# PATIENT REGISTRATION AND ENROLLMENT SYSTEM (PRES) USER GUIDE

June 2025

VERSION 2.21.3

Office of Information Technology

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Clear cookies	

## **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 <u>https://pres.ccr.cancer.gov</u> 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

ogin × +
https://auth.nih.gov/CertAuthV3/forms/mfa/Signin_AuthApp.aspx?TYPE=33554433&RE 🖞   🦁 📭 🕸 🙆 💿 💿 🐼 📓 🖤 🗯 =
National Institutes of Health Turring Discovery Into Health
ign in
Smart Card Login Insert your PIV card into your smart card reader or sign in using your mobile PIV-D credentials. Need help? Sign in
Authenticator App         Use your account credentials and check your phone for a one-time code or push notification.         Need help?         Username       Password         I       Sign in

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 <u>Issues and Feedback</u> 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)

$\equiv$ <b>PRES</b> Patients Protocols Repo	orts Pharmacy Admin <del>-</del>	🕜 Help 🛛 Pavan Kumar Jadda 👻
	Help	
User's Manual		
Training Video		
Pharmacy App Instructions		
<> API Documentation		

## Frequently Asked Questions (FAQs)

What is PRES?	^
PRES stands for Patient Registration and Enrollment System in short PRES. It is a web application built and managed by CCR OIT.	
How do I login to PRES?	~
What browsers are supported?	~
I am new to PRES, whom should I contact for access?	~
I can not login to PRES, what should I do?	~
I see error "Unable to login due to Internal Server error. Please try after few minutes", what should I do?	~
PRES website does not load, All I see is blank white screen?	~
How do I contact support?	~

Still Need Help? Click below on Need Assistance button below

Need Assistance? Click here Version: 2.13.0 (Backend: )

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.

<b>PRES</b> Patients Prot	ocols Reports Pharma	acy Admin <del>-</del>	🥐 Help 🛛 Pavan Kuma	ar Jadda 🔻
a Pa	tients	🖨 Protocols	II. Reports	
Enter a partial or full p or first name and click selection	atient MRN, last name E on to view that to	nter a partial Protocol Number and click o view that selection	on Choose a Report from the list below to view selection	
Search for Patient		earch for Protocol	Search for Report	
Choose an option from	armacy			
selection				
Select Pharma	cy Report 👻			
	Need Assi	stones? Olick here, weig		
	Need Assi	STANCE? CIICK NETE Version	1: 2. 13.0 (Backend: )	

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.



other links provide shortcuts to each page in the application.

PRES
Protocols

Protocols

Protocols

Protocols

Protocols

Protocols

Pharmacy

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 on home page or patient view page, enter at least 2 characters which will open a drop-down list of patients already in PRES matching those characters:

<b>PRES</b> Patients	Protocols	Reports	Pharmacy	Admin 👻
			S	earch for Patient
	Search for Patient			•
Patient Lookup:	Please enter 2	or more chara	acters	

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:

Enter a pa first name	artial or full patient MRN, last name or and click on to view that selection
Search for Pa	atient
DOE, J	OHN [1234567]

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. Selecting a patient will open the <u>Patient View</u>

## ADDING CRIS PATIENT

Sometimes new patient information may not be available via CRIS if the CRIS database is not available. In that case, if patient needs to enroll on to study with in time, the patient can be created in PRES and should be synced at later point of time.

To do this, select a protocol first and enter patient MRN, from dropdown select "MRN (NOT FOUND – Create New)" option. Enter all the demographics and create patient. Then proceed with registration as planned.

	Ado	New Patien	t		
Organization* National Institutes of	of Health Cl	inical Center			
First Name*		Last Name*			
Middle Name		Date Of Birth*			
MRN* 7881221		Sex*	•		
Gender	•	Race(s)*	•		
Ethnicity*	•				
				Close +	Create Patien

PRES also supports selecting multiple races. Here is how it works.

- a) If the patient has multiples races and individual races are known. Select all races from drop down and **do not** select "Multiple Race" from dropdown
- b) If the patient has multiples races and individual races are not available. Select "**Multiple Race**" from dropdown
- c) Otherwise select single race
- d) If the races information is not available, select "Unknown" as race

## ADDING AN OUTSIDE PATIENT

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

≡ PRES	Patients P	rotocols Reports	Pharmacy	Review 🔫	Admin 🛨	? Help
<			Re	gister I	Patient	
Protocol	Details					
	Num	ber: 000048 Q Char	nge Protocol			
	Descript	ion: A Multi-Center Nat	tural History Study	of Precision-Ba	sed Genomics in Prostate	e Cancer
	Catego	ory: Observational Stu	dy			
	Amendment D	ate: 01/25/2024				
	Is Screen	ing: No				
	Multi-Institutio	nal: Yes				
	Allow Re- Enrollment:	No				
	Randomiz	zed: No				
Patient De	Organization: Uni	versity of California San	Diego			× <del>-</del>
Si	ubject Type: Patie	nt/Subject		× •		
Patie	ent Lookup: 2222	22 [NOT FOUND - Crea	te New]	× •		<b></b>

#### 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. For demographics like Ethnicity, Gender, Races and Sex, select values from dropdown. If a particular demographic is not available, select "**Unknown**" from dropdown.

Ad	d New Patient
Organization* University of California San Diego First Name*	Native Asian Reak or African American
Middle Name	Black or African American     Multiple Race
MRN* 9993333	<ul> <li>Native Hawaiian or Other Pacific Islander</li> <li>Unknown</li> </ul>
Gender -	Race(s)*
Ethnicity* 👻	
	Close + Create Patient

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

<					Patient:					
		Ful Medical R	I Name: La contraction of the second	), National Institute edical Record	Change Patient s of Health Clinical Ce	nter				
			DOB: 🗰 10/23/19	58						
			DOD:							
		(	Gender: Male							
		-	Race: White							
			innerg. Horriepane	of Latito						
Particip	pating P	rotocols							R	egister New
PDF		Excel	Search for en	nollments						
Source	Protocol	Protocol Status	Protocol Phase	Ы	Registration Date ↓	Last Event Date	Last Event Type	Sequence Number	Organization	Actions
PRES	20-C-0076	Open - Recruiting	Clinical Trial Phase II	Kreitman, Robert	10/29/2020	10/29/2020	Fully Eligible	1010001	National Institutes of Health Clinical Center	View
PRES	01-C-0129	Open - Recruiting		Gulley, James	09/22/2020	09/22/2020	Fully Eligible	17522	National Institutes of Health Clinical Center	View
CDR	96-C-0071	Open - No Longer Recruiting - Follow-up Only		Gulley, James	06/08/2016	06/08/2016	Fully Eligible	980	NCI	N/A
PRES	10-C-0066	Open - Recruiting		Kreitman, Robert	04/30/2015	04/30/2015	Fully Eligible	307	National Institutes of Health Clinical Center	View
PRES	01-C-0129	Open - Recruiting		Gulley, James	04/30/2015	06/17/2015	Off-Study	10675	National Institutes of Health Clinical Center	View
								Iter	ns per page: 10 ▼ 1 − 5 of 5   <	< > >

FIGURE 11 - PERSON VIEW

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

Add MRN and Institution	×
Select Organization	Ŧ
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 with CRIS** button on patient view. Remember this is only available for the users who can create enrollments in PRES.

<	Patient: M	🖯 Sync
Full Name:	La MI Q Change Patient	
Medical Records:	National Institutes of Health Clinical Center	
	Add Medical Record	
DOB:	₩ C	
DOD:	🗹 Add	
Gender:	Male	
Race:	White	
Ethnicity:	Not Hispanic or Latino	
	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)

÷	- → c	ኛ 🕜			https://pres-	test.ccr. <b>cancer.g</b>	ov/person/17						ት 🔐	J 🚺 🕻	0		»
	≡ PF	RES	Patients	Protocols	Reports	Pharmacy	Admin 👻								😧 Help	jaddap2 👻	
	<						Sync	CRIS and	PRES Pat	ient Inforn	nation					🔁 Sync	
					Source	MRN	Last Name	First Name	Gender	Race	Ethnicity	DOB	Date of Death	I			
					CRIS	1234567	DOE	JOHN	Male	White	Not Hispanic or Latino	01/01/1970		1			
				L	PRES	1234567	DOE	JACK	Female	American Indian or Alaska Native	Hispanic or Latino	05/13/1970					
				L	n∎ patie n∎	PRES Patient info nt Remember this a	ormation is not in s	ync with CRIS infr e current patient i	ormation. Click o	n <b>Update PRES F</b> CRIS information	Patient button belo and can not be re	ow to update the versed	PRES 🗙				
	Pa	rticip	ating P	ro											Regist	er New	
		PDF		cel		_	_	_		_	Close	e D Update	e PRES Patient	J			
							Fie	GURE <b>14 – C</b>	REATE PA	TIENT							

