

NINDS Parkinson's Disease Biomarkers Program Data Management Resource

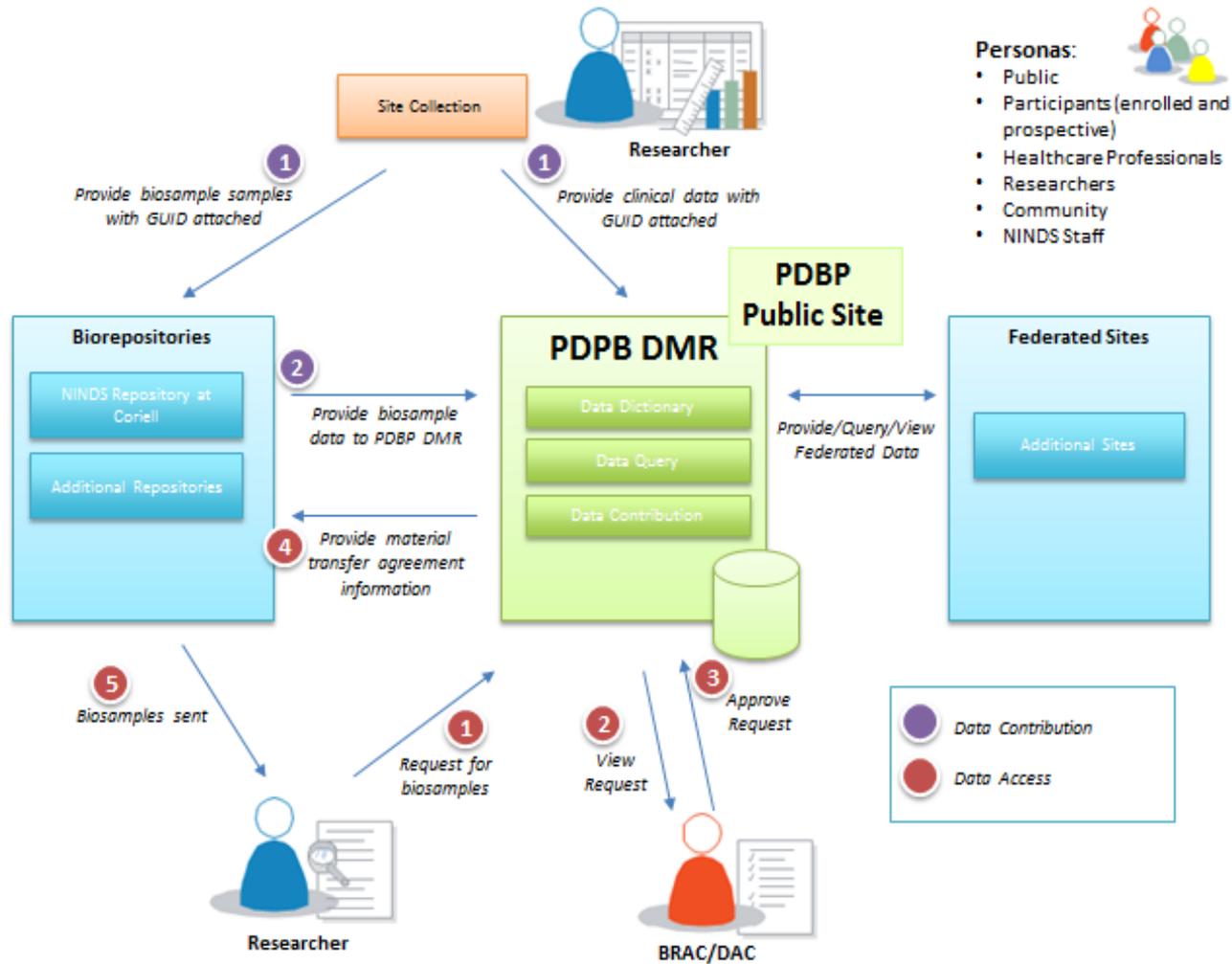
May 2013



Agenda

-  Overview
-  ProFoRMS High Level Process Flow
-  ProFoRMS Demonstration
-  Reporting
-  Roles and Privileges
-  Demo environment
-  Next Steps
-  Contacts
-  Questions

Overview

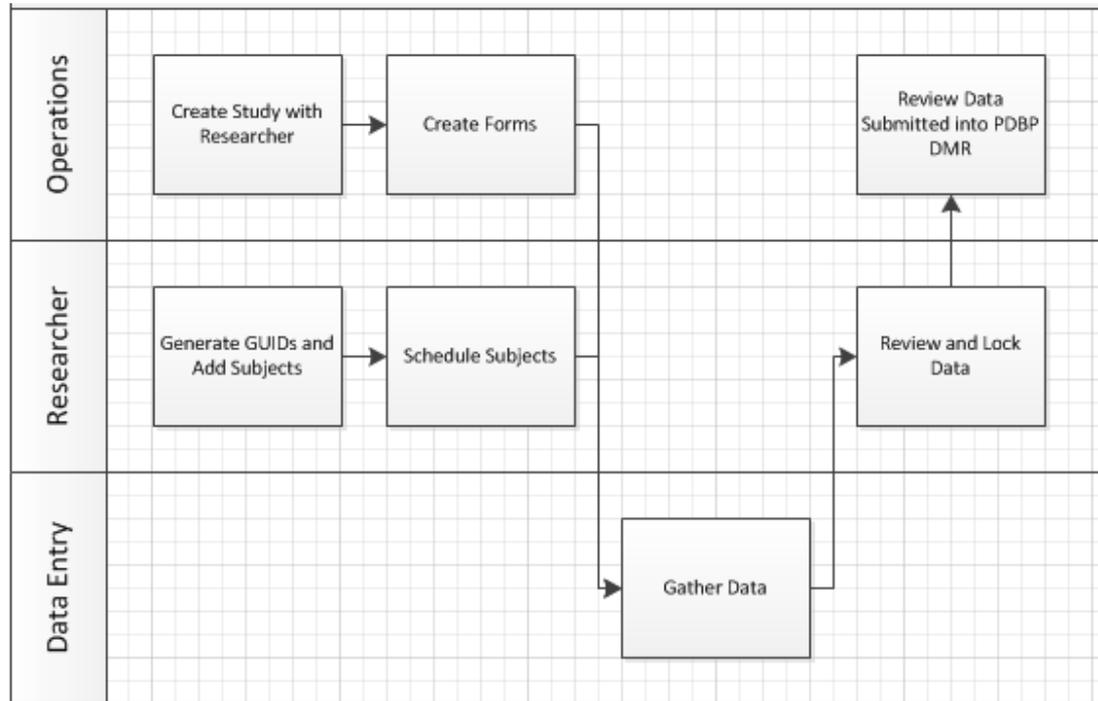


Overview

The system consists of a collection of modular components that can be used as stand-alone modules or in-conjunction with the other functional modules. The modules consist of the following:

-  **Protocol and Forms Research Management System (ProFoRMS)**: Manage studies, manage subjects, manage forms, collect data.
-  **Account Management**: Manage your user profile and password.
-  **Global Unique Identifier (GUID)**: Enables data to be associated with a subject without exposing/transferring Personally Identifying Information (PII).
-  **Data Dictionary**: Provides common definitions (NINDS common and unique data elements) to enable data to be consistently captured and recorded across PDBP studies.
-  **Data Repository**: Long-term repository for PDBP data.

