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**Chapter**

**3**

# **ProFoRMS**




## CHAPTER 3 - PROFORMS

**T**he **Protocol and Form Research Management System (ProFoRMS)** module provides the tools for protocol management, data capture, and is a clinical trial/research module. ProFoRMS is a web-based data collection/research application organized by modules, with a user-friendly interface designed to help researchers to manage individual protocols, subjects, eCRFs (electronic Case Report Forms), data collection, define electronic case report forms, schedule, and collect clinical data, and then export, analyze, and report on the data. This module is based on NICHD's Clinical Trial Database (CTDB).

### WARNING!



#### ICON KEY

 Notes

 Important

Information

#### Things to Note:

-  Before a protocol can be created, please make sure that the following has been completed:
-  A study has been created and approved in the Data Repository;

### 3.1 OBJECTIVE

This chapter provides information for users on how to:

- ❖ Manage Protocol
- ❖ Manage Subjects
- ❖ Collect Data
- ❖ Reports and Data Query

### 3.2 SYSTEM FUNCTIONS

The main function of ProFoRMS is to provide the tools that help to optimize the clinical study process including the basic functions of managing protocols, subjects as well as data access and account management. Early deployment of ProFoRMS in the study start-up activities, such as site identification, initiation of subject visits, and collection of all the necessary regulatory documents, can save researchers' time and improve the overall process.

As a web-based database application, BRICS provides real-time tools that support:

- ❖ Data Contribution
- ❖ Report and Query Data
- ❖ Collect Data

Once protocol is running, ProFoRMS can assist users to keep track of subject visits, data collection and of all the relevant forms and regulatory documents. This provides a strong snapshot of progress in terms of study progress and site activation. The ability to track this information ensures that any potential delays can be identified quickly and addressed.

### 3.3 PROFORMS ROLES AND PRIVILEGES

The table below describes the specific roles with associated privileges to ProFoRMS module.

<b>Role/Access</b>	<b>Privilege</b>
<b>Associate Investigator</b>	Same as PI, except cannot add/initiate a study
<b>Clinical Research Associate</b>	View protocols, visit types, forms, questions, create and manage queries
<b>Clinical Coordinator</b>	View protocols, visit types, forms, add/edit schedule visits, data collection and form reassignments
<b>Data Entry</b>	View protocols, visit types, forms, data entry and oversight, add/edit schedule visits and data collections
<b>PDBP DMR Administrator</b>	PDBP DMR Operations team members have full access to all ProFoRMS privileges
<b>PDBP Limited User</b>	View-only rights
<b>Principal Investigator</b>	Create, design, and administer forms for prospective collection
<b>Research Associate</b>	View protocols, create forms, create visit types, schedule visits, and collect data




## 3.4 USING PROFORMS

The **ProFoRMS** module (including sub-modules) are available within the BRICS Workspace.

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### ICON KEY


 Notes

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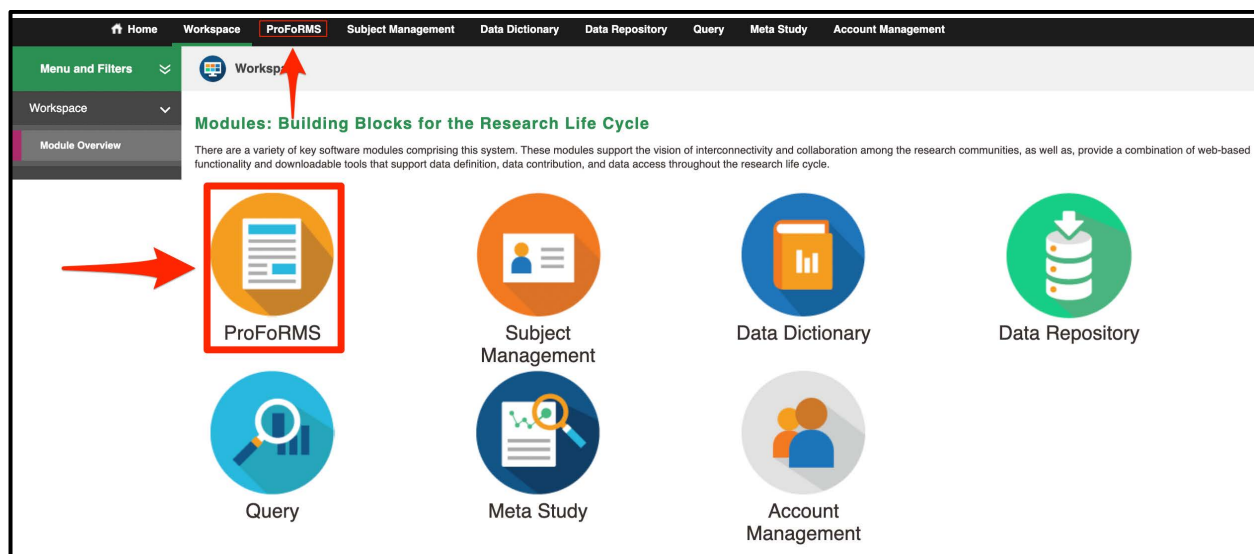
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### Things to Note:


-  The best user experience with navigating through the ProFoRMS module is with the latest Chrome or Firefox browser

To access the [ProFoRMS](#) module: Perform the following actions:

1. Login and navigate to the **Workspace** screen where all modules you have access to are displayed
2. Click on the **ProFoRMS** module or select **ProFoRMS** from the top navigation bar.



### Things to Note:

-  A Protocol must be created first before users can navigate to My Subjects and start adding subjects or managing and/or editing subjects. See [3.5](#)

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### ICON KEY

 Notes

 Important

Information

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### 3.4.1 PROFORMS FLOW OVERVIEW

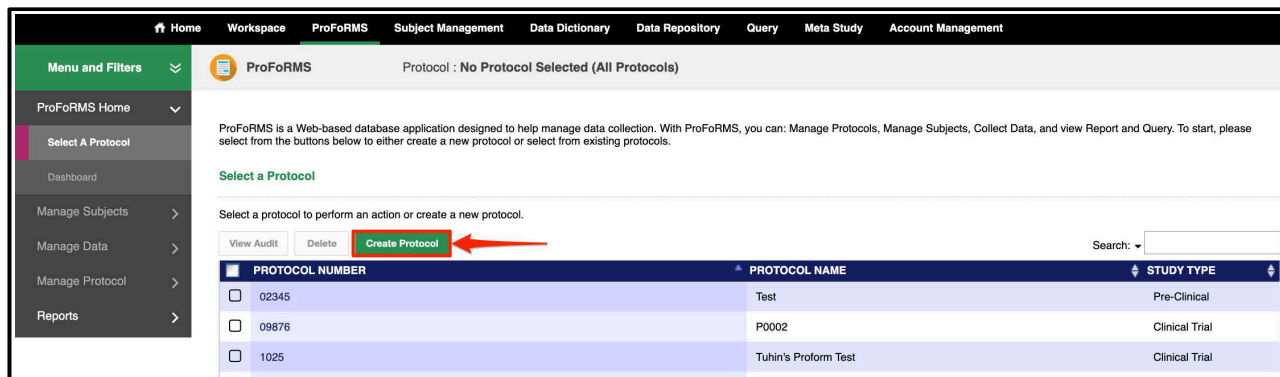
The basic overview of the flow for the Proforms Module:

Create a Protocol / Select a Protocol > Add subjects to that protocol > Create visit types and attach published eForms to it > Schedule a visit for the subject(s) to come in > Collect data on the subject(s) for that visit type.

### 3.5 CREATE A PROTOCOL

To create a Protocol: perform the following actions:

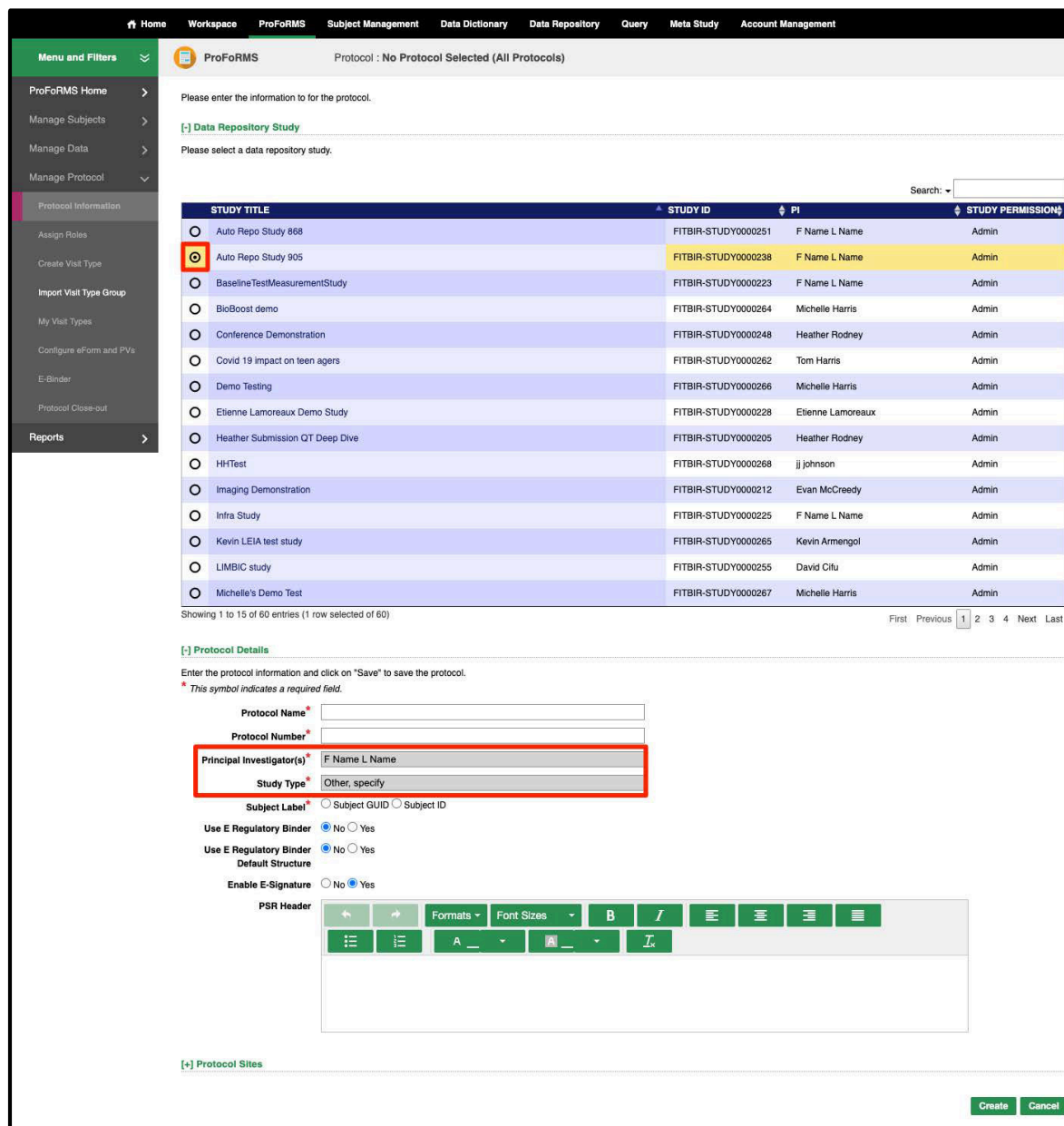
1. Navigate to the **ProFoRMS** module
2. Click the **Create Protocol** button



The screenshot shows the ProFoRMS web application interface. The top navigation bar includes Home, Workspace, ProFoRMS, Subject Management, Data Dictionary, Data Repository, Query, Meta Study, and Account Management. The left sidebar contains Menu and Filters, ProFoRMS Home, Select A Protocol, Dashboard, Manage Subjects, Manage Data, Manage Protocol, and Reports. The main content area displays the ProFoRMS module with the text: "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." Below this text, there is a "Select a Protocol" section with the instruction: "Select a protocol to perform an action or create a new protocol." This section contains three buttons: "View Audit", "Delete", and "Create Protocol". The "Create Protocol" button is highlighted with a red box and a red arrow. Below the buttons is a table with the following data:

PROTOCOL NUMBER	PROTOCOL NAME	STUDY TYPE
<input type="checkbox"/> 02345	Test	Pre-Clinical
<input type="checkbox"/> 09876	P0002	Clinical Trial
<input type="checkbox"/> 1025	Tuhin's Proform Test	Clinical Trial

3. **Select** a study from the **Data Repository Study** table that the protocol is associated with (doing this will automatically populate the Principal Investigator(s) and Study Type field information)



The screenshot shows the ProFoRMS interface. The top navigation bar includes Home, Workspace, ProFoRMS, Subject Management, Data Dictionary, Data Repository, Query, Meta Study, and Account Management. The left sidebar contains a 'Menu and Filters' section with options like ProFoRMS Home, Manage Subjects, Manage Data, Manage Protocol, Protocol Information, Assign Roles, Create Visit Type, Import Visit Type Group, My Visit Types, Configure eForm and PVs, E-Blinder, Protocol Close-out, and Reports.

The main content area is titled 'ProFoRMS' and shows 'Protocol : No Protocol Selected (All Protocols)'. Below this is a 'Data Repository Study' table with columns: STUDY TITLE, STUDY ID, PI, and STUDY PERMISSION. The table lists 15 studies, with 'Auto Repo Study 905' selected and highlighted in yellow. The selected study's details are shown in the 'Protocol Details' form below the table, which includes fields for Protocol Name, Protocol Number, Principal Investigator(s), Study Type, Subject Label, and various regulatory options. The 'Principal Investigator(s)' and 'Study Type' fields are highlighted with a red box. At the bottom right, there are 'Create' and 'Cancel' buttons.

STUDY TITLE	STUDY ID	PI	STUDY PERMISSION
<input type="radio"/> Auto Repo Study 868	FITBIR-STUDY0000251	F Name L Name	Admin
<input checked="" type="radio"/> Auto Repo Study 905	FITBIR-STUDY0000238	F Name L Name	Admin
<input type="radio"/> Baseline Test Measurement Study	FITBIR-STUDY0000223	F Name L Name	Admin
<input type="radio"/> BioBoost demo	FITBIR-STUDY0000264	Michelle Harris	Admin
<input type="radio"/> Conference Demonstration	FITBIR-STUDY0000248	Heather Rodney	Admin
<input type="radio"/> Covid 19 Impact on teen agers	FITBIR-STUDY0000262	Tom Harris	Admin
<input type="radio"/> Demo Testing	FITBIR-STUDY0000266	Michelle Harris	Admin
<input type="radio"/> Etienne Lamoreaux Demo Study	FITBIR-STUDY0000228	Etienne Lamoreaux	Admin
<input type="radio"/> Heather Submission QT Deep Dive	FITBIR-STUDY0000205	Heather Rodney	Admin
<input type="radio"/> HHTest	FITBIR-STUDY0000268	jj johnson	Admin
<input type="radio"/> Imaging Demonstration	FITBIR-STUDY0000212	Evan McCreedy	Admin
<input type="radio"/> Infra Study	FITBIR-STUDY0000225	F Name L Name	Admin
<input type="radio"/> Kevin LEIA test study	FITBIR-STUDY0000265	Kevin Armengol	Admin
<input type="radio"/> LIMBIC study	FITBIR-STUDY0000255	David Cifu	Admin
<input type="radio"/> Michelle's Demo Test	FITBIR-STUDY0000267	Michelle Harris	Admin

Showing 1 to 15 of 60 entries (1 row selected of 60)

[-] 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

Use E Regulatory Binder  No  Yes

Use E Regulatory Binder Default Structure  No  Yes

Enable E-Signature  No  Yes

PSR Header

[+] Protocol Sites

Create Cancel

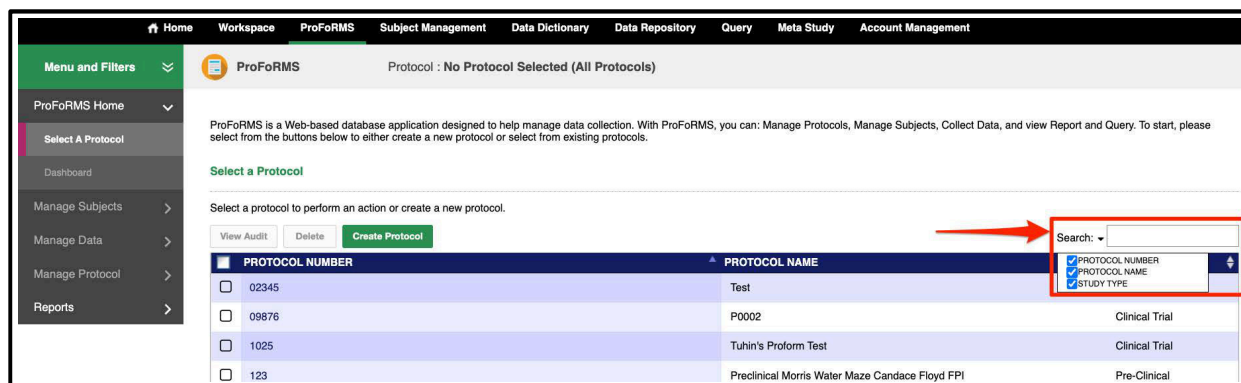
4. **Complete** all of the required fields (fields marked with a red asterisk (\*))
5. Select **Create** after all desired fields have been filled out.

### 3.5.1 Selecting a Protocol

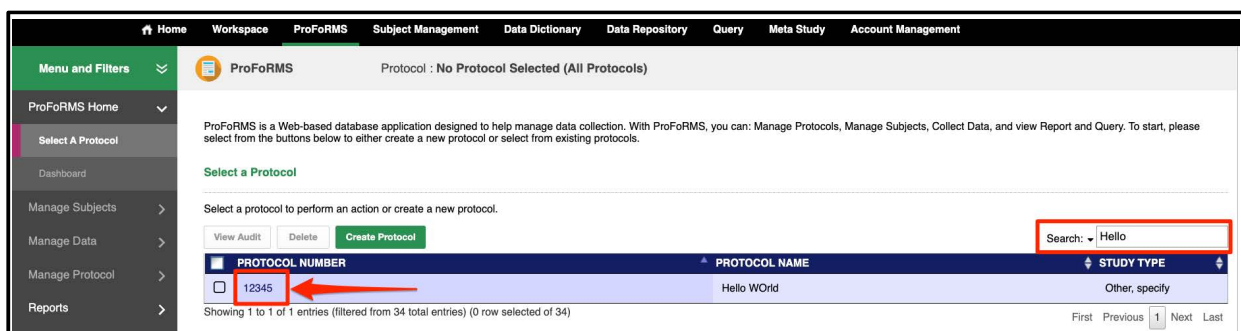
Searching and selecting a protocol in ProFoRMS.

#### Using the Search

1. Navigate to the ProFoRMS module
2. Select the **search box** at the top right of the **Select A Protocol** page.
  - a. After clicking the search box, you will see a drop-down list with check-boxes next to them. Currently you can search by **Protocol Number**, **Protocol Name**, or **Study Type**. You can deselect search fields you do not wish to search for.
3. The Protocol table will filter as you type your search into.



4. **Click** on the desired protocol. The system will load the selected protocol data including the list of subject visits.



### 3.6 MANAGE SUBJECTS

This section of ProFoRMS is designed to help you view the subjects in your protocol, add subjects to your protocol and schedule subject visits. The sub-sections available in the Manage Subjects menu are as follows:

- ❖ My Subjects
- ❖ Add Subject
- ❖ Schedule Visit

#### 3.6.1 My Subjects

The **My Subjects** page lists all subjects currently enrolled into the protocol. The user can sort the list of subjects by **GUID**, **Subject ID**, **Status**, **Validation**, and **Protocol**. The table also includes a simple search function.

