

BRICS Demo:

ProFoRMS

February 8th, 2024





Audio/Video	Please keep your microphone muted
Recording	<ul style="list-style-type: none">• Today's session will be recorded• Will be posted on the BRICS website: https://brics.cit.nih.gov/demo
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 demo.• There will also be time after each speaker and at the end of the demo to ask live questions.



Time	Topic	Speaker(s)
9:00 AM-9:15 AM	Introduction	Dr. Matthew McAuliffe
9:15 AM-9:50 AM	Overview on ProFoRMS	Dr. Dominic Nathan
9:50 AM-10:00 AM	Questions & Closing Remarks	Dr. Matthew McAuliffe



BRICS - Brief Introduction

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

[Home | BRICS \(nih.gov\)](https://brics.nih.gov)
<https://brics.cit.nih.gov>





ENGINEERING

Engineering is the practice of using natural science, mathematics, and process to solve technical problems.

DESIGN

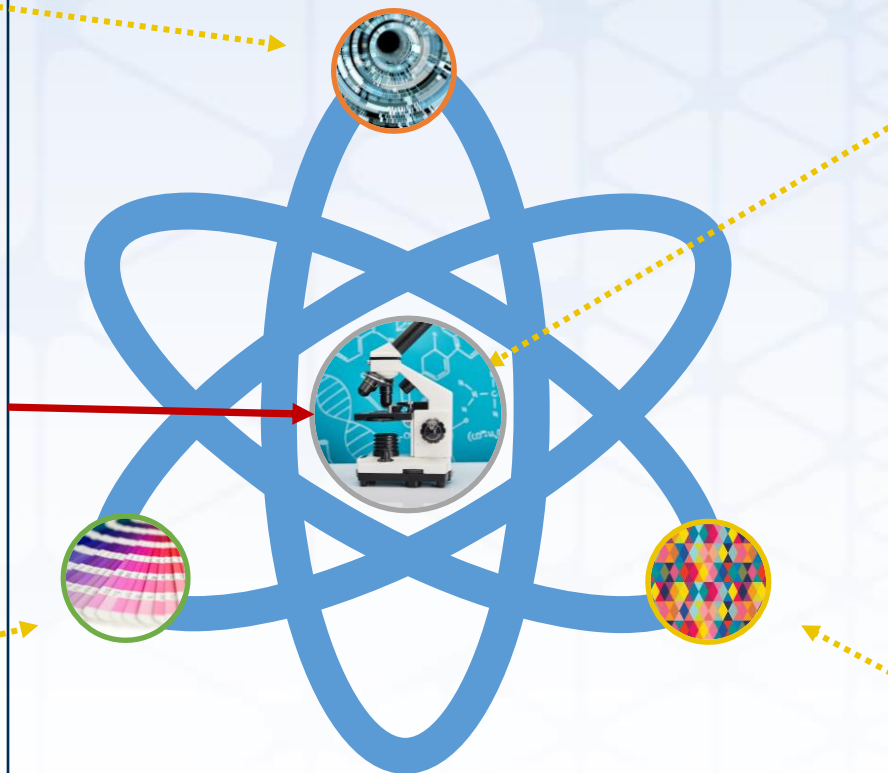
The creative art of executing aesthetic or functional designs

SCIENCE

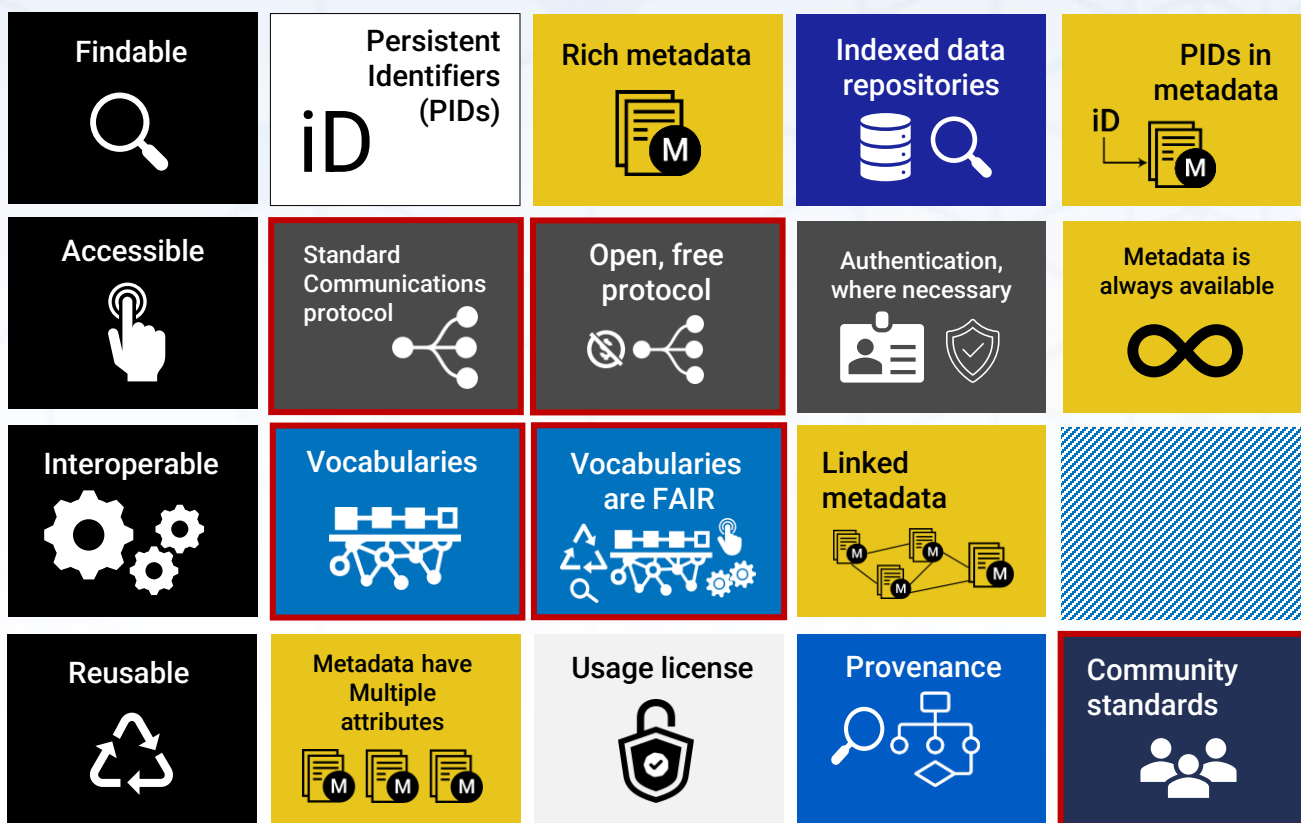
The knowledge or pursuit of knowledge of things as they are and why they act as they do.

