

ClinicalTrials.gov Modernization Public Meeting

Tuesday, April 25, 2023
12:30–3 p.m. ET





Anna Fine

Acting Director of
ClinicalTrials.gov and
Today's Moderator

Housekeeping Items and Agenda

| Housekeeping Items



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



All participants will be muted but will have the opportunity to interact via polls, moderated chat, and open chat during the breakout sessions.



If you have technical issues during the meeting, please contact Tech Support via the chat.

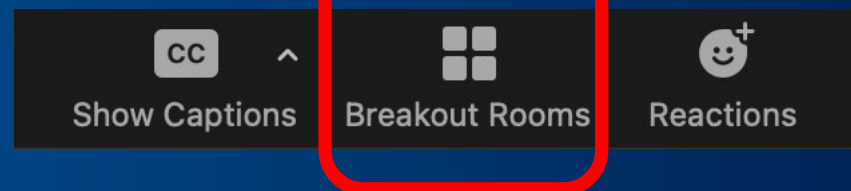
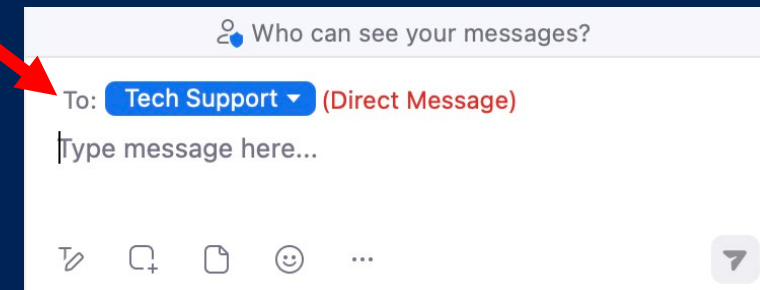
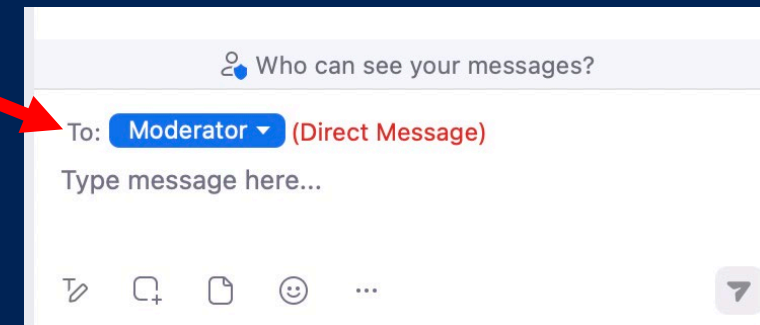
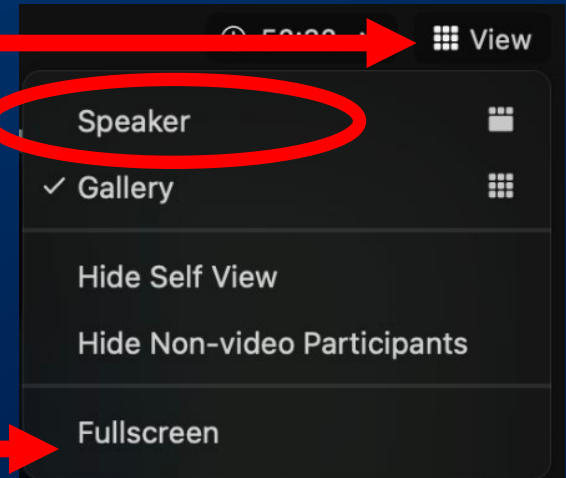
Housekeeping Items—Continued

To make the most of your experience, we recommend the following:

- Use the **Esc** key (at top left of keyboard) to exit the Fullscreen mode.
- Select “**View**,” then “**Speaker**” or “Speaker Side-by-Side” mode in the top right corner of your Zoom window.
- To ask content-related questions, select “**Moderator**” in the Chat box at the lower right.
- For technical questions, select “**Tech Support**” in Chat.
- Look for Breakout Rooms in your Zoom tool bar. You will be prompted later to select the room that interests you.

Change to Speaker mod in top right of Zoom window.

Use **Esc** key to exit Fullscreen mode to view chat.



Agenda

Description	Time	Presenters
<p>Housekeeping Items and Agenda</p> <p>Welcome and Introduction to the NLM Board of Regents Public Service Working Group on ClinicalTrials.gov Modernization</p> <p>Orientation to the ClinicalTrials.gov Modernization Effort</p>	<p>12:30–1:05 p.m. (35 min.)</p>	<p>Anna Fine</p> <p>Patricia Brennan Lourdes Baezconde-Garbanati</p> <p>Anna Fine</p>
<p>The Children’s Inn at NIH</p> <p>How We Got Here: A Summary of Our User- Centered Process for the Design and Development of the ClinicalTrials.gov Website</p> <p>Get to Know ClinicalTrials.gov Beta</p> <p>Get to Know PRS Beta</p> <p>Break</p>	<p>1:05–2 p.m. (55 min.)</p>	<p>Jennie Lucca</p> <p>Wendy Harman Catherine Kihara</p> <p>Christina Robinson</p> <p>Nachiket Dharker</p>
<p>Breakout Rooms</p> <p>1. ClinicalTrials.gov Beta</p> <p>2. PRS Beta</p> <p>Summary</p>	<p>2–3 p.m. (60 min.)</p>	<p>Steven Woloshin Christina Robinson</p> <p>Carrie Dykes Nachiket Dharker</p> <p>Anna Fine</p>



Patricia Brennan

Director of the National
Library of Medicine

Welcome

National Library of Medicine

The National Library of Medicine (NLM) was founded in 1836 and is the world's largest biomedical library. Its mission is to enable biomedical research, support health care and public health, and promote healthy behavior.



National Library of Medicine
Bethesda, MD

Serving Science and Society Since 1836

Research Enterprise for Biomedical Informatics and the World's Largest Biomedical Library



1836–1968

A Collection of Books and Journals

NLM began in the office of the United States Army Surgeon General until Congressional authorization moved NLM to the Public Health Service. NLM opened its doors on the NIH Campus in Bethesda, MD, in 1965.



1968–2000

Foundation of a Modern Library

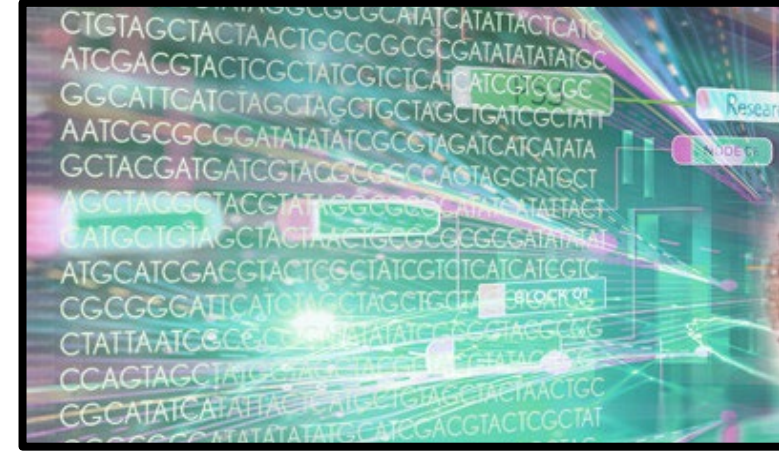
Expansion and impact in the Information Age:



Lister Hill National Center for Biomedical Communications



National Center for Biotechnology Information (NCBI)



2000–2036

The 21st Century Library

Lead innovative research to accelerate the mission of NIH and reach scientists and society with trustworthy health information.

ClinicalTrials.gov Modernization

To 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

Goals of the Public Meeting

- Present an overview of the modernization effort.
- Share information about the new ClinicalTrials.gov website and Protocol Registration and Results System (PRS) features that are coming soon.
- Provide an opportunity for users and stakeholders to ask questions.



NIH Natcher Conference Center
Bethesda, MD

National Library of Medicine Board of Regents

The NLM Board of Regents was established in 1956 by the same Act that created the National Library of Medicine.

Serves as an advisory body to the Secretary of Health and Human Services, the Assistant Secretary for Health, and others

Meets three times a year

Forms various smaller working groups that address topics of importance to NLM



Summary of the Working Group's Charge

The NLM Board of Regents Public Service Working Group on ClinicalTrials.gov Modernization is charged with exploring topics related to ClinicalTrials.gov modernization such as, but not limited to, ways that NLM can:

Maintain the *integrity* of ClinicalTrials.gov as a trusted resource

Maximize the *utility* of the growing corpus of information

Connect with stakeholders through *engagement* to ensure that evolving needs are understood and considered

Reports regularly in open session to the NLM Board of Regents



**Lourdes
Baezconde-
Garbanati**

Working Group Chair

Introduction to the NLM Board of Regents Public Service Working Group on ClinicalTrials.gov Modernization

NLM Board of Regents Public Service Working Group on ClinicalTrials.gov Modernization



Lourdes Baezconde-Garbanati
University of Southern California



Carrie Dykes
University of Rochester



Anna Fine
National Library of Medicine, NIH



Alissa Gentile
Dana-Farber Cancer Institute



Sally Gore
University of Massachusetts
Medical School



Lyric Jorgenson
NIH Office of Science Policy



Pamela Kearney
NIH Office of Extramural Research



Barbara Kress
Merck



Jennie Lucca
The Children's Inn at NIH



Seth Morgan
National Multiple Sclerosis Society



Omolola (Lola) Ogunyemi
Charles R. Drew University of
Medicine and Science



Stephen Rosenfeld
North Star Review Board and Freeport
Research Systems



Joseph Ross
Yale School of Medicine



Nancy Smider
Epic



Steven Woloshin
The Dartmouth Institute

Icebreaker Question

What perspective do you represent today?

- A. Patients and their advocates
- B. Data researchers
- C. Academia, data submitters
- D. Industry, data submitters
- E. Government, data submitters
- F. Information specialists/librarians
- G. Regulators or regulatory affairs staff
- H. Other



Working Group Efforts To Date

15 Working Group Meetings

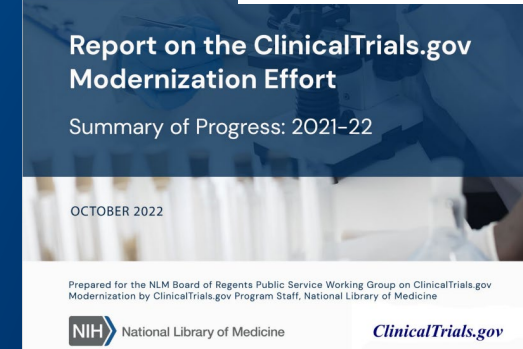
- December 13, 2019
- December 20, 2019
- February 3, 2020
- May 1, 2020
- August 28, 2020
- September 11, 2020
- December 11, 2020
- February 26, 2021
- August 20, 2021
- August 30, 2021
- January 28, 2022
- April 29, 2022
- September 2, 2022
- December 19, 2022
- January 13, 2023

Public Activities and Events

- **Request for information (RFI)** on ClinicalTrials.gov modernization accepted comments between December 30, 2019, and March 14, 2020.
- **Summary of RFI responses**, reported on April 28, 2020, provided a high-level summary of the 268 responses received, by RFI question, and described the main themes of suggestions for modernizing ClinicalTrials.gov.
- **First virtual public meeting**, on April 30, 2020, was hosted by NLM to discuss topics of interest identified by the RFI and to provide opportunities for virtual interaction and clarification of key topics with stakeholders.
- **Reports on the ClinicalTrials.gov modernization effort:**
 - Summary of Progress: 2019–21, issued in Sept. 2021
 - Summary of Progress: 2021–22, issued in Dec. 2022
- **This virtual public meeting**, on April 25, 2023, is being hosted by NLM to provide a detailed look at the current beta websites, progress updates, and an opportunity to hear from modernization team members and other stakeholders.

