	FS_Title_Jun 13 13:55:33
		Demographics_Virtual	Demographics_15_Virtual	DRAFT	2020-06-17 15:21	PDBP Demographics_Virtual
		eFormTitle_Dec 17 14:35:24	eFormName_Dec_17_14_32_11	PUBLISHED	2021-12-17 14:35	FS_Title_Dec 17 14:34:01
		eFormTitle_Jun 13 11:36:23	eFormName_Jun_13_11_36_05	PUBLISHED	2018-06-13 11:36	FS_Title_Jun 13 11:33:47
		eFormTitle_Jun 13 13:44:59	eFormName_Jun_13_13_44_42	PUBLISHED	2018-06-13 13:44	FS_Title_Jun 13 13:42:27
		eFormTitle Jun 13 13:58:08	eFormName Jun 13 13 57 49	PUBLISHED	2018-06-13 13:58	FS Title Jun 13 13:55:33

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ff Home	Workspace ProFoRMS Subject Management Data Dictionary Dat	a Repository Query Meta Study Accou	nt Management	
Menu and Filters 🛛 💝	Data Dictionary			
Data Dictionary Tool 🗸 🗸 🗸	Search Form Structures			
Form Structures 🗸 🗸	Search Form Structures	Advanced Search		Search Form
Search	* Keyword search will be performed within the following form fields: Short Name, Title,			Structures
Create				Showing 1 to 78 of 78 entries
Data Elements	TITLE Activities Specific Balance Confidence Scale (ABC-Scale)	ABCScale_FITBIR	STATUS Published	♥ MODIFIED DATE ♥ 2019-05-22
eForms >	August21	August21	Published	2020-08-27
	AutoFS Feb 01 11:38:46	Auto_Form_Feb01_11_38_4	47 Published	2021-09-30
Narrow your search	AutoFS Jun 13 10:48:38	Auto_Form_Jun13_10_48_5	38 Published	2018-06-13
Clear Filters Restore Default	AutoFS Jun 14 15:44:02	Auto_Form_Jun14_15_44_(03 Published	2018-06-14
Ownership 🗸 🗸	Filter Options	BESS	Published	2019-08-18
All O Mine	Blast Exposure	BlastExposure	Published	2018-06-14
I O Mine	Brief Symptoms Inventory-18 (BSI-18)	Select a Form BSI18	Published	2019-08-18
FITBIR 🗸	Center for Epidemiologic Studies-Depression Scale (CES-D)	Structure	Published	2018-09-06
All	demoMe	demoMe	Published	2020-05-04
O Program Specific	February12	February12	Published	2020-02-12
	EITBIR Demographics Form	DemogrFITBIR	Published	2018-01-31
Form Types 🛛 🗸	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



4.7.3 Create eForms

To Create eForms: Perform the following actions:

