

## NLM Webinar: Modernized ClinicalTrials.gov Update, June 6, 2024 - Transcript

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Good afternoon. Before we begin this afternoon's webinar, let's review housekeeping items. The webcast is being recorded, and the recording will be made available with the PowerPoint presentation slides at the National Library of Medicine website within one month.

For those joining the webinar live today, the slides can also be downloaded. Our moderators have posted the slides in the chat box. Be advised, for those who joined the webinar late, they will not see previous postings. Therefore, our moderators will periodically drop the slides into chat. You only need to download them once, and if you experience technical issues, please type your concerns in the questions and answers box with attention to tech support.

This webinar includes two speakers who will provide updates on the overall ClinicalTrials.gov modernization effort and highlight features of the modernized ClinicalTrials.gov website. Both speakers will be available to address your questions at the end of the presentation portion.

Let's begin with introductions. I'm Anna Fine, and I currently serve as the acting program head at ClinicalTrials.gov within the National Library of Medicine.

I am honored to lead the program and to be a part of this modernization effort since its infancy. Allow me to define the two aims of ClinicalTrials.gov. The first aim is to support the collection and dissemination of complete, accurate, and timely information about studies that are submitted, and this is accomplished through a database known as the Protocol Registration and Results System, or as I'll refer to it from here on out, the PRS.

Secondly, the information is then processed and displayed on the ClinicalTrials.gov website, making it easy for patients, clinicians, and researchers to use and find. With these two aims in mind, our primary customers are the sponsors and investigators who use the PRS to submit their studies and are integral in keeping the study record up to date so that the other primary users, such as patients, health care professionals, or caregivers, can find studies of interest.

And of course, equally important are the data researchers who are looking for studies on particular topics or for decisions where to invest unmet medical needs or research needs.

And of course, we serve many other users such as librarians, investors, media, journal editors, or third party websites.

We strive to support a variety of customers who may have unique needs. The information on ClinicalTrials.gov continues to grow over the years and as growth took place, technology also has advanced over the years. We then recognize it was timely for us to invest in our technology platform to support this growth of information, and we began the modernization effort in 2019.

And since beginning the modernization effort, we have increased by 150,000 records. And we're very close to hitting a half a million records, potentially later this month.

The multi-year effort was to modernize our system and strictly to improve the user experience using the modern design, usability expertise, upgrading the technical infrastructure, and it supported the existing legal, regulatory, and policy framework.

We did not seek to create any additional burden on the sponsors or investigators that submit the information. It has been extremely important to us to engage users like you from the beginning with opportunity to submit your comments in an RFI, which is a request for information, participate in public meetings, and hear from colleagues in your community at some of these meetings or webinars that we have hosted through the years.

All of this information that we've gathered along the way has informed the direction of the effort, and it established our roadmap.

In year two, we worked on creating and launching the beta environments for the ClinicalTrials.gov website and PRS so anyone could test the product and provide feedback.

We continued to conduct usability research and make releases of new features to both the PRS and beta ClinicalTrials.gov, all while continuing to provide access to the classic versions of the products.

In June of 2023, we made the modern ClinicalTrials.gov website the primary experience while still allowing users to return back to classic if needed. And the features of the PRS Beta also expanded for data submitters to provide feedback on.

Users have had over a year to explore the modernized ClinicalTrials.gov website and take advantage of its benefits, which include web components that improve navigation and make important information easier to find. We are now in a place where the classic website will be retired on June 25th, 2024.

And, later this summer, we will make the modern PRS registration the primary experience for our data submitters. This was a lot of workstreams on our end to keep in the air. We basically managed multiple websites to ensure the least disruption to your workflow and allow for smooth transition.

We maintained two versions of a public website for over one year, while also maintaining the PRS, as well as the PRS Beta. And we also have a sandbox environment for both of those.

If you think it's a lot, this just shows a very simplified version of all the streams and all that we're keeping up in the air at the same time.

It is time for us to retire that classic website. We will continue to add features to the modern website after retirement, and this will free our staff from maintaining two websites.

Before we share details about the modern website and highlight its features, I will take a few minutes to provide updates on the progress of the PRS modernization. The PRS is following in the footsteps of the modern ClinicalTrials.gov website. The beta site has been available for almost three years. Users who have an account are able to explore the features that were being added throughout the years.

