

# PATIENT REGISTRATION AND ENROLLMENT SYSTEM (PRES) USER GUIDE

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*VERSION 2.0*

# PRES User Guide

## PRES User Guide

### DOCUMENT REVISIONS

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03/02/2018	0.1	Initial Draft
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# PRES User Guide

## 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 Mozilla Firefox, Google Chrome, and Apple Safari. It has been developed by the Office of Information Technology, CCR, NCI, NIH, that also supports and updates the system.

## GETTING TO PRES

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

## LOGIN SCREEN

Users are prompted to login by entering a User Name and Password (NIH user name and password).

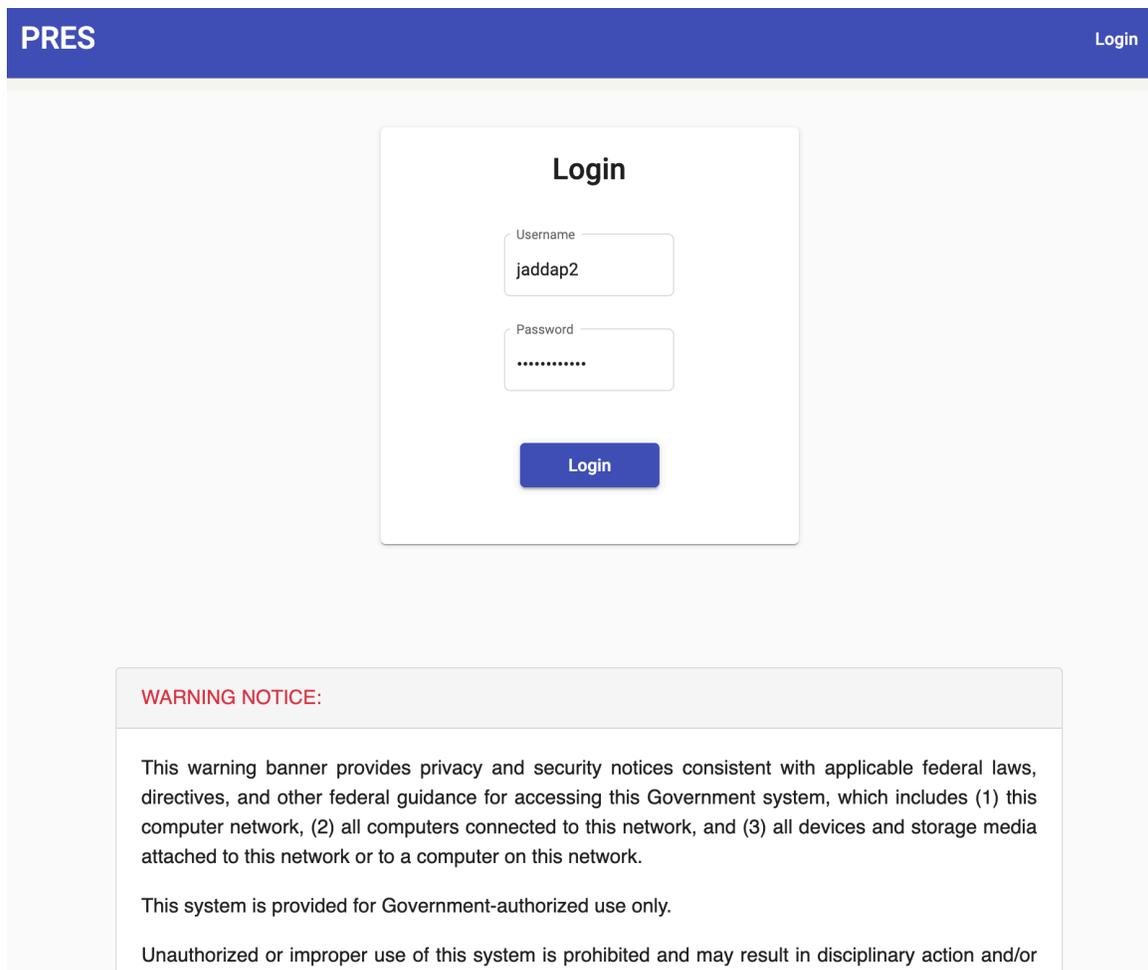


FIGURE 1 - LOGIN SCREEN

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If you are not able login or you receive an error message, please use the “Need assistance? Click here!” button located at the lower left part of the home page. This will display the [Issues and Feedback](#) menu.

