

| Housekeeping Items



The webinar is being recorded, and the recording will be made available with the slides.



Questions submitted through the Q&A box will be answered at the end of the presentation.

ClinicalTrials.gov Modernization Update and Beta Website Demonstration

December 10, 2021

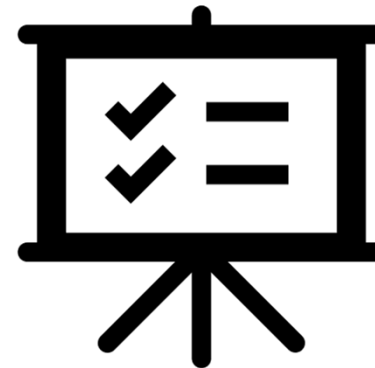
Anna M. Fine, PharmD, MS, ClinicalTrials.gov Acting Director

Christina Robinson, MA, ClinicalTrials.gov Beta Website Product Owner



| Webinar Goals

- Provide an update on the **ClinicalTrials.gov** modernization effort
- Share an overview and demonstration of the new **ClinicalTrials.gov** Beta website, highlighting the changes that users will see
- Communicate next steps
- Answer questions



ClinicalTrials.gov Modernization Overview

Ensure that ClinicalTrials.gov continues to be a trusted and valued premier public health resource that provides maximum value to the public and serves its mission well into the future



Improve the user experience

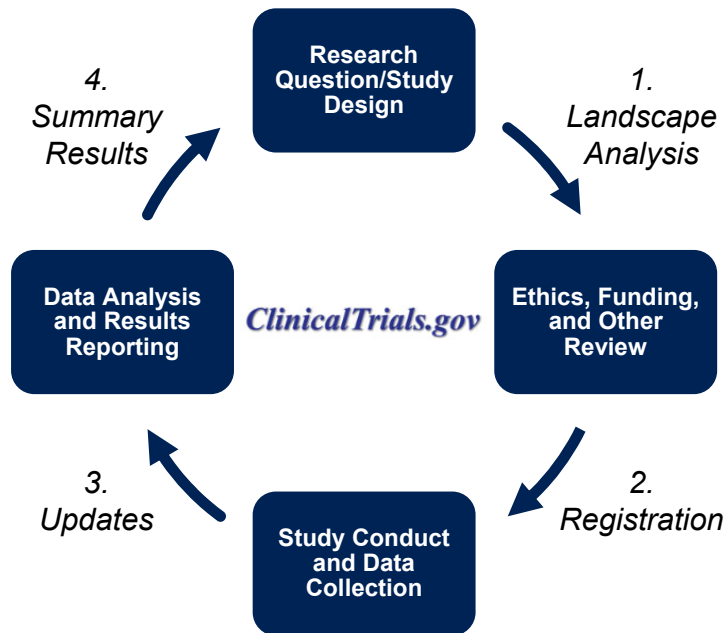


Upgrade the technical infrastructure and processes to enhance sustainability



Support the existing legal, regulatory, and policy framework

ClinicalTrials.gov Modernization Overview



Year 1: Engagement

- Engage stakeholders to determine and validate approach and specifications
- Enhance internal business processes
- Develop modernization roadmap

Year 2: Implementation

- Upgrade system infrastructure
- Conduct usability testing/evaluation
- Continue engaging stakeholders

Years 3–5: Expand Features

- Conduct usability testing/evaluation
- Continue engaging stakeholders
- Add features over time

National Library of Medicine (NLM) Board of Regents Working Group

Key Findings

- Importance of NLM's role as a central data aggregator
- Need to serve all primary stakeholders, while clarifying where NLM can directly vs. indirectly address user needs
- Need to manage user expectations by clearly communicating the site's purpose and limitations

Available at:

https://www.nlm.nih.gov/od/bor/clinicaltrialswg/NLM_BOR_CTG_WG_Modernization_Update_Report.pdf



Report on the ClinicalTrials.gov Modernization Effort

Summary of Progress: 2019–21

SEPTEMBER 2021



Prepared for the NLM Board of Regents Public Service Working Group on ClinicalTrials.gov Modernization by ClinicalTrials.gov Program Staff, National Library of Medicine



ClinicalTrials.gov

| Who Do We Want to Impact?