ART

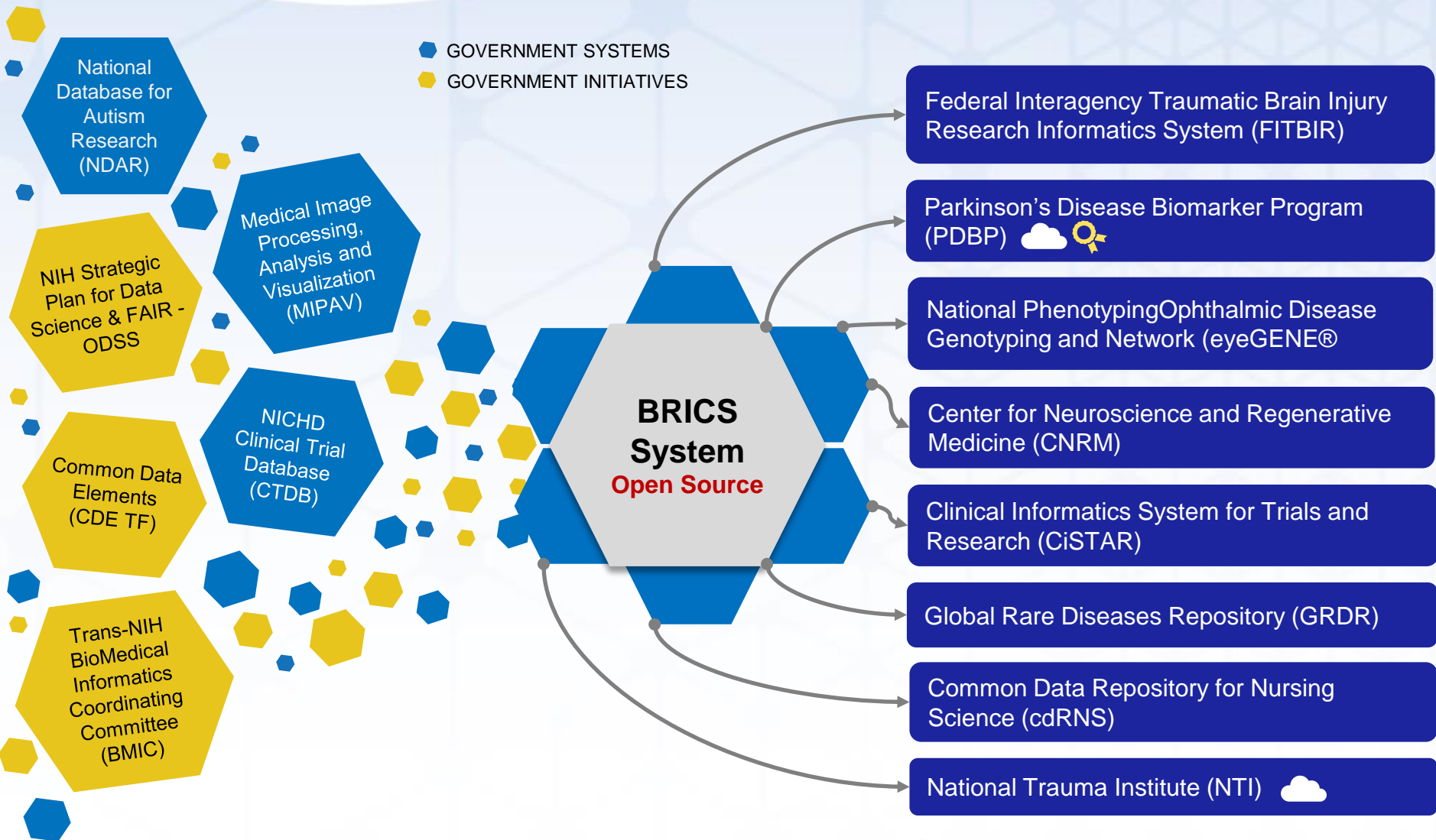
The conscious use of skill and creative imagination especially in the production of aesthetic objects



















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



Building from existing projects



 14th Annual Excellence.gov Awards Overall winner

 FITBIR <small>Federal Interagency Traumatic Brain Injury Research I N F O R M A T I C S - S Y S T E M</small>	 PDBP	 cdRNS <small>Common Data Repository for Nursing Science</small>	 eyeGENE® <small>National Eye Institute Department of Health and Human Services</small>	 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	Cloud	

Datatypes: Phenotypic, Imaging, and Omics



Raven Minor Release: (February 2024)

- CASA Merge: Harmonize the code changes from CASA and CiSTAR instances
 - Add the capability to import Form Structures using the JSON format
 - Optimize the Data Dictionary searches and filters
 - Security Updates
-

Spiderman Release: (June 2024)

- Real time saving of locked ProFoRMS data to the repository (Migrating to Mongo DB from PostGres)
- Submission Tool | Globus Integration
- UI Enhancements for the Accounts and Query Tool modules
- Centralized GUID Enhancements
- Tech library updates as needed
- Various UI and feature enhancements across the BRICS modules





BRICS Tools | 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, 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 (PPRL) system

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. (RAS enabled)



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.



The screenshot shows the BRICS system interface. At the top left is the FITBIR logo (National Institutes of Health Biomedical Research Informatics Computing System). The top right shows a user login: "Welcome Administrator, Preeti" and a "Log Out" button. A navigation bar contains links for Home, Workspace, ProFoRMS, Subject Management, Data Dictionary, Data Repository, Query, Meta Study, Account Management, and Forum. A left sidebar menu includes "Menu", "Workspace", "Admin Dashboard", and "Module Overview". The main content area is titled "Workspace" and features the heading "Modules: Building Blocks for the Research Life Cycle". Below this heading is a paragraph: "There are a variety of key software modules comprising this system. These modules support the vision of interconnectivity and collaboration among the research communities, as well as, provide a combination of web-based functionality and downloadable tools that support data definition, data contribution, and data access throughout the research life cycle." Eight circular icons represent the modules: ProFoRMS (document with bar chart), Subject Management (person icon), Data Dictionary (book with bar chart), Data Repository (database with download arrow), Query (magnifying glass over bar chart), Meta Study (magnifying glass over document with bar chart), Account Management (two people icons), and Forum (speech bubbles).

Demo on ProFoRMS module



BRICS

Biomedical Research
Informatics Computing System

Biomedical Research Informatics Computing System (BRICS)

ProFoRMS

Dr. Dominic Nathan



MTBI²





BRICS

Biomedical Research
Informatics Computing System

Disclaimer

The views expressed in this presentation are those of the author and do not reflect official policy of the US Government, or any US Government agency.