1. Select Create under eForms in the left navigation.

🕇 Hom	e	Workspace ProFoRMS	Subject Management	Data Dictionary	Data Repository	Query Me	ta Study Account Manage	ement	
Menu and Filters		Data Dictionary	1						
Data Dictionary Tool	~	Search eForms							
Form Structures									
Data Elements									Search: 👻
eForms		EFORM TITLE		A SHORT NA	ME	STATUS	MODIFIED DATE	FORM STRUCTURE	TITLE
Search		AAAFITBIR Demographic	:s Form	AAADemo	grFITBIR	PUBLISHED	2018-07-01 14:20	FITBIR Demograph	nics Form
Create		ABC Demo for Self Repo	rting	ABCScale	_FITBIR	PUBLISHED	2019-05-22 11:36	Activities Specific B	Balance Confidence Scale (ABC-Scale)
Cieate		Activities Specific Balance	e Confidence Scale (ABC-Scale	a) mine		DRAFT	2020-05-04 12:15	Activities Specific B	Balance Confidence Scale (ABC-Scale)
nership		August21		August21		DRAFT	2019-08-21 09:52	August21	
		Auto_EFORM		Auto_EFO	RM2	PUBLISHED	2021-09-09 12:32	AutoFS Feb 01 11:	38:46
line		Auto EFORM		Auto_EFO	RM	DRAFT	2021-09-09 12:31	AutoFS Feb 01 11:	38:46
		Balance Error Scoring Sy	stem (BESS)	BESS		DRAFT	2021-07-22 16:24	Balance Error Scori	ing System (BESS)
		Balance Error Scoring Sy	stem (BESS)	SSS		PUBLISHED	2021-09-09 12:24	Balance Error Scori	ing System (BESS)
		Balance Error Scoring Sy	stem (BESS)	Error_Den	10	PUBLISHED	2021-09-09 12:24	Balance Error Scori	ing System (BESS)
		Blast Exposure		BlastExpo	sure	PUBLISHED	2018-07-19 11:54	Blast Exposure	
		Demographics		Demograp	hics_15	DRAFT	2018-05-31 14:51	PDBP Demographic	CS
		Demographics 001		eFormNar	ne_Jun_22_2018	DRAFT	2018-06-22 13:31	FS_Title_Jun 13 13	3:55:33
		Demographics Virtual		Demograp	hics_15_Virtual	DRAFT	2020-06-17 15:21	PDBP Demographic	cs_Virtual
		eFormTitle_Dec 17 14:35	:24	eFormNar	ne_Dec_17_14_32_11	PUBLISHED	2021-12-17 14:35	FS_Title_Dec 17 14	4:34:01
		eFormTitle Jun 13 11:36:	23	eFormNar	ne_Jun_13_11_36_05	PUBLISHED	2018-06-13 11:36	FS_Title_Jun 13 11	:33:47
		eFormTitle_Jun 13 13:44	:59	eFormNar	ne_Jun_13_13_44_42	PUBLISHED	2018-06-13 13:44	FS_Title_Jun 13 13	3:42:27
		eFormTitle_Jun 13 13:58	:08	eFormNar	ne Jun 13 13 57 49	PUBLISHED	2018-06-13 13:58	FS Title Jun 13 13	3:55:33

2. Click on the No Form Structure Linked (Click here to link)

Edit eForm						
eForm Basics	Advanced Settings	eForm Formatting	Section Formatting	Permissions		
el eForm S	rm Structure No Form Name * Short Name *	o Form Structure Linked	click here to link)		eForm Status :	Draft
						SAVE AND CONTINUE CANCEL



3. Use the Search box to narrow the results for the Form Structure you're looking for and click the radio button to the left of the SHORT NAME to select it.

Form	n Structure			
Pleas	se select a form structure for th	is form		
				Search: - demographics
	SHORT NAME	VERSION 🖨	DESCRIPTION	
0	Demographics	2.0	This form contains data elements that are collected to describe the demographics of th used to compare baseline characteristics among study groups and to identify confound	
0	DemogrFITBIR	1.0	FITBIR Demographics standard form	
Showi	ing 1 to 2 of 2 entries (filtered from 101	total entries) (1	row selected of 101)	First Previous 1 Next Las
				SELECT

4. After selecting a Form Structure, click SELECT at the bottom right to continue.



5. The Edit Form Details panel will display. See description of each tab below

PDBP Demographics Demographics: Draft			(+)	=,	G	=/	Z	\otimes
Edit eForm								
eForm Basics Advanced Setti	ngs eForm Formatting Section Formatting Permissions							
Form Structure eForm Name* eForm Short Name*	Demographics PDBP Demographics			eF	orm Status	: Dr	aft	
eForm Short Name* eForm Description	Demographics This form contains data elements that are collected							
	A A A A A A A A A A A A A A A A A A A							
						SA	VE AND CON	TINUE

eForm Basics: The basic settings of the eForm: Form Structure, eForm Name, eForm Short Name (MUST BE UNIQUE), eForm Description.

Advanced Settings:

- Allow Multiple Instances: Allows the form to be used multiple times when it is the same visit type and same user. When unchecked you will not be able to use this form if it is the same visit type with the same patient.
- eForm Category for Proforms: This will indicate the category in Proforms. We recommend leaving it as Normal.

eForm Formatting: Change the Font, Font Size, Font Color, Padding, etc. Add a Header/ Footer.

