NLM Webinar: Introduction to the Modernized Protocol Registration and Results System, October 8, 2024 - Transcript

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

Good afternoon. Welcome, everyone. Thank you for joining our webinar. Allow me to introduce myself, I am Anna Fine. I currently serve as the acting program head at ClinicalTrials.gov within the National Library of Medicine, and I'm honored to lead the program and to be part of this modernization effort since its infancy.

We have a great agenda for you this afternoon. I will provide a very brief overview of the modernization effort. Joining me are two speakers, Drs. Dharker and Arnold, who are excited to share updates on their work on the modernized PRS, and they'll give you some tips on navigating the system. And then, of course, we'll take your questions. So, let's begin.

All of the work of ClinicalTrials.gov is to support the collection of complete, accurate, and timely information about clinical trials via the Protocol Registration and Results System, also known as the PRS. And to make this information available for patients, researchers, and clinicians on the ClinicalTrials.gov website.

Both the database and website underwent a modernization effort to upgrade the technical infrastructure and improve the user experience, and we were not making any changes to the information that we collected or the existing laws and legal context that already exists.

This effort from day one relied on input from users like you. And based on the input we received, we continue to receive throughout the effort, we launched new technology and we look forward to your feedback throughout the years to continue to make it better and release more features.

We learned from everything that you've provided and you're going to hear from my colleagues, Dr. Dharker who's going to summarize some of the feedback that we've received. And I'll comment just briefly on the modern ClinicalTrials.gov website as well, which has already matured from beta to the primary platform as of June of this year that stands alone as your experience that you're using when searching for clinical trials.

We did retire the classic ClinicalTrials.gov. And so let's just talk a little bit about the ClinicalTrials.gov website and the features. Though the journey is coming towards an end of the modernization effort of this, we do still continue to collect your feedback, and we do still have some planned features to be released.

Before the end of the year, we'll have the expert search capability that will be released. And we do also have plans to release the ability to browse studies on a map and browse studies on a topic.

So rest assured, we are still collecting feedback on the public site, and we welcome any feedback that you'd like to give us, and we'll continue to take that into consideration.

Now, we do have a big, exciting announcement to make about our PRS and everything that we've made thus far in this area, as well as providing some tips.

So before I do that, let's just talk about the development cycle. The modernized ClinicalTrials.gov website has completed its development and adoption journey.

Both the modern website and the PRS Beta began their journeys by making beta sites available to you. This allowed us to introduce new technology and gather your feedback on features that we should expand, and that are very much desired.

We incorporated these throughout the life cycle and refined it to a point where we felt comfortable that the website was mature enough, that it could be the standalone experience.

It's really important to acknowledge that, even though we're at the end of that journey, we are still just at the beginning of the PRS journey.

We've had a PRS Beta available to you for a couple of years now, and as you know why we're here today, we recently made the modern PRS the primary experience for registering your record. We're just at the beginning of this curve. We're looking forward to you utilizing it, for those who haven't already logged in, and for those who have, thank you for the feedback we've received. There's a long way to go.

There's lots of questions that we received as you registered for this webinar in terms of when will the classic website be retired? And I know Dr. Dharker is going to address those questions.

But rest assured, we're at a point where we're expecting you to use it and give us your feedback. And we know there's so much more features to add.

So I won't delay any further. I'm going to introduce my colleague, Dr. Dharker, who's going to talk about this journey of the modern PRS and how we got here today. Dr. Dharker, all yours.

Nachiket Dharker, PRS Product Owner:

Thanks, Anna. Hi, everybody. I'm Nachiket Dharker. I serve as the product owner for the modernized PRS. I'm excited to be here to share the updates on the modernized PRS.

As Anna mentioned, one of the big milestones for the modernized PRS was on August 28th when we made the modernized PRS the primary way to register the study protocols. The users do have the option to go back to the classic PRS if the modernized PRS is not serving your needs yet.

Since it has been almost six weeks that we released, and made PRS Beta primary, we are curious to know how many of you have actually registered a study and have used the modernized PRS to enter the protocol data.

We will start with a poll as I'm seeing people have already started responding, which is great.

So far I'm seeing that there are a lot of you who have already used the modernized PRS to register the studies or enter the study protocol data.

I would strongly encourage those who have still to use these new features, and have still not used the modernized system, to register the study protocol. Please, start using and providing your feedback.

As I will show in the next couple of slides. That is how we can improve the system. We are still seeing some responses. We can give a couple of more seconds and then close the poll.

Half of you are using and a little more than half are still using the classic system primarily. I will strongly encourage you to use the new system.

Can we stop the poll, share the results? Alright, moving on.

This is a recap of the chronology of how we released and built the modernized PRS. Starting in 2022 we rolled out the first iteration of our beta site, which was the basic record list. And on top of that, in subsequent releases, we added more features, protocol data entry, and other advanced features.

