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Chapter

3

ProFoRMS





CHAPTER 3 - PROFORMS

The **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.

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

ICON KEY

 Notes

 Important

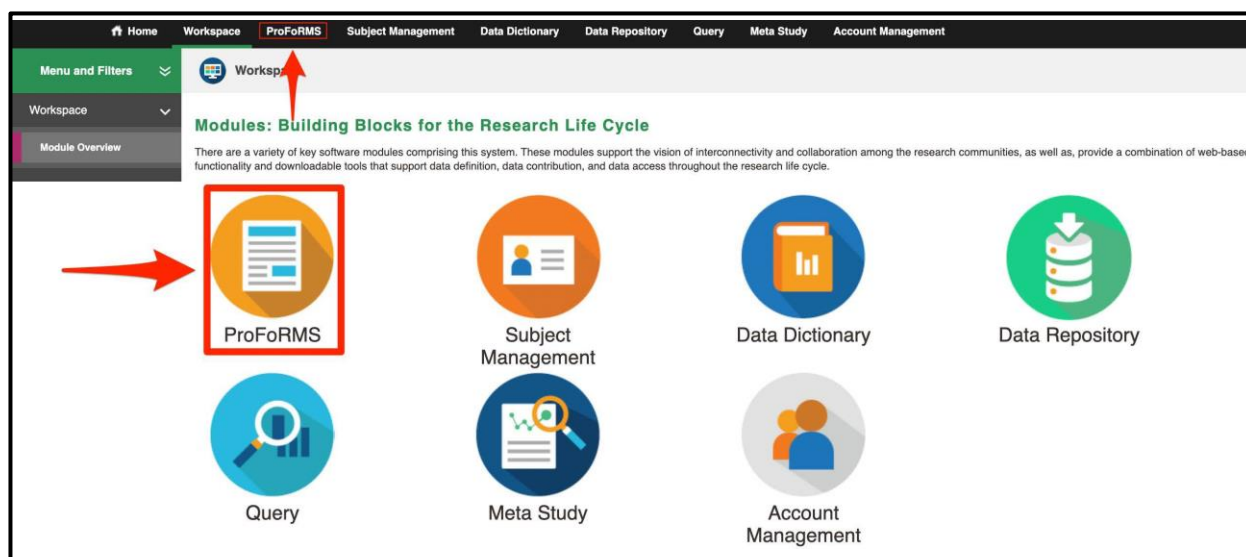
Information

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](#)

ICON KEY

 Notes

 Important

Information

3.4.1 PROFORMS FLOW OVERVIEW

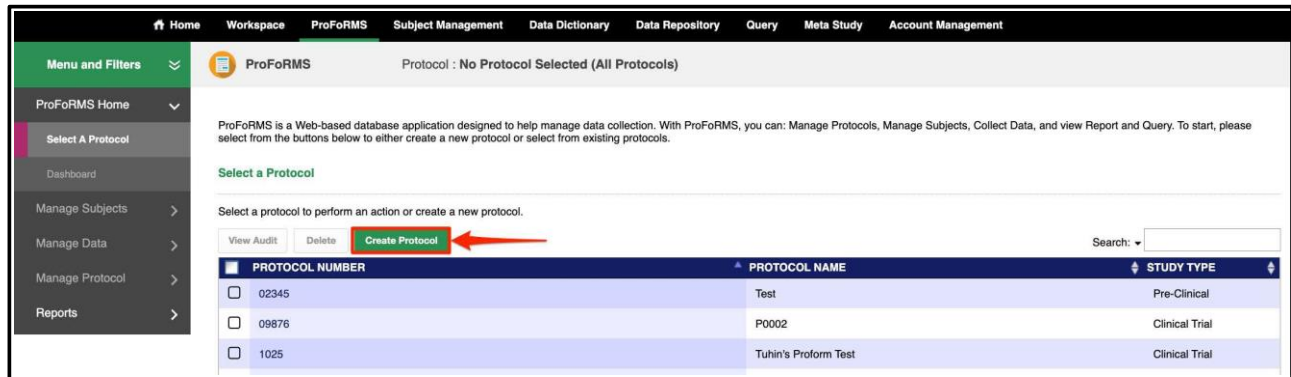
The basic overview of the flow for the Proforms Module:

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:

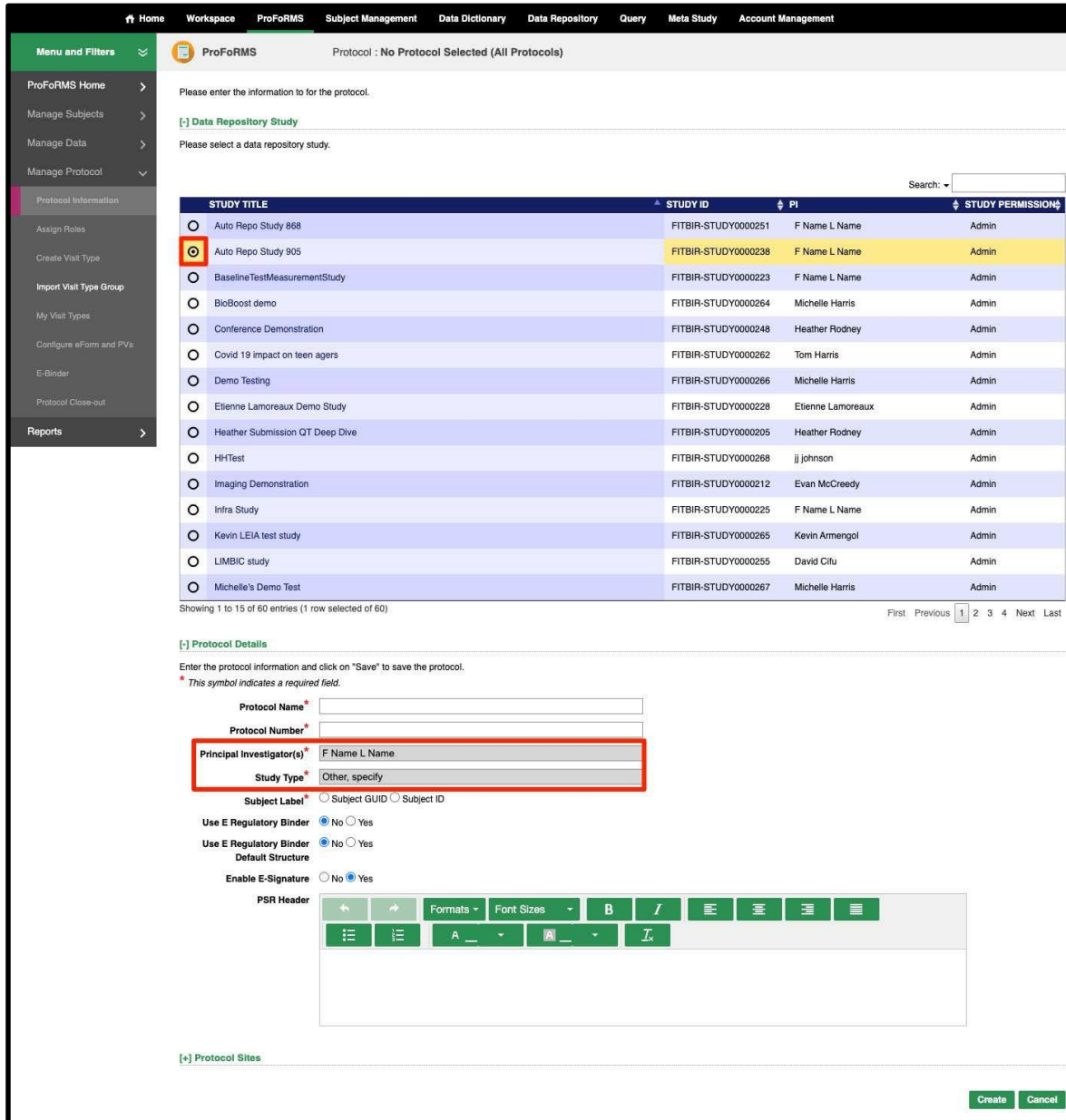
1. Navigate to the **ProFoRMS** module
2. Click the **Create Protocol** button



The screenshot shows the ProFoRMS interface. The top navigation bar includes Home, Workspace, ProFoRMS, Subject Management, Data Dictionary, Data Repository, Query, Meta Study, and Account Management. The left sidebar has a 'Menu and Filters' section with options like ProFoRMS Home, Select A Protocol, Dashboard, Manage Subjects, Manage Data, Manage Protocol, and Reports. The main content area is titled 'ProFoRMS' and 'Protocol : No Protocol Selected (All Protocols)'. It contains a description of ProFoRMS and a 'Select a Protocol' section with a table of existing protocols. A red arrow points to the 'Create Protocol' button in the table's action column.

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, there is a section for 'Data Repository Study' with a search bar and a table of studies. The table has columns for 'STUDY TITLE', 'STUDY ID', 'PI', and 'STUDY PERMISSION'. The study 'Auto Repo Study 905' is selected, highlighted in yellow, and its details are populated in the 'Protocol Details' form below.

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

The 'Protocol Details' form includes the following fields:

- Protocol Name*
- Protocol Number*
- Principal Investigator(s)*: F Name L Name
- Study Type*: Other, specify
- Subject Label*: Subject GUID Subject ID
- Use E Regulatory Binder: No Yes
- Use E Regulatory Binder: No Yes
- Default Structure
- Enable E-Signature: No Yes
- PSR Header: A rich text editor with formatting options (bold, italic, underline, list, link, unlink, indent, outdent).

At the bottom right, there are 'Create' and 'Cancel' buttons.

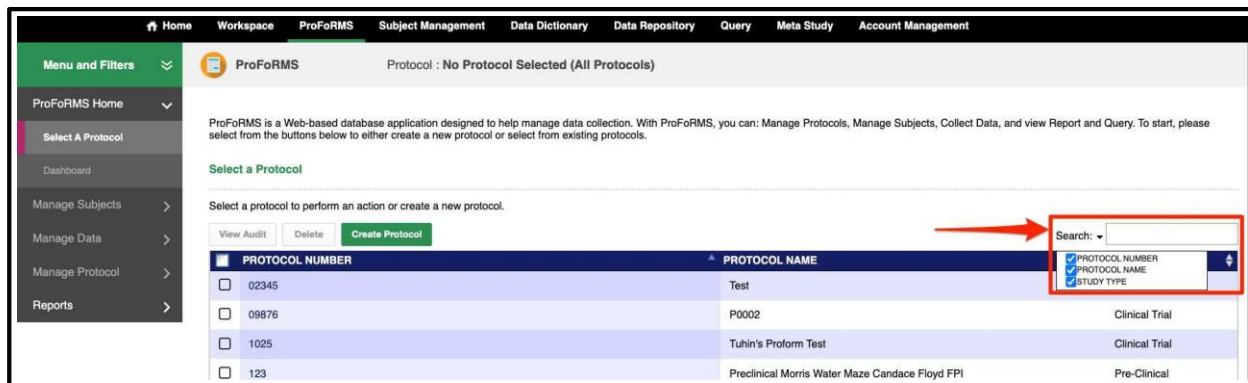
4. **Complete** all of the required fields (fields marked with a red asterisk (*))
5. Select **Create** after all desired fields have been filled out.

3.5.1 Selecting a Protocol

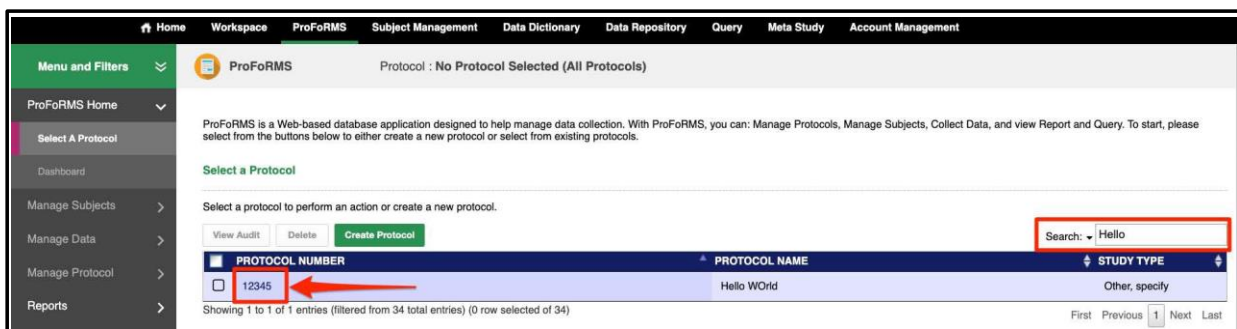
Searching and selecting a protocol in **ProFoRMS**.

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**, and **Protocol**. The table also includes a simple search function.