Section Formatting: Similar to eForm Formatting but specifically for the sections.

Permissions: See and modify the permissions for this eForm. You give a user the following permissions: Owner: Has full access to Read/Write/Admin and can modify the Owner Permission.

NOTE: Each eForm can ONLY have ONE Owner. Admin: Has full access to Read/Write. and can also add additional admins. Write: Has full access to Read and can also edit the eForm. Cannot edit the Permissions. Read: Cannot make any edits to the eForm. Read access will only allow the user to view the eForm.



6. Fill out the required fields: **eForm Name** and **eForm Short Name**. **NOTE:** eFORM short name must be unique.

Edit eForm						
eForm Basics	Advanced Setting	gs eForm Formatting	Section Formatting	Permissions		
eF eForm S	m Structure Form Name * hort Name * Description	Demographics PDBP Demographics Demographics This form contains data elements that are collected	d		eForm Status :	Draft
						SAVE AND CONTINUE CANCEL

- 7. Advanced Settings: Leave as default values unless needed for your use case.
 - Allow Multiple Instances: Allows the form to be used multiple times when it is the same visit type and same user. When unchecked you will not be able to use this form if it is the same visit type with the same patient. Recommended to leave this field unchecked.
 - **eForm Category for Proforms:** This will indicate the category in Proforms. We recommend leaving it as Normal.

Edit eForm Blast Exposure	
eForm Basics Advanced Settings eForm Formatting Section Formatting Permissions	
Allow Multiple Instances eForm Category for Proforms Normal V	
	SAVE AND CONTINUE CANCEL

8. **eForm Formatting & Section Formatting**: Change to meet your formatting needs here.

	Advanced Settings	eForm Formatting	Section Format	tting Permissions					
eF	Form Name Font	Arial	~	eForm Name Font Size	10	~	eForm Name Color	Black	
	eForm Header			eForm Footer			Borders Aroun	d Entire eForm	0
	eForm Font	Arial	<i>h</i>	eForm Font Size	10	~	eForm Description Color	Black	
E	lement Padding	2	~	eForm Questions Border				Dider	
	.nih.gov/dictionary/dictio	ionary/eFormAction!creat	teEform.action#for	mat				SAVE AND C	
	.nih.gov/dictionary/dicti	onary/eFormActionIcreat	teEform.action#for	mat				SAVE AND C	ONTINUE CA
fitbir-demo.cit		onary/eFormActionIcreat	teEform.action#for	mat				SAVE AND C	ONTINUE C
fitbir-demo.cit Form Blast Ex	xposure						_	SAVE AND C	ONTINUE C
		eForm Formatting	teEform.action#for					SAVE AND C	ONTINUE C.

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9. Permissions: To modify your eForms permissions:

Select a username from the drop-down list. Click **GRANT PERMISSION**. Then select the permission access for the user in the list. The different permissions are **Read**, **Write**, and **Admin**. Click on the **Grant Permission** button.

To remove a user from the permission group, click **Remove.**

Read: Allows user to view this eForm.

Write: Allows user to view this eForm, edit eForm details, manage documentation, manage data, and specify keywords and labels.

Admin / Owner: Allows user to view this eForm, edit eForm details, manage documentation, manage data, specify keywords and labels, and grant permissions. There can only be one Owner.

Edit eForm							
eForm Basics Advanced Settings eForm Formatting Section Formatting	Permissions						
Individual access to the eForm is granted below. Select the intended individual from the drop de	own to grant access. The permissions include rea	d, write, or admin. The default permission is	read. Also, individuals can be removed from the permission group here.				
Read - Allows user to view this eForm, Write - Allows user to view this eForm, edit eForm details, manage documentation, manage da Admin / Owner - Allows user to view this eForm, edit eForm details, manage documentation,		trant nermissions. There can only be one Ow	ner.				
Admin, Portal	nanege data, specify keywords and ladels, and i	pant permissions. There can only be one on	1904				
USER / PERMISSION GROUP	PERMISSION	/	REMOVE?				
Smith, Patrick	Owner	~ ~	remove				
			SAVE AND	CONTINUE			

