



BRICS

Biomedical Research
Informatics Computing System



2023 BRICS WG SEMINAR

Biomedical Research Informatics Computing
System (BRICS)

November 8th, 2023





Audio/Video	Please keep your microphone muted
Recording	<ul style="list-style-type: none">• Today's seminar will be recorded• Will be posted on the BRICS website: https://brics.cit.nih.gov/
Break	<ul style="list-style-type: none">• There is one (15) minute break midway through today's seminar• Scheduled for 10:20-10:35 am
Questions & Comments	<ul style="list-style-type: none">• We encourage your participation today• Please use the chat for questions & comments. The chat will be monitored throughout today's seminar.• There will also be time after each speaker and at the end of the seminar to ask live questions.



Time	Topic	Speaker(s)
9:00-9:10	Logistics Introduction	Alison Garcia Dr. Matthew McAuliffe
9:10-9:40	Innovative approach to clinical trials research: The NIH BRICS Unified platform	Dr. Dominic Nathan
9:40-10:00	BRICS: Data Science Platform for Accelerating Discovery	Dr. Matthew McAuliffe
10:00-10:20	BRICS: Advancing FAIR Data Principles and NIH's 2023 Data Sharing Plan	Dr. Olga Vovk Dr. Henry Ogoe
10:20-10:35	BREAK	
10:35-11:00	NIA Use Case API Query Tool- Using Python/R	Fatima Irfan Dan Gillis
11:00-11:20	FITBIR Use Case	Dr. Nsini Umoh
11:20-11:40	PDBP Use Case PDBP Google Cloud Migration	Andrea Lutz Kristine Treece
11:40-12:00	Questions & Closing Remarks	Alison Garcia Dr. Matthew McAuliffe



Chief, Scientific Application Services (SAS)

Dr. McAuliffe has been at NIH since 1998 and is currently the Chief of the Scientific Application Services (SAS) section in the Office of Scientific Computing Services (OSCS). He provides computational and engineering expertise to a variety of clinical and biomedical informatics activities at NIH and is committed to supporting data sharing and making data **FAIR** (Findable, Accessible, Interoperable, and Reusable). He leads the development of the Biomedical Research Informatics Computing System (BRICS) (<http://brics.cit.nih.gov/>) which is a comprehensive data informatics system designed to efficiently collect, validate, harmonize, and analyze research datasets.

In addition, Dr. McAuliffe strives to advance and empower scientific imaging research in the NIH intramural program, to this end, SAS has created and continues the development of the successful Medical Image Processing Analysis and Visualization application (MIPAV: <http://mipav.cit.nih.gov>).



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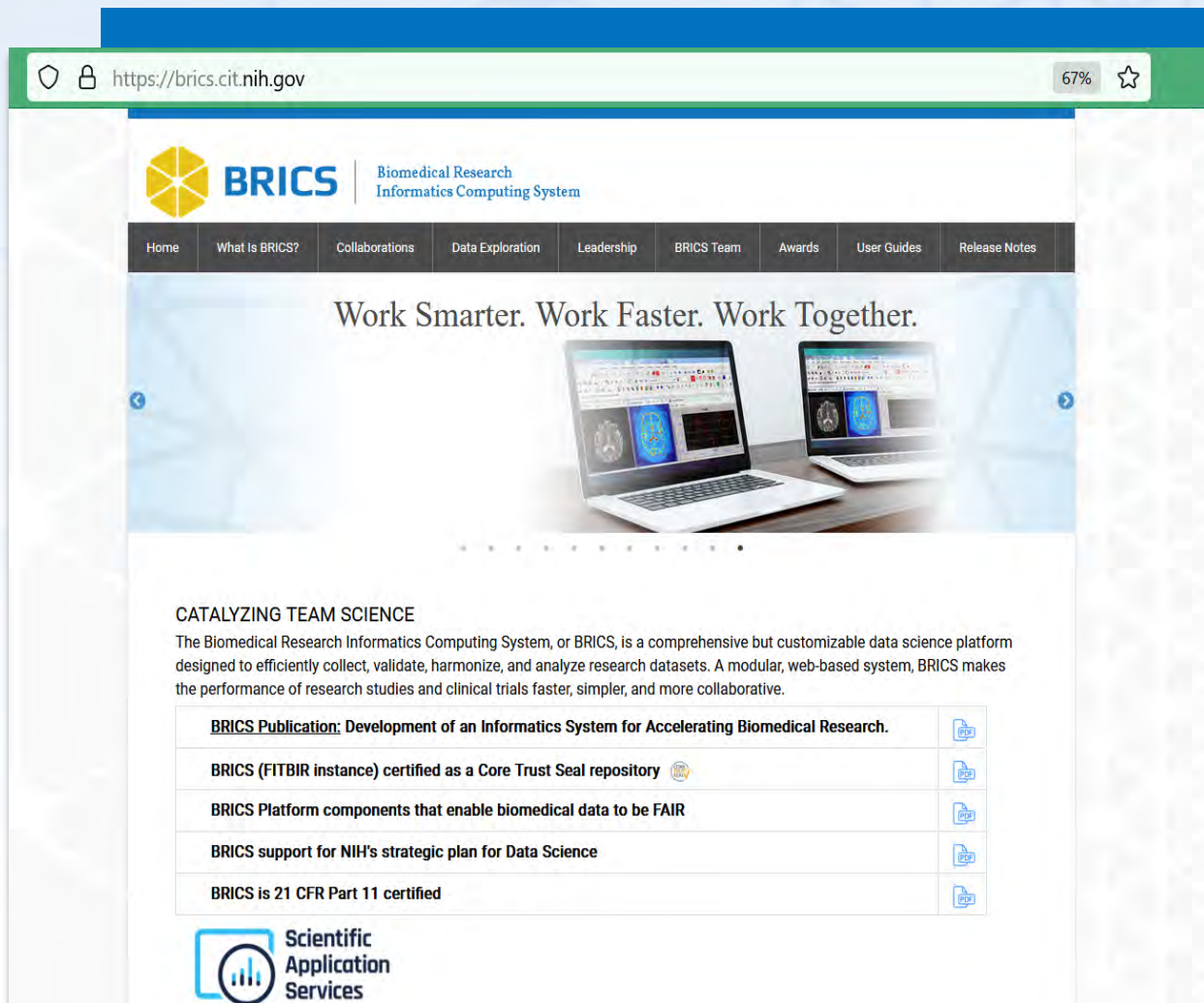
BRICS - Brief Introduction

Matthew J. McAuliffe, PhD (Biomedical Engineering)
Chief, Scientific Applications Services (SAS), CIT



MTBI²





The screenshot shows the BRICS website homepage. At the top, there is a navigation menu with links: Home, What Is BRICS?, Collaborations, Data Exploration, Leadership, BRICS Team, Awards, User Guides, and Release Notes. Below the menu is a large banner with the text "Work Smarter. Work Faster. Work Together." and an image of two laptops displaying data visualizations. Underneath the banner, there is a section titled "CATALYZING TEAM SCIENCE" with a paragraph describing the BRICS platform. Below this is a list of five items, each with a PDF icon to its right:

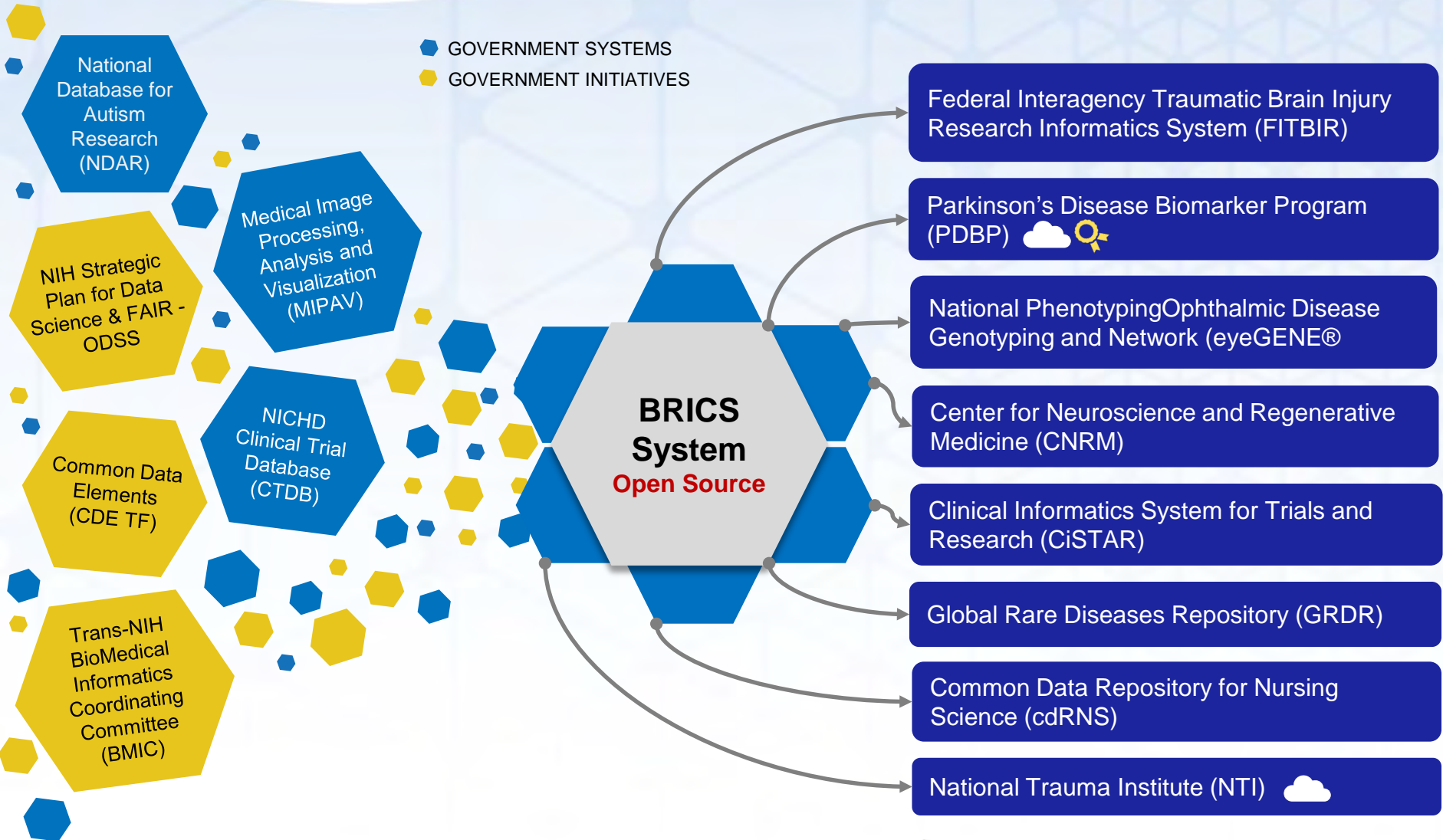
- BRICS Publication: Development of an Informatics System for Accelerating Biomedical Research.**
- BRICS (FITBIR instance) certified as a Core Trust Seal repository**
- BRICS Platform components that enable biomedical data to be FAIR**
- BRICS support for NIH's strategic plan for Data Science**
- BRICS is 21 CFR Part 11 certified**

At the bottom left of the page, there is a logo for "Scientific Application Services" featuring a stylized bar chart icon.



Building from existing projects

- GOVERNMENT SYSTEMS
- GOVERNMENT INITIATIVES



14th Annual Excellence.gov Awards Overall winner

BRICS Statistics Across Instances

















NATIONAL INSTITUTE OF
NEUROLOGICAL
DISORDERS AND STROKE**~150****VIRTUAL
SERVERS****300+****RESEARCH
STUDIES****Close to
300K****RESEARCH
PARTICIPANTS****7M+****RESEARCH
RECORDS**



Data fabric (Single BRICS instance): a data fabric is a single environment consisting of a unified architecture, and services or technologies running on that architecture, that helps organizations manage their data. The ultimate goal of data fabric is to maximize the value of your data and accelerate digital transformation

Data mesh – Ecosystem (multiple BRICS instances, Other Repos): Data mesh emphasizes data decentralization, autonomy, and productization. It's ideal for complex, large-scale data ecosystems where multiple domain teams must work independently and share data products. (RAS, FHIR, CDE, GA4GH –DRS)

Data lake (Meta Study) a centralized repository that allows you to store all your structured and unstructured data at any scale. You can store your data as-is, without having to first structure the data, and run different types of analytics—from dashboards and visualizations to big data processing, real-time analytics, and machine learning to guide better decisions.

 FITBIR <small>Federal Interagency Traumatic Brain Injury Research Informatics System</small>	 PDBP	 cdRNS <small>Common Data Repository for Nursing Science</small>	 eyeGENE®	 NIH National Institute on Aging	 NIH National Institute of Neurological Disorders and Stroke	 NIH National Center for Advancing Translational Sciences	
FITBIR	PDBP	cdRNS	eyeGENE	NIA	NINDS	GRDR	BRICS Intramural
Accounts	Accounts	Accounts	Accounts	Accounts	Accounts	Accounts	Accounts
ProFoRMS	ProFoRMS	ProFoRMS	ProFoRMS				ProFoRMS
Subject Mgmt.	Centralized Global Unique Identifier (GUID:PPRL)						Subject Mgmt.
Shared Data Dictionary		Data Dictionary	Data Dictionary				Data Dictionary
Data Repository	Data Repository	Data Repository	Data Repository				Data Repository
Query	Query	Query	Query				Query
Meta Study	Meta Study	Meta Study	Meta Study				Meta Study
							
On Premise	Cloud	On Premise	On Premise	On Premise	On Premise	On Premise	On Premise

Datatypes: Phenotypic, Imaging, and Omics

Interactive exploration of BRICS Studies, CDEs and Forms across all BRICS instances

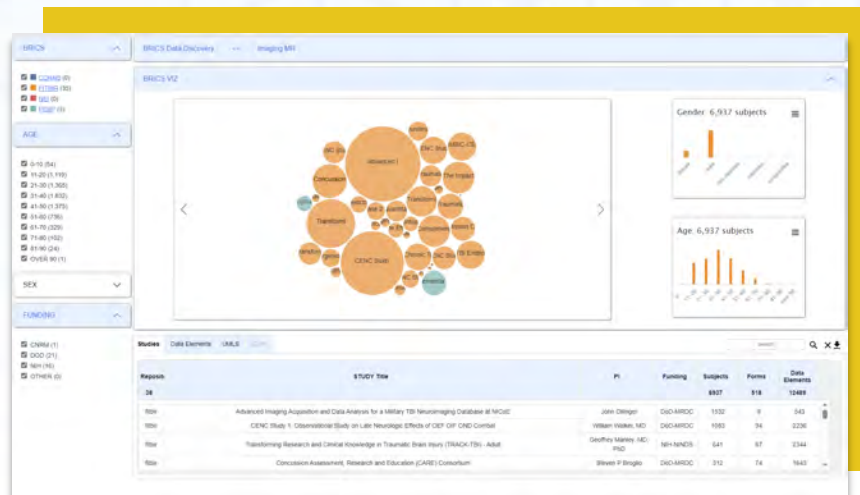
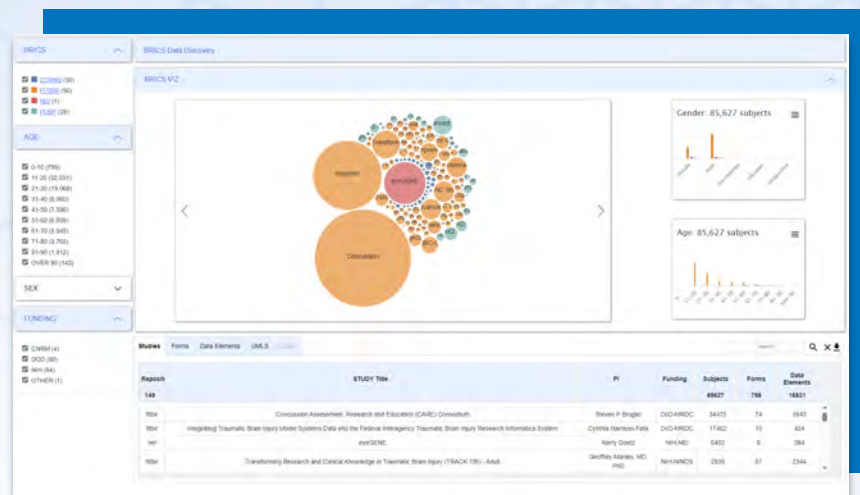
- CDRNS, FITBIR, NEI, PDBP, etc.

Find common FORMS / CDEs and explore how they're used across instances

- Which studies use common forms/CDEs
- See study participant demographic information by form/CDEs

Match CDEs through UMLS codes across instances

- Find CDEs with matching UMLS codes and see commonality / subject demographic information across instances





Dominic E. Nathan, PhD
Informatics Core Director
Military Traumatic Brain Injury Initiative

Dr. Dominic Nathan currently serves as the Bioinformatics Director for the Military Traumatic Brain Injury Initiative (MTBI2), [as a contractor]. Dr. Nathan manages inter-agency collaborative research information systems and resources to support MTBI2 and NIH research, clinical trials, and various repositories; where he has developed informatics infrastructure and tools and in an accelerated timeline to meet critical needs. Dr. Nathan completed post-doctoral training at Walter Reed National Military Medical Center, the Uniformed Services University of the Health Sciences and the NIH. Dr. Nathan is an adjunct professor at the USUHS and a research collaborator at the NIH. His past non-academic experience includes developing and managing an enterprise IT program for a fortune 500 company, and managing a stroke research lab at the VA. Dr. Nathan serves on several national and international biomedical engineering advisory committees, and he is a reserve officer in the US Public Health Service Commissioned Corps. Dr. Nathan's research interests are in advancing translational clinical research and applications.



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Innovative approach to clinical trials research: The NIH BRICS Unified Platform

Dominic E. Nathan, PhD

Bioinformatics Director,

Military Traumatic Brain Injury Initiative

Uniformed Services University of the Health Sciences

(Contractor)



MTBI²



PDBP
Parkinson's Disease
Biomarkers Program

NATIONAL INSTITUTE OF
NEUROLOGICAL
DISORDERS AND STROKE





“The presenter has no conflicts of interest to disclose. The views, information or content, and conclusions presented do not necessarily represent the official position or policy of, nor should any official endorsement be inferred on the part of, the Uniformed Services University, the Department of Defense, the U.S. Government, Department of Health and Human Services, National Institutes of Health, or the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc.”



- Emphasis on practical applications for direct care/treatment
- Very diverse and rich areas of clinical trials
 - Growing number of disparate data sources
 - Large amounts of data
 - Increasing burden (admin, support, regulatory resource, financial cost)
- Increasing use of AI and multi-modal analytics
- Systems:
 - Multiple siloed, localized systems (institutes, centers and labs)
 - Disparate and unequal resources
 - A uniform solution across the NIH is absent
- Data collection practices are highly variable, and curation is not emphasized
- Limited ROI for research investments

An unspoken research problem?

- >70% of researchers have tried and failed to reproduce another scientist's experiments ++
- >50% have failed to reproduce their own experiments ++
- Best-known reproducibility analyses, from psychology and cancer biology, found rates of around 40% and 10%, respectively ++



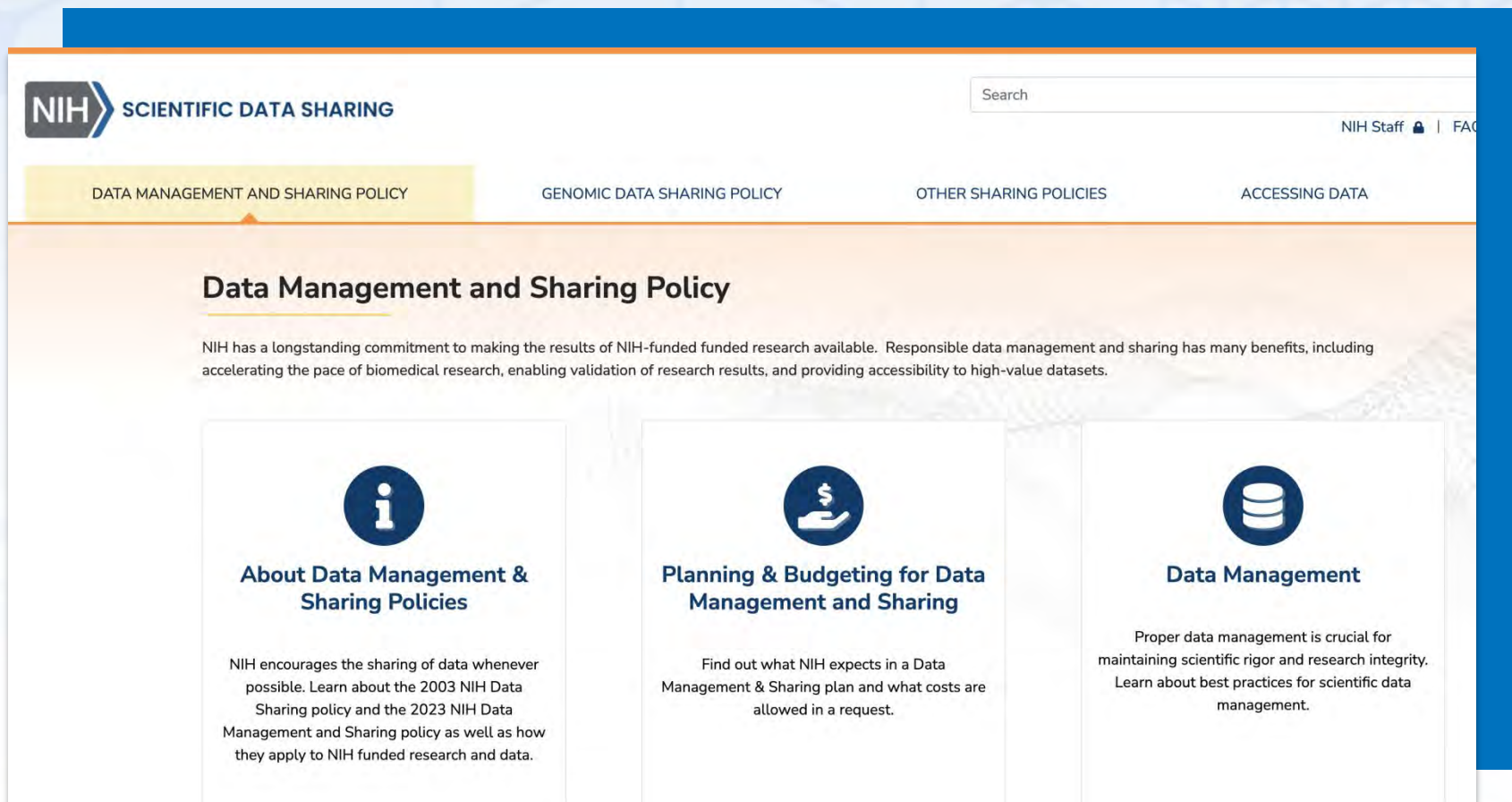
If you torture the data long enough, it will confess to anything
~ Ronald Coase



It is irresponsible to support research but not data stewardship,
says Barend Mons.

Barend Mons

++Baker, M. 1,500 scientists lift the lid on reproducibility. *Nature* **533**, 452–454 (2016). <https://doi.org/10.1038/533452a>



The screenshot shows the NIH Scientific Data Sharing website. At the top left is the NIH logo and the text "SCIENTIFIC DATA SHARING". To the right is a search bar and user information "NIH Staff | FAC". Below the header is a navigation menu with four items: "DATA MANAGEMENT AND SHARING POLICY" (highlighted), "GENOMIC DATA SHARING POLICY", "OTHER SHARING POLICIES", and "ACCESSING DATA". The main content area features a heading "Data Management and Sharing Policy" followed by a paragraph: "NIH has a longstanding commitment to making the results of NIH-funded funded research available. Responsible data management and sharing has many benefits, including accelerating the pace of biomedical research, enabling validation of research results, and providing accessibility to high-value datasets." Below this are three columns, each with an icon and a title: 1. Information icon: "About Data Management & Sharing Policies" with text: "NIH encourages the sharing of data whenever possible. Learn about the 2003 NIH Data Sharing policy and the 2023 NIH Data Management and Sharing policy as well as how they apply to NIH funded research and data." 2. Budget icon: "Planning & Budgeting for Data Management and Sharing" with text: "Find out what NIH expects in a Data Management & Sharing plan and what costs are allowed in a request." 3. Database icon: "Data Management" with text: "Proper data management is crucial for maintaining scientific rigor and research integrity. Learn about best practices for scientific data management."

Study 1

PLANNING

HYPOTHESIS/GOALS

DATA TO BE COLLECTED

DATA ACCESS

COLLECTION INSTRUMENTS



EXECUTION

DATA COLLECTION

ANALYSIS

QA/QC

PUBLICATION

CLOSE OUT

STORAGE

Study 2

PLANNING

HYPOTHESIS/GOALS

DATA TO BE COLLECTED

DATA ACCESS

COLLECTION INSTRUMENTS



EXECUTION

DATA COLLECTION

ANALYSIS

QA/QC

PUBLICATION

CLOSE OUT

STORAGE



Rethinking Protocol Design: Emphasis on Curation

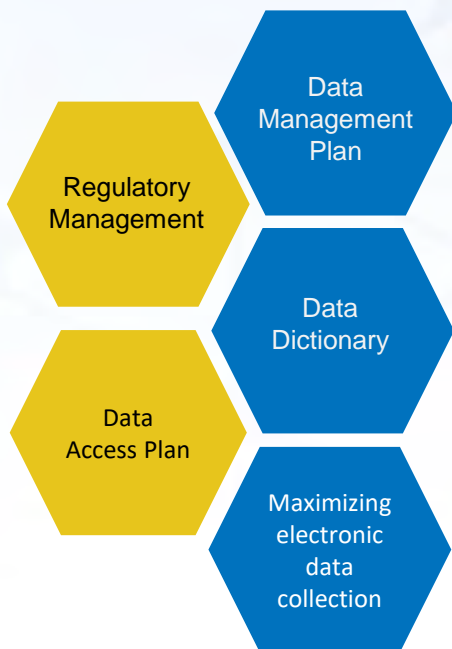
PLANNING

HYPOTHESIS/GOALS

DATA TO BE COLLECTED

DATA ACCESS

COLLECTION INSTRUMENTS



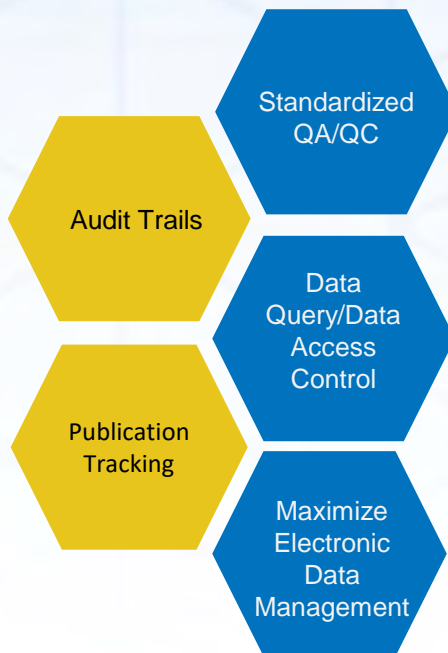
EXECUTION

DATA COLLECTION

ANALYSIS

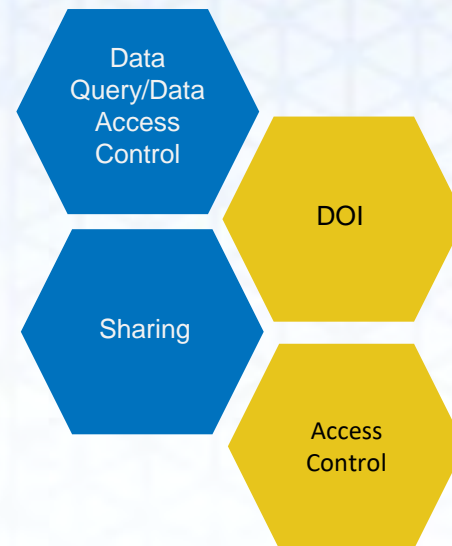
QA/QC

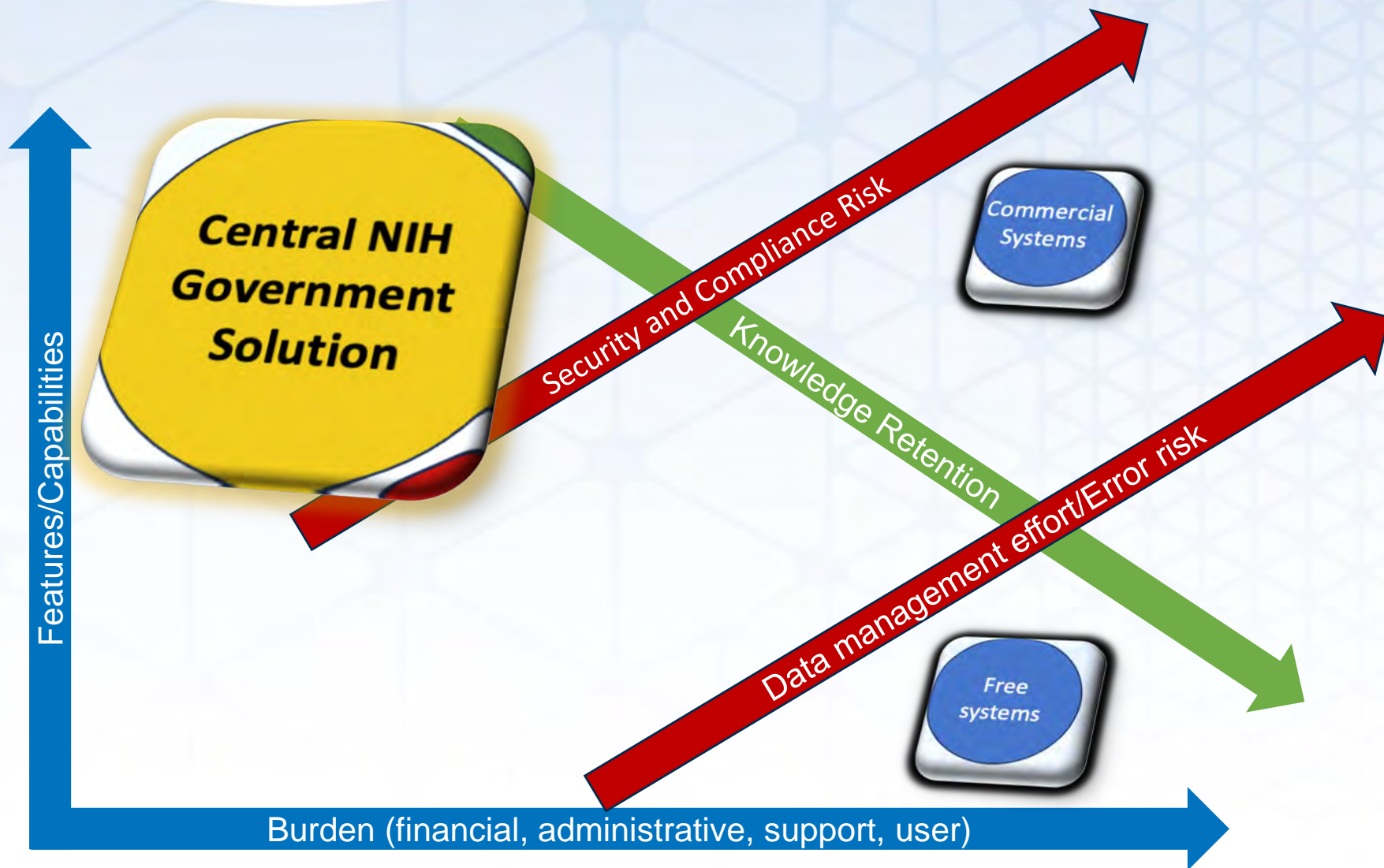
PUBLICATION



CLOSE OUT

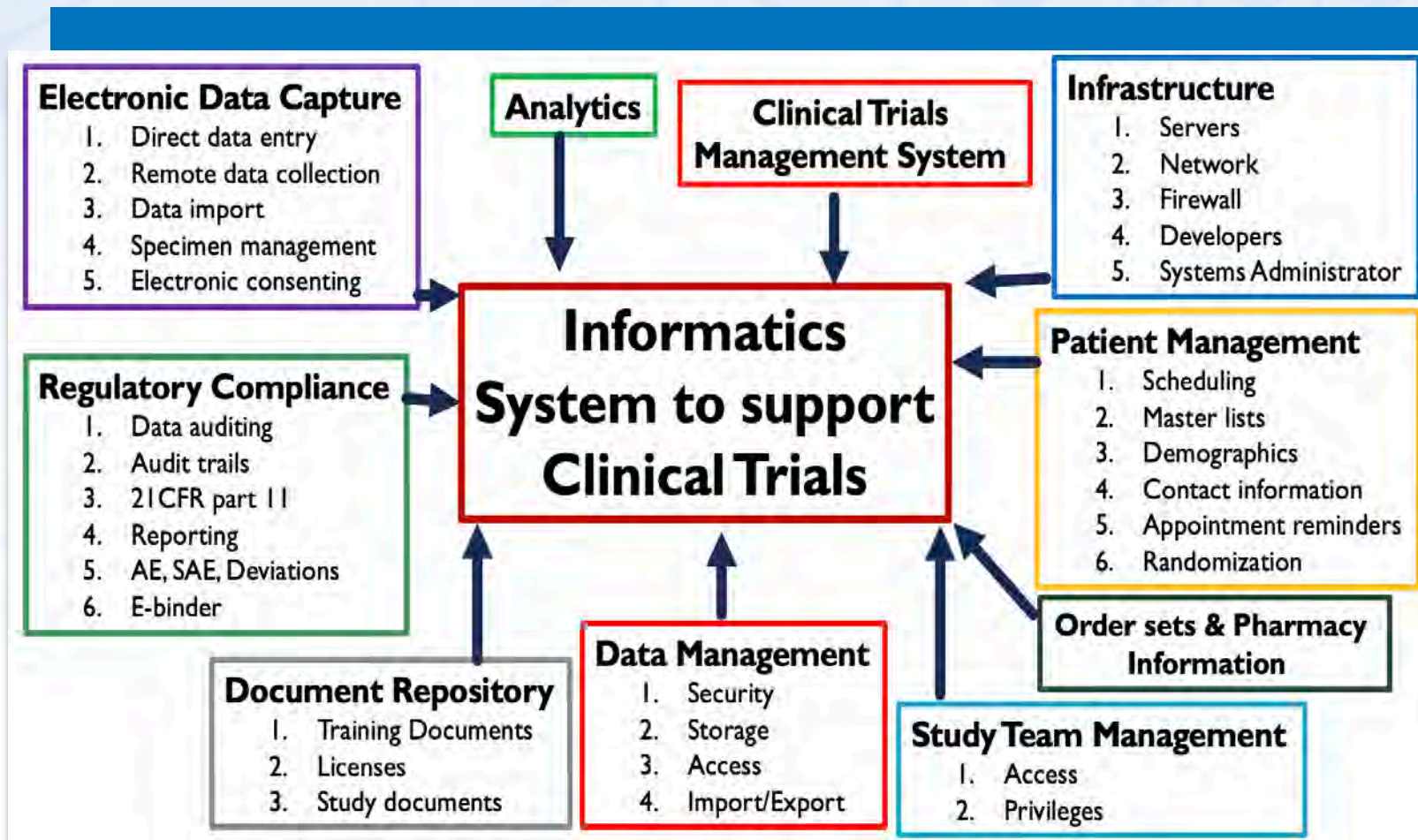
STORAGE



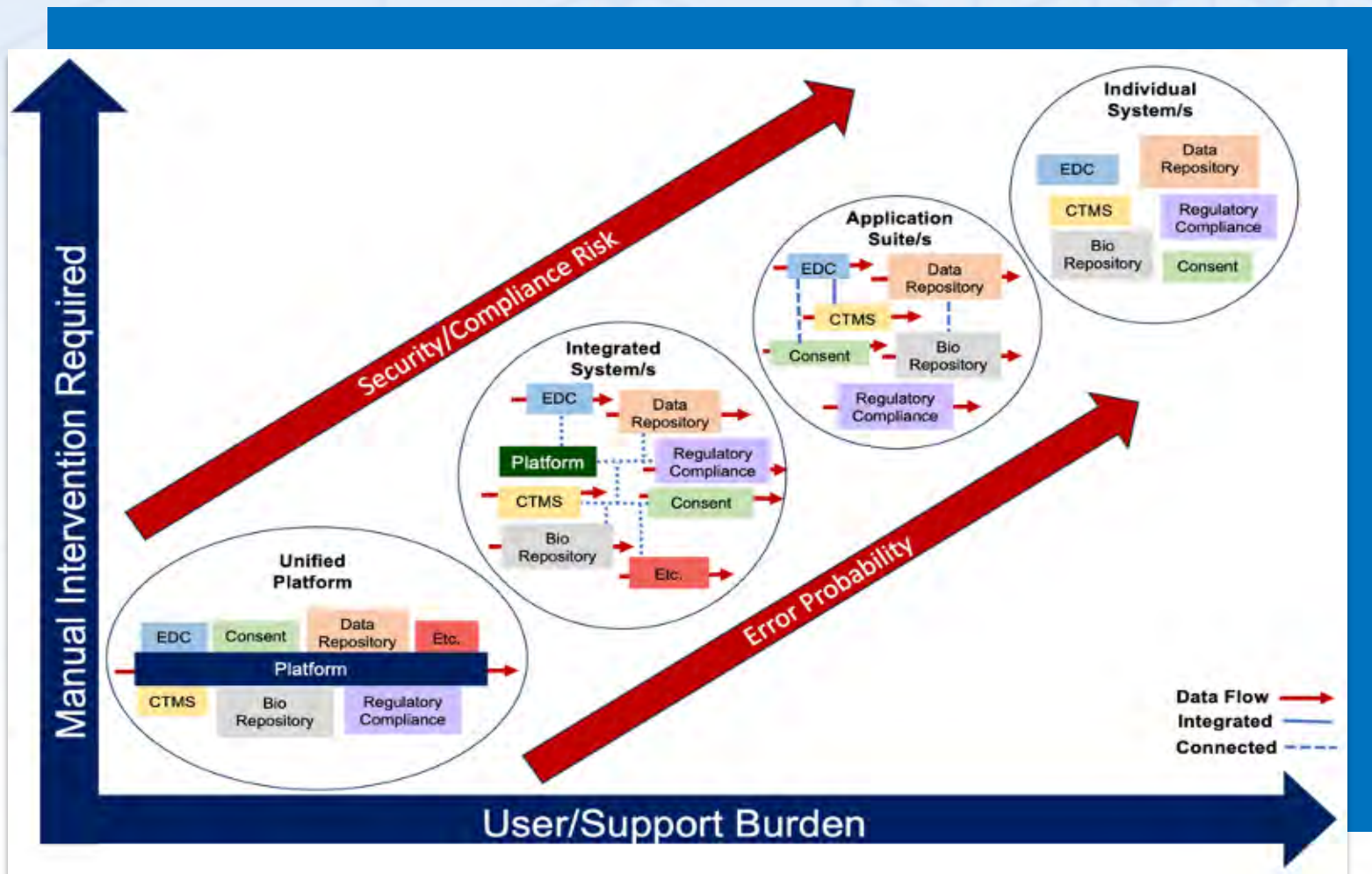




Informatics considerations for clinical trials



Why a Unified PLATFORM?



