ClinicalTrials.gov Modernization and Beta Sites Progress

Webinar Moderator: Anna M. Fine, PharmD, MS
Acting Director, ClinicalTrials.gov

October 27, 2022
1–2 p.m. ET

NIH National Library of Medicine

Webinar Housekeeping Items

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

We will address questions submitted through the Q&A box at the end of the webinar, as time permits. Unanswered questions may be addressed in future communications.

Webinar Goals

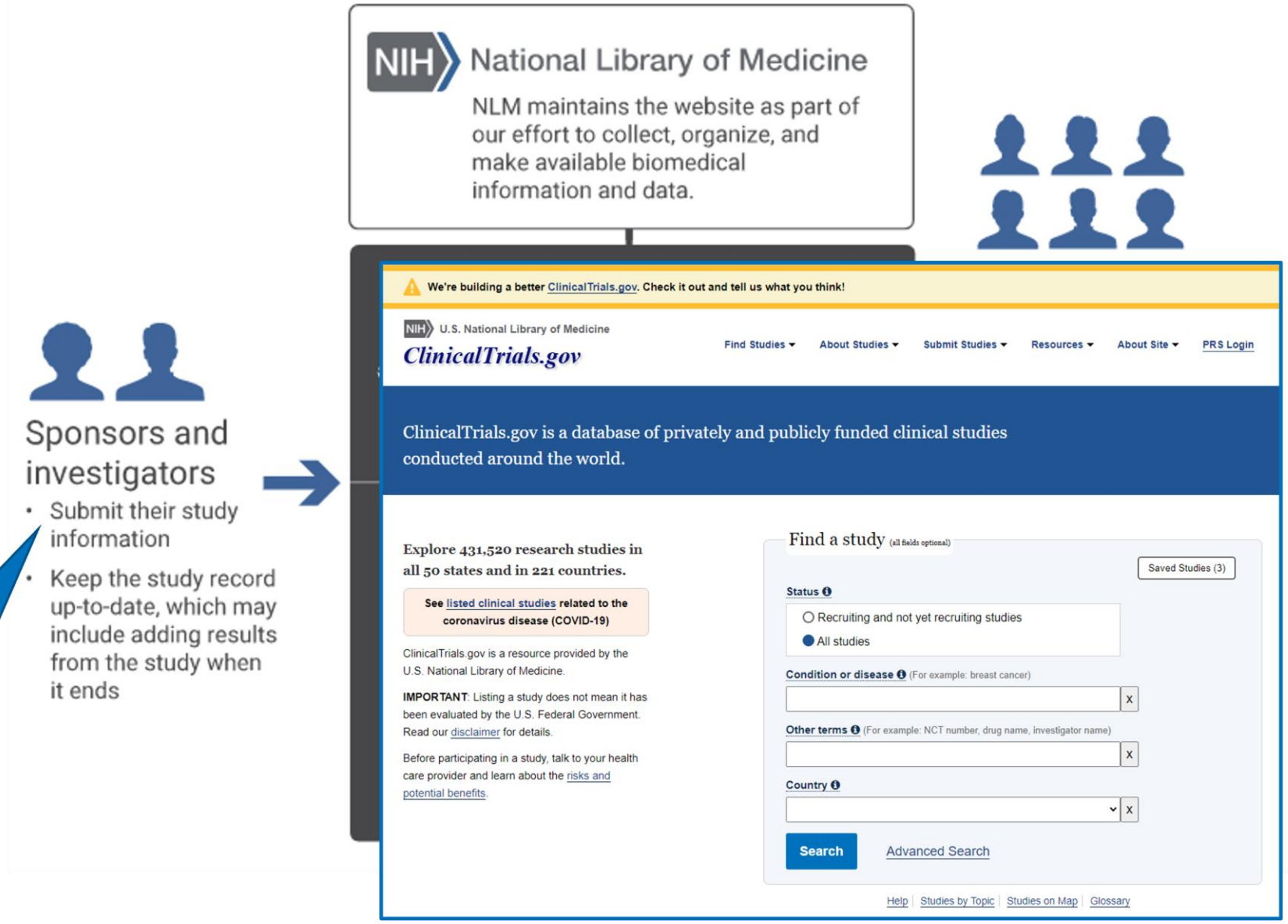
- **Provide an update on the ClinicalTrials.gov modernization effort**
- **Present the current beta sites and what users will see in the future**
  - Protocol Registration and Results System (PRS) Beta
  - ClinicalTrials.gov Beta
- **Share the modernization timeline and next steps**
- **Answer questions**

ClinicalTrials.gov Modernization Overview

Dr. Anna M. Fine, Acting Director,
ClinicalTrials.gov

What Is Clinical Trials.gov?

The submission database is called the Protocol Registration and Results System, or the **PRS.**



Polling Question-1

How would you describe your role in relation to ClinicalTrials.gov?

a. Sponsor/Data Submitter
b. Patient/Caregiver
c. Data Researcher
d. Health Care Professional
e. Other

ClinicalTrials.gov Modernization Objectives

Improve the user experience

Upgrade the technical infrastructure and processes to enhance sustainability

Support the existing legal, regulatory, and policy framework

Modernization Overview

YEAR 1
Engagement

- 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 the ClinicalTrials.gov Beta website
- Issued modernization summary report for 2019–21
- Communicated availability of beta release to stakeholders