EXTERNAL STAKEHOLDERS



Patients and Their Advocates



Data Submitters



Data Researchers

INTERNAL STAKEHOLDERS

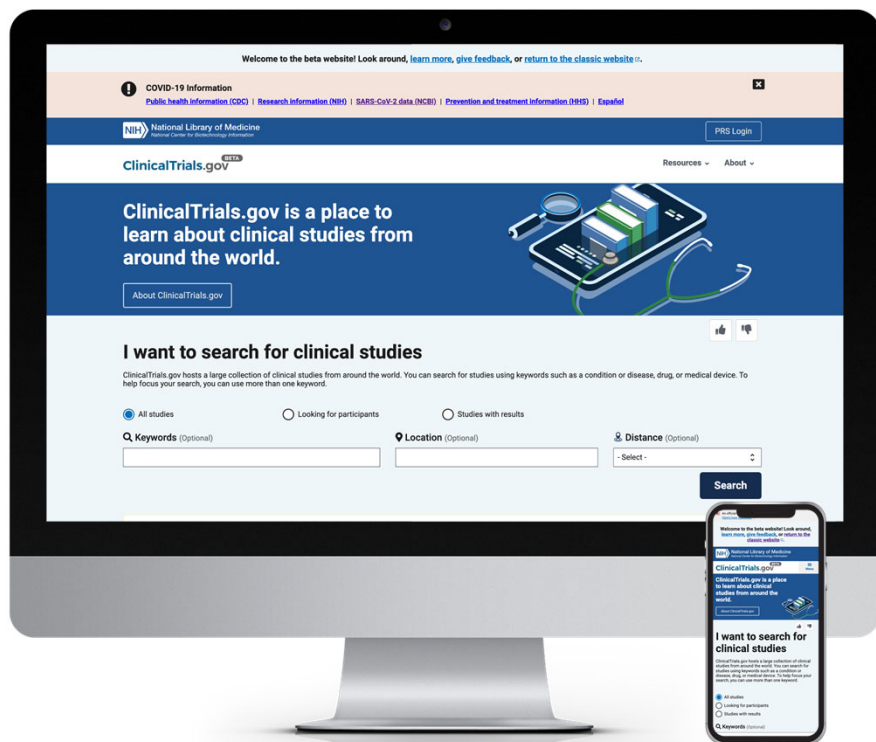


Policy and Oversight Teams



Information Specialists,
Reviewers, and
Developers

First Release of ClinicalTrials.gov Beta Website Launched on December 8, 2021



- Directly available at: <https://beta.clinicaltrials.gov/>
- Modern look and feel
- Ease of use on mobile devices
- Easy-to-understand information
- New cloud-based infrastructure

User Research: Overall Design Goals

Onboarding	Make the purpose of the site and how to use it clear to users, regardless of entry point.
Search Experience	Allow users to easily find studies of interest and narrow search results. Provide the ability to implement complete parameters from the outset.
Study Record Experience	Allow users to easily navigate study records and comprehend content areas. Organize study records to be fit for purpose.
Information Architecture	Provide intuitive navigation and enable users to efficiently provide feedback.
Easy-to-Understand Content	Visually present background information with clear next steps.
Appropriate Context	Connect users to useful and trustworthy content related to the research.

New Look for the Home Page

Classic Website

The classic website features a top navigation bar with links for COVID-19 information, public health information, research information, SARS-CoV-2 data, and prevention and treatment information. Below this is a banner for the modernized beta website. The main content area includes a search box with filters for status (Recruiting and not yet recruiting, All studies), condition or disease, other terms, and country. There are also sections for Patients and Families, Researchers, and Study Record Managers.