- Collaborative NIH CIT, NIH NINDS, DoD platform
- Secure comprehensive web-based electronic data capture, storage, analytics and sharing platform
- Defined and documented data structures, conforms to NIH CDE guidelines for data collection and harmonization
- Fast Healthcare Interoperability Recourses (FHIR)
- Available API for more dynamic data analysis including AI and ML applications.
- Role based permissions and access
- Fulfills regulatory compliance needs
- Inbuilt subject management capabilities
- Ability to import and host any data
- BRICS is un-branded and un-associated with a particular disease or organization, it is highly customizable
- 21 CFR Part 11 compliant, and meets other federal regulatory requirements for clinical trials research
- Ability to pull data from CRIS via BTRIS

Plug & Play Components for the Full Research Lifecycle

BRICS offers researchers a secure platform and a suite of web-based and downloadable tools that can be shared across disease categories or deployed and branded independently, depending on the needs of your program.



Data Mapping & Transformation

Tool that translates data into CDEs used by BRICS to prepare for validation



Data Dictionary

Intelligent clinical research data dictionary that supports cross-system exchange



Data Repository

Functionality to define and manage studies and contribute or store data



ProFoRMS

Module for electronic data capture, subject management, and scheduling



Meta Study

Workspace that aggregates data and metadata across studies for reference



Global Unique Identifier

Cross-study Privacy Preserving Record Linkage System (PPRLS)

Continues...



Query

Tool enabling filtering of submitted data using data elements and form structures



Clinical Trials Management System (CTMS)

Management of Clinical Trials by enabling insight into trial performance.



BRICS Imaging Tools

Enables quantitative analysis and viewing of medical images, such as PET, MRI, CT, or microscopy.



Forum

Discussion board for account users for posting messages, interacting with each other, and discussing various topics



Account Management

Create, approve, and manage user accounts.



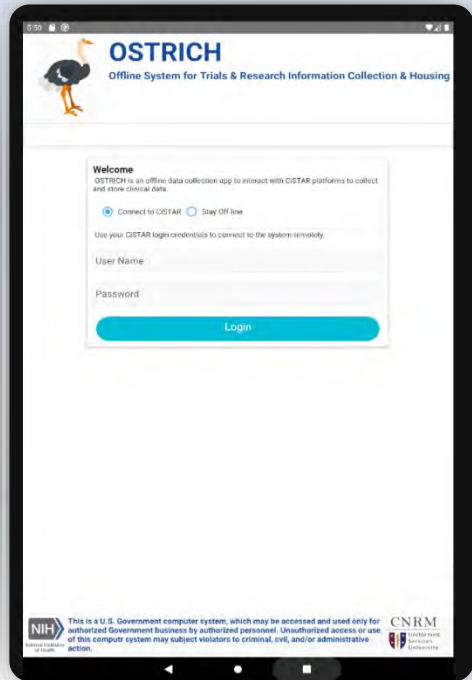
InET

Application for assigning new training, tracking current training, licenses and compliance.



Specimen Tracking and Management System (STAMS)

STAMS provides the path to container storage locations (e.g. freezer) that guides the user to the specific container and sample.



1. Collection occurs via electronic case report forms (eCRFs/eforms)
2. E-forms:
 - Standard forms
 - Non-standard/unique forms
3. Includes PROMIS library and measures (CAT assessments)
4. In built workflow for QA/QC – individual form locking
5. Full audit trail for data collection
6. Output data in PDF or CSV format
7. Clinical data (Direct pull from BTRIS)
 - Consent information
 - Subject demographics
 - Clinical data – assessments, labs, etc.
8. Offline data collection capabilities





Data Dictionary Form Structure Example

▼ PCL-5 (Appears Up To 1 Time)

#	TITLE	SHORT DESCRIPTION	VARIABLE NAME	REQUIRED?	TYPE
1	<u>PTSD Checklist for DSM-5 (PCL-5) - Memories of stressful experiences scale</u>	Severity scale of repeated, disturbing and unwanted memories of stressful experiences, as part of PTSD checklist for DSM-5 (PCL-5)	PCL5MemoStrsExpSci	Recommended	CDE
2	<u>PTSD Checklist for DSM-5 (PCL-5) - Dreams of stressful experiences scale</u>	Severity scale of repeated, disturbing and unwanted memories of stressful experiences, as part of PTSD checklist for DSM-5 (PCL-5)	PCL5DreamsStrsExpSci	Recommended	CDE
3	<u>PTSD Checklist for DSM-5 (PCL-5) - Upset when being reminded of stressful experiences scale</u>	Severity scale of suddenly feeling or acting as if stressful experiences happen again, as part of PTSD checklist for DSM-5 (PCL-5)	PCL5UpsetRemindStrsExpSci	Recommended	CDE
4	<u>PTSD Checklist for DSM-5 (PCL-5) - Strong physical reaction scale</u>	Severity scale of upset feeling when people remind the subject of stressful experiences , as part of PTSD checklist for DSM-5 (PCL-5)	PCL5StrgPhysicalReactnSci	Recommended	CDE
5	<u>PTSD Checklist for DSM-5 (PCL-5) - Stressful experiences happen again scale</u>	Severity scale of strong physical reactions when people remind the subject of stressful experiences , as part of PTSD checklist for DSM-5 (PCL-5)	PCL5StressfulExpHappenAgnSci	Recommended	CDE
6	<u>PTSD Checklist for DSM-5 (PCL-5) - Avoid memories, thoughts feelings scale</u>	Severity scale of avoiding memories, thoughts and feeling related to stressful experiences , as part of PTSD checklist for DSM-5 (PCL-5)	PCL5AvdMemoThtsFeelingReltdSci	Recommended	CDE
7	<u>PTSD Checklist for DSM-5 (PCL-5) - Avoid external reminders scale</u>	Severity scale of avoiding external reminders of stressful experiences, as part of PTSD checklist for DSM-5 (PCL-5)	PCL5AvdExtalRemindersSci	Recommended	CDE





Please enter subject information, add protocol information and other fields to add a subject.

[-] Subject Information

MRN*	<input type="text"/>	Recruited	<input type="checkbox"/>
Last Name*	<input type="text"/>	Date of Birth	<input type="text" value="Format: YYYY-MM-DD"/>
First Name*	<input type="text"/>		<input type="button" value="Get From BRICS"/>
Birth City	<input type="text"/>	Middle Name	<input type="text"/>
Birth Country	<input type="text"/>	Sex	<input type="text"/>
Home Address 1	<input type="text"/>	E-Mail	<input type="text"/>
Home Address 2	<input type="text"/>	Home Phone	<input type="text"/>
City	<input type="text"/>	Work Phone	<input type="text"/>
State	<input type="text"/>	Mobile Phone	<input type="text"/>
Zip	<input type="text"/>		
Country	<input type="text"/>		



View scheduled visits, add new visits or select a visit to perform an action.
*This symbol indicates a required field

MRN * TestUserE

Date and Time * 2020-05-01 09:00

End Date and Time 2020-05-01 10:00

Visit Type * Baseline

Comments / Notes

Clinical Point * Vivek Mannur - test procedure 0001 - Vivek Mannur

Visit Type

- Baseline
- 3 Months
- 6 Months
- Final
- VisitTypeNew
- btris test

Status

- Scheduled
- Scheduled
- Not Scheduled
- Not Scheduled
- Not Scheduled
- Not Scheduled

Baseline

3 Months

6 Months

✓ Final

[+] Scheduled Calendar

Select a date to view schedule: OP5 Headache Assessment. Dr. James Hope

Time	End Time	Clinical Location	Procedure Name	POC
00:00 am	9:13 pm		AVAILABLE	
9:13 pm	11:59 pm	Vivek Mannur	test procedure 0001	Vivek Mannur
		7T MRI	Brain Scan	Scott Samuel

Time: 09:00

Hour: _____

Minute: _____

✓ -----

OP5 Headache Assessment Dr. James Hope

7T Spine Scan Dr. Sarah Summers

Scheduled Visits

Search: _____

MRN	Last Name	First Name	Visit Type	Date and Time	Self Reporting Token	Comments / Notes
<input type="checkbox"/>	TestUserE	UserE	Baseline	2019-07-24 12:54		
<input type="checkbox"/>	TestUserE	UserE	3 Months	2019-06-26 16:03		

Showing 1 to 2 of 2 entries (0 row selected of 2)

Baseline

3 Months

6 Months

✓ Final

✓ -----

OP5 Headache Assessment Dr. James Hope

7T Spine Scan Dr. Sarah Summers





Generate Schedule

Duration: Start Date End Date

Schedule Filters:

Protocol

Clinical Location

Subject

Generate Report

Protocol Number	Patient ID (MRN / GUID / Subjectid)	Patient Name	Visit Type	Visit Date / Time	Procedure	Clinical Location	Point Of Contact	Comments / Notes
VIVEK_002	Patient_1 / CISTARUA812CL8 / Patient_1	1, Patient	Baseline	2019-05-29 00:00:00	test procedure 0001	OP5	Vivek Mannur	
VIVEK_002	Patient_1 / CISTARUA812CL8 / Patient_1	1, Patient	3 Months	2020-01-31 11:11:00	60cc	CC1	Vivek Mannur	
VIVEK_002	Patient_1 / CISTARUA812CL8 / Patient_1	1, Patient	Final	2019-07-26 13:21:00	60cc	OP5	Vivek Mannur	
VIVEK_002	Patient_1 / CISTARUA812CL8 / Patient_1	1, Patient	6 Months	2019-06-24 12:46:00	HAM Brain	CC1	Vivek Mannur	
VIVEK_002	Patient_1 / CISTARUA812CL8 / Patient_1	1, Patient	3 Months	2019-05-29 00:00:00	60cc	OP5	Vivek Mannur	
VIVEK_002	Patient_2 / CISTARUH677BCX / Patient_2	2, Patient	brtis test	2020-05-20 21:13:00	test procedure 0001	CC1	Vivek Mannur	



SIGNATURE OF PARTICIPANT

BY SIGNING THIS CONSENT FORM, YOU FREELY AGREE TO TAKE PART IN THE RESEARCH IT DESCRIBES I agree to take part in the research described in this consent form.

Printed Name of Participant

Sarah Summers

Participant's Signature

Date and Time

2020-06-24. 01:25 PM

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT

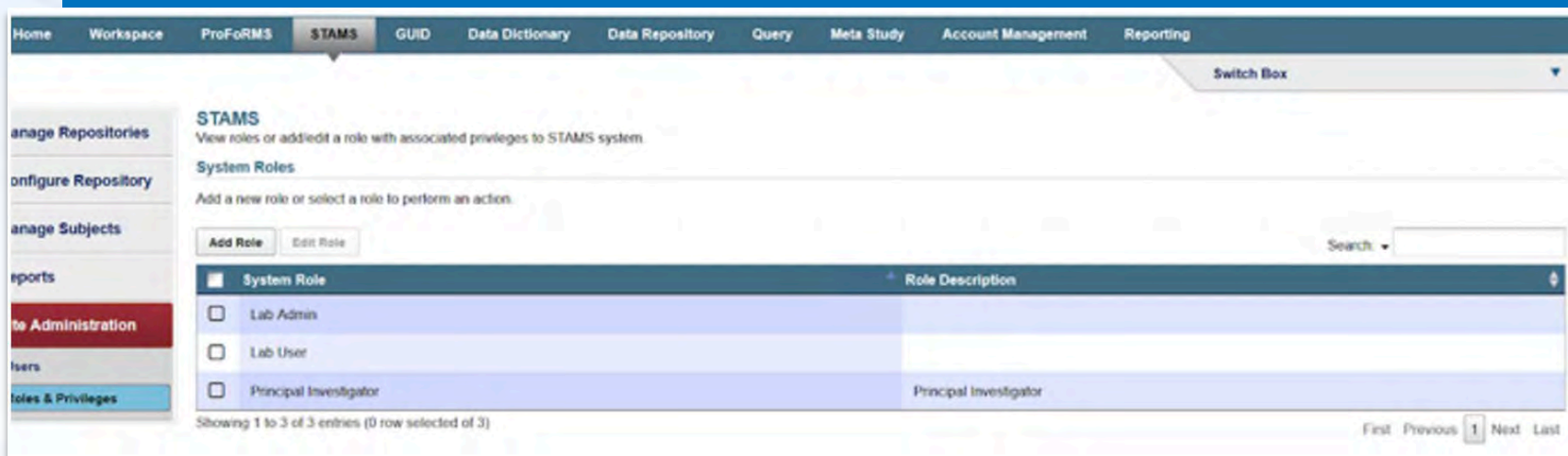
Printed Name of Administering Individual

Janice Joplin

Signature of Administering Individual

Date and time

2020-06-24. 01:25 PM



The screenshot displays the STAMS (System Roles and Privileges) management interface. The top navigation bar includes links for Home, Workspace, ProFoRMS, STAMS (selected), GUID, Data Dictionary, Data Repository, Query, Meta Study, Account Management, and Reporting. A 'Switch Box' is visible on the right. The left sidebar contains menu items: Manage Repositories, Configure Repository, Manage Subjects, Reports, Site Administration (highlighted), Users, and Roles & Privileges (highlighted).

The main content area is titled 'STAMS' and contains the following text: 'View roles or add/edit a role with associated privileges to STAMS system.' Below this is the 'System Roles' section with the instruction 'Add a new role or select a role to perform an action.' There are 'Add Role' and 'Edit Role' buttons and a search field.

<input type="checkbox"/>	System Role	Role Description
<input type="checkbox"/>	Lab Admin	
<input type="checkbox"/>	Lab User	
<input type="checkbox"/>	Principal Investigator	Principal Investigator

Showing 1 to 3 of 3 entries (0 row selected of 3) First Previous 1 Next Last

Option to link samples and clinical data.

Samples Management and Tracking

My Cell Types

Select a cell type to view or perform an action.

Search

Icon	Name	Description	Unit	Cryo Solution	Note	Parent
	Blood Sample	Test	mL		Test	
	Bone Marrow		mL			
	DNA Cell Pellet		mL			

Showing 1 to 3 of 3 entries (1 row selected of 3)

First Previous **1** Next Last

Box1/Rack5/Freezer4

	A	B	C	D	E	F	G	H	I
1		DNA Cell 2		DNA Cell 2	Blood Sa. 1234			DNA Cell 2	
2		Blood Sa. 1234	Blood Sa. 1234	Blood Sa. 1234	Blood Sa. 1234	Blood Sa. 1234	Blood Sa. 1234	Blood Sa. 1234	
3		Blood Sa. 1234	Blood Sa. 1234					Blood Sa. 1234	
4			DNA Cell 2	Bone Mar. 2	Bone Mar. 2	DNA Cell 2		DNA Cell 2	
5		Bone Mar. 2	DNA Cell 2	DNA Cell 2					

Bone Mar. DNA Cell Bone Mar. DNA Cell Bone Mar.

Cell Type Information

Cell/Sample Type Name* Blood Sample

Cell Type Description

Cell Type Note

Cryo Solution

Source/Patient Sample Information

Protocol/Project Number* CISTAR_GENERIC

Source/Patient* Patient B

MRN 12-123-1234

Other Id 1234

Patient Note

Date Collected 2020-05-01

Time Type Base Line

Time Collected (H:MM AM/PM)

Sample Number

Date Drawn 2020-05-12

Date Frozen* 2020-05-12

Time Frozen (H:MM AM/PM)

Frozen By Admin, Portal

Additional Sample Information

Sample Barcode(s)

Position X / Y E/1

Serial No.

TNS Solution

Cells Per Unit 5 /ml

Volume 100 ml

Concentration

Age

Passage Number

Note

Sample Parent Info Independent Sample, No Parent

Sample Tracking Remapping Samples

Processed Person Information:

Sample Processed By or

Menu

ProFoRMS Protocol : MW PROTOCOL

Adverse Events Log

The study team will log Adverse Events associated with the protocol

MRN: 963741

Patient Name: White Snow

Site: [Dropdown]

[-] MedDRA Information

LLT MedDRA Term: Anemia

LLT MedDRA Code: 10002272

SOC MedDRA Term: Blood and lymphatic system disorders

SOC Code: 10005329

[-] CTCAE Information

CTCAE Term: Anemia

CTCAE Definition: A disorder characterized by a reduction in the amount of hemoglobin in 100 ml of blood. Signs and symptoms of anemia may include pallor of the skin and mucous membranes, shortness of breath, palpitations of the heart, soft systolic murmurs, lethargy, and fatigability.

CTCAE Grade: Hgb <8.0 g/dL; <4.9 mmol/L; <80 g/L; transfusion indicated

MedDRA Integration

CTCAE Integration



ProFoRMS

Dashboard VIVEK_002

ProFoRMS Home

Manage Subjects

Collect Data

Manage Protocol

Reports

Protocol Report

Detailed Protocol Report

Without Collections

Forms Requiring

Completion & Lock

Locked Forms

Submission Summary

Form Status

Schedule

Adverse Event

View Auditor Comments

Non-Compliance Report

Site Administration

[-] View Auditor Comments

View Auditor Comments Summary

Download Search:

Subject	E-form	# of Auditor Comments
4321876	Hamilton Anxiety Rating Scale (HAM-A)	3
4321876	Acute Care Panel BTRIS test	2

Showing 1 to 2 of 2 entries First Previous **1** Next Last

View Auditor Comments Details

Download Search:

Subject	E-form	Date/Time	Question Text	Audit Status
4321876	Hamilton Anxiety Rating Scale (HAM-A)	2019-10-24 11:03:16	Age in years	Completed
4321876	Hamilton Anxiety Rating Scale (HAM-A)	2020-06-24 12:01:05	Respiratory symptoms Pressure or constriction in chest choking feelings sighing dyspnea.	In Progress
4321876	Acute Care Panel BTRIS test	2020-06-03 16:10:35	Sodium Value	Completed

Showing 1 to 3 of 3 entries First Previous **1** Next Last

Very severe

*Cardiovascular symptoms Tachycardia palpitations pain in chest throbbing of vessels fainting feelings missing beat.


Not present
 Mild
 Moderate
 Severe
 Very severe

*Respiratory symptoms Pressure or constriction in chest choking feelings sighing dyspnea.

Not present
 Mild
 Moderate
 Severe
 Very severe

*Gastronintestinal symptoms Difficulty in swallowing wind abdominal pain burning sensations abdominal fullness nausea vomiting borborygmi looseness of bowels loss of weight constipation.

Not present
 Mild
 Moderate
 Severe
 Very severe





Audit Comment Response

Audit Comment Response*

Audit Comments History

Search:

Name	Date/Time	Section Name	Data Element Name	Question Text	Answers Before	Answers After	Audit Comment
Nathan, Dominic	2020-06-24 12:01	HAM-A	HAMARespiratorySymptomScore	Respiratory symptoms Pressure or constriction in chest choking feelings sighing dyspnea.		Moderate	This question was blank, was this intentional?

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

Data Collection Audit Log

eForm Name: Headache Diary - CGRP
Protocol Name: Test-102
Subject ID: TBI_INVVA809RTY
Collection Visit Date: 2022-01-19 16:01
Scheduled Visit Date: 2022-01-19 16:01
Visit Type: diary test

Form Summary Status

[Download](#)

 Search:

NAME	DATE/TIME	ACTION	# OF QUESTIONS ANSWERED	E-SIGNATURE
Subject	2022-01-19 16:02	Started		
Subject	2022-01-19 16:02	Completed		Signed

Showing 1 to 2 of 2 entries

 First Previous **1** Next Last

In Progress Entries

[Download](#)

 Search:

NAME	DATE/TIME	SECTION NAME	DATA ELEMENT NAME	QUESTION TEXT	ANSWERS BEFORE	ANSWERS AFTER
Subject	2022-01-19 16:02	Main	GUID	Global Unique ID (GUID) which uniquely identifies the subject:		TBI_INVVA809RTY
Subject	2022-01-19 16:02	Main	VisitDate	Visit date:		2022-01-19 16:01
Subject	2022-01-19 16:02	Main	SiteName	Name of the site:		Twinbrook
Subject	2022-01-19 16:02	Headache Diary	HPFIDDayRecordInfoDate	For what day are you recording information?		2022-01-04
Subject	2022-01-19 16:02	Headache Diary	HPFIDTimeRightNowTxt	What time is it right now:		3
Subject	2022-01-19 16:02	Headache Diary	HPFIDAM_PMTyp	AM or PM		AM
Subject	2022-01-19 16:02	Headache Diary	HATodayInd	Did you have a headache today (select one)?		Yes

Menu ☰

- ProFoRMS Home >
- Manage Subjects >
- Manage Data >
- Manage Protocol ☑
 - Protocol Information
 - Assign Roles
 - Create Visit Type
 - Import Visit Type Group
 - My Visit Types
 - Order Visit Type
 - Configure Data Elements Pre-Population
 - Configure eForm and PVs
 - Configure eForm Display
 - E-Binder
 - Regulatory E-Binder
 - Protocol Close-out
 - Randomization List
 - Reports >
 - Logs >
 - Site Administration >

📄 **ProFoRMS** Protocol : **TEST-102**

Randomization List

Please select a file to import. Note: The selected file must be in CSV format.

For reference purposes, you may download the [Randomization Import Template](#).

File:

Import
InActive

Search:

SEQUENCE	GROUP NAME	GROUP DESCRIPTION	GROUP CATEGORY	SITE NAME
16	SIZE : Placebo	Placebo	Male	WAMC
17	SIZE : Placebo	Placebo	Female	WBAMC
18	SIZE : Drug	Drug	Male	WBAMC
19	SIZE : Drug	Drug	Female	WAMC
20	SIZE : Placebo	Placebo	Female	WBAMC
21	SIZE : Placebo	Placebo	Male	WAMC
22	SIZE : Drug	Drug	Female	BAMC
23	SIZE : Drug	Drug	Male	BAMC

Showing 1 to 15 of 824 entries

First Previous **1** 2 3 4 5 ... 55 Next Last

Menu >

- ProFoRMS Home >
- Manage Subjects >
- My Subjects >
- Add Subject >
- Schedule Visit >
- Import Subjects >
- Import Scheduled Visits >
- Manage Data >
- Manage Protocol >
- Reports >
- Logs >
- Site Administration >

ProFoRMS

Protocol : TEST-102

View subject list, search for a subject, or select subjects to perform an action.

[+] Advanced Search

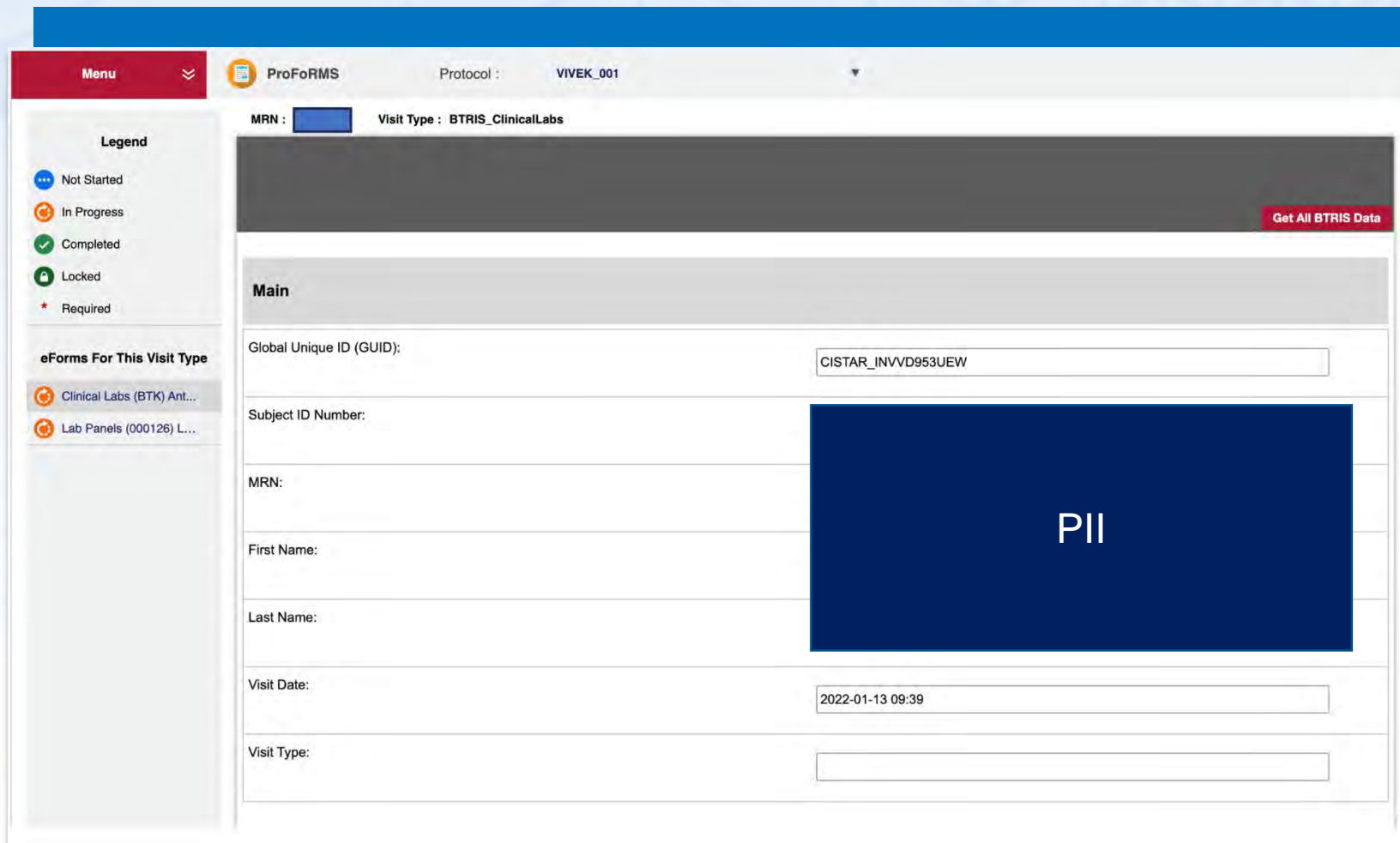
My Subjects

Select a subject to perform an action.

Column Visibility ▾
Edit / Delete
View Patient Info
View Audit
More Actions
Randomization
Download / Export

Search:

☐	SUBJECT ID	LAST NAME	FIRST NAME	ENROLLMENT D	RANDOMIZATION	PASSWORD STATUS	SITE NAME	RANDOMIZATION GROUP NAME	RANDOMIZATION GROUP DESCRIPTION
☐	Test-120	Jane	Doe				NIH	I	Treatment
☐	Test-101	Jane	Doe		Active		NIH	H	Control
☐	Test-105	Test-105	Test-105		Active		NIH	F	Control
☐	Test-103	Test-103	Test-103		Active		NIH	D	Control
☐	Test-102	Test	Test		Active		Twinbrook	C	Treatment
☐	Test-110	Test-110	Test-110		Active		NIH	B	Control
☐	Test-104	Test-104	Test-104		Active		Twinbrook	A	Treatment
☑	4411FD	Day	Fri		Active				
☐	102938	Test	OSTRICH		Active				
☐	382910	Test	PSQI		Active				



Menu

ProFoRMS Protocol : VIVEK_001

MRN : Visit Type : BTRIS_ClinicalLabs

Legend

- Not Started
- In Progress
- Completed
- Locked
- Required

eForms For This Visit Type

- Clinical Labs (BTK) Ant...
- Lab Panels (000126) L...

Main

Global Unique ID (GUID):

Subject ID Number:

MRN:

First Name:

Last Name:

Visit Date:

Visit Type:

[Get All BTRIS Data](#)

CBC with Diff									
WBC Date:	Wed Mar 28 21:16:00 EDT 2018	Value:	5.00	Unit:	K/uL	Range:	4.23-9.07	Indicator:	
RBC Date:	Wed Mar 28 21:16:00 EDT 2018	Value:	5.00	Unit:	M/uL	Range:	4.63-6.08	Indicator:	
HGB Date:	Wed Mar 28 21:16:00 EDT 2018	Value:	12.0	Unit:	g/dL	Range:	13.7-17.5	Indicator:	L
HCT Date:	Wed Mar 28 21:16:00 EDT 2018	Value:	67.0	Unit:	%	Range:	40.1-51.0	Indicator:	H
MCV Date:	Wed Mar 28 21:16:00 EDT 2018	Value:	100.0	Unit:	fL	Range:	79.0-92.2	Indicator:	H
MCH Date:	Wed Mar 28 21:16:00 EDT 2018	Value:	29.0	Unit:	pg	Range:	25.7-32.2	Indicator:	
MCHC Date:	Wed Mar 28 21:16:00 EDT 2018	Value:	32.0	Unit:	g/dL	Range:	32.3-36.5	Indicator:	L
RDW Date:	Wed Mar 28 21:16:00 EDT 2018	Value:	12.0	Unit:	%	Range:	11.6-14.4	Indicator:	

Basic Metabolic Panel

Sodium Date: Thu Aug 15 13:45:00 EDT 2019
 Value: 146
 Unit: mmol/L
 Range: 136-145
 Indicator: H

Potassium Date: Thu Aug 15 13:45:00 EDT 2019
 Value:
 Unit:
 Range:
 Indicator:

Chloride Date: Thu Aug 15 13:45:00 EDT 2019
 Value:
 Unit:
 Range:
 Indicator:

Total CO2 Date: Thu Aug 15 13:45:00 EDT 2019
 Value:
 Unit:
 Range:
 Indicator:

Cr Creatinine Date: Thu Aug 15 13:45:00 EDT 2019
 Value:
 Unit:
 Range:
 Indicator:

BUN Blood Urea Nitrogen Date: Thu Aug 15 13:45:00 EDT 2019
 Value:
 Unit:
 Range:
 Indicator:

Glucose Date: Thu Aug 15 13:45:00 EDT 2019
 Value:
 Unit:
 Range:
 Indicator:

Calcium Date: Thu Aug 15 13:45:00 EDT 2019
 Value:
 Unit:
 Range:
 Indicator:

Phosphorus Date: Thu Aug 15 13:45:00 EDT 2019
 Value:
 Unit:
 Range:
 Indicator:

Alkaline Phosphatase Date: Thu Aug 15 13:45:00 EDT 2019
 Value:
 Unit:
 Range:
 Indicator:

Aspartate Aminotransferase Date: Thu Aug 15 13:45:00 EDT 2019
 Value:
 Unit:
 Range:
 Indicator:

Alanine Aminotransferase Date: Thu Aug 15 13:45:00 EDT 2019
 Value:
 Unit:
 Range:
 Indicator:

Gamma-GT Date: Thu Aug 15 13:45:00 EDT 2019
 Value:
 Unit:
 Range:
 Indicator:

Triglycerides Date: Thu Aug 15 13:45:00 EDT 2019
 Value:
 Unit:
 Range:
 Indicator:

HDL Cholesterol Date: Thu Aug 15 13:45:00 EDT 2019
 Value:
 Unit:
 Range:
 Indicator:

LDL Cholesterol Date: Thu Aug 15 13:45:00 EDT 2019
 Value:
 Unit:
 Range:
 Indicator:

Very Low Density Lipoprotein Cholesterol Date: Thu Aug 15 13:45:00 EDT 2019
 Value:
 Unit:
 Range:
 Indicator:

Multiple Entries in BTRIS

	OBSERVATION NAME	RANGE	VALUE NUMERIC	VALUE TEXT	COMMENT	UNIT OF MEASURE	PRIMARY DATE TIME	Indicator:
<input type="radio"/>	Sodium	136-145	146.0	146	H	mmol/L	2019-08-15T13:45:00-04:00	<input type="text"/>
<input type="radio"/>	Sodium	136-145	145.0	145		mmol/L	2019-02-28T16:38:00-05:00	<input type="text"/>
<input type="radio"/>	Sodium	136-145	145.0	145		mmol/L	2018-05-22T08:26:00-04:00	<input type="text"/>
<input type="radio"/>	Sodium	136-145	150.0	150	H	mmol/L	2018-02-08T14:14:00-05:00	<input type="text"/>

Get BTRIS Data Close

- Change in perspective - protocol development – emphasis on data curation
- Optimal solution maximizing ROI – NIH government solution
- BRICS demonstrates practical applications of research best practices
- Many mature tools (data dictionary, access control, in built QA/QC, etc.)
- Ability to share data with industry harmonization practices
- Robust data management capabilities and access control
- Intuitive features and user interface
- FHIR, API – AI/ML support
- Truly unified platform



Dominic Nathan,
PHD Lead



Lan Wang



Lily Fan



Lloyd Dalias



Mahlet
Wondemagegn



Rohith
Vallabhaneni



Sindhu
Prasannakumar



Siresha Kolla



Sridevi Sharvira



Vivek Mannur



Alaa Haddad



Alex Trudov



Alexander
Burnett



Alexandra
Bokinsky



Alison Garcia



Andrea Lutz



Andy Van Avery



Basir Kader



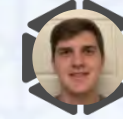
Benjamin
Richmond



Brandi Williams



Christina Nguyen



Colton Farlow



Dagm Sirak



Dan Gillis



Derrick Fox



Erkan Ince



Erik Meyer



Fatima Irfan



Francis Chen



George Popkhadze



Henry Ogoe



Josh Eng



Joshua Park



Kevin Armengol



Krisy Treece



Lakshmi Katuri



Mallisa Johnson



Michelle Harris



Michael Strump



Mihir Bhawe



Nalaka
Premathilaka



Nikhil Chamarthi



Nishith Pandya



Olga Vovk



Priya Raju



Preeti Roy



Rajeev
Nedumpally



Regina Ball



Ronnie Tan



Ryan Stewart-
Frederick



Sanghursh Jain



Scott Mitchell



Sid Ambarkar



Taylor Truong



Tuhin Zaman



Warren Overholt



BRICS

Biomedical Research
Informatics Computing System

**We thank all our users, and
contributors to the various
working groups**





BRICS

Biomedical Research
Informatics Computing System

Questions?