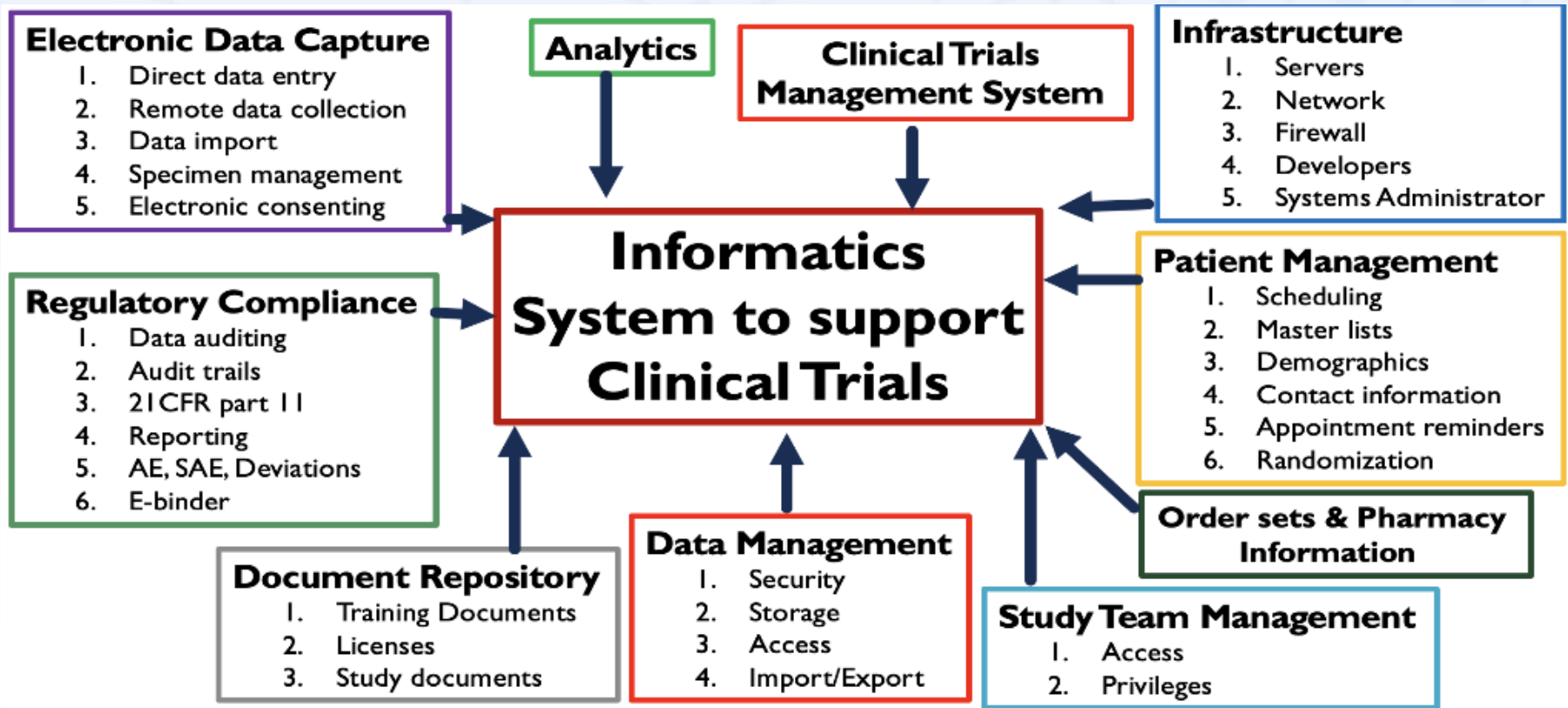


PROFORMS – BRICS

1. Integrated Platform
2. Ease of use, access and maintenance
3. Established process for data collection and curation
4. Fulfills regulatory compliance requirements
5. Government Solution
 - Reduce cost, re-use technology/resources, accelerate science



What is needed to support Clinical Trials and Research?





Patient Management – Subject Profile

Patient Management:

1. Subject Profile
 1. Demographics information
 2. Contact information
 3. Diagnosis information
2. Randomization
3. Protocol Status
4. Attachments
5. eForm Completion Status
6. Protocol compliance status
7. GUID – Global Unique Identifier



Patient Management – Subject Profile



ProFoRMS

Protocol :

001-007-0123



[-] Subject Information

MRN*

Date of Birth

Get From BTRIS

Birth Country

Ethnicity

E-Mail

Home Phone

Work Phone

Mobile Phone

Cell Phone Service Provider

First Name*

Middle Name

Last Name*

Sex

Birth City

Race

Home Address 1

Home Address 2

City

State

Country

Zip

Notes



Patient Management – Subject Profile

Get From Subject Info MRN First Name Last Name **Get From BTRIS**

Functions About

<p>Required Fields</p> <ol style="list-style-type: none"> Complete legal given (first) name of the subject at birth Does the subject have a middle name? Complete additional (middle) name or names at birth Complete legal family (last) name of subject at birth Day of birth [1-31] Month of Birth Year of Birth [####] Name of city/municipality in which subject was born Country of Birth <p>Optional Fields</p> <ol style="list-style-type: none"> Physical sex of subject at birth [M/F] Government Issued or National ID Country Issuing Government-issued or National ID <p>GUID</p>	<p>Please Enter Subject's Information (PII)</p> <input type="text" value="No"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <p>Do not use abbreviations (e.g. Saint Louis not St Louis)</p> <input type="text"/> <input type="text"/> <input type="text"/>	<p>Please Confirm (Re-Enter) the Subject's Information</p> <input type="text" value="No"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <p>Do not use abbreviations (e.g. Saint Louis not St Louis)</p> <input type="text"/> <input type="text"/> <input type="text"/>
--	---	---

GUID or Pseudo-GUID*

✔ VALID

[-] Protocol

Please enter protocol information

Subject ID*

Subject Site

Status in Current Protocol:

Protocol Enrollment Date

[+] Attachments



Subject Management – Subject Status

[-] Protocol

Please enter protocol information

Subject ID *

Subject Site

Status in Current Protocol:

Active

Completed

Withdrawn

Protocol Enrollment Date

[+] Attachments

Save **Reset** **Cancel**



Patient Management – Randomization

Control options:

1. Screening eForm
2. Automatic assignment
3. Manual assignment

Randomization list options:

1. Simple – direct sequence
2. Factor ex. Male/female
3. Location balancing – Site 1, Site 2, Site 3

Patient Management – Randomization List Example

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
1	Group 1	Treatment		
2	Group 1	Treatment		
3	Group 1	Treatment		
4	Group 1	Treatment		
5	Group 1	Treatment		
6	Group 1	Treatment		
7	Group 1	Treatment		
8	Group 1	Treatment		
9	Group 1	Treatment		
10	Group 1	Treatment		
11	Group 1	Treatment		



Patient Management – Randomization Eligibility

Randomization	
Data Element : Randomization.randomGrpCatChoTyp	 
Randomization group category:	<ul style="list-style-type: none"><input type="radio"/> 1. Male <=45 and <=14<input type="radio"/> 2. Male <=45 and >14<input type="radio"/> 3. Male >45 and <=14<input type="radio"/> 4. Male >45 and >14<input type="radio"/> 5. Female <=45 and <=14<input type="radio"/> 6. Female <=45 and >14<input type="radio"/> 7. Female >45 and <=14<input type="radio"/> 8. Female >45 and >14
Data Element : Randomization.randomEligibility	 
Eligible for randomization?	<ul style="list-style-type: none"><input type="radio"/> No<input type="radio"/> Yes



Patient Management – Randomization Assignment

Select a subject to perform an action.

Search:

<input type="checkbox"/>	MRN	SUBJECT ID	LAST NAME	FIRST NAME	ENROLLMENT DATE	STATUS	SITE NAME	RANDOMIZATION GROUP NAME	RANDOMIZATION GROUP DESCRIPTION
<input type="checkbox"/>	7387283	CISTAR_INVAA977XTQ	nihcctest	dcrione		Active			
<input type="checkbox"/>	11-N-0084-Sub	subj001	11-N-0084-Sub	11-N-0084-Sub		Active			
<input type="checkbox"/>	1985198	1234567	Jones	Thomas		Active			
<input type="checkbox"/>	7657377	CISTAR_INVWF329LUC	nihcctest	dcrinotecetera		Active			
<input type="checkbox"/>	467	subj002	Test	Test2		Active			
<input type="checkbox"/>	39874	subject020	Adams	Samuel		Active	NIH		
<input type="checkbox"/>	3746453	subject021	John	Olivia		Active	NIH	Group 1	Treatment
<input type="checkbox"/>	38167309167	CISTARRR192RT9	Smith	Edward		Active			

Showing 1 to 8 of 8 entries (0 row selected of 8)



Data Collection in PROFORMS

Options:













1. Electronic Case Report Forms
 1. Common Data Elements
 2. Unique Data Elements
2. Adaptive Testing – PROMIS
3. File uploads
4. Pull from BTRIS

Collection Methods:

1. Direct Data Entry
2. Patient Self Report via email/phone SMS
3. Offline Collection – OSTRICH
4. Anonymized online survey