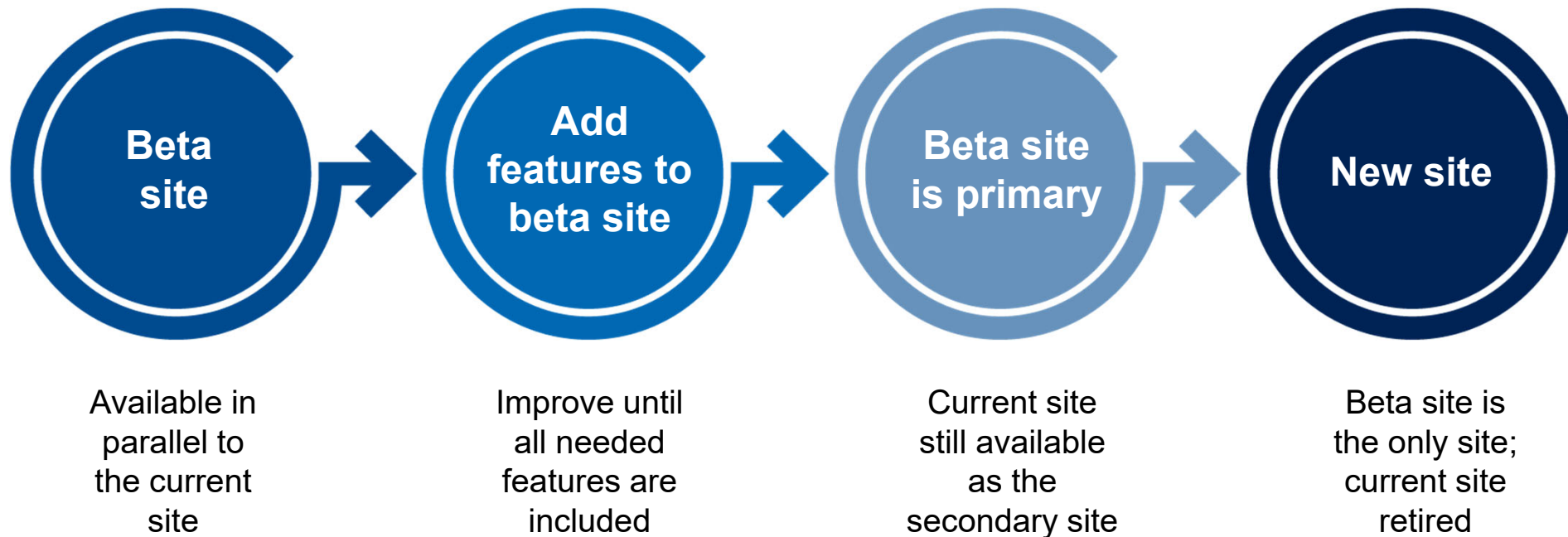
<https://clinicaltrials.gov/>

Beta Website

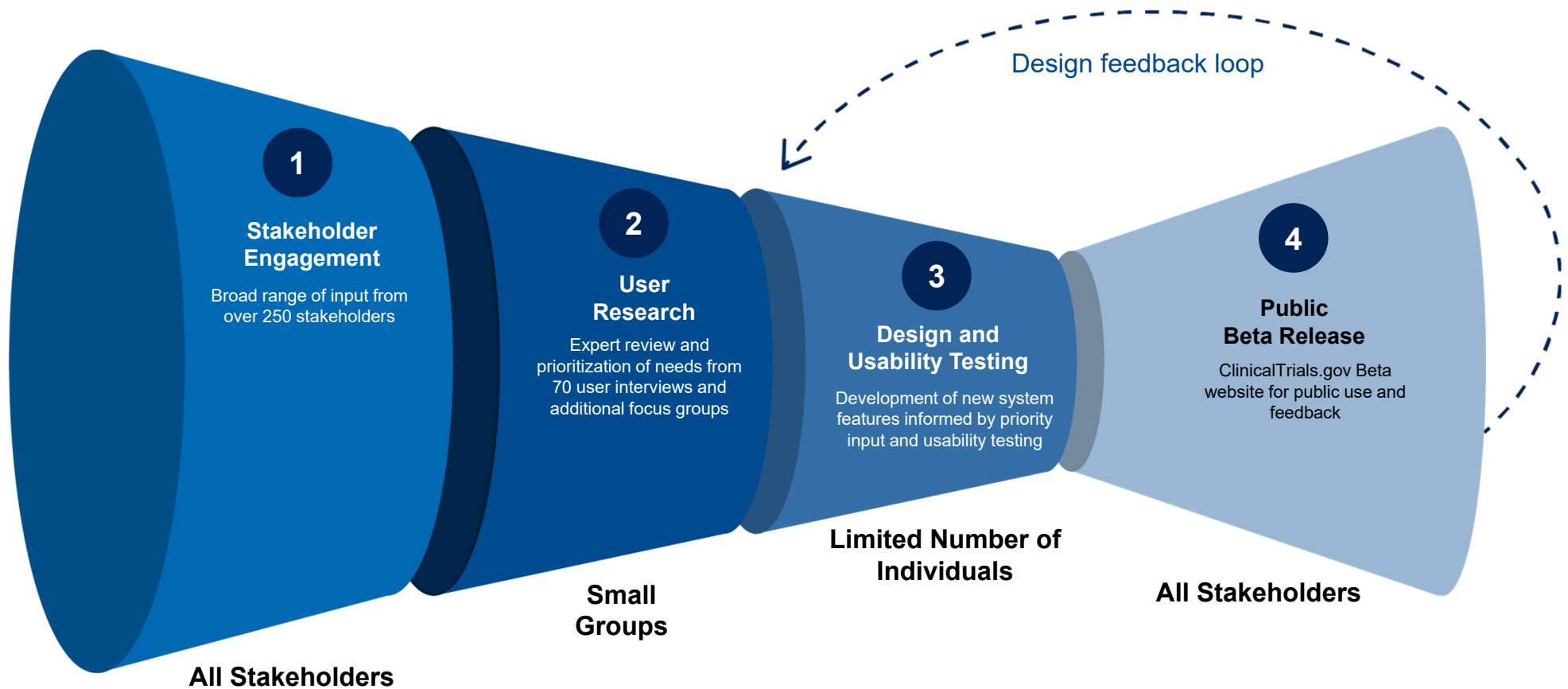
The beta website features a more modern design with a prominent header for COVID-19 information. The main content area includes a large banner with the text 'ClinicalTrials.gov is a place to learn about clinical studies from around the world.' Below this is a search section titled 'I want to search for clinical studies' with filters for status (All studies, Looking for participants, Studies with results), keywords, location, and