

Standard Operating Procedure (SOP)

BRICS System Design Document

Document Information

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The SOP approval/distribution process is as follows:

1. The SOP author sends the SOP SharePoint link to their peers/subject matter experts (SMEs) for review.
2. After editing, the SOP author decides whether the SOP is ready for approval. If the SOP is ready, the author adds the SOP to the ITBP Manager meeting agenda.
3. At the ITBP Managers meeting or via email, NINDS Management formally approves/disapproves the SOP.
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Approved By:

Name	Title	Organization	Approval Date
Yang Fann	IT Director	NINDS DIR ITBP	03/28/19
Matthew McAuliffe	BIRSS Chief	CIT OIR ISL BIRSS	03/28/19
Dominic Nathan	Informatics Core Director	CNRM	03/28/19

Name	Title	Organization	Approval Date
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Peer Reviewers

This Standard Operating Procedure was reviewed by the peers (i.e., subject matter experts) listed below. The procedure will be reviewed by the peer reviewers at least annually.

Reviewed By:

Name	Title	Organization	Date
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Leonie Misquitta	Sr Scientific Advisor	CIT OIR ISL BIRSS	03/27/19
Dominic Nathan	Informatics Core Director	CNRM	03/27/19

Distribution List

This Standard Operating Procedure impacts the individuals on this Distribution List. The SOP author should notify everyone on this list about changes to this SOP *within one week* of NINDS approval.

Distributed To:

Name / Department / Group / Team
Yang Fann
Matthew McAuliffe
Dominic Nathan
Willy Calderon

1. Introduction

1.1 Overview

System Design document describes the system requirements, operating environment, system and subsystem architecture, database design, human-machine interfaces and external interfaces. The intended audience for this procedure includes the groups/individuals listed below:

- NINDS DIR Clinical Informatics Development Team
- CIT OIR ISL BIRSS Development Team
- Business stakeholders and partners

1.2 Purpose

The purpose of this System Design Document is to provide a description for how the new BRICS will be constructed. The System Design Document was created to ensure that the design meets the requirements specified in the System Requirements Specification (SRS). BRICS is a collaboration and extensible web-based system designed to support the collection of research studies and clinical trials. It consists of modular components including:

- Global Unique Identifier (GUID) tool
- Data Dictionary tool
- Data Repository
- Meta Study
- Protocol and Form Research Management System (ProFoRMS)
- Query Tool
- Account Management

1.3 Scope

This Standard Operating Procedure is applicable to the collection of components that comprise custom software development of the BRICS and its associated systems such as CiSTAR, CASA, and ProFoRMS at NINDS, CIT and CNRM.

1.4 Roles and Responsibilities

The following table defines the System Design roles and responsibilities and also serves as the list of points of contact for issues and concerns relating to the BRICS system design.

Name	Title	Responsibility
Clinical Trial Unit	NINDS DIR CTU	NINDS Governance committee for approvals
Steering Committee	Informatics Core	CNRM Governance committee for approvals
Yang Fann	BRICS Co-Director NINDS IT Director	Authorizing Official to operate Approve requirements
Matthew McAuliffe	BRICS Co-Director CIT BIRSS Chief	Approve requirements
Dominic Nathan	Informatics Core Director	Manage the project
Leonie Misquitta	Sr Scientific Advisor	Provide scientific consulting
Tsega Gebremichael	Sr Software Engineer	Provide technical guidance
Change Control Board	Subject Matter Experts	Manage and approve change requests and system enhancements
Business, Product owner, Instance Program Manager	Key Stakeholders	Review and validate requirements and work products
NINDS/CIT Clinical Informatics Development team	Software Engineer	Responsible for understanding and following the scrum development processes outlined in this document.

1.5 Key Words

The following key terms are used in this SOP.

- BRICS – Biomedical Research Informatics Computing System
- CiSTAR – Clinical Informatics System for Trials and Research
- CASA – Collection Access Sharing Analytics Platform
- CNRM – Center for Neuroscience and Regenerative Medicine
- SRS – System Requirements Specification

1.6 Design Constraints

This section identifies any constraints in the system design, trade-off analyses, conflicts with other systems, or assumptions made by the project team in developing the system design. No design constraints have been identified.

2. System Architecture

This section describes the overall system software and hardware architecture for the BRICS project.

2.1 Software Architecture

The platform architecture comprises three layers as shown in Figure 1 below:

- a) Presentation Layer
- b) Application Layer
- c) Data Layer

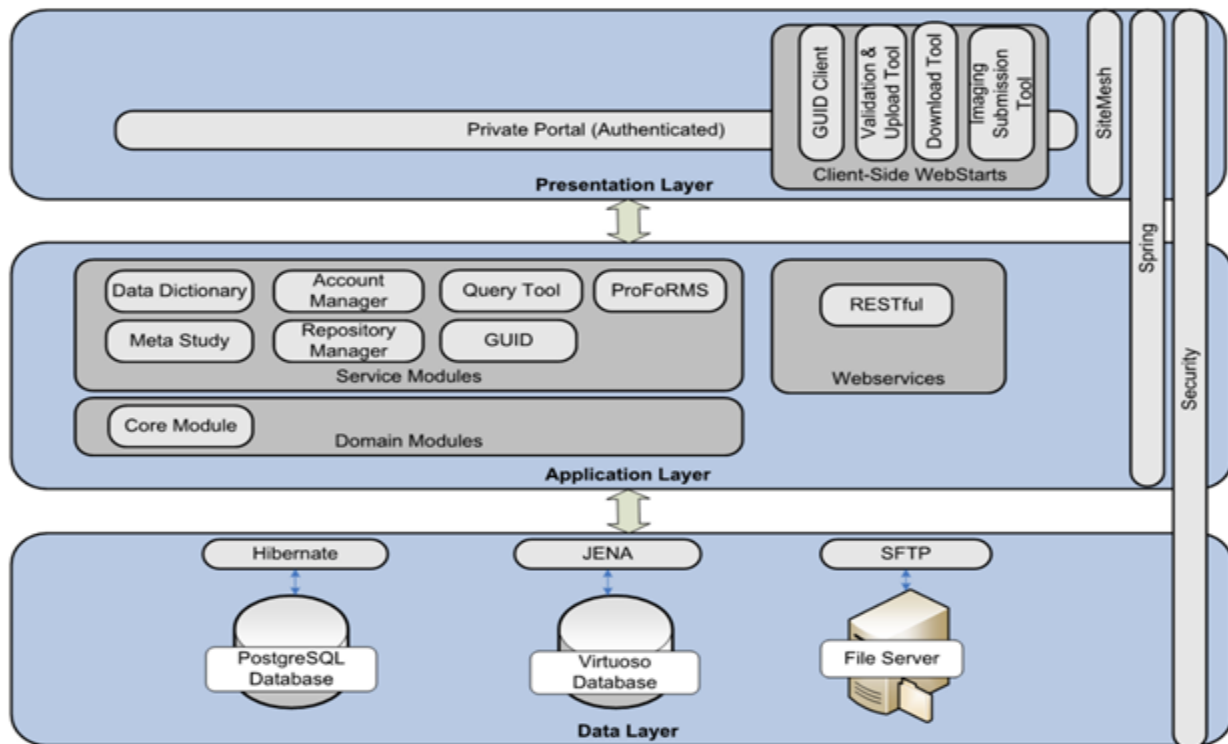


Figure 1. BRICS Platform Architecture

The Presentation Layer serves as the entry point to the BRICS portal, allowing users to securely login by verifying that their credentials are valid, and displaying requested information on the portal web page. The presentation layer uses various open source technologies and libraries, including Java Server Pages (JSP), jQuery, JavaScript libraries (e.g. such as Backbone.js, Asynchronous JavaScript), and XML (AJAX), etc. to make web-pages interactive. This layer also includes WebStart applications: the Global Unique Identifier (GUID) client, Validation and Upload tools, and Download and Image Submission tools, all of which run on users' machines. Although these WebStart tools run on users' machines, they make secure calls to WebServices to obtain data for users. Once the data is returned from the WebServices, it is processed and displayed on the user interface.

The Application Layer processes information received from the Presentation Layer and communicates the requested information back to the Presentation Layer. The Application Layer is responsible for the logic that determines the fundamental capabilities of the BRICS modules and tools. There are seven service modules within the Application Layer that are integrated together to provide a collaborative, extensible web-based data capture, processing, data repository, and access environment(s). The modules (shown in Figure 1) comprise the GUID tool, Data Dictionary (DD), Data Repository, Meta Study, Protocol and Form Research Management System (ProFoRMS), Query Tool, and Account Management.