Electronic Case Report Form - Example

NSI	
Data Element : NSI.FeelingDizzyNum	 
1. Feeling dizzy	<input type="text"/>
Data Element : NSI.LossBalanceNum	 
2. Loss of balance	<input type="text"/>
Data Element : NSI.PoorCoordClumsyNum	 
3. Poor coordination clumsy	<input type="text"/>
Data Element : NSI.HeadachNum	 
4. Headaches	<input type="text"/>
Data Element : NSI.NauseaNum	 
5. Nausea	<input type="text"/>
Data Element : NSI.VisionProblBlurSeeingNum	 
6. Vision problems blurring trouble seeing	<input type="text"/>

Form Structure- Example

▼ NSI (Appears Exactly 1 Time)

#	TITLE	SHORT DESCRIPTION	VARIABLE NAME	REQUIRED?	TYPE
1	<u>Feeling dizzy number</u>	Document Feeling dizzy number	FeelingDizzyNum	Recommended	UDE
2	<u>Loss of balance number</u>	Document Loss of balance number	LossBalanceNum	Recommended	UDE
3	<u>Poor coordination clumsy number</u>	Document Poor coordination clumsy number	PoorCoordClumsyNum	Recommended	UDE
4	<u>Headaches number</u>	Document Headaches number	HeadachNum	Recommended	UDE
5	<u>Nausea number</u>	Document Nausea number	NauseaNum	Recommended	UDE
6	<u>Vision problems blurring trouble seeing number</u>	Document Vision problems blurring trouble seeing number	VisionProblBlurSeeingNum	Recommended	UDE
7	<u>Sensitivity to light number</u>	Document Sensitivity to light number	SensitivityLightNum	Recommended	UDE
8	<u>Hearing difficulty number</u>	Document Hearing difficulty number	HearingDifficultyNum	Recommended	UDE
9	<u>Sensitivity to noise number</u>	Document Sensitivity to noise number	SensitivityNoiseNum	Recommended	UDE
10	<u>Numbness or tingling on parts of my body number</u>	Document Numbness or tingling on parts of my body number	NumbnessTinglingBodyNum	Recommended	UDE
11	<u>Change in taste and/or smell number</u>	Document Change in taste and/or smell number	ChangeTasteSmellNum	Recommended	UDE
12	<u>Loss of appetite or increased appetite number</u>	Document Loss of appetite or increased appetite number	Loss_Incre_AppetiteNum	Recommended	UDE
13	<u>Poor concentration can't pay attention easily distracted number</u>	Document Poor concentration can't pay attention easily distracted number	PoorConcentDistractNum	Recommended	UDE
14	<u>Forgetfulness can't remember things number</u>	Document Forgetfulness can't remember things number	ForgetfulnessNum	Recommended	UDE
15	<u>Difficulty making desisions number</u>	Document Difficulty making desisions number	DiffMakeDesisionNum	Recommended	UDE



Data Element - Example

Unique Data Element: **Feeling dizzy number**

[view more in the data dictionary](#)

Status: Published
Variable Name: FeelingDizzyNum
Definition: Document Feeling dizzy number

Guidelines & Instructions:

References:

Preferred Question Text: 1. Feeling dizzy

Notes:

Population: Adult and Pediatric

Input Restrictions: Free-Form Entry

Data Type: Numeric Values

Minimum Value: 0

Maximum Value: 4

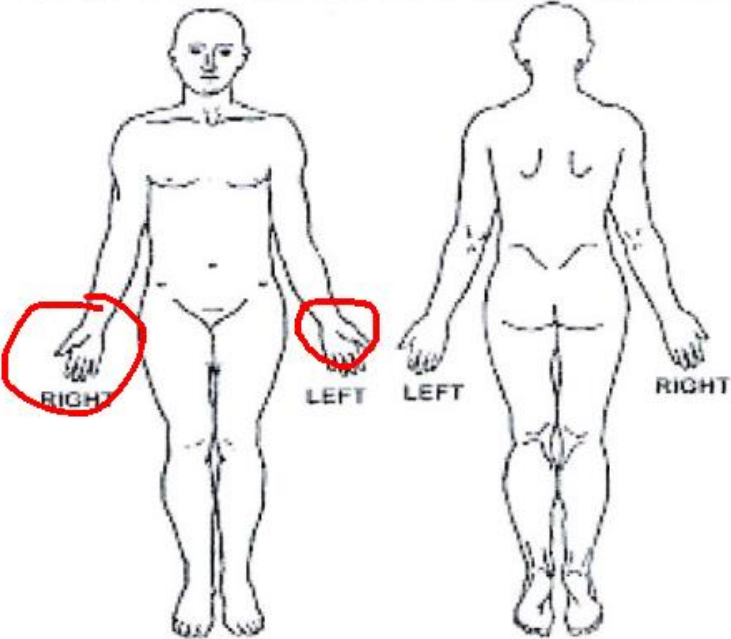
[Mapping to external dictionaries](#)

Example E-Form - Drawing

Clear

**Please mark on the figure(s) below
the location of any implant or metal
inside of or on your body.**

Green Blue Red Black Pencil



RIGHT LEFT LEFT RIGHT



Example E-Form – Electronic Consent/Signature

SIGNATURE OF PARTICIPANT	
Data Element : SIGNATURE OF PARTICIPANT.CmplLegalFiLaNameName	
Complete legal first and last name:	<input type="text" value="Jane Doe"/>
Data Element : SIGNATURE OF PARTICIPANT.eSignature	
eSignature	
Data Element : SIGNATURE OF PARTICIPANT.GeneralDate	
Date	<input type="text" value="2024-02-08 05:41"/>

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT	
Data Element : SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT.CmplLegalFiLaNameName	
*Complete legal first and last name:	<input type="text" value="John Doe"/>
Data Element : SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT.eSignature	
eSignature	



Example E-Form – BTRIS Lab Pull

MRN : 7387283 Visit Type : DEMO 8 FEB

Acute Panel Labs

test to pull information from BTRIS for the acute panel, testing 3 elements, sodium, chloride and potassium

[Get All BTRIS Data](#)

Main

Global Unique ID (GUID):	<input type="text" value="CISTAR_INVAA977XTQ"/>
Participant MRN:	<input type="text"/>



Example E-Form – BTRIS Lab Pull

Questions Having BTRIS Data



Acute Lab Panel

Value:

Showing 1 to 5 of 5 entries (5 rows selected of 5)

First Previous **1** Next Last

Get Latest BTRIS data

Get BTRIS Data

Get BTRIS data from specific date range

Start Date

2024-02-08 00:11

End Date

2024-02-15 00:11

Get BTRIS data in Selected Date Range

Update Multiple Values

Update Multiple Values

Close



Data Collection Process

Initial Setup:

1. Visit
 1. List of eforms
 2. Auto-populated data elements

Collection Methods:

1. Direct Data Entry
2. Patient Self Report
3. Offline Collection – OSTRICH
4. Survey
5. Multi-collect eform



Patient Management – Subject Scheduling

MRN *

Select All MRNs

Select MRNs from List

Date and Time *

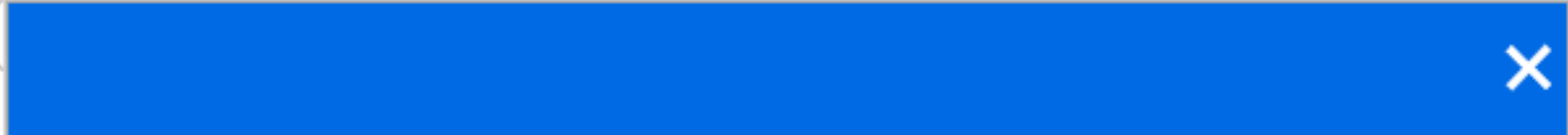
End Date and Time **February 2024** few items

