PATIENT REGISTRATION AND ENROLLMENT SYSTEM (PRES) USER GUIDE

December 2023

VERSION 2.14.11

Office of Information Technology

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INTRODUCTION

Patient Registration and Enrollment System (PRES) is an application that allows the user to register and enroll patients into trial protocols.

The user interface (UI) is a Web Application compatible with Google Chrome, Microsoft Edge, Mozilla Firefox, and Apple Safari. It has been developed by the Office of Information Technology, CCR, NCI, NIH, that also supports and updates the system.

GETTING TO PRES

To access PRESS, open your preferred Web Browser and enter https://pres.ccr.cancer.gov in the URL bar. PRES is only accessible while connected to the NIH network.

LOGIN

Users are prompted to login by using PIV card or NIH Username and Password with Authenticator

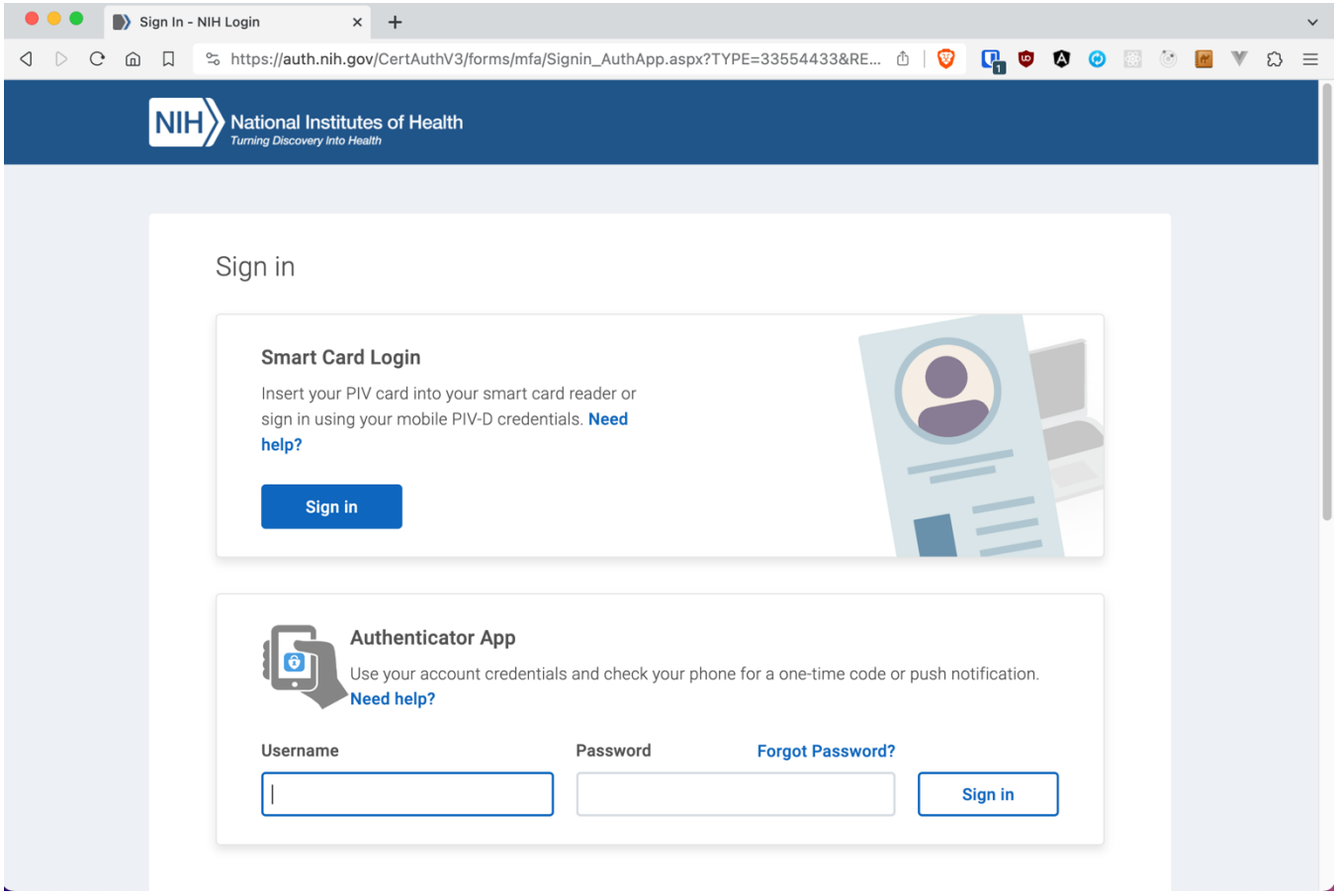


FIGURE 1 - LOGIN SCREEN

If you are not able login or you receive an error message, please use the “Need assistance? Click here!” button located at the lower left part of the home page. This will display the Issues and Feedback menu. Help button also present in upper right side before Login/Logout button on every page. Help page lists User Manual link, API Documentation, Pharmacy App Instructions and frequently asked questions (FAQs)

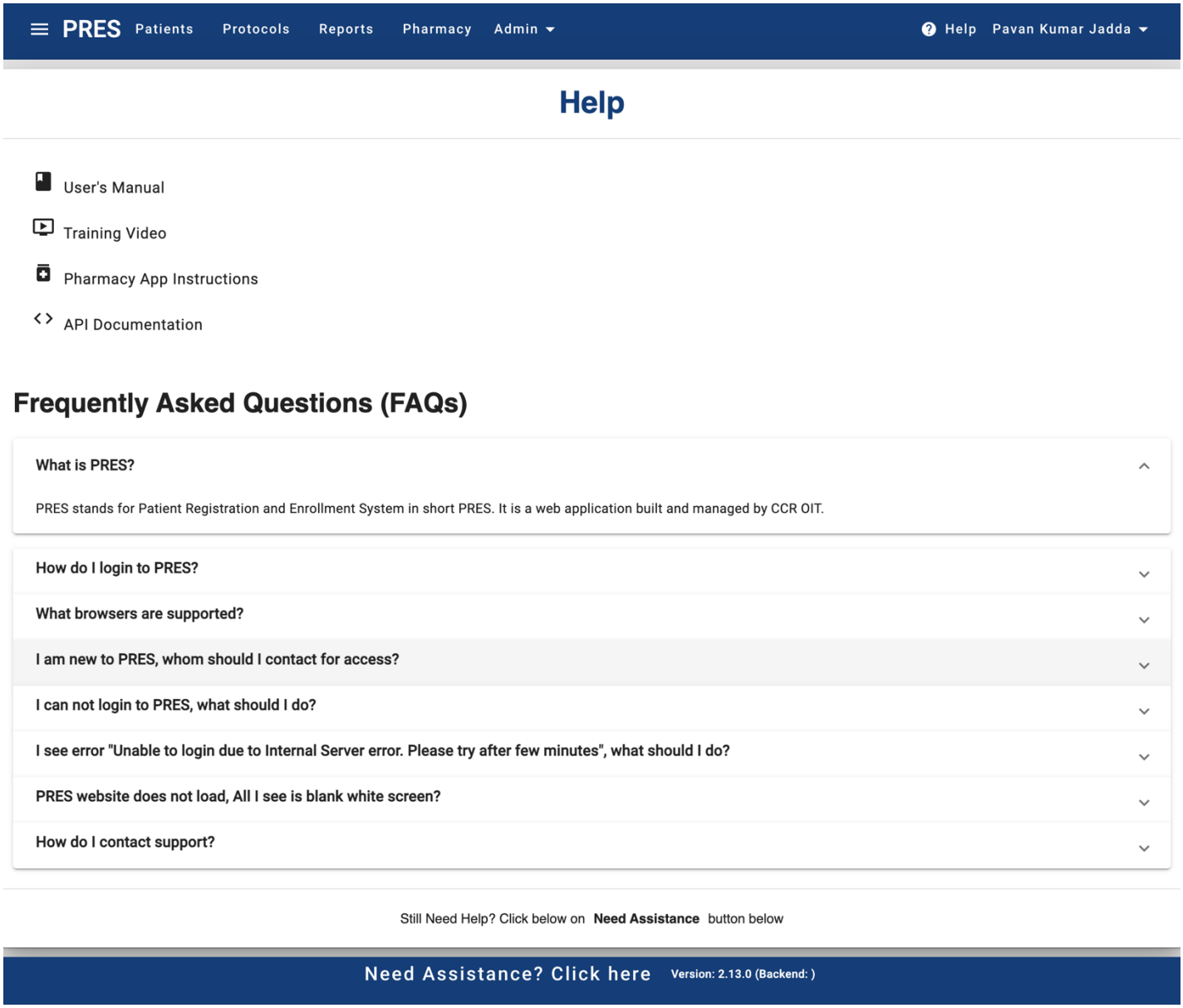


FIGURE 2 - HELP

USEFUL LINKS

At the bottom of the login page and every page in the application, the user will find links to useful functions, policies and organizations.

HOME PAGE

After entering a valid Username and Password, the system will redirect you to the home page. The tiles on the home page will enable the user to access different sections based on the user's privileges. The tiles that appear in the figure below belong to a System Admin. Other users will not be able to see all sections.

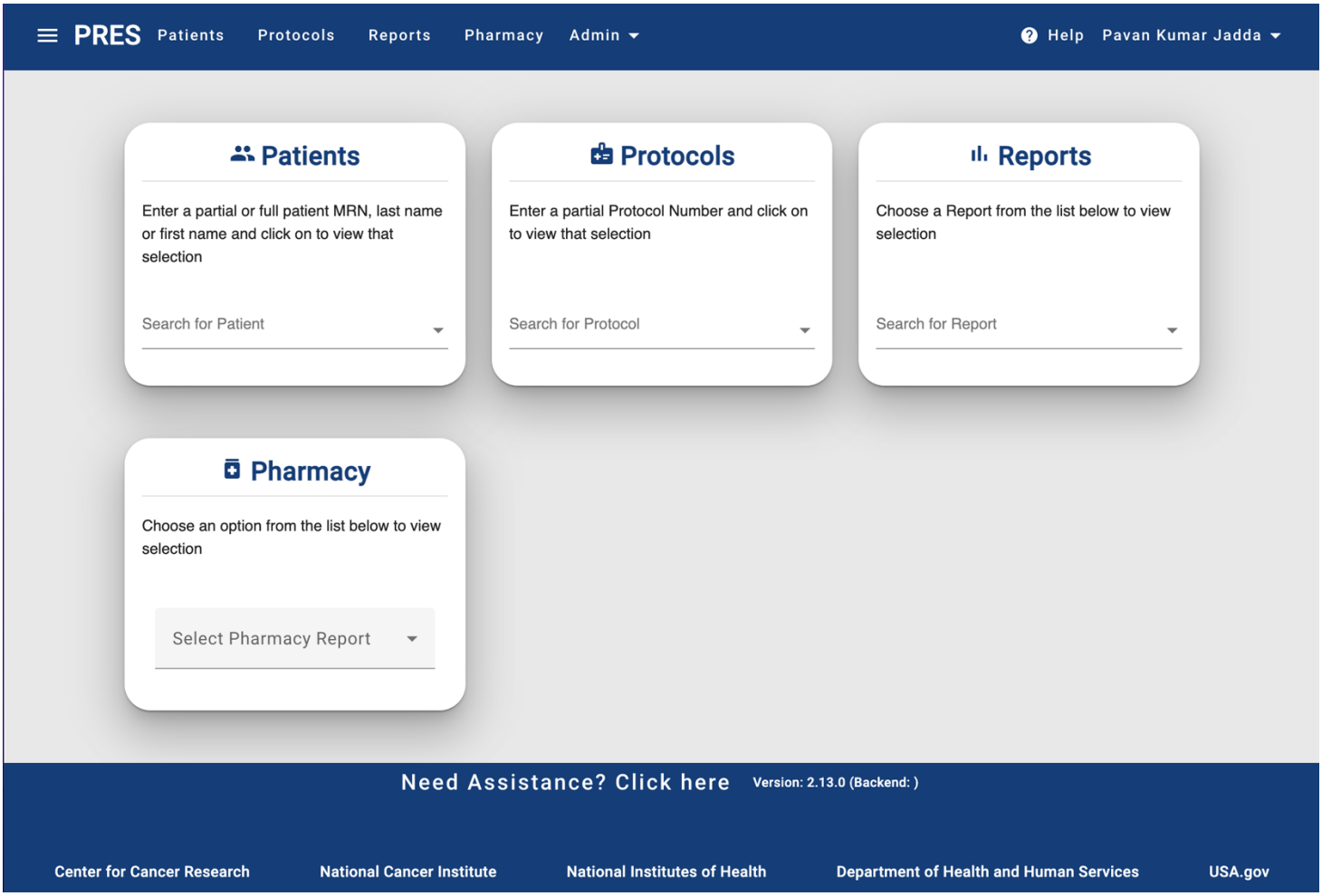


FIGURE 3 - HOME PAGE

On every page of the application the user can go back to the home page by clicking the PRES link at the top of every page.

FIGURE 4 – MENU BANNER The

other links provide shortcuts to each page in the application.

Clicking the list icon in the title bar opens yet another navigation shortcut as seen below.

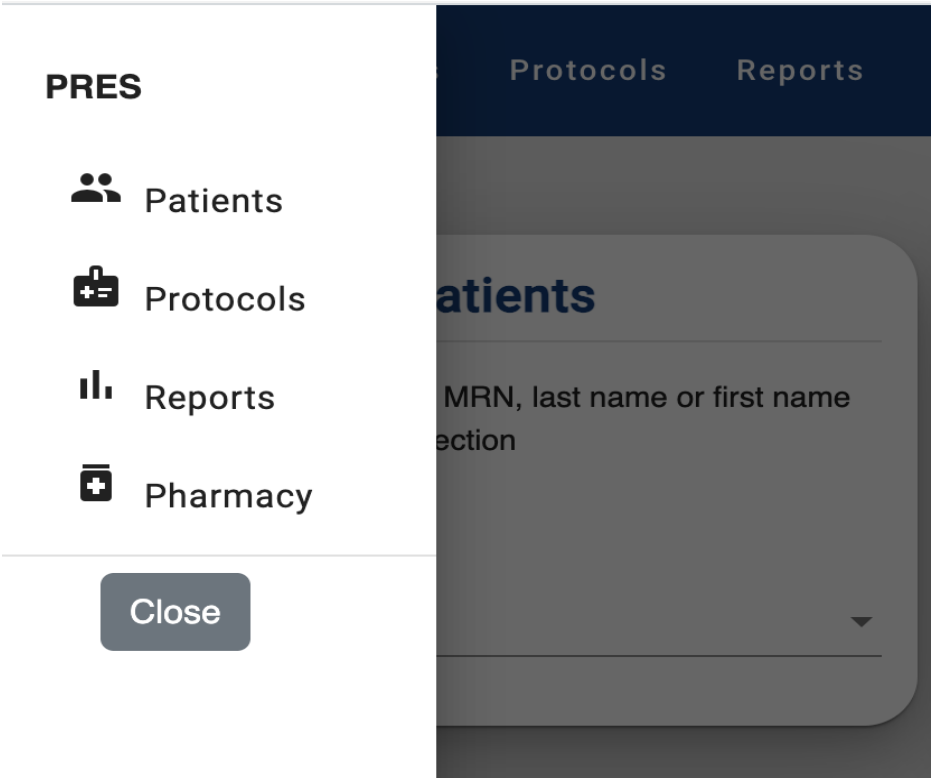


FIGURE 5 – MENU BANNER

The Patients tile on the home page allows the user to search for patients with partial (at least 2 characters) MRN or name.

The Protocols tile allows the user to search protocols by partial protocol number with or without dashes.

The Reports tile (for those with the privilege) allows the user to select and run standard reports.

The Pharmacy tile allows pharmacy users to quickly find new registrations.

There is no Register tile because the user must first select a patient or a protocol before the Register button is available.

SEARCHING AND SELECTING A PATIENT

You can find a patient in 3 different ways in PRES. First, on home page in Patients tile, Second on patient view page and Third on registration page.

To find a patient enter at least 2 characters which will open a drop-down list of patients already in PRES matching those characters:

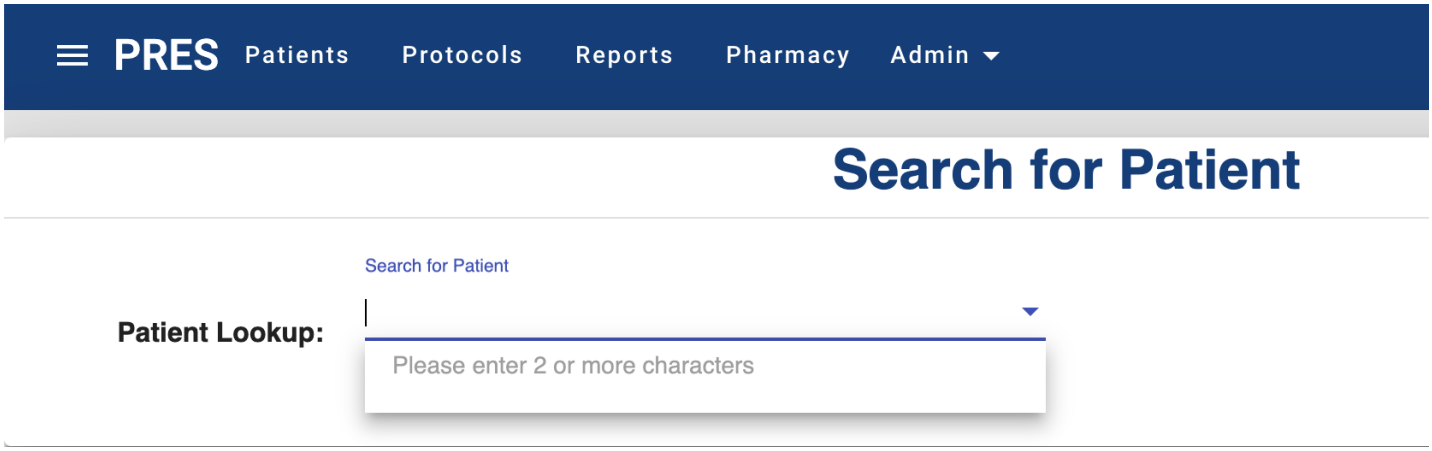


FIGURE 6 – MATCHING PATIENTS IN PRES

Select a patient by clicking on it or continue entering characters until the desired patient is found.

If a valid CRIS MRN is entered that is NOT found in PRES, the search result will indicate “CRIS” as the source of the patient as follows:

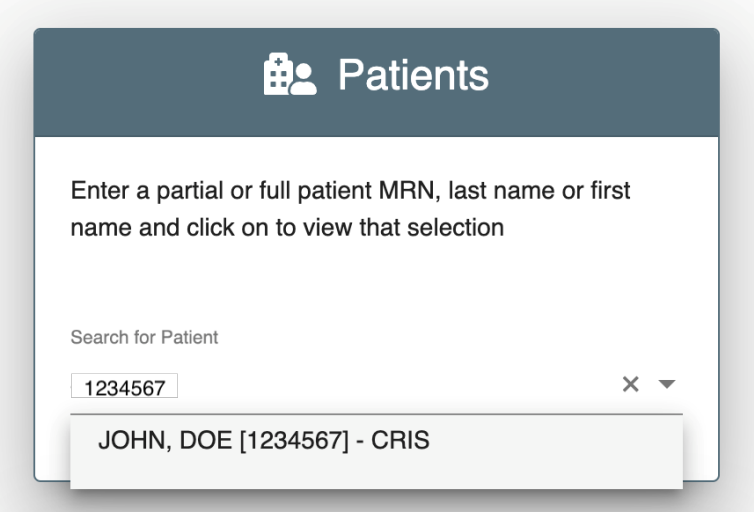


FIGURE 7 – CRIS PATIENT NOT IN PRES

Selecting a CRIS patient will import that patient into PRES.

If a valid CRIS MRN is entered and not found, please contact CRIS to verify the MRN.

If an outside patient is not found in PRES, the user is directed to select a multisite protocol first:

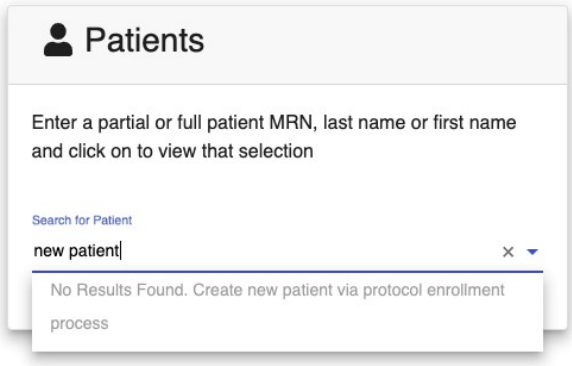


FIGURE 8 - ADDING A PATIENT

Selecting a patient will open the Patient View

ADDING AN OUTSIDE PATIENT

Outside patients can ONLY be created while registering an outside patient to a multisite protocol after selecting an outside Institution:

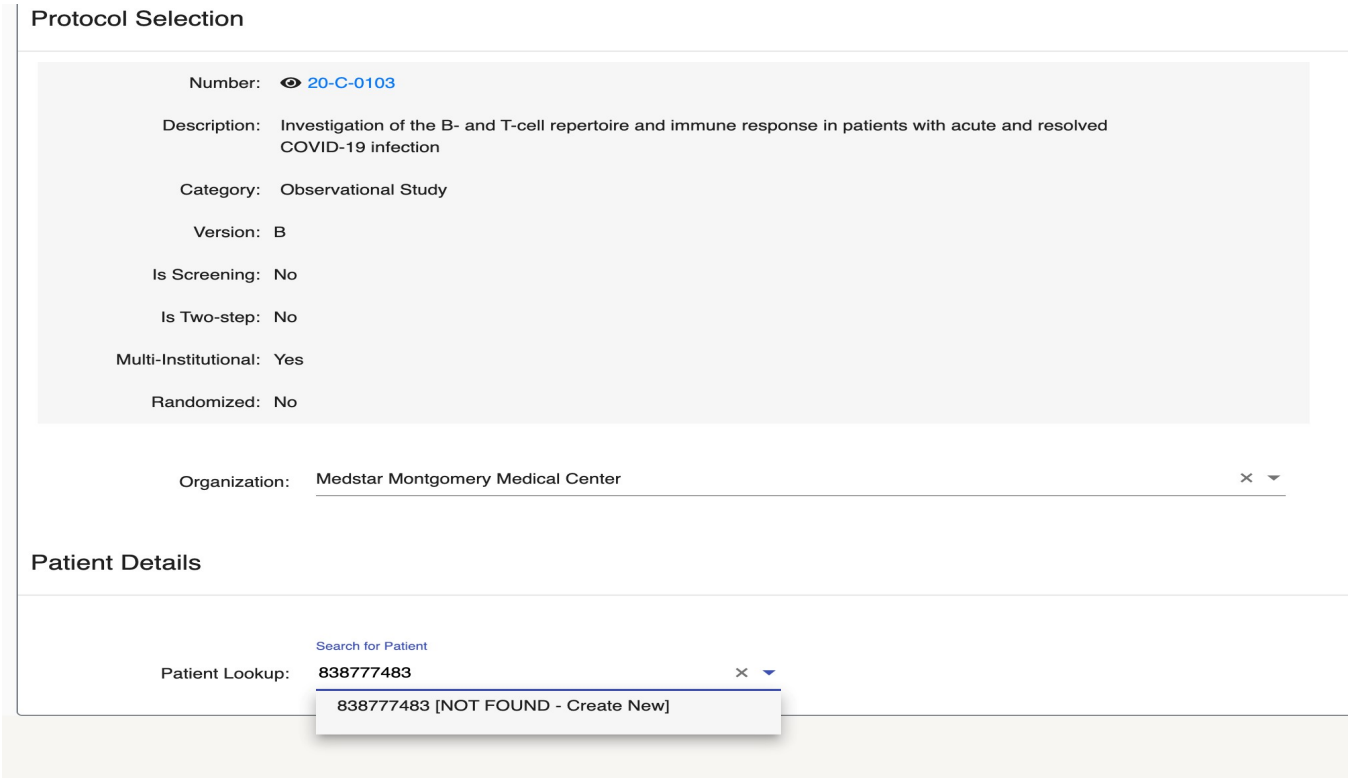


FIGURE 9 - ADDING A PATIENT

After clicking "(NOT FOUND – Create New)" in the Patient Lookup drop down the user will be able to enter the outside patients' demographics:

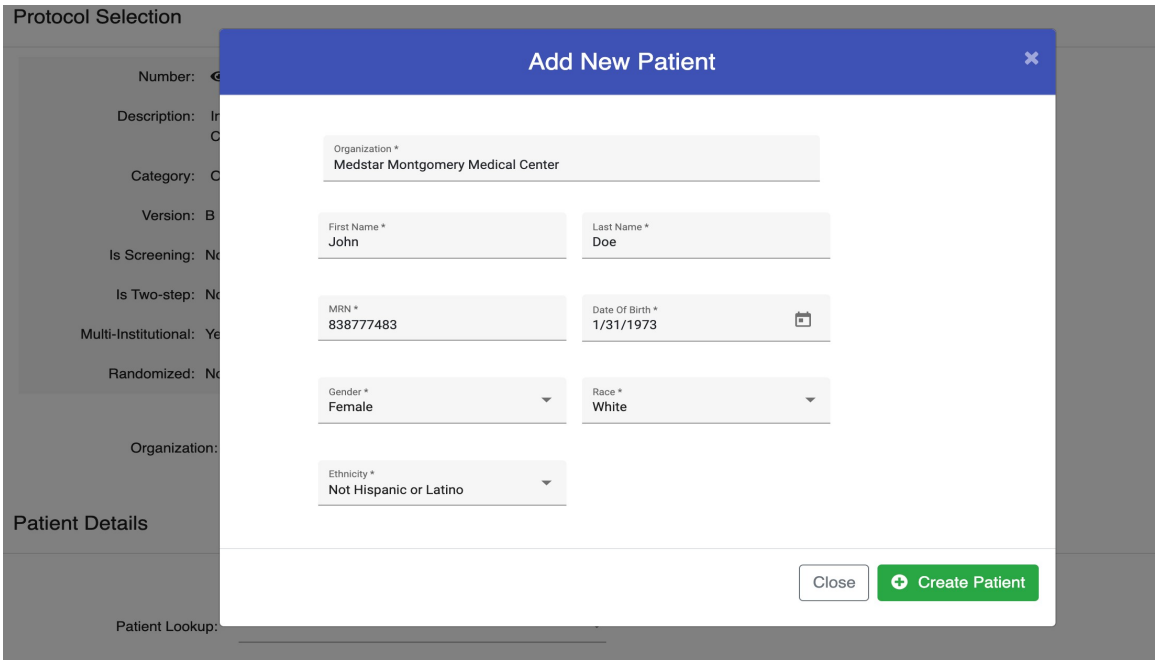


FIGURE 10 – CREATE PATIENT

PATIENT VIEW

The Patient View page displays patient information such as demographics, the protocols in which the patient is participating, and the medical records for each institution that the patient is been treated by.

Patient participating protocols table shows patient enrollments from PRES and CDR applications. Enrollment with PRES value in source column present in PRES and CDR source enrollment retrieved from CDR. However only PRES protocols and enrollments can be viewed in detail

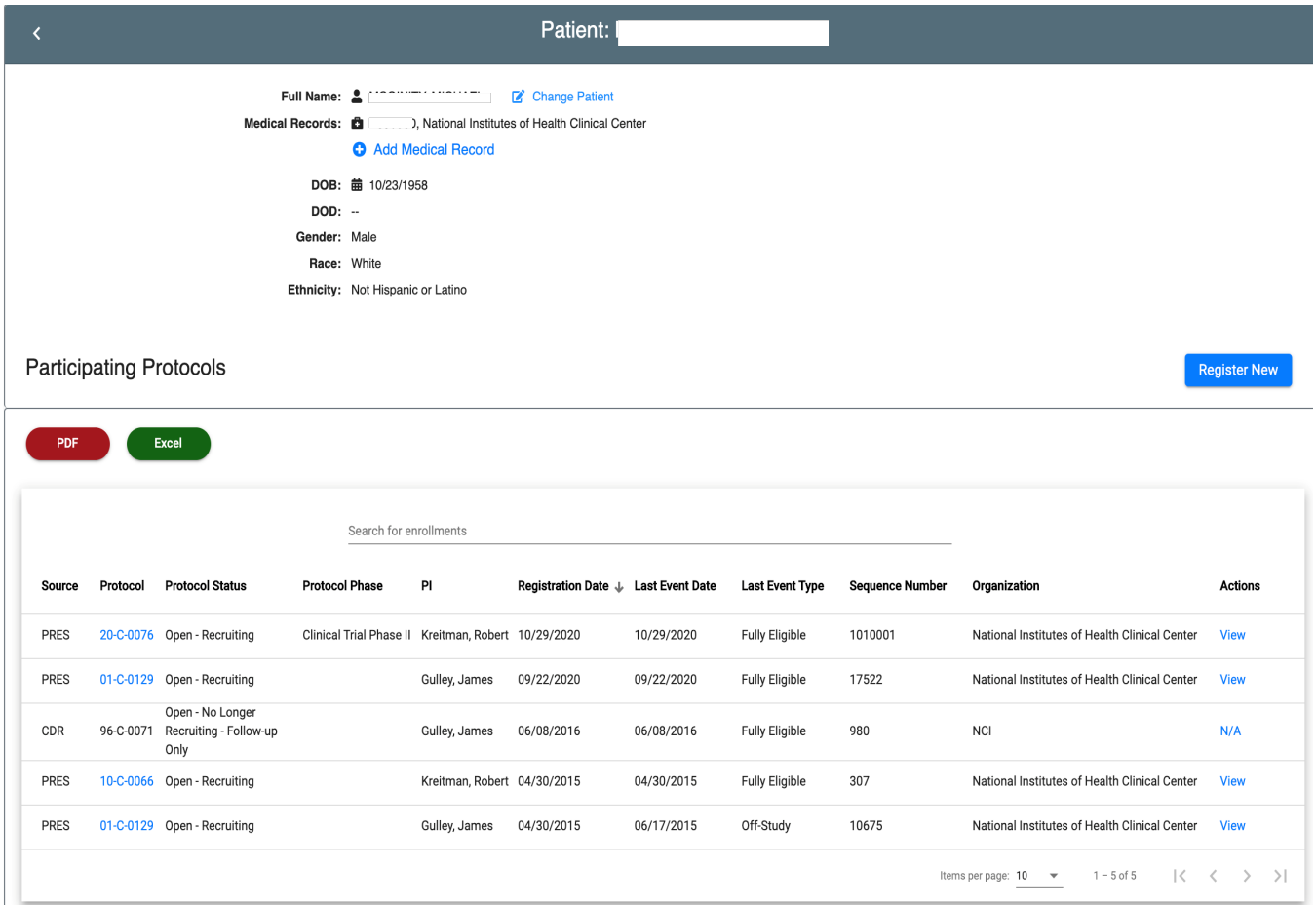


FIGURE 11 - PERSON VIEW

From this view it is possible to modify an existing outside MRN, retrieve protocol data, register the patient to a new protocol, and view the patient's enrollment status for the selected protocol.

ADD MEDICAL RECORD

Clicking the "Add Medical Record" button of the details section of the person view allows the user to add an outside institution's MRN to the selected patient. This section also allows to edit existing outside MRNs. CRIS MRNs can NOT be modified as they are validated against CRIS. PRES will ensure that MRNs are unique within an institution.

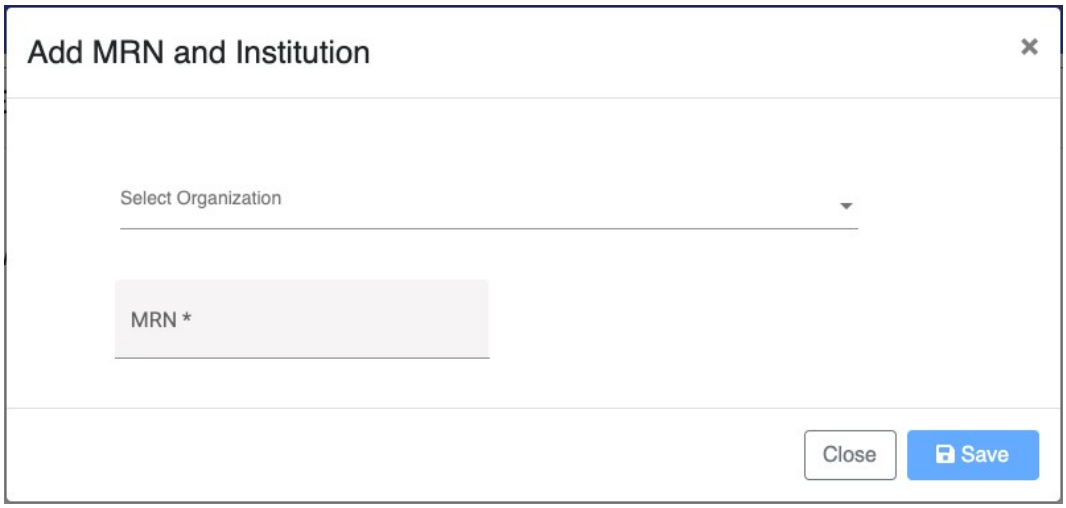


FIGURE 12 - ADD OR MODIFY MRN

SYNC PATIENT INFORMATION WITH CRIS

PRES initially pulls the patient information from CRIS once and any changes made there (in CRIS) after it pulled the data, it does not reflect in PRES. To manually sync the patient, click on Sync button on patient view. Remember this is only available for the users who can create enrollments in PRES.