And finally, on August 28th, we made the PRS Beta primary. Throughout this, our first iteration through August 28th, we have been continuously assessing and reviewing the user feedback, and trying to iterate, fix issues, and iterate on the important features and all the great feedback that you have been providing us.

Currently, our biggest or highest priority is to address all the differences between the modernized PRS and the classic PRS app, especially to do with validations that are not working properly, or other high priority feedback or the urgent feedback that you all have provided us.

We are in the process of resolving or fixing those issues. And at the same time, we are also continuing to progress with updating or building the results screens, well the results system, which is what we are starting to release in PRS Test shortly.

And finally, when we have supported all the features and built all the features that are in progress into the modernized PRS, and we've given ample time to our users to transition to the new PRS, then will come the stage where we retire the classic.

Although it's still not in the horizon, there's still a lot of time, as you will see and as you are seeing, and we will give you ample notice before we do that.

So again, to give you a visual of our first version of the record list that we released in 2022. This was the basic record list. And on top of that, in subsequent releases we added customized views, planning view, advanced filters, and other options.

And since our first release of PRS Beta, we have received a lot of feedback. And this is summarized feedback that we received from the first iteration through just before the time point when we made beta primary. And, as you can see, the top categories in which we received the feedback was record list.

You suggested a lot of changes, and a lot of great ideas on how we can improve the record list usability. And of course, there are continuing to be a lot of comments on protocol data entry.

And that makes sense because these are the biggest features that we have supported so far in the modernized PRS.

So next, I will give you two examples to convey how we take the user feedback to create new screens and further make improvements through iterations.

The first example that I want to give is our protocol data entry screens. And at the beginning of the modernization effort, we had collected user feedback through RFI, where we asked you to provide your comments on what you would want to see in the modernized PRS.

And these are some of the comments that we received, and what you conveyed very clearly to us is that on the classic PRS the UI is difficult to navigate. It is not easy to shift through different pages of the application. We also got comments such as improved navigation and user friendly features are needed to facilitate registration and results reporting.

Based on all these feedback, we went to the drawing board and started our first iteration.

And while we were doing that, this is to basically give you a visual of what the classic PRS currently looks like and where we started and then went to the drawing board to recap some of the feedback that we received.

So just to summarize, remind you of the classic experience. Users have to work through this, the main protocol summary screen. And then they can go one section at a time. For example, you enter the data for study identification, save your work. Then you go back to the previous screen and then go on to the next section, then subsequently enter data for the next screens.

It's basically a lot of back and forth involved, which you clearly conveyed to us that you wanted to see improvement on.

While we were still building the new PRS or the new data protocol data entry screens, we took further feedback from a panel of select users. And we conducted moderated testing sessions.

To the left, we asked very specific questions this time drilling down to the section or module levels. For example, we asked users questions such as, do you want to include a different sorting order? Or a different order for these protocol section modules? Or to the right is another question that we asked users. Should we group certain sections or protocol modules? Or should we split a module into multiple, smaller modules?

And again, we took all this feedback and finally, as you are seeing now in the modernized PRS, this is how, the architecture looks like. We have really flattened the architecture to include all the sections, all the protocol section modules on the same screen.

And so users can, giving the same example, click on study identification, enter the data, then on the same screen without going back to any other screen, select study status. Enter data for that section. Save the work. I would click through all the sections or the protocol section modules on the same screen.

The next example I want to give is the record access. In the classic system it was called the access list. And the new name is record access. Just kind of trying to be more intuitive.

On the left is a visual of how the record access looks or module looks in the classic system. To the right is a summary of the feedback we had received in the beginning of modernization.

Users wanted a better search mechanism. You thought that especially when this access list is long,

it is cumbersome to search for the names. And so, a better searching mechanism was needed.

Some people ask for sorting capacity in the access list. We took this initial feedback and rolled out our first iteration where we did include a search bar. And we tried to consolidate the long list by including some pagination. We also included a mechanism to email, directly from this access list.

But while users liked some of the new features, you also gave us some critical feedback on some things that didn't work for you. For example, you thought that the pagination is a problem because you now only could see in the first iteration five names at a time, for example. You also gave us another recommendation, based on what you liked, which was the email, capacity to email, from the access list directly.

And you requested that can we have one single click that could allow emailing to all the users on the access list. You also wanted to have a better clear indication of who has access versus who does not have access.

So we took all this feedback after the first iteration and came up with the current version, which we are currently, at least as of now, creating the final iteration.

Since we want to now devote time to other features too. And in this new access list that we just recently rolled out, we have improved the search mechanism. We also got rid of the pagination based on the feedback and introduced the scroll bar so that you can have all the names on one screen.