To communicate and exchange information between the modules, representational state transfer (RESTful) Webservices are used. For example, when submitting data-to-data repository, the data is validated against the Data Dictionary definition. During the process of data validation, the dictionary's Webservice is called to acquire the definition of the given form structure and CDEs, including permissible values.

The Data Layer receives data from the Application Layer. Based on the user's request, the data layer executes queries against a database and returns the results back to the Application Layer. Using the same data validation example, the data layer queries the database to obtain detailed information about the given form structure and sends that information back to the Application Layer. The Data Layer consists of open source databases such as PostgreSQL and Virtuoso databases, and file servers, and data persistence frameworks. The Virtuoso database is used to store the Query Tool and parts of the Data Dictionary data. The Repository module uses the PostgreSQL database to store and retrieve data. Also present are Object-Relational Mapping (ORM) frameworks such as Hibernate and Apache Jena, which are open-source libraries and are used to store and retrieve data from databases.

The three layers intercommunicate with each other, enabling BRICS developers to deploy reusable components for the platform. The layered architecture makes it easier to maintain and allow for scalability. Maintenance is easier because some of the components are shared by different parts of the platform and changes can be applied simultaneously. For example, the same dictionary Webservice is used by the ProFoRMS and Imaging Submission tools. A change to the dictionary Webservice logic only needs to be done once, within the Application Layer, to make it available throughout the system without the need to change code in any other layers. This allows code reuse, minimizes redundancy, and makes maintenance easier.

2.2 Hardware Architecture

BRICS design is based on existing hardware architecture at NIH. The physical infrastructure is located within the NIH Data Center in Bethesda, Maryland, supported by an alternate backup site in Sterling, Virginia. The infrastructure is supported by Storage devices (Dell EqualLogic) and switches (10GbE Cisco) that connect to host servers (Dell R630). A virtualized environment (using VMware Inc. products) is used to host the various applications and services. The operation of various BRICS instances is 24x7 with redundancies and backups done on a nightly schedule.

3. Database Design

Structured data stored in the database will be searchable and sortable in order to meet the reporting requirements. The database field names are consistent with all fields built into specific module and tool. The final design of the DBMS includes the following data dictionary information:

- Refined logical model - normalized table layouts, entity relationship diagrams, and other logical design information.
- A physical description of the DBMS schemas, sub-schemas, records, sets, tables, storage page sizes, etc.
- Access methods (such as indexed, via set, sequential, random access, sorted pointer array, etc.)
- Estimate of the DBMS file size or volume of data within the file, and data pages, including overhead resulting from access methods and free space.
- Definition of the update frequency of the database tables, views, files, areas, records, sets, and data pages, estimate the number of transactions.

The BRICS database will be backed up in accordance with NINDS and CIT Security Policies and Guidelines and provide a failover capability to revert to in the event of a database corruption or system failure.

Additional technical specifications of the database design can be found in the database management system (DBMS) addendum to the Project Plan.

4. System Security and Integrity Controls

BRICS design incorporates several security and integrity controls to ensure the system and its associated systems are continually protected. This is done through a multi-tiered approach to ensuring data integrity is achieved through only authorized user functions and assignments.

The first design consideration is user authorization and permissions. These users will be unable to perform any transactions outside of their assigned areas. System administrators will grant proper roles and operating boundaries for each of their assigned users.

The next design consideration is to establish control points. Firewalls will be placed to partition the functions each instance is able to perform. The purpose is to reinforce work areas, permissions, and access to prevent any duplication, unintentional changes, or malicious changes of data.

The system design also incorporates the important audit trail capability which will allow administrators to track the history of all users in order to provide history, error identification, and accountability for system users.

Security is a critical component during biomedical informatics platform development. Planning for security must carry out as initial part of design work because maintaining privacy of patient data is essential for meeting various compliance regulations (e.g. HIPPA privacy rule). The BRICS security design is compliant at the Federal Information Security Modernization Act (FISMA) Moderate level. Confidentiality of research subjects is maintained, but data and study protocols are shared to promote scientific collaboration. Appropriate controls and assurance requirements conform to the Federal Information Processing Standards (FIPS) 200 and NIST SP 800-53 Revision 3, and the Department of Health and Human Services policies for information systems.

5. Modular Process Design

Modular design emphasizes separating the functionality of a program into independent module. BRICS platform offers a suite of tools to promote standardization, communication, and collaboration across the research community and a data repository to hold genetic, phenotypic, clinical, and medical imaging data. These plug-and-play

modules can be shared across disease categories or deployed and branded independently.

The platform architecture and the associated functionalities discussed in the system software architecture (section 2.1) provided the basis for implementing a complete Biomedical Research Data Life Cycle Management (BRDLCM) methodology. The essential processes in the BRDLCM are as follows:

- data de-identification
- preparation of submission information packages for data collection
- development of archival information packages for storage within established repositories
- creation of access information packages with tools and techniques for data analysis, sharing and reuse.

5.1 De-identification of Data

BRICS uses the GUID method to support the storage of de-identifying patient/subject research data. The GUID is a Global Unique Identifier for each study participant that allows researchers to aggregate and share a participant's data without exposing personally identifiable information (PII). The GUID is made up of random alpha-numeric characters and is not generated from PII/PHI. The GUID is generated at the researcher's site by using the BRICS GUID generation tool. The PII fields used as part of the hashing process can include complete legal given (first) name of subject at birth, middle name (if available), complete legal family (last) name of subject at birth, day of birth, month of birth, year of birth, name of city/municipality in which subject was born, and country of birth. The PII data is not sent to the server but rather one-way encrypted hash codes are created and returned to the server, allowing the PII to reside only on the researcher's computer. A random number, the GUID, is generated by the server and returned to the researcher. The GUIDs have been designed to be BRICS 'instance' specific, stored within a MongoDB database (illustrated in Figure 2). The GUID is the primary subject identifier.

In addition, the GUID server can be configured to support multiple BRICS instances thereby making the GUID truly more "global". This is especially useful in multi-center clinical trials, and investigations where subjects can be enrolled across studies or repositories.

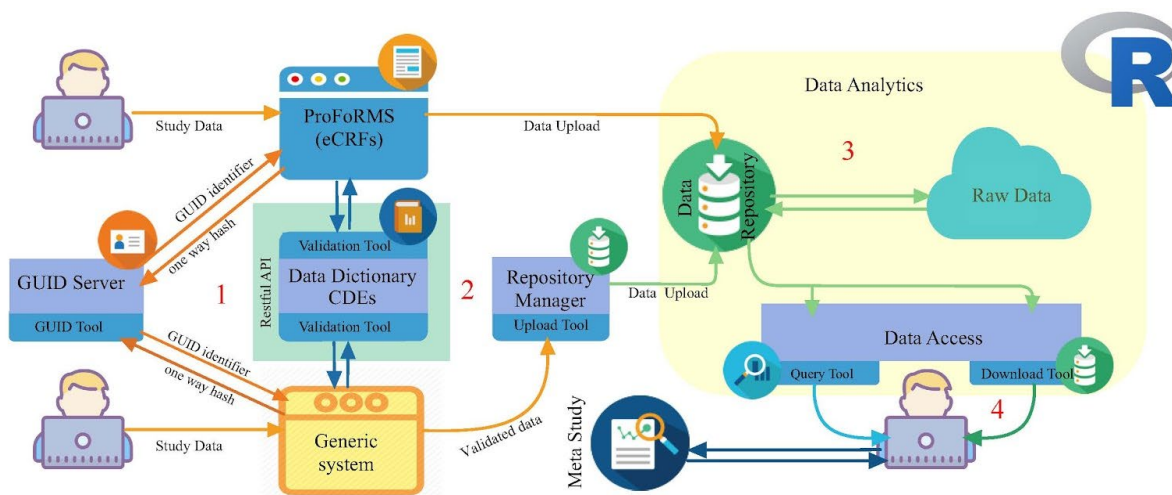


Figure 2 - Schematic representation of making data Findable (F), Accessible (A), Interoperable (I), and Reusable (R) by the deployment of BRICS modules. Data lifecycle is indicated by 1- preparation of Submission Information Packages (SIPs), 2 - development of Archival Information Packages (AIPs), 3 - storage of AIPs, and 4 - access to Dissemination Information Packages (DIPs).