We plan to make the protocol registration the primary experience later this summer, and even when that happens, the classic will continue to be available well into 2025.

For those who are less familiar with the PRS, here is an image of the current login screen used by sponsors or investigators of trials. And once logged in, the green button allows optional access to

the PRS Beta home page so the users can explore the new look and feel, also, accomplish tasks, including registration of their trial protocol.

Any information entered and saved in one version of the PRS will be available in the other, so your work will not be lost and it's accessible in either the classic or the beta version. We encourage users to explore the beta PRS. If you even feel more comfortable, as I mentioned, there's also a PRS test and a PRS Beta test site.

Essentially, it's a sandbox environment for you to explore and play with the systems. And as previously mentioned, later this summer, when a user logs into the PRS they will be presented with the modern PRS and they'll have the option to enter back to classic.

Of course, more to come and we'll be sure to communicate on this before it happens.

Any information as I said as you save in one version is also available in the other version, and your work will be accessible and will not be lost.

We try to make this as easy as possible for you, and we really welcome our PRS users to explore and provide us feedback to make sure things are working as you would expect them to.

As you can see, the new design and colors are similar to those employed on the modern ClinicalTrials.gov. The left shows the classic PRS Record List and the Record Summary pages, and the right shows, the modern PRS Record List and the Record Summary page.

Again, I encourage you to please look at these and use them in real time as much as possible. This is our time to get your feedback and make sure we're making proper improvements for you.

So to summarize, currently, users can complete the entire protocol registration process and submit the protocol section of the study record to ClinicalTrials.gov for review using the modernized PRS.

Users can control who can access a record and email others with record access directly from the modernized PRS record list, as well as copy and download the protocol section of their records. PRS administrators can access the planning view and public site view to manage records, and reviewers can add, edit, and delete comments on protocol registration records directly in the modernized PRS.

We have yet to release the results reporting capability of the modern PRS, which will be coming later this year, as well as an ability to review those results records in the modern PRS. Development of the modernized PRS is continuing into 2024.

Stay tuned.

We'll share more details about the PRS in the future. And thank you for allowing me to provide you updates on the PRS.

Now that I shared the progress with the PRS on the modernization update, let's do a deeper dive into the ClinicalTrials.gov website.

The exciting news is that the modern website will become the singular website experience for all users as of June 25, when NLM retires, the classic version of the website and its application programming interface.

And I'd like to introduce our second speaker, Christina Robinson, who will share an update on the modern website and highlight some of the important features.

Ms. Robinson, thank you for joining us today.

Christina Robinson, ClinicalTrials.gov Product Owner:

Hi, Anna. Thank you so much for that introduction. I'm excited to be here and share a little bit with all of you about the modernized ClinicalTrials.gov and how we hope that meets all of your needs.

First, I want to talk a little bit about how users have seen change to the public website over the last few years. As Anna mentioned, we spent the first couple of years really reviewing that user input and research, and building up our teams, and doing initial development. And the result of that was that we launched the beta website in December of 2021.

That was available in parallel to, the classic website. And we continued to release features and improvements over about a year and a half period and made the beta website the modernized ClinicalTrials.gov website in June of 2023.

So, when you go to ClinicalTrials.gov, starting in June of 2023, you'll see the modernized website or you saw the modernized website. The classic website has continued to be available in parallel at a slightly altered URL, that's classic.ClinicalTrials.gov.

And since then, in that last year, we have again continued to release features and make improvements to the public website. And as you heard, we will actually be retiring that classic website on June 25th. So, in just a few weeks.

But the work is never done. We'll continue to make improvements and even release additional functionality. And I'll get into that just a little bit later.

So, next I want to share, this is not a comprehensive list, but it does give all of you, I hope, an idea of all of the work that went into the modernized website. I'm going to call out just a few of these things that you see in bold.

One of the items that has changed from the classic website is the download functionality. So, download is available in JSON, CSV, and, as of yesterday, it is now available in RIS as well. I know that's going to make some users very, very happy.

RIS is a file format for citation or reference management software such as EndNote. So, that's a really great change. And I hope a wonderful addition for many of our users. We also have a modifiable table view of search results. Now, that is available in classic as well where you can add and remove columns. The difference here is that you can actually adjust the order of those columns. So, that's been an improvement that we've made on the modernized website.