We also relabeled the tabs on the top so that it is now clearly visible who has access and who does not. And of course, based on your needs, we also included one single button at the top that you can use by single click you can email all the users that have access in this list.

We are continuing to follow this process for all our features that we still have to build. This is an overview of features that are currently available in the modernized PRS.

As I already said, we are supporting protocol registration submission. Record list and record management tools are currently available. But as you can see from this slide, there is still a long way, with respect to, the journey of the modernized PRS. It's still ongoing. And it's going to take a while until we support all the remaining features.

Our highest priority remains fixing all the issues in the protocol registration. Mainly the difference is that you are notifying us between the classic PRS versus modernized PRS, especially with validations.

And, while we do that, we are also continuing to develop the result screens: participant flow, baseline characteristics, outcome measures, and adverse events.

Then we will move on to some other, the other remaining screens: study document upload, validations for results, And results QA/QC. Once we get done with the results part, we have to support the remaining features like XML upload, delayed results, etc. So a lot of work is still, going to happen in the modernized PRS.

So, as I just said, we are taking all the feedback that we are receiving very seriously. We review each and every feedback that is sent to us.

And we would like all of our users to take the time to send this feedback to us. Even if we can try to replicate all the scenarios on our side, it's not possible to cover each and every case. And as we are seeing now, since we rolled out on August 28th, it has been four weeks.

In just four weeks, we have received more comments and more emails than what we had received in the last two years. And that is playing a critical role for us to know these issues and to fix these issues. So in just four weeks, we got 200 plus comments, 250 plus emails.

Although we cannot respond to each and every email, we are treating or responding based on urgency and where we think some of the things that you are experiencing are blockers and you need our help. We absolutely respond to our users.

And to that effect, we have sent more than 340 emails in these last four weeks. To the right, I summarized some of the feedback you have provided us. Mainly, it's about differences between classic versus modernized PRS.

And, finally, I just wanted to update you that based on the feedback we already fixed certain issues, as hot fixes as we call them. That means we didn't wait till we have a release. As we were noticing and fixing these issues, we were deploying or making them available for our users to use them, to see these fixes in the modernized PRS.

But recently, we also have formally released the updates to the modernized PRS where we fix even more issues. And this from now on, we are going to in our subsequent releases, continue fixing issues as we are being notified of them.

So that, is the end of my presentation.

I will pass it on to Stacey Arnold, who is going to walk you through how to navigate in the modernized PRS. Stacey, you can take over.

Stacey Arnold, PRS Subject Matter Expert:

Thank you, Nachiket. I'm just going to take over control. Okay, so I think I've got control. As Nachiket said, I'm Stacey Arnold. I'm serving as a subject matter expert for the PRS modernization efforts.

This is an overview of our record list. So this is what you see when you log in now to the new PRS modernized experience. And at the top of the page, we've included a banner. So this is a welcome banner. It just gives you a bit of information about the experience that you're going to have with the system as we continue modernizing the site.

So, it indicates that you can actually go back and forth between the modernized site and the classic PRS. And, we actually have a resource that tells you all of the ways that you can go back to the classic system and get back to the modernized site from there. And I'll be going into that in a couple of slides.

It also indicates that there are some reasons you may need to go back to the classic PRS, including if you're running across some validation issues that you might need to correct in the classic system,

as well as if you have records that at the current time, already have results, delayed results, or study document sections. We don't currently have these developed in the modernized site. So to access those sections of a record, we direct you back to the classic site for those records in their totality.

So as part of our modernization, Nachiket told you about how we responded to user feedback. And we sought to make some improvements. So I'll cover some of the new features of our record list.

So the first feature that I'll highlight is the ability to now reorder columns in your view. In order to reorder the columns, you would just hover over the Customized Columns button. Click on that and it'll pull up a window of a customized column display. And in that display you can hover over information icons next to each of the headers to obtain more information about what is contained in each of the columns.

You can use a mouse to drag and drop the columns in relation to one another, or you can use the up and down arrows to move the columns in relation to one another. You can also in this list select or deselect columns. The only columns you can't de-select are those that have a lock box next to them.

And once you've made your changes, you can save and click out of this window. Once you have the columns in the order and the columns that you want in that view, you can actually save your view now. So you'd go to our Saved Views menu and select Save Current View As, and you can actually name the view however you would like. And this is also the menu where you can return to the Default View.

So that is the view that you saw when you logged in. And admin users can actually also access the Planning View on the Public Site View from this menu.

We also now have the ability to filter for information in all of the columns. And so in the previous experience in classic there were certain columns that you could filter. We've actually tried to make sensible filters for each of the columns now.

And finally, another new feature that I think a lot of people have been happy with is the ability to email users directly from the record list. So you would just hover over a link, that has somebody's name, and it'll show you that, if you click on the link, you can actually send an email to that user.