distance. A disclaimer is present: 'The U.S. government does not review or approve the safety and science of all studies listed on this website.' The footer includes navigation links for About, Help, Legal, and ClinicalTrials.gov.

<https://beta.clinicaltrials.gov/>

| How Are You Seeing Change?

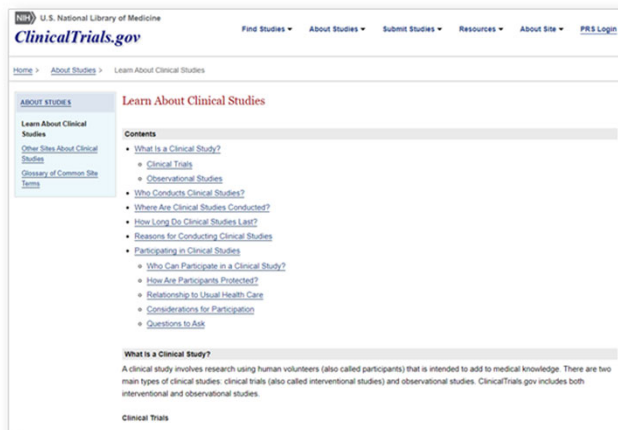


Approach to Addressing User Experience

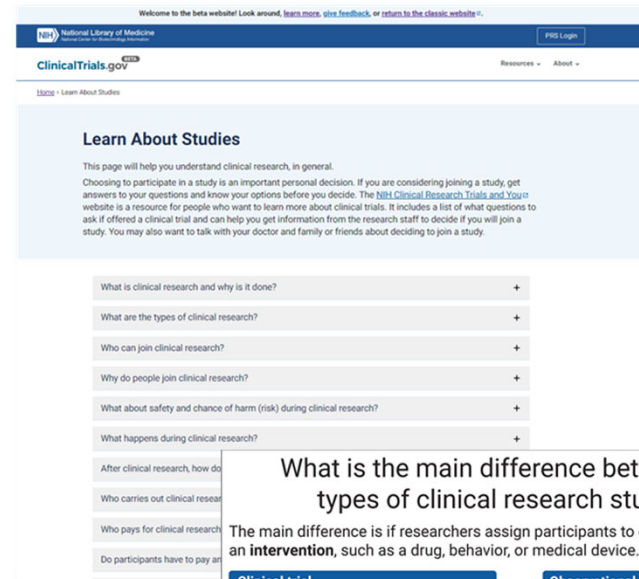


Informational Content in Plain Language

Before



After



What is the main difference between the types of clinical research studies?