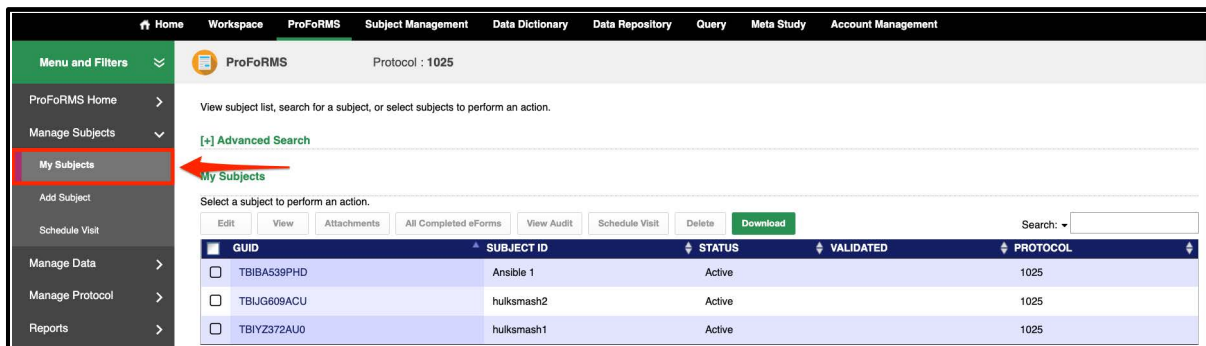
The table menu options allow the user to:

- ❖ View and edit subject’s information;
- ❖ View and upload subject related documents;
- ❖ View eForms completed for a selected subject;
- ❖ View the audit information;
- ❖ Schedule a visit;
- ❖ Delete selected subjects;
- ❖ Download table information; and
- ❖ Search for information in the table using a keyword

##### 3.6.1.1 Access My Subject

To access **My Subjects** page, perform the following actions:

1. Log into the system
2. Navigate to the **ProFoRMS** module
3. Select a protocol (see section [3.5.1](#))
  - a. **Note:** Many of the features on the left-hand side will not be active until a protocol is selected. If you are unable to select a protocol, please contact the Operations Team for assistance.
4. The ProFoRMS Dashboard opens. Click the **Manage Subjects** tab on the left-side tool bar.
5. Select the **My Subjects** page. The page will have a list that can be sorted by clicking on the arrows within each column header.
6. Select a subject to perform any desired action available in the table menu options.



### 3.6.2 Add Subject

To add a subject (research participant) to a protocol, the subject must be provided with a unique Identification number (ID). This is done by creating a Global Unique Identifier (GUID) in the Subject Management tool. The GUID serves as an ID that allows researchers to associate data with the subject without exposing or transferring the subject's Personally Identifiable Information (PII). For more information about the GUID, please refer to [Chapter 6 Subject Management](#).

To **Add Subject**, perform the following actions:

1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.
4. The **My Subjects** page appears.
5. Click the **Add Subject** tab on the left-side tool bar.
6. Select the subject that you want to add to the protocol from the subject table. Doing so will auto-populate the **GUID or Pseudo-GUID** field in the **Subject Information** section  
**NOTE:** If the subject does not have a GUID or Pseudo-GUID created in the system, click on the **Add Subject** button to launch the Subject Management tool and refer to the Subject Management user guide for directions on how to create a GUID.
7. Enter the **Protocol Subject ID**. This ID is unique across the system and is determined by the user and clinical site.

The screenshot displays the ProFoRMS interface for adding a subject to a protocol. The left sidebar shows the 'Add Subject' button highlighted in red. The main area shows a table of subjects with columns: ID, TYPE, ENTITY, ORGANIZATION REGISTERED BY, USER REGISTERED BY, DATE REGISTERED, and LINKED TO. The row for 'TBIDEMOKB275ZR0' is selected and highlighted in yellow. Below the table, the 'Subject Information' form is visible, with a red box highlighting the 'GUID or Pseudo-GUID' field (containing 'TBIDEMOKB275ZR0') and the 'Protocol Subject ID' field (containing '12345').

ID	TYPE	ENTITY	ORGANIZATION REGISTERED BY	USER REGISTERED BY	DATE REGISTERED	LINKED TO
TBIDEMO_INVUX373DKQ	PseudoGUID	FITBIR	NIH	portalAdminAutoQA, portalAdminAutoQA	2022-07-20	
TBIDEMO_INVNR005APU	PseudoGUID	FITBIR	NIH	Trudov, Alex	2022-06-29	TBIDEMORM115KMU
TBIDEMOHC132ZUW	GUID	FITBIR	NIH	Trudov, Alex	2022-05-11	TBIDEMO_INVDL399WRL
TBIDEMOUH009RLF	GUID	FITBIR	BRICS	Rutherford, John	2022-05-11	TBIDEMO_INVTE119KL2
TBIDEMOXJ179YKS	GUID	FITBIR	BRICS	Rutherford, John	2022-05-11	
TBIDEMO_INVAL372XWY	PseudoGUID	FITBIR	BRICS	Rutherford, John	2022-05-11	
TBIDEMOKB275ZR0	GUID	FITBIR	BRICS	Rutherford, John	2022-05-11	
TBIDEMOUR081KDB	GUID	FITBIR	BRICS	Rutherford, John	2022-05-11	
TBIDEMO_INVTE119KL2	PseudoGUID	FITBIR	BRICS	Rutherford, John	2022-05-11	TBIDEMOUH009RLF
TBIDEMO_INVFK004JWH	PseudoGUID	FITBIR	BRICS	Rutherford, John	2022-05-11	
TBIDEMOFD007MKE	GUID	FITBIR	BRICS	Rutherford, John	2022-05-11	
TBIDEMO_INVXT756YL4	PseudoGUID	FITBIR	NIH	johnson, mallisa x	2022-04-19	
TBIDEMOVU290XTM	GUID	FITBIR	NIH	Frouin, Jordane	2022-04-13	
TBIDEMO_INVFX348JG5	PseudoGUID	FITBIR	NIH	Frouin, Jordane	2022-04-08	
TBIDEMOYX966TYA	GUID	FITBIR	NIH	Frouin, Jordane	2022-04-08	

Showing 1 to 15 of 2,398 entries (1 row selected of 2398)

[-] Subject Information

\* This symbol indicates a required field

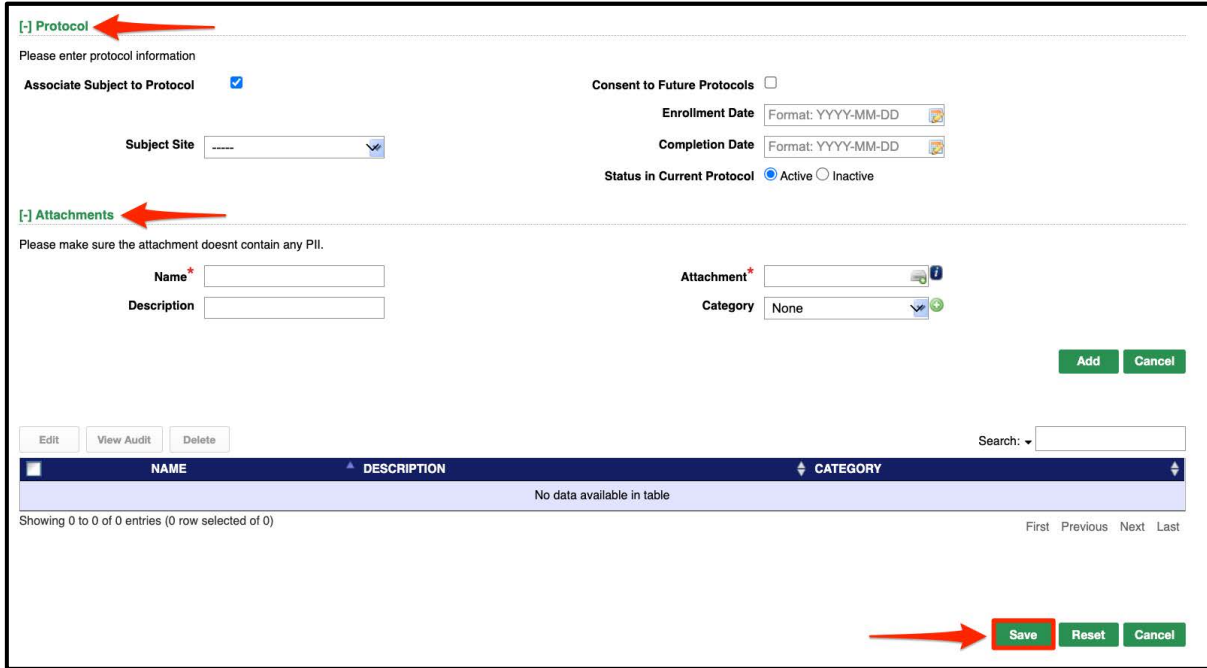
GUID or Pseudo-GUID\* TBIDEMOKB275ZR0

Additional Information Associated with Subject

Protocol Subject ID\* 12345

Recruited

- Expand the **Protocol** and **Attachments** section to add any relevant documents as required, making sure the attachment does not contain any PII.
- After entering all the required protocol information, click the **Save** button.



**[-] Protocol**

Please enter protocol information

Associate Subject to Protocol  Consent to Future Protocols

Enrollment Date  Completion Date

Subject Site  Status in Current Protocol  Active  Inactive

**[-] Attachments**

Please make sure the attachment doesn't contain any PII.

Name\*  Attachment\*

Description  Category

Search:

NAME	DESCRIPTION	CATEGORY
No data available in table		

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

- After selecting the **Save** button, the platform returns you to the **My Subjects** page where the newly added subject can be viewed.

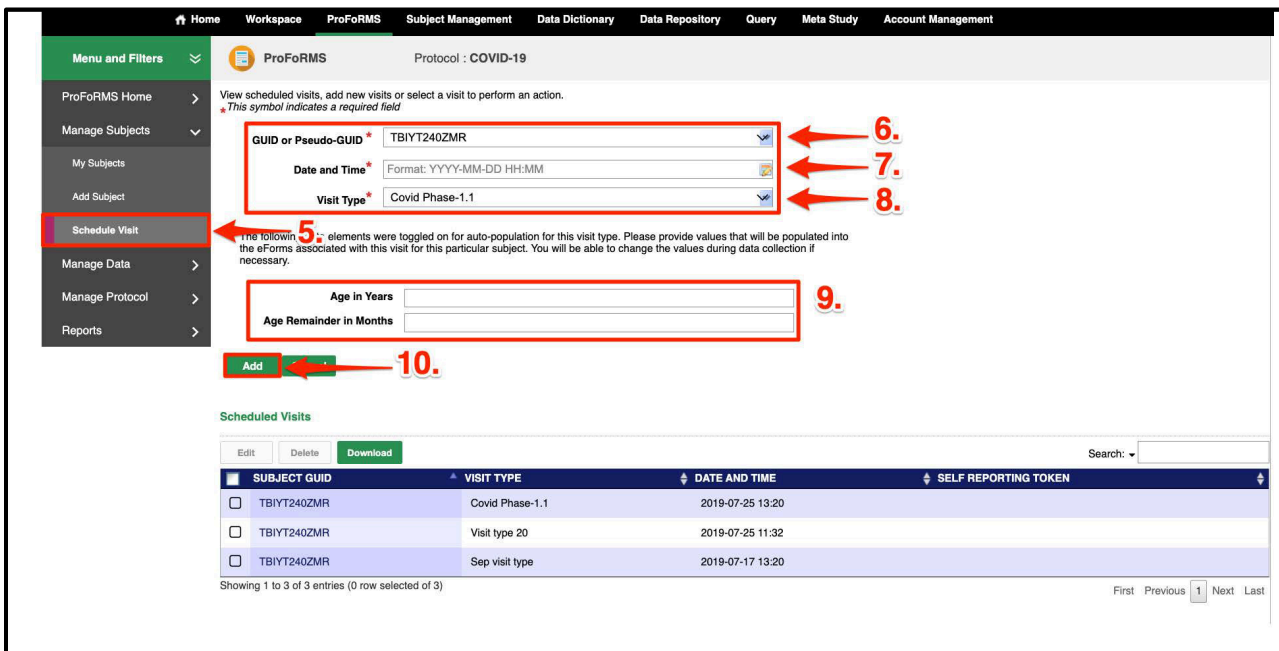


### 3.6.3 Schedule Visit

The **Schedule Visit** feature provides you with the ability to schedule visits as well as perform other functions such as **Edit** visits (see section 3.6.3.1) and **Delete** visits (see section 3.6.3.2).

To **Schedule a Visit**, perform the following actions:

1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.
4. The **My Subjects** page appears.
5. Click the **Schedule Visit** tab on the left-side tool bar.
6. Select the GUID or Pseudo-GUID of the subject you would like to schedule a visit for from the **GUID or Pseudo-GUID** drop-down menu.
7. Click the **Calendar** icon to choose the desired **Date and Time** for the visit.
8. Select the **Visit Type** from the drop-down menu.
9. After selecting the Visit Type, the **Age in Years** and **Age Remainder in Months** fields appear. If you enter data into these fields, this data will auto-populate on all data collection eForms for this Visit Type.
10. Click the **Add** button to finish “scheduling” the visit.



The screenshot shows the ProFoRMS interface for scheduling a visit. The left sidebar has 'Schedule Visit' highlighted. The main area contains a form with the following fields and callouts:

- 5:** Points to the 'Schedule Visit' button in the sidebar.
- 6:** Points to the 'GUID or Pseudo-GUID' dropdown menu.
- 7:** Points to the 'Date and Time' field with a calendar icon.
- 8:** Points to the 'Visit Type' dropdown menu.
- 9:** Points to the 'Age in Years' and 'Age Remainder in Months' input fields.
- 10:** Points to the 'Add' button at the bottom of the form.

Below the form is a table titled 'Scheduled Visits' with the following data:

SUBJECT GUID	VISIT TYPE	DATE AND TIME	SELF REPORTING TOKEN
<input type="checkbox"/> TBIYT240ZMR	Covid Phase-1.1	2019-07-25 13:20	
<input type="checkbox"/> TBIYT240ZMR	Visit type 20	2019-07-25 11:32	
<input type="checkbox"/> TBIYT240ZMR	Sep visit type	2019-07-17 13:20	

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

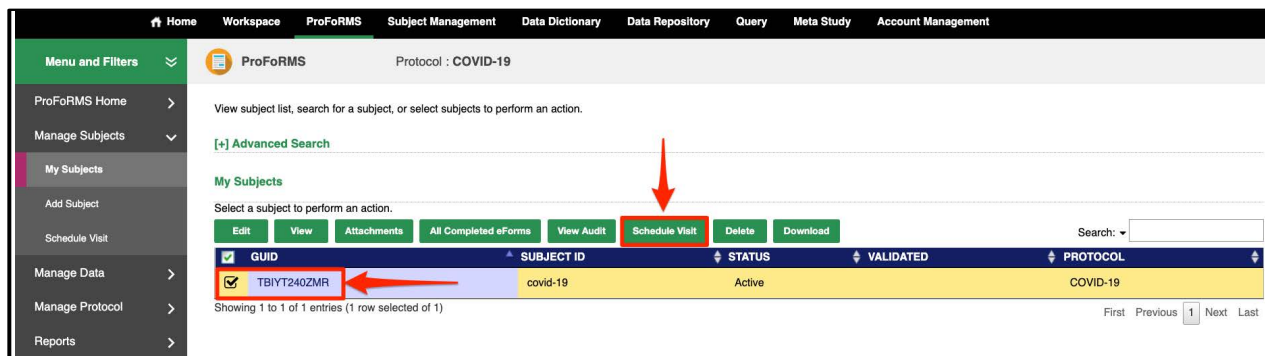
11. The newly scheduled visit will be displayed in the **Schedule Visit** table and will include a list of all visits that have been scheduled for subjects on the protocol.



**\*NOTE:** you may also schedule a visit for a specific subject by selecting a subject on the **My Subjects** page (which will enable numerous table buttons for use) and selecting the **Schedule Visit** button located at the top of the table.

This will direct you to the **Schedule Visit** page with the **GUID** or **Pseudo-GUID** field prepopulated with the subject's ID you selected.

This step is recommended as the user can search/filter for a specific GUID through the search bar instead of searching for the GUID using the drop-down menu



The screenshot displays the ProFoRMS interface for the COVID-19 protocol. The 'My Subjects' section shows a table with the following data:

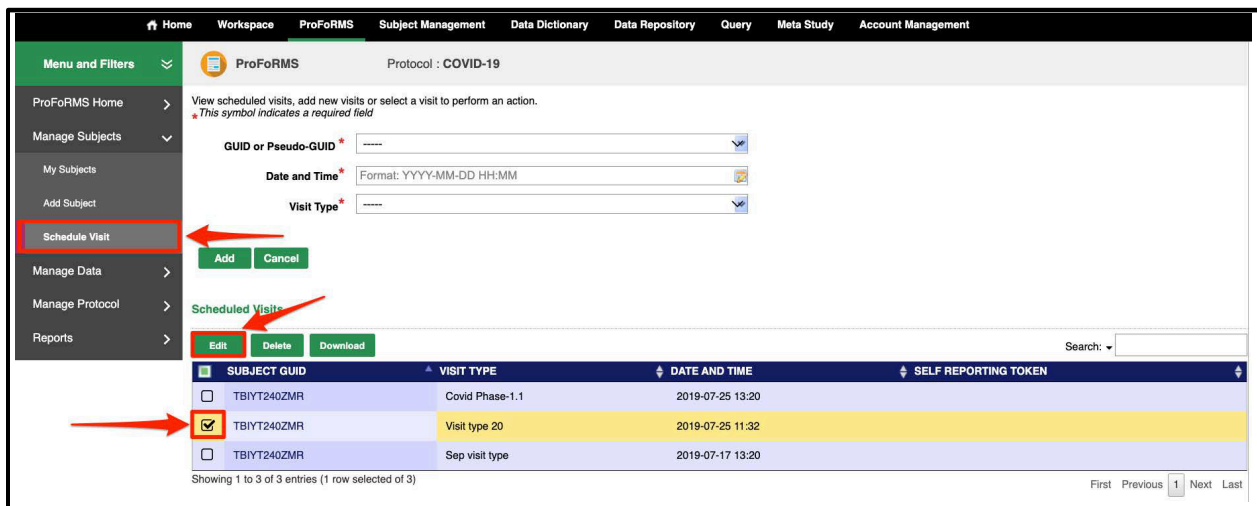
GUID	SUBJECT ID	STATUS	VALIDATED	PROTOCOL
TBIYT240ZMR	covid-19	Active		COVID-19

Navigation buttons include Edit, View, Attachments, All Completed eForms, View Audit, Schedule Visit, Delete, and Download. The 'Schedule Visit' button is highlighted with a red arrow. The selected subject row is also highlighted with a red arrow.

### 3.6.3.1 Editing Scheduled Visits

To **Edit** scheduled visits, perform the following actions:

1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.
4. The **My Subjects** page appears.
5. Click the **Schedule Visit** tab on the left-side tool bar.
6. The **Schedule Visit** table appears where you can **View Scheduled Visits**, **Add New Visits**, or **Select a Visit** to perform an action.
7. Select the **Subject GUID** and the corresponding **Visit Type** from the table, that you would like to edit, then select the **Edit** button at the top of the table



The screenshot shows the ProFoRMS interface for Protocol: COVID-19. The left sidebar has 'Schedule Visit' highlighted. The main content area includes a form for adding a visit with fields for 'GUID or Pseudo-GUID', 'Date and Time' (Format: YYYY-MM-DD HH:MM), and 'Visit Type'. Below the form is a 'Scheduled Visits' table with columns: SUBJECT GUID, VISIT TYPE, DATE AND TIME, and SELF REPORTING TOKEN. The table contains three rows, with the second row selected. The 'Edit' button in the table's action bar is highlighted with a red box and an arrow. The selected row shows Subject GUID TBIYT240ZMR, Visit Type 'Visit type 20', and Date and Time 2019-07-25 11:32.