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

$\leftarrow$ $ ightarrow$ C $\textcircled{a}$		https://pres-	test.ccr.cancer.g	<b>jov</b> /person/17							··· ☆ 【	/ 👳 🐵	»
$\equiv$ <b>PRES</b> Patients	Protocols	Reports	Pharmacy	Admin 👻								😧 Help	jaddap2 👻
<	Ι.			Sync	CRIS and	PRES Pa	itient Info	rmation					ට Sync
		Source	MRN	Last Name	First Name	Gender	Race	Ethnicity	DOB	Date of Death			
		CRIS	1234567	DOE	JOHN	Male	White	Not Hispanic or Latino	01/01/1970				
		PRES	1234567	DOE	JOHN	Male	White	Not Hispanic or Latino	01/01/1970				
			٢	PRES Patient infor	mation is already	in sync with CF	RIS information.	No action necessary	×				
								Close		• PRES Patio	ot		
Participating P	rotocol	5	-		-	-	-	Close				Regist	er New

FIGURE 15 - SKIP UPDATE TO PRES PATIENT

### VALIDATE CRIS PATIENT

If the NIHCC patient added via new registration process, then the information needs to validate against CRIS database after it's available. To do this, go to patient view and click on "here" as shown below



A comparison of the CRIS and PRES data is shown in table. If the CRIS data is correct, select "Update PRES Patient" option, otherwise select "Keep PRES Data"

				Validat	e the patient	data and u	ipdate it				
Source	MRN	Last Name	First Name	Sex	Gender	Race	Ethnicity	DOB	Date of Death	Zip Code	Country
CRIS	1234567	DOE	JOHN	Male			Hispanic or Latino	01/01/19 60		20850	United States of America
PRES	1234567	DOE	JOHN	Male			Hispanic or Latino	07/23/19 62		20850	United States of America

## FIX INCORRECT MRN

If NIHCC patient added via registration process and incorrect MRN entered, below message is displayed to sync data with CRIS. Click on "here" link to enter correct MRN and search in CRIS. Accept the CRIS changes.

<	Patient: DOE, JOHN	🕻 Edit 🔋 Delete
	NIHCC MRN does not exist in CRIS, Click here to fix it	

## **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

<b>PRES</b> Patients Protoc	ols Repo	orts Pharmac	ey Admin <del>-</del>				? Help	Pavan Kumar Jadda 👻
<				Edi	t Patient			
Demographics								
First Name * JOHN			Last Name * DOE					
Middle Name MICHAEL		Date Of Birth 1/1/1951						
Date Of Death	Ē	Gender * Male		Ŧ				
Race * White	•	Ethnicity * Not Hispanic o	or Latino	•				
Address								
Street Name			Apartment or Suite					
City	•	State		•				
Country United States of America	•	Zip Code 27455			_			
Update Patient								
Medical Records	Activi	ty Log						
							+ Add N	ew Medical Record
MRN	Organizati	ion			Protocol	Actions		
12345678	National li	nstitutes of Healt	n Clinical Center			C) Sync with CRIS		

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.

MRN * 123456789			
Protocol * 000048	•		
Organization * Lurie Cancer Center at North	western University	~	

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

Protocol: 10-C-	Protocol: 10-C-0025							
Number:	# 10-C-0025	Change Protocol			Ceiling:	74 (-16 Open)		
Branch:	Laboratory of Mole	ecular Biology		P	rotocolCategory:	Interventional or Clinical Trial		
Status:	Open - Recruiting				Is Screening:	No		
Randomized:	Yes			Colle	ct Registering PI:	No		
PI:	& Robert, Kreitm	an			Is two-step:	No		
Masking:	Open				Cohorts:	Cohort 1 (Dose escalation): Up to 12 pts with HCL, HCLv or un	mut. IGHV4-34+	
Description:	Randomized Phas Multiply Relapsed	e II Trial of Rituximab with Eith or Refractory Hairy Cell Leuke	ner Pentostatin or Bendamus emia	tine for	Constan	HCL/HCLv enrolled to Arm 1/2 for tolerability; pts with relaps// crossover to Arm 4 (closed) Cohort 2 (Dose expansion; randomized): Up to 56 evaluable p	ts with HCL, HCLv or	
Multi-Institutional:	Mutt-institutional: Yes 📀 View - (U sites) characteristic and a situation of an advector of the situation of a							
						be randomized and to be enrolled to Arm 3 or 4		
					Arms:	4 O View		
Enrolled Patients							Begister New	
PDF Excel								
		Search for data						
Full Name	MRN	Registration Date $\downarrow$	Last Event Date	Last Event Type	Sequence Numb	er Organization	Actions	
± 1	7	3 05/08/2020	05/08/2020	Fully Eligible	64	National Institutes of Health Clinical Center	View	
<b>≜</b> €	8	1 03/23/2020	05/08/2020	Off-Treatment	63	National Institutes of Health Clinical Center	View	
۹. د	7	1 03/17/2020	03/17/2020	Fully Eligible	62	National Institutes of Health Clinical Center	View	
<b>±</b> ¢	7	0 09/23/2019	09/23/2019	Fully Eligible	61	National Institutes of Health Clinical Center	View	
± N	7	8 09/16/2019	09/16/2019	Fully Eligible	60	National Institutes of Health Clinical Center	View	
± 1	7	1 05/13/2019	05/13/2019	Fully Eligible	59	National Institutes of Health Clinical Center	View	
<b>2</b> 6	3	1 04/03/2019	04/03/2019	Fully Eligible	58	National Institutes of Health Clinical Center	View	
<b>A</b> J	7	7 03/22/2019	02/10/2020	Off-Treatment	57	National Institutes of Health Clinical Center	View	
A 0	7	8 03/20/2019	03/20/2019	Fully Eligible	56	National Institutes of Health Clinical Center	View	
<b>A</b> (	7	1 03/07/2018	10/08/2019	Off-Study	55	National Institutes of Health Clinical Center	View	
						Items per page: 10 - 10 of 90	$\langle \rangle \rightarrow \rangle$	

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 dropdown list of protocols already in PRES matching those characters:

Enter a partial Protocol Numbe selection	er and click on to view that
earch for Protocol	
-	×
06-C-0150	
09-C-0005	
09-C-0025	
10-C-0025	
10-C-0025 10-C-0066	

#### 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.

	Select Protocol	
	Protocol* Select Protocol	
	00-C-0074	
-	00-C-0078	
_	00-C-0133	Close
	000021	
	000030	

#### 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.

<		Register Patient						
Protocol De	tails							
	Number:	01-C-0129 Q Change Protocol						
	Description:	Eligibility Screening for the NIH Intramural Research Program Clinical Protocols						
	Category:	Observational Study						
	Amendment Date:	01/27/2022						
	Is Screening:	Yes						
	Multi-Institutional:	No						
	Allow Re-Enrollment:	Yes						
	Randomized:	No						
Patient Details	Organization: National Institutes of Health Clinical Center Patient Details							
	Subject Type: Patient/Subje	ect × •						
	Patient Lookup: Search for Pa	atient						

#### 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.

	Add Other Disease
i Please s	earch for the disease in MedDRA. If you can't find it, click on <b>Not available in MedDRA</b> and enter the disease name in the text box below
	Search for meddra disease
MedDRA Disease:	hairy ×
	Hairy cell leukaemia
	Oral hairy leukoplakia
	Hairy cell leukaemia recurrent
	Close Save

• 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.

	Add Other Disease
Please s	earch for the disease in MedDRA. If you can't find it, click on <b>Not available in MedDRA</b> and enter the disease name in the text box below
MedDRA Disease:	Search for meddra disease
	✓ Not available in MedDRA
	Other Disease* Enter Other Disease
	Other Disease Comments
	Close 🖬 Sat

### 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.

Disease		
Disease:	<b>~</b>	
	The disease I am looking for is not available in the list	
Registering PI/Brancl	h	
Registering Branch:	Select Registering Branch	•
Registering PI:	Select Registering PI from drop-down	▼
Screened for Protocols:	Select screened Protocols from drop-down	•

#### 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

## Consent

Date of Consent:	5/20/2022	Ē	
Consent Language:	English		× •
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

## **Embedded Agreements**

Identifiable specimens and data to be stored and used by the study team for future studies

Yes O No O Not Applicable

De-identified specimens and data to be shared with and used by other researchers for future studies



Identifiable specimens and data to be shared with and used by other researchers for future studies

Yes 🔿 No 🔿 Not Applicable

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

Eligibility Status		
<ul> <li>Eligible for Treatment</li> <li>Not Eligible</li> </ul>		
Fully Eligible Date: 7/1/2	<u>2020</u>	
Cohort:	Search for a Cohort	

#### FIGURE 22-REGISTER PATIENT TO PROTOCOL PAGE

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

Fully Eligible Date Assignment Details	· 7/1/2020 🖻
Assignment Details	
с	Cohort: Cohort 1 (Dose escalation): Up to 12 pts with HCL, HCLv or unmut. IGHV4-34+ HCL/HCLv enrolled to Arm 1/2 for tolerability; pts with relapse/no response may crossover to Arm 4 (closed)
Online A	Search for a Cohort Arm
Conort A	Arm 1: Rituximab +bendamustine at 70 mg/m2 for initial tolerability study (closed)
	Arm 2: Rituximab +bendamustine at 90 mg/m2 for initial tolerability study (closed)

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.