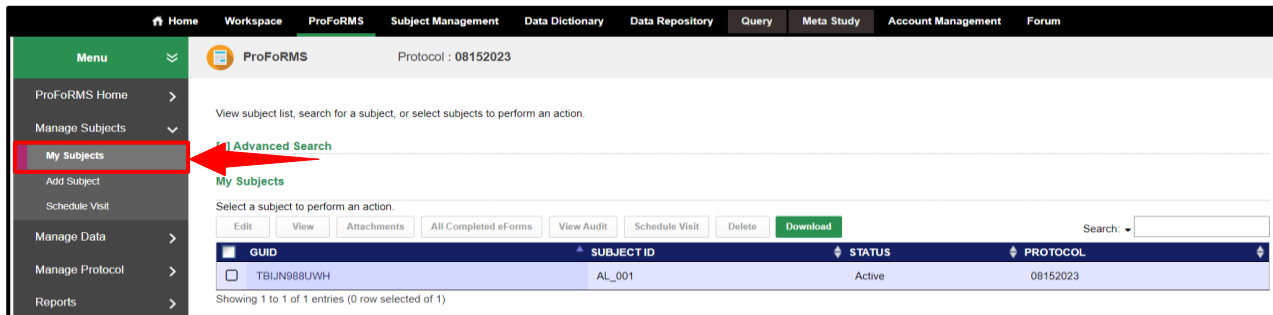
The table menu options allow the user to:

- ❖ 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. The left sidebar shows the 'Add Subject' button highlighted in red. The main area shows a table of subjects with the following columns: ID, TYPE, ENTITY, ORGANIZATION, REGISTERED BY, USER REGISTERED BY, DATE REGISTERED, and LINKED TO. The subject 'TBIDEMOKB275ZR0' is selected and highlighted in yellow. Below the table, the 'Subject Information' section is shown with a red box around 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
TBIDEMOXJ179YK5	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	
TBIDEMOYX366TYA	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

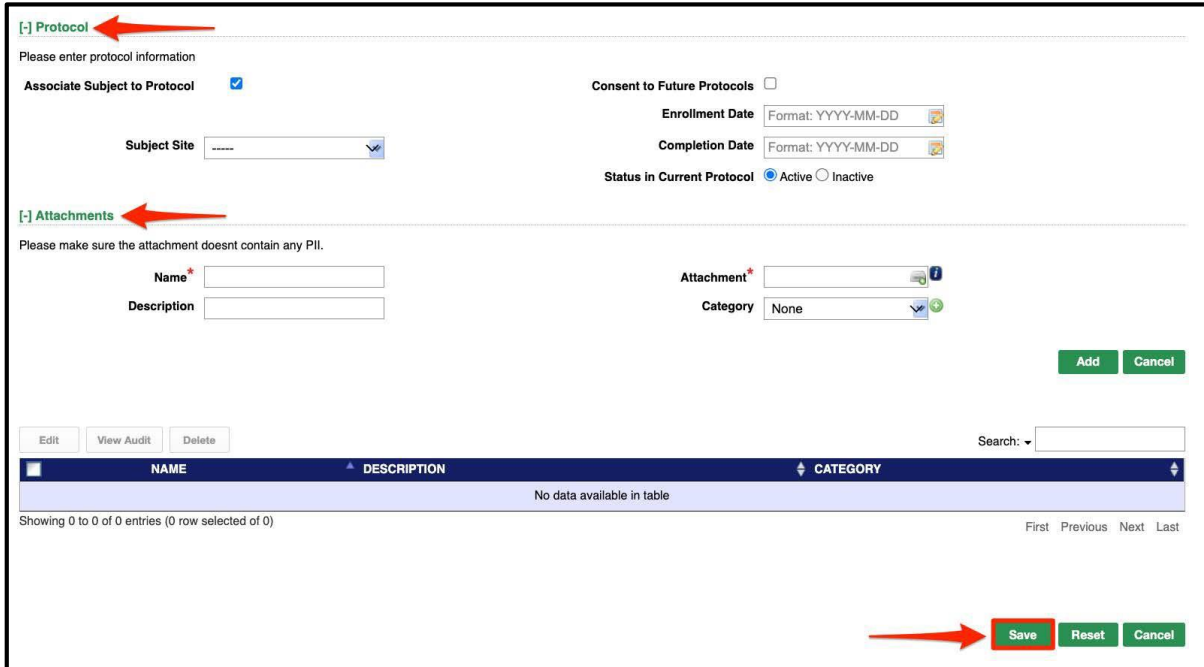
GUID or Pseudo-GUID* TBIDEMOKB275ZR0

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

Subject Site

Enrollment Date

Completion Date

Status in Current Protocol Active Inactive

[-] Attachments

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

Name*

Description

Attachment*

Category

Add Cancel

Edit View Audit Delete 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

Save Reset Cancel

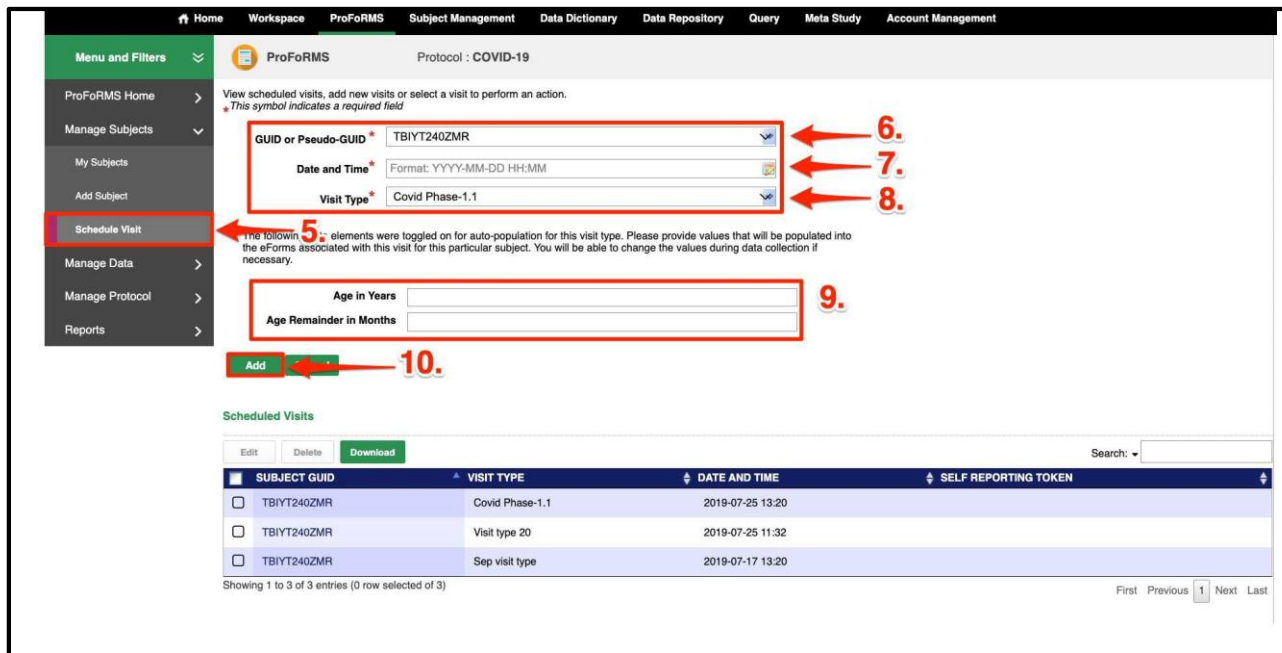
- After selecting the **Save** button, the platform returns you to the **My Subjects** page where the newly added subject can be viewed.

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 form contains the following fields:

- GUID or Pseudo-GUID**: TBIYT240ZMR (Callout 6)
- Date and Time**: Format: YYYY-MM-DD HH:MM (Callout 7)
- Visit Type**: Covid Phase-1.1 (Callout 8)
- Age in Years**: (Callout 9)
- Age Remainder in Months**: (Callout 9)
- Add** button (Callout 10)

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	

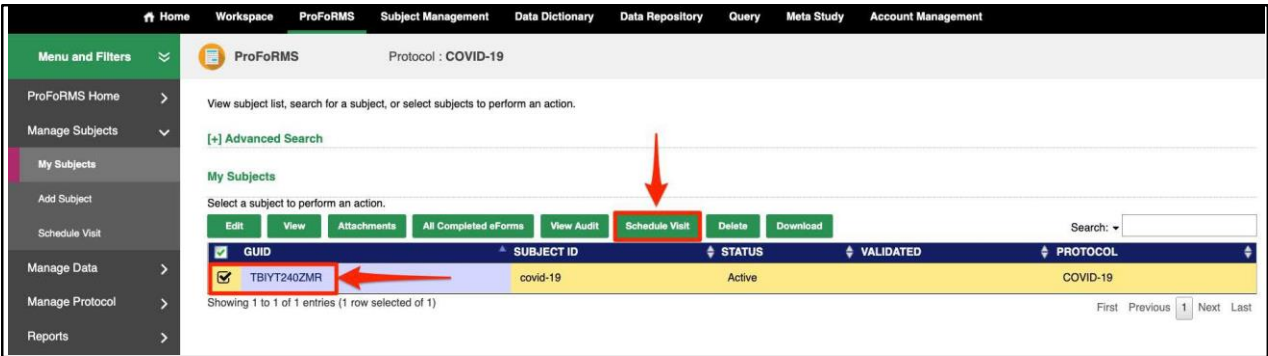
Showing 1 to 3 of 3 entries (0 row selected of 3)

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.

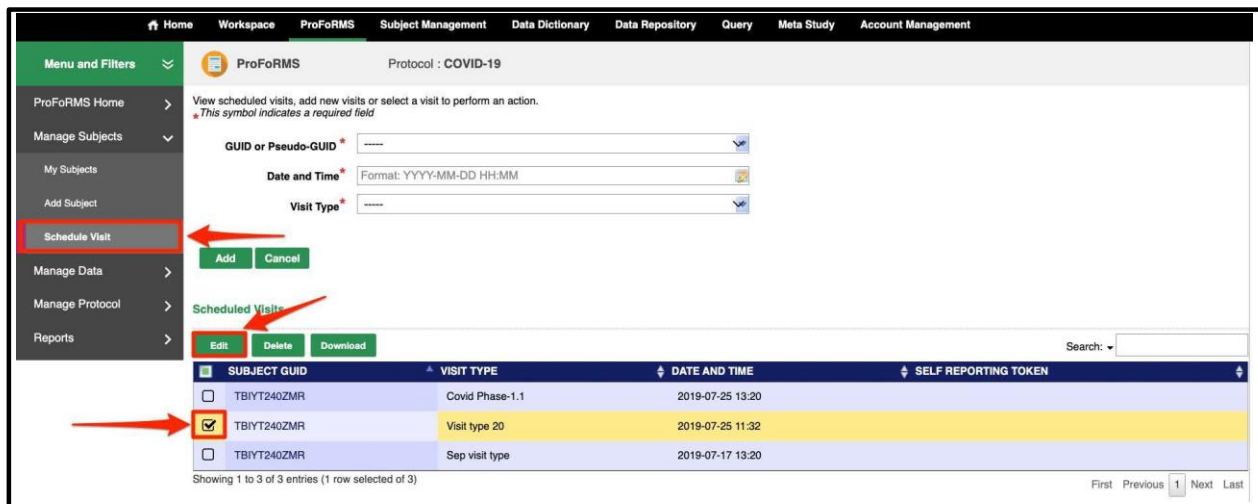
This step is recommended as the user can search/filter for a specific GUID through the search bar instead of searching for the GUID using the drop-down menu



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 displays the ProFoRMS interface for editing scheduled visits. 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 'Schedule Visit' highlighted. The main content area shows a form for adding new visits with fields for 'GUID or Pseudo-GUID', 'Date and Time', and 'Visit Type'. Below the form is a table of 'Scheduled Visits' with columns for 'SUBJECT GUID', 'VISIT TYPE', 'DATE AND TIME', and 'SELF REPORTING TOKEN'. The table contains three rows, with the second row selected. The 'Edit' button is highlighted in the table's toolbar.

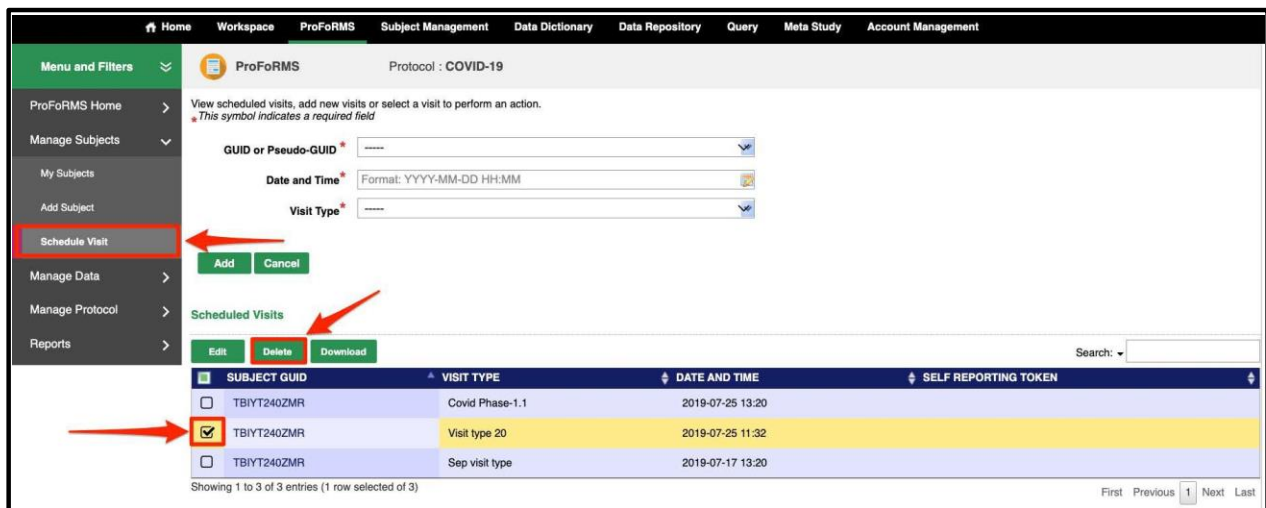
	SUBJECT GUID	VISIT TYPE	DATE AND TIME	SELF REPORTING TOKEN
<input type="checkbox"/>	TBIYT240ZMR	Covid Phase-1.1	2019-07-25 13:20	
<input checked="" type="checkbox"/>	TBIYT240ZMR	Visit type 20	2019-07-25 11:32	
<input type="checkbox"/>	TBIYT240ZMR	Sep visit type	2019-07-17 13:20	

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.

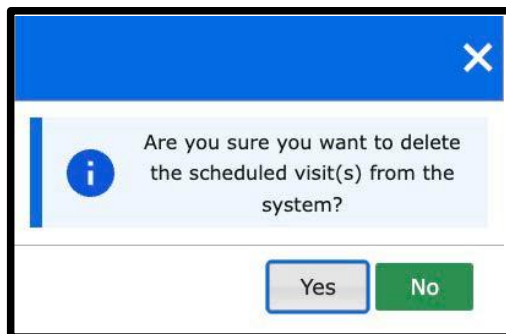
3.6.3.2 Deleting Scheduled Visits

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



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.