Issued Two Summary-of-Progress Reports

- Summary of Progress: 2019–21 report and Summary of Progress: 2021–22 report both present:
 - ClinicalTrials.gov modernization overview and updates on the current phase of the effort
 - Working Group and other stakeholder input



ClinicalTrials.gov Modernization Team

- **Stacey Arnold**, ClinicalTrials.gov Results Subject Matter Expert (SME)
- **Ben Babics**, PRS Beta Engineering Lead*
- **Eric Babin**, PRS Beta Back-End Team Lead*
- **Ram Basava**, ClinicalTrials.gov Beta Developer*
- **Gunnar Baskin**, PRS Beta Business Analyst*
- **Steven Bedrick**, PRS Automation Support Developer*
- **Annice Bergeris**, ClinicalTrials.gov Information Research Specialist, Acting Deputy Director, and Operations Team Product Owner
- **Landon Bressler**, PRS Beta Business Analyst*
- **Monica Corley**, PRS Beta Business Analyst*
- **Vinod Danam**, PRS Beta Developer*
- **Mandy Davis**, ClinicalTrials.gov User Experience (UX) Researcher*
- **Austin Devereux**, PRS Beta Developer*
- **Nachiket Dharker**, PRS Beta Product Owner*
- **Sergey Dikunov**, ClinicalTrials.gov Beta Technical Lead*
- **Sarah DiPasquale**, ClinicalTrials.gov UX Researcher*
- **Kayode Enwerem**, PRS Beta Developer*
- **Madhurima Gade**, ClinicalTrials.gov Beta Developer*
- **Rithika Ganni**, PRS Beta Developer*
- **Jenn Glas**, PRS Beta UX Designer*
- **Elisa Golfiopoulos**, ClinicalTrials.gov Policy Analyst and PRS Automation Support Team Product Owner
- **Jesus Mendiola Gomez**, ClinicalTrials.gov Beta Developer*
- **Slava Gorelenkov**, ClinicalTrials.gov Technical Program Manager
- **Eugene Gribov**, ClinicalTrials.gov Developer*
- **Karen Hanson**, ClinicalTrials.gov Technical Writer*
- **Wendy Harman**, ClinicalTrials.gov UX Lead*
- **Jimithy Hawkins**, ClinicalTrials.gov Product Strategist/Business Analyst*
- **Brad Henry**, PRS Beta Developer*
- **Sam Hirapara**, PRS Beta Developer*
- **Rafis Ismagilov**, ClinicalTrials.gov Beta Developer*
- **Catherine Kihara**, ClinicalTrials.gov UX Research Lead*
- **Janine Lewis**, PRS Automation Support Project Manager*
- **Russell Loane**, PRS Automation Support Developer*
- **John Lopez**, ClinicalTrials.gov Technical Lead*
- **Hibah Nazir**, ClinicalTrials.gov Product Manager*
- **Ngoc Nguyen**, ClinicalTrials.gov Developer*
- **Ken Ni**, ClinicalTrials.gov Beta User Interface (UI) Designer*
- **Justin Pallini**, PRS Beta UI Designer*
- **Hardik Parekh**, PRS Beta Technical Lead*
- **Chris Pemberton**, PRS Beta Developer*
- **Alison Powell**, ClinicalTrials.gov Communications Specialist*
- **Rupinder Randhawa**, ClinicalTrials.gov Modernization Project Manager*
- **Christina Robinson**, ClinicalTrials.gov Beta Product Owner
- **Mary Sanders**, ClinicalTrials.gov Project Director*
- **Michael San Gabriel**, PRS Beta Developer*
- **Gurdeep Sayal**, ClinicalTrials.gov Technical Consultant*
- **Max Shestopalov**, ClinicalTrials.gov Scrum Master*
- **Stephen Shoemaker**, ClinicalTrials.gov Content Strategist/Information Architect*
- **Colin Small**, ClinicalTrials.gov Beta UX Lead*
- **Scott Smith**, PRS Beta Product Manager*
- **Maureen Strange**, ClinicalTrials.gov SME*
- **Tony Tse**, ClinicalTrials.gov Analyst
- **Maria Vargas**, ClinicalTrials.gov Beta UX Designer*
- **Susan Wimmer**, ClinicalTrials.gov Senior Editor*
- **Tirsit Wondemu**, PRS Beta Developer*
- **Allison Yu**, ClinicalTrials.gov Developer*
- **Rici Yu**, ClinicalTrials.gov Developer*
- **Chris Ziegler**, PRS Beta UX Designer*
- **Maya Zuhl**, PRS Automation Support Technical Lead*



Anna Fine

Acting Director of
ClinicalTrials.gov

Orientation to the ClinicalTrials.gov Modernization Effort

ClinicalTrials.gov Modernization Effort

To 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.

Who Is Being Served by Modernization?

External Stakeholders



Patients and Their Advocates



Data Submitters



Data Researchers

Internal Stakeholders



Policy and Oversight Teams



Information Specialists,
Reviewers, and Developers

ClinicalTrials.gov Modernization Overview



YEAR 1

Initial Engagement Activities

- Engaged stakeholders to determine and validate approach and specifications
- Enhanced internal business processes
- Developed modernization roadmap



YEAR 2

Development

- Developed new product experiences
- Launched first release of ClinicalTrials.gov Beta
- Communicated availability of the beta release to stakeholders



YEAR 3

Implementation

- Launched first release of PRS Beta and released updates
- Conducted usability research and made iterative improvements to the beta sites
- Released updates to ClinicalTrials.gov Beta



Where we are now

YEARS 4–5

More Releases and Refinements

- Continue releasing updates and refinements to the beta sites until they can stand alone
- Continue engagement, usability testing, and evaluation
- Make ClinicalTrials.gov Beta the primary landing page
- Release PRS Beta protocol registration and results reporting components

Meet Our Beta Websites

ClinicalTrials.gov **BETA**

NIH National Library of Medicine
National Center for Biotechnology Information

PRs Login

About This Site | Data About Studies | Resources

ClinicalTrials.gov is a place to learn about clinical studies from around the world.

Warning: The U.S. government does not review or approve the safety and science of all studies listed on this website. Read our full [disclaimer](#) for details.

Search (all filters optional)

Conditions or disease **1**

Other terms **1**

Intervention/Treatment **1**

Location
Search address, city, state, or country

Search Facility Name

ClinicalTrials.gov
PRS Protocol Registration & Results System **BETA**

PRS Beta Home Page

Record List

10 per page | Viewing 1 - 10 | 36 records | Clear Filters

Customize Columns | Search All Columns

View Record	Unique Protocol ID	Tags	NCT Number	Secondary IDs	Brief Title	Record Status	Last Update	Record Owner	Responsible Party	Problems
Open	TTTOrossover				Crossover Study Design Example	In Progress	2022-03-14 14:03	Stacey Arnold QA21	[Sponsor]	• Entry Not Completed • Never Released
Open	TTTParallel	PR			Parallel Study Design Example	Released	2022-03-10 14:03	Stacey Arnold QA21	[Sponsor]	
Open	TTTUnidOtherThanPar				Units Other Than Participants Study Design Example (With Results)	In Progress	2021-11-09 15:11	Stacey Arnold QA21	[Sponsor]	• Entry Not Completed • Never Released
Open	TTTClusterRandomized				Cluster Randomized Study Design Example (With Results)	In Progress	2021-11-09 15:11	Stacey Arnold QA21	[Sponsor]	• Entry Not Completed • Never Released
Open	Test for User				Test Access List for Record Owner	In Progress	2021-07-22 09:07	Stacey Arnold qa21U	[Sponsor]	• Entry Not Completed • Never Released

36 total

Tag Key: **PR** Results **PR** Delayed Results **PR** PRS Review **PR** No Longer Public **PR** Study Documents **PR** XML **PR** PRS Review Comments

About PRS Beta
Give Feedback

Release Notes

April 11, 2023	–
What's new <ul style="list-style-type: none"> Study record page <ul style="list-style-type: none"> Record history <ul style="list-style-type: none"> Summary table: added "recruitment status" to show the study record version where this change occurred Comparing two versions <ul style="list-style-type: none"> Two versions of a study record can now be compared using a single button at the bottom of the list <ul style="list-style-type: none"> Clicking on the "Compare" button will take users to the classic ClinicalTrials.gov site Single version view <ul style="list-style-type: none"> For interventional studies, a single version of the study record with a complete set of details can now be viewed in ClinicalTrials.gov Beta A study record history bar was added showing the date of the version being viewed Left side menu has been added for improved navigation 	
Improvements <ul style="list-style-type: none"> Homepage <ul style="list-style-type: none"> The Search box now says, "all fields optional" to help clarify how to search from this page "Location terms" is no longer a default field Study record page <ul style="list-style-type: none"> In the Table view, a link was added at the top of the Outcome Measures table so that users can view all versions of the study record in the classic ClinicalTrials.gov <ul style="list-style-type: none"> If there is only one version of the study record, a message will state, "No changes posted", and no link will be available General <ul style="list-style-type: none"> "Resources" in the site menu is now called "Study Basics" "About This Site" in the site menu now includes the full disclaimer Search button function is now working correctly when a manual age range is selected 	
Coming soon <ul style="list-style-type: none"> A new streamlined Search experience 	
March 08, 2023	+
January 31, 2023	+
December 19, 2022	+
November 17, 2022	+
August 22, 2022	+
April 27, 2022	+
March 8, 2022	+
December 8, 2021	+

Release Notes Are Publicly Available

ClinicalTrials.gov Beta Release Notes

<https://beta.clinicaltrials.gov/about-site/release-notes>

PRS Beta Release Notes

<https://prstest.clinicaltrials.gov/prs/beta/public/release-notes>

Release Notes

April 13, 2023	–
<p>The Contacts and Locations module was updated in the Protocol Section in PRS Beta and is available in the PRS Test system. Several other modules have also been completed. All modules now include new or updated onscreen guidance, slide-out drawers with additional help, and content specific to the type of study (interventional, observational, or expanded access). This release also includes bug fixes for general content and formatting issues.</p>	
What's new <ul style="list-style-type: none"> Protocol Section <ul style="list-style-type: none"> Contacts and Locations module: We updated the design and navigation and added onscreen and drawer guidance. Arms and Interventions module: The Cross References table was added. Outcome Measures module: New onscreen and drawer guidance added. 	
March 29, 2023	+
February 9, 2023	+
January 26, 2023	+
December 15, 2022	+
November 10, 2022	+
October 24, 2022	+
July 06, 2022	+
May 09, 2022	+
January 27, 2022	+

Coming Up . . .

1:05–2 p.m.

The Children’s Inn at NIH

Jennie Lucca, The Children’s Inn at NIH

How We Got Here: A Summary of Our User-Centered Process for the Design and Development of the ClinicalTrials.gov Website

Wendy Harman, ClinicalTrials.gov UX Lead

Catherine Kihara, ClinicalTrials.gov UX Research Lead

Get to Know ClinicalTrials.gov Beta

Christina Robinson, ClinicalTrials.gov Beta Product Owner

Get to Know PRS Beta

Nachiket Dharker, PRS Beta Product Owner

Break





A PLACE LIKE HOME

The Children's Inn at NIH

Jennie Lucca
NLM Board of Regents Public
Service Working Group
April 25, 2023





A PLACE LIKE HOME

The Inn's Mission

Everything we do strives to reduce the burden of illness on families, make childhood possible, and help advance NIH clinical research.



IN OUR 32 YEARS OF SERVICE:

537

Children and young adults ages 0–29 participated in 537 clinical trials, representing advances in treating cancer, bone and growth disorders, mental illness, genetic conditions and other serious health issues.



of Inn families felt a greater sense of community thanks to our enriching activities

Families have come to The Inn from



106
countries



50
states



to help advance medical discoveries around the world

More Than



15,236
families have stayed
at **The Inn**
free of charge

Making Childhood Possible





A PLACE LIKE HOME

The Inn of the Future





The Children's Inn and NLM

2016

Dr. Brennan visited
The Inn after
becoming director of
NLM.

The Inn launched #INN2025
with a goal of better
supporting NIH's research
initiatives and the families
who participate.

2018

2020–
2021

Formal collaboration
began, and the
Caregiver Café was
implemented.

The Inn's team began
working with NLM to
provide feedback on
the ClinicalTrials.gov
Beta website.

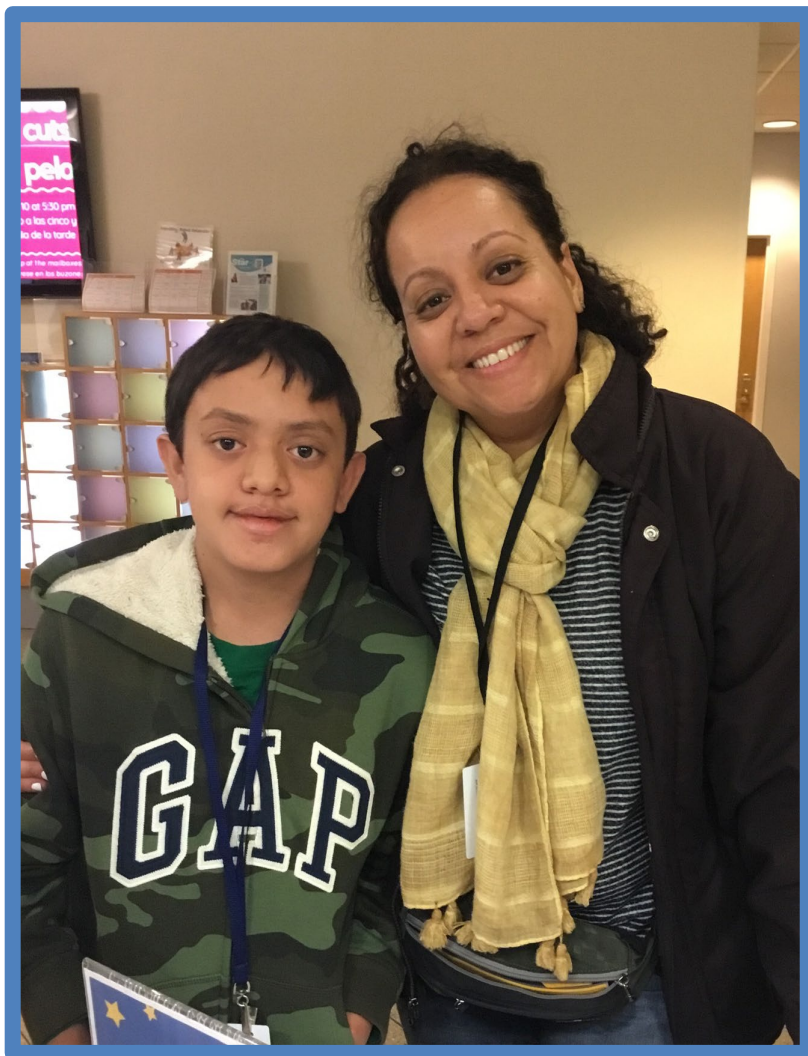
2022

2023

Inn families will
provide feedback on
the ClinicalTrials.gov
Beta website and
receive additional
education on clinical
trials.



Billy and Gabriela



- 16 years old
- From El Salvador and have been coming to The Inn since 2018
- Billy is diagnosed with Job's syndrome and is participating in a clinical trial led by NIAID.



Autumn



A PLACE LIKE HOME

Thank you!



Wendy Harman

ClinicalTrials.gov UX Lead

and

Catherine Kihara

ClinicalTrials.gov UX Research Lead



How We Got Here: A Summary of Our User-Centered Process for the Design and Development of the ClinicalTrials.gov Website

Modernization is a user-centered process. Today we will share how we are using stakeholder input to design and develop the new ClinicalTrials.gov public website and PRS.