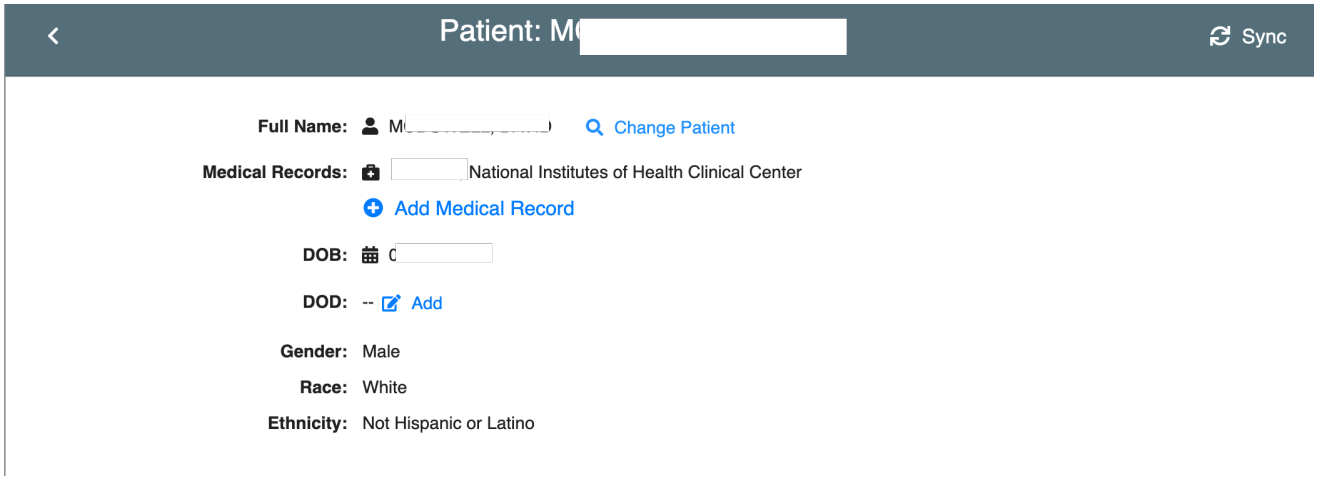


FIGURE 13 - CREATE PATIENT

When you click on it and if the patient information in CRIS is different from PRES i.e., Gender, Race, DOB etc., you will see both CRIS and PRES patient information as shown below. You would be given an option to Update PRES Patient (and also shown ramifications of the change)

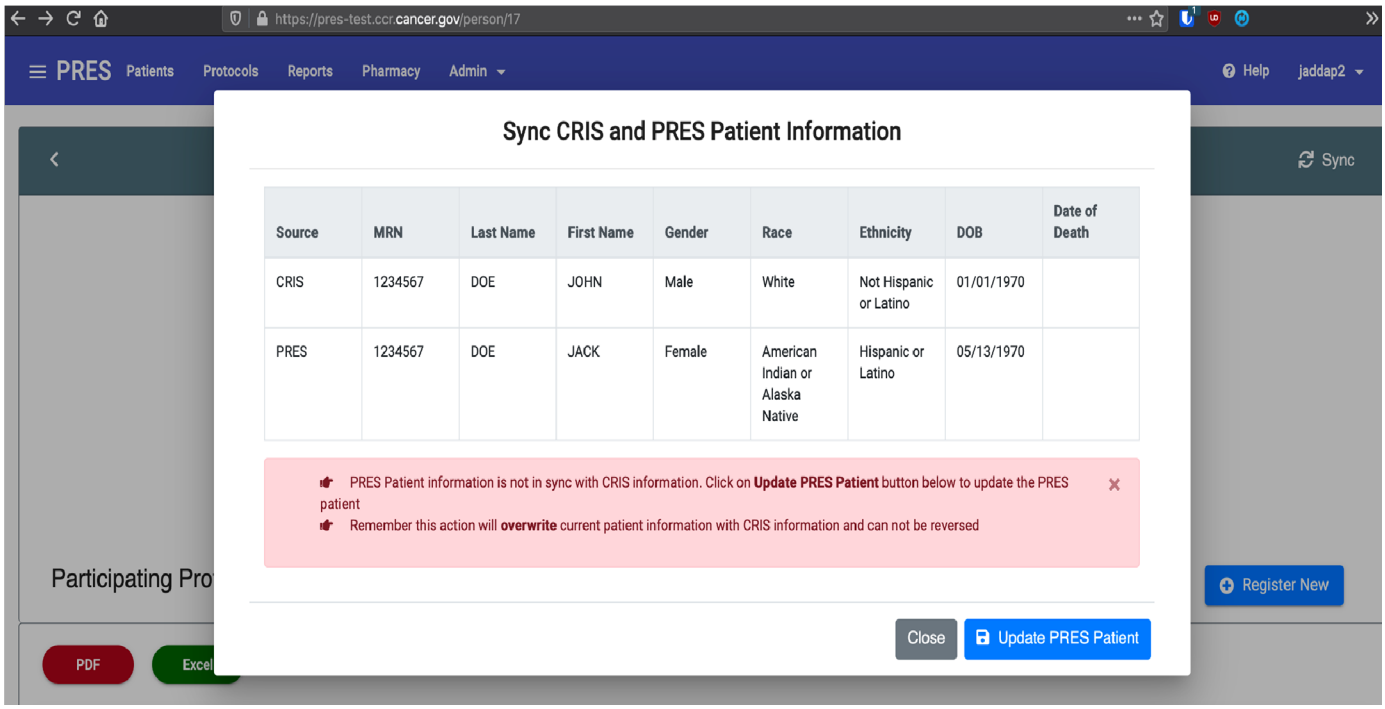


FIGURE 14 – CREATE PATIENT

And if the patient information is already in sync, then you don't have to do anything, and Update button is disabled

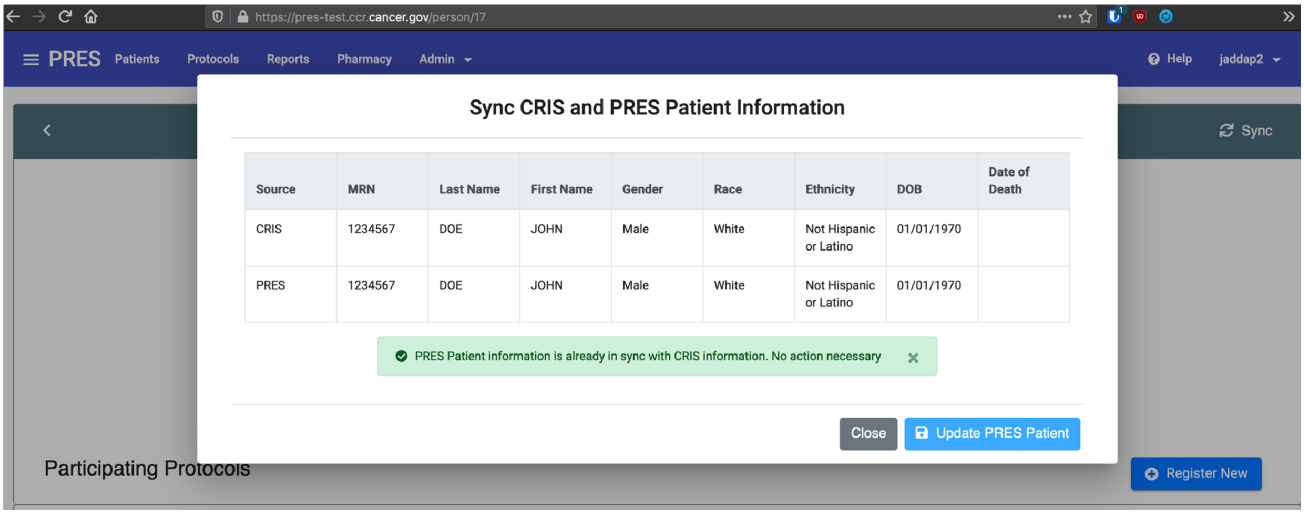
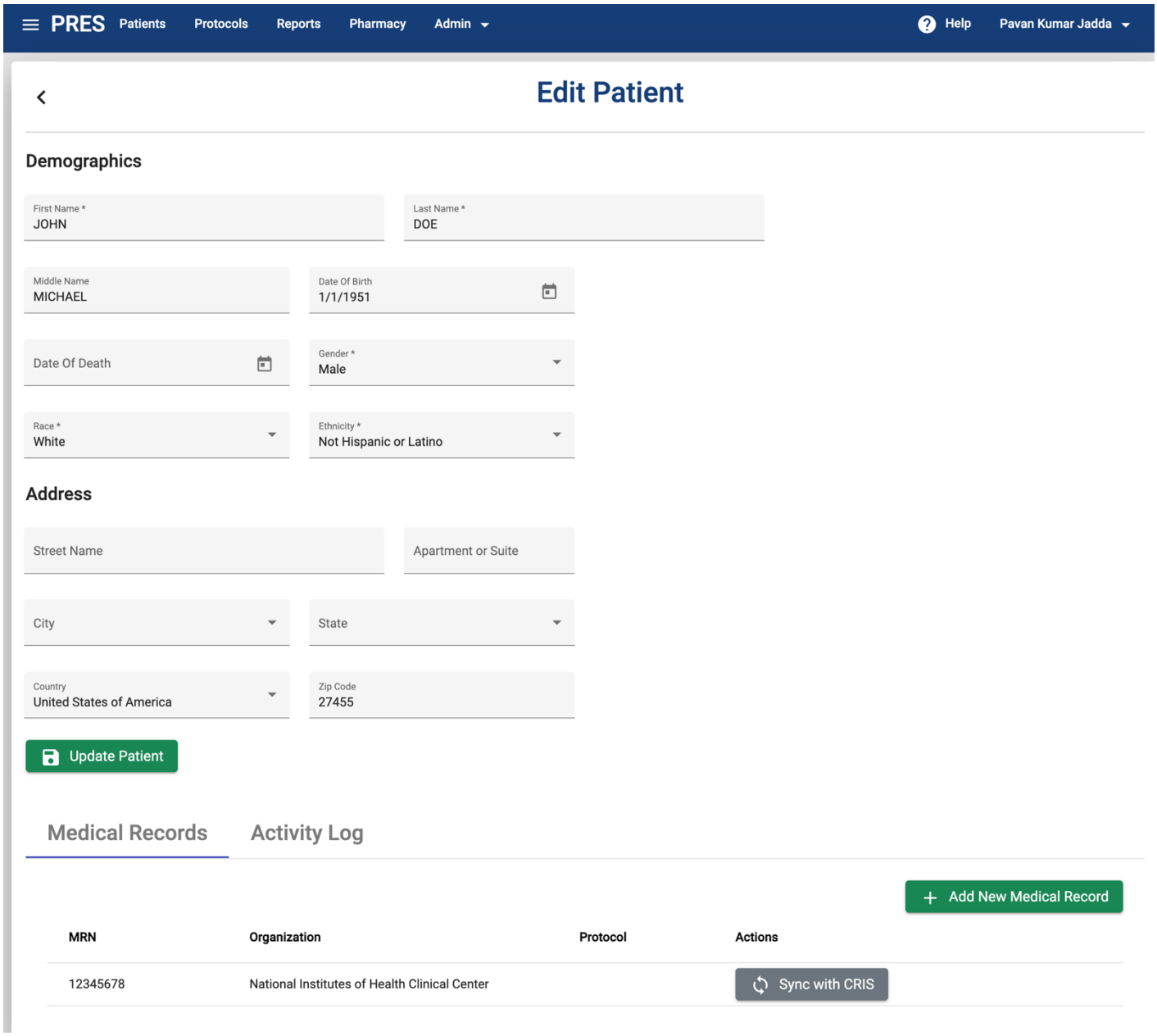


FIGURE 15 – SKIP UPDATE TO PRES PATIENT

EDIT PATIENT

For outside site patients, the demographics can be edited in PRES. Remember, if the patient record in CRIS and you update the information, it will be overwritten by **Sync with CRIS** option. To edit patient information, click on **Edit** button in patient view, it takes you to Edit Patient page

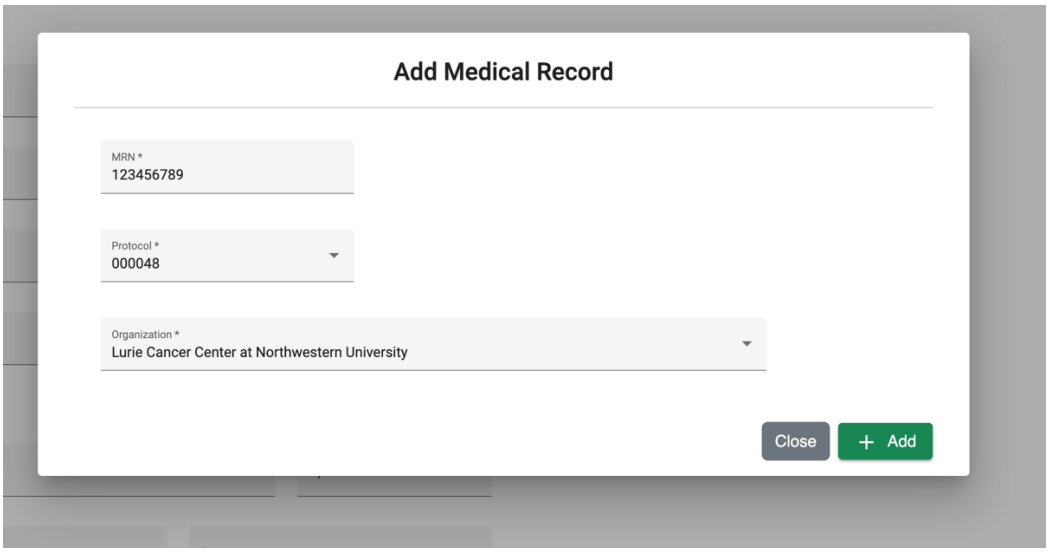


As shown above, this page has two sections

- Demographics
- Medical Records

In Demographics section, you can update the patient information and click on **Update Patient** button to save changes.

Medical Records section shows patient existing medical records and the ability to add a new medical record. To add a new medical record, click on **Add New Medical Record** button, it opens a dialog, provide required MRN, Protocol and Organization or Site information. It is necessary to select Protocol before selecting Organization as each site tied to Protocol.



And for NIH medical record, you see an option to sync medical record from CRIS

PROTOCOL VIEW

The protocol view page displays the available information for the protocol. For a detail of the available information

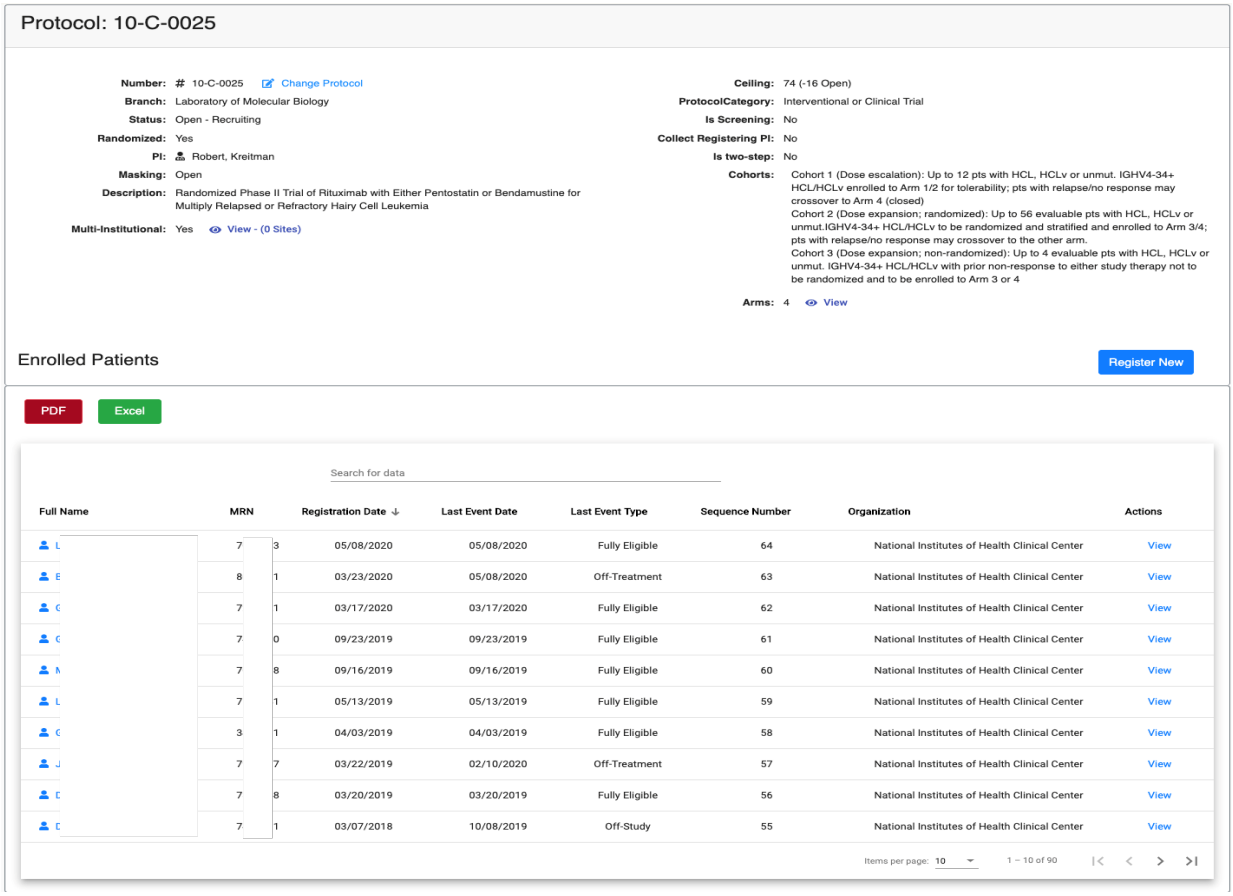


FIGURE 16 - PROTOCOL VIEW

SEARCHING AND SELECTING A PROTOCOL

To find a protocol click on the “Search for a Protocol” field and enter at least 2 characters which will open a drop-down list of protocols already in PRES matching those characters:

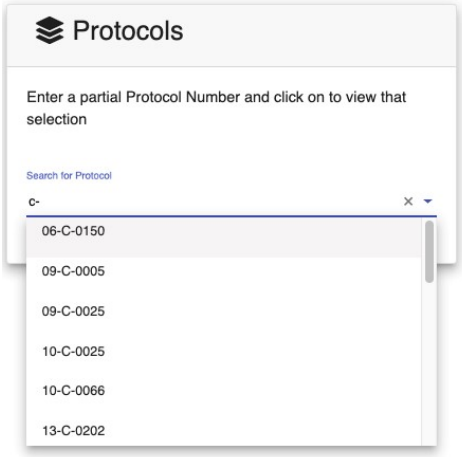


FIGURE 17-PROTOCOL SEARCH Clicking on a protocol will open the Protocol View page.

CREATING A REGISTRATION

A registration can be created from the Patient View or the Protocol View as illustrated below by clicking the “Register New” button to the right of the “Participating Protocols” or the “Enrolled Subjects” header.

In both cases, after selecting the “Register New” button, the user will be redirected to the Register Patient page.

REGISTER PROTOCOL FROM PATIENT PAGE

Since the patient is already selected the protocol must be selected from dropdown which contains list of protocols that are already present PRES.

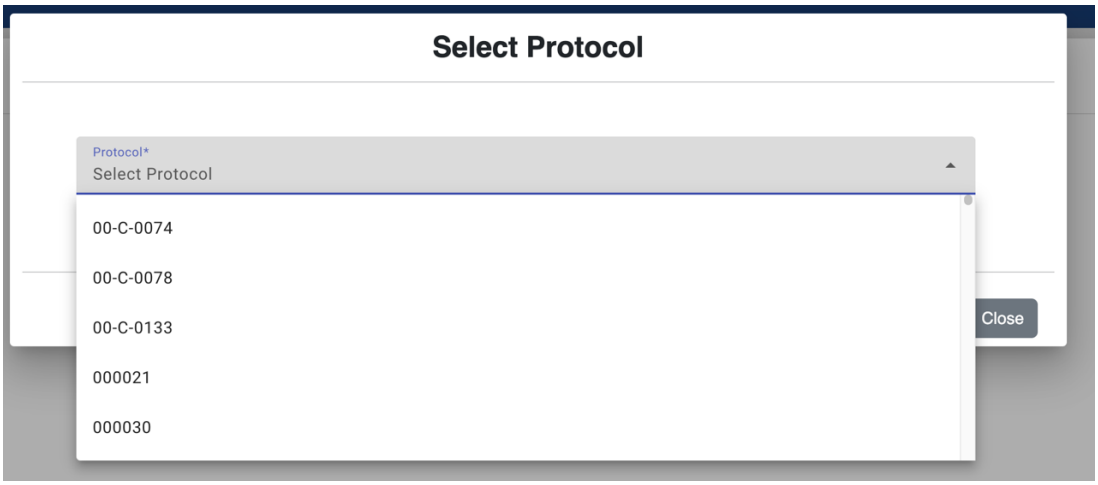


FIGURE 18-REGISTER PROTOCOL TO PATIENT PAGE

The protocol will be selected by clicking the desired protocol from the results drop down. After selecting the protocol, you are redirected to registration page and a summary of the protocol's information will be displayed. This information also notifies the user if it is open to enrollment or not.

In the figure below the selected protocol is not open for enrollment. The error banner in red explains the reason. In this case there are no cohorts available in the protocol.

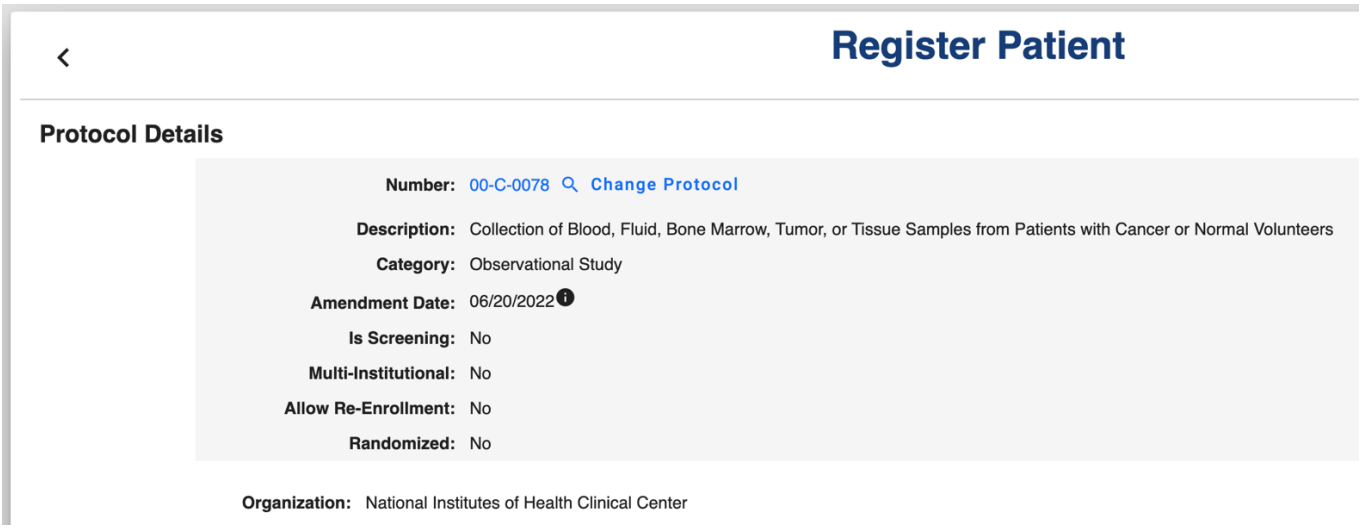


FIGURE 19-REGISTER PROTOCOL TO PATIENT

REGISTER PATIENT FROM PROTOCOL PAGE

PRES also allows a patient to be added to a protocol from the protocol page.

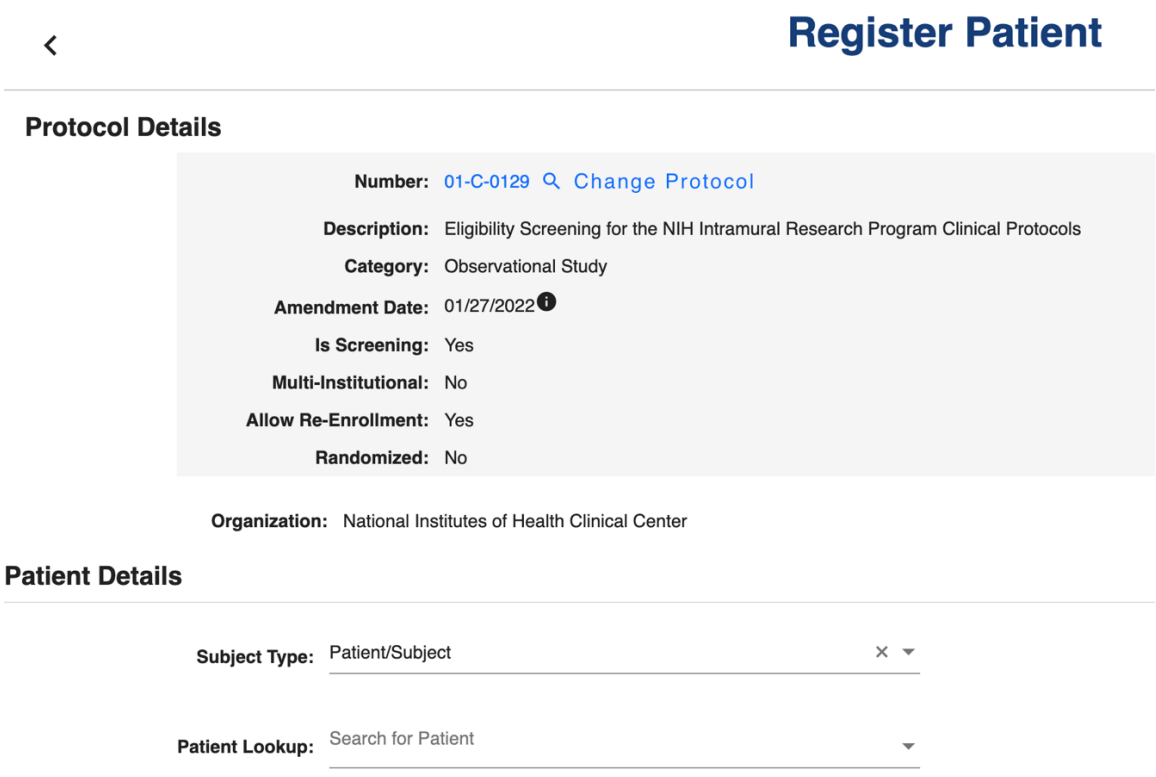


FIGURE 20-REGISTER PATIENT TO PROTOCOL PAGE

Since the protocol is already selected the user must use the "Select Subject Type" dropdown to select Subject Type. If the Subject Type is "Patient/Subject", then a disease will be required in next step. If not, then Disease section will be hidden.

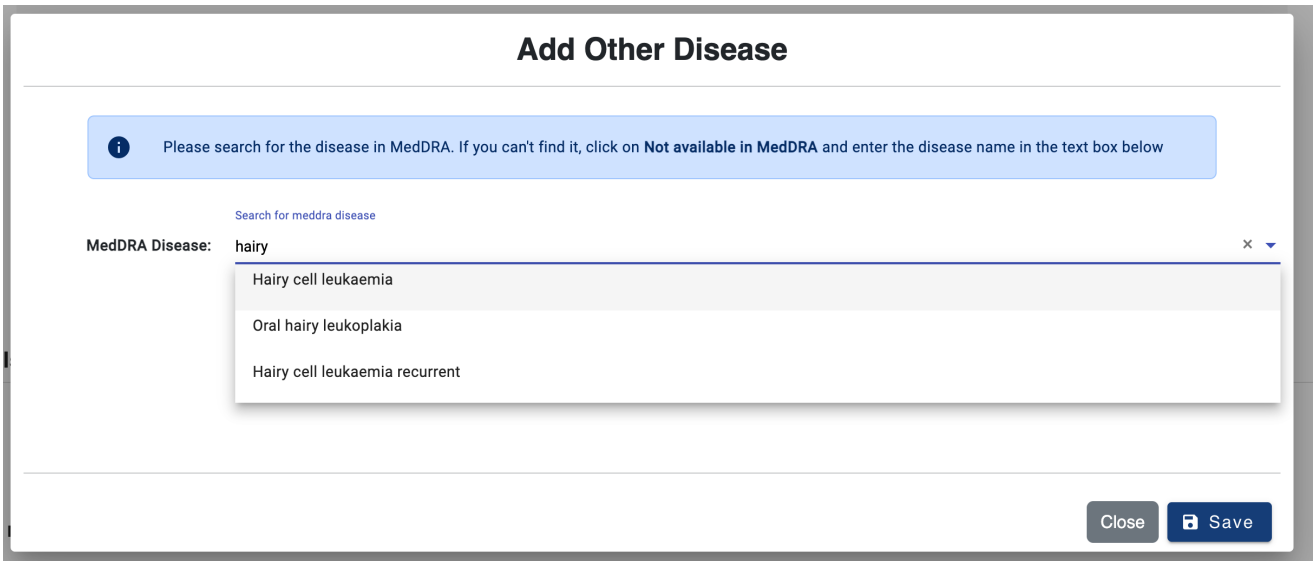
After subject type click "Search for a Patient" field to select a patient. Once the Patient and Protocol are selected the user can proceed to provide additional details on the Register Patient page which is dynamic and displays additional fields as data is entered. The Register button will remain inactive until all fields have been populated.

DISEASE

In Disease section disease input is required. For registration purposes, PRES uses higher level group terms in MedDRA with more disease specific details in the clinical database.

If the subject type is "Patient/Subject", then you have 3 options.

- Select a disease from dropdown and complete registration as you do now.
- Or click on "**The disease I am looking for is not available in the list**" checkbox and search for a disease in MedDRA. Enter at least 2 characters and select a disease from dropdown. The requested disease will be sent for an approval. Upon approval/rejection, you will receive an email with same information.



- If the requested is not available in MedDRA, click on "**Not available in MedDRA**" check box and enter desired disease name and reason/comments. The requested disease will be sent for OEC team approval. Upon approval/rejection, you will receive an email with updated disease name.

MISCELLANEOUS

In miscellaneous section and Registering Branch, Registering PI and Screened for Protocols inputs are only shown and required for screening protocols i.e., 01C0129.

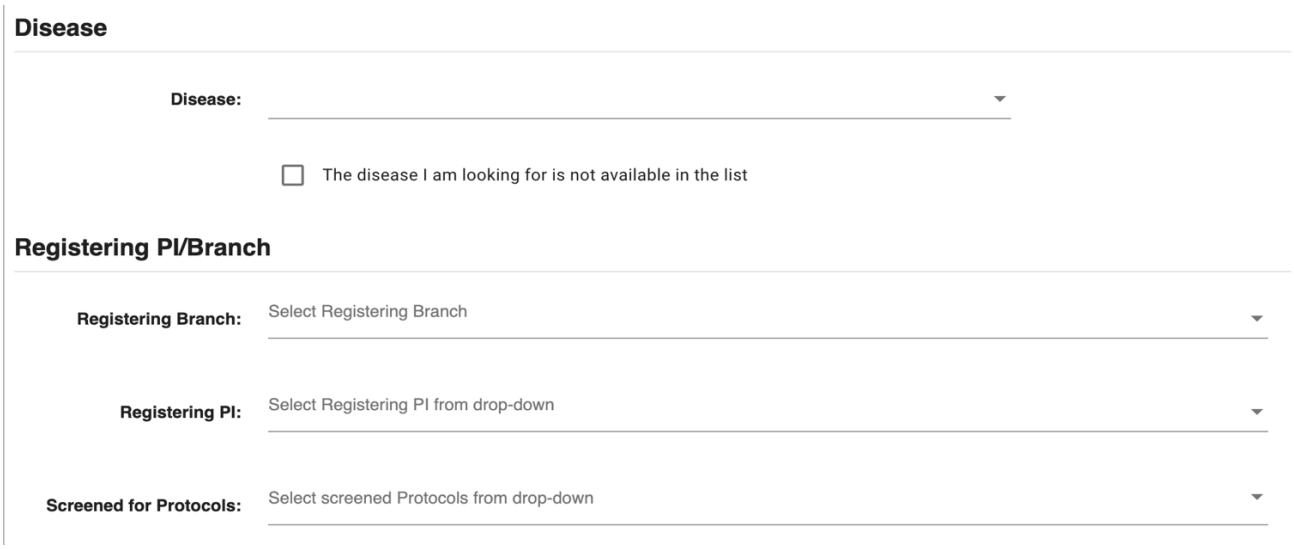
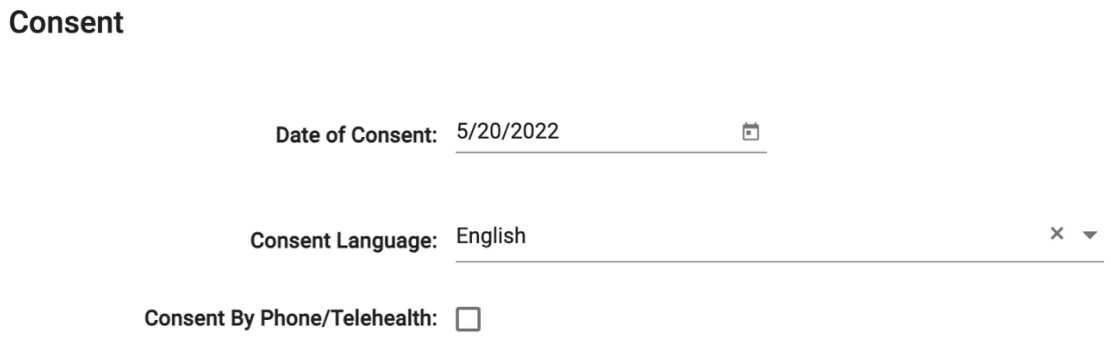


FIGURE 21- MISCELLANEOUS SECTION

CONSENT

Next, the Consent section captures Patient consent information, and it contains three inputs.

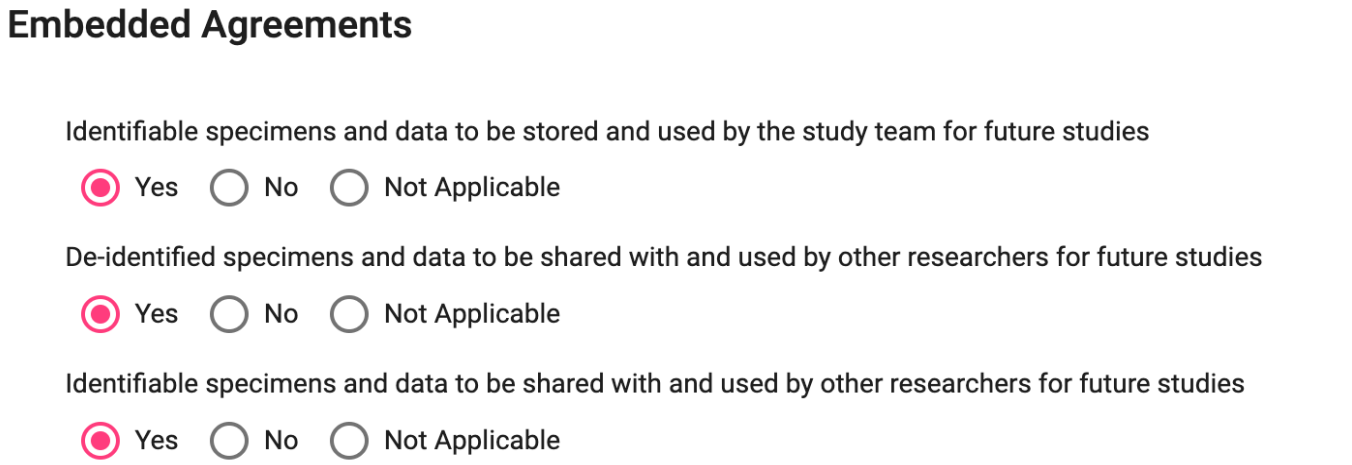
1. Date of Consent
2. Consent Language
3. And Consent by Phone/Telehealth



Both Consent Date and Language are mandatory. And check Consent by Phone/Telehealth checkbox if the Patient consented via Phone, Skype, Zoom Call, WebEx, Microsoft Teams, Google Meet or any other means video communication.

EMBEDDED AGREEMENTS

Next, the section captures Embedded Agreements responses and it's mandatory to answer the questions. If the responses are not available during enrollment, you can select Not Applicable which can be changed in Enrollment page



Once the Eligible for Treatment box is checked the Cohort selection field will be displayed.

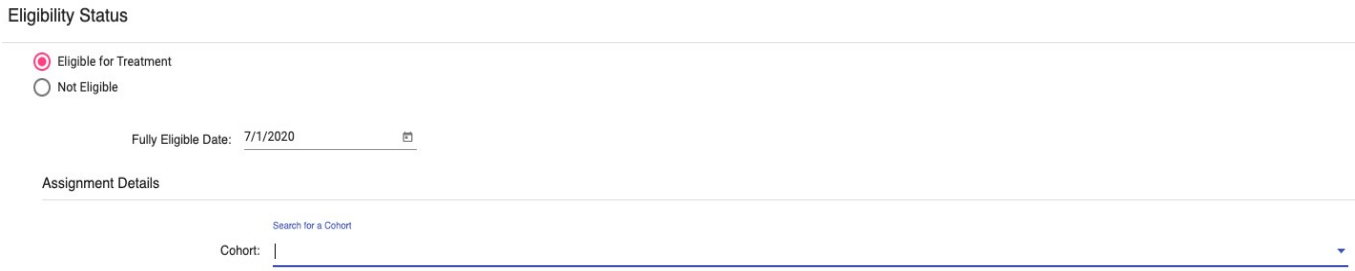


FIGURE 22-REGISTER PATIENT TO PROTOCOL PAGE

After selecting a Cohort, the Arm selection field is displayed showing only the selected cohort's arms.

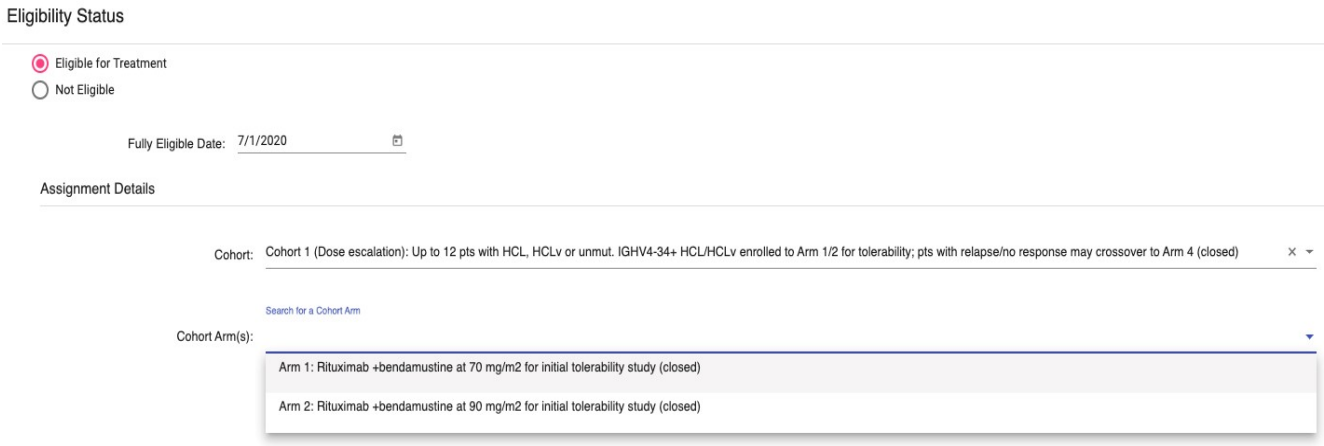


FIGURE 23-SELECT ARM

Once all fields have been populated the Register button will be activated. The registration will be recorded after clicking the Register button. After successful registration the user will be taken to the Enrollment View.

RANDOMIZATION

For randomized cohorts the arm will be assigned as per the randomization sheets and blinded as necessary. Protocols are randomized in one of the 2 ways, Stratified and Non-Stratified. For Stratified protocols, Cohort, Stratification Factor question and answer must be selected. For Non-Stratified protocols just Cohort selection is required.

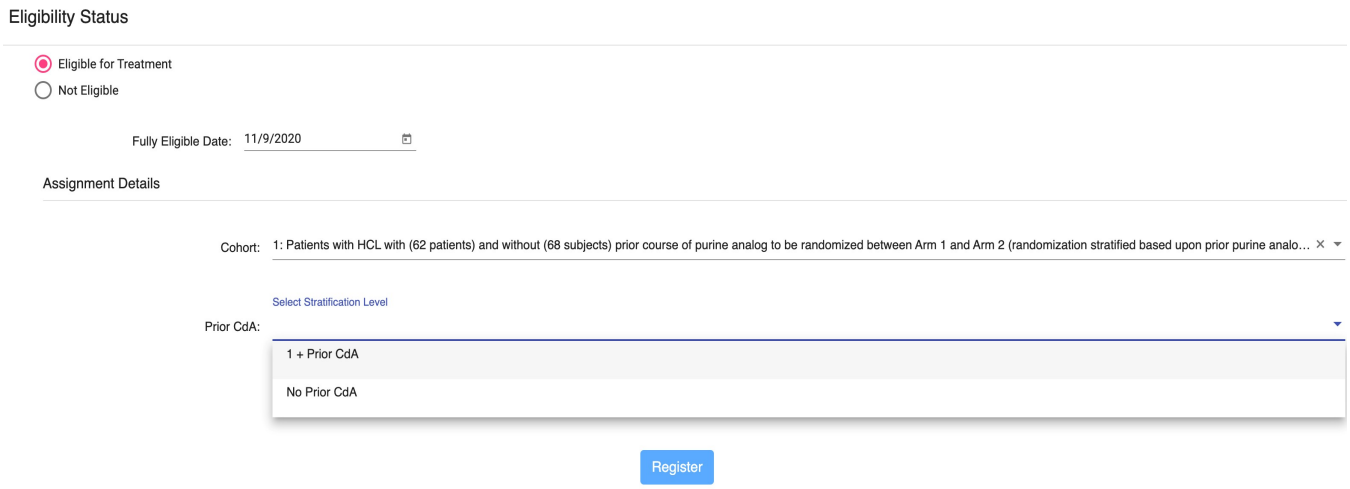


FIGURE 24-SELECTION RANDOMIZATION INFORMATION

TWO STEP AND THREE STEP PROTOCOLS

For two step and three step protocols the Eligibility Status includes the “Eligible for Screening” option.