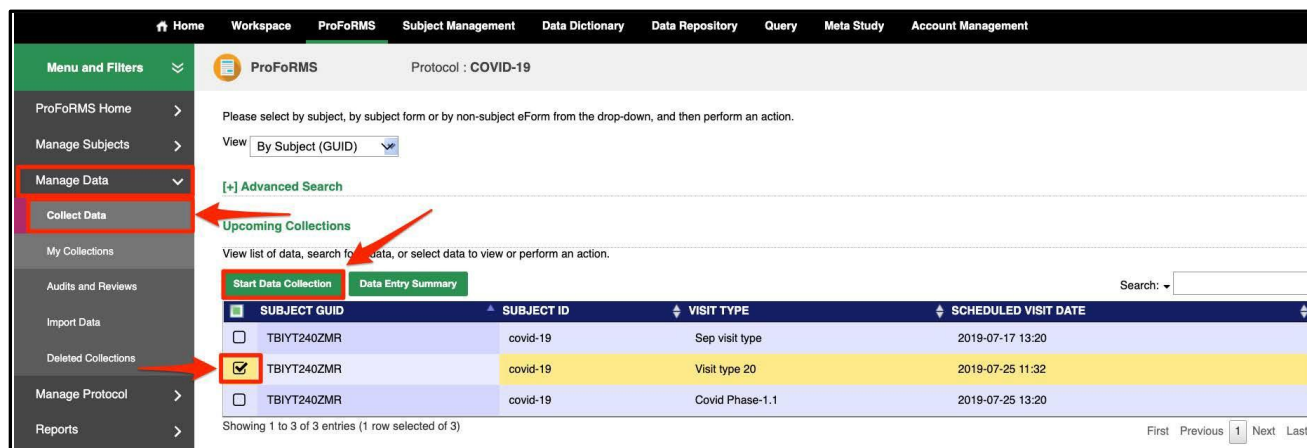
Clinical data may be captured electronically at its source, or in paper form and later transcribed into the system. There are two options for collecting data in ProFoRMS.

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.

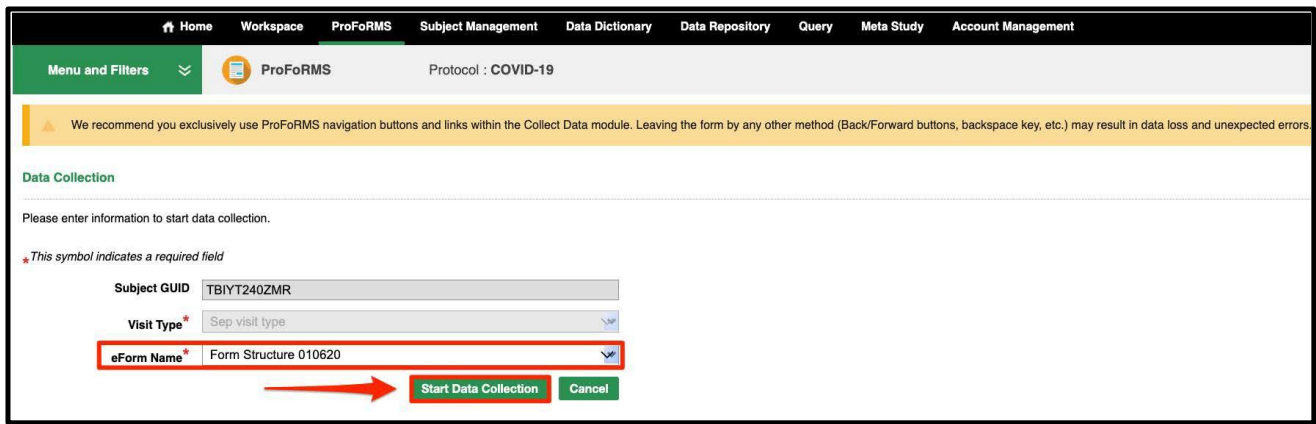


The screenshot shows the ProFoRMS interface for Protocol COVID-19. The sidebar on the left has 'Manage Data' and 'Collect Data' highlighted. The main content area shows a table of upcoming collections. A red box highlights the 'Start Data Collection' button, and a red arrow points to the checkbox for the selected subject TBIYT240ZMR.

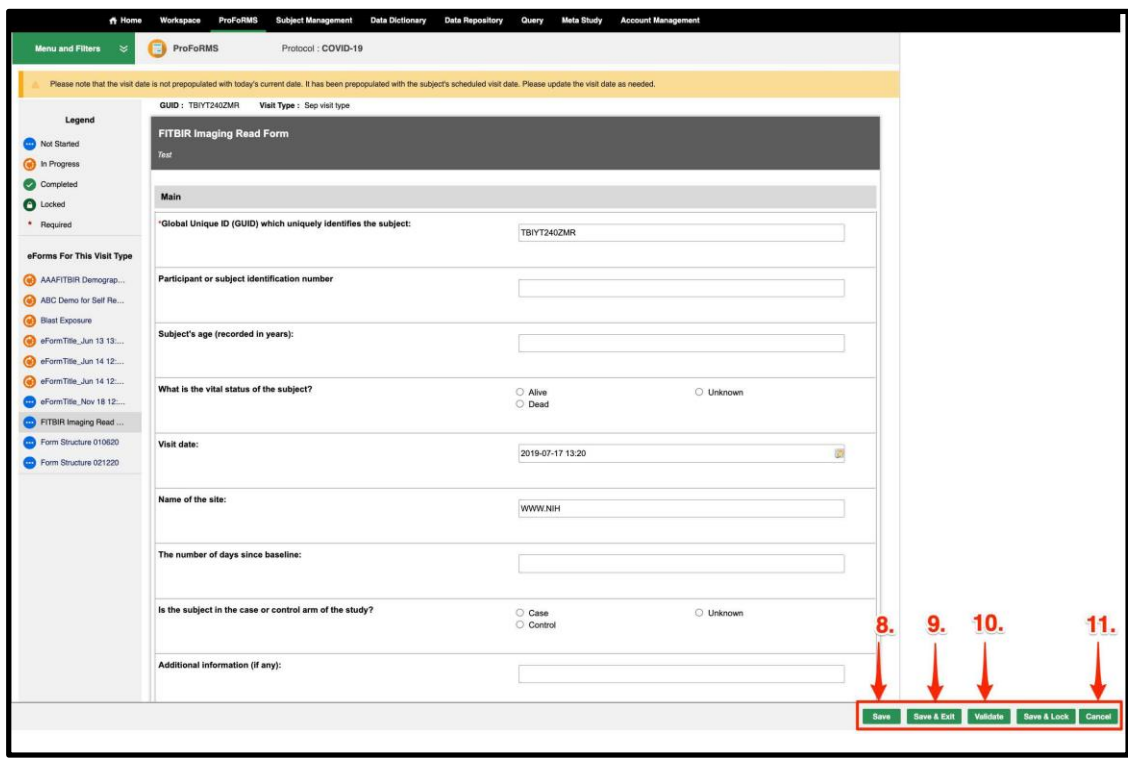
SUBJECT GUID	SUBJECT ID	VISIT TYPE	SCHEDULED VISIT DATE
<input type="checkbox"/>	TBIYT240ZMR	Sep visit type	2019-07-17 13:20
<input checked="" type="checkbox"/>	TBIYT240ZMR	Visit type 20	2019-07-25 11:32
<input type="checkbox"/>	TBIYT240ZMR	Covid Phase-1.1	2019-07-25 13:20

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.



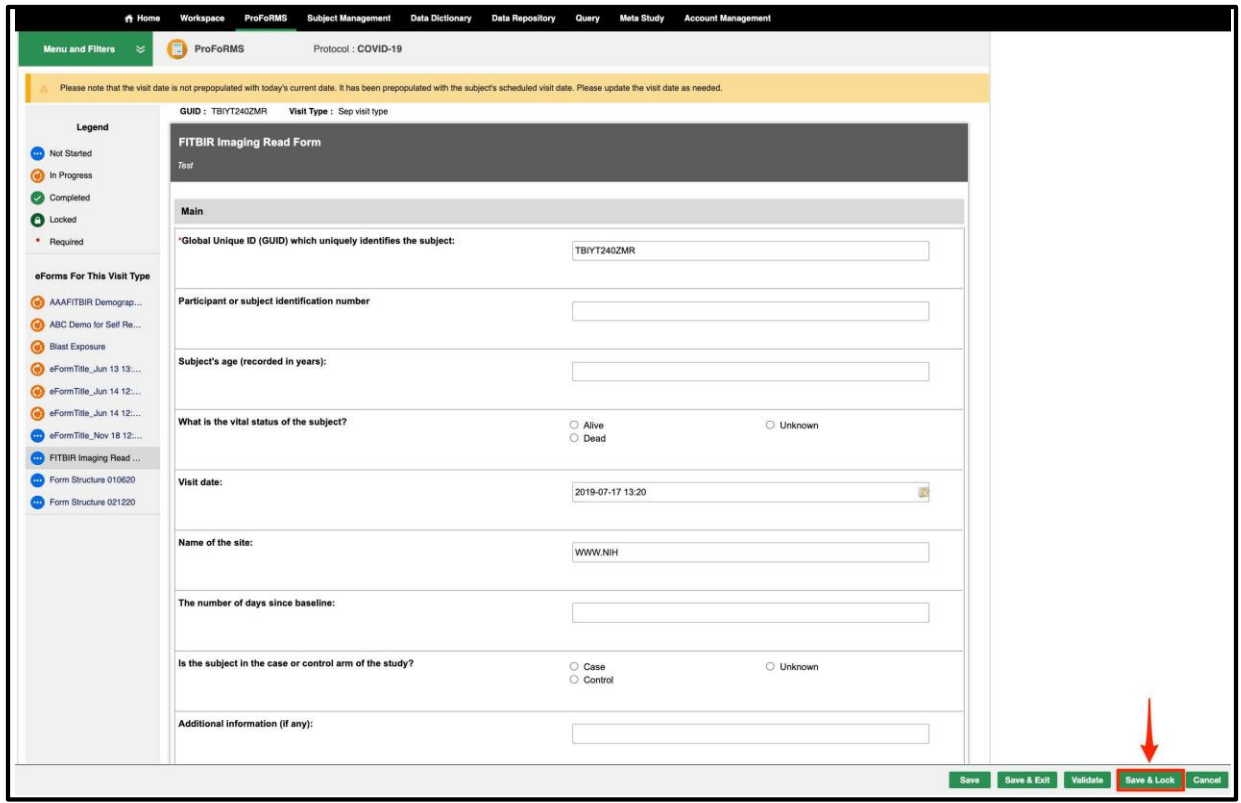
3.7.1.1 Locking the eForm

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.



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: rutherfordjrp

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 & Previous eForm** or **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:




ICON KEY

 Notes

 **Important**

Information

-  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**

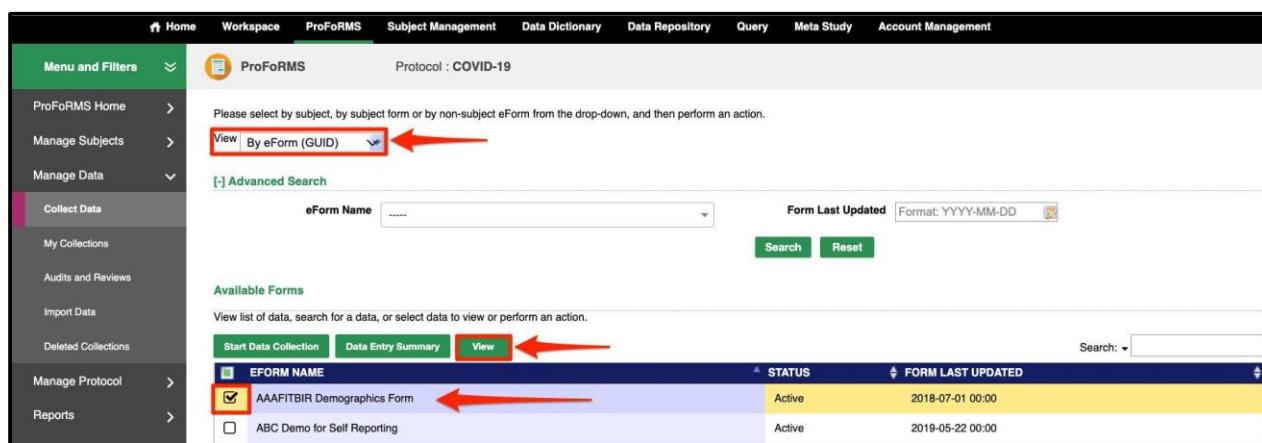
-  Auto-calculated fields appear in several forms. Answers will appear if you click on them, but it is **NOT** necessary to save the eform.
-  Green sections are collapsible. User can expand/hide to read further instructions or view scoring sections.
-  To leave the form and complete it at a later date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



ProFoRMS 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.

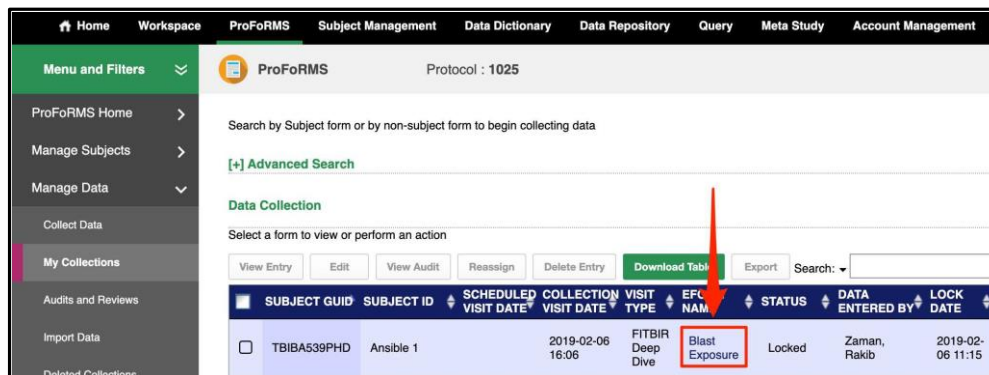
Start Data Collection Data Entry Summary **View**

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.