ProFoRMS High Level Process Flow



- 🌱 IRB-approved studies created in ProFoRMS by Operations Team
- 🌱 Submission to long-term repository will begin in the summertime

ProFoRMS Demonstration

-  Requesting permission to ProFoRMS
-  Adding Subjects
 - Creating GUIDs within ProFoRMS
 - Validating GUIDs created in the GUID tool
-  Scheduling Visits
-  Collecting Data
-  Reviewing and Editing Data
-  What to do if you have a problem?

ProFoRMS Demonstration

Requesting permission to ProFoRMS

Adding Subjects

- Creating GUIDs within ProFoRMS
- Validating GUIDs created in the GUID tool

Scheduling Visits

Collecting Data

Reviewing and Editing Data

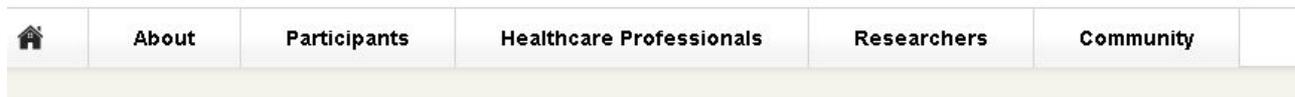
What to do if you have a problem?

Navigating to the PDBP DMR

- 🌸 Best experience is with latest [Firefox browser](#)
- 🌸 Java Runtime Environment (JRE) version 6 or higher is required (click [here](#) to check your version of Java)
- 🌸 Navigate to PDBP public website <http://pdbp.ninds.nih.gov>
 - Click on the red Data Management Resource button in the Researchers tab



NATIONAL INSTITUTE OF
NEUROLOGICAL
DISORDERS AND STROKE



Home > Researchers

Researchers

Data Management Resource

Overview of PDBP Data Management Resource

The National Institute of Neurological Disorders and Stroke (NINDS) Parkinson's Disease Biomarkers Program Data Management Resource (PDBP DMR) is a web-based tool and resource for the Parkinson's Disease Biomarkers Community.

The PDBP DMR includes development of a web-based data management system that provides tools to PDBP supported projects for both the collection and quality assurance of data in a standardized format. The PDBP DMR also coordinates the assembly of de-identified data into a common database thus enabling the query and distribution of aggregate data for the acceleration of PD biomarkers discovery and validation. The PDBP DMR synchronizes efforts across government and non-government organizations involved in PD biomarker research as well, by developing a federated database. It also serves the general public by providing a website with updated content on projects and their scientific discoveries funded via the NINDS PDBP.

Requesting permission to ProFoRMS

A. If you are a new user, click Request a New Account

- Fill out the required information and click Continue
- Click the checkbox for Account Privileges to ProFoRMS
- Click Submit Request

B. If you have a Username and Password, log in to the DMR

- Click on the Account Management tab
- Click Request Additional Privileges on the left-hand tool bar
- Click the checkbox for Account Privileges to ProFoRMS
- Click Request Privileges



You will receive an email when your account is approved

[Request A New Account](#) | [Forgot your username?](#) | [Forgot your password?](#)

For security reasons, we require authentication. Please Log Out and Exit your web browser when you are done accessing services that require authentication.

Warning Notice

This is a U.S. Government computer system, which may be accessed and used only for authorized Government business by authorized personnel. Unauthorized access or use of this computer system may subject violators to criminal, civil, and/or administrative action.

All information this computer system may be intercepted, recorded, read, copied, and disclosed by and to authorized personnel for official purposes, including criminal investigations. Such information includes sensitive data encrypted to comply with confidentiality and privacy requirements. Access or use of this computer system by any person, whether authorized or unauthorized, constitutes consent to these terms. There is no right of privacy in this system.

Enter your Username and Password

Username:

Password:

[clear](#)

Password Management

Account Management

Account Management

- My Profile
- Change Password**
- Upload Documentation
- Request Additional Privileges

Change Password

To change your password, please enter your current password, then select a new password.

Current Password :

New Password :

Case sensitive. 8-15 alpha/numeric characters. Must contain at least 3 d. Capital Letter, Lowercase letter, Numbers, and/or Special character.

Confirm Password :

CHANGE PASSWORD [Cancel](#)

Yellow arrows with numbers 1, 2, and 3 point to the 'Account Management' menu item, the 'Change Password' option in the sidebar, and the password input fields respectively.

To change your password, login, then:

1. Select the Account Management module
2. Select Change Password from the left-hand navigation bar
3. Follow the steps listed on the screen

- 🌸 NIH policy requires a new password every 60 days
- 🌸 You will receive an email 14 days (and daily thereafter) prior to password expiration. Click the link in the email to login and update your password. If your password expires, a message containing a link to help you reset your password will appear upon login attempt.

Forgotten Password



If you forget your password:

- Navigate to the DMR
- Click on the “Forgot your password?” link near the top of the page
- Follow the steps listed in the system. You will receive an email with a link to change your password.

The screenshot shows a login interface with a dark header bar. On the left, a light gray box contains the text "Enter your Username and Password" above two input fields labeled "Username:" and "Password:". Below these fields is a "LOGIN" button and a "clear" link. To the right of the login box, there are three links: "Request A New Account", "Forgot your username?", and "Forgot your password?". The "Forgot your password?" link is highlighted with a yellow box and a yellow arrow pointing to it. Below the links, there is a security notice: "For security reasons, please Log Out and Exit your web browser when you are done accessing services that require authentication!". This is followed by a "Warning Notice" section with a bold heading and a paragraph of text: "This is a U.S. Government computer system, which may be accessed and used only for authorized Government business by authorized personnel. Unauthorized access or use of this computer system may subject violators to criminal, civil, and/or administrative action." Below the warning notice is another paragraph: "All information this computer system may be intercepted, recorded, read, copied, and disclosed by and to authorized personnel for official purposes, including criminal investigations. Such information includes sensitive data encrypted to comply with confidentiality and privacy requirements. Access or use of this computer system by any person, whether authorized or unauthorized, constitutes consent to these terms. There is no right of privacy in this system."