And so this replaces the need in the classic system to go and open up the record to obtain contact information for individuals.

So as I mentioned, in the banner we have said that there are ways to go back and forth between the classic system and the new system. And I'll get into that in just a moment. But, to be able to get more information about that and other features of the record list, you go to the About menu. And so this is at the top of every page.

And the first item that we have here is a document that you can open up called About the Modernized PRS. And so if you click open this document, you'll see a menu, right now, that includes links to information about how to navigate the record list.

We are looking to expand this document. So we'll be adding information about the record summary page and features of the record.

In addition to this we'll also be updating our PRS Guided Tutorials in the future with newer content. Also in this menu, to obtain more information about the modernized system, you can click on our How to Videos link. And so this will take you to our PRS Fast Forward videos. You'll see that there are also videos that will orient you to the new public site experience. But the videos for the PRS experience are at the bottom. And as of right now, we have developed four videos.

So these videos include How to Navigate Between the Modernized and Classic PRS Websites. And that's what I kept referencing before. How to Filter the Modernized PRS Record List for Records with Problems, How to Create and Find Record List Views in the Modernized PRS, and How to Find and View ClinicalTrials.gov Quality Control Review Comments in the Modernized PRS.

And so a couple other features that we have added as the modernization effort has gone on to our record list, include an ability to filter for all of your records in the planning view that have an action expected. And so we've added these new tabs to the top of the planning view, that include Action Expected and All Records.

So it by default shows records filtered for Action Expected. And if you click on that menu and open it up, you can see that, this has selected for any records that have dates associated with an expected update, with expected corrections, with results expected, or with all study results expected.

And if you want to just see all of the records in your list, you can click on the All Records tab. We also had heard from people that they miss the problems button that is in the classic record list view.

However, this functionality has been present since the record list came out in the modernized system. And so I'll just show you quickly how to filter for records with problems.

So what you would do is hover over the Filter Menu below the Problems header. This will open up a list that includes records with any problems at the very top. And so if you click on that selection, you'll see that all of the types of problems in the list below it are highlighted. And so this is a way to determine how many of your records have any problems. Once you apply this filter, you'll see only records that have problems. And if you scroll down to the bottom of this list of records, you'll see how many total records have problems.

And another new feature of the modernized system that I'd like to point out is the addition of a Help Drawer. So we have added information icons to data elements. And if you click on the information icon, much like the glossary terms on the public site, it'll pull up a drawer on the side that has information about the data element.

And so each of these has some brief guidance about what to include in the field as well as a data element definition. And a large number of these also have an accordion that has additional information. So if there's more that we want to say about that data element that isn't on the screen or already in the drawer in those other fields.

This is a pop up feature that can remain on the page as you scroll down the page. It can be used to replace content. So if you click on a different icon, or information icon for a different data element, it'll just replace the information in the drawer. And you can of course click out of the drawer if you want to go back to the screen.

We've also, in the new system, added side panel navigation. And so a great feature of the side panel navigation is the fact that now instead of having to go through in order and add your information for each module in the defined order, as in the classic system, you can actually jump to whichever module you're ready to fill in.

We also have a protocol summary in this side panel. And you can scroll through. You can review the information that you've added already in the record. And if there are any edits that you want to make, you can actually use an edit link in each module to jump quickly to that section.

And we also have a toggle for editable mode. So if you want to just have the record in a read-only view, you can disable the edit mode. Or if you want to make edits, you can enable it.

And finally, I just wanted to show as a new feature, we have a new dashboard on the record summary page. And this will actually tell you how many total validations are associated with the record prior to releasing the record for PRS review, as well as how many review comments you've received once the record has gone through a review. And so first the Protocol Validation tab on the left-hand side tallies the total number of errors or warnings or notes that you have in the protocol section.

And you can see, there's also a display on the right-hand side. And this shows a breakdown of how many of these errors or warnings or notes are in each module. And we also have flagged any of the modules that have errors that absolutely need to be addressed before the record can be released for review.

So there's a similar look and feel to the Review Comments dashboard. On the left-hand side, and you see that the total number of major issues that have been identified as well as the total number of advisory comments that have been made are tallied. And then on the left, on the right-hand side you can see that these are broken down overall.

So if there are any general comments on the record, those appear at the top, or the numbers of those comments appear at the top. And then it's also broken down by module. So, you can see that the modules that have any issues are flagged. The ones with major comments are flagged.

And you can click on the module name, both here and in the validation dashboard, to go directly to that module to make any changes.

So with that I will jump to a poll question. Hopefully you got a good sense, I know I went through it quickly, of what videos we currently have available. They're really focused on the record list at this point.