Under Study Record Experience, we added on-page navigation to the study record and actually many of our content pages as well. That left-hand menu, which you'll see a little bit later, actually stays with you as you scroll through the page, but makes it much, much easier to move through very lengthy records, study records.

We also have an integrated record history that is now part of the study record, as opposed to being on a separate web page. And we have a streamlined information architecture. Again, I'll speak a little bit more about that in just a moment.

So, I'm going to give you an orientation to the modernized ClinicalTrials.gov and highlight just a few other features that I think are really important to call out.

First, you'll see a couple of headers at the top. And these are in line with the U.S. Web Design System principles. This lets everyone know that this is an official website of the U.S government. And we have used those web design system principles or USWDS throughout development of the modern, of modernization and throughout development of the website.

Next up, you'll see that we have added the information architecture, which I mentioned on a previous page. So, this is actually an improvement in that all of the relevant contact content is on the main ClinicalTrials.gov website.

Previously ClinicalTrials.gov, had information under multiple URLs. One microsite called PRS Info houses policy and regulatory information, and the classic API existed on its own microsite as well. The updated site menu and headers were tested extensively with users from all of our audiences.

Next, you see the location field. The location is available on the classic website. The improvement here is that this now uses a geo-based API. Users can search by ZIP code, address, city, state, country, or even a facility name. The remaining search options are available under More Filters. There is now no need to go to a separate page to find advanced search, and users can actually build complex queries in the existing form for more precise searching.

Finally, the entire website has been optimized for mobile use and for accessibility. This is a huge improvement over the classic website. We know about half of our users are actually patients and caregivers, and they are typically on a mobile device. So, this will greatly improve that experience.

I'm going to go briefly through some of the improvements to the search results. First, you'll see the Focus Your Search on the left-hand side. This allows users to modify their search or start a completely new one without leaving the page. So, you don't need to go to a separate page to actually update your search.

Next, we have two different ways to view the search results. You can see the card view, which is what's available here. That's actually the default. Or you can switch to a table view. That's where you can adjust those columns, you can adjust the order, or add or remove columns.

Card view is, geared more toward our patient users. And so that is the only view that's available on mobile. Table view is a little bit more so for data researchers and journal editors, because they want to see as much data as possible at a time. Underneath that, we have an action bar. This is where you can download those file formats I mentioned earlier. You can save studies or create an RSS feed to get updates on a particular search. In the mobile experience, the Focus Your Search is under that dark blue banner and the action bar is just underneath that.

Now I'm going to walk through just a few of the improvements to the study record.

First up is the study intro. This shows the study status at the top, in this case recruiting, the title, the National Clinical Trial or NCT number, that's the unique identifier for this particular record, sponsor, and then the date that the record was last updated.

Next up, you'll see the tabs. This gives you again navigation among all the different pieces of the study record. Study Details being a little bit more oriented for the patient group, Researcher View for researchers, results are included, and Record History again is integrated here. This is that left-hand navigation that I mentioned earlier. Again, study records get, can be, some of them are quite, quite long, and this allows you to move up and down that record more easily.

On the mobile view, you see on the right-hand side, you've got the tabs again there as well. Once you scroll down past those tabs, you'll see a bar across the top of the page called On this page, and that's your on-page navigation where you can skip ahead to different sections of the study record.

Next up, I want to talk just a little bit about the modernized API. This has been another big improvement. First, we use OpenAPI specification version three. This is the most popular format for describing Rest APIs. So, it makes generating documentation really easy. And the documentation is easy to read and understand. It's also agnostic of any specific programming language. Again, this exists within the main website as opposed to on its own separate microsite. So, just making it easier and faster to access.

And finally, we do have support within the modernized API for some of those legacy XML endpoints. So, for users who still need the data in XML, this is where you would find that. So, I want to go through a few of the hidden benefits of modernization, things that are a little bit more so behind the scenes or under the hood, that that you might not realize, but that make the website function a lot better. This was built using Angular. It's an open source framework that makes the website easier to maintain and offers scalability. So, as the as the web, the database continues to grow, so can the website. It also allows the pages to be more complex and dynamic. The website now lives in the cloud. This is, provides more reliability and again allows scalability so that it can continue to grow.

Finally, the modernized website uses Elasticsearch. This is a lightning fast search. And it, because it doesn't require as much work from the developers, it frees some of their time up to focus on user-facing features.