### 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.

After entering a valid Username and Password, the system will redirect you to the home page.

## HOME PAGE

The tiles on the home page will enable the user to access different sections based on the user’s privileges. The tiles that appear in the figure below belong to a System Admin. Other users will not be able to see all sections.

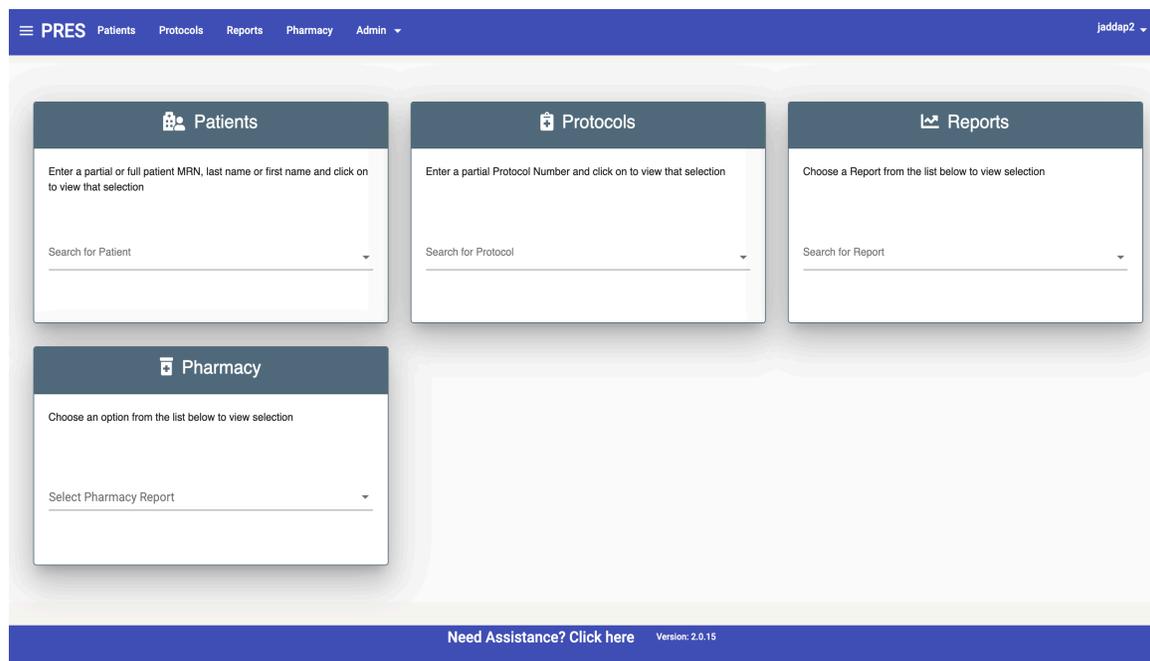


FIGURE 4 – ADMIN HOME PAGE

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

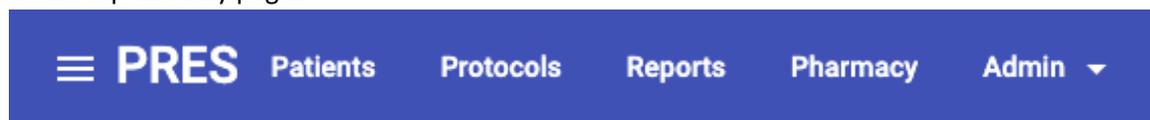


FIGURE 5 – MENU BANNER

The other links provide shortcuts to each page in the application.