10. After completing all your desired changes click Save and Continue button.



4.7.4 Modifing an eForm Page

After either creating an eForm or edit an eForm you will be taken to this page:

PDBP Demographics Demographics: Draft	G	•	Ð	≡₀	G	=/	\otimes
✓ Required Fields							
Otata Element: Required Fields.SiteName Name of the site:							
Solution Solution	 12 months 18 months 24 months 30 months 36 months 42 months 48 months 				 54 month 6 months 60 month 72 month Baseline Screenin 	15	
 ⊘ Solution ⊘ Data Element: Required Fields.VisitDate Visit Date: 							
 Solution (GUID) Solution (GUID) Solobal Unique ID (GUID) which uniquely identifies the subject: 							
Image: Constraint of the constraint							



There are various changes you can make to your eForm from this page. If you do not wish to make any changes then click the Save Icon at the top to save your eForm and exit back to the eForm module.

When on the modifying an eForm page, you will see a row of icons at the top of the page like in the photo below. Each icon is described below the image.

PDBP Demographics Demographics: Draft			⊕ =₀ =₂ ⊠ ⊗
∽ Req	quired Fields		
2 🛞 Data Element: Required Fi Name of the site:	ields.SiteName		
Ø Solution Data Element: Required Fi Enter Question Text	ields.VisitTypPDBP	12 months 18 months 24 months 30 months 36 months 42 months 48 months	 54 months 6 months 60 months 72 months Baseline Screening
	Preview: Click to show a preview of what the eForm will look like with the current edits. (See next page for screenshot of the preview page)		Add Section: Add a section to your eForm. NOTE: Additional sections can only contain text. You cannot add questions to a newly created section
	Save: Click to save the changes and exit the Modify eForm Page.	=,	Edit Form Details: Opens the Edit Form Details Panel.
(+)	Add Data Element: Click to add any data elements you have removed. NOTE: You can remove optional fields from the eForm. Once removed, they will show up in this list. This list will only contain fields you have removed.		Edit Layout: Move Text/Questions/Sections or Create a Table (Putting questions/text side by side) NOTE: You cannot rearrange the order of questions. You can only move them to be side by side.
E	Add Text: Click here to add additional text to your eForm.	\mathbf{x}	Cancel: Cancel Creating or Editing the eForm.



An eForm is made up of different Sections and each section is made up of Questions. You are able to change various settings of those sections and questions as well as easily view what attributes each question has from the **Question Indicators** (Check guide below image).

PDBP Demographics Demographics: Draft		•	÷	≡,	G	=/		۲	
> Required Fields									
A collapsed section (Click the arrow to expand/collapse)	Click on a section to select it. A selected section will show settings and delete icons.								
Demographics An expanded section		011-1							
Quanties Indianters Quickly identify		Click.on						-	_
Question Indicators. Quickly identify what attributes this question has.				ion will show 🔅				1	
PD (F0745):, PD (F0753): Gender	O Female				O Unknown				
	O Male				O Undiffer	entiated/Indete	erminant/Inter	sex	
	O Not Reported								
Ø 🛞									
Data Element; Demographics.EthnUSACat									
What is the subject's ethnic background?	O A person of C	uban, Mexicar	٦,		O Not prov	vided or availal	ble		
	Puerto Rican, Central Ameri				 Could n unsure 	ot be determin	ed or		
	Spanish cultu		e		unsure				
	O A person not								
	definition for H	lispanic or							
	Latino.								

Question Indicator Guide

Ø	This question is linked to a Data Element.	א ^ע	This question is collapsible.
*	This question is Required.	E	This question is repeatable.
	This question has Validation Requirements. (e.g. Answer must be a number)		This section has a grid layout.
ŧ.	This question has a Calculation Rule.		This question is prepopulated.
(2)	This question has a Conversion Factor		This question is FHIR.
0	This question has a Skip Rule.		This question has an Email notification.
	This question is a Count.		