YEAR 3
Implementation

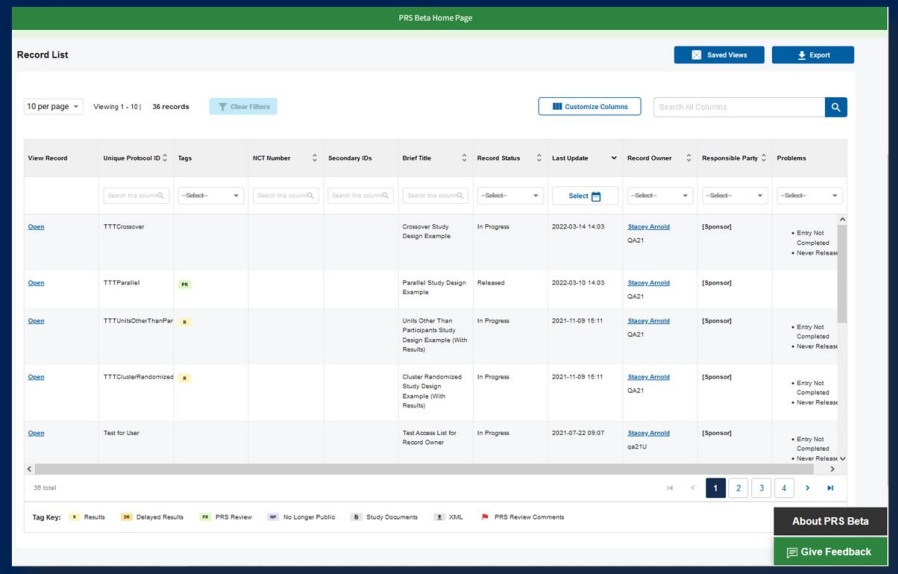
- Launch first release of PRS Beta and release updates
- Conduct usability research and make iterative improvements to the beta sites
- Release updates to ClinicalTrials.gov Beta

YEARS 4–5
More Releases and Refinements

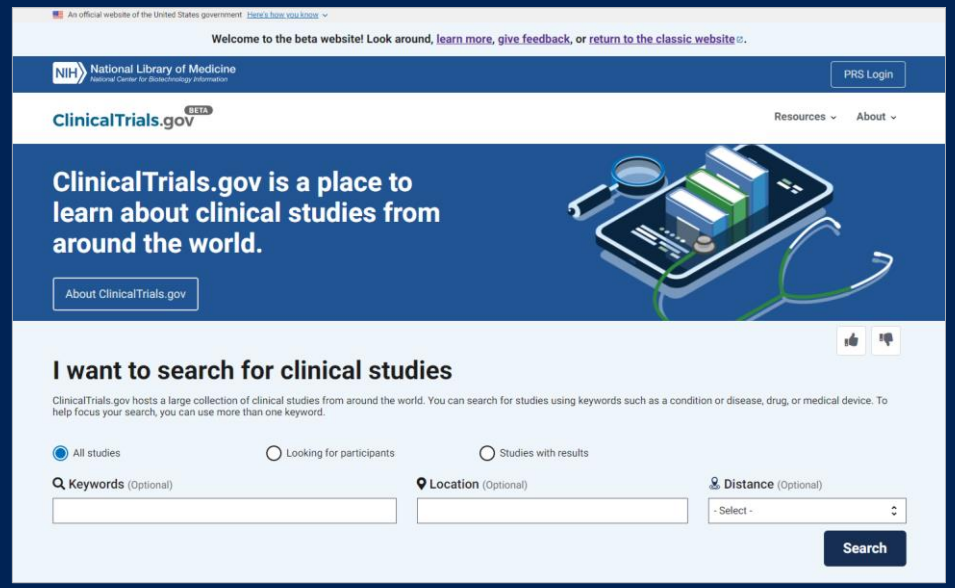
- Continue release of updates and refinements to beta sites until they can stand alone
- Continue engagement, usability testing, and evaluation
- Make ClinicalTrials.gov Beta the primary landing page
- Release PRS Beta protocol registration and results reporting components