Visit Type * **Sa** Blood Work test

Comments / Notes **3** assessment

ession 1 **10**

Visit Type	Status
BTRIS demo	Scheduled
Unpublished demo eform	Scheduled
Visit 1	Scheduled
Baseline	Scheduled
Blood Work test	Scheduled
assessment	Scheduled



To allow the subject to self-report, send this URL to the subject with GUID CISTAR_INVAA977XTQ:

<https://cistar-demo.ninds.nih.gov/proforms/selfreporting/list?token=yqe5efeaj5rwhb5z>

Send Email **Send SMS** **Copy** **Cancel**

<input type="checkbox"/>	7387283	nihcctest	dcrione	DEMO 8 FEB	2024-02-08 00:11	yqe5efeaj5rwhb5z	Not Started	0 out of 3	2024-02-23
<input type="checkbox"/>	7387283	nihcctest	dcrione	demo a few items	2022-07-19 00:00	7aetbp6p8lhx3vk	Not Started	0 out of 2	Expired on 2022-08-03



Electronic Data Capture – Direct Data Entry

Menu ⌵

ProFoRMS
Protocol : 001-007-0123
⌵

Please select by subject, by subject form or by non-subject eForm from the drop-down, and then perform an action.

View By Subject (MRN) ⌵

Upcoming Collections

View list of data, search for a data, or select data to view or perform an action.

Start Data Collection
Data Entry Summary
Search:

	MRN	SUBJECT NAME	VISIT TYPE	SCHEDULED VISIT DATE
<input type="checkbox"/>	39874	Samuel Adams	Randomization Eligibility	2024-02-08 06:24
<input checked="" type="checkbox"/>	1985198	Thomas Jones	DEMO 8 FEB	2024-02-08 00:20
<input type="checkbox"/>	7387283	dcrione nihcctest	DEMO 8 FEB	2024-02-08 00:11
<input type="checkbox"/>	3746453	Olivia John	Visit 1	2022-08-26 00:00
<input type="checkbox"/>	1985198	Thomas Jones	MoCA test	2022-08-04 16:34
<input type="checkbox"/>	7387283	dcrione nihcctest	demo a few items	2022-07-19 00:00
<input type="checkbox"/>	1985198	Thomas Jones	skip test	2022-07-11 12:19
<input type="checkbox"/>	1985198	Thomas Jones	Conmed	2022-07-06 11:52
<input type="checkbox"/>	7387283	dcrione nihcctest	evening assessment	2022-07-01 16:25
<input type="checkbox"/>	7387283	dcrione nihcctest	Unpublished demo eform	2022-04-25 11:16
<input type="checkbox"/>	1985198	Thomas Jones	Unpublished demo eform	2022-04-25 11:09
<input type="checkbox"/>	7657377	dcrinotecetera nihcctest	000428 Blood Work test	2021-07-23 11:33
<input type="checkbox"/>	7387283	dcrione nihcctest	000428 Blood Work test	2021-07-23 11:33
<input type="checkbox"/>	7387283	dcrione nihcctest	Baseline	2021-07-20 12:09
<input type="checkbox"/>	1985198	Thomas Jones	Visit 1	2021-07-07 15:55

Narrow your search

Clear Filters

MRN ⌵

Scheduled Visit Date ⌵



Electronic Data Capture – Direct Data Entry

Form Administration

Time frame related context (if any) to which the questions were answered:

- After injury
- At time of assessment
- Before injury
- Last 2 weeks
- Last 6 months
- Last 24 hours
- Last month
- Last week
- Last year
- Prior to death
- Since the last interview
- Time of injury
- Other, specify

Other, specify

From whom/ what were the medical history data obtained

- Brother
- Chart/Medical record
- Daughter
- Family, specify relation
- Father
- Friend
- Mother
- Participant/subject
- Physician
- Sister
- Son
- Spouse
- Unknown
- Other, specify

Other, specify

D
E
M
C
Build Version



Electronic Data Capture – Patient Self Report



Listed below are the forms that are available to you for completion. These forms will be available from 01/24/2024 until 02/23/2024.

- To begin, click on the form name.
- You can click Save at any time and come back to complete the survey.
- For Computer Adaptive Test (CAT) surveys, you will not be able to save your progress, and will need to complete the survey in its entirety. Further, CAT surveys cannot be edited once they are submitted. CAT surveys are identified via a notation at the top of the survey.
- At the end of the form, click the Complete button.
- Once you have completed a form, you will see the status change to "complete".
- After a form is completed, you will be unable to edit the form.
- If you are unable to complete these forms within the timeframe, please contact your study coordinator.

My Forms

Search:

EFORM NAME	STATUS	LAST UPDATED
Neurobehavioral Symptom Inventory (NSI)	Not Started	Not Started
Pittsburgh Sleep Quality Index (PSQI)	Not Started	Not Started
PTSD Checklist for DSM-5 (PCL-5)	Not Started	Not Started

Showing 1 to 3 of 3 entries (0 row selected of 3)

First Previous **1** Next Last

Data Management – My Collections Table

- ProFoRMS Home >
- Manage Subjects >
- Manage Data >
 - Collect Data
 - My Collections
 - Audits and Reviews
 - Import Data
 - Deleted Collections
 - Attachments in Data Collections
- Manage Protocol >
- Reports >
- Logs >
- Site Administration >

Data Collection

Select a form to view or perform an action

► **Narrow your search**

Column Visibility ▼	View Entry	Edit	View Audit	Reassign	Delete Entry	Download / Export	Adjudicate	Refresh	Search: <input type="text"/>	
<input type="checkbox"/>	SUBJECT ID	SUBJECT NAME	SCHEDULED VISIT DATE	COLLECTION VISIT DATE	VISIT TYPE	EFORM NAME	STATUS	DATA ENTERED BY	LOCK DATE	INSTANCE
<input type="checkbox"/>	Test-101	Doe Jane	2020-08-31 19:48	2020-08-31 19:55	Visit 5	PCL5 multi test	Locked	Mersha, Megdelawit	2020-12-28 12:40	1
<input type="checkbox"/>	Test-101	Doe Jane	2020-08-31 19:48	2020-08-31 19:56	Visit 5	PCL5 multi test	In Progress	Mersha, Megdelawit		2
<input type="checkbox"/>	Test-101	Doe Jane	2020-08-31 19:48	2020-08-31 19:57	Visit 5	PCL5 multi test	Locked	Mersha, Megdelawit	2021-08-31 10:20	3
<input type="checkbox"/>	Test-101	Doe Jane	2020-08-31 19:48	2020-09-18 15:10	Visit 5	PCL5 multi test	In Progress	Mersha, Megdelawit		4
<input type="checkbox"/>	Test-101	Doe Jane	2020-08-31 17:30	2020-08-31 17:31	Visit 4	Physiological and Balance Measures - Neurotech	Locked	Mersha, Megdelawit	2020-08-31 17:33	
<input type="checkbox"/>	Test-101	Doe Jane	2020-09-18 13:44	2020-09-18 13:45	Visit 20	TestForm_6.3V2Release	In Progress	Mersha, Megdelawit		
<input type="checkbox"/>	Test-120	Doe Jane	2020-09-14 13:29	2020-09-14 13:29	Visit 2	TestForm_6.3Release	In Progress	Mersha, Megdelawit		
<input type="checkbox"/>	Test-101	Doe Jane	2020-08-31 18:30	2020-10-02 10:58	Visit 2	OLD - Pittsburgh Sleep Quality Index (PSQI) - INVICTA	Locked	Mersha, Megdelawit	2021-07-13 12:22	
<input type="checkbox"/>	Test-120	Doe Jane	2020-09-14 13:25	2020-09-14 13:26	Visit 11	PCL5 multi test	In Progress	Mersha, Megdelawit		1
<input type="checkbox"/>	Test-120	Doe Jane	2020-09-14 13:25	2020-09-14 13:27	Visit 11	PCL5 multi test	In Progress	Mersha, Megdelawit		2
<input type="checkbox"/>	Test-120	Doe Jane	2020-09-14 13:25	2020-10-21 10:35	Visit 11	PCL5 multi test	In Progress	Mersha, Megdelawit		3
<input type="checkbox"/>	Test-120	Doe Jane	2020-09-14 13:25	2020-10-21 10:36	Visit 11	PCL5 multi test	In Progress	Mersha, Megdelawit		4
<input type="checkbox"/>	Test-101	Doe Jane	2020-10-29 19:55	2020-10-29 19:58	Visit 11	PCL5 multi test	In Progress	Mersha, Megdelawit		1
<input type="checkbox"/>	Test-101	Doe Jane	2020-09-08 13:28	2020-09-08 13:29	Visit 10	Alcohol Use Disorders Identification Test - Consumption Questions (AUDIT-C)-Test	Locked	Mersha, Megdelawit	2020-09-08 13:58	