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

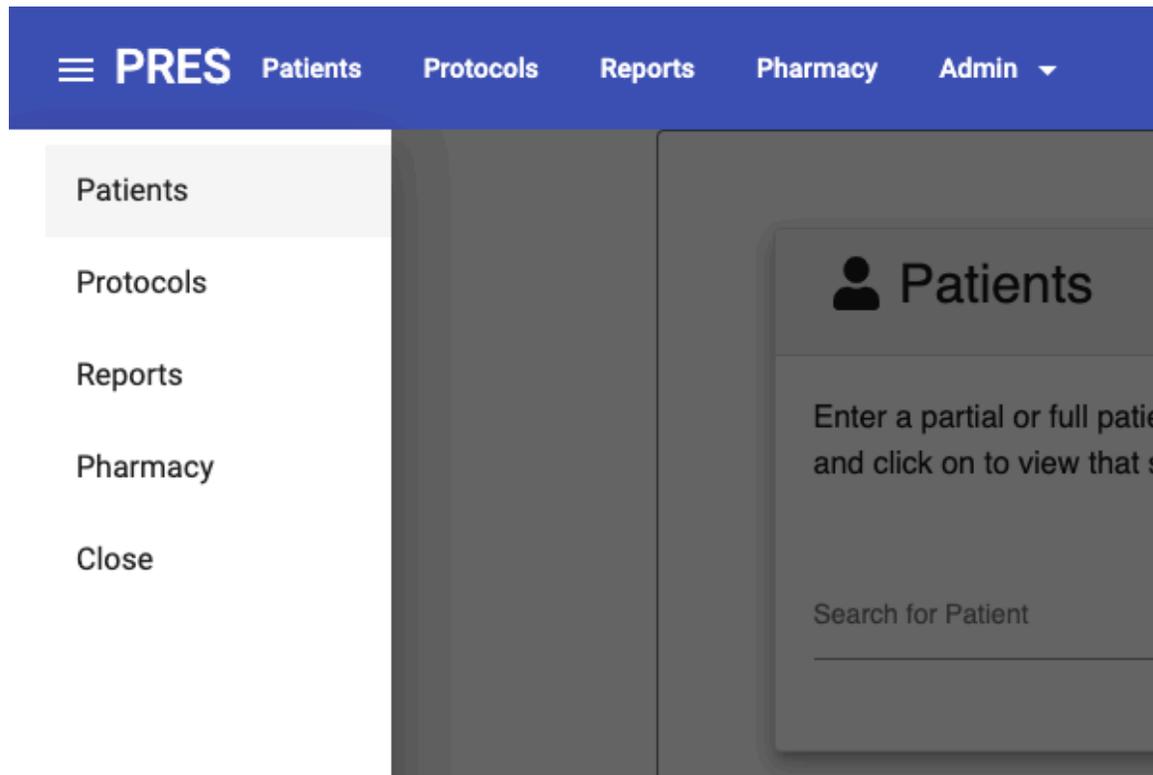


FIGURE 6 – SIDE MENU

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

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

# PRES User Guide

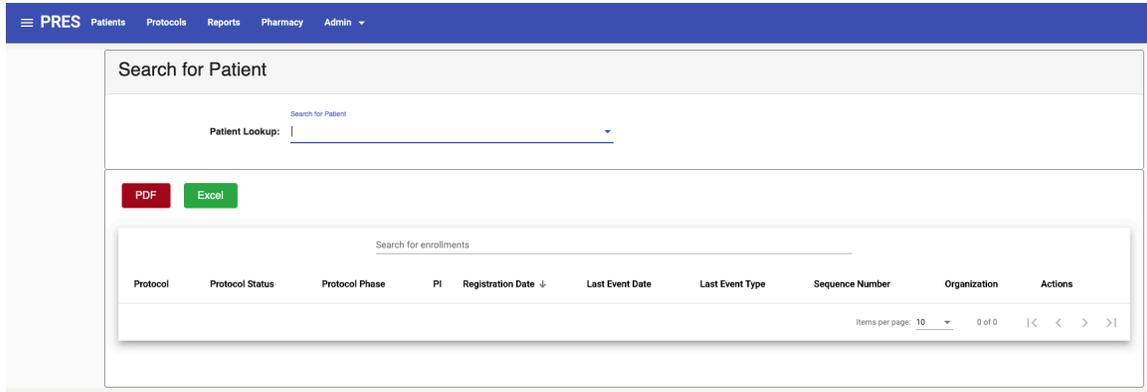


FIGURE 7 – MATCHING PATIENTS IN PRES

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

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

FIGURE 7 – CRIS PATIENT NOT IN PRES

Selecting a CRIS patient will import that patient into PRES.

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

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

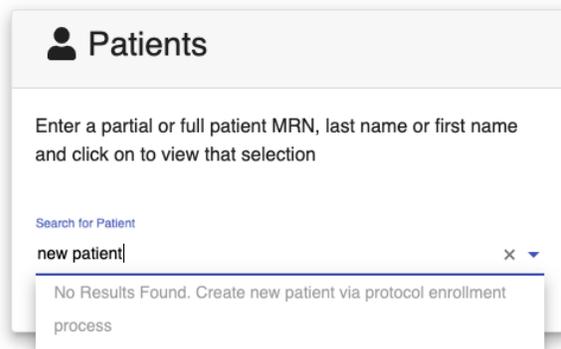


FIGURE 8 - ADDING A PATIENT

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Selecting a patient will open the [Patient View](#)

### ADDING AN OUTSIDE PATIENT

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

**Protocol Selection**

Number: [20-C-0103](#)

Description: Investigation of the B- and T-cell repertoire and immune response in patients with acute and resolved COVID-19 infection

Category: Observational Study

Version: B

Is Screening: No

Is Two-step: No

Multi-Institutional: Yes

Randomized: No

Organization: Medstar Montgomery Medical Center ✕ ▾

**Patient Details**

Search for Patient

Patient Lookup: 838777483 ✕ ▾

838777483 [NOT FOUND - Create New]