Meet Our Beta Sites

PRS Beta



ClinicalTrials.gov Beta



Dr. Nachiket Dharker

PRS Beta Product Owner

PRS Beta Update

Chronology of the PRS Beta Releases and Features Available

ClinicalTrials.gov
PRS Protocol Registration & Results System BETA

February 3, 2022
New Record List in the PRS

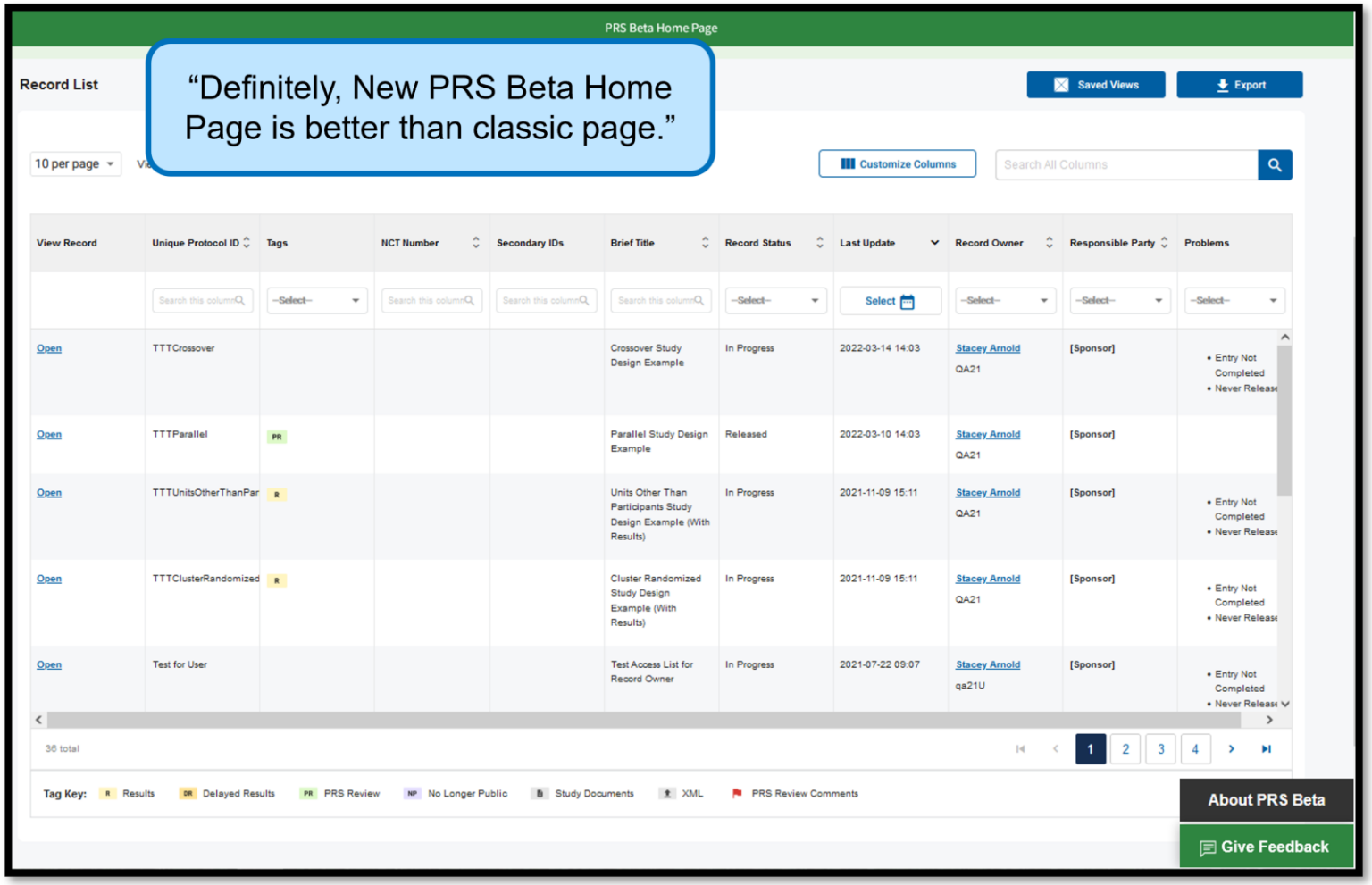
May 20, 2022
Updates in the PRS

July 14, 2022
Updates in the PRS

Features Available

- Updated Record List
- Planning View and Public Site View
- About PRS Beta page
- Release Notes page

PRS Beta Record List



Key Features

- Modern and intuitive design
- Ability to email study staff directly from the Record List
- Customizable display
  - Reorder, add, and hide columns
  - Apply multicolumn filters
  - Search and sort in each column separately
- Additional content, including more study dates with date type (actual or anticipated)
- Available for download in Microsoft Excel and comma-separated values (CSV) formats

About Menu

PRS Beta Home Page. Back to Classic Home Page

version v-0.8.5

An official website of the United States government Here's how you know

NIH National Library of Medicine
National Center for Biotechnology Information

Contact ClinicalTrials.gov

ClinicalTrials.gov
PRS Protocol Registration & Results System BETA

Pop-up content:
- Navigation tips added to About PRS Beta
- Release Notes added

About
About PRS Beta
Release Notes

Nachiket Dharker
PRS

Records—Default View

Saved Export

10 per page | Viewing 1 - 10 | 882 records | Clear Filters | Customize Columns | Search All Columns

View Record	Unique Protocol ID	Tags	NCT Number	Secondary IDs	Brief Title
	Search this column	Select...	Search this column	Search this column	Search this col

Improved Feature: A Filter for Each Column

PRS Classic: Checkboxes for select columns and one search field

Record List

Org: PRS | All Records (13) | Problem Records (13) | Custom Filter

Symbols: R, DR, D, PR, U, NP

Overall Status: Not yet recruiting, Recruiting, Active, not recruiting, Enrolling by invitation, Completed, Suspended, Terminated, Withdrawn

Record Status: In Progress, Entry Completed, Approved, Released, PRS Review, Public, No Longer Public (e.g., duplicates)

Results Status: No Results, Created, Released, Posted

Delayed Results Status: No Delayed Results, Created, Released, Processed

Problems: No Problems, PRS Review Comments, Entry Not Completed, Not Recently Updated, Record Has Errors, Missing FDAAA Information, Late Results - per FDAAA, Incomplete Results - per FDAAA, Never Released, Update Not Released, Ready for Review and Approval

Showing: 1-10 of 13 records | 10 records per page | Search: | Show/Hide Columns

PRS Beta: Drop-down list or search field for each column

"I appreciate the search boxes for each field. It allows for more complex searching."

10 per page | Viewing 1 - 10 | 13 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
	Search this column	--Select--	Search this column	Search this column	Search this column	--Select--	Select	--Select--	--Select--	--Select--

Dr. Stacey Arnold
PRS Subject Matter Expert

PRS Beta Record List Prerecorded Demonstration

We Welcome Your Feedback!

PRS Beta Home Page. Back to Classic Home Page

version v-0.8.5

An official website of the United States government Here's how you know

NIH National Library of Medicine
National Center for Biotechnology Information

Contact ClinicalTr

ClinicalTrials.gov
PRS Protocol Registration & Results System BETA

About

Nac
PRS

Records—Default View

Saved Views

Export

10 per page

Viewing 1 - 10 | **884 records**

Clear Filters

Customize Columns

Search All Columns

View Record	Unique Protocol ID	Tags	NCT Number	Secondary IDs	Brief Title
	Search this column	Select...	Search this column	Search this column	Sea
Open	ParallelStudyZFTest	R			Asdf

Feedback

Continuing PRS Beta Development

Protocol Registration

Record Summary | Preview | Edit All | Help | Definitions

Edit **Study Identification**

Unique Protocol ID: Test_Parallel 11

Brief Title: A 24-Week Placebo-Controlled Trial of Remuverol in Adults With Condition A

Edit Study Identification

Help | Definitions

* Organization's Unique Protocol ID:	Test_Parallel 11
* Brief Title:	A 24-Week Placebo-Controlled Trial of Remuverol in Adults with Condition A
[*] Acronym: (if any)	If specified, will be included at end of Brief Title in parentheses.
* § Official Title:	A 24-Week Placebo-Controlled Trial of Remuverol in Adults with Condition A
[*] Secondary IDs: (if any)	+ Add Secondary ID