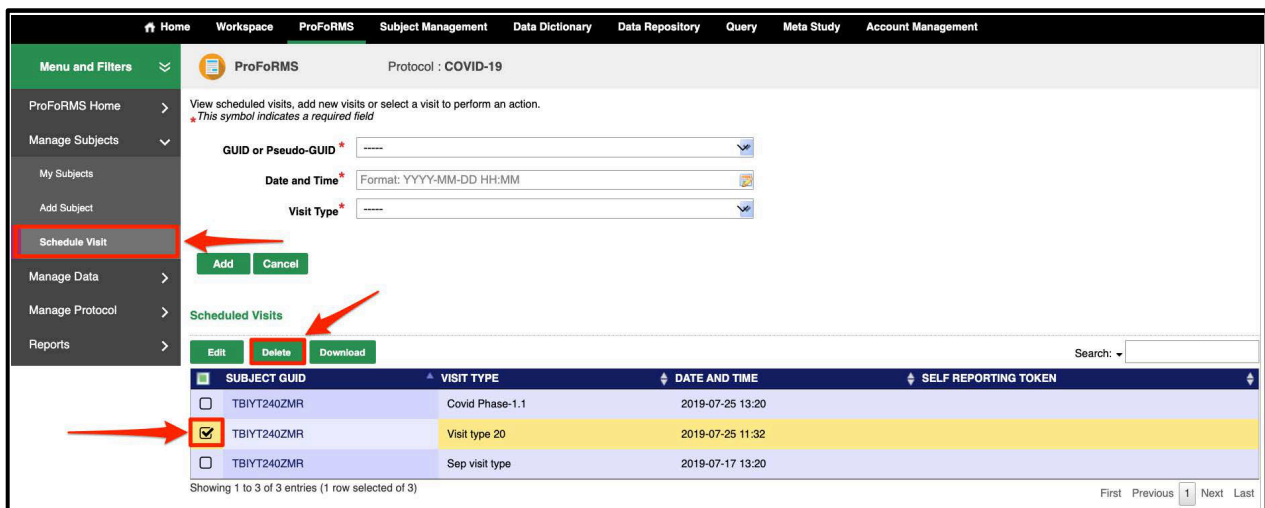
SUBJECT GUID	VISIT TYPE	DATE AND TIME	SELF REPORTING TOKEN
<input type="checkbox"/> TBIYT240ZMR	Covid Phase-1.1	2019-07-25 13:20	
<input checked="" type="checkbox"/> TBIYT240ZMR	Visit type 20	2019-07-25 11:32	
<input type="checkbox"/> TBIYT240ZMR	Sep visit type	2019-07-17 13:20	

8. Make desired edits to the **Date and Time** and **Visit Type** fields then select the **Update** button to complete the edit action.
9. The newly updated **Scheduled Visit** will be displayed in the **Schedule Visit** table.

### 3.6.3.2 Deleting Scheduled Visits

To **Delete** scheduled visits, perform the following actions:

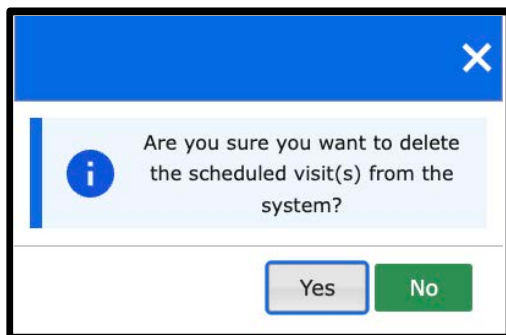
1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.
4. The **My Subjects** page appears.
5. Click the **Schedule Visit** tab on the left-side tool bar.
6. The **Schedule Visit** table appears where you can **View Scheduled Visits**, **Add New Visits**, or **Select a Visit** to perform an action.
7. Select the **Subject GUID** and the corresponding **Visit Type** from the table, that you would like to delete, then select the **Delete** button at the top of the table



The screenshot shows the ProFoRMS interface for Protocol: COVID-19. The left sidebar has 'Schedule Visit' highlighted. The main area shows a form for adding visits and a table of 'Scheduled Visits'. The table has columns: SUBJECT GUID, VISIT TYPE, DATE AND TIME, and SELF REPORTING TOKEN. The second row is selected, and the 'Delete' button is highlighted.

SUBJECT GUID	VISIT TYPE	DATE AND TIME	SELF REPORTING TOKEN
<input type="checkbox"/> TBIYT240ZMR	Covid Phase-1.1	2019-07-25 13:20	
<input checked="" type="checkbox"/> TBIYT240ZMR	Visit type 20	2019-07-25 11:32	
<input type="checkbox"/> TBIYT240ZMR	Sep visit type	2019-07-17 13:20	

8. A pop-up notification appears asking if you would like to delete the scheduled visit(s) from the system:



9. Select the **Yes** button to confirm that you want to delete the scheduled visit(s) from the system. Select the **No** button to cancel the update process.
10. The deleted visit will be removed from the **Schedule Visit** table.

## 3.7 COLLECT DATA

This feature allows researchers to collect data for subjects and/or specific eForms to add data or modify previously collected data entries, to view and resolve data discrepancies if double data entry is specified, perform quality assurance of collected data and monitor subject safety. The module has a functionality that assures that changes are tracked in the system and can be viewed in Audit Logs.

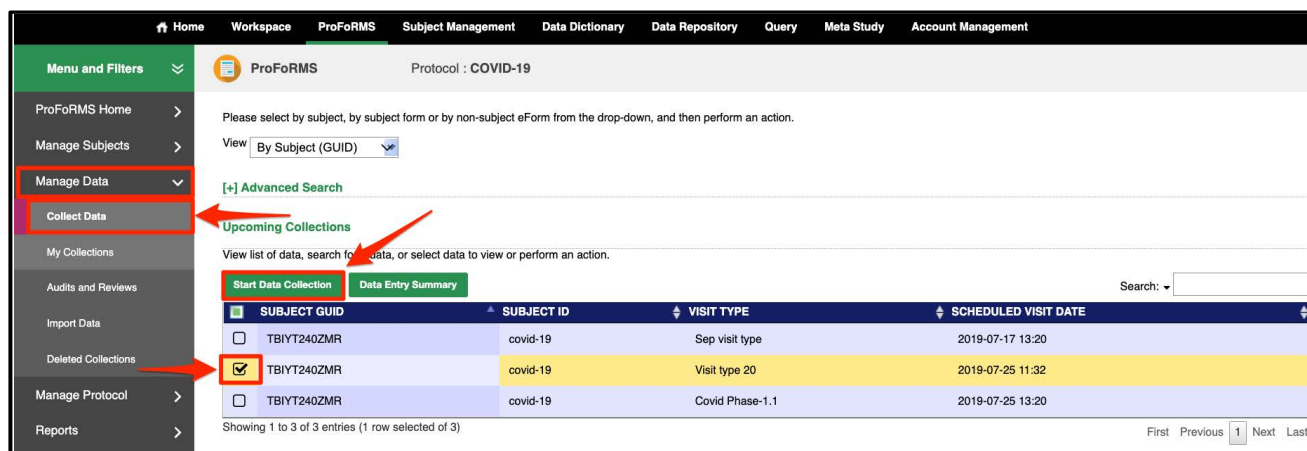
Clinical data may be captured electronically at its source, or in paper form and later transcribed into the system. There are two options for collecting data in ProFoRMS.

1. Real-time data entry method; and
2. Pen and paper method, which is then transcribed into ProFoRMS at a later date

### 3.7.1 Data Collection

To start **Data Collection**, perform the following actions:

1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Click the **Collect Data** tab on the left-side tool bar.
4. The **Data Collection** page appears.
5. To start data collection, select the check-box beside the Subject GUID/Subject ID then select the **Start Data Collection** button.
  - a. **Note:** we recommend that you exclusively use ProFoRMS navigation buttons and links within the Collect Data tab. Leaving the form by any other method (back/forward buttons, backspace key, etc.) may result in data loss and unexpected errors. We also recommend that you do not open multiple database tabs in your browser when collecting data.

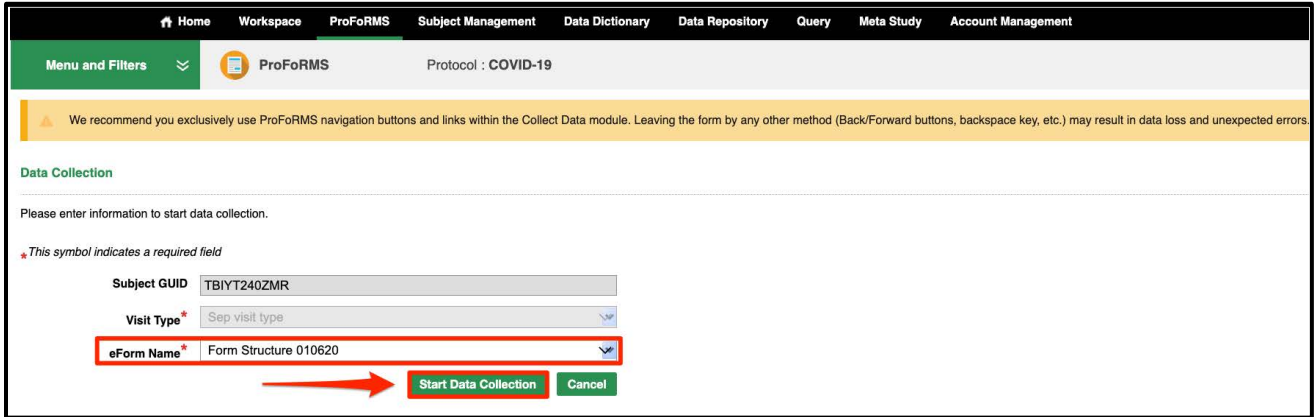


The screenshot displays the ProFoRMS interface for data collection. The left sidebar contains a 'Menu and Filters' section with 'Collect Data' highlighted. The main content area shows the 'ProFoRMS' dashboard for Protocol: COVID-19. It includes a search bar, a table of data entries, and a 'Start Data Collection' button. The table has the following data:

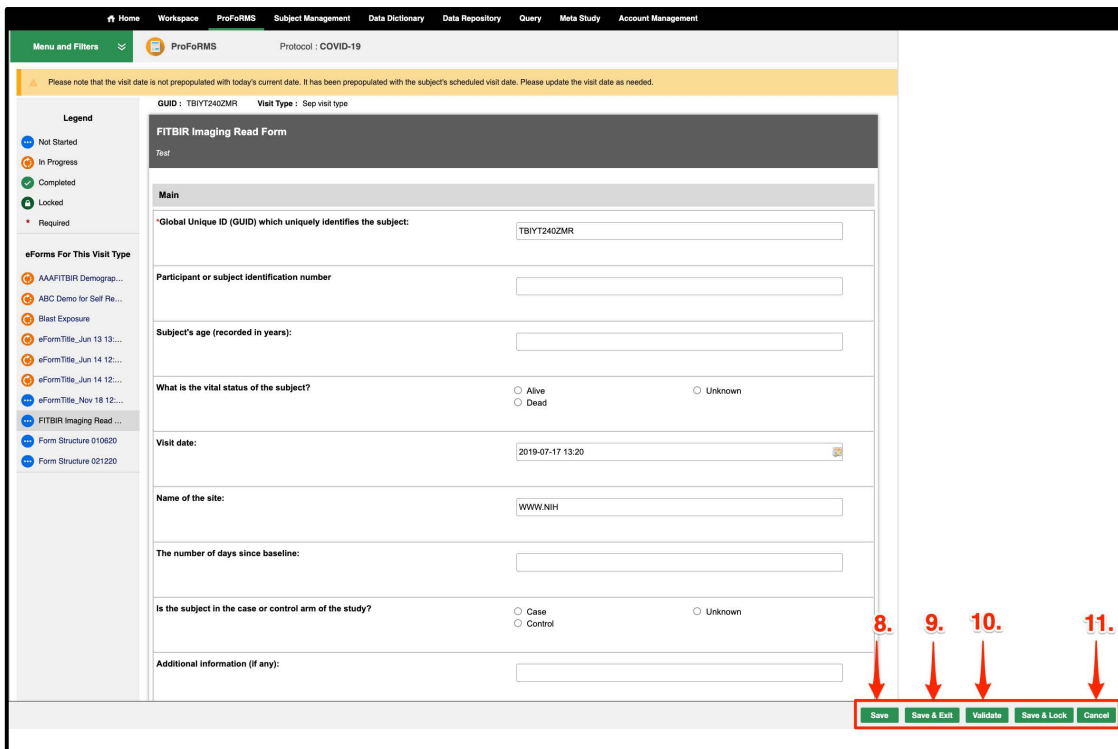
SUBJECT GUID	SUBJECT ID	VISIT TYPE	SCHEDULED VISIT DATE
<input type="checkbox"/> TBIYT240ZMR	covid-19	Sep visit type	2019-07-17 13:20
<input checked="" type="checkbox"/> TBIYT240ZMR	covid-19	Visit type 20	2019-07-25 11:32
<input type="checkbox"/> TBIYT240ZMR	covid-19	Covid Phase-1.1	2019-07-25 13:20

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

6. Select the **eForm Name** from the drop-down list that you want to collect data for, then select **Start Data Collection**.
  - a. **Note:** Subject GUID and Visit Type are auto-populated



7. Enter data into the form and make sure all mandatory fields (marked with an asterisk\*) are completed.
8. Select **Save** to save your progress on the form.
9. Select **Validate** to validate and confirm you are completing the fields properly.
10. Select **Save & Exit** to save your progress on the form and leave the eForm data collection page. You will then be directed back to the **My Collections** page.
  - a. Your form will show a status of “In Progress” in the My Collections table.
11. Select **Cancel** when you want to leave the form and not save any work.



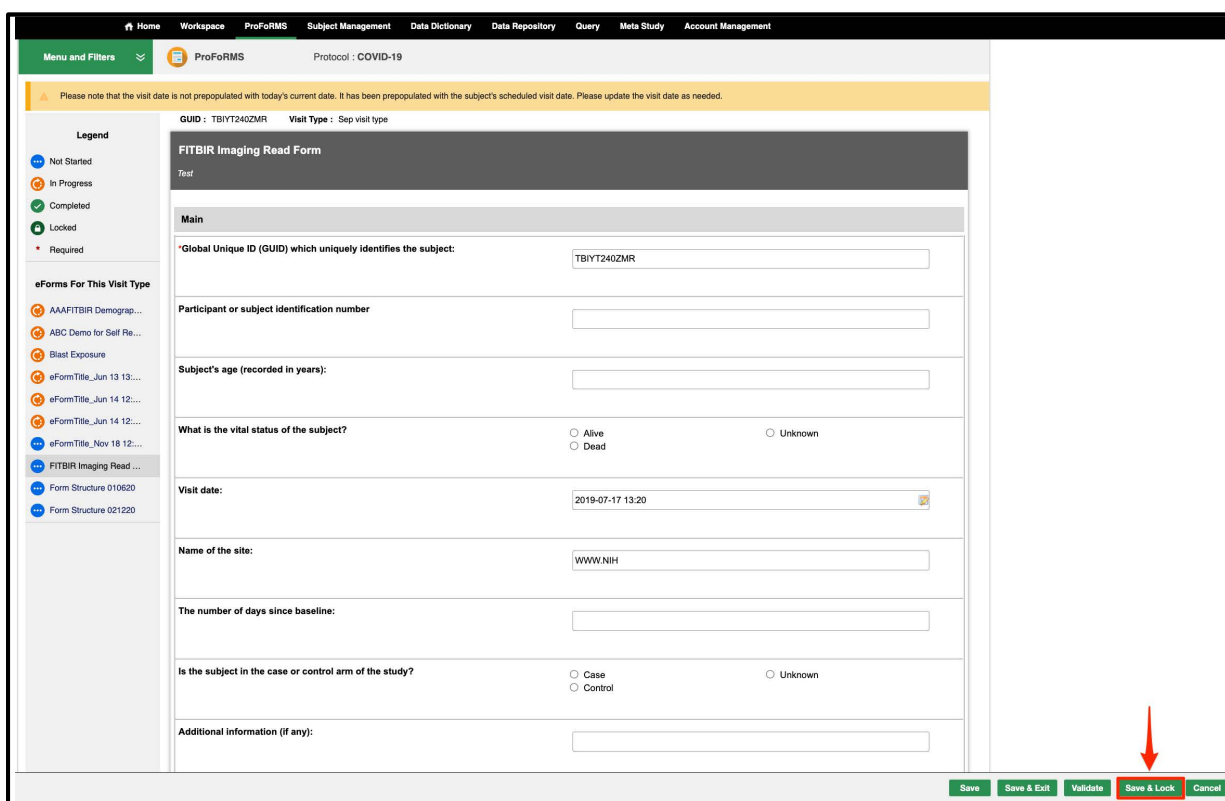
### 3.7.1.1 Locking the eForm

After you have filled out the eForm and verified that the data is complete and accurate, you can **Save & Lock** the eForm. eForms should not be locked until reviewed and ready for final submission.

After the eForm is **Saved & Locked** the data will be added to the **Data Repo** and can be accessed using the **Query Tool**.

To **Save & Lock** your eForm, perform the following actions:

1. Select the GUID and form you want to lock from the My Collections table and make sure the eForm is complete and accurate.
2. Select the **Save & Lock** button.



The screenshot shows the ProFoRMS interface for a 'FITBIR Imaging Read Form'. The form is titled 'FITBIR Imaging Read Form' and is currently in a 'Test' state. The GUID is 'TBIYT240ZMR' and the Visit Type is 'Sep visit type'. The form contains several fields: 'Global Unique ID (GUID) which uniquely identifies the subject' (filled with TBIYT240ZMR), 'Participant or subject identification number', 'Subject's age (recorded in years)', 'What is the vital status of the subject?' (radio buttons for Alive, Dead, Unknown), 'Visit date' (2019-07-17 13:20), 'Name of the site' (WWW.NIH), 'The number of days since baseline', 'Is the subject in the case or control arm of the study?' (radio buttons for Case, Control, Unknown), and 'Additional information (if any)'. At the bottom right, there are five buttons: 'Save', 'Save & Exit', 'Validate', 'Save & Lock', and 'Cancel'. A red arrow points to the 'Save & Lock' button.

3. A **Collect Data Lock Confirmation** notification will appear asking you to confirm that all data entry for the form is accurate and complete to the best of your knowledge.
4. Select the checkbox to confirm.
  - a. If the e-signature is enabled in the protocol, you will also be asked for your electronic signature by inputting your password.

**Collect Data Lock Confirmation - Signature Required**

**Protocol Name:** Covid-19 Study  
**eForm Name:** FITBIR Imaging Read Form  
**Subject GUID:** TBIYT240ZMR  
**Collection Visit Date:** 2019-07-17 13:20  
**Scheduled Visit Date:** 2019-07-17 13:20  
**Visit Type:** Sep visit type  
**Data Entered By:** rutherfordjdp

I hereby confirm that all data entry for this form is accurate and complete to the best of my knowledge.