**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:

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The screenshot shows a modal window titled "Add New Patient" with a close button (X) in the top right corner. The form contains the following fields:

- Organization \*: Medstar Montgomery Medical Center
- First Name \*: John
- Last Name \*: Doe
- MRN \*: 838777483
- Date Of Birth \*: 1/31/1973 (with a calendar icon)
- Gender \*: Female (dropdown menu)
- Race \*: White (dropdown menu)
- Ethnicity \*: Not Hispanic or Latino (dropdown menu)

At the bottom right of the form, there are two buttons: "Close" and "Create Patient" (with a plus icon).

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.

## PRES User Guide

Patient: T [ ] T

Full Name: [ ] [Change Patient](#)

Medical Records: [ ] , National Institutes of Health Clinical Center  
[Add Medical Record](#)

DOB: [ ] 09/03/19

Gender: Male

Race: White

Ethnicity: Not Hispanic or Latino

Participating Protocols [Register New](#)

[PDF](#) [Excel](#)

Search for enrollments

Protocol	Protocol Status	Protocol Phase	PI	Registration Date	Last Event Date	Last Event Type	Sequence Number	Organization	Actions
<a href="#">10-C-0025</a>	Open - Recruiting	Clinical Trial Phase II	Robert, Kreitman	08/10/2011	08/10/2011	Fully Eligible	20	National Institutes of Health Clinical Center	<a href="#">View</a>
<a href="#">10-C-0066</a>	Open - Recruiting		Robert, Kreitman	09/09/2010	09/09/2010	Fully Eligible	29	National Institutes of Health Clinical Center	<a href="#">View</a>