5.2 Data Submission and Processing

User support is provided for data stewardship activities that include training and assistance to authorized users, for CDE implementation, data validation and submission to the repositories. Access is controlled by a Data Access Committee (DAC) that reviews studies for relevance to a BRICS instance. In addition, access to the system is role based and specific permissions are associated with roles such as PI, data manager, and data submitter.

Researchers are responsible for most of the data submission activities, which includes study FS approval, eForms review, curation, mapping of data elements, and providing associated study documentation. Data curation is carried out by identifying the available standard forms and CDEs in the Data Dictionary. In the event no corresponding CDEs are available, then the user can define the data elements and obtain approval during the submission process.

There are two routes of data submission:

- a) One approach uses the ProFoRMS tool (Figure 2, stage 1) for clinical data acquisition that supports scheduling subject visits, collecting data, adding new data, modifying previously collected data entries, and correcting discrepancies that are tracked and maintained in audit logs (in compliance with 21 CFR Part 11).

- b) The other data submission mode uses a generic data collection system (e.g. RedCap), where output is uploaded into the repository module (Figure 2, stage 2).

Both routes of data submission validate the submitted data using specific data dictionaries for a BRICS instance.

The Validation Tool supports the data repository and ProFoRMs modules, by using common data elements with defined range and value metrics for data quality checks, to make data reusable (**R**). Once the data has been validated and uploaded via the submission upload tool, data is stored in its raw form within the repository module in a database that can be accessed by the Query Tool (Figure 2, stage 3).

5.3 Data Storage and Management

The data Repository module for the various BRICS instances serves as a central hub, providing functionality for defining and managing study information and storing the research data associated with each study (Figure 2, stage 3). When an investigator is authorized to submit data to a BRICS instance, they can organize one or many datasets into a single entity called a Study. In general terms, a 'Study' is a container for the data to be submitted, allowing an investigator to describe, in detail, any data collected, and the methods used to collect the data, which makes data accessible (**A**). In addition, the repository module provides download statistics for specific studies, enabling the investigator to obtain information on their respective data that has been downloaded for other research activities, and overall increase data sharing and collaboration for additional research goals. Depending on the research studies, BRICS based repositories can host high throughput gene expression, RNA-Seq, SNPs, and sequence variation data sets (Figure 2, stage 3).

Through the Repository user interface, researchers can generate Digital Object Identifiers (DOIs) that can be referenced in research articles. BRICS mints its DOIs through the Interagency Data ID Service (IAD), which is operated by the U.S. Department of Energy Office of Scientific and Technical Information (OSTI). The IAD service acts as a bridge to DataCite, which is one of the major registries of DOIs.

5.4 Data Sharing

There are two sharing options – private and shared. By default, the system assigns the sharing preference as 'private' where only users to that specific study can access the data. When the data is in the private state, the PI has the option to share data with specific collaborators (preferential sharing). After a certain period (defined by the data sharing policy for each BRICS instance), the data enters a new 'shared' state, which is accessible (**A**) to the approved users.

Raw data is available for querying within 24 hours of data submission. For the data to be available via the Query Tool module, the raw data is processed through the 'MIRTH' tool (integrated interface engine) and Resource Description Framework (RDF) data

interchange tool (Figure 2, stage 4). Shared data is available to all system users (approved by DAC) to search, filter, and download via the Query Tool functionality. The Query Tool offers three types of functionalities - (a) querying and filtering data, (b) data package downloads based on query, and (c) data package to the Meta Study module.

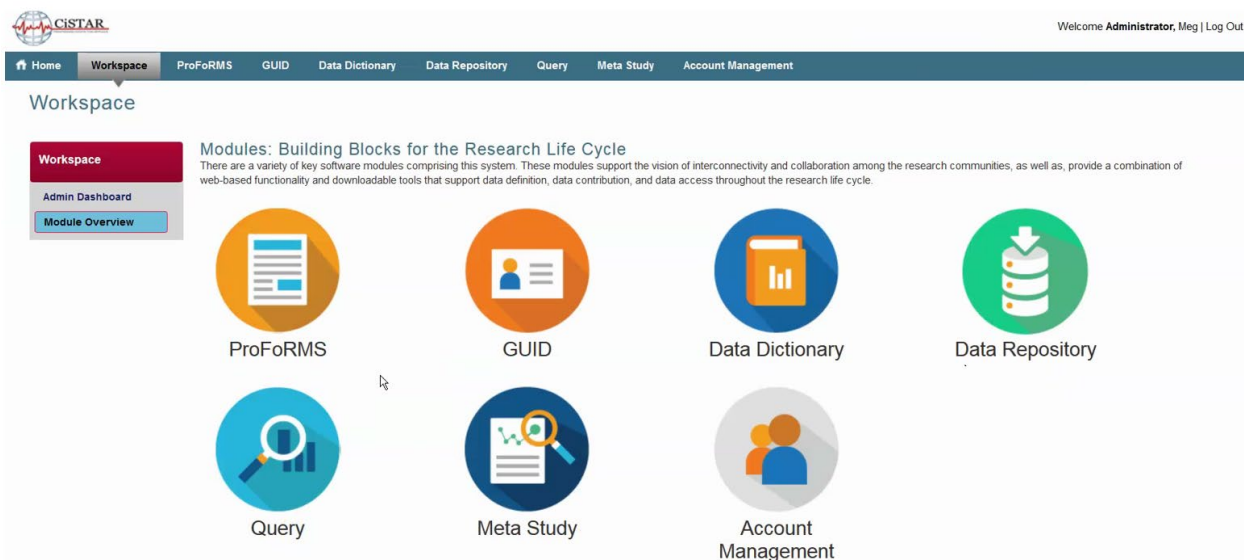
The Meta Study module is used for meta-analysis of the data as well as a collaboration tool between scientific groups. A Meta Study contains findings from studies that can be aggregated by researchers to conduct additional analysis. The Query tool can also support the statistical computing language R as well as structured visualization of data (Figure 2, stage 4).

5.5 Data Access

The Query Tool (QT) enables users to browse studies, forms and CDEs, to select clinical data, use filters, and to sort and combine records. Using the GUID and a standard vocabulary via CDEs in forms, the QT provides an efficient means to reuse data by searching through volumes of aggregated research data across studies, find the right datasets to download and perform offline analysis using additional tools (e.g. SAS, SPSS, etc.). The statistical 'R-box' tool, integrated with BRICS, has been incorporated in the QT, to support analysis without having to download data.

6. GUI Interface Design

All modules in the BRICS platform will have the similar graphical user interface to prove the users a consistent user experience across different modules of the system. Each user's name will be displayed on the top right corner of the banner after login. All the screen shots or mockups below represent one of the systems.



Data Repository is the central hub of the BRICS system, providing functionality for defining and managing study information, and for contributing, uploading, and storing the research data associated with each study.

View Studies

View Studies lists the studies that the user has permissions to view. The provided filters will allow users to filter the list by ownership, data submission status, and data type. The search capability allows users to search by Study Title, Study ID, Principle Investigator (PI), and by the Permission Type that the user holds for a particular study (Owner, Admin, Read, Write).

Results are shown in a tabular format to include the following:

Ownership: all | All studies | All data types | All Study Types | Search: []

TITLE	ORGANIZATION	STUDY ID	PI	DATA TYPES	PERMISSION	FUNDING SOURCE	SHARED DATA
CISTAR Proform Testing Protocol	CNRM	CISTAR-STUDY0000208	Jane Doe	🔍📄	Owner	CNRM	N
CNRM Demo	Henry M Jackson Foundation	CISTAR-STUDY0000206	Megdelawit Mersha	🔍📄	Owner	CNRM	N
CNRM Test Protocol - BK	CNRM	CISTAR-STUDY0000209	Bahar Kost	🔍📄	Owner	CNRM	N
Effect of Traumatic Brain Injury on Service Members - 10-N-2001	NIH	CISTAR-STUDY0000211	John Peterson	🔍📄	Owner	NIH	N
Effects of holding two tremulous hands on the tremor in ET patients - IK1	NINDS	CISTAR-STUDY0000204	Dietrich Haubenberger	🔍📄	Owner	NIH-NINDS	N
Octanoic Acid in Patients with Parkinsonian Tremor a proof-of-concept study	NIH	CISTAR-STUDY0000210	Dietrich Haubenberger	🔍📄	Owner	NIH	N
Test Study	CNRM	CISTAR-STUDY0000207	Test PI	🔍📄	Owner	CNRM	N
werwer	wer	CISTAR-STUDY0000205	wer wer	🔍📄	Owner	NIH-NCI	N

Showing 1 to 8 of 8 entries | First Previous 1 Next Last

Researchers can define electronic case report forms, schedule and collect clinical data and then export, analyze, and report on the data using the ProFoRMS module.

