

ClinicalTrials.gov Modernization Update

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| Webinar Goals

Provide background on the ClinicalTrials.gov modernization effort

Share information on how users will be able to view and explore upcoming changes

- Protocol Registration and Results System (PRS)
- ClinicalTrials.gov website

Communicate next steps

Answer questions

ClinicalTrials.gov Modernization

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

Modernization Overview



**Improve the
user experience**



**Upgrade the technical
infrastructure and processes
to enhance sustainability**



**Support the existing legal,
regulatory, and policy
framework**

Vision and Strategic Goals

Vision

ClinicalTrials.gov serves as an essential, transparent, and trusted part of the research ecosystem to advance medical knowledge.

Strategic Goals

1

Clinical trial information is current, complete, and reliable.



2

Anyone can easily find and use information about clinical trials.



3

Trial information, resources, and tools provide value to the research ecosystem.



Vision: 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

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

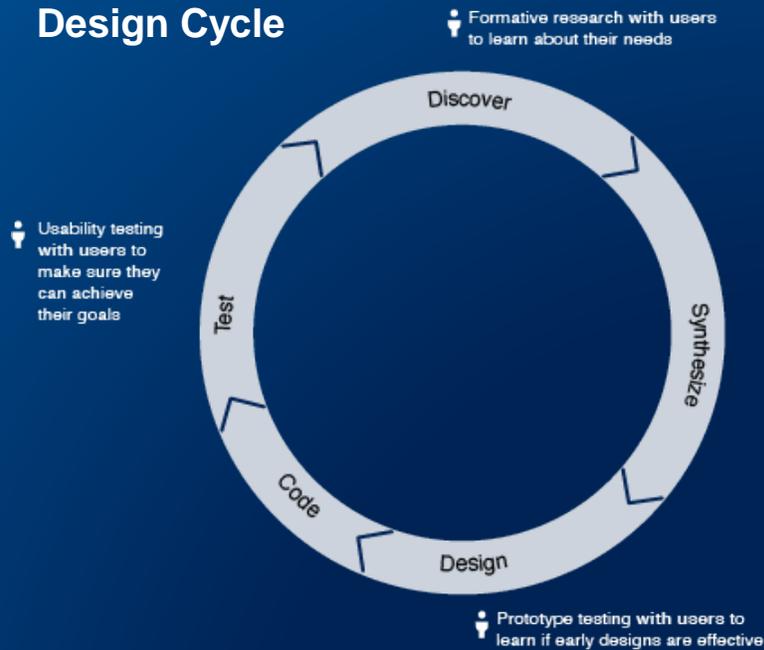
SEPTEMBER 2021



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

Focus on User Needs

Design Cycle



Engagement Activities Defined User Needs

Over 250 request for information (RFI) responses about PRS information submission, website functionality, and data standards