1,000+

Comments with ideas for improving the public site and PRS from an RFI in 2020

70

Hour-long interviews with data submitters, data researchers, and patients in 2020

1,800+

Feedback comments submitted by users of the beta public site

15

Working Group meetings to provide expert user input to the design and development process

→ **How We Got Here**

How We Got Here

(1 of 2)



How We Got Here

(2 of 2)

I want to understand more of the information in my search results and study record.

I want advanced search on the home page.



I want search to be as easy as Google.

I want to see as much study data in as small a space as possible on the search results page.

I want to enter my trial data as fast and as easily as possible, even if it means that the information available in the API and on the public site isn't as complete as it could be.

ClinicalTrials.gov Beta User Feedback Process

An official website of the United States government [Here's how you know](#) ▾

Welcome to the beta website! Look around, [learn more](#) ↗, [give feedback](#) ↗ or [return to the classic website](#).

NIH National Library of Medicine
National Center for Biotechnology Information

PRIS Login

ClinicalTrials.gov ^{BETA} About This Site ▾ Data About Studies ▾ Study Basics ▾

ClinicalTrials.gov is a place to learn about clinical studies from around the world.

Search (all filters optional) ✕

Condition or disease ⓘ

Other terms ⓘ

Location

Within 50 miles ⇅ address or place

In country, state, or city

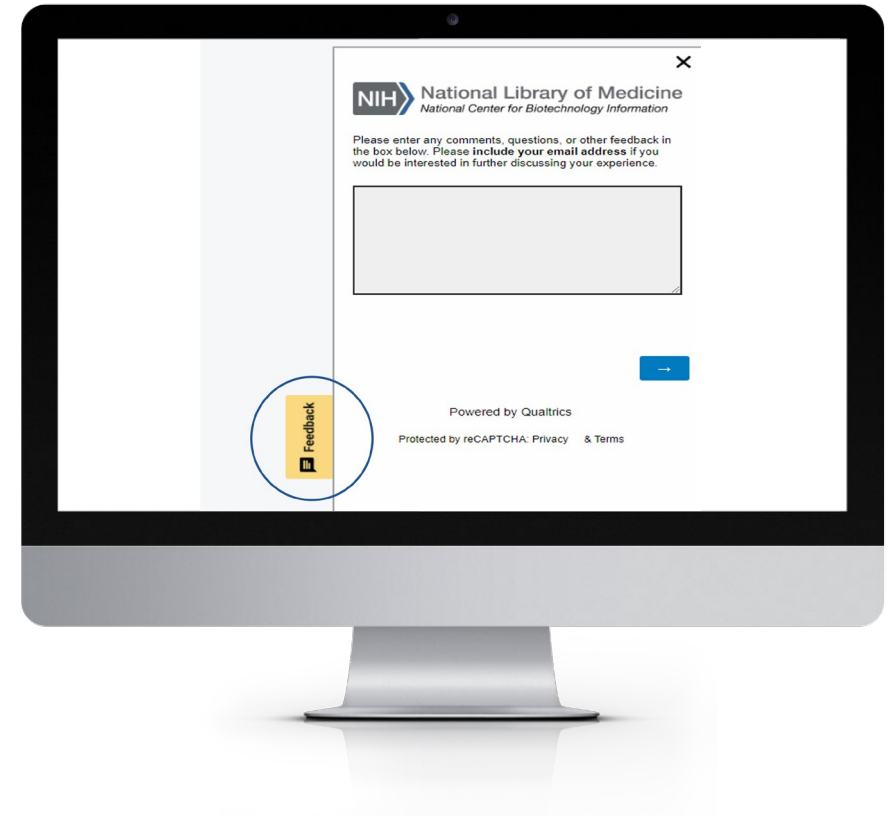
Advanced Filters ^ Search

- We read every single comment.
- We analyze the feedback continuously to identify bugs and issues or requests that come up repeatedly and warrant changes.
- Users who provide an email address with their comment are often invited to participate in Zoom sessions or other activities (e.g., a survey) to provide additional feedback.



PRS Beta User Feedback Process

- We read every single comment, and we are currently working on refining our process.
- Users are encouraged to try PRS Beta and leave a comment using the site's **Feedback** button.
- We also encourage users to provide an email address with their comment, so we can contact them about opportunities to provide additional feedback.



User Feedback in Action

BEFORE

Select Fields ▾ + Add All Fields ↻ Reset to Default

Search

Search

Condition or disease ⓘ
Text ×

Other terms ⓘ
Text ×

Location
 Within 50 miles ⇅ address or place
 In city, state, or country

Location terms ⓘ
Text ×

Many users commented that the color scheme made the **Search** button hard to see and that it was confusing to go back to the top of the form to click on **Search**.

AFTER

Search (all filters optional) ×

Condition or disease ⓘ
[Text Input]

Other terms ⓘ
[Text Input]

Location
 Within 50 miles ⇅ address or place
 In country, state, or city

Advanced Filters ^

Search

For the next release of the beta site, we increased the contrast between the **Search** button and its background; moved the button to the bottom of the form; and made it “sticky” so that it is always visible on the page, no matter how many search fields are added.

| We Value Your Feedback!

“I’m really happy that you’re reading [the comments]. Usually you leave a feedback and you never get a response. I was so happy, honestly . . . Reaching out to the person in two weeks, two months...makes you feel more connected, kind of feel more loyal to the system, that okay, they’re also working on something.”

—Data Researcher



“I think this is really, really important work. The easier you can make it for busy clinicians to find clinical trials, the faster we’ll develop the field, and you know it’s not often that you think about the design of a website as being life-saving. But I think it is. It is potentially life-saving. So it’s important work, and I’m glad I responded positively to your invitation [to participate in the usability testing session].”

—Clinician/Data Researcher

Poll Question 1

**How did you learn about
ClinicalTrials.gov Beta?**

- A. Word of mouth
- B. Referral from a health care provider
- C. Google search
- D. Social media
- E. A link on the classic website
- F. Hot Off the PRS! e-bulletin
- G. Other



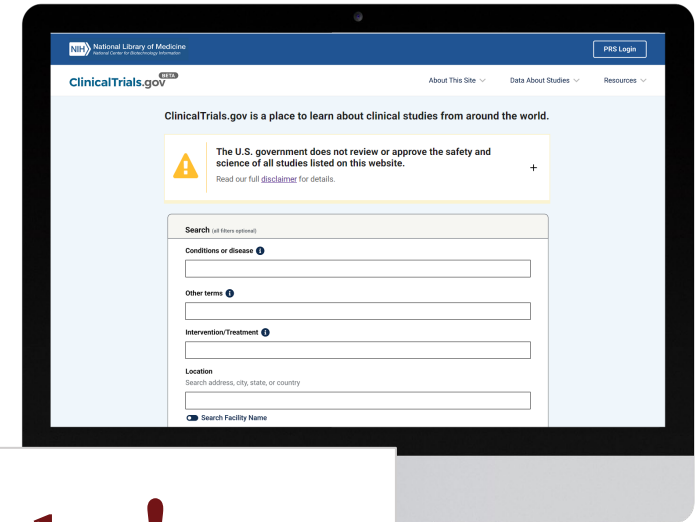


**Christina
Robinson**

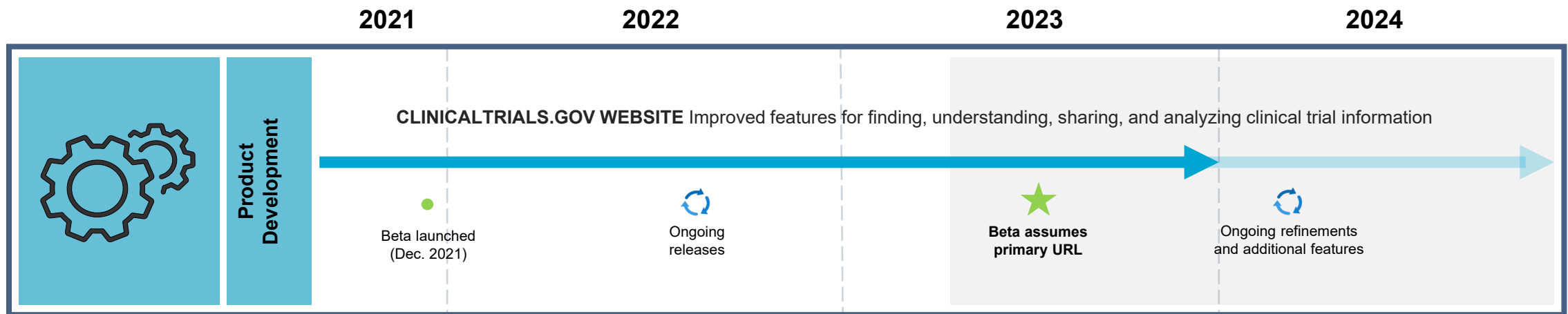
ClinicalTrials.gov Beta
Product Owner

Get to Know ClinicalTrials.gov Beta

2021–24 Strategic Roadmap: ClinicalTrials.gov Beta

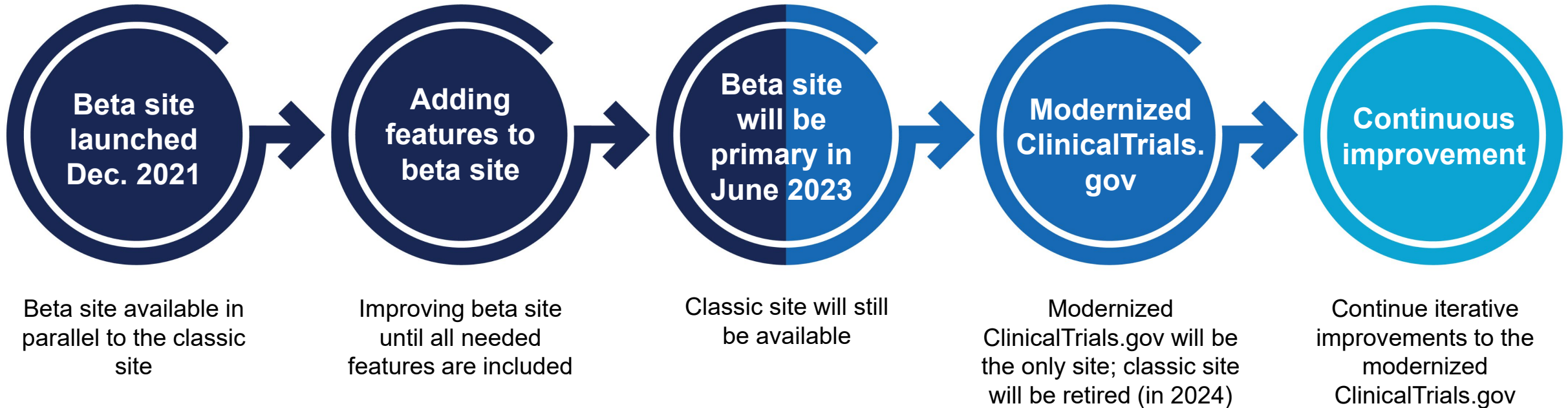


The finish line is in sight!