ProFoRMS 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: _____

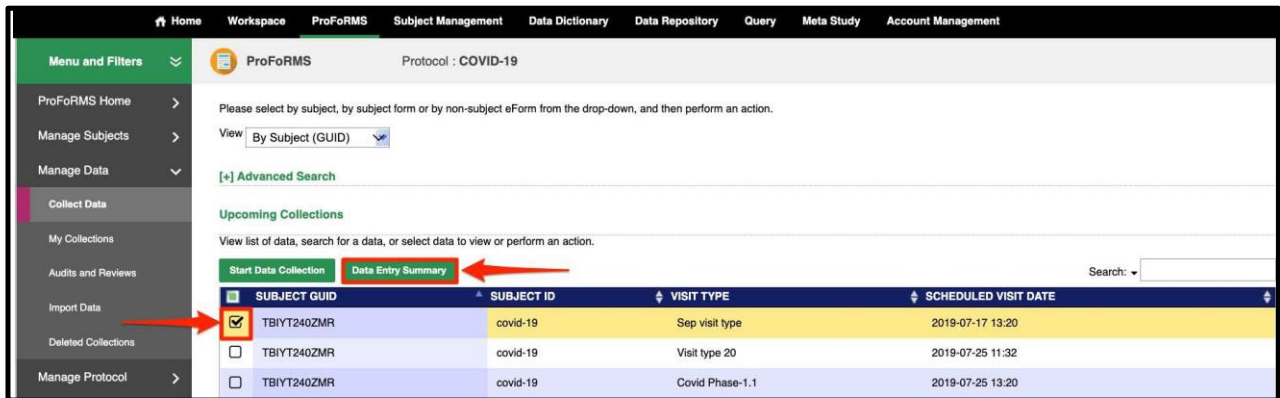
SUBJECT GUID	SUBJECT ID	SCHEDULED VISIT DATE	COLLECTION VISIT DATE	VISIT TYPE	EFOR NAME	STATUS	DATA ENTERED BY	LOCK DATE
<input type="checkbox"/>	TBIBA539PHD	Ansible 1	2019-02-06 16:06	FITBIR Deep Dive	Blast Exposure	Locked	Zaman, Rakib	2019-02-06 11:15

3.7.1.3 Viewing Data Entry Summary

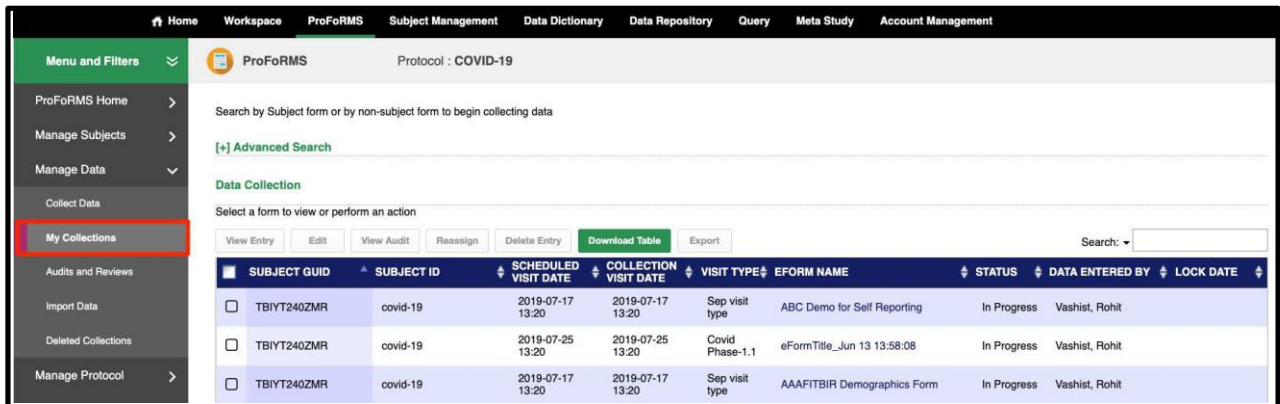
Data Entry Summary allows the user to view all data collected for a subject at one time in the My Collections table.

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**



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

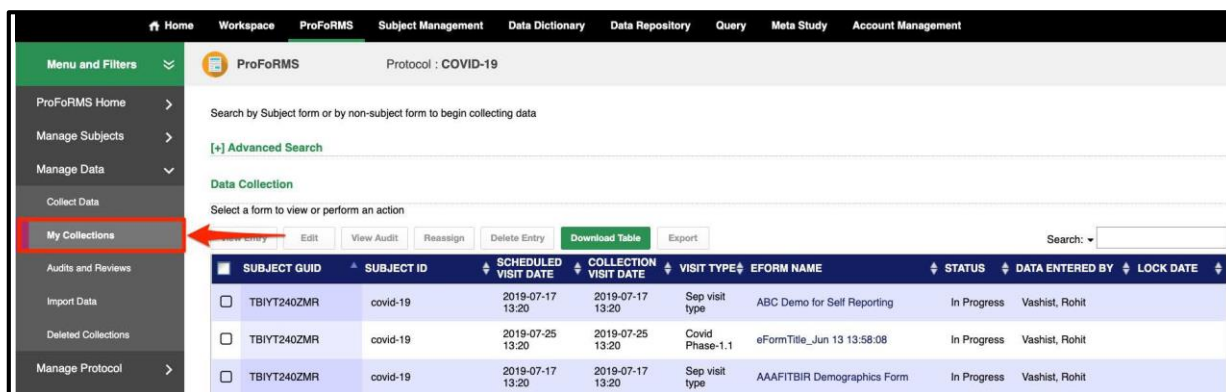


3.7.2 My Collections

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 **Manage Data** tab on the left-side tool bar then select the **My Collections** tab.
4. The **Data Collection** page appears.



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	

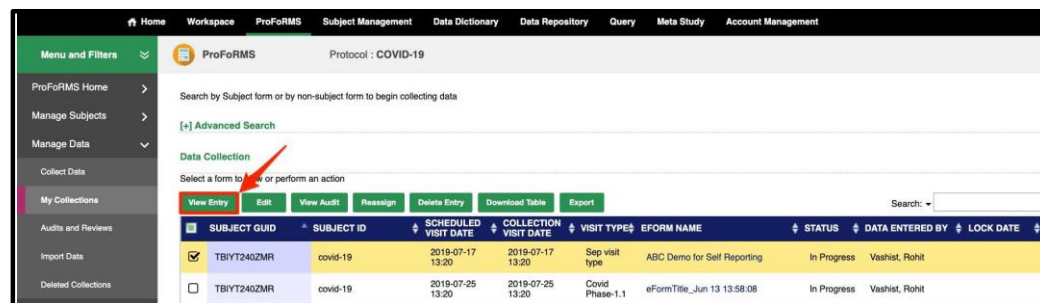
A user can perform the following actions in the **My Collections** table:

- ❖ 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 1-4 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.

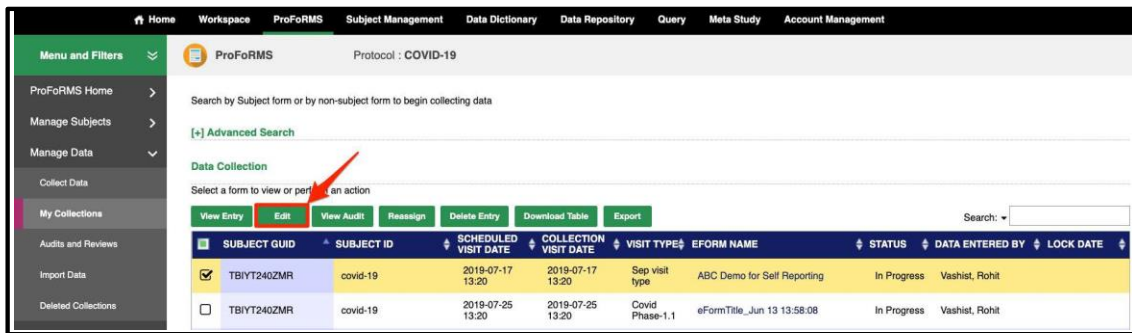


SUBJECT GUID	SUBJECT ID	SCHEDULED VISIT DATE	COLLECTION VISIT DATE	VISIT TYPE	EFORM NAME	STATUS	DATA ENTERED BY	LOCK DATE
<input checked="" type="checkbox"/> TBIYT240ZMR	covid-19	2019-07-17 13:20	2019-07-17 13:20	Sep visit type	ABC Demo for Self Reporting	In Progress	Vashist, Rohit	
<input type="checkbox"/>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

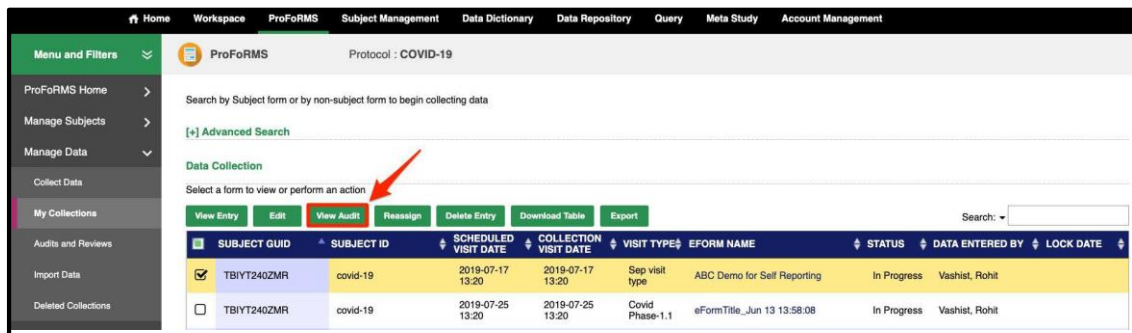
1. Perform steps 1-4 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in editing, then select **Edit**.
 - a. **Note:** non-admin users are only able to edit forms with an **In Progress** or **Completed** status. If your form 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:

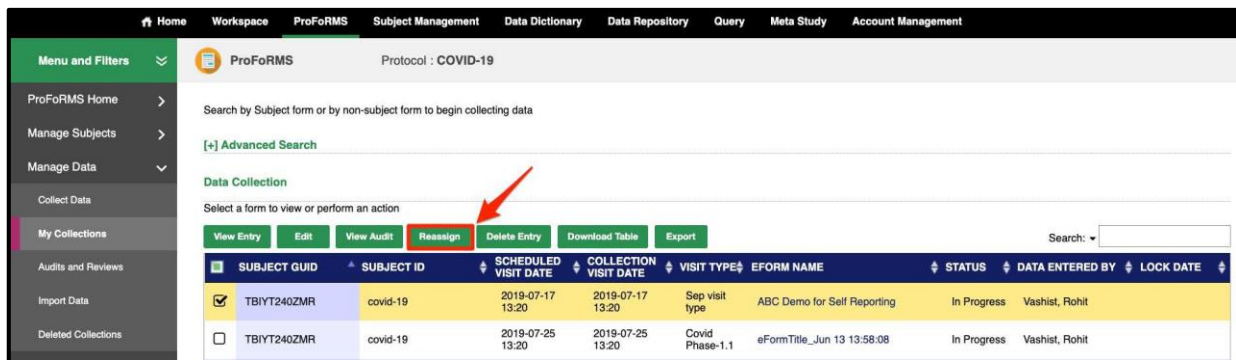
1. Perform steps 1-4 in section 3.7.2.
2. Select the check-box next to the **Subject GUID** or **Subject ID** and the eForm that you are interested in viewing, then select **View Audit**.
3. A new browser page will open with the **Data Collection Audit Log** details.



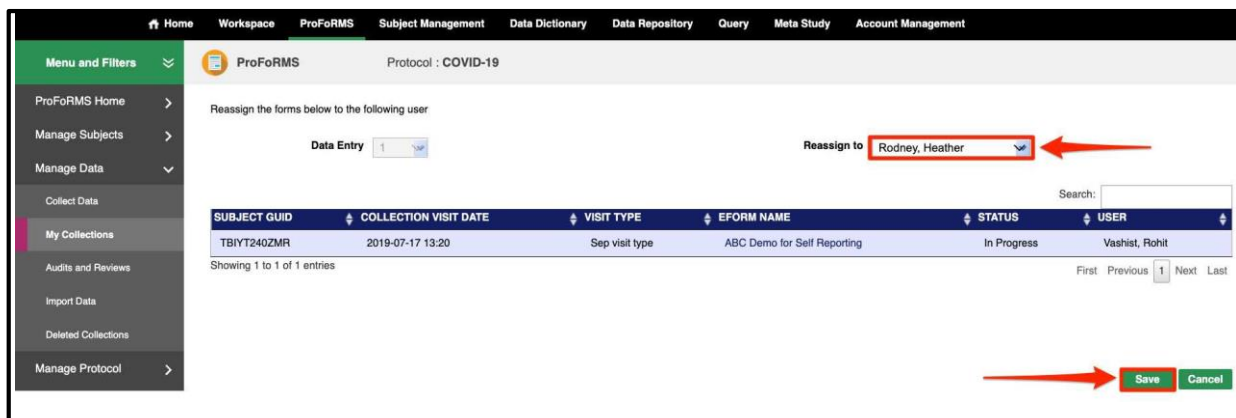
3.7.2.4 Reassign eForm

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

1. Perform steps 1-4 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*



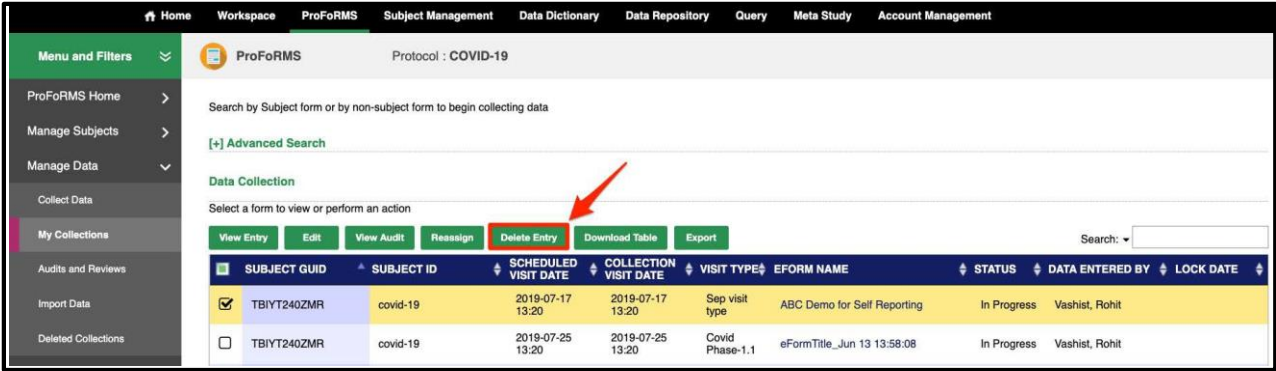
3. The **Reassign** data entry page appears.
4. Using the drop-down menu, select the desired user to reassign the eForm to, then select **Save**.
5. The **My Collections** page appears with the reassigned form update.