Items per page: 10 1 - 2 of 2 |< < > >|

FIGURE 11 - PERSON VIEW

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

## ADD MEDICAL RECORD

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

### Add MRN and Institution ✕

Select Organization ▼

---

MRN \*

---

Close
Save

FIGURE 12 - ADD OR MODIFY MRN

## 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).

Enrollment View: TEMMER, ROBERT on 10-C-0025 W

---

**Patient Details**

Full Name:  IT

Medical Records:  37, National Institutes of Health Clinical Center

DOB:  09/03/19

DOD: --

**Protocol Details**

Number: # 10-C-0025 W #

Name:  10-C-0025

PI:  Kreitman, Robert

**Interventional**

Model: Crossover

---

**Assignment Details**

Sequence Number: 20 [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 response may crossover to the other arm.)

**Stratification Group:** Purine: Purine Sensitive

**Allocated Slot:** 53

**Arm Details:** Arm 3 Rituximab + Bendamustine (at the tolerated dose)

**Disease Code:** Hairy Cell Leukemia [Edit](#)

---

**Events of Significance**

Type of Date:  Select Date Type \*

Date:  7/1/2020 📅

Comments:  Enter your comments here ↵

Add Event

Date	Date Type	Comments	Actions
08/10/2011	Consent	#53_Sensitive	<a href="#">Edit</a>
08/10/2011	Registration	#53_Sensitive	
08/10/2011	Fully Eligible	#53_Sensitive	<a href="#">Edit</a>

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FIGURE 13 - ENROLLMENT VIEW

By clicking in the patient name the user will be redirected to the [Patient View](#), clicking in the protocol number will show the [Protocol View](#).

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

While editing the Sequence Number the next available sequence number is displayed along with a link to Use This Number.

Sequence Number:  Next Available Sequence Number: 65 [Use This Number](#)

Show used sequence numbers for 10-C-0025

Close Save Changes

FIGURE 14 – SEQUENCE NUMBER

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

Sequence Number:  Next Available Sequence Number: 65 [Use This Number](#)

Hide used sequence numbers for 10-C-0025

Search

Patient	Consent Date	Sequence Number
L	05/08/2020	64
B	03/23/2020	63
G	03/17/2020	62
G	09/23/2019	61
N	09/16/2019	60
L	05/13/2019	59
G	04/03/2019	58
J	03/22/2019	57
D	03/20/2019	56
D	03/07/2018	55

Items per page: 10 1 - 10 of 64 |< < > >|

Close Save Changes

FIGURE 15 – USED SEQUENCE NUMBERS

## SEARCHING AND SELECTING A PROTOCOL

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

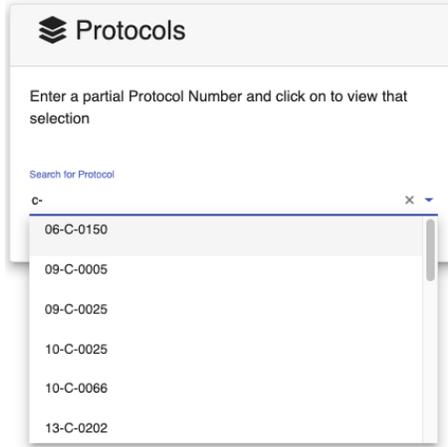


FIGURE 16 - PROTOCOL SEARCH

Clicking on a protocol will open the [Protocol View](#) page.

## PROTOCOL VIEW

The protocol view page displays the available information for the protocol. For a detail of the available information please see the figure below:

**Protocol: 10-C-0025**

**Number:** # 10-C-0025 [Change Protocol](#)

**Branch:** Laboratory of Molecular Biology

**Status:** Open - Recruiting

**Randomized:** Yes

**PI:** Robert, Kreitman

**Masking:** Open

**Description:** Randomized Phase II Trial of Rituximab with Either Pentostatin or Bendamustine for Multiply Relapsed or Refractory Hairy Cell Leukemia