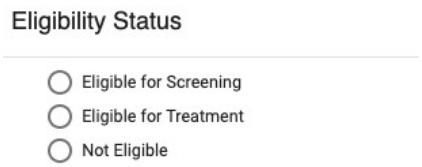


FIGURE 25-TWO STEP

After screening the Eligibility Status can be updated to Eligible for Treatment or Not Eligible.

ENROLLMENT VIEW

The enrollment view shows the patient's status of the enrollment for the selected protocol. This section can only be accessed re by clicking the view icon in the participating protocols (Patient view) or enrolled patients (protocol view).

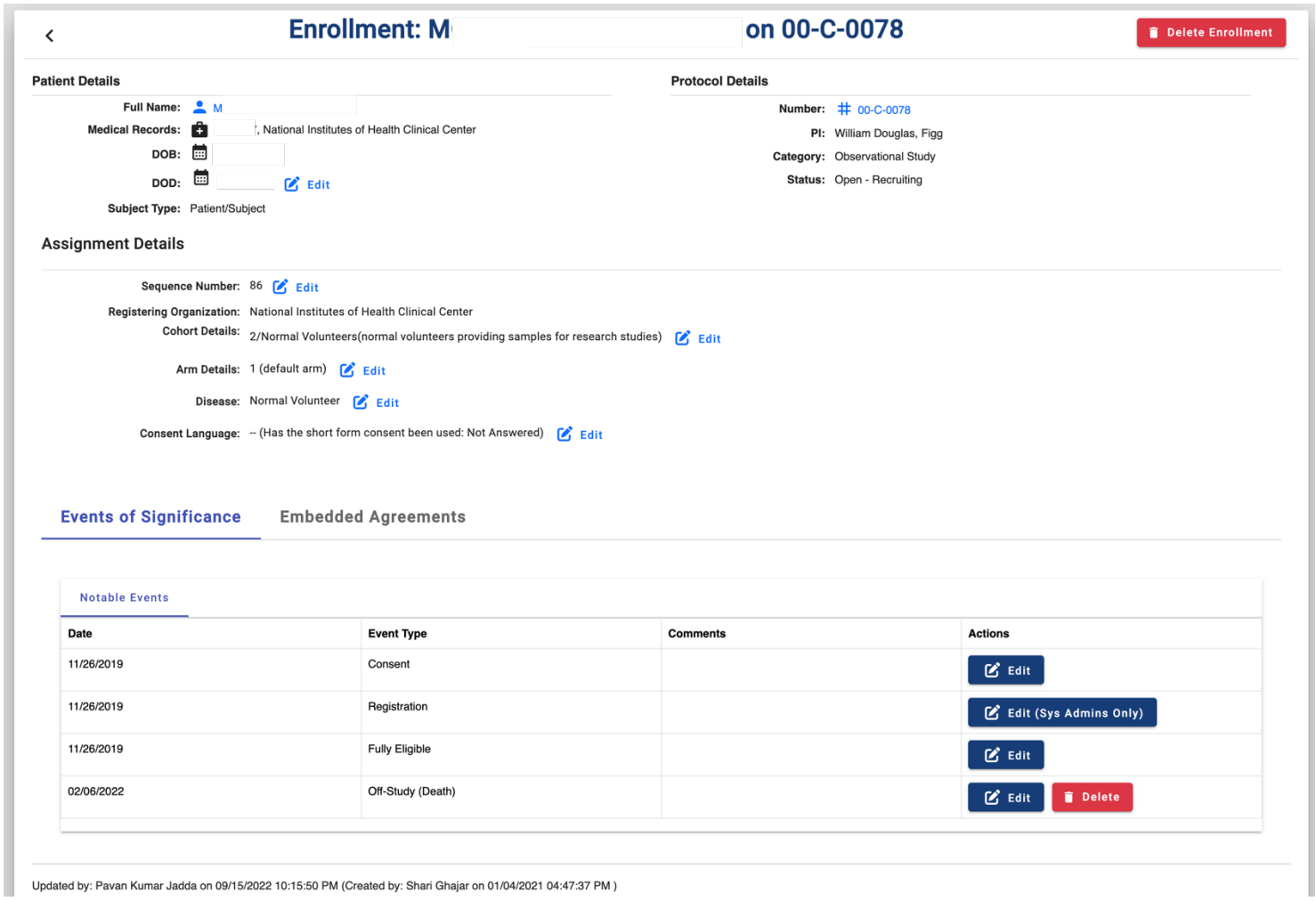


FIGURE 26-ENROLLMENT VIEW

By clicking in the patient name the user will be redirected to the Patient View, clicking in the protocol number will show the Protocol View.

It is also possible to add/edit the Sequence Number, add/modify the dates of the events of significance, for the patient in the selected protocol.

ADD/EDIT SEQUENCE NUMBER

The Sequence Number can be added after creating the enrollment. To enter sequence number, click on **Edit** button right next to Sequence Number on enrollment view. It opens a pop-up window that provides text box to enter sequence number. The system can also show next available sequence number along with a link to Use This Number.

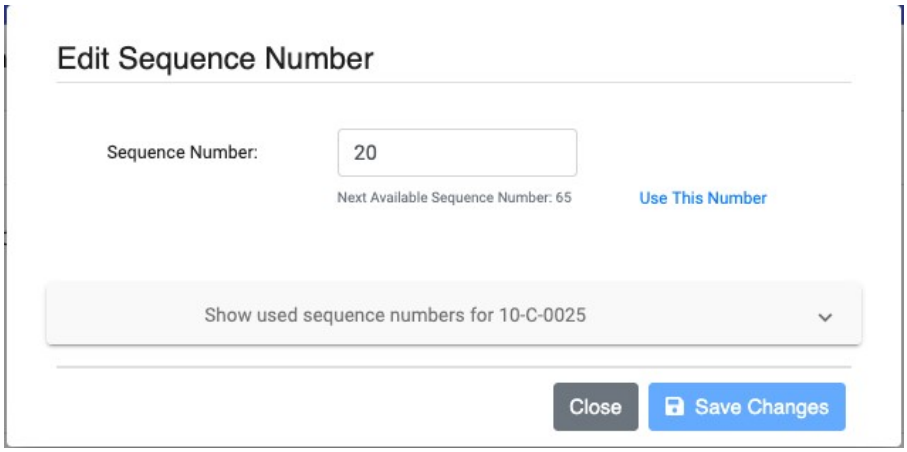


FIGURE 27-SEQUENCE NUMBER

In addition, there is an option to view and search the existing Sequence Numbers in this Protocol.

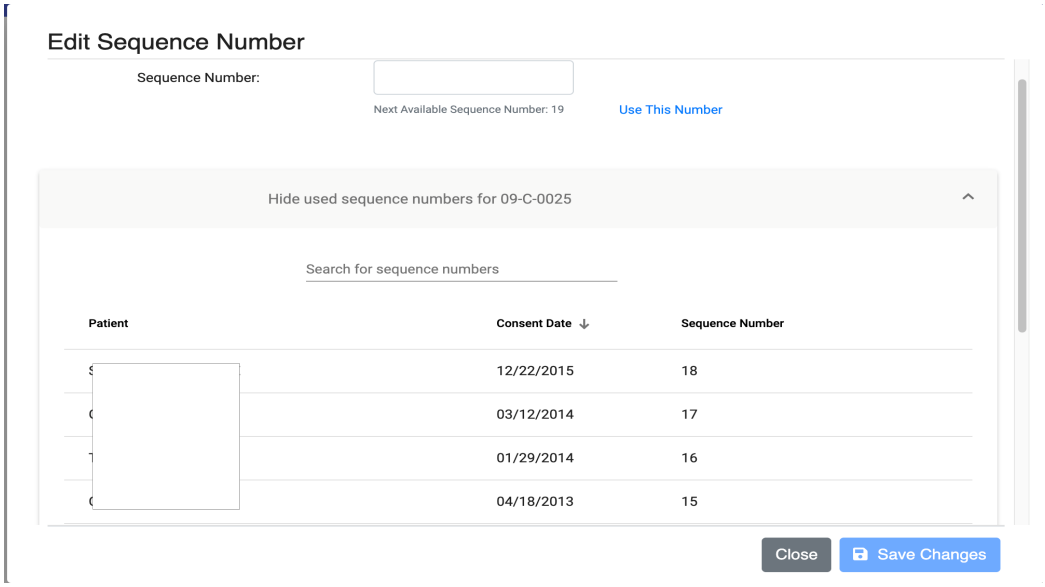
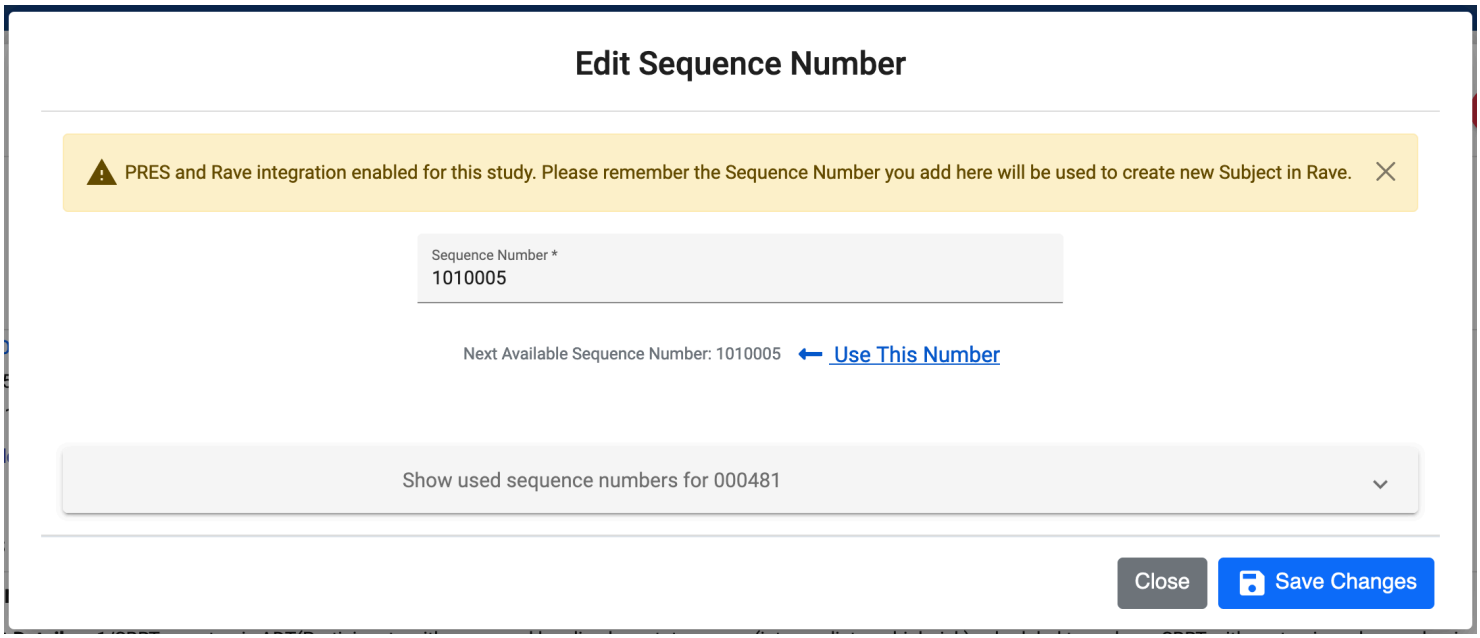


FIGURE 28-USER SEQUENCE NUMBERS

Once the sequence number entered, it can be saved by clicking on **Save Changes** button. PRES also integrated with Rave via Rave web services. For studies in which Rave integration is enabled, user must enter Sequence

Number in order for the subject to be created in Rave and a warning message shown to the user about the integration



TWO STEP PROTOCOLS

Patients registered with Eligible for Screening option during initial registration for 2 step and 3 step protocols are eligible receive treatment. Patient Cohort/Arm can be selected on enrollment view. For randomized protocols Cohort (and stratification information for stratified protocols) needs to be selected.

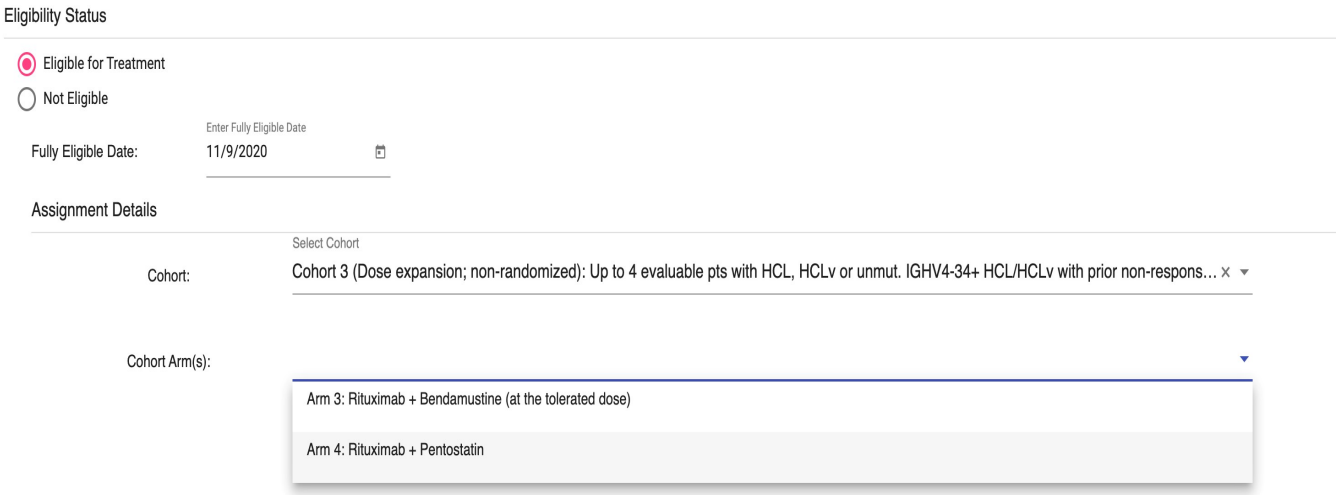


FIGURE 29-ELIGIBLE FOR TREATMENT

Checking Not Eligible will prompt the user to confirm that the patient should be taken off study. These patients counted as screen failure

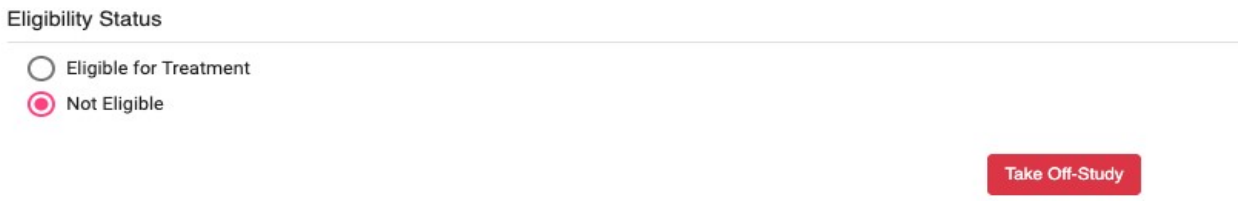


FIGURE 30-NOT ELIGIBLE

THREE STEP PROTOCOLS

Three step protocols follow the same process as two step protocols and in addition they have 3rd step, in which patient assigned to different Cohort and Arm.

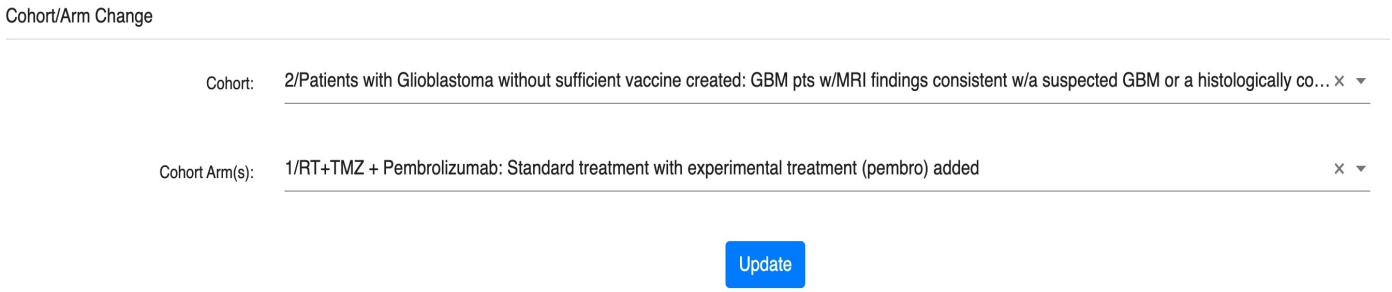


FIGURE 31-THREE STEP PROTOCOL

For example, 17-C-0034 is three step protocol with three steps.

1. Screening
2. Radiation Therapy
3. Receive Treatment

Patients are initially screened to the protocol, then receive radiation therapy, and receive actual treatment in 3rd step.

UPDATE DISEASE

The disease can be edited after creating enrollment. Similar to the process mentioned in Registration, click on Edit button next to Disease.

- Select a disease from dropdown.
- Or click on "**The disease I am looking for is not available in the list**" checkbox and search for a disease in MedDRA. Enter at least 2 characters and select a disease from dropdown. The requested disease will be sent for an approval. Upon approval/rejection, you will receive an email with same information.

- If the requested is not available in MedDRA, click on "**Not available in MedDRA**" check box and enter desired disease name and reason/comments. The requested disease will be sent for OEC team approval. Upon approval/rejection, you will receive an email with updated disease name.

RANDOMIZATION

For randomized cohorts the arm will be assigned as per the randomization sheets and blinded as necessary. Protocols are randomized in one of the 2 ways, Stratified and Non-Stratified. For Stratified protocols, Cohort, Stratification Factor question and answer must be selected. For non-stratified protocols just Cohort selection is required.

In masking(blinding) protocols, if the enrollment blind is broken, users with appropriate privilege can Skip the assigned slot for the next available after providing a justifying comment.

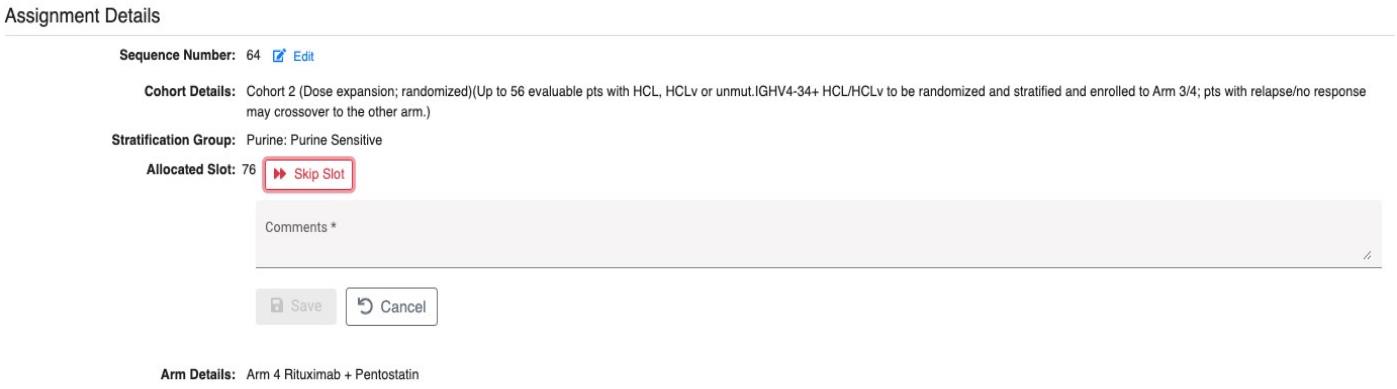


FIGURE 32-SKIP SLOT

EVENTS OF SIGNIFICANCE

Depending on the study each enrollment has following notable events in study

1. Consent/Consent by Phone
2. Registration
3. Fully Eligible
4. Re-Consent
5. Crossover
6. Off-Treatment
7. Off-Study

When the patient initially enrolled into PRES, Consent and Registration events are automatically generated based on selections made at the time of enrollment. Fully Eligible event will also be generated if the study is single step or two-step, but Cohort and Arm/Randomization information is selected at the time of initial enrollment

RE-CONSENT EVENT

Re-Consent event needs to be entered when patient signs Consent form again after recent amendment to study or any other reason. In order to enter Re-Consent event, go to enrollment view, under Events of Significance block select Re-Consent event type, Date and comments. The Re-Consent date should be after Fully Eligible date and before Off-Study Date.

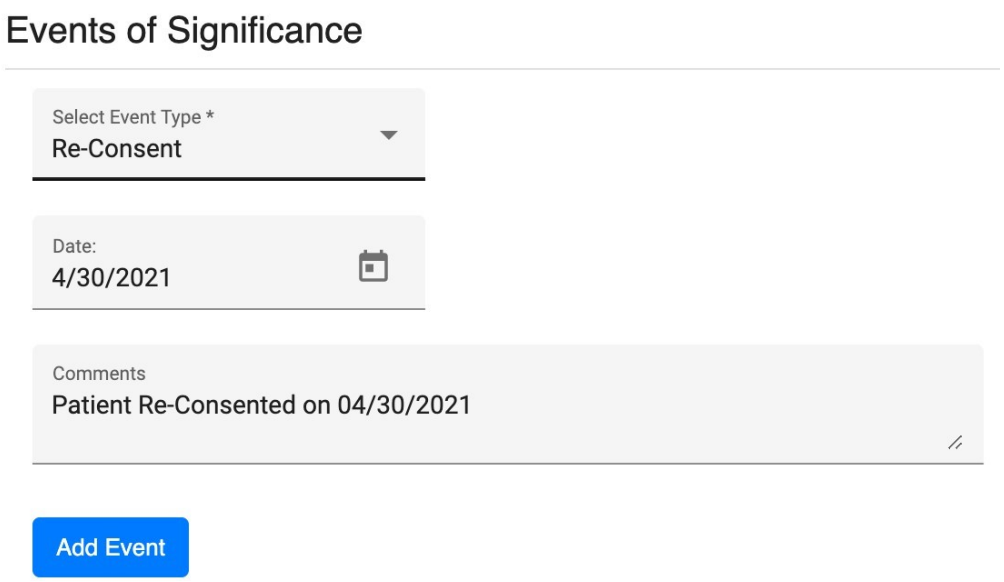


FIGURE 33-RE-CONSENT EVENT

CROSSOVER EVENT

Certain protocols allow patients to crossover from one arm to another in the same cohort. For such protocols the Crossover Event of Significance is available until the patient is take Off Treatment.

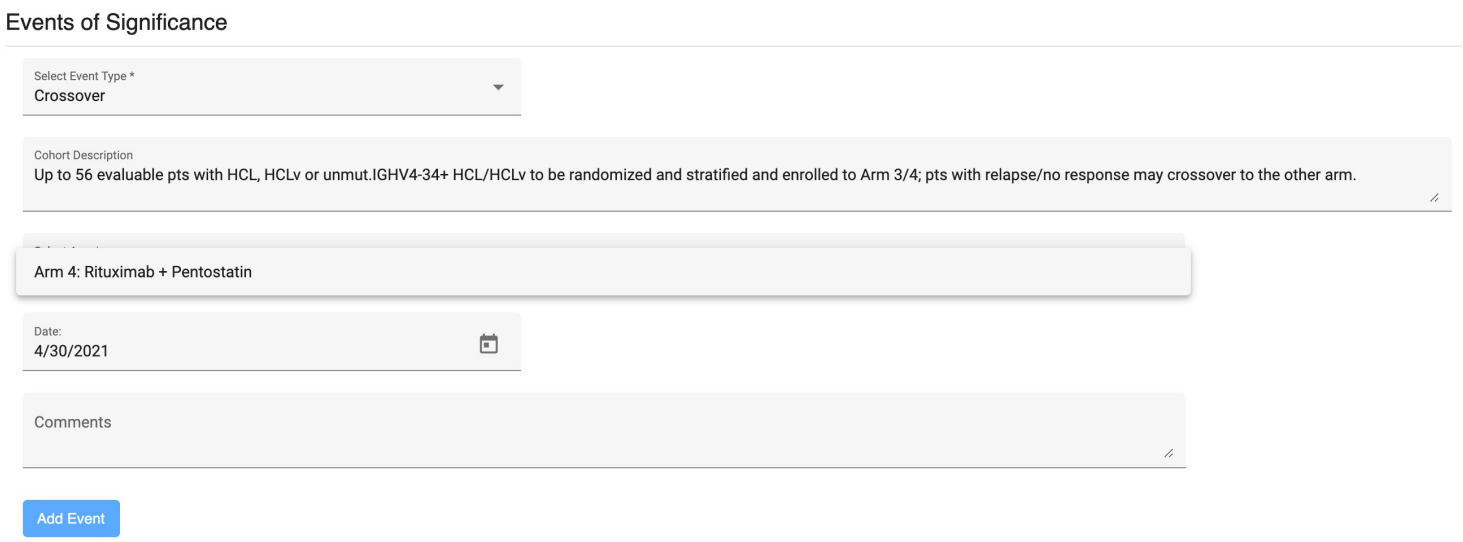


FIGURE 34-CROSSOVER EVENT

OFF-TREATMENT/OFF-STUDY EVENT

All registrations on treatment protocols have the option to enter Off-Treatment/Off-Study event. Select Off Treatment/Off-Study event type, event reason, event date and comments. If the patient is Off-Treatment/Off-Study due to death, select Death date as event date.

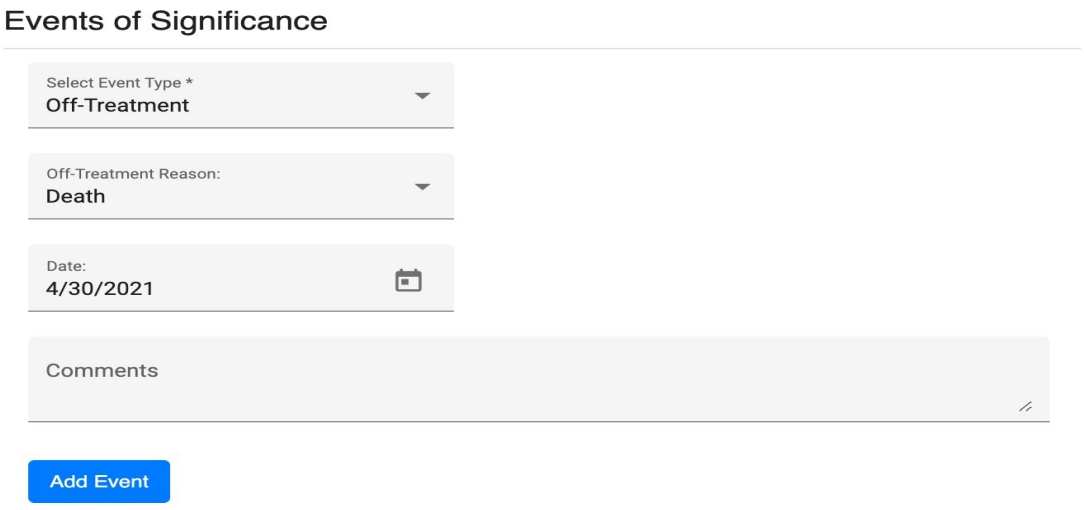


FIGURE 35-OFF TREATMENT/OFF STUDY EVENT

The Enrollment View displays the history of Events off Significance and allows users to edit the comments.

Date	Date Type	Comments	Actions
03/07/2018	Consent	Refractory_NonRandomized	Edit
03/07/2018	Registration	Refractory_NonRandomized	
03/07/2018	Fully Eligible	Refractory_NonRandomized	Edit
10/08/2019	Off-Study	Refractory_NonRandomized	Edit

FIGURE 36-HISTORY OF EVENTS

EMBEDDED AGREEMENTS

Starting with date 05/20/2022 (or application version 2.6.0), Embedded Agreement responses can be added or updated in PRES. Embedded Agreements section present in Enrollment view in separate tab right next to Events of Significance. It shows current responses and history of responses in a table.

Below is guidance to help you best select the answers to the embedded agreement questions when you register a patient. These are the 2 most often alternative options for consent language/questions related to storage and future use that do not exactly mirror the current questions in PRES. We have provided you with the guidance below on how to answer the 3 embedded agreement questions in PRES based on these other options.

Option 1 (e.g., prior CCR consent language telling participants of our intent for future use):

Text:

> "We plan to keep some of your specimens and data that we collect and use them for future research and share them with other researchers. We will not contact you to ask about each of these future uses. These specimens and data will be stripped of identifiers such as name, address, or account number, so that they may be used for future research on any topic and shared broadly for research purposes. Your specimens and data will be used for research purposes only and will not benefit you. It is also possible that the stored specimens and data may never be used."

PRES Answers:

1. I give permission for my identifiable specimens and data to be stored and used by the study team for future studies as described above. **Yes**

2. I give permission for my de-identified specimens and data to be shared with and used by other researchers for future studies. **Yes**

3. I give permission for my identifiable specimens and data to be shared with and used by other researchers for future studies. **No**

Option 2 (e.g., the NIH IRBO template embedded questions for future use prior to March 2020):

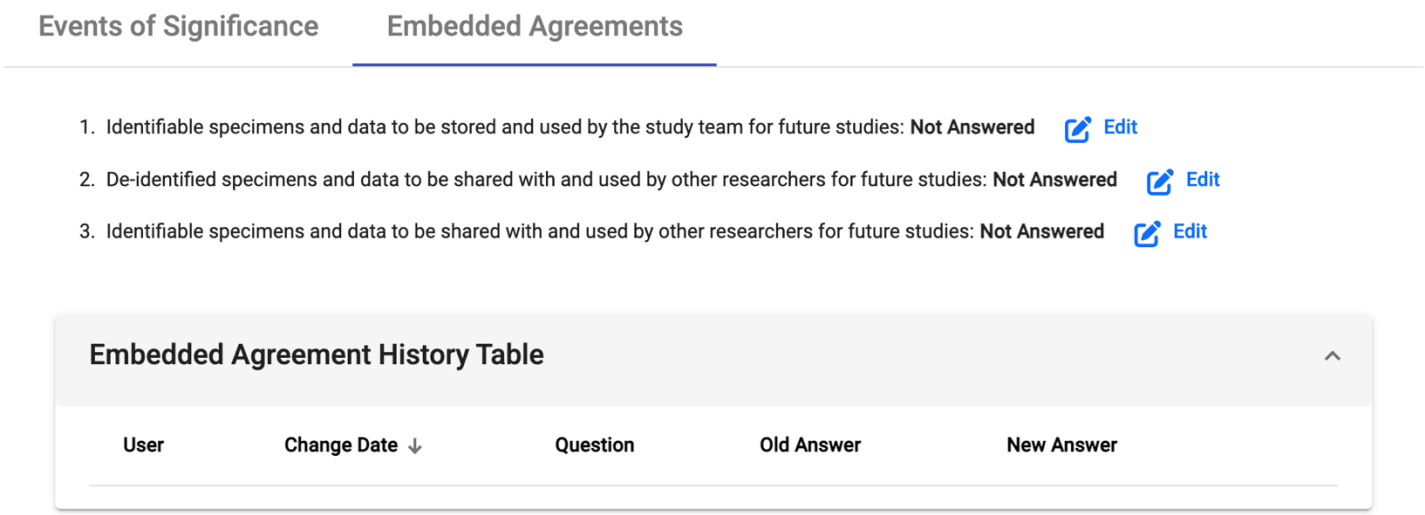
Text/Questions:

1. I give permission for my coded specimens and data to be stored and used for future research as described above.
2. I give permission for my coded specimens and data to be shared with other researchers and used by these researchers for future research as described above.

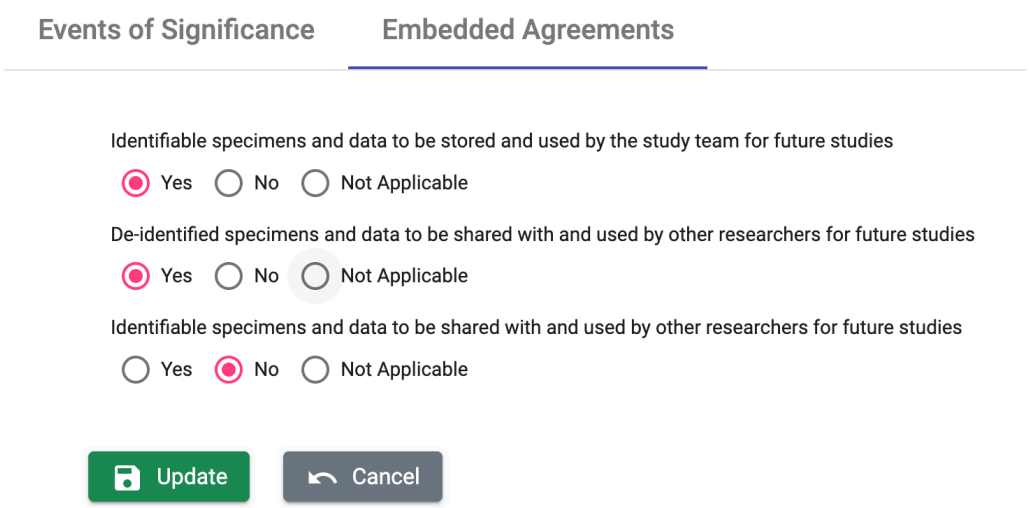
PRES Answers:

1. I give permission for my identifiable specimens and data to be stored and used by the study team for future studies as described above. **Yes**
2. I give permission for my de-identified specimens and data to be shared with and used by other researchers for future studies. **Yes**
3. I give permission for my identifiable specimens and data to be shared with and used by other researchers for future studies. **No**

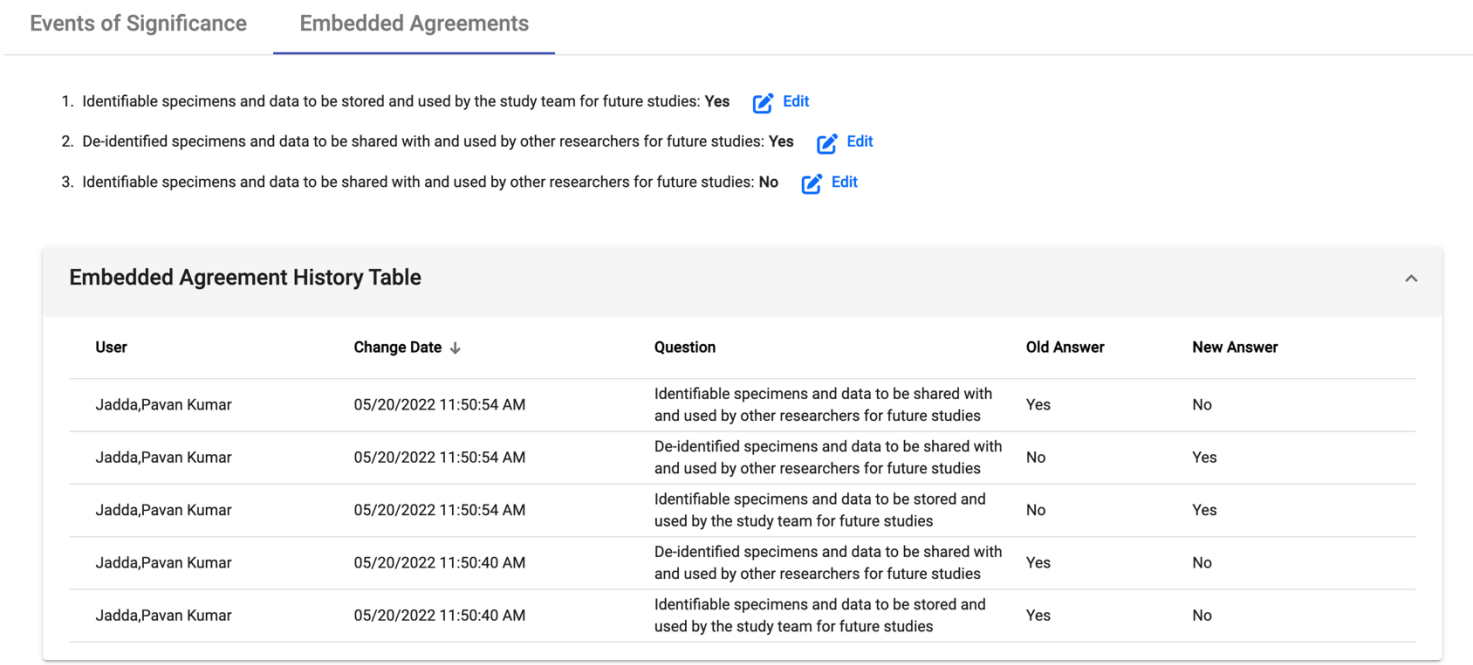
If the questions are not answered before the default response will be **Not Answered**. See below image for reference.