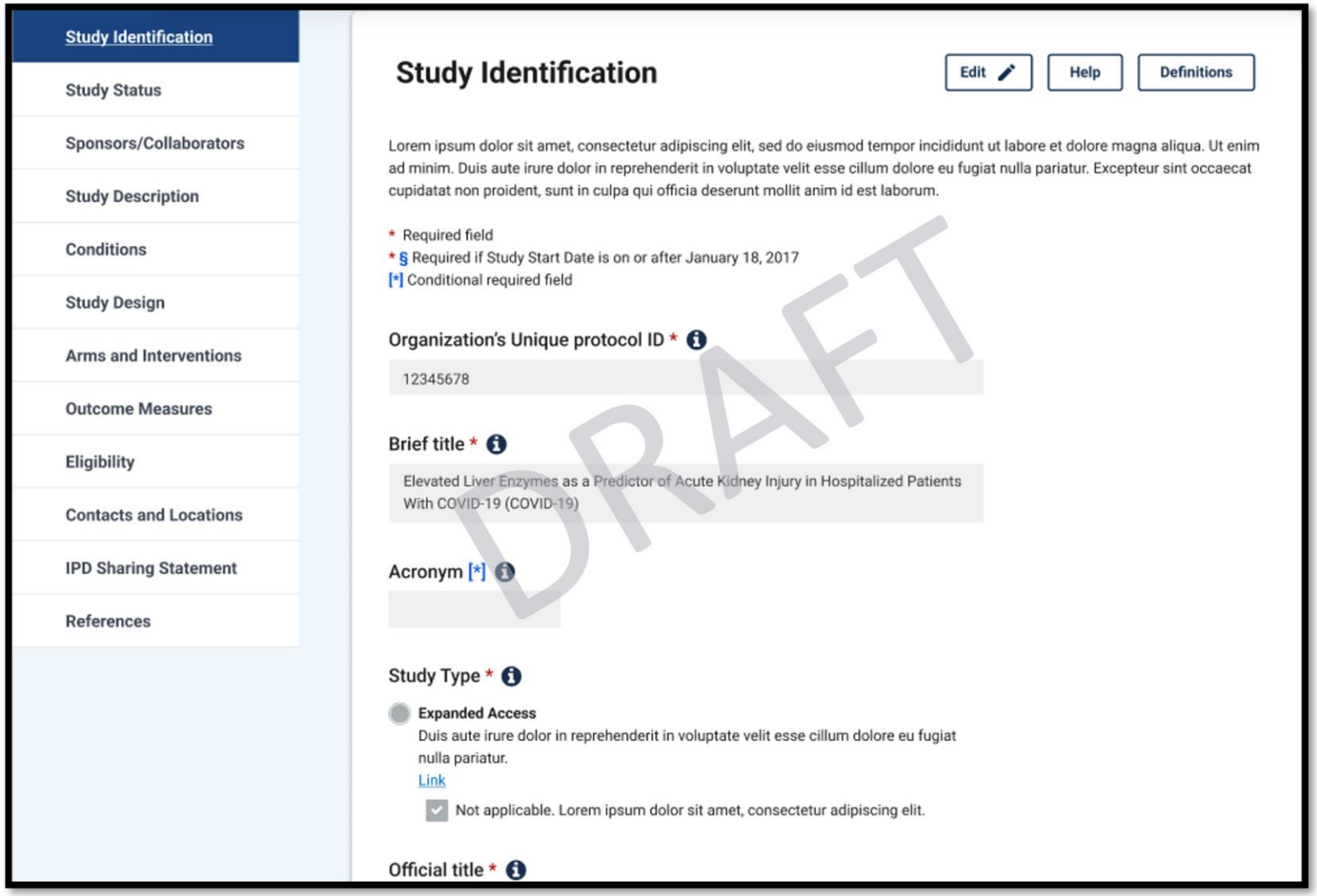
Collaborators:

Edit **Oversight**

U.S. FDA-regulated Drug: Yes

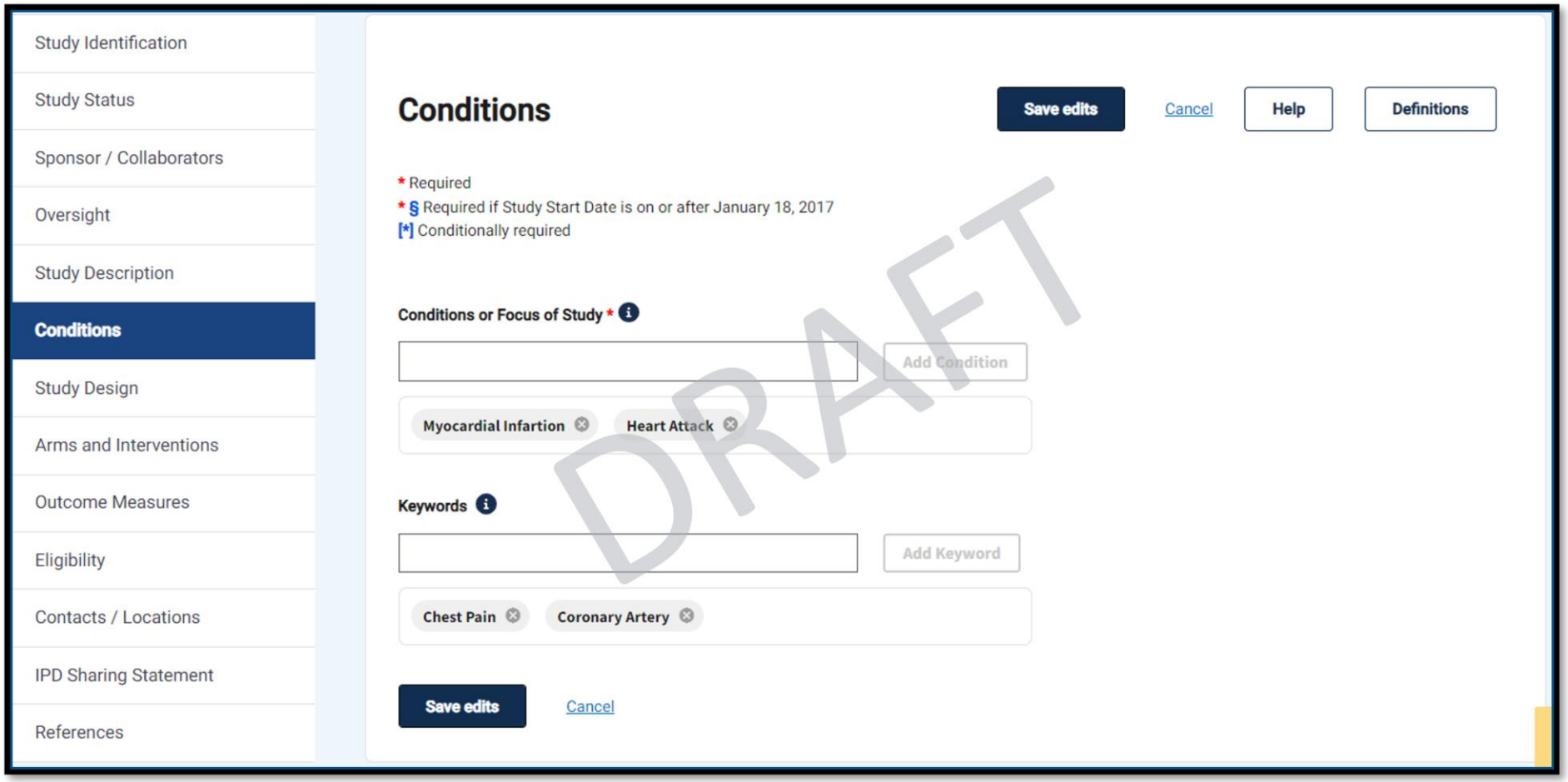
Continuing PRS Beta Development (Cont.-1)