User Research Identified Design Opportunities

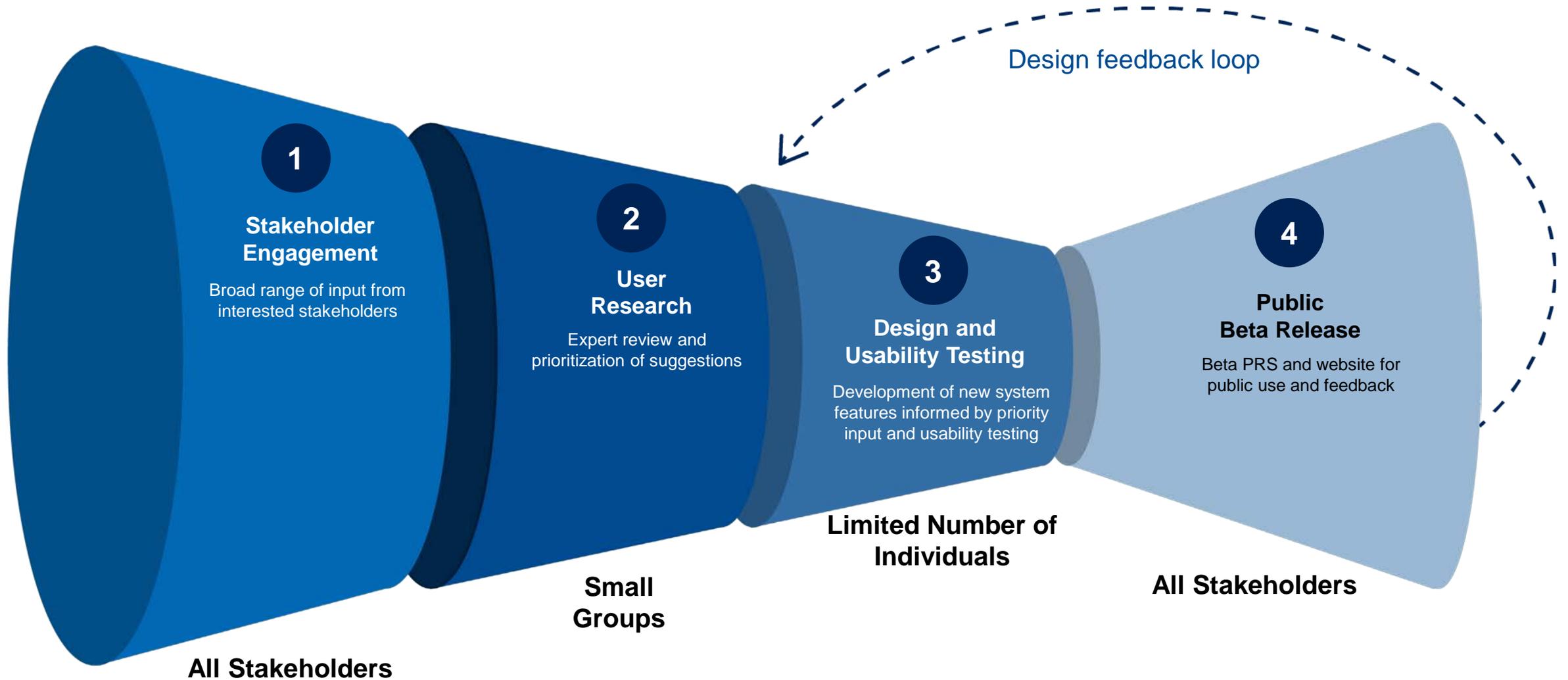
Over 70 individual interviews with people representing the three primary external user groups

Usability Testing Evaluated Designs with Users

Multiple rounds of individual users providing feedback on wireframes and prototypes

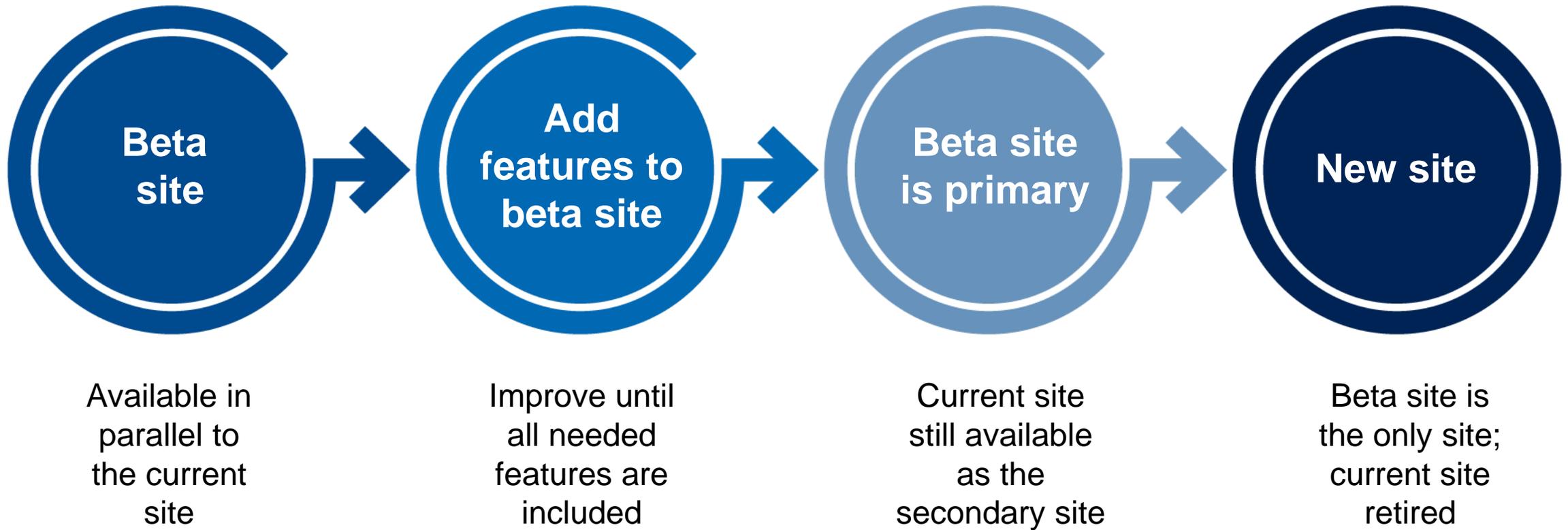
Focus groups providing feedback on site content