An NIH Data Science Platform for Accelerating Discovery

Matthew J. McAuliffe, PhD (Biomedical Engineering)
Chief, Scientific Applications Services (SAS), CIT





Our Team



SAS Team



Clinical Trials Research Team



Sapient

Federal Staff

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Dominic Nathan,
PhD Lead



Lan Wang



Lily Fan



Lloyd Dalias



Mahlet
Wondemagegn



Megdelawit
Mersha



Rohith
Vallabhaneni



Sindhu
Prasannakumar



Sireesha Kolla



Sridevi Sharvirala



Vivek Mannur



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Alex Trudov



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Bokinsky, PhD



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Erkan Ince



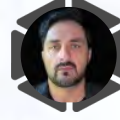
Erik Meyer



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Ronnie Tan



Ryan Stewart-
Frederick



Sanghursh Jain



Scott Mitchell



Sid Ambarak



Taylor Truong



Tuhin Zaman



Warren Overholt



Desired Characteristics For Repositories [NOT-OD-21-016](#)

This supplemental information is intended to help researchers choose data repositories suitable for the preservation and sharing of data (i.e., scientific data and metadata) resulting from National Institutes of Health (NIH)-funded and conducted research. NIH promotes the use of established data repositories because deposit in a quality data repository generally **improves the FAIRness (Findable, Accessible, Interoperable, and Re-usable) of the data.**

Desirable Characteristics for All Data Repositories.

The characteristics in this section are relevant to all repositories that manage and share data resulting from Federally funded research:

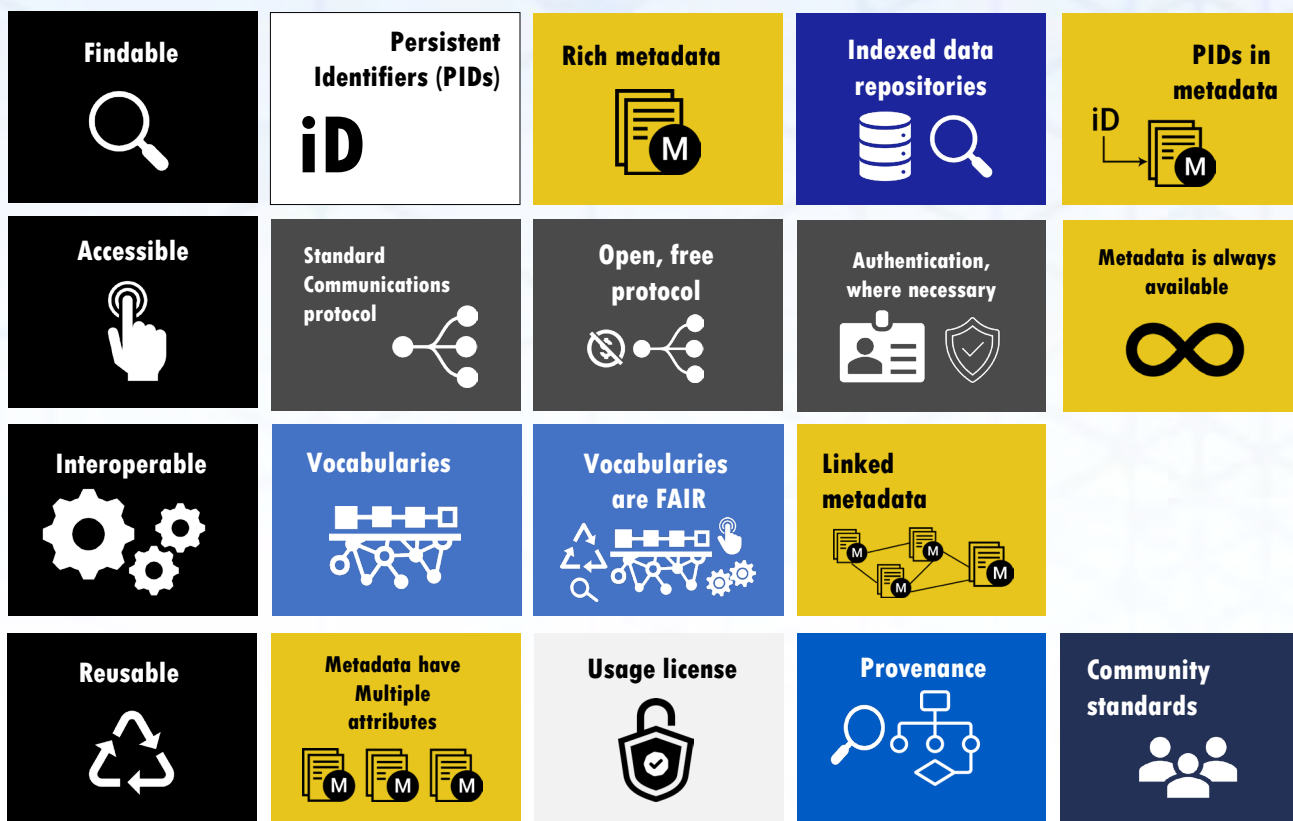
- A. Unique Persistent Identifiers
- B. Long-Term Sustainability
- C. Metadata
- D. Curation and Quality Assurance
- E. Free and Easy Access
- F. Broad and Measured Reuse
- G. Clear Use Guidance
- H. Security and Integrity
- I. Confidentiality
- J. Common Format
- K. Provenance

II. Additional Considerations for Repositories Storing Human Data (even if de-identified)

- A. Fidelity to Consent
- B. Restricted Use Compliant
- C. Privacy
- D. Plan for Breach
- E. Download Control
- F. Violations
- G. Request Review



Committed to compliance with Findability, Accessibility, Interoperability, and Reusable (FAIR) principles for scientific data.





The TRUST Principles

T

Transparency

Public evidence of the repository services offered.

R

Responsibility

Commitment to provide high quality services.

U

User community

Focus on the uses of the data and services offered.

S

Sustainability

Capability to support long-term data preservation & use.

T

Technology

Commitment to infrastructure to support operations.





R16. The technical infrastructure of the repository provides for protection of the facility and its data, products, services, and users.

Compliance Level:

4 – The guideline has been fully implemented in the repository

Reviewer Entry

Reviewer 1

Comments:

4 – The guideline has been fully implemented in the repository
Accept with changes.

Reviewer 2

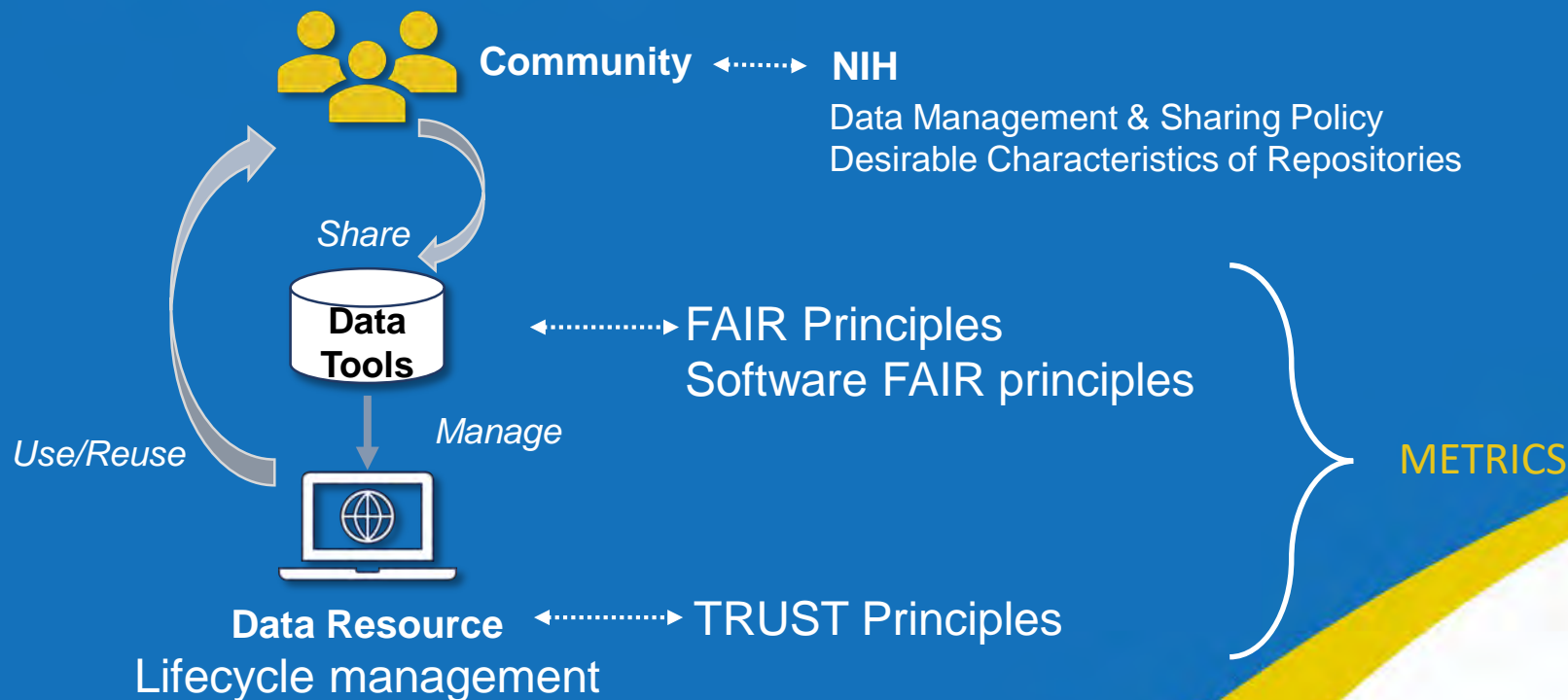
Comments:

Acceptable at Compliance Level 4 after some clarifications. See comments below.



Response:

The FITBIR system resides in a badged, monitored, and audited secure data center within CIT on the restricted NIH Campus. The backup infrastructure is supported by an alternate secured backup site in Sterling, Virginia. The hardware, software, networking and applications are all maintained by the FITBIR system administration team, in accordance with NIH policies and procedures. The FITBIR admin team maintains all servers and storage according to strict and well-defined laws and regulations (e.g. FISMA moderate; <https://www.nist.gov/programs-projects/federal-information-security-management-act-fisma-implementation-project>). In accordance to FISMA Moderate systems, the FITBIR systems adhere to the NIST 800-53 (<https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf>) security standards and guidelines. All documentation is held in either NSAT system at NIH or Confluence, the content management system. Both NSAT and Confluence are internal only.





BRICS Major Capabilities



Provides a fully functional Data Dictionary that supports Common Data Elements (CDEs) and automated curation using the CDEs as well as Unique DEs.

- a. OMOP 6.0 version
- b. BTRIS support
- c. **FHIR resources/profiles**



Supports **FHIR** connectivity/data – Prototype using HAPI server.



Core Trust Seal certified – (FITBIR, working on NEI commons)



Uses a hashcode ID system (PPRL), called the GUID, to support de-identified data collection across data types and studies



Automated DAC and Biospecimen Review Access Committee (BRAC) support



Deployable on prem servers as well as the **Cloud**.



Electronic data collection (eCRF – ProFoRMS) that is [21CFR part 11](#) compliant. Provides access to PROMIS tools, PSR, offline collection ...



Translation/mapping tool source data to BRICS instance data consistent with CDEs



Data types supported: phenotypic, imaging, omics

BRICS systems supported:

<https://brics.cit.nih.gov/partners>





BRICS Tools | Plug & Play Components for the Full Research Lifecycle

BRICS offers researchers a secure **comprehensive** platform and a suite of web-based and downloadable tools that can be shared across disease categories or deployed and branded independently, depending on the needs of your program.



Data Mapping & Transformation

Tool that translates data into CDEs used by BRICS to prepare for validation



Data Dictionary

Intelligent clinical research data dictionary that supports cross-system exchange, CDEs



Data Repository

Functionality to define and manage studies and contribute or store data



ProFoRMS

Module for electronic data capture (EDC), subject management and scheduling, etc, (21 CFR part 11 compliant)



Meta Study

Workspace that aggregates data and metadata across studies for reference



Global Unique Identifier

Cross-study Privacy Preserving Record Linkage System (PPRLS)

[Introducing BRICS | BRICS \(nih.gov\)](https://brics.nih.gov)

Continues...



**Query**

Tool enabling filtering of submitted data using data elements and form structures

**Clinical Trials Management System (CTMS)**

Management of Clinical Trials by enabling insight into trial performance.

**BRICS Imaging Tools**

Enables quantitative analysis and viewing of medical images, such as PET, MRI, CT, or microscopy.

**Forum**

Discussion board for account users for posting messages, interacting with each other, and discussing various topics

**Account Management**

Create, approve, and manage user accounts.

**InET**

Application for assigning new training, tracking current training, licenses and compliance.

**STAMS: Specimen Tracking And Management System**

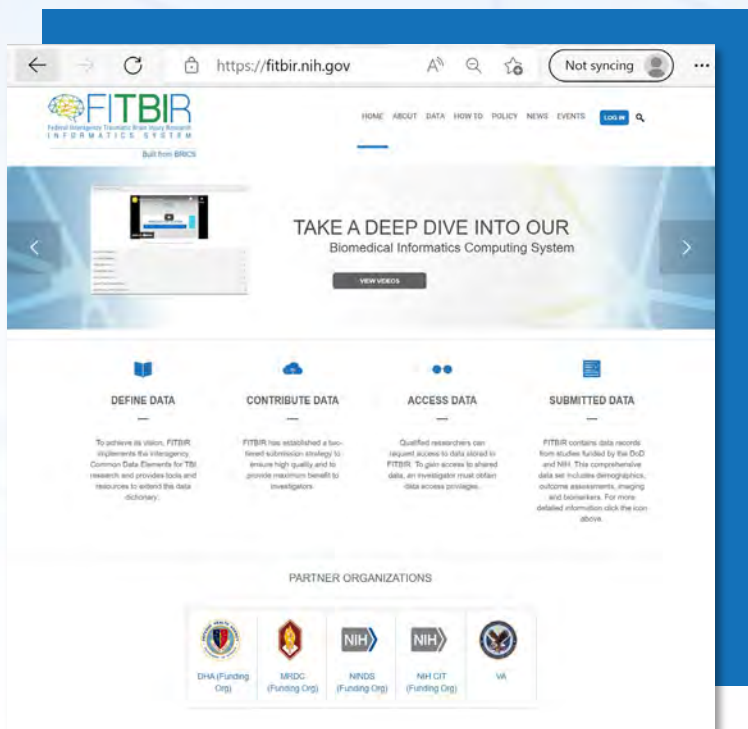
Provides the path to container storage locations (e.g. freezer) that guides the user to the specific container and sample.

[Introducing BRICS | BRICS \(nih.gov\)](https://brics.nih.gov)

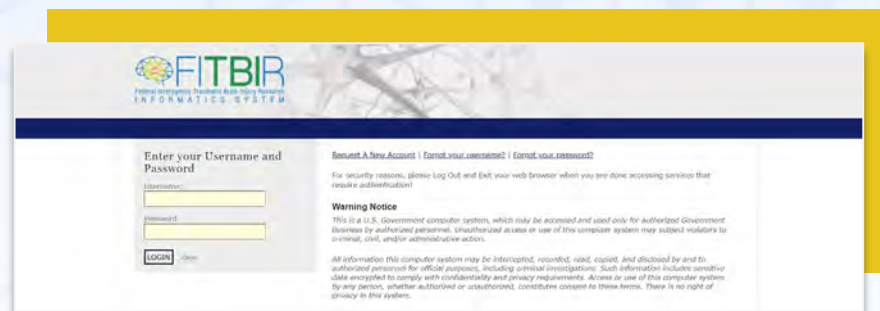


BRICS programs can create a public-facing landing page that provides access to a login portal for authorized customers.

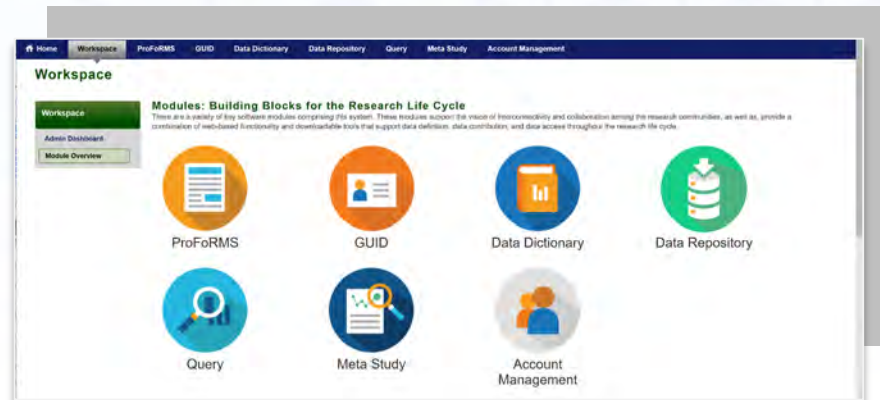
Public Landing Page



Portal Login Page

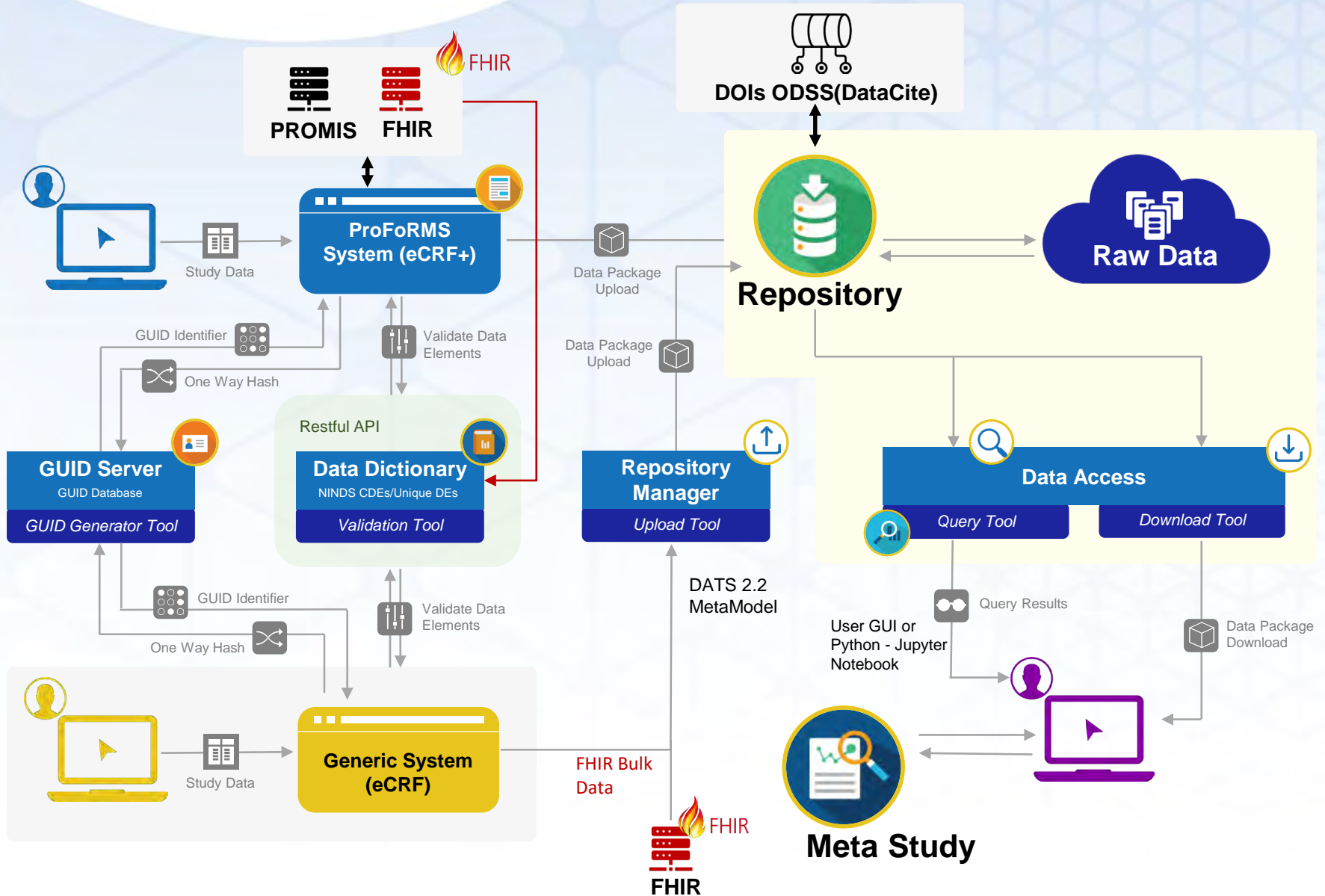


Controlled Access Portal



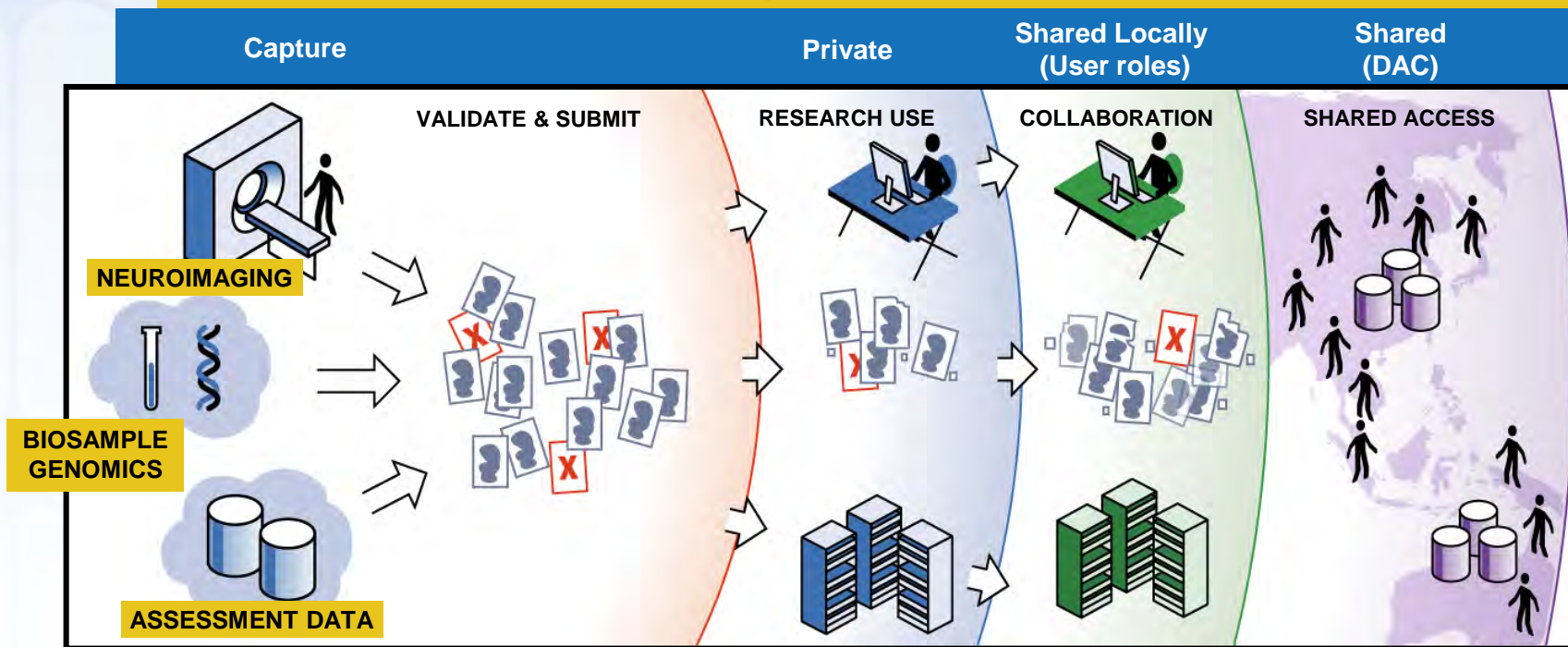


System Overview





Submission/Data Sharing Dataflow





New functionality Cloud (STRIDES)

- Parkinson's Disease Biomarker Program (PDBP)

AMP | PD

Google

- All BRICS instances – backup





Privacy Preserving Record Linkage (PPRL) Global Unique Identifier System (GUID)

[1] Johnson SB, Whitney G, McAuliffe M, Wang H, McCreedy E, Leon Rozenblit L, Evans CC. Using Global Unique Identifiers to Link Autism Collections. J. Am. Med. Inform. Assoc., Vol. 17, No. 6, 689-695, 2010. PMID: PMC3000750.



Global Unique Identifier System

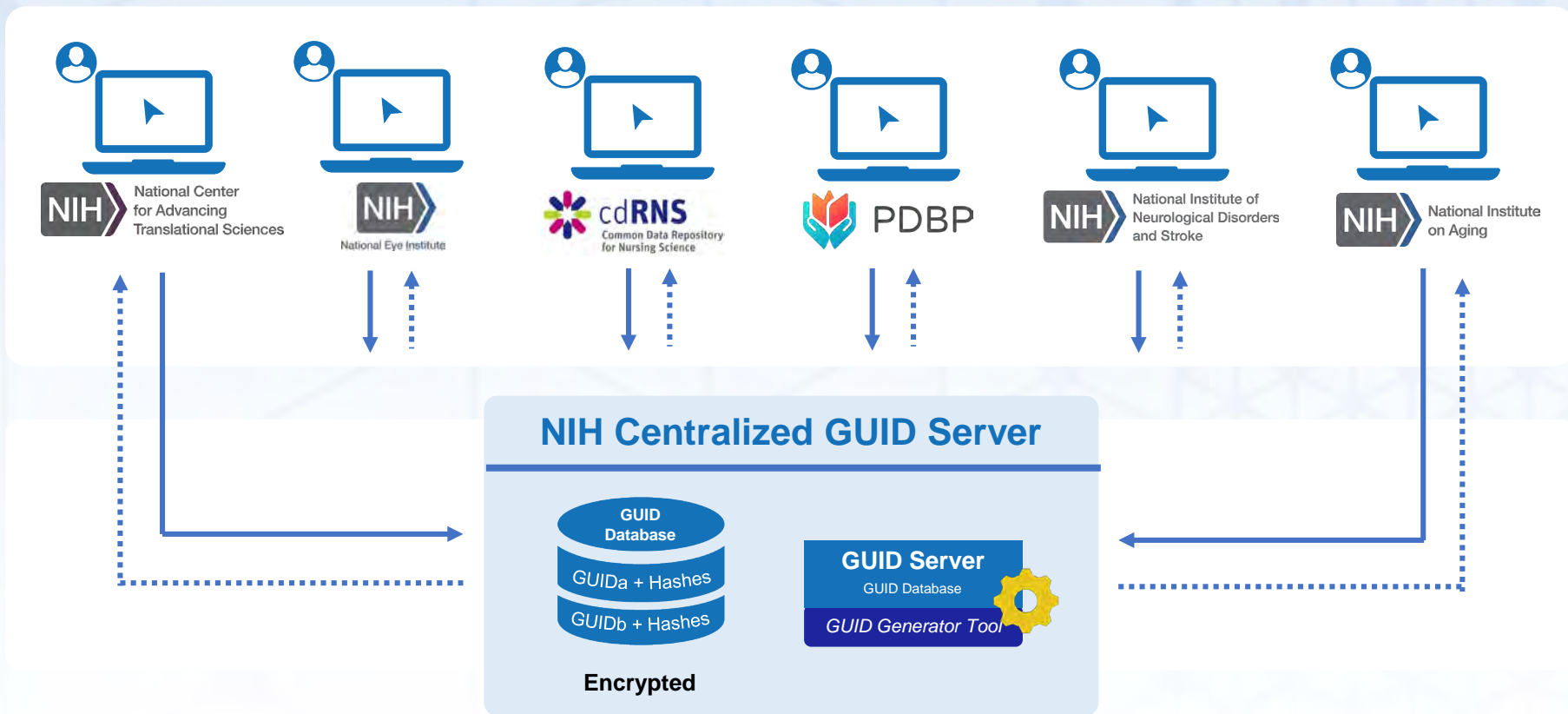
- Creates unique random subject identifiers without exposing personally identifiable information (PII)
- Protects privacy of each research participant
- Associates participants across data types and studies

Helps researchers

- Aggregate data for specific study participants over time and space



New Functionality Intramural Centralized PPRL





Data store for primary and secondary research data

The **Meta Study** module's main use cases are:

1. Meta Analyses:

- Facilitates aggregation of data from different studies within the BRICS Repository module for meta-analyses
- Accommodates upload(s) of data **external** to BRICS to be included in meta-analyses.

2. Data Store (Data lake):

- Facilitates storage of data from studies that do not have requirements to upload data to the BRICS Repository module.
- Supports the **NIH Data Management and Sharing Policy**
- NOTE: data stored inside of the Meta Study Data Store will not be validated or stored in the Data Repository module and it also will not be queryable.





Digital Object Identifiers (DOIs) (ODSS\DataCite)

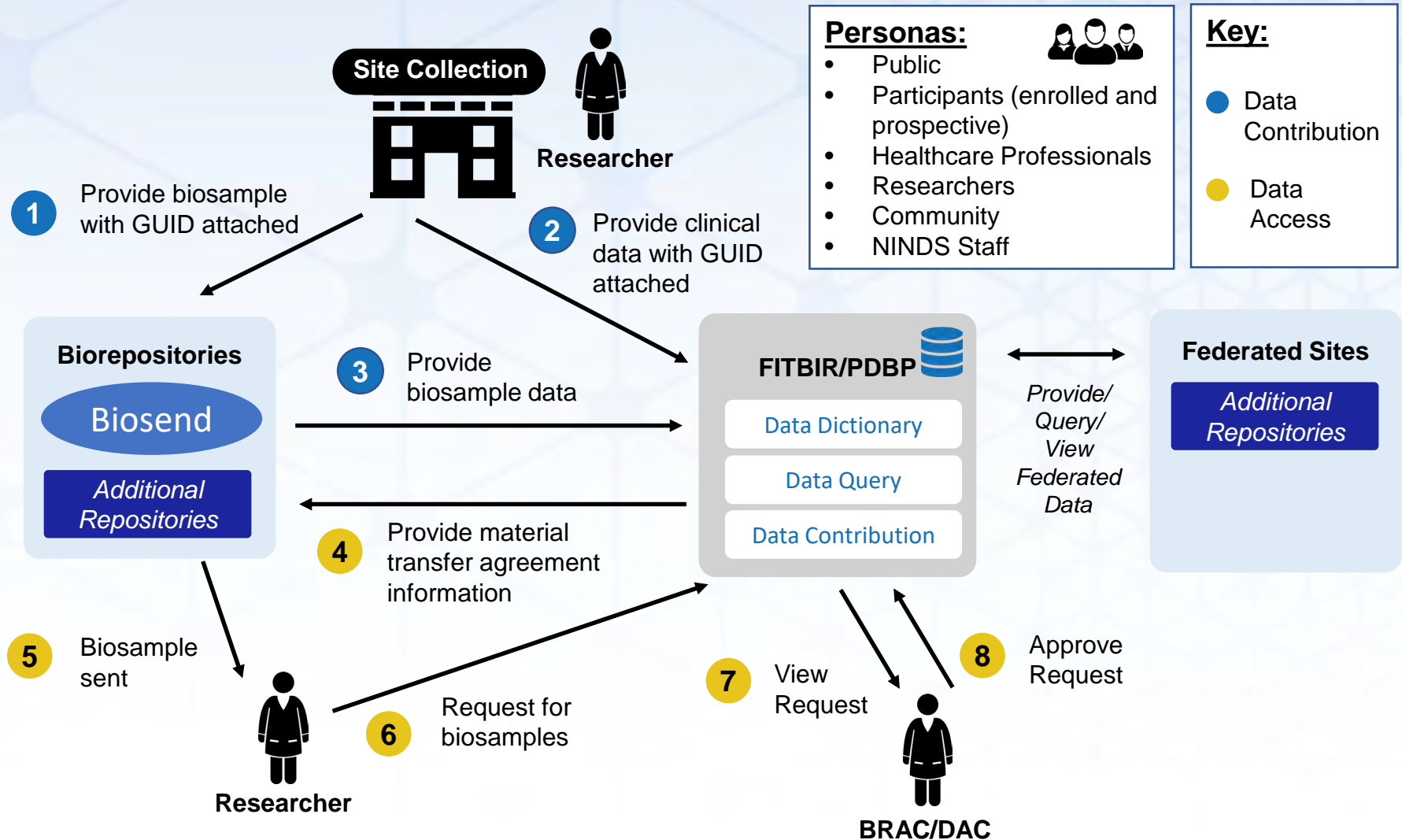
Makes research more effective by connecting research outputs and resources—from data and preprints to images and samples

Connecting data and publications supports:

- Research validation
- Data Reuse
- Metrics



FITBIR/PDBP Biosample Workflow





Validate and Upload Tool (Submission Tool) - JavaScript Application

Getting started and need help? Download the [Submission Tools User Guide \(pdf\)](#)

Validation Tool

Upload Tool

Working Directory

Upload Files

To upload file with attached/associated files, choose 'Upload Directory'.

Files

Hidden files will not be displayed on this table. Exp: DS_Store, Thumbs.db, desktop.

Color Legend Requires Validation Valid Excluded Error

Search:

<input checked="" type="checkbox"/>	NAME	TYPE	STRUCTURE	STATUS	RESULT	SUMMARY
<input checked="" type="checkbox"/>	ADAPTDemographics.csv	FORM STRUCTURE	ADAPTDemographics	Published	PASSED	29 Warnings

Showing 1 to 1 of 1 entries (1 row selected of 1)

Result Details

100 Warnings and Errors will be displayed.

Disable Warnings

Search:

TYPE	DESCRIPTION
WARNING	ADAPTDemographics contains following Retired DE: BiologicalGenderTyp. Please contact ops for more information.
WARNING	The data entry at row 3, column 1, for the data element "Demographics reason" is empty. Data structure ADAPTDemographics identifies this element as RECOMMENDED.