Protocol Registration



Continuing PRS Beta Development (Cont.-2)

Protocol Registration



Continuing PRS Beta Development (Cont.-3)

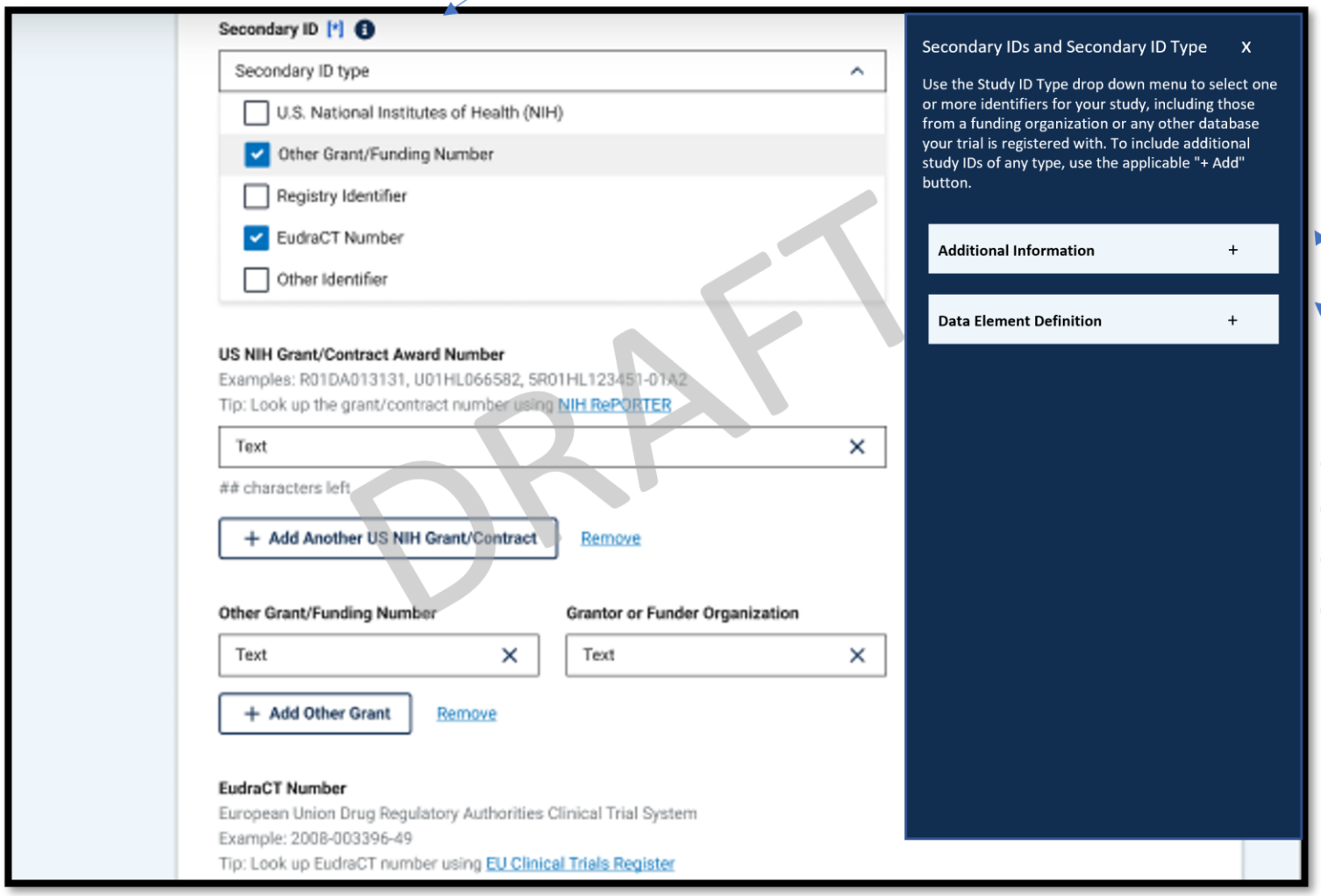
Help Drawer

Includes the following for each data element:

- Brief text
- Additional information
- The data element definition

The brief text and additional information are presented in lay language to better support PRS users.

User clicks on the information icon to open the help drawer.



Content in accordions can be expanded or collapsed.