3.7.2.5 Delete Entry

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

1. Perform steps 1-4 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.

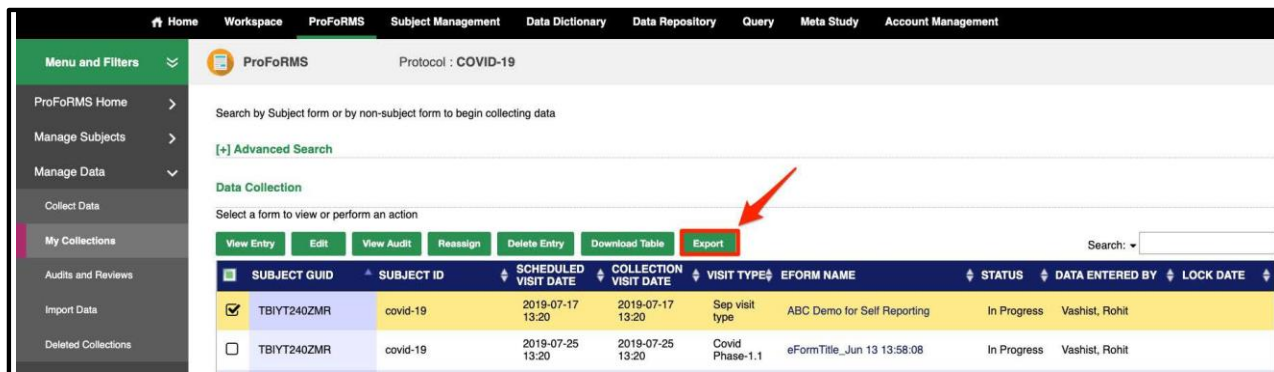


The dialog box is titled 'Reason for Deletion' and has a close button (X) in the top right corner. It contains a text input field with the label 'Reason for Deletion*' and two buttons at the bottom: 'OK' and 'Cancel'.

3.7.2.6 Export Data

The **Export** feature is an Admin feature. To **Export** data, perform the following actions:

1. Perform steps 1-4 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.



The screenshot shows the ProFoRMS interface for Protocol: COVID-19. The 'Data Collection' section is active, displaying a table of data collections. The 'Export' button is highlighted with a red arrow. The table below shows two entries:

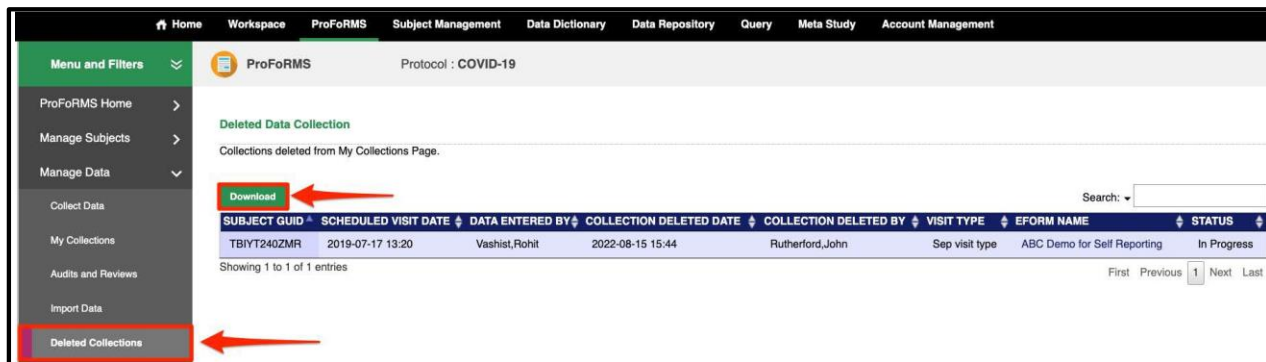
SUBJECT GUID	SUBJECT ID	SCHEDULED VISIT DATE	COLLECTION VISIT DATE	VISIT TYPE	EFORM NAME	STATUS	DATA ENTERED BY	LOCK DATE
<input checked="" type="checkbox"/>	TBIYT240ZMR	covid-19	2019-07-17 13:20	2019-07-17 13:20	Sep visit type	In Progress	Vashist, Rohit	
<input type="checkbox"/>	TBIYT240ZMR	covid-19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

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. Deleted Collections page is only visible to system Admins.

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

1. Perform steps 1-4 in section 3.7.2.
2. Select a **Protocol** (see section 3.5.1).
3. The ProFoRMS Dashboard opens. Select the **Manage Data** tab on the left-side tool bar, then select the **Deleted Collections** tab.
4. Select the **Download** button to download an Excel or CSV file of the **Deleted Data Collection** table



The screenshot shows the ProFoRMS interface for Protocol: COVID-19, specifically the 'Deleted Data Collection' page. The 'Deleted Collections' tab is selected in the left sidebar, and the 'Download' button is highlighted with a red arrow. The table below shows one entry:

SUBJECT GUID	SCHEDULED VISIT DATE	DATA ENTERED BY	COLLECTION DELETED DATE	COLLECTION DELETED BY	VISIT TYPE	EFORM NAME	STATUS
TBIYT240ZMR	2019-07-17 13:20	Vashist,Rohit	2022-08-15 15:44	Rutherford,John	Sep visit type	ABC Demo for Self Reporting	In Progress

Showing 1 to 1 of 1 entries

3.8 MANAGE PROTOCOL

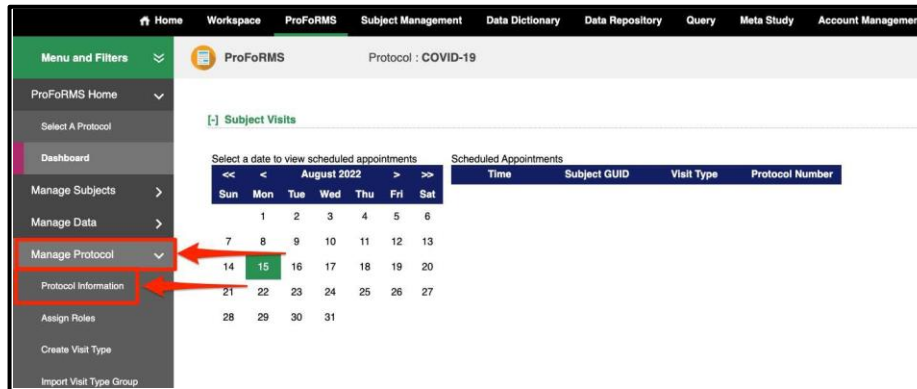
This feature is designed to help the researchers to add and edit study information, schedule create study visits, manage visit types individual subjects across multiple studies within the system, upload subject related document. The sub-sections available in the Manage Subjects menu are as follows:

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

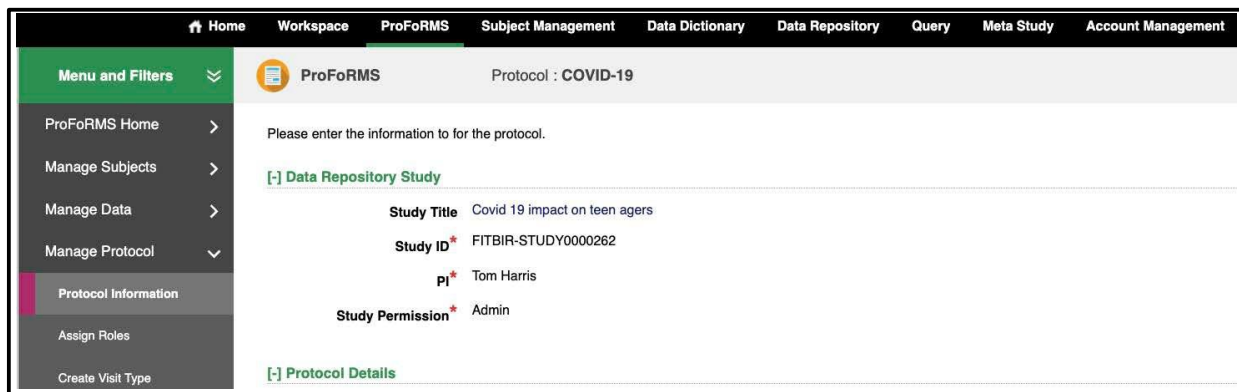
3.8.1 Viewing Protocol Information

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.



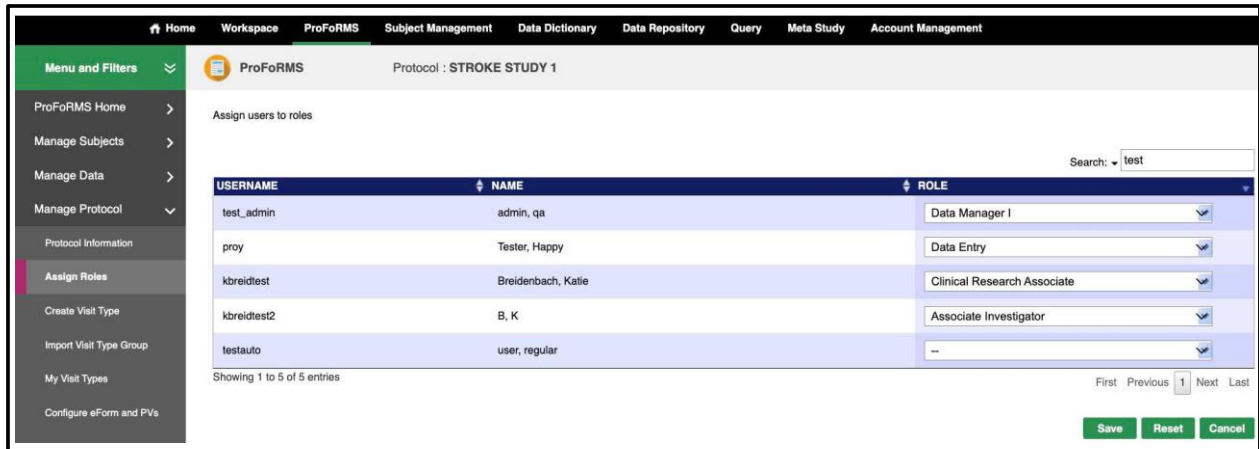
4. Click the **Protocol Information** on the left-side tool bar. The Study Information page appears.



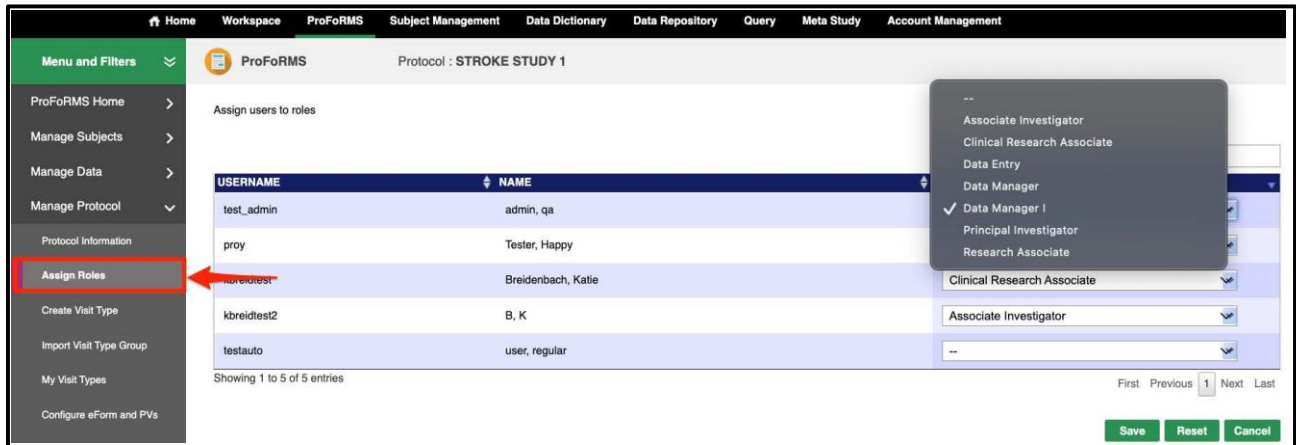
3.8.2 Assign Roles

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.