- More universal implementation – From Java Webstart to JavaScript
- Validation at CDE level and Form level





Translation Tool

Data Mapping and Transformation Tools - Beta version 0.0 (Final)

Help

Currently Connected to: <https://ftbir.nih.gov/>

Mapping Tool | Transform Tool

Get Form Structures			Select Form Structure			Load Source DEs			
Group	Element Name	Title	Type	Reference PVs	Required	Sourc...	Source Type	Sourc...	PV Mappings
Main	GUID	GUID	GUID		REQUIRED	GUID	GUID		
Main	SubjectIDNum	Subject identifier number	ALPHANUMERIC		OPTIONAL				
Main	AgeYrs	Age in years	NUMERIC		RECOMMENDED	Age	Numeric		
Main	VitStatus	Vital status	ALPHANUMERIC	Alive,Dead,Unknown	OPTIONAL				
Main	VisitDate	Visit date	DATE		RECOMMENDED				
Main	SiteName	Site name	ALPHANUMERIC		RECOMMENDED				
Main	DaysSinceBaseline	Days since baseline	NUMERIC		OPTIONAL				
Main	CaseControlInd	Case control indicator	ALPHANUMERIC	Case,Control,Unknown	OPTIONAL				
Main	GeneralNotesTxt	General notes text	ALPHANUMERIC		OPTIONAL				
Form Administration	ContextType	Context type	ALPHANUMERIC	After injury,At time of asse	RECOMMENDED				
Form Administration	ContextTypeOTH	Context type other text	ALPHANUMERIC		RECOMMENDED				
Form Administration	DataSource	Data source	ALPHANUMERIC	Brother,Chart,Medical reco.	RECOMMENDED				
Form Administration	DataSourceOTH	Data source other text	ALPHANUMERIC		RECOMMENDED				
Glasgow Coma S...	GCSConfounderTyp	Glasgow Coma Scale (GCS) - Con	ALPHANUMERIC	Alcohol/drugs of abuse C...	RECOMMENDED				
Glasgow Coma S...	GCSEyeResponsS	Glasgow Coma Scale (GCS) - Eye	ALPHANUMERIC	1,2,3,4,Unknown,Unlestab.	RECOMMENDED	scoreX	Numeric	1,2,3	1,1,2,1,3,Unknown
Glasgow Coma S...	GCSMotorRespons	Glasgow Coma Scale (GCS) - Mot	ALPHANUMERIC	1,2,3,4,5,6,Unknown,Unst.	RECOMMENDED				
Glasgow Coma S...	GCSVerbalRespons	Glasgow Coma Scale (GCS) - Ver	ALPHANUMERIC	1,2,3,4,5,Unknown,Unst.	RECOMMENDED				
Glasgow Coma S...	GCSTotalScore	Glasgow Coma Scale (GCS) - Tot	ALPHANUMERIC	10,11,12,13,14,15,3,4,5,6	RECOMMENDED				
Glasgow Coma S...	PupilReactivityLgh	Pupil reactivity light left eye result	ALPHANUMERIC	Brisk,Nonreactive,Sluggis	RECOMMENDED				
Glasgow Coma S...	PupilReactivityRht	Pupil reactivity light right eye result	ALPHANUMERIC	Brisk,Nonreactive,Sluggis	RECOMMENDED				

Output Directory for mapping result files:

Output log

This Tool has successfully connected and configured to <https://ftbir.nih.gov/>
 Successful retrieval of form structures from Prod environment.
 Successful retrieval of data elements for form structure: GCS
 All required data elements have been mapped - mapping file can now be saved
 All required data elements have been mapped - mapping file can now be saved

- ✦ The tool supports data definition, data mapping, data transformation, and data access through the research cycle.
- ✦ Researchers can easily load their Data Elements (DEs) and Permissible Values (PVs) in the form of a data dictionary to be paired with (or mapped to) eligible BRICS elements and their values within the BRICS Data Dictionary.





Welcome Administrator, Matthew | Log Out

Home Workspace ProFoRMS Subject Management Data Dictionary Data Repository **Query** Meta Study Account Management Forum

Step 1: Filter Data Step 2: Refine Data Admin Only: Clear Cache **Data Cart: 1 forms in 17 studies** Clear Data Cart Save New Query

Data Cart

Select a form to refine your query

Glasgow Outcome Scale Extended (GOS-E)

Download Data Cart To Queue Reset

Drag here to join forms

First Form

Second Form

Third Form

Fourth Form

Fifth Form

Query Logic Box

Clear Filters Copy Query Export Query Run Query

Select Criteria Datatable View Permissible Value Hide All Blank Columns Download Options

Glasgow Outcome Scale Extended (GOS-E) (12656 Rows of Data)

FORMS: GOS_STANDARD

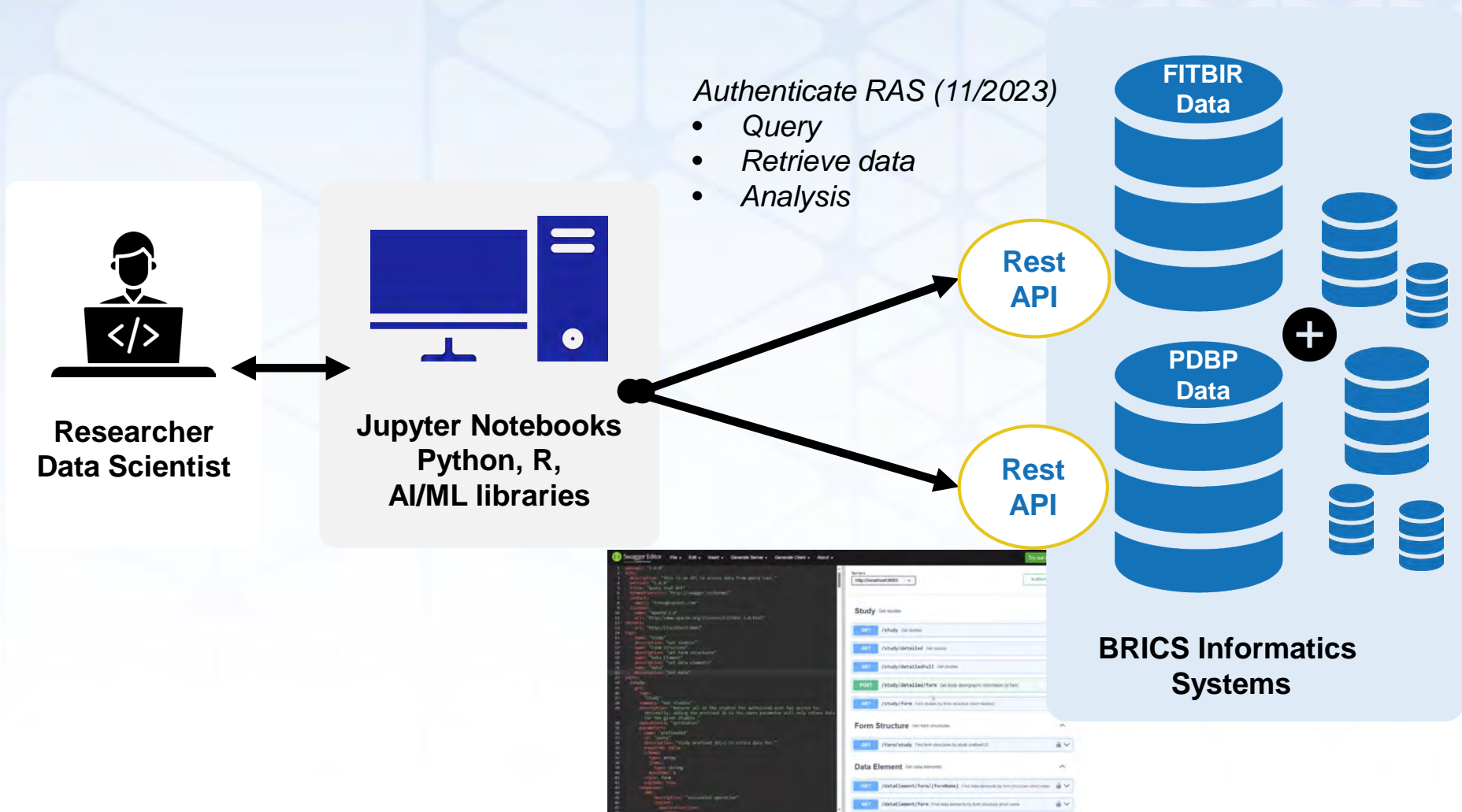
REPEATABLE GROUPS: MAIN

ROW NO.	STUDY ID	DATASET	GUID	ASSOCIATED GUID	SUBJECTIONUM	AGEYRS
1	392	FITBIR-DATA0014496	TBIYY662YVC		06C1078	42
2	392	FITBIR-DATA0014496	TBIAT815JWE		06C1073	36
3	392	FITBIR-DATA0014496	TBIHP667JA8		06C1071	37
4	392	FITBIR-DATA0014496	TBIYZ282KH1	TBL_INVXC402VAA	06C1067	38
5	392	FITBIR-DATA0014496	TBIDU897NEN		06C1087	43
6	392	FITBIR-DATA0014496	TBIHG854XG9		06C1085	39
7	392	FITBIR-DATA0014496	TBIXL521DJW		06C1082	53
8	392	FITBIR-DATA0014496	TBINY280KGH		06C1080	41
9	392	FITBIR-DATA0014496	TBICB635ZEX		05C1215	42
10	392	FITBIR-DATA0014496	TBIHN386UZP		05C1214	56
11	392	FITBIR-DATA0014496	TBIJZ524AVJ		05C1213	50
12	392	FITBIR-DATA0014496	TBICE408HE0		06C1004	45
13	392	FITBIR-DATA0014496	TBIBR360EWL		06C1003	63
14	392	FITBIR-DATA0014496	TBIBV552XZW		06C1001	34
15	392	FITBIR-DATA0014496	TBIDG482PX9		05C1216	42
16	392	FITBIR-DATA0014496	TBIRZ273YR2		06C1016	31
17	392	FITBIR-DATA0014496	TBIHX400NYG		06C1013	36
18	392	FITBIR-DATA0014496	TBIFA001JYG		06C1011	41
19	392	FITBIR-DATA0014496	TBIAL553PCD		05C1203	49
20	392	FITBIR-DATA0014496	TBIMW968ARK		05C1202	39

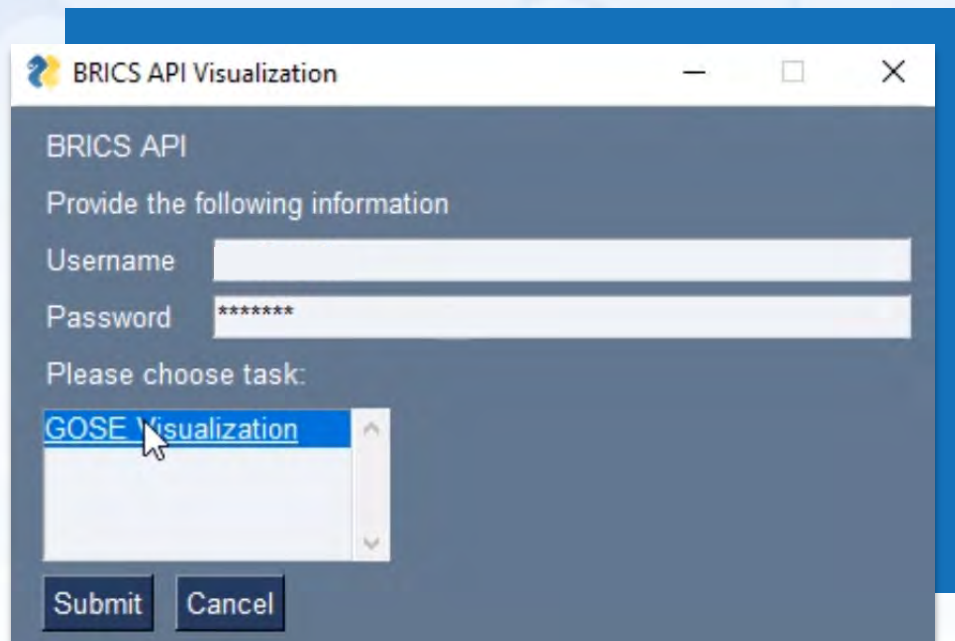
- Query *across* studies, CDEs, and data types
- API

API Query Tool

Programmatic access to the data



Python Code



BRICS API Visualization

BRICS API

Provide the following information

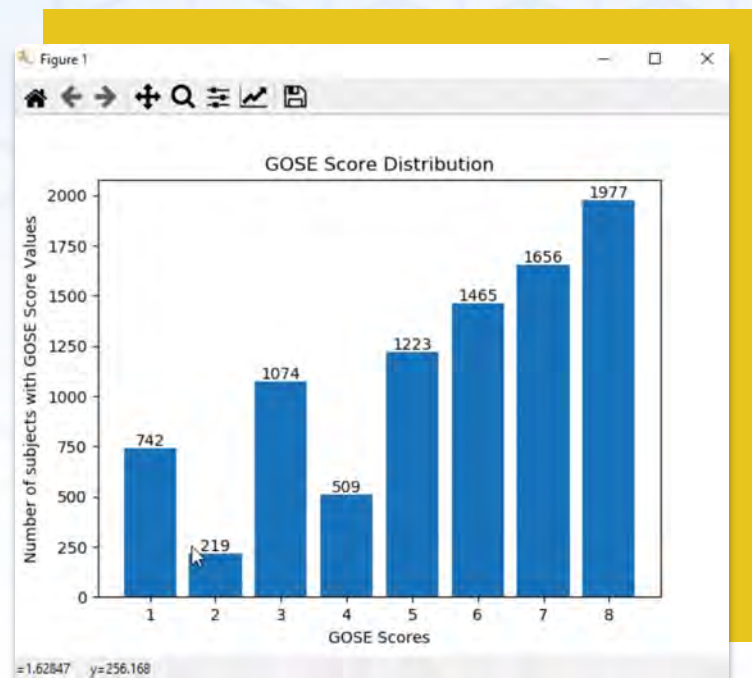
Username

Password

Please choose task:

GOSE Visualization

Submit Cancel





BRICS

Biomedical Research
Informatics Computing System

Why We Need Common Data Elements (CDEs)

Common data elements (CDEs) help researchers share and combine datasets, meet funding requirements, and save time.



National
Institutes
of Health



Center for
Information
Technology



Learn more about BRICS at: <https://brics.cit.nih.gov>



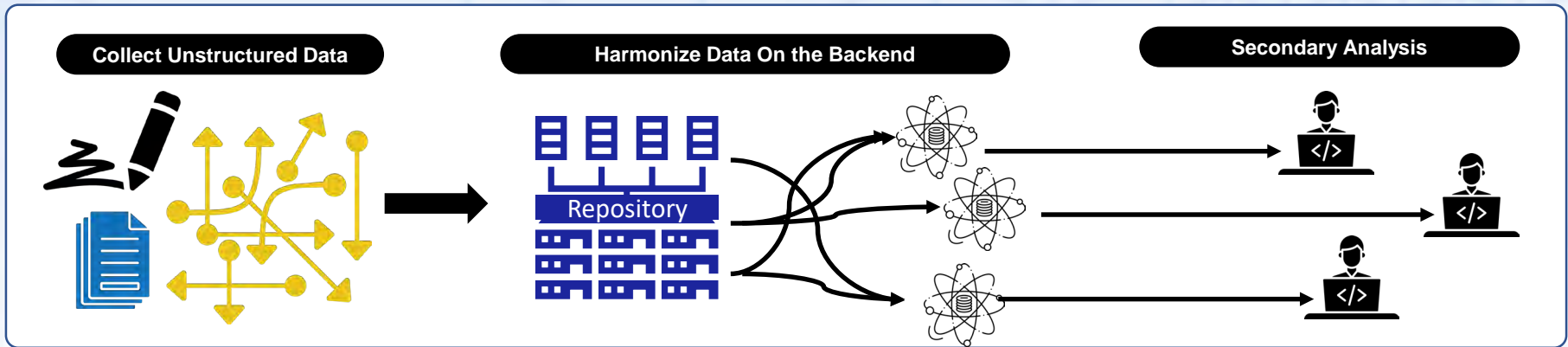
Why We Need CDEs

- 1 Interoperability:** CDEs facilitate data integration across studies.
- 2 Data Quality:** They ensure accurate and consistent data collection.
- 3 Time and Cost Savings:** CDEs expedite research project startup.
- 4 Statistical Power:** Pooling data enhances statistical robustness.
- 5 Comparative Analysis:** Researchers can compare data with existing datasets.
- 6 Collaboration:** Common data language fosters interdisciplinary cooperation.
- 7 Data Sharing:** CDEs promote reproducibility and data sharing.
- 8 Regulatory Compliance:** They may be required by regulatory bodies and funders.
- 9 Mapping Consistency:** Enables consistent mapping to UMLS concepts, making it easier to update mappings as UMLS evolves.

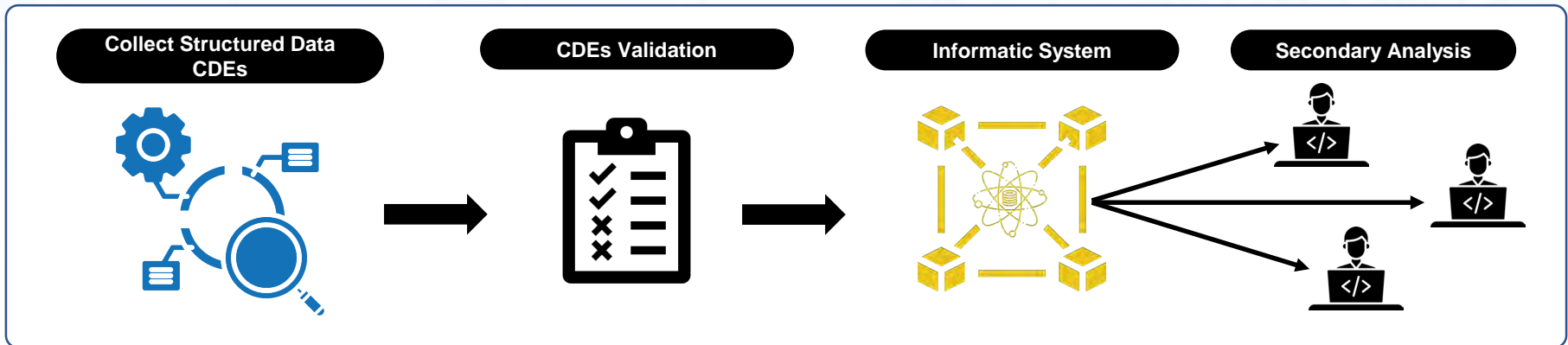


CDEs and Harmonization

Collection of unstructured data from each study independently and harmonize data on the backend – highly inefficient – e.g. 50-70% researchers/postdoc time is spent on data wrangling (QAQC, validation, harmonization). B. Mons DATA STEWARDSHIP FOR OPEN SCIENCE Implementing FAIR Principles, CRC Press Taylor & Francis Group, 2018

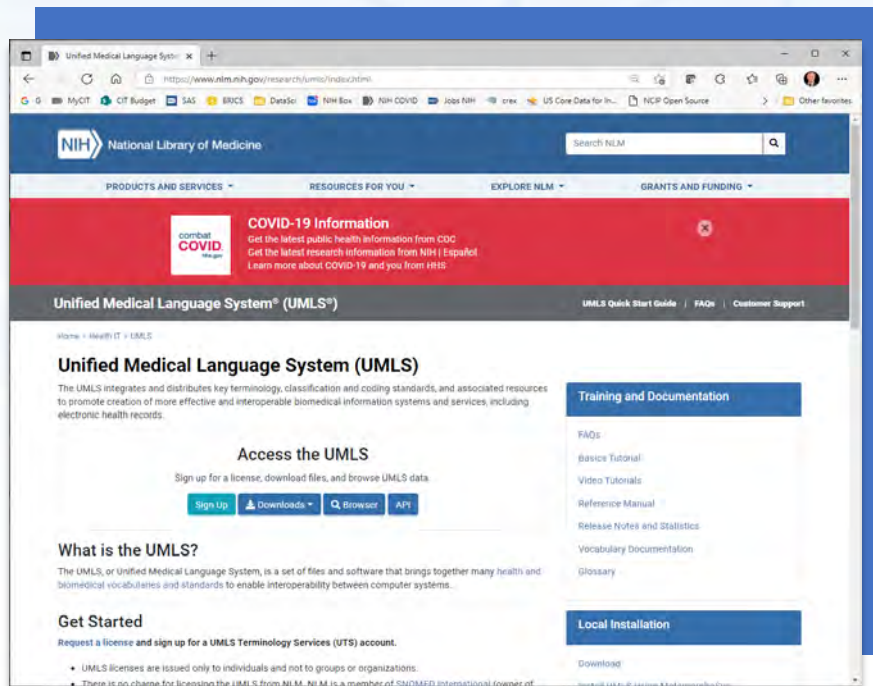


Structured data using **CDEs** and validating data on submission – supports FAIR



Unified Medical Language System (UMLS)

The UMLS integrates and distributes key terminology, classification and coding standards, and associated resources to promote creation of more effective and interoperable biomedical information systems and services, including electronic health records.



Adding UMLS coding per CDE, UDE and Permissible Values

- Supports programmatic analysis of the data making data stored in a BRICS repository more AI ready.
- Makes BRICS DEs more consistent with NLM's DE efforts supported by the CDE Governance group.



Common Data Element: Gender Type

[view more in the data dictionary](#)

Status: Published

Variable Name: GenderTyp

Definition: Self-reported gender of the participant/subject. Gender is the socially constructed identity of sex. Gender is equated with phenotypic sex. Gender may differ from the sex of an individual determined genetically.

Guidelines & Instructions: Choose one. Response is obtained by report of the participant/subject or caretaker.

References: The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 (http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm)

Preferred Question Text: What is the subject's gender?

Notes: The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 (http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm)

Population: Adult and Pediatric

Input Restrictions: Single Pre-Defined Value Selected

Data Type: Alphanumeric

[Mapping to external dictionaries](#)

Search:

ROW NO	PERMISSIBLE VALUE	DESCRIPTION	CODE	CONCEPT IDENTIFIER	CONCEPT NAME	TERMINOLOGY SOURCE
1	Female	Female	1	C0086287/C1705497	Females/Female, Self-Report	UMLS
2	Male	Male	2	C0086582/C1706180	Males/Male Gender, Self Report	UMLS
3	Not reported	Not Reported	222	C1706613	Not Stated	UMLS
4	Unknown	Unknown	999	C0439673	Unknown	UMLS
5	Unspecified	Undifferentiated/Indeterminant/Inte	555	C1704620	Intersex	UMLS

Showing 1 to 5 of 5 entries

**Research Authentication Service
(includes MFA)****RAS PHASE 1: (End of October 2023)**

The traditional username/password Log in flow for BRICS will soon be replaced by NIH's Researcher Auth Service (RAS). This change will require all users to follow a set of steps to Log in/sign up for RAS and link your BRICS account to your RAS account. RAS supports 2 identity providers, a NIH PIV/CAC card, or an account with Login.gov.

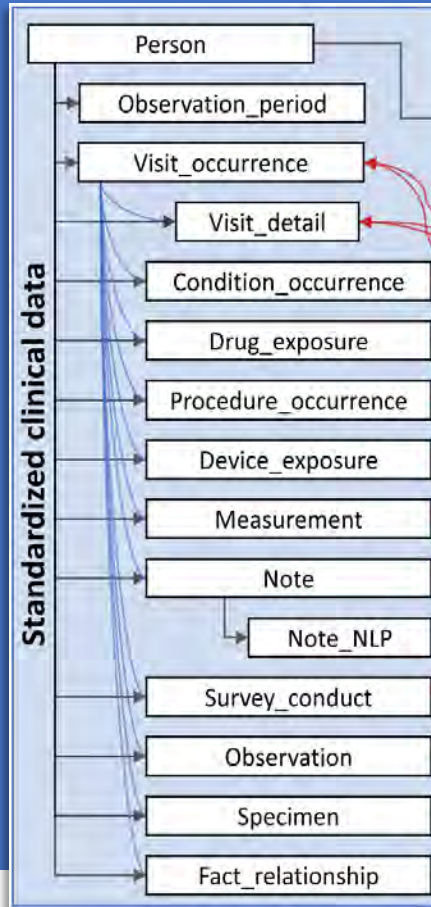
RAS PHASE 2: (Spring 2024)

Include additional Identity Providers as needed. Enhancement request that come from the users based upon the initial release




OMOP Observational Medical Outcomes Partnership Common Data Model (v6.0)

~ 38 Tables
~ 395 Data Elements
Open Community Data Std



fitbir-demo.cit.nih.gov/content/data-dictionary#form-structures



Federal Interagency Traumatic Brain Injury Research
INFORMATICS SYSTEM

Built from BRICS

Narrow your search

Clear Filters Restore Default

FITBIR

- All
- Program Specific

Form Types

- Biosample
- Clinical Assessment
- Genomics
- Imaging
- Other -Omics
- Preclinical

Standardization

- Standard NINDS-CDE
- Standard

Labels

- February

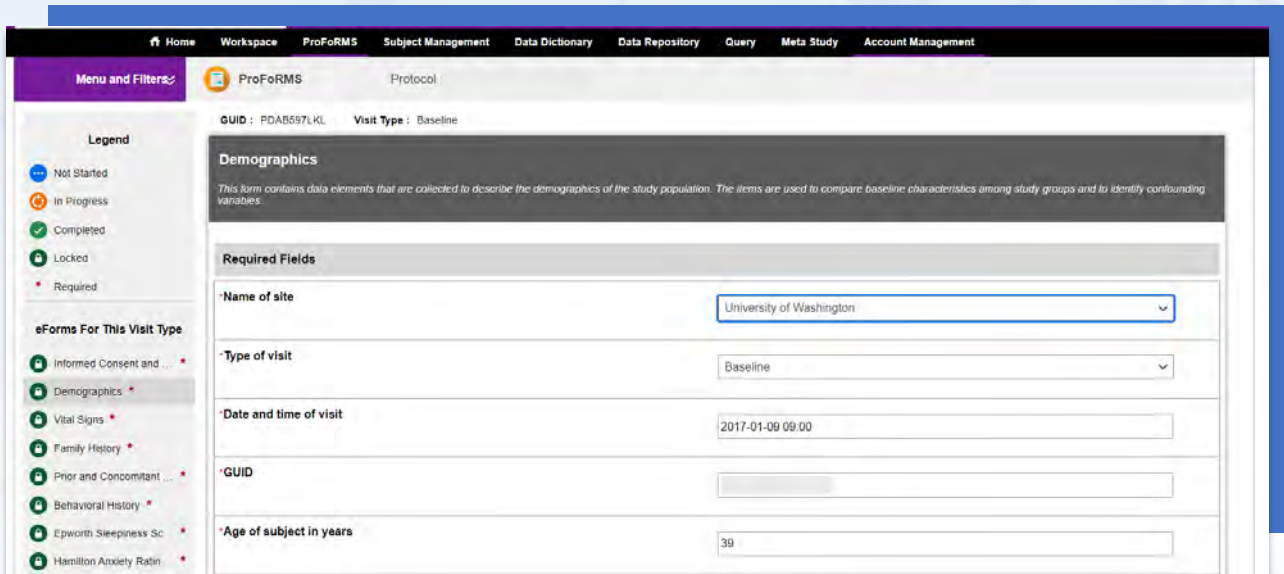
Show 25 entries

TITLE	SHORT NAME	STATUS	MODIFIED DATE
OMOP_CDM Vocabulary Form	Vocabulary_OMOP_CDM	Published	2023-01-12
OMOP_CDM Specimen Form	Specimen_OMOP_CDM	Published	2023-01-12
OMOP_CDM Measurement Form	Measurement_OMOP_CDM	Published	2023-01-12
OMOP_CDM Note NLP Form	Note_NLP_OMOP_CDM	Published	2023-01-12
OMOP_CDM Observation Period Form	Obs_Period_OMOP_CDM	Published	2023-01-12
OMOP_CDM Observation Form	Observation_OMOP_CDM	Published	2023-01-12
OMOP_CDM Survey Conduct Form	Survey_Conduct_OMOP_CDM	Published	2023-01-12
OMOP_CDM Visit Detail Form	Visit_Detail_OMOP_CDM	Published	2023-01-12
OMOP_CDM Drug Exposure Form	Drug_Exposure_OMOP_CDM	Published	2023-01-11
OMOP_CDM Device Exposure Form	Device_Exposure_OMOP_CDM	Published	2023-01-11
OMOP_CDM Note Form	Note_OMOP_CDM	Published	2023-01-11
OMOP_CDM Fact Relationship Form	Fact_Relationship_OMOP_CDM	Published	2023-01-11
OMOP_CDM Visit Occurrence Form	Visit_Occurrence_OMOP_CDM	Published	2023-01-11
OMOP_CDM Procedure Occurrence Form	Procedure_Occur_OMOP_CDM	Published	2023-01-11
OMOP_CDM Condition Occurrence Form	Con_occurrence_OMOP_CDM	Published	2023-01-11
OMOP_CDM Payer Plan Period Form	Payer_Plan_Period_OMOP_CDM	Published	2023-01-10

Showing 1 to 25 of 38 entries

ProFoRMS – Renders Form Structures to Acquire Subject Data








ProFoRMS, BRICS' subject data entry tool, offers a secure, seamless, and functional customer experience.



The screenshot displays the ProFoRMS interface with the following details:

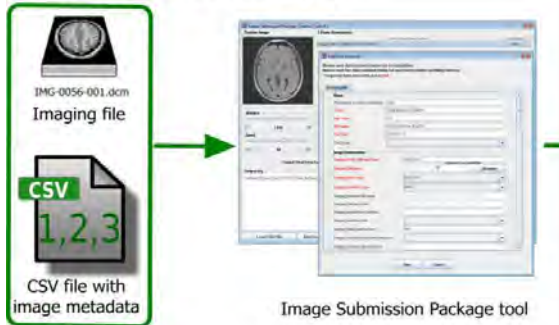
- Navigation:** Home, Workspace, ProFoRMS, Subject Management, Data Dictionary, Data Repository, Query, Meta Study, Account Management.
- Page Header:** ProFoRMS, Protocol: [blank]
- Legend:**
 - Not Started (blue circle)
 - In Progress (orange circle)
 - Completed (green circle)
 - Locked (grey circle)
 - Required (red asterisk)
- eForms For This Visit Type:**
 - Informed Consent and ... (locked)
 - Demographics (required)
 - Vital Signs (required)
 - Family History (required)
 - Prior and Concomitant ... (required)
 - Behavioral History (required)
 - Epworth Sleepiness Sc. (required)
 - Hamilton Anxiety Ratin. (required)
- Demographics Section:**

This form contains data elements that are collected to describe the demographics of the study population. The items are used to compare baseline characteristics among study groups and to identify confounding variables.
- Required Fields:**
 - Name of site: University of Washington
 - Type of visit: Baseline
 - Date and time of visit: 2017-01-09 09:00
 - GUID: [redacted]
 - Age of subject in years: 39

- 
21 CFR Part 11
Fully compliant with 21 CFR Part 11
- 
Network Connectivity
Supports offline data collection
- 
Scheduling
Built-in subject scheduler
- 
PSRs
Supports patient self-report modules (PSRs), such as PROMIS
- 
BTRIS
Enables access to BTRIS data
- 
Reporting
Built-in reports generator
- 
Open source



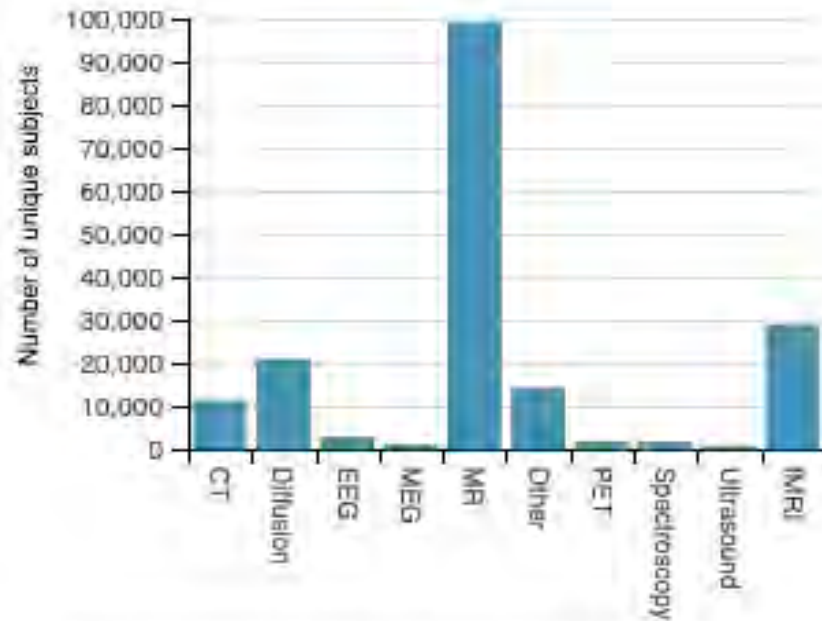
Imaging data submission



Clinical data submission



Image Volumes Per Modality



Total number of Image Volumes: 179729



Welcome Administrator, Portal | Log Out

Home Workspace ProFoRMS Subject Management Data Dictionary Data Repository **Query** Meta Study Account Management

Step 1: Filter Data Step 2: Refine Data Admin Only: Clear Cache Data Cart: 26 forms in 1 studies Clear Data Cart Save New Query

Data Cart Download Data Cart To Queue Reset

Select a form to refine your query

- Brief Symptoms Inventory-18 (BSI-18)
- FITBIR Demographics Form
- Functional Independence Measure (FIM) Scale
- Pediatric Glasgow Outcome Scale - Extended (GOS-E Peds)
- Glasgow Outcome Scale Extended (GOS-E)
- Imaging CT

Drag here to join forms

First Form

Second Form

Third Form

Fourth Form

Fifth Form

Query Logic Box Clear Filters Copy Query Export Query Run Query

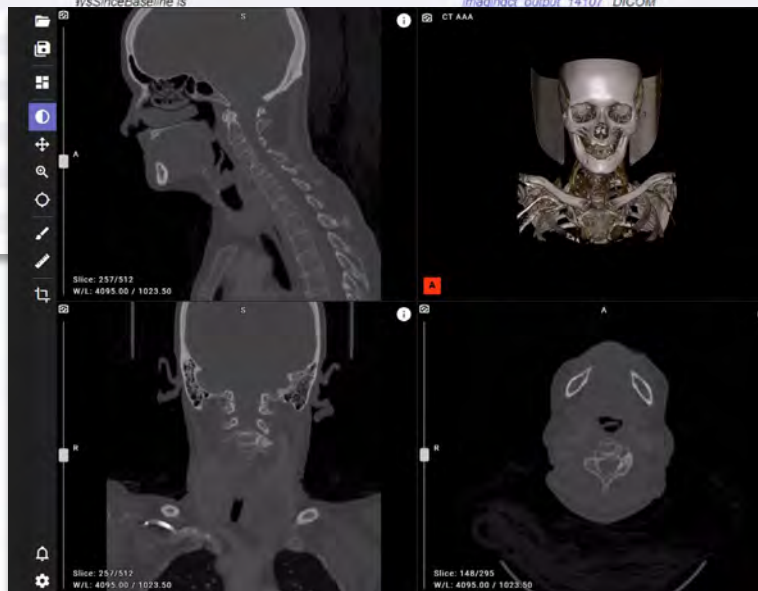
Select Criteria Datatable View Permissible Value Hide All Blank Columns Download Options

Imaging CT (3508 Rows of Data)

FORMS:

REPEATABLE GROUPS: ON

ROW NO.	NERALNOTESTXT	IMGSTDYDATE TIME	IMGFILE	IMGFILEFORMAT TYP	IMGFILEFORM
1	ysSinceBaseline is		imagingct_output_14107	DICOM	
2	ysSinceBaseline is		imagingct_output_14107	DICOM	
3	ysSinceBaseline is		imagingct_output_14107	DICOM	
4	ysSinceBaseline is		imagingct_output_14107	DICOM	



BRICS integrates VolView
[\(https://volview.kitware.com/\)](https://volview.kitware.com/) into the
Query Tool



Data Use/Collaboration Visualization Metrics



December 3, 2021

Funding Agency (43)

- CNRM (4)
- DoD (23)
- NIH (16)
- Other (0)
- unknown (0)

Data

- shared (43)
- no data (22)
- private (82)

Data Type

- clinical (40)
- imaging (20)
- genomics (3)

Visualization

- Map view
- PI view (91)
- Filter Sunburst
- Data Flow
- Study Table

Search Name

Study Name	Avail	Dwnld
CENC Study 1: Observational Study on Late Neurologic Effects of OEF/OIF/OND Combat	1.3 TB	103 GB
Concussion Assessment, Research and Education (CARE) Consortium	1,1 TB	329 GB
Targeted Evaluation, Action, and Monitoring of Traumatic Brain Injury (TEAM-TBI)	321 GB	155 GB
Tauopathy Consensus Study of Pathology Images	295 GB	295 GB
Soccer heading: potential for brain injury and opportunities for its mitigation	201 GB	10.2 GB
Brain injury and mechanisms of action of hyperbaric oxygen for persistent post-concussive symptoms after mild traumatic brain injury (BIMA)	170 GB	7.8 GB
Mission Connect Mild TBI Research Consortium	140 GB	43.6 GB
Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI) Pilot	133 GB	43.6 GB
Traumatic Brain Injury Data for FITBIR Informatics system: Maryland MagNeTS Prospective Dataset	127 GB	127 GB
Development of normative datasets for assessments used in patients with post-concussive symptoms due to mild traumatic brain injury (NORMAL)	94.1 GB	3.6 GB
Quantitative MRI and 1H MRS in Traumatic Brain Injury	64.9 GB	32.9 GB
Frontoparietal priority maps as biomarkers for mTBI	64.2 GB	30.2 GB
Approaches and Decisions in Acute Pediatric TBI Trial (ADAPT)	49.5 GB	10 GB
Progesterone for the Treatment of Traumatic Brain Injury (ProTECT III)	48.5 GB	56.6 GB

Studies

Data consumers

Users: 21
Study count: 1
Total downloaded: 173 GB
Sharing metric: 4

min 109 KB max 329 GB

Click to open study website

1 month 6 months 1 year all
 Remove Owner Downloads

Downloaded: 173 GB
Total Data Size: 1023 GB
Users: 21

Downloads

Datasize



- Data workbench - develop comprehensive data analysis tools
- Continue API development – validation and submission
- Continue UMLS mapping to CDEs
- Deploy to the Cloud for other BRICS instances
- Research Authentication Services (RAS) phase 2
- CommonAPI
- FISMA high





BRICS

Biomedical Research
Informatics Computing System

BRICS: Advancing FAIR Data Principles and NIH's 2023 Data Sharing Plan

Unified Medical System (UMLS)

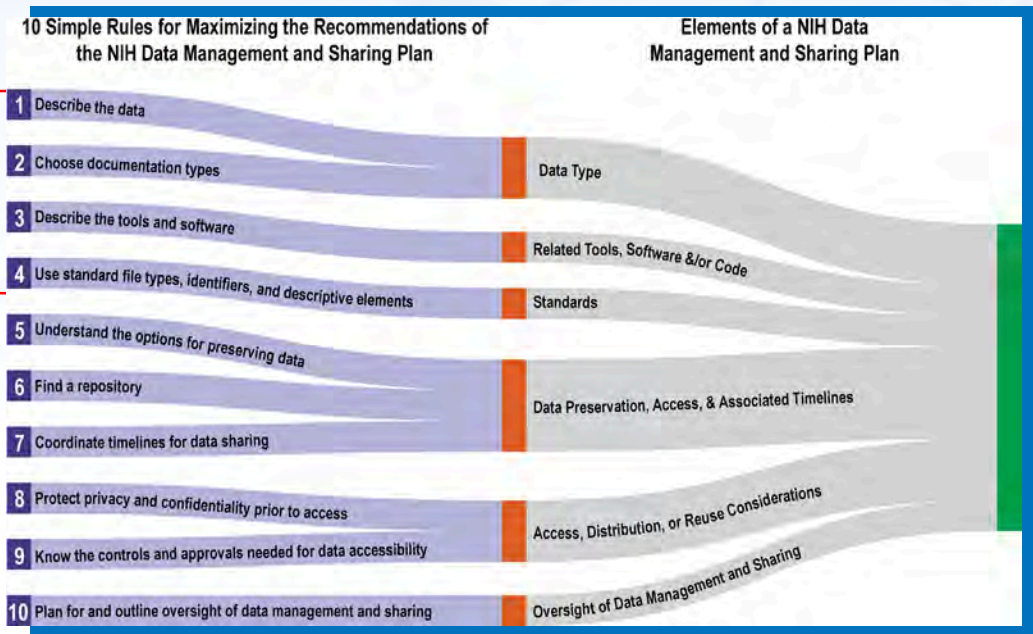
Olga Vovk



Advancing FAIR Data Principles and NIH's 2023 Data Sharing Plan

The National Institute of Health (NIH) has issued a new [NIH Policy for Data Management and Sharing](#). The policy came into effect on January 25, 2023.