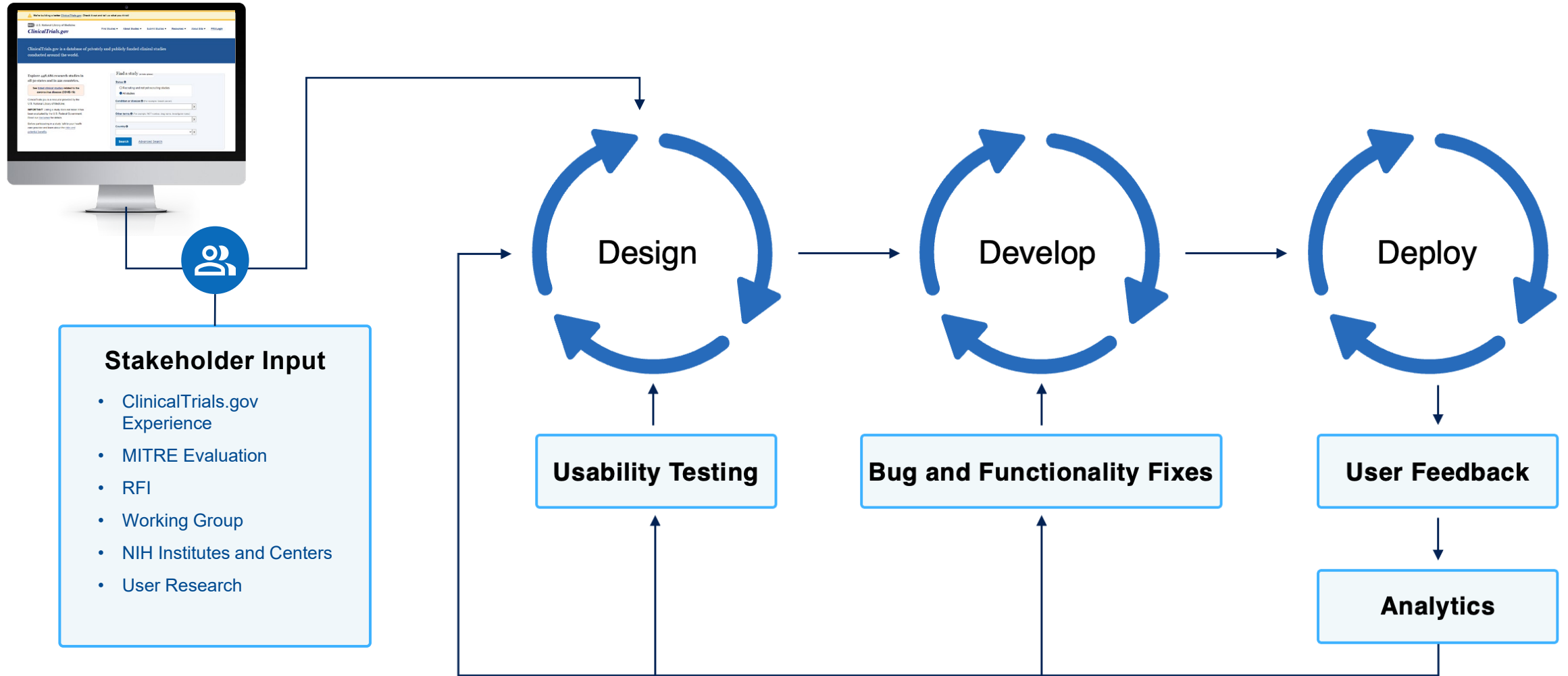


How Users See Change: ClinicalTrials.gov Website

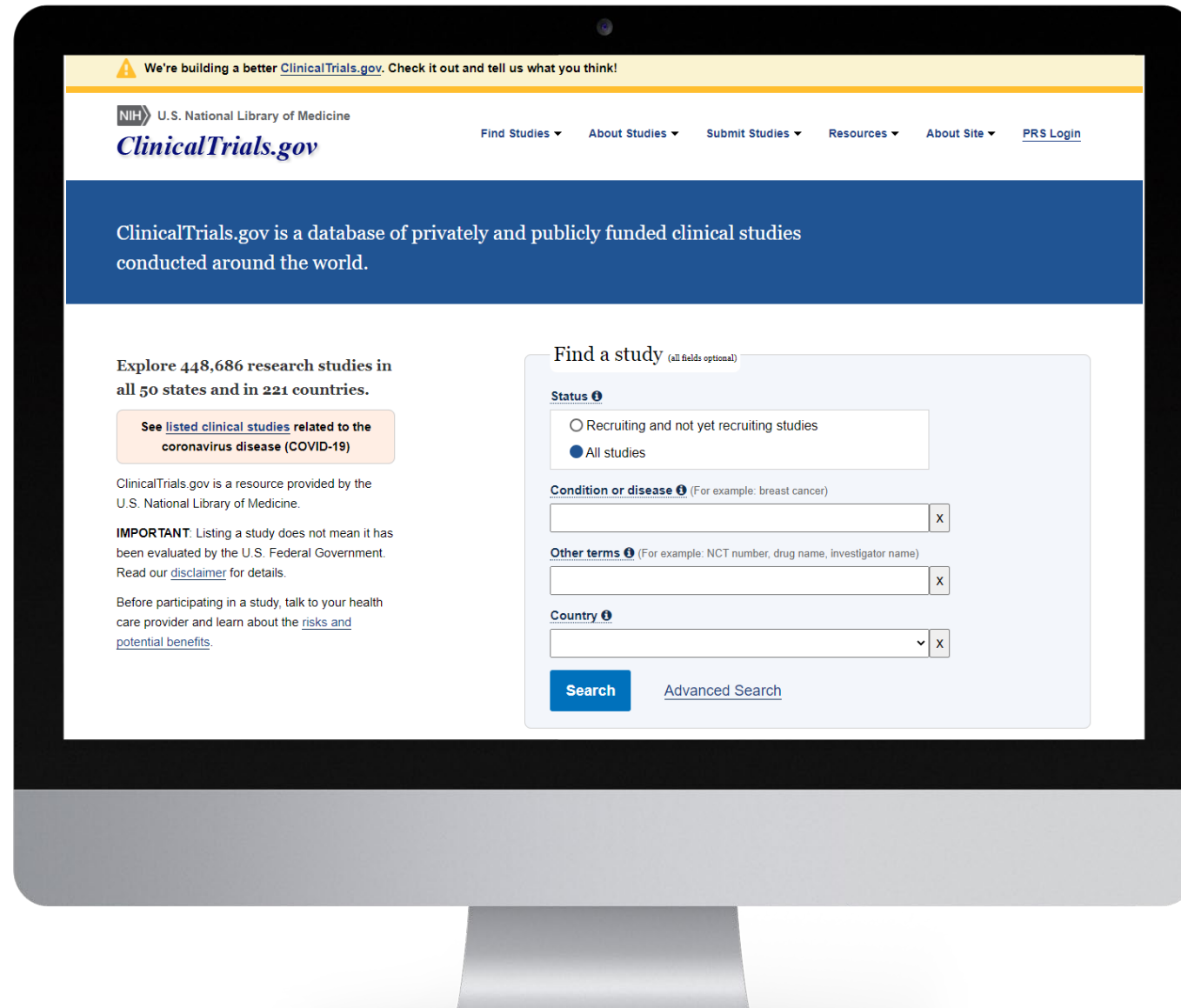
----- Continuous Feedback -----



Incorporating User Input

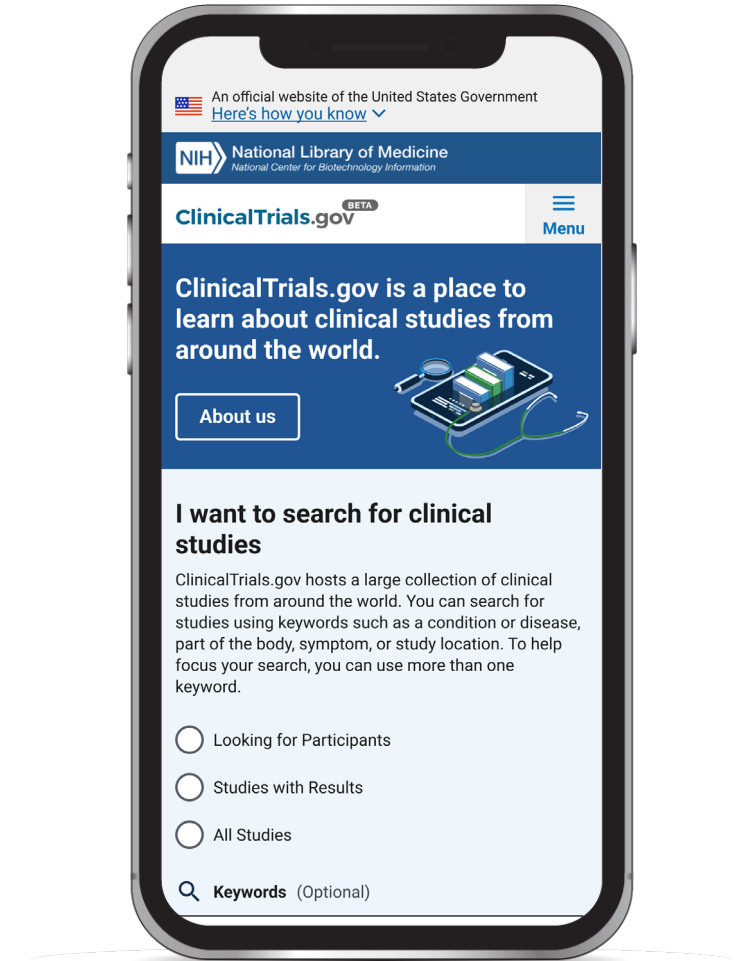
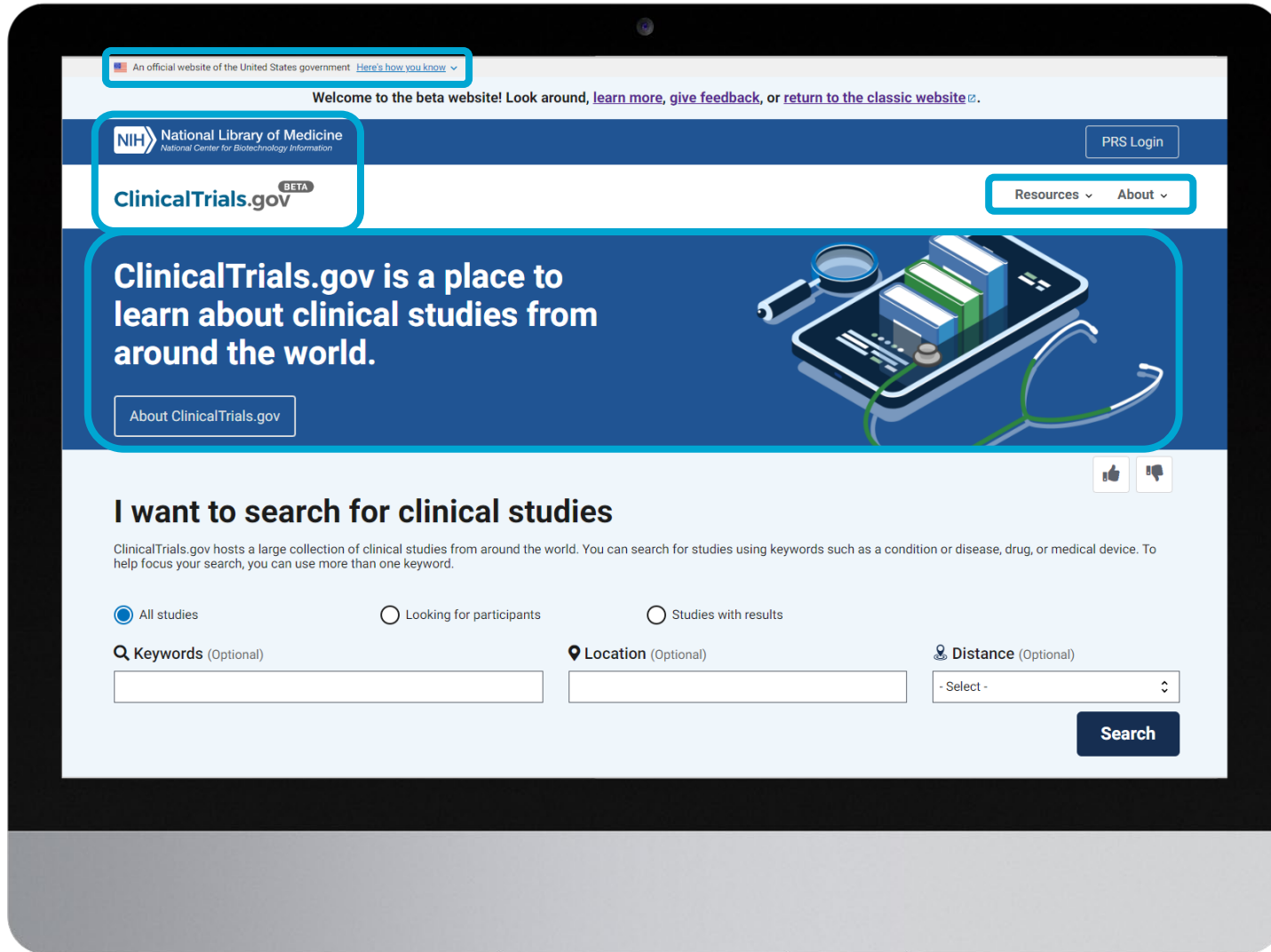


Classic ClinicalTrials.gov



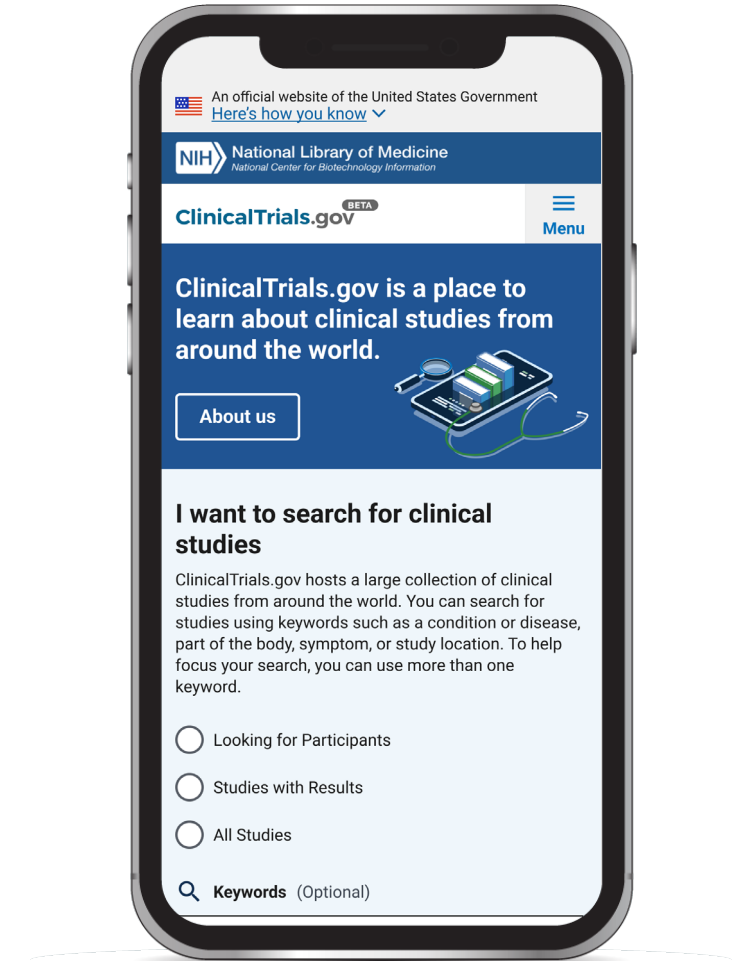
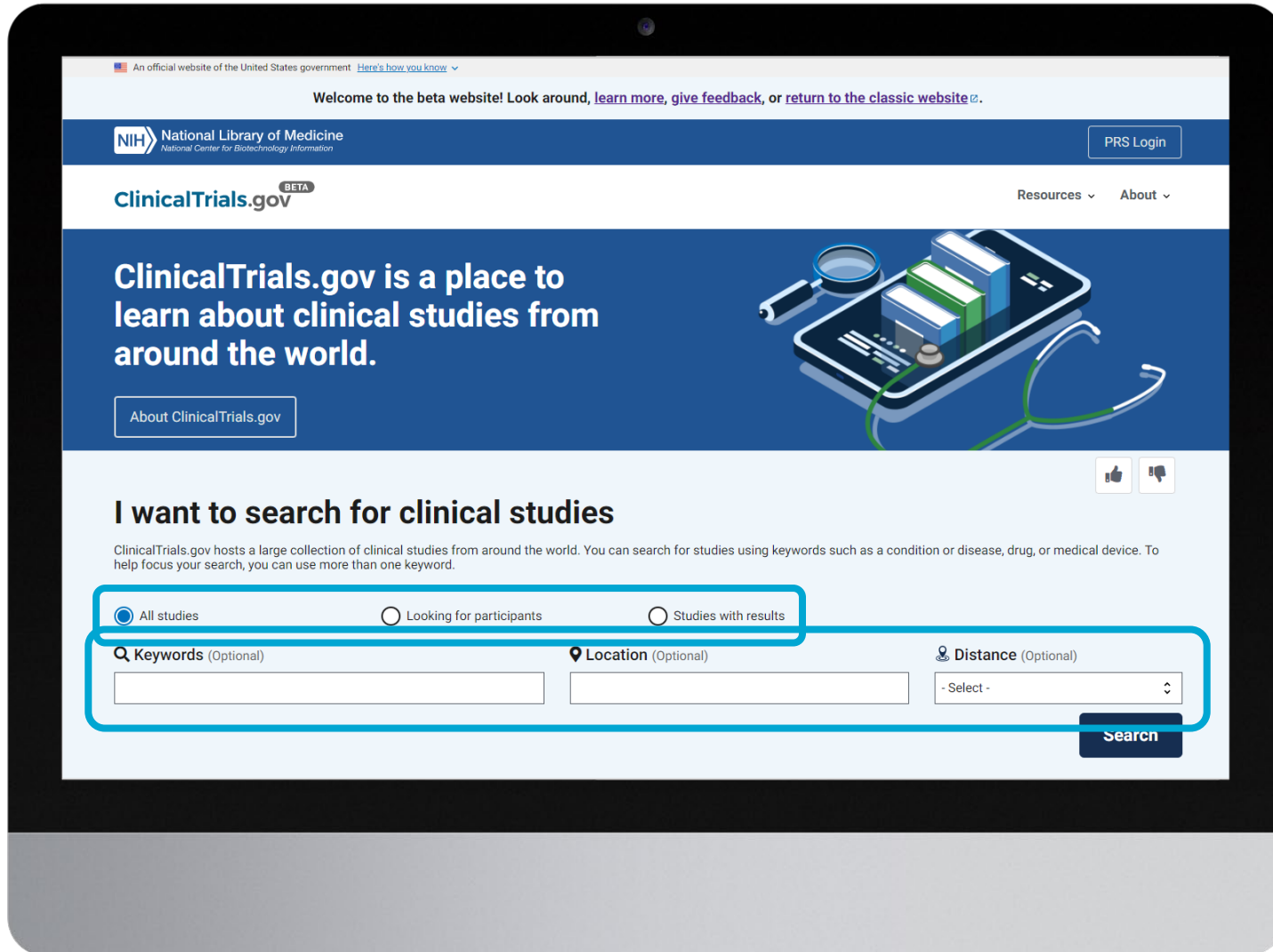
ClinicalTrials.gov Beta at Launch