The responses can be edited by clicking on Edit button. And again, it's mandatory to answer all the questions.



And the history of responses shown in a table with detailed history of who and when they were changed



User	Change Date	Question	Old Answer	New Answer
Jadda,Pavan Kumar	05/20/2022 11:50:54 AM	Identifiable specimens and data to be shared with and used by other researchers for future studies	Yes	No
Jadda,Pavan Kumar	05/20/2022 11:50:54 AM	De-identified specimens and data to be shared with and used by other researchers for future studies	No	Yes
Jadda,Pavan Kumar	05/20/2022 11:50:54 AM	Identifiable specimens and data to be stored and used by the study team for future studies	No	Yes
Jadda,Pavan Kumar	05/20/2022 11:50:40 AM	De-identified specimens and data to be shared with and used by other researchers for future studies	Yes	No
Jadda,Pavan Kumar	05/20/2022 11:50:40 AM	Identifiable specimens and data to be stored and used by the study team for future studies	Yes	No

REPORTS

The reports tile on the home page is a drop down which allows the user to run a series of pre-determined reports within PRES.

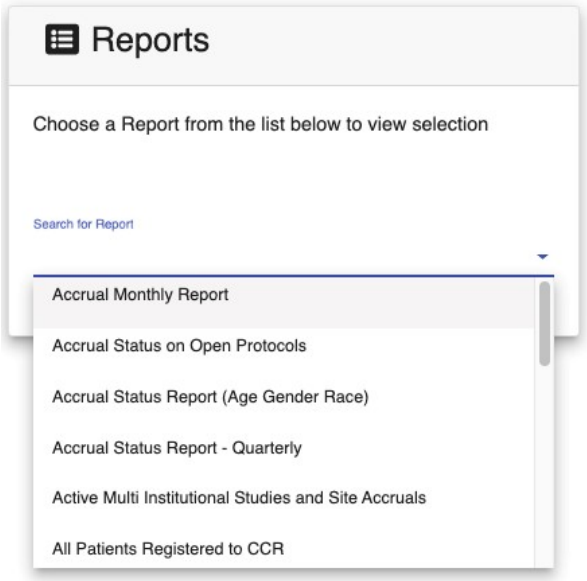


FIGURE 37-SEARCH FOR A REPORT

Here is the list of reports available in PRES

1. Accrual Monthly Report
2. Accrual Status on Open Protocols
3. Accrual Status Report (Age Gender Race)
4. Accrual Status Report - Quarterly
5. Active Multi Institutional Studies and Site Accruals
6. All Patients Registered to CCR
7. CCR Clinical Trail Accrual Report
8. Cumulative Inclusion Enrollment Report
9. Disease Accrual Report
10. Disease Accrual Summary Report
11. Enrollment Demographic report
12. Language of Consent Report
13. Monitoring Study List
14. Non-English Language Consents Report
15. OCD Consent Language Summary Report
16. Open Protocol for the VA Report
17. Patient Cohort and Arm Report
18. Patient Enrollment Information Report
19. Patient List and Other Participated Protocols Report
20. Patient List Report
21. Patient Off-Study Confirmation Report
22. Patient Off-Study Entered Report
23. Patient Off-Study Report
24. Patient On-Study Report
25. Patient Re-Consent Report
26. Protocol Accrual Status Report
27. Protocol Cohort and Arm Report
28. Protocol Embedded Agreement Report
29. Protocol Embedded Agreement Summary Report
30. Randomized Protocol Accrual Ceiling Report
31. Randomized Protocol Patients Report
32. Registration Report
33. Theradex Registration Report

Many of the reports accept parameters including Branch and Protocol.

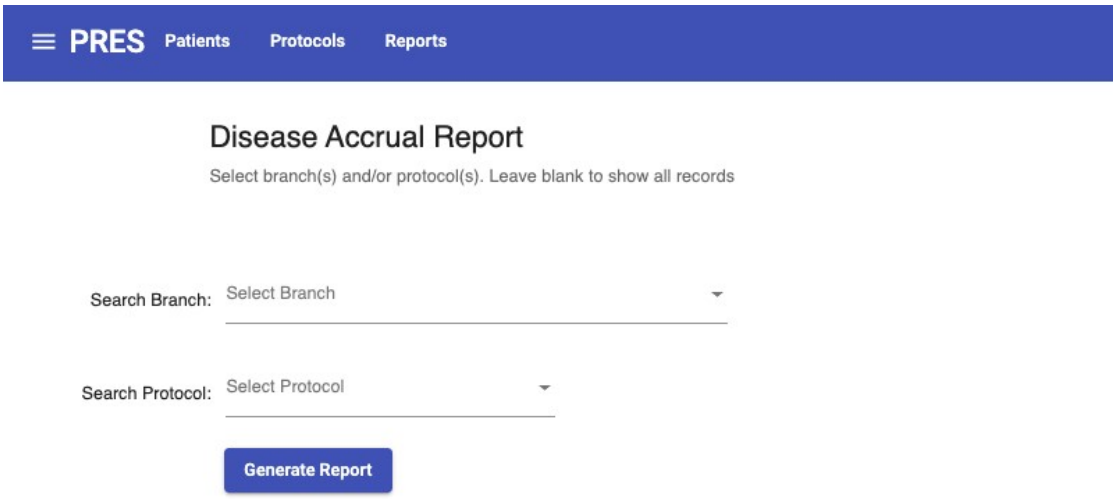


FIGURE 38-REPORT PARAMETERS

On some reports these parameters are optional, and the report can be generated for all protocols. Some reports have date parameters.

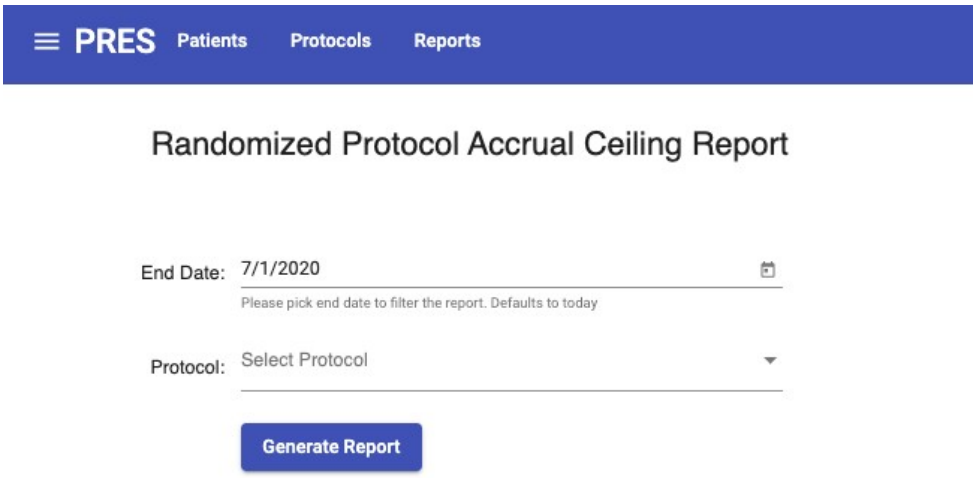


FIGURE 39-REPORT DATE

Accrual Monthly Report

Accrual Monthly Report shows last 12 months enrollment accruals by grouped by Branch, PI, Protocol, and Month. This report only visible to users with PRES Data Admin role. It accepts 3 optional parameters as shown below

- Branch (Protocol Branch)
- End Date (end date of the report, defaults to today)
- Limit to Active Treatment (Check this if the report needs to show only Active Treatment protocols)

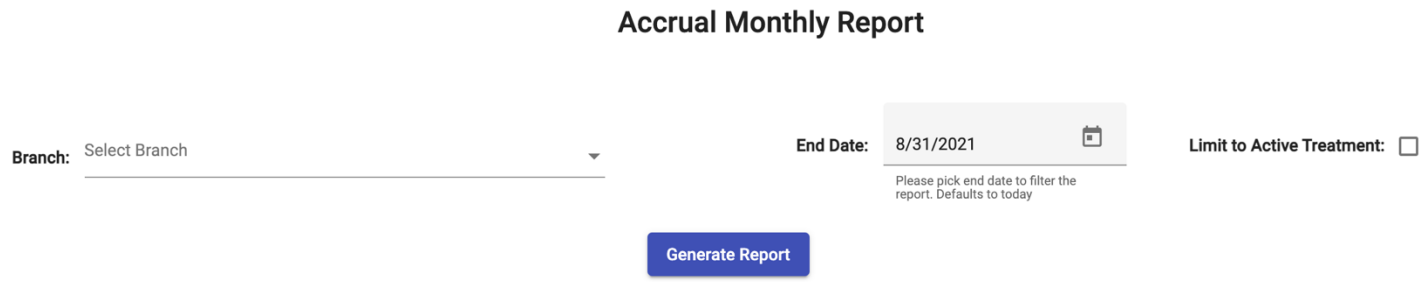
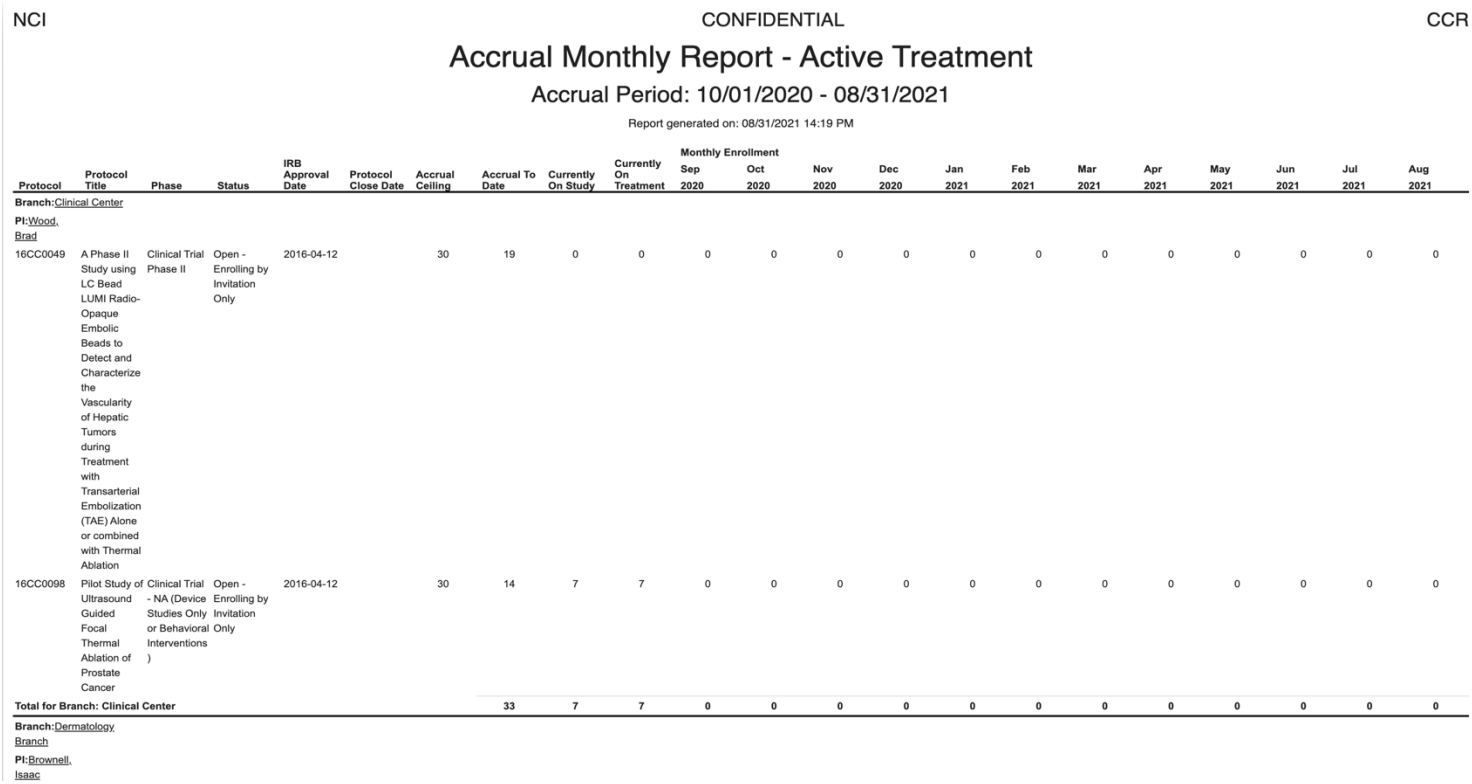


FIGURE 40-ACCRUAL MONTHLY REPORT INPUTS

After picking the inputs, click on Generate Report button. Depends on the inputs selected, the report may take a while to run. Here is the sample report.



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Accrual Monthly Report - Active Treatment

Accrual Period: 10/01/2020 - 08/31/2021

Report generated on: 08/31/2021 14:19 PM

Protocol	Protocol Title	Phase	Status	IRB Approval Date	Protocol Close Date	Accrual Ceiling	Accrual To Date	Currently On Study	Currently On Treatment	Monthly Enrollment Sep 2020	Oct 2020	Nov 2020	Dec 2020	Jan 2021	Feb 2021	Mar 2021	Apr 2021	May 2021	Jun 2021	Jul 2021	Aug 2021
Branch: Clinical Center																					
PI: Wood, Brad																					
16CC0049	A Phase II Study using LC Bead LUMI Radio-Opaque Embolic Beads to Detect and Characterize the Vascularity of Hepatic Tumors during Treatment with Transarterial Embolization (TAE) Alone or combined with Thermal Ablation	Clinical Trial Phase II	Open - Enrolling by Invitation Only	2016-04-12		30	19	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16CC0098	Pilot Study of Ultrasound Guided Focal Thermal Ablation of Prostate Cancer	Clinical Trial - NA (Device Studies Only or Behavioral Interventions)	Open - Enrolling by Invitation Only	2016-04-12		30	14	7	7	0	0	0	0	0	0	0	0	0	0	0	0
Total for Branch: Clinical Center							33	7	7	0	0	0	0	0	0	0	0	0	0	0	0
Branch: Dermatology Branch																					
PI: Brownell, Isaac																					

FIGURE 40-ACCRUAL MONTHLY REPORT INPUTS

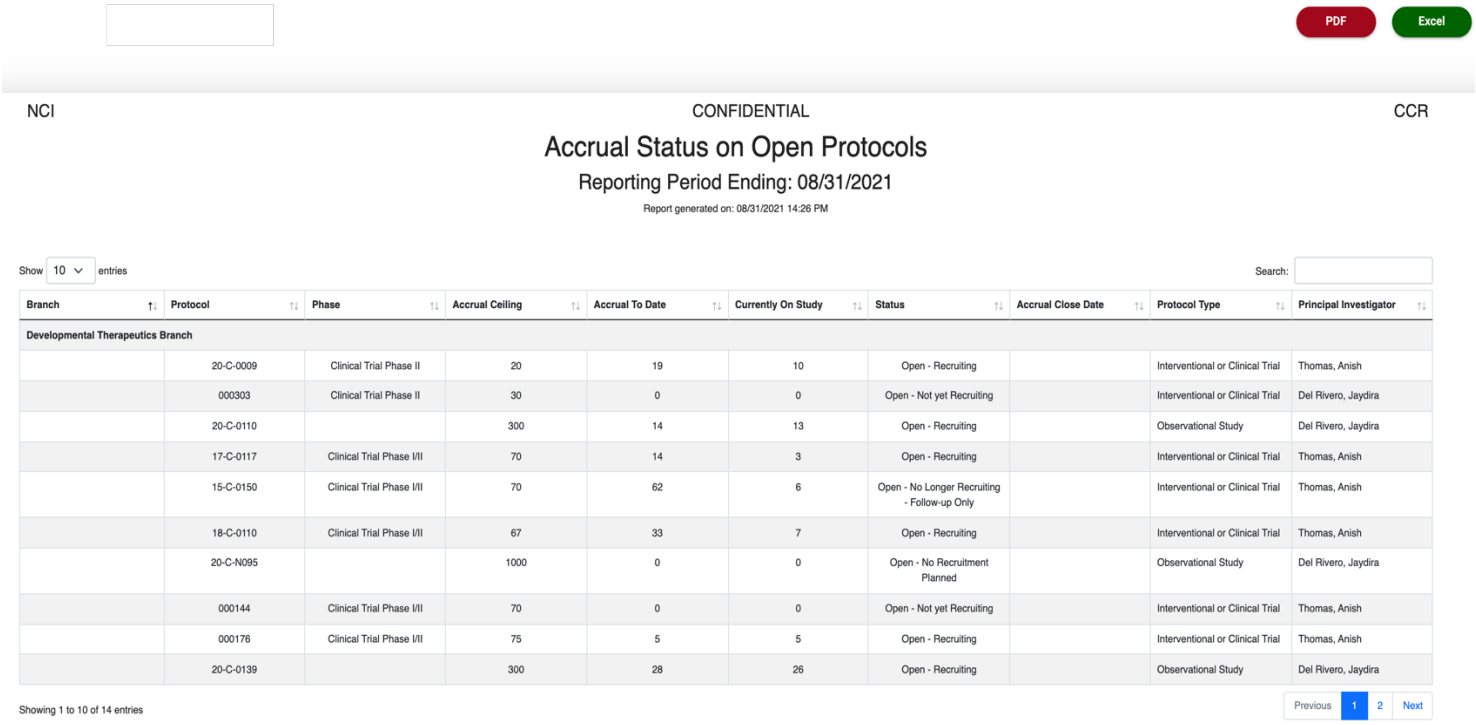
The report can be exported into PDF document or Excel sheet by clicking on appropriate button.

Accrual Status on Open Protocols

Accrual Status on Open Protocols report shows Protocol accrual numbers grouping by branch name. It accepts one optional input parameter **Branch** (Protocol Branch Name), and the report (table) has the following columns

- Branch
- Protocol
- Phase (Protocol Phase)
- Accrual Ceiling
- Accrual To Date
- Currently On Study
- Status (Protocol Status)
- Accrual Close Date
- Protocol Type
- Principal Investigator

Here is the sample report generated by selecting **Developmental Therapeutics Branch** as input. The table data can be sorted or filtered using any one of the columns data and can also be exported to PDF document or Excel sheet



PDF Excel

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Accrual Status on Open Protocols

Reporting Period Ending: 08/31/2021

Report generated on: 08/31/2021 14:26 PM

Show 10 entries Search:

Branch	Protocol	Phase	Accrual Ceiling	Accrual To Date	Currently On Study	Status	Accrual Close Date	Protocol Type	Principal Investigator
Developmental Therapeutics Branch									
	20-C-0009	Clinical Trial Phase II	20	19	10	Open - Recruiting		Interventional or Clinical Trial	Thomas, Anish
	000303	Clinical Trial Phase II	30	0	0	Open - Not yet Recruiting		Interventional or Clinical Trial	Del Rivero, Jaydira
	20-C-0110		300	14	13	Open - Recruiting		Observational Study	Del Rivero, Jaydira
	17-C-0117	Clinical Trial Phase I/II	70	14	3	Open - Recruiting		Interventional or Clinical Trial	Thomas, Anish
	15-C-0150	Clinical Trial Phase I/II	70	62	6	Open - No Longer Recruiting - Follow-up Only		Interventional or Clinical Trial	Thomas, Anish
	18-C-0110	Clinical Trial Phase I/II	67	33	7	Open - Recruiting		Interventional or Clinical Trial	Thomas, Anish
	20-C-N095		1000	0	0	Open - No Recruitment Planned		Observational Study	Del Rivero, Jaydira
	000144	Clinical Trial Phase I/II	70	0	0	Open - Not yet Recruiting		Interventional or Clinical Trial	Thomas, Anish
	000176	Clinical Trial Phase I/II	75	5	5	Open - Recruiting		Interventional or Clinical Trial	Thomas, Anish
	20-C-0139		300	28	26	Open - Recruiting		Observational Study	Del Rivero, Jaydira

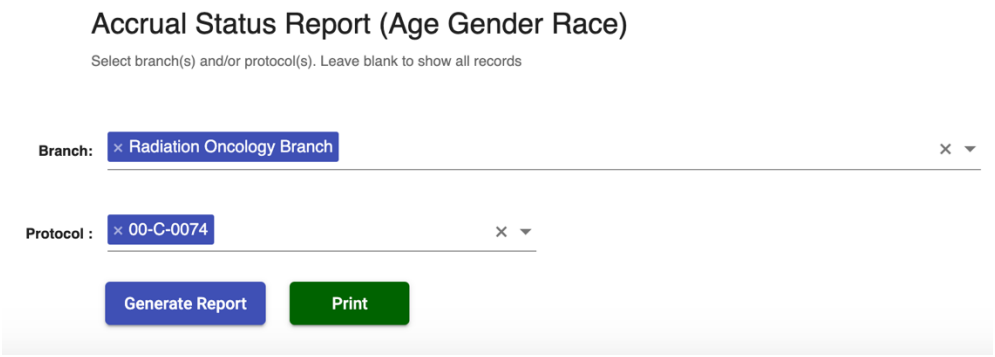
Showing 1 to 10 of 14 entries Previous 1 2 Next

Accrual Status Report (Age Gender Race)

The Accrual Status Report (Age Gender Race) shows enrollment accruals by Subject Race, Gender and Race. It accepts 2 optional parameters. If none selected, the report runs on all branches and protocols, which may take a while

- Branch (Multiple branches can be selected)

- Protocol (Multiple protocols can be selected)



Resulting report has the following columns

- Branch
- PI
- Protocol
- Protocol Title
- Phase
- Status
- Open Date
- Close Date
- Accrual Ceiling
- Gender
- Accrual To Date
- White
- Black
- Asian
- Native American
- Native Hawaiian
- Other
- Unknown
- Age: Less than 18
- Age: Between 18-65
- Age: Greater than 65

Here is the sample report based on inputs selected as shown above.

- First row contains branch name
- Second row contains PI name, Protocol number, Protocol title
- Third row contains Protocol information such as Status, Open Date, Close Date, Accrual Ceiling.

- Then next two rows contain Gender break down of accruals for each Race and Ages.

NCI CONFIDENTIAL CCR

Accrual Status Report (Age Gender Race)

Reporting Period Ending: 08/31/2021

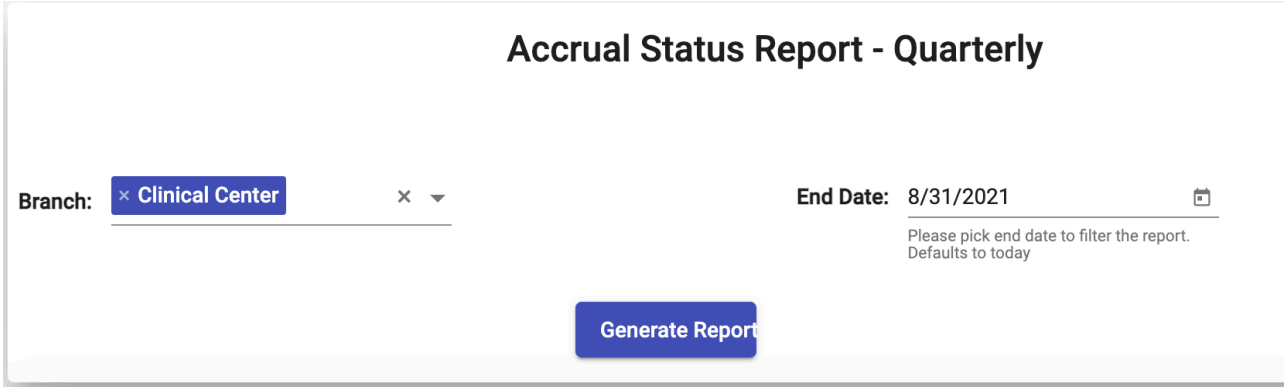
Report generated on: 08/31/2021 14:51 PM

Branch/PI	Protocol	Protocol Title	Phase	Status	Open Date	Close Date	Accrual Ceiling	Gender	Accrual To Date	White	Black	Asian	Native American	Native Hawaiian	Other	Unknown	<18>	18-65	>65
Branch: Radiation Oncology Branch																			
Camphausen, Kevin	00-C-0074	Evaluation of Late Effects and Natural History of Disease in Patients Treated with Radiotherapy																	
				O	01/28/2000		700												
								Female	91	72	8	5	1	1	2	2	0	35	54
								Male	364	270	64	19	2	0	5	4	0	67	286
									455	342	72	24	3	1	7	6	0	102	340

Accrual Status Report - Quarterly

Quarterly Accrual Status Report shows enrollment accruals in last 4 quarters before end date. It accepts 2 inputs

- Protocol Branch
- End Date (defaults to today)



The report has following list of columns

- Protocol
- Protocol Title
- Protocol Phase
- Protocol Status
- IRB Approval Date
- Protocol Close Date

- Accrual Ceiling
- Accrual to Date
- Currently On Study
- Currently On Treatment
- Q3 2020 (when end date is 08/31/2021)
- Q4 2020 (when end date is 08/31/2021)
- Q1 2021 (when end date is 08/31/2021)
- Q2 2021 (when end date is 08/31/2021)

Here is the sample report. The report is grouped by Branch, then PI and Protocol. Each of these shown in separate rows. At the end of each branch, sum of each quarter accruals for shown.

NCI CONFIDENTIAL CCR

Accrual Status Report - Quarterly

Reporting Period Ending: 08/31/2021

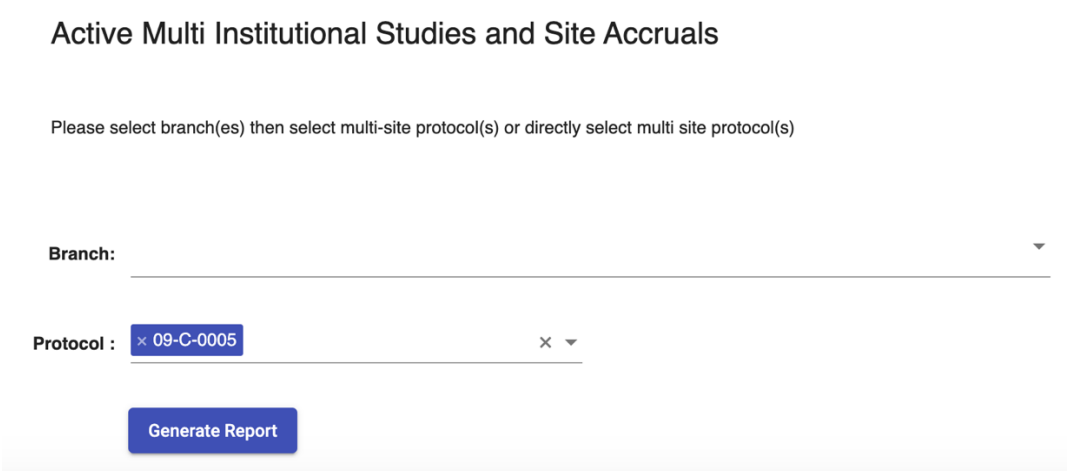
Report generated on: 08/31/2021 15:25 PM

Protocol	Protocol Title	Phase	Status	IRB Approval Date	Protocol Close Date	Accrual Ceiling	Accrual To Date	Currently On Study	Currently On Treatment	Q3 2020	Q4 2020	Q1 2021	Q2 2021
Branch: Clinical Center													
PI: Wood, Brad													
16-CC-0049	A Phase II Study using LC Bead LUMI Radio-Opaque Embolic Beads to Detect and Characterize the Vascularity of Hepatic Tumors during Treatment with Transarterial Embolization (TAE) Alone or combined with Thermal Ablation	Clinical Trial Phase II	Open - Enrolling by Invitation Only	04/12/2016		30	19	0	1	0	0	0	0
16-CC-0098	Pilot Study of Ultrasound Guided Focal Thermal Ablation of Prostate Cancer	Clinical Trial - NA (Device Studies Only or Behavioral Interventions)	Open - Enrolling by Invitation Only	04/12/2016		30	14	7	7	0	0	0	0
Total for Branch: Clinical Center							**33**	**7**	**8**	**0**	**0**	**0**	**0**

Active Multi Institutional Studies and Site Accruals

Active Multi Institutional Studies and Site Accruals report shows enrollment accruals of active multi-site protocols grouped by site name. It accepts two optional inputs, if none of the selected, the report runs all active multi-site protocols.

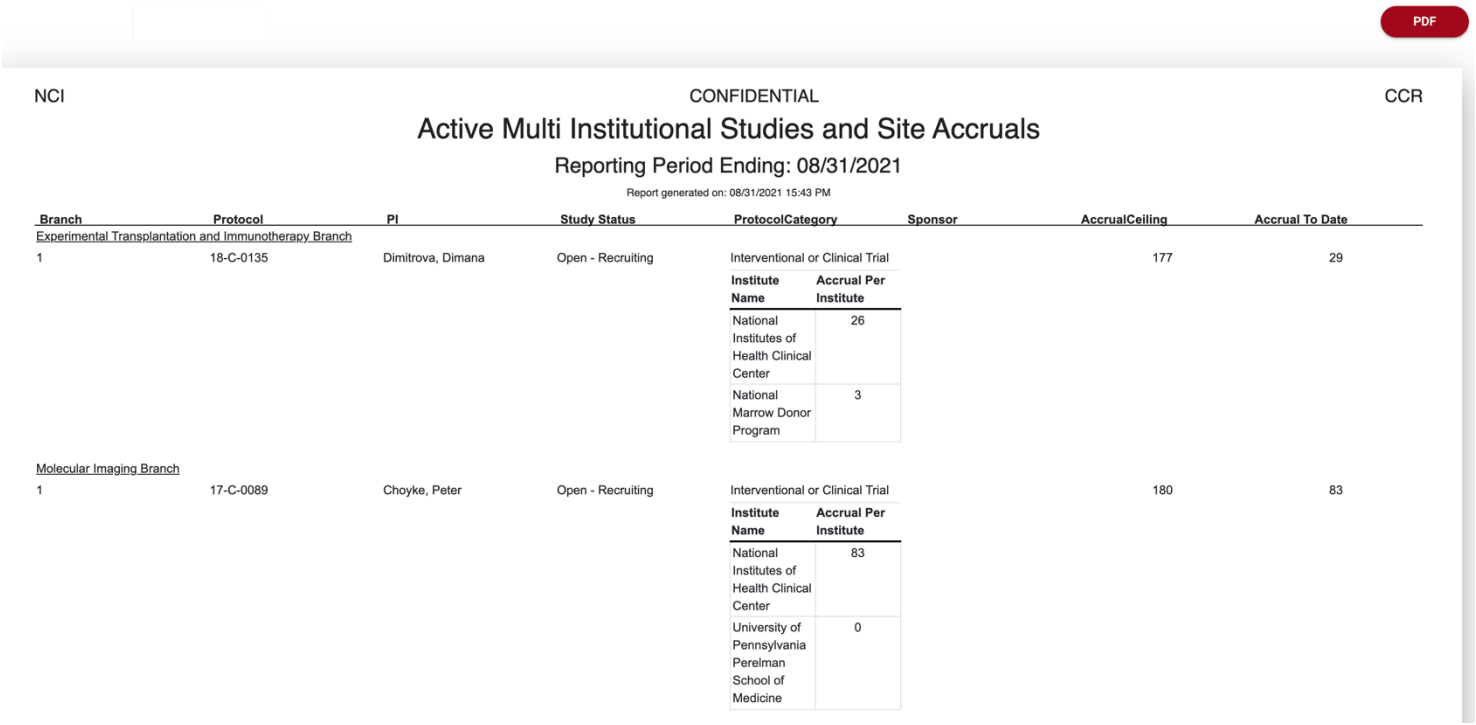
- Protocol Branch(es)
- Protocol Number(s)



The report has the following columns

- Branch
- Protocol
- PI
- Study Status (Protocol Status)
- Protocol Category
- Sponsor
- Accrual Ceiling
- Accrual To Date

The report is grouped by Branch and Protocol. For each branch, protocols are listed in ascending order and site accruals are shown in next row as shown below. The report can be exported as PDF document by clicking on PDF button shown below.



PDF

NCI CONFIDENTIAL CCR

Active Multi Institutional Studies and Site Accruals

Reporting Period Ending: 08/31/2021

Report generated on: 08/31/2021 15:43 PM

Branch	Protocol	PI	Study Status	ProtocolCategory	Sponsor	AccrualCeiling	Accrual To Date
Experimental Transplantation and Immunotherapy Branch							
1	18-C-0135	Dimitrova, Dimana	Open - Recruiting	Interventional or Clinical Trial		177	29

Institute Name	Accrual Per Institute
National Institutes of Health Clinical Center	26
National Marrow Donor Program	3

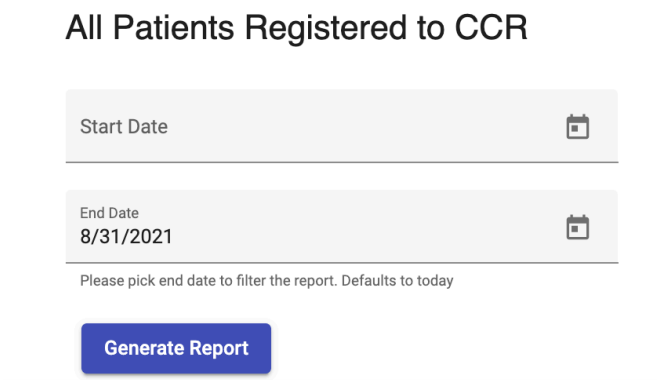
Molecular Imaging Branch							
1	17-C-0089	Choyke, Peter	Open - Recruiting	Interventional or Clinical Trial		180	83

Institute Name	Accrual Per Institute
National Institutes of Health Clinical Center	83
University of Pennsylvania Perelman School of Medicine	0

All Patients Registered to CCR

All Patients Registered to CCR report created for CRO to see enrollments between specific dates. It accepts 2 optional parameters

- Start Date
- End Date (defaults to Today)

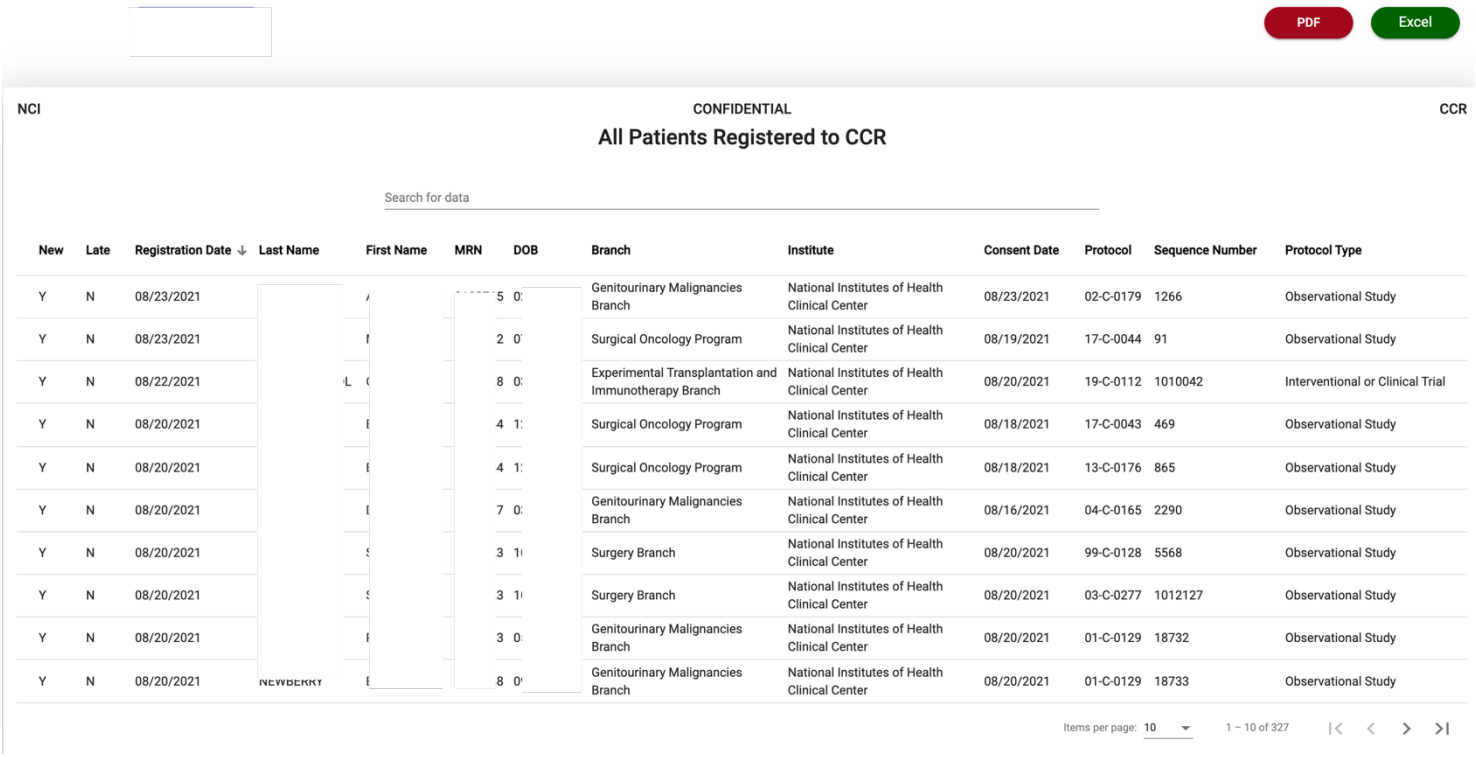


The report has the following columns.

- New
- Late
- Registration Date
- Subject Last Name
- Subject First Name
- Subject MRN

- Subject DOB
- Protocol Branch
- Institute
- Consent Date
- Protocol Sequence Number
- Protocol Type

See below for sample report. Subject PII/PHI information has been redacted. Enrollment data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.