But we wanted to know what other videos people might be interested in. And so you can answer A) How do you add users to the access list for a record. That could be a new Fast Forward video. B) How to update the Protocol Section of an existing record, C) How to find information on the Record Summary page, or D) something else. And if you do answer "Other" and you would like to give us a suggestion, please do so in the Q&A box.

And so I'll give that a moment to see how people are feeling about additional Fast Forward videos. So we're getting a lot of responses. I'm going to wait just a little bit longer.

We have about half of the people responding so far. And then I can share those results. Okay. I think we've got a good number.

So it's looking like How to update the Protocol Section of an Existing Record, is getting a lot of votes. With How to Find Information on the Record Summary page coming in second, and How to Add Users to the Access List for a Record coming in third. And I think that's kind of where we're ending up.

So, I'll just show those results to everybody.

And again, if the 20 or so people who answered "Other" would like to give some suggestions in the Q&A section, we would love to hear them. All right. And with that, I think I'm going to pass it back to Dr. Fine.

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

Thank you, Dr. Arnold. And thank you to both of you for the great presentation. Let me just make sure I'm moving forward and not backwards in our presentation. Great.

So we are going to turn over to Q&A in just a few minutes. So Dr. Arnold and Dr. Dharker are not going too far. Just a reminder for those on how to ask your question. There is a Q&A box, ideally in the bottom of your taskbar. Maybe some people have it at the top. We do have a chat box that's really reserved for if you're having any technical issues, so please use that if you can't hear something. Or I'm having Audio issues, use that for the chat box.

But for questions, please go to the Q&A box. It does allow us to have them all in one area. So if we can't get through all of them, we are still able to download them, read them, and make sure that we are responding in some way, whether through our Top Questions or through our Fast Forward videos. So please do keep them coming.

We'll be reading through some of those very shortly. But before we do, just wanted to do a Key Takeaways from the presentation. And I did read some of the questions that I want to address some live as well.

But just a reminder that Modernized PRS is available for protocol registration to boost this real world experience that we're getting and the feedback from you. You heard from Dr. Dharker for two years the PRS Beta was available, and then for about six weeks, we've had the modern PRS available as the primary way for you to register your record. And we've received more feedback in the last three to four weeks than we had over the past two years. So this has been very helpful for us. We do appreciate you using it.

And again, don't worry if you're frustrated or some of the features aren't there, you can still go back to classic. We haven't taken anything away. Your continuous feedback is encouraged and helps us prioritize the work.

I think that's a very common question we have, that we'll be addressing, is about the feedback. And so we'll dive into that in just a second.

I do want to also just point out, as we're giving you lots of great tips here, some people have noted that they really can only complete certain functions in classic. Some things are not working for them in modern.

And that's okay. We want to hear that. That is great feedback, but we don't want you to be frustrated. We are just beginning this journey of really trying to shift users to adopt the new technology so we can hear from you, learn from you. But we're not here to frustrate you. So if you'd like to still continue to go to classic, once you log in, you can always click and go to classic. But if you also need to bypass for some reason, you're having trouble even logging in.

We have this little secret login code on our login screen. If you can see where there is a classic underscore here, the PRS, if you click on that, it will expand this screen where you can choose to go into classic directly or modernized before you even log in. So that's just a tip, especially for some of those that we might have heard from earlier this week, said that they, for some reason, were spinning and couldn't even get into modernized. And so that would be really hard for you to get that link to get to classic. So there's a way to do it.

Just want to make sure you were aware of that.

I also just want to remind you in terms of communication, it's always been a priority for us. And so we have been doing webinars such as this. Someone made a comment, it'd be great to be able to have webinars where you can ask questions. Here's your opportunity. We're giving you tips on how to use the new PRS. We want to hear your questions on navigating the system and definitely want to do some demonstration videos that will be helpful to you.

There's a lot of feedback also coming in on when you get feedback from us, what are you doing? How do I know if the feature has been implemented? As Dr. Dharker had previously pointed out, we just had a release this week that incorporated a lot of the feedback we got from the last three weeks. That comes out in our News and Updates. You can get it through our Hot Off the PRS! and definitely on our website where you can see the recent release and all the new features.

So we're going to continue to build new features in the modern PRS. There will be more things coming. So you can get all those features and updates in our release notes.

Then, of course, if anything's not going well, we definitely use banners. We let you know that you can go back where you need to. Or if there's something that we're seeing, that's not working on our site, we make sure that is another form of communication. So please do let us know even in the Q&A box if there's other ways you want us to communicate. This is really helpful to us.

We are continually updating our materials based on your feedback. So thank you for that.

And so when you had registered, we asked you if you had some questions for us. So we're taking your live Q&A here. But we do want to address some of the pressing questions that we saw and the big themes with your registration. So we have about five or six of these questions. And then we're going to turn it over to the live questions as well.