Eligibility Status	
Eligible for Treatment	
O Not Eligible	
Fully Eligible Date: 11/9/	2020 🖻
Assignment Details	
Cohort:	1: Patients with HCL with (62 patients) and without (68 subjects) prior course of purine analog to be randomized between Arm 1 and Arm 2 (randomization stratified based upon prior purine analo × *
Prior CdA:	Select Stratification Lavel
	1 + Prior CdA
	No Prior CdA
	Register

FIGURE 24-SELECTION RANDOMIZATION INFORMATION

## **TWO STEP AND THREE STEP PROTOCOLS**

The use of the two step or three step process is used when a patient will be screened after consenting to a protocol. The protocol has one consent or two consents (screen and main consent). For two step and three step protocols the Eligibility Status includes the "Eligible for Screening" option.

Eligibility Status	
O Eligible for Screening	
<ul> <li>Eligible for Treatment</li> </ul>	
O Not Eligible	
FIGURE 25-TWO STEP	

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

For protocols with one consent: After a patient has been fully consented, the first registration step is to select Eligible for Screening, then screening procedures can begin. Once eligibility is either confirmed or not, the second registration step is to either complete the registration (Eligible for Treatment) or to remove the patient from the protocol (Not Eligible).

For protocols with two consents: After a patient has been consented to the protocol specific screening consent, the first registration step is to select Eligible for Screening, then screening procedures can begin. If eligibility is confirmed and the patient has been fully consented to the treatment consent, the second registration step is to complete the registration (Eligible for Treatment). If the patient is not eligible after screening, the second registration step is to remove the patient from the protocol (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).

					Delete Enrol
nt Details		Protocol Details			
Full Name:  💄 M		Number:	# 00-C-0078		
Medical Records:	, National Institutes of Health Clinical Center	PI	William Douglas, Figg		
DOB:		Category:	Observational Study		
DOD:	Fdit	Status:	Open - Recruiting		
Subject Type: Patient/Sub	piect				
signment Details	,				
Sequence Number:	86 🕑 Edit				
Registering Organization:	National Institutes of Health Clinical Center				
Cohort Details:	2/Normal Volunteers(normal volunteers providing samples for research	h studies) 🔀 Edit			
Arm Details:	1 (default arm) 🔀 Edit				
-					
Disease: Consent Language:	Normal Volunteer 🗭 Edit (Has the short form consent been used: Not Answered) 🗭 Edit				
Disease: Consent Language: Events of Significance	Normal Volunteer 🗭 Edit (Has the short form consent been used: Not Answered) 🗭 Edit Embedded Agreements				
Disease: Consent Language: Events of Significance Notable Events Date	Normal Volunteer 🗭 Edit (Has the short form consent been used: Not Answered) 🗭 Edit Embedded Agreements Event Type	Comments		Actions	
Disease: Consent Language: Events of Significance Notable Events Date 11/26/2019	Normal Volunteer <table-cell> Edit (Has the short form consent been used: Not Answered) <table-cell> Edit Embedded Agreements Event Type Consent Consent</table-cell></table-cell>	Comments		Actions	
Disease: Consent Language: Events of Significance Notable Events 11/26/2019 11/26/2019	Normal Volunteer       C Edit         - (Has the short form consent been used: Not Answered)       Edit         Embedded Agreements       Edit         Embedded Agreements       Consent         Eonsent       Registration	Comments		Actions C Edit Edit (Sys Admins Only)	
Disease: Consent Language: Events of Significance Notable Events 11/26/2019 11/26/2019	Normal Volunteer       Calit         - (Has the short form consent been used: Not Answered)       Calit         Embedded Agreements       Calit         Embedded Agreements       Calit         Consent       Calit         Registration       Fully Eligible	Comments		Actions C Edit Edit (Sys Admins Only) C Edit	
Disease: Consent Languages Events of Significance Notable Events 11/26/2019 11/26/2019 11/26/2019	Normal Volunteer       Edit         - (Has the short form consent been used: Not Answered)       Edit         Embedded Agreements       Edit         Image: Consent       Event Type         Image: Consent       Consent         Image: Consent       Event Type         Image: Consent       Event Type         Image: Consent       Event Type         Image: Consent       Event Type         Image: Consent       Image: Consent         Image: Consent       Image: Consent	Comments		Actions Edit         Edit (Sys Admins Only)         Edit         Edit         Edit	

ated by: Pavan Kumar Jadda on 09/15/2022 10:15:50 PM (Created by: Shari Ghajar on 01/04/2021 04:47:37 PM )

FIGURE 26-ENROLLMENT VIEW

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

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.

Sequence Number:	20	
	Next Available Sequence Number: 65	Use This Number
Show used	sequence numbers for 10-C-0025	3

FIGURE 27-SEQUENCE NUMBER

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

Sequence Number:		
	Next Available Sequence Number: 19	Use This Number
Hide u	sed sequence numbers for 09-C-0025	
S	earch for sequence numbers	_
Patient	Consent Date $\ \downarrow$	Sequence Number
	12/22/2015	18
	03/12/2014	17
	01/29/2014	16
	04/18/2012	15

#### 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

Edit Sequence Number	
RES and Rave integration enabled for this study. Please remember the Sequence Number you add here will be used to create new Subject in Rave.	×
Sequence Number * 1010005 Next Available Sequence Number: 1010005	
Show used sequence numbers for 000481	~
Close Save Cha	anges

## **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.

Eligibility Status			
Eligible for Treatment			
O Not Eligible			
	Enter Fully Eligible D	late	
Fully Eligible Date:	11/9/2020		
Assignment Details			
Coho	rt:	Cohort 3 (Dose expansio	i; non-randomized): Up to 4 evaluable pts with HCL, HCLv or unmut. IGHV4-34+ HCL/HCLv with prior non-respons× *
Cohort A	rm(s):		•
		Arm 3: Rituximab + Benda	nustine (at the tolerated dose)
		Arm 4: Rituximab + Pento	tatin
			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

<ul> <li>Eligible for Treatment</li> </ul>	
Not Eligible	
	Take Off-Study

## THREE STEP PROTOCOLS

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

Cohort/Arm Change		
Cohort:	2/Patients with Glioblastoma without sufficient vaccine created: GBM pts w/MRI findings consistent w/a suspected GBM or a histo	ologically co× 👻
Cohort Arm(s):	1/RT+TMZ + Pembrolizumab: Standard treatment with experimental treatment (pembro) added	X *
	Update	
	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 3<sup>rd</sup> 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.

Assignment Details		
Sequence Number:	64 📝 Edit	
Cohort Details:	Cohort 2 (Dose expansion; randomized)(Up to 56 evaluable pts with HCL, HCLv or unmut.IGHV4-34+ HCL/HCLv to be randomized and stratified and enrolled to Arm 3/4; pts with relapse/no respon may crossover to the other arm.)	se
Stratification Group:	Purine: Purine Sensitive	
Allocated Slot:	76 🕨 Skip Slot	
	Comments *	1
	Save D Cancel	
Arm Details:	Arm 4 Rituximab + Pentostatin	

#### 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.

## **Events of Significance**

Select Event Type * Re-Consent	•			
Date: 4/30/2021	Ē			
Comments Patient Re-Consented	on 04/30/20	21		1,
Add Event				
		FIGURE 33-RE-CC	DNSENT 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.

#### Events of Significance

Select Event Type * Crossover	•	
Cohort Description Up to 56 evaluable pts with HCL, HCLv or unmut.IGHV4-34+ HCL/	HCLv to be randomized and stratified and enrolled to Arm 3/4; pts with relapse/no response may	crossover to the other arm.
Arm 4: Rituximab + Pentostatin		
Date: 4/30/2021	c	
Comments	,	
Add Event		_
	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.

#### **Events of Significance**

Select Event Type * Off-Treatment	-
Off-Treatment Reason: Death	~
Date: 4/30/2021	Ē
Comments	
Add Event	

#### 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.

Events of Significan	ce Embedd	ed Agreements	_		
1. Identifiable specime	ns and data to be stored	d and used by the study t	eam for future studies:	Not Answered 🔀 Edir	t
2. De-identified specim	ens and data to be shar	red with and used by oth	er researchers for future	e studies: Not Answered	🕑 Edit
3. Identifiable specime	ns and data to be share	d with and used by other	researchers for future	studies: Not Answered	🕑 Edit
Embedded Agre	ement History T	able			^
lleer	Change Date	Question	Old Answer	Now Appwor	
0381	Change Date 🔸	Question	olu Aliswei	New Allswei	

The responses can be edited by clicking on Edit button. And again, it's mandatory to answer all the questions.
Events of Significance	Embedded Agreements
Identifiable specimens and d	ata to be stored and used by the study team for future studies ot Applicable
De-identified specimens and	data to be shared with and used by other researchers for future studies of Applicable
Identifiable specimens and d	ata to be shared with and used by other researchers for future studies ot Applicable
Update	Cancel

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

Events of Significance Embedded Agreements

1. Identifiable specimens and data to be stored and used by the study team for future studies: Yes 🛛 🙆 Edit

2. De-identified specimens and data to be shared with and used by other researchers for future studies: Yes 🛛 🔀 Edit

3. Identifiable specimens and data to be shared with and used by other researchers for future studies: No 🛛 🌈 Edit

Embedded Agreement Histo	ory Table				^
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	

## **Enrollment Change Request**

Starting with version 2.21.3, users can request changes to enrollment-related changes within the application. Each request requires approval from branch team leads and PRES admin. The following types of change requests are supported:

- Delete Off-Study or Off-Treatment or Fully Eligible event
- Delete Enrollment

- Update Cohort or Arm
- Update Sequence Number for Rave integrated studies

#### **Delete Notable Event or Enrollment**

To request a deletion, go to the Enrollment view and click the new Delete button next to a Notable Event or Enrollment. This will open a dialog with two required fields:

- Select the Team Lead who needs to approve the request
- Provide a detailed description of the change

Once submitted, the request will be routed for approval.