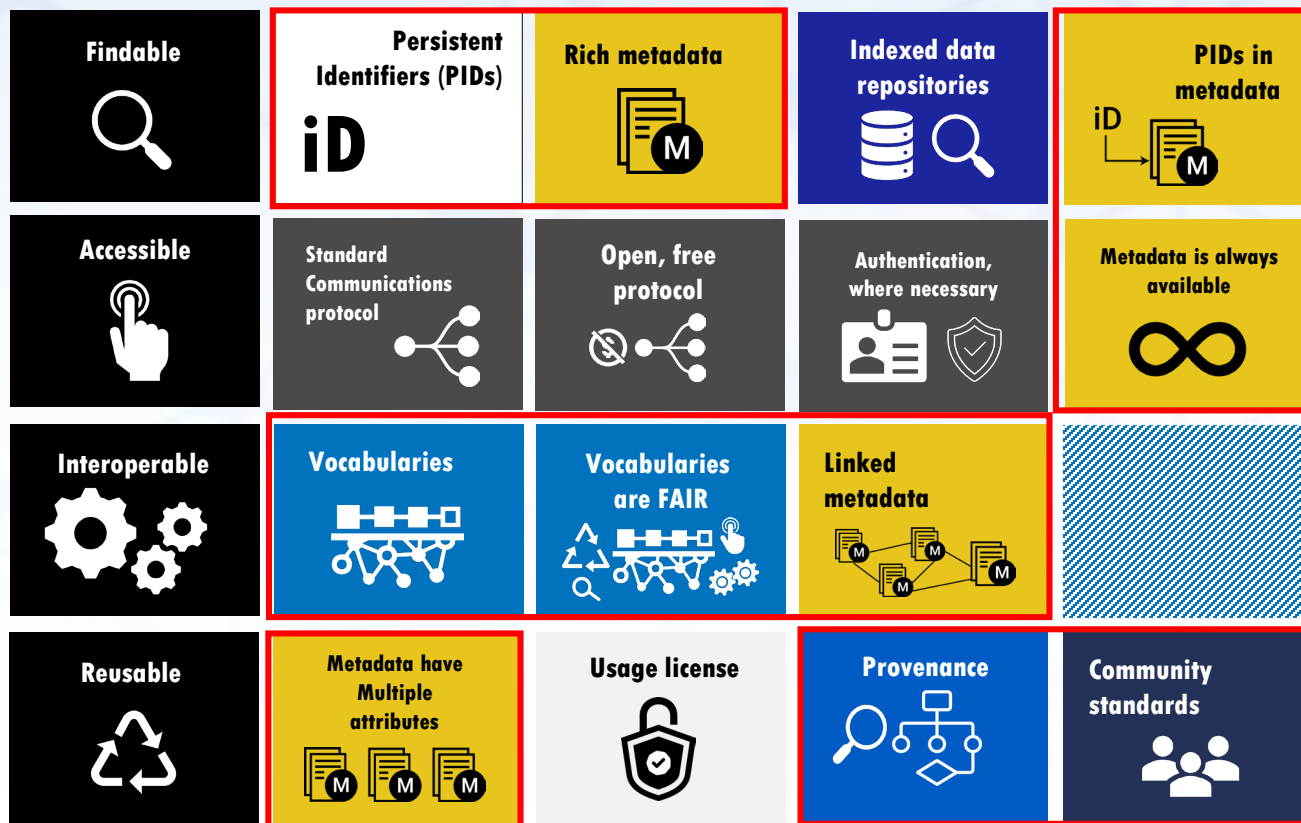
- It requires researchers, who submits an NIH research application, to submit a plan outlining how scientific data from their research will be **managed and shared**.



Source: Gonzales S, Carson MB, Holmes K. Ten simple rules for maximizing the recommendations of the NIH data management and sharing plan. PLoS Comput Biol. 2022 Aug 3;18(8):e1010397. doi: 10.1371/journal.pcbi.1010397. PMID: 35921268; PMCID: PMC9348704.

BRICS data dictionary is built on FAIR principles:

Findability, Accessibility, Interoperability, and Reusability (FAIR) principles

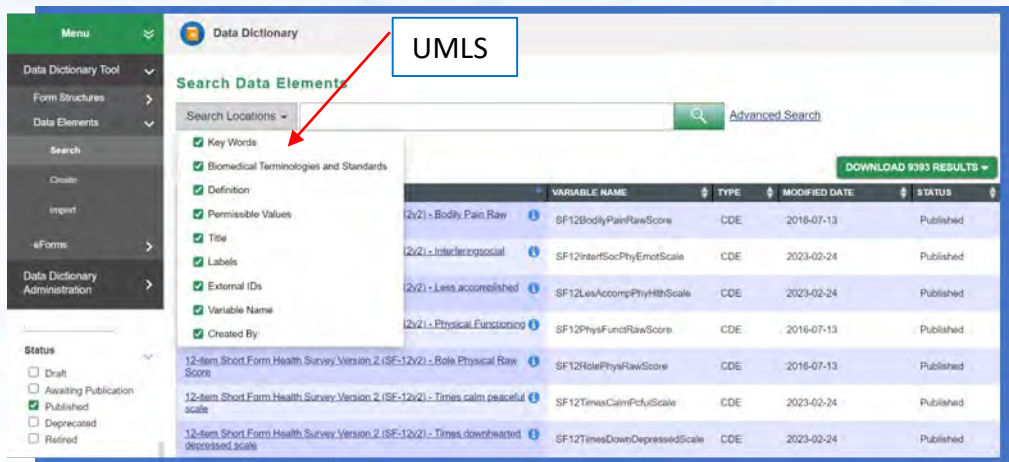


- Uses common data elements (CDEs) to collect data;
- Incorporates standard controlled vocabularies Effectively find, query, and report data;
- Supports data exchange between independent informatics systems.

Advancing FAIR Data Principles and NIH's 2023 Data Sharing Plan

- The count of CDEs in BRICS DDs is big (~9 K published CDEs in FITBIR only) and growing.
- That affects how we manage data dictionaries, including searching, curating, creating, and the most important - re-using of CDEs.
- That affects data analysis and data discovery.

Issues common for all large CDE repositories



The screenshot shows the 'Data Dictionary' search interface. A red arrow points to the 'UMLS' checkbox in the search filters. The interface includes a search bar, a list of search locations, and a table of search results. The table has columns for 'VARIABLE NAME', 'TYPE', 'MODIFIED DATE', and 'STATUS'. The results list various CDEs such as 'SF12BodyPainRawScore', 'SF12InterfemSocial', and 'SF12LessAccompPhyHlthScale'.

Over the years, we tried various ways to organize CDEs, such as:

- Keywords;
- CDE/UDE cross-mapping;
- Linking CDEs with close semantics
- Building the ETL tool(s).
- **The most recent initiative** we took to make BRICS to comply with the latest [NIH Policy for Data Management and Sharing](#)
 - is adding the option of organizing CDEs based on their semantics.



New Functionality: mapping CDE semantics to UMLS concepts

UMLS as a terminology source

[The Unified Medical Language System \(UMLS\) Metathesaurus](#), supported by NLM is a large biomedical thesaurus that is organized by concept, or meaning. It links synonymous names from over **200 different terminologies and vocabularies**.

Unified Medical Language System® (UMLS®)

Home > Health IT > UMLS

Unified Medical Language System (UMLS)

The UMLS integrates and distributes key terminology, classification and coding standards, and associated resources to promote creation of more effective and interoperable biomedical information systems and services, including electronic health records.

Access the UMLS

Sign up for a license, download files, and browse UMLS data.

[Sign Up](#) [Downloads](#) [Browser](#) [API](#)

What is the UMLS?

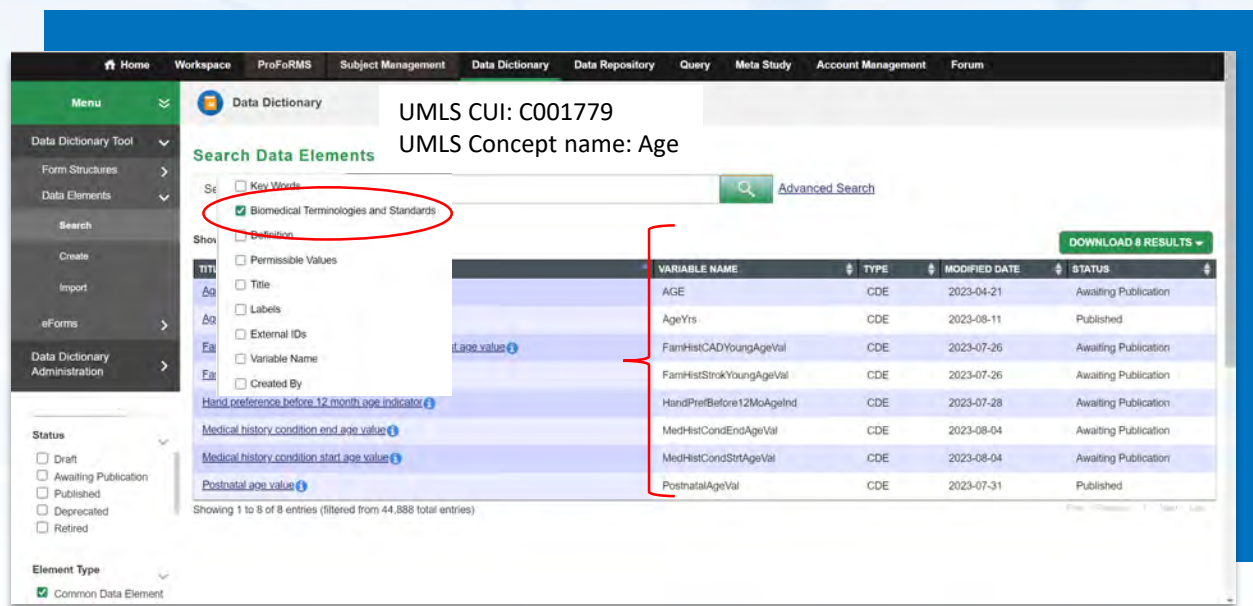
The UMLS, or Unified Medical Language System, is a set of files and software that brings together many health and biomedical vocabularies and standards to enable interoperability between computer systems.

Why UMLS?

- The Unified Medical Language System (UMLS) has been a critical tool in biomedical and health informatics for more than 30 years.
- The UMLS brings together vocabularies and standards in the biomedical field **to facilitate interoperability among different computer systems, projects, and applications.**

New Functionality: mapping CDE semantics to UMLS concepts

- Added UMLS coding per CDE, UDE and Permissible Values
- Added the ability to search for CDEs/UDEs by concept name and/or concept identifier



The screenshot shows the BRICS Data Dictionary interface. The search criteria are: UMLS CUI: C001779 and UMLS Concept name: Age. The search results table is as follows:

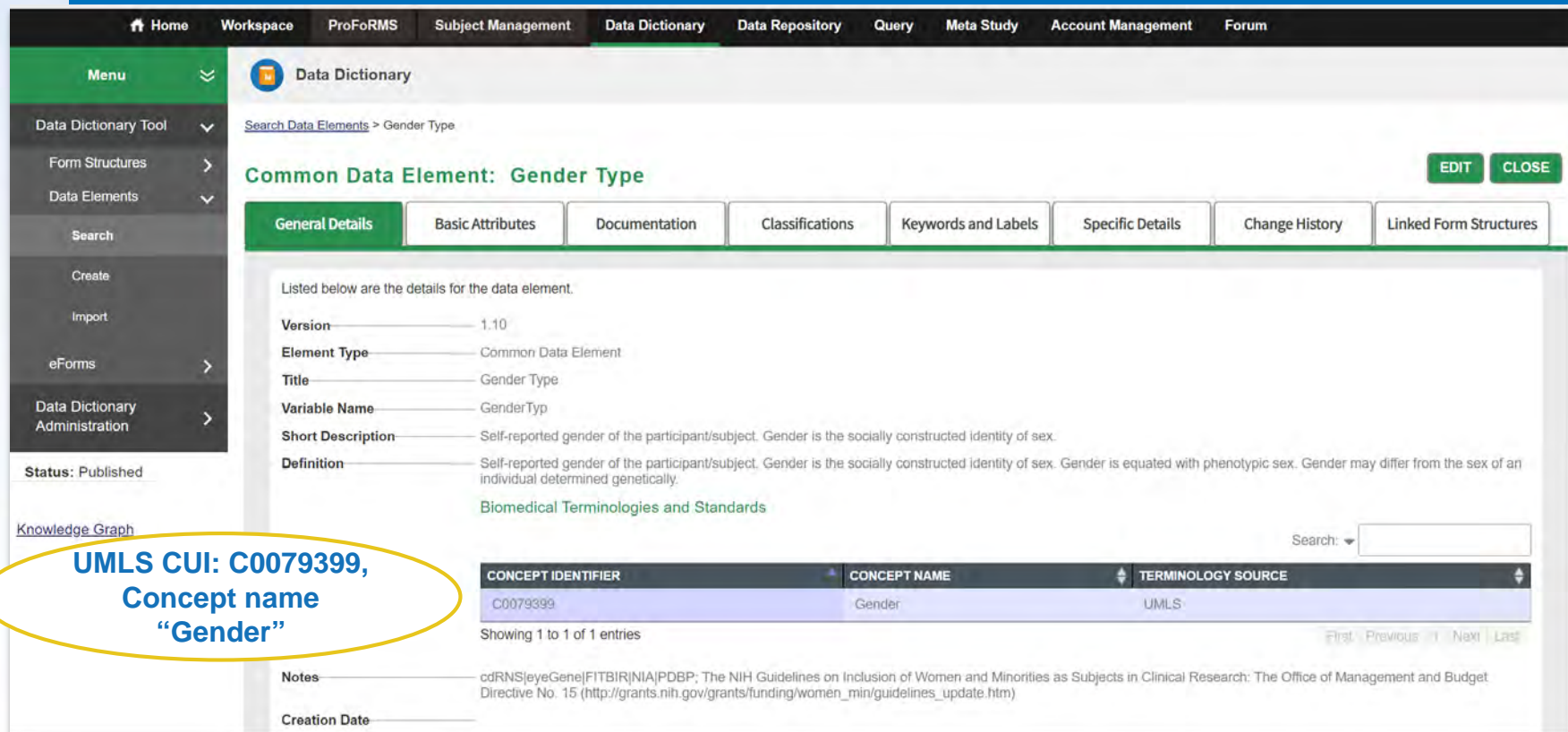
VARIABLE NAME	TYPE	MODIFIED DATE	STATUS
AGE	CDE	2023-04-21	Awaiting Publication
AgeYrs	CDE	2023-08-11	Published
FamHistCADYoungAgeVal	CDE	2023-07-26	Awaiting Publication
FamHistStrokYoungAgeVal	CDE	2023-07-26	Awaiting Publication
HandPrefBefore12MoAgeIrd	CDE	2023-07-28	Awaiting Publication
MedHistCondEndAgeVal	CDE	2023-08-04	Awaiting Publication
MedHistCondStrtAgeVal	CDE	2023-08-04	Awaiting Publication
PostnatalAgeVal	CDE	2023-07-31	Published

The interface also shows a search filter for 'Biomedical Terminologies and Standards' which is checked. The status filter is set to 'Draft', 'Awaiting Publication', 'Published', 'Deprecated', and 'Retired'. The element type is set to 'Common Data Element'.

- Supports programmatic analysis of the data.
- Makes data stored in a BRICS repository more AI ready.
- Supports data discovery.

So far, we mapped ~2K CDEs to UMLS concepts

Adding UMLS CUIs to BRICS data element attributes' list



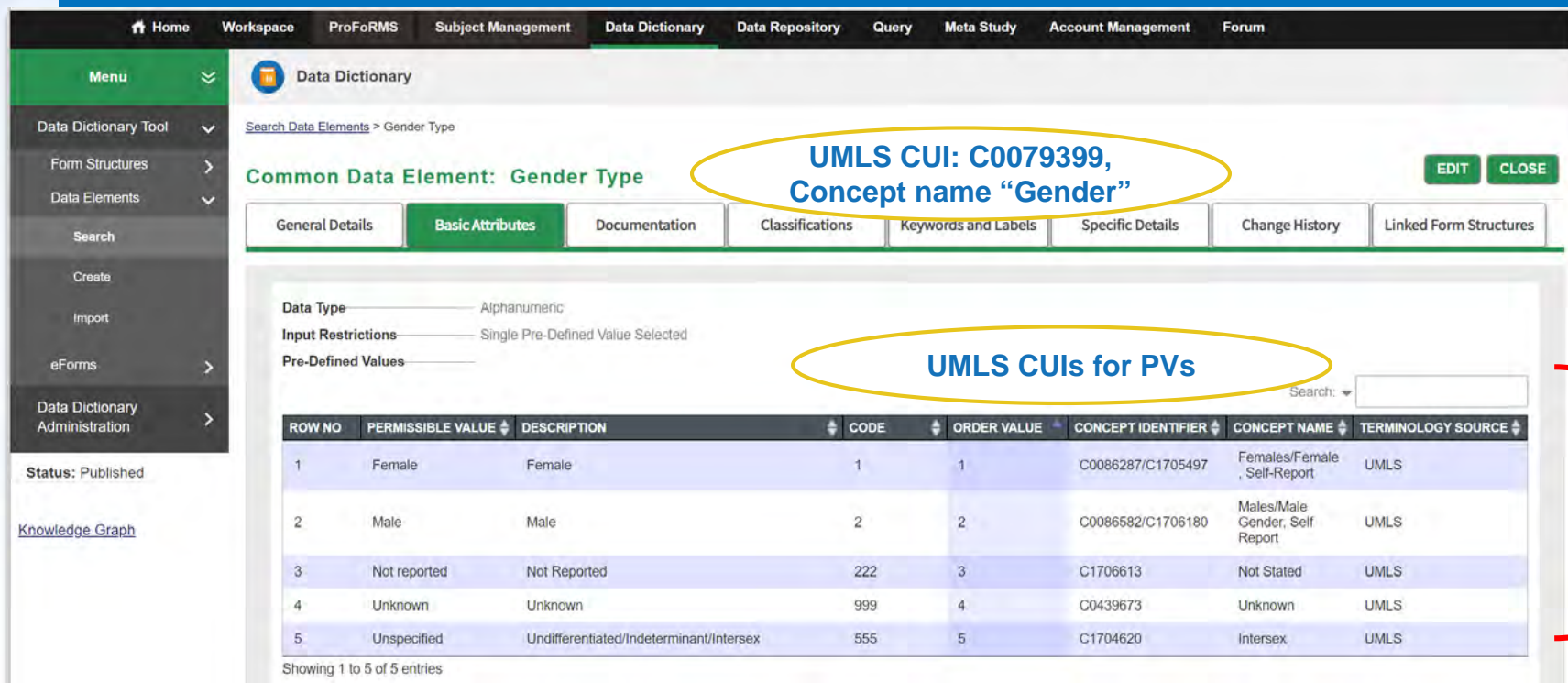
The screenshot shows the BRICS Data Dictionary interface. The main content area displays the details for the 'Gender Type' data element. Below the details, there is a section titled 'Biomedical Terminologies and Standards' which contains a table of UMLS concepts. A yellow oval highlights the first row of the table, which contains the UMLS Concept Identifier (CUI) 'C0079399' and the concept name 'Gender'.

UMLS CUI: C0079399, Concept name "Gender"

CONCEPT IDENTIFIER	CONCEPT NAME	TERMINOLOGY SOURCE
C0079399	Gender	UMLS

New Functionality: mapping CDE semantics to UMLS concepts

Adding UMLS CUIs to reflect semantics of permissible values



The screenshot displays the 'Data Dictionary' interface for 'Gender Type'. The 'UMLS CUI: C0079399, Concept name "Gender"' is highlighted in a yellow oval. Below this, the 'UMLS CUIs for PVs' section is also highlighted in a yellow oval, containing a table of permissible values. A red bracket on the right side of the table indicates the mapping of these values to UMLS concepts.

Common Data Element: Gender Type

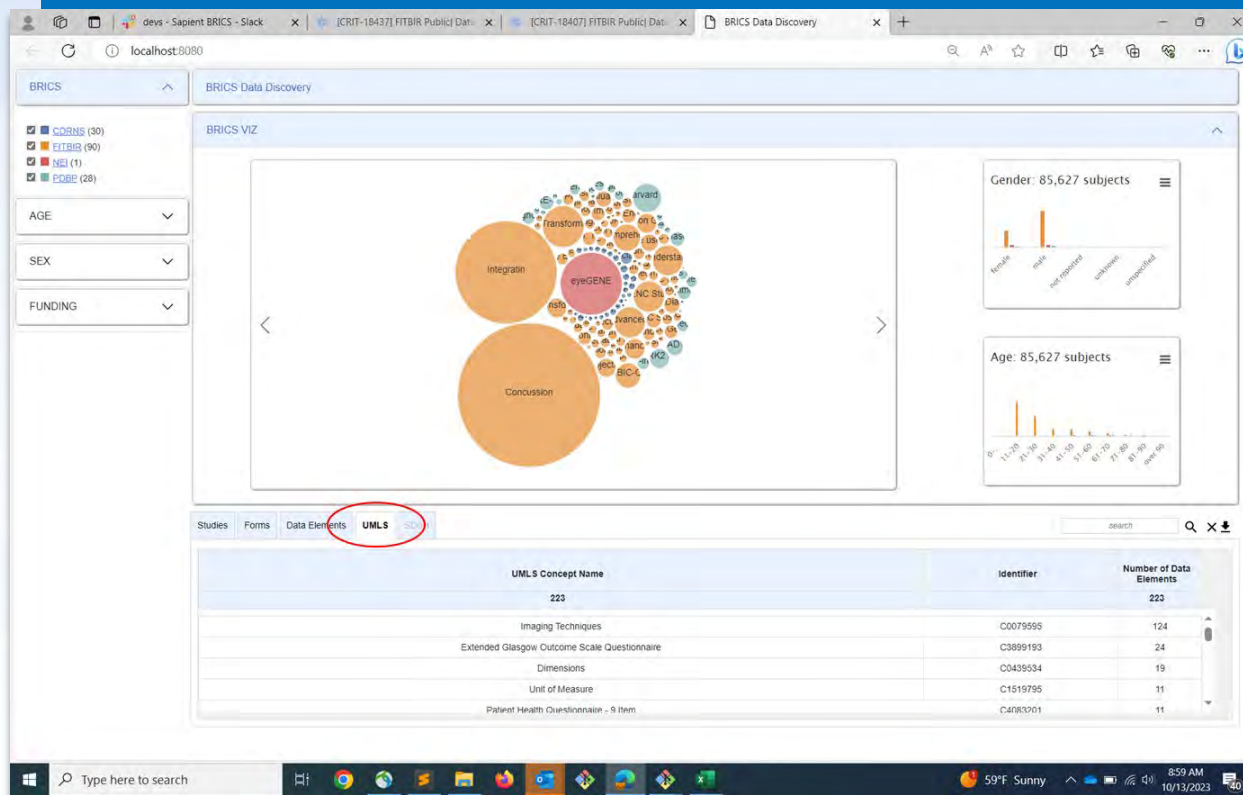
UMLS CUI: C0079399, Concept name "Gender"

UMLS CUIs for PVs

ROW NO	PERMISSIBLE VALUE	DESCRIPTION	CODE	ORDER VALUE	CONCEPT IDENTIFIER	CONCEPT NAME	TERMINOLOGY SOURCE
1	Female	Female	1	1	C0086287/C1705497	Females/Female, Self-Report	UMLS
2	Male	Male	2	2	C0086582/C1706180	Males/Male Gender, Self Report	UMLS
3	Not reported	Not Reported	222	3	C1706613	Not Stated	UMLS
4	Unknown	Unknown	999	4	C0439673	Unknown	UMLS
5	Unspecified	Undifferentiated/Indeterminant/Intersex	555	5	C1704620	Intersex	UMLS

Showing 1 to 5 of 5 entries

New Functionality: use of UMLS CUIs for data discovery



BRICS Data Discovery Tool interface showing a bubble chart visualization of data elements, a table of UMLS Concept Names, and summary statistics for Gender and Age.

UMLS Concept Name	Identifier	Number of Data Elements
223		223
Imaging Techniques	C0079595	124
Extended Glasgow Outcome Scale Questionnaire	C3899193	24
Dimensions	C0435034	19
Unit of Measure	C1519795	11
Patient Health Questionnaire - 9 Item	C4083201	11

BRICS Data Discovery Tool searches for data across BRICS instances

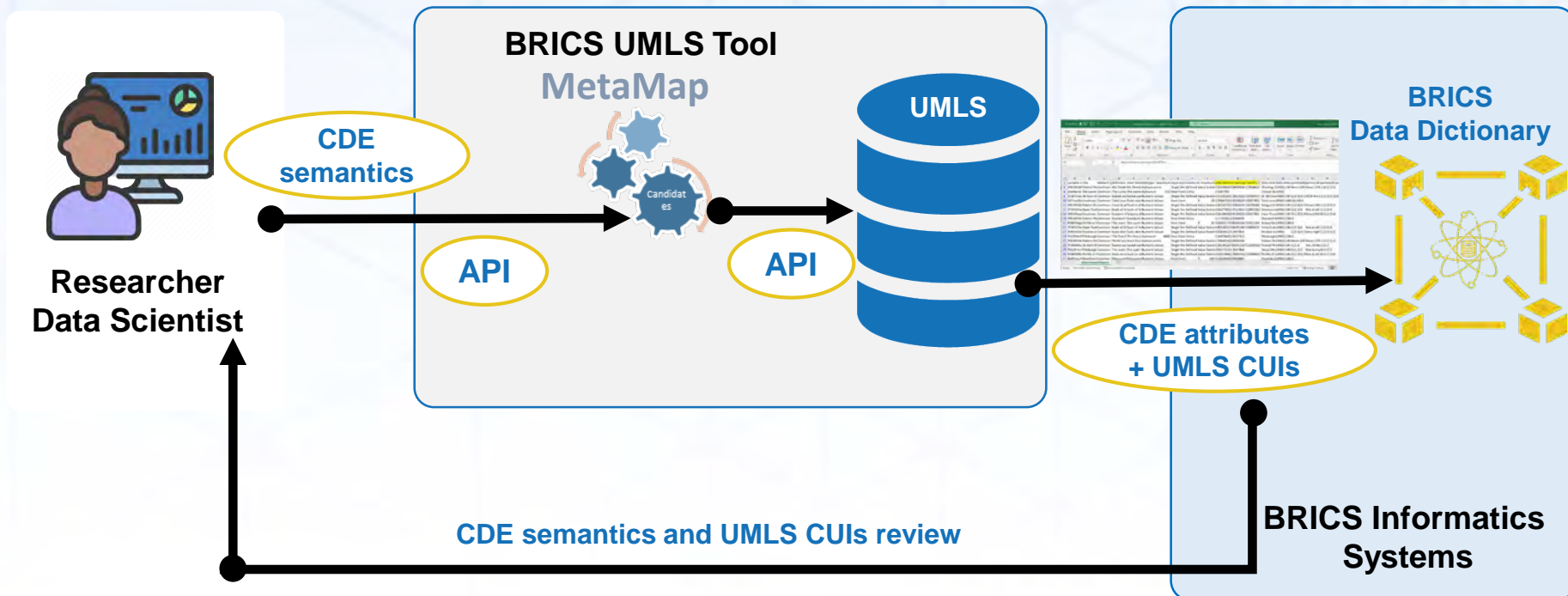
1. based on CDE/UDE or when there is no common elements across instances,
2. based on DE UMLS concepts.

- If CDEs/UDEs have shared semantics/UMLS CUIs they will be found.

We did not want to have the mapping CDEs semantic to UMLS as a manual process.

We built BRICS UMLS Tool

- Highly configurable.
- Semi-automatic querying and assigning relevant UMLS CUIs to selected CDE attributes.





1. Expanding the use of UMLS CUIs for data discovery
2. Ability to query data for UMLS CUIs/concepts in the Query tool
3. Enhance the **BRICS UMLS tool** with ability to:
 - Search in data dictionary for CDEs/UDEs with similar semantics
 - Provide the user with a feedback regarding CDE semantics



Enriching the FAIRness of BRICS using the OMOP CDM

Henry Ogoe, PhD (Biomedical Informatics)

Contractor, OSCS - CIT



MTBI²



What is OMOP CDM?

Raw data

Multiple SAS/R Coding



North America



Southeast Asia



Europe



OMOPed data

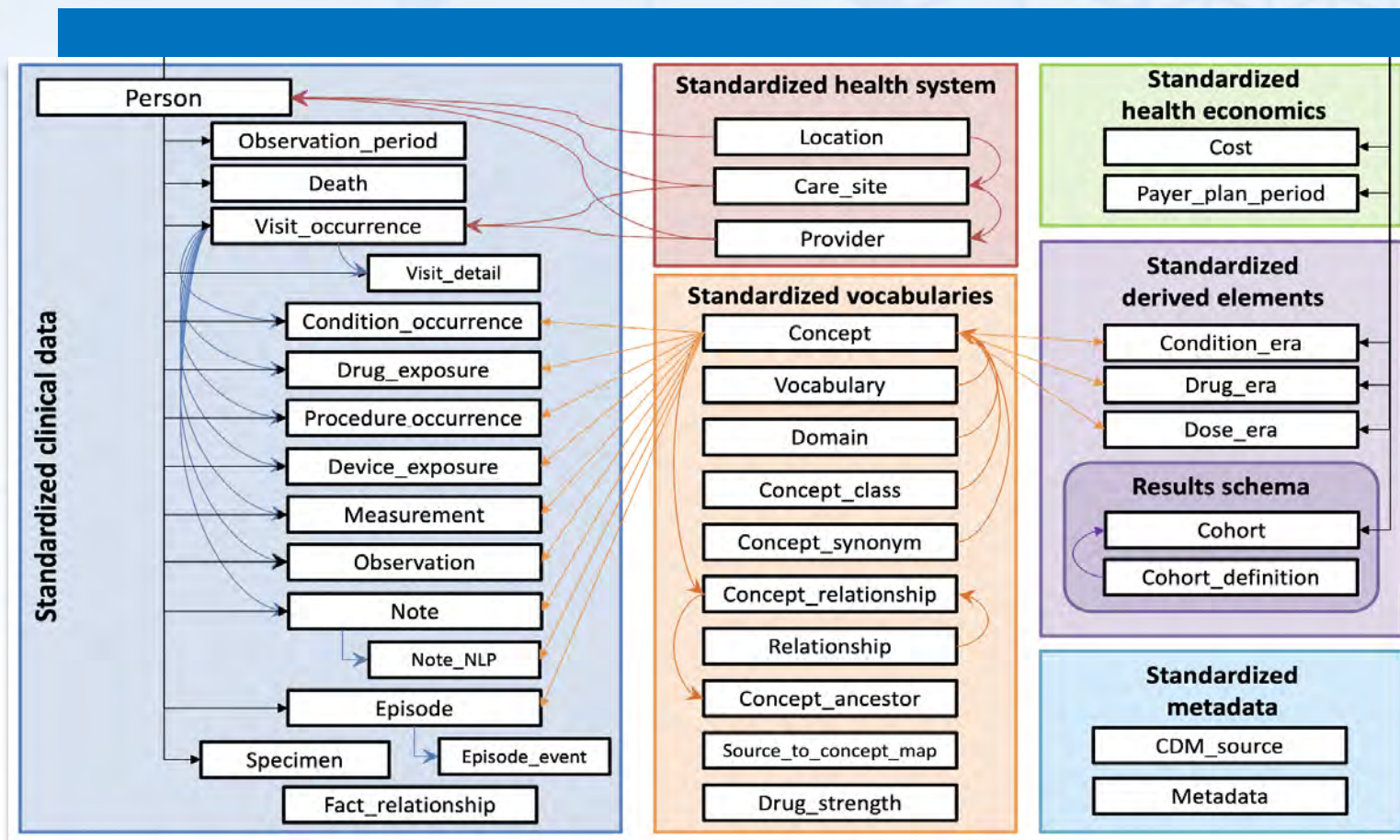
Standardized Analytics



The Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) is an open community data standard, designed to standardize the structure and content of observational data and to enable efficient analyses that can produce reliable evidence.