These are just some of the things that mean the modernized website will run more smoothly, and better meet the needs of users well into the future.

Last, I want to speak about some of those features that are still to come. The classic website is no longer being updated as the content has been fully migrated to the modernized website. Speaking of content, we put many redirects in place, so most bookmarks and hyperlinks should continue to work. When using those, you'll be redirected to the corresponding information on the modernized website. In terms of these upcoming features, I first want to mention the Expert Search Capabilities. Those are already available on the existing search form, but we are looking into ways to expand the, the capabilities there.

Next up is Browse Studies by Topic, a feature currently available on the classic website. Users can find lists of conditions, interventions, and more. All are available alphabetically and many are also listed by category. And those are essentially pre-built searches for users who are looking for a

specific topic. This is a really useful feature, and we'll be implementing it on the modernized website.

Finally, Next Steps for Patients is a feature that points users to information once they've found a study record of interest. If they're looking for a study to join, we can point them to additional, study status or contact information. or if they want to learn about a condition or disease, it might point them to additional resources on that condition.

As we're always building and improving ClinicalTrials.gov, we continue to welcome your feedback. Please use the Feedback button in the bottom right corner to give us feedback about the website specifically. We're not able to help users conduct a search or help patients enroll in a study, but we do want your feedback on the website. We look at all of the comments and analyze them regularly, so our work continues to meet users' needs as best as we possibly can.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Thank you, Ms. Robinson, for highlighting the modern ClinicalTrials.gov and its benefits. We know the website has a wealth of features that were organized in a way that supported the feedback received from users.

Now, I'd like to poll the audience and hear from you what areas of the website could we highlight in the future? Please select any of the topics, and I recognize this list is not exhaustive. We'll pull up the poll, and you're able to respond. But do acknowledge that if you would like to give us some open feedback, please go to the Q&A box and drop it in there as well. We welcome your ideas. If there's other ways we can highlight or provide education around the new website, we're happy to do that for you. And so this list is just a few ideas. Pick the ones that you think are ideal, but also drop into the Q&A box and we'll be able to read those, even once the Zoom is done, we'll be able to download them. We'll run the poll for about a minute. And so please feel free to click on the poll that's right for you.

Okay.

Just want to give people enough time in case they didn't open the poll yet and see it. And also go ahead and use the Q&A to drop in your ideas as well. Okay, let's close the poll and maybe show the results?

Wonderful.

This is very helpful feedback to us. And, again, this is not to be exhaustive list. We do welcome, use the Q&A box. Feel free to drop other ideas and things that you'd like to have additional educational opportunities on, webinars on. We're happy to accommodate those. Great. So, let's close the poll and we'll move on. Thank you again for taking the time to share your thoughts. We will download those comments, as I said, that you put in the Q&A box throughout this, and we'll be able to review them, even once this meeting's over.

So, if you're sitting there and still thinking about certain ideas and topics that are not even a question for us, but more like, hey, idea, we really would love to have more information on this. Feel free to drop that in. That's really helpful for our communications team.

Okay, just make sure I have control. Here we go.

So, engaging with our users and in a variety of formats has really always been a leading principle. We strive to keep you informed with every major release that we've done. We're proud of the features that the teams worked so hard to build and release, and it really came from all of your feedback throughout the years.

We recognize the content that you need is available, but it may not be presented in a way that you're used to. It's changed from the way it's been displayed on the classic site. Therefore, as I mentioned, that feedback in the poll, dropping things into Q&A, it's very helpful to us so we can help you and give you the tips that you need. And, with that said, I actually do also want to introduce a brief demonstration video that we've created with tips for using the modern website. We'll play one for you now.

(Video) Speaker: How to find the total number of studies in ClinicalTrials.gov. ClinicalTrials.gov is the largest clinical trial database in the world, with studies added daily. If you want to know how many studies are on the website, go to the About section of the menu. Click once on About, then click on Trends and Charts. That's it. Just under the title Trends and Charts on Registered Studies, you will see a statement that tells you how many studies are listed on the website. That's how to find the total number of studies on ClinicalTrials.gov.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Great. This is an example of some of the educational materials that we can be providing. And our moderators have dropped into chat the link where you can find this video and on additional topics. So, again, with your feedback, we are glad to create additional videos to assist your navigation of the new website. And yes, we are thinking about them as well for the PRS and making sure we provide some tips there as well. And, I also want to just point people that we do have a wealth of information on our website, including reports with updates on the modernized ClinicalTrials.gov as well as the PRS Beta. We made sure to document throughout the, throughout this process, the progress that we have made on the modernization effort, on our strategic goals, on stakeholder input received this past year and throughout the years, as well as the communication strategies that we've taken and all the effort we've put in in there, and an overview of all the research in support of the modernization effort.