PRS Beta Features

ClinicalTrials.gov
PRS Protocol Registration & Results System BETA

	Record and Account Management Experience	Data Submission and Review Experience	Technology Modernization
AVAILABLE	Intuitive Record List Search, filter, and sort functionality Customizable columns and views		Migration to NCBI secured platform
IN PROGRESS	Secure log-in	Protocol registration submission Easy navigation Improved error-handling Just-in-time help	Move to cloud Improve system architecture Optimize database with performance and data integrity
FUTURE	Create and modify accounts Manage groups and permissions Notifications Dashboards	Results reporting Study document upload Review workflow	Optimize database design

Ms. Christina Robinson

ClinicalTrials.gov Beta
Product Owner

ClinicalTrials.gov Beta Update

Polling Question-2

Have you visited the ClinicalTrials.gov Beta website?

a. Yes

b. No

Chronology of the ClinicalTrials.gov Beta Releases and Features Available

ClinicalTrials.gov BETA

December 8, 2021
Beta website launched

March 8, 2022
Update released

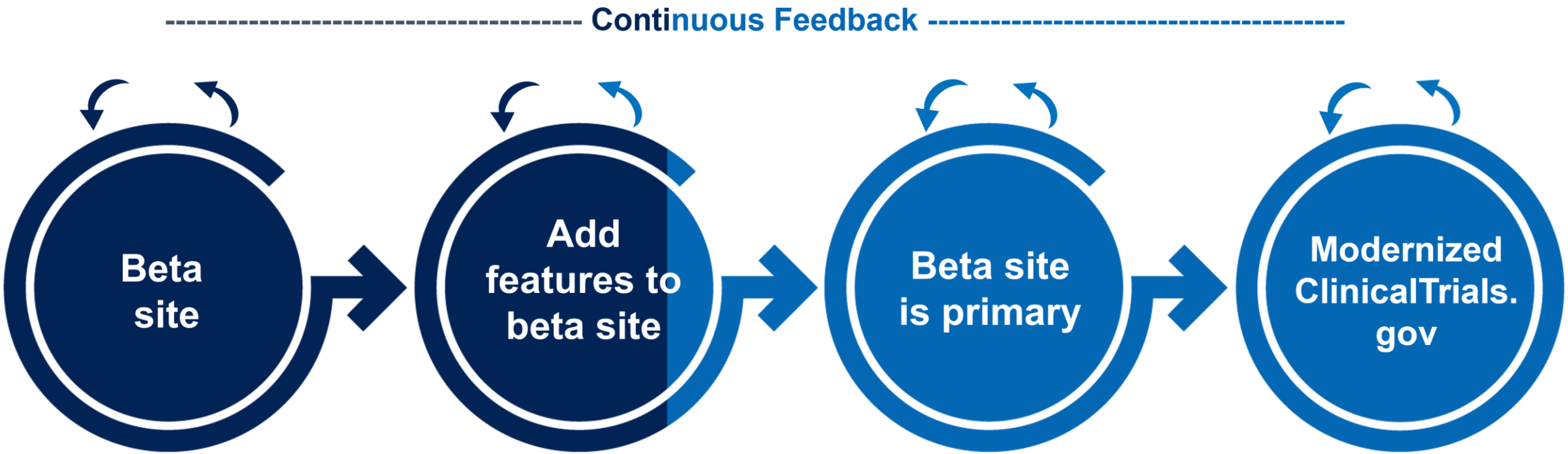
April 27, 2022
Update released

August 22, 2022
Update released

Features Available

- Release Notes page
- Study record page
- Glossary
- Search results download options
- Tabular view of search results
- Enhanced search

How Users See Change



Available in parallel to the current site

Improve until all needed features are included

Current site still available as the secondary site

Beta site is the only site; current site retired

Ms. Christina Robinson
ClinicalTrials.gov Beta Product Owner

ClinicalTrials.gov Beta Prerecorded Demonstration

ClinicalTrials.gov Beta Features

ClinicalTrials.gov BETA

	Search Experience	Study Record Experience	Easy-to-Find and Easy-to-Use Content
AVAILABLE	Expanded download formats Enhanced search* Improved ability to refine search results* Tabular view of search results*	Expanded study record data Fast Healthcare Interoperability Resources (FHIR) API pilot*	Learn About Studies About ClinicalTrials.gov Learn About FHIR*
IN PROGRESS		Tabular view of study records Improved study record history	Content migration and information architecture Support materials for using search
FUTURE	Beta Application Programming Interface (API) access Download to XML	Connections to trusted health information Next steps to join a study	Onboarding users

* Features released on August 22, 2022

Release Notes

Release Notes | Beta ClinicalTrials

beta.clinicaltrials.gov/release-notes

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

About ClinicalTrials.gov

Release Notes

Home › Release Notes

Release Notes

August 22, 2022

ClinicalTrials.gov Beta has been updated with a new search experience that combines the features of the basic search for clinical studies with the ability to narrow your search using additional criteria. Other updates and improvements have also been made to the search results and study record pages.

What's new

- Home page
  - Replaced the separate basic and advanced searches with a single, fully customizable combined search
  - Made the customizable combined search available right on the home page
- Search results page
  - Added a table view of search results