PDF Excel

NCI CONFIDENTIAL CCR

All Patients Registered to CCR

Search for data

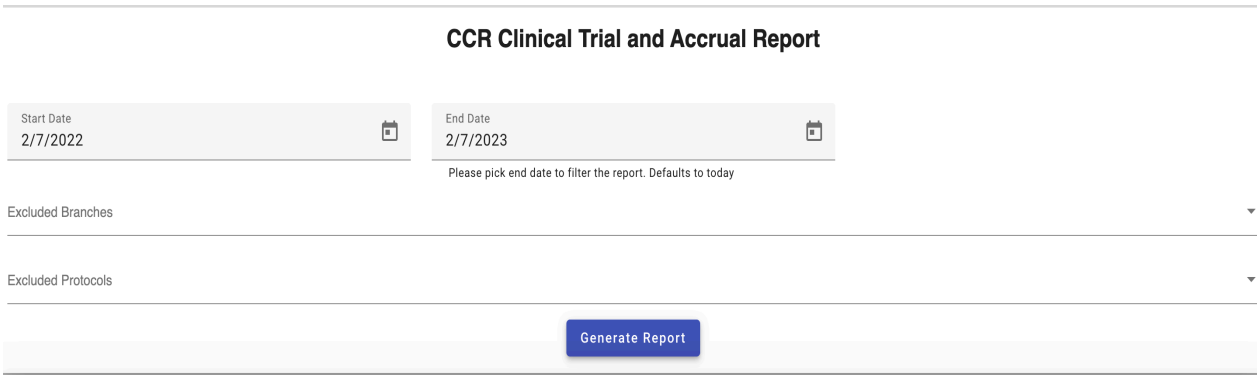
New	Late	Registration Date	Last Name	First Name	MRN	DOB	Branch	Institute	Consent Date	Protocol	Sequence Number	Protocol Type
Y	N	08/23/2021			5	0	Genitourinary Malignancies Branch	National Institutes of Health Clinical Center	08/23/2021	02-C-0179	1266	Observational Study
Y	N	08/23/2021			2	0	Surgical Oncology Program	National Institutes of Health Clinical Center	08/19/2021	17-C-0044	91	Observational Study
Y	N	08/22/2021			8	0	Experimental Transplantation and Immunotherapy Branch	National Institutes of Health Clinical Center	08/20/2021	19-C-0112	1010042	Interventional or Clinical Trial
Y	N	08/20/2021			4	1	Surgical Oncology Program	National Institutes of Health Clinical Center	08/18/2021	17-C-0043	469	Observational Study
Y	N	08/20/2021			4	1	Surgical Oncology Program	National Institutes of Health Clinical Center	08/18/2021	13-C-0176	865	Observational Study
Y	N	08/20/2021			7	0	Genitourinary Malignancies Branch	National Institutes of Health Clinical Center	08/16/2021	04-C-0165	2290	Observational Study
Y	N	08/20/2021			3	1	Surgery Branch	National Institutes of Health Clinical Center	08/20/2021	99-C-0128	5568	Observational Study
Y	N	08/20/2021			3	1	Surgery Branch	National Institutes of Health Clinical Center	08/20/2021	03-C-0277	1012127	Observational Study
Y	N	08/20/2021			3	0	Genitourinary Malignancies Branch	National Institutes of Health Clinical Center	08/20/2021	01-C-0129	18732	Observational Study
Y	N	08/20/2021	NEWBERRY		8	0	Genitourinary Malignancies Branch	National Institutes of Health Clinical Center	08/20/2021	01-C-0129	18733	Observational Study

Items per page: 10 1 – 10 of 327

CCR Clinical Trial and Accrual Report

CCR clinical Trail and Accrual Report shows the accrual list of clinical trials. It accepts four optional inputs, if none of the selected, the report runs all

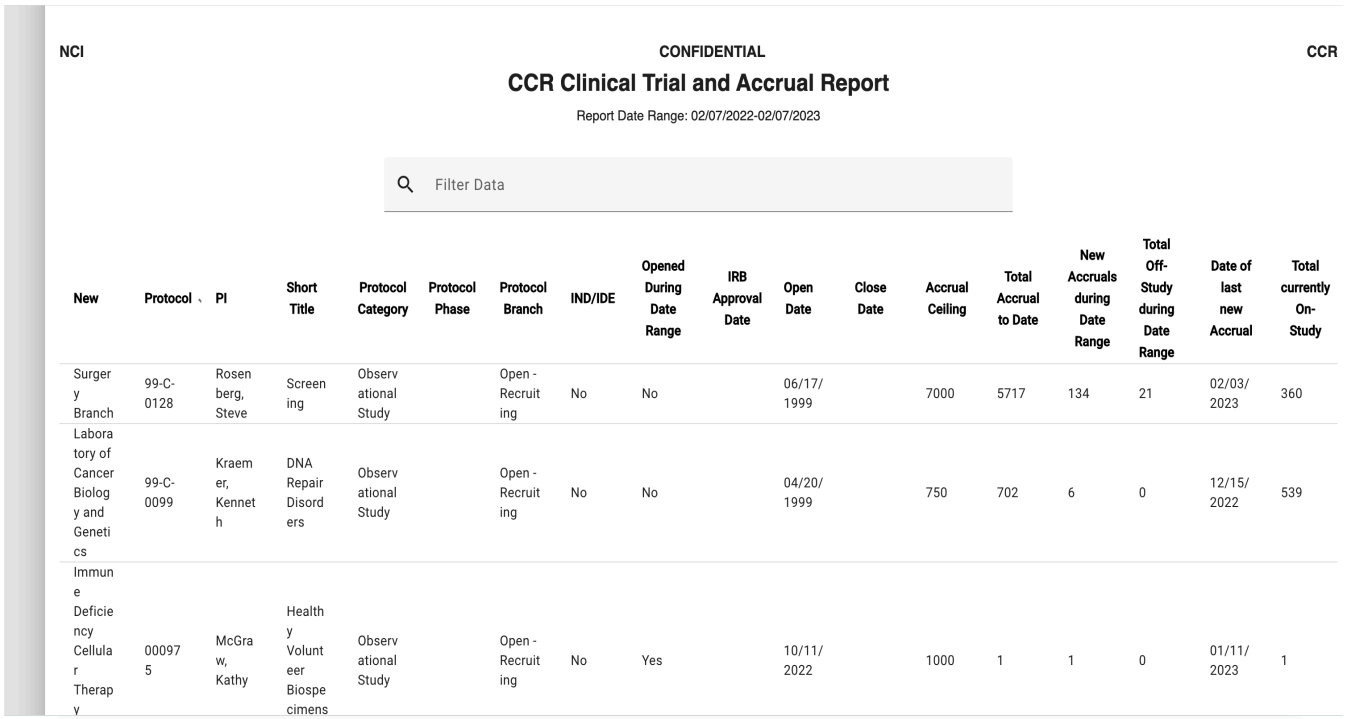
- Protocol Branch(es)
- Protocol Number(s)
- Start Date
- End Date (Default to today)



The report has the following columns

- New
- Protocol
- PI
- Short Title
- Protocol category
- Protocol Phase
- Protocol Branch
- IND/IDE
- Opened During Date Range
- IRB Approval Date
- Open Date
- Close Date
- Accrual Ceiling
- Total Accrual to Date
- New Accrual during Date Range
- Total Off-Study During Date Range
- Date of last new Accrual
- Total Currently On-Study

See below for sample report. Accrual data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.



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CCR Clinical Trial and Accrual Report

Report Date Range: 02/07/2022-02/07/2023

Filter Data

New	Protocol	PI	Short Title	Protocol Category	Protocol Phase	Protocol Branch	IND/IDE	Opened During Date Range	IRB Approval Date	Open Date	Close Date	Accrual Ceiling	Total Accrual to Date	New Accruals during Date Range	Total Off-Study during Date Range	Date of last new Accrual	Total currently On-Study
Surgery Branch	99-C-0128	Rosenberg, Steve	Screening	Observational Study		Open - Recruiting	No	No		06/17/1999		7000	5717	134	21	02/03/2023	360
Laboratory of Cancer Biology and Genetics	99-C-0099	Kraemer, Kenneth	DNA Repair Disorders	Observational Study		Open - Recruiting	No	No		04/20/1999		750	702	6	0	12/15/2022	539
Immune Deficiency Cellular Therapy	000975	McGraw, Kathy	Healthy Volunteer Biospecimens	Observational Study		Open - Recruiting	No	Yes		10/11/2022		1000	1	1	0	01/11/2023	1

Cumulative Inclusion Enrollment Report

Cumulative Inclusion Enrollment report shows cumulative accruals from last CR Date (Continuing Review) to End date (defaults to Today). The resulting report shows two tables (three tables for multi-site studies)

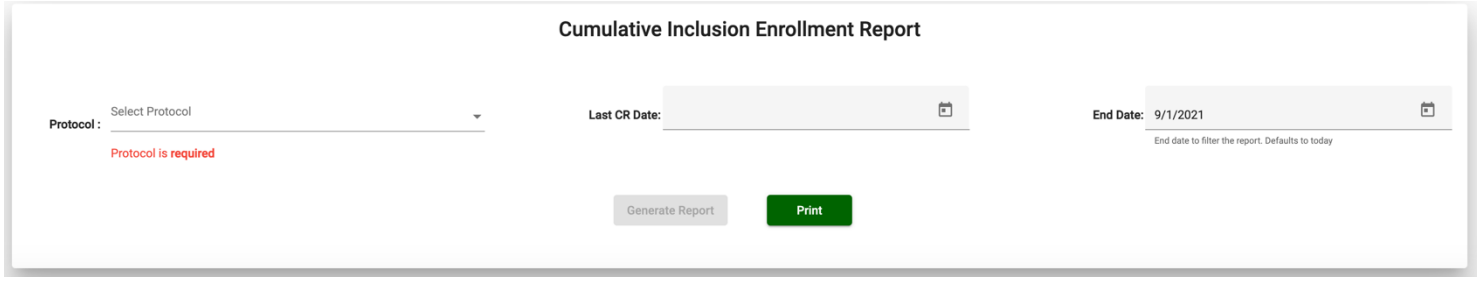
- First table shows NIH and Non-NIH sites accruals

Second table shows NIH enrolled patients Accruals break down of each Race group by Ethnicity and Gender

Third table only shown for multi-site studies**,** shows break down of non-NIH site enrolled patients of each Race group by Ethnicity and Gender

The report accepts three inputs, of which Protocol is mandatory.

- Protocol
- Last CR Date
- End Date (Defaults to Today)



And here is the sample report of patients enrolled on to NIH

NCI CONFIDENTIAL CCR

Cumulative Inclusion Enrollment Report

Cumulative to Date: 09/01/2021

Protocol Number: 00-C-0074
Principle Investigator: Camphausen, Kevin
Date First Subject Enrolled: 02/14/2000
Total Enrollment: 455
Study Title: Evaluation of Late Effects and Natural History of Disease in Patients Treated with Radiotherapy

NIH/CC	Other Domestic Sites	Foreign Sites	Total	
-	-	-	700	Accrual Ceiling
455	0	0	455	New Subject Since Last CR(02/14/2000)
455	0	0	455	Aggregate Total Accrued

NIH CC Site

	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
Racial categories	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Total
American Indian or Alaska Native	1	2	0	0	0	0	0	0	0	3
Asian	4	19	0	1	0	0	0	0	0	24
Native Hawaiian or Other Pacific Islander	1	0	0	0	0	0	0	0	0	1
Black or African American	8	63	0	0	1	0	0	0	0	72
White	71	263	0	1	7	0	0	0	0	342
Other	0	2	0	2	3	0	0	0	0	7
Unknown	0	1	0	1	3	0	1	0	0	6
Total	85	350	0	5	14	0	1	0	0	455

And for multi-site studies, the report may look like below

NIH CC Site

	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
Racial categories	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Total
American Indian or Alaska Native	0	1	0	0	0	0	0	0	0	1
Asian	1	0	0	0	0	0	0	0	0	1
Native Hawaiian or Other Pacific Islander	0	2	0	0	0	0	0	0	0	2
Black or African American	0	3	0	0	0	0	0	1	0	4
White	17	65	0	0	0	0	0	4	0	86
Other	0	0	0	0	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0	0	0	0
Total	18	71	0	0	0	0	0	5	0	94

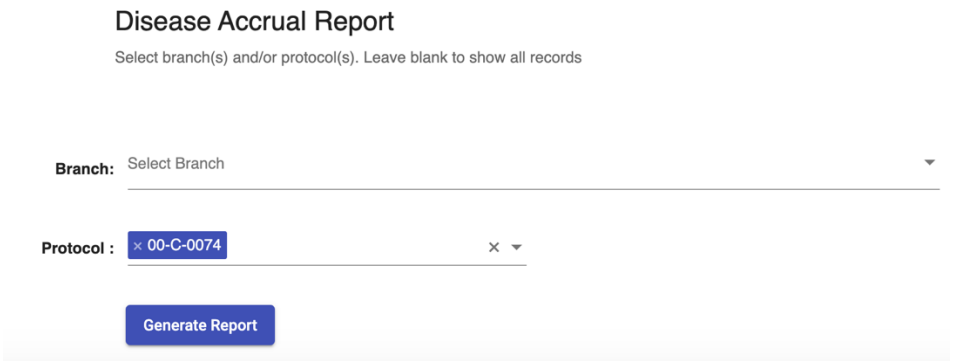
Other Sites

	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
Racial categories	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Total
American Indian or Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Disease Accrual Report

Disease Accrual report shows enrollment accruals grouped by branch and disease name. It accepts two optional inputs, if none of the selected, the report runs all branches and all protocols.

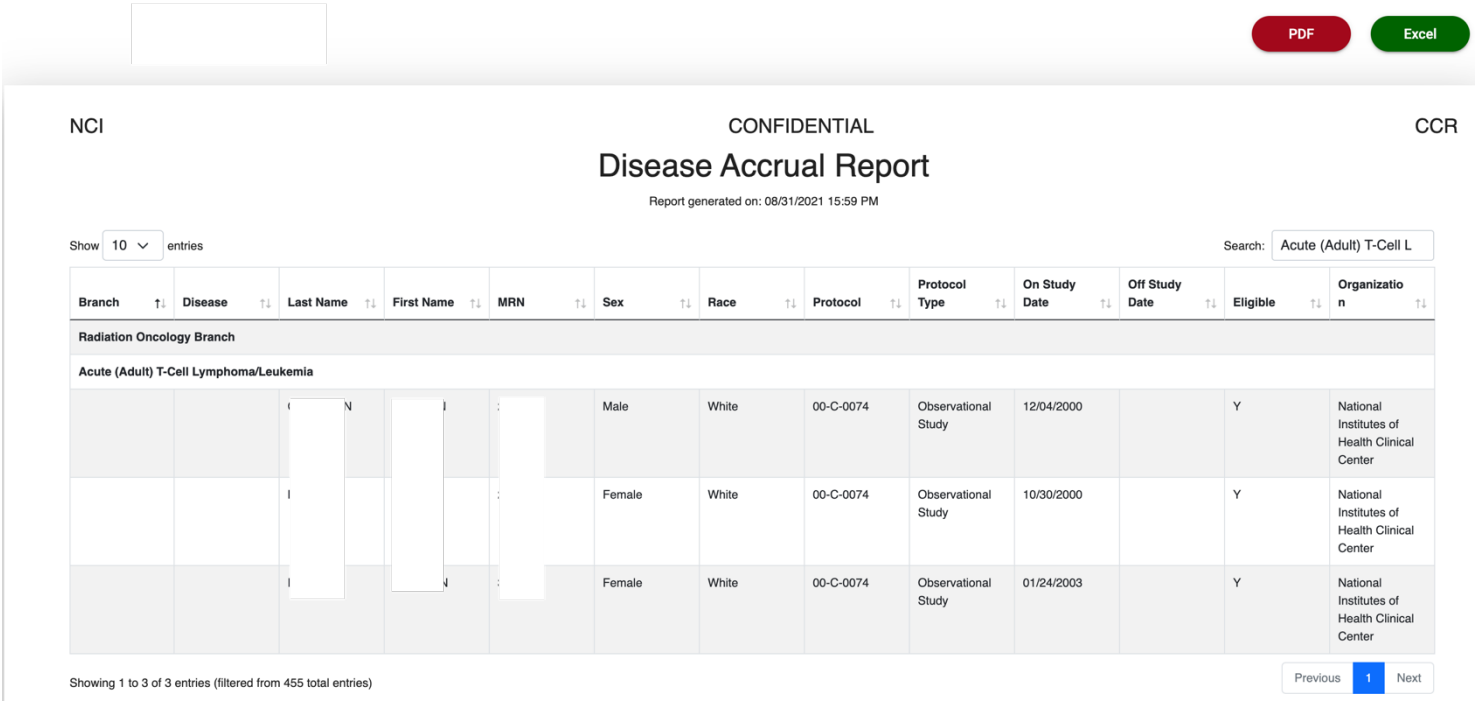
- Protocol Branch(es)
- Protocol Number(s)



And the report has the following columns

- Branch
- Disease
- Subject Last Name
- Subject First Name
- Subject MRN
- Subject Sex
- Subject Race
- Protocol Number
- Protocol type
- On Study Date (Fully Eligible Date)
- Off-Study Date
- Eligible
- Organization

See below for sample report. Subject PII/PHI information has been redacted. Enrollment data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.



PDF Excel

NCI CONFIDENTIAL CCR

Disease Accrual Report

Report generated on: 08/31/2021 15:59 PM

Show 10 entries Search: Acute (Adult) T-Cell L

Branch	Disease	Last Name	First Name	MRN	Sex	Race	Protocol	Protocol Type	On Study Date	Off Study Date	Eligible	Organization
Radiation Oncology Branch												
Acute (Adult) T-Cell Lymphoma/Leukemia												
		[redacted]			Male	White	00-C-0074	Observational Study	12/04/2000		Y	National Institutes of Health Clinical Center
		[redacted]			Female	White	00-C-0074	Observational Study	10/30/2000		Y	National Institutes of Health Clinical Center
		[redacted]			Female	White	00-C-0074	Observational Study	01/24/2003		Y	National Institutes of Health Clinical Center

Showing 1 to 3 of 3 entries (filtered from 455 total entries) Previous 1 Next

Disease Accrual Summary Report

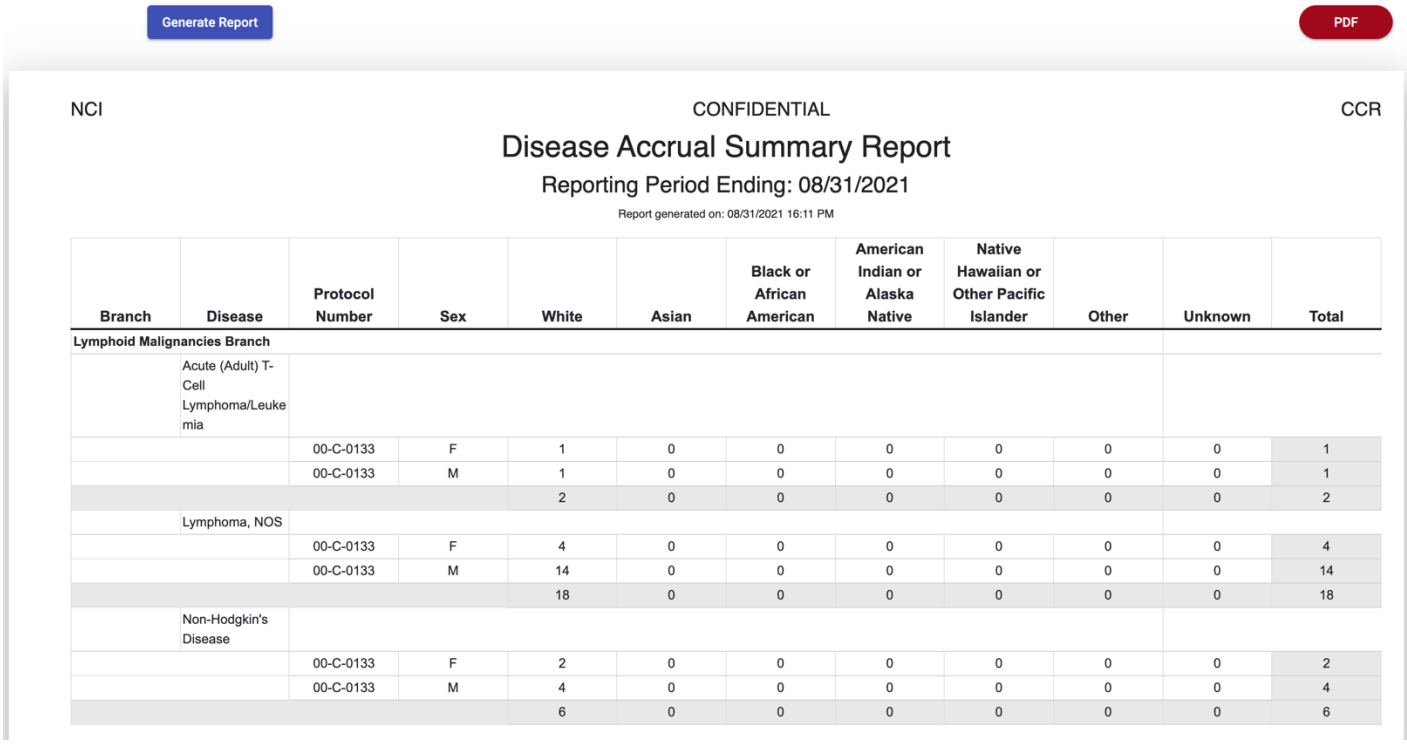
Disease Accrual Summary report shows enrollment accrual summary grouped by branch and disease name for each Race. It accepts two optional inputs, if none of the selected, the report runs all branches and all protocols.

- Protocol Branch(es)
- Protocol Number(s)

And the report has the following columns

- Branch
- Disease
- Protocol Number
- Sex Type (M/F)
- White
- Asian
- Black or African American
- American Indian or Alaskan Native
- Native Hawaiian or Other Pacific Islander
- Protocol type
- Other
- Unknown
- Total

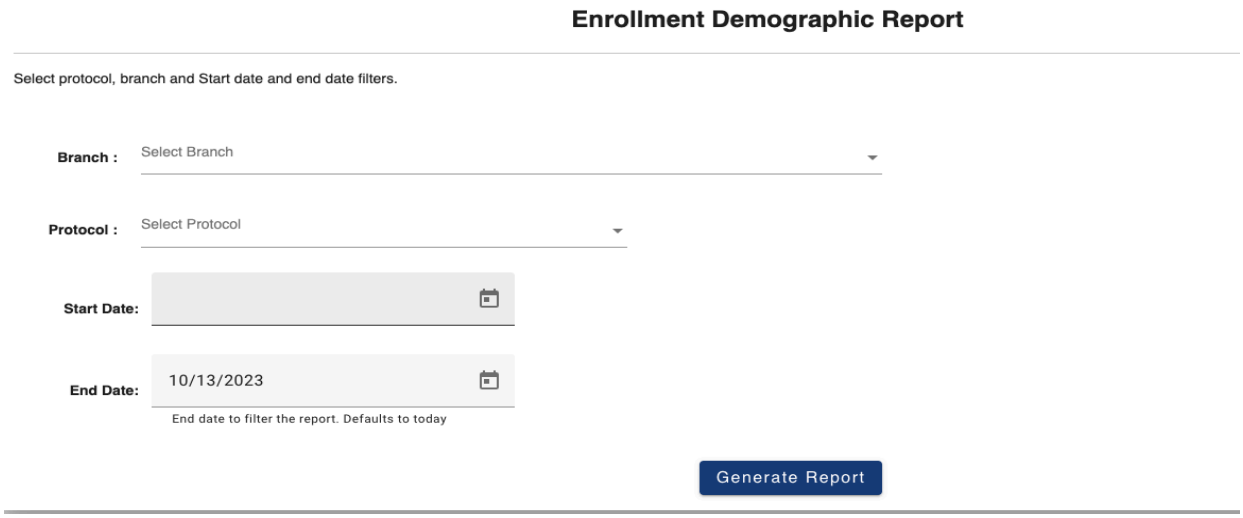
See below for sample report. First row contains branch name, second row contains Disease name, Protocol Third row contains disease accruals of each Race for Female and Fourth row contains disease accruals of each Race for Male.



Branch	Disease	Protocol Number	Sex	White	Asian	Black or African American	American Indian or Alaska Native	Native Hawaiian or Other Pacific Islander	Other	Unknown	Total
Lymphoid Malignancies Branch											
	Acute (Adult) T-Cell Lymphoma/Leukemia										
		00-C-0133	F	1	0	0	0	0	0	0	1
		00-C-0133	M	1	0	0	0	0	0	0	1
				2	0	0	0	0	0	0	2
	Lymphoma, NOS										
		00-C-0133	F	4	0	0	0	0	0	0	4
		00-C-0133	M	14	0	0	0	0	0	0	14
				18	0	0	0	0	0	0	18
	Non-Hodgkin's Disease										
		00-C-0133	F	2	0	0	0	0	0	0	2
		00-C-0133	M	4	0	0	0	0	0	0	4
				6	0	0	0	0	0	0	6

Enrollment Demographic Report

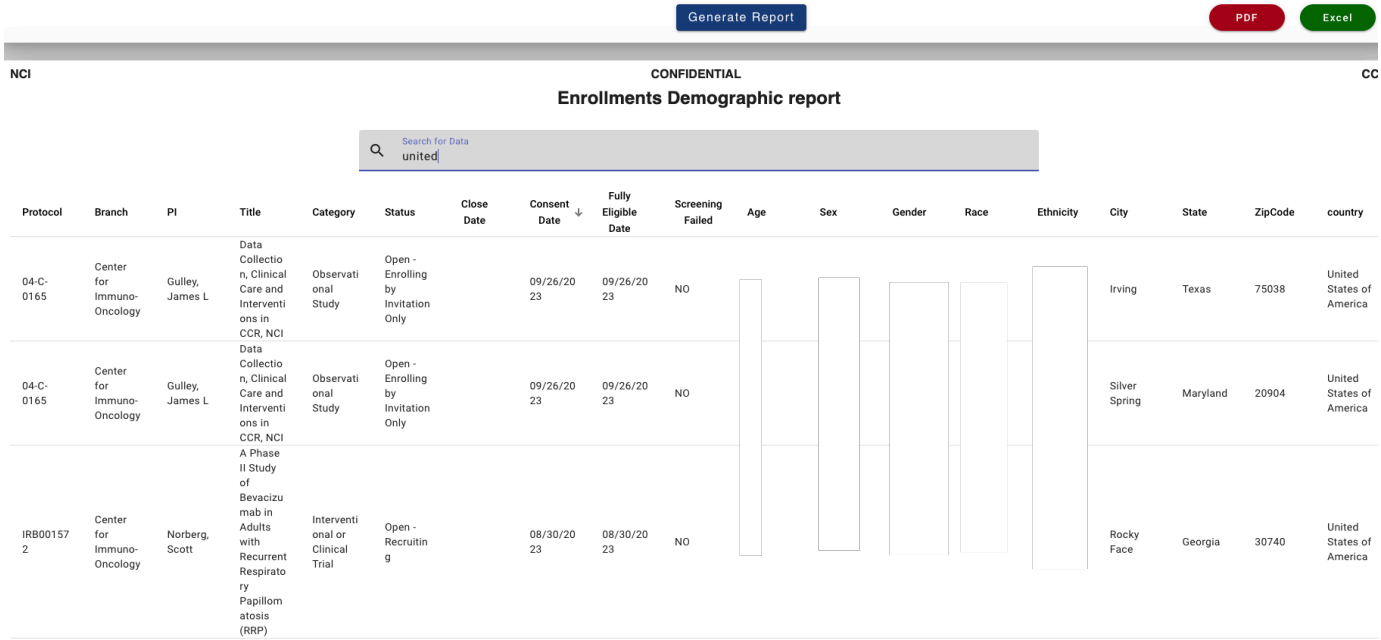
Enrollment Demographic Report contain demographics of patient without patient's personal data. It accepts four optional inputs, if none of the selected, the report runs on all branches, and all protocols with start date as system start date and end date defaults to Today.



And the report has the following columns.

- Protocol
- Branch
- PI
- Title
- Category
- Status
- Close Date
- Consent Date
- Fully Eligible Date
- Screening Failed
- Age
- Sex
- Gender
- Race
- Ethnicity
- City
- State
- Zip code
- Country

See below sample report. Enrollment data can be filtered using the search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document and Excel sheet.

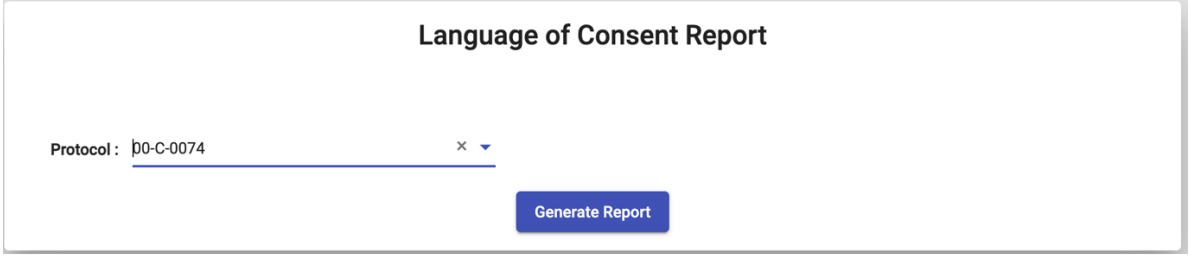


Protocol	Branch	PI	Title	Category	Status	Close Date	Consent Date	Fully Eligible Date	Screening Failed	Age	Sex	Gender	Race	Ethnicity	City	State	ZipCode	country
04-C-0165	Center for Immuno-Oncology	Gulley, James L	Data Collection, Clinical Care and Interventions in CCR, NCI	Observational Study	Open - Enrolling by Invitation Only		09/26/2023	09/26/2023	NO						Irving	Texas	75038	United States of America
04-C-0165	Center for Immuno-Oncology	Gulley, James L	Data Collection, Clinical Care and Interventions in CCR, NCI	Observational Study	Open - Enrolling by Invitation Only		09/26/2023	09/26/2023	NO						Silver Spring	Maryland	20904	United States of America
IRB001572	Center for Immuno-Oncology	Norberg, Scott	A Phase II Study of Bevacizumab in Adults with Recurrent Respiratory Papillomatosis (RRP)	Interventional or Clinical Trial	Open - Recruiting		08/30/2023	08/30/2023	NO						Rocky Face	Georgia	30740	United States of America

Language of Consent Report

Language of Consent report contains enrollment records with patient consent language and other enrollment information. The Protocol is required field and must be selected.

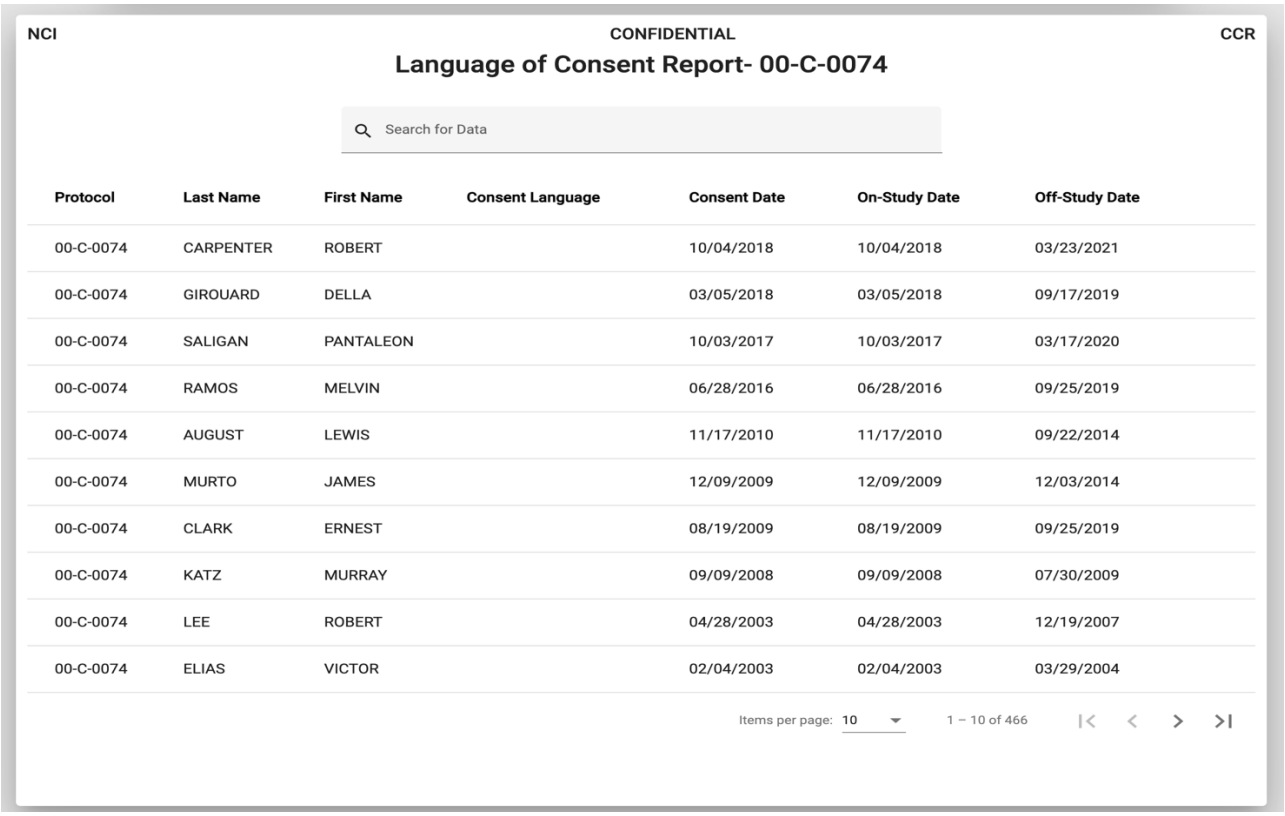
- Protocol Number



And the report has the following columns

- Protocol
- Patient Last Name
- Patient First Name
- Consent Language
- Consent Date
- On-Study Date
- Off-Study Date

See below for sample report. Subject PII/PHI information has been redacted. Enrollment data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.



NCI CONFIDENTIAL CCR

Language of Consent Report- 00-C-0074

Search for Data

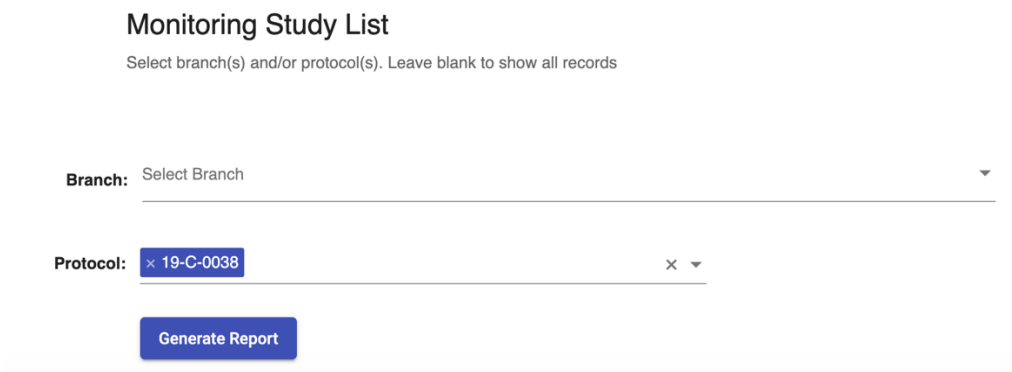
Protocol	Last Name	First Name	Consent Language	Consent Date	On-Study Date	Off-Study Date
00-C-0074	CARPENTER	ROBERT		10/04/2018	10/04/2018	03/23/2021
00-C-0074	GIROUARD	DELLA		03/05/2018	03/05/2018	09/17/2019
00-C-0074	SALIGAN	PANTALEON		10/03/2017	10/03/2017	03/17/2020
00-C-0074	RAMOS	MELVIN		06/28/2016	06/28/2016	09/25/2019
00-C-0074	AUGUST	LEWIS		11/17/2010	11/17/2010	09/22/2014
00-C-0074	MURTO	JAMES		12/09/2009	12/09/2009	12/03/2014
00-C-0074	CLARK	ERNEST		08/19/2009	08/19/2009	09/25/2019
00-C-0074	KATZ	MURRAY		09/09/2008	09/09/2008	07/30/2009
00-C-0074	LEE	ROBERT		04/28/2003	04/28/2003	12/19/2007
00-C-0074	ELIAS	VICTOR		02/04/2003	02/04/2003	03/29/2004

Items per page: 10 1 – 10 of 466

Monitoring Study List

Monitoring Study List report contains enrollment accrual of monitored studies. These studies have monitor flag true in PRES. It accepts two optional inputs, if none of the selected, the report runs on all branches, and all monitored protocols.