So, please feel free to check out those reports as well. And I'm sure my moderators have dropped the link to those where you can find them. We're going to continue to make this information, including top questions about the transition, available and we deploy a variety of tools. Our moderators are also dropping in links to all the different places, such as our News and Updates webpage, we have release notes, we're trying to use social media to make sure we're getting all the audiences, and especially if we're taking a website away, we want to make sure that you are aware of that. That there are no surprises. So, just a reminder that communication is a top priority for us. If there's other ways that we could be communicating, we do welcome that feedback. So, you can drop that into the Q&A as well.

So, with that, I want to thank you for allowing us to share our updates. We will take your questions, and we ask you to use the questions-and-answer box that we've been using throughout. If you don't know where that is or how to find it, it should be at the bottom of your Zoom toolbar.



And if it's not readily displayed, you can also go under More and it could be provided there within a list. So, we'll get through as many questions as we possibly can. We wanted to allow ample time for this. And I'm welcoming my colleague Christina Robinson back to assist me with the questions. Just allow me a minute, because I am reading very furiously as I'm presenting at the same time, to see what your questions are that we can take live. And I know that you've already had some questions as we were speaking, so I want to make sure I will get to those questions as well.

So, before I go to some of these, Christina, I believe I can direct this first question to you. I've provided feedback in the past about a feature or an idea, how do I know if my idea is going to be implemented? Do you think you can take that one?

Christina Robinson, ClinicalTrials.gov Product Owner:

Absolutely. Great question. Thank you, Anna. So, as I mentioned previously, we do look at all of the feedback that comes in through the website. It is quite a lot. So, unfortunately we are not able to respond to each and every person. However, we do reach out when contact information is included. We will occasionally reach out to some who have submitted feedback about a specific feature or use case and ask if they want to participate in usability testing. So, that would be the only time that you hear from us. Unfortunately, again, we are not able to respond to every piece of feedback that we get.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Great, thank you. Let's see, with the modernized website, am I still able to search for the same studies that I found on classic? So, I can take the first part of that. Yes. The modernized website contains information on all the clinical studies that are found on classic website. Now, while modernizing, we have preserved all of the records. So, don't worry. Just because one website goes away, that does not mean that access to all the records that have consistently been there for the last 20 something years, they will not go away. They will still be there.

And I think, Christina, maybe you can talk a little bit more about the search feature and how it's been enhanced and how that's changed.

Christina Robinson, ClinicalTrials.gov Product Owner:

Absolutely, yes. So, there are changes, there have been some changes to the way that the search feature actually functions. So, the search results that you see for a particular search on the modern and the classic website will be a little bit different. The search, the search mechanism on the modernized website is actually a little bit more precise. And we take, a variety of things into account, such as relevance, the date the newness of the record or the date that it was last updated. And location if location was entered as part of that search. So, yes, the search results will be a little bit different between the modernized and the classic website. But we actually think in this case it's an improvement over classic. So, we, and then of course, if you have feedback on that, you're always welcome to submit it through the website.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Great, thank you, Christina. Have a lot of questions here for you. Will the classic website URLs redirect to the modern website? Also, when you answer that about the links, there's a follow up on

that, like specific trials. If you had a link to a specific trial, would that link also be preserved and redirected to the modern site?

Christina Robinson, ClinicalTrials.gov Product Owner:

So, we have set up many redirects. We might have missed a couple, but the vast majority of bookmarks and hyperlinks should still work. You will be redirected to the corresponding information or study on the modernized website, so you shouldn't have any issues with that. If you do have any problems again, please feel free to submit feedback for us.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Thank you. I think this question is about being alerted for specific trials. So, is there a way to save search, or create and receive alerts to any new trials that are registered?

Christina Robinson, ClinicalTrials.gov Product Owner:

Absolutely. So, once you conduct a search on the website and you're looking at the search result, in that action bar that I mentioned, there is an RSS feature. You'll see that off to the right-hand side just above the search results.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Great. Christina, are you able to download PDFs of the entire study protocol or of the records like you could in classic?