Approach to Addressing User Needs

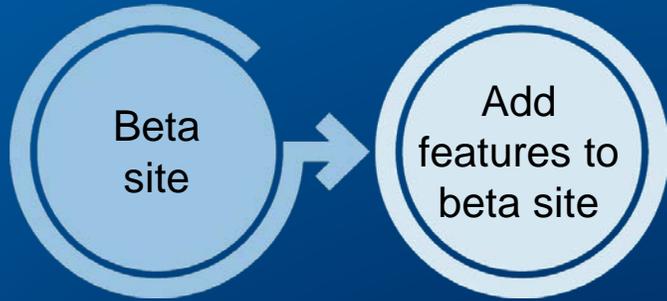


How Users Will Be Able to View and Explore Upcoming Changes

| How Will Users See Change?



Goals



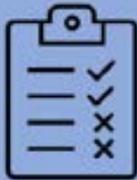
Goals of First Beta Releases

- Introduce the new technology platform and evaluate real-world performance
- Provide improved user experiences
 - PRS — Improved workflow and functionality to manage record portfolios
 - Website — Foundational site features that are more inclusive for all users
- Gather user input for further development

Protocol Registration and Results System

1

**Clinical trial
information is
current, complete,
and reliable.**



PRS Users and Accounts

218,000

PRS users

+

28,000

organizational accounts

Types of PRS users and organizations

- Frequent users with extensive organizational support
- Frequent users with minimal organizational support
- Infrequent users with varying levels of organizational support