- Protocol Branch(es)
- Protocol Number(s)



Monitoring Study List

Select branch(s) and/or protocol(s). Leave blank to show all records

Branch: Select Branch

Protocol: × 19-C-0038

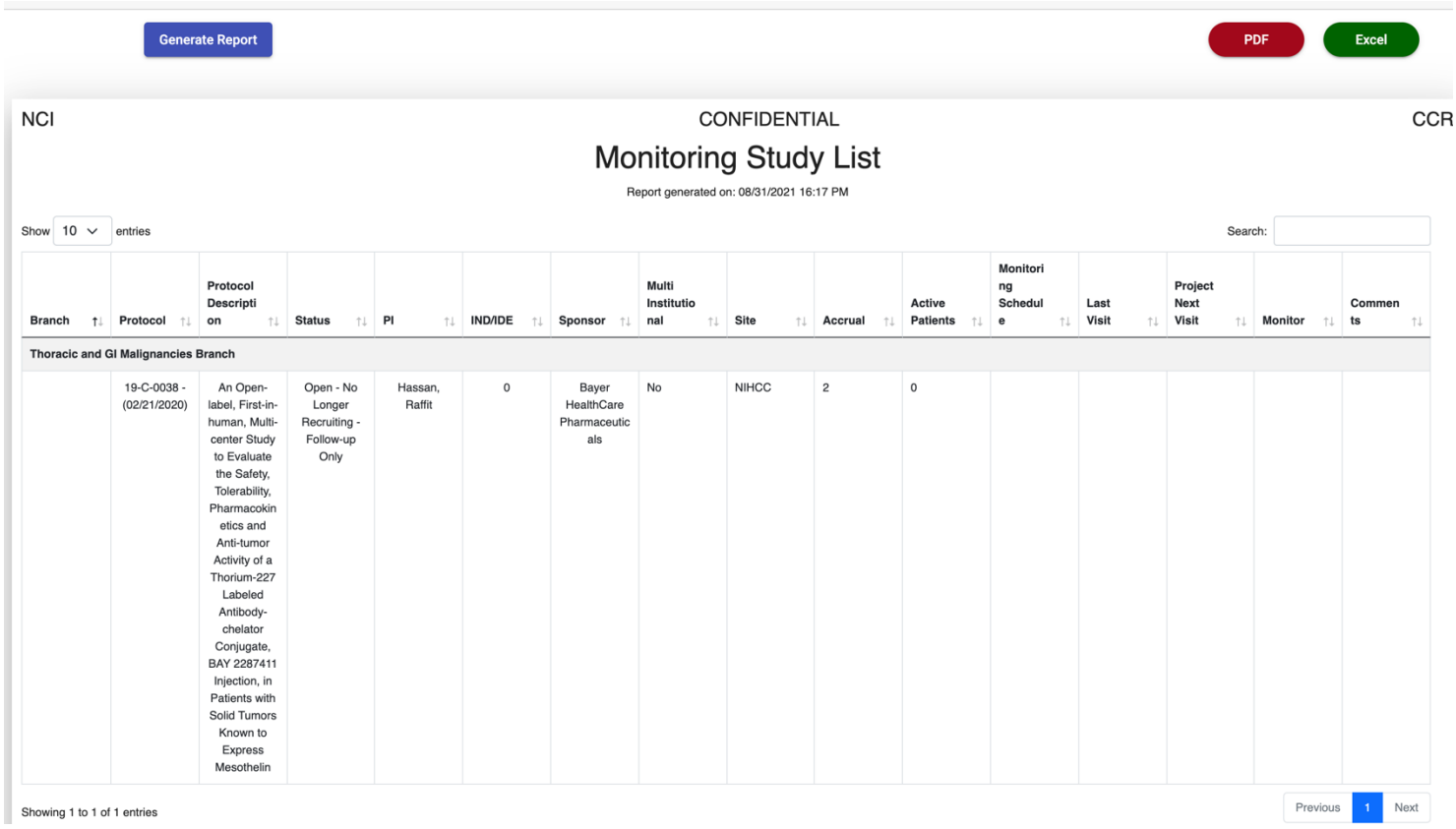
Generate Report

And the report has the following columns

- Branch

- Protocol Number
- Protocol Description
- Protocol Status
- PI
- IND/IDE (Investigational New Drug or Investigational Device Exemption)
- Sponsor (Sponsor of the Study)
- Multi Institutional (Yes/No)
- Site (Name)
- Accrual (To Date)
- Active Patients (On Study Patients)
- Monitoring Schedule
- Last Visit
- Project Next Visit
- Monitor
- Comments

See below for sample report



Generate Report

PDF Excel

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Monitoring Study List

Report generated on: 08/31/2021 16:17 PM

Show 10 entries Search:

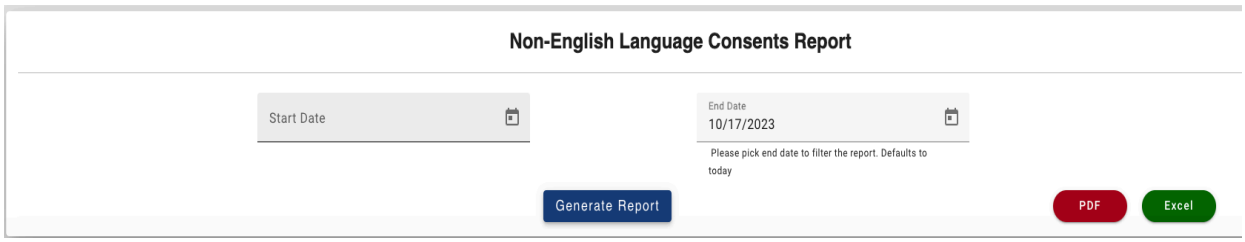
Branch	Protocol	Protocol Description	Status	PI	IND/IDE	Sponsor	Multi Institutional	Site	Accrual	Active Patients	Monitoring Schedule	Last Visit	Project Next Visit	Monitor	Comments
Thoracic and GI Malignancies Branch															
	19-C-0038 - (02/21/2020)	An Open-label, First-in-human, Multi-center Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Anti-tumor Activity of a Thorium-227 Labeled Antibody-chelator Conjugate, BAY 2287411 Injection, in Patients with Solid Tumors Known to Express Mesothelin	Open - No Longer Recruiting - Follow-up Only	Hassan, Raffit	0	Bayer HealthCare Pharmaceuticals	No	NIHCC	2	0					

Showing 1 to 1 of 1 entries Previous 1 Next

Non-English Language Consents Report

Non-English Language Consents Report shows the list of non-English language consents in all protocol.

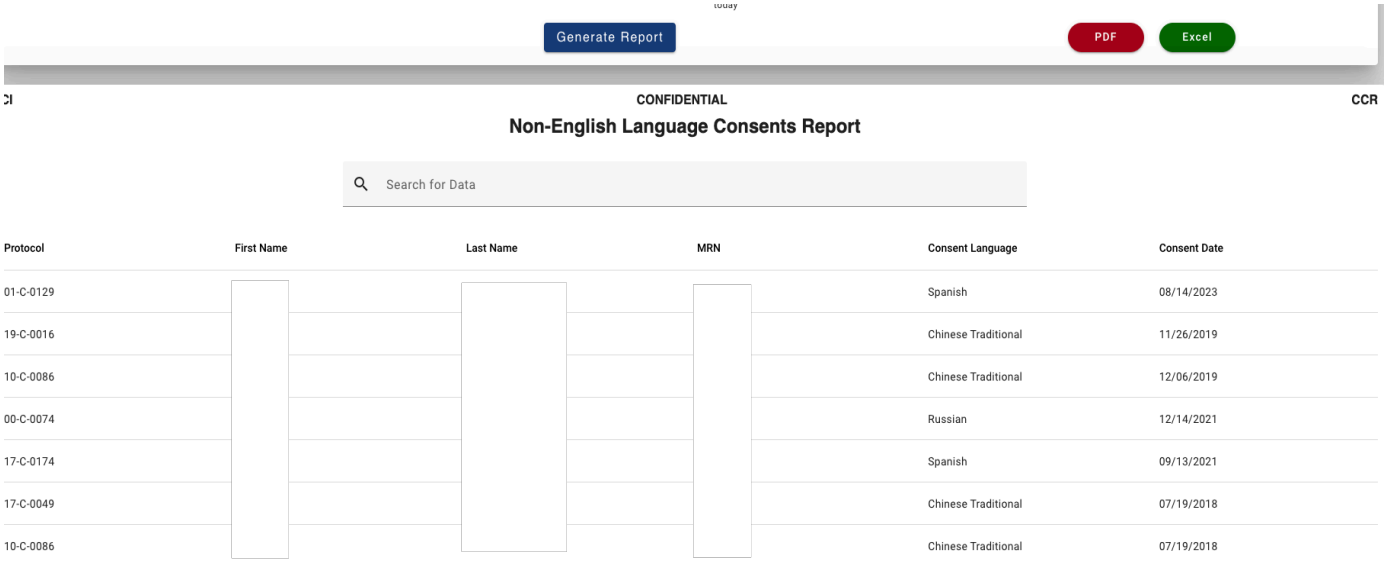
It accepts two optional parameters Start Date and End Date. End date is defaulted to the day on which report is generated.



The report has the following columns.

- Protocol
- First Name
- Last Name
- MRN
- Consent Language
- Consent Date

See below sample report. Enrollment data can be filtered using the search box shown in the table. The table also supports sorting, filtering and page by page pagination. The report can be exported to Excel sheet and pdf.



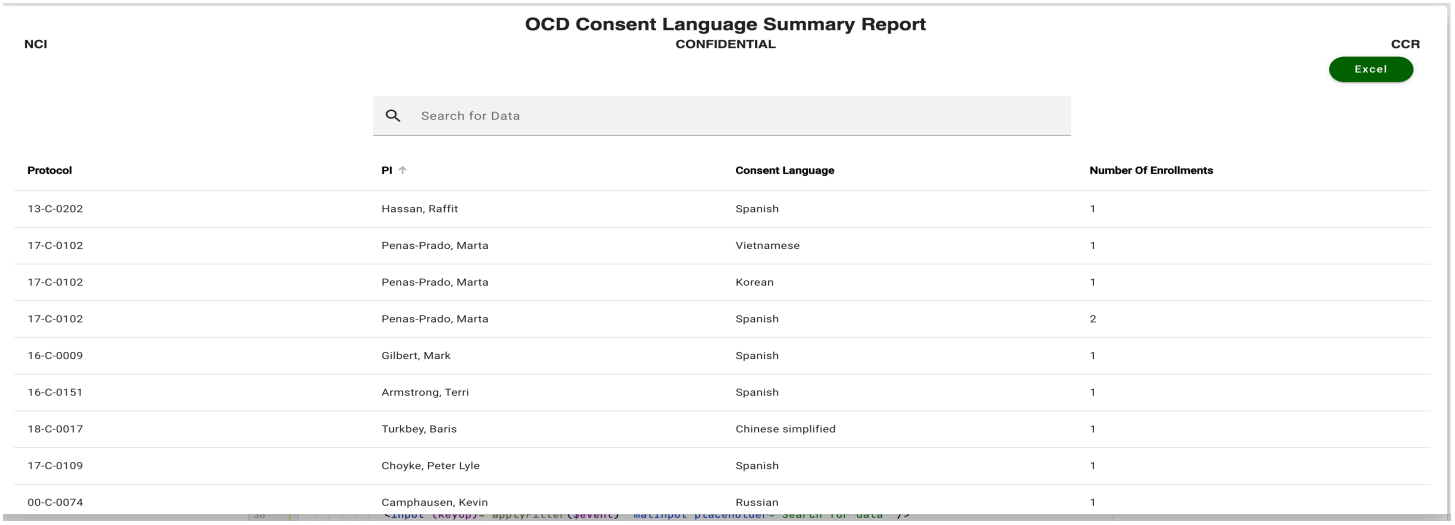
OCD Consent Language Summary Report

OCD consent language summary report shows summary of non-English language consents used in protocols. It does not require input parameters.

The report has the following columns.

- Protocol Number
- PI
- Consent Language
- Number of Enrollments

See below for sample report. Protocol data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to Excel sheet.



OCD Consent Language Summary Report

NCI CONFIDENTIAL CCR

Excel

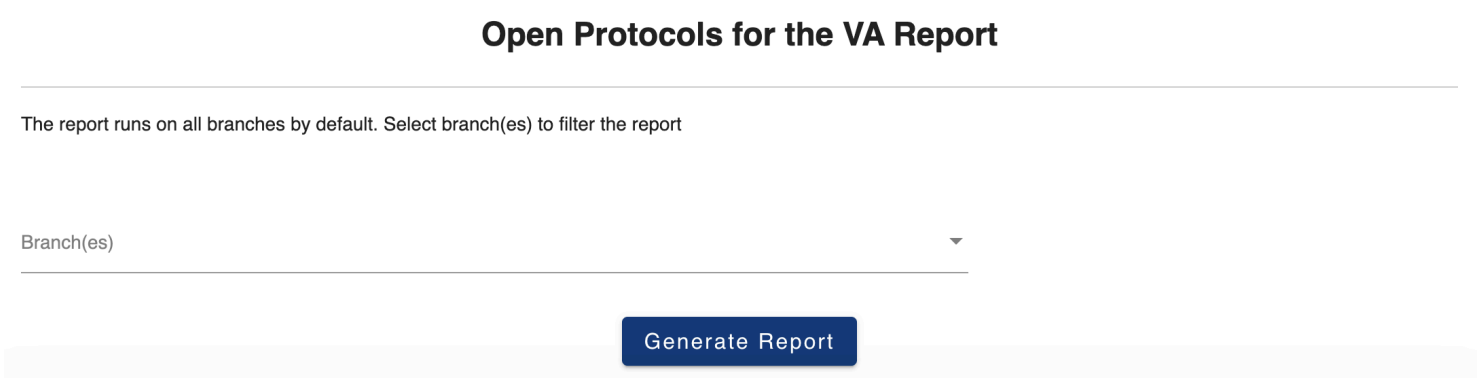
Search for Data

Protocol	PI	Consent Language	Number Of Enrollments
13-C-0202	Hassan, Raffit	Spanish	1
17-C-0102	Penas-Prado, Marta	Vietnamese	1
17-C-0102	Penas-Prado, Marta	Korean	1
17-C-0102	Penas-Prado, Marta	Spanish	2
16-C-0009	Gilbert, Mark	Spanish	1
16-C-0151	Armstrong, Terri	Spanish	1
18-C-0017	Turkbey, Baris	Chinese simplified	1
17-C-0109	Choyke, Peter Lyle	Spanish	1
00-C-0074	Camphausen, Kevin	Russian	1

Open Protocols for the VA Report

Open Protocol for the VA Report shows the list of open protocols in the given branch if none of the selected, the report runs on all branches.

- Branch(es)



Open Protocols for the VA Report

The report runs on all branches by default. Select branch(es) to filter the report

Branch(es)

Generate Report

Multiple branches can be selected. And the report has the following columns.

- New
- Protocol
- PI

- Long Title
- Protocol Phase
- Protocol Status
- Referral Contacts
- NCT Number

See below for sample report. Protocol data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.

NCI CONFIDENTIAL CCR

Open Protocols for the VA Report

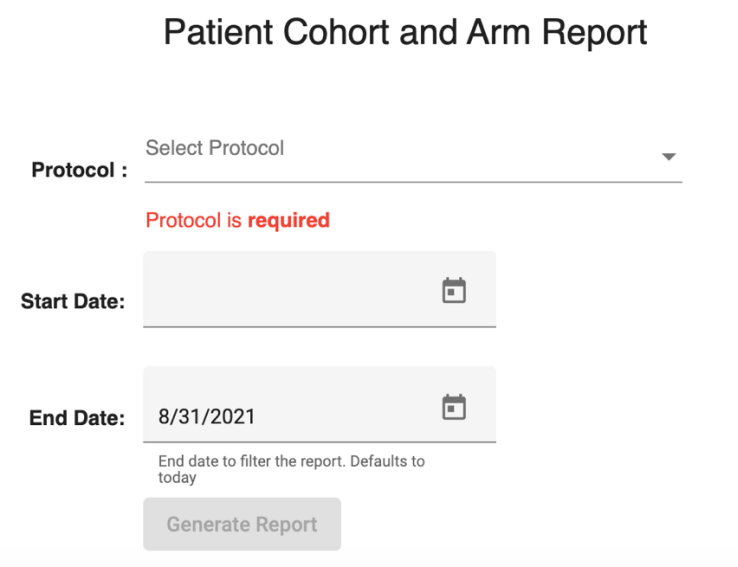
Filter Data

New	Protocol	PI	Long Title	Protocol Phase	Protocol Status	Referral Contacts	NCT Number
Surgery Branch	18-C-0049	Rosenberg, Steve	A Phase II Study Using the Administration of Autologous T-Cells Genetically Engineered to Express T-Cell Receptors Reactive Against Neoantigens in Patients with Metastatic Cancer	Clinical Trial Phase II	Open - Recruiting	Immunotherapy Recruitment Center(IRC@nih.gov)	NCT03412877
Developmental Therapeutics Branch	20-C-0149	Thomas, Anish	Phase II Trial of Olaparib (LYNPARZA) plus Durvalumab (IMFINZI) in EGFR-Mutated Adenocarcinomas that Transform to Small Cell Lung	Clinical Trial Phase II	Open - Recruiting	Linda Sciuto(linda.sciuto@nih.gov)	NCT04538378

Patient Cohort and Arm Report

Patient Cohort and Arm report shows patients enrolled on specific dates and their Cohort, Arm assignments. It accepts 3 inputs parameters

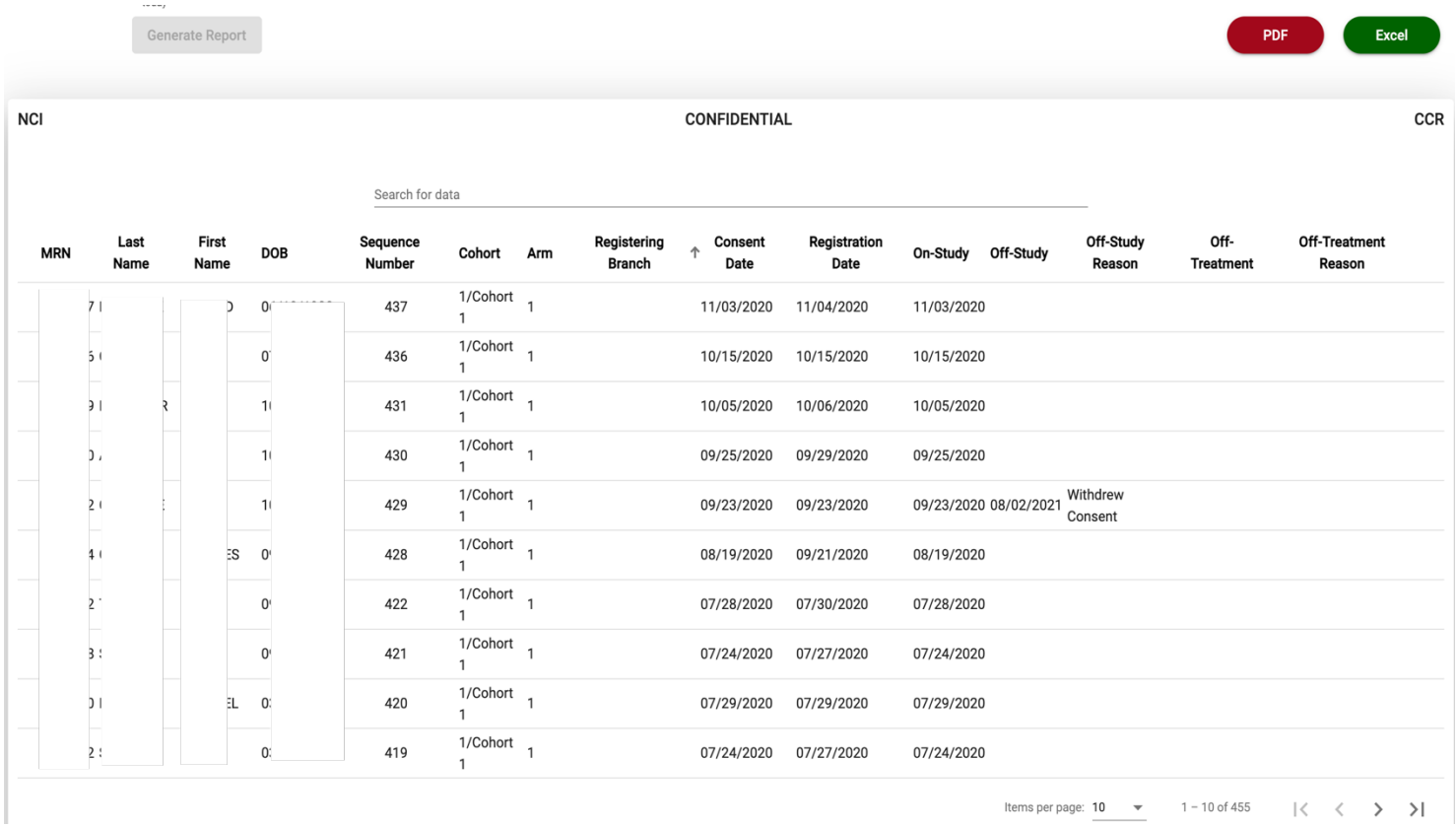
- Protocol Number (Mandatory)
- Start Date
- End Date (defaults to Today)



The Protocol is required field and must be selected. And the report has the following columns

- Subject MRN
- Subject Last Name
- Subject First Name
- Subject DOB (Date of Birth)
- Sequence Number
- Cohort Name
- Arm Name
- Registering Branch
- Consent Date
- Registration Date
- On Study Date (Fully Eligible Date)
- Off-Study Date
- Off-Study Reason
- Off-Treatment Date
- Off-Treatment Reason

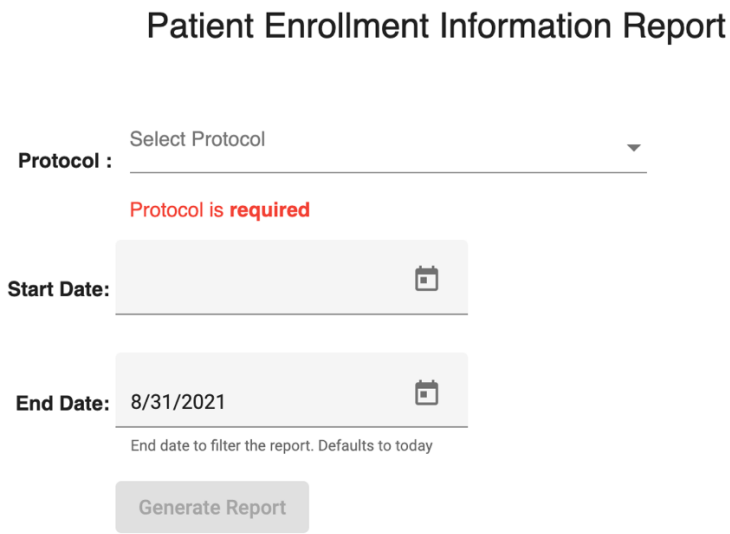
See below for sample report. Subject PII/PHI information has been redacted. Enrollment data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.



Patient Enrollment Information Report

Patient Enrollment Information report shows patients enrolled on to Protocol between given dates and their information. It accepts 3 inputs parameters

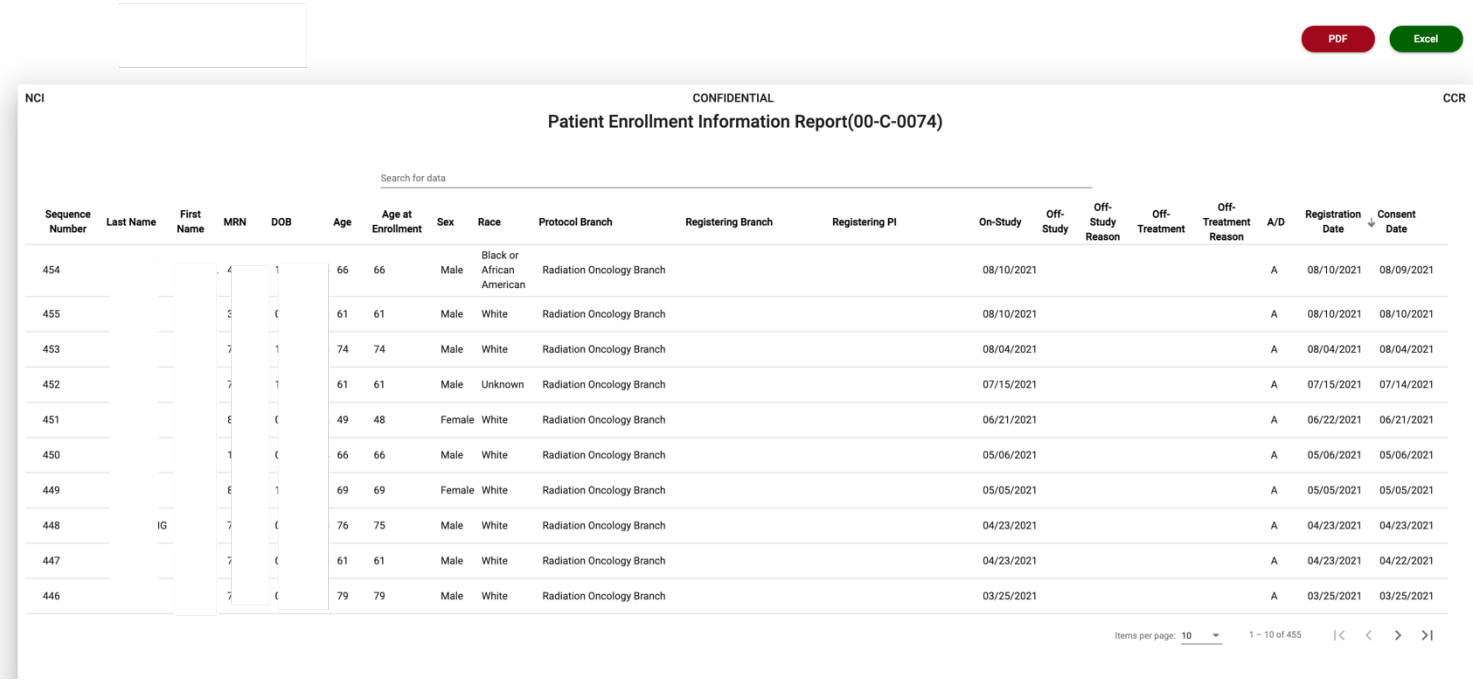
- Protocol Number (Mandatory)
- Start Date
- End Date (defaults to Today)



The Protocol is required field and must be selected. And the report has the following columns

- Sequence Number
- Subject Last Name
- Subject First Name
- Subject MRN
- Subject DOB (Date of Birth)
- Subject Age
- Subject Age at Enrollment
- Subject Sex
- Subject Race
- Protocol Branch
- Registering Branch (Applies only to Screening protocols like 01C0129)
- Registering PI (Applies only to Screening protocols like 01C0129)
- Registered By
- On Study Date (Fully Eligible Date)
- Off-Study Date
- Off-Study Reason
- Off-Treatment Date
- Off-Treatment Reason
- A/D (Alive or Dead)
- Registration Date
- Consent Date

See below for sample report. Subject PII/PHI information has been redacted. Enrollment data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.



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Patient Enrollment Information Report(00-C-0074)

PDF Excel

Search for data

Sequence Number	Last Name	First Name	MRN	DOB	Age	Age at Enrollment	Sex	Race	Protocol Branch	Registering Branch	Registering PI	On-Study	Off-Study	Off-Study Reason	Off-Treatment	Off-Treatment Reason	A/D	Registration Date	Consent Date
454			4	1	66	66	Male	Black or African American	Radiation Oncology Branch			08/10/2021					A	08/10/2021	08/09/2021
455			3	0	61	61	Male	White	Radiation Oncology Branch			08/10/2021					A	08/10/2021	08/10/2021
453			7	1	74	74	Male	White	Radiation Oncology Branch			08/04/2021					A	08/04/2021	08/04/2021
452			7	1	61	61	Male	Unknown	Radiation Oncology Branch			07/15/2021					A	07/15/2021	07/14/2021
451			8	0	49	48	Female	White	Radiation Oncology Branch			06/21/2021					A	06/22/2021	06/21/2021
450			1	0	66	66	Male	White	Radiation Oncology Branch			05/06/2021					A	05/06/2021	05/06/2021
449			8	1	69	69	Female	White	Radiation Oncology Branch			05/05/2021					A	05/05/2021	05/05/2021
448		IG	7	0	76	75	Male	White	Radiation Oncology Branch			04/23/2021					A	04/23/2021	04/23/2021
447			7	0	61	61	Male	White	Radiation Oncology Branch			04/23/2021					A	04/23/2021	04/22/2021
446			7	0	79	79	Male	White	Radiation Oncology Branch			03/25/2021					A	03/25/2021	03/25/2021

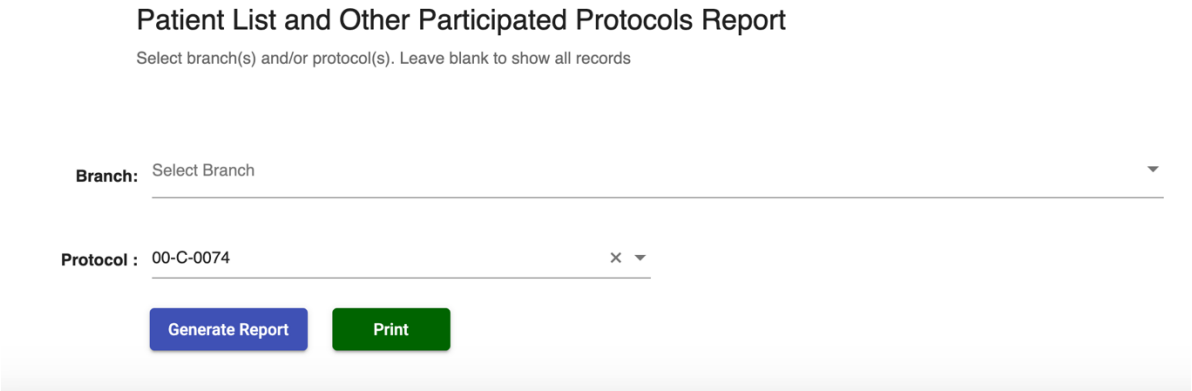
Items per page: 10 1 – 10 of 455

Patient List and Other Participated Protocols Report

Patient List and Other Participated Protocols Report shows list of patients from selected branch(es)/protocol(s) and their enrollments in other protocols. The report shows groups the enrollments by branch name, pi name. First row shows Branch name, and second row shows PI full name, and third row (and after wards) shows patient MRN, Name and other enrollment information.

It accepts two optional inputs, if none of the selected, the report runs on all branches, and all monitored protocols.

- Protocol Branch(es)
- Protocol Number(s)

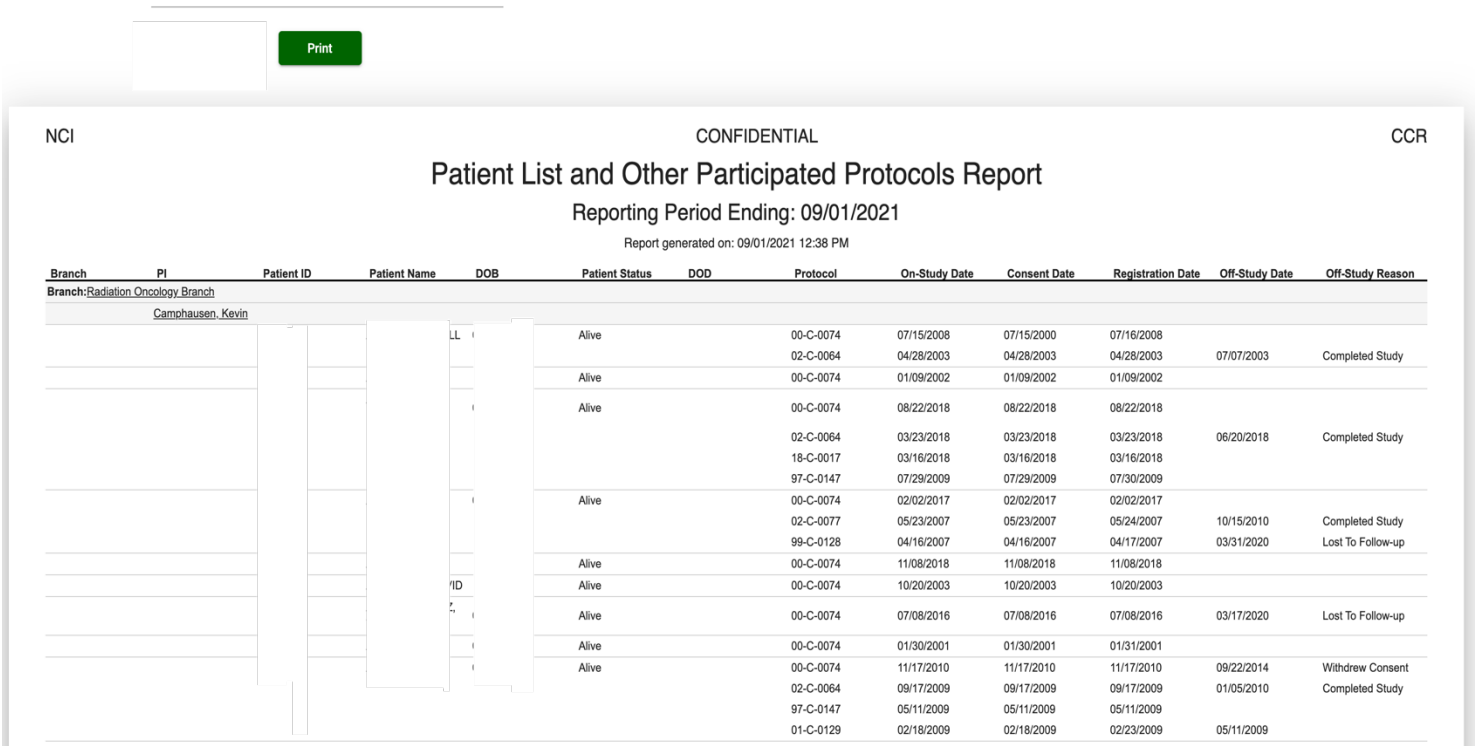


And the report has the following columns

1. Branch

2. PI Full Name
3. Patient ID (MRN)
4. Patient Name
5. DOB (Date of Birth)
6. Patient Status (Alive/Dead)
7. DOD (Date of Death)
8. Protocol
9. On-Study Date
10. Consent Date
11. Registration Date
12. Off-Study Date
13. Off-Study Reason

See below for sample report. Subject PII/PHI information has been redacted. Enrollment data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document.



Branch	PI	Patient ID	Patient Name	DOB	Patient Status	DOD	Protocol	On-Study Date	Consent Date	Registration Date	Off-Study Date	Off-Study Reason
Branch: Radiation Oncology Branch												
	Camphausen, Kevin											
					Alive		00-C-0074	07/15/2008	07/15/2000	07/16/2008		
							02-C-0064	04/28/2003	04/28/2003	04/28/2003	07/07/2003	Completed Study
					Alive		00-C-0074	01/09/2002	01/09/2002	01/09/2002		
					Alive		00-C-0074	08/22/2018	08/22/2018	08/22/2018		
							02-C-0064	03/23/2018	03/23/2018	03/23/2018	06/20/2018	Completed Study
							18-C-0017	03/16/2018	03/16/2018	03/16/2018		
							97-C-0147	07/29/2009	07/29/2009	07/30/2009		
					Alive		00-C-0074	02/02/2017	02/02/2017	02/02/2017		
							02-C-0077	05/23/2007	05/23/2007	05/24/2007	10/15/2010	Completed Study
							99-C-0128	04/16/2007	04/16/2007	04/17/2007	03/31/2020	Lost To Follow-up
					Alive		00-C-0074	11/08/2018	11/08/2018	11/08/2018		
					Alive		00-C-0074	10/20/2003	10/20/2003	10/20/2003		
					Alive		00-C-0074	07/08/2016	07/08/2016	07/08/2016	03/17/2020	Lost To Follow-up
					Alive		00-C-0074	01/30/2001	01/30/2001	01/31/2001		
					Alive		00-C-0074	11/17/2010	11/17/2010	11/17/2010	09/22/2014	Withdrew Consent
							02-C-0064	09/17/2009	09/17/2009	09/17/2009	01/05/2010	Completed Study
							97-C-0147	05/11/2009	05/11/2009	05/11/2009		
							01-C-0129	02/18/2009	02/18/2009	02/23/2009	05/11/2009	

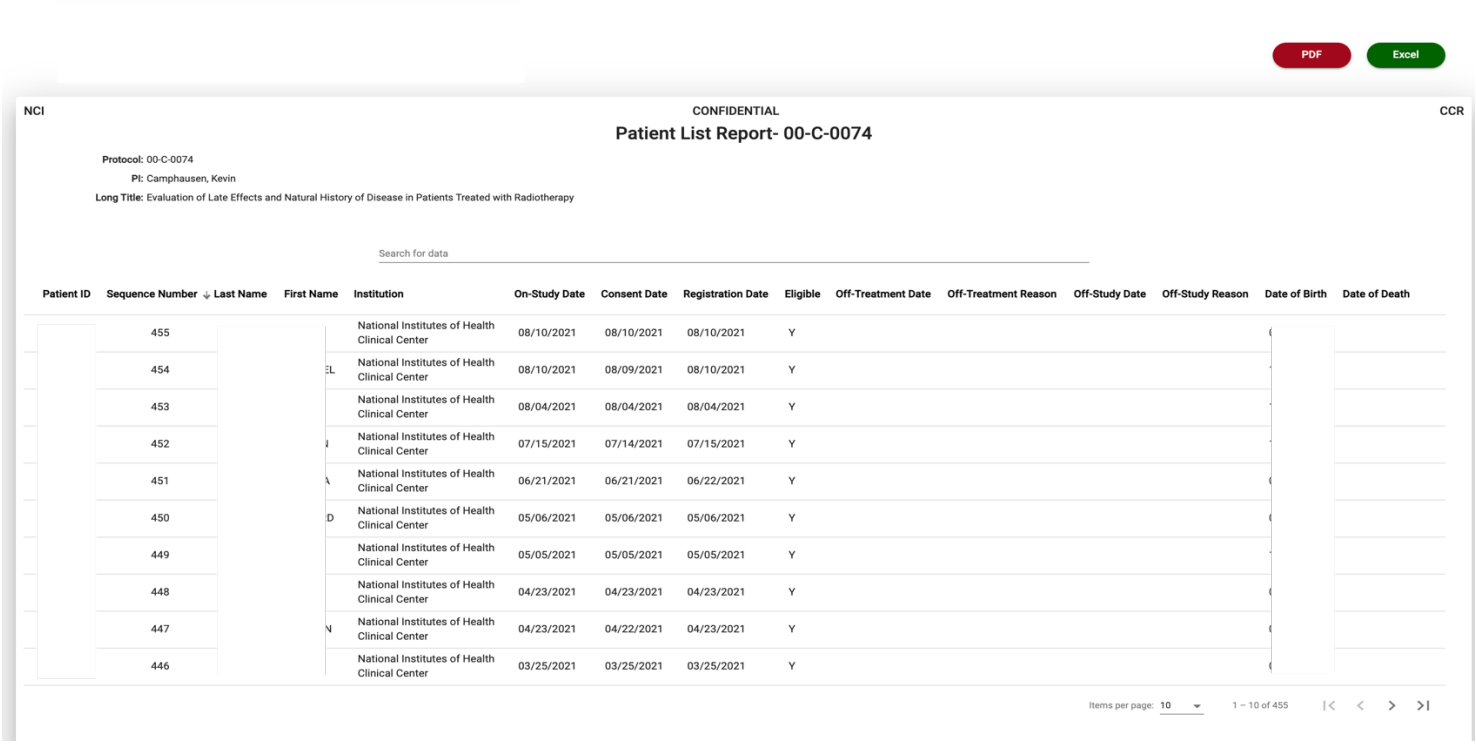
Patient List Report

Patient List Report shows patients enrolled on to Protocol. It accepts one mandatory inputs parameter, Protocol.