**Name:** John Rutherford

Enter your password to complete the form.


**Password:**


5. Select **Lock & Next eForm** to continue collecting data for the study visit or select **Lock & Exit** to be taken back to the My Collections page.
  - a. Your eForm will show a status of “**Locked**” and will have a locked date and time in the My Collections table.

### THINGS TO NOTE:






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#### ICON KEY

 Notes

 Important  
Information

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-  To reset the questions on the eform, double-click on the Radio buttons
-  To save the eform, use the **Save** button at the bottom of the eform
-  To cancel the data collection process, simply click on the **Cancel** button
-  All Required fields are marked by **red asterisks**
-  Certain questions are greyed-out by **Skip logic**

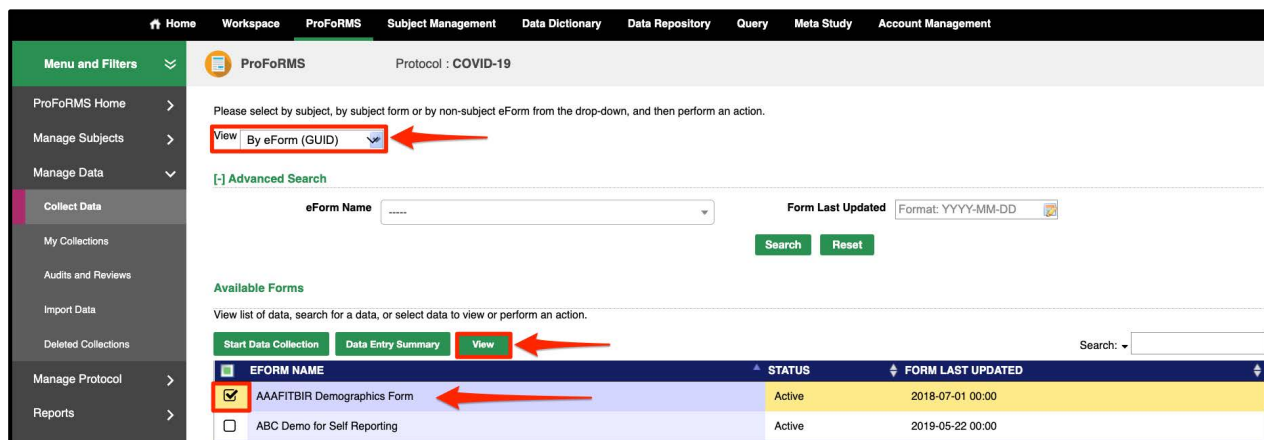
-  Auto-calculated fields appear in several forms. Answers will appear if you click on them, but it is **NOT** necessary to save the eform.
-  Green sections are collapsible. User can expand/hide to read further instructions or view scoring sections.
-  To leave the form and complete it at a later date and time, use the **Save & Exit** button

### 3.7.1.2 Viewing Data Collection eForms

There are two ways to view Data Collection eForms using the **Collect Data** or **My Collections** pages.

#### Collect Data Page:

1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Select the **Collect Data** tab on the left-side tool bar.
4. The **Data Collection** page appears.
5. Select **By eForm (GUID)** from the View drop-down
6. Select the **eForm Name** link OR select the check-box next to the **eForm Name** you want to view then select **View**



Protocol : COVID-19

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

View: By eForm (GUID)

Advanced Search

eForm Name: [ ] Form Last Updated: [Format: YYYY-MM-DD]

Search [ ] Reset [ ]

Available Forms

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

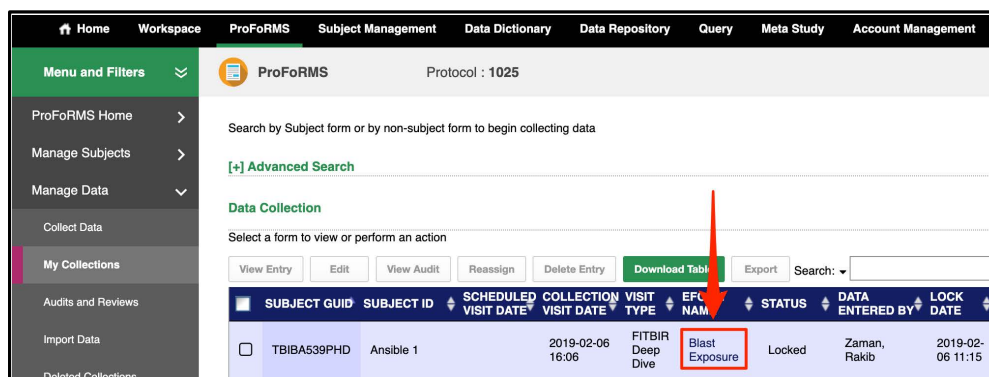
Start Data Collection [ ] Data Entry Summary [ ] View [ ]

<input type="checkbox"/>	EFORM NAME	STATUS	FORM LAST UPDATED
<input checked="" type="checkbox"/>	AAAFITBIR Demographics Form	Active	2018-07-01 00:00
<input type="checkbox"/>	ABC Demo for Self Reporting	Active	2019-05-22 00:00

7. A new tab will open in your browser displaying the eForm details in **View Mode**
8. You can view the data **By Subject (GUID)**, or **By eForm (GUID)**. Depending on the view you selected, the table will display either the list of subjects, or the list of eForms.

#### My Collections Page:

1. Repeat steps 1 and 2 from above.
2. Select the **My Collections** tab on the left-side tool bar.
3. The **My Collections** page appears.
4. Select the **eForm name** you wish to view inside of the table.



Protocol : 1025

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 [ ] Download Table [ ] Export [ ] Search: [ ]

<input type="checkbox"/>	SUBJECT GUID	SUBJECT ID	SCHEDULED VISIT DATE	COLLECTION VISIT DATE	VISIT TYPE	EFORM NAME	STATUS	DATA ENTERED BY	LOCK DATE
<input type="checkbox"/>	TBIBA539PHD	Ansible 1	2019-02-06 16:06	2019-02-06 16:06	FITBIR Deep Dive	Blast Exposure	Locked	Zaman, Rakib	2019-02-06 11:15

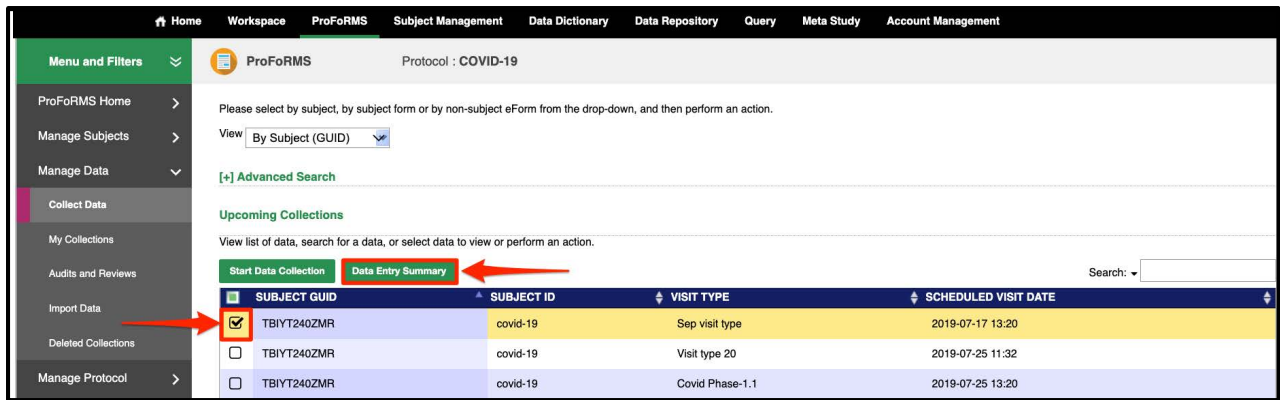


### 3.7.1.3 Viewing Data Entry Summary

**Data Entry Summary** allows the user to view all data collected for a subject at one time in the My Collections table.

To view the **Data Entry Summary**, perform the following actions:

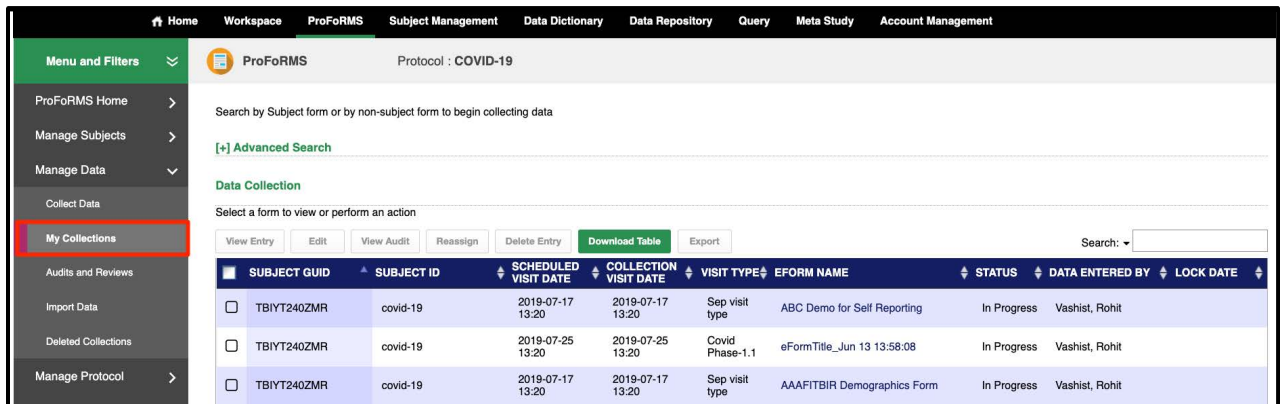
1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Select the **Collect Data** tab on the left-side tool bar.
4. The **Data Collection** page appears.
5. Select the check-box next to the **Subject GUID** that you are interested in viewing then select **Data Entry Summary**



The screenshot shows the ProFoRMS interface for Protocol: COVID-19. The left sidebar has 'My Collections' selected. The main area shows 'Upcoming Collections' with a table of subjects. The 'Data Entry Summary' button is highlighted in red, and a red arrow points to the first row's checkbox in the table.

SUBJECT GUID	SUBJECT ID	VISIT TYPE	SCHEDULED VISIT DATE	
<input checked="" type="checkbox"/>	TBIYT240ZMR	covid-19	Sep visit type	2019-07-17 13:20
<input type="checkbox"/>	TBIYT240ZMR	covid-19	Visit type 20	2019-07-25 11:32
<input type="checkbox"/>	TBIYT240ZMR	covid-19	Covid Phase-1.1	2019-07-25 13:20

6. You will then be brought to the **My Collections** table where all of the started and completed data collections will appear.



The screenshot shows the 'My Collections' table in ProFoRMS. The table lists data collection entries with columns for Subject GUID, Subject ID, Scheduled Visit Date, Collection Visit Date, Visit Type, EForm Name, Status, Data Entered By, and Lock Date.

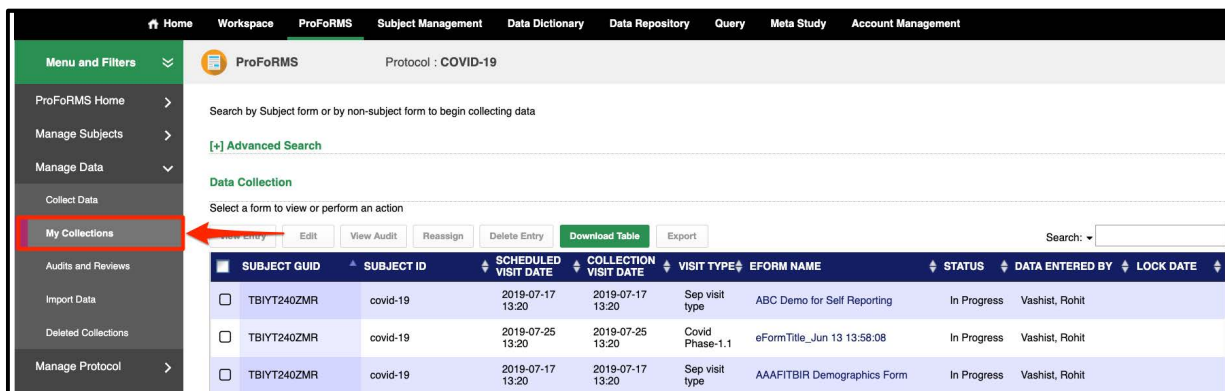
SUBJECT GUID	SUBJECT ID	SCHEDULED VISIT DATE	COLLECTION VISIT DATE	VISIT TYPE	EFORM NAME	STATUS	DATA ENTERED BY	LOCK DATE
<input type="checkbox"/>	TBIYT240ZMR	2019-07-17 13:20	2019-07-17 13:20	Sep visit type	ABC Demo for Self Reporting	In Progress	Vashist, Rohit	
<input type="checkbox"/>	TBIYT240ZMR	2019-07-25 13:20	2019-07-25 13:20	Covid Phase-1.1	eFormTitle_Jun 13 13:58:08	In Progress	Vashist, Rohit	
<input type="checkbox"/>	TBIYT240ZMR	2019-07-17 13:20	2019-07-17 13:20	Sep visit type	AAAFITBIR Demographics Form	In Progress	Vashist, Rohit	

### 3.7.2 My Collections

The **My Collections** page displays a table with all of the clinical assessments or eForms that were collected for a subject in the selected Protocol.

To view the **My Collections** page, perform the following actions:

1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Select the **Collect Data** tab on the left-side tool bar.
4. The **Data Collection** page appears.
5. Select the **My Collections** tab



<input type="checkbox"/>	SUBJECT GUID	SUBJECT ID	SCHEDULED VISIT DATE	COLLECTION VISIT DATE	VISIT TYPE	EFORM NAME	STATUS	DATA ENTERED BY	LOCK DATE
<input type="checkbox"/>	TBIYT240ZMR	covid-19	2019-07-17 13:20	2019-07-17 13:20	Sep visit type	ABC Demo for Self Reporting	In Progress	Vashist, Rohit	
<input type="checkbox"/>	TBIYT240ZMR	covid-19	2019-07-25 13:20	2019-07-25 13:20	Covid Phase-1.1	eFormTitle_Jun 13 13:58:08	In Progress	Vashist, Rohit	
<input type="checkbox"/>	TBIYT240ZMR	covid-19	2019-07-17 13:20	2019-07-17 13:20	Sep visit type	AAAFITBIR Demographics Form	In Progress	Vashist, Rohit	

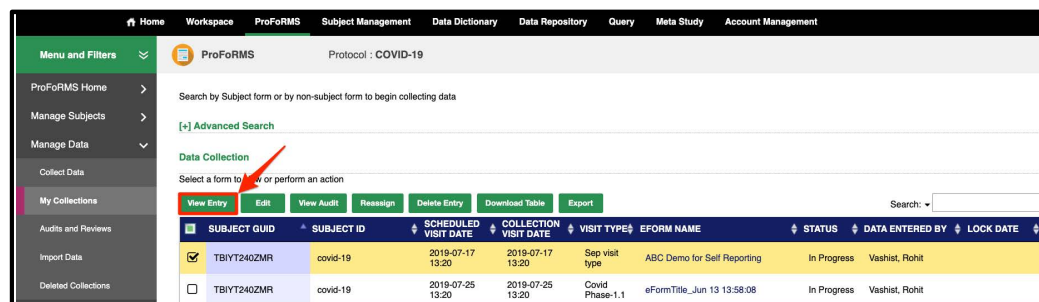
A user can perform the following actions in the **My Collections** table:

- ❖ View Entry ([section 3.7.2.1](#));
- ❖ Edit (section 3.7.2.2);
- ❖ View Audit (section 3.7.2.3);
- ❖ Reassign (section 3.7.2.4);
- ❖ Delete Entry (section 3.7.2.5); and
- ❖ Export (section 3.7.2.6)

#### 3.7.2.1 View Entry

To **View Entry** or eForm information, perform the following actions:

1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in viewing, then select **View Entry**.
3. The **eForm View Mode** will open, displaying the data that has been entered on the eForm.

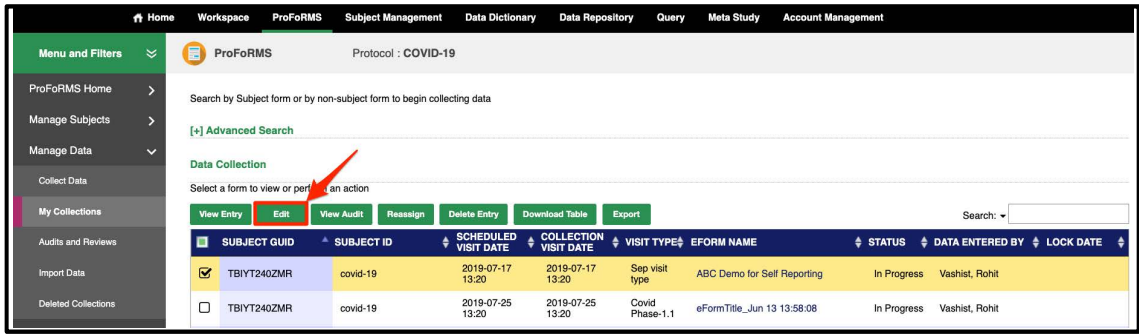


<input checked="" type="checkbox"/>	SUBJECT GUID	SUBJECT ID	SCHEDULED VISIT DATE	COLLECTION VISIT DATE	VISIT TYPE	EFORM NAME	STATUS	DATA ENTERED BY	LOCK DATE
<input checked="" type="checkbox"/>	TBIYT240ZMR	covid-19	2019-07-17 13:20	2019-07-17 13:20	Sep visit type	ABC Demo for Self Reporting	In Progress	Vashist, Rohit	
<input type="checkbox"/>	TBIYT240ZMR	covid-19	2019-07-25 13:20	2019-07-25 13:20	Covid Phase-1.1	eFormTitle_Jun 13 13:58:08	In Progress	Vashist, Rohit	

### 3.7.2.2 Edit eForm

To **Edit eForm**, perform the following actions:

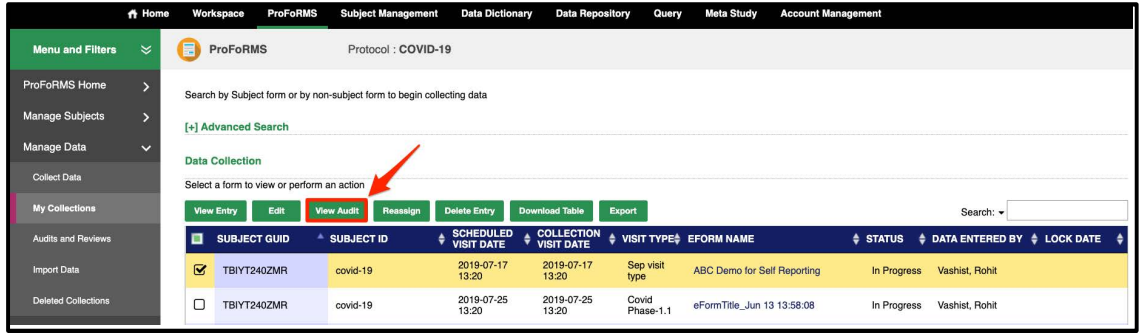
1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in editing, then select **Edit**.
  - a. **Note:** non-admin users are only able to edit forms with an **In Progress** or **Completed** status. If your form is showing a **Locked** status and you need to make edits, reach out to the Operations Team for assistance.