	Delete Off-Study Event Request	
Team Lead*		•
Description of the change:*		<i>i</i> ,
	<ul> <li>The request will go fo approval to the Team Lead and PRES Admin.</li> <li>Once approved, Off-Study Event will be deleted</li> </ul>	
		Close Create Request

#### **Update Cohort or Arm**

To request a Cohort or Arm update, go to the Enrollment view and click the new Edit button next to Cohort or Arm. This will open a dialog with a few required fields:

- Select the new Cohort and Arm
- Select the Team Lead who needs to approve the request
- Provide a detailed description of the change

All fields are mandatory. Once submitted, the request will be sent for approval.

	Change Cohort/Arm Request		
Current Cohort: Current Arm:	2/Normal Volunteers (normal volunteers providing samples for research studies) 1 (default arm)		
New Cohort* 2/Normal Volunteers		<b>~</b>	
New Arm* 1		<b>.</b>	
Team Lead*		Ŧ	
Description of the char	ge*		
		11	
		Close +	Create Request

#### **Update Sequence Number**

To request a Sequence Number update, go to the **Enrollment** view and click the new **Edit** button next to **Sequence Number**. This will open a dialog with a few required fields:

- 1. Enter the new Sequence Number
- 2. Select the Team Lead who needs to approve the request
- 3. Provide a detailed description of the change

All fields are mandatory. Once submitted, the request will be sent for approval.

	Edit Sequence Number	
	Sequence Number 6010038 Next Available Sequence Number: 6010039 → Use This Number	
Team Lead*	Ţ	
Description of the ch	ange:*	//
• Th • On • Cli	e change request will go fo approval to the <b>Team Lead</b> and <b>PRES Admin</b> . Ince approved the sequence number will be updated lick the <b>Update</b> button below to submit the request.	
		Close 🕞 Update

Once the request is submitted, the user will receive an email with the change details. A new tab called **Enrollment Change Requests** will also appear in the Enrollment view. This tab lists all the change requests submitted for that enrollment.

# **Team Lead Approval**

This section applies to team leads only. Team leads can view list of change requests by clicking on **Enrollment Change Requests** on **Review** tile in home page or **Review**  $\rightarrow$  **Enrollment Change Requests** on header or. The Enrollment Change Requests page provides a centralized view of all submitted enrollment-related change requests in PRES. From this screen, users can track status, filter pending approvals, and take action.

You can narrow the view using these checkboxes:

- Show My Pending Approvals Requests where you are assigned as an approver
- Show Pending Team Lead Approvals Requests waiting for any Team Lead's review
- Show Pending Admin Approvals Requests waiting for PRES Admin approval

≡ F	PRES Patients	Protocols Report	ts Pharmacy	Review <del>-</del> Adı	min <del>v</del>			🕜 Help	Pavan Kumar Jadda
	<			Enrolln	nent Change	e Requests	5		
	Q       Search Enrollment Change Request         Image: Show My Pending Approvals       Image: Show Pending Team Lead Approvals       Image: Show Pending Admin Approvals								
	Туре	Status	Team Lead Approved	Admin Approved	Created By	Last Updated 🕠	Last Updated By	Enrollment	Actions
	Off-Study Removal	Pending Team Lead Approval	No	No	pavankumar.jad da@nih.gov	06/04/2025 01:43:30 PM Items per page:	pavankumar.jad da@nih.gov 10 💌 1	✓ 45648 − 1 of 1 <	♥ View < > >1
			_		_				_

Click on View button under actions column to view the request details.

All enrollments change requests require branch team lead approval. Once new request created, assigned team lead along <u>CCRORNLeadership@mail.nih.gov</u> will the email. See below for sample email. It contains summary of the request and a link to approve/reject the change request.

From: noreply-pres@mail.nih.gov <noreply-pres@mail.nih.gov> Date: Thursday, May 29, 2025 at 12:17 PM To: Bryla, Christine (NIH/NCI) [E] <<u>christine.bryla@nih.gov</u>> Subject: [LOCAL]-Enrollment Change Request has been reassigned

Hello,

An enrollment change request for a subject with sequence number under protocol 00-C-0074 has been reassigned to you.

Details are available below.

- Summary: Delete Off-Study notable event with date: 2005-07-14
- Type: Off-Study Removal
- Assigned To: <u>christine.bryla@nih.gov</u>
- Approve/Reject: <u>https://localhost:4200/review/ecr/1</u>
- Enrollment: <a href="https://localhost:4200/enrollment/45648">https://localhost:4200/enrollment/45648</a>

If you experience any issue in accessing this information, please contact support

Sincerely, The PRES Team

This email was automatically generated from a mailbox that is not monitored. If you have any questions, please contact support.

### **Approving/Rejecting Request**

Clicking on the above Approve/Reject link will take you to change request page. It is divided into 3 sections.

The Enrollment and Requester Information section displays key details such as:

- A link to the Enrollment
- The associated Protocol
- The current Assigned User
- The Sequence Number
- Requester information

The **Request Change Information** section shows the specific changes requested by the user.

The **Approvals** tab displays a history of approvals for the request.

Lastly, the **Activity Log** section lists all actions taken on the request.

<		Enrollment Change Request						
		The enrollment change request is as	signed to you. Please review and approve or reject it.					
rollment			Assigned To					
648 🖸			Pavan Kumar Jadda 🛛 🗭					
rotocol			Sequence Number					
0-C-0074 🗹			550					
equested By vankumar.jadda@nih.gov			Requested On 05/29/2025 01:07:50 PM					
equested Change Info	mation							
nange Type			Status					
f-Study Removal			Pending Team Lead Approval 🕓					
<b>Immary</b> elete Off-Study notable event wit	h date: 2005-07-14		Description Test					
		Review and Approve	Reject with Comments					
Approvals Ac	tivity Log							
State	Approver	Comments		Updated On $\downarrow$				

Team Leads assigned to approve will see action buttons:

- Review and Approve to accept the request
- Reject with Comments to deny and leave notes

Each of these actions require comments for approving or rejecting.

#### **Reassigning Request**

Team Leads or PRES Admins can reassign a request to another user if needed.

To do this:

- 1. Click the Edit icon next to the Assigned To field in the request view.
- 2. Select a new **Team Lead** from the dropdown.

Once reassigned, the new Team Lead will receive an email notification informing them of the assignment.

# **PRES Admin Approval**

This section applies to PRES Admin only. Once a request is approved by the Team Lead, it is routed to the **PRES Admin** for final approval. The admin can approve or reject the request

- If approved, the request will be processed, and the user will receive a notification. If the study is integrated with **Rave** but requires manual intervention (e.g., Delete Enrollment), the PRES Admin must coordinate with the Rave **team** to complete the action.
- If rejected, the user will receive a **notification** about the rejection and reason.

# **R**EPORTS

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.

Reports
Choose a Report from the list below to view selection
Search for Report
Accrual Monthly Report
Accrual Status Report (Age Gender Race)
Accrual Status Report - Quarterly
Active Multi Institutional Studies and Site Accruals
All Patients Registered to CCR

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. NIH Participant Age Data Report
- 15. Non-English Language Consents Report
- 16. OCD Consent Language Summary Report
- 17. Open Protocol for the VA Report
- 18. Patient Cohort and Arm Report
- 19. Patient Enrollment Information Report
- 20. Patient List and Other Participated Protocols Report
- 21. Patient List Report
- 22. Patient Off-Study Confirmation Report

- 23. Patient Off-Study Entered Report
- 24. Patient Off-Study Report
- 25. Patient On-Study Report
- 26. Patient Re-Consent Report
- 27. Protocol Accrual Status Report
- 28. Protocol Cohort and Arm Report
- 29. Protocol Embedded Agreement Report
- 30. Protocol Embedded Agreement Summary Report
- 31. Randomized Protocol Accrual Ceiling Report
- 32. Randomized Protocol Patients Report
- 33. Registration Report
- 34. Theradex Registration Report

Many of the reports accept parameters including Branch and Protocol.