The main difference is if researchers assign participants to get an **intervention**, such as a drug, behavior, or medical device.

Clinical trial	Observational study
 <p>In clinical trials, researchers do assign participants to one or more interventions. Sometimes, researchers randomly assign participants to interventions.</p>	 <p>In observational studies, researchers do not assign participants to an intervention. If there is an intervention, participants were already using it as part of their regular health care or daily life.</p>

- Full health literacy review of “Learn About Studies” and “Background” webpages
- Formative research, survey, and two rounds of focus group testing
 - Revised the text
 - Created visuals to communicate key concepts

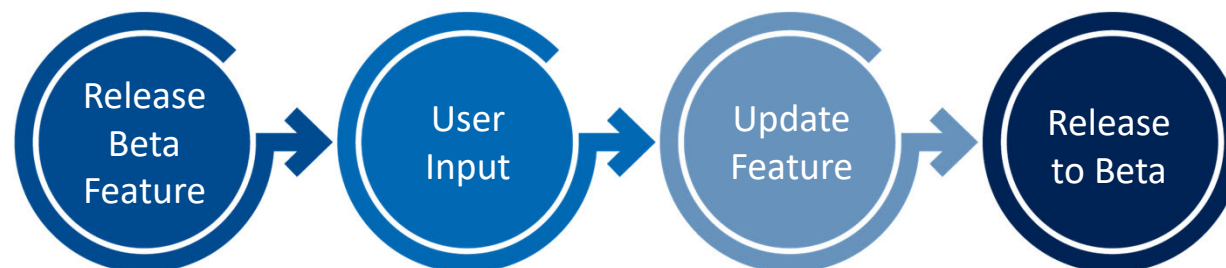
Demonstration of the ClinicalTrials.gov Beta Website

Christina Robinson, MA
ClinicalTrials.gov Beta Website Product Owner

Releases to ClinicalTrials.gov Beta

- ClinicalTrials.gov Beta will have frequent releases in 2022.
- We will collect and implement the user feedback received.
- We will provide updates on the [ClinicalTrials.gov Modernization webpage](#) for each release.

Public Site Approach



Planned User-Centric Features

- Release Notes Page:
Inform users of what has changed recently
- Study Record and Results:
Expand to include more data elements and add functionality
- Download Functionality:
Add more formats and customization

Poll: Which feature would you like to see next on ClinicalTrials.gov Beta?

- A. Download search results in additional formats
- B. Advanced search feature
- C. Customizable view of search results
- D. Personalized updates on records or search results of interest to me (similar to RSS feed)
- E. History of record changes feature

Previous Webinar on ClinicalTrials.gov Modernization

- ClinicalTrials.gov provided an update on the modernization effort and a preview of this week's beta launch.
- A recording of the October 7, 2021, webinar and the presentation slides are available on the ClinicalTrials.gov Modernization webpage: <https://clinicaltrials.gov/ct2/about-site/modernization#events>.



What about the PRS?

The screenshot displays the PRS ClinicalTrials.gov interface. At the top, there is a header with the NIH logo and the text "National Library of Medicine". Below this, the PRS logo is visible, along with a welcome message: "Welcome to Your New PRS Homepage (Beta). The National Library of Medicine (NLM) has launched an effort to modernize ClinicalTrials.gov. We will be continuously delivering improvements throughout the modernization effort." A "Back to Classic Homepage" button is also present.

The main section is titled "Record List" and features a table with the following columns: Record, Brief Title, Tags, Protocol ID, ClinicalTrials ID, Record Status, Last Update, Record Owner, and Problems. The table contains several rows of clinical trial records, each with a status indicator (e.g., "Open Record", "Locked") and a list of associated errors or issues.