Data Management – Export Options

Collect Data

My Collections

Audits and Reviews

Import Data

Deleted Collections

Attachments in Data Collections

Manage Protocol >

Reports >

Logs >

Site Administration >

Narrow your search

Column Visibility View Entry Edit View Audit Reassign Delete Entry Download / Export Adjudicate Refresh

Search:

<input type="checkbox"/>	SUBJECT ID	SUBJECT NAME	SCHEDULED VISIT DATE	COLLECTION VISIT DATE	VISIT TYPE		STATUS	DATA ENTERED BY	LOCK DATE	INSTANCE#
<input checked="" type="checkbox"/>	Test-101	Doe Jane	2020-08-31 19:48	2020-08-31 19:56	Visit 5		In Progress	Mersha, Megdelawit		2
<input checked="" type="checkbox"/>	Test-101	Doe Jane	2020-08-31 19:48	2020-08-31 19:57	Visit 5		Locked	Mersha, Megdelawit	2021-08-31 10:20	3
<input checked="" type="checkbox"/>	Test-101	Doe Jane	2020-08-31 19:48	2020-09-18 15:10	Visit 5	PCL5 multi test	In Progress	Mersha, Megdelawit		4
<input type="checkbox"/>	Test-101	Doe Jane	2020-08-31 17:30	2020-08-31 17:31	Visit 4	Physiological and Balance Measures - Neurotech	Locked	Mersha, Megdelawit	2020-08-31 17:33	
<input type="checkbox"/>	Test-101	Doe Jane	2020-09-18 13:44	2020-09-18 13:45	Visit 20	TestForm_6.3V2Release	In Progress	Mersha, Megdelawit		
<input type="checkbox"/>	Test-120	Doe Jane	2020-09-14 13:29	2020-09-14 13:29	Visit 2	TestForm_6.3Release	In Progress	Mersha, Megdelawit		
<input type="checkbox"/>	Test-101	Doe Jane	2020-08-31 18:30	2020-10-02 10:58	Visit 2	OLD - Pittsburgh Sleep Quality Index (PSQI) - INVICTA	Locked	Mersha, Megdelawit	2021-07-13 12:22	
<input checked="" type="checkbox"/>	Test-120	Doe Jane	2020-09-14 13:25	2020-09-14 13:26	Visit 11	PCL5 multi test	In Progress	Mersha, Megdelawit		1
<input checked="" type="checkbox"/>	Test-120	Doe Jane	2020-09-14 13:25	2020-09-14 13:27	Visit 11	PCL5 multi test	In Progress	Mersha, Megdelawit		2
<input checked="" type="checkbox"/>	Test-120	Doe Jane	2020-09-14 13:25	2020-10-21 10:35	Visit 11	PCL5 multi test	In Progress	Mersha, Megdelawit		3
<input checked="" type="checkbox"/>	Test-120	Doe Jane	2020-09-14 13:25	2020-10-21 10:36	Visit 11	PCL5 multi test	In Progress	Mersha, Megdelawit		4
<input type="checkbox"/>	Test-101	Doe Jane	2020-10-29 19:55	2020-10-29 19:58	Visit 11	PCL5 multi test	In Progress	Mersha, Megdelawit		1
<input type="checkbox"/>	Test-101	Doe Jane	2020-09-08 13:28	2020-09-08 13:29	Visit 10	Alcohol Use Disorders Identification Test - Consumption Questions (AUDIT-C)-Test	Locked	Mersha, Megdelawit	2020-09-08 13:58	
<input type="checkbox"/>	Test-101	Doe Jane	2020-09-08 13:28	2020-09-08 13:39	Visit 10	NP - Beck Depression Inventory II (BDI-II) - 0118	Locked	Mersha, Megdelawit	2020-09-08 13:59	

Download Table to CSV

CSV - Single Sheet

EXCEL - Multiple Sheet

Export Filter



Data Management - Export Filter

Export Filter**PCL5multitest**

<input type="checkbox"/> Check	Main
<input type="checkbox"/>	Q: Global Unique ID (GUID) which uniquely identifies the subject:
<input type="checkbox"/>	Q: Subject ID number:
<input type="checkbox"/>	Q: Subject's age (recorded in years):
<input type="checkbox"/>	Q: Visit date:
<input type="checkbox"/>	Q: Name of the site:
<input type="checkbox"/>	Q: Is the subject in the case or control arm of the study?
<input type="checkbox"/>	Q: Additional information (if any):

<input type="checkbox"/> Check	PCL-5
<input type="checkbox"/>	Q: How much were you bothered by: Repeated, disturbing, and unwanted memories of the stressful experience?
<input type="checkbox"/>	Q: How much were you bothered by: Repeated, disturbing dreams of the stressful experience?
<input type="checkbox"/>	Q: How much were you bothered by: Suddenly feeling or acting as if the stressful experience were actually happening again (as if you were actually back there reliving it)?
<input type="checkbox"/>	Q: How much were you bothered by: Feeling very upset when something reminded you of the stressful experience?
<input type="checkbox"/>	Q: How much were you bothered by: Having strong physical reactions when something reminded you of the stressful experience (for example, heart pounding, trouble breathing, sweating)?
<input type="checkbox"/>	Q: How much were you bothered by: Avoiding memories, thoughts, or feelings related to the stressful experience?
<input type="checkbox"/>	Q: How much were you bothered by: Avoiding external reminders of the stressful experience (for example, people, places, conversations, activities, objects, or situations)?
<input type="checkbox"/>	Q: How much were you bothered by: Trouble remembering important parts of the stressful experience?
<input type="checkbox"/>	Q: How much were you bothered by: Having strong negative beliefs about yourself, other people, or the world (for example, having thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)?
<input type="checkbox"/>	Q: How much were you bothered by: Blaming yourself or someone else for the stressful experience or what happened after it?
<input type="checkbox"/>	Q: How much were you bothered by: Having strong negative feelings such as fear, horror, anger, guilt, or shame?
<input type="checkbox"/>	Q: How much were you bothered by: Loss of interest in activities that you used to enjoy?