**Multi-institutional:** Yes [View - \(0 Sites\)](#)

**Ceiling:** 74 (-16 Open)

**ProtocolCategory:** Interventional or Clinical Trial

**Is Screening:** No

**Collect Registering PI:** No

**Is two-step:** No

**Cohorts:** 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)  
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 response may crossover to the other arm.  
Cohort 3 (Dose expansion; non-randomized): Up to 4 evaluable pts with HCL, HCLv or unmut. IGHV4-34+ HCL/HCLv with prior non-response to either study therapy not to be randomized and to be enrolled to Arm 3 or 4

**Arms:** 4 [View](#)

**Enrolled Patients** [Register New](#)

[PDF](#) [Excel](#)

Search for data

Full Name	MRN	Registration Date ↓	Last Event Date	Last Event Type	Sequence Number	Organization	Actions
[Redacted]	7	3	05/08/2020	05/08/2020	Fully Eligible	64	National Institutes of Health Clinical Center <a href="#">View</a>
[Redacted]	8	1	03/23/2020	05/08/2020	Off-Treatment	63	National Institutes of Health Clinical Center <a href="#">View</a>
[Redacted]	7	1	03/17/2020	03/17/2020	Fully Eligible	62	National Institutes of Health Clinical Center <a href="#">View</a>
[Redacted]	7	0	09/23/2019	09/23/2019	Fully Eligible	61	National Institutes of Health Clinical Center <a href="#">View</a>
[Redacted]	7	8	09/16/2019	09/16/2019	Fully Eligible	60	National Institutes of Health Clinical Center <a href="#">View</a>
[Redacted]	7	1	05/13/2019	05/13/2019	Fully Eligible	59	National Institutes of Health Clinical Center <a href="#">View</a>
[Redacted]	3	1	04/03/2019	04/03/2019	Fully Eligible	58	National Institutes of Health Clinical Center <a href="#">View</a>
[Redacted]	7	7	03/22/2019	02/10/2020	Off-Treatment	57	National Institutes of Health Clinical Center <a href="#">View</a>
[Redacted]	7	8	03/20/2019	03/20/2019	Fully Eligible	56	National Institutes of Health Clinical Center <a href="#">View</a>
[Redacted]	7	1	03/07/2018	10/08/2019	Off-Study	55	National Institutes of Health Clinical Center <a href="#">View</a>

Items per page: 10 1 - 10 of 90 |< >|

FIGURE 17 - PROTOCOL VIEW

## 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 Patients” 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 by clicking on the “Search for a Protocol” field and entering at least 2 characters which will open a drop down list of protocols already in PRES matching those characters:

The screenshot shows a web form titled "Register Patient". It is divided into two main sections: "Protocol Selection" and "Patient Details".

- Protocol Selection:** Contains a search field labeled "Protocol:" with the placeholder text "Search for a Protocol".
- Patient Details:** Contains several fields:
  - Full Name: A text input field with a blue cursor and a small "Y" icon.
  - Medical Records: A field showing a camera icon, a number "7", a dropdown arrow, and the text "National Institutes of Health Clinical Center".
  - DOB: A date input field showing "04/06/19".
  - Gender: "Male".
  - Race: "White".
  - Ethnicity: "Not Hispanic or Latino".

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, 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.

The screenshot shows the "Register Patient" form with a protocol selected. The "Protocol Selection" section shows "Protocol: 13-C-0202" with a close button (X) and a dropdown arrow. Below this, a grey box displays the following details:

- Number: 13-C-0202
- Description: Tissue Procurement and Natural History Study of Patients with Malignant Mesothelioma and Other Mesothelin Expressing Cancers
- Version: J
- Is Screening: No
- Is Two-step: No
- Multi-Institutional: No
- Randomized: No

Below the grey box, the "Organization: National Institutes of Health Clinical Center" is listed. The "Patient Details" section is visible at the bottom but contains no data.