Give feedback

Classic website

https://beta.clinicaltrials.gov/release-notes

Ongoing User Research

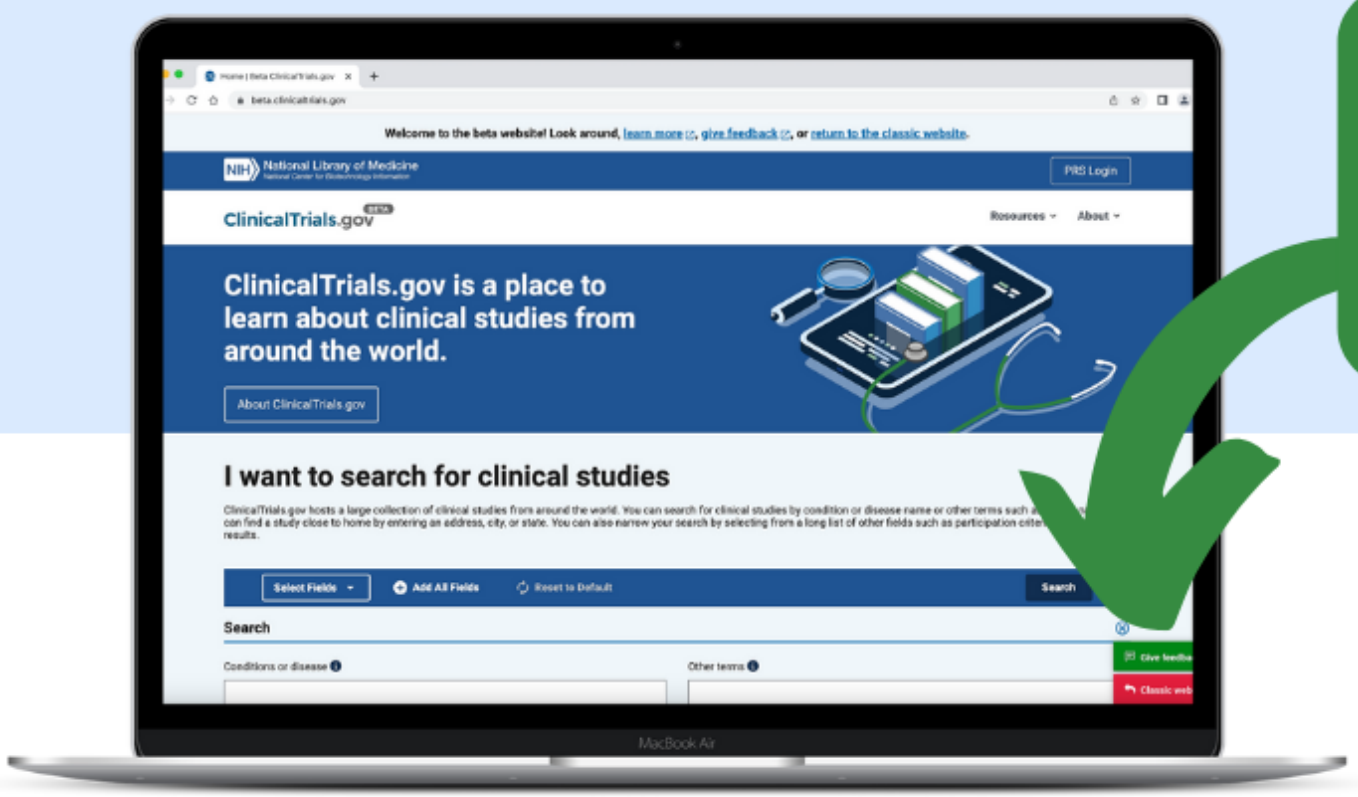
ClinicalTrials.gov is seeking data submitters, pharmaceutical administrators, academic administrators, clinical research coordinators, and individual investigators to provide feedback on the beta website.

To help us improve the user experience, participants will be asked to do one or more of the following: perform tasks on the beta website, take a survey, complete a card-sorting activity, or take part in a virtual interview.

The session may last from 15 to 60 minutes.

Use the **Give feedback** button and include your email address to express interest and learn more.

Feedback



GIVE US FEEDBACK!

We're building a modernized ClinicalTrials.gov website and want to hear from you!

NIH National Library of Medicine

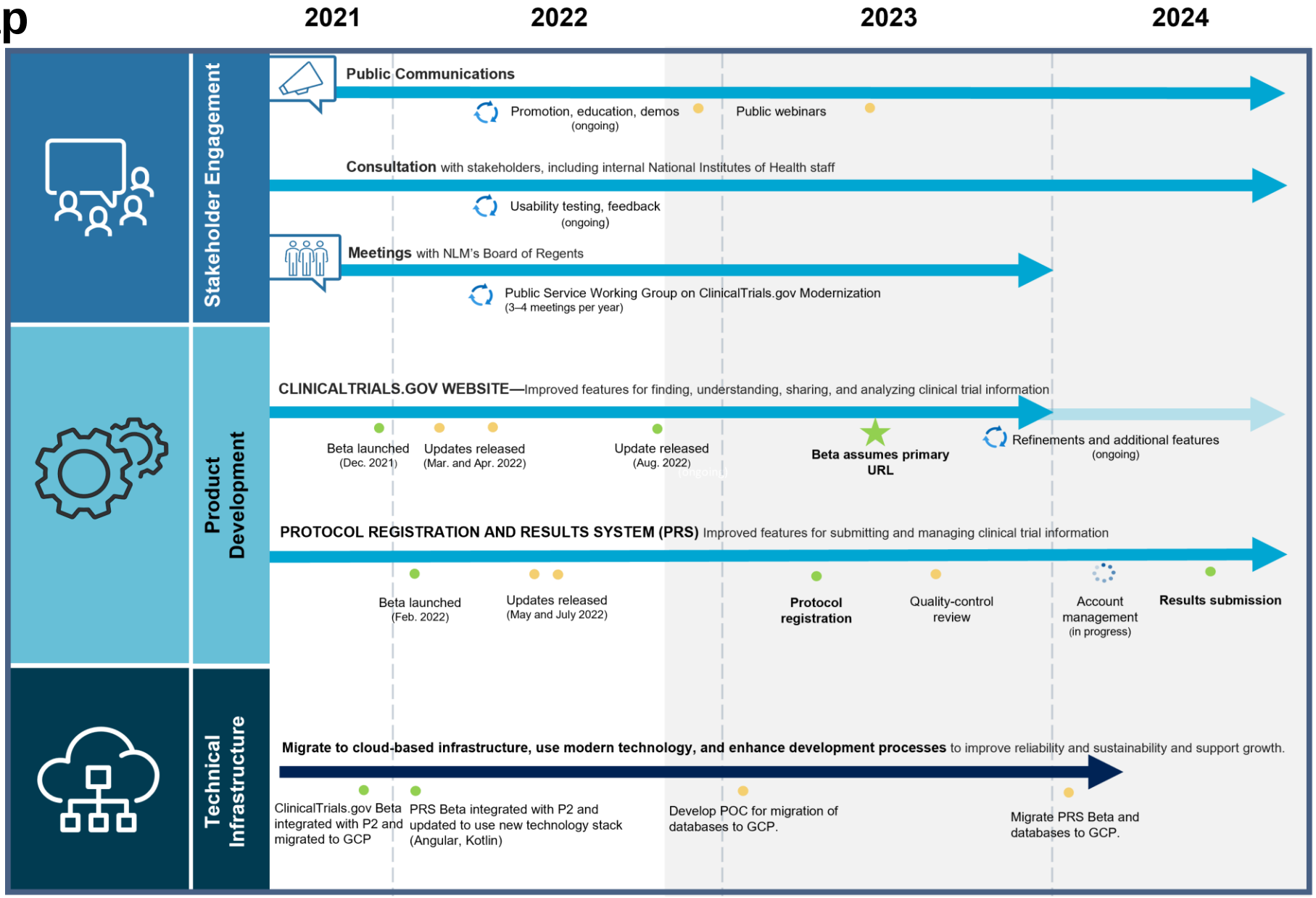
ClinicalTrials.gov BETA

Dr. Anna M. Fine

Acting Director, ClinicalTrials.gov

ClinicalTrials.gov Modernization Communications

Strategic Roadmap



Strategic Roadmap for ClinicalTrials.gov Modernization

Key:
GCP = Google Cloud Platform
P2 = NCBI's DevOps Platform v.2
POC = Proof of concept