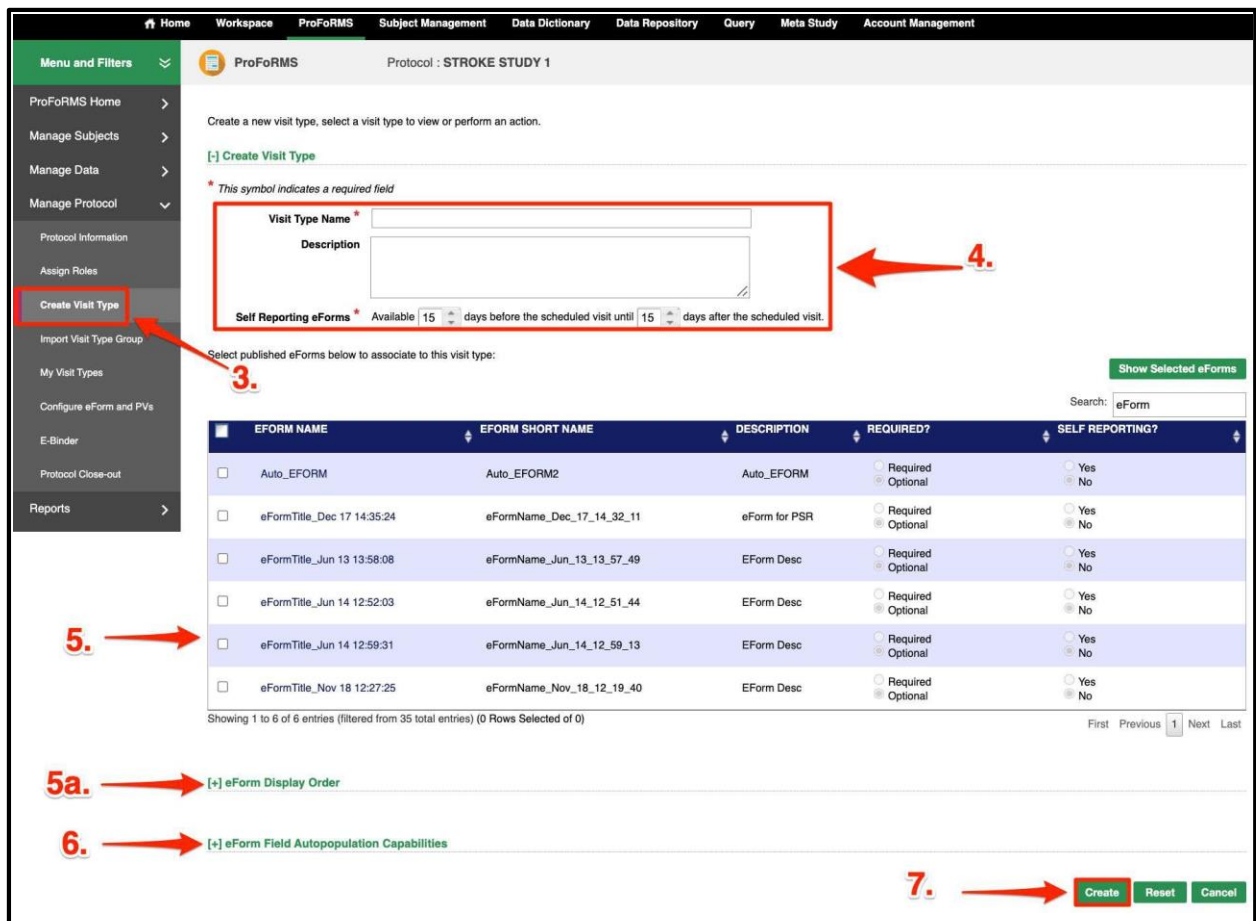


5. Click the **Save** button. The new user role(s) appear in the protocol setup.

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** 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 **My Visit Types** page.



The screenshot shows the 'Create Visit Type' page in the ProFoRMS system. The interface includes a navigation menu on the left, a header with the protocol name 'STROKE STUDY 1', and a main content area with several sections:

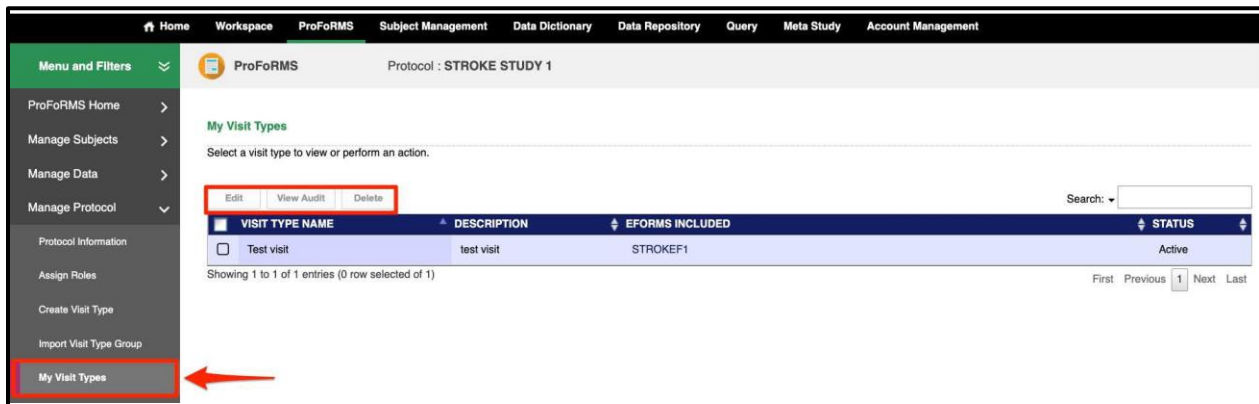
- 3.** A form for creating a new visit type with fields for 'Visit Type Name' and 'Description'. A red box highlights these fields, and an arrow points to them with the number 4.
- 5.** A section for selecting published eForms to associate with the visit type. A red box highlights the 'eForm Name' column, and an arrow points to it with the number 5.
- 5a.** A section for ordering the selected eForms, with an arrow pointing to the '[+] eForm Display Order' button.
- 6.** A section for enabling autopopulation capabilities, with an arrow pointing to the '[+] eForm Field Autopopulation Capabilities' button.
- 7.** A 'Create' button at the bottom right, with an arrow pointing to it and the number 7.

EFORM NAME	EFORM SHORT NAME	DESCRIPTION	REQUIRED?	SELF REPORTING?
<input type="checkbox"/> Auto_EFORM	Auto_EFORM2	Auto_EFORM	<input type="radio"/> Required <input type="radio"/> Optional	<input type="radio"/> Yes <input 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 main content area is titled 'My Visit Types' and contains the instruction 'Select a visit type to view or perform an action.' Below this is a table with the following data:

<input type="checkbox"/>	VISIT TYPE NAME	DESCRIPTION	EFORMS INCLUDED	STATUS
<input type="checkbox"/>	Test visit	test visit	STROKEF1	Active

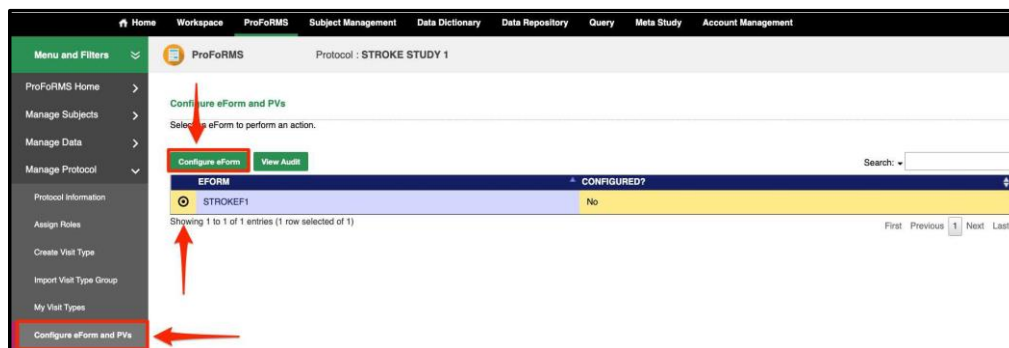
Below the table, it says 'Showing 1 to 1 of 1 entries (0 row selected of 1)'. Navigation links 'First', 'Previous', '1', 'Next', and 'Last' are visible. In the left-hand navigation menu, the 'My Visit Types' option is highlighted with a red box and a red arrow points to it.

3.8.5 Configure eForm and PVs

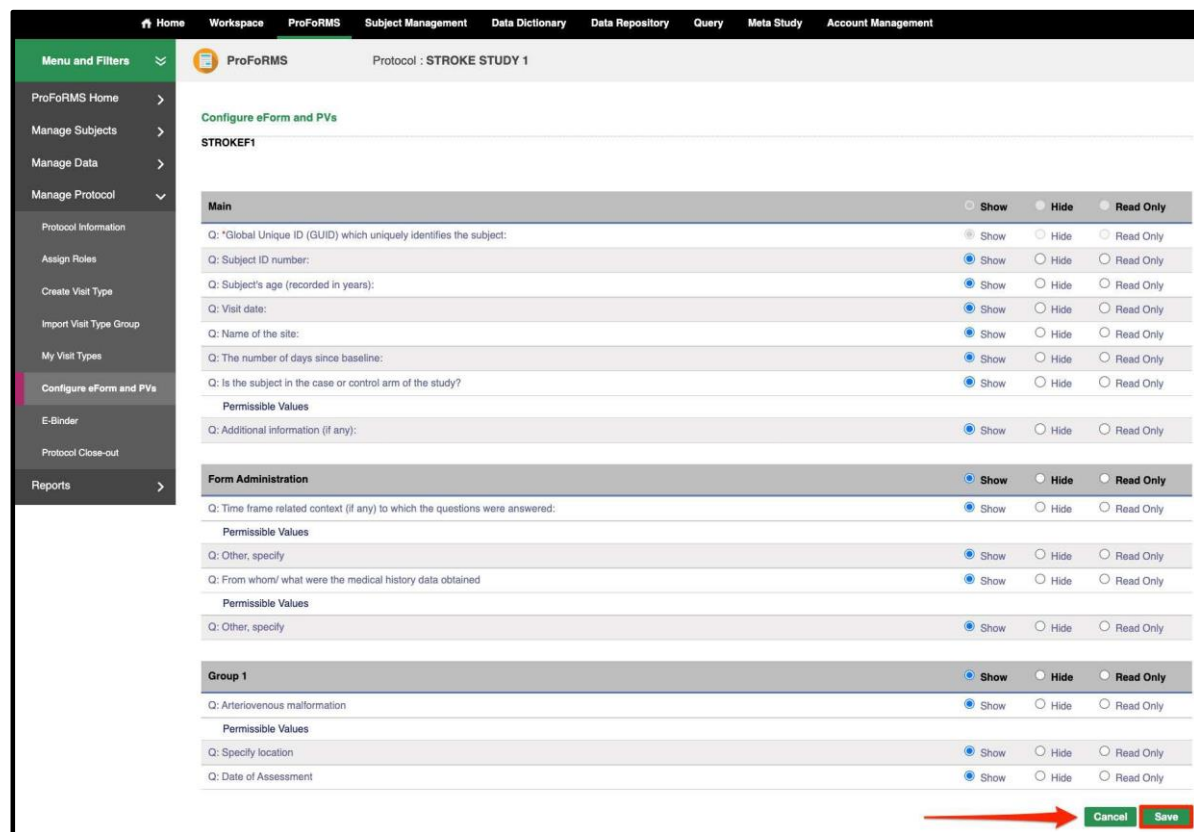
There is a feature where you are able to choose which fields of the eForm and PVs to either **Show**, **Hide**, or **Read Only**.

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**.

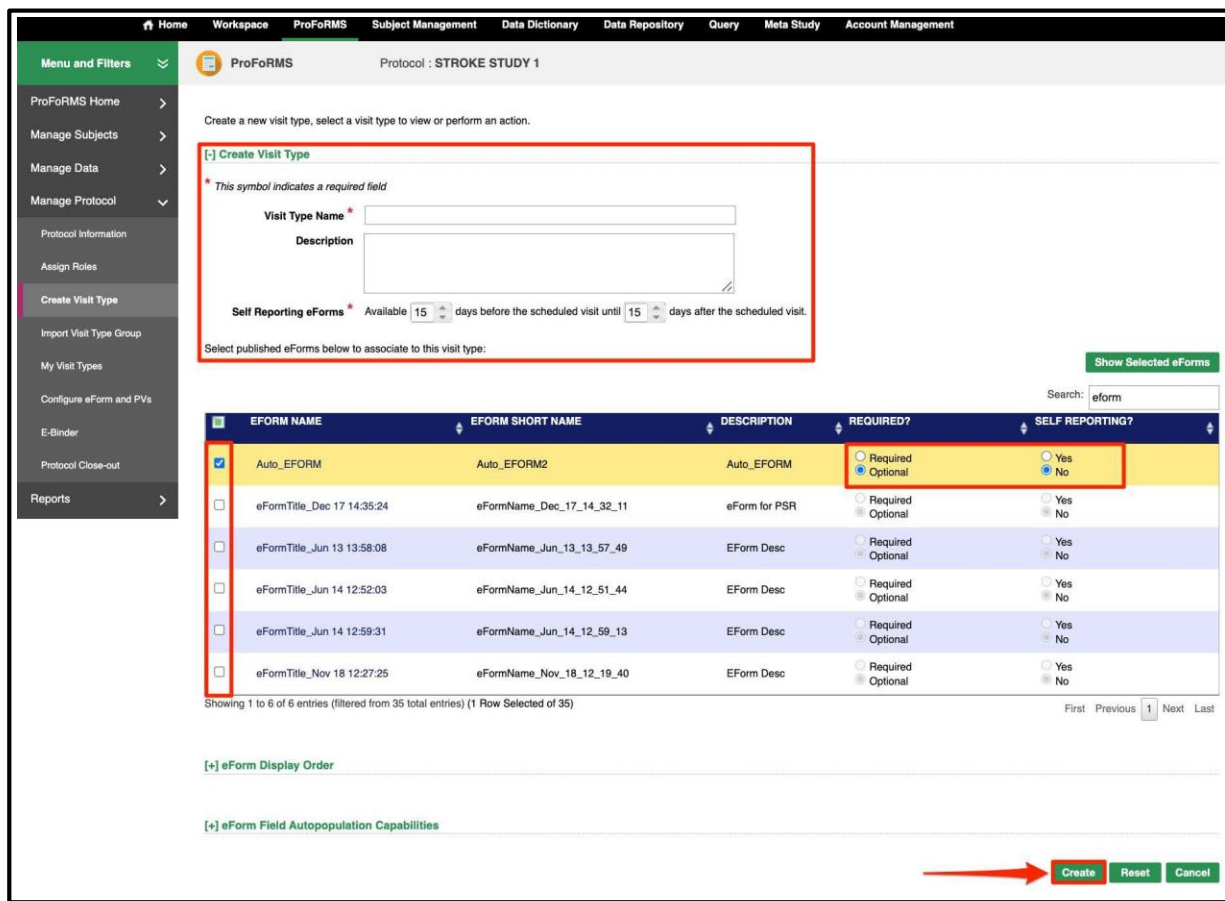


3.8.6 Patient Self-Reporting

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** 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.