The Protocol is required field and must be selected. And the report has the following columns

- Patient ID (Patient MRN)
- Sequence Number
- Patient Last Name
- Patient First Name
- Institution (Organization enrolled into, like NIHCC)
- On Study Date (Fully Eligible Date)
- Consent Date
- Registration Date
- Eligible
- Off-Treatment Date
- Off-Treatment Reason
- Off-Study Date
- Off-Study Reason
- Date of Birth
- Date of Death

See below for sample report. Subject PII/PHI information has been redacted. Enrollment data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.



Patient Off-Study Report

Patient Off-Study Report shows list of patients taken Off-Study between start date and end date. It accepts 3 inputs parameters. If none selected, the report runs all branches and all protocols

- Protocol Number
- Start Date
- End Date (defaults to Today)

And the report has the following columns

- Protocol Number
- Patient ID (Patient MRN)
- Patient Full Name
- Consent Date
- Registration Date
- On Study Date (Fully Eligible Date)
- Off-Treatment Date
- Off-Treatment Reason

- Off-Study Date
- Off-Study Reason
- Off-Study Entered Date

See below for sample report. Subject PII/PHI information has been redacted. Enrollment data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.

Protocol	Patient Id	Patient	Consent Date	Registration Date	On Study Date	Off-Treatment Date	Off-Treatment Reason	Off-Study Date	Off-Study Reason	Off Study Entered Date
00C0074			12/08/2020	12/08/2020	12/08/2020			08/10/2021	Refused Further Treatment	08/10/2021
00C0074			09/23/2020	09/23/2020	09/23/2020			08/02/2021	Withdrew Consent	08/03/2021
00C0074			10/04/2018	10/04/2018	10/04/2018			03/23/2021	Other	03/23/2021
00C0074			08/17/2016	08/17/2016	08/17/2016			03/20/2021	Death	05/11/2021
00C0074			11/04/2008	11/04/2008	11/04/2008			01/24/2021	Death	08/13/2021
00C0074			11/29/2011	11/29/2011	11/29/2011			06/26/2020	Death	11/19/2020
00C0074			05/03/2016	05/03/2016	05/03/2016			06/02/2020	Withdrew Consent	11/19/2020
00C0074			10/03/2017	10/03/2017	10/03/2017			03/17/2020	Withdrew Consent	11/19/2020
00C0074			07/08/2016	07/08/2016	07/08/2016			03/17/2020	Lost To Follow-up	11/19/2020
00C0074			11/09/2017	11/09/2017	11/09/2017			01/28/2020	Disease Progression	11/19/2020

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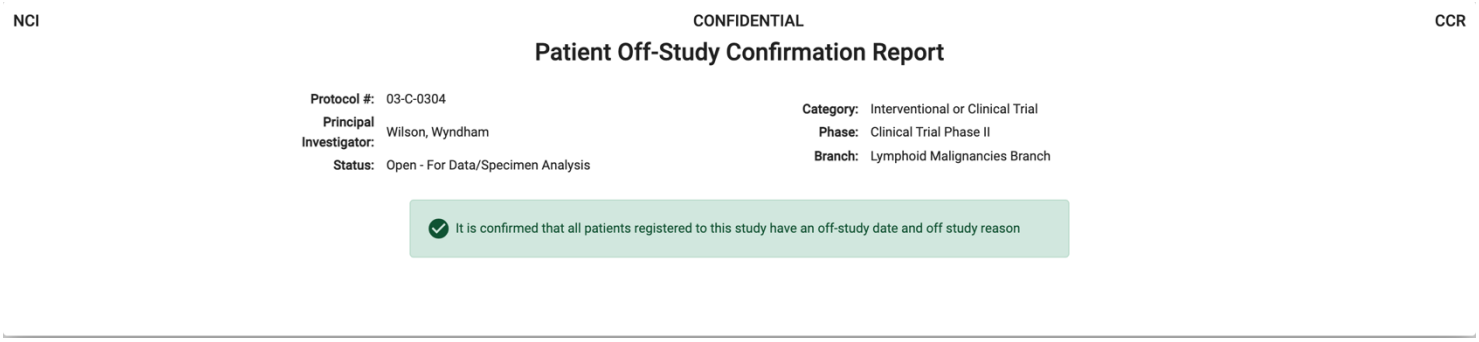
Patient Off-Study Confirmation Report

Patient Off-Study Confirmation Report shows if all the patients on a study are taken Off-Study. It accepts 1 mandatory input parameter.

- Protocol Number

And the report shows protocol information along with the Patients Off-Study confirmation message. See below for sample message across all three scenarios.

All the Patients are taken Off-Study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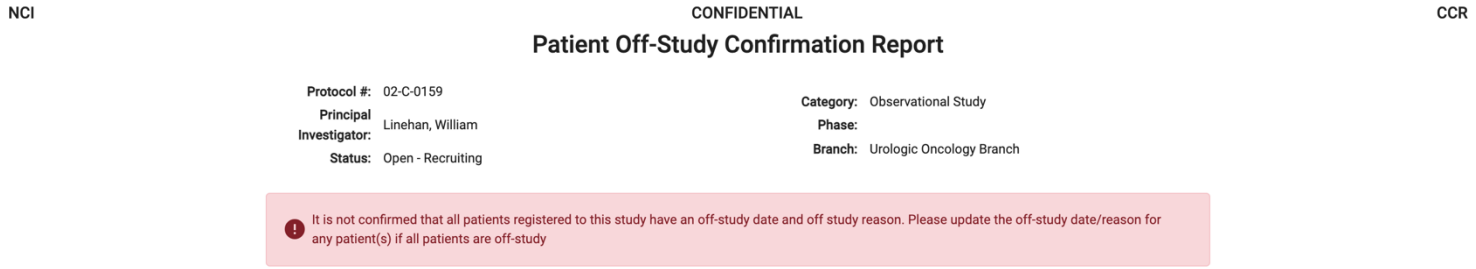
Patient Off-Study Confirmation Report

Protocol #: 03-C-0304
Principal Investigator: Wilson, Wyndham
Status: Open - For Data/Specimen Analysis

Category: Interventional or Clinical Trial
Phase: Clinical Trial Phase II
Branch: Lymphoid Malignancies Branch

It is confirmed that all patients registered to this study have an off-study date and off study reason

All the Patients are not taken Off-Study


NCI CONFIDENTIAL CCR

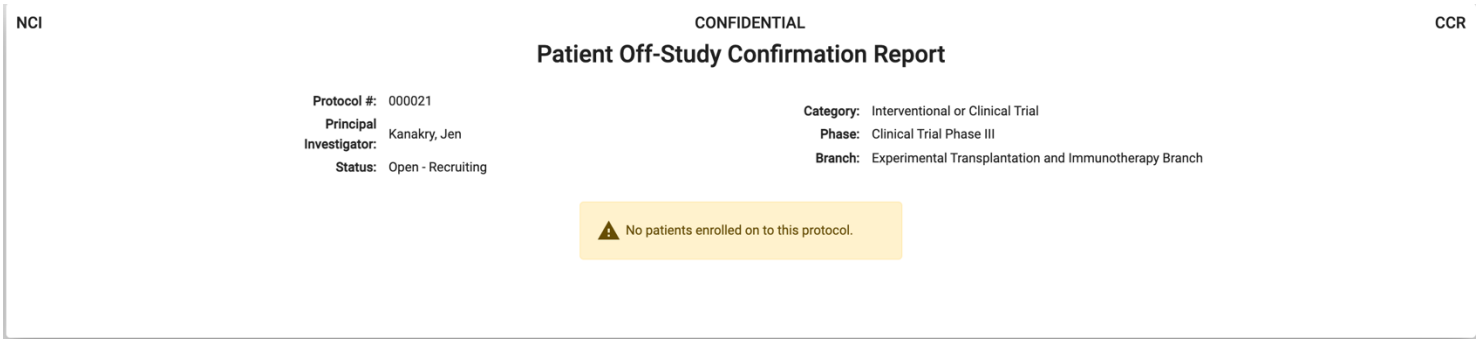
Patient Off-Study Confirmation Report

Protocol #: 02-C-0159
Principal Investigator: Linehan, William
Status: Open - Recruiting

Category: Observational Study
Phase:
Branch: Urologic Oncology Branch

It is not confirmed that all patients registered to this study have an off-study date and off study reason. Please update the off-study date/reason for any patient(s) if all patients are off-study

No patients enrolled onto the study


NCI CONFIDENTIAL CCR

Patient Off-Study Confirmation Report

Protocol #: 000021
Principal Investigator: Kanakry, Jen
Status: Open - Recruiting

Category: Interventional or Clinical Trial
Phase: Clinical Trial Phase III
Branch: Experimental Transplantation and Immunotherapy Branch

No patients enrolled on to this protocol.

Patient Off-Study Entered Report

Patient Off-Study Entered Report shows list of patients taken Off-Study between start date and end date. It accepts 3 inputs parameters.

- Protocol Number (Required)
- Start Date
- End Date (defaults to Today)

And the report has the following columns.

- Protocol Number
- Patient ID (Patient MRN)
- Patient
- Consent Date
- Registration Date
- On Study Date
- Off-Treatment Date
- Off-Treatment Entered Date
- Off-Treatment Reason
- Off-Study Date
- Off-Study Reason
- Off-Study Comments
- Off-Study Entered Date

See below for sample report. Subject PII/PHI information has been redacted. Enrollment data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.

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Patient Off-Study Entered Report

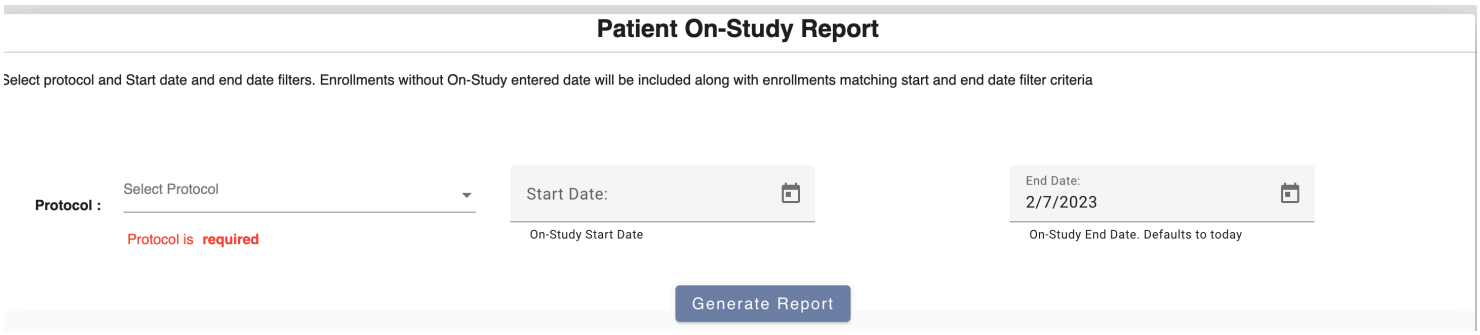
Search for Data

Protocol	Patient Id	Patient	Consent Date	Registratio Date	On Study Date	Off-Treatment Date	Off Treatment Entered Date	Off-Treatment Reason	Off-Study Date	Off-Study Reason	Off-Study Comments	Off Study Entered Date
08C0079			04/09/2008	04/10/2008	04/09/2008				11/29/2017	Death	Patient	03/12/2021
08C0079			02/12/2015	02/19/2015	02/12/2015				04/26/2017	Death	Pt Q 1-9	03/12/2021
08C0079			08/01/2013	08/01/2013	08/01/2013				10/09/2016	Death		03/12/2021
08C0079			08/10/2009	08/12/2009	08/10/2009				07/03/2016	Death		03/12/2021
08C0079			01/11/2016	01/11/2016	01/11/2016				06/18/2016	Death	Neurofibromatosis type 1 (NF1)	03/12/2021
08C0079			10/27/2009	10/27/2009	10/27/2009				12/07/2015	Death	Patient	03/12/2021
08C0079			05/21/2010	05/21/2010	05/21/2010	07/06/2015	03/12/2021		07/06/2015	Death		03/12/2021

Patient On-Study Report

Patient On-Study Report shows list of patients taken On-Study between start date and end date. It accepts 3 inputs parameters. Protocol Number is mandatory.

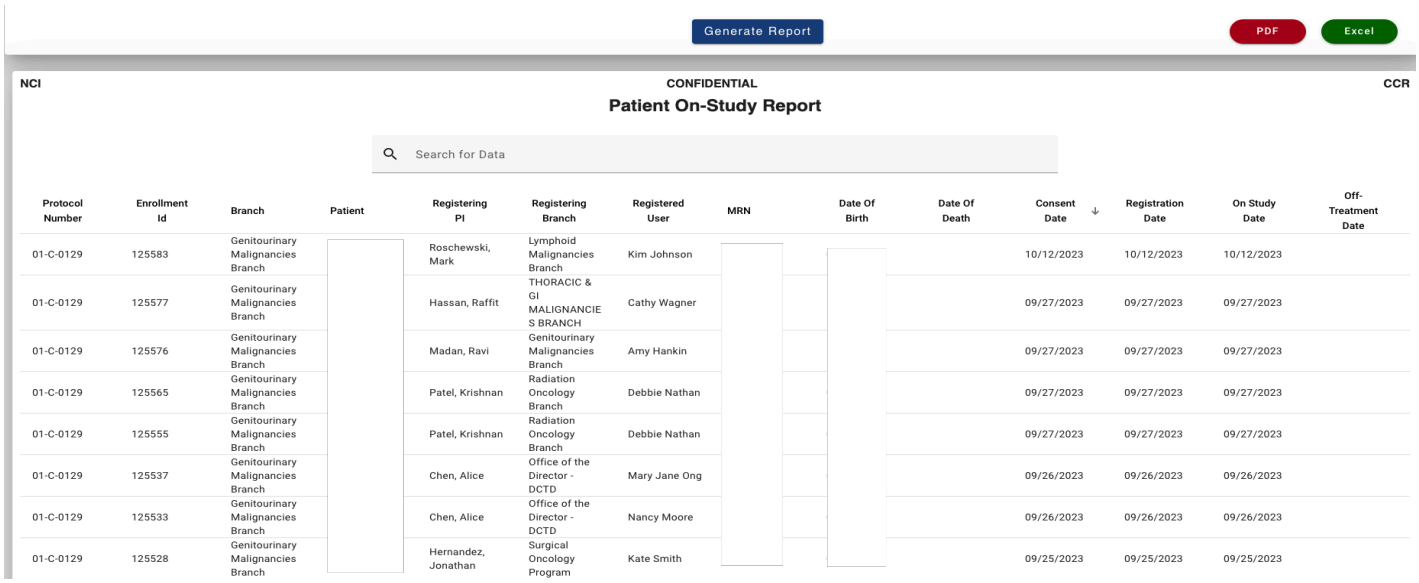
- Protocol Number
- Start Date
- End Date (defaults to Today)



And the report has the following columns.

- Protocol Number
- Enrollment ID
- Branch
- Patient Full Name
- MRN (Patient Id)
- Registering PI
- Registering Branch
- Registered By
- Date Of Birth
- Date Of Death
- Consent Date
- Registration Date
- On Study Date
- Off-Treatment Date

See below for sample report. Subject PII/PHI information has been redacted. Enrollment data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.

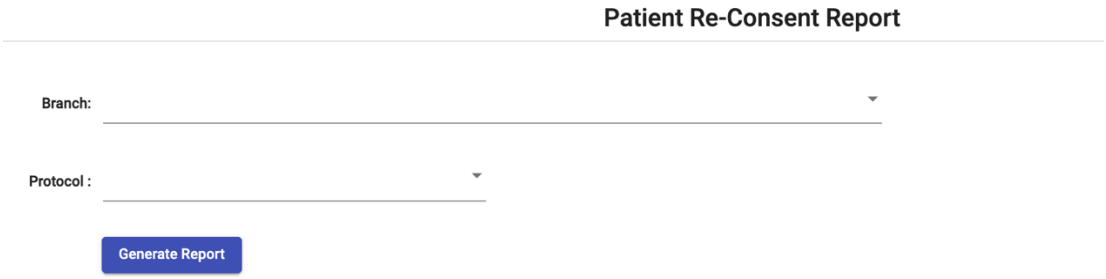


Patient Re-Consent Report

Patient Re-Consent report shows list of patients Re-Consented after the initial enrollment. If multiple re-consent dates present, they are shown in same row as comma separated values

It accepts two optional inputs, if none of the selected, the report runs all branches, and all protocols.

- Protocol Branch(es)
- Protocol Number(s)

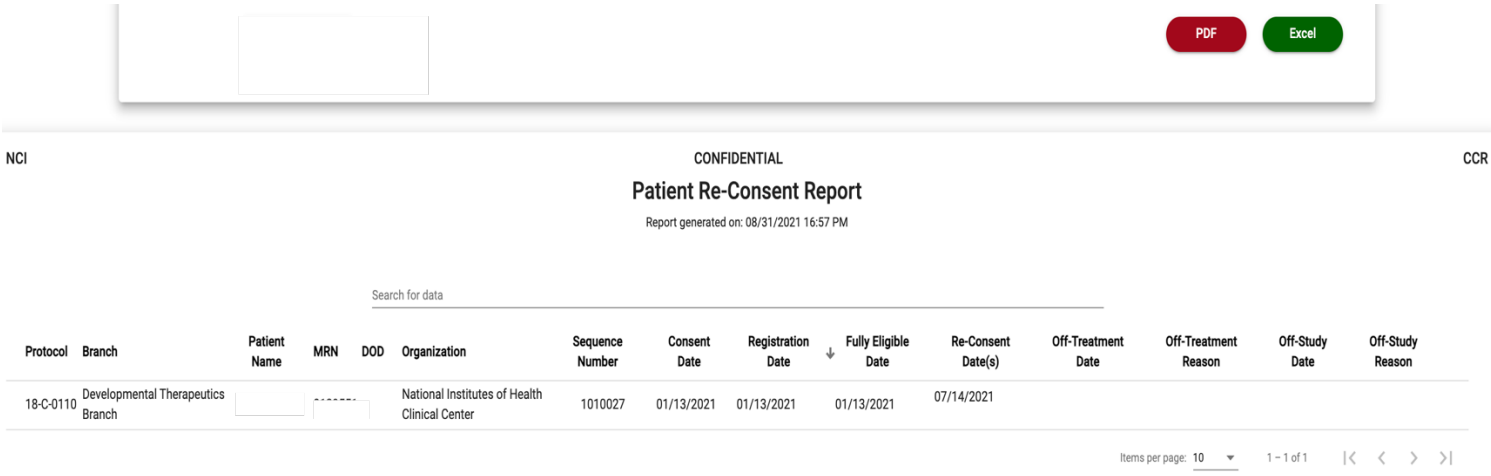


And the report has the following columns

- Protocol Number
- Branch
- Patient Full Name
- Patient ID (Patient MRN)
- Date of Birth
- Sequence Number
- Consent Date

- Registration Date
- On Study Date (Fully Eligible Date)
- Re-Consent Dates(s)
- Off-Treatment Date
- Off-Treatment Reason
- Off-Study Date
- Off-Study Reason

See below for sample report. Subject PII/PHI information has been redacted. Enrollment data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.

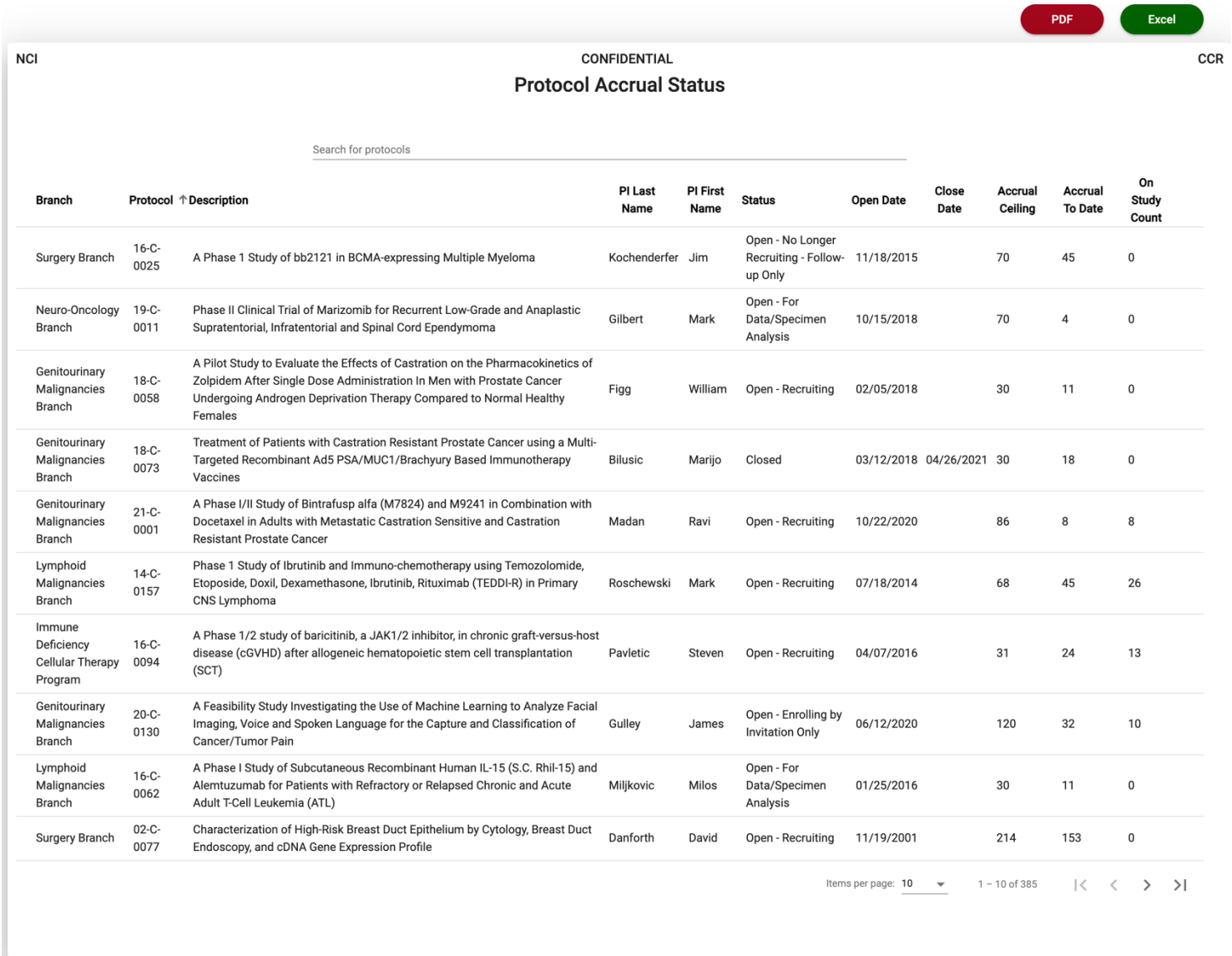


Protocol Accrual Status Report

Protocol Accrual Status report shows list of active Protocols and accrual information. It does not need any inputs. And the report has the following columns

- Branch
- Protocol Number
- Description
- PI Last Name
- PI First Name
- Protocol Status
- Open Date
- Close Date
- Accrual Ceiling
- Accrual To Date
- On Study Count

See below for sample report. Protocols data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.



PDF Excel

NCI CONFIDENTIAL CCR

Protocol Accrual Status

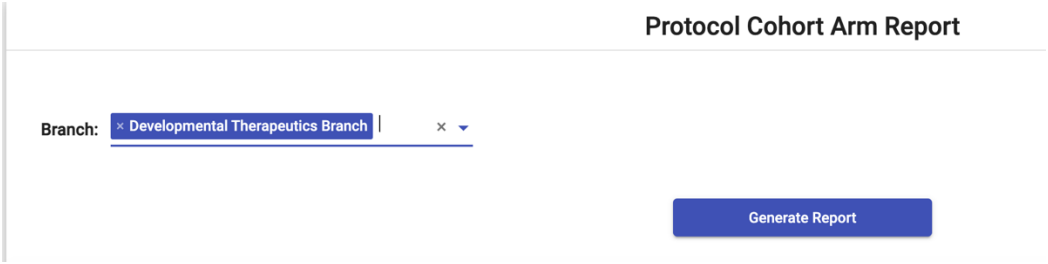
Search for protocols

Branch	Protocol	Description	PI Last Name	PI First Name	Status	Open Date	Close Date	Accrual Ceiling	Accrual To Date	On Study Count
Surgery Branch	16-C-0025	A Phase 1 Study of bb2121 in BCMA-expressing Multiple Myeloma	Kochenderfer	Jim	Open - No Longer Recruiting - Follow-up Only	11/18/2015		70	45	0
Neuro-Oncology Branch	19-C-0011	Phase II Clinical Trial of Marizomib for Recurrent Low-Grade and Anaplastic Supratentorial, Infratentorial and Spinal Cord Ependymoma	Gilbert	Mark	Open - For Data/Specimen Analysis	10/15/2018		70	4	0
Genitourinary Malignancies Branch	18-C-0058	A Pilot Study to Evaluate the Effects of Castration on the Pharmacokinetics of Zolpidem After Single Dose Administration In Men with Prostate Cancer Undergoing Androgen Deprivation Therapy Compared to Normal Healthy Females	Figg	William	Open - Recruiting	02/05/2018		30	11	0
Genitourinary Malignancies Branch	18-C-0073	Treatment of Patients with Castration Resistant Prostate Cancer using a Multi-Targeted Recombinant Ad5 PSA/MUC1/Brachyury Based Immunotherapy Vaccines	Bilusic	Marijo	Closed	03/12/2018	04/26/2021	30	18	0
Genitourinary Malignancies Branch	21-C-0001	A Phase I/II Study of Bintrafusp alfa (M7824) and M9241 in Combination with Docetaxel in Adults with Metastatic Castration Sensitive and Castration Resistant Prostate Cancer	Madan	Ravi	Open - Recruiting	10/22/2020		86	8	8
Lymphoid Malignancies Branch	14-C-0157	Phase 1 Study of Ibrutinib and Immuno-chemotherapy using Temozolomide, Etoposide, Doxil, Dexamethasone, Ibrutinib, Rituximab (TEDDI-R) in Primary CNS Lymphoma	Roschewski	Mark	Open - Recruiting	07/18/2014		68	45	26
Immune Deficiency Cellular Therapy Program	16-C-0094	A Phase 1/2 study of baricitinib, a JAK1/2 inhibitor, in chronic graft-versus-host disease (cGVHD) after allogeneic hematopoietic stem cell transplantation (SCT)	Pavletic	Steven	Open - Recruiting	04/07/2016		31	24	13
Genitourinary Malignancies Branch	20-C-0130	A Feasibility Study Investigating the Use of Machine Learning to Analyze Facial Imaging, Voice and Spoken Language for the Capture and Classification of Cancer/Tumor Pain	Gulley	James	Open - Enrolling by Invitation Only	06/12/2020		120	32	10
Lymphoid Malignancies Branch	16-C-0062	A Phase I Study of Subcutaneous Recombinant Human IL-15 (S.C. Rhil-15) and Alemtuzumab for Patients with Refractory or Relapsed Chronic and Acute Adult T-Cell Leukemia (ATL)	Miljkovic	Milos	Open - For Data/Specimen Analysis	01/25/2016		30	11	0
Surgery Branch	02-C-0077	Characterization of High-Risk Breast Duct Epithelium by Cytology, Breast Duct Endoscopy, and cDNA Gene Expression Profile	Danforth	David	Open - Recruiting	11/19/2001		214	153	0

Items per page: 10 1 – 10 of 385

Protocol Cohort Arm Report

Protocol Cohort Arm report shows list of protocols and each Cohort, Arm information. It accepts one optional input parameter Branch. If no branch selected, the report runs across all branches



And the report has the following columns

- Protocol Number
- Protocol Branch
- Protocol Status
- Cohort Name
- Cohort Description
- Cohort Closed (Yes/No)
- Cohort Randomized (Yes/No)
- Arm Name
- Arm Description
- Arm Closed (Yes/No)

See below for sample report. Protocols data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.

Protocol Embedded Agreement Report

Protocol Embedded Agreement report shows the list of subjects and their embedded agreement responses. It accepts one mandatory input

- Protocol Number

And the report has the following columns

- MRN
- First Name

- Last Name
- Sequence Number
- Identifiable (not closed) specimens and data to be stored and used by the study teams for future studies
- De-Identified (coded) specimens and data to be shared and used by other researchers for future studies
- Identifiable (not closed) specimens and data to be shared with and used by other researchers for future studies

See below for sample report. Subject PII/PHI information has been redacted. Enrollment data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.

Search for Data

MRN	First Name	Last Name	Sequence Number ↓	Identifiable (not coded) specimens and data to be stored and used by the study team for future studies	De-identified (coded) specimens and data to be shared with and used by other researchers for future studies	Identifiable (not coded) specimens and data to be shared with and used by other researchers for future studies
			26	Not Available	Not Available	Not Available
			25	Not Available	Not Available	Not Available
			24	Not Available	Not Available	Not Available
			23	Not Available	Not Available	Not Available
			22	Not Available	Not Available	Not Available
			21	Not Available	Not Available	Not Available
			20	Not Available	Not Available	Not Available
			19	Not Available	Not Available	Not Available

Protocol Embedded Agreement Summary Report

Protocol Embedded Agreement Summary report shows the summary of protocol embedded agreements by subjects. It accepts one mandatory input

- Protocol Number

The Report has the following columns

- Question
- Yes
- No
- Not Applicable
- Not Available

See below the sample report. You can export the report into pdf form.

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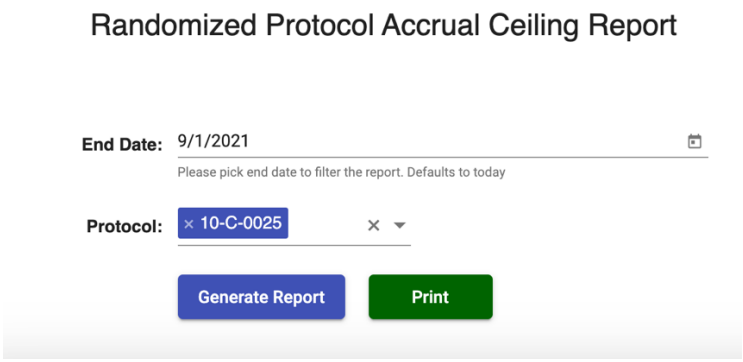
Protocol Embedded Agreement Summary Report

Question	Yes	No	Not Applicable	Not Available
De-identified specimens and data to be shared with and used by other researchers for future studies	0	0	0	0
Identifiable specimens and data to be shared with and used by other researchers for future studies	0	0	0	0
Identifiable specimens and data to be stored and used by the study team for future studies	0	0	0	0

Randomized Protocol Accrual Ceiling Report

Randomized Protocol Accrual Status Report shows Randomized protocol enrollment accruals in last 4 quarters and cumulative accrual before end date grouped by each Arm. It accepts two optional inputs

- End Date (Defaults to Today)
- Protocol (Allows multiple selection)

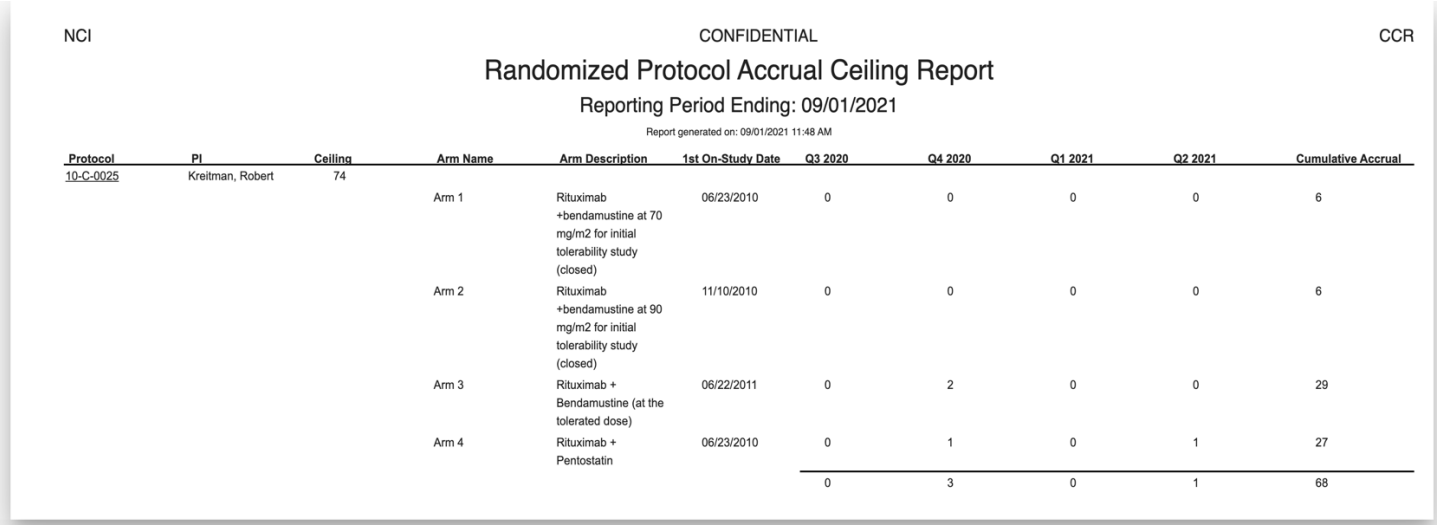


And the report has the following columnsProtocol

- PI Full Name
- Accrual Ceiling

- Arm Name
- Arm Description
- 1st On Study Date
- Q3 2020 (based in selected end date)
- Q4 2020 (based in selected end date)
- Q1 2021 (based in selected end date)
- Q2 2021 (based in selected end date)
- Cumulative Accrual

See below for sample report. First row shows Protocol information, and second row (and after wards) shows Arm Name, Description, and accruals of Arm in each Quarter



NCI CONFIDENTIAL CCR

Randomized Protocol Accrual Ceiling Report

Reporting Period Ending: 09/01/2021

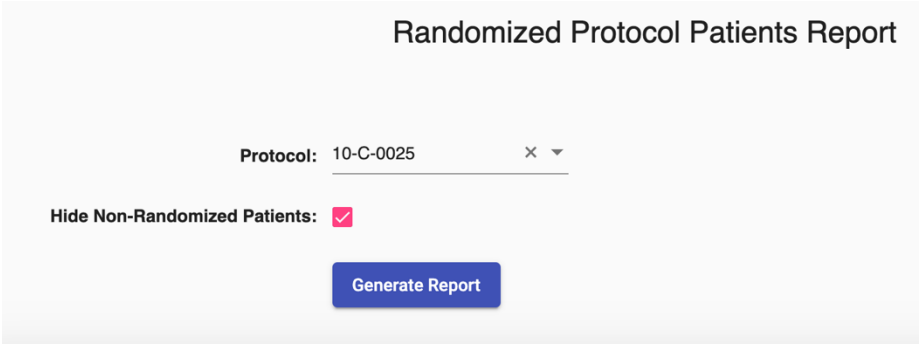
Report generated on: 09/01/2021 11:48 AM

Protocol	PI	Ceiling	Arm Name	Arm Description	1st On-Study Date	Q3 2020	Q4 2020	Q1 2021	Q2 2021	Cumulative Accrual
10-C-0025	Kreitman, Robert	74								
			Arm 1	Rituximab +bendamustine at 70 mg/m2 for initial tolerability study (closed)	06/23/2010	0	0	0	0	6
			Arm 2	Rituximab +bendamustine at 90 mg/m2 for initial tolerability study (closed)	11/10/2010	0	0	0	0	6
			Arm 3	Rituximab + Bendamustine (at the tolerated dose)	06/22/2011	0	2	0	0	29
			Arm 4	Rituximab + Pentostatin	06/23/2010	0	1	0	1	27
						0	3	0	1	68

Randomized Protocol Patients Report

Randomized Protocol Patients Report shows enrollment records of randomized protocol. Be default the report hides non-randomized patients, but that can be changed by checking “Hide Non-Randomized Patients” check box.