Requesting ProFoRMS Permissions

1. Select Account Management
2. Select Request Additional Privileges
3. Check the ProFoRMS box
4. Click Request Privileges

You will receive an email once you have been granted access

The screenshot shows the ProFoRMS web application interface. At the top is a navigation bar with tabs: Home, Workspace, GUID, Data Dictionary, Data Repository, and Account Management. The 'Account Management' tab is selected and highlighted with a yellow arrow labeled '1'. Below the navigation bar, the 'Account Management' section is displayed. On the left is a sidebar menu with options: Account Management (highlighted in red), My Profile, Change Password, Upload Documentation, Request Additional Privileges (highlighted in yellow with a yellow arrow labeled '2'), and Request Additional Privileges (highlighted in yellow with a yellow arrow labeled '3'). The main content area is titled 'Request Additional Privileges' and contains a table of 'Account Privileges'.

PRIVILEGE	STATUS	EXPIRATION DATE
User (Default Access)	Active	No Expiration Date

Below the table, there is a section titled 'Request Additional Privileges' with a warning message: 'You may request additional privileges below. Please note that requesting privileges requires an administrator's approval and in some cases, will require additional documentation to be uploaded.'

High-Level Privileges

- User (Default Access)** - General access to the system
- Dictionary** - Gives access to the Data Dictionary and allows users to view, define and create unique data elements, form structures, and Common Data Elements
- GUID** - Allows users to access the GUID Tool and generate a Global Unique Identifier (GUID) for each study participant
- Study** - Allows users to create and view Studies which contain research data and supporting documentation
- Query Tool** - Grants users permission to query and download shared data from the repository. Users must submit the SF-424 (R&R) and Data Access Agreement documents.
- ProFoRMS** - Protocol Management and Electronic Form Capture and Creation

Specific Permission Groups

No permission groups available

Federated Sites

Federated site access requires you to apply for through their external site. Once access has been granted from their site, your request will be approved here.

No federated sites available

At the bottom of the page, there are two buttons: 'REQUEST PRIVILEGES' (highlighted in red with a yellow arrow labeled '4') and 'Cancel'.

Navigating to ProFoRMS

- After login, Workspace screen shows modules you have access to in white
- Click the ProFoRMS module to enter ProFoRMS

The screenshot shows the ProFoRMS Workspace interface. At the top is a navigation bar with tabs: Home, Workspace (selected), ProFoRMS, GUID, Data Dictionary, Data Repository, and Account Management. Below the navigation bar is the 'Workspace' section, which includes a sidebar with 'Workspace', 'My Dashboard', and 'Module Overview' (highlighted). The main content area is titled 'Module Overview' and contains a description: '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.' Below this are five module cards, each with an icon, title, and list of features. A large yellow arrow points to the 'PROFORMS' card.

Workspace

Module Overview

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.

DATA REPOSITORY

Features

- Contribute, upload, and store research data that is associated to each study
- Define and manage study information

DATA DICTIONARY

Features

- Search for approved common and unique data elements
- Browse and re-use existing forms
- Create unique data elements (if necessary)
- Create additional form structures (if necessary)

GUID

Features

- Generate unique IDs for subjects (required for submission)
- View your existing GUIDs and where else they might have been used

ACCOUNT MANAGEMENT

Features

- Update your profile
- Change your password
- Upload documentation
- Request privileges

PROFORMS

Features

- Create & manage protocols
- Enroll & schedule subjects
- Create or Reuse eCRFs
- Collect subject data

ProFoRMS Demonstration

 Requesting permission to ProFoRMS

 Adding Subjects

- Creating GUIDs within ProFoRMS
- Validating GUIDs created in the GUID tool

 Scheduling Visits

 Collecting Data

 Reviewing and Editing Data

 What to do if you have a problem?

Creating Global Unique Identifier (GUID) in ProFoRMS

1. Click on the ProFoRMS tab at the top of the screen
2. Click on Manage Subjects → Add Subject on the left-hand toolbar
3. Click the “No” radio button to indicate subject does not yet have a GUID

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Account Management

Dashboard PDBP GENERIC DEMO STUDY

ProFoRMS

ProFoRMS Home

Manage Subjects

My Subjects

Add Subject

Schedule Visits

Manage Monitor Queries

Attachment Categories

Collect Data

Manage Forms

Add Subject

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

[] Subject Information

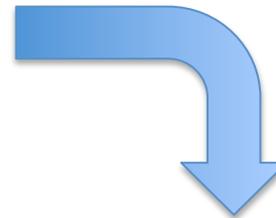
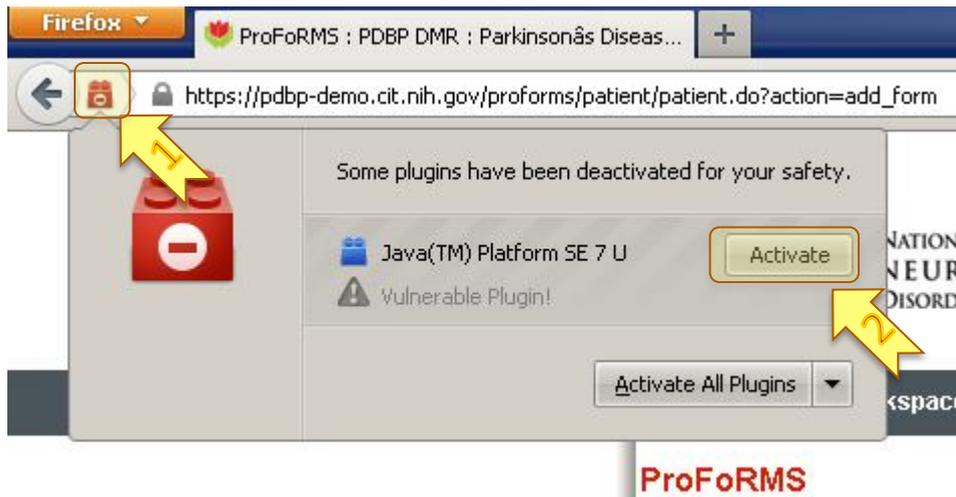
Does subject have either a GUID or Pseudo-GUID? Yes No

* This symbol indicates a required field

PII Fields for GUID	Subject's Information (PII)	Confirm The Subject's Information
First Name at Birth *	<input type="text"/>	<input type="text"/>
Has Middle Name? *	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> No <input checked="" type="radio"/> Yes

Creating GUID in ProFoRMS

1. To ensure Java plug-ins are activated in Firefox, click on the red Lego brick near the browser address bar
2. Select Activate
3. Click Yes to verify the web site's certificate and run the GUID tool



Creating GUID in ProFoRMS

 Double-enter subject information into the fields and click Generate GUID

[-] Subject Information

Does subject have either a GUID or Pseudo-GUID? Yes No

* This symbol indicates a required field

PII Fields for GUID	Subject's Information (PII)	Confirm The Subject's Information
First Name at Birth *	<input type="text"/>	<input type="text"/>
Has Middle Name? *	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> No <input checked="" type="radio"/> Yes
Complete Middle Name *	<input type="text"/>	<input type="text"/>
Last Name at Birth *	<input type="text"/>	<input type="text"/>
Date of Birth *	Format: YYYY-MM-DD 	Format: YYYY-MM-DD 
City of Birth *	<input type="text"/>	<input type="text"/>
Country of Birth *	<input type="text" value="▼"/>	<input type="text" value="▼"/>
Physical Sex at Birth[M/F] *	<input type="text" value="▼"/>	<input type="text" value="▼"/>
Government Issued ID (GIID)	<input type="text"/>	<input type="text"/>
Country of GIID	<input type="text" value="▼"/>	<input type="text" value="▼"/>