FIGURE 19 – REGISTER PROTOCOL TO PATIENT

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# REGISTER PATIENT FROM PROTOCOL PAGE

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

**Register Patient**

---

**Protocol Selection**

Number: 10-C-0025

Description: Randomized Phase II Trial of Rituximab with Either Pentostatin or Bendamustine for Multiply Relapsed or Refractory Hairy Cell Leukemia

Version: W

Is Screening: No

Is Two-step: No

Multi-Institutional: Yes

Randomized: Yes

Organization: National Institutes of Health Clinical Center x ▾

---

**Patient Details**

Patient Lookup: Search for Patient ▾

**FIGURE 20 - REGISTER PATIENT TO PROTOCOL PAGE**

Since the protocol is already selected the user must use the “Search for a Patient” field to select a patient.

## REGISTRATION

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.

**Miscellaneous**

Disease: Select Disease ▾

---

**Consent**

Date of Consent: 7/1/2020 📅

Consent By Phone:

---

**Eligibility Status**

Eligible for Treatment

Not Eligible

Register

**FIGURE 21 - REGISTER PATIENT TO PROTOCOL PAGE**

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

Eligibility Status

Eligible for Treatment  
 Not Eligible

Fully Eligible Date: 7/1/2020

Assignment Details

Search for a Cohort

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.

Eligibility Status

Eligible for Treatment  
 Not Eligible

Fully Eligible Date: 7/1/2020

Assignment Details

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)

Search for a Cohort Arm

Cohort Arm(s):

- 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)

FIGURE 23 – SELECT ARM

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

### TWO STEP PROTOCOLS

For two step protocols the Eligibility Status includes the Eligible for Screening option.

Eligibility Status

Eligible for Screening  
 Eligible for Treatment  
 Not Eligible

FIGURE 24 – TWO STEP

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

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Checking Not Eligible will prompt the user to confirm that the patient should be taken off study.

### Eligibility Status

- Eligible for Treatment  
 Not Eligible

Take Off-Study

FIGURE 25 – NOT ELIGIBLE

## RANDOMIZATION

For randomized cohorts the arm will be assigned as per the randomization sheets and blinded as necessary.

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 response may crossover to the other arm.)

Stratification Group: Purine; Purine Sensitive

Allocated Slot: 76 [Skip Slot](#)

Comments \*

[Save](#) [Cancel](#)

Arm Details: Arm 4 Rituximab + Pentostatin

FIGURE 26 - SKIP

## EVENTS OF SIGNIFICANCE

The Enrollment View shows the assignment details for a particular patient on a particular protocol.

### CROSSOVER PROTOCOLS

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.

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Events of Significance

Type of Date: Crossover

Date: Off-Study

Comments:

[Add Event](#)

FIGURE 27 - CROSSOVER

## TREATMENT PROTOCOLS

All registrations on treatment protocols have the following Events of Significance

Events of Significance

Type of Date: Off-Study

Date:

Comments:

[Add Event](#)

FIGURE 28 – OFF EVENTS

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	<a href="#">Edit</a>
03/07/2018	Registration	Refractory_NonRandomized	
03/07/2018	Fully Eligible	Refractory_NonRandomized	<a href="#">Edit</a>
10/08/2019	Off-Study	Refractory_NonRandomized	<a href="#">Edit</a>

FIGURE 29 – HISTORY OF EVENTS

## REPORTS

This option allows the user to run a series of pre-determined reports within PRES.

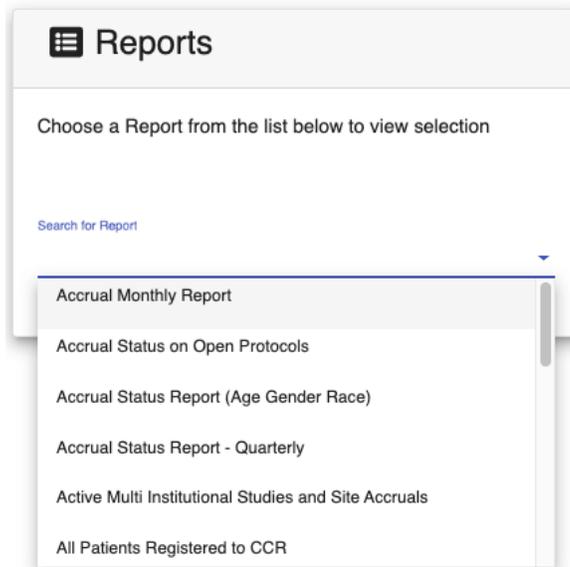


FIGURE 30 - REPORTS

Many of the reports accept parameters including Branch and Protocol.