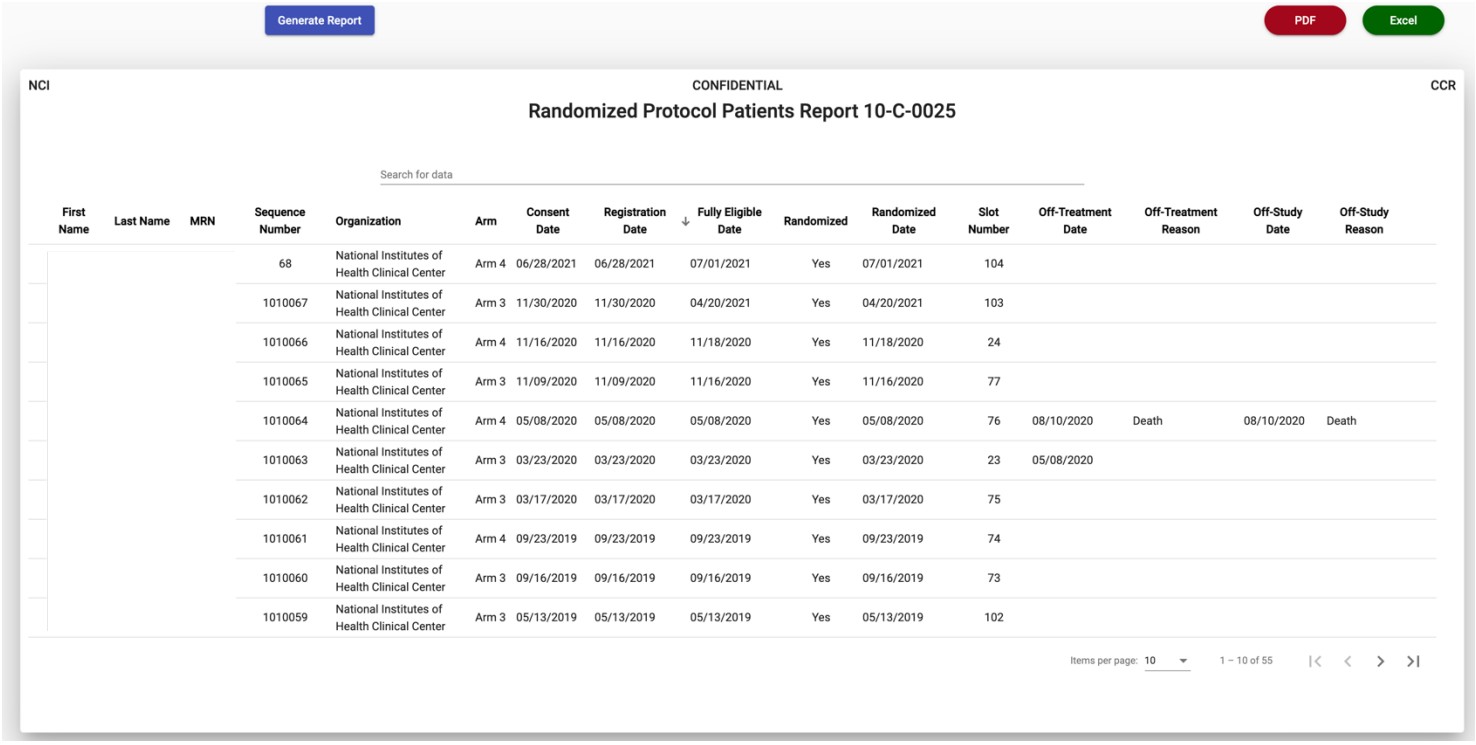
- Protocol Number (Mandatory)
- Hide Non-Randomized Patients (Select this check box if you want to hide non-randomized patients)



And the report has the following columns

- Patient First Name
- Patient Last Name
- Patient ID (Patient MRN)
- Sequence Number
- Organization
- Arm Name
- Consent Date
- Registration Date
- Fully Eligible Date
- Randomized (Yes/No, value is Yes if the patient is randomized. Otherwise No)
- Randomized Date
- Slot Number (Slot number assigned in Randomization Sheet)
- Off-Treatment Date
- Off-Treatment Reason
- Off-Study Date
- Off-Study Reason

See below for sample report. Subject PII/PHI information has been redacted. Enrollment data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.



First Name	Last Name	MRN	Sequence Number	Organization	Arm	Consent Date	Registration Date	Fully Eligible Date	Randomized	Randomized Date	Slot Number	Off-Treatment Date	Off-Treatment Reason	Off-Study Date	Off-Study Reason
			68	National Institutes of Health Clinical Center	Arm 4	06/28/2021	06/28/2021	07/01/2021	Yes	07/01/2021	104				
			1010067	National Institutes of Health Clinical Center	Arm 3	11/30/2020	11/30/2020	04/20/2021	Yes	04/20/2021	103				
			1010066	National Institutes of Health Clinical Center	Arm 4	11/16/2020	11/16/2020	11/18/2020	Yes	11/18/2020	24				
			1010065	National Institutes of Health Clinical Center	Arm 3	11/09/2020	11/09/2020	11/16/2020	Yes	11/16/2020	77				
			1010064	National Institutes of Health Clinical Center	Arm 4	05/08/2020	05/08/2020	05/08/2020	Yes	05/08/2020	76	08/10/2020	Death	08/10/2020	Death
			1010063	National Institutes of Health Clinical Center	Arm 3	03/23/2020	03/23/2020	03/23/2020	Yes	03/23/2020	23	05/08/2020			
			1010062	National Institutes of Health Clinical Center	Arm 3	03/17/2020	03/17/2020	03/17/2020	Yes	03/17/2020	75				
			1010061	National Institutes of Health Clinical Center	Arm 4	09/23/2019	09/23/2019	09/23/2019	Yes	09/23/2019	74				
			1010060	National Institutes of Health Clinical Center	Arm 3	09/16/2019	09/16/2019	09/16/2019	Yes	09/16/2019	73				
			1010059	National Institutes of Health Clinical Center	Arm 3	05/13/2019	05/13/2019	05/13/2019	Yes	05/13/2019	102				

Items per page: 10 1 – 10 of 55

Registration Report

Registration report shows list of patients enrolled on to selected protocol/branch. It accepts two optional inputs, if none of the selected, the report runs on all branches, and all protocols.

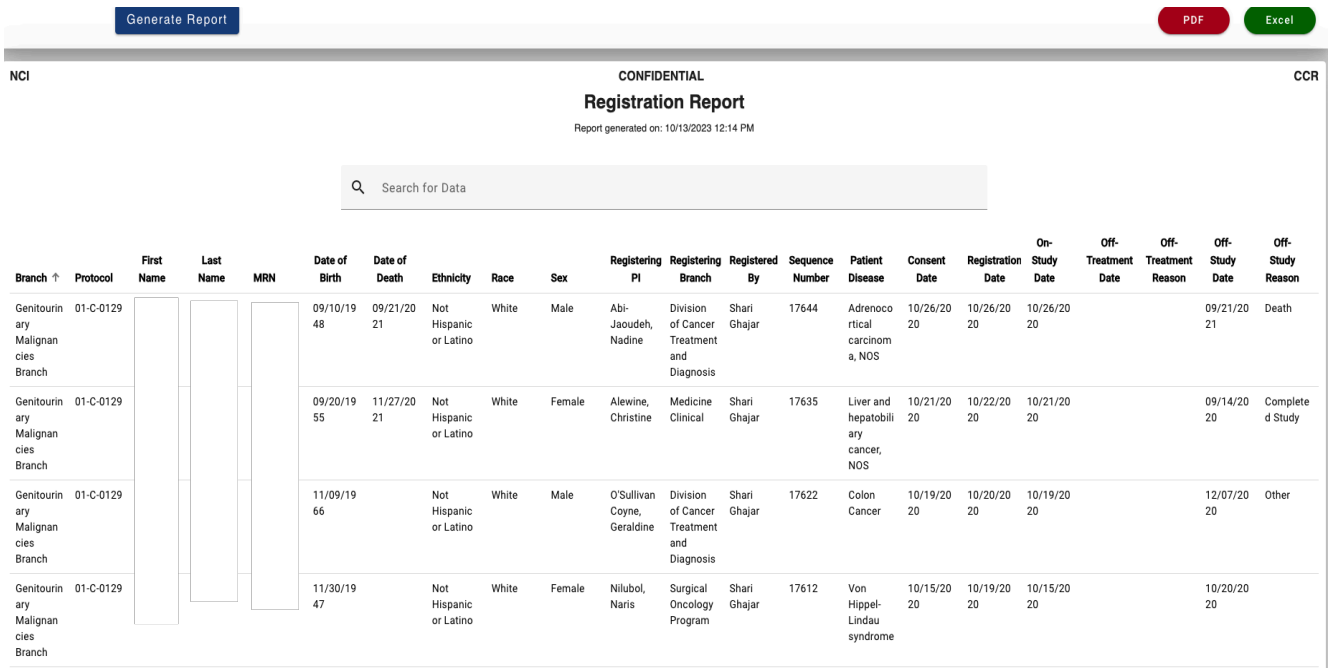
- Protocol Branch(es)
- Protocol Number(s)

And the report has the following columns

- Protocol Branch
- Protocol Number
- Protocol Status

- Sequence Number
- Consent Date
- Registration Date
- Fully Eligible Date
- Off-Treatment Date
- Off-Treatment Reason
- Off-Study Date
- Off-Study Reason
- Disease
- First Name
- Last Name
- MRN
- Date of Birth
- Date of Death
- Ethnicity
- Race
- Sex
- Registering Branch
- Registering PI
- Registered By

See below for sample report. Subject PII/PHI information has been redacted. Enrollment data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.

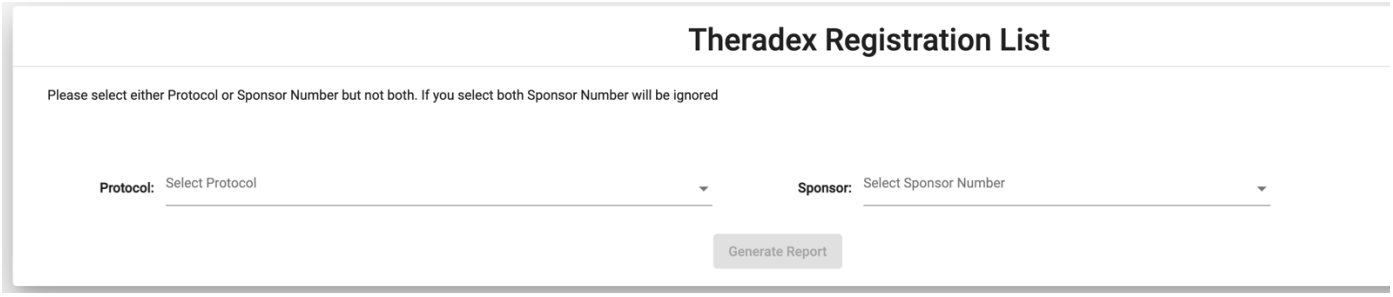


Branch	Protocol	First Name	Last Name	MRN	Date of Birth	Date of Death	Ethnicity	Race	Sex	Registering PI	Registering Branch	Registered By	Sequence Number	Patient Disease	Consent Date	Registration Date	On-Study Date	Off-Treatment Date	Off-Treatment Reason	Off-Study Date	Off-Study Reason
Genitourinary Malignancies Branch	01-C-0129				09/10/1948	09/21/2021	Not Hispanic or Latino	White	Male	Abi-Jaoudeh, Nadine	Division of Cancer Treatment and Diagnosis	Shari Ghajar	17644	Adrenocortical carcinoma, NOS	10/26/2020	10/26/2020	10/26/2020			09/21/2021	Death
Genitourinary Malignancies Branch	01-C-0129				09/20/1955	11/27/2021	Not Hispanic or Latino	White	Female	Alewine, Christine	Medicine Clinical	Shari Ghajar	17635	Liver and hepatobiliary cancer, NOS	10/21/2020	10/22/2020	10/21/2020			09/14/2020	Completed Study
Genitourinary Malignancies Branch	01-C-0129				11/09/1966		Not Hispanic or Latino	White	Male	O'Sullivan Coyne, Geraldine	Division of Cancer Treatment and Diagnosis	Shari Ghajar	17622	Colon Cancer	10/19/2020	10/20/2020	10/19/2020			12/07/2020	Other
Genitourinary Malignancies Branch	01-C-0129				11/30/1947		Not Hispanic or Latino	White	Female	Nilubol, Naris	Surgical Oncology Program	Shari Ghajar	17612	Von Hippel-Lindau syndrome	10/15/2020	10/19/2020	10/15/2020			10/20/2020	

Theradex Registration Report

Theradex Registration report shows list of patients enrolled on to selected protocol/sponsor number. It accepts two inputs, either protocol number or sponsor number must be selected. If both are selected, then Sponsor Number will be ignored

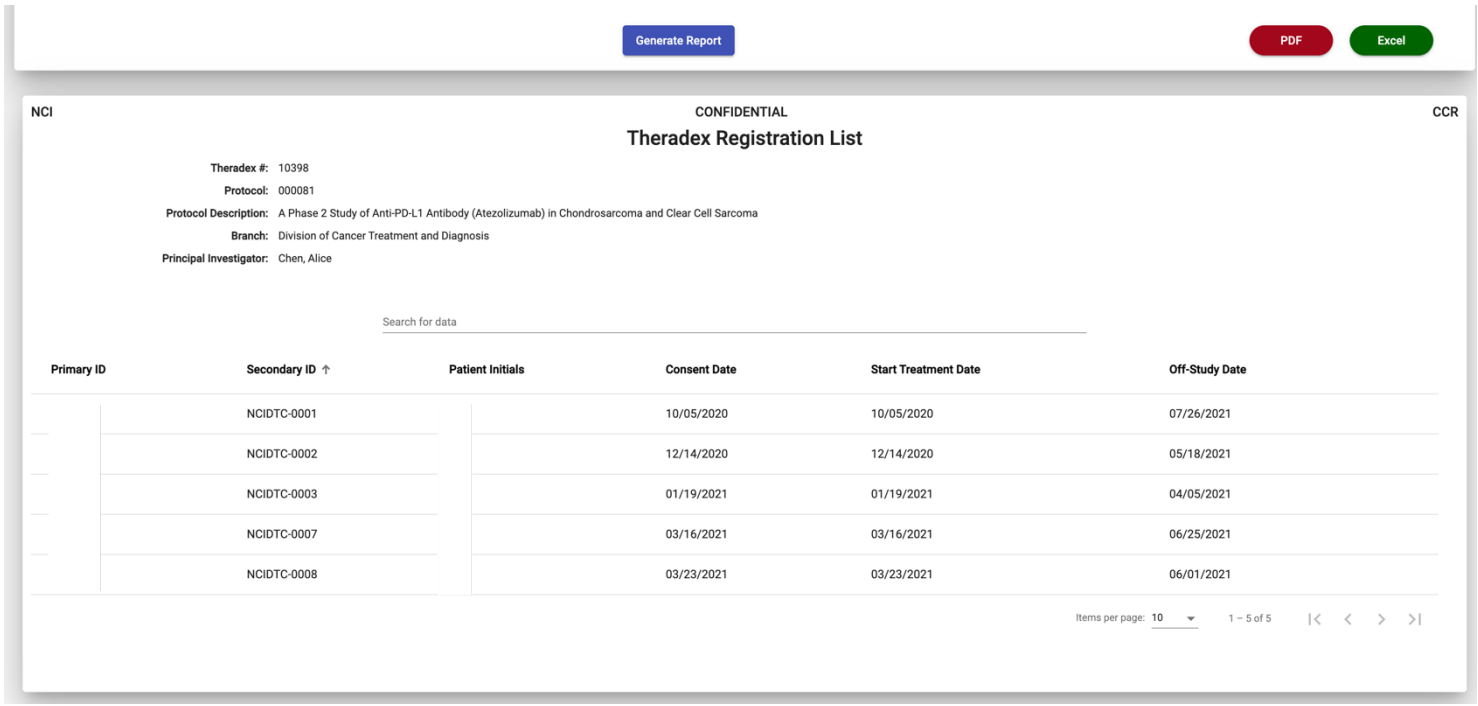
- Protocol
- Sponsor Number



And the report has the following columns

1. Primary ID (Patient MRN)
2. Secondary ID (Sequence Number)
3. Patient Initials
4. Consent Date
5. Start Treatment Date
6. Off-Study Date

See below for sample report. Subject PII/PHI information has been redacted. Enrollment data can be filtered using the Search box shown in the table. The table also supports sorting, filtering and page by page navigation. The report can be exported to PDF document or Excel sheet.


Generate Report
PDF
Excel
NCI
CONFIDENTIAL
CCR
Theradex Registration List
Theradex #: 10398
Protocol: 000081
Protocol Description: A Phase 2 Study of Anti-PD-L1 Antibody (Atezolizumab) in Chondrosarcoma and Clear Cell Sarcoma
Branch: Division of Cancer Treatment and Diagnosis
Principal Investigator: Chen, Alice
Search for data
Primary ID
Secondary ID
Patient Initials
Consent Date
Start Treatment Date
Off-Study Date
NCIDTC-0001 10/05/2020 10/05/2020 07/26/2021
NCIDTC-0002 12/14/2020 12/14/2020 05/18/2021
NCIDTC-0003 01/19/2021 01/19/2021 04/05/2021
NCIDTC-0007 03/16/2021 03/16/2021 06/25/2021
NCIDTC-0008 03/23/2021 03/23/2021 06/01/2021
Items per page: 10
1 – 5 of 5

Support

Clicking the “Need Assistance?” link at the bottom of every page opens a dialog box that allows the user to report issues or suggestions regarding the use of the application.

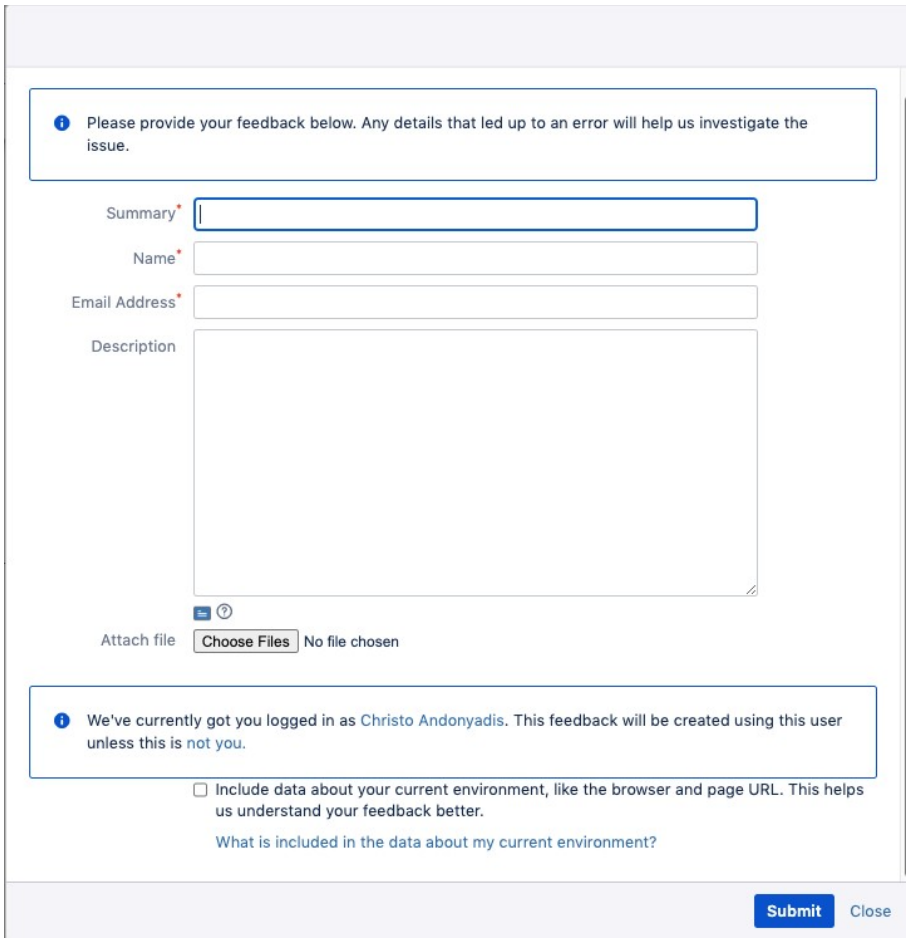


FIGURE 41-ISSUES AND FEEDBACK

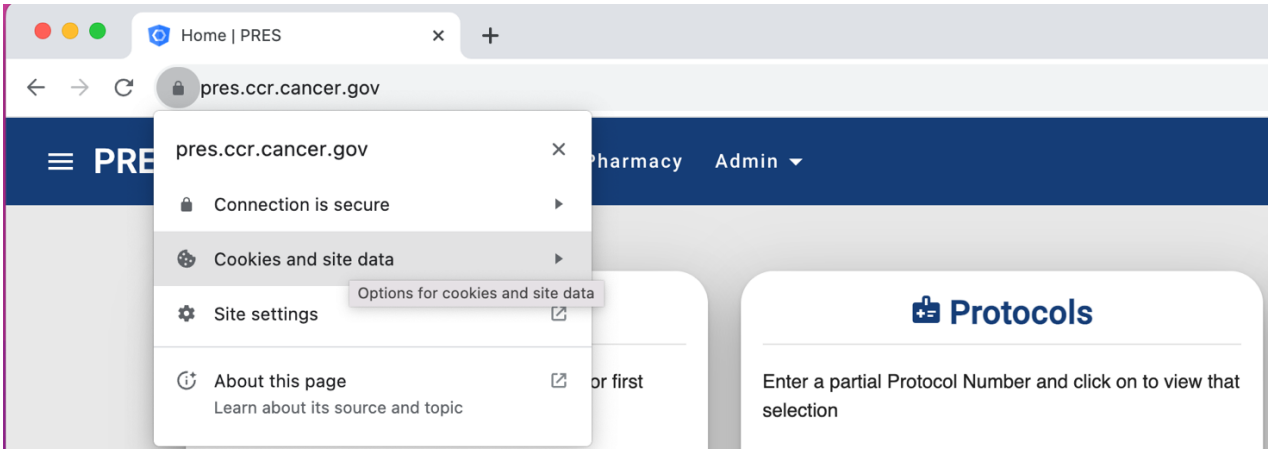
We recommend checking the “Include data about your current environment” box if the assistance is needed for a particular protocol or patient or report. The Office of Information Technology (OIT) will receive the feedback, the user will be identified as the reporter of the issue and receive an email confirming that the ticket has been received.

Clear cookies

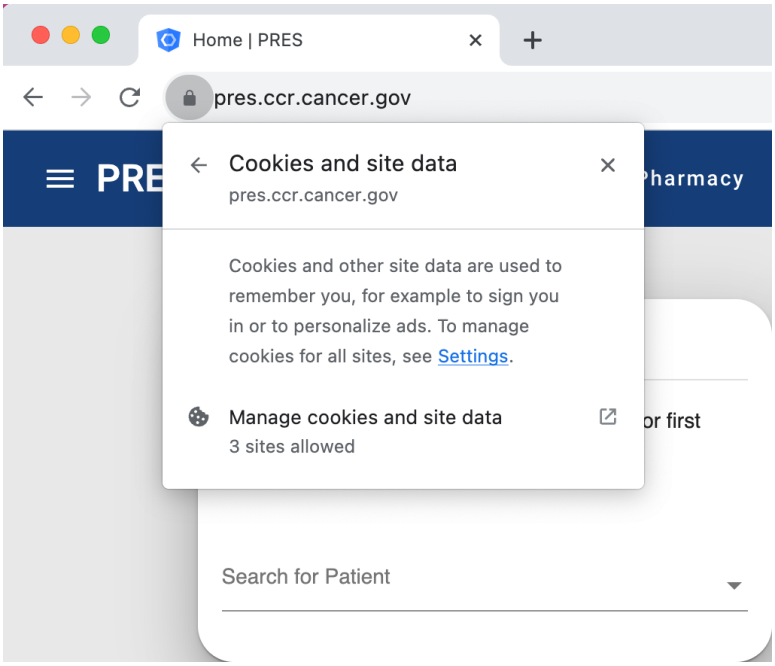
To clear PRES website cookies, use following instructions based on the browser you use.

Chrome/Edge

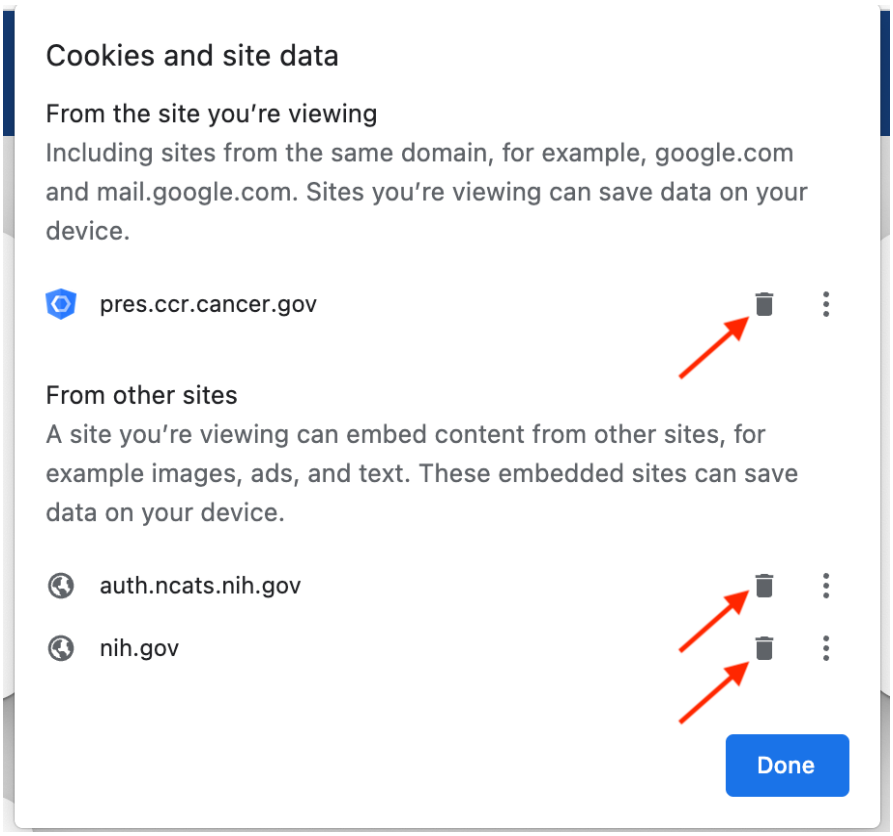
1. Go to https://pres.ccr.cancer.gov and click on pad lock icon. Then click on **Cookies and site data.**



2. Then click on **Manage cookies and site data** link.



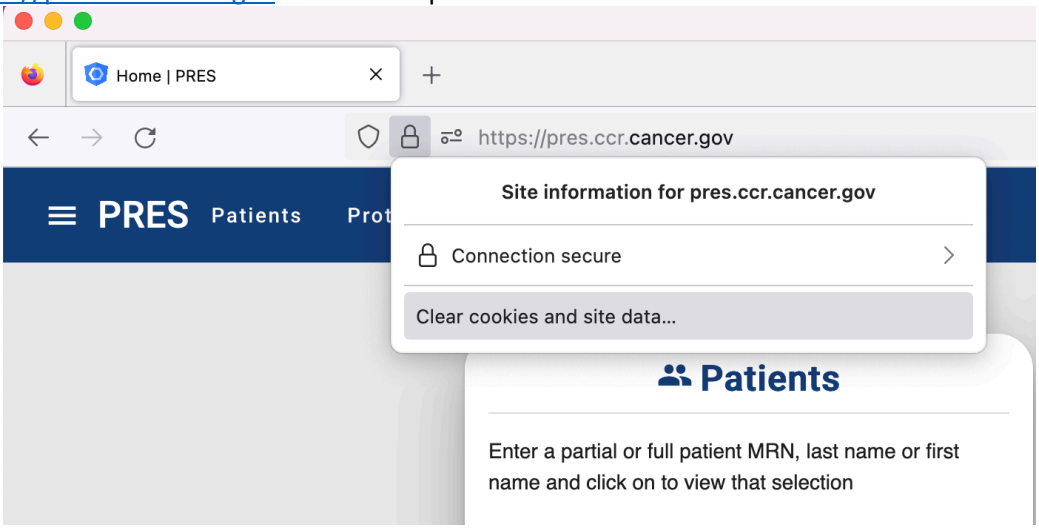
3. and then click on delete icons next all the websites you see.



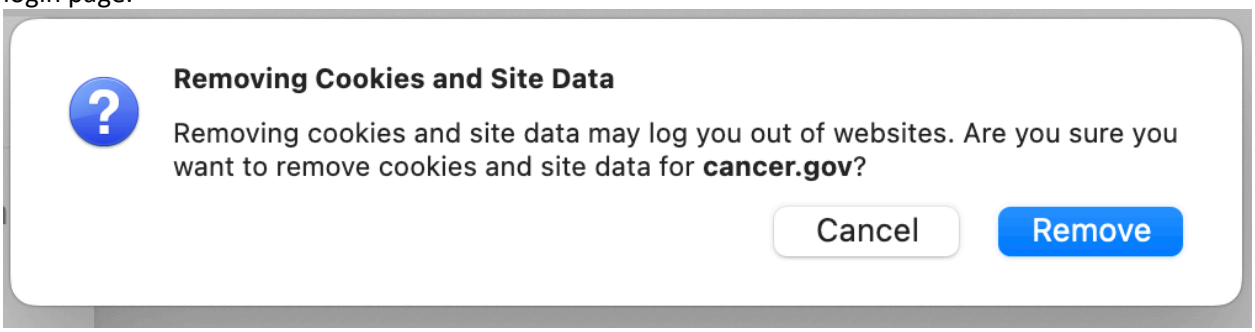
4. Now reload the website and it should redirect you to NIH login page.
5. Login using PIV card or Username, Password and Authenticator. It should redirect you to PRES home page.

Firefox

1. Go to https://pres.ccr.cancer.gov and click on pad lock icon. Then click on **Clear cookies and site data.**



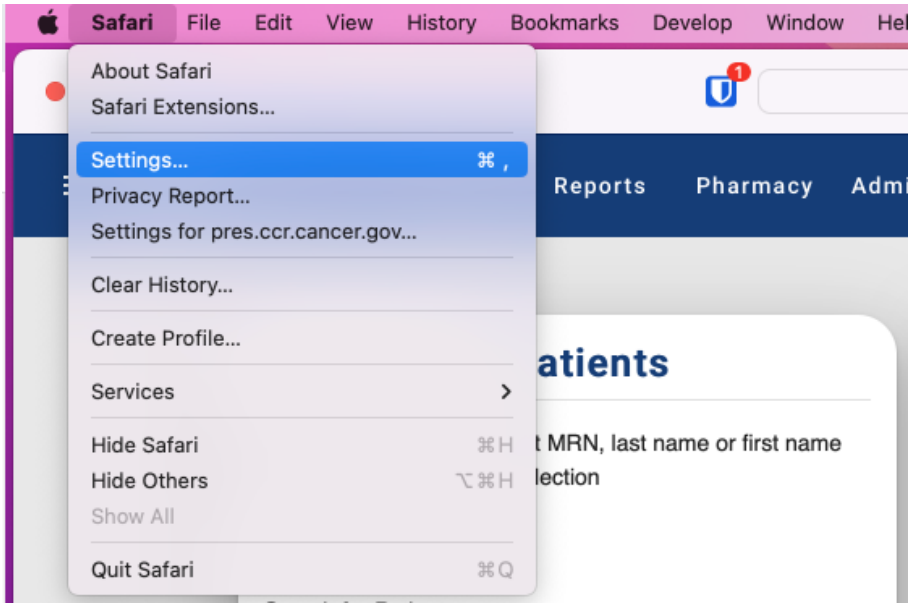
2. It will show an alert for confirmation. Click and **Remove** and reload the website and it should redirect you to NIH login page.



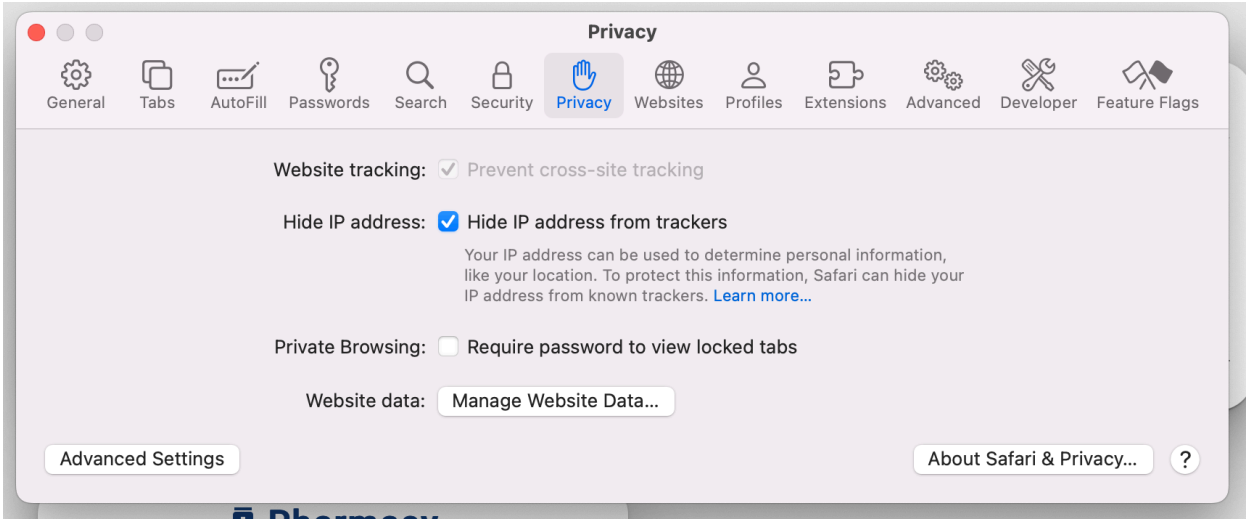
3. Login using PIV card or Username, Password and Authenticator. It should redirect you to PRES home page.

Safari

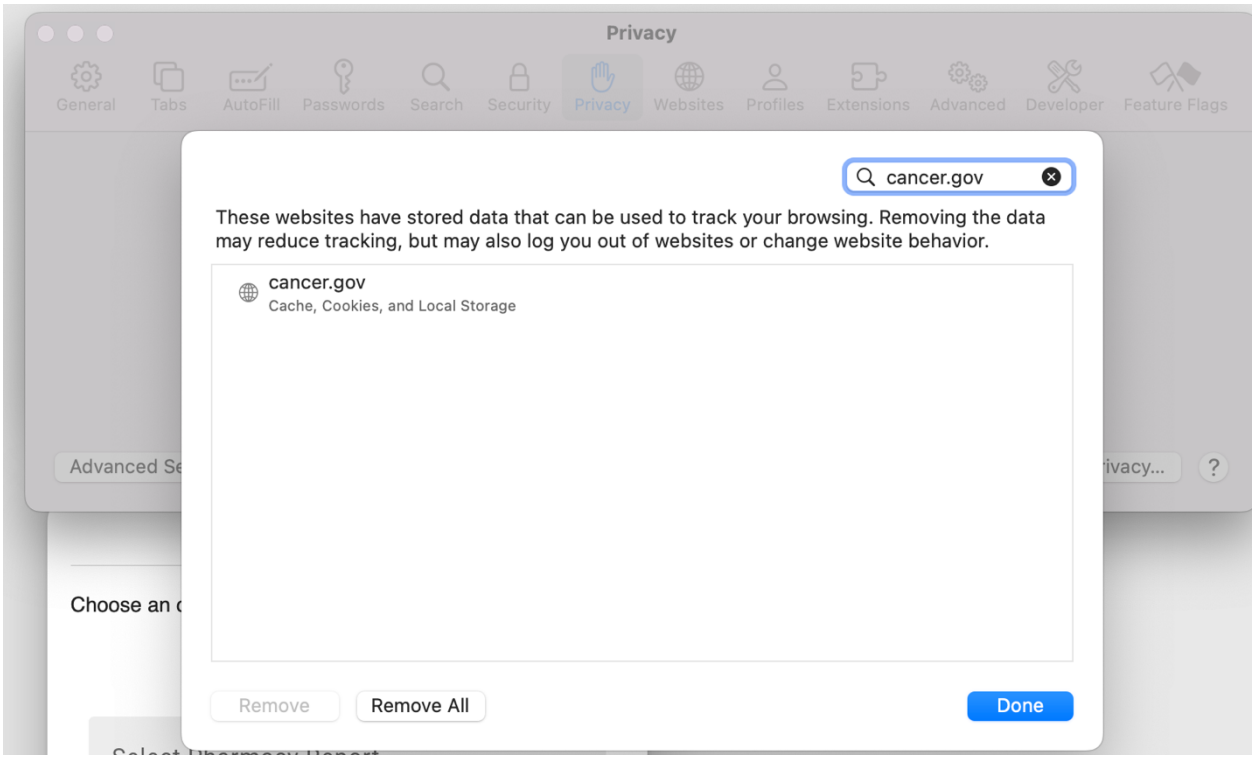
1. Go to https://pres.ccr.cancer.gov and click on **Safari→ Preferences**



2. Click the **Privacy** tab and select **Manage Website Data...**.



3. In the **Search** bar, enter cancer.gov and select it. Then click **Remove All**



4. Now reload the website and it should redirect you to NIH login page.
5. Login using PIV card or Username, Password and Authenticator. It should redirect you to PRES home page.