This subject does not have all the required PII to generate GUID

Generate GUID



Creating GUID in ProFoRMS

1. Enter your site-specific Subject ID; *see note below*
2. If desired, enter the Coriell ID into the Biorepository Subject ID field
3. Click Save

Add Subject

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

[+] Subject Information

Does subject have either a GUID or Pseudo-GUID? Yes No

* This symbol indicates a required field

GUID or Pseudo-GUID *  VALID

Additional Information Associated with Subject

Subject ID *

Biorepository Subject ID

Recruit

Subject ID numbers must be unique across the system; please use a prefix (e.g., last three digits of your study number)

[+] Study

[+] Schedule Visit

[+] Attachments

Save

Reset

Cancel

Creating GUID in ProFoRMS

- 🌸 You are returned to the My Subjects screen
- 🌸 Notice the new subject has been added

My Subjects

The Subject 09025197 has been added successfully.

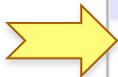
View subject list, search for a subject, or select subjects to perform an action.

[+] Advanced Search

My Subjects

Select a subject to perform an action.

	GUID	Subject ID	Status	Subject Group	Validated	Study	Monitor Query
<input type="checkbox"/>	PDP005GUD		Active			PDBP GENERIC DEMO STUDY	
<input type="checkbox"/>	PDUW781MJ3	09025197	Active			PDBP GENERIC DEMO STUDY	



Validating GUIDs created in GUID tool

🌸 If you have already created GUIDs in the DMR, you will need to validate these in ProFoRMS before collecting form data:

1. Click on the GUID tab at the top of the screen
2. Click on My GUIDs on the left-hand toolbar
3. Highlight the GUID you wish to validate in ProFoRMS, right click, and choose copy



GUID (Global Unique Identifier) 



My GUIDs

The table below displays a list of all GUIDs that you have registered from the one-way hashed PII information.

9 Results Found Page 1 of 1 

GUID 	REGISTERED BY ORGANIZATION	REGISTERED BY	DATE REGISTERED
PDAA503EF5	UT Southwestern Medical	Heather Askew	2012-Dec-18
PDCF366Z	h Medical	Heather Askew	2013-Jan-22
PDCK878M	ge of Medicine	Sarah Ryan	2013-Jan-21
PDDE924R	ge of Medicine	Sarah Ryan	2013-Jan-15
PDEK037K	ge of Medicine	Sarah Ryan	2013-Jan-17
PDET591Y	ge of Medicine	Sarah Ryan	2013-Jan-03
PDFD062B	ge of Medicine	Sarah Ryan	2013-Jan-24
PDFP184NXJ	UT Southwestern Medical Center	Heather Askew	2012-Dec-18

A context menu is open over the first GUID, PDAA503EF5, with the 'Copy' option highlighted by a yellow arrow. The menu options are: Open Link in New Tab, Open Link in New Window, Bookmark This Link, Save Link As..., Copy Link Location, Copy, Search Google for "PDAA503EF5", View Selection Source, and Inspect Element (Q).

Validating GUIDs in ProFoRMS

1. Click on the ProFoRMS tab at the top of the screen
2. Click on Manage Subjects → Add Subject on the left-hand toolbar. (Click Yes to accept the web site certificate, if prompted.)
3. Paste the GUID you wish to validate in GUID textbox and click Validate GUID
4. Add a Subject and Biorepository Subject IDs, if desired, and click Save

The screenshot shows the ProFoRMS web application interface. The top navigation bar includes 'Home', 'Workspace', 'ProFoRMS', 'GUID', 'Data Dictionary', 'Data Repository', and 'Account Management'. The 'ProFoRMS' tab is highlighted. Below the navigation bar, there is a 'Dashboard' section with 'PDBP GENERIC PROD STUDY' selected. The left sidebar contains several menu items: 'ProFoRMS Home', 'Manage Subjects' (highlighted in red), 'My Subjects', 'Add Subject' (highlighted in yellow), 'Schedule Visits', 'Manage Monitor Queries', 'Attachment Categories', 'Collect Data', 'Manage Forms', and 'Manage Study'. The main content area displays the 'Add Subject' form. The form includes a heading 'Add Subject' and a sub-heading '[] Subject Information'. Below this, there is a question 'Does subject have either a GUID or Pseudo-GUID?' with radio buttons for 'Yes' and 'No'. A note states '* This symbol indicates a required field'. The form has three input fields: 'GUID or Pseudo-GUID' (with a 'Validate GUID' button), 'Subject ID', and 'Biorepository Subject ID'. A 'Recruit' checkbox is also present. A yellow callout box on the right contains the text: 'Subject ID numbers must be unique across the system; please use a prefix (e.g., last three digits of your study number)'. Four yellow arrows point to the 'ProFoRMS' tab, the 'Add Subject' button, the 'Validate GUID' button, and the 'Subject ID' field.

Viewing your subjects

1. Click on the ProFoRMS tab at the top of the screen
2. Click on Manage Subjects → My Subjects on the left-hand toolbar
3. Your subjects appear in a list that can be sorted by clicking on the arrows on any field

ProFoRMS

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Account Management

Dashboard PDBP GENERIC PROD STUDY

ProFoRMS

ProFoRMS Home

Manage Subjects

My Subjects

Add Subject

Schedule Visits

Manage Monitor Queries

Attachment Categories

Collect Data

Manage Forms

Manage Study

Report & Query

My Subjects

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.

Edit View Attachments All Completed Forms Add Monitor Query View Audit Schedule Visit Delete

Search:

	GUID	Subject ID	Status	Subject Group	Validated	Study	Monitor Query
<input type="checkbox"/>	PDXN792ZLQ	DMR_Test_Subj	Active			PDBP GENERIC PROD STUDY	

Showing 1 to 1 of 1 entries

ProFoRMS Demonstration

- 🌱 Requesting permission to ProFoRMS
- 🌱 Adding Subjects
 - Creating GUIDs within ProFoRMS
 - Validating GUIDs created in the GUID tool
- 🌱 Scheduling Visits
- 🌱 Collecting Data
- 🌱 Reviewing and Editing Data
- 🌱 What to do if you have a problem?
 - Set expectations for how long it will take to fix a problem

Scheduling subject visits

- ProFoRMS allows you to schedule subject visits
- In ProFoRMS tab, click on Manage Subjects → Schedule Visits on the left-hand toolbar

ProFoRMS

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Account Management

Dashboard PDBP GENERIC DEMO STUDY

ProFoRMS Home

- Manage Subjects
- My Subjects
- Add Subject
- Schedule Visits**
- Manage Monitor Queries
- Attachment Categories
- Collect Data
- Manage Forms
- Manage Study
- Report & Query
- Site Administration