PRRS

Key RFI Response Themes

Data Structure and Format

Additional standardization for some data elements

More flexibility for data elements and the record structure

Structural support for a variety of study designs

Data Entry, Submission, and Quality-Control (QC) Review

More tools to simplify data entry

Additional streamlining of the QC review process

Workflow Management

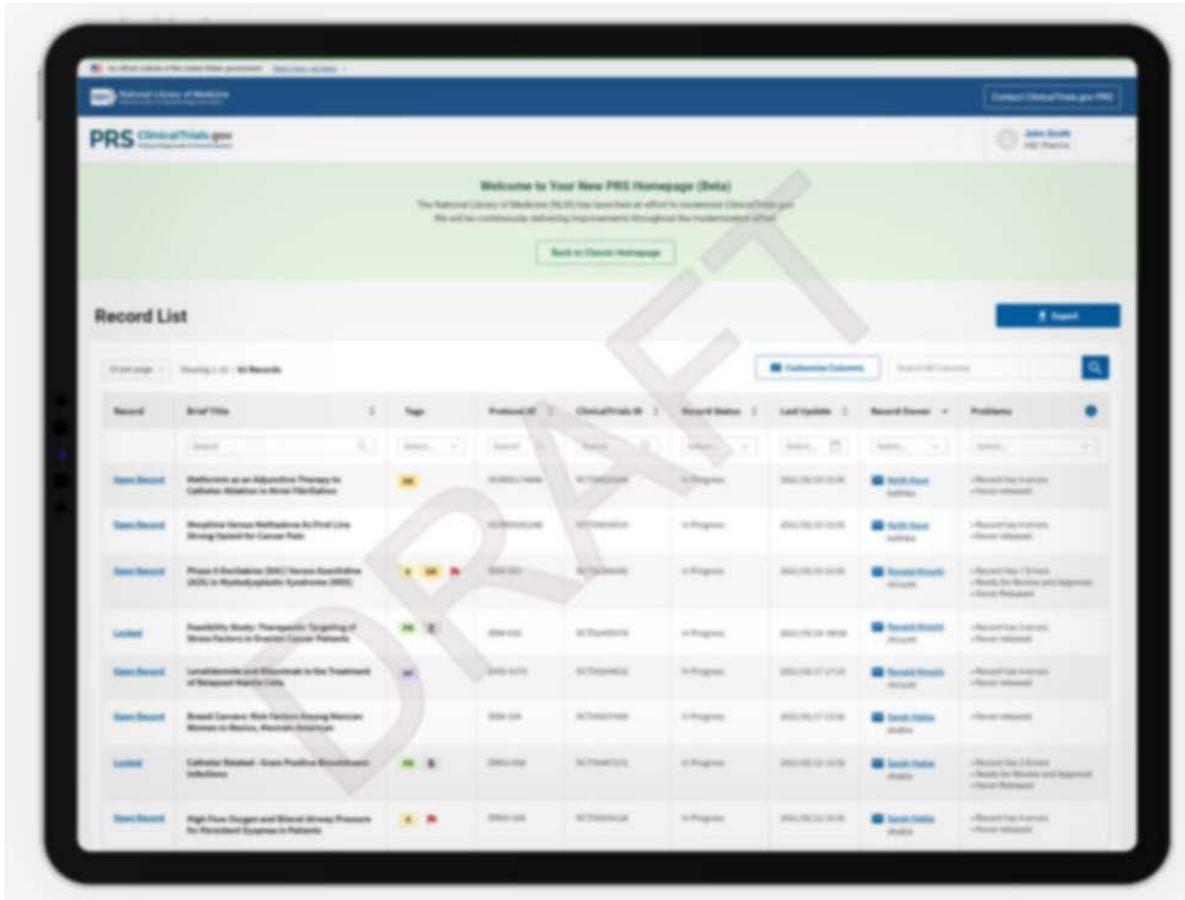
More customizable features to manage workloads

| User Research: Workflow Management

PRS users want to

- Keep study record information up to date
- Report study information in accordance with regulatory and policy expectations
- Easily identify and access study records that need attention
- Minimize the number of steps needed to accomplish registration and results reporting tasks
- Interact with a streamlined and intuitive user interface
- Save time!

Beta PRS User Experience (DRAFT)