(1 of 2)



ClinicalTrials.gov Beta at Launch


(2 of 2)



ClinicalTrials.gov Beta Enhanced Search

An official website of the United States government [Here's how you know](#) ▾

Welcome to the beta website! Look around, [learn more](#), [give feedback](#), or [return to the classic website](#) ↗.


 National Library of Medicine
National Center for Biotechnology Information

PRS Login

ClinicalTrials.gov ^{BETA} Resources ▾ About ▾

ClinicalTrials.gov is a place to learn about clinical studies from around the world.

[About ClinicalTrials.gov](#)



I want to search for clinical studies

ClinicalTrials.gov hosts a large collection of clinical studies from around the world. You can search for clinical studies by condition or disease name or other terms such as a drug name. You can find a study close to home by entering an address, city, or state. You can also narrow your search by selecting from a long list of other fields such as participation criteria or study results.

[View All Fields](#) [Reset to Default](#) [Search](#)

Conditions or disease

Other terms

Location

Location terms

Study Status

Eligibility Criteria

Sex

Age

Accepts Healthy

Other terms ⓘ

Location terms ⓘ


Address or place

[Give feedback](#)

[Classic website](#)

An official website of the United States government [Here's how you know](#) ▾


Welcome to the beta website! Look around, [learn more](#), [give feedback](#), or [return to the classic website](#) ↗.

 National Library of Medicine
National Center for Biotechnology Information

ClinicalTrials.gov ^{BETA} [Menu](#)

ClinicalTrials.gov is a place to learn about clinical studies from around the world.

[About ClinicalTrials.gov](#)



I want to search for clinical studies

ClinicalTrials.gov hosts a large collection of clinical studies from around the world. You can search for clinical studies by condition or disease name or other terms such as a drug name. You can find a study close to home by entering an address, city, or state. You can also narrow your search by selecting from a long list of other fields such as participation criteria or study results.

[Select Fields](#) [Search](#)

Search ⓘ

Conditions or disease ⓘ

ClinicalTrials.gov Beta Streamlined User Interface



An official website of the United States government [Here's how you know](#) ▾

Welcome to the beta website! Look around, [learn more](#) ↗, [give feedback](#) ↗ or [return to the classic website](#).

National Library of Medicine
National Center for Biotechnology Information

PRS Login

ClinicalTrials.gov ^{BETA} Resources ▾ About ▾

ClinicalTrials.gov is a place to learn about clinical studies from around the world.

Search ✕

Condition or disease ⓘ

Other terms ⓘ

Location

Within 50 miles ▾ address or place

In country, state, or city

Location terms ⓘ

Advanced Filters ^

Search

[Give feedback](#)

[Classic website](#)

An official website of the United States government [Here's how you know](#) ▾

Welcome to the beta website! Look around, [learn more](#) ↗, [give feedback](#) ↗ or [return to the classic website](#).

National Library of Medicine
National Center for Biotechnology Information

ClinicalTrials.gov ^{BETA} Menu

ClinicalTrials.gov is a place to learn about clinical studies from around the world.

Search ✕

Condition or disease ⓘ

Other terms ⓘ

Location

Within 50 miles ▾

address or place

In country, state, or city


Advanced Filters

Search


[Give feedback](#)

[Classic website](#)

ClinicalTrials.gov Beta “Simple Search” Prototype

 An official website of the United States government [Here's how you know](#) ▾

Welcome to the beta website! Look around, [learn more](#), [give feedback](#), or [return to the classic website](#).

 National Library of Medicine
National Center for Biotechnology Information


ClinicalTrials.gov ^{BETA} [Resources](#) ▾ [About](#) ▾

ClinicalTrials.gov is a place to learn about clinical studies from around the world.

Search

 ✕

[Advanced Filters](#) ▾ [Search](#)



The U.S. government does not review or approve all studies listed on this website.
Read our full [disclaimer](#) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and their results. The National Library of Medicine (NLM) maintains the website. The study sponsor or investigator is responsible for the safety and science of the study they list on the site. NLM depends on the study sponsor or investigator to submit complete, accurate, and up-to-date information about their study.

Before joining a study, talk to your health care professional. To learn more about taking part in studies, read [Learn About Studies](#).

ClinicalTrials.gov Beta User-Preferred Search

An official website of the United States government [Here's how you know](#)


Welcome to the beta website! Look around, [learn more](#), [give feedback](#), or [return to the classic website](#).

NIH National Library of Medicine
National Center for Biotechnology Information

PRIS Login

ClinicalTrials.gov ^{BETA} About This Site Data About Studies Resources

ClinicalTrials.gov is a place to learn about clinical studies from around the world.



The U.S. government does not review or approve the safety and science of all studies listed on this website. [Read our full disclaimer](#) for details.

Search (all filters optional)

Conditions or disease ⓘ

Other terms ⓘ

Intervention/Treatment ⓘ

Location

Search address, city, state, or country

Search Facility Name

Study Status ⓘ

All studies

Looking for participants


More Filters +

Search

NIH National Library of Medicine
National Center for Biotechnology Information

ClinicalTrials.gov ^{BETA} Menu

ClinicalTrials.gov is a place to learn about clinical studies from around the world.



The U.S. government does not review or approve the safety and science of all studies listed on this website. [Read our full disclaimer](#) for details.

Search (all filters optional)

Condition or disease ⓘ

Other terms ⓘ

Intervention/Treatment ⓘ

Location

Search address, city, state, or country

Search facility name

Searching all studies **looking for participants**. [Edit](#)

More Filters +

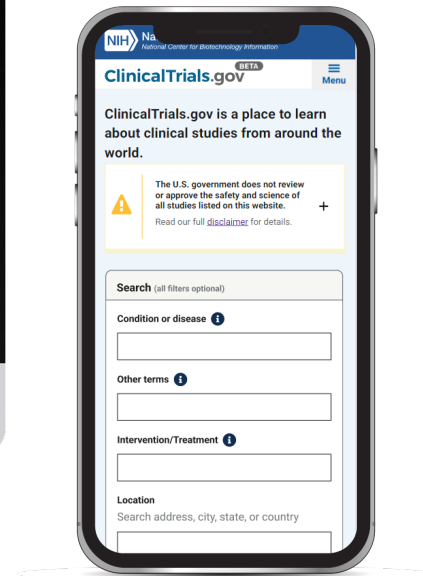
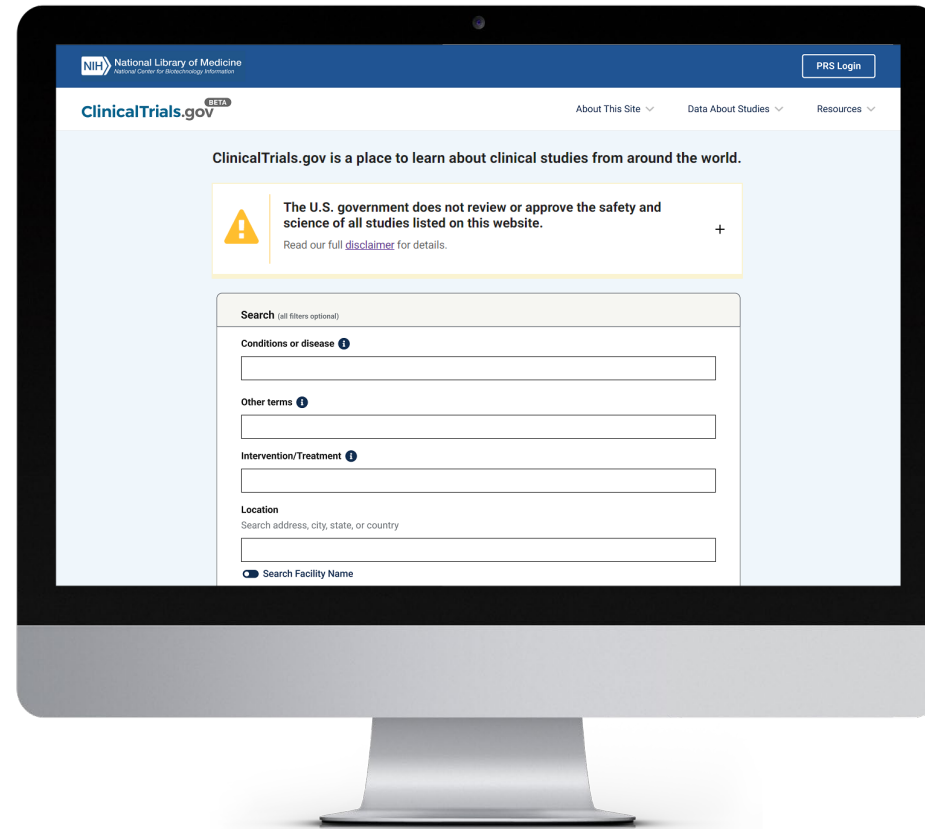
Search

ClinicalTrials.gov Beta Features

	Search Experience	Study Record Experience	Easy-to-Find and Easy-to-Use Content
AVAILABLE	<ul style="list-style-type: none"> Download (JSON, CSV) Search v 2 Search Results—Table View Search Results—Table View v 2 Enhanced search UI Print view of search results Application programming interface (API) v 1 	<ul style="list-style-type: none"> Expanded study record data Fast Healthcare Interoperability Resources (FHIR) API pilot Print view of study registration Table view of study record Study record history v 1 Study record history v 2 	<ul style="list-style-type: none"> Learn About Studies About ClinicalTrials.gov Learn About FHIR Data About Studies API documentation
IN PROGRESS	<ul style="list-style-type: none"> Search v 3 	<ul style="list-style-type: none"> Study record history v 3 	<ul style="list-style-type: none"> Information architecture Content migration Support materials for using search Onboarding users
FUTURE	<ul style="list-style-type: none"> XML download Save search/get search updates API v 2 Rewrite ingest 	<ul style="list-style-type: none"> Connections to trusted health information Next steps to join a study Save studies/get study updates 	

ClinicalTrials.gov Beta Plan for 2023

- **Currently** available at beta.clinicaltrials.gov
- **In June**, it will be the primary website!
- **In 2023**, the classic site will remain available.