Schedule Visit

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

GUID or Pseudo-GUID*

Date and Time*

Visit Type

Scheduled Visits

Search:

	GUID	Subject ID	Visit Type	Date and Time
<input type="checkbox"/>	PDAC429BJU	PD-8750		2012-11-14 09:30
<input type="checkbox"/>	PDGD558PEV	Subject 2		2012-11-14 10:38
<input type="checkbox"/>	PDAC429BJU	PD-8750		2012-11-15 10:30
<input type="checkbox"/>	PDDF879FDG	Subject 1		2012-11-19 09:00
<input type="checkbox"/>	PDVR346VBX	Subject 3		2012-12-03 11:00
<input type="checkbox"/>	PDAC429BJU	PD-8750		2012-12-12 10:00
<input type="checkbox"/>	PDDF879FDG	Subject 1		2013-01-31 00:00
<input type="checkbox"/>	PDGD558PEV	Subject 2		2013-05-16 00:00

Showing 1 to 8 of 8 entries

Scheduling subject visits

1. Select the GUID of the subject you would like to schedule
2. Choose the date and time for the visit
3. Choose the visit type (see Required Forms slide for PDBP protocol)
4. Click Add

Schedule Visit

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

* This symbol indicates a required field

GUID or Pseudo-GUID* PDAC429BJU

Date and Time* 2013-03-13 10:30

Visit Type Baseline

Add Cancel



Scheduled Visits

Edit Delete Search:

GUID	Subject ID	Visit Type	Date and Time
No data available in table			

Showing 0 to 0 of 0 entries

Scheduling subject visits

- 🌱 Notice the visit now appears in the scheduled visits window
- 🌱 Continue adding visits using the same process
- 🌱 Click the checkbox next to a visit and click Edit to update as needed

Schedule Visit

The subject visit date has been added successfully.

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

* This symbol indicates a required field

GUID or Pseudo-GUID*

Date and Time*

Visit Type

Add Cancel

Scheduled Visits

Edit Delete Search:

	GUID	Subject ID	Visit Type	Date and Time
<input type="checkbox"/>	PDAC429BJU	PD-8750	Baseline	2013-03-13 10:30

Showing 1 to 1 of 1 entries



Viewing scheduled visits

- Using the Schedule Visits page, you can view all your scheduled visits (default view)
- Sort by GUID, Subject ID, Visit Type or Date and Time by clicking on the blue arrows in the column headers

Schedule Visit

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

* This symbol indicates a required field

GUID or Pseudo-GUID*

Date and Time*

Visit Type

Scheduled Visits

	GUID	Subject ID	Visit Type	Date and Time
<input type="checkbox"/>	PDDF879FDG	Subject 1	Baseline	2012-11-19 09:00
<input type="checkbox"/>	PDDF879FDG	Subject 1	6 Months	2013-01-31 00:00

Showing 1 to 2 of 2 entries

Schedule Visit

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

* This symbol indicates a required field

GUID or Pseudo-GUID*

Date and Time*

Visit Type

Scheduled Visits

	GUID	Subject ID	Visit Type	Date and Time
<input type="checkbox"/>	PDGD558PEV	Subject 2	6 Months	2012-11-14 10:38
<input type="checkbox"/>	PDDF879FDG	Subject 1	Baseline	2012-11-19 09:00
<input type="checkbox"/>	PDVR346VBX	Subject 3	Baseline	2012-12-03 11:00
<input type="checkbox"/>	PDDF879FDG	Subject 1	6 Months	2013-01-31 00:00
<input type="checkbox"/>	PDAC429BJU	PD-8750	Baseline	2013-03-13 10:30
<input type="checkbox"/>	PDGD558PEV	Subject 2	Baseline	2013-05-16 00:00

Showing 1 to 6 of 6 entries



OR select a GUID to view the visits scheduled for a particular subject

Viewing scheduled visits

1. To view all visits scheduled on a particular day, click Dashboard
2. Click on the day you wish to view appointments

The screenshot shows the ProFoRMS Dashboard for the study 'PDBP GENERIC DEMO STUDY'. The navigation bar includes Home, Workspace, ProFoRMS, GUID, Data Dictionary, Data Repository, and Account Management. The ProFoRMS sidebar contains links for Home, Select A Study, Manage Subjects, Collect Data, Manage Forms, Manage Study, Report & Query, and Site Administration. The main content area is titled 'Dashboard' and includes a 'Messages' section with a search bar and a table showing 'No data available in table'. Below this is the 'Subject Visits' section, which features a calendar for January 2013 and a table of 'Scheduled Appointments'.

Calendar: January 2013. The 31st is highlighted in red.

Scheduled Appointments Table:

Time	Subject GUID	Visit Type	Study Number
11:00 am	PDUG001CZG	6 Months	PDBP GENERIC DEMO STUDY
1:00 pm	PDDF879FDG	Baseline	PDBP GENERIC DEMO STUDY

ProFoRMS Demonstration

 Requesting permission to ProFoRMS

 Adding Subjects

- Creating GUIDs within ProFoRMS
- Validating GUIDs created in the GUID tool

 Scheduling Visits

 Collecting Data

 Reviewing and Editing Data

 What to do if you have a problem?

Collecting Data with Scheduled Visit

🌸 When you are ready to enter form data for a subject, navigate to Collect Data → Data Collection

The screenshot shows the ProFoRMS web application interface. The top navigation bar includes Home, Workspace, ProFoRMS, GUID, Data Dictionary, Data Repository, and Account Management. The ProFoRMS dropdown menu is open, showing options like Home, Manage Subjects, Collect Data, Data Collection (highlighted with a yellow arrow), My Collections, Resolve Discrepancies, Manage Forms, Manage Study, Report & Query, and Site Administration. The main content area is titled 'Data Collection Forms' and includes a 'View' dropdown set to 'By Subject', an 'Advanced Search' link, and an 'Upcoming Collections' section. The 'Upcoming Collections' section contains a table with columns for Subject GUID, Visit Type, Visit Date, and Subject ID. The table lists six entries, each with a checkbox for selection. Below the table, it indicates 'Showing 1 to 6 of 6 entries'.