But I'm going to address the first question straight to Dr. Dharker. There's been common questions here about seeing differences in modernized PRS and classic record lists. Do I need to do anything?

Do I need to report them? How will they be resolved? Could you address that question, Dr. Dharker?

Nachiket Dharker, PRS Product Owner:

Yes, sure. We have already acknowledged that there are differences between modernized and classic PRS that we are actively trying to resolve. And with every release or even before release, some of these, will be fixed and you will see that change reflected as you are working with the modernized PRS.

So, just continue reporting these differences that you see using the Feedback button on the modernized website. And keep in mind that you can rely on the classic system if you see these differences. So treat that as the source of truth.

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

Great, thank you. Dr. Arnold, I know you addressed this a little bit with some of the materials that you already have available. there's lots of questions here about training, training materials. We're very excited to hear that you are interested in learning more. So could you maybe address a little more about training materials and what people can anticipate?

Stacey Arnold, PRS Subject Matter Expert:

Sure. It's mostly a repeat of things that I already said but we do have that About menu where you can obtain help with navigating the system. The record list primarily at the moment is the focus of our About the Modernized PRS document as well as the videos.

But we are looking for suggestions to add additional videos in future. And thank you for your feedback on some of the things that we were thinking about adding. As of right now, we are in the midst of trying to update the PRS Guided Tutorials, and so those will be coming in the future.

And we're also aware that the User's Guide is a resource that a lot of people use. And we think that that's still in pretty good shape, so we don't have immediate plans to update that.

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

Great, thank you. And so, Dr. Dharker, questions about the PRS XML upload. Is it available?

Nachiket Dharker, PRS Product Owner:

Yes. On the classic site, PRS XML upload or the XML upload feature continues to be available. And the development on the modernized PRS is being planned.

The classic XML feature is available from the modernized PRS on the menu. When you click on it, you will be navigated to the classic site.

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

Great, thank you. I believe this is for Dr. Arnold about seeing names displayed in the Group column that seem to be different from what was expected. Were the names changed by ClinicalTrials.gov? Or what's going on here?

Stacey Arnold, PRS Subject Matter Expert:

So, for those who aren't aware, the Group column is a column that different organizations use to try to corral some of the records for their admins. If you have a lot of records, you might assign certain administrators to groups so that they only see a subset of the records when they log in.

People were noticing that in the column in the modernized site they were seeing a name that wasn't what they were expecting to see. Please rest assured that this was pulling information from the entry of the group when it was created. It was just pulling the full name as opposed to what would be called a nickname for the group.

We have restored it to match what's in the classic system. But we are not going in, we don't have time to go in and change anyone's information. So anything that you're seeing there that you don't expect to see is probably just coming from a slightly different source. And please do let us know when you notice something like that. We will fix it.

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

Wonderful. So that's a great example of how important feedback is and what quick changes we're making. So with that, Dr. Dharker, do you still want feedback if it's already been reported or you're aware of it?

Nachiket Dharker, PRS Product Owner:

Yep. Please continue sending feedback. It helps us to know if there is an ongoing issue versus what has already been fixed.

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

Wonderful. And I believe this might also be for you. When will results be available in the modernized PRS?

Nachiket Dharker, PRS Product Owner:

As I said earlier in my talk, we are actively building the new results screens. So, you will start seeing something, in PRS Test by the end of this year. And we will continue releasing module by module in PRS Test first.

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

Great. And I'm going to turn to some of the live Q&A that we got. There is one that I did want to address that came early in the presentation. I think it was referring to my slide and the adoption curve. So I just wanted to make sure that I addressed that when we mentioned the word standalone.

So the ClinicalTrials.gov public website is the only experience right now, the modern site, it is the standalone site. And in our development, we wanted to make sure that we're slowly transitioning everyone to the new technology, getting your experience. and getting real world data, and of course, releasing more features that you're looking to see.

So just to make it very clear that the PRS is not standalone, you have the option to use the modern PRS or the classic PRS. We encourage you to use modern, but we don't want you to be frustrated if it's still something that if it's not for you, it's totally okay. But we're only going to make it better based on your feedback.

So, similar to what Dr. Dharker said, we're going to have the results modules available in the test system. So you'd have to really navigate over there and start using it. But please do because we want to start getting feedback on that too. And we'll talk a little more. I'm sure there's questions about our timelines. I think we addressed them, but they keep coming.

So let's go over to some of the questions. I think the first one that I do have is for you, Dr. Arnold. It's around columns and saving your columns. And if that can that be your default view? And if you log out or log in, what happens there?

Stacey Arnold, PRS Subject Matter Expert:

That's a good question. People have asked about the ability to save and have it be saved in future. I will note that, it is dependent on the browser that you're using and it's saved to the browser history.