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4.6.5 Search Form Structures

To search From Strucutes, peform 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 morespecific.
- 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 andtry again.

ff Home	Workspace ProFoRMS Subject Management Data Dictionary Data Repository Query	Meta Study Account Man	nagement
Menu and Filters 🛛 😒	Data Dictionary		
Data Dictionary Tool 🗸 🗸 🗸	Search Form Structures		
Form Structures 🗸 🗸		Ivanced Search	Search Form
Search	* Keyword search will be performed within the following form fields: Short Name, Title, Description, and Created		Structures
Create	TITLE	SHORT NAME	Showing 1 to 78 of 78 entries STATUS
Data Elements 💦 🗲	Activities Specific Balance Confidence Scale (ABC-Scale)	ABCScale_FITBIR	Published 2019-05-22
eForms >	August21	August21	Published 2020-08-27
	AutoFS Feb 01 11:38:46	Auto_Form_Feb01_11_38_47	Published 2021-09-30
Narrow your search	AutoFS Jun 13 10:48:38	Auto_Form_Jun13_10_48_38	Published 2018-06-13
Clear Filters Restore Default	AutoFS Jun 14 15:44:02	Auto_Form_Jun14_15_44_03	Published 2018-06-14
Ownership 🗸 🗸	Filter Options	BESS	Published 2019-08-18
All O Mine	Blast Exposure	BlastExposure	Published 2018-06-14
	Brief Symptoms Inventory-18 (BSI-18)	BSI18	Published 2019-08-18
FITBIR \lor	Center for Epidemiologic Studies-Depression Scale (CES-D)	CESD	Published 2018-09-06
All	demoMe	demoMe	Published 2020-05-04
O Program Specific	February12	February12	Published 2020-02-12
Form Types 🗸 🗸	FITBIR Demographics Form	DemogrFITBIR	Published 2018-01-31
	FITBIR EEG form	EEG_FITBIR	Published 2020-01-07
	EITBIR Imaging Read form	ImagingRead_FITBIR	Published 2018-02-16
-	Form Structure 010620	FS010620	Published 2020-08-27
1	Form Structure 0201	FS0201	Published 2020-08-27

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

VANCED SEARCH. The following operators can b	e 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

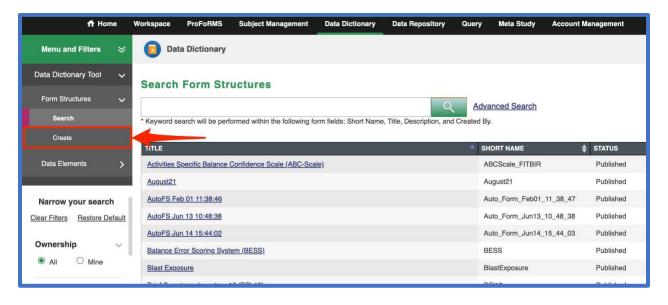
To be able to create form structures in BRICS, you should have the permissions to do that in Data Dictionary. Permissions/privileges are assigned to the user when he/she is requesting an account to the BRICS instance.

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





3. 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**:

📅 Home	Workspace	ProFoRMS	Subject Management	Data Dictionary	Data Repository	Query	Meta Study	Account Management	
Menu and Filters 🛛 💝	Dat	ta Dictionary							
Data Dictionary Tool 🗸	1. Bas	lic Information	2. Documentation	3. Data	Elements	4. Permission:	s 5. R	keview	
Search	Create	Form Stru	cture						
Create			grouping/collection of vario re linked together for collec		nents (CDE) and data	elements used	d to gather inform	ation for a study. A form structure is analogous to a case report form (CRF) (c	electronic or
Data Elements >	Fill out the d	letails below to cre	ate a form structure. On th	e following pages, yo	u may attach data eler	ments and app	ly permissions.		
eForms >	General I Fields marke	Details ed with a * are req	uired.						
		Title	••[]		
		Short Name	•:[]		
		Description	:			1.			
		Disease	*: Spinal Cord Injury Spinal Muscular Atro Stroke Traumatic Brain Injur						
		Organizatio	n:				1		
		Form Type	· Select One -			~	~		
		Standardization	· : - Select One -			~	-		
		Lab	- Select One or More February January NEUROPATH ASSE			1			
	Is this a	program Require Form?	nd O Yes 🖲 No						
	Do	es this represent opyrighted form?	a O Yes O No						
		Versio							
			s: Draft y: Rutherford, John						
		Created Dat							
	CONTINU	JE Cancel							

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 torepresent the standard instrument, its title must contain the name of the instrumentand 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 clickto 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.

