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
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 ClinicalTrials.gov?

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

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

YEAR 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

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
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

Pop-up content:
- Navigation tips added to About PRS Beta
- Release Notes added
Improved Feature: A Filter for Each Column

PRS Classic: Checkboxes for select columns and one search field

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.”
Dr. Stacey Arnold
PRS Subject Matter Expert

PRS Beta Record List
Prerecorded Demonstration
We Welcome Your Feedback!
Continuing PRS Beta Development

Protocol Registration

[Screen shot of Protocol Registration form with details filled in]

Unique Protocol ID: Test_Parallel 11
Brief Title: A 24-Week Placebo-Controlled Trial of Remuverol in Adults With Condition A

Organization's Unique Protocol ID: Test_Parallel 11
Brief Title: A 24-Week Placebo-Controlled Trial of Remuverol in Adults with Condition A

Official Title: A 24-Week Placebo-Controlled Trial of Remuverol in Adults with Condition A

Secondary IDs: (+ Add Secondary ID)
Continuing PRS Beta Development (Cont.-1)

Protocol Registration
Continuing PRS Beta Development (Cont.-2)

Protocol Registration

Conditions

- Conditions or Focus of Study
- Keywords

NIH National Library of Medicine
ClinicalTrials.gov
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

## Record and Account Management Experience

**AVAILABLE**
- Intuitive Record List
- Search, filter, and sort functionality
- Customizable columns and views

**IN PROGRESS**
- Secure log-in

**FUTURE**
- Create and modify accounts
- Manage groups and permissions
- Notifications
- Dashboards

## Data Submission and Review Experience

**AVAILABLE**
- Protocol registration submission
- Easy navigation
- Improved error-handling
- Just-in-time help

**IN PROGRESS**
- Move to cloud
- Improve system architecture
- Optimize database with performance and data integrity

**FUTURE**
- Results reporting
- Study document upload
- Review workflow

## Technology Modernization

**AVAILABLE**
- Migration to NCBI secured platform

**IN PROGRESS**
- Optimize database design
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

Features Available

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

December 8, 2021
Beta website launched

March 8, 2022
Update released

April 27, 2022
Update released

August 22, 2022
Update released
How Users See Change

Continuous Feedback

1. Beta site
   - Available in parallel to the current site

2. Add features to beta site
   - Improve until all needed features are included

3. Beta site is primary
   - Current site still available as the secondary site

4. Modernized ClinicalTrials.gov
   - 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

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

* Features released on August 22, 2022

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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

https://beta.clinicaltrials.gov/release-notes
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!
Dr. Anna M. Fine
Acting Director, ClinicalTrials.gov

ClinicalTrials.gov
Modernization Communications
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

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

Questions may be submitted through the Q&A box.

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

Thank you!