Nachiket Dharker

PRS Beta Product Owner

Get to Know PRS Beta

2021–24 Strategic Roadmap: PRS Beta

View Record	Unique Protocol ID	Tags	NCT Number	Secondary IDs	Brief Title	Record Status	Last Update	Record Owner	Responsible Party	Problems
Class	TTC000over				Overview Study Design Examples	In Progress	2022-03-14 14:03	Stacey_Accost	[Approved]	• Entry Not Completed • Never Released
Class	TTCParallel	IN			Parallel Study Design Examples	Released	2022-03-10 14:03	Stacey_Accost	[Approved]	
Class	TTCOtherThanPar				Other Than Parallel Study Design Examples (With Results)	In Progress	2021-11-09 15:11	Stacey_Accost	[Approved]	• Entry Not Completed • Never Released
Class	TTCOverRandomized				Other Randomized Study Design Examples (With Results)	In Progress	2021-11-09 15:11	Stacey_Accost	[Approved]	• Entry Not Completed • Never Released
Class	Test for User				Test Access List for Record Owner	In Progress	2021-07-22 09:57	Stacey_Accost	[Approved]	• Entry Not Completed • Never Released

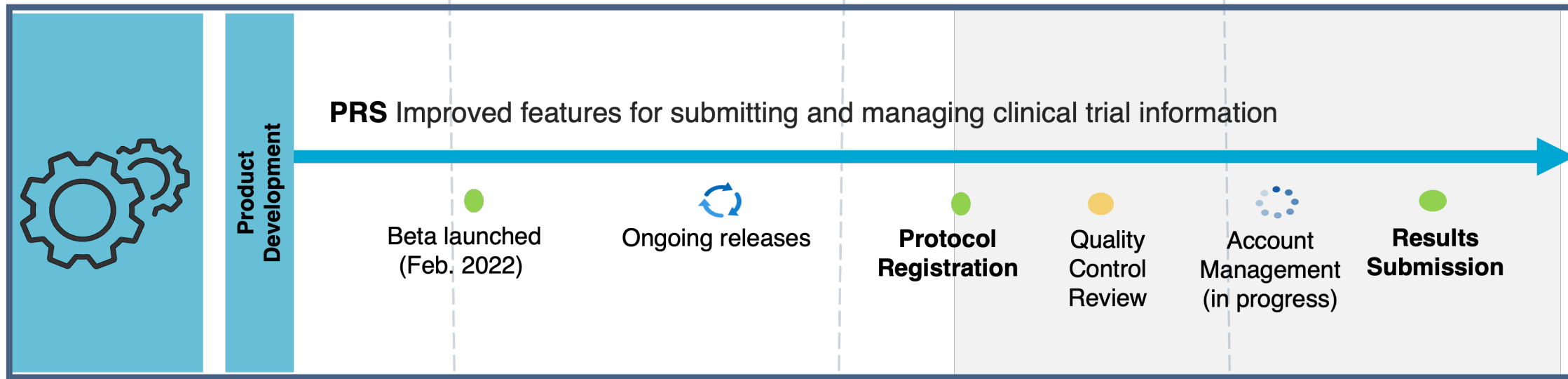


2021

2022

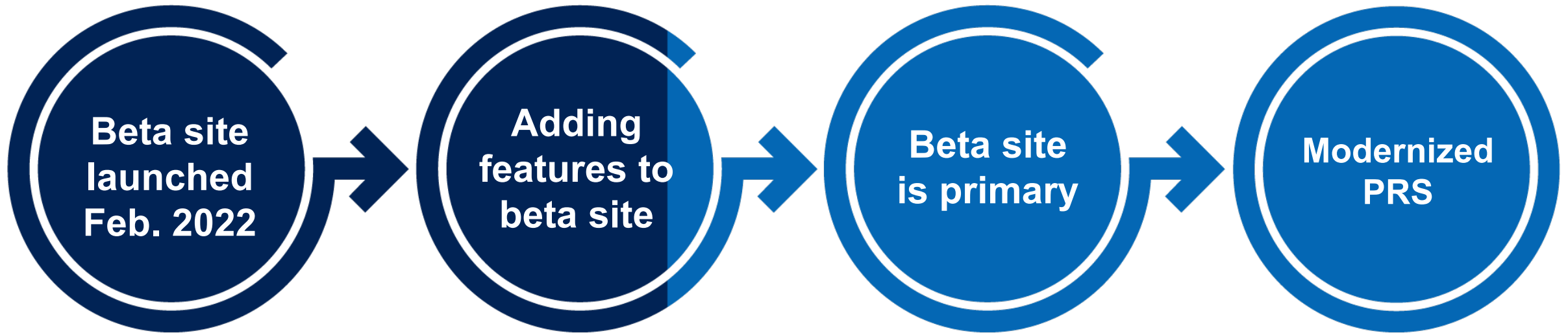
2023

2024



How Users See Change: PRS

----- Continuous Feedback -----



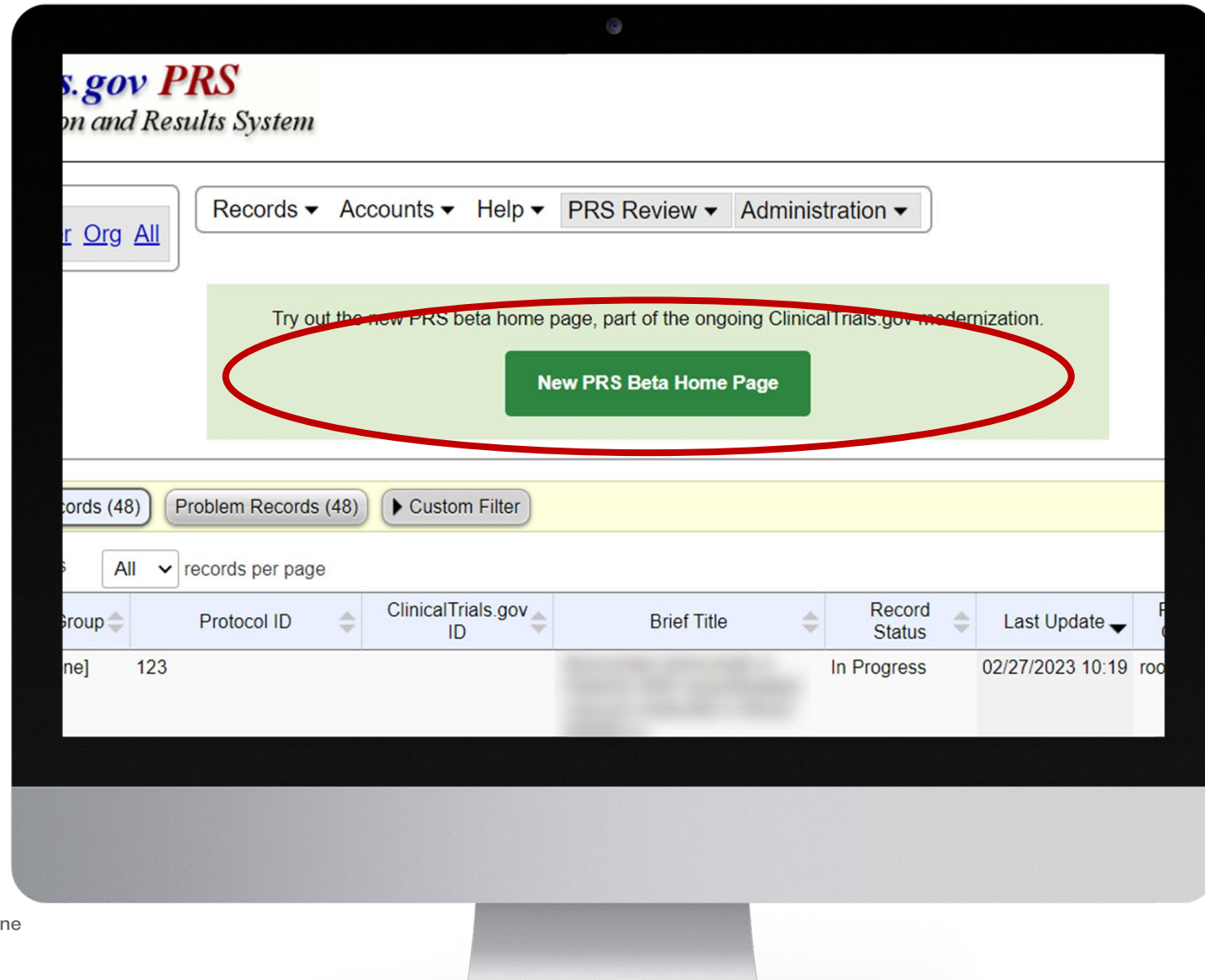
Beta site available in parallel to the classic site

Improving beta site until all needed features are included
Latest features available in PRS Test (sandbox environment)

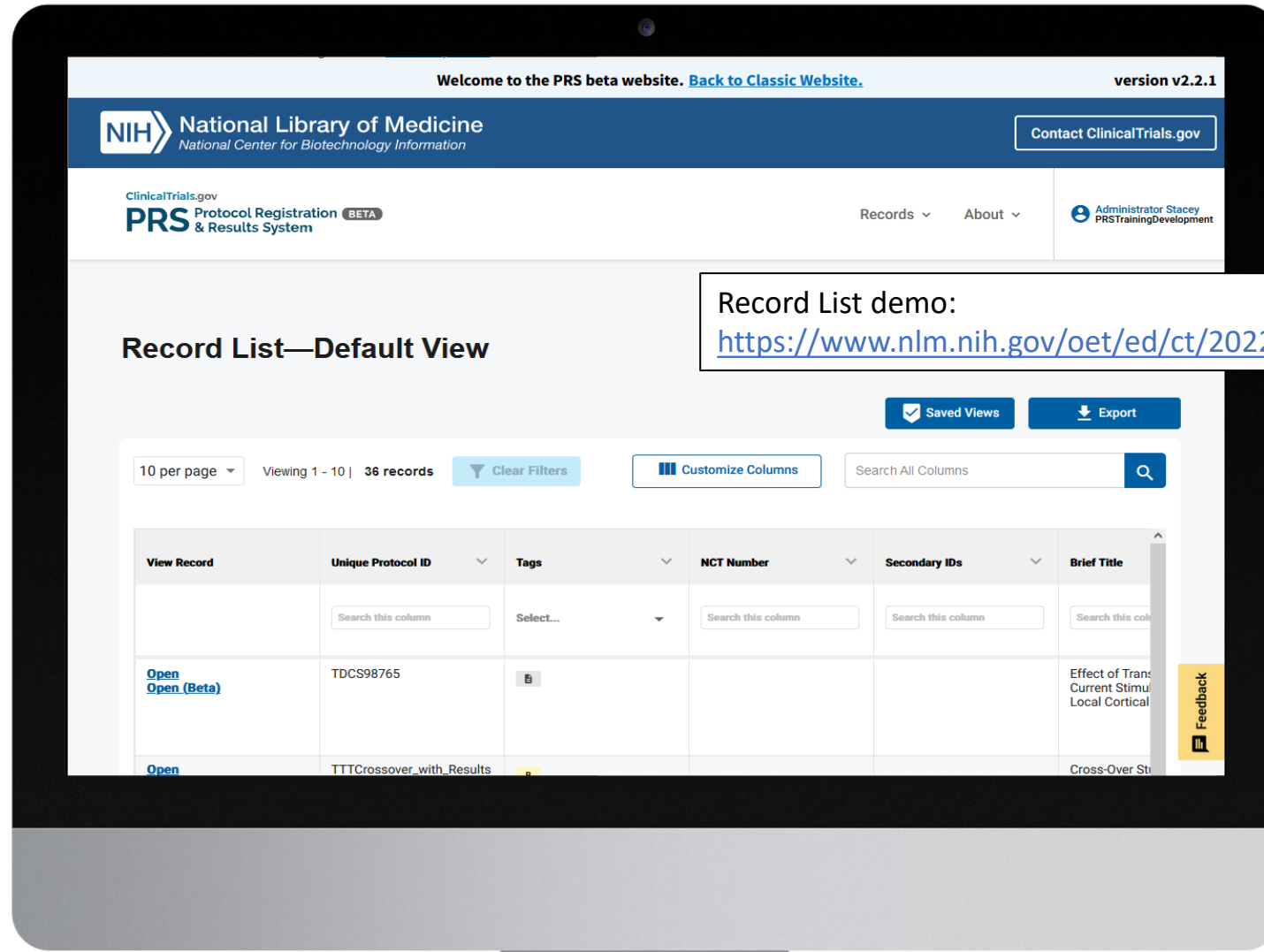
Classic site will still be available as the secondary site

Modernized PRS will be the only site; classic site will be retired (anticipated in 2025)