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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.

🕇 Hom	•	Workspace	ProFoRMS	Subject Management	Data Dictionary	Data Repository	Query	Meta Study	Account Management	
Menu and Filters	×	📵 Dat	ta Dictionary							
Data Dictionary Tool	~	Search Form	Structures > demol	Me > Edit Form Structure						
Form Structures	~	Data D	Dictionary	/						
Search		1 Dec	ic Information	2. Documentation	3. Data E	lamonte .	4. Permissions	5. Re		
Create		1. bas	ic information	2. Documentation	3. Data E	iements	4. Permissions	5. He	view	
Data Elements	>	Upload	Documen	tations: demoM	e					
eForms	>								-	
		Delete	dit							Search: 🕶
		MAI NAI	ME					ТҮРЕ	DESCRIPTION	¢
10						٨	No data available	in table		
		Showing 0 to	0 0 of 0 entries (0	row selected of 0)						First Pravious Next Last
		CONTINU	E Review Ca	ncel						

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:

- F	Form Administration (Appears Up To 1 Time)				
#	TITLE	SHORT DESCRIPTION	VARIABLE NAME	REQUIRED?	ТҮРЕ
1	Context type	The context to which the questions were answered	ContextType	Recommended	CDE
2	Context type other text	The free-text related to ContextType specifying other text	ContextTypeOTH	Recommended	CDE
3	Data source	Source of the data provided on the case report form	DataSource	Recommended	CDE
4	<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:

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.

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":