ProFoRMS Home

ProFoRMS is a Web-based database application designed to help manage data collection. With ProFoRMS, you can: Manage Protocols, Manage Subjects, Collect Data, and view Report and Query. To start, please select from the buttons below to either create a new protocol or select from existing protocols.

Select a Protocol

Select a protocol to perform an action or create a new protocol.

View Audit | Delete | Create Protocol | Search: []

Protocol Number	Protocol Name	Study Type
<input type="checkbox"/> 10-N-2001	TBI and Service Members	Natural History
<input type="checkbox"/> 3456-98	Test Study 2	Other
<input type="checkbox"/> 99-M-12	Proform Module Testing	Natural History
<input type="checkbox"/> CISTAR-STUDY0000208	CNRM Test Protocol - BK	Natural History
<input type="checkbox"/> CISTAR_GENERIC_STUDY	CISTAR Generic Study	
<input type="checkbox"/> IK1-DEMO	IK1 - Demo	Epidemiology
<input type="checkbox"/> MASTER	master	Natural History
<input type="checkbox"/> OC1	Octanoic Acid	Clinical Trial
<input type="checkbox"/> TEST	test	Natural History

Showing 1 to 9 of 9 entries (0 row selected of 9) | First Previous 1 Next Last

ProFoRMS Dashboard 10-N-2001

ProFoRMS Home

Select A Protocol

Manage Subjects

Collect Data

Manage Protocol

Reports

Site Administration

View Messages and Subject Visits

[-] Messages
View messages or select a message to perform an action.

Delete Search:

Protocol Number	Alert Type	Comments	Date
No data available in table			

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

[-] Subject Visits

Select a date to view scheduled appointments

December 2018						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

Scheduled Appointments

Time	Subject GUID	Visit Type	Protocol Number
9:00 am	CISTARPH167YR7	Baseline	10-N-2001

ProFoRMS – Manage Protocol – Protocol Information

ProFoRMS Home

Manage Subjects

Collect Data

Manage Protocol

Protocol Information

Assign Roles

Create Visit Type

Manage Visit Types

E-Binder

Reports

Site Administration

[-] Data Repository Study
Please select a data repository study.

Search:

Study Title	Study ID	PI	Study Permission
<input type="radio"/> CISTAR Proform Testing Protocol	CISTAR-STUDY0000208	Jane Doe	Admin
<input type="radio"/> CNRM Demo	CISTAR-STUDY0000206	Megdelawit Mersha	Admin
<input type="radio"/> CNRM Test Protocol - BK	CISTAR-STUDY0000209	Bahar Kost	Admin
<input checked="" type="radio"/> Effect of Traumatic Brain Injury on Service Members (10-N-2001)	CISTAR-STUDY0000211	John Peterson	Admin
<input type="radio"/> Effects of holding two tremulous hands on the tremor in ET patients - IK1	CISTAR-STUDY0000204	Dietrich Haubenberger	Admin
<input type="radio"/> Octanoic Acid in Patients with Parkinsonian Tremor a proof-of-concept study	CISTAR-STUDY0000210	Dietrich Haubenberger	Admin
<input type="radio"/> Test Study	CISTAR-STUDY0000207	Test PI	Admin
<input type="radio"/> werwer	CISTAR-STUDY0000205	wer wer	Admin

Showing 1 to 8 of 8 entries (1 row selected of 8) First Previous 1 Next Last

[-] Protocol Details
Enter the protocol information and click on "Save" to save the protocol.

* This symbol indicates a required field.

Protocol Name*

Protocol Number*

Principal Investigator(s)*

Study Type*

Subject Label* Subject GUID Subject ID MRN

Use E Regulatory Binder No Yes

Enable E-Signature No Yes

ProFoRMS – Manage Protocol – Assign Roles

The user roles depending on the study setup can be as follows: Principal Investigator, Associate Investigator, Clinical Research Associate, Research Associate, Data Entry, Data Manager, etc.

Welcome Administrator, Meg | Log Out

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

Dashboard 10-N-2001

ProFoRMS Home

Assign users to roles

Search:

Username	Name	Role
administrator	Admin, Portal	--
test_admin	Admin, QA	--
sahmed1	Admin, Sikandar	Associate Investigator Clinical Research Associate Data Entry
testadmin	Admin, Test	Data Manager Principal Investigator Research Associate
ahmadof	Ahmad, Omar	--
Battlem	Battle, Melonise	--
yang.fann	Fann, Yang	--
afontana	Fontana, Anthony	--
tgebre	GM, Tsega	--
tgebre_nonadmin	GM, Tsega2	--
Dietrich_123	Haubenberger, Dietrich	--

ProFoRMS – Site Administration – Roles & Privileges

Welcome Administrator, Meg | Log Out

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

Dashboard 10-N-2001

ProFoRMS Home

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

System Roles

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

Add Role Edit Role

Search:

System Role	Role Description
<input type="checkbox"/> Associate Investigator	Same as PI, except AI cannot add/initiate a study.
<input type="checkbox"/> Clinical Research Associate	Can view anything but not allowed to change except adding QA Monitor query
<input type="checkbox"/> Data Entry	Users with this role can view forms and collect data
<input type="checkbox"/> Data Manager	
<input type="checkbox"/> Principal Investigator	PI can add and edit studies, forms, subjects and collect data.
<input type="checkbox"/> Research Associate	RA can view studies, create forms, create visit types, schedule visits and collect data.

Showing 1 to 6 of 6 entries (0 row selected of 6)

First Previous 1 Next Last

ProFoRMS | Dashboard | 10-N-2001

Please enter information to add new role.
* This symbol indicates a required field

Role Name*
(Format: letters, numbers, and spaces only)

Role Description

Privileges*
(Check/Uncheck All)

<input type="checkbox"/> Edit Studies	<input type="checkbox"/> View Studies
<input type="checkbox"/> Assign Users to Study	<input type="checkbox"/> Add/Edit Visit Types
<input type="checkbox"/> View Visit Types	<input type="checkbox"/> Add/Edit Publications
<input type="checkbox"/> Add/Edit Forms	<input type="checkbox"/> View Forms
<input type="checkbox"/> Add/Edit Questions	<input type="checkbox"/> View Questions
<input type="checkbox"/> Manage Event Forms	<input type="checkbox"/> Import/Export Forms
<input type="checkbox"/> Data Entry	<input type="checkbox"/> Edit Answer

ProFoRMS – Manage Protocol – Manage Visit Types

Researchers can add and edit study information, schedule and create study visits, manage visit types for individual subject across multiple studies within the system, and upload subject related documents.

ProFoRMS | Dashboard | 10-N-2001

My Visit Types
Select a visit type to view or perform an action.

Search:

<input type="checkbox"/>	Visit Type Name	Type	Category	Description	#Forms Included
<input type="checkbox"/>	1-Year	Scheduled		1 year since baseline. Self Reporting	SWLS_1
<input type="checkbox"/>	180-days	Scheduled		180-days since baseline	PriorAndConcomitantMeds_8 and BSI18
<input type="checkbox"/>	30-days	Scheduled		30 days since baseline visit	CSSRS, PriorAndConcomitantMeds_9, and PHQ8_1
<input type="checkbox"/>	Baseline	Scheduled		Initial Visit	FamilyHistory_7 and PCLC_Standard

Showing 1 to 4 of 4 entries (0 row selected of 4)

First Previous **1** Next Last

ProFoRMS – Manage Protocol – Create Visit Type



Welcome Administrator, Meg | Log Out

ProFoRMS

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

Dashboard 10-N-2001

ProFoRMS Home
Manage Subjects
Collect Data
Manage Protocol
Protocol Information
Assign Roles
Create Visit Type
Manage Visit Types
E-Binder
Reports
Site Administration

Create a new visit type, select a visit type to view or perform an action.
[+] Create Visit Type

* This symbol indicates a required field

Visit Type Name * 180-days
Visit Type Scheduled
Category
Description * 180-days since baseline

Self Reporting eForms * Available 15 days before the scheduled visit until 15 days after the scheduled visit.