PRS Beta Orientation: Log-in Page and Link to PRS Beta

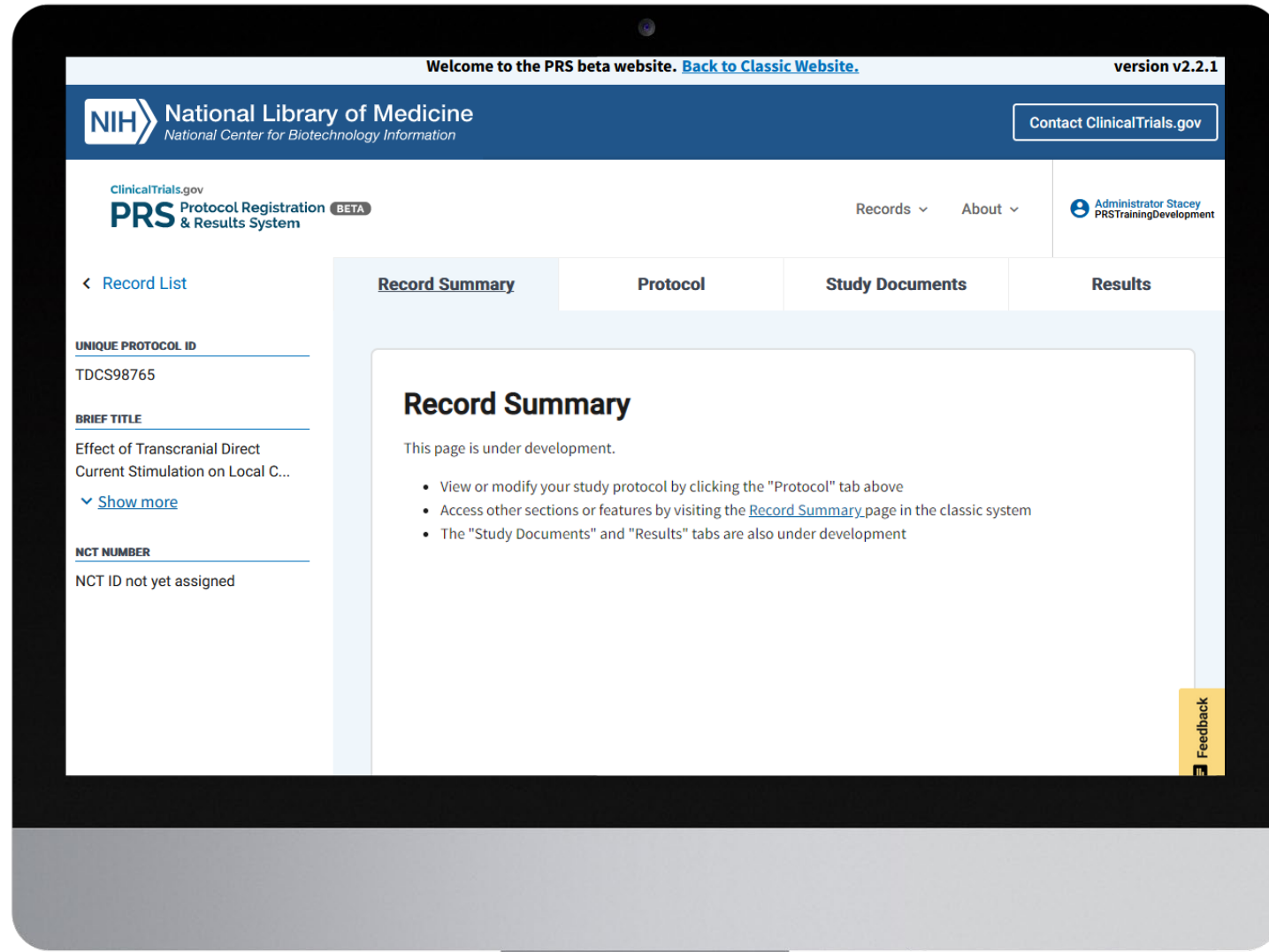


PRS Beta Orientation: Record List

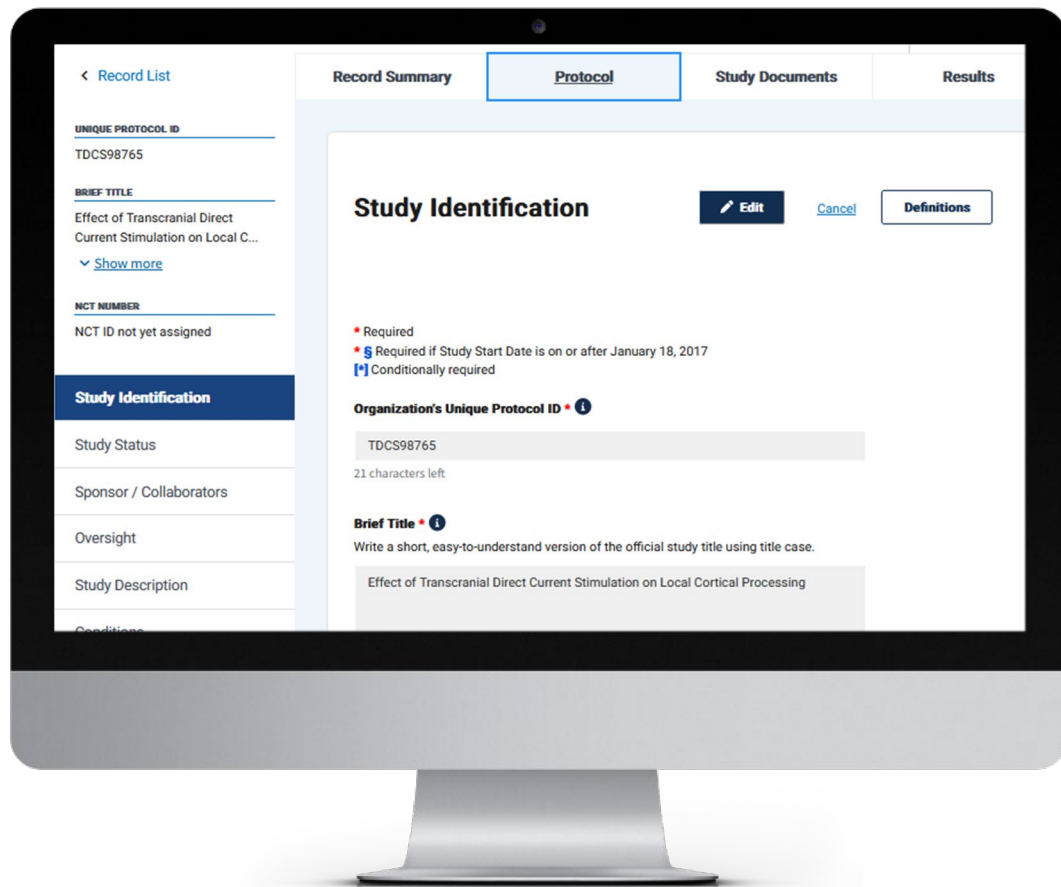


Record List demo:
https://www.nlm.nih.gov/oet/ed/ct/2022_prs/2022_prs_demo.html

PRS Beta Orientation: Record Summary



PRS Beta Orientation: Study Identification



< Record List

Record Summary **Protocol** Study Documents Results

UNIQUE PROTOCOL ID
TDCS98765

BRIEF TITLE
Effect of Transcranial Direct Current Stimulation on Local C...
[Show more](#)

NCT NUMBER
NCT ID not yet assigned

Study Identification [Edit](#) [Cancel](#) [Definitions](#)

• Required
• S Required if Study Start Date is on or after January 18, 2017
• [i] Conditionally required

Organization's Unique Protocol ID • i

TDCS98765
21 characters left

Brief Title • i
Write a short, easy-to-understand version of the official study title using title case.

Effect of Transcranial Direct Current Stimulation on Local Cortical Processing
222 characters left

Acronym • i
Required if one exists. It will be included in parentheses at the end of the Brief Title.

14 characters allowed

Study Type • i

Interventional
Participants are assigned to one or more interventions, based on a protocol.

Observational
Participants are **not** assigned to interventions based on a protocol.

Expanded Access
Participants receive an experimental drug or device outside of a clinical trial protocol.

Study Status
Sponsor / Collaborators
Oversight
Study Description
Conditions
Study Design
Arms and Interventions
Outcome Measures
Eligibility
Contacts / Locations
IPD Sharing Statement
References

Feedback

PRS Beta Orientation: Help Drawer

New Help Drawer

- Includes the following for each data element:
 - Brief guidance (plain language)
 - Additional information (plain language)
 - Data element definition (technical)
- Pop-out feature is easy to see while entering data anywhere on the page.
- Drawer is consistent with the ClinicalTrials.gov Beta glossary design.
- **Definitions** link is also provided at the top of the page.

The screenshot displays the ClinicalTrials.gov PRS Beta interface. On the left, a sidebar menu lists various data elements: Study Identification, Study Status, Sponsor / Collaborators, Oversight, Study Description, Conditions, Study Design, Arms and Interventions, Outcome Measures, Eligibility, Contacts / Locations, IPD Sharing Statement, and References. The 'Study Identification' element is selected and highlighted in blue.

The main content area shows the 'Record Summary' for a study with the following details:

- UNIQUE PROTOCOL ID:** TDCS98765
- BRIEF TITLE:** Effect of Transcranial Direct Current Stimulation on Local C... (with a 'Show more' link)
- NCT NUMBER:** NCT ID not yet assigned

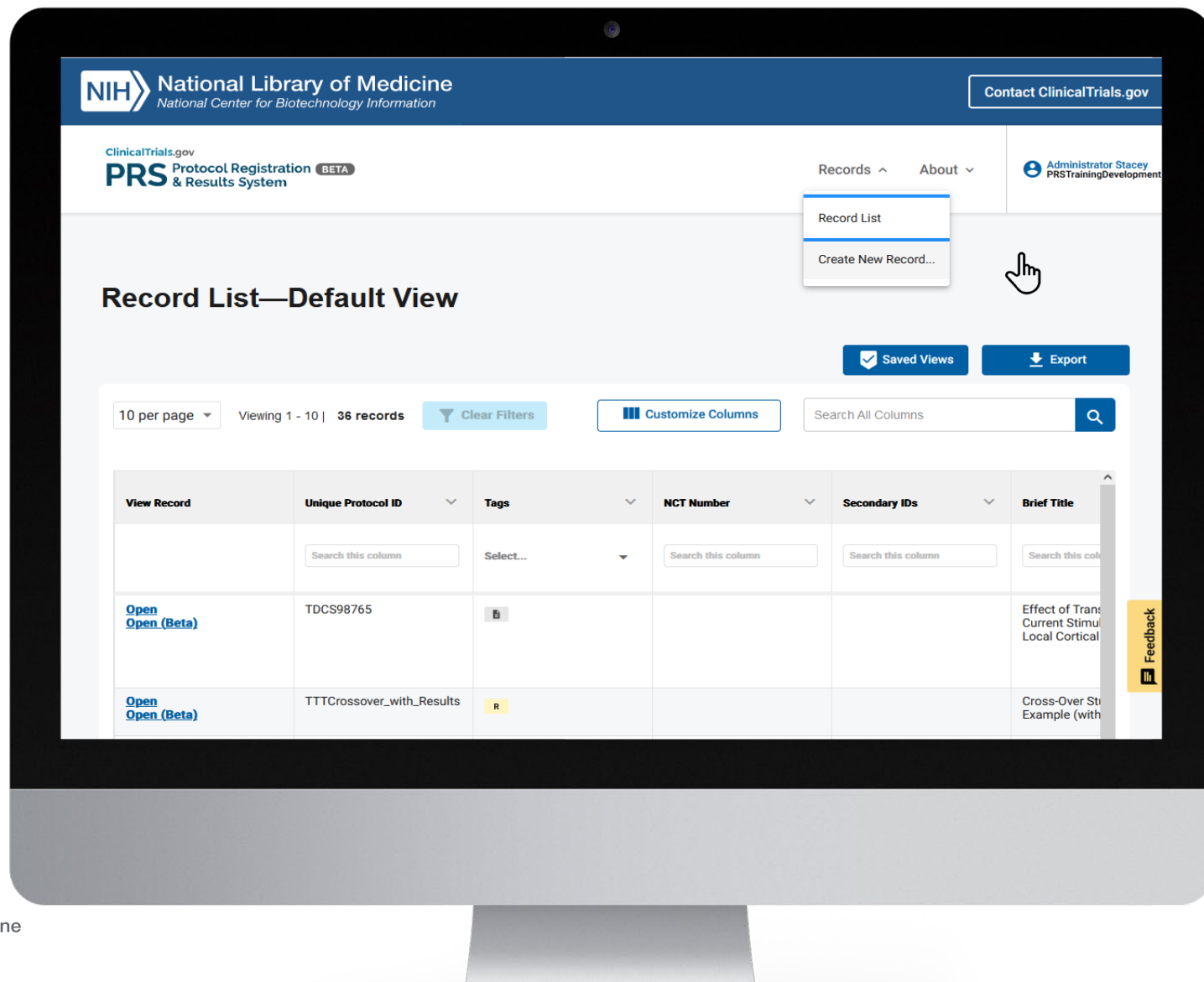
The 'Study Identification' section includes the following fields:

- Organization's Unique Protocol ID:** TDCS98765 (21 characters left)
- Brief Title:** Write a short, easy-to-understand version of the official title. (222 characters left)
- Acronym:** Required if one exists. It will be included in parentheses. (14 characters allowed)
- Study Type:** Radio buttons for Interventional, Observational, and Expanded Access.

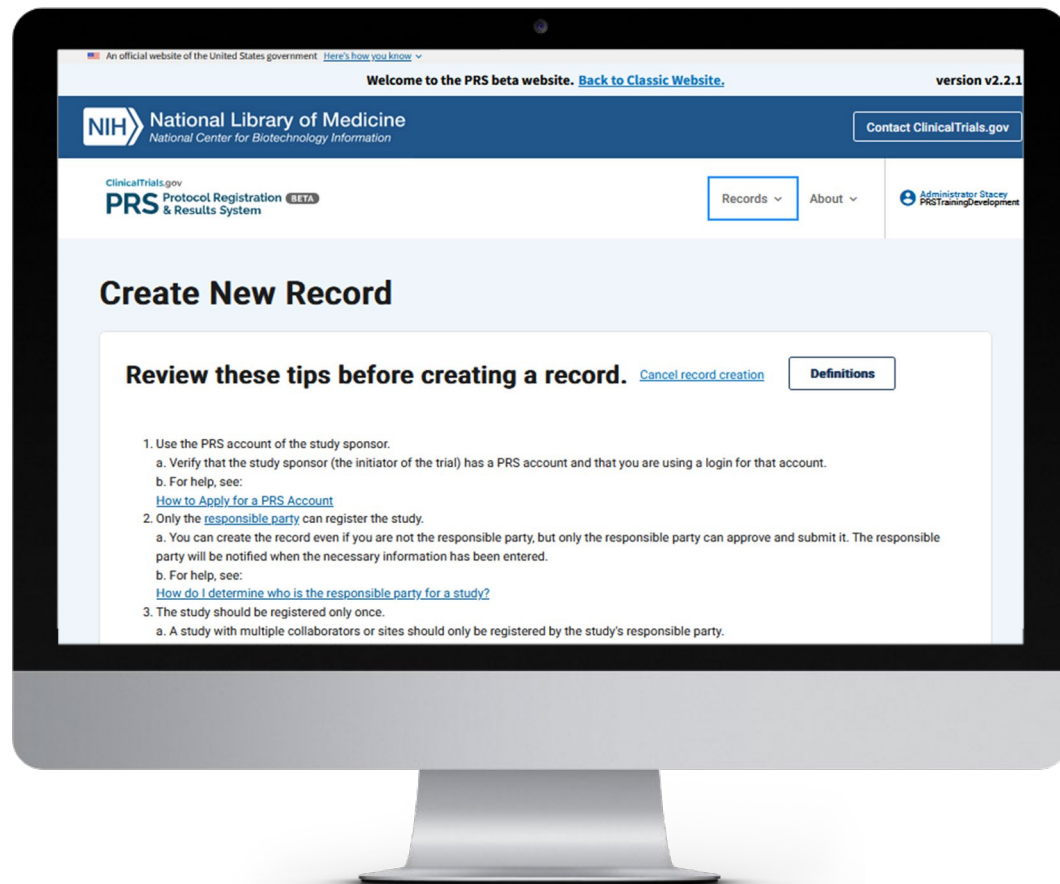
On the right, a dark blue 'Help Drawer' is open, showing 'Additional Information' and 'Data Element Definition' for the 'Organization's Unique Protocol ID' field. The 'Additional Information' section explains that the ID can be the study's ethics committee approval number, grant number, institutional review board number, or any similar unique identifier, and that it can only be used for one record in the organization's PRS account. The 'Data Element Definition' section provides a technical definition: 'Unique Protocol Identification Number' is any unique identifier assigned to the protocol by the sponsor, with a 30-character limit and a 'Link to DED'.