ProFoRMS Protocol : STROKE STUDY 1

Create a new visit type, select a visit type to view or perform an action.

[-] Create Visit Type

* This symbol indicates a required field

Visit Type Name *

Description

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

Select published eForms below to associate to this visit type:

Show Selected eForms

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


Showing 1 to 6 of 6 entries (filtered from 35 total entries) (1 Row Selected of 35)

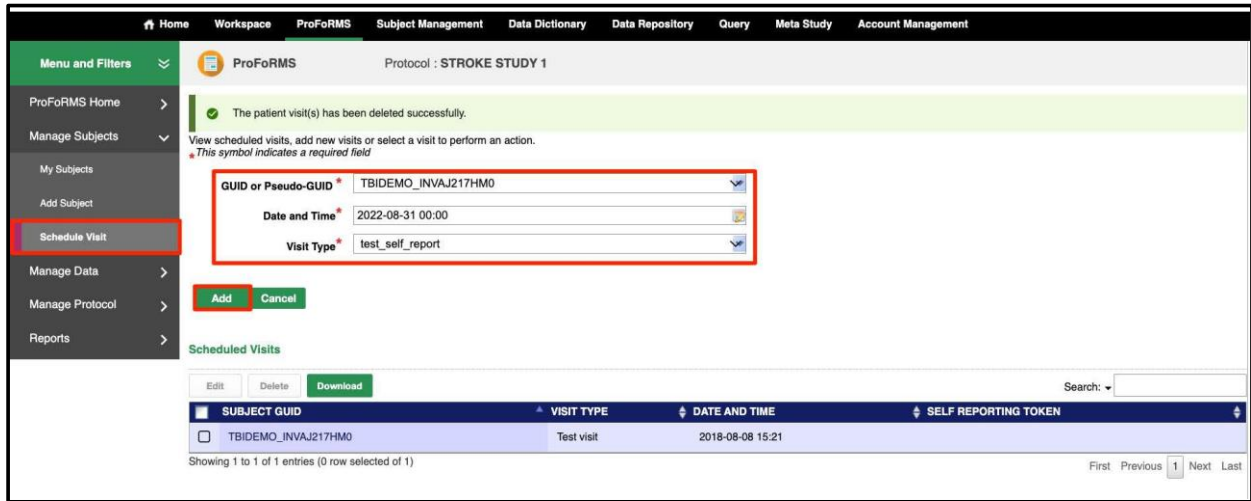
First Previous 1 Next Last

[+] eForm Display Order

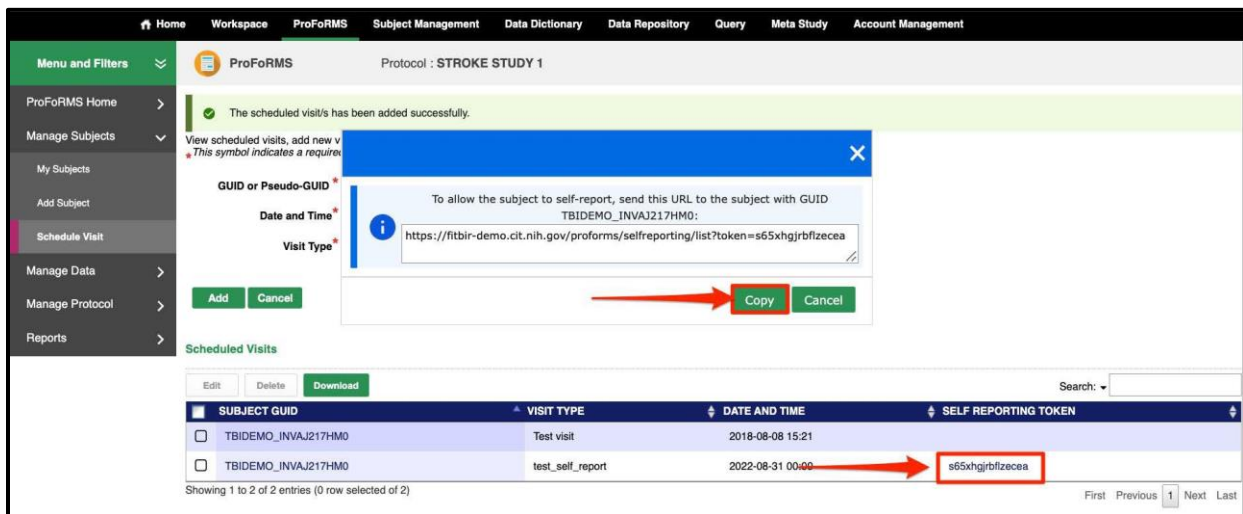
[+] eForm Field Autopopulation Capabilities

Create **Reset** **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.

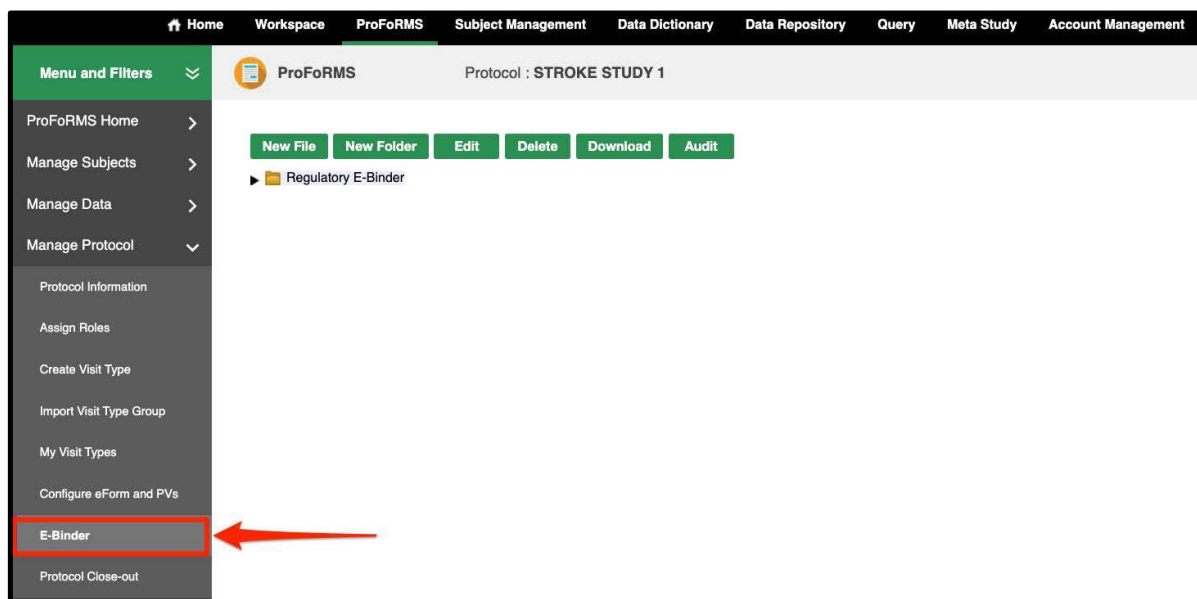


3.8.7 E-Binder

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



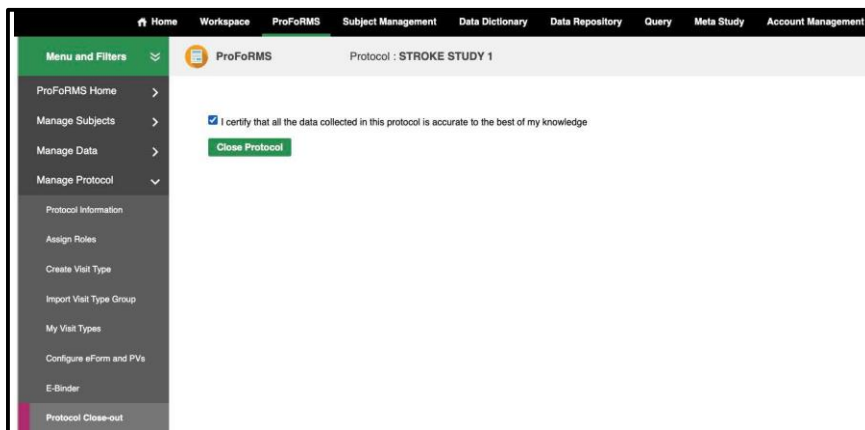
3.8.8 Protocol Closeout

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:

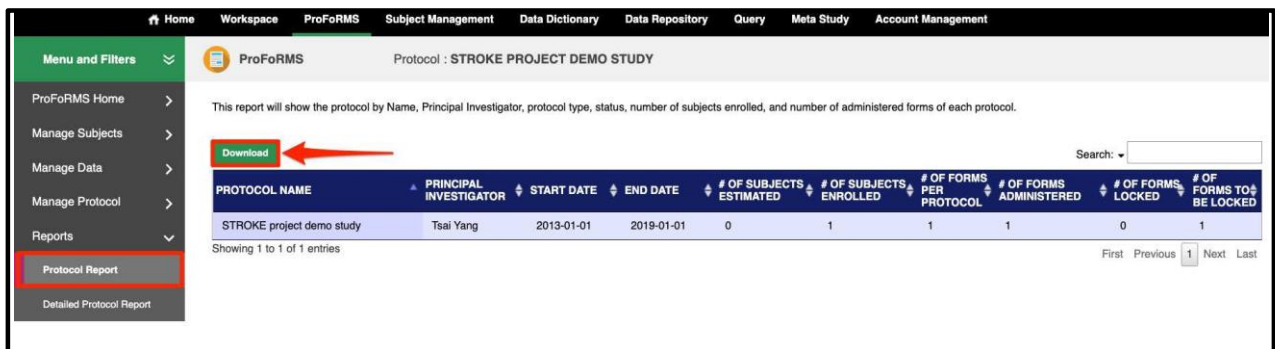
- ❖ Protocol Reports
- ❖ Detailed Protocol Report
- ❖ Without Collections
- ❖ Forms Requiring Completion & Lock
- ❖ Locked Forms
- ❖ Submission Summary
- ❖ Form Status
- ❖ View Auditor Comments
- ❖ View Reviewer Comments

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 for a COVID-19 protocol. The left sidebar contains a 'Menu and Filters' section with 'Detailed Protocol Report' highlighted. 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	AAFTIBR 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) FITIBR Imaging Read Form (1) Form Structure 010620 (1) Form Structure 021220 (0)

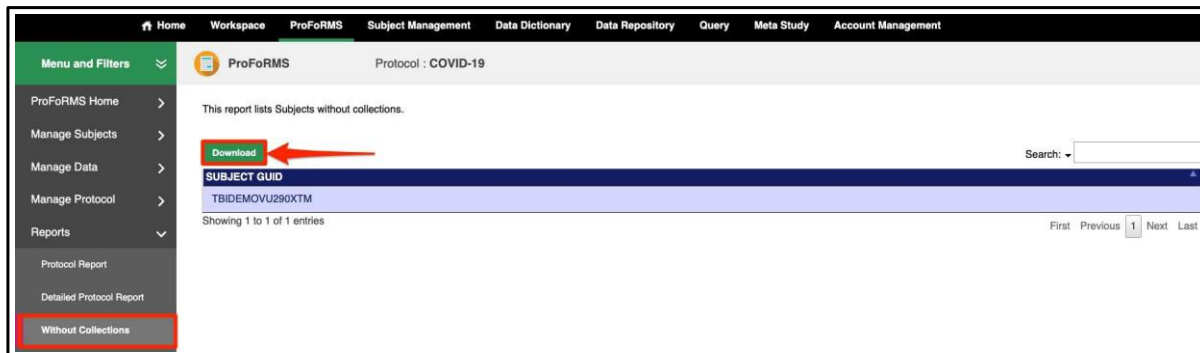
A red arrow points to a 'Download' button located above the table. The interface also includes a search bar and pagination controls at the bottom right.

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.

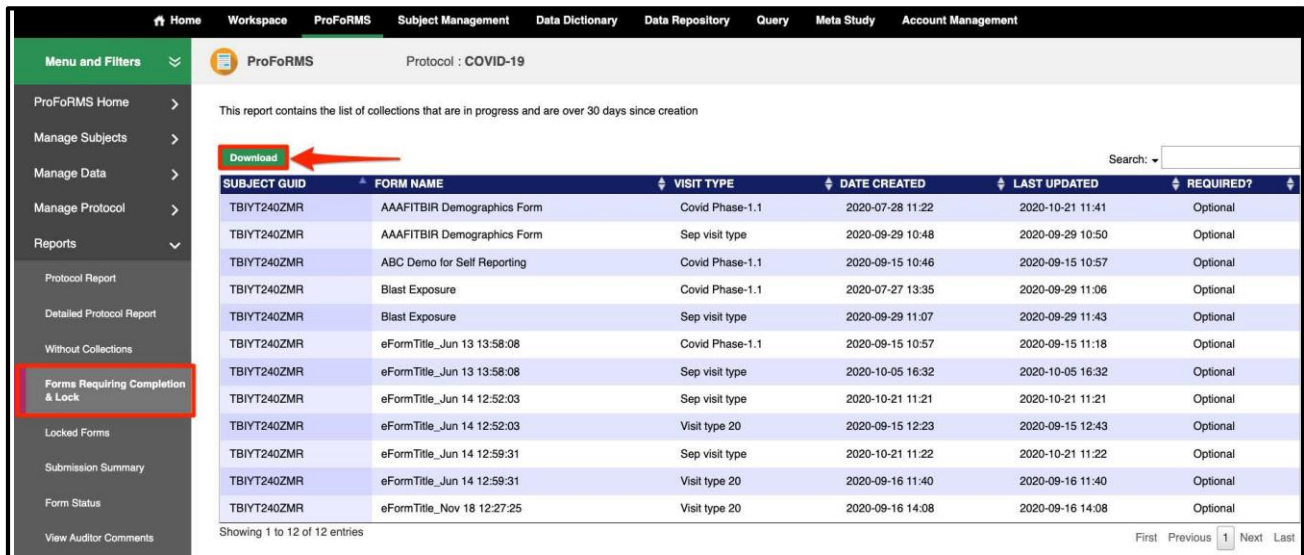


3.9.4 Forms Requiring Completion & Lock

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.