$\equiv$ <b>PRES</b> Patient	ts Protocols Re	eports		
[ s	Disease Accru Select branch(s) and/or p	al Report protocol(s). Leave blank to show	all records	
Search Branch:	Select Branch		-	
Search Protocol:	Select Protocol	•		
	Generate Report			
		FIGURE 38-REPORT PARAME	TERS	

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



### **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)

#### **Accrual Monthly Report**

Branch:	Select Branch	•	End Date:       8/31/2021         Please pick end date to filter the report. Defaults to today         Generate Report			
-				Please pick end date to filter th report. Defaults to today		
			Generate Report			

#### 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.

NCI						А	ccrua	al Mo Accrua	onthly	сс 7 <b>Пер</b> d: 10/	00000000000000000000000000000000000000	NTIAL <b>Activ</b> 20 - 08	<b>/e Tre</b> /31/20	eatm 21	ent						CCR
									Report of	generated of	on: 08/31/202	1 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 Sep 2020	Enrollment Oct 2020	Nov 2020	Dec 2020	Jan 2021	Feb 2021	Mar 2021	Apr 2021	May 2021	Jun 2021	Jul 2021	Aug 2021
Branch: <u>Clin</u> PI: <u>Wood,</u> Brad 16CC0049	A Phase II	Clinical Trial	Open -	2016-04-12		30	19	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	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	Phase II	Enrolling by Invitation Only																		
16CC0098	Pilot Study o Ultrasound Guided Focal Thermal Ablation of Prostate Cancer	f Clinical Trial - NA (Device Studies Only or Behaviora 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:Der Branch Branch PI:Brownell,	anch: Clinical matology	Center					33	7	7	0	0	0	0	0	0	0	0	0	0	0	0
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	Exce		
NCI				CON	ΕΙΔΕΝΤΙΔΙ				C	CB		
	CONFIDENTIAL Accrual Status on Open Protocols Reporting Period Ending: 08/31/2021 Report generated on: 08/31/2021 14/26 PM											
Show 10 v entries								Search:				
Branch 1	Protocol ↑↓	Phase 1	Accrual Ceiling	Accrual To Date	Currently On Study	Status 1	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)

Accrual Status Report (Age Gender Race) Select branch(s) and/or protocol(s). Leave blank to show all records												
Branch:	× Radiation Oncology Branch		× •									
Protocol :	× 00-C-0074	× •										
	Generate Report Pri	nt										

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

# Accrual Status Report (Age Gender Race)

#### Reporting Period Ending: 08/31/2021

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

Branch/Pl	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:Radia	ation Oncolog	y Branch																		
Camphause n, Kevin	00-C-0074	Evaluation of	f Late Effects a	nd Natural His	story of Diseas	e in Patients T	reated with Ra	diotherapy												
				0	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	

CCR

### **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)

	Accrual Status Report - Quarterly												
Branch:	× Clinical Center	× +	End Date:	8/31/2021 Please pick end date to filter the Defaults to today	e report.								
			Generate Report										

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.

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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 Co	enter												
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	Cilnical 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)

Active Multi Institutional Studies and Site Accruals

Please s	elect branch(es) then select multi-site protocol(s) or directly select multi site protocol(s)
Branch:	
Protocol :	× 09-C-0005 × 👻
	Generate Report

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 CONFIDENTIAL CONFIDENTIAL CONFIDENTIAL														
Reporting Period Ending: 08/31/2021														
Report generated on: 08/31/2021 15:43 PM														
Branch	Protocol	PI	Study Status	ProtocolCatego	ory	Sponsor	AccrualCeiling	Accrual To Date						
Experimental Transp 1	plantation and Immunotherapy Bra 18-C-0135	<u>nch</u> Dimitrova, Dimana	Open - Recruiting	Interventional or Institute A Name II	Clinical Trial Accrual Per		177	29						
				National Institutes of Health Clinical Center	26									
				National Marrow Donor Program	3									
Molecular Imaging B	Branch													
1	17-C-0089	Choyke, Peter	Open - Recruiting	Interventional or Institute A Name In	Clinical Trial Accrual Per		180	83						
				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)

### All Patients Registered to CCR

Start Date	Ē
End Date 8/31/2021	
Please pick end date to filter the report. Defaults to today	
Generate Report	

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 All Patients Registered to CCR Search for data														
New	Late	Registration Date 🔸	Last Name	First Na	ame MI	RN	DOB	Branch	Institute	Consent Date	Protocol	Sequence Number	Protocol Type				
Y	N	08/23/2021		1		5	0:	Genitourinary Malignancies Branch	National Institutes of Health Clinical Center	08/23/2021	02-C-0179	1266	Observational Study				
Y	Ν	08/23/2021		ı		2	0.	Surgical Oncology Program	National Institutes of Health Clinical Center	08/19/2021	17-C-0044	91	Observational Study				
Y	Ν	08/22/2021		L (		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	Ν	08/20/2021		E		4	1:	Surgical Oncology Program	National Institutes of Health Clinical Center	08/18/2021	17-C-0043	469	Observational Study				
Y	Ν	08/20/2021		E		4	1:	Surgical Oncology Program	National Institutes of Health Clinical Center	08/18/2021	13-C-0176	865	Observational Study				
Y	Ν	08/20/2021		ι		7	0:	Genitourinary Malignancies Branch	National Institutes of Health Clinical Center	08/16/2021	04-C-0165	2290	Observational Study				
Y	Ν	08/20/2021		ę		3	1	Surgery Branch	National Institutes of Health Clinical Center	08/20/2021	99-C-0128	5568	Observational Study				
Y	Ν	08/20/2021		ę		3	1	Surgery Branch	National Institutes of Health Clinical Center	08/20/2021	03-C-0277	1012127	Observational Study				
Y	Ν	08/20/2021		F		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	NEWBERKI	E		8	0'	Genitourinary Malignancies Branch	National Institutes of Health Clinical Center	08/20/2021	01-C-0129	18733	Observational Study				
										lt	ems per page:	<b>10</b> • 1 - 10 o	f 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)

		CCR Clinical Trial a	nd Accrual Report	
Start Date 2/7/2022	Ē	End Date 2/7/2023	E Defaulte to today	
Excluded Branches		Prease pick end date to finter the report	. Delauits to touay	
Excluded Protocols				
		Generate	Report	

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.

ICI					CONFIDENTIAL CCR Clinical Trial and Accrual Report Report Date Range: 02/07/2022-02/07/2023												CCR
New	Protocol 、	PI	Short Title	Q Protocol Category	Filter D: Protocol Phase	ata 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	Date of last new Accrual	Total currently On- Study
Surger y Branch	99-C- 0128	Rosen berg, Steve	Screen ing	Observ ational Study		Open - Recruit ing	No	No		06/17/ 1999		7000	5717	134	21	02/03/ 2023	360
Labora tory of Cancer Biolog y and Geneti cs	99-C- 0099	Kraem er, Kennet h	DNA Repair Disord ers	Observ ational Study		Open - Recruit ing	No	No		04/20/ 1999		750	702	6	0	12/15/ 2022	539
Immun e Deficie ncy Cellula r Therap	00097 5	McGra w, Kathy	Health y Volunt eer Biospe	Observ ational Study		Open - Recruit ing	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)

	Cumulative Inclusion Enrollment Report													
Protocol :	Select Protocol Protocol is required	- Li	.ast CR Date:	Ē	End Date:	9/1/2021 End date to filter the report. Defaults to today								
			Generate Report	Print										

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

NCI       CONFIDENTIAL         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       Total Enrollment: 455														
						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														
		Not Hispanic or Latino			Hispanic or Latino		Uni							
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		Unkr	own/Not Reported Ethnicit	у	
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		U	nknown/Not Reported Ethn	licity	
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

### **Disease Accrual Report**

Black or African

American

White

Other

Unknown

Total

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)

#### **Disease Accrual Report**

S	Select branch(s) and/or proto	col(s). Leave blank to show all	l records	
Branch:	Select Branch			•
Protocol :	× 00-C-0074	× •	-	
	Generate Report			

And the report has the following columns

- Branch •
- Disease ٠
- Subject Last Name •
- Subject First Name •
- Subject MRN •
- Subject Sex ٠
- Subject Race
- Protocol Number •
- Protocol type •
- On Study Date (Fully Eligible Date) •
- Off-Study Date •
- Eligible ٠
- 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.

NCI							Diseas Report g	CONFIE e Accru enerated on: 08/31/2	DENTIAL al Repo 2021 15:59 PM	ort					
Show 10 v	entries												Search:	Acute (	Adult) T-Cell
Branch †	t↓ Disease ↑↓	Last Nar	ne †↓	First Na	me †↓	MRN 11	Sex ↑↓	Race ↑↓	Protocol 14	Protocol Type ↑↓	On Study Date ↑↓	Off Study Date ↑↓	Eligible	ţ↓	Organizatio n
Acute (Adult) 1	T-Cell Lymphoma/Le	ukemia	N		1	1	Male	White	00-C-0074	Observational Study	12/04/2000		Y		National Institutes of
															Health Clinic
		I				2	Female	White	00-C-0074	Observational Study	10/30/2000		Y		National Institutes of Health Clinic Center

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

### **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)

[	Disease Accrual Summary Report
S	Select branch(s) and/or protocol(s). Leave blank to show all records
Branch:	Select Branch
Protocol :	× 00-C-0074 × ▼
	Generate Report

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.