A 'Feedback' button is visible in the bottom right corner of the help drawer.

PRS Beta Orientation: Records Drop-down Menu



PRS Beta Orientation: Create New Record



An official website of the United States government [Here's how you know](#) version v2.2.1

Welcome to the PRS beta website. [Back to Classic Website.](#)

NIH National Library of Medicine
National Center for Biotechnology Information [Contact ClinicalTrials.gov](#)

ClinicalTrials.gov
PRS Protocol Registration & Results System **BETA** [Records](#) [About](#) [Administrator Stacey PRS Training/Development](#)

Create New Record

Review these tips before creating a record. [Cancel record creation](#) [Definitions](#)

1. Use the PRS account of the study sponsor.
 - a. Verify that the study sponsor (the initiator of the trial) has a PRS account and that you are using a login for that account.
 - b. For help, see:
[How to Apply for a PRS Account](#)
2. Only the [responsible party](#) can register the study.
 - a. You can create the record even if you are not the responsible party, but only the responsible party can approve and submit it. The responsible party will be notified when the necessary information has been entered.
 - b. For help, see:
[How do I determine who is the responsible party for a study?](#)
3. The study should be registered only once.
 - a. A study with multiple collaborators or sites should only be registered by the study's responsible party.
 - b. All study sites should be listed in a single study record.

Required
S Required if Study Start Date is on or after January 18, 2017
I Conditionally required

Organization's Unique Protocol ID **i**

30 characters allowed

Brief Title **i**

300 characters allowed , at least 18 characters required

[Feedback](#)

PRS Beta Plan for 2023–24

Protocol Registration Data-Entry Forms

- **Currently** available in PRS Test
- **In May**, will release to the PRS Beta production site

Coming in 2023–24

- Record submission workflow and Record Summary
- Protocol registration quality assurance (QA)/quality control (QC) processes
- Results submission

The screenshot displays the 'Protocol' tab of the PRS Beta interface. On the left is a navigation menu with a 'Record List' link and a list of sections: 'Study Identification' (highlighted), 'Study Status', 'Sponsor / Collaborators', 'Oversight', 'Study Description', 'Conditions', 'Study Design', 'Arms and Interventions', 'Outcome Measures', 'Eligibility', 'Contacts / Locations', 'IPD Sharing Statement', and 'References'. The main content area shows the 'Study Identification' form for protocol ID TDCS98765. The form includes fields for 'Organization's Unique Protocol ID' (filled with TDCS98765), 'Brief Title' (filled with 'Effect of Transcranial Direct Current Stimulation on Local Cortical Processing'), and 'Acronym'. The 'Study Type' section has three radio button options: 'Interventional' (selected), 'Observational', and 'Expanded Access'. A 'Feedback' button is located in the bottom right corner.

Record List

Record Summary Protocol Study Documents Results

UNIQUE PROTOCOL ID
TDCS98765

BRIEF TITLE
Effect of Transcranial Direct Current Stimulation on Local C...
[Show more](#)

NCT NUMBER
NCT ID not yet assigned

Study Identification

Study Status

Sponsor / Collaborators

Oversight

Study Description

Conditions

Study Design

Arms and Interventions

Outcome Measures

Eligibility

Contacts / Locations

IPD Sharing Statement

References

Study Identification [Edit](#) [Cancel](#) [Definitions](#)

Required

Required if Study Start Date is on or after January 18, 2017

Conditionally required

Organization's Unique Protocol ID

TDCS98765
21 characters left

Brief Title

Write a short, easy-to-understand version of the official study title using title case.

Effect of Transcranial Direct Current Stimulation on Local Cortical Processing
222 characters left

Acronym

Required if one exists. It will be included in parentheses at the end of the Brief Title.

14 characters allowed

Study Type

Interventional
Participants are assigned to one or more interventions, based on a protocol.

Observational
Participants are **not** assigned to interventions based on a protocol.

Expanded Access
Participants receive an experimental drug or device outside of a clinical trial protocol.

Feedback

Up Next . . .

2–3 p.m.

Breakout Rooms

Room 1: ClinicalTrials.gov Beta

Steven Woloshin, The Dartmouth Institute

*Christina Robinson, ClinicalTrials.gov Beta
Product Owner*

Room 2: PRS Beta

Carrie Dykes, University of Rochester

Nachiket Dharker, PRS Beta Product Owner

Summary

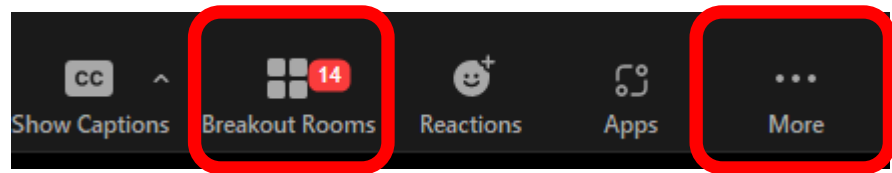
Anna Fine, Acting Director of ClinicalTrials.gov

We are currently
on a break and will
resume at 2 p.m.



Breakout Rooms

Choose a room for 2–2:45 p.m.
Room 1: ClinicalTrials.gov Beta
Room 2: PRS Beta





Anna Fine

Acting Director of
ClinicalTrials.gov

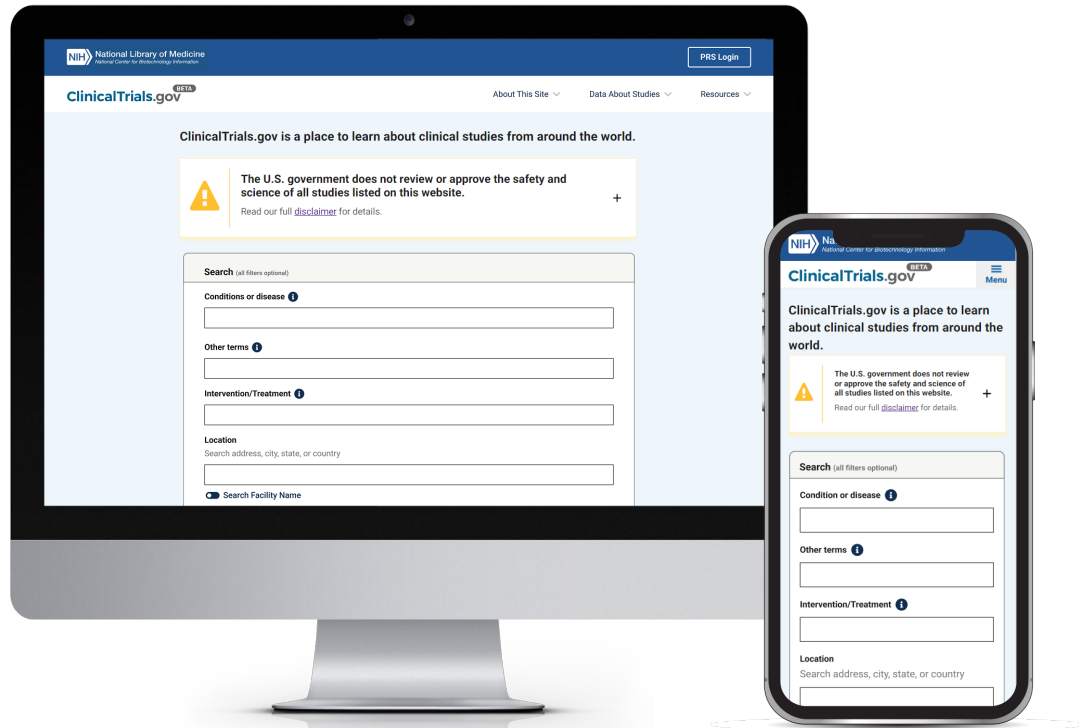
Summary

Starting at approximately 2:45 p.m.,
after the breakout rooms close

Recap of the Breakout Room Discussions

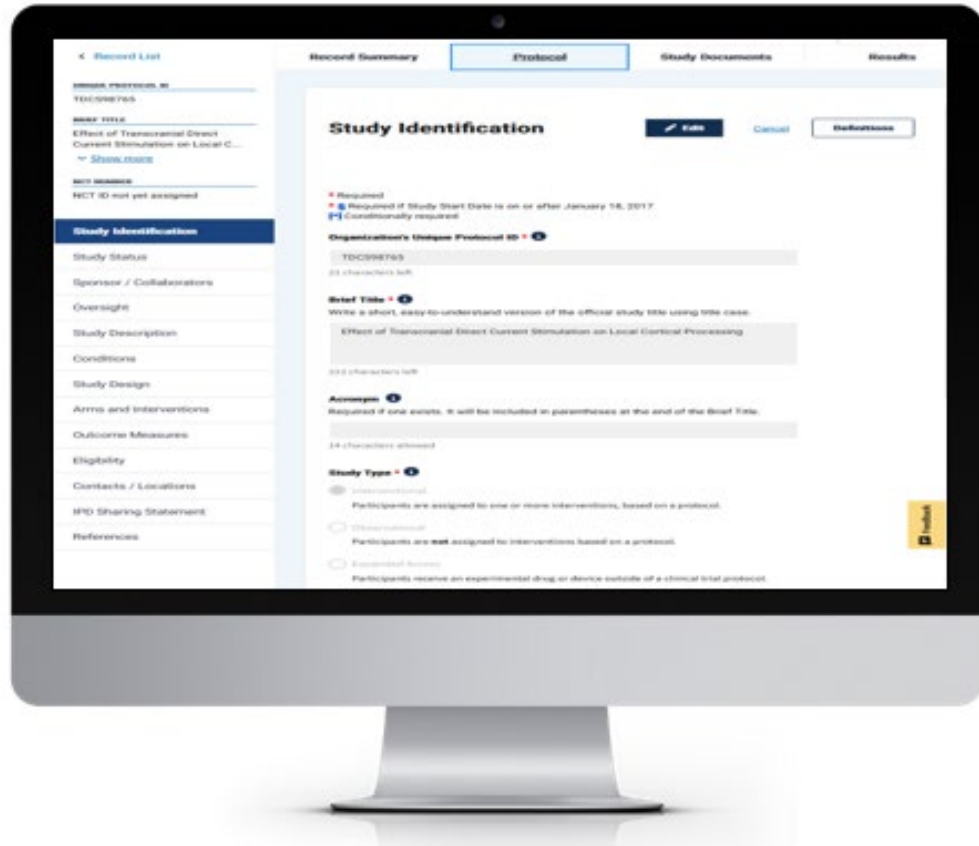
- The breakout rooms were recorded. The recordings and slides for both rooms will be made available.
- Highlights from Room 1: ClinicalTrials.gov Beta
- Highlights from Room 2: PRS Beta

ClinicalTrials.gov Beta Summary

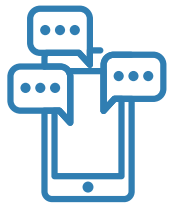


- By June, the beta site will be the primary website!
 - In 2023, the classic site will remain available. (Will be retired sometime in 2024)
- Currently available at beta.clinicaltrials.gov
- Modern look and feel
- Ease of use on mobile devices
- Easy-to-understand informational content
- New cloud-based infrastructure

PRS Beta Summary



- In May, the protocol registration data-entry forms will be available in the PRS Beta production site.
 - Currently available in PRS Test
- Modern look and feel
- Results reporting module coming in late 2024
- Easy navigation, with integrated help content



ClinicalTrials.gov Modernization

Outreach and Engagement

27

Social media posts sent from NCBI and NLM accounts to an audience of **850,000**



1,000+

Comments with ideas for improving the public site and PRS from an RFI in 2020 and comments received from an expert review

1,800+

Feedback comments submitted by users of the beta public site



65

Communications sent or posted, including 25 Hot Off the PRS! e-bulletins, 26 What's New updates, 7 *NLM Technical Bulletin* articles, 5 NLM Announces, 1 NLM Musings from the Mezzanine: Director's Update, and 1 OER Open Mike **to an audience of 50,000**



100+

Interviews with data submitters, data researchers, patients, and patient advocates

2

Public meetings

5

Webinars reaching **1,900+ attendees**

5

Blog posts and 1 mention from *Musings from the Mezzanine* **to an audience of 500,000**

3

Educational videos **viewed 1,100+ times**

2

Progress reports **viewed 140 times**

15

Working Group meetings to provide expert user input to the design and development process

Poll Question 2

What's your preferred method for staying informed about the modernization effort?

- Social media (Facebook, Twitter, LinkedIn)
- Webinars
- Webpage postings
- Blog posts
- Office hours
- Training sessions
- e-Bulletins/newsletter (e.g., Hot Off the PRS!)
- Meetings like this



| Next Steps

- **NLM** will:
 - Announce when the meeting recording and slides are available in Hot Off the PRS!
 - Announce when the protocol registration data-entry forms are available in the PRS Beta production site
 - Announce when ClinicalTrials.gov Beta becomes the primary public website
- **Attendees** will continue to provide their feedback on our modernized website and PRS!



Thank You!



About the modernization effort

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



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

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



Contact us

register@clinicaltrials.gov