### 3.7.2.3 View Audit

To **View Audit**, perform the following actions:

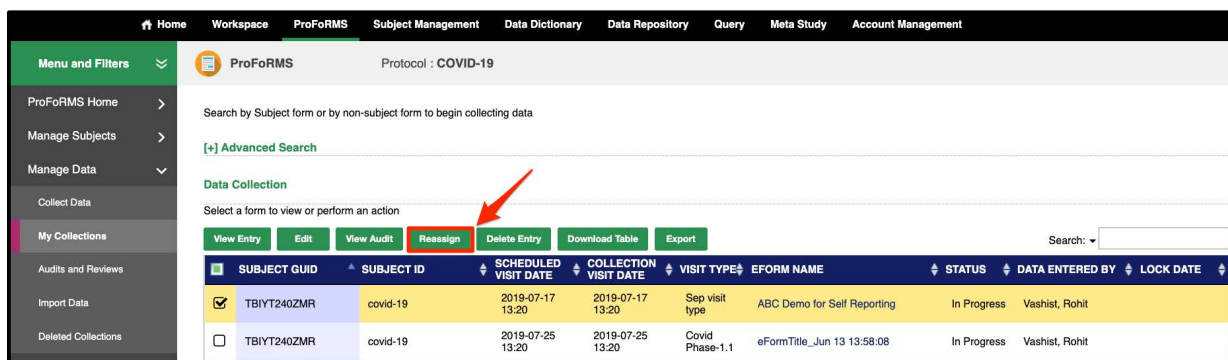
1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in viewing, then select **View Audit**.
3. A new browser page will open with the **Data Collection Audit Log** details.



### 3.7.2.4 Reassign eForm

To **Reassign** an eForm, perform the following actions:

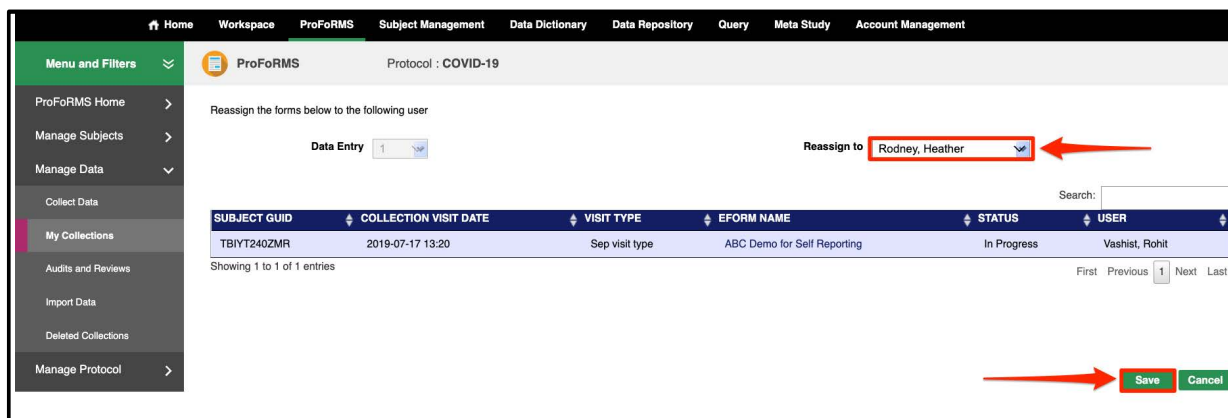
1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in reassigning, then select **Reassign**.
  - a. **Note:** the ability to assign the form to another user for editing are limited to:
    - i. *Global Admin Users;*
    - ii. *Non-Admin Users with Primary Investigator (PI) Role;*
    - iii. *Non-Admin Users with Clinical Coordinators Role;*
    - iv. *Non-Admin Users with Study QA Role; and*
    - v. *Non-Admin Users with a role that has the privileges to Reassign Data Entry*



The screenshot shows the ProFoRMS interface for Protocol: COVID-19. The 'Data Collection' section is active, and the 'Reassign' button is highlighted with a red arrow. Below the buttons is a table with columns: SUBJECT GUID, SUBJECT ID, SCHEDULED VISIT DATE, COLLECTION VISIT DATE, VISIT TYPE, EFORM NAME, STATUS, DATA ENTERED BY, and LOCK DATE. Two rows are visible, with the first row selected.

SUBJECT GUID	SUBJECT ID	SCHEDULED VISIT DATE	COLLECTION VISIT DATE	VISIT TYPE	EFORM NAME	STATUS	DATA ENTERED BY	LOCK DATE
<input checked="" type="checkbox"/>	TBIYT240ZMR	covid-19	2019-07-17 13:20	2019-07-17 13:20	Sep visit type	ABC Demo for Self Reporting	In Progress	Vashist, Rohit
<input type="checkbox"/>	TBIYT240ZMR	covid-19	2019-07-25 13:20	2019-07-25 13:20	Covid Phase-1.1	eFormTitle_Jun 13 13:58:08	In Progress	Vashist, Rohit

3. The **Reassign** data entry page appears.
4. Using the drop-down menu, select the desired user to reassign the eForm to, then select **Save**.
5. The **My Collections** page appears with the reassigned form update.



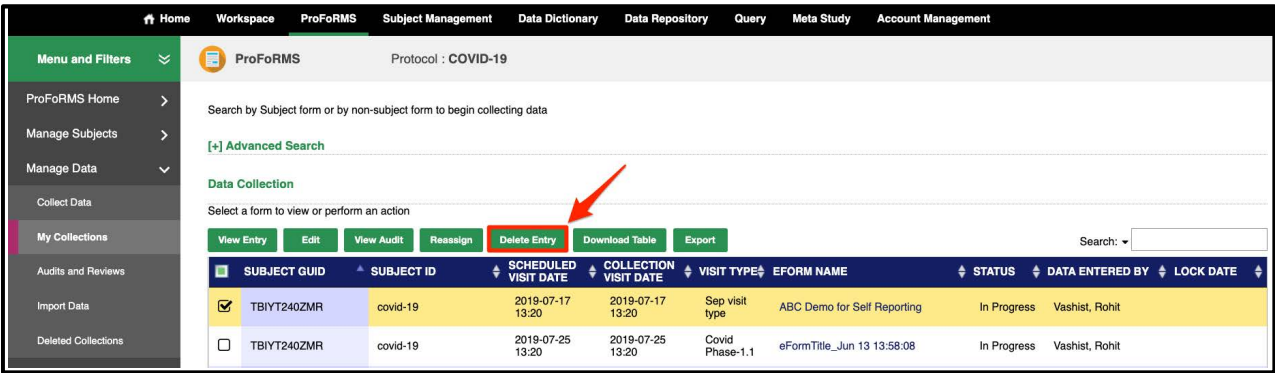
The screenshot shows the 'Reassign' data entry page. The 'Reassign to' dropdown menu is open, and 'Rodney, Heather' is selected, highlighted with a red box and a red arrow. Below the dropdown is a table with columns: SUBJECT GUID, COLLECTION VISIT DATE, VISIT TYPE, EFORM NAME, STATUS, and USER. The table contains one entry for TBIYT240ZMR. At the bottom right, the 'Save' button is highlighted with a red arrow.

SUBJECT GUID	COLLECTION VISIT DATE	VISIT TYPE	EFORM NAME	STATUS	USER
TBIYT240ZMR	2019-07-17 13:20	Sep visit type	ABC Demo for Self Reporting	In Progress	Vashist, Rohit

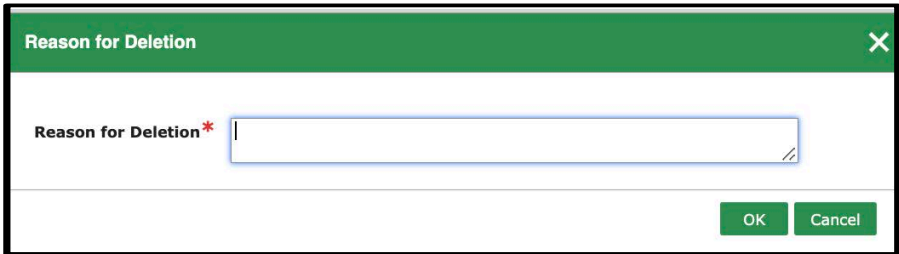
### 3.7.2.5 Delete Entry

To **Delete** an eForm entry, perform the following actions:

1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in deleting, then select **Delete Entry**.
  - a. **Note:** non-admin users are only able to delete forms with an **In Progress** or **Completed** status. If your form is showing a **Locked** status and you need to delete the form, reach out to the Operations Team for assistance.



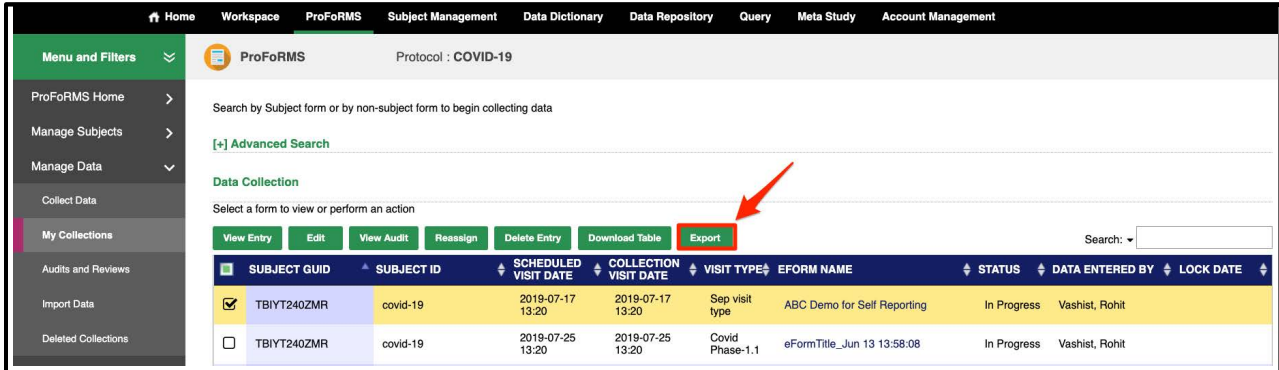
3. Enter your reason for deleting the entry and click **OK**.
4. The My Collections page appears with the confirmation of the deleted eForm.



### 3.7.2.6 Export Data

To **Export** data, perform the following actions:

1. Perform steps 1-6 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in exporting, then select **Export**.
  - a. **Note:** only forms with a **Locked** status can be exported
3. When prompted, select **OK** to open the CSV file.

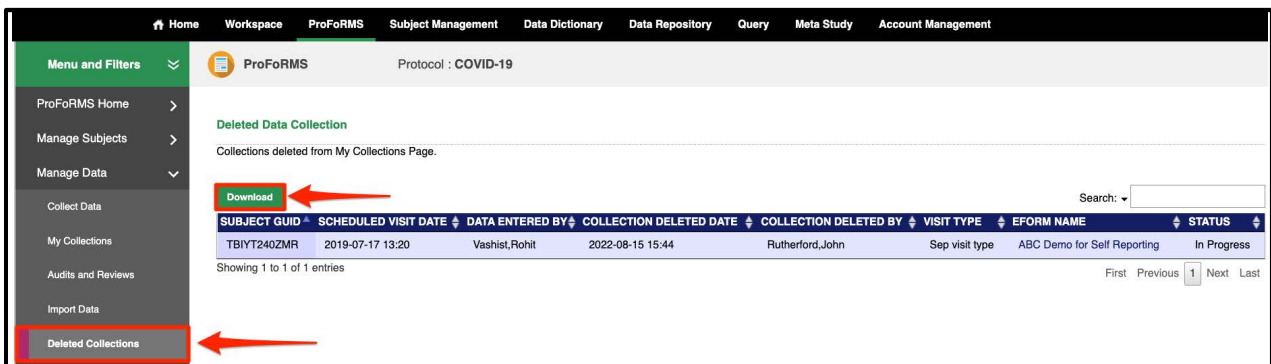


### 3.7.3 Deleted Collections

The **Deleted Collections** page displays a table with any eForm data collections that were deleted from the **My Collections** table.

To view the **Deleted Collections** page, perform the following actions:

1. Navigate to the **ProFoRMS** module.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Select the **Collect Data** tab on the left-side tool bar.
4. The **Data Collection** page appears.
5. Select the **Deleted Collections** tab
6. Select the **Download** button to download an Excel or CSV file of the **Deleted Data Collection** table





## 3.8 MANAGE PROTOCOL

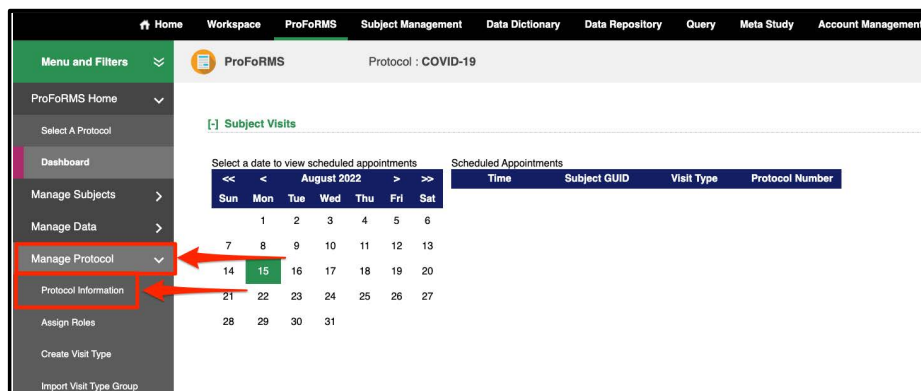
This feature is designed to help the researchers to add and edit study information, schedule create study visits, manage visit types individual subjects across multiple studies within the system, upload subject related document. The sub-sections available in the Manage Subjects menu are as follows:

- ❖ Protocol Information
- ❖ Assign Roles
- ❖ Create Visit Type
- ❖ Manage Visit Types
- ❖ Configure eForm and PVs
- ❖ Patient Self Reporting
- ❖ E-Binder
- ❖ Protocol Close-out

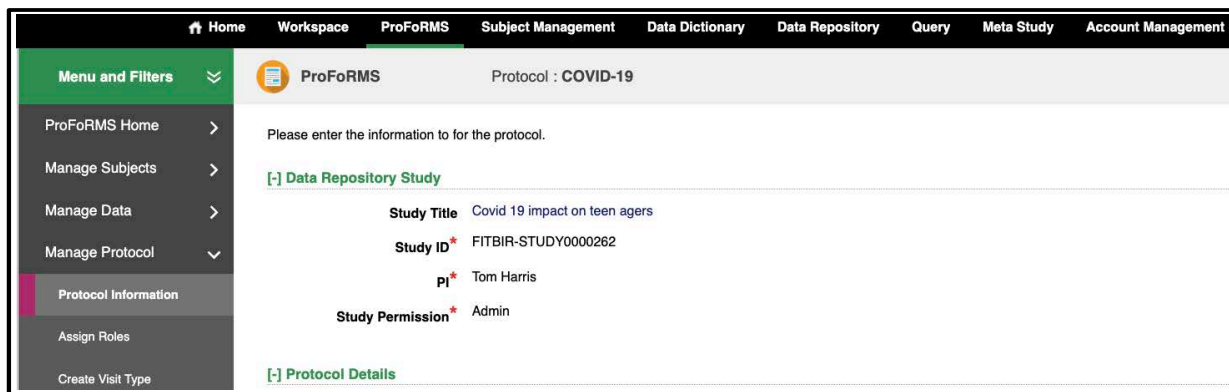
### 3.8.1 Viewing Protocol Information

To view **Protocol Information**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar.



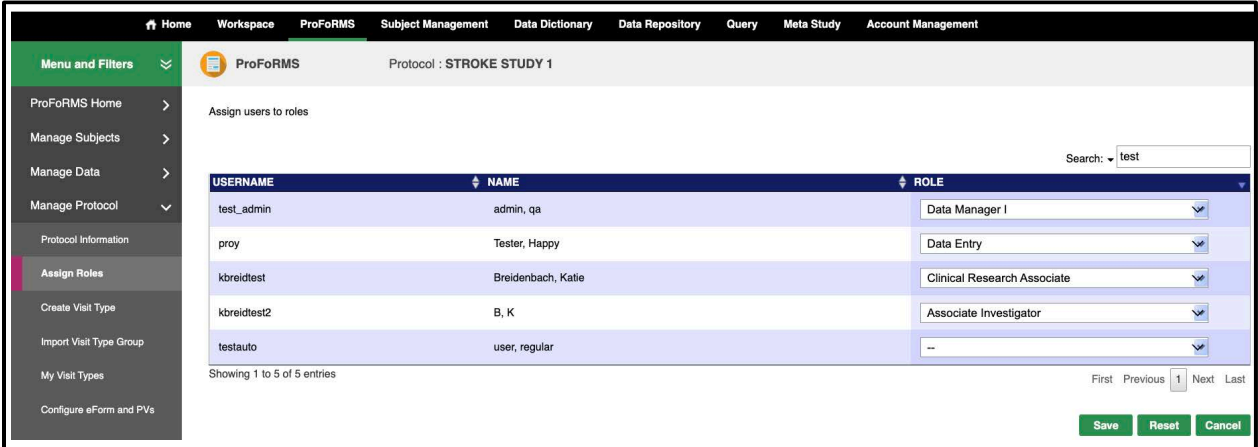
4. Click the **Protocol Information** on the left-side tool bar. The Study Information page appears.



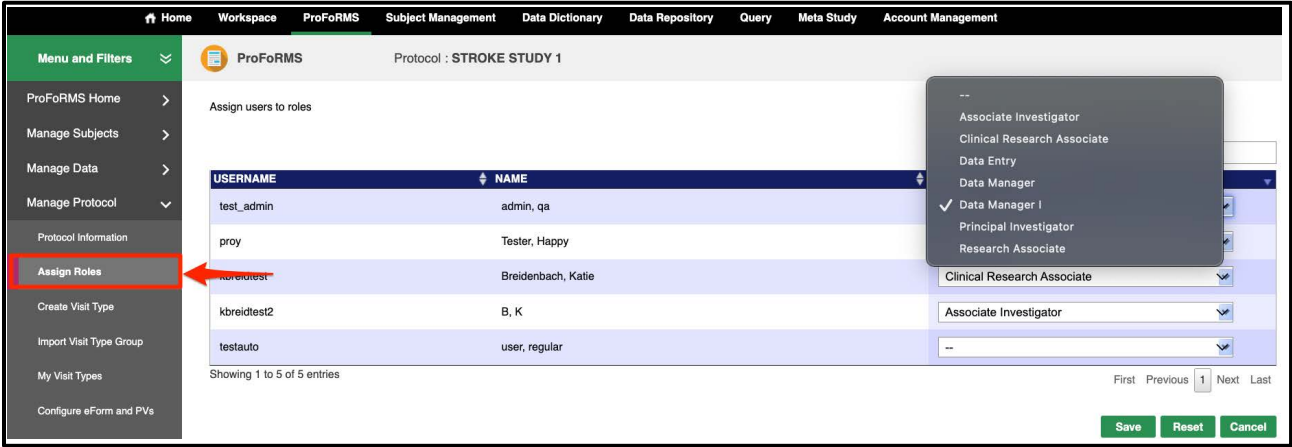
### 3.8.2 Assign Roles

To **Assign Roles** within a study, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar then select the **Assign Roles** tab.



4. In the **Assign Roles** page, find a user from the list of users. Use the drop-down menu to select and assign roles for a user in that study. The user roles depend on the study set up and can be as follows: Principal Investigator (max privileges), Research Associate, Data Entry, etc.