Menu and Filters ⇒	Data Dictionary				
Data Dictionary Tool 🗸 🗸	Search Data Elements				
Form Structures	Search Locations -	Q Advanced Se	arch		
Data Elements 🗸 🗸					
Search	Show 25 V entries			RESET ALL D	OOWNLOAD ALL 4762 RESULTS
Create	TITLE	VARIABLE NAME	TYPE	MODIFIED DATE	STATUS
Import	12-item Short Form Health Survey Version 1 (SF-12v1) - Times calm peaceful scale_CR	SF12TimesCalmPcfulScaleModCR	UDE	2019-07-18	Published
eForms >	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
larrow your search	36-item Short Form Health Survey. (SF-36) - Bodily pain score ()	SF36BodyPainScore_jeng2	CDE	2022-04-06	Draft
ar Filters Restore Default	36-Item Short Form Health Survey (SF-36) - Bodily pain score ()	SF36BodyPainScore_jeng1	CDE	2021-09-30	Published
vnership All	36-item Short Form Health Survey (SF-36) - Cut time on work activities emotional problems 1 indicator	SF36CutTmeWrkActEmotProbInd	CDE	2019-02-01	Published
Mine	36-item Short Form Health Survey (SF-36) - Cut time on work activities physical health indicator	SF36CutTimeWrkActPhyHlthInd	CDE	2019-07-18	Published
odified Date	36-item Short Form Health Survey (SF-36) - Difficulty work activities physical health indicator ()	SF36DiffcltWrkActPhyHlthInd	CDE	2019-07-19	Published
~	36-item Short Form Health Survey (SF-36) - Excellent health score (1)	SF36ExcelHithScore	CDE	2019-07-19	Published
atus	36-item Short Form Health Survey (SF-36) - Expect worse health score f	SF36ExpWorsHithScore	CDE	2019-05-21	Published
Draft					
Awaiting Publication Published	36-item Short Form Health Survey (SF-36) - General health score ()	SF36GenHlthScore	CDE	2020-02-12	Published
Deprecated	36-Item Short Form Health Survey (SF-36) - Health limited bathing dressing score ()	SF36HlthLimtBthDrssScore	CDE	2019-05-08	Published
Retired	36-item Short Form Health Survey (SF-36) - Health limited bending kneeling stooping score ()	SF36HlthLmtBndKnlStpScore	CDE	2019-05-08	Published
ement Type	36-item Short Form Health Survey. (SF-36) - Health limited carrying groceries score ()	SF36HlthLmtCrryGrocryScore	CDE	2019-05-08	Published
Unique Data Element	36-item Short Form Health Survey (SF-36) - Health limited climbing one stair score	SF36HlthLmtClmb1StairScore	CDE	2019-05-08	Published
Common Data Element	36-item Short Form Health Survey. (SF-36) - Health limited climbing several stairs score ()	SF36HlthLmtClmbSvrlStairScore	CDE	2019-05-08	Published
ease_⑦	36-item Short Form Health Survey (SF-36) - Health limited moderate activities score 1	SF36HlthLmtModActScore	CDE	2019-05-08	Published
General (For all diseases) Parkinson's Disease	36-item Short Form Health Survey (SF-36) - Health limited vigorous activities score	SF36HlthLmtVigorActScore	CDE	2018-08-03	Awaiting Publication
Traumatic Brain Injury	36-item Short Form Health Survey (SF-36) - Health limited walking miles score	SF36HlthLmtWlkSvrlMilScore	CDE	2018-08-03	Awaiting Publication
more	36-item Short Form Health Survey (SF-36) - Health limited walking one block score ()	SF36HlthLmtWlk1BlckScore	CDE	2018-08-03	Awaiting Publication
pulation	36-item Short Form Health Survey (SF-36) - Health limited walking several blocks score	SF36HithLmtWikSvrlBickScore	CDE	2018-08-03	Awaiting Publication
Adult Pediatric	36-item Short Form Health Survey (SF-36) - Healthy as anybody score 1	SF36HithyAsAnybodyScore	CDE	2018-08-03	Awaiting Publication
Adult and Pediatric					
Preclinical	36-item Short Form Health Survey (SF-36) - Interfered social activities physical emotional problems score	SF36InterfSocPhyEmotScore	CDE	2018-08-03	Awaiting Publication
	36-item Short Form Health Survey (SF-36) - Less accomplished emotional problems indicator ()	SF36LesAccompEmotProbInd	CDE	2018-08-03	Awaiting Publication
	36-item Short Form Health Survey (SF-36) - Less accomplished physical health indicator	SF36LesAccompPhyHithInd	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.

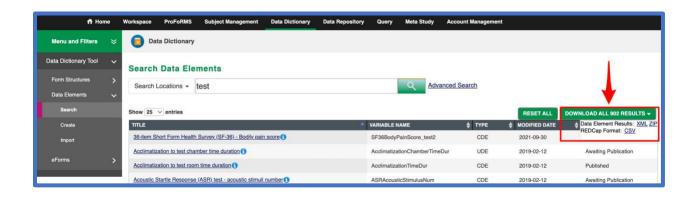
ZIP – downloads the list of DEs as a ZIP file. That is the most used option. The ZIP file has the following name "dataElementDetailExport.zip" contains 2 files:

- "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.





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 <u>4.5.5</u>).
- 2. Select "Edit" from the Menu on the right. Ten 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.