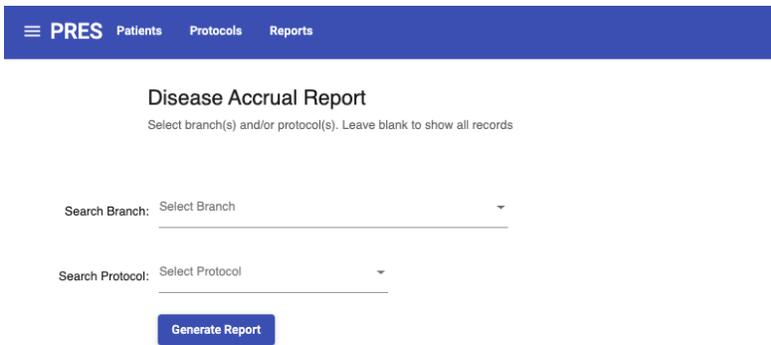


FIGURE 31 – REPORT PARAMETERS

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

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FIGURE 32 – REPORT DATE

One PRES report currently allows the user to Include CDR Data. This is the Accrual Monthly Report as it needs to include all accruals whether in PRES or CDR.

FIGURE 32 – CDR DATA

When selecting to include CDR data there is another checkbox to indicate whether the CDR data to include should be Limited to Active Treatment protocols.

Following is the result page for the Randomized Protocol Accrual Ceiling report:

Randomized Protocol Accrual Ceiling Report

End Date: 7/1/2020  
Please pick end date to filter the report. Defaults to today

Protocol: Select Protocol

Generate Report Print

Protocol	PI	Ceiling	Arm Name	Arm Description	1st On-Study Date	S1	S2	S3	S4	Cumulative Accrual
18-C	0028	74	Robert, Kreitman							
			Arm 1	Rituximab + bendamustine at 70 mg/m2 for initial tolerability study (closed)	06/23/2010	0	0	0	0	6
			Arm 2	Rituximab + bendamustine at 90 mg/m2 for initial tolerability study (closed)	11/10/2010	0	0	0	0	6
			Arm 3	Rituximab + Bendamustine (at the tolerated dose)	06/22/2011	1	0	2	0	28
			Arm 4	Rituximab + Pembrolizumab	06/24/2010	1	0	0	1	24
						2	0	2	1	64
18-C	0028	177	Robert, Kreitman							
			1	Cisplatin with Immediate Rituximab	04/06/2009	1	0	0	0	62
			2	Cisplatin with Rituximab delayed by at least 6 months after Cisplatin if and when minimal residual disease is detected	04/02/2009	0	0	0	0	59
			3	Non-randomized group receiving Cisplatin with Immediate Rituximab (before rather than after the 1st of the 5 daily doses of cisplatin on day 1)	04/22/2009	0	0	0	0	44
						1	0	0	0	165

FIGURE 33 - RANDOMIZED ONLY WITH ARMS REPORT

## ISSUES AND FEEDBACK

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.

**i** Please provide your feedback below. Any details that led up to an error will help us investigate the issue.

Summary\*

Name\*

Email Address\*

Description

Attach file  No file chosen

**i** We've currently got you logged in as **Christo Andonyadis**. This feedback will be created using this user unless this is not you.

Include data about your current environment, like the browser and page URL. This helps us understand your feedback better.

What is included in the data about my current environment?

FIGURE 34 - 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.

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