Summary of Progress: 2021–22 Report

Focus areas include:

- Overview of ClinicalTrials.gov and the current phase of the modernization effort
- ClinicalTrials.gov and PRS beta releases and their alignment with modernization priorities and goals
- NLM Board of Regents Public Service Working Group on ClinicalTrial.gov Modernization and other stakeholder input on modernization
- Public communications related to modernization and the beta releases
- Research in support of the modernization effort
- Future modernization activities

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

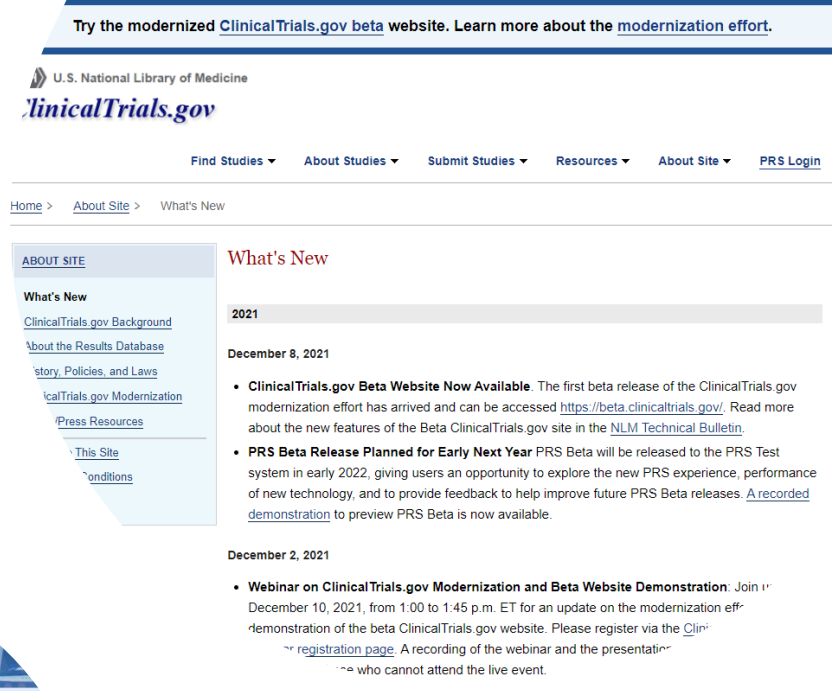
NIH National Library of Medicine

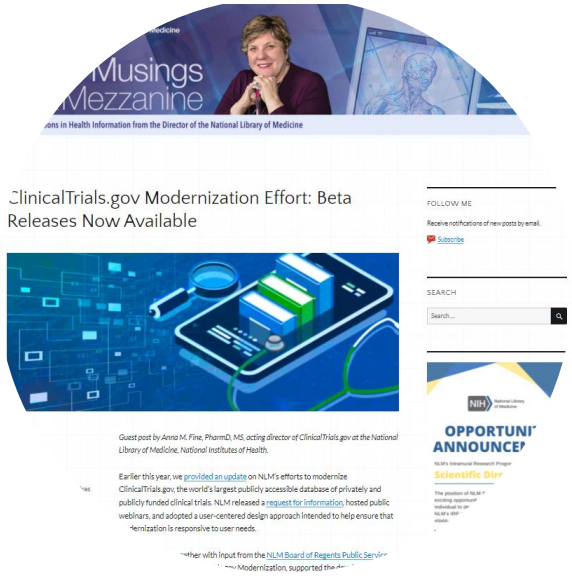
ClinicalTrials.gov

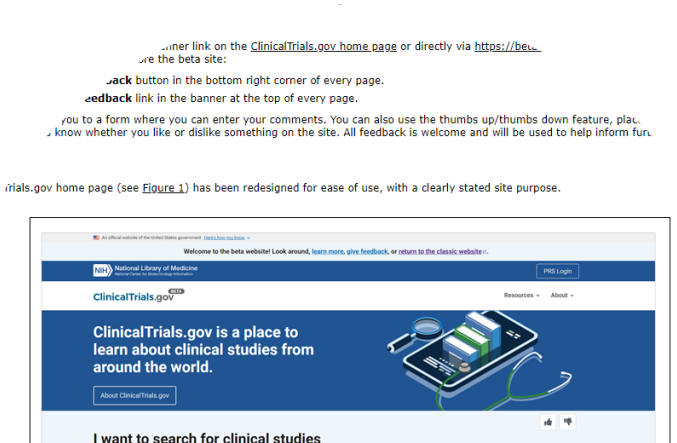
Issued the Report on the ClinicalTrials.gov Modernization Effort, Summary of Progress: 2019–21 in September 2021

Communications

- NLM Musings from the Mezzanine blog posts
- NLM Technical Bulletin articles
- LinkedIn posts
- What's New and ClinicalTrials.gov Modernization webpage updates
- NLM and NCBI tweets
- Hot Off the PRS! e-bulletin to 8,000+ subscribers
- Meetings with stakeholders
- Presentations at conferences
- ClinicalTrials.gov classic site banner
- Public webinars and prerecorded demonstrations







ClinicalTrials.gov Modernization and Beta Sites Progress Information

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Questions may be submitted through the Q&A box.

Sign up to receive Hot Off the PRS! email updates at: https://bit.ly/33qcZBb

Dr. Anna M. Fine
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Questions?

Thank you!