NCI					CO	NFIDENTIAL					
					A	0		ч			
				Disease	Accruai	Summai	у неро	τ			
				Reporti	ng Period I	Ending: 08/3	31/2021				
				-	Report generated on	: 08/31/2021 16:11 PM					
							American	Native			
						Black or	Indian or	Hawaiian or			
		Protocol				African	Alaska	Other Pacific			
Branch	Disease	Number	Sex	White	Asian	American	Native	Islander	Other	Unknown	Т
Lymphoid Mal	gnancies Branch										
	Acute (Adult) T- Cell Lymphoma/Leuke mia										
		00.0.0100	-								
		00-C-0133	F	1	0	0	0	0	0	0	
		00-C-0133 00-C-0133	M	1	0	0	0	0	0	0	
		00-C-0133 00-C-0133	M	1 1 2	0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	
	Lymphoma, NOS	00-C-0133 00-C-0133	M	1 1 2	0	0 0	0 0 0	0 0 0	0 0 0	0 0 0	
	Lymphoma, NOS	00-C-0133 00-C-0133 00-C-0133	F	1 1 2 4	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0	0 0 0	0 0 0 	
	Lymphoma, NOS	00-C-0133 00-C-0133 00-C-0133 00-C-0133	F M F M	1 1 2 4 14	0 0 0	0 0 0	0 0 0	0 0 0 0	0 0 0 0	0 0 0 0 0	
	Lymphoma, NOS	00-C-0133 00-C-0133 00-C-0133 00-C-0133	F M F M	1 1 2 4 14 18	0 0 0 0 0 0	0 0 0 0 0 0	0 0 0 0 0	0 0 0 0	0 0 0 0 0 0	0 0 0 0 0 0 0	
	Lymphoma, NOS Non-Hodgkin's Disease	00-C-0133 00-C-0133 00-C-0133 00-C-0133	F M F M	1 1 2 4 14 18	0 0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 0 0 0	0 0 0 0 0	0 0 0 0 0 0	
	Lymphoma, NOS Non-Hodgkin's Disease	00-C-0133 00-C-0133 00-C-0133 00-C-0133 00-C-0133	F M F M	1 1 2 4 14 18 2	0 0 0 0 0 0	0 0 0 0 0 0	0 0 0 0 0 0	0 0 0 0 0 0 0	0 0 0 0 0 0	0 0 0 0 0 0 0	

### **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.

			Enroll	ment	Demogra	phic R	leport	
Select protocol, bra	anch and Start date and end date filters.							
Branch :	Select Branch					•		
Protocol :	Select Protocol		-					
Start Date								
End Date	10/13/2023	Ē						
	End date to filter the report. Defaults to today							
					Generate R	eport		

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.

									Genera	ate Repo	ort						PDF	Excel
NCI							Enr	c ollments		n raphic	c report							cc
					Q Search fo united	r Data												
Protocol	Branch	Ы	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 Collectio n, Clinical Care and Interventi ons in CCR, NCI	Observati onal Study	Open - Enrolling by Invitation Only		09/26/20 23	09/26/20 23	NO						Irving	Texas	75038	United States of America
04-C- 0165	Center for Immuno- Oncology	Gulley, James L	Data Collectio n, Clinical Care and Interventi ons in CCR, NCI	Observati onal Study	Open - Enrolling by Invitation Only		09/26/20 23	09/26/20 23	NO						Silver Spring	Maryland	20904	United States of America
IRB00157 2	Center for Immuno- Oncology	Norberg, Scott	A Phase II Study of Bevacizu mab in Adults with Recurrent Respirato ry Papillom atosis (RRP)	Interventi onal or Clinical Trial	Open - Recruitin g		08/30/20 23	08/30/20 23	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

Language of Consent Report								
Protocol :	þo-C-0074	X 👻						
		Generate Report						

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		Lan	co guage of Conse	NFIDENTIAL nt Report- 00-C-	-0074		CCR
		Q Search f	or 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 pag	e: <u>10 ▼</u> 1 - 10 e	of 466  < <	> >I

### **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** ٠
- ΡI •
- IND/IDE (Investigational New Drug or Investigational Device Exemption) •
- Sponsor (Sponsor of the Study) •
- Multi Institutional (Yes/No) ٠
- Site (Name) ٠
- Accrual (To Date) •
- Active Patients (On Study Patients) •
- **Monitoring Schedule** •
- Last Visit •
- Project Next Visit ٠
- Monitor ٠
- Comments •

See below for sample report.

		Genera	ate Report												DE	Excel
NCI								cc	ONFIDENT	IAL						C
							Мо	nitorin	g Stud	y List						
01							R	eport generated of	on: 08/31/2021 16	6:17 PM				0		
Snow	J ~	entries										Monitori		Sea	'cn:	
Branch	t.	Protocol 1	Protocol Descripti	Status †	PI ti		Sponsor 1	Multi Institutio	Site 1	Accrual	Active Patients	ng Schedul	Last Visit ↑	Project Next Visit	Monitor 1	Commen
Thoraci	c and G	I Malignancies I	Branch	otatao 1.			oponoon 1;			Ploor dui 1	T ution to 14	• 1+		rion (*	1.	
		19-C-0038 - (02/21/2020)	An Open- label, First-in- human, Multi- center Study to Evaluate the Safety, Tolerability, Telerability, Telerability, et as and Antioexa and Antioexa and 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 Pharmaceutic ais	No	NIHCC	2	0					
Showing	I to 1 of	1 entries													Previous	s 1 Next

CCR

### **NIH Participant Age Data Report**

NIH Participant Age Data Report shows the list of patient age, gender, race, ethnicity, site data for all patients registered in a protocol.

It accepts three parameters.

- Protocol Number (Mandatory)
- Start Date
- End Date (Defaults to today)

#### **NIH Participant Age Data Report**

Protocol :	Select Protocol	•	Start Date:	ē		End Date: 5/17/2024	ē
	Protocol is required					Defaults to today	
				Generate Repo	ort		

The report has following columns.

- Protocol
- Sequence Number
- Gender
- Race(s)
- Ethnicity
- Age
- Age Units
- Site

See below sample report. NIH Participant Age 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.

			Gene	rate Report		PDF	Excel
NCI		N	сом IH Participant /	FIDENTIAL Age Data Repo	rt		c
		<b>Q</b> Search for Da	ta				
Protocol	Sequence Number ↓	Race(s)	Ethnicity 1	Gender	Age	Age Unit	Site
04-C-0165		White	Not Hispanic or Latino	Male		Years	NIH site
04-C-0165		Other	Hispanic or Latino	Male		Years	NIH site
04-C-0165		White	Not Hispanic or Latino	Male		Years	NIH site
04-C-0165		White	Not Hispanic or Latino	Female		Years	NIH site
04-C-0165		White	Not Hispanic or Latino	Male		Years	NIH site
04-C-0165		White	Not Hispanic or Latino	Male		Years	NIH site

### **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.

	Non-	English Language	e Consents Report		
Start Date	Ē		End Date 10/17/2023		
			Please pick end date to filter the report. Defaults to today		
		Generate Report		PDF	Excel

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.

		C	touay		PDF Excel	
וכ		Non-E	CONFIDENTIAL	sents Report		CCR
		Q Search for Data				
Protocol	First Name	Last Name	MRN	Consent Language	Consent Date	
01-C-0129				Spanish	08/14/2023	
19-C-0016				Chinese Traditional	11/26/2019	
10-C-0086				Chinese Traditional	12/06/2019	
00-C-0074				Russian	12/14/2021	
17-C-0174				Spanish	09/13/2021	
17-C-0049				Chinese Traditional	07/19/2018	
10-C-0086				Chinese Traditional	07/19/2018	

### **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.

NCI	OCD Consent Lang CONF	uage Summary Report	CCR
	Q 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 Samphausen, 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)		<b>•</b>	
	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.

	C	ONFI	DENTI	AL		
Open	Protocols	for	the	VA	Repo	rt

		Q Filter Dat	а				
New	Protocol	Ы	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	lmmunotherap y Recruitment Center(IRC@ni h.gov)	NCT03412877
Developmental Therapeutics Branch	20-C-0149	Thomas, Anish	Phase II Trial of Olaparib (LYNPARZA) plus Durvalumab (IMFINZI) in EGFR-Mutated Adenocarcino mas that Transform to Small Cell Lung	Clinical Trial Phase II	Open - Recruiting	Linda Sciuto(linda.sci uto@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

NCI

• End Date (defaults to Today)

### Patient Cohort and Arm Report

Protocol :	Select Protocol		•
	Protocol is <b>required</b>		
Start Date:			
End Date:	8/31/2021		
	End date to filter the report. Defaults to today		
	Generate Report		

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

• Subject MRN

CCR

- 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.