Associate Published eForms:

eForm Name	eForm Short Name	Description	Required?	Self Reporting?
<input type="checkbox"/> Adverse Events	AdverseEvents_3	Adverse events (AEs) document medical events th ...	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Adverse Events	AdverseEvents_2	Adverse events (AEs) document medical events th ...	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Adverse Events	AdverseEvents_1	Adverse events (AEs) document medical events th ...	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Adverse Events	AdverseEvents_9	Adverse events (AEs) document medical events th ...	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Adverse Events	AdverseEvents_8	Adverse events (AEs) document medical events th ...	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input type="radio"/> No

ProFoRMS – Manage Protocol – E-Binder

ProFoRMS

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

Dashboard 10-N-2001

ProFoRMS Home
Manage Subjects
Collect Data
Manage Protocol
Protocol Information
Assign Roles
Create Visit Type
Manage Visit Types
E-Binder
Reports
Site Administration

New File New Folder Edit Delete Download

- Regulatory E-Binder
 - asdf
 - ad

ProFoRMS – Manage Subjects – Add Subject



Welcome Administrator, Meg | Log Out

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

Dashboard 10-11-2001

ProFoRMS

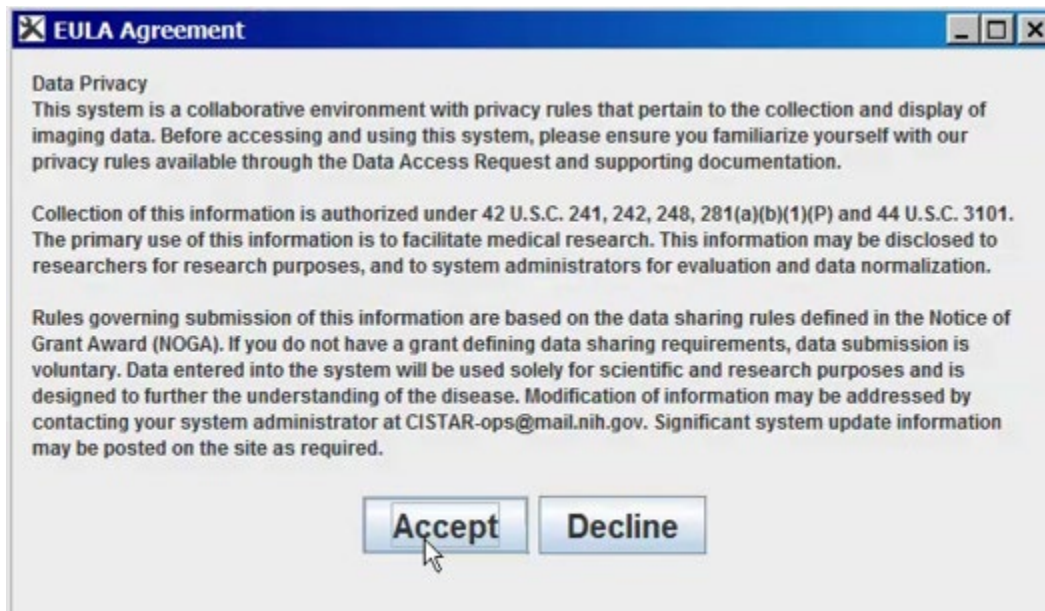
ProFoRMS Home

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"/>	Birth City	<input type="text"/>
Middle Name	<input type="text"/>	Birth Country	<input type="text" value="United States of America"/>
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" value="Alabama"/>
Mobile Phone	<input type="text"/>	Zip	<input type="text"/>
		Country	<input type="text" value="United States of America"/>

If the subject does not have a GUID or Pseudo-GUID created in the system, click on the "Create GUID" button below to launch the GUID Tool. The GUID Tool will allow you to enter the information necessary to generate a GUID or Pseudo-GUID for a subject. Once the GUID is generated, a pop-up will appear. The "Copy" button will copy the GUID to your clipboard so the generated ID can be pasted into the "GUID or Pseudo-GUID" text field in the Subject Information section. The "OK" button will exit the pop-up without saving the GUID to your clipboard; however, the generated ID can still be copied to your clipboard by clicking on the "Copy GUID" button on the GUID Tool.



ProFoRMS – Manage Subjects – My Subjects

The My Subjects page lists all subjects currently enrolled into the protocol. The user can sort the list of subjects by GUID, Last/First Name, Status, etc. by clicking on the column heading. This help the researchers to add and edit subject information, schedule subject visits, upload documents, and track across multiple studies.



Welcome Administrator, Meg | Log Out

ProFoRMS

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.

GUID	Last Name	First Name	Status	Validated	Protocol
<input type="checkbox"/> CISTARCR243ENZ	James	Martha	Active		10-N-2001
<input checked="" type="checkbox"/> CISTAREY302LUH	Belay	Hanna	Active		10-N-2001
<input type="checkbox"/> CISTARPH167YR7	Smith	Eric	Active		10-N-2001
<input type="checkbox"/> CISTARTP289EMD	Jerome	Kira	Active		10-N-2001

Showing 1 to 4 of 4 entries (1 row selected of 4)

First Previous 1 Next Last

ProFoRMS – Manage Subjects – Schedule Visit



Welcome Administrator, Meg | Log Out

ProFoRMS

View scheduled visits, add new visits or select a visit to perform an action.

* This symbol indicates a required field

GUID or Pseudo-GUID* CISTAREY302LUH

Date and Time* 2018-12-18 09:49

Visit Type December 2018

GUID	First Name	Visit Type	Date and Time	Self Reporting Token
<input type="checkbox"/> CISTAREY302LUH	Hanna	1-Year	2018-12-27 00:00	adtp3y5bv530zecr
<input type="checkbox"/> CISTAREY302LUH	Hanna	30-days	2018-12-17 21:11	
<input type="checkbox"/> CISTAREY302LUH	Hanna	Baseline	2018-12-15 14:03	

Showing 1 to 3 of 3 entries (0)

First Previous 1 Next Last

ProFoRMS – Collect Data – Data Collection

Clinical data may be captured electronically at its source, or in paper form and later transcribed into the system. Researchers can manage protocols, manage subjects, collect data, view Report and Query, perform quality assurance, monitor subject safety, and view audit logs to assure the changes are tracked in the system.



Welcome Administrator, Meg | Log Out

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

Dashboard 10-N-2001

ProFoRMS

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

View: **By Subject (GUID)**

[+] Advanced Search

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

<input type="checkbox"/>	Subject GUID	Subject Name	Visit Type	Visit Date
<input type="checkbox"/>	CISTARCR243ENZ	Martha James	Baseline	2018-12-17 16:20
<input type="checkbox"/>	CISTARCR243ENZ	Martha James	30-days	2019-01-14 00:00
<input type="checkbox"/>	CISTARCR243ENZ	Martha James	180-days	2019-04-14 12:00
<input type="checkbox"/>	CISTARCR243ENZ	Martha James	1-Year	2019-12-10 13:00
<input type="checkbox"/>	CISTAREY302LUH	Hanna Belay	Baseline	2018-12-15 14:03
<input type="checkbox"/>	CISTAREY302LUH	Hanna Belay	30-days	2018-12-17 21:11
<input type="checkbox"/>	CISTAREY302LUH	Hanna Belay	180-days	2018-12-18 09:49
<input type="checkbox"/>	CISTAREY302LUH	Hanna Belay	1-Year	2018-12-27 00:00
<input type="checkbox"/>	CISTARPH167YR7	Eric Smith	Baseline	2018-12-15 13:59
<input type="checkbox"/>	CISTARPH167YR7	Eric Smith	30-days	2018-12-16 16:01



Welcome Administrator, Meg | Log Out

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

Dashboard 10-N-2001

ProFoRMS

We recommend you exclusively use ProFoRMS navigation buttons and links within the Collect Data module. Leaving the form by any other method (Back/Forward buttons, backspace key, etc.) may result in data loss and unexpected errors.

[+] Data Collection

Please enter information to start data collection.

*This symbol indicates a required field

Subject GUID: CISTARTP289EMD

Visit Type*: Baseline

eForm Name*: - Please Select

Visit Date/Time*: 2018-12-17 16:20

Start Data Collection Cancel

ProFoRMS – Collect Data – My Collections

My Collections view will be displayed after entering data in the form and click the Save button.