Data Management - Attachment Management

Manage Subjects >

Manage Data v

Collect Data

My Collections

Audits and Reviews

Import Data

Deleted Collections

Attachments in Data Collections

Manage Protocol >

Reports >

Logs >

Site Administration >

Narrow your search

Clear Filters

Subject ID v

This report shows the forms that have attachments in data collection.

Download Search:

SUBJECT ID	EFORM NAME	VISIT TYPE NAME	ATTACHMENT FILE NAME	ATTACHMENT SIZE
<input type="checkbox"/> 419	V1 Baseline Visit Checklist-INVICTA	15 year eform test	Capture.JPG	163.56 KB
<input type="checkbox"/> 406	Pre-processed MRI (Raw Data) - INVICTA	Test-Attachment	CISTARStage6.5.1Release-1_6_21Demo.xlsx	11.82 KB
<input type="checkbox"/> 419	Pre-processed MRI (Raw Data) - INVICTA	MRIUploadTst	test100MB	95.37 MB
<input type="checkbox"/> 424	Pre-processed MRI (Raw Data) - INVICTA	Test-Attachment	CISTARStage6.5.1Release-12_29_2020.xlsx	11.50 KB
<input type="checkbox"/> 1323	Pre-processed MRI (Raw Data) - INVICTA	Visit1	1.9GiB.zip	1.90 GB
<input type="checkbox"/> 2023	Pre-processed MRI (Raw Data) - INVICTA	MRIUploadTst	CISTAR Study Monitors Guide_fnl V1.3.docx	1.69 MB
<input type="checkbox"/> 406	PET Scan Upload 1 - 18-03690	Test upload	test100MB	95.37 MB
<input type="checkbox"/> 419	PET Scan Upload 1 - 18-03690	Test upload	test100MB	95.37 MB
<input type="checkbox"/> 424	PET Scan Upload 1 - 18-03690	Test upload	test100MB	95.37 MB
<input type="checkbox"/> 2233	PET Scan Upload 1 - 18-03690	MIR upload test	cnrm.nih.gov_recepit.pdf	49.58 KB
<input type="checkbox"/> 426	Document Attachment MBLT	upload testing	testfle2k.txt	2.00 KB
<input type="checkbox"/> 426	Document Attachment MBLT	upload testing	testfle1k.txt	1.00 KB
<input type="checkbox"/> 428	Document Attachment MBLT	upload testing	testfle1k.txt	1.00 KB



Regulatory Compliance Tools

1. eBinder
2. Electronic Logs (examples)
 1. Adverse events
 2. Delegation of authority
 3. Non-compliance
 4. Enrollment
3. Audit Trail
4. Protocol Auditing



Regulatory Compliance - eBinder

- test main
- Demo test
 - Documents
 - Study Contact List
 - Monitoring Visit Log
 - Screening and Enrollment
 - Delegation of Authority
 - Site Training Log
 - Serious Adverse Events
 - Deviation or Violation
 - Unanticipated Adverse Events
 - Unanticipated Protocols
 - Personnel
 - Protocol Signature
 - Curriculum Vitae
 - Training Certificate
 - Medical Licenses
 - Financial Disclosure
 - Institutional Review Board
 - IRB Roster
 - IRB Submission Log
 - IRB Approval Notification
 - IRB Submissions
 - Approved Protocol
 - Approved Informed Consent Form
 - Other Approved Study Documents
 - Communication
 - Monitoring

Current Dir: /Demo test/Institutional Review Board(IRB)/
Audit **Clipboard** 0 Items

Upload
New Directory
Paste
Select all
Deselect all

Menu	Name	Type	Size	Last Modified	Author
	...Back	Dir			
☰	IRB Roster	Dir	0	2023-04-11 10:39:59	Dominic Nathan
☰	IRB Submission Log	Dir	0	2023-04-11 10:39:59	Dominic Nathan
☰	IRB Approval Notification	Dir	0	2023-04-11 10:39:59	Dominic Nathan
☰	IRB Submissions	Dir	0	2023-04-11 10:39:59	Dominic Nathan
☰	Approved Protocol	Dir	0	2023-04-11 10:39:59	Dominic Nathan
☰	Approved Informed Consent Form	Dir	0	2023-04-11 10:39:59	Dominic Nathan
☰	Other Approved Study Documents	Dir	0	2023-04-11 10:39:59	Dominic Nathan



Regulatory Compliance – Logs – Adverse Event

Adverse Events Log

The study team will log Adverse Events associated with the protocol

MRN

Patient Name

Site

[\[-\] CTCAE Information](#)

Select CTCAE

CTCAE Term

CTCAE Category

Definition

Navigational Note

Description

Grade



Regulatory Compliance – Logs – Adverse Event

[-] MedDRA Information

Select MedDRA

Select MedDRA

LLT MedDRA Term

Headache - Nervous system disorders

x



LLT MedDRA Code

10019211

SOC MedDRA Term

Nervous system disorders

SOC Code

10029205



Regulatory Compliance – Audit Trail

Export To PDF

Export to CSV

Data Collection Audit Log

eForm Name: Testing_M
Protocol Name: Vivek_001
Collection Visit Date: 2022-04-20 17:09
Scheduled Visit Date: 2022-04-11 12:59
Visit Type: 12 months

Form Summary Status

Download

Search:

NAME	DATE/TIME	ACTION	# OF QUESTIONS ANSWERED	E-SIGNATURE
Wondemagegn, Mahlet	2022-04-20 17:10	Started		

Showing 1 to 1 of 1 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
Wondemagegn, Mahlet	2022-04-20 17:10	Main	GUID	Global Unique ID (GUID):		CISTAR_INVVD953UEW
Wondemagegn, Mahlet	2022-04-20 17:10	Main	VisitDate	Visit Date:		2022-04-20 17:09
Wondemagegn, Mahlet	2022-04-20 17:10	Main	VisitOTH	Visit Type		2
Wondemagegn, Mahlet	2022-04-20 17:10	Inclusion Criteria	AdultAgeGT18Ind	Adult age >18 years		No
Wondemagegn, Mahlet	2022-04-20 17:10	Inclusion Criteria	DefiniteProbablePMLInd	Definite or Probable PML		Yes
Wondemagegn, Mahlet	2022-04-20 17:10	Inclusion Criteria	EffectiveBirthControl_Ind	Agreement to use effective method of birth control during and up to 3 months after:		Yes
Wondemagegn, Mahlet	2022-04-20 17:10	Exclusion Criteria	HxUnderlAutoDxCNS	History of underlying autoimmune disease involving the CNS indicator		No
Nathan, Dominic	2024-02-08 06:06	Inclusion Criteria	AdultAgeGT18Ind	Adult age >18 years	No	Yes

Showing 1 to 8 of 8 entries

First Previous **1** Next Last



Regulatory Compliance – Audit Trail

Answers Edited After Being Completed/Locked

Download

Search:

NAME	DATE/TIME	SECTION NAME	DATA ELEMENT NAME	QUESTION TEXT	ANSWERS BEFORE	ANSWERS AFTER	REASON FOR CHANGE	FORM STATUS	E-SIGNATURE
------	-----------	--------------	-------------------	---------------	----------------	---------------	-------------------	-------------	-------------

There are no edited answers to display at this time.