Christina Robinson, ClinicalTrials.gov Product Owner:

Yes. There is the option to print to PDF. So, either using the print option in your browser or hitting control-P, you should be able to save a study as a PDF.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

So, someone had mentioned, I think I could probably take this one. Can't you retain the classic website until all of your features are complete?

So, that's a great question. We are going to continually always make improvements to the site. It's going to be part of our ongoing O&M making sure that we're following new technologies and employing the best that we can. Unfortunately, it is not feasible to maintain two websites in perpetuity because you're always going to be improving on one. And we were maintaining the other. So, we do have additional capabilities that people are searching for, and we are looking at your feedback and seeing what those are, and we will continue to make those available. But it's not going to really prevent us right now. Let's say that the majority of the functionality that people are looking for, in one way or another, they are able to accomplish what they can do on classic now. But thank you for that that question.

Christina, is there a preferred browser to use for the modernized site?

Christina Robinson, ClinicalTrials.gov Product Owner:

So, we have actually built for the website to be used in multiple browsers. Any of the typical browsers that you would use on your computer or your phone should work. Chrome, Mozilla, you know, Apple. I cannot remember the name of their browser at the moment, but, yes, those should all be fine to work when accessing ClinicalTrials.gov.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Thank you. I think there's a question here I can take. Did I miss when the PRS classic website will be retired? You did not miss it. There is no date. We do not have a date at this point. It will definitely not be for at least a year to two years at minimum. And if there were a date, we would make sure we are communicating that aggressively. But at this point, the modern PRS still has little ways to go. We got to make sure we make all the modules and functionality available to you. And so we don't even have a date in sight at this point, even internally. But that's a great question. You didn't miss it.

But on the public website, that date of classic retiring is June 25th of this month. So, just make sure that you're preparing for that.

Christina, can you speak to the API? Will that, we're trying to prepare and will that also be going away on June 25th?

Christina Robinson, ClinicalTrials.gov Product Owner:

So, yes, the classic API will also be retired on June 25th. This is part of the reason why we made those XML legacy endpoints available in the modernized API. There is actually a migration guide on the modernized website. It is, actually pretty thorough. Please take a look at that. That should provide, hopefully, all of the guidance that you need to make the transition to the modernized API. And, again, please submit questions if you have feedback or if you run into any trouble.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Great. There's a question here about any changes for a data preparer in terms of the modernization effort. So, as of right now, I'm not sure, that's a very, that's a very broad question here. So, I'll just attempt to take it. But we tried to make this as smooth as possible. We're not right now changing anything that you need to be preparing or doing differently. You are able to submit your studies, whether you choose to do it in classic or in the modern PRS right now. But there's no changes in terms of those requirements. We do hope that the modernization effort at least makes it a little more intuitive and a lot more user friendly for you. So, no changes to what we're collecting, but thank you for that question.

Hold on, as I still go through a few more.

Christina, I think we still have, a few questions here. Okay. This must be from potentially a health care professional or or a patient, but I have a specific medical condition. Can you help me join a study?

Christina Robinson, ClinicalTrials.gov Product Owner:

So, no, unfortunately, we're not able to help you join a study. ClinicalTrials.gov is part of the National Library of Medicine. So, our responsibility is to make the information available. However, we do provide educational content. One of the new videos, that we provide actually shows you where to look for the study status, that is to let you know if it is or is not looking for volunteers and how to find contact information. So, please look at those demo videos and and hopefully that will help. For those who submit feedback through the website, please, please do not share your medical information with us. We are not able to help with a specific search or help other patients enroll in a study. So, we want that information to be kept private. Again, the demo video will show you where

and how to look for that information. So, this is a great question and sounds like something we can maybe even address in one of our future video vignettes.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

How can someone easily tell the number of study sites that are present within one study record?

Christina Robinson, ClinicalTrials.gov Product Owner:

That's a great idea. Yes, we will take a look at that and think about creating a vignette specifically for that.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Is there any tips you can provide now, Christina? I know it was a little bit in one of the videos that we alluded.

Christina Robinson, ClinicalTrials.gov Product Owner:

Yeah, absolutely. So, if you go into the study record and you scroll down to the menu, you click on Contacts and Locations. That should show you all of the study sites available for a particular study. It doesn't list the total number, but it will list all the sites that are part of that study.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Great. Thank you. So, is there any way to find out the status of the feedback we've specifically given to you?