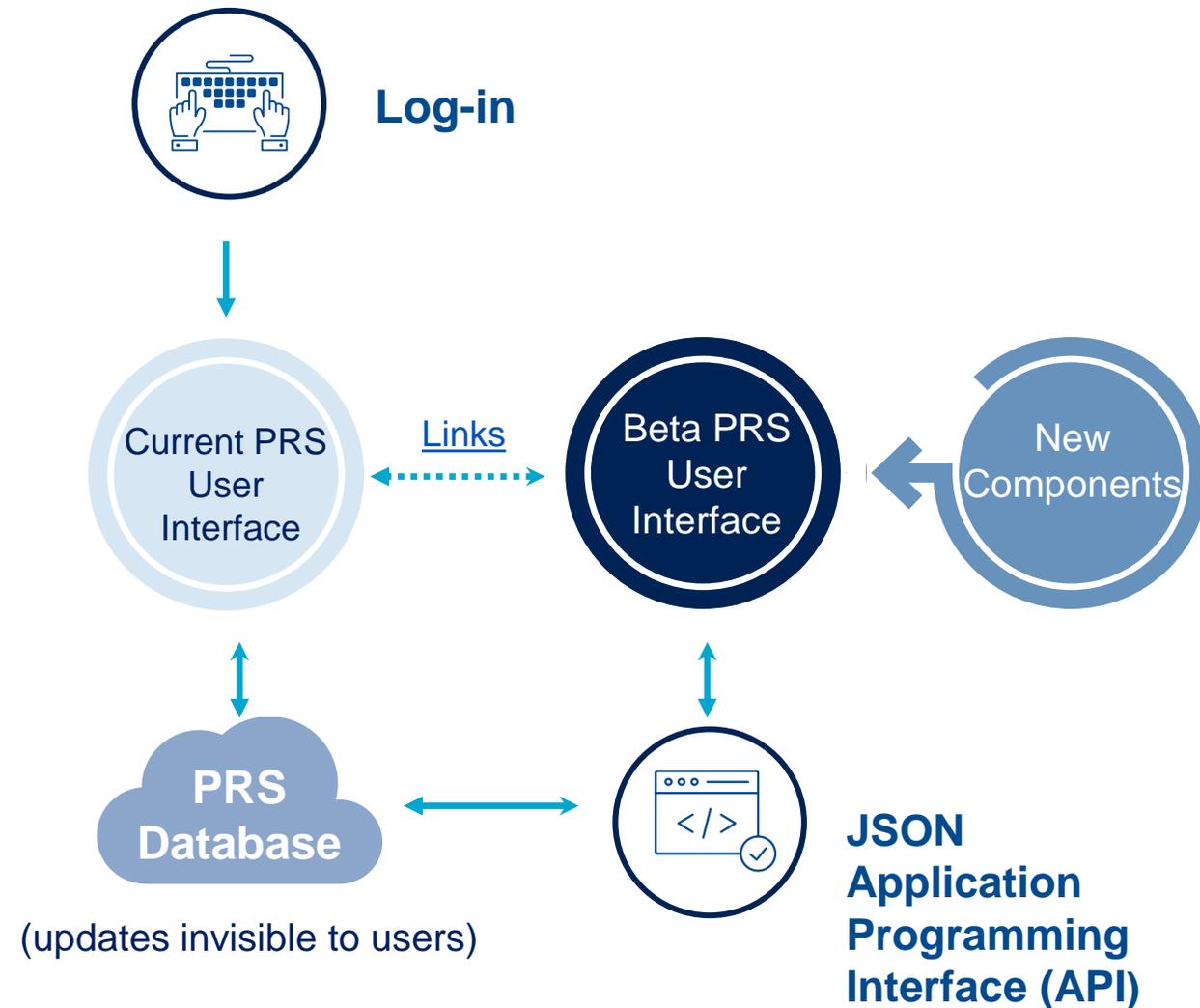
Key Features

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

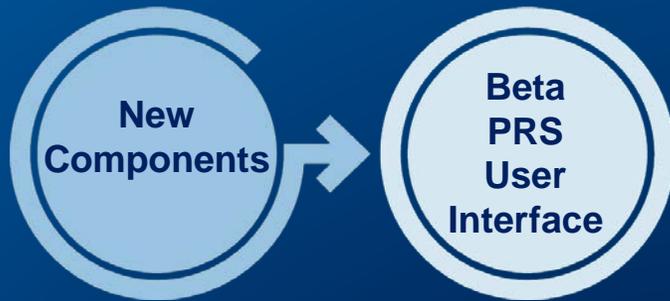
How to Use the Beta PRS

Key Facts

- Access the beta site from the current PRS home page after log-in.
- The beta site uses the same data as the current PRS.
- Choose whether to use the current or beta site components (try beta!).
- New beta components will be added in useful increments that deliver user value.
- Data saved in the beta site will also be saved in the current PRS (most relevant to later components).



PR Approach



Constantly conducting usability testing and collecting feedback for iterative improvements

Planned New User-Centric Components

- Record List Home Page
- Planning Report Functionality
- Account Management
- Registration Workflow and Addressing QC Review
- Results Workflow and Addressing QC Review
- QC Review Internal Workflow
- PRS Reports



We will share specifics about what to expect for each release as we approach the release date.

| Specific PRS User Considerations

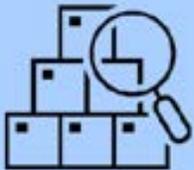
- **PRS users are accustomed to the current workflow.**
 - We aim to improve the workflow without disrupting it.
- **PRS users are familiar with the current update process, so beta updates will follow existing PRS practices.**
 - Updates will be applied to the PRS Test site first for testing.
 - After that, updates will be applied to the PRS production site, and users will be able to use either the current or beta site.
- **Organizations have processes and educational materials centered on the current PRS.**
 - We will communicate early and clearly about timelines to allow organizations to easily transition.