So if you do anything like clear the cache or clear the history on the browser that you're using, your view won't be available. Or if you use a different browser to log in. I think that when you log back in, you will see the last view that you had open. Barring any of those other changes that I mentioned to the view.

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

Wonderful. Thank you. Columns seems to be a very common question. One more follow up to that. Are you able to adjust the width? There's questions about navigating the record list and the columns. And maybe if you're able to adjust width, especially if you're using a laptop.

Stacey Arnold, PRS Subject Matter Expert:

You can adjust widths. I don't think you can save adjusted widths at this time. And so we are taking a lot of feedback about the record list. And we have been looking into making adjustments and making it more user friendly for everyone. So please keep that feedback coming in because we want to know what people really need to see from the record list experience.

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

Great, thank you. Dr. Dharker, question for you. This one we've got a few on. It's related to numbering outcome measures similar to classic. Can you comment on that or explain what that question might be about?

Nachiket Dharker, PRS Product Owner:

Up until recently, the outcome measures, as in the classic system, when you enter outcome measures and save them, they get numbered which is important not only for you but also for us, our staff, for our reviewers who basically use their comments to add to these outcome measures.

In the protocol summary the numbering was always there. But we acknowledge that in the data entry screens the numbering was missing. In our latest release that went out on October 2nd we have added the outcome measure numbering on the protocol data entry screens.

So take a look. Confirm. If you still are seeing issues or for some reason are not seeing it, report to us. We want to definitely know about it.

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

Wonderful. Dr. Dharker, could you comment also if someone's making revisions in the modern PRS will that save in classic and just kind of navigating between the two?

Nachiket Dharker, PRS Product Owner:

That's a great question. You can simultaneously work on both systems.

For example, you are working on the modernized system but either come across a blocker or want to use a feature that is not yet available in the modernized system. There is on every record summary page on the top right, we have a Go to Record in classic link available that will open in a new tab that you can use to go to the classic site.

Just keep in mind that the information will only be transferred across systems if you save that. On either system you will have to press the Save button so that the information is saved in the database. That can be then accessed from either of the systems. Hopefully that is clear.

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

Wonderful. I'm not letting you off the hot seat, Dr. Dharker, you can leave that unmute button on. directly to those that have provided feedback.

Nachiket Dharker, PRS Product Owner:

So, I touched upon this during my presentation. We have in the last four or last six weeks sent more than 350 emails in response to what we have been receiving on using the feedback button or via email. It is not possible for us to answer every email.

However, we are going by what we think is an urgency. For example, if we receive a comment using the feedback button that you are stuck somewhere and you provide your email address in that feedback form, we know that you are not able to proceed. And we absolutely do not want you to be frustrated, as Anna said.

In that case, we will respond to you, tell you either to go to classic or provide you guidance for how to proceed in the modernized system. So that is our highest priority. But if it is simply reporting feedback or a difference, we will acknowledge it in many cases. And in some cases we will review all the feedback but it is not going to be possible for us to acknowledge each and every feedback. We are just going by what we think is a priority.

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

Thank you. And so a few more questions. I think this will be related to spell check, some of the features that people are asking for. I don't know if you can address that one directly, or if that's just one of those on your list or anything you can answer about that.

Nachiket Dharker, PRS Product Owner:

We have been receiving a lot of feedback on that or questions on that. All the modern browsers are well equipped to handle or to support spell check feature.

In addition to that, the tool that is available on the classic side is outdated. It can no longer be used in the modern system and it has also not been updated in the classic system. Our team currently has no plans in renewing or developing another tool, given that spell check is so common in browsers. You can also create your own dictionaries and add more spellings using your browsers. So as of now that's what is our thought process behind this.

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

Wonderful. Thank you. And this might be for you, Dr. Arnold, and I'm not sure if you are able to answer this, but is there a button or a link in the record list default view to be able to email not just the record owner but any of those who are in that access list?

Stacey Arnold, PRS Subject Matter Expert:

I think that the way to access the folks in the access list it's really best to go into the individual record and pull up the access list in there. I think, as Nachiket described you can email one or more of the users at a time. But for the access list, that's really the place to go. The record list is more for the record owner, responsible party, the primary individuals who hold certain roles.

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

And not letting you off the hook yet either. Regarding training materials, I know you mentioned that you'll be updating them, and there was a question specifically, will it include modernized screenshots when you update them?

Stacey Arnold, PRS Subject Matter Expert:

Yes. Really that's what the modernization of the PRS Guided Tutorials is all about. It's including new screenshots and really, including steps that represent the experience that you're going to have in the modernized system.

The way that the steps are described will change as well. But the underlying content that really talks about the data elements and the kind of information that you want to include for those, that will largely remain the same.