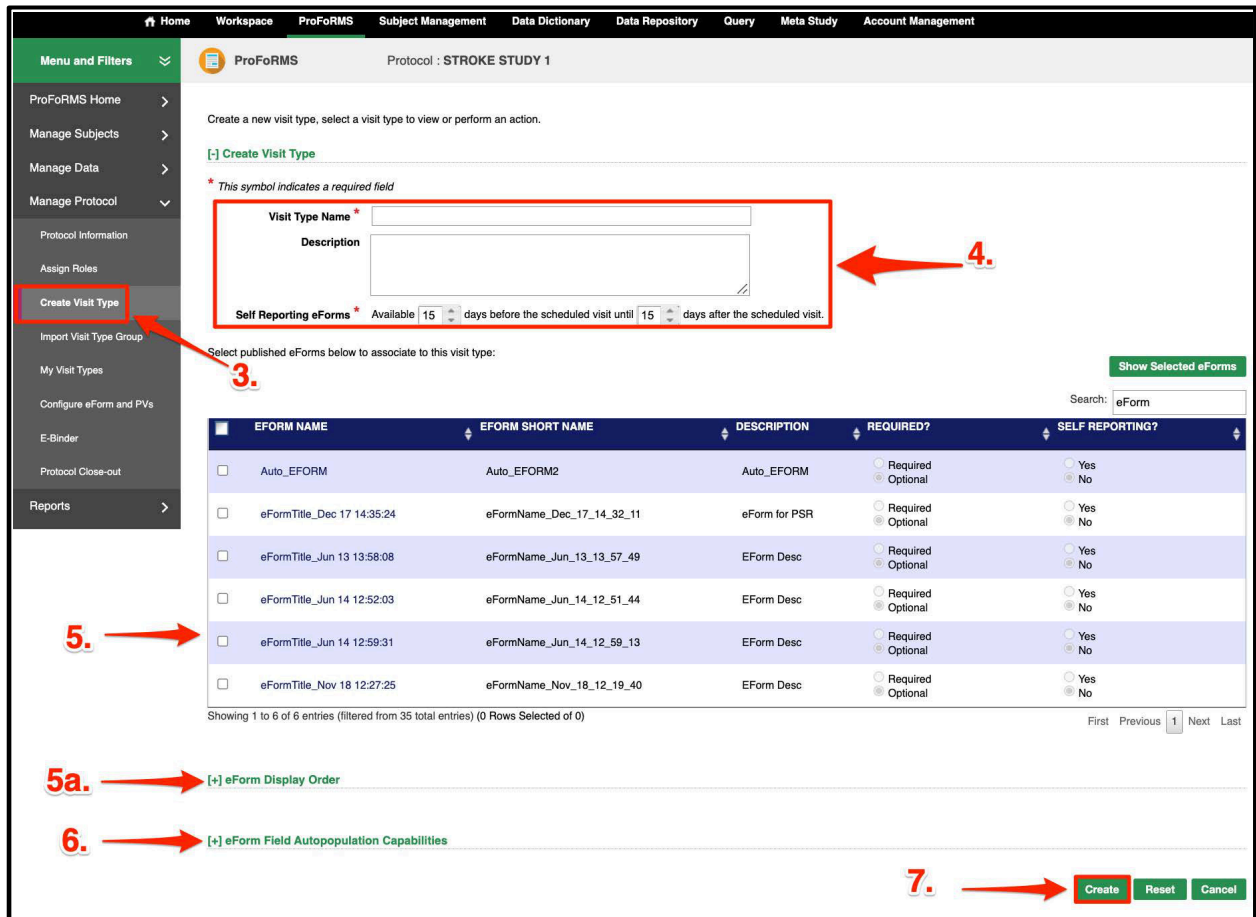
5. Click the **Save** button. The new user role(s) appear in the protocol setup.



### 3.8.3 Create Visit Types

To **Create Visit Types**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar then select the **Create Visit Type** tab.
4. Create a new Visit Type by entering the **Visit Type Name**, **Visit Type**, and a **Short Description**
5. Select the check-boxes beside the **eForm Name** to associate published eForms to that Visit Type. Then, use the up and down button to change the order under **[-] eForm Display Order**
  - a. The list only contains the eForms that are selected within the visit type
6. Finally, the fields within the eForms associated with this visit type have the ability to be autopopulated during data collection. Select the fields under **[-] eForm Field Autopopulation Capabilities** to enable autopopulation within this Visit Type.
  - a. You may have to provide additional information when scheduling a visit for a particular subject.
7. Click the **Create Visit Type** button. The new Visit Type(s) appear in the **Manage Visit Types** page.



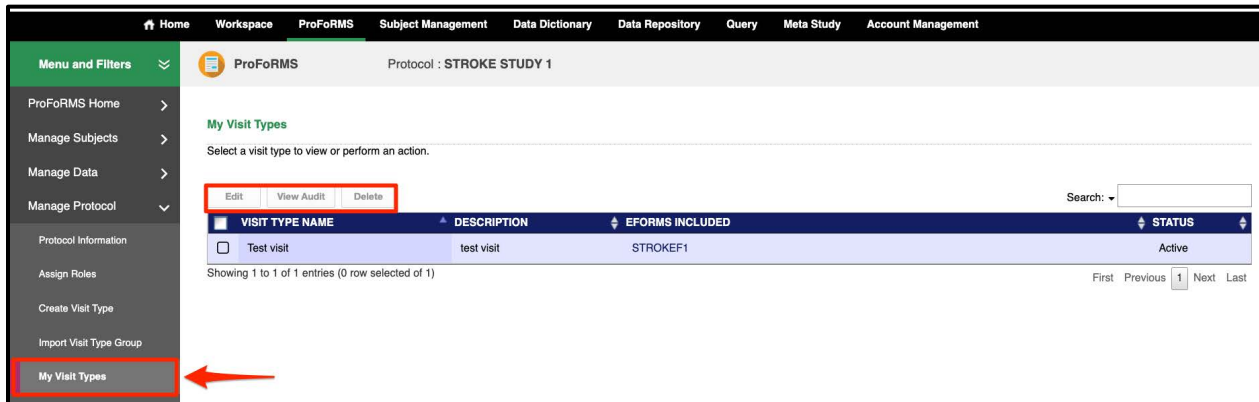
The screenshot shows the 'Create Visit Type' form in the ProFoRMS interface. The form includes fields for 'Visit Type Name', 'Description', and 'Self Reporting eForms' (with 'Available' checked and '15' days before and after the visit). Below the form is a table of eForms to be associated with the visit type. The table has columns for 'EFORM NAME', 'EFORM SHORT NAME', 'DESCRIPTION', 'REQUIRED?', and 'SELF REPORTING?'. The 'REQUIRED?' column has radio buttons for 'Required' and 'Optional'. The 'SELF REPORTING?' column has radio buttons for 'Yes' and 'No'. The table shows 6 eForms, with the first one 'Auto\_EFORM' selected. Below the table are sections for '[-] eForm Display Order' and '[-] eForm Field Autopopulation Capabilities'. At the bottom right, there are 'Create', 'Reset', and 'Cancel' buttons.

EFORM NAME	EFORM SHORT NAME	DESCRIPTION	REQUIRED?	SELF REPORTING?
<input checked="" type="checkbox"/> Auto_EFORM	Auto_EFORM2	Auto_EFORM	<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input type="radio"/> Yes <input checked="" type="radio"/> No
<input type="checkbox"/> eFormTitle_Dec 17 14:35:24	eFormName_Dec_17_14_32_11	eForm for PSR	<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input type="radio"/> Yes <input checked="" type="radio"/> No
<input type="checkbox"/> eFormTitle_Jun 13 13:58:08	eFormName_Jun_13_13_57_49	EForm Desc	<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input type="radio"/> Yes <input checked="" type="radio"/> No
<input type="checkbox"/> eFormTitle_Jun 14 12:52:03	eFormName_Jun_14_12_51_44	EForm Desc	<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input type="radio"/> Yes <input checked="" type="radio"/> No
<input type="checkbox"/> eFormTitle_Jun 14 12:59:31	eFormName_Jun_14_12_59_13	EForm Desc	<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input type="radio"/> Yes <input checked="" type="radio"/> No
<input type="checkbox"/> eFormTitle_Nov 18 12:27:25	eFormName_Nov_18_12_19_40	EForm Desc	<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input type="radio"/> Yes <input checked="" type="radio"/> No

### 3.8.4 My Visit Types

To view **My Visit Types**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar then select the **My Visit Types** tab.
4. Select the check-box beside the **Visit Type Name** to perform an action: **Edit**, **View Audit**, and **Delete** functions.



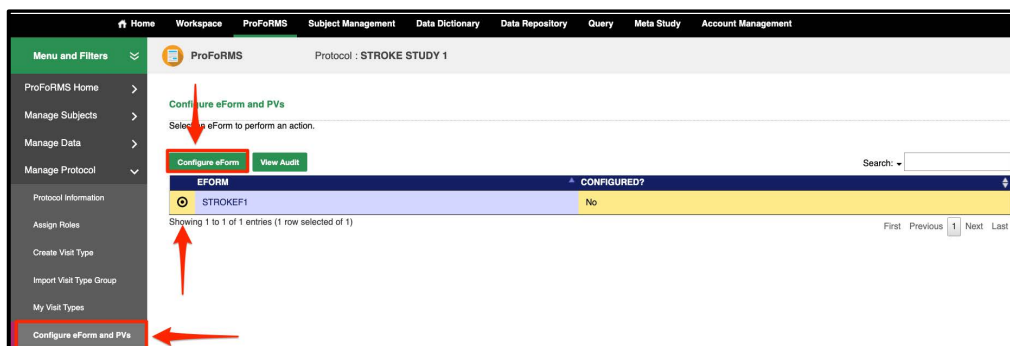
The screenshot shows the ProFoRMS interface for 'Protocol : STROKE STUDY 1'. The left sidebar contains a 'Menu and Filters' section with 'My Visit Types' highlighted in a red box and a red arrow pointing to it. The main content area displays 'My Visit Types' with a search bar and a table. Above the table, buttons for 'Edit', 'View Audit', and 'Delete' are highlighted in a red box. The table has columns for 'VISIT TYPE NAME', 'DESCRIPTION', 'EFORMS INCLUDED', and 'STATUS'. One entry is visible: 'Test visit' with description 'test visit', 'STROKEF1' eforms, and 'Active' status. Below the table, it says 'Showing 1 to 1 of 1 entries (0 row selected of 1)' and includes pagination controls: 'First', 'Previous', '1', 'Next', 'Last'.

### 3.8.5 Configure eForm and PVs

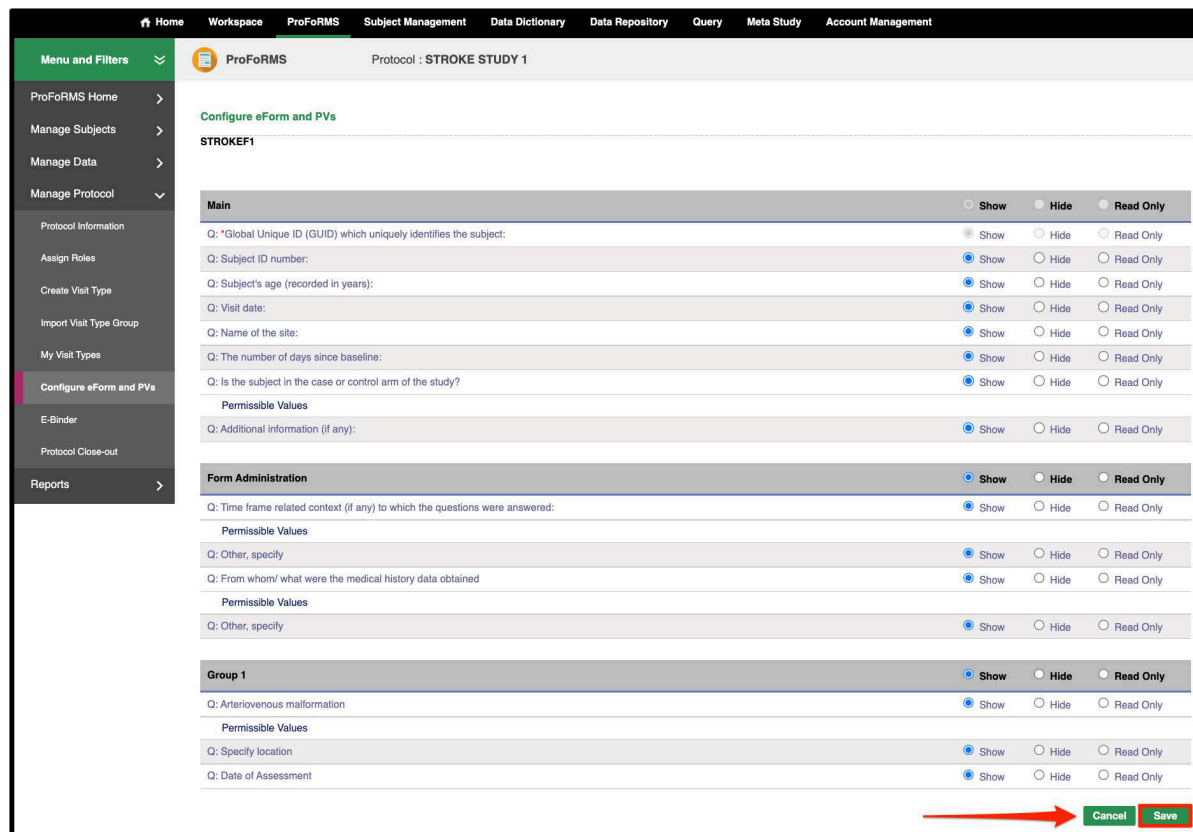
There is a feature where you are able to choose which fields of the eForm and PVs to either **Show**, **Hide**, or **Read Only**.

To **Configure eForm and PVs**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar then select the **Configure eForm and PVs** tab.



4. Choose which fields of the eForm and PVs you want to **Show**, **Hide**, or **Read Only**, then select **Save**.

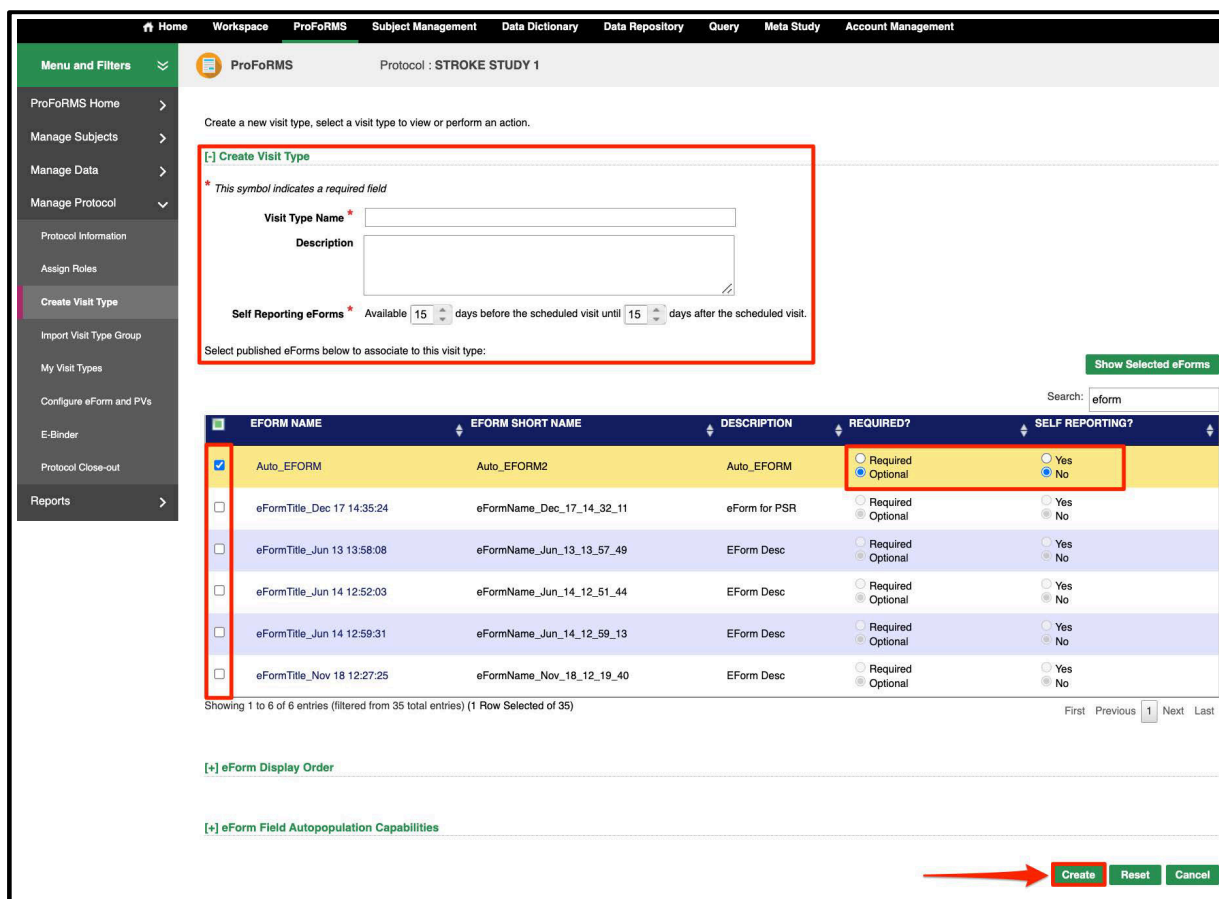


### 3.8.6 Patient Self-Reporting

Patient Self-Reporting is an Admin-enabled function. You must have an administrative privilege in order to use this feature. Ensure you have Administrative privileges enabled before attempting to set up patient self-reporting in ProFoRMS.

To use **Patient Self-Reporting**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar then select **Create Visit Type**.
4. Create a new Visit Type by entering the **Visit Type Name**, **Visit Type**, and a **Short Description**
5. Select the check-boxes beside the **eForm Name** to associate published eForms to that Visit Type.
6. Under the **Self Reporting** column, select **“Yes”** next to the eForms that you want to have self-reporting capabilities.
7. Refer back to section 3.8.3 for **[+] eForm Display Order** and **[+] eForm Field Autopopulation Capabilities** information.
8. Select the **Create** button once you are finished.




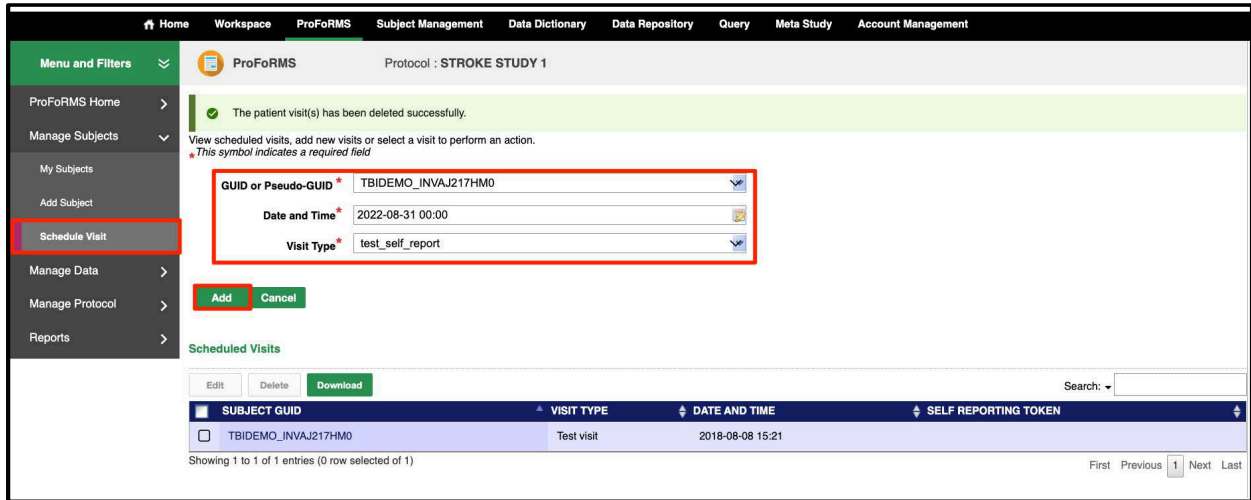
The screenshot displays the ProFoRMS interface for creating a new visit type. The top navigation bar includes Home, Workspace, ProFoRMS, Subject Management, Data Dictionary, Data Repository, Query, Meta Study, and Account Management. The left sidebar shows a menu with options like ProFoRMS Home, Manage Subjects, Manage Data, Manage Protocol, Protocol Information, Assign Roles, Create Visit Type (highlighted), Import Visit Type Group, My Visit Types, Configure eForm and PVs, E-Binder, Protocol Close-out, and Reports.