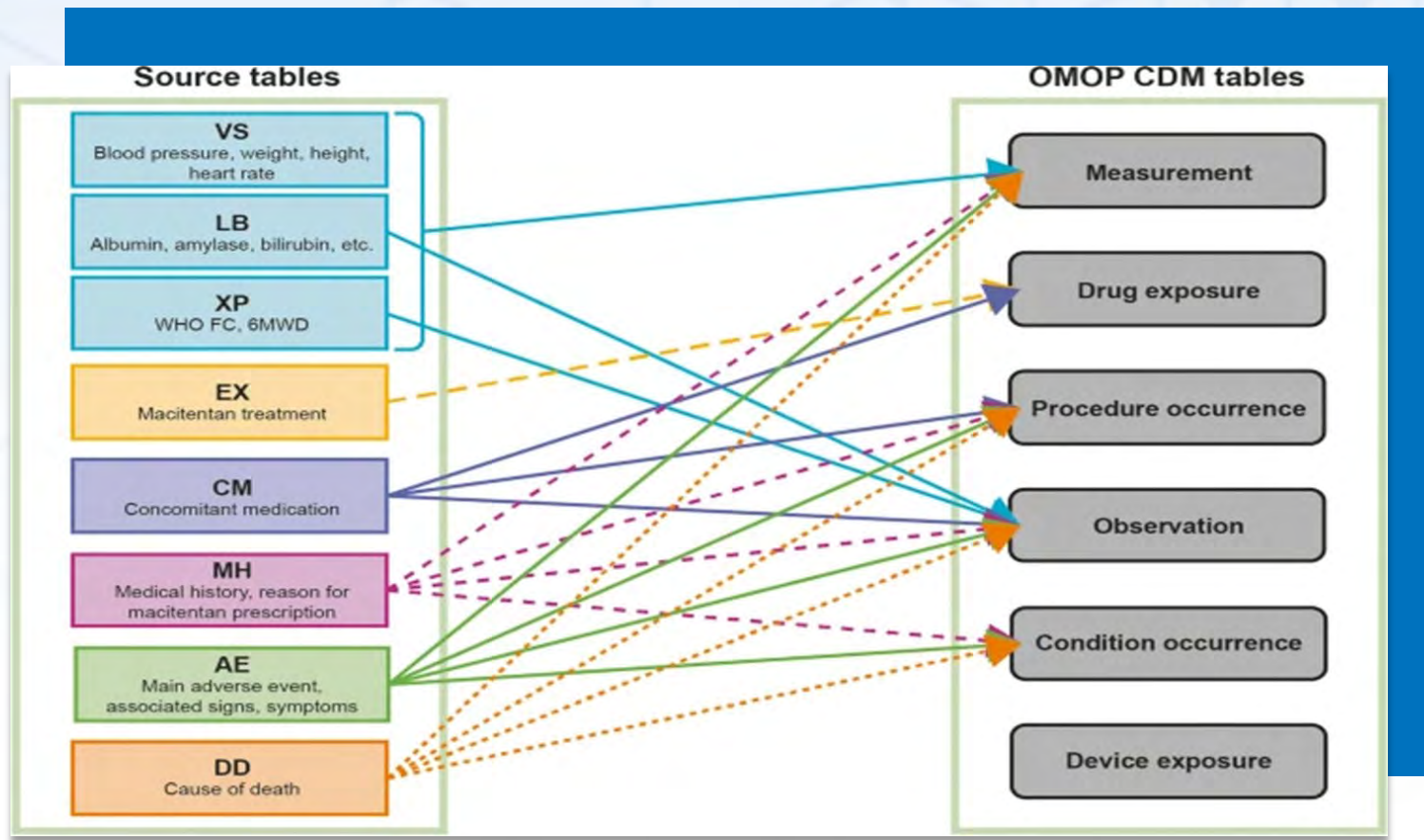


Person-centric, relational database schema; ~38 Tables & ~ 400 DE



Why would I care about OMOP in BRICS?

Regardless of data source (registry, EHR, or Claims) all we need is 38 FS & ~ 400 DE





Showing 1 to 38 of 38 entries

TITLE	SHORT NAME	STATUS	MODIFIED DATE
OMOP_CDM Care Site Form	Care_Site_OMOP_CDM	Published	2023-08-10
OMOP_CDM CDM Source Form	CDM_Source_OMOP_CDM	Published	2023-08-10
OMOP_CDM Cohort Definition Form	Cohort_Definition_OMOP_CD M	Published	2023-08-10
OMOP_CDM Cohort Form	Cohort_OMOP_CDM	Published	2023-08-10
OMOP_CDM Concept Ancestor Form	Concept_Ancestors_OMOP_C DM	Published	2023-08-10
OMOP_CDM Concept Class Form	Concept_Class_OMOP_CDM	Published	2023-08-10
OMOP_CDM Concept Form	Concept_OMOP_CDM	Awaiting Publication	2023-09-06
OMOP_CDM Concept Relationship Form	Concept_Relation_OMOP_CD M	Published	2023-08-10
OMOP_CDM Concept Synonym Form	Concept_Synonym_OMOP_C DM	Published	2023-08-10
OMOP_CDM Condition Era Form	Condition_Era_OMOP_CDM	Published	2023-08-10
OMOP_CDM Condition Occurrence Form	Con_occurrence_OMOP_CDM	Published	2023-08-10
OMOP_CDM Cost Form	Cost_OMOP_CDM	Published	2023-08-10
OMOP_CDM Device Exposure	Device_Exposure_OMOP_CD M	Published	2023-08-01
OMOP_CDM Domain Form	Domain_OMOP_CDM	Published	2023-08-10

Showing 1 to 38 of 38 entries

Data Elements >

eForms >

Data Dictionary Administration >

Standard NINDS CDE

Standard

Standard Modified

Appendix

Unique

Labels

CDISC

FHIR

HHS CARES

OMOP

Status

Draft

Awaiting Publication

Published

Archived

Shared Draft



Form Structure: OMOP_CDM Person

EDIT FORM

CLOSE

This form structure is an organized set of data definitions for a form that has not been copyrighted

Form Details

Data Elements

eForms

Documentation

Keywords

Change History

Logically grouped data elements with defined frequency at which they repeat.

#	TITLE	SHORT DESCRIPTION	VARIABLE NAME	REQUIRED?	TYPE
1	GUID_	Global Unique ID (GUID) which uniquely identifies a subject	GUID	Required	CDE

Additional Element Groups

Listed below are your additional element groups

Form Administration (Appears Up To 1 Time)

#	TITLE	SHORT DESCRIPTION
1	<u>Data source</u>	Source of the data provided on the report form
2	<u>Data source other text</u>	The free-text field related to Data source specifying other text. Source the data provided on the case report form

CDM Person (Appears Up To 1 Time)

#	TITLE	SHORT DESCRIPTION
1	<u>Person id</u>	A unique identifier for the person (subject/participant).
2	<u>Gender concept id</u>	An identifier (foreign key from the CONCEPT table) that represents the

Unique Data Element: Person id

General Details

Basic Attributes

Documentation

Classifications

Keywords and Labels

Specific Details

Change History

Linked Form Structures

Listed below are the details for the data element.

Version..... 1.0

Element Type..... Unique Data Element

Title..... Person id

Variable Name..... person_id

Short Description..... A unique identifier for the person (subject/participant).

Definition..... A unique identifier for the person (subject/participant).

[Biomedical Terminologies and Standards](#)

Search:

CONCEPT IDENTIFIER	CONCEPT NAME	TERMINOLOGY SOURCE
C2348585	Clinical Trial Subject Unique Identifier	UMLS

Showing 1 to 1 of 1 entries

First Previous

Notes..... From PERSON table OMOP_CDMv6.0



Why does it enrich BRICS' FAIRness?

Findable



- Persistent identifiers (person_id, event_id, concept_id) for metadata

Interoperable



- OMOP CDM
- Standard Vocabularies
- Relationships between source and standard vocabularies

Accessible



- Standardized data accessibility, and
- Communications via BRICS Query Tools

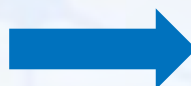
Reusable



- OMOP CDM
- Standard Vocabulary
- Methods Library for best-practice observational research*

Proof-of-Concept: ETL CMS Synthetic Patient Data to BRICS Instance

 **CMS Synthetic Patient Data OMOP**



 **OMOP CDM v6.0**



Form Structure: OMOP_CDM Person Form

This form structure is an organized set of data definitions for a form that has not been copyrighted

Form Details

Data Elements

eForms

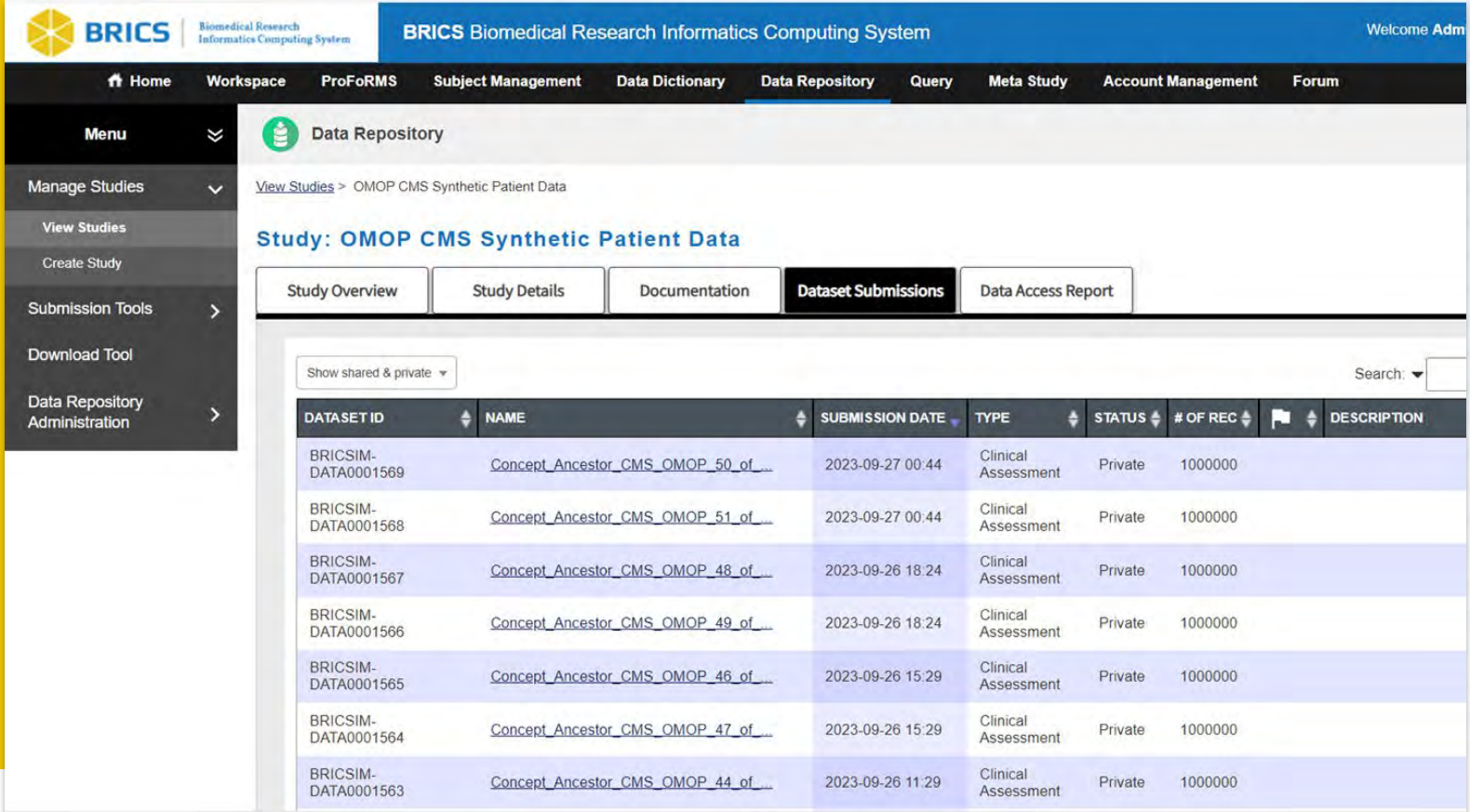
Documentation

Change History




Validation Tool

Upload Tool



The screenshot displays the BRICS Biomedical Research Informatics Computing System interface. The top navigation bar includes links for Home, Workspace, ProFoRMS, Subject Management, Data Dictionary, Data Repository (selected), Query, Meta Study, Account Management, and Forum. A left sidebar menu contains options like Manage Studies, View Studies, Create Study, Submission Tools, Download Tool, and Data Repository Administration. The main content area shows the 'Data Repository' section for the study 'OMOP CMS Synthetic Patient Data'. Below the study title are tabs for Study Overview, Study Details, Documentation, Dataset Submissions (active), and Data Access Report. A table lists dataset submissions with columns for Dataset ID, Name, Submission Date, Type, Status, # of Rec, and Description. A search bar and a 'Show shared & private' dropdown are also visible.

DATASET ID	NAME	SUBMISSION DATE	TYPE	STATUS	# OF REC	DESCRIPTION
BRICSIM-DATA0001569	Concept_Ancest..._CMS_OMOP_50_of_...	2023-09-27 00:44	Clinical Assessment	Private	1000000	
BRICSIM-DATA0001568	Concept_Ancest..._CMS_OMOP_51_of_...	2023-09-27 00:44	Clinical Assessment	Private	1000000	
BRICSIM-DATA0001567	Concept_Ancest..._CMS_OMOP_48_of_...	2023-09-26 18:24	Clinical Assessment	Private	1000000	
BRICSIM-DATA0001566	Concept_Ancest..._CMS_OMOP_49_of_...	2023-09-26 18:24	Clinical Assessment	Private	1000000	
BRICSIM-DATA0001565	Concept_Ancest..._CMS_OMOP_46_of_...	2023-09-26 15:29	Clinical Assessment	Private	1000000	
BRICSIM-DATA0001564	Concept_Ancest..._CMS_OMOP_47_of_...	2023-09-26 15:29	Clinical Assessment	Private	1000000	
BRICSIM-DATA0001563	Concept_Ancest..._CMS_OMOP_44_of_...	2023-09-26 11:29	Clinical Assessment	Private	1000000	


Biomedical Research Informatics Computing System
Welcome Administrator, Mihir | Log Out

Home
Workspace
ProFoRMS
Subject Management
Data Dictionary
Data Repository
Query
Meta Study
Account Management
Forum

Step 1: Filter Data Admin Only: ✖ Clear Cache 🛒 Data Cart: 0 forms in 0 studies 🗑️ Clear Data Cart 💾 Save New Query

Search GUID ✖ 🔍

Studies Forms Data Elements Defined Queries

Search Studies ✖ 🔍 Data Type - All ▼

Filter forms by: 1 Studies Selected ✖

⊖ Studies (24 Results) Reset Filter

- CRISPI_BTRIS_NIEHS Test Data (# of Forms: 20)
- CRISPI_BTRIS_NIMH Test Data (# of Forms: 20)
- CRISPI_BTRIS_NINDS Test Data (# of Forms: 20)
- CRISPI_BTRIS_NINR Test Data (# of Forms: 20)
- CRISPI_BTRIS_UNKNOWN Test Data (# of Forms: 20)
- OMOP CMS Synthetic Patient Data (# of Forms: 17)
- Study with Imaging Data (# of Forms: 2)

Forms

Search Forms ✖ 🔍 Data Type - All ▼ Results: (17 Forms) 🛒 Add All +

Hide Not Available

⊕ OMOP_CDM Care Site Form 🛒 <div style="text-align: right; font-size: small;">📄 1 👤 0</div>	⊕ OMOP_CDM Concept Ancestor Form 🛒 <div style="text-align: right; font-size: small;">📄 1 👤 0</div>
⊕ OMOP_CDM Concept Class Form 🛒 <div style="text-align: right; font-size: small;">📄 1 👤 0</div>	⊕ OMOP_CDM Concept Synonym Form 🛒 <div style="text-align: right; font-size: small;">📄 1 👤 0</div>
⊕ OMOP_CDM Condition Era Form 🛒 <div style="text-align: right; font-size: small;">📄 1 👤 4224</div>	⊕ OMOP_CDM Condition Occurrence Form 🛒 <div style="text-align: right; font-size: small;">📄 1 👤 4224</div>
⊖ OMOP_CDM Device_Exposure 🛒 <div style="text-align: right; font-size: small;">📄 1 👤 1846</div>	⊕ OMOP_CDM Dose_Era Form 🛒 <div style="text-align: right; font-size: small;">📄 1 👤 4279</div>

- Explore and leverage OHDSI Analytics libraries like ATLAS to support various data-analytics use cases in the BRICS **Query Tool** to enhance **Reusability**





BRICS

Biomedical Research
Informatics Computing System

Take-home

It is now possible to stand up
a **BRICS** instance that is
OMOP CDM enabled





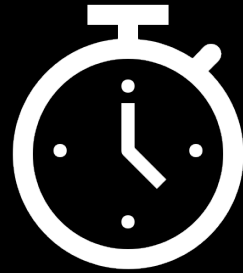
BRICS

Biomedical Research
Informatics Computing System

Thank you!

Q&A





BREAK: 10:20AM – 10:35AM



BRICS

Biomedical Research
Informatics Computing System

Biomedical Research Informatics Computing System (BRICS)

NIA (National Institute on Aging) Pilot Project

Fatima Irfan



MTBI²



NATIONAL INSTITUTE OF
NEUROLOGICAL
DISORDERS AND STROKE





Health & Retirement Study (HRS)

Health, Aging, and Body
Composition Study (Health ABC)

Minority Aging Research Study
(MARS)

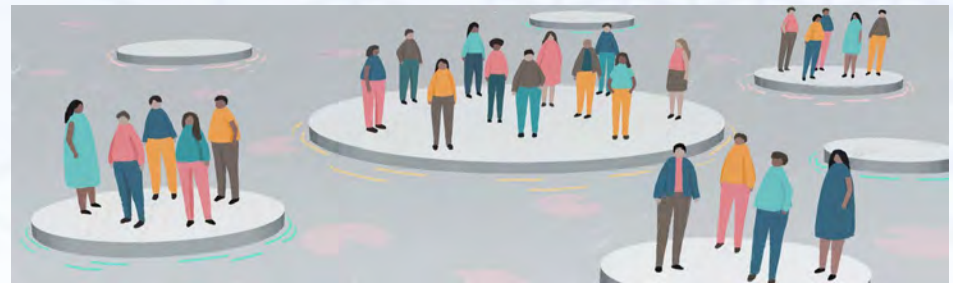
Louisiana Osteoporosis Study
(LOS)

BRICS NIA Platform





- Collaborative approaches among cohorts could expedite epidemiological discovery by assembling multi-level data collected across the lifespan and providing a framework for multi-disciplinary work
- Foster communication among investigators leading cohort studies on aging research
- Promote collaborative research projects for topics not easily addressed by a single study



- We looked across study data to identify ~120 Common Data Elements, defined as variables that are present in 2+ studies

CDE Title	Health ABC	HRS	MARS	LOS
Data source	[Redacted]			
Data source other	[Redacted]		[Redacted]	[Redacted]
General notes	[Redacted]			
Language of form	[Redacted]			
Site name	[Redacted]			
Subject ID	[Redacted]			
Visit date			[Redacted]	[Redacted]
Year data collected	[Redacted]		[Redacted]	[Redacted]
Study year	[Redacted]			

Snapshot of Data Inclusion Factsheet

- This was an iterative process, as it required multiple phases of combing through data documentation and dictionaries



Process Overview: 4 Form Structures

- We grouped those 120 variables into 4 form structures

NIA
Demographics
Form

NIA Medical
History Form

NIA Vital Signs
Form

Daily Living and
Physical Ability
Form



Process Overview: Data Transformation

- We transformed the data to fit into our CDE definitions
- Data elements are sometimes collected differently across studies, so we sought to harmonize them

Variable	General Description	Value labels
DIFFPP	Difficulty pushing/pulling	0=No 1=Yes

Health ABC

How difficult is it for you to...

B4r. ...pull or push large objects like a living room chair? [IMPUTED]

V318 Code	Frequency
1	9303
2	1577
3	766
4	843
6	163

HRS



General ETL Process

Data access and
data definition



Create and build
upon existing
forms in BRICS
system



Data
transformation



Data validation
and upload





- Currently, we have data across 4 studies and 4 forms, reflecting 1 year of study data for 16,613 participants
- We can query data across studies, with lots of flexibility in filtering
- We can now download harmonized data from multiple studies with a complete data dictionary





- Currently, we are working on uploading year 2 data across 4 studies
- We are also working on uploading all year 1 data for HRS
 - Still a pilot, with all data remaining private
 - Will be able to run analyses in system, with all the data and documentation in a clear, accessible, and easy to use format





Demo



BRICS

Biomedical Research
Informatics Computing System

Biomedical Research Informatics Computing System (BRICS)

Query Tool API

Dan Gillis
FITBIR Imaging



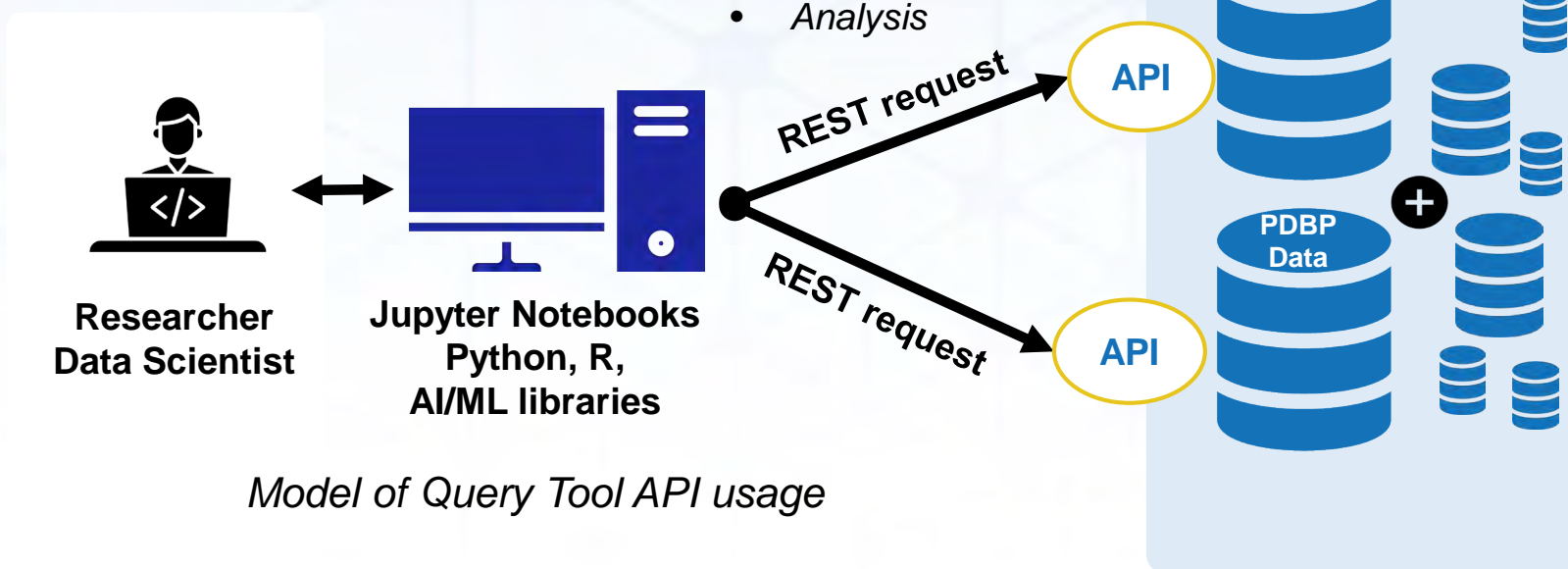
MTBI²



- Two methods to query data on a BRICS instance
 - Web Query Tool – GUI, access through browser
 - **Query Tool API – Programmatic access through REST services**
- This presentation gives an overview of this API

API services

- Query
- Retrieve data
- Analysis

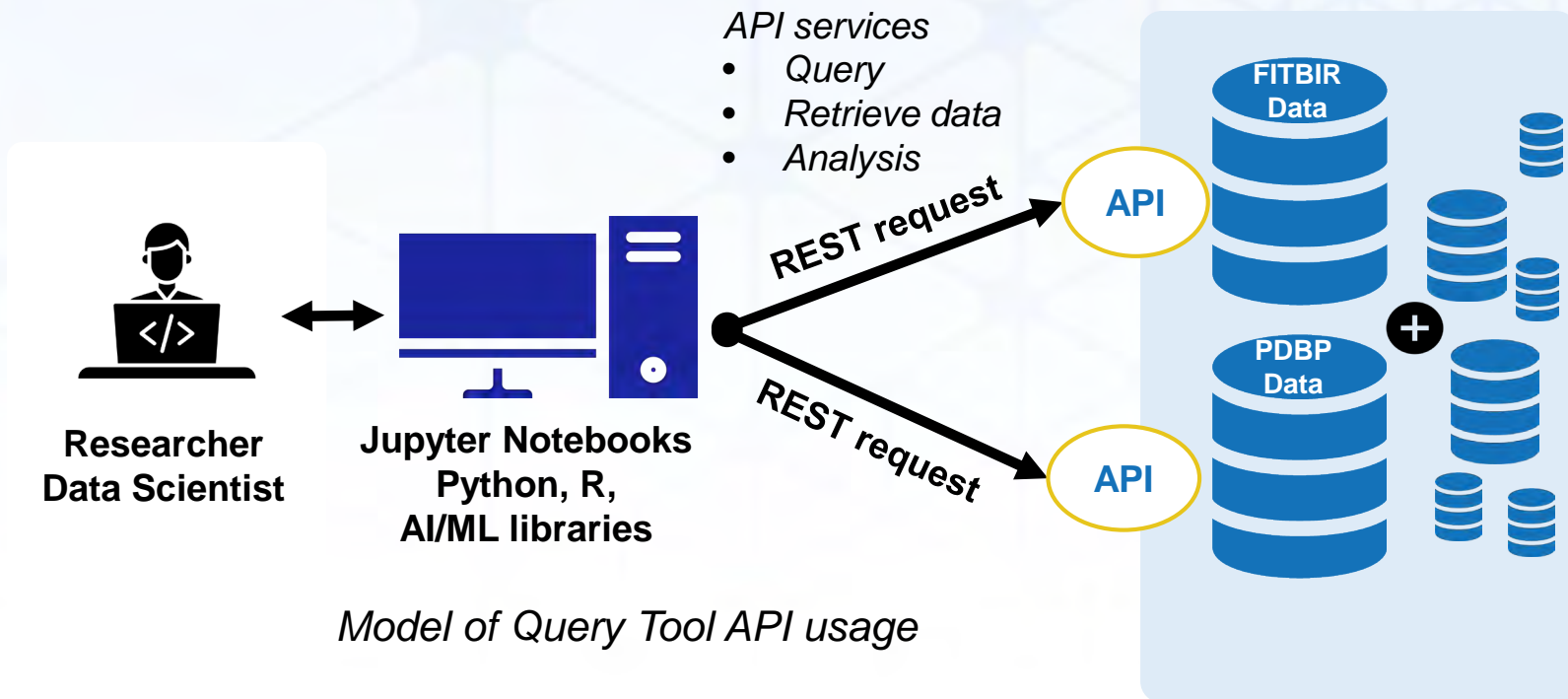


Model of Query Tool API usage

- Application Program Interface for the Query Tool
- A way for computer programs to communicate with the Query Tool
- The API defines services that the Query Tool can perform for users
 - Each service is accessed through its own endpoint URL
- Access using authentication token

API services

- Query
- Retrieve data
- Analysis



Model of Query Tool API usage

- Find all studies using a specific form structure
- Find every form structures submitted for a study
- Query data across multiple studies and form structures
 - Filter results based on data element values
 - Perform joins across form structures
- Download files associated with query results
- **Everything we can do with the browser-based Query Tool**



Why would we want to use the API?

- **The API provides programmatic access to the Query Tool**
 - Data accessors can use the Query Tool services in their own programs & notebooks
- **Using the API extends the power of the Query Tool**
 - Instantly create plots of data returned
 - Directly download query results
 - Generate filters based on the results of previous queries
 - Build data transformation pipelines and easily apply them to multiple queries





API Examples
GOSE Scores

- Example scenario for using the API
- Suppose we are interested in seeing how age affects outcomes from patients suffering from traumatic brain injuries
 - Target metric: GOSE (Glasgow Outcome Scale Extended) total score
- To start, we want to see the distribution of GOSE scores for:
 - All subjects with GOSE data on FITBIR
 - Subjects ages 20 to 30

- We want to do the following:
 - Find which studies have GOSE data submitted
 - Find all GOSE scores submitted to FITBIR
 - Find GOSE scores for our filtered age range
 - Create bar graphs to view the distribution of scores
- We can do all of this with the API
- For next slides, **output of code outlined in red**



- Get authentication token
 - Obtained by logging in using RAS
- Generate header to be used in API requests

```
token = getpass.getpass("Enter your user token")
```

```
Enter your user token .....
```

```
def gen_base_headers(token):  
    return {"Authorization": f"Bearer {token}"}
```

```
base_headers = gen_base_headers(token)
```

Add token to notebook to authenticate requests

- Find all studies with GOSE data
- Input: GOSE form structure name
- Output: data about studies with GOSE form structure

```
base_gt_url = "https://fitbir.nih.gov/gateway/query-api"
gose_form_name = "GOSE_Standard"

## 1. Find studies which have GOSE data

def find_studies_with_form(form_names, headers):

    studies_with_form_url = f"{base_gt_url}/study/form"
    form_params = {"formName": form_names}
    return requests.get(studies_with_form_url, params=form_params, headers=headers)

studies_with_gose_request = find_studies_with_form(gose_form_name, base_headers)
studies_with_gose_request.raise_for_status()
studies_with_gose_metadata = studies_with_gose_request.json()[0]
```

Query code

There are 17 studies with form: GOSE_Standard

	abstract	status	id	title
0	Traumatic brain injury (TBI) in older adults i...	Public	FITBIR-STUDY0000266	AIM: TBI Impact of Aging on the Immune Respons...
1	Traumatic brain injury (TBI) is a major cause...	Public	FITBIR-STUDY0000240	Adding Legacy Clinical Data to the Federal Int...
2	Background:\r\n\r\n- A person who has a trauma...	Public	FITBIR-STUDY0000272	Biomarkers-Driven Development of Experimental...
3	This study's overall goal is to establish a la...	Public	FITBIR-STUDY0000263	CENC Study 1: Observational Study on Late Neur...

Query results



- Retrieve all GOSE data on FITBIR
- Input: GOSE form structure name
- Output: all GOSE data on FITBIR

```
def make_query(form_data, headers, filters=None):
    # form_data and filters should be lists
    query_url = "https://fitbir.nih.gov/gateway/query-api/data/csv"
    form_and_filter = {
        "formStudy": form_data,
    }
    if filters is not None:
        form_and_filter["filter"] = filters
    return requests.post(query_url, headers=headers, json=form_and_filter)

gose_form_data = [make_form_data(gose_form_name)]

overall_gose_request = make_query(gose_form_data, headers=base_headers)
```

Query code

Number of rows for GOSE_Standard is 12656.

Study ID	Dataset	GOSE_Standard.Main.GUID	GOSE_Standard.Main.ASSOCIATED GUID
0 392	FITBIR-DATA0014496	TBIYY662YVC	NaN
1 392	FITBIR-DATA0014496	TBIAT815JWE	NaN
2 392	FITBIR-DATA0014496	TBIHP687JA8	NaN

Query results

- **Retrieve filtered age GOSE data**
 - Join with demographics form to filter by age
- **Input:**
 - GOSE and demographics form names
 - Ids of studies with GOSE data
 - Age filter
- **Output:** filtered age GOSE data

```

fitbir_demo_form_name = "DemogrFITBIR"

gose_form_data_20_30 = [
    make_form_data(gose_form_name),
    make_form_data(fitbir_demo_form_name, studies=study_ids_with_gose_data)
]
filters_20_30 = [
    make_filter(
        fitbir_demo_form_name,
        "Main Group",
        "AgeYrs",
        rangeStart="20",
        rangeEnd="30",
        mode="inclusive"
    )
]

gose_20_30_response = make_query(
    gose_form_data_20_30, filters=filters_20_30, headers=base_headers
)

```

Query code

Number of rows for GOSE_Standard is 2410.