Showing 0 to 0 of 0 entries

First Previous Next Last

Auditor Comments

Download

Search:

NAME	DATE/TIME	SECTION NAME	DATA ELEMENT NAME	QUESTION TEXT	ANSWERS BEFORE	ANSWERS AFTER	AUDITOR COMMENT	E-SIGNATURE
------	-----------	--------------	-------------------	---------------	----------------	---------------	-----------------	-------------

There are no edited answers to display at this time.

Showing 0 to 0 of 0 entries

First Previous Next Last

Sent Emails

Download

Search:

DATE SENT	SENT TO	CARBON COPY	EMAIL SUBJECT	TRIGGERED ANSWER
-----------	---------	-------------	---------------	------------------

No emails have been sent.

Showing 0 to 0 of 0 entries

First Previous Next Last

Track Downloads

Download

Search:

NAME	DATE/TIME	EFORM NAME	SHORT NAME	MRN	VISIT TYPE	SCHEDULED VISIT DATE	DATA ENTERED BY	STATUS	INSTANCEVERSION
------	-----------	------------	------------	-----	------------	----------------------	-----------------	--------	-----------------

Nathan, Dominic	2023-06-21 12:04	Testing_M	Testing_M	7387283	12 months	2022-04-11 12:59	wondamagegnmg	In Progress	
Nathan, Dominic	2023-06-21 12:05	Testing_M	Testing_M	7387283	12 months	2022-04-11 12:59	wondamagegnmg	In Progress	
Wondamagegn, Mahlet	2023-06-05 13:45	Testing_M	Testing_M	7387283	12 months	2022-04-11 12:59	wondamagegnmg	In Progress	
Wondamagegn, Mahlet	2023-06-05 13:45	Testing_M	Testing_M	7387283	12 months	2022-04-11 12:59	wondamagegnmg	In Progress	



Regulatory Compliance – Protocol Auditing

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. **Please answer all questions.**

1. During

Reviewer Comment



(Use the Example.

Reviewer Comment *

*Hour

Save Comments

Verify

Close

*2. During night? NI

Reviewer Comments History

Archive Comments

Search: ▾

3. During

(Use the Example.

<input type="checkbox"/>	NAME	DATE/TIME	SECTION NAME	DATA ELEMENT NAME	QUESTION TEXT	ANSWERS BEFORE	ANSWERS AFTER	REVIEW COMMENT
<input type="checkbox"/>	Nathan, Dominic	2024-02-08 06:11	PSQI	PSQIBedPstMnt MinTime	Minutes			This field was left empty

*Hour

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

First Previous **1** Next Last



Regulatory Compliance – Protocol Auditing

View Auditor Comments Summary

Download

Search:

SUBJECT	EFORM	# OF AUDITOR COMMENTS
1985198	Alcohol Use Disorders Identification Test: Self-Report Version (AUDIT)	5
1985198	(000089) Vaccine information Form	2

Showing 1 to 2 of 2 entries

First Previous **1** Next Last

View Auditor Comments Details

Download

Search:

SUBJECT	EFORM	DATE/TIME	QUESTION TEXT	AUDIT STATUS
1985198	Alcohol Use Disorders Identification Test: Self-Report Version (AUDIT)	2021-07-08 11:20	Is the subject in the case or control arm of the study?	Locked
1985198	(000089) Vaccine information Form	2022-07-28 12:23	If other, please specify:	In Progress
1985198	Alcohol Use Disorders Identification Test: Self-Report Version (AUDIT)	2021-07-08 11:14	How often do you have a drink containing alcohol?	In Progress

Showing 1 to 3 of 3 entries

First Previous **1** Next Last



Regulatory Compliance – Protocol Auditing

Auditor Comment Response



Auditor Comment Response*

Save Comments

Close

Auditor Comments History

Archive Comments

Search: ▾

<input type="checkbox"/>	NAME	DATE/TIME	SECTION NAME	DATA ELEMENT NAME	QUESTION TEXT	ANSWERS BEFORE	ANSWERS AFTER	AUDIT COMMENT
<input type="checkbox"/>	Nathan, Dominic	2022-07-28 12:23	First Dose	YesNoOther1Tx t	If other, please specify:	/null		this was blank

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

First Previous **1** Next Last



Access Control – User Roles

- ProFORMS Home >
- Manage Subjects >
- Manage Data >
- Manage Protocol >
- Reports >
- Logs >
- Site Administration ▾
 - Dashboard Configuration
 - Users
 - Roles & Privileges**
 - Create Visit Type Group
 - Manage Visit Type Groups
 - Manage Diagnosis
 - Manage MedDRA Version
 - Import MedDRA Information
 - Import CTCAE Information
 - Admin Form Submit
 - Admin Form Search

View roles or add/edit a role with associated privileges to ProFoRM system.

System Roles

Add a new role or select a role to perform an action.

Search:

<input type="checkbox"/>	SYSTEM ROLE	ROLE DESCRIPTION
<input type="checkbox"/>	Associate Investigator	NINDS role
<input type="checkbox"/>	Auditor	NINDS role
<input type="checkbox"/>	Clinical Research Associate	Legacy role not used by NINDS
<input type="checkbox"/>	Data Manager	NINDS role
<input type="checkbox"/>	Lead Associate Investigator	NINDS role
<input type="checkbox"/>	Principal Investigator	NINDS role
<input type="checkbox"/>	Principal Investigator Unblinded	Principal Investigator Unblinded not able to see randomization details
<input type="checkbox"/>	Principle Investigator No Dashboard	NINDS role (no dashboard)
<input type="checkbox"/>	Protocol Navigator	NINDS role
<input type="checkbox"/>	Protocol Navigator AE Permission	Protocol Navigator with AE Permission (temporary role)
<input type="checkbox"/>	Research Associate	Legacy role not used by NINDS
<input type="checkbox"/>	Research Associate No Dashboard	NINDS role - no dashboard
<input type="checkbox"/>	Research Coordinator	NINDS role
<input type="checkbox"/>	Research Coordinator No Dashboard	NINDS role (no dashboard)
<input type="checkbox"/>	STAMS Lab Personnel	Lab personnel access to get subject demographics

Showing 1 to 15 of 18 entries (0 row selected of 18)



Access Control – User Role Assignment

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 >

Assign users to roles

Search:

USERNAME	NAME	ROLE	PROTOCOL SITE	EBINDER NOTIFICATION
kunnathiv	Kunnath, Isac	Protocol Navigator	-- Select Site --	--
Faith07058	rothenberg, faith	Principal Investigator	-- Select Site --	--
Meg	Mersha, Meg	Auditor	-- Select Site --	--
administrator	Admin, Portal	--		--
sahmed1	Admin, Sikandar	--		--
testadmin	Admin, Test	--		--
ctubrad	Alvarez, Bradley	--		--
LeonelAmpie	Ampie, Leonel	--		--
andersoncf	Anderson, Caroline	--		--
augustink	Augustine, Karen	--		--
ELBarnhart	Barnhart, Elizabeth	--		--
ebartrum	Bartrum, Elizabeth	--		--



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Biomedical Research
Informatics Computing System

Live Demo



Acknowledgements

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9. Mrs. Lan Wang
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12. Mrs. Mahlet Wondemagagn
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20. Dr. PJ. Cimino
21. Mrs. Gretchen Scott
22. Mrs. Tasneem Malik
23. Dr. Debra Ehrlich
24. Mr. Mark Edwards
25. Mr. Amar Yvatkar
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30. CIT BRICS team
31. CiSTAR and CASA Users



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A huge “Thank You”
to our users and various working
groups



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Questions?





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Closing Remarks

