

Tips for Working in the ClinicalTrials.gov PRS Beta Site

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1. Purpose

Beginning August 28, 2024, users will land on the modernized Beta site when logging into the ClinicalTrials.gov Protocol Registration and Results Reporting System (PRS; <u>https://register.clinicaltrials.gov/</u>)

This document can help users manage the switch from PRS Classic to PRS Beta. Some items identified here may change while development of the PRS Beta site is ongoing.

2. Log into PRS Beta or PRS Classic

- To log into PRS Beta, enter your credentials and click Login.
 - The Organization is UArizona
 - To request an account or if you have forgotten your credentials, email regulatory@arizona.edu
- To log into PRS Classic, first click the links in the *Notice* on the sign in page, then enter your credentials and click *Login*.
- PRS Beta can only be used to enter and submit *registrations*.
- Use PRS Classic to enter *study documents* or *results*.

3. Switch between PRS Beta and PRS Classic

The landing page when logging into PRS is called the *home page*.

- To switch between homepages (PRS Beta/PRS Classic), click the link at the top of the page.
- Changes made on one site are seen on the other (both sites save to the same database).

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4. Navigating the PRS Beta Home Page

The PRS Beta home page opens with the Record List in Default View (displaying default columns).

Record	List—Default View
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Customize Columns

• Add columns to see more information about your records when viewing the record list.



- You can rearrange the order in which the columns appear (either use arrows, or drag-and-drop).
- Once columns are added and in the desired order, click Save.

Customize Column Display			
Select or deselect columns to view in the record list table reorder the columns in the table.	e. Click and drag	the labels or use the arrows to	
Select All 1. Check boxes	to display a	dditional columns	Selected Columns: (12)
1 Unique Protocol ID	•	I2 Record Status ❶	$\uparrow \downarrow$
a 02 ClinicalTrials.gov ID 0	\checkmark	✓ 13 Last Update	$\wedge \downarrow$
☑ 03 Overall Recruitment Status [●] ↑	\checkmark	🔲 14 Last Updated By 🕚	↑ ↓
☑ 04 Primary Completion Date IIII ↑	\checkmark	15 Record Owner	↑ ↓
🔒 05 Problems 🕚	\checkmark	☑ 16 Responsible Party	↑ ↓
2. Use arrows (or drag-and-drop) to reor	der columns	3. Click Save	Save

NOTE: To access these columns in this order again, you will need to create a "Saved View" (next page).

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Saved Views

After customizing the columns, you have the option to create a *Saved View*, which allows you to access this view again in the future.

You can create multiple saved views. Toggle between different views using the same drop-down menu.



NOTE: Saved views are stored in the computer / web browser you are using. If you sign into a different computer or use a different web browser, you will need to create new saved views.

An example of a custom Saved View (named "Status View" in this example) includes the columns *Overall Recruitment Status, Primary Completion Date*, and *Problems* on the left where they are easy to see and status is easy to assess.

Record List—	-Status View	Quick Start Guide	Problem Resolution Guide	Records - Help	Create New Record
Customize Columns	Saved Views 👻 Exp	port -		Search All Colum	ns Q
View Record	Unique Protocol ID 🗘	ClinicalTrials.gov ID	↓ Overall Recruitment ↓ Status	Primary Completion Date	Problems Results modules not included.
Clear Filters	Search Column	Search Column	Select Y	Select	Select 🗸
Open	992229s		Not yet recruiting	2025-12 Anticipated	Entry Not Completed Update Not Released
Open	992229t		Enrolling by invitation	2025-07 Anticipated	Entry Not CompletedNever Released
			Cus	stom Saved View	

Scrolling the Record List Left to Right

Some columns are hidden from view (initially on the right; scroll to see them).

If you can't locate a scroll bar, click anywhere in the list of studies then use arrow keys to scroll.

Open	992229s	1.	Not yet recruiting
Open	992229t	2. —	Enrolling by invitation



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5. Entering Registration Information in PRS Beta

• On the PRS Beta home page, click *Open* (located next to the record you want to edit), to navigate to the *Record Summary* tab.

View Record Unique Protocol	
Clear Filters	Search Column
Open	992229t

• Once you reach the Record Summary tab, click the *Protocol* tab.

Record Summary	Protocol	Study Documents	Results
Record Summary			Reset to In-Progress Approve
Use this page to see the current status of a record in the PRS and find controls for managing the record. This page also has status information for the modules in the Protocol Section, along with links for editing those modules.			

The Protocol Tab is the registration portion of the CT.gov record.

• Toggle *Edit Mode* to *Enabled* (top of the left-hand navigation pane).



• Use the left-hand pane to navigate to sections you want to edit.

Record Summary	Protocol	
Edit Mode Enabled	Protocol Summary	
Protocol Summary		
Study Identification		
Study Status	Study identification	
Sponsors and Collaborators	Organization's Unique Protocol ID	

- As you edit, you can learn more about what ClinicalTrials.gov expects for a given entry by clicking on the information symbol (1) next to each data element to open a right-hand pane with *Data Element Definitions* and *Additional Information*.
- Click *Save Changes* when finished editing a section (at the bottom of page).
- To discard edits, click *Clear Unsaved Changes*.

See <u>https://research.uahs.arizona.edu/regulatory/clinicaltrialsgov</u> for additional registration resources



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Resolving Errors

Errors are displayed at the top of the protocol section module you are editing.

Scroll down to find the data element that you need to edit to resolve the error.

Errors must be resolved before submitting information to CTgov.

Incorrect Errors and Problem Messages

You may encounter errors and/or problem messages in PRS Beta that are artifacts of PRS Beta and not true record errors.

Study Status			Definitions
Error Found (1)			7
Anticipated Primary Comple	tion Date cannot be in the past	1	0
Primary Complet Final data collection da The Day field is optiona	ion Date * (i) te for the primary outco I for anticipated dates.	ome measures.	
Month	Day	Year	
Jul 🗸		2024	×
Type Error: Anticipated Pr Anticipated	imary Completion Date	cannot be in the past	

If you suspect an error you see in PRS Beta is such an artifact, switch to PRS Classic, where errors and problem messages populate correctly.

6. Submitting Registrations in PRS Beta

After entering information in the ClinicalTrials.gov record, you must submit the record to PRS and pass their QC review before the information you have entered is posted to the public website.

The process for submitting registrations is the same in PRS Beta as PRS Classic.

1. Go to the <i>Record Summary</i> ta	ıb
2. Click Entry Complete	• Can be done anyone with access to the record
Entry Complete	• Button appears once the required information is entered and any errors are resolved
3. Click <i>Approve</i>	• Can only be done by the Responsible Party
Approve	• Verifies the information is accurate and complete
4. Click <i>Release</i>	• Can only be done by the Responsible Party
Release In Ves, release In	• Need to click <i>release</i> twice on 2 screens

7. Questions / Need Help?

Non-cancer studies:

• UAHS Research Administration Regulatory Team: regulatory@arizona.edu

Cancer studies:

• UACC IIT Team: <u>UACC-IIT@uacc.arizona.edu</u>

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