Welcome Administrator, Meg | Log Out

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

Dashboard 10-N-2001

ProFoRMS

Search by Subject form or by non-subject form to begin collecting data

[+] Advanced Search

Data Collection

Select a form to view or perform an action

View Entry Edit View Audit Reassign Delete Entry Export Search:

<input type="checkbox"/>	Subject GUID	Visit Date	Visit Type	eForm Name	Short Name	Status	User	Lock Date
<input type="checkbox"/>	CISTARCR243ENZ	2018-12-10 12:00	Baseline	Demographics_10	Demographics_10	Locked	Mersha, MegM	2018-12-10 10:39
<input type="checkbox"/>	CISTARCR243ENZ	2018-12-10 12:00	Baseline	FamilyHistory_7	FamilyHistory_7	Locked	Mersha, MegM	2018-12-10 10:37
<input type="checkbox"/>	CISTARCR243ENZ	2018-12-10 12:00	Baseline	PCLC_Standard	PCLC_Standard	Locked	Mersha, MegM	2018-12-10 10:54
<input type="checkbox"/>	CISTARCR243ENZ	2018-12-16 16:04	30-days	CSSRS	CSSRS	In Progress	Mersha, Meg	
<input type="checkbox"/>	CISTARCR243ENZ	2018-12-16 16:04	30-days	PHQ8_1	PHQ8_1	Locked	Mersha, Meg	2018-12-16 16:08
<input type="checkbox"/>	CISTAREY302LUH	2018-12-15 14:03	Baseline	FamilyHistory_7	FamilyHistory_7	In Progress	Mersha, Meg	
<input type="checkbox"/>	CISTAREY302LUH	2018-12-15 14:03	Baseline	PCLC_Standard	PCLC_Standard	Locked	Mersha, Meg	2018-12-15 14:09
<input checked="" type="checkbox"/>	CISTARPH167YR7	2018-12-14 15:43	Baseline	PCLC_Standard	PCLC_Standard	In Progress	Mersha, Meg	
<input type="checkbox"/>	CISTARTP289EMD	2018-12-17 16:23	Baseline	FamilyHistory_7	FamilyHistory_7	In Progress	Mersha, Meg	
<input type="checkbox"/>	CISTARTP289EMD	2018-12-17 16:23	Baseline	PCLC_Standard	PCLC_Standard	Locked	Mersha, Meg	2018-12-17 16:30

Showing 1 to 10 of 10 entries (1 row selected of 10) First Previous 1 Next Last



Welcome Administrator, Meg | Log Out

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

Dashboard 10-N-2001

ProFoRMS

[+] Data Collection

Locked
 In Progress
 Completed
 Not Started*

Letter R inside circle means required form for that visit type

eForms For This Visit Type

- FamilyHistory_7
- PCLC_Standard

Posttraumatic Stress Disorder Checklist (PCL) Civilian Version

The Posttraumatic Stress Disorder Checklist (PCL) Civilian Version is a 17-item self-reported measure composed of the DSM-IV symptoms of Posttraumatic Stress Disorder (PTSD). Respondents rate on a five-point scale how much they were bothered by each symptom "in the past month." The PCL-C (Civilian) is not focused on any one traumatic event. For more information, refer to <http://www.ptsd.va.gov/professional/assessment/adult-sr/ptsd-checklist.asp>

Main

Global Unique ID (GUID) which uniquely identifies the subject: Subject ID number:

Subject's age (recorded in years):

Visit date:

Name of the site:

The number of days since baseline:

Is the subject in the case or control arm of the study?

Additional information (if any):

Questions

Repeated, disturbing memories, thoughts, or images of the stressful experience? 1-Not at all 2-A little bit

Forms will continue to show as “In Progress” until they are locked. Data should not be locked until reviewed and ready for final submission.

The screenshot shows a clinical form with several questions and radio button options. A pop-up window titled "Signature Required" is overlaid on the form. The pop-up contains a checkbox with the text "I hereby confirm that all data entry for this form is accurate and complete to the best of my knowledge." Below this is a password field with the label "Enter your password to complete the form." and "Password: [masked]". At the bottom of the pop-up are "OK" and "Cancel" buttons. The background form includes questions like "Trouble falling or staying asleep?", "Feeling irritable or having angry outbursts?", and "Having... Being... Feeling...". At the bottom of the form, there is a checkbox labeled "Mark As Completed and Enable Locking for Submission" and buttons for "Save", "Save & Exit", "Save & Lock", and "Cancel". A total score of 16 is displayed at the bottom of the form.

Once all of the required questions have been completed, and “Mark as Completed and Enable Locking for Submission” checkbox is checked, a pop-up will be display and asking for the user’s electronic signature if the e-signature is enabled in the protocol information section.

The screenshot shows a "Collect Data Lock Confirmation" pop-up window. The window contains the following information: "Protocol Name: TBI and Service Members", "eForm Name: Posttraumatic Stress Disorder Checklist (PCL) Civilian Version", "Subject GUID: CISTARPH167YR7", "Visit Date: 2018-12-14 15:43", "Visit Type: Baseline", and "Data Entered By: Mersham". Below this information is a checkbox with the text "I hereby confirm that all data entry for this form is accurate and complete to the best of my knowledge." At the bottom of the pop-up are "View Completed Form", "Lock & Exit", and "Cancel" buttons. The background shows the bottom of the clinical form with the "Mark As Completed and Enable Locking for Submission" checkbox checked and the "Save & Lock" button highlighted. The footer of the page includes the NIH logo and "USA.gov" link.

A “Collection Data Lock Confirmation” pop-up window will appear once the form is locked. User will need to select the validation checkbox and click on “Lock & Exit” button.



Welcome Administrator, Meg | Log Out

ProFoRMS Dashboard 10-N-2001

The administered form Posttraumatic Stress Disorder Checklist (PCL) Civilian Version has been Locked successfully

Search by Subject form or by non-subject form to begin collecting data

[+] Advanced Search

Data Collection

Select a form to view or perform an action

View Entry Edit View Audit Reassign Delete Entry Export

Subject GUID	Visit Date	Visit Type	eForm Name	Short Name	Status	User	Lock Date
<input type="checkbox"/> CISTARCR243ENZ	2018-12-10 12:00	Baseline	Demographics_10	Demographics_10	Locked	Mersha, MegM	2018-12-10 10:39
<input type="checkbox"/> CISTARCR243ENZ	2018-12-10 12:00	Baseline	FamilyHistory_7	FamilyHistory_7	Locked	Mersha, MegM	2018-12-10 10:37
<input type="checkbox"/> CISTARCR243ENZ	2018-12-10 12:00	Baseline	PCLC_Standard	PCLC_Standard	Locked	Mersha, MegM	2018-12-10 10:54
<input type="checkbox"/> CISTARCR243ENZ	2018-12-16 16:04	30-days	CSSRS	CSSRS	In Progress	Mersha, Meg	
<input type="checkbox"/> CISTARCR243ENZ	2018-12-16 16:04	30-days	PHQ8_1	PHQ8_1	Locked	Mersha, Meg	2018-12-16 16:08
<input type="checkbox"/> CISTAREY302LUH	2018-12-15 14:03	Baseline	FamilyHistory_7	FamilyHistory_7	In Progress	Mersha, Meg	
<input type="checkbox"/> CISTAREY302LUH	2018-12-15 14:03	Baseline	PCLC_Standard	PCLC_Standard	Locked	Mersha, Meg	2018-12-15 14:09
<input type="checkbox"/> CISTARPH167YR7	2018-12-14 15:43	Baseline	PCLC_Standard	PCLC_Standard	Locked	Mersha, Meg	2018-12-18 09:58
<input type="checkbox"/> CISTARTP289EMD	2018-12-17 16:23	Baseline	FamilyHistory_7	FamilyHistory_7	In Progress	Mersha, Meg	
<input type="checkbox"/> CISTARTP289EMD	2018-12-17 16:23	Baseline	PCLC_Standard	PCLC_Standard	Locked	Mersha, Meg	2018-12-17 16:30

Reason for Change

Question Text: Repeated, disturbing dreams of the stn

Original Entry 1: 4-Quite a bit

Final Answer: 1-Not at all

Reason for Change*

OK

Legend: Locked (Green), In Progress (Red), Completed (Yellow), Not Started (Grey)

Letter R inside circle means required form for that visit type

Disorder (PTSD) tic event. For more

is the subject in the case or control arm of the study?