	GUID	GOSE_Standard.Study ID	GOSE_Standard.Dataset	GOSE_Standard.Main.GUID
0	TBICX708BGN	NaN	NaN	NaN
1	TBICU683PDB	NaN	NaN	NaN
2	TBI_INVHZ302UH8	246.0	FITBIR-DATA0000712	TBI_INVHZ302UH8
3	TBI_INVHZ302UH8	246.0	FITBIR-DATA0000712	TBI_INVHZ302UH8

Query results

Bar graph code

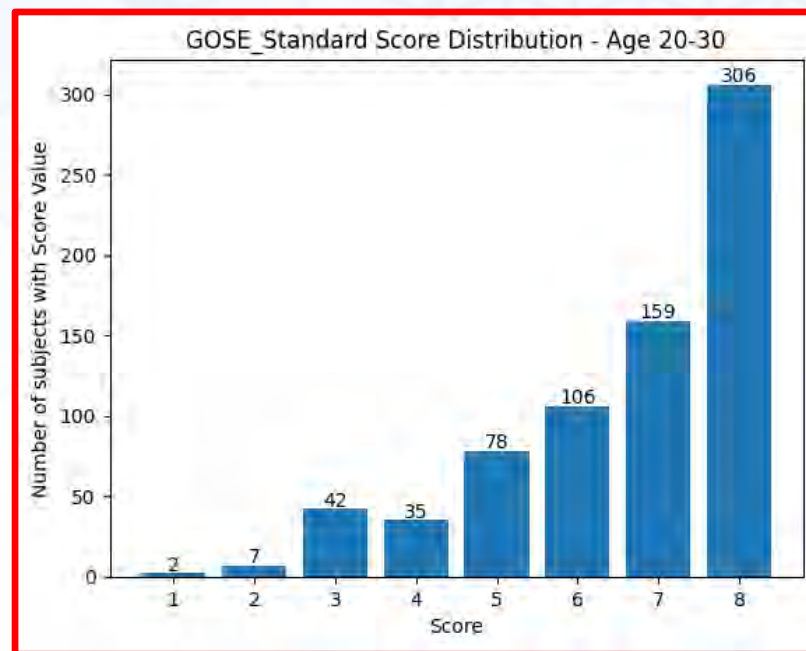
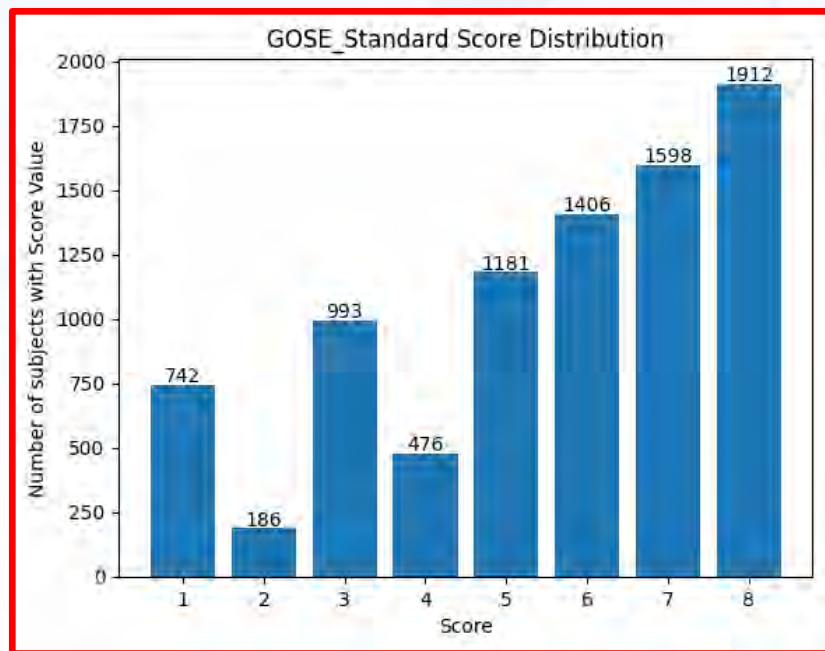
- Generate bar graphs
 - Overall scores
 - Filtered age scores

```
gose_outcome_score_de = "GOSE_Standard.Form.Completion.GlasgowOutcomeScaleExtScore"
overall_score_data = overall_gose_df[gose_outcome_score_de].value_counts()
```

```
make_graph_of_counts(overall_score_data)
```

```
score_20_30_data = gose_20_30_df[gose_outcome_score_de].value_counts()
```

```
make_graph_of_counts(score_20_30_data, title_addition="- Age 20-30")
```



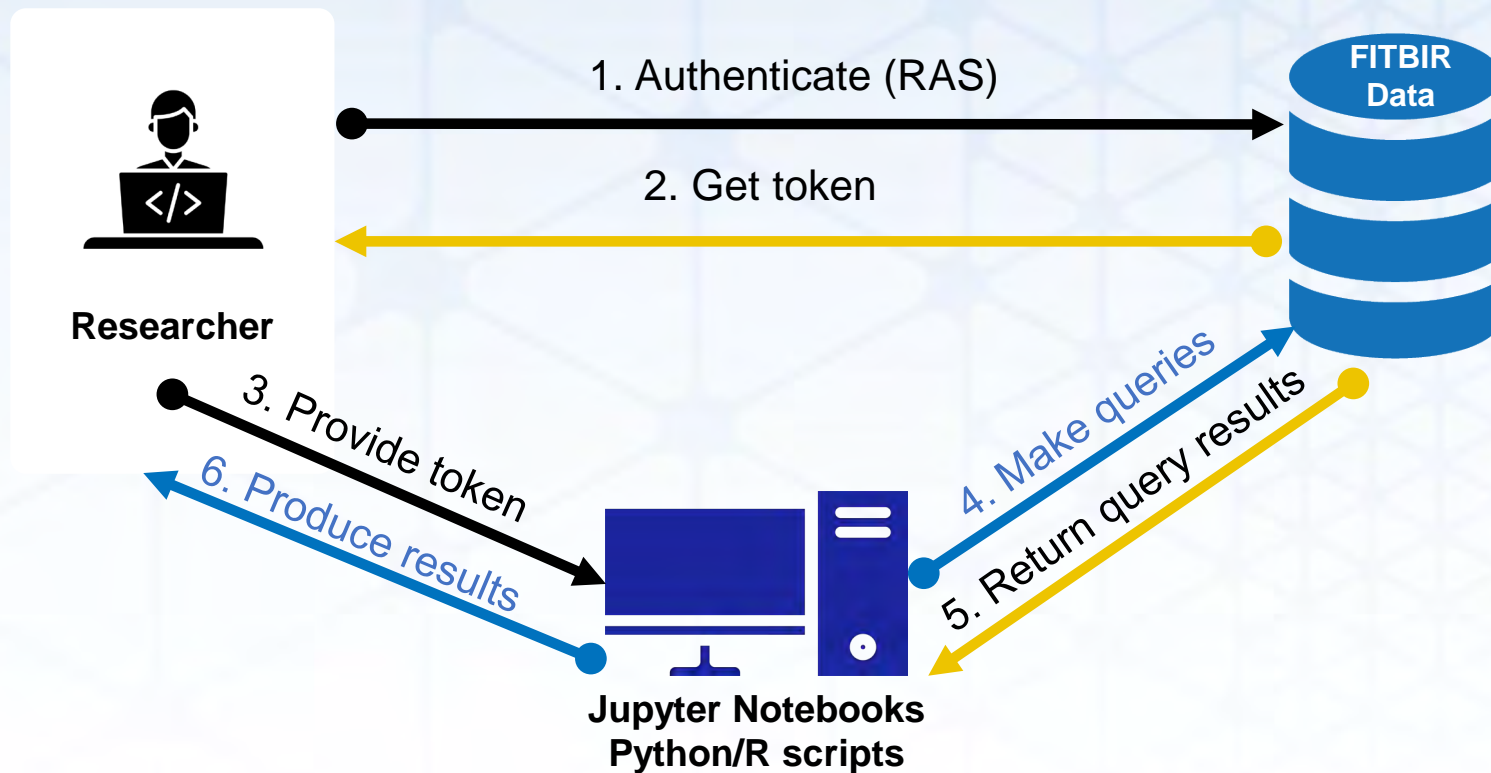
Bar Graphs Showing Distribution of Scores



BRICS

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Informatics Computing System

Additional Slides





BRICS

Biomedical Research
Informatics Computing System

FITBIR USE CASE

Nsini Umoh, PhD, Program Director, Repair and
Plasticity NIH/NINDS



MTBI²



PDBP
Parkinson's Disease
Biomarkers Program

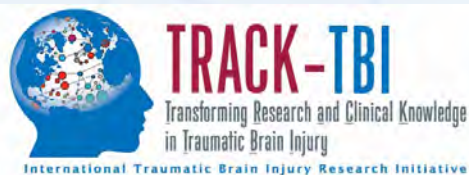
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NEUROLOGICAL
DISORDERS AND STROKE



The Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System is a national registry for clinical TBI research data that integrates heterogeneous datasets allowing access to high quality, multi-study, metadata analyses

- Prospective clinical TBI studies
 - U.S Army Medical Research & Development Command (MRDC) and NIH Requirements to submit data to FITBIR
- Includes high-quality and reproducible data such as: Patient Characteristics and Demographics, Neuroimaging, Clinical Assessments, Behavioral History, Varied Data Types (text, numeric, image)
- Aggregates raw data from all investigators in a common format
 - Common Data Elements (CDEs) – information that describes a piece of data collected in a study
 - Global Unique Identifiers (GUIDs) – identifiers for study participants to facilitate deidentified data sharing and tracking across multiple studies





A collaborative for advancing diagnosis and treatment of TBI





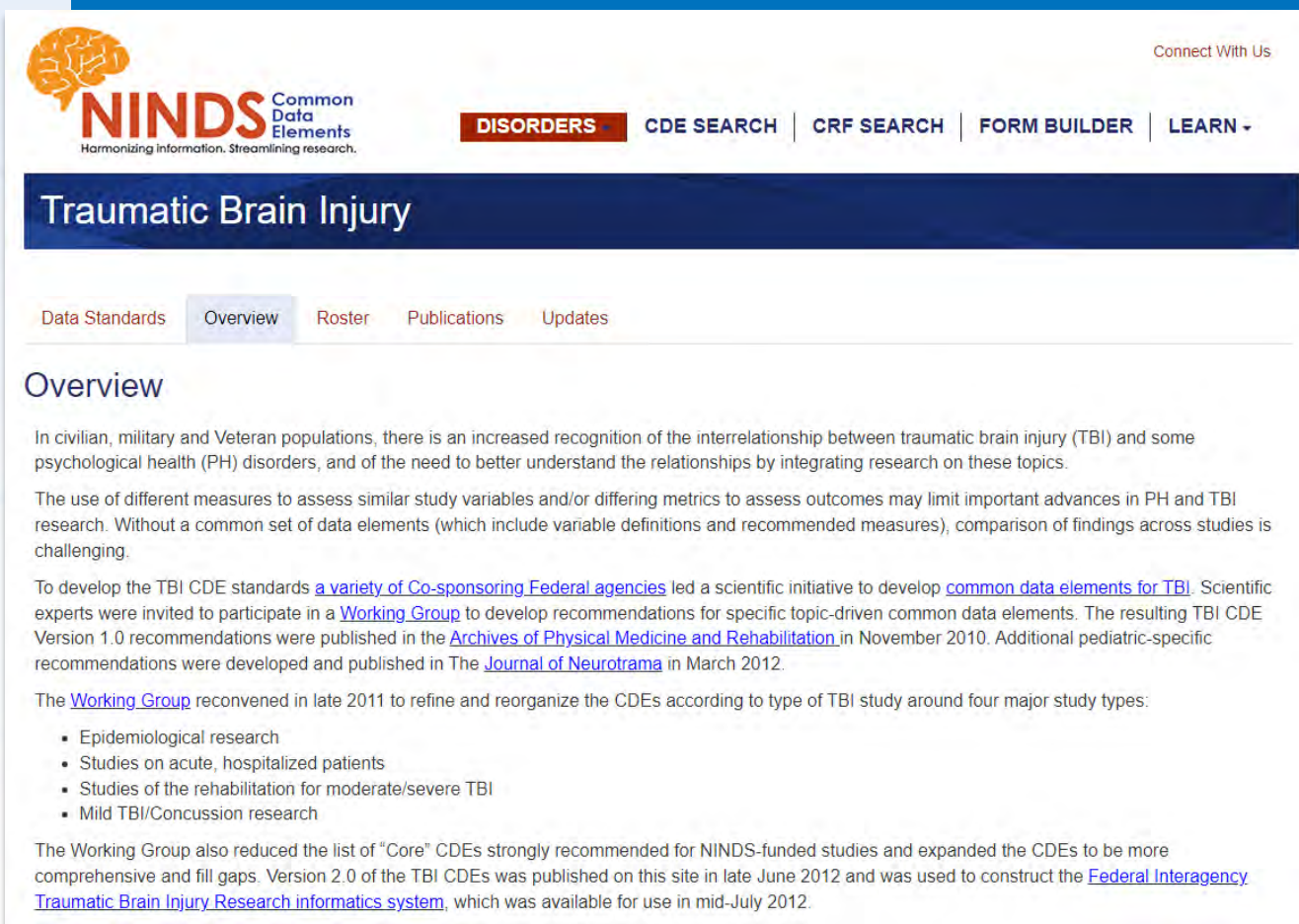
Today

- Human Subject Data
- Clinical
- Imaging
- Genomics
- `Neuropathology Data

Future

- Preclinical Data





The screenshot shows the NINDS Common Data Elements website. At the top left is the NINDS logo with the tagline "Harmonizing information. Streamlining research." To the right is a "Connect With Us" link. Below the logo is a navigation menu with "DISORDERS" highlighted in red, followed by "CDE SEARCH", "CRF SEARCH", "FORM BUILDER", and "LEARN". The main heading is "Traumatic Brain Injury". Below this is a sub-navigation menu with "Data Standards", "Overview" (selected), "Roster", "Publications", and "Updates". The "Overview" section contains the following text:

In civilian, military and Veteran populations, there is an increased recognition of the interrelationship between traumatic brain injury (TBI) and some psychological health (PH) disorders, and of the need to better understand the relationships by integrating research on these topics.

The use of different measures to assess similar study variables and/or differing metrics to assess outcomes may limit important advances in PH and TBI research. Without a common set of data elements (which include variable definitions and recommended measures), comparison of findings across studies is challenging.

To develop the TBI CDE standards [a variety of Co-sponsoring Federal agencies](#) led a scientific initiative to develop [common data elements for TBI](#). Scientific experts were invited to participate in a [Working Group](#) to develop recommendations for specific topic-driven common data elements. The resulting TBI CDE Version 1.0 recommendations were published in the [Archives of Physical Medicine and Rehabilitation](#) in November 2010. Additional pediatric-specific recommendations were developed and published in The [Journal of Neurotrauma](#) in March 2012.

The [Working Group](#) reconvened in late 2011 to refine and reorganize the CDEs according to type of TBI study around four major study types:

- Epidemiological research
- Studies on acute, hospitalized patients
- Studies of the rehabilitation for moderate/severe TBI
- Mild TBI/Concussion research

The Working Group also reduced the list of "Core" CDEs strongly recommended for NINDS-funded studies and expanded the CDEs to be more comprehensive and fill gaps. Version 2.0 of the TBI CDEs was published on this site in late June 2012 and was used to construct the [Federal Interagency Traumatic Brain Injury Research informatics system](#), which was available for use in mid-July 2012.

- **Use of Common Data Elements**
 - Researchers conducting NIH- and DOD-supported TBI human-subjects research are required to use the TBI Common Data Elements (CDEs), in an effort to create standardized definitions and guidelines about the kinds of data that should be collected, and how to collect this data in clinical studies of TBI.
- **Data Sharing**
 - Investigators have 12 months from the end of the award period before data and supporting materials will be available to the general research community (via a controlled and tracked approval process, i.e., Data Access Committee Approval).
- **FITBIR Data Access**
 - Investigators and institutions seeking data from the FITBIR Informatics System will be expected to meet data security measures (such as physical security, information technology security, and user training) and will be asked to submit a Data Access Request that is signed by the investigator.

Data Dictionary Form Structures & Data Elements

Data Dictionary

Search Form Structures

Search Locations

* Keyword search will be performed within the following form fields: Short Name, Title, Description, and Created By.

Showing 1 to 218 of 218 entries

TITLE	SHORT NAME	STATUS	MODIFIED DATE
12-Item Short Form Health Survey Version 2 (SF-12v2)	SF12	Published	2018-09-18
36-Item Short Form Health Survey (SF-36) version 1	SF_36_FITBIR_V1	Published	2020-02-05
36-Item Short Form Health Survey (SF-36) version 2	SF36v2	Published	2020-02-05
Abbreviated Injury Scale (AIS)	AIS	Published	2020-03-27
Activities Specific Balance Confidence Scale (ABC-Scale)	ABCScale_FITBIR	Published	2017-06-26
Alcohol Use Disorders Identification Test - Consumption Questions (AUDIT-C)	AUDITC	Published	2020-08-28
Alcohol Use Disorders Identification Test - Self-Report Version (AUDIT)	AUDIT_FITBIR	Published	2020-02-05
Alcohol, Smoking, and Substance Use Involvement Screening Test (ASSIST)	ASSIST_FITBIR	Published	2020-03-06
ANAM Code Substitution Delayed	ANAMCodeSubDelayed	Published	2015-03-27
ANAM Code Substitution Learning	ANAMCodeSubLearning	Published	2015-03-27
ANAM Logical Relations	ANAMLogicalRelations	Published	2021-09-23
ANAM Matching to Sample	ANAMMatchToSample	Published	2015-03-31
ANAM Mathematical Processing	ANAMMathProcessing	Published	2015-03-31
ANAM Procedural Reaction Time	ANAMProcReactTime	Published	2015-03-31
ANAM Running Memory Continuous Performance Task	ANAMRunningMemoryCPT	Published	2021-09-23
ANAM Simple Reaction Time	ANAMSimpleReactTime	Published	2015-03-31
ANAM Simple Reaction Time 2nd Administration	ANAMSimpleReactTime2nd	Published	2015-03-31

of Standard NINDS TBI Form Structures in FITBIR: **179**

of TBI CDEs in FITBIR: **8,099**

Data Dictionary

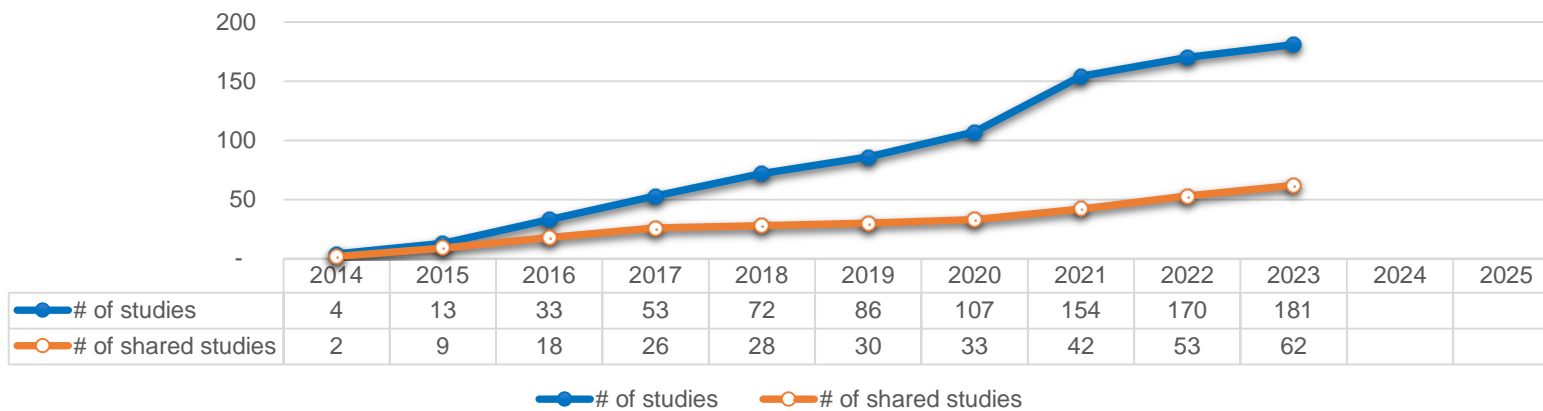
Search Data Elements

Search Locations

Show 25 entries

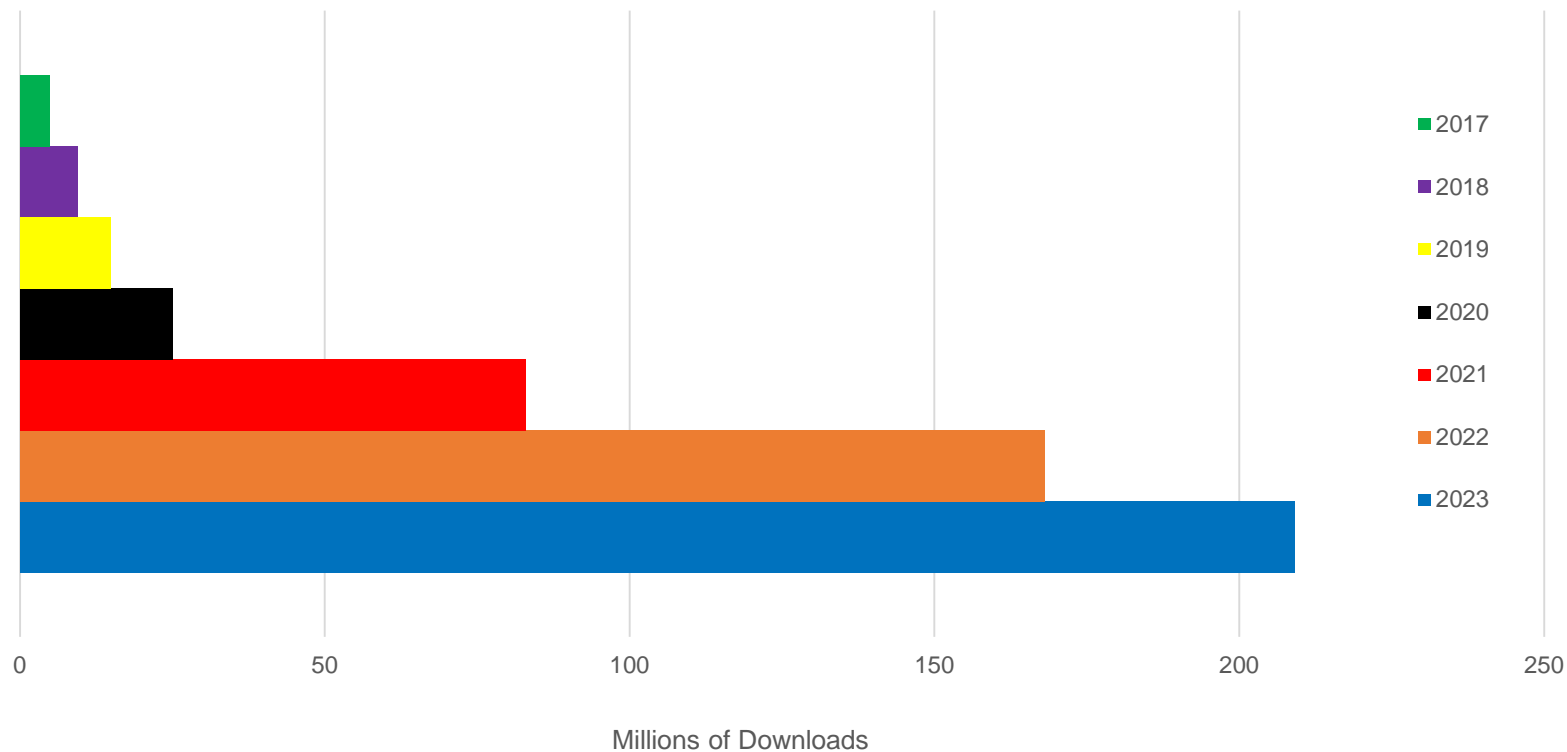
TITLE	VARIABLE NAME	TYPE	MODIFIED DATE	STATUS
12-Item Short Form Health Survey Version 2 (SF-12v2) - Body Pain Raw Score	SF12BodyPainRawScore	CDE	2018-07-13	Published
12-Item Short Form Health Survey Version 2 (SF-12v2) - Interferesocial activities emotional scale	SF12InterSocPhyEmotScale	CDE	2023-02-24	Published
12-Item Short Form Health Survey Version 2 (SF-12v2) - Less accomplished physical health scale	SF12LessAccompPhyHtmScale	CDE	2023-02-24	Published
12-Item Short Form Health Survey Version 2 (SF-12v2) - Physical Function Raw Score	SF12PhysFuncRawScore	CDE	2018-07-13	Published
12-Item Short Form Health Survey Version 2 (SF-12v2) - Role Physical Raw Score	SF12RolePhysRawScore	CDE	2018-07-13	Published
12-Item Short Form Health Survey Version 2 (SF-12v2) - Times can be careful scale	SF12TimesCanbCfulScale	CDE	2023-02-24	Published
12-Item Short Form Health Survey Version 2 (SF-12v2) - Times downhearted depressed scale	SF12TimesDownDepressedScale	CDE	2023-02-24	Published
12-Item Short Form Health Survey Version 2 (SF-12v2) - Times energy scale	SF12TimesEnergyScale	CDE	2023-02-24	Published
12-Item Short Form Health Survey Version 2 (SF-12v2) - Work not carefully emotional problems indicator	SF12WntCaretfEmotProbScale	CDE	2023-02-24	Published
12-Item Short Form Health Survey Version 2 (SF-12v2) - General Health Raw Score	SF12VitalyRawScore	CDE	2018-10-31	Published
12-Item Short Form Health Survey Version 2 (SF-12v2) - Mental Health Raw Score	SF12MentalHealthRawScore	CDE	2018-07-13	Published
12-Item Short Form Health Survey Version 2 (SF-12v2) - Role Emotional Raw Score	SF12RoleEmotnlRawScore	CDE	2018-07-13	Published
12-Item Short Form Health Survey Version 2 (SF-12v2) - Scaled score	SF12ScaleScore	CDE	2018-07-13	Published
12-Item Short Form Health Survey Version 2 (SF-12v2) - Social Functioning Raw Score	SF12SocFuncRawScore	CDE	2018-07-13	Published
12-Item Short Form Health Survey Version 2 (SF-12v2) - Vitality Raw Score	SF12GeneralHealthRawScore	CDE	2018-07-13	Published
12-Item Short Form Health Survey Version 2 (SF-12v2) - Less accomplished emotional scale	SF12LessAccompEmotProbScale	CDE	2023-02-24	Published
12-Item Short Form Health Survey Version 2 (SF-12v2) - Limited work activities physical health scale	SF12LmtWkActPhyHtmScale	CDE	2023-02-24	Published
150 Quality of Life Questionnaire version 2 (150.2) - Breathing scale	QOL150BreathingScI	CDE	2018-04-19	Awaiting Publication

Studies in FITBIR Jan 2014 - Oct 2023

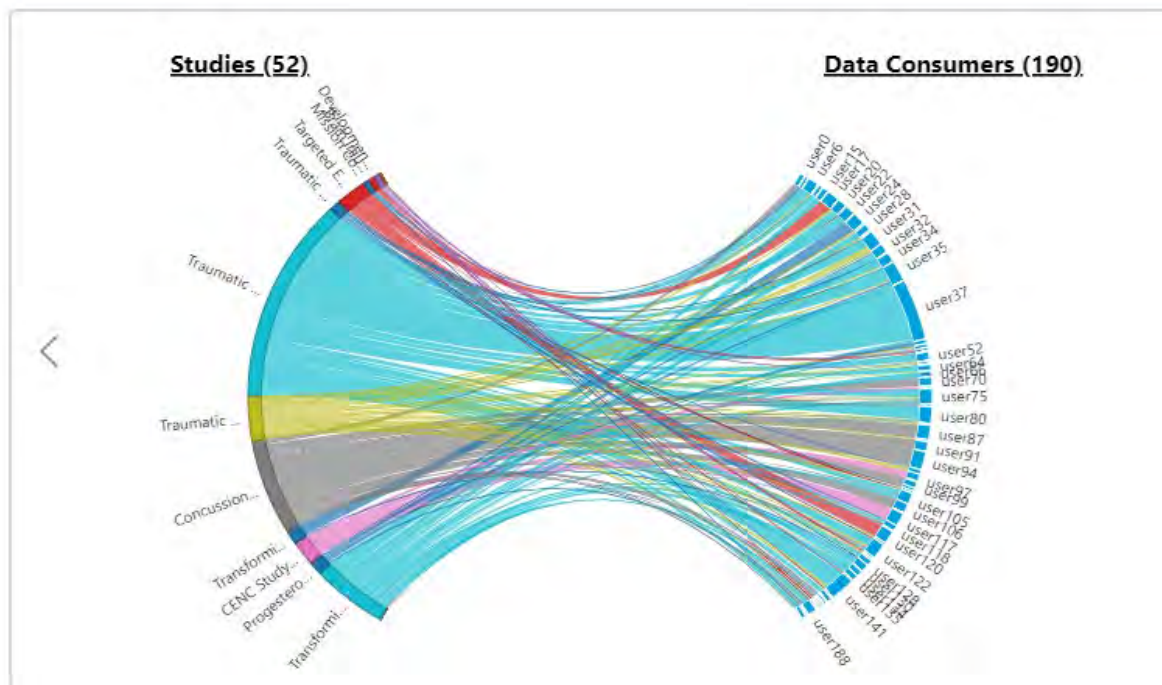




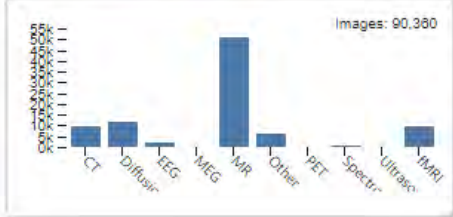
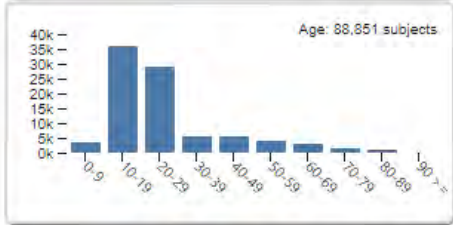
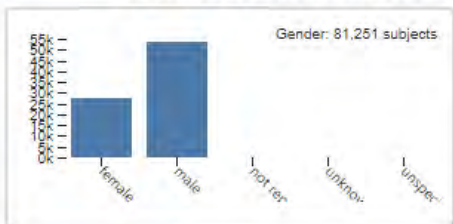
FITBIR | # Records Downloaded

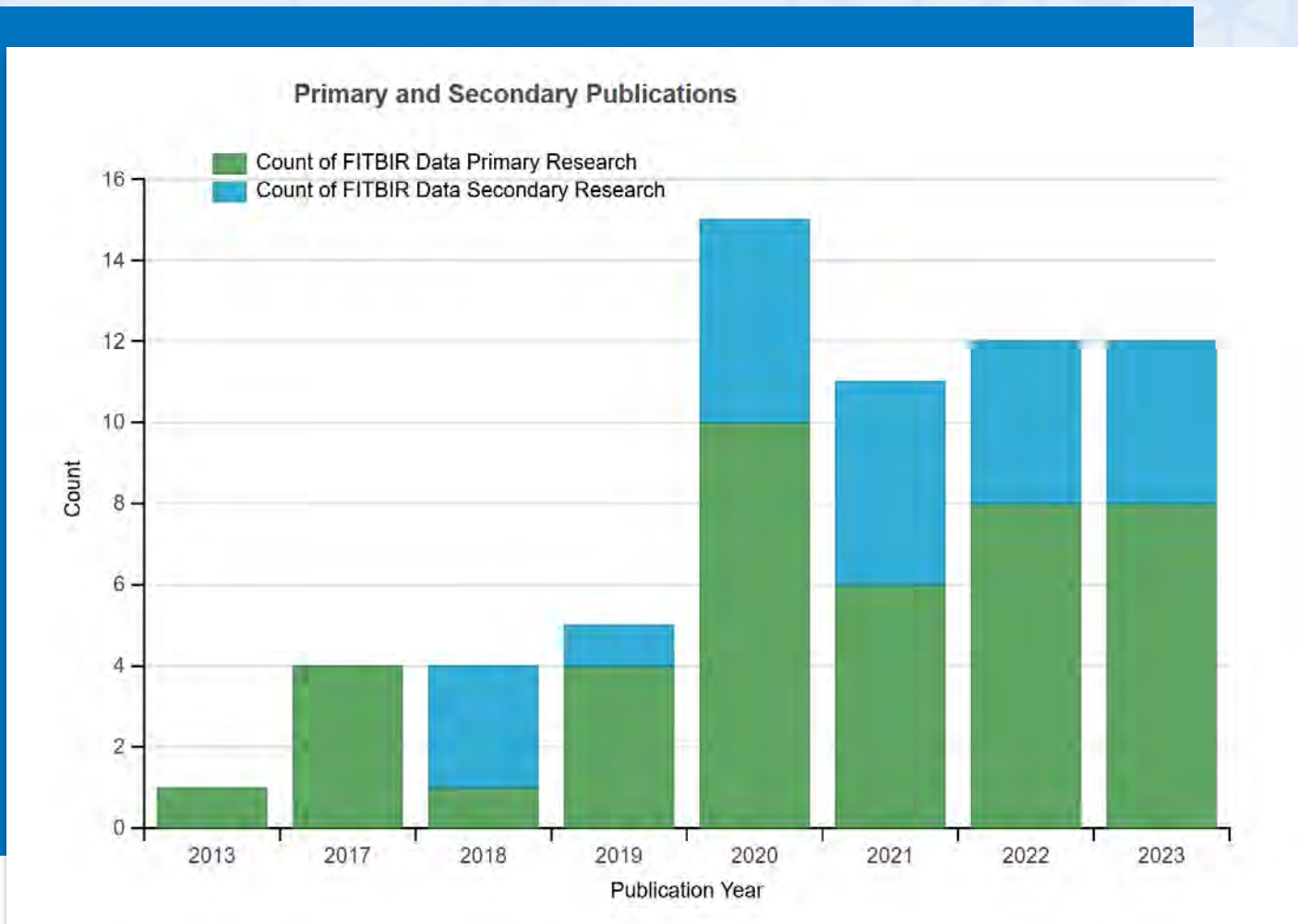


Visualization



88,851 SUBJECTS IN 60 STUDIES





Applications for Receipt Dates
BEFORE Jan 25 2023

Applications for Receipt Dates
ON/AFTER Jan 25 2023

NIH has issued the Data Management and Sharing (DMS) policy (effective January 25, 2023) to promote the sharing of scientific data. Sharing scientific data accelerates biomedical research discovery, in part, by enabling validation of research results, providing accessibility to high-value datasets, and promoting data reuse for future research studies.

Under the DMS policy, NIH expects that investigators and institutions:

- Plan and budget for the managing and sharing of data
- Submit a DMS plan for review when applying for funding
- Comply with the approved DMS plan

Each of the steps below will help you integrate data management and sharing into your funding application and research process. Select a step to learn more.

PLANNING & BUDGETING

SUBMISSION & REVIEW

IMPLEMENTING

What is a Meta Study?

- A workspace where research data and metadata can be stored and referenced.
- A Meta Study can contain many different types of "data"
 - Tabular data
 - Software files
 - Scripts
 - Reference documents
 - FITBIR queries
- The Meta Study is assigned a DOI that can be cited for journal publications
- Notice to the community

post-concussion Black/African-American athletes comprise a greater proportion of athletes in concussion-risk sports and may be more susceptible to health inequalities due to the social inequalities. Both White and Black/African-Americans use the same cognitive assessment tools and currently it is unknown if performance on these assessments is similar. This is a retrospective study that includes cross-sectional assessments using cognitive assessment data from The Federal Interagency Traumatic Brain Injury Research (FITBIR) database. We will examine race-based differences in changes in cognitive post-concussion symptoms and neurocognitive performance.

Aims: To identify race-based differences in performance on cognitive assessments in concussed individuals.

Permission Admin
 Owner [REDACTED]
 Owner Email [REDACTED]

+ Study Research Management
 + Study Information
 - Documentation

Search

TITLE	DOCUMENTATION	TYPE	DESCRIPTION	DATE UPLOADED
Background	Backgroud and Significance.docx	Background	Background information and significance of th... more	2021-04-13 15:07
Research Plan	Research Plan (Implications of Race) (2) copy.docx	Methods	Protocol/research plan for this study.	2021-04-13 15:08

Showing 1 to 2 of 2 entries

- Data

Search

DATA	SOURCE	TYPE	DESCRIPTION	DATE UPLOADED
249 Demo + NQS_TBI (age limited)_zip	Query Tool	Results	combination of demographic informati... more	2021-05-23 17:35
264 Demo + CVLT II.zip	Query Tool	Results	age limited appropriate demographic... more	2021-05-28 14:02
264 Demo + NQS_TBI (Age limited)_zip	Query Tool	Results	combination of Demographic informat... more	2021-05-23 17:37
264 Demo + TMT.zip	Query Tool	Results	Age limited date (18 to 25 years ol... more	2021-05-24 21:30
Demo + GPT .zip	Query Tool	Results	Combination of demographic data and... more	2021-05-20 13:55
Demographic - Golden stroop_impact1_scat	Query Tool	Results	Combination of FITBIR demographic f... more	2021-04-20 12:57

Preclinical CDEs developed to foster **reproducibility and transparency** among laboratories.