The screenshot shows the ProFoRMS interface for Protocol: COVID-19. The left-hand navigation menu has 'Forms Requiring Completion & Lock' highlighted with a red box. The main content area displays a table with the following columns: SUBJECT GUID, FORM NAME, VISIT TYPE, DATE CREATED, LAST UPDATED, and REQUIRED?. A 'Download' button is located above the table, with a red arrow pointing to it. The table contains 12 entries, showing details for various forms and their completion status.

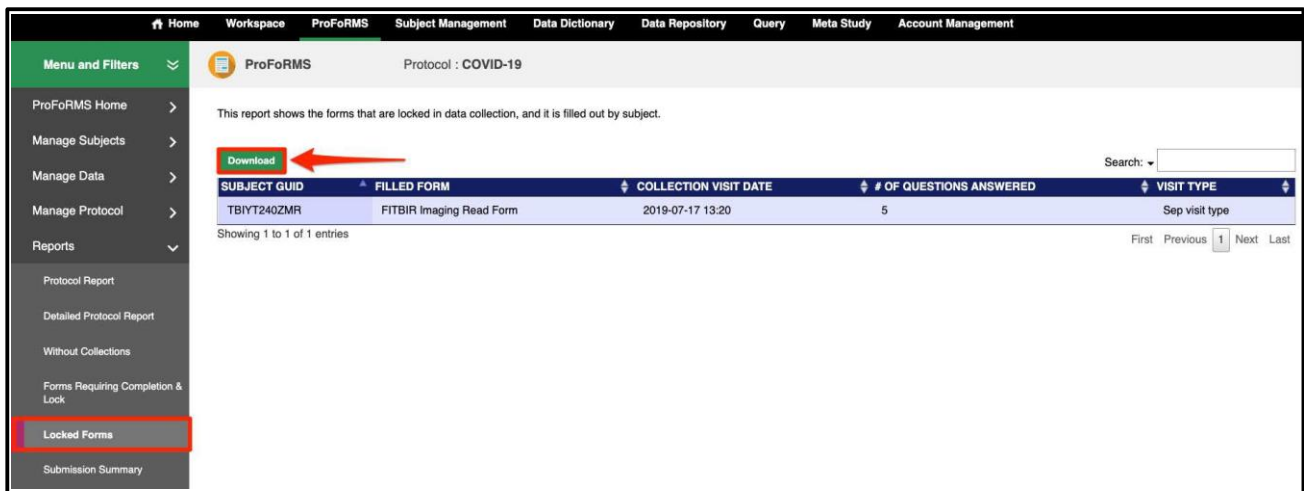
SUBJECT GUID	FORM NAME	VISIT TYPE	DATE CREATED	LAST UPDATED	REQUIRED?
TBIYT240ZMR	AAAFITBIR Demographics Form	Covid Phase-1.1	2020-07-28 11:22	2020-10-21 11:41	Optional
TBIYT240ZMR	AAAFITBIR Demographics Form	Sep visit type	2020-09-29 10:48	2020-09-29 10:50	Optional
TBIYT240ZMR	ABC Demo for Self Reporting	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

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.



ProFoRMS Protocol : COVID-19

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

Download

SUBJECT GUID	FILLED FORM	COLLECTION VISIT DATE	# OF QUESTIONS ANSWERED	VISIT TYPE
TBITY240ZMR	FITBIR Imaging Read Form	2019-07-17 13:20	5	Sep visit type

Showing 1 to 1 of 1 entries

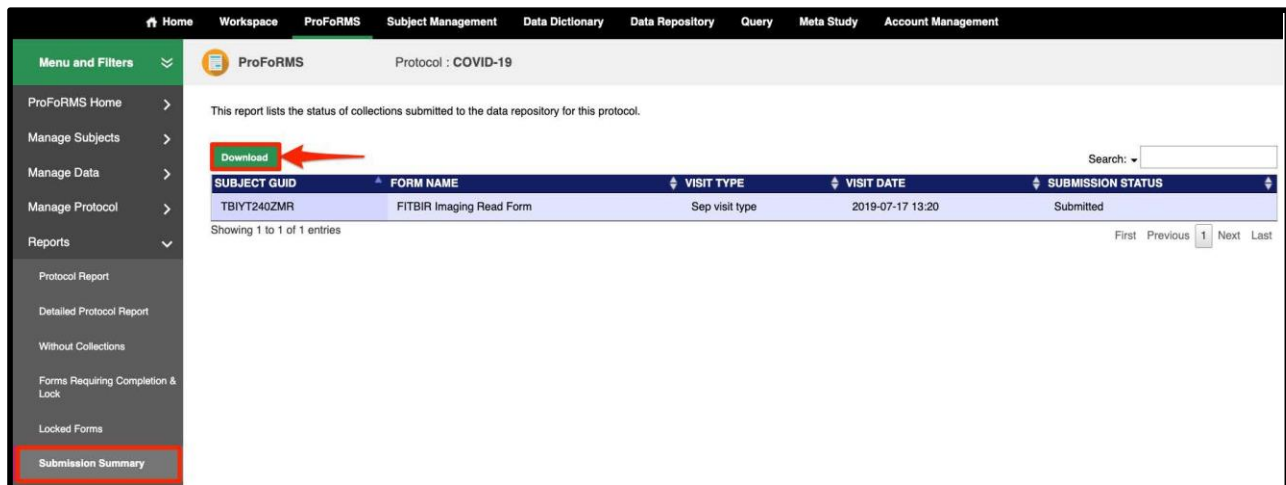
First Previous 1 Next Last

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

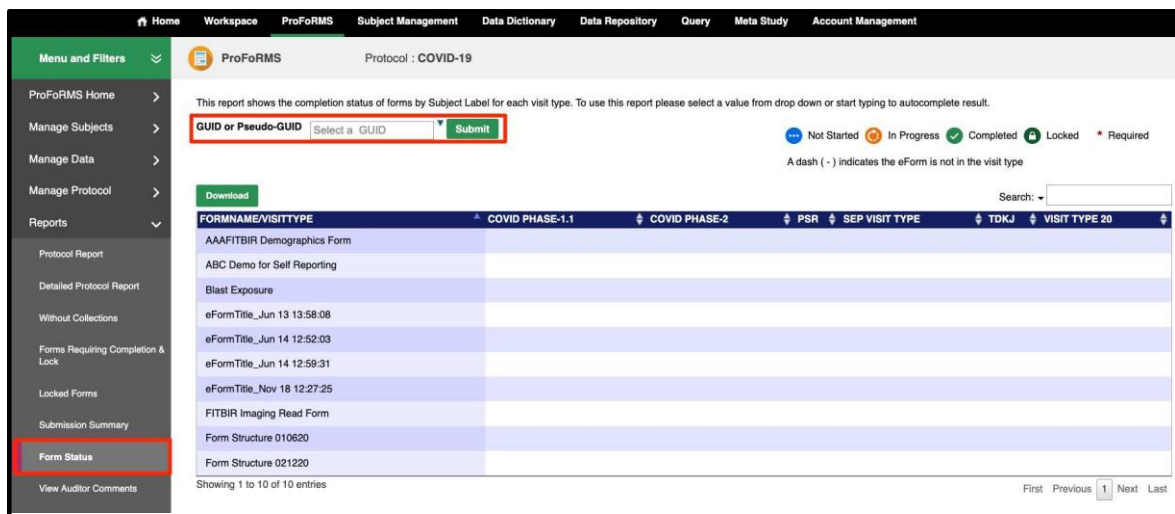
First Previous 1 Next Last

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.



Protocol : COVID-19

This report shows the completion status of forms by Subject Label for each visit type. To use this report please select a value from drop down or start typing to autocomplete result.

GUID or Pseudo-GUID

Not Started
 In Progress
 Completed
 Locked
 * Required

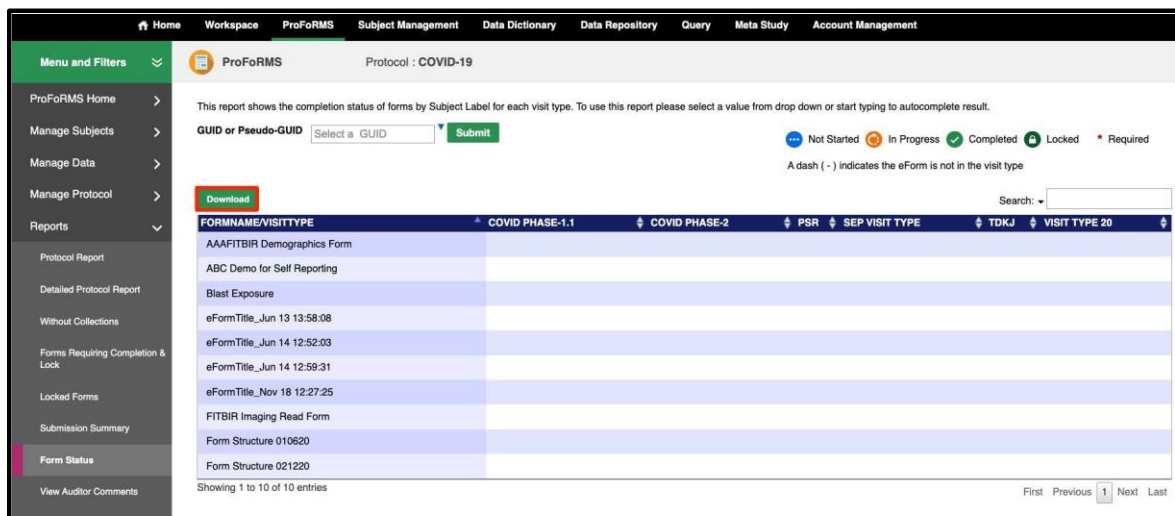
A dash (-) indicates the eForm is not in the visit type

Download

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						

Showing 1 to 10 of 10 entries First Previous 1 Next Last

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



Protocol : COVID-19

This report shows the completion status of forms by Subject Label for each visit type. To use this report please select a value from drop down or start typing to autocomplete result.

GUID or Pseudo-GUID

Not Started
 In Progress
 Completed
 Locked
 * Required

A dash (-) indicates the eForm is not in the visit type

Download

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						

Showing 1 to 10 of 10 entries First Previous 1 Next Last

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:

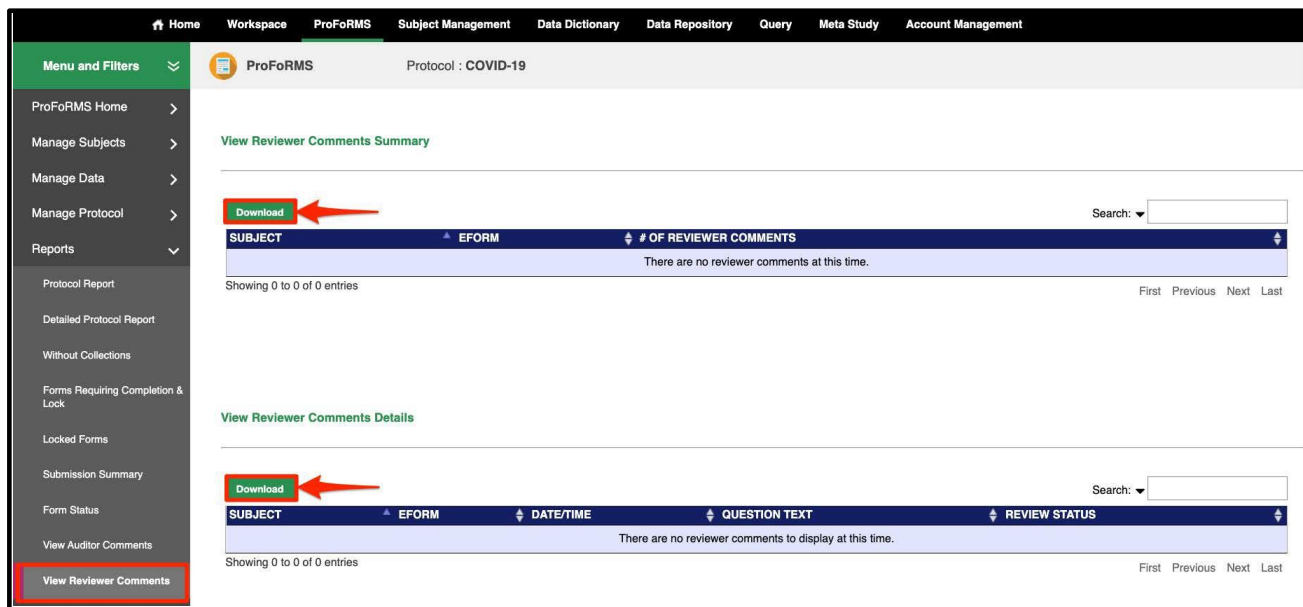
1. Navigate to the **ProFoRMS** module
2. Select a **Protocol** (see section 3.5.1)
3. The ProFoRMS Dashboard opens. Select the **Reports** tab on the left-side tool bar then select the **View Auditor Comments** tab.
4. This report shows the GUID or Subject, eForm, and Number of Auditor Comments that 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.



The screenshot displays the ProFoRMS interface for a protocol named 'COVID-19'. The left sidebar contains a 'Menu and Filters' section with 'View Reviewer Comments' highlighted in red. The main content area is divided into two sections:

- View Reviewer Comments Summary:** This section features a 'Download' button (highlighted in red with a red arrow) and a search input field. Below it is a table with columns: SUBJECT, EFORM, and # OF REVIEWER COMMENTS. The table content indicates 'There are no reviewer comments at this time.' and shows 'Showing 0 to 0 of 0 entries'.
- View Reviewer Comments Details:** This section also features a 'Download' button (highlighted in red with a red arrow) and a search input field. Below it is a table with columns: SUBJECT, EFORM, DATE/TIME, QUESTION TEXT, and REVIEW STATUS. The table content indicates 'There are no reviewer comments to display at this time.' and shows 'Showing 0 to 0 of 0 entries'.

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