The main content area is titled 'Protocol : STROKE STUDY 1' and contains a form for creating a new visit type. The form includes fields for 'Visit Type Name', 'Description', and 'Self Reporting eForms' (with dropdowns for 'Available' and 'days before the scheduled visit until', and 'days after the scheduled visit'). Below the form is a table of published eForms to associate with the visit type.

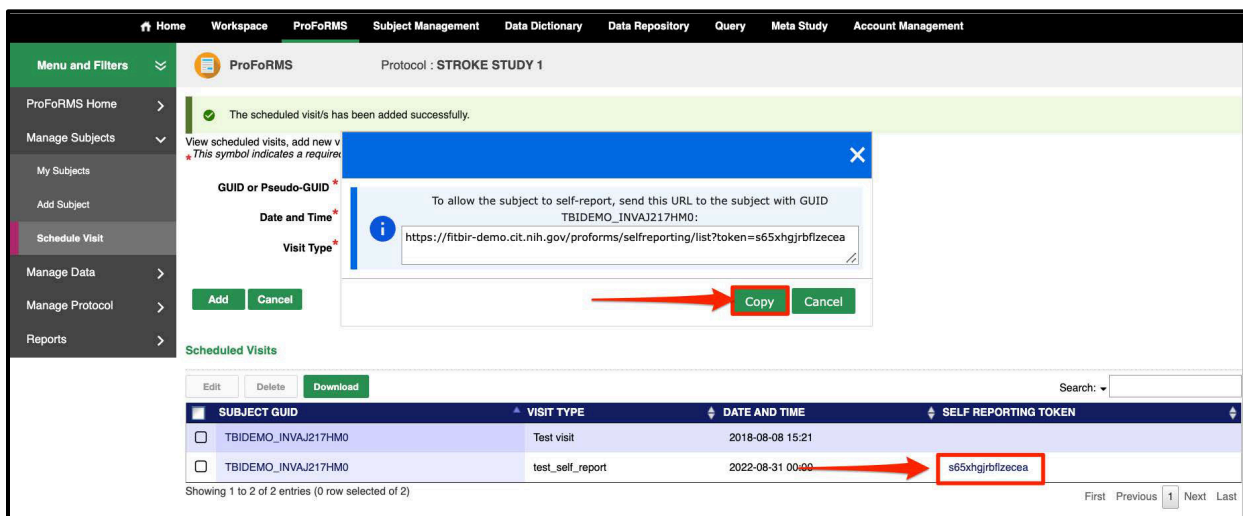
EFORM NAME	EFORM SHORT NAME	DESCRIPTION	REQUIRED?	SELF REPORTING?
<input checked="" type="checkbox"/> Auto_EFORM	Auto_EFORM2	Auto_EFORM	<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input type="radio"/> Yes <input checked="" type="radio"/> No
<input type="checkbox"/> eFormTitle_Dec 17 14:35:24	eFormName_Dec_17_14_32_11	eForm for PSR	<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input type="radio"/> Yes <input checked="" type="radio"/> No
<input type="checkbox"/> eFormTitle_Jun 13 13:58:08	eFormName_Jun_13_13_57_49	EForm Desc	<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input type="radio"/> Yes <input checked="" type="radio"/> No
<input type="checkbox"/> eFormTitle_Jun 14 12:52:03	eFormName_Jun_14_12_51_44	EForm Desc	<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input type="radio"/> Yes <input checked="" type="radio"/> No
<input type="checkbox"/> eFormTitle_Jun 14 12:59:31	eFormName_Jun_14_12_59_13	EForm Desc	<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input type="radio"/> Yes <input checked="" type="radio"/> No
<input type="checkbox"/> eFormTitle_Nov 18 12:27:25	eFormName_Nov_18_12_19_40	EForm Desc	<input type="radio"/> Required <input checked="" type="radio"/> Optional	<input type="radio"/> Yes <input checked="" type="radio"/> No

At the bottom right, a red arrow points to the **Create** button, which is highlighted in green. Other buttons include **Reset** and **Cancel**.

9. The new Visit Type(s) appear in the **Manage Visit Types** page.
10. Select **Manage Subjects** on the left-side tool bar then select **Schedule Visit**.
11. Add new visit or select a visit from the drop-down menu. \* This symbol indicates a required field. Select the desired visit date by clicking on the calendar  icon then select a Visit Type from the drop-down.
12. Select the **Add** button.
13. The scheduled visit will be updated successfully.



14. To allow the subject to self-report, select the **Self-Reporting Token** link and send it to the subject with the GUID.

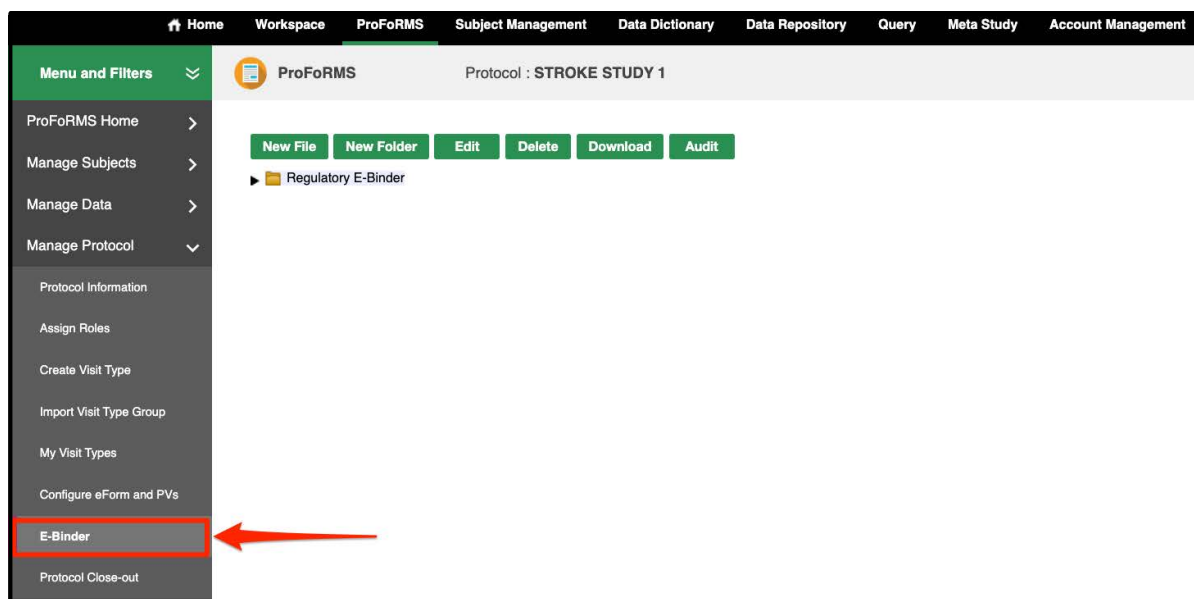


### 3.8.7 E-Binder

The E-Binder is used to Add/Edit documents or view existing documents.

To access the **E-Binder**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar then select **E-Binder**.
  - a. Use the New File option to upload a new document
  - b. Use the New Folder to create a new folder
  - c. Use the Edit option to edit your uploaded document
  - d. Use the Delete option to delete a document
  - e. Use the Download option to download documents



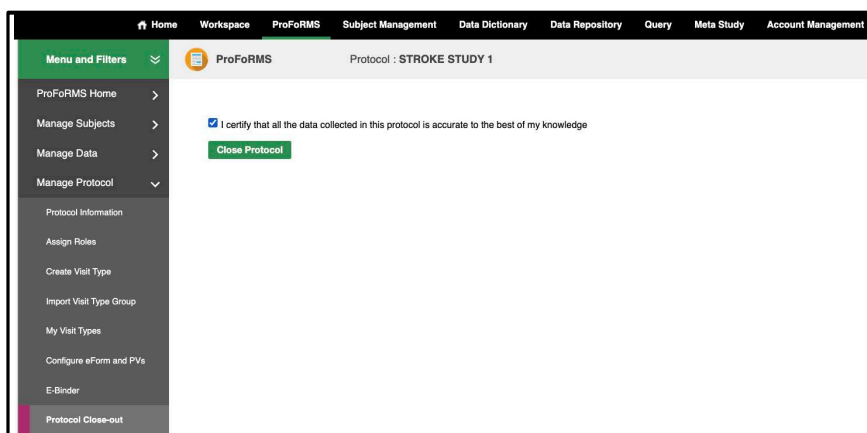
### 3.8.8 Protocol Closeout

At the end of the study, there needs to be a record that the PI or all investigators acknowledge that the data collected and entered in the repository are clean and accurate.

- ❖ The e-form will state that the PI acknowledges that the data collected is accurate to the best of their knowledge
- ❖ The e-form will capture the signature of the PI
- ❖ The e-form will capture the full legal name of the PI
- ❖ The e-form will capture the date and time that the form was signed
- ❖ The PI will be required to lock this e-form
- ❖ This e-form will be sent to the data repository and will be part of the study's data set

To access the **Protocol Closeout**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Manage Protocol** tab on the left-side tool bar then select **Protocol Close-out**.
4. Select the box next to “I certify that all the data collected in this protocol is accurate to the best of my knowledge” then select **Close Protocol**.
5. A confirmation will appear notifying you that the Protocol has been successfully closed out.



**Signature Required**

I certify that all the data collected in this protocol is accurate to the best of my knowledge

**Name:** John Rutherford

Enter your password to complete the form.

**Password:**

### 3.9 REPORTS

The ProFoRMS reporting feature provides the following report outputs:

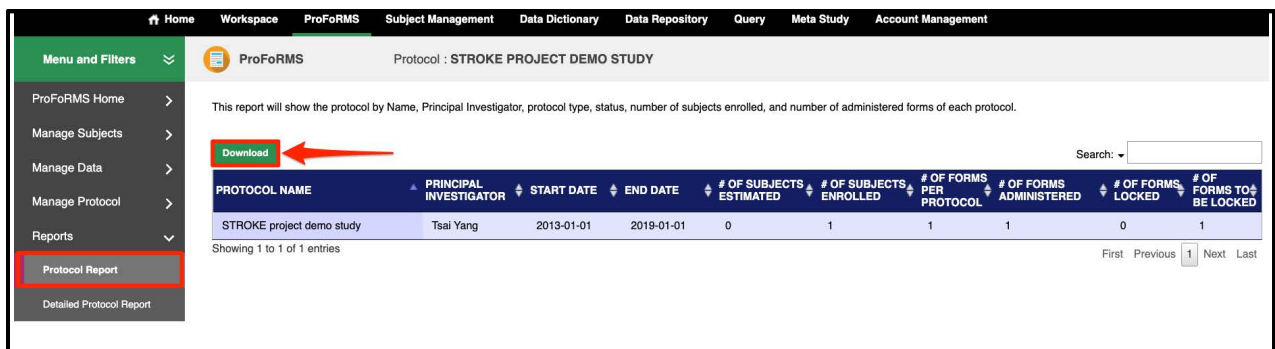
- ❖ Protocol Reports
- ❖ Detailed Protocol Report
- ❖ Without Collections
- ❖ Forms Requiring Completion & Lock
- ❖ Locked Forms
- ❖ Submission Summary
- ❖ Form Status
- ❖ View Auditor Comments
- ❖ View Reviewer Comments

#### 3.9.1 Protocol Report

This report will show the Protocol Name, Principal Investigator, Start Date, End Date, Number of Subjects Estimated, Number of Subjects Enrolled, Number of Forms per Protocol, Number of Forms Administered, Number of Forms Locked, and Number of Forms to be Locked.

To view the **Protocol Report**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar. The **Protocol Report** information page appears.
4. The **Protocol Report** appears. You may use the export feature to export the report to either CSV or Excel formats.



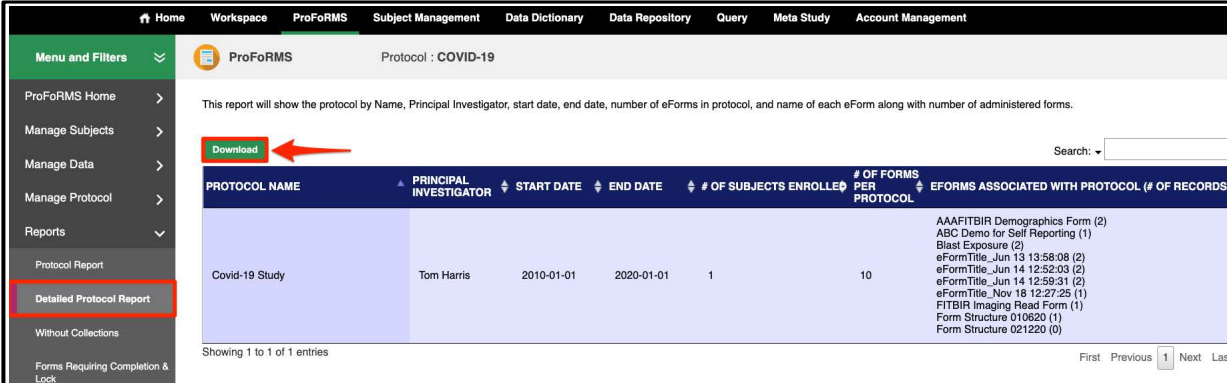


### 3.9.2 Detailed Protocol Report

This report will show the Protocol Name, Principal Investigator, Start Date, End Date, Number of Subjects Enrolled, Number of Forms per Protocol, and eForms Associated with Protocol (Number of Records).

To view the **Detailed Protocol Report**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **Detailed Protocol Report** tab.
4. The **Detailed Protocol Report** appears. You may use the export feature to export the report to either CSV or Excel formats.



The screenshot shows the ProFoRMS interface with the 'Detailed Protocol Report' selected in the left-hand menu. The main content area displays a table with the following data:

PROTOCOL NAME	PRINCIPAL INVESTIGATOR	START DATE	END DATE	# OF SUBJECTS ENROLLED	# OF FORMS PER PROTOCOL	EFORMS ASSOCIATED WITH PROTOCOL (# OF RECORDS)
Covid-19 Study	Tom Harris	2010-01-01	2020-01-01	1	10	AAAFITBIR Demographics Form (2) ABC Demo for Self Reporting (1) Blast Exposure (2) eFormTitle_Jun 13 13:58:08 (2) eFormTitle_Jun 14 12:52:03 (2) eFormTitle_Jun 14 12:59:31 (2) eFormTitle_Nov 18 12:27:25 (1) FITBIR Imaging Read Form (1) Form Structure 010620 (1) Form Structure 021220 (0)

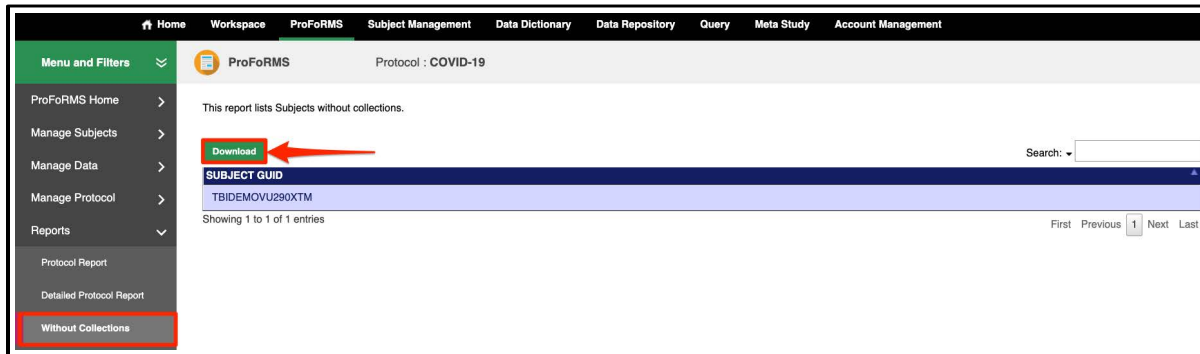
Below the table, it indicates 'Showing 1 to 1 of 1 entries' and includes navigation buttons: First, Previous, 1, Next, Last. A red box highlights the 'Download' button in the top left of the report area, with a red arrow pointing to it.

### 3.9.3 Without Collections

This report lists the GUIDs (including Pseudo-GUIDs) without collections.

To view GUIDs **Without Collections** Report, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **Without Collections** tab.
4. The **Without Collections** Report appears. You may use the export feature to export the report to Excel.

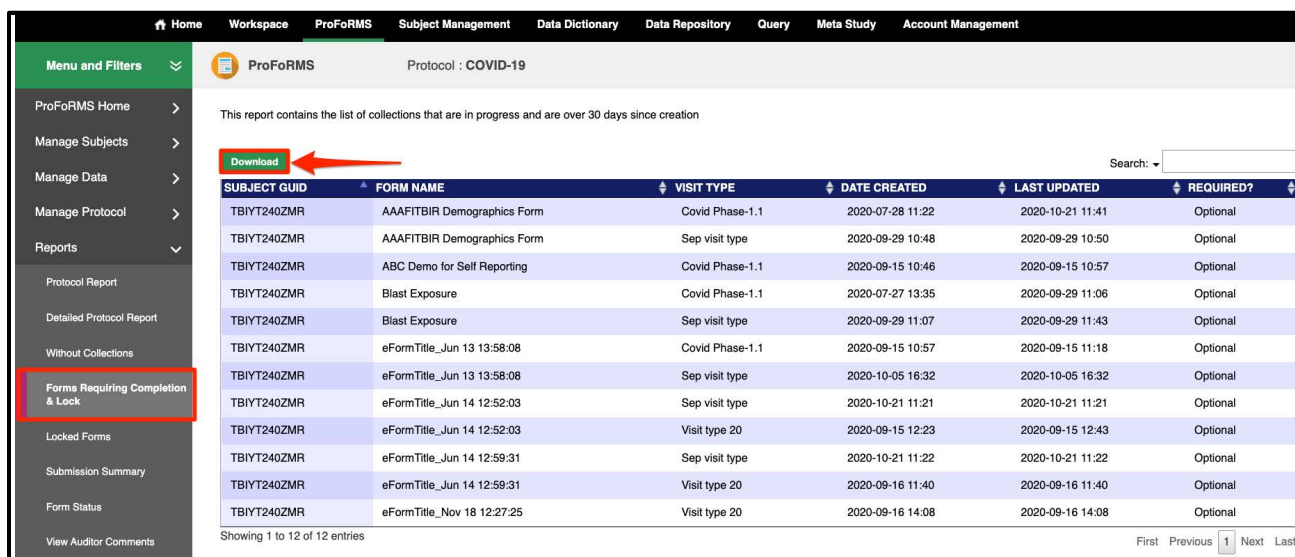


### 3.9.4 Forms Requiring Completion & Lock

This report contains the list of collections that are in progress and are over 30 days since creation. In addition, this table also provides collections that have been completed, but not locked.