| ClinicalTrials.gov Website

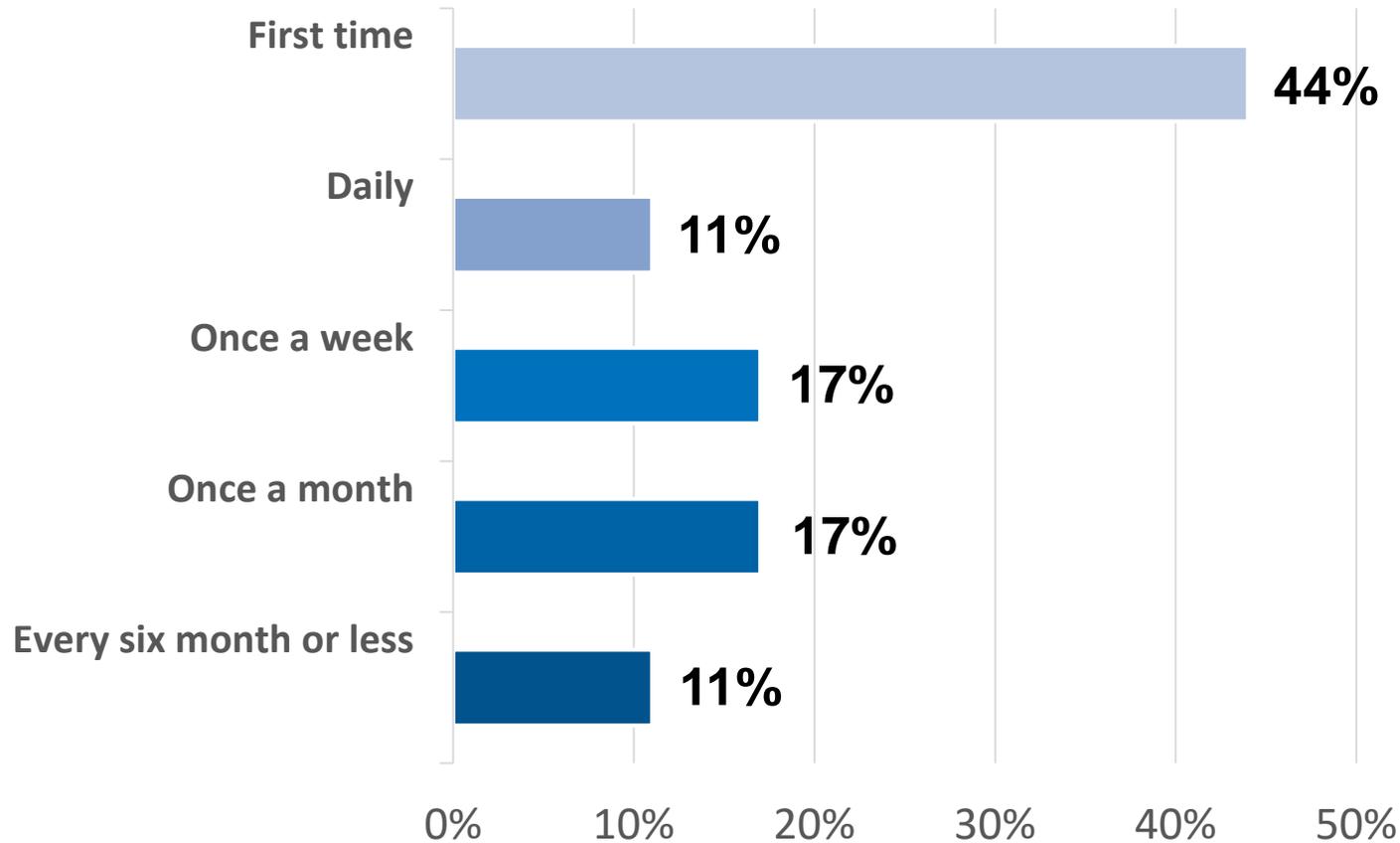
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**Anyone can easily
find and use
information about
clinical trials.**



ClinicalTrials.gov Users and Frequency of Use

Frequency of Use (n = 12,495)



User Types (n = 12,515)