ProFoRMS

Dashboard | PDBP GENERIC DEMO STUDY

Data Collection Forms

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

View

[+] Advanced Search

Upcoming Collections

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

Search:

	Subject GUID	Visit Type	Visit Date	Subject ID
<input type="checkbox"/>	PDVR346VBX	Baseline	03/10/2014 11:00	Subject 3
<input type="checkbox"/>	PDGD558PEV	6 Months	10/15/2013 10:00	Subject 2
<input type="checkbox"/>	PDDF879FDG	6 Months	07/31/2013 09:00	Subject 1
<input type="checkbox"/>	PDGD558PEV	Baseline	05/16/2013 00:00	Subject 2
<input type="checkbox"/>	PDAC429BJU	Baseline	03/13/2013 10:30	PD-8750
<input type="checkbox"/>	PDDF879FDG	Baseline	01/31/2013 11:00	Subject 1

Showing 1 to 6 of 6 entries

Collecting Data with a Scheduled Visit

1. Check the box next to the GUID and Visit Type for which you wish to enter data (Note: the GUID may appear multiple times for different visits)
2. Click Start Data Collection

Data Collection Forms

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

View

[+] 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:

	Subject GUID	Visit Type	Visit Date	Subject ID
<input type="checkbox"/>	PDVR346VBX	Baseline	03/10/2014 11:00	Subject 3
<input type="checkbox"/>	PDGD558PEV	6 Months	10/15/2013 10:00	Subject 2
<input type="checkbox"/>	PDDF879FDG	6 Months	07/31/2013 09:00	Subject 1
<input type="checkbox"/>	PDGD558PEV	Baseline	05/16/2013 00:00	Subject 2
<input type="checkbox"/>	PDAC429BJU	Baseline	03/13/2013 10:30	PD-8750
<input checked="" type="checkbox"/>	PDDF879FDG	Baseline	01/31/2013 11:00	Subject 1

Showing 1 to 6 of 6 entries

Collecting Data with a Scheduled Visit

1. Verify the Subject and Visit Type, then choose the Form Name for which you wish to begin entering data.
2. A list of Required Forms per Visit Type is available from the PDBP Operations Team (contact PDBP-OPS@mail.nih.gov for assistance)
3. Update the Visit Date/Time field, if necessary

Start Collection

[] Data Collection

Please enter information to start data collection.

* This symbol indicates a required field

Subject	<input type="text" value="Subject 1"/>
Visit Type*	<input type="text" value="Baseline"/>
Form Name*	<input type="text" value="- Please Select"/>
Visit Date/Time*	<input type="text" value="2013-01-31 11:00"/>

Start Data Collection

Cancel

Required Forms (Case & Control)

Form Name	Screening Visit	Baseline	6 months	12 months	18 months	24 months	30 months	36 months	42 months	48 months	54 months	60 months
Adverse Events												
Behavioral History		x										
CSF Collection Data Form												
CSF Collection Follow Up Phone Call												
Demographics		x										
Early Termination Questionnaire												
Epworth Sleepiness Scale		x		x		x		x		x		x
Family History		x										
Hamilton Anxiety Rating Scale (HAM-A)		x		x		x		x		x		x
Hamilton Depression Rating Scale (HDRS)		x		x		x		x		x		x
Informed Consent and Enrollment		x										
Laboratory Tests and Tracking												
MDS-UPDRS (Movement Disorder Society - Unified Parkinson's Disease Rating Scale)		x	x	x	x	x	x	x	x	x	x	x
Modified Schwab and England Activities of Daily Living Scale		x		x		x		x		x		x
Montreal Cognitive Assessment (MoCA)7_1		x		x		x		x		x		x
Neurological Exam		x		x		x		x		x		x
PDBP Inclusion and Exclusion Criteria	x	Req. if not completed during screening visit										
PDBP Sample Record Summary & Shipment Notification												
PDQ-39		x		x		x		x		x		x
Prior and Concomitant Medications		x	x	x	x	x	x	x	x	x	x	x
Protocol Deviations												
Rapid Eye Movement Behavior Disorder Questionnaire		x		x		x		x		x		x
University of Pennsylvania Smell Identification Test (UPSIT)		x		x		x		x		x		x
Vital Signs		x	x	x	x	x	x	x	x	x	x	x

Forms Requiring Individual Site Licenses

 Several forms require individual site licenses.

PDQ-39

– Fill out the license agreement available at:

<http://www.isis-innovation.com/outcomes/apply/index.html>

MDS-UPDRS

– Fill out the license agreement available at:

https://ssl47.pair.com/mds/publications/rating_scales/request_form.php

Epworth Sleepiness Scale

– Fill out the license agreement available at:

<http://www.mapi-trust.org/services/questionnairelicensing/catalog-questionnaires/229-ess>

Form Ordering

- 🌸 Forms can be custom-ordered to your needs by visit type
- 🌸 Operations Team will send you a form ordering template and build to your requirements

Subject	PDDF879FDG
Visit Type*	Baseline
Form Name*	- Please Select
Visit Date/Time*	- Please Select

- PDBP Inclusion and Exclusion Criteria
- Informed Consent and Enrollment
- Neurological Examination
- Demographics
- Behavioral History
- Family History
- Prior and Concomitant Medications
- Vital Signs
- University of Pennsylvania Smell Identification
- MDS-UPDRS
- Rapid Eye Movement Behavior Disorder Questionnaire
- Epworth Sleepiness Scale
- PDQ-39
- Modified Schwab and England Scale
- Hamilton Depression Rating Scale (HDRS)
- Hamilton Anxiety Rating Scale (HAM-A)
- Montreal Cognitive Assessment (MoCA)
- CSF Collection Data Form
- CSF Collection Follow Up Phone Call

Collecting Data

- 🌱 The information on this page will be used for pre-populating selected Required Fields, so be certain to double-check your entries.
- 🌱 Click Start Data Collection
- 🌱 Note that you cannot collect data in a form which has already been started for a particular GUID and Visit Type. If you need to edit an existing form, please refer to the Reviewing and Editing Data section of this presentation

Start Collection

[] Data Collection

Please enter information to start data collection.

* This symbol indicates a required field

Subject	<input type="text" value="Subject 1"/>
Visit Type*	<input type="text" value="Baseline"/>
Form Name*	<input type="text" value="Informed Consent and Enrollment"/>
Visit Date/Time*	<input type="text" value="2013-01-28 12:21"/>



Collecting Data

- 🌱 Fields with red asterisks are required
 - Selected Required Fields will be pre-populated: Name of site, Type of visit, Date of visit, and GUID will be populated with values from the Start Collection page
 - Pre-populated fields can be updated, if necessary (e.g. date of visit may not equal scheduled visit date).
- 🌱 Form will auto-save every 8 minutes
- 🌱 Questions with radio buttons can be reset by double-clicking
- 🌱 Skip logic will grey out certain questions at times
- 🌱 Auto-calculated fields appear in several forms. Answer will appear if you click on them, but it is not necessary to save the form.
- 🌱 Green sections are collapsible. You can expand/hide to read further instructions or view scoring sections.
- 🌱 Validation checks will provide errors at the top of the screen upon Save
- 🌱 We recommend you do not Lock your data until you are ready to submit to the long-term repository; additional instructions and training will be scheduled
- 🌱 None of the forms require double-entry data so you can ignore the references to Entry 1 and Entry 2 that appear in the system

Entering Data

1. Required fields marked with red asterisk
2. Date calendar pop-out
3. Auto-calculated field
4. Date-Time calendar pop-out
5. Repeat button

Vital Signs

Required Fields

*Name of site	<input type="text"/>
*Type of visit	<input type="text"/>
*Date of visit	Format: YYYY-MM-DD 
*GUID	<input type="text"/>
*Age of subject in years	<input type="text"/>
*Plus months	<input type="text"/>
*Age of subject in months (auto-calculated field)	<input type="text"/>

Vital Signs

1. Date and time:	Format: YYYY-MM-DD HH:MM 
2. Heart rate/pulse (beats/minute):	<input type="text"/>
3. Respiratory rate (breaths/minute):	<input type="text"/>

4. Blood Pressure

Blood pressure while sitting is required. Click Repeat if also taken standing and/or supine.