Menu and Filters	*	Data Dictionary	
Data Dictionary Tool	~	Search Data Elements > ABS injury model - distance from detonation measurement value	
Form Structures	>	Common Data Element: ABS injury model - distance from detonation measurement value	Status: Awaiting Publication
Data Elements	~	Listed below are the details for the data element.	Edit
Search		- General Details	Delete
Create		Version: 1.0	Close
Critici		Element Type: Common Data Element	
Import		Title: ABS injury model - distance from detonation measurement value	
eForms	>	Variable Name: ABSDistDetonMeasVal	
		Short Description: Value of measurement of the distance from detonation (in meters, use for open field explosions), as part of ABS injury models	
		Definition: Value of measurement of the distance from detonation (in meters, use for open field explosions), as part of ABS injury models	
		Notes: ABS	
		Creation Date: 2018-04-17	
		Created By: VOVK, OLGA	
		Historical Notes:	
		References: Rodriguez Uylissa A., Zeng Yaping , Deyo Donald , Parsley Margaret A., Hawkins Bridget E., Prough Donald S., and DeWitt Douglas S., Effects of Mild Blast Traumatic Brain injury on Cerebral Vascular, Histopathological, and Behavioral Outcomes in	
		- Basic Attributes	
		Data Type: Numeric Values	
		Input Restrictions: Free-Form Entry	
		Unit of Measure: Meter (Length)	
		Minimum Value: 2	
		Maximum Value: 100	
		External Schema Permissible Value Mapping	
		Population: Preclinical	
		Guidelines/Instructions: Enter value in meters	
		Preferred Question Text: ABS injury model - distance from detonation measurement value	
		+ Documentation	
		+ Category Groups and Classifications	
		+ Keywords and Labels	
		+ Specific Details	
		+ Change History	

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

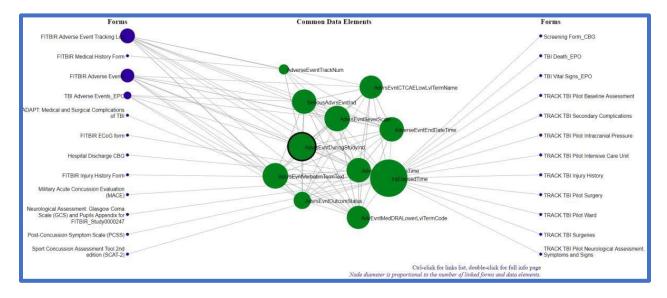
The knowledge graph is available for those DEs, for which the DE linking information was added to the See Also column. It is available in the Data Dictionary and in the Query tool.

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.

ft Hon	ne	Workspace ProFoRMS Subject Management Data Dictionary Data Repository Query Meta Study Account Management					
Menu and Filters		Data Dictionary					
Data Dictionary Tool		Search Data Elements > Acute/subacute gross hemorrhage					
Form Structures	>	Unique Data Element: Acute/subacute gross hemorrhage	Status: Published				
Data Elements		Listed below are the details for the data element.	Knowledge_Graph				
Search		- General Details					
Create		Version: 1.0 Element Type: Unique Data Element					
Import		Title: Acute/subacute gross hemorrhage					
•Forme		Variable Name: NPPATH5					
eForms	>	Short Description: Acute/subacute gross hemorrhage					

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).

ft Ho	ome	Workspace	ProFoRMS	Subject Management	Data Dictionary	Data Repository	Query	Meta Study	Account Management
Menu and Filters		🔁 Dat	ta Dictionary						
Data Dictionary Tool	~								
Form Structures			Data Elem		to alamanta into the d	ata diationany Blaaco c	plast a file to	import data alam	ents to this data structure. Note: The selected file must be in CSV format.
Data Elements				nay download the Import Te		ata ulcilolialy. Piease si	elect a file to	import data elem	enis lo uns data su doure. Note, me selected me must be in 034 ionnat.
Search			Fi	e: Choose File No file	chosen				
Create		UPLOAD							
Import									
eForms									

- 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:

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- **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: BPAQProvokedHitScl10.

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:

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- 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 arealphanumeric), 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 setappropriate 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 validvalues by inputting a minimum and maximum value.
- 2. Only input data to these fields for Data Elements with Datatype: Numeric Valuesand 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 anew 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 4000characters, 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 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 10where 1=Never and 10=All the time, then the PV Description would showNever 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-DefinedValues 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 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. Orit should be left blank if the instrument publisher insists of not providing the question text.

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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, <u>disease category</u>, 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

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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	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, defined meaning or subjective	Score
Site	Alphanumeric	measurement the field to describe the area (not	Site
Source Alphanumeric th so		anatomic) the text describing where something is available or referenced	Source
Status	Alphanumeric	the condition or state at a particular time	Stat or Status

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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
Туре	Alphanumeric	the enumerate descriptive information to identify an item	Тур
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