		G	ienerate l	Report												PDF E	ixcel
NCI										CONFIDENTIA	L						CCF
N	MRN	Last Name	Fi Na	irst ame	DOB	Search for d Sequence Number	ata Cohort	Arm	Registering Branch	Consent ↑ Date	Registration Date	On-Study	Off-Study	Off-Study Reason	Off- Treatment	Off-Treatment Reason	t
	7	1		D	0(	437	1/Cohort 1	1		11/03/2020	11/04/2020	11/03/202	0				
	5	(			0.	436	1/Cohort 1	1		10/15/2020	10/15/2020	10/15/202	0				
	Ð	I	२		1	431	1/Cohort 1	1		10/05/2020	10/06/2020	10/05/202	0				
	þ				1	430	1/Cohort 1	1		09/25/2020	09/29/2020	09/25/202	0				
	2	(	:		1(	429	1/Cohort 1	1		09/23/2020	09/23/2020	09/23/202	0 08/02/2021	Withdrew Consent			
	4	(		ES	0'	428	1/Cohort 1	1		08/19/2020	09/21/2020	08/19/202	0				
	2				0'	422	1/Cohort 1	1		07/28/2020	07/30/2020	07/28/202	0				
	3	:			0'	421	1/Cohort 1	1		07/24/2020	07/27/2020	07/24/202	0				
	D	1		EL	0:	420	1/Cohort 1	1		07/29/2020	07/29/2020	07/29/202	0				
	2	:			0:	419	1/Cohort 1	1		07/24/2020	07/27/2020	07/24/202	0				
													ltems per pa	ge: 10 💌	1 – 10 of 455	I< < >	>

### **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)

### Patient Enrollment Information Report

Protocol :	Select Protocol		 •
	Protocol is required		
Start Date:		Ē	
End Date:	8/31/2021		
	End date to filter the report	. Defaults to today	
	Generate Report		

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.

																		PDF	Excel
NCI									Patient Enrollme	CONFIDENTIAL	eport(00-C-0074)								
<b>6</b>		First				Search for	data						0#	Off-	0#	Off-		Desistantias	0
Number	Last Name	Name	MRN	DOB	Age	Age at Enrollment	Sex	Race	Protocol Branch	Registering Branch	Registering PI	On-Study	Study	Study Reason	Treatment	Treatment Reason	A/D	Date	↓ Date
454			. 4	1	66	66	Male	Black or African American	Radiation Oncology Branch			08/10/2021					А	08/10/2021	08/09/2021
455			3	C	61	61	Male	White	Radiation Oncology Branch			08/10/2021					А	08/10/2021	08/10/2021
453			7	1	74	74	Male	White	Radiation Oncology Branch			08/04/2021					А	08/04/2021	08/04/2021
452			7	1	61	61	Male	Unknown	Radiation Oncology Branch			07/15/2021					А	07/15/2021	07/14/2021
451			٤	c	49	48	Femal	e White	Radiation Oncology Branch			06/21/2021					А	06/22/2021	06/21/2021
450			1	c	66	66	Male	White	Radiation Oncology Branch			05/06/2021					А	05/06/2021	05/06/2021
449			٤	1	69	69	Femal	e White	Radiation Oncology Branch			05/05/2021					А	05/05/2021	05/05/2021
448	IG		7	c	76	75	Male	White	Radiation Oncology Branch			04/23/2021					А	04/23/2021	04/23/2021
447			7	C	61	61	Male	White	Radiation Oncology Branch			04/23/2021					А	04/23/2021	04/22/2021
446			7	C	79	79	Male	White	Radiation Oncology Branch			03/25/2021					А	03/25/2021	03/25/2021
														Ite	ems per page: 10	• • 1	- 10 of 45	55  <	< > >I

### **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)
#### Patient List and Other Participated Protocols Report

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

Branch:	Select Branch		•
Protocol :	00-C-0074	× •	
	Generate Report Print		

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.

Print

ICI						CONFIL	DENTIAL					CCF
			Pa	atient Li	st and Oth	er Parti	cipated Pr	otocols Re	eport			
					Reporting	Period En	ding: 09/01/2	021				
					Report g	enerated on: 09	01/2021 12:38 PM					
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:Radiati	on Oncology Branch											
	Camphausen, Kevir											
			. L	L (	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		
				1	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		
			,	ID	Alive		00-C-0074	10/20/2003	10/20/2003	10/20/2003		
			2	,	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 0 0120	02/18/2000	02/18/2000	02/22/2000	05/11/2000	

# **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

						Patient	CONFIDENTIAL List Report-	- 00-C	-0074					
L	Protocol: 00-C-0074 PI: Camphausen, Ke .ong Title: Evaluation of Lat	evin te Effects an	nd Natural Histo	ory of Disease in Patients Treated wit	th Radiotherapy									
				Search for data										
atient ID	Sequence Number 🕁 La	ast Name	First Name	Institution	On-Study Date	Consent Date	Registration Date	Eligible	Off-Treatment Date	Off-Treatment Reason	Off-Study Date	Off-Study Reason	Date of Birth	Date of Death
	455			National Institutes of Health Clinical Center	08/10/2021	08/10/2021	08/10/2021	Y					6	
	454		EL	National Institutes of Health Clinical Center	08/10/2021	08/09/2021	08/10/2021	Y						
	453			National Institutes of Health Clinical Center	08/04/2021	08/04/2021	08/04/2021	Y						
	452		1	National Institutes of Health Clinical Center	07/15/2021	07/14/2021	07/15/2021	Y						
	451		A	National Institutes of Health Clinical Center	06/21/2021	06/21/2021	06/22/2021	Y					6	
	450		D	National Institutes of Health Clinical Center	05/06/2021	05/06/2021	05/06/2021	Y					0	
	449			National Institutes of Health Clinical Center	05/05/2021	05/05/2021	05/05/2021	Y						
	448			National Institutes of Health Clinical Center	04/23/2021	04/23/2021	04/23/2021	Y					0	
	447		N	National Institutes of Health Clinical Center	04/23/2021	04/22/2021	04/23/2021	Y					0	
	446			National Institutes of Health Clinical Center	03/25/2021	03/25/2021	03/25/2021	Y					(	

### 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)

Protocol: 00-C-0074 × • Start Date: End Date: 8/31/2021 Constrained and to filter the report. 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

										PDF Excel	
NCI					Patio	CONFIDENTIAL	port				CCR
					Fallel	iii Oli-Sluuy ke	port				
			Search for data						_		
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	
									Items per page: 10 👻 1	- 10 of 72  < < >	>

**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

NCI	CONFIDENTIAL Patient Off-Study Confirmation Report									
	Protocol #: Principal Investigator: Status:	03-C-0304 Wilson, Wyndham Open - For Data/Specimen Analysis	Category: Phase: Branch:	Interventional or Clinical Trial Clinical Trial Phase II Lymphoid Malignancies Branch						
		It is confirmed that all patients reg	gistered to this study have an off-stud	ly date and off study reason						

### All the Patients are not taken Off-Study

NCI	CCR			
	Protocol #: 02-C-0159 Principal Investigator: Status: Open - Recruiting	Category: Phase: Branch:	Observational Study Urologic Oncology Branch	
	It is not confirmed that all patients reg any patient(s) if all patients are off-stu			
No patients enrolled o	onto the study			
NCI		CONFIDENTIAL		CCR
		Patient Off-Study Confirmation	n Report	
	Protocol #: 000021 Principal Investigator: Status: Open - Recruiting	Category Phase Branch	Interventional or Clinical Trial Clinical Trial Phase III 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)

# **Patient Off-Study Entered Report**

Select protocol and Off-Study entered Start date and end date filters. Enrollments without Off-Study entered date will be included along with enrollments matching start and end date filter criteria

Protocol :	Select Protocol	<b>•</b>	Start Date:		End Date: <b>4/21/2023</b>	
	Protocol is required		Off-Study Entered Start Date	e	Off-Study Entered End Date Defaults to today	
			Generate	Report		

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.

NCI

#### CONFIDENTIAL

# Patient Off-Study Entered Report

0	Search	for	Data
<u> </u>	Search	101	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
08C007 9			04/09/ 2008	04/10/ 2008	04/09/ 2008				11/29/ 2017	Death	Patient	03/12/ 2021
08C007 9			02/12/ 2015	02/19/ 2015	02/12/ 2015				04/26/ 2017	Death	Pt Q 1- 9	03/12/ 2021
08C007 9			08/01/ 2013	08/01/ 2013	08/01/ 2013				10/09/ 2016	Death		03/12/ 2021
08C007 9			08/10/ 2009	08/12/ 2009	08/10/ 2009				07/03/ 2016	Death		03/12/ 2021
08C007 9			01/11/ 2016	01/11/ 2016	01/11/ 2016				06/18/ 2016	Death	Neurofi bromat osis type 1 (NF1)	03/12/ 2021
08C007 9			10/27/ 2009	10/27/ 2009	10/27/ 2009				12/07/ 2015	Death	Patient	03/12/ 2021
08C007 9			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)

	Patient On-Study Report												
Select protocol and Start date and end date filters. Enrollments without On-Study entered date will be included along with enrollments matching start and end date filter criteria													
Protocol :	Select Protocol	<b>•</b>	Start Date:			End Date: <b>2/7/2023</b>							
	Protocol is required		On-Study Start Date			On-Study End Date. Defau	ults to today						
Generate Report													

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.

			_				G	ienerate R	eport					PDF	Excel
NCI							CONFID	Study R	eport						CCR
				۹	Search for Data										
Protocol Number	Enrollment Id	Branch	Patient		Registering Pl	Registering Branch	Registered User	MRN		Date Of Birth	Date Of Death	Consent ↓ Date	Registration Date	On Study Date	Off- Treatment Date
01-C-0129	125583	Genitourinary Malignancies Branch			Roschewski, Mark	Lymphoid Malignancies Branch	Kim Johnson					10/12/2023	10/12/2023	10/12/2023	
01-C-0129	125577	Genitourinary Malignancies Branch			Hassan, Raffit	THORACIC & GI MALIGNANCIE S BRANCH	Cathy Wagner					09/27/2023	09/27/2023	09/27/2023	
01-C-0129	125576	Genitourinary Malignancies Branch			Madan, Ravi	Genitourinary Malignancies Branch	Amy Hankin					09/27/2023	09/27/2023	09/27/2023	
01-C-0129	125565	Genitourinary Malignancies Branch			Patel, Krishnan	Radiation Oncology Branch	Debbie Nathan					09/27/2023	09/27/2023	09/27/2023	
01-C-0129	125555	Genitourinary Malignancies Branch			Patel, Krishnan	Radiation Oncology Branch	Debbie Nathan					09/27/2023	09/27/2023	09/27/2023	
01-C-0129	125537	Genitourinary Malignancies Branch			Chen, Alice	Office of the Director - DCTD	Mary Jane Ong					09/26/2023	09/26/2023	09/26/2023	
01-C-0129	125533	Genitourinary Malignancies Branch			Chen, Alice	Office of the Director - DCTD	Nancy Moore					09/26/2023	09/26/2023	09/26/2023	
01-C-0129	125528	Genitourinary Malignancies Branch			Hernandez, Jonathan	Surgical Oncology Program	Kate Smith					09/25/2023	09/25/2023	09/25/2023	

# **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)

			Pat	ient Re-Conse	nt Report
Branch:					*
Protocol :		*			
	Generate Report				

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



# **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.

#### NCI

#### CONFIDENTIAL Protocol Accrual Status

		Search for protocols								
Branch	Protocol 1	<sup>▶</sup> 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
					Item	ns 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

PDF

Excel

CCR

			Protocol Cohort Arm Report
Branch: X	Developmental Therapeutics Branch	× <del>•</del>	Generate Report

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

	Protocol Embedded Agreement Report													
Protocol :	Select Protocol Protocol is required	•												
			Run Report											

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

		Sea	rch for Data				
MRN	First Name		Last Name	Sequence Number $\downarrow$	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

	Protocol Embedded Agreement Summary Report														
Protocol :	Select Protocol Protocol is required	•													
			Run Report												

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.

NCI

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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)

End Date:	9/1/2021	
	Please pick end date to filter the report. Defaults to today	
Protocol:	× 10-C-0025 × 👻	
	Generate Report Print	

And the report has the following columnsProtocol

- PI Full Name
- Accrual Ceiling

# Randomized Protocol Accrual Ceiling Report

- Arm Name
- Arm Description
- 1<sup>st</sup> 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 CCI Randomized Protocol Accrual Ceiling Report														
			Rar	ndomized Pro	otocol Accr	ual Ceilir	ng Report								
	Reporting Period Ending: 09/01/2021 Report generated or: 09/01/2021 11:48 AM														
Protocol	ol PI Ceiling Arm Name Arm Description 1st On-Study Date Q3 2020 Q4 2020 Q1 2021 Q2 2021 Cu														
10-0-0025	kreitman, Kobert	74 Arm 1 Rituximab +bendamustir mg/m2 for init tolerability stu (closed)		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)

	Randomized Protocol Patients Report
Protocol: Hide Non-Randomized Patients:	10-C-0025 × •
	Generate Report

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

			Generate	Report										PDI		cel
NCI								СС								
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					
												ltems per p	bage: <u>10 ▼</u>	1 – 10 of 55	< < >	>1

# **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)

Regist	tration Report	
Branch:	Select Branch	•
Protocol :	× 00-C-0074 × 🔻	
l	Generate Report	

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

	C	Generate	Report																PD		Excel
NCI	CONFIDENTIAL Registration Report Report generated on: 10/13/2023 12:14 PM																			CCR	
Branch 个	Protocol	First Name	Last Name	MRN	Q Date of Birth	Date of Death	for Data	Race	Sex	Registering Pl	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
Genitourin ary Malignan cies Branch	01-C-0129				09/10/19 48	09/21/20 21	Not Hispanic or Latino	White	Male	Abi- Jaoudeh, Nadine	Division of Cancer Treatment and Diagnosis	Shari Ghajar	17644	Adrenoco rtical carcinom a, NOS	10/26/20 20	10/26/20 20	10/26/20 20			09/21/20 21	Death
Genitourin ary Malignan cies Branch	01-C-0129				09/20/19 55	11/27/20 21	Not Hispanic or Latino	White	Female	Alewine, Christine	Medicine Clinical	Shari Ghajar	17635	Liver and hepatobili ary cancer, NOS	10/21/20 20	10/22/20 20	10/21/20 20			09/14/20 20	Complete d Study
Genitourin ary Malignan cies Branch	01-C-0129				11/09/19 66		Not Hispanic or Latino	White	Male	O'Sullivan Coyne, Geraldine	Division of Cancer Treatment and Diagnosis	Shari Ghajar	17622	Colon Cancer	10/19/20 20	10/20/20 20	10/19/20 20			12/07/20 20	Other
Genitourin ary Malignan cies Branch	01-C-0129				11/30/19 47		Not Hispanic or Latino	White	Female	Nilubol, Naris	Surgical Oncology Program	Shari Ghajar	17612	Von Hippel- Lindau syndrome	10/15/20 20	10/19/20 20	10/15/20 20			10/20/20 20	

# **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

	Theradex Registration List									
Please select either	r Protocol or Sponsor Number but not both. If you select both Sponsor Number will be igno	ored								
Protocol:	Select Protocol	•	Sponsor:	Select Sponsor Number	<b>*</b>					
		Gene	rate Report							

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 Theradex Registration	List		CCR
	Theradex #: 10398 Protocol: 000081 Protocol Description: A Phase 2 Study of Anti-PD-L1 A Branch: Division of Cancer Treatment an Principal Investigator: Chen, Alice	ntibody (Atezolizumab) in Ch d Diagnosis	ondrosarcoma and Clear Cell Sarcoma			
Primary ID	Search for	data 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  <	< > >1

# 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.

Summary	
Summary	
Name	
Email Address*	
Description	
Attach file	
Attach hie	Choose Files No file chosen
<ol> <li>We've current unless this is r</li> </ol>	ly got you logged in as Christo Andonyadis. This feedback will be created using this use not you.
	Include data about your current environment, like the browser and page URL. This has a second page URL.
	us understand your teedback better.

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 <u>https://pres.ccr.cancer.gov</u> 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 <u>https://pres.ccr.cancer.gov</u> and click on pad lock icon. Then click on **Clear cookies and site data.** 

😜 🧿 Home   PRES	× +
$\div$ $\rightarrow$ G	○ A = https://pres.ccr.cancer.gov
<b>PRES</b> Patients	Site information for pres.ccr.cancer.gov
	Connection secure
	Clear cookies and site data
	* Patients
	=- i dicito

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

?	<b>Removing Cookies and Site Data</b> Removing cookies and site data may log you out of websites. Are you sure you want to remove cookies and site data for <b>cancer.gov</b> ?							
	Cancel Remove							

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

# Safari

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



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

Privacy												
ණ	C	····/·	P	Q	8	<b>B</b>		$\bigcirc$	్రా	: : : : : : : : : : : : : : : : : : :	×	
General	Tabs	AutoFill	Passwords	Search	Security	Privacy	Websites	Profiles	Extensions	Advanced	Developer	Feature Flags
Website tracking: 🗹 Prevent cross-site tracking												
	Hide IP address: 🗹 Hide IP address from trackers											
Your IP address can be used to determine personal information, like your location. To protect this information, Safari can hide your IP address from known trackers. Learn more												
Private Browsing: 🗌 Require password to view locked tabs												
			Website	data: N	Nanage W	/ebsite Da	ata					
Advanc	ed Settin	ngs								About	Safari & Pri	vacy ?

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

	Privacy	
	Q cancer.gov	
	These websites have stored data that can be used to track your browsing. Removing the data may reduce tracking, but may also log you out of websites or change website behavior.	
Advanced Se	Cache, Cookies, and Local Storage	ivacy ?
		_
Choose an o		
Colort	Remove All Done	

- 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.