Christina Robinson, ClinicalTrials.gov Product Owner:

So, I think this goes back a little bit to you know, the first question that I got, which was asking, you know, is the suggestion that I submitted going to be implemented. So, no, we are not able to, again, reach out to individuals when they submit comments. We get quite a few of those. Again, we do look at all of those and we analyze them regularly. And based on the amount of feedback that we're getting around a particular feature or functionality or content, that really drives our work. So, you know, when we make choices about what to implement, that plays a part in what we're able to provide for users.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Great. Thank you. All right. I have a couple questions I think I can take. So, there's a question here about can we receive a certificate of attendance for this presentation? There's no attendance certificates being handed out today. But for those who did attend live, you will have the copy of the slides. If you didn't receive them already, our moderators have been dropping them in chat. I know if you entered a little later into the program, you don't see the previous chat links so we can drop them in again. So, your slides are sort of a certificate of attendance. And for those who weren't able to join or participate today, this is being recorded, and the recording along with the slides will be posted on our website, but it'll take about a month or so to make sure we go through the transcript and make sure it's, posted with that.

There's also a question here about the new PRS and will, will we still use our current login credentials? So, yes, right now, especially the way you login to the classic PRS, you enter it and then you get to select yourself at this point in time to go check out the new modern PRS. And you can switch between the two, similar to how the public website has been where you can still go to the public site and you've been able to go back and see classic as well. And so there are no changes to

your login credentials at this time. And when you, when we do make beta primary later this year, you will still be logging in as you have been logging in. And it'll just be that the home screen is going to look different than what it looks like on classic now, it'll be what you're seeing in beta.

I think that answered that question.

I think, Christina, can you talk a little bit more about one of the releases yesterday, someone had asked about additional download, and I think you have some exciting news that you mentioned, but if there's any more that you can say about RIS.

Christina Robinson, ClinicalTrials.gov Product Owner:

Absolutely. So, yes, we did have a release yesterday that included RIS as a file format for download. So, you can now get information in RIS format for citation software. So, things like Endnote when you need to manage references. We are very excited to be able to provide that. Please try it, provide feedback on it. Let us know if there's any additional improvements that need to be made. But we're very glad to be able to make that format available for download.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

I'm going to attempt to take some of these questions. Hopefully, I have the right answer here. Someone had asked about that currently, we see that it's great that Clinical Trials links to published articles in PubMed for some of these trials. But can publications can also be added manually? So, this is for data providers, not someone from the public who sees a record. You can't just go ahead and add, but a data provider is able to link to additional materials to their study record if they'd like. So, that already exists whether in classic or however. So, any additional resources that are provided, that is provided by the data provider who owns that record. I think that covers that one.

Christina, there was a question here, and I'm not sure if you're able to answer this, that the status of a record recruiting or not sometimes disappears, you may not know what the status is. So, I don't know if that's something you'd put someone into record history or how, how would they be able to find if it was recruiting but not recruiting and status changes. So, like if it disappears, I think they're a little confused on that.

Christina Robinson, ClinicalTrials.gov Product Owner:

It shouldn't disappear. There should always be a status available. It does change over the life of the study record and the life of the study. So, you know, it would go from not yet recruiting to recruiting to active. And there are some other statuses such as unknown. So, if the status is unknown, for example, on a, you know, historical record that was submitted, you know, early in the life of ClinicalTrials.gov, that study status might be unknown. But there should always be one available.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Thank you. I'm going to put you on the hook on another one here, is record history available using the API?

Christina Robinson, ClinicalTrials.gov Product Owner:

That's a great question. I don't know the answer to that one. I will have to look into that one and get back to you.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Okay. We'll have to follow up on that one, but thank you. And someone had asked if there's any materials now to help with researchers at their institute for navigating the PRS.

Christina Robinson, ClinicalTrials.gov Product Owner:

So, that is a great question. As of right now, we do still have the guided tutorials and of course, the guided tutorials right now are available, especially in support of classic with some of the images. But the information itself, in terms of the information that you provide, where you provide it, pretty much remains the same because we did not change the data elements. And we are working on, although there's no public date of when we're going to be announcing that it's available, making sure that we update those screens that are within those guided tutorials. So it is, mirrors what the modern site will look like in the future. And I think it's also really great feedback because we do hope to provide some mini video vignettes on how to navigate the new PRS. So, that's also a question from you, but it's great feedback as well for us. It sounds like it's something that you would love to have for your researchers. So, thank you for that.