A call for transparent reporting to optimize the predictive value of preclinical research

Story C. Landis¹, Susan G. Amara², Khusrul Asadullah³, Chris P. Austin⁴, Rob Blumenstein⁵, Eileen W. Bradley⁶, Ronald G. Crystal⁷, Robert B. Darnell⁸, Robert J. Ferrante⁹, Howard Filbin¹⁰, Robert Finkelstein¹¹, Marc Fisher¹², Howard E. Gendelman¹³, Robert Golub¹⁴, John L. Goudreau¹⁵, Robert A. Gross¹⁶, Amelie K. Gubitz¹⁷, Sharon E. Hesterlee¹⁸, David W. Howells¹⁹, John Huguenard²⁰, Katrina Kelner²¹, Walter Koroshetz²², Dimitri Kraine²³, Stanley E. Lazic²⁴, Michael S. Levine²⁵, Malcolm Macleod²⁶, John M. McCall²⁷, Richard T. Moxley III²⁸, Kalyani Sarasinhan²⁹, Linda J. Noble³⁰, Steve Perrin³¹, John D. Porter³², Oswald Steward³³, Ellis Unger³⁴, Ursula Utz³⁵ & Shal D. Silberberg³⁶

NINDS **BIOSEND**

NINDS funded biofluid repository is receiving samples from multiple NINDS TBI studies and is coordinating their catalog with FITBIR to allow for searching and ordering. <https://biosend.org/>

Incorporating additional trauma data into FITBIR

- Ongoing Discussion with JPC-6
 - Data Types
 - CDE development by SMEs specific to trauma
 - Criteria for accepting data
 - Metastudy module vs data repository



BRICS

Biomedical Research
Informatics Computing System

Parkinson's Disease Biomarker Program

Andrea Lutz





- Who's involved?
- PDBP DMR Stats
- Data Collection
- Biosample Request & Order Process



- **PDBP Investigators**

- Roger Albin, Roy Alcalay, Alberto Ascherio, Thomas Beach, Sarah Berman, Bradley Boeve, F. DuBois Bowman, Shu Chen, Alice Chen-Plotkin, William Dauer, Ted Dawson, Paula Desplats, Richard Dewey, Ray Dorsey, Jori Fleisher, Kirk Frey, Douglas Galasko, James Galvin, Dwight German, Lawrence Honig, Xuemei Huang, David Irwin, Kejal Kantarci, Anumantha Kanthasamy, Daniel Kaufer, Qingzhong Kong, James Leverenz, Allan Levey, Carol Lippa, Irene Litvan, Oscar Lopez, Jian Ma, Lara Mangravite, Karen Marder, Laurie Orzelius, Vladislav Petyuk, Judith Potashkin, Liana Rosenthal, Rachel Saunders-Pullman, Clemens Scherzer, Michael Schwarzschild, Nicholas Seyfried, Tanya Simuni, Andrew Singleton, David Standaert, Debby Tsuang, David Vaillancourt, David Walt, Andrew West, Cyrus Zabetian and Jing Zhang

- **PDBP Program and Review Staff**

- Deb Babcock, Chris Swanson-Fischer, Sophie Cho, Christina Fang, and Rebecca Price

- **PDBP Data Management Resource (DMR) Operations Team**

- Andrea Lutz, Ronnie Tan, Kristine Treece

- **Biorepositories**

- BioSEND & NINDS Human Cell and Data Repository (NHCDR)

342 DMR
USERS



26

Countries



>56,000
Submissions



>62M
Downloads



Study Population

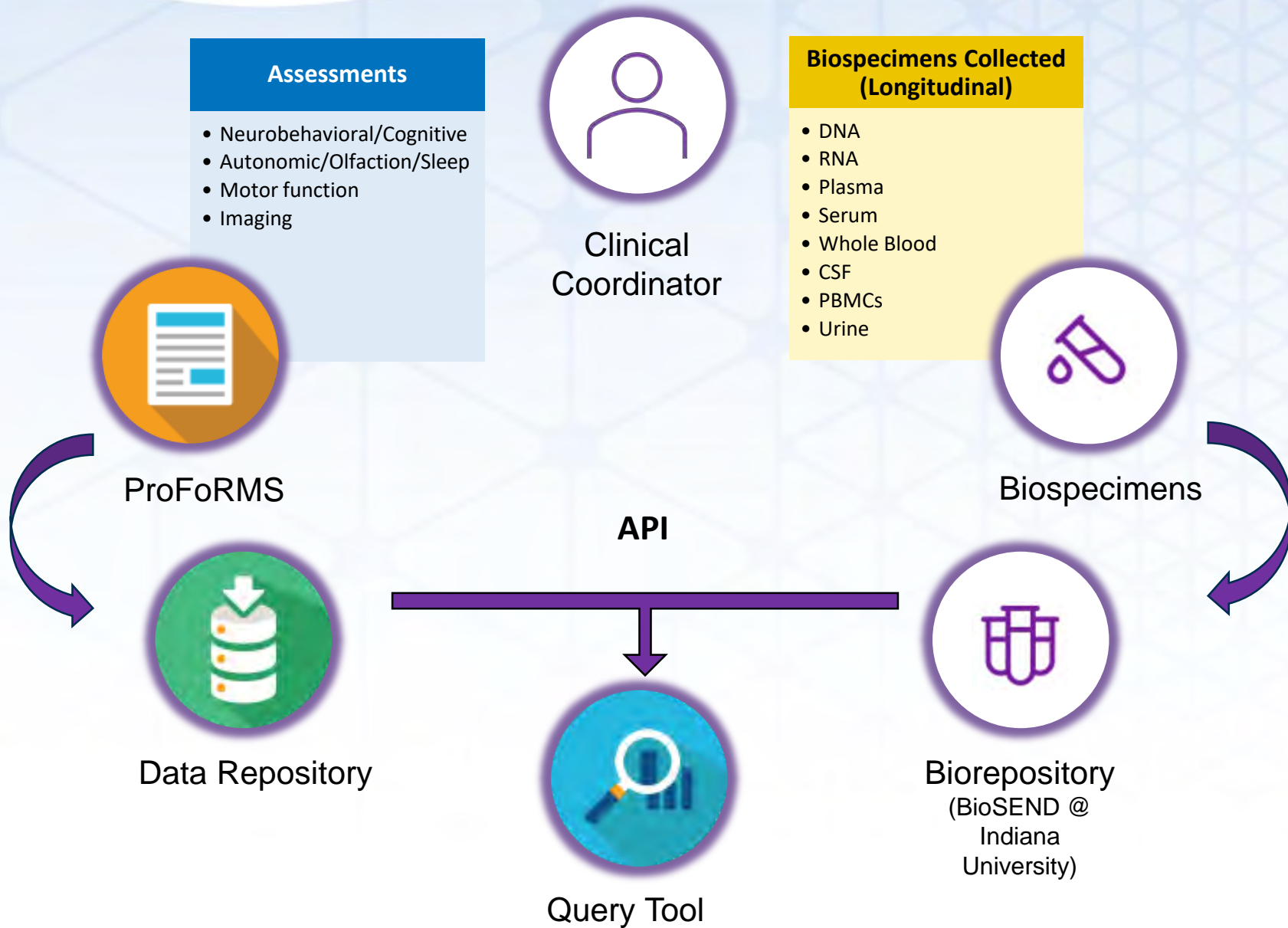
- Parkinson's Disease (2002)
- Dementia with Lewy Bodies (373)
- PSP (120)
- MSA (99)
- CBD (7)
- ET (30)
- Healthy Controls (792)

Assessments

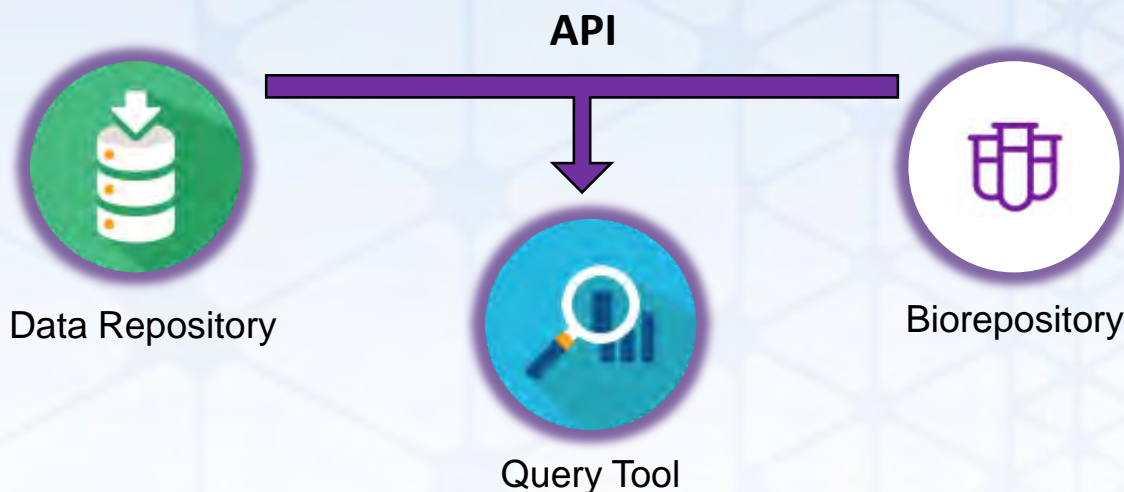
- Neurobehavioral/Cognitive
- Autonomic/Olfaction/Sleep
- Motor function
- Imaging

Biospecimens Collected (Longitudinal)

- DNA
- RNA
- Plasma
- Serum
- Whole Blood
- CSF
- PBMCs
- Urine



NINDS Biorepository PDBP Biosample Catalog



SAMPLE INFORMATION			
NEURODIAGNOSIS	ORDERABLEBIOSAMPLEID	SELECT ALL	SAMPCOLLTYP
Dementia with Lewy Bodies	1732322	+	Serum
Dementia with Lewy Bodies	1732342	+	DNA
Dementia with Lewy Bodies	1732310	+	RNA
Dementia with Lewy Bodies	1732314	+	Plasma
Dementia with Lewy Bodies	1732330	+	CSF
Parkinson's Disease	2200324	+	DNA
Parkinson's Disease	2200327	+	Plasma
Parkinson's Disease	2200336	+	Blood
Parkinson's Disease	2200321	+	RNA

Are you
interested in
acquiring these
samples?

How to Apply for PDBP Biosamples



Step 1: Determine Sample Availability

Investigators are encouraged to learn about samples held in the various repositories before applying.

Make sure you have an account in the PDBP DMR

Search for sample availability in the Query Tool



Step 2: Submit Online Application

All investigators interested in obtaining biosamples must submit an online application for approval.

Applications are submitted through an online webform

- Biosketch
- Research Strategy
- Table Summary of Samples of Interest



Step 3: PD BRAC Reviews Application

All applications are submitted to the PD BRAC for review. Upon approval, an investigator is able to obtain biosamples.

Investigators notified of the outcome by email

- Approve
- Approve upon revisions
- Deny

Onboarding/Sample Distribution meeting

PDBP Biosample Order Demo



National Institute of
Neurological Disorders
and Stroke

6001 Executive Blvd.
NSC Bethesda, MD. 20892-9535
Phone: 301-496-5745
Fax: 301-402-1501
Email: karen.david@nih.gov

14 November 2019

Jane Doe, PhD
University of PDBP
jdoe@PDBP.edu

RE: Parkinson's Disease Biospecimen Resource Access Committee Approval

Dear Dr. Doe,

You have been approved access to the samples summarized in the table below, for your project "TBD". Samples to be released are subject to availability.

Name of Cohort Sample and Data Set	Number of Samples	Biosample Type	Volume or concentration	Any other criteria to be considered	# Longitudinal subjects, visit types and number of samples per visit
PDBP – PD Cases	30	CSF	1 x 200 μ L	Hemoglobin <0.2	Baseline visit
PDBP – Controls	30	CSF	1 x 200 μ L	Hemoglobin <0.2	Baseline visit

Sincerely,



Margaret Sutherland, PhD
Program Director, Parkinson's Disease Biomarkers Program



Karen David, PhD
Parkinson's Disease Biomarkers Program Biospecimen Resource Access Committee Coordinator

Selecting & Ordering Samples

Step 1: Filter Data | Step 2: Refine Data | Admin Only: Download Report | Clear Cache | Data Cart: 1 forms in 1 studies | Clear Data Cart | Save New Query

Search GUID: [x] [Q]

Studies | **Forms** | Data Elements | Defined Queries

Search Studies: [x] [Q] | Data Type - All [v]

Filter forms by:

- Studies (71 Results) Reset Filter
- Adaptive immune response and cognition in Parkinson's Disease-ELISA-Plasma/CSF (IgG, Albumin) (# of Forms: 1)
- Amyloid Burden in patients with Dementia with Lewy Bodies-Lumpulse G-

Forms

Text: "catalog" [x] [Q]

catalog [x] [Q] | Data Type - All [v] | Results: (1 Forms) | Add All [+] [x]

Hide Not Available

NINDS Biorepository PDBP Biosample Catalog [Shopping Cart Icon] ←

1 3316

NINDS Biorepository PDBP Sa [Shopping Cart Icon]
mple Catalog

Step 1: Filter Data | Step 2: Refine Data | Admin Only: Download Report | Clear Cache | Data Cart: 3 forms in 31 studies | Clear Data Cart | Save New Query

Data Cart [Shopping Cart Icon]

Download Data Cart To Queue [Download Icon] | Reset [Reset Icon]

Select a form to refine your query

PDBP MDS-UPDRS [Shopping Cart Icon]

Drag here to join forms

- NINDS Biorepository PDBP Biosample Catalog** [Shopping Cart Icon]
- PDBP Demographics** [Shopping Cart Icon]
- Third Form
- Fourth Form
- Fifth Form

Query Logic Box [Close Icon]

Clear Filters [X] | Copy Query [Copy Icon] | Export Query [Export Icon] | **Run Query** [Run Icon]

Select Criteria | Datable View | Permissible Value [v] | Hide All Blank Columns [Hide Icon] | Download Options [Download Icon]

- NINDS Biorepository PDBP Biosample Catalog** Show All/Hide in Datatable [x]
- + DataSet Info [x]
- + Subject Information [x]
- + Sample Information [x]
- + Quality Control [x]
- + Inventory [x]
- PDBP Demographics** Show All/Hide in Datatable [x]
- + DataSet Info [x]
- + Required Fields [x]
- + Demographics [x]

Old way

Select Criteria Datable View Permissible Value Hide All Blank

NINDS Biorepository PDBP Biosample Catalog joined with PDBP MDS-UPDRS

The MDS-UPDRS part III section has been rescored for a subset of Penn State subjects - records are highlighted in RED. For additional details visit the Data Repository or the PDBP public website and view the study: Multimodal MRI markers of nigrostriatal

FORMS: MDS_UPDRS

REPEATABLE GROUPS:				SAMPLE INFORMATION			REQUIRED FIELDS			
ROW NO.	GUID	VISIT	NEURODIAGNOSIS	ORDERABLEBIO	SELECT ALL	STUDY ID	DATA SET	SITENAME	GUID	
1	NIHZX783LKYYX	12 months	Parkinson's Disease	2529076	<input type="checkbox"/>	CSF	PDBP-DATA0055782	Mount Sinai Beth Israel	12 months	NIHZX783LKYYX
2	NIHZX783LKYYX	Baseline	Parkinson's Disease	2189735	<input type="checkbox"/>	CSF	PDBP-DATA0044850	Mount Sinai Beth Israel	Baseline	NIHZX783LKYYX
3	NIHZX783LKYYX	24 months	Parkinson's Disease	2868285	<input type="checkbox"/>	CSF	PDBP-DATA0064918	Mount Sinai Beth Israel	24 months	NIHZX783LKYYX

New way

Select Criteria Datable View Permissible Value Hide All Blank

NINDS Biorepository PDBP Biosample Catalog joined with PDBP MDS-UPDRS

The MDS-UPDRS part III section has been rescored for a subset of Penn State subjects - records are highlighted in RED. For additional details visit the Data Repository or the PDBP public website and view the study: Multimodal MRI markers of nigrostriatal

FORMS: MDS_UPDRS

REPEATABLE GROUPS:				SAMPLE INFORMATION			REQUIRED FIELDS			
ROW NO.	GUID	VISIT	NEURODIAGNOSIS	ORDERABLEBIO	SELECT ALL	STUDY ID	DATA SET	SITENAME	GUID	
1	NIHZX783LKYYX	12 months	Parkinson's Disease	2529076	<input type="checkbox"/>	CSF	PDBP-DATA0055782	Mount Sinai Beth Israel	12 months	NIHZX783LKYYX
2	NIHZX783LKYYX	Baseline	Parkinson's Disease	2189735	<input type="checkbox"/>	CSF	PDBP-DATA0044850	Mount Sinai Beth Israel	Baseline	NIHZX783LKYYX
3	NIHZX783LKYYX	24 months	Parkinson's Disease	2868285	<input type="checkbox"/>	CSF	PDBP-DATA0064918	Mount Sinai Beth Israel	24 months	NIHZX783LKYYX



Step 1: Filter Data | Step 2: Refine Data | Admin Only: Download Report | Clear Cache | Data Cart: 3 forms in 31 studies | Clear Data Cart | Save New Query

Data Cart

Select a form to refine your query

Download Data Cart To Queue | Reset

Drag here to join forms

- NINDS Biorepository PDBP Biosample Catalog
- PDBP Demographics
- PDBP MDS-UPDRS

Fourth Form

Fifth Form

Query Logic Box

Clear Filters | Copy Query | Export Query | Run Query

NINDS Biorepository PDBP SampCollTyp

Inclusive

- Blood
- Blood pelle
- Blood Refe
- CSF
- CSF Refer

Select Criteria | Datatable View | Permissible Value | Hide All Blank Columns | Download Options

(45373 Rows of Data)

NINDS Biorepository PDBP Biosample Catalog joined with PDBP Demographics joined with PDBP MDS-UPDRS

The MDS-UPDRS part III section has been rescored for a subset of Penn State subjects - records are highlighted in RED. For additional details visit the Data Repository or the PDBP public website and view the study: Multimodal MRI markers of nigrostriatal pathology in Parkinson's disease (U01).

FORMS: BIOSAMPLECATALOGV6

REPEATABLE GROUPS: SUBJECT INFORMATION

ROW NO.	GUID	STUDY ID	DATASET	REPOSITORYNAME	PDBPSTUDYID	GUID
1	NIH_INVUJ332BXN					
2	PDFB026ATQ_6	209	PDBP-DATA0076889	NINDS	PDBP-STUDY0000233	PDFB026ATQ
3	PDFB026ATQ_6	209	PDBP-DATA0076889	NINDS	PDBP-STUDY0000233	PDFB026ATQ
4	PDFB026ATQ_6	209	PDBP-DATA0076889	NINDS	PDBP-STUDY0000233	PDFB026ATQ
5	PD_INVHN764FMK_					
6	PDRW811MJH_36					
7	PD_INVKV571TYV_					
8	PDTT221UHE_24					
9	PDAM788JGZ_12	209	PDBP-DATA0076889	NINDS	PDBP-STUDY0000235	PDAM788JGZ
10	PDAM788JGZ_12	209	PDBP-DATA0076889	NINDS	PDBP-STUDY0000235	PDAM788JGZ

Select Criteria | Datatable View | Permissible Value | Hide All Blank Columns | Download Options

(247 Rows of Data)

NINDS Biorepository PDBP Biosample Catalog joined with PDBP Demographics joined with PDBP MDS-UPDRS

The MDS-UPDRS part III section has been rescored for a subset of Penn State subjects - records are highlighted in RED. For additional details visit the Data Repository or the PDBP public website and view the study: Multimodal MRI markers of nigrostriatal pathology in Parkinson's disease (U01).

FORMS:

REPEATABLE GROUPS: SAMPLE INFORMATION

ROW NO.	NEURODIAGNOSIS	ORDERABLEBIOSAMPLEID	SELECT ALL	SAMPCOLLTYP	SAMPLEUNITNUM
1	Dementia with Lewy Bodies	1218581	+	CSF	200
2	Dementia with Lewy Bodies	1538834	+	CSF	200
3	Dementia with Lewy Bodies	955708	+	CSF	200





Select these samples to order

SAMPLE INFORMATION		
	ORDERABLEBIOSAMPLEID	SELECT ALL
<input checked="" type="checkbox"/>	1732330	+
<input checked="" type="checkbox"/>	1617981	+
<input checked="" type="checkbox"/>	1501633	+
<input checked="" type="checkbox"/>	1930693	+
<input checked="" type="checkbox"/>	2211653	+

Download to CSV & continue additional analysis & filtering





Query Logic Box

Clear Filters Copy Query Export Query Run Query

NINDS Biorepository PDBP Biosample Catalog
OrderableBiosampleID

Inclusive Exact

- 1931492
- 2007930
- 2139107
- 2211650
- 2253614
- 2554233
- 2613200
- 2613235
- 2697420
- 2697490
- 2760690

Show Blanks

Select Criteria Datable View Hide All Blank Columns Download Options

Permissible Value

NINDS Biorepository PDBP Biosample Catalog (37320 Rows of Data)

FORMS:

REPEATABLE GROUPS: LE INFORMATION

ROW NO.	NEURODIAGNOSIS	ORDERABLEBIOSAMPLEID	SAMP	SAMPCOLLYTYP
1	Dementia with Lewy Bodies		Serum	200
2	Parkinson's Disease		Blood	500
3	Dementia with Lewy Bodies		RNA	1
4	Parkinson's Disease		Plasma	200
5	Parkinson's Disease	<input type="checkbox"/> 981265	Plasma	200
6	Dementia with Lewy Bodies	<input type="checkbox"/> 979352	DNA	3
7	Dementia with Lewy Bodies	<input type="checkbox"/> 979510	Serum	200
8	Dementia with Lewy Bodies	<input type="checkbox"/> 979360	Plasma	200
9	Dementia with Lewy Bodies	<input type="checkbox"/> 979310	DNA	3
10	Parkinson's Disease	<input type="checkbox"/> 975894	Plasma	200
11	No neurological diagnosis	<input type="checkbox"/> 611036.2	RNA	1
12	Parkinson's Disease	<input type="checkbox"/> 610978	Plasma	200
13	Parkinson's Disease	<input type="checkbox"/> 468740	Blood	500

Add Selected Samples to Cart

Select Criteria Datable View Hide All Blank Columns Download Options

Permissible Value

NINDS Biorepository PDBP Biosample Catalog (100 Rows of Data)

FORMS:

REPEATABLE GROUPS: LE INFORMATION

ROW NO.	NEURODIAGNOSIS	ORDERABLEBIOSAMPLEID	SAMP	SAMPCOLLYTYP
1	Dementia with Lewy Bodies	<input checked="" type="checkbox"/> 1170895	CSF	200
2	Dementia with Lewy Bodies	<input checked="" type="checkbox"/> 1170828	CSF	200
3	Dementia with Lewy		CSF	200
4	Dementia with Lewy		CSF	200
5	Dementia with Lewy		CSF	200
6	Dementia with Lewy		CSF	200
7	Parkinson's Disease		CSF	200
8	Dementia with Lewy		CSF	200
9	Dementia with Lewy		CSF	200
10	Dementia with Lewy		CSF	200
11	Dementia with Lewy Bodies	<input checked="" type="checkbox"/> 1117326	CSF	200
12	Dementia with Lewy Bodies	<input checked="" type="checkbox"/> 1654811	CSF	200
13	Dementia with Lewy Bodies	<input checked="" type="checkbox"/> 4007470	CSF	200

The item(s) has been added to your queue. Visit your queue here.

Add Selected Samples to Cart



Update aliquot
here



View Your Bio Materials Queue

Remove From Queue

Mass Quantity:

Update

Search: ▾

<input type="checkbox"/>	SAMPLE ID	REPOSITORY	SAMPLE TYPE	GUID	VISIT TYPE	INV	INV DATE	QTY	UNIT #	UOM
<input type="checkbox"/>	816295	NINDS	CSF	PDDJ916LE2	Baseline	31	2023-02-22 19:00:00.0	<input type="text" value="1"/>	200	ul
<input type="checkbox"/>	816330	NINDS	CSF	PDDD367DR5	Baseline	37	2023-02-22 19:00:00.0	<input type="text" value="1"/>	200	ul
<input type="checkbox"/>	839609	NINDS	CSF	PDXJ187HKB	Baseline	36	2023-02-22 19:00:00.0	<input type="text" value="1"/>	200	ul
<input type="checkbox"/>	839679	NINDS	CSF	PDVA055XLM	Baseline	40	2023-02-22 19:00:00.0	<input type="text" value="1"/>	200	ul
<input type="checkbox"/>	862076	NINDS	CSF	PDNL259EGP	Baseline	22	2023-02-22 19:00:00.0	<input type="text" value="1"/>	200	ul
<input type="checkbox"/>	862109	NINDS	CSF	PDFW922MC1	Baseline	37	2023-02-22 19:00:00.0	<input type="text" value="1"/>	200	ul
<input type="checkbox"/>	885081	NINDS	CSF	PDWF428BU7	Baseline	38	2023-02-22 19:00:00.0	<input type="text" value="1"/>	200	ul
<input type="checkbox"/>	885118	NINDS	CSF	PDHW849XZE	Baseline	38	2023-02-22 19:00:00.0	<input type="text" value="1"/>	200	ul
<input type="checkbox"/>	885152	NINDS	CSF	PDJT283PFW	Baseline	29	2023-02-22 19:00:00.0	<input type="text" value="1"/>	200	ul
<input type="checkbox"/>	885221	NINDS	CSF	PDHE978YX5	Baseline	34	2023-02-22 19:00:00.0	<input type="text" value="1"/>	200	ul
<input type="checkbox"/>	890190	NINDS	CSF	PDZE783AFK	Baseline	37	2023-02-22 19:00:00.0	<input type="text" value="1"/>	200	ul
<input type="checkbox"/>	890228	NINDS	CSF	PDMP821KF0	Baseline	31	2023-02-22 19:00:00.0	<input type="text" value="1"/>	200	ul
<input type="checkbox"/>	890263	NINDS	CSF	PDUZ232NGV	Baseline	36	2023-02-22 19:00:00.0	<input type="text" value="1"/>	200	ul
<input type="checkbox"/>	927789	NINDS	CSF	PDEH060EUK	Baseline	37	2023-02-22 19:00:00.0	<input type="text" value="1"/>	200	ul
<input type="checkbox"/>	941541	NINDS	CSF	PDUL086YY3	Baseline	30	2023-02-22 19:00:00.0	<input type="text" value="1"/>	200	ul

Showing 1 to 15 of 100 entries (0 row selected of 100)

First Previous 1 2 3 4 5 6 7 Next Last

Select samples then
add to order



ADD TO ORDER



Biosample Orders

Owner: Lutz, Andrea
Owner Organization: PDBP

Order #:

Fields marked with a * are required.

Order Title: *

Add Supporting

Documentation *

A signed copy of your Parkinson's Disease Biospecimen Resource Access Committee (BRAC) approval letter should be uploaded with your order.

UPLOAD SUPPORTING DOCUMENTATION

Attached Files:

FILENAME

Add Comment

(limit 4000 char)

Shipping Address

Ship To Name: *

Ship To Institution: *

Ship To Phone: *

Affiliation: *

Affiliation Phone: *

Affiliation Email: *

Affiliation Special Instructions: *

Address 1: *

Address 2:

City: *

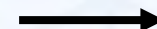
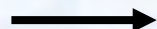
State: *

Zip: *

CANCEL

SAVE AND EXIT

SAVE AND SUBMIT



DMR Admin

Reviews, approves
& submits order in
PDBP DMR

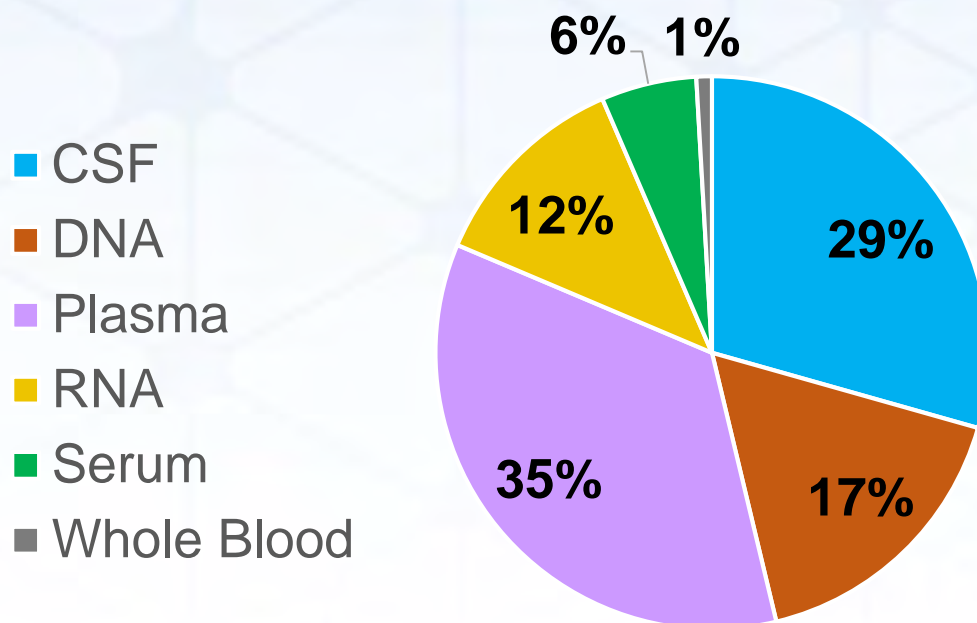
BioSEND

Receives & prepares order,
ships blinded samples to
researcher

Researcher

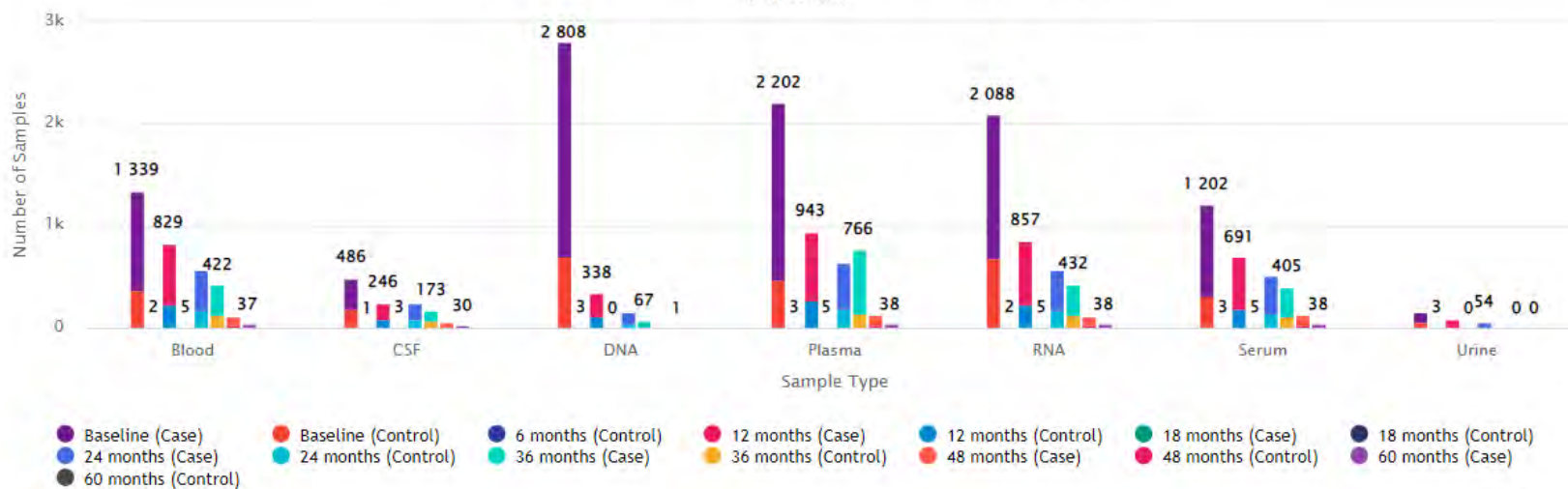
Receives samples,
performs analysis, submits
results back to PDBP DMR

**108 distributions to
52 separate investigators totaling 34,403 sample aliquots.**



Biospecimens Currently Available for Distribution or Request

Source: DMR



Highcharts.com



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Questions?





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PDBP Cloud Initiative

Krissy Treece, Project Manager PDBP

- In early 2022, the BRICS team started investigating a potential move to the Cloud for PDBP
- December 16, 2022, the BRICS team successfully deployed PDBP to the Cloud





Motives

- NIH encouragement to move projects to the cloud
- Allow for future enhancements to PDBP's scalability and performance
- Prepare for large AMP PD data merge



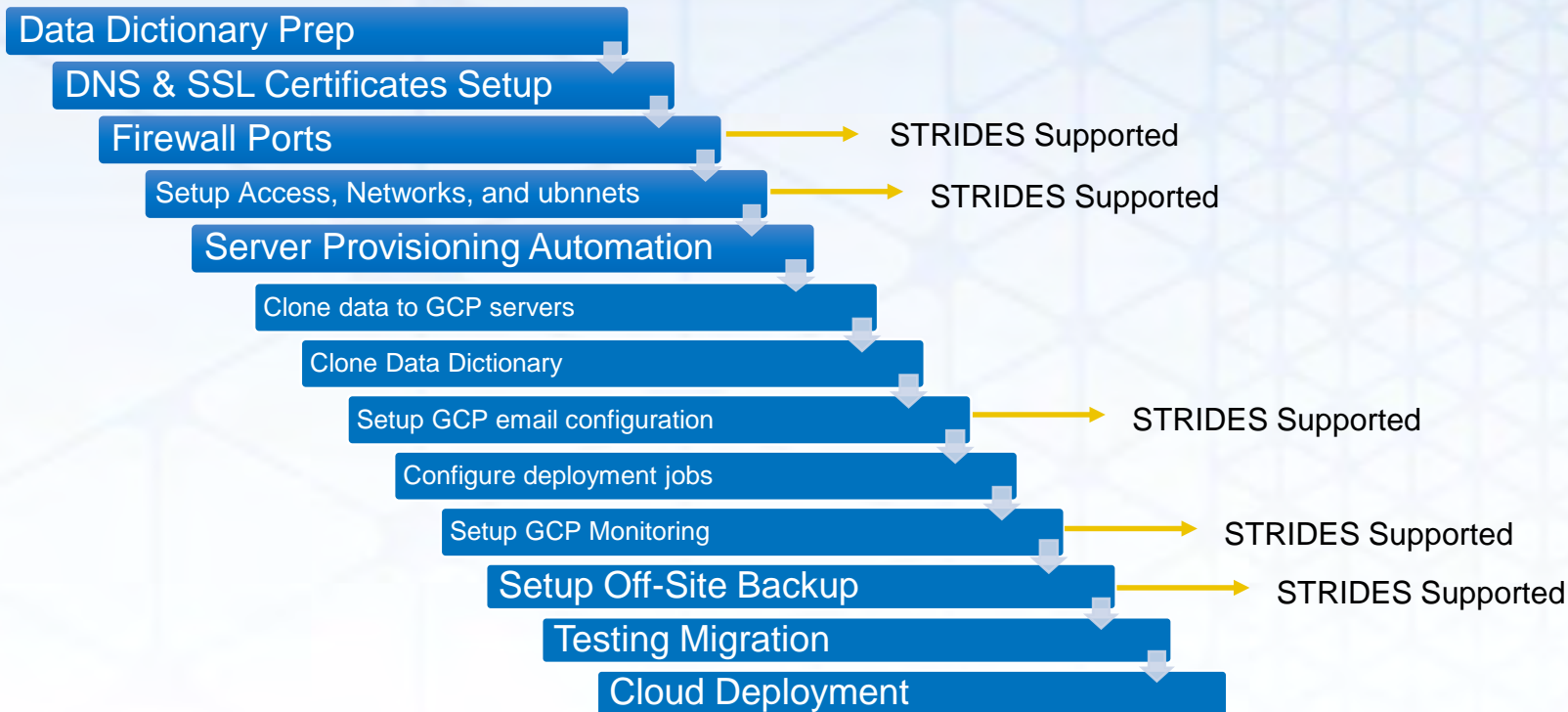
Accelerating Medicines Partnership Parkinson's Disease (AMP PD)



- The Accelerating Medicines Partnership Parkinson's Disease (AMP PD) program is a public-private partnership between the National Institutes of Health (NIH), multiple biopharmaceutical and life sciences companies, and non-profit organizations.
- It is managed through the Foundation for the NIH (FNIH)
- It contains over 2TB of data and is currently housed in the Google Cloud
- **Future plans are to merge all of the AMP PD data into PDBP**

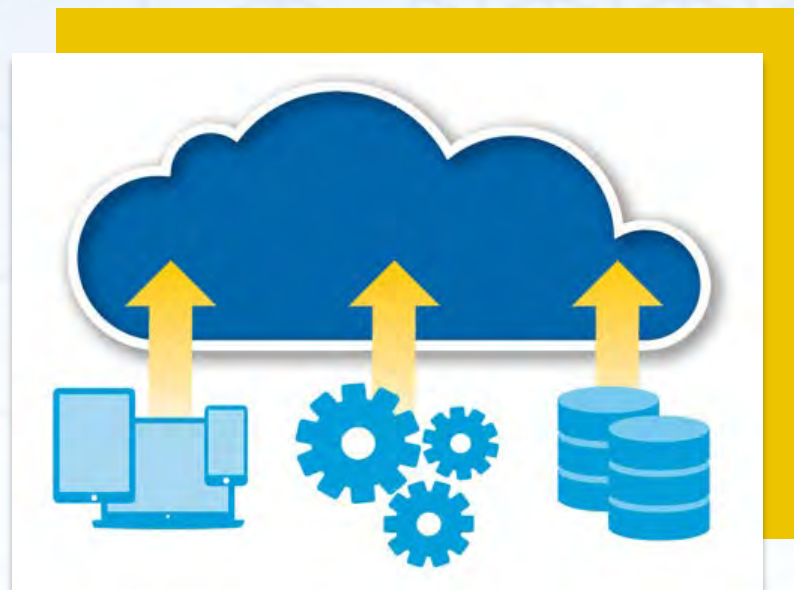
- BRICS team interviewed Google Cloud and Amazon Cloud support teams
- We prepared a full comparison of the two platforms based on our needs
- After completing our analysis, the NIH PDBP team was able to select **Google Cloud** as the best option
 - Cost, support, enhancement capabilities, ease of data transfers
- Deployed under the STRIDES model







- On December 2022, the BRICS team deployed the PDBP instance to the Google Cloud.
 - This was a lift and shift operation
- 3 different environments (Stage, UAT, and Production)
- Roughly 6-7 TB of data
- Transition went smoothly with strong support from the STRIDES team





Assessment and Authorization (A&A)



- The A&A process is a comprehensive assessment and/or evaluation of an information system policies, technical / non-technical security components, documentation, supplemental safeguards, policies, and vulnerabilities.
- Based on the NIST 800-53 Rev 5 Framework - ([Rev 5 Control Families](#))
- Required to receive and maintain the Authority To Operate (ATO)
- Full review is required before being put into production, and every 5 years thereafter
- **BRICS is in the process of a full review**
- A&A stages:
 - Assessment Stage - The assessment is a comprehensive analysis of the management, operational, and technical security controls in an information system, made in support of A&A.
 - Authorization Stage - The final authorization decision, final ATO received



The PDBP Cloud initiative has laid the groundwork for the accelerated deployment of future instances to the cloud.





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Take the Poll

Access Code:

99

93

48

99

<https://www.menti.com/bltm2op5jcnk>





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Closing Remarks