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

Wonderful. Thank you. Just reading the questions along here. So, Dr. Dharker, any announcements on when classic will be retired?

Nachiket Dharker, PRS Product Owner:

Classic PRS?

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

Right.

Nachiket Dharker, PRS Product Owner:

As I mentioned earlier in my presentation, there is no timeline for retirement of classic. As I showed you on the slide, we still have a long way with respect to the journey of the modernized PRS. We still have to add a lot of features, and then we will give sufficient time to make sure everything is working well.

You continue to provide us feedback. And only when we know that we have resolved all the issues and supported all the necessary features, and provided our users sufficient time to transition, that's when we will provide sufficient communication. Only then we can even think about it.

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

Wonderful. Thank you. And thank you for that question. I know that's definitely top of everyone's mind.

Dr. Arnold, I'm not sure if you're able to answer this question, but does the modernized PRS allow us to edit our saved master list of trial locations, for instance, to remove duplicates or sites entered in error. Can we do that?

Stacey Arnold, PRS Subject Matter Expert:

We haven't yet developed that in the modernized system, and I'm not sure what our plans are with the locations. I know that's something that's still available on the classic system. Or at least the ability to add locations from a master list is available on the classic system still.

Again, any feedback that you have about what you'd like to see with respect to your locations, please let us know as we continue to develop.

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

Anna Fine: Excellent. Great answer. So we had a question here. I think I could probably try to address this.

The question is, if we're using AI in the modernized PRS to help with search or any other functionality.

I think, Dr. Dharker, you could probably echo when we say at this time there is no AI for searching or for the users. We are dabbling a little bit on AI just for our review process, but it's very early stages and nothing that we've found to be fruitful yet. So that's a great question about AI. That's definitely a hot topic in technology.

Let's see another question that we have. Is there any type of assistance that you are offering one on one or anything to users at this time? I know you touched a little bit about that, Dr. Dharker, and how you're prioritizing all the feedback.

Nachiket Dharker, PRS Product Owner:

We are responding to urgent feedback or urgent help that people are requesting. Keep in mind that we have to balance between how much one-on-one support we can even think of supporting versus actually doing the work making the forward progress.

But yeah, if you have a specific question or you're stuck, just email us at register@clinicaltrials.gov. You know how to contact us and our team will look at it. And if there is a one on one need, we can always address that.

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

I know we just have a couple minutes left. Let me squeeze in one or two more questions here. I know you've talked about when classic will be not announced yet to be retired. And you also mentioned that you're going to start slowly releasing some PRS results modules, the modern ones in test. Is there any timeframe for when we will start to be able to register our results records in modern PRS?

Nachiket Dharker, PRS Product Owner:

We will start with releasing these modules on the test system first and then we will need to, by your help and internally also, we will do a lot of testing, and only when we reach a point, sometime next year, when we have resolved issues, addressed some critical feedback, then we reach the next stage of making the results data entry available to our users in our production system or the modernized system.

We may have a phased approach or we'll have to plan it based on what kind of issues we see or where we are at that point.

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

Great. Thank you. Dr. Arnold, I think this will be your final question. Can you confirm if NIH grants column is self added by a person registering the study? Is the information linked to an NIH grants database?

Stacey Arnold, PRS Subject Matter Expert:

So the information that appears in the NIH grants column is about what NIH institutes are affiliated with the record. And so if you want the record to be identified as one that might be subject to NIH reporting requirements, you want to make sure that you're adding information about your NIH grants into the record yourself.

There's no outward linking to any NIH grants, sort of record keeping. So it's really about, if you have an NIH grant, add it as a secondary ID. If you are collaborators that are with the NIH, you have to include that information in the record.

That's the only way that we can identify that record as having NIH affiliation and potentially being subject to those requirements.

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

Wonderful. I am being told that we are definitely at the top of the hour. I do see just a few more questions came in. We are going to be looking at those, like I said, thank you for the questions.

Thank you for the feedback that we've received. Thank you for being patient with us and understanding that we are just trying to build a system and make it better for you.

So please, for those, there's about half of you that haven't logged in and used it yet, please do. It's only going to become a better place with your feedback. And so please keep those feedbacks coming.

We're going to continue to read the questions that came in. We're always going to be updating our materials, and we are always happy to schedule future webinars. When the recording's available and the slides will be posted at that time on our site, we'll make sure we announce it through our Hot Off the PRS!

Please do continue to share your feedback. If you haven't already, do log in. Do try using it. Then keep an eye out. Coming soon for the PRS: modern results in the PRS Test. Thank you to Dr. Dharker and Dr. Arnold. We appreciate you with the presentations and being on the hot spot and taking these questions.

Thanks to everyone for joining. This will conclude today's webinar. Have a great afternoon.