Additional information (if any):

Data Collection Audit Log

eForm Name: Posttraumatic Stress Disorder Checklist (PCL) Civilian Version
 Protocol Name: TBI and Service Members
 Subject GUID: CISTARTP289EMD
 Visit Date: 2018-12-17 16:23
 Visit Type: Baseline
 Data Entered By: Mersham

Original Entry 1

Username	Start Date/Time	Action	# of Questions Completed
Mersham	2018-12-17 16:24	Started	-
Mersham	2018-12-17 16:29	Completed	5
Mersham	2018-12-17 16:30	Locked	5

Showing 1 to 3 of 3 entries

Locked

Username	Date/Time
Mersham	2018-12-17 16:30

Showing 1 to 1 of 1 entries

Edit Answer

Search:

Username	Start Date/Time	Section Name	Data Element Name	Question Text	Answers After	Data Element Name	Reason for Change
Mersham	2018-12-17 16:31	Questions	PCLSMemorieshd	Repeated, disturbing memories, thoughts, or images of the stressful experience?	null	3-Moderately	Making updates
Mersham	2018-12-18 09:59	Questions	PCLSDreamshd	Repeated, disturbing dreams of the stressful experience?	4-Quite a bit	1-Not at all	correction

Showing 1 to 2 of 2 entries

First Previous **1** Next Last

Sent Emails


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

ProFoRMS – Reports – Protocol Report



Welcome Administrator, Meg | Log Out

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

Dashboard 10-N-2001

ProFoRMS

This report will show the protocol by Name, Principal Investigator, protocol type, status, number of subjects enrolled, and number of administered forms of each protocol.

Download

Protocol Name	Principal Investigator	Protocol Type	# of Subjects Enrolled	# of Administered Forms
TBI and Service Members	John Peterson	Natural History	4	10

Showing 1 to 1 of 1 entries

First Previous **1** Next Last

- ProFoRMS Home
- Manage Subjects
- Collect Data
- Manage Protocol
- Reports**
 - Protocol Report**
 - Without Collections
 - Forms Requiring Completion & Lock
 - Locked Forms
 - Submission Summary
 - Form Status
- Site Administration

ProFoRMS – Reports – Form Status



Welcome Administrator, Meg | Log Out

ProFoRMS Dashboard 10-N-2001

ProFoRMS Home Manage Subjects Collect Data Manage Protocol Reports Protocol Report Without Collections Forms Requiring Completion & Lock Locked Forms Submission Summary Form Status Site Administration

This report shows the completion status of forms by Subject Label for each visit type. To use this report please select a value from drop down or start typing to autofill result.
 GUID or Pseudo-GUID: CISTARPH167YR7 Submit

Legend: ● Locked ● In Progress ● Completed ○ Not Started
 - = Not Administered(or form not in visit type)
 * Letter R inside circle means required form for that visit type

FormName/VisitType	180-days	1-Year	30-days	Baseline
BSI18	○	-	-	-
CSSRS	-	-	○	-
FamilyHistory_7	-	-	-	○
PCLC_Standard	-	-	-	●
PHQ8_1	-	-	○	-
PriorAndConcomitantMeds_8	○	-	-	-
PriorAndConcomitantMeds_9	-	-	○	-
SWLS_1	-	○	-	-

Showing 1 to 8 of 8 entries

Data Collections Export

ProFoRMS Dashboard 10-N-2001

ProFoRMS Home Manage Subjects Collect Data Data Collection My Collections Manage Protocol Reports Site Administration

Search by Subject form or by non-subject form to begin collecting data
 [*] Advanced Search

Data Collection

Select a form to view or perform an action
 View Entry Edit View Audit Reassign Delete Entry

You can not export collections for different forms

OK

Subject GUID	Visit Date	Name	Status	User	Lock Date
<input checked="" type="checkbox"/> CISTARTP289EMD	2018-12-17 16:23	FamilyHistory_7	In Progress	Mersha, Meg	
<input checked="" type="checkbox"/> CISTARTP289EMD	2018-12-17 16:23	PCLC_Standard	Locked	Mersha, Meg	2018-12-17 16:30
<input checked="" type="checkbox"/> CISTARPH167YR7	2018-12-14 15:43	PCLC_Standard	Locked	Mersha, Meg	2018-12-18 09:58
<input type="checkbox"/> CISTAREY302LUH	2018-12-15 14:03	Baseline FamilyHistory_7	In Progress	Mersha, Meg	
<input type="checkbox"/> CISTAREY302LUH	2018-12-15 14:03	Baseline PCLC_Standard	Locked	Mersha, Meg	2018-12-15 14:09
<input type="checkbox"/> CISTARCR243ENZ	2018-12-10 12:00	Baseline Demographics_10	Locked	Mersha, MegM	2018-12-10 10:39
<input type="checkbox"/> CISTARCR243ENZ	2018-12-10 12:00	Baseline FamilyHistory_7	Locked	Mersha, MegM	2018-12-10 10:37
<input type="checkbox"/> CISTARCR243ENZ	2018-12-10 12:00	Baseline PCLC_Standard	Locked	Mersha, MegM	2018-12-10 10:54
<input type="checkbox"/> CISTARCR243ENZ	2018-12-16 16:04	30-days CSSRS	In Progress	Mersha, Meg	
<input type="checkbox"/> CISTARCR243ENZ	2018-12-16 16:04	30-days PHQ8_1	Locked	Mersha, Meg	2018-12-16 16:08

Showing 1 to 10 of 10 entries (3 rows selected of 10)



Welcome Administrator, Meg | Log Out

ProFoRMS

Search by Subject form or by non-subject form to begin collecting data

[*] Advanced Search

Data Collection

Select a form to view or perform an action

View Entry Edit View Audit Reassign Delete Entry Export

<input type="checkbox"/>	Subject GUID	Visit Date	Visit Type	eForm Name	Lock Date
<input type="checkbox"/>	CISTARTP289EMD	2018-12-17 16:23	Baseline	FamilyHisto	
<input checked="" type="checkbox"/>	CISTARTP289EMD	2018-12-17 16:23	Baseline	PCLC_Stand	2018-12-17 16:30
<input checked="" type="checkbox"/>	CISTARPH167YR7	2018-12-14 15:43	Baseline	PCLC_Standard	2018-12-18 09:58
<input type="checkbox"/>	CISTAREY302LUH	2018-12-15 14:03	Baseline	FamilyHistory_7	
<input type="checkbox"/>	CISTAREY302LUH	2018-12-15 14:03	Baseline	PCLC_Standard	2018-12-15 14:09
<input type="checkbox"/>	CISTARCR243ENZ	2018-12-10 12:00	Baseline	Demographics_10	2018-12-10 10:39
<input type="checkbox"/>	CISTARCR243ENZ	2018-12-10 12:00	Baseline	FamilyHistory_7	2018-12-10 10:37
<input type="checkbox"/>	CISTARCR243ENZ	2018-12-10 12:00	Baseline	PCLC_Standard	2018-12-10 10:54
<input type="checkbox"/>	CISTARCR243ENZ	2018-12-16 16:04	30-days	CSSRS	
<input type="checkbox"/>	CISTARCR243ENZ	2018-12-16 16:04	30-days	PHQ8_1	2018-12-16 16:08

Showing 1 to 10 of 10 entries (2 rows selected of 10)

First Previous 1 Next Last

Opening exportCollections_PosttraumaticStressDisorderChecklist(P...
You have chosen to open:
...erChecklist(PCL)CivilianVersion_2018-12-18_10.03.26.csv
which is: Chrome HTML Document
from: https://cistar-demo.ninds.nih.gov
What should Firefox do with this file?
 Open with Google Chrome (default)
 Save File
 Do this automatically for files like this from now on.
OK Cancel

The Data Dictionary provides functionality for creating, managing, and searching data dictionary components (data elements and form structures), as well as services for validating research data against the standardized common data elements (CDEs).