- 56% Researchers
- 35% Patients
- 9% Other

Data Source: Website Survey, July 2019–June 2021

Website

Key RFI Response Themes

Search Options and Managing Search Results

Make the search feature more user friendly

Add more options to the search feature

Improve the tools for managing search results

Study Record Format and Content

Standardize more content

More prominently display certain content; make more content available

Add features to make using content easier

Plain Language Information

General health information and learning about study participation

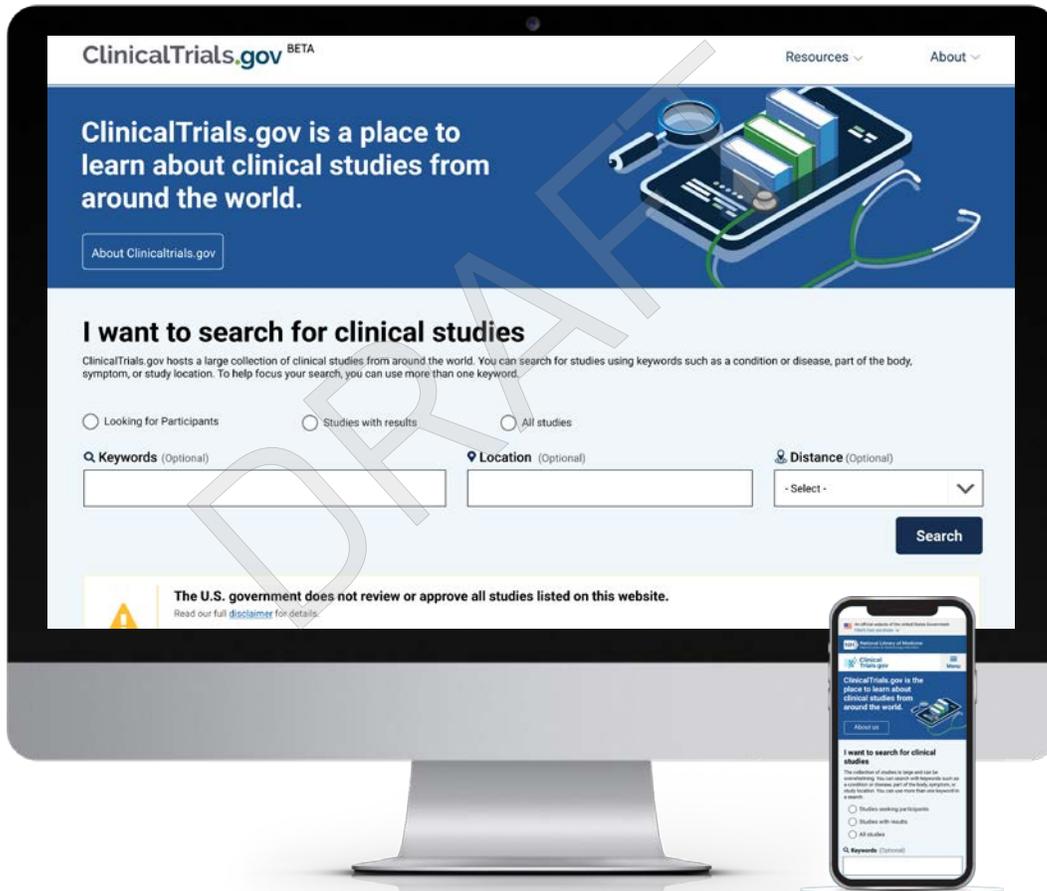
Resources for using site features

Study record content

User Research: Overall Design Goals

Onboarding	Make the site's purpose 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.

Beta ClinicalTrials.gov Website (DRAFT)



- Modern look and feel
- Ease of use on mobile device
- Easy-to-understand information
- New cloud-based infrastructure

User-Focused Features in the First Beta Release

- **Home page** redesigned with a clearly stated site purpose
- **Search** experience updated
- **Search results page** redesigned with
 - Study records displayed in “cards” that highlight key study information
 - Filters to refine search results
- **Study records** reorganized with
 - Improved navigation with floating side menu and expandable/collapsible sections
 - Integrated Google Maps for viewing study location information
 - Updated results table design
- **Plain language** used to provide background and contextual information

Website Modernization Overview



Current Public Site

Will be available until the beta site is complete and fully tested. Will be retired when the beta site becomes the main site.



Beta Public Site

Basic features will be available to explore later this year, with new features released over time until the site is complete. Will then become the main site.

Next Steps

Communication of Modernization Releases



Prior to Launch (Now)

Public Webinar: Preview
of What's to Come



Liftoff (End of 2021)

Public Webinar: Stay
Tuned. More Information
to Follow!



Launched (2022)

Follow-up and Feedback



Thank You!



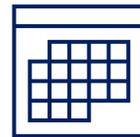
Webinar

Recording and slides will be made available on the modernization webpage.



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>