4a. Subject's position when the blood pressure was taken?	<input type="text"/>
4b. Systolic blood pressure (mmHg):	<input type="text"/>
4c. Diastolic blood pressure (mmHg):	<input type="text"/>

Repeat

Navigating Forms

<<Previous Form Next Form>>



Saves current form and moves you to previous form in your custom order



Saves current form and moves you to next form in your custom order

Save & Exit Cancel



Saves current form and takes you to the My Collections page



Cancels work on current form and takes you to the My Collections Page (unless after 8 minute auto-save)

- At the bottom of the form, you will see these buttons and a list of your custom form order and an indication of which are required and optional for that visit type
- You can navigate through the forms by choosing the Previous and Next buttons, or by clicking on the link to the form name in the table
- A visit will be considered “Complete” when all required forms for a particular visit type are labeled “In Progress

[] Forms For This Visit Type

Clicking on a form link will save the current form and jump to the selected form.

Form Name	Data Collection Status	Required?
PDBP Inclusion and Exclusion Criteria	In Progress	Required
Informed Consent and Enrollment	In Progress	Required
Neurological Examination	Not Started	Required
Demographics	Not Started	Required
Behavioral History	Not Started	Required
Family History	Not Started	Required
Prior and Concomitant Medications	Not Started	Required
Vital Signs	Not Started	Required
University of Pennsylvania Smell Identification	Not Started	Required
MDS-UPDRS	Not Started	Required
Rapid Eye Movement Behavior Disorder Questionnaire	Not Started	Required
Epworth Sleepiness Scale	Not Started	Required
PDQ-39	Not Started	Required
Modified Schwab and England Scale	Not Started	Required
Hamilton Depression Rating Scale (HDRS)	Not Started	Required
Hamilton Anxiety Rating Scale (HAM-A)	Not Started	Required
Montreal Cognitive Assessment (MoCA)	Not Started	Required
CSF Collection Data Form	Not Started	Optional
CSF Collection Follow Up Phone Call	Not Started	Optional
Adverse Events	Not Started	Optional

Collecting Data

- After you enter data into the form and click Save, you will be taken to the My Collections view
- Forms will continue to show as “In Progress” until they are Locked. Data should not be locked until reviewed and ready for final submission.

ProFoRMS Home

Manage Subjects

Collect Data

Data Collection

My Collections

Resolve Discrepancies

Manage Forms

Manage Study

Report & Query

Site Administration

My Collections

The administered form Informed Consent and Enrollment has been saved successfully.

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

View

[+] Advanced Search

Data Collection

Select a form to view or perform an action

Search:

	Subject GUID	Visit Date	Visit Type	Form Name	Data Entry 1 Status	Data Entry 2 Status
<input type="checkbox"/>	PDDF879FDG	01/28/2013 12:37	Baseline	Informed Consent and Enrollment	In Progress	--

Showing 1 to 1 of 1 entries

Collecting Data without a Scheduled Visit

1. To enter data for a subject without a scheduled visit, go to Collect Data → Data Collection
2. Select “By Form (Subject)” from the View dropdown
3. Click the checkbox next to the form you wish to enter data for
4. Click Start Data Collection

ProFoRMS Home

Manage Subjects

Collect Data

Data Collection

My Collections

Resolve Discrepancies

Manage Forms

Manage Study

Report & Query

Data Collection Forms

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

View

[+] Advanced Search

Available Forms

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

Search:

<input type="checkbox"/>	Form Name	Status	Form Last Updated
<input type="checkbox"/>	PDBP Sample Record Summary & Shipment Notification	Active	2013-02-07 11:11:51
<input checked="" type="checkbox"/>	PDQ-39	In Progress	2013-02-05 16:00:30
<input type="checkbox"/>	Adverse Events	Active	2013-02-05 12:49:11
<input type="checkbox"/>	Hamilton Depression Rating Scale (HDRS)	Active	2013-01-31 12:55:08
<input type="checkbox"/>	PDBP Inclusion and Exclusion Criteria	Active	2013-01-31 12:54:41

Collecting Data without a Scheduled Visit

1. Choose the Subject you are entering data for
2. Choose the Visit Type
3. Select the Visit Date and Time
4. Click Start Data Collection

Start Collection

[] Data Collection

Please enter information to start data collection.

* This symbol indicates a required field

Subject*	<input type="text" value="- Please Select"/>
Visit Type*	<input type="text" value="- Please Select"/>
Form Name	<input type="text" value="PDQ-39"/>
Visit Date/Time*	<input type="text" value="Format: YYYY-MM-DD HH:MM"/>

ProFoRMS Demonstration

- 🌱 Requesting permission to ProFoRMS
- 🌱 Adding Subjects
 - Creating GUIDs within ProFoRMS
 - Validating GUIDs created in the GUID tool
- 🌱 Scheduling Visits
- 🌱 Collecting Data
- 🌱 Reviewing and Editing Data
- 🌱 What to do if you have a problem?

Reviewing and Editing Data

- To review and edit data on forms that have already been entered, navigate to the Collect Data → My Collections screen

ProFoRMS

Home Workspace **ProFoRMS** GUID Data Dictionary Data Repository Account Management

Dashboard PDBP GENERIC DEMO STUDY

ProFoRMS Home

Manage Subjects

Collect Data

Data Collection

My Collections

Resolve Discrepancies

Manage Forms

Manage Study

Report & Query

Site Administration

My Collections

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

View

[+] Advanced Search

Data Collection

Select a form to view or perform an action

Search:

	Subject GUID	Visit Date	Visit Type	Form Name	Data Entry 1 Status	Data Entry 2 Status
<input type="checkbox"/>	PDDF879FDG	01/28/2013 14:47	Baseline	Neurological Examination	In Progress	--
<input type="checkbox"/>	PDAC429BJU	01/28/2013 12:42	Baseline	Informed Consent and Enrollment	Locked	--
<input type="checkbox"/>	PDDF879FDG	01/28/2013 12:37	Baseline	Informed Consent and Enrollment	In Progress	--

Showing 1 to 3 of 3 entries

Reviewing Data

- Sort by any column heading you wish to view the data
- Mark the checkbox next to the form you wish to review
- Click View Entry 1 to view the data in static HTML
- This view can be printed for paper review