To view **Forms Requiring Completion & Lock**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **Forms Requiring Completion & Lock** tab.
4. The **Forms Requiring Completion & Lock** Report appears. You may use the export feature to export the report to either CSV or Excel formats.



ProFoRMS Protocol : COVID-19

This report contains the list of collections that are in progress and are over 30 days since creation

**Download**

SUBJECT GUID	FORM NAME	VISIT TYPE	DATE CREATED	LAST UPDATED	REQUIRED?
TBIYT240ZMR	AAAFITBIR Demographics Form	Covid Phase-1.1	2020-07-28 11:22	2020-10-21 11:41	Optional
TBIYT240ZMR	AAAFITBIR Demographics Form	Sep visit type	2020-09-29 10:48	2020-09-29 10:50	Optional
TBIYT240ZMR	ABC Demo for Self Reporting	Covid Phase-1.1	2020-09-15 10:46	2020-09-15 10:57	Optional
TBIYT240ZMR	Blast Exposure	Covid Phase-1.1	2020-07-27 13:35	2020-09-29 11:06	Optional
TBIYT240ZMR	Blast Exposure	Sep visit type	2020-09-29 11:07	2020-09-29 11:43	Optional
TBIYT240ZMR	eFormTitle_Jun 13 13:58:08	Covid Phase-1.1	2020-09-15 10:57	2020-09-15 11:18	Optional
TBIYT240ZMR	eFormTitle_Jun 13 13:58:08	Sep visit type	2020-10-05 16:32	2020-10-05 16:32	Optional
TBIYT240ZMR	eFormTitle_Jun 14 12:52:03	Sep visit type	2020-10-21 11:21	2020-10-21 11:21	Optional
TBIYT240ZMR	eFormTitle_Jun 14 12:52:03	Visit type 20	2020-09-15 12:23	2020-09-15 12:43	Optional
TBIYT240ZMR	eFormTitle_Jun 14 12:59:31	Sep visit type	2020-10-21 11:22	2020-10-21 11:22	Optional
TBIYT240ZMR	eFormTitle_Jun 14 12:59:31	Visit type 20	2020-09-16 11:40	2020-09-16 11:40	Optional
TBIYT240ZMR	eFormTitle_Nov 18 12:27:25	Visit type 20	2020-09-16 14:08	2020-09-16 14:08	Optional

Showing 1 to 12 of 12 entries

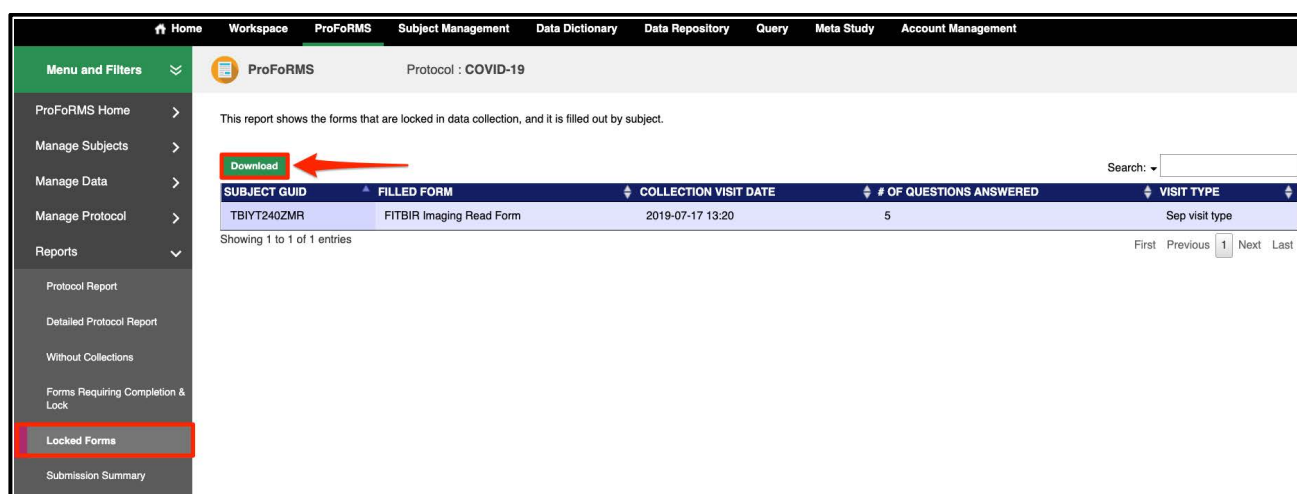
First Previous 1 Next Last

### 3.9.5 Locked Forms

This report shows the forms that are locked in data collection, and it is filled out by subject.

To view **Locked Forms**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **Locked Forms** tab.
4. The **Locked Forms** Report appears. You may use the export feature to export the report to either CSV or Excel formats.



The screenshot displays the ProFoRMS interface for Protocol: COVID-19. The left sidebar shows the 'Reports' section with 'Locked Forms' selected. The main content area shows a table with the following data:

SUBJECT GUID	FILLED FORM	COLLECTION VISIT DATE	# OF QUESTIONS ANSWERED	VISIT TYPE
TBIYT240ZMR	FITBIR Imaging Read Form	2019-07-17 13:20	5	Sep visit type

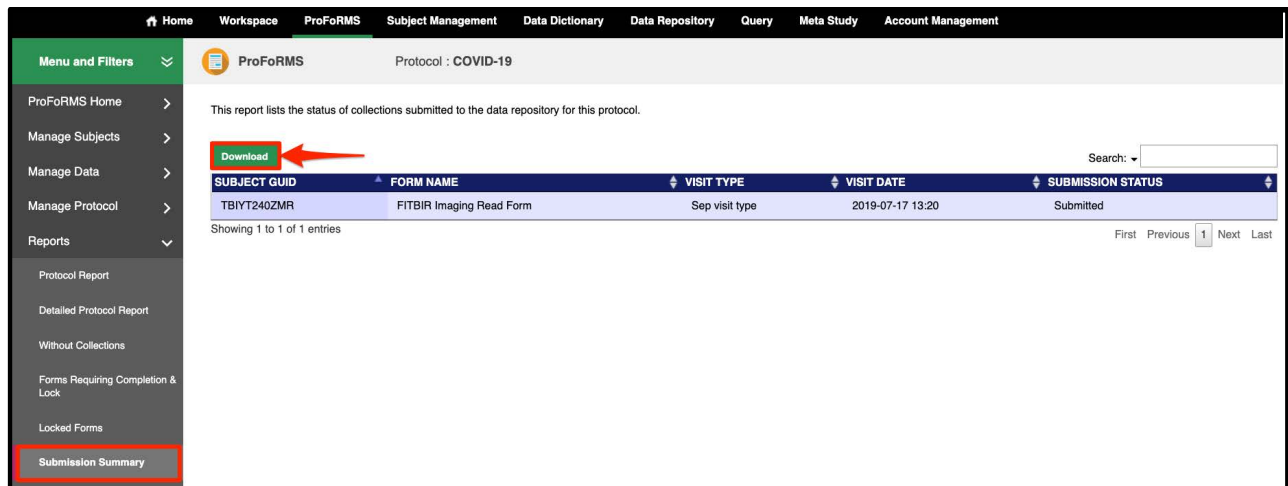
Additional interface elements include a 'Download' button (highlighted with a red box and arrow), a search bar, and pagination controls showing 'Showing 1 to 1 of 1 entries'.

### 3.9.6 Submission Summary

This report lists the status of collections submitted to the data repository for this protocol.

To view **Submission Summary**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **Submission Summary** tab.
4. The **Submission Summary** Report appears. You may use the export feature to export the report to either CSV or Excel formats.



ProFoRMS Protocol : COVID-19

This report lists the status of collections submitted to the data repository for this protocol.

**Download**

SUBJECT GUID	FORM NAME	VISIT TYPE	VISIT DATE	SUBMISSION STATUS
TBIYT240ZMR	FITBIR Imaging Read Form	Sep visit type	2019-07-17 13:20	Submitted

Showing 1 to 1 of 1 entries

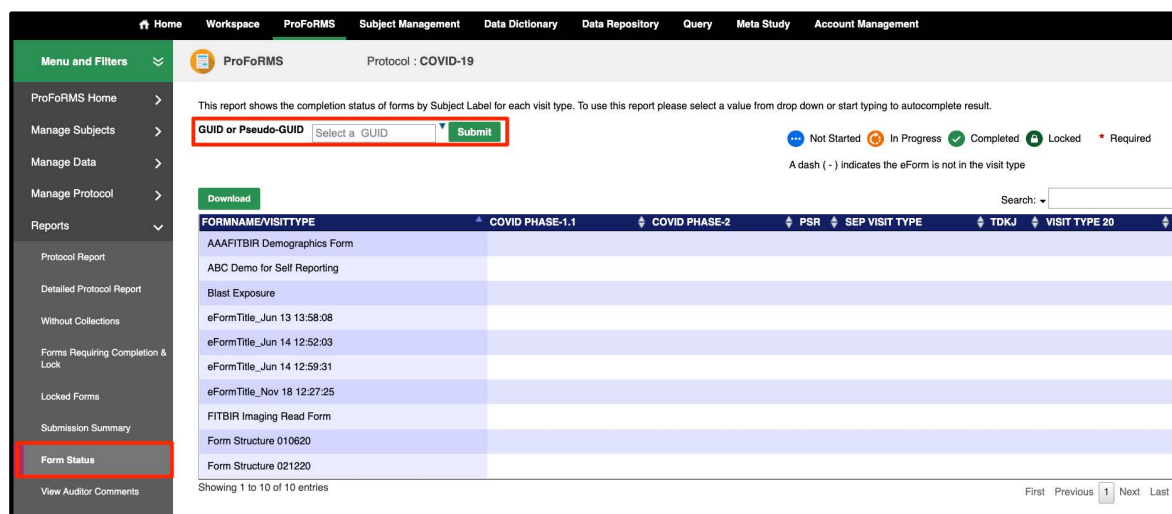
First Previous 1 Next Last

### 3.9.7 Form Status

This report shows the completion status of forms by Subject Label for each visit type.

To view **Form Status**, perform the following actions:

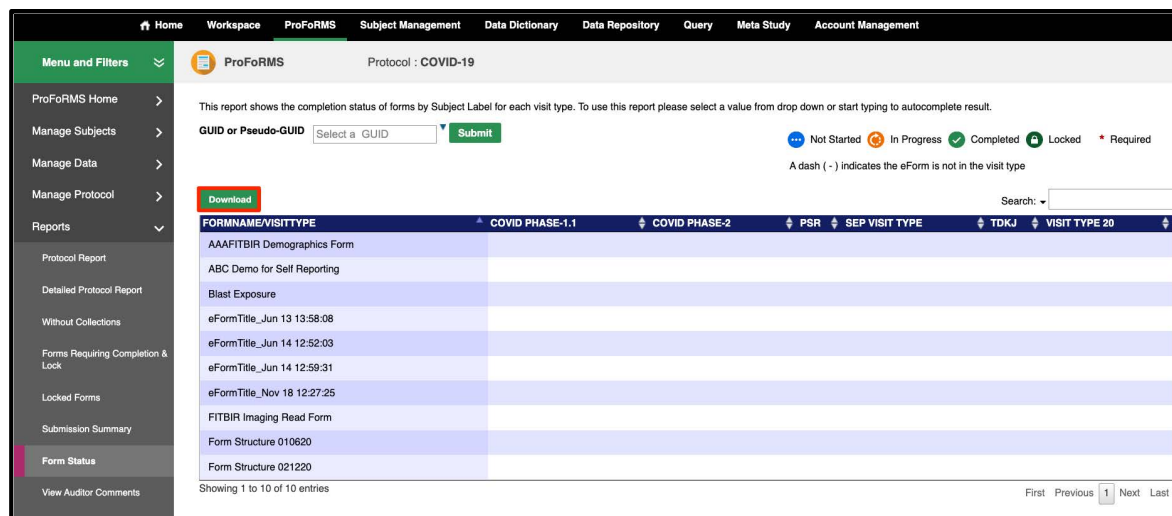
1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **Form Status** tab.
4. To use this report, you must select a GUID or Subject ID from the drop-down menu or start typing to autocomplete the result in search field then select **Submit** to generate the report.



The screenshot shows the ProFoRMS interface for the 'COVID-19' protocol. The 'Form Status' report is displayed, showing a table of forms and their completion status across different visit types. The 'Form Status' menu item in the left sidebar is highlighted in red. The search field and 'Submit' button are also highlighted in red.

FORMNAME/VISITTYPE	COVID PHASE-1.1	COVID PHASE-2	PSR	SEP VISIT TYPE	TDKJ	VISIT TYPE 20
AAAFITBIR Demographics Form						
ABC Demo for Self Reporting						
Blast Exposure						
eFormTitle_Jun 13 13:58:08						
eFormTitle_Jun 14 12:52:03						
eFormTitle_Jun 14 12:59:31						
eFormTitle_Nov 18 12:27:25						
FITBIR Imaging Read Form						
Form Structure 010620						
Form Structure 021220						

5. You may use the export feature to export the report to either CSV or Excel formats.



The screenshot shows the ProFoRMS interface for the 'COVID-19' protocol. The 'Form Status' report is displayed, showing a table of forms and their completion status across different visit types. The 'Download' button is highlighted in red.

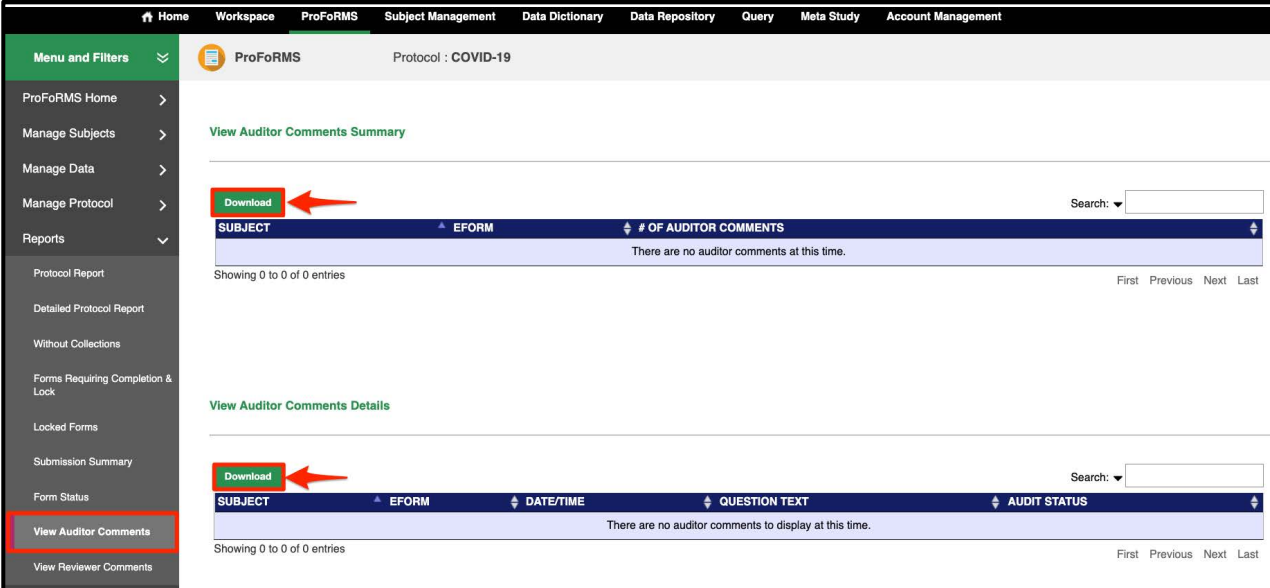
FORMNAME/VISITTYPE	COVID PHASE-1.1	COVID PHASE-2	PSR	SEP VISIT TYPE	TDKJ	VISIT TYPE 20
AAAFITBIR Demographics Form						
ABC Demo for Self Reporting						
Blast Exposure						
eFormTitle_Jun 13 13:58:08						
eFormTitle_Jun 14 12:52:03						
eFormTitle_Jun 14 12:59:31						
eFormTitle_Nov 18 12:27:25						
FITBIR Imaging Read Form						
Form Structure 010620						
Form Structure 021220						

### 3.9.8 View Auditor Comments

This report shows a summary of auditor comments that are made in the data collections.

To **View Auditor Comments**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **View Auditor Comments** tab.
4. This report shows the GUID or Subject, eForm, and Number of Auditor Comments that have been made as well as the Date/Time, Question Text, and Audit Status of a collection.
5. You may use the export feature to export the report to either CSV, Excel, or PDF formats.

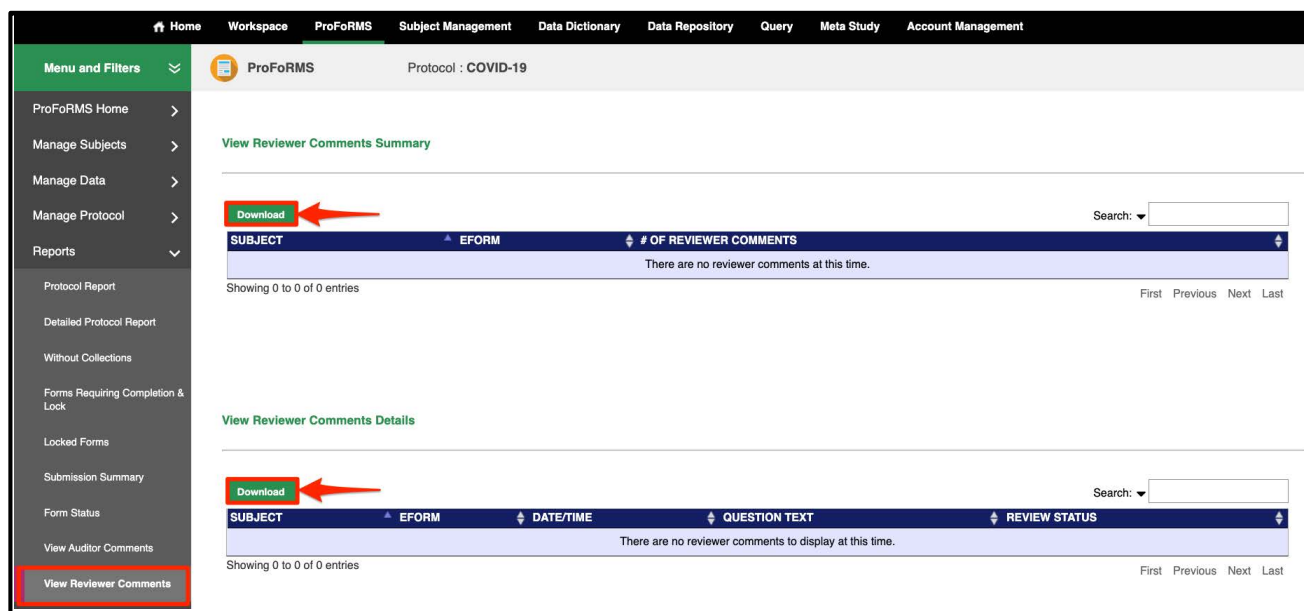


### 3.9.9 View Reviewer Comments

This report shows a summary of reviewer comments that are made in the data collections.

To **View Reviewer Comments**, perform the following actions:

1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **View Reviewer Comments** tab.
4. This report shows the GUID or Subject, eForm, and Number of Reviewer Comments that have been made as well as the Date/Time, Question Text, and Review Status of a collection.
5. You may use the export feature to export the report to either CSV, Excel, or PDF formats.





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