CiSTAR

Welcome Administrator, Meg | Log Out

Home Workspace ProFoRMS GUID Data Dictionary Data Repository Query Meta Study Account Management

Search Form Structures

Whole Word or Phrase

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

Narrow your search

CLEAR FILTERS RESTORE DEFAULT

Ownership
All
Mine

CiSTAR
All
Program Specific

Form Types
 Clinical Assessment
 Omics
 Imaging
 Preclinical

Standardization
 Standard NINDS CDE
 Standard
 Standard Modified
 Appendix
 Unique

Status
 Draft
 Awaiting Publication

Show 25 entries

Title	Short Name	Status	Modified Date
12-Item Short Form Health Survey Version 2 (SF-12v2)	SF12	Published	2016-11-22
36-Item Short Form Health Survey (SF-36) version 1	SF_36_FITBIR_V1	Published	2017-01-11
36-Item Short Form Health Survey (SF-36) version 2	SF36v2	Published	2017-08-18
Activities Specific Balance Confidence Scale (ABC-Scale)	ABCScale_FITBIR	Published	2017-06-26
Alcohol Use Disorders Identification Test - Consumption Questions (AUDIT-C)	AUDITC	Published	2016-06-01
Alcohol Use Disorders Identification Test - Self-Report Version (AUDIT)	AUDIT_FITBIR	Published	2016-06-22
Alcohol, Smoking, and Substance Use Involvement Screening Test (ASSIST)	ASSIST_FITBIR	Published	2015-07-22
ANAM Code Substitution Delayed	ANAMCodeSubDelayed	Published	2015-03-27
ANAM Code Substitution Learning	ANAMCodeSubLearning	Published	2015-03-27
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 Simple Reaction Time	ANAMSimpleReactTime	Published	2015-03-31
ANAM Simple Reaction Time 2nd Administration	ANAMSimpleReactTime2nd	Published	2015-03-31
Auditory Consonant Trigrams	ACT	Published	2015-12-23

Showing 1 to 25 of 332 entries

The screenshot shows the CISTAR Data Dictionary interface. The top navigation bar includes Home, Workspace, ProFoRMS, GUID, Data Dictionary, Data Repository, Query, Meta Study, and Account Management. The main content area displays details for the '12-Item Short Form Health Survey Version 2 (SF-12v2)'. A left sidebar menu is open, showing options like 'Data Dictionary Tool', 'Form Structures', 'Data Elements', 'eForms', and 'Data Dictionary Administration'. The main content area includes a search bar, a description of the form, and a right-hand panel with actions like 'Edit', 'Create Draft Copy', and 'Data Element Report'. Below the description, there are fields for 'Publication Date: 2016-03-31', 'Version: 1.3', 'Date Created: 2016-03-29', 'Created By: Vovk, Olga', 'Owner:', and 'Number of Data Elements: 25'.

Account Management

The Account Management module is for creating, approving, and managing user accounts, including management of access controls, roles, permissions groups, and authorization to other BRICS modules.

The screenshot shows the FITBIR Account Management interface. The top navigation bar includes Home, Workspace, ProFoRMS, GUID, Data Dictionary, Data Repository, Query, Meta Study, Account Management, and Reporting. The main content area displays the 'User Log' section. A left sidebar menu is open, showing options like 'Account Management', 'Account Admin', 'Account List', 'Account Group List', 'User Log', 'Create User', 'Create Account Group', 'Create/Edit Account', 'Guidance Emails', 'Account Reviewer', and 'Biosample Orders'. The 'User Log' section includes a search bar with 'Status' dropdown, 'start date', and 'end date' fields. Below the search bar is a table with columns: USERNAME, FULL NAME, E-MAIL, SESSION STATUS, TIME LOG IN, and TIME LOG OUT.

7. Records Management

All data and/or records generated during this procedure are stored in the NINDS SharePoint-based Document Library.

8. Review/Revision History

Date	Author	Description of Change
03/09/2019	Gladys Wang	Document Creation

Appendix A. RTM

The table below depicts traceability from the requirements and design of the major components for each of the modules within the system. Please refer to the Requirements Traceability Matrix (RTM) in the System Requirements Specification (SRS) to identify the allocation of the functional requirements into this design document.

Key	Requirement	Design	Reference								
PS-4420	Remove/hide the 'Biorepository Subject ID' field and user inputs in ProFoRMS	PS-4422									
PS-4378	"See also" - need to increase the size of the field in the database and the text box that displayed in DD	PS-4403									
PS-4331	Add to GUID tool Country of Birth	PS-4383									
PS-4268	As user, system should let me refresh my session in Data Dictionary	PS-4282	PS-4312								
PS-4267	As an Operation User, data error report email should be get updated with no of request for archived, deleted data set and requested study.	PS-4275	PS-4276	PS-4309							
PS-4266	As a user, system should allow me to change subject label GUID to Subject ID or vice versa in Manage Protocol Section of ProForms	PS-4273	PS-4311	PS-4424	PS-4425						
PS-4135	As a admin user, I need my previous admin noted migrated into the new admin note functionality box.	PS-4147									
PS-4031	As cdRNS user, I should able to see cdNRS specific Form Structures	PS-4067									
PS-4028	As FITBIR Public site data dictionary - default DE view to Awaiting Publication and Published DEs	PS-4162	PS-4163								
PS-4027	As a user, I should know which environment my email came from	PS-4171	PS-4207								
PS-3830	Data Repository - Research Management Table Sort Recommendation	PS-4146									
PS-3827	As a Account Admin/Reviewer, I should able to identify user, whose privileges been expired.	PS-3891	PS-4264	PS-4310							
PS-3821	As a user, I should see consistent in data set statuses across table	PS-4183	PS-4206	PS-4221							

PS-3659	Supporting Documentation The "File" field information appears under the Column Name.	PS-4176	PS-4177	PS-4181						
PS-3441	As a user, I want files I'm attempting to upload to be maintained when there is a validation error in related fields when trying to upload the file (PF, Act, DD)	PS-3444	PS-3445	PS-3446	PS-4160	PS-4161				
PS-3309	As a user, I should have the Ability to make an optional/recommended question required on the eform level	PS-3996								
PS-3226	As an admin or end user, I want the data dictionary search to support special characters *,? and "" in order to increase the likelihood of returning a result the user is searching for.	PS-4164	PS-4165	PS-4166	PS-4167					
PS-3214	Implementation of converting byte array to hex is flawed	PS-4218								
CRIT-9581	As a developer, I should be able to migrate GUID information from one MongoDB instance to another	CRIT-9582								
CRIT-9549	As a user, I should be able to generate GUIDs in a batch process	CRIT-9737	CRIT-9738	CRIT-9739	CRIT-9740	CRIT-9741				
CRIT-9535	As a user, my PII should be sent to the server as a Hashcode	CRIT-9536								
CRIT-9534	As a user, I should be able to interface with the GUID server	CRIT-9546	CRIT-9547							
CRIT-9533	As a user, I should be able to see the interface of the GUID client	CRIT-9539	CRIT-9540	CRIT-9580						
CRIT-9532	As a user, I should not be able to enter invalid PII	CRIT-9673	CRIT-9674	CRIT-9675	CRIT-9677					
CRIT-9531	As a user, I should be able to validate that a GUID exists	CRIT-9564	CRIT-9565							
CRIT-9530	As a user, I should be able to convert a pseudoGUID to a GUID	CRIT-9560	CRIT-9561	CRIT-9562	CRIT-9563					
CRIT-9520	For large result sets in QT, adding to download queue crashes the server	CRIT-9521	CRIT-9522	CRIT-9595	CRIT-9623					
CRIT-9356	NINDS/NIA/GRDR Code Merge	CRIT-9357	CRIT-9358	CRIT-9359	CRIT-9383	CRIT-9394	CRIT-9396	CRIT-9397	CRIT-9508	CRIT-9509
CRIT-9223	GUID Javascript Client Design	CRIT-9224	CRIT-9225							
CRIT-8571	Design Basic GUID JS Framework	CRIT-8572								
CRIT-7779	As a user, I should be able to access the GUID user guide	CRIT-9272	CRIT-9273							
CRIT-7655	As a user, I should be able to generate a GUID through the new JS Client	CRIT-7657	CRIT-9543	CRIT-9544	CRIT-9545	CRIT-9548	CRIT-9879			
CRIT-7613	As a NINDS user, I should be able to access legacy NINDS GUIDs	CRIT-7622	CRIT-7623	CRIT-7624	CRIT-7625	CRIT-7626	CRIT-7627			
CRIT-7612	As an NIA user, I should be able to access legacy NIA GUIDs	CRIT-7616	CRIT-7617	CRIT-7618	CRIT-7619	CRIT-7620	CRIT-7621			