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
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 meet user needs

• Need to manage user expectations by clearly communicating the site’s purpose and limitations

Focus on User Needs

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

1. **Stakeholder Engagement**
   - Broad range of input from interested stakeholders
   - All Stakeholders

2. **User Research**
   - Expert review and prioritization of suggestions
   - Small Groups

3. **Design and Usability Testing**
   - Development of new system features informed by priority input and usability testing
   - Limited Number of Individuals

4. **Public Beta Release**
   - Beta PRS and website for public use and feedback
   - All Stakeholders

Design feedback loop
How Users Will Be Able to View and Explore Upcoming Changes
How Will Users See Change?

Beta site
- Available in parallel to the current site

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

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

New site
- Beta site is the only site; current site retired
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
Key RFI Response Themes

PRS

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).
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

Anyone can easily find and use information about clinical trials.
ClinicalTrials.gov Users and Frequency of Use

Frequency of Use (n = 12,495)

- First time: 44%
- Daily: 11%
- Once a week: 17%
- Once a month: 17%
- Every six month or less: 11%

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

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