Anna, I'm going to go back to the previous question on the API quickly. I already got an answer to that one. So, historical data on study records is not yet available through the API. We know there is a desire to get historical information available for download, and we're looking at the possibility of doing that, but it is not yet currently available.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Great. Thank you. And I had a question here that I was holding for you, but I can't, it's just disappeared. Sorry. The screen moves very quickly as you guys type your questions, so I apologize. Can you talk about the downloads? Will XML continue to be available in the format that it is now?

Christina Robinson, ClinicalTrials.gov Product Owner:

So, again, I'm going to point users to the legacy endpoints in the API. So, that is in line with what was available or what is available at the moment in the classic ClinicalTrials.gov. So, the schema would not be changing from what is already in use. But you would have to go to the API to access that data in that format.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Great. Thank you. And this, this must have been taken care of. Someone mentioned that the Hot Off the PRS! link wasn't working. So, that's for our moderators. Thank you for that.

So, the XML schema that they are used to using, will that be disabled on June 25th, Christina?

Christina Robinson, ClinicalTrials.gov Product Owner:

Through the classic ClinicalTrials.gov, yes. That will no longer be available. You know, maybe I missed, Okay. It's the upload feature. Nothing's changing in the PRS right now. Anything that you've been doing and how you've been entering your records, it is currently available. There's two very different systems here.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

I see that there's questions about XML and about the API on the public website for those who are doing research and downloading materials.

Christina Robinson, ClinicalTrials.gov Product Owner:

But I believe you're asking about the XML upload for the PRS, and that is not changing at the moment. On June 25th, as I said, the classic PRS continues to be progressing. It is available as you're used to doing. And you have the option to continue to use the new modern PRS and give us feedback on that. So, there is nothing that will change for you.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

So, I think, I apologize if I've misconstrued the two XML questions here. And I wanted to confirm the PRS portion will be permanent on June 25<sup>th</sup> also, not just the search portion? So, I just want to make sure that I'm understanding this and not conflating two issues, this is the part where I had the airplane slide. We have a lot of balls in the air and we understand. I mean, we have a lot of work streams on our end as well. There is the PRS where you're entering your data and information. There are no changes to that at this time. There will be changes in the future and we will communicate around that. So, this is very helpful to make sure that we clear up any of that confusion. It's the public website. So, those who continue to submit your study records, please continue to do how you have been. And we always want to make sure a smooth transition, nothing's changing to your workflow. It's those who are on our public website looking for studies. That old website that we had that we had just replaced for the last year or so, that's what's going away. So, I just make sure that's very clear to our users.

Christina Robinson, ClinicalTrials.gov Product Owner:

So Anna, I know we have lots of great questions and comments that continue to come in. We are a few minutes over time. So, I just wanted to let you know, and, maybe we could take one last question.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Sure. Well, there's so many here. Is there a specific time limit for the URL redirects after June 25th?

Christina Robinson, ClinicalTrials.gov Product Owner:

Those redirects will actually be in place for quite some time. So, I can't say that they will be available indefinitely, but there shouldn't be, that shouldn't be an issue anytime soon.

Moderator, Anna Fine, ClinicalTrials.gov Acting Program Head:

Okay. Great. We did go over time so thank you guys for bearing with us. I really appreciate it. I mean, your questions are really important and we're going to continue to read through them. As I said, there's many ways that we can provide information to you and, and try to address your questions. We do have a top questions document that's helping with this transition. So, we want to make sure that we can continually update that. So, this is really helpful to us. Thank you for your questions. Please feel free to keep typing them even now. We will continue to read them. All our updates will be coming out through Hot Off the PRS! So, when we have a recording or slides or anything available, we'll make sure it's announced there. We will definitely be announcing more information on PRS itself and any changes that we're going to have there. And please do continue to give us your feedback. We really appreciate this opportunity that you took the time to spend with us, and the extra time that you gave us. And here is also the links, just as we conclude. So, for those who need them, we'll just leave them up here for a minute. Thank you again, Christina. And thank you again to our attendees for all your questions and support today. And this concludes today's webinar. So, thank you.