My Collections

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

View

[+] Advanced Search

Data Collection

Select a form to view or perform an action

View Entry 1 **View Entry 2** **Edit** **Edit 1** **Edit 2** **View Audit** **Monitor Data** **Reassign** **Delete Entry 1**

Delete Entry 2

Search:

	Subject GUID	Visit Date	Visit Type	Form Name	Data Entry 1 Status	Data Entry 2 Status
<input checked="" type="checkbox"/>	PDDF879FDG	01/28/2013 14:47	Baseline	Neurological Examination	In Progress	--
<input type="checkbox"/>	PDAC429BJU	01/28/2013 12:42	Baseline	Informed Consent and Enrollment	Locked	--
<input type="checkbox"/>	PDDF879FDG	01/28/2013 12:37	Baseline	Informed Consent and Enrollment	In Progress	--

Showing 1 to 3 of 3 entries

Editing Data

- 🌸 From the My Collections page, sort by any column heading you wish
- 🌸 Mark the checkbox next to the form you wish to edit
- 🌸 Click Edit to open the form for editing
 - Note that the form can only be edited by the person to whom it is assigned

My Collections

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

View

[+] Advanced Search

Data Collection

Select a form to view or perform an action

	Subject GUID	Visit Date	Visit Type	Form Name	Data Entry 1 Status	Data Entry 2 Status
<input checked="" type="checkbox"/>	PDDF879FDG	01/28/2013 14:47	Baseline	Neurological Examination	In Progress	--
<input type="checkbox"/>	PDAC429BJU	01/28/2013 12:42	Baseline	Informed Consent and Enrollment	Locked	--
<input type="checkbox"/>	PDDF879FDG	01/28/2013 12:37	Baseline	Informed Consent and Enrollment	In Progress	--

Showing 1 to 3 of 3 entries

Reassigning Owner to Edit Data

 To assign the form to another user for editing:

NOTE: Only PI, Clinical Coordinators, and Study QA roles are able to perform this action

1. Click on the form you wish to reassign
2. Click Reassign
3. On the next screen, choose the user name of the person to whom you wish to assign the form; then click Save to reassign the form

My Collections

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

View

[+] Advanced Search

Data Collection

Select a form to view or perform an action

<input type="button" value="View Entry 1"/>	<input type="button" value="View Entry 2"/>	<input type="button" value="Edit"/>	<input type="button" value="Edit 1"/>	<input type="button" value="Edit 2"/>	<input type="button" value="View Audit"/>	<input type="button" value="Monitor Data"/>	<input type="button" value="Reassign"/>	<input type="button" value="Delete Entry 1"/>
<input type="button" value="Delete Entry 2"/>		Search: <input type="text"/>						
	Subject GUID	Visit Date	Visit Type	Form Name	Data Entry 1 Status	Data Entry 2 Status		
<input checked="" type="checkbox"/>	PDDF879FDG	01/28/2013 14:47	Baseline	Neurological Examination	In Progress	--		
<input type="checkbox"/>	PDAC429BJU	01/28/2013 12:42	Baseline	Informed Consent and Enrollment	Locked	--		
<input type="checkbox"/>	PDDF879FDG	01/28/2013 12:37	Baseline	Informed Consent and Enrollment	In Progress	--		

Showing 1 to 3 of 3 entries

Reassign Data Entry

Reassign user to Data Entry

Form Name Neurological Examination
Start Date 2013-01-28 14:50
Subject Subject 1
Interval Name Baseline
User Name pdadmin
Visit Date 2013-01-28 14:47
Reassign to

ProFoRMS Demonstration

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- 🌱 Reviewing and Editing Data
- 🌱 What to do if you have a problem?

What to do if you have a problem?

PDBP DMR

- PDBP-HELP@mail.nih.gov for technical issues
- PDBP-OPS@mail.nih.gov for procedural and policy questions
- PDBP Helpline: **301-402-6781**

 Help available Monday-Friday from 9 AM to 4 PM ET

 You will receive a response within 24 hours; resolution time will depend on nature of problem

 Additional training can be scheduled by contacting us

PDBP DMR Contacts

- Matthew McAuliffe, Ph.D. (matthew.mcauliffe@nih.gov)
- Susan K. Baker, PMP (sbaker@sapient.com)
- Jenna Linde (jenna.linde@nih.gov)

ProFoRMS Reporting

- 🌱 Limited reporting is now available through ProFoRMS
- 🌱 Reports can be exported in CSV or Excel format



- Study Report: Number of subjects enrolled and Number of forms In progress or Locked
- Completed Visits: Number of completed visits for first four required visit types; completed visit counted when all required forms are complete
- Performance Overview: Number of forms in your study for overall performance tracking (i.e., CSF Collection, Adverse Events, etc.)
- Forms Requiring Lock: Not currently in use; shows forms created more than 30 days ago that have not been locked; will be useful once submission to long-term repository is in place
- Resolved Discrepancies: Not currently in use
- Documents: List of uploaded documents in your study
- Form Status: List of forms in your study
- Locked Forms: List of locked forms in your study

Roles and Privileges

- 🌱 Operations Team will work with each site to set-up your study and its details
- 🌱 Users are assigned roles per study
- 🌱 Operations Team will work with your site to determine correct level of privileges for your user community

Assign Roles
Assign users to roles

Search:

name	Role
TestDemo, PDBP	PDBP Principal Investigator
Admin, PD	PDBP DMR Administrator
admin, guest	--
admin, pd-Demo	--

Roles and Privileges

	Principal Investigator	Clinical Coordinator	Study QA	Data Entry	Limited
Add subjects	✓	✓		✓	
View subjects	✓	✓	✓	✓	✓
Schedule visits	✓	✓		✓	
View study forms	✓	✓	✓	✓	✓
Collect data	✓	✓		✓	
View collected data	✓	✓	✓	✓	✓
Edit data	✓	✓		✓	
Reassign form owner	✓	✓	✓		

Demo Environment

- 🌱 Use demo environment to test out functionality from this presentation:
 - Link to demo environment:
<http://pdbp-demo.cit.nih.gov/>
 - Username: PDBP_Test_Demo
Password: contact the Operations Team (PDBP-HELP@mail.nih.gov)
- 🌱 Please note that data entered into the Demo Environment will be **deleted** periodically
- 🌱 We recommend you do not bookmark Demo site to reduce risk that you will enter data incorrectly
- 🌱 Environment undergoes regular maintenance and may not be available 24/7

Next Steps

- 🌱 Request permission to ProFoRMS
- 🌱 Work with DMR Operations Team to set up access permissions for your site
- 🌱 Access ProFoRMS quickly by bookmarking the following:
<https://pdbp.ninds.nih.gov/proforms>
- 🌱 Process for locking data and submitting to long-term repository will be finalized in the summertime
- 🌱 Additional training sessions will be scheduled to train users on submission and query
- 🌱 Contact us to schedule additional training and one-on-one support
- 🌱 Please send ideas for improving the system to the PDBP Operations Team; enhancements may be scheduled for future releases

Contacts

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Questions