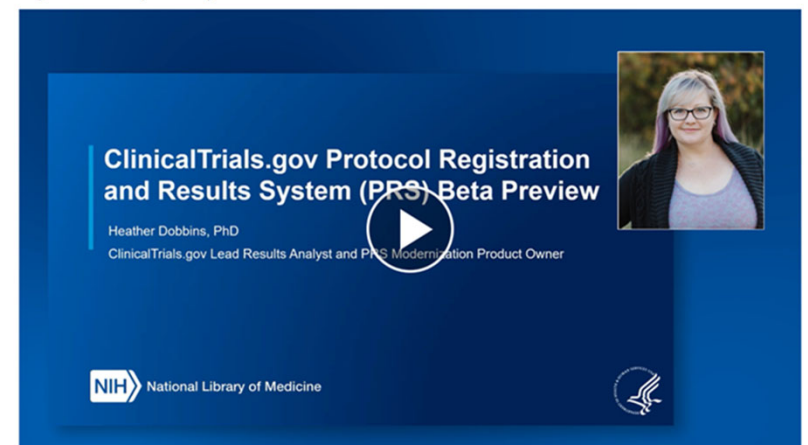
Record	Brief Title	Tags	Protocol ID	ClinicalTrials ID	Record Status	Last Update	Record Owner	Problems
Open Record	Metformin as an Adjunctive Therapy to Catheter Ablation in Atrial Fibrillation	DR	HUM00174946	NCT04259966	In Progress	2022/05/19 15:35	Keith Kaye keithka	• Record has 4 errors • Never released
Open Record	Morphine Versus Methadone As First Line Strong Opioid for Cancer Pain		HUM00181248	NCT00634010	In Progress	2022/05/19 15:35	Keith Kaye keithka	• Record has 4 errors • Never released
Open Record	Phase II Decitabine (DAC) Versus Azacitidine (AZA) in Myelodysplastic Syndrome (MDS)	R DR	ID99-203	NCT02249280	In Progress	2022/05/19 15:35	Ronald Hirschi rhrschi	• Record Has 7 Errors • Ready for Review and Approval • Never Released
Locked	Feasibility Study: Therapeutic Targeting of Stress Factors in Ovarian Cancer Patients	PR	ID98-035	NCT02405078	In Progress	2022/05/18 08:58	Ronald Hirschi rhrschi	• Record has 3 errors • Never released
Open Record	Lenalidomide and Rituximab in the Treatment of Relapsed Multiple Myeloma	NP	2005-0379	NCT00294632	In Progress	2022/05/17 17:16	Ronald Hirschi rhrschi	• Record has 4 errors • Never released
Open Record	Breast Cancer: Risk Factors Among Mexican Women in Mexico, Mexican-American		ID99-334	NCT00837499	In Progress	2022/05/17 13:32	Sarah Habla shabla	• Never released
Locked	Catheter Related - Gram Positive Bloodstream Infections	PR B	DM93-058	NCT00467272	In Progress	2022/05/12 15:35	Sarah Habla shabla	• Record Has 2 Errors • Ready for Review and Approval • Never Released
Open Record	High-Flow Oxygen and Bilvel Airway Pressure for Persistent Dyspnea in Patients	R	DM90-106	NCT00934128	In Progress	2022/05/12 15:35	Sarah Habla shabla	• Record has 4 errors • Never released
Phase Record	Sublingual Estrone for the Management of		MPL010805-131	NCT00161393	In Progress	2022/05/12 15:35	Sarah Habla shabla	• Record has 2 errors

What about the Beta PRS?



- Planned release in the PRS Test system in early 2022
- A prerecorded preview and demonstration, presented by Heather Dobbins, PhD, Lead Results Analyst and PRS Modernization Product Owner, is now available at: https://www.nlm.nih.gov/oet/ed/ct/2021_prs.html

ClinicalTrials.gov Protocol Registration and Result Reporting system (PRS) Beta Preview – December 2021



Questions



| Thank You!



**Learn more about
modernization**

<https://clinicaltrials.gov/ct2/about-site/modernization>



**Stay up to date with the Hot
Off the PRS! e-bulletin**

<https